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# ***The Write Stuff***

The Journal of the European Medical Writers Association

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## ***The Regulatory World: Submissions and Approvals***

**Bundesinstitut für Arzneimittel und  
Medizinprodukte**

**Läkemedelsverket**

***Medicines Control Agency***

*European Agency for the Evaluation of Medicinal Products*

**Agencia Española del Medicamento**

**Medicines Evaluation Board, The Netherlands**

**US Food and Drug Administration**

**Agence Française de Sécurité Sanitaire des  
Produits de Santé**

***Irish Medicines Board***

**EMWA** European  
Medical Writers  
Association

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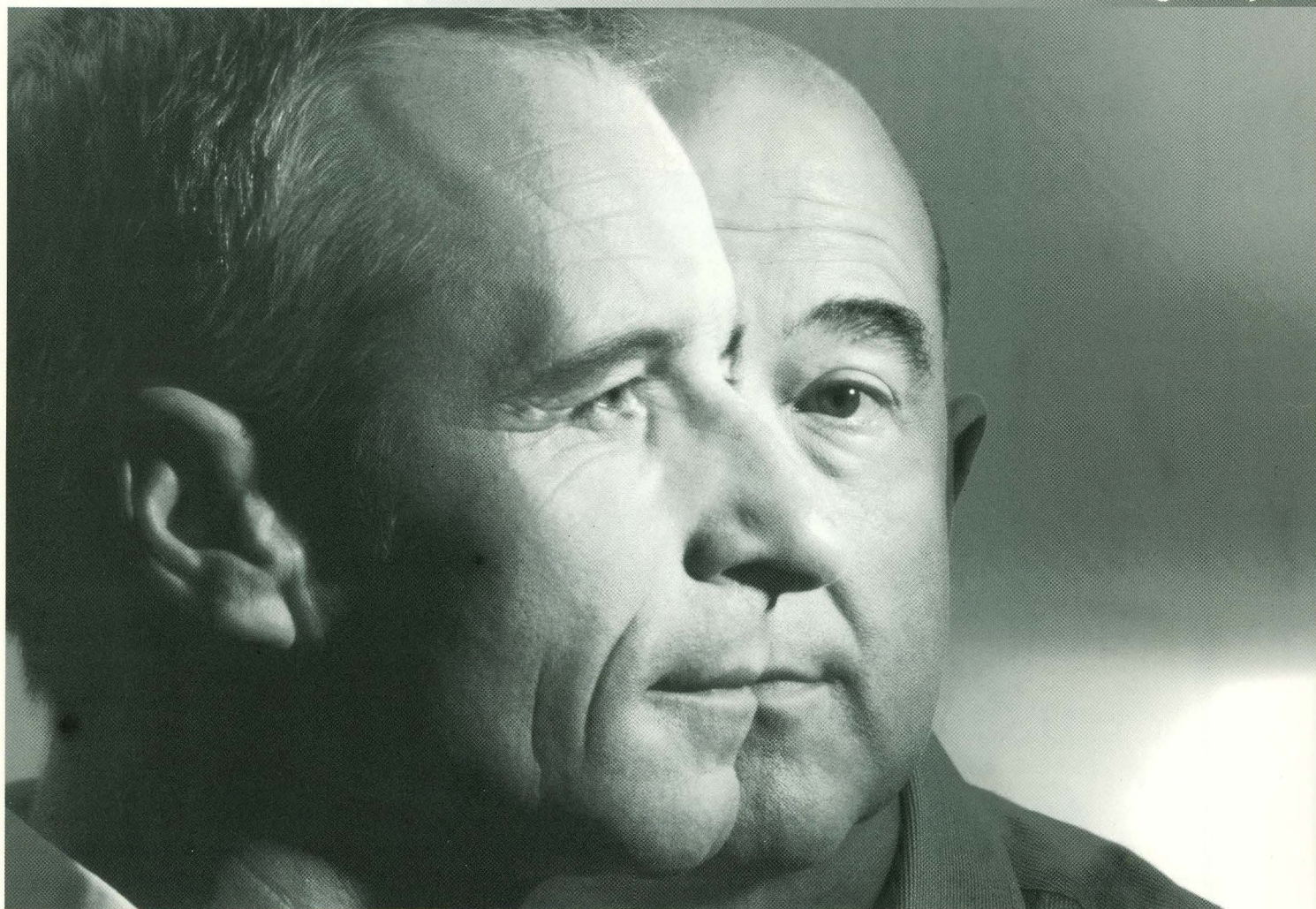
Vol. 10, No. 2, 2001



***Connecting minds is  
the key to faster innovation.  
Aventis Pharma.***



*Our challenge is life.*



Aventis Pharma is one of the world's leading pharmaceutical companies. We are dedicated to converting scientific knowledge into innovative drugs for unmet medical needs. A key to this is the unique approach to research and development in our seamless drug innovation and approval organization – where we rapidly share new insights and build knowledge by leveraging our internal expertise with a large number of international strategic alliances. Cross-functional project teams work simultaneously around the globe to further reduce time-to-market of promising products. This ensures that innovative treatments get to patients faster. Our ability to harness new technologies and our research and development resources enable us to open new horizons for science-based medicine. At Aventis Pharma, there is no higher priority than health and quality of life.



## ***The Regulatory World: Submissions and Approvals (Spring 2001) Vol. 10, No. 2***

### ***The Best and the Worst of EMWA*** **32**

***Barry Drees***

"The truth is out there, Scully." Here it is – warts and all. The first results from the EMWA Questionnaire 2000, where members said what they liked and disliked about EMWA as an organisation. The editorial board of TWS promises to hold nothing back!

### ***Guidelines for Medical Writers: Recent News from the EMEA*** **34**

***Alison Rapley***

Sick and tired of scrolling around websites and trying to read SCRIP. Fret no longer, as Alison brings us all the latest from the European Agency for the Evaluation of Medicinal Products. [INT]

### ***The Common Technical Document*** **37**

***Paul Gisby***

Is it a bird? Is it a plane? No, it isn't even Superman. Here it comes, the object of more speculation than the last version of Windows or the Millennium Dome – the dreaded CTD or Common Technical Document. Billed as the future of international submissions, the idea is to stop having to submit completely different dossiers in the European Union, the US, and Japan. Find out all about it here. [INT]

### ***What the Regulatory Authorities Want to See*** **40**

***Eva Pike***

Here is a unique opportunity to find out from the source. EMWA member Eva Pike has worked for the Norwegian Medicines Agency and regales us with tales from dossiers she's seen. Now we can find out from a writer what the reviewer really likes to see and, even more important, what they hate to see. [INT]

### ***Medical Writing Questions and Answers: Size Matters*** **43**

***Chris Priestley***

A frequently asked question is how to handle the often huge computer files that result from writing Clinical Study Reports, Investigator Brochures, and other documents of modern pharmaceutical industry writing. Here we'll explore some of the theory and practice of how an experienced medical writer deals with these behemoths and that, as the advertising campaign for the movie Godzilla stated, "Size Matters".

## **Regular Columns**

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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>

The cover image is constructed from PowerPoint ClipArt and information from the EMEA website.

## 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
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## **From the Editor's Desk: Leading by Communicating**

by Barry Drees

Well, it was great being away for a while. I just wish I could tell you that I spent the 20 or so hours it takes to put one of these issues together (note the sly underestimate to entice others of you to give it a try) on a nice tropical island enjoying the sun. Alas, as I always tell childless couple friends of mine: "You think you have no free time, but you actually have huge amounts. If you don't believe me, wait until you have a child!" Tasks, unfortunately, like water, fill all available space and time. However, as my PhD advisor used to say: "Some people are smart and some are lucky", and I got lucky in being able to line up another volunteer for deputy editor before she had a chance to read Judi's comments. Yes, Varsha Imber at Nycomed Amersham will be sitting in for me in an upcoming issue. Gosh, this could get habit forming (in my dreams!).

I am particularly pleased in this issue to be able to offer the contribution from Eva Pike, a former reviewer with the Norwegian regulatory authorities. One of the most important potential functions of EMWA is to give medical writers access, on an unofficial basis, to members of the European regulatory authorities. I always start my writing workshops with "Think of who your reader is and why they are reading this document". For those of us who work in the pharmaceutical industry, our most important readers are the regulatory authorities. They, however, are understandably reluctant to discuss presentation details objectively with company employees. EMWA, however, has the possibility to offer a public forum where medical writers can meet and discuss their needs and wants as readers. Our new president, Julia (see following article), is also interested in pursuing this, so I am hopeful that we may finally see something tangible to increase our contact with the European authorities.

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***Nothing seems to be  
more conducive to poor  
decision making than  
secrecy***

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Although I kept hoping for a few final questionnaires to come in, I think that it really is time now to close the Questionnaire for 2000 and report some of the results. Over the next few issues I'll be covering different parts of it in articles like, "The Best and Worst of EMWA" (what members said they liked and disliked about the organisation, "The Changing Face of EMWA" (membership details past and present), "EMWA Writes" (the results of our style poll), and of course we'll see more comments about TWS in Vital Signs. I was particularly interested to read about what people liked and disliked, since this really should be the guide to show us our strengths and weaknesses as perceived by the common member (as opposed to the Executive Committee [EC]). I hope that we'll be able to follow some of the suggestions and make EMWA a better organisation for serving the members. Of course, don't feel restrained by the Questionnaire; if any of the comments or opinions from the Questionnaire inspire or annoy you, drop me a line and maybe we can even get a lively discussion going.



### *From the Editor's Desk*

One of the things that has really impressed me recently in helping to discuss and determine personnel policy of the company that employs me, is the importance of openness. Despite almost universal management sympathies and traditions to the contrary, nothing seems to be more conducive to poor decision making than secrecy. Knowing that decisions made will be subjected to scrutiny usually seems to result in fairer, more just decisions that consider everyone's interests rather than those of just the decision makers. If you don't believe that, then just briefly consider the kinds of decisions made by dictatorships as opposed to democracies. Although some situations require bold leadership when there is not the time for consensus building, this only really works well when the leadership is already used to making the kind of thoughtful, inclusive decisions required by an atmosphere of openness. Instead of what most management groups practice, i.e. keeping all decision making secret unless there is a

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***Many people seem to have the strange idea that if they explain what they are doing and why, it will diminish their authority somehow.***

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compelling reason not to, I think that it should be the other way around, keeping all decision making open, unless there is a really compelling reason for secrecy.

Many people seem to have the strange idea that if they explain what they are doing and why, it will diminish their authority somehow. Actually I would argue that an open leadership style creates real authority based on respect rather

than fear. I also think that such a leadership style builds better teams. Although we seem to hear about teamwork constantly these days, what builds a real team is not blind, child-like loyalty of the team members to the leader, but rather trust based on understanding and a shared sense of purpose. Soldiers are trained to blindly follow orders because they are required to do something that is against human nature, i.e. to give their lives for their country. Most of us non-soldiers, however, are not being asked to do this, yet I am constantly amazed at how many managers or organisation officers seem to think that they should use the military analogy.

What does all this have to do with EMWA? At the recent conference (reviews will appear in the next issue), I heard from several people that many of the actions of the EC, such as election of officers, workshop selection, who pays for what, etc., seem to be cloaked in mystery. This is not a healthy sign. I think that over the last few years, as EMWA has increased in size and profile, it has necessarily changed somewhat in character. Although a very informal decision process (the EC discussing and making decisions in the bar every night of the annual conference) may have been perfectly acceptable in the past, we now have to face the fact that to many members, particularly new members, it may appear secretive and elitist. Thus, in the coming issues of TWS, the members of the EC will be making an effort to explain and describe how and why EMWA does what it does. I hope that this will serve to both illuminate the members as to how EMWA functions as well as inspire more people to get involved and feel that they can participate more in the running of the organisation. After all, that is the real reason for EMWA's existence.

Barry Drees  
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## Message from the President . . .

by Julia Forjanic Klapproth

There it was again. Another annual conference that just whizzed by in a whirl of hearty discussions, lots of laughter and a chance to enjoy the company of good friends, old and new. The seamless succession of interesting workshops and entertaining social events was the result of a year's worth of hard work by Dominique Chenon, Julia Cooper and the EPDP committee and, of course, Phillipa Clow and her group. They all did a great job of organising a conference that had something for everyone and went off without a hitch (with the exception of our badges and mugs, which spent a few days touring France without us).

By now you will have had a chance to taste the jam and wine you received in your conference bags. These were made by local artisans and are both specialties of the region that you won't find anywhere else, in France or the rest of the world. I hope they serve as memories of your stay in Montpellier, and extend the pleasure a little longer.

As I look forward to the year ahead of us, I find myself pondering the good ideas that many of you raised during the conference. One idea, in particular, is ripe to be explored, and that is the establishment of a dialogue between EMWA and the European authorities. The role of the medical writer is taking on ever larger dimensions in the context of regulatory coordination of submission dossiers. There is an industry-wide trend emerging that recognises the synergistic value added of having a medical writer on a submission project, whose function is not only to write many parts of a submission dossier, but to oversee and coordinate the documentation and to ensure consistency in the message being expressed throughout the dossier. In this role as a submission dossier manager, the medical writer must have a solid understanding of the regulatory intent and purpose of the different documents that are being compiled. The writer serves as a cross-functional interface, integrating the take-home message of several different areas into a single, concise story for the authorities to review.

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***The writer serves as a cross-functional interface, integrating the take-home message of several different areas into a single, concise story for the authorities to review.***

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The authorities benefit from this consolidating function, as the dossier they get is easier to review and the message is clearly spelled out. When the submission documents are well written, the reviewer's job of generating an assessment report often becomes a simple job of cut and paste from the summary documentation, which saves time and nerves for everyone. I'm sure it is no coincidence that EMEA advertised last year that they were creating a position for a medical writer at Canary Wharf. The effectiveness that medical writing brings to all document creation is not going unnoticed.



### ***Message from the President***

In this respect, many members have shown interest in establishing a forum of exchange between EMEA and EMWA. I hope to bring this idea to fruition in the coming year, by organising a small meeting that would bring EMWA members and EMEA delegates together to discuss how the two groups can benefit from interacting. It is important that EMEA be made aware of everything medical writing brings to the submission process, and for EMWA to explore what role we can play in the regulatory arena. Is there room for medical writing support in drafting regulatory guidelines (that's a rhetorical question)? Shouldn't the authorities be aware of the integral role the lead medical writer or submission coordinator plays in bringing the message to the authorities? If the authorities recognise this, would they be inclined to establish guidelines that would outline how they could make use of the medical writing function when communicating project-specific information?

These are just a few questions that beg to be asked once one starts to ponder the new levels of responsibility medical writers are enjoying in industry. This issue of TWS focuses specifically on the regulatory side of medical writing, and I am sure you will all find some new insight from the articles presented. This is definitely an exciting time for medical writers working on the regulatory side of the fence, with new opportunities presenting themselves on a regular basis. While I can't tell you where the future will take us, I can promise you that it won't be boring.

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## ***NEWS FLASH***

### ***Help by and for medical editors***

Six years ago, the World Association of Medical Editors (WAME) was launched at the Rockefeller Foundation Bellagio Study and Conference Center in Italy. The aim was to improve standards of editing in medical journals worldwide. Now WAME boasts more than 500 members representing journals in over 60 countries. In January this year, 20 editors met at Bellagio to plan WAME's activities for the next few years. One of the main objectives formulated at this meeting was an educational and training programme, in which WAME's website ([www.wame.org](http://www.wame.org)) would have a vital role. WAME recognises the needs of editors in countries with scarce resources and limited access to publishing and printing expertise. Plans include an online distance-learning package (mostly for new editors) and support for regional initiatives for building local editorial capacity. The group also developed a statement of principles on the professional standards and responsibilities of editors and agreed to assess how much these principles are reflected in practice, as well as barriers to their adoption. You can find the full report at WAME's website.



## **The Best and the Worst of EMWA**

### **Results from the EMWA Questionnaire 2000**

**compiled by Barry Drees**

As we were designing EMWA Questionnaire 2000, I couldn't resist adding in a new question asking what members felt were the best and the worst things about EMWA as an organisation. I've found that when trying to get feedback from people either as a manager, team leader, parent, or in leading an organisation, many people are hesitant to make critical comments. The best way to get really valuable negative feedback (and let's be honest, egos notwithstanding, negative feedback is much more valuable than positive feedback) is to actually prompt people for it. Thus, I was very curious to see what kind of a response we'd get to this question. Sure enough, it made for some interesting reading and should be of special interest to all of us on the Executive Committee. However to keep things in perspective, we also prompted for positive feedback. So, without any further ado, here's what the members had to say (the number in parentheses is the number of people with a similar response).

#### ***The Worst***

- Problems/infighting with AMWA and losing core-curriculum credits (3x)
- Too much emphasis on regulatory/technical writing (3x)
- Nothing! (3x)
- It lacks the status of other medical organisations (3x)
- Needs promoting to employers (who pay for you to go to conferences etc.) (2x)
- Takes a long time to reach decisions.
- I would like more focus in editorial matters in TWS.
- Distance from practical clinical research
- Too small, limits networking possibilities.
- Need to provide more advanced workshops/further education (2x)
- Workshops do not change much over the years (2x)
- Need certificates for attending courses or certificates of accreditation.
- Workshops are not very interactive
- It is difficult to get a certificate. In Dublin I took 4 courses, of which one was from the foundation courses list. The other courses mentioned there were not that interesting to me anymore as I already had English lessons (punctuation, syntax, meaning and word order, etc.) and I am located within a biometrics department, so statistics are not that difficult to have explained. Therefore, to follow 3 additional courses on topics already known, just for a certificate, seems to me a bit overdone.
- Doesn't seem very well organized. Often had problems with renewing membership.
- Having all invoices in £ sterling.
- Not being able to go to all the meetings.



- The EMWA get-togethers at AMWA meetings are a very poor example of EMWA, whereas they should be a showcase, unless EMWA want to foster a small "clubby" atmosphere.
- Not enough fun team games at conferences.
- The website should be more interactive.
- An international worldwide management, with AMWA and EMWA being the first 2 chapters, would be better. Then all AMWA and EMWA members could be IMWA members (International Medical Writing Association)
- Travel expenses and fees too high for freelancers

### ***The Best***

- Social aspects: friendliness of members, willingness to support others, open and relaxed atmosphere, etc., etc. (22x)
- Networking (11x)
- The educational programme (8x)
- Excellent range and quality of workshops (5x)
- Annual conferences are educational and enjoyable (3x)
- TWS (3x)
- Diversity: linguistic and otherwise (2x)
- Great Website (2x)
- Work to raise standards (and status) of the profession
- The Executive Committee members are friendly and approachable.
- I got seriously turned off at the Bruges meeting (1995) by the behaviour and attitude of members of the committee, and didn't want anything further to do with EMWA. Happily, I got to the Dublin meeting and was hugely cheered by the atmosphere - and re-motivated and energised, to get actively involved again.
- Information on useful websites
- The annual conference
- Opportunity to discuss specific MW-related issues, e.g. ICH guideline E3, with experienced writers
- Adjustment to the needs of European regulatory requirements
- Youth, energy, quality
- The feeling that anyone and everyone has something to contribute and is encouraged to go for committee positions.
- To have meetings nearer than with the AMWA conferences and now independence from AMWA (Yes).
- Possibility to develop personal skills.





## **Guidelines for Medical Writers: recent news from the European Agency for the Evaluation of Medicinal Products (EMA)**

by Alison Rapley

Those amongst you who regularly write documents for regulatory submissions will need no introduction to the invaluable list of EMA guidelines available at <http://www.eudra.org>. They cover a very wide area and can also provide useful information to those writers outside the regulatory scene, particularly if you need to discover what is accepted practice in an unknown area. These guidelines are now available at the new EMA web site, <http://www.ema.eu.int>. This article reviews the latest guidelines released by the EMA. It is not a comprehensive list of new guidelines, but a review of those considered most useful to medical writers. You can access the full text of all the guidelines at the new EMA site. This site will replace the old EUDRA site, and new guidelines will be available only at the EMA site. They can be found at "Human Medicines/Regulatory Guidance and Procedures/Notes for Guidance", and are arranged into files on blood products, biotechnology, efficacy, general guidance, herbal medicines, ICH, orphan medicinal products, pharmacovigilance, quality, and safety. "Concept Papers" and "Points to Consider" provide preliminary guidance before release of a full guideline.

If you are interested in peripheral arterial occlusive disease, epilepsy, irritable bowel syndrome or diagnostic agents you should check out the following. They give background information on the disease and incidence as well as providing guidance on the recommended drug development programme, including the type of trials that should be carried out, patient population, trial design, recommended efficacy and safety assessments, and type of analysis.

***Note for Guidance on Clinical Investigation of Medicinal Products in the Treatment of Epileptic Disorders (CPMP/EWP/566/98)***

***Note for Guidance on Clinical Investigation of Medicinal Products for the Treatment of Peripheral Arterial Occlusive Disease (CPMP/EWP/714/98 DRAFT)***

***Concept Paper on the Development of a CPMP Points to Consider on the Evaluation of Drugs for the Treatment of Irritable Bowel Syndrome (CPMP/EWP/785/97)***

***Points to Consider on the Evaluation of Diagnostic Agents (CPMP/EWP/1119/98)***

The guidance on bioavailability and bioequivalence studies is essential reading for those of you involved with generic compounds. It provides a clear definition of the two terms and explains how these studies should be conducted and analysed, and the acceptance criteria for the pharmacokinetic parameters tested:

***Note for Guidance on the Investigation of Bioavailability and Bioequivalence (CPMP/EWP/QWP/1401/98 DRAFT).***



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### *Guidelines for Medical Writers*

There are also new safety guidelines relating to safety pharmacology studies and non-clinical local tolerance testing.

***Note for Guidance on Safety Pharmacology Studies for Human Pharmaceuticals (CPMP/ICH/539/00 ICH Topic 57A)*** discusses what safety pharmacology studies are, why they are needed and how they should be designed. It provides a useful overview of such pharmacology studies.

***Note for Guidance on Non-clinical Local Tolerance Testing of Medicinal Products (CPMP/SWP/2145/00)*** covers the design of local tolerance tests and the type and extent of testing required, with specific information for the ocular, dermal, parenteral, rectal and vaginal routes of administration.

New quality guidelines cover metered dose inhalation products, herbal drugs and even the grade of pharmaceutical water to be used! These quality guidelines relate to the methods of preparation and stability and, as such, are probably less relevant to medical writers in general.

***Note for Guidance on Requirements for Pharmaceutical Documentation for Pressurised Metered Dose Inhalation Products (CPMP/QWP/2845/00 DRAFT)***

***Note for Guidance on Specifications: Test Procedures and Acceptance Criteria for Herbal Drugs, Herbal Drug Preparations and Herbal Medicinal Products (CPMP/QWP/2820/00 DRAFT)***

***Concept Paper on the Development of a CPMP/CVMP Note for Guidance on the Quality of Water for Pharmaceutical Use (CPMP/QWP/1676/00 DRAFT)***

The guidance paper on tradenames has also been revised. This details situations where a proposed tradename may be refused for reasons of confusion with an existing product or misleading therapeutic or pharmaceutical connotations.

***Revised Guidance Paper on the Acceptability of Tradenames for Human Medicinal Products Processed through the Centralised Procedure (CPMP/328/98 rev. 2 DRAFT)***

For those of you involved in producing regulatory documents, the ICH guideline on the common technical document gives an idea of how things will be organised in the future:

***Common Technical Document for the Registration of Pharmaceuticals for Human Use: Organisation of Common Technical Document (CPMP/ICH/2887/99 ICH Topic 4)***

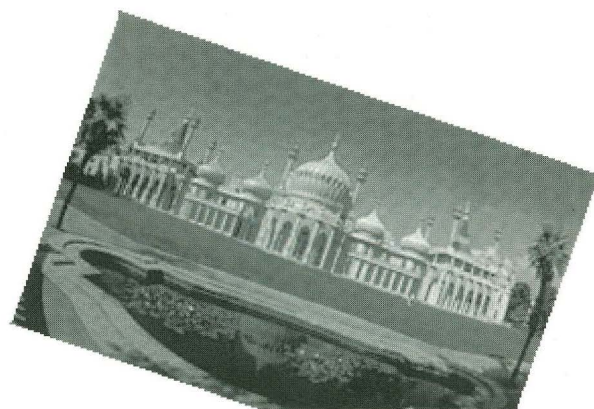
The majority of these guidelines are written in a clear, easy to understand way - perhaps they have employed a few medical writers! They can provide a good overview of a particular therapeutic area or type of study. There is also a lot of other useful stuff on this web site, but that's another article, for another issue of TWS - any volunteers?

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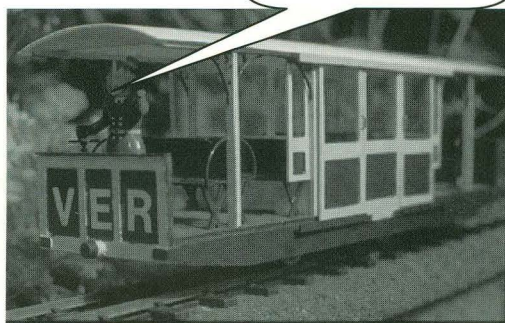
[www.ukattraction.com](http://www.ukattraction.com)



[www.tourism.brighton.co.uk](http://www.tourism.brighton.co.uk)

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Calling all EMWA  
members! Next  
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[www.soft.net.uk/downes/ver1.htm](http://www.soft.net.uk/downes/ver1.htm)

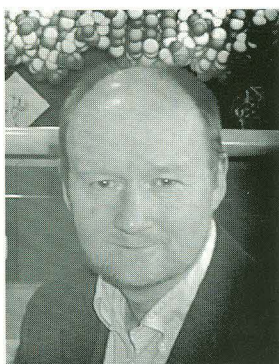
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[www.tourism.brighton.co.uk](http://www.tourism.brighton.co.uk)







## **Common Technical Document (CTD) - the communication opportunity of a lifetime**

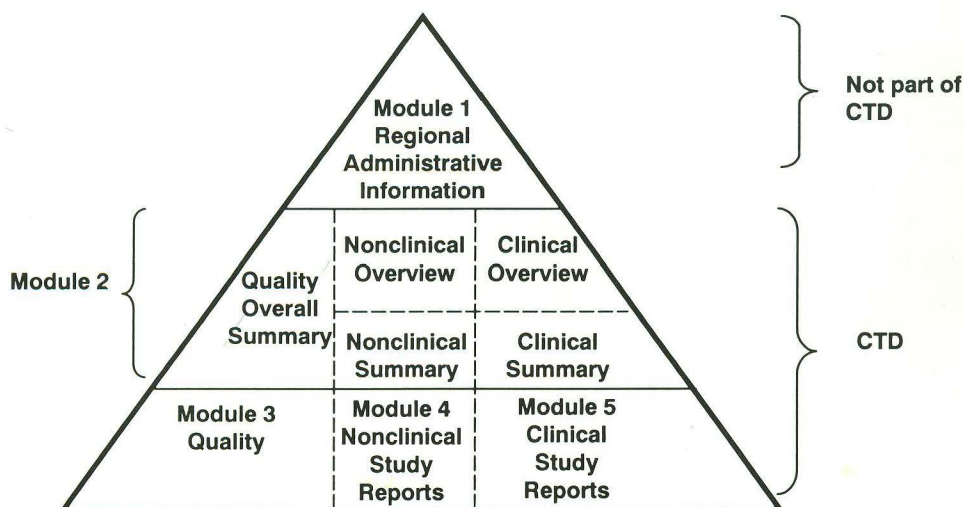
by Paul Gisby

The Common Technical Document (CTD) is the latest multi-disciplinary initiative to come out of the International Conference on Harmonisation (ICH). It represents an effort to "harmonize the format and content of the technical data in the areas of Quality, Safety and Efficacy". Step 5, the implementation of the guidelines at a regional level, is due to be completed soon, and from July 2001, CTD will start to become the new way in which we submit applications across the world.

I will outline the contents of the Efficacy section of the CTD guidelines (CTD-E). Rather confusingly this covers the clinical efficacy and clinical safety data submitted in support of the application. The so-called Safety section actually contains the pre-clinical data and the Quality section the chemistry, manufacturing and control data. I shall also describe why I believe that CTD presents a superb opportunity for medical communicators worldwide

### **Structure**

The overall organisation of the CTD and its position within a submission dossier is shown in the pyramid below. Module I is where regional administrative information, including the draft label/prescribing information, is placed. This part of the dossier has not been harmonised and does not form part of the CTD. Module II has two levels; IIA contains overview documents, and IIB and IIC the non-clinical and clinical written summaries. These documents are equivalent to the so-called summary or high-level documents currently required as part of NDAs, MAAs and JNDAs (e.g., Integrated Summary of Efficacy, Expert Report and Gaiyo). It is proposed that the Clinical Overview and Clinical Summary will replace most of the current high-level clinical documents in applications in the US, Europe and Japan.





#### **Clinical Overview**

The Clinical Overview will be a critical overview of the clinical programme. It builds upon much of the thinking currently contained with the European Clinical Expert Report (CER). It is a relatively short document of approximately 30 pages, and although it will necessarily refer to data provided in other sections of the CTD, it will primarily present the conclusions and implications of those data, without repeating them at length.

The main headings are :

- Product Development Rationale
- Overview of Biopharmaceutics
- Overview of Clinical Pharmacology
- Overview of Efficacy
- Overview of Safety
- Benefits and Risks

Just as with the CER, the Clinical Overview is intended to be a concise analysis of information pertinent to the clinical use of the medicinal product, including references to relevant information from the Quality and Safety sections of the CTD. It should present the strengths and limitations of the development programme and study results, analyse the benefits and risks of the medicinal product in its intended use, and describe how the study results support critical parts of the prescribing information.

#### **Clinical Summary**

The Clinical Written Summary will consist of 5 main sections, each themselves summaries of specific aspects of the clinical programme :

- Summary of Biopharmaceutics and Associated Analytical Methods
- Summary of Clinical Pharmacology Studies
- Summary of Clinical Efficacy
- Summary of Clinical Safety
- Synopses of Individual Studies

The first three of the above will provide factual summaries of the trials conducted within each category. Where appropriate, data will also be summarised across studies. The guideline specifically directs that any critical analysis of data should be placed in the Clinical Overview. For each separate indication, an individual Summary of Clinical Efficacy will be required. The Summary of Clinical Safety will summarise relevant safety data in the intended patient population, integrating the results from individual study reports and other relevant reports. The last part of the Clinical Summary document will contain the synopses of individual studies, copied over from the study reports themselves. Interestingly the CTD-E guidelines remark that a study synopsis should generally be of 3 pages in length, but that for complex, important studies this may rise to up to 10 pages. Overall, the guidelines estimate that the Clinical Summary (not including attached tables) will be between 50 and 400 pages in length.

#### **Application of the guidance**

An important feature of the proposed CTD-E guidelines is that they provide guidance, not rules. As Dr Jennifer Jackson, the Topic Leader for the ICH Expert Working Group that produced the guidelines emphasised at the ICH meeting in November last year, this is not a cookbook to be followed slavishly. In applying the guidance and preparing dossiers in CTD-E format, applicants will need to think carefully about how to construct their documents to best present the story of their drug. There are major headings that will be used as the skeleton for the documents, and this organisation will



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### ***Common Technical Document***

be important for regulatory reviewers needing to know where to find the information that they need. However, much of the guidance for the major sections is in the form of bulleted lists of points to be considered, and the table formats provided are illustrative examples, not mandatory prototypes. The message is clear; guidance not rules, examples not templates.

#### **Implementation**

The regulatory authorities in the US, Europe and Japan, have been working on interpreting the guidelines within the context of their own regulatory environment. A key aspect of implementation will be how well authorities believe that CTD can meet their needs and in particular what extra documentation will be required for individual territories. The guidelines for Efficacy, are written to meet as many of the current requirements of FDA, MHLW and the European authorities as possible. It is hoped that much of the CTD-E will replace high-level clinical documentation within the NDA, MAA and JNDA. However, it is apparent that some territory-specific documents will still be required, probably the most significant being the Integrated Summary of Safety, that the FDA have already said will be required for most applications.

#### **Timetable**

At the ICH Steering Committee meeting in Tokyo, it was confirmed that "voluntary applications" in CTD format will be accepted in all 3 major regions. It was also agreed that July 2003 would be the date when CTD would be mandatory in Europe and Japan and "expected" by FDA. It is likely that most non-ICH territories will adopt a similar timetable. All 3 regions will soon be issuing detailed guidance on the introduction of CTD, including clarification on scope (OTC and generics look like being included in Europe and USA, but not in Japan). It appears also that CTD will be used for supplementary applications, but extant data and documents will not need to be re-formatted.

#### **Opportunity**

So why do I think that CTD is an opportunity for medical communicators? Three reasons. Firstly there are going to be an awful lot of people unnerved by the change in format, and these people are going to want advice on which documents are needed and which are now redundant. Who better to give this advice than us? Secondly, to gain full advantage from the CTD approach requires true global co-operation and communication. Of all the skill types we have in drug development, no-one is better placed to make this work than medical communicators. Thirdly, the way the Efficacy guidelines are written specifically avoids providing a template for the Overview and the Summary. There are major headings, and lists of points "to be considered", but beyond that the emphasis is on applicants deciding on how to present their data to optimally communicate the points addressed by that data. If ever there was a charter for medical communicators, this is it!

For a look at the guidelines themselves, go to the ICH website at [www.ifpma.org/ich5c.html](http://www.ifpma.org/ich5c.html)

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## What the Regulatory Authorities Want to See

by Eva Pike

Since this is the first time I'm writing in TWS, I would like to take the opportunity to introduce myself: I am Norwegian and have worked for the last 3 years as a consultant. My main customer was and still is the Norwegian Medicines Agency, where I evaluated and approved Summaries of Product Characteristics (SPCs), Patient Information Leaflets (PILs), Type II changes, and notifications for clinical trials. Earlier in my career, I was employed by the agency as the Head of the Section for Clinical Trials where I also had the responsibility for evaluating the clinical submission dossiers for marketing approval. I was educated as a pharmacist in Edinburgh, and I have a PhD in pharmacology from Oslo. In the 6 years before I started as a consultant, I worked as the Medical Manager for Eli Lilly Norway AS. Now I want to spend more time as a medical writer. During the last 2 years, I have written clinical reports and articles for various sponsors.

My aim in this article is to share with you some of the thoughts and expectations of regulatory authorities when evaluating submissions. For all types of submissions, I assume that readers are familiar with the respective rules, directives and guidelines. If you want your submission to move smoothly through the approval process, you should always do the following:

- Read the latest rules, directives, and guidelines and **use** them!
- Do not trust that the ones you got from the sponsor are the most current.
- Make your submission neat, clear and easy to read and understand.
- Do not hide or avoid negative results.

### Expert Reports (ERs)

The guidance on how to prepare an ER is given in the latest edition of the Notice to Applicants [1]. This guidance contains a very important sentence: "It is important to emphasise that well prepared Expert Reports greatly facilitate the task of the competent authority in evaluating the dossier and contribute towards the speedy processing of applications. For these reasons particular care should be taken in the preparation of Expert Reports, following the guidance on the preparation of Expert Reports given in this volume."

Working for the authority makes you realise how true this is. High quality, easy to read and understand, and well-prepared ERs written in the form and with the standard formats described in the Notice to Applicants will not only hasten the review process, but will also help to get the reviewer in a better mood! The writing of an ER may seem to be a small bit of work compared to the many years of clinical development, but it cannot be stressed too heavily how important their writing is

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***Amazingly, most of the problems in submissions I've seen are because the writers did not check the latest guidelines and templates and use them***

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### *What the Regulatory Authorities Want to See*

for the actual approval process. And as we all know, any steps which can reduce the **time to market** are worth gold for the pharmaceutical industry.

Some of the most common weaknesses of ERs include:

- the ER isn't signed by the expert,
- there is no **critical** assessment of the methodology, results and conclusions,
- deviations from the relevant EU guidelines on the conduct of trials on a medicinal product were not discussed and justified,
- references to specific studies did not include precise volume and page references for where to find the study in the full dossier,
- the ER was too long (the Clinical ER is limited to 25 pages),
- the standard tabular formats [1] were not used (there are formats for the presentation of the documentation in tabular form and for the tabular overview of the Written Summary),
- negative results were not openly discussed with suggested explanations, etc. Weaknesses in the data, will usually be found by the reviewer, and this leads them to search for an explanation, resulting in a very negative impression.

Some practical advice for writing Clinical ERs:

- Discuss the medicinal product, the indication and dosage as well as the risk/benefit ratio with regard to clinical practice and currently available treatments. Do not forget to stress the contribution of the new product.
- The tabular overview presentation of all clinical trials should be given using the standard format [1]. The studies should be successively presented starting with controlled trials (divided between placebo and reference therapy), followed by non-controlled studies. The number of trials showing a positive and negative result should be indicated and accompanied by appropriate explanations in the text.
- The most important and significant studies should be summarised **individually** in tabular format with special emphasis on the assessment of trials with unequivocal evidence of efficacy. There is also a standard format for this presentation which differs from the tabular overview format.
- Provide a justification for the dosage recommendations. Typically the authorities ask whether the lowest possible effective dose has been found. Justify why the selected dosage regimens were used in the dose-finding studies, and give the rationale for selecting the actual dose(s) in the comparative studies and the dosage recommendation(s) in the SPC. The dose regimen should be justified and defined for each indication and in the different subgroups of patients. If the treatment could be improved through plasma concentration monitoring, you must remember to include documentation for an optimal therapeutic plasma range.
- Comment on any differences between man and the animal species used in the pre-clinical documentation.

#### **Summary of Product Characteristics (SPC)**

In accordance with Article 4a of Directive 65/65/EEC, as amended by Directive 83/570/EEC, a proposal for an SPC must be included in the marketing application. Part 1B in Volume 2 B(1) of the Notice to Applicants gives the proposal for the SPC. Further, Article 4b of Directive 65/65/EEC requires that the content must be approved by the competent authority. Thus the SPC forms an intrinsic and integral part of the marketing authorisation.



The main problem sections for the authorities are as follows:

- Use the standard headings provided.
- *Section 4.3, Contraindications*: Include only absolute contraindications.
- *Section 4.6, Pregnancy and lactation* and *Section 4.7, Effects on the ability to drive and use machines*: These sections often are not written clearly. Use examples of wording for these sections as given in Annex 1 of the guideline.
- *Section 4.8, Undesirable effects*: This section is in many cases not in agreement with the guideline. The adverse drug reactions should be presented in a table according to a standard system for organ classes such as MedDRA with the system organ classes presented in the order given in Annex 2 in the guideline [2]. Within each system organ class, the adverse drug reactions should be ranked by frequency, with the most frequent reactions first, using the convention given in the guideline. This section is the one which, in my experience, seems to most often get negative comments from the regulatory authorities.
- *Section 5.3, Preclinical safety data*: This section is often incomplete. Available data according to the explanation given in the guideline should be included.

#### **Patient Information Leaflet (PIL)**

The format to be used and a guideline for the readability of the PIL are described in: "A guideline on the readability of the label and package leaflet of medicinal products for human use [3]. Again, most problems could have been avoided by reading this guideline carefully before you start writing. Points to remember:

- Language should be phrased so that it is readily understandable for patients. Examples are given in Annex 1a of the guideline. Use an active and direct style, by placing the verb at the beginning of the sentence.
- The content of the text must agree with the SPC.
- "Possible side effects" is a section which could have been improved in most of the PILs I have evaluated. All side effects listed in the SPC should be included and grouped according to their seriousness. Remember, if the consumer needs to seek help urgently, use the term "*immediately*", whereas for less urgent conditions use the phrase "*as soon as possible*".

Most of these problems can be solved by following my general advice: check the latest rules, directives, guidelines, and templates and *use* them. Then make a submission which is neat, clear and easy to read and understand without hiding results. This should result in a smoother and faster evaluation and, with a good drug, approval.

#### **References:**

1. European Commission: Notice to Applicants, Volume 2B: Presentation and Content of the Dossier, Part 1C Expert Reports, 1998.
2. European Commission: Notice to Applicants, Volume 2C: A Guideline on Summary of Product Characteristics, Dec 1999.
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## **Medical Writing Questions and Answers: Size Matters**

**by Chris Priestley**

*Dear TWS Experts,*

*Recently we had some trouble with large MS Word documents, especially reports. These documents had a large number of tables and were heavy formatted in a way that they become unstable: headings change their numbering, changes are not accepted, table numbering goes haywire etc. We are now also implementing a document management system (Documentum) with a view to submit electronically. What system does your company use for those large complicated documents or do you chop large documents up and keep the tables apart?*

Over the past 15 years, I have seen a great increase in the size of regulatory clinical documents in the pharmaceutical industry. Nowadays, some protocols can be 100 pages long. Study reports are sometimes many thousands of pages long. You would need a lorry to transport the hard-copy version of some submission dossiers.

In the past, within our department, the medical writer was responsible for finalising study reports. The process involved many manual steps. The final official version of the study report was the paper copy. Some parts were available electronically, some only as photocopies or printouts. The report was provided to the authorities only on paper. Compilation of submission dossiers was a labour-intensive activity, including many separate documents.

Despite moves to automate table generation, the increase in document size over time has meant that the creation of many documents can no longer be efficiently managed in the paper environment. The use of electronic document management and publishing software is becoming more and more common. Such systems can help us in our fight against the constant growth in size of regulatory dossiers. They make it relatively easy to combine different types of file, including Microsoft Word, Excel, TIFF and SAS output files, with the final output as a PDF file. This is particularly useful when your tables are programmed SAS output. In addition, such systems provide a means of creating the cross-references and hyperlinks between documents that are becoming more and more a desired characteristic of large electronic documents. They can thus benefit both the user and the creator.

But are they the answer for all documents? I often see a tendency to break down documents into smaller documents, so that the individual parts can be worked on in parallel by different authors. Afterwards, the documents are then published, i.e. attached to an outline in the publishing system and "reborn" as the complete document in PDF format. This can be a useful exercise if the complete document is, for example, more than 100-150 pages in length. It seems to be also especially useful if the file would otherwise exceed a certain size (e.g. 2 megabytes). Such files will increasingly



tax your computer's memory, and – at least sometimes – appear to develop a life of their own and become prone to crash your computer.

There are many documents that are unlikely to fall into this category, however. Many simple study protocols, investigator brochures, clinical expert reports, and briefing documents for regulatory authorities, to name but a few. Such documents are probably best managed as single files, both from the creator's point of view and for ease of use by other people destined to be the recipients of our documents.

For there is a down-side to splitting up your Word files into smaller "sectional" files. For example, you cannot use Microsoft Word's cross-reference facility to automate your literature references. Indeed, this applies to cross-references in general. Similarly, autonumbering of section headings can only be used within an individual Word file. Splitting your document up into separate files also means you have to take more time and care about pagination. Usually, the table of contents has to be created using a publishing system. And let's face it: the more complex you make your documents, the more likely it is that other people may not be able to understand what you have done. How do you send your document to a reader or reviewer if it is made up of many separate files? How do they send you back their comments?

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***Let's face it: the more complex you make your documents, the more likely it is that other people may not be able to understand what you have done***

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Finally, if that weren't enough, let's not forget the important task of ensuring that the content of a document is consistent and coherent.

Someone (usually the medical writer) has to coordinate this activity. The larger the document, the more difficult this task is, and it is aggravated by having to search for the information in separate files.

Using a publishing tool enables you to reconstruct the complete document, but the publishing step itself requires time and effort. Not least, someone has to do that work, and someone (you?) has to make sure that your separate files are actually placed in the correct order so that your document can be published. Keeping information in separate files can provide flexibility with regard to order and re-use, e.g. in various locations in a dossier or even in different dossiers. But this is probably most relevant to information in tabular format. Text, unfortunately, is less amenable to recycling.

The management of large documents has become a major part of our work as medical writers. Document management and publishing systems are an aid to this work, but do not solve all the difficulties for us. While they offer powerful solutions for big clinical study reports and regulatory dossiers, small to medium-size documents can probably still be more simply managed using the day-to-day functionality of Microsoft Word and similar word-processing programs.

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### In the Spotlight...

**Michelle Hughes**  
Medical Writer  
Sanofi-Synthelabo  
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*Meet Michelle Hughes. Michelle has been a medical writer at a pharmaceutical company for the last 3 years. As a British national whose native language is English, she works in France and speaks fluent French. She has a languages background, and got started in medical writing after taking a course on technical writing in France, after which she was hired by a CRO that was willing to show her the ropes.*

**What qualities do you think a medical writer must/should have?** I think patience is important, because preparing a clinical study report is never really straightforward; there is quite a lot of "rethinking" and that can be a bit frustrating. I think you also have to be rather "thick-skinned" as well, as there is inevitably some criticism of the draft, and it doesn't help to take it too personally.

**What keeps you doing medical writing?** I like the variety of tasks and people, and the satisfaction of seeing a report through from beginning to end.

**What was your worst mistake as a writer and what did you learn from it?** I once misread some data, and confused the number of survivors with the number of deceased, which made for quite shocking reading.

**In your opinion, what do you like least and most about medical writing as a profession?** I like the autonomy of the job and the mix of technical and language skills. I don't like sending out what I hope are nearly-finished drafts and getting feedback that necessitates practically rewriting the report.

**If you could change one thing in your job as a medical writer, what would it be?** I'd like to have the luxury of more time to read around the subject and to learn more about the products and indications I'm writing about.

**Do you consider yourself foremost a writer or a scientist, and why?** I have a language background, so I consider myself to be more of a writer.

**What would you recommend to someone who is thinking of becoming a medical writer?** That's a difficult question. So much would depend on what kind of background the person already had. I tend to tell people that it's a worthwhile job, and I would encourage anyone interested to persevere.

**What was the funniest/oddest/most interesting job you ever did?** When I was a student I briefly worked for a market research company. My job entailed repeatedly watching a video of a major motorway junction and counting the number of cars and lorries that went along every single road. After 8 hours a day of clicking a counter at a screen, it is no exaggeration to say that I was approaching hysteria.



**What do you consider your greatest achievement?** I think a true achievement is something that remains behind after you die, and I really don't think of my life in those terms; I don't think I'm ambitious enough.

**What are your hobbies?** If inviting people over for cups of tea is a hobby, then that's probably one of mine. Living in Paris means I have visitors all year round, so they are in fact my biggest hobby. Otherwise I'm pretty keen on making giant-size soft toys for unsuspecting nephews and nieces (I don't seem to be able to do anything normal-size; probably the side effect of too many hours spent looking at the computer screen).

**Who are some of your favourite authors and why?** Dostoevsky springs to mind - I studied Crime and Punishment as a student, and I've rarely been so gripped by the suspense of a book. I just finished reading Pierre Loti's novel about the Icelandic fisherman and that was wonderfully melancholic.

**What magazines/newspapers do you regularly read?**

The Sunday Times, to catch up on what's going on in England in one fell swoop. And the National Geographic, for the pictures.

**What are you writing when you aren't medical writing?**

Letters to the "folks back home" and friends.

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***I'd like to have the luxury of more time to read around the subject, to learn more about the products and indications I'm writing about.***

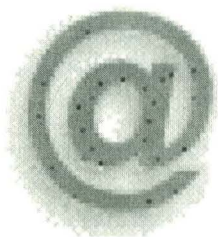
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### ***From Russia with Love***

***"We have read your article 'Alternative Medicine in Germany' by Anna Kassnel. Perhaps she would be willing to be of assistance in answering some questions we have."***

***Ivan Gesse  
Institute of Eniology and Social Research  
St.Petersburg Russia***





## Networking: the Webscout

by Amanda Bennett

My first Networking column featured the realm of search engines. It is time for an update. Google has long since linked up with Yahoo but continues to provide a clutter-free, yet engaging search interface embroidered by topical graphics (Sydney Olympics kangaroos, St Patrick's Day leprechauns etc). We are now living in a world of information overload. More and more we need help to find information which is genuinely relevant and useful.

One site that attempts to do this is **www.northernlight.com** – this site classifies documents by topic and assigns them to custom folders based on each individual search. You can use Northern Light in a much more context-specific way than most search engines. It has a dizzyingly extensive database with 200 million items and growing!

It is a good idea to keep in touch with the latest developments in search engine technology. Two sites that will help you do this are: **www.searchenginewatch.com** and **www.zdnet.com/searchiq**.

**www.mwsearch.com** – This website provides tools to search across the highest quality medical sites on the Web, linking to a medical terminology thesaurus. It has three components: the Web crawler, the indexer, and the query processor. MWS has a database of over 500,000 medical terms including relationships between these terms, such as synonyms, more specific or more general terms, and definitions.

TLC Information Services has announced that it has entered a partnership programme with ICARE4Learning.com to jointly market the online authoring, teaching and learning system (I-CARE) for the CME (Continuing Medical Education) market. The I-CARE system is a comprehensive Internet-based teaching and learning system (**www.icare4learning.com**) equipped with a user-friendly authoring tool as well as an exam tool. A demo system of I-CARE has been posted on the MWSearch website.

On a more general level, when Encyclopaedia Britannica recently made its 32-volume set freely available online, at **www.britannica.com**, it received so many visitors that the site became temporarily inaccessible! The bare fact that this amount of content is now freely available shows how the Internet is changing the business model of the publishing world.

Three sites which although still in their infancy might be worth keeping an eye on are:

**www.emedicine.com** - emedicine features up-to-date, searchable, peer-reviewed, free online medical textbooks in medicine, surgery, paediatrics, ophthalmology etc.

**www.medicalpages.co.uk** - Medical Pages is the first UK Health Portal developed and supported by nationally accredited medical specialists. Over the next few months it is going to rapidly expand, with many health-related and other services. Hit the



### ***Networking: the Webscout***

"entrance for health professionals" button to find websites written by medical specialists, links to MEDLINE, the latest health headlines, etc.

**www.wame.org** - The World Association of Medical Editors (WAME) was launched six years ago to improve standards of editing in medical journals worldwide (see description in *Newsflash*, on page 31).

For help with more specific medical information, try these sites:

**community-1.webtv.net/lany25/CommonMedicalTests** - This page lists normal ranges for some of the more common blood and urinary diagnostic studies.

**healthweb.org/index.cfm** - HealthWeb is a collaborative project of health sciences libraries.

**www.eicd.com/eicdmain.htm** - An online version of the International Classification of Diseases with clinical modifications. The ICD-9-CM was developed by the National Center for Health Statistics for use in the United States. It is based on the WHO International ICD-9.

And finally, since we are writers, some good sites dealing with written English:

**www.phon.ucl.ac.uk/home/dick/enc-gen.htm** - An Encyclopaedia of English Grammar and Word Grammar by Richard Hudson. This encyclopaedia is freely available for consulting or downloading from the Net (WordPerfect or MS-Word). All the downloadable versions are in **hypertext** form, so that you can move around the document by clicking on cross-links (in addition, of course, to being able to print them).

Lexicographers amongst you will find diversion at **www.wordsmith.org**; there is an addition to the debate on how the Internet is changing the universality of language at **news.bbc.co.uk/hi/english/uk/newsid\_1235000/1235945.stm**; and for a real writing challenge, see how to create a masterpiece in miniature at the Guardian text message poetry competition site (winners will be mentioned in TWS):  
**www.guardian.co.uk/Archive/Article/0,4273,4161923,00.html**)

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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