

# The Write Stuff

The Journal of the European Medical Writers Association

## Celebrating Linguistic Diversity







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## **Celebrating Linguistic Diversity (Summer 2000) Vol. 9, No. 3**

### ***Regulatory Questions and Answers: the Investigator's Brochure* 7** ***Douglas Fiebig***

As the first offering in our new series, we look at the seemingly irreconcilable goals of making an Investigator's Brochure attractive enough to get the investigators to read it while still keeping it simple enough for the next update and getting it finished on time. [INT]

### ***Becoming a Non-native English-speaking Freelance Medical Writer* 10** ***Annemieke Van Hest***

Another in our series by non-native English speakers, here we'll find out about a possibility which might at first glance seem challenging in the extreme – becoming a non-native English freelance medical writer!

### ***Life after Medical Writing: Message from Outer Space* 12** ***Leen Vanherle***

One of EMWA's most dynamic and influential early members, Leen Vanherle, (sometimes referred to as the mother of EMWA) who was instrumental in bringing EMWA into its modern, professional era. Now she's an auditor, of all things, and even more unbelievable, she seems to enjoy it!

### ***Rule Britannia, McDonald's and Other Things* 15** ***Norbert de Clercq***

Chatting about Medical Writing (particularly as done by non-native speakers) with various members of the TWS editorial board in a bar in Dublin inspired Norbert to fire off this commentary. Those of you who've had the pleasure of meeting him will know what a colorful, witty and controversial person he is and this article certainly lives up to expectations and its title!

### ***In the Bookstores . . . A New Resource for Teachers of Scientific Writing: Turning Data into Manuscripts* 22** ***Karen Shashok***

This issue, our intrepid book reviewer tackles a volume intended "to help scientists strengthen their mental powers by preparing their publications in a strictly logical fashion, expressing themselves straightforwardly, and working ethically". [INT]

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[INT] - this symbol indicates that the article also has been or will be published at the EMWA internet site:  
<http://www.emwa.org>



## Journal Insights

**The Write Stuff** is the official publication of the European Medical Writers Association. It is issued quarterly 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.

Articles or ideas should be submitted to the Editor-in-Chief (see back cover for address) or another member of the Editorial Board.

### Subscriptions:

Subscriptions are included in EMWA membership fees. Non-members can subscribe at an annual rate of:

- £20 within Europe
- £30 outside Europe

### Instructions for Contributors:

- **The Write Stuff** typically publishes articles of 500 - 1500 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/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 electronically on computer disc or by e-mail as an MS Word file using Arial font (or equivalent), 11-point, and single spacing.
- Published articles generally include a recent photograph of the author (portrait picture, CV or passport style).

### Back Issues:

Subject to availability, previous issues of **The Write Stuff** can be obtained for the cost of mailing by contacting the EMWA secretariat.

### Advertising Rates:

#### Corporate

- Full page £200
- Half page £100
- Quarter page £50

#### Private

Freelance members only

- Full page £100
- Half page £50
- Quarter page £25

(all rates in pounds sterling)

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### Behind the Press, The Editorial Board:

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## From the Editor's Desk: Celebrating Linguistic Diversity

by Barry Drees

Greetings fellow members,

The observant among you may have noticed that the title for this issue has changed from what it was in the "Coming Next Issue" page from last issue. What started out as "Non-native English Speakers as Medical Writers" has transmogrified into "Celebrating Linguistic Diversity". I can imagine that your first reaction is probably to think that I have sold my soul to political correctness, but I have been looking for a better way to describe this important segment of EMWA's population for a while. First of all, call it political correctness or spin making if you will, characterising any group of people as "Non-somethings" is a failure of the imagination, not to mention poor writing. Do we define ourselves by what we are not? Much as I tried though, I just couldn't seem to come up with something better.

The idea for linguistic diversity (one person I asked suggested "Euro-babble") only came to me while working with Susan Quinn, our new Artistic Director, on an idea for an image to put on the title page. When she suggested using translations of "*The Write Stuff*" into various languages, it suddenly occurred to me that other languages are a resource, not a handicap. Rather than harping on the fact that many medical writers in Europe are not native English speakers, what we should be doing is celebrating the diversity of linguistic backgrounds and viewpoints that these members bring to EMWA and to medical writing in general. As some of our contributors note in this as well as previous issues, writing in English when it is not your native language brings a different perspective from which even we native speakers can definitely learn. As I often stress in my workshops, the most important thing about any task is to think about it before starting, and probably no one thinks about their writing as much as one who writes in a foreign language. Witness the many examples we all know of native speakers who think that being a native speaker makes them good writers even though they are actually appallingly bad writers.

I think that this principle of diversity as a resource is not just pertinent to language, but rather it is a basic law of the universe. Diversity is one of the cornerstones of evolution by natural selection. Without species diversity arising from random mutation, natural selection has nothing to work on and evolution ceases. Species that become too specialised to a specific way of life are inviting extinction, since the conditions in which they live and to which they have adapted will inevitably change. To survive, a species needs a healthy range of variation in behaviour and physical attributes.

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***Diversity is the key to survival  
for anything, whether species,  
society or institution, and it  
should be celebrated wherever  
it occurs.***

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### *From the Editor's Desk*

Similarly, diversity is one of the essential ingredients in making a great and lasting society or civilisation. Diversity, therefore, is the key to long-term survival for anything, whether species, society, or institution and it should be celebrated wherever it occurs.

Speaking of diversity, what better symbol of diversity is there today than the internet. The feeling had been growing in me that we really needed to follow-up on our previous article about websites of interest to medical writers (TWS 1999; 8 [3] 22-23) on. It seemed that every time I turned around, I was looking at a journal or magazine with a regular column on websites of interest. And if ever there was something pertinent to and of interest to medical writing, then it is the Internet. So, using the method that I've learned in this job as editor, I decided that what we needed was to find someone for web editor. I was thinking about running an advertisement in TWS. However, as luck would have it, someone wrote to me right then and asked how they could help with TWS. Imagine my delight when they replied that the web editor would be just the thing for them! Thus, I'm happy to introduce Amanda Bennett, our new TWS web scout, who will search out, evaluate and describe websites of interest to medical writers every issue.

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***This could even form the basis for the EMWA style guide that a number of members are dreaming of creating in the future.***

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And finally, how about sampling EMWA's diversity! Yes, it is that time of year again – time for another EMWA questionnaire! This year we've even introduced a section on EMWA style and usage. I'm hoping that this will provide us with an interesting glimpse of how medical writers do things throughout Europe. There are only a few questions this time, but if it works well, I would like to expand it. Eventually, this could even form the basis for the EMWA style guide that a number of members are dreaming of creating in the future. Yes, I know that it takes a whole 5 to 10 minutes to fill out the questionnaire and send it back to me, and that you're all terribly busy. Please remember, however, that the information we collect from this helps the EMWA Executive Committee decide in which directions to take EMWA and helps me to decide what to do with TWS. As I've said many times before, it's the members that make EMWA great, but this only works when we have your input. Many people give selflessly by serving on the EC, the Education Committee, or by working on TWS; the least the rest of you can do is fill out the questionnaire and send it back to me!

Barry Drees  
Aventis Pharma  
Editor-in-Chief

Several people wrote asking for more information about "The Physical Side" (TWS 2000; 9 (2):22-23). The article was actually derived from a book, *The Disposition of the Musician* by G.O. van de Klashorst; published by Broekmans & Van Poppel, Amsterdam (in press). Details can be obtained by contacting Diana Klein-Franke ([g.klein-franke@excite.com](mailto:g.klein-franke@excite.com)).

I would like to thank the various EMWA members with translating and linguistic skills who did the translations of "The Write Stuff" for our cover image: Anne Bartz, Elena Guardiola, Alistair Reeves, Cito Habicht, Ernesta Palombo-Kinne, and Anne-Marie Delay. What a perfect demonstration of EMWA's linguistic diversity! I would also like to express my deepest gratitude to Hilde Joosen for helping me conceive of and develop something for TWS to reach out to non-native English speaking medical writers.





## Message from the President

by Keith Veitch

One of the things which distinguished EMWA from AMWA when we were still joined at the hip was the different membership profiles of the two organisations. The members of AMWA come from a wider variety professional backgrounds, including science writers, medical writers, journalists, editors and medical practitioners, while EMWA is dominated by those who write within the pharmaceutical industry for the industry and the regulatory authorities. This may explain why I find the word professional to be appropriate in the context of the European Professional Development Programme (EPDP), for those who have attended AMWA conferences will be aware that quite a few of the workshops on offer have little to do with our profession. When attending an AMWA discussion group on Journal Writing I was relieved to find out that I was not the only one to be disappointed upon learning that it concerned keeping a diary!

Anyway, having made my plug for the EPDP I want to note that for me, the main difference between AMWA and EMWA is that one is a North American organisation, and the USA, despite the increase in Spanish, is still a one language nation, while EMWA covers that patchwork of countries called Europe (apologies to those members from farther afield, I am generalising as usual) with a patchwork of languages. The European Union is a phrase which is frequently used in a derogative sense because there often appears to be little "union" between the constituents, but membership of organisations such as the European Agency for the Evaluation of Medicinal Products (EMA) does unite us in the use of English as a lingua franca (and that phrase is a good example of what a mix the English language is!). Common regulatory submissions from multi-national pharmaceutical companies located in different sites across the continent, communicating electronically over the Internet or private Intranets is breaking down the language barriers and, some may say, forcing English down the throats of many.

As a writer I am privileged to be able to practice my profession in my mother tongue, English (although those who know that I am a Geordie from Newcastle upon Tyne may raise an eyebrow at that statement). And even though I work in a country with three different official languages, the working language is English. However, many of our members are not so fortunate. As well as the common problems of getting statisticians to talk in a language ordinary human beings can understand, while at the same time trying to simplify things sufficiently that their

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***As well as the common problems of getting statisticians to write in a language ordinary human beings can understand, while at the same time trying to simplify things sufficiently for their bosses, they have the additional burden of coping with English as a foreign language.***

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### *Message from the President*

bosses can understand, they have the additional burden of coping with English as a foreign language. In EMWA we consider one of our main roles is to provide whatever assistance is necessary or required by non-English native speaking members, as shown by the focus of this issue of *The Write Stuff*. To do so we need input, so if you consider that you have something to offer non-native speakers, or if you need help with any aspect of English as a foreign language please let us know. We wish to develop this aspect of EMWA, and the EPDP, so that we truly are a European organisation representing and providing for everyone. It has been said that the USA and the UK are two nations divided by a common tongue – our responsibility is to ensure that EMWA is truly united by a common tongue.

And finally... Barry suggested that if I did not want to discuss linguistic diversity I could write about pharmaceutical corporate mergers, the meaning of life or the parlous state of the English and German football teams. Well, on the latter subject I would just like to say to our Portuguese and Romanian members (do we have any?) that the best teams won the day and no hard feelings, and to my German colleagues, eins zu null!

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### ***NEWSFLASH:***

#### ***The Write Stuff enters the Citation Index***

Yes, *The Write Stuff* has finally entered the BIG TIME – we've been cited! An article in the European Society for Regulatory Affairs journal, the *ESRA Rappoteur* (July/August 2000, pages 5-8), entitled "Medical writing in regulatory affairs: improving the quality of reporting and electronic media challenges" by Paolo M. Biffignandi makes two references to TWS! One reference is to the article "Medical Writing in the Old World" from 1999; 8 (3): 8-9 and the other, believe it or not, is to "The Lighter Side: what they really mean" from 1999; 8 (4): 21. Good to see that one thing EMWA gets noted for is a sense of humour.





## Regulatory Questions and Answers: The Investigator's Brochure

by Douglas Fiebig

*Dear TWS Experts*

*I work for Novo Nordisk and I'm responsible for our IB SOP. I've been asked if I know about any official guidelines for the format of AE tabulations for IBs. I have not been able to find any, so our AE tabulations are based on the tabulations we use for our clinical trial reports. Do you know if there are official guidelines? And then I have another question. Does your department ever receive comments such as, "No comments on the content, BUT, I have a general comment that I have raised many times, must our IB's be such boring documents, not at all inviting the investigators to read them? I think they should be written much more like our product monographs, using colours, figures, graphs, and even pictures, etc. I mean this very seriously!"*

The first part of the question is quickly answered. The only official guidance for preparing an IB is given in the ICH E6 guideline on GCP (e.g. CPMP/ICH/135/95). However, this guideline provides only general recommendations for the structure and content of an IB, and the style of presentation is left to the discretion of the sponsor. Thus the most pragmatic approach to generating AE tabulations in IBs is to use the format chosen by the sponsor for other documentation, such as study reports or registration summaries. In this way, data programmers don't have to establish a specific format for IBs, and often it will probably be possible to use tabulations in the IB that were originally generated for other documentation.

Regarding whether IBs could be made less "boring", as most of us know from personal experience, boring literature tends not to be read in any detail, if at all, and so a boring IB is unlikely to be regarded by an investigator as an essential resource from which relevant information can be gleaned about the product being tested. The issue of what exactly constitutes a boring document (IB or otherwise) is undoubtedly subjective, but in general terms I would consider a document as inherently boring when its style of presentation, for whatever reason, tends to deter the intended audience from reading it.

The style of presentation in any document has two basic components: the organisation of the material to be included and the formatting of the content (the colour, figures, pictures, etc. referred to in the question). As medical writers, we generally have little influence on the scope of the material to be included in an IB, and no influence on whether an investigator is predisposed to consult an IB, but what we certainly can and should aim to influence is the ease with which investigators can access the material presented should they turn to the IB for information.

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***Medical writers can and should aim to influence the ease with which investigators can access the material presented.***

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So the question is: what is an appropriate style of presentation to achieve this aim? Personally I see no need for flashy colours, input from graphic artists, luxury quality



### *The Investigator's Brochure*

papers, etc. We have to remember that a common problem confronted by medical writers when preparing an IB is a shortage of time and information. The realities of deadlines being brought forward, reports often existing only as drafts, if at all, (particularly the case with preclinical studies in early-stage IBs), "final" tables of data needing further cycles of revision, etc, mean that preparing an IB often becomes the classic dilemma of doing the best job with the information available, in the time available. Under these conditions, the scope for artistic input to an IB is obviously limited, especially for early editions in view of the high attrition rate of compounds in Phase I of clinical development. The time involved for any such artistic input would not be justified under the generally tight timelines involved when preparing an IB, where the emphasis clearly has to be placed on ensuring the accuracy and completeness of the material presented (i.e. the quality of the content). Perhaps we also shouldn't underestimate the potential for glossy literature produced by the pharmaceutical industry to arouse suspicion.

Apart from the general lack of time for artistic input, while it might be tempting to think that the use of colours and pictures might make an IB inherently more interesting, in fact a user-friendly layout, the intelligent use of in-text tables and graphs, and a clear and concise text are undoubtedly the medical writer's most potent weapons for reducing boredom in any documentation. The basic principle behind a well-prepared IB that captures the reader's attention is much the same as in all medical writing, which is to highlight the important features of the development programme to date in a competent fashion, with the medical writer providing the competence. In essence, given the often extensive amount of research that has to be reported, the readability of the IB really needs to be ensured by having the main body of the text provide a series of take-home messages for the investigator. Further details are then provided in a hierarchical manner, with the text supported by in-text tables and graphs, which in turn are supported by the tables of all studies, which themselves are supported by the original reports archived by the sponsor. Realistically, the items most likely to be read, at least in the first instance, are the high-level summaries (one to two pages for each major section) and perhaps selected in-text tables and graphs, so special attention has to be paid to ensuring that these summaries really do convey the required messages.

***My take-home messages in response to the original questions are therefore:***

- ***There are no official guidelines on AE tabulations for IBs. Use the format your company uses for other documentation.***
- ***Elaborate artwork is generally not justified or necessary to make IBs less "boring".***
- ***The use of clear and concise text together with intelligently planned in-text tables and figures ensures that an IB is not only a document that fulfills a legal obligation, but also a useful resource for investigators who need to be informed about the product they are testing.***

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## EMWA One-day Conference



Novotel, Lille Centre, France  
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### FEATURING:

DATA PRESENTATION I: TABLES & GRAPHS  
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WRITING CLINICAL STUDY REPORTS USING ICH E3  
MEDICAL WRITING AND DRUG SAFETY







## **Becoming a Non-native English-Speaking Freelance Medical Writer**

**by Annemieke Van Hest**

When Hilde Joosen asked me to put some thoughts on paper about non-native medical writing, I was hesitant to agree because I was not sure if I would be able to contribute something new and meaningful to the ongoing discussion in TWS. But when I was driving home from a meeting with one of my well-respected sponsors, I thought that it might be a good idea to tell you how a Dutch native-speaking psychologist became a non-native English-speaking freelance medical writer. By telling you this little story, I want to illustrate what skills I think are essential for success as a medical writer, and that fluency in English is only part of it.

I certainly had no intention of becoming a medical writer when I went to university some 25 years ago. Frankly speaking, I had never heard of medical writing at that time, and, as I realise now, maybe the profession as such didn't exist back then. After a few months at university, I found out that my real interest was in physiology, psychopharmacology and statistics. So I spent the next couple of years in the animal laboratory, studying the relationship between brain and behaviour in rats. I did my PhD thesis on the effects of gonadal hormones on learning and memory in rats at the Netherlands Institute for Brain Research, and afterwards I joined a well established Belgian pharmaceutical company (no, not the company that Hilde is working for) as a group leader in preclinical pharmacology of the central nervous system. After having spent 10 years amidst rats, mice and pigeons, I was eager to learn how drugs were being further developed after they left the laboratory and I took up a job as a clinical research director at the Clinical Pharmacology Department within the same company. As a substantial part of the job consisted of contracting out Phase I volunteer studies, the next logical step for me was to join a rather small CRO that had been involved in some of the Phase I studies that I had set up. My job description said "medical writer", but being one of the seniors I was involved in almost every aspect of the process, and soon became interim head of the Biometrics Department, responsible for everything from data entry to the integrated medical and statistical report. Then there was a merger, the offices were moved, and I suddenly became freelance!

Looking back, I dare say that the foundation of everything that I achieved as a writer later on was laid during my years at the Netherlands Brain Institute. In the first place, I became thoroughly familiar with all aspects of data analysis. I attended a SAS course, and handled and analysed all experimental data by myself. Support of a data management or statistical department was a luxury I could only dream of. One other extremely important skill that I acquired in those years was the ability to write an article. There

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***I handled and analysed all experimental data by myself. Support of a data-management or statistical department was a luxury I could only dream of.***

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was no special training course for that part of the job so, needless to say, the first few articles came back all blackened by the many, many valuable suggestions for improvement that reviewers and editors had scribbled in the margins. Even now, I quite often revert to their suggestions, which have been at the back of my mind ever since that time. But gradually I learned, and one paper after another was accepted and published. That was the time when writing really became fun!

The years I worked in the pharmaceutical industry were essential to come to a clear understanding of the drug development process in its broadest sense. I never did much medical writing at that time because most of the reports were contracted out, but I reviewed quite a lot of them, which was also rather instructive. At the time that I started writing clinical reports myself at the CRO that I mentioned, the ICH guideline E3: Structure and Content of Clinical Study Reports was being drafted, and I tried to follow that process as closely as possible. This transitional period put great demands on one's creativity and flexibility as a writer, in order to be able to produce a report that was fully compliant with the different sponsors SOPs and templates, but would not contradict the ICH guidelines once they became final. Two other things that I learned from that time and still consider prerequisites for successful medical writing: a client-

***A medical writer must possess many more skills than fluency in English alone.***

centred approach, and never missing a deadline. A third skill that I acquired - how to negotiate prices - might not be essential, but there is also no harm in it for a freelance writer.

Having been responsible for the conduct of clinical trials myself, I can only see the report as the end product of a study that should demonstrate the sponsor's commitment to conducting clinical trials to the highest standards. A good clinical report adheres to SOPs and guidelines, is compliant with formatting requirements, and shows internal consistency and accuracy. Furthermore, it is complete, with a sufficient level of detail, easy to review, and, most of all, it must be acceptable to regulatory authorities worldwide. And last but not least, a good report is one that is also on time. To be able to fulfil all these requirements, a medical writer must possess many more skills than fluency in English alone. A good command of the language certainly is an advantage, but in the first place, this is not exclusively given to native speakers, and secondly, it is only one of the many skills that are needed to become a good medical writer.

Nowadays, as a freelance medical writer, I find pleasure in the contacts with different Sponsors, the diversity of therapeutic areas, and all the different styles of working. I never intended to write for a living, but once I became a non-native English-speaking freelance medical writer, I decided to stay one for life.

Annemieke Van Hest  
author@euronet.nl

**Postscript:** Annemieke reports that she's having difficulties with her tax declaration in The Netherlands. These people claim that medical writing is not a profession, but "a gift" (a talent), and that, as a result, she will have to pay more taxes...! Another "extra" difficulty for those rare non-native English-speaking medical writers, perhaps? On the other hand, however, it sounds as if we're really special!





## Life after Medical Writing: Message from Outer Space

by Leen Vanherle

The only reason I was allowed to leave the field of medical writing was the promise to my good old friend Barry Drees that I would provide you with a detailed report of life on the other side of the fence. You see, after 6 years of medical writing and intense involvement with AMWA, then EMWA, ending up as president of EMWA in 1994, I decided to cross over to the enemy in 1997. You know the saying, if you can't beat them, join them. So why has it taken me so long to tell you what it is I am doing now? Well, the initial shock, the doubts, the counselling and finally picking up the courage to tell you the truth has been a lengthy process... I have become an auditor. Now please don't go turning over this page in disgust.

I know that most of you, understandably, see the world of auditing according to the "truths" of Dilbert:

*"I'm exiled to the Quality Assurance Department. My career is doomed."*

or

*"The best of all worlds is to be asked to check the writing of a co-worker. You get to savor the experience of shredding another person's ego while taking no personal risk. It can be a very satisfying experience."*

*Adams, S. The Dilbert principle. Harper Business 1996*

How on earth does a medical writer of clinical trial documents become involved with audits and inspections? Well, let's look at what the qualities (there are some, believe me) of a good auditor are and maybe you'll be shocked by the results.

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***I know that most of  
you see the world  
of auditing accord-  
ing to Dilbert***

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First, a good auditor has to understand the science behind and development within the clinical trial world. As a medical writer, you also have to develop these skills through your involvement with protocol development, project team meetings, data and analysis review before finally writing the report. Secondly, a good auditor knows their GCPs, SOPs, guidelines, regulations, and what have you. Most of you writers are familiar with ICH and work according to GCP rules anyway, so this is not exactly new. This is a matter of constant studying and updating for an auditor. When we're not travelling or writing reports, we're usually updating our brain storage with new amazing rules to be complied with.



Thirdly, a good auditor understands the process and the pitfalls of clinical trial execution. How are sites selected, how are sites initiated and trained, what makes a good monitor tick, drug accountability, what are the systems that make a clinical trial run smoothly, what exactly is expected from an Ethics Committee, etc. This is maybe one area medical writers might be less familiar with, and a knowledge that has to be acquired (in case you want to join me!). Even so, this is also an area where you can develop your skill as a good communicator and analyst. An auditor has to understand, analyse and spot the pitfalls in a certain process.

Analysis and communication are actually the essence of auditing, and to me, these are actually the most fascinating and challenging aspects of the job. Auditing is a lot about ignorance, misunderstanding and broadcasting on parallel communication channels. I have been audited before, so I know what the feeling is when somebody comes snooping through your work with the only purpose to nail and crucify you (admit it, you think, "What the hell does this fool think they are doing telling me what I do wrong"). Well, if there are auditors like that out there, you have my permission to shoot them because that is not what auditing is about. Misunderstanding, huh, don't tell me that writers don't have years of experience of being misunderstood and misinterpreted. So there you go, another skill you have. Auditing is all about trouble shooting and not about trouble snooping. So, when you, the auditor, find that things have gone wrong, you first have to identify the correct cause, before you make the parties involved aware that something is wrong and what the consequences are if the situation is not rectified. It is important that you discuss the situation and not the people; and remember that you are the catalyst in process improvement or process quality maintenance.

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***Skill is required to pour a bad message into a form that is acceptable to all parties involved***

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And where does all this lead to? That facts have to be presented correctly, diplomatically and clearly in an audit report! Yes, writers definitely have the advantage here compared with auditors who have had more practical experience in the clinical trial world. I have written long clinical trial reports before, but I can honestly say that I pour more brain power and energy into writing a 10 page audit report than into a 60 page trial report. While you are truly assessing processes and systems instead of people, no matter how you turn it, there are people behind those processes. Since most people take pride in their work, they often tend to identify themselves with those processes, so feel assessed in the end. You can see that skill is required to pour a bad message into a form that is acceptable to all parties involved. No matter how bad you feel about the situation yourself, you have to stick to the finding and present it in the fairest way possible. No matter how much bullying or cajoling you get subjected to, you must never lose your temper or give in. It is unbelievable what people will do to change an audit observation to their advantage or delegate the blame to someone else. I sometimes get tangled in endless dialectics and end up with a woolly brain. And then, I'm just talking about the discussion in English, I'm not even mentioning the German, French, Polish. Absolutely fascinating, I love this part of the job. It keeps me on my toes, and I make sure everybody else does too. So, an auditor has a thick skin, is firm, is the perfect diplomat. Do you recognise yourself?



### ***Message from Outer Space***

There is maybe one area the auditor is easily defeated, and that's the travelling part. I've been sick on the Heathrow airport floor (no wonder it looks like a mess now); I've been stuck on the tarmac for three hours in a snowstorm; I've missed planes; I've had the Virgin Express experience (based on the intimate proximity the passengers are subjected to in their planes, I think maybe it was not opportune to choose the name "Virgin"). Considering we travel at least 25% of our working lives, this can be the most tedious, exasperating and challenging part of the job. But let's face it folks: this has nothing to do with auditing or medical writing. It's just the normal survival-of-the-fittest travel experience. To tell you the truth, I love being in different countries, to meet the people in our different affiliates, to see for myself how CROs work, to compare the differences in healthcare management, discover how interested and dedicated most trial teams and investigator sites are...

I'm no longer afraid to admit it, I love this job. I do not regret for one minute about saying medical writing farewell (sorry guys). Well, I must be honest. There is one thing I do miss. That's those great EMWA meetings and all that fantastic "networking". I think back with fond memories to those early rebel days when we wanted to go our own way, all the brainstorming sessions about AMWA's and EMWA's future, the development of our first newsletter, our own EMWA annual conference, the booze-ups afterwards, the great joke-telling sessions. I would not have wanted to miss that experience for the world. I've learnt a lot and made some great friends. Keep up the excellent work and make sure Keith keeps his word about keeping his speeches short!

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### ***Department of Corrections – Spring 2000***

At the very last second before printing, a very distracted, overworked, and underpaid Editor-in-Chief, following the advice of one of his copyeditors, added some information about David Sharp's position. Alas, although the Editor-in-Chief knows David personally and has even consulted with him on the layout of *The Lancet*, BMJ got typed in somehow instead! Just for good measure, the date of the Madrid conference was also wrong (just like the bags from that conference).

The first paragraph on page 14 of the article "Good Publication Practice . . ." by Liz Wager and Leni Grossman should read:

*"The reaction of David Sharp, deputy editor of The Lancet, to information from a communications agency at the 1998 EMWA conference is a good example of such views."*





## **Rule Britannia, McDonald's and Other Things**

by Norbert de Clercq

If Peter Stuyvesant and his fellow Dutchmen had not been thrown out of Manhattan all those years ago, I might have been writing in Dutch and not about what follows.

I have been a scientific writer for the best part of three years now and I have a confession to make. To my annoyance, sometimes I get comments from referees on publications I have written: "Please correct the Belgian English and have the text reviewed by a native English-speaking person". Thus my English is NOT perfect, far from it, and the texts I write are full of clues to the reason for this. Indeed, English is not my mother tongue. Though the business I am in requires me not only to speak but also to write in English, be it British or American English. You could say, stop doing what you do and go do something else but - bad luck - I actually enjoy what I am doing, and that is to write. Thus, I have to do my best and continuously improve it, together with numerous fellow non-native English-speaking medical writers. My attendance at the last EMWA conference in Dublin prompted me to write this and continue the dialogue on being a non-native English-speaking medical writer. I hope this will help those out there who may encounter difficulties with acceptance of their English texts.

I must admit that I am fortunate, being born in Belgium, where language is a continuous reason for quarrel among fellow citizens, and people are very aware about language usage. Not only do we have three official languages (Dutch or Flemish; French and German) but also, English is all over the place. It is part of the core curriculum of every kid from 12 years onwards (oops, I should not use "core curriculum"). When you switch on the radio in Belgium (and in many other European countries), more than half the songs you hear are in English, films or series on the television are shown in their original version, at least in the Flemish-speaking region, and more and more advertising is done in English. The latter is probably done for convenience in this multi-lingual society. However, it upsets some people, although so far it has not become anywhere near as bad as in France, where the drive to ban English is much stronger. The continuous immersion in English of course is very useful when your profession is to write in English. But I must admit that this is not the only advantage I have.

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***If Peter Stuyvesant and  
his fellow Dutchmen had  
not been thrown out of  
Manhattan all those years  
ago, I might have been  
writing in Dutch and not  
about what follows.***

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### ***Rule Britannia?***

I have been on the post-doc trail in an English-speaking country, actually in the core of it, London. Such an experience forces you to speak English as your main language but also living there gives you great opportunity to read newspapers, watch television and listen to the radio on a continuous basis. It is when you are actually there, that you finally start to pick up and use the finesses of a language. For instance, little did I know what "I feel knackered" meant when I arrived. Again, immersion in English is the key for improvement and there are plenty of opportunities to do it - so do it.

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***Little did I know what  
"I feel knackered"  
meant when I arrived  
in London***

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It is also a question of attitude. We do not write novels, nor do we try to match ourselves with James Joyce. We report on facts and data, interpret and give our views. As long as your English is as correct as possible, you should not worry. But this does not mean you should be complacent. On the contrary, you have to work on improving your English every day. And because you are a non-native speaker, you will probably do this better than many a native speaker. Let's face it, who among us has not read text written by a native speaker that was far from perfect?

Finally, I would like to suggest something for those of you who occasionally have to give presentations in English. People are often reluctant to do so because they fear comments on their language use. Again, this can be overcome with an offensive rather than defensive attitude. If the people in the audience would speak in your language to the same standard you try to do in theirs, then they have every right to comment. My message for those who do not dare, is to simply go out there and do it, and more importantly, learn from your mistakes and be open for constructive comments.

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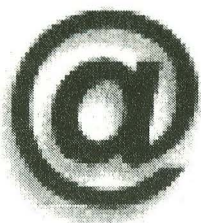


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## Networking: the Webscout

by Amanda Bennett

The Net is massive. Just the Web alone houses some 500 million pages of text, and millions are added daily. How many times have you entered a keyword into Yahoo or Altavista only to wade through irrelevant results and sites of little interest? So if you need to find something – particularly if you want to research it in depth – you are going to need some help. There are three basic types of Web search tools: search engines, search agents and hand-built directories that differ by how and what they search. Try using several for any particular search to get a feel for the differences in the sites they pull up.

A promising newcomer is:

**<http://www.google.com>**

- Its homepage could not be simpler, a single input box and not a banner ad in sight. It has a large database, an intelligent system of ranking hits by relevancy, and local cache access to pages that have disappeared since its last crawl (the program periodically "crawls" around the internet looking for new sites) or are otherwise unavailable. Check it out, it looks set to become a future champ!

If you need more results, rather than visit several engines in turn query them simultaneously using a search agent. Good examples are:

**<http://www.copernic.com>**

- A more sophisticated program that can query several search engines at once. It filters out duplicates, displays the results on a single page and even retrieves them automatically for off-line browsing. You can download the Copernic 2000 package for free, so don't delay!

**<http://www.dogpile.com>**

- Another powerful meta-index that searches "best of breed" search engines. Currently twenty-five search engines are supported. Great for searching for extremely obscure topics.

For a variant on this theme try:

**<http://www.kenjin.com>**

- Kenjin is a consumer offering from the "knowledge management" software house Autonomy. Knowledge management is one of the current hot topics, the theory being that these tools can mine through vast expanses of unstructured information on the Internet and deliver relevant packets of information to individuals based on their pattern of PC use. This free download sits on the desktop and responds automatically to the content of new documents, e-mails and web pages, suggesting recommended links to relevant information (information not just on the web but on your local PC, network and those of similar minds in the Kenjin community). The hype is intoxicating: "Kenjin obviates the need for search engines" - but whether people take to this new kind of subliminal agent remains to be seen!



Other sites of interest for this issue's web watch are:

**<http://www.ingenta.com>**

- A global medical information portal. Ingenta.com provides free comprehensive article searching and personalised delivery of new research material. The site also fosters subject-specific online communities in co-operation with key content providers.

**<http://www.dianthus.co.uk/resources/statistics/statistics.htm>**

- A site intended to provide information on statistical topics that should be of use to medical writers. The aim is to alert medical writers to the problems they may face in interpreting and presenting statistical analyses rather than to explain how to do the analyses.

**<http://www.bartleby.com/141>**

- English usage in a nutshell. This site contains Strunk's classic reference book. The Elements of Style – a must-have for any writer. Believing that one must first know the rules to break them, it briefly outlines the principal requirements of plain English style and concentrates attention on the rules of usage and principles of composition most commonly violated.

**<http://leo.stcloudstate.edu>**

- This site is a nicely organised and fairly extensive collection of self-help documents on the writing process, organisation and cohesion, grammar, punctuation, citing sources, stylistic concerns, different types of writing, etc. The site makes use of examples to illustrate grammar and punctuation rules. It is probably the best place to start if you need a brush-up on English grammar or don't understand a particular grammatical rule. The documents are indexed by general area and also as links from a sort of questionnaire to which the user responds.

**<http://www.grammarbook.com>**

- An easy-to-use reference guide and workbook which is now available as an on-line resource. This is an indispensable and entertaining guide for writers, proofreaders, and editors. Use this site to find the answers to your questions concerning proper English grammar and punctuation.

**<http://www.safemedication.com>**

- This searchable database features more than 650 drugs and includes brand and generic names. Important information on how to take medicines, potential side effects, storage recommendations, and precautions are discussed in easy-to-understand language.

If you should come across an interesting or useful website that you think fellow writers would enjoy, please send the URL of the site to [Bennetta@iconuk.com](mailto:Bennetta@iconuk.com). Also, let me know if there is a particular area or topic that you would like to see included.

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## **The Lighter Side: Lightbulb Changing in Publishing**

*Sent to TWS by an EMWA member after a long e-mail chain.*

*Dedicated to all the contributors to TWS and the members of the TWS editorial board.*

Q. How many **editors-in-chief** does it take to change a lightbulb?

A. Three: one to screw it in, two to hold down the author.

Q. How many **managing editors** does it take to change a lightbulb?

A. You were supposed to have changed that lightbulb last week!

Q. How many **art directors** does it take to change a lightbulb?

A. Does it HAVE to be a lightbulb?

Q. How many **copy editors** does it take to change a lightbulb?

A. The last time this question was asked, it involved art directors. Is the difference intentional? Should one or the other instance be changed? It seems inconsistent.

Q. How many **marketing directors** does it take to change a lightbulb?

A. It isn't too late to make this neon instead, is it?

Q. How many **human resource directors** does it take to change a lightbulb?

A. Are we sure that the lightbulb WANTS to change?

Q. How many **proofreaders** does it take to change a lightbulb?

A. Proofreaders aren't supposed to change lightbulbs. They should just query them.

Q. How many **writers** does it take to change a lightbulb?

A. But why do we have to CHANGE it? It's already perfect as it is!

Q. How many **contributing authors** does it take to change a lightbulb?

A. Well I haven't done it yet but I have a pretty firm outline of the process in mind.

Q. How many **cover artists** does it take to change a lightbulb?

A. Why is there...an eggbeater, I think, sticking out of this light fixture?

Q. How many **sales directors** does it take to change a lightbulb?

A. (pause) I get it! This is one of those lightbulb jokes, right?

Q. How many **translators** does it take to change a lightbulb?

A. In this context, the more formal "light fixture" would usually be used instead of the pedestrian-sounding "lightbulb."

Note: for more on this timely issue, see Simpson, N. How many psychiatrists does it take to change a lightbulb? *BMJ* 2000; 321:519.





## From the Literature ... Reporting Results?

by Liz Wager

Have you heard the definition of a medical statistician? It's somebody who won't accept that Columbus discovered America because he set out to discover a different country. Joking aside, medical writers need to understand at least some basic statistics and a couple of recent articles prove that an interesting statistics article isn't necessarily an oxymoron. The *BMJ* published a survey of the use of intent-to-treat analysis in papers published in four major journals (*BMJ* 1999; 319:670-4). Having had many battles with statisticians about how to report patients who accidentally received the wrong treatment, I found it full of refreshing advice. The authors suggest that "intent-to-treat analysis is most suitable for pragmatic trials of effectiveness rather than for explanatory investigations of efficacy". Another nice feature of this paper is that the authors (Sally Hollis & Fiona Campbell) represent a collaboration between academia and the pharmaceutical industry (coming from Lancaster University and AstraZeneca respectively). A response to the paper (*BMJ* 2000; 320:1007-1008) also cheered me by pointing out that, although reporting of intent-to-treat analyses is generally poor, studies funded by the pharmaceutical industry were more likely to include this.

Still on statistics, a recent paper in *The Lancet* (2000; 355:1064-9) reports a similar survey of clinical trials published in the *BMJ*, *JAMA*, *Lancet* and *NEJM* during 1997 looking at their use of subgroup analyses. This highlights deficiencies in trial reporting, especially the over-use and over-interpretation of subgroup analyses, and provides some useful recommendations, for example that significance testing is inappropriate for baseline characteristics. An editorial accompanies the article (*Lancet* 2000; 355:1033-4) and exhorts authors to follow the CONSORT guidelines to improve this aspect of trial reporting.

For those of you still awake despite these serious column-inches about statistics, my last offering is statistics-free. Neville Goodman (the author of one of my favourite books on medical writing<sup>1</sup>) has surveyed the titles of papers reporting clinical trials between 1970 and 1997. He reports that "assertive sentence titles" (i.e. those that describe the research results instead of just the nature of the study) are on the increase but warns that they may be "improper and imprudent and too often plain wrong". He suggests that journals should insist on indicative titles. In a short commentary, Richard Smith notes that the *BMJ* currently avoids declarative titles for original studies but suggests that they are tempted to use them and comments that "The trend is undoubtedly for journals to become more like newspapers and for newspapers to become more tabloid. It's about readability and trying to grab people's attention in an ever more crowded world". My next installment will therefore be entitled "Sexy medical writing: hot tips from the boffins".

### Reference

1 Goodman NW, Edwards MB. *Medical Writing. A Prescription for Clarity* 2nd edition, 1997. Cambridge University Press, 1991.





**In the Bookstores . . .**  
**A New Resource for Teachers of Scientific Writing: Turning Data into Manuscripts**

**by Karen Shashok**

*F. Peter Woodford, with the collaboration of Maureen E. Goode and Barbara Gastel. How to teach scientific communication. Reston, Virginia: Council of Biology Editors, 1999. ISBN 0 914 34011 5.*

This book, intended for the instructor as a guide for teaching scientific communication, is a completely rewritten and updated version of the well-known *Scientific Writing for Graduate Students*, first published in 1968 by the Council of Biology Editors (now known as the Council of Science Editors). The first section devotes nine chapters to the writing of journal articles, and the second section contains separate chapters on teaching how to prepare conference posters and their abstracts, scientific talks, dissertations, research grant proposals, and presentations to the lay public.

Each chapter is organised around a specific goal (for example, deciding whether the author is ready to publish, choosing the target journal, designing tables and figures, editing the text, final submission, and responding to the journal editor). To help the instructor (especially the less experienced one) get down to business, each chapter begins with a clear statement of the objectives, recommended background reading for the instructor, material to be handed out to students, assignments, and approximate timing. At the end of each chapter (which represents a single "lesson" in the course structure) is a list of references relevant to the specific topic, and a useful summary of the points that ideally will have been dealt with. This last element is a great practical aid in evaluating the effectiveness of the course.

The usefulness of the book is enhanced by the inclusion of a full suite of back matter. There are four appendices dealing with style guidelines, editing assignments for students to complete, warning words and phrases, and points of grammar and punctuation. In addition, there is an annotated bibliography, a subject index and an author index.

In his preface, the main author provides practical guidelines on how the book can best be used. He recommends that the class consist of 12 to 20 students, because of "the efficiency of teaching more than one person at a time and because the interaction with other members of the class as well as the instructor is stimulating". He assumes that students will be active scientists who have produced some research results they wish to publish. Ideally, the major assignment for the course built around this teacher's guide should be to prepare a journal article or conference poster based on each scientist's own findings. However, alternative assignments are also described for those students who may not have publishable data in hand yet when they enrol in the course.



As for the instructor, Woodford believes that the course should be taught by working scientists because of their familiarity with "the problems and pitfalls not only of publishing but of doing research". Nonetheless, he also considers this instructor's manual suitable for "those with a scientific background who are not ... in active research but are in frequent contact with scientists and scientific publishing". He clarifies that "the subject is most effectively taught by focusing on science, not language: on the scientific qualities of logic, precision, and clarity of reasoning, not on skill in turning a neat or elegant phrase". Further to this, he emphasises that the book's "major concern is not with weak style or even bad grammar, but with sound logic, good structure, and honesty. ... The book's major purpose is to help scientists strengthen their mental powers by preparing their publications in a strictly logical fashion, expressing themselves straightforwardly, and working ethically".

These values are an excellent basis for teaching scientific writing, but also assume that the students who will be taught with the help of this book are from an English-speaking cultural background. What scientists with English as their first language will consider sound logic, straightforward structure and honesty may differ from how colleagues from a different cultural background see language as a tool to communicate science. Accordingly, writing instructors who work with researchers from different cultural backgrounds will need to make selective use of the lessons, exercises and recommendations laid out so clearly in this book, and adapt them to the needs and expectations of their own students. Colleagues with a background in applied linguistics as it pertains to science writing, may disagree with some recommendations on the "marshalling of facts and ideas into section files" (chapter 3), "topic and sentence outlines" (chapter 5), and the process of revising successive drafts, but of course, experienced writing instructors will know where to mine this and other resources to extract practical solutions.

*How to teach scientific communication* is a valuable addition to the stock of resources writing instructors use to prepare their courses. Its strong points are excellent organisation and generous complementary information provided in the appendices and bibliography. Its only weak point as a teaching aid is chapter 9, titled "Responding to the journal editor", which is somewhat short and superficial, and includes no assignments or practical exercises. This was probably intentional, as the students are assumed to be at a stage where they are just beginning to prepare their first real manuscript, and have not yet reached the stage in their publication career where they are asked to respond to the reviewers' and editor's suggestions for revision. In fact, an entire book could probably be written on strategies for responding to these requests, and it would perhaps not have been practical to lengthen this chapter any further.

By the way, the title of this section of TWS notwithstanding, this excellent book is not available "in the bookstores", but can be ordered direct from the Council of Science Editors (see advertisement in this issue). Check their new homepage for details ([www.councilscienceeditors.org](http://www.councilscienceeditors.org)), or email them at [cbehdqts@aol.com](mailto:cbehdqts@aol.com).

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## Meetings of Interest

The following list is presented as a service to EMWA members and is not meant to be complete. EMWA does not endorse these meetings in any way. Those having the [EMWA] symbol include presentations from EMWA members. All meetings are conducted in the English language unless otherwise indicated. If you would like to have something listed here to share with other members, please contact Barry Drees (details on back cover).

Date	Meeting/Sponsor	Location
Oct 3 [EMWA]	<b>Effective Writing</b> Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: <a href="http://www.timalbert.co.uk">www.timalbert.co.uk</a>	London, UK
Oct 4-5 [EMWA]	<b>Successful Medical Writing</b> FORUM Institut für Management GmbH Postfach 10 50 60 D-69040 Heidelberg, Germany Tel: (+49) 6221 500 500; Fax: (+49) 6221 500 505	Frankfurt, Germany
Oct 5-6	<b>Survival Skills for Medical Writers</b> Drug Information Association P.O. Box 7777-W8405, Philadelphia, PA, USA 19175 Tel: (+1) 610 341 2243; Fax (+1) 610 989 4580 Internet: <a href="http://www.diahome.org">www.diahome.org</a>	Baltimore, USA
Oct 6 [EMWA]	<b>Writing a Scientific Paper</b> Tim Albert Training Paper Mews Court, Dorking, Surrey, RH4 9AU, UK Tel: (+44) 1306 877993; Internet: <a href="http://www.timalbert.co.uk">www.timalbert.co.uk</a>	London, UK
Oct 25-27 [EMWA]	<b>Successful Medical Writing</b> Management Forum Ltd., 48 Woodbridge Rd, Guildford, Surrey, GU1 4RJ, UK Tel: (+44) 1483 570 099	London, UK
Nov 13	<b>Integrierte Studienberichte nach ICH (German)</b> Kendle Munich Postfach 81 04 09 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: <a href="mailto:info.muc@kendle.com">info.muc@kendle.com</a>	Munich, Germany
Dec 5-6	<b>Rapports d'Etudes Cliniques (French)</b> Institute for International Research (SARL) 150 rue Gallieni BP112, 92100 Boulogne, France Tel: (+33) 1 4699 5096; e-Mail: <a href="mailto:goubaou@iir-fr.com">goubaou@iir-fr.com</a>	Paris, France
Dec 14	<b>Projektmanagement klinischer Prüfung (German)</b> Kendle Munich Postfach 81 04 09 D-81904 Munich, Germany Tel: (+49) 8999 3913 160; e-Mail: <a href="mailto:info.muc@kendle.com">info.muc@kendle.com</a>	Munich, Germany



## **Coming Next Issue . . . (Autumn 2000)**

### ***Interpersonal Working Relationships***

#### ***The Clients from Hell***

**Anne Bartz**

Yes, we've all experienced them in our nightmares and on late-night television, but do these medieval horrors still haunt the dark woods of the freelance world? Indeed, these clients have to be read about to be believed. And to think that they question evolution in Kansas . . . wait until you read about this bunch!

#### ***The Contractor-client Relationship***

**Adam Jacobs**

Adam writes about relations between clients and contractors from the contractor's point of view. Since he has worked in a CRO, an agency, and as a freelancer, he has had a chance to experience much of what contractors have to do. Although he also looks at the "client from hell", he examines what happens when the relationship works well. In fact, here we will learn why some clients turn out to be CFHs (aside from too much corporal punishment when they were young) and why others are a joy to work with, and what both clients and contractors can do to make things run smoothly.

#### ***Setting the Brief***

**Tim Albert**

One of the great mistakes we make when writing is to start too early, without really knowing where we want to end up. Here we will learn what author Tim Albert (see following) recommends: that the first thing to do is to draw back from writing - and think very carefully about what you want to do. This process is called "setting the brief" and Tim gives 5 basic steps on how to go about it. By all means, let your writing be a voyage of discovery, but at least look into the existing charts before you set out.

#### ***In the Bookstores . . . A-Z of Medical Writing***

**Karen Shashok**

Writer, editor, manager and trainer Tim Albert gives both amateur communicators and experienced writers and editors a concise, practical and entertaining guide to semicolons, polyfontophilia, advertorials, post-spelling bee traumatic disorder, and much more in his new A-Z of medical writing.

#### ***Do you have what it takes to work in a team?***

**Diana Klein-Franke**

We have all noticed in the "Work Available" section of the EMWA website that many companies request (or require) the ability to work in a team. But what exactly is team work and what do you need to have to work in a team? Let's face it, even if you're a freelancer working for a client and thus in a team of two, medical writers always work in teams. This article will give you some pointers to determine whether you have what it takes.



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