Universidade de Aveiro
2013

Secção Autónoma de Ciências da Saúde

TIAGO GABRIEL OLIVEIRA CAMPOS

RELATÓRIO DE ESTÁGIO: 9 MESES COMO *MEDICAL WRITER* NA ARC PUBLISHING

INTERNSHIP REPORT: 9 MONTHS AS A MEDICAL WRITER AT ARC PUBLISHING

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Tese apresentada à Universidade de Aveiro para cumprimento dos requisitos necessários à obtenção do grau de Mestre em Biomedicina Farmacêutica, realizada sob a orientação científica do Professor Doutor Luís Almeida, Managing Partner na ARC Publishing e do Professor Doutor Bruno Gago, Professor Assistente Convidado da Secção Autónoma de Ciências da Saúde da Universidade de Aveiro.

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agradecimentos

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palavras-chave

Estágio Curricular, Medicina Farmacêutica, ARC Publishing, Redação Científica, Conhecimento Médico, Investigação Médica, Comunicação Científica, Publicação Científica, Gestão Editorial, Publicação de Acesso Livre.

resumo

Este trabalho apresenta uma experiência de estágio curricular com a duração de 9 meses, desenvolvido na ARC Publishing, uma empresa que opera nos ramos da comunicação e publicação científica.
O estágio curricular foi orientado para a área da redação científica, no entanto, atividades em outras áreas, aqui designadas de atividade multidisciplinar, também foram executadas. A atividade multidisciplinar variou desde atividades relacionadas com o desenvolvimento de negócio e marketing até atividades relacionadas com a gestão editorial de revistas científicas. Já as atividades de redação científica incluíram a redação de artigos de investigação original, traduções de documentação relacionada com a investigação clínica, edição de livros e controlo de qualidade de outros tipos de documentação científica.
Globalmente, este estágio curricular representou um ótimo complemento à minha formação académica. Tive a oportunidade de aprofundar o meu entendimento acerca dos processos envolvidos na produção e na comunicação de conhecimento médico/científico. Descobri novos tópicos de interesse. E, fiquei com uma visão mais ajustada daquilo que é a realidade do mercado de trabalho e das oportunidades disponíveis. Por fim, a junção destes fatores permitiu-me maturar as minhas perspetivas de desenvolvimento de carreia.

keywords

Curricular training, Internship, Pharmaceutical Medicine, ARC Publishing, Medical Writing, Medical Knowledge, Medical Research, Medical Communications, Medical Publishing, Editorial Management, Open Access Publishing.

abstract

The present work reports a 9-month curricular training experience developed at ARC Publishing, a company operating in the fields of medical communication and medical publishing.
The training experience was oriented towards the medical writing field, but activities in other fields, here designated as multidisciplinary activity, were also conducted. Multidisciplinary activity ranged from business development and marketing, to editorial management. Whereas medical writing activities included preparation of original research reports, translation of clinical documents, book editing, and quality control of scientific documentation.
Overall, this training period was an excellent complement to my academic education. I advanced my understanding of the processes involved in medical knowledge generation and communication. I discovered new topics of interest. And, I also improved my vision of the real marketplace and the opportunities it poses. Lastly, the combination of all these factors, allowed me to mature my perspectives for future career development.

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LIST OF ABBREVIATIONS

CONSORT	Consolidated standards of reporting trials
CRO	Clinical research organisation
EDC	Electronic data capture
FDA	Food and Drug Administration
HTML	Hypertext markup language
ICH	International conference on harmonisation of technical requirements for registration of pharmaceuticals for human use
ICMJE	International committee of medical journal editors
IND	Investigational New Drug
IT	Information technologies
JIF	Journal impact factor
NDA	New Drug Application
OA	Open Access
PLOS	Public Library of Science
SOP	Standard operating procedure
STROBE	Strengthening the reporting of observational studies in epidemiology

CHAPTER 1 - INTRODUCTION

This document presents an overview of a curricular training period as a medical writer at ARC Publishing. This training period is encompassed in the Masters in Pharmaceutical Biomedicine (which is a part of the IMI PharmaTrain affiliated Training Programme in Pharmaceutical Medicine) by the University of Aveiro, Portugal. The master's program is organised in manner that allows students to gain professional experience during the second year, through long-term curricular internships.

This internship in particular, started in September 2012 and lasted up to May 2013. During this period I held the *Associate Medical Writer* position. However, the internship was also intended to provide me with a much broader perspective of the working environment, and thus I also executed several activities beyond the medical writing field.

The main objectives for this internship were:

- To apply the knowledge acquired during my academic education, particularly during the Masters in Pharmaceutical Biomedicine.
- To get a better understanding of the working marketplace, particularly in medical research and communication.
- To develop a broad range of activities, improving my soft skills and general working capabilities.
- To develop my medical writing skills, complementing the learning from the masters' program and achieving a fairly high level of expertise.

To purse these objectives, the internship comprised diversified activities. The first three to four months were more heavily dedicated to multidisciplinary activity that went beyond the medical writing field. The remaining months were more heavily occupied with medical writing activity. However, this categorisation represents only a tendency; the types of tasks executed at different times were not strictly divided and many interlinks existed.

To present this training experience I divide this document into four chapters. Here, on the first chapter, I present an overview of the state of the art for the fields in which ARC Publishing operates. Then, I describe the specific characteristics of ARC Publishing. The following two chapters contain a comprehensive description of activity developed during the training period. In chapter 2, I present the range of undertakings not directly associated with the medical writer position. Whereas in chapter 3, I describe the range of projects I was involved in as a medical writer. Finally, in chapter 4, I discuss the overall training

experience. I also conclude on the relevance of this curricular training for my academic and professional development.

1.1. STATE OF THE ART

Medical knowledge communication is a very comprehensive topic. In this section I overview the main activities and stakeholders. I start with a historical perspective on how medical knowledge has evolved over the years. Then, I present the main features of medical research and knowledge generation. Lastly, I present the main platforms used up until now to communicate medical knowledge, and also mention future trends in these fields.

1.1.1. Medical knowledge evolution

Since ancient times the way we approach health has greatly evolved. For many centuries we tried to tackle disease based on beliefs and religion. These strategies were not, however, particularly effective. As the centuries past, human ambition towards a better understanding of the world open the way to more reason-oriented lines of thought, progressively dooming religious endeavours to secondary roles [1].

The shift towards evidence-based medical interventions has its deepest roots in the Enlightenment period. This intellectual movement placed its emphasis on reason. As a result, the application of reasoning to all aspects of human life unravelled the great potential of science. In fact, scientific thought was increasingly adopted because it provided explanations based on evidence, which could actually be confirmed through experimentation. With increasing influence from science, health-related approaches also changed and the basic foundations of modern medicine were laid down [1].

Since then, medical knowledge evolved at great pace. Once thought reasonable explanations for health-related phenomena have been proved wrong and deeper—and hopefully more accurate—understandings of the mechanisms involved in health and disease have been established. The increasing success of biomedicine's approaches to tackle disease was also accompanied by increasing social support. In fact, most societies across the globe today embrace biomedicine as their main strategy to address disease [1].

Particularly in the past few decades, medical knowledge boomed. New specialties arose, and for most cases we now have several levels of sub-specialties. In fact, some medical specialties today are almost knowledge universes in themselves. These developments were only possible with increasing support from all branches of society. But, perhaps even most importantly, these developments were possible because they were accompanied by developments in other—sometimes seen as unrelated—branches of science. Only with these developments, medical scientists—the origin of medical

knowledge—had access to the tools that allowed them to generate and massively distribute large quantities of information.

Now, we reached the era of evidence-based medicine. Confirmation of theories by experimentation—as initially proposed by the Enlightenment ideas—is not enough. We actually need to study diverse sources and critically analyse the results to identify the best alternatives. This is where systematic reviews and meta-analysis assume their crucial role. By leveraging the information technologies available now, these studies combine evidence from different sources and apply sound statistical analysis techniques to provide us with unifying evidence on which strategies actually work better. This kind of research is increasingly adopted, and in an environment of cost constraints it is reasonable to assume that in the future more and more of these studies will be conducted [2].

Unfortunately, these great advancements in modern medicine also pose great challenges for health professionals who need to keep up with the innovations. Medical knowledge is generated at great pace all around the globe by millions of researchers. Although, health professionals do not need to be up-to-date with every innovation, at least those innovations that might impact their professional practice they should be aware of. But, the problem is not only confined to truly disruptive innovations: medical knowledge is also target of constant renewal; what is accepted today may be updated or even discarded tomorrow. Therefore, this environment of constant change obliges health professionals to follow the evolution of medical knowledge (particularly in their fields of action) with great attention.

Furthermore, this ever-growing rhythm of medical knowledge production does not show signs of reduction. On the contrary, with the increasing trend towards the "Big Data" age, more and more information related to human health will be produced. With personalised medicine we will be basically building knowledge on every patient—and if we think of health promotion on higher levels, we will probably be building knowledge on every citizen on a given community. Computational techniques, such as artificial intelligence or data mining, will also contribute to generate increasing amounts of health-related information. In fact, these techniques may even contribute to actively generate signals, analyse hypothesis, and ultimately distil the overwhelming information that health professionals are confronted with [3, 4].

1.1.2. Medical research

To build this wide and varied body of medical knowledge, diverse research players have historically looked to a variety of sources. Today most of modern medical research is perhaps based on well-structured sources, but is has not always been this way. In fact, we can divide the sources of medical knowledge into four wide categories, such as Figure 1 illustrates [5].

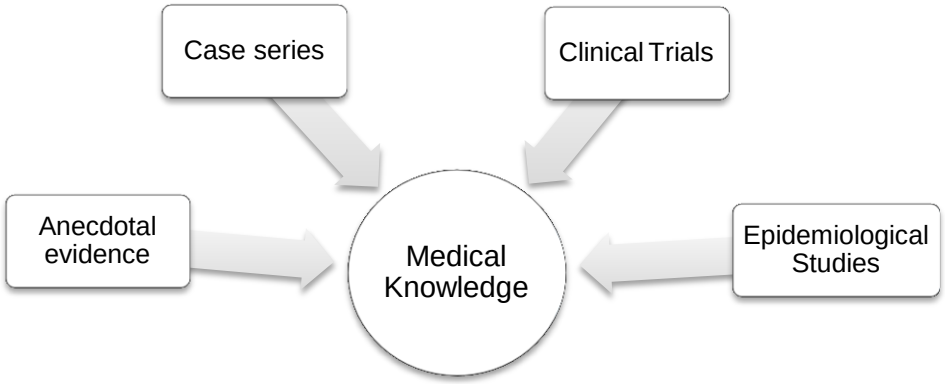

Figure 1. Historical sources of medical knowledge
Adapted from: Chin R, Lee BY. Principles and Practice of Clinical Trial Medicine: Elsevier Science; 2008.

Historically, we turned from occasional, less structured data sources to well-structured, aggregated data sources. Less structured data sources include anecdotal evidence (from clinicians' experience) and case series. Since these sources do not oblige to rigorous study methodology (e.g. inclusion or exclusion criteria), they usually do not provide definitive conclusions. Nevertheless, they have played major roles in the evolution of modern medicine—even today these sources are being used, most medical journals still have case report and case series sections—passing down experience-based knowledge through generations of health professionals [5].

As for epidemiological studies and aggregate data from clinical trials the situation is different: these sources are well accepted as reliable and accurate. Epidemiological studies are somewhat in between anecdotal and aggregate data from clinical trials. Epidemiology uses formal collection and analysis methods, but there is not an active intervention, and therefore, epidemiological studies usually do not lead to causal inferences. On the contrary, aggregate clinical trial evidence is based on well-established methods (randomisation, control, etc.) to account for the sources of bias that afflict epidemiologic approaches. Clinical trials include active interventions, and thus they may lead to causal inferences [5].

All these sources are important to generate a strong and valid body of medical knowledge. Less structured sources are mainly used to generate hypothesis and provide preliminary information. Whereas epidemiology and clinical trial evidence is best suited to validate or discard these preliminary hypothesis. Independently of the data source used, it is of the most importance to assure the quality of the evidence. Less structured data sources should always follow good reporting practices. But, this is particularly crucial for methodological research. For the latter, several reporting guidelines are available: the most important are the STROBE guidelines for epidemiological studies and the CONSORT guidelines for clinical trials. And there is, of course, the good clinical practices as well as other applicable regulatory requirements that should always be followed [5].

In terms of research players, we see a huge variety of entities involved, but some trends are still identifiable. Basic medical research is usually undertaken by academic or

medical institutions. This research intends to establish the basis of healthy physiology as well as disease mechanisms. Normally, these undertakings are carried out with the objective of advancing medical knowledge and do not specifically focus on practical applications. This kind of medical research has been historically funded by public grants, privately held funds from the institutions themselves, or other non-profit organisations. Partnerships with private organisations are increasing, but they are still somewhat incipient at this point [5, 6].

Applied research—building on the information from basic research to provide health interventions—is typically more commercially attractive, and consequently, populated with private initiatives (mainly from pharmaceutical, medical devices, and other biotechnology industries). This trend is easily understandable since health-related interventions actually provide direct revenue, in contrast to basic research where most of the times researchers only "add value" to the body of medical knowledge [5, 6].

Development of health interventions (i.e. applied research) is typically aimed at producing interventions based on medicines (either chemical- or biological-based) or medical devices. Usually, a quite strict pathway is followed. Findings from basic research are thoroughly analysed to find the best targets to act on and, ultimately, obtain a desired outcome. Then, researchers speculate on which compounds are best suited to exert the intended action on the target. At this stage several compounds undergo extensive batteries of in silico and in vitro testing, so that only compounds with true potential for successful intervention are further developed. Then, animal testing takes place to mimic, at the best extent possible, the effects on humans; here toxicology testing is of extreme importance. Lastly, we have clinical trials (i.e. human testing) that test potential interventions in controlled environments with the main intent of ensuring that only safe and efficacious interventions are introduced [5, 6].

The clinical stage of drug development is typically divided into four phases. Despite some increasing trends for streamlining this development model, this is still the model in place for most drugs in clinical development today. Phase I studies usually enrol healthy subjects, intend to assess the safety of the compound under consideration, and provide useful insists on drug dosage for consequent studies. Phase II studies enrol patients (with the target disease), and intend to provide preliminary information on the safety and efficacy of the intervention for the target disease. Phase III studies (sometimes called pivotal studies) also enrol patients, but have much larger study populations (sometimes several thousands); these studies intend to establish the safety and efficacy profiles of the intervention and compare these characteristics with those of the existent standard interventions. Phase IV studies are conducted after the medicine is approved and in use by the general population; given that these studies include "real-life" patients, they intend to provide evidence of the actual benefits and risks for the intervention. Figure 2 depicts the characteristics and relationships of each drug development stage [5, 7].

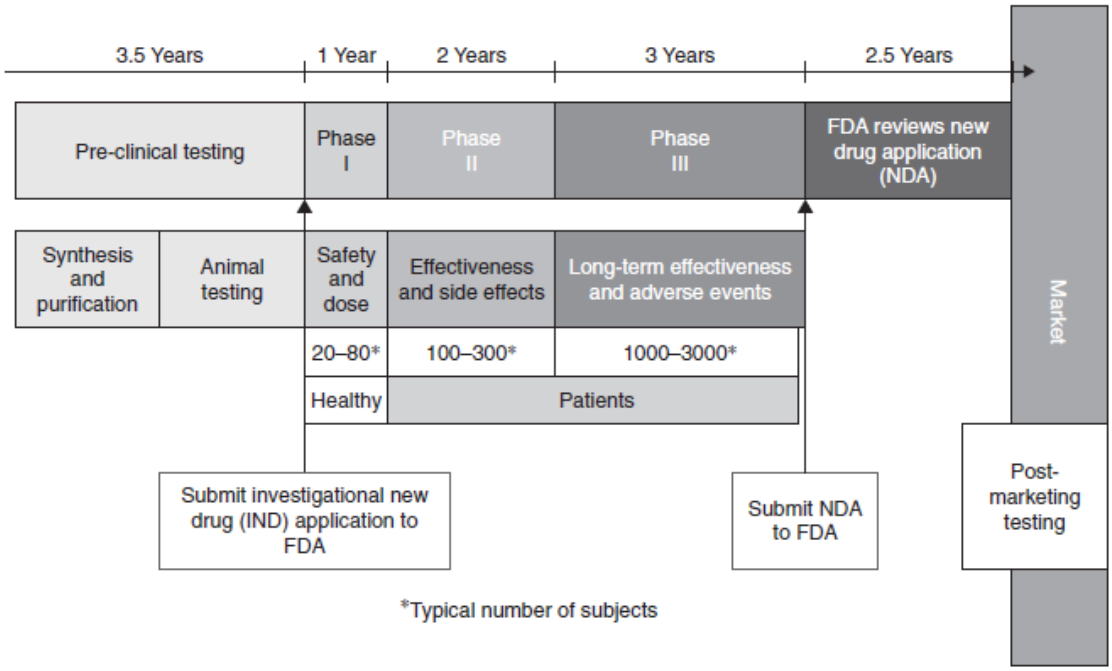

Figure 2. Drug development phases
Source: Chin R, Lee BY. Principles and Practice of Clinical Trial Medicine: Elsevier Science; 2008.

Developing medical devices is quite different from developing medicines. Although medical devices are around for quite some time, regulatory requirements for these kinds of interventions are usually not so tight. Medical devices are developed with a scientific rationale similar to that applied in drug development: a target for intervention is selected, a form of intervention is designed (i.e. a medical device), and the device is consecutively tested to ensure safety and effectiveness. The main difference is the fact that here the amount of testing highly depends on the device's characteristics, particularly on the risks it poses. Low risk devices may only have to be registered with the competent authorities, while high risk devices may need to undergo extensive animal and clinical testing [8, 9].

Independently of the types of interventions under study, applied research is always associated with stricter regulatory requirements. This is particularly true for studies involving interventions on human subjects—clinical trials. Regulatory requirements improved overtime in an attempt to ensure safety and effectiveness of medical interventions available. Nowadays, most—if not all—developed countries have competent authorities to evaluate medicines and medical devices. In the European Union for instance, there are centralised (European Medicines Agency) and decentralised authorities (member state's specific authorities). And despite the wide range of competent authorities around the world, we have today a worldwide organisation—the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)—that has actually harmonised (to the extent possible) the requirements for developing medicines. These endeavours have facilitated the development process, mainly through the use of harmonised guidelines, but there are still some challenging regulatory

hurdles that drug developers need to overcome in order to successfully commercialise their products.

But, these regulatory hurdles also represent an opportunity for clinical research organisations (CRO) providing specially conceived, highly effective services. This is true for the full-service CROs market that emerged in the last decades, but also for the niche CROs, which have the capacity to provide specialised, high-quality services. The medical writing niche CROs, are particularly favoured with the increasing regulatory requirements, since well-developed documentation is crucial to meet them. These CROs have particularly good business opportunities in developing top-quality study protocols and study reports, but also other types of scientific documentation required by competent authorities for marketing authorisation applications.

While this whole model of medical knowledge generation has been in place for decades, the new circumstances that have arisen in the past decade will lead most players to rethink their strategies and refocus their efforts. This change is particularly important for the applied research sector. Here, productivity (number of new medicines marketed) has been declining despite the growing costs. Pharmaceutical industries faced with this scenario will probably reshape their development model in order to share the increasing risks with other entities. This includes partnering with academia, leaving the early steps of applied research for properly equipped academic centres. But, also includes embarking in larger public-private enterprises to develop cost-effective solutions [10].

In the information era, the development model itself will tend to become more flexible. The concept of developing medicines for large a population—associated with potential high profits—is almost over, and tailored solutions will emerge as we walk towards a personalised medicine paradigm. Very strict clinical development phases—where most development costs come from—will probably fade and more efficient processes will emerge. This may include in-life testing models where aggregate clinical data but also simulated data sources will be jointly used to safely introduce therapies in patient populations or indications for which they have been proven adequate. These flexible approaches will make therapies readily available for patients, but will also reduce the impact of high upfront development investments, and most importantly, the high costs of failure [11-14].

Of course, to successfully transform this historically so complex knowledge generation model, good communication will be crucial. Players involved in developing and commercialising health innovation (medicines, devices, etc.) have historically bet on marketing-based communication strategies, but there is an increasing demand for more scientific-based, balanced, and accurate communication. With the increasing trend for flexibility in the development model, access to balanced and trustworthy information will also be increasingly valued by health professionals. This represents a good business opportunity for entities specialised in communicating science, which will make the bridge between scientific information hunger health professionals and marketing oriented pharmaceutical or medical devices industries.

1.1.3. Communicating medical knowledge

Throughout the years, medical knowledge has been communicated by a variety of methods. We can divide these methods into a personal communication level or a broad communication level. Personal communication includes experience-based teaching and other person to person communication forms where health professionals exchange experiences to increase their knowledge. Communicating medicine on a personal level was particularly crucial during the early stages of modern medicine, centuries ago. Back then, most professionals did not have access to more elaborated communication forms, and advancements in their practices were highly dependent on exchanging personal experiences. Nevertheless, this kind of medical communication continued to play significant roles, and even today health professionals look up to their peers for information, despite the increasing information sources available.

Broad communication platforms include health professionals' organisations, scientific meetings, and medical journals. Organisations of health professionals are intrinsically an extension of the personal communication paradigm. Health professionals associated with these organisations have communication with their peers facilitated; these organisations also provide a way to keep up with their professional fields of interest. Scientific meetings also provide direct personal contact with professional peers. Those kinds of meetings facilitate a more formal approach to medical communication, which sometimes include oral communications or poster presentations to potentially wide audiences. Historically, scientific meetings have actually historically been one of the major ways of communicating medical knowledge. In this age of increasing specialisation in medicine, scientific meetings tend to retain their place in medical knowledge communication as more specialised meetings are held [15].

Finally, at a much broader communication level we have the medical literature. The first general medical journals were originally published towards the end of the 18th century, and sometimes these journals were an extension to scientific meetings. As the time past, more specialised journals began to arise, and already during the 20th century even sub-specialty journals were already available. Medical journals assumed increasing importance and portrayed themselves as very powerful tools for medical knowledge communication, and most importantly, knowledge dissemination to an ever growing variety of audiences. Besides their major role of knowledge communication, medical journals also constituted important forums for medical discussions, entertained their readers, and even proved effective tools for certain types of campaigns [15].

Of course, these different communication forms are associated with different relative importance. Communicating on a person to person basis with professional peers has a very small potential to influence medical practices at a universal level. As for communications at broader level, intervening at scientific meetings is somewhere in the middle of this potential impact scale. Here, fairly large numbers of professionals might be gathered, so fairly large numbers of medical practices might be affected. Additionally, communications held at scientific meetings are sometimes published in the medical literature, which allows

further dissemination. Nonetheless, publications on medical journals—particularly peer-reviewed journals—are generally seen as more relevant contributions to the body of medical knowledge. This is justified by the incomparably larger audiences reached by medical journals and the potential impact of those in actual medical practices. However, all of these publication forms remain suitable approaches for different types of communications; the key is to properly match the relative importance of the communication form with the relevance of the communication content.

Medical journals are not all the same. We have peer-reviewed broad-based journals, which publish on most medical topics. Examples of this class are the *New England Journal of Medicine* or *The Lancet*. These types of journals tend to be well known among a wide variety of health professionals; they have very large audiences, and at least for the most reputed ones, they are seen as the go-to journals for really ground-breaking research reports. Then we have peer-reviewed specialty journals, which only publish on a specific area of medicine. These journals are sometimes associated with organisations of health professionals for a particular specialty. Although they do not guarantee the kind of exposure broad-based journals do, they can be important when the authors are particularly interested in being read by professionals in a given specialty. These days, specialty journals have reached the sub-specialty level, and in extreme cases even the sub-sub-specialty level was reached. Lastly, we also have controlled circulation journals. These journals usually aim to provide practical information for clinicians. They may contain large quantities of articles reviewing the medical literature, summaries of research reports, and practical guides for health professionals. Even here, there also journals specialised in diverse areas of medical knowledge [16].

Medical journals publish diverse contents. Table 1 summarises the types of articles most broadly published among journals. Given the singular characteristics of each type of article, they are usually regarded with different relative importance. This classification is based on criteria such as the work involved in producing the paper, the scientific relevance of the paper, the validity of the methods employed, etc. Original research reports, meta-analysis and systematic reviews (which in a way also constitute a research article) are regarded as the most important journal publications. Letters to the editor, editorials, and case reports are normally regarded as less important publications, which is comprehensible in the sense that these publications are much more simple (and easy to prepare), may represent personal opinions, and do not rely on a very strict scientific methodology. This categorisation of articles is, of course, not so straightforward, because a wide variety of factors can affect the importance of journal articles. Nevertheless, this evaluation plays important roles in career development as well as attribution of grants. But, despite the different levels of importance for journal articles, authors should still keep in mind that different types of articles meet different communication needs, thus they should wisely select the types of articles they will write [16].

Table 1. Types of articles published in medical journals.

Type of article	Characteristics
Original research report	Reports findings from carefully designed scientific experiments. The article usually follows a strict structure: Introduction, Methods, Results, and Discussion.
Traditional review article	Presents an overview of a specific medical topic. The article is designed to present what is known about the topic, but a strict research methodology is not employed. This type of article usually does not add new facts to the literature.
Literature review	Presents the state of the art. Literature reviews summarise the knowledge in a given topic taking into consideration large quantities of articles. This kind of article is usually written by experts in the topic at hand.
Systematic review/meta-analysis	Reports scientific investigations that analyse data from previously published studies. A careful research methodology is implemented to select the studies analysed. A qualitative systematic review only summarises the studies, whereas a quantitative systematic review (also called meta-analysis) actually combines the data using specially designed statistical methods.
Case report	Presents a single (or small number) of interesting clinical cases. Case reports focus on unusual disease manifestations, therapeutic outcomes, or combinations of other unusual clinical presentations.
Editorial	Greatly varies in terms of contents. Usually editorials are written by the journal editors or an invited expert. Editorials reflect the author's personal opinion on the subject at hand. In some cases, the editorial is merely a comment on the contents of the journal issue.
Letter to the editor	Provides a platform for readers to discuss aspects from previous editions. Letters to the editor allow readers to express concerns, present new perspectives, and even share knowledge from their experience that did not qualify for a "regular article".

The peer-review process is defined by the International Committee of Medical Journal Editors (ICMJE) as: "the critical assessment of manuscripts submitted to journals by experts who are not part of the editorial staff." This is the preferred method to guarantee quality in the medical literature: it is designed to prevent erroneous materials from being published and help authors improve the overall quality of their papers. But, the peer review process is not a perfect quality assurance tool. In fact, several studies have demonstrated serious faults associated with the process: it's inefficient, often biased and arbitrary, and not very good at detecting errors or fraud. Nonetheless, at this time the expression "peer-

reviewed journal" still carries a lot of importance among the community and alternative procedures have not yet proved effective enough to be seen as credible go-to alternatives [15, 17-19].

To assess the quality of publications on medical journals, other tools besides employing the peer-review process are used. One of the most widely used is the journal impact factor (JIF), which provides a rough estimation of the journal's relevance and prestige based on the number of times the articles on the journal are cited. The JIF was invented in the 60's, based on Thomson Reuters (by then known as Institute of Scientific Information) scientific articles indexing tools. A JIF provides a 2-year average of the number of citations each article in the journal receives. Figure 3 illustrates the formulae used to calculate the impact factor.

$$\textit{2013 Impact Factor} = \frac{\text{2013 cites to articles published in 2011-2012}}{\text{number of articles published in 2011-2012}}$$

Figure 3. Impact factor formulae

Despite the increasing concerns associated with the JIF (even some notes from Thompson Reuters itself about using the JIF with caution), it remains widely used for a variety of purposes: guiding authors in selecting journals, assisting publishers in market research activities, and even helping assess merits for academic career development and grant attribution [20].

Beyond the JIF, the number of citations itself can also be a useful indicator of quality. High numbers of citations generally indicate scientific relevant publications, which are useful for other authors when preparing their papers. But, the number of citations should also be used with caution: articles might be highly cited because they contain serious errors. Other methods have been proposed to evaluate journals, individual articles, or even authors. Table 2 provides an overview of the most widely disseminated alternative methods to assess quality in the medical literature. Despite the merits of these alternatives, the JIF and the number of citations continue to be highly regarded in the community.

Independently of the measures used, when assessing the quality of items in the medical literature, we should be cautions, since the several methods proposed and in use today present faults and there is not an undeniably fail proof approach [20, 21].

Table 2. Alternative measures of journal impact

Measure	Description
Eigenfactor	Provides an estimate of impact on a given year, based on the number of citations in the Web of Knowledge database. Citations from highly cited journals weigh more than those from less-cited ones. This measure considers a 5-year timeframe and does not include self-citations [22, 23].
Article Influence	Is derived from the Eigenfactor and provides an estimate of the average influence of articles during de first 5 years after publication [22]. This measure is normalised to allow easy interpretation (i.e. values above 1 indicate higher influence while values bellow 1 indicate lower influence).
Immediacy Index	Estimates the frequency in which articles are cited in the year of publication. The Web of Knowledge database is used [22].
Cited Half-Life	Indicates the median age of the articles cited on a given year on the Web of Knowledge database, reflecting for how long articles continue to have impact on the scientific community [22].
SCImago Journal Rank	Provides an estimation of the journal impact based on citations from a 3-year timeframe. Citations from high impact journals weight more in the calculation. Self-citations are ignored and all articles in the journal are considered (i.e. "citable" and "non-citable" items). This measure is based on the Scopus database, which more comprehensive than the Web of Knowledge, especially for new and non-English journals [22].
h-index	Reflects the number of articles (h) that is cited at least h times. This measure was originally designed to assess both impact and productivity of individual scientists, but now it is also used to assess journals and even countries. The h-index can be calculated from a variety of databases and refer to specific time periods of times (e.g. Google Scholars' metrics page provides 5-year h-index for indexed journals). The calculation is not normalised to the number of articles published, favouring high numbers of publications [22, 24, 25].

The number of medical journals available worldwide boomed as modern medicine entered the information era. This fact is easily illustrated by searching the literature for articles on "How to keep up with the medical literature". In 1954, Flaxman published such an article, in which he stated: "One of the commonest complaints of physicians is their practicing difficulty in keeping up with medical literature. With some 400 medical journals in the English language alone listed in the Quarterly Cumulative Index Medicus, this literary ailment seems almost entirely justifiable" [26]. He describes some practical tips for health professionals to search periodicals for possibly relevant information for their practice. In 1986, Haynes et al already mentioned: "Access to the medical literature through personal computers is now readily available and can greatly reduce logistical barriers to using recently published journal articles to support clinical decisions"[27]. Here, the authors

already described an advanced computerised search method, which reflects the change in the way health professionals interact with the medical literature due to the overwhelming increasing number of publications. Today, PubMed indexes more than 22 million articles in life sciences and biomedical topics. And, the rhythm of indexed content continues to increase every year (at rates higher than 500,000 articles per year) [28].

This crowded publication environment not only represents increased difficulties to professionals searching through the literature for relevant scientific data, but also makes it very difficult for authors to get their ideas and results out there with the desired impact. This is particularly critical for academicians trying to build a solid career, since in academia the "publish or perish paradigm" prevails. Thus, it is very important to stand out from the crowd when health professionals publish their work in the medical literature. This represents a huge business opportunity for organisations providing highly effective medical writing and data presentation services. Often, health professionals do not have the technical capabilities to prepare exquisite reports, and partnering with professionals in this area can really add value to the final product and help ensuring that the impact of the publication is properly maximised.

Still, the revolution in the way medical knowledge is communicated is far from being complete. The advent of the internet brings up exciting new possibilities. Today, the internet already reaches the most inhospitable places and continues to be extended every day. This constitutes an amazing platform to extend the potential audience for many medical publications. Besides, digital content transmission also provides interactive capabilities, which have the potential to facilitate communication at both ends of knowledge transmission. Even new ways of communicating medicine may arise based on advanced social media platforms already available. And all of this is at a very low cost, in fact, with the increasing adoption of cloud computing solutions, more effective resource usage can be attained, leading to reduced costs and eventually reaching residual costs when compared with the potential gains [29-31].

1.1.3.1. Movement towards Open Access publishing

Traditionally, medical journals were funded by subscriptions, which were mostly acquired by institutional libraries, but also individual researchers. In this model, the authors provided the contents to publish—along with the copyrights over the contents—and the reader (or the libraries of their institutions) paid a subscription to access the journal (more recently, readers could also pay a given fee to access just a specific article). Revenue from subscriptions was sufficient to cover expenses with the peer-review, editorial, and publishing process. Given that most journals were paper-based, articles took variable times from submission to print, but usually several months were required. However, as the Internet became more widely available, there was an increasing trend to make contents freely available on-line. In this context, open access (OA) publishing promised to give authors wider audiences and faster publication times, since contents were readily available online.

In fact, the medical publishing industry has seen an increasing trend towards open access publishing in the past decade. The Public Library of Science (PLOS) (one of the pioneers in OA publishing) defines OA as "free immediate access to, and unrestricted reuse of, original works of all types". This definition admits that open access materials besides being readily and freely available, do not contain restrictions of use, including the ability to create derivative works or even make commercial use of published materials. However, that is not always the case for all publications broadly defined as OA. Particularly, for publishers previously in the business of restricted access publishing, some restrictions may apply to materials denominated as "OA". Given this diversity in the terms in of use, several OA models were implemented over the years. Table 3 describes the main models in place [32, 33].

Table 3. Open Access models [30, 34].

Open Access Model	Characteristics
Gold Open Access	Materials are immediately freely accessible online. All articles in the journal are freely accessible. Authors may be required to pay a publication fee to support the editorial and publishing processes.
Hybrid Open Access	Some articles are immediately freely accessible online in an otherwise restricted access journal. Authors are usually required to pay an "open access fee" to overcome the potential loss in revenue from subscriptions and pay-per-view fees.
Green Open Access	Authors publish the final article on a personal, institutional, or central repository. Depending on the agreements with the journal, the article may only be freely available after an "embargo period" designed to minimise revenue losses to the publisher.

The main advantage associated with OA publishing is the wider audience these journals provide: since articles are available on the web for free, virtually anyone can read them. Providing an unrestricted audience means a great deal in this environment, because authors write to have impact on the development of medicine and not to receive royalties derived from potential sales. In fact, studies show that OA access articles have more full-text downloads when compared with similar restricted access articles. Thus, OA actually ensures dissemination of the work [35, 36].

The increased exposure associated with OA publishing is sometimes also identified as a chance to increase the number of citations and consequently the JIF. But, studies have yet failed to demonstrate this advantage. Several factors can affect this trend, one of which is the reputation of long established restricted journals vs. newly established OA journals, which leads authors to publish their best study reports on more prestigious restricted journals, affecting the citation rates [32, 35].

Another advantage is the existence of fewer—if any—copyright restrictions. OA journals usually allow authors to retain the copyrights. This facilitates the use of the contents in future works, and allows the authors and even other parties to make derivative works without having to ask for permissions (which most of the times have to be paid for) [30].

Additionally, over the last few years public funding institutions issued policies stating that results from public-funded research must be made available to the public. These policies were introduced because there was a general understanding that in many instances public institutions—and ultimately the taxpayers—were paying to produce knowledge and then paying again to access it. For instance the American National Institutes of Health issued this policy in 2008, requiring that all peer-reviewed journal articles were submitted to a central repository (PubMed Central) and made publicly available after acceptance. Similar rules are also already in place in the European Union and continue to be implemented worldwide [32, 37].

One of the main arguments against OA publishing is that OA journals tend to have lower quality than traditional ones. The peer-review system of these journals is sometimes seen as too quick, with articles not properly scrutinised. But, over the years this argument has been refuted by the emergence of high quality peer-reviewed OA journals. These developments led to a general understanding that, if well prepared, OA publications can reach the same level of quality than traditional, well-established, restricted access ones [30, 37].

Another problem usually pointed to OA journals is the possible transfer of costs from the readers to the authors. Publishing an article has associated costs, even when journals are "online-only". These costs depend on a variety of factors (e.g. the rejection rate for the journal), but recent estimates point to costs of at least $2,000-2,500 per article in online only OA journals [31]. OA tend to charge authors a publication fee, which in many instances may represent another hurdle for authors with limited research funds—think for instance of authors with limited budget and negative results, will they pay to publish? But, the costs of publishing in OA journals are also reason for concern in highly active research institutions. Several studies already demonstrate that the major players in academic research worldwide will actually pay more to make their articles OA, than they would pay to continue in the traditional model of subscribing journals for their libraries. For instance Cornell University would have to spend an additional 1.5 million USD if switching to OA publishing, while Harvard Medical School—with its 10000 articles per year—would require an additional 9.75 million USD to fully switch to OA publishing [30, 31].

During the past decade, several strong OA publishers have emerged. PLOS is perhaps the most well-known case. PLOS published its first journal in 2006: PLOS ONE. During 2006 they published 138 articles. Impressively, only 5 years later that same journal published 13,798 articles, corresponding to 1 in 60 articles indexed to PubMed that year. The same trend is visible in other journals also published by PLOS. The same success story happened with BiomedCentral. This OA publisher was funded by venture capital in 2000 and due to its success was later acquired by Springer—the biggest publisher in the

biomedical area. Contrary to allegations of lack of financial sustainability for OA publishing, these examples prove that well-designed OA business models might actually work. In fact, today many other important players exist, including Hindawi, Dove Press, or Medknow. Also, traditional publishers such as Sage or Nature groups are increasing their OA portfolios [30, 32].

This growth in OA publishing is also demonstrated by specific studies assessing the proportions of OA articles published throughout the years. Laakso et al [38] found that from 2000 to 2009 OA publishing grown at remarkable rates: 18% more journals and 30% more articles per year. In 2011 Laakso et al [39] also found 340,130 articles published in OA journals, which accounted for 17% of all articles published. While, this figures group all fields of science, medical publishing may even present an higher OA publishing rate: Bjork et al [40] already estimated that, in 2009, 13,9% of medical articles were published in Gold OA and 7,8% were published in Green OA, which only by itself already accounts for 21,7%—already higher that the general estimates for 2011.

Thus, OA publishing appears to be at least an important trend in the future of medical (and generally all scientific) publishing. Estimates point that this growth in market share is to be continued in the coming years, and by 2019 OA publishing will represent 60% of the market [30]. Nonetheless, traditional restricted access journals will co-exist with OA ones for a long time—after all who will turn down a possible publication on Nature for a publication on an OA journal? Traditional journals still enjoy—and probably will for some time—valuable reputations gained over the years. This provides a reward for authors that when publishing scientific articles tend to value reputation and impact over openness and availability. Therefore, there is a clear trend for medical journals to move towards OA, but restricted access journals will still have their place, particularly the more reputed ones.

1.2. ARC PUBLISHING

ARC Publishing is a Portuguese start-up company acting in the areas of medical communication and medical publishing. Medical communication agencies are companies specialised in providing communication services to most players in the medical research area, but particularly to the pharmaceutical industry from which most centralised investments (i.e. single projects with large budgets) come from. Medical communication agencies address a wide range of communication platforms: legal and regulatory documents, scientific publications, poster presentations, medical education materials, and even promotional materials. Some go even further, and provide market research or public research services. Some agencies provide a wide range of these services, but perhaps most medical communication agencies focus on a particular area [41].

Medical publishers provide publishing platforms for players in the medical research arena. Traditionally, medical journals and books were the more widely used platforms. This business area has presented continued growth for decades, and was even thought “recession proof” up until recently. Nowadays, new paradigms threaten the business

models traditionally used. The challenges brought by the digital era are still to be overcome by most publishers, but two main trends at medium- to long-term can be identified: the growth in digital publishing and OA. Digital publishing presents particular challenges for book publishing undertakings due to the lack of efficient legal protection to ensure financial sustainability. OA assumes particular relevance for medical journals, with potential to take a dominant market position within this decade (see section 1.1.3.1). For both these issues, medical publishers continue to look for the right business model, but there are already indications that digital and OA publishing will play major roles, and therefore they represent good business opportunities for companies trying to establish themselves in the business and gain market relevance [30].

ARC Publishing takes advantage of these business opportunities in medical communication and medical publishing. ARC Publishing aims to deliver high quality services in both of these areas, tailored to the Portuguese reality, but also aiming for international exposure, particularly for the publishing services. These services are particularly centred in the medical education business of medical communication agencies (i.e. medical writing for scientific publications), and in the OA journals as well as book publishing services of medical publishers.

1.2.1. Mission

ARC Publishing's mission statement is as follows:

"The ARC Publishing mission is to provide superior medical writing, statistics and publication services, helping you to get out the most of your work, to enhance your reputation among peers, and transfer to society the best of your knowledge."

This mission reflects the two threads of ARC Publishing's operations. In fact, at ARC Publishing's website homepage, this mission is even identified as a double mission, comprising the following parts:

- To provide superior medical writing, statistics and training services, allowing you to comply with the highest clinical research quality standards and to get the most of your data.
- To promote the sharing of scientific knowledge through any form of publication.

1.2.2. Services provided

The range of services provided by ARC Publishing can be can be categorised as follows: Medical Writing, Statistics, Publishing, and Training.

1.2.2.1. Medical Writing

Medical writing services are tailored for two kinds of clinical research players: individual clinician or small groups of clinicians, and large organisations (e.g. pharmaceutical industry).

Medical writing for clinicians comprises two different kinds of projects:

Report/publication preparation – writing service aimed at assisting clinicians with limited resources (e.g. time, writing expertise, etc.). This service comprises the most diverse publication forms: journal articles, poster presentations, oral communications, or abstracts for medical conferences. Additionally, the service also includes revision and editing of other types of scientific documentation, such as book chapters, academic thesis, etc.

Clinical research support – integrated solution to assist in the implementation and execution clinical research activities. This service is well beyond the medical writing field as it provides support throughout the entire clinical research process, but since most tasks actually consist of preparation of writing documentation, it is included here for conceptualisation purposes. Support to clinicians includes preparation of the study protocol and related documentation, assistance in database development, statistical analysis, and report writing.

In terms of medical writing for large organisations, services range from translation of clinical research documentation to writing online informative contents. As with individual clinicians, preparation of scientific publications is also available (for all publication forms previously described), but large organisations have also available editing and publishing services for conference proceedings or even medical journals.

1.2.2.2. Statistics

Statistical consultancy services provide clinical research players with validated and cost-efficient support for their studies. Statistical consultancy can be used at most phases of clinical research projects, but early assistance is advised. These services add value to the research project by providing statistically sound techniques for clinically well-developed studies.

1.2.2.3. Publishing

Publishing services provide easy access to high quality publishing platforms. These services include the most varied types of scientific publication forms. ARC Publishing is a valuable option for publishing periodical medical journals, but also books, book series, and conference proceedings. The publishing services are specifically designed to ensure the quality of the publications, as well as to maximise their scientific impact.

1.2.2.4. Training

ARC Publishing makes available several types of training sessions on the areas of expertise of the company. Training topics include Medical writing and scientific communication as well as biostatistics. Training sessions are tailored to the audience's specific needs in order to provide attendees with easily applicable knowledge.

1.2.3. Working environment

ARC Publishing is a small enterprise with home-based associates. Given the nature of services provided, the company takes advantage of the new communication channels made available by information technologies, so all associates remain home-based. In-person meetings are held as required, depending on the projects under development. Therefore, the activities described in the following chapters of this report were developed under these circumstances.

CHAPTER 2 – MULTIDISCIPLINARY ACTIVITY

One of the advantages of working for a start-up company is the chance to participate in a wide range of activities. As such, during this internship at ARC Publishing, I enjoyed the opportunity to develop varied multidisciplinary tasks. This gave me the chance to gain general working experience.

In this chapter, I group the main multidisciplinary activities into four broad categories: business development and marketing, information technologies, quality assurance, and editorial management. Nevertheless, this is not rigid structure: several interlinks between those categories are present.

2.1. BUSINESS DEVELOPMENT AND MARKETING

Developing a successful company requires sound business development strategies. Business development includes a wide range of activities that aim to take advantage of potential growth opportunities. These activities range from traditional management tasks to marketing strategies and even sales.

During my internship I got to know the company's business strategies. I also implemented some activities to achieve the business goals defined. In the following sections, I describe particular tasks carried out in this area.

2.1.1. Website content preparation and translation

One of my first tasks when I arrived at ARC Publishing was accompanying the development of the contents for ARC Publishing's website, and then translating them from English to Portuguese.

Developing website contents is a very challenging task. The contents should be adequate for the broad audience that might access the website, but at the same time sufficiently directed for particular stakeholders (i.e. the prospective clients). The website is the image of the company, and therefore it is crucial that the messages are carefully crafted: readers actually capture the core values, missions, processes, and added-value the

company represents. For a medical communications company the website assumes an even greater importance, since it is in some way a reflection of the company's capacities in getting the right messages through.

To achieve this level of refinement, the contents went through several iterations of conceptualising, writing, and revising until the text was considered ready for publication. Accompanying this process made me understand that in the marketplace, relatively simple and not often though of tasks might represent great challenges. Thus, they should be well-planned and not underestimated.

At the company English is considered the main language, since this is the language in which most scientific knowledge is transmitted worldwide. Thus, documentation is initially prepared in English and then translated as required. In this case, since the website is available in English and Portuguese, I translated the contents to Portuguese.

Despite Portuguese being my native language, this was not as straightforward as it may look. Good translations ensure that the meaning remains intact. But, maintaining the meaning is challenging, particularly when idiomatic expressions are used in the original. I have also encountered additional challenges associated with translating personal pronouns, because in Portuguese these words are applied in a substantially different manner. Therefore, translating the contents to Portuguese presented me with some unexpected challenges. But it also allowed me to gain experience in dealing with these issues and develop strategies to tackle them in future projects.

2.1.2. Development of electronic newsletters

Most marketing strategies today try to improve online presence, and electronic newsletters help achieving this goal. My work in this area was analysing the best technical tools to implement ARC Publishing's marketing strategy.

Developing electronic newsletters requires extensive work. To be successful, we have to make sure the right message reaches the right audience. Additionally, newsletters have to stand out, since internet users receive dozens, if not hundreds of these messages per month. Users are likely to spend only a few seconds on each newsletter—that is if they even open it at all—so it is crucial to insert visually appealing elements in addition to the targeted text to gain their attention and make sure they keep reading.

Besides targeting the message, technically building the newsletter is also a defiant task. Electronic newsletters are usually written in HyperText Markup Language (HTML) (traditionally the most widely used programing language on websites) and then sent over email. Nevertheless, programing these emails is a tricky task, since most email clients (the software in which internet users read their email) are very selective in terms of the technologies associated with HTML they support. For most of them the programmer can only use the HTML technologies existent in the 90's. Even though some clients support more advanced technologies, newsletters have to be built in a manner that ensures they are supported by all email clients, so that the message correctly reaches all addressees.

To carry out this task I considered the specifics of this kind of communication and also the technical difficulties involved. I came across several solutions, including the use of specialised software and web services. Eventually, I settle on a strategy for electronic newsletter preparation and sending. This knowledge was later applied as part of a communication strategy (see section 2.4.1.2).

2.1.3. Development of contacts databases

To successfully implement a communication and marketing strategy, gathering the right contacts is also vital. My work here consisted of defining the format for a database of contacts, followed by a process of narrowly gathering contacts.

During this task I had to try different types of database in order to understand which of them provided the best integration with tools where the final contacts were going to be used. Then I developed a written procedure indicating how these databases should be handled.

Once the technical platform was defined, I started to collect contacts. These contacts consisted of stakeholders in the clinical research area with potential interest in ARC Publishing's services. For instance, I made a comprehensive search on scientific societies holding conferences, so that these contacts can be used for future targeted marketing campaigns. These activities contributed to increase my knowledge on the environment in which the company operates.

2.2. INFORMATION TECHNOLOGIES

Information technologies (IT) play a huge role in today's world, and at ARC Publishing we try to take advantage of the opportunities they provide. In this section I describe the main IT-related activities developed during my internship: from testing web-apps to writing IT Documentation.

2.2.1. Web-app development and testing

From the beginning of my work at ARC Publishing, I accompanied the development of a very important IT infrastructure. This process was outsourced to an external IT development company and turn out to be extended throughout most of the internship. During this process, I tested—along with other company colleagues—the "preview" versions of the applications produced, both from the administrator as well as the end-user perspective.

These activities gave me some experience with outsourcing, and particularly with outsourcing that does not goes so well. The web-apps under development consisted of a

peer-review platform for scientific publications (namely scientific journals) and ARC Publishing's website itself. Given, the complexity involved in these applications, carefully prepared requirements were developed when the project was outsourced (before I began my internship). Nevertheless, even with very specific requirements laid out, some misunderstandings arisen (mainly associated with the applications' functionally) and consecutively delayed the project. By the time of writing of this report the website was already accessible online. Appendix 1 provides a screenshot of the final product.

Accompanying this process allowed me to understand de importance of properly monitoring outsourcing activities. In this project, detailed requirements were defined, but problems at this level still arisen. This proves how important it is to thoroughly monitor the development process to make sure everyone involved is on the same page.

2.2.2. Web-app documentation preparation

Highly associated with the development of web-apps is the development of proper documentation. Besides testing the web-apps mentioned in the previous section, I also developed documentation specially tailored for the system at hand, namely privacy policies, terms of use, and user guides. In the following sections I describe noteworthy aspects associated with developing each kind of documentation.

2.2.2.1. Privacy policies

Privacy policies assume an ever growing importance. Users are becoming more concerned with their digital privacy and even legal requirements are tighter now. To prepare the privacy policies for the web-apps previously mention, I had to follow the applicable legal requirements, which are now particularly extensive within the European Union. Additionally, I had to benchmark privacy policies for similar web-apps in order to understand which would be the best approach. Finally, with the requirements and examples in mind, I prepared the privacy policies adjusted to the characteristics of the systems.

With this activity I learned that privacy policies are about being rigorous and honest. The policy should be clear, easy to read and understand, and most importantly, it should honestly represent how personal data will be handled. Users' personal data should always be respected. But, besides putting in place all reasonably measures to achieve this goal, it is crucial to properly inform the users.

2.2.2.2. Terms and conditions

To develop the terms and conditions I followed a process similar to the one described for privacy policies: I analysed the requirements, did some benchmark, and then build a tailored document.

Terms and conditions are the documents in which the company states how the users should use the services provided. I understood that it is very important to mention that the application must be used for its intended purpose. Associated with these clauses, the company also reserves the right to restrict access, and states the conditions in which such restrictions apply. The rights of the users are also described. Then some legal clauses are usually added to prevent the company from being legally liable from possible damages or having the right to compensation in case these damages arise from misuse of the system.

2.2.2.3. User guides

Once the systems were ready, I prepared the user guides that accompany the peer-review system. These guides are end-user oriented and so were divided into three different guides: the author's guide, the reviewer's guide, and the editor's guide. For each guide I described the normal flow of use for the system in a particular user perspective and try to be very comprehensive in my approach.

During this activity I understood that it is not always easy to think of all situations possible and place them in these documents. It is crucial to describe every little detail and always use the simplest language possible. Is not, however, an easy task easy to place ourselves in the end-user position when we already have great experience with the system (much less in the naive-user position). Thus, building user guides is always a work in progress, these documents will probably need to be updated as new usage issues arise, but we should always try to cover the biggest set of situations reasonably possible.

2.2.3. Electronic Data Capture software

Electronic data capture software (EDC) is tailored to facilitate the collection of data from clinical research. EDC provides gains in efficiency, since it allows the users to enter, review, and analyse data in real-time. It also allows gains in data quality since validation checks can be easily implemented to identify possible errors at the time of entry. This type of software has been increasingly adopted in clinical research. Now, it is widely used in large industry-funded clinical trials, but is also starting to be used in other initiatives, such academic studies or disease registries [42, 43].

In the following sections, I describe the two main activities performed during my internship with relation to this kind of software. Initially, I describe the main learning outcomes of some "hands-on" experience with open source EDC software. Then, I state the main findings from extensive market research on commercial EDC software.

2.2.3.1. Testing "off-the-shelf" open-source solutions

OpenClinica is one of the most widely known open source EDC solutions. In fact, according to OpenClinica's website: "OpenClinica become one of the world's most widely adopted clinical trial software technologies powering research in over 100 countries". This

software is available in two versions: Enterprise edition and Community edition. I tested the community edition, which is freely available to download (https://openclinica.com) and can be easily deployed.

To start testing OpenClinica on a "real-life environment", I had to find a server to install the software. After some research on the subject, I came to the conclusion that it would be better to install the software on a cloud computing platform (these platforms provide users with computing capacity in real-time, without the need for upfront investments; hardware is maintained by the provider; the user has access to this computing capacity through the internet). So, I set up an Amazon E2C computing instance and after some trial and error attempts got the system to function.

While testing OpenClinica I had the opportunity to understand how very complete this EDC software is. I also had to experiment with cloud computing, particularly with Linux servers, which proved to be an enjoyable task in the sense that it gave me some insight on how these technologies actually work. I also investigated the regulatory requirements involved in the use of EDC software for clinical trials conducted with the intent to be submitted within a market authorisation application. These requirements are very extensive, and although OpenClinica is prepared to support them, the effort required to prepare all the documentation needed makes it very difficult to implement a regulatory compliant installation of OpenClinica community edition. Thus, several commercial EDC solutions are available, with a pre-defined validation package, to facilitate this implementation—OpenClinica Enterprise edition being one of those solutions.

2.2.3.2. Market research on commercial Electronic Data Capture solutions

Having in mind the limitations of open source EDC solutions for regulated clinical trials, I set out to evaluate the different types of commercial alternatives. This was a very enriching activity because it provided me some insights on how the international marketplace operates. I had to search the alternatives available and then contact the providers; this gave me the chance to practice my English communication skills, mainly because most providers contacted me directly by phone.

In terms of the software itself, I learned how to prepare a set of requirements when making this kind of inquiries. I also got a good understanding of the business models involved, the types of technological implementation, and the different pricing models used. Most importantly, I overviewed the international landscape for this kind of technology, which may be of good use for my professional development in the future.

2.3. QUALITY ASSURANCE

In today's competitive world, the quality of work produced assumes an ever growing importance. Quality assurance is the designation usually employed to define a whole range of activities carried out by organisations to ensure that products or services meet the quality requirements. A vital part of these activities is the development of written procedures, which ensure tasks are carried out in a pre-defined manner, leading to quality and efficient results. Next, I explore the development process for written procedures.

2.3.1. Writing Standard Operating Procedures for Information Technology activities

The Standard Operating Procedures (SOP) that I develop were related to the handling of IT at ARC Publishing. These SOPs were mainly associated with defining the requirements for the IT infrastructure as well as requirements for IT users.

When developing these SOPs I had to think about IT processes that I would not otherwise thought of. I identified details in these processes that I would probably not notice otherwise. Also, I gained some experience in SOP writing—a vital skill for most professionals in this area—particularly in terms of understanding how crucial it is to properly define every aspect, but still maintaining the procedure practical and achievable.

2.4. EDITORIAL MANAGEMENT

During my internship period, I also accompanied and, in some cases, participated in activities associated with the publication of an international peer-reviewed journal. The following sections describe these activities.

2.4.1. Launching an international peer-reviewed journal

The International Journal of Clinical Neurosciences and Mental Health is an international peer-reviewed journal launched by ARC Publishing in April 2013. This is an open access journal aimed at providing high-quality publications in the areas of Psychiatry, Mental Health, Neurology, Neurosurgery and Medical Psychology. The journal's editorial board is composed by international expert leaders in these medical areas. I had the opportunity of accompanying the development of this journal prior to launching and then participating in the activities associated with its launching in April 2013.

2.4.1.1. Website preparation (review of contents and testing)

One of my functions in this regard was to prepare the website for launching. I reviewed the contents previously prepared and adapted them to the website structure and technical capabilities, so that they were the most user-friendly and professional looking possible. Appendix 2 provides a screenshot of the final product.

I also had to deal with implementation problems that arose when the website and peer-review platform were placed in their final form. Dealing with these issues posed a substantial challenge: I did not have the technical capabilities to resolve them, but had to expedite their resolution because they the systems' function and journal's credibility could be potentially impacted.

Additionally, I also reviewed the journal's documentation (e.g. authors or reviewers instructions). Here, I tried to anticipate potential doubts and make the text the most self-explanatory possible. In this preparatory phase, I also organised a database of contacts to publicise the journal once it was officially launched.

2.4.1.2. Call for papers

To publicise the journal once it was launched, I prepared a general "Call for Papers" email. I used the knowledge acquired when working with electronic newsletters to prepare this email. In fact, I adapted the format of the newsletter for this purpose and then massively send it to the contacts in the journal's database.

I tried to make the announcement visually appealing in order to overcome the "direct to trash" effect of these kinds of campaigns: users receive various emails with this format and visually appealing elements can be very important in gaining their attention for more than just a few seconds, and hopefully get them to visit the website to learn more about the journal.

This call for papers was also distributed by other means besides email. A Magazine advertisement was derived from the call for papers. This advertisement was published on the magazine of the Northern Section of the Portuguese Medical Association, "nortemédico". The advertisement consisted of an entire magazine page with the information from the call for papers, and some details on the aims of the journal as well as the editorial board. This advertisement is shown in Appendix 3.

CHAPTER 3 – MONO-DISCIPLINARY ACTIVITIES: MEDICAL WRITING

Medical Writing is about communicating medical science with the right message, to the right audience, using the right communication form. Basically, it is about achieving maximum communication effectiveness. Although medical writing is an activity thousands years old, only in the past century it was established as a clear, separate profession. Nowadays, medical writing professionals write high quality pieces in a variety of communication/publication forms. Medical writing activities can be broadly categorised as follows:

Regulatory medical writing – producing high quality documentation for regulatory purposes. These activities are usually associated with highly regulated areas such as research and development of pharmaceuticals and medical devices. This includes the production of documentation for clinical trials, but also observational studies or non-clinical studies.

Medical communications – producing scientific writing pieces with informational or didactic purposes. Medical literature publications (journal articles, books, etc.) are included here, but other more teaching-oriented materials are also included, such as slide kits, manuals, etc. In broad terms, marketing-oriented medical writing activities may also be included in this category, since these marketing campaigns focus on providing scientific information with commercial goals [41].

Medical writers are employed (of contracted) by a variety of organisations, from the pharmaceutical industry, to specialised medical communication agencies. Thus, the range of activities performed and outputs produced are increasingly large. Nonetheless, some main tasks/outputs can be identified.

Medical writers have historically been involved in producing regulatory documentation associated with development and marketing of pharmaceuticals (e.g. clinical trials' protocols and reports, protocols and reports for non-clinical studies, as well as marketing authorisation applications). Writing for the medical literature is also a crucial task for medical writers; these activities include the preparation of original research reports (for instance, presenting the results of clinical trials to the scientific community), literature reviews, book chapters, among others. In a globalised world, in which medical research is

often multicentre and multinational, medical writers also translate essential documents to facilitate the conduction of research activities or eventually to comply with regulatory requirements. Additionally, medical writers may also prepare medical information/education materials, such as slide kits and brochures, or participate in marketing campaigns, providing scientific writing support [41, 44].

Usually associated with medical writing is the concept of medical editing. Medical editing can be described as fine-tuning medical writing pieces. These activities can be performed by medical writers (some companies adopt this strategy) or by specialised medical editors (although such professionals tend to have broader roles, including late-stage proofreading and publication). Nonetheless, in a broad sense "Medical Writing" usually includes both writing and editing. When editing, it is important to check for scientific accuracy, grammar, and editorial errors (style inconsistencies, lack of clarity, etc.). Editing includes "quality assurance" of documents prepared by a medical writer, but also critical revision of documents prepared by other professionals. These activities play a crucial role in medical writing, since quality is of essence and only with meticulous review we can achieve it [41, 44].

One may ask himself if professional medical writing services are so essential when authors can simply prepare their documents and then have them reviewed by appropriate reviewers/proof-readers. In fact, this question probably goes through the mind of many when they first hear of medical writers. Nevertheless, professional medical writing services play a crucial—quiet, but crucial—role in today's medical science and knowledge communication [41, 44].

On the industry front, medical writing is a great asset: regulatory hurdles are tackled with tailored, professionally prepared solutions ensuring efficiency and reducing marketing introduction times, which may signify great economic added-value. Additionally, educational medical writing also presents great added value to the industry since it allows prescribers to get to know the industry's best proposals and solutions. This is particularly relevant in today's crowded market, where prescribers often have difficulties discerning the added-value of each alternative [41, 44].

On the individual investigators front, medical writing consulting also presents significant benefits. Medical experts contracting medical writing services often do so because to remain experts in their fields they do not have the time or the motivation to improve their writing skills and prepare high quality documents. Thus, medical writing services portrait as a great tool, since they allow the experts to transmit their insights to their peers in an efficient and pleasant manner for both the author (the ideas expressed are still the expert's, is the manner in which they are communicated that is perfected by the medical writer) and the reader [41, 44].

Medical writers come from a variety of backgrounds. Most have had some experience with academic research; many even have PhDs, but at some point decided they wanted to get away from the frustrations of "hands-on" research. The common denominator is enjoying writing scientific documents and wanting to be able to keep in touch with medical science, and perhaps get to know new medical subjects. Independently of their origin,

medical writers need to have good organisation and search (through the medical literature) skills. They also need to have multidisciplinary knowledge and keep up-to-date on applicable regulations and guidelines. Therefore, the medical writer profession constitutes a good platform for people aiming at contributing to the development of medical knowledge, who prefer working in differentiated but challenging environments on a regular basis.

There are, however, still some controversies about the use of medical writing services in the medical literature. Most of which are associated with the so-called "Ghost-writing" practices: employing medical writing services to prepare manuscripts without proper acknowledgement and sometimes even without proper input from the authors—sometimes authors have absolutely no input at all.

Medical writers associations (e.g. the American Medical Writers Association or the European Medical Writers Association) issued strict guidelines for ethical conduct in medical writing. These guidelines generally agree in considering that listed authors should have significantly contributed to the analysis and interpretation of results and feel comfortable taking responsibility for the contents of the publication. Thus, for most research articles, medical writers do not qualify as authors. Nevertheless, guidelines also mention that in these circumstances medical writers should be properly acknowledged, with their role and source of funding specified [45, 46].

In this chapter, I describe the main activities performed as a Medical Writer at ARC Publishing. Since this is my area of specialisation, a major proportion of the internship period was spent on these activities. My tasks fall mainly within the "Medical Communications" field previously described. They range from writing original research reports to accompanying the translation of clinical research documents, to editing books, and to editing other diverse scientific documentation.

3.1. MANUSCRIPT WRITING (ORIGINAL RESEARCH REPORT)

Preparing an original research report was one of the most challenging tasks I had the opportunity to undertake during this internship. This was a manuscript for publication on a highly regarded peer-reviewed journal. The manuscript was jointly prepared by me and another ARC Publishing associate. It combined data from three different clinical trials on bipolar disease treatment. Data was already analysed: our job was to present the findings in a scientific manuscript, using the clinical trial reports as a starting point.

First, we analysed the clinical trial reports and prepared an outline for the manuscript. This allowed us to make sure the writing was aligned with the clients' intents. Then we went back to the reports and studied them in great detail to capture all important findings and understand which would be the best presentation form.

At this point, we started to define which figures and tables would be presented. Constructing these tables and figures revealed to be a quite challenging task, because the clinical trial reports did not always presented information in the clearest way. Here, the

situation was aggravated by the fact that the reports for the three studies had been prepared by different organisations, and thus the presentation forms were slightly different. Nonetheless, after some effort putting these tables and figures together, we were able to capture the main findings for the three studies.

Afterwards, we began writing the text around the data presentations. I found the "Methods" section relatively easy to write because the methods employed were already very well defined in the clinical trial protocol and clinical trial report. The results section was not so straightforward because it had to complement the tables and figures. We pointed out the main findings, exposing what the data in the tables and figures meant without actually repeating these data.

To write the introduction I conducted a literature search, to make sure relevant recent publications were mentioned as needed. I found this activity particularly enriching because it gave me additional knowledge on the subject at hand. As to the "Discussion" section it was important to make sure the authors' views were properly represented, but it was also important to be cautious about all the claims made—once something is written it can be taken back!

Finally, we wrote the abstract, based on the whole manuscript. Here, good summarising skills were crucial to portrait the best picture of the manuscript in a very limited space. Nevertheless, I found that as I worked on the whole document, summarising the main points came relatively naturally, with exception from some sentences, of course.

This was a very important assignment in developing my medical writing skills. It gave me experience with two types of medical writing: regulatory writing, in the form of clinical trial protocols and clinical trial reports; and medical communications, in the form of peer-reviewed journal publications. Besides, giving me experience with this two, perhaps most crucial, areas in all medical writing, this assignment was also pleasant to develop since it required a comprehensive, rigorous, and methodological approach.

3.2. TRANSLATION OF CLINICAL DOCUMENTS

During the internship, I also participated in the process of translating clinical documentation. The clinical study protocol, the informed consent form, and the case report forms were included. The documents were originally in Spanish and were translated into Portuguese. My task was editing the Portuguese translation.

This task provided me experience with clinical study documentation (whereas the previous task encompassed clinical trial documentation). Besides, I had the chance to understand some particularities of Spanish-Portuguese translations. I also improved my editing and proofreading capacities, which is are crucial skills for medical writers.

3.3. BOOK EDITING

Book editing activities encompassed two books: one very preliminary book in need for major content revisions, and one late-stage book ready for proof-reading, production, and print. Thus, working with either one of these provided me quite different experiences and learning outcomes.

The first book—the preliminary one—was about special topics in therapeutics. Here, the chapters were prepared by authors without much writing experience. Despite some chapters being reasonably good, most needed substantial editing (and even content revision). Since this assignment took a fair among of time to conclude, it was central in improving my writing and editing skills. I learn to spot bad writing signals. I acquired the capacity to better suggest alternative forms of writing. And, I even built somewhat predefined mental schemes for implementing corrections. Here, I also learned that editing can be tough since the editor cannot change meaning without the authors' consent. Moreover, I recognised the value of my multidisciplinary academic training: in technically understanding what I was reading, I was able to come up with better editing solutions.

As for the second book—the late stage one—it addressed health informatics issues. Since, this book was already in an advanced stage when I first started working on it, here I learned about the final stages of book production and publishing. I learned how to use specialised software (Adobe InDesign) and absorbed particular aspects of book publishing previously unknown to me. This assignment was particularly interesting because I was constantly learning as I was going through the production process.

3.4. REVISION AND QUALITY CONTROL OF SCIENTIFIC DOCUMENTS

During this internship I also had the chance to review different types of scientific documentation. I gained knowledge on the contents of those types of documents, most of which I had some previous knowledge at the macro-structure level from my academic training. Here, I built upon that knowledge and gained new insights on scientific documentation to produce those documents, which may prove to be very important for my career development.

More importantly, I improved my editing skills. I saw good writing examples. I improved my capacity to critically review writing pieces. And, I learned new ways for streamlining writing. With time I began to incorporate these insights in my writing and editing on a daily basis. Next, I will probably start using these approaches without even thinking about them.

3.5. LESSONS LEARNED AS A MEDICAL WRITER

If had to identify the most important lesson from my medical writing activities, I would probably say that it was the understanding that in medical writing simplicity is key. By simplicity I mean presenting the same complexity of thought in the clearest and straightest way possible. Not reducing the scientific accuracy or the deepness of the ideas transmitted, just making the text flow better and be enjoyable to read. Before, I often tried to make text overly complicated. I thought it better reflected my good writing skills. Now, I understand text should be simple, well-crafted, and lively. This way, readers actually enjoy the pieces, and thus are much more likely to keep reading.

I also understood that to prepare scientific documents, one should also be rigorous. All calculations should be performed with caution, and then double-checked. Spelling is, of course, of the outmost importance in professional writing. Professional writers have the obligation of identifying misspellings—after all that is what proof-reading is for. Other than these technical glitches, the ideas transmitted in the text must also be well-thought of. All statements should be carefully considered and clear enough so that alternative interpretations don't arise.

Before I start this training as a medical writer I was already a big fan of planning, but now I appreciate even more these activities. Planning not only improves efficiency, but also ensures alignment—very important between writers and editors on the same project, but, perhaps even more vital between the writing staff and the client. Planning involves preparation of outlines, determining the roles of each staff member, and of course, scheduling. During my internship I learned how to perfect the use of these tools, which allowed me to improve my work efficiency and increase my self-fulfilment as I was seeing my tasks performed at an ever-growing pace.

Finally, I also learned that, perhaps contrary to common belief, good writing skills can actually be learned and trained. For medical writing in particular, training and experience play essential roles. Medical writers have to learn the specificities about every document they produce, have to understand their audiences, and have to do so in record times. Therefore, while medical writers should have some degree of natural writing talent, they should also work hard to improve their scientific communication skills on a daily basis.

CHAPTER 4 - DISCUSSION AND CONCLUSIONS

During this curricular training period, I had the opportunity to develop an array of diversified tasks. As planned, my efforts were divided between medical writing-related activities and other varied activities.

Developing this set of tasks provided me a complete training experience. While I greatly improved my specialised skills in medical writing, I also improved my multidisciplinary capacity. This training model proved to be a great asset for someone just starting after several years of academic education.

In the following sections, I discuss how these curricular training activities contributed to my learning experience and impacted my skill's set. I start by discussing my experience with multidisciplinary activities. Then, I go through the medical writing activities. Finally, I conclude on the overall learning experience and its implications to my future career development.

4.1. MULTIDISCIPLINARY ACTIVITY

Multidisciplinary activity provided me a wide work experience during this internship. With these undertakings, I got to know new working environments, develop new working routines, and got better understandings of the "real marketplace". Besides, when undertaking multidisciplinary tasks, I also learned about potentially interesting new topics, such as medical publishing.

These activities also contributed to widen my spectrum of professional competences. In terms of web-app development, I understood how important it is to define the right set of requirements—detailed as reasonably possible, and then even more detailed! I acknowledge how crucial it is to tailor website's contents to deliver the right message to the right audience. And finally, I also incorporated new technical concepts on information technologies and even got some experience with IT administration.

Also, I got a better perception of the clinical data management fields. I learned about the different types of EDC alternatives (open source vs. commercial) and the different types of EDC needs (i.e. different types of studies require different types of technical

capabilities). I also approached regulated clinical data management and learned about specific EDC solutions while inquiring providers.

Finally, I also learned about the promising new opportunities in medical publishing. Working on the development and launching of a new international medical journal provided me a deep understanding of these fields of activity. Besides, I also learn about the increasing trend in Open Access publishing and the opportunities it poses. Working with book publishing was also very rewarding, since I approached processes that I would not otherwise thought about, but which are very interesting.

Thus, I look forward to continue developing work in these areas. I have always had particular interest in IT-related subjects, therefore carrying out IT tasks constituted an enjoyable experience. With the medical publishing fields I was not so familiar, nonetheless discovering the opportunities medical publishing presents was particularly gratifying, and thus I intend to keep exploring this area.

4.2. MEDICAL WRITING EXPERIENCE

My medical writing experience, as I was expecting from the beginning, was very pleasing and fulfilling. This was an area of great interest to me since I first heard of it. Working in medical writing allows people to keep in touch in full-blown science without actually having to deal with many of the disappointments and frustrations associated with it. I find this notion particularly interesting for developing a career, in opposition to the instability and ever-changing environment associated with other scientific activities.

During this internship, I greatly developed my medical writing skills. I started using new tools: from computer applications to medical dictionaries. I improved my planning capacities before start writing. I worked with different types of documents, and understood important differences in the preparation of each type. And lastly, I improved my overall writing skills: using new vocabulary, proactively alternating punctuation, applying adequate structural forms, developing visual aids, simplifying texts, and tailoring messages and contents.

In the future, I look forward to also keep developing medical writing activities. One thing I learn during this training period was that a medical writer is continuously learning. In my case, a beginner in these fields, I still have much to learn. Medical writing is a broad field, with many little details that only with continued experience are uncovered. This continued activity will also give me chance to understand which areas I enjoy the most, so that then I can try them as a specialisation.

4.3. OVERALL LEARNING EXPERIENCE

Activities developed at ARC Publishing were a great complement to my academic training. Although my academic training was already oriented to the practical application of the knowledge I was acquiring, here I had the chance to understand how the actual marketplace looks like.

The bachelors (in Biomedical Sciences) and masters (in Pharmaceutical Biomedicine) degrees provided me with very good visions of medical science, with particular emphasis on pharmaceutical medicine and clinical research. Here, I went even further and got to know an even more specialised area: medical communication and publishing. This specialisation was very much facilitated by my broad academic background, since I already had some degree of knowledge on most subjects I worked on. This asset was particularly noticeable when carrying out my medical writing functions, because my medical science background allowed me to get very good understandings of what I was writing about.

Additionally, this internship provided me the opportunity to learn about issues not usually addressed in most courses—if any. I worked in new fields of medical publishing, such as Open Access publishing. I even accompanied some business development activities. Thus, this multifaceted experience was also a great complement to the academic education because it better prepared me to join the working marketplace.

During this training period I have also encountered some difficulties. I had to enhance my interpersonal communication skills, which due to my quiet style were not always the most desirable. I also faced some hurdles during the IT development tasks. Here, the difficulties (and their resolution) were not controlled by me, but I still had to make considerable efforts to expedite their resolution. To develop some tasks that I was not so familiarised with, I also had to conduct some research, but on a general manner I was able to overcome the difficulties.

This internship period also represented added-value for ARC Publishing. Some of the activities I executed during this period included large components of research, and thus contributed to expand the company's body of knowledge. Other activities were directly related to the commercial activity of the company. For example, I had an active role in preparing and launching the company's website, launching the International Journal of Clinical Neurosciences and Mental Health, and conducting medical writing work. Additionally, some of my undertakings laid the foundations for future business development in areas not yet explored by the company. These activities are of particular importance, since at a start-up company refinement in the existent processes and development of new business areas might be key factors for success.

The objectives laid out for these 9 months of training (and outlined in Chapter 1) were largely accomplished. I got the chance to apply the knowledge I acquired during my academic education. Both my general training on biomedical sciences as well as my views on pharmaceutical medicine constituted a great asset and were very important in successfully conducting the assigned tasks. This training also provided me a better insight

of the marketplace in the fields of medical research and communication. I got a better understanding on the business opportunities available, I overviewed the business processes involved, and learn about new areas of interest.

The wide range of activities I worked on helped me improve my general work capability, since I had little previous work experience. The activities defined here as "Multidisciplinary" had a crucial role in attaining this objective. As for the medical writing experience, I learned on a daily basis, complementing my previous medical writing notions, and achieving a fairly high level of expertise (taking into consideration, of course, my limited experience).

Hence, this curricular internship provided me a solid experience, complementing my previous knowledge and introducing me to the working environment. Additionally, it also widened my perspectives for future career development.

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APPENDICES

Appendix 1. Screenshot of ARC Publishing's website on May 2013

ARC Publishing

ARC PUBLISHING | MEDICAL WRITING | STATISTICS | PUBLISHING | TRAINING | ABOUT US | CONTACT | EN | PT

News

Launching the International Journal of Clinical Neurosciences and Mental Health

ARC Publishing

Outstanding services in medical writing, statistics and publishing.

We at ARC Publishing have a double mission:

- To provide superior medical writing, statistics and training services, allowing you to comply with the highest clinical research quality standards and to get the most of your data.
- To promote the sharing of scientific knowledge through any form of publication.

Just publishing is not enough anymore, you have to make it count and take all the juice from that fresh orange.

LOGIN

Login

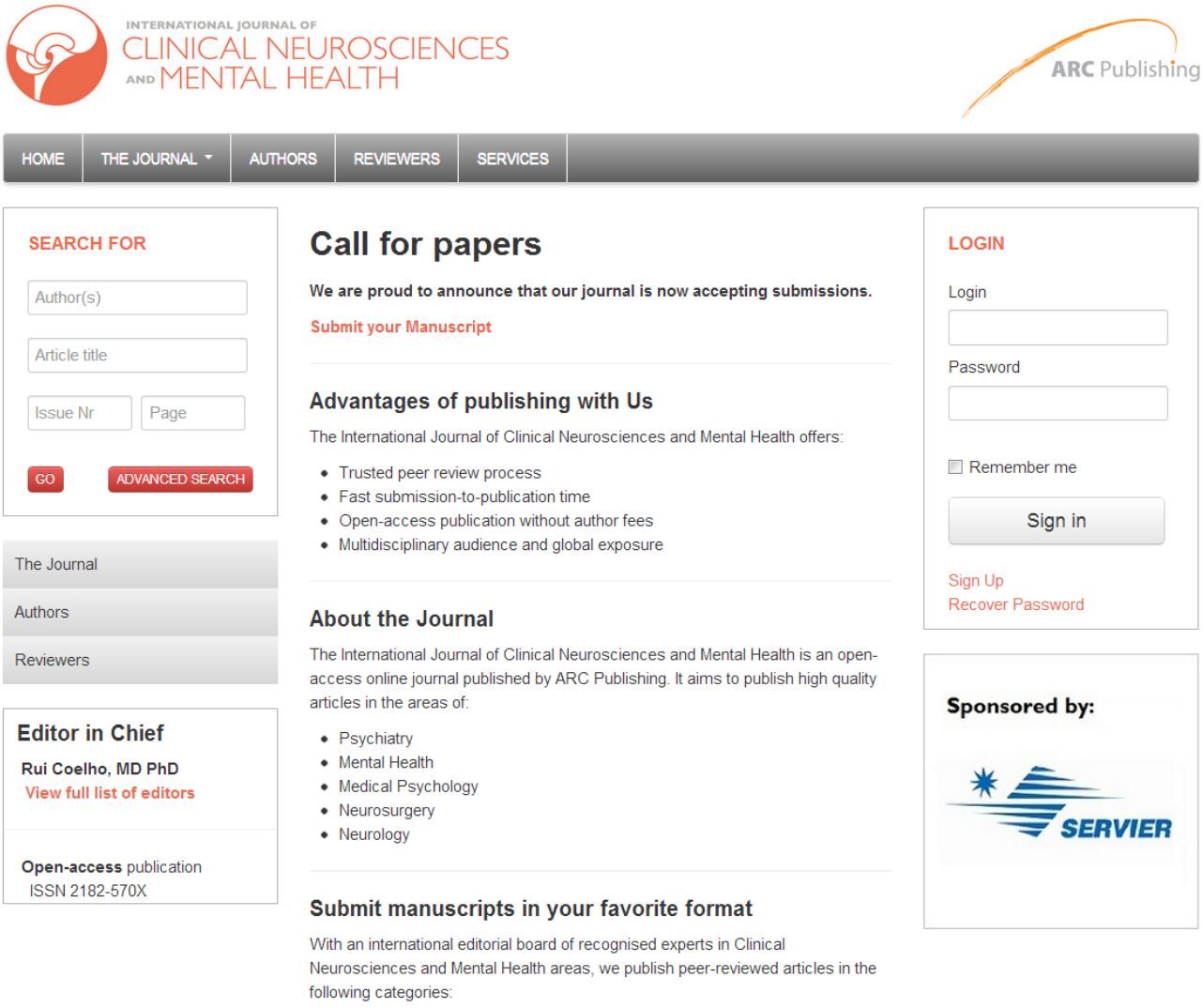
Password

Remember me

Sign in

Sign Up
Recover Password

Appendix 2. Screenshot of the International Journal of Clinical Neurosciences and Mental Health website upon launching



Appendix 3. Advertisement published on the magazine of the Northern Section of the Portuguese Medical Association, “nortemédico”.