

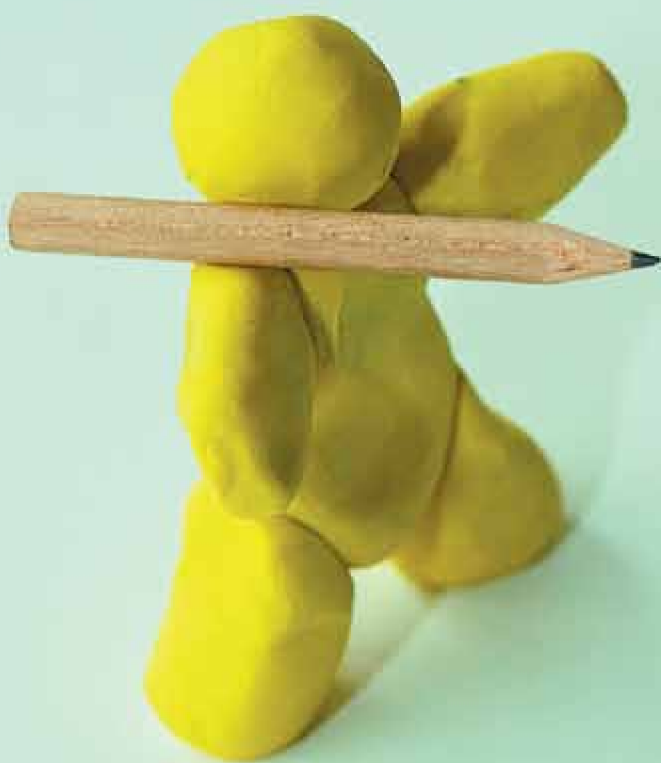


European  
Medical Writers  
Association

# The *Write Stuff*

The Journal for **European Medical Writers**

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## Business

**EMWA Executive Committee***President:*

**Laurence Auffret**  
CINETIQUE Translations  
Manchester, UK  
laurence@cinetique.co.uk

*Vice President:*

**Rita Wellens**  
Wellens Clinical Research Consulting  
Rillaar, Belgium  
rita.wellens@telenet.be

*Treasurer:*

**Gillian Pritchard**  
Sylexis Limited  
Dundee, UK  
g.pritchard@sylexis.co.uk

*Honorary Secretary:*

**Laura Hollyhead**  
Laura Hollyhead PPD  
Cambridge, UK  
Laura.Hollyhead@ppdi.com

*Public Relations Officer:*

**Andrea Palluch**  
Inpharmedia  
London, UK  
apalluch@inpharmedia.co.uk

*Website Manager:*

**Shanida Nataraja**  
Axon Communications  
London, UK  
snataraja@axon-com.com

*Education Officer:*

**Stephen de Looze**  
Accovion GmbH  
Frankfurt, Germany  
stephen.delooze@accovion.com

*Conference Director*

**Sunethra Wimalasundera**  
Eisai UK  
Hatfield, UK  
Sunethra\_Wimalasundera@eisai.net

*Journal Editor*

**Elise Langdon-Neuner**  
Baxter BioScience  
Vienna, Austria  
editor@emwa.org

**EMWA Head Office**

Durford Mill, Petersfield, GU31 5AZ, United Kingdom  
Tel: +44 (0)173 071 5216, Fax: (+44) 870 442 9940  
info@emwa.org  
EMWA website: www.emwa.org

## Journal insights

The *Write Stuff* is the official publication of the European Medical Writers Association. It is issued 4 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims, but opinions expressed in individual articles are those of the authors and are not necessarily those held by EMWA as an association.

Articles or ideas should be submitted to the Journal Editor (see below) or another member of the Editorial Board.

## Subscriptions

Subscriptions are included in EMWA membership fees. By writing to [emwatws@associationhq.com](mailto:emwatws@associationhq.com) non-members can subscribe at an annual rate of:

- €35 within Europe
- €50 outside Europe

## Instructions for contributors

- The *Write Stuff* typically publishes articles of 800–2500 words although longer pieces or those with tables or graphics will be considered.
- All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
- Submissions should include the full address of the author, including the telephone and fax numbers and e-mail address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
- Material should be submitted by e-mail as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 360 x 510 pixels).

## Timelines

Month distributed	Deadline for receipt of articles	Deadline for receipt of adverts
March	1 <sup>st</sup> January	15 <sup>th</sup> February
June	1 <sup>st</sup> April	15 <sup>th</sup> May
September	1 <sup>st</sup> July	15 <sup>th</sup> August
December	1 <sup>st</sup> October	15 <sup>th</sup> November

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• Half page €500	• Half page €100

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The *Write Stuff* is printed on 100% recycled paper.

**Business****Vol 19, No. 2, 2010***Serina Stretton, Rachel Cameron and Karen Woolley***The business case for  
peer-reviewed publications 96***Andrea Rossi and Giulia Calamai***Medical writing:  
The added-value enigma 99***Judith Grice***Stand out from the crowd—by  
understanding European pharmaceutical  
industry codes and compliance 101***Ruth Whittington***Publications management methods:  
A comparison of tracking programs 105***Sunethra Wimalasundera***Patents: Converting technology  
into a business asset 110***Diarmuid De Faoite***A crash course in marketing  
for medical writers 112***Anders Holmqvist***Expanding your market  
by involving graphic design 115***Alison Rapley***Managing projects outside  
the traditional medical writing area 117***Adam Jacobs***From medical writing  
to global domination 119***Karen Shashok***Crossing the thin line between  
paraphrasing without citation and  
plagiarism: The Sticklen retraction 122***Alistair Reeves***Everything has its place:  
Word order in English 124**

Freelance Section

*Sam Hamilton***Freelance choices:  
Business development  
or developing a business? 136***Stefan Lang***Marketing tools for new freelancers 138***Raquel Billiones***The downsides of a home office  
(and what you can do about them) 140***Claudia Frumento***The ‘fuzzy logic’ of the European  
medical device world:  
Interview with an expert 144***Alistair Reeves***Third EMWA Freelance  
Business Survey 2010 147***Andrea Palluch***Are you doing the (copy)right thing?  
A NetworkPharma lunchtime briefing 150**

Translation Section

*Gabi Berghammer***Medicine at the multilingual  
crossroads 161****Cover picture**by Nadja Meister  
(nadjameister@inode.at)**Regular features**

<b>From the Editor's desk</b>	<b>80</b>
<b>Message from the President</b>	<b>82</b>
<b>In the bookstores...</b>	<b>129</b>
<b>Journal watch</b>	<b>132</b>
<b>Webscout</b>	<b>152</b>
<b>Linguistics corner</b>	<b>153</b>
<b>Biomedical publishing shorts</b>	<b>154</b>
<b>Words, Grammar &amp; Co</b>	<b>157</b>
<b>For regulatory writers</b>	<b>160</b>

## ■ From the Editor's desk



## Business and being better in it

by Elise Langdon-Neuner

The idea of a business theme issue emerged during the *TWS* editorial meeting at last year's EMWA conference in Ljubljana. This was a problem for me as I was left with the task of putting together an issue with this bright idea. I feel that I am more an observer than a player when it comes to business, and maybe this feeling is not unusual for a medical writer. My hunch is that the average medical writer has little active interest in business. In my experience science, independence, social interaction and even writing are the main interests of a typical medical writer—as far as work is concerned, because as a bunch medical writers seem to have many outside and diverse interests. A medical writer rarely chooses the path of line management. 'Head of the medical writing department' is the end of the line for most medical writers. We are not likely to become CEOs of pharmaceutical companies, although we might take on prominent roles in CROs and medical communication firms.

It is not that business is not interesting for the observer. Management books, for instance, regularly become best-sellers. Gone are the days when officials at General Motors doubted that Peter Drucker would be able to find a publisher for his study of their company because no one would be interested in a book on management. After the book's publication in 1946 Drucker went on to become a management guru and nowadays his successors can command \$60,000 for a single lecture. David Bolchover's book about office life, *The Living Dead*, is one of the most fascinating accounts of business in practice on my bookshelf. He describes how millions of people are disengaged from their jobs and spend years sitting in offices doing hardly anything in abysmally managed large organisations that waste their talents. They remain in place only to shore up their manager's empire. Then there's Lammers and colleagues recent study [1] in which they tested the moral pliability of volunteers, characterising them in two groups: high-powered and low-powered. They proved Lord Acton's dictum that power tends to corrupt. In one of their experiments, for instance, they asked volunteers how acceptable it was for them and for others to transgress in various ways. The high-powered expected higher standards from others than they adopted themselves whereas the low-powered were inclined to hold themselves to stricter standards than they

***I suspect I'm not alone amongst medical writers in having a mild contempt for 'business'***

expected from others. In another set of experiments they discovered that high-powered people feel entitled to abuse the system and not only in minor ways such as cheating for extra lottery tickets but also in committing legal offences. The depressing conclusion is that the victims—that's us folks—of a system contribute to corruption and hypocrisy by their acceptance. However, gossiping about leaders may bring their behaviour back to their espoused standards or if they fail to change cause their downfall. Thereby office gossip takes on a new significance!

It's all fascinating stuff, but I suspect that I am not alone amongst medical writers in having a mild contempt for 'business'. So what was I going to ask people to write about that would interest medical writers? Typically for a medical writer, I thought about the word. But the more I thought about 'business' the more bewildering the task in hand loomed. "The question is," said Alice, "whether you can make words mean so many different things" (Lewis Carroll). As far as 'business' is concerned it seems that you can, because not only does it mean a particular company or firm—it's also a particular market sector, e.g. the medical writing business, and (most daunting of all) it includes every activity by the community of suppliers of goods and services. These activities include R&D, production, marketing, management, selling....

A quick check in Wikipedia revealed that the etymology of 'business' relates to the state of being busy, on the part of

an individual or society as a whole, doing commercially viable and profitable work. This seemed to fit to medical writers. We are busy (that's for certain and unlike Bolchover's friends usually far too much so) and of course we do viable and profitable

***The hankering for independence is probably responsible for our adeptness in setting up small businesses***

work. Or do we? The work is profitable for us because we receive remuneration, but what is the benefit to our employers/contractors? Whether medical writers add value that can be seen as a tangible investment must be important for the future of medical writing in these times of cost savings and is indeed an issue of interest to all medical writers! Two articles in this issue of *TWS* tackle the question; one by Serina Stretton and colleagues and the other by Andrea Rossi and Giulia Calamai. Both articles conclude that more research is needed. The first article refers

## From the Editor's desk

to initiatives from American and Australian medical writing associations to help fund such research. What about EMWA?

Beyond discussing the *raison d'être* of medical writers in the business world, I wondered what other aspects of this gigantic word 'business' would be of interest to medical writers. The hankering for independence, which I am assuming is characteristic of many medical writers, is probably responsible for our adeptness in setting up small companies or working as lone freelancers offering medical writing services. Many articles in this issue are therefore addressed to medical writers working in smaller companies or going it alone. The bumper freelance section, as detailed in the introduction to the section, has articles covering marketing tools for new freelancers, developing a business, what you can do about the downsides of working at home and the eagerly awaited freelance survey.

To be successful in business you need to be better than the competition, as graphically depicted on the cover of this issue. In which ways can you outwit the competition? Command of more knowledge is one possibility and medical writers are, in my experience again, acquisitive when it comes to knowledge. Hence the issue contains a small collection of acquiring-knowledge-to-help-you-in-business articles. Judith Grice explores how you can stand out from the crowd by understanding European pharmaceutical industry codes and compliance. Ruth Whittington compares two electronic tracking programs for managing publications with a view to keeping compliant with Good Publication Practice. Sunethra Wimalasundera advises on how technology (patents) can be turned into a business asset, Andrea Palluch writes about copyright and Diarmuid De Faoite gives us a crash course in marketing. There is also an interview with Susanne Gerbl-Rieger of the TÜV (a German commercial certification body that validates the safety of products) about regulation relating to medical devices, which can be found in the freelance section. Non-native speakers of English have an additional hurdle to overcome in the medical writing business. They need to meet the writing standard in English of native speakers. Alistair Reeves' new series of articles on word order in English starts on page 124 of this issue and will be an invaluable help to the non-natives. Word order is rarely written about and is generally poorly understood, even by the natives. I for one have been looking forward to this series for a long time. There is also the translation section which you should not miss whether or not translation is part of your business. Gabi Berghammer's 'Bengali for pharmacists' makes delightful reading but with a serious undertone emphasising the vital importance of providing clear information to patients.

Another possibility for keeping ahead of the competition is to venture into unconventional areas. For example, you could expand the scope of your business by taking graphic

designers on board or by branching into a project outside what is considered traditional medical writing. Articles by Anders Holmqvist and by Alison Rapley will help with such enterprises. The new trend of topic based writing is also likely to produce work opportunities for medical writers. Joelyn Flauaus explains the concept in Webscout and points to sites offering more information. But what about the aspect of self-plagiarism? I think the trend could bring some new ethical challenges for us, at least in manuscript writing.

Quite apart from all this serious business there's also some fun and intrigue, as Karen Shashok reports on the Sticklen affair, Ursula Schoenberg takes a light-hearted look at the hazards of freelancing and Adam Jacobs revisits his youth in Journal watch. Talking about Adam's youth we can trace the development of ambition to rule the world through the unlikely route of medical writing in his article 'From medical writing to global domination' and at the same time gain an amusing yet worthwhile insight into strategy of growing a medical writing business.

A new section providing news and information for regulatory writers makes its debut on page 160. Greg Morley (greg.morley@docuservicio.com) will be running this section and would be pleased to hear from anybody who comes across something they would like to share with fellow regulatory writers.

Sadly, in this issue we also publish Geoff Hall's obituary. Geoff Hall has been with EMWA since its beginning. He was a valued and very well-liked member of EMWA who contributed greatly to its development and collegial tone. Geoff Hall was immensely kind in supporting me with *The Write Stuff*. He often wrote for *TWS*, most recently in the last issue. It was difficult for him to write his article about Lisbon, a city he loved, because his eyesight was failing. He dictated to his wife Pat, but had problems meeting the deadline because of treatment appointments. I told him that he should not worry about the article, his health was more important, but clearly he felt that he would be letting me and EMWA down if the article did not make the print deadline. He wrote saying he was getting there and he was sorry for being difficult. My tribute to Geoff is in the e-mail exchange that followed. I wrote "Difficult? You have no idea how much I appreciate your help and admire your fighting spirit. EMWA is lucky to have you!" He replied "Thanks for the encouragement. I think I'll always be in EMWA's debt, though."

#### Elise Langdon-Neuner

*Editor-in-Chief*  
editor@emwa.com

#### Reference:

1. Lammers J, Stapel DA, Galinsky AD. Power increases hypocrisy: moralizing in reasoning, immorality in behavior. *Psychological Science* 2010;21(5):737-744.

## ■ Message from the President



# Of clouds and crowds...

by Laurence Auffret

I am so pleased to report the great success of our spring conference in Lisbon in May. The recipe is actually simple: take a lively crowd of medical writers of all nationalities and level of experience, an outstanding programme of accredited workshops (EPDP), generously spiced up with plenary sessions and seminars about medical writing in an electronic era, the special topic of our 30<sup>th</sup> conference. Allow to steep for 4 days... Season with an AGM, some animated discussions over coffee and a few stellar social events.

The results are obvious:

- A useful platform for networking, sharing knowledge and experience
- A plethora of opportunities for developing professional skills
- A comprehensive set of best practices to support the decisions of managers
- A growing voice for medical communicators based on a collective decision-making process
- ... And a really pleasant learning experience.

Those who attended expressed great satisfaction, and according to some long-standing members it was “one of the best conferences ever.” It was certainly the largest to date with 287 delegates, 54 workshop leaders and 54 new members. The Professional Development Programme (EPDP) boasted 13 new workshops running for the first time, which was about 25% of the total workshops on offer, and this was more than at any previous EMWA conference.

I am always humbled by the work done by our volunteers—the workshop leaders for passing on their knowledge and trade secrets, the executive committee (EC), the executive professional development committee (EPDC) and all sub-committee members for organising the workshop, seminar and plenary sessions programmes. They carry the founding spirit of the association, and it has been ever so strong for the past 15 years. I would like to thank and congratulate every EMWA volunteer for taking initiatives and for playing key supporting roles to make EMWA and this last conference a major success. I would love to mention everyone by name, but I would need a big book to list them and their achievements.<sup>1</sup>

Our next meeting is in Nice (11 - 13 November) and we are currently working on a full programme of workshops, seminars, master classes, discussion forums, presentations

and social events. You can keep up-to-date by joining our LinkedIn or Facebook groups or consulting the Website.

I intend to dedicate this year to focusing on our 3-year strategy (see last issue of *TWS*; 19(1):7-10); a four-pillar plan to build the association, further our profession, share expertise and grow membership. I am particularly interested in the issues of diversity (in terms of members, training, communication platforms, etc) and professionalism. In my view, these are the strength and power that support all associations, and they will also take EMWA to new challenging grounds. These challenges face us, and our experience as medical communicators will surely guide us well.

I would also like to welcome on the EC Rita Wellens (Vice-President) and Sunethra Wimalasundera (Conference Director), as well as Alison McIntosh, Thomas Schindler, Barbara Grossman and Marian Hodges on the EPDC. Many thanks to you all for joining us and helping EMWA to achieve its mission. Helen Baldwin, who stepped down as EMWA's president in May, also deserves a big round of applause for the boundless energy she brought to EMWA, a great inspiration to many of us.

Finally, a little secret that the no weatherman will ever tell you: November 2010 is the best month of the decade to visit the French Riviera. Swimming may be off the list, but there is a lively crowd of medical writers on the horizon (see back cover).

With these words, I'd like to wish you a fruitful time as you read *TWS* and hope you have a lovely summer. We look forward to seeing you in Nice.

**Laurence Auffret**

*CINETIQUE Translations*  
Manchester, UK  
[Laurence@cinetique.co.uk](mailto:Laurence@cinetique.co.uk)



photo: Nadja Meiser

<sup>1</sup> If you want to add your name to the list, please contact me.

## Obituary: Geoff Hall remembered by...

**Geoff Hall** (1945-2010), who was a founding member of EMWA, passed away recently after a long and well-fought battle with cancer. Geoff is remembered fondly by many of us at EMWA, and below are a few thoughts of farewell to celebrate and remember Geoff.

**Geoff was** one of those rare people that made you feel completely at ease within seconds of meeting him. His innate cheerfulness and open friendliness were so overwhelming that it was easy to overlook what an accomplished person he really was in so many fields: journalism, medicine, sports, family, business, etc. Many current members may be unaware of the important role Geoff played in the early and difficult founding days of EMWA (EMWA Vice-president, 1998-1999; EMWA President, 1999-2000; Workshop leader, 1995-2003). I got to know Geoff as an integral part of the EMWA conference scene at my very first conference, and he was always there, eager to help out the growing organisation in any way necessary, which in those days was a big reason why EMWA survived at all. I believe that this is a great way to be remembered, to have accomplished many things and helped people in important ways, all the while sharing your friendship and joy of life with everyone around you. So, Ol' Zulu Warrior, here's to a life well lived, an example to all of us.

**Barry Drees**

**My recollections** of Geoff begin in the antediluvian period of EMWA. Geoff was one of those 'characters' who contribute to the personality of an organisation. Geoff Hall was never alone. He could always be found (usually in the bar) holding court, surrounded by his multitude of friends—some of decades standing, and some made just minutes prior. Geoff was a raconteur with a welcoming, inclusive air about him—always beaming and highly-energised, he seemed to exert a gravitational pull as he moved through the EMWA meeting venues. He was one of those rare individuals who just seem to bring out the best characteristics of those who came within his field of attraction: friendliness, camaraderie, humour, and inclusiveness.

During his EMWA presidency, Geoff was instrumental in the attempt to forge more formal relationships with AMWA... his diplomatic skills and patience were admirable. I remember vividly the high emotion and pride he felt upon receiving the Nick Thompson Award. He will be greatly missed.

**Art Gertel**

**My first** encounter with Geoff was in 1992 in Brussels at what has become known as the first 'proper' meeting of what later became EMWA. We crossed paths at annual conferences as EMWA grew, and I last saw him at the Montpellier meeting in 2001. How do I remember Geoff after such a long interval?

Geoff seemed to me to have so many contradictions about him. Not a scientist but a heavyweight medical writer (or, as he put it, a writer first and a scientist second [or even third]). Self-effacing and yet quite sure of himself. Jolly and yet capable of acerbic commentary. Certainly not your average member of EMWA and yet absolutely instrumental in its coming of age.

His work on growing the mainstream activities of EMWA, from which so many of us have benefited, is a matter of record. My personal enjoyment of EMWA was also hugely enriched by Geoff. For example at the Dublin 2000 meeting where he introduced Michael Paling, a pharmaceutical advertising guru who gave us a hugely entertaining and completely off-piste insight into the creative world of advertising copywriting. And the previous year in Denmark at an offbeat and rather risky panel discussion I proposed and then ran on careers, with absolutely no planned agenda. Geoff came along and injected energy, controversy and humour into a debate which could so easily have dried up but never did. His beaming face as he shook my hand afterwards still makes me smile now, thinking back.

You can get a flavour of Geoff's sly sense of humour, his writing style and indeed his contribution to EMWA, by reading his own article on its history [1]. Note the characteristic humorous aside in its title, by the way. But the article is accurate.

**Mike Matthews**



1. Hall G. The history of EMWA: Personal (and possibly unreliable) recollections. *The Write Stuff* 2008;17(1):9-11.

**How do I remember Geoff? As:**

The avuncular character sitting at the bar, comfortable with himself and so good at making others comfortable and welcome.

An educator and entertainer, as he led his workshop on 'Understanding Research Ethics Committees' at my first EMWA conference (Bruges 1995).

The discreet mentor in my early days as EMWA Treasurer to his President, able to see the big picture.

The active supporter as Marian (Hodges) and I led our first workshop (Montpellier 2001). His open honesty—"I've no idea how to spell that word [meiosis], get the dictionary"—made everyone relax.

How incredibly sad—it is truly the end of an era. EMWA will not be the same without you Geoff, and I shall miss you.

**Barbara Grossman**

**I met** Geoff at my first EMWA conference in 1995. He was clearly a well established member, but he made me feel welcome. That's one of the things that impressed me at all the conferences—he talked to first-time conference attendees and remembered ones who'd been before. His enthusiasm and inclusiveness reaped benefits for EMWA as he encouraged many other members to participate, stand for office or run workshops.



## Obituary: Geoff Hall remembered by...

- When Barbara Grossman and I prepared for our first EMWA workshop, the thought of a talented writer and workshop leader like Geoff attending did nothing to lower my anxiety levels! On the day, though, we couldn't have asked for a more supportive participant. Geoff's comments were informative and entertaining, but he never sought to take over.

Geoff helped make an EMWA conference a social gathering as well as professional one. He made a major contribution to making EMWA a friendly and supportive group. I will miss him,

**Marian Hodges**

**I first** met Geoff at the EMWA conference in Copenhagen in 1999, which had been organised by Geoff, who had been vice-president of EMWA for the previous year and became president during the conference. I was very nervous when I attended the conference. It was my first EMWA conference, I didn't know anyone there, and didn't really know what to expect. I was instantly made to feel completely welcome, not only by Geoff, but by the whole atmosphere of the conference, which looking back and knowing Geoff as I do now, had clearly been greatly influenced by his warm and generous personality. By the end of the first evening, I knew I was among friends, and I was lucky enough to count Geoff among my good friends at many convivial evenings at the bar in many EMWA conferences since.

But Geoff was much more than just the kind of person you were always delighted to end up next to at the bar. Apart from having been a successful businessman (I can't tell you much about the details of his business ventures, as he was a modest man who didn't talk much about his past successes), he was also an experienced and knowledgeable medical ethicist, and I am very grateful to him for introducing me to the world of research ethics committees, in which I have had some fascinating experiences since Geoff told me of a vacancy on his committee 7 years ago.

I shall miss Geoff greatly, but it is a comfort to know that his spirit will live on at future EMWA conferences.

**Adam Jacobs**

**Like many** EMWA members who counted Geoff as a friend, we first met at an EMWA conference—in the bar. He was always fun to be with and was always surrounded by people who were also fun to be with. Lasting memories include the Hofbräuhaus in Munich and the ritual singing of Clementine to the Welsh hymn tune Cwm Rhondda on the bus on the way to the conference banquet. My last meeting with Geoff was a most enjoyable day in one of the Members' stands at Lord's cricket ground as his guest, watching England on their way to a rare defeat of Australia in last year's Ashes series (2009). Although very unwell at the time and in considerable discomfort, he was as entertaining as ever. This is how I will remember him—fun to be with.

**John Carpenter**





**The first** time I went to an EMWA conference I met Geoff. Not that it was really surprising, because Geoff was at pretty well every EMWA conference and it would have been hard not to meet him. His genuine friendliness and warmth in welcoming newcomers as well his delight upon greeting old friends were so contagious that he was inevitably at the centre of everything. Always surrounded by a crowd of listeners, he would entertain us all with his stories until the small hours of the morning. Nobody wanted to leave, even if they had to give a workshop in the morning, it was just so much fun. I don't really want to think about going to the next conference and not seeing Geoff. It is going to be so hard, so very sad, and I will miss him terribly.

**Susan Bhatti**

**I can't** remember the first time I met Geoff—definitely at an EMWA conference, almost certainly in the hotel bar. The reason I can't remember has nothing to do with alcohol though—it is simply that to have met him once, was to know him for life, and think he had always been there. His outgoing and inclusive personality, the greatest recruiting asset EMWA had, made him an instant friend, and in a friendship that persisted. In *The Write Stuff* he wrote “several of the people I consider among my closest friends are people who I only see for a few days each year”... so true, and in a way I am glad, because it makes it easier to pretend that he is still there.

**Keith Veitch**

**In the** years that I knew him, I learned an immense amount from Geoff, and not just about writing. When I needed advice he was usually the first person I would ask, and no matter how busy he was he would always find time for me. He also shared with me his love of music, not to mention some truly awful humour.

Meeting Geoff was like staring at a bright light—look away and he is still in your mind! He may have left us far too soon but for me, he will always be there, telling his stories and singing his songs. Geoff's rendition of *Men of Harlech* at the whiskey distillery dinner in Dublin, will stay with me forever. I suspect right now that Geoff has already found the bar, is organising a crown green bowling league, finding out when the next cricket match is on, and organising his next trip to EMWA!

**Judi Proctor**

**Most people** have very few true friends; those who give their friendship freely and unconditionally, and who seem to know instinctively what to say or do to make you feel better. Geoff Hall was one of those people—everyone gravitated towards him. Whether he was in a bar or at the back of a coach belting out ‘Clementine’, he was surrounded by a sea of smiling faces, and he would be beaming back at them. His personality was only outshone by the size of his heart: he approached life with a joy and enthusiasm that were infectious, and a certainty that even if things didn't work out, he'd enjoy the ride. The world was a better place for having Geoff in it. He has an amazing family who will miss him deeply, but he touched many more lives.

Most people have very few true friends. I was incredibly lucky—Geoff Hall was one of mine.

**Lisa Chamberlain James**

**So many** people  
Spend their lives caught up in excuses  
There's this and that  
Work, kids, sleep  
Getting in the way of making things happen

But every once in awhile  
You meet someone  
Who has figured it out  
All those things – life  
Don't hold them back  
And while everyone else is busy  
Sinking into the quagmire of the quotidian  
That someone is busy making things happen

Like a beacon of inspiration  
They're out there  
Turning their ideas into reality  
They try things out  
Stay true to their visions  
Believe in themself  
And if it starts to rain...  
They settle into the nearest pub  
And tell stories until the sun comes out again

In a world with so few of these beacons  
I'm fortunate to know a couple of them  
But a star fell from my sky last night  
One that burned especially bright  
For among the stars out there making things happen  
Few get it all right

In their drive to achieve  
They forget  
About family and fun, laughter and love  
The pleasure of savouring what they've reaped

But not all  
I knew one who understood that life is a stage  
And it's up to us to make the show worth watching  
His life was more than just success  
There was abounding heaps of play  
Which wasn't a coincidence

With the fervour of pursuit he gave to all his ideas  
Geoff pursued and created a life  
Brimming with pleasure  
Time for family, sport, culinary delights  
Friends and beer  
Was a priority

The man loved to sing  
Played his guitar with a passion  
Adored his amazing wife  
Burst with pride at his lovely children  
Was always good for a story (or five)  
Knew everyone and had done everything

Simply put  
He was a true connoisseur of life  
Something rare and precious  
And a friend I will miss indeed

**Julia Forjanic Klapproth**

## ■ What's news at EMWA

# The EMWA Spring Conference

Lisbon, 2010

The run up to EMWA's 30<sup>th</sup> conference held in Lisbon on 11-15 May was an anxious time for EC members, especially for the President and Vice President, Helen and Laurence. Would delegates be able to dodge the volcano ash cloud which was edging its way towards Portugal? Obviously the gods are on EMWA's side because the problem blew over and all turned out well on the day. *TWS* brings you a full report of all the events at the conference. A new feature for EMWA conferences, posters and oral presentations of abstracts, which was Helen's brain child, was a great success. Networking and socialising have always been a stalwart of EMWA conferences—Lisbon was no exception. I hope you enjoy reading the report of your conference.

## First timer impressions

### Volcanic ash, the pope and a little porto...

Here is a brief account of my experience of my first EMWA Summer meeting in Lisbon. I flew from Rome to Lisbon the day before my first workshop. I was a bit preoccupied about the fact that the flight may not actually leave from Rome, thanks to volcanic ash clouds still hovering over regions of Portugal. Fortunately, the plane departed and although a slight change in flight path was required (via Morocco), I arrived safely in Lisbon early afternoon. Actually, this particular week, the Pope was in town spreading the good word, and as a result, the taxi (a cream Merc with over 750,000 Km on the clock!) needed to perform a lengthy detour to arrive at my destination, The Hotel Fenix Garden (overlooking the *Eduardo VII* park); about a 5-min walk from the Tiara Park Atlantic (TPA), where the conference was held. After registering I went to a presentation on a tribute to Geoff Hall, a founder of EMWA. It was extremely touching to see how many senior EMWA members paid their respects and portrayed this wonderful person. Following this was an interesting 'Introduction to Portuguese' lecture before a welcome drinks reception. Thanks to a bright green ribbon attached to my name card (for all 'first timers') other non-green ('black-belt') members must have had sympathy for me and welcomed me into their conversation. This simple differential colour coding was a neat idea by EMWA. From that moment onwards it has been analogous to being welcomed as a member into a large family. I quickly got to know many different and interesting people with wide ranging backgrounds and experiences. My medical writing experience to date has been mainly based on that gained from scientific research. Although I have experience in statistical analysis, I wanted to improve my knowledge of specific aspects,

in addition to developing my understanding of regulatory documents. Therefore, I chose 4 courses, 2 statistical and 2 on regulatory documents/study design. All 4 courses were extremely well organised and I learnt a substantial amount of information, which I will be able to develop further.

Every day followed a fairly well-defined routine. Three other EMWA members were staying in the same hotel as I, so normally we would breakfast together before making our way to the TPA. There was usually a plenary lecture at 8 am followed by coffee and workshops kicked off at 9 am with coffee at 10.30 am, finishing at 12.30 pm. Lunch was buffet format and a great chance to meet new members. The food was first class as you would expect, and was included in the registration fee. Afternoon workshops went from 2.00 to 5.30 pm. Three of my 4 workshops were in the morning, so afternoons were spent recovering (from a late night of Porto consumption), catching up on regular work or sight-seeing/shopping. The second evening was the night of the official banquet. It was an evening that started late and finished extremely late. It was a little expensive but worth it. The food was splendid. A few senior members provided entertainment in the form of recounting personal experiences and anecdotes. It was a great opportunity to mingle. During the week I participated in the city tour by tram, which I thoroughly enjoyed. During the tram ride we were offered at least 2 glasses of Porto, which for some, made the walk up the hill to the castle of St George that bit more challenging. I also participated in the Porto wine tour which proved to be very informative. My evening meals were never alone, either pre-planned from the EMWA programme or organised with other people I met. I flew out the day after the conference ended. It was a wonderful experience and I am looking forward to attending the autumn conference which will be held in Nice. I am sure it will live up to more than its name.

**Colin Egan**

*colinegan@gmail.com*

### My first EMWA Conference

Three years ago, after a variety of veterinary and non-veterinary career moves, I found myself working in the registration department of a veterinary pharmaceuticals company. Since then I have been somewhat of a hybrid regulatory affairs cum pharmacovigilance manager, with a particular remit for biologicals (not that I don't end up dealing with pharmaceuticals on occasion too).

The various mergers and acquisitions in our industry left me facing the prospect of redundancy. Looking around at the various career options available, I realised that medical writers do quite a few of the things that I'm already doing, and I love writing.

## What's news at EMWA

I attended Adam Jacob's and Alison McIntosh's one day 'Introduction to Medical Writing' course in London, and knew that my hunch had been correct. They advised me to attend at least one EMWA conference while I still had my current job, which is how I found myself in Lisbon this year.

*An aside: I love conferences; I love conventions; I love those events that can't quite make up their minds what they are, and just use the word 'Con' in their title. I'm not one of those people that stays in the bar until some unearthly hour, but I am one of the people who will talk to anyone else wearing the relevant ID badge.*

My conference got off to an excellent start, when Adam found me by the departure gate at Heathrow, and suggested we share a taxi to the hotel. Our taxi driver gave us a highly original and detailed guided tour, which instilled in me a great love for Lisbon and Portugal, even though I saw not nearly enough of the city outside the hotel for the rest of the week.

Tuesday evening consisted of an introduction to Portuguese in the main hall, followed by various rounds of socialising, until I decided I was too tired and hungry to continue (the hotel bar provided some excellent salads and club sandwiches for not too scary a price).

On Wednesday I was up bright and early for the plenary lecture, which set my pattern for the week. I attended all four, and found them very useful to get my brain going before the serious business of workshops. The lectures revolved around the conference theme of medical writing in the electronic era, which I found most interesting as one who could be using the web (Web 2.0!) more, and who is just getting the hang of e-books.

As far as the workshops went, I found the balance between presentations and group work was about what I needed for all four. My little netbook (Acer Aspire One mini laptop) came in handy both for taking notes during the presentations and for writing up our group discussions. The pre-workshop assignments had been taxing in places, because for two of them I'd had to make the jump from animals to humans in my consideration of clinical trials. Also there are far more journals to wade through for publication planning, and when considering which audience to write for, than in the purely veterinary realm.

I didn't have any workshops booked on the Friday, but I'm very glad I decided to attend the abstract presentations. Some were serious, some less so, but all were informative and thought-provoking.

I didn't neglect the social side of the conference: I visited the Oceanarium, and ate out at two pre-booked dinners. The allocation of lime green lanyards to first-time attendees to distinguish them from the experienced EMWA conference-goers made starting conversations and asking for advice very easy, not that it was ever difficult to find someone to talk to or to sit with at meals. I managed to explore a little of Lisbon on Wednesday evening and Friday afternoon: EMWA conferences are always held in interesting places, and it is well worth finding the time to gain an impression of them.

I'm looking forward to completing my post-workshop assignments, and considering the ways I can practice what I've learned within my current role (the clinical trial I was involved in when choosing my workshops has been postponed until at least next year). The conference gave me a

good grounding too in which of the skills I use now can be transferred into other areas of 'real' medical writing.

In conclusion, the EMWA conference offers something for everyone involved in any job that involves medical writing or medical editing, or even for those of us who are just thinking of making that career jump.

**Gina M Dungworth**

[gina.dungworth@vetsturgeon.org](mailto:gina.dungworth@vetsturgeon.org)

## The Annual General Meeting (AGM)

The AGM was held on Wednesday, 12<sup>th</sup> May 2010. The Executive Committee (EC) were delighted that members came with many ideas and suggestions and as a result the discussions were lively and informative.

The following motions were successfully passed:

- Approval of the minutes from the 2009 AGM and President's report
- Approval of the Treasurer's report, 2009 budgets, re-forecast of the 2010 budget, proposed 2011 budget and the petition by the EC to forecast budgets in November of the previous year and to gain approval by the membership by electronic vote.
- Approval of the proposal to increase membership fees by €10 from January 2011.
- Approval of motion to allow EC to finalise the new Articles of Association on the provision that 'Poll votes' are defined in the Articles.

Helen Baldwin was released from the position of President. Helen was thanked for all her hard work over the last few years and presented with a bouquet of flowers. As per the Articles of Association, Laurence Auffret moved from the position of Vice-President to President.

Candidates for the position of Conference Director and Vice-President were asked to present a short piece to the AGM before stepping out of the meeting room while the members present voted. Both candidates were successful.

Executive Committee Members:

**Laurence Auffret**

**Rita Wellens**

Stephen de Looze

**Sunethra Wimalasundera**

Gillian Pritchard

Laura Hollyhead

Andrea Palluch

Shanida Nataraja

Elise Langdon-Neuner

**President**

**Vice-President**

Education Officer

**Conference Director**

Treasurer

Honorary Secretary

Public Relations Officer

Web Manager

Journal Editor

All members who attended the AGM were included in a prize draw. Samaila Jawaaid (a first time conference attendee) was the lucky winner of £90 of Amazon Vouchers.

Thank you to all those who contributed to such a successful meeting!

**Laura Hollyhead**

[Laura.Hollyhead@ppdi.com](mailto:Laura.Hollyhead@ppdi.com)

## What's news at EMWA

**Plenary and keynote lectures**

The three plenary lectures and the keynote lecture were well received. Judith Grice has written an article covering the substance of her plenary which you can read on page 101 and Iain Hrynaskiewicz is writing an article based on his Keynote lecture 'Biomedical Publishing in the Internet Age' for the September issue of *TWS*.

**Web 2.0 and Medical Education**

**Anne Cunningham**, Principal Lecturer, Faculty of Applied Sciences, City Campus, Sunderland, UK:  
*anne.cunningham@sunderland.ac.uk*

It was a great privilege to be invited to Lisbon to speak about my hobby (Web2.0) and day job (medical education) and to meet the medical writing fraternity from Europe and beyond. I set the presentation in the context of my experiences, which include running a Biomedical Sciences Programme that prepares students for registration with the Health Professions Council (HPC) but also on my involvement with CETL4HealthNE. Highlights from this large consortium include the increase in interprofessional education (including practice based simulations), the use of service users (e.g. 'audio' stories in a narrative archive which can be used in teaching sessions) and technological advances including the use of RECAP, a lecture capture service, 'Dr Companion' mobile devices and other electronic simulation devices (e.g. Sim man). I then tried to define Web2.0 as an idea and not a 'thing' which you buy off the shelf, but also to illustrate how useful I, and others, find it in an educational context. I aimed to deliver my presentation in a participative Web2.0 style, and used a text wall to elicit contributions which included:

- Great lecture. Please could you send a copy of the slides to ....Thanks
- h'way the lads
- great lecture
- very interesting
- what about LinkedIn? So far it hasn't lived up to my expectations
- Please give examples of how to use twitter professionally.
- which is the best tool that you use?
- How best can we use web 2.0 tools and services in our existing face to face EPDP Programme?

Luckily it worked and raised some of the issues of user generated content. Not all of it was useful, the feedback was useful and the questions are interesting. So, to answer some of them—there are many uses of web2.0 for PDP, and Universities are increasingly using a social networking platform called Mahara for this purpose. It makes building and sharing 'artefacts' relatively easy, and includes sections on goals, skills and building a resume. I have found twitter very useful to communicate with my students and elicit rapid feedback. It is useful to share /

find good resources—there are some prolific 'sharers' out there, you just need to find those who are posting information relevant to you. I followed a conference (in Glasgow), and participated in the discussion with delegates, and other twitter users (on the South coast) even though I was actually ill in bed at the time (in Newcastle!). In terms of social networking, our interactions on the web are no different from real life. So, if you go to a party but stand in a corner and don't talk to anyone, then it is difficult to get much out of it. I picked up a great list (from twitter) on what your grandmother can teach you about social media (see below, I retweeted, of course!).

The web also offers interesting possibilities to simulate things that are difficult to do in real life. There are many health applications in second life (the most commonly used online 'multiverse') which create authentic, content rich simulations for healthcare students to practice decision making skills. It is easy to get carried away with the exciting possibilities for participative, content rich learning spaces—our students are the 'net generation', already comfortable with social networking. However there are also challenges for educators, and issues relating to the digital divide and information literacy are important as are advising students on how best to manage their online identity, particularly given the current emphasis on fitness for practice. Self-published material can be of variable quality, and issues around ownership, hosting and archiving need to be considered. Finally I encourage you to 'play', but be clear what you want to achieve, and if you are using this media professionally, then keep it relevant and interesting (and not what you ate for breakfast!).

**Further reading**

Anderson P (2007) What is Web 2.0? Ideas, technologies and implications for education. JISC Technology & Standards Watch. <http://www.jisc.ac.uk/media/documents/techwatch/tsw0701b.pdf>

CETL4HealthNE home page <http://www.cetl4healthne.ac.uk>

Conference proceedings: ePortfolios, identity and personalised learning in healthcare education (2008) [http://www.medev.ac.uk/workshop\\_resources/105/105\\_ePortfolios\\_L.R.pdf](http://www.medev.ac.uk/workshop_resources/105/105_ePortfolios_L.R.pdf)

Fulwiler E. 10 things your grandmother can teach you about social media <http://www.socialmediatoday.com/SMC/191214>

Kerrimuir J Virtual world activity in UK universities and colleges. An academic year of expectation? Snapshot #7: Winter 2009 <http://virtualworldwatch.net/2009/12/12/activity-snapshot-7-winter-2009/>

**Further watching**

... In Plain English Series (Common Craft). This example is 'Social Networking in plain English' [http://www.youtube.com/watch?v=6a\\_KF7TYKVc](http://www.youtube.com/watch?v=6a_KF7TYKVc)

An overview of Mahara by Solent University <http://www.youtube.com/watch?v=KOFsrV3QOWM>

The Faculty of Medicine at Imperial College London has developed a region in Second Life that aims to design game-based learning activities for delivery of virtual patients. <http://secondhealth.wordpress.com/movies/>

St Georges—paramedic scenarios / Coventry University—health & social care scenarios [http://www.elu.sgu.ac.uk/preview/blog/?page\\_id=2](http://www.elu.sgu.ac.uk/preview/blog/?page_id=2)

## What's news at EMWA

**Managing Knowledge and Information in Medical Writing**

**Oliver Renn**, Director, Scientific Information Center, Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach, Germany

*oliver.renn@boehringer-ingelheim.com*

Today, there is definitely a need for managing knowledge and information—not only for medical writers but for all knowledge workers—as, at least in Oliver Renn's opinion, information overload and information burnout can prevent us from being innovative and creative. He gave short definitions of the terms Information Management (IM), Personal Information Management (PIM), Knowledge Management (KM) and Personal Knowledge Management (PKM) as well as Web 1.0 to 4.0 and Enterprise 2. but focused on practical examples.

With regard to IM and PIM, several examples of tools that allow better sharing of information were given. Renn demonstrated how easy it is to set up a blog or wiki, or use information sharing tools like Citeulike or gimmicks such as twitterwallr. Yammer was presented as an example of a tool useful for corporations. Other examples focused on how to organise information better, how to let only the 'right' information come to your desktop and how to mine information. Especially in the biomedical field, there are many more (free) search tools than simply Google, quite apart from commercial text analytics tools that were also shown.

Examples of KM and PKM were given: Wikis and blogs can also be used for knowledge sharing, as well as social communities that can also easily be built on free tools. Renn briefly explained the knowledge organisation concept of the Semantic Desktop. Another example showed how easy it is to generate new knowledge nowadays—even reasonable looking but faked papers on medical

writing can be created in a few seconds. The lecture finished with 'Useful tips and Tricks you Might not Know', e.g. leveraging the full power of Google (tools), tips basically aimed at saving time and thus overcoming the growing problem of information generation by copy-paste approaches, which generate information that may be read but most likely not understood.

**Writing Within the Online Marketing Environment**

**Mark Millar**, PraeMedica Limited, Saintfield, Northern Ireland, UK

*mark@praemedica.com*

Significant changes are being witnessed in communications to patients and health care professionals (HCPs).

New media channels and technology innovations have introduced an unprecedented choice for how they can find, assimilate and share information.

Educational sites such as Univadis in the UK provide hundreds of peer-reviewed CME courses to many thousands of HCPs around the world. Social media sites such as Sermo in the US provide for instant peer-peer discussions on all types of clinical issues. Pharmaceutical companies and medical societies are using Facebook and YouTube to reach patients and professionals in their channel of choice. Most journals are making efforts to keep up, with the *New England Journal of Medicine (NEJM)* and *The Lancet* both using blogs, podcasts and their own Facebook pages.

Studies have shown that HCPs spend considerable time online, at all times of the day, and that they consider the Internet essential to their clinical practice.

Communicating through digital channels, however, requires a different approach than print at all levels including medical writing.

Most people do not enter a web site on the Home page and can follow any number of paths through it.

Usability studies have shown that people often scan and snack on chunks of information online. Reading is more cumbersome and people are less tolerant of poor design and writing—an alternative is only a click away. Even search engine ranking is affected by the text on a page.

Writing and formatting therefore should not be copied from hardcopy but considered specifically for online.

Despite all these changes, there is still much to be positive about. Through these channels we have the opportunity to create rich, engaging user experiences. The writer may be involved in scripts for webcasts or briefs for video interviews, storyboarding for interactive case studies or podcast summaries.

So great change can result in opportunity as much as threat.

For a free copy of this presentation visit [www.praemedica.com](http://www.praemedica.com).



photo: Laura Hollyhead

## What's news at EMWA

**Brief oral abstract presentation session and posters**

For the first time at an EMWA conference, the Lisbon programme included a brief oral abstract presentation session and a poster session. EMWA sent out a call for abstracts and posters last year inviting members to contribute something on their work or any other topic of interest to medical writers. Several excellent contributions were received on a wide range of subjects. Abstracts were presented in a half-day session in Lisbon.

This event was a great success with much lively and constructive discussion between the presenters and members of the audience. Below we have included the abstract for each presentation and a summary of the main discussion points. It was great to have an opportunity to share points of view on such a varied range of topics. Several participants said afterwards how much they had enjoyed this session and that we should continue with the idea and perhaps even expand this event for future conferences.

**Why Sensible People Write Daft Things**

**Alistair Reeves** (Ascribe Medical Writing and Translation)

*Editors in our field often find that the sensible, rational scientists they work for write the craziest things in English or observe conventions that have no logical basis—not with regard to content, but the way they present their research with the written word. Some of these things are trivial, but many show evidence of insecurity—the authors are often thrown to the lions with little instruction. With a few examples of such inexplicable formulations and conventions, I aim to stimulate some lively discussion on why people do this and explore whether there is anything we can do about it.*

Alistair's hilarious account of the very real afflictions suffered by *some* medical writers (surely not us, we hoped, as we mentally trawled through recent work) was certainly a hard act to follow. The diagnoses began with Andorra Syndrome, the incessant use of 'and/or' in text, to be cured only by a prolonged period of cold turkey. Drivel's disease, otherwise known as *Morbus nonsensicus* was to follow, identified by the pages of utter drivel churned out by those afflicted. Perhaps my favourite was *Opticomaximistis*, in which the writer blinds the reader with data in the hope that no-one will notice that you don't actually have a clue what to do with it all. Alastair's prescription was a strict instruction to write it out by hand 30 times before breakfast every morning for a month. The brighter among us would create a table on Day 1 and be done with it; perhaps the rest would simply develop chronic wrist pain and quietly take early retirement...

I'm not going to spill all the beans to those of you who unfortunately missed this presentation because Alastair has gamely agreed to reprise the presentation for a future event. Suffice to say that I implore you not to be so negligent as to miss your second chance to attend what should surely be a compulsory part of every medical writer's training.

**How Can We Help Potential Medical Writers Gain Medical Writing Experience?**

**Alison McIntosh** (AAG Medical Writing)

*I receive numerous enquiries from people hoping to start out in medical writing and asking for advice. They find themselves in a 'Catch 22' situation because more and more advertised positions are asking for candidates with medical writing and/or pharmaceutical industry experience. The age-old conundrum is how to deal with this prerequisite when you cannot access a relevant job.*

*I would like to explore ways that EMWA members might help people to gain valuable work experience. This could be through short-term voluntary placements, or internships.*

*Could we perhaps set up a list of companies who run such schemes or are willing to accept applications from people hoping to gain work experience? Could we allow or encourage potential employers to advertise on the EMWA website when they have such an opportunity available?*

*Do employers recognise the value of credits gained within the EPDP when the person is not already working as a medical writer? Is the EPDP recognised as a way of gaining relevant experience whilst trying to obtain a medical writing position? Do enough employers accept people without experience and train them accordingly?*

Alison started what was to become a lively discussion by describing her experience of being asked for advice as to the best way to break into the medical writing industry. New writers can gain experience through the EMWA professional development programme (EPDP), through short-term work experience placements or through on-the-job training, but Alison identified a relative lack of experience as a major stumbling block to aspiring medical writers as they try to get their first jobs. She asked the audience to consider whether internships would be worthwhile for writer and employer. Internships are often arranged via word of mouth or through LinkedIn and one audience member offered experience that showed they can result in a job offer being made, but other contributors advised that, from the employer perspective, it was a time-consuming and cost-inefficient process that often resulted in limited training for the intern, and disappointment for the company as the intern often left at the end of the placement, taking their newly gained experience elsewhere. Several contributors suggested that the agencies for which they work would prefer to offer permanent jobs to promising but inexperienced writers and give them on-the-job training, increasing the likelihood of loyalty to the company.

Alison asked whether a bursary scheme co-ordinated by EMWA, with support from writing agencies, facilitating attendance at EMWA conferences and participation in a



## What's news at EMWA

collection of core workshops as a 'starter' qualification was a viable alternative to university-led courses which may encourage individuals to sign up for (paid-for) courses which actually have little practical relevance to the work of a medical writer and may still churn out writers with little aptitude for the job. This has not been feasible until now but could certainly be worth further exploration. There are a number of ways EMWA can act as a link between writers and potential employers and discussions around this are sure to continue beyond the Lisbon conference.

### Who is Reading your E-mail? A Risk Inventory of E-mail Management

**Ingrid Edsman** (Edsman Medical Writing)

*Document exchange is an integral part of medical writing and many of the documents contain confidential information. Nowadays most documents are sent by e-mail, and this calls for increased awareness of the risks involved in e-mail management. Sending an e-mail is the start of a distribution chain that poses hazards of different kinds to you as a supplier and also to your client. These risks may be technical or human. By identifying, defining and organising the risks, you will be able to make an inventory, which is the basis for an overall risk analysis. This presentation provides a brief risk inventory of e-mail management with the aim of giving food for thought on how to handle e-mail security.*

Ingrid gamely followed Alistair to the podium with a salutary reminder that we should all consider another matter that could seriously impact our livelihood. In a discussion of the risks we face every time we send an e-mail, Ingrid highlighted the many ways in which sensitive data can pass into the wrong hands. By doing a risk inventory, then evaluating the risks and deciding on countermeasures, we can prevent unauthorised e-mail access. Ingrid's suggestion was to encrypt sensitive e-mails prior to sending—this method does incur a cost, but this may be justified on a risk-benefit analysis. In discussion, the need to distribute decryption keys was identified as a significant barrier to the feasibility of this process, though, and password protection was suggested as an easier alternative; although less secure, it is better than no protection at all and may be easier for recipients to deal with. Another option suggested was to use a secure file transfer (STF) server to transfer files from one user to another, which may be used by larger clients. Different clients will have different needs and different systems in place and Ingrid pointed out that when we are working with several different clients we may have several different protocols to follow. The key issue for medical writers is to be aware of the potential for sensitive information to fall into the wrong hands and to discuss with our clients their protocols and procedures to ensure that we are playing our part in keeping data secure.

### Setting up a Medical Writing Unit in India—A Novel Co-Sourcing Business Model

**Roopa Basrur** (Wyeth Pharmaceuticals—now a part of Pfizer)

*Medical writing is a function that can be, and is, outsourced in this electronic era. As a sponsor, we entered into a unique partnership, where we provided functional expertise, while the service provider gave us operational support. Our goal was to rapidly increase writing resources, which proved difficult to recruit on-shore. In a country where regulatory medical writing experience was rare, a higher level of involvement of the sponsor was necessary for our purpose.*

*This was achieved by placement of our management personnel onsite, at our service provider's facility. Regular sponsor presence and support ensures increased commitment and is critical in efficiently managing issues requiring immediate decisions. This resulted in faster growth and better integration of the outsourced group.*

*Finding talent with the right background and skills is a challenge, though changing, with recent growth of the profession in India. Training is not just a matter of providing templates, standard operating procedures and timelines. Great effort has been spent on metrics and improving quality, project management, independence, and communication. The outcome is a stable, developing unit that takes ownership, is quality focused and a reliable resource for a growing portfolio of documents. Challenges and lessons learnt will be discussed.*

The audience were very interested in this novel 'co-sourcing' model and there was a lively discussion following Roopa's presentation. When asked what she would do differently if she was to go through this process again, Roopa said that she would better define the medical writer recruitment criteria and make more efforts to improve the acceptance of the Indian writers within the US and EU sponsor teams, especially in the start-up phase. Staff training and motivation were key aspects in the success of the project. One approach taken was to send the Indian writers to the US office for a 2-month period to work on a particular project. This allowed the US team to get to know the writer better as well as being very motivating for the writer. However, writers needed to have proved themselves for a certain time-period before having the opportunity to work in the US office. The audience asked several questions about attrition and Roopa admitted that while it had been challenging to keep staff, retention had been acceptable. A few writers had moved on to jobs with better salaries or different writing roles, after getting the initial training in the unit. When asked about external training opportunities, Roopa said that the All India Medical Writers Association (AIMWA) had very few workshops to date and had not yet started to run conferences. The possibility of collaborating with EMWA was discussed briefly and would certainly be worth looking into further. In conclusion, Roopa said that the process of co-sourcing had been a success, but definitely required "persistence, patience and perseverance".

## What's news at EMWA

**10 years of Orphan Drug Applications in the EU**

Christiane Breithaupt (Premier Research)

*The EU regulation 141/2000 has been in place for almost 10 years now. The number of orphan drug applications has been continuously increasing. A common application form for parallel submission in the US has been developed and a number of guidelines on the format and content of orphan drug applications have been published by the EMA. Nearly all communication with the EMA in this field can be accomplished electronically via e-mail, and pre-submission meetings can be held as telephone conferences. A short overview over the procedure and the developments in this area are given.*

Orphan drugs are products intended to treat diseases so rare that sponsors are reluctant to develop them under usual marketing conditions. Christiane gave an interesting and informative presentation on the regulations and procedures for orphan drug applications. She mentioned that, in the US, the general public became aware of orphan diseases following a special episode of Quincy (an American 'whodunit' television series about a pathologist). This

television programme kick-started awareness in the US and finally led to the Orphan Drugs Act. Christiane described the EU orphan drug regulatory procedures and mentioned that there is a guideline on calculation of the prevalence of these very rare diseases. There was a discussion about the difficulties of calculating very low prevalence rates, particularly when only EU data are admissible. It was agreed that in some cases a statement from an EU expert may be valuable when very few published data are available. Following a question from the audience Christiane mentioned that medical writing for orphan drugs was very similar to that for other products. For example, the clinical study report requirements are not different for orphan drugs.

**Poster session**

Three stimulating posters were presented: 'Communicating the Value of a Drug: Developing a Global Value Dossier' by Catherine Rycroft, 'Witnessing the Revolution in Scientific Writing over the Last Decade' by Jai Tilik- Jain and 'Point-contact review—making sense out of chaos' by Andrew Walker.

**Helen Baldwin**

helen.baldwin@scinopsis.com

**Jenny Fanstone**

Jenny.Fanstone@caudex.com

**EMWA Conference in Lisbon***Dirk Fall has the inside scoop...*

I was very happy to arrive in Lisbon for the 30<sup>th</sup> EMWA conference. Within my first few hours I noticed that Lisbon was often wrongly spelled with an 'a' in place of the 'n' for some bizarre reason. As a top medical writer I always carry a large red correcting pen with me so I was able to amend a lot of signs during my five-day sojourn there. However, instead of thanks I was subjected to abuse by a lot of the locals. Some people just can't stand to be corrected you know.

The journey to my hotel was interrupted by the streets being blocked off for the arrival of the Pope. "That's exciting," I thought, "I didn't know he was in EMWA." I kept an eye out for him over the next few days but I guess he was enrolled on advanced workshops because our paths did not cross again.

At the wine reception to open the conference I decided to engage in a bout of navel-gazing... other people's navels because that was where their name badge generally was. I noticed that a minority of people had blank badges. I decided to sidle up to one or two of these anonymous ladies and engage them in conversation.

"So, I see you are hiding your name. Is it because you don't want your husband to find out that you're here?"

Each of these nameless women looked at me strangely and left. I always thought that you needed a certain level of English to be in EMWA but based on my odd experiences obviously not! I hope they got on ok at the lectures.

Speaking of frosty receptions, EMWA decided to hold most of the workshops in the hotel's cold storage facility.

It meant we could enjoy chilled drinks while learning about publication strategy, but one negative aspect was that we lost a few participants to frostbite. I found a toe in one of the rooms by the way so please get in touch with me through this journal if you want it back.

I was disappointed with some of the workshops I attended and am thinking of suing EMWA for false advertising. "Abstract Presentations"—instead of being the free-flowing, mind-bending, avant-garde happening you would expect—was in fact a pretty normal presentation on writing. "Drug Safety for Medical Writers" gave me absolutely NO information on the amount and type of beta-blockers etc. I should be taking.

That said, I really liked some of EMWA's ideas to make the conference more enjoyable. I particularly enjoyed the message board. I left notes like "F-sharp, B-flat" and "Desperate Medical Writer Seeks Female Medical Writer for Proofreading, Discussions about Adverbs and Walks in the Park," before being asked to stop doing so by EMWA's spoilsport Head Office Team. "I pay your wages you know," I screamed as security carted me off and deposited me outside. After a minute or two in the glorious sunshine I noticed that I was thawing out so it was a case of all's well that ends well.

Banned from the hotel bar I had to find some other watering hole. Thankfully Lisbon has a million restaurants and bars to choose from. I can attribute my walking home unsteadily each night to the city's uneven pavements and not the amount of lovely Portuguese wine I consumed.

People kept telling me that the autumn conference will be Nice so I'm looking forward to that one already. If they let me back that is!

## Social programme

### Conference banquet: The night of a thousand courses.....

OK, so maybe 'a thousand courses' is a bit of an exaggeration, but it's not too wide of the mark. You would imagine that the venue for EMWA's 30<sup>th</sup> conference banquet should be something a little bit special, and it was. We were promised that Adego do Kais would be 'glamorous', but this converted 19<sup>th</sup> century warehouse combined the super-trendy 'shabby chic' with old school allure.

We were led over the polished cobblestones to the lower ground restaurant, which was brimming with over sized wooden tables and benches, topped with gigantic candlesticks throwing a dappled yellow glow onto the wooden barrels lining the walls. Now, I'm only 5 foot 5 (and a bit), so I'm used to feeling small, but even I felt Lilliputian compared with these monsters.

Having acclimatised, the food, wine, and sangria started to flow. Beaming waiters carrying enormous platters wound their way through the tables to deposit tapas-sized portions of the most delicious Portuguese dishes onto our plates. I would love to be able to tell you what we had, but my memory started to fade a little after course number nine. However, our incoming President came to the rescue and diverted us from the flow of food with her welcome speech, followed by John Carpenter who both regaled and terrified us with tales from the world of conference and meeting organisation.

Those of us still able to walk (perhaps waddle is a more accurate description) made it upstairs to the famous 'Kais bar' on the first floor with its stunning melted wax centre-pieces. The room was simply breathtaking, and certainly deserved its reputation. Adego do Kais should be on everyone's 'to do' list when they visit Lisbon.....although next time I think I will fast for a week beforehand!

**Lisa Chamberlain James**

*[lisa@claritymed.co.uk](mailto:lisa@claritymed.co.uk)*



photo: Lisa Chamberlain James



photo: Andrea Rossi

### Tram experience

The central district of Lisbon, the Baixa, slopes gently down from the Parque Eduardo VII to the Praça de Comércio on the waterfront with its statue of King José I. This central strip is flanked by elevated districts—the Bairro Alta and Estrela on the west and the Alfama topped by the Castelo de São Jorge to the east. We joined our tram in the Estrela district, near the Basilica de Estrela, and set off past the Palácio São Bento. As we rattled along, a guide in national costume plied us with port (was it my imagination or did she struggle to keep up with demand?) Our route then climbed steeply up towards Castelo de São Jorge, through narrow streets, with fantastic little glimpses down even narrower, steeper streets, up and up, past the Romanesque cathedral (the Sé), until we stopped at a little square overlooking the oldest, originally Moorish, part of the city. A further short climb on foot through more narrow, cobbled streets brought us, panting, to the castle itself, with further fantastic views over the whole city, the river and the wide estuary of the river Tagus with its famous suspension bridge.

### Anoraks' Corner

The first trams (horse-drawn) appeared in Lisbon in 1873 and were replaced by electric trams in 1901—some of these were still in operation in the 1990s. The current fleet consist of modern-looking trams (multi-car) and old-style trams—either heavily refurbished machines from the 1930s or recently built copies. Some of the slopes in Lisbon are extremely steep—among the steepest tramways in the world without cog-wheels—and some of the corners so tight that the tracks cross over to allow trams on the inside to swing out to make the turns. The trams used on these very routes with steep gradients and tight turns have only 4 wheels and a very short wheelbase.

*Note—if you visit Lisbon, take tram number 28 from the Praça de Comércio up to its terminus in the Alfama, just below the castle. This is much cheaper than the special tourist tram, but takes almost exactly the same route up to the castle.*

**John Carpenter**

*[john.carpenter.medcom@btinternet.com](mailto:john.carpenter.medcom@btinternet.com)*

## What's news at EMWA



photo: Julia Foganic Klapproth

**Porto wine tasting**

For wine lovers, no trip to Portugal would be complete without a tasting of Porto wine. José Carneiro Pinto, one of the proprietors of Wine O'clock and our guide, started our evening off by explaining that Porto wine is produced exclusively in the Douro valley in northern Portugal. Porto wine is named after the city of Porto, where it has been brought to market since the 17<sup>th</sup> century. It is made by the addition of *aguardente*, a type of distilled alcohol, to fermenting wine, which increases the alcohol level to around 20% and stops the fermentation so that residual sugar remains.

We were introduced to four types of Porto during the tasting:

- **White Porto.** Made from white grapes and, although not actually dry, is less sweet than other types of Porto. Best served cold as an aperitif.
- **Tawny Porto.** Made from red grapes and aged in oak barrels, causing it to become progressively browner, less intense in colour, and mellower in taste due to oxidation. Best served slightly cooled and along with a dessert.
- **Ruby Porto.** Red wines that retain their fruit aromas because they are aged in stainless steel. Considered dessert wines.
- **'Late bottled vintage' Porto.** Wines originally destined for bottling as a vintage Porto but not granted that status. Deep red in colour with complex flavours and aromas because they are aged and are unfiltered. Pleasant as aperitifs, these wines benefit from being allowed to 'breathe' before serving.

We definitely appreciated Mr. Carneiro Pinto's knowledge and friendliness, and what a wonderful way for us all to end a long day of medical writing workshops. I think all of us who attended this event look forward to more wine tastings at future EMWA conferences.

**Phil Leventhal**

[pleventhal@4clinics.com](mailto:pleventhal@4clinics.com)

For more information: Wine o'Clock Matosinhos, <http://www.wineoclock.com.pt/>

**Walking tour of Lisbon**

The city walking tour is a popular fixture at EMWA spring conferences, and the tradition carried on in Lisbon this year. Around 40 delegates took part, split into two groups led by local guides. Walking tours are a great chance to stop and look at things in a city you'd normally either miss or fail to appreciate through lack of information. It's an easy way to absorb some history and some local colour, without needing to bury your nose in a guidebook. It's also great for getting talking with fellow EMWA members, whether old friends or people you've never met before.

I cannot pretend to be an expert on Lisbon after taking part, and I fear I would fail any post-tour exam dismally. But plenty of impressions remain. Our attention was drawn to the city's wonderful pavements. These are made of endless small blocks of white stone, about 5 cm square, each individually cut and laid down. Black blocks are inlaid at intervals to form patterns or motifs, culminating in beautiful wave forms which fill one of the wide central squares in recognition of the city's maritime heritage. We also learned that Lisbon's trams were brought from California. Some are over 100 years old and still used as public transport.

No EMWA walking tour would be complete without the social afterwards. Our guides left us in a 'happening' area of Lisbon where our fine conference organisers, MCI, had booked a group dinner. Others of us did our own thing and ended up squeezing into a small restaurant in the narrow backstreets nearby, where later in the evening the restaurant owners sang *Fado*, which Wikipedia defines as 'a form of music characterized by mournful tunes and lyrics, often about the sea or the life of the poor'. The words were a mystery, but the effect was beautiful.

**Jo Whelan**

[whelan.jo@gmail.com](mailto:whelan.jo@gmail.com)



photo: John Carpenter





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**STRICTLY NO AGENCIES.**



## The business case for peer-reviewed publications

by Serina Stretton, Rachel Cameron and Karen Woolley



### Introduction

Doctors want it.  
Payers want it.  
Regulators want it.  
Life sciences companies desperately need it.  
And professional medical writers can deliver it.

‘It’ is evidence and ‘it’ comes in the form of peer-reviewed publications.

In this era of evidence-based medicine, it is not surprising that there is a demand for evidence-based marketing. However, considering the importance of peer-reviewed publications in evidence-based medicine and marketing, it is surprising that so few life sciences companies give peer-reviewed publications the priority or the budget they deserve. In this brief article, we will provide an overview of the business case for peer-reviewed publications. We recognise that it would be commercially naïve to think companies would prioritise or fund peer-reviewed publications without a favourable return on investment. Therefore, we will also present evidence to show how peer-reviewed publications can help life sciences companies meet their commercial, as well as their ethical and scientific, objectives. Indeed, peer-reviewed publications, and the professional medical writers who make them happen, can allow companies to achieve each of these objectives in a complementary manner.

### Peer-reviewed publications—More important to sales and marketing than sales representatives?

Peer-reviewed publications are the foundation of medical knowledge; they disseminate advances in medicine, contribute to the development of evidence-based clinical practice guidelines, and influence clinicians’ prescribing habits [1]. Not only that, peer-reviewed publications are needed so that investigators and sponsors can fulfil their contracts with trial participants, government agencies, and ethics boards. Given the commercial challenges facing life sciences companies, a strong focus on peer-reviewed publications could provide companies with a powerful way to re-invigorate sales and to do so in a way that enhances corporate reputations and relationships with doctors, payers, and regulators. Life sciences companies have started to

realise that saturating the market with sales representatives (i.e., the ‘more feet on street’ sales model) is no longer providing a favourable return on investment [2]. As one executive stated bluntly: “The days when armies of sales reps in the field drove revenues are over” [2]. This sentiment was reinforced in a survey of life sciences company executives from Europe, North America, and the Asia-Pacific region [3]. These executives identified the sales and marketing function as the area of their business that required the biggest improvement in performance if companies were to be successful in 2015.

We urge leaders within life sciences companies to shift money from the increasingly ineffective ‘more feet on street’ budget to the increasingly important ‘peer-reviewed publications’ budget. We are not advocating that sales and marketing drive publications; indeed, as suggested in a recent survey of 25 US-based pharmaceutical companies, authors, not marketing, drive publication content [4]. Rather, we are advocating that publication budgets need to reflect the importance of peer-reviewed publications. Numerous surveys conducted in Europe, North America, and the Asia-Pacific region have shown that, quite appropriately, peer-reviewed publications are important to, and have a greater influence on, prescribers than many of the other initiatives prioritised and funded by life sciences companies, particularly sales representatives (Figure 1; [1, 5-9]).

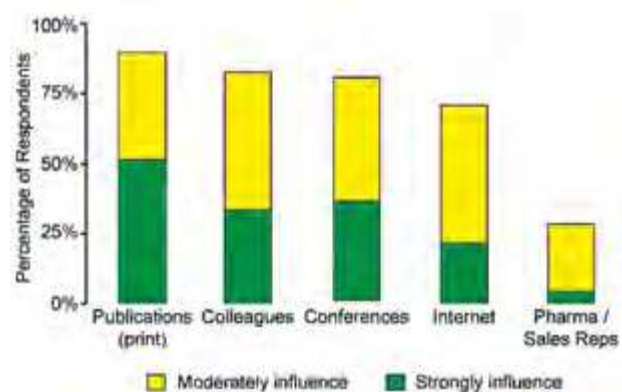
### Shift money from the increasingly ineffective ‘more feet on street’ budget to the increasingly important ‘peer-reviewed publications’ budget

With the predicted increase in the importance of specialist-driven markets [10], the need for robust peer-review publications is likely to intensify. Further, in contrast to sales representatives, peer-reviewed publications can have immediate geographic reach and can provide cost-effective and credible support to the product or device throughout its lifecycle. Perhaps most tellingly, whilst prescribers around the world are being actively discouraged from seeing sales representatives, they are certainly being encouraged to access peer-reviewed publications. Leaders in life sciences companies need to ask whether their budget for publications exceeds their budget for sales representatives—if it doesn’t, surely they should ask themselves: ‘Why are we paying more for a less influential resource?’



## The business case for peer-reviewed publications

Figure 1. Relative influence of different communication strategies on European Union-based physicians (N = 390). Sales representatives were deemed the least influential. Adapted figure reproduced with permission [9].



Importantly, given the rapidly increasing and influential role that payers are having on commercial outcomes [10], life sciences companies should also realise that peer-reviewed publications are the first choice of information for payers who make access, coverage, and reimbursement decisions [4]. In addition, in a climate where safety and transparency concerns are paramount, investing in the ethical preparation of peer-reviewed publications is likely to be well received by risk-averse regulators. Industry analysts have stressed that "...cultivating better relationships with regulators and reimbursement authorities is paramount" if the life sciences industry is going to transform itself [3].

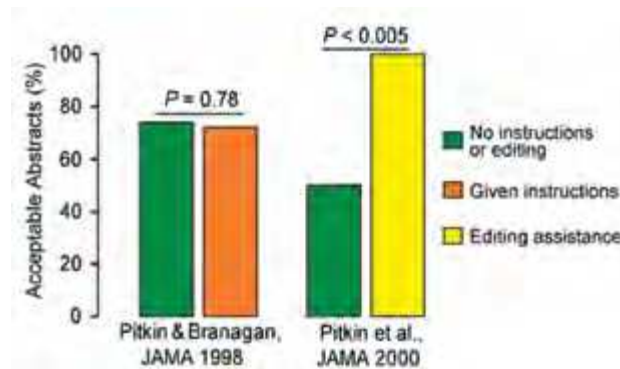
We propose that if life sciences companies truly want to enhance their reputations and relationships with doctors, payers, and regulators, they should seriously consider a strategic and financial shift toward peer-reviewed publications. As sales and marketing budgets account for more than 30% of the revenue of life sciences companies [2], shifting just part of this budget to a peer-reviewed publications budget is an affordable and pragmatic step that should yield highly favourable returns.

### Peer-reviewed publications—What is the value of having professional medical writers?

Despite the value of peer-reviewed publications to all stakeholders, we seem to be missing out on, and waiting a long time for, publication of clinical trial data. We know from the largest study on non-publication, that less than half of biomedical research results that are initially presented as abstracts ever appear as full peer-reviewed publications [11]. Not only that, we know from the same study, that there is quite a long lag between the presentation of results at a conference and a corresponding full-text publication; only 20% of conference abstract results appear as full-text publications within two years. Contrary to the assertions that unscrupulous commercial influences are responsible for preventing publications, numerous studies have shown that the primary reason for non-publication is because authors have limited time [12-14].

Professional medical writers have the project management and communication expertise to ensure that high quality manuscripts are prepared in a timely manner. A systematic review of 11 studies indicated that technical editing (which professional medical writers can do) can enhance the readability and quality of manuscripts, as well as the accuracy of references [15]. Moreover, two studies of manuscripts published in JAMA have shown that technical review and editing improves the quality of manuscript abstracts, whereas providing authors with instructions alone does not (Figure 2; [16, 17]). In addition, a survey of US-based authors indicated that the main reasons authors would use a medical writer are that the manuscript would be better written, of higher quality, and take less of the authors' time [18]. Our own research has shown that the involvement of professional medical writers in peer-reviewed publications was associated with a faster turnaround time from manuscript submission to acceptance [19]. From a sample of 1,000 original research articles published in high-ranking peer-reviewed journals, we found that in the subset of articles with industry funding (n = 102), the mean time to acceptance for publications with declared medical writing assistance was 83.6 days vs 132.2 days for articles without declared assistance (relative risk difference, 95% confidence interval = 0.63, 0.40-1.01;  $P = 0.053$ ).

Figure 2. Comparison of the effect of instructions to revise (N = 250) or technical editing assistance (N = 100) on the quality of abstracts published in a peer-reviewed journal.



Not only can professional medical writers help companies and authors in terms of manuscript quality and speed, we believe professional medical writers can help reduce the risks and costs of unethical publication practices. Unlike ghostwriters, professional medical writers are aware of, and abide by, ethical medical writing guidelines [20]. Given the cost of unethical publications practices to author and company reputations, it makes commercial sense to involve a professional medical writer in the manuscript preparation process. In the largest study conducted to date on publications retracted for misconduct, we showed that the involvement of professional medical writers was associated with an extremely low risk of manuscripts having to be retracted because of misconduct [21]. Professional medical writers are becoming acutely aware of the need

## The business case for peer-reviewed publications

➤ to distinguish themselves from ghostwriters [22, 23]. Life sciences companies should seek out professional medical writers who have clearly documented evidence of their adherence to international medical writing guidelines. In this regard, leaders in life sciences companies should also be aware of the results shared in the 'Scientific' writing issue of *The Write Stuff* last year, where Jacobs and Hamilton showed that the risk of unethical medical writing practices (i.e., ghostwriting) was highest for writers who were: unaware of medical writing guidelines; freelancers; writers who prepared more than 10 manuscripts per year; and writers who were mainly involved in the preparation of review articles [23]. Many journal editors now recognise the legitimate role that professional medical writers have in assisting authors to prepare peer-reviewed publications [22]. In the future, editors may also realise that professional medical writers can minimise the risk of unethical publication practices, particularly when assisting authors who are unaware of publication practice guidelines. We acknowledge that further evidence on the ethics and value of professional medical writers is needed. We applaud recent initiatives from medical writing associations (such as the American Medical Writers Association and ARCS Australia) to help fund such research.

**"...cultivating  
better relationships  
with regulators  
and reimbursement  
authorities is  
paramount"**

### Conclusion

We believe there is a strong business case for pursuing peer-reviewed publications. Providing doctors, payers, and regulators with credible and compelling publications not only allows life sciences companies to meet their ethical and scientific objectives, but will also help them achieve their commercial objectives. Nevertheless, we also believe that peer-reviewed publications need to be handled with care; they cannot be left to chance, to amateurs, to those with expertise, but no time or, worst of all, left to ghostwriters. Professional medical writers can help life sciences companies solve their publication challenges and can help to plan and deliver publications in an ethical and effective manner. With this in mind, leaders in life sciences companies should check whether their budget for peer-reviewed publications reflects the credible and commercially important influence that publications have...not doing so would be commercially naïve.

#### Serina Stretton

Senior Medical Writer  
ProScribe Medical Communications  
Sydney, NSW, Australia.

#### Karen Woolley

CEO, ProScribe Medical Communications  
A/Prof, University of Queensland,  
and University of the Sunshine Coast  
Noosaville, QLD, Australia  
kw@proscribe.com.au

#### Rachel Cameron

Client Relations Manager  
ProScribe Medical Communications  
Melbourne, VIC, Australia

### References:

1. Accenture. Physicians seek more detailed, comparative and customized information from pharmaceutical reps, Accenture Research Finds [News release]. July 16, 2003. Available from: [http://newsroom.accenture.com/article\\_display.cfm?article\\_id=4020](http://newsroom.accenture.com/article_display.cfm?article_id=4020). Accessed: March 21, 2010.
2. Danner S, Ruzicic A, Bucella A, Entraygues B. The European pharmaceutical industry: Delivering sales excellence in turbulent times [White paper]. Roland Berger Strategy Consultants; 2006. Available from: [www.rolandberger.com/expertise/publications/he\\_European\\_pharmaceutical\\_industry/2006-08-08-rb-sc-pub-The\\_European\\_pharmaceutical\\_industry.html](http://www.rolandberger.com/expertise/publications/he_European_pharmaceutical_industry/2006-08-08-rb-sc-pub-The_European_pharmaceutical_industry.html). Accessed: March 21, 2010.
3. Wyke A, Rhodes J, Go R. The future of the life sciences industries: Transformation amid rising risk [White paper]. Deloitte; 2009. Available from: [www.deloitte.com/view/en\\_GX/global/industries/life-sciences-health-care/6c3049642d4ff0210VgnVCM100000ba42f00aRCRD.htm](http://www.deloitte.com/view/en_GX/global/industries/life-sciences-health-care/6c3049642d4ff0210VgnVCM100000ba42f00aRCRD.htm). Accessed: 21 March 2010.
4. Suh C, Combates N, Matheis R, Ramchandani-Toddywala M, Frimpter J, Huang T, et al. Benchmarking medical publication policies, procedures, and practices across pharmaceutical companies. 5<sup>th</sup> Annual Meeting of International Society for Medical Publication Professionals; 2009 April 20-22; Pennsylvania, USA.
5. Research Australia. Portrait of a researcher: Research Australia's Health and Medical Researcher poll 2003. *Australasian Biotechnology*. 2004 March;14(1):22-3.
6. UK Hospital Readership Survey. 2005.
7. UK Hospital Readership Survey. 2007.
8. Research Australia. Portrait of a researcher: Research Australia's Health and Medical Researcher poll 2003. *Australasian Biotechnology*. 2004 March;14(1):22-23.
9. EPG Health Media. Source and influence of medical information from healthcare professionals. November 3, 2009. Available from: <http://epgonline.blogspot.com/search?updated-min=2009-01-01T00%3A00%3A00-08%3A00&updated-max=2010-01-01T00%3A00%3A00-08%3A00&max-results=7>. Accessed: March 21, 2010.
10. IMS forecasts global pharmaceutical market growth of 4 - 6% in 2010; Predicts 4 - 7% expansion through 2013 [Press release]. IMS; October 7, 2009. Available from: <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4d4f3db4b3d88f611019418c22a/vgnnextoid=500e8fabe424210VgnVCM100000ed152ca2RCRD&vgnextchannel=41a67900b55a5110VgnVCM10000071812ca2RCRD&vgnextfmt=default>. Accessed: March 21, 2010.
11. Scherer RW, Langenberg P, von Elm E. Full publication of results initially presented in abstracts. *Cochrane Database Syst Rev*. 2007(2):MR000005.
12. Camacho LH, Bacik J, Cheung A, Spriggs DR. Presentation and subsequent publication rates of phase I oncology clinical trials. *Cancer*. 2005 Oct 1;104(7):1497-1504.
13. Krzyzanowska MK, Pintilie M, Tannock IF. Factors associated with failure to publish large randomized trials presented at an oncology meeting. *JAMA*. 2003 Jul 23;290(4):495-501.
14. Sprague S, Bhandari M, Devereaux PJ, Swiontkowski MF, Tornetta P, 3rd, Cook DJ, et al. Barriers to full-text publication following presentation of abstracts at annual orthopaedic meetings. *J Bone Joint Surg Am*. 2003 Jan;85-A(1):158-163.
15. Wager E, Middleton P. Effects of technical editing in biomedical journals: a systematic review. *JAMA*. 2002 Jun 5;287(21):2821-2824.
16. Pitkin RM, Branagan MA. Can the accuracy of abstracts be improved by providing specific instructions? A randomized controlled trial. *JAMA*. 1998 Jul 15;280(3):267-269.
17. Pitkin RM, Branagan MA, Burmeister LF. Effectiveness of a journal intervention to improve abstract quality. *JAMA*. 2000 Jan 26;283(4):481.
18. Phillips S, Carey L, Biedermann G. Attitudes towards writing and writing assistance in peer-reviewed articles. *AMWA Journal*. 2001;16(3):10-16.
19. Woolley KL, Ely J, Woolley M, Lynch F, McDonald J, Findlay L, et al. Declaration of medical writing assistance in international, peer-reviewed publications and effect of pharmaceutical sponsorship. International Congress on Peer Review and Biomedical Publication; 2005 September 16-18; Chicago, Illinois, USA. Available from: [www.ama-assn.org/public/peer/abstracts.html#declaration](http://www.ama-assn.org/public/peer/abstracts.html#declaration).
20. Woolley KL. Goodbye Ghostwriters!: How to work ethically and efficiently with professional medical writers. *Chest*. 2006 Sep;130(3):921-923.
21. Woolley K, Woolley M, Lew R, Bramich N, Ely J, Stretton S, et al. Round up the usual suspects? Involvement of medical writers and the pharmaceutical industry in retracted publications. International Congress on Peer Review and Biomedical Publication; 2009 September 10-11; Vancouver, BC, Canada. Available from: [www.ama-assn.org/public/peer/abstracts\\_2009.html](http://www.ama-assn.org/public/peer/abstracts_2009.html).
22. Gotzsche PC, Kassirer JP, Woolley KL, Wager E, Jacobs A, Gertel A, et al. What should be done to tackle ghostwriting in the medical literature? *PLoS Med*. 2009 Feb 3;6(2):e23.
23. Jacobs A, Hamilton C. Decreased evidence of ghostwriting in a 2008 vs 2005 survey of medical writers. *The Write Stuff*. 2009;18(2):118-123.



## Medical writing: The added-value enigma

by Andrea Rossi and Giulia Calamai



The contribution of specialist medical writers to the production of clinical trial documentation is widely recognised as important, and as needed at several stages, for example, when designing a new protocol or disclosing the results of a trial to regulatory authorities or medical journals. Ad-hoc training in medical writing for researchers is also appreciated and considered really useful by attendees [1]. Medical writing activities are increasingly regarded as necessary and valuable, in particular for the disclosure of study results.

The concept of Return on Investment, the so-called ROI of a particular activity, is widely recognised and is calculated by dividing the company's net profit from a product or action by the total investment made by the company into the product or action, and then multiplying by 100 [2].

Using the ROI concept seems an obvious approach to assessing the added value given by the activities of medical writers, regardless of the cost. Thinking about the service they provide and the time and effort that they put into a piece, the cost of a writer should be considered money well spent [3,4].

The value of medical writing seems even more evident, when the costs of medical writing activities are compared with the total costs of clinical trials. Total expenditures forecast for medical writing activities are likely to be less than 1% of total costs of phase II or phase III trials and, in the case of phase I trials, may not even be included in the study budget plan [5]. This seems contradictory, considering the importance of medical writing activities: an outstanding study with excellent outcomes can be greatly underestimated by regulatory authorities or journal editors if it is not well presented, wasting all of the investment to save the relatively small costs of medical writing activities. Moreover, just as poor writing performance may lead to the rejection of a manuscript or a dossier, a poor concept, however well presented, will not necessarily be accepted. So, even if we do not want to consider the added value of medical writing, we must consider the potentially lost value if medical writing activity is not properly performed. This aspect leads us from ROI to Potentially Missed Value (PMV), which is even more difficult to estimate.

Drug development has become an even more complex and less productive process in recent years, and any contribution to the design and performance of research or the disclosure of research data on any pharmacological compound must be assessed. Furthermore, healthcare administrators

and company managers need to examine the costs of all services (including medical writing and editing) in order to assess their productivity and value for the company or institution. Some administrators believe that anything that is not measured cannot be managed [6]. If the added value of medical writing input cannot be measured, there is a serious risk that this figure becomes invisible to managers, which is a worrying scenario.

In the 1990s, Tom Lang measured the productivity of medical editing at the Cleveland Clinic [7] and determined the range of hours needed to edit different types of manuscripts [8]. He also recently emphasised the need to assess the productivity and the added value of professional medical writers' activities [6].

His records showed that the time effectively spent on medical editing was 2-3 'stopwatch hours' per day. ('Stopwatch hours' should not be confused with clock hours because they indicate only the time spent in 100% concentration on editing; they do not count time spent on phone calls, breaks, answering e-mail, hallway conversations, and other 'shadow functions' of office work.) This time varied greatly, depending on the number of projects managed each day [7]. This research also determined that even relatively well-written manuscripts needed considerable input from professional editors to bring them to Clinic standards. Furthermore, after the number of medical editors was increased, the number of manuscripts submitted for editing also increased, indicating that perhaps other authors at the Clinic were beginning to value editing more [7].

Productivity, as a measure of the quality and quantity of medical writers' activities, could be evaluated through several different instruments. Quantitative measures are relatively simple (e.g. total number of pages edited or written in one working day, number of slide sets created in one month, number of authors requesting support in one year), while quality is often difficult to measure. As Tom Lang indicates, medical writers are information workers, and information is extremely difficult to measure and value: how can 'clarity' or 'critical thinking' or 'problem solving' be measured [8]? Market research uses how much a customer is 'willing-to-pay' for a certain service, to try to understand its value. Several methods have been developed to measure consumer willingness to pay, including actual or potential, direct or indirect payment for certain goods. Answers to the questions 'How much are you potentially willing to pay for someone who edits 10 pages for you?' ➤

## Medical writing: The added-value enigma

- and then 'How much are you able to pay?' for the same activity may be very different: in the first case, the urgency or importance of the support requested doesn't matter, whereas in the second, budget limitations will strongly influence the concept of urgency and willingness to pay.

Productivity measurements assume that medical writing activity gives an added value in terms of cost reduction, time reduction, and quality improvement, but this is not so obvious for any manager in any circumstance, especially

in an even more resource-limited environment. For this reason, the estimation of ROI or PMV would be extremely useful for any manager who has to decide where limited resources are best invested for their company.

It should be a priority to try to agree on a common way to collect data on the quantity and quality of medical writer activities. However, any study should be scientifically well conducted, with a solid main objective, an adequate design and a sound approach to sampling. Data collection, management and analysis should be planned, as well as the disclosure of results. The process, in fact, needs to be changed. Before beginning the study, we need to discuss and decide also what is to be written and how the results are to be disclosed. This should be specified in the protocol. So a coordinating group should develop a study protocol to determine the value of different medical writing activities. The protocol should include the minimum number of writers to be enrolled and the type of tasks they should be involved in. Time frames, data to be collected, and instructions for data collection should be described and shared with the coordinating group. Data management and analysis should be partially specified in the protocol, according to study objectives, but possible unplanned further analyses, driven by the data collected and the results of the principal analyses, should also be considered. Moreover, even if the data are negative or different from those expected, they should be published. So a plan of the disclosure of the results should be considered in any case.

In conclusion, assessing the productivity of professional medical writers or editors, or indeed the added value or quality of their interventions, is not a simple task. In any study of these aspects, as in any other study, compromises and assumptions will have to be made on the basis of the main objective agreed. Tom Lang's article in the *AMWA Journal* outlines the potential value of performing such an evaluation, highlighting its professional and personal usefulness [8]. Such a study would be equally useful for European medical writers.

### Andrea Rossi and Giulia Calamai

*Medical Writers,  
Medical Department,  
Eli Lilly Italia S.p.A., Italy  
rossi\_andrea\_a@lilly.com*

#### References:

1. Bydder S. Packer D. Semmens J. The Value of a Scientific Writing Training Workshop for Radiologists and Radiation Oncologists. *Australas Radiol* 2006;50:29-32.
2. Bright hub. <http://www.brighthub.com/office/entrepreneurs/articles/49928.aspx>. Accessed 7 May 2010.
3. Article neighbour. <http://www.mdneighbor.com/>. Accessed 7 May 2010.
4. Article King. [www.articleking.com/writing-speaking/5](http://www.articleking.com/writing-speaking/5). Oficina Cubana de la Propiedad Industria.
5. [www.oepi.cu/doc/noticias/conferencias/03%20Total%20Cuba.pdf](http://www.oepi.cu/doc/noticias/conferencias/03%20Total%20Cuba.pdf)
6. Lang T. Just who are we and what are we doing, anyway? Needed research in medical writing. *AMWA Journal* 2009; 24: 106-12.
7. Lang T. A. Assessing the Productivity and Value of a Hospital-Based Editing Service. *AMWA Journal* 1997;12: 6-14.
8. Lang T.A. Physical and Processing Characteristics of Manuscripts Submitted for Substantive Editing. *CBE Views* 1996;19: 111-5.

## P.S.—A powerful marketing tool

A good tip from Victoria Giordano at EMWA Head Office is to use the P.S. of an email or letter as a marketing tool. According to an article by Ray Jutkins of the National Mail Order Association research has shown that 79% of people read a P.S. first. The article sets out the sort of things that can be in your P.S. as quoted below:

1. Remind your reader of a premium, a gift, a special 'something' they will get, earn, make, save—if they respond. Remind them of your 'goodies'! The extras you bring—you offer.
2. Emphasise your guarantee. A product or service guarantee in direct mail can play a critical role in reaching your objective. People get 'comfortable' with you when you talk guarantee. This can be particularly important when your audience is a marketplace that has not previously done business with you.
3. Talk about savings. Talk about money, and what can be earned, or saved. Talk profits. Talk bottom-line results. Talk measurability. Facts and figures get attention—use them in your P.S.
4. Repeat your key benefits. You may have a laundry list of product and service benefits ... yet you know the top of the list has 2 or 3 or maybe 4 real reasons why people do business with you. In your P.S. remind your readers of these key benefits.
5. Repeat your telephone and facsimile numbers. Remind people they can visit you at the office or a trade show stand—let your marketplace know you are available to do business. And want to do business with them.
7. Repeat the last call to action. Obviously, in direct mail you are asking your marketplace to do something. To take some action. To call this number, visit this place, sign-up for this conference—Do something! Repeat your call to action in the P.S.
8. Summarise your entire message in your P.S. A 2-page letter/email can be summarised in a single paragraph P.S.

Source: [http://www.nmoa.org/articles/dmnews/Postscripts407\\_RJ.htm](http://www.nmoa.org/articles/dmnews/Postscripts407_RJ.htm)



## Stand out from the crowd— by understanding European pharmaceutical industry codes and compliance

by Judith Grice

### Introduction

In these times of financial constraint, winning pitches for work from pharmaceutical companies is increasingly difficult and competition is often fierce. So ways to ‘add value’ and therefore make either yourself or your agency ‘stand out from the rest’ has become increasingly important.

The pharmaceutical industry is often in the global media spotlight and has, for several years, received heavy criticism from politicians and the lay and medical press for the way it commercialises [1-3] its products. Many pharmaceutical companies have realised that they must improve their public image and business reports such as the one from Price Waterhouse Coopers [4] have reinforced that this makes sound business sense. This has resulted in companies producing internal guidance on promotional activities, additional compliance officers being appointed, more internal audits and generally a tightening of the company procedures for the approval of promotion. This has then placed increasing pressure on those involved in the promotion of pharmaceuticals both in terms of sales and marketing departments and the medical and regulatory departments who have to approve promotional materials to ensure compliance. This in turn has cascaded to the ‘coal face’ workers the medical writers, who interpret the raw data into clinical papers, product monographs and many other medical-marketing materials.

Medical writers are experts in their field and well used to communicating complex medical technical data with clarity and precision. However technical writing proficiency alone is no longer enough. Communications must also be compliant with regulations and self-regulatory frameworks. For those working on a European or global project this is further complicated in that it can mean compliance with the plethora of laws and national self-regulatory codes of conduct that exist across Europe or even the world. Failure to understand the national differences may mean re-writing large sections of work, leading to increased costs either to the client or agency and often, more importantly, an extended production time.

This article can only skim the surface of these ‘compliance requirements’ but it is hoped that it will provide a basic understanding of compliance in written communications across Europe and how an awareness of the applicable codes can help you and your agency ‘stand out from the crowd’.

### How promotion of prescription medicines is controlled in Europe

The promotion of prescription medicines across Europe is regulated by the European directive 2001/83/EC as amended. This directive is implemented into national law in each of the European countries for example by The Medicines Act 1968 in the UK, the law on advertising in the field of healthcare in Germany and the French Public Health Code in France. Therefore, although the directive forms the basis of the law, differences may occur in the way it is interpreted and implemented nationally.

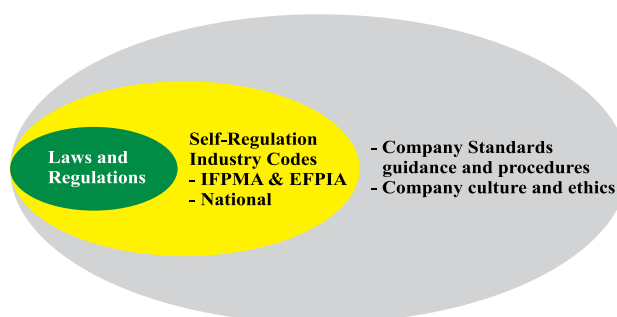


Figure1: The compliance framework

Additionally most countries in Europe have their own national industry association, for example the Association of British Pharmaceutical Industry (ABPI) in the UK, the Irish Pharmaceutical Healthcare Association (IPHA) in Ireland and Pharmig in Austria. These national associations are members of the European association, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and /or The International Federation of Pharmaceutical Industry and Associations (IFPMA). Both the IFPMA and EFPIA produce overarching codes of conduct which provide the minimum standards that must be implemented into the national codes of conduct at a national level by their members, so again variations may occur at a national level.

Individual pharmaceutical companies then adopt these standards into company standard operating procedures, policies and guidance producing a compliance framework for the ethical promotion of their products.

### Differences between the codes/ regulations across Europe

As previously mentioned because the legal and self-regulatory frameworks are the same across Europe, there are many similarities in the way that pharmaceuticals can be



## Stand out from the crowd...

- promoted in the individual countries of Europe; however, the interpretation and implementation at a national level also leads to many differences. There is also variation in the prominence of the self-regulatory code of practice mechanisms for dealing with complaints relative to regulatory authority actions and inter-company legal action. This can make life complex for those who are involved in producing or reviewing materials for European use.

The main national variations are in the following areas:

- Whether the dissemination of information regarding unauthorised medicines is allowed under certain circumstances
- Whether it is a requirement to certify promotional materials and, if it is a requirement, who is allowed to approve promotional materials (the EFPIA Code designates a medical doctor or pharmacist)
- Whether pre-approval of advertising materials by competent authorities is required
- Whether teaser and/or reminder advertisements are allowed
- Requirements when giving samples
- Requirements for internet sites
- Requirements when providing hospitality
- Requirements for comparative advertisements
- Requirements for disease awareness campaigns and
- Differences in penalties for breaches of the code.

### Why codes exist and what is covered by them

Medicines are very different to other commodities and the codes of conduct exist to ensure that their promotion is carried out in a professional and ethical manner. It is important that accurate, fair and objective information is provided to healthcare professionals about medicinal products so that rational decisions can be made as to their use.

The promotion of prescription medicines is defined as any activity undertaken by a pharmaceutical company or with its authority which promotes the prescription, supply, sale or administration of its medicines.

Therefore the codes apply to:

- Medical and marketing personnel
- Sales forces
- Third parties
  - meeting organisers
  - speakers
  - health professionals acting on the company's behalf
  - agencies

### Why compliance is important

Non-compliance with the national law or self-regulatory code may result in different sanctions and/or legal redress depending on the country and the severity of the breach. These sanctions could range from fines to revoking the marketing authorisation or even criminal prosecution.

However this is not the only reason for pharmaceutical companies to be interested in compliance ensuring that the system of self-regulation continues is vital to them. The alternative of increased government regulation could result in a situation where research, development, sales and marketing are heavily monitored or even controlled by government. If for example concerns about the safety of marketed medicines are not adequately addressed then more control over the clinical trial process or even a lengthening of it may result. Any of these scenarios would result in reduced profit and the already high-risk investments in research and development would intensify.

In order to be successful the industry must implement a balanced strategy that allows profitability and sustained growth while maintaining an ethical approach to the commercialisation of its products. It must have a culture that embraces self-regulation together with processes, structures, people and other resources that enable effective compliance across the organisation.

### The scope of the codes

The scopes of the codes are broad and cover both promotional and non-promotional activities.

#### Promotional areas

- Advertising both in journals and direct mail
- Activities of sales representatives
- Supply of samples
- Provision of hospitality for promotional purposes
- Sponsorship of promotional meetings
- Sponsorship of scientific meetings, including payment of travelling and accommodation expenses
- Promotional aids, including written materials such as detail aids, product monographs and sometimes clinical papers.
- The Internet.

#### Non-promotional areas

- The codes also apply to a number of areas which are non-promotional, including:
- Information made available to the public about prescription only medicines
- Donations and grants
- Relationships with patient organisations
- Non-interventional studies of marketed medicines and
- The use of consultants by pharmaceutical companies.

### Focus on written materials

The following basic principles of the codes apply to many different forms of promotional materials and must be borne in mind when producing written materials for pharmaceutical companies.

#### Basic principles [5]

##### **Comparison and hanging comparatives**

Hanging comparatives should not be used when promoting medicines. A hanging comparative is where, for example, product X is said to be better, faster, cheaper, etc. without saying compared to what. Further examples of hanging



## Stand out from the crowd...

comparatives would be the following if the claim is not further qualified.

- Increased response
- Decreased response
- More effective
- Better tolerability and
- Stronger.

**Disguised promotion**

Promotion must not be disguised as non-promotional activity. Examples of activities that could be ruled as disguised promotion if not conducted appropriately include:

- Clinical assessments
- Medical information letters
- Post-marketing surveillance and experience programmes
- Post-authorisation studies and
- Market research.

Such assessments, programmes and studies must be conducted with a primarily scientific or educational purpose. Promotion must not involve discrediting reports regarding the clinical and scientific opinions of health professionals and must be ethical at all times.

**Exaggerated, false or misleading claims**

It is important that claims made for medicines do not mislead either intentionally or unintentionally. Therefore it is important to consider whether the information presented in advertising and promotion can be misconstrued in any way.

The ways that graphs are presented and statistics are used in promotional items are common causes of false or misleading claims. Graphs will therefore be looked at in more detail:

**Graphs**

The main principles behind the codes of conduct are that data is presented in a clear, accurate way so as not to mislead the reader.

**DO**

- Label axes of graphs with parameter and unit of measurement
- Ensure adequate and accurate referencing
- Include statistical information and ensure that this is accurately presented, e.g. p values where relevant or stating 'not statistically significant' if the data presented does not have statistical significance
- Include all relevant data, e.g. patient numbers and
- Make it clear if the data presented is from different studies. It is misleading to present data from two or more studies in one graph as though it were all from the same study. This is because for example there will be differences in study protocols, patient demographics and numbers.

**DO NOT**

- Use suppressed zeros when the aim is to convey the message that drug X gives better results than drug Y.
- Extrapolate the graph into an area where there are no data.
- Select only part of the data for use in a graph if this gives a misleading impression.

However suppressed zeros can be used and are not considered misleading, if the message is that the two products are

similar. In all cases the statistical significance (or lack of it) should be stated.

**Superlatives and exaggerated claims**

Superlatives are grammatical expressions which denote the highest quality or degree, such as best, strongest, widest, etc. for a product. They are only allowed if they are factual statements that can be substantiated, e.g. 'the most widely prescribed'. In contrast 'the best' would not be acceptable. Examples of superlatives are claims such as:

- The best
- The most effective
- The most prescribed.

Exaggerated and all-embracing claims are not permitted. An unqualified claim that a product is 'safe' will always be considered a breach but a claim for 'unique' might, in exceptional circumstances, be defensible (the argument that every product is unique in some way would not be sufficient!). The particular circumstances and the evidence supporting the claim will determine whether it is judged unacceptable but here are some examples of potentially exaggerated and all-embracing claims:

- Safe
- Unique
- The standard for
- The number one
- The drug of choice and
- The gold standard.

**Side effects**

It is extremely important that any claims that are made regarding the safety and side effects of a product are accurate and reflect the product licence and any available evidence. In general the following rules should be adhered to:

- The word 'safe' must never be used to describe a medicinal product without proper qualification
- It must not be stated that a product has no side effects, toxic hazards or risks of addiction or dependency.

**Substantiation**

Substantiation is the verification of claims or statements made in promotional materials. This verification is usually provided in promotional material by citing references. Substantiation must be provided to healthcare professionals, including competitors, if requested as soon as possible. In general terms, substantiation by referencing is required in promotion in the following circumstances:

- When a quotation is used
- When a clinical trial is used and
- When graphs, tables, figures and illustrations are used.

It is not necessary to substantiate claims that are within the terms of the licence. In broad terms there are four types of data used to substantiate claims:

- Published data, e.g. from journals in the public domain
- Abstracts, e.g. from data presented at international conferences
- Posters, e.g. presented at international conferences
- Data on file. This is data that is not in the public domain, e.g. unpublished clinical studies from the pharmaceutical company making the claim.

The type of data allowed to substantiate statements varies from country to country.



## Stand out from the crowd...

> **Practical examples**

Here are just a few practical examples of the many ways an understanding of the codes and compliance may help when producing written communications.

- The first point is always to ascertain the intended audience, e.g. HCP or general public and the countries where the written communication is to be used. Your knowledge of the codes and compliance will then highlight any compliance issues and national differences. An example is 'data on file' being used to substantiate a claim. This is only allowed in a few countries in Europe, e.g. UK, Greece and Ireland, but is not allowed in many others such as Germany, France and Italy.
- Never make the claim of 'safe' in a written document, even in a clinical paper where the statement is endorsed by a key opinion leader. Many clinical papers resulting from publication of pivotal studies have had their use restricted by such claims. For example a clinical paper making such claims should not be provided to sales representatives for use in discussions with health-care professionals. The utility of the article is therefore greatly reduced to the pharmaceutical company; a better alternated would have been to use the words 'well tolerated' instead.
- Know whether pre-approval of advertising materials is required by the competent authorities in the intended market and scheduling this into production time. This can save the problems as some authorities may have lengthy lead times for approval.

**Summary**

In conclusion, by understanding the impact country codes and legislation have on marketing pharmaceutical products across Europe, you will be better able to judge any compliance issues when writing new material. By recognising possible issues early you can save time and avoid many of the pitfalls associated with writing (and re-writing!) pan European communications.

'Standing out from the crowd' with a good knowledge of applicable codes can only improve your customer relationships and ultimately lead to increased business for both you and your agency.

**Judith Grice<sup>1</sup>**

Director PharmaCodes Medical Communications Ltd  
Jordans Village, UK  
judith.grice@pharmacodes.com

**References:**

1. Abbasi K, Smith R No more free lunches. Patients will benefit from doctors and drug companies disentangling. *BMJ* 2003;326(7400):1155-1156.
2. The House of Commons Health Committee. The influence of the Pharmaceutical Industry 4<sup>th</sup> report 2004-5 Volume1
3. Boseley S. Drug Firms a danger to health. *The Guardian* June 26, 2006
4. PriceWaterhouseCooper's Health Research Institute: Recapturing the Vision: Integrity driven performance in the pharmaceutical Industry: 2005
5. Grice J. Compliance, Codes and Communications (2009) Stanford Publishing

<sup>1</sup> Judith Grice delivers European Marketing Compliance Training and can be contacted by e-mail for further details.

**A series of fascinating talks**

If you ever need some mental stimulation or even a short break after being numbed by a few hours of writing regulatory or some other boring documents try the TED website (<http://www.ted.com/>). It is the venue of over 500 "riveting talks by remarkable people". The talks are categorised as fascinating, courageous, inspiring, ingenious, funny, informative or persuasive. A couple of examples are the Nigerian, Chimamanda Adichie, who introduces herself as a story teller, talking about the danger of a single story and Michael Specter, who is a staff writer for the New Yorker, talking about the danger of science denial.

**A victory for free speech in discussing science—but British libel laws must be reformed**

*Guardian* journalist Simon Singh's ordeal defending his statement in the newspaper in 2008 that accused the Chiropractic Association of "happily promoting bogus treatments" has finally reached closure. The Court of Appeal in the UK ruled that his statement was fair comment or his honest opinion, which implies that views expressed in the course of scientific debate can be viewed as comment rather than fact. The Chiropractic Association, which had sued Singh for libel, has announced that it will not appeal against this judgement. Singh said (as quoted in the *BMJ*) "In the area of medicine alone, fear of libel means that good research is not always published because those with vested interests might sue, and bad research that should be withdrawn is not pulled because the authors might sue the journal, and in both cases it is the public that loses out because the truth is never exposed." A decision is still awaited on cardiologist Peter Wilmhurst's case in which he is being sued by an American device manufacturer over comments he made on a cardiology website based in the US. The action was brought against him in the UK because Britain does not have the equivalent of the First Amendment free speech rights which protects scientists and journalists who make statements of public interest or that are fair comment. The Coalition for Libel Reform in the UK will continue to exert pressure on the government to reform British libel laws to include a public interest defence which will protect open discussion of research.

<sup>1</sup> Dyer C. Chiropractors drop libel action against writer Simon Singh. *BMJ* 2010;340:886-887



## **Publications management methods: A comparison of tracking programs**

by Ruth Whittington

*“Search for the truth is the noblest occupation of man; its publication is a duty.”*

*Madame de Staël French woman of letters, political propagandist, 1766-1817*

The act of publication is **to make information or content publicly known** (not always the case when publishing in obscure journals)—but the term ‘publication’ also has legal and copyright implications, especially significant when coupled with the issue of authorship.

With all the coverage in the press and journals regarding the ethics of publications, and with the latest version of Good Publication Practice guidelines (GPP2) now published [1], it seems appropriate to consider why the topic is important and how we know whether we are compliant.

This article briefly overviews the broader aspects of publications management within organisations that produce a large number of publications, the key aspects that such an organisation should consider, and how to monitor performance and compliance with the use of publications tracking software. It will not address policy issues—a larger topic that deserves separate consideration. It also offers a subjective (and possibly outspoken) opinion of the two publication tracking software options currently dominating the market—their advantages, disadvantages and a little on your alternative options. I stress that this is an opinionated article based on my own experiences with the tracking systems under discussion. The points of view and experiences of other users may be entirely different.

### **Why is the topic important?**

Publication of original research or other material (e.g. a review, editorial or commentary) reflects on the authors/investigators, sponsors/funding bodies, peer reviewers and the journal or congress that published it. The act of publication in itself changes the perception of the veracity and authenticity of the piece (however unjustified). Publication of written work implies that the author stands by the opinions expressed therein, and that the journal editors and peer reviewers believe the argument to be valid, well founded and of interest to their readership.

Good publications activity enhances the careers of the authors and journal editors (which can be endangered with bad publications) so these two stakeholder groups are especially risk-averse. Good publications enhance the prestige of funding bodies, and, for both pharmaceutical companies and academic institutions, can substantially affect their reputation and commercial viability.

So it is in everyone’s interest to ensure that the process of developing publications follows procedures that ensure the content of those publications accurately and objectively reflect the data, conform to legal and ethical requirements, and are able to be scrutinised.

### **Does publication tracking have a benefit for the end users (readers)?**

Ignoring the commercial and career requirements of publications for a moment, what are the requirements for a publication to satisfy the intended audience? These are in no particular order—the priority depends on the publication in question:

- Accuracy—the data and information in the publication must be correct
- Completeness—the publication should tell the whole story (i.e. no cherry-picking). If it cannot due to size, complexity/volume issues, it must state this and why
- Context—the information should be in context, giving sufficient background about the circumstances of the research (e.g. patient population, perspective for health economics analyses, country).
- Timeliness—results from clinical trials should be published in a timely manner in accordance with regulatory requirements
- Clarity—methodology, relevance, limitations—all information should be expressed clearly and without ambiguity
- Accessibility—the article must be accessible to the audience it concerns—the right journal or congress is an important part of this
- Summary and conclusions must be consistent with the data and the rest of the publication content (for those readers who skim or skip the main text)
- Overt provenance. It must be clear how the publication was produced, with any conflicts of interest that could affect the accuracy of the reporting disclosed.

A publications tracking system of sorts can assist with meeting some of the requirements of stakeholders and the intended audience—in particular, the provenance and timeliness. It may also influence other requirements by improving the review process.

### **What should a publication tracking tool be able to do?**

Let’s look at the critical requirements first.

## Publications management methods: A comparison of tracking programs

### > 1. **Safety—legal and ethical**

A priority for any institution is to ensure that the publications activity is ‘safe’; for example, that publications are not putting that institution’s reputation or commercial concerns at risk. This can be problematic for academic departments where researchers are largely autonomous. Nonetheless, a publications tracking tool that monitors and records all publications activity can assist in showing where publications come from and when, and encourage more stringent review prior to journal or congress submission. If questions later arise as to the objectivity or authorship of the publication, a tracking tool can help show the history of the publication, who contributed, and at what stage in its development. ‘Safety’ would also cover issues such as confidentiality; for example any commercially or time-sensitive information in a particular publication. (For example, publication of an individual country manuscript might jeopardise the pivotal manuscript from a multinational trial; release of early data on a commercially important compound might alert competitors).

### 2. **Accountability**

A tracking tool encourages sponsors, authors and any writing or editorial support to be accountable and responsible, by allocating tasks, deadlines and monitoring progress. When an open system is employed that enables everyone to see the status, the resulting peer pressure encourages people to fulfil their obligations. (This can also be a reason for opposition to setting up such a system within a business; managers *and* their staff may prefer blissful ignorance to the hard truth regarding the actual compliance with their publications policy, and their publications performance!)

### 3. **Publication Quality**

Using key performance indicators (e.g. review processes, acceptance and rejection rates, timelines, quality of content, journal impact factor, etc.), a good tracking tool will allow benchmarking, can highlight areas for improvement and encourage better practices. By assisting with publication planning, it can also help ensure that publications reach the right audience at the optimal time.

## **Features of a good tracking tool**

### **Essentials:**

1. Documentation and control of all inputs
2. Monitor progression—to timelines
3. Keep all specific information about the publication together—e.g. data sources, reviewers and amendments, comments, topic, authors, meetings/journals etc.
4. Version control
5. Provide an overview of the activities—i.e. reports for planning and monitoring
6. Keep confidential information confidential (i.e. limited access)
7. Be easy to use by newcomers
8. Ensure (and demonstrate) compliance with organisational policies and legal requirements

### **Nice-to-haves:**

1. A searchable interlinked history/bibliography of completed projects with reporting functionalities
2. Information on relevant journals and congresses for planning purposes
3. Ability for use as a strategic tool for ‘what if’ scenarios and future planning against study timelines
4. Records of clinical data disclosure, automated posting and associated publication timelines
5. Records of financial issues concerning the publication—honoraria, funding, etc.

## **Available publication tracking solutions**

Many tools are not specifically designed for tracking but can be adapted and used as such.

### **Spreadsheets**

The simplest solution with some functionality is the spreadsheet of key parameters—such as a basic Excel spreadsheet (e.g. Figure 1). For small numbers of publications and an enthusiastic publications manager with no budget, this may be all you need. Hyperlinks to other worksheets and files can improve user-friendliness, although this approach can become unwieldy with the file prone to crashing.

The main advantages of this solution are ease of use and low expense; typically the software is already familiar in-house. Limited reporting with filters and functions is possible, but version control and monitoring inputs can be problematic (hence the need for an enthusiastic publications manager with another recording system). Timelines won’t update without a sophisticated series of functions. A spreadsheet system will work best with one owner/inputter, and other stakeholders committed to supplying the necessary information to keep it current.

The downside is that the system fails as soon as people don’t comply or cooperate, and indeed, it can be difficult to see from the spreadsheet whether they are doing so. Another very human tendency with such a system is for people to start keeping their own information in separate files, thus creating silos of information and introducing the problem of version control in the tracking tool itself. This is common with a multinational group of stakeholders who can’t meet often and so tend to end up doing their own thing. The system becomes very cumbersome with a large number of parameters or a high volume of publications; moreover, it doesn’t easily lend itself to keeping a bibliographic record.

### **Generic databases**

These tools (e.g. Access databases) are not specifically designed for publications tracking, but can fulfil many of the required functions. For example, Access allows sophisticated reporting and a relational array of fields, giving greater flexibility and advanced functionality than Excel. However, a well-designed system requires advanced IT skills. And software upgrades can undo all your hard work.



## Publications management methods: A comparison of tracking programs

- when policies, processes, or reporting categories are not clearly defined or adequately considered. Although both systems claim to upload data seamlessly from one another or from .csv files, merging two differing systems (for example after a merger or company acquisition) can take considerable time and effort. When merging two companies together, it is usually better to start from scratch rather than try cobbling them together.

Both tools allow good publication planning and monitoring, and can assist greatly in helping define publication strategy. The conference and journal selection functions of both systems are very good, although I would give PubSTRAT a slight edge for recency and comprehensiveness of the information. The PubSTRAT suite is modular with add-on functions such as ‘Please Review’, a program which enables authors to comment on the same document and have an appended discussion of issues. This is a great advantage; many of us who offer medical writing services have experienced situations where one author comments and another contradicts that comment. This system allows the authors (and medical writer) to resolve the issue during the review process, significantly improving speed and efficiency, and indeed the final publication. Datavision also has version control; however, it has less functionality than PubSTRAT (with Please Review), and there is a limit to the number of versions that can be linked directly to the project. Datavision has a very robust platform with regular, well-orchestrated upgrades; their system of user forums to gather feedback is excellent, if limited to client attendees only. One drawback with Datavision is that the company has its own communications agency and so won’t sell the system to other agencies, although it will make the program available via the purchasing client licence to agencies and welcomes added revenue from training other agency personnel in its use. PubSTRAT, however, is available for purchase by agencies and research-generating clients alike.

The major disadvantage of both publication tracking tools is cost. Both Datavision and PubSTRAT have annual licence fees, and their pricing is based on either the number of products or therapeutic areas or volume of publications; the more you use it the more you pay. Unlike an in-house system, if you stop paying you essentially lose access to your data. When I last compared pricing a year ago, it seemed that the costs for each were fairly similar for the same level of functionality, although with PubSTRAT you can limit the number of add-ons and therefore the cost.

Although costs for such a publications tracking system are substantial, they pale into insignificance when considered alongside legal costs for noncompliance with government legislation for data disclosure, or for authorship disputes.

### So what to use?

Table 1 summarises the main points of each type of system discussed against the 3 major criteria: Safety (or peace of mind) accountability, and publication quality.

TABLE 1. Comparison of critical requirements for publications tracking tools

	Spread-sheets e.g. Excel	Databases e.g. Access	Document-sharing e.g. Share-point, Documentum	Publications Management software e.g. Datavision, PubSTRAT
Safety (monitoring and controlling inputs, version control)	Limited	Limited	Good	Good
Accountability	Limited	Limited	Limited	Good
Publication quality	Indirect only	Indirect only	Direct	Direct

Table 2 compares the features of each of the types of tracking tool, assuming an average competency with each type of system, i.e. the average professional publication manager with average IT skills. Therefore, while very sophisticated functions are feasible for highly skilled users, I’ve assumed that these have not been used beyond set-up.

TABLE 2. Comparison of publications tracking solutions features and benefits

Features	Spread-sheets e.g. Excel	Databases e.g. Access	Document-sharing e.g. Share-point, Documentum	Publications Management software e.g. Datavision, PubSTRAT
Documents all inputs	poor	mod	good	good
Monitors progress to timelines	mod	mod	poor	good
Keeps information together	poor	mod	good	good
Version control	poor	poor	good	good
Reporting	poor	mod	poor	good
Ease of use	good	mod	good	mod
Enforcing compliance with policies	poor	poor	mod	good
Volume of publications best handled	Low	High	High	high
Upgrades easily managed	Mod – poor	Poor	Mod	mod
Authorship trail	Poor	Poor	Good	good
Conference advice	Poor	Poor	Poor	good
Journal advice	Poor	Poor	Poor	good
Access control	Poor-mod	Poor – mod	good	good
Offsite hosting	no	no	no	yes
Set-up and customisation	Very fast	fast	fast	slow

Note: rankings were awarded on an average user basis; i.e. generally proficient with IT but not a wizard. Poor—the system can’t do it or needs a great deal of expertise to accomplish; the average user would need to find a work-around solution. Mod—can be done but someone with my level of skills would need expert help. Good—is a built-in feature of the system.



## Publications management methods: A comparison of tracking programs

Table 3. Subjective comparison of Datavision and PubSTRAT

Features	Datavision	PubSTRAT
Conference information	++	+++
Journal information	++	+++
Reporting	+++	++
Version control/review of manuscripts	++	+++
Strategic planning	+++	++
Performance and reliability	++++	++
Data disclosure compliance	++	+++
Ease of use	+++	++
Filtering/customised reports	++	++
Use with external authors	++	+++
Use with external writing agencies	+++	++++
Assistance with set up and training	++++	++

Note: subjective comparison, based on 1 year's use of both systems within an agency environment. Rankings are not quantitative, and versions of the software after 2009 have not been evaluated.

### A last word of advice

In conclusion, I remind you that a system is only as good as its implementation—having systems and policies in place is no guarantee that they are followed and used correctly. However, a system that can highlight the shortcomings is a first step in the right direction. It is then up to you to take the corrective actions.

### Acknowledgements and caveats:

In compiling this article, I interviewed Dan Donovan, CEO of Envision Pharma, now part of United Biosources Corporation (Datavision), and Tim Bacon, CEO of Peer-View, now part of Sylogent (PubSTRAT). In addition, over a period of about 18 months, I had hands-on experience of both systems and also talked to many publications managers from pharmaceutical companies. Both companies were given the opportunity to comment on the article and add further information or clarification. No financial incentives were offered, and I have no conflicts of interest to declare.

### Ruth Whittington

Rx Communications Ltd  
Mold, UK  
ruth.whittington@rxcomms.com  
www.rxcomms.com

### References:

1. Graf C, Battisti WP, Bridges D, et al. International Society for Medical Publication Professionals. Research Methods & Reporting. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009 Nov 27;339:b4330. doi: 10.1136/bmj.b4330.

*"Given the importance of medical writing to the progress of civilization, one might expect the art to be widely cultivated and highly perfected. Such is not the case at all. Modern medical literature is some of the most vapid, obscure, tortuous, and unreadable material in print."*

Dirckx, JH. The language of medicine. 2<sup>nd</sup> ed., Praeger. New York, NY (1983)



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## Patents: Converting technology into a business asset

by Sunethra Wimalasundera

Recently, there has been a lot of discussion about ghost-writing and plagiarism in *The Write Stuff*. As a medical writer with an intellectual property law degree, I would like to add to this theme on means of protecting one's identity or property and discuss the strongest mode of intellectual protection available to an individual or company using a legal system, which is a patent. A patent is basically a set of instructions to teach the reader to create the invention from scratch. Any man made invention can be patented as long as certain criteria are met and they do not fall into one of the excluded categories. A patent can be given for the process involved in creating the invention (a process patent) and the design of the invention (design patent). The biggest impact to the pharmaceutical industry and most interesting for me as a biologist came with the legislature which allowed the patentability of inventions based on genetically modified products derived from genes (Biotechnology Directive 98/44/EC). Prior to this, it was a challenge for patents based on gene-based discoveries to be approved. This is highlighted in the case of the Oncomouse (which was one of the most exciting advances in oncology). The Oncomouse was a genetically modified mouse which was made more susceptible to cancer. Despite the many potential applications of this technology, the Oncomouse patent took 8 years from application in 1984 in the European Patent Agency to its granting in 1992. Today, although the debate on patenting of life continues, it is estimated that, at least one fifth of the human genome is patented or has a pending patent application.

Once a patent is obtained, it can provide the owner with exclusive rights over the patent for up to 20 years from the date of filing. This time limited monopoly, affords owners a very valuable business asset and allows them to restrict others from doing certain activities using the invention. Of course in the pharmaceutical industry, most of this time is taken up in developing a drug from the bench to the clinic which can take up to 10 years. However, in recognition of this, the Supplementary Protection Certificate (SPC) was created to allow the industry an additional 5 years or 5.5 years if the patent is for a medicinal product for humans with an agreed paediatric investigational plan in place (Article 36 of Regulation (EC) No 1901/2006).

***A patent is basically a set of instructions to teach the reader to create the invention from scratch***

So how is a patent obtained and what form of protection does it provide? Patents are a registered legal right given to an inventor(s) by the state. Having a right registered gives the owner stronger case in courts in contesting an infringement with very clear legislature to back them up. Applications can be made nationally (in the UK, the legislation governing patents is the Patents Act 1977), or via the European Patent Office (EPO) (governed by the European Patents Convention) by the inventor(s). A patent will be given a priority date (filing date), which is the date that the patent is filed. If a patent is in dispute, this date is used to determine if an infringement has occurred.

A patent may be given to an invention if it meets 3 main criteria. Firstly the invention must be novel. This means that the invention must not have been made available to the public anywhere else in the world, in writing, orally or by use. If an invention has been made available to the public, even inadvertently during a meeting, discussion with a peer or in a scientific journal, this is prior disclosure and can invalidate the novelty requirement. The next requirement for a patent is to have an inventive step. This is more complex to determine and requires that the invention is not obvious to the notionally skilled worker. This is someone that lacks imagination but is within the field

***Inadvertent prior disclosure during a meeting, discussion with a peer or in a scientific journal can invalidate the novelty requirement***

of research and has read the relevant material. It is often very difficult for the courts to decide the level of knowledge and lack of imagination requirement of this person. This step asks whether there is an inventive step involved and if the notionally skilled worker based on information

available in the literature is capable of arriving at the same conclusions. Finally, the last requirement for a valid patent is that the invention has to be capable of an industrial application. In other words, does it have a useful purpose? The excluded categories mentioned above also include discoveries, scientific theories or mathematical methods. This is where the Biotech Directive comes into force. Although it excludes substances that occur freely in nature or are a part of the human body in its various stages of development (including sequencing or partial sequencing of genes), if the gene sequence has a useful purposes ascribed to it and has been isolated from its natural environment by a technical process, a patent can be obtained. Genentech in

## Patents: Converting technology into a business asset

1994 were able to obtain a patent for the gene sequence for Relaxin based on these grounds.

A patent does not allow the owner to use the patent as this may infringe another's patent. It does however allow the owner to prevent others from using, making, selling, offering to use, disposing of, offering to dispose of, importing or keeping the patented product.

Once you have the patent, how do you use it to generate an income? In most cases, developing the product from the patent may require considerable financial resources and time and the owner may decide to sell it or license some or all of the patent. Licensing can be very lucrative means of recouping some of the costs incurred in obtaining a patent such as application fees and maintenance fees. If the patent is broad (covers many applications for the use of the invention), the owner can divide up the patent and license out areas that may not be of interest to them. This provides a low risk investment for the owner which is a mutually beneficial arrangement as it allows the licensee to improve the invention and the licensor to receive some of the financial benefit from this improvement. Any further improvements to the invention can also be patented.

A patent is a means of converting technology into a business asset. Business development in large pharmaceutical companies use patent licenses to establish alliances with other companies. Thus companies can in-license patents to expand their portfolios and out-license patents as a means of generating a revenue for therapeutic area which the company may not want to develop further in. Revenues can be generated in the form of an upfront payment, milestone payments or royalties. Other means of using a

***companies can in-license patents to expand their portfolios and out-license patents to generate revenue***

license as a bargaining tool may include a co-promotion or co-marketing deal, equity purchase or just quid pro quo, i.e. an exchange of licenses as a dispute resolution. Before a licensing deal can be established, a process called due diligence will be performed. This would include searches into the ownership of the patent. In some cases this may be complicated if there are many inventors involved as would be the case in a university research collaboration. Due diligence will also ensure that any disputes or infringements pertaining to the patent have been resolved.

A patent itself is simply an agreement between the owner and the state. Its purpose is to encourage innovation by rewarding the owner with exclusivity or a time limited monopoly to develop and commercialise the invention. In return for this exclusivity, the inventor agrees to allow this information to be made freely available to the public after the patent expires.

### Sunethra Wimalasundera

Eisai UK  
European Knowledge Creation Centre  
Hatfield, Hertfordshire, UK  
[Sunethra.Wimalasundera@eisai.net](mailto:Sunethra.Wimalasundera@eisai.net)

### Useful websites

UK Patent Office: <http://www.ipo.gov.uk/pro-home.htm>  
European Patent Convention, revised in 2000: <http://www.epo.org>  
Bioethics and Patent Law:  
[http://www.wipo.int/wipo\\_magazine/en/2006/02/article\\_0009.html](http://www.wipo.int/wipo_magazine/en/2006/02/article_0009.html)  
Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions

## Let your colleagues benefit from your publications in other journals too!

A year ago, in the June 2009 issue of *TWS* [18(2)146], we published a list of medical writing articles written by EMWA members in other journals. It's time to update the list!

EMWA members are invited to send citations to articles relevant to medical writing/biomedical publication or on other topics of general interest to medical writers which they have published in the last 12 months. (Details of articles published earlier, which you might have forgotten to send last time around, are also welcome.)

Please send the citations to [editor@emwa.org](mailto:editor@emwa.org) for inclusion in the list which will be published in the September 2010 issue and also on [www.emwa.org](http://www.emwa.org).

## Corrections

The last issue of *The Write Stuff* (2010, volume 19, number 1), unfortunately contained some errors that should be corrected. The first error appears in the print version only but is rather embarrassing as it relates to the title of my own article. I failed to take my own advice of always paying extra attention to the title of an article when proof reading, but looking on the bright side, things can always be worse (see paragraph 'Error beyond the politically incorrect' on page 159).

The title of the article 'Responsibility of medical writers who draft articles reporting clinical trials. Commentary on: Authorship—More than just writing, but how much more?' by Elise Langdon-Neuner on page 22 should read 'Responsibility of medical writers who draft articles reporting clinical trials. Commentary on: Authorship—More than just writing, but how much more?'

In the article by Karen Shashok 'How AuthorAID in the Eastern Mediterranean helps researchers become authors' on pages 43-46, the affiliation mentioned for Hooman Momen in the first paragraph was wrong. His correct affiliation is 'Special Coordinator for the promotion of Multilingualism in the World Health Organization.'



## A crash course in marketing for medical writers

by Diarmuid De Faoite

Evidence of marketing activity is all around us. I'm willing to bet that if you glance up from reading this article you can see the logos of different companies scattered around the room. But what is marketing exactly and how can medical writers profit from an understanding of the concept? This article attempts to answer these questions by outlining general marketing principles and using examples applicable to freelance medical writers whenever possible. I am assuming that the reader has little to no previous experience studying marketing.

You may be thinking what relevance does marketing have to me? I am only a one-person company and have my list of clients I've built up. I have no time or budget for marketing. Think about it however, why are you saying no to the possibility of having higher paying clients instead of your current ones? Have you thought strategically about how you conduct your business? Why are you limiting yourself by calling yourself a one-person company? Have you investigated linking up with others (e.g. translators or medical writers specialised in an area you are not) to offer a more complete suite of services and to generate more income for yourself?

As you can see, this article will challenge the way you think about your business and give you some ideas as to where it could go. Let's start with the basics.

### What is marketing?

Many different definitions exist but in the main, marketing is concerned with meeting the needs and wants of customers.

**Implication for medical writers:** Marketing begins with what the customer wants and informs what it is you will offer. In order to find clients don't just look to promote yourself and your skills. An easier approach is to look to the market and see what kind of work is being actively sought. Can you offer this kind of writing? If not, can you learn it/team up with someone who can?

### Isn't marketing the same as selling?

In a word, no, but the concepts are related with selling viewed as a subsection of marketing. Selling implies that a good/service/idea has been produced and a buyer has to be found. Marketing begins before a product is even produced. This means that market research is conducted to see if unmet needs can be identified and a product developed to meet those needs. The theory is that such a product will 'sell itself' because consumers will want it. Cynics

contend that a lot of marketing dollars are spent creating artificial needs, the classic example being the creation of the deodorant market.

**Implication for medical writers:** Increase your attractiveness to clients by having a customised profile that meets their individual needs. For example, if applicable, create 3 lists of your publications ready to be sent out to prospective customers, each one tailored to show off your respective work in the regulatory, educational and promotional fields. A simple rearranging of your list to have the most appropriate work for the potential client at the top will trigger interest quicker than if they have to go trawling through the entire list for evidence of your experience in regulatory writing for example.

### The marketing mix—aka the 4 Ps

A classic concept in marketing is the 4 Ps of product, price, promotion, and place—known as the marketing mix. The theory is that if all four elements are correctly in place the marketer has done a lot to ensure success.

**Product:** This can be a good (tangible), service (intangible), or idea (concept). As medical writers we are mostly selling a service, which can be difficult for people to visualise.

**Implication for medical writers:** Always include tangible elements to your service. This could include a 'press pack' of your work or a branded red pen give-away to reinforce the impression they have of you as a 'corrector' of text.

**Price:** The price charged should be competitive and allow for a profit.

**Implication for medical writers:** Keep yourself informed about what others are charging and adapt as necessary. If you set a premium rate make sure you can justify this by offering service elements that others do not, e.g. certified translation, guaranteed completion times etc.

**Promotion:** How you raise awareness of your service in your target market.

**Implication for medical writers:** Good freelance medical writers, a lot like films, often achieve success through word of mouth advertising. Make it easy for people to recommend you by ensuring they have all your contact details.

I am surprised at how many people on the EMWA freelancer list don't have their own website. i.e. don't have a place to promote themselves online by making public their publications, testimonies, CV etc. Ask yourself, why

## A crash course in marketing for medical writers

would potential customer phone a complete stranger when they can get an impression of what other medical writers are like/can offer from their website first before calling? If you can't afford a professional website development company, there are plenty of simple templates available which can be used to create an Internet presence at a minimum cost. Even if you are a complete Luddite, it shouldn't be too hard to find someone you know who can help you to do this.

**Place:** The channels by which you reach your customers. For service providers this also encompasses accessibility to your services.

**Implication for medical writers:** Although a lot of business is conducted over the Internet, there is still a role for face-to-face communication. Conferences and trade get-togethers can be important sources of information/new work. How proactive are you? Do you ask satisfied customers to recommend you further and send them some extra business cards to pass along? Do you ever check back with clients you haven't heard from in a while to see if there is any work in the pipeline or a reason why they haven't used you lately? Have you registered yourself with local chambers of commerce, trade associations, scientific organisations? Have you made it your business to meet with local firms, hospitals, and university representatives involved in your line of work?

### The extended marketing mix

As interest and research in marketing has grown, some extensions to the original 4 Ps have been suggested for services and I include a selection of them here:

**People:** Consider your business in terms of the people working for and with you.

**Implication for medical writers:** Obviously a lot of freelancers are a one (wo)man band. But take a look at people/companies who are successful in the industry. What separates them from others? Can any of the things they do that work well be assimilated into your work style?

**Positioning:** The mental impression people have when they think of you and your product. This can be a wide spectrum for the same product, e.g. although they are both airlines, what do you think of when you compare Cathay Pacific to Ryanair?

**Implication for medical writers:** Consider the impression you make on your clients. Do you always meet your deadlines? Are you available to talk to clients at times that suit them? Will you go the extra mile for them? Only by presenting yourself professionally can you make the best impression.

**Process:** The customer management plan you have in place.

**Implication for medical writers:** Do you have an ordered system in place to deal with clients? If not, why not? Take some time to examine every step a customer goes through with you and try to eliminate wasteful processes. This could be something as simple as setting aside one

afternoon every two weeks to send out invoices (instead of every 2-3 months!) or creating a form template to ensure you have received all the necessary details for a job.

### Some more useful marketing concepts

**Market research:** This is something which you can conduct at little to no cost in order to improve your services. There is a lot of secondary research out there which is available for free. Learn from others. Take an afternoon to browse the websites of others in the same industry. What are the good points you can identify? Are there positive elements to their business processes you could integrate into yours?

Of more value, but more difficult to compile, is to conduct your own primary research. However, this need not necessarily be a burden. For example, whenever you have finished a substantial job for a client take the time to ask them what they thought of your service. Collect the comments and see if a pattern appears—either to eliminate elements (if bad), or to promote certain aspects (if good) to others as the parts of your service which are valued in the marketplace. Talk to your clients about their experiences with other service providers.

If you would like to take a more measured approach, [www.surveymonkey.com](http://www.surveymonkey.com) offers a free survey package which you can use to ask people to fill out online.

**AIDA:** Not the Verdi opera but an acronym which describes the process someone goes through before deciding to buy your product/engage your services. It is important to keep in mind that you can lose a potential customer at any stage of the process. The acronym stands for **A**wareness, **I**nterest, **D**esire, and **A**ction.

- a) **Awareness** (sometimes called **A**ttention instead) describes how someone becomes conscious of your service. Obviously customers can only select a company from the ones they know about so it is important that you are visible in the marketplace. Give a lot of consideration to how you can increase your profile (see **Promotion** and **Place**).
- b) **Interest** is the stage where, once aware of your service, people realise that it may be useful to them. For this reason it is important to highlight the benefits your services bring to awaken interest from as many people as possible.
- c) **Desire** is the penultimate step where a potential customer knows about and wants your services. Potential barriers to taking it further might include price, a contractual arrangement with another company etc.
- d) **Action** is generally (but not necessarily) viewed as the point when the sale is made. As you can see, the path to this stage which actually generates money is fraught with potential pitfalls. Since it is easier (and cheaper) to have repeat business than to find new customers, an '**S**' for **Satisfaction** may be added to the end of the model to create the **AIDAS** model. ➤

## A crash course in marketing for medical writers

- **SWOT analysis:** The classic strategic exercise. Divide a page into four panels and in one panel each, list what your (internal) Strengths and Weaknesses are, then write out what the (external) Opportunities and Threats are. Once identified, you should look to eliminate weaknesses and negate threats while defending, exploiting, and extending your strengths and opportunities.

Even going through the process of completing this exercise should help you to start thinking more strategically about yourself, your company, and the industry in general.

### Some final thoughts

Knowledge of marketing should be viewed as a useful business tool, not as a panacea to your/your firm's problems. All too often people see marketing as a once-off or yearly exercise when it should be all-pervasive. This is not to say that you should always be trying the hard sell, rather, be perceptive of the environment you work in and continually question and examine how you can improve both yourself and your business. Remember, the greatest tools at your disposal are your own knowledge and that of others.

There are plenty of basic marketing books available if you would like to read up on the subject. I highly recommend you invest in one if this article has piqued your interest. For some more practical tips, simply search online for "basic marketing principles for freelancers" or a similar combination of words.

### Diarmuid De Faoite

*AO Clinical Investigation and Documentation,  
Dübendorf, Switzerland  
defaoite@aofoundation.org  
www.aofoundation.org/cid*

Diarmuid is a medical writer who began his career in marketing. He holds several marketing qualifications and completed a research Masters in Business Studies on the subject of entrepreneurship in Ireland and The Netherlands. In addition, he has lectured in marketing at colleges in both Ireland and Switzerland.

## Report on COPE UK seminar 2010

The COPE seminar in London on 26<sup>th</sup> March 2010 was an instructional event for anyone interested in plagiarism and the progress publishers and journals are making in detecting plagiarism/duplicate publication in biomedical manuscripts submitted for publication. The seminar comprised presentations given by Harold Sox, former editor of *Annals of Internal Medicine*, on plagiarism in the electronic age by Vasilij Vlassov of the Moscow Medical Academy on cultural differences in plagiarism and by Kirsty Meddings of CrossRef on an update of CrossCheck (see Brand A. CrossRef: From cross-publisher reference linking to cross-publisher plagiarism screening in eight short years. *TWS* 2008;17(4):171-172). The presentations were followed by workshops in which specific cases were discussed and a 'Plagiarism clinic' panel discussion.

Some cases of plagiarism have been spotted by reviewers before publication but more often plagiarism is picked up by the authors of plagiarised publications. Harold Sox described some unpublished data obtained by the *New England Journal of Medicine*. About 700 submitted articles were investigated using Ithenticate software. Of these 35 were found to have long strings of words similar to published material, 2 manuscripts were duplicates and 1-2 of the articles they were interested in publishing had in the investigators' view been plagiarised. Ithenticate is the software used by CrossCheck. It can pick up similar strings of words including those in which some words from the original text are substituted with others in the new text. Sox highlighted the problem of deciding

the threshold at which strings of words similar to those found in previously published articles should be considered unacceptable.

Kirsty Meddings reported that publishers and journals are increasingly making use of Ithenitcate. CrossCheck had surveyed 24 organisations of which 45% had reported detecting plagiarism using Ithenitcate. Checking on submission was most prevalent with a view to identifying duplicate submissions. Sample checks were made rather than including all submitted manuscripts into the system. So far Ithenticate can only be used to detect similar text but clearly it would be useful to be able to compare figures and images using technology. CrossCheck are currently looking into detecting similarities between translated and original language texts. The question was raised as to whether authors should be asked to search for duplicate text before they submitted a manuscript to a journal but Meddings wondered if such a course could lead to authors becoming cleverer in concealing plagiarised text.

Vasilij Vlassov spoke about the accusation that had been made against Vladimir Putin that he had plagiarised around 16 pages and six figures in his economics dissertation at the University of Pittsburg from a 1982 translation of a 1978 textbook (for details see <http://www.rferl.org/content/article/1067113.html>). If he had it would not have been so unusual. One third of the dissertations at Russian universities had been bought in 2006. In 2007 3% of the dissertations presented had been rejected as having been plagiarised. Russia first introduced computer checks for detecting plagiarism at universities in 2008.





## Expanding your market by involving graphic design

by Anders Holmqvist

Experience and competence are probably the two major qualities that you will have acquired after some years of medical writing. On the other hand, there is a risk you may get stuck in the same old rut, by habit or because “business has been successful so far, so I’ll carry on as usual”. And this I say from my own experience: there are quite a few of us who have taken one or more blows as a consequence of the ongoing financial crisis. In order to continue making a living in our chosen field, we may have to widen our perspective and maybe even take the plunge into the unknown.

When I started my career as an art director/illustrator, photographer and project manager within the field of medical communications in the early 90s, my clients in the pharmaceutical industry appeared to have inexhaustible supplies of cash. Collaborating with medical writers I produced ads, leaflets, brochures, booklets, books, monographs, educational items, branding, exhibitions, newsletters, symposia, conference reports etc. In addition to our scientific productions, clients also seemed to be able to afford expensive travelling and hiring posh advertising agencies for flashy campaigns, exhibitions and events.

### ‘Mini agencies’

Today the situation is somewhat different. Our clients still have the desire to commission agencies, but the budget has become limited despite an unchanged need for scientific copy writing. What can we as freelancers do to meet this need? My answer would be: transform ourselves into ‘mini agencies’.

By writing about scientifically complex medical topics you will already have created a unique personal image for yourself which allows you to stand out from the faceless crowd of agencies. But do you ever concern yourself with what happens to your text once it’s delivered and paid for? Well, typically somebody else is supposed to edit the text, choose adequate typography, perhaps add (in an ideal world) explanatory illustrations and graphs, and finally present your text in print. Your influence on (or for that matter, responsibility for) this process is zero. Is this scenario desirable to you? By taking an interest in matters further down the line you may be able to make your text more interesting and comprehensible, as well as making your own contribution more worthwhile.

Whilst we will all of us be aware of the importance of graphic presentation for the overall message, it cannot be reiterated often enough to our clients: a piece of text may

be magnificently written, with exhilarating content—if it’s not presented in an appropriate and attractive way (that is, with adequate typography, layout, and illustrations/pictures) there is a huge risk that it will remain unread by most of its intended audience. So, what has your client gained by ordering this job from you in the first place? You may be thinking “this has got nothing to do with me, it’s my client’s problem.” But many pharmaceutical clients are unaware of these matters—they are so ‘in love with’ their subject or excited about their presented scientific data that they completely overlook the fact that typography and layout matters have the potential to give the text a much greater impact. If you were able to persuade your clients (and prospective clients) to pay greater attention to these aspects, and if you could include these services as part of your core services, it is likely that you’d be increasing your chances of landing a wealth of interesting new freelance projects.

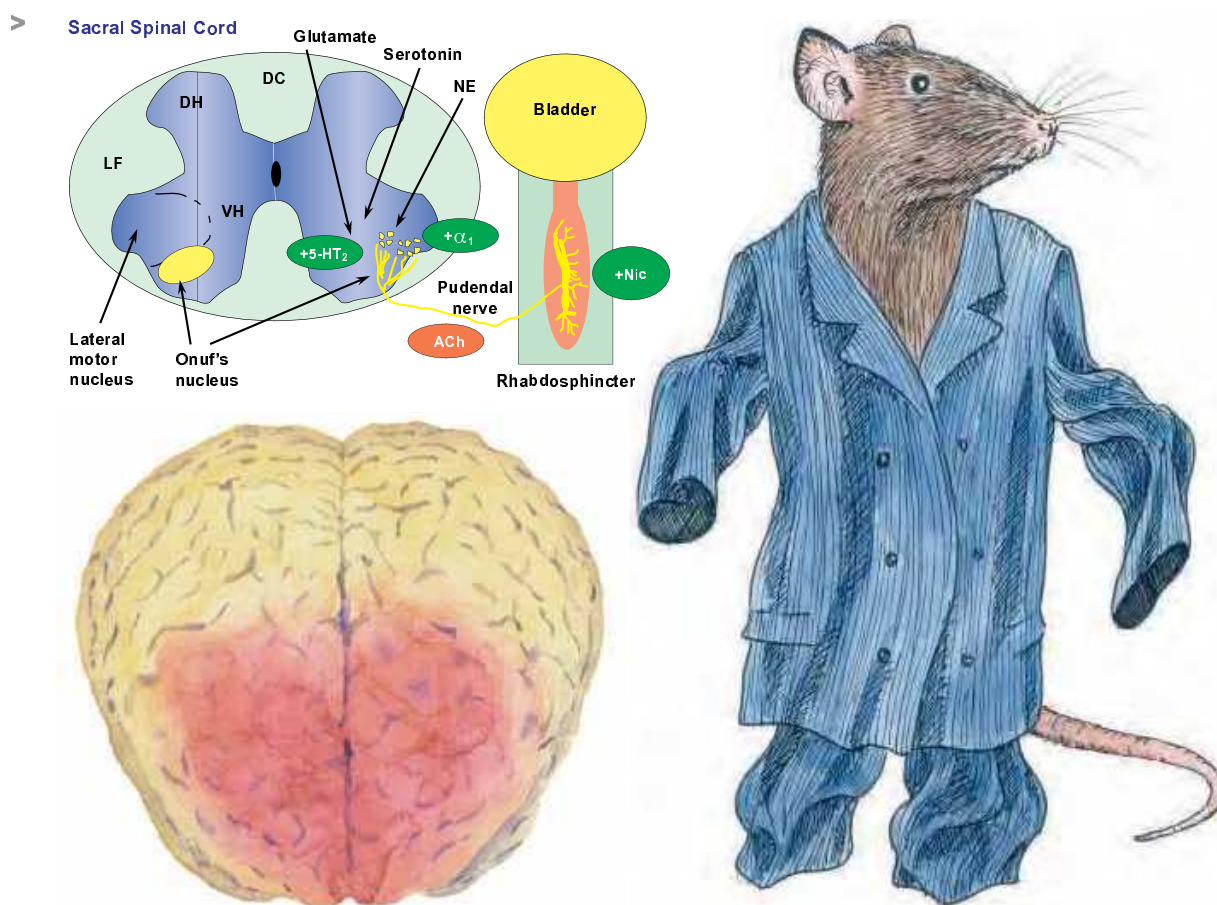
### Ad hoc partnerships

“Ok, sounds fair enough, but I’m not interested in these sorts of things—I prefer to focus my time and effort on medical writing, as this is what I specialise in”, you might think. Point taken—there’s no need to abandon what you’re good at. But allow yourself to consider teaming up with a partner who can assist you with the other bits. Being a freelance medical writer is often hard, lonely work. Exchanging thoughts and ideas with another person from a slight different field may generate fruitful discussions and ideas. Here I speak from experience—I have worked in this way for a long time, and oddly enough, there have been times when I, the graphic designer, have come up with a suitable headline, whilst the writer has had a clever idea for a smashing illustration! The beauty of working in these ad hoc partnerships is that you retain all the advantages of working on your own, whilst at the same time you are able to reap the benefits of being part of a well-established professional team. Not everyone is thrilled by the thought of procuring these services from the graphic designer—should this be the case, it is perfectly feasible for the two of you to invoice your client separately, thus removing the risk-taking aspect of forging a new business relationship and allowing you to proceed with the commissioned writing work with complete confidence.

Let me conclude by illustrating this type of collaboration based on my own experience. Once the medical writer and myself have been commissioned to produce a report or



## Expanding your market by involving graphic design



Illustrations such as these from the areas of urology, neuroscience and genetics (the mouse represents similarities between the human and mouse genome) will enhance the presentation of a text and promote the delivery of key messages

newsletter from a symposium or conference things usually proceed as follows: we attend the congress/symposium together; I take pictures of the slide shows, the lecturers, various posters etc, whereas my medical writer colleague records the sessions using audiotape, takes notes and makes any speaker interviews required. Back home in our respective offices (which may be in different countries), we collate everything into a brochure of typically 8-16 pages (although this will of course be customised to the client's requirements). My medical writer colleague prepares the copy (with the help of audio recordings and my photographed slides) and I do the layout, the graphs and any other illustrations and photos. Following copy approval and final sign-off from the client, I attend to things like printing and delivery. Feedback from a long line of pharmaceutical clients in a range of therapeutic areas supports my notion that this way of working provides the client with the major advantage of getting the whole package in one hit: text, photos, accurate graphs and references in a design and format that is fit for its purpose, without the additional hassle of commissioning and managing a full agency.

### Benefits of 'the whole package'

To be even more specific—what did our last client gain from working with us? Well, in my view, the ad hoc

team of myself and an experienced medical writer with specialist knowledge in the therapeutic area concerned was able to deliver a professionally written report from an international conference, to an extremely tight deadline and—from the client's point of view—a very limited budget, and with a minimum of admin and overheads for ourselves.

I suggest that you as a freelance medical writer ask yourself if one or more of your clients might benefit from working with not only an experienced writer, but with a tight team capable of offering 'the whole package', including texts, graphs, illustrations, an appealing layout, and the project management involved as well. Sometimes the whole is indeed greater than the sum of the parts. And the fun you have along the way is for free!

### Acknowledgements

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### Anders Holmqvist

*Art director, illustrator, photographer, project manager (freelance)*  
Holmqvist AD & Bild  
Lund, Sweden  
adobild@yahoo.se



## Managing projects outside the traditional medical writing area

by Alison Rapley

In recent years the role of the medical writer has extended significantly. Writers are increasingly responsible for complex projects where medical writing is only part of the work required and where there is no existing guidance or template available. This type of project requires significant forward planning and project management. Our medical writing group were recently asked to carry out one such project. In this article I would like to share some of the details of that project and provide some tips for ensuring a successful outcome to projects such as these.

The request was prompted by the new labelling requirements brought in by the FDA in 2006<sup>1</sup>. The safety section of this labelling is required to discuss only information useful to health care practitioners making treatment decisions and monitoring and advising patients. Exhaustive lists of every adverse event (AE) must be avoided. We were approached by a client with a large number of established products that required updated labelling to provide details of suspected adverse drug reactions (ADRs) rather than all AEs. These were old products, many approved over 40 years ago, some bought in from other companies. For a number of the products, no safety databases were available. The only available information was the clinical study reports (CSRs) and so a systematic method of determining ADRs from CSRs was needed.

This task was a team effort including project managers, medical writers, drug safety physicians, and data managers. The first step was to obtain the original CSRs for those products. In some cases the reports were available electronically, in other cases we had to dearchive the material and trawl through cardboard boxes to obtain hard copies of the reports, which were then scanned.

The next step was to determine which studies should be included in the review of safety data. We based this on a standard set of criteria to ensure that we included only studies of formulations that were still marketed and where the population and indication were for a current labelled use. Further information that could impact on the safety profile, such as age range, formulation, and dose, and key aspects of the text, were then extracted and documented in a spreadsheet. Once the studies to be included had been

confirmed, all the AE terms mentioned in each CSR were reviewed and recoded to MedDRA.

Following recoding, AE frequency tables were created for each individual study and overall in order to provide incidence rates. The drug safety physician then reviewed the terms to determine which should be included as ADRs. This was done using selected criteria from the 39 relevant threshold criteria identified by CIOMS III. These criteria identify the factors or criteria that are useful in determining the threshold for adding an AE to the Company Core Safety Information (CCSI) and include criteria such as “recognised class effect of the drug”, “relative increase in frequency in the treated group compared with placebo group”<sup>2</sup>. The medical writer then used this assessment to create clinical ADR tables as required by the FDA<sup>3</sup> and prepared the summary document to justify any label change.

So what would I recommend for those of you asked to take on similar ‘unusual’ projects?

### 1. Agree realistic timelines and identify areas where timelines are critical

For this project there were over 40 products that needed to have the safety data reviewed and updated. The original timelines for completion were soon seen to be over ambitious. The same team members were involved with a number of products and could not work on more than 2 or 3 products at once. The client had underestimated the time their staff would need for review and approval. Identifying and obtaining the original study reports took longer than expected for some products.

Resource implications for all team members (including both client and contractor if the work is outsourced) should be carefully considered at the start of the project. Do not be too ambitious. Determine which, if any, timelines are critical and why. If timelines start to slip, review and adjust the overall timelines of the project rather than asking for extensions at each step. In this case we identified those products with critical regulatory commitments and gave them priority. Work on other projects was adjusted to fit available resource.

1 Guidance for Industry: Labeling for Human Prescription Drug and Biological Products—Implementing the New Content and Format requirements, Jan 2006

2 Guidelines for preparing core clinical safety information on drugs. CIOMS Working groups III and V, CIOMS 1999

3 Guidance for Industry: Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products—Content and Format, Jan 2006

## Managing projects outside the traditional medical writing area

### > 2. Ensure good communication for all the team

Put together a communication plan and make sure that everyone in the team, including both client and contractor if applicable, knows who is responsible for what. Distinguish between communications requiring action and communications providing information. Communications providing information need to go to all the relevant members of the team so that everyone knows what is happening. In contrast communications requiring action need to be sent only to those involved in the action. Addressing an e-mail to the whole team in the hope that you have included the person who is responsible for providing a response is not a good approach. E-mails addressed to two or more people

tend to be answered by everyone causing an unnecessary flurry of e-mails, or by no one, causing delays.

### 3. Agree and clearly document the process, but be flexible

Where you have a large team of people working on a project it is essential that the process is clearly documented to ensure consistency of approach. You cannot depend on word of mouth; however the process must be flexible. For this project, the exact approach for each product has varied depending on the volume of data etc., although the overall process has remained the same.

It is unrealistic to think that you will have the perfect process first time round. Monitor the process and obtain feedback. Do not be afraid to make changes to the process, particularly in the early stages. These will need to be discussed and approved by the project stakeholder and incorporated into the process document to ensure that it is always up to date. Work with one 'current' set of instructions rather than the original process document and endless 'clarifying' e-mails. This will avoid confusion and rework.

### 4. Ensure all your team are fully trained

This should go without saying but it is critical that all the team know what they should be doing. Provide training as soon as a clear process has been finalised and update the training whenever there are significant changes to the process. Make sure everyone has access to all of the documentation and to contact details of other team members so that they can discuss any problems

### 5. Ensure effective storage and access to all required documentation

It is essential in a complex project involving staff in several different countries that all documentation is kept in one place and that all team members have access. This increases efficiency, ensures version control and reduces the amount of e-mail traffic. We did this by the use of a web-based electronic document management system.

### 6. Use the right staff for the right job

This task was a team effort including project managers, medical writers, drug safety physicians, and data managers. Use the most appropriate staff for the job to ensure the quality of the job and also cost effectiveness. Routine extraction of data should not be done by expensive medically qualified staff whereas final decisions on medical issues must have their input.

Hopefully you will find these tips useful when you are next asked to take on a project in an area completely new to you, and they will allow you to show—that we all know already—that the skills of a medical writer equip us to successfully take on tasks outside the traditional medical writing areas of manuscripts and clinical study reports.

#### Definitions box

### Therapeutic index

There is no such thing as a drug without adverse effects. To be useful, a drug must produce its beneficial effects at a dose that does not produce an unacceptable level of adverse effects. In other words the difference between the therapeutic dose and the toxic dose should be large (the former being lower than the latter!) The term therapeutic index expresses the size of this difference. It is usually taken to be the ratio between the toxic dose and the therapeutic dose. In order to standardise how these doses are defined, it is convention to use a term that expresses the potency rather than dose (see Potency *TWS* 2010;19(1):57). The therapeutic index then becomes the ratio between the toxic potency and the therapeutic potency. A common definition of potency for therapeutic effect is  $ED_{50}$  (Effective Dose 50%—the dose that produces half the maximal effect). On the same basis  $TD_{50}$  (Toxic Dose 50%) can be defined as the dose that produces half the maximal toxic effect. The therapeutic index would then be  $TD_{50} \div ED_{50}$ . In reality, it is seldom possible to obtain a true estimate of the  $ED_{50}$  or  $TD_{50}$  in humans, so surrogate values that represent the drug's therapeutic and toxic potencies are usually used to express therapeutic index. For example, the median therapeutic dose (MTD) and the median maximum tolerated dose (MMTD) from Phase II studies. In this case, the therapeutic index would be  $MMTD \div MTD$ . The larger the ratio, the higher the range of therapeutic doses that can be given without unacceptable adverse effects. It is usually the case that higher levels of adverse effects are acceptable for drugs used to treat serious illnesses than for drugs intended for mild illnesses. Anti-cancer drugs therefore tend to have smaller therapeutic indices than drugs for athletes' foot or headache, for example.

**John Carpenter**

*john.carpenter.medcom@btinternet.com*

**Alison Rapley**

*Medical Writing Services Europe  
PAREXEL International  
Farnborough, UK  
Alison.rapley@parexel.com*



## From medical writing to global domination

by Adam Jacobs

My entry to the medical writing profession was never really part of some grand plan. It just happened. I expect it's a familiar story to many *TWS* readers: after starting out on a science career, and deciding that science would be quite fun if it weren't for those pesky labs (something I had been thinking for a while anyway until a little incident involving some phosgene gas and a night in hospital for me and a few of my colleagues made it even more obvious that labs were not necessarily a fun place to be), I sort of drifted into a job in medical writing.

That was not necessarily such a bad thing. It was a fun career to be in. But nonetheless, having realised that I had got there without any kind of plan and that perhaps the rest of my career might benefit from having a bit more pre-specified direction, I began to think about what I wanted to achieve from my career.

And after giving it some thought, I decided that the answer was global domination. I rather liked the idea of becoming some kind of Blofeld-like character, sitting in my hollowed-out volcano<sup>1</sup> and ruling the world. So it was clear that the plan for my next career move should be to take me in that direction.

OK, I'll admit it: medical writing is not the most conventional route to global domination. It would be more usual to go to Evil Criminal Mastermind school first, perhaps then serving an apprenticeship as an orange-boiler-suited henchman on the way, before going for the top job. But I saw no reason why medical writing couldn't be a perfectly valid route into the profession nonetheless.

What was clear, however, was that no matter how much I got promoted in any medical writing job that I had or might conceivably have in the future, that was not going to allow me to achieve my goals. No, to do that, I would need to be running my own business. That way, my career would be limited only by the extent to which I was able to develop the business. It seemed logical to me that running a small business in medical writing would be a more challenging career than simply being a medical writer, and that running a larger business would be more challenging

still. Eventually, once my medical writing business got to the right size, then I should be able to easily change the strategic business direction from medical writing to global domination.

That was the plan. So how did it work out? In the rest of this article I'd like to share with you some of my experiences of growing my medical writing business.

I left a salaried medical writing job in 1999 to work as a freelance medical writer. That was a slightly scary thing to do, as any of the many *TWS* readers who have made a similar move will appreciate. But only slightly scary. As a lone freelance writer working from home, my business outgoings were almost nil, and Carolyn's salary was just about enough to pay the mortgage and allow us to eat even if I failed to bring in any income at all, so it seemed like nothing too bad could happen. As it turned out, I found enough freelance work to keep me busy, and I felt like I'd made a good move. After 2 years of working by myself, I had enough work coming in from regular clients that I was able to contemplate my first move towards expanding the business and taking on a medical writer to work for me.

Taking on my first employee was considerably more scary than my initial move to freelance working. I needed to move into an office, so suddenly I went from having no

outgoings to having to pay the rent on the office as well as pay a salary each month.

That was a serious commitment, and I had to be sure

I would keep enough work coming in to pay for it. But,

***Then I realised the road to global domination might not run smoothly***

if I was serious about global domination, it had to be done. It was also not easy to find a good medical writer to work for me. Working in a company where it's just you and the boss is not everyone's cup of tea, and I had to interview a good few candidates before I found the right match. But in the end I was very lucky to find Shanida Nataraja, whom many *TWS* readers will now know as EMWA's web manager. Shanida worked for me for the next 4 years, until 2005, and her hard work and support in that critical period of my company's development was invaluable in helping to build the business.

To rewind a little, back to 2000, I had always been aware ever since I started in medical writing of how important an understanding of statistics is to being a good medical writer. So I decided to study part-time for an MSc in medical statistics. ➤

<sup>1</sup> Just in case anyone who has been caught up in recent travel disruption is wondering, it wasn't me who's been hollowing out that volcano in Iceland. Honest.

## From medical writing to global domination

➤ That, I reasoned, would make me a better medical writer. In fact, that's not quite how it worked out. Although my improved understanding of statistics was a huge help in many of the medical writing projects I worked on, once my clients discovered I was a qualified statistician I began to find my services as a statistician much in demand, and I had less time to spend on medical writing.

So, by about 2002, once I'd finished my statistics MSc, my company's services had expanded from being simply medical writing to including statistical consultancy and analysis as well. This led in turn to another major development in the company's growth. Some time in 2003, one of our clients to whom we were already providing statistical services for a clinical trial asked if we could do the data management for the trial as well. At the time, we had no systems in place for clinical data management, but it seemed to me that it would be a logical service for us to provide to complement our statistics and medical writing services, and something other clients could well ask for in the future. "How hard could it be?", I thought, and agreed to the client's request. Over the following year or two, I discovered the answer to that question. It was "[expletive deleted] hard".

Having ruled out using one of the commercially available hard-core clinical data management software packages on the grounds of cost, I proceeded to construct my own clinical data management system out of Microsoft Access and bits of sticky-backed plastic. I had, in a moment of spectacularly extreme naivety, thought this might take me a few weeks to complete. In fact, it took a little over a year. Making sure that everything was sufficiently robust and validated to be suitable for use in a GCP-regulated environment was a huge undertaking, and had I realised just how much work it was going to be, I suspect I would never have started on it. However, with hindsight, I am glad that I did, as adding clinical data management to our range of services gave us a much more complete package, allowing us to go all the way from an unruly pile of case report forms to a beautiful clinical study report all by ourselves. Adding this service certainly helped the business to grow:

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***One school of thought  
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not only did the data management work add to our revenue by itself, but it also allowed us to increase the amount of medical writing we were doing, as the vast majority of clients who contracted us to manage and analyse their data wanted us to write the study report as well.

By the end of 2005, things were looking good. We were a team of 5 at that stage: myself, a clinical data manager, and 3 medical writers. We were now providing services in medical writing, statistics, and clinical data management, and had a steady flow of work coming in from some delightful clients. By the end of 2006, as we contemplated expanding further, I realised that the business centre that had been our home (in ever increasing sizes of office suites) since 2001 was now no longer the most suitable premises for our needs, and it would make more sense to look for a larger self-contained office space.

This was the point at which I first realised that the road to global domination might not always run smoothly.

As I was viewing potential offices, I saw one office that looked good on paper. It was in a convenient location, about the right size for us, and had a suitably modest rent. However, when I saw it I found that very little of the space had any natural daylight, and decided it would be too gloomy to be a pleasant working environment. When I came home from work that day and told Carolyn about the office I had seen and rejected, she pointed out that my plans to occupy a hollowed-out volcano were never likely to amount to much if I was going to insist on natural daylight.

Anyway, we found a more suitable office, on a 5-year lease, and moved in at the beginning of 2007, so that was something I wouldn't have to worry about again for a while. During 2007 the business grew quickly. We started the year as 5 of us, and ended the year as 10 of us, having added 2 more medical writers, a statistician, and 2 administrative staff to the team. That doubling in size in the space of a year resulted in a significant change in the internal dynamics of the company, and I found it quite challenging to adapt to the larger company. Many ways of working that work well for a team of 5 start to break down in a team of 10. Luckily, my initial good fortune when I recruited Shanida at the beginning of my time as an employer had continued, and I was greatly aided in this challenge by having a brilliant team working for me who were all committed to ensuring that the company continued to be successful.

So I made a conscious decision not to expand the company further during 2008 (apart from taking on another clinical data manager in December), and instead to have a period of consolidation to make sure that all our systems and processes were working well in the larger size company we had become. The plan was then to continue expanding the company in 2009.

The best laid plans of mice and medical writers, however, don't always work out as intended. 2009 turned out not be a good year for growth, but rather a year that saw the



photo: Nadja Meiser



worst economic recession since the 1930s. We were not immune from this, and although the medical writing side of the business held up quite well, the data management and statistics side of the business suffered from a worrying reduction in volume, and for the first time ever, we made a financial loss for the year as a whole.

There is a school of thought that says recessions are good for businesses, as they force them to adapt and become stronger. I can now see why. One thing that became clear was that we couldn't really justify having 2 administrative staff in a company of our size, and although making people redundant shortly before Christmas was undoubtedly the most painful thing I have had to do in the 11 years I have been in business, there is no doubt it was necessary. I have also been forced to take a step back from day-to-day matters and think more about our business strategy, which I probably should have done far sooner, but always managed to put off when times were good and we were constantly busy working for clients. In the long run, that is certain to be beneficial.

So, as we go into 2010, things are starting to look more promising. We have more work coming in than we did this time last year, and I am hopeful that the worst of economic times are now behind us and we can resume our growth.

Will that growth still lead to global domination? Actually, I no longer think it will. My priorities have changed since 1999. I thoroughly enjoy running a relatively small team, where I know all my staff well. By far the best thing about running my own company is that I have been incredibly fortunate to be able to recruit such a fantastic team of supremely talented people. I don't want to become remote from that and lose the satisfaction of seeing at first hand the work that truly first-class medical writers do. I would like to continue to grow the company, for sure, but not by very much. Right now, I feel it would be nice to be running a company of maybe double the size of the 10 of us that we are currently. But not much larger. I doubt I could maintain that sense of team spirit in a larger company.

One day, I shall sell Dianthus Medical to new owners, who probably will grow the company further. That day is not imminent: I'm having far too much fun for that. Whether it will be when I retire or sometime before then to give me a chance to do something else in my career is a decision I shall make another day.

So, even though I have abandoned—for now, at least—the idea of global domination, I am still sure that setting up my own company was the right decision. It hasn't always been easy, and as with any job, there are days when I just want the ground to open up and swallow me. But it has certainly provided me with a career that has been both challenging and rewarding. Really, who needs global domination?

#### **Adam Jacobs**

*Dianthus Medical Limited*  
London, UK  
ajacobs@dianthus.co.uk  
www.dianthus.co.uk

## From medical writing to global domination



## **The Write Stuff and the Japanese Journal of Medical English Education**

*The Write Stuff* is delighted to announce that it has entered into a cooperation with *The Journal of Medical English Education* published by JASMEE (the Japanese Society for Medical English Education) whereby each journal may re-print up to two papers published in any issue of the other journal. The re-printed version will clearly state the original publication and the name(s) of the author(s).

This cooperation between our two journals, which have mutual interests in promoting high quality medical English but target different audiences, will strengthen EMWA's ties with Japan.

### **About JASMEE**

JASMEE was established 13 years ago with the aim of raising the standards of English in the medical professions in Japan. The society holds an annual conference in July and publishes *The Journal of Medical English Education* two times a year. The journal is a peer-reviewed academic journal, and most of the papers are devoted to the subject of teaching English for Medical Purposes (EMP) and practicing it.

The journal is bi-lingual in English and Japanese and the contents are posted on the home page at <http://www.medicalview.co.jp/JASMEE/journal.shtml>. Non-members who wish to read a paper can do so by purchasing it.

The society also administers the Examination of Proficiency in English for Medical Purposes which is carried out once a year for people in the medical and related professions.

# Crossing the thin line between paraphrasing without citation and plagiarism: The Sticklen retraction

by Karen Shashok

An invited review article published in *Nature Reviews Genetics* (*NRG*) in 2008 was retracted earlier this year [1–3]—an uncomfortable first for journals in the Nature Reviews group. The reason given was “a paragraph being paraphrased without attribution”. Despite this sensitive wording, investigation by the author’s institution based in part on manuscript records provided by *NRG* and *Plant Science*, a smaller, more specialized journal, found that plagiarism had occurred. The case was controversial because the copying involved heavy paraphrasing of text that reported a combination of previously published research and original ideas.

Mariam B. Sticklen, author of the retracted article, used material from a *Plant Science* manuscript which she reviewed for that journal—without advising the editor that she was preparing a review herself on a similar topic. Peer review and revision of the plagiarized article, published in *Plant Science* in February 2010, took longer than for the *NRG* article. Moreover, *Plant Science* delayed the publication of their review to await the outcome of the investigation by Sticklen’s university [4]. Hence the backwards publication sequence and the gap between publication dates of the two articles.

When the *NRG* review was published, the authors of the *Plant Science* article noticed suspicious similarities to their own paper, still under revision at the time. The authors of the plagiarized paper—also an invited review—advised Jonathan Gressel, reviews editor of *Plant Science*, of the similarities between the *NRG* article and their own, which contained a novel synthesis of original and previously published information regarding a transgenic mechanism with potential applications in the biofuel industry. They asked Gressel whether Sticklen had peer reviewed their manuscript.

The editor of *Plant Science* agreed to investigate but wisely refrained at that time from confirming the identity of the reviewer. Gressel promised to look into the matter if the whistleblower sent him “a detailed side by side comparison” of the texts. When he received this material he found that “the irksome paragraph was indeed almost identical in both papers except that two literature citations in Dr Sticklen’s paper were changed to ones that were totally irrelevant to the subject”. He felt that “this was a sign that indeed there was an issue of plagiarism, especially intellectual plagiarism where a well known important scientist abused the confidentiality that reviewers accept in return for anonymity” [J Gressel, personal communication, April 2010].

At the request of Sticklen’s home institution, Michigan State University (MSU), Gressel and Louisa Flintoft,

handling editor at *NRG*, submitted evidence from both journals’ editorial records. The university’s investigation found Sticklen guilty of misconduct. In her defense, Sticklen—now on medical leave—noted that the misattribution was inadvertent and occurred because of a medical condition that impaired her memory and cognition [2]. It is unclear whether she intended to blame the illness itself [2] or the effects of treatment [5] for the misattributed material and incorrect references. She apparently maintains that her medical condition should have exonerated her and that she did no wrong [2,5].

However, Sticklen’s conflict of interest might have influenced her citation behavior. When she reviewed the *Plant Science* manuscript, she suggested, according to Gressel, that “there are already too many reviews in that area” and that “perhaps this should not be published to avoid duplication” [J Gressel, personal communication, April 2010]. This suggestion could not have been inadvertent since at that time she was preparing her own review article for *NRG*.

Some felt that the wording of the retraction statement was more lenient than circumstances justified. The copied information was added “during the final stages of revision at *NRG*” [2], so this change, along with the switch in the references, was also unlikely to be inadvertent. If the changes were made after peer review at *NRG* had concluded, this may explain why nobody at *NRG* detected the questionable references before publication.

From where I sit, Sticklen’s actions seem unlikely to be due to inadvertent error or a mix-up in her index cards—an explanation she provided to The Scientist [2]—but instead suggest she 1) had a conflict of interest (her own invited review article in preparation) which she did not divulge to the editor of *Plant Science*, 2) intended to credit herself for material and insights taken from another source, 3) tried to disguise the origin of the copied material by replacing original references with irrelevant references, and 4) tried to game the peer review process to her own benefit by suggesting that the *Plant Science* review article did not need to be published.

Using novel information from a manuscript obtained through confidential review is wrong, but peer reviewers may be tempted to try it because the advantages to their career are potentially substantial, especially in applied research areas that involve patents, royalties and glory for authors and their institutions. Peer reviewers can escape being held accountable for ethical abuses if they remain anonymous. Sticklen’s behavior, fortunately, was investigated and as a result she has been disqualified from receiving university research funds or salary increases for two years

## Crossing the thin line between paraphrasing without citation and plagiarism...

[5]. To his credit, Jonathan Gressel at *Plant Science* decided to follow up when the plagiarized authors blew the whistle. To her credit, Louisa Flintoft at *NRG* went on the record as concurring with Gressel's interpretation of the events: "A novel idea, not simply a restatement of previously published ideas, was not credited to the source. Furthermore, the idea was obtained by breaching the confidentiality of the peer review process" [6]. Given the difficulty of deciding whether a synthesis of previously published ideas from a review article can be plagiarized or not, how many editors would have simply washed their hands of the matter?

I thank Lawrence B Ebert, Jonathan Gressel, Elise Langdon-Neuner and Liz Wager for e-mail conversations that stimulated some of my interpretations of this case.

**Karen Shashok**

Translator and Editorial consultant  
kshashok@kshashok.com

## Clinical trial disclosure in the European Union—Update

Over the past few years, public disclosure of information on clinical study protocols of *planned* clinical studies (registration) and on *completed* study results (results disclosure) has attracted strong interest worldwide, from stakeholders involved in planning, performing, and evaluating such studies [1-3]. In the European Union (EU), two European Community (EC) regulations govern the public access to such information; they are enforced by the European Medicines Agency (EMA) and are summarized below.

Two lists of the data fields that will be made public through European Union Drug Regulating Authorities Clinical Trials (EudraCT) were finalized in February 2009 [4,5]. Although most of the information that will eventually be made public is already at EMA, the technical aspects of transitioning to a public database are proving to be a challenge. According to the latest information from the EMA, public access to *protocol-related information* through EudraCT is scheduled for July 2010. Access to *results-related information* for completed clinical studies will follow in 2011.

### Article 41 of Regulation (EC) No 1901/2006 (specifically for pediatric trials)

- Applies to *all pediatric trials within EU* and third country trials if these countries are part of Pediatric Investigation Plan (PIP)
- Protocol-related information at time of trial authorisation
  - Submitted by the sponsor of the study at the time of application to EMA
  - Required fields of information will be made public at the time of clinical trial authorisation/refusal
  - Data entry by National Competent Authority (NCA) for EU trials and by Marketing Authorisation Holder, Sponsor, or PIP addressee via European Medicines Agency for non-EU trials

### References:

1. Sticklen MB. Retraction, Plant genetic engineering for biofuel production: towards affordable cellulosic ethanol. *Nature Reviews Genetics* 11, 308 | doi:10.1038/nrg2777. Available from: <http://www.nature.com/nrg/journal/v11/n4/full/nrg2777.html>. Accessed 28 April 2010.
2. Grant B. Plagiarism retracts review. Entry posted at 1<sup>st</sup> April 2010 03:37 PM GMT. *The Scientist*. Available from: <http://www.the-scientist.com/blog/display/57267/>. Accessed 28 April 2010.
3. Ebert LB. Plagiarism by Michigan State professor. IPBiz. Intellectual property news affecting business and everyday life. Blog posting. Available from: <http://ipbiz.blogspot.com/2010/04/plagiarism-by-michigan-state-professor.html>. Accessed 28 April 2010.
4. Gressel J. Note from review editor of *Plant Science*. Comment posted 2010-04-02 00:18:53. In Grant B. Plagiarism retracts review. *The Scientist*. Available from: <http://www.the-scientist.com/blog/display/57267/>. Accessed 28 April 2010.
5. Miller M. MSU professor retracts article over plagiarism. Available from: <http://www.lansingstatejournal.com/article/20100407/NEWS06/4070324/MSU-professor-retracts-article-over-plagiarism>. Accessed 28 April 2010.
6. Flintoft L. Response from *Nature Reviews Genetics*. Comment posted 2010-04-07 08:40:46. In Grant B. Plagiarism retracts review. *The Scientist*. Available from: <http://www.the-scientist.com/blog/display/57267/>. Accessed 28 April 2010.

- Results-related information
  - Data entry by Marketing Authorization Holder, Sponsor, or PIP addressee via EMA
  - Submission of results *within 6 months* of completion of trials
  - Made public immediately after submission

### Article 57(2) of Regulation (EC) No 726/2004 (all trials)

- Applies to *all clinical trials* contained in EudraCT with the *exception of Phase I* trials, including trials of products without a marketing authorisation
- Protocol-related information
  - Submitted by sponsor, at the time of the clinical trial application trial authorisation, entered by NCAs
  - Made public at the time of the clinical trial authorisation
- Results-related information
  - Submission of results *within 1 year of the end of the trial*, via EMA
  - Made public immediately after submission

**Kathy B. Thomas**

Medical & Scientific Writer  
Medical & Scientific Writing  
& Publication Services  
Meersburg, Germany  
kathy-b.thomas@t-online.de

**Kelly Goodwin Burri**

Medical Communications Manager  
CSL Behring  
Bern, Switzerland  
Kelly.Goodwin@cslobehring.com

### References:

1. Thomas KB, Tesch C. Clinical trial disclosure: the ongoing debate on public registers for clinical trials. *The Write Stuff* 2007; 16:67-72.
2. Thomas KB, Tesch C. Clinical trial disclosure: focusing on results. *The Write Stuff* 2008; 17:70-73.
3. Thomas KB, Joergensen M, Lynch G, Rubison M, Porter BD, Sayers J, Tesch C. 2010; Clinical trial disclosure: global overview and implications on new laws and guidelines. *Drug Information Journal* 44:213-225.
4. European Medicines Agency. "List of fields to be made public from EudraCT for paediatric clinical trials in accordance with Article 41 of Regulation (EC) NO 1901/2006 and its implementing guideline 2009/C28/01." ([http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-10/2009\\_02\\_04\\_guidelines\\_paed\\_en.pdf](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-10/2009_02_04_guidelines_paed_en.pdf))
5. European Medicines Agency. "List of fields contained in the 'EudraCT' clinical trials database to be made public, in accordance with Article 57(2) of Regulation (EC) NO 726/2004 and its implementing guideline 2008/C168/02." ([http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-10/2009\\_02\\_04\\_guideline\\_en.pdf](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/eudralex/vol-10/2009_02_04_guideline_en.pdf))



## Everything has its place: Word order in English

by Alistair Reeves

One of the many claims made about English is that its word order is more flexible than in other languages, and this is supposed to make it 'easy'. I have been working with English and several other languages from different language groups for nearly 40 years, and I cannot confirm, in my empirical experience, that word order in English is more flexible. It is certainly different—but that is not surprising because word order in any language has its peculiarities. In some respects, English is less flexible than other languages. For example, we cannot start a sentence with the indirect object, and it is very unusual to start a sentence with the object, complement or with an adjective as a subject (unless used lyrically, jocularly or ironically)—both are normal in other languages (more later). It is also much more frequent and natural in other languages to start sentences with prepositional, adverbial and long noun phrases or subordinate clauses, which sometimes sounds strange in written English and can be very irritating for readers. In our field, where we often have no alternative but to write long(ish) sentences, particular attention has to be paid to the order of words and sentence elements that the reader expects.

So what are the rules about word order in English? Well, as usual, there aren't many *rules*, and we do have some sentence elements that can appear almost anywhere, sometimes changing the meaning completely, sometimes with little effect on meaning. As usual, speaking is different from writing. Without delving too deeply into grammar, I will be giving you some guidance on word order in written English in this series. I start here with expected word order in sentences where you don't wish to stress anything, followed by a few words on the position of adjectives. Then I'll be looking at the problems you can get into by starting your sentence with a subordinate clause and adverbial elements—one of the most common problems I come across. This is usually because of interference from the author's first language, because starting sentences with such elements is more acceptable in languages other than English, and is often considered good style. But this is also a problem for native speakers of English, particularly when several ideas of time, manner and place have to be accommodated in a sentence.

### Unstressed sentences with expected word order

Let's start with what I call the 'sentence with unstressed word order' in English; by that I mean the 'natural' word

order you would choose when you don't want to stress any element of a sentence using its position. There is no doubt that the basic unstressed word order in English expected by the reader is subject–verb–object/complement or agent.

### Simple sentences

[1] Active voice

Subject (S)	Verb (V)	Object (O)
The man	damaged	the car

'SVO' is the first set of letters to remember in unstressed word order in English in the active voice.

Indeed, for simple sentences in the active voice, it is the *only* word order we can use. I stated above that we cannot start sentences in English with the object. We cannot, for example say *The car damaged the man* when we mean that the man damaged the car, as is possible in other languages. It is possible in such languages because *the car* is identified as the object by an accusative article or an accusative ending on the noun (neither of which we have in English: *the* is invariable and none of our nouns inflect except in the plural). Inversion of this sort in other languages may be done to achieve stress, but is often just one of the expected ways you say things. If we want to introduce stress in English, we have to be more radical by introducing a dummy subject (e.g. *it*), perhaps also a relative pronoun (*that* or *who*), and a more complex structure: *It was the (that) car that the man damaged* to stress the car, or *It was the man who damaged the car* to stress the man.

Or, if we want to remain neutral, we choose the passive voice [2], and again, this is the only order we can choose:

[2] Passive voice

Subject (S)	Sentence (V)	Prepositional phrase with adverbial function modifying the sentence; the agent (A)
The car	was damaged	by the man

The subject of a passive sentence is not the person or the thing that appears to have acted in the sentence, it is the subject of the verb 'to be' used in the sentence, in this case the car. If it is important who damaged the car, *by the man* is added, and *the man* becomes the agent of the sentence in a prepositional phrase (begins with a preposition) which is also an adverbial phrase because it modifies the meaning of the sentence.

## Everything has its place: Word order in English

‘SV(A)’ is therefore the second set of letters to remember in unstressed word order in English in the passive sentence. The A is in brackets because sometime you may need or want to mention the agent, but often it will be unimportant.

When we are reporting on methods or results in our texts, the agent is often completely unimportant to the reader. It just doesn’t matter who gave the injection, as long as it was given, or who calculated the value, as long as it was calculated, or who approved the drug, as long as it was approved. This is one reason why the passive is often the most appropriate voice in your clinical study report for reporting on methods, amendments and results.

### Complex sentences

In our field, sentences are often complex, so let’s move on to the complicating factors manner, place and time, again in unstressed sentences. These three complicating factors are ‘how’ we do something (manner or M), ‘where’ we do something (place or P), and ‘when’ we do something (time or T). Some languages have fixed places for these concepts in sentences after the subject and verb, and if they are not in these places, it is wrong. Also, these ideas often appear before the subject, but not because the author wanted to stress them, just to bring in some variety regarded as good style.

You will be aware that there is no *rule* for the position of these ideas in English, but as with SVO, there is an expected order in the unstressed sentence. The unstressed sentence always starts with the subject, but as you see from [3], M may come between the subject and the verb, and is also often after the object. This is very unusual in German, for example, where the verb is most often the second idea in the sentence regardless of what starts the sentence (and this can be an adjective in German!). In [4], it is after the composite (passive) verb (*was applied*) but can also come between the auxiliary verb and the past participle (*was gently applied*), with no change in meaning. The important thing is that M and P in a sentence with unstressed word order in English come before T, and that P and T do not precede the subject and verb.

#### [3] Active sentence

Subject	Adverb	Verb	Object	Indirect object	Prepositional phrase modifying indirect object	Adverbial phrase modifying verb
The physician	gently	applied	pressure	at the site	of the lesion	10 minutes later
	<b>Manner</b>			<b>Place</b>		<b>Time</b>

#### [4] Passive sentence

Subject	Verb	Adverb	Indirect object	Prepositional phrase modifying indirect object	Adverbial phrase modifying verb
Pressure	was applied	gently	at the site	of the lesion	10 minutes later
		<b>Manner</b>	<b>Place</b>		<b>Time</b>

So we have the following basic patterns to remember: SVO-MPT or -PMT for the active voice and SV(A)-MPT or -PMT for the passive voice.

Most deviations from these patterns in English in our type of text will be because of stress on M, P or T, or logical grouping of parts of sentences to maintain sense, or

because these ideas appear in separate clauses. They will not be to ‘vary things to make the text more interesting’ or because ‘it is good style to do so’.

### Other basic word order considerations

#### Reader expectations

Readers of English, whether native-speakers or not, like an (easily identifiable) subject at or near the beginning of the sentence followed closely by its verb. Otherwise, they soon become frustrated and disturbed. Why? One reason is that they have to backtrack. So what do ‘near’ and ‘closely’ mean? These may seem complex ideas, but they are well illustrated by the examples below.

In our types of text, ‘near’ means:

- One short M, P or T phrase may precede the subject without disturbing the reader:
  - [5a] *10 minutes later, pressure was applied gently at the site of the lesion*
  - [5b] **Not acceptable:** *During the planning of this multicentre, randomized, placebo-controlled, parallel-group study stratified according to KPS and patient age at entry conducted at 61 centres in 7 countries in North-Western Europe, several modifications were ...*
- A T and an M phrase, or a combined P and T phrase, for example, can also precede the subject without disturbing the reader if they are both very short [6a], or are combined in one phrase [6b]:
  - [6a] *In June 2009, after validation was complete, the questionnaire was released*
  - [6b] *At the London Conference in December, we presented ...*
- If you start a sentence with a subordinate clause (part of a sentence with its own subject and verb), the subject of the main clause must come immediately after the end of the subordinate clause:
  - [7a] *Although all adults enrolled were eligible, 22/212 adolescents had to be excluded because ...*
  - [7b] **Not acceptable:** *Although all adults enrolled were eligible, because they had no baseline FEV<sub>1</sub> value in the CRF and this was unavailable in the source documentation, 22/212 adolescents ...*



## Everything has its place: Word order in English

### > And 'closely' means:

- If you start a sentence with the subject of a main clause and follow this immediately with a subordinate clause, the subordinate clause should not be longer than about half a line, and the verb of the subject of the main clause must follow the subordinate clause immediately. The verb could be preceded by an adverb, e.g. *quickly* in [8].
- [8] *The government, once it had realized that a 100% ban was unrealistic, lifted restrictions on ...*
- If you have a long compound subject (which you often cannot avoid), nothing should be placed between the subject and the verb.
- [9] *Regulation 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) as amended by Statutory Instrument 2006/1928 (subject of sentence) contains a requirement for the notification of 'serious breaches' of GCP or the trial protocol to the MHRA.*

In our type of writing, native English-speaking writers spontaneously use the SVO or SV(A) structure in 80% of the sentences they write<sup>1</sup>. This is much more frequently than in German, for example, where the spontaneous occurrence of SVO or SV(A) is about 50%<sup>2</sup>. Readers, including those whose first language is not English, also expect this order more frequently in English, because this is what they become familiar with. Frequent deviation from SVO/SV(A)-MPT is irritating for the reader, disturbs reading flow, and makes readers wonder why the author is doing it.

The simplicity of SVO(SV[A])-MPT when speaking and the absence of cases and inflection are what have given English its reputation of being 'easy'. You can get through life in most situations with about 400 words in English and SVO or SV(A) plus simple use of M, P and T, the position of P and M often being interchangeable: *We went down-town by bus yesterday* or *We got there really quickly by car before 2 o'clock*. But it is different when you write.

### Adjectives as modifiers before nouns

A few words about the position of noun modifiers and adjectives in English, because word order here is also basically always expected. These are simple (*high*, *mild*) or compound (*exceedingly high*, *mild-to-moderate*) adjectives, colours, numbers or adjectival nouns (the word *patient* in *patient diary*), and come before the noun, unlike French, but like German. From recent studies of Italian, I gather there is no usual position, which must make life complicated. But I bet that there are plenty of collocations that 'just sound right'. Adjectival position is usually not

a problem in English, but I mention it because there are exceptions.

If a modifier comes after a noun in English, it often has a different meaning from the same modifier used before a noun, and such modifiers are often past participles: *The tubes used held 100 mL; Used tubes were discarded. The methods involved are easy; He described a very involved method*. I will be looking at this in more detail in the next article, because the past participle is often positioned incorrectly by continental European authors (or is superfluous). And is it really an adjective when it follows the noun?

Further exceptions are the lyrical use of modifiers (... *new broils in stronds afar remote* ... [Shakespeare, Henry IV 1]), which is of no consequence for us, and fixed phrases (*lords temporal*, *letters patent*), which are also rare in our types of text.

### Deviating from expected word order

Any deviation from expected word order should be a conscious decision and should not be done to vary the text to make it more interesting or to observe style conventions as in languages other than English.

#### Simple deviations

Using example [3], here are illustrations of M, T, and P before the subject:

[10a] M: *Gently, pressure was applied at the site of the lesion 10 minutes later.*

[10b] P: *At the site of the lesion, pressure was applied gently 10 minutes later*

[10c] T: *10 minutes later, pressure was applied gently to the site of the lesion*

In all cases, the context should require deviation from unstressed word order. For example, in [10a], the previous sentence might have stated that something had been done rapidly or vigorously, and positioning *gently* at the beginning says 'but we did THIS gently', or [10b] might have been preceded by references to other body sites, and positioning *at the site of the lesion* at the beginning signals to the reader 'Now I'm back to talking about the lesion itself'.

One of the most frequent deviations I see in texts by non-native speakers is to start the sentence with the time idea, as in [10c]. This adds importance to the time idea, because its usual position in English is at the end. But if the previous sentence said 'Heat was applied after 5 minutes' you might want to pull forward the idea of '10 minutes later' to add some stress. With longer sentences, as we shall see later, it can be useful to bring the time idea upfront even if you don't want to add stress, especially if other adverbials have to be accommodated.

Further examples with the time idea upfront:

[11a] *At baseline, spirometry according to the current ATS/ERS recommendations was performed.*

<sup>1</sup> My empirical count in randomly selected clinical study reports at three different times in one year of how frequently 6 native English-speaking colleagues (British, US American and Canadian) used the SVO structure for sentences with S at the beginning of the sentence.

<sup>2</sup> Counts done by me on articles written in English by German speakers that I edit and rewrite. I also work for other nationalities, and this is a general observation.



## Everything has its place: Word order in English

[11b] *At baseline, however, spirometry according to the current ATS/ERS recommendations had been performed.*

[11a] illustrates that if positioned at the beginning for no particular reason, the time idea often just sounds unusual and awkward. This is also because the verb can only be at the end of the sentence and we are often uncomfortable with this in English if there is no reason. [11b], however, shows that this sounds normal if you wish to stress that this test was conducted at baseline, in this case underlined by 'however', and the verb at the end doesn't feel uncomfortable.

### Complex deviations

The two most frequent word order problems I see are positioning unstressed ideas in phrases or clauses (sometime very long) at the beginning of a sentence and splitting up phrases which belong together. These unstressed ideas are often put into prepositional phrases, other types of adverbial phrase, or adverbial clauses, which just complicate the sentence for the reader—and for you, the author, by the way!

Apart from shifts in meaning (which is not the case in examples [12a–c]), the simplest problem is that more punctuation is often needed when deviating from expected word order by putting a prepositional phrase before the subject:

[12a] *In the adolescent population, the most frequent concomitant disease was acne, and in the adult population(,) hypertension.*

[12b] *The most frequent concomitant disease in the adolescents was acne and in the adults(,) hypertension.*

[12c] *Acne was the most frequent concomitant disease in the adolescents and hypertension in the adults.*

[12a] needs at least 2 commas, [12b] might need one, but [12c] needs none! A great deal of (unnecessary) agonizing goes on over the need for commas in English, so if you choose a formulation that does not need them, you avoid that problem too!

You should carefully examine all sentences that you start with a prepositional phrase to see whether you have a good reason. I will be looking at good reasons for deviation in the next article. If there is not a good reason, you should stick to SVO-MPT.

The first sentence in the previous paragraph illustrates the problem of splitting up phrases which belong together:

[13a] *You should **carefully** examine all sentences that you start with a prepositional phrase to see whether you have a good reason.*

[13b] *You should examine **carefully** all sentences that you start with a prepositional phrase to see whether you have a good reason.*

[13c] *You should examine all sentences that you start with a prepositional phrase **carefully** to see whether you have a good reason.*

[13d] *You should examine all sentences **carefully** to see whether you have a good reason to start with a prepositional phrase.*

[13c] was the first sentence that I wrote (this is how we often speak, but when speaking, speed and intonation usually group the words for the listener). Then I realized that the adverb *carefully* was too far away from the verb it modifies, *examine*, because they are separated by the object (*all sentences* + a defining clause, *that ...*). Even only these few words are enough to weaken the link between the two, but *carefully* cannot be placed between the object and the defining clause. The link is further weakened by the position of *carefully* before the infinitive *to see*. Adverbs often modify infinitives, so in a split second the mind has to test whether *carefully* is linked to *examine*, or whether *carefully to see*, *to carefully see*, or *to see carefully* make sense here. The reader can only backtrack to do this—and one of the basic principles of Good Writing Practice is 'Never make the reader backtrack!'.

I then chose [13b], but some lingering doubt about whether it really is elegant to split a conditional auxiliary (*should*) from the verb with an adverb made me opt for [13a], which sounds like 'normal word order'. On editing this article, I then realized that [13d] is much better and demonstrates that an adverb can be separated from the verb it modifies as long as only one simple element is interposed. With only the object *all sentences* in-between, the link between *examine* and *carefully* is strong enough that the reader has no cause to consider a link between *carefully* and *to see* at all, and—most important—does not have to backtrack.

Another reason why authors often deviate from SVO is because they try to accommodate too much information in one sentence—but sometimes the information you are providing just has to stay together. I will be looking at this and other aspects of word order in the next article.

### Alistair Reeves

*Ascribe Medical Writing and Translation*  
Wiesbaden, Germany  
a.reeves@ascribe.de  
www.ascribe.de



photo: Nadja Meister

## Be careful what you wish for

The Science, Technology, Engineering and Mathematics (STEM) Ambassadors programme in the UK is a government-backed scheme that is intended to inspire children in schools to pursue careers in STEM subject areas. There is a skills shortage in the STEM subjects and so STEM Ambassadors are people like us who volunteer to act as role models to young people, switching their minds to the excitement and potential of STEM subjects and careers.

As a governor of the first school in the village that I live in, I decided to register as a STEM Ambassador and to run a science club for Year 4 (about 9 years of age). I have plenty of experience of training adults but none with children so I knew that I would have a steep learning curve. But preparing the materials was fun and I was excited about running the club.

The Usborne Science Books [1, 2] are full of wonderful experiments using everyday materials. The book of 100 experiments [1] is the most appropriate for children in this age group. The STEM Ambassador scheme also has a link with the British Science Association CREST Star Scheme, which is a UK-wide award scheme that is designed for science clubs, whilst supporting the science curriculum. Unfortunately, to receive the award most appropriate for this age group, the Superstar award, the children would have to complete 12 investigations but we only have time for eight sessions this academic year. Therefore, I used some of the ideas from the CREST Star Scheme to structure each session, and added some fun ideas from the Usborne books. The Superstar award is on hold until next year.

All of you who are parents may now take a moment to gather up your best feelings of being smug as you count the mistakes made by someone who does not have children and has not previously worked with them.

When asked about maximum numbers for the club, I was reluctant to exclude any children who were keen but was also concerned about crowd control. I set the maximum at eight children unless the class teacher would be available to keep order, in which case I could manage more than that. So we settled on 12 with the class teacher present but then there was some confusion over one child and possibly another so I agreed to 14.

We started the first session well, although there was something inevitable about the class teacher being away that day. Fortunately, the mother of one of the children had offered to help and I was not on my own. The children were excited but were well behaved. I had done my preparation well and had one folder per child in which they could keep the various handouts. There were 15 folders because there were going to be 14 children and I had one folder spare. There were 16 children present! Fortunately, the son of the mum who was helping is an easy-going child and he agreed to wait until next week for his folder.

Our first experiment was about bubbles. Each child was given a bottle of commercial bubbles—thankfully, there were 16 of these. I had anticipated that the children would moan and would complain that they had grown out of such baby toys. I was then going to explain to them why bubbles were interesting. There was no need for explanation. They were so excited and thrilled with the bubbles, you might think it was Christmas. Consequently, once they had had a few minutes to mess about with the commercial bubbles and make a lot of noise, it was quite a feat to get them to sit down again so that I could explain about the experiment they were to do. They were provided with measuring jugs, washing up liquid, water, sugar, liquid glucose, golden syrup and glycerine. They were told that a good starting solution was 100 mL washing up liquid plus 400 mL water. This solution was to be divided up, and one teaspoonful of each of the other ingredients added to portions of solution, with one portion kept as a control. There was also a Mystery Solution, which was 1 part washing up liquid, 4 parts water and 1 teaspoonful of glycerine but I had made the solution 2 days earlier. Having researched the subject in depth, I was confident that the mystery solution would produce the best bubbles. The children's task was to find out which of all of the solutions produced the biggest bubbles. They were given worksheets to help them to organise their ideas and results.

Within 5 minutes, the worksheets were saturated. The children who tried to do the experiment properly quickly lost track of which solution contained which sugar. Most of the children decided to mix up all of the sugars in the same pot. The remaining children discovered that if you put washing up liquid and water in an empty bubbles pot and shake it vigorously, the top blows off and foam spurts out.

Getting them to sit down again so that we could discuss our results was impossible (for me). I then handed out 'certificates' that included some information about bubbles plus a star sticker, which was another mistake. The stickers were in different colours so we then had squabbles and sulks about who had which colour sticker.

The children clearly enjoyed their first science club session and said that they wanted it to last for 5 hours but that is longer than my life expectancy. Next week, we will be building bridges out of dry spaghetti and marshmallows—assuming that any marshmallows are left over after the children have eaten enough to make themselves sick. Maybe we'll use plasticine instead.

### Wendy Kingdom

Somerset, UK  
info@wendykingdom.com  
www.wendykingdom.com

### References:

1. Andrews G, Knighton K, Baggott S. 100 Science Experiments. Usborne Publishing Ltd. 2005. ISBN-10: 0746057571. ISBN-13: 978-0746057575.
2. Smith A. Usborne Big Book of Experiments. Usborne Publishing Ltd. 1995. ISBN-10: 0746022883. ISBN-13: 978-0746022887

## In the bookstores ... ■

## Easy to follow practical advice to improve your scientific and medical writing



Janice R. Matthews and Robert W. Matthews. *Successful Scientific Writing: A Step-by-Step Guide for the Biological and Medical Sciences* (3<sup>rd</sup> edition). Cambridge University Press; 2009. ISBN 978-0521699273. £35. 256 pages

The earlier, 2<sup>nd</sup> edition of this book has the distinction of being the first medical writing book I

bought after I became a freelance medical writer in 2000. At the time, I remember reading with great interest and excitement the chapter on “Scientific Writing in the Computer Age” - how old fashioned does that sound now? This new edition of the book is thoroughly revised, rewritten and updated.

What I look for in a book is advice that you can implement in your daily work, and this book is full of nuggets of useful information. It provides practical and helpful suggestions for oral and poster presentations, as well as publications. It is written in an easy, accessible style, and follows a logical structure. There are chapters dedicated to researching, planning, and writing your article as well as interacting with journals. The authors have provided a number of relevant exercises to practice various topics with suggested answers given in an appendix.

Oral presentations are an important aspect of medical communications and often overlooked in medical writing books. In this book the authors have dedicated a large section of one chapter to oral presentations and how to present information in a way that will not alienate and overwhelm your audience. Practical advice includes what font size to use in your slide presentation or how to use colour to differentiate text and backgrounds, as well as suggestion on the best way to lay out slide content. In the section dedicated to giving a talk they also include advice on delivering your presentation and handling questions arising from it.

The book contains enough grammar to keep me interested, but not so much that I am put off! I particularly liked the chapter on improving word choice, style and syntax. In this chapter, the authors provide helpful advice on recognising and minimising jargon. This is something we medical writers need to be on our guard against or we risk being found guilty of writing in a “pseudo-scholarly way.” The authors suggest choosing shorter everyday terms and when employing technical terms ensuring their accurate use. To help, they provide several examples of overused words and phrases with suggested replacements.

This new edition now encompasses the guidelines more seasoned writers have become familiar with but which newer writers may be unaware of, including the ICMJE

guidelines for submitting manuscripts to journals for publication (1). The authors also give helpful advice on other issues pertinent to medical and scientific writing including plagiarism.

By revising and updating this book the authors continue to provide practical and useful information to enhance and improve your medical writing skills.

### Alison McIntosh

Loughborough, UK  
aagmedicalwriting@btinternet.com

### References:

1. Uniform Requirements for Manuscripts Submitted to Biomedical Journals  
<http://www.icmje.org/>

## Can books about writing really improve your writing?



Ann Bless and Ed Hull. *Reader-friendly scientific documents: How to write them!* Van Zuiden Communications B.V., Alphen aan den Rijn, 2005, ISBN 90-8523-095-0 €26.50 Paperback, 93 pages.

Judging by the large number of books on scientific writing, there are plenty of academic authors

who feel the need to improve their writing. Of course, just reading one (or more) of these books won't transform your writing overnight, but (without wanting to sound too much like an agony uncle) the realisation that you can improve is important and they can force you to think about the way you write. I also think that what constitutes good writing is personal, and approaches that work for some might not necessarily work for others. Thus there is no definitive book with the magic formula for good writing, but by absorbing a little here and a little there, you can improve.

So on to the book in question: *Reader friendly scientific documents: How to write them!* This differs from other books on my bookshelf about writing in that it is slim (93 pages). As the authors explain in publicity material available on the publisher's website, “...researchers do not want to study linguistics or ‘wade’ through 500 pages to learn how to write an article.” Certainly, this seems to be true for many hard-pressed researchers who have little time to dedicate to writing. (Indeed many of these authors will turn to the services of a medical writer—an indication perhaps that writing is not so easy.)

Given that 93 pages are not enough to present wordy treatises on, say, when the use of the passive is appropriate (something that is far from clear in my opinion), the advice is inevitably concise and pithy. After the introduction, the authors take a look at reader-friendly sentences before moving on to how to structure similarly readable



## In the bookstores ...

- paragraphs. The last part of the book is dedicated to particular types of document: review articles, poster presentations, letters (for example, covering letters), curriculum vitae, and finally abstracts. There are short exercises (with suggested solutions) to help reinforce the main points of the book.

In the chapter about sentences, the authors, in line with the opinions expressed in most other books on the topic, stress that shorter is better. They go on to give numerous examples. Few would argue that writing “Balancing the budget by Friday is impossible without extra help” is preferable to “Balancing the budget by Friday is an impossibility without any kind of extra help,” but I’m not sure whether there is much to gain from saving two words by saying “The medical profession currently focuses on disease prevention,” rather than “The current focus of the medical profession is disease prevention”. In fact, I would argue that the two phrases have slightly different nuances, with the first emphasizing the medical profession and the second the present situation. I think it would also be useful to distinguish between eliminating wordiness (or “flabby sentences” as they put it) and using short sentences for the sake of it. While wordiness should rightly be considered an obstacle to the reader’s comprehension, too many short sentences in quick succession can make for a jerky read. Furthermore, sentences in my view should not usually be considered in isolation; they link together to form a texture which may make a text more engaging (rather than just clearer). Anyway, these are minor gripes, and I would heartily subscribe to most of the advice given in this chapter.

The chapter on paragraph structure also provides good advice that is hard to argue with, in particular about where to put the important information, with information at the beginning and, particularly, at the end of a paragraph having greatest impact. This was something I had not thought about specifically before; the approach I am most familiar with places introductory information at the beginning and argumentation in the middle before arriving at a conclusion at the end of the paragraph, although I suppose the end result is similar.

An original aspect of this book was to single out certain types of document, such as curriculum vitae, poster presentations and review articles for special attention. Advice about curriculum vitae is potentially tricky because of cultural differences, for example between Spain (where every course, however insignificant, seems to be included) and the United Kingdom (which, as in the authors examples, are much more abbreviated). I should imagine that CVs also differ greatly according to target sector, with academic CVs being longer and more exhaustive in contrast to an ‘impact’ CV for a marketing position. The same could be said about covering letters for article submissions. As the authors point out, it is wise to consult the instructions for authors about what information has to be included. Indeed,



If only the author of that book had followed the advice of *Reader-friendly scientific documents...* (Painting by Pieter Codde, c. 1630.)

although not explicitly mentioned in the book, most *The Write Stuff* readers would apply that advice to article writing in general. The section on review articles provided some interesting points, particularly given the different approach compared to original articles. As someone not very familiar with writing review articles (though I do of course read a fair few), it was helpful to be reminded of the distinction between narrative reviews and meta-analyses, the need to define the purpose of the review from the outset, and the different search methodologies used.

In summary, although no single book is going to magically transform someone into a good writer, this is a handy book. The advice is accessible and the examples are clear. The book will perhaps be more useful to time-pressed researchers who want a quick introduction to some of the important points of good scientific writing rather than professional medical writers. Nevertheless, as mentioned earlier, from time to time, writers of all levels and abilities can benefit from reminders about the need for clarity and conciseness.

### Gregory Morley

Madrid, Spain

Freelance medical writer, editor and translator

[g.morley@docuservicio.com](mailto:g.morley@docuservicio.com)

[www.docuservicio.com](http://www.docuservicio.com)

In the bookstores ...

## Not quite Nobel



Alex Boese. *Elephants on Acid and other Bizarre Experiments*. Pan Macmillan Ltd; 2007. ISBN 978-0-330-50664-9. £8.99. €11.50. 290 pages

“Hey Honey, listen to this: ‘A recent study shows that subjects deprived of sleep for more than 24 hours showed slower reaction times than persons intoxicated with a blood-alcohol content of 0.1%.’”

“What a load of nonsense! I don’t believe that for a second. Where did that study come from, anyway?”

“I don’t know, they just state it in the newspaper, there’s no reference. But it could be true.”

If you’re anything like me, frustrating breakfast conversations such as this one may be a common occurrence in your family. I, for one, tend to be an optimist and a believer, enthusiastically spouting the latest unsupported ‘statistics’, while my husband is a sceptic and always trying to pop my little balloons with the rational assertion that most of the information about research quoted in modern articles is, shall we say, scientifically scantily clad. He’s right, of course, but I am often left wishing I had the time to track down those elusive studies about sleep intoxication, the mating habits of wild turkeys, or the time it takes for the person behind you to honk when the light turns green. Unfortunately, being merely mortal, I have to do things like type reports and feed the baby, leaving little time in between for tracking down those elusive ‘facts’. How wonderful, then, to discover a book in which all that wading through dusty old journals has been done for you! Alex Boese’s *Elephants on Acid and other Bizarre Experiments* is a treasure-trove of condensed vignettes on topics that vary widely, from hypersexual cats to the tipping behaviours of restaurant customers. It’s a goldmine for those who may have wondered about the truth behind many commonplaces, like cockroaches taking over after a nuclear holocaust, or the positive effect of Mozart on children’s IQs.

These stories have their origins in published research, which Boese has condensed and illuminated with dramatic flair. By reading this book, I was able to scratch many a lingering itch of curiosity that I just never got around to confirming, like whether menstruation among women in institutions is really synchronized, and what actually happens to people if you tell them not to think about a white bear. It also includes many historical anecdotes of ridiculous experiments that people nonetheless gave credence to, such as the assertion that souls could be weighed or that insects could be generated spontaneously by applying electricity to a special stone.

The book presents itself as a ‘bathroom reader’ and so breaks up its anecdotes into topics based on general premises, animating dead bodies being one example. The format of the book repeats itself over and over, so it’s not a good book to try to read all at a go. It lends itself much more to, as advertised, the toilet or to commuter reading on the subway.

The stories come from the realms of biology and psychology; depending on your scientific background, many (such as the mix-up involving the Skinner Box and Skinner’s baby-care Box) may be familiar to you, but large headings make it easy to skip the ones you already know. Boese’s tendency to close every story with an amusing recapitulation occasionally becomes annoying, but otherwise the book is as fascinating as its flashy title implies and hops from one conversation-starter to the next.

Just as interesting as the stories themselves are the questions they raise—I found the penultimate chapter, which summarises the obedience experiments conducted by Stanley Milgram, and follow-up experiments involving shock treatment, to be absolutely chilling. It left me thinking, ‘Are we as humans destined to be depraved? Is it possible to avoid such a fate?’ On the other hand I had the comfort of thinking that, if I had done something cowardly or evil, I was in good company with about two-thirds of the general population, which according to experimental results is willing to obey to the point of killing an innocent victim. On the third hand, I felt sorry for all the poor people who had to sweat through the experiments under false pretences in the first place, only to find out something about themselves they really didn’t want to know. Boese doesn’t do much moralising and keeps the tone of the book light, but I was both disturbed and intrigued by the hair-raising implications of these and other experiments. Particularly mental patients, it seems, have been victimised by extreme psychological experiments that altered subjects’ personalities or destroyed their minds. Finally, the many needlessly cruel and unusual methods of bringing animals to their deaths (including the titular elephant) came up against my personal borders of what I consider scientifically useful. All in all, the book is a good advertisement for ethics committees. An alternate title for the book might have been, “Not quite Nobel: how far would you go?”

Next time you are curious about zombie kittens, repressed memories, or whether chimps outstrip humans in infant development, pick up *Elephants on Acid and other Bizarre Experiments* by Alex Boese. As a pulp-fiction array of the extremes that scientists reach in their search for the answers to why things are the way they are, it can’t be beat. I promise, your breakfast conversations will never be the same again.

**Renée Albe**

[spinsnit@yahoo.com](mailto:spinsnit@yahoo.com)



## Journal watch



# Special retro edition

by Adam Jacobs

This edition of journal watch fails to bring you the latest developments from the medical literature, but rather looks back to times gone by, when there were nonetheless some fascinating papers published. One of the papers I shall write about here, from 1973, is apparently a true classic, but as I had never heard of it until recently I thought perhaps that other TW S readers might also be unfamiliar with it. So today I bring you 3 thought-provoking papers published between 1973 and 1980. They share a common theme of telling us some unsettling things about the way we perceive written (or even spoken) descriptions of research.

On to the first paper then, published in 1973 by N aftulin et al, which describes an experiment known as 'The Doctor Fox Lecture' [1]. The authors were all educationalists, who were interested in the effectiveness of teaching and how it is measured. Although it was common for educators to be assessed by having students complete satisfaction questionnaires (and indeed still is), N aftulin et al were concerned that student satisfaction with a specific teaching encounter is a poor measure of how much students actually learned, being more influenced by the charisma or popularity of the lecturer than by the effectiveness of the lecture content. They wondered whether not only students, but also professional educators, would be similarly influenced. They thus described the hypothesis of their study as follows:

"Given a sufficiently impressive lecture paradigm, an experienced group of educators participating in a new learning situation can feel satisfied that they have learned despite irrelevant, conflicting, and meaningless content conveyed by the lecturer."

To test this hypothesis, they embarked on what sounds like a tremendously fun piece of research. They recruited a professional actor, invented an impressive-looking CV for him that made him appear to be an expert on the application of mathematics to human behaviour, gave him the name of 'Dr. Myron L. Fox', and had him deliver a lecture to a group of professional educators from the fields of psychiatry, psychology, and social work, as part of a conference designed to help them become more effective educators of other health professionals. His lecture was on the topic of 'Mathematical Game Theory as Applied to Physician Education'. N aftulin et al coached him in how to deliver the lecture and handle the subsequent question and answer session "with an excessive use of double talk, neologisms, non sequiturs,

and contradictory statements." The lecture was videotaped and subsequently shown to 2 similar groups of professional educators.

Despite the nonsensical nature of the talk, most of the educators gave favourable responses in their feedback questionnaires, and none of them realised that the lecture was not genuine. Although there are some limitations to this study, particularly the lack of a control lecturer (we don't know how the group of educators would have rated a genuine lecturer), the authors' conclusions that student satisfaction scores are influenced more by style than by substance seems perfectly plausible, a worrying thought as I write this on UK general election day.

The As an aside, I have my suspicions that I may have sat through a repeat of this experiment earlier this year when I listened to an utterly incomprehensible lecture on the philosophy of research ethics review, as regular readers of my blog will know [2].

Another paper, published in 1980 by Armstrong, followed on from the Doctor Fox experiment by investigating whether the same effect was applicable to the written word. Armstrong summarised the 'Doctor Fox hypothesis' as follows: "An unintelligible communication from a legitimate source in the recipients' area of expertise will increase the recipient's rating of the author's competence." He then went on to point out that the purpose of scientific writing should, looked at rationally, be to communicate knowledge, but that this conflicts with a desire for scientific writing to increase the writer's prestige if unintelligible writing is rated by readers as being more impressive.

He investigated this by 2 separate methods. First, he took a sample of 10 management journals, and rated each one for readability using the Flesch reading ease test. He then determined the prestige of each journal by asking a sample of 20 academics in the field to give each journal a rating. He found a significant correlation between the complexity of writing and the prestige of the journal.

Realising that one possible explanation for the results was that more prestigious journals handle more complex topics, requiring more complex language, Armstrong then went on to test his hypothesis with a further experiment. He took the conclusions sections from papers in 4 management journals, and rewrote them to alter their readability scores without affecting the content. He produced both simplified



and more complex versions for each passage. He then asked academics to rate the competence of the research described in the articles. Based on 32 responses, he found that passages written in a simplified style were rated of significantly lower competence than the others, despite the way in which he had controlled for the nature of the research described.

This makes depressing reading for medical writers. As medical writers, we are trained to write in a style that is straightforward and easy to read. Although this is a good way to communicate information, it is actually not a good way to impress your readership, who may be more impressed if you write in a more complex and less easily understood style. Perhaps this explains a phenomenon that I'm sure most medical writers have experienced when a document comes back with a client's edits, many of which seem to make the document less easy to read. In the 30 years since Armstrong's paper was published, I doubt that very much has changed.

My own perspective on the above 2 studies is that most people, particularly if they are supposed to be knowledgeable in a subject, don't like to admit if they have failed to understand something about that subject. There is probably a tendency for people to assume that the reason why they have not understood something is a function of their own poor understanding, rather than the poor communication of the person who delivered the information. The world would be a better place if we were all not afraid to say quite clearly when we don't understand something.

My last paper, published by Mahoney in 1977 (round about the same time as the picture of me at the top of this article was taken), looks at the way cognitive biases can affect the peer review process [4]. I first came across this paper a few years ago when working on a paper on cognitive biases in medicine [5]. I thought it was fascinating then, and I still do.

Mahoney was concerned about the extent to which peer review of academic journals might be affected by a phenomenon that psychologists describe as confirmatory bias: the tendency for humans to welcome experiences that support their pre-existing beliefs, and to be suspicious of anything that contradicts them. To investigate this, Mahoney wrote 5 different versions of a manuscript describing a fictitious experiment on the effects of extrinsic reinforcement on intrinsic interest, which was a controversial topic among psychologists at the time. He then sent the manuscript to peer reviewers, who were unaware that they were taking part in an experiment and asked to rate the manuscript on various aspects of its quality. The reviewers' perspective on the controversial topic was inferred by their association with a journal which had taken a clear line on the controversy. Some versions of the manuscript gave results that were consistent with the reviewers' presumed pre-existing ideas, and some gave results that contradicted those

ideas. The introduction and methods sections of the manuscript were identical in all cases.

The reviewers' ratings of the manuscript were significantly affected by the content of the results section. Crucially, there were significant differences in the reviewers' ratings of the methods sections, despite identical methods in all versions of the manuscript. As you have probably guessed by now, reviewers rated the methods as being of better quality when the results supported their pre-existing beliefs. Not only that, but the reviewers were more likely to recommend such manuscripts for acceptance in the journal.

Mahoney's paper shows very clearly that peer reviewers of papers are just as susceptible to cognitive biases as anyone else, a fact that probably doesn't come as a great surprise to most medical writers. He concludes "Without further scrutiny of the purposes and processes of peer review, we are left with little to defend it other than tradition." There may have been plenty of further scrutiny of peer review in the intervening 33 years, but I doubt that there is much more to defend it despite that further scrutiny. It is worrying that after all that time since the bias inherent in peer review was demonstrated so clearly, it still forms the cornerstone of scientific publishing.

Adam Jacobs  
Dianthus Medical Limited  
ajacobs@dianthus.co.uk  
www.dianthus.co.uk

#### References:

1. Nafstulin DH, Ware JE, Donnelly FA. The Doctor Fox Lecture: A Paradigm of Educational Seduction. *J Med Educ* 1973; 48(7): 630-6
2. Jacobs A. Mission Impenetrable. <http://dianthus.co.uk/mision-impenetrable>
3. Armstrong JS. Unintelligible Management Research and Academic Prestige. *Interfaces* 1980; 10(2): 80-86.
4. Mahoney MJ. Publication prejudices: an experimental study of confirmatory bias in the peer review system. *Cognit Ther Res* 1977; 1: 161-175.
5. Klein J. Five pitfalls in decisions about diagnosis and prescribing. *BMJ*. 2005; 330: 781-783

In keeping with the retro theme of this article, I have tried to use 1970s typographic and bibliographic conventions, although I must confess I'm struggling to remember what the convention for referring to a blog entry was back then.

## ■ Out on our own

### Out on our own

We echo the business theme of this issue of *TWS* with some reflections from Sam Hamilton and Stefan Lang on business development and self-marketing for freelancers. In past issues, both Stefan and Sam told us about their experiences as newcomers to freelancing after careers in industry. Now, 3 and 4 years later, both have taken stock on their sources of work, how they marketed themselves and how they became known in the industry, and the challenges and problems that arose. Stefan quantified his experiences by analysing his contracts over the past year, whilst Sam looks at the question of whether we are engaged in pure business development ensuring that work comes in, or developing a business, where the role of the freelancer and the function of the business evolve.

Raquel Billiones and Ursula Schoenberg take a look at some of the occupational hazards when freelancing and the adverse effects of working in a home office. Raquel is in the enviable position of being able to tell us she has the 'home office environment fully figured out', and has some straightforward, creative suggestions for remaining sane and healthy if you do not have daily contact with colleagues in an office environment. Ursula has basically mastered the freelancing existence, but still has a few problems and has learned the hard way, like I did—for example, I have learned that I must use a timer when cooking and working at the same time, and I must be able to hear the timer if I don't want to burn food and ruin pans.

As one of our few freelance members who specialises in medical device documentation, Claudia Frumento wanted to clear up a few unclear issues in this area and interviewed Susanne Gerbl-Rieger, an expert member of the TÜV SÜD in Germany, one of the institutions responsible for Conformité Européenne (CE) approval. Claudia provides us with a wealth of information and resources in this difficult area, which makes for interesting reading, even if you are not involved in device applications.

We also report on the Freelance Business Forum in Lisbon. At the time of writing, we are expecting record attendance, but this may not happen if Eyjafjallajökull throws its atmospheric spanner into the works—so we are hoping that the wind keeps blowing in the right direction.

Our Freelance section in this issue is rounded off by a report on the 3<sup>rd</sup> Freelance Business Survey conducted in February and March 2010, which includes a question on indemnity insurance this time, a question also tackled by Rosie Bischoff in this issue. We originally planned to put the full report on the survey on the website and include only a brief summary here, but decided to publish the full report, as this will be available on the website in the Journal section.

**Alistair Reeves**  
a.reeves@ascribe.de

**Sam Hamilton**  
sam@samhamiltonmwservices.co.uk

## Report on the Lisbon Freelance Business Forum, May 2010

Attendance was good at the Freelance Business Forum (FBF) at the Lisbon Conference on Wednesday 12 May 2010. Alistair Reeves, Sam Hamilton and Barbara Grossman started the meeting by introducing themselves. The following topics were then discussed.

### 1. 2010 Business Survey

Alistair presented the results of the 2010 Business Survey, which was carried out in February and March 2010. Results were similar to previous years (2003 and 2007) although, because some questions were changed for this year's survey, comparison with previous years was not always possible. 128 people responded to the survey from a wide geographical area. Outliers were excluded, for example, hourly rates of pay of €4500 and €5000. The 2003 survey included small businesses with ≤7 employees, unlike the current survey. Alistair stressed that the results were intended to serve only as a guide with no sound statistical basis. The majority of respondents were full-time freelance writers who did not have indemnity insurance and received most of their work from longstanding customers.

A full report on the survey is in this issue in the Out On Our Own section.

### 2. Freelance User Group

A freelance user group was established at the Ljubljana meeting 1 year ago. Relevant issues are discussed on a regular basis, and a Freelance Support Centre has been created with approximately 100 items, which were collated and categorised by Ingrid Edsman and Neil Fisher into the following groups:

1. Advice on starting up and running a freelance business
2. Legal aspects of running a freelance business
3. Technical advice
4. The personal experience of freelancers
5. Journalism and translation, careers typically dominated by freelancers
6. Conference forum and email discussions
7. A general category, covering miscellaneous articles not fitting into the above categories

## Out on our own

Information was derived from various sources, for example: *TWS*, the Freelance Business Forum, and Freelance Email Discussion Forum. The dedicated centre went live on the EMWA website in January 2010, with links to each item. The centre is accessible to all. Ingrid Edsman welcomes feedback and suggestions for additional items.

The user group has a 'rolling membership' with no formal rules; it was suggested that membership should change every 1–2 years. The intention is to feed back to the EC to ensure the committee is aware of freelancer views.

### 3. FDF on the Website

Use of the Freelance Discussion Forum on the EMWA website was discussed at length. It was generally regarded as having been taken over by electronic advances such as 'LinkedIn' and 'Facebook'. Laura Russell noted that a discussion panel on 'Web 2.0 for Medical Writers' was to take place the following day. A demonstration was requested for the next FBF, however, as many freelancers are not familiar with these social and business networking tools. In addition, a request was made to flag up this type of training need to the EC.

Postmeeting note: Shanida Nataraja, the EMWA website manager, stated that there would be no objection to starting an EMWA Freelance area in Facebook, for example.

### 4. Policy Development for the Freelance Listing on the Website

Laura Russell, with support from Claudia Frumento, presented this item following a request at the last FBF in Frankfurt (November 2009) to develop a simple policy for those who wish to appear on the freelance listing on the website. The following specific points were discussed:

- A 'qualifying statement' on the freelance listing. Text was presented and considerable discussion ensued covering the relationship between entry on the freelance listing and conference attendance. Jo Whelan reminded attendees that we need to ensure that the Home Page of the Freelance Listing remains a marketing tool—we must not frighten away potential clients with statements and policies. It was also noted that EMWA cannot endorse those on the list; Wendy Kingdom stated that if this is the case, EMWA cannot 'set the rules'. Following a show of hands, the majority of attendees did not want a 'qualifying statement' such as: "Freelancers must have attended at least 1 EMWA conference in the past 3 years or be enrolled in the EPDP." A revised text will be submitted to the EC for inclusion on the website.
- There has been a mixed reception to the members' listing: the 'A to Z' order cannot be changed; and it is not feasible to list by area of expertise or geographical area in each country.
- Currently, if a freelancer advertises in more than one country, the fee for the '2<sup>nd</sup> country entry' is 100% of the original full fee. A 2<sup>nd</sup> entry fee of 50% of the

original fee was proposed as the information is exactly the same. Alistair Reeves stated that this would apply to just 2 or 3 people at present.

- John Carpenter stated that he knows people who are not joining because of cost issues. Alistair Reeves reminded attendees that many members profess to receive some or even a great deal of work from the listing and feel it is well worthwhile being a member. There is, however, a small group who think that €130 per year is too expensive and have chosen not to join, and a few members say that they receive very little work from this source.
- Following a computer problem at the beginning of the year, some freelance email addresses have been lost. If you are not receiving freelance-related emails, please contact Alistair Reeves or Sam Hamilton.

### 5. Member questions/points

- Sam Hamilton: regarding manuscript authoring services, how do individual freelancers handle the question of submitting manuscripts that they have authored to the chosen journal, if asked to do so? If you do submit to the journal on behalf of the lead author, do you have direct contact with the journal editor, or do you defer back to the lead author? How often are you asked to provide such a service as a proportion of the manuscripts you prepare? Cito Habicht responded that he provides this service, charging standard rates, and enjoys the work. Alistair Reeves stated that he no longer does this type of work. Belinda Butcher cautioned that some journals want the actual author to submit; if an author asks her to submit on their behalf, she keeps an email trail to cover herself in case the problem of ghost writing is raised. John Carpenter advised to be open and show everything to the journal; like Cito, he charges at his normal rate.
- Karen Shashok: current 'Good Writing Practice' guidelines expect that the medical writer on a publication should not only be acknowledged but should ideally be an author if their contribution to the paper justifies this. Karen wondered how things look for editors. She will not work for an author who does not acknowledge her. Alison McIntosh suggested asking Liz Wager. Dave Edwards stated that it should be standard practice to acknowledge. There was general agreement that this issue 'deserves' a *TWS* article. Would anyone like to tackle this issue?

### 6. Contributions for 'Out on Our Own' in *TWS*

A plea was made for *TWS* OOOO articles, particularly as there were none in the last issue. Iain Patten also appealed for attendees to the Friday *TWS* Editorial Meeting.

Thanks to:

- Alistair and Sam for chairing the meeting
- All those who attended
- Barbara for doing the minutes.



## Freelance choices: Business development or developing a business?

by Sam Hamilton

Many freelance regulatory medical writers begin their career as salaried contract research organisation (CRO) employees. All freelancers, unlike their salaried counterparts, are in the unique position of not only making the product, but having to win writing commissions. Given that most of us are not specifically trained in business development (BD), contract acquisition and negotiation skills have to be learned on the hoof. Here, I describe some of the business challenges as they arise and evolve alongside a developing freelance regulatory medical writing business. Regardless of the approach to BD—proactive or reactive—each business decision determines the direction for the freelance enterprise. So, are we engaged in business development, or developing a business?

### Business awareness as a salaried employee

Company employment represents a safe harbour in which operational employees can concentrate on doing their job without worrying about the source of their next piece of work. This is the job of non-operational BD executives. To more junior members of larger companies, their BD colleagues are almost invisible, as work just seems to materialise. However, more senior employees, including senior writers and managers, are often more aware of these background activities because they are drawn into the BD process by contributing to written proposals or bids, and later on, by defending the written bid. This understanding of the BD process is essential to the wider realisation that to make the move from employment to successful freelancing, besides writing ability and good organisational skills, you need to be able to 'get the work in'. This is a significant concern for many prospective freelancers, and may well be the first stumbling block to setting up their own enterprise. Many realise that some of the seemingly obvious business avenues may actually be restricted. Pharmaceutical companies and CROs now routinely write 'non-compete' clauses into their standard employment contracts that restrict the outgoing employee from soliciting business from clients with whom they have worked in the last six or twelve months of their employment, and this restriction may be effective for six to twelve months after leaving the company. If a recent client approaches the employee independently, however, this may not contravene the 'non-compete' clause, although this depends on the wording of the contract. With a range of new concerns in setting up independently, outgoing employees may elect to avoid such potentially 'grey' situations until their period of restriction is over. This may represent less of a loss of

potential business than some may fear, as pharmaceutical clients who outsource business to CROs may do so because their current process demands it. They may not be able to outsource to freelancers even if they wanted to. It is, however, worth remembering that paradigms change as business models become obsolete in an ever-changing environment. Pharmaceutical companies that once only outsourced to CROs, frequently rewrite their standard operating procedures (SOPs) and strategic processes to allow outsourcing to different types of service providers, and this often means to freelancers.

### First thoughts for prospective freelancers

Certain practicalities require consideration before giving up the safety of salaried employment: which sector(s) of the market will the expected workflow originate from? How will this work be found? In the event that it takes some weeks or months to generate income, are savings available to live on? These are just a few of the questions addressed by preparing a business plan (BP). This can be a focussing exercise, even for experienced writers who think they know where their work will come from. There are bound to be other points you have not previously thought of that arise from the exercise of business planning. Another positive aspect of preparing a BP is that grants or start-up loans may be available, contingent on the BP, so it is worth careful consideration.

### Self-marketing for new starters

So, the budding freelancer, not discouraged by any of this, needs to find clients. There are a myriad of ways to do this, and perhaps the most obvious is to advise old friends and colleagues of what you are planning. This is, after all, a small professional community that people circulate within. It is also acceptable to contact old clients not covered by the time restrictions in a non-compete clause. Other start-up self-marketing activities include establishing a website; writing to potential clients; advising agencies of your forthcoming availability; joining a professional networking site, such as LinkedIn; and for the brave of heart, cold calling. This assumes that you are already a member of EMWA, of course, because the importance of networking at EMWA conferences should not be underestimated.

In the early months of establishing a freelance business, hard work is required to win contracts and some disappointments are inevitable. Once the all-important first contract is secured, others will follow, either through repeat business (by far the easiest option), or as a function

## Freelance choices: Business development or developing a business?

of time because of word-of-mouth or self-marketing—and the longer the self-marketing activities have been up and running, the more likely they are to bear fruit.

### Established business—evolving challenges

Once a freelance business is established and the flow of work is sufficient to support you (and your family), this does not mean that there will be no further business challenges. These will need very careful thought as seemingly innocuous business arrangements can be fraught with complexities. The challenges arising at this stage of a developing business may include:

- **Effective resource management:**
  - Support with sub-tasks. As a salaried employee, it is likely that support activities such as quality control (QC) and literature searching were either provided within the company framework or were outsourced. Effective resource management requires some thought when company infrastructure is unavailable. QC will inevitably need to be performed by an individual who did not author the document, but it is also worth considering outsourcing stand-alone pieces of work such as individual literature searches, particularly when the workload is high.
  - Additional authoring support. If a freelancer regularly has to decline work because of lack of capacity, the possibility of sub-contracting or even expanding your business to employ another writer may arise.
- **Maintaining quality:** as work is sub-contracted, or additional writers are employed, the quality of deliverables should not be compromised. A good way to assure quality is for the freelancer to provide training, instruction and perhaps even a style guide before writing, and following this up with personally performed QC of the deliverable before submission to the client. Quality of sub-tasks should also be tightly controlled. Established links with known colleagues are often the best way to maintain it.
- **Keeping existing clients and generating repeat business:** this is inevitably a result of maintaining quality over time, but is also highly dependent on initiating and nurturing good personal relationships.
- **Ongoing training and professional development:** as the range of documents required in regulatory submission dossiers increases, opportunities for expanding the writing portfolio should not be overlooked. The best way to keep abreast of current industry practice and requirements is to stay current and well trained.
- **Networking outside the medical writing function:** clients may call upon experienced freelancers to source and work with professionals outside of their own area to produce multi-component deliverables. Freelance statisticians, pharmacokineticists or pre-clinical writers may be required. These links once established can prove their worth repeatedly.

Clearly, the challenges are varied and will continue to develop with the business. At this point, it seems sensible to take a step back and think of the reasons for going freelance in the first place. For many making the move from a

CRO, a love of writing, freedom to allow flexible working, and a desire no longer to have staff responsibility probably figure somewhere on the list.

This brings us back to the original question of whether, in an evolving business, we are engaged in pure business development (i.e. simply ensuring the work continues to come in) or developing a business (i.e. where the role of the freelancer and function of the business change). The question is an important one as it may well determine strategic direction. And so to the answer: to run a successful freelance enterprise, you must always be engaged in business development and in acquiring new business. Just where that takes the individual and how the business is developed involves some careful thought and active decisions.

After the first few years of freelancing, the exercise of writing a follow-up BP can be useful. Pertinent questions about strategic direction, company growth and where you see yourself in 5 years' time will undoubtedly make for interesting reading ...

### Sam Hamilton

*Sam Hamilton Medical Writing Services Limited*  
Newcastle Upon Tyne, UK  
[sam@samhamiltonmwservices.co.uk](mailto:sam@samhamiltonmwservices.co.uk)  
<http://www.samhamiltonmwservices.co.uk/>

## New: TWS archive on [www.emwa.org](http://www.emwa.org)

*TWS* is a comprehensive repository for information about all aspects of medical writing, thanks to the hard work of all of its contributors. To build our profession, it is important to raise the profile of EMWA's journal and make this information more accessible, which is why exciting things are happening to the *TWS* archive on the EMWA website.

**Archive content:** the new online archive of *TWS* contains articles from 1998 onwards. The archive can be searched using keywords making it easier to access this invaluable resource.

**Archive access:** access to the online archive is free for EMWA members. When logged into the members-only part of EMWA's website, EMWA members will be able to browse the archive, and all articles, and individual issues, can be downloaded as PDFs or viewed on screen.

**Non-EMWA members:** access can be gained to the full archive by paying an online subscription fee. Alternatively, non-EMWA members can browse the archive and download individual articles, or an entire issue, on a pay-per-view basis.

**Comment facility:** EMWA members can submit their response to a particular article by posting a comment, and these comments will be visible to all visitors to the archive.



## Marketing tools for new freelancers

by Stefan Lang

When you think of marketing, you probably envision something that is very expensive. But how can freelance newcomers promote their business on a shoestring marketing budget?

Colleagues who worked as salaried medical writers for many years might draw on their long-established network of contacts when they decide to go freelance. However, others who are new in the business have to ask themselves how to attract new clients before they start self-employment. Additionally, this question should be regularly reassessed during the first years of freelancing. Therefore, the question arises whether new freelancers can increase their public visibility without investing their whole income in advertising, and if so, what the most promising and least expensive marketing tools are.

I tried to answer these questions by evaluating the clients I had during my third year of freelancing. For this evaluation, customer inquiries were only included if they resulted in real assignments during the 12-month period. Contacts that could not be ascribed to a distinct source were excluded even if they led to an assignment.

The following sources were compared:

- Internet search (clients who found me on the Internet via search engines but not via paid Internet advertisements)
- European Medical Writers Association (EMWA) freelancer list (clients who searched the EMWA freelancer list directly)
- Mailing (clients who responded to a direct mailing of approx. 300 letters)
- Networking (clients who contacted me on the recommendation of colleagues)
- Publications (these include articles about writing which I published on my own behalf)
- Internet advertising (ads were placed during two one-month-campaigns)
- Freelance agency (agencies that deliver assignments and receive a certain fee)

The assignments I procured during that time came from different sources. Seven out of twenty-four evaluated assignments (29.2%) came from clients I had worked with previously. These follow-up jobs were excluded from analysis. Of the remaining assignments, I received 35.3% from clients who found me via search engines (Figure 1). Other clients selected me from the EMWA freelancer list, responded to direct mailing, or were referred by colleagues (17.6% each). Some clients were attracted by articles that I

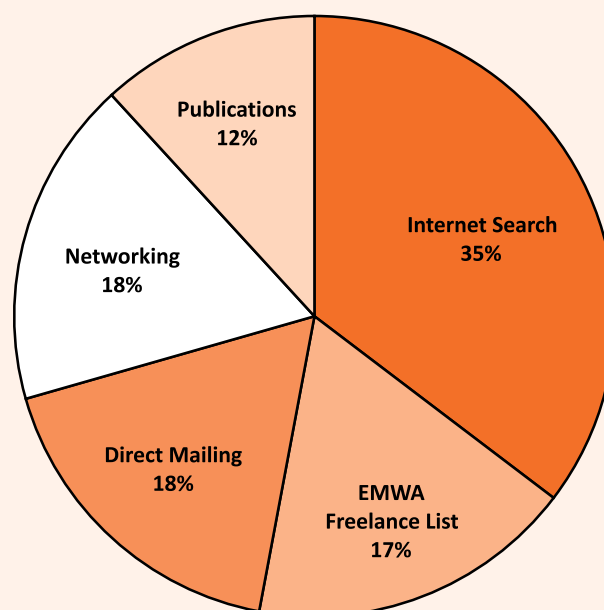


Figure 1. Source of assignments during the 12-month period. Follow up jobs were not taken into account.

had published in print media (11.8%). During the period of the examination, my business was additionally listed with an agency for freelance scientific writers, but no assignment arrived from this source. Similarly, advertising on the Internet resulted in many 'clicks' and some contacts, but no jobs.

Interestingly, the percentage of sources from which most assignments came depended on the category of job (Table 1). I offer scientific and medical writing, editorial services, and training in both academic and scientific writing. At this time, assignments were distributed across writing (37.5%), editing (20.8%), and training (41.7%). In the category 'scientific and medical writing,' most clients found me through the EMWA freelance list (60%), followed by Internet searches and publications (20% each). In contrast,

Table 1. Sources of assignments arranged according to job category (percent of assignments in each category).

	Writing	Editing	Training
Internet Search	20	100	22.2
EMWA Freelance List	60	-	-
Direct Mailing	-	-	33.3
Networking	-	-	33.3
Publications	20	-	11.1
Advertising (Internet)	-	-	-
Freelance Agency	-	-	-



## Marketing tools for new freelancers

100% of clients who needed editorial help found me through an Internet search. Contacts to clients who later booked a workshop in scientific or academic writing were established by direct mailing (33.3%), networking (33.3%), and Internet searching (22.2%).

Obviously, the sample size is low, and most sources cannot always be clearly differentiated from each other. Clients from the different sources might have additionally consulted my website before they decided to contact me, and even clients who clearly referred to articles in print media when they contacted me might actually have found these articles on the Internet. Moreover, not every possible method of promoting a business was tested.

None of these marketing strategies require large financial investments. However, expenditure of time varies considerably depending on the activity. For example, optimising your website to improve your search engine ranking might require a huge amount of time, while joining the EMWA freelance list takes a couple of minutes.

I draw the following conclusions from my small evaluation:

- It does not require a huge marketing budget to increase your public visibility.

- It is the mix that counts. Surviving as a new freelancer depends on a combination of different marketing activities.
- The appropriate marketing strategy strongly depends on the services you offer.
- Not surprisingly, the Internet is a major source of customers. Anything that increases your prominence on the Internet might help.

During my first years of self-employment, follow-up assignments continued to grow in importance. Therefore, activities that strengthen your customer loyalty should be top priority as you develop your marketing strategies.

In summary, it does not seem reasonable to concentrate on a single marketing strategy, and, as the focus of your work might change, successful marketing requires continuous re-evaluation of various strategies. Because low cost strategies require a huge amount of time, expenditures in time and money should be carefully balanced.

**Stefan Lang**

Osdorf, Germany

contact@scientific-medical-writing.de

www.scientific-medical-writing.de

## Themes of upcoming issues of TWS

**Manuscript writing:** Articles are invited for an issue on manuscript writing, which will be kindly guest edited by Phil Laventhal. Articles on aspects of writing a manuscript, common errors, responding to reviewers/editorial offices, publication planning, communications within manuscript writing teams, manuscript QC etc. are all welcome. Please contact Phil at pleventhal@4clinics.com.

**Women:** The cover of the first 2010 issue of *The Economist* sported the question "What happens when women are over half of the workforce?" The question was prompted by the imminent event of women crossing the 50% threshold to become the majority in the American workforce. As the medical writing profession has long been in this happy situation TWS is calling for articles about women and medical writing. Please submit articles (up to 2500 words) and short reports/boxes (up to 100 words) to editor@emwa.org.

**Careers in medical writing:** Following the interest provoked by Alison McIntosh's oral abstract presentation

(see page 90) on how we can help potential medical writers gain experience, Alison has kindly agreed to guest edit the March 2011 issue to cover educating and recruiting medical writer and the range of careers encompassed by medical writing. Please contact Alison (aagmedical-writing@btinternet.com) with ideas for contributions to this issue.

**Medical devices:** Claudia Frumento, whose interview with Susanne Gerbl-Rieger from one of the institutions responsible for the *Conformité Européenne* (CE) approval can be read in the Freelance section in this issue, has kindly agreed to guest edit an issue on medical devices. Please contact Claudia (c.frumento@icimt.com) with ideas for contributions.

As always articles or short reports on subjects of interest to medical writers which are outside the theme are also very welcome.

Please send articles, letters to the editor and suggestions for individual articles or future issue themes to me, Elise, at langdoe@baxter.com.



## The downsides of a home office (and what you can do about them)

by Raquel Billiones

Many of us work from home for one reason or another, be it as a self-employed professional, as a small business entrepreneur, or as a home-based employee. As a freelance medical and scientific writer, I am one of those whose workplace is a home office. Other home-based people I have met are translators, artists, web designers, and market researchers.

Working from home can be considered a privilege or a drag depending on how you look at it. It has some advantages which include independence, flexible working hours, solitude and the perfect way to balance job and family. There are however, some downsides to this working configuration.

### Adverse effects on productivity

Working from home presents a lot of distractions. The washing machine, the vacuum cleaner, and the television are the just a few. The biggest distraction, however, is the Internet. Without bosses and colleagues to look over your shoulder or remind you of deadlines, it is easy to get lost on Facebook or any another online social network platform. Before you know it, the working day has ended with nothing done. Working from home requires discipline. Without discipline, the well-prized flexibility can lead to slackness. Productivity suffers.

Somebody tweeted this “I hate my boss. Sometimes he’s too demanding and other times he’s too lax when it comes to work ethics! Unfortunately, I’m self-employed”. I guess that just about sums it up.

### Adverse effects on physical health

The flexible working hours of a home office is a major pitfall that can also affect a solo home office worker’s health. The boundaries between day and night, between working hours and free time become blurred, the meal and sleeping times become irregular. There are no colleagues to have lunch with or share a much-needed coffee break. The only exercise one gets is a trip to the bathroom or to the fridge. I prided myself to be extra-savvy about health (as a medical writer should be) but I actually had some health issues when I first started freelancing.

Two years ago, the *New York Times* dubbed the home office as the ‘digital era sweatshop’ where people are toiling in front of their computer day and night [1]. The article warned about the health hazards of blogging (sleep disorders, poor nutrition, lack of exercise, and eventually cardiovascular disease) but it is not unthinkable that a home-based medical writer is faced with similar hazards.

### Adverse effects on mental health

The home office scenario is a great way to dispense with the commuting and the corporate politics. Yet, many people, including myself, have experienced depression while working from home. The well-prized solitude can turn into isolation. Humans are social animals by nature and the lack of social interaction in a home office is unhealthy. Colleagues may be a source of stress and bad vibes but they are also an invaluable source of information, and yes—that uniquely human activity called conversation. Researchers at the University of Arizona report that people engaging in ‘substantive conversation’ are much happier than those who engage only in small talk [2]. No wonder the home office worker (who doesn’t get to converse at all) is depressed.

### Adverse effects on the ego

Many people do not take home office workers seriously. Who would, when the typical home office worker is often depicted as a caffeine-addicted computer nerd in pyjamas? There is respectability and even glamour to the traditional work set up where people show up in suits and business casual that the home office lacks. Other than showing them your income tax returns, it is hard to convince people that home-based medical writing is a truly respectable and even well-paying job. I’m sure my neighbours wonder why my kids are at the daycare while I ‘sit around’ all day. Outside the core family, my ‘job’ is sometimes the butt of jokes, with hidden hints of reproof. My husband’s aunt complimented me for finding the time to earn some ‘pocket money’. My father-in-law refers to me jokingly as his ‘entrepreneur’ daughter-in-law, yet asked what I need business cards for.

With all these adverse effects, I realised rather early on that my version of a home office is not a sustainable one. One day, I sat down and listed the downsides of my home office and tried to find feasible remedies. Here are some coping measures I’ve come up with:

### Treat it like it is a real office

This means not working in pyjamas though sweat pants and crocs are allowed. Maintaining a regular office work schedule, with regular lunch and coffee break is important. No washing and cleaning are allowed on working days and work is forbidden on weekends unless absolutely necessary. When the spouse/partner comes home, sees the mess and asks “What have you been doing the whole day?”, shove your recent invoices statement under his nose.

## The downsides of a home office (and what you can do about them)

### Do social networking

By social networking here, I mean networking with real people in real space. In every city, there is a local club who would be willing to provide you with social life for an annual membership fee. However, choose the right group that fits you and your needs. When I first moved to Zurich, I checked out the ladies clubs but I got tired of hearing about expat woes and exchanging diaper stories.

Find a group to whom you don't have to explain yourself. Luckily, I discovered a professional women's group where I fitted in better. Okay, I still have to explain what a medical writer does but in these circles, freelancing and home office are acceptable (even enviable) constellations.

### Share resources with other freelancers

If the home office really gets on your nerves, try renting something outside your home. I know of a group of freelance professionals who share office space and telecom resources to save on expenses and provide each other company. Somebody suggested to me once that freelancers can take turns in occasionally hosting a 'guest officemate' in their home offices to break the monotony. I still have to find a fellow freelancer (and there are not that many in my area) who is amenable to the idea, though.

### Work somewhere else

You need not work in the home office the whole time. A change of scenery can do wonders. With today's technology, you can basically work anywhere you want. I have several alternative rent-free offices. I sometimes work at the nearest shopping mall which offers free Internet access. When I need to chase a deadline and want to avoid the distractions of food and the Internet, then I grab a desk at the Zurich Central Library. It is quiet and uncluttered and if needed, Internet access is still available through hotspots. Coffee shops ('coffices') could also be a good place to work for a couple of hours. The nearest Starbucks offers a free 30-minute Internet access for every cup of coffee.

### Hang your business sign on your door

There is nothing like a business sign to convince people that indeed you are a working professional, albeit a home-bound one. I must admit I never went that far but I did put my business sticker on my mailbox, for the benefit of the postal service—okay, of my neighbours, too.

### Work onsite once in a while

An occasional onsite stint can help to put things back into perspective. Earlier this year, I worked 4 days a week for 4 weeks at the client site. It was a great project financially and socially, and the client was great to work with, but at the end of the 4<sup>th</sup> week when we wrapped up the project, there was this overwhelming feeling of relief that it was all over. Then came the delightful realisation that I can take a break right after because my boss (that's me) thinks I deserve it. Yes, working onsite makes you realise that freelancing gives you the luxury of not getting into a rut.

### Go to EMWA conferences

Now, this is really a place where you don't have to explain yourself, where people know where you're at and what you are talking about. I also love telling people around me about my going to these conferences. It sounds, well, business-like to go on business trips from time to time. And it's tax deductible, too.

In this digital age, the home office is not just a passing fad. It is here to stay. Employers are finding out that a good medical writer can work from anywhere. In the last three months alone, I have been contacted by companies and headhunters for home-based positions. That's a good first step. The next thing they should realise is that home-based medical writers may not want to work full-time. I am biding my time. Maybe the 80% home-based job is just around the corner. And if it is, I am ready for it. I have the home office environment (almost) fully figured out.

### Raquel Billiones

Brüttisellen, Switzerland  
medical.writing@billiones.biz

### References:

1. Richtel M. In Web World of 24/7 Stress, Writers Blog Till They Drop. *The New York Times*. April 6, 2008. Available at: <http://www.nytimes.com/2008/04/06/technology/06sweat.html?ex=1365134400&en=31ff8262bb73cea2&ei=5124&partner=permalink&exprod=permalink>
2. Mehl M, Vazire S, Holleran S, Clark C. Eavesdropping on happiness: Well-being is related to having less small talk and more substantive conversations. *Psychological Science* published online 18 February 2010. Available at: <http://pss.sagepub.com/content/early/2010/02/17/0956797610362675.full.pdf+html>.

## What is 'Open Access'?

The term 'Open Access' is often used carelessly and without sufficient qualification when referring to biomedical publication, leaving the reader confused as to what exactly is meant by 'Open Access'. Maged Kamel Boulos, Associate Professor in Health Informatics, University of Plymouth, UK (mnkamelboulos@plymouth.ac.uk) recently gave the following lucid explanation of the different models (or variants of existing models) on the WAME listserver.

Open Access (author-pays model): authors retain copyright. Articles are free to readers.

Open Scholarship (OS) model: authors retain copyright but grant a creative commons licence to the publisher (see <http://creativecommons.org/licenses/by-nd/3.0>). Articles are free to both authors and readers who can download immediately after publication (e.g. <http://jvwresearch.org/>)

Free-to-Authors-with-Copyright-Remaining-with-Authors model: authors retain the copyright to the *non-formatted* text of their paper and can freely re-use it or disseminate it in any way (in this form), as long as it is not the formatted, publisher's final version of the paper; some publishers allow this to happen immediately upon acceptance, while others ask the authors to wait 6 months (e.g. <http://www.blackwellpublishing.com/pdf/HIR-ELF-05.PDF> and <http://www.iospress.nl/authco/copyright.html>).

## Indemnity insurance and an attempt to answer the question: What, exactly, does a freelance medical writer actually do—or rather, not do?

Recently I was—once again—sent a draft contract by a pharmaceutical company that included the standard paragraph about an obligation to carry insurance cover. This topic has come up a few times amongst EMWA freelancers, and I think several points need considering.

Firstly, it is a cost, which in the present climate, I would find difficult to pass on to customers. Secondly, it would be advantageous to stick together on this issue. If one of us starts carrying cover, clients will start expecting it, and it will become a knee jerk reaction because “everybody else has it”. Thirdly, it is very unlikely that a client would countenance the effort of documenting his financial loss and the legal expense of suing a poor old uninsured medical writer, simply because we probably do not own enough to make it worth their while. On the other hand a small start-up about to run out of funding might just be tempted if they knew there was an insurance company providing indemnity insurance\* in the background. Even if your insurance company misguidedly paid up, your reputation would probably be permanently tarnished and your premium would rocket up. Fourthly, the suggestion has been made that since CROs carry insurance cover, we should. However, we are not required to recruit qualified investigators, package or distribute the correct drug, generate accurate data and we do not assume GCP and legal responsibilities, such as checking informed consent. Lastly, it has been suggested that the fact that insurance companies are willingly to provide cover is proof that we really do need it because they understand the risks better than we do. That does not convince me in the least because insurance companies want to make money just like the rest of us and will quote for anything, particularly if there is an all but zero risk that they will ever be forced to pay up.

And that brings me to the crux of this matter: the demand for indemnity insurance suggests to me that pharmaceutical companies (or at least their legal departments) do not really understand what a freelance medical writer does, or more precisely, what we do not do. Under what circumstance would a client ever be able to claim damages against me for errors? The answer must be never, because ultimately I do not carry the responsibility for what I write. Of course, this does not mean that I am not responsible for fulfilling my contractual agreement in terms of best efforts, deadlines, content, sources, adherence to SOPs, guidelines and templates etc. if I want my invoice paid. However, the ultimate responsibility with regard to the rest of the world remains with the client. This is also true if my client is a CRO, and although personally most of my work is regulatory, I feel this must hold for medical communications agencies as well.

My response to my client’s contract proposal might be of interest to others. I wrote the following:

*“This paragraph should be deleted. I hold no professional insurance including no indemnity insurance. This is in line with voluntary practice amongst freelance medical writers who are members of the European Medical Writers Association.*

*The reasoning is that our sources are supplied or specified by you or by a third party under contract to you (e.g. a CRO), and that the responsibility for what we write remains with you. This view is in line both with your GCP responsibilities and with your responsibility as the submitter of a licence application or as a licence holder.*

*For example, if chest pain is listed as an AE in the data but I, as a freelance medical writer, forget to mention it, and this discrepancy is then missed, both by your clinical reviewers and your audit department, the responsibility for the omission vis-a-vis the regulators remains with you. The case is the same, for example, if I forget to mention an exclusion criterion in a study protocol which then passes unnoticed through a protocol review committee and an ethics committee and subsequently causes damage to a patient. In neither of these examples will you be in a strong position to sue a freelance medical writer for negligence and financial damage. Furthermore, if you make a faulty business decision based on a discrepancy between, for example, your own data and a text from me; the suggestion that I should carry the financial responsibility for your losses will hardly carry weight. The same applies to faulty or misleading promotional material or scientific text that goes out in your name or in the name of your investigator, even if I am acknowledged as the medical writer.”*

My client’s legal department concurred without a further murmur, deleted the passage and I took the job.

However, this is not quite the end of the matter. I would be interested in a debate as to whether the bold statement I made above, ‘ultimately I do not carry responsibility for what I write’, is shared by other freelance medical writers. The wider issue concerns our role in medical research and of course goes much further than the mundane question of indemnity insurance. It leads on to a discussion of what I can only call our moral responsibility. When we write reviews or original articles for publication in medical journals our professional good practice guidelines say we do take on responsibility and that we should be acknowledged for our contribution. The big issue is not really that we receive acknowledgement but that the ‘authors’ do not get credit for what they have not done.

As a professional group we disclaim financial responsibility for the consequences of our regulatory writing but we claim moral responsibility for our part in publications in medical journals. Agreed?

**Rosemary Bischoff**  
rcb@clinwrite.com

\* Indemnity insurance would compensate a client for financial damages that I might cause him through negligent writing i.e. if I make a mistake.

## Occupational hazards when freelancing

Freelancing should come with one of those black-border labels that read "Freelancing can be dangerous for your physical and mental health." This goes double for those freelancers (many, if not most of us, I assume) who work from home, and in triplicate for what the Americans, with their love of acronyms, have dubbed WAHMs (read: work-at-home-moms). Much has been said and written about the classic pitfalls awaiting this segment of the working population: isolation, administration and procrastination, to name but a few. Some aspects have gone largely uncommented, however, and I would like to supply several real-life examples from my own freelance existence for readers' enlightenment.

### Phone amnesia

The advent of those wonderful gadgets, cell phones, has given rise to a new threat to efficiency. I call it 'phone amnesia', and it goes hand-in-hand with that urban myth called multi-tasking. Brrring-brring! When my office phone goes and I answer it (after checking the number identification to make sure it's not that telephone marketer again), I invariably end up getting out of my chair and pacing around. This is, of course, highly recommended by health gurus who are always encouraging us to replace our desk chair with an exercise ball chair and spend as little time as possible sitting around on our backsides.

So I could pace with a clear conscience if I didn't simultaneously have the habit of picking things up while talking, and then moving from room to room with them. And then - you guessed it - I mislay them. For anyone who is interested in the cumulative effects of this behaviour, I will cheerfully send you my husband's phone number at work. Just call him, say the words 'concert tickets' and then be sure to hold the phone 10 cm away from your ear. All will be revealed. The term 'phone amnesia' can also be used to describe the reverse phenomenon—that of not knowing where you have put your cell or home phone. In a pinch, however, you can solve that problem by calling the number and hoping that the cell is switched on and/or the battery of the hand-held home phone isn't dead yet.

### Multi-tasking + 'flow' = chaos

As the above example illustrates and recent research has confirmed, the original concept of multi-tasking, defined as the brain's capability of mastering several activities in parallel, is deeply flawed. Instead, it seems that the right and the left lobe of the brain concentrate on different tasks, making it difficult to successfully tackle more than two tasks at the same time [1]. Thus, I was concentrating on the essential tasks of talking and walking, not on those tickets.

Even more toxic is the effect of mixing one's perceived multi-tasking capability with the unexpected onset of 'flow', that pleasurable state of mind in which you are so engrossed in your subject that you forget time and space around you [2]. I have taken to buying only the most basic kind of kitchen hardware after several unpleasant and malodorous experiences when I had the hubris

to think I could combine cooking dinner with writing. I suppose it can be considered a credit to my powers of concentration and dedication to my work that I forget the kitchen when I leave it, but I can reliably report that it takes weeks for the smell of burnt carrots to dissipate from a home. Of course, creative re-framing can take you far in this case, too—put the pot outside and, when they come home from school, show your offspring that vegetables are carbon-based life forms.

### Incomprehension and envy

When I started out as a freelancer, I found it rather challenging to deal with the attitudes of some people vis-à-vis my career choice. Even if you yourself are blithely confident that things will work out and you will be able to make a living out of this 'revolutionary' way of working, be assured that some of your nearest and dearest will not. (People seem to forget or have never internalised the fact that contractual employment, unions and pension plans are all very recent inventions, seen historically. My grandmother, born in 1884, never knew where her next 6-month teaching contract was coming from, either [3].)

To this day I sense my mother-in-law's unasked question behind the query: "And how is your work doing?" which is most certainly "And are you earning enough not to plunge you all into penury?" This wouldn't make me quite so annoyed if people in 'steady' jobs were living in a kind of professional paradise. But they aren't, and whether any job (other than a civil servant's) is steady, is a moot point in my opinion. On the other hand, you can spend quite some time disabusing people of unrealistic notions of freelancing. I can't count the times I've heard variations on "Gosh, it must be great to be your own boss." Yes, of course. And no, of course not. Just like everything else in life.

### Virtual reality

Both of these reactions, incomprehension and envy, subtly seem to imply that freelancing isn't 'real' work, somehow. Real work is something you do in a real office. This is, of course, one of the great barriers to successful teleworking models for people with those 'steady' jobs, with managers finding it hard to relinquish control and trust their employees to put all their energy into their tasks. I must admit, though, after a day at the computer keyboard and with few face-to-face interactions, I sometimes get the impression of not being 'all there' or, conversely, to have melded with the machine somehow. So be careful what you believe: Maybe a hyper-sophisticated bot [4] is writing this, and you'll never know it!

### Ursula Schoenberg

*Creative Communications*  
Frankfurt/M, Germany  
u.schoenberg@t-online.de  
<http://uschoenberg.wordpress.com>

### References:

1. Charron S, Koechlin E. Divided representation of concurrent goals in the human frontal lobes. *Science*. 2010 Apr 16;328(5976):360-3.
2. Csikszentmihalyi, M., Abuhamed, S., & Nakamura, J. (2005). Flow. In A. Elliot (Ed.), *Handbook of Competence and Motivation* (pp. 598-608). New York: The Guilford Press.
3. <http://paulandclara.wordpress.com>
4. [http://en.wikipedia.org/wiki/Internet\\_bot](http://en.wikipedia.org/wiki/Internet_bot)



## The ‘fuzzy logic’ of the European medical device world: Interview with an expert

by Claudia Frumento

If a pharmaceutical company had wanted to have aspirin approved 20 years ago, it would have been more than a headache, if not an impossible task: too many side effects; too many safety issues; too many products already on the market with better safety and therapeutic profiles.

This was not the case at that time for new, revolutionary therapeutic medical devices such as the implantable cardiac defibrillator: all that companies had to do was to show that the device did what the specifications described, e.g. it delivered an XX Joules shock to the heart under certain conditions. Were the therapeutic advantages worth the risk of the surgery needed to implant the device? Was an analysis of the complications vs. the efficacy of the therapy carried out? Only the Food and Drug Administration (FDA) seemed to care, and they approved the device after it had been implanted in many patients in Europe. In their article for *The Write Stuff*, Arte Gertel and Nancy J Stark, both American medical writers and aware of the differences, recommended that first-in-human and pivotal clinical trials should be conducted where it is easier to get clinical trials started as they believed it would be in Europe [1].

The situation has changed a lot since those days and is still changing in the right direction, with new therapeutic medical devices undergoing clinical testing programmes similar to pharmaceutical products. But change sometimes complicates things: last year, I was trying to find out which regulations applied for a clinical investigation plan for a new set of disposable catheters for percutaneous surgery and I ended up wandering around the fuzzy regulatory world of medical devices. Nobody seemed to be responsible for this type of documentation; neither the European Medicines Agency (EMA), nor the National Health Association (NHA) could answer my questions. Fortunately, the clinical research organisation (CRO) I was working for offered the help of a real expert, Dr Susanne Gerbl-Rieger, who has been working more than 18 years for the TÜV SÜD1 in Germany (one of the institutions responsible for the *Conformité Européenne* [CE] approval) and has vast experience in this field. She agreed to an interview for *The Write Stuff*.

1 The TÜV Süd is a commercial certification body that validates the safety of products to protect humans and the environment against hazards. As independent consultants, they examine plants, motor vehicles, energy installations, devices and products which require monitoring.

**CF:** *Dr Gerbl-Rieger, thank you for giving me the opportunity to interview you on this difficult topic.*

*Why did it take so long for things to change, even though many of us in the medical device world felt that the CE requirements were not enough to guarantee therapeutic efficacy of new medical devices?*

**Susanne Gerbl-Rieger:** One of the reasons for this ‘slow’ development is the enormous range of different medical devices. There are some medical devices that pose little risk for patients or users and other medical devices that pose high risks for patients, users and even third parties. This is not the case with pharmaceutical products, which mainly affect only the patient. The medical device directives and their ‘translation’ into national laws have to address all medical devices and the three groups of individuals that might be affected by them. This was, and still is, quite complex.

In the past, the Notified Bodies (see below) always asked whether the technical specifications of the device provided by the manufacturer were met, as you correctly mentioned before, but not only that, in general, the manufacturer had (and still has) to provide evidence that all essential requirements as specified in Annex I of the Medical Device Directive (MDD) were fulfilled. Devices have always been tested for biocompatibility depending on the degree and duration of contact with the patient before CE approval and, quite often, the clinical data had and has to be complemented with market follow-up studies. The basic principle for CE approval has always been to evaluate the risk-benefit ratio for patients, users, and third parties.

But the speed of innovation in the area of medical devices has been very fast and has posed many new challenges. Combined medical device and drug products require specific involvement of the Notified Bodies and authorities. Innovations using new production technologies or new materials and high risk products need to be tested for safety and performance with clinical investigations. According to the new EC Directive 47/2007, the approval of the ethics committees and competent authorities is required to conduct a clinical investigation.

**CF:** *Dr Gerbl-Rieger, you have mentioned the “Notified Bodies”. What are these?*

**Susanne Gerbl-Rieger:** A Notified Body is an organisation appointed by the national accreditation authorities and notified by the European Commission to approve products according to the MDD and the national laws.



## The 'fuzzy logic' of the European medical device world

**CF:** *One aspect complicating matters even more is that medical devices are classified in many different groups. Could you briefly explain the classification and which regulations apply for each of the classes?*

**Susanne Gerbl-Rieger:** There are actually two large categories: 1) Medical Devices and 2) In Vitro Diagnostics.

1. The MDD (Council Directive 93/42/EEC) is the legal framework for the first category. A classification based on the risk posed by the medical devices is outlined in Annex IX. There are basically four classes, ranging from low risk to high risk.
  - a. Class I (including Is: sterile and Im: measurement function)
  - b. Class IIa
  - c. Class IIb
  - d. Class III

There are additional specific directives regarding breast implants (Directive 2003/12/EC), hip, shoulder and knee implants (Directive 2005/50/E) and active implantable medical devices (Directive 90/385/EEC) that classify these as Class III medical devices.

The authorization of medical devices belonging to Classes Is, Im, IIa, IIb and III must be verified by a Certificate of Conformity issued by a Notified Body (CE mark). Active implantable medical devices also have to comply with the specific requirements of the Council Directive 90/385/EE.

Class I medical devices that do not need to be sterilised or are not used to measure a function can be marketed after a self-assessment done by the manufacturer.

2. In vitro diagnostic devices are covered by the Council Directive 98/79/EEC. They are classified in 2 groups: A and B in Annex II. The procedures and requirements to obtain the Certificate of Conformity are described in the Annexes III-VII of this directive.

**CF:** *What has really changed over the past years?*

**Susanne Gerbl-Rieger:** The most important changes are:

- upgrading of the classification of hip, shoulder, knee and breast implants
- new classification rules in Directive 47/2007
- clarification that in some cases software can be considered as a stand-alone medical device
- updated essential requirements that will be enforced in March 2010.

Another important change is that this directive requires a more stringent approach to assess the need for running clinical investigations for all Class III medical devices or implantable devices and invasive devices of Classes IIa and IIb for long term use. If there is enough data available from previous studies or from similar devices, the sponsor may be able to justify that there is no need to perform

further clinical investigations. If a clinical investigation has to be done, the authorities will review and approve the submission documents and ethics committee reviews, the study outline, and related documents. According to Directive 47/2007 and its national implementations (21 March 2010) all serious adverse events occurring during the clinical investigation, whether a causal relationship with the device is suspected or not, must be reported. It is also mandatory to inform the authorities if a manufacturer (sponsor of a study) stops a study because of safety issues. How and to which organisation to report this may be different in each country, but reporting is a must. Nowadays we are in the process of implementing these changes.

In any case, the manufacturer is responsible for analysing which method or legal framework and standards are appropriate to provide evidence of product safety and performance at an acceptable risk/benefit ratio for patient, user and third parties.

**CF:** *Are there many aspects that are defined by the local authorities or are we lucky enough to have standard regulations throughout Europe?*

**Susanne Gerbl-Rieger:** The European directives have been implemented or 'translated' into national laws and many have been harmonised and standardised, but this does not mean that all procedures are exactly the same in different countries. The submission, notification and reporting procedures for clinical investigations still have some particular differences in each country of the EU.

In the EU, the Notified Bodies design the conformity assessment process for devices other than Class I. The manufacturer can choose any notified body in the EU. The CE mark has a specific four number code that identifies which Notified Body was involved in the CE approval process.

**CF:** *Are the authorities and Notified Bodies following up the performance of medical devices that are marketed in the EU?*

**Susanne Gerbl-Rieger:** Yes, of course. One area which is standardized is the medical device vigilance or incidents reporting process MEDDEV 2-12-1 rev 5:2007. The authorities collect and analyse incidents and, if indicated, they can recall a product from the market.

Additionally, the requirements to have a post-marketing surveillance (PMS) plan, a plan for post-market clinical follow-up (MEDDEV 2.12-2:2004), and a risk-management system according to EN ISO 14791: 2007, enhance the protection of patients, users, and third parties.

**CF:** *Have we reached the end of this process or are more changes still coming?*

**Susanne Gerbl-Rieger:** In the future, the approval for conducting clinical investigations will be in the hands of the authorities. This means that parts of the technical documentation will have to be available for review at an early phase of the product's development. The Notified Bodies will take a more critical look at the available clinical data during auditing and technical file review, particularly when evaluating whether additional clinical investigations are required to provide evidence on safety and performance. ➤

## The 'fuzzy logic' of the European medical device world

- Most probably, we will also have more product-specific standards for the planning and performance of clinical investigations.

**CF:** *Which are the best information sources for medical writers involved in regulatory documents for medical devices, and, who like me, do not have the support of a big organisation behind them?*

**Susanne Gerbl-Rieger:** The most important documents are the EN ISO 14155 part 1 and 2. Additionally, product-specific requirements on clinical investigations can be found in ISO 5840 for cardiovascular implants and cardiac valve prostheses, MEDDEV 2.7.1 Annex 1, 2008 – Clinical Investigations of Coronary Stent. A more general document on clinical evaluation is the new MEDDEV 2.7.1:2009.

The best sources of information are the websites of EMA, the Notified Bodies or the authorities. In Germany, the authorities are the BfArM and the Paul Ehrlich Institut (PEI) and the Notified Bodies include the TÜV SÜD Product Service GmbH, TÜV Rheinland, SGS, Dekra, BSI or KEMA, amongst others. The TÜV SÜD Akademie also provides specific training sessions on these topics.

The following websites and documents all contain further information:

The European Medicines Agency (EMA) website: [www.ema.europa.eu](http://www.ema.europa.eu).

The Notified Bodies in the European countries are found under the links <http://www.ema.europa.eu/exlinks/exlinks.htm> and

[http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/index\\_en.htm](http://ec.europa.eu/enterprise/sectors/medical-devices/regulatory-framework/index_en.htm) provides a comprehensive list of directives and interesting links.

Another useful link is [http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm) which lists all the harmonized standards and ISOs in numerical order and with a short description of their content. Here you can find the correct and complete name of the ISOs mentioned above, e.g.:

EN ISO 14155-1:2003

Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)

EN ISO 14155-2:2003

Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)

**CF:** *Dr Gerbl-Rieger, this interview was very interesting for us, and I am sure that many colleagues will be grateful for these tips and will be able to acquire a better understanding of the legal framework for the approval of medical devices. Thank you very much for sharing your expertise.*

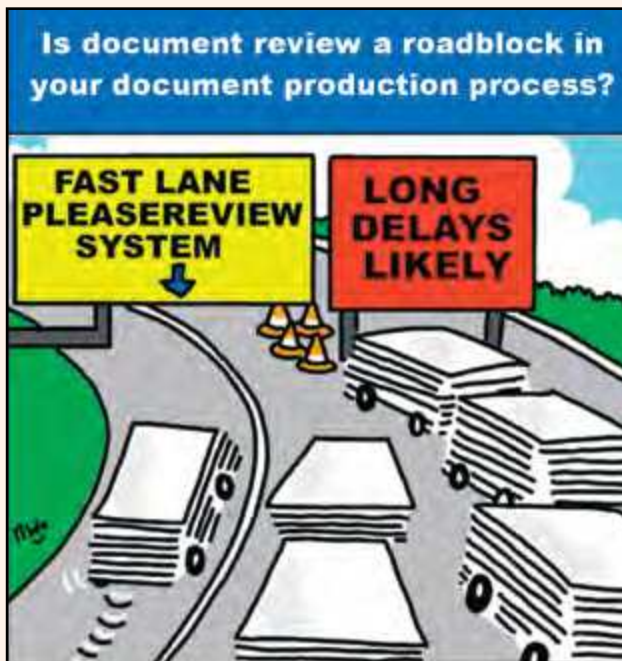
**Dr Susanne Gerbl-Rieger** ([sgerbl-rieger@msource-cro.com](mailto:sgerbl-rieger@msource-cro.com)) studied biology, genetic engineering, molecular biology, human genetics and pharmacology at the LMU in Munich. She gained her doctorate at the Max Planck Institute and Munich Technical University, and then started to work for TÜV SÜD in 1992. During her 18 years at TÜV SÜD, she has worked as an expert in genetic engineering and biotechnology, as an auditor for medical devices and as a design reviewer of non-active medical devices. From 2001–2005, she was the CEO and head of the Certification Body of the SÜD Vitacert (food certification). In 2005, she joined the business development group of TÜV SÜD Life Sciences, and since 2008 she has been member of the board and Director of Quality Assurance and Regulatory Affairs of the MSOURCE group in Munich. MSOURCE is the CRO of TÜV SÜD with subsidiaries in 6 European countries and provides services related to clinical studies for medical devices, pharmaceutical and biotechnical products.

**Claudia Frumento**

ICiMT – International Communication in Medicine and Technology  
Gießen, Germany  
[c.frumento@icimt.com](mailto:c.frumento@icimt.com)  
[www.icimt.com](http://www.icimt.com)

### References:

1. Gertel A and Stark NJ. The world of medical devices—serving two masters. *TWS* 2008;17(2):74-77.



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# Third EMWA Freelance Business Survey 2010

by Alistair Reeves

This was the second EMWA Freelance Business Survey conducted using a web-based questionnaire. The first survey was conducted on paper in 2003, and the second in 2007. The EMWA Freelance User Group reviewed the 2007 Questionnaire towards the end of 2009. Our aim was to further simplify the questionnaire to improve the completion rate, although we did add two new questions the group felt were important. After the questionnaire was set up by Head Office, it was tested by the User Group, and then released for completion between 12 February and 31 March 2010.

We received 63 responses to the first survey in 2003, 103 to the second in 2007, and 130 this year – and hardly any questions were skipped in 2010.

This report on the 2010 survey includes some comparisons with the results of the 2003 and 2007 surveys. Comparison was not always appropriate because the content of some of the questions had been simplified or the responses had been newly grouped. Also, the 2003 questionnaire was addressed to individual freelancers and small businesses with up to 7 employees (the latter accounted for 27% of the sample), whilst the 2007 and 2010 surveys were addressed only to freelancers.

## Number of responses and countries

130 responses were received: 44 (34%) from the United Kingdom (including 2 from 'England'), 29 (22%) from Germany (including 1 'Germany, USA and other countries'), 8 (6%) from France, 7 (5%) from Spain, 4 (3%) from Switzerland, 3 (2%) from Sweden, 2 each from Australia, Belgium, Ireland and the USA, and 1 each from Austria, Canada, Czech Republic, Denmark, European Union, India, Israel, Italy, Japan, Netherlands, Norway, Poland, Singapore, and Turkey. 11 (9%) respondents skipped this question, and there were 2 invalid responses.

## Type of freelancer and hours worked

Respondents decided whether they were full-time or part-time. 80 (62%) respondents were full-time freelancers, 34 (26%) part-time freelancers, and 14 (11%) were in full-time employment and doing freelance work. The figures for 2007 were 59%, 33% and 7%. 65 (50%) respondents work 31–50 hours per week, presumably mostly full-timers, and 63 (49%) work 1–30 hours per week, presumably mostly part-timers. 2 respondents skipped this question. The full-time/part-time split was the same in 2007.

## Indemnity insurance

This was a new question in 2010 and was added because this topic has been discussed at almost all Freelance

Business Forums for the past 10 years. What has always emerged is that nobody has any idea how many freelancers have indemnity insurance and, if they do, why they do. This is our first attempt to quantify this and to find out why colleagues take out indemnity insurance.

103/130 (79%) respondents do not have indemnity insurance. Amongst the 27 (21%) respondents who have indemnity insurance, 12 (44%) said that this was because they offer 'services that go beyond medical writing (e.g. advice on regulatory strategy or GCP)' (*answer prompted in questionnaire*). The 'services going beyond medical writing' were 'handling submissions of applications to ethics committees', 'hosting miniconferences', 'consultancy or advice on drug development', 'safety review of data', 'biostatistics', 'advice on pharmacovigilance', 'perform readability testing and validation for patient information', and 'translation of critical documents'. Although no conclusions on the *need* for indemnity insurance can be drawn from the above, it is clear that most colleagues do not feel that it is necessary, and that if they do, it is often because they are involved in activities which go beyond the normal scope of medical writing or which might affect client strategy. 15/130 (12%) respondents have indemnity insurance but do not offer services that go beyond medical writing.

## Sources of work

Respondents were asked to indicate their sources of work (totalling 100%) from the categories given in Table 1, which shows the mean percentage of work obtained from each source.

Table 1: Sources of freelance work (N=123)

Source	Mean % of work <sup>a</sup>	
	2010	2007
Longstanding customers	56	49
Referrals from colleagues	24	22
Referrals from customers	20	10
Own advertising	19	8
EMWA Freelance Directory	14	10
CROs/agencies	13	21
Other freelance directories	13	3
'Looking for a medical writer' <sup>b</sup>	-	1
Networking with EMWA colleagues <sup>c</sup>	6	-
Other	11	1

Table is sorted on 2010 column except for category 'Other'

CRO=contract research organisation

<sup>a</sup> The columns do not add up to 100 because the cells in each row are the mean of the percentages given for each source

<sup>b</sup> Category not present in 2010 survey

<sup>c</sup> Category not present in 2007 survey

## Third EMWA Freelance Business Survey 2010

- The pattern was similar to those of the 2003 and 2007 surveys. It is worth noting, however, that the mean percentage of work from CROs and agencies decreased from 21% in 2007 to 13% in 2010, possibly reflecting the economic crisis from 2009 onwards. And it is pleasing to see that the mean percentage of work derived from the EMWA Freelance Directory rose from 5% in 2003 and 10% in 2007 to 14% in 2010, even though the 2007–2010 increase for other directories was greater.

### Types of activity

Respondents were asked to indicate their types of activity (totalling 100%) from the categories given in Table 2, which shows the mean percentage of each type of activity.

Table 2: Types of freelance activity (N=122)

Type of activity	Mean % of work <sup>a</sup>	
	2010	2007
Writing	63	67
Translation	23	11
Editing	20	18
Consultancy work	18	6
Training events	11	6
Quality control	9	6
Proofreading	7	3
E-publishing	4	1
Other	11	3

Table is sorted on 2010 column except for category 'Other'

<sup>a</sup> The columns do not add up to 100 because the cells in each row are the mean of the percentages given for each activity

Writing was the major activity in 2003 (57%), 2007 (67%) and 2010 (63%), followed by editing and translation, with a clear shift to more translation and consultancy from 11% and 6% in 2007 to 23% and 18% in 2010. Respondents also felt that they were doing more training in 2010 (11%) than in 2007 (6%).

### Types of documentation

Respondents were asked to indicate the type of documentation they generally work on (totalling 100%) from the categories given in Table 3, which shows the mean percentage of each type of document worked on. These categories were simplified and regrouped so direct comparison with 2007 and 2003 is not possible.

Table 3: Types of document (N=122)

Type of documents	Mean % of work <sup>a</sup>
Regulatory documentation	57
Peer reviewed articles for journals	39
Medical communications materials	25
Consultancy documentation	18
Articles for the scientific press	16
Medical and scientific text books	11
Training documentation	9
User manuals	4
Other	20

<sup>a</sup> The column does not add up to 100 because the cells are the mean of the percentages given for each type

As in 2003 and 2007, the mean percentage of time spent on documents used for drug approval and journal articles for the medical and scientific press were greatest. The 2007 survey did not include the category 'medical communications materials' which accounted for a mean of 25% of work in 2010 (the closest category in 2007 was 'marketing materials' at 12%). This presumably reflects the increase in EMWA members working in medical communications over the past few years.

### Preferred methods of charging for work

121/130 (93%) of respondents provided information on their preferred method of charging, and 128/130 (99%) on clients' preferred methods of charging (Table 4).

Table 4: Preferred method of charging for work

Method	Number of responses (%)	
<b>Respondent</b> (N=121)		
Hourly rate with or without a contract-specified upper limit on hours	69	(57)
Fixed price contingent on assumptions in the contract	30	(25)
No preference	16	(13)
Fixed daily rate contingent on assumptions in the contract	6	(5)
<b>Client</b> (N=128)		
Depends on client	38	(30)
Fixed price contingent on assumptions in the contract	35	(27)
Hourly rate with or without a contract-specified upper limit on hours	25	(20)
Depends on job	17	(13)
Fixed daily rate contingent on assumptions in the contract	4	(3)

It is not surprising that more than half of the respondents prefer to invoice for hours worked, nor is it surprising that this is less popular amongst clients. As many as 25% of respondents prefer to quote fixed prices and 27% felt that their clients preferred this too. This is presumably always with provisos, as my experience, at least, is that jobs generally take longer than the client thinks (or wants), and such contingencies always have to be built in. Depends on job or client: that these account for the largest client category is also not surprising, because clients will very much more easily commit a few hundred euros to a small editing job on a hourly-basis than thousands to the preparation of a CTD with all sorts of other people involved. And this also depends on whether the work is coming direct from the client or via a CRO.

### Hourly charges for medical writing and related activities

115 (89%) respondents provided information on charges. All charges were to be given in euros as *average* hourly rates for the activity in question. Some respondents entered implausible hourly rates. These are listed below and have been excluded from the analysis (€; a value may have been mentioned by more than 1 respondent):

- Medical writing: 572, 460, 350, 250
- Editing: 350, 250, 200

## Third EMWA Freelance Business Survey 2010

Table 5: Average hourly rates for medical writing and related activities

Activity	Hourly rate (€) <sup>a</sup>							
	2010			2007			2003 <sup>b</sup>	
	N	mean ± SD	median (range)	N	mean ± SD	median (range)	N	median (range)
Medical writing	96	79 ± 27	80 (11–200)	76	76 ± 23	75 (29–140)	55	80 (20–160)
Editing	72	68 ± 22	65 (25–130)	52	71 ± 26	75 (29–140)	48	70 (20–150)
Quality control	35	73 ± 28	74 (10–150)	26	73 ± 31	65 (30–150)	21	75 (20–>160)
Proofreading	38	63 ± 26	59 (20–140)	34	69 ± 29	62 (25–140)	24	55 (20–150)
Consultancy	33	106 ± 52	87 (50–300)	26	105 ± 50	91 (29–250)	26	105 (20–>160)
E-publishing	10	93 ± 21	93 (63–125)	3	€ 65 (2) and 200 (1)		not included	

SD=standard deviation

<sup>a</sup> Inclusion of the implausible responses hardly affected the median values. The effect on the mean (± SD) values is illustrated by the following (€): consultancy 154 ± 137; medical writing 95 ± 78; editing 75 ± 43; QC 99 ± 96; proofreading 75 ± 52; E-publishing 121 ± 95.

<sup>b</sup> Mean ± SD was not calculated for 2003.

- Proofreading: 300, 200, 180
- QC: 572, 320, 250, 190
- Consultancy: 550, 500, 460, 350.
- E-publishing: 400

The average hourly rates for 2003, 2007 and 2010 (mean ± standard deviation; median [range]) for the different activities are given in Table 5, rounded to full figures, and excluding those listed above.

The median hourly rate for editing decreased from €75 in 2007 to € 65 in 2010, whilst the mean hourly rates were similar. In 2007, the medians and ranges for writing and editing were the same at €75 (29–140), but had moved apart again in 2010 at €80 (11–200) and € 65 (25–130). Even though a definition was supplied (advising clients on scientific and medical documentation and communications issues), ‘consultancy’ can be interpreted in different ways, which may explain the difference of more than €15 per hour for the median between 2003 and 2010. The mean and median rates for 2007 and 2010 were, however, largely the same.

After excluding the implausible rates listed above, only 8 responses for any activity were ≥ €150 per hour (1 each for medical writing and QC, and 6 for consultancy). Between 10 and 20% of responses for all activities were ≥ €100 per hour, and this means that some colleagues can evidently earn as much as this per hour *on average*. Some writers, however, are still obviously charging *very low average* rates, although it is gratifying to see that the proportion of these was lower in 2010 than in 2007 (for example, 13% of responses for writing and 25% for editing were between € 29 and 49 per hour in 2007; the figures for 2010 were 7% and 16%).

Table 6: Charges for training

Activity	Charge (€) <sup>a</sup>							
	2010			2007			2003 <sup>b</sup>	
	N	mean ± SD	median (range)	N	mean ± SD	median (range)	N	median (range)
Whole day	21	766 ± 502	950 (500–2500)	19	815 ± 406	1000 (400–2300)	16	955 (850–>1150)
Half day	27	390 ± 271	500 (120–1200)	15	510 ± 238	475 (200–1000)	14	517 (475–775)
Hourly	27	83 ± 33	85 (50–200)	7	107 ± 62	100 (46–200)	8	NC (40–190)
Prep/h	18	73 ± 27	80 (50–143)	8	84 ± 34	84 (48–150)	3	NC

SD=standard deviation; NC=not calculated; Prep/h=hourly rate for preparation

<sup>a</sup> Inclusion of the implausible responses hardly affected the median values. The effect on the mean (± SD) values is illustrated by the following (€): whole day 1384 ± 1321; half day 750 ± 720; hourly 142 ± 158; hourly for preparation 135 ± 142.

<sup>b</sup> Mean ± SD was not calculated for 2003.

### Charges for training

64 (49%) respondents gave details of training charges. Of these, 26 (41%) provided charges for half-day training, 32 (50%) for whole-day training, and 31 (48%) gave hourly training rates. 39 (61%) make no charge for preparation and 24 (38%) make an hourly charge (3 gave no rate).

Again, some respondents entered implausible values (€; a value may have been mentioned by more than 1 respondent):

- Half day: 2500, 2000
- Whole day: 5000, 4000; 460, 400, 300
- Hourly rate: 750, 500
- Hourly rate for preparation: 650, 400, 250

The average rates for 2003, 2007 and 2010 (mean ± standard deviation; median [range]) for training activities are given in Table 6, rounded to full figures, and excluding those listed above.

No substantial shifts in median charges for half-day or whole-day training events were seen between 2003 and 2010. Based on a reasonable numbers of respondents in 2010 for the first time, hourly rates for training and preparation of about €80 are acceptable.

Thanks to the Freelance User Group for their assistance in developing the questionnaire, Melanie Foster at Head Office for setting it up, and Alison MacIntosh for checking the numbers.

And thanks very much to all readers who took the time to complete the survey.

### Alistair Reeves

Ascribe Medical Writing and Translation  
Wiesbaden, Germany  
a.reeves@ascribe.de  
<http://www.ascribe.de>



## Are you doing the (copy)right thing? A NetworkPharma lunchtime briefing

by Andrea Palluch

Copyright was a hot topic at the Freelancers' Forum which was held on 13<sup>th</sup> November 2009 at EMWA's 29<sup>th</sup> Conference in Frankfurt. I had attended a meeting on 1<sup>st</sup> October 2009 titled 'The Ins and outs of copyright licences', which had been organised by Peter Llewellyn of NetworkPharma Ltd, where I had picked up some interesting information about copyright and after attending the Freelancers' Forum I offered to write a report on that meeting.

At the meeting held in London, Jackie Marchington of Caudex Medical introduced the subject using a few real-life examples. Three experienced employees of the Copyright Licensing Agency Ltd. (CLA) were present to answer questions. Seventy percent of the audience represented medical communication agencies (med comms). As the meeting went on, it became pretty clear why they were present en masse!

CLA operates in the United Kingdom (UK), licenses copyright material published in the UK, United States of America and other countries with which an agreement is in place, and offers licence solutions to all sectors. According to the information on their website [1], CLA is a not-for-profit licensing body created in 1983, and owned by the Authors' Licensing Society Ltd and the Publishers' Licensing Society Ltd. They also have an agreement with Design and Artists Copyright Society Ltd, and perform licensing activities on behalf of these three bodies. After deducting costs, licence fees are distributed to copyright owners, who have exclusive rights over their own work [2].

To comply with legal requirements, a licence will be most likely required when copying (photocopying, scanning or re-using) published or copyright-protected material. This is when CLA comes into play: it facilitates legal access to published material and prevents copyright infringement in a cost-effective way. Its licence covers titles not only from the UK but also from more than 30 other countries.

The relevant information presented here concerns pharmaceutical and business licences. The 'pharma licence' was negotiated through the Association of the British Pharmaceutical Industry (ABPI) on behalf of the industry. It covers the needs of the pharmaceutical industry but does not include cover for sales or promotional use. The 'business licence' is the standard licence for businesses and other organisations. Med comms operate under this 'generic' licence so it is easy to understand why the specific needs of this industry are not fully met. Shortcomings hinder both the pharmaceutical and med comms industry, and were acknowledged by the CLA during the meeting.

According to the CLA presentation, the pharma licence permits

- Internal copying from paper and digital editions
- Project-specific network storage
- Copies for regulatory approvals, medical information and sales representatives
- Sending to overseas offices
- Receipt of unencrypted articles from the British Library.

The business licence

- Covers copying and scanning from journals, magazines and books
- Permits further internal copying of material received via document delivery suppliers and press cuttings agencies
- Permits storage of electronic (scan of hard copies) copies on local hard drives
- Enables electronic copies to be placed on a intranet for a period of up to 30 days
- Does not permit systematic storage or indexing (searchable pdf attached to citation database) of electronic copies.

In many scenarios of med comms and their pharmaceutical company clients, depending on the traffic of information (copies of copyright material from/to), neither licence would apply or suffice! Both pharma and business licences have different scopes and are not complementary to each other.

As if these restrictions weren't complicated enough, there are a couple more to note:

- Paper and digital subscriptions or copies are treated differently
- There are limits to the amount of content that can be copied on a single occasion (e.g. up to one article from a single issue; one chapter of a book).

Real-life case studies were presented from the med comms point of view and used as examples to generate discussion. After hearing about the first three cases, more than 70% of the attendees confessed to having infringed the CLA business licence! I'm sure that, if you work in med comms, the following transgressions will sound very familiar [3].

- Systematic storage: licensed material is stored electronically on a central server (intranet site or shared drive), and citation manager software is used to organise reference material
- Reference sharing and freelancers: references are provided to freelancers (who work directly for med comms) as digital copies via e-mail or ftp



## Are you doing the (copy)right thing?

- Reference sharing and approval copies: med comms make copies of references they already have, mark them up, keep one copy and send the other to clients requesting supporting documentation for approval purposes
- Reference sharing and advisory boards: med comms send references to consultants working directly for clients (and not for med comms). Often, clients consider they 'own' references because they paid (med comms was reimbursed) for these.

I hope you are not shocked to learn that you might not be doing the right thing—at least you know you're not alone!

Enough of the bad news, the good news is that the open and extremely honest discussion at the meeting led to the consensus that the business licence currently offered by

CLA does not fit the bill for med comms. There is now an ongoing discussion between Jackie Marchington, representing the medical communications industry, and Leon Skelton of CLA to address specific needs. If you want to get involved, have your say or want your own questions answered, please go to <http://www.medcommsnetworking.co.uk/event28.html> where you can also follow the progress of the negotiations and check the slide presentation.

**Andrea Palluch**

London, UK

[apalluch@inpharmedia.co.uk](mailto:apalluch@inpharmedia.co.uk)

#### References:

1. [http://www.cla.co.uk/about/who\\_we\\_are/](http://www.cla.co.uk/about/who_we_are/). Accessed on 22<sup>nd</sup> April 2010
2. Heywood E and Chandler V. Legal considerations in the selection of article, book and journal titles. *The Write Stuff* 2007;16(3):156-157.
3. <http://www.medcommsnetworking.co.uk/event28.html>. Accessed on 22<sup>nd</sup> April 2010

## Report from a Foresight conference in Oslo, Norway

In futures studies, especially in Europe, the term 'foresight' has become common as of 2005, embracing activities of critical thinking concerning long-term developments, debate and effort to create wider participation in decisions and shaping the future, especially by influencing public policy and strategic decisions. I was fortunate enough to attend (and write minutes for) an interesting 1-day Foresight conference on 15 April 2010 and would like to share some impressions.

The director of research at Accenture spoke about how IT will change the world in the next 3-5 years. Cloud computing is a significant shift that enables solutions tailored more to business needs than technology constraints. We are entering a world where any device can deliver any content. A key principle of the new paradigm is that users will mix access patterns towards whatever maximises their own convenience and productivity. The job of enterprise IT will be to provide a secure transport layer for work information. Social networks are emerging as a rich source of information about consumer sentiment, preferences and desires (free focus groups). As analytic tools are becoming incorporated into standard offerings from software vendors, the analytic process is rendered obsolete—data acquisition and decision-making remain. What may truly differentiate an organisation is how they manage to turn information into action.

The chief technology advocate at Google (Michael T. Jones) told us "my friends and I built Google Earth in my living room". It has actually been used to unearth a new human species, the technology has helped people find out where to dig. Jones specifically mentioned that Google Inc. would like us to post our health records on the net to enable studying associations between drug use and adverse events. In the future we will not have to

bring our computers with us, we will relate to them as we do to power plants, they will just be there—readily available for use. In 2050, it will be enough to look at the computer and it will work like a contact lens (Google's vision).

Daniel Erasmus, futurist and founder of Digital Technology Network (DTN), gave us the first public presentation of the new Scenario Console technology. Artificial and social intelligence has been combined to enable prediction of future trends and creation of scenarios—much faster than what is currently possible. The Scenario Widget is a news-streaming program, hosted as a web service in the cloud, that deals with vast amounts of information (can scan 1 million articles daily). The system collects essentially all news, including information from some business blogs, local newspapers and think tanks—such as Fortune (covers 500 companies)—and presents it in a partly edited (they still need people) user-friendly format.

A Swedish company, Kairos Futures, presented how they help companies understand and shape the future by identifying critical success factors and reduce complexity to a few manageable scenarios. The name Kairos means 'the right time' or 'time for change'. The word comes from a Greek legend about the God Kairos who runs around in the Olympus and tries to catch chronos (measurable quantitative time); if he could catch chronos, time could be stopped and there would be time for afterthought and reflection (wouldn't that be something?). Kairos Futures use foresight to ask new questions and find new answers early enough to enable timely intervention. How should we be to succeed? Answer; decisive, curious, daring, brave, challenging and inquisitive. Who is like that? Children of course, look and learn!

**Kari Skinningsrud**

[kari@jimwric.no](mailto:kari@jimwric.no)

■ **Webscout**

## The latest trend in medical writing—Topic based writing

by Joeyn Meike Flauaus

The regulations that affect our daily work are changing constantly. Thus, keeping up-to-date in this rapidly changing environment of clinical development and clinical documentation is key in our business. One of the latest trends in the medical writing world is topic based writing, which will change the way we currently work tremendously.

What is topic based writing? It is a new approach of thinking; information will now be structured in a modular way instead of a linear way, which is currently the case. With the new approach, each document is broken down into small bits of information which are called topics. These topics are stand-alone pieces of information and will be saved as such in a database. Each topic has a title defining the content and can be for example a single sentence, a couple of paragraphs, or longer. Try to think of it as content of a section in a document.

Topics are reusable; they can be pulled together in any imaginable combination for different types of documents and audiences. One of the requirements for topics is of course a consistent writing style and strict adherence to a style guide. The idea behind it is that a topic will be written and reviewed once and then will be approved and reusable. If the content of a topic needs to be updated, the topic will be updated only once and will be simultaneously updated in all documents where the specific topic is used. This concept ensures consistency between documents.

Darwin Information Typing Architecture (DITA) is a standard for supporting information and is an XML-based architecture to help authors in producing and delivering readable information using the topic approach. The standard is managed by the Organization for the Advancement of Structured Information Standards (OASIS) DITA Technical Committee. OASIS is a not-for-profit organisation that promotes the development, convergence and adoption of open standards for the global information society.

Think of DITA as a content supply chain for regulatory or internal documents throughout the compound lifecycle. The DITA map, a separate XML file, presents the table of contents for deliverables and is used to compose various topics to create the documents. At the end, a single document can be published in any required format (e.g. PDF, XML, DOC)

Short tutorials on the key concepts of DITA topics and on how to create DITA topics are provided at:

[http://www.ditainfocenter.com/eclipsehelp/index.jsp?topic=/ditaotug\\_top/topics/abouttopic\\_authoring.html](http://www.ditainfocenter.com/eclipsehelp/index.jsp?topic=/ditaotug_top/topics/abouttopic_authoring.html)

The webinar 'Defining DITA for Pharmaceutical Documentation' on the webpage of the OASIS DITA Pharmaceutical Content Subcommittee ([http://www.oasis-open.org/committees/tc\\_home.php?wg\\_abbrev=dita-pharma](http://www.oasis-open.org/committees/tc_home.php?wg_abbrev=dita-pharma)) provides a good introduction on topic based writing and the use of DITA.

The DITA Pharmaceutical Content Subcommittee (<http://xml.coverpages.org/DITA-Pharm-Proposal.html>) was founded to support creation, maintenance, and publishing of pharmaceutical documentation using DITA. This DITA Subcommittee defines DITA topics and maps to implement content specifications that are required in the pharmaceutical industry, such as ICH CTD, US IND, EU CTA etc. Everyone who is interested to get involved in the work of the DITA Pharmaceutical Content Subcommittee can join as participation is open to all interested parties, especially those responsible for designing and documenting clinical and nonclinical studies as well as dossiers for regulatory submissions.

If you want to learn more about topic based writing, a trip to Washington DC might be of interest. One of the medical writing sessions at the DIA meeting in June is: 'Topic-based Content: Is the New Paradigm for Authoring Regulatory Submissions a Modern Miracle or a Frankenstein?'

Please let me know what you think about topic based medical writing at: [Joeyn.Flauaus@sanofi-aventis.com](mailto:Joeyn.Flauaus@sanofi-aventis.com). Any ideas for the next issue, comments or suggestions are also welcome.

**Joeyn Meike Flauaus**

*Sanofi-Aventis Deutschland GmbH  
Frankfurt am Main, Germany*

## New edition of medical writing careers guide

An updated edition of Annick Moon's book 'From academic to medical writer' is now available at <http://www.medcommsnetworking.co.uk/careersguide.pdf>. The previous edition was reviewed by *TWS* in 2009 (see vol 18(4) page 244).

## Current medical discourse research

The Linguistic corner aims to publish abstracts of papers related to oral or written medical discourse of interest to the *TWS* readership. Abstracts are numbered consecutively to build into a series that can be saved as a collection. Contributions should be in English but can relate to papers published in other languages. Francoise Salager-Meyer invites you to send abstracts to her at: francoise.sm@gmail.com.

### Keep the writer in mind—Differing strategies across cultures?

Oana Maria Carciu (oana.carcu@gmail.com) obtained a BA in French and English Language and Literature at the University of Bucharest (Romania) in 2006 and an MA in Textual and Cultural Studies in English at the University of Zaragoza (Spain) in 2008. At present, she is research assistant at the University of Zaragoza. She is currently working on her PhD thesis on intercultural and interlinguistic variation of authorial stance in biomedical research writing.



Her main research interests are related to the application of genre analysis and contrastive rhetoric in academic and research settings.

#### Abstract 6

Carcu OM. An intercultural study of first person plural references in biomedical writing. *Ibérica* 2009;18:71-92.

Both in multi-authored and single authored papers, first person references attest the intrusion of the writer(s) in their texts for interpersonal purposes [1-4]. One interesting enquiry into the role of first person references in academic writing is that which identifies discourse roles associated with the use of 'we' or 'I' -these roles being those of 'representative', 'guide', 'architect', 'recounters of the research process', 'opinion-holder' and 'originator' [5]. These various roles of the 'we' pronoun often converge in academic writing for rhetorical reasons. But, to what extent do these roles coexist in the same text [6] and, more specifically, in a highly objective and impersonal scientific academic text such as a biomedical research article? How are these roles distributed across the rhetorical sections, i.e. across the IMRaD structure [7] of multi-authored biomedical research articles? Furthermore, in the context of the widespread use of English as the international language of scientific academic communication and research [8-9], is there a difference between native and non-native English-speaking writers in the distribution and use of the discourse roles of 'we'? To explore the above issues, an analysis of first person plural references ('we', 'our' and 'us') has been conducted with a corpus of 48 biomedical research articles. From these, 24 were written in English (L2) by Spanish scholars and the remaining 24 written in English (L1) by scholars from an Anglophone-based context.

The analysis of the frequency of first-person plural references and their discourse functions [5] in the different sections of the articles discloses that both L1 and L2 (Spanish) scholars keep the writer in mind when they write. Hence, results show that 'we' is present particularly in the Introduction section, and then in the Results and Discussion sections. In Introductions first person-plural references rhetorically construct the writers as 'architects' focused on text-internal realities to 'create a research space' (*we report here*). This role is juxtaposed with that of the 'recounters of the research process' in Results (*we next measured*) where authors need to identify procedures 'in sufficient detail to allow others to reproduce the results' [10]. Finally, since Discussion sections point out the significance of research outcomes in relation to previous outcomes, writers are represented as 'guides' (*we show that*), 'opinion-holders' (*we think, we believe*) and 'originators' (*we defined, we propose*). The similarities revealed by the corpus analysis as regards the use of these discourse roles by L1 and L2 scholars reflect the existence of genre conventions and the influence of standard academic English. However, the corpus analysis further brings out differences concerning the higher frequencies of 'we' registered in the Introductions written by L2 scholars. Their rhetorical effect is that of creating a more visible authorial identity in L2 texts, a visibility possibly triggered by their non-native status, hence necessary in the context of a highly competitive academic world such as that of biomedical sciences. In conclusion, findings on the use and discourse roles of 'we' in biomedical research articles appear to indicate writers' awareness of the specific communicative purposes of first person-plural references most likely due to the well-established rhetorical conventions of the genre. Differences, however, may suggest some culture-specific variation in the use of the standard academic English (as argued by Mauranen et al. [11]).

#### References

- Hyland K. Humble servants of the discipline? Self-mention in research articles. *English for Specific Purposes* 2001;20:207-226.
- Breivega KR, Dahl T, Fløttum K. Traces of self and others in research articles: a comparative pilot study of English, French and Norwegian research articles in medicine, economics and linguistics. *International Journal of Applied Linguistics* 2002;12:218-239.
- Harwood N. We do not seem to have a theory ... The theory I present here attempts to fill this gap: inclusive and exclusive pronouns in academic writing. *Applied Linguistics* 2005;26: 343-375.
- Matsuda PK and Tardy CM. Voice in academic writing: The rhetorical construction of author identity in blind manuscript review. *English for Specific Purposes* 2007;26(2):235-249.
- Tang R and John S. The 'I' in identity: exploring writer identity in student academic writing through the first-person pronoun. *English for Specific Purposes* 1999;18:S23-S39.
- Kuo C-H. The use of personal pronouns: role relationships in scientific journal articles. *English for Specific Purposes* 1998;18:121-138.
- Swales JM. *Genre Analysis. English in Academic and Research Settings*. Cambridge: Cambridge University Press, 1990.
- Benfield JR and Howard KM. The language of science. *European Journal of Cardiothoracic Surgery* 2000;18:642-648.
- Ferguson G. The global spread of English, scientific communication and ESP: questions of equity, access and domain loss. *Ibérica* 2007;13:7-38.
- International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals: writing and editing for biomedical publication. URL: <http://www.icmje.org/> [25/02/09].
- Mauranen A, Pérez-Llantada C, Swales JM. Academic English: A standardised knowledge? in A. Kirkpatrick (ed.), *The Routledge Handbook of World Englishes*. London, New York: Routledge (in press), 2010.

## ■ Biomedical publishing shorts

### New CONSORT

The CONSORT (Consolidated Standards for Reporting Trials) statement lays down standards for reporting randomised clinical trials. By these standards authors are required to follow a check list of items that should be included in a manuscript and to provide a flow diagram which relates to such things as sampling, selection of participants and their progress through the study.

The CONSORT statement which was published in 2001 has recently been updated ([www.consort-statement.org](http://www.consort-statement.org)). The updated version extends the allocation concealment and blinding requirements and includes new provisions whereby trials must be registered before inception, and details of where the protocol can be accessed and the source of funding are to be given. According to **Gerd Antes**, writing in the *BMJ*<sup>1</sup>, inadequate reporting of trials is common. The editorial refers to a study by Hopewell and colleagues which has been published with the updated CONSORT statement. The study compared over 600 reports of randomised trials indexed in PubMed in 2000 with a similar sample published in 2008. Although the researchers found that there have been improvements in reporting quality since 2001, even now fewer than 50% of high impact journals recommend that authors comply with the CONSORT statement. Antes asks why better adherence to the CONSORT statement has not been achieved despite evidence that compliance improves the standard of reporting and concludes that the main reason is the general lack of awareness coupled with the reluctance of journals to require that authors follow the guidelines. The reluctance is probably due to a perceived increase in workload in policing the guidelines. Antes suggests that this problem could be overcome by incorporating the CONSORT checklist into the peer review process and thus shifting the workload to authors.

### WAME issues a new policy statement on 'conflict of interest'

The World Association of Medical Editors (WAME) has updated its recommendations to journals on conflicts of interest. The policy statement<sup>2</sup> defines a conflict of interest (COI) as existing "when there is a divergence between an individual's private interests (competing interests) and his or her responsibilities to scientific and publishing activities such that a reasonable observer might wonder if the individual's behavior or judgment was motivated by considerations of his or her competing interests."

COI policies differ between journals but this statement summarises the main policies and gives examples and options for disclosure and management. Competing interests are not just financial ties but can be academic commitments, personal relationships, political or religious beliefs or institutional affiliations. Examples of each of these interests are given. Journals should publish all COI disclosures with the publication.

There is no standard or consensus for defining even a financial conflict but journals are advised to inform their authors and reviewers about their criteria of the amount of financial benefit above which a declaration is required and when the requirement to declare expires after the benefit has ceased, e.g. a declaration may not be necessary if a person has ceased to be a shareholder of a company more than 5 years before. Journals are also encouraged to reveal the action they will take if there is a failure to declare an interest which is subsequently discovered. Finally the statement lists the responsibilities of all participants: authors, reviewers and editors.

### Tips for getting your paper rejected

A delightful satire written by Horacio Plotkin and published in the *BMJ* in 2004<sup>3</sup> points out that, as we all know, you need to publish to get promotions. Alas what we might not have thought about is that promotion only brings more paperwork and increased income tax. So, writes Plotkin, what you should really be aiming for is rejection. To this end the article gives some useful tips:

"Start by looking at your data randomly. Something will come out. Why bother with writing a protocol when you already have results?"

In the introduction, criticise the work of possible reviewers. Be particularly nasty. This is your chance for revenge.

Calculate the sample size needed based in the size of your sample.

Have your 4 year old daughter proofread your spelling, and your 2 year old son proofread the grammar.

You know that results often tell more than what is evident. Feel free to draw imaginative conclusions.

What you think is obviously the answer, must be the right answer. Do not look for alternative explanations that will make everything even more confusing."

1 Antes G. The new CONSORT statement. *BMJ* 2010;340:c1432. available at: [http://www.bmj.com/cgi/content/full/340/mar23\\_1/c1432](http://www.bmj.com/cgi/content/full/340/mar23_1/c1432)

2 Conflict of interest in peer-reviewed medical journals available at: <http://www.wame.org/conflict-of-interest-in-peer-reviewed-medical-journals>

3 Plotkin H. How to get your paper rejected. *BMJ* 2004;329:1469. Available at <http://www.bmj.com/cgi/content/full/329/7480/1469>

## Animal studies bias publication raises proposal for ClinicalTrials.gov equivalent

Publication bias in clinical trials has long been established but a new study shows that the bias is even greater when it comes to animal studies. Macleod and his coworkers analysed 525 animal studies from the Collaborative Approach to Meta Analysis and Review of Animal Data from Experimental Stroke (CAMARADES). The database was set up in 2004 to aid translation from animal studies to clinical trials. The experiments on the database tested 16 different stroke treatments. Macleod and coworkers found that reports of large effects were published in journals far more often than reports of small effects. They calculate that 16% of the research carried out in the field has never been published resulting in a 30% overestimate of treatment efficacy. Of the 500 stroke treatments reported as effective in animals, only aspirin and early thrombolysis with tissue plasminogen activator are effective in humans. Macleod's group views the failure to publish negative results as unethical because it results in unnecessary use of animals and premature clinical trials. They propose that animal trials be registered in the same way as clinical trials. They also suggest that animal experiments could be improved by randomising or blinding strategies.

**Source:** Sena ES, van der Worp HB, Bath PMW, Howells DW, Macleod MR. Publication bias in reports of animal stroke studies leads to major overestimate of efficacy. *PLoS Biology* 2010 8, e1000344. Available at <http://www.plosbiology.org/article/info:doi/10.1371/journal.pbio.1000344>

## Most often ignored instructions to authors

Tom Lang recently asked editors on the WAME listserver (<http://www.wame.org>) which instructions to authors are most ignored by authors.

- Ignoring word counts came out as the main complaint. Other instructions which were ignored were
- reference formats and in-text citations or referencing was incorrect.
- inserting tables and figures in the text rather than at the end of the manuscript or as separate files.
- poor quality/resolution figures/photos or non-standard formats.
- failure to write out abbreviations the first time they are written in the manuscript
- lack of consent/confidentiality of photos of patient body parts

One editor commented that she found that on double checking no-conflict statements authors often were found to have conflicts. Plagiarism was also mentioned as a problem.

## Reporting bias in medical research—The need to put an end to a never-ending story

Publication bias and outcome reporting bias, i.e. the selective publication of studies and the selective reporting of outcomes depending on the nature and direction of the results [1], are well-known phenomena in the medical literature. (The terms are hereafter referred to as “reporting bias”, the umbrella term used by the Cochrane Collaboration [1]). The first report of the preferential publication of positive study results was published in the 1950s in psychological research. Prominent later examples in medicine, the revelation of which resulted among other things in the withdrawal of drugs from the market and court decisions against manufacturers, include research on antidepressants (e.g. paroxetine) and selective COX-2 inhibitors (e.g. rofecoxib). The German Institute for Quality and Efficiency in Health Care screened a literature pool of articles on reporting bias to gain an overview of how widespread the problem is beyond the well-known examples. The narrative review has recently been published in *Trials* [2]. Over 60 examples of reporting bias were found, comprising pharmacological, surgical (e.g. vacuum-assisted closure therapy), diagnostic (e.g. ultrasound), and preventive (e.g. cancer vaccines) interventions. Regarding pharmacological interventions, cases of reporting bias were identified in numerous conditions including depression, schizophrenia, anxiety disorder, Alzheimer's disease, pain, migraine, cardiovascular disease, irritable bowel syndrome, urinary incontinence, atopic dermatitis, type-2 diabetes mellitus, hypercholesterolaemia, thyroid disorders, menopausal symptoms, and various types of cancer and infectious diseases. These cases involved the non-submission or withholding of study data not only by manufacturers, but also by regulatory agencies or university researchers.

Only few studies quantified the effects of reporting bias: substantial overestimation of efficacy was, for example, found for cancer therapies and treatment with antidepressants. Published evidence also underestimated potential harm, for instance, the risk of rhabdomyolysis with lipid-lowering drugs.

In conclusion, reporting bias affects a wide range of therapeutic areas and interventions and endangers the health of patients. Although the implementation of the US FDA Amendments Act is a milestone in the campaign to achieve public access to clinical trial data, this legislation nevertheless has a number of loopholes. Moreover, mandatory prospective registration of trials and public access to study data via results databases need to be introduced on a worldwide scale. This will allow for an independent review of research data, help fulfil ethical obligations towards patients, prevent the waste of resources on ineffective and harmful therapies, and ensure a basis for fully-informed decision making in the health care system. ➤

## Biomedical publishing shorts

- Medical writers normally do not decide whether a study is submitted for publication or not. However, they should be aware of the problem of outcome reporting bias in published studies and provide input to contribute to the unbiased reporting of study methods, results and conclusions.

**Natalie McGauran and Beate Wieseler**

*n.mcgaوران@iqwig.de*

## References

1. Sterne J, Egger M, Moher D. Addressing reporting biases. In: Higgins JPT, Green S, editors. *Cochrane handbook for systematic reviews of interventions*. Chichester: Wiley; 2008. p. 297-334.
2. McGauran N, Wieseler B, Kreis J, Schuler YB, Kolsch H, Kaiser T. Reporting bias in medical research - a narrative review. *Trials* 2010 Apr 13;11(1):37. Available at: <http://www.trialsjournal.com/content/11/1/37>

## Medical writer listed as an author of a review article

The *Journal of Managed Care Pharmacy* requires the principal author of a manuscript to complete a declaration form and confirm that all authors and contributors to drafts or revisions are included in the list [1]. The percentage contribution of every person who contributed effort in each of the categories concept and design, data collection, data interpretation, writing of the manuscript and revision of the manuscript must be stated on the form. The journal uses 25% contribution in at least 1 of the 5 categories as a rule of thumb by which a contribution of 25% or more is considered to warrant authorship. If the contribution is less than 25% the contributor should generally be listed in the acknowledgements with a description of the contribution. However, determination of substantive contribution is subjective, and the number of authors and contributors to a manuscript will influence percentage contributions.

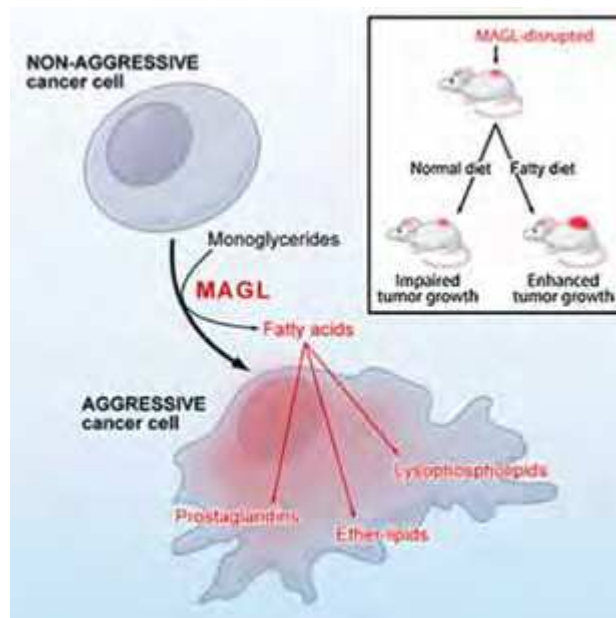
Interestingly a review article published in the June 2009 issue of the journal listed Catherine Rees, a medical writer for Adis Communications, and Sarah Spinler, a professor of clinical pharmacy from the University of the Sciences in Philadelphia as the two authors [2]. The article was prepared with financial support from Daiichi Sankyo and Eli Lilly. The disclosure statement published with the article states "Rees performed the majority of data collection and writing the initial draft, and both authors shared equally in the revision."

## References:

1. *Journal of Managed Care Pharmacy* Instructions to authors. Available at: <http://www.amcp.org/amcp/ark?p=A44214B7>
2. Spinler SA, Rees C. Review of Prasugrel for the secondary prevention of atherothrombosis.
3. *J Manag Care Pharm*. 2009;15(5):383-95. Available at: <http://www.amcp.org/data/jmcp/383-395.pdf>

## Cell revolutionises online article format

Despite the transition to online publishing in the mid-1990s, online biomedical journals essentially look like a facsimile of the traditional print article. But *Cell* journal are changing this and are "bringing the powers of new technologies to bear on the structure, organisation and presentation of the article itself". As of their first issue this year they have gone beyond citation links and have changed the traditional linear organisation of their articles to a more integrated and linked structure. Tabs have been inserted that, for example, allow a reader to scan through the data and then connect from an individual figure to the related discussion of the finding. A description of the new functions and a video about the format can be seen at <http://beta.cell.com/index.php/2010/01/cell-launches-article-of-the-future-format/>



A graphical abstract complements the traditional summary on the landing page



photo: Nadja Meiser



## One way around ‘one’

When we speak, we often make use in English of ‘one’ as an object—one might even call it a *demonstrative* object, as in *No, I don’t like that one, I prefer this one*, if the person you are speaking to you knows what you are talking about. Using *one* in this way often doesn’t sound right when writing, as in the following sentence from a PhD thesis I recently edited:

*As pointed out by Johansson, fallibilism is an epistemological standpoint rather than an ontological one.*

Nobody will misunderstand this, but it sounds ‘spoken’. In a short sentence like this, there is an easy way around it. Write:

*As pointed out by Johansson, fallibilism is an epistemological rather than an ontological standpoint.*

## Common sense (despite a native speaker!)

*143 patients were men and 90 women. Their median age was 48 years (range 11–97; Q1–Q3 24–72).*

Workshop participant (not a native speaker of English): A native speaker told me that in the above sentence you have to repeat *years* after 97 and 72.

Workshop leader: Did the native speaker tell you why?

Workshop participant: Yes. To avoid confusion.

Workshop leader: Confusion about what?

Workshop participant: Well ... the 97 might have been understood to mean months or something else ...

Workshop leader: Do you agree with what the native speaker said?

Workshop participant: No.

Let us be thankful for non-native speakers with common sense!

## Always check the referent of ‘it’ as a pronoun ...

*It is a pronoun or a dummy subject (It is a sad fact, but ...).* When used as a pronoun, the reader needs to be able to unequivocally link it back to a noun they have read in the preceding sentence or in the same sentence, without having to backtrack. Here is a typical sentence I see where the reader has to backtrack and finds that the sentence is not comprehensible:

*Study ABC-DEF-123 differentiated between ‘rush’ and ‘conventional’ up-dosing because it was the primary objective of this study.*

It doesn’t help to use *this* here either. The problem is the same. You either need a complete rewrite, which is probably what I would go for, or *former* or *latter*, whichever is appropriate.

## Repetition of % or not?

*Sensitivity in our sample increased from 86.4% to 95.5% when the two above patients were excluded.*

Do you need a % sign after the two values, or only after the second value, e.g. *...from 86.4 to 95.5% ...* ? This is what we would do when speaking. But somehow, I resist this when writing. With all other units though, I write it and think it sounds fine, e.g.:

*After 4 weeks treatment with DrugX, mean blood pressure had decreased from 143/98 to 118/86 mmHg.*

Do I need to bother about this, or is % just like any other unit?

## When a dummy subject is OK

I am definitely not a fan of dummy subjects (*there, it*) and strongly advise against them. Your sentence is always less direct and longer if you use them, because your readers are usually held in suspense until they get the real subject and the real active verb. If you have written a sentence that starts with ‘There is/was/were’ or ‘It is/was’, you can almost always find a better solution, e.g.: (with dummy subject ‘there’) *There was a tendency for the medication to reduce cardiac output.* Better: *The medication tended to reduce cardiac output.* But there is no 100% in language (note the dummy subject in this clause), and sometimes a dummy subject is better. I think that *There are two reasons for this* is much better than *The reasons for this are twofold* when you mean that you wish to describe two reasons. How can a reason ‘be’ twofold, and even if it can, does this mean that here we have more than one reason (the subject is in the plural) and that each has two parts? The same applies to *The reasons for this are manifold*. Why not just take the simple option and write: *There are many reasons for this?*

## Easily written ... and sure to confuse

This is a good one:

*A patient may respond favourably to one class of antihypertensives but not another; and vice versa.*

The first time you read it, you think “OK”. But halfway through the next sentence you glance back and think “What is ‘vice versa’ here actually trying to tell me?” It is, of course, telling you nothing, but it takes you a little while to realise that. Not kind to the reader.

## Words, Grammar &amp; Co

**Breath deeply and enjoy it! The perils of the spell checker.**

I suspect that the spell checker was responsible for the following, which went unnoticed through company, principal investigator and ethics committee review as an exclusion criterion from a study on a hay-fever preparation:

*Secondary changes in the reactive organs (e.g. emphysema or bronchial ecstasy)*

The unfortunate thing about this is that it is not even amusing: as we all know, breathing is no fun with either emphysema or bronchiectasis.

**Don't shoot them ...**

... they're only the authors!

I am on the brink of committing a terrible crime because I have just edited about 170 pages of text where *during the course of the study* instead of *during the study*, *with the exception of* instead of *except*, and *within the 7 days prior to study start* instead of *in the week before the study*—amongst other overblown phrases—were used on almost every page. I suppose I should be pleased that authors make it easy for me to shorten their texts, but several days of this type of correction, when you have done it for the same author countless times before, can easily make you feel as though you want to reach for that gun ...

**Alistair Reeves**

[a.reeves@ascribe.de](mailto:a.reeves@ascribe.de)

**When is a suffix not a suffix?**

A suffix is an ending which is added to a base word to form a new word. There are too many suffixes in the English language to list them here. See <http://www.examples-help.org.uk/definition-of-words/list-of-suffixes.htm> for a list of over 100 common suffixes. The Dummies.com website 'Meeting the Most Often Used Suffixes' is also useful for learning more about suffixes and includes a table in which meanings, examples and part of speech definitions are given for the suffixes *-ment*, *-ence/-ance*, *-able/-ible*, and *-ion*, (<http://www.dummies.com/how-to/content/meeting-the-most-often-used-suffixes.html>). These endings are often used for modifying active verbs in scientific text. Unfortunately using them makes the text unnecessarily cumbersome—so it is worth being familiar with these particular suffixes if only to improve your writing by eliminating them.

Suffixes can

- change the grammatical property of a word, e.g. adding *s* to a word changes it from singular to plural,
- change the meaning of a word, as in for example adding *logy* to *zoo* or

- shift a word from one to another syntactic category, e.g. adding *ly* to *graceful* changes this adjective into an adverb.

When then is a suffix not a suffix? The suffix *-ful* is not uncommonly added to a noun or verb to change it into an adjective indicating something or someone is 'full' of something. Thus a person who is willing to offer help is a helpful person. You could have a hand full of money. Alternatively, you could have a handful of money, in which case *handful* is an adjective describing the quantity of money. All is very simple unless, it seems, you have a bowl full of Jordan's muesli.

**Books for lovers of the English language—and minority languages**

An interview with Robert Lane Greene, a foreign correspondent for *The Economist*, produced a comprehensive list of books about language. Greene's own book *You Are What You Speak* will be published by Bantam (Random House) next spring. His interest in Language was sparked by Steven Pinker's book *The Language of Instinct*. Greene says that "It's hard to read the book and then happily go back to seeing language as a set of iron-bound rules that are constantly being broken by the morons around you. Instead, you start seeing this human behaviour as something to be enjoyed in its fascinating variability." He recommends Merriam-Webster's *Dictionary of English Usage* as the best usage book because it is an empirical study that explains the history of the rules. For example, John Dryden relied on Latin when he condemned ending sentences with prepositions but Merriam-Webster cites great writers who break this 'rule'. Greene also mentions the classic H.W. Fowler's *Dictionary of Modern English Usage* describing the older editions as fun because they show what raised hackles a hundred years ago. Greene would like to imagine a world in which "neither fish, flesh nor good red herring" was irritatingly common.

In answer to the question of whether we should care about languages becoming extinct Greene says he has not been able to find a utilitarian argument for preserving tiny languages. He was not convinced by Suzanne Romaine's *Vanishing Voices* as knowledge is not lost because language is lost but rather because a way of life is lost. The only reason he sees for keeping language alive is that it is an irreplaceable part of our common human heritage. The thought of a planet where everyone speaks just a few languages depresses him and he cites Mark Abley's *Spoken Here* as an enjoyable tour of threatened languages. A reader commented on the article saying that if we don't strive to cultivate linguistic diversity, we'll soon be stuck with one standard, commercialised McLanguage. But another reader thought that one of the greatest things happening in the world today is that more people can understand and communicate with each other than ever before.

## Words, Grammar &amp; Co

Readers' comments on the interview added the following books to the list: *A mouthful of Air* by Anthony Burgess (Vintage Books, 1993), *Language Myths* by Laurie Bauer and Peter Trudgill (Penguin, 1998), *Resurrecting Hebrew* by Ilan Stavan (Schocken, 2008), *History in English Words* by Owen Barfield (Faber & Faber, 1953), *Cambridge Encyclopedia of the English Language* by David Crystal and finally one reader asked what had happened to *Roget's Thesaurus*, which he saw as a valuable treasure because English as a world language is generally badly spoken.

However, a comment from another reader was that somebody writing on language always sits in a glasshouse. The phrase in the article "where everybody speaks just a few languages" had probably not meant to imply that everyone is a polyglot but rather should have been written "where only a few languages are spoken."

**Source:** The best books: The Economist's international correspondent on books about language. Available at: [http://www.economist.com/displaystory.cfm?story\\_id=16052199](http://www.economist.com/displaystory.cfm?story_id=16052199)

## Seriously, you need to get the grammar right

Grammar Nazis is a short take for fans of the film *Glorious Bastards* (and sticklers for grammar) and was kindly sent to *TWS* by Adam Jacobs. Have a look at <http://www.collegehumor.com/video:1935115>

## Error beyond the politically incorrect

Any misprint is embarrassing for publishers and authors, but usually after a temporary mortification it's possible to get on with life again—not always. Potential repercussions and expense of misprints can be catastrophic. Although they are apparently particularly difficult to proof read, cook books do not spring to mind as obvious candidates for catastrophic misprints, that is unless a Pasta Bible bids its followers to indulge in cannibalism. Penguin books in Australia reprinted 7,000 copies of its Pasta Bible at a cost equivalent to 12,000 GBP because a recipe for tagliatelle with sardines and prosciutto also included the ingredients "salt and freshly ground black people".

**Source:** <http://news.bbc.co.uk/2/hi/asia-pacific/8627335.stm>

## The Oxford Dictionary got it wrong?

Yes, it did and nobody spotted it for 99 years. But now they have been put right by no lesser mortal than a scientist. Dr Stephen Hughes from the University of Technology, Brisbane, Australia noticed that the *Oxford English Dictionary* (OED) in its definition of 'siphon' states that atmospheric pressure makes siphons work whereas it is in fact the force

of gravity that moves fluid into a siphon. And what was the OED spokesman's excuse for this? That the definition was written by editors who were not scientists.

**Source:** Malkin B. Australian sets Oxford dictionary to rights. *Telegraph* 19<sup>th</sup> May 2010 page 19.

## Live Valerie



This Ginglesh invitation to a concert in a bar by the Danube begs the question of the type of entertainment on offer. It's not a horror show. Clearly Valerie is expected to be alive (otherwise she would be 'Dead Valerie' won't she?)—but perhaps nearing her end if we are to encourage her with the explanation "Live Valerie!" Why 'Valerie Live' would have been a better formulation is something you will be able to learn from Alistair Reeves in his second article in the series 'Everything has its place' to be published in the next issue of *TWS*.

## Orwellian buzzwords

Nigel Hawkes' grouch in the *BMJ* about buzzwords advocates government intervention to "purge the NHS of its ridiculous jargon"<sup>1</sup>. A ban would save having to search sites like *TheOfficeLife.com* dictionary<sup>2</sup> to discover where your co-workers picked up all the things they say that mean nothing. Hawkes' article has a great quote from George Orwell in which he compared the abuse of language to the abuse of drink: "A man may take to drink because he feels himself to be a failure and then fail all the more completely because he drinks...the English language becomes ugly and inaccurate because our thoughts are foolish, but the slovenliness of our language makes it easier for us to have foolish thoughts". Some examples of candidate words for the ban are given in the article, such as the Orwellian English *service user*, which means patient or possibly, client.

1 Hawkes N. Message to new government: ban buzzwords. *BMJ* 2010; 340:1001

2 <http://www.theofficelife.com/business-jargon-dictionary-G.html>

## ■ For regulatory writers

**Demand for public access to drug dossiers and more**

In their article in the *BMJ*, Garratini and Bertele [1] call for more information about drugs to be made available by EMA (which releases less information than the FDA) and by drug companies. In particular the results of toxicological tests and clinical trials should not be kept confidential. They argue that the drug industry is not the sole financier of research but draws on the results of laboratory and clinical studies carried out by academic institutions which are supported by public money. Patients also take part in clinical trials without receiving remuneration. Furthermore Garratini and Bertele complain that summaries of product characteristics describe single drugs whereas a comparison with drugs for the same indications would reveal differences in efficacy and safety (which might have avoided the problems with the flu drug oseltamivir). In the same issue of the *BMJ*, Nicholas Moore [2] discusses pharmacovigilance in Europe and comments on Garratini and Bertele's proposals detailed in their article suggesting that making individual patient data publicly available would allow predictors of individual patient's outcomes to be identified, leading to a reduction in their exposure to drugs. This in turn would benefit national health services by reducing their drug bills, but would probably not be greeted with the same enthusiasm by the drug industry.

**References:**

1. Moore N. Improving pharmacovigilance in Europe. *BMJ* 2010;340:821-822
2. Garratini S and Bertele V. Europe's opportunity to open up drug regulation. *BMJ* 2010;340:842-843

**Clinical Trial Magnifier**

Check out the free monthly e-newsletter from the University of Hong Kong called the *Clinical Trial Magnifier* (<http://www.clinicalresearchclinic.com/>). Recent issues have covered, amongst other topics, medical publication trends by geographical area, clinical trial subject characteristics—ages and gender, industry sponsored oncology trials and industry sponsored medical device clinical trials.

The site also advertises a book titled *Reviewing Clinical Trials: A Guide for the Ethics Committee*, which has apparently been developed mindfully to be relevant and useful to all other categories of professionals entering the clinical trial research area. The guide can be downloaded free of charge as a pdf file from the *Magnifier's* web site and will be available as a printed version that can be purchased on line.

Trish Groves, deputy editor of the *BMJ*, wrote on the *BMJ* group blogs (<http://blogs.bmj.com/bmj/2010/03/22/what-were-reading-19-march-2010/>)

that she considers the *Magnifier* to be a good read, despite the mass of technical detail. She went on to say that she was interested to learn about the earliest recorded clinical trial documented in the Old Testament. Daniel followed a diet of pulses and water instead of the meat and wine recommended by King Nebuchadnezzar II. But readers of *TWS* would have made this discovery 4 years ago by reading Susanna Dodgson's article on the evolution of clinical trials (*TWS* 2004;15(1):20-21). Nevertheless, the *BMJ* group blogs make interesting reading themselves.

**Ten years of orphan drugs in Europe**

The term "orphan drug" refers to a product approved for patients with so-called rare diseases (defined, in the European Union, as those affecting 1 out of 2000). In addition, a drug will only be considered for orphan status if the condition for which it is indicated is life-threatening or chronically debilitating and there is no satisfactory alternative treatment available. For the most part, rare diseases are of genetic origin (approximately 80%). Although the prevalence of any given rare disease is by definition low, up to 8000 have been identified and the overall number of patients affected may be quite high. Approximately 75% of patients affected are children and it is estimated that 35% of infant deaths can be attributed to rare diseases.

Development of orphan drugs can be financially unattractive given the low sales potential, not to mention the uncertainties that come with recruitment difficulties and a poor understanding of the basic science in many cases. Thus, in April 2000, the European legislative framework for orphan drug designation came into effect<sup>1</sup>. (Europe had lagged far behind the United States, where orphan drug legislation was in place as early as 1983.) The framework allows for streamlined clinical development. Often, the burden of proof may be set lower and, indeed, for very rare conditions, a collection of peer-reviewed case reports of clinical use (for example, in a compassionate setting) may suffice. The review process is expedited and, once approved, the sponsor can enjoy up to 10 years' market exclusivity from the date of the product's launch.

The impact of the framework is reflected by the number of approvals during different periods. Between 1995 and 2000, only 12 drugs had been approved for rare diseases whereas between 2000 and 2007, 44 products had been granted marketing authorisation for a total of 492 indications. To further encourage development of orphan products, in 2007, the EMA provided additional financial incentives in the form of reduced fees and fee waivers for protocol assistance and certain regulatory procedures and requirements. These measures should further accelerate development of products for orphan diseases and provide hope for patients who, in the past, may have felt abandoned by the pharmaceutical industry.

For further information, the following document on the EMA website entitled 'Orphan drugs and rare diseases at a glance' (<http://www.ema.europa.eu/pdfs/human/comp/29007207en.pdf>) provides a brief overview and some useful links.

**Gregory Morley**

Freelance medical writer, editor and translator  
g.morley@docuservicio.com  
[www.docuservicio.com](http://www.docuservicio.com)

1 The legislative framework (Regulation (EC) No 141/2000 adopted on 16 December 1999 (OJ No L 19, 22.1.2000) and Commission Regulation (EC) No 847/2000 of 27 April 2000 (OJ No L103/5, 28.4.2000)) introducing an EU public health policy on orphan medicinal products

## Medicine at the multilingual crossroads



*"Translation is not a matter of words only: it is a matter of making intelligible a whole culture."*

Anthony Burgess

### Bengali for Pharmacists

**New law requires New York pharmacies to translate medicines prescriptions into their clients' native languages**

Once all of our study material has been properly filed away and the drug has been licensed, the communication challenge shifts to pharmacies. Whereas in Europe, medicines are dispensed in fully labelled packages that come with a patient information leaflet in each of our national languages, the predominant practice in the USA is dispensing from bulk. One of the implications of this practice is highlighted by recent legislation having pharmacists provide counselling to clients with limited English proficiency (LEP) in their own language.

The story reads like a recent addition to the folklore of the Wise Men of Gotham, known since the 12th century for their rather grotesque actions. In the year 2000, then US president Bill Clinton signed Executive Order 13166 aimed at improving access to services for persons with LEP. So far, so good.

Among the US cities most challenged by Executive Order 13166 is polyglot New York, where about 1 in 2 residents speaks a language other than English at home. In 2007, immigrant organisations filed a complaint with the NY State Attorney General, decrying pharmacies for not providing adequate translation services to clients with LEP [1]. As a result, the Language Access in Pharmacies Act was passed in September 2009, requiring chain pharmacies in Big Apple to offer language assistance and translated medicine labels to their customers speaking 1 of the 7 most common foreign languages spoken in the city, i.e. Spanish, Chinese–Cantonese–Mandarin, Russian, Korean, Italian, French Creole, and Bengali.

The NY Times quoted Attorney General Andrew Cuomo as saying that "The need to understand prescription information can literally be a matter of life and death." For New Yorkers who do not speak English as a first language, he continued, "this agreement will ensure they have the medical information needed to protect their health and well-being and that of their families" [2]. Yet, considering the

complexity of the translation process and the multitude of target languages covered by the new legislation, Mr Cuomo's statement may have been a little too optimistic a little too soon.

Sharif from Montefiore Medical Center, New York, and Tse from Dartmouth College, New Hampshire, set out to determine how many pharmacies in the Bronx, where 44% of residents are Spanish-speaking, were able to provide Spanish-language prescription labels and to evaluate the accuracy of the translated labels [3]. Each participating pharmacy was presented with 4 different prescriptions made up for a fictitious patient and were asked to translate them the way they normally would for a client.

Of 316 pharmacies, 286 (91%) participated. Overall, 209 (73%) provided medicine labels in Spanish. To translate the labels, 86% of pharmacies used computerised translation software—with 70% of respondents using 1 of 3 major programs—, 11% used lay staff members, and 3% used a professional translator.

Sharif and Tse evaluated 76 medicine labels generated by 13 different computer programs. Overall, 32 Spanish labels (42%) included a mixture of English and Spanish and 6 labels contained misspellings or grammatical errors, resulting in an overall error rate of 50%. Phrases that were not translated because they were not present in the translation database included 'dropperfuls' or 'apply to affected areas', resulting in translations such as "Aplique to affected areas dos veces al dia for 7 days".



*"Apply to breast twice daily? Seems kind of extreme for a hangover cure. Oh well, here goes!"*



## Gained in translation

- > While most grammatical errors will not cause any harm, some of the misspellings may. For example, one of the prescriptions read “ferrous sulfate (15 mg/0.6 mL), 0.6 mL administered **orally** twice per day; give with juice”. It was translated into Spanish as “toma 0.6 mL dos veces al dia **por la boca** con jugo” and back-translated into English as “taking 0.6 mL 2 times to the day **by the little** with juice”. Because the Spanish word *boca*, meaning ‘mouth’, was misspelled for *poca*, **orally** ended up being translated as **little**. In another instance, the phrase **once a day** became **eleven times a day** in translation.

In view of the results reported by Sharif and Tse, the current system of translating medicines prescriptions, in addition to probably incurring not insignificant extra costs, clearly has the potential to do more harm than good. The authors conclude that regulations whereby medicine labels be made available in a variety of languages should be assessed in the light of the technological capabilities of pharmacies. To this one might add that consulting language experts before embarking on any language-related project would be a good idea—they can give valuable advice and realistic input into a translation strategy that will really work.

One option that comes to mind is making available multi-lingual prescription forms, enabling physicians to merely fill in the dosage. Rather than using words only, such forms could make heavy use of pictograms. In view of the known limitations of machine translation, any translation software should be based on fixed standard phrases rather than on individual words, and it should be subject to strict quality control measures to avoid mistranslations from being programmed into the system in the first place: software does not replace *boca* with *poca* unless programmed to do so. Finally, because prescription information ‘can literally be a matter of life and death’, translation output must be checked for accuracy before being handed to the patient.

Having found major problems with the English-Spanish pair—a fairly common language combination in the USA—the authors added that they found it “worrisome to consider what the status of translation for other languages might be” [3].

To deter King John from building a castle close to the town of Gotham in England’s Nottinghamshire, the residents of Gotham decided to act like fools, attempting to fish the moon out of a pond or to drown an eel. Ultimately, their ruse was successful and the King left the village voluntarily. Ironically, American writer Washington Irving, apparently seeing some similarities between the English Gothamites and his fellow New Yorkers, popularised the nickname Gotham for New York City some 200 years ago. Assuming that the 2009 Language Access in Pharmacies Act was passed with the best of intentions and not to deter non-English speakers from settling in New York, the city will have to work a little harder to effectively put the regulation into practice. In modern-day Gotham City—perhaps Batman could lend a helping hand.

## Speaking of prescriptions and pictograms...



Source: public domain [6]

Ever wondered where the crossed ‘R’ used in prescriptions comes from? One interesting hypothesis holds that it is derived from the Eye of Horus [4, 5]. In Egyptian mythology, Horus was one of five children of Ra and Rhea, i.e., Horus, Osiris, Set, Isis, and Nephthys. Osiris succeeded Ra as king of Egypt and

married his sister Isis. After their brother Set murdered Osiris, the widow Isis requested her brother Horus to destroy Set. During the battle that ensued, Horus’s right eye was torn out, but was magically restored. Since that time, the stylized symbol of his eye has been a representation of health and happiness.



Source: public domain [6]

The Eye of Horus, consisting of a human eye with the cheek markings of a falcon, is depicted as consisting of 6 parts, with each part corresponding to one of the six senses, i.e., touch, taste, hearing, thought, sight, and smell. In Ancient Egypt, the

Eye of Horus represented a fractional quantification system to measure parts of a whole. The entire eye measured 1 heqat, and each part of the eye made up a fraction of the heqat. This system was used to record land, grain, and prescriptions. Interestingly, however, the fractions add up to 63/64ths only.

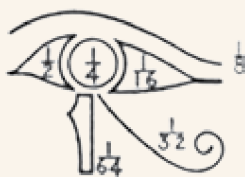


Image created by Jeff Dahl [8]

The symbol was apparently still present in the times of Tutankhamen (1341–1323 BC) [5]. In the 8<sup>th</sup> century BC, Homer described the Egyptians as having been skilled physicians, and the symbol of the Eye of Horus was later adopted by Greek physicians, who then brought it to Rome. Nero attempted to ascribe the symbol to the Roman god Jupiter and strove to establish it as a sign of the submission of physicians to the state. The Christian Church tried to Christianise the symbol, changing it into a double R—the response of Raphael, and the medieval alchemists returned to the original Greek symbol. In the Age of Reason in the early 17<sup>th</sup> century, the meaning of the ‘R’ was rationalized to derive from the Latin imperative of the verb *recipere*, i.e. *recipe*, meaning ‘take’—a direction addressed to the pharmacist.

An alternative theory holds that the symbol originated in medieval manuscripts and is an abbreviation of the Latin *recipe*. It has been noted that this hypothesis does not explain the ‘x’ at the bottom of the ‘Rx’ symbol. According to Alan D Corre, Emeritus Professor of Hebrew Studies of the University of Wisconsin, this is not to be read as an ‘x’



[9]; rather, when Jesus talked about the ‘tittles’ in sacred texts, he referred to the small decorations on certain letters in a manuscript. The line on the ‘R’, Corre says, is such a tittle, showing that the ‘R’ is an abbreviation.

Thus, the origin of the crossed ‘R’ used in English prescriptions appears to have enough explanations to suit every possible political, philosophical, or religious leaning. By the way—the German equivalent for ‘Rx’ is ‘Rp’, clearly deriving from *recipe* and leaving less room for interpretation as to its origin.

## Translation resources

### EDQM Standard Terms

The collection of Standard Terms compiled by the European Directorate for the Quality of Medicines & Health-Care (EDQM) covers dosage forms, routes of administration, and containers used for human and veterinary medicines [10]. It gives the equivalents of several hundred terms in 31 world languages.



The lists of Standard Terms were drawn up by the European Pharmacopoeia Commission at the request of the EU Commission for use in marketing authorisation applications, SPCs, and product labels. Online access costs €72.00. Although not all terms are available in all languages, the lists are being updated regularly and also include non-EU languages, such as Chinese. As such, they may be a good starting point for translation software developers servicing New York pharmacies...

**Gabi Berghammer**

*gabi@the-text-clinic.com*

#### References:

1. Barnard A. Non-English Speakers Charge Bias in Prescription Labeling. *New York Times*, 31 October 2007.
2. Semple K. Pharmacies Agree to Provide Prescription Data in Many Languages. *New York Times*, 22 April 2009.
3. Sharif I and Tse J. Accuracy of computer-generated, Spanish-language medicine labels. *Pediatrics* 2010;125:960-5.
4. The Eye of Horus (editor's note). *Australian Prescriber* 1995;18:23.
5. The Eye of Horus (letters to the editor). *Australian Prescriber* 1995; 18:84-6.
6. [http://en.wikipedia.org/wiki/File:Rx\\_symbol.png](http://en.wikipedia.org/wiki/File:Rx_symbol.png)
7. Ellis SR. [http://human-factors.arc.nasa.gov/ihh/spatial/papers/pdfs\\_se/pcpsu/Ellis\\_1993\\_Pictorial\\_Communication.html](http://human-factors.arc.nasa.gov/ihh/spatial/papers/pdfs_se/pcpsu/Ellis_1993_Pictorial_Communication.html).
8. [http://en.wikipedia.org/wiki/User:Jeff\\_Dahl](http://en.wikipedia.org/wiki/User:Jeff_Dahl), 2007.
9. <http://groups.google.com/group/sci.lang/topics?lnk>, 2 March 1995.
10. EDQM Standard Terms. <http://www.edqm.eu/StandardTerms/>.

## First non-Latin web addresses launched

According to Rod Beckstrom president of the net regulator Icaann “Over half the Internet users around the world don’t use a Latin-based script as their native language”. His company is the first to provide a system that allows full web addresses that contain no Latin characters. Up until now websites could use some non-Latin letters, but the country codes such as .eg for Egypt had to be written in Latin script.

Egypt, Saudi Arabia and the United Arab Emirates are the first countries to have country codes written in Arabic scripts.

Egypt: رصم

Saudi Arabia: دة دوعسلا

United Arab Emirates: تاراما

Web addresses in other scripts including Chinese will be coming soon. This development should avoid a split in the Internet with countries or groups developing their own exclusive non-Latin Internets.

Source: <http://news.bbc.co.uk/2/hi/technology/10100108.stm>

## Could anyone on the planet have missed this...?

**“First species on the planet to have its parent being a computer”**

This is how Craig Venter described the creation of a synthetic living cell at the J Craig Venter Institute in an interview with the BBC [1]. The achievement has already been hailed as “one of the most important scientific achievements in the history of mankind”. In their paper published in *Science Magazine* [2] the group reports on the design, synthesis, and assembly of the 1.08-Mbp *Mycoplasma mycoides* JCVI-syn1.0 genome starting from digitised genome sequence information and its transplantation into a *Mycoplasma capricolum* recipient cell to create new *Mycoplasma mycoides* cells. These cells are capable of continuous self-replication. One obvious use for the cells is in vaccines.

#### References:

1. <http://news.bbc.co.uk/2/hi/programmes/newsnight/8696148.stm>
2. Gibson et al. Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome. Available at: <http://www.sciencemag.org/cgi/content/abstract/science.1190719>

# **31<sup>st</sup> EMWA Conference**

11 – 13 November 2010

Hotel Radisson  
Nice, France



We are delighted to announce that the venue for EMWA's 31<sup>st</sup> conference will be Nice, France.

This beautiful city on the French Mediterranean coast is easily accessible from most major European cities, and the conference hotel, which overlooks the sea, is a perfect location for our 2-day autumn conference, to be held from Thursday 11<sup>th</sup> to Saturday 13<sup>th</sup> November 2010.

Many workshops will be on offer covering a wide range of medical writing topics for those wishing to obtain credits towards their foundation or advanced EMWA professional development programme certificates or simply to update their knowledge and skills.

In addition there will be a chance to meet old friends and make new ones at the welcome buffet on the Thursday evening and the conference dinner on the Friday evening. These social events are excellent opportunities for networking with other medical writers from Europe and beyond.

Further details will be posted on the website at [www.emwa.org](http://www.emwa.org).