Universidade de Aveiro Departamento de Línguas e Culturas
2019

ANA MAFALDA ÁGUAS AREIAS

Tradução de elementos visuais e textuais da *Toolbox* do Projeto EUPATI

Universidade de Aveiro Departamento de Línguas e Culturas
2019

ANA MAFALDA ÁGUAS AREIAS

Tradução de elementos visuais e textuais da *Toolbox* do Projeto EUPATI

Projeto apresentado à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Tradução Especializada em Saúde e Ciências da Vida, realizada sob a orientação científica da Doutora Maria Teresa Roberto, Professora Auxiliar do Departamento de Línguas e Culturas da Universidade de Aveiro e sob a coorientação científica do Doutor Bruno Gago, Professor Auxiliar do Departamento de Ciências Médicas da Universidade de Aveiro

Dedico este trabalho à minha irmã e aos meus pais pelo apoio e por sempre acreditarem em mim.

o júri

presidente

Professora Doutora Maria Teresa Murcho Alegre
professora Auxiliar da Universidade de Aveiro

vogais

Doutora Elsa do Céu Dias de Almeida Frazão Mateus
Coordenadora da Associação EUPATI (European Patients' Academy on Therapeutic Innovation) – Portugal (arguente)

Professora Doutora Maria Teresa Costa Gomes Roberto Cruz
professora Auxiliar da Universidade de Aveiro (orientadora)

agradecimentos

À minha irmã Ana pela paciência durante todo o processo do mestrado, assim como pelo encorajamento para o terminar. E à Ísis, minha sobrinha eternamente energética, por me ajudar a descontrair durante os dias mais cansativos. E ao Gustavo pelo *comic relief* e pelo álcool oportuno.

Aos meus pais por me terem ensinado a nunca desistir daquilo que realmente quero.

Ao meu namorado Quim pelas noites intermináveis de aconselhamento e apoio, és a pessoa que mais acreditou em mim, ainda mais que eu própria.

À comunidade educativa das instituições de ensino por onde passei, em especial aos docentes do ISCAP e da UA, assim como os colegas que marcaram a minha evolução académica.

Aos meus orientadores de projeto, tanto à Prof. Doutora Teresa Roberto como ao Prof. Doutor Bruno Gago por apoiarem este projeto durante a sua interminável duração e se disponibilizarem para me ajudarem a concluir o mestrado.

E por último, aos meus amigos pela inspiração, pelo carinho e pela paciência, em particular à Soraia, minha companheira de todas as aventuras de mestrado. Não seria a mesma coisa se não fizesses parte disto tudo. E ao João e à Ana, pelo brunch e pequenos-almoços inspiradores e por serem os meus confidentes

palavras-chave

tradução, tradução especializada, terminologia, tipologia textual, Investigação e Desenvolvimento de medicamentos, EUPATI

resumo

A Investigação e Desenvolvimento (I&D) de medicamentos tem um papel fulcral na nossa sociedade, contribuindo com inúmeros benefícios para a melhoria da qualidade de vida das populações e para o avanço científico. Para que estes sejam possíveis de alcançar, é indispensável o contributo dos doentes no processo de desenvolvimento de novos medicamentos. Por forma a que esta participação seja efetiva, é necessário capacitar os doentes e seus representantes com as competências adequadas potenciando, assim, a sua futura participação neste processo. O projeto europeu EUPATI (European Patients' Academy on Therapeutic Innovation) pretende responder a este desafio com iniciativas dedicadas a formar doentes peritos em todo o processo de desenvolvimento de novos medicamentos.

Este projeto só atinge o seu potencial máximo ao ser disponibilizado em diferentes idiomas, de modo a garantir que doentes de vários países tenham acesso à informação formativa necessária. Logo, surge a tarefa fulcral de traduzir os seus elementos.

Para esse efeito, o presente trabalho pressupõe a tradução, do inglês para o português, de elementos visuais e textuais inseridos na *Toolbox* do projeto EUPATI, bem como a explanação do processo de tradução. Apresenta o projeto bem como o domínio do mesmo, passando por uma breve descrição do processo de Investigação e Desenvolvimento. São abordadas as metodologias utilizadas para o concluir, discutindo cada fase do processo de tradução, assim como os principais problemas de tradução encontrados, e oferecendo, no final, uma análise crítica do trabalho realizado.

keywords

translation, specialized translation, terminology, text typology, drug Research and Discovery, terminology, EUPATI.

abstract

Drug Research and Development (R&D) has a pivotal role in our society, given that it contributes with numerous benefits to the improvement of the quality of life of the population and to scientific advancement. For these benefits to be achieved, the role of the patients in the developmental process of new medicines is indispensable. To ensure that this participation is effective, it is necessary to enable patients and their advocates with the adequate competences and in this way promote their future participation in this process. The European project EUPATI (European Patients' Academy) endeavors to fulfill this challenge with initiatives dedicated to the training of expert patients and their integration into the whole process of developing of new medicines.

This project can only reach its maximum potential by being available in different languages, in order to guarantee that patients from different countries have access to the necessary educational information. There is, therefore, the need to translate these elements.

To this effect, this assignment involves the translation, from English into Portuguese, of visual and textual elements from the EUPATI Project's Toolbox, as well as the explanation of the translation process. It introduces the project as well as its domain providing a brief description of the Research and Development process. It presents the methodologies used to conclude it, discussing each step of the translation process, as well as the main translation difficulties found, and offering, at the end, a critical analysis of the whole project

Índice

Índice de figuras

Lista de abreviações e siglas

ADME – Absorção, Distribuição, Metabolismo, Eliminação

CE – Comunidade Europeia

EMA - Agência Europeia de Medicamentos

EUPATI - European Patients' Academy on Therapeutic Innovation

I&D - Investigação e Desenvolvimento

IATE - Interactive Terminology for Europe

IMI - Innovative Medicines Initiative

LPCDR – Liga Portuguesa contra as Doenças Reumáticas

NLT EUPATI – National Liaison Team para a plataforma EUPATI

PLATA – Patient Library & Advocate Tool Box Article

SNS – Sistema Nacional de Saúde

TC – Texto de chegada

TP – Texto de Partida

UE – União Europeia

1. Introdução

Este projeto, inserido no mestrado de Tradução Especializada em Saúde e Ciências da Vida, tem como objetivo explanar o processo de tradução de elementos gráficos a figurar na *toolbox* do projeto EUPATI (European Patients' Academy on Therapeutic Innovation). Estes elementos dizem respeito ao processo de I&D de medicamentos, desde a descoberta até à introdução no mercado de novos medicamentos, discriminado as várias etapas do mesmo.

O trabalho em questão opera sobre a tradução de elementos gráficos (imagens) e documentos que os acompanham com a devida legenda e explanação dos conceitos nelas presentes (PLATA).
Os elementos visuais figuram, na sua forma original, no website da EUPATI, e futuramente, as versões traduzidas estarão disponíveis na versão portuguesa do mesmo. Só mesmo os documentos PLATA não serão disponibilizados, dado tratar-se de documentação interna utilizada dentro do sistema de gestão da qualidade para registo de alterações nos recursos e para providenciar uma representação escrita de todo o conteúdo gráfico.

Compete, também, expor todo o trabalho efetuado até à conclusão do mesmo, desde a escolha do tema, da colaboração com a representação portuguesa da EUPATI, do processo tradutológico e das conclusões que esta jovem tradutora tira de todo o trabalho. Sendo assim, o projeto terá como ponto de partida a apresentação da origem deste trabalho, bem como uma introdução à organização EUPATI e subsequente participação portuguesa, e ainda uma breve discussão sobre a I&D e relação da tradução com esta área.

Quanto à seguinte fase, passar-se-á à explanação dos processos teóricos e metodológicos da tradução, desde a pré-tradução, tradução e pós-tradução.
Para concluir, será apresentada uma análise geral de todo o processo, bem como uma reflexão crítica sobre o projeto.

2. O projeto

O domínio deste projeto de mestrado prende-se, com a área da Farmácia e Farmacologia. Este projeto só foi possível graças ao Prof. Doutor Bruno Gago, professor auxiliar do Departamento de Ciências Médicas, que me convidou a participar na tradução de textos presentes no projeto EUPATI.

2.1. EUPATI (European Patients' Academy on Therapeutic Innovation)

O European Patients' Academy on Therapeutic Innovation (EUPATI) é um projeto pan-europeu criado por um consórcio de várias partes interessadas da indústria farmacêutica, academia, organizações sem fundos lucrativos e representantes dos doentes. Iniciado e desenvolvido como um projeto da IMI (Innovative Medicines Initiative) e cuja liderança está a cargo do European Patient's Forum, o EUPATI foi implementado para educar doentes especialistas, focando-se na formação de quem representa os doentes, de modo a capacitar os mesmos para melhor contribuir para a Investigação e Desenvolvimento (I&D), mas também, para melhorar a qualidade da informação divulgada ao público acerca da mesma.

Desde a sua criação, este projeto europeu já treinou cerca de 96 doentes peritos sobre o desenvolvimento de medicamentos, ensaios clínicos, regulamentação de medicamentos e avaliação das tecnologias de saúde. Para além disso, também oferece e mantém uma Caixa de Ferramentas (Toolbox) sobre Desenvolvimento de Medicamentos e coordena plataformas nacionais para as associações de doentes.

Através deste projeto, foi desenvolvido material educacional em sete idiomas (Inglês, Alemão, Espanhol, Polaco, Francês, Russo e Italiano), abrangendo um largo espectro de países com as línguas acima mencionadas como língua nativa. A adição do Russo permitiu alcançar ainda mais população, e, em 2017, projetaram-se novos idiomas a adicionar ao projeto, como o Português.

Este projeto conta com material destinado a dois públicos-alvo distintos: "Expert Level" e "Education Level". O primeiro refere-se ao material visado para os representantes dos doentes, aos embaixadores dos doentes e aos jornalistas, material este que compreende os Cursos de Formação para os Doentes Peritos. O segundo refere-se aos recursos da Caixa de Ferramentas sobre a I&D de

medicamentos destinada aos representantes dos doentes, doentes e ao público em geral com interesse sobre os tópicos aqui discutidos.

O trabalho executado incide, sobretudo, sobre os elementos ilustrativos que figuram na Caixa de Ferramentas. Considerada o segundo "*core product*", a Caixa de Ferramentas da EUPATI foi lançada em janeiro de 2016 e cobre quase todos os tópicos integrantes dos cursos de formação. Até ao fim de janeiro de 2017, cerca de 110 000 utilizadores independentes fizeram uso deste recurso, que está atualmente traduzido para cerca de 9 idiomas.

Jan Geissler (2017), afirma no "Eupati project: Executive Summary" que prova viva do impacto do projeto em questão, é o facto de que "*additional countries continue to request Toolbox translations."* O facto de que este recurso já conta com utilizadores de diversos países, cujas versões traduzidas permitem uma utilização mais eficaz e informada, permite-nos perceber o impacto deste projeto, que dada a importância, tem vindo a ser requerido por outros países, de modo a que também possam ter acesso a este na sua língua materna. Um dos países que fez parte do alargamento posterior da EUPATI foi Portugal, e daí a necessidade de se traduzirem os seus conteúdos.

2.2. EUPATI Portugal

A participação portuguesa neste projeto inicia-se em 2014 com ações de formação especializada com o Patient Expert Training Course, com representantes da LPCDR e da GAMIAN EUROPE, os primeiros portugueses selecionados para esta primeira edição o curso EUPATI, que pouco depois começam a trabalhar para criar uma plataforma nacional deste projeto, através da comunicação “EUPATI: Porque o saber dos doentes conta”, no Fórum de Apoio ao Doente Reumático sobre a Centralidade do Doente.

Dada a importância e grande necessidade de promover o conhecimento público sobre a I&D de medicamentos, vários foram os parceiros interessados nesta iniciativa. E a junho de 2016 é realizada a primeira reunião de trabalho da NLT EUPATI, com a participação de elementos representantes dos doentes, academia, indústria e da Autoridade Nacional do Medicamento e Produtos de Saúde, I.P. Destes elementos destaco o Prof. Doutor Bruno Gago da Universidade de Aveiro, em representação da academia, e a pessoa que me introduziu a este projeto.

Desde o início de 2017, a EUPATI Portugal está estabelecida como uma organização sem fins lucrativos e trabalha com os mesmos pressupostos do projeto EUPATI original, de promover o saber, capacitando e envolvendo doentes peritos e cidadãos no processo de Investigação e Desenvolvimento de novos medicamentos.

A investigação clínica vive uma relação de simbiose com os seus participantes, e, portanto, faz todo o sentido que se queira aprimorar o participante de modo a obter resultados mais apurados e da forma mais célere. O ponto central do projeto EUPATI é o doente e a possibilidade de este ser capacitado para colaborar nos planos de desenvolvimento e para estar presente em futuros ensaios com melhores resultados, celeridade e maior eficácia. E tendo em conta que os doentes envolvidos nas formações dadas pelo projeto serão sujeitos a um grande

número de recursos visuais/textuais, será necessário adaptá-los para a língua dos doentes. É aí que se insere o meu trabalho.

3. Investigação e Desenvolvimento (I&D) de medicamentos

A Lei nº21/2014, publicada em Diário da República a 16 de abril de 2014, considera investigação clínica "todo o estudo sistemático destinado a descobrir ou a verificar a distribuição ou o efeito de fatores de saúde, de estados ou resultados em saúde, de processos de saúde ou de doença, do desempenho e, ou, segurança de intervenções ou da prestação de cuidados de saúde. (…)". Esta destina-se, acima de tudo, à promoção da evolução do setor assim como à valorização e fortalecimento do mesmo, para que possam produzir resultados benéficos a um largo espectro de setores e pessoas.

Desconstruindo a expressão "Investigação e Desenvolvimento", podemos interpretá-la, partindo do termo "Investigação", que o Priberam define como "Indagação ou pesquisa que se faz buscando, examinando e interrogando.". Este remete para todo um trabalho inicial de recolha e análise, para que depois, no "Desenvolvimento", se proceda ao "Ato ou efeito de desenvolver" como também ao "Aumento" ou até mesmo, "Progresso". Após um trabalho inicial de angariação de informação, passar-se-á então à análise e criação de conteúdos/resultados com a mesma, alargando assim, o conhecimento de quem investiga e da ciência em si, logo, creio ser pertinente dar relevo ao conceito de expansão e aumento, presentes nos sinónimos acima mencionados.

É de facto isso que se pretende com a I&D dos medicamentos: recolher informação, realizar estudos, para que em seguida, se ponham em prática, e quiçá, com estes, partir para a descoberta e a criação de algo novo, para a expansão do setor e do conhecimento do mesmo.

A indústria farmacêutica tem um papel fulcral nos dias que correm, primando sempre pela inovação, pelo progresso e pelos vários benefícios que traz aos subsequentes setores que afeta. Analisando o investimento em I&D na CE (Comunidade Europeia), podemos comprovar que, em 2018, dos €199.9 mil milhões investidos, €44.9 mil milhões destinaram-se à indústria da Saúde, representando 22% do investimento europeu neste setor, posicionando-se no

segundo lugar das indústrias com maior investimento, antecedido apenas pelo setor Automóvel e dos Transportes[1].

Os resultados deste investimento profundo são notáveis em vários domínios, passando pela economia, pela ciência e pela saúde das populações. Tendo por base o relatório sobre os Ensaios Clínicos em Portugal, encabeçado pela APIFARMA, podemos observar que de um ponto de vista económico, a I&D promove a diminuição da despesa pública e contribui para a sustentabilidade do SNS, assim como cria valor para as indústrias e também emprego, atraindo também investimento. Relativamente à comunidade científica, o relatório aponta também para benefícios como o aumento do conhecimento e o desenvolvimento investigacional; não excluindo, obviamente, os benefícios para os doentes, como o acesso precoce e gratuito aos medicamentos, assim como a melhoria da qualidade e tempo de vida geral.

Para que possamos disfrutar destes benefícios acima mencionados cabe então à indústria trabalhar no sentido de investigar e desenvolver medicamentos, munindo-se da realização de ensaios clínicos para avaliar a eficácia e impactos dos mesmos.

1 Hernandez Guevara; H. Grassano; N. Tuebke, et al. Industrial R&D EU Investment Scoreboard (2018). Publications Office of the European Union. 978-92-79-97293-5 (online)

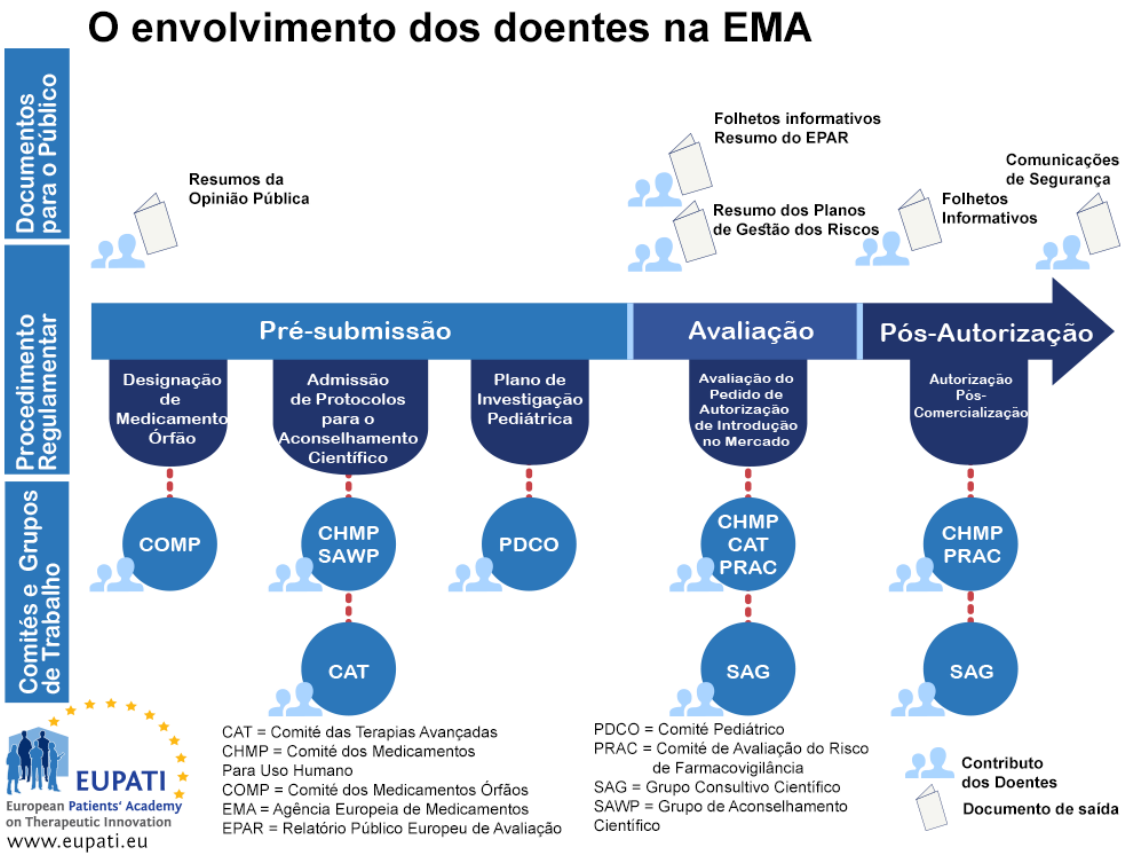


Figura 1. Envolvimento dos doentes na EMA

Este processo é largamente acompanhado pela presença dos doentes, cuja participação influencia em grande parte o desfecho de todo o processo.

Como podemos verificar na Figura 1, é indiscutível a importância do papel dos doentes, já que o vemos presente em cada etapa. A opinião dos doentes é relevante e é tomada em consideração em todos os comités, grupos de trabalho e documentos.

O documento (Fig.1) é um dos vários elementos traduzidos que figurará na versão portuguesa da Caixa de Ferramentas da EUPATI. O ícone azul-claro representa o contributo dos doentes no processo de criação do medicamento, sendo que este descreve, em específico, o trabalho desenvolvido na EMA (Agência Europeia de Medicamentos).

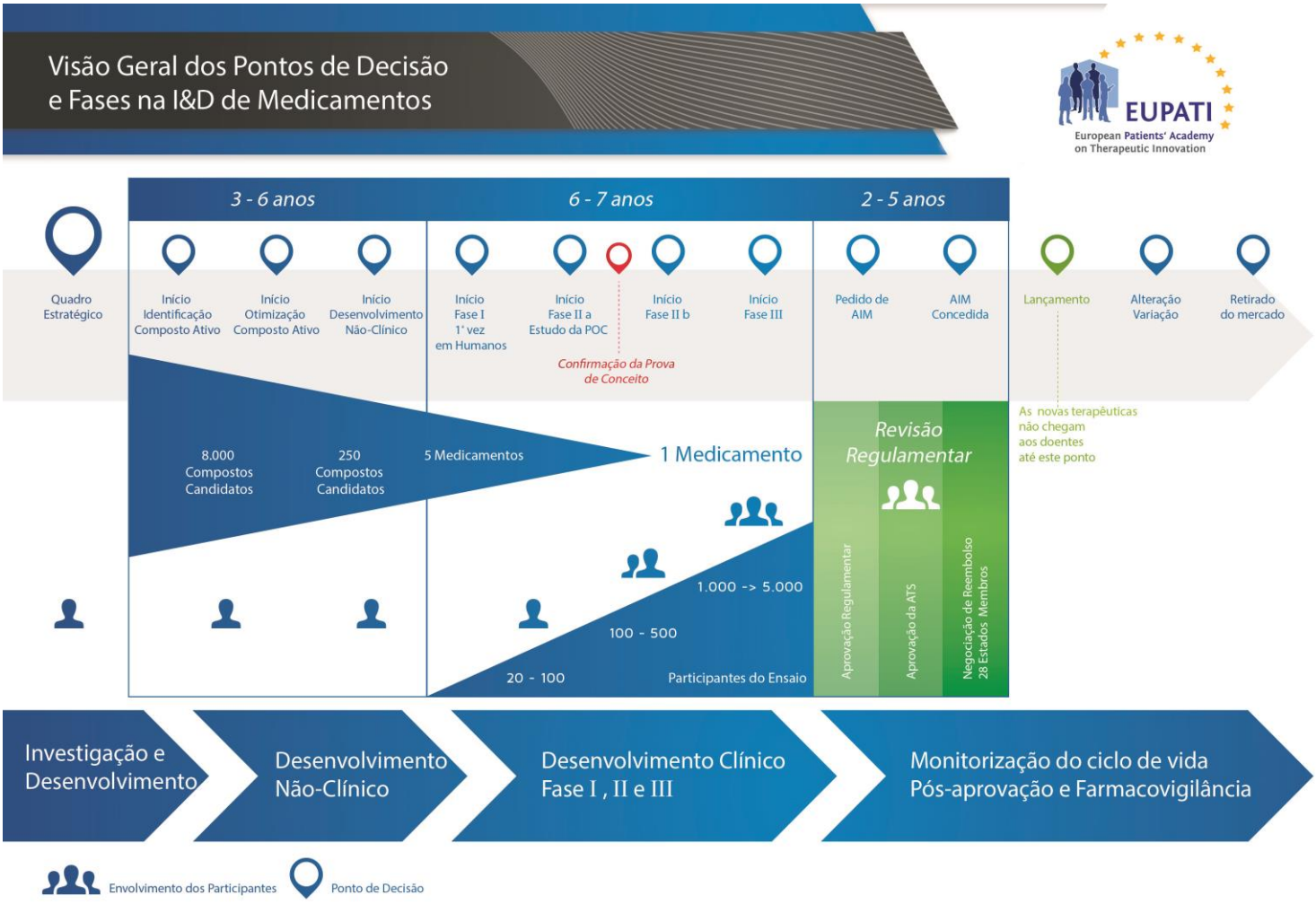


Figura 2.Fases de I&D de medicamentos e o envolvimento dos doentes

Neste diagrama já é possível quantificar o envolvimento dos doentes nas diversas fases de desenvolvimento clínico. Sendo a I&D de medicamentos um percurso vasto, é legítimo ter-se em consideração o foco de todo o espectro da EUPATI como o doente e subsequentes representantes. O diagrama (Fig.2) revela que, à medida que o processo de investigação e desenvolvimento de medicamentos avança, o número de participantes aumenta. Ou seja, este é um processo acima de tudo moroso e que requer um grande número de recursos humanos para o seu sucesso. Através de um doente participante bem informado e apto, será possível que estes processos decorram com melhores resultados, celeridade e maior eficácia.

O seguinte excerto, retirado do TC, descreve as quatro fases da I&D de medicamentos, detalhando, não só, os processos que ocorrem durante cada uma das fases, bem como o número de doentes necessários às mesmas:

“Há quatro fases principais de I&D: Investigação e Desenvolvimento, Desenvolvimento Não-clínico, Desenvolvimento Clínico e Gestão do Ciclo de Vida Pós-aprovação e Farmacovigilância. A fase de Investigação e Desenvolvimento demora entre três a seis anos, e vai desde a criação de um quadro estratégico à identificação de compostos ativos, ponto em que o número de compostos candidatos é reduzido de 8000 para aproximadamente 250. A fase de desenvolvimento não-clínico ocorre também dentro dos primeiros três a seis anos, desde o início da otimização do composto ativo até ao fim do período de desenvolvimento não-clínico, e nessa altura, os 250 candidatos são reduzidos a cinco medicamentos. Os próximos seis a sete anos são ocupados pelo desenvolvimento clínico. O desenvolvimento clínico é dividido em três fases: I, II e III. Após a conclusão da Fase I, os primeiros ensaios em humanos (com aproximadamente 20 a 100 participantes), a Fase IIa tem início com um estudo de prova de conceito. Geralmente, na Fase IIa estão envolvidos entre 100 e 500 participantes. Quando a Prova de Conceito é aceite, a Fase IIb tem início, com ensaios clínicos com 1000 a 5000 participantes, reduzindo os compostos candidatos a apenas um medicamento. A Fase III é a maior de todas as fases de ensaio e termina com a submissão do medicamento para revisão regulamentar. O processo de revisão regulamentar pode demorar entre dois a cinco anos. Apenas após a aprovação por parte das entidades reguladoras é que um medicamento pode ser lançado e as novas terapêuticas podem serem disponibilizadas aos doentes.

Este processo de revisão e lançamento do medicamento marca o início da gestão do ciclo de vida pós-aprovação e da fase da farmacovigilância, que duram até o medicamento ser removido do mercado e durante as quais, as mudanças são monitorizadas e controladas.” [2]

2 Retirado do PLATA da Fig. 2.

Apesar de esta participação se concentrar maioritariamente na fase de desenvolvimento clínico, ela é evidente em todas outras fases, desde o início até ao fim do processo.

Porém, tudo depende da qualidade dos recursos apresentados aos doentes que se visa formar, daí a necessidade e importância da tradução especializada.
Dada a especificidade do tema, poderíamos entrar na falácia de que só os entendidos do mesmo poderão encontrar a melhor maneira de adaptar os recursos linguisticamente, porém, é certo que a Tradução Especializada assume aqui o papel preponderante. Antes de mais, em termos práticos, não é viável nem seria sustentável em termos laborais para um especialista em farmacologia trabalhar na sua área e, para além disso, lidar com todas as questões tradutológicas. Para além deste facto, saber traduzir não se resume à aptidão que um sujeito tem para determinado idioma ou domínio. Há que dominar, para além das questões linguísticas, as melhores estratégias para adaptar o conteúdo original para uma língua de partida. Cabe então ao tradutor especializado a árdua tarefa de aprender a trabalhar dentro de um contexto complexo e denso como a I&D e desenvolver as melhores técnicas de reprodução do conteúdo original para o traduzido.

4. Tradução Especializada em Saúde

Gouadec (2007, p.30) afirma que a tradução técnica concerne a tradução de “any material belonging to a particular area of knowledge, technical field or technology (e.g. mechanical engineering, hydraulics, electrical engineering, business management, etc.)”. A tradução técnica pressupõe uma compreensão detalhada de uma área em particular do saber, levando a uma necessidade de criar não um especialista na área, mas sim um especialista em tradução numa área em específico. Traduzir dentro de um domínio tão específico, requer um cuidado e compreensão redobrados, bem como uma boa tática de abordagem aos variados problemas e dificuldades a enfrentar. Cabe ao tradutor utilizar as melhores estratégias de adaptação de modo a obter um texto de chegada fiel à função do original e igualmente esclarecedor para os leitores da língua de partida.

A tradução no domínio da Saúde acarreta diversas responsabilidades. Postolea (2016, p.62) remete para a constante preocupação de responder às necessidades do TP e do(s) seu(s) criador(es), como também às necessidades do TC e dos futuros leitores.

Para além destas preocupações iniciais, a tradução em Saúde acarreta uma responsabilidade acrescida, dado o objeto público e uso do texto reproduzido. Neste domínio temos textos orientados para uma melhor compreensão das questões de saúde e da própria Ciência. Logo, cabe ao tradutor encontrar as melhores táticas para que toda a informação dada no TP se mantenha no TC. Isto é, a prioridade neste tipo de tradução não é a transmissão do efeito que TP exerce sobre o leitor. A principal necessidade é a obtenção dos conteúdos do TP traduzidos com precisão científica para o TC. Deve prevalecer um rigor técnico e científico, para que o TC cumpra os objetivos informativos e educativos presentes no TP. Tratando-se de um domínio marcado por questões de tratamento e informação vital ao utilizador de chegada dos textos a traduzir, a informação reproduzida deve ser rigorosamente igual à do original.

A tradução é um ato implícito em todos os tipos de comunicação, pois há e haverá sempre uma necessidade de comunicar com diferentes recetores, e esse mesmo ato pressupõe a compreensão por parte do recetor da mensagem veiculada pela pelo texto original. Ora, sem a tradução, perde-se um elo de ligação entre os dois. Já Steiner confirma esta necessidade, dizendo que "[t]ranslation is formally and pragmatically implicit in every act of communication, in the emission and reception of each and every mode of meaning, be it in the widest semiotic sense or in more specifically verbal exchanges" (Steiner, 1998, p.13).

A língua surge como instrumento da transmissão de informação, sendo até mesmo referida por Jackson (citado por Bowen, 2015, p.9) como a "tecnologia mais essencial da medicina". Neste trabalho, a informação é apresentada quer verbalmente, quer através de representações gráficas. Pretende-se que os leitores das publicações tenham uma compreensão mais alargada e esclarecida do processo de I&D de medicamentos e, para tal, é imperativo manter a intenção educativa do original e transferi-la, de modo a que se adeque aos parâmetros da língua de chegada.

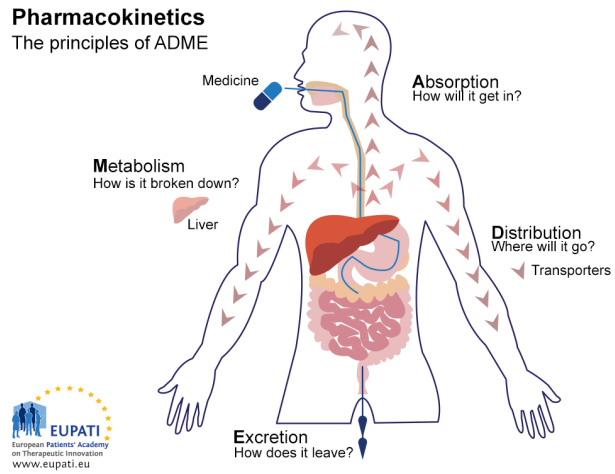


Figura 3. The principles of ADME

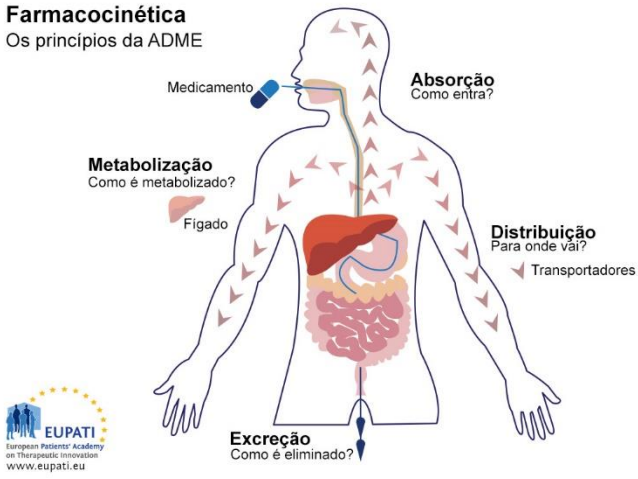


Figura 4. Os princípios da ADME

Na Fig.3 (versão original) e Fig. 4 (versão traduzida), vemos representada uma intenção de informar sobre o processo de absorção, distribuição e eliminação do medicamento pelo organismo. Este processo é exemplificado através do detalhe de cada fase com uma legenda, e também através de cores e de um esquema de representação gráfica apelativos. Apresenta uma interface com o leitor bem clara

e fácil de assimilar. Esta objetividade da informação transmitida pelo TP tem de se manter no TC e torna-se imperativo recriar um produto dentro do mesmo registo. Foi mantida uma linguagem bem direta e funcional, onde imperam as frases curtas interrogativas, por exemplo, “Como é eliminado?”. Neste caso em particular surgiu a questão de adaptar o termo *leave* dentro do contexto do esquema. Ora, tratando-se de um processo referente à forma como um medicamento entra e sai do organismo de uma pessoa, pensei primeiro manter uma variação do termo que dá título à última fase do processo de ADME. “Excreção” é o termo usado no foro médico como referente ao processo de eliminação do medicamento, logo poderia ter mantido a mesma, adaptando-o então para “Excretado”, mas tendo em conta que a legenda deste em inglês menciona apenas a sua saída, e não o exato movimento pelo qual ela sai, foi possível então encontrar o termo “eliminado” como alternativa, dado que pressupõe uma saída do organismo, ficando claro ao leitor o que acontece com o medicamento nesta fase.

4.1. Metodologias

O nível de exigência terminológica deste projeto levou a uma necessidade de compreensão alargada dos tópicos a traduzir, mas que se refletiu mais num processo em constante desenvolvimento, do que propriamente num estudo intensivo sobre todo o mundo do desenvolvimento dos medicamentos.

Sendo assim, a estratégia principal de tradução foi a da leitura comparativa de textos da especialidade redigidos por entendidos da área de ambas as línguas. Esta abordagem facilitou a tentativa de recriar o tão desejado efeito original do texto de partida para o texto de chegada. Recorrendo a recursos como websites da *APIFARMA*, *Infarmed* e os Manuais MSD, foi possível obter material necessário para um aprofundar do conhecimento e da possibilidade de encontrar neles a melhor forma de abordar a escrita no contexto farmacológico e burocrático da criação dos medicamentos. Outra forma de obter material fiável e uma perspetiva terminológica abrangente, foi através do *Research Gate*, onde foi possível encontrar artigos científicos que utilizavam a terminologia com a qual eu trabalhei.

Apesar de nem sempre legítimas e confiáveis, as ferramentas de tradução automática como o *Reverso* e o *Linguee* também desempenharam um papel crucial na execução deste projeto, já que apesar de não providenciarem o tradutor com a tradução mais acertada em grande parte dos casos, permitem ter uma noção ampla do contexto em que o termo ou expressão pesquisada são utilizados, e, perante tal, permitem que o tradutor analise as diferentes aplicações que o termo em questão pode ter, e, até mesmo, consultar outros textos da especialidade.

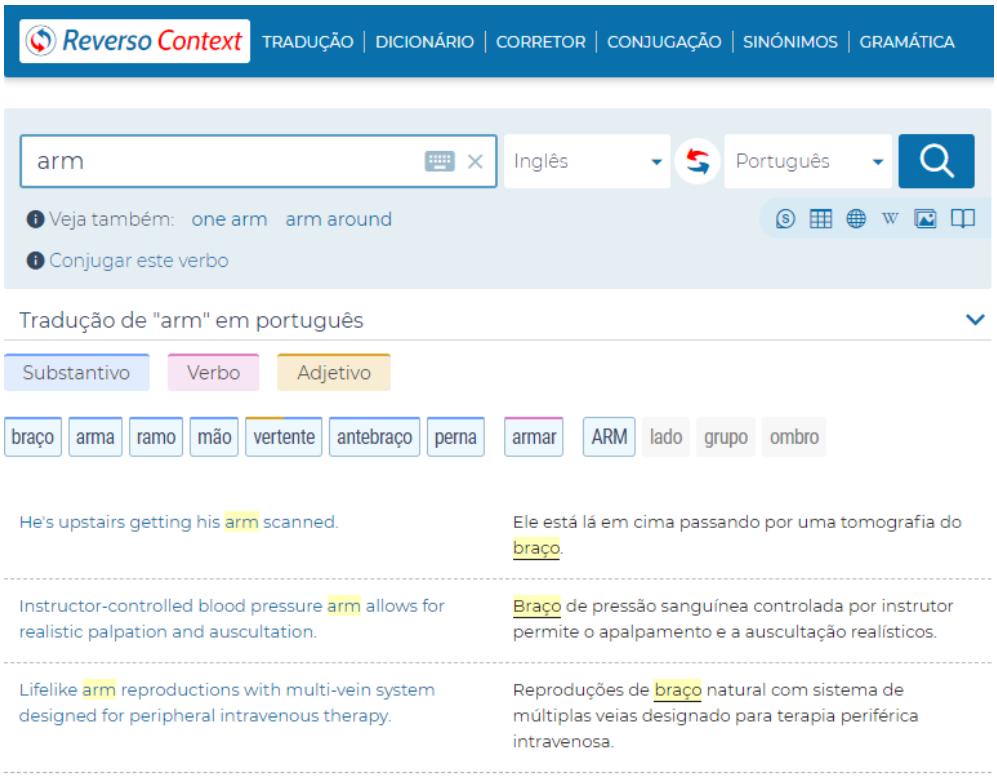


Figura 5. Página do Reverso

Na Fig.5 é apresentada uma pesquisa de contexto, com possibilidade de ver as diferentes opções terminológicas que este recurso oferece. Numa primeira fase, apresenta os equivalentes mais comuns e pesquisados, sempre aliado a textos que oferecem o termo aplicado no contexto.

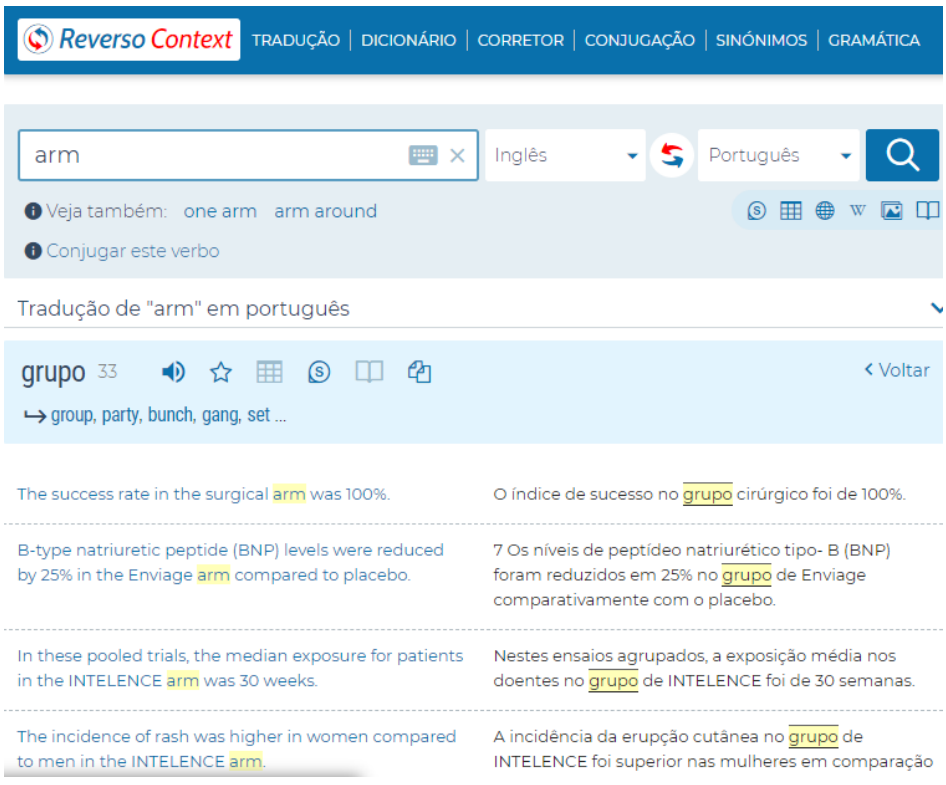


Figura 6. Página do Reverso com pesquisa refinada

Numa segunda fase, é possível selecionar qual o equivalente que será mais adequado ou aquele que fará mais sentido à área científica com a sugestão de *surgical arm*. Com a opção de "grupo", ficando em aberto a sua utilização ou não, a tradução sugerida oferece um significado que, à partida, não seria evidente para mim. Apesar de manter "braço" na tradução, foi-me possível decifrar qual a sua utilização e possíveis sinónimos, caso sejam necessários.

Outra forma de adaptar os diversos nomes de organizações, siglas e acrónimos, foi através do EUR-Lex, que permite a consulta de diversos documentos legais apresentados em diversos idiomas e dentro das normas europeias. Este recurso não só se provou útil na medida em que permitiu, em muitos casos, decidir qual o termo mais apropriado, como também forneceu material fiável e que não causou grandes dúvidas.

Também recorri a dicionários como o Priberam, uma referência de qualidade, que permite consultar sinónimos e antónimos bem como palavras parecidas e pertencentes da mesma árvore terminológica. Fiz uso de bases de dados terminológicas como o IATE e o EuroTermBank, credíveis e fiáveis acima de tudo, com amplo espetro e recursos normalizados dentro da União Europeia.

Numa perspetiva mais formal, foi-me possível analisar questões de tradução com a abordagem das técnicas de tradução de Newmark (1988, p.81), que as propõe, na tradução de frases e pequenos fragmentos de linguagem. Analisando o material traduzido, grande parte do texto é de extensão curta, passando por textos descritivos, legendas e pequenas frases que detalham determinado processo burocrático ou farmacológico.

Newmark propõe algumas técnicas de tradução que, partindo de uma abordagem virada para o TP, permitem manter as estruturas originais, mantendo assim, o efeito que este transmite. A tradução palavra por palavra (que mantém a ordem de palavras do TP, traduzindo sem contexto) e a tradução literal (que converte as estruturas textuais do TP para o TC, mas as palavras continuam a ser traduzidas

individualmente, sem apoio ao contexto) beneficiam a pré-tradução. Estas técnicas permitem alinhavar o processo de tradução, e a identificação dos principais problemas.

4.2. Tipologias textuais

Para compreender a estrutura do TP, é necessário identificar a sua tipologia, para, deste modo, o enquadrar em textos da especialidade, e, através de uma leitura comparativa, obter uma base de análise concreta para melhor encabeçar a tarefa tradutiva que se avizinha.

A tipologia textual tem vindo a ser alvo de debate por aqueles que reconhecem a importância da categorização dos textos no meio da tradução. Katharina Reiß (2013) aponta para a necessidade de haver equivalência textual de base e de pormenor do TP para o TC. A ideia de equivalência compreende a necessidade de igualar as funções e efeitos criados pelo TP, fornecendo as mesmas condições no texto que se procura traduzir. Já House (1997) refere a equivalência como a relação entre um original e a sua tradução quando ambos servem a mesma função comunicativa. A obtenção de equivalência textual está associada à identificação da tipologia textual, que é imprescindível à tarefa de tradução. Um melhor enquadramento do TP em textos semelhantes garante benefícios ao processo de tradução em si, como também a uma posterior análise do trabalho executado no TC. Balizar a tipologia do texto com a qual um tradutor se depara permite, de facto, identificar necessidades, dificuldades e criar estratégias. É através destas etapas que é possível coadunar o TC aos moldes dos textos existentes dentro da mesma tipologia. E ao perspetivar o texto em moldes semelhantes, torna-se possível, numa fase posterior, identificar quais os sucessos e falhas de todo o exercício de tradução, assim como obter uma análise crítica mais rigorosa para que de futuro haja melhoria e incentivo ao aprimoramento do trabalho.

Fundamentada a necessidade de identificar a tipologia de um texto, há que também procurar identificar tipos de texto possíveis. A divisão mais simples, e aquela que, aliada à tradução, é a mais comum, é da distinção entre Tradução Literária e Tradução Não Literária. Esta divisão, não deixando de ser legítima, não me parece suficiente para verdadeiramente identificar toda a complexidade de um texto a traduzir.

No que toca a distinções entre tipologias, as soluções são várias e mais aprofundadas que a dicotomia Texto Literário e Texto Não-Literário. Basta atentar que diversos autores procuraram resolver este problema, através da sua própria categorização tipológica.

4.3. Abordagens à classificação textual

4.3.1. Katharina Reiß

Reiß e Vermeer (2013) definem três tipos de texto: expressivo, operativo e informativo, dando exemplos para cada um destes. O primeiro é adequado a textos evocativos de sensações no leitor como nos poemas; o segundo remete para uma ação inerente à informação veiculada, como a informação contida num panfleto de propaganda; e o terceiro à transmissão de informações como vemos presente em manuais de instruções. Cada um destes tipos oferece caraterísticas fáceis de identificar na sua denominação, sendo que no expressivo pressupõe-se o exercício artístico e o despoletar de uma emoção forte no leitor; enquanto o tipo operativo induz a uma ação, é chamativo e há nele conteúdo persuasivo, tal como o esquema presente no livro *Towards a General Theory of Translation of Translational Action: Skopos Theory Explained.* Já o tipo informativo apela a uma função de disseminação de informação, e será de facto o tipo mais adequado para enquadrar o texto do projeto em questão.

		informative	expressive	operative
ENCODING LEVEL	content (+ aesthetic organization); persuasive configuration			x
	content; aesthetic organization		x	(x)
	content	x	x	x

Figura 7. Esquema de Reiss e Vermeer (2013) referente aos diferentes tipos de texto

4.3.2. Werlich

Werlich (citado por Bernardo, 2012, p.85) apresenta uma tipologia textual mais extensa do que a de Reiß, identificando cinco tipos de texto: descritivo, narrativo, expositivo, argumentativo e instrutivo. Relacionado estes tipos com as tipologias apresentadas por Reiß, é possível fazer-se uma correspondência parcial. A tipologia informativa poderá corresponder ao tipo descritivo ou expositivo; a tipologia operativa, ao texto argumentativo e, em parte, ao instrutivo, realçando a necessidade de provocar uma ação através do texto. A tipologia expressiva remete para um domínio literário, sendo que poderia corresponder aos tipos descritivo, narrativo ou expositivo. O texto trabalhado neste projeto apresenta características semelhantes à descrição, dada a natureza explanatória dos recursos que oferece. Ainda assim, aponto para a falta de uma exploração das possibilidades híbridas das tipologias, sendo que, por muito reguladoras e benéficas que estas sejam, não devem dispensar a análise de outros tipos e categorias, de modo a alargar os horizontes de quem traduz.

No entanto, a identificação da tipologia textual não deve ser limitadora do trabalho feito. O propósito de um “fio condutor” é de facto dar linhas orientadoras, mas não resolverá os desafios do tradutor. A tipologia deve ajudar a entender o contexto do TP e saber como a estrutura do texto a traduzir se enquadra na LC. A tradução no domínio da saúde envolve complexidade, desafios e a existência de textos híbridos, onde abundam diferentes tipologias. De facto, podemos encontrar numa mesma tipologia, o texto apresentado de formas diferentes (como é o caso do texto trabalhado neste projeto). Logo, é importante saber usar a tipologia textual como uma vantagem e não como uma distração. Nos textos traduzidos neste projeto, a informação é apresentada tanto por meio de diagramas e esquemas, como por legendas e longas descrições transcrevendo as imagens. Neste caso, não será possível orientar a tradução através de um único exemplo de tipologia, mas ter em conta uma tipologia de texto híbrido, representado tanto em texto simples como em esquematização gráfica.

5. Fases da Tradução

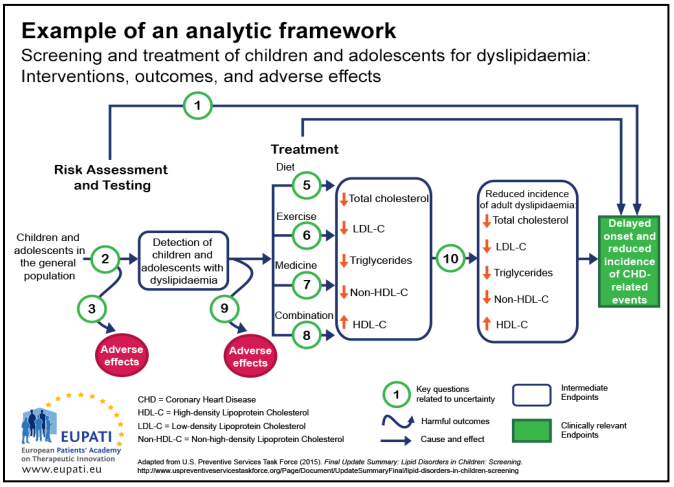
Até à obtenção do texto de chegada, com a tradução validada e pronta para uso do seu público-alvo, é necessário percorrer um longo caminho faseado. Fases essas que permitem seccionar o trabalho e melhor o organizar para uma resolução da tarefa de tradução. Partindo do modelo faseado de Gouadec (2007, p.13) é possível identificar três etapas na fase da tradução: Pré transferência (*pre-transfer*), Transferência (*transfer*) e Pós-Transferência (*post-transfer*).

5.1. Pré Transferência

Compreendido como o processo que antecede o ato de tradução, é nesta fase em que se irão delinear todos os passos e recursos a usar no momento da execução do trabalho. Esta é uma fase imprescindível, pois permite criar uma base de análise e criar um plano de ação para que o processo de tradução decorra com maior fluidez. Segundo Gouadec "[p]re-transfer includes all operations leading up to the actual 'translating', including preparation of the material, documentary searches, alignment, memory consolidation, terminology mining, deciding on options, etc." (Gouadec, 2017 p.13).

Este processo compreende uma leitura, levantamento de tópicos-chave, levantamento terminológico, tudo aquilo que se considere terminologicamente relevante, independentemente do conhecimento prévio de alguns termos.

A primeira tarefa executada nesta etapa foi a de análise, tanto do PLATA como da imagem que o acompanha. Ler atentamente e identificar todos os elementos provou ser algo de bastante benéfico já que permitiu ter uma ideia do caminho a percorrer. Estas imagens apresentam uma escrita bem direta e informativa. A maioria das imagens apresenta um título, subtítulo, diagrama, e uma legenda e o logótipo da EUPATI.



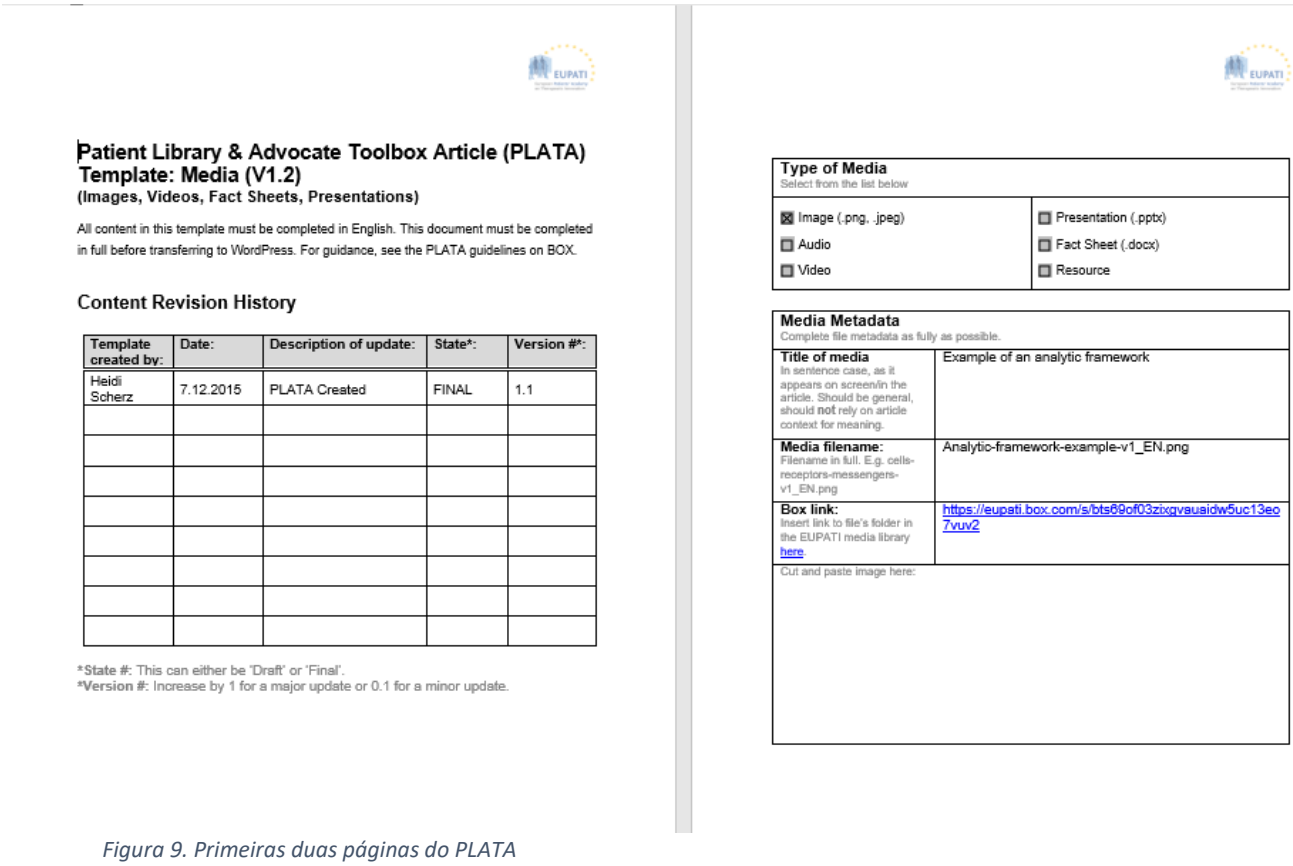
←**Título** (a negrito)
← **Subtítulo** (mais descritivo)

← **Diagrama** (uso das cores para uma representação mais apelativa, bem como de formas geométricas para esquematizar a informação)

← **Legenda** (diz respeito ao esquema de cores utilizado e sua função bem como pode esclarecer siglas e acónimos)

Figura 8. Example of an analytic framework

Olhando depois para o documento facultado para a descrição da imagem, podemos identificar os elementos-chave do mesmo. Tendo sido requerida apenas a tradução dos diagramas e textos acompanhantes (descrição longa "*long description*", texto alternativo "*alt text*" e legenda "*caption*") a figurar na *ToolBox*, este trabalho de tradução focou-se nas páginas que contêm essa mesma informação.



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)
(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	7.12.2015	PLATA Created	FINAL	1.1

*State #: This can either be 'Draft' or 'Final'.
*Version #: Increase by 1 for a major update or 0.1 for a minor update.

Type of Media
Select from the list below

☒ Image (.png, .jpeg)	☐ Presentation (.pptx)
☐ Audio	☐ Fact Sheet (.docx)
☐ Video	☐ Resource

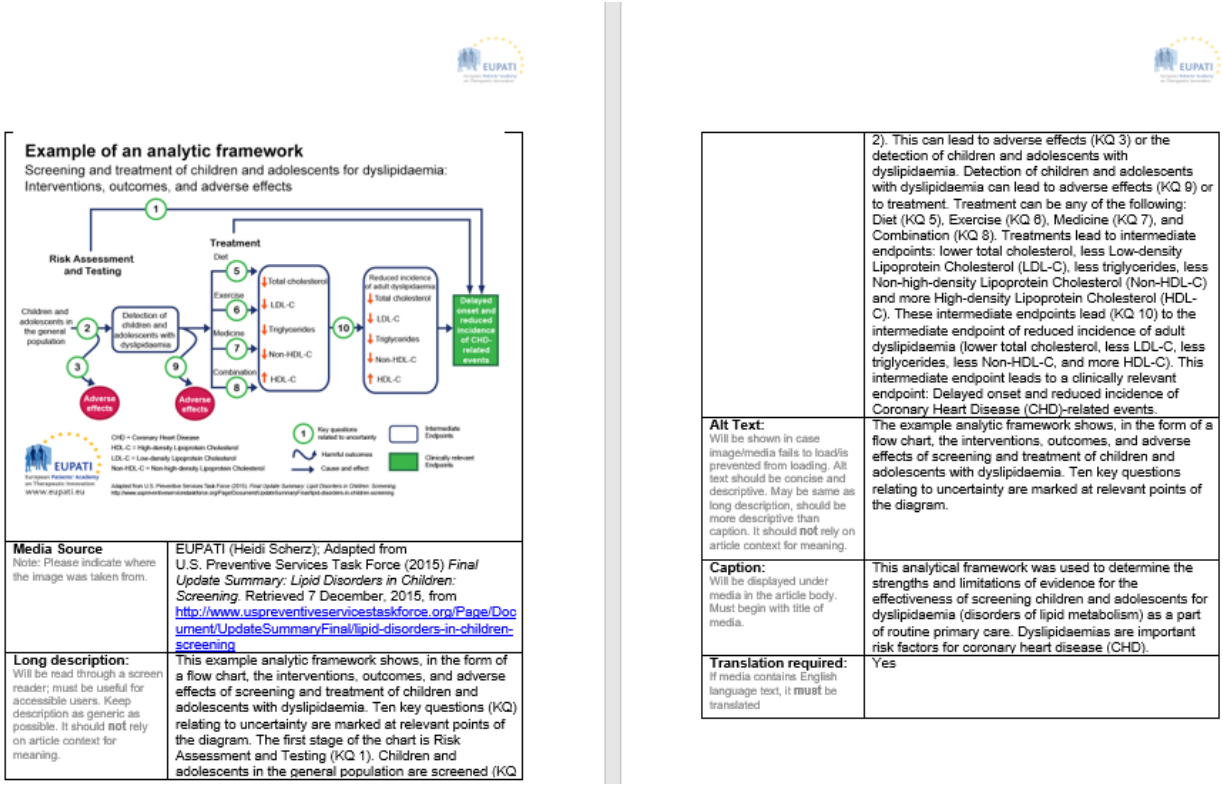
Media Metadata
Complete file metadata as fully as possible.

Title of media In sentence case, as it appears on screen/in the article. Should be general, should not rely on article context for meaning.	Example of an analytic framework
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Analytic-framework-example-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here	https://eupati.box.com/s/bts69of03zixgvauaidw5uc13eo7vuv2

Cut and paste image here:

Figura 9. Primeiras duas páginas do PLATA

Nas páginas da Fig.9, encontramos informação de registo da imagem para posterior carregamento na plataforma da EUPATI. Informação tanto de registo das revisões à imagem, bem como a tipologia da mesma (imagem, apresentação, vídeo…) e posteriores identificadores como o título, nome do ficheiro e link. Ora, como a disponibilização destes conteúdos a traduzir ainda não está definida (falando apenas do caso da versão portuguesa da Toolbox), procedeu-se apenas à análise dos elementos nos dois anexos seguintes.



Example of an analytic framework

Screening and treatment of children and adolescents for dyslipidaemia: Interventions, outcomes, and adverse effects

Media Source Note: Please indicate where the image was taken from.	EUPATI (Heidi Scherz); Adapted from U.S. Preventive Services Task Force (2015) *Final Update Summary: Lipid Disorders in Children: Screening*. Retrieved 7 December, 2015, from http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-children-screening
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	This example analytic framework shows, in the form of a flow chart, the interventions, outcomes, and adverse effects of screening and treatment of children and adolescents with dyslipidaemia. Ten key questions (KQ) relating to uncertainty are marked at relevant points of the diagram. The first stage of the chart is Risk Assessment and Testing (KQ 1). Children and adolescents in the general population are screened (KQ 2). This can lead to adverse effects (KQ 3) or the detection of children and adolescents with dyslipidaemia. Detection of children and adolescents with dyslipidaemia can lead to adverse effects (KQ 9) or to treatment. Treatment can be any of the following: Diet (KQ 5), Exercise (KQ 6), Medicine (KQ 7), and Combination (KQ 8). Treatments lead to intermediate endpoints: lower total cholesterol, less Low-density Lipoprotein Cholesterol (LDL-C), less triglycerides, less Non-high-density Lipoprotein Cholesterol (Non-HDL-C) and more High-density Lipoprotein Cholesterol (HDL-C). These intermediate endpoints lead (KQ 10) to the intermediate endpoint of reduced incidence of adult dyslipidaemia (lower total cholesterol, less LDL-C, less triglycerides, less Non-HDL-C, and more HDL-C). This intermediate endpoint leads to a clinically relevant endpoint: Delayed onset and reduced incidence of Coronary Heart Disease (CHD)-related events.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	The example analytic framework shows, in the form of a flow chart, the interventions, outcomes, and adverse effects of screening and treatment of children and adolescents with dyslipidaemia. Ten key questions relating to uncertainty are marked at relevant points of the diagram.
Caption: Will be displayed under media in the article body. Must begin with title of media.	This analytical framework was used to determine the strengths and limitations of evidence for the effectiveness of screening children and adolescents for dyslipidaemia (disorders of lipid metabolism) as a part of routine primary care. Dyslipidaemias are important risk factors for coronary heart disease (CHD).
Translation required: If media contains English language text, it **must** be translated	Yes

Figura 10. Páginas com informação a traduzir

É então na Fig.10 que encontramos o que pretendemos, informação acerca do diagrama a adaptar. A primeira, *"long description",* referindo-se àquilo que vai ser lido pelos utilizadores da Toolbox, uma informação que se pretende manter acessível e genérica, não sendo necessária a leitura do artigo para compreensão do seu significado. Já o "*alt text*", tal como o nome indica, deverá ser o texto alternativo à imagem, na eventualidade desta não carregar, será este o texto apresentado aos leitores. Pode ter o mesmo conteúdo que o "*long description*", mas devendo ser mais descritivo que a "*caption*". Esta última refere-se à legenda

que acompanhará a imagem na Toolbox, apresentada por baixo da imagem e começando sempre pelo nome da mesma. Bastante útil de um ponto de vista de acessibilidade, pois para pessoas com deficiência visual pode ser traduzido através da ferramenta de leitura de texto, sendo possível "ouvir a imagem". Todos estes elementos introduzem o esquema apresentado na toolbox através de uma representação textual.

Analisando todos os elementos presentes no material a traduzir, procedeu-se ao levantamento de termos-chave, e, dada a vasta amplitude deste projeto em termos de temas explorados, foi possível identificar os tópicos das etapas de Investigação e Desenvolvimento de medicamentos:

1. *Discovery of Medicines & Planning of Medicine Development*
2. *Non-Clinical Testing and Pharmaceutical Development*
3. *Exploratory and Confirmatory Clinical Development*
4. *Clinical Trials*
5. *Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmacoepidemiology*
6. *Health Technology Assessment (HTA) principles and practices*[3]

Estes detalham todo o processo de criação do medicamento, desde a descoberta dos fármacos e consequente plano de desenvolvimento do medicamento (1); aos testes não-clínicos e desenvolvimento farmacêutico (2); ao desenvolvimento clínico exploratório e confirmatório (3); aos ensaios clínicos (4), às questões de regulamentação, de segurança e farmacovigilância (5); à avaliação das tecnologias de saúde (6).

O trabalho de tradução prendeu-se com estes subtemas, sendo que cada um deles se desdobra em diferentes conceitos e pressupostos. Os temas acima mencionados descrevem o longo processo de criação de medicamentos, passando por uma inicial descoberta do composto ativo e subsequente

3 Tópicos apresentados no relatório de atividade do projeto EUPATI entre 2012 e 2017 https://www.eupati.eu/closing-report-eupati-2012-2017/

desenvolvimento do fármaco, passando pelos processos desenvolvimento de não-clínico e clínico.

Cada um destes tópicos obrigou também a uma pesquisa extensa sobre o complexo processo de criação de um medicamento e cada etapa necessária. Após a conclusão da tradução, estes termos foram compilados num glossário para referência futura e agilização de futuras traduções dentro da área.

Algo que também é importante compreender nesta fase inicial, é a função do texto e a quem ele se destina. Ora, sabemos pela descrição do projeto que este visa informar e capacitar sobretudo os doentes especialistas e seus representantes, mas também é passível de ser lido por leigos, isto é, por qualquer pessoa interessada na área e que vise aprofundar o seu conhecimento da mesma. Portanto, podemos definir como recetor principal destes textos, os doentes participantes nos ensaios clínicos e representantes dos mesmos. Partindo do princípio de que estes são possuidores de alguma informação relevante da área, é possível manter o registo formal e técnico do TP. Esta possibilidade deixa espaço para que se possam encontrar equivalentes dos termos propostos no texto de partida com a mesma carga formal e técnica. E apesar de ter referido antes que qualquer um dos textos da Toolbox pode ser consultado por um público-alvo sem formação ou grande conhecimento da área, manter-se-á igualmente, o mesmo registo e expressões terminologicamente desafiantes.

Antes de passar à tradução dos recursos, foi definido um plano de ação. Comecei pela tradução dos PLATA e depois, com a informação neles contida, passar à adaptação das imagens, dado que grande parte da terminologia presente nas imagens estaria também presente no PLATA com uma breve explicação e contextualização.

5.2. Tradução

Na etapa da tradução, Gouadec (2007, p.13) apresenta *transfer*, como “the well-known core activity of shifting to another language-culture combination.” Uma etapa onde são utilizadas não só estratégias de tradução como também ferramentas que facilitam o processo em si.

Esta etapa contou com a ajuda de um grande número de recursos e ferramentas para a sua conclusão. Os ficheiros PLATA foram consultados e analisados através do Microsoft Word, pois foram executados no formato .*docx*. Para a tradução dos mesmos, recorri a um dos softwares mais utilizados dentro do mundo da Tradução, o SDL Trados. Para concluir este projeto, fiz uso da versão 2017. Graças à interface do SDL Trados, criei uma memória de tradução, bem como uma base de dados à medida em que realizei a tradução em questão.

Mas para a adaptação das imagens, cujo ficheiro editável se encontrava em formato .*psd* ou .*ai,* foi necessário fazer uso do Adobe Photoshop, bem como do Adobe Illustrator. Foi a primeira vez com que lidei com ferramentas deste tipo. O primeiro obstáculo foi definir quais as funções a utilizar dentro do software, sendo que, como a tarefa incumbida foi a de tradução, na verdade, só teria de aprender e saber como editar o texto nelas. E de facto, foi isso mesmo que foi feito. De modo a não alterar a formatação original dos elementos visuais, recorri às ferramentas de edição de texto, tanto no Adobe Photoshop e Illustrator e pouco mais. Portanto, apesar do choque inicial causado por software desconhecido, rapidamente foi possível ultrapassar o obstáculo e passar à tradução de todo o material fornecido.

5.3. Problemas de tradução

O caminho a percorrer até ao produto final envolve sempre a resolução de problemas de tradução. Por mais preparado e capaz que um tradutor seja, haverá sempre questões que surgem durante o processo de tradução, que exigem uma redobrada atenção e, na maioria das vezes, consomem grande parte do tempo de trabalho, tal como é confirmado por Montalt e Davies, “[i]t should be noted that in the translation process more than half of the time is invested in detecting and solving terminological problems.” (Montalt e Davies. 2007 p.53).

Perante os desafios da especialidade em questão, há que procurar como tomar certas decisões de modo a resolver os problemas terminológicos. Destaco algumas das principais dificuldades sentidas dentro do trabalho.

5.3.1. Acronímia/Siglas

O grande desafio neste trabalho foi a procura de equivalências no que toca a siglas, acrónimos referentes a nomes de instituições e procedimentos regulamentares. Aqui a estratégia foi decifrar o que cada uma das siglas representavam, em inglês, para depois, na eventualidade de não encontrar um equivalente já na sua versão traduzida e usada dentro do contexto português, poder dar uma descrição do termo em questão, mantendo-o fiel ao original. Dos exemplos abaixo descritos, foi possível encontrar os respetivos equivalentes, até porque na grande parte dos exemplos abaixo referenciados, o consenso nos textos da especialidade é o uso do acrónimo/sigla original em inglês e depois a explicação/tradução do mesmo, na descrição deste. Por vezes, até mesmo havendo uma tradução dos mesmos, é mais comum o uso da versão em inglês, por falta de consenso ou uso generalizado do português. Em geral, faz sentido que, por estas entidades operarem internacionalmente, sejam referidas pelo seu acrónimo/sigla oficial, na língua em que foram criadas. Para uma compreensão destas siglas há uma legenda em grande parte dos esquemas. Deste modo, justifica-se a não alteração das siglas, através da tradução do nome de cada entidade.

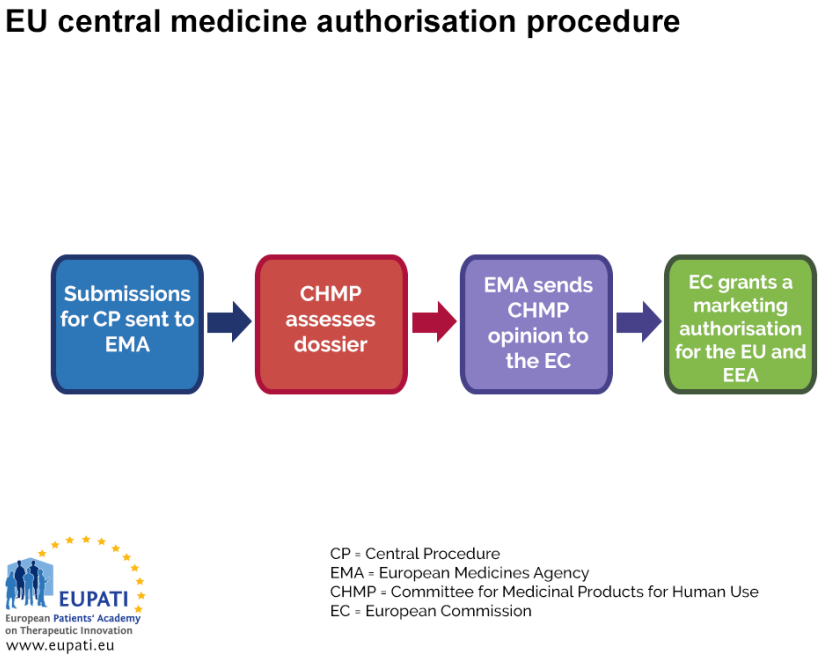


Figura 11. EU central medicine authorisation procedure

Alguns exemplos:

PDCO – Comité Pediátrico (Paediatric Comittee)

EMA – Agência Europeia de Medicamentos (European Medicines Agency)

CHMP – Comité dos Medicamentos para Uso Humano (Committee for Medicinal Products for Human Use)

CAT – Comité das Terapias Avançadas (Committee for Advanced Therapies)

COMP – Comité dos Medicamentos Órfãos (Committee for Orphan Medicinal Products)

5.3.2. Polissemia

É frequente o tradutor deparar-se com palavras cujo significado representa um conceito já existente num contexto não-formal e, quando aplicado ao contexto pertencente ao TP, pode criar alguma confusão. É o caso de "Multi-arm multi-stage design (MAMS)". Ora, sabendo que *arm* (braço) remete para uma parte do corpo na zona superior do mesmo, o raciocínio inicial perante este termo, é o de procurar que outro significado poderá ter este aplicado ao ensaio clínico. E após alguma pesquisa, foi com espanto que descobri que é utilizado o termo "braço" da seguinte forma: *"An arm of a clinical trial is a group of patients receiving a specific treatment (or no treatment)*[4]*.* Portanto, dado que a palavra "braço" adota um significado relevante no contexto do projeto, foi possível transferir o seu significado e mantê-lo tal como no original, cuja palavra também é polissémica. Obteve-se, assim, na tradução final "Ensaio multifaseado de vários **braços**". "Braços" significa aqui os diferentes grupos de doentes num dado ensaio, sujeitos a um determinado tratamento.

[4] Retirado de https://www.focr.org/randomized-and-single-arm-trials.

5.3.3. Expressões com várias palavras

Aqui, as dificuldades prendem-se com uma questão de sintaxe, sendo que no inglês há uma estrutura diferente de posição das palavras em comparação com o português. O exemplo mais evidente surge com os tipos de desenho dos ensaios, onde observamos um título extenso e que compreende diferentes termos que devem ser analisados individualmente. É em exemplos destes que a tradução palavra por palavra ajuda a descodificar o que se pretende traduzir, numa primeira fase, para que depois se possam aplicar as corretas estruturas sintáticas, de modo a que o recetor entenda o que foi adaptado. No caso do ensaio com título *"Multi-arm multi-stage design (MAMS)"* encontramos vários elementos que individualmente até não podem ter muita conexão entre si, mas que em conjunto, produzem o significado deste desenho de ensaio.

Multi-arm – múltiplos braços (tendo já estabelecido que "braço" é aceite neste contexto com um significado diferente como foi exemplificado no ponto 2).
Multi-stage – Múltiplas fases; aqui não restam muitas dúvidas, mas em todo o caso verificou-se o uso de fase neste contexto particular.
Design – Desenho, pois trata-se da esquematização do ensaio, isto é, a abordagem usada neste ensaio em particular.

Ora, perante esta tradução inicial dos vários segmentos obtemos, caso não se fizesse nenhuma alteração sintática "Múltiplos braços, múltiplas fases desenho". Mas, como na sintaxe portuguesa, o nome surge no início do grupo nominal, são necessárias algumas alterações, obtendo então "Desenho múltiplos braços múltiplas fases". Não contente com o resultado e temendo uma receção confusa por parte dos recetores do texto, procedi a mais uma alteração da sintaxe "Ensaio multifaseado de vários braços". Ora, o que mudou? Primeiramente, sugeri a tradução de "design" para "ensaio" pois de facto o que se apresenta no esquema é o ensaio que compreende o desenho multifaseado de vários braços. Para uma melhor compreensão, o uso do termo "ensaio" em detrimento da tradução inicial permite ao leitor inferir que o esquema irá abordar um tipo específico de ensaio,

sendo este “multifaseado”, ou seja, de várias etapas, que irão elas compreender diferentes grupos de doentes a receber um tratamento específico (braços). Portanto alterando a estrutura, é possível apresentar uma expressão facilmente compreendida por quem a receber, independentemente de ser versado na terminologia dos ensaios clínicos, é possível, pelo menos, saber de que se trata o esquema (um ensaio) e que esquema segue (multifaseado de vários braços). Cabe depois ao doente perito, aprender, dentro do contexto de formação da EUPATI, os diferentes desenhos de ensaios aos quais poderá participar e decifrar o uso do termo “braço”.

5.3.4. Predomínio do inglês como língua franca nos textos de Saúde

Este tópico não se apresenta como um problema tão linear como os outros mencionados nos tópicos 5.1 a 5.6, mas sim como uma situação que faz parte do quotidiano dos tradutores. Tal como Karwacka (2015) evidencia, a multiplicidade de recursos apenas em inglês ou então o uso recorrente de termos em inglês em textos escritos em português é uma constante no que toca a artigos científicos e texto relativos à saúde e medicina.

> The scientific world is predominantly English-speaking and major scientific journals publish papers in English. The share of scientific papers written in English in the total number of papers published is 80% according to Montgomery (2009) and 85% according to Kaplan (2001). (Karwacka, 2015, p.273)

Dado que o inglês é a língua mais utilizada no contexto científico, no âmbito da pesquisa para esta tradução, encontrei poucos textos académicos sobre esta temática redigidos em português. Mesmo em textos produzidos em português, é frequente o uso de empréstimos. Noutras instâncias, deparei-me com textos produzidos ou disseminados apenas em inglês, apesar de se destinarem a públicos falantes de português. É curioso verificar que, por vezes, mesmo existindo equivalentes em português, grande parte dos textos científicos está repleta de estrangeirismos. Este facto dificultou a minha tarefa e tornou a pesquisa de textos de referência numa verdadeira aventura.

Acredito na uniformização da terminologia como um passo necessário para a adequação dos termos a usar, através de um esforço conjunto entre tradutores, linguistas e especialistas. Seria assim possível garantir a completa adequação das escolhas de um tradutor, já que sem uma uniformização, o tradutor está limitado ou dependente da escolha e validação do especialista ao qual submete as suas sugestões. Ora, com um registo convencionado de terminologia científica, haveria, portanto, um grande incentivo à celeridade dos trabalhos de tradução,

bem como à sua eficácia e correção. Grande parte desta solução poderá passar pela elaboração de glossários, bases de dados ou até mesmo, repositórios de termos, abrangendo as variadas áreas da Saúde e Ciências da Vida.

5.3.5. Aumento de carateres do inglês para português

Para um tradutor, a tradução do inglês para o português implica vários fatores que dificultam a sua execução. Um deles sendo, nomeadamente, a quantidade de carateres que tem tendência a aumentar aquando da tradução do inglês para o português. Dizer que o português é uma língua desafiante não faz jus à sua riqueza linguística. O que se impõe aqui é o facto de na língua inglesa, geralmente se utilizarem menos carateres, permitindo uma comunicação técnica muito mais eficiente e económica. No que toca ao português, não se torna impossível, mas é muito mais exigente traduzir para esta língua sem aumentar o número de carateres utilizados pelo TC.

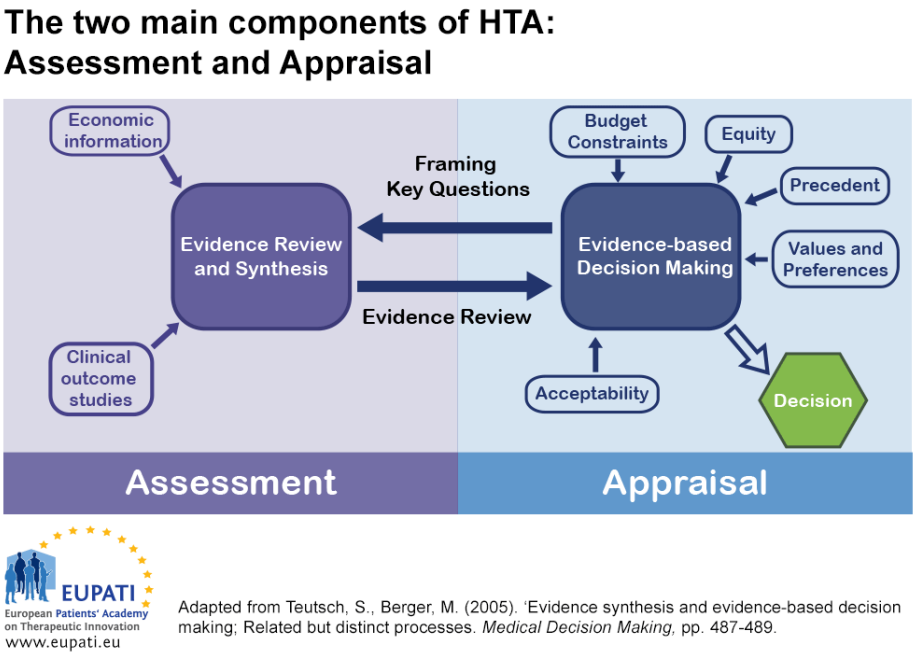


Figura 12. The two main components of HTA: Assessment and Appraisal

Na Fig.12, vemos formas geométricas definidas e toda uma informação bem encaixada nas mesmas. Vejamos agora o que acontece ao transferir para o português a mesma informação.

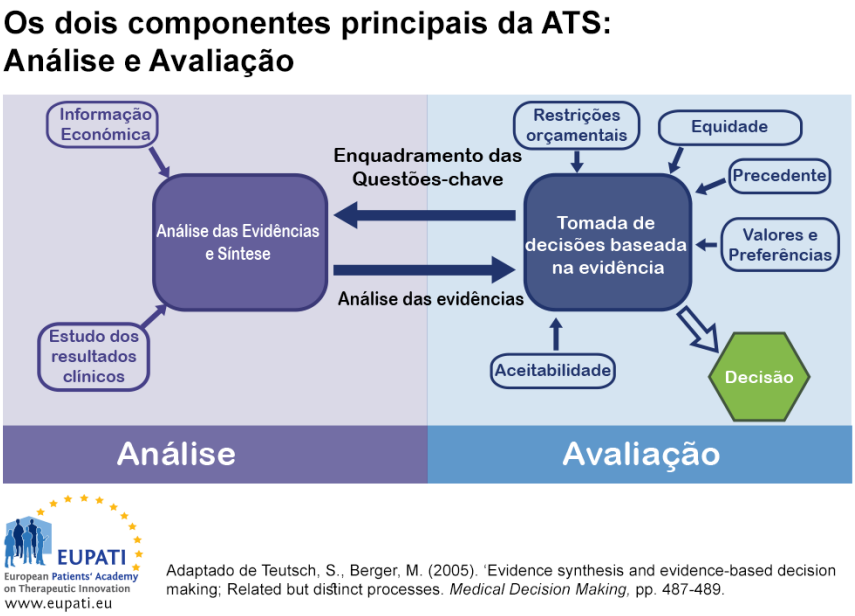


Figura 13. Os dois componentes principais da ATS: Análise e Avaliação

Na Fig.13, foi diminuído o tamanho de letra do quadro roxo na seção "Análise das Evidências e Síntese" para que fosse possível caber todo texto sem proceder à alteração do formato do esquema. Na Fig.14, é possível ver como o tamanho das letras do quadrado "*Evidence based Review*" é ligeiramente maior.

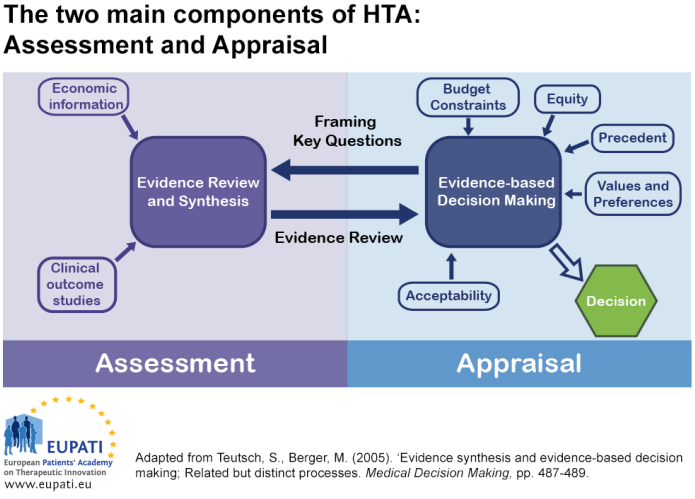


Figura 14. The two main components of HTA: Assessment and Appraisal

"*Evidence Review and Synthesis*" apresenta 29 carateres e em "Análise das Evidências e Síntese" já se contam 32 carateres. Uma ligeira diferença, mas que

já obriga a uma formatação diferente. Neste caso, foi alterado o tamanho de letra para não alterar o design do esquema.

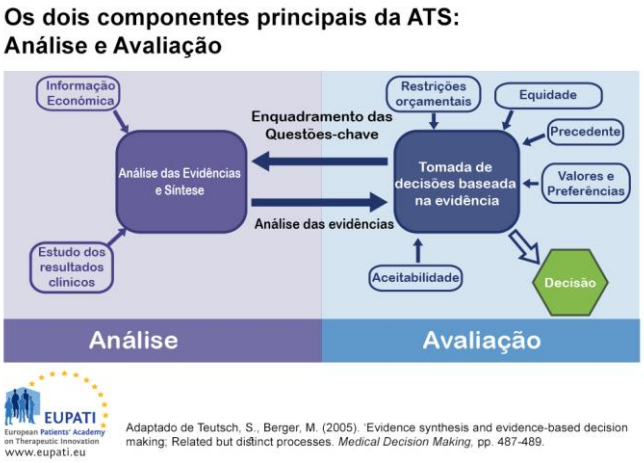


Figura 15. Os dois componentes principais da ATS: Análise e Avaliação

Este é o exemplo de como o aumento dos carateres de uma língua para a outra pode obrigar a uma formatação diferente dos moldes esquemáticos. E apesar de esta não ser a função principal do tradutor, pode-lhe ser requerida a atenção ao detalhe para um posterior trabalho de pós-edição. O feedback do tradutor quanto às necessidades de carateres e espaço na figura onde traduz, poderá vir a ser relevante na fase de adaptação dos conteúdos visuais.

Este problema dos carateres torna-se mais evidente na tarefa executada neste projeto, quando as imagens facultadas possuem já uma formatação definida, sendo que qualquer alteração necessária ao design da imagem, requer toda uma reavaliação do espaço e das decisões esquemáticas da mesma. Para facilitar a leitura e compreensão dos documentos do projeto, procedi a uma sugestão de alteração no tamanho das letras de modo a poder apresentar uma tradução clara e apresentável. Com a perfeita consciência, no entanto, de que, com a introdução destes elementos na Toolbox da EUPATI, estas alterações são meras sugestões e não definitivas opções estilísticas para as imagens.

5.3.6. Outros exemplos

Ensaio vs. Estudo clínico

Uma das primeiras questões levantadas foi o surgimento destes dois termos erroneamente utilizados como equivalentes. *Clinical study* e *Clinical trial* são apresentados em inglês tanto para representar estudos ou ensaios clínicos, mas nunca é apresentada uma clara distinção entre ambos. Já no português vemos bem uma distinção entre os dois, sendo que Ensaio Clínico envolve o uso de medicamentos no ser humano, enquanto Estudo Clínico não compreende que haja aplicação de medicamentos no ser humano. Para aplicar o conceito correto basta olhar para o pressuposto dessa mesma intervenção (com ou sem uso de medicamentos) e a decisão terminológica torna-se muito mais simples.

Endpoint

Sobre o termo *Endpoint* recai um problema de contexto. Um termo que leva a diferentes interpretações, *Endpoint* pode ser considerado um parâmetro ou um resultado, sendo que, na maior parte da documentação relativa ao processo de desenvolvimento de medicamentos, este se referia mais aos resultados obtidos ou a obter do que particularmente a um parâmetro. Mas neste caso em particular, cabe ao tradutor avaliar e decidir qual a melhor opção baseada no contexto em que o termo se insere. Em último caso, a consulta com o especialista é a melhor abordagem, de modo a retirar qualquer dúvida.

5.4. Pós Tradução

Após completar todas as tarefas de tradução, foi feita uma revisão extensiva, passando por uma leitura aprofundada e comparativa com outros textos dentro da mesma especialidade. E foram identificadas a(s) tipologia(s) em que este se insere, de modo a aferir se a transmissão de informação tanto num como noutro, se mantinha dentro do mesmo registo. Gouadec (2007 p.13) refere os processos necessários para garantir a qualidade do produto final, ao referir que "[p]ost-transfer covers anything that has to be done to meet the quality requirements and criteria prior to delivery of the translated material. It mostly pertains to quality control and upgrading. It also includes formatting and various preparations for delivery.".

Para obter correção científica nas opções tomadas, e de modo a obter validação das sugestões de tradução, foram consultados dois especialistas - Paula Pinto e Tiago Campos, colegas do Prof. Doutor Bruno Gago, para rever as questões mais preocupantes e aferir se o trabalho realizado se coadunava com os parâmetros e exigências a que a especialidade obriga.

A tradução foi revista e alterada mediante as sugestões dadas pelos especialistas e pela leitura atenta para que o produto final se apresente como definitivo e em concordância com os objetivos estabelecidos no projeto.

6. Análise Crítica

Relativamente ao trabalho executado, concluo que foi possível realizar os objetivos propostos. Apesar de um longo e moroso caminho percorrido é com certeza que afirmo que o trabalho foi concluído dentro daquilo que foi requerido pela representação portuguesa da EUPATI.

Apesar da grande especificidade deste trabalho, foi-me possível conhecer e enfrentar as diferentes questões de tradução que foram surgindo, bem como as dúvidas múltiplas que o trabalho despertou. Não foi um processo fácil, houve um grande esforço despendido para o concluir. No entanto, o facto de este projeto ser bem desafiante, fez com que a tarefa de o concluir fosse ainda mais interessante. Apesar do nível de exigência e dificuldade, foi um trabalho que reconfirmou a necessidade de uma especialização por parte do. Os subtemas do trabalho em questão foram variados, como foi possível observar neste projeto, o que obrigou a uma incrível flexibilidade e capacidade quase camaleónica de adaptação este terreno desconhecido e torná-lo algo acessível a futuros leitores do projeto, como também aos futuros utilizadores da Toolbox portuguesa da EUPATI.

Encontrar novos desafios numa área que se mantém em constante atualização não é uma tarefa difícil, mas dadas as necessidades de adaptação ao rápido crescimento das novas tecnologias, torna-se verdadeiramente interessante trabalhar com teorias basais do universo da Tradução, transpondo-as para os desafios atuais, exemplo disso foi a questão das tipologias textuais. Discutidas no âmbito da tradução há alguns anos, e mesmo assim, ainda pertinentes, úteis e moderna na forma como se inserem nas questões contemporâneas da tradução.

Ainda no tópico da tipologia, é também importante comprovar as capacidades camaleónicas que os tradutores desenvolvem com a sua contínua atividade, ao saber lidar com projetos onde o corpo do texto a transferir apresenta uma forma híbrida (texto + esquemas) e onde a abordagem terá de ser cuidada e passível de ser capaz de alternar entre os dois tipos com rapidez e precisão.

É de facto surpreendente e eu sinto que esta área tem tanto para me ensinar como eu tenho para aprender com ela. E surpreendo-me a mim ao demonstrar capacidade de gestão destes desafios com entusiasmo e curiosidade.

De referir que, quanto mais experiências de tradução um tradutor tem, mais descobre o quão delicado e exigente é o mundo da tradução. Apesar de os entendidos da área saberem bem o valor do seu ofício e seu contributo para a área, não deixa de ser importante refletir como um domínio tão específico como o deste trabalho desperta ou reforça a o trabalho árduo que um tradutor tem. Novamente, é bem sabido que a especialização em tradução é, cada vez mais, uma opção benéfica não só para o enriquecimento do profissional de tradução como para o incremento do trabalho colaborativo entre tradutores e distintos profissionais das mais diversas áreas do saber, provando ser um estímulo para que ambos tenham plena noção e consideração pelas respetivas áreas de trabalho.

7. Conclusão

Este projeto teve como objeto a tradução de elementos visuais e textuais pertencentes à Toolbox do projeto EUPATI. O projeto foi inicialmente introduzido, apresentando-se a organização por detrás da Toolbox e sua organização em Portugal. Foram também apresentadas as motivações que levaram à escolha deste projeto.

Seguidamente, foram apresentados conceitos relevantes dentro da área da Investigação e Desenvolvimento de medicamentos, partindo de uma definição proveniente da Lei da Investigação Clínica. Foi possível analisar o seu significado, para uma melhor compreensão do domínio a explorar na tarefa de tradução. Referiu-se também a importância do setor e resultantes contributos económicos.

Com recurso a elementos visuais do trabalho realizado, foi possível evidenciar a complexidade do processo de criação de medicamentos e qual o contributo dos doentes em todo este processo. Foi possível observar que o doente exerce uma influência e um papel de destaque, visto que o vemos presente nas diversas fases. Explanando brevemente as fases com recurso ao texto traduzido, pôs-se também, em evidência a relevância do papel do tradutor, que nada mais é do que uma ponte entre o doente e núcleos de desenvolvimento de medicamentos. Neste contexto, a tradução de materiais irá capacitar o participante nos ensaios clínicos a uma melhor compreensão do processo em questão, de modo a que possa melhor participar neles.

Passando ao tópico da tradução especializada, esta foi caraterizada, e esclarecendo-se o papel desta, bem como as funções e responsabilidades do tradutor especializado perante o público das suas traduções.

No processo de tradução, foram mencionadas as bases teóricas, as chamadas linhas condutoras na execução do trabalho prático e teórico, que orientam o pensamento do tradutor e o levam a uma melhor conceção do trabalho a realizar. Usando a tipologia textual como critério de análise do trabalho, foi possível ver

como a identificação da tipologia pode facilitar a vida do tradutor, se bem aplicada.

Foram também descritas as fases de tradução, sendo elas a pré tradução, a tradução e a pós-tradução. Dentro da fase da tradução são também esclarecidas algumas dificuldades e obstáculos de tradução, bem como a respetiva solução. O trabalho é finalizado com a análise crítica, que põe em relevo a perspetiva pessoal do processo de tradução e aprendizagem que este projeto de mestrado providenciou.

Logrou-se, portanto, concluir as traduções bem como o projeto explanatório das mesmas, permitindo assim concluir uma etapa de formação académica, que é o Mestrado em Tradução Especializada em Saúde e Ciências da Vida.

8. Referências

Bernardo, A.M. (2012). Tipo, género e espécie de texto para uma classificação textual relevante para a tradução. *Estudos Linguísticos/Linguistic Studies, 8, Edições Colibri/CLUNL,* Lisboa, 2012, p. 73-89
Disponível em:
http://clunl.fcsh.unl.pt/wpcontent/uploads/sites/12/2018/02/73_90.pdf
(última consulta 2019/12/01)

De Beaugrande, R. & Dressler, W. U. (1981). *Introduction to text linguistics*. London, New York: Longman.

Geissler, J. (2017) *EUPATI Project: Executive Summary*
Disponível em: https://www.eupati.eu/CLOSING-REPORT-EUPATI-2012-2017/
(última consulta em: 2019/12/01)

Gouadec, D. (2007). *Translation as a Profession*. Philadelphia: J. Benjamins Pub. Co.

House, J. (1979). *Translation Quality Assessment: A Model Revisited*. Tübingen: G. Narr.

Bowen, S. (2015). The Impact of Language Barriers on Patient Safety and Quality of Care. Société Santé en français.
Disponível em:
http://www.reseausantene.ca/wp-content/uploads/2018/05/Impact-language-barrier-qualitysafety.pdf
(última consulta em 2020/01/06)

Hernandez Guevara; H. Grassano; N. Tuebke, et al. (2018) *Industrial R&D EU Investment Scoreboard*. Publications Office of the European Union. 978-92-79-

97293-5 Disponível em: https://ec.europa.eu/jrc/en/publication/2018-eu-industrial-rd-investment-scoreboard

Karwacka, W. (2015). Medical Translation. In: Ł. Bogucki, S. Goźdź-Roszkowski, P. Stalmaszczyk (eds.) *Ways to Translation*. Wydawnictwo Uniwersytetu Łódzkiego, p. 271-298.
Disponível em:
https://www.researchgate.net/publication/314404773_Medical_translation
(última consulta em 2019/11/30)

Lei n.º 21/2014. *Lei da investigação clínica*. Diário da República: Série I, n.º 75 (2014). Disponível em: https://dre.pt/web/guest/legislacao-consolidada/-/lc/56927694/view?jp=true&w=2018-08-14.
(última consulta em 2019/11/30)

Montalt, V e Davies, González, M. (2007). *Medical Translation Step by Step: Learning by Drafting*. Londres/Nova Iorque: Routledge.

Newmark, P. (1988). *A Textbook of Translation.* Prentice-Hall International. Michigan University.

Reiss, K. e Vermeer, H. (2013). *Towards a general theory of translational action: Skopos theory explained.* Trad. C, Nord. Nova Iorque: Routledge.

Sorina, P. (2016). Translating in a Specialised Context: Challenges and Risks. *Bulletin of the Polytechnic Institute of Iasi. Section: Social Sciences*, LXII (LXVI), f, 1, (p. 51-66).
Disponível em:
https://www.researchgate.net/publication/304062105_TRANSLATING_IN_A_SPECIALIZED_CONTEXT_CHALLENGES_AND_RISKS
(última consulta em 2019/11/29)

Steiner, G. (1998*). Language and silence: Essays on language, literature, and the inhuman.* Yale University Press.

9. Recursos on-line

APIFARMA - https://www.apifarma.pt/

Dicionário Priberam - https://www.priberam.pt/

EUPATI - https://www.eupati.eu/

EUR-LEX - https://www.eur-lex.europa.eu/

Eurordis - https://www.eurordis.org/

Eurotermbank - https://www.eurotermobank.com/

IATE - https://iate.europa.eu/home/

Infarmed - https://www.infarmed.pt/

Linguee - https://www.linguee.pt/

MSD Manuals - https://www.msdmanuals.com/

Reverso - https://www.context.reverso.net/traducao/

Jostrans - http://www.jostrans.org/

Research Gate - https://www.researchgate.net/

10. Anexos

11. Anexos – Textos na Língua de Partida

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

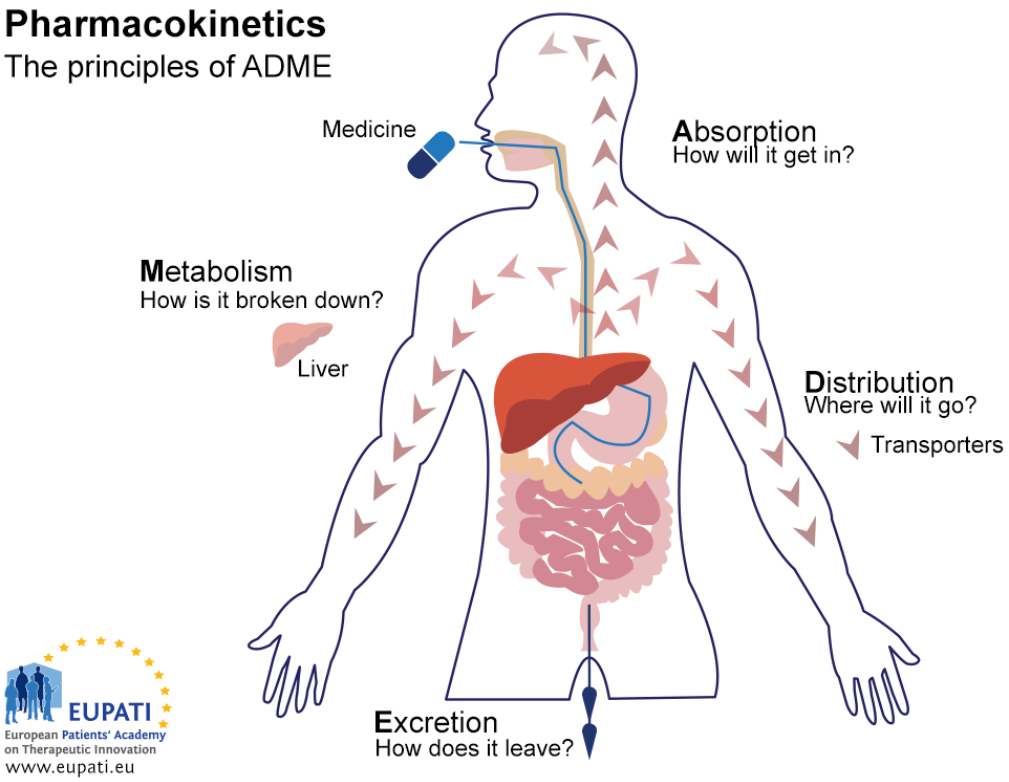
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	6.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	21.9.2015	New version updated w/ Logo, Spelling, etc. Metadata updated.	FINAL	4

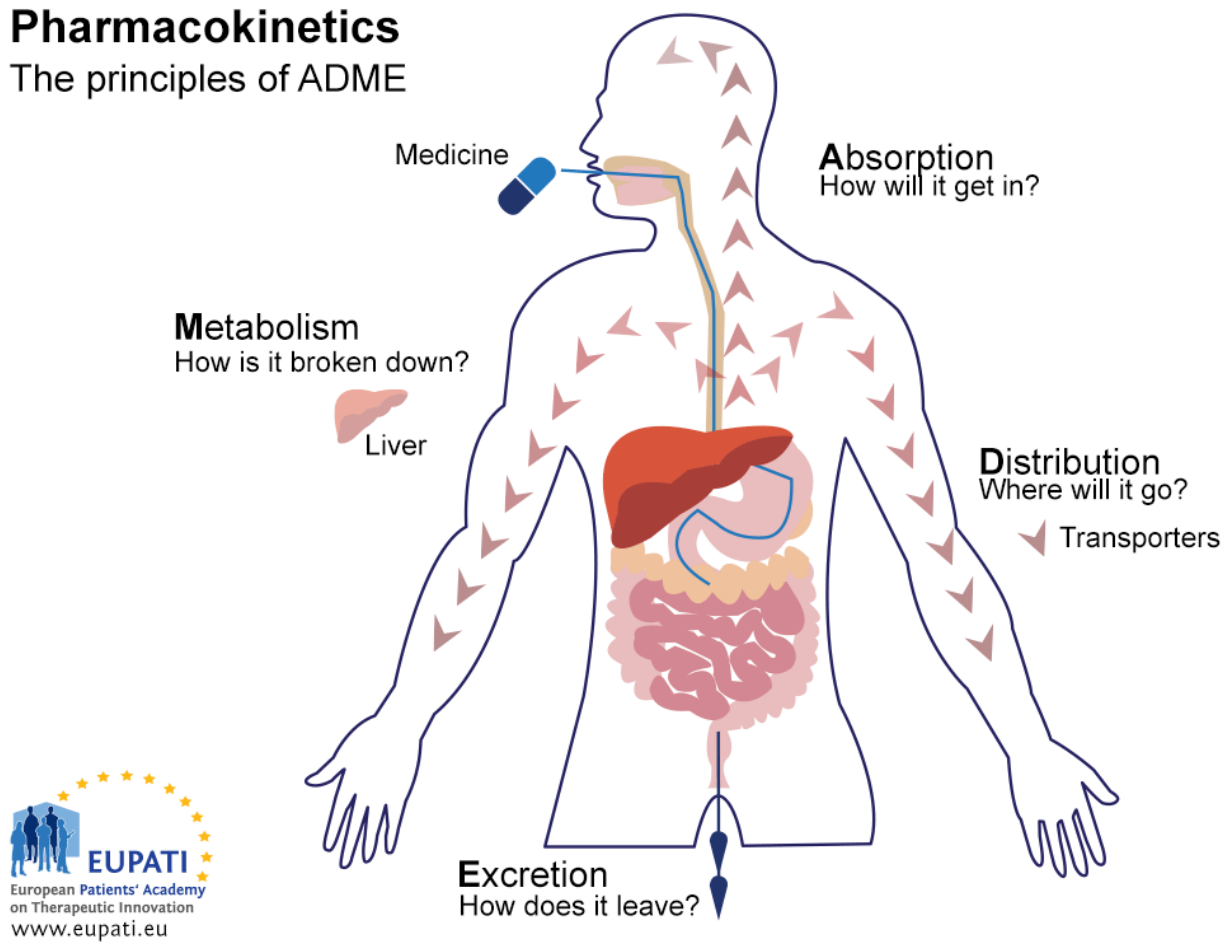
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	ADME
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	ADME-v4_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4164449665/ADME
Cut and paste image here:  	
Media Source	EUPATI

Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram explaining the principles of Pharmacokinetics: ADME. The diagram shows the outline of a human body, including the digestive system (mouth, oesophagus, stomach, small and large intestines) and liver. The principles of ADME concern the interaction of the medicine with the body and vice versa. Absorption (represented by the administration of a tablet) asks the question 'How will it get in?' Distribution asks the question 'Where will it go?' The distribution of the medicine from the stomach via the bloodstream to the body is represented here by a series of arrows. Metabolism asks the question 'How is it broken down?' This is represented by the presence of the liver in the diagram. Excretion asks the question 'How does it leave' and is represented with arrows proceeding from the colon.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram explaining the principles of Pharmacokinetics: ADME. The diagram shows the outline of a human body, including the digestive system (mouth, oesophagus, stomach, small and large intestines) and liver. The principles of ADME concern the interaction of the medicine with the body and vice versa. Absorption (represented by the administration of a tablet) asks the question 'How will it get in?'. Distribution asks the question 'Where will it go?' The distribution of the medicine from the stomach via the bloodstream to the body is represented here by a series of arrows. Metabolism asks the question 'How is it broken down?' This is represented by the presence of the liver in the diagram. Excretion asks the question 'How does it leave' and is represented with arrows proceeding from the colon.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The key principles of Pharmacokinetics – the study of the effect the body has on a medicine – are represented in the acronym ADME.
Translation required:	Yes

If media contains English language text, it **must** be translated	


Pharmacokinetics
The principles of ADME
Medicine
Absorption
How will it get in?
Metabolism
How is it broken down?
Liver
Distribution
Where will it go?
Transporters
Excretion
How does it leave?
EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

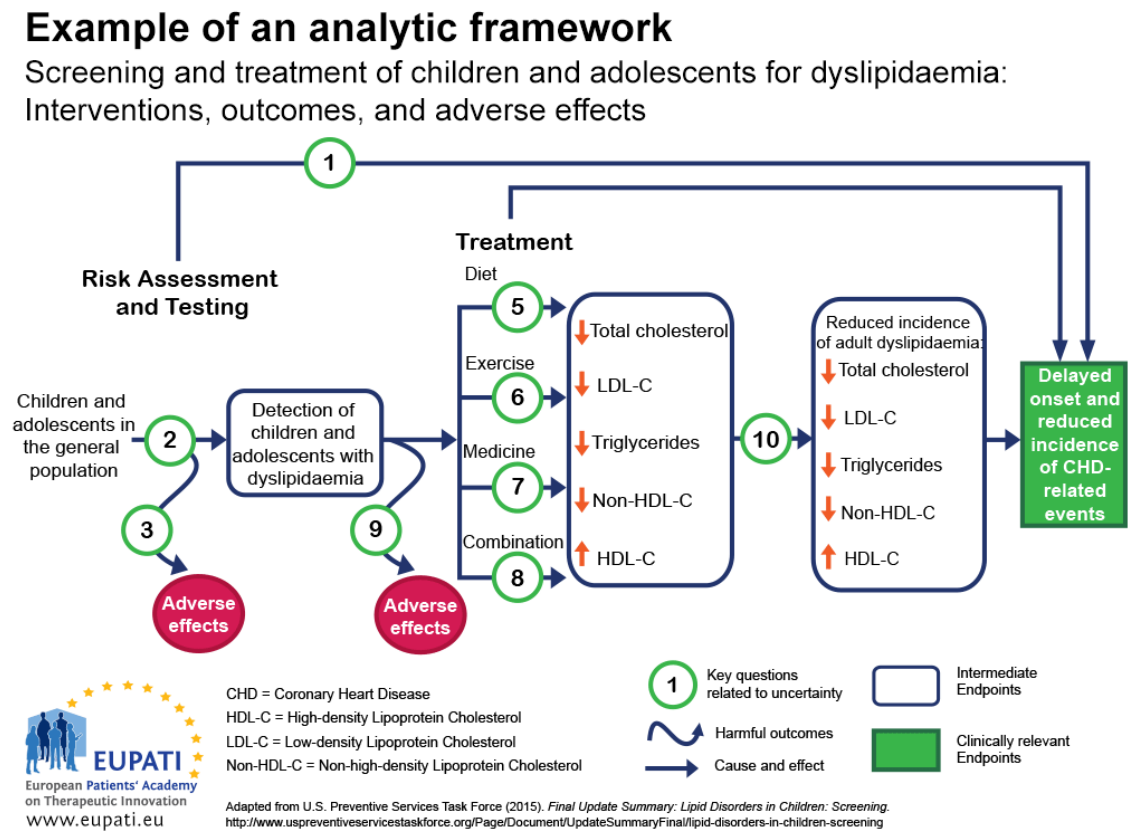
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	7.12.2015	PLATA Created	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Example of an analytic framework
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Analytic-framework-example-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/bts69of03zixgvauaidw5uc13eo7vuv2

Cut and paste image here:

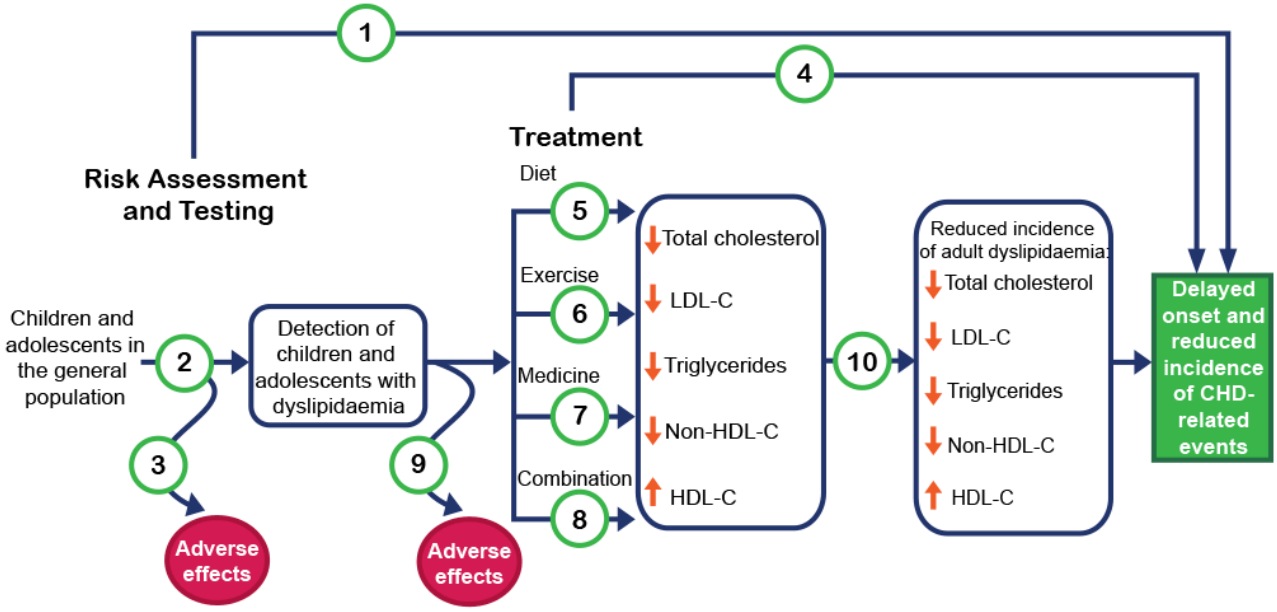


Media Source Note: Please indicate where the image was taken from.	EUPATI (Heidi Scherz); Adapted from U.S. Preventive Services Task Force (2015) *Final Update Summary: Lipid Disorders in Children: Screening*. Retrieved 7 December, 2015, from http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-children-screening
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	This example analytic framework shows, in the form of a flow chart, the interventions, outcomes, and adverse effects of screening and treatment of children and adolescents with dyslipidaemia. Ten key questions (KQ) relating to uncertainty are marked at relevant points of the diagram. The first stage of the chart is Risk Assessment and Testing (KQ 1). Children and adolescents in the general population are screened (KQ 2). This can lead to adverse effects (KQ 3) or the detection of children and adolescents with dyslipidaemia. Detection of children and adolescents with dyslipidaemia can lead to adverse effects (KQ 9) or to treatment. Treatment can be any of the following: Diet (KQ 5), Exercise (KQ 6), Medicine (KQ 7), and Combination (KQ 8). Treatments lead to intermediate endpoints: lower total cholesterol, less Low-density Lipoprotein Cholesterol (LDL-C), less triglycerides, less Non-high-density Lipoprotein Cholesterol (Non-HDL-C) and more High-density Lipoprotein Cholesterol (HDL-C). These intermediate endpoints lead (KQ 10) to the intermediate endpoint of reduced incidence of adult dyslipidaemia (lower total cholesterol, less LDL-C, less

	triglycerides, less Non-HDL-C, and more HDL-C). This intermediate endpoint leads to a clinically relevant endpoint: Delayed onset and reduced incidence of Coronary Heart Disease (CHD)-related events.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	The example analytic framework shows, in the form of a flow chart, the interventions, outcomes, and adverse effects of screening and treatment of children and adolescents with dyslipidaemia. Ten key questions relating to uncertainty are marked at relevant points of the diagram.
Caption: Will be displayed under media in the article body. Must begin with title of media.	This analytical framework was used to determine the strengths and limitations of evidence for the effectiveness of screening children and adolescents for dyslipidaemia (disorders of lipid metabolism) as a part of routine primary care. Dyslipidaemias are important risk factors for coronary heart disease (CHD).
Translation required: If media contains English language text, it **must** be translated	Yes

Example of an analytic framework

Screening and treatment of children and adolescents for dyslipidaemia: Interventions, outcomes, and adverse effects



CHD = Coronary Heart Disease
HDL-C = High-density Lipoprotein Cholesterol
LDL-C = Low-density Lipoprotein Cholesterol
Non-HDL-C = Non-high-density Lipoprotein Cholesterol

1 Key questions related to uncertainty
Harmful outcomes
Cause and effect
Intermediate Endpoints
Clinically relevant Endpoints

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adapted from U.S. Preventive Services Task Force (2015). *Final Update Summary: Lipid Disorders in Children: Screening.* http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-children-screening

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

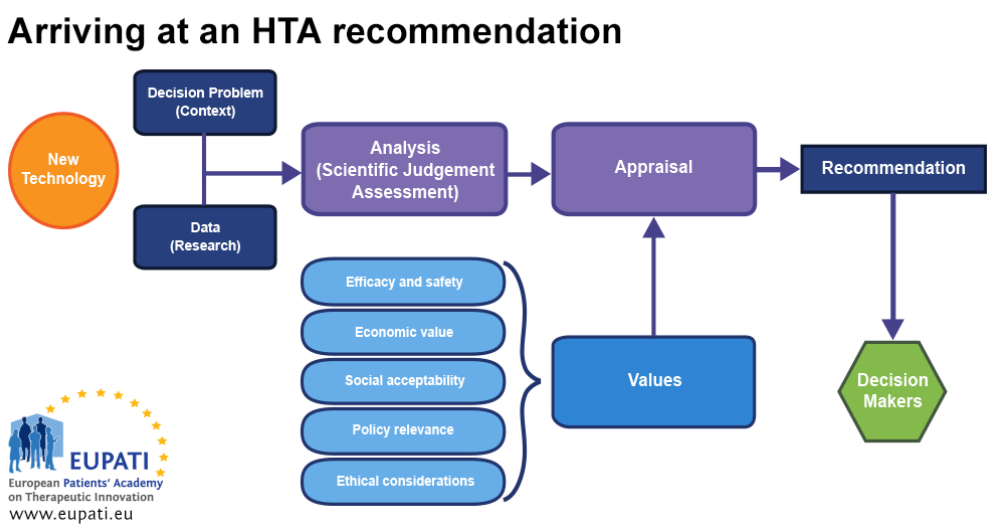
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	1.3.2016	PLATA Created	Draft	1.1

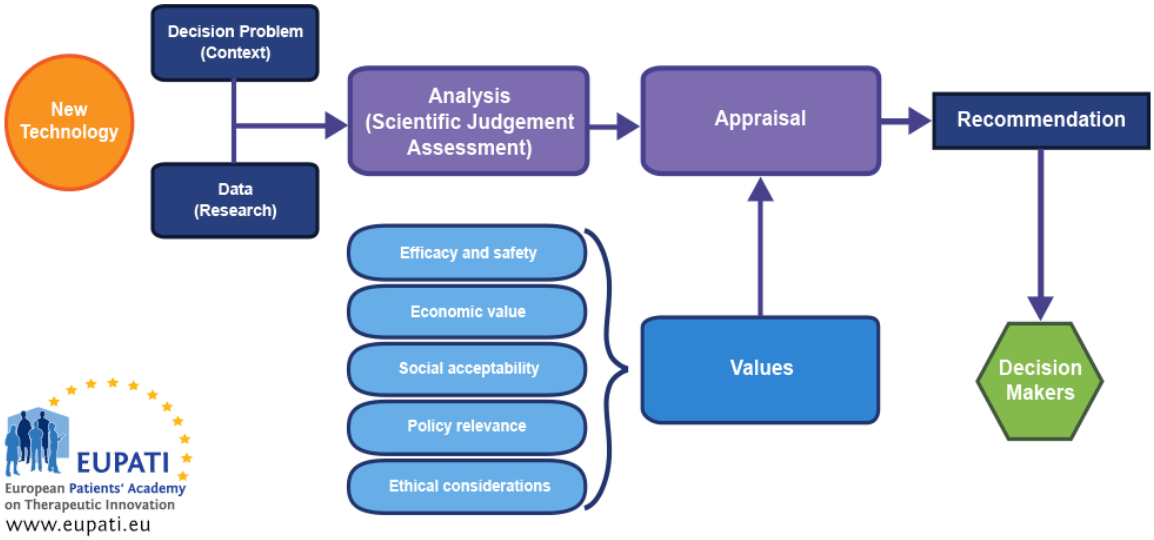
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Arriving at an HTA recommendation
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	HTA-decision-detail-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/yxcvwaayzh8ewls1h4nzzw296jdoqnor
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A flow chart envisioning the process of arriving at an HTA recommendation. The process begins with a new technology. There are then two main processes, each with their own inputs: Analysis (Scientific Judgement Assessment) and Appraisal. The decision problem (context) and data (research) are the main inputs into the Analysis process. The results of the analysis process are an input into the appraisal process, which must also take Values into consideration. Values include: Efficacy and safety, economic value, social acceptability, policy relevance, and ethical considerations. The end of the appraisal process results in a recommendation, which is then delivered to the decision makers.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A flow chart envisioning the process of arriving at an HTA recommendation.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The process and considerations of arriving at an HTA recommendation for decision makers.
Translation required: If media contains English language text, it **must** be translated	Yes

Arriving at an HTA recommendation



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

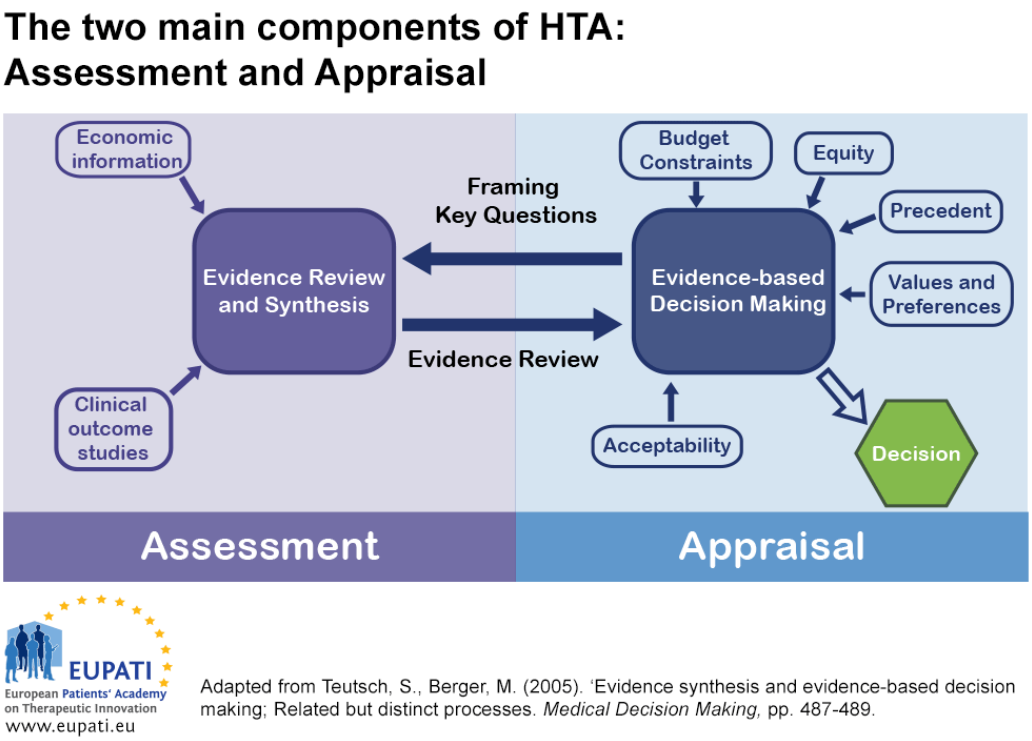
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	11.1.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The two main components of HTA: Assessment and Appraisal
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Assessment-appraisal-HTA-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/5438329297

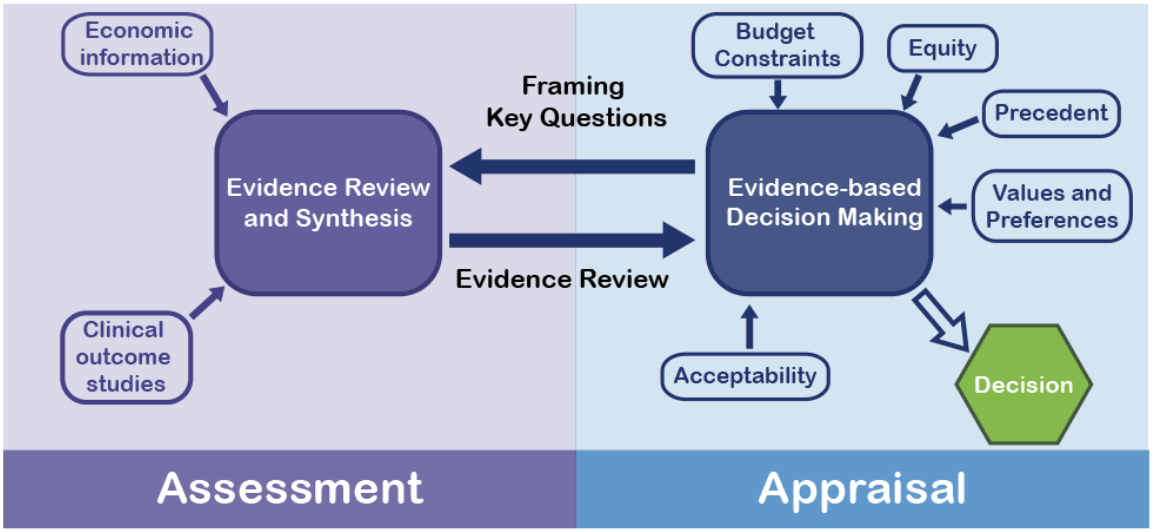
Cut and paste image here:



Media Source Note: Please indicate where the	EUPATI, adapted from Teutsch, S., Berger, M. (2005). 'Evidence synthesis and evidence-based

image was taken from.	decision making: Related but distinct processes'. *Medical Decision Making*, pp. 487-489.
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	This diagram shows the reciprocal relationship between assessment and appraisal in health technology assessment (HTA). In the assessment phase, evidence such as economic information or the results of clinical outcome studies are reviewed and synthesised. This evidence review informs the appraisal, or evidence-based decision making, which also takes into account other aspects such as budget constraints, equity, precedent, values and preferences, and acceptability. These considerations, in turn, inform the way that the key questions are framed during assessment. Ultimately a decision is made based on the evidence that has been assessed and appraised in light of other
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram showing the reciprocal relationship between assessment and appraisal in health technology assessment (HTA).
Caption: Will be displayed under media in the article body. Must begin with title of media.	The reciprocal relationship between assessment and appraisal informs decision-making in Health Technology Assessment (HTA).
Translation required: If media contains English language text, it **must** be translated	Yes

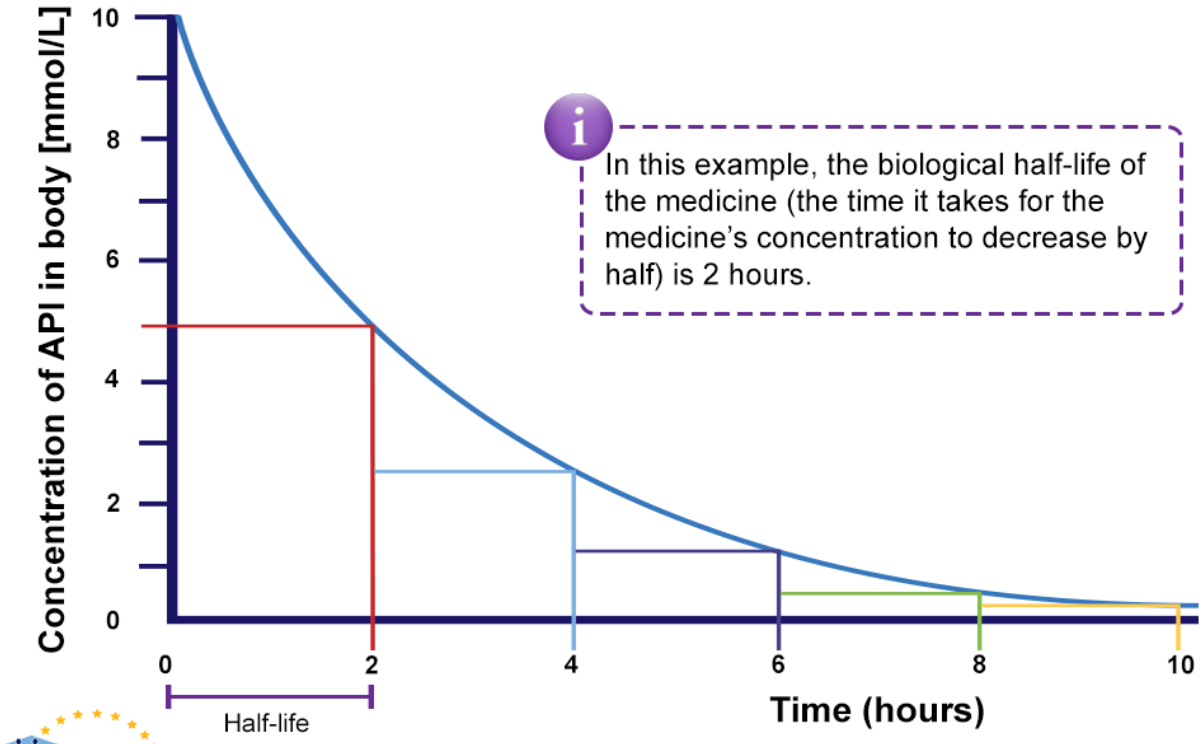
The two main components of HTA: Assessment and Appraisal



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adapted from Teutsch, S., Berger, M. (2005). 'Evidence synthesis and evidence-based decision making; Related but distinct processes. *Medical Decision Making,* pp. 487-489.

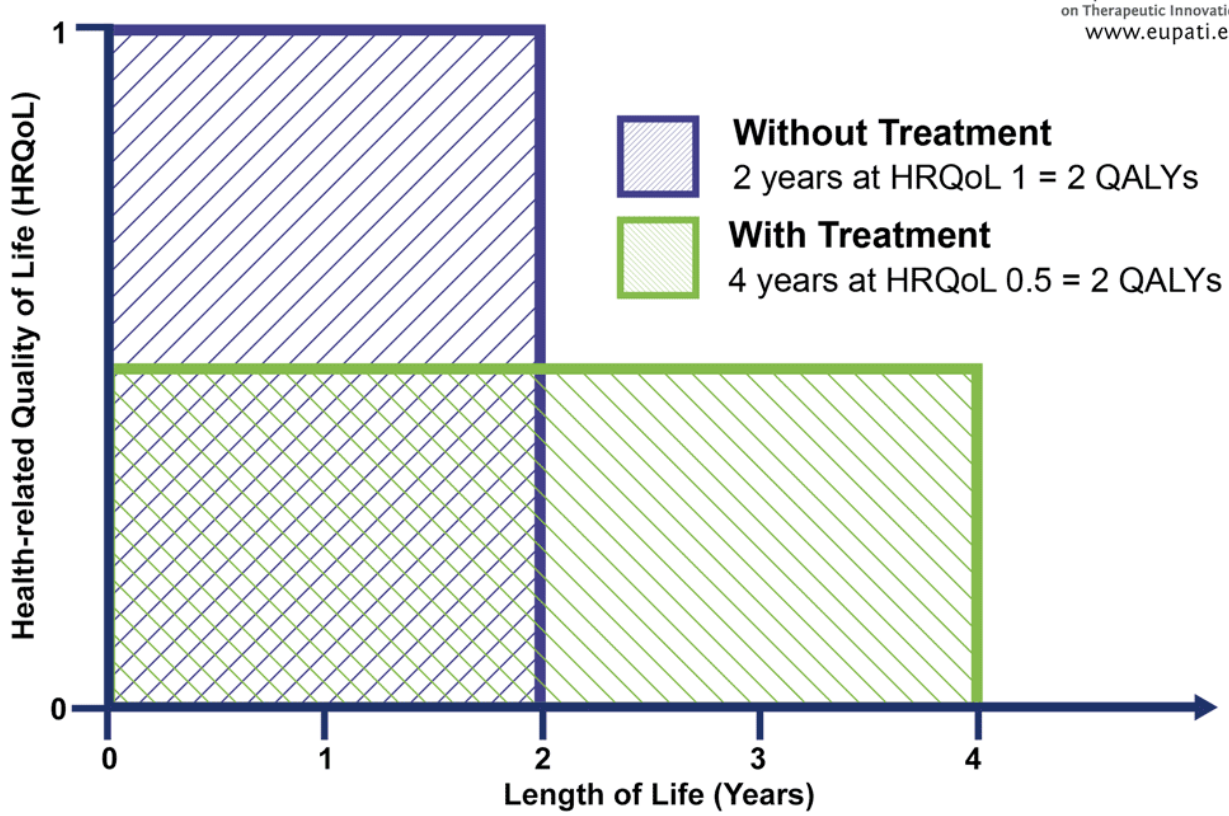
Biological half-life of a medicine



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

API = Active Pharmaceutical Ingredient

Calculating Quality-Adjusted Life Years



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

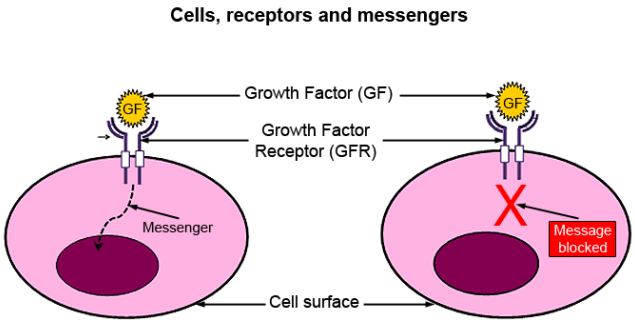
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

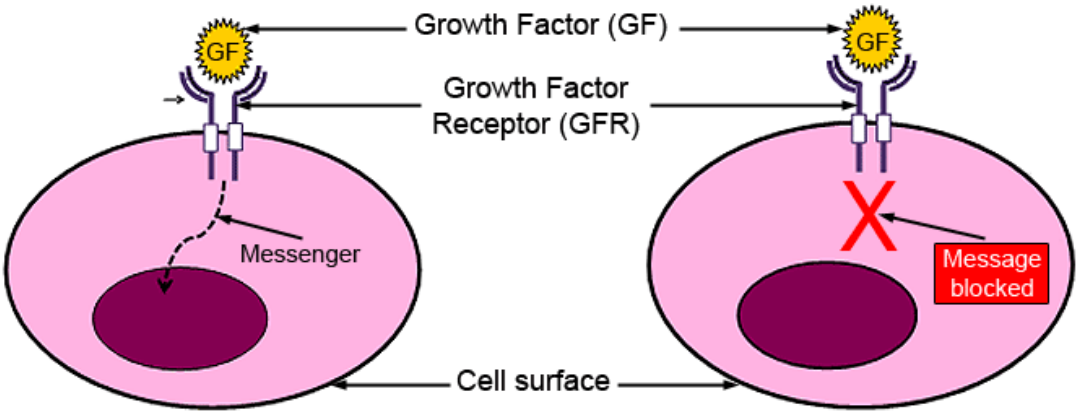
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Cells, receptors, and messengers
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	cells-receptors-messengers-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/oej4i6h4vtq1hy01slj53lrddn1ss7ee
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Cells, receptors and messengers. A simple diagram of a cell, showing the cell nucleus in the centre and with a representation of a receptor on the cell surface. The receptor – in this case labelled as a 'Growth Factor Receptor' – is shaped like a cup. A round chemical messenger – the growth factor – fits in the cup of the receptor. A message is then sent from the receptor on the surface of the cell to the nucleus. On the right of the diagram, a representation of the same cell, except that the message triggered by the growth factor and sent from the receptor to the nucleus has been blocked.

Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Cells, receptors and messengers. A simple diagram of a cell, showing the cell nucleus in the centre and with a representation of a receptor on the cell surface. The receptor – in this case labelled as a 'Growth Factor Receptor' – is shaped like a cup. A round chemical messenger – the growth factor – fits in the cup of the receptor. A message is then sent from the receptor on the surface of the cell to the nucleus. On the right of the diagram, a representation of the same cell, except that the message triggered by the growth factor and sent from the receptor to the nucleus has been blocked.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Cells, receptors and messengers. The growth factor, a chemical messenger, combines with the growth factor receptor on the surface of the cell, triggering a message to the nucleus. Blocking the receptor will prevent transmission of the message and thus uncontrolled cellular growth. The 'target' in this diagram is the growth factor receptor.
Translation required: If media contains English language text, it **must** be translated	Yes

Cells, receptors and messengers



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	30.01.2017	PLATA Created	Draft	1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

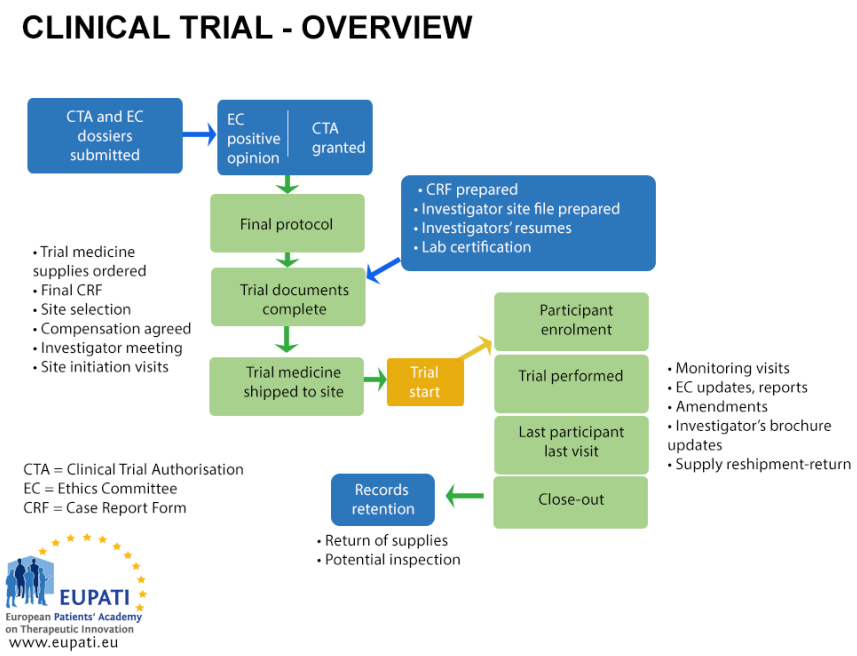
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	30.01.2017	PLATA Created	Draft	1

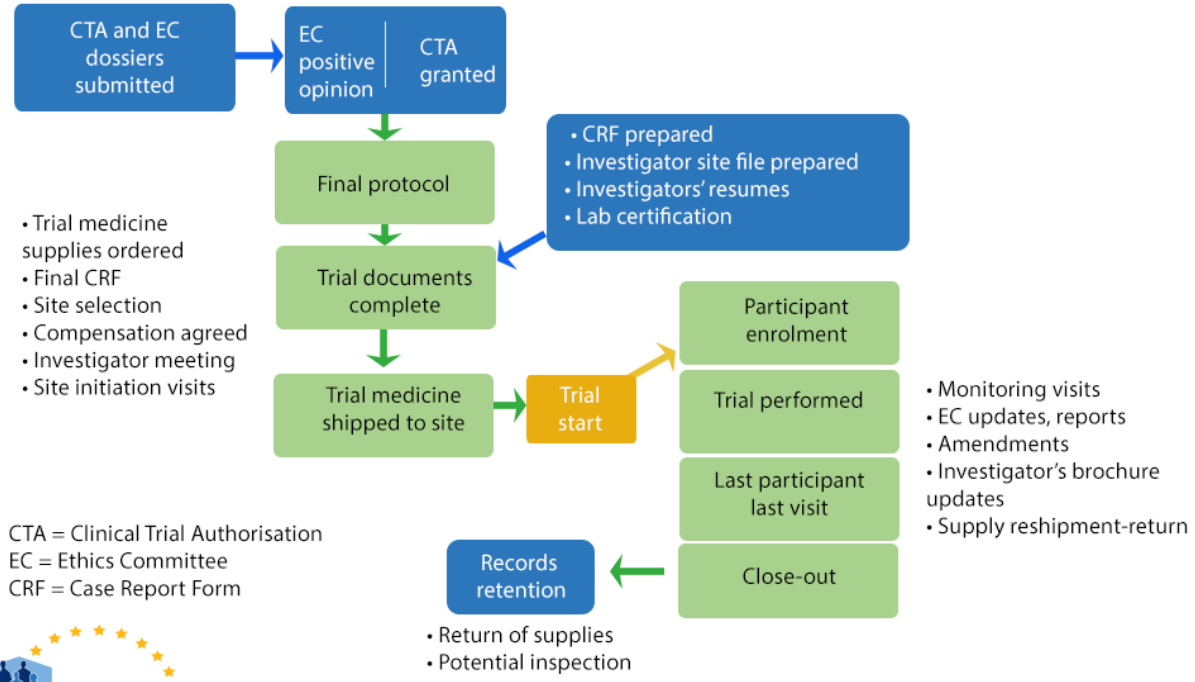
***State #:** This can either be ‘Draft’ or ‘Final’.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Clinical trial management
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Clinical-trial-overview_V3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/bsz94ku260bq978t05qb04iiki4qfcli
Cut and paste image here:  	
Media Source Note: Please indicate where the image was	EUPATI

taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A graphical representation of the clinical trials management process.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A graphical representation of the clinical trials management process.
Caption: Will be displayed under media in the article body. Must begin with title of media.	A graphical representation of the clinical trials management process.
Translation required: If media contains English language text, it **must** be translated	YES

CLINICAL TRIAL - OVERVIEW



CTA = Clinical Trial Authorisation
EC = Ethics Committee
CRF = Case Report Form

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

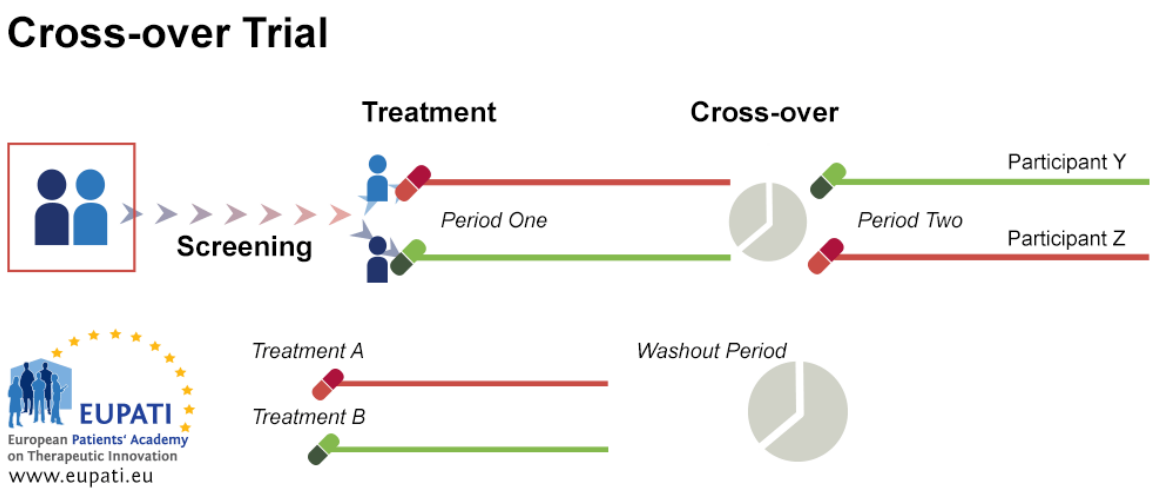
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	Final	1.1
Heidi Scherz	9.9.2015	PLATA Updated	FINAL	2
Heidi Scherz	21.9.2015	Image finalised	FINAL	3

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Cross-over trial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Crossover-trial-ve_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4305678547/crossover-trial

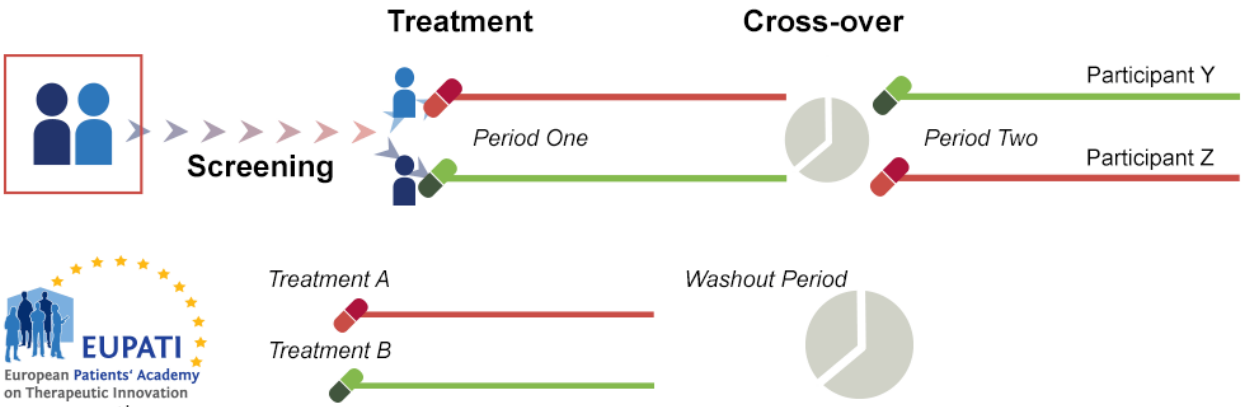
Cut and paste image here:



Media Source Note: Please indicate where the image was taken from.	EUPATI; Bonnie Le Page

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram depicting the cross-over trial design. For instance: Patient X and Y are randomised into two different treatment arms. Patient X receives Treatment A during the first period of the study; Patient Y receives Treatment B. After the first period is over, there is a washout period. Patient X then receives Treatment B for the second period of the study while Patient Y receives Treatment A.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram depicting the cross-over trial design. For instance: Patient X and Y are randomised into two different treatment arms. Patient X receives Treatment A during the first period of the study; Patient Y receives Treatment B. After the first period is over, there is a washout period. Patient X then receives Treatment B for the second period of the study while Patient Y receives Treatment A.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Patient X and Y are randomised into two different treatment arms. Patient X receives Treatment A during the first period of the study; Patient Y receives Treatment B. After the first period is over, there is a washout period. Patient X then receives Treatment B for the second period of the study while Patient Y receives Treatment A.
Translation required: If media contains English language text, it **must** be translated	Yes

Cross-over Trial



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

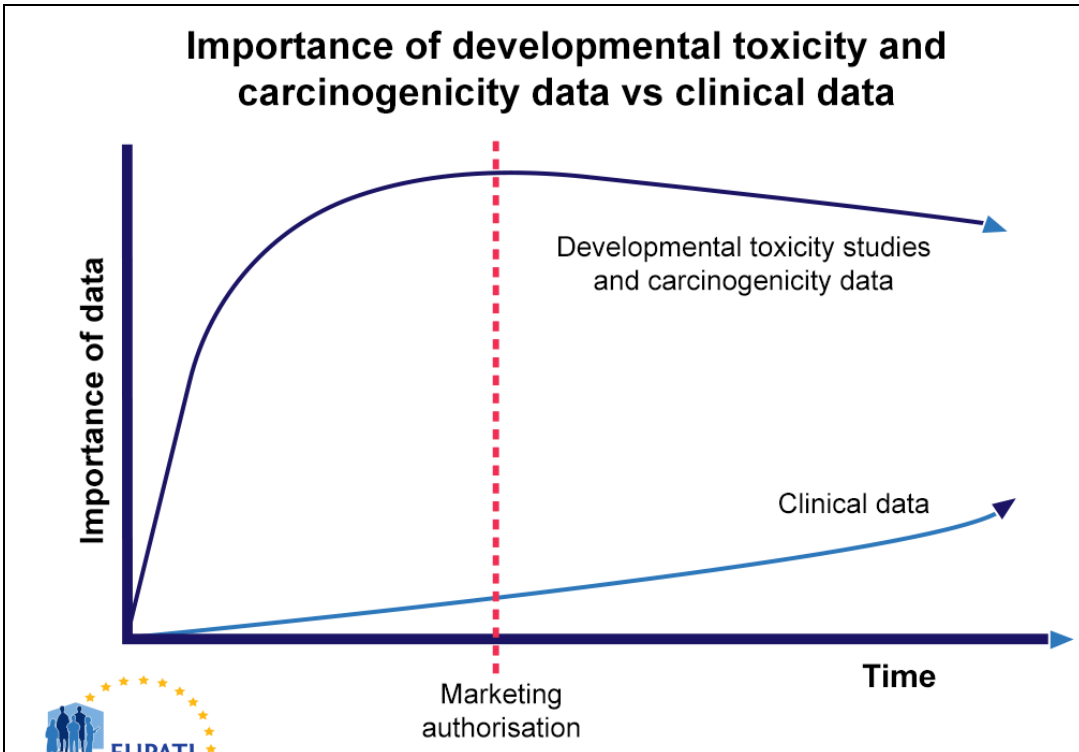
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	23.9.2015	PLATA updated for final version of image	FINAL	4

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

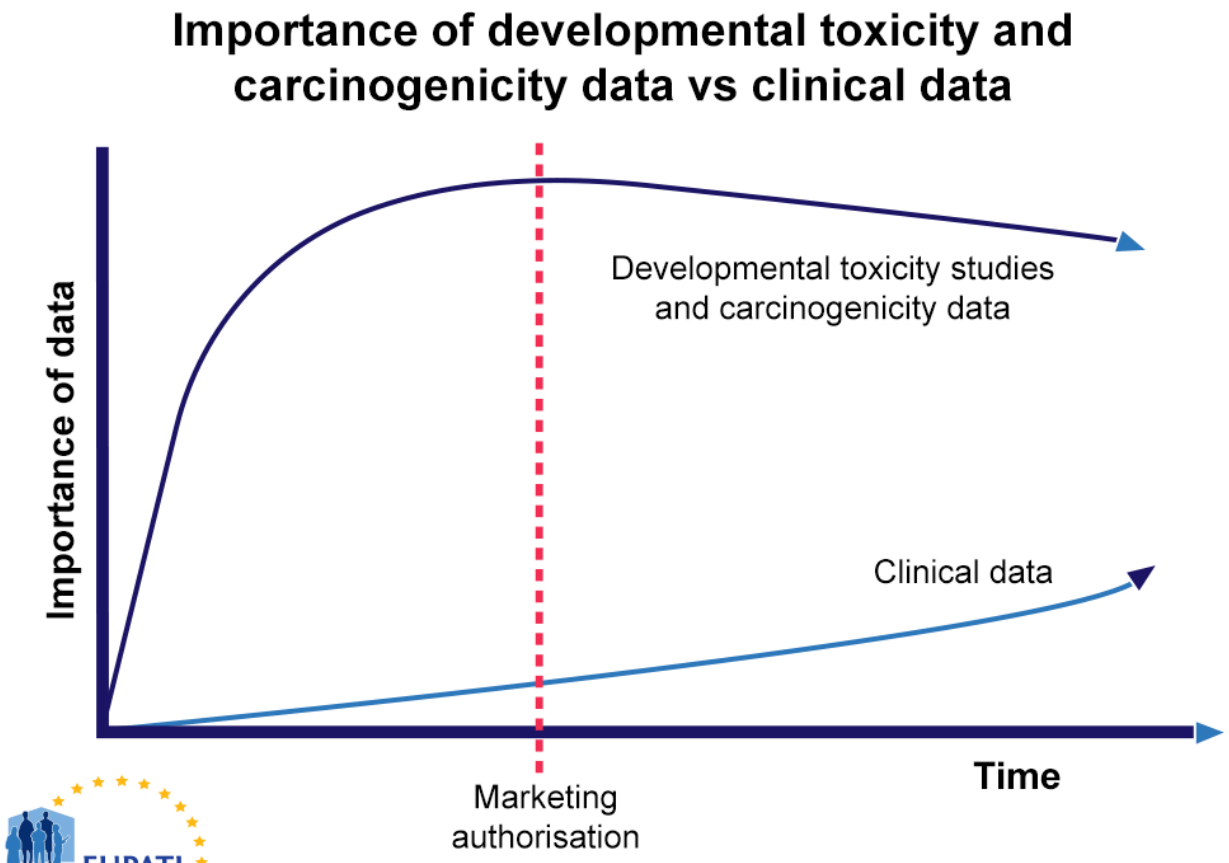
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Importance of developmental toxicity and carcinogenicity data vs clinical data
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	developmental-and-toxicity-studies-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4286181327/developmental-and-toxicity-studies
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	EUPATI reproduced from Nieto-Guiterrez, M. (2011). Non-clinical assessment requirements. London: EMA Retrieved 24 July, 2015, from http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2011/06/WC500107868.pdf
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for	A graphical illustration of the importance of and reliance on data from non-clinical developmental toxicity and genotoxicity studies for the assessment of human safety relative to that gathered in clinical trials over time. Time is marked on the X-axis; importance to human safety assessments on the Y-axis. The time of marketing authorisation is marked approximately half-way along the X-axis. Although the importance of non-clinical developmental toxicity and carcinogenicity remains more important than clinical data throughout the developmental process and beyond the point of marketing authorisation, clinical data does begin to grow in importance gradually even as the importance of non-clinical data begins to fall off.

meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A graphical illustration of the importance of and reliance on data from non-clinical developmental toxicity and genotoxicity studies for the assessment of human safety relative to that gathered in clinical trials over time. Time is marked on the X-axis; importance to human safety assessments on the Y-axis. The time of marketing authorisation is marked approximately half-way along the X-axis. Although the importance of non-clinical developmental toxicity and carcinogenicity remains more important than clinical data throughout the developmental process and beyond the point of marketing authorisation, clinical data does begin to grow in importance gradually even as the importance of non-clinical data begins to fall off.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Data from developmental toxicity studies and carcinogenicity studies continue to be relied upon more than clinical data throughout development and after marketing authorisation.
Translation required: If media contains English language text, it **must** be translated	Yes



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

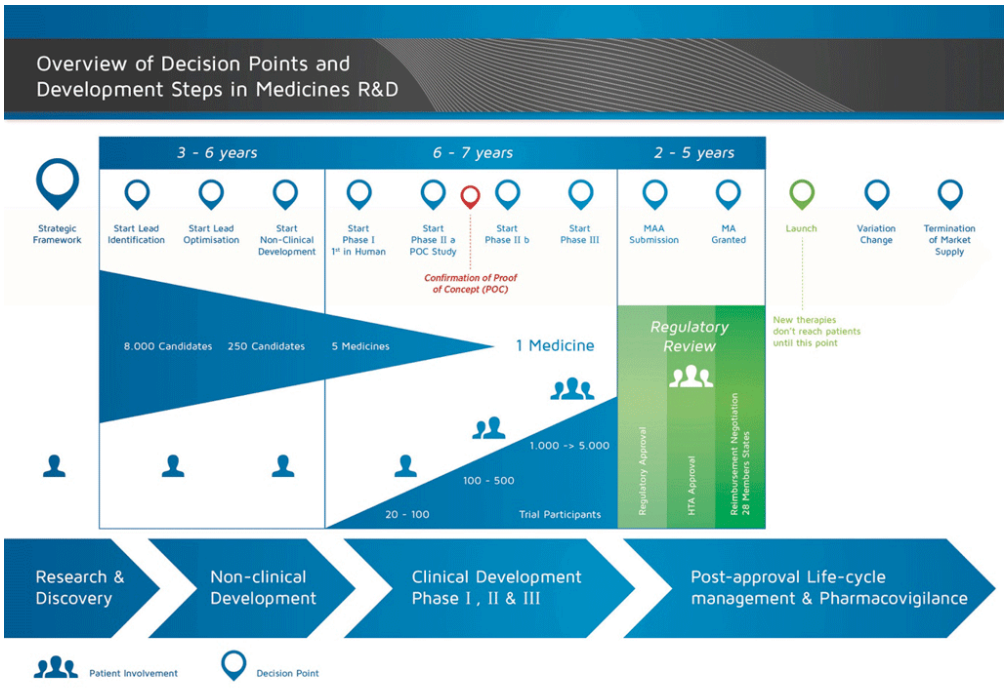
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	22.10.2015	PLATA Created (copied from old format)	Final	1.1
		Changes that need to be made highlighted		

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Overview of the medicine development process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	development-steps-in-medicines-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/5092531034/developmental-steps-in-medicine
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A slide describing the decision points and development steps in the research and development (R&D) of medicines. There are four main phases of medicines R&D: Research & Discovery, Non-clinical development, Clinical Development, and post-approval life-cycle management and pharmacovigilance. Research and discovery lasts from three to six years, from the development of the strategic framework to lead identification, at which point the number of medicinal candidates has been narrowed from approximately 8,000 to 250. Non-clinical development also occurs within the first three to six years, from the start of lead optimisation to the end of the non-clinical development period, at which point the 250 candidates have been narrowed down to just five medicines. The next six to seven years are occupied by clinical development. Clinical development is split into three phases: I, II, and III. After the completion of Phase I, the first trials in humans (with approximately 20 to 100 participants), Phase IIa begins with a proof of concept study. Phase IIa usually sees testing in 100 to 500 participants. When the Proof of Concept has been confirmed, Phase IIb begins, with clinical trials of between 1,000 and 5,000 participants, narrowing candidates down to just one medicine. Phase III is the largest of trials, and ends in the submission of the medicine for regulatory review. The regulatory review process can take between two to five years. Only after approval from the regulatory boards can the medicine be launched and new therapies made accessible to patients. The review process and launch of the medicine mark the beginning of the post-approval life-cycle management and pharmacovigilance phase, during which change is monitored and managed, and which lasts until the medicine is terminated and removed from the market.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be	A slide describing the decision points and development steps in the research and development (R&D) of medicines. There are four main phases of medicines R&D: Research & Discovery, Non-clinical development, Clinical Development, and post-approval life-cycle management and pharmacovigilance. Research and

more descriptive than caption. It should **not** rely on article context for meaning.	discovery lasts from three to six years, from the development of the strategic framework to lead identification, at which point the number of medicinal candidates has been narrowed from approximately 8,000 to 250. Non-clinical development also occurs within the first three to six years, from the start of lead optimisation to the end of the non-clinical development period, at which point the 250 candidates have been narrowed down to just five medicines. The next six to seven years are occupied by clinical development. Clinical development is split into three phases: I, II, and III. After the completion of Phase I, the first trials in humans (with approximately 20 to 100 participants), Phase IIa begins with a proof of concept study. Phase IIa usually sees testing in 100 to 500 participants. When the Proof of Concept has been confirmed, Phase IIb begins, with clinical trials of between 1,000 and 5,000 participants, narrowing candidates down to just one medicine. Phase III is the largest of trials, and ends in the submission of the medicine for regulatory review. The regulatory review process can take between two to five years. Only after approval from the regulatory boards can the medicine be launched and new therapies made accessible to patients. The review process and launch of the medicine mark the beginning of the post-approval life-cycle management and pharmacovigilance phase, during which change is monitored and managed, and which lasts until the medicine is terminated and removed from the market.
Caption: Will be displayed under media in the article body. Must begin with title of media.	It takes well over 10 years of careful planning and research for a medicine to go from molecule to a marketable treatment.
Translation required: If media contains English language text, it **must** be translated	(Yes/No) Yes

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

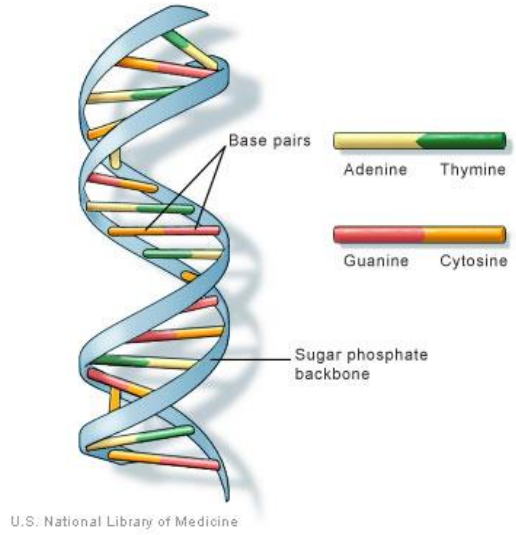
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

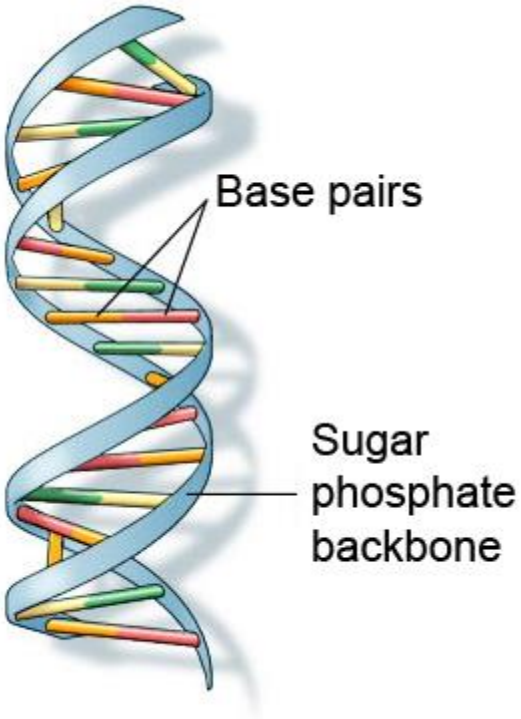
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	FINAL	1.1

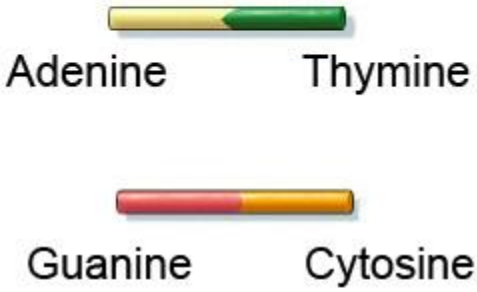
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	DNA structure
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	DNA-structure_EN.jpeg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/9xyeorf62qb74ker2nuc4ob0m0kq7jk1
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	US National Library of Medicine

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	DNA has a spiral staircase-like structure. The steps are formed by the nitrogen bases of nucleotides. The nucleotide adenine pairs with thymine, and cytosine with guanine. The nucleotide base pairs are connected by a sugar phosphate backbone. (Source: US National Library of Medicine, see reference no. 1).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrammatic representation of DNA. DNA has a spiral staircase-like structure. The steps are formed by the nitrogen bases of nucleotides. The nucleotide adenine pairs with thymine, and cytosine with guanine. The nucleotide base pairs are connected by sugar phosphate backbone. (Source: US National Library of Medicine, see reference no. 1).
Caption: Will be displayed under media in the article body. Must begin with title of media.	DNA structure. (Source: US National Library of Medicine[1]). DNA has a spiral staircase-like structure. The steps are formed by the nitrogen bases of nucleotides. The nucleotide adenine pairs with thymine, and cytosine with guanine. The nucleotide base pairs are connected by a sugar phosphate backbone.
Translation required: If media contains English language text, it **must** be translated	Y





U. S. National Library of Medicine

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

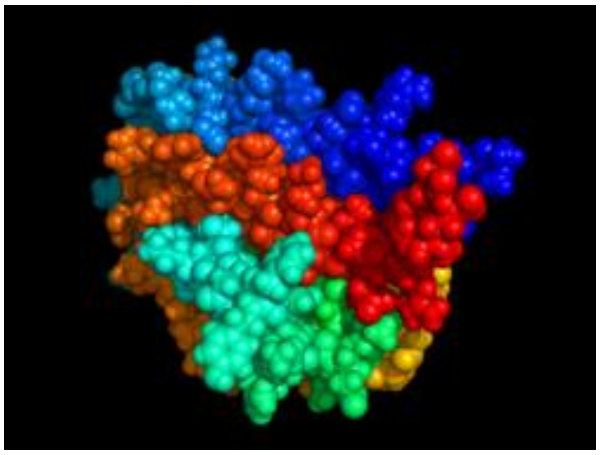
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

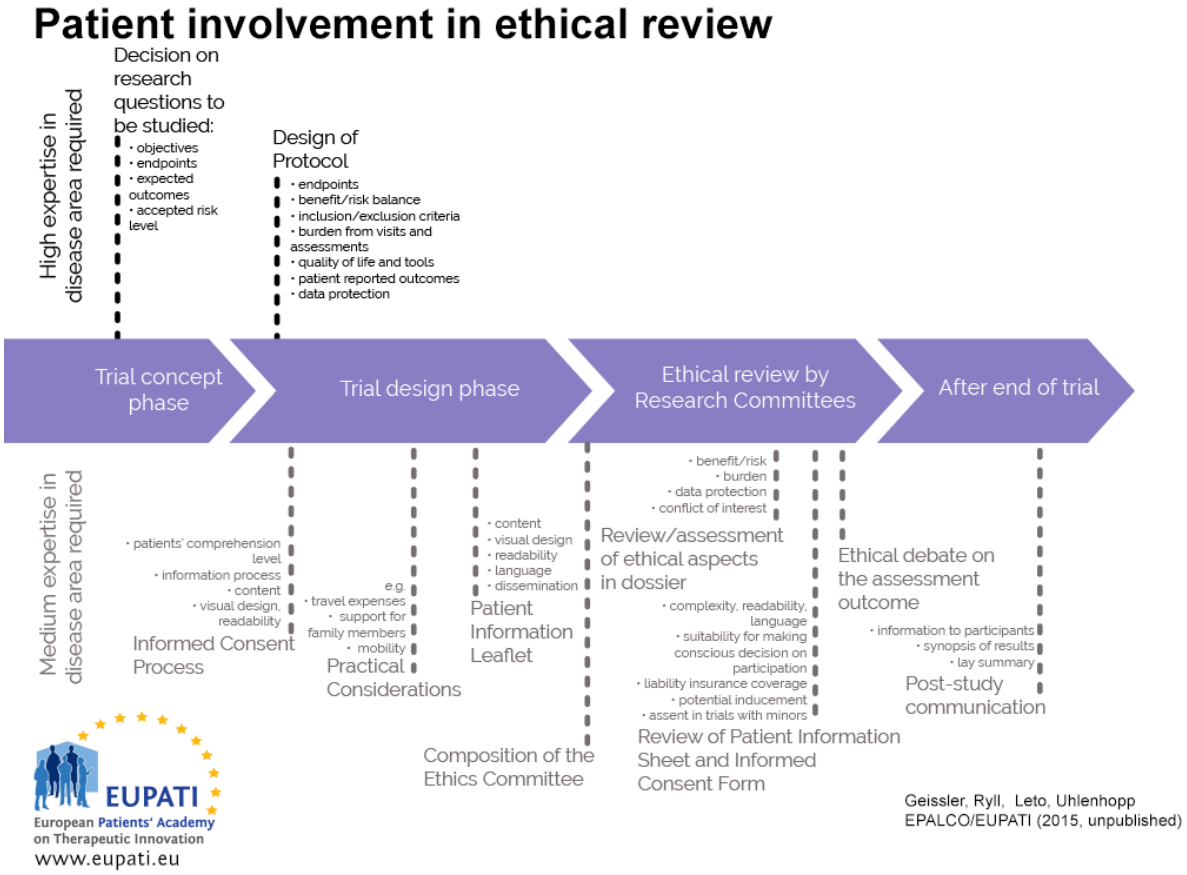
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Representation of erythropoietin, a very large protein.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	erythropoietin.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/zmlspot9xuihkcdam157mppobhx6hn1t
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A computer-generated representation of Erythopoietin, which is a very large protein.

Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A computer-generated representation of Erythopoietin, which is a very large protein.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Erythropoietin is a naturally occurring protein, but it has been used as a biologic therapy in patients whose bodies cannot produce sufficient amounts of it. The cells in the fermentation vats have been genetically engineered so that they produce large amounts of erythropoietin.
Translation required: If media contains English language text, it **must** be translated	No


Patient involvement in ethical review
High expertise in disease area required
Decision on research questions to be studied:
• objectives
• endpoints
• expected outcomes
• accepted risk level
Design of Protocol
• endpoints
• benefit/risk balance
• inclusion/exclusion criteria
• burden from visits and assessments
• quality of life and tools
• patient reported outcomes
• data protection
Trial concept phase
Trial design phase
Ethical review by Research Committees
After end of trial
Medium expertise in disease area required
• patients' comprehension level
• information process
• content
• visual design, readability
Informed Consent Process
e.g.
• travel expenses
• support for family members
• mobility
Practical Considerations
• content
• visual design
• readability
• language
• dissemination
Patient Information Leaflet
Composition of the Ethics Committee
• benefit/risk
• burden
• data protection
• conflict of interest
Review/assessment of ethical aspects in dossier
• complexity, readability, language
• suitability for making conscious decision on participation
• liability insurance coverage
• potential inducement
• assent in trials with minors
Review of Patient Information Sheet and Informed Consent Form
Ethical debate on the assessment outcome
• information to participants
• synopsis of results
• lay summary
Post-study communication
EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu
Geissler, Ryll, Leto, Uhlenhopp
EPALCO/EUPATI (2015, unpublished)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

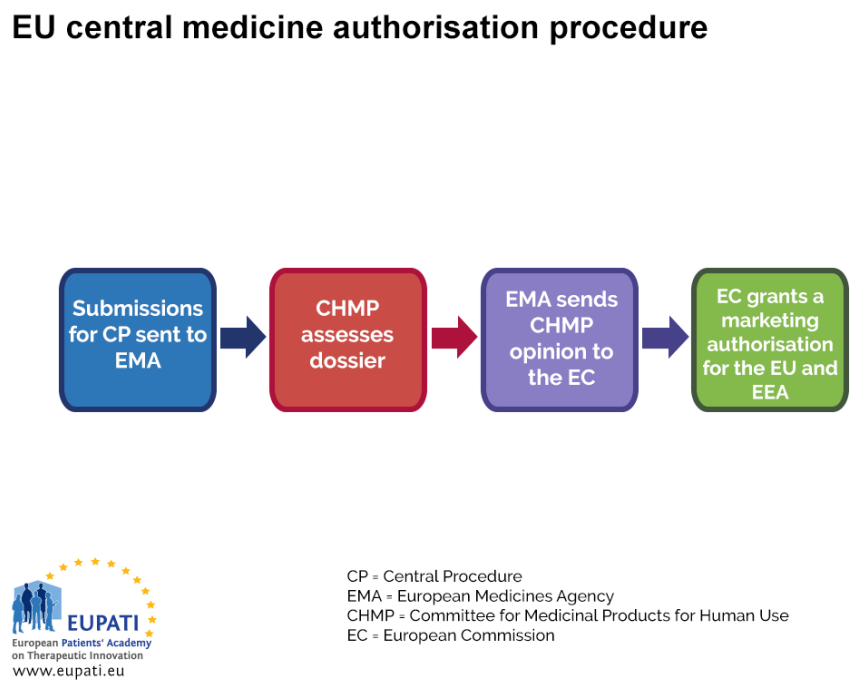
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	11.11.2016	PLATA Created	Final	1.1

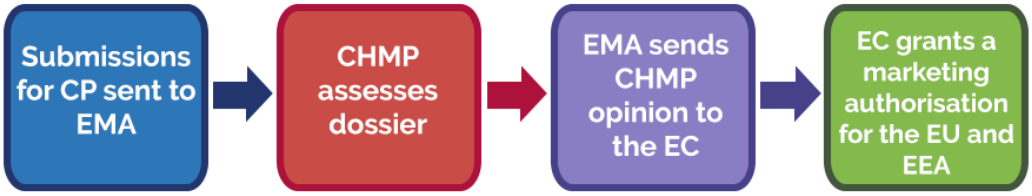
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EU Central Procedure to authorise medicine
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	EU-central-procedure-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/12041823143/EU_central_procedure
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken	EUPATI;

from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram showing the centralised procedure to authorise a medicine in all EU and EEA countries.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram showing the centralised procedure to authorise a medicine in all EU and EEA countries.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The centralised procedure used to authorise a medicine in all EU and EEA countries.
Translation required: If media contains English language text, it **must** be translated	Yes

EU central medicine authorisation procedure



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

CP = Central Procedure
EMA = European Medicines Agency
CHMP = Committee for Medicinal Products for Human Use
EC = European Commission

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

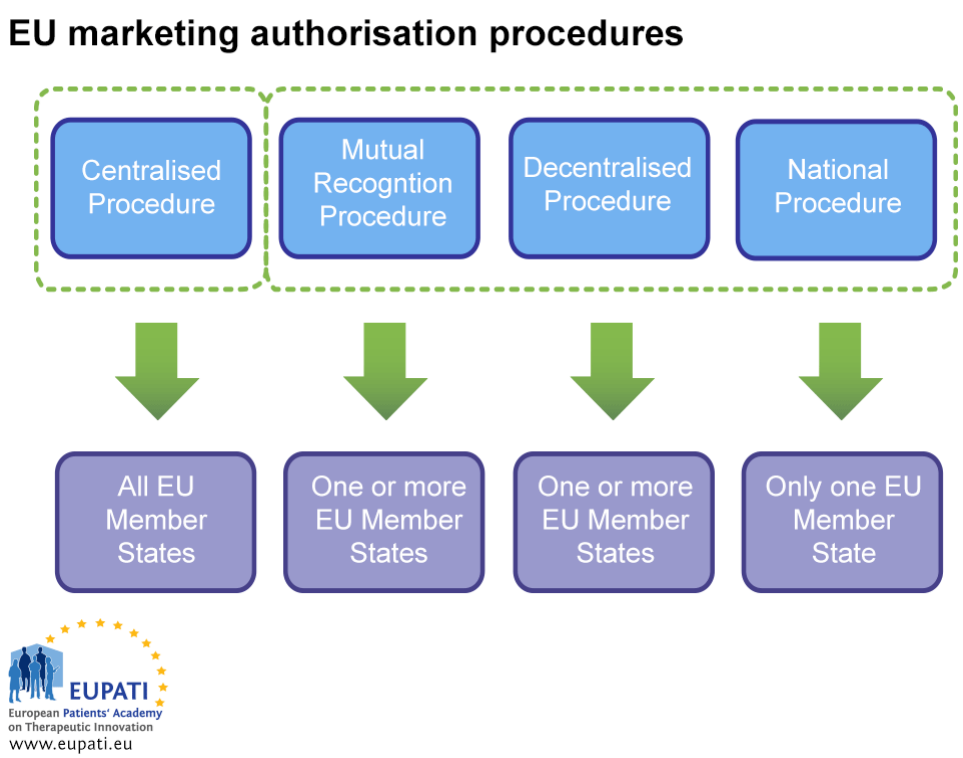
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	9.9.2015	PLATA Created	Final	1.1

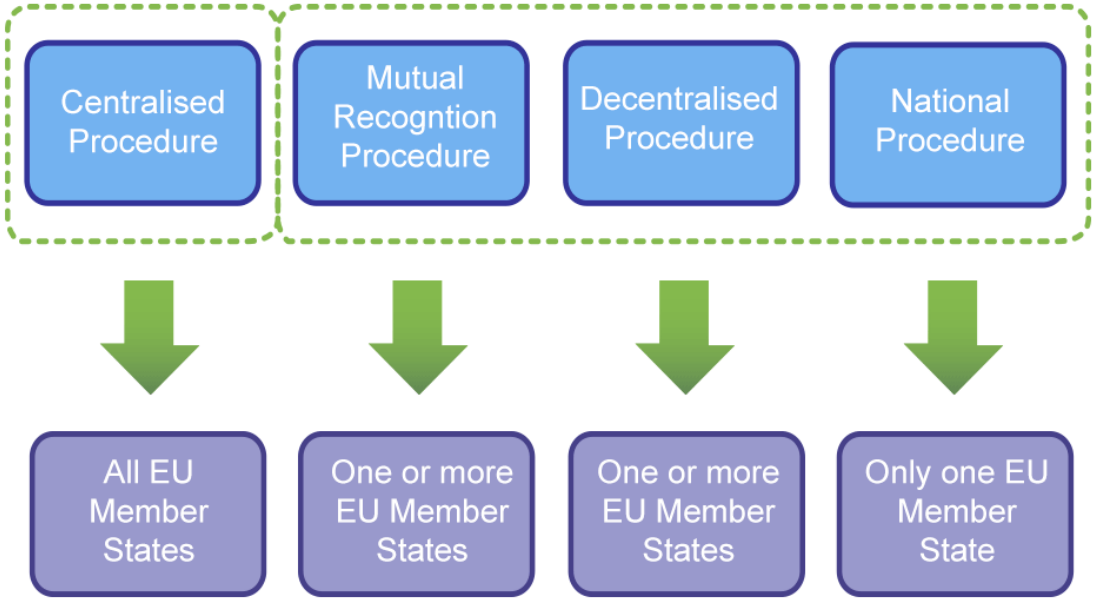
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EU Marketing Authorisation Procedures
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	EU-marketing-authorisation-procedures-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4494075486
Cut and paste image here:  	
Media Source	EUPATI; Heidi Scherz

Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram showing the different EU marketing authorisation procedures. There are four procedures of two different types and with different members involved. The centralised procedure is a type of its own; all EU Member States are involved in this marketing authorisation procedure. The other three procedures are all types of decentralised procedures. The Mutual Recognition Procedure involves one or more EU Member States. The Decentralised procedure also involves one or more EU Member States. The National procedure involves just one single EU Member State.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram showing the different EU marketing authorisation procedures. There are four procedures of two different types and with different members involved. The centralised procedure is a type of its own; all EU Member States are involved in this marketing authorisation procedure. The other three procedures are all types of decentralised procedures. The Mutual Recognition Procedure involves one or more EU Member States. The Decentralised procedure also involves one or more EU Member States. The National procedure involves just one single EU Member State.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Different actors are involved in the marketing authorisation of a medicine depending on which procedure the sponsor opts (or is obliged) to follow.
Translation required: If media contains English language text, it **must** be translated	Yes

EU marketing authorisation procedures



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

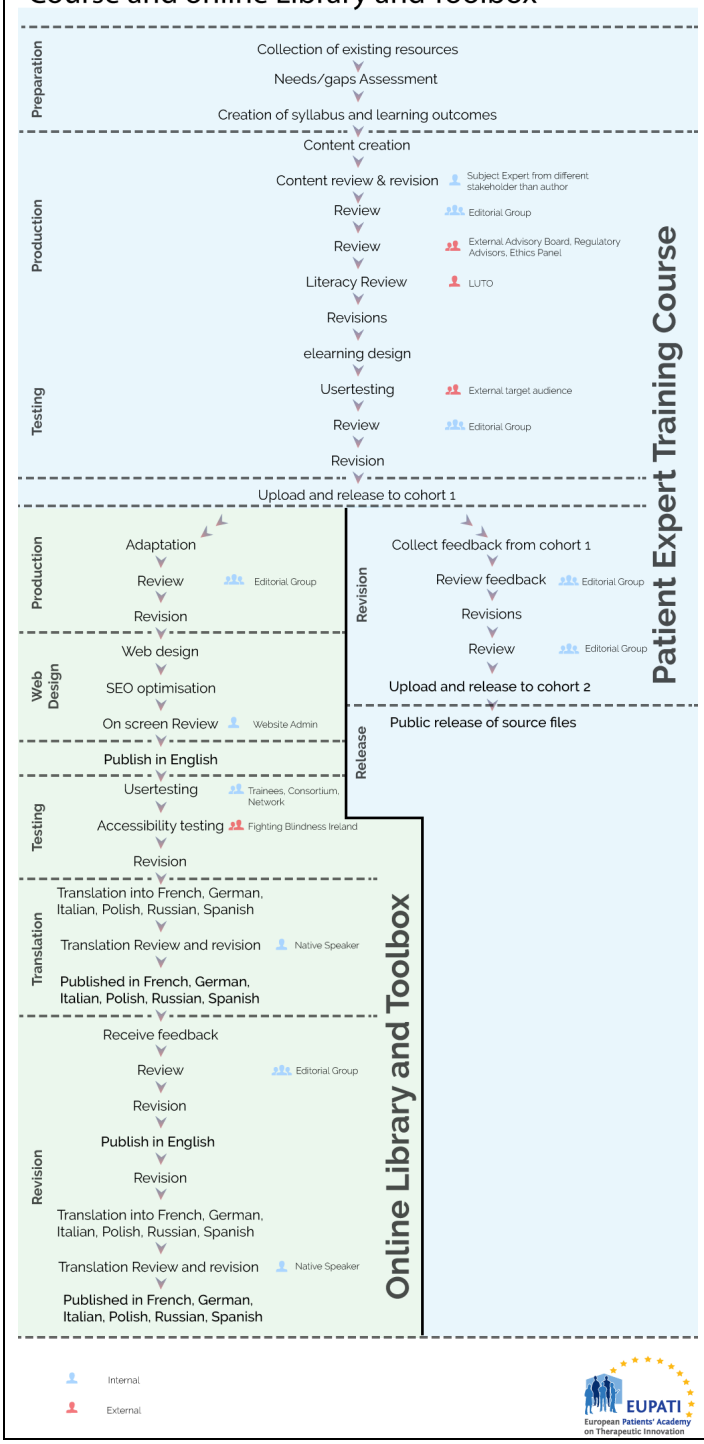
Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	13.09.2016	PLATA Created	Final	1.0

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EUPATI Production Process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	content-workflow-v1-EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/11286918170/EUPATI_Production_Process
Cut and paste image here:	

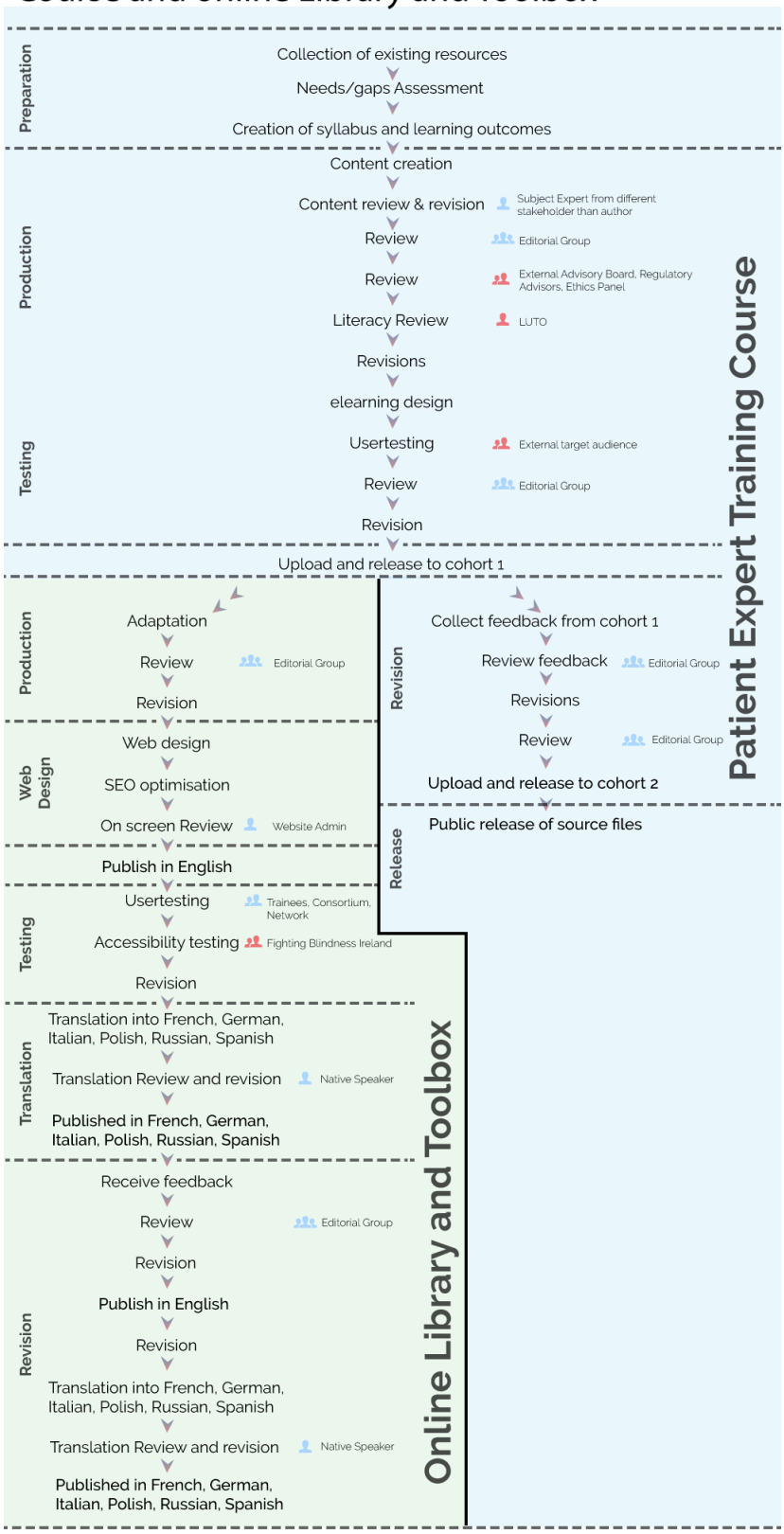
EUPATI Production Process for Patient Expert Course and online Library and Toolbox



Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	All content has been written by experts coming from different backgrounds, who have worked within the subject area. It was then checked by further experts who come from a different background working for a different stakeholder group. For example content written by a clinical researcher in industry would be checked by an academic or patient expert. To check for factual accuracy, transparency, neutrality, and readability the content was reviewed by our independent review boards, experts, and committees. For example, content related to regulatory affairs was reviewed from staff members of regulatory authorities in Germany, Italy, Switzerland, Spain and Ireland. HTA content was reviewed by HTA experts from HTAi and EUnetHTA . Material on ethics was reviewed by ethicists of EUPATI's Ethics Panel. To validate whether the material in the online modules is understandable and readable by the health-interested public, EUPATI has also tested significant proportions of its material with patient advocates, including testing screen reader accessibility of the website with Fighting Blindness Ireland. Feedback from all reviewers has has been incorporated in editorial cycles of EUPATI's content. An editorial group chaired by DIA (a global non-profit providing education and discussion forums to further pharmaceutical development) and consisting of representatives from Bayer, University of Copenhagen, University of Bochum, Rare Diseases Europe (EURORDIS), European AIDS Treatment Group (EATG), GlaxoSmithKline and the Irish Platform for Patient Organisations, Science and Industry (IPPOSI) reviewed all comments and changes and conducted consistency, style and factual reviews of the material.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A graphical representation of the EUPATI Production Process. You can read about the production process in the Production of EUPATI Patient Expert Training Course document and Production of EUPATI Library and Toolbox document.
Caption: Will be displayed under media in the article body. Must begin with title of media.	In the creation of all material for EUPATI a robust production, review, and approval process was developed involving internal and external independent reviews from multiple stakeholders.
Translation required:	Yes

If media contains English language text, it **must** be translated	

EUPATI Production Process for Patient Expert Course and online Library and Toolbox



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

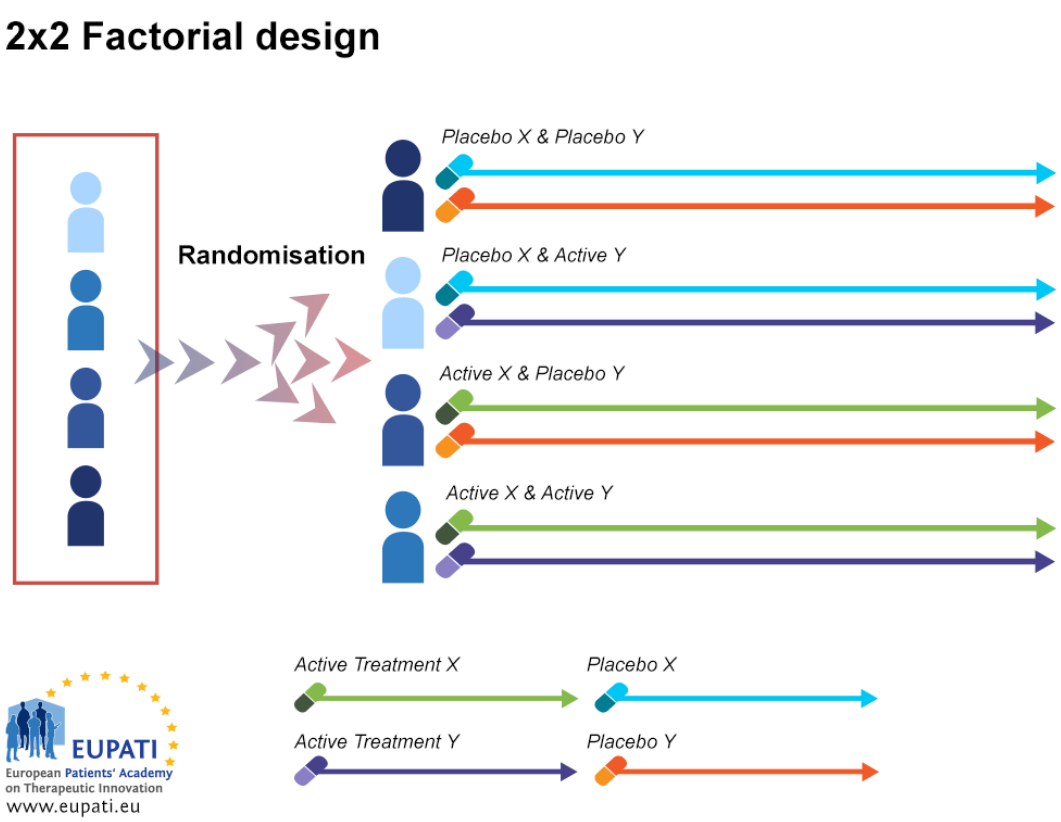
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA CREATED	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

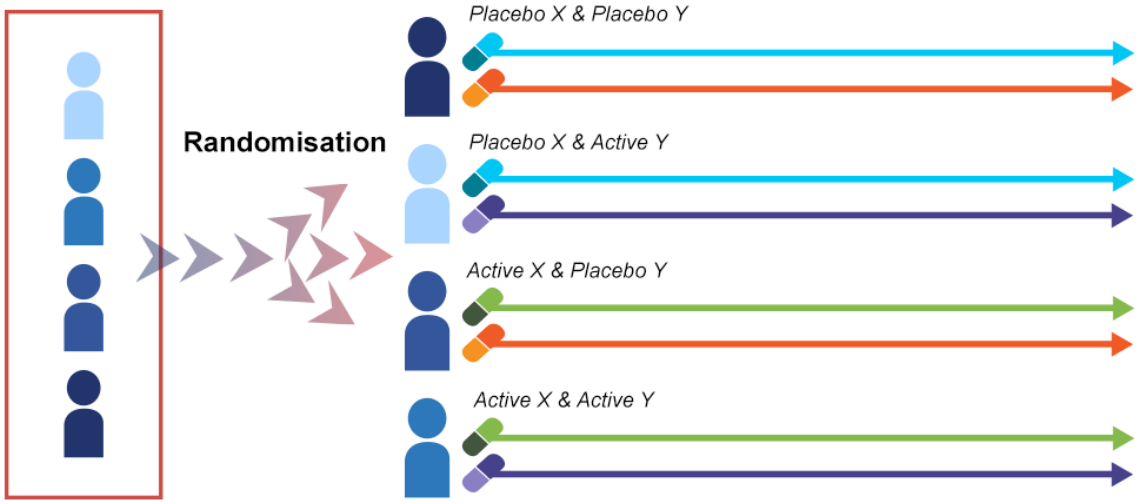
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	2x2 Factorial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Factorial-design-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/0nbmi1iail6t6ux410mkagt41aq64aao

Cut and paste image here:

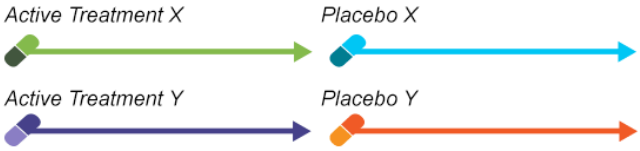


Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram showing an example of a trial using a 2x2 factorial design.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	This diagram shows an example of a trial using a 2x2 factorial design. In this example, patients are randomised into one of four groups. There are two active treatments, Treatment X and Treatment Y. Both treatments also have a placebo treatment, Treatment X Placebo and Treatment Y Placebo. Each group receives two treatments simultaneously. Group 1 receives Placebo X and Placebo Y. Group 2 receives Placebo X and Active Y. Group 3 receives Active X and Placebo Y, and Group 4 receives Active X and Active Y.
Caption: Will be displayed under media in the article body. Must begin with title of media.	An example of a trial using a 2x2 factorial design.
Translation required: If media contains English language text, it **must** be translated	Yes

2x2 Factorial design



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

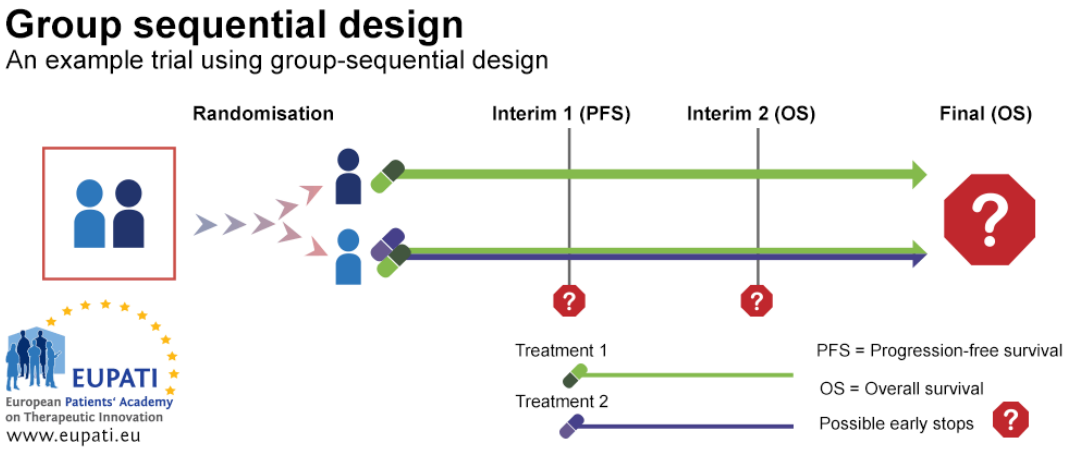
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

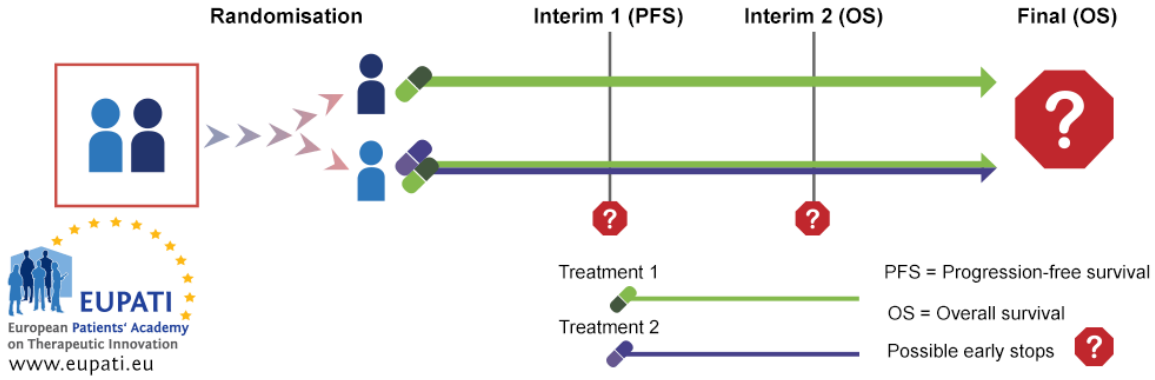
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Group sequential design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Group-sequential-design-v1.1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/mpoqvhnrdd4mv9uothpd1bkq93cnxqud
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram depicting an example trial using a group sequential design. There are two interims specified across the timeline of the trial at which there are possible early stops. Interim 1 allows for early stops on the basis of a progression-free survival assessment. Interim 2 allows for early stops on the basis of an overall survival assessment. After the

	trial ends, an overall survival assessment is also carried out. In this example trial, participants are randomised onto one of two arms. In the first arm, the participants receive treatment one. In the second arm, participants receive a combination of treatment one and treatment two.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram depicting an example trial using a group sequential design. There are two interims specified across the timeline of the trial at which there are possible early stops. Interim 1 allows for early stops on the basis of a progression-free survival assessment. Interim 2 allows for early stops on the basis of an overall survival assessment. After the trial ends, an overall survival assessment is also carried out. In this example trial, participants are randomised onto one of two arms. In the first arm, the participants receive treatment one. In the second arm, participants receive a combination of treatment one and treatment two.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Group sequential design allows for early stops on the basis of progression-free survival or overall survival. In this example, participants were randomised onto one of two arms, and received either Treatment 1, or a combination of Treatment 1 and Treatment 2.
Translation required: If media contains English language text, it **must** be translated	Yes

Group sequential design

An example trial using group-sequential design



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1
Matthew May	31.05.2016	Corrections	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Herbal medicines.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	herbal-medicines-v1.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/u8sfp8v1qscyquncgbluc8wk1lfbkp5p
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Herbal medicines. Photographs of the plant sources of three different herbal medicines. Echinacea purpurea is a large, bright pink flower; St. John's wort has smaller clusters of star-shaped yellow flowers; and Gingko biloba is a large, green leafy tree.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and	Herbal medicines. Photographs of the plant sources of three different herbal medicines. Echinacea purpurea is a large, pink flower with many long, thin petals; St. John's wort has smaller clusters of star-shaped yellow flowers; and Gingko biloba is a large, green, leafy tree.

descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	
Caption: Will be displayed under media in the article body. Must begin with title of media.	Herbal medicines. From left to right: Echinacea purpurea, St. John's wort, and Gingko biloba.
Translation required: If media contains English language text, it **must** be translated	No

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

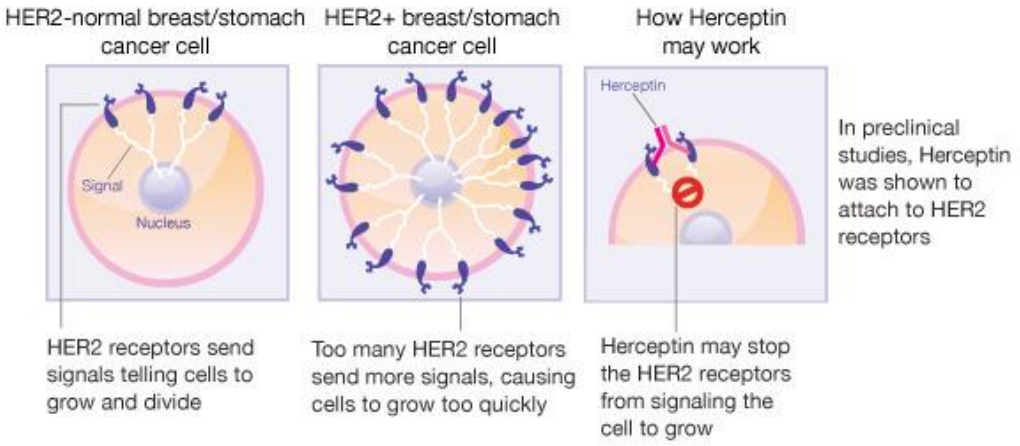
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	How Herceptin affects breast cancer cells
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Herceptin-affects_EN.jpg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/um2xo1tu2s4uhaelka0zwzf8g771douu

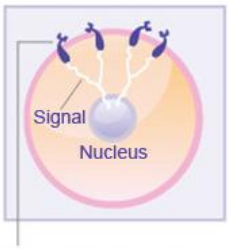
Cut and paste image here:



Media Source Note: Please indicate where the image was taken from.	https://beyondthedish.wordpress.com/2012/06/04/smart-bomb-successfully-treat-advanced-breast-cancer-in-clinical-trials/
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on	How Herceptin affects breast cancer cells. (Source: beyondthedish.wordpress.com). A diagram showing how Herceptin may work on breast or stomach cancer cells. HER2 receptors send signals that tell a cell to grow and divide; too many HER2 receptors cause breast or stomach cancer cells to grow too quickly. In preclincial studies, Herceptin was shown to attach to HER2 receptors, which may stop the receptors from

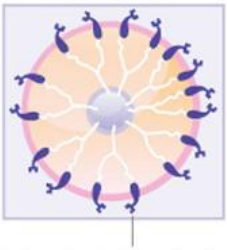
article context for meaning.	signalling the cell to grow.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	How Herceptin affects breast cancer cells. (Source: beyondthedish.wordpress.com). A diagram showing how Herceptin may work on breast or stomach cancer cells. HER2 receptors send signals that tell a cell to grow and divide; too many HER2 receptors cause breast or stomach cancer cells to grow too quickly. New research in personalised medicines has shown that Herceptin attached to HER2 receptors, which may stop the receptors from signalling the cell to grow.
Caption: Will be displayed under media in the article body. Must begin with title of media.	How Herceptin affects breast cancer cells. (Source: beyondthedish.wordpress.com). Preclinical studies show that Herceptin may work on breast or stomach cancer cells by blocking HER2 receptors and preventing them from stimulating cell growth and division.
Translation required: If media contains English language text, it **must** be translated	Yes

HER2-normal breast/stomach cancer cell



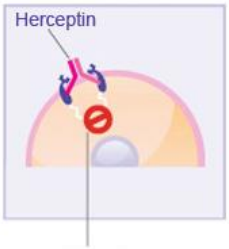
HER2 receptors send signals telling cells to grow and divide

HER2+ breast/stomach cancer cell



Too many HER2 receptors send more signals, causing cells to grow quickly

How Herceptin may work



Herceptin may stop the HER2 receptors from signaling the cell to grow

In preclinical studies, Herceptin was shown to attach to HER2 receptors

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

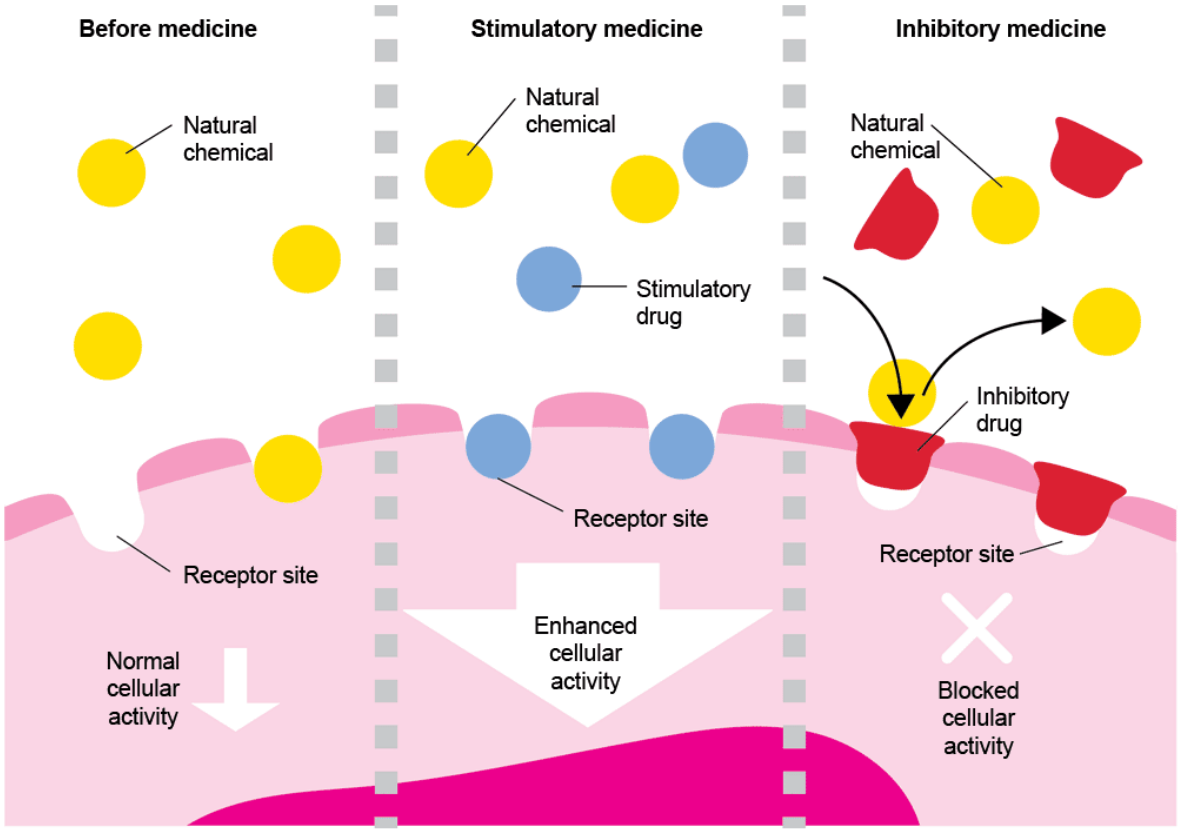
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	FINAL	1.1

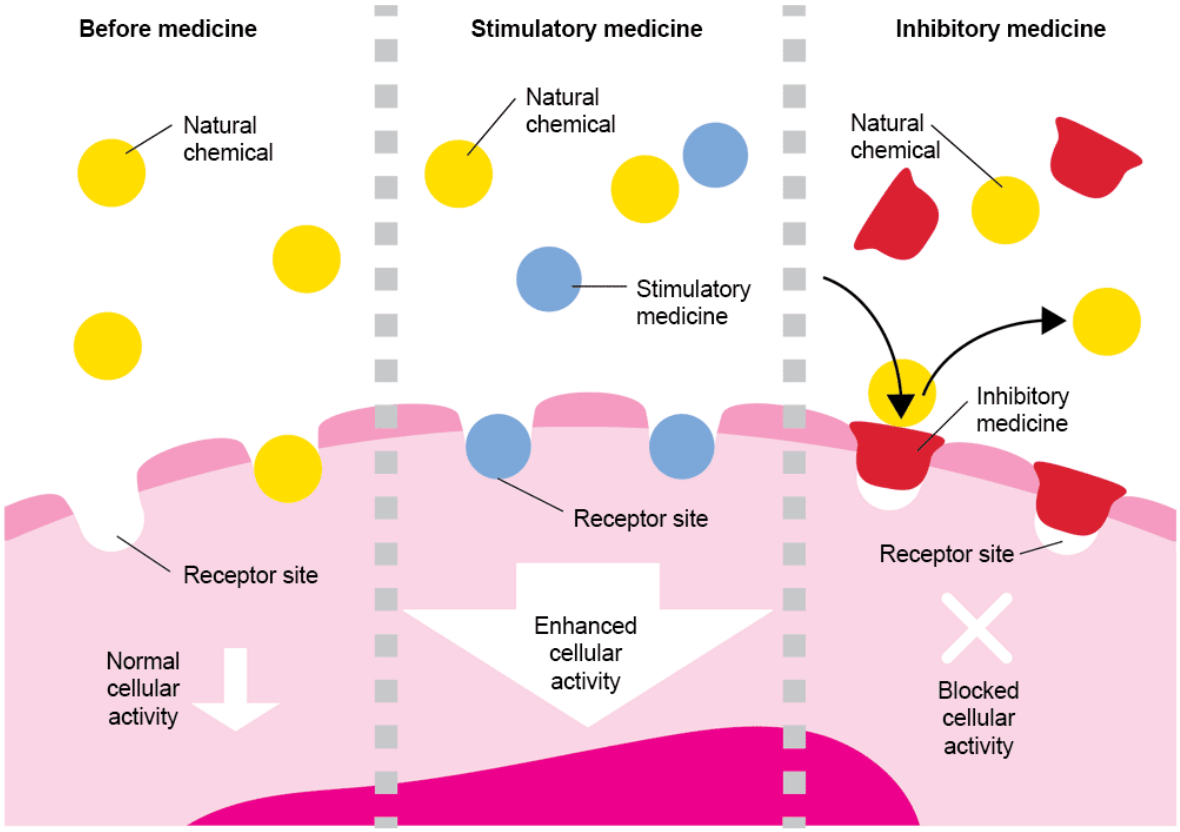
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	High-throughput screening process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	high-throughput-screening.jpeg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/5c7swr6cru8ngfv62fa9kwpyed7hhycj
Cut and paste image here:	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	An image of part of the high-throughput screening process. A machine with many pipettes and vials allows the simultaneous testing a large amount of potentially useful molecules.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt	An image of part of the high-throughput screening process. A machine with many pipettes and vials allows the simultaneous testing a large amount of potentially useful molecules.

text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	
Caption: Will be displayed under media in the article body. Must begin with title of media.	Part of the high-throughput screening process. A machine with many pipettes and vials allows the simultaneous testing a large amount of potentially useful molecules.
Translation required: If media contains English language text, it **must** be translated	No


Before medicine
Stimulatory medicine
Inhibitory medicine
Natural chemical
Natural chemical
Natural chemical
Stimulatory drug
Inhibitory drug
Receptor site
Receptor site
Receptor site
Enhanced cellular activity
Normal cellular activity
Blocked cellular activity


Before medicine
Stimulatory medicine
Inhibitory medicine
Natural chemical
Natural chemical
Natural chemical
Stimulatory medicine
Inhibitory medicine
Receptor site
Receptor site
Receptor site
Enhanced cellular activity
Normal cellular activity
Blocked cellular activity

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

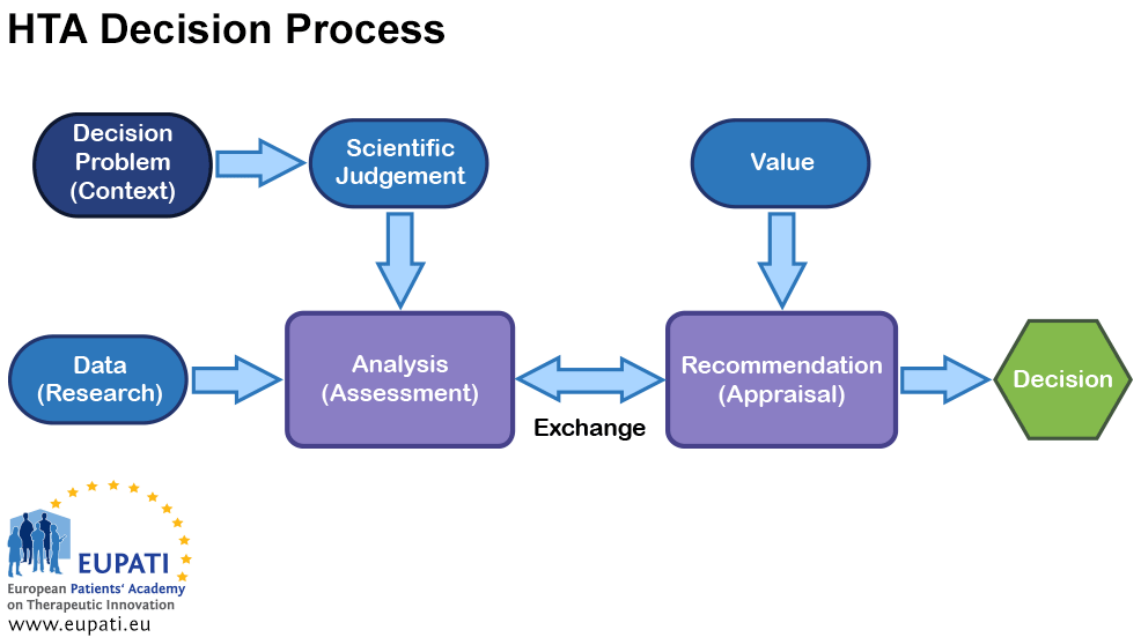
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	18.11.2015	PLATA Created	FINAL	1

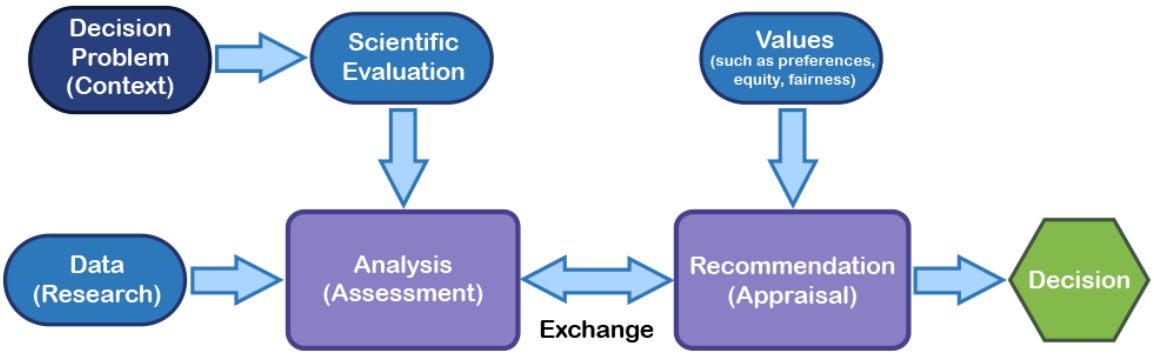
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	HTA Decision Process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	HTA-decision-process-diagram-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/yrvhb5apevmtwnfjc5odqnedqz8xc5mu
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI (Heidi Scherz)

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	An image with a flow chart showing the HTA decision process
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	An image showing the HTA decision process in the form of a flow chart. There are two action nodes: Analysis (Assessment) and Recommendation (Appraisal). Information is exchanged between these two nodes, and each node has its own inputs that feed information into them. Analysis (assessment) pulls information from Data (research) and Scientific judgement (which in turn pulls information from the decision problem (context). Recommendation (appraisal) pulls information from Value. The Recommendation (appraisal) node leads to the decision.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Various inputs are relevant at different points in the HTA decision process.
Translation required: If media contains English language text, it **must** be translated	YES

HTA decision process



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

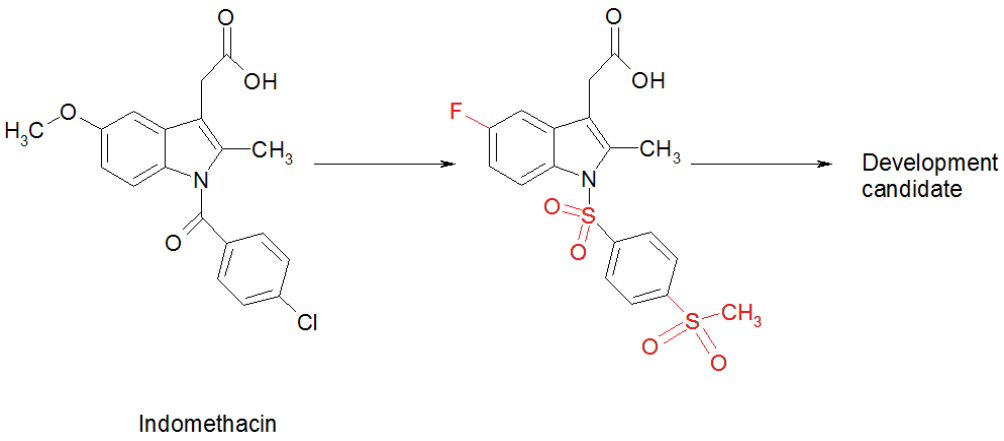
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

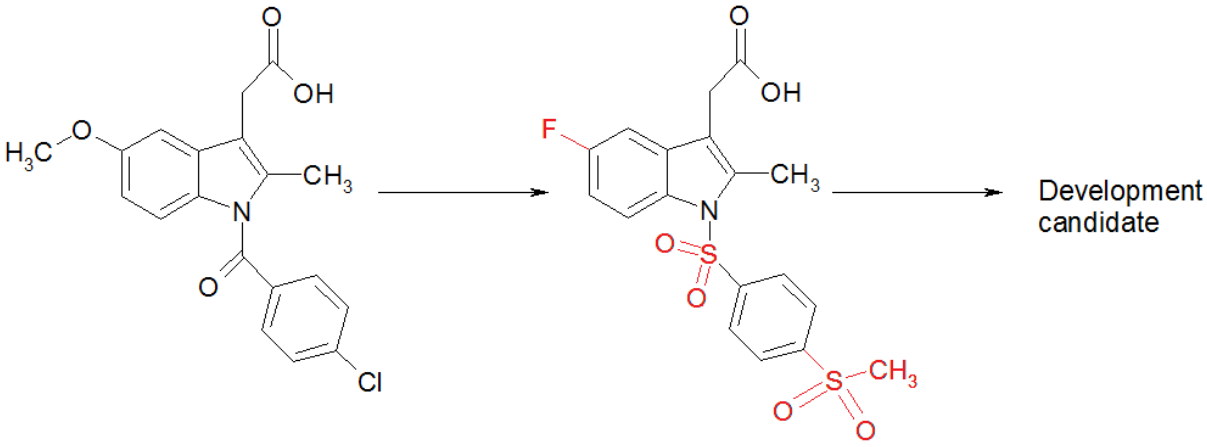
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Optimisation of indomethacin to a potent CRTH2 antagonist.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Indomethacin-optimisation-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/q2ioiun4ms7jw73dg7n5cv26xxxpeg8z
Cut and paste image here:  Indomethacin	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Optimisation of indomethacin to a potent CRTH2 antagonist. The diagram shows how the original molecule indomethacin has been chemically altered in order to turn it into a candidate drug for a development project.
Alt Text: Will be shown in case image/media fails to load/is prevented from	Optimisation of indomethacin to a potent CRTH2 antagonist. The diagram shows how the original molecule indomethacin has been chemically altered in order to turn it into a candidate drug for a

loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	development project.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Optimisation of indomethacin to a potent CRTH2 antagonist. The original molecule on the left (called indomethacin) has been chemically altered (changes shown in red) to turn it into a candidate drug for a development project.
Translation required: If media contains English language text, it **must** be translated	Yes



Indomethacin

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

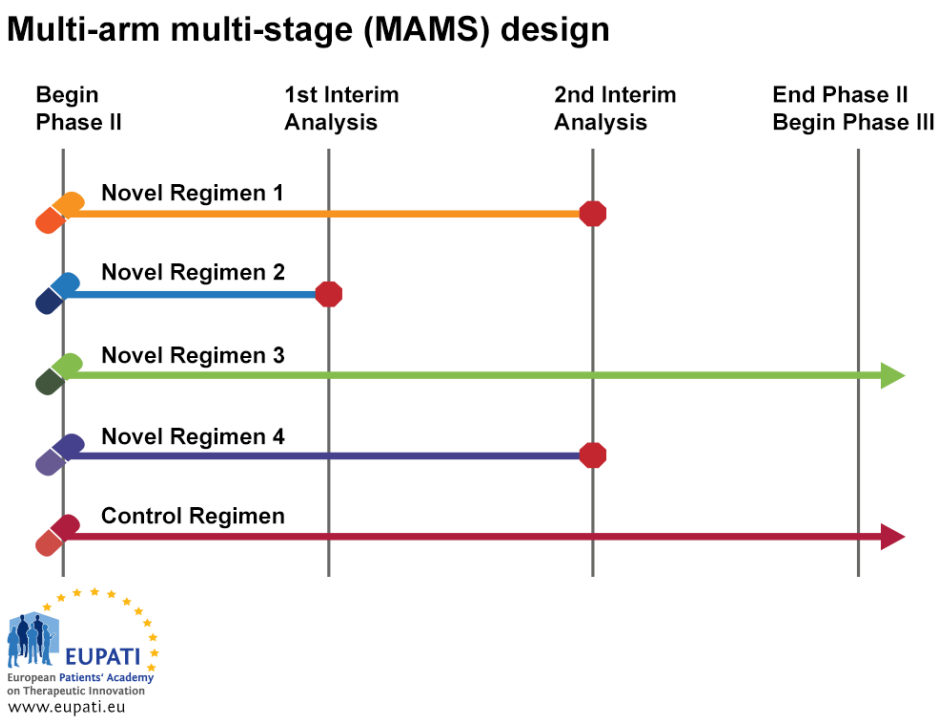
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Multi-arm multi-stage design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Mams-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/u0g0nr14gg0rsy2f9kx9bu15dgor2i70

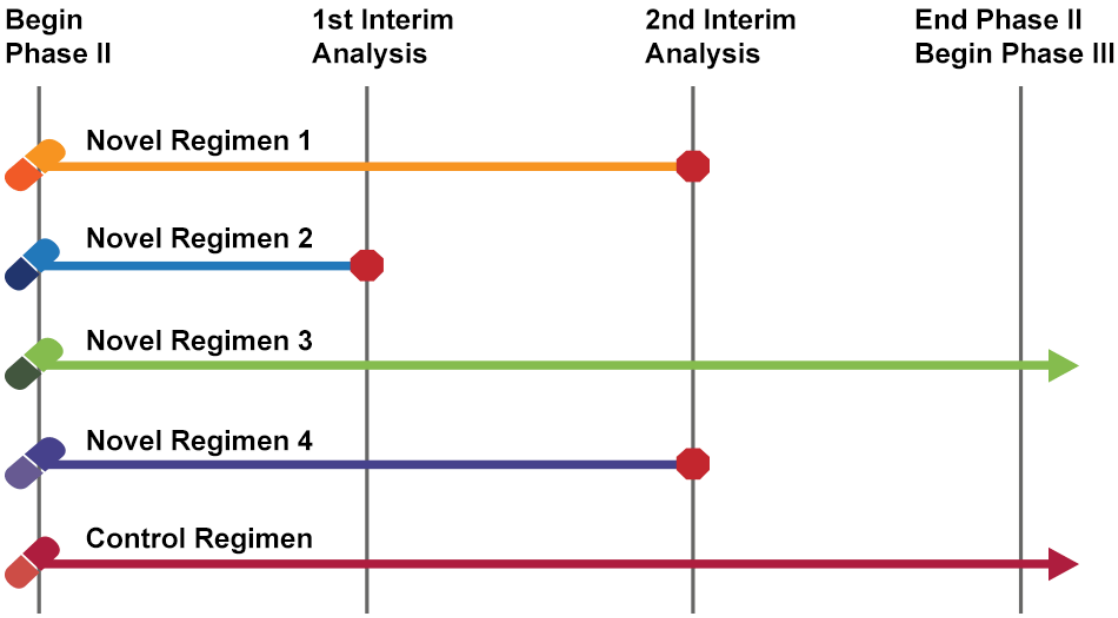
Cut and paste image here:



Media Source Note: Please indicate	Treatment Action Group; EUPAT

where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram depicting a multi-arm multi-stage design (MAMS) trial. The MAMS design allows simultaneous assessment of a number of research treatments against a single control arm. In this example, there are four novel regimens and a control regimen. The MAMS trial begins at the beginning of phase II. There are two interim analyses planned between the beginning of Phase II and the end of Phase II/beginning of Phase III. The control regimen continues throughout the trial until the end of Phase II/Beginning of Phase III. Novel regimen 1 is stopped at the second interim analysis. Novel regimen 2 is stopped at the first interim analysis. Novel regimen 3 continues until the end of Phase II/beginning of Phase III. Novel regimen 4 is stopped after the second interim analysis.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram depicting a multi-arm multi-stage design (MAMS) trial. The MAMS design allows simultaneous assessment of a number of research treatments against a single control arm. In this example, there are four novel regimens and a control regimen. The MAMS trial begins at the beginning of phase II. There are two interim analyses planned between the beginning of Phase II and the end of Phase II/beginning of Phase III. The control regimen continues throughout the trial until the end of Phase II/Beginning of Phase III. Novel regimen 1 is stopped at the second interim analysis. Novel regimen 2 is stopped at the first interim analysis. Novel regimen 3 continues until the end of Phase II/beginning of Phase III. Novel regimen 4 is stopped after the second interim analysis.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The multi-arm multi-stage design (MAMS) allows multiple treatments to be tested simultaneously against a single control.
Translation required: If media contains English language text, it **must** be translated	Yes

Multi-arm multi-stage (MAMS) design



EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

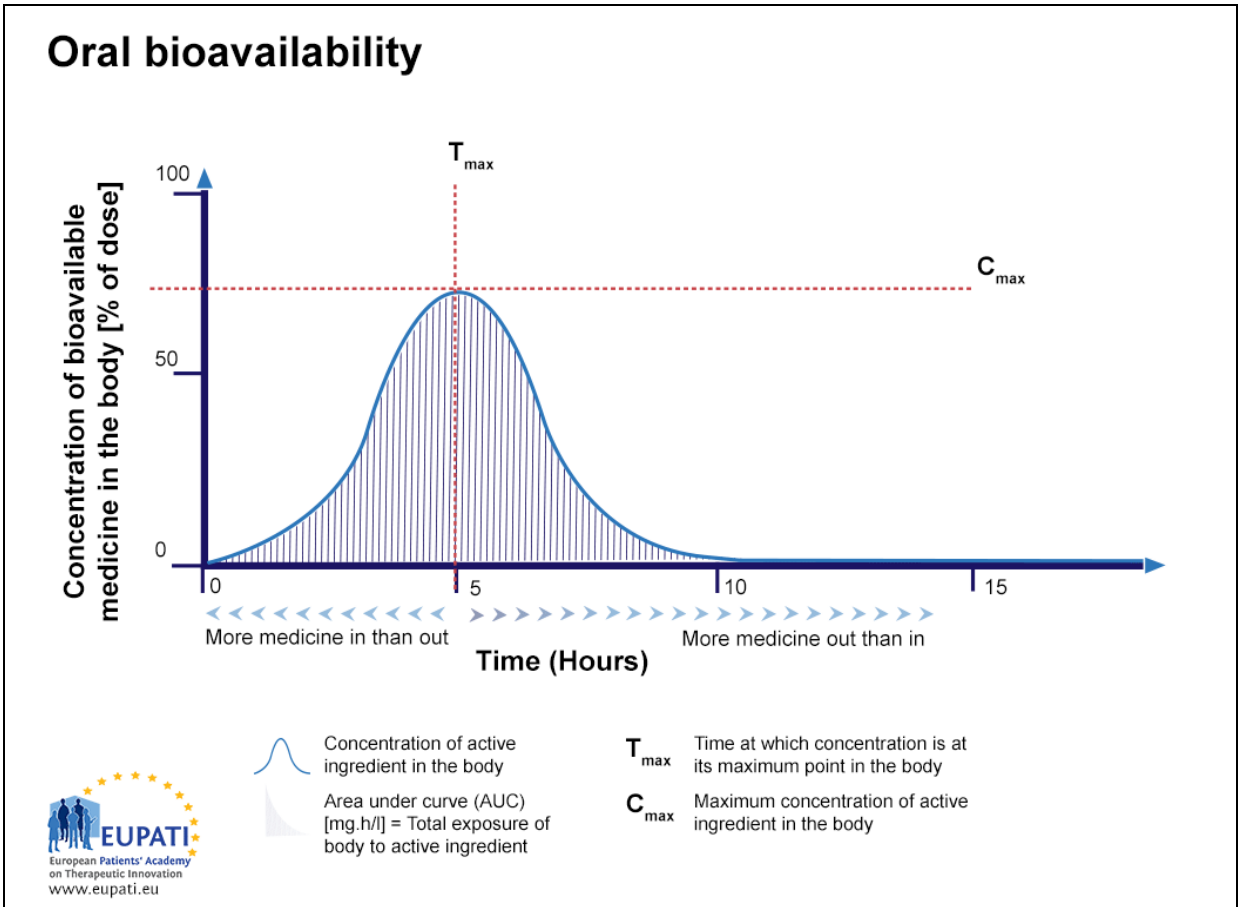
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	21.9.2015	PLATA Created	FINAL	2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

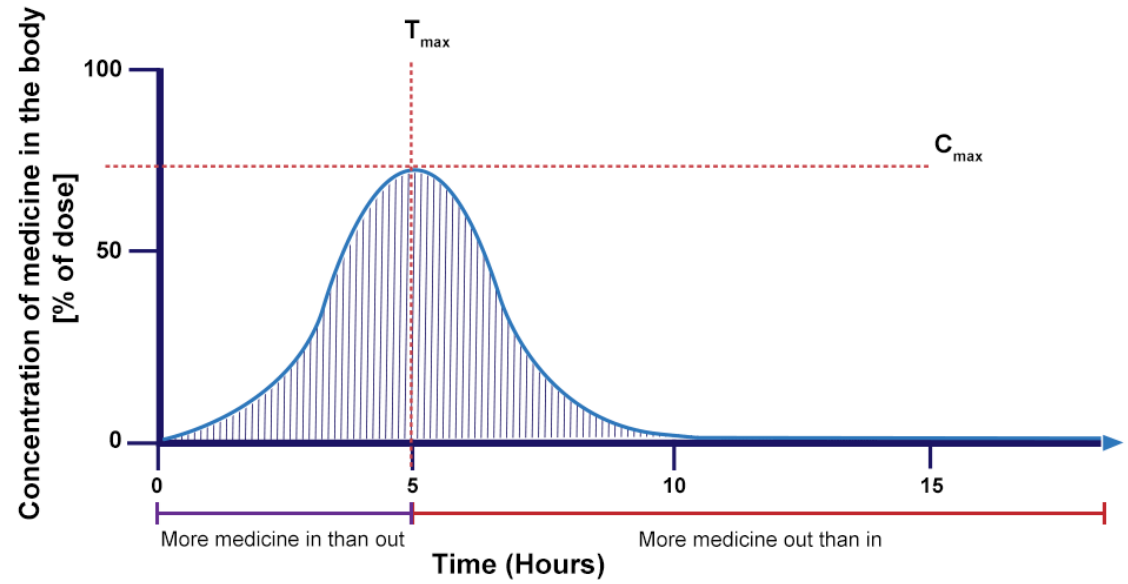
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Oral bioavailability
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Oral-bioavailability-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4660417118/oral-bioavailability-graph
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	Eupati, Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A graphical representation of the concentration of active substance in the blood stream. The percentage of active substance after a tablet is swallowed, studied over the period of 15 hours. The area under the curve (AUC) is shaded. T_{max} is the time where the highest concentration of the medicine is found in the bloodstream, whereas C_{max} is the maximum concentration of the medicine found in the bloodstream.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be	A graphical representation of the concentration of active substance in the blood stream. The percentage of active substance after a tablet is swallowed, studied over the period of 15 hours. The area under the curve (AUC) is shaded. T_{max}

concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	is the time where the highest concentration of the medicine is found in the bloodstream, whereas C_{max} is the maximum concentration of the medicine found in the bloodstream.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The percentage of active substance after a tablet is swallowed, studied over the period of 15 hours. The area under the curve (AUC) is shaded and represents the total amount of active substance which was in the bloodstream over the period studied. T_{max} is the time where the highest concentration of the medicine is found in the bloodstream, whereas C_{max} is the maximum concentration of the medicine found in the bloodstream.
Translation required: If media contains English language text, it **must** be translated	YES

Oral bioavailability



Concentration of active ingredient in the body

Area under curve (AUC) [mg.h/l] = Total exposure of body to active ingredient

T_{max} Time at which concentration is at its maximum point in the body

C_{max} Maximum concentration of active ingredient in the body

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

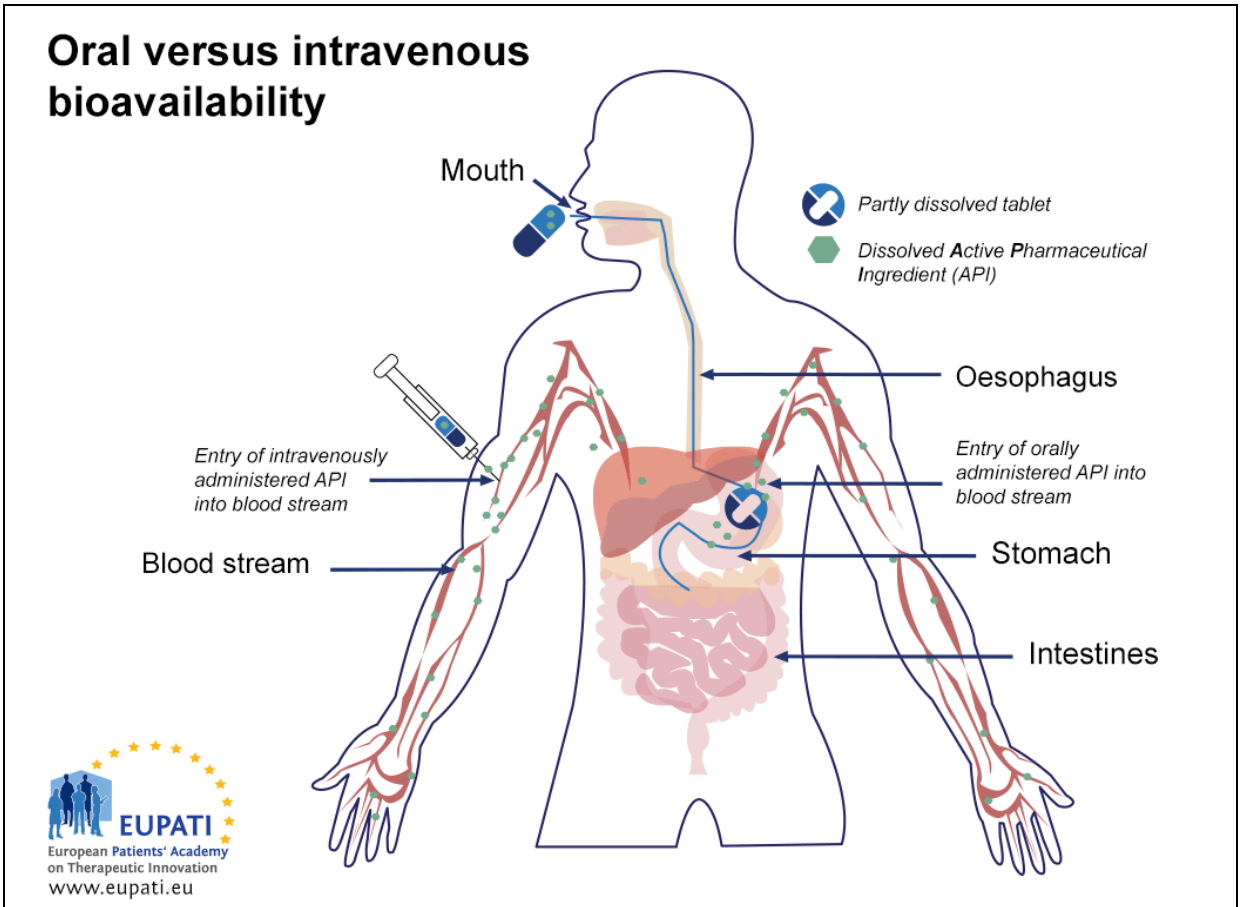
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	21.9.2015	PLATA Created; Image updated	FINAL	3

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

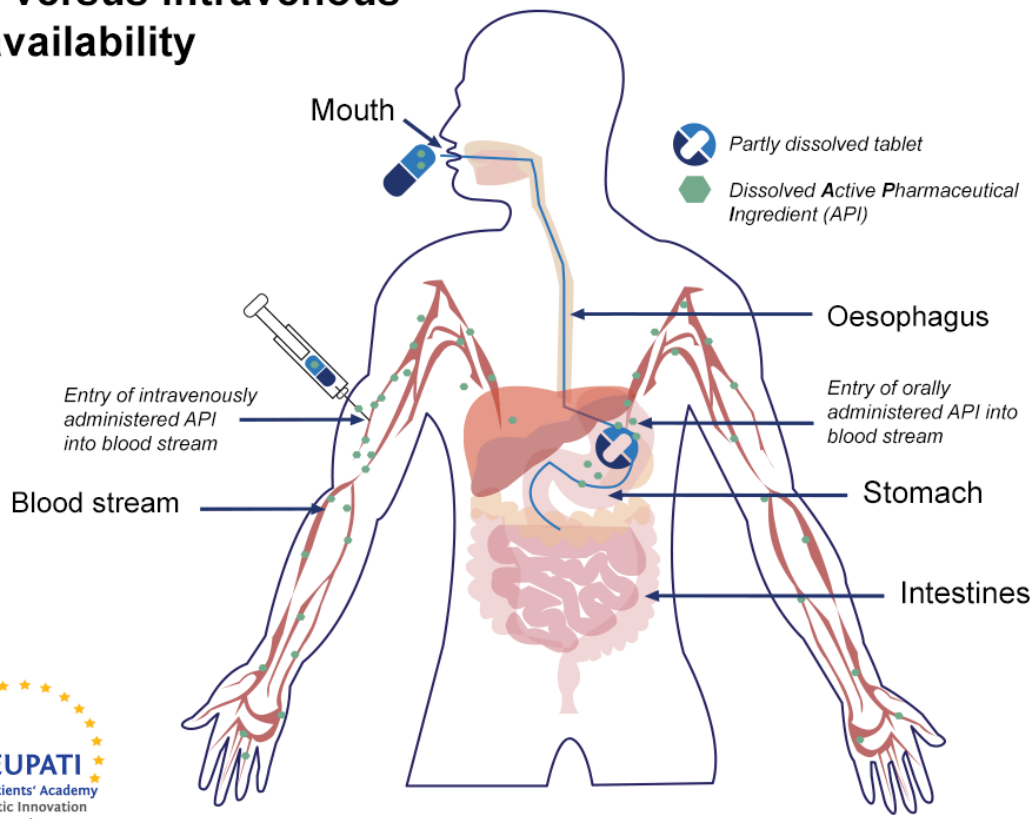
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Oral versus intravenous bioavailability
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Oral-vs-Intravenous-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4114426611/oral-v-intravenous-bioavailability
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	Eupati; Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diagram showing the difference in bioavailability between oral and intravenous administration of a medicine. When a medicine is administered intravenously, the dissolved Active Pharmaceutical Ingredient (API) is available in the blood stream immediately. When a medicine is administered orally, it travels from the mouth via the oesophagus into the stomach. There, the tablet begins to dissolve. Only then does the dissolved API begin to enter the blood stream.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be	Diagram showing the difference in bioavailability between oral and intravenous administration of a medicine. When a medicine is administered intravenously, the dissolved Active Pharmaceutical Ingredient (API) is available in the blood

concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	stream immediately. When a medicine is administered orally, it travels from the mouth via the oesophagus into the stomach. There, the tablet begins to dissolve. Only then does the dissolved API begin to enter the blood stream.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Comparing the bioavailability of Active Pharmaceutical Ingredients administered orally and intravenously. An API is said to be 'biologically available' (bioavailable) when it enters the blood stream.
Translation required: If media contains English language text, it **must** be translated	Yes

Oral versus intravenous bioavailability



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

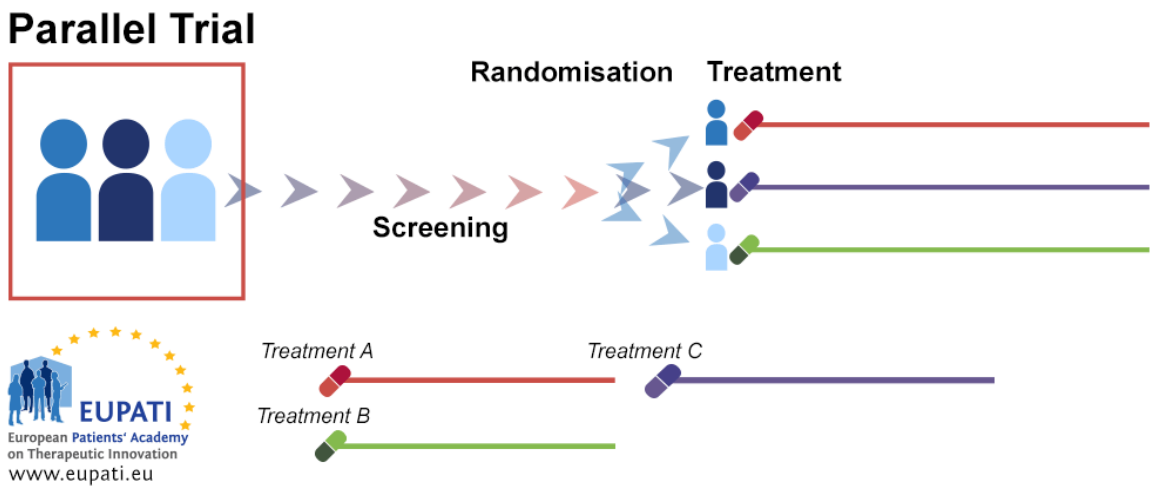
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

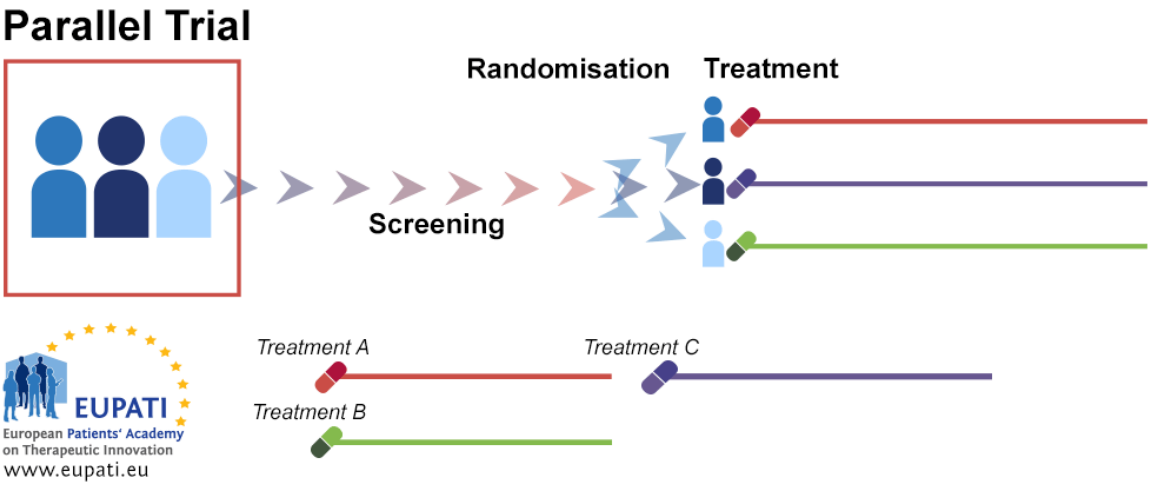
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	Final	1.1
Heidi Scherz	9.9.2015	PLATA Updated	FINAL	2
Heidi Scherz	21.9.2015	Final updates	FINAL	3

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Parallel group trial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Parallel-trial-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4305673405/parallel-trial
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI; Bonnie Le Page

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram depicting the parallel group trial design. After screening, patients are randomised into separate treatment groups. They remain in these treatment arms for the duration of the trial, analysis, and follow-up activities.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram depicting the parallel group trial design. After screening, patients are randomised into separate treatment groups. They remain in these treatment arms for the duration of the trial, analysis, and follow-up activities.
Caption: Will be displayed under media in the article body. Must begin with title of media.	After screening, patients are randomised into separate treatment groups. They remain in these treatment arms for the duration of the trial, analysis, and follow-up activities.
Translation required: If media contains English language text, it **must** be translated	Yes


Parallel Trial
Randomisation
Treatment
Screening
EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu
Treatment A
Treatment C
Treatment B

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

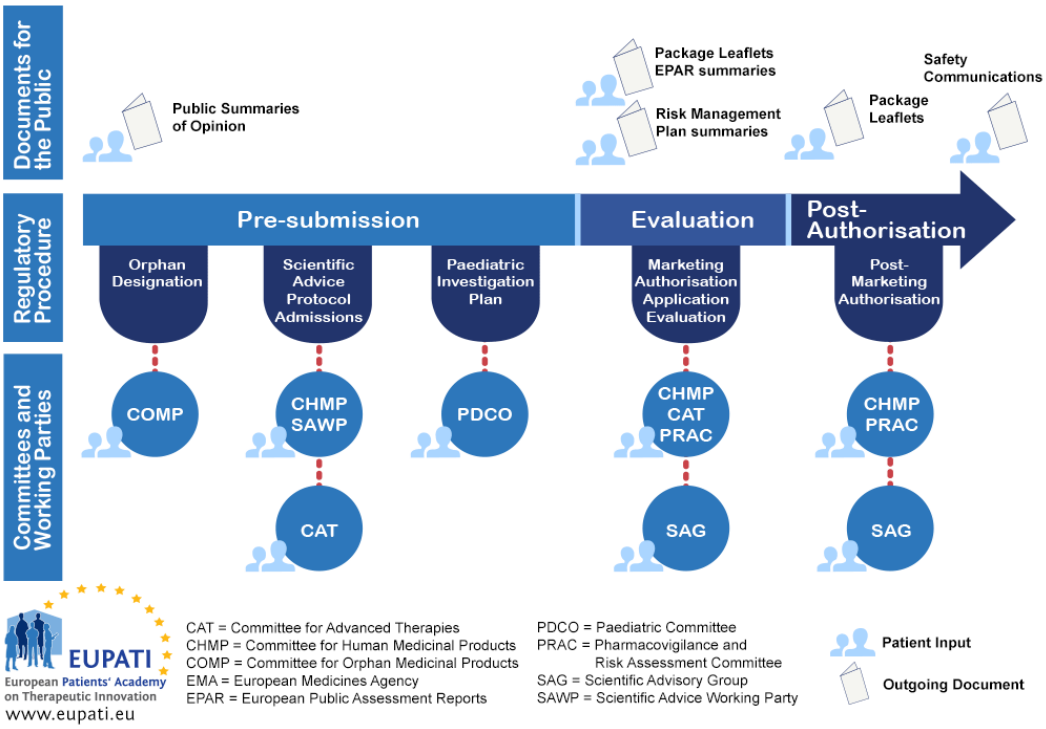
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	31.8.2015	PLATA Created	Draft	1.1
Heidi Scherz	23.11.2015	Updated PLATA	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Patient involvement in EMA activities
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Patient-involvement-EMA-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4370361734/Patient-involvement-EMA
Cut and paste image here:	

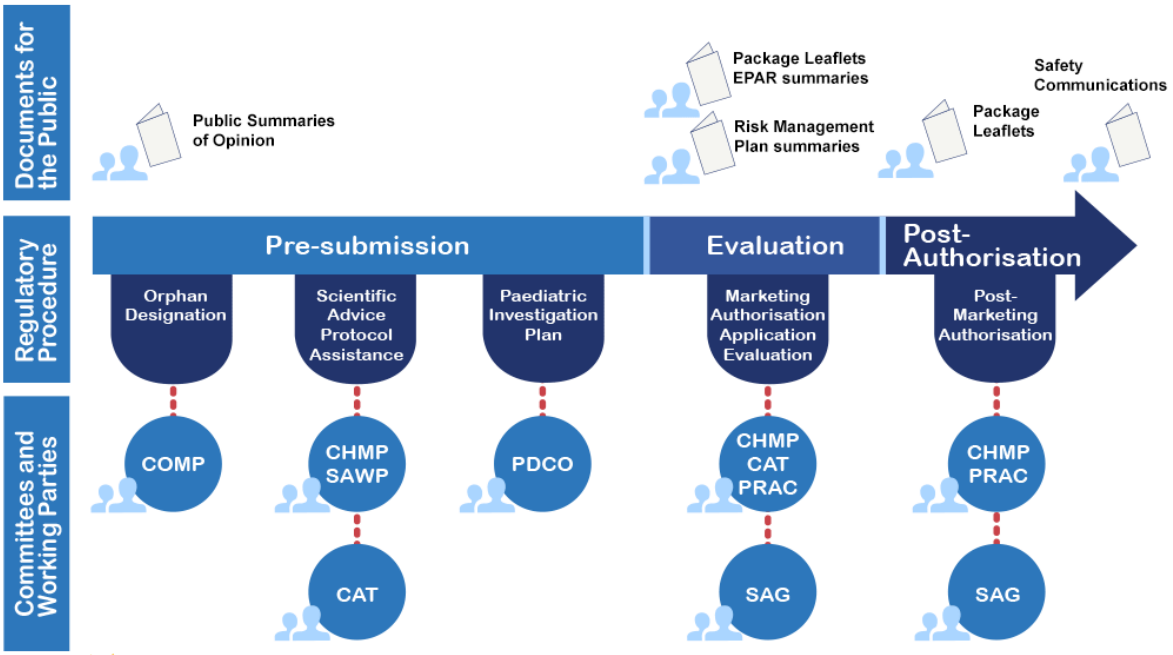


Media Source Note: Please indicate where the image was taken from.	Adapted from European Medicines Agency (2014). *Annex II: EMA activities where patients* and consumers are involved*. Retrieved 31 August, 2015 from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179568.pd
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for	A diagram showing the various activities of the European Medicines Agency (EMA), the associated committees and work groups, the documents for the public that are produced, and patient involvement in those committees, groups, and documents. There are three phases depicted: Pre-submission, evaluation, and post authorisation. During each phase, there is a succession of different regulatory procedures. Each regulatory procedure is associated with one or more committees or work groups. Some of these procedures are also associated with documents for the public. Patient input is considered in all of these committees, work groups, and documents. The first regulatory procedure of the pre-submission phase is 'Orphan Designation'. The associated committee is the Committee for Orphan Medicinal Products

meaning.	(COMP). At the beginning of the Orphan Designation, the Public Summaries of Opinion (PSO) is prepared as a document for the public. The next procedure of the pre-submission phase is 'Scientific Advice, Protocol assistance'. The associated committees are the Committee for Human Medicinal Products (CHMP), the Scientific Advice Working Party (SAWP), and the Committee for Advanced Therapies (CAT). There are no associated documents for the public during this procedure. The final procedure of the pre-submission phase is the Paediatric Investigation Plan (PIP). The associated committee is the Paediatric Committee (PDCO). There are no associated documents for the public during this procedure. The second phase is 'Evaluation'. There is just one regulatory procedure that occurs during this phase – the Marketing Authorisation Application Evaluation. The committees associated with this procedure are: the CHMP, the CAT, the Pharmacovigilance and Risk Assessment Committee (PRAC), and the Scientific Advisory Group (SAG). During this procedure, several documents for the public are prepared. They are: the Package Leaflets (PL), European Public Assessment Report (EPAR) summaries, and tentative Risk Management Plan summaries. The third and last phase is 'Post Authorisation'. There is just one regulatory procedure during this phase: Post Marketing Authorisation. The committees associated with Post Marketing Authorisation are the CHMP, the PRAC, and the SAG. During this phase, the documents prepared for the public are renewed Package Leaflets and safety communications.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It	A diagram showing the various activities of the European Medicines Agency (EMA), the associated committees and work groups, the documents for the public that are produced, and patient involvement in those committees, groups, and documents.

should **not** rely on article context for meaning.	
Caption: Will be displayed under media in the article body. Must begin with title of media.	Patients can be involved at the EMA in a variety of different ways throughout the regulatory procedure.
Translation required: If media contains English language text, it **must** be translated	Yes

Patient Involvement at the EMA



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

CAT = Committee for Advanced Therapies
CHMP = Committee for Human Medicinal Products
COMP = Committee for Orphan Medicinal Products
EMA = European Medicines Agency
EPAR = European Public Assessment Reports

PDCO = Paediatric Committee
PRAC = Pharmacovigilance and Risk Assessment Committee
SAG = Scientific Advisory Group
SAWP = Scientific Advice Working Party

Patient Input
Outgoing Document

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	27.10.2016	PLATA Created	Draft	1.1
Matthew May	09.11.2016	PLATA checked	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Obligatory pharmacy logo
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	obligatory-pharmacy-logo-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/md8kzp8ckomj9xaxrb9gntkkl6jly6rs
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	http://ec.europa.eu/health/files/eu-logo/logosancointernet_charte_v2.pdf
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely	EU online pharmacy logo (UK version) consisting of a white cross over four green lines on the top third of the logo, the national flag of the member state where the pharmacy is operating, and text asking the consumer to click in the logo to verify if the website is operating legally. The logo is intended to allow patients and consumers to be able to

on article context for meaning.	identify online pharmacies and retailers that have been approved and that provide authorised medicines.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	EU online pharmacy logo (UK version) consisting of a white cross over four green lines on the top third of the logo, the national flag of the member state where the pharmacy is operating, and text asking the consumer to click in the logo to verify if the website is operating legally. The logo is intended to allow patients and consumers to be able to identify online pharmacies and retailers that have been approved and that provide authorised medicines.
Caption: Will be displayed under media in the article body. Must begin with title of media.	EU online pharmacy logo (UK version) that should appear on the websites of all online medicine vendors in the EU.
Translation required: If media contains English language text, it **must** be translated	Yes, but instead, use the national versions of the logo from the original document here: http://ec.europa.eu/health/files/eu-logo/logosancointernet_charte_v2.pdf

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

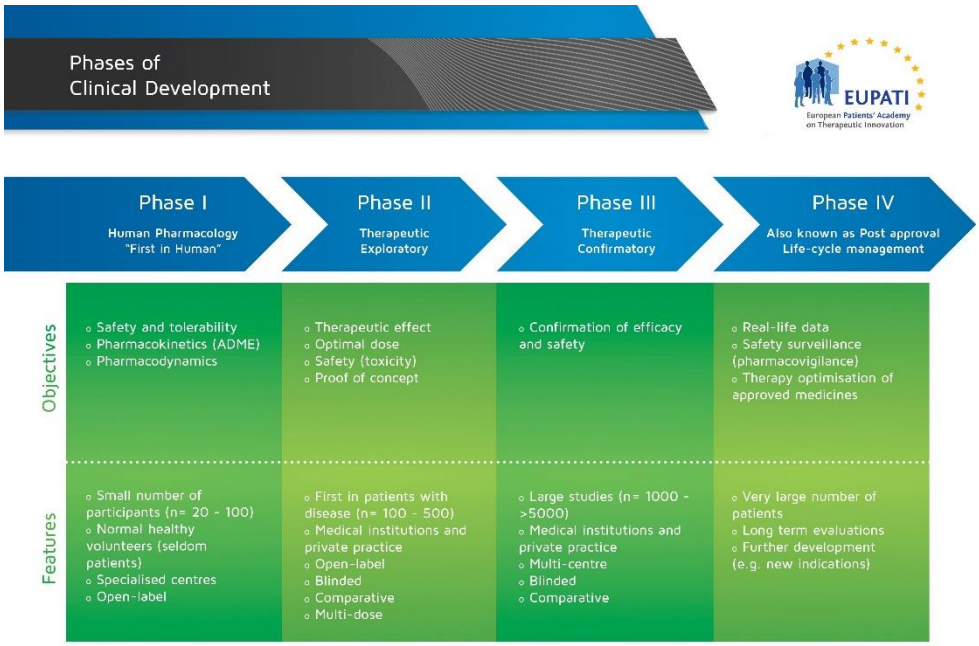
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	25.8.2015	PLATA Created	Draft	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Phases of clinical development
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	phases-clinical-development-v1_EN.jpg
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4297790721/phases-clinical-development

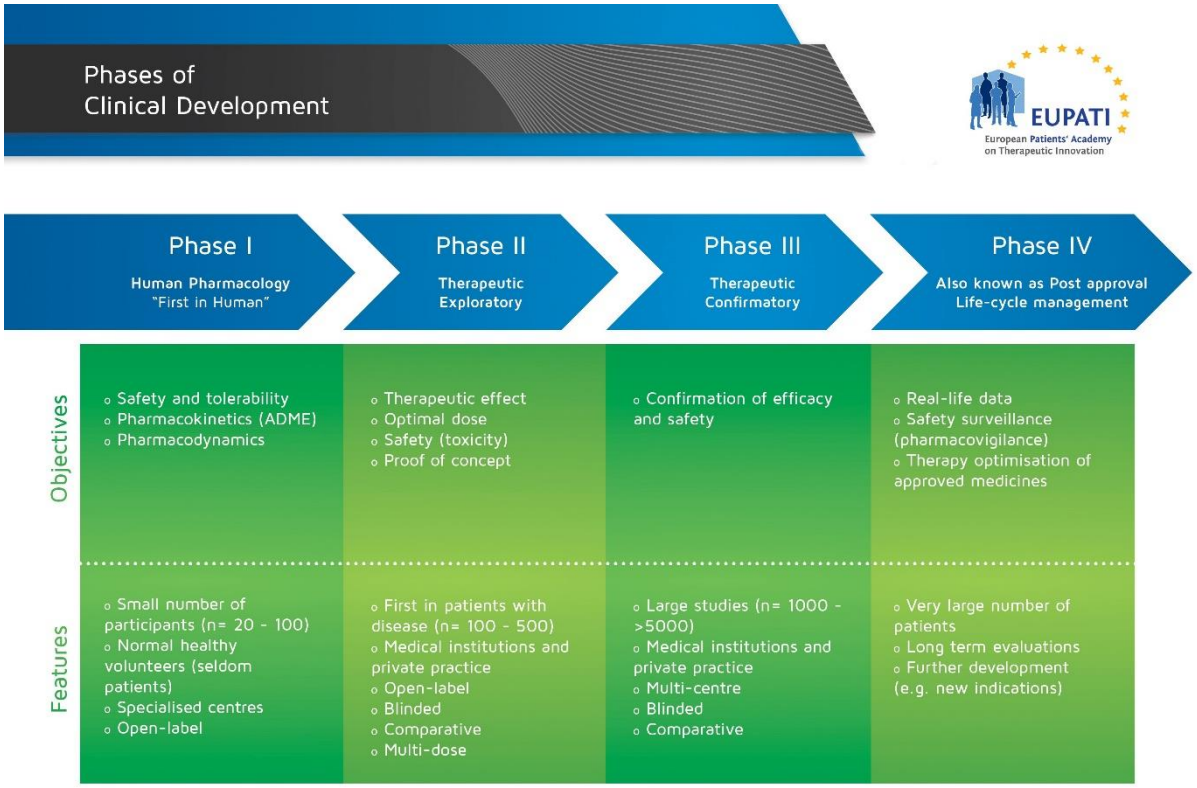
Cut and paste image here:



Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram explaining the details of the four phases of clinical development in terms of their objectives and features. Phase I, also known as 'First in Human', covers human pharmacology. The objectives of this phase are: Safety and tolerability, Pharmacokinetics (ADME), and Pharmacodynamics. The features are: Small number of participants (n = 20-100), normal healthy volunteers (seldom patients), specialised centres, and open-label. Phase II is the therapeutic exploratory phase. The objectives of Phase II are to discover therapeutic effect, optimal dose, safety (toxicity), and proof of concept. The features of Phase II are: First in patients with disease (n = 100-500), medical institutions and private practice, open-label, blinded, comparative, multi-dose. Phase III is the therapeutic confirmatory stage. The objective of Phase III is the confirmation of efficacy and safety. The features of Phase III are: Large studies (n = 1000- >5000), medical institutions and private practice, multi-centre, blinded, and comparative. Phase IV is also known as Post-approval and Life-cycle management. The objectives of Phase IV are: real-life data, safety surveillance (pharmacovigilance), and therapy optimisation of approved medicines. The features of Phase IV are: Very large numbers of patients, long-term evaluations, and further development (e.g. new indications).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram explaining the details of the four phases of clinical development in terms of their objectives and features. Phase I, also known as 'First in Human', covers human pharmacology. The objectives of this phase are: Safety and tolerability, Pharmacokinetics (ADME), and Pharmacodynamics. The features are: Small number of participants (n = 20-100), normal healthy volunteers (seldom patients), specialised centres, and open-label. Phase II is the therapeutic exploratory phase. The objectives of Phase II are to discover therapeutic effect, optimal dose, safety

	(toxicity), and proof of concept. The features of Phase II are: First in patients with disease (n = 100-500), medical institutions and private practice, open-label, blinded, comparative, multi-dose. Phase III is the therapeutic confirmatory stage. The objective of Phase III is the confirmation of efficacy and safety. The features of Phase III are: Large studies (n = 1000- >5000), medical institutions and private practice, multi-centre, blinded, and comparative. Phase IV is also known as Post-approval and Life-cycle management. The objectives of Phase IV are: real-life data, safety surveillance (pharmacovigilance), and therapy optimisation of approved medicines. The features of Phase IV are: Very large numbers of patients, long-term evaluations, and further development (e.g. new indications).
Caption: Will be displayed under media in the article body. Must begin with title of media.	The four phases of clinical development differ in terms of their objectives and features.
Translation required: If media contains English language text, it **must** be translated	Yes


Phases of
Clinical Development
EUPATI
European Patients' Academy
on Therapeutic Innovation
Phase I
Human Pharmacology
"First in Human"
Phase II
Therapeutic
Exploratory
Phase III
Therapeutic
Confirmatory
Phase IV
Also known as Post approval
Life-cycle management
Objectives
Features
o Safety and tolerability
o Pharmacokinetics (ADME)
o Pharmacodynamics
o Therapeutic effect
o Optimal dose
o Safety (toxicity)
o Proof of concept
o Confirmation of efficacy and safety
o Real-life data
o Safety surveillance (pharmacovigilance)
o Therapy optimisation of approved medicines
o Small number of participants (n= 20 - 100)
o Normal healthy volunteers (seldom patients)
o Specialised centres
o Open-label
o First in patients with disease (n= 100 - 500)
o Medical institutions and private practice
o Open-label
o Blinded
o Comparative
o Multi-dose
o Large studies (n= 1000 - >5000)
o Medical institutions and private practice
o Multi-centre
o Blinded
o Comparative
o Very large number of patients
o Long term evaluations
o Further development (e.g. new indications)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

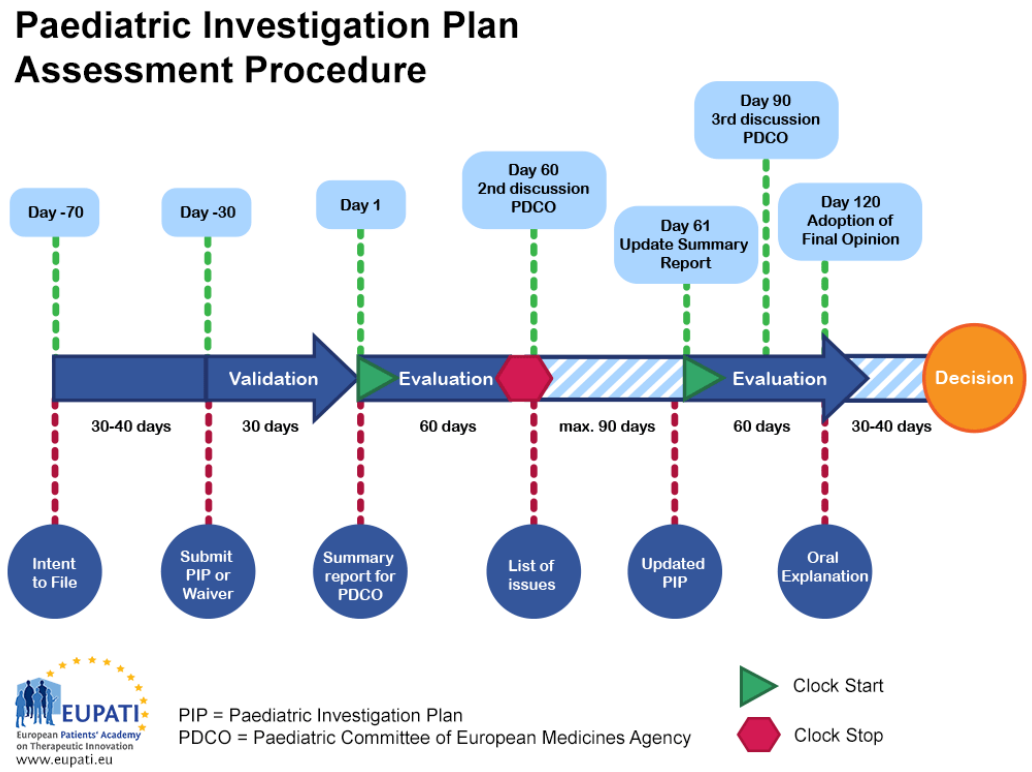
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA Created	Draft	1.1
Matthew May	13.01.2016	Fields updated and finalised	FINAL	1.1

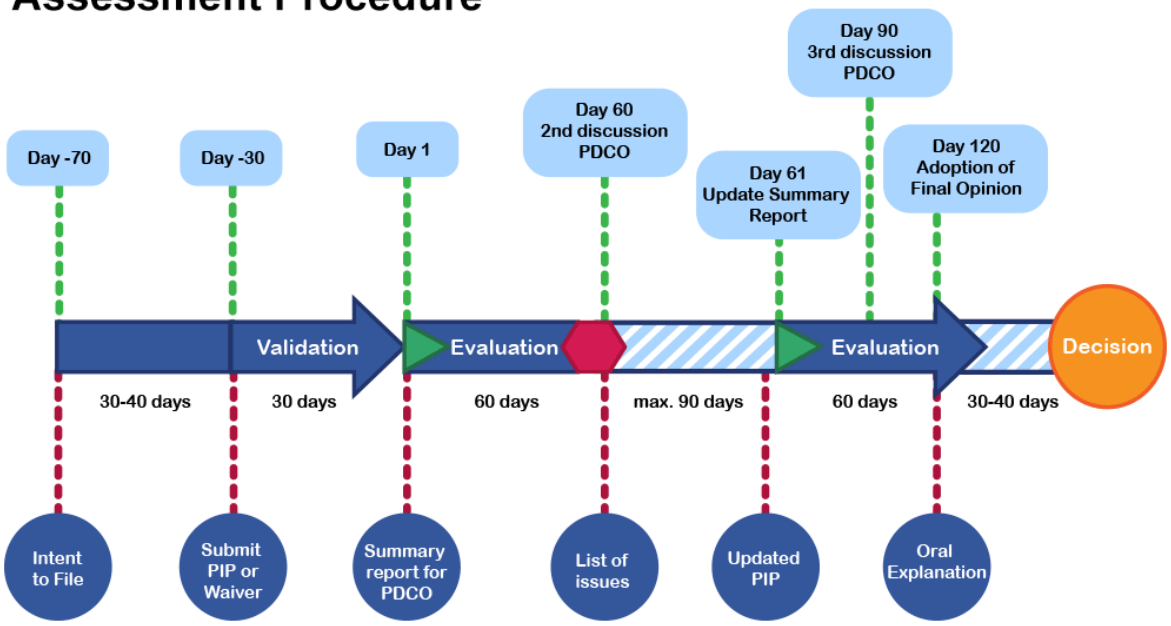
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Paediatric Investigation Plan Assessment Procedure
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	PIP-decision-process-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/5356114209/PIP-decision-process
Cut and paste image here: 	
Media Source Note: Please indicate where	EUPATI, Bonnie Le Page, Heidi Scherz

the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram showing the assessment procedure for a Paediatric Investigation Plan (PIP).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	This diagram gives an overview of the assessment procedure for a Paediatric Investigation Plan. The review process takes the form of a 120-day procedure (excluding a possible clock stop of up to 90 days at Day 60). The assessment procedure if carrier out by the Paediatric Committee of the European Medicines Agency.
Caption: Will be displayed under media in the article body. Must begin with title of media.	A Paediatric Investigation Plan is assessed by the Paediatric Committee of the European Medicines Agency and follows a set procedure with defined timelines.
Translation required: If media contains English language text, it **must** be translated	Yes

Paediatric Investigation Plan
Assessment Procedure



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

PIP = Paediatric Investigation Plan
PDCO = Paediatric Committee of European Medicines Agency

Clock Start
Clock Stop

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

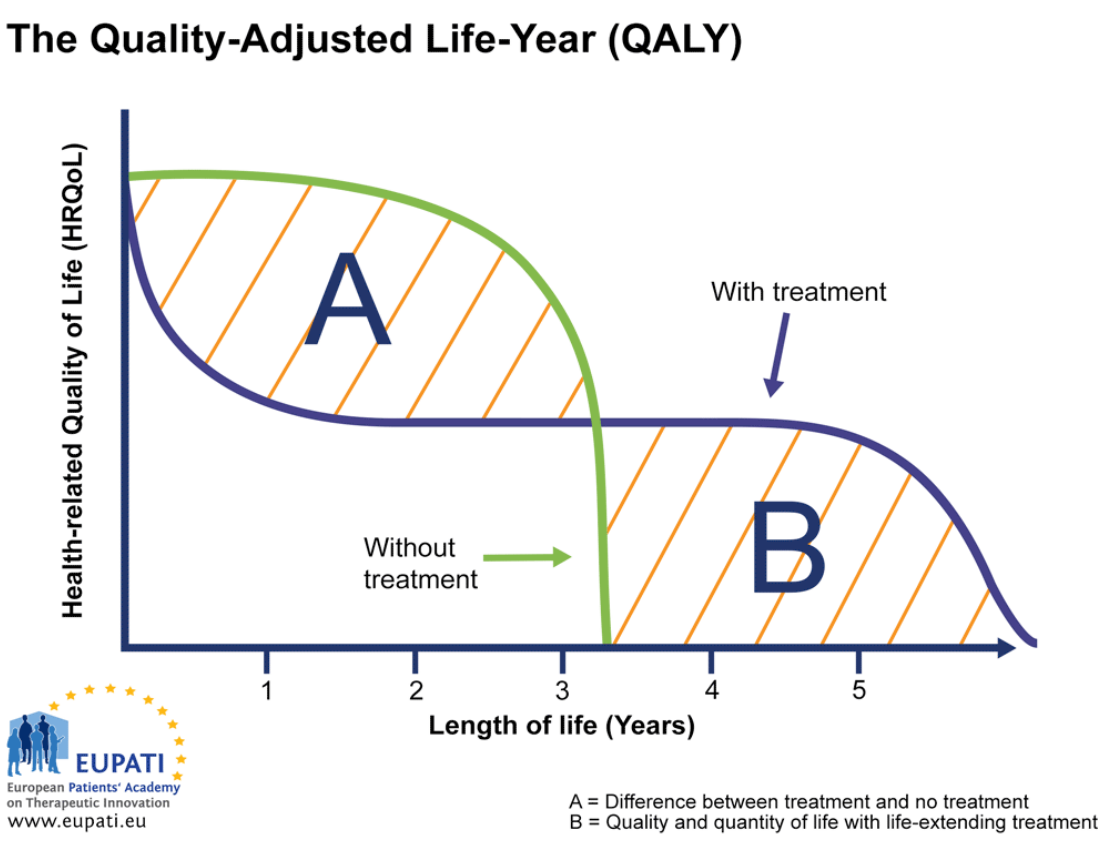
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	07.03.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

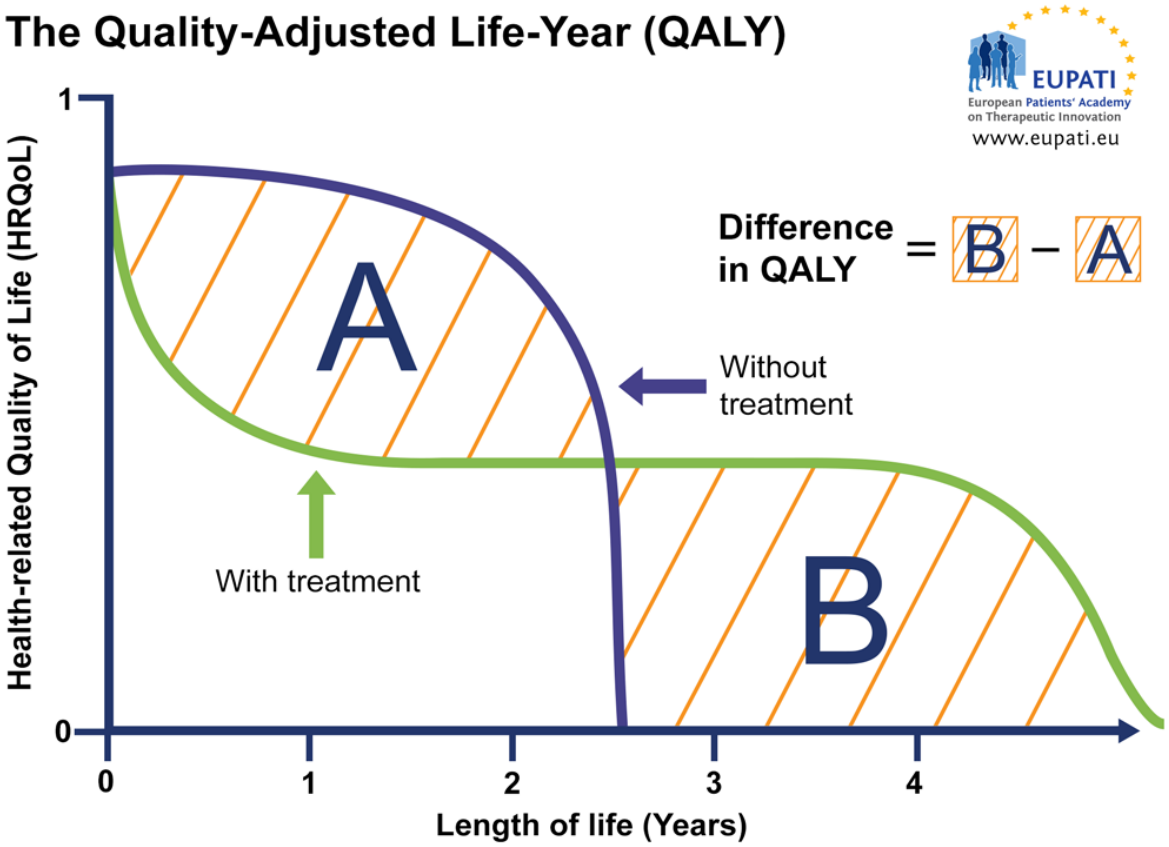
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The Quality Adjusted Life Year
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	QALY-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/6520894593/QALY

Cut and paste image here:



Media Source	EUPATI

Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	The graph in this image shows the calculation of a Quality-Adjusted Life-Year (QALY), a representation of the length of life adjusted by quality of life. By putting length of life (in years) on the horizontal (X) axis and Health-related Quality of Life (HRQoL) on the vertical (Y) axis, we can depict the relationship of quality and quantity of life experienced with a life-extending therapy. Two lines are plotted on the graph, one representing With Treatment and the other Without Treatment. In this example, the treatment extends life by two years with an approximately 50% reduction in quality of life. The total area under the curve (AUC) is approximately the same for both lines, and the two areas between the two lines are also roughly the same. In this scenario, two years of extended life are multiplied by a reduction of 50% quality of life, and can be thought of as equivalent to a single year in perfect health.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Graph representing the Quality-Adjusted Life-Year.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The Quality-Adjusted Life-Year (QALY) is a measure in health economics that expresses the additional number of years a person lives as a result of receiving treatment, taking into account the quality of life of those years.
Translation required: If media contains English language text, it **must** be translated	Yes


The Quality-Adjusted Life-Year (QALY)
EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu
Difference in QALY = B – A
A
B
Without treatment
With treatment
Health-related Quality of Life (HRQoL)
1
0
0
1
2
3
4
Length of life (Years)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

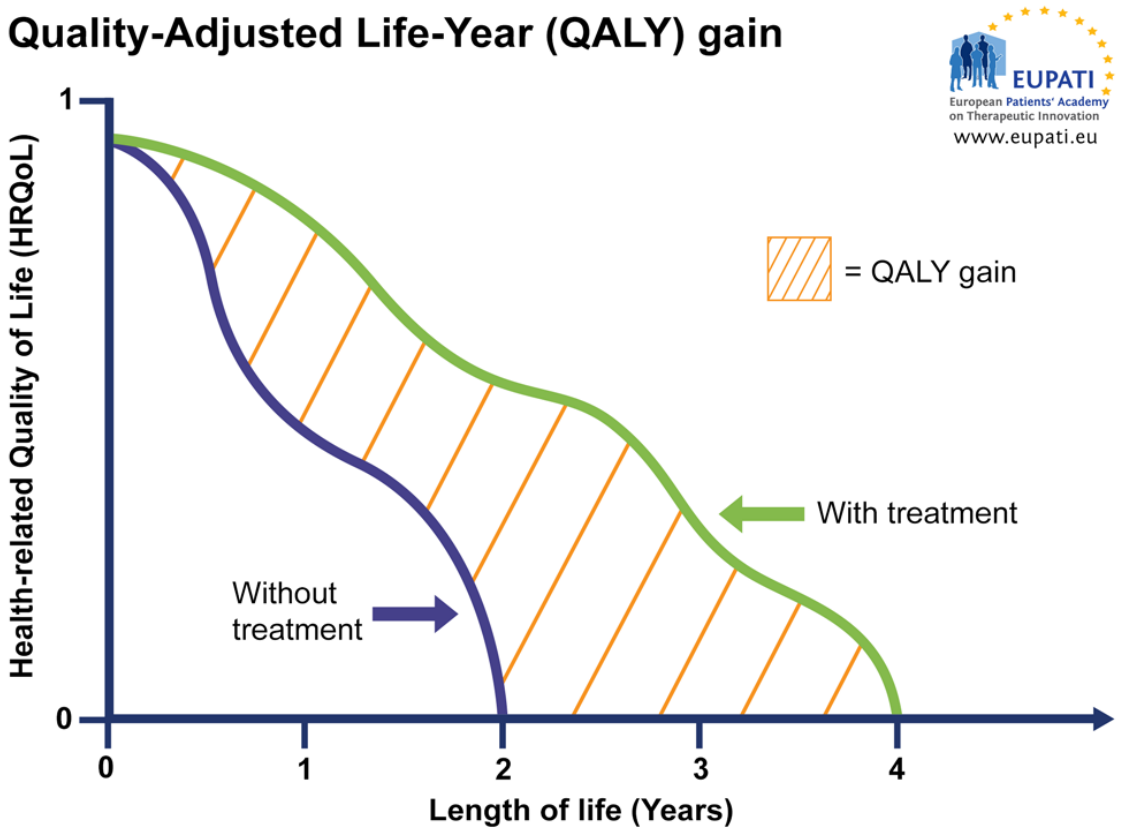
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	31.05.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

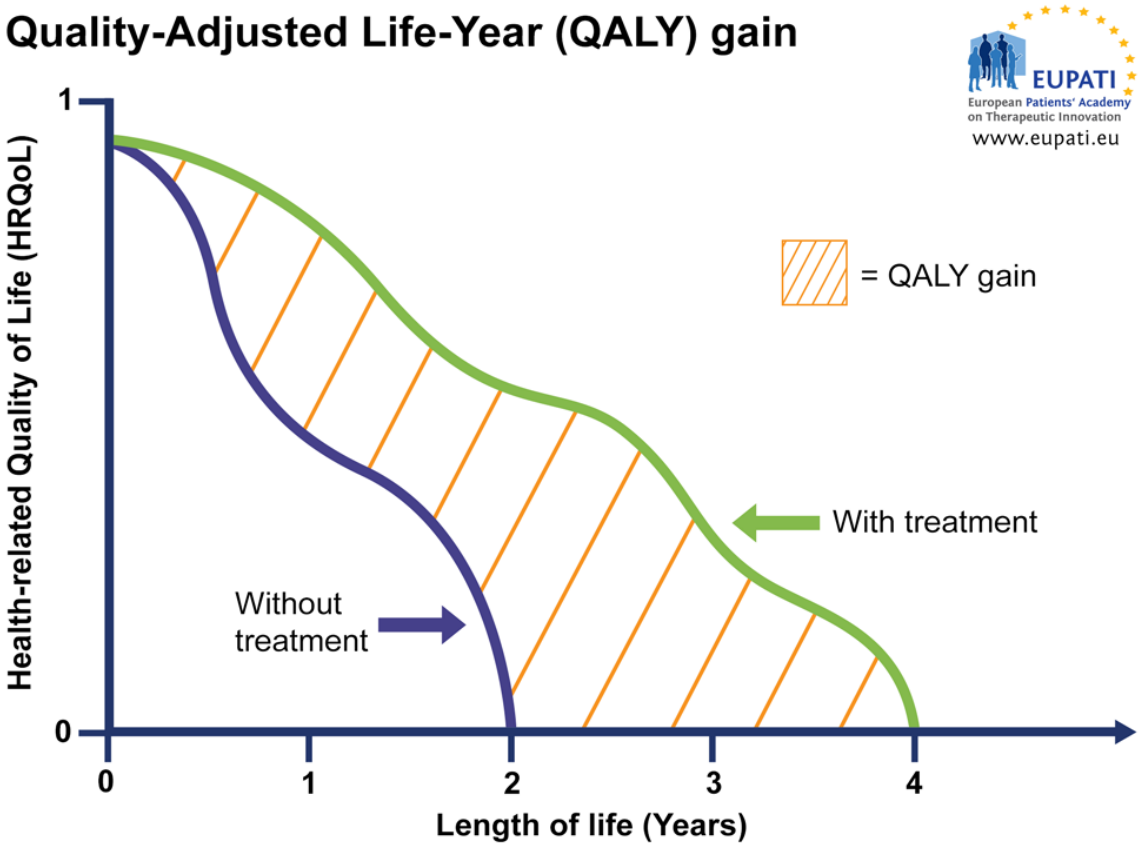
Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Quality-Adjusted Life-Year (QALY) gain
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	QALY-gain_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/l7at72n77dx7i8bpotktim1pv490g6wm
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	This image shows the changes in Health-related Quality of Life (HRQoL) over time with and without treatment, providing a visualisation of the increase in HRQoL as well as an extension of life, resulting in a net Quality-Adjusted Life-Year (QALY) gain. By putting length of life (in years) on the horizontal (X) axis and HRQoL on the vertical (Y) axis, we can show the relationship of quality and quantity of life experienced with a life-extending therapy. Two lines are plotted on the graph, one representing 'With Treatment' and the other 'Without Treatment'.

	The difference in area under the curve (AUC) represented by the orange area, shows the QALY gain between someone using the treatment versus someone who does not.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Graph representing the Quality-Adjusted Life-Year (QALY) gain of a patient receiving the treatment versus a patient who receives no treatment.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The Quality-Adjusted Life-Year (QALY) gain of a patient receiving the treatment versus a patient who receives no treatment can be shown visually. The difference in area under the curve (AUC) represented by the orange area, shows the QALY gain between someone using the treatment versus someone who does not.
Translation required: If media contains English language text, it **must** be translated	Yes


Quality-Adjusted Life-Year (QALY) gain
EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu
= QALY gain
With treatment
Without
treatment
Health-related Quality of Life (HRQoL)
1
0
0
1
2
3
4
Length of life (Years)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

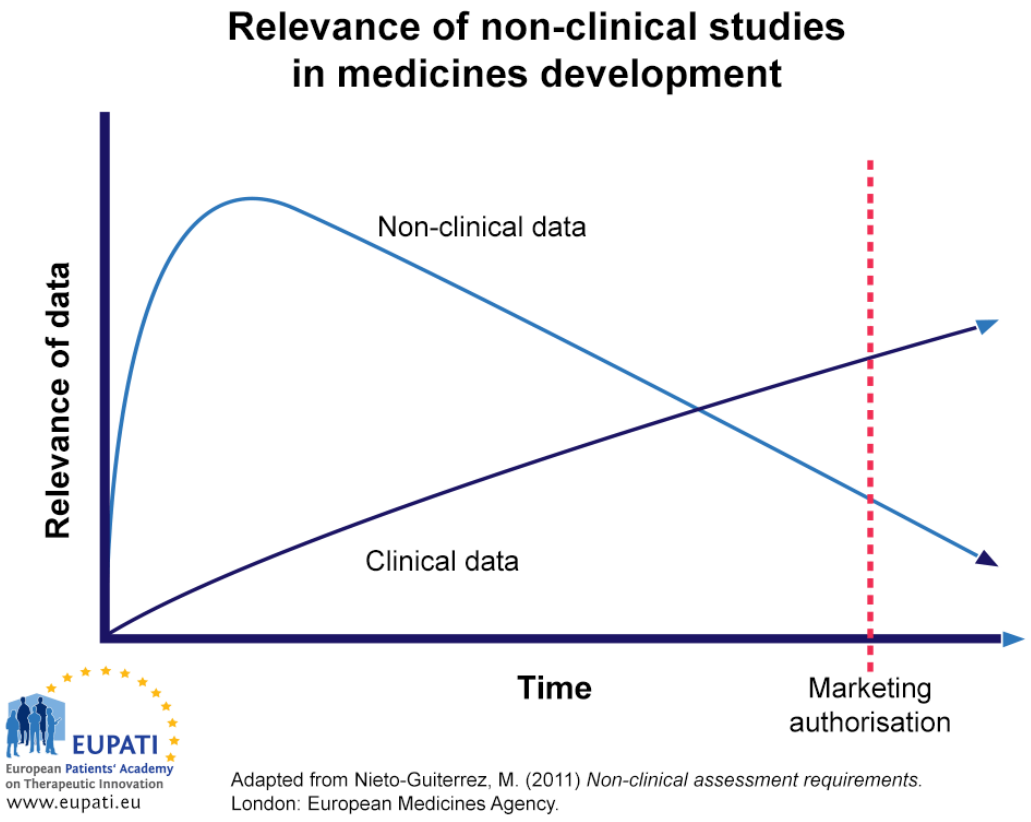
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	23.9.2015	PLATA updated, final version	FINAL	4

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Relevance of non-clinical studies in medicines development
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Relevance-non-clinical-data-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4286180767/relevance-non-clinical-data

Cut and paste image here:

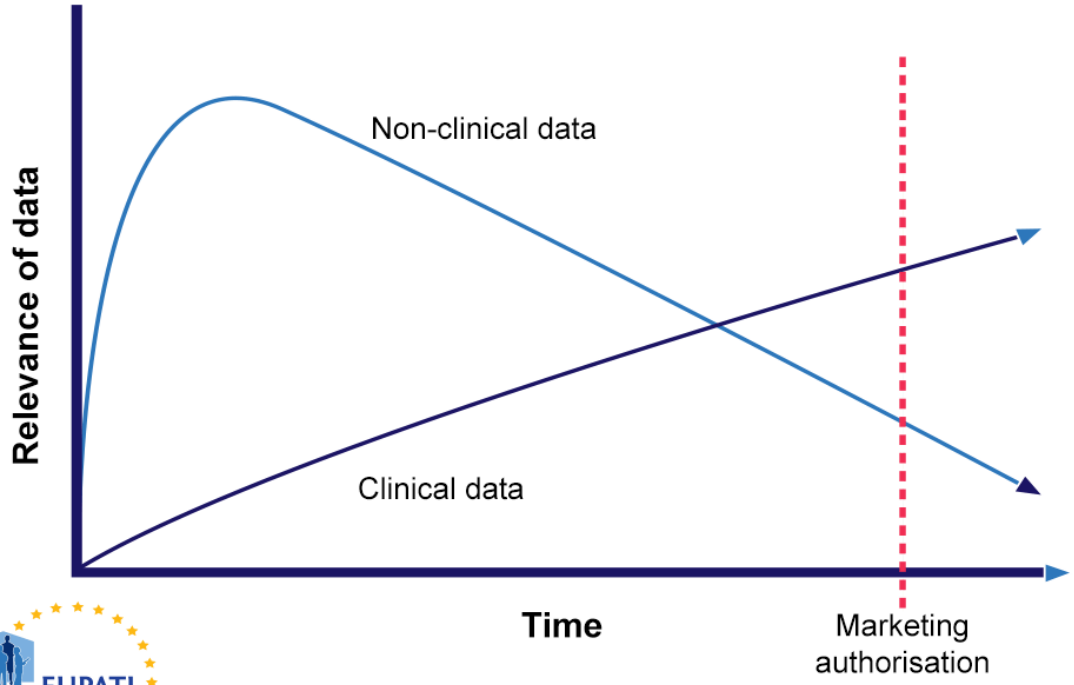


Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Media Source Note: Please indicate where the image was taken from.	EUPATI. Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements*. London: European Medicines Agency.
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A graph depicting the importance and relevance of clinical and non-clinical data in medicines development over time. Degree of relevance is indicated on the Y-axis; Time is indicated on the X-axis. Towards the beginning of the development period, the relevance of Non-clinical data rises steeply, while the relevance of clinical data increases more gradually. At some point, fairly close to the beginning of the development period, the relevance of non-clinical data peaks, and from there begins a gradual decline as the relevance of clinical data continues to gradually rise. At a given point, sometime before Marketing Authorisation (which is an event marked on the X-axis), the relevance of clinical data eclipses that of non-clinical data. This trend continues until Marketing Authorisation and beyond, with clinical data becoming more relevant as non-clinical data becomes less so.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A graph depicting the importance and relevance of clinical and non-clinical data in medicines development over time. Degree of relevance is indicated on the Y-axis; Time is indicated on the X-axis. Towards the beginning of the development period, the relevance of Non-clinical data rises steeply, while the relevance of clinical data increases more gradually. At some point, fairly close to the beginning of the development period, the relevance of non-clinical data peaks, and from there begins a gradual decline as the relevance of clinical data continues to gradually rise. At a given point, sometime before Marketing Authorisation (which is an event marked on the X-axis), the relevance of clinical data eclipses that of non-clinical data. This trend continues until Marketing Authorisation and beyond, with clinical data becoming more relevant as non-clinical data becomes less so.
Caption: Will be displayed under media in	While non-clinical data is much more relevant to the medicines development process early on, over time

the article body. Must begin with title of media.	its relevance is eclipsed by that of clinical data.
Translation required: If media contains English language text, it **must** be translated	Yes

Relevance of non-clinical studies in medicines development



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

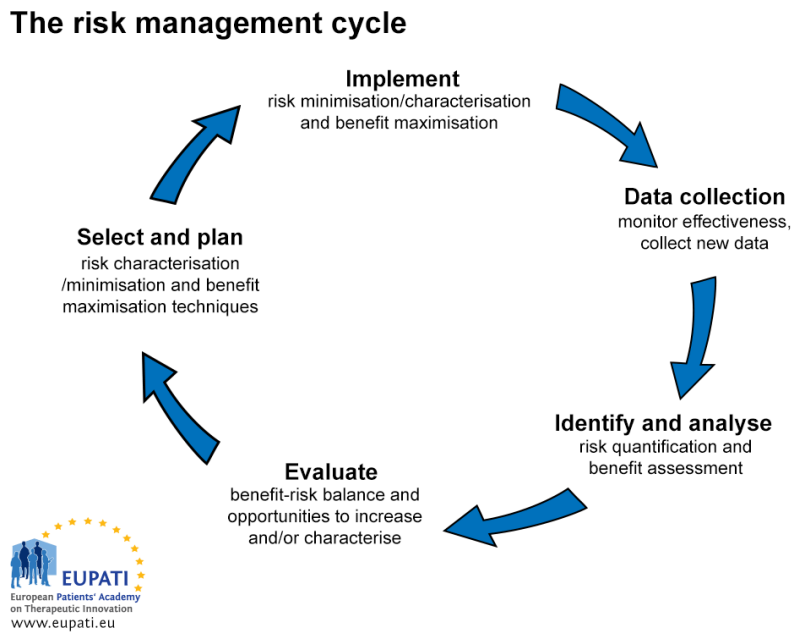
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	30.9.2015	PLATA Created	Final	1

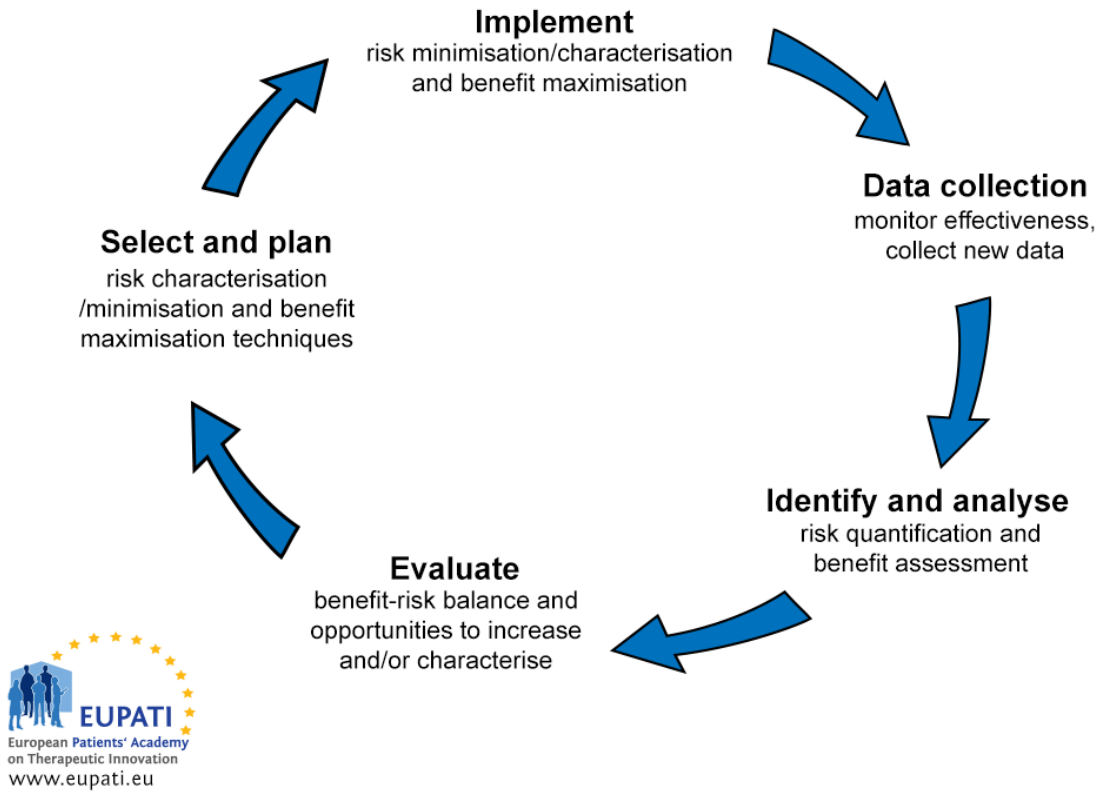
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The risk management cycle
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Risk-management-cycle-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/w4qvc081725nvn5siyv9583ts204wdil
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI; Heidi Scherz

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	An image showing the five steps of the risk management cycle in a continuous circuit. First, the identify and analyse step seeks to quantify risk and assess benefits of a medicinal product. In the evaluate step, the benefit-risk balance is evaluated, as are opportunities to increase benefits and/or characterise the risk. After evaluation, the select and plan step involves the selection and planning of risk characterisation and minimisation techniques as well as benefit maximisation techniques. Then, the implementation step implements the planned risk minimisation/characterisation and benefit maximisation techniques. Thereafter, the data collection step monitors the effectiveness of the implemented techniques and collects new data, after which the cycle begins again to identify and analyse risks and benefits.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	An image showing the five steps of the risk management cycle in a continuous circuit. First, the identify and analyse step seeks to quantify risk and assess benefits of a medicinal product. In the evaluate step, the benefit-risk balance is evaluated, as are opportunities to increase benefits and/or characterise the risk. After evaluation, the select and plan step involves the selection and planning of risk characterisation and minimisation techniques as well as benefit maximisation techniques. Then, the implementation step implements the planned risk minimisation/characterisation and benefit maximisation techniques. Thereafter, the data collection step monitors the effectiveness of the implemented techniques and collects new data, after which the cycle begins again to identify and analyse risks and benefits.
Caption: Will be displayed under media in the article body. Must begin with title of media.	There are five steps in the risk management cycle.
Translation required: If media contains English language text, it **must** be translated	Yes

The risk management cycle



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

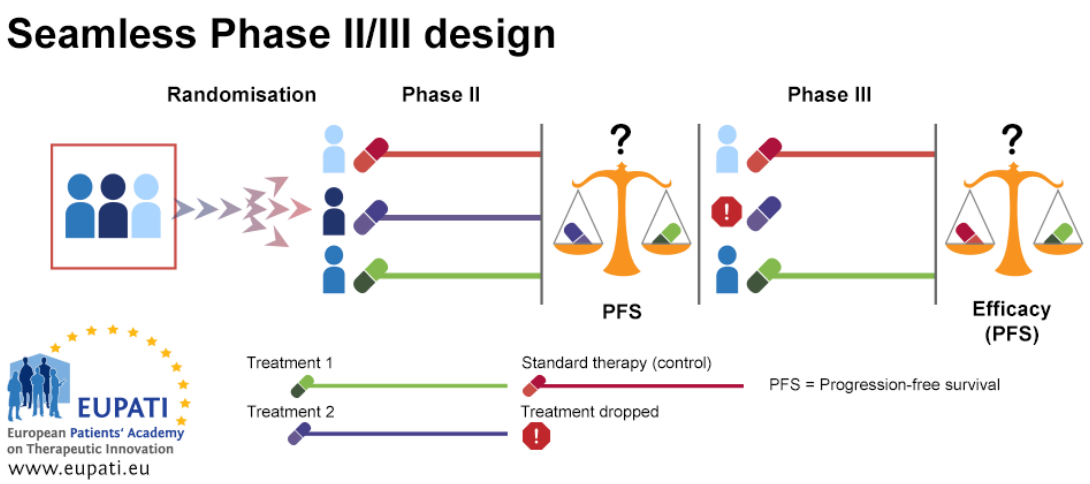
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	1.1

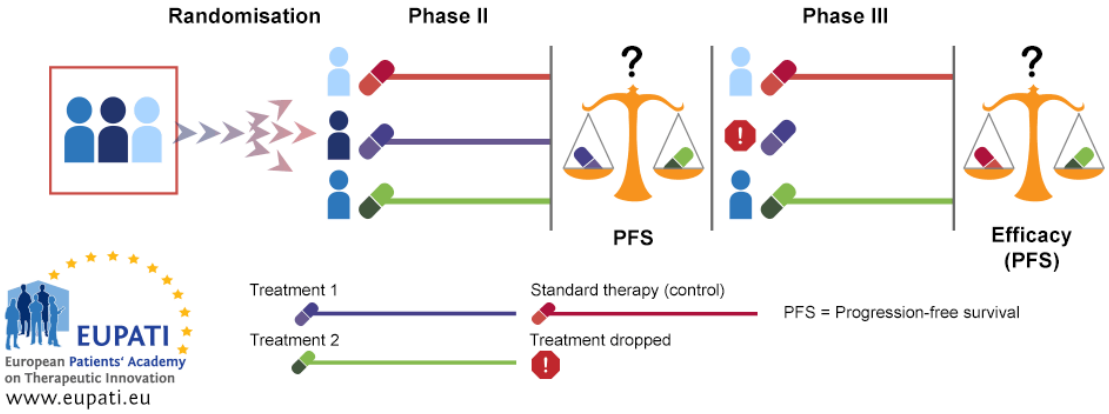
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Seamless Phase II/III design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	seamless-phase-II-phase-III-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/gmhxcqg6pqt0oirguls56sgalvawx0tx
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on	A diagram depicting a trial using seamless Phase II/Phase III design. During Phase II, participants are randomised onto one of three treatment arms. Participants on the first treatment arm receive the standard of care therapy (acting as the control). On

article context for meaning.	the second treatment arm, participants receive Treatment 1. On the third treatment arm, participants receive Treatment 2. At the end of phase II, Treatments 1 and 2 are assessed for progression-free survival. Phase III begins. Participants on the first treatment arm continue to receive the standard therapy. The second treatment arm (and Treatment 1) has been dropped after the progression-free survival assessment. Participants on the third treatment arm continue to receive Treatment 2. At the end of Phase III, the standard therapy and Treatment 2 are compared in an efficacy (progression-free survival) assessment.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram depicting a trial using seamless Phase II/Phase III design. During Phase II, participants are randomised onto one of three treatment arms. Participants on the first treatment arm receive the standard of care therapy (acting as the control). On the second treatment arm, participants receive Treatment 1. On the third treatment arm, participants receive Treatment 2. At the end of phase II, Treatments 1 and 2 are assessed for progression-free survival. Phase III begins. Participants on the first treatment arm continue to receive the standard therapy. The second treatment arm (and Treatment 1) has been dropped after the progression-free survival assessment. Participants on the third treatment arm continue to receive Treatment 2. At the end of Phase III, the standard therapy and Treatment 2 are compared in an efficacy (progression-free survival) assessment.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The seamless Phase II/III design allows Phase II and Phase III to be performed in the context of one trial.
Translation required: If media contains English language text, it **must** be translated	Yes

Seamless Phase II/III design



EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

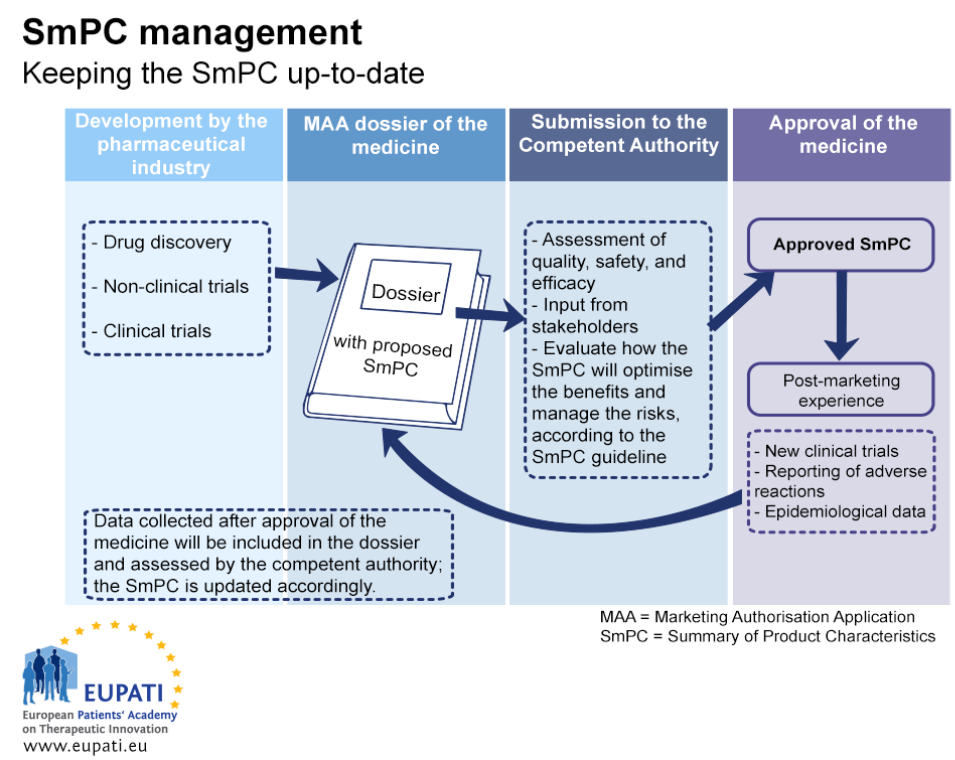
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	9.9.2015	PLATA Created	Final	1.1
Cecilia Carino	12.10.2016	Replaced figure	Final	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	SmPC management
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	SmPC-management-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/gmg3m58my87v1n9s03efgrvn74ta8s6g

Cut and paste image here:

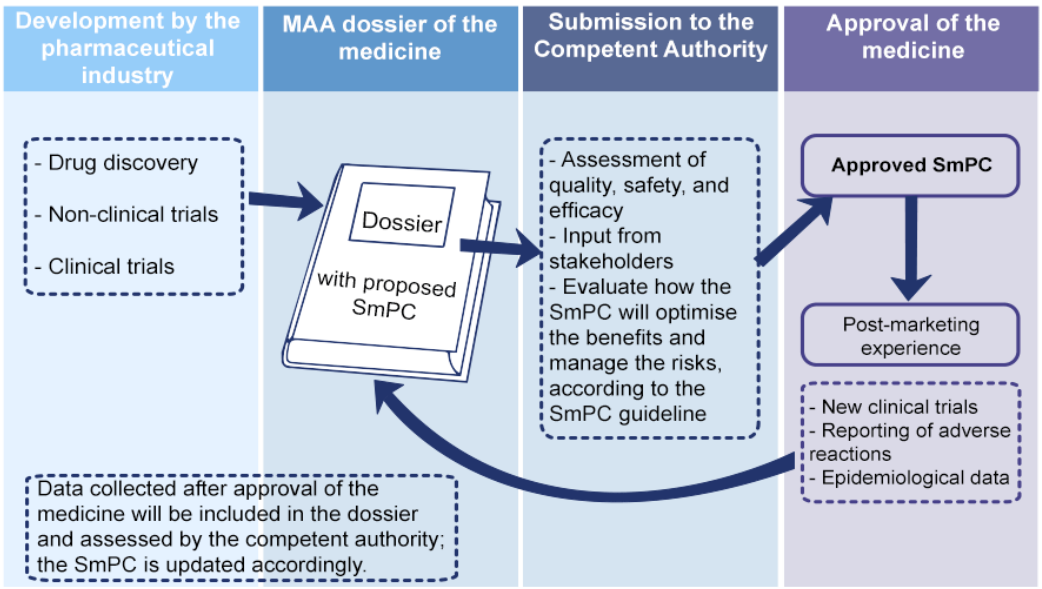


Media Source Note: Please indicate where the image was taken from.	EUPATI; Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram describing the activities required to keep the Summary of Product Characteristics (SmPC) up-to-date. The diagram describes four broad stages: Development by the pharmaceutical industry; Marketing Application Authorisation (MAA) Dossier of the medicine; Submission to the Medicine Competent Authority; and Approval of the medicine. During Development by the pharmaceutical industry, information is gathered through drug discovery, non-clinical and clinical trials. This information is compiled in the medicine's dossier which contains a proposed SmPC which is then submitted to the competent authority. The competent authority assess quality, safety, and efficacy; consider input from stakeholders, and evaluate how the SmPC will optimise the benefits and manage the risks, according to the SmPC guideline. When the medicine is approved, the SmPC is also approved. After this approval, post-marketing experience is gathered through new clinical trials, reports of adverse reactions, and epidemiological data. This information is collected and included in the dossier, which is later assessed again by the competent authority. The SmPC is updated accordingly. This process continues as needed throughout the medicine's lifecycle.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text	A diagram describing the activities required to keep the Summary of Product Characteristics (SmPC) up-to-date. The diagram describes four broad stages: Development by the pharmaceutical industry; Marketing Application Authorisation (MAA) Dossier of the medicine; Submission to the Medicine

should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Competent Authority; and Approval of the medicine. During Development by the pharmaceutical industry, information is gathered through drug discovery, non-clinical and clinical trials. This information is compiled in the medicine's dossier which contains a proposed SmPC which is then submitted to the competent authority. The competent authority assess quality, safety, and efficacy; consider input from stakeholders, and evaluate how the SmPC will optimise the benefits and manage the risks, according to the SmPC guideline. When the medicine is approved, the SmPC is also approved. After this approval, post-marketing experience is gathered through new clinical trials, reports of adverse reactions, and epidemiological data. This information is collected and included in the dossier, which is later assessed again by the competent authority. The SmPC is updated accordingly. This process continues as needed throughout the medicine's lifecycle.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The Summary of Product Characteristics (SmPC) must be kept up-to-date throughout the lifecycle of a medicine.
Translation required: If media contains English language text, it **must** be translated	Yes

SmPC management

Keeping the SmPC up-to-date



MAA = Marketing Authorisation Application
SmPC = Summary of Product Characteristics

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

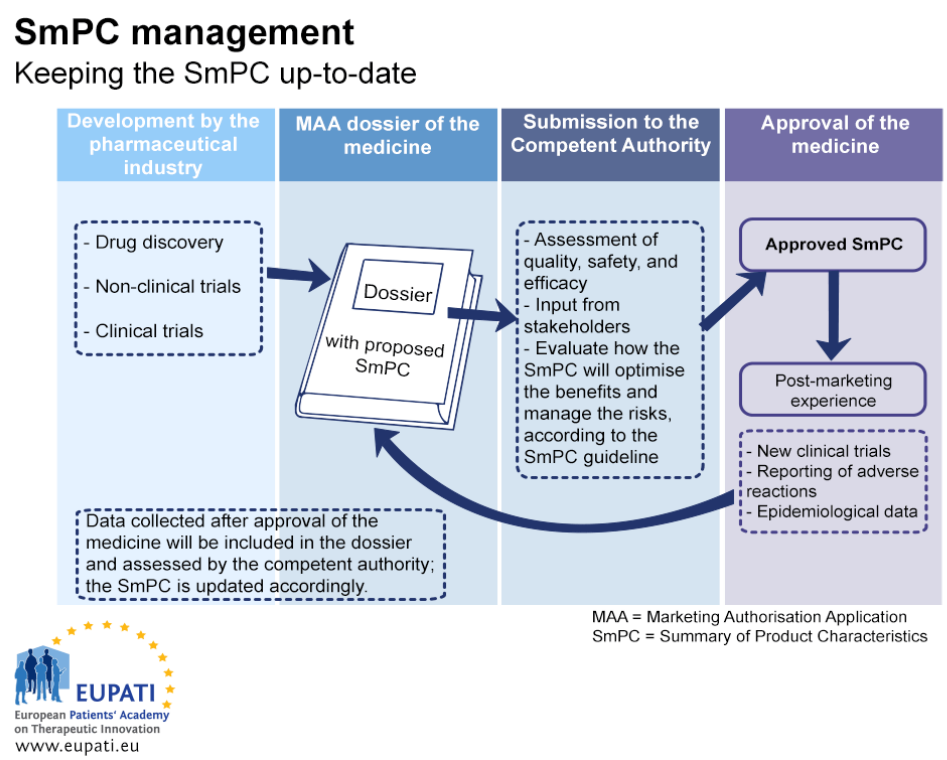
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	9.9.2015	PLATA Created	Final	1.1
Cecilia Carino	12.10.2016	Replaced figure	Final	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	SmPC management
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	SmPC-management-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/gmg3m58my87v1n9s03efgrvn74ta8s6g

Cut and paste image here:

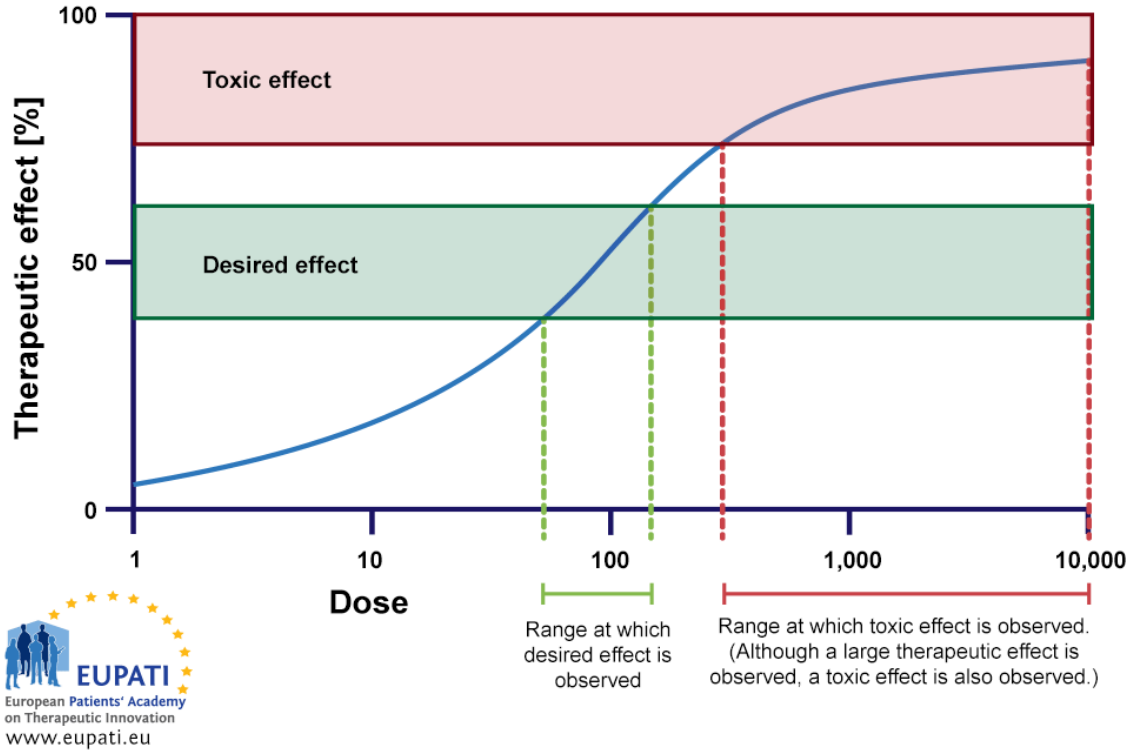


Media Source Note: Please indicate where the image was taken from.	EUPATI; Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram describing the activities required to keep the Summary of Product Characteristics (SmPC) up-to-date. The diagram describes four broad stages: Development by the pharmaceutical industry; Marketing Application Authorisation (MAA) Dossier of the medicine; Submission to the Medicine Competent Authority; and Approval of the medicine. During Development by the pharmaceutical industry, information is gathered through drug discovery, non-clinical and clinical trials. This information is compiled in the medicine's dossier which contains a proposed SmPC which is then submitted to the competent authority. The competent authority assess quality, safety, and efficacy; consider input from stakeholders, and evaluate how the SmPC will optimise the benefits and manage the risks, according to the SmPC guideline. When the medicine is approved, the SmPC is also approved. After this approval, post-marketing experience is gathered through new clinical trials, reports of adverse reactions, and epidemiological data. This information is collected and included in the dossier, which is later assessed again by the competent authority. The SmPC is updated accordingly. This process continues as needed throughout the medicine's lifecycle.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text	A diagram describing the activities required to keep the Summary of Product Characteristics (SmPC) up-to-date. The diagram describes four broad stages: Development by the pharmaceutical industry; Marketing Application Authorisation (MAA) Dossier of the medicine; Submission to the Medicine

should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Competent Authority; and Approval of the medicine. During Development by the pharmaceutical industry, information is gathered through drug discovery, non-clinical and clinical trials. This information is compiled in the medicine's dossier which contains a proposed SmPC which is then submitted to the competent authority. The competent authority assess quality, safety, and efficacy; consider input from stakeholders, and evaluate how the SmPC will optimise the benefits and manage the risks, according to the SmPC guideline. When the medicine is approved, the SmPC is also approved. After this approval, post-marketing experience is gathered through new clinical trials, reports of adverse reactions, and epidemiological data. This information is collected and included in the dossier, which is later assessed again by the competent authority. The SmPC is updated accordingly. This process continues as needed throughout the medicine's lifecycle.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The Summary of Product Characteristics (SmPC) must be kept up-to-date throughout the lifecycle of a medicine.
Translation required: If media contains English language text, it **must** be translated	Yes

Finding the optimum dose

An example of observed therapeutic effect changing with dose



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	19.09.2016	PLATA Created	DRAFT	1.1
Cecilia Carino	17.10.2016	Minor corrections in title	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☒ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

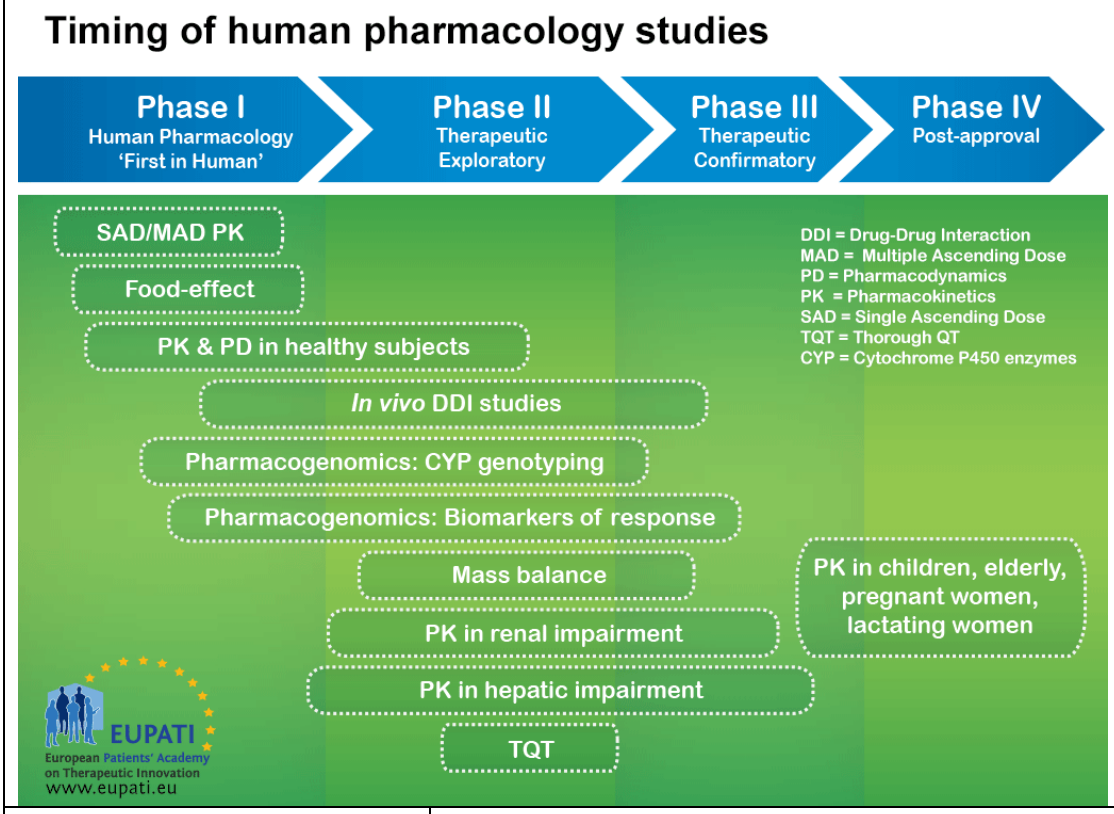
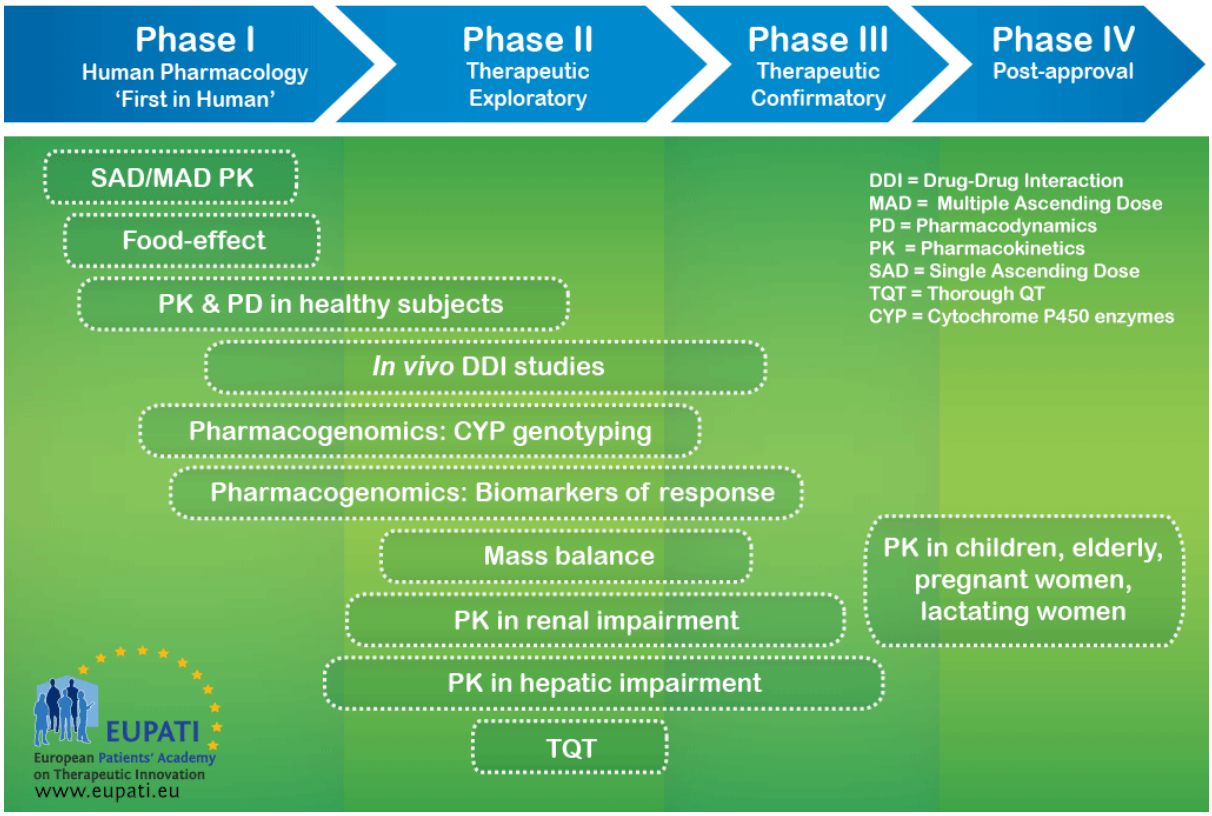
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Timing of human pharmacology studies
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	https://eupati.app.box.com/files/0/f/6785755046/timing-human-pharmacology-studies
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/6785755046/timing-human-pharmacology-studies
Cut and paste image here: 	
Media Source Note: Please indicate where the	EUPATI

image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A diagram showing the different types of clinical studies that take place during the clinical development of a medicine. The logic behind representing medicines development in a series of consecutive phases comes from the idea that the results of prior studies should influence the plans for later studies: emerging data will frequently initiate modifications of the development strategies.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A diagram showing the different types of clinical studies that take place during the clinical development of a medicine. The logic behind representing medicines development in a series of consecutive phases comes from the idea that the results of prior studies should influence the plans for later studies: emerging data will frequently initiate modifications of the development strategies.
Caption: Will be displayed under media in the article body. Must begin with title of media.	The logic behind representing medicines development in a series of consecutive phases comes from the idea that the results of prior studies should influence the plans for later studies: emerging data will frequently initiate modifications of the development strategies.
Translation required: If media contains English language text, it **must** be translated	Yes

Timing of human pharmacology studies



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

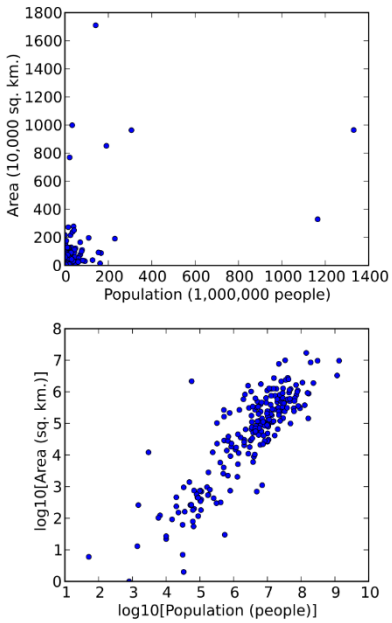
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	11.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	11.25.2015	Updated ALT text	FINAL	1.2

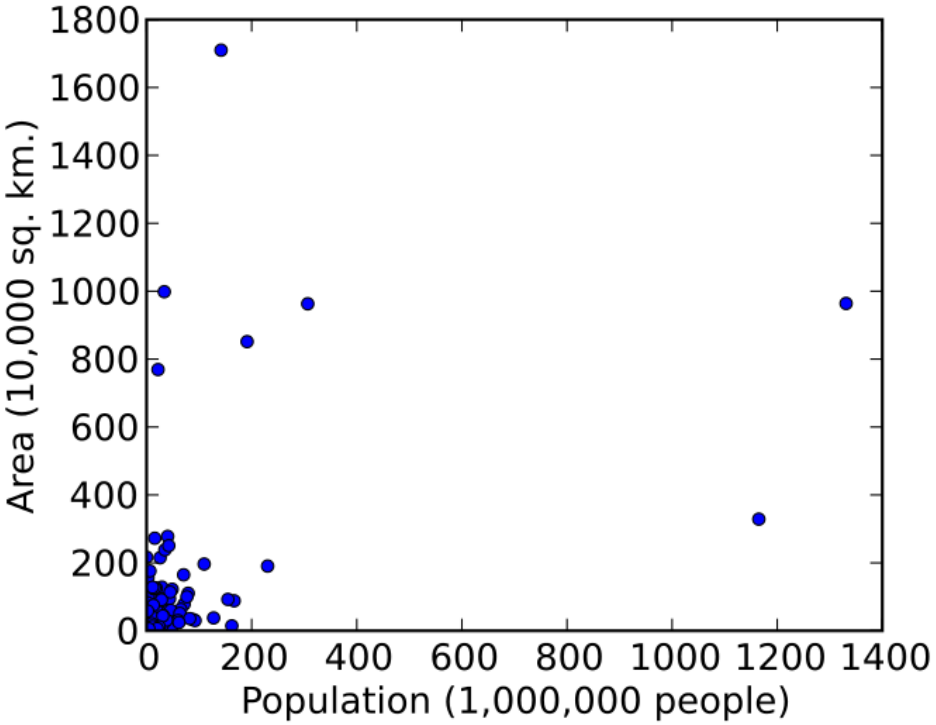
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

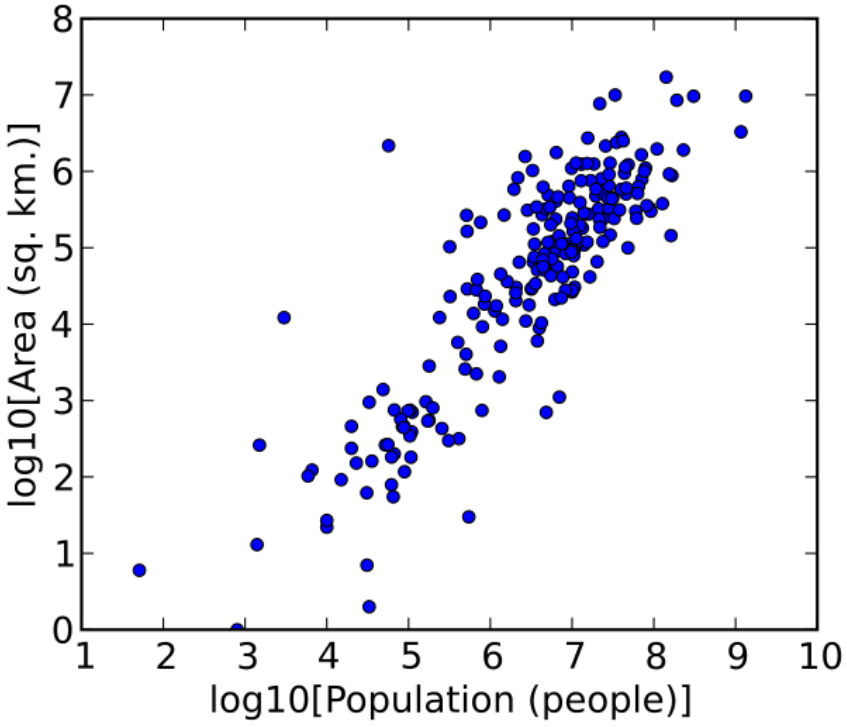
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Example of data transformation
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	transformation-pop-v-area-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4198709241/transformation-pop-v-area
Cut and paste image here:  	

Media Source Note: Please indicate where the image was taken from.	https://upload.wikimedia.org/wikipedia/commons/0/00/Population_vs_area.svg
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	This image shows two graphs. In the first graph, Area (in units of 10,000 square kilometres, with a range from 0 to 1800) is on the Y axis, plotted against Population on the X axis (in units of 1,000,000 people, with a range from 0 to 1400). The data points in this graph are largely clustered in the bottom left-hand corner of the graph, between 400 on the Y axis and 200 on the X axis. There are a few stray data points across the graph. The second graph uses a logarithmic scale on both axes. That is, the units on the Y axis are given as log10[Area (square kilometres)], ranging from 0 to 8; on the X axis, the units are given as log10[Population(People)], ranging from 1 to 10. In this graph, the data points are much more evenly spread, on a diagonal that runs from the bottom left-hand corner to the top right-hand corner of the graph. There are a few outlying data points, but most of the data is incorporated in the general trend. The data spread is much more obvious in the second graph with a logged scale than it is in the first.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	This image shows two graphs in order to demonstrate data transformation.
Caption: Will be displayed under media in the article body. Must begin with	An example of data transformation: Using a logged scale to better observe trends in data.

title of media.	
Translation required: If media contains English language text, it **must** be translated	Yes


Area (10,000 sq. km.)
Population (1,000,000 people)
0
200
400
600
800
1000
1200
1400
1600
1800


log10[Area (sq. km.)]
log10[Population (people)]
0
1
2
3
4
5
6
7
8
9
10

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.11.2015	PLATA Created from original (1.15)	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Translational medicine
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Translational-medicine.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/qngo9tlaud482ng13qgdo35rkxzqcczd
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	Adapted from http://oacu.od.nih.gov/posters/21.html
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely	Diagrammatical representation of the translational medicine feedback loop, where discoveries at the laboratory bench feed in to discoveries at the bedside, which in turn feed back into further discoveries at the laboratory bench.

on article context for meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrammatical representation of the translational medicine feedback loop.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Translational medicine forms a feedback loop from bench-to-bedside-to-bench.
Translation required: If media contains English language text, it **must** be translated	Not of image

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

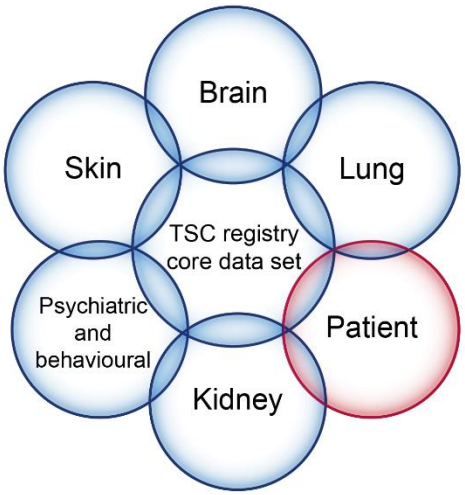
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

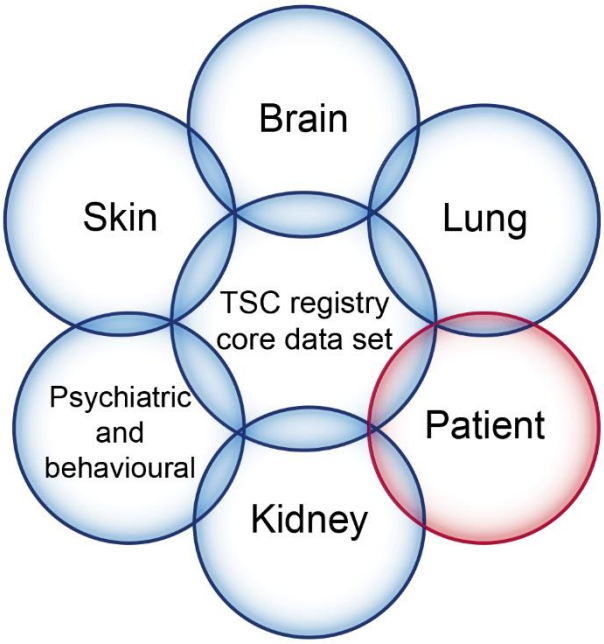
Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	25.01.2017	PLATA Created	DRAFT	1.0

***State #:** This can either be ‘Draft’ or ‘Final’.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	TSC Registry core data set
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	tsc-bubbles_EN-v1.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/an9coljqgybms31q25qiihk3583acslz
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	A graphical illustration of the registry core data set to address knowledge gaps in the history and management of tuberous sclerosis complex (TSC).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	A graphical illustration of the registry core data set to address knowledge gaps in the history and management of tuberous sclerosis complex (TSC).
Caption: Will be displayed under media in the article body. Must begin with title of media.	An illustration of the registry core data set to address knowledge gaps in the management of tuberous sclerosis complex (TSC).
Translation required: If media contains English language text, it **must** be translated	Yes


Brain
Skin
Lung
TSC registry
core data set
Psychiatric
and
behavioural
Patient
Kidney

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

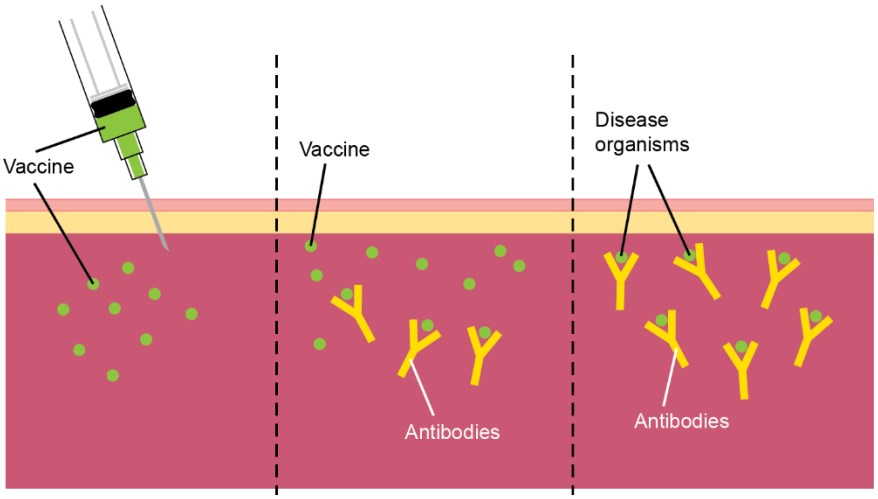
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

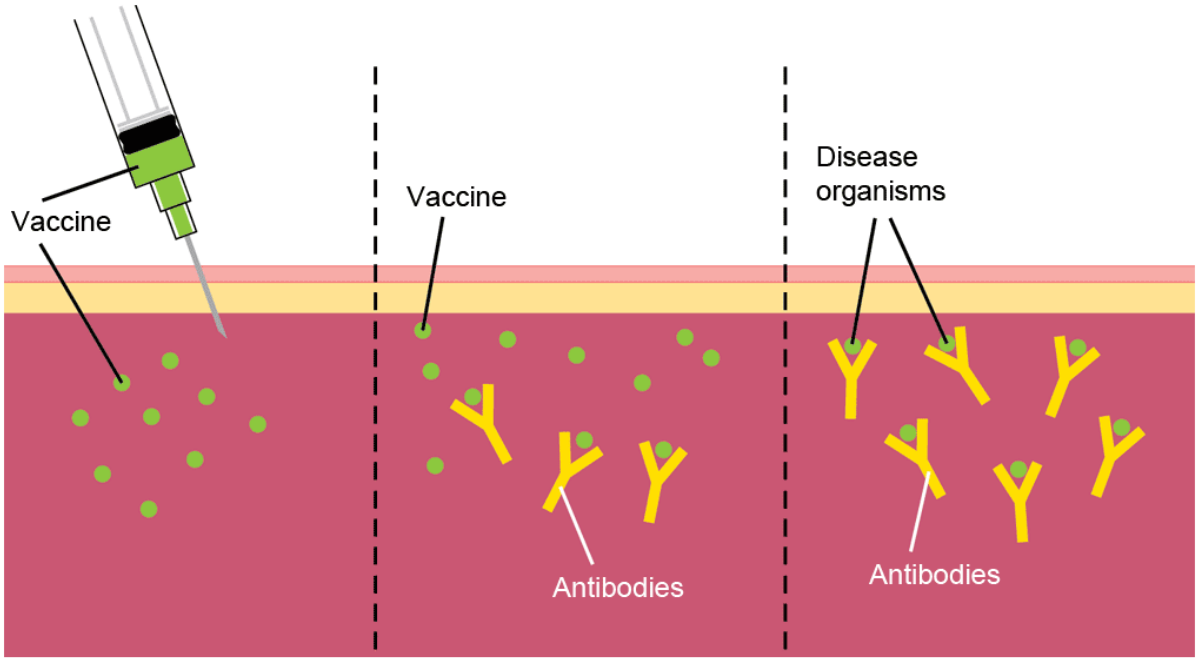
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Vaccine immunity
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	vaccine-immunity-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/c3lq9navd158p4stdba6rp79l0l3p3ac
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diagrammatic representation of the process of vaccination. During vaccination, a vaccine with modified forms of viruses or bacteria is injected into the body. The vaccine stimulates the immune system to produce antibodies against the microorganism. The immune system learns to recognise the microorganism, so that if the body is later infected with the live disease it will produce antibodies to attach to the microorganisms and stop the infection.

Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrammatic representation of the process of vaccination. During vaccination, a vaccine with modified forms of viruses or bacteria is injected into the body. The vaccine stimulates the immune system to produce antibodies against the microorganism. The immune system learns to recognise the microorganism, so that if the body is later infected with the live disease it will produce antibodies to attach to the microorganisms and stop the infection.
Caption: Will be displayed under media in the article body. Must begin with title of media.	During vaccination, a vaccine with modified forms of viruses or bacteria is injected into the body (left). The vaccine stimulates the immune system to produce antibodies against the microorganism (centre). The immune system learns to recognise the microorganism, so that if the body is later infected with the live disease it will produce antibodies to attach to the microorganisms and stop the infection (right).
Translation required: If media contains English language text, it **must** be translated	Yes


Vaccine
Vaccine
Disease
organisms
Antibodies
Antibodies

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

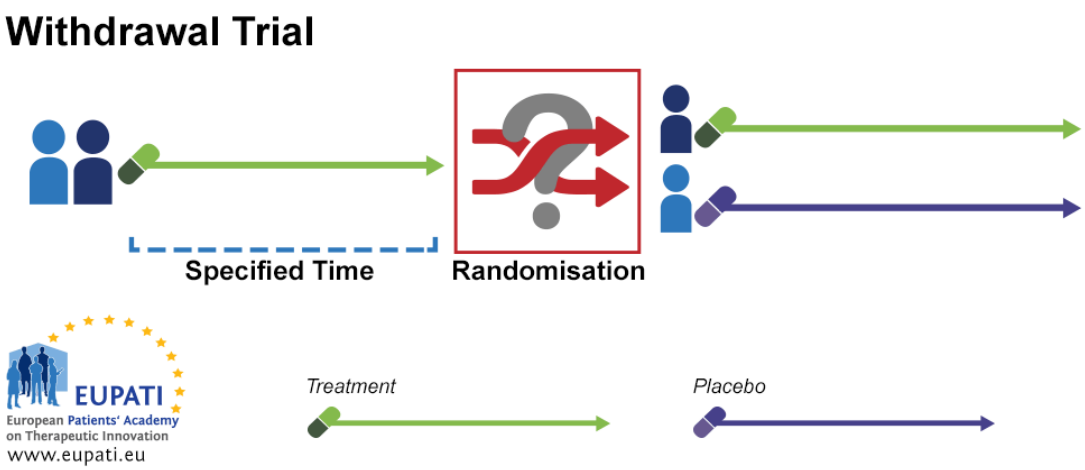
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA Created	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Withdrawal Trial
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Withdrawal-trial-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/kcgun493i8w6coj06aqw6rqu495bpo9r
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It	A diagram showing an example of a withdrawal trial.

should **not** rely on article context for meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	This diagram shows an example of a withdrawal trial. In this example, during the first period of the trial, all participants receive the active treatment for a specified amount of time. After this time elapses, the participants are randomised into two groups. Group 1 continues to receive the active treatment, while Group 2 is given a placebo treatment.
Caption: Will be displayed under media in the article body. Must begin with title of media.	During a withdrawal trial, after the first specified period of time has elapsed, participants are randomised into two groups, one of which receives a placebo instead of continuing to receive the active treatment.
Translation required: If media contains English language text, it **must** be translated	YES

Withdrawal Trial

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

12. Anexos – Textos na Língua de Chegada

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	6.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	21.9.2015	New version updated w/ Logo, Spelling, etc. Metadata updated.	FINAL	4

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

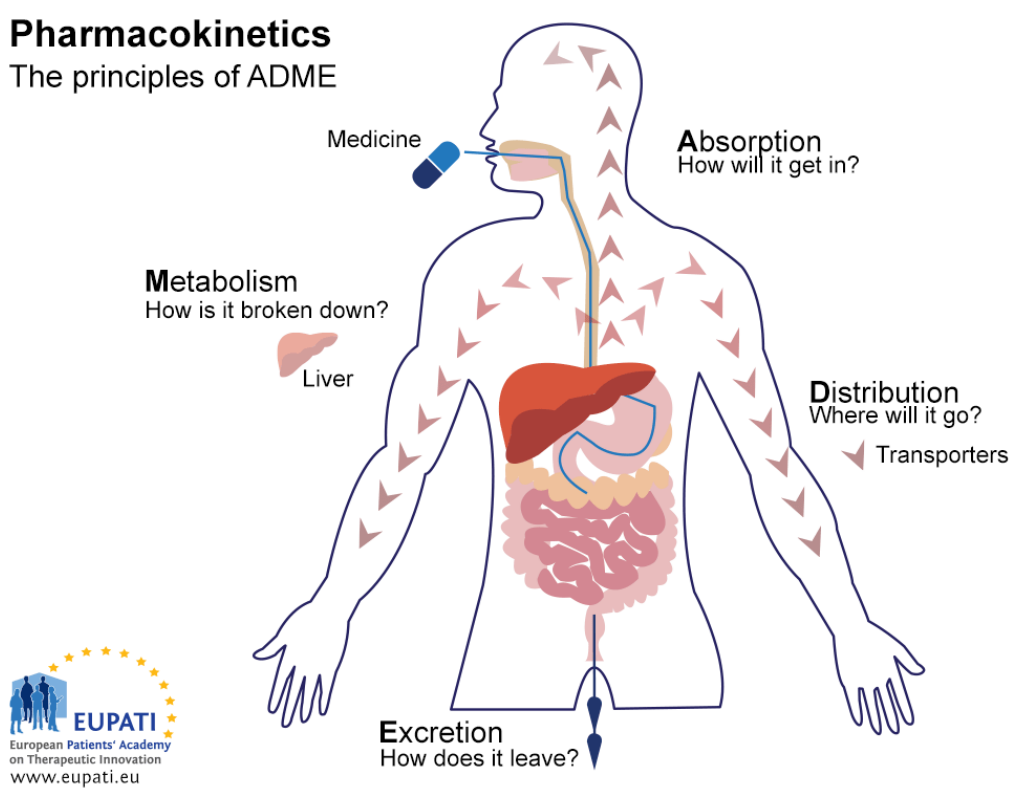
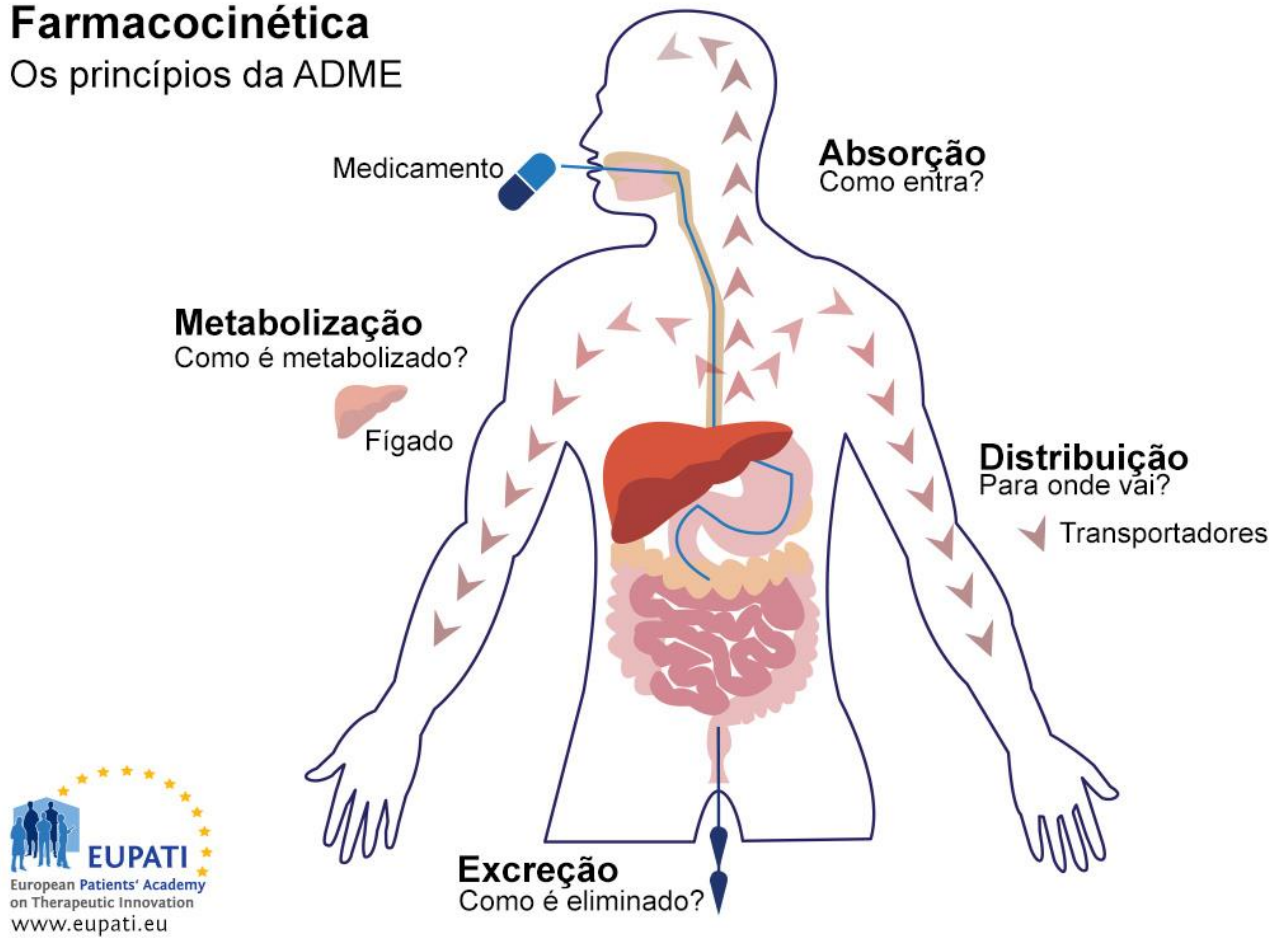
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	ADME
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	ADME-v4_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4164449665/ADME
Cut and paste image here:  	
Media Source Note: Please indicate where the	EUPATI

image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Um diagrama que explica os princípios da Farmacocinética: ADME. O diagrama apresenta um esquema do corpo humano, incluindo o sistema digestivo (boca, esófago, estômago, intestino delgado e grosso) e fígado. Os princípios da ADME dizem respeito à interação do medicamento com o corpo e vice-versa. Absorção (representada pela administração de um comprimido) coloca a questão "Como entra?" A Distribuição faz a pergunta "Para onde vai?" A distribuição de um medicamento do estômago através da corrente sanguínea para o corpo é representada aqui por um conjunto de setas. O Metabolismo faz a pergunta "Como é metabolizado?" Isto é representado pela presença do fígado no diagrama. A Excreção faz a pergunta "Como é eliminado?" e é representada através de setas que saem do cólon.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Um diagrama que explica os princípios da Farmacocinética: ADME. O diagrama apresenta um esquema do corpo humano, incluindo o sistema digestivo (boca, esófago, estômago, intestino delgado e grosso) e fígado. Os princípios da ADME dizem respeito à interação entre o medicamento com o corpo e vice-versa. Absorção (representada pela administração de um comprimido) coloca a questão "Como ?" A Distribuição faz a pergunta "Para onde vai?" A distribuição de um medicamento do estômago através da corrente sanguínea para o corpo é representada aqui por um conjunto de setas. O Metabolismo faz a pergunta "Como é metabolizado?" Isto é representado pela presença do fígado no diagrama. A Excreção faz a pergunta "Como é eliminado?" e é representada através de setas que saem do cólon.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Os princípios chave da Farmacocinética – o estudo do efeito do corpo sobre um medicamento – são representados pelo acrónimo ADME.
Translation required: If media contains English	Yes

language text, it **must** be translated	


Farmacocinética
Os princípios da ADME
Medicamento
Absorção
Como entra?
Metabolização
Como é metabolizado?
Fígado
Distribuição
Para onde vai?
Transportadores
Excreção
Como é eliminado?
EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

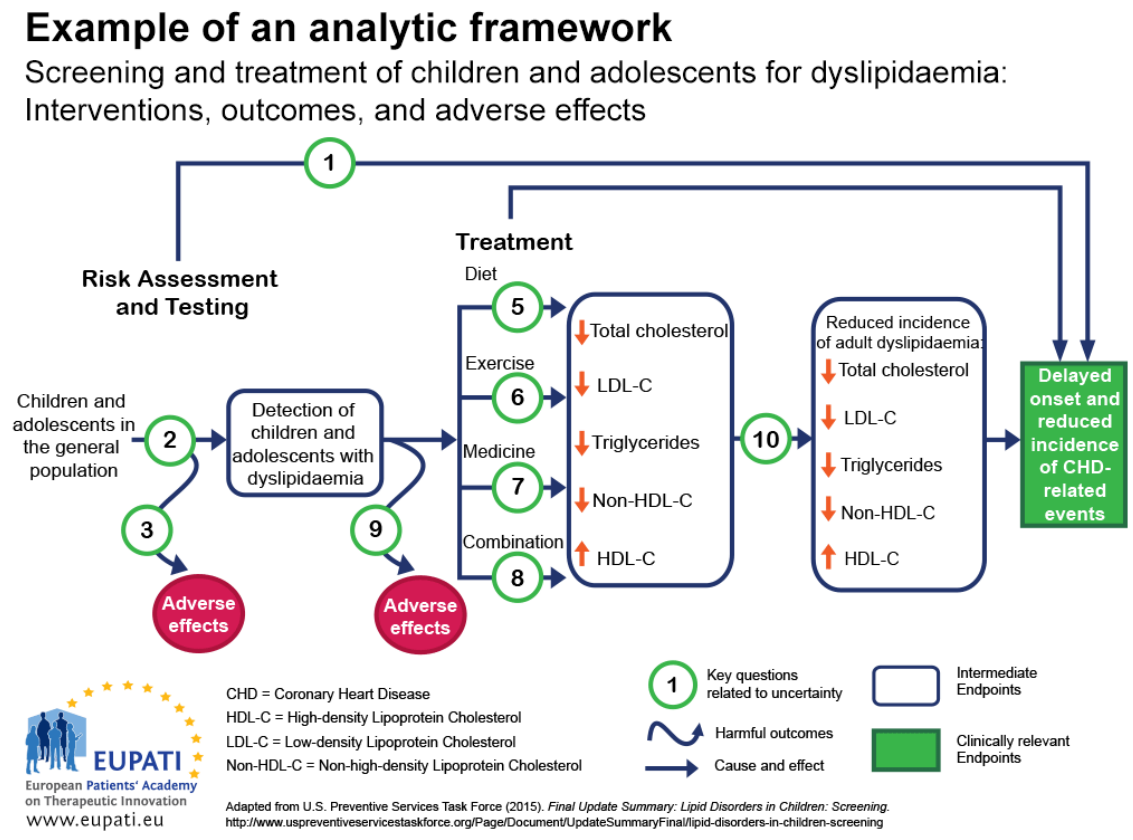
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	7.12.2015	PLATA Created	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Example of an analytic framework
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Analytic-framework-example-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/bts69of03zixgvauaidw5uc13eo7vuv2

Cut and paste image here:

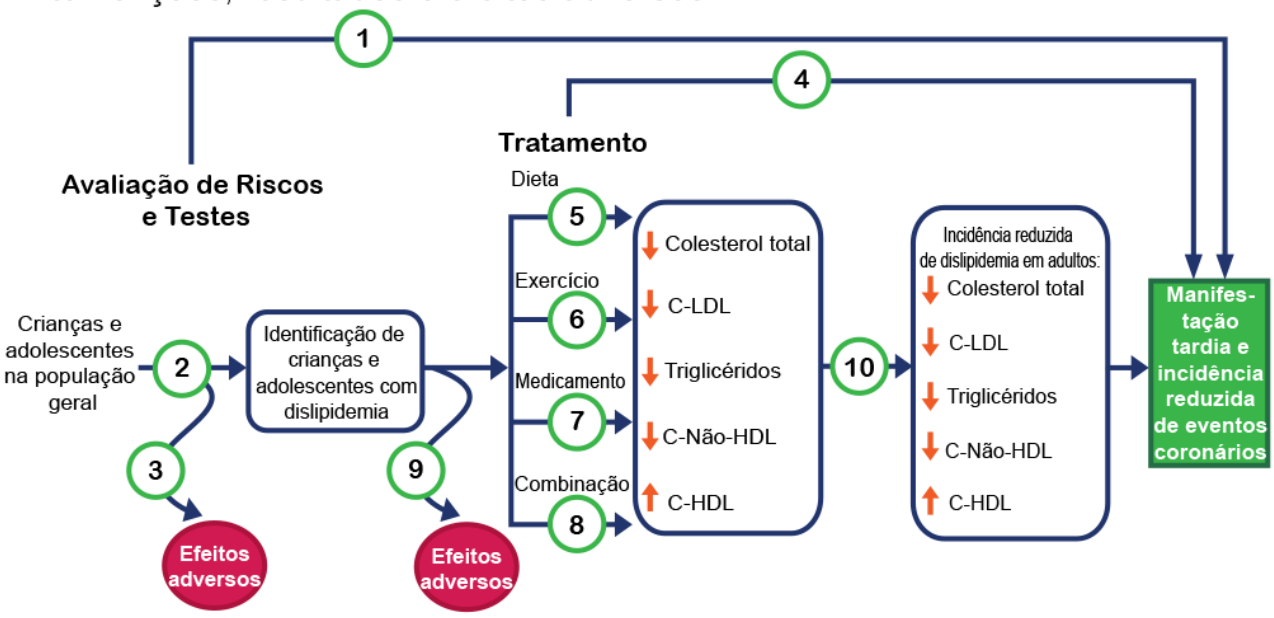


Media Source Note: Please indicate where the image was taken from.	EUPATI (Heidi Scherz); Adapted from U.S. Preventive Services Task Force (2015) *Final Update Summary: Lipid Disorders in Children: Screening*. Retrieved 7 December, 2015, from http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-children-screening
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Este exemplo de uma estrutura analítica representa, através de um fluxograma, as intervenções, resultados e efeitos adversos da triagem e tratamento de crianças e adolescentes com dislipidemia. São assinaladas em pontos relevantes do diagrama, dez questões-chave, (QC) relativas à incerteza. A primeira etapa do fluxograma é referente à Avaliação dos Riscos e Teste (QC 1). Crianças e adolescentes na população geral são triados (QC 2). Isto pode levar a efeitos adversos (QC 3) ou à deteção de dislipidemia em crianças e adolescentes. A deteção de crianças e adolescentes com dislipidemia pode levar a efeitos adversos (QC 9) ou a tratamento. O tratamento poderá ser qualquer um dos seguintes: Dieta (QC 5), Exercício (QC 6), Medicamentos (QC 7), e Combinação (QC 8). Os tratamentos levam a resultados intermediários: colesterol total mais baixo, menos Colesterol com Lipoproteínas de Baixa Densidade (C-LDL), menos triglicéridos, menos Colesterol não HDL (C-não-HDL) e mais Colesterol com Lipoproteínas de Alta densidade (C-HDL). Estes resultados intermediários levam (QC 10) a um resultado intermediário de incidência reduzida

	de dislipidemia em adultos (colesterol total mais baixo, menos C-LDL, menos triglicéridos, menos C-não-HDL, e mais C-HDL). Este resultado intermediário leva a um resultado clinicamente relevante: Manifestação tardia e incidência reduzida de eventos coronários.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Este exemplo de uma estrutura analítica representa, através de um fluxograma, as intervenções, resultados e efeitos adversos da triagem e tratamento de crianças e adolescentes com dislipidemia. São assinaladas em pontos relevantes do diagrama, dez questões-chave, (QC) relativas à incerteza.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Esta estrutura analítica foi usada para determinar os pontos fortes e as limitações da efetividade da triagem de crianças e adolescentes relativamente a dislipidemia (distúrbios do metabolismo lipídico) como parte de cuidados primários de rotina. As dislipidemias são fatores de risco importantes para a doença coronária (DC).
Translation required: If media contains English language text, it **must** be translated	Yes

Exemplo de um quadro analítico

Rastreio e tratamento de dislipidemia em crianças e adolescentes: Intervenções, resultados e efeitos adversos.



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adaptado de U.S. Preventive Services Task Force (2015). *Final Update Summary: Lipid Disorders in Children: Screening.* http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lipid-disorders-in-children-screening

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

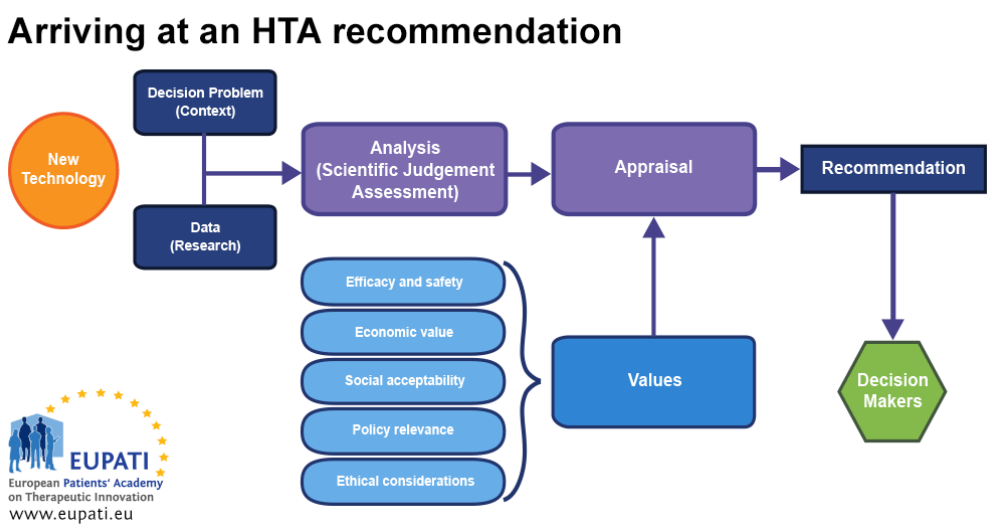
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	1.3.2016	PLATA Created	Draft	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Arriving at an HTA recommendation
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	HTA-decision-detail-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/yxcvwaayzh8ewls1h4nzzw296jdoqnor
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Fluxograma que projeta o processo de criação de uma recomendação ATS.O processo inicia com uma nova tecnologia. Há assim dois processos principais, cada um com os seus próprios dados: Análise (Avaliação de julgamento científico) e Avaliação. O problema de decisão (contexto) e os dados (pesquisa) são os dados principais para o processo de Análise. Os resultados do processo de Análise integram o processo de Avaliação, que também deve ter em consideração o tópico Valores. O tópico Valores inclui: Eficácia e segurança, valor económico, aceitação social, relevância política e considerações éticas. O final do processo de avaliação resulta numa recomendação, que é depois entregue aos órgãos de decisão.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Fluxograma que projeta o processo de criação de uma recomendação ATS.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Processo e questões relativos à criação de uma recomendação da ATS pelos órgãos de decisão.
Translation required: If media contains English language text, it **must** be translated	Yes

O processo de uma recomendação ATS

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

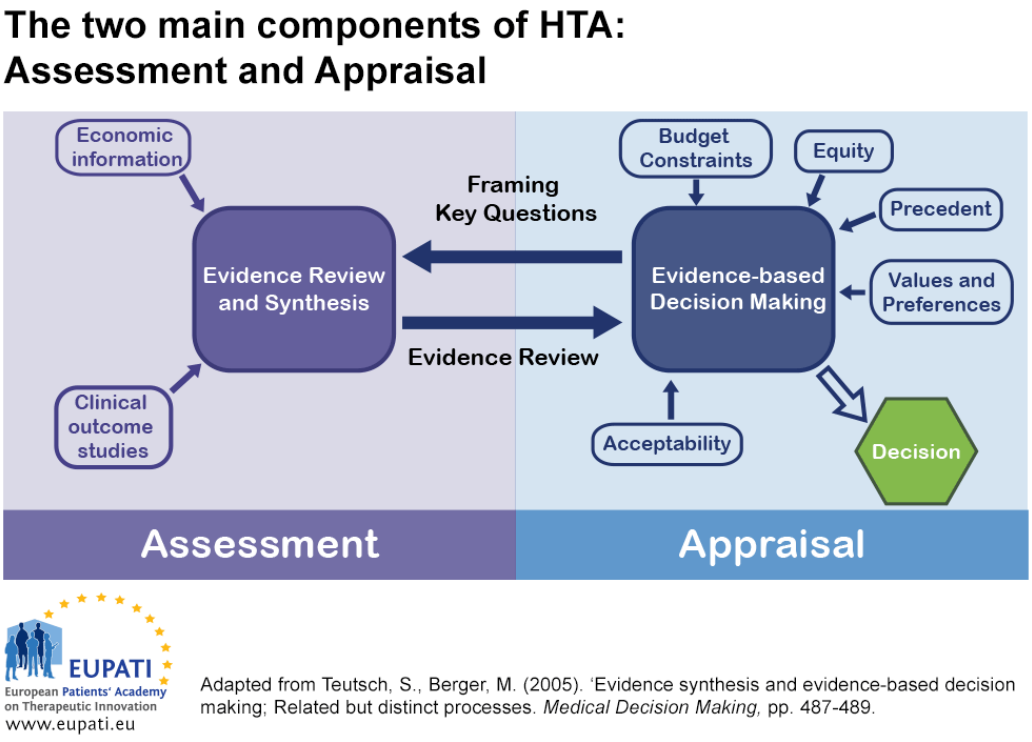
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	11.1.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The two main components of HTA: Assessment and Appraisal
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Assessment-appraisal-HTA-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/5438329297

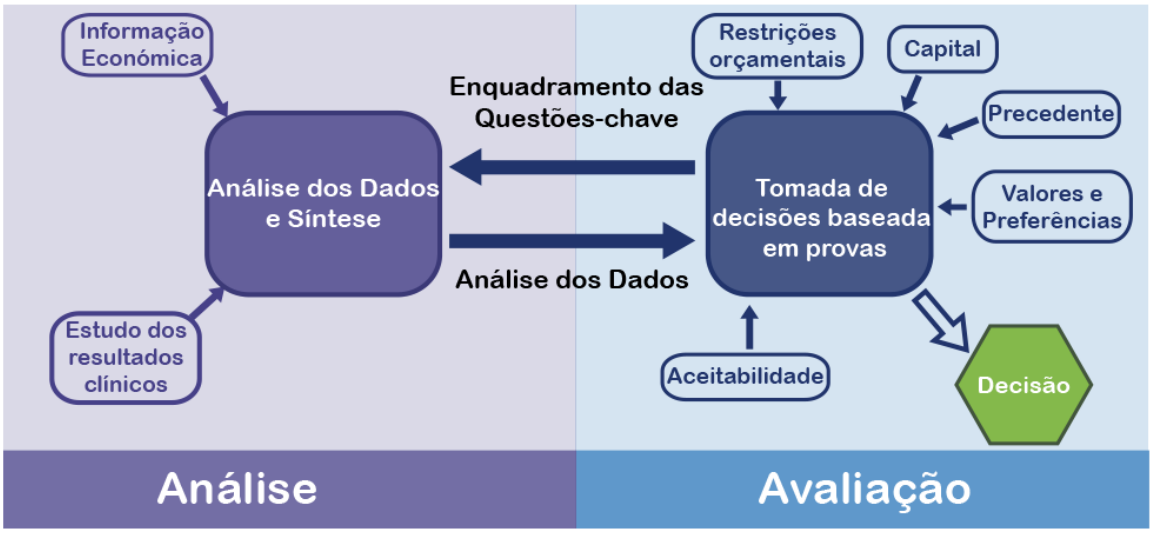
Cut and paste image here:



Media Source Note: Please indicate where the	EUPATI, adaptado de Teutsch, S., Berger, M. (2005). 'Evidence synthesis and evidence-based decision

image was taken from.	making: Related but distinct processes'. *Medical Decision Making*, pp. 487-489.
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Este diagrama representa a relação recíproca entre a análise e a avaliação na Avaliação de Tecnologias da Saúde (ATS). Na fase de análise, dados como informação económica ou resultados clínicos são analisados e sumariados. Esta análise de dados informa a avaliação, ou a tomada de decisões baseada na evidência, que também tem em consideração outros aspetos tais como restrições orçamentais, equidade, precedentes, valores e preferências e aceitabilidade. Estas considerações, por sua vez, dão a conhecer a forma como as questões-chave são enquadradas durante a análise. Em última análise, uma decisão é tomada baseada na evidência que foi analisada e avaliada, considerando outros parâmetros.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrama que representa a relação recíproca entre análise e avaliação na Avaliação de Tecnologias da Saúde (ATS).
Caption: Will be displayed under media in the article body. Must begin with title of media.	A relação recíproca entre análise e avaliação informa a tomada de decisão na Avaliação de Tecnologias da Saúde (ATS).
Translation required: If media contains English language text, it **must** be translated	Yes

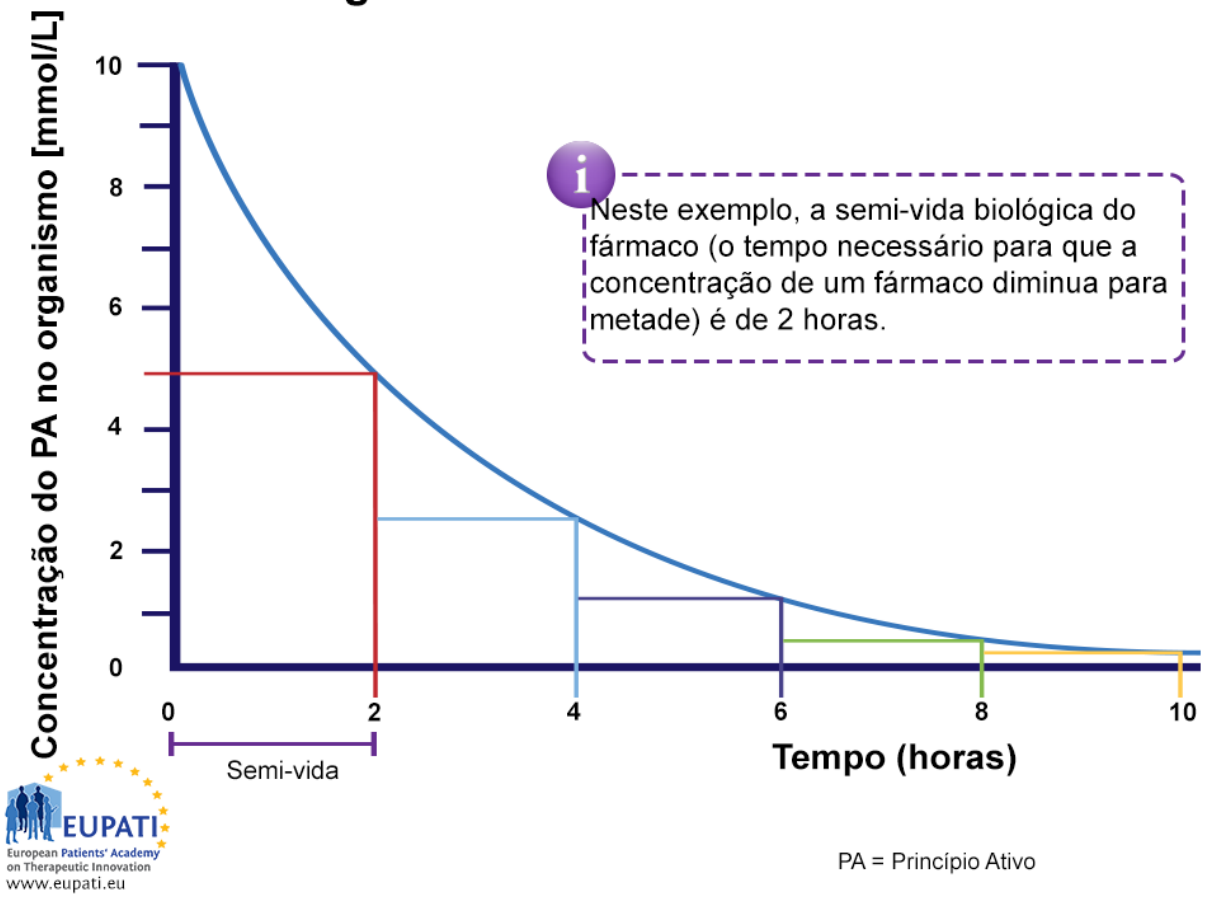
Os dois componentes principais da ATS: Análise e Avaliação



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

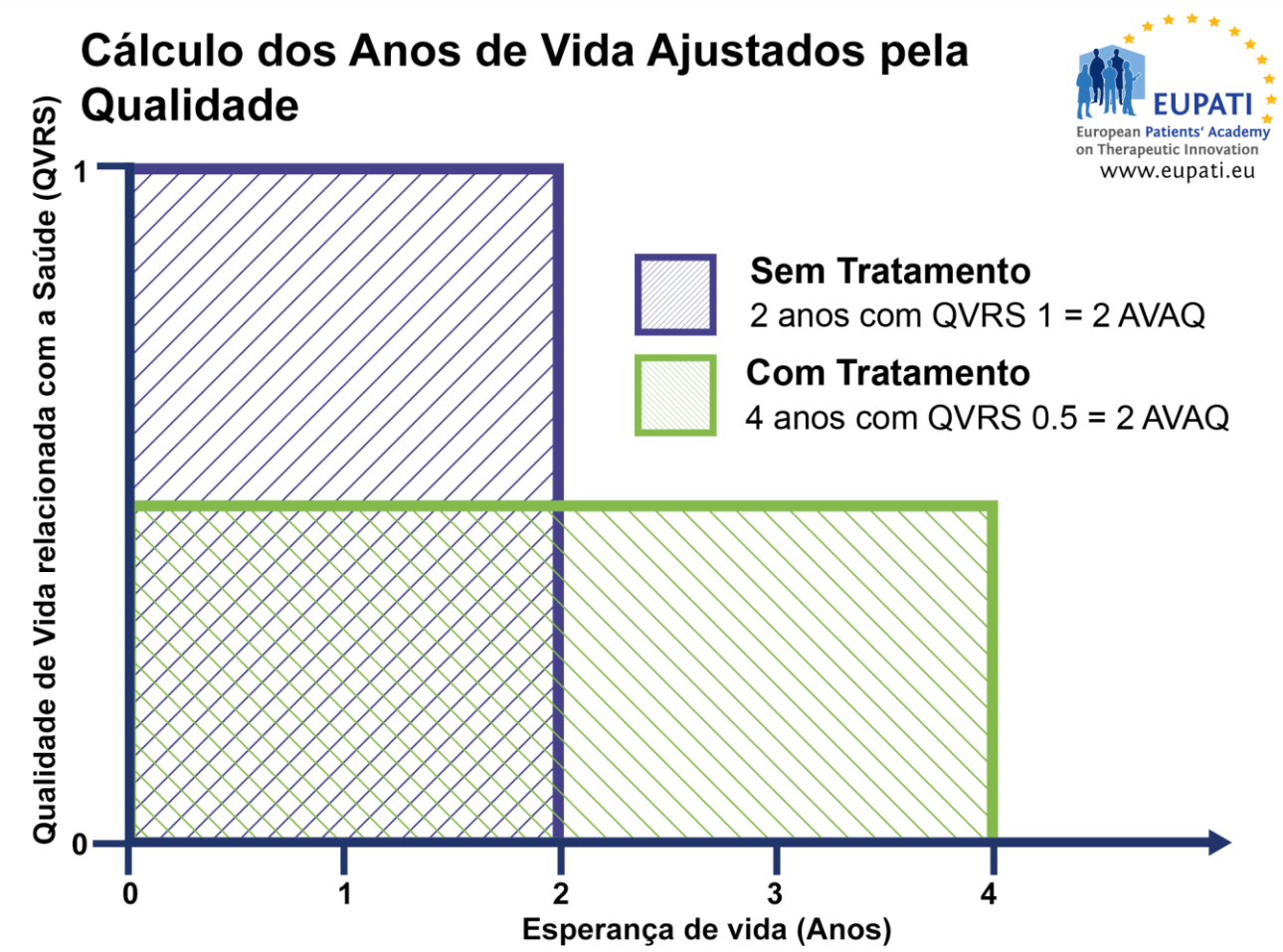
Adaptado de Teutsch, S., Berger, M. (2005). 'Evidence synthesis and evidence-based decision making; Related but distinct processes. *Medical Decision Making,* pp. 487-489.

Semi-vida biológica de um fármaco



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

PA = Princípio Ativo


Cálculo dos Anos de Vida Ajustados pela Qualidade
EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu
Qualidade de Vida relacionada com a Saúde (QVRS)
1
0
Sem Tratamento
2 anos com QVRS 1 = 2 AVAQ
Com Tratamento
4 anos com QVRS 0.5 = 2 AVAQ
0
1
2
3
4
Esperança de vida (Anos)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

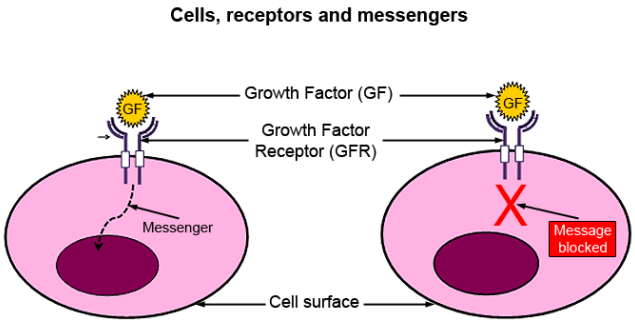
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

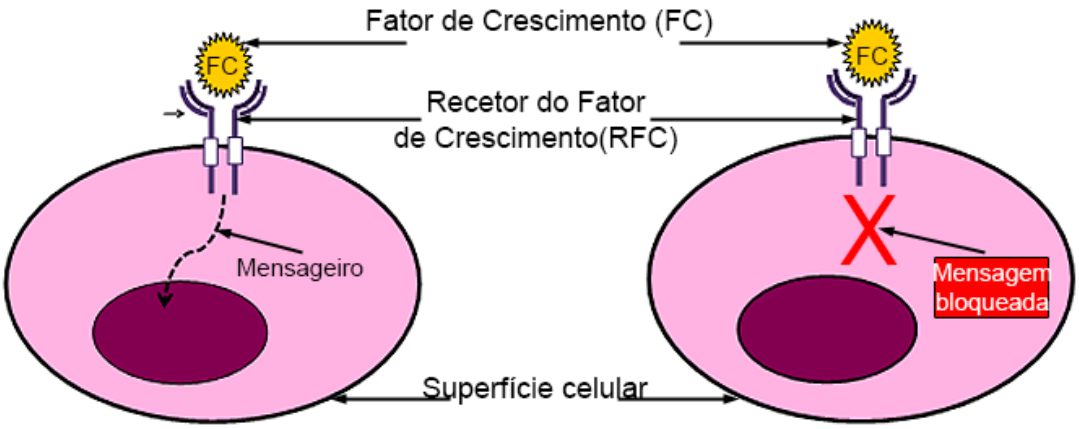
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Cells, receptors, and messengers
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	cells-receptors-messengers-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/oej4i6h4vtq1hy01slj53lrddn1ss7ee
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Células, recetores e mensageiros. Diagrama simples de uma célula, que representa o núcleo celular no centro e um recetor na superfície celular. O recetor – neste caso identificado como um 'Recetor do Fator de Crescimento' – tem a forma de um copo. Um mensageiro químico redondo – o fator de crescimento – cabe no espaço do recetor. É depois enviada uma mensagem ao núcleo do recetor na superfície da célula. À direita, uma representação da mesma célula, mas em que a mensagem desencadeada pelo fator de crescimento e enviada ao núcleo do recetor foi bloqueada.

Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Células, recetores e mensageiros. Diagrama simples de uma célula, que representa o núcleo celular no centro e um recetor na superfície celular. O recetor – neste caso identificado como um 'Recetor do Fator de Crescimento' – tem a forma de um copo. Um mensageiro químico redondo – o fator de crescimento – cabe no espaço do recetor. É depois enviada uma mensagem ao núcleo do recetor na superfície da célula. À direita, uma representação da mesma célula, mas em que a mensagem acionada pelo fator de crescimento e enviada ao núcleo do recetor foi bloqueada.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Células, recetores e mensageiros. O fator de crescimento, um mensageiro químico, liga-se ao recetor do fator de crescimento na superfície da célula, desencadeando uma mensagem para o núcleo. O bloqueio do recetor irá impedir a transmissão da mensagem e, por conseguinte crescimento celular não controlado. Neste diagrama, o "alvo" é o recetor do fator de crescimento.
Translation required: If media contains English language text, it **must** be translated	Yes

Células, recetores and mensageiros



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

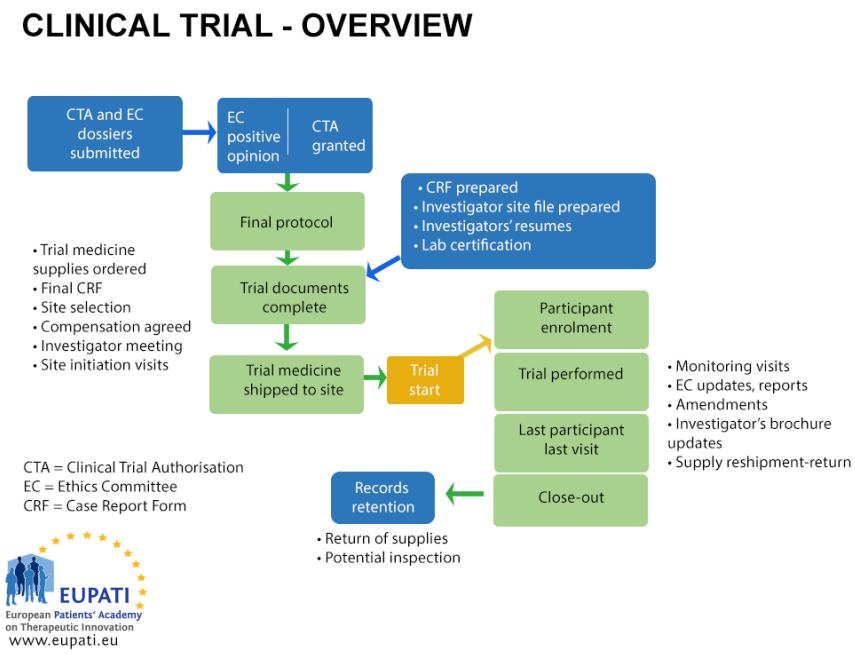
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	30.01.2017	PLATA Created	Draft	1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Clinical trial management
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Clinical-trial-overview_V3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/bsz94ku260bq978t05qb04iiki4qfcli
Cut and paste image here:  	
Media Source Note: Please indicate where the image was	EUPATI

taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Representação gráfica do processo de gestão de ensaios clínicos.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Representação gráfica do processo de gestão de ensaios clínicos.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Representação gráfica do processo de gestão de ensaios clínicos.
Translation required: If media contains English language text, it **must** be translated	YES

Ensaio clínico - Síntese

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

RNEC= Registo Nacional de Estudos Clínicos
CEIC= Comissão de Ética para a Investigação Clínica
FRD = Formulário de Registo de Dados

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

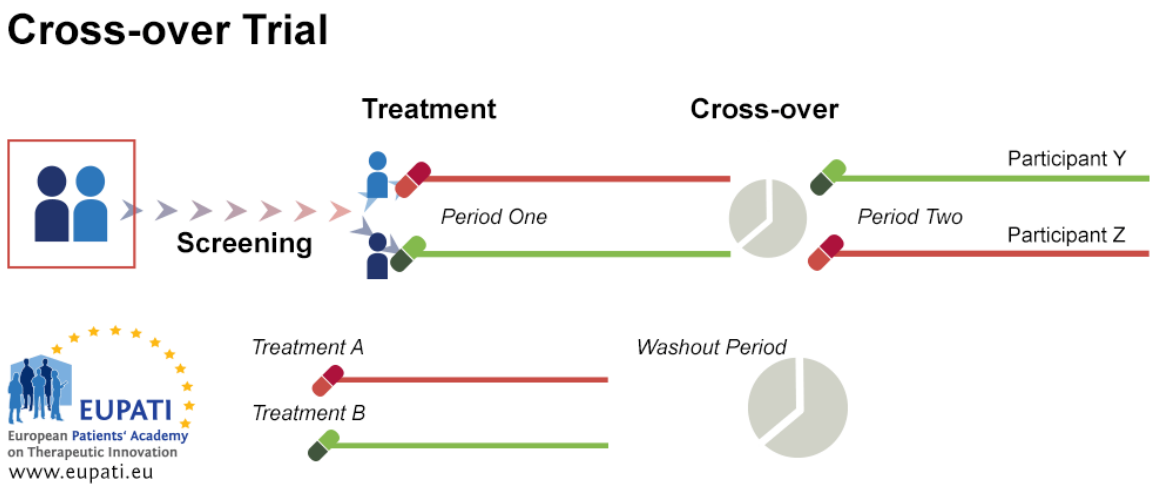
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	Final	1.1
Heidi Scherz	9.9.2015	PLATA Updated	FINAL	2
Heidi Scherz	21.9.2015	Image finalised	FINAL	3

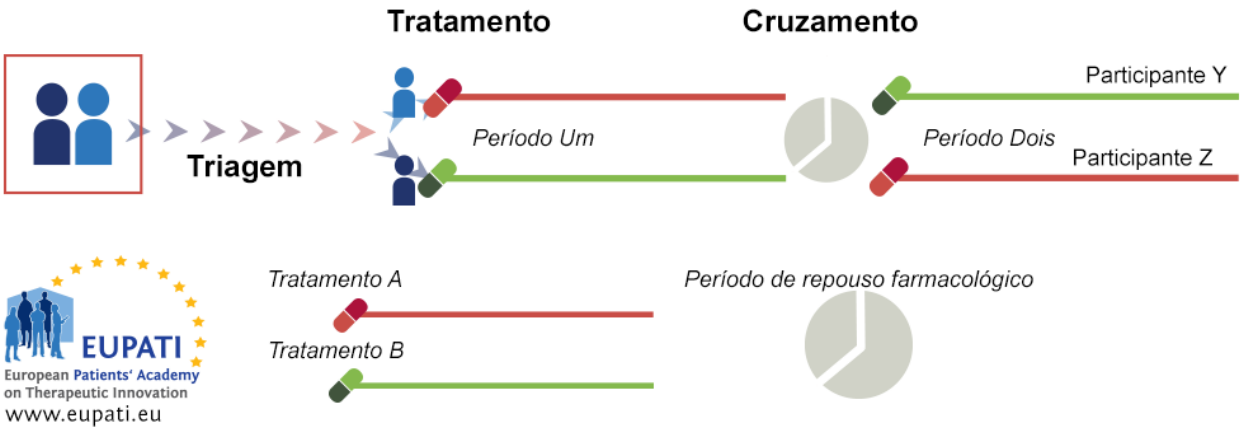
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Cross-over trial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Crossover-trial-ve_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4305678547/crossover-trial
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI; Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not**	Diagrama que descreve a estrutura de um ensaio cruzado. Por exemplo: O Paciente X e Y são randomizados em dois braços de tratamento. O Paciente X recebe o Tratamento A durante o primeiro período do estudo; o Paciente Y recebe o Tratamento B. Após o primeiro período estar concluído, há um período de repouso farmacológico. O Paciente X recebe, depois, o Tratamento B durante

rely on article context for meaning.	o segundo período do estudo, enquanto que o Paciente Y recebe o Tratamento A.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrama que descreve a estrutura de um ensaio cruzado. Por exemplo: O Paciente X e Y são randomizados em dois braços de tratamento. O Paciente X recebe o Tratamento A durante o primeiro período do estudo; o Paciente Y recebe o Tratamento B. Quando o primeiro período acaba, há um período de repouso farmacológico. O Paciente X recebe, depois, o Tratamento B durante o segundo período do estudo, enquanto que o Paciente Y recebe o Tratamento A.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O Paciente X e Y são randomizados em dois braços de tratamento. O Paciente X recebe o Tratamento A durante o primeiro período do estudo; o Paciente Y recebe o Tratamento B. Quando o primeiro período acaba, há um período de repouso farmacológico. O Paciente X recebe, depois, o Tratamento B durante o segundo período do estudo, enquanto que o Paciente Y recebe o Tratamento A.
Translation required: If media contains English language text, it **must** be translated	Yes

Ensaio cruzado



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

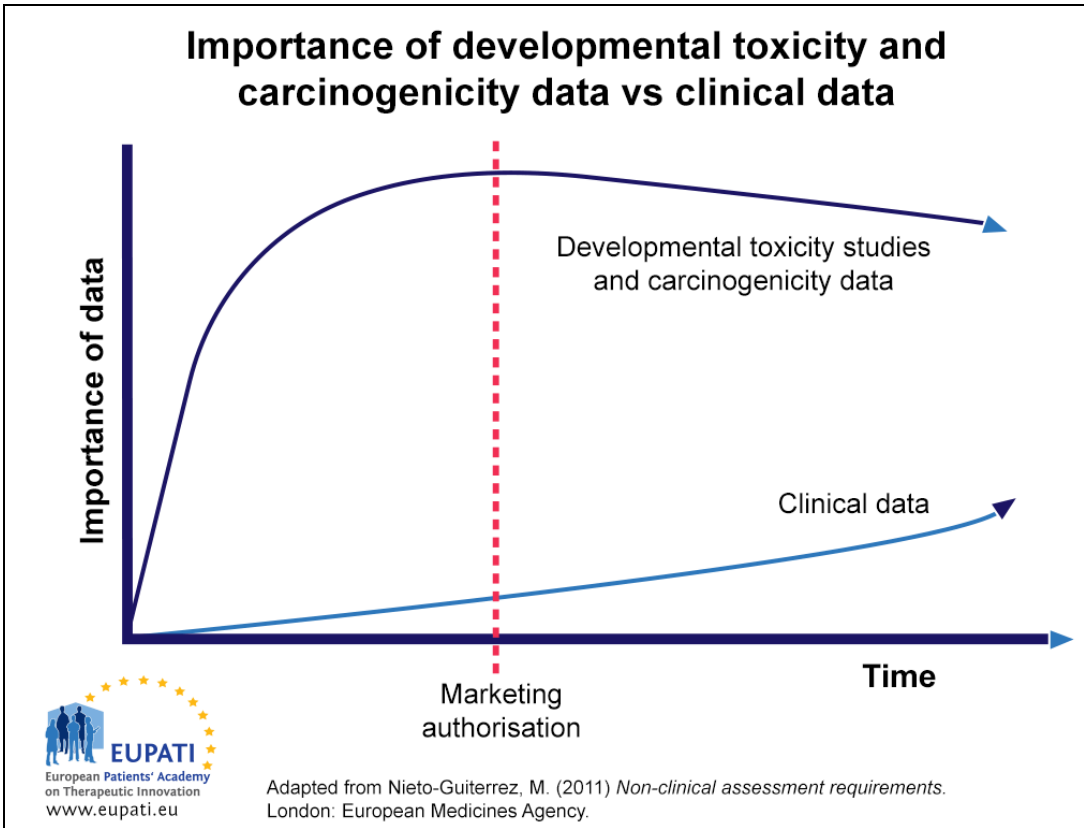
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	23.9.2015	PLATA updated for final version of image	FINAL	4

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

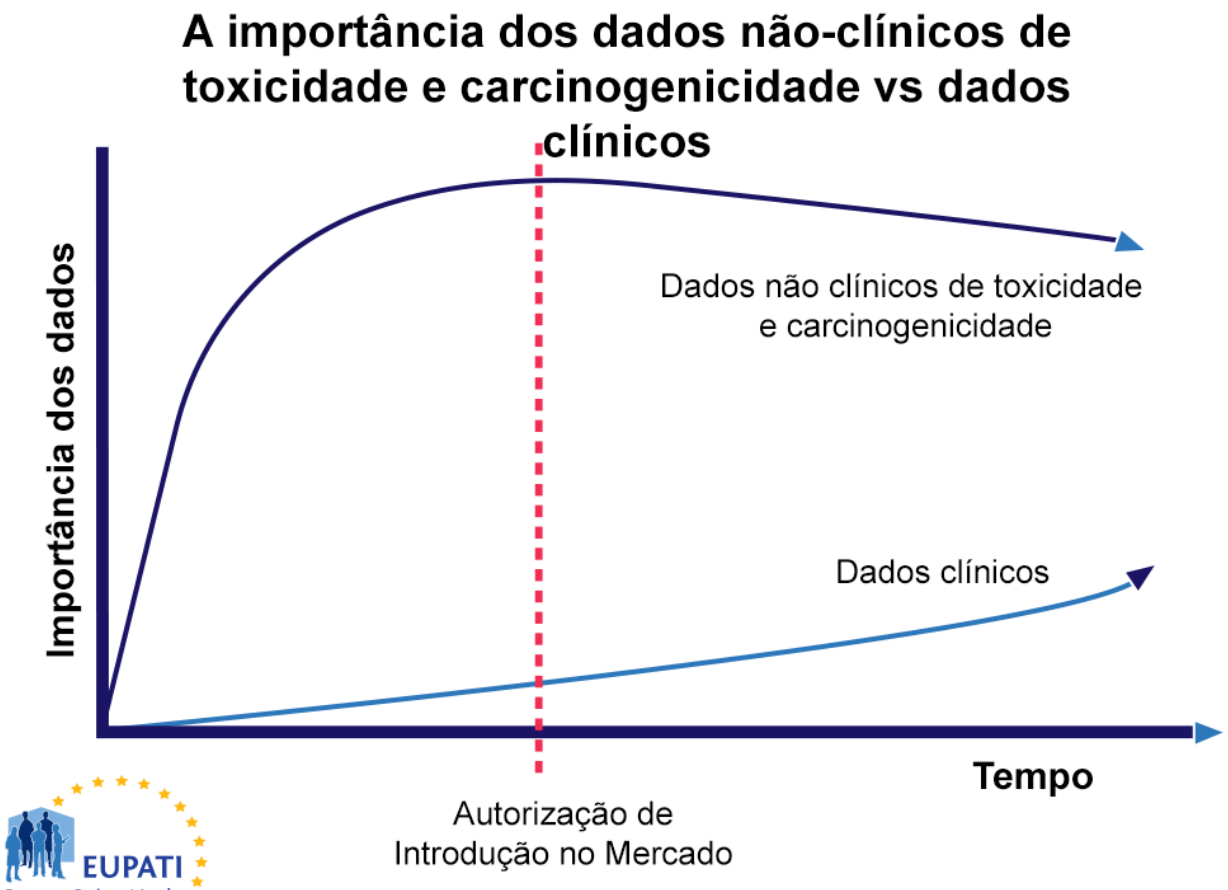
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Importance of developmental toxicity and carcinogenicity data vs clinical data
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	developmental-and-toxicity-studies-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4286181327/developmental-and-toxicity-studies
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	EUPATI reproduced from Nieto-Guiterrez, M. (2011). Non-clinical assessment requirements. London: EMA Retrieved 24 July, 2015, from http://www.ema.europa.eu/docs/en_GB/document_library/Presentation/2011/06/WC500107868.pdf
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for	Ilustração gráfica da importância e confiança de dados de estudos não-clínicos de toxicidade e genotoxicidade na avaliação da segurança em humanos relativamente aos dados recolhidos em ensaios clínicos ao longo do tempo. O tempo corresponde ao eixo X; a importância para a avaliação da segura em humanos corresponde ao eixo Y. O tempo em que se obtém a Autorização de Introdução no Mercado está marcado aproximadamente a meio do eixo X. Apesar da toxicidade e carcinogenicidade não clínicas serem mais importantes que os dados clínicos recolhidos durante o processo de desenvolvimento e depois da obtenção da autorização de introdução no mercado, a importância dos dados clínicos cresce gradualmente mesmo quando a importância dos dados não-clínicos começa a diminuir.

meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Ilustração gráfica da importância e confiança de dados de estudos não-clínicos de toxicidade e genotoxicidade na avaliação da segurança em humanos relativamente aos dados recolhidos em ensaios clínicos ao longo do tempo. O tempo corresponde ao eixo X; a importância para a avaliação da segura em humanos corresponde ao eixo Y. O tempo em que se obtém a Autorização de Introdução no Mercado está marcado aproximadamente a meio do eixo X. Apesar da toxicidade e carcinogenicidade não clínicas serem mais importantes que os dados clínicos recolhidos durante o processo de desenvolvimento e depois da obtenção da autorização de introdução no mercado, a importância dos dados clínicos cresce gradualmente mesmo quando a importância dos dados não-clínicos começa a diminuir.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Os dados de estudos não clínicos de toxicidade e carcinogenicidade continuam a ser mais utilizados que os dados recolhidos durante o desenvolvimento e após a autorização de introdução no mercado.
Translation required: If media contains English language text, it **must** be translated	Yes



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adaptado de Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

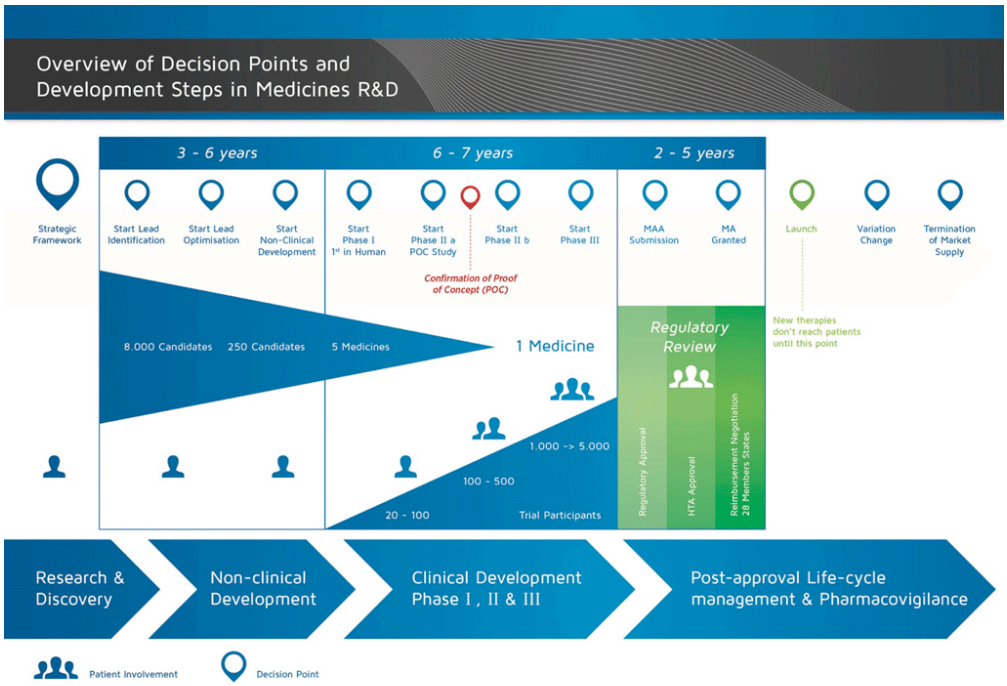
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	22.10.2015	PLATA Created (copied from old format)	Final	1.1
		Changes that need to be made highlighted		

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

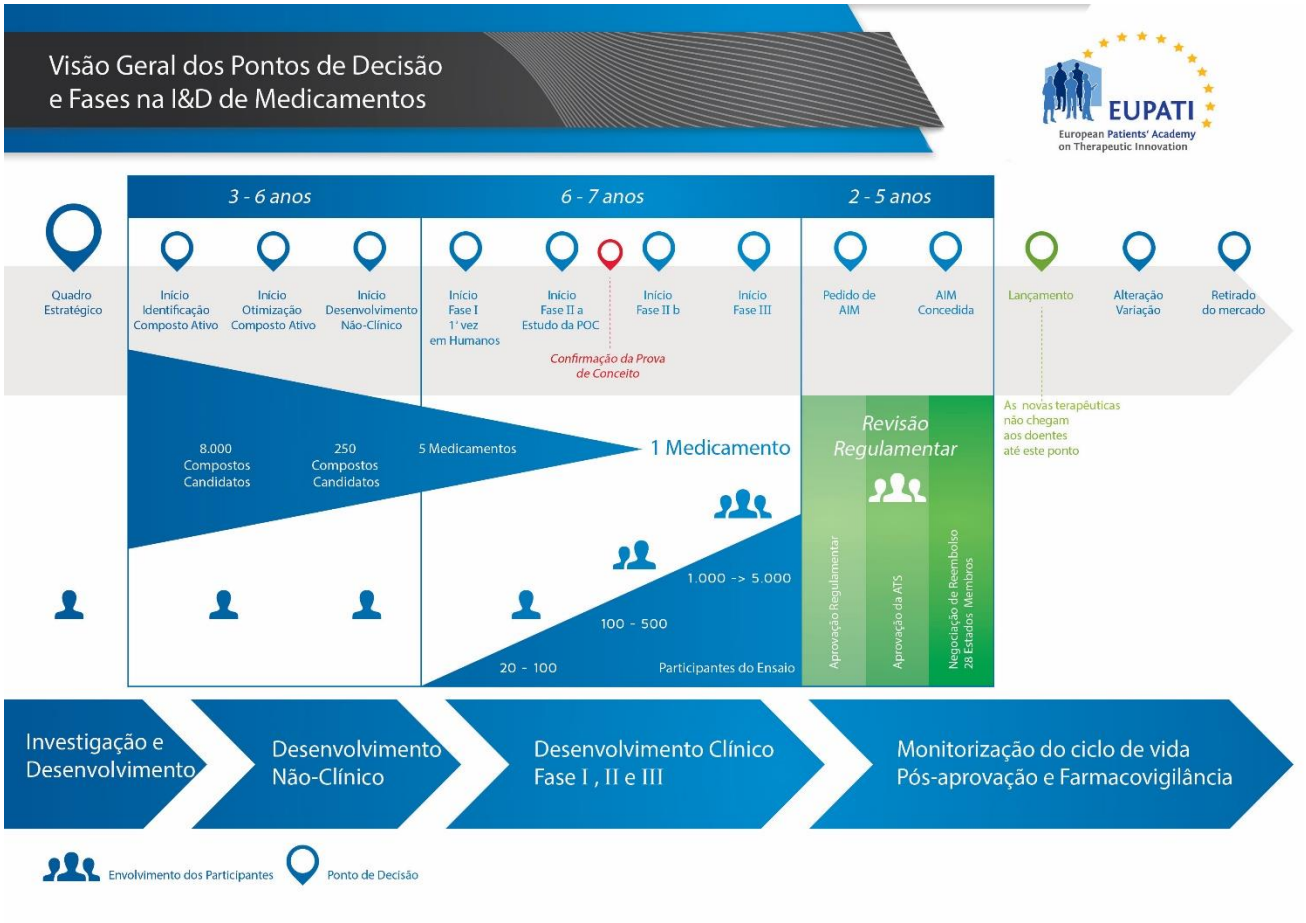
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Overview of the medicine development process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	development-steps-in-medicines-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/5092531034/developmental-steps-in-medicine
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diapositivo que descreve os pontos de decisão e as fases de Investigação e Desenvolvimento (I&D) de novos medicamentos. Há quatro fases principais de I&D: Investigação e Desenvolvimento, Desenvolvimento Não-clínico, Desenvolvimento Clínico e gestão do ciclo de vida pós-aprovação e farmacovigilância. A fase de Investigação e Desenvolvimento demora entre três a seis anos, e vai desde a criação de um quadro estratégico à identificação de compostos ativos, ponto em que o número de compostos candidatos é reduzido de 8000 para aproximadamente 250. A fase de desenvolvimento não-clínico ocorre também dentro dos primeiros três a seis anos, desde o início da otimização do composto ativo até ao fim do período de desenvolvimento não-clínico, e nessa altura, os 250 candidatos são reduzidos a cinco medicamentos. Os próximos seis a sete anos são ocupados pelo desenvolvimento clínico. O desenvolvimento clínico é dividido em três fases: I, II e III. Após a conclusão da Fase I, os primeiros ensaios em humanos (com aproximadamente 20 a 100 participantes), a Fase IIa inicia com um estudo de prova de conceito. Geralmente, na Fase IIa estão envolvidos entre 100 e 500 participantes. Quando a Prova de Conceito é aceite, a Fase IIb inicia, com ensaios clínicos com 1000 a 5000 participantes, reduzindo os compostos candidatos a apenas um medicamento. A Fase III é a maior de todas as fases de ensaio e termina com a submissão do medicamento para revisão regulamentar. O processo de revisão regulamentar pode demorar entre dois a cinco anos. Apenas após a aprovação por parte das entidades reguladoras é que um medicamento pode ser lançado e as novas terapêuticas podem serem disponibilizadas aos doentes. Este processo de revisão e lançamento do medicamento marca o início da gestão do ciclo de vida pós-aprovação e da fase da farmacovigilância, que duram até o medicamento ser retirado do mercado e durante as quais, as mudanças são monitorizadas e controladas.
Alt Text:	Diapositivo que descreve os pontos de decisão e as

Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	fases de Investigação e Desenvolvimento (I&D) de novos medicamentos. Há quatro fases principais de I&D: Investigação e Desenvolvimento, Desenvolvimento Não-clínico, Desenvolvimento Clínico e gestão do ciclo de vida pós-aprovação e farmacovigilância. A fase de Investigação e Desenvolvimento demora entre três a seis anos, e vai desde a criação de um quadro estratégico à identificação de compostos ativos, ponto em que o número de compostos candidatos é reduzido de 8000 para aproximadamente 250. A fase de desenvolvimento não-clínico ocorre também dentro dos primeiros três a seis anos, desde o início da otimização do composto ativo até ao fim do período de desenvolvimento não-clínico, e nessa altura, os 250 candidatos são reduzidos a cinco medicamentos. Os próximos seis a sete anos são ocupados pelo desenvolvimento clínico. O desenvolvimento clínico é dividido em três fases: I, II e III. Após a conclusão da Fase I, os primeiros ensaios em humanos (com aproximadamente 20 a 100 participantes), a Fase IIa inicia com um estudo de prova de conceito. Geralmente, na Fase IIa estão envolvidos entre 100 e 500 participantes. Quando a Prova de Conceito é aceite, a Fase IIb inicia, com ensaios clínicos com 1000 a 5000 participantes, reduzindo os compostos candidatos a apenas um medicamento. A Fase III é a maior de todas as fases de ensaio e termina com a submissão do medicamento para revisão regulamentar. O processo de revisão regulamentar pode demorar entre dois a cinco anos. Apenas após a aprovação por parte das entidades reguladoras é que um medicamento pode ser lançado e as novas terapêuticas podem serem disponibilizadas aos doentes. Este processo de revisão e lançamento do medicamento marca o início da gestão do ciclo de vida pós-aprovação e da fase da farmacovigilância, que duram até o medicamento ser retirado do mercado e durante as quais, as mudanças são monitorizadas e controladas.
Caption: Will be displayed under	São necessários mais de dez anos de planeamento cuidado e investigação para que um medicamento

media in the article body. Must begin with title of media.	passe de uma molécula para uma terapêutica comerciável.
Translation required: If media contains English language text, it **must** be translated	(Yes/No) Yes


Visão Geral dos Pontos de Decisão
e Fases na I&D de Medicamentos
EUPATI
European Patients' Academy
on Therapeutic Innovation
3 - 6 anos
6 - 7 anos
2 - 5 anos
Quadro Estratégico
Início Identificação Composto Ativo
Início Otimização Composto Ativo
Início Desenvolvimento Não-Clínico
Início Fase I 1ª vez em Humanos
Início Fase II a Estudo da POC
Início Fase II b
Início Fase III
Pedido de AIM
AIM Concedida
Lançamento
Alteração Variação
Retirado do mercado
Confirmação da Prova de Conceito
As novas terapêuticas não chegam aos doentes até este ponto
8.000 Compostos Candidatos
250 Compostos Candidatos
5 Medicamentos
1 Medicamento
Revisão Regulamentar
1.000 -> 5.000
100 - 500
20 - 100
Participantes do Ensaio
Aprovação Regulamentar
Aprovação da ATS
Negociação de Reembolso 28 Estados Membros
Investigação e Desenvolvimento
Desenvolvimento Não-Clínico
Desenvolvimento Clínico Fase I , II e III
Monitorização do ciclo de vida Pós-aprovação e Farmacovigilância
Envolvimento dos Participantes
Ponto de Decisão

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

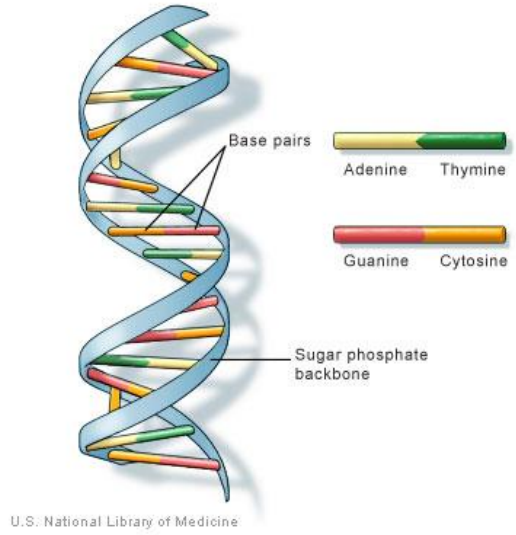
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

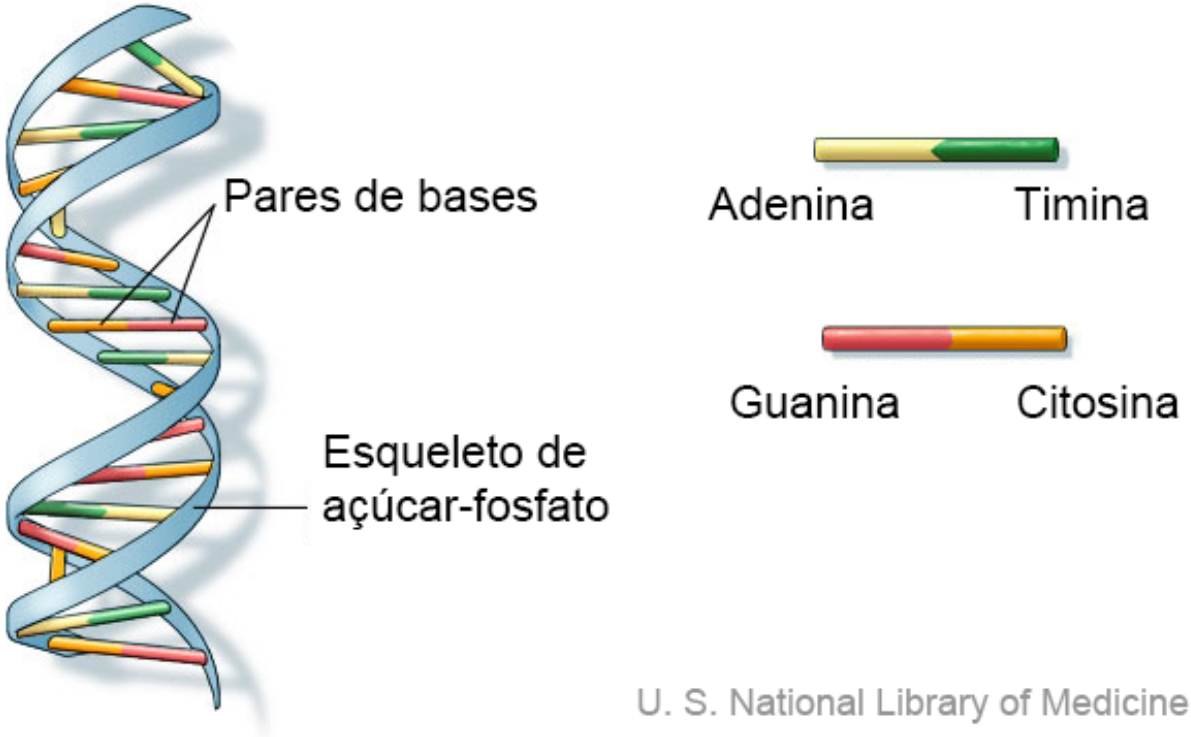
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	DNA structure
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	DNA-structure_EN.jpeg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/9xyeorf62qb74ker2nuc4ob0m0kq7jk1
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	US National Library of Medicine

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	O ADN tem uma estrutura semelhante à de uma escada em espiral. Os degraus são constituídos por bases nitrogenadas de nucleótideos. O nucleótideo adenina faz par com a timina, e a citosina com a guanina. Os pares de base de nucleótidos são ligados por um esqueleto de açúcar-fosfato. (Fonte: US National Library of Medicine, ver referência no. 1).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Representação esquemática do ADN. O ADN tem uma estrutura semelhante à de uma escada em espiral. Os degraus são constituídos por bases nitrogenadas de nucleótideos. O nucleótideo adenina faz par com a timina, e a citosina com a guanina. Os pares de base de nucleótidos são ligados por um esqueleto de açúcar-fosfato. (Fonte: US National Library of Medicine, ver referência no. 1).
Caption: Will be displayed under media in the article body. Must begin with title of media.	Estrutura do ADN. (Fonte: US National Library of Medicine[1]). O ADN tem uma estrutura semelhante à de uma escada em espiral. Os degraus são constituídos por bases nitrogenadas de nucleótideos. O nucleótideo adenina faz par com a timina, e a citosina com a guanina. Os pares de base de nucleótidos são ligados por um esqueleto de açúcar-fosfato
Translation required: If media contains English language text, it **must** be translated	Y


Pares de bases
Esqueleto de
açúcar-fosfato
Adenina
Timina
Guanina
Citosina
U. S. National Library of Medicine

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

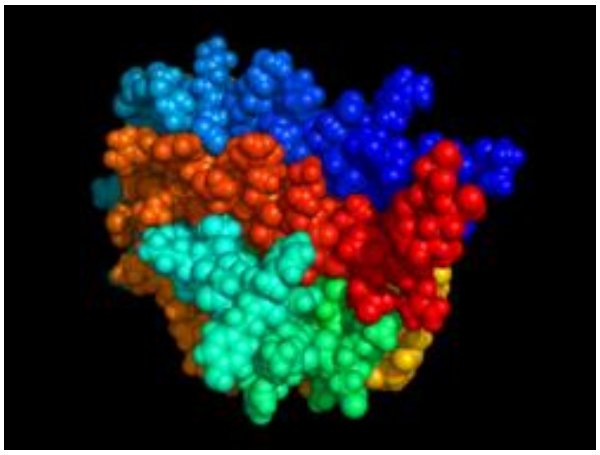
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

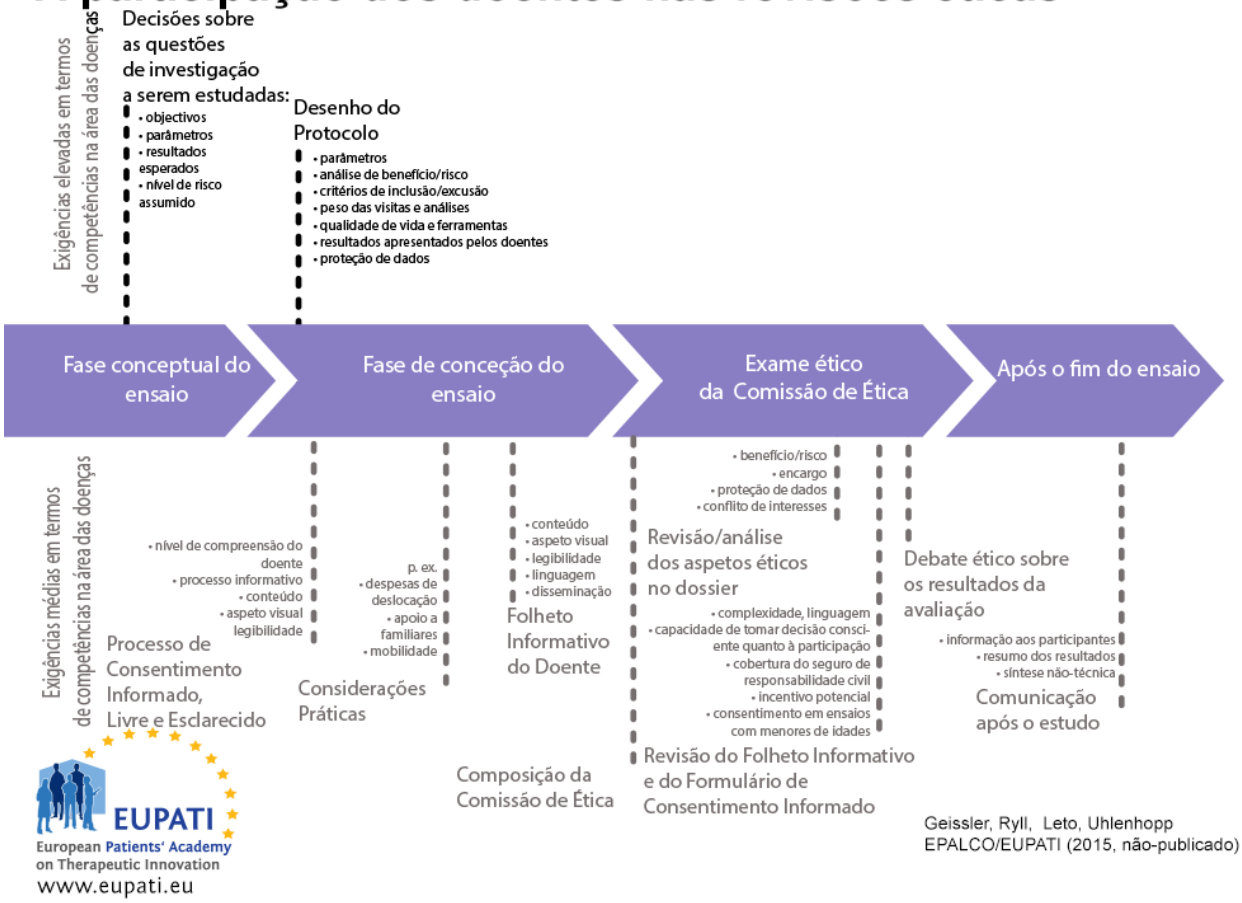
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Representation of erythropoietin, a very large protein.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	erythropoietin.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/zmlspot9xuihkcdam157mppobhx6hn1t
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Representação gerada por computador da Eritropoietina, que é uma proteína grande.

Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Representação gerada por computador da Eritropoietina, que é uma proteína grande.
Caption: Will be displayed under media in the article body. Must begin with title of media.	A Eritropoietina é uma proteína natural, mas tem sido utilizada como terapêutica biológica em doentes cujos corpos não são capazes de produzir quantidades suficientes da mesma. Células em cubas de fermentação são geneticamente manipuladas para que possam produzir grandes quantidades de eritropoietina.
Translation required: If media contains English language text, it **must** be translated	No

A participação dos doentes nas revisões éticas



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

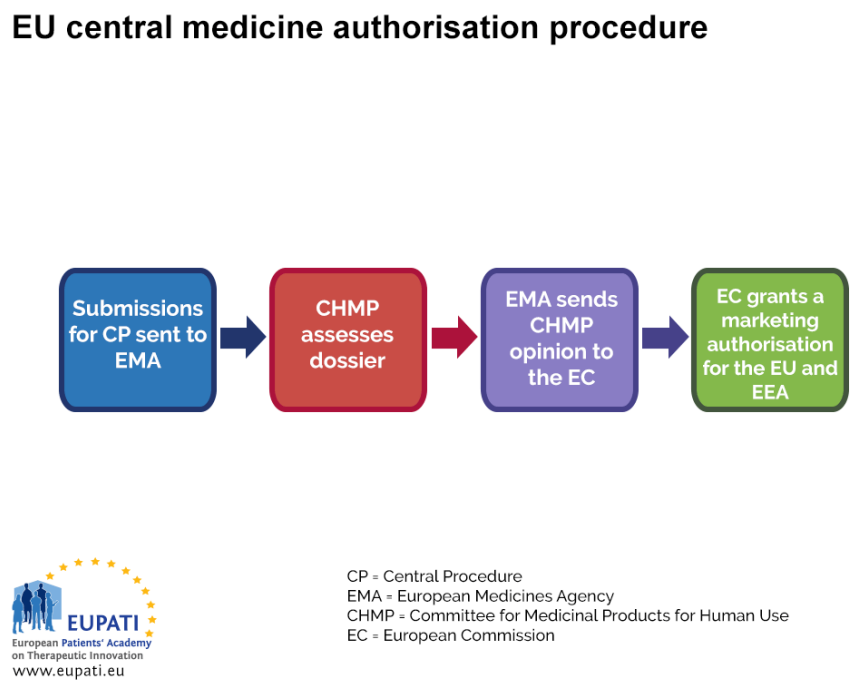
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	11.11.2016	PLATA Created	Final	1.1

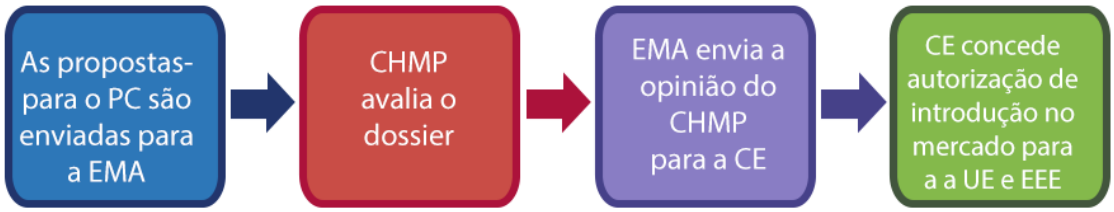
***State #:** This can either be ‘Draft’ or ‘Final’.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EU Central Procedure to authorise medicine
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	EU-central-procedure-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/12041823143/EU_central_procedure
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken	EUPATI;

from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diagrama que representa o procedimento centralizado para a autorização de introdução no mercado de um medicamento em todos os países da EU e do EEE.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrama que representa o procedimento centralizado para a autorização de introdução no mercado de um medicamento em todos os países da EU e do EEE.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O procedimento centralizado utilizado na autorização de introdução de medicamentos no Mercado em todos os países da EU e do EEE.
Translation required: If media contains English language text, it **must** be translated	Yes

Procedimento centralizado de autorização de introdução de medicamentos no mercado na UE



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

PC = Procedimento Centralizado
EMA = Agência Europeia do Medicamento
CHMP = Comité dos Medicamentos de Uso Humano
CE = Comissão Europeia

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

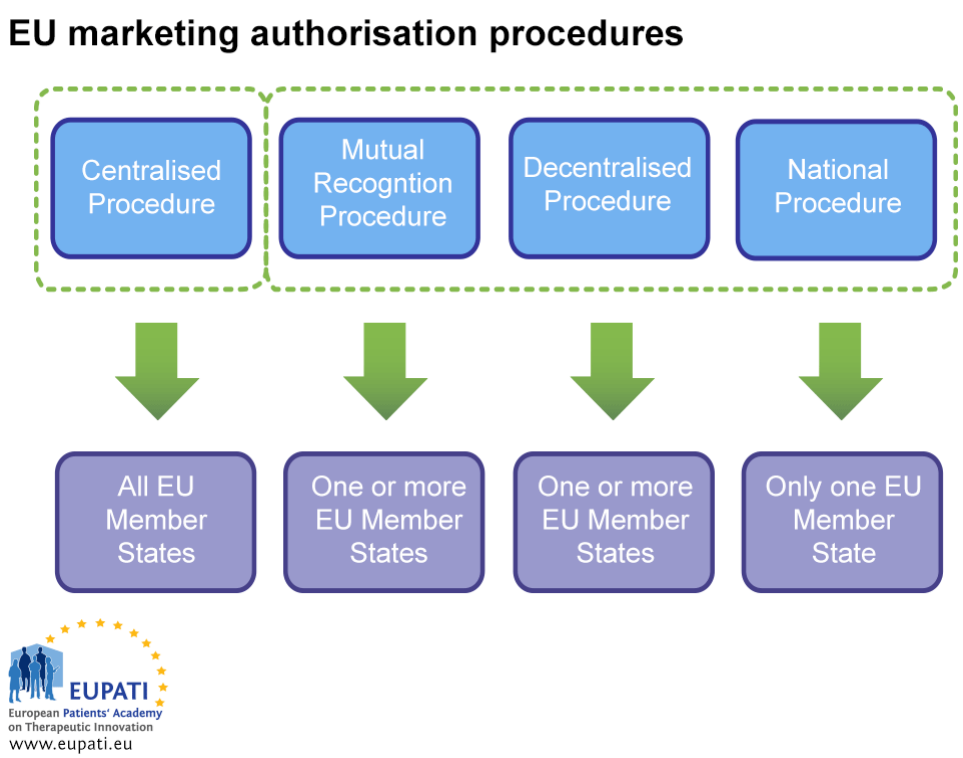
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	9.9.2015	PLATA Created	Final	1.1

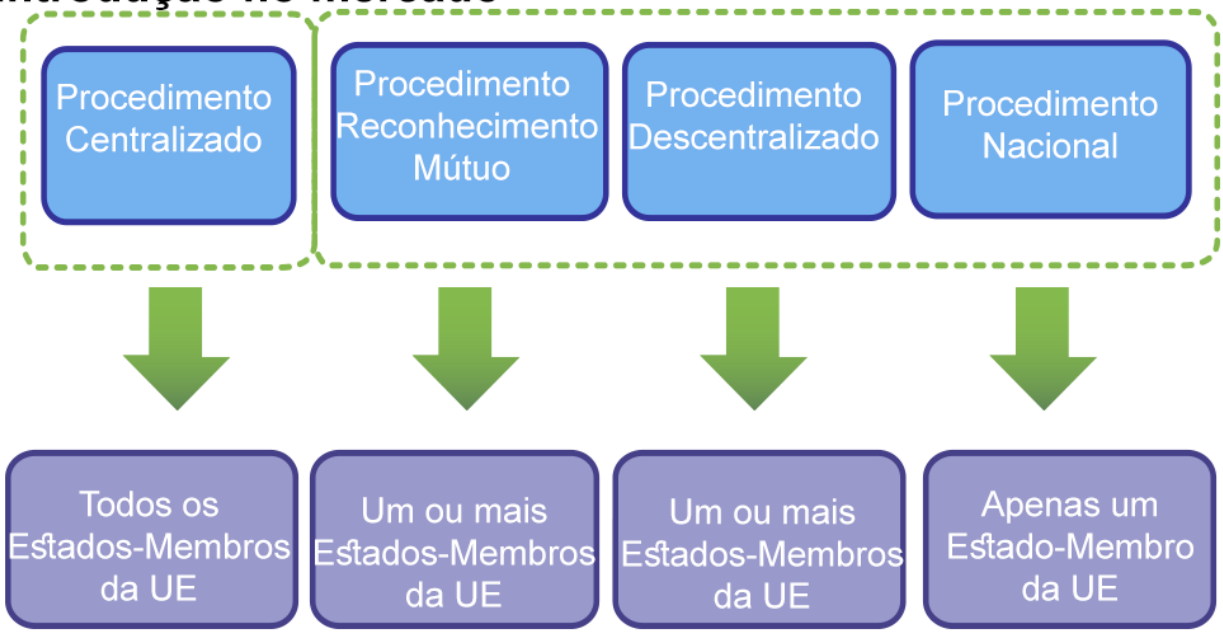
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EU Marketing Authorisation Procedures
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	EU-marketing-authorisation-procedures-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4494075486
Cut and paste image here:  	
Media Source	EUPATI; Heidi Scherz

Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa os diferentes procedimentos de autorização de introdução no mercado da UE. Há quatro procedimentos de dois tipos e com diferentes membros envolvidos. O procedimento centralizado é um tipo próprio; todos os Estados-Membros da UE estão envolvidos neste procedimento. Os outros três procedimentos são todos tipos de procedimentos descentralizados. O Procedimento de Reconhecimento Mútuo envolve um ou mais Estados-Membros da UE. O Procedimento Descentralizado também envolve um ou mais Estados-Membros. O Procedimento Nacional envolve apenas um Estado-Membro da UE.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esquema que representa os diferentes procedimentos de autorização de introdução no mercado da UE. Há quatro procedimentos de dois tipos e com diferentes membros envolvidos. O procedimento centralizado é um tipo próprio; todos os Estados-Membros da UE estão envolvidos neste procedimento. Os outros três procedimentos são todos tipos de procedimentos descentralizados. O Procedimento de Reconhecimento Mútuo envolve um ou mais Estados-Membros da UE. O Procedimento Descentralizado também envolve um ou mais Estados-Membros. O Procedimento Nacional envolve apenas um Estado-Membro da UE.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Diferentes entidades intervêm na autorização de introdução no mercado de um medicamento, dependendo de qual o procedimento o responsável opta por (ou é obrigado a) seguir.
Translation required: If media contains English language text, it **must** be translated	Yes

Procedimentos na UE de autorização de introdução no mercado



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

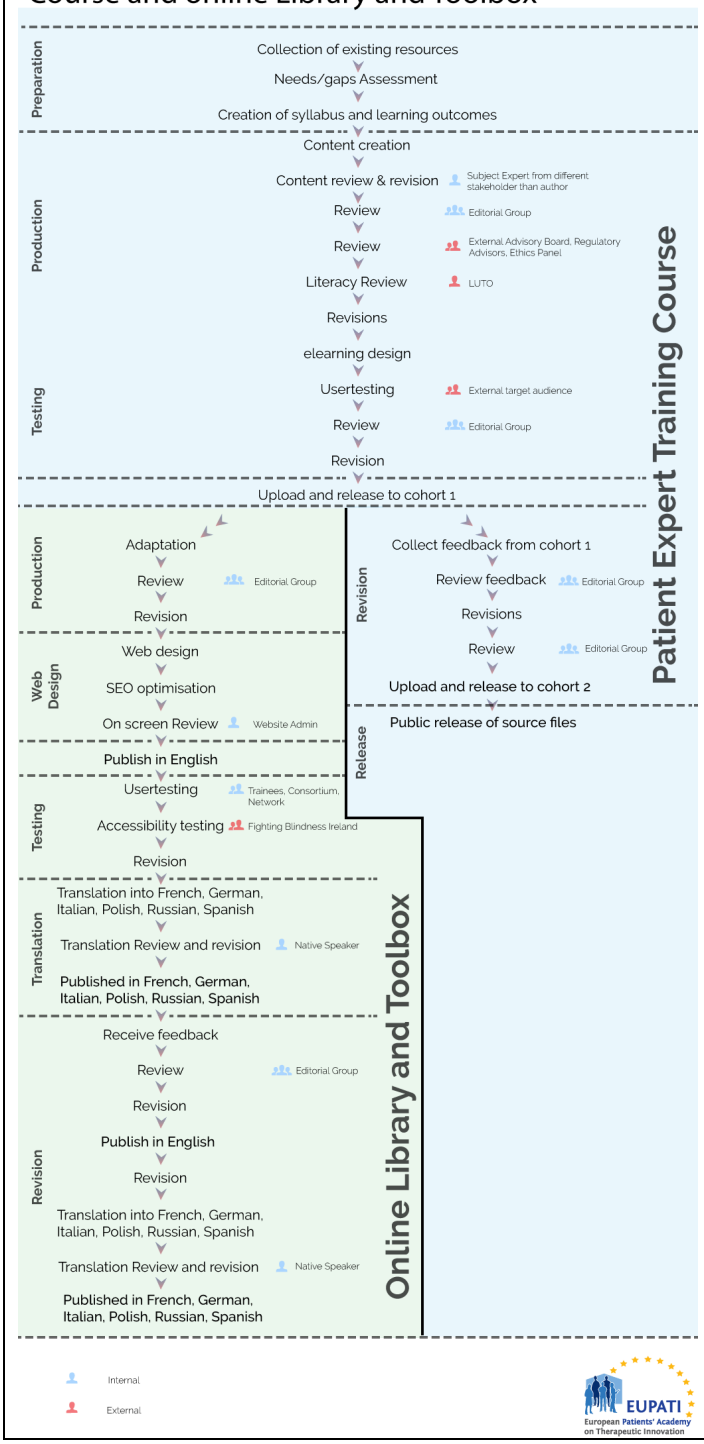
Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	13.09.2016	PLATA Created	Final	1.0

***State #:** This can either be ‘Draft’ or ‘Final’.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	EUPATI Production Process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	content-workflow-v1-EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/11286918170/EUPATI_Production_Process
Cut and paste image here:	

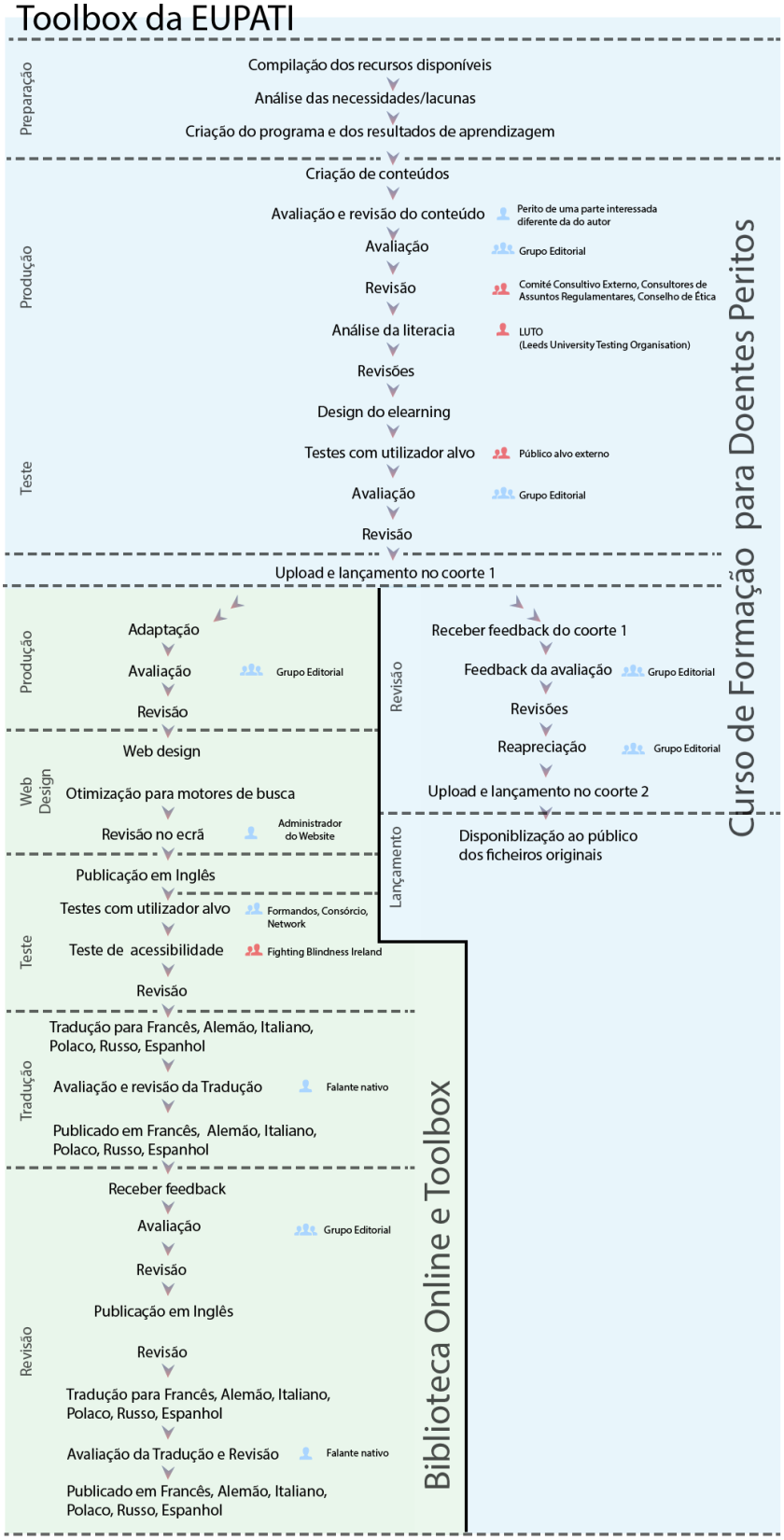
EUPATI Production Process for Patient Expert Course and online Library and Toolbox



Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Todo o conteúdo foi redigido por especialistas de diferentes contextos, que já trabalharam dentro da área em questão. Foi depois revisto por outros especialistas que provêm de diferentes contextos, que trabalham para um grupo diferente de partes interessadas. Por exemplo, o conteúdo redigido por um investigador clínico da indústria seria revisto por um especialista em doentes ou um académico. Para verificar a exatidão dos fatos, transparência, neutralidade e legibilidade, o conteúdo foi revisto pelos nossos órgãos de revisão independentes, especialistas e comités. Por exemplo, conteúdo relacionado com questões de regulamentação foi revisto por membros do staff de autoridades regulamentares da Alemanha, Itália, Suíça, Espanha e Irlanda. Conteúdo da ATS foi revisto por especialistas da mesma da HTAi e EUnetHTA. O material sobre ética foi revisto por especialistas em ética do Painel de Ética do EUPATI. Para validar caso o material nos módulos online era compreensível e legível para o público interessado em saúde, o EUPATI também testou grandes porções do seu material com defensores dos direitos dos pacientes, incluindo testes à acessibilidade da leitura no ecrã do website com a Fighting Blindness Ireland. O feedback de todos revisores foi incorporado nos ciclos editoriais do conteúdo do EUPATI. Um grupo editorial presidido pela DIA (uma associação global sem fins lucrativos que oferece educação e fóruns de discussão para promover o desenvolvimento farmacêutico) que consistia de representantes da Bayer, Universidade de Copenhaga, Universidade de Bochum, Rare Diseases Europe (EURORDIS), European AIDS Treatment Group (EATG), GlaxoSmithKline e a Irish Platform for Patient Organisations, Science and Industry (IPPOSI) reviu todos os comentários e fizeram análises de consistência, estilo e conteúdo fatual do material.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Uma representação gráfica do Processo de Produção do EUPATI. Pode ler sobre o processo de produção no documento intitulado Produção do Curso de Formação Especializada para Doentes EUPATI e no documento Produção da Biblioteca e Toolbox EUPATI.

Caption: Will be displayed under media in the article body. Must begin with title of media.	Na criação de todo o material para EUPATI foi desenvolvido um processo robusto de produção, revisão e aprovação envolvendo revisões internas e externas de diferentes partes interessadas.
Translation required: If media contains English language text, it **must** be translated	Yes

Processo de Produção do Curso de Formação Especializado para Doentes e Biblioteca online e Toolbox da EUPATI



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

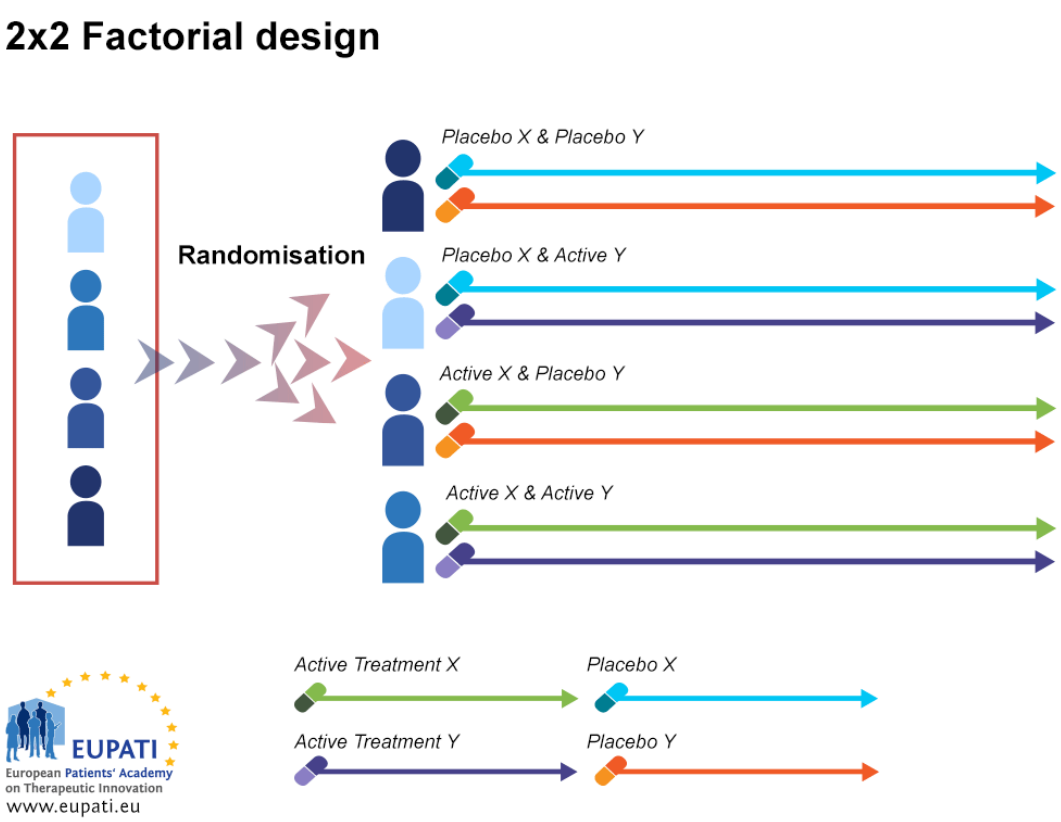
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA CREATED	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	2x2 Factorial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Factorial-design-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/0nbmi1iail6t6ux410mkagt41aq64aao

Cut and paste image here:

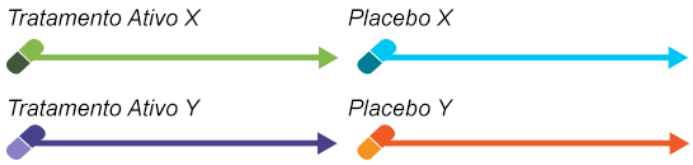


Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa o exemplo de um ensaio que recorre a um desenho fatorial 2x2.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Este esquema representa o exemplo de um ensaio que recorre a um desenho fatorial 2x2. Neste exemplo, os doentes são randomizados em um de quatro grupos. Há dois tratamentos ativos, o Tratamento X e o Tratamento Y. Ambos os tratamentos têm um tratamento placebo, Placebo do Tratamento X e Placebo do Tratamento Y. Cada grupo recebe dois tratamentos em simultâneo. O grupo 1 recebe o Placebo X e o Placebo Y. O grupo 2 recebe o Placebo X e o Ativo Y. O grupo 3 recebe o Ativo X e o Placebo Y, e o grupo 4 recebe o Ativo X e o Ativo Y.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Exemplo de um ensaio que recorre a um desenho fatorial 2x2.
Translation required: If media contains English language text, it **must** be	Yes

translated	

Desenho Fatorial 2x2

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

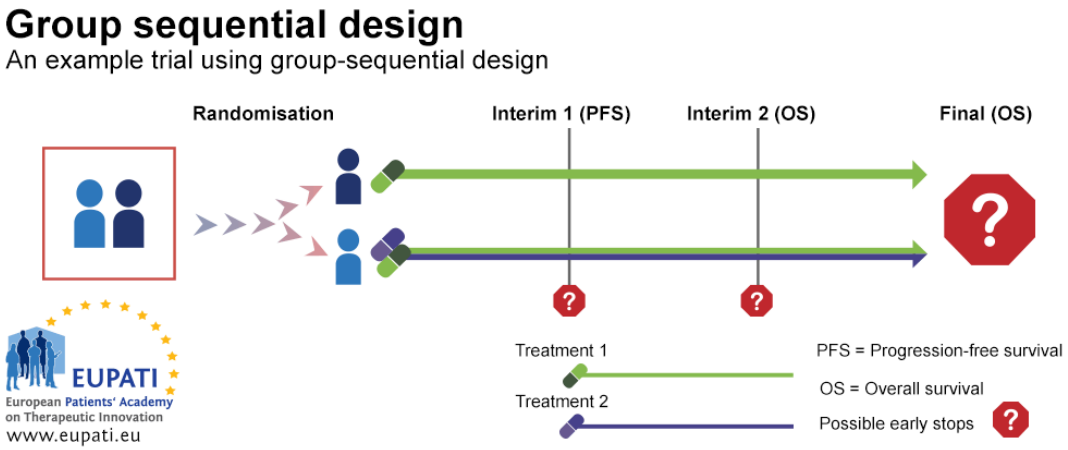
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

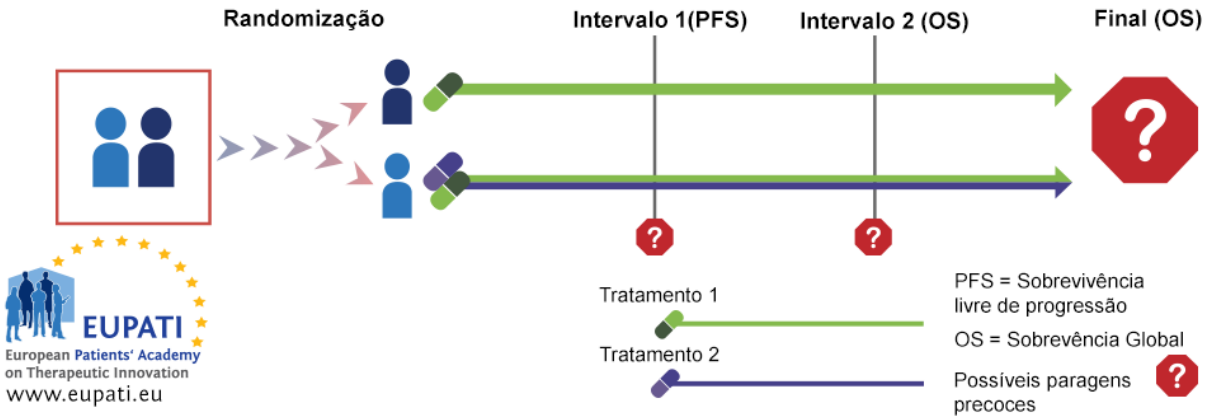
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Group sequential design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Group-sequential-design-v1.1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/mpoqvhnrdd4mv9uothpd1bkq93cnxqud
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa um exemplo de um ensaio com desenho sequencial. Há duas análises intermédias indicadas na linha cronológica do ensaio, onde há possíveis paragens precoces. A análise intermedia 1 permite paragens precoces em função da análise da sobrevivência livre de progressão. A análise intermedia 2 permite

	paragem precoces em função da análise da sobrevivência global. Após o fim do ensaio, também é feita uma análise de sobrevivência global. Neste exemplo de ensaio, os participantes são randomizados em um de dois braços de tratamento. No primeiro braço, os participantes recebem o tratamento um. No segundo braço, os participantes recebem uma combinação do tratamento um e do tratamento dois.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esquema que representa um exemplo de um ensaio com desenho sequencial. Há duas análises intermédias indicadas na linha cronológica do ensaio, onde há possíveis paragens precoces. A análise intermedia 1 permite paragens precoces em função da análise da sobrevivência livre de progressão. A análise intermedia 2 permite paragem precoces em função da análise da sobrevivência global. Após o fim do ensaio, também é feita uma análise de sobrevivência global. Neste exemplo de ensaio, os participantes são randomizados em um de dois braços de tratamento. No primeiro braço, os participantes recebem o tratamento um. No segundo braço, os participantes recebem uma combinação do tratamento um e do tratamento dois.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O desenho sequencial por grupos em ensaios clínicos permite paragens precoces com base na sobrevivência livre de progressão ou na sobrevivência geral. Neste exemplo, os participantes foram randomizados num de dois braços, e receberam o Tratamento 1 ou uma combinação de Tratamento 1 e Tratamento 2.
Translation required: If media contains English language text, it **must** be translated	Yes

Desenho sequencial por grupos

Exemplo de um ensaio que usa desenho sequencial por grupos.



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1
Matthew May	31.05.2016	Corrections	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Herbal medicines.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	herbal-medicines-v1.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/u8sfp8v1qscyquncgbluc8wk1lfbkp5p
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Medicamentos à base de plantas. Fotos das plantas que originam três medicamentos à base de plantas. A Echinacea purpurea é uma flor grande, cor de rosa, com várias pétalas longas e finas; a Erva-de-São-João tem cachos mais pequenos de flores amarelas em forma de estrela; e a Gingko Biloba é uma árvore frondosa, grande e verde.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and	Medicamentos à base de plantas. Fotos das plantas que originam três medicamentos à base de plantas. A Echinacea purpurea é uma flor grande, cor de rosa, com várias pétalas longas e finas; a Erva-de-São-João tem cachos mais pequenos de flores amarelas em forma de estrela; e a Gingko Biloba é uma

descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	árvore frondosa, grande e verde.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Medicamentos à base de plantas. Da esquerda para a direita: Echinacea purpurea, Erva-de-São-João, e Gingko Biloba.
Translation required: If media contains English language text, it **must** be translated	No

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

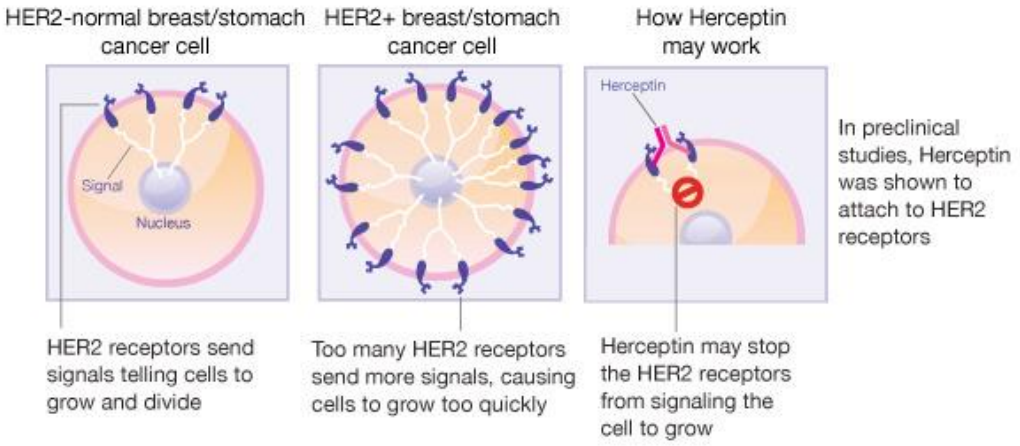
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA transferred	Final	1.1

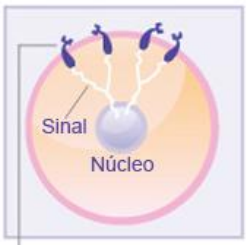
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	How Herceptin affects breast cancer cells
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Herceptin-affects_EN.jpg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/um2xo1tu2s4uhaelka0zwzf8g771douu
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	https://beyondthedish.wordpress.com/2012/06/04/smart-bomb-successfully-treat-advanced-breast-cancer-in-clinical-trials/
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on	Como a Herceptina afeta as células do cancro da mama. (Fonte: beyondthedish.wordpress.com). Esquema que mostra como a Herceptina pode atuar nas células do cancro da mama e do estômago. Os recetores HER2 enviam sinais que fazem com que as células cresçam e se dividam; demasiados recetores HER2 fazem com que as células do cancro da mama e do estômago cresçam de forma demasiado rápida.

article context for meaning.	Estudos pré-clínicos comprovaram que a Herceptina se liga aos recetores HER2, o que pode impedir os recetores de enviarem sinais para as cédulas crescerem.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Como a Herceptina afeta as células do cancro da mama. (Fonte: beyondthedish.wordpress.com). Esquema que mostra como a Herceptina pode atuar nas células do cancro da mama e do estômago. Os recetores HER2 enviam sinais que fazem com que as células cresçam e se dividam; demasiados recetores HER2 fazem com que as células do cancro da mama e do estômago cresçam de forma demasiado rápida. Investigações recentes em medicamentos personalizados comprovaram que a Herceptina se liga aos recetores HER2, o que pode impedir os recetores de enviarem sinais para as cédulas crescerem.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Como a Herceptina afeta as células do cancro da mama. (Fonte: beyondthedish.wordpress.com). Estudos pré-clínicos demonstram que a Herceptina pode atuar em células do cancro da mama ou do estômago ao bloquear recetores HER2 e impedir que estimulem o crescimento e divisão celulares.
Translation required: If media contains English language text, it **must** be translated	Yes

HER2-célula normal do cancro da mama/estômago

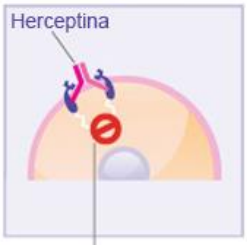


recetores HER2 enviam sinais que fazem com que as células cresçam e se dividam

HER2+ célula do cancro da mama/estômago

Demasiados recetores HER2 enviam mais sinais, fazendo com que as células cresçam rapidamente

Como a Herceptina pode atuar



A herceptina pode impedir os recetores HER2 de enviarem sinais que promovam o crescimento da célula

Em ensaios pré-clínicos, foi demonstrado que a Herceptina se liga aos recetores HER2

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

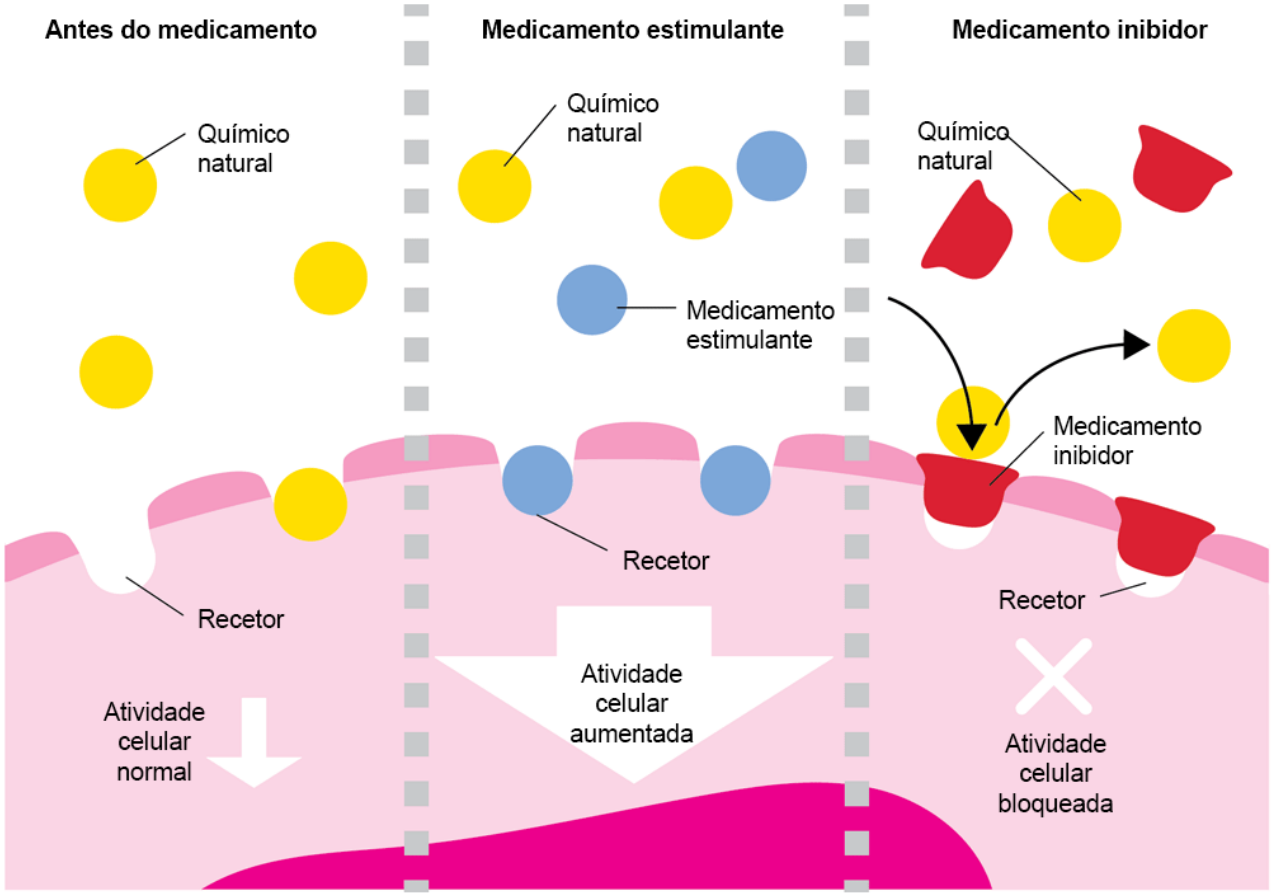
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	FINAL	1.1

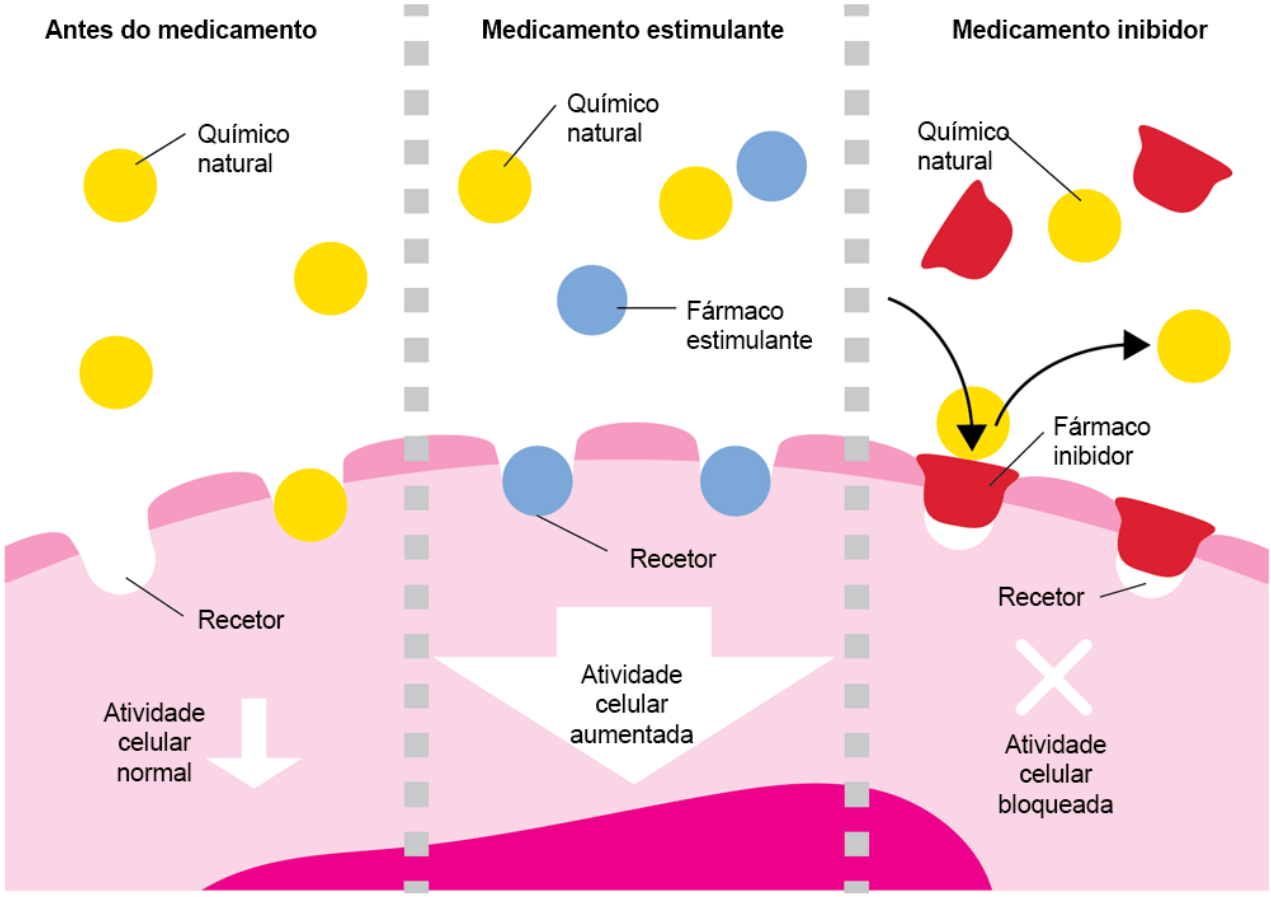
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	High-throughput screening process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	high-throughput-screening.jpeg
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/5c7swr6cru8ngfv62fa9kwpyed7hhycj
Cut and paste image here:	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Imagem que representa parte do processo de monitorização automatizada, em larga escala. Um aparelho com várias pipetas e frascos permite a análise simultânea de uma grande quantidade de moléculas potencialmente úteis.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt	Imagem que representa parte do processo de monitorização automatizada, em larga escala. Um aparelho com várias pipetas e frascos permite a análise simultânea de uma grande quantidade de moléculas potencialmente úteis.

text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	
Caption: Will be displayed under media in the article body. Must begin with title of media.	Imagem que representa parte do processo de monitorização automatizada, em larga escala. Um aparelho com várias pipetas e frascos permite a análise simultânea de uma grande quantidade de moléculas potencialmente úteis.
Translation required: If media contains English language text, it **must** be translated	No


Antes do medicamento
Medicamento estimulante
Medicamento inibidor
Químico natural
Químico natural
Químico natural
Medicamento estimulante
Medicamento inibidor
Recetor
Recetor
Recetor
Atividade celular normal
Atividade celular aumentada
Atividade celular bloqueada


Antes do medicamento
Medicamento estimulante
Medicamento inibidor
Químico natural
Químico natural
Químico natural
Fármaco estimulante
Fármaco inibidor
Recetor
Recetor
Recetor
Atividade celular normal
Atividade celular aumentada
Atividade celular bloqueada

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

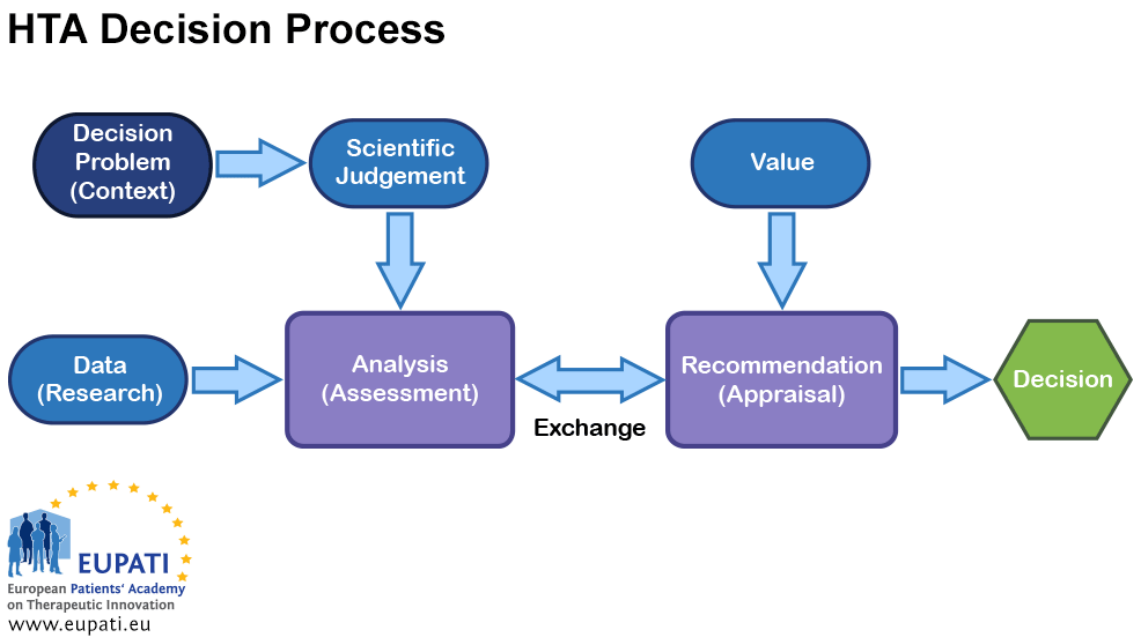
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	18.11.2015	PLATA Created	FINAL	1

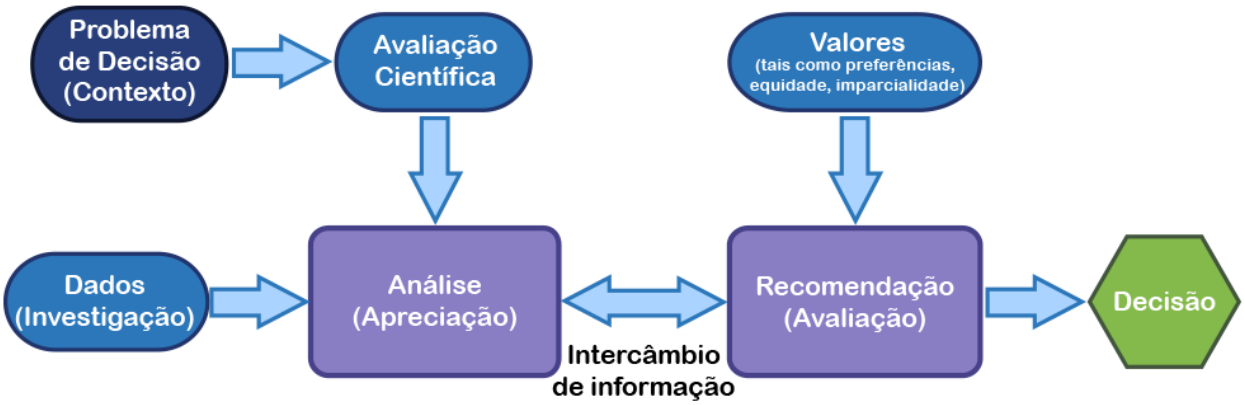
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	HTA Decision Process
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	HTA-decision-process-diagram-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/yrvhb5apevmtwnfjc5odqnedqz8xc5mu
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI (Heidi Scherz)

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Imagem com um fluxograma que descreve o processo de decisão ATS.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Imagem com um fluxograma que descreve o processo de decisão durante a ATS. Há dois cenários de ação: Análise (Apreciação) e Recomendação (Avaliação). A informação é trocada entre estes dois cenários, e cada um deles tem os seus próprios contributos que lhes fornecem informação. A Análise (apreciação) recolhe informação dos Dados (investigação) e da Avaliação Científica (que retira informação do Problema de Decisão (contexto). A Recomendação recolhe informação dos Valores. O cenário da Recomendação (avaliação) leva à decisão. .
Caption: Will be displayed under media in the article body. Must begin with title of media.	Os distintos contributos são relevantes em diferentes pontos do processo de decisão durante a ATS.
Translation required: If media contains English language text, it **must** be translated	YES

Processo de decisão ATS



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

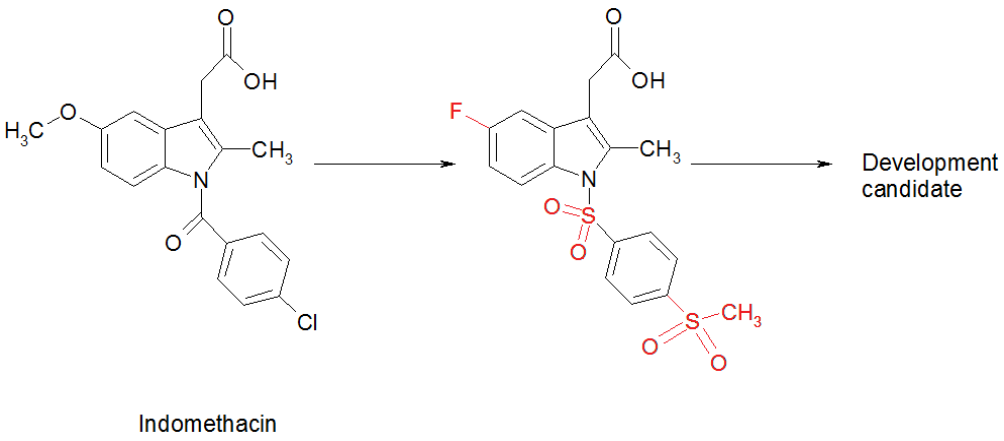
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

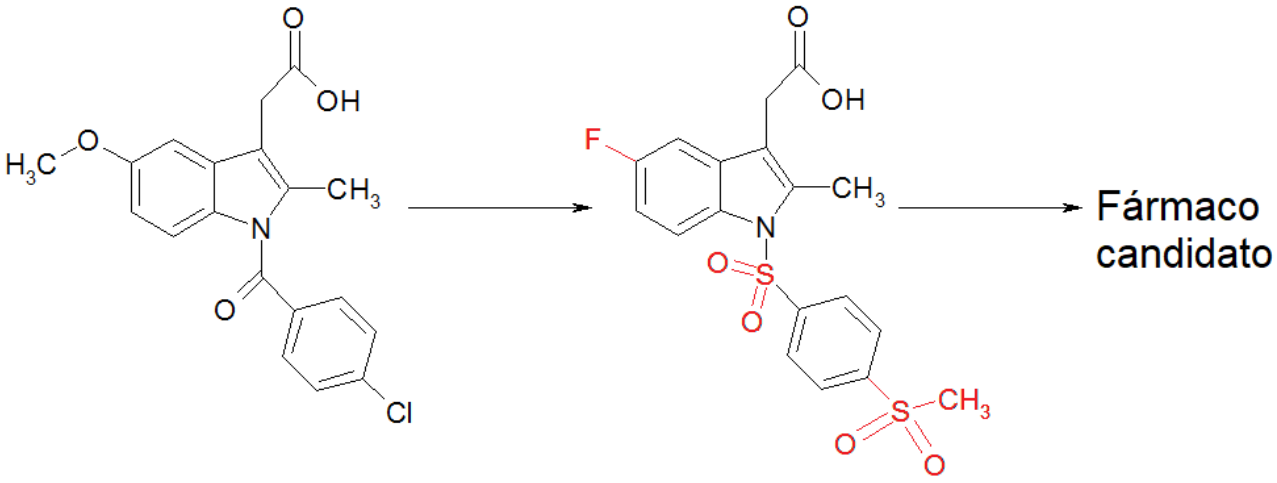
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Optimisation of indomethacin to a potent CRTH2 antagonist.
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Indomethacin-optimisation-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/q2ioiun4ms7jw73dg7n5cv26xxxpeg8z
Cut and paste image here:  Indomethacin	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Otimização da indometacina num antagonista CRTH2 potente. O esquema demonstra como a molécula original de indometacina foi quimicamente alterada de modo a transformá-la num fármaco candidato a um projeto de desenvolvimento.
Alt Text: Will be shown in case image/media fails to load/is prevented from	Otimização da indometacina num antagonista CRTH2 potente. O esquema demonstra como a molécula original de indometacina foi quimicamente alterada de modo a transformá-la num fármaco

loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	candidato a um projeto de desenvolvimento.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Otimização da indometacina num antagonista CRTH2 potente. O esquema demonstra como a molécula original de indometacina foi quimicamente alterada de modo a transformá-la num fármaco candidato a um projeto de desenvolvimento.
Translation required: If media contains English language text, it **must** be translated	Yes



Indometacina

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

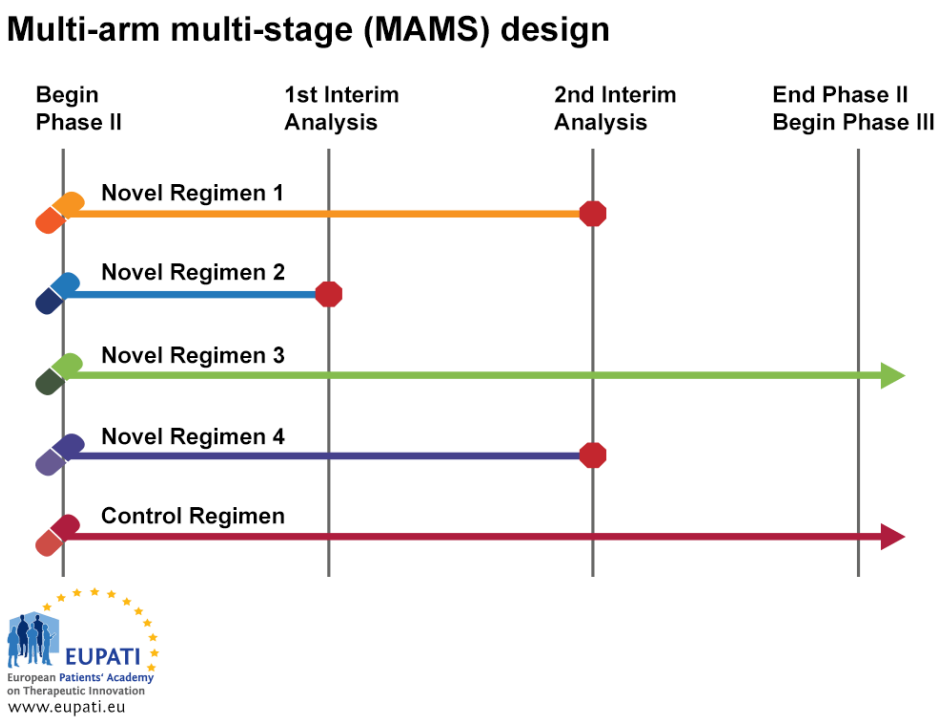
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Multi-arm multi-stage design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Mams-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/u0g0nr14gg0rsy2f9kx9bu15dgor2i70

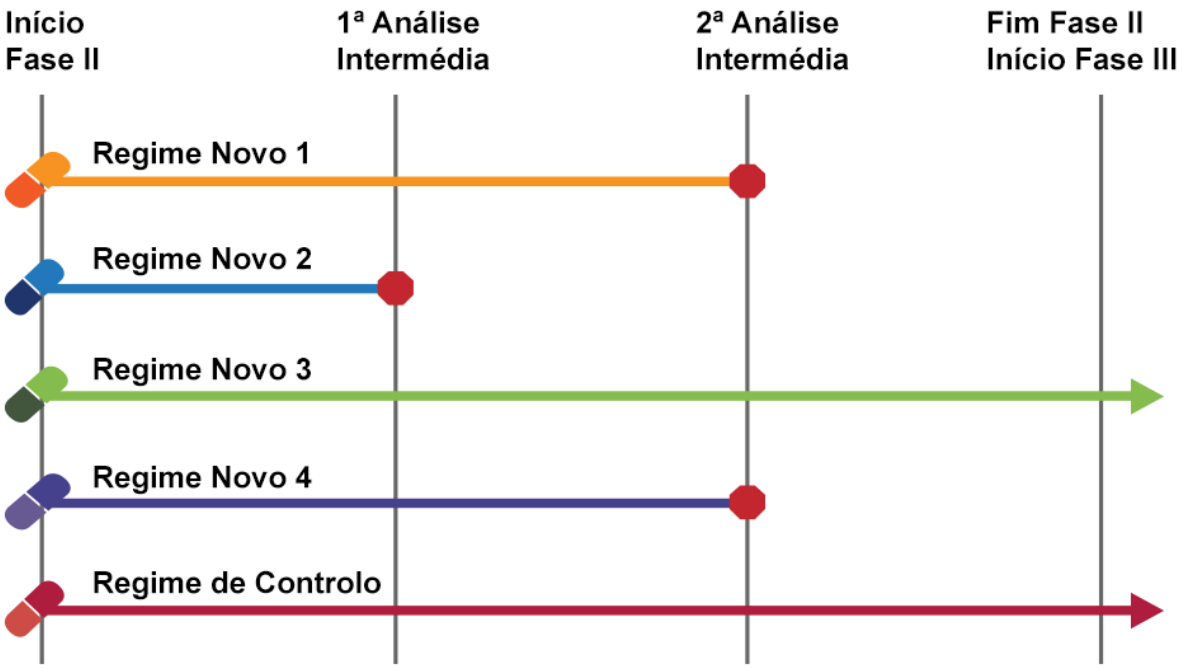
Cut and paste image here:



Media Source Note: Please indicate	Treatment Action Group; EUPAT

where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa um ensaio de desenho multifaseado de vários braços (MAMS). O MAMS permite analisar em simultâneo vários tratamentos contra um só braço de controlo. Neste exemplo, há quatro regimes novos e um regime de controlo. O ensaio MAMS começa no início da fase II. Há duas análises intermédias planeadas entre o início da Fase II/início da Fase III. O regime de controlo continua durante o ensaio até ao fim da Fase II/Início Fase III. O regime novo 1 é interrompido na segunda análise intermédia. O regime novo 2 é interrompido na primeira análise intermédia. O regime novo 3 continua até ao fim da Fase II/início da Fase III. O regime novo 4 é interrompido após a segunda análise intermédia.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esquema que representa um ensaio de desenho multifaseado de vários braços (MAMS). O MAMS permite analisar em simultâneo vários tratamentos contra um só braço de controlo. Neste exemplo, há quatro regimes novos e um regime de controlo. O ensaio MAMS começa no início da fase II. Há duas análises intermédias planeadas entre o início da Fase II/início da Fase III. O regime de controlo continua durante o ensaio até ao fim da Fase II/Início Fase III. O regime novo 1 é interrompido na segunda análise intermédia. O regime novo 2 é interrompido na primeira análise intermédia. O regime novo 3 continua até ao fim da Fase II/início da Fase III. O regime novo 4 é interrompido após a segunda análise intermédia.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O desenho de ensaio multifaseado de vários braços (MAMS) permite que vários tratamentos sejam testados em simultâneo com um único controlo.
Translation required: If media contains English language text, it **must** be translated	Yes

Ensaio multifaseado de vários braços (MAMS)



EUPATI
European Patients' Academy
on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

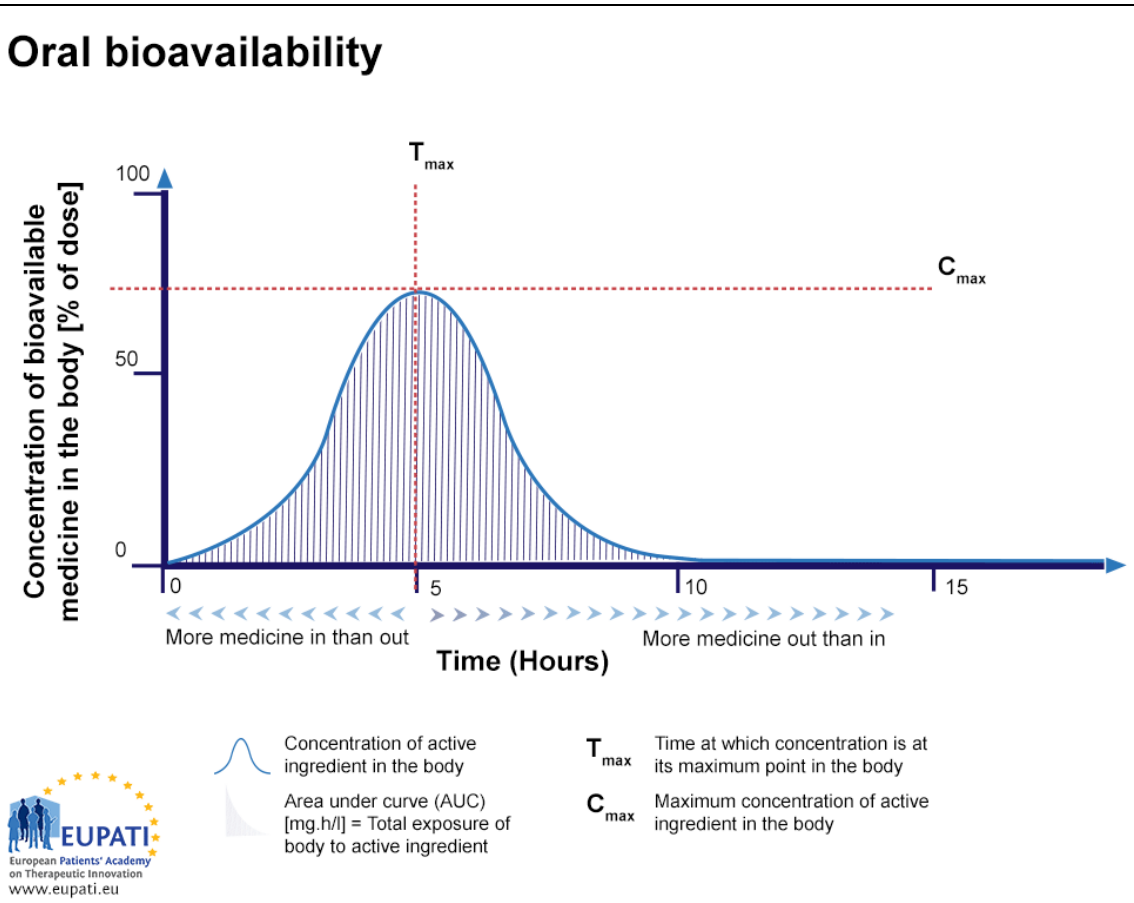
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	21.9.2015	PLATA Created	FINAL	2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

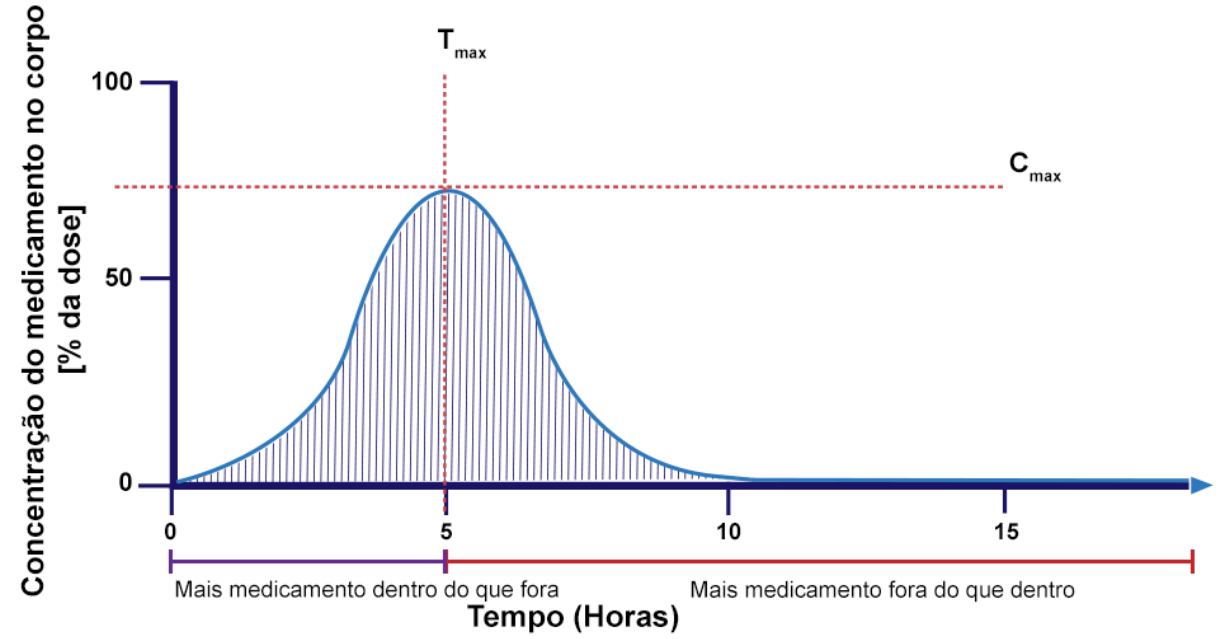
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Oral bioavailability
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Oral-bioavailability-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4660417118/oral-bioavailability-graph
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	Eupati, Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Representação gráfica da concentração do princípio ativo na corrente sanguínea. Avaliou-se a percentagem de princípio ativo, após o comprimido ser engolido, durante um período de 15 horas. A área sob a curva (AUC) está destacada a sombreado. T_{max} é o tempo ao fim do qual é atingida a concentração máxima de medicamento na corrente sanguínea, enquanto que C_{max} é a concentração máxima do medicamento na corrente sanguínea.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and	Representação gráfica da concentração do princípio ativo na corrente sanguínea. Avaliou-se a percentagem de princípio ativo, após o comprimido ser engolido, durante um período de 15 horas. A área sob a curva (AUC) está destacada a sombreado. T_{max} é o

descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	tempo ao fim do qual é atingida a concentração máxima de medicamento na corrente sanguínea, enquanto que C_{max} é a concentração máxima do medicamento na corrente sanguínea.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Avaliou-se a percentagem de princípio ativo, após o comprimido ser engolido, durante um período de 15 horas. A área sob a curva (AUC) está destacada a sombreado. T_{max} é o tempo ao fim do qual é atingida a concentração máxima de medicamento na corrente sanguínea, enquanto que C_{max} é a concentração máxima do medicamento na corrente sanguínea.
Translation required: If media contains English language text, it **must** be translated	YES

Biodisponibilidade oral



Concentração do princípio ativo no corpo

Área sob a curva (AUC) [mg.h/l] = Exposição total do corpo ao princípio ativo

T_{max} Tempo ao fim do qual é atingida a concentração máxima de medicamento na corrente sanguínea

C_{max} Concentração máxima do princípio ativo no corpo

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

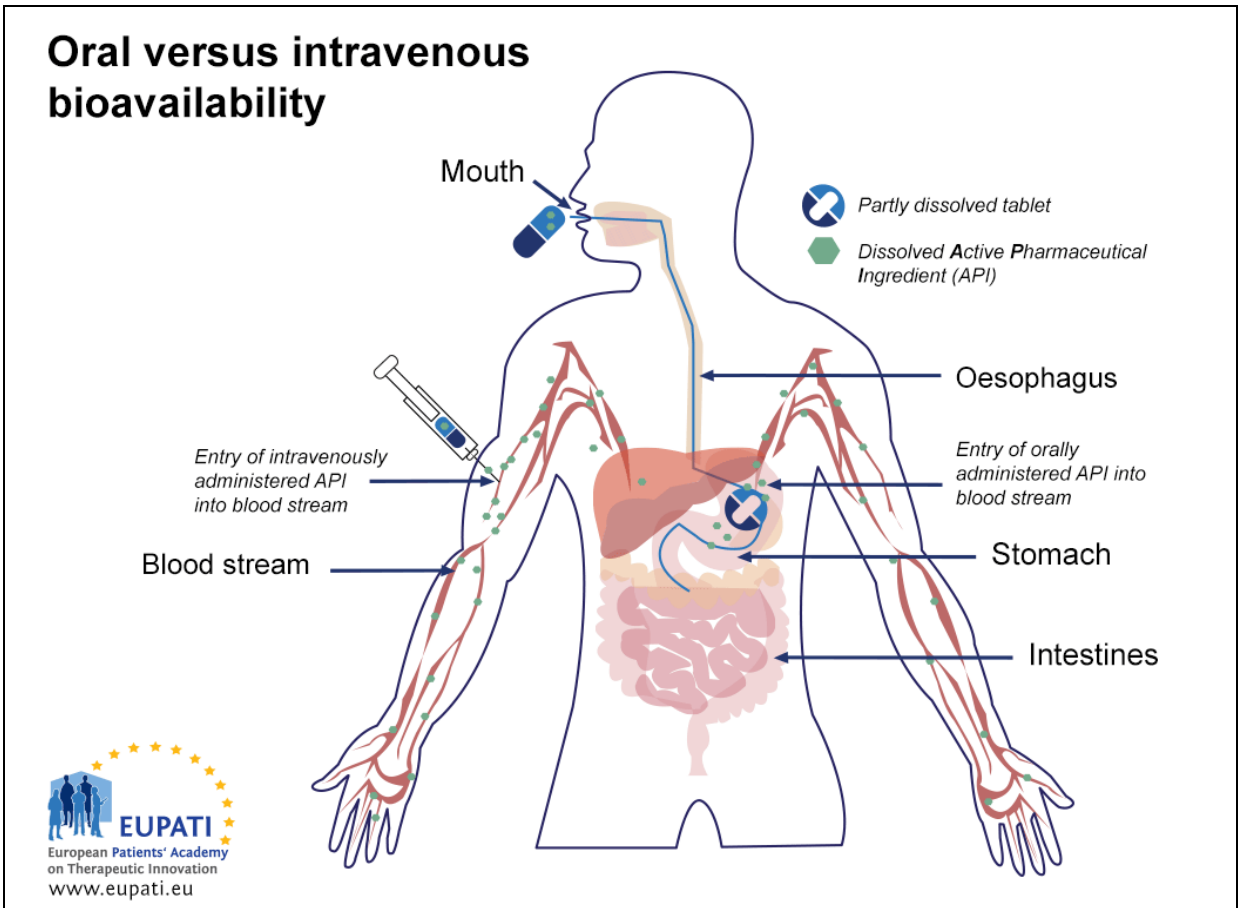
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	21.9.2015	PLATA Created; Image updated	FINAL	3

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

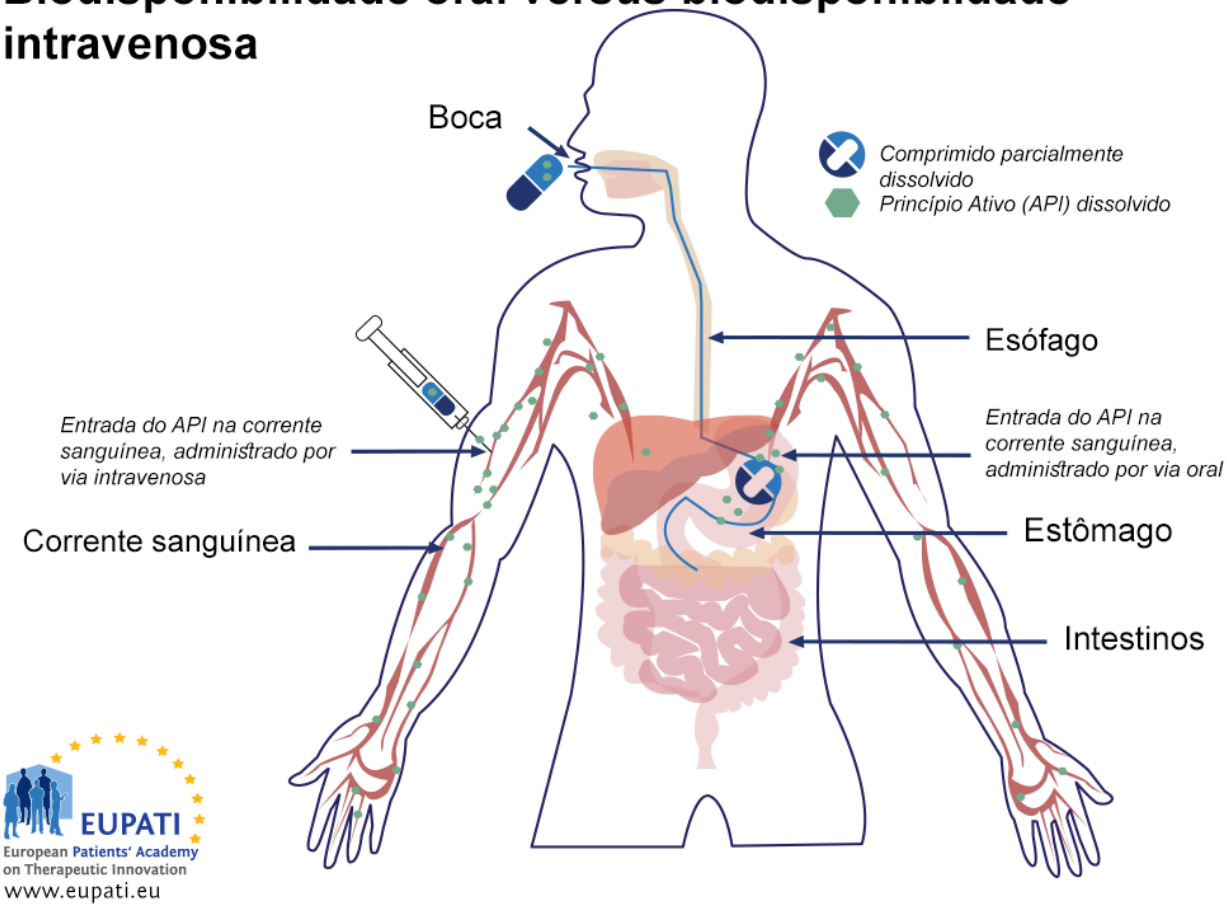
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Oral versus intravenous bioavailability
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Oral-vs-Intravenous-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4114426611/oral-v-intravenous-bioavailability
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	Eupati; Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diagrama que representa a diferença na biodisponibilidade com diferentes tipos de administração - oral e intravenosa. Quando um medicamento é administrado de forma intravenosa, o princípio ativo (API) dissolvido fica imediatamente disponível na corrente sanguínea. Quando um medicamento é administrado oralmente, viaja da boca ao estômago, através do esófago. É no estômago que o comprimido se dissolve. Só aí é que o princípio ativo dissolvido entra na corrente sanguínea.
Alt Text: Will be shown in case image/media fails to load/is prevented from	Diagrama que representa a diferença na biodisponibilidade com diferentes tipos de administração - oral e intravenosa. Quando um medicamento é administrado de forma

loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	intravenosa, o princípio ativo (API) dissolvido fica imediatamente disponível na corrente sanguínea. Quando um medicamento é administrado oralmente, viaja da boca ao estômago, através do esófago. É no estômago que o comprimido se dissolve. Só aí é que o API dissolvido entra na corrente sanguínea.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Comparação da biodisponibilidade de princípios ativos administrados por via oral e via intravenosa. Um princípio ativo é considerado “biologicamente disponível” (biodisponível) quando entra na corrente sanguínea.
Translation required: If media contains English language text, it **must** be translated	Yes

Biodisponibilidade oral versus biodisponiblidade intravenosa



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

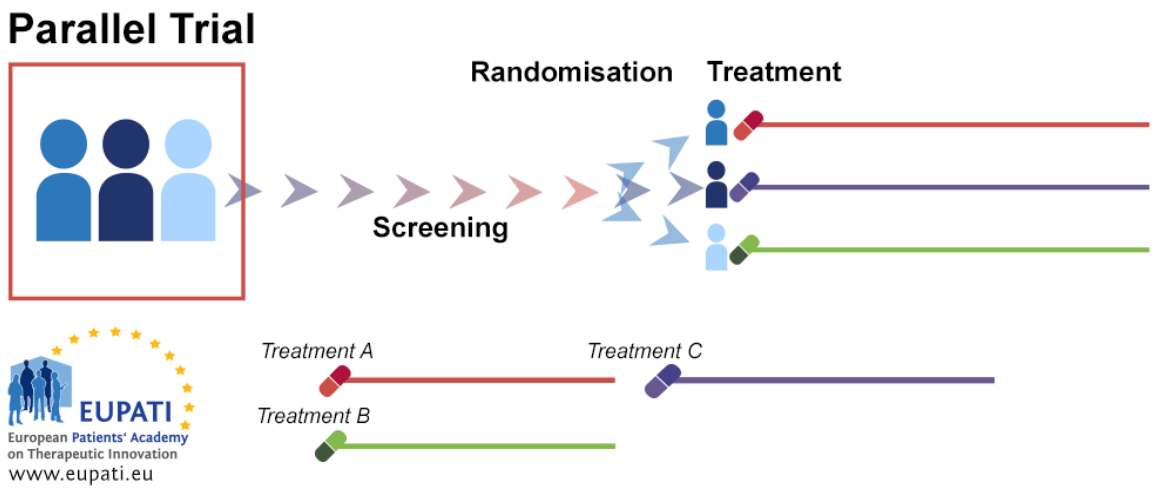
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	26.8.2015	PLATA Created	Final	1.1
Heidi Scherz	9.9.2015	PLATA Updated	FINAL	2
Heidi Scherz	21.9.2015	Final updates	FINAL	3

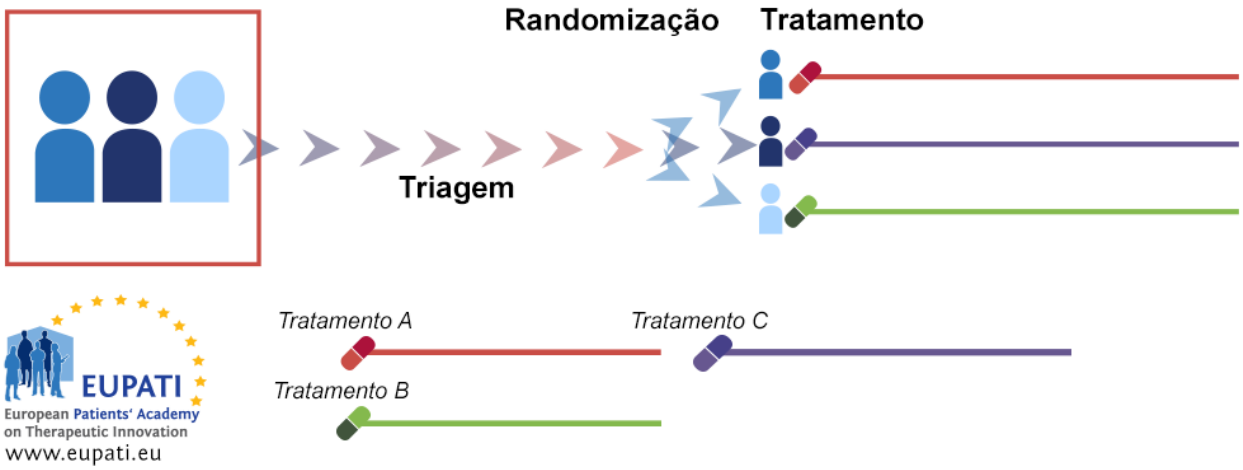
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Parallel group trial design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Parallel-trial-v3_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4305673405/parallel-trial
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI; Bonnie Le Page
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not**	Diagrama que representa um ensaio com desenho paralelo por grupos. Após a triagem, os doentes são distribuídos aleatoriamente em diferentes grupos de tratamento. Os doentes permanecem nestes braços de tratamento durante todo o ensaio, na fase de análise e durante as atividades de seguimento.

rely on article context for meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Diagrama que representa um ensaio com desenho paralelo por grupos. Após a triagem, os doentes são distribuídos aleatoriamente em diferentes grupos de tratamento. Os doentes permanecem nestes braços de tratamento durante todo o ensaio, na fase de análise e durante as atividades de seguimento.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Após a triagem, os doentes são distribuídos aleatoriamente em grupos diferentes de tratamento. Os doentes permanecem nestes braços de tratamento durante todo o ensaio, na fase de análise e durante as atividades de seguimento.
Translation required: If media contains English language text, it **must** be translated	Yes

Ensaio paralelo



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	31.8.2015	PLATA Created	Draft	1.1
Heidi Scherz	23.11.2015	Updated PLATA	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

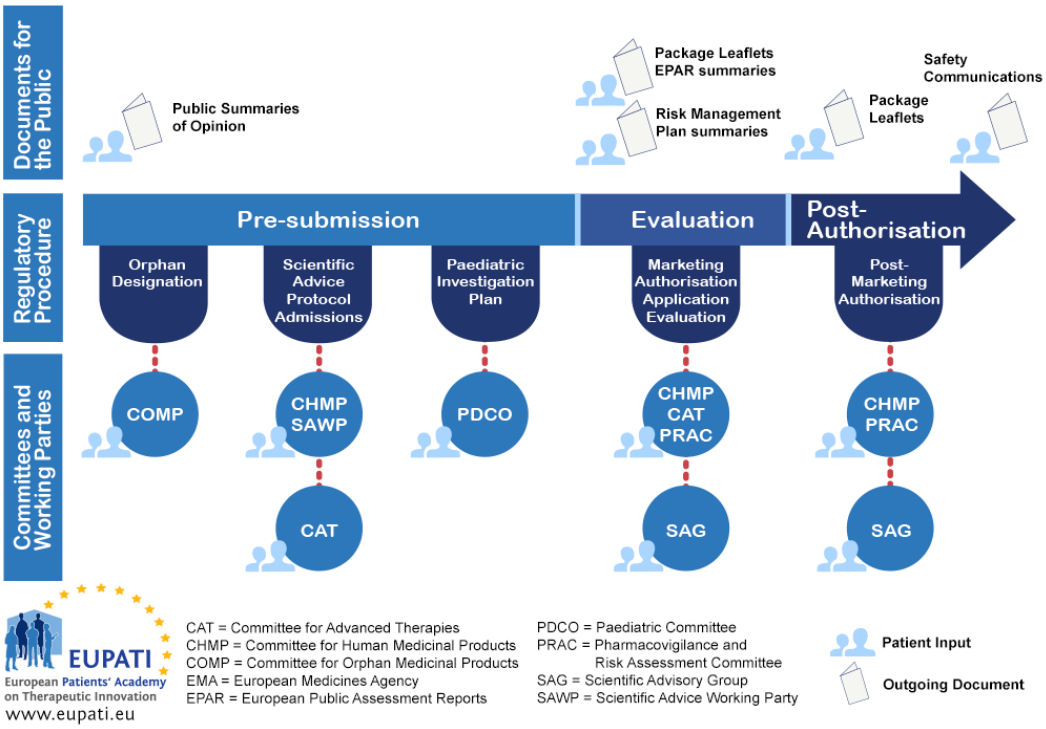
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata

Complete file metadata as fully as possible.

Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Patient involvement in EMA activities
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Patient-involvement-EMA-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4370361734/Patient-involvement-EMA

Cut and paste image here:

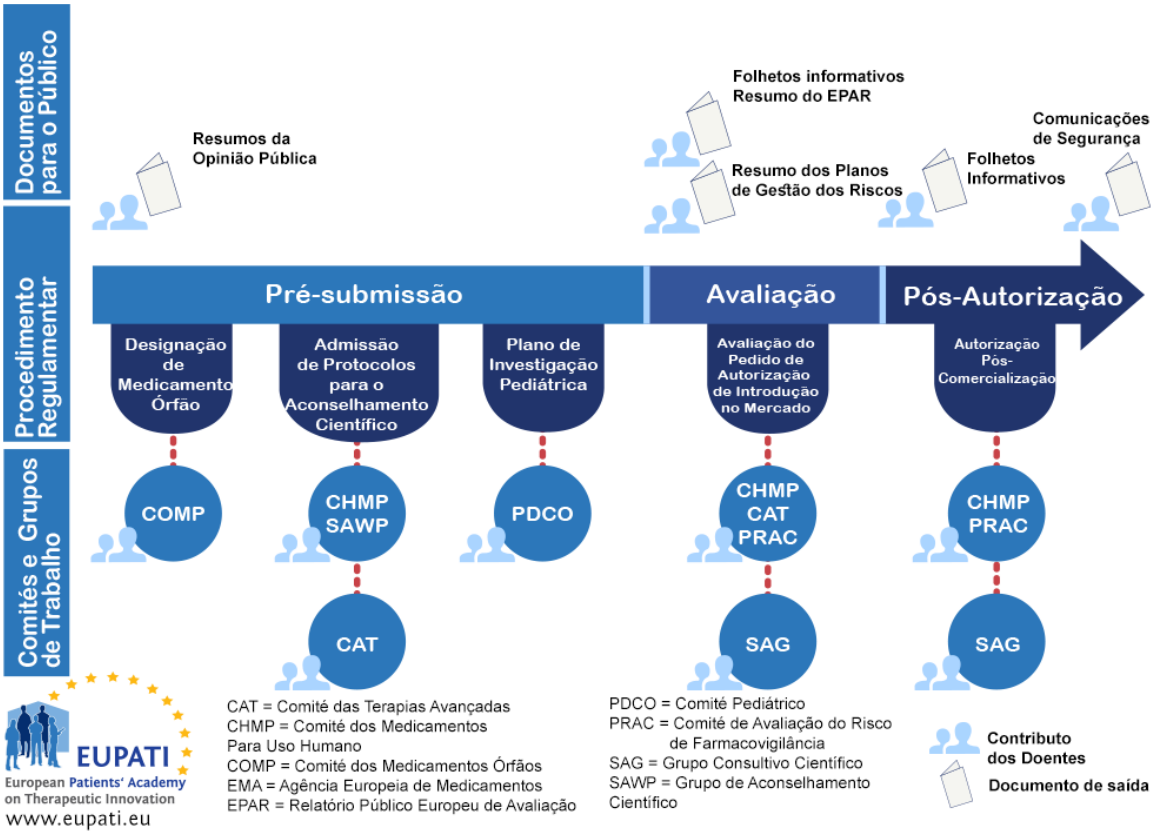


Media Source Note: Please indicate where the image was taken from.	Adapted from European Medicines Agency (2014). *Annex II: EMA activities where patients and consumers are involved*. Retrieved 31 August, 2015 from http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/12/WC500179568.pd
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for	Um diagrama que representa as várias atividades da Agência Europeia de Medicamentos (EMA), os comités associados e grupos de trabalho, os documentos são produzidos para o público e a participação dos doentes nesses comités, grupos e documentos. São descritas três fases: Pré-Apresentação, Avaliação e Pós Autorização. Durante cada fase, há diferentes procedimentos regulamentares. Cada procedimento regulamentar está associado a um ou mais comités ou grupos de trabalho. Alguns destes procedimentos estão também relacionados com documentos para o público. A opinião dos doentes é tomada em consideração nos comités, grupos de trabalho e documentos. O primeiro procedimento regulamentar da fase de pré-apresentação é "Designação do Medicamento Órfão". O comité associado é o Comité dos Medicamentos Órfãos

meaning.	(COMP). No início da Designação do Medicamento Órfão, os Resumos Públicos do Parecer são preparados como um documento para o público. O procedimento seguinte da fase de pré-apresentação é o "Admissão de Protocolos para o Aconselhamento Científico". Os comités associados são o Comité dos Medicamentos para Uso Humano (CHMP), o Grupo de Trabalho para Pareceres Científicos (SAWP), e o comité das Terapias Avançadas (CAT). Não há documentos associados para o público durante este procedimento. O procedimento final da fase de pré-apresentação é o Plano de Investigação Pediátrica. Não há documentos associados para o público durante este procedimento. A segunda fase é "Avaliação". Há apenas um procedimento regulamentar que ocorre nesta fase – a Avaliação do Pedido de Autorização de Introdução no Mercado. Os comités associados a este procedimento são o CHMP, o CAT, o Comité de Avaliação do Risco em Farmacovigilância (PRAC), e o Grupo Consultivo Científico (SAG). Durante este procedimento, são preparados vários documentos para o público: Folhetos informativos, Resumo do Relatório Público Europeu de Informação, e Resumos provisórios do Plano de Gestão do Risco. A Terceira e última fase é "Pós-Autorização". Há apenas um procedimento regulamentar nesta fase: Autorização Pós-Comercialização. Os comités associados com a Autorização Pós-Comercialização são o CMHP, O PRAC e o SAG. Nesta fase, os documentos disponibilizados para o público são os Folhetos informativos renovados e as comunicações de segurança.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be	Um diagrama que representa as várias atividades da Agência Europeia de Medicamentos (EMA), os comités associados e grupos de trabalho, os documentos são produzidos para o público e a participação dos doentes nesses comités, grupos e documentos.

more descriptive than caption. It should **not** rely on article context for meaning.	
Caption: Will be displayed under media in the article body. Must begin with title of media.	Os doentes podem colaborar de várias formas com a EMA durante o procedimento regulamentar.
Translation required: If media contains English language text, it **must** be translated	Yes

O envolvimento dos doentes na EMA



- Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	27.10.2016	PLATA Created	Draft	1.1
Matthew May	09.11.2016	PLATA checked	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Obligatory pharmacy logo
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	obligatory-pharmacy-logo-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/md8kzp8ckomj9xaxrb9gntkkl6jly6rs
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	http://ec.europa.eu/health/files/eu-logo/logosancointernet_charte_v2.pdf
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely	Logótipo comum das farmácias que vendem online na UE (versão do Reino Unido) que consiste numa cruz branca sobre quatro linhas verdes no topo do logótipo, bandeira do país do site em causa e texto com um link para verificar se o website está a funcionar de forma legal. O logótipo surge como uma medida para ajudar os consumidores a

on article context for meaning.	identificarem as farmácias e revendedores que aprovados e que fornecem medicamentos autorizados..
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Logótipo comum das farmácias que vendem online na UE (versão do Reino Unido) que consiste numa cruz branca sobre quatro linhas verdes no topo do logótipo, bandeira do país do site em causa e texto com um link para verificar se o website está a funcionar de forma legal. O logótipo surge como uma medida para ajudar os consumidores a identificarem as farmácias e revendedores aprovados e que fornecem medicamentos .
Caption: Will be displayed under media in the article body. Must begin with title of media.	Logótipo comum das farmácias que vendem online na UE (versão do Reino Unido) que deve estar presente nos websites de todos os revendedores online de medicamentos na UE.
Translation required: If media contains English language text, it **must** be translated	Yes, but instead, use the national versions of the logo from the original document here: http://ec.europa.eu/health/files/eu-logo/logosancointernet_charte_v2.pdf

A Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

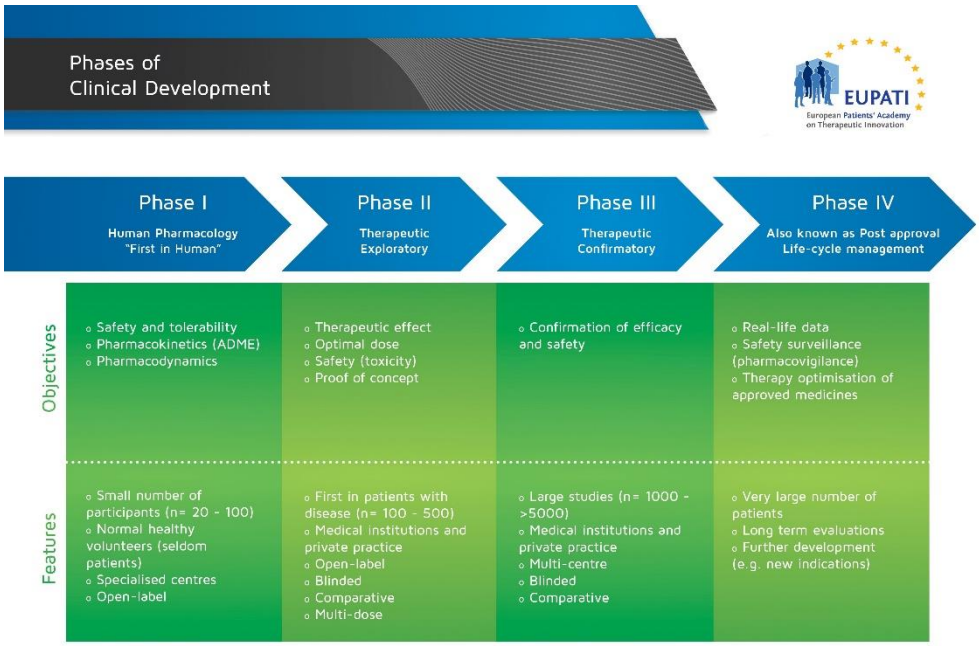
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	25.8.2015	PLATA Created	Draft	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Phases of clinical development
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	phases-clinical-development-v1_EN.jpg
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4297790721/phases-clinical-development

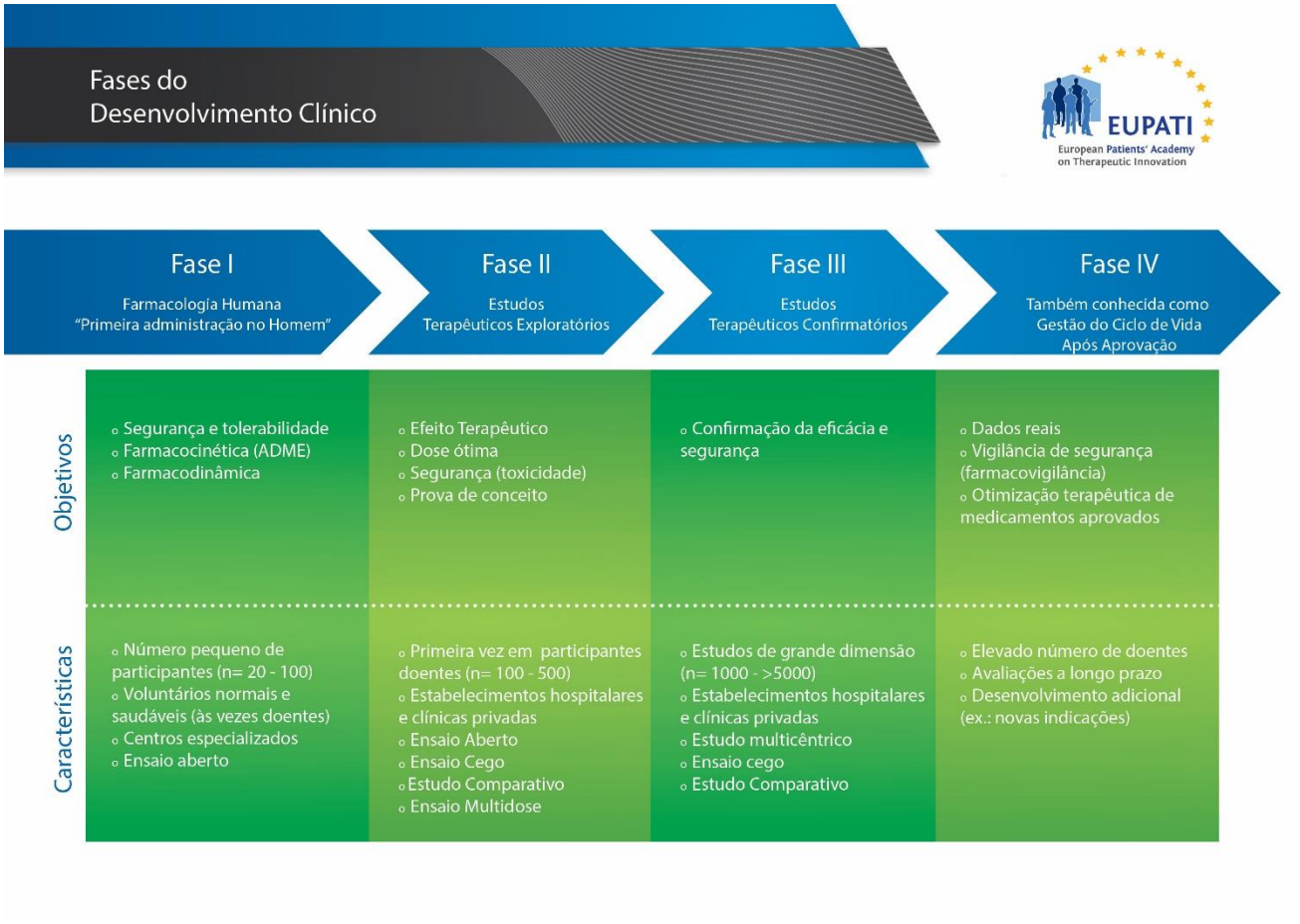
Cut and paste image here:



Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Diagrama que explica os detalhes das quatro fases do desenvolvimento clínico no que toca aos seus objetivos e características. Fase I, também conhecida como “Primeira administração no Homem”, diz respeito à farmacologia humana. Os objetivos desta fase são: Segurança e tolerabilidade, Farmacocinética (ADME), e Farmacodinâmica. As características são: pequeno número de participantes (n = 20-100), voluntários normais e saudáveis (às vezes doentes), centros especializados e ensaio aberto (sem ocultação). A Fase II é a fase dos estudos terapêuticos exploratórios. A Fase II tem como objetivos descobrir o efeito terapêutico, dose ótima, segurança (toxicidade) e prova de conceito. As características da Fase II são: primeira administração em participantes doentes (n = 100 – 500), estabelecimentos hospitalares e clínicas privadas, ensaio aberto, cego, comparativo e de multidose. A Fase III é a fase dos estudos terapêuticos confirmatórios. O objetivo desta fase é a confirmação da eficácia e segurança. As características da Fase III são: estudos de grade dimensão (n = 1000 – >5000), estabelecimentos hospitalares e clínicas privadas, estudo multicêntrico, ensaio cego e comparativo. A Fase IV é também conhecida por Gestão do Ciclo de Vida Após Aprovação. Tem como objetivos: dados reais, vigilância da segurança (farmacovigilância), e otimização terapêutica dos medicamentos aprovados. As suas características são: elevado número de doentes, avaliações a longo prazo e desenvolvimento adicional (ex.: novas indicações).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for	Diagrama que explica os detalhes das quatro fases do desenvolvimento clínico no que toca aos seus objetivos e características. Fase I, também conhecida como “Primeira administração no Homem”, diz respeito à farmacologia humana. Os objetivos desta fase são: Segurança e tolerabilidade, Farmacocinética (ADME), e Farmacodinâmica. As características são: pequeno

meaning.	número de participantes (n = 20-100), voluntários normais e saudáveis (às vezes doentes), centros especializados e ensaio aberto (sem ocultação). A Fase II é a fase dos estudos terapêuticos exploratórios. A Fase II tem como objetivos descobrir o efeito terapêutico, dose ótima, segurança (toxicidade) e prova de conceito. As características da Fase II são: primeira administração em doentes (n = 100 – 500), estabelecimentos hospitalares e clínicas privadas, ensaio aberto, cego, comparativo e de multidose. A Fase III é a fase dos estudos terapêuticos confirmatórios. O objetivo desta fase é a confirmação da eficácia e segurança. As características da Fase III são: estudos de grade dimensão (n = 1000 – >5000), estabelecimentos hospitalares e clínicas privadas, estudo multicêntrico, ensaio cego e comparativo. A Fase IV é também conhecida por Gestão do Ciclo de Vida Após Aprovação. Tem como objetivos: dados reais, vigilância da segurança (farmacovigilância), e otimização terapêutica dos medicamentos aprovados. As suas características são: elevado número de doentes, avaliações a longo prazo e desenvolvimento adicional (ex.: novas indicações).
Caption: Will be displayed under media in the article body. Must begin with title of media.	As quatro fases do desenvolvimento clínico diferem no que toca aos seus objetivos e características.
Translation required: If media contains English language text, it **must** be translated	Yes


Fases do
Desenvolvimento Clínico
EUPATI
European Patients' Academy
on Therapeutic Innovation
Fase I
Farmacologia Humana
"Primeira administração no Homem"
Fase II
Estudos
Terapêuticos Exploratórios
Fase III
Estudos
Terapêuticos Confirmatórios
Fase IV
Também conhecida como
Gestão do Ciclo de Vida
Após Aprovação
Objetivos
Características
Segurança e tolerabilidade
Farmacocinética (ADME)
Farmacodinâmica
Efeito Terapêutico
Dose ótima
Segurança (toxicidade)
Prova de conceito
Confirmação da eficácia e segurança
Dados reais
Vigilância de segurança (farmacovigilância)
Otimização terapêutica de medicamentos aprovados
Número pequeno de participantes (n= 20 - 100)
Voluntários normais e saudáveis (às vezes doentes)
Centros especializados
Ensaio aberto
Primeira vez em participantes doentes (n= 100 - 500)
Estabelecimentos hospitalares e clínicas privadas
Ensaio Aberto
Ensaio Cego
Estudo Comparativo
Ensaio Multidose
Estudos de grande dimensão (n= 1000 - >5000)
Estabelecimentos hospitalares e clínicas privadas
Estudo multicêntrico
Ensaio cego
Estudo Comparativo
Elevado número de doentes
Avaliações a longo prazo
Desenvolvimento adicional (ex.: novas indicações)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

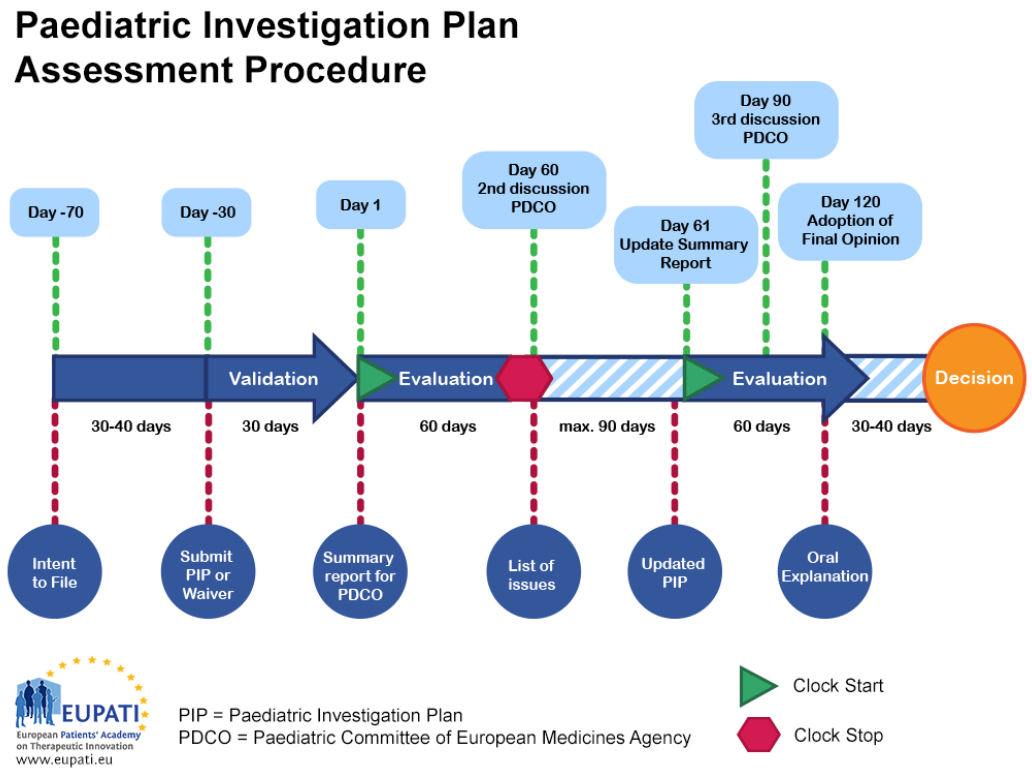
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA Created	Draft	1.1
Matthew May	13.01.2016	Fields updated and finalised	FINAL	1.1

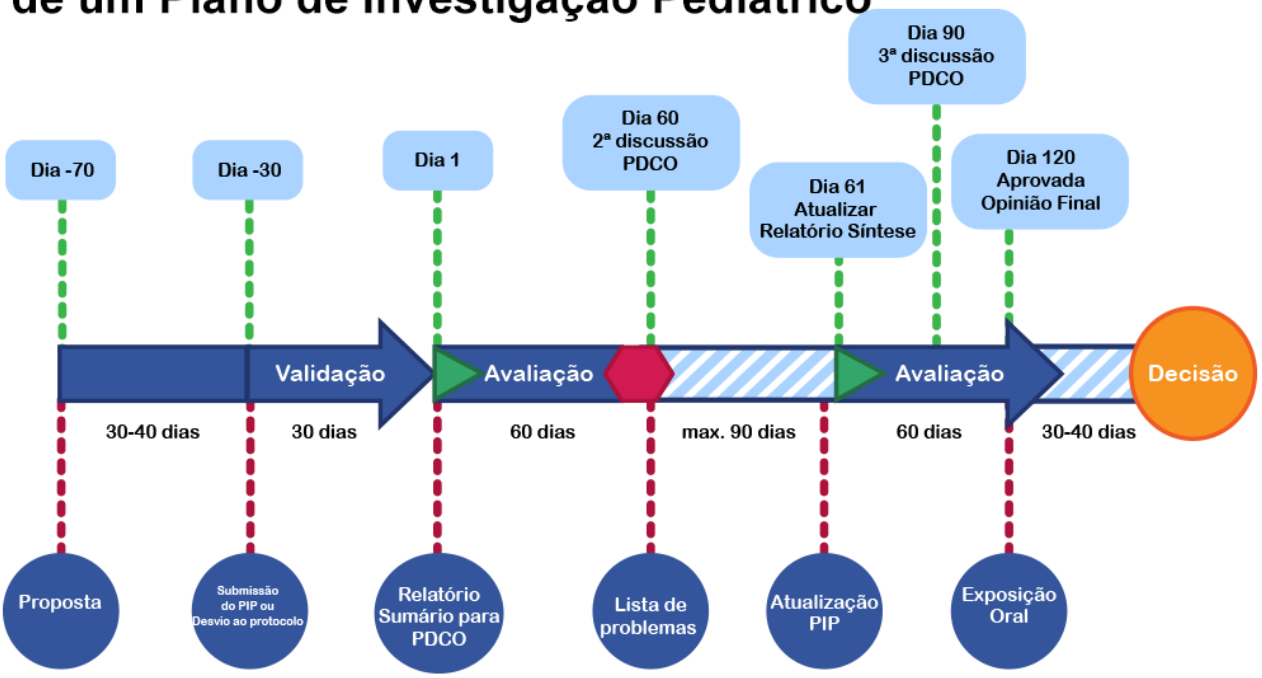
***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Paediatric Investigation Plan Assessment Procedure
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	PIP-decision-process-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/5356114209/PIP-decision-process
Cut and paste image here: 	
Media Source Note: Please indicate where	EUPATI, Bonnie Le Page, Heidi Scherz

the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa o processo de avaliação de um Plano de Investigação Pediátrico (PIP).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Este esquema dá uma visão geral do processo de avaliação de um Plano de Investigação Pediátrico. O processo de revisão assume a forma de um procedimento de 120 dias (excluindo a possível paragem ao dia 60, que pode durar até 90 dias). O processo de revisão é realizado pelo Comité Pediátrico da Agência Europeia de Medicamentos.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O Plano de Investigação Pediátrico é avaliado pelo Comité Pediátrico da Agência Europeia de Medicamentos e segue um procedimento fixo com prazos definidos.
Translation required: If media contains English language text, it **must** be translated	Yes

Processo de Avaliação de um Plano de Investigação Pediátrico



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

PIP = Plano de Investigação Pediátrico
PDCO = Comité Pediátrico da Agência Europeia de Medicamentos

Início
Paragem

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

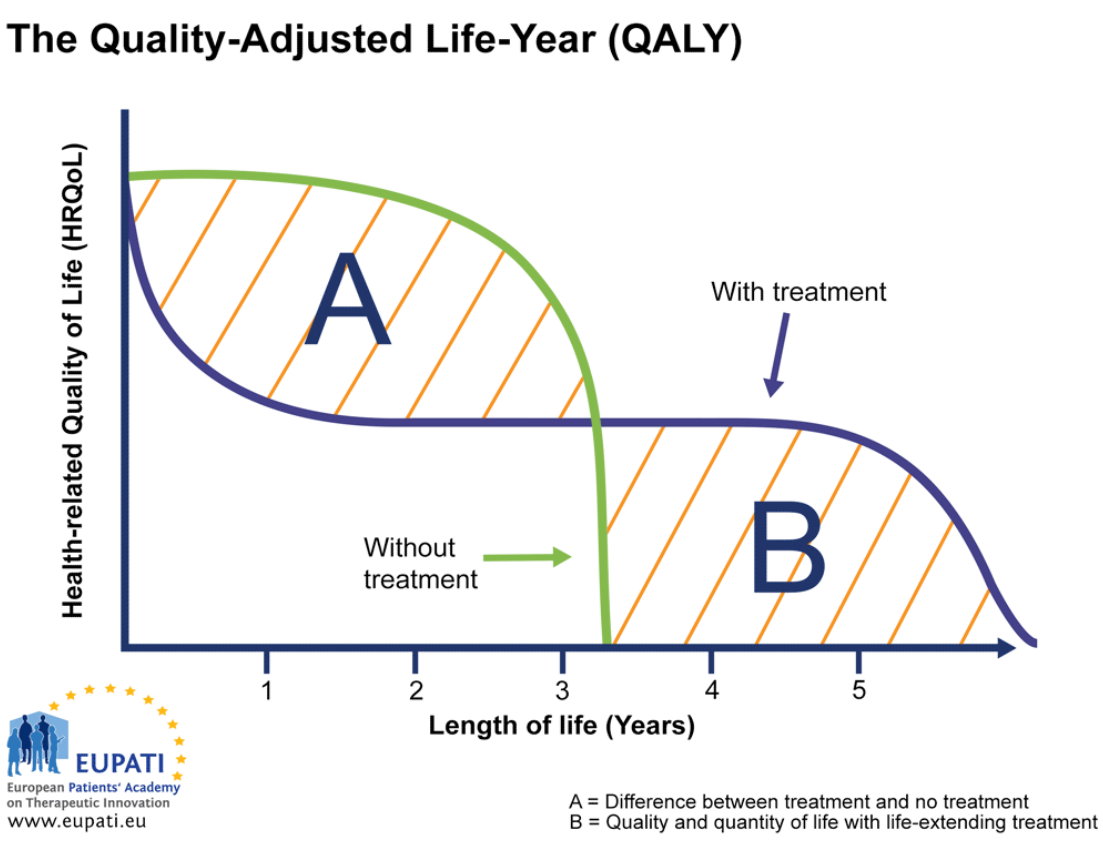
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	07.03.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

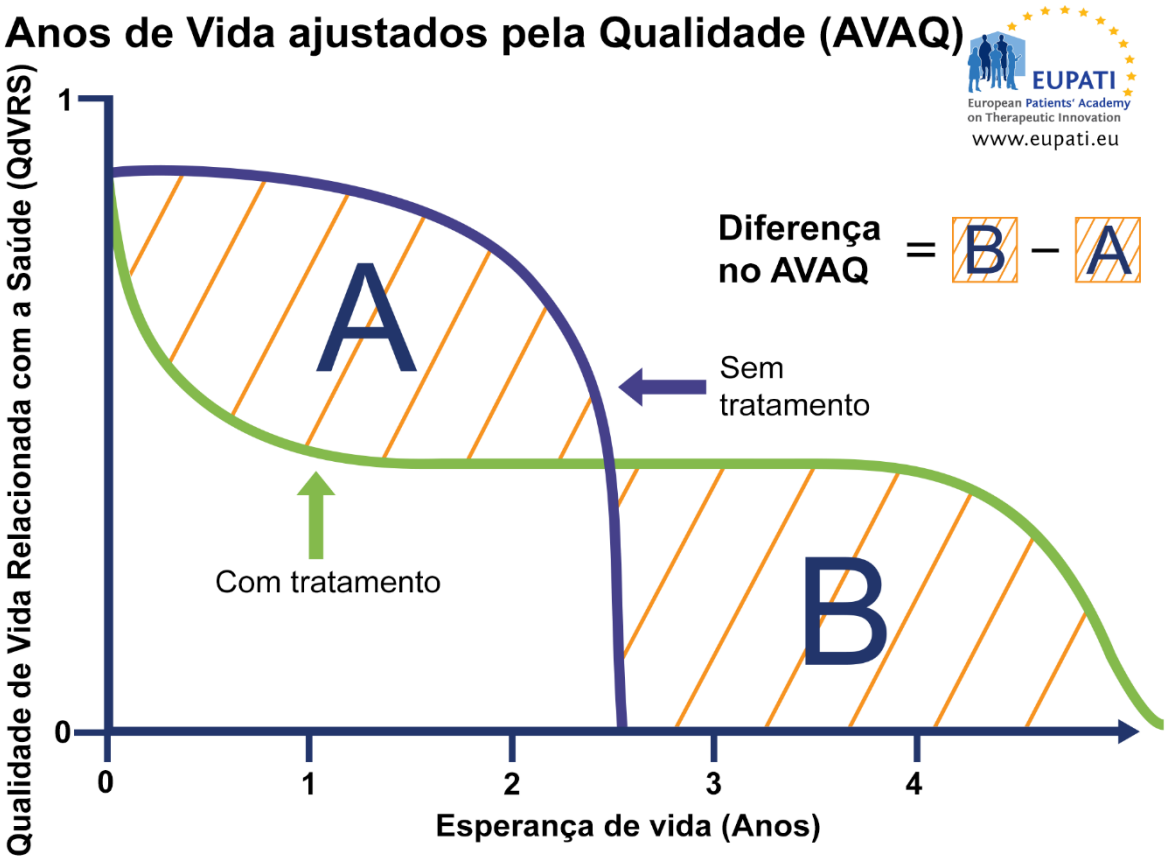
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The Quality Adjusted Life Year
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	QALY-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/6520894593/QALY

Cut and paste image here:



Media Source	EUPATI

Note: Please indicate where the image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	O gráfico nesta imagem mostra o cálculo dos anos de vida ajustados pela qualidade (AVAQ); uma representação da expectativa da vida ajustada à qualidade da mesma. Ao colocar a esperança de vida (em anos) no eixo horizontal (X) e a QdVRS no eixo vertical (Y), é possível evidenciar a relação da qualidade com a quantidade de vida através de uma terapêutica que aumenta a esperança de vida. Existem duas linhas no gráfico: uma representando a situação “Com Tratamento” e a outra “Sem Tratamento”. Neste exemplo, o tratamento aumenta a vida por dois anos com uma redução de aproximadamente 50% da qualidade de vida. A área total sob a curva (AUC) é aproximadamente a mesma para as duas linhas, e as duas áreas são quase iguais. Neste cenário, dois anos de aumento de vida são multiplicados por uma redução de 50% de qualidade de vida o que pode ser considerado como equivalente a um ano em perfeita saúde.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Gráfico que representa os anos de vida ajustados pela qualidade.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Os anos de vida ajustados pela qualidade (AVAQ) são uma medida na economia da saúde que representa o número adicional de anos que uma pessoa vive em virtude de um tratamento, tendo em consideração a qualidade de vida desses mesmos anos.
Translation required: If media contains English language text, it **must** be translated	Yes


Anos de Vida ajustados pela Qualidade (AVAQ)
EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu
Diferença no AVAQ = B – A
A
B
Sem tratamento
Com tratamento
Qualidade de Vida Relacionada com a Saúde (QdVRS)
1
0
0
1
2
3
4
Esperança de vida (Anos)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

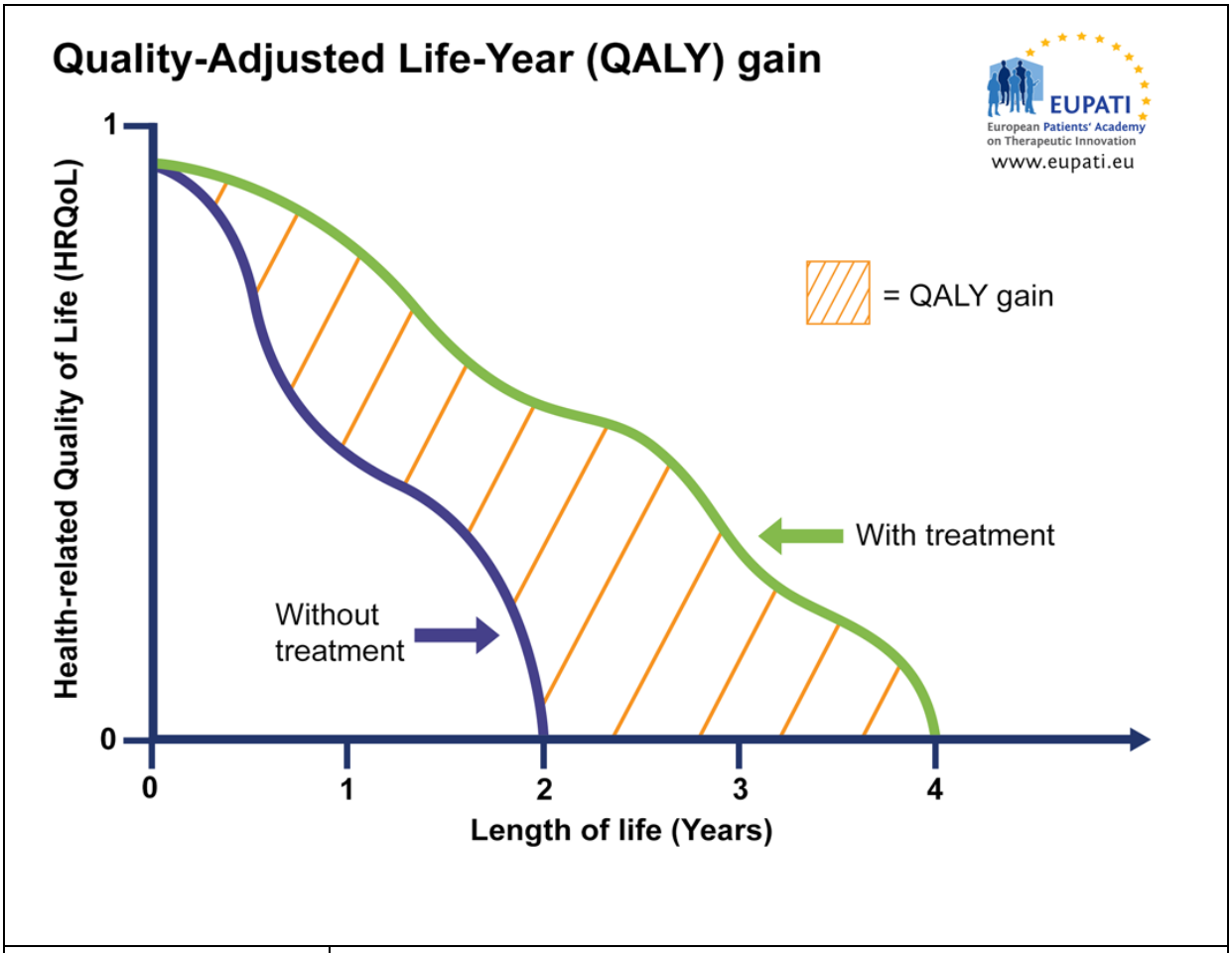
Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	31.05.2016	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

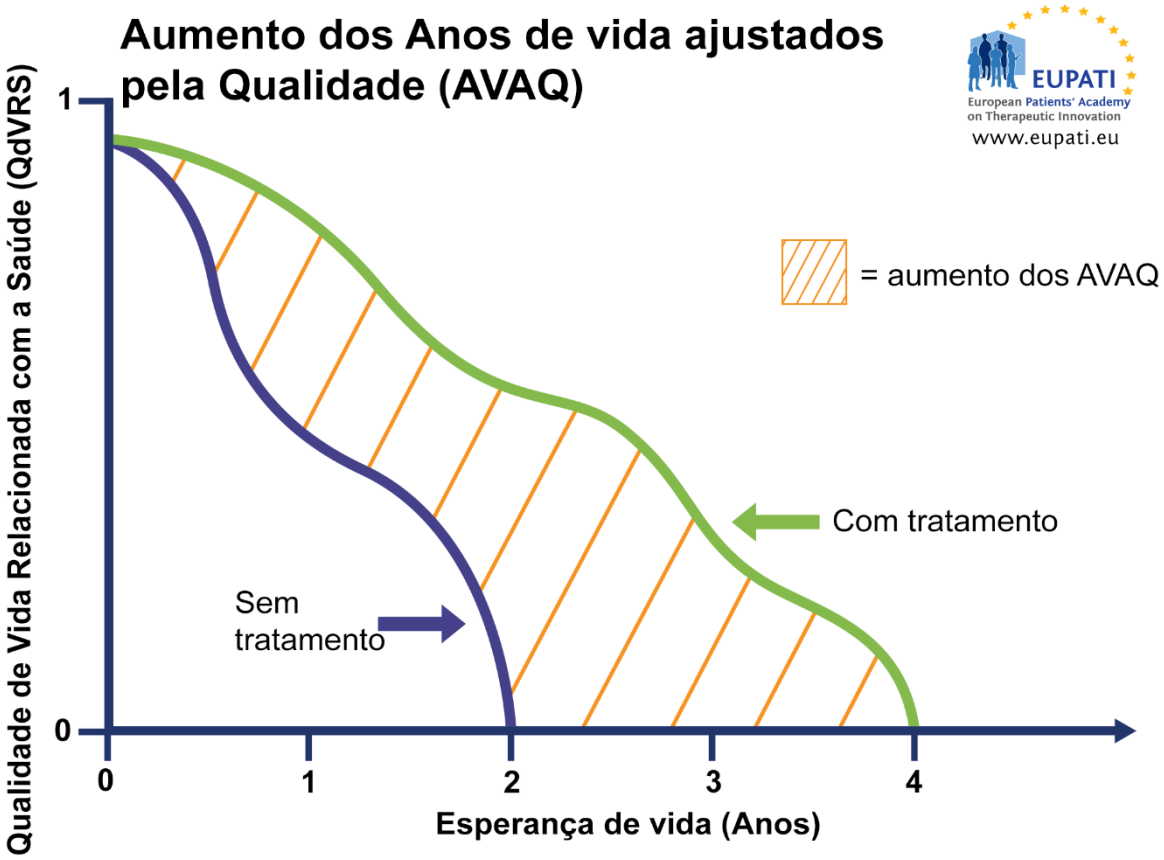
Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Quality-Adjusted Life-Year (QALY) gain
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	QALY-gain_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/l7at72n77dx7i8bpotktim1pv490g6wm
Cut and paste image here:	



Media Source Note: Please indicate where the image was taken from.	EUPATI
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esta imagem mostra as alterações na Qualidade de Vida Relacionada com a Saúde (QdVRS) ao longo do tempo, sem tratamento, permitindo visualizar o aumento da QdSRV, assim como da esperança de vida, resultando num aumento dos anos de vida ajustados pela qualidade(AVAQ). Ao colocar a esperança de vida (em anos) no eixo horizontal (X) e a QdVRS no eixo vertical (Y), é possível evidenciar a relação da qualidade e da quantidade de vida com um tratamento que aumenta a esperança de vida. Existem duas linhas no gráfico: uma que representa a situação “Com Tratamento” e a outra a situação “Sem Tratamento”.

	A diferença na área sob a curva (AUC) representada pela área laranja, mostra o aumento dos AVAQ em alguém que faz o tratamento em comparação com alguém que não o faz.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Gráfico que representa o aumento anos de vida ajustados pela qualidade de um doente a receber tratamento, em relação a um doente que não recebe tratamento.
Caption: Will be displayed under media in the article body. Must begin with title of media.	O aumento dos anos de vida ajustados pela qualidade (AVAQ) de um doente a receber tratamento em relação a um doente que não recebe tratamento pode ser representado visualmente. A diferença na área sob a curva (AUC) representada pela área laranja, mostra o aumento de AVAQ em alguém que faz o tratamento em comparação com alguém que não o faz.
Translation required: If media contains English language text, it **must** be translated	Yes


Aumento dos Anos de vida ajustados pela Qualidade (AVAQ)
EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu
= aumento dos AVAQ
Com tratamento
Sem tratamento
Qualidade de Vida Relacionada com a Saúde (QdVRS)
1
0
0
1
2
3
4
Esperança de vida (Anos)

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

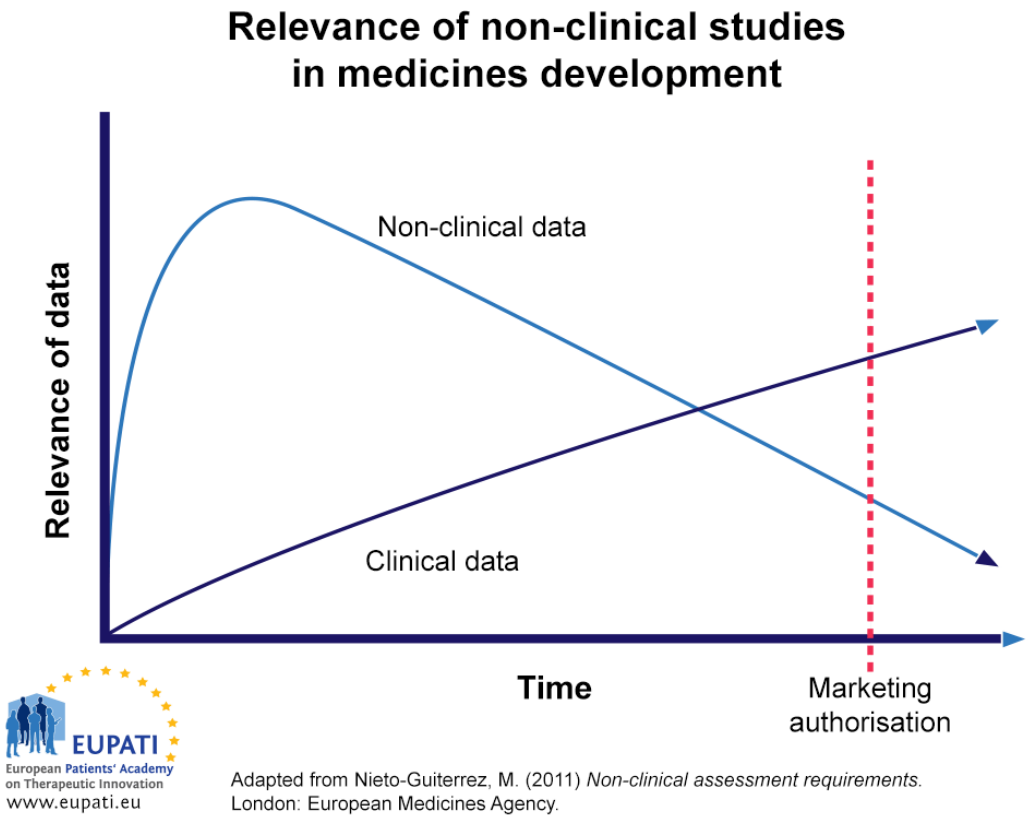
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	9.9.2015	PLATA Updated for new version	FINAL	2
Heidi Scherz	23.9.2015	PLATA updated, final version	FINAL	4

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Relevance of non-clinical studies in medicines development
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Relevance-non-clinical-data-v2_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4286180767/relevance-non-clinical-data

Cut and paste image here:

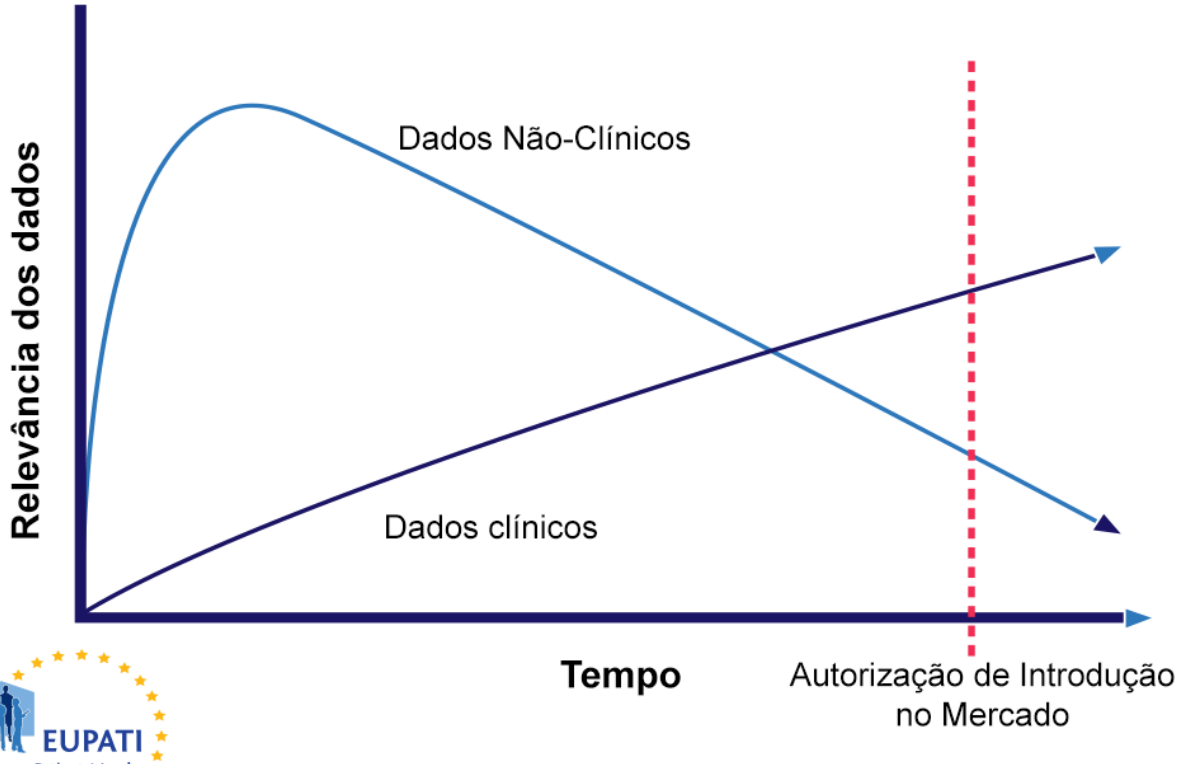


Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Media Source Note: Please indicate where the image was taken from.	EUPATI. Adapted from Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements*. London: European Medicines Agency.
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Gráfico que apresenta a importância e relevância dos dados clínicos e não-clínicos no desenvolvimento de medicamentos ao longo do tempo. O grau de relevância está representado no eixo Y; o tempo é indicado no eixo X. No início do período de desenvolvimento, a relevância dos dados não-clínicos cresce exponencialmente, enquanto que a relevância dos dados clínicos sobe de forma gradual. A certa altura, perto do início do período de desenvolvimento, a relevância dos dados não-clínicos atinge o seu auge, e a partir desse momento começa a diminuir de forma gradual, à medida que a relevância dos dados clínicos continuam a subir gradualmente. Em determinado ponto, algures antes da Autorização de Introdução no Mercado (que é um evento marcado no eixo dos XX), a relevância dos dados clínicos oculta a dos dados não-clínicos. Esta tendência mantém-se até à Autorização de Introdução no Mercado e também após, com os dados clínicos a tornarem-se mais relevantes à medida que os dados não-clínicos perdem a sua relevância.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Gráfico que apresenta a importância e relevância dos dados clínicos e não-clínicos no desenvolvimento de medicamentos ao longo do tempo. O grau de relevância está representado no eixo Y; o tempo é indicado no eixo X. No início do período de desenvolvimento, a relevância dos dados não-clínicos cresce exponencialmente, enquanto que a relevância dos dados clínicos sobe de forma gradual. A certa altura, perto do início do período de desenvolvimento, a relevância dos dados não-clínicos atinge o seu auge, e a partir desse momento começa a diminuir de forma gradual, à medida que a relevância dos dados clínicos continuam a subir gradualmente. Em determinado ponto, algures antes da Autorização

	de Introdução no Mercado (que é um evento marcado no eixo X), a relevância dos dados clínicos oculta a dos dados não-clínicos. Esta tendência mantém-se até à Autorização de Introdução no Mercado e também após, com os dados clínicos a tornarem-se mais relevantes à medida que os dados não-clínicos perdem a sua relevância.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Ainda que os dados não-clínicos sejam muito mais relevantes para o processo de desenvolvimento de medicamentos numa fase mais precoce, com o decorrer do tempo, a sua relevância é ocultada pela dos dados clínicos.
Translation required: If media contains English language text, it **must** be translated	Yes

Relevância dos estudos não-clíncos no desenvolvimento de medicamentos



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Adaptado de Nieto-Guiterrez, M. (2011) *Non-clinical assessment requirements.* London: European Medicines Agency.

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

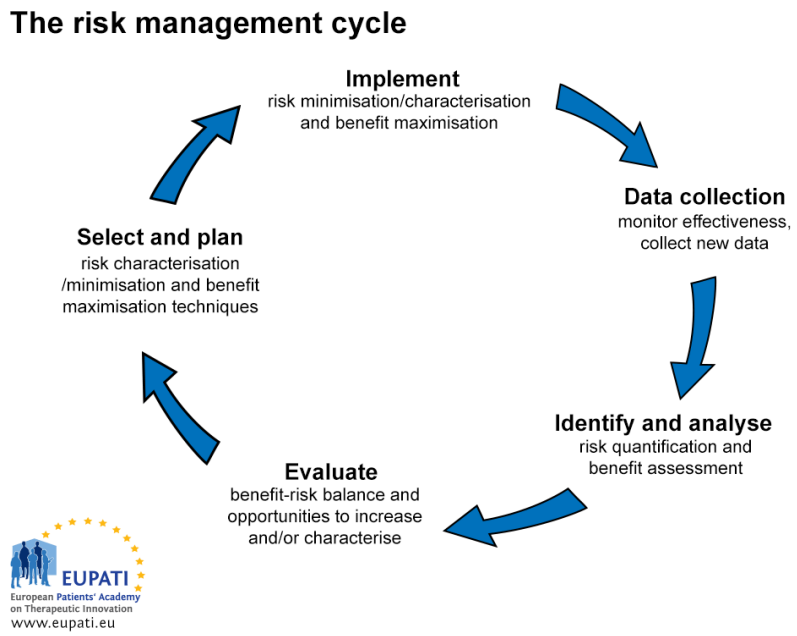
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	30.9.2015	PLATA Created	Final	1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

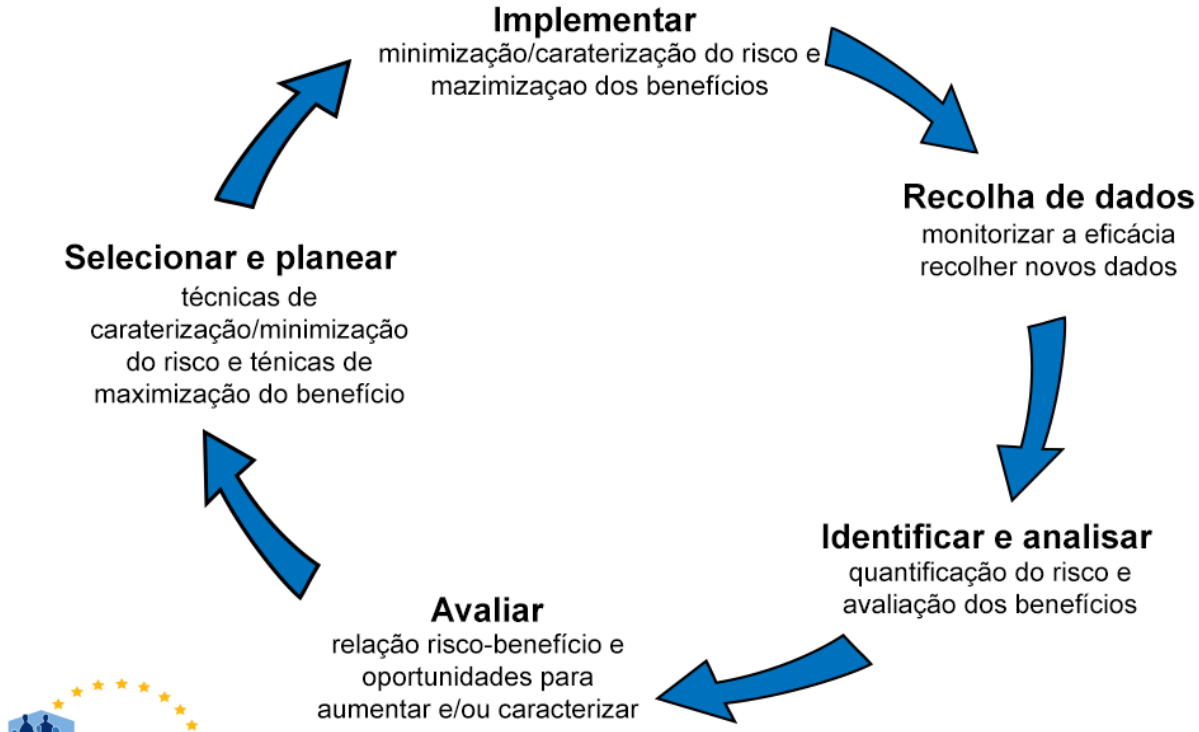
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	The risk management cycle
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Risk-management-cycle-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/w4qvc081725nvn5siyv9583ts204wdil
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI; Heidi Scherz

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Imagem que apresenta as cinco etapas do ciclo de gestão do risco num circuito contínuo. Nas etapas de identificação e análise pretende-se quantificar o risco e avaliar os benefícios de um medicamento. Na etapa seguinte, é avaliada a relação risco-benefício, assim como as oportunidades de aumentar benefícios e/ou caracterizar o risco. Após a avaliação, a etapa de seleção e planeamento envolve a seleção e planeamento das técnicas de caracterização e minimização do risco assim como de técnicas de maximização do benefício. Na etapa seguinte, são implementadas as técnicas de minimização/caracterização do risco e de maximização dos benefícios planeadas. Posteriormente, a etapa de recolha de dados monitoriza a eficácia das técnicas implementadas e recolhe novos dados. Em seguida, um novo ciclo inicia para identificar e analisar os riscos e os benefícios.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Imagem que apresenta as cinco etapas do ciclo de gestão do risco num circuito contínuo. Nas etapas de identificação e análise pretende-se quantificar o risco e avaliar os benefícios de um medicamento. Na etapa seguinte, é avaliada a relação risco-benefício, assim como as oportunidades de aumentar benefícios e/ou caracterizar o risco. Após a avaliação, a etapa de seleção e planeamento envolve a seleção e planeamento das técnicas de caracterização e minimização do risco assim como de técnicas de maximização do benefício. Na etapa seguinte, são implementadas as técnicas de minimização/caracterização do risco e de maximização dos benefícios planeadas. Posteriormente, a etapa de recolha de dados monitoriza a eficácia das técnicas implementadas e recolhe novos dados. Em seguida, um novo ciclo inicia para identificar e analisar os riscos e os benefícios.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Há cinco passos no ciclo de gestão do risco.

Translation required: If media contains English language text, it **must** be translated	Yes

O ciclo de gestão do risco



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

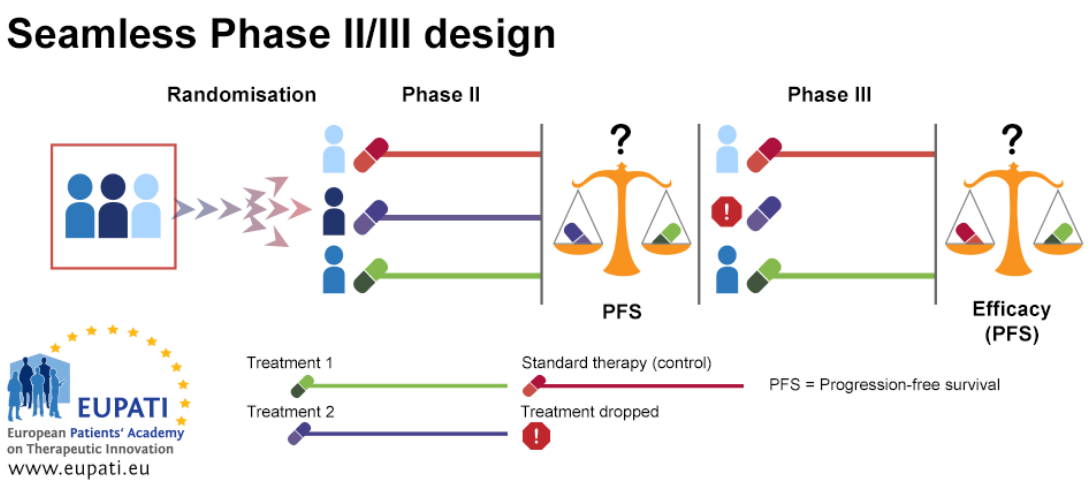
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	23.10.2015	PLATA Created	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

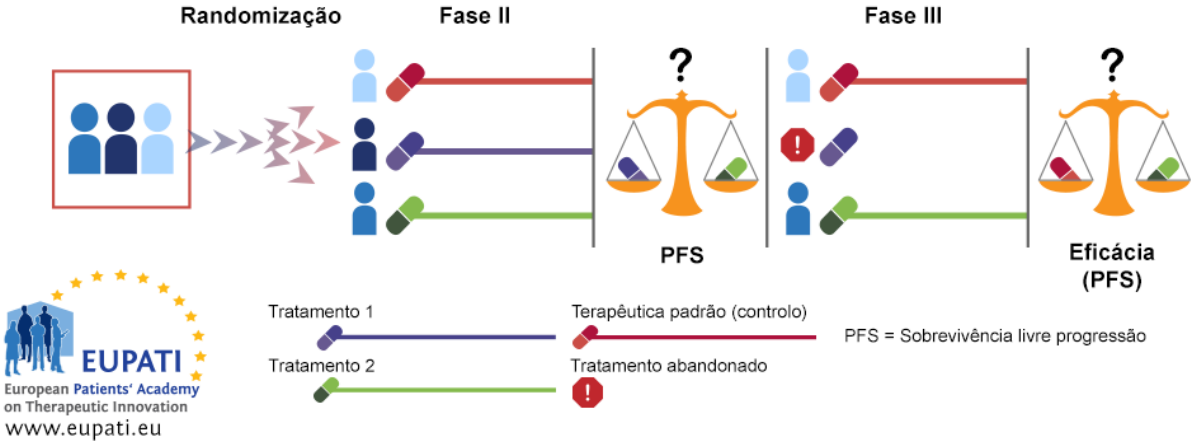
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Seamless Phase II/III design
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	seamless-phase-II-phase-III-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/gmhxcqg6pqt0oirguls56sgalvawx0tx
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on	Esquema que representa um ensaio com desenho contínuo de Fase II/Fase III. Durante a Fase II, os participantes são randomizados num dos três braços de tratamento. Os participantes no primeiro braço de tratamento recebem a terapêutica padrão

article context for meaning.	(que funciona como controlo). No segundo braço de tratamento, os participantes recebem o Tratamento 1. No terceiro braço de tratamento, os participantes recebem o Tratamento 2. No fim da fase II, os tratamentos 1 e 2 são avaliados em termos de sobrevivência livre de progressão. Na Fase III, os participantes do primeiro braço de tratamento continuam a receber a terapêutica padrão. O segundo braço de tratamento (e o Tratamento 1) foi abandonado após a avaliação de sobrevivência livre de progressão. Os participantes no terceiro braço de tratamento continuam a receber o Tratamento 2. No fim da Fase III, a terapêutica padrão e o Tratamento 2 são comparados numa em termos de eficácia (sobrevivência livre progressão).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esquema que representa um ensaio com desenho contínuo de Fase II/Fase III. Durante a Fase II, os participantes são randomizados num dos três braços de tratamento. Os participantes no primeiro braço de tratamento recebem a terapêutica padrão (que funciona como controlo). No segundo braço de tratamento, os participantes recebem o Tratamento 1. No terceiro braço de tratamento, os participantes recebem o Tratamento 2. No fim da fase II, os tratamentos 1 e 2 são avaliados em termos de sobrevivência livre de progressão. Na Fase III, os participantes do primeiro braço de tratamento continuam a receber a terapêutica padrão. O segundo braço de tratamento (e o Tratamento 1) foi abandonado após a avaliação de sobrevivência livre de progressão. Os participantes no terceiro braço de tratamento continuam a receber o Tratamento 2. No fim da Fase III, a terapêutica padrão e o Tratamento 2 são comparados numa em termos de eficácia (sobrevivência livre progressão).
Caption: Will be displayed under media in the article body. Must begin with title of media.	O desenho contínuo de Fase II/III permite que as Fases II e III sejam implementadas no contexto de um ensaio único.

Translation required: If media contains English language text, it **must** be translated	Yes

Ensaio com desenho contínuo de Fase II/III



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

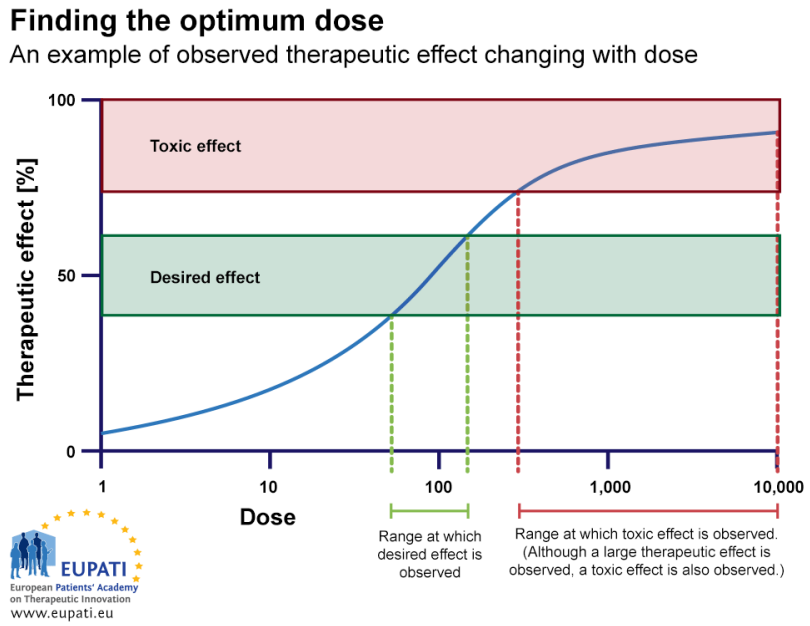
Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	20.09.2016	PLATA Created	DRAFT	1.1
Matthew May	20.09.2016	PLATA Checked	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Finding the optimum dose
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	therapeutic-effect-dose-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/lucfgti892wv1z9koqisx3np4jhfrnn2

Cut and paste image here:

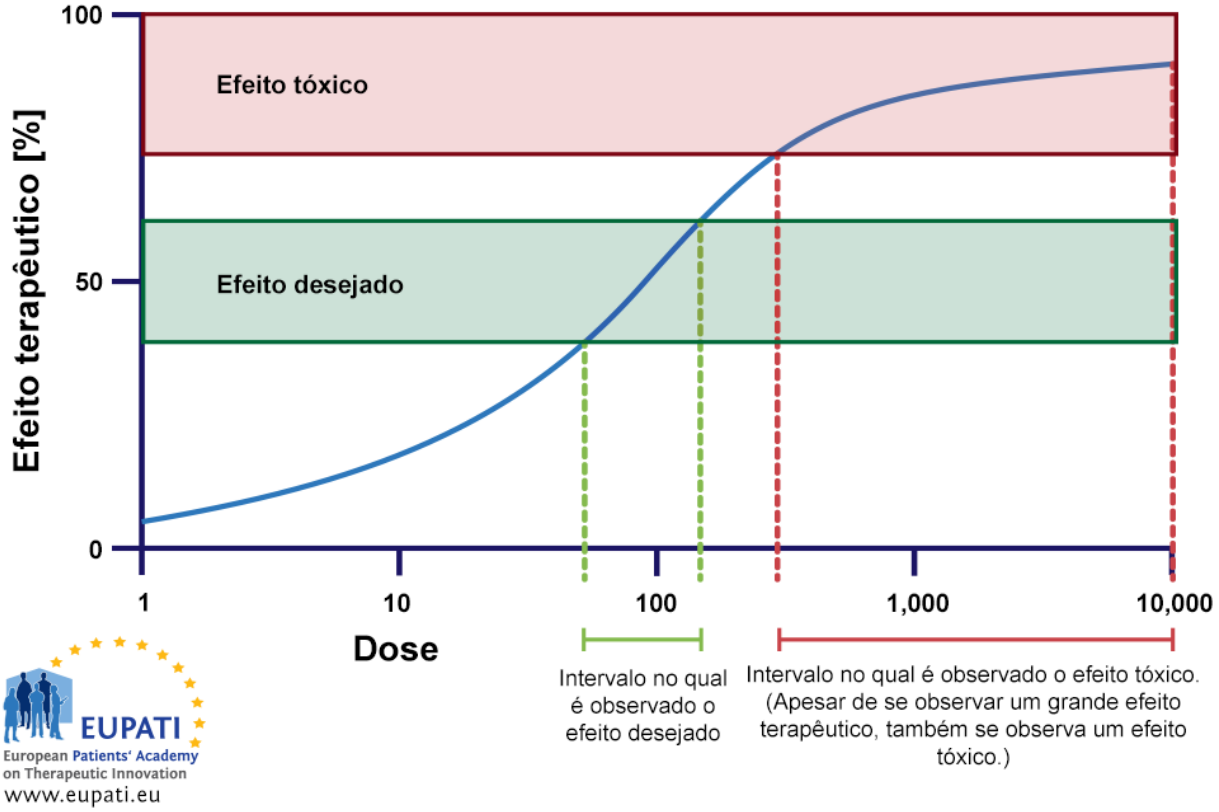


Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Ilustração gráfica de um estudo de dose-resposta para encontrar a dose ótima com efeito terapêutico de um medicamento experimental. O gráfico mostra um exemplo da alteração do efeito terapêutico observado em função da dose. A dose está assinalada no eixo X; o efeito terapêutico (%) no eixo Y. O estudo avalia vários níveis de dose para avaliar a resposta e estabelecer a dose mínima eficaz e a dose ótima, sem atingir um efeito tóxico. A meio do eixo X, é observado o efeito desejado e, após essa dose, o efeito terapêutico estabiliza e começam a surgir efeitos tóxicos. O gráfico mostra os intervalos nos quais se observam efeitos desejados e efeitos tóxicos.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Ilustração gráfica de um estudo de dose-resposta para encontrar a dose ótima com efeito terapêutico de um medicamento experimental. O gráfico mostra um exemplo da alteração do efeito terapêutico observado em função da dose. A dose está assinalada no eixo X; o efeito terapêutico (%) no eixo Y. O estudo avalia vários níveis de dose para avaliar a resposta e estabelecer a dose mínima eficaz e a dose ótima, sem atingir um efeito tóxico. A meio do eixo X, é observado o efeito desejado e, após essa dose, o efeito terapêutico estabiliza e começam a surgir efeitos tóxicos. O gráfico mostra os intervalos nos quais se observam efeitos desejados e efeitos tóxicos.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Gráfico de um estudo sobre o efeito de diferentes doses, numa tentativa de encontrar a dose ótima.
Translation required: If media contains English language text, it **must** be translated	Yes

Em busca da dose ótima

Exemplo em que o efeito terapêutico que se altera em função da dose



EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Matthew May	19.09.2016	PLATA Created	DRAFT	1.1
Cecilia Carino	17.10.2016	Minor corrections in title	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☒ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

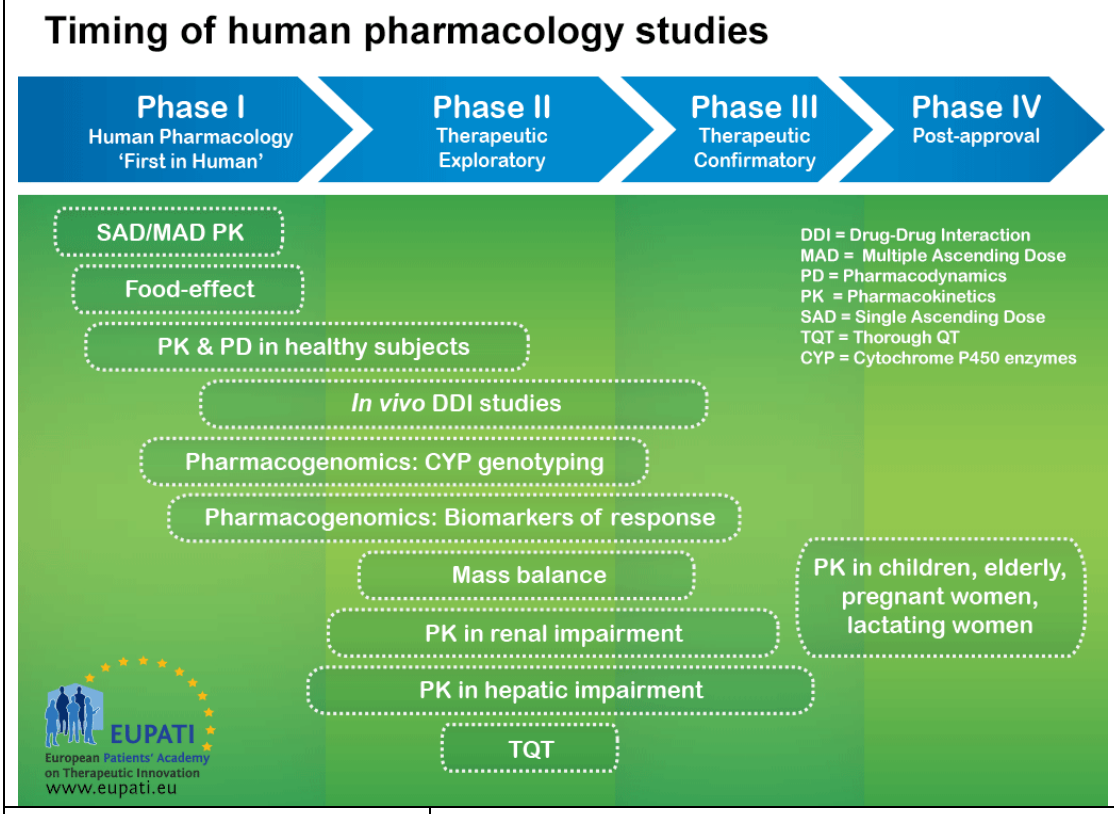
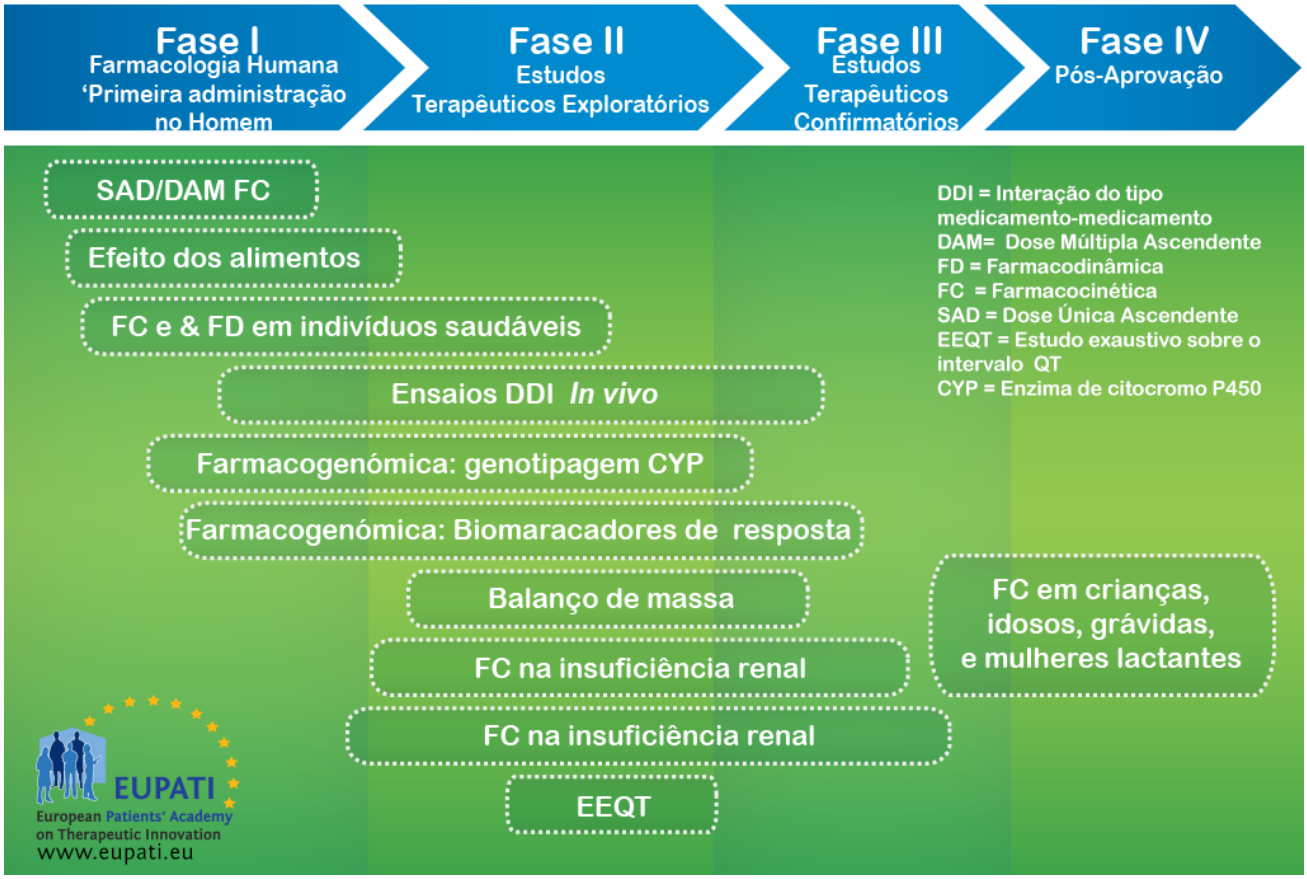
Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Timing of human pharmacology studies
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	https://eupati.app.box.com/files/0/f/6785755046/timing-human-pharmacology-studies
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.app.box.com/files/0/f/6785755046/timing-human-pharmacology-studies
Cut and paste image here: 	
Media Source Note: Please indicate where the	EUPATI

image was taken from.	
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que mostra os diferentes tipos de estudos clínicos que ocorrem durante o desenvolvimento de um medicamento. A representação do desenvolvimento de medicamentos como uma série de fases consecutivas, provém da ideia de que resultados de estudos prévios devem influenciar os planos para estudos posteriores: novos dados originam frequentemente modificações das estratégias de desenvolvimento seguintes.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esquema que mostra os diferentes tipos de estudos clínicos que ocorrem durante o desenvolvimento de um medicamento. A representação do desenvolvimento de medicamentos como uma série de fases consecutivas, provém da ideia de que resultados de estudos prévios devem influenciar os planos para estudos posteriores: novos dados originam frequentemente modificações das estratégias de desenvolvimento seguintes.
Caption: Will be displayed under media in the article body. Must begin with title of media.	A representação do desenvolvimento de medicamentos como uma série de fases consecutivas, provém da ideia de que resultados de estudos prévios devem influenciar os planos para estudos posteriores: novos dados originam frequentemente modificações das estratégias de desenvolvimento seguintes.
Translation required: If media contains English language text, it **must** be translated	Yes

Timing dos estudos de farmacologia humana



Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	11.8.2015	PLATA Created	FINAL	1.1
Heidi Scherz	11.25.2015	Updated ALT text	FINAL	1.2

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

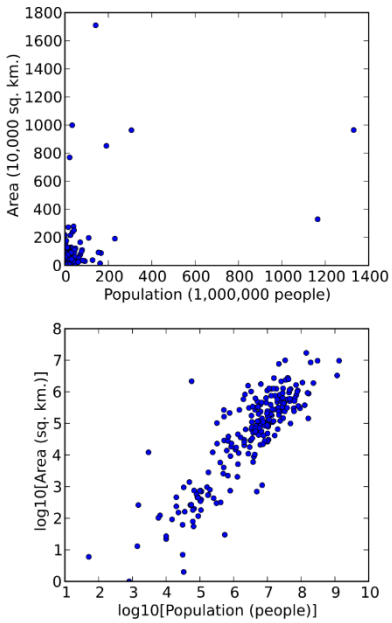
Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata

Complete file metadata as fully as possible.

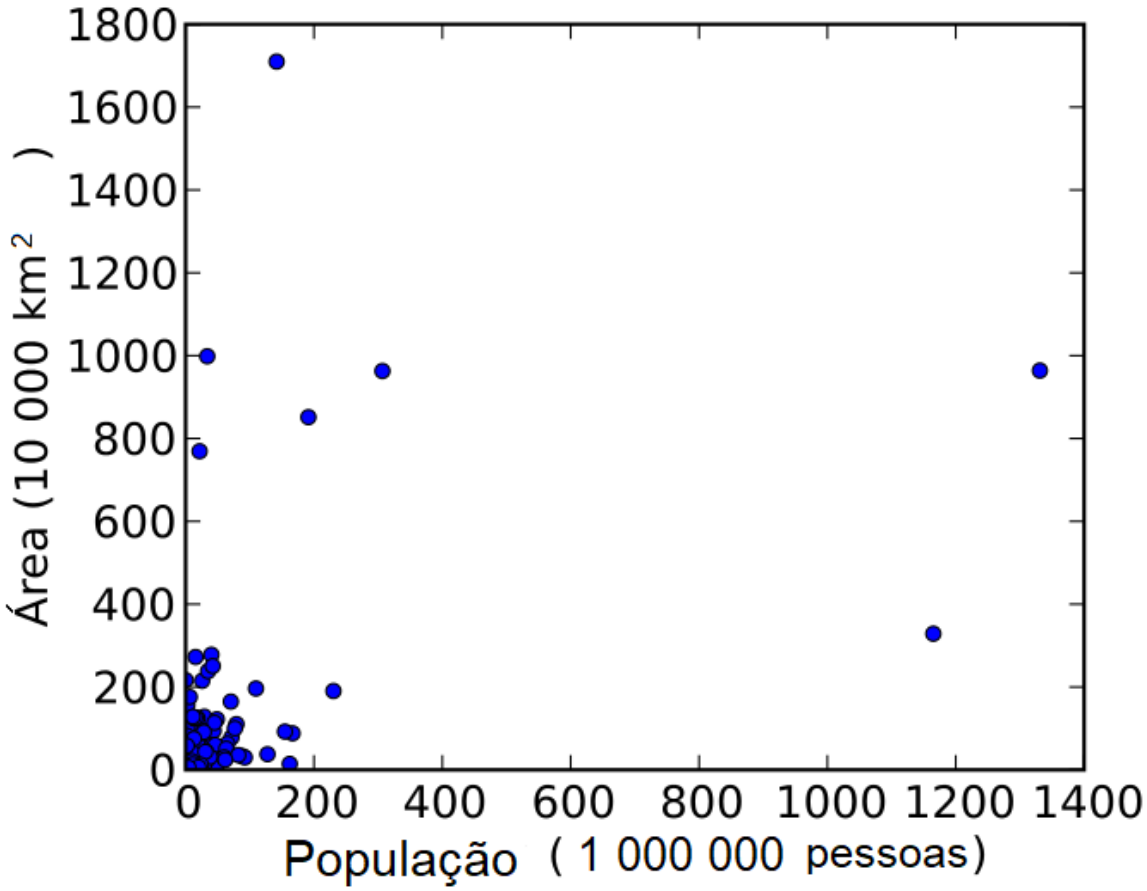
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Example of data transformation
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	transformation-pop-v-area-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://app.box.com/files/0/f/4198709241/transformation-pop-v-area

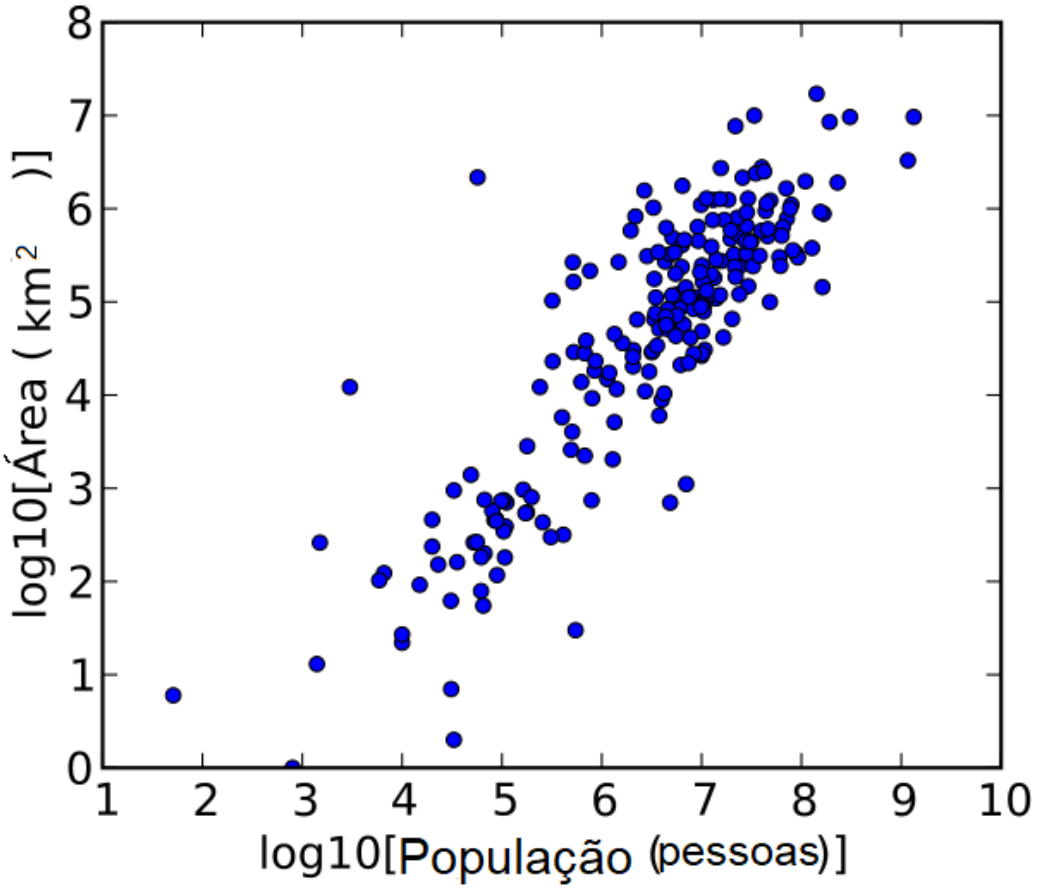
Cut and paste image here:



Media Source Note: Please indicate where the image was taken from.	https://upload.wikimedia.org/wikipedia/commons/0/00/Population_vs_area.svg
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esta imagem apresenta dois gráficos. No primeiro gráfico, a área (em unidades de 10 000 quilómetros quadrados, com um intervalo de 0 a 1800) está no eixo Y, em função da população, no eixo Y (em unidades de 1 000 000 pessoas, com um intervalo de 0 a 1400). Os pontos neste gráfico estão agrupados em grande parte no canto inferior esquerdo, entre 400 no eixo Y e 200 no eixo X. Como há alguns dados perdidos pelo gráfico, no segundo gráfico usa-se uma escala logarítmica em ambos os eixos. Isto é, as unidades no eixo Y são dadas como log10[Área (Km^2)], variando desde 0 a 8; no eixo X, as unidades são dadas como log10[População(Pessoas)], variando de 1 a 10. Neste gráfico, os pontos estão espalhados de forma mais uniforme, numa linha diagonal que vai desde o canto inferior esquerdo até ao canto superior direito do gráfico. Há alguns pontos de dados mais afastados, mas a maioria dos dados está incorporado na linha de tendência. A distribuição dos dados é muito mais óbvia no segundo gráfico com uma escala logarítmica que no primeiro gráfico.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Esta imagem apresenta dois gráficos que pretendem demonstrar a transformação de dados.
Caption: Will be displayed under media in the article body.	Um exemplo de transformação de dados: Utilização de uma escala logarítmica para melhorar a observação da tendência dos dados.

Must begin with title of media.	
Translation required: If media contains English language text, it **must** be translated	Yes


1800
1600
1400
1200
1000
800
600
400
200
0
Área (10 000 km²)
0
200
400
600
800
1000
1200
1400
População (1 000 000 pessoas)


8
7
6
5
4
3
2
1
0
log10[Área (km²)]
1
2
3
4
5
6
7
8
9
10
log10[População (pessoas)]

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.11.2015	PLATA Created from original (1.15)	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Translational medicine
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Translational-medicine.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/qngo9tlaud482ng13qgdo35rkxzqcczd
Cut and paste image here: 	
Media Source Note: Please indicate where the image was taken from.	Adapted from http://oacu.od.nih.gov/posters/21.html
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely	Representação esquemática do ciclo de feedback da medicina translacional, onde descobertas no laboratório contribuem para descobertas clínicas e, por sua vez, estas contribuem para descobertas no laboratório.

on article context for meaning.	
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Representação esquemática do ciclo de feedback da medicina translacional.
Caption: Will be displayed under media in the article body. Must begin with title of media.	A medicina translacional cria um ciclo de feedback do laboratório para o doente e vice-versa.
Translation required: If media contains English language text, it **must** be translated	Not of image

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

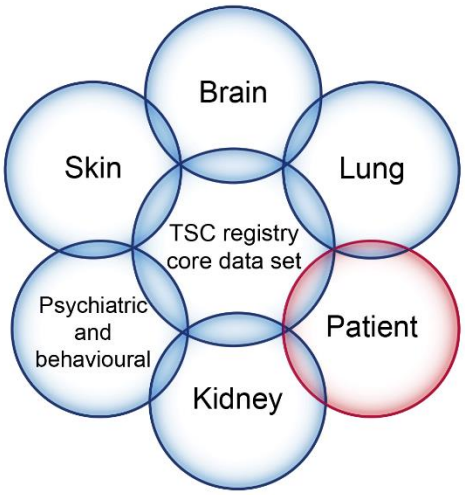
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

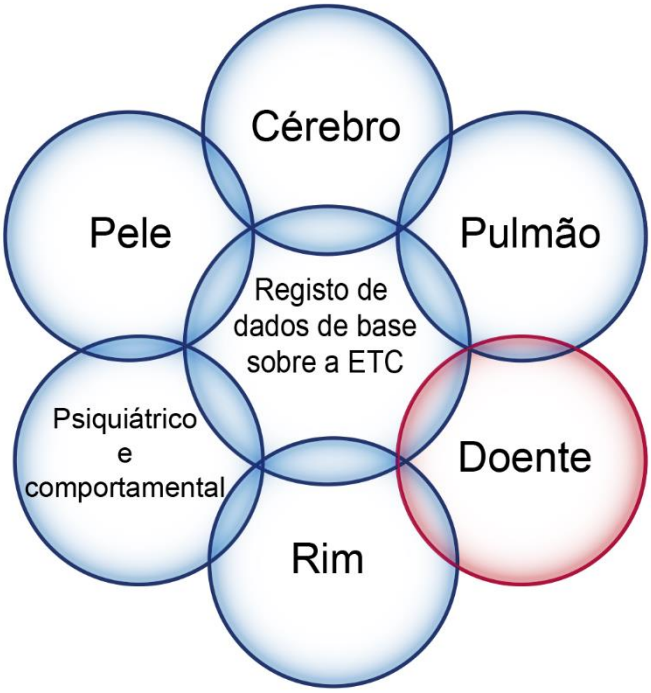
Template created by:	Date:	Description of update:	State*:	Version #*:
Cecilia Carino	25.01.2017	PLATA Created	DRAFT	1.0

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	TSC Registry core data set
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	tsc-bubbles_EN-v1.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/an9coljqgybms31q25qiihk3583acslz
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI

Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Ilustração gráfica do registo de dados de base para abordar as falhas de conhecimento na história e gestão da esclerose tuberosa complexa (ETC).
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Ilustração gráfica do registo de dados de base para abordar as falhas de conhecimento na história e gestão da esclerose tuberosa complexa (ETC).
Caption: Will be displayed under media in the article body. Must begin with title of media.	Uma ilustração do registo de dados de base para abordar as falhas de conhecimento na história e gestão da esclerose tuberosa complexa (ETC).
Translation required: If media contains English language text, it **must** be translated	Yes


Cérebro
Pele
Pulmão
Registo de dados de base sobre a ETC
Psiquiátrico e comportamental
Doente
Rim

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

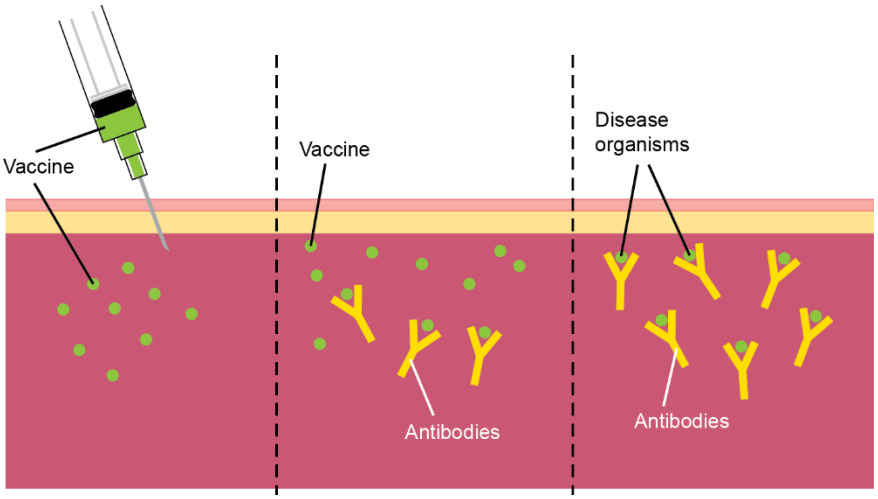
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

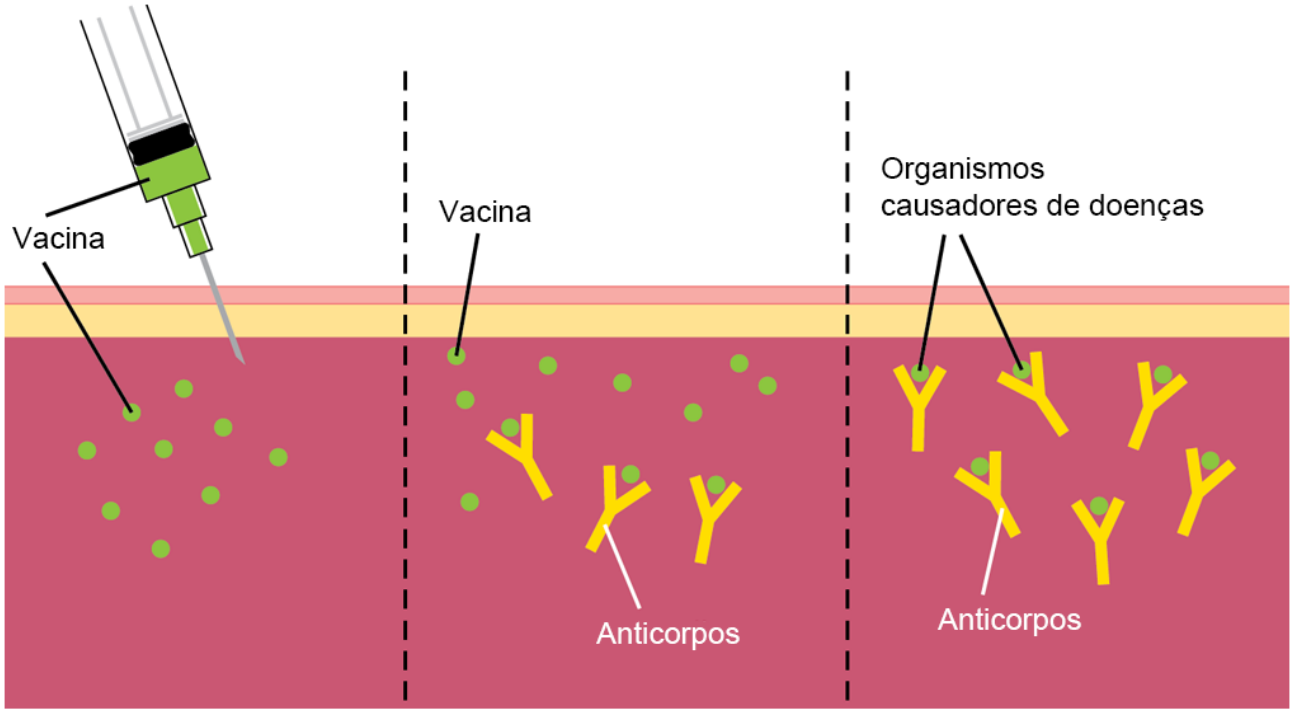
Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	24.2.2016	PLATA Transferred	Final	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☒ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Vaccine immunity
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	vaccine-immunity-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/c3lq9navd158p4stdba6rp79l0l3p3ac
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	Insert here
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Representação esquemática do processo de vacinação. Durante a vacinação, uma vacina com formas modificadas de vírus ou de bactérias é injetada no corpo. A vacina estimula o sistema imunitário para produzir anticorpos contra o microrganismo. O sistema imunitário aprende a reconhecer o microrganismo para que, se o corpo for infetado com a doença, consiga produzir anticorpos

	que se liguem aos microrganismos e parem a infeção.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Representação esquemática do processo de vacinação. Durante a vacinação, uma vacina com formas modificadas de vírus ou de bactérias é injetada no corpo. A vacina estimula o sistema imunitário para produzir anticorpos contra o microrganismo. O sistema imunitário aprende a reconhecer o microrganismo para que, se o corpo for infetado com a doença, consiga produzir anticorpos que se liguem aos microrganismos e parem a infeção.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Durante a vacinação, uma vacina com formas modificadas de vírus ou de bactérias é injetada no corpo (esquerda). A vacina estimula o sistema imunitário para produzir anticorpos contra o microrganismo (centro). O sistema imunitário aprende a reconhecer o microrganismo para que, se o corpo for infetado com a doença, consiga produzir anticorpos que se liguem aos microrganismos e parem a infeção (direita).
Translation required: If media contains English language text, it **must** be translated	Yes


Vacina
Vacina
Organismos
causadores de doenças
Anticorpos
Anticorpos

Patient Library & Advocate Toolbox Article (PLATA) Template: Media (V1.2)

(Images, Videos, Fact Sheets, Presentations)

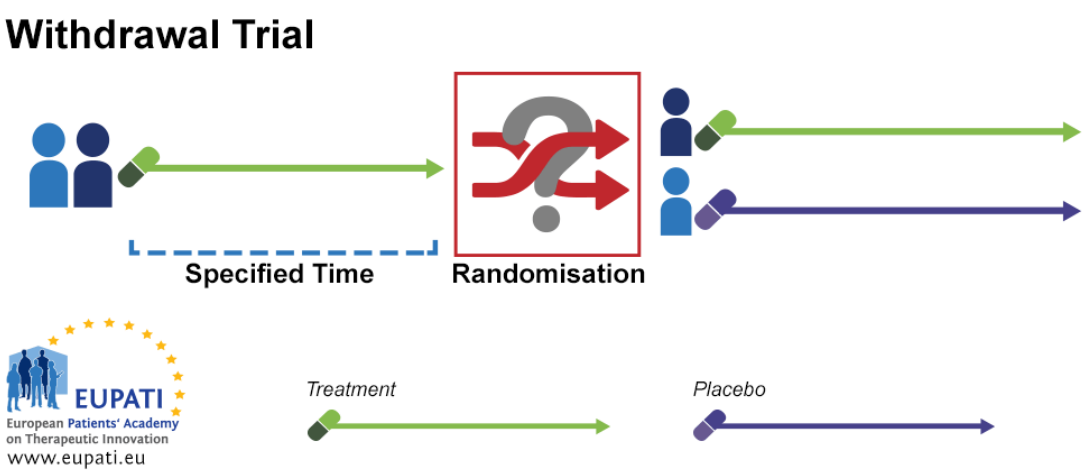
All content in this template must be completed in English. This document must be completed in full before transferring to WordPress. For guidance, see the PLATA guidelines on BOX.

Content Revision History

Template created by:	Date:	Description of update:	State*:	Version #*:
Heidi Scherz	19.11.2015	PLATA Created	FINAL	1.1

***State #:** This can either be 'Draft' or 'Final'.
***Version #:** Increase by 1 for a major update or 0.1 for a minor update.

Type of Media Select from the list below	
☐ Image (.png, .jpeg) ☐ Audio ☐ Video	☐ Presentation (.pptx) ☐ Fact Sheet (.docx) ☐ Resource

Media Metadata Complete file metadata as fully as possible.	
Title of media In sentence case, as it appears on screen/in the article. Should be general, should **not** rely on article context for meaning.	Withdrawal Trial
Media filename: Filename in full. E.g. cells-receptors-messengers-v1_EN.png	Withdrawal-trial-v1_EN.png
Box link: Insert link to file's folder in the EUPATI media library here.	https://eupati.box.com/s/kcgun493i8w6coj06aqw6rqu495bpo9r
Cut and paste image here:  	
Media Source Note: Please indicate where the image was taken from.	EUPATI, Heidi Scherz
Long description: Will be read through a screen reader; must be useful for accessible users. Keep description as generic as possible. It should **not** rely on article context for meaning.	Esquema que representa um ensaio de privação.
Alt Text: Will be shown in case image/media fails to load/is prevented from loading. Alt text should be	Este esquema mostra um exemplo de um ensaio de privação. Neste exemplo, durante a primeira parte do ensaio, todos os participantes recebem o tratamento ativo durante um período de tempo definido. Após este passar, os participantes são randomizados em dois grupos. O

concise and descriptive. May be same as long description, should be more descriptive than caption. It should **not** rely on article context for meaning.	Grupo 1 continua a receber o tratamento ativo, enquanto que o Grupo 2 recebe um tratamento placebo.
Caption: Will be displayed under media in the article body. Must begin with title of media.	Durante um ensaio de privação, após o período de tempo definido passar, os participantes são randomizados em dois grupos, em que um dos grupos recebe um placebo em vez de continuar o tratamento ativo.
Translation required: If media contains English language text, it **must** be translated	YES

Ensaio de Privação

EUPATI
European Patients' Academy on Therapeutic Innovation
www.eupati.eu

Tratamento

Placebo