European Medical Writers Association

The Write Stuff

The Journal for European Medical Writers

Vol. 15, No. 3, 2006

Behind the Net

Journal insights

The *Write Stuff* is the official publication of the European Medical Writers Association. It is issued 4 times a year and aims to provide EMWA members with relevant, informative and interesting articles and news addressing issues relating to the broad arena of medical writing. We are open to contributions from anyone whose ideas can complement these aims.

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

Subscriptions

Subscriptions are included in EMWA membership fees. By writing to info@emwa.org non-members can subscribe at an annual rate of:

– €35 within Europe
– €50 outside Europe

Instructions for contributors

– The *Write Stuff* typically publishes articles of 700–2800 words although longer pieces or those with tables or graphics will be considered.
– All articles are subject to editing and revision by the Editorial Board. Any changes will be discussed with the author before publication.
– Submissions should include the full address of the author, including the telephone and fax numbers and email address. Suitable quotes for side boxes can be indicated or they can be selected by the Editorial Board.
– Material should be submitted by email as an MS Word file using Times New Roman (or equivalent), 10 point size, and single spacing.
– Published articles generally include a recent photograph of the author (portrait picture, CV or passport style, min. 930 x 1290 pixels).

Back issues

Subject to availability, previous issues of The *Write Stuff* can be obtained for the cost of mailing by contacting the EMWA Head Office (see below).

Advertising rates (in euros, €)

Corporate		**Private** / Freelance members only	
– Full page	**€1000**	– Full page	**€200**
– Half page	**€500**	– Half page	**€100**

Behind the press

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Cover picture

Photograph from the "Reflection of Memory" cycle, a collection from Antonio Živkovič.

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European Medical Writers Association

EMWA 8th Autumn Meeting

16-18 November 2006, Brussels

The Executive Committee has the pleasure of inviting you to the 8th autumn meeting to be held in Brussels. The meeting will be held from 16 to 18 November 2006 at the Courtyard by Marriott Hotel.

Brussels is more than 1000 years old. Today, as the European capital, the city is home to the European Commission and to the Council of Ministers of the European Union. Brussels is also the bilingual capital of Belgium. This means that both French and Dutch are the official languages of the city. So beware, as street names and traffic signs are always in two languages, which can sometimes cause confusion. Furthermore, it is a cosmopolitan city where many different cultures live together and where different languages can be heard on every street. This liveliness and international flair is, of course, intimately related to its role as a crossroads for all of Europe.

The workshop programme will cover a wide range of medical writing subjects and will also include advanced workshops for experienced writers looking to keep their knowledge up-to-date or refresh their skills. Further details are available on www.emwa.org/ConfAut06/Introduction.html

Looking forward to seeing you there!

Michelle Derbyshire
EMWA President

Times are changing, photos are staying

The cover photograph was taken by Antonio Živkovič. His work has been selec-ted by the Slovenian Ministry for the Culture for special support. In the course of researching for his next exhibition, which will feature mining, he found another photograph of the same tower taken by an anonymous photographer almost 50 years ago. This photograph, from the archive of the Trbovlje-Hrastnik Mining Company, is reproduced here with the company's kind permission. To quote Antonio "Times are changing, photos are staying".

From the editor's desk:

Behind the Net: Do we know who stands behind the word?

By Elise Langdon-Neuner

"Are you going to write about it?" asked my 20-year-old male companion, unaware that I was a medical writer or ever had any inclination to put pen to paper. I had become separated from my trekking group and was sitting in a shepherd's hut cut into a steep mountainside in Hunza, Northern Pakistan. The hut was dominated by his aunt, who stoked a fire under a large pot from which she dished out stew to members of the family between plying me with chai and yoghurt. My companion, a university student who was earning money as a porter in his vacation, wanted information about me. What was my mission in coming to Pakistan? Up to this point I had not thought about summer holidays in terms of missions, but perhaps this one was becoming a mission—about information. How old was I? Clearly, at the same age as his mother, I was old. With a life expectancy of 60 years, she was in her final third. What was my religion? This is a difficult one to answer. The guidebooks say it is best to be anything, rather than admitting to being nothing. I evaded. No matter, my Ismaili Muslim companion had no doubt that respect and humanity, not religion, were what was really important. These frank questions might not have been those with which I would have initiated a conversation with a new member at an EMWA conference. But maybe such questions seek out more essential facts than "How was the weather when you left home this morning?"

My companion had not yet finished what he wanted to say because he was keen for me to take back a message to my country. He had never been outside Pakistan but he knew only too well the image of his country painted by Western media. A couple of days before, extremist terrorists had been arrested at Heathrow and in Islamabad. "We want peace," he said. "This can only be achieved through tolerance and co-operation between all peoples of the world. Will you tell that to people in Europe when you go back?" I returned home to Austria, to a country plastered with election placards. One in particular caught my eye. It read 'Peaceful retirement or millions of asylum immigrants?', offering voters peace from worrying about the injustice, torture, illness and death suffered by others.

I realised that only a small part of our opinions, feelings, and ultimately our actions are influenced by information we gain from a firsthand source. We are bombarded with information from an ever-expanding variety of faceless channels. Possibilities for communicating information have expanded and evolved in parallel with mankind's evolution. Language was the first powerful tool to facilitate mankind's elevation above creatures that rely on the genetic code to convey information from generation to generation. Writing then introduced distance to communication. Telegraph, radio and television continued the process, effortlessly breaching new frontiers. This issue of *TWS* is about a new entrant to the field of communication. One that is bringing a gigantic explosion of information and becoming the most influential source of knowledge this earth has ever seen—the Internet. The wide availability of so much information that can penetrate every nook and cranny on the earth's surface has tremendous potential for educating the world in rationality and for pooling resources to make it a better place for us all. But its anonymity makes it vulnerable to unprecedented possibilities for corrupting information. *TWS*'s cover picture represents a world 'behind a fence'. It is a graphic depiction of what a world that relies on information from behind the Net might mean. The remote tower is caged by a wire fence. We cannot see inside the tower, do not know who might be in there, what they are doing and what agenda they might be following. The land around the tower is barren, devoid of life and inquiry. How often do we question the reliability of processed information that we receive secondhand, and its influence on the inner sanctum of our mind? Do we question whether it might be biased or be downright untrue? To what extent do we use and manipulate others—people we have never met and spoken to face-to-face? And to what extent are we being used and manipulated ourselves?

Information is the very essence of medical writing. As medical writers we extract oral and written information, interpret it and reformulate it for decision-makers such as licensing authorities and health authorities, and for individuals through the media. It is an onerous responsibility, especially if those authorities and others are living in a bar-

ren environment in which they do not ask the questions that seek out the essential facts. Although ours is only a minutely small part of the overwhelming mass of all the world's information, it is not to be underestimated in its importance. Sooner or later every human will be confronted with some aspect of physical or mental misfortune, be it ill health, or physical or mental trauma. At this point bodily and mental well-being will surpass all other aspects of life in its significance for that person. Do we care about this individual person? He or she will rely on the integrity and the inquiring intellect of a good medical writer. Honest and accurate communication about physical and mental health and medicine is no trivial part of the respect and humanity, which my companion in a remote shepherd's hut reminded me are the things that really matter.

In this issue of *TWS*

This issue of *TWS* is packed with articles which in one way or another are about the Internet. The articles are to help medical writers battle through the vast amount of information the Net provides using a selective and critical approach. Matt Cockerill's article dealing with how to seek out the most important research is a good start. 'In the book stores' features a book helpful for a medical writer in evaluating the methodological and editorial quality of health information. Unfortunately the book is only currently available in Italian. However, Karen Shashok reviews the book's website, which is partly in English and offers resources to steer a safer course in the perilous waters of contemporary biomedical research.

A topic of utmost importance to medical writers is the electronic Common Technical Document (eCTD). This standard instrument has been developed to transfer pharmaceutical regulatory information from industries to agencies electronically through the Internet. Stan van Belkum, from the Medicines Evaluation Board, kindly agreed to follow up the excellent presentation he gave at the EMWA meeting in Lyon with an article for *TWS*. His article is invaluable for medical writers working in or in association with the pharmaceutical industry. In it he traces the history of electronic submissions and describes the eCTD's specification, the current status of implementation in the EU and developments that are anticipated for the future.

Mary Ellen Keran's article on using language corpus data to guide usage is about how, when writing or editing text, the Internet can be used as a tool for finding versatile and quick solutions to language problems. Language data trawled from the Internet are more relevant for us as medical writers than that from any other source, she argues, because the subtle usage differences between disciplines are grasped more efficiently. Mary Ellen's article guides us in the linguistic approach as well as the practical aspects of how to set up our own corpus of specialist words using the Internet.

There are possibilities of course for turning the Internet to you own advantage, as a freelancer for instance for advertising services. Jeremy Grierson in his article, 'A website of my own', provides useful tips on starting your own website. He was inspired to write the article after attending a workshop at an EMWA conference given by Shanida Nataraja, EMWA's website editor. Then there are blogs or online diaries. Ursula Schoenberg tells us in her article, 'Welcome to the blogsphere' that there are almost 30 million blogs in the Internet, with a new one being added every second. Their popularity is probably due to the easy with which they can be updated with information about new events as they happen. Microsoft has now even built automatic blogging tools into its Word 2007 version. Ursula suggests that blogs are a good way to keep up with friends scattered across the globe. A colleague lamented to me recently that since her son had left home for university she missed his evening-mealtime conversations about his daily life, but at least his photo-packed blog enables her to see what his new friends look like from. Ursula mentions some useful blogs for medical writers and Joeyn Flauaus gives an interesting selection of science blogs in her webscout column. For a sceptical approach to what is being undertaken in the name of science http://amr2you.blogspot.com could be added to the list or even www.improbable.com, which provides a scurrilous overview of the most ridiculous research being undertaken at the moment.

Finally Alistair Reeves warns against the perils of becoming dissociated from personal contact in 'Too much 'Google''. The Internet must not be viewed as the only source of information. One of the joys of membership of EMWA is that fellow members have firsthand information we can draw on.

Of course this issue of *TWS*, like all others, seeks to cover a broad spectrum of topics of interest to medical writers. As well as regular items, there is an article by Ian Metcalfe on grant writing. Inclusion of the article, which follows up on an article on the same subject published in the last issue of *TWS*, recognises the importance of this emerging area for medical writer involvement. Medical writers are not infrequently called upon to help write letters to the editors of medical journals. Richard Clark's article has some useful tips for writing to editors.

It is always a pleasure for EMWA to welcome medical writers from outside Europe. Both Peter Tobin and Jack Aslanian attended the EMWA conference in Lyon. In this issue of *TWS* Peter reports on medical writing in Australia and Jack gives an American medical writer's impression of an EMWA conference with a few words of reflection about the camaraderie, enthusiasm, inquisitiveness, and eagerness to learn shared by members of EMWA and AMWA.

Elise Langdon-Neuner
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Message from the President

by Michelle Derbyshire

The theme of this issue of *TWS* 'using the Internet' is something that is essential to me, as a freelancer. In fact I wouldn't be able to work without it. Remote working has definitely changed the way people carry out their work and the Internet definitely has a huge impact on us as writers being able to do our work remotely. For better or worse the Internet is here to stay and will only influence our lives more and more in the future.

The theme of the next spring conference 'communications' is another subject that is close to my heart, having just brought a 'mini me' into the world. It's amazing how these little aliens can communicate with you without using a single word! If only the rest of us were so adept? I guess it's fortunate for us that we're not; otherwise most of us would be out of a job. Communication is in fact the essence of what we, as writers, do for a living. Getting the point across clearly and concisely, whether it be in a press release, journal article or an FDA file, is our bread and butter. That's why our next spring conference is dedicated to this subject. Our new Vice President (Julia Forjanic Klapproth) is already getting to grips with the next spring conference, which is to be held in Vienna in 2007. Keep an eye on the website (www.emw.org) for further information. We again plan to include not just workshops, but extra offerings to tempt even the most experienced writer. There will be discussion forums, demonstrations and question time sessions along side the workshops. We, as the EC and the EPDC are constantly striving to offer more of what you as members want. While EMWA remains highly focussed on the training aspect of medical writing, as it is felt that this is the foundation of good writing, we also hope to expand on this and be able to increase what we offer to experienced writers. This is where your input is required. Don't hold back—we don't bite!! Please feel free to contact either myself (president@emwa.org) or one of the other EC members. Your comments and suggestions are always welcome and in fact are essential to the growth of the organisation.

Don't forget to register now for the Autumn Meeting which will be held in Brussels on the 16-18th November. Places are already filling fast, so there's no time to delay if you want to get your workshops of choice.

Hope to see you in November in Brussels.

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TWS has to be the journal for you

In the past eighteen months *The Write Stuff* (*TWS*) has introduced full colour (June 2005), and had a design makeover (March 2006). The average number of pages has increased from 32 in 2004 to what will be 36 in 2006, but with an even greater increase in content thanks to the new design. It's nice to have a journal that looks good, and the feedback from readers has been very encouraging. However, *TWS* wants to achieve more than just good looks.

The Write Stuff is the journal for European medical writers. It's a journal especially for you, a member or prospective member of EMWA. As your medical writing journal, it should

- Provide you with all you need and want to read about with a view to maintaining a high standard in your work,
- Fill in any gaps in your knowledge,
- Help you when you embark on new projects in your career,
- As you chose the job in the first place, give you topics to read about that stimulate your particular interests,
- Give you something to think about—whether the views expressed concur or conflict with your own,
- Provide a letters section to give you the chance to state your views,
- Tell you what's going on in EMWA and inform you of the opportunities the organisation is, or is planning, to provide for you,
- Keep you up to date with news and recent developments in your field of work and related fields,
- Last but not least, amuse you and give you something to chuckle over.

Your contributions, suggestions and critique are always welcome. Please address them to me at langdoe@baxter.com

Elise Langdon-Neuner

Identifying the most important research–is there more to life than Impact Factors?

By Matthew Cockerill

Citation-metrics have played an important role in identifying the best research ever since the pioneering work of Eugene Garfield in the 1960s.

Whereas standard bibliographic indexing services allow users to search for relevant works by keyword, a citation-tracking service differs in that it also includes the citation list of articles, and identifies which articles cite which other articles. This allows the most highly cited work on a given topic to be easily identified, which is useful because a highly-cited piece of work tends to be an important one. For this reason, the founders of Google cite Eugene Garfield's work on bibliometrics as a key inspiration for their 'PageRank' algorithm, which highlights those web pages that are most linked to (i.e. cited) by other web pages.

The problem with looking at the number of citations of a given article to get an idea of its importance, however, is that because of the timescale of the publication process, it takes a year or two following publication for citations to appear. In the fast moving world of research, this is often inadequate. For this reason, the most heavily used metrics based on citation information are not article metrics, but journal metrics that identify which journals have, on average, the most highly cited articles. Such journal metrics have come to play a hugely important, but controversial, role in the evaluation of research.

Developments in citation tracking services

Although the information provided by citation tracking services is immensely valuable, it has also traditionally been extremely expensive to compile. Manually entering the reference information for 50 citations per paper, for hundreds of thousands of papers, was a massive undertaking. As a result, for more than 30 years, the field of citation tracking has been dominated by the Institute for Scientific Information (ISI), founded by Eugene Garfield, and now owned by Thomson Corporation.

The Thomson-ISI "Impact Factor" journal citation metric has become a *de facto* standard, playing a critical role when authors select a publication outlet for their research. The perception (and sometimes the reality) is that evaluation by potential employers and funders will focus less on the research itself than on the quality of the journal in which it was published, and that Impact Factor ends up serving a proxy for the quality of the research [1].

As journals have moved online however, the situation has started to change. It is no longer necessary to manually key-in bibliographic citation data since in most cases publishers already have this data in digital form. This means it is now relatively simple to build a citation indexing service if you can persuade publishers to make their data available for indexing. As such indexing will tend to encourage citation of the work concerned, and will tend to bring more readers to the work, many publishers are willing to make their citation data available for indexing in this way.

Google has used this approach to create its free bibliograpic service, Google Scholar, which incorporates citation tracking. While the search functionality offered by Google Scholar is basic compared to the Thomson-ISI Web of Science service, it is nevertheless impressive for a free service. Several studies have found that Google Scholar's coverage is comparable to Thomson-ISI's in many areas [2]. The data in Google Scholar is not entered by human indexers, but is entirely harvested by computers from online journal web pages and data feeds. Google Scholar does not yet generate journal-metrics based on the data that it has compiled, but such metrics, analogous to the PageRank that Google calculates for web sites, would be of great interest if created.

Scopus, meanwhile, is a commercial service launched by Elsevier in late 2004 as an alternative to Web of Science, offering welcome competition for Thomson-ISI, which should help stimulate innovation. A useful example of such innovation is the Author ID feature that has recently been introduced by Scopus. The Author ID system aims to disambiguate multiple authors who have the same name, using sophisticated algorithms. This goes some way towards solving a problem that will be familiar to anyone who has ever tried to find all papers published by a particular author named Smith (or Yamamoto).

Online journal systems such as HighWire, Science Direct, PubMed Central and BioMed Central also offer basic facilities for navigating forwards and backwards through a web of citations, within the journals which are hosted within that particular system, and in some cases to other systems too, thanks to the CrossRef system.

CrossRef is a collaborative initiative between publishers, which focused initially on ensuring that the reference list of an article on one publisher's site could include links to the full text of the cited articles, even when those articles

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appeared on another publisher's site. Recently CrossRef has also encouraged publishers to deposit full reference list data. This then allows the cross-publisher linking system to be extended to 'forward linking' from earlier articles to the subsequent articles which have gone on to cite them.

Lastly, several non-commercial services such as CiteSeer and Citebase make use of material that is openly accessible on the web to provide a citation tracking service.

Alternatives to citation tracking services

For all the importance of citation tracking, however, it is not a full solution to the problem of identifying the most important papers.

As already mentioned, article-level citation information takes time to emerge, while journal-level citation information can misleadingly imply that all research in a given journal is of equal interest. There is therefore a need for other, better ways to highlight the most important articles as soon as possible following publication.

Online journals naturally suggest one obvious metric that can be used–the number of downloads that an article receives. Other things being equal, the more downloads an article receives, the more likely it is to be of broad interest. Many publishers, including BioMed Central, regularly make available 'most viewed' lists, to highlight hot articles.

BioMed Central has taken this approach one step further by introducing a 'highly accessed' logo which appears on any BioMed Central article that has received an unusually large number of accesses, considering its age and the journal in which it was published. Roughly 10% of articles receive such a 'highly accessed' logo, which remains permanently associated with the article so that the author can refer to it on their résumé.

Although download metrics are popular and useful, they should be treated with caution as they can be vulnerable to manipulation. BioMed Central devotes significant effort to ensure that robot accesses and other suspicious patterns of activity do not distort these measures.

While citation and download metrics attempt to provide an objective measure of an article's importance, subjective measures can also play just as important a role in highlighting key articles. Traditionally, the main way in which subjective evaluations of research publications would be conveyed would be through review literature, ranging from broad annual surveys of a field, to tightly focused mini-reviews. The problem with review articles, however, is that they generally appear months after the research concerned has been published, whereas readers really want to know about the very latest research.

Faculty of 1000 is an opinion-driven literature awareness service which attempts to solve this problem. The "Faculty Members" do not write full-blown reviews. Instead, they regularly contribute short, structured 'evaluations' of recent research articles that have caught their attention. The Faculty of 1000 website automatically aggregates many such evaluations, to create a literature awareness service which can rapidly identify important articles. As well as providing a numeric rating (the F1000 Factor), the system lets users see which faculty members have rated the article as of special interest, and why. A "Hidden Jewels" section of the website calls attention to articles which received high ratings from Faculty Members, despite having been published in relatively obscure journals.

Researchers doing it for themselves?

Faculty of 1000 depends on a set of experts within each field, whose reputation adds authority to their evaluations. Other, less regulated approaches are possible however. Recently there has been an explosion of activity in areas such as "social networking", and "user-generated content". Wikipedia is just one example that shows how a surprisingly high quality end result can be produced by taking advantage of network effects, and opening up systems to anyone motivated to contribute.

CiteULike and Connotea are two very similar sites which take this approach. Each site allows users to conveniently bookmark their favourite scholarly articles, and to "tag" those articles according to topic. In this way, these systems simply provide a convenient bibliographic record-keeping system, similar to software like EndNote. What is special about these sites, however, is that by default, the information about which user has tagged which article is shared with other users of the site. This creates a rich web of information that can be used to assist in navigating the literature. For example, users can see which articles in a given field have been tagged by the most users. They can also see which topics are hot by

Figure 1
CiteULike's popular tags

Identifying the most important research

reviewing the list of most highly-used tags (Figure 1). If you find that other users seem to have similar interests to you, you can even add them to a "watch list" so that if they tag an article, your attention is automatically called to it. These systems are still in their infancy, but they show a great deal of promise. By taking advantage of so-called "semantic web" technology, it may even be possible that one day, systems such as CiteULike might act not only as a personal filing system, but could also evolve to be a personal knowledge management system, with the ability to distil facts from many different papers and relate them to one another, seeking patterns of correlation or contradiction.

More immediate benefits are promised by approaches based on another modern web phenomenon – blogging. Postgenomic and Mixed States are two sites which serve the needs of biologists and physicists respectively. They each collate data from dozens of scientific web logs, and use the assembled data to identify research articles attracting the attention of scientifically inclined bloggers. The relevance and comprehensiveness of the information delivered by these sites is clearly dependent on the quality and quantity of the blogs on which they are based. However, with more and more scientists blogging, the usefulness of such services, especially for casual browsing, is only likely to increase.

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Special *TWS* subscription rates for MET members

The European Medical Writers Association (EMWA) has extended to The Mediterranean Editors and Translators (MET) members a special subscription rate of €30 for a year's subscription (4 issues) to *The Write Stuff*. To subscribe and for further information, please contact EMWA at info@emwa.org. You will need to provide your MET membership number.

Upcoming events of interest

International Communication—Promising Practices (METM 06)

27th – 28th October 2006, Barcelona, Spain

The 2nd meeting of the recently formed association Mediterranean Editors and Translators (METM) will include a mix of panel discussions, presentations, training workshops and plenary discussions targeted at editors, translators, linguists and oral communication coaches who work in the Euro-Mediterranean area.

Go to http://www.metmeetings.org/pagines/metm06.htm for more information.

EMWA Autumn conference

16th - 18th November 2006, Brussels, Belgium

Professional training on a broad spectrum of topics for medical communicators.

Go to http://www.emwa.org/ConfAut06/Introduction.html for more information.

Practical Solutions for Filing Variations 2006 (IIR)

29th - 30th November 2006, Hilton London Green Park, London,

Gain an in-depth understanding of the most up-to-date and successful regulatory strategies for filing compliant variations.

Go to
www.iir-events.com/IIR-conf/PTI/Default.aspx?EventSector=49
for more information.

Compiling eCTD Variations (a post-conference workshop to the above)

1st December 2006, Hilton London Green Park, London

SAVE! EMWA members receive up to £300 discount by booking before the 20th of September 2006. Quote VIP code: CQ5030ELTWS.

Registration of Pharmaceuticals in the EU 2006 (IIR)

11th - 14th December 2006, Corinthia Towers Hotel, Prague, Czech Republic

A practical course addressing current requirements for Marketing Authorisation applications in the modular CTD format. It will also review electronic submissions (eCTD).

SAVE! EMWA members receive a 10% discount by quoting: CQ5017EMWA.

Go to http://www.informa-ls.com/registrationeu/
for more information.

Electronic submissions: Past, present and future

By Stan van Belkum

The business case

Some ten to fifteen years ago, two trends became visible in the pharmaceutical regulatory world. First, the ever expanding rules, regulations, directives, laws, guidelines, etc. led to an enormous growth in the size of a regulatory dossier for a new human medicinal product. Dossiers for new chemical entities of more than 100,000 pages became common practice rather than the exception, and those for products derived from or with biotechnology were even larger. Secondly, the pharmaceutical industry was undergoing rapid consolidation, with mergers and acquisitions leading to the creation of truly global conglomerates. To quote just one of many examples: Glaxo acquired first the Wellcome Foundation, and soon thereafter SmithKline Beecham, forming the pharmaceutical giant GSK.

As a result of such developments, managing large numbers of enormous pharmaceutical dossiers globally became an almost impossible task. At the same time, the computer and computerized systems—databases, but also document management and tracking systems—found their way into day-to-day office life. So the two partners in regulation—industry and authorities—focussed their hope on the computer and electronic systems. Electronic regulatory submission became the buzzword or magical term that was going to solve many problems.

From a regulatory perspective, the business case was not only the review but also the facilitation of logistic and administrative procedures (no more endless corridors with pallets of paper), enhancement of agency transparency (both regulatory and financial), knowledge management, and last but not least the dissemination of information on medicinal products to healthcare professionals, patients and the general public. With regard to review, the main problem an electronic submission was intended to solve was life-cycle management. With a paper archive of regulatory information, it is obviously difficult to find the most up-to-date information. Finding the currently valid Summary of Product Characteristics or the most recently approved specifications of the finished product is a time-consuming and problematic task in the paper world. With an electronic dossier, this information should be just a click away. Another critical review issue is navigation within and between files: a clear benefit of electronic files is the ability to (hyper)link information. However, electronic dossiers with poor navigation (e.g. scanned pages only, with no bookmarking or hyperlinks) are worse than a paper-based file!

For the pharmaceutical companies, the main aspect of interest is to keep their business manageable at the global level while at the same time gaining time in the approval process for their pharmaceutical products.

Early initiatives

In the late 1980s and early 1990s, several national and international initiatives tried to set a standard for electronic submission of regulatory information. Examples are:

- MANSEV (Market Authorization by Network Submission and EValuation): an initiative of the European Commission and the national agencies of the UK and France
- DAMOS (Drug Application Methodology with Optical Storage): an initiative of the German authority and German pharmaceutical companies
- MERS (Multi-agency Electronic Regulatory Submissions): an international working group with members from the FDA, Health Canada and the national agencies of Sweden and the Netherlands
- SEDAMM (Soumission Electronique des Dossiers d'Authorisation de Mise sur le Marche): a French initiative
- IRF (International Reviewer Forum): a forum for actual users of electronic submissions

Despite their good intentions, none of these groups succeeded in developing a real solution. Each initiative favoured a specific standard, ranging from all PDF-based submissions, to TIFF-based solutions, to HTML and SGML structured information. As a consequence, regulatory agencies were confronted with many different systems for the submission of electronic regulatory information. Each of the systems had a learning curve for the reviewers, and sometimes even very specific software and hardware had to be used. Although some experience was gained, the anticipated benefits were not met, and basically the situation was more complex than in the old days with only paper submissions.

The breakthrough finally came about with the International Conference on Harmonisation (ICH). Within ICH, the Common Technical Document (CTD) was under development. The goal of the CTD was to harmonise the table of contents for pharmaceutical dossiers in the three regions involved: the US, Japan and Europe. Given the developments mentioned above and the problems encountered with electronic submissions, it seemed a logical idea to

charge one of the ICH Expert Working Groups, the M2 EWG, with the development of an exact electronic version of the CTD. This result would be a globally acceptable standard for the submission of electronic regulatory information. The work started at the end of the 1990s and led in September 2002 to the first international standard, the electronic CTD (eCTD) specification version 3.0.

The eCTD specification

The eCTD specification version 3.0 is a detailed description of the eCTD. However, it should be noted that the eCTD is an exchange standard. It only describes how regulatory information is transferred from a pharmaceutical company to a regulatory agency. It does not describe how an eCTD should be generated nor how an eCTD can be used in a regulatory agency. The heart of the specification is the so-called Document Type Definition (DTD) describing the table of contents of the CTD and adding meta—data to the files contained in the submissions in XML, eXtensible Mark-up Language. XML is considered the next—generation Internet meta-language, and its choice has been the subject of long and heated debate in the ICH M2 EWG.

An eCTD has four basic components:

- A directory structure which mainly contains PDF documents; the names of both the directories and the files are based on a standardized nomenclature.
- Two XML files: a so-called XML backbone for Modules 2 to 5 of the CTD and a regional XML backbone for Module 1
- An MD5 checksum[1] for the total submission
- A stylesheet allowing the eCTD to be read in a web browser

Details of the eCTD specification can be found on http://estri.ich.org/ and http://esubmission.emea.eu.int/tiges/index.html.

Current status of implementation of the eCTD in the EU

After the development of the eCTD specification, according to normal ICH working procedures, the standard had to be implemented in the three regions. This procedure is already quite complex in the EU for ordinary ICH guidelines, but for a technical standard like the eCTD, this was even more complicated. The specification not only had to pass the CHMP; it also had to be supplemented by the regional standard for the Module 1 and explained to the Member States. The refusal of the FDA to start implementation was a further complicating factor. The FDA needed additional pieces of information and re-started the discussion within ICH on the eCTD specification. This caused a considerable delay in the EU.

The main organisational structure to do the implementation work was fortunately already in place. Information and Communication Technology (ICT) projects at the European level were run through a Telematics Steering Committee (TSC) chaired by the Commission, controlled through a Telematics Management Committee and performed by so-called Telematics Implementation Groups (TIGs) in which all Member States are represented. In this case, the TIG on electronic submissions (TIGes) was responsible for the work. The TIGes established the necessary working relations with important partners that had to be part of this implementation. The Notice to Applicants (NtA) Group, Quality Review of Documents (QRD) group at the EMEA and several industry associations were and are part of this network.

The results of this cooperation between the different organisations over the last couple of years are quite impressive:

- The EU Module 1 Specification
- Electronic Application Form Specification
- Electronic Variation Application Form
- Guidelines on the eCTD and paper eCTD
- Question and Answer document
- Questionnaires on statistics on the eCTD

Although the implementation of the eCTD specification in the EU can be considered relatively successful, several important lessons have been learned:

Lesson 1: The development of a standard is one thing, but the actual software implementation is another.

At the time the eCTD specification version 3.0 was finalised, no software was available to either generate an eCTD or accept an eCTD. Basically the XML file had to be written by hand in XML editors and could only be read by simple stylesheets. This led to a slow acceptance by industry and regulators. The reason for the delay between finalisation of the specification and the development of dedicated software was the fact that vendors were involved only at a very late stage in the development. Now, however, there is a large choice of eCTD software[2] available. In general, the software provides the following functionality:

- Use of templates
- Drag and drop of files in a predefined directory structure
- Automated generation of the relevant XML files and MD5 checksums
- Validation of the output XML files
- Viewing of an eCTD, i.e. tables of contents per submission, cumulative views of the table of contents, document information, document pane, etc.

With the variety of software tools, a new problem arose. eCTDs generated with tool A could not be viewed with tool

1 An MD5 checksum is a hashcode of 32 characters and numbers allowing integrity checks if the eCTD is copied from the hard media to a different location. Not only the complete submission has a checksum, but also all the individual files have checksums that are part of the meta-data included in the XML backbone.

2 Software is available from ISI, Lorenz, Datafarm, IBM, Liquent, IAGB, Sendar-Menlha, GlobalSubmit, etc.: check their websites for more information.

>>>

B and vice versa. There was clearly a difference in interpretation of the specification. This led to the development of a list of validation criteria by the ICH M2 EWG that should solve future validation problems and stimulate the development of interoperable tools.

Lesson 2: Setting up the relevant working relations has taken too much time

The eCTD is an area where the interests of regulators and industry might have more in common than in other areas. Too much time has been lost by the regulators trying to solve all the implementation problems on their own, while many of the solutions were within the jurisdiction of the pharmaceutical industry or software vendors. Vendors in particular need to be involved at an early stage in the development of an electronic standard.

Lesson 3: Setting a clear business driver is critical

Although around the year 2005 all the basic components for successful introduction of the eCTD were available—specifications, software, cooperation—the eCTD did not fly. An overview of the number of eCTDs filed in the EU by the end of 2005 can be found in Table 1.

Table 1. Number of eCTDs filed in the EU by the end of 2005

Organisation	Number of eCTDs	Maximum life-cycles	Remarks
EMEA	46	Around 50	About 10% of the total applications to the EMEA are in eCTD format
All Member States	115	Around 50	Range per MS from 0 to 79 eCTDs
The Netherlands: – National – MRP CMS – CP	 32 1 46	 Around 40 Around 50	In 2006, already more than 50 eCTD submissions have been made to the Dutch agency.

CMS=Concerned Member State, CP=Centralised Procedure, MRP=Mutual Recognition Procedure, MS=Member State

From this table and the total number of submissions in the EU, the conclusion can be drawn that less than 1% of all submissions are in eCTD format. An initial analysis of this fact provided the following possible causes:

– Underestimation of the technological impact
– Underestimation of the business impact
– Unclear or weak business case for pharmaceutical companies
– No strong regulatory driver (i.e. providing regulators with eCTDs is not mandatory)

In particular the lack of a regulatory driver was often heard as an excuse from companies for not starting the internal development of streamlining business processing to focus on production of an eCTD. Clarity on the business driver was given by the Heads of Medicines Agencies (HMAs) in 2005. Their statement contained the following important points:

– The HMAs endorsed a target date of end of 2009 for implementation of eCTD submission without paper by all National Competent Authorities.
– The European Regulatory Network will, by the end of 2009, have the infrastructure and the processes in place to handle electronic submissions of eCTD for marketing authorisation applications without paper and to be able to make the best use of them.

At the same time, the HMAs made it very clear that this doesn't mean that eCTD submission would be mandatory in all states by that date. However, authorities and industry should not wait until this date to implement the eCTD. This approach allowed Member States and the EMEA to move to eCTD-only submissions at different speeds. There is some evidence of rapid adoption of the eCTD-only situation:

– In Belgium, electronic submission is mandatory with a high preference for the eCTD.
– The EMEA has set a target date of December 2006 for eCTD-only submissions.
– In the Netherlands, electronic submission will become mandatory at the end of 2006, and eCTD-only submission is targeted for 2007.
– Several other authorities are very active in this area (UK, Portugal and Ireland).

Future eCTD developments

Two developments are considered critical for the future success of the eCTD: further improvement and refinement of the current specification and continuous harmonised implementation of the standard.

eCTD specification beyond 2007

For the following reasons, the ICH process to develop message standards for the pharmaceutical world is currently being reviewed:

– More work is being brought to the ICH M2 EWG by other working groups (e.g. in the area of pharmacovigilance), and there are insufficient skills and manpower to keep up with the expectations.
– There are limitations in the scope of the ICH M2 remit, i.e. the limitation of participants to pharmaceutical industry and regulators, the limitation to the three ICH regions and Canada, and the limitation to human therapeutics.

This had led to consideration of several options for a future process, ranging from changing nothing to abolishing the M2 EWG and transferring the work fully to Standard Development Organisations (SDOs). SDOs like the International Organization for Standardization (ISO), the Comité Européen de Normalisation (CEN), and Health Level Seven (HL7) have come about mainly due to FDA recommendations within ICH. In their last meeting in June 2006 in Yokohama, the ICH Steering Committee charged the M2 EWG with exploring the possibility of the formation of one or more consortia between ICH and SDOs to develop message standards. The first consortium to be formed will be between ICH and ISO, CEN and HL7. The basic idea behind a consortium is the linking into regional law. As an example, any standard for the EU must be "CEN-approved".

The major consequence of this shift to SDOs will be that message specifications will then be developed in an open environment. Anyone with an interest in the standard can participate: industry associations, individual companies, regulators, software vendors, etc. One of the major advantages of this approach will be that software necessary for support in the implementation will be almost ready when the standard is finalised. Today, actual software development to support the practical implementation of a message standard will only occur after the finalisation of the standard. Any draft specification poses too big a risk for software vendors in terms of major changes in the finalisation of the standard.

There are certainly risks as well. As an open arena will give ICH less control over the final standard, the actual process should be carefully constructed to maintain as many ICH controls as necessary and to limit commercial influence in the process.

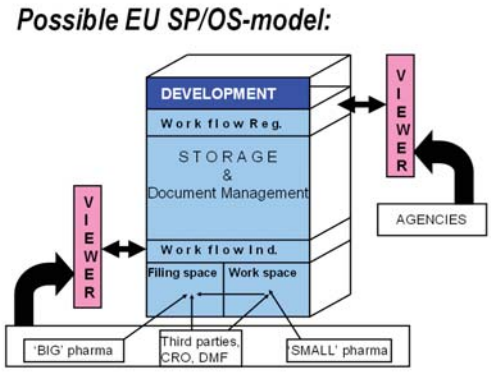
It is anticipated that the next major release of the eCTD specification—version 4.0—will be developed in the ICH-SDO consortium.

EU eCTD implementation

The current approach to implementation of the eCTD specification in the Member States and at the EMEA at different speeds is a logical choice. Nevertheless, it also contains a major risk that is already coming to the surface. National implementation actually means local portals for filing eCTDs using local application forms based on different technologies. In the end, this could mean that a pharmaceutical company in a European procedure has to go through many filing procedures, filing every time (slightly) different eCTDs in the different Member States. This is like the old situation with paper before the CTD. In the coming years, it will be crucial for Member States and the EMEA to bring their individual initiatives into line with each other or even to undertake joint activities in this area. In order to come to a solution, an idea from the beginning of the new millennium should be revived: an information broker, service provider, trusted third party or whatever one would like to call it should be part of the business process between regulators and industry. This trusted third party can have many roles and responsibilities:

- Provision of a secure ICT environment, available 24 hours a day, 7 days a week and access controlled
- Provision of work-flows
- Provision of document and dossier management, including records management and archiving
- Development, deployment and maintenance of databases: safety, product information, etc.
- Provision of filing and work space
- Development of standards, tools and systems

The possible activities of such an intermediate partner are illustrated in the following simple diagram.



However, the actual realisation of such a model is a huge task. There are legal, financial, technical and political issues to be resolved. However, although it might look impossible, the idea should seriously be further explored, investigated and elaborated because it might be the critical factor for a successful implementation of the eCTD in the EU.

Conclusion

Over the last ten years, much effort has been invested in developing electronic standards for the transfer of pharmaceutical regulatory information from industry to agencies. We have come to a point in time where all the prerequisites for successful implementation are now in place: business requirements, standards, software, implementation plans and clear business drivers. It is anticipated that the amount of actual electronic transfer of information in the pharmaceutical world will increase dramatically in the EU in the next few years. This does not imply that regulators and industry can sit back and relax. There is still much work to be done in streamlining business processes between the parties at the pan-European level. At the same time, technology will change, and those changes will have to be taken into consideration. The frequency of change in current standards and the development of new standards to be implemented will speed up through the new approach with SDOs. In other words, the next five years will be critical and exciting in this area of regulatory interaction.

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More Swift and more nets

The reasons why so few marriages are happy, is, because young ladies spend their time in making nets, not in making cages.

Jonathon Swift in Thoughts on Various Subjects (1711)

Grammarians or linguists? On using language corpus data to guide usage

by Mary Ellen Kerans

The grammarian and the linguist talk about the same objects—the rule-driven patterns that sounds and symbols make—but their approaches are very different. I'll argue that the attitude of one type of linguist—the 'corpus linguist'—is more relevant for technical writers, editors and translators because it helps us grasp subtle usage differences between disciplines efficiently. Embarrassingly easy to begin applying, a linguist's approach and tools enable us to handle language confidently but respectfully. The grammarian's approach is limited, authoritarian, and often idiosyncratic. Both can produce appropriate texts—but a linguist is more versatile and quicker at finding solutions to new problems.

Opposite poles

Introductory linguistics courses distinguish the two simply: the grammarian is prescriptive while the linguist is descriptive. The grammarian imposes structure, whereas the linguist looks for the system that has evolved and is expected to change. Proof of that concept is given to budding linguists in stories of the earliest English grammars, which were little more than imposed Latin categories at a time when English variation was great and confusing to the newly, barely literate of the generations following the introduction of print. Today the paradigmatic grammarian is a remembered school teacher: bespectacled and judgmental. The paradigmatic linguist? The missionary-anthropologist writing up a dying tribe's oral language, maybe: Indiana Jones with an interest in tagmemes and the like.

That distinction, like all dichotomies, is simplistic. David Crystal [1] tells of more benign early interaction between Latin and English: 'Participial constructions became extremely common and added greatly to the length of sentences.... There was conscious experimentation with new grammatical patterns.... By the 17th century, highly sophisticated and carefully crafted sentences, following a variety of Latin models, were commonplace...' (p. 70). And the new grammarians of the late 20th century were certainly benign and helpful in their highly descriptive attitude. Corpus linguists Randolph Quirk and Sidney Greenbaum broke ground in the early 1970s with grammars welcomed on both sides of the Atlantic and published in various forms. (For instance, see the American edition of 1975 [2].)

Still, a distinction remains clear. However descriptive a grammar might be, we refer to it saying, 'Quirk and Greenbaum say....' Grammar books are meant to provide authority, guidance: we consult them. I see polarization separating prescriptive and descriptive camps whenever I'm privy to practical discussions of language—in publishing houses, on e-lists, in teacher's workrooms, at translators' and editors' meetings. Grammarians worry that a descriptive approach is too democratic, saying that it will have us following horrendous examples. Where they think bad examples come from varies. I've heard declining English standards blamed on 'EuroEnglish', on users from the western side of the Atlantic, or on the undereducated young. It seems politically incorrect to ascribe them to the unwashed masses these days, but non-native users of English—even highly educated post-colonial ones—take hard knocks.

Why take up with linguists?

The linguist's statements, on the other hand, are driven by data (samples collected according to specifications) and are couched in non-judgmental terms. Observations are of usage in characterized text samples—a 'corpus', which might hold as few as 200,000 words or over 100 million like the British National Corpus [3]. A linguist reads a corpus the same way Luther, Knox and Calvin's followers read the first printed vernacular Bibles—in a community of watchful peers but in the expectation of personal revelation.

Such a cocky attitude is heaven-sent for people like me. By 'like me' I mean many readers of this paper—those who need to satisfy high expectations in varieties of language that may not come naturally. We are writers of other people's ideas—whether journalists, ghosts, co-authors, translators, editors or anthropologists. We may be editors and translators in specialties we were not educated in. We might work in languages other than the tongues of our mothers or teachers. Some of us are native speakers who have long lived abroad and acquired a hesitant familiarity with varieties and registers we didn't grow up with, concerned our learned usage may not be quite right.

Example of how a corpus linguist approaches problems

Acquiring the approach is easy—but as with riding a bicycle, skill comes with practice. I'll now show how a problem can be solved through corpus consultation. I'll then name some of the basics one needs to know to create a specialized corpus like the one used in the example.

Not long ago, *TWS* editor Elise Langdon-Neuner posted a query on the e-mail listserve of the European Association

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of Science Editors (EASE-Forum) [4]. A copyeditor had changed 'Based on these findings, we depleted T cells from spleen cells....' to 'From these findings, we depleted....' Elise wondered what 'the linguists' thought of an apparent ban (later confirmed by the journal) on beginning a sentence with *based on*.

Figure 1: A KWIC display generated by AntConc, a freeware concordancer that helps a linguist—or any practical wordsmith—analyze usage patterns. With the view scrolled to the right, it's possible to see that based on is used in this 350,000-word corpus of peer-reviewed articles by native speakers of English to introduce phrases that function as context frames for the sentences that follow.

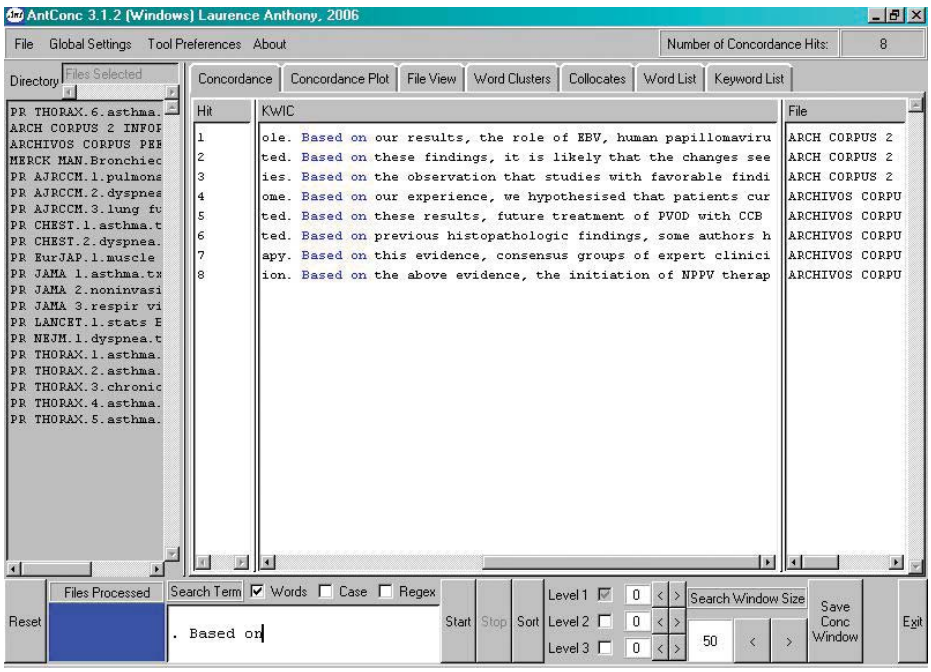
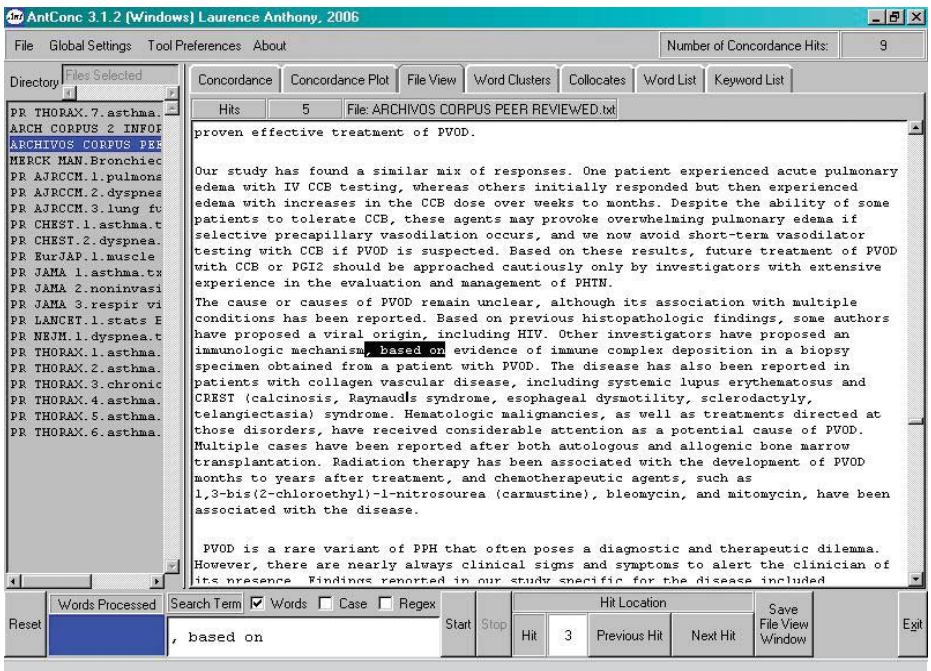


Figure 2: 'File View' display that reveals the adverbial nature of a *based on* hit that looked as if it might be adjectival in the shorter KWIC display. Clicking on any hit in an aligned KWIC display in the freeware AntConc concordancer toggles quickly to this view.



I participate in the Forum and remember my first reaction to the invitation. First of all, I thought, most linguists make it a point not to think too much about any text problem until they've looked at a corpus. So I entered *based on* into the search box of a concordancing program open on my desktop. Such a program—with texts already loaded—lets me see relevant patterns in seconds through a display called 'key word in context' (KWIC). (See Figure 1.) The loaded corpus contained articles in a discipline similar to that of the Forum query: papers from respected peer reviewed journals plus a few tutorials from teaching hospital websites and similar sources. The corpus is designed to give me information on language usage and expectations in a 'discourse community'. That term comes from 'genre analysis', a variety of corpus linguistics that looks at large rhetorical patterns as well as phrasal ones. Swales [5] defines a discourse community as a set of individuals with a common goal and means for member communication (information and feedback) that include specific genres, or text types, and lexis.

It was obvious from the first KWIC display of 136 hits (not shown) that many were in a verb phrase plus complement construction. They were irrelevant to the query, so I searched again with a period and *Based on* in the box. Figure 1 shows 8 good hits of uses exactly like the one in the EASE-Forum posting. For a small corpus (about 350,000 words), and for a specific construction and word, that frequency is high. Normally a consultation like that, taking seconds, would be enough to assure me that the author's wording should be left alone. Had I been the journal's copyeditor and insecure about participles because I'd been keeping company with grammarians, the KWIC display would have reassured me that the author's discourse community would be as comfortable with the phrase as the author and I were.

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>>> Grammarians or linguists?

Looking for a more complete answer for a posting to the EASE-Forum, though, I continued querying. I'd noticed several of the original 136 hits were preceded by commas—suggesting they might be end-of-sentence versions of the introductory participial phrase. So putting a comma plus *based on* into the search box, I retrieved 9 more hits. Of those, 4 were discarded because they introduced postnominal adjectival modifiers (eg, 'An alternative approach, based on...'). Four hits were adverbial sentence endings similar to the introductory phrase. (If this adverbial use of *based on* falls at the beginning, it would introduce a 'context frame', as it's called by the newest linguist/grammarians who analyze 'systemic functional grammar' [SFG]. Falling at the end, it would be part of a 'rheme' or the rheme itself if it contains the kernel of new information focus. SFG analyzes units that wed structure to rhetorical function.) To complete the analysis, I needed more context to confirm that an end-sentence hit was also adverbial, not adjectival. Clicking on the word to open the 'file view' (Figure 2) confirmed both pattern and sentence adverbial function clearly.

Thirteen hits for an adverbial use of based on in an appropriate corpus strongly supported Elise's complaint against intrusive copyediting. I'd looked at 4 displays in about a minute and a half. Concluding my EASE-Forum reply, I said that the sentence was well supported in its original form and the copyeditor had improved nothing by implying that T cells were depleted from spleen cells from findings!

I'll concede that efficient small corpus consultation does not solve all problems. The approach was useful in a similar EASE-Forum query on the use of the suffixes *–ic* and *– ical*, but for another about multivariate versus multivariable analysis, it was relevant but insufficient. We needed statistical concepts to answer that question, as frequency and patterning were not the whole issue. So, while this approach is pivotal for one who is outside a target discourse community, it's no substitute for knowledge.

Do you really need a corpus?

Could I have found the answer in a grammar book? Both Quirk and Greenbaum [2] and Fowler [6] in his first edition discussed the matter of the 'attachment' of such participial sentence introducers. To check Quirk and Greenbaum I needed to know that the section called 'non-finite or verbless clauses' would be helpful. Those authors give sensible, open-minded statements about the 'attachment rule'. Fowler's advice, found under 'unattached participles', comes in his superior tone. Both books mention exceptions. Here are excerpts from the entries:

> ... Commonly, however, this 'attachment rule' is violated:
>
> > ?Since leaving her, life has seemed empty
>
> In this case, we would assume that the superordinate clause means 'Life has seemed empty *to me*.... Such 'unattached' ('pendant' or 'dangling') clauses are frowned on, however...
>
> Note
> [a] The attachment rule does not need to be observed with disjuncts:
>
> > *Speaking candidly* (S='I'), John is dishonest
>
> [Quirk and Greenbaum, p. 329]

> ...[It] is to be remembered that there is a continual change going on by which certain participles or adjectives acquire the character of prepositions or adverbs, no longer needing the prop of a noun to cling to; we can say *Considering the circumstances you were justified, or Roughly speaking they are identical*.... The difficulty is to know when this development is complete.... In all such cases, it is best to put off recognition. A good example of what may prove to have been such a development caught in the act is the phrase *due to*. Every illiterate in the land is now treating *due to* as though *due to* had passed into an adverb not needing a noun to agree with, just as *owing*, in *owing* to, has actually done....
>
> [Fowler, p. 675]

Perhaps it's personal, but those grammarians leave me feeling less confident than the foregoing linguistic approach did. Quirk and Greenbaum's question mark makes me feel I might be naughty to use such frowned-upon sentences and the negative term disjunct—exactly what *based on* is—might give me permission to dangle the introductory phrase bravely, or it might leave me still feeling sheepish. And how is one to know if a phrase has become an adverb like *owing to*, as Fowler says, or a disjunct to which the rule does not apply, as Quirk and Greenbaum say? There's an implied caste of people who know such things and one suspects that if one has to consult a book one might not be a member. If we keep consulting, we'll see that *The New Fowler's*... of Burchfield [7] spares us allusions to illiteracy but explicitly admonishes us not to use *based on* to introduce sentences; and where Fowler hedged by referring to expressions acquiring the character of adverbs (correctly I think) or prepositions, Burchfield confuses me by referring to 'marginal prepositions' for the same usage shift (p. 804) (incorrectly I think). It's no wonder that copyeditors are intimidated into changing to *on the basis of*, though to the linguist that looks no better founded.

How to set up as a linguist

The main concept to grasp is that it is an attitude toward language and an approach to problem solving you're buying into. The approach is through the description of patterns—based on adequate sampling and a well-characterized corpus of exemplary language—with the support of member informants for complex questions as in anthropology. I'd characterize the attitude as one of respect for specific discourse communities. This leads to defining exemplary users of language worth emulating. A part of the definition of such communities I haven't mentioned yet is that membership changes and community survival depends on a threshold level of individuals with discoursal expertise [5]. This is why corpus design is the key to the validity of observations and why the corpus must be well characterized. To borrow the grammarian's aura of expertise: any authority a linguist's appraisal might have rests as much on the appropriateness and adequacy of the corpus as on discernment.

Building a specialist corpus takes time, but how much depends on how fussy you are. My largest corpus, now at about 350,000 words, is fairly clean and I know exactly what's in it. A clean corpus is free of the sorts of artifacts that web pages insert, of images and tables that take up space but give little language information, and of references. It's also free of duplications, which plague corpus builders who collect haphazardly, job by job. Logging texts and cleaning off artifacts like html or other coding takes a bit of time, but that's no excuse for ruling out corpus creation. Even a quickly assembled 'dirty' one can give good service [8]. I know someone who works happily with a dirty corpus of a million words compiled in little time and thinks cleaning unnecessary. Still, I've found it's worthwhile to have a display that's rich and compact and find very dirty corpora more difficult to scan and draw inferences from. As for size, I started to get useful information from a highly specialized corpus at only 200,000 words.

How to build a corpus lies outside the scope of this article, but here are some principles for anyone who'd like to get started:

- Define the scope of the language you're interested in, state how you'll identify exemplary texts, and find a free electronic source.
- Store samples in 2 ways: as intact files and as text files. This is fair use if the corpus is for personal research or for sharing with a small group of colleagues or students.
- Name text ('notepad' files) and intact (html or pdf files, for instance) identically so their correspondence and content will be evident at a glance and log them so you know what you have. Use intact files to study rhetorical patterns and process text files in a concordancer to study frequency and collocations.

The concordancer I recommend is freeware—AntConc, available for Windows and Linux [9]. Developed by Laurence Anthony, currently at Waseda University in Tokyo, AntConc is simple and the two most basic displays (KWIC and file view) are intuitive. For more advanced functions, Anthony's help file is short and indeed helpful. To know more, read Susan Hunston's [10] overview. It's no more technical than necessary.

The linguist's approach is useful, efficient and enjoyable. I am a wordsmith—not a proper applied linguist. But this attitude toward language has been a key to acquiring competence quickly when I've had to deal with new varieties or genres. It's also helped me avoid insecurity while working abroad in a language without an Academy, with competing regional varieties and awash with prejudices that grow out of overgeneralization from idiolect. Concepts from linguistics help me form sets, describe patterns and develop algorithms for applying them. Like statistical data processing, corpus analysis is an aid to inductive reasoning and can be used to generate or refine a hypothesis, falsify one, or simply confirm intuition.

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Word usage: Let the Web decide!

A useful site for finding the preferred spelling of a word, which of two words is more commonly used or whether a word is more often or not hyphenated is http://www.spellweb.com. Here you can enter your two alternatives, choose the search venue, either Google, Alexa or Yahoo, and SpellWeb will come up with the number of times each alternative appears in your selected venue and pronounce the winner.

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A website of my own

By Jeremy Grierson

For the EMWA members who are freelancers, the most important step in getting new clients is probably their listing on the EMWA freelancers' page on the web. However, it's widely said that to have real business success in this 'Internet-age' one should really have one's own website. A number of the EMWA freelancers have already made this step, particularly the continental members, who show an overall acceptance rate of 69%, but curiously only 43% of the UK freelancers have taken this step. But the willingness to have a site does appear to be there, as attested by the number of people who have enrolled in the EMWA workshop on website development. I hesitated for a considerable time, with doubts over the possible advantages. I took the plunge in 2005 and my website finally appeared last summer. What follows is an account of my motivations and decisions that led to its creation.

Why?

While the freelance listing on the EMWA site presents an excellent advertising opportunity by providing a springboard to budding freelancers, the listing is necessarily uniform and concise. In contrast, a business website, with a personalised and more comprehensive explanation of services and experience, allows the differentiation of one's offer, with the hope of making a lasting impression in the minds of potential clients. In an increasingly competitive field such as medical writing, I believe this is important.

How?

Although I had toyed with the idea of building my own site since becoming a freelancer and gone as far as to buy a book (still unopened), the precipitating moment was my attendance at Shanida Nataraja's course at the EMWA conference in Budapest. I had fairly high hopes of building a site myself; I had some past experience of computer programming and the logical process intrigued me–but the course left me a little deflated (Sorry Shanida!). For me, the take-home message was that one really needs to fork out £600+ for the best program and I know from experience the learning curves for these things are steep. So my project entered a sort of hiatus for 6 months as I dithered my next step.

Importantly however I had started to think more constructively about what I wanted to achieve. For me, it was necessary to present my services in French and English in a fairly comprehensive manner but not to create a site that was overly complex or overly detailed. The salient features were to be a professional appearance and speed of loading. I also decided that my time was relatively more limited than my budget. So I began to look at other sites with a more critical eye and to think about how users would eventually use my site.

Then, early in 2005, while attending a conference for start-up companies, I happened across a company that offered turn-key sites at a set price (three levels of sophistication: three prices). That was an attractive idea! So I searched the internet for other similar companies and asked them for details. The company I choose in the end was not the one I had first seen, but one whose portfolio of sites impressed me more and who seemed willing to please.

So, after some negotiation over features and price, I committed myself to the development of a bilingual 3-page site, with a 'home' page, an 'about us' page and a contact page, thus, 3 pages in English and 3 in French. The site was to be adapted from a template, purchased from an American site specializing in such templates. (Perhaps had I known that such templates existed, I might have been tempted to go it alone, but then again, even having a template, one still needs to know what one is doing). From what I saw of the American site, there are hundreds of models to choose from, all grouped according to user occupation. Needless-to-say, 'medical writing' did not feature amongst the occupations and, with the advice of my 'consultant', I ended up selecting one for accountants (!). The product is rather like a PowerPoint template with text boxes and a header/title section that appears on each page. The drawbacks of this approach are the text boxes are not very flexible in terms of position and size (or at least that's what I was told!) and that somebody 'out there' may have a site very much like mine. The advantages, however, are that the site is already 'optimized' for different internet browsers and screen formats, and therefore relatively inexpensive to develop. And, in a certain sense, it is perhaps not such a bad idea to have the constraints of predefined windows: there is great pressure to be concise.

Naming

The most important item is, of course, the name of the site: the company's name. In a way it defines the company. How it looks, including choice of font and colour, should become standard on letterheads and business cards; so it is important to get it right. For the past few years I had been trading under my own name, but for a website I decided that this was not the best option; it was not catchy enough.

A website of my own

I had had one or two names in my head over the past few years but when it came to commit them to print they didn't seem quite right. They were either too difficult for non-English speakers or not quite right for a service of scientific writing. However after a brain-storming session, I settled on Carduus Consulting (Carduus being a genus of thistles and so keeping a link to my Scottish roots). I checked on the internet to see if the name was already taken and, wouldn't you know it, there is an English company with this name (but no web site). Although it was doubtful that the name had been registered as an international trademark, I decided not to waste time and effort and to register my company name as Carduus Script Consulting. The website consultancy had been pressing me for the domain name for my site and while I was tempted to propose 'www.CarduusScriptConsulting.com', I felt that it was too long and I object to using hyphens and dots within the name. As www.Carduus.com was not an option, I quickly settled on www.CarduusScript.com.

Content

Selecting the model had been the easy bit! I now had to decide what to put in and how to organise it. The idea of subject headings with hyperlinks had attracted me at first because they are rapid (especially if they reference a different part of the same page) but I feel that when there are numerous headings in which one is interested, then the process of going forward and back on hyperlinks become tedious. So I fell back on the trusty old bulleted lists to present my services. The headings and the description of services (plus the translations) took quite a bit of thought and several evenings of deliberation to get right.

The second page concerned the company: I wanted to briefly summarise my experience, enough to give a good impression, mention my Scottish links (much appreciated by my French clients) and explain the name of the company. Once again to write the words and to get them to fit neatly in the space available required several evenings of trial and error.

The third page, the contact page, was relative straight forward because the basics were already in the template and my website consultant just had a few technicalities to deal with. Importantly, I am assured that in its present form the contact page cannot be accessed by web crawlers, which are pernicious software devices used to collect contact details from sites with the goal of sending junk mail.

I had expected to be able to fit three to four images into the site and had gone to some trouble to find and prepare suitable photos, but it turned out that the space on the site was rather too limited with the template, and the possibilities for adaptation less flexible than anticipated. Consequently there are just two (very small) photos on the site.

Success?

So, with a bit of juggling and numerous evenings spent over a hot computer, the site was finished. It is not perhaps perfect, but it looks tidy and professional. What is still left to do is the optimisation of the key words to improve the rankings in the search results of search engines. Although the site was entered manually to numerous search engines following its completion, it does not come up high when one taps 'medical writer' into Google. This, I am told is a whole different ball-game and a new art in getting sites well-ranked. I'll soon be back in contact with my consultant for this.

Have I had any new clients because of it? Well, I think the answer would have to be "no"–not for the moment. But I do think that it is a worthwhile investment and it has forced me to develop my company's name and logo and to look critically at my offering. Clearly these are all long-term benefits.

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Dramatically fewer home-grown scientists in the pipeline in Britain

School children in the UK have little interest for science. The numbers of 15-year-olds taking physics and chemistry exams have dropped by over 70% since the mid-1980s and the students taking A-level chemistry, maths and physics have fallen by 34% since the early 1990s. Robert Matthews writing in July's issue of *BBC Focus* believes it would be difficult to persuade teenagers that science is fun or a means to get rich quick. This just leaves the possibility of presenting a career in science as a rebellious course of action—a way to be different from your parents. Parents are those people who grumble about the state of the world but don't do anything about it. Science could be sold to teenagers as a means of actively making the world a better place. This strategy was successful in enthusing many to take up scientific careers in the 1950s but then fervour was dampened somewhat by the ozone hole, Chernobyl, and DDT debacles.

According to a survey conducted by the National Union of Students, university students also place a premium on companies with sound ethics policies. In the survey 79% of the students said they did not want to work for a company with a poor ethical record. Scientists for Global Responsibility is a UK-based organisation that promotes ethical science, accountability, peace, social justice and environmental sustainability. It has produced a booklet featuring 12 scientists from different disciplines who have prioritised ethical concerns in their careers. The hope is that their stories will help others to confront issues and map out their own career paths (http://www.tinyurl.com/oard2).

Source: 'Handful of Know-nothing science students will be taught by teachers who know even less' by Robert Matthews in *BBC Focus* July 2006.

Welcome to the blogosphere

by Ursula Schoenberg

Everyone is doing it. Well, of course not everyone, but quite a lot of people are entering the world of weblogs (or 'blogs' for short)—either to read them or to write one themselves. For the uninitiated among you: A blog is a kind of online journal that anyone can create with a few clicks (for example at www.blogger.com) and that other web-users can access and comment. The content of a blog can be driven by issues personal, political, corporate, consumer, philosophical or anything else you can think of. A special format called RSS (for Really Simple Syndication) allows you to keep updated on favourite sites.

According to blog-monitoring services (www.technorati.com or www.blogpulse.com) there are almost 30 million blogs out there, and a new one is being added every second. That being said, even though the software makes a blog seductively easy to create, maintaining an interesting and effective blog requires a good deal of commitment and stamina. Surveys have shown that many blogs are abandoned after only one entry, and that the average life of a blog is four months. On average, most active blogs are updated every 2 weeks, and only a small percentage is updated daily [1].

So why would you want to take time out of your otherwise busy day writing, watering the cat and feeding the plants to read a weblog? Well, for one thing, informative professional blogs can keep you up-to-date on industry 'pitter-patter' and can also be a powerful networking tool. Our American colleagues have recently started the Medical Writing Blog (www.medwritingblog.com) which is a good place to start. I personally enjoy the Pharmablogger (http://pharmablogger.blogspot.com) who gives funny and opinionated insights from inside the pharmaceutical company in which he (or she) works.

More specialized blogs can also be worth visiting: Resources on the visual presentation of medical work can be found at the blog 'The Eyes Have It' (www.leepotts.com/tehi), and the editors at the *American Journal of Bioethics* tackle ethics issues big and small in their blog (http://blog.bioethics.net). If you suffer from writer's block or tend to procrastinate, you may find some helpful advice at www.lifehack.org. For pure fun, the current blog champion Boingboing (www.boingboing.net), which touts itself as 'a directory of wonderful things', is hard to beat for everything eclectic and ephemeral.

Whether to blog yourself is a moot point, and will depend a good deal on what you hope to achieve with the blog. Any professional blog will require the commitment mentioned above, but if you want to keep in touch with friends scattered across the globe, a personal blog is a fun and efficient way of keeping them up-to-date. And maybe EMWA should join in on the AMWA blog or create its own?! What do you think?

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Reference

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Is the 'Internet' a proper noun?

Foldoc at http://foldoc.org/foldoc/index.html, supported by the Imperial College of Computing, is an invaluable free on-line dictionary of computing. It is unambiguous in treating the 'Internet' as a proper noun and on searching 'Internet' you will be told that 'The Internet is the largest internet (with a small 'i') in the world'.

But other opinions challenge this—not that it is the largest Internet in the world but that it is written with an initial capital letter. Tony Long, the copy chief of the online computer journal *Wired* (www.wired.com), says there is simply no reason to capitalise 'internet', or 'web, and 'net' for that matter. Although he's aware that 'If It's Capitalised, It Must BE Important', he believes the move by his journal to use lowercase initial letters for these words should not be interpreted as some kind of symbolic demotion but thought of as a stylistic reality check. The Collins English Dictionary also changed its mind between its 2000 edition, in which Internet is capitalised, and the 2005 edition where it isn't. The *Guardian*, Economist.com and BBC likewise use lower case initial letters for 'internet' and other web-related words. On the other hand again the *Zen Internet newsletter* still considers Internet to be a proper noun which should be capitalised ('Internet goes lower case' at http://www.journalism.co.uk/news/story1040.shtml).

Grant writing: Satisfying all the criteria

by Ian Metcalfe

In the world of scientific research, the writing of grants has long been the realm of funding-starved academics desperate to push forward the boundaries of their specialist research areas. While the academics' situation may not have intrinsically changed, modifications to the intentions and structure of granting bodies, such as the European Commission Framework Programme (EC FP), the United States National Institute of Health (NIH) and the Gates Foundation Grand Challenges in Global Health (GCGH), have successfully drawn commercial organisations into the net.

R&D departments increasingly have to look for funds outside their organisation

Take for example the Lisbon Summit of 2000; it was here that the EU defined the need to build Europe as "a knowledge-based society". Since then many of the EC FP initiatives have stressed the need for the inclusion of industrial partners, particularly small and medium sized enterprises (SMEs) who are seen as the drivers of modern economies, To focus the development of research programmes towards a more product-oriented approach.

Furthermore, there is an increasing drive within institutions and organisations for research departments to be less reliant on other departments for their financial needs and this means they have to go out looking for funds.

The end result is that many researchers, and indeed research departments, spend vast amounts of time, energy and other resources in drafting proposals for potential funds. Unfortunately, a lot of these time-consuming proposal preparations meet with failure: the EU quotes a success rate of 1 in 5. It is here that professional writing skills are beginning to make their mark.

Recently, several companies specialising in the preparation of grant proposals have become established. While none of them guarantee the success of a submission, mainly due to the nature of the review and selection process, many of them carry titles alluding to improved chances of success: "Writing a Successful Grant Proposal", "Successful Grant Writing" and "How to write a competitive proposal for framework 6".

Only four years ago the nail biting, teeth grinding and hair pulling was firmly in the grasp of the researchers. Now many organisations and institutions "have a writer that can handle that". For my sins I have spent the last few years more or less dedicated to the art of writing grant proposals. I learnt many of the "do's and don'ts" the hard way. Although I believe there is no real substitution to "learning by doing" I do feel that if some key pointers are given, that strangely enough are not in the various "Guides for Proposers", life would be a little simpler—at least for grant writers.

The various institutions have spent a lot of time and energy on creating detailed guidelines on the plethora of criteria for a grant proposal. On face value these instructions may seem fairly straightforward, but (isn't there always a "but"?) when one sits down and tries to satisfy these criteria there is little or no advice or guidance as to how one accomplishes this. The NIH proposal writing instructions go as far as to say 'the completion of this application should take no more than 40 hours'. An interesting and amusing thought (British sense of humour required). In fact, at one point I was thinking of having that particular phrase framed and mounted above my office door[1]. Just reading the instructions requires a good ten hours!

The writing process is also often complicated by apparent conflicts within the instructions. Conflicts that one only comes across when one sits down to write the application. For instance, there is often a comprehensive list of points required to be covered within certain sections, but (there's that "but" again) you are limited to a certain page length for that section. “Ah” some might say, “I'll shrink the font and squeeze the paragraphs together”. Unfortunately, the granting bodies are one step ahead of you: they have defined fonts, font sizes and line spacing. The budding grant writer has to be a little more imaginative than that.

Bearing these and other criticisms of the guidelines in mind, they are essential in drafting the proposal. A lot of the time they include specific questions that need to be answered and important pointers towards the areas that will be considered important by the reviewers. This brings me on to the second set of documents that are important for a grant application: the guidelines for reviewers. It is worth obtaining a copy of these (freely available on the various websites of the granting bodies). For obvious reasons these documents often give a little more insight as to the key points that you must cover. These guidelines for reviewers break the review process down and show you the structure of how your proposal will be assessed; they may help you understand a little more about your target audience.

1 By the way, if there are any readers out there who have managed to complete a successful NIH RFP grant application within 40 hours, I'd like to shake you by the hand.

>>> Grant writing

Having got past the initial gatekeepers of the review process, by completing your application on time and with the right number of sections all within the correct length, your proposal is then dropped in the lap of the "experts". Anyone can volunteer to be an "expert". With most of the granting bodies this is achieved by filling in the equivalent of an application form on the respective web site, although it must be said that most "experts" are hand picked and invited to evaluate the proposals.

The writing process is often complicated by apparent conflicts within the instructions

Following the submission deadline, the chosen experts are presented with a mountain of proposals to assess, normally in record-breaking time, prior to their participation in an evaluation panel. This part of the evaluation procedure is important to bear in mind, particularly when it comes to your description of complex scientific issues or management concepts. Keep your ideas clear and use diagrams wherever possible. Flow, Gantt, and Pert charts all help to convince the reviewer that what you are intending is achievable, well managed and of significance to the field. Looking at the guidelines for reviewers will enable you to decide what particular diagrams should be placed where and how much detail they should include. Remember, if the experts can't fully comprehend what it is you are trying to achieve and how exactly you are going to achieve it, then they will think it impossible and you will get a poor score in the evaluation.

In addition to these documents it is worthwhile doing some background reading on the issues that have raised the call for proposals in the first place. Often there is a political agenda behind the call as it has been generated to address a perceived scientific or technological shortfall. It certainly pays to know the source of the scientific or technological problem that your grant will solve in order to target your solution properly. Having an inside perspective is always valuable and many of the granting bodies are surprisingly open to communication. The NIH actually provide you with your own personal contact whom you can question about all aspects of your project. The EU have also helped me a great deal during the proposal preparation process, but getting hold of the right person to speak to can often be a challenge.

When it comes to the physical writing of the proposal, the value a professional writer can add is multi-faceted.

– Writers tend to be a little more detached from the science than the researchers themselves. This provides alternative perspectives and perhaps a more pragmatic view of the actual requirements of the project in order to achieve the defined aims.
– Writers generally have a good eye for detail and consistency in the presentation of facts, this goes hand-in-hand with being able to present these facts in an understandable and logical manner, introducing a flow to the sections of the proposal and minimising repetition.
– Writers generally enjoy writing and do not have to be dragged away from the laboratory to do something they perceive as not being their core competency.

As with most complex documents it helps to start with a template and a firm idea of what the proposal is about. After all, like most good stories, it needs a beginning, middle and end. For this reason I like to have all the scientists together to thrash out who exactly the partners are, what each will be contributing (in terms of scientific deliverables) and when the various deliverables and milestones are for the project. This can be a far from simple task but once it is done a lot of the information that will be required to answer the granting body's questions in the proposal will have been clarified. My personal favourite to achieve this is to lock everyone in a room with a large flipchart and not let anyone leave untill the complete timelines and deliverables have been defined. At this point writers must keep their feet on the ground and stress the importance of keeping the proposal realistic and not let the researchers get carried away. By this I mean that many of the funding structures carry a maximum in terms of amounts of money that will be granted. For example, if one is applying for a Strategic Targeted Research Project (STREP), which carries a maximum funding of around 3 million Euro for 3 years, there is no point in designing a research proposal with 20 partners – it wouldn't even equate to a 50% postdoc per partner per year! It is therefore imperative that at this early stage the partners are aware of the funding limitations and scale the project accordingly.

Make the Partners aware of the funding limitations at an early stage

Once you have the backbone of the science together you then have to make sure you are achieving the right balance between the scientific aspects and the managerial aspects. Even if you have a Nobel Prize winning idea, if you do not show that you have both the resources and the managerial structure to carry out your concept it will almost certainly fail the evaluation. Be aware of the potential effect of your research and make sure you convey this clearly to the reviewers. It is also important that you know where your project fits in the grand scheme of things and that you portray your research as an intrinsic part of the programme. There are also political issues to consider: will your research provide a competitive edge and address potential transatlantic imbalances in know-how or intellectual property?

Although successful grant writing comprises many other factors, including budgeting and the detail of form filling, I hope that some of the pointers I've laid out here will help budding grant writers avoid the first pitfalls.

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Better letters to the editor

By Richard Clark

Most of us reading *The Write Stuff* like writing in one form or another, which is probably why we ended up as medical writers. Two recent events have made me think about how I go about writing. The first was the threatened closure of a school that my niece goes to, which triggered a request by my sister to write a 'protest' letter[1]. The second was being asked to write a chapter on how to write a letter to the editor for a book about medical writing [1].

I'd never thought about *how* to write a letter before—it's never seemed to be difficult. Maybe I've just been on autopilot? Then again, I began to wonder how good some letters to the editor I'd written had been. Looking through my files I read one I'd written quite a long time ago to the *Lancet* and wasn't best pleased [2]. It was trying to make too many points, some of which were quite complex, and it wasn't very convincing as a result. I remembered it had gone through 13 drafts, thanks to various authors, and had changed out of all recognition from my first draft. This made me feel a little bit better, but not much. Clearly I needed to give the matter of how to write a letter a bit more thought, both for the sake of my niece's school, as well as the book chapter.

The first step in writing a letter is to ask yourself why you are writing it

I've always found that asking yourself questions is a good place to start, and often the stupid (i.e. obvious) questions are the ones most worth asking. My favourite question is 'why?' To put this in context, as a doctoral student at the Department of Biochemistry at Oxford I was forced to spend several hours every week listening to what I can only describe as the most exceedingly dull lectures, all given by eminent visiting scientists. Without exception they gave a detailed account of their last 30 or 40 years' research in a muddled, often chronological order, and I burned to ask the question 'why have you done all this?' I never did though. Ever since I have been making up for lost time with my 'why' questions. So, the first step in writing a letter to a journal is to ask yourself why you are doing it–and not just because someone is paying you! The main reasons would be disagreeing with a published article, praising or supporting a paper published by someone else or exercising a 'right of reply' to letters criticising an article you have published. A letter may cover several of these categories, but I feel that it's important to know which aspect will form the main focus.

The next steps to think about are how to get the letter past the editor so that it is published and how to make sure your letter is worth reading. Essentially, these can be dealt with in the same way – one main focus, keep it short, make it persuasive, and back-up your opinions with facts from good sources. I'm sure that as medical writers we all know about how to achieve these, so I won't dwell on them.

One further factor to consider is the structure of the letter. There are many different types of structure, and no one of these is always the best. However, it is a good idea to think before you write and then make a very brief plan of what you are going to say and how you plan to order the content of your letter. This imposes a style that hopefully makes your letter easier to read, clearer in your communication of your points and more persuasive, as your evidence will be presented in a straightforward and understandable manner. One favourite when dealing with a response to another letter or published study that you disagree with is the classical 'sandwich' structure. For example, the first paragraph might briefly refer to the article, and then refer to something complementary about the study, before stating what it is about the study that you disagree with (i.e. communicate the point of the letter). The middle section might expand on why you disagree with parts of the article in some more detail. Here, you can use published or unpublished data, personal anecdotes or statistics that support your views. This is the longest section, but is still concise. Finally, restate your major point, and wrap-up with a succinct conclusion.

There are many different structures, and no one of these is always the best

Another structure that is useful is the so-called EPIC style, which can be used to develop a defined and persuasive structure to your letter, regardless of the type of response (supportive or negative). This has the following elements:

- **Engage** the reader with a startling fact, or a strong statement of a serious problem or unmet need.
- **Propose** a specific action in which this need or problem can be dealt with.
- **Illustrate** how the proposal would work and why it's important. Maybe give a few details or examples, either from your own experience or from published studies.
- **Call to action** for the readership to undertake specific measures to deal with the problem along the lines of your proposal.

[1] The school has been saved - which is very good news. Apparently there were thousands of letters in support of the school, and not one in favour of the closure, so people power works sometimes.

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>>> Better letters to the editor

Here are a few more tips for writing a good letter. Keep sentences short. If you write long sentences, each making several points, the reader may have to re-read parts of your letter to understand what you've written. The use of abbreviations should be kept to a bare minimum. Again, these can make your letter less readable. Avoid sounding pompous and using flowery, pseudoscientific language. Thus, 'administered' can become 'given' and 'utilise', 'use'. If it is possible to cut out a word, always cut it out. (e.g. ~~past~~ history, ~~forward~~ planning, ~~close~~ scrutiny). Avoid the rather meaningless (or at least easily misunderstood) 'buzz words' such as 'proactive' and 'stakeholder'. Avoid dissociating authors from results. This can lead to statements such as 'these data suggest', which is not accurate. Data show and writers suggest. Most importantly, if you gave your letter to a well-informed person with little or no experience of medicine, pharmacology or science, would they understand the main point(s) you are trying to make?

Anyway, I hope that these tips have been useful. Returning to the problem of writing my own protest letter to the Local Education Authority, this was eventually completed using the principles I'd written about in the book chapter. I'd like to think that these helped me to write a more persuasive letter. Maybe someone will read it, and I hope the letter may help, albeit in a small way, to make (or change) opinions! I guess that's the main reason for writing a letter to the editor too.

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The question 'Why?'

Perhaps the suggestion of asking 'why?' made by Richard Clark in his article about letters could also be extended to published studies. The following is a genuine email sent by a Taiwanese researcher to an author of a journal article.

"Dear Professor…

I have read your article…in the journal of…I read the article again and again. Your examinations are fine, but I cannot find out the most important reason why you wanted to do the research on this topic and why this examination means a lot. Would you tell me about it? Thank you and hope your research goes on smoothly and successfully."

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Why is Yahoo called Yahoo?

Although his book *Gulliver's Travels* was never widely read some of the words Dean Jonathon Swift made up have become well known. H.G. Wells in the *Time Machine* borrowed from Swift and wrote about the Eloi providing meat for the repulsive Morlocks. The *Planet of the Apes* films have dark aspects taken from Swift. The search engine Yahoo took its name from a vile and savage humanoid creature with unpleasant habits that Lemuel Gulliver encountered in Book IV of his travels.

Dean Jonathon Swift, whose chair remains in St Patrick's Cathedral, Dublin, had a strong social conscience. He was appalled at the privations of the poor and remonstrated with the British authorities over their inaction. He turned his attention to political satire and wrote *Gulliver's Travels*, set in 1699-1709.

Gulliver's Travels has never faced the same scrutiny as *Alice in Wonderland*, probably due to Swift's archaic, and ponderous style of writing, he wrote as though thinking out loud. There are four parts to the book, all have different themes. Book I is acclaimed as a children's story, that is all. Book IV is savage and virtually unknown to the modern world.

The work was intended to attack the corrupt political party (Whigs) in power which had displaced Swift's Tories in London. This early political satire highlighted the universal human tendency to abuse political power, manipulate others and deceive ourselves. Thus the Lilliput setting is a microcosm where man is 15 cm tall, their squabbles are petty, their pomp and ceremony ridiculous. Lilliput selected persons for high Government jobs by the length of time they could dangle on ropes. Brains and ability had no place in politics. Only lunatics study politics.

It all started in Book I when Lemuel Gulliver signed on as a ship's surgeon, dreaming of adventure. In Book IV he was set to shore by an angry crew. There he is attacked by hairy animals with goat-like beards; he was rescued by two Houyhnhnms (horses) who told him, by gesturing, that his attackers were called Yahoos. The Houyhnhnms were orderly and rational and travelled in sleds drawn by four Yahoos. The Houyhnhnms kept Yahoos in sheds. Gulliver met the King of the Houyhnhnms, to whom he explained money and the English Constitution. The King said money led to avarice. He found the actions of man difficult to comprehend, honour is more important than net worth. The King could not imagine war with another country. The Houyhnhnms had a language without trace of political and ethical nonsense, perhaps also reflecting Swift's concern about the corruption of the English language, which he believed was in need of reform.

In Book IV Swift evaluates the human condition. The gentle Houyhnhnms are compared and contrasted with the horrible Yahoos as with the dichotomy between reason and unreason, sanity and insanity and fairness and unfairness. Swift implies mankind is neither a rational intellect nor wholly passionate, neither Houyhnhnm nor Yahoo. Man inclines to bestial behaviour. At the end of the final book Gulliver returns to England where he is revolted by his countrymen and sees them as Yahoos. He lives in stables to be near horses. Swift abandons Gulliver to despairing visions of reality between the dreamy utopia and ironically ideal society of Houyhnhnms and the abyss of Yahooism.

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Medical writing in Australia

By Peter Tobin

G'day from Australia. I have recently returned from the 2006 Annual European Medical Writers Association (EMWA) conference in Lyon, stuffed full of new and exciting ideas on publication planning, strategy, and some practical tips on how to improve my writing. In return for some invaluable advice, I would like to provide a short report on medical writing in Australia and one of our key educational bodies, the Association of Regulatory and Clinical Scientists (ARCS).

Although, medical writing is not as firmly established in Australia as it is in Europe, there is *increasing demand for 'good' medical writers*. By 'good', I mean writers that are technically proficient and aware of relevant guidelines, some of which are listed below [1-3]. However, I believe that being a 'good' medical writer also involves a commitment to upholding the principles of transparency and honesty in reporting research that are embodied in these guidelines. For example, it is often overlooked that potential conflicts of interest can introduce bias into studies and it is therefore critical that readers are aware of these so that they can objectively assess reported studies.

ARCS is one of the key educational bodies in Australia and New Zealand that is helping to develop young medical writers like myself and ensure that the medical writing industry within Australia is a professional and highly ethical industry. ARCS Australia is a not-for-profit association with approximately 2200 members throughout Australia and New Zealand, in a wide range of fields including medical writing, regulatory affairs, clinical research, health economics, medical devices, and the provision of medical information (www.arcs.com.au). Each of these disciplines has an education subcommittee that meets regularly to exchange information, to discuss the changing healthcare environment in Australia, and to arrange educational seminars.

I am a member of the ARCS Medical Writing Education Subcommittee. This group currently consists of 54 active members, predominantly from multi-national pharmaceutical companies and contract research organizations specializing in medical writing. This year our group has organised seminars on: the interactions between medical writers and statisticians; systematic reviews and meta-analyses; and information on medical writing for those who are new to this field or interested in entering the medical writing arena. The high attendance at these seminars is an indication of the level of interest in medical writing in Australia.

As well as being instrumental in shaping the medical writing industry, ARCS also provides a *social forum for medical writers*. In a large country like Australia this fills a critical need for an often-overlooked area: networking. I have found that often the most valuable information is obtained in informal settings, by just chatting to other medical writers (don't underestimate the value of new ideas over beers). If nothing else, it has helped me appreciate that the difficulties and challenges I face are shared by other medical writers in Australia. And certainly the EMWA conference in Lyon highlighted to me that my European colleagues share these challenges as well.

In conclusion, Australia offers great opportunities for medical writers, both in terms of contract and full-time employment. ARCS has helped create a well-informed and close-knit community of medical writers within Australia. In this way ARCS performs a similar role in Australia to that provided by EMWA in Europe. I believe that future collaborations between ARCS and EMWA would be of great benefit to both associations.

Affiliations and competing interests
Dr Peter Tobin is a Medical Writer for Janssen-Cilag Pty. Ltd, Sydney, Australia. Peter is a member of the Association of Clinical and Regulatory Scientists (ARCS) Australia and the European Medical Writers Association (EMWA).

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Disclaimer statement
Opinions expressed in this article are those of the writer and do not necessarily reflect those of ARCS or Janssen-Cilag Pty. Ltd. Australia.

Worth reading

'Ethical writing should be taught', a commentary by Miguel Roig. *BMJ* 2006;333:596-7.

An AMWA[1] member reports on an EMWA conference

By Jack Aslanian

By most criteria applicable to such events the 15th annual conference of EMWA, held in Lyon, France, May 2 - 6, 2006, was very satisfying: a record attendance, a serious, varied, and engaging educational program, ample networking, an inviting locale, memorable food, and at least for this writer, the wish to make it to the next one—which will be held in Vienna, Austria.

I attended, for general education, most of the open sessions on electronic submissions and other national or international regulatory topics, and came away from them exposed to a plethora of acronyms and jargon and with the sense that those areas are experiencing change and tweaking of systems, uncertainties, and attempts to instill coordination and reconciliation between various levels of data and document generation and use—including coordination between European nations and compliance with both national and European Community laws and FDA expectations. It should go without saying that most, but not all, of this pertains to the regulatory domain. Any resentments and concerns medical writers and editors may have about digital documentation and submission and their mandated formats probably are rooted in the facts that (1) this a new way of doing things, requiring some learning and habituation, (2) the various interested and guidelines- and format-imposing agencies are not yet fully coordinated between themselves, and (3) the new guidelines and the deadlines to conform to them are imposed on medical writers from outside by authorities (administrators and gatekeepers), most of whom are neither practicing medical scientists nor medical writers.

Medical writers must be a very friendly and mutually supportive lot. The same camaraderie, enthusiasm, inquisitiveness, and eagerness to learn notable at AMWA meetings were present and equally intense in Lyon. On the train after the conference had ended, I wondered about the reasons for these shared organizational traits. It cannot be that certain types are attracted to medical writing. The way an organization is started and by whom could, however, account for the personality of the organization. Shared traits bring the founders of an organization together; these traits then help motivate new members to join and emulate them. Another explanation for the collegial personality of medical writers that is worth thinking about is the view that medical writing is a service and advocacy industry, with a high level of expertise and thoughtfulness required. There are, of courses, true authors among us, independent, creative, original. Most of us, however, labor within the constraints imposed by common goals: precision and correctness of language; communication of truthful information; the awareness that the information to which our communicative skills are applied, though at times seemingly of minimal or transitory values, is ultimately a matter of life and death. We also have masters, the true originators of the information we process, and formats to abide by. It is possible that the awareness, maybe only subconscious, of being 'servants' of a common cause results in the emergence of a sense of fellowship and the ways of comportment and relating to each other that EMWA and AMWA members manifest. Whatever the underlying reason(s), these organizations are the stronger and more appealing for the shared collegial personalities of their members.

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A new threat to freedom: Internet censorship

Can you imagine that one day you might be sitting at your desk and the police march in and arrest you. You then spend 10 years in prison. It happens. But what might you have done? Sent an email to a friend expressing a political opinion your government did not like? Amnesty International has launched a campaign to fight for Internet freedom. The Internet "is the new frontier in the battle between those who want to speak out, and those who want to stop them. We must not allow it to be suppressed." Amnesty International is asking for support for the representations they will be making to the United Nations when it meets in November to discuss the future of the Internet.

See: http://irrepressible.info

[1] AMWA = American Medical Writers Association

A subject requiring great patience

by Alistair Reeves

Elise Langdon-Neuner recently provided *TWS* readers with a useful table of terms for animals and people in nonclinical and clinical trials (What takes part in a clinical trial—subjects, individuals, controls, or even people? *TWS* 2005;14(4):118).

Let's take a closer look at the options. And at the same time, I'd like to give you my opinion on each.

Before that, however, a typical scenario for us medical writers when writing a protocol or study report:

- I am given a template and instructions at the kick-off meeting that says 'use patient', even though the official title of the report says 'subjects'.
- I prepare a draft with 'patient', and during the first review cycle, one reviewer crosses out 'patient' and scribbles 'Company terminology is "subject"; please use'. I try once to point out that the template and instructions say use 'patient'. No response.
- I change everything to 'subject' for the next review cycle (I have learned to check for 'insubject(s)' and 'outsubject(s)' after using search and replace!). During this cycle, one reviewer writes in the margin 'I thought we were supposed to use "patient", please change'.
- I check with the report coordinator who says he will have to contact the line manager to ask about this one. The line manager says she 'knows the template says "patient" but actually prefers "subject", and that she'll discuss this with colleagues'. Answer: use 'patient'.
- I change everything back to 'patient'.
- The report goes to the US subsidiary for review. One of the reviewers asserts: 'FDA says we have to use "subject"! Please change!'
- I am told by the European Head Office to ignore this and stick with patient.
- The report goes into wider review, including Regulatory Affairs. Someone in Regulatory Affairs says that ICH says you 'have to say "subject" so we have to change it back'. I change everything and check for 'insubject(s)' and outsubject(s)' again.
- OK, but when the report goes to QC, they say 'our template says "patient" so we have to use patient'.
- At the report finalisation meeting, I ask the report manager what we should do. I sit back while several very highly paid people once again discuss the merits of each term for about 10 minutes and then decide that they will have to address this with line management.
- Line management, QC and Regulatory Affairs have various telephone conversations and tell me to stick with patient.
- I change everything back to patient.

Moral of the story: this is a subject requiring great patience.

People in clinical trials

Patients and subjects

For me, the term for people in clinical trials is **subjects**, and **patients** are a subgroup of subjects. And that is basically it.

Elise pointed out that 'many physicians were dismayed by the FDA's suggestion that trial participants be called subjects rather than patients. They considered such a label to be hurtful to the physician-patient relationship'. Maybe it's because I am not a physician (although I am a patient from time to time), but I see nothing wrong with the word 'subject'. In fact, I think it is a good, neutral word, and I prefer it to 'participant' or 'volunteer' (see below). In our field, we use many words with a specific meaning that they do not have in general usage, because it is expedient and, as long as abuse or denigration of people is not evident, I don't think this means we are seeing the thin end of the wedge with the term 'subject'. It is quite different, of course, if you use the verb '*to subject to*': then the word 'subject' has very different connotations. Also, I am not really happy about being a *subject* of Queen Elizabeth II, although it is actually still quite legitimate to describe me as such!

My basic approach: ***Subjects*** are enrolled into Phase I–IV trials; ***patients*** are enrolled into Phase II–IV trials. You decide which to use and remain consistent.

Of course, there is a grey area with Phase I and IIa trials:

- Pharmacodynamic (PD) investigations in persons with a target disorder: ***patients*** or ***subjects***.
- Pharmacokinetic (PK) investigations in persons with renal or hepatic impairment: ***subjects***. Even though the people/persons enrolled have renal or hepatic impairment and are therefore not healthy, the aim of the study is not to establish whether the drug has any effect on the renal or hepatic impairment (although this may be an incidental finding), but whether the absorption, distribution, metabolism and excretion pattern is different from in healthy ***subjects***.
- PD and PK investigations: ***subjects***.

>>>

>>> A subject requiring great patience

Participant
I am always for brevity, so why use a four-syllable word when you have shorter alternatives: men, women, subjects, patients? 'Participant' also does not work so well used adjectivally (consider 'participant diary' instead of 'patient diary', for example).

Volunteer
My objections to volunteer are: i) it is also longer than alternatives; and ii) all people in all clinical studies, regardless of the phase, are volunteers. Using volunteer only for healthy subjects in Phase I studies does not seem correct since it suggests a different quality of participation, as if patients are not volunteers, whereas, in fact, both healthy subjects and patients have to give informed consent, have to meet inclusion criteria and not violate exclusion criteria, and may withdraw from the study at any time without giving reasons. But it would be ridiculous to talk about 'healthy and patient volunteers', for example ('unhealthy volunteers' would be a possible formulation, but 'unhealthy' has negative connotations, includes almost a 'moral' component, and often means more than just the opposite of 'healthy'). Back to: healthy subjects and patients!

Individual, male and female
You should never have cause to describe a person as a 'male', a 'female' or an 'individual'. To me, 'individual' as a noun smacks of a comic police report ("*I was proceeding down Grey Street in Newcastle when I was approached by an individual in a flat cap.*") and it is not commonly used in spoken and written British English. I appreciate that those more used to American English may feel differently about this, as I think it enjoys wider currency in the American English-speaking world.

I agree with Elise that 'male(s)' and 'female(s)' as nouns should be reserved for animals and that 'individual' should only be used adjectivally, and even then should be used sparingly, because 'single' or 'isolated' is often better.

Wherever possible, I also always prefer to use 'girl', 'boy', 'man', 'woman' or the plural. For example, if you are writing a patient narrative, in almost all cases it will be obvious that you are talking about a patient. Why not start with 'A 26-year-old man was admitted …' rather than 'A 26-year-old male patient …'? In your inclusion criteria, why not put 'Men and women aged 18 years' instead of 'Male and female patients/subjects …', or worse 'Patients of both genders …' or worse still 'Patients of either gender …'? 'Adolescent' can be a problem if it needs to be qualified to indicate the sex of the young person: 'adolescent boy(s)' or 'adolescent girl(s)' is certainly preferable to 'male/female adolescents'. The same goes for 'teenage(r)'. Do not use 'juveniles' or 'youths' for young people in our context. 'Juvenile' is used almost exclusively adjectivally: in common parlance, it is frequently collocated with the words 'delinquent' and 'offender' in British English and therefore has a negative connotation, and also often means 'immature' in the negative sense. 'Juvenile neutrophils' and 'juvenile diabetes sufferers' are quite different: here it just means 'not yet adult or mature'). 'Youth' used as a **concrete (countable) noun** is used to refer **only** to young men (at least in British English) and is also not generally used in a positive context. 'Youth' used an **abstract (uncountable) noun** is used for men and women and can have a romantic touch: 'She may be 69 years old, but she has such youth and vitality!' The adjectival use of 'youth' (youth projects, youth organisations, youth studies) is usually positive and applies to both sexes.

Untreated people in studies or people who receive placebo or vehicles
Control subject(s), untreated subject(s) or healthy subject(s), whatever is appropriate (be consistent). However tempting it may be to write, people are never just plain 'controls'—it makes them sound like rats or contact persons in a spy ring.

Other designations
What about terms like 'diabetic(s)' and 'hypertensive(s)'? Such terms are linguistically interesting because they are actually—wait for it—adjectival nouns, a device used much less frequently in English than in other languages. This is a familiar concept to speakers of languages other than English, because in many languages they are inflected (are gender-, number- and case-dependent) in some way (and are a difficult aspect of foreign languages for native English speakers to master). They are therefore often sex-specific without a modifying adjective in such languages.

When you are speaking, I think no-one could take exception to your saying 'Diabetics have a hard life because they have to stick to a very rigid diet'. As a 'hypertensive' myself, I have no problem in being referred to as just that in spoken English: 'a hypertensive'. But I think writers of English in our field should make it a general rule that they say 'diabetic girls/boys/men/women/children/patients' even sometimes 'people', perhaps 'persons' or 'the diabetic population', for example. 'Epilepsy sufferers' should also always be used in preference to 'epileptics'. This does not mean you shouldn't write 'She is epileptic' (adjective): it is 'she is **an** epileptic' (adjectival noun) which is objectionable.

I have done very little work in the psychiatric field, but I have learned from a relative of mine who works in this area in England that the accepted term for a person under treatment for psychiatric illness is now a 'client', at least in the non-hospital setting: again, a specific use of a word in our field that is different from its meaning in general usage. The problem I see here in English for us writers is how to make this sex-specific without saying 'female/male client'. This is just about the only option in this case. 'A woman client' does not sound strange, but 'a man client' does. Maybe you just have to use it often enough to make it sounds all right.

Animals in nonclinical trials

Here it is much simpler. Use the name of the species in common usage (e.g. mice, rabbits, pigs, guinea pigs [use a capital 'G' if you want], stump-tailed Macaque monkey) or just

'animals' after having mentioned the species, qualified by 'female' or 'male' for sex-specificity. It is quite acceptable, and indeed usual, to refer to animals as 'females', 'males' or 'controls'. If you object to this, then use 'female animals', 'male animals', 'control animals' or 'control group'.

Let me also get something off my chest here: 'Groups of 6 beagle dogs (each with 3 males and 3 females)' is a contradiction in terms and sounds strange. As we all know, beagles are dogs, but within the dog species, when you add the word 'dog' to the name of the subspecies (beagle, labrador, poodle) it means 'male' and when you add the word 'bitch' it means female. The latter is perfectly legitimate when used in this way ('Do you have a dog or a bitch?')—really—even though it does have a negative meaning in vulgar use. The correct general term is just 'beagle': the use of 'dog' and 'bitch' in this way, however, is usually limited to private pet ownership; in scientific investigations, the qualifying adjective that indicates the sex is 'female' or 'male', hence 'female/male beagles' and not 'female/male beagle dogs'.

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Sorting out Word's document properties

A valuable contribution was made by John Carpenter (JohnCarpenter21@aol.com) to the Ghostwriting Forum at the EMWA Spring conference in May this year. John suggested that medical writers who work on manuscripts for journals should make a habit of checking the information given in Word's document properties. In this way you can avoid wrong information being attached to the document. For example, if you are preparing a document using a template that has been sent to you, it will appear with the name of whoever drew up the template. As a medical writer you should ensure that your own name appears there, rather than the agency's or the pharmaceutical company's.

The document details can be checked as follows: with the document open, click on File (Alt F on an English keyboard), select Properties (i on an English keyboard), then select Summary (no hot key as far as John knows). Click in the field you want to change and delete or type in whatever you want.

Three of the other buttons (General, Statistics & Contents) give useful information (especially Statistics) but there's nothing you can change by overtyping. The other area (Custom) can be used to attach any information you like to the file (e.g. about other authors, agency, contributors, whether it supports product claims, whether it's been submitted, rejected, who last reviewed it, whether it's in the public domain, etc, etc.).

Reply: Words say a lot

I thank Alistair for his useful commentary and expansion on terms for animals and people partaking in nonclinical and clinical trials.

But I join issue with him on referring to people as subjects. As I stated in the box on the topic[1] many physicians were dismayed by the FDA's suggestion that trial participants should be referred to as subjects. Why should a mere word move physicians to 'dismay'? Words carry connotations. When we use the word 'subject' for another person, whether that person minds or not, it says something about how *we* consider other human beings.

Subject has a passive connation—something is done to subjects. They are used. Participant has an active connotation implying the person of his/her freewill has agreed to experiments being conducted on his or her body—a partner in the enterprise. Put another way it is a question of where the emphasis lies, as explained by Michael Sly in his editorial urging authors to avoid 'asthmatic' as a noun. Substitution of 'asthmatic patients' places more emphasis on the patient as a person[2].

You could argue that our aim in clinical trials is to help humanity but the importance of the individual should not be lost. Thus I am also worried about the attempts by the FDA to make it more difficult for a person to bring legal action against a drug manufacturer for harm caused by one of its products[3]. Likewise I was concerned when 'permanent brain damage' was listed as a 'drawback' in a drug development document that I read. This is a little more than a drawback for the individual person who suffers it, although it could be a drawback in getting the product to market.

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1 *TWS* 2005;14(4):118.
2 *Annals of Allergy, Asthma & Immunology* 1996;(6)77:435–7.
3 *NEJM* 2006;354:2409–11.

Some useful words for tight word limits

Some useful words that mean two things (albeit two different things):

Irpadake =	ripe and unripe	(Tulu, India)
Sitoshna =	cold and hot	(Tulu, India)
Merripan =	life and death	(Romani, Gypsy)
Gift =	poison and married	(Norwegian)
Danh t =	a church and a brothel	(Vietnamese)
Magazinschik =	a shopkeeper and a shoplifter	(Russian)

Source: The meaning of Tingo by Adam Jacot de Boinod, Penguin Books 2005

Too much 'Google'—Kinderwunschsprechstunde

by Alistair Reeves

For professional purposes, I generally spend about 10 hours per day at the PC or looking at paper. Sometimes I have to do longer hours and it is tough, because I have been lazy and gone off to the shops or indulged myself in some other way, and have to catch up. Whatever, I look at a computer screen almost all day, almost every day, and if I want a quick piece of information or an answer to a question, nothing seems easier than to look on Google. The answer is there somewhere—not always straightaway—but if you get your head down and refine your search, you usually find something helpful. I also have shelves full of books, of course, but I am using them decreasingly.

Once upon a time we had books and telephones and no Internet, and this is not very long ago. Some of you—like me—will remember the advent of the electric typewriter with a very small memory—and we are not ***that*** old. However, I have never been a great 'telephoner', so Google and other search engines seem made for me. But one day this year, after a frustrating Google search, I decided to telephone a few fellow EMWA members, with an amazing result.

I was working on a website dealing with a delicate subject: the surgical creation of a neovagina in women who have been unfortunate enough to be born without a vagina (this is not as uncommon as you may think: about 1 in 5,000 new births in Europe!). The syndromes responsible for this (the most common is Mayer-Rokitansky-Küster-Hauser syndrome) also mean that the women concerned cannot have children because they usually also have only a rudimentary uterus, despite normally functional ovaries. If these women wish to have children, they can do so by adopting, of course, or by using surrogate mothers, if a country's legislation permits this. The website concerned directed the women with this disorder to the 'Kinderwunschsprechstunde' at the university hospital concerned in Germany. Part of my task in writing the text for the website was to find a reasonable English expression for 'Kinderwunschsprechstunde' (literally: 'Desire-for-children clinic'). Speakers of German will be familiar with the problems with 'Kinderwunsch': finding adequate English for 'mit dringendem Kinderwunsch' (literally: 'with urgent desire-for-children) is not easy, but it sounds perfectly normal in German.

I rang several colleagues throughout Europe. If they didn't speak German, I explained the problem, and left messages with quite a few. OK: I had nothing in the screen straight away, but over the next 2 or 3 days, I had calls and messages from all of them with all sorts of suggestions, from their own experience, websites to look at, and, from all, the promise that they'd be in touch again if anything else occurred to them. And indeed, several did get in touch again more than once with helpful suggestions—and a couple even asked me months later at the conference in Lyon if I had found anything suitable.

I also learned quite a bit on the way: for example, the nuances behind the term 'parenting', that 'infertility', unlike the German 'Unfruchtbarkeit', is quite acceptable in English in this context, and that family planning 'sounds very 50s or 60s' and would be understood to mean only 'contraception'. 'Parenting' is interesting: I liked 'Parenting Clinic', because there was no idea of 'fertility' or 'infertility' in the name and the women and their partners cannot even be helped by IVF (so 'infertility' sounded a bit inappropriate: surgery is possible, so they can enjoy sexual intercourse, but pregnancy is not possible). But I learned that 'parenting', in the UK at least, is used to refer to the upbringing of children and the long-term process of 'being a parent', and not just the act of having a child.

So, not only had I received a huge amount of help with my problem, I had also actually been in contact with people rather than a machine. Those of you working for companies with daily contact with a team may feel differently about this. Those of us sitting alone can forget about the people factor, and rely all too often on only electronic help.

The only problem was, we didn't find a term we were 100% happy with—and after much deliberation finally settled on simple 'Infertility Clinic', because it is in common use in the UK. It doesn't reflect the 'desire-for-children' terminology, but these clinics perform the same function. That is sometimes how it is between different languages, there just isn't a direct equivalent. It's not too late to change, however: if anyone has any suggestions, please let me know!

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In the Bookstores and on the Net...

A guide from Italy to methodological and editorial quality

by Karen Shashok

Tom Jefferson. Attenti alle Bufale/Beware of red herrings (Internet site). Available at: http://www.attentiallebufale.it/index_en.html. Accessed 8 September 2006.

Tom Jefferson, a medical epidemiologist at the Cochrane Vaccine Field in Rome, Italy, is one of the editors of the Cochrane Acute Respiratory Infections Group and a researcher in peer review and technical editing. Along with Fiona Godlee, he co-edited *Peer Review in Health Sciences* (2nd edition, BMJ Publishing Group 2003, reviewed in the autumn 1999 issue of *TWS*). He recently published a book (in Italian) with advice about evaluating the methodological and editorial quality of health information, in an attempt to help close the gap between academia and practice. His description of the book is reproduced in the box opposite. The following is a brief review of the website inspired by the book.

Jefferson has looked at the quality of information—what information is reported and what information is missing, and how clearly the information is communicated—from the viewpoint of an epidemiologist. His judgements are thus informed by his specialist skills in weighing evidence from different sources and deciding how reliable it is. This approach to information has enabled him to develop a set of simplified instruments to evaluate the reliability of different types of print and oral documents such as original research reports, systematic reviews, clinical guidelines, adverts, websites and lectures.

The coverage of different document types and media is what makes this resource useful to researchers as well as to practising physicians and other interested parties (medical writers, authors' editors and translators, for example, as well as patients) who need to consult specialized information but who may feel underequipped to understand and use it. Jefferson has used knowledge gained from systematic reviews to develop his Quick instruments, designed so that users can reach a decision efficiently on the probable reliability of the information they need to assess. He also provides links to Full instruments when these are available elsewhere on the Net, for those with enough time to analyse the material in greater depth.

Much of the advice is applicable to information in other areas of knowledge in addition to health sciences. This is particularly so for the section "Assessing a journal", where readers will find a list of 15 criteria for editorial transparency and quality control. These features tell readers more

Tom Jefferson's description of his book Attenti alle *Bufale*

Tom Jefferson. Attenti alle Bufale. Come usare la evidence-based medicine per difendersi dai cattivi maestri, 2nd edition. Rome: Il Pensiero Scientifico Editore, 2006. 178 pages. ISBN 88 490 0153 3.

We live in a world in which incentives to produce poor research outstrip those for producing good-quality studies. At the same time healthcare workers are bombarded by unstructured information and media sound bites. Everyone is out to sell something, often themselves. Keeping up-to-date with current research and new discoveries is proving increasingly difficult, and because of the uncertain effectiveness of quality control mechanisms (such as editorial peer review), quality of research has become a real issue.

Evidence-based medicine (EBM) has evolved rapidly in part to solve the quantity and quality issues. However, classic EBM is not easy to digest or use for someone who has little or no grounding in epidemiology, statistics or health economics.

I wrote *Attenti alle Bufale* ("Beware of Red Herrings") to redress the balance between academia and practice. In Italian slang *bufale* are red herrings but in real life *bufale* are female water buffaloes. Their milk is the basic ingredient of the famous mozzarella cheese (*mozzarella di bufala*). The book offers a series of 3-minute (Quick) instruments to help healthcare workers and others who need to decide whether what they are listening to or what they are reading is worth acting on or whether it is just another red herring. Full instruments are also described alongside the Quick instruments for those readers who want to take their time going through the evidence on the topic of their choice.

The book is at present only available in Italian, but our colourful website (www.attentiallebufale.it) is partly in English and offers resources to steer a safer course in the perilous waters of contemporary biomedical research. Take a look and let us know what you think.

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>>>

>>> In the Bookstores and on the Net...

than any single numerical score can about the professionalism of editorial and review processes, and hence the trustworthiness of what the journal publishes.

At times the author can sound rather severe, as in his curt recommendation to ignore all advertisements given that their purpose is to convince readers of something that may not be entirely accurate. Hence the low "Bufala potential" of adverts, i.e., their limited ability to fool readers, since their very purpose is known in advance to be to peddle something the reader may not want. Jefferson points out, however, that advertisements are inherently biased and therefore useless as a source of reliable information (although many reputable journals happily continue to publish them.)

Regarding another type of document—economic evaluations—his warning about the high potential of these reports to contain misleading spin and red herrings is worth remembering. Jefferson may sound acerbic in his recommendation to disregard any such study which lacks a conflict of interest statement or explicit mention of who funded the work. However, the assumption that journals' editorial requirements for transparency will prevent red herrings may be too optimistic, and readers would do well to keep their scepticism close at hand. A spate of recent cases in leading journals (e.g., *The Lancet*, *JAMA*, *Science*, *Nature Neuroscience* and *Neuropsychopharmacology*) in which conflicting interests were concealed from editors, reviewers and readers suggests that the time has come to insist on full disclosure so that readers can judge for themselves whether the content might be biased in any way.

If you don't speak Italian you'll miss much of the humour on the website. In particular, the B(ufala) Movies section and board game may tantalize some of you enough to go out and learn the language. Fortunately the Quick evaluation instruments Jefferson has developed are available in both languages. The author's succinct introductory material (where he notes the limitations of his Quick instruments), the links to fuller evaluation instruments, and the generally clear and eye-catching layout make the website an efficient resource for information users who wish to brush up on their critical reading, critical listening and critical thinking skills.

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Call for mentors (for new workshop leaders)

The EPDC is continually striving to introduce new and varied workshops into the EMWA educational programme. Whilst preparing their workshop, all workshop leaders are assigned a mentor who assists in the development and introduction of their workshop by offering advice and support. In addition to needing new workshop leaders, the EPDC is also looking for experienced mentors. If you would like to apply for a mentoring role and fit the mentors job description, please contact Virginia Watson (virginia.watson@cardinal.com).

Job description

Key attributes:

Essential	Desirable
Experienced workshop leader at EMWA	Experienced trainer outside EMWA
Knowledgeable about EMWA and the EPDP	EPDC or EC member
Able to invest time and energy	Knowledge of workshop subject
Able to listen, question, challenge and support	

Key responsibilities

- Liaise between workshop leader and EPDC
- Discuss expectations and timelines with prospective workshop leader
- Guide workshop leader through defined steps of workshop development (according to Workshop Leaders' Handbook; http://emwa.org/Mum/EPDPHandbook4.pdf); providing prompting and support as appropriate
- Review materials
- Attend and evaluate workshop
- Deliver feedback to workshop leader (personal and from EPDC)
- Take a continued interest in the workshop

Webscout:

A potpourri of links introducing the world of blogs

by Joeyn Flauaus

The way we use the Internet is currently shifting in a dramatic way because blogs were invented. A blog (short for weblog) is a web site where users can easily publish their thoughts, comments, and philosophies on a ongoing basis and where literally millions of people are allowed to comment. Blogs are a dynamic medium and they usually include philosophical reflections, opinions on the Internet and social, political or science issues. With an increasing number of people reading and writing blogs, they have become a powerful source of online publication. By means of blogs, people around the world have the chance to actively design the Internet.

Here is a selection of interesting links which also includes some science blogs written by scientists and science writers. Enjoy!

http://www.seedmagazine.com

The goal of this site is the nurturing of science-savvy people around the globe. This site provides information on the most relevant, insightful and entertaining scientific results. The site includes news, features, columns and reviews from the world of science. Podcasts, slideshows and videos are also provided.

http://www.scienceblogs.com

This site aims to provide you with new insights and discoveries in the world of science (i.e., neuroscience, theoretical physics, genetics). Leading bloggers from a wide array of scientific disciplines are using ScienceBlogs as a forum for passionate dialogues about science.

http://twistedphysics.typepad.com/cocktail_party_physics

This blog from a former English major turned science writer is serving up physics with a twist as physics can be both fun and fascinating. The author is sharing the continually unfolding story of physics with people around the globe by writing about physics in a funny, funky and unconventional way.

http://www.sciencebase.com

This page gives you an overview of the latest news in the scientific world by linking to the leading online sciences sources. You can also access Sciencebase's own Elemental Discoveries and the Sciencebase Blog, which is a science blog from a freelance science writer in the fields of the physical, biomedical and life sciences.

http://www.technorati.com

If you want to know what is going on in the world of blogs and who's saying what then you have to try out Technorati. The search engine Technorati is to blogs what Google is to web sites and is currently tracking 53.3 million blogs worldwide. You can't get a better view of the current global conversation on the web. Get involved in the present discussion through your own blog by registering.

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Trilogy Writing & Consulting GmbH
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If you find a page that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at: **joeyn@trilogywriting.com**.

Paper jam

Freelance writers amass vast amounts of paper (and have to buy lots of paper too). Alison McIntosh and I recently discovered that we have the same problem. What do you do with all the tables and listings provided by clients when the job is finished, also to maintain your confidentiality agreement? If they're nearby, I sometimes drive there and say 'Please dispose of this', or I take along files no longer required to the next meeting. Otherwise, the pile grows and grows until the next paper collection (in my area in Germany, every 4 weeks—paper bins have been abolished), when it goes into the bin on the morning of the collection to minimise the time window in which a third party might see the content. Also, they come at about 07:00, so it's an early morning job and great fun in 20 cm of snow. My printer jams if I try to use the reverse side. Alison uses a shredder, but spends so long at the shredder she is thinking of adding the time to her bills. Also a personal shredder costs around £20-£30 (around 35-50 Euros) but buckles under the pressure of dealing with that amount of paper. A 'small' office shredder costs around £200 (around 320 Euros) but where on earth do you store it in your house? What do you do?

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Journal watch:

Statistics, authorship and abstracts

by Nancy Milligan

In this edition of journal watch, I will discuss a number of issues found in the recent literature: the role of medical writers in the development of the statistical analysis plan (SAP), how the structure of disclosure of contributions statements can influence the validity of authorship, the believability of significant results in abstracts, and a recent conflict-of-interest case that has caused a stir.

Medical writer's role in the statistical analysis plan

In recent years, medical writing has become an increasingly important part of the drug development process, primarily through the production of regulatory documents. The regulatory work of most medical writers involves protocols, clinical study reports (CSRs), and investigators' brochures among others; however, medical writers may also be involved in the development of SAPs. In a recent article Deborah McPhail et al [1] recommend that medical writer involvement in reviewing the SAP can benefit both the biostatistics and the subsequent medical writing of a project. They suggest that 'medical writers are an integral part of the project team and can make a significant contribution to the preparation of the SAP' and recommend that 'medical writing review of the SAP becomes a routine activity within all pharmaceutical companies and contract research organisations'. According to McPhail et al, the medical writer's familiarity of the SAP aids the planning and production of the CSR, providing them with a preview of the planned analyses and data presentations. The medical writer will also be in an ideal position to identify any deficiencies in the planned analyses described in the SAP. A medical writing review can also benefit biostatistics by minimising the number of late changes required to statistical outputs, which can reduce timelines and programming costs. McPhail et al go on to outline five key points of guidance to assist medical writers in reviewing the SAP. They suggest that the medical writer should ensure (1) completeness and consistency with the details in the protocol, (2) the key methods of statistical analysis are outlined, (3) the appropriate choice of planned data presentation and content of tables and listings, (4) clarity, and (5) correct grammar and spelling.

Authorship contributions

Our next topic concerns the issue of authorship contributions. Although the misuse of authorship is far from the worst infringement of professional integrity in biomedical research, it is a much discussed subject and clearly a questionable practice. Ana Marušic et al [2] recently published a study in which the relationship between the method of contribution disclosure and the prevalence of inappropriate authorship was investigated. 1462 authors of 332 articles submitted to the *Croatian Medical Journal* were randomly allocated to answer one of three types of research and authorship contribution disclosure form: (1) open-ended–respondents were required to describe in their own words their contributions; (2) categorical–respondents chose their contributions from a list of 11, and (3) instructional–respondents were guided through the International Committee of Medical Journal Editors [3] authorship criteria and instructed on how contributions satisfy individual criteria. The structure of the disclosure form affected the reported contributions. Although the number of authors per article did not differ between groups, compared with those completing the open-ended or categorical forms, the group completing the guided instructional form had significantly fewer honorary authors (whose reported contributions failed to meet the ICMJE criteria), in other words those who shouldn't have really been authors in the first place. This suggests that journal editors should think more about the structure of their contribution disclosure forms to elicit more accurate authorship information from their authors.

Reliability of results in abstracts

Most medical writers realise that the abstract is the first, and often the only, part of a research article that is read, which is why we go to such great lengths to communicate the most important findings in them. However, a recent paper by Peter Gøtzsche [4] investigated the reliability of the results presented in abstracts. Gøtzsche compared the distribution of P values in 520 abstracts of randomised controlled trials and observational studies that contained 'relative risk' or 'odds ratio' calculations. The results were alarming. In the majority of abstracts (≥70%), the first result given in the abstract was statistically significant, even though in 98% of the studies these findings were from subgroup or secondary analyses, or a biased selection of results. Gøtzsche also checked the accuracy of P values given in the abstract that were between 0.04 and 0.06 by comparison with the results section of the full article. The distribution of P values was extremely skewed; for example, in the controlled trials only, five trials had a P value ≥0.05 and < 0.06, whereas 29 studies gave a P value ≥0.04 and < 0.05. Further investigation found a minority of signifi-

cant results were wrong or doubtful. The lesson here for medical writers, therefore, is that care should be taken when reporting results in abstracts to ensure that what is stated reflects the true results of study, fairly and without bias.

Conflict of Interest

Finally, a heated debate has been raging after the journal *Neuropsychopharmacology* published a positive review of research on vagus nerve stimulation for treatment-resistant depression without disclosing the financial links of eight of the authors to the company that makes the treatment device (Cyberonics Inc, Texas, USA) [5]. A recent news item in *Science* has discussed the incident and said that the American College of Neuropsychopharmacology, who publish the journal, have promised a thorough investigation of the matter [6]. The journal has also published a correction. The principal author Dr Charles Nemeroff, chairman of psychiatry at Emory University and editor-in-chief of *Neuropsychopharmacology*, claimed that this was a simple omission and that all of the authors submitted disclosures although they were not printed because of what appears to be an oversight by the journal. As a consequence, Dr Nemeroff has subsequently felt it necessary to resign from his post at the journal. Of greater importance to us, however, is the uproar in the press over the preparation of the first draft of the paper by Sally Laden, a medical writer hired by Cyberonics but not listed among the authors. As you know, EMWA is strongly against ghostwriting and argues for complete transparency in declaring writing assistance; however, in this case, the medical writer and her support from Cyberonics is recognised quite clearly in the acknowledgements section of the paper. In fact, the article appears to correctly follow EMWA guidelines on the disclosure of medical writers in peer-reviewed publications [7]. This has since been pointed out in a letter to *Science* by EMWA members Adam Jacobs, Liz Wager, and Karen Shashok, which if printed will be discussed in the next journal watch. In conclusion, it seems unfortunate that even when a medical writer is properly acknowledged that some journalists still find it necessary to criticise their role.

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Where does Google come from and where is it going?

Google —go ogle— is the most successful search engine and continues to increase its share of searches over those of its closest rivals Yahoo, Microsoft MSM and Ask. Google was critically reviewed in the May issue of the *Economist* [1].

Google is the brainchild of Sergey Brin and Larry Page, both still in their early 30s. Brin, of Russian descent, is the son of a professor of statistics and a mother who works at NASA. Both Page's parents are computer-science teachers. These tailor-made backgrounds combine with the mathematical brilliance of the two founders to ensure Google's success. The search engine can return more relevant search results than those of other engines due to the calculations its founders made of the link structures between web pages. Mathematics are also behind its reliance on advertising rather than licence fees for revenue and the innovation that advertisers only pay once an internet user clicks on their links.

Within a year of its release, says the *BMJ*, more visitors were led to many biomedical journal websites by Google Scholar led than by PubMed [2]. In this article the *BMJ* also asks what will happen to physical libraries and whether doctors will still be needed to make diagnoses when this can be done through Google. The most useful feature added to Google Scholar last year according to the article was "cited by" referencing. But we are also warned that Google Scholar should not be used alone for searches for clinical trials and systematic review searches.

The *Economist* article quotes a futurist who believes Google ultimately intends to link all digital synapses created by its users into what the science fiction writer H.-G. Wells called the 'world brain'. But its critics complain that it is not adhering to its motto of simplicity and rather than continuing to add new features it should concentrate on fixing the things in its system that are not working so well. Google Video has been overtaken by YouTube, its news is not as good as Yahoo's and its instant-messaging software is tiny compared with AOL's, Yahoo's and MSN's.

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