Medical Writing

The Medical Writing Business

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Contents

Themes of upcoming issues of *Medical Writing*

December 2015: The theme will be '**Writing for lay audiences**'. The issue will include articles on writing patient education materials, and medical journalism. *The deadline for feature articles has passed.*

March 2016: The theme will be '**Authorship and transparency**'. The issue will include articles on interpreting the revised ICMJE guidelines and the Sunshine Act, how to deal with conflicts about who should and should not be an author on publications, the results of the ISMPP medical writing practice/ghost writing survey, and updates on the European Medicines Agency's transparency initiative for clinical studies. *The deadline for feature articles is 7 December 2015.*

If you would like to submit an article, have ideas for issue themes or articles, or would like to discuss any other issues, please write to **editor@emwa.org**.

In this issue...

The Medical Writing Business

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As medical writers, we strive not just to survive but to thrive. Threats, opportunities, and complications come from many directions, and how to best position ourselves, our departments, and our companies requires much thought. Money is important but so too is finding the best way to operate within the competitive business of medical writing.

A recurrent topic in the medical writing business – and one that frequently creates a great deal of concern – is the threat of cheap outsourcing. Related to this is how to convince clients to pay decent rates for quality work. I myself have had several conversations in the last year about this and have spent much time thinking about it. **Michelle Guillemard** takes on this subject directly, asking 'Is cheap outsourcing a threat to your career?' Her answer is no – with caveats – and she tells us how to combat it. **Julia Forjanic Klapproth** takes on this question from a different angle, explaining how clients can optimise outsourcing to professional medical writers. In essence, their conclusions are the same: in the end, you get what you pay for.

Those of us working as freelancers or for agencies understand that the business of medical writing is competitive. Clients are always trying to get more for less, and freelancers and agencies are trying to beat their competition for good-paying work. But is it time for medical writing agencies to not just compete but to cooperate for the common good? **Karen Wooley and colleagues** describe the results of the Agency Executive Forum, sponsored by ISMPP (the International Society for Medical Publication Professionals). The Forum came up with a number of areas of potential collaboration, including proposing best practices for working with freelance medical writers and for responding to procurement-driven requests for information.

As individuals, we often ask ourselves if another type of business would be better for us. For example, many medical writers working for an employer fantasize about the independence of freelancing. Other medical writers might be thinking about creating their own company or running a medical writing department within a company or institution. For someone thinking about switching business types, there is much to consider. **Kathryn White** gives some practical advice about taking the leap from employee to freelancer and provides helpful advice for those already freelancing who want to maintain or grow their business. **Helen Baldwin**, founder of Scinopsis, follows with an article about setting up a medical writing company and what she has learned about how to build and maintain its success. **Stephen Palmer** and **Marianne Mallia** add their experience in setting up and running the Section of Scientific Publications at the Texas Heart Institute, an excellent model for a scientific or medical writing service within a company or institution.

For providers, the medical writing business is about selling. But selling is not limited to services; it also applies to the writer. As explained in **Laura C. Collada Ali's** profile of professional coach Dawn Bentley, whether you realise it or not, you are a brand, even if you are an employee. Your work, behaviour, and ability to communicate leave an impression – a 'personal brand' – that you sell to clients or employers. Dawn describes the benefits of this way of thinking and provides tips on how to create and polish your own personal brand.

I hope that these articles and the regular features in this issue of *Medical Writing* provide you with information that can help you better navigate the medical writing business.

Bonne chasse!

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President's Message

Sam Hamilton

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Dear EMWA Members,

When we surged *en masse* onto the dance floor at the Dublin Conference Spring Dinner, supercool ceilidh band 'Perfect Friction' were astonished, wondering '…what are these medical writers all about?' We certainly breathed life into the Irish saying 'the craic was ninety' (meaning – *a wild and wonderful time was had by all*). We may have surprised the band, but we all know that EMWA likes to surprise occasionally and push the boundaries often.

According to you, the conference was not just fun but a great success, with a continuing professional development programme of 51 workshops; the third Symposium Day on Risk Management and Risk Benefit Evaluation; the inaugural Expert Seminar Series (ESS); and a host of additional events that provided educational content tailored for you and provided value for money. You told us what you liked and shared your ideas for improvements – and we are listening as we plan The Hague November 2015 and the Munich May 2016 conferences.

In Dublin, we said thanks and farewell to retiring Executive Committee (EC) members Julia Donnelly, Sarah Choudhury, and Laura C. Collada Ali, and welcomed Alison Rapley (Vice President), Raquel Billiones (Honorary Secretary), and Beatrix Doerr (Public Relations) to the team. Dublin's energy and enthusiasm seeped into the new EC's busy first quarter, as we plan for the coming year.

To appreciate how our short-term goals fit into the longer-term planning for the association, it's important to understand some **key aspirations** that will underpin EMWA's growth and longevity:

- Retain experienced members
  - The ESS programme brings learning opportunities
  - Special Projects bring involvement opportunities
- Influence our industry
  - Symposium Day's inclusion of industry, patient representatives, and regulator representatives encourages dialogue, fosters positive relationships, and helps EMWA develop multidimensional perspectives
  - Symposium Day's impact is wider than EMWA
  - Links with other organisations and our social media presence increase EMWA's visibility

We are working on multiple targeted activities to meet these aspirations. More news and involvement opportunities will follow in The Hague.

Please get involved. We need volunteers to help maintain quality and deliver the content that you tell us you want. Help keep EMWA offerings fresh by supplying a pipeline of new ideas. I look forward to welcoming you to The Hague in November 2015.

Best wishes,
Sam Hamilton

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41st annual EMWA Conference

November 5–7, 2015
The Hague, Netherlands

The 41st EMWA Conference will be held on 5–7 November 2015 at the BelAir Hotel, The Hague, Netherlands. This conference will offer approximately 30 foundation and advanced-level workshops covering a wide range of topics, as well several other special events, all free:

Thursday, November 5

- Introduction to Medical Writing seminar
- Welcome Event and Networking Reception

Friday, November 6

- Industry-sponsored lunch symposium
- Update on the Clarity and Openness in Reporting: E3 (CORE)-based Reference and Clinical Study Protocol guidance projects
- Freelance Business Forum

Saturday, November 7

- Update on the second EMWA Special Project, including launch of the EMWA PVSIG (Pharmacovigilance Special Interest Group)

The EMWA spring and autumn conferences provide forums for networking, active discussions, and extensive, cost-effective, professional training for EMWA members. The venues and career-enhancing programmes are chosen to offer the best possible learning environment. In addition, EMWA conferences offer an excellent opportunity to benefit from the experiences of other medical writers. The conferences have a relaxed, friendly atmosphere that is ideal for networking opportunities and that encourages attendees to meet medical writers and communicators at all stages in their careers.

Registration for 2015 Autumn Conference at The Hague is now open. To view the programme and sign up for workshops, please visit the EMWA website at http://www.emwa.org.

Setting up and running a medical writing company

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Abstract

I am the founder and managing director of Scinopsis, a medical writing company based in France. Scinopsis is specialised in providing regulatory documents and medical communications to the pharmaceutical, biotechnology, and medical device industries. I created the company in 2006 and today we have 15 permanent staff (including myself). I believe the keys to our success are the quality of the documents we provide to our clients and the friendly attitude of my team. This article describes why and how I created Scinopsis, how the company is organised, and the challenges I have encountered over the years.

Keywords: Medical writing company, Scinopsis, Medical writer, Small business, Freelance

Getting started

I set up my medical writing company, Scinopsis, in 2006 after having worked as a freelance medical writer for seven years. Freelancing was great when my three kids were young and it was really practical to work from home. But once the kids were all at school full-time, I felt increasingly bored and lonely at home. I am a very outgoing person and I found working alone in an empty house too quiet for my taste. So at some point I started to realise that I needed colleagues to have tea-breaks with. However, after 7 years of freedom, I wasn't willing to go back to having a boss, being obliged to arrive at work on time, asking for holidays, etc. So I started to think about the possibility of employing and training a junior medical writer to work (and have tea-breaks) with me. A few months later, one of my best clients asked me to write eight abbreviated clinical study reports in two months and I realised I could never manage the project single-handedly. So I bit the bullet and decided to advertise for staff and start a medical writing company.

I had no idea whether my business would be successful, but I knew I definitely couldn't afford to pay for experienced medical writers. Nevertheless, I was confident of my ability to train people as long as I chose them well. So I decided to look for native-English scientists with a flair for writing. This was already tricky as, here in the South of France, the majority of native-English people in the area work in restaurants or on luxury yachts! Nevertheless, I placed an advert on the internet and I was delighted and astonished to receive a dozen suitable-looking applications. Following a friend's advice, I invented a medical writing test and emailed this to the applicants. Two participants did a surprisingly good job of the test and so I invited them for an interview. I couldn't choose between them and eventually ended up employing them both. What a great decision that was! One of them, Antonia, is still with us today and she has played a key role in our evolution and success since the beginning.

The next challenge was to rent office space and to manage the legal aspects of setting up a business. France is famous for its bureaucracy and high employment taxes, and several cautious friends tried to advise me against creating a company and employing staff in this country. However, I didn't let their fears dissuade me and I succeeded in jumping over all the legal hurdles with the help of my excellent French accountant.

When I first told my clients I had launched my company they were mostly rather reticent. They wanted me to continue to be their 'personal medical writer' and didn't want to risk having a junior writer on their projects. However, I managed to convince them that I would be overseeing and reviewing the work at every stage and that the quality of the documents would remain as high as when I was working alone. Nevertheless, training the new staff was a much bigger job than I had imagined and it took at least a year before the new writers could be left to their own devices on relatively simple projects. I soon discovered that it was necessary to invest a lot of my time in training my staff and re-reading their documents if I wanted Scinopsis to be a success. It was not as easy as I expected to explain to two scientists with

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no experience in medical writing why it was important for them to use perfect spelling and grammar, align their bulleted lists, define their abbreviations, harmonise their Word styles etc. But after a certain number of drafts covered in a lot of red pen, they finally started to get the hang of it. I learnt as much as they did over the first couple of years and I was so proud to see them mature into professional medical writers and to receive positive feedback from the clients.

Growing the company

As the company continued to do well, we gradually employed more writers, which meant that we could take on more projects and increase our revenues. This was great except for the fact that the volume of administrative work continued to increase and all of that fell on my plate. When I first set up the business, I spent approximately 60% of my time doing medical writing, 20% of my time training my team, and 20% of my time doing administrative tasks. But by the time I had five staff I was spending almost 100% of my time on administration and was feeling stressed and demotivated. At this point I realised I needed an assistant and it was an enormous relief when Kristina joined us in 2010.

There is always a price to pay for success, and I experienced another hurdle three years later when I had around 10 people in my team. At this point we had so many requests for proposals that I found myself spending 100% of my time preparing cost estimates and, once again, I started to feel frustrated and stressed. Furthermore, we had so many ongoing projects that I could no longer manage to keep track of every draft of every document we were producing. I felt overwhelmed and stopped enjoying my job for a while. At this point I decided to employ a business developer/project manager and have never regretted this decision as she gave me my life back!

Today Scinopsis has 15 permanent staff including 11 medical writers, 1 quality controller, and 4 managerial staff (including myself). The more experienced writers train and manage the less experienced writers, which works extremely well. Our two project managers prepare the cost estimates and liaise with the clients regarding budgets and timelines. Our finance manager deals with the administrative aspects of the business. I oversee the overall running of the company and am involved in strategic activities such as the recent design of our new website and company film, presenting the company to potential clients and at conferences, recruiting new staff, making financial decisions, and giving general advice to the team about medical writing issues.

Keys to our success

I no longer do any medical writing myself and I hardly ever even have time to review documents any more. It is a shame as I used to really enjoy this, but it's impossible to do everything, and other members of my team are doing an excellent job of these activities. I think one of the reasons for our success has been my ability to delegate (some might call this 'bossiness'!). It is essential to choose highly competent staff and to trust and empower them to handle as much of the work as possible.

> *'Many companies fail because the boss continues to try to keep control of every single aspect of the company as it grows: these control-freaks usually end up having a nervous breakdown (and the business collapses) or being so fed up with their job that they decide to close down the business. I haven't fallen into this trap and I still enjoy my job thanks to my fantastic team'.*

The wonderful thing about having a team is that we are continually increasing our knowledge and expertise. When I first started out as a freelance medical writer, I only felt confident in a limited number of therapeutic areas and document types. But now I have employed a team of experts coming from a wide range of scientific fields and, as a team, we have written many different types of regulatory documents and medical communications in a large number of indications. These days, when a new client calls me to ask if we have the experience and capabilities necessary for their project, my answer is almost always a very confident 'yes'.

Having a larger team also enhances our flexibility. Clients' timelines often change and we always manage to keep smiling even when deadlines are tight. Excellent in-house communication ensures harmonisation across our team and means that clients never have to give us the same information more than once.

As the company has grown we have, of course, had to improve our quality procedures. This didn't seem necessary at first when there were only three of us, but with 15 staff, it is important to ensure that everyone is working in the same way. In 2014, we developed a new quality system with 24 standard operating procedures and numerous templates and listings. It was an enormous, and somewhat painful, undertaking to write and approve all of these documents. However, it was well worth the effort, and we are very proud of our new system. Additionally, at various stages in our development, we have had to make significant investments to improve our

computer server and backup procedures: these are now fully compliant with our clients' requirements.

With all the extra staff, we also found that we needed new office space last year. We really didn't want to move as we all love our offices, which are located in a traditional Provençale house in a cobbled pedestrian street in Fréjus. I was delighted when the house next door became available and so I decided to buy it for Scinopsis. This enabled us to triple our office space whilst remaining in the same location. The sea view from my office is stunning – I feel so lucky to work here.

Choosing staff and keeping them motivated

The recruitment process that we have gone through for each new team member has been absolutely essential to our success. We put a great deal of effort into this selection process because we know how important it is not to make a mistake at this stage. All our staff members are highly qualified scientists, most with PhDs and several years of post-doctoral research experience, and they all have excellent writing skills. The medical writers are either native-English speakers or have lived and worked in an English-speaking country for 5–15 years. They are also all really lovely people.

'When building a small company it is essential to choose people who will fit into the existing team. I always involve my team in the recruitment process and we have often rejected applicants with excellent CVs and medical writing tests just because we felt their personalities wouldn't suit Scinopsis'.

It is essential not to compromise on this aspect and we have sometimes not selected a single applicant out of 50–100 received because we didn't find anyone who would be a perfect fit.

Once you've chosen good people, it's important to keep them happy in their jobs. It's important to train them well and to give them the appropriate amount of responsibility. Our system of mentoring of more junior staff by more senior staff works really well. The junior writers know they can ask as many questions as they need, and the senior writers feel valued and useful in their managerial role. Projects are allocated based on the writers' availability and experience, with the most complex or demanding projects allocated to the most senior writers. This is motivating for the experienced staff and gives the junior staff something to aim for.

At Scinopsis we put a lot of emphasis on the company atmosphere and we have always done a lot to ensure we maintain this. I never forget that I was bored and lonely working from home and that the main reason I created the company was to have friends and colleagues. We are lucky enough to be based in the South of France and to have a sunny roof terrace where we all eat lunch together every day (we each take it in turns to cook for the others). This creates a really nice family atmosphere and is a great opportunity to chat and get to know each other better.

'I always try to find ways to keep each staff member happy and to be as flexible as possible. In return, everyone in the team is very hard-working, positive, and willing to make extra effort on a project when needed'.

A photo of my team in September 2012. It's not all work and no play at Scinopsis!

Highs and lows

Of course it hasn't all been plain sailing. We have had some very profitable years and some less profitable ones. There doesn't seem to be much logic to the medical writing market, and we sometimes suddenly find that we have too much work for our team to cope with or, alternatively, that we don't have enough work to keep all our staff busy. When we have too much work we can always use freelancers, but when we don't have enough work the sense of responsibility weighs heavily on my shoulders. However, I am grateful to say that, until now, we have always managed to continue to ride the highs and lows and to remain steadily standing on our surfboard even during stormy weather.

It's all been worth it

So, would I do it all over again if I had the chance? Yes definitely! The last 9 years of my life have been fantastic since I created Scinopsis. I am so proud of the quality of the documents that we provide and of the excellent reputation that we have managed to earn in the industry. I care about every member of my team and I am so happy to have been able to help them progress in their careers and to give them the opportunity to live in such a beautiful part of the world. I am confident that we will continue to grow and to be successful for many more years to come.

Acknowledgements

I am very grateful to my fantastic team for their hard work and dedication to the company and to our clients. Scinopsis wouldn't exist without you! Thank you Antonia, Sarah, Kristina, Fiona, Monica, Gaële, Magali, Sarah, Hélène, Céline, Bryony, Séverine, Hannah, and Adam.

I would also like to thank our previous team members: Doug, Alex, Becks, Lucy, Victoria, and Meryem.

Author information

Helen Baldwin is a PhD pharmacologist and the founder and managing director of Scinopsis. She has been a medical writer for 16 years and is experienced in a wide range of regulatory documents and medical communications. Helen is a past-president of EMWA and a regular presenter at EMWA conferences.

For the greater good…Can agency competitors cooperate to advance medical publication practices?

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Abstract

The business of medical writing is competitive, but can it be cooperative? Is it time for agencies, which provide professional and ethical publication support to authors, to cooperate for the greater good of the medical publication profession? Formal collaborations have occurred among competitors in the biopharmaceutical and the contract research organisation sectors but rarely among competitors in the medical communications sector. In holding the inaugural Agency Executive Forum, sponsored by the International Society for Medical Publication Professionals (ISMPP), representatives of nine large international agencies met to rectify this situation. We identified a number of areas where we might cooperate, including proposing best-practices for working with freelance medical writers and for responding to procurement-driven requests for information. We are actively looking to cooperate with other groups, such as EMWA, to help ensure outputs that are valuable to the relevant stakeholders.

Keywords: Medical writing, Medical communication agency, Freelance, Compliance, Training, Procurement

> *Effectively, change is almost impossible without industry-wide collaboration, cooperation, and consensus.*
>
> – Simon Mainwaring (Australian social media specialist)

Any business involves buyers and sellers. In the field of medical publications, biopharmaceutical, vaccine, diagnostic, and device companies and the authors they work with need timely and high-quality publications to meet their ethical and scientific obligations. Publication professionals, working in medical communication agencies or as freelancers, can help companies and authors meet these obligations, ethically and effectively.

We are used to thinking of medical communication agencies operating in a competitive marketplace; indeed, intense competition has influenced the success of each agency and will continue to do so. Has the time come, however, for us to expand our perspective and see agencies as being able to operate in a *collaborative* marketplace? Could focussed cooperation add to the success not just of a few agencies but also of the agency sector and the authors and clients we work for? If agency competitors were to cooperate, where would they start and what would they do?

In this article, we describe the rationale for one starting point in this discussion, the first Agency Executive Forum. We highlight business-focused initiatives identified at the Forum that are now being considered by agency ~~competitors~~ collaborators. One initiative, the 'best practices between clients and freelancers' checklist, may be of particular interest to many of the freelance members of EMWA and the American Medical Writers Association (AMWA). Through this publication, we hope to raise awareness of the Forum and the resulting initiatives. As participants at the Forum we welcome the opportunity to cooperate with EMWA members in the months ahead.

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Competitors cooperating?

On Sunday, 26 April 2015, leaders from medical communication agencies walked, perhaps with a mix of hope and trepidation, into a boardroom at the Hyatt Regency Crystal City hotel in Arlington, Virginia, USA to attend the inaugural Agency Executive Forum, which was sponsored by ISMPP. In time, this meeting may well be remembered as either inconsequential or as the start of cooperative initiatives amongst competitors that led to meaningful advances in the medical publication profession.

The impetus for this Forum started a year earlier when a few agency leaders met informally to discuss whether agencies were in a unique position to advance the medical publication profession. Notably, we already had an evidence-based catalyst for this informal discussion: the publication of the Global Publication Survey (GPS).[1] The GPS highlighted areas in which agencies were performing exceptionally well but also revealed areas of potential risk for agencies and, by extension, for their clients. Was there an opportunity, if not a responsibility, for those in the agency sector to respond to this evidence and actively seek to change practices affecting or being affected by agencies? The consensus amongst this small and informal gathering of agency leaders was 'yes'.

With this embryonic, but determined, sense of cooperation, plans were made to reconvene. We recognised that leaders from biopharmaceutical and device companies had been attending the ISMPP-sponsored Industry Executive Forum for years, but there was no equivalent meeting for agency leaders. As agency staff account for approximately half of ISMPP's membership and comprised half of the GPS respondents, we believed there was a strong organisational and evidence-based rationale for an Agency Executive Forum at the next ISMPP Annual Meeting. The ISMPP Board agreed, and the first Forum was held in 2015.

Cooperating for the greater good?

Bringing competitors together to cooperate for the greater good is not without precedent. At the Forum, we reflected on how the TransCelerate initiative (http://www.transceleratebiopharmainc.com/) brought clinical research competitors together and how subsequent cooperative efforts were addressing common areas of risk and inefficiency. Although this clinical research initiative is far more advanced than our embryonic agency initiative, it serves as an inspirational example of outcomes-focused cooperation.

During our discussions, we sought to prioritise issues that could potentially expose agencies to risk or inefficiency and how, through cooperative efforts, we might be able to address these issues to help the agency sector, and by extension, the authors and clients we serve (Table 1). Although these two issues generated the most discussion, we recognised that the agency sector could contribute to initiatives focused on other issues, including:

Table 1: Agency-relevant issues that could benefit from cooperation

What is the issue?	How could cooperation help?	Potential next steps
The Global Publication Survey[1] revealed gaps in how agencies trained, monitored, and audited freelancers. These gaps could expose agencies and their clients to compliance risks.	• Agencies could cooperate to share best practices for identifying, training, monitoring, and auditing freelancers and becoming a 'preferred client'. • Agencies could collaborate with freelancers to help them gain insight into agency concerns and selection criteria.	• Draft a 'best practices' checklist for agencies to use to reduce potential compliance risks and to enhance working practices with freelancers. • Invite leaders from EMWA and the American Medical Writers Association, which have high freelance memberships, to provide feedback on the draft checklist. • Make the checklist readily accessible to agencies, clients, and freelancers so that each stakeholder group is aware of the proposed best practices to reduce compliance risks.
Procurement staff want timely and robust information from agencies, but there appears to be unjustified variation in the type of information requested. Although client-specific information requests are justified, some level of standardisation during the request for information/request for proposal process may benefit both agencies and clients.	• Agencies could cooperate to identify the type of information that is commonly requested and collaborate with clients (procurement and publication departments) to standardise these requests. • Agencies could ensure data are collected to meet these standards. • Procurement could benefit by gaining timely and more robust responses, which could be readily compared across agencies and across time.	• Identify the most common types of informaton requested and the extent to which there appears to be unjustified variation. • Share this background information with clients (publication departments and procurement) to determine if there is interest in reducing inefficency and enhancing effectiveness through some level of standardisation of information requests. • If there is interest, agencies and clients could collaborate to prepare a checklist of standardised questions that could be used (in whole or in part) during the request for information/request for proposal process.

- **Identifying best (and worst) practices for bringing on board a new agency**. How might we share our insights, gained from years of agency experience across many clients and from being clients ourselves, with the industry sector? How might we gain input from industry clients to enhance how agencies prepare for the onboarding process?
- **Proposing novel ways to meet increasing levels of client-driven compliance training**. How can we do this efficiently and cost-effectively? Are there areas of redundancy amongst client training programs that could be reduced via some level of standardisation?
- **Explaining the role and value of agencies to help authors prepare timely, trusted, and high-quality publications to address the specific concerns and information needs of different audiences**. These audiences may include industry clients who have limited experience with outsourcing publication planning and delivery; critics who judge the whole agency sector based on poor practices from a select few; and agencies that undermine the professionalism of the sector through the use of inappropriate terminology on websites or recruitment advertisements, or by not committing to comply with ethical publication practice guidelines.
- **Developing a guideline on potential ways to manage agency-relevant issues that can arise regarding conflicts of interest**. How do different clients and agencies define a conflict? What are the most common stipulations in confidentiality agreements? How long after a conflict ceases should work be declined? What is considered best practice for firewalls when a single agency network separates conflicting work amongst its divisions?

Where to from here?

Attendees at the Agency Executive Forum shared the common desire to avoid turning future Forums into 'talkfests'. We will strive to focus on practical issues where contributions from the agency sector would be a critical element of any proposed solution. We will seek out best practices for turning ideas into innovative and cooperative solutions, such as those highlighted in a 2010 TED talk by Steven Johnson.[2] We will aim to meet regularly between Forums and share our progress with the broader publication profession via industry conferences. While we do not want to interfere with other initiatives that seek to advance the publication profession, we do believe that the time has come for the agency sector to take responsibility for enhancing the efficiency and effectiveness of agency-relevant practices. When it comes to 'the business of medical writing', arguably, those leading businesses in the publication sector should be playing a visible and meaningful role. The authors we support and the clients who trust us should expect no less. We welcome feedback and would enjoy the chance to cooperate with EMWA members on our proposed initiatives.

Acknowledgements

We acknowledge and thank ISMPP for providing administrative and logistical support for the Agency Executive Forum. We also acknowledge the helpful contributions from Angela Cairns (Ashfield Healthcare Communications), Carolyn S. Clark (Peloton Advantage), Jeff Keller (The CHC Group), and Angie Miller (MedThink SciCom) who participated in the Forum.

Conflicts of interest and disclaimers

The authors are employed by medical communication agencies that provide GPP2-compliant publication planning and delivery services to the biopharmaceutical industry. All authors are also active members of not-for-profit associations that support ethical publication practices.

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2. Johnson S. Where good ideas come from. Available from: https://www.youtube.com/watch?v=eNwMut3-z1Y.

	Professor Karen L. Woolley ProScribe – Envision Pharma Group	*'Healthy competition and healthy collaboration can co-exist – those whom agencies employ and those whom agencies serve stand to benefit from both.'*
	Sarah L. Feeny Complete Medical Comunications	*'Trust and the ability to see a discussion through the eyes of another: Two requirements for successful collaboration'*
	Julia Ralston MedErgy HealthGroup	*'There is value in every activity that creates more consistency in application of best publication practices: this surely includes agency collaboration'*
	Jackie Marchington Caudex	*'Although we are competitors, we cooperate every day by conducting our businesses according to standards that benefit us all'*
	Steven M. Palmisano MedThink SciCom	*'Having been both a client and an agency professional, I realise that competition isn't as productive as collaboration. Collaboration gives each partner the opportunity to focus on their strengths, which, in turn, allows all of us advance our client partnerships.'*
	Bryce McMurray inScience Communications – Springer	*'Companies in the agency sector should cooperate to help to set standards and demonstrate and communicate the value that they bring to the field of medical publications.'*

Author information

Karen L. Woolley leads ProScribe, part of the international Envision Pharma Group. She is an ISMPP Trustee and Chair of its Asia-Pacific Advisory Committee, a Professor (University of Queensland, University of the Sunshine Coast, Australia), and a government-appointed director of a large tertiary hospital and health service (5000 healthcare employees).

Sarah L. Feeny is Head of Scientific Direction at Complete Medical Communication. She is a charter member of ISMPP and served on the ISMPP Board of Trustees (2011–2014).

Julia Ralston is founder and head of MedErgy HealthGroup, a group of medical communications agencies with a strong competency in publication planning. She is a former member of the ISMPP Board of Trustees, and was Chair in 2010–2011.

Jackie Marchington is Director of Operations and General Manager (UK) of Caudex. She is co-Chair of the ISMPP Advocacy and Outreach Committee and a member of the Global Alliance of Publication Professionals (GAPP).

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The Section of Scientific Publications at the Texas Heart Institute

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Abstract

The Section of Scientific Publications is a service within the Texas Heart Institute created to help our roughly 200 clinicians and scientists present, publish, and obtain funding for their research. We provide substantive and language editing, scientific writing services, and other services that make publication easier. In this article, we describe how the Section of Scientific Publications was built and how it operates.

Keywords: Editing, Editorial services, Publications, Publication rate, Writing

Located at the Texas Heart Institute (THI) in Houston, Texas, USA, the Section of Scientific Publications (SciPubs) is a group dedicated to helping authors present, publish, and obtain funding for their work. Scientific Publications provides editorial support and a host of other services.

SciPubs was started in 1981 by Marianne Mallia, BA, ELS, although the seeds were planted in 1976 when Ms Mallia went to work as a research coordinator in THI's Cullen Cardiovascular Surgical Research Laboratory, which had been established and was directed by John C. Norman, MD. Over the next few years, as it became clear that the front-line researchers, largely biomedical engineers, were not able to write up their results as quickly as they could produce them, Ms Mallia's job gradually shifted from coordinating studies to editing and writing medical journal articles.

When Dr Norman left THI in 1981, Ms Mallia went to work for THI founder and surgeon-in-chief Denton A. Cooley, MD. She hired a second editor to take over her editorial work with the cardiovascular research lab. In 1989, a third editor was added, and at that point, SciPubs was formed, with Ms Mallia as its manager.

Gradually, the section grew, adding more editors, an assistant position, and even an internship program. Today, the SciPubs staff consists of six manuscript editor/writers, a grant editor/writer, and an editorial assistant. Five of the editors have advanced degrees in the sciences (including four with PhDs), and four are certified by the Board of Editors in the Life Sciences.

Although SciPubs' editors have diverse educational backgrounds, we have increasingly hired those with degrees in the basic sciences, which is the fastest-growing area of research at THI. Two of our editors, who formerly worked in our office in Houston, now work off-site—one a few hundred miles away in Dallas, the other thousands of miles away in Germany.

What we do at SciPubs

SciPubs was created to benefit THI and its medical and scientific personnel by making it possible to publish more and better reports of their work. Although SciPubs began as a writing service, it now provides both editing and writing services, with editing constituting the bulk of our work.

Within SciPubs, the same people provide both writing and editing services. We edit any type of academic material, including journal articles, books, book chapters, monographs, conference abstracts, posters, slide sets, and grant proposals. Typically, authors email their manuscript to us, an editor is assigned, and if the project is of standard length (e.g., a typical journal article), the manuscript is edited and returned to the author within 2 weeks. The shortest projects (mainly conference abstracts) are returned within 24 hours. Authors can work with us via email, by phone, or in person.

We perform several levels of editing. We emphasise accuracy and consistency in grammar and usage, organisation and content, data reporting, reference citation, and the content and appearance of figures and tables. These tasks include ensuring that terms are used consistently throughout the

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manuscript, that the data reported in the abstract are consistent with those reported in the main text and the tables, and that statistics are reported properly. The editors query authors regarding issues they might find in the presentation of the data or in how the discussion is worded, for example. These are substantive suggestions. Once the authors receive the edited manuscript, make any additional changes they wish, and address any questions raised by the editor, the editor reviews the manuscript again and, if no further problems are identified, finalises it for submission.

Several of our editors are experts in the field in which they edit. These editors are generally called upon by their authors to help draft the manuscript. For some projects, they may draft only sections or tables; for other projects, such as a review article, they may write the entire first draft. In these cases, they are included as co-authors or are acknowledged for their contributions to the writing of the piece.

In addition to editing and writing, we ensure that papers meet publishers' formatting requirements, draft cover letters for submissions, submit manuscripts on authors' behalf, track the submitted manuscripts to make sure they are reviewed in a timely fashion, edit revised drafts and 'response to the reviewers' letters, and review galley proofs. Our editorial assistant handles many of these tasks, obtains written permission for authors to reproduce previously published materials, and communicates with journal staff and publishers, allowing the editors to focus on editing.

Most editing is done in Microsoft Office software, and we use EndNote for references. All projects are tracked in a Microsoft Access database. Access queries are used by the editorial assistant to prepare a monthly report of each editor's open projects so that none are neglected.

How we operate

All SciPubs salaries and expenses are paid for out of THI's general operating fund. SciPubs' services are available, free of charge, to all members of THI's Professional Staff and to residents, fellows, and other personnel who work with Professional Staff members on manuscripts. The decision to offer SciPubs' services without charge was made by THI's leadership in an effort to make THI especially attractive to physicians with substantial interest in research, as well as to scientists. In addition, not having a billing structure saves the time and expense involved in tracking billable hours, invoicing clients, and processing payments.

Recruiting and training at SciPubs

Hiring new editors

Candidate editors go through a rigorous hiring process. Applicants' résumés, cover letters, and writing or editing samples are scrutinised for form as well as content. Candidates whose documents contain multiple spelling or grammatical errors are immediately rejected. Although 5 years of editorial experience is required for senior-level positions, for entry-level positions, we do not require formal work experience but tend to favour applicants with some background in editing, such as work for a university newspaper or completion of a summer internship with a publishing company.

Applicants who meet these initial requirements are brought in for an interview and for a sentence-level editing and formatting test. Next, they are sent a 'take-home' paragraph-level editing test. Applicants are selected on the basis of the results of these tests, combined with their experience, sample work, and impressions from interviews. If the candidate does not have sufficient samples of marked work to show us, we give the applicant a take-home manuscript editing test. This take-home manuscript test is given for all positions, although the tests vary depending on the job classification.

Training

The first year is a probationary period for new editors. During this time, the editor is encouraged to thoroughly review various resources relevant to our work, including the *American Medical Association Manual of Style* and several of the American Medical Writers Association's self-study modules, which cover such subjects as grammar, usage, punctuation, and statistics. In addition, the new editor's tracked changes are reviewed and commented on by a senior editor. New editors typically do not do any writing for at least 1 year.

An important aspect of training new editors is teaching them to recognise when an editorial change might affect the meaning. Sometimes, making such a change is unavoidable, particularly if the original meaning is unclear, but in such cases, the editor is instructed to indicate this to the author.

Challenges in our work

SciPubs editors face challenges that are common in the medical communications field. We work with highly technical material that we do not always understand, so we often must educate ourselves about new topics. We frequently work with

authors for whom English is not a first language. Our authors use every type of computer, various versions of Word (with various language settings), different software programs for reference management, and different email systems, and the authors use these tools with varying degrees of skill. Emailing manuscripts back and forth can also create version control problems, particularly when the editor must work directly with multiple authors on a given manuscript. Finally, authors cannot always accommodate our standard 2-week turnaround time; sometimes, manuscripts arrive mere days before a submission deadline, and we cannot always guarantee that the work we do on these rush projects will be up to our usual standards.

Recruiting editor/writers who meet our standards is another challenge. We can spend 6 to 9 months looking for someone we believe will fit in with the group and be able to be trained to do the work. As a result, we work hard at keeping our employees happy by remaining very flexible. For example, we allow flex time for daily hours, and we allow editors to work from home when they need to. We try to do other small things to make their lives easier.

Benefits of SciPubs

A challenge common to medical editors is proving that our work has value. We have plenty of anecdotal evidence in the form of comments from manuscript and grant reviewers, describing submissions as 'well written', 'logical and well organized', or 'a pleasure to read'. But more objective evidence is difficult to obtain.

Nonetheless, we have some such evidence supporting the value of our work. A few years ago, we examined the publication rate—probably the simplest metric of author success—of a surgical group that had formed at another institution but physically moved to THI and began sending manuscripts to SciPubs for editing in 2003. Using the Scopus database, we determined the number of publications produced by the group's chief surgeon each year since his first publication in 1983, through 2003 when his group joined THI, and for 6 years afterwards. We found that the chief surgeon's output remained stable at approximately five articles per year between 1983 and 2003 but that his annual publication rate increased every year thereafter, reaching 23 in 2009 (Figure 1).

Encouraged by these findings, we decided to perform an informal analysis comparing nine SciPub users and nine non-users. Included authors had published articles during the 3 years before and the 3 years after they came to THI and had less than 10% of their publications involving other authors included in the study. Users had to have used SciPubs' services at least once a year, and non-users could not have used SciPubs at all. We found that during the 3 years before coming to THI, users' and nonusers' publication rates were fairly similar. By the third year after they began working at THI, however, the users' average publication rate was roughly double that of the nonusers (Figure 2). Admittedly, this was an informal analysis with few subjects, and we cannot discount the possibility of self-selection bias. Furthermore, the users' average publication rate was on the rise even

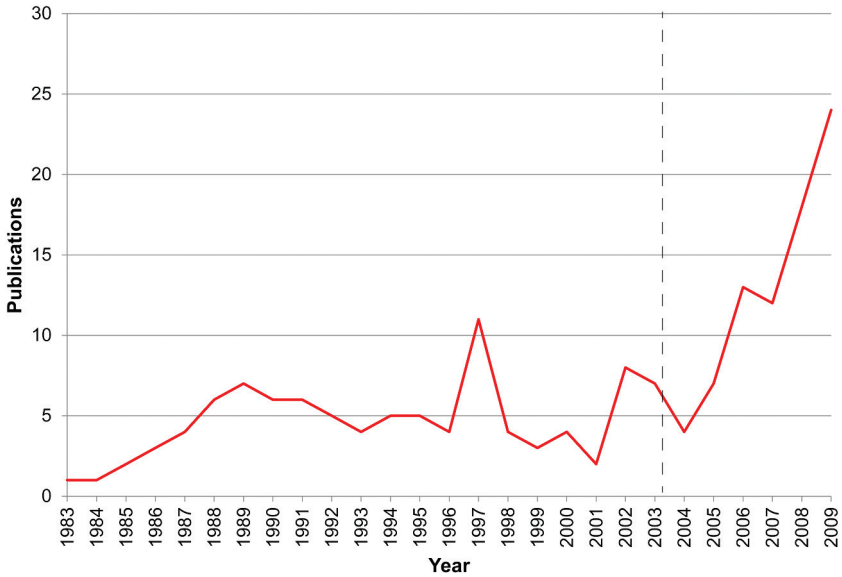

Figure 1: Publication rate of a surgical group that began working with SciPubs in 2003.

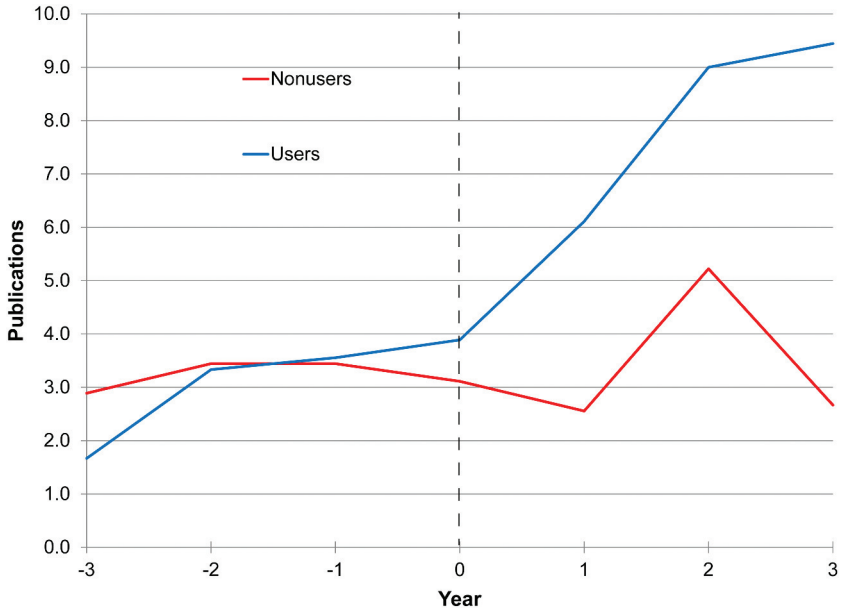

Figure 2: Mean number of publications per year before, during, and after the first year at THI for authors who used SciPubs' services at least once annually (Users; n = 9) and authors who never use them (Nonusers; n = 9). Year 0 refers to the year in which the author started working at THI.

before those authors came to THI and began working with SciPubs' editors, although their publication rate rose faster afterwards.

The future of SciPubs

No doubt, SciPubs will continue to evolve with THI's needs and with the tools available to do the work. Because we are among THI's heaviest computer users, we are participating in the pilot of a new computer system that may help resolve problems with version control, simplify the tracking of projects, and enable us to communicate with one another more effectively. And we continue to adapt to the changing requirements of journals and medical conferences.

Conclusion

In providing editorial services free of charge to our institution's physicians and scientists, SciPubs enhances academic life at THI. Creating such a service requires that the host institution be willing to invest the necessary resources today to improve its academic productivity in the future. In addition, the effort should be guided by a manager who is able to recognise, recruit, and train persons with editorial talent and skill.

Author information

Stephen N. Palmer is manager of the Section of Scientific Publications at the Texas Heart Institute, where he has worked as a medical writer and editor since 2003. He is also President-elect of the American Medical Writers Association.

Marianne Mallia was manager of the Section of Scientific Publications from its inception in 1989 until 2015. She currently works as a medical editor at the Mayo Clinic in Scottsdale, Arizona, and she is a past President of the American Medical Writers Association.

Is cheap outsourcing a threat to your career?*

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Abstract

Many writers are concerned that the rise of cheap freelance medical content outsourcing will be a threat to their careers. Yet while outsourcing may be a cheaper option, there is no guarantee that the quality will be superior. There are also numerous ethical considerations associated with the practice of outsourcing content.

Keywords: Freelance medical writing, Outsourcing, Writing rates

As a freelance medical writer who has clients all around the world, I think about my writing rates most days. Whether I'm quoting for new jobs, competing for ongoing work or bookkeeping, my rates help to give me drive, focus, and a competitive edge. And I'm not alone in this.

Setting rates, as I just discovered after running my freelance medical writing webinar with the Australasian Medical Writer Association, is a topic of interest to most writers. Knowing what to charge and how to charge it and how to get clients to pay is something all freelancers are all concerned with.

There are many tactics I advise writers to use when trying to convince their clients that their rates, while on the more expensive side, are of good value. Yet getting clients to pay a reasonable rate is becoming an increasing concern for many writers amidst the rising climate of medical content outsourcing.

Perception versus reality in freelancing rates

As any freelancer or solo business owner knows, we don't fully pocket our hourly rate. Rates are a complex formula incorporating allowances for tax, superannuation, expenses, holiday pay, sick pay, and many other bits and pieces. But obviously, our clients don't care about any of this – they only care about the dollar figure we quote.

My quotes are formulated from a combination of factors, including industry benchmarking. Hourly rates for general writers can be anywhere from AUD$50-$250. Medical content writers tend to be at the higher end of this scale – particularly if they are also qualified health professionals (namely medical doctors or PhD holders).

Also, the more years of relevant health writing experience you have and the higher the quality of your previous client work, the more you can charge.

Ultimately, when you're working out your rates, you need to be comfortable that the quality of the work you deliver is reflected in your prices.

So what happens when other writers claim that they can deliver the same quality of work as you, for significantly less than your quote?

Medical content writing – The battle has begun

This is a very real scenario that many medical content writers are facing as outsourcing websites continue to grow in popularity. These websites enable clients to find very cheap medical writers. Local businesses that might ordinarily have found a local skilled writer to complete a project can easily outsource work online at one tenth of the price you or I charge.

Outsourcing websites are transparent, in the sense that a writer's skill, previous work and client reviews are all publicly available. This setup helps to make clients feel comfortable in a writer's abilities – regardless of where writers may be based in the world. On these websites, writers can bid on medical content projects advertised by individuals and organisations. On the surface it seems great – yet when you take a look at the projects advertised, you may think otherwise.

*This is an edited version of 'Cheap medical content outsourcing: A threat to your career?', which was originally published on Health Writer Hub on May 20, 2014 (http://www.healthwriterhub.com/medical-content-outsourcing/).

> *Write 3000 word article on anticoagulation guidelines. Must have perfect English. Must be able to design 4 creative images. A medical background is an advantage. No plagiarism. Maximum 50 pounds.*

50 pounds for 3,000 words? I'd be charging 6 times that fee for the article alone and more for the image design.

What is possibly more disturbing is that individuals commonly request medical writers to ghostwrite PhD dissertations, as well as theses and student papers. And there are plenty of writers bidding for these jobs. This means outsourcing websites are playing a serious role in allowing people to gain doctorate degrees and university qualifications by paying writers to do the writing.

The million-dollar question

Does the competitive outsourcing market mean all freelancers will go out of business if we don't start charging 50 pounds for one week's work?

No.

Good clients are willing to pay going rates. So my advice is to find these clients, and if you can't convince the others who are just looking for the cheapest option otherwise, then you're better off without them – because they clearly *only* care about saving money, and their businesses won't survive in the long run with this mantra.

Good clients do exist

Good clients tend to have the mind-set that cheap offshore outsourcing is good for a one-off task, or a more menial task, like data entry. But it is not so great for projects that, if not completed well, would result in serious consequences.

In the health industry, medical content writers operate their businesses on the proviso that they have specialty skills, experience, knowledge, and understanding that comes from years of training and experience in health and medicine.

This ensures that, among other things, we are less likely to make an error which would have dire consequences – for example, accidentally influence a decision a reader made about their health in a fatal way.

Clients who think the same quality of work can be sourced by writers charging cheap hourly rates and churning out projects should consider why we charge what we do. It is not for the hell of it – our rates are based on our skill level. Yet unfortunately, we humans are conditioned to look for the best offer, the cheapest deal.

Who has the skills?

It is not that writers who bid for projects on outsourcing websites aren't as skilled as the rest of us. I am sure some are just as skilled. But I question why a writer would work for $10 per hour if he or she could charge $100 per hour.

Also, writers who charge less are often under pressure to complete projects in a hurry so they can start the next project, because completing a high volume of work could be the only way they will generate income in the cheap outsourcing model. Quality inevitably suffers in such circumstances.

Ethical medical content freelancing

There are many ethical issues that taint the practice of medical content outsourcing.

When you come across medical writers with five-star ratings who have 30 projects on the go at once, it's pretty clear that these writers are outsourcing their work to others. What are those poor souls getting paid if the chief project rate is $10 per hour?

It is a vicious cycle, and clients need to take responsibility for it. These fundamental issues are no different to those experienced in any other industry rife with cheap offshore labour.

We are all probably losing out on some work to outsourcing websites – and we will continue to do so for the foreseeable future.

But I do believe that if we shouldn't feel threatened by the outsourcing movement – that is, medical writers who offer to do the same work as us for a substantially reduced rate via freelance marketplaces – if we continue to work on developing our skills and experience, care deeply about the quality of our medical content and find the best types of clients who don't rely on outsourcing models.

Author information

Michelle Guillemard is an Australian health writer and the editor of Health Writer Hub, a resource helping writers to hone their health writing skills (http://www.healthwriterhub.com). Michelle teaches health writing courses, offers coaching services for writers, and blogs about health and medical writing.

Successfully outsourcing medical writing

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Abstract

A large proportion of medical writing activities are now outsourced. This means the need for medical writing service providers is growing, and with increased demand there comes an increased supply of providers. The challenge that arises in such a rapidly growing field is to develop a system that enables outsourcing departments to efficiently select and utilise the right vendors for their needs. This article will provide some practical advice on how to optimise outsourcing with professional medical writers and to bring their particular skill sets to bear to help clinical teams prepare their regulatory documentation more efficiently.

Keywords: Strategic outsourcing, Medical writing, Vendor management

Outsourcing activities have grown steadily over the last two decades, and the newest forecasts do not show signs of a slow-down in this trend. Recent analyses suggest the global contract research organisation (CRO) market will grow with a compound annual growth rate of 9.83% between 2014 and 2019.[1] Since medical writing activities are needed throughout a clinical programme, the demand for these services is a constant in the clinical development landscape. Medical writing activities begin as early as writing the clinical development plan, continue through the many stages of a study life cycle (Figure 1), and culminate in writing the clinical dossier of a common technical document (CTD) and responses to questions raised by the regulators and supporting teams at European oral hearings or FDA advisory committee meetings. With an increased regulatory focus on transparency in sharing clinical data and pharmacovigilance strategies during clinical development, the demand for writing services is expanding.

However, outsourcing activities to a medical writing service provider is a different beast than outsourcing activities such as monitoring or performing a clinical study. The challenge lies in finding experienced, professional medical writers and managing the outsourcing process such that clinical teams have the right support at the times needed. There are four main stages involved in outsourcing medical writing: (1) identifying what and when best to outsource, (2) finding and selecting the medical writing company, (3) managing the activities of the services provided, and (4) evaluating performance (of both the provider and the client) at the end of the project. The process should enable you to select a provider who can meet the needs of the clinical team by producing documents that communicate key messages effectively and help reviewers find the information they need. The ultimate goal should be to build a productive, long-term relationship with a core team of writers who are an integral part of your clinical team.

Box 1: The four main stages of outsourcing medical writing

1. Defining what and when to outsource
2. Finding and selecting the medical writing company
3. Managing the services provided
4. Evaluating performance at the end of the project (of both the provider and the client)

So, what's the trick to getting this right? The following is a set of guidelines and suggestions that can help make the outsourcing of medical writing activities a better experience for everyone.

Stage 1: What and when to outsource?

Once a clinical development plan is in place and the studies are planned, the timing for almost all of the documents that will be needed to support that plan can be defined fairly well (usually to within a

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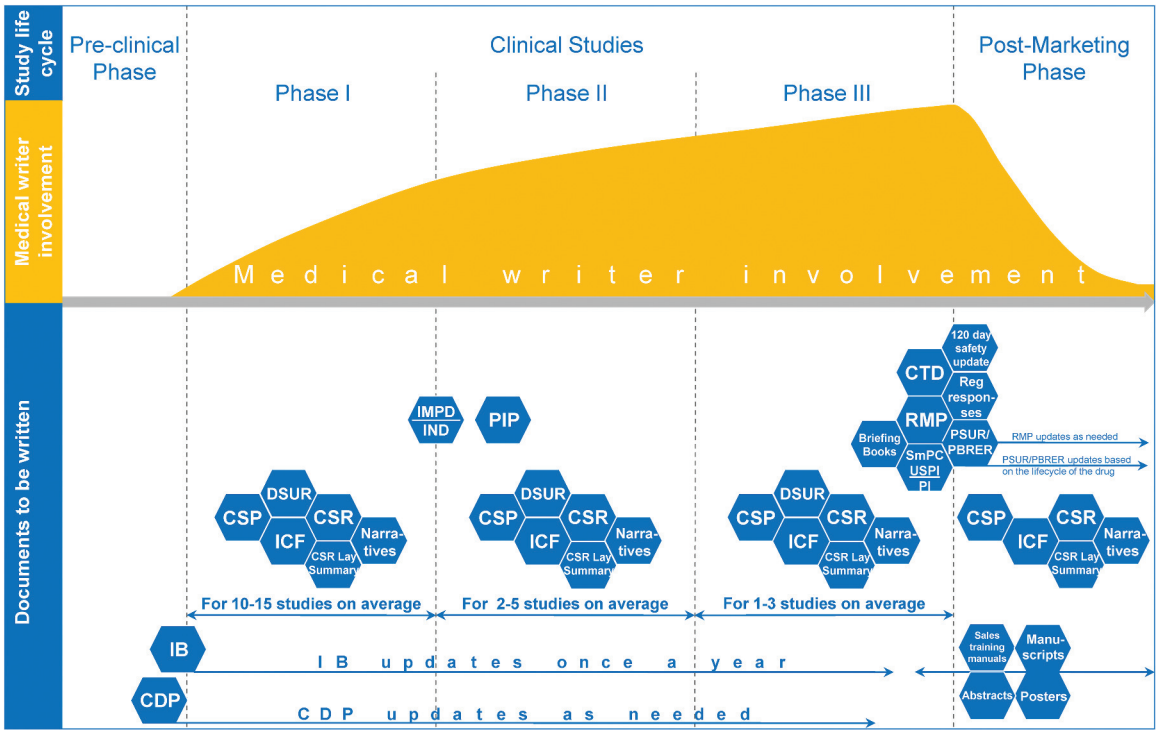

Figure 1: Medical writer involvement in clinical development. Medical writing activities begin as early as writing the clinical development plan, continue through the many stages of a study life cycle, and culminate in writing the clinical dossier of a Common Technical Document and responses to questions raised by the regulators and supporting teams at European oral hearings or FDA advisory committee meetings. With an increased regulatory focus on transparency in sharing clinical data and pharmacovigilance strategies during clinical development, the demand for writing services is expanding. Abbreviations: ASR, annual safety update report; CDP, clinical development plan; CSP, clinical study protocol; CSR, clinical study report; CTD, common technical document; IB, investigator brochure; ICF, informed consent form; IMPD, investigational medicinal product dossier; IND, investigational new drug; PIP, paediatric investigation plan; PSUR, periodic safety update report; RMP, risk management plan; SmPC, summary of product characteristics; USPI, United States Packaging Insert.

quarter of a given year). Teams know they will need a protocol for each study planned, that an Investigators Brochure will be needed from the start of the first study and will be updated annually, that Development Safety Update Reports will be needed throughout the programme, and that clinical study reports will be needed within a year of completing each study. None of the deadlines for these documents needs to come as a surprise and cause unnecessary stress on teams as they scramble to find resources and time to prepare the documents.

When a team has identified that it will need medical writing support, outsourcing of the medical writing activities should begin with a plan of what documents will be needed and when. Sit down with the clinical team and walk through the clinical development plan with them. Map out which documents will be outsourced and when they will be needed. Repeat this exercise every 6 to 12 months, and keep your vendors updated of shifts in the plan in a timely manner.

Helpful tip: Having well written documents earlier in a clinical programme improves all subsequent documents. An experienced writer who gets involved early will ensure that the rationale, strategies, and storyline of the planned development are well crafted in the early documents. Since the documents needed in a clinical programme quickly multiply, early documents serve as core resources for text and ideas in later documents. Having these nicely crafted in the early stages of a programme reduces the time needed for writing and reviewing of later documents. So think about ways to get medical writers involved earlier rather than later.

Stage 2: Finding and selecting a medical writing company

Ask the right questions

There are many different types of companies offering medical writing services, all promising quality documents that will be delivered on time. But on closer inspection, medical writing is often not a core competency for many of them. The core expertise of most CROs is the running of studies, data management, and/or statistical analyses; many CROs only offer medical writing because clients want the convenience of having a single vendor

run the study and provide the associated study documents.

The difficulty thus lies in determining which companies truly have writers with the skill sets and experience to meet the medical writing needs of your clinical teams. There are several things you can ask to find this out, including the following:

- **Does the company offer medical writing as a true expertise, or is it a tag-on function?** Ask how many years their medical writers have been writing and how many types of documents they have written. It is the breadth of experience with different types of documents and indications that gives a writer the ability to suggest creative and effective ways to communicate an idea and present your data.
- **Does the company recommend timelines for preparing the documents? How detailed are they?** An experienced medical writing group will provide a time schedule that outlines all the activities that will be involved from kick-off to delivery of the final draft. Getting this from the writer tells you how well they understand the reality of writing, reviewing, and finalising a document. It also lets you know if they understand the scope and resources expected from their side. And it will make clear whether or not the expectations from your team's side are realistic.
- **What kind of questions do they ask you?** Good medical writers are more than simply collators of information. Are they noticing gaps in material you provided and asking about it? Do they question or point out to you the challenges they see in the request you have made (e.g. in the required timelines)? Do they make any counter-suggestions for helping the team overcome these challenges? Their questions give you some insight into not only how much experience they have, but also whether or not they seem willing and able to work with you to find pragmatic solutions to get the job done.
- **Do they recommend that their writers have direct access to the key team members?** This shows they understand that integrating the writer into the clinical team is one of the most effective ways to streamline the writing process. Removing the need for a middle-person to get explanations and clarifications on specific topics avoids the 'Chinese whispers' approach to getting information to and from the writer, which has the inherent risk that some information may get lost along the way. When the writer is a fully-fledged member of the clinical team, they are empowered to keep the project moving by proactively getting the information they need from the team when and as they need it.
- **What is their system for dealing with review comments?** Does their company have a well-defined procedure in place that outlines how to process reviewer comments? Is it practical or complicated? How will they communicate open issues with the team?

The answers to these (and other similar) questions will give you a fairly accurate idea of whether or not the provider is truly a specialist in the area of medical writing and will give more depth to your choice than basing it purely on cost.

Provide the right information

Part of ensuring you get a meaningful response to your request for proposal (RFP) depends on providing sufficient information for the vendors to make a fair assessment of the scope of the project and to give them enough time to prepare the bids. Make it very clear what your expectations are for the project. And be realistic: if you know the plan according to your SOPs is for two drafts and a final version, but no team in the history of your company has ever achieved this, then you cannot be surprised if the vendor comes back needing a change order when they get to the third draft. So be honest with yourself and give them a realistic description of what to expect. Tell them things like:

- How many rounds of review your company usually has (i.e. how many drafts are likely to be needed for each document).
- How many reviewers will be involved in each review round. Will their comments be consolidated before coming back to the writer, or will the writer need to consolidate them?
- Whether you want the writing company to do a quality control check or if it will be done by an internal group.
- Whether you want them to prepare the appendices of a report. Do you want them to publish the report electronically as a single, consolidated file?

An RFP that simply defines the project as 'the writing of the clinical part of a CTD' is like asking the provider 'How long is a piece of string?' Get into the habit of collecting sufficient background information about each project and giving this to the providers from the start. Clearly define each of the activities you are requesting and be open to

discuss any suggestions the writing company has (they may have some clever ideas on how to optimise some activities). Understanding exactly what you want to outsource not only helps the vendor make a realistic bid, it also helps you know what you are really buying and gives you a better chance of selecting the right company to do it.

Most problems that arise during RFPs are a direct result of too little time for the RFP process.[2] A survey performed in 2008 by Industry Standard Research Reports[3] found that most pharmaceutical companies give CROs only 10 working days and limited information to prepare their proposals. In recent years I have witnessed requests with as little as 3 to 5 days' turn-around time. When bidders have too little time they tend to provide less information and standardised responses, which gives you less insight into the individuality of the provider. Giving bidders sufficient time to prepare their proposals, including time to ask, get answers to, and digest the answers to all their questions, will get you more meaningful information on which to make your choice.

Helpful tip: See the RFP process as the opportunity for both sides to get to know each other. Make time to personally meet the vendors you are interested in, including their lead writers, together with the clinical lead from the team they will be working with. Ask questions about their experience as writers, why they think they have the skills to prepare the documents you need, and how they measure their success as writers. This is an opportunity to answer any other open questions they may have and to see how well the two sides communicate and negotiate about the project. Begin building a relationship with the service provider at this early stage and to establish an interaction based on open and transparent communication.

Stage 3: Managing the services provided

Outsourced service providers in general, and medical writers in particular, should be 'part of the family' and not just 'one of the servants'. It can be very difficult for a writer to communicate the right messages if companies don't integrate them into the clinical teams. Unfortunately, medical writers are often not invited to strategic meetings, e.g. with management or key opinion leaders, which leaves them out of the loop on background, decisions, and strategy.

Think about this for a minute. What does a medical writer provide? If you think they just get the data down on paper and make sure there are no spelling mistakes, you have already lost out on what they can offer your clinical teams. An experienced medical writer brings a wealth of knowledge about how to structure thought, present information effectively, and guide you through the documentation process. A well written document communicates without the reader having to work at it, which ultimately reduces the time for assessors to review the document.[4]

Communicating well is about capturing the many nuances behind an idea. If your medical writer is never able to listen to discussions about the study or the product, they cannot have an in-depth understanding of the decisions and choices made. How then can they accurately communicate the implications behind these decisions and choices in the texts they write? Effectively explaining the rationale and strategy, and understanding how they may apply to different parts of a document, is equally important when writing a clinical study protocol as it is when writing the summaries of a clinical dossier. By understanding the argumentation behind the thoughts, a writer can suggest how best to build the information into a coherent story that says exactly what it needs to.

In addition, writers who have been working on your projects for some time may bring invaluable insights from across studies and documents. If they are present during strategy meetings, they may see gaps in reasoning or details that can be important to making the right decisions.

Managing the ongoing medical writing services should consist of making sure the writer is an empowered member of your clinical team. This means there has to be a company culture that educates internal teams to embrace their external members. You should ensure that:

- The writer has all of the relevant information needed as soon as it becomes available. It is a shame for a writer to work on a document after a decision has been made or new data are available that will change what they have written. This results in unnecessary costs and potential time delays that could have been avoided.
- There are regular team meetings. These will address the status of timelines for all deliverables (e.g. due dates for tables, figures, and listings, input from team members, impact on upcoming drafts of the document), as well as changes in strategy or new information (e.g. recent feedback from the key investigator about a protocol).
- Team meetings include all contractors. If separate providers are involved for different services

(e.g. one company to perform the study, another to do the statistics, and another to write the documents), they should all be at the regular team meetings. It is important that all issues are discussed as a cohesive team. Having meetings with each provider separately slows the process of communication and increases the risk that not all information is communicated to all involved parties.

- Internal teams listen to and use the expertise of their external providers. There is no point in hiring someone as specialist and then not listening to them. Writers often have good suggestions for planning, coordinating, and performing the writing activities and these can help teams optimise getting the job done. So listen to them and take their advice. That is what you are paying them for.

Helpful tip: When you first start working with a new provider, consider starting with a small document or a well-defined series of documents as a pilot project. This gives both sides a chance to get to know each other and learn how to work together. Remember, you are building a relationship, and investing in ironing out bumps at the beginning can go a long way to solidifying the team for the long-run. It also gives you a chance to see how the writers work and if they fit well with the clinical teams they will be supporting.

Stage 4: Evaluating performance at the end of the project

You want to avoid an outsourcing model designed to find the cheapest bidder on a one-document-at-a-time basis. Clinical teams benefit by having the same writers write several, if not all, of the documents on a project because they become familiar with the background and strategy of the product. Over time, a writer better understands the dynamics of the team they are working with, which helps them establish a more efficient working rapport with that group. In addition, they accumulate knowledge from across documents and can better ensure that subsequent documents are consistent with each other. So, if a writer or group of writers is good, it is in everyone's interest to keep them as part of the clinical team once they have started on a programme. Much as you would the clinical lead or the statistician.

Evaluating the performance at the end of the project is therefore important to decide whether to continue with the same writing company for future projects. Once the final activities on a project are complete, take the time to meet with the key clinical team members and the medical writer to share and discuss everyone's thoughts on how well the collaboration worked. Prepare a list of those things that both sides felt worked well and those things that need improvement. Then discuss these and work together to decide how to resolve areas that were bumpy.

Listen to the feedback from the writer about areas that need improvement. Many writing projects spiral out of control because the team is unable to give the writer clear instructions. Common reasons for this are divided opinions within the company, lack of communication internally, and/or lack of leadership within the clinical team. This frequently results in the writer receiving mixed messages (about content, changes in deadline, etc.). To save face, internal groups often put the blame on external providers rather than acknowledging that the problem was really a failure in their own team dynamics. It is a shame to lose a good writer, who has already become familiar with your product and company processes, just because nobody took the time to identify the true source of a problem (which might have nothing to do with the writer).

Working together with your writing provider to identify and resolve problems is worth the effort and is an important part of optimising the overall process of outsourcing medical writing. But don't just take my word for it. A survey conducted in 2009[5] found that the top four relationship management tools considered moderately to highly effective were:

- Negotiating a relationship management plan with the provider.
- Co-developing performance metrics with the provider.
- Conducting periodic lessons learned reviews with the provider.
- Allowing the provider to use its own SOPs (after the sponsor has reviewed them for adequacy).

Helpful tip: When developing metrics to measure key performance indicators, remember to include metrics for measuring your internal group's role in the process. It is not sufficient to simply measure whether the draft of the report was delivered late. You need to look and see whether deliverables from your side (e.g. source materials, review comments, etc.) were delivered on time too. Perhaps the drafts were all late, but upon scrutinising the statistics you will find that they were all delivered within the predefined turn-around time for writing activities, and it was the source delivery date that skewed the timeline.

Box 2: Helpful tips

1. Having well written documents earlier in a clinical programme improves all subsequent documents. Think about ways to get medical writers involved earlier rather than later.
2. See the RFP process as an opportunity for both sides to get to know each other. Spend time talking to the vendor, including their lead writers, to see if it feels right at the individual level, and not just on paper.
3. Consider starting with a pilot project to help both sides get to know each other.
4. Metrics of key performance indicators should measure your internal group's role in the process as well as that of the medical writer to fully understand the source of problems.

Conclusion

Successfully outsourcing medical writing requires choosing medical writers who not only understand the needs of each document, but are also proficient coordinators and who will challenge your clinical teams to present a clear, well-argued story. It will hinge on developing a good relationship with a vendor and you should be aiming for a long-term commitment to get the most from your investment. The key to success lies in working together, communicating frequently, integrating the writers onto the clinical team, and sharing good and bad experiences to develop and maintain a relationship that is mutually beneficial. The suggestions presented here will help identify and retain a company with medical writing expertise, which will ultimately help your company save time and money at all stages of your clinical development programme.

Author information

Julia Forjanic Klapproth became a medical writer in 1997. Since then she has been president of EMWA twice and is actively involved in the medical writing community. As Senior Partner of a medical writing consultancy for the last 13 years, she is keenly aware of the challenges in successfully outsourcing medical writing.

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I would like to thank Evija Kümmel who created Figure 1 by very effectively translating my thoughts on the relationship of documents and the clinical development process into a graphic image.

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Freelancing – Are you ready to go solo?

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Abstract

Freelancing offers an ideal way of making a living for many of us, providing the opportunity to work from home, and be our own boss. However, working for yourself comes with its own set of challenges and is definitely not an easy option. Success is never a certainty, nor is the level of income you will generate. This article provides some basic points to consider before making the transition and provides helpful advice for those already freelancing and want to maintain or grow their business.

Keywords: Freelancing, Marketing, Business management, Networking

The reasons why people become freelance are many (Box 1): redundancy, or being fed-up with a long daily commute, or increased family commitments (so that working from home or having flexible working hours better suits their lifestyle). The reason I set up my own freelance business was because I wanted to work from home, to learn business skills I wouldn't learn while working for someone else, and to enjoy a greater freedom in managing my own time. My role as medical writer within a large pharmaceutical company meant the variety of documents I worked on was limited. Additionally, increased line management responsibilities made me feel I was getting further away from the actual writing I loved. My desire to develop my skills as a medical writer and widen my experience led me to become freelance in 2010. Here, I will share my thoughts and ideas on starting and growing your freelance business, based on my own experiences. I have assumed that you have a good level of medical writing experience to give you the confidence to freelance, and that you have funding in place to start your business.

Box 1: Ten top questions to ask yourself before you take the leap into freelancing[1]

Emotional:

1. Am I self-reliant, self-motivated, self-disciplined and self-confident?
2. Do I have the temperament to work on my own – to be my own manager and right-hand (wo)man?
3. Will I be able to cope with 'feast or famine' – both in terms of workload and income?

Practical:

4. Can I cope without the resources/back-up provided by an employer such as IT help, secretarial assistance, pension and sick pay?
5. Do I have plenty of industry contacts/sources of contract work?
6. Am I comfortable negotiating my own contracts/rates and have I got a good grip on the range of rates my industry pays?
7. Do I have a clear idea on which of my skills/experience/interests I wish to focus?

Financial:

8. Have I sought advice from a qualified accountant who knows my industry?
9. Is a fluctuating income acceptable, relative to my ongoing financial commitments (e.g. rent, mortgage repayments, school fees, etc.)?
10. Should I set up my own company or work as a sole trader? Or maybe I should work through an umbrella company or even an agency payroll?

Before you take the leap

Freelancing is not for everyone. Becoming a business owner, or 'solopreneur', requires a mind-set shift from employee to employer. You may not employ staff, but you are responsible for your own success

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and leading business decisions: 'the buck stops with you'!

Besides having the necessary medical writing experience, you should assess if you have the personality for self-employment (Box 2). Freelancing comes with its own unique challenges. Write down the pros and cons of freelancing and be brutally honest about your personal strengths and weaknesses. Ask close friends and family, with no vested interest in your decision, to give you feedback and discuss your decision with those who are impacted, e.g. partners/spouses and other family members. Glenny gives some excellent advice on personal considerations before transitioning to self-employment.[1] Further personality traits and advice can be found in Reuvid.[2]

Box 2: Why go freelance? An experienced freelancer's story

Helen Glenny became a freelancer in 1992 after taking a redundancy package on relocation of her employer's clinical research strategy and planning team. She had worked full-time for major pharmaceutical companies for about 14 years prior to going freelance. Helen opted to work on a sole trader basis as she wanted to keep things as simple as possible. As she was aware that some clients preferred to deal with a limited company, Helen decided to set up Glenny Clinical Research Ltd. in 2003. She keeps this as a dormant company through which she can operate at short notice if need be. It suited Helen to work flexibly, part-time and home office-based whilst her son was young. Twenty three years later she would be extremely reluctant to return to a full-time, office-based role as she relishes the flexibility, challenges and independence of being freelance and working from home. Helen also appreciates having the opportunity to work in a variety of roles and in a wide range of projects with different clients.

In a conversation with an experienced freelance colleague soon after I went self-employed, I explained how nervous I felt whenever I received a request for my services, because invariably, the work would be in an area I wasn't overly familiar with. My colleague informed me this was normal and that I should take on the project confidently. It's true. The more experience you gain as a freelancer, the more your comfort zone expands. Therefore, you become more confident in writing a wide variety of documents across a range of therapy areas. So, where do you begin when creating your own freelance business?

Creating your own business

Networking

Networking is critical (see also page 175). Assuming you are in employment beforehand, tell as many colleagues as possible of your intention to become self-employed. Ask if you can keep in touch with them regarding a possibility of contracting work in the future. Congratulations! You are already networking.

Many freelancers gain their first projects from their former employer and this is a great first step. Write down all the people you know who could be potential contacts for obtaining work like former colleagues, managers, and people you've met on training courses and at conferences. Contact everyone on your list or connect with them through LinkedIn or other social media networks. Let them know that you are freelancing and available for work. Remember, these people will know other people and may move jobs or companies – so your list expands. Attend relevant conferences, training courses, and other events where potential contacts can be made. These occasions are also paramount for your personal and professional development.

Your working environment

Ensure you have an appropriate space from which to work and conduct your business – ideally, a separate room with a door you can shut. This minimises distractions and interruptions from other household members and after a day's work, you can tell yourself you are finished for the day. This way you have a definite separation between work and home life. Consider even renting an office space locally – this may also offer the chance to network with other business owners.

You need to be able to focus fully on your work when you're 'in the office'. Ensure family and friends respect your time in the office and clients also respect these boundaries. Overworking is a common problem when working from home so be strict with yourself and take breaks. Remember, good ideas often arise when your mind is quiet and you're not actively thinking about a specific issue or piece of work. Having a separate phone line or mobile phone for business calls also provides appropriate boundaries between family life and business.

Try to invest in an affordable and ergonomically designed desk and chair. You will spend a lot of time in this environment, so you need to look after your health and wellbeing. Remember to budget for buying and upgrading office equipment and

don't forget the cost of consumables such as ink, paper, and other stationery items.

Having an online presence

Several articles have been written about the utility of social media and improving your online profile.[3–6] Nowadays, I think an online presence is vital to ensure the success of your business. You can start with having a website. It ensures you have a professional, online 'face' to your business. It shows potential clients you are serious about investing in your business and success. You can create your own web site but it might be better to hire a professional website designer because you will have enough to do. Additionally, a web designer will know how to optimise your website with regards to search engines and should be aware of any country-specific legalities. This doesn't mean you can't write your own website content – in fact I would suggest you do. After all, it's good writing practise and means your content is authentic to you – it speaks to your ideal client in your own words, which is all part of your marketing strategy. Consider buying a website domain and email address that contain your business name (e.g., http://www.businessname.com; *yourname@businessname.com)*. Again, I think this gives a professional edge although there are many freelancers who are successful using more generic websites and emails, such as gmail. Keep your website content and other profiles (e.g., LinkedIn) up-to-date. I've found LinkedIn to be an invaluable way of generating interest in my business.

Marketing

Love it or hate it, all freelancers are marketers! The term 'marketing' seems to sound alarm bells to many freelancers, but it doesn't have to. Useful resources include De Faoite's workshop on marketing (EMWA Workshop PTF19: An Introduction to Marketing for Medical Writers), De Milto,[7] and Storm Lane[8] on how to build your business profile. Marketing doesn't have to be a 'hard sell'. In fact, this is probably the least successful way of getting clients. Be yourself! Think about it: we buy from people who we connect with, who give us great customer service and make us feel valued. The same applies to your potential clients. Consider having a professional photograph of yourself for your LinkedIn and social media profiles and website. As freelancers, we are the face of our company. Frequently we work remotely from our clients, some of whom we may never meet in person, so it is helpful for them to 'connect' with us through a photograph. Increase exposure and build your credibility by writing articles, blogs and newsletters or giving seminars and workshops.

Legalities

Get legal advice on the kind of business you want (limited company, sole trader, etc.). Research the insurances you may need to run your business. Requirements will differ depending on whether you have set up a limited company or whether you are working as a sole trader. Some clients may insist you have certain insurance policies in place, e.g. indemnity insurance, before they contract your services. For more information see Lane[9,10] and the UK Association for Independent Professionals and the Self Employed (IPSE) website (Box 3). You should have an accountant to ensure compliance with tax legislation and help you manage your business finances, which can take a substantial amount of time. You can then concentrate on other aspects of your business, especially your client project work.

Box 3: Useful resources for freelancers

- The Association of Independent Professionals and Self Employed have also published a guide to freelancing which can be downloaded as a pdf from http://www.ipse.co.uk.
- The website of business coach, Christine Kane, president and founder of Uplevel You™, is another great resource for those who wish to improve their business management skills. For more information and to sign up to her weekly eZine, please go to http://www.christinekane.com.

Maintaining and growing your business

If you are now an established freelancer, you cannot relax entirely. You need to stay focussed to keep your business running smoothly and efficiently for long-term success. Most small businesses fold within the first five years.[11] Why? Burnout! As freelancers we wear many different hats (Figure 1). As you become more established, managing work flow on top of managing your business becomes a greater challenge, and efficiency is critical to avoid exhaustion. You need to manage your time effectively to take care of your business and client responsibilities.[12] Experienced EMWA colleagues have provided some helpful hints on how to ensure longevity as a freelancer.[13] Here are some more useful tips to help you maintain that work-life balance.

Figure 1: Freelancers have to juggle a lot of different roles.

Boundaries

If you want clients to respect your time, then you have to respect your time too. Managing work flow is a key challenge for freelancers working with several clients and different projects. Also, projects rarely run within the agreed timelines. When clients try to change timelines, let them know what you *can* do, rather than what you can't do. Negotiate in a positive way. Learn how to centre or ground yourself before entering these conversations to give yourself the best chance of getting the outcome you require. Being a solopreneur requires strong self-leadership.

Systems and processes

Try to avoid 'you' becoming the bottleneck in your own business. Look for ways in which you can semi–automate tasks you always have to do. For example, create templates for frequently sent emails such as those accompanying invoices. Adopt good habits to keep on top of essential business-related tasks, such as setting time aside each week for book keeping and marketing. Consider delegation. Virtual assistants are becoming popular for outsourcing administrative tasks. Think outside the 'business box' – consider employing a gardener or cleaner to create more time. Not only are you investing in a local business, it frees up your time to do your 'high value' work, which generates the most income. If workload continues to increase, you can subcontract some work to fellow freelancers, who you know have good working standards, so you keep your clients happy without overstretching yourself.

Personal and professional development

It's easy to neglect your own personal and professional development when you become freelance. But it's important to set time for this to ensure longevity of your business. Keep up to date with developments in your specific working areas and continue to cultivate your medical writing skills by attending seminars, workshops, etc. Consider hiring a business coach. Mine has not only opened my mind to opportunities I wouldn't have otherwise known about or considered, it has also extended by network of business and potential client contacts and expanded that comfort zone.

Loneliness can be an issue if you work alone from home. However, joining a local business owners' forum or meeting up with other freelancers can be a great way of combating the feeling of isolation. And, if there isn't a freelancers' group close by, create one!

So, are you ready to freelance?

Freelancing presents its own unique challenges and worries. The degree of flexibility of working hours and work load will depend on how well you set your boundaries, and how much financial value you place on your services. However, it can be rewarding in so many ways. For example, you can get to know other freelancers to share ideas, experiences and challenges with. You can also gain skills on managing a business, which I believe are also transferable if you later decide to go back into employment.

Often, people refrain from going freelance because of worries of not having enough work. This is an important consideration so you have to discuss your decision to go freelance with those affected by it. However, medical writing seems to be an area in which freelancers thrive. I firmly believe that a positive attitude makes you come across to clients differently. It changes your personal energy or confidence which means you're more likely to attract clients. In fact, once you've

managed to overcome this 'mental hurdle', you may find that the new issue holding you back is the fear of coping with success.

Self-employment is not for the faint-hearted and mistakes are inevitable as we push the boundaries and expand our comfort zone. But, 'what the rest of the world calls failure, marketers and business owners call "R&D"'.[14] If you want to expand your medical writing skills and gain business management experience, while enjoying the freedom to work from home and autonomy of self–leadership, freelancing may just be for you.

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Conflicts of interest and disclaimers

The views given in this article are those of the authors and do not guarantee business success.

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Author information

Kathryn White worked as a medical writer in the pharmaceutical industry before embarking on a freelance career. Since then, she has worked alongside business coaches in the UK and US to improve her business management skills. She has presented seminars and published articles about working more effectively as a freelancer.

News from the EMA

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The articles included in this section are a selection from the EMA's news and press release archive for March–June 2015.

More information on the work of the EMA can be found on its website: http://www.ema.europa.eu.

Preventing medication errors in the European Union

14 April 2015 – The European Medicines Agency (EMA), on behalf of the European Union (EU) Regulatory Network, has released two draft good practice guides that aim to improve the reporting, evaluation and prevention of medication errors by regulatory authorities and pharmaceutical industry throughout the EU. The deadline for stakeholders to send their comments to EMA was 14 June 2015.

Medication errors are unintended mistakes in the prescribing, dispensing and administration of a medicine that could cause harm to a patient. They are the most common preventable cause of undesired harmful effects (adverse events) in medication practice and present a major public health burden.

With the entry into force of the EU pharmacovigilance legislation in 2012, reporting of all suspected adverse reactions resulting from medication errors became mandatory. Pharmaceutical companies and national regulatory agencies in the EU Members States are obliged to enter these adverse events in EudraVigilance, the EU adverse reaction collection and management system. The primary purpose of the two guides released today is to support industry and regulators in the implementation of these legal requirements.

One of the two guides focuses on the prevention of medication errors. It describes the main sources and types of these errors and proposes measures to minimise the risk of medication errors throughout the life cycle of a medicine.

The other guide provides guidance on how suspected adverse reactions that are caused by medication errors should be recorded, coded, reported and assessed. It also gives recommendations for marketing-authorisation holders on how to report information on medication errors that are brought to their attention but have not caused adverse reactions. This information must be provided in periodic safety update reports and in the risk management plans that are compulsory for all medicines. This allows a continuous evaluation of the benefits and risks of a medicine based on real life data by regulators.

The guidance released today is one of the key deliverables of the EMA/Heads of Medicines Agencies (HMA) joint action plan on medication errors agreed in 2013. It was developed in consultation with the European Commission's Patient Safety Quality of Care Working Group and takes into account recommendations from stakeholders that were gathered during a workshop held at EMA in February 2013.

Scientific advice leads to stronger applications from industry

17 April 2015 – The majority of clinical development plans submitted for scientific advice to the European Medicines Agency (EMA) prior to a marketing authorisation application were found not suitable for future benefit-risk assessment. Companies that changed their clinical development plans in accordance with the recommendation from EMA were more likely to be granted a marketing authorisation.

These are the main findings of an analysis of marketing authorisation application outcomes between 2008 and 2012 conducted by staff members of EMA and its Scientific Advice Working Party (SAWP) and published in Nature Reviews Drug Discovery.

EMA, through its SAWP, provides scientific advice to companies during the development of their medicines to help them design trials that are scientifically sound and generate adequate data for the benefit-risk assessment by EMA's Committee for Medicinal Products for Human Use (CHMP).

Scientific advice is the Agency's key instrument to support the development of high-quality, effective and safe medicines that meet the needs of patients. By providing scientific advice to developers of medicines, EMA also protects patients from

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participating in clinical trials that are unlikely to lead to the approval of new medicines.

Detailed analysis of marketing authorisation applications received by EMA that had an opinion between 2008 and 2012 and of the scientific advice provided to these applicants shows that:

- Two out of three programmes submitted for scientific advice had poor clinical trial designs that were inadequate to generate data for the assessment of the benefits and risks of the medicine;[1]
- An acceptable trial design at the time of scientific advice, or a change of a deficient trial design to conform with scientific advice recommendations, equally increased the likelihood of a positive outcome with success rates of 84% and 86% respectively, compared with only 41% when a deficient clinical trial design was not adapted according to scientific advice recommendations;[1]
- Compliance with scientific advice on clinical trial design was associated with a reduction in major objections raised by CHMP during the assessment of the application, and a 61-day shorter assessment procedure on average, meaning that these medicines may be available to patients earlier.

A number of medicines fail to obtain a marketing authorisation due to deficiencies in the clinical trial design and the inability to demonstrate that the benefits of the medicine outweigh its risks. This not only deprives patients of new medicines but also means that patients may participate in clinical trials that are not suitable for generating data for regulatory assessment.

Scientific advice offers an opportunity to initiate a scientific dialogue on all aspects of the development of a medicine including clinical trial design. Scientific advice should be sought sufficiently early in the development of a medicine to ensure that appropriate changes can be implemented where necessary.

A request for scientific advice is voluntary and sponsors are not obliged to comply with it.

Provision of scientific advice is not a guarantee for pharmaceutical companies to obtain a marketing authorisation.

The assessment of the data that have been generated through a company's development programme is independent from scientific advice.

A positive recommendation on marketing authorisation by EMA's CHMP is based on an assessment concluding an overall positive benefit-risk balance.

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Progress in science, medicines, health

30 April 2015 – The annual report published by the European Medicines Agency (EMA) today focuses on the Agency's key priorities, including the evaluation of medicines and the support to research and development of new and innovative medicines. In 2014, the Agency recommended 102 new medicines for marketing authorisation, both for human (82) and animal (20) use. The number of applications for orphan designation increased by 63% and requests for scientific advice for human medicines by 16% compared to 2013. Developers of medicines are making more and better use of EMA's tools aimed at helping patients to get access to effective and safe medicines more quickly.

The capacity for safety monitoring has been strengthened as patients, healthcare professionals and companies followed up on their commitment to report side effects to the Agency. This is reflected in the increase in the number of suspected side effects reported in EudraVigilance, the EU adverse drug reaction collection and management system. For human medicines, the number of side effects reported rose by 6.5% and for veterinary medicines by 27% compared to 2013. A range of new pharmacovigilance activities has become part of the Agency's core business as a consequence of the implementation of the EU pharmacovigilance legislation. For example, the periodic safety update reports for centrally and nationally authorised medicines that contain the same active substance are now routinely assessed together.

The annual report also highlights some of the main projects, initiatives and achievements in 2014 that had and still have a profound impact on the Agency and the way it operates. Among these are: the adoption of EMA's policy on the publication of clinical data which sets a new standard for transparency in public health and pharmaceutical research and development; the launch of a pilot project on adaptive pathways to accelerate access to new medicines for patients; the involvement of patients in the discussions on benefits and risks of medicines assessed by the Committee for Medicinal Products for Human Use (CHMP); the implementation of various new pieces of legislation; and EMA's move to its new office building.

European Medicines Agency agrees policy on publication of clinical trial data with more user-friendly amendments

6 June 2015 – The European Medicines Agency Management Board on 12 June 2014 agreed the policy on publication of clinical trial data, together with more user-friendly amendments proposed by EMA Executive Director Guido Rasi, that will not only allow the Agency to proactively publish clinical trial data that are submitted as part of marketing authorisation applications, but also give the possibility to download, save and print the trial data for academic and non-commercial research purposes.

In light of discussions at the Board, the wording of the policy, including practical arrangements for academic and non-commercial research users, will now be finalised with a view to its adoption by the Board through written procedure by mid-July 2014, and will be effective from 1 October 2014. Importantly, the Agency will ensure that the policy will not prejudice citizens' rights under existing access to documents legislation and the new clinical trials regulation.

Since embarking on its plans for the proactive publication of clinical trial data, the Agency has aimed to achieve the broadest possible consensus among its stakeholders and their often competing views and interests. After an extensive consultation phase that took place between June and September 2013, the Agency carried out a second round of targeted consultation in May 2014 that showed broad support for the policy, but highlighted concerns over the proposed view-on-screen-only access.

The Agency's policy is an important step forward towards achieving increased transparency in the regulation of medicines in Europe. It takes the Agency beyond its legal obligations and provides an unprecedented level of access to clinical trial data that are used as part of decision-making for new medicines.

European Science Editing: May 2015 picks

In the ironically titled 'The increasing pseudodignification of medical prose', retired consultant Neville W. Goodman bemoans the failure of medical writers (by which he means people who write scientific papers) to use simple words.[1] Goodman explores trends in word usage from 1930 to 2010 using PubMed as a source of data on scientific writing and Google's Ngram Viewer (English Fiction corpus) for general writing. He finds that for many pairs of words comprising an approved (simple) and disapproved alternative (e.g. *given* and *administered*) the approved word is more likely to be chosen by writers of fiction than by writers of scientific papers. He presents evidence that this is an old problem, but one that is getting worse. He highlights the rise of the disfavoured word *novel* (prefer *new*), which appeared in no less than 8.5% of abstracts in 2014. All this in spite of concerted efforts to encourage the adoption of plain English (as explored in the March 2015 issue of *Medical Writing*). Goodman is downbeat about the outlook for scientific English but offers no solutions to the problems afflicting it.

On the same subject, regular contributor Denys Wheatley looks at recent trends in English (or Englishes – British and American).[2] He rues the fact that *measure* has been superseded by the less precise *evaluate*, and that nowadays it is more common for an enzyme to *play a role* than to *function*. He complains about the amount of *exhibiting* and *performing* and *revealing*. 'The rule now seems to be never to use a short word if a long one can be found', he writes with palpable exasperation. But he also takes aim at seemingly innocuous words such as *outcome* and *clearly*. Acknowledging his own pessimism, Wheatley calls on native English speakers to set a good example and journal editors to halt the decline.

Other articles in the May 2015 issue of *European Science Editing* look at the importance of journals having legal protection for their editorial freedom,[3] and how the ORCID (Open Researcher and Contributor ID) initiative is streamlining research administration and may give insights into researcher productivity.[4] Finally, in the regular *This site I like* section,[5] Silvia Maina presents Coursera, which provides massive open online courses (MOOCs) on a range of topics, some relevant to medical writers (the next issue of *Medical Writing* will feature an example in *The Webscout*).

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Profile

An interview with Dawn Bentley: How personal branding can advance your professional career!

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According to Wikipedia, coaching is 'training or development in which a person called 'coach' supports a learner in achieving a specific personal or professional goal'.[1] While on the other side, 'personal branding' is defined as 'people and their careers marketed as brands'.[2] Nevertheless, we have the impression that there is much more to these simple definitions and we have turned to expert Dawn Bentley to better understand how 'branding' can help medical writers advance their careers.

Dawn is a professional coach accredited with the International Coaching Federation and a trained coach supervisor. In addition, she has a Masters degree in Business Administration from Sussex University, is a Master practitioner in Neuro Linguistic Programming and a somatic coach to boot. She offers executive coaching and facilitation to individuals and teams who want to explore more their potential and be the best that they can be. She has worked both with individuals (e.g., freelancers and entrepreneurs) and companies. Her corporate clients include Eurostar, Cisco Systems, Zurich Insurance, and Swarovski.

Medical Writing (MEW): First of all, we would like to hear about your own definition of what coaching and personal branding are?

Dawn Bentley (DB): When people hear the word 'coach', many think of sport as most sports people and sports teams have someone who is their coach. In simple terms the coach's role is to help the team or individual play at their best. Quite often this allows the team or individual to fine tune their performance and recognise how much more potential they have. As a coach who works with business people, I do the same.

We start by exploring the specific topic they want to work on and then establish where they want to get to. The journey is then about enabling an individuaI to get there by sharing tools and techniques, providing feedback and a safe environment where they can experiment, practise and become more confident.

Personal branding, on the other hand, is about who you are. It's what you leave behind when you walk out of a room or office, or what people say about you when you are not there.

So whether you are aware of it or not, we all have a brand. The question is, are you optimising yours?

Are you letting people know your:

- Values
- Beliefs
- Skills
- Experience

Personal branding is all about you and how you operate. In short it's your reputation.

What makes YOU UNIQUE.

MEW: Why is personal branding so important and how can it help professionals to advance their careers?

DB: When you understand your personal brand you can articulate, with great clarity, who you are and what you bring to the organisation and team you are working with. This clarity allows you to communicate confidently and congruently.

Many people think they know themselves well, however in an interview situation, struggle to explain what qualities they bring to a situation. They may waffle or be very generic – neither of which would leave a lasting impression and encourage someone to choose you for a job or piece of work.

When you really understand what your strengths, your beliefs and what motivates you, you can also easily discern between those jobs/organisations that play to your strengths and those that will make you unhappy and dissatisfied. When you are clear about your identity (brand), you will be able to:

Positively manage your impact. You can more easily behave in a way that is authentic to you to create the desired impact, rather than how you think others want you to be.

Clearly articulate who you are and what is important to you. You will be clear about your

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values, your purpose, your skills and the value you bring to any organisation, or team.

Connect your ability to the reputation you have/want. You can clearly express what you are expert at, what you do best and what you are the 'go to' person for in terms of your experience and skills.

Differentiate yourself from others. You will easily be able to differentiate yourself from your competitors and communicate what makes you unique.

You will be 100% authentic and do the work you love, taking charge of your career rather than your career taking charge of you.

MEW: Building a personal brand and an online presence through Internet networks allow for individuals to network with potential clients. Does online personal branding differ from an in-person one?

DB: Great question and no it's not different. How you are online should portray exactly who you are as a person and professional. To build connections you have to be prepared to be yourself and by that I mean your best self. There is nothing worse than meeting someone who you first connected with online and finding out they are very different 'in person'.

Once you are clear about who you are, what you deliver and how you are different, you can be clear who your audience is. This takes time and the clearer you are, the easier it is to connect with them in the right medium and the right social network.

The danger with online networks is that many people can access them, so be consistent and authentic. Be focussed rather than taking a scattergun approach in the hope that something might hit the target.

The key to a successful personal branding is focus!

MEW: How long does it take to gain clarity on one's personal brand?

DB: Another great question! The honest answer is … it depends, and it probably isn't what your readers want to hear. Most people want a quick fix.

The start to personal branding is knowing yourself, as Shakespeare said, 'To thine own self be true…'.

When I work with someone on personal branding, we start with a brief online questionnaire to understand 'what makes them tick'. This becomes the doorway to explore everything I've mentioned so far and understand their story to identify the essence of their brand.

However, knowing yourself also requires getting feedback, so I always include this as part of the process. Remember, personal branding is what others say about you when you are not there. So, you have to be prepared to ask for and receive feedback and enter into a conversation about it. This can be scary! Many people are not great at asking for, or giving specific feedback and this is what's needed – and we could do a whole other interview on feedback!

From here it's then about reviewing what you've discovered and practising how you talk about yourself and how you demonstrate what you are great at. This is what takes time. It's a constant process of refinement, from the emails you write to the way you communicate to potential clients.

Dawn has given us a broad view of what personal branding means to her. It is, indeed, a topic that is highly relevant to freelance and employed medical writers alike, so we hope you found food for thought in this interesting interview.

Dawn Bentley can be contacted at dawn@aurora4success.co.uk, @AuroraSuccess.co.uk, uk.linkedin.com/in/dawnbentleyaurora/, or http://www.aurora4success.co.uk

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The Webscout

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Happy business

When thinking about the topic of this issue I questioned why for some people business is a source of fun while for others it is not. We all know that factors like time pressure, an inadequate working environment and a lack of variety in our tasks can make us unhappy with what we actually like to do. But what in the end makes us feel happy about what we do and what is the best strategy to achieve happiness at work? I decided to dedicate this Webscout to happiness in and from business.

> *'Do something you love and you'll never have to work a day in your life'.*
>
> John Lasseter, Chief Creative Officer, Pixar

This is one of the most important points. Breaking it down a little more, do it at your pace but do it, stick to your beliefs and values, and learn to say 'no' are messages you can take from '10 things we've learnt that we wish we'd known back then':

http://ow.ly/NkAIu

The 'Spook Studio' website shows what it can look like if business people just do things their way. They do not obey conventional business traditions. They have fun and show it:

http://www.spookstudio.com

The people behind Spook Studio have co-founded the 'Happy Startup School'. You can follow them on Twitter: @happystartups. Their free e-book on '4 steps to a happy startup' further explores the question of 'how you can build a happier, more successful and sustainable business whilst living a balanced, fulfilling life':

http://www.thehappystartupschool.com/ebook

You might also want to find out what your purpose is:

http://ow.ly/NkHMK

You might say that none of this applies to your medical writing business. That all this is only for people who want do something completely different, something unconventional. This is not the case, as you can conclude from an interview with Penina Shepherd from a UK law firm that specialises in business law. She provides conventional law services, but does so differently from others. And she obviously feels happy doing so:

http://vimeo.com/120792172

You do not need a completely new start if you feel unsatisfied with your job or your own business. However, keep in mind that happiness at work is important. It contributes to your success and even more importantly to your happiness in your life as a whole:

https://youtu.be/Eq81wx6aPbA

It is thus worth seeking happiness in your job.

Perhaps happiness is a mental choice. Maybe you can decide to be happy or feel miserable in the same job. Watch a video on the idea 'Happiness is a choice':

http://vimeo.com/19036262

Sometimes you just do not see what you have, what you have already achieved. You might have just lost your enthusiasm about what you do. Maybe the strategies found here will help you be happy with your work (again):

https://youtu.be/xYdTkfJ5zhU

The final message might be this: It all starts with you. You are your own way to happiness in business, you just need to recognise the reasons to be happy, and I am sure there are enough of them:

http://ow.ly/NkQyK.

Get more inspiration at *http://ow.ly/NkQWT.*

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In the Bookstores

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In the Bookstores is taking a rest this issue

There are no new book reviews in this issue of *Medical Writing*. However, upcoming book reviews in future issues of the journal should include:

Writing for Science Journals: Tips, Tricks, and a Learning Plan
written by Geoffrey Hart and reviewed by Laura Williams

Statistical Thinking for Non-Statisticians in Drug Regulation
written by Richard Kay and reviewed by Nicholas Churton

Visual Complexity: Mapping Patterns of Information
written by Manuel Lima and reviewed by Carola Kraus

In the meantime, EMWA has negotiated a special discount for members on books sold by Wisepress Online Medical Bookshop (http://www.wisepress.com). EMWA members can receive a 15% discount on medical titles (including eBooks) from all the major publishing companies.

To claim your discount, please visit the Member Offers section of the EMWA website to get the special promotional code you should enter at the online checkout. If you can't find what you are looking for, or would like to place an order over the phone, please call +44 (0)208 715 1812 or email bookshop@wisepress.com and the bookshop team will be happy to help.

Full details of the offer can be found at http://www.emwa.org/EMWA/Resources/Book_Reviews/EMWA/Resources/Book_Reviews.aspx?hkey=0c41ba29-e4d1-45e6-a680-0cdcdf3b3355.

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Regulatory Writing

New developments in public disclosure of clinical trials

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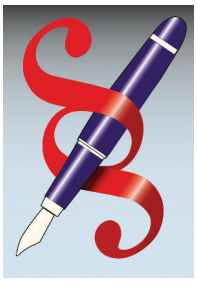

In April this year, the World Health Organisation (WHO) issued a statement on the public disclosure of clinical trial results (the full statement is available from http://www.who.int/ictrp/results/reporting/en/). In essence, this statement reiterates the previous WHO statement on registration of trial methods prior to initiation and extends it to include the timely publication of results, both in clinical trial registries and in peer reviewed journals. The aim is to ensure that negative results are not underreported, thereby distorting efficacy conclusions derived from publicly available data. The statement also calls for sponsors to make the results of past trials available. Finally, the statement suggests more rigorous identification of trial registry identification in subsequent publications and data sharing initiatives, presumably to make meta-analyses easier. The statement was accompanied by a detailed rationale published in PLoS[1] and a commentary, also in PLoS,[2] by Ben Goldacre, a prominent campaigner for full disclosure of clinical trial results.

Current disclosure levels

Well before publication of this statement, there has been a general shift towards greater disclosure and transparency. Several factors have driven these changes, not least, the Food and Drug Administration Amendments Act (FDAAA) in 2007, which in its Section 801 required all applicable trials to report summary results at ClinicalTrials.gov within a year of the primary completion date. However, the rationale for the statement, published in PLoS cites evidence that even trials registered in this new transparency era still often fail to publish results. In a recent estimate of compliance with mandatory reporting requirements on the ClinicalTrials.gov registry, the investigators used an algorithm to identify 'highly likely applicable clinical trials', that is trials legally obliged to report results according to the FDAAA.[3] Only 13% of the trials identified by this algorithm reported summary results within the statutory 12 months of trial completion. This percentage rose to 38% when the whole study period was considered.

The percentage of reporting was higher for industry-sponsored trials and also for later-phase studies. On manual review of a subset of the trials selected by the algorithm, for industry-sponsored trials, some 45% were not actually required to report results, leading the authors to conclude that 'approximately 79% to 80% of industry-funded trials reported summary results or had a legally acceptable reason for delay'. When I did a quick manual search of industry-sponsored trials on clinicaltrials.gov that had completed at least one year ago and that did not have any results posted, the sponsors in my admittedly not particularly exhaustive sample were all small companies. Most large companies now take disclosure very seriously and most will have dedicated disclosure groups to ensure that they meet their reporting obligations. Smaller companies, however, will be unlikely to have such resources available. In cases of start-ups with a single product in their pipeline, if the study fails, the company will likely disappear and the study results will never see the light of day. Thus, there may be a reporting bias in favour of trials with products that are more likely to continue in clinical development (and hence for trials that may have an impact on clinical practice later). This, in combination with a higher reporting rate for later phase clinical trials, suggests that a high percentage of industry trials relevant for clinical practice are now being disclosed.

Compliance is lower for trials with institutional sponsors (such as the National Institute for Health [NIH] for example). As many of these trials will be intended to answer 'real-world' questions rather than being part of a drug-development programme, whose goal is to get a drug registered, the gaps in knowledge are potentially more significant. Industry has shown that it can react to new reporting requirements (for example, by setting up dedicated disclosures groups), but in the case of institutions, bureaucratic inertia, as well as limited funds, may be a substantial barrier to change.

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It has been argued that disclosure of early-phase clinical trials is important from a safety point of view. For example, if a particular drug is associated with a life-threatening reaction, caution should also be exercised with another drug that shares the same target (as tragically illustrated by the case of TGN1412, where greater transparency with a previous trial in a similar molecule may have helped prevent the severe reactions seen[4]). In this case, some sort of adverse drug reaction registry may be of help and would probably not require extensive resources as serious adverse events would have to be notified to the health authorities anyway.

Publishing in peer-reviewed journals

One novelty of the WHO statement is that these results should also be published in peer-reviewed journals (with open access) within 12 months to address the well documented issue of publication bias. These timelines for publishing look very tight given that the turnaround time between manuscript submission and publication can be anywhere between 2 and 6 months. As might be expected given the relative complexities of publishing in a peer-reviewed journal and the lack of legal requirements, the publication rates compared to results disclosure on trial registries are lower.[5] Ben Goldacre[2] suggests the this battle may not be worth fighting, arguing that journal articles are often 'spun' and may not report the primary outcome measure. He also points out that academic publishing decisions can be arbitrary, even though many journals may pay lip service to consideration of negative trials.

Retrospective disclosure

The most substantial novelty in the statement is the requirement that the results for old trials are made available on the grounds that evidence-based decisions today are based on potentially biased data collected in the past. Although this argument is persuasive, implementation in practice is fraught with problems. Ben Goldacre recognises that throwing resources at disclosure of trials with no bearing on current clinical practice is not an efficient approach.[2] He suggests a directed approach, whereby preliminary retrospective registration of clinical trials can serve as a guide for researchers who wish to request more details and results.

Even with this directed approach, disclosure may not always be feasible. First, retrospective trial registration is likely to leave gaps in the record. And even if a trial is identified and further details requested, the pertinent information may be hard to retrieve. Many companies will have undergone restructuring or mergers, and the employees responsible for an old project will almost certainly have changed project, company, or even country. And this is not to mention changes in archiving systems and the fact that, at best, some of the older studies will only be available as scanned versions. In principle, the health authorities should also have these trials archived somewhere, but many of the problems applicable to data retrieval by companies would apply. Furthermore, the rigorous requirements of ICH only started to be universally applied from the mid 1990's onwards. Prior to that, it would also be a bit hit and miss which information was recorded, whether the primary endpoint was properly reported, and even whether there was a pre-defined statistical analysis plan.

Conclusion

Progress in the disclosure of clinical trial results is undeniable. Although there is always room for improvement, disclosure rates for the most recent industry-sponsored trials are relatively high. Attention is now shifting to the disclosure of the results of past trials. Although this is a desirable goal, it will be difficult to achieve in practice.

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Lingua Franca and Beyond

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Lingua Franca and Beyond – Working together

Business models in the field of medical and regulatory writing – can you think of a more suitable topic for discussing: collaboration, team working, and sharing complementary skills across different native languages? In this issue of *Medical Writing*, we have articles written by Julia Archbold and Amy Whereat who present different points of view concerning global business models. Both authors are Australian, which makes it even more global - welcome Australia to the European community of medical writers! Julia lives mainly in Australia and started her professional career in medical writing following a successful career in biomedical research; Amy lives in France and has several years of experience working as a medical writer and medical communications consultant.

Julia discusses, in her well-structured article, the advantages of and considerations for working in multinational teams, going beyond pure language problems in writing; she also gives some practical tips for working across different time zones and economic environments. Amy shares with us more general thoughts on the role multilingual native (or near native) English speaking medical writers play in supporting non-native English authors to communicate more effectively in English. She also recalls the history behind the birth of English as the *lingua franca*, when scientific communication switched from mainly French and German to English.

Both articles are written by native English speaking medical writers. What about the perspective of non-native English speaking medical writers? Well, I as a non-native English speaking medical writer can assure you that I agree with all points raised in both texts. I would only add that having the support of a native speaking medical writer in our team makes us feel more secure and comfortable in our professional role. Only recently, one of my non-native English speaking clients, when reviewing the first draft of an article on a topic, which I knew well, asked me if a certain phrase was correct in English; I was very quick to reassure her that once the content was confirmed the manuscript will be checked by a native English speaking medical writer.

Obviously, there are other issues related to overall medical communication, for example, the use of abbreviations and acronyms, which Americans particularly love and which often makes us Europeans very confused, but let's leave that for a forthcoming issue.

For now, I wish you all *interesting reading* and I welcome your feedback and thoughts.

Acknowledgements

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Effective multinational medical writing teams: What do native and non-native English speakers bring to the table?

Introduction

By definition, a team is a group of people with complementary skills that come together to achieve a common goal. Likewise, medical writing teams consist of individuals with unique skill sets that work together to achieve a common goal: communicating science effectively. Often, these teams will span countries and continents; they are multinational medical writing teams.

After spending 14 years as a biomedical researcher, I understand how crucial collaboration and teamwork are for success. In a research team, each scientist will have unique skills that they have accumulated throughout their career. For example, they may be an expert on a particular scientific technique or have specialised knowledge in a field. These individual skill sets become important for

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determining the best way to tackle a problem. It is only by working together that scientists can answer research questions both efficiently and effectively.

Similarly, in medical writing teams, each writer will have unique skills developed from previous experiences. For example, they may have been trained in journalism, science, medicine, or education. We each have a unique approach to medical writing problems but we must work cooperatively in order to serve our clients efficiently and effectively.

Not only do medical writers come from diverse educational backgrounds, we often come from diverse cultural backgrounds. We can be native English speakers (NEs) or non-native English speakers (NNEs). For example, as a freelancer, I have colleagues in Poland, China, and the UK, and often my fellow medical writing team members are NNEs. But do medical writers who are NEs and NNEs have different skills to bring to the table? And how can we make the most of these multinational teams? Here I will outline some of the advantages and considerations for working in multinational teams of medical writers consisting of NEs and NNEs.

Advantages of multinational teams in medical writing

Multinational teams can offer a number of advantages to medical writing companies. NEs and NNEs will bring unique skills that help serve our clients more efficiently and effectively (Figure 1). Teamwork can also improve client satisfaction and overall productivity of your business.

Multinational teams are more efficient

Working across time zones as part of a multinational team can sometimes speed up the medical writing process. For example, if my colleagues in the UK can work on a manuscript during their own business hours and send me the version at the end of their day, it will be morning in Australia. I can continue to edit the manuscript during Australian business hours before sending it back. Therefore, the clients effectively gain almost 24 hours straight of medical writing time, and the entire process becomes more efficient.

It is also important to consider that a substantial proportion of our clients are NNEs and, therefore, working with NNEs can make the medical writing process more efficient. A 2014 white paper from BioMed Central and the Edanz group reported that nearly 70% of publications in the Scopus database came from NNEs countries.[1] This has increased from past estimates; in 2006, only approximately 50% of publications were estimated to come from NNEs.[2] Due to this increasing percentage of clients from NNEs countries, it will become even more important to continue working closely with NNEs. Medical writers with the same native language as the client can often simultaneously translate the article into English and edit the text. This unique

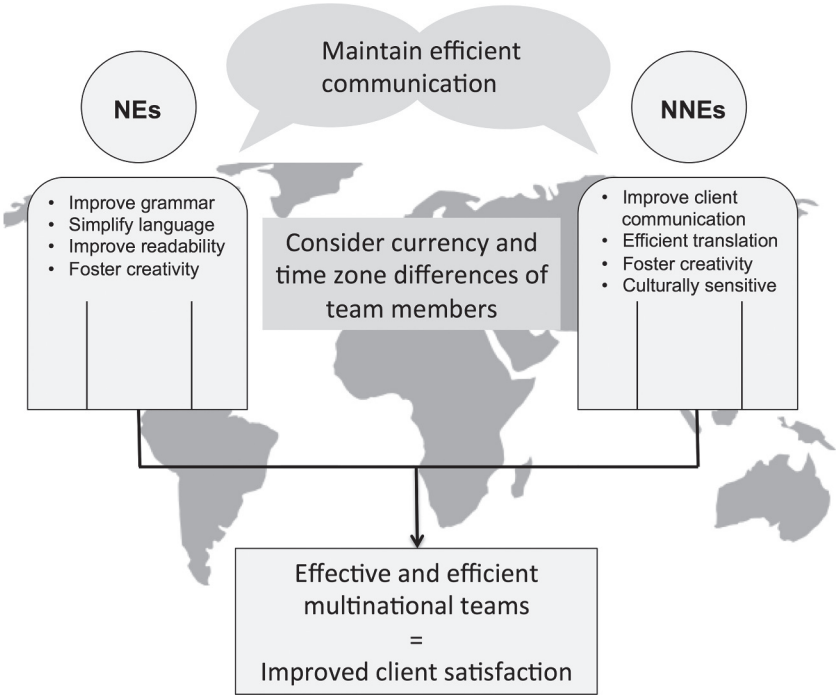

Figure 1: Effective multinational medical writing teams consisting of NEs and NNEs.

skill saves time during the medical writing process. As Mariel Marlow, a native Portuguese speaker, explained:

> Although you would expect revising an already translated paper would take less time than translating an entire manuscript, I eventually came to prefer translation. Revisions tend to take me twice as long. Online translators may be partly to blame for this phenomenon. Not only did I spend hours being frustrated by confusing phrases resulting from simple mistakes, but I also spent the majority of my time fixing the *same* mistakes over and over again.[3]

Similarly, it often takes me much longer to edit a translated paper than it takes my medical writing colleagues who are NNEs to simultaneously translate and edit the manuscript. When NNEs edit these manuscripts, they have the added advantage of understanding the authors' intended meaning more easily than NEs. This helps them to retain the authors 'voice' in translated text, which is an extremely important skill.

On the other hand, NEs are skilled in simplifying the writing, and making the manuscript more concise and readable. It was previously stated that 'the scientific and medical literature is still abundant with lengthy, unclear prose that is likely to confuse readers'.[4] Lengthy sentences and paragraphs may still be present in writing from NNEs as this style is usually more typical of their native language. For example, Indian and French have a much more formal language structure and NNEs from India or France may not realise that a more informal writing style is perfectly acceptable in English.[5] When working in teams with NNEs, I often find my role is to shorten lengthy paragraphs, remove duplication in the introduction and the discussion, and make sure the scientific arguments are clear to the reader. I may be a terrible gardener, but I can prune a sentence back! Therefore, together with my colleagues who are NNEs, we can efficiently produce clear, concise and correct manuscripts for our clients.

Multinational teams have improved client communication and satisfaction

NNEs that have the same cultural and linguistic background are able to communicate more effectively with the client in their native language. They are able to build stronger client relationships with their fellow NNEs. In my own experience working with medical writers from Poland, this has been an enormous asset. Polish medical writers can communicate much more effectively and efficiently with Polish clients. Without that client interaction, my job would become extremely difficult. Similarly, there are a number of cultural sensitivities that come into play when interacting with Asian cultures. My Asian colleagues are more attuned to these issues, and by working closely with them I can avoid unintentionally offending the client due to cultural differences.

Working in a team can also improve our client service by helping the client develop their own English writing skills. NNEs are often better able to explain grammatical changes to the client when the text is translated into English. They sometimes have a better understanding of English grammatical 'rules' than NEs themselves. This point was raised by Alistair Reeves when describing common myths surrounding English in a previous article published in this journal.[6] He explained that NNEs often 'know some of the real rules better than native speakers (e.g. how to use the apostrophe), while those with English as a first language are often unaware that the way they express something naturally is actually following a rule'.[6] As NNEs are able to explain these 'rules' to the client, the client's own writing skills will improve and in turn, the client will be more satisfied with the service.

Multinational teams are more creative

Another advantage in working as part of a team is that each person will have their own opinions when it comes to writing styles. While medical research articles are usually published only in English, they will be read by NEs and NNEs alike. Having the unique viewpoints of both NEs and NNEs can ultimately improve the overall readability of the paper. In addition, working with multiple writers from different backgrounds improves creativity in the writing. As Breden and van Roy wrote: 'The better a paper is written, the more readers it will attract and the more citations it is likely to receive'.[4] Therefore, having multiple opinions on a piece of writing will ultimately improve the end product and be beneficial to the client.

Multinational teams are more productive

Often, medical writers spend a lot of time working independently, so interactions with fellow team members can help you feel less isolated and improve your morale. Especially as a freelancer, working as part of a team can give you a social outlet. While working from home has its advantages, interactions with your colleagues, even via email, can make you feel happier.

In *How to Become a Medical Writer?*, Suhasini Sharma explains that in order to be a good medical writer, you must have good communication and coordination with various people throughout the writing process.[7] In my opinion, to improve team morale, it is important to be encouraging in your emails. For example, tell your colleagues when they have done a great job or thank them for meeting a deadline. By having regular positive interactions with your colleagues, you will strengthen your team, which can only benefit the overall productivity of your business.

Considerations for working in multinational teams

As it is often difficult to find a time that overlaps with the multiple offices in your team, email is the most effective way of communicating. It is important to be mindful of tone and to be polite, kind and respectful of cultural differences in all your correspondence. Some other considerations for working with people in other countries include budgeting in different currencies and the challenges of working across multiple time zones.

Working out the budget

When you are working with medical writers from another country, it is important to consider the different costs that may be involved. For example, the typical salary in India may differ from that in Australia. Will the company pay you in your local currency or in theirs? Does the company pay per word or will they give you a fixed budget for the entire project? It is important to be very clear in your initial emails, making sure that you state both the currency and the expected costs before you begin. Working out these details before you start is important to avoid any tension or misunderstandings over payment.

Working in different time zones

Timelines and deadlines for jobs can become difficult when working across time zones. To remove any confusion, make sure you are clear which time zone you are referring to (e.g. time in London or time in Sydney) when you state a deadline. It also helps to be consistent when you refer to time zones. For example, use your own time zone (or your colleague's time zone) in all your communications.

Considering the time zone where your colleague is working is really important. I know that if I send an email at 9am Australian time, I'm not going to hear back from the UK until about 5pm when they start arriving at the office. I don't encourage working 24/7 but sometimes when a project has an urgent deadline, longer working hours will be required. For example, if working a couple of hours later means that you send the paper back to your co-worker so they have it first thing in the morning, this is better than wasting a whole day because you logged off at 5pm. Similarly, sometimes you may have to work on a Saturday, when it is still Friday for your other team members, in order to meet deadlines.

Being open and flexible to working outside typical office hours can benefit your business. Personally, I try to respond to emails as often as I can, even if it is outside of my typical working hours. Sometimes, someone on your team will need a quick response for the client, and although it may be 10pm at night, a quick email back can be really helpful. If it is difficult to respond to emails outside your normal working hours, consider putting an automatic out-of-office reply on your email for when you log off for the day to help remind your colleagues of your different time zone.

Conclusions

Teams of medical writers consisting of NEs and NNEs are highly efficient and effective in meeting the needs of our clients. While science is currently communicated in the *lingua franca*, the translation of research into some of the world's more common languages (e.g. Mandarin, Spanish, Portuguese, or French) may become increasingly more common. Therefore, in the future, these multinational medical writing teams of NEs and NNEs will only become more in demand. We must continue to work together with the common goal of communicating science effectively. If we recognise the unique skills that both NNEs and NEs bring to the table, multinational teams of medical writers will only grow stronger, and our clients will be the ones who benefit.

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Can multilingual medical writers with native English level the playing field for non-native English speakers?

English became the *lingua franca* of medical science

At the turn of the twentieth century, at least 40% of publications in the New England Journal of Medicine (NEJM) were in French, 10% were in German, the remaining 50% in English. This reflects the multicultural attitude of scientific research at that time. Even in Australia, students of science at the University of Sydney were studying scientific French and German. In 1981, less than 1% of NEJM publications were in either French or German and hardly any medical or science students were studying French or German (unless as an elective). What happened?

During World War II, isolated, national medical communities and single authors began to collaborate. Afterwards, these scholarly exchanges gave way to substantial transnational research teams and the English language became *the language* for international scientific communication. It would become a means to gain general professional recognition and allowed medical communities to participate in and adapt to modernisation. The publish or perish race was on![1]

Later on, medical collaboration took yet another breathtaking step into the future. One unusually warm morning in London, June 1957, an elite group of American and British physicians were linked (for more than an hour) via the new undersea cable. This *joint meeting* of the American Medical Association, then in annual session in New York, and the Harvey Tercentenary Congress, convened in London, for the first time heard distinguished panellists on both sides of the Atlantic exchange information on cardiac surgery. International medical communication was born![2]

By the 1980s the Institute for Scientific Information (ISI) had greatly stimulated citations with the *Science Citation Index*. Studies from these data[1] showed that, across the globe in science in general, an increasing number of non-Anglophone investigators were publishing in English in both their local and Anglo-Saxon journals. If scientists expected to be read and cited, they had to publish in English. Unsurprisingly, by the early 1990s English had been well and truly established as the *lingua franca* for scientific and medical communication.[3–5]

Nowadays, with English as the universal language of international scientific and medical collaboration, specialists and researchers from all around the world can share their knowledge and experience more easily and with multilingual audiences. International scientific meetings in particular provide a formal venue for transnational interactions and online open access has brought groundbreaking science to desktops in the farthest corners of the world. This is particularly important in science, as different ideas create an environment for debate! The unique knowledge that these specialists have gained from their local experience using local techniques, traditions or medicines is valuable for finding solutions that the medical world faces. Being able to effectively communicate in scientific English allows researchers to openly question the science on the table and propose other valid ideas.

The codified norms that give scientific English its style

In recent years, scientific English has been developing a particular style of its own that is (perhaps, thankfully for some) different from Shakespeare, Bronte, or Dickens. Scientific English is a style of language that is specific to medical and scientific research. It has well recognised norms in terms of content and presentation, which are now clearly defined in published guidelines such as International Committee of Medical Journal Editors (ICMJE)[6] and CONsolidated Standards Of Reporting Trials (CONSORT).[7] The tone of voice is direct and factual and, increasingly, authors employ simple sentence structures and a restricted vocabulary of common words that can be understood by an international audience. This is an advantage for non-native speakers of English (NNEs)! There is no need to have the descriptive powers of the Bronte sisters to write a good paper in English. Yet, it is important to master this style of writing to be taken seriously on the international playing field.

Although many researchers drawn to the international spotlight are experts in their professional field, they have not always had the appropriate training to use scientific English effectively.

The role of the multilingual medical writer goes beyond editing

So, the multilingual medical writer with native or near native English (NE) has a unique position when working with these medical and scientific experts that goes beyond editing and proofreading. Being able to communicate with the authors in their own language means that the medical writer can easily discuss the project and understand the story that the author wants to tell. Then, they effectively translate these ideas into scientific English style.

When it comes to writing or proofreading clinical study manuscripts, once the text is clean in terms of grammar and punctuation, the multilingual NE medical writer can focus on the key messages and work the text so that the story and logic flows smoothly and is in line with the data. They can also check that the manuscript meets with author and publication guidelines and even identify problems that may arise during peer review. Often, NNE authors are so focused on getting their ideas on to paper and in English that they lose track of what they really wanted to say! The reasoning and logic becomes lost behind *stuck and pasted* sentences and jumbled paragraphs. So, in this case, the multilingual, NE medical writer not only helps to ensure that the English is correct, and fit for purpose, but more importantly helps the author to arrange their ideas and information clearly in scientific English style.

Being a multilingual NE medical writer also has specific advantages when it comes to medical communication publications. These publications differ from clinical study manuscripts in that there is no clinical study report from which to work. Although the story is based on current literature, the key messages contain certain experience-based conclusions. They contain practical, real life knowledge that is becoming increasingly valuable as it complements or explains clinical research data. Usually, the authors know what story needs to be told. In fact, it has probably already been formulated in their mind, told and tested with colleagues over dinner, or between conferences, before arriving at a publishable conclusion. The multilingual NE medical writer works with the authors in their native language to plan the article structure and define the key recommendations or take-home messages to be communicated. Afterwards, the NE medical writer can build the manuscript following scientific English style, base the story on the published literature, and also fine-tune the text with the authors. Multilingual NE medical writers need to pay particular attention to the story that NNE authors tell. This ensures that their ideas and reasoning are correctly communicated and not confused by an Anglo-Saxon way of thinking.

Another area that is particularly interesting for multilingual medical writers is training. Experienced NE medical writers with knowledge of international scientific style can train NNE speakers to write, speak, and manipulate the language appropriately. Often, non-native researchers can read and understand most technical language but they cannot produce the language themselves. Often, the sentence structure and syntax reflect their native language; some researchers have a working knowledge of casual English but do not know how to speak or write in the professional manner required for publication. Others may be able to communicate well in their area of expertise but not be able to manipulate their spoken or written language sufficiently to deliver powerful messages. These authors require specific training that combines both communication skills with appropriate language.

Therefore, multilingual NE medical writers are well placed to provide NNE authors with much more than correcting spelling and grammar. By assisting them with their written and oral communications, authors can get their message across clearly and they move a step closer to achieving their professional objectives. On the same score, the scientific world moves to a more balanced arena where innovative ideas can be presented and discussed and conclusions reached using a common *lingua franca*.

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Gained in Translation

Editorial

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Welcome to my second Gained in Translation editorial!

Translation consulting networks are an interesting 'assisted-translation tool', which have had a remarkable appeal for professionals in the field since the late 1990s. Newsgroups, online discussion forums and professional mailing lists, together with professional social media accounts, definitely provide a most valuable resource to fight against the well-known isolation of translators, who normally work as freelancers from their home office. Nevertheless, they have survived during all these years of never-ending new online resources not because of this characteristic, but because of their value as 'mutual assistance tools'. There is a myriad of resources out there, but you really need to know their characteristics in depth – their flaws and strengths - in order not to get lost and get the most out of them! If you are interested in knowing them better, keep reading, and if you are already a subscriber to a professional mailing list for translators, please do share some info about it with us!

Please remember that the aim of this section is to provide a medium for open discussion among translators, and a written agora where we can exchange different and, maybe, amusing experiences. If you would like to contribute, please contact me. You are warmly invited to share your knowledge and thoughts.

Enjoy the article!

Laura

Translation consulting networks

Among the most popular translation consulting networks we find mailing lists, discussion forums and discussion groups. All of these are groups of professionals who interact, network, share knowledge and build fruitful relationships at a professional level. The first mailing lists for and run by translators started to appear in the mid-1990s, yet they are not commonly known to many professionals. Indeed, they are often not public and you need to be a member in order to get a grasp of content.

Translation consulting networks can be:

- Profession-oriented, where subscribers are linked by a common interest in promoting translation as a professional activity.
- Practice-oriented, where the common interest linking subscribers is the actual performance of translation-related activities.
- Education-oriented, where the focus is on training.[1]

What is a professional mailing list?

They are different to discussion groups or forums as, instead of logging on to a website to view the latest threads, you receive posts from fellow members directly to your Inbox. They are a simple way of organising emails so that all subscribers to the list receive questions from, and answers to, any other member of the list.

Mailing lists can have memberships of different sizes, from a few dozen with slow activity, to several thousand and more than 100 messages a day, which normally adopt policies to manage the flow of information, allowing for filtering and summaries on a weekly or daily basis. All subscribers are free to leave or rejoin the list at any time.

Such lists can be an extraordinarily useful tool for translators who need an immediate answer to an urgent question. Experience shows that questions addressed to professional mailing lists never go unanswered. These communication channels create a sense of community, and give individuals access to the collective expertise of translators across the world, at virtually no cost. Within this large repository of expertise it is not always easy to find one's way. You need to know your fellow colleagues and take into consideration only those opinions from expert members.[2] It is obviously a flaw, but really outweighed by the strength of the lists.

The issues discussed go far beyond simple questions of terminology, even though these account for a large number of the exchanges. Indeed, generally, subscribers to mailing lists discuss a variety of topics, some of which are listed in Table 1. The effect of these lists is such that nowadays we could speak about 'subscriber-assisted translation' or 'mutual assistance tools', as they definitely represent

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Table 1: Recurrent discussions on professional mailing lists

Provide permanent assistance in solving terminology problems (a kind of terminological help line that translators call routinely when they do not understand a text segment or cannot find the name for something or are not quite sure about their translation).
Occasionally engage in in-depth analyses of terminological or linguistic issues.
Provide systematic assistance and advice in the use of translation tools.
Regularly discuss questions relating to rates and content of the service provided to clients.
Launch or revive major discussions on perennial questions such as punctuation, the use of upper case letters, style, etc.
Discuss issues relating to translators' status.
Exchange information on notoriously unreliable clients.
Discuss what attitude freelance female translators should adopt vis-à-vis their clients when taking maternity leave.
Keep each other informed of travel arrangements, and organise informal meetings.
Create an on-line portrait gallery to put a face to an email address.
Discuss a wide range of technical queries on topics such as: computer platforms, equipment (backup systems), software (voice recognition applications), Internet access providers, etc.
Compare the respective merits of different search engines.
Pass on to fellow subscribers extra work that they themselves are unable to carry out.

Source: Goudaec.[3]

a supplement to traditional problem-solving strategies.[3,4]

There are now many such lists for translators or on the subject of translation. Most of them are restricted or 'moderated' lists:

- Restricted lists, by definition, are not accessible to all. Many of the mailing lists for translators have been set up and are managed by professional associations, and are, for obvious reasons, open to members only. Membership requirements greatly affect whether or not the network is composed of professionals.[3]
- Moderated or 'regulated' lists are supervised by someone similar to an editor-in-chief, who receives all the messages sent to the list, sorts them out, sometimes synthesises them and forwards them on to the list. So, the moderator can vet certain requests or offers and filter some of the information on the list to avoid unwanted messages.

Your virtual extended family of colleagues

The list becomes a kind of virtual professional 'club', making freelance translators feel less isolated. Indeed, they offer an antidote to the oft-lamented isolation and loneliness of translation professionals.[3] Discussion lists eventually create some kind of virtual extended family. Messages from subscribers who suddenly feel lonely late at night, or stressed out by impossible-to-meet deadlines or furious over software bugs or outrageous client behaviour, prompt for messages of solace and support in return. The subscribers come to represent a living, closely-knit community, and in cases where a member is in dire trouble, everyone comes together to provide psychological or moral and even financial support, which in some cases has gone as far as helping a subscriber retain clients who otherwise might have been lost due to protracted illness. Friendship is no less supportive for being expressed via cyberspace. At the same time, as in any other community, there is also indignation, violent contradiction, passionate debate and even outrage at times – usually starting from some trivial linguistic question.

Where do I find the one that works for me?

Discussion groups and mailing lists on translation can be accessed from https://groups.yahoo.com, from Facebook Groups, by contacting the translators' association in the country of reference, or by asking any web browser. In some countries, you may also find professional mailing list platforms created by government bodies. This is the case, for example, in Spain with RedIRIS, which is an academic and research network that provides advanced communication services to the scientific community and national universities. It was funded by the Ministry of Economy and Competitiveness and has over 500 affiliated institutions. Medical translators working from or into Spanish often communicate thanks to a professional, specific, practice-oriented mailing list in this platform – MedTrad – *Foro de traductores profesionales de biomedicina* (http://www.rediris.es/list/info/medtrad.html).

In Table 2, I have listed some mailing lists and discussion groups. Although it is not a comprehensive list, it includes interesting references; you are obviously invited to share your own 'must-know groups' with us; a more detailed list could be published in the future!

Personal experience using professional mailing lists for translators

Currently, I subscribe to two specific practice-oriented medical translation mailing lists and to a generalist one. I am also a member of several discussion groups both on Facebook and LinkedIn.

In my opinion, mailing lists tend to be more practical:

- Messages arrive directly into your Inbox, which may result in an overload of messages to read

Table 2: Professional medical translation discussion groups and mailing lists

Name	Topic	Languages	Platform	Restricted
Frensemble	Generalist (G)	FR <> EN	Yahoo Groups	Yes: Société Française des Traducteurs
French Translation	G	FR <> Any language	Yahoo Groups	Yes: Members of the group
MedTrad	*Specific to medical translation* (S)	ES <> Any language	http://www.rediris.es	Yes: Medical translators and writers
AITI Discussion Forum	G	IT <> Any language	http://www.aiti.org	Yes: Associazione Italiana Traduttori e Interpreti
IAPTI Discussion Forum	G	Any language combination	http://www.iapti.org	Yes: International Association of Professional Translators and Interpreters
Universitas Forum	G	DE <> Any language	http://www.universitas.org	Yes: UNIVERSITAS Austria Interpreters' and Translators' Association
Tradutores Com Vida	G	PT <> Any language	Facebook	Yes: Members of the group
SFÖ Medtrans	S	SV<> Any language	Yahoo Groups	Yes: Swedish Association of Medical Translators
Übersetzer/innen	G	DE <> Any language	Facebook	Yes: Members of the group
Swiss Translation	Translation queries related to Switzerland	Any language combination	Yahoo Groups	Yes: Members of the group
Peempip	G	EL <> Any language	Facebook	Yes: Translators from the Ionian University
Translatum	G	EL <> Any language	http://www.translatum.gr	No
Norskjal	G	DA, NB, SV, FI, FO, KL, IS and EN	http://listar.ismennt.is/mailman/listinfo/norskjal	Yes: Members of the group
Magyar Forditok Elektronikus Foruma	G	HU <> Any language	Yahoo groups	Yes: Members of the group
Medivert	G	NL <> Any language	Yahoo Groups/Facebook	Yes: Members of the group
MedPharm	S	Any language combination	Yahoo Groups	Yes: Members of the group

Abbreviations: G, Generalist; S, Specific to medical translation; DA, Danish; DE, German; EL, Greek; EN, English; ES, Spanish; FI, Finnish; FO, Faeroese; FR, French; HU, Hungarian; IS, Icelandic; IT, Italian; KL, Greenlandic; NB, Norwegian; NL, Dutch; PT, Portuguese; SV, Swedish.

but you can set a rule so that the messages go into a specific folder, which you can consult at the end of the day or whenever you wish.

- Professional mailing lists group expert professionals who are already working in the field and passionate about what they do – you would not join one if you were not really interested, as the risk is to have your Inbox overloaded with messages.
- They are an excellent repository of colleagues, should you need someone to share some extra work.
- They provide the largest technical library of articles that I know, and what's even better, articles are presented by colleagues, which means you already have a summary and can decide whether to allocate some time to them or not.

Discussions are extremely interesting and constructive. I have learned a lot being a subscriber and find they are a must for any professional working in the field. They not only represent a means to share knowledge but are also a way to be updated immediately with any news in the field in which you are working.

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HIV research fraudster handed stiff prison sentence

In the December 2014 issue of *Medical Writing*, I reported that disgraced Iowa State University researcher Dong-Pyou Han was facing fraud charges for faking experiments on a new HIV vaccine.[1] In spite of a guilty plea, on 1 July 2015 Dr Han was sentenced to 57 months in prison. He was also ordered to repay $7.2 million to the NIH and faces probable deportation on his release.

In a poll on Nature.com, opinion was divided as to whether the punishment is fair.[2] It is rare for research fraud to result in a prosecution and so Han's sentence is exceptional. By way of comparison, infamous anaesthesiologist Scott Reuben was sentenced to a more modest 6 months in prison in 2010 for fabricating data and even patients in upward of 20 papers.

The involvement of Senator Charles Grassley, who first proposed the Sunshine Act, is thought by some to be a factor in the Han case coming to court. Although the impact of the sentence cannot be measured, it certainly sends out a clear message.

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English Grammar and Style

Good Writing Practice

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Myths 46, 47, and 48

I reached Myth 45 about English in *Medical Writing*, Vol. 21(1) 2012. Three more have turned up since then, which all fit into the category of language users who rule by whim. All were – as so often – claims made by native speakers, which again just goes to show that we native speakers of English do not know it all.

Myth 46: The word 'timepoint' does not exist

Huh?!? It does not exist in German, French, Cebuano, and Brezhoneg, or any language other than English, where it has a firm place. This sounds to me like a claim made by one of those people who discovered by chance that 'timepoint' was not in the Oxford English Dictionary or Merriam Websters (at least in older paper versions) and wishes to bask in their own (hollow) erudition. True, it is not in either of these noble works on paper that I have, nor did I find it in my copy of the Oxford English Reference Dictionary, but that is far from proof that it does not exist or is not in common use and understood by many. The SpringerExemplar* text database of more than 9 000 000 documents published by Springer Press throws up more than 117 000 articles that match the strings 'timepoint', 'time-point', and 'time point', with first use in 1953. Of these, about 115 000 (94%) are found in the following subject areas: Medicine and Public Health, Biomedicine, Life Sciences, Oncology, and General Biochemistry. This number does not include the immeasurable amount of documentation produced the world over to gain and maintain marketing authorisation for a vast number of drugs and devices, where I know from my own experience the term 'timepoint' abounds. Nor does it include all of those other areas of science and technology where 'timepoints' are also in common usage.

I think we can say that 'timepoint' is a fairly new term which has established itself in life science research over the past half century and that it has an unequivocal meaning. It is not unusual to find that terms in common use are not in dictionaries. 'Evaluable' was only recently admitted into Merriam Websters, but had already earned respect in writing for more than a century (first use documented in 1880), and 'to code for' in its genetic sense is now rearing its dictionary-worthy head.

It is true to claim that 'timepoint' is often used where the word 'time' would suffice, but it is also true that the extra precision added by the word 'point' is equally as often desirable, with a grey area that is just as large. To claim that 'measuring time' is 'better' is spurious, because 'measuring time' and 'timepoint' can mean the same thing, so what is important is consistency in one document.

In case you are wondering whether timepoint should be written with or without a hyphen or as two words. The answer is very simple: it is of no importance whatsoever, just be sure to be consistent in one document and don't waste your and everybody else's time arguing about it!

Myth 47: You cannot say 'a neonate aged two days…'

The rather weird explanation given for this one was that the client claimed that the word 'aged' is not appropriate for neonates as 'they can't be aged'. Here it sounds as though someone really has confused the words 'aged' pronounced 'AYJD' meaning 'of the age of' and 'aged' pronounced 'AYJID' with the first syllable stressed meaning 'having lived long'. The fact is that neonates can be two days old or aged (ayjd) two days and centenarians can be 100 years old or aged (ayjd) 100 years, but only the centenarians are amongst the aged (ayjid). If the client's claim were true, which it patently is not, this makes me wonder: when does being 'aged' begin?

Myth 48: My client says we should be 'diagnosing diseases in people' and not 'diagnosing people with diseases'

Yet again, evidence that our clients have time on their hands to play around with words and invent rules we don't need. 'To diagnose a patient with a

*Exemplar is a collaboration between Springer Science & Business Media and the Center for Biomedical and Health Linguistics (exemplar@springer.com).

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disease' is a perfectly respectable collocation (a combination of words that sounds 'right') and implies the process of diagnosing up to diagnosis, hence 'a 66-year-old man was diagnosed with Crohn's disease' tells you that he went through all the usual tests to arrive at the diagnosis. 'Crohn's disease was diagnosed in a 66-year-old man' is also perfectly respectable and tells you the same. Both also have the same number of words, so neither has the advantage of brevity. A quick check in SpringerExemplar in their database of more than 9 million life-science documents showed more than 92 000 hits for 'diagnosed with' and just fewer than 17 000 for 'was diagnosed in'. The difference is so small and the search terms are vague which means that the only conclusion we can draw is that both formulations are in common use.

This client's objection hinges on what the adverbial phrase *with a disease* modifies. In the sentence *he was diagnosed with hypertension*, *with hypertension* does not modify *was diagnosed* but *He*, i.e. the disease is not being used to make the diagnosis. This is the common-sense way of reading this formulation and so familiar that it is always understood and can safely be used. Anyone claiming the contrary is looking for a problem where there is none.

In short, the two formulations are interchangeable, but given the following sentence:

Hypertension was diagnosed in a 66-year-old man in 1972, angina pectoris in 1977, and COPD in 1980.

I would rather see:

A 66-year-old man was diagnosed with hypertension in 1972, angina pectoris in 1977, and COPD in 1980.

This keeps the list together and does not put undue stress on the hypertension.

Another four-letter word

I am surprised I have not yet found myself writing about ***each***. A recent question in an EMWA workshop and an email from a valiant teacher of medical English in Germany gave me cause to spend some time thinking about this sometimes challenging little word.

Each is used adjectivally – *Each ward has 25 beds* – and as a pronoun – *The hospitals have 10 wards each or The hospitals each have 10 wards or Each of the hospitals have 10 wards*.

When used adjectivally it immediately precedes the noun it modifies as is almost always the case in English:

Each patient on the ward was receiving antibiotics.

We have defibrillators on each ward.

When used as a pronoun, it usually indicates that several groups or factors had the same number of characteristics, and the main problem is where to position it in your sentence or whether to render it by expressing it differently – and there is no single answer to this.

Let's consider the following:

Statement	Comment
1. Nausea and headache were the most common TEAEs (each in 12% of patients).	No misunderstanding this – it can only mean that 12% had nausea and 12% headache. But why put important information – that it was 12% – in brackets?
2. Nausea and headache were the most common TEAEs, each in 12% of patients.	No misunderstanding this either. And the important information – that it was 12% – is no longer deemphasised. But the position of *each* interrupts the flow of the sentence.
3. Nausea and headache were the most common TEAEs in 12% of patients each.	This is also clear and the sentence flows well, avoiding the comma needed if you position *each* before *in.*
4. Nausea ([in]12%) and headache ([in] 12%) were the most common TEAES.	Avoids the *each* problem, but cumbersome with the repetition of (in) 12%.
5. Nausea and headache (both [in] 12%) were the most common TEAEs.*	Elegantly avoids the *each* problem by using *both*.
6. 12% of patients each had nausea and headache…	Having each before the two symptoms is not incorrect here, but it is disturbing, although the meaning will still be understood.
7. 12% had nausea and 12% had headache …	Repetition of the 12% is a little cumbersome, but this is not the case for *12% had nausea and 10% had headache*. This is how to avoid *each* and *both* if you are not sure where to position them.

*If you had a list of 3 TEAEs or more, e.g. nausea, vomiting, and headache, then 1–5 would be constructed in the same way, except that you would use *all* instead of *both* in 5.
TEAE, Treatment-emergent adverse event.

Exactly how you deal with this is a matter of personal style and preference. Using each, I prefer sentence 3 with *each* at the end, or the solution with *both*. And as we are talking about what was most common here, I would prefer to make this the subject of the sentence in both cases:

The most common TEAEs were nausea and headache in 12% of patients each.

The most common TEAEs were nausea and headache, both in 12% of patients.

Points of view

Let's stay personal

Am I the only one amongst us who deplores the use of *that* instead of *who*, as in the following examples?

Patients that were enrolled before amendment 6…

The group of physicians that opted for…

Patients that received…

The freelancers that opted to set up a private pension…

I still prefer to retain the distinction between people, animals, and things here and reserve *that* for them and who for people or groups composed of people, like teams, groups and patients. I cannot claim that *that* used in this way would be misunderstood or lead to confusion, but it forms part of the use of depersonalizing language and, as such, should be avoided.

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Did you know that EMWA has an archive of webinar material on our website?

Since January 2015, EMWA has held a number of webinars on different topics. The most recent EMWA webinar was presented by Helen Baldwin on 25 June 2015 and was entitled 'What you always wanted to know about medical writing - but never dared to ask'. This webinar was aimed at new medical writers who had questions about establishing or advancing their careers.

Questions answered during the webinar included:

- What sort of documents do medical writers work on?
- What is the difference between regulatory writing and medical communications?
- What training is available for medical writers?
- What resources and guidelines are available?
- What are my career options for the future?

A recording of the webinar is available to EMWA members in the webinar archive (see below for link).

Other webinars in the archive include:

- 'Introduction to medical writing', presented by Helen Baldwin on 15 January 2015
- 'Patient registries as a source of medical information', presented by Maria Kołtowska-Haggstrom on 4 February 2015
- 'Efficiency: Make it your business', presented by Kathryn White on 26 February 2015
- 'Medical writing tips that will change your texts in English', presented by Amy Whereat on 29 April 2015

Upcoming webinars include:

- *September 2015:* 'You don't need to be an industry expert to publish an article in *Medical Writing*…but it can help you become one!' This webinar will specifically focus on writing for *Medical Writing* and will be presented by Editor-in-Chief Phil Leventhal.
- *October 2015:* 'Your professional association: A great way to expand your skills and advance your career'. Presented by former EMWA PR Officer Laura C. Collada Ali, this webinar will highlight the advantages of joining professional associations and ways to get the most out of your EMWA membership.
- *December 2015*: 'Quality by design in clinical trial protocol writing'. This webinar will discuss how medical writers can enhance clinical research quality by defining quality and setting quality objectives at the design stage. It will be presented by Patrick Bohan.

For each of these upcoming webinars there are a maximum of 100 places. To participate in any of them, you just need to register and then connect to the webinar platform. By participating you can ask questions and contribute to an active discussion.

The webinars are organised by the EMWA webinar team (Laura C. Collada Ali, Gavin Morse, Patrick Bohan, Sweta Bhattacharya, and Gail Zona), as well as our current PR Officer, Beatrix Dörr.

In keeping with the EMWA tradition that 'EMWA is run by the members for the members', if you think you have something interesting to communicate to other EMWA members and would like to run a webinar of your own, please contact Beatrix at pr@emwa.org. Your proposal will then be evaluated by the webinar team.

The webinar archive can be accessed at: http://www.emwa.org/EMWA/Training/EMWA_Webinars_Programme_Archive/EMWA/Training/Webinars_Archive.aspx

Registration information and full details of upcoming webinars can be found at http://www.emwa.org/EMWA/Training/EMWA_Webinars_Programme_2014-2015.aspx.

Medical Communications

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Editorial

Dear all,

However experienced you are, and whatever 'level' medical writer you may be, we all share the same pain… document review processes. Every medical writer has at least one horror story related to review cycles going awry, and the mere mention of reviewing will elicit a universal paling and shuddering around EMWA – not because we are precious about our work, but because of the havoc and heartache that poor reviewing practices leave in their wake. If you are reading this in blissful ignorance of the woes of a terrible review cycle experience, be warned – your own tailor-made horror story is waiting for you around the corner, like Freddie Krueger at Halloween….

But fear not! This issue's contributor is here to banish your fears. In his article, Douglas Fiebig from Trilogy Writing explains clearly the problems that woeful review cycle practices can cause. His brave and honest real-life examples are not for the faint hearted, but he lays out his six 'vital ingredients' for great review cycle processes, along with his reasoning for why they are so important.

There IS light at the end of the review cycle process tunnel – now all we have to do is convince our reviewers to follow it…

Bestest,
Lisa

Back to the future… or the amazing lack of progress in effective document review

In 1999, as a still relatively inexperienced medical writer, I was introduced to some software that was going to revolutionise document preparation: Documentum, a collaborative reviewing tool for regulatory documents. These documents would be drafted in a secure environment. Version control would be guaranteed. Workflows would ensure that documents were reviewed in a neatly structured process within defined timeframes. Reviewers could see each other's comments and respond to them during the review. Collation of comments would be automated. The software would also remind reviewers of their obligations and provide an audit trail of their reviewing activities. This was the way to go. And remember, this was the year 1999.

This brave new world was going to solve the technical inefficiencies involved in document preparation at the time. No more distribution for review by email. No more comments received in multiple documents. Or worse, multiple permutations of comments on top of other people's comments, needing to be pored over by medical writers to ensure nothing was overlooked. No one would review the wrong version. Medical writers would no longer have to consolidate comments into a single file, this would all happen automatically.

In fact, add a few other ingredients to the process, like training the team in reviewing expectations, and some coordinated planning, and you have a genuine increase in the efficiency of document review. It's a win-win situation. Documents are reviewed more effectively, quality goes up, and time and cost go down. Surely there isn't a manager in the industry who can resist that?

Is this how your review process happens? If yes, then you're probably one of the lucky few. Already back in 1999, with Documentum in place, my first sobering experience was discovering that the company in question had decided to disable the workflow function. So the plethora of separate files with review comments, and the painful and costly process of collating and consolidating comments by hand, continued unabated. But at least there was a functional document repository in place.

Since then, working as a contractor, experiencing the inherent diversity of different companies has been quite an eye-opener. Our clients encompass the entire bandwidth of the industry, from global multinational to biotech start-up. Their document production processes range from the well-structured and technologically advanced to the poorly structured (to put it mildly) and technologically challenged.

Unfortunately, 'well-planned' and 'technologically advanced' is the exception. 'Poorly planned' and 'technologically challenged' tends to be the

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rule. The use of Documentum or any of the other collaborative reviewing tools remains an exception. Note, though, I'm now talking about the year 2015.

So what has happened since first encountering the brave new world of document review back in 1999? Apparently, very little in the case of many companies, if not in the majority of them. Since 1999, my company has worked with around 100 different clients of all sizes. Only five of these clients (not all of them 'big pharma') actually use the collaborative reviewing tools as intended. Many clients possess the software but don't use its full capability. This is in effect the same situation as in 1999. Only three of these five clients have a well-structured process integrated with the effective use of a reviewing tool. These clients are truly leading lights in the field of document production. For reasons of confidentiality, they unfortunately have to remain anonymous.

Of course there's more to document review than a reviewing tool. There is also a need for effective management and planning of resources, which are also frequently lacking. As medical writers, we're often confronted with the absurd situation of having to prepare documents that are reviewed using less than optimal procedures, even though software solutions are either already available or could be available for little cost.

So given this current situation, it's worth discussing what it takes for effective document review. I believe there are six vital ingredients to the process, all of which are used effectively by the leading lights mentioned above.

Define a structured review process

This may sound obvious, but surprisingly often it's either partially or completely absent. Especially because we operate within a highly regulated world, the obvious approach is to have a standard operating procedure (SOP) or some other written guidance detailing the process step by step. Procedures should be defined for what is to be reviewed, how the review is to be conducted, when, and by whom. These procedures should be pragmatic and non-negotiable. There's nothing new or even mysterious about the management and planning skills needed for effective document review.

All too often, companies have some form of guidance in place, but it isn't rigorously applied, sometimes even if an SOP is involved (see *Enforce the review process*, below). When a structured review process is lacking, confusion within the reviewing team is almost guaranteed. Diverse approaches to reviewing can result, and it can be challenging for medical writers to obtain the consensus needed to move documents forward.

As part of a structured review process, a kick-off meeting for any given project should also be used for clarifying timelines in terms of what is realistic, where inter-dependencies and potential threats lie, and mitigation strategies for any potential threats. Agreement and commitment to the timelines is then needed at this stage from *all* stakeholders, including contractors. Ideally, the timelines should then be actively managed during the course of the project, and agreement and commitment obtained from *all* stakeholders when changes to the original plan are needed.

Use a collaborative reviewing tool

When used correctly, a reviewing tool increases the effectiveness of document review dramatically. The benefits have been listed above, and they translate into true reviewing efficiency. There are a number of such tools on the market, either within the environment of regulatory software such as Documentum or SCORE, or as an online subscription service such as PleaseReview or, specifically for manuscripts, Datavision or Pubshub.

Of course, there are challenges to implementing a reviewing tool. Often the greatest of these is resistance to change. While some clients have insisted that reviewing tools are impossible to use, others have used them successfully for years. It's a question of enforcement (see below).

Another perceived challenge is the cost of implementation. This is not because the company cannot afford the software (any company that can afford to develop drugs can also afford the resources for effective planning and a collaborative reviewing tool), but because there's been a failure to justify the cost in the right places, perhaps exacerbated by the resistance to change. However, no one can seriously claim that it's more cost-effective to have medical writers manually collate comments from multiple files rather than having the software do it automatically with a medical writing cost of almost zero.

Another challenge is the training required for using a reviewing tool, especially when external collaborators are involved who may also face technical challenges when accessing the software. But such challenges are certainly anything but unsurmountable.

Clarify reviewing expectations

It never ceases to amaze me how little attention is given to providing training in reviewing expectations. Everybody involved in writing and reviewing documents should receive mandatory training in how to review documents. This should include training on how to prioritise comments (e.g., major, critical–must be addressed; minor, not criticial–can

be addressed at the team's discretion; and cosmetic), how to respond to other reviewers' comments (assuming a collaborative tool is used), and how reviewers should focus primarily on their own area of expertise. A clinician should not check whether abbreviations have been defined at first use, or invest time in imposing personal linguistic preferences on text that is already linguistically correct.

Another major role of training is to impress upon reviewers the need for constructive, specific, and unambiguous comments. Any changes requested must be specific enough for the medical writer to understand the issue and obtain consensus on whether the change should be implemented. Reviewers must understand that open comments with no specific direction are unhelpful and usually counterproductive. A couple of real-life examples: 'Can this be phrased more clearly' (what exactly is meant by 'more clearly'?); in a study report: 'Who decided on this study design?' (the medical writer may or may not know, but this is irrelevant when writing up the results). Or an all-time favourite of mine from a Global Head of Regulatory Affairs, placed nowhere in particular within the final draft of a study report written under extreme time pressure: 'This is bad' (did he mean the results? The conclusion? Was the study poorly executed, or was he complaining about the writing?). The man was senior, so this type of comment (he had more of them) couldn't simply be ignored, but he certainly didn't understand how to review a document.

A good understanding of reviewing expectations is also needed for resolution meetings. Reviewers should attend such meetings (see *Reviewing as a defined activity*, below), understanding the need for pragmatic resolution of outstanding issues. It's important that everyone understands the need to avoid hijacking resolution meetings with specific issues, especially those that are less relevant for the overall document goals. All reviewers must aim to resolve all comments within the framework of the meeting.

Implement staged reviews

To reduce the writing and reviewing burden during later stages of document preparation, when time will probably be tight, it can be helpful to plan a staged writing and reviewing process. Taking the example of a study report, usually data-independent sections of a document can be written and reviewed ahead of the data becoming available. The aim should be to obtain consensus on these sections without the complication of having to think through the results at the same time, and this process can also help with structuring and reporting the results.

Teams usually find staged reviews attractive as they are a promising means of ensuring that timelines are met. While they will readily agree to implement the concept, they often don't fully comprehend the consequences. These are that the review of these initial sections then really does have to happen in advance in the earlier time slot allotted, and that true commitments in terms of structure and messaging, etc. have to be made at this time.

Assuming that this takes place as planned, the reviewed sections should be 'locked down' with the clear understanding that they will not be revisited and reviewed again at a later stage of document preparation. Locking down can be achieved by changing the colour of the text and instructing the team appropriately. This should come as no surprise to the team if a structured review process is in place and everyone understands the processes to be followed (see above).

Plan reviewing as a defined activity

Although managers are loathe to understand this, reviewing documents really does take time. So it is essential that reviewing is planned as a defined activity with realistic and negotiated timelines, including resolution meetings. This reduces the risk of an excess of competing priorities, with reviewers finding themselves having to review multiple complex documents simultaneously.

Practiced unfortunately only rarely, an effective approach is to have reviews scheduled in electronic calendars as all-day appointments for the intended review period. These appointments don't block reviewers' calendars, or prevent multiple reviewing requests or workflows being issued, but they do help to visualise the reviewing burden at any given time. Electronic calendars should also be used for generating automated advance notices for impending reviews and appropriate reminders during reviews. If timelines are extremely tight, then blocked reviews on a particular day, as specific activities that exclude competing activities, can be effective.

Another essential component of having reviewing as a defined activity is a defined follow-up procedure for stakeholders who don't complete their review as planned. Ideally, the overall process should be conducive to reviewers being able to review in the allotted time period, i.e., through the minimisation of competing priorities. However, a culture should prevail from the outset that failing to respect reviewing timelines is inconsiderate to other team members and unacceptable. The extent to which this is enforced is highly variable across companies, but the leading lights enforce this vigorously.

Even under the best of conditions, circumstances will always arise when a reviewer cannot deliver on time. Ultimately, the response to this situation depends on how essential a given reviewer's input is. Some companies have a 'no response is agreement' policy and move on, but this can be problematic when, say, senior management input is needed. But even with such influential reviewers, an agreed-upon strategy for non-responders is needed to enable the team to advance the document to the next stage.

Enforce the review process

Even when a defined review process is available in writing, often the company fails to enforce it, in part or even completely. This can be due to inadequate project leadership or an aspect of corporate culture at the company involved. In the few cases I have witnessed an effective review process, this was because the process had, and was seen to have, management authority at the highest level.

Initial and refresher training events are needed to reinforce reviewing principles and processes, together with management's expectations that defined procedures are mandatory. In this way, a culture can develop where it is absolutely clear that the reviewing process is not negotiable.

The training must also reinforce the idea that any delay in providing review comments complicates the writing of subsequent drafts, can delay timelines, and disadvantages other stakeholders in the project. Almost every medical writer can recount any number of projects where the lack of reviewing discipline, especially in terms of comments being provided late, has been a substantial challenge. The diversity among companies is quite amazing, but in companies where good reviewing practices and discipline are lacking, there's often resignation and indifference to the situation, and 'muddling along' seems to pervade as an acceptable corporate culture in the absence of empowerment to change the situation.

So, having briefly summarised some of the cornerstones of effective document review, I think it's clear that many medical writers are, for any number of reasons, still having to write documents within a framework of ineffective document review processes. While medical writers are in many respects best positioned to advise on enhancing the efficiency of document reviews, in some ways we also partly contribute to the problem. This is because we often act as a buffer, enabling teams to meet their timelines despite all the inefficiencies along the way.

The classic situation to illustrate this is how we react to delayed comments. Recently, I was working on a complex document with a team of writers. The client, with no negotiation, suddenly reduced the timelines for the project by 4 weeks, so review cycles had to be compressed. Despite the new situation (or because of it), a key reviewer failed to deliver any comments by the planned deadline. The reviewer then delivered comments in five different Word files staggered over the following 2 weeks, and even then didn't review the entire document (the missing parts were saved for the next draft, making this later review more complex than planned for). The last of these files arrived just a couple of days before the next draft was due to be issued. Besides the time pressure to work through the comments for the next draft, there was no opportunity for team resolution of issues that the writing team couldn't resolve, so these also had to be saved for the next draft.

All this happened in 2015, and it's already clear from the brief description of this example that this client is no leading light in terms of its document review process. Most of the vital ingredients described above were lacking. In this type of situation, which is certainly not unique, I've often discussed with the client why things are the way they are and what we, as contractors, could do for that specific client. The responses are fascinating. Some clients tell me that certain practices (included in the vital ingredients above) are unenforceable at their company, in which case I reflect on the fact that I've experienced exactly these practices enforced and working well at other companies….

Clearly, for quite a number of companies, some aspects of document review really haven't changed much since 1999. Good organisation and management (the majority of the vital ingredients above) will probably always remain a challenge, implemented with varying degrees of success. But while we otherwise embrace technological advances that can enhance efficiency (there were no smartphones back in 1999, but who doesn't have one now?), the brave new world of collaborative reviewing tools available even back then has certainly not been fully embraced across the pharmaceutical industry. In this respect, it's clearly time to go back to the future….

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Out On Our Own

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Editorial

None of us like to think of getting older, and retirement may seem like a long way off for many. However, planning for your pension is critical if you want to ensure greater financial freedom without the need to take on so much work later in life. As freelancers, this is particularly important since we don't have access to employer pension schemes. Don't worry! Michelle Storm Lane of the Association of Independent Professionals and the Self Employed (IPSE) has come to our rescue. In this issue, Michelle explains some of the nuances relating to pensions and gives advice for your pension plans.

At the other end of the freelancing spectrum, you may be just starting out. How to gain your first client is a question frequently asked at the Freelance Business Forum and so Kathryn White has provided a comprehensive guide to networking that may help you obtain that important first contract. In addition, Matt Craven dispels some common myths associated with interview techniques and CV writing to help you market yourself appropriately in writing and in person.

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The future is bright when you plan it right

It always amazes me how many freelancers I meet who tell me they never want to retire. One truly inspiring man we heard about–an Auschwitz survivor–was still delivering high-level projects on his 90th birthday!

Unlike so many who dream of retiring early, there appears to be a distinct group of people who would prefer to keep their minds active by working for as long possible.

Perhaps this is because the majority of freelancers have more flexibility and freedom of choice than their employed counterparts, and therefore don't feel the same urge to escape the restrictions of working life. This is reflected in a study of 62 600 European workers, comparing differences in job satisfaction between self-employment and employment. The study concluded that 'the self-employed report significantly higher levels of satisfaction with the type of work they do'.[1]

On a less positive note, there are increasing concerns that freelancers are not making adequate provisions for retirement. Nigel Meager from the Institute for Employment Studies in the UK asks whether the self-employed are 'postponing retirement in the face of dwindling pension pots (savings for pensions)?'[2]

It goes without saying that working into old-age is only desirable if it is a matter of choice, not necessity.

To be able to have that choice, we need to plan ahead.

The three pillars

According to economists, our future rests on three pillars.

The first pillar is the state pension system, which is paid for via our social security or national insurance contributions. The second consists of occupational pensions arranged by trade unions or employers (which could include a pension scheme set up by a company owned by you). The third pillar is made up of personal pensions, savings and investments.

This is a standard way to categorise the three main sources of retirement income that may be available to you wherever you are in the world. However, many different types of pension exist within each pillar, and they vary enormously from country to country.

When it comes to the first pillar, most countries require workers to pay social security contributions to cover healthcare, state pension and other statutory benefits. There is usually a minimum compulsory level, but some countries allow you to increase your contributions voluntarily to qualify for a higher state pension when you reach retirement age.

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Can we rely on the state?

The country, or countries, where you have worked will dictate how much weight you should be putting on each pillar.

For example, workers in the UK cannot rely solely on Pillar 1 because the state pension is extremely limited, whereas in Spain, a freelancer who has paid the maximum level of social security contributions can receive an annual state pension of up to 35 000 euros. The Spanish advisory firm Advoco says:

> Most people attach little value to these accrued pension rights and focus on the health benefits. This can be short-sighted as, with today's low annuity rates (which show no sign of rising), it would cost a lot of money to buy a state pension of the magnitude possible in the Spanish system (between 150 000 and 200 000 euros).[3]

Germany and Sweden also have more generous social security provisions than the UK.[4] If you are in Germany, bear in mind that pension contributions are only obligatory for certain professions, although there is a possibility that obligatory cover may be extended to all self-employed professions.

If you are based in a country with limited state provision, such as the UK, you are well advised to arrange your own investment vehicle in Pillars 2 or 3 to save for retirement. In fact, the UK government has now made it compulsory for companies to auto-enrol employees into an occupational pension scheme (Pillar 2).

If you have a UK limited company, you can invest in Pillar 2 by setting up a scheme that your company pays into, and the payments can be off-set against corporation tax. IPSE members can take advantage of group rates to set up such a scheme via http ://www.ipse.co.uk/futures/ipse-pension.

Even if you are based in a country with higher state pensions, it is important to consider how sustainable the country's system is. Will the current level of state pension pay-out still be available to you when you retire? Many commentators are concerned that we are sitting on a ticking time bomb as ageing populations across Europe put more and more pressure on national pension systems.

But not all predictions are that bleak. The 2015 Ageing Report by the European Commission observes:

> Recent sustainability-enhancing reforms, particularly of pensions, help to keep costs in check and the cost of age-related public expenditure in the EU is projected to decrease from 11.3% of GDP in 2013 to 11.1% of GDP in 2060.[5]

It is also worth remembering that if you have worked in several EU countries and paid social security or national insurance for at least one year, then each of those countries will pay you a pension. The rules also apply if you have worked in Iceland, Liechtenstein, Norway, or Switzerland. You should apply for your pension in the country where you live.[6]

Arranging a private pension or other savings and investments

Investing in Pillar 3 allows you to diversify your risk through a range of alternative investment vehicles.

If you don't have a company, or cannot set up a Pillar 2 scheme, then you can consider a wide range of private pension schemes, which include personal pension plans and stakeholder pensions. Stakeholder pensions are a form of defined-contribution personal pension. They have low and flexible minimum contributions and a default investment strategy is available. Self-employed people can start one for themselves.

Most of the world's governments tax pension savings more lightly than other types of savings. However, some people prefer to invest their money into areas that offer more control or flexibility, such as personal savings plans, or even the riskier approach of building a property portfolio.

If you are tax resident in the UK you can invest in an Individual Savings Account (ISA), which allows tax free savings up to a limit of just over £15,000. However, because the limit is so low, this is unlikely to be the most tax efficient route.

Other alternatives include WRAP account and SIPPS (Self Invested Personal Pension Plans), which provide a legal framework for you to invest in a much wider range of investment options. If you have the time, desire and confidence to manage your assets individually, these could be of interest.

The IPSE Guide to Retirement Savings, available to members at http://www.ipse.co.uk/advice/finance, provides more detailed insight into the complex art of planning for the future.

To conclude, please remember that all investment carries an element of risk, and successful investing involves balancing the different kinds of risk. These decisions are not to be taken lightly and you should seek qualified professional advice.

UK residents are advised to speak to an Independent Financial Adviser.[7] To find an adviser outside the UK, please contact the relevant association for freelance professionals in the country where you are based. You can find a list of associations at http://www.efip.org/whos-involved.

And finally, if you are an IPSE member, don't forget that you can join pension, life assurance,

and private health insurance schemes at a fraction of the cost you would pay as an individual. For details visit http://www.ipse.co.uk/futures.

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Networking and securing that crucial first client

How do I get my first client? This is a question asked frequently at the Freelance Business Forum. For any fledgling contractor this is the critical first step on the freelancing ladder. Once you start building a client base, the question becomes: How do I keep my existing clients and attract new ones? Networking, building a contacts list, keeping in touch and marketing yourself and your business are key elements in creating and maintaining your client base.

Finding freelance work

Box 1 lists three places where you can find clients.

Box 1: Three places where you can find your clients:
1. People you know
2. People other people know
3. People who gather at events

Existing contacts

Ideally before you begin freelancing, or as soon as you have made the transition, write down the names of all the people you know, including former and current work colleagues. Also include friends, family and neighbours. One of my long-standing clients is a company based in my home town and is my neighbour's employer! Unbeknown to me, she worked for a publishing company that specialises in medical guidelines. After I told her I had gone freelance, she put my name forward and the rest is history. So, take 10 minutes and write down a list of 30 people you know. Contact them. Write to them via email or connect with them via social media such as LinkedIn and let them know that you are now freelancing.

Referrals

Remember, each of your contacts has their own list of contacts so there is the opportunity to expand your contact list by referrals and word of mouth. Business coach, Christine Kane, describes the importance of giving an existing or potential client a 'call to action' whenever you get in touch. In this instance, let your contacts know that you are happy for them to pass your details onto their colleagues and contacts if they feel that they could use your services. Ultimately, you need to be in contact with the person responsible for hiring contractors and the associated budgets, but take it one step at a time.

Congratulations! You have started the ball rolling…

Agencies and contracting

Some pharmaceutical companies, contract research organisations, and medical writing agencies offer contracts to freelancers for defined periods. Additionally, recruitment agencies may offer opportunities for freelancers or part-time contract work. It is worth considering that agencies will take a percentage of the original fee, and the contract may require you to work from the client's office. While you are working for this client, particularly if it is full-time,

you may not be able to work for other clients from your list who may contact you about possible projects. However, it is another viable option to consider for widening your contacts and experience.

Networking

Attend relevant conferences, training courses and networking events for business owners and freelancers. Attending conferences and training courses relevant to your business provides the perfect opportunity to meet potential clients and colleagues. Not only that, it shows you are committed to your professional development and improving your skills. The EMWA conferences are an excellent example. The combination of workshops, forums and social events means there are ample opportunities to learn new, or improve existing skills, while meeting like-minded people. The Freelance Business Forum provides another great opportunity to share ideas and challenges with fellow freelancers and is held every conference.

Find out if there are any freelancer groups local to where you live and go along. Martina Reiter provided information about networking groups throughout the DACH region of Europe for Out On Our Own in March 2014.[1] Some groups may be specifically for freelancers working in medical writing or clinical research, but even if they are not, you never know who you may meet and what potential leads may be generated.

Increasing your visibility

Speaking at events

Yes, really! See if you can find opportunities to share your knowledge. Perhaps you can offer to give a seminar, webinar, or a workshop? How about giving a presentation to students at a local school or college about medical writing or freelancing? You may get some reimbursement for these appearances, or you may volunteer to do them for free, depending on the type of event. If you aren't paid, your appearance may create leads for future contracts and therefore generate income indirectly. Furthermore, you are helping others by sharing your expertise.

Writing articles, blogs, newsletters

This is another great way of getting your name out there and building your reputation. You want to establish yourself as the 'go-to person' for your field of expertise. Writing articles for publications related to your business and background, builds your credibility as well as showcasing your writing talents and style.

Freelance directories

Another way to increase your profile is by registering with a freelance business directory such as the one offered to EMWA members. Search for other similar directories and ask fellow freelancers for recommendations. Yet another way for potential clients to 'find you'.

Be prepared to market your business

Personal branding

Being a freelancer means that – like it or loathe it – you are a marketer. You are the face of your own company, so every meeting is an opportunity to market 'Brand You'. Be prepared – always have business cards ready and be confident about telling people what you do in a succinct and engaging manner. This takes preparation and practice and is known as your 'elevator pitch'. This is not about a 'hard sell' or being pushy, because that suggests desperation. It's about being authentic and relaxed – people are more likely to work with those they feel a connection with. Be clear on who you want to work with – your ideal clients – because this will help you to market your business more effectively and authentically (Box 2).

Box 2: Who is your ideal client?

- What service does your client want or need?
- What is your client trying to achieve?
- What three mistakes is your client making?
- How can you help your client achieve their goals?
- What stops my client from taking action?

If contacting people remotely, by email or post, have an up-to-date CV and a brief summary of your experience ready to distribute. Generate a list containing details of all the articles you have written or have had published that you can disseminate.

Feedback and testimonials

Even before you start freelancing, you can ask your former and current colleagues to provide feedback on your abilities. Ask them to write a short testimonial that you can include on your website or in marketing material. This helps to build your credibility even before you get your first client and gives potential customers confidence in your services. Whenever you work with a client, ask them for a critique of your performance at the end of each project and get their permission to share this feedback on your website. This is not only invaluable for your personal and business development; it also generates testimonials that will help you to attract new clients.

Keeping in touch

Once you have contacted your list of potential clients, and even when you have one or two clients on your books, it's important to keep in touch with them. They are busy people and your name or business won't always be at the forefront of their mind. Consider writing a blog, or a newsletter that you distribute periodically. Alternatively, send an email containing a topic that would be of help or interest to your clients. Be mindful that we all suffer information overload these days due to the number of emails we receive daily. Think carefully about how frequently you publish newsletters or blogs and only send information to a client if it is sent with a genuine desire to help them – if this action generates more business for you in the future, that's a bonus.

Resources

Christine Kane is a successful business mentor based in the US. Her website at http://www.christinekane.com contains advice on how to be a successful solopreneur. 'The No-Brainer Strategy for Getting Clients' by Christine Kane can be downloaded at http://christinekane.com/the-no-brainer-strategy-for-getting-clients/#sthash.qqdNvgvx.NHWjatSn.dpbs.

The Mighty Marketer. Your Guide to Making More Money as a Freelance Medical Writer is a useful book written by freelancer, Lori De Milto. The first edition, dated 2014, is published by BookLocker.com Inc.

Conflicts of interest and disclaimers

The views given in this article are those of the author based on her own experience of running a freelance business. Following the advice given here does not guarantee business success.

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Four common myths about finding a contract

Myth 1: A CV has to be two pages long. I'm just fresh from a conversation with someone about this issue and I am on record as calling the two-page CV assertion a complete and utter myth. Yes, there might be some recruiters out there who are dearly holding onto the two-page theory, but talk to any well-informed modern-day recruiter and they'll quickly tell you that a CV can be longer. I have read some recent research from a UK business school that echoes my own, which found that hiring managers are seeking more information and not less, and that the desired length of a CV is longer than it has ever been. Coupled with the fact that 85% of hiring managers will check you out on LinkedIn, it is clear that more information is required before making a shortlisting decision – and not less. My final word on this is that many of the leading banks give guidance to their chosen recruitment agencies on length of CVs, and current guidelines state that up to four pages for a contractor is perfectly acceptable.

Myth 2: LinkedIn is social media. I talk to far too many people who are failing to embrace LinkedIn because they are not a fan of Facebook and Twitter and see LinkedIn as just another social media channel where people talk about what they had for dinner. LinkedIn is far from a social media platform; it is a professional networking site with over 347 million members worldwide. The sheer volume of professionals who use LinkedIn on a daily basis has rendered the site the largest candidate database in the world, so it stands to reason that this is where recruiters are fishing for talent. Coupled with the fact that 85% of hiring managers will check you out on LinkedIn before shortlisting you, it is clear that it is a key element in a freelancer's armoury. Once you have embraced the fact that LinkedIn is critical, it is important to realise that like any other marketing channel, it needs to be approached with care and attention. A LinkedIn profile with minimal information or one full of uninspiring content will not do you any favours. It is critical that your LinkedIn profile fits together with your CV and is written with as much care and attention as your CV.

Myth 3: I am good at communicating so I am good at interviewing. Many people think they are born with a talent for selling themselves in interviews. The trap here is to think that being a good talker means you are good at interviewing. I am a good talker but ask me to go and sell a €20 million yacht and I wouldn't have a clue. Why? Because I don't know anything about yachts! 'But I know myself!' I hear you cry. You may know yourself on a personal level but do you know yourself professionally? Do you know your value proposition? Where you can add value to a future employer or client? Your key achievements? Or when you

successfully handled conflict in the workplace? Or when you settled an issue with an unsupportive stakeholder? These things don't just spring to mind, they have to be thought through, prepared and rehearsed. Simply talking confidently and authoritatively about nothing in particular won't score you points in an interview; your responses must demonstrate that you have the skill that is being explored by that particular question. Finally, how can you be good at something you have done no more than half a dozen times in your entire life? Being good at something requires training and practice and those who really excel in interviews reach out for both.

Myth 4: Two hours for each job application is sufficient. I have something that I call the quarter of a million pound theory which is predicated on the fact that a €50k candidate over a 3-year period (a decent stint for an employee in anyone's book) will cost their future employer over a quarter of a million pounds when the full remuneration package and payroll costs are added up. Think of how much work you would do if you were pitching for a three-year €250k medical contract! Would you knock up a basic proposal and do two hours of preparation for that client meeting? The answer has to be no, so let me ask why you would knock up a basic CV and do two hours of interview preparation for a three year, €250k freelance contract? My point is that the average freelancer puts far less care, attention and effort into securing a contract than they should. Most companies invest in professionally created marketing materials and freelancers who take the same approach with their marketing materials (e.g. their website, CV and LinkedIn profile) are the ones who succeed. Those who do a bit of cursory online research and simply read through the job spec are setting themselves up for failure. Those who do 15 hours of preparation for an interview are the ones who get the contract–so it's worthwhile spending the time and effort to ensure your application is of a high standard.

Matt Craven runs The CV & Interview Advisors who offer a range of CV writing, LinkedIn and interview coaching services.

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Freelance foraging

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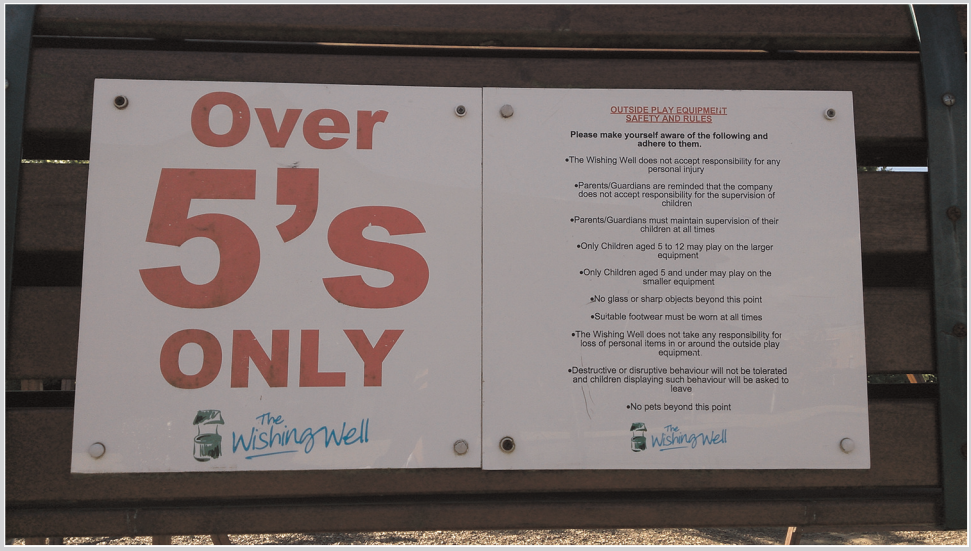

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