The Write Stuff

The Journal of the European Medical Writers Association

Post-conference Issue

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EMWA European Medical Writers Association

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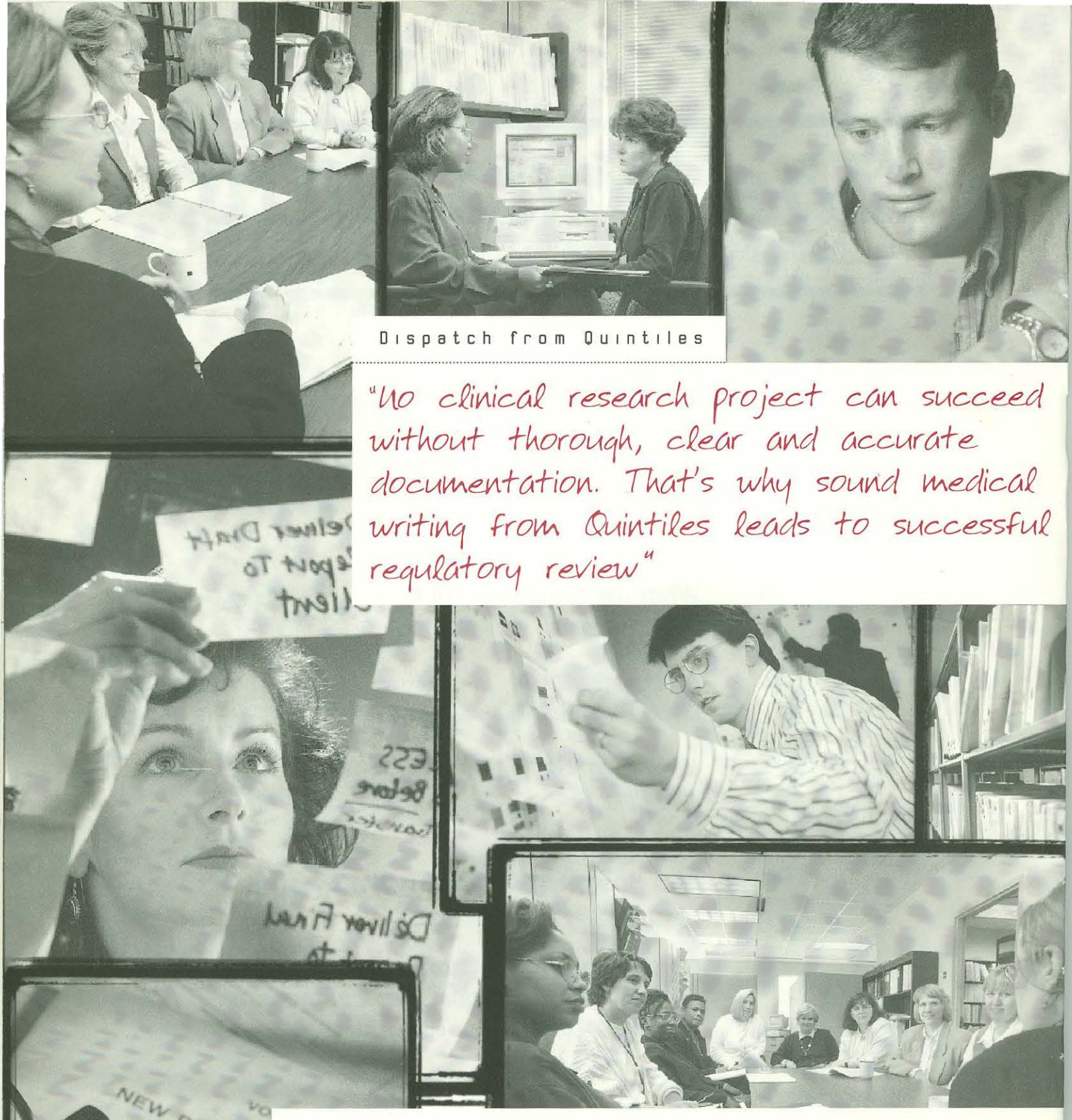

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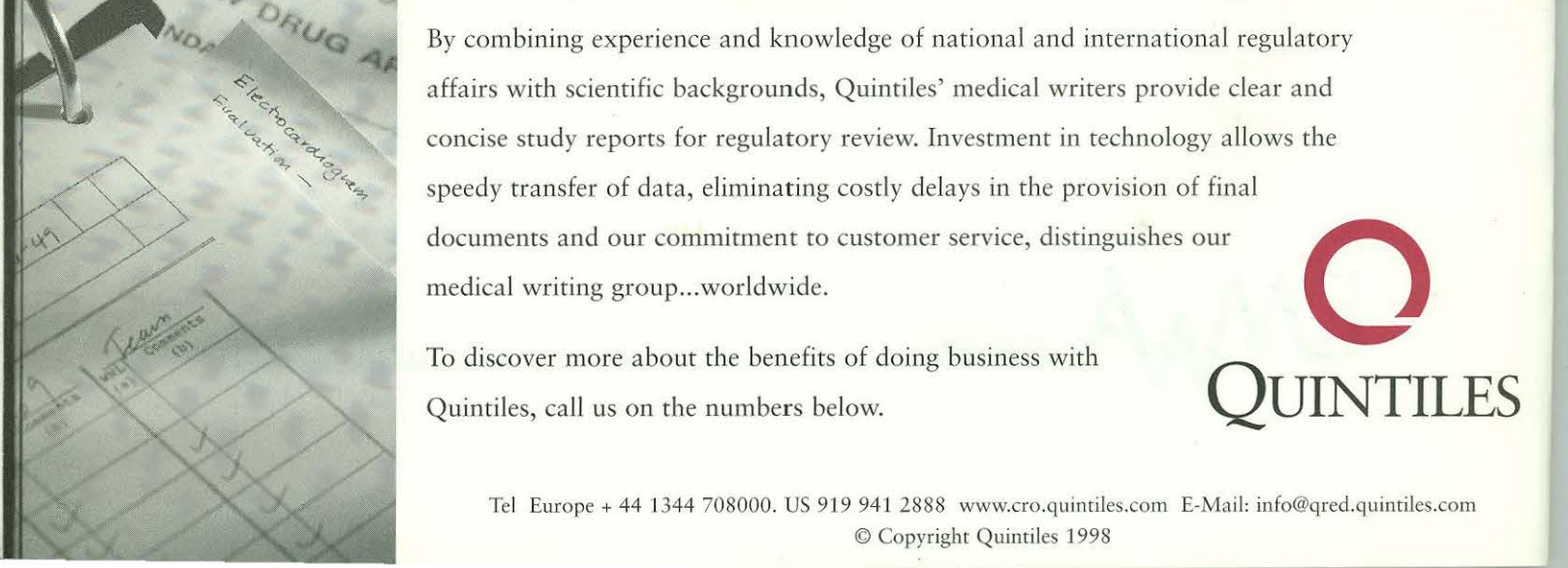

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Post-Conference issue (July)...

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

The Editor's Red Pencil

Barry Drees

Greetings fellow members,

As most of you undoubtedly have heard, I have been appointed the new editor of the EMWA Newsletter. The former editor, Keith Veitch, was overjoyed when I offered to take the position from him, but he was savvy enough to save his horror stories of trying to get people to contribute pieces until after I'd offered to do it. I would, however, still like to express both my own gratitude and that of EMWA as a whole for the heroic job that Keith performed as editor under extremely trying conditions keeping in mind that he initially took over in the days when the editor was not only responsible for the content of the newsletter but also for distribution, which was often a major headache.

I believe that one of the more pressing concerns for EMWA, as those of you who used to read my "From the President's Desk" messages last year will know, is to continue the evolution of our newsletter into an organ befitting one of the most dynamic organisations around. It was obvious to me then, even before I was editor, that this is clearly not a one-person job, especially for one person who also has a full-time position. So one of the first things I'm going to do as editor, is to establish an editorial board to help spread the various tasks around and to hopefully increase interest and participation. I spoke with some of you in Madrid and I will be contacting all of you again shortly so that hopefully I can announce the first members of our new editorial board whose responsibility will be to help me solicit and review material for the newsletter. Of course, if there are any of you out there reading this who think that you might have something to offer, would like to get a little experience as an editor, or just think it might be fun and look cool on your CV, please, by all means write or call me today, before you reconsider.

As a member of the EMWA Executive Committee for almost three years now, I've been involved in countless discussions about the newsletter and how to improve it. One thing that everyone agrees on is that it HAS to come out more often than the twice yearly we've been doing in the past, so we are going to try to bring it out four times a year. This means that we will be producing a new issue every three months, which is a very ambitious undertaking. I won't make any promises yet; but I'm certainly going to do my best.

This issue already reflects some of the changes you'll be seeing as our newsletter evolves into a really first-class member forum. First of all it has a completely new look and a new name. Many people have spoken longingly of the AMWA journal with its high gloss production, but discussions with printers convinced Gerold Wilson and I that for the time being such a format is beyond our budget. I still felt strongly, though, that we needed to give our newsletter something a bit more classy and I hope you'll agree that we've certainly achieved that. After all, we are medical writers and I've always felt that layout and presentation are important parts of what we do. We may not be up to high gloss yet, but its still an important step. Another thing that has been endlessly discussed (see the Summer/Autumn Newsletter) but never got

anywhere was the name, as everyone felt that we needed something better than just "Newsletter" but no one could agree on a new name. After sifting through a number of old suggestions (WordlyWise, First Draft, Writer's Block, Doublespeak) and some new ones (Roundtable, Report, EMWA Quarterly) I finally stole a name from an article in Nature which many people seemed to like. I hope it doesn't seem too autocratic, but I decided to just rename it without a lengthy wait for suggestions, contest and vote. Later this year we'll address the topic in depth in here and we'll reconsider a new name if people feel strongly about it.

In the issues ahead, I'm hoping to establish a number of regular features. Although EMWA membership is usually considered fairly uniform, we do have some surprising diversity which I'd like to showcase starting with the geographic diversity (this and next issue) and continuing with the various backgrounds we all bring to medical writing. Other features I'm going to pursue include: Regulatory Matters (where new drug approval issues can be discussed), Tables from the Crypt (where we will present and discuss disastrous data presentations from the literature), Medical Writing with English as a Second Language, From the President's Desk, Land of the Freelance (where our ever-increasing number of freelancers can discuss their issues), a (hopefully tasteful) humour section, and, of course, you'll be hearing from the editor every issue (and to think that I was afraid I'd lost the opportunity as president to mouth off to the membership every 3 months!).

It should be painfully obvious by now that without contributions from the members, there is no newsletter. I could probably fill four newsletters a year with my own blather, but no one wants to read that. I know that as president I've nagged you about this before (as did Keith as editor before me), but it can't be repeated enough: we NEED contributions. Please, even if you don't know what you'd like to write about, I have lots of ideas, give me a call and we'll develop something. Together we can make this an EMWA newsletter worthy of the name.

Finally, as editor, I am the person responsible for what gets printed. This doesn't necessarily mean I agree with everything that will appear here, but I hope it will always be interesting and thought-provoking. Some things we'll be presenting will be deliberately provocative with the hope of generating a response. So if you don't like something (like the new name) or disagree strongly with an article you see here, drop us a line or two, or better yet, write a response!

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What the Members Think

by Gerold Wilson

Results from the questionnaire - Madrid, March 1998

From the approximately 100 questionnaires that were given out, 29 were returned. This is really frustrating! I don't know what we can do to encourage more participation in surveys like this one, but I can't see how we can make the process even less troublesome.

I hesitate to analyse the results of the questionnaires for the simple fact that the 29 returned questionnaires represent the opinions of fewer than 15% of all members. Instead, the following is a summary of the responses to the questions. The only opinion that I would draw for the results is that workshops that cover regulatory issues or the preparation of regulatory documents appear to be those that the majority of respondents want to see offered in the future. On the other hand, this result might have come about from the fact that the majority of those who filled out questionnaires work with regulatory documentation and do not reflect the opinions of the 85% that we did not hear from.

Summary of the responses to the questions.

How did you first hear about EMWA?

AMWA: 3 responses

Colleagues: 19 responses

Literature: 7 responses

Other: 1 response (not specified)

How long have you been a member?

The average length of membership was 3.8 years. Eight respondents had been members for 1 year or less. Twelve had been members for 2 years or less. One respondent claimed to have been a member for 9 years.

What do you look to EMWA for? (more than one reply was possible)

Networking: 22 responses

Education: 26 responses

Information: 21 responses

Social contacts: 13 responses

Freelance work: 1 response

Other: response (not specified)

How many meetings have you attended?

The average number of meetings attended was 2.3. Ten of 29 respondents were at their first meeting.

We are currently considering having a second conference to increase access to the workshops. It would be a one-day meeting with no general session and would be significantly less expensive. Would you be interested in attending?

Yes: 22 responses No: 7 responses

Have you visited the EMWA internet website?

Yes: 20 responses

No (doesn't interest me, no time): 1 response

No (don't know about it): 3 responses

No (I don't have internet access): 5 responses

What do you think would improve the EMWA internet website?

There were fewer than 29 responses here. Some examples are: a site map, more dialogue, reviews of good training courses, more hyperlinks (FDA, EMEA), more PR for EMWA, and "discussion sessions" (?chats?).

How do you feel about the costs of EMWA?

Membership: Too high - 2 responses; just right - 23 responses; what a bargain - 3 responses

Conferences: Too high - 6 responses; just right - 20 responses; what a bargain - 2 responses

Workshops: Too high - 2 responses; just right - 24 responses; what a bargain - 2 responses

What is your job status? (more than one response was checked on one questionnaire)

Freelance: 5 responses

Industry: 22 responses

Academic: 1 response

Other: 2 responses (both consulting)

What was your background before becoming a medical writer? (several questionnaires had more than one response)

Life science research: 10 responses

Biometrics/Statistics: 0 responses

Pharmaceutical industry: 15 responses

Publishing: 1 response

Direct from college/university: 5 responses

Which of the following EMWA/AMWA workshops would you be interested in attending at the next conference or sometime in the future? (more than one choice was possible)

Business Aspects of a Freelance Career: **5 responses**

Writing a Clinical Study Report: **10 responses**

Data vs. Information: the CER: **8 responses**

Introduction to Pharmacokinetics: **10 responses**

Punctuation for Clarity and Style: **6 responses**

Project Management: **5 responses**

Organising the Biomedical Paper: **9 responses**

Author/Editor Relationship: **8 responses**
Making Effective Presentations: **5 responses**
Tables and Graphs: **6 responses**
Understanding Ethics Committees: **5 responses**
Advanced Tables and Graphs: **11 responses**
Regulatory Aspects of Drug Development: **15 responses**
Statistics: **6 responses**
Writing/Editing for Non-Native Speakers: **13 responses**
Effective Paragraphing: **7 responses**
Writing an Investigator's Brochure: **22 responses**
Improving Comprehension: **13 responses**
Introduction to Population Kinetics: **6 responses**
Proof Reading: **7 responses**
Ins-and-Outs of ICH: **10 responses**
Diagnosing Flaws: **4 responses**
The Study Protocol: **5 responses**
Preparing a Dossier: **15 responses**
Good Clinical Practices and Clinical Studies: **5 responses**
Basic Accounting for Freelancers: **3 responses**

Do you have any suggestions for workshop topics you would like to see offered?

Individual responses were too many and varied to fully recount here, but many respondents expressed interest in topics that are related to desktop publishing, internet, multimedia, and a number of other topics related to electronic technology and its application to medical writing.

Are you interested in obtaining AMWA Core Curriculum/Advanced certification?

Core Curriculum

Already certified: 3 responses
Already enrolled: 19 responses
Not yet enrolled, but would like to enrol: 3 responses
Not interested: 5 responses

Advanced Curriculum

Already certified: 0 responses
Already enrolled: 1 response
Not yet enrolled, but would like to enrol: 8 responses
Not interested: 7 responses

A Ghostly Crew

THE LANCET Vol. 351, April 11, 1998
(reprinted with kind permission of The Lancet and David Sharp)

Ghostwriting is what you do for a football player when it is painfully obvious from his every utterance on and of the field that he has little to say but still needs help to say it. The practice ought to have no place in scientific writing, yet it happens, notably with reports of clinical trials. Investigators do have something to say –namely, their findings and their interpretation of them– and even if writing has been neglected in their research training they will not entirely lack the means to say it. What is missing sometimes is the inclination, and what is often present is the temptation of a drafting service within or contracted to the company that sponsored the trial.

Members of the European Medical Writers Association are freelancers or emloyees of pharmaceutical companies or of contract research organisations, over half of whom are PhDs or medical graduates, who offer highly professional writing assistance. That service includes ghost writing, openly presented as exactly that by two of the organisations advertising their skills at the EMWA meeting in Madrid on March 25-27. Medical writers often work on submissions to drug-regulatory authorities, including clinical-trial material. How tempting then to treat a regulatory report as the starting point for an article to send to a journal– and how irresistible to the future signatories on that paper to have much of the tedious task of authorship removed.

At its worst company-inspired ghosted review articles[1] –the practice is one that the drug industry and writers' organisations alike should outlaw[3]. Assistance with translation, or through an author's editor service of the sort that many universities offer, is entirely legitimate. The concerns are threefold. The professional medical writer serves a client who is not usually the principal author yet has first sight of and often therefore first input into the draft; the ghost-writing arrangement goes against the spirit of author responsibility that editors have been struggling to introduce,[2, 4] and the assistance is seldom declared, it being argued presumably that, since money has been handed over by a third party, there is no need to acknowledge that not every sentence was composed by one or more of the declared authors.

"Final tables to final report– in 6 weeks", offers one such service. If a drug dossier is the object, the provenance and the style of that report are matters for the regulators. However, journal publication should mean genuine author involvement from the start, and that implies agreement on authorship way back, at the protocol stage. Not all drafting of randomised trial reports takes such a circuitous route, and most activities of medical writers do not fall into the research-publication category. Nonetheless, the issues seem worth airing, and EMWA deserves credit for allowing such mildly heretical thoughts to intrude in Madrid.

David Sharp
The Lancet, London WC18 3SL, UK

1. Editorial. Ghost with a chance in publishing undergrowth. Lancet 1993; 342: 1498-99.
2. International Committee of Medical Journal Editors. Uniform requirements for manuscripts submitted to biomedical journals. BMJ 1997; 314:2.
3. Horton R. The unmasked carnival of science. Lancet 1998; 351:688-89:
4. Rennie D, Yank V. Emanuel L. When authorship fails: a proposal to make contributors accountable. JAMA 1997; 278: 579-85.

The View from the East

Impressions of the EMWA conference and what it's like to be a Medical Writer at the farthest outpost of our organization

by Jing Ping Yeo

Despite the long flight, not to mention jet lag, I am glad I made it to the recent EMWA annual conference in Madrid, Spain. It was this EMWA meeting that gave me the opportunity to get to know many of you. I was impressed by the high level of professionalism of the participants and enjoyed sharing relevant experience and making new friends. Many thanks to the EMWA Executive Committee members, the workshop leaders and speakers for the hard work which made the conference such a valuable learning experience and enjoyable event.

During the conference, I was asked about the nature of work of a medical writer in Singapore and how it is different from the west. Currently, I am employed by Novo Nordisk Healthcare Asia Pacific Centre, a regional office in Singapore. You may be curious to know how many medical writers there are in the company and how many in Singapore? I hope the answer will not be disappointing if I reply that there is one and only one. As to the nature of the job, it is similar to Europe - producing study reports for regulatory submission and manuscripts for publications.

Are there many pharmaceutical companies and what are the job opportunities in Singapore? There is definitely a growing demand for experienced medical writers in Singapore if one looks at the increasing numbers of pharmaceutical companies and contract research organisations setting up their offices in Singapore in recent years. The growing affluence and rising living standards throughout the world have fuelled a strong demand for healthcare products and services and nowhere is this more evident than in the Asian Pacific area, the world's most economically dynamic region. To tap the numerous opportunities offered by this booming market, many enterprising pharmaceutical, healthcare and biotechnology companies have chosen Singapore as their strategic hub and springboard to Asia. Currently, more than 80 pharmaceutical companies/contract organisations have made Singapore their regional research and development base or manufacturing base. These companies include Baxter Healthcare, Becton-Dickinson, Merck, Glaxo Wellcome, Smithkline Beecham, Rhone-Poulence Rorer, Pfizer, Eli Lilly, Schering - Plough, Covance, Quintiles, Genelabs Diagnostics and Biocode.

Active steps are being taken to ensure a conducive regulatory environment to support the development of a pharmaceutical, biotechnology and healthcare cluster. The Ministry of Health (MOH) in Singapore is establishing a New Drug Unit to approve new drugs developed in Singapore. Currently, the Drug Administration Department in MOH is responsible for approval if drugs. In the area of clinical trials, Singapore hosted the inaugural Asia Pacific Ethic Committee Co-ordinating Centre for Good Clinical Practice (GCP) in 1996 to promote GCP in the region. Recently, a Singapore site is part of a multinational multicenter study to gather pivotal data for submission to the United States Food and Drug Administration (FDA) as part of a new drug application (NDA). Many existing pharmaceutical companies have carried out clinical trials in the region using Singapore as a base. Although there is still no legislation concerning GCP in some Asian countries, there is a considerable and ever growing body of expertise as

clinical investigators are well-informed and gaining increasing experience in handling the necessary documentation required in studies carried out to GCP standards.

What is it like working in a regional office? Although the scope of responsibilities is wider, it also means that you will never be bored with not having enough to do. At times, the day in the office is rather trying and you feel drained by the time you reach home. Apart from the routine job responsibilities (including the preparation of reports or key clinical documents on clinical studies for regulatory submission; involvement in the creation of project-specific databases, data validation, statistical analysis plans throughout clinical trials; initiation and preparation of publications based on clinical trial results) one also has to prepare presentation materials for investigators or medical advisors in conferences as well as filing, archiving and maintenance of all journal articles and library reading materials within the office. Hence, a lot of activities are revolving around various project groups, switching from one therapeutic field to another within the same day.

In addition to the learning experience in the various therapeutic fields, another major attraction is the exposure to studies conducted in different countries with different cultural, socioeconomic and healthcare organization backgrounds. Clinical trials are normally performed in Singapore for local registration of a new drug that has been clinically tested but not yet registered in the applicant's country (such as China, India and Korea) or for obtaining further clinical data on drugs that have already been registered. In many other Asian countries (like Malaysia, Thailand, Vietnam, Indonesia, Philippines,or Taiwan), clinical trials are carried out either for marketing purpose or for international registration; only China, Korea and India require local studies for registration. The language used for drug registrations in Asia varies depending on the country: the native language is required for China (Mandarin) and Korea (Korean); English is acceptable for Singapore, Phillipines, and Malaysia; and a combination of English and the country's native language (certain parts must be in the native language) for Thailand, Vietnam, and Taiwan. Working as a medical writer in Singapore has definitely allowed me to acquire broader business experience. Being in a regional office, which is a miniature of the headquarters in every aspect, requires: lots of perseverence, the ability to work in a team, and almost infinite flexibility.

The EMWA conference was an eye-opening experience and a great opportunity to meet all the other members. I look forward to continued interaction within the organisation and the next upcoming EMWA meeting in Copenhagen. And who knows, perhaps someday to welcoming you all to an EMWA meeting in Singapore!

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View from the West, or a Boston Yankee in EMWA's Court

EMWA, Madrid 1998 - First Impressions from Across the Atlantic
by Alice Buckley

Was it the jet lag from flying from Boston to Madrid? The melatonin I took to reset my body clock? Or was I imagining that the first gathering of EMWA colleagues I stumbled upon was sprinkled liberally with American accents - and not just my own? After a few calls to AMWA headquarters, this medical writer did become the first AMWA member to seek official citizenship with EMWA. But did they provide all these ex-pats to welcome my arrival?

Upon entering the reception area, I was met by the smile of Barry Drees. "Yup", I thought, "he does resemble his web photo." I was surprised to hear his American accent and wondered why they let an American hold the reigns of the EMWA presidency until I learned that he has been living in Germany for 13 years and considers himself more European than American. This was apparently a common phenomenon as I went on to meet Ben Young, the Madrileño who greeted me warmly, and unexpectedly, with yet another American accent, his pleasingly Southern, and Gerold Wilson, who I learned to be the incoming EMWA president with an, you guessed it, American accent. But to reassure me that I was indeed in Madrid at the annual EMWA meeting, Philippa Clow and Keith Veitch made their introductions next, aah -- finally those BBC accents we all know and love.

The remainder of the week was a terrific experience. Lots of new people, different perspectives, and some interesting sessions. Still a bit out of place, though. And it didn't have much to do with my American passport. I was on a mission to meet freelancers experienced in pharmaceutical analysis. Medical writers-- but with a different focus. After several years in the AMWA camp, I half-expected to find writers like myself who contributed to industry trade publications, like Scrip or Financial Times Healthcare. Or who were familiar with consumer-focused newsletters, patient education materials, continuing medical education packages, product monographs, or web copy. So, workshops on Good Clinical Practice and Clinical Studies, or Preparing a Dossier were not familiar to me. Where were the workshops on Techniques for Writing Public Relations Materials, Effective Interviewing, and Writing and Copyediting the Multimedia Project?

My dilemma was brought home further by a comment overhead at dinner one evening. A colleague was discussing the many differences she perceived between AMWA and EMWA. She seemed surprised that the world of medical writing in the United States includes "those who write for health newsletters". It does and it includes much more than newsletters. Particularly for freelancers, the world of medical writing in the United States offers many varied, lucrative, dare I say fun assignments. This author was paid to create a 1,000 word story on sexual frequency in America! Maybe not the most intellectually-challenging piece ever written but a nice break from the adult glioma treatise also in the works.

I came away from Madrid with an appreciation that EMWA is a very focused group dedicated to clinical pharmaceutical writing. I also wondered if this focus would expand to include a broader definition, one that welcomes other forms of medically-oriented publications (not to mention multimedia presentations) outside the domains of study protocols and clinical trial reports. Would it welcome medical journalism - the art of translating current scientific information for a technically unsophisticated audience?

In my opinion, EMWA is something special. It has the intimacy of a colleagial group all pursuing similar goals. The shared experiences seem helpful. I sought out joint EMWA/AMWA membership because I wanted to learn more about these experiences. Although I had a tour of duty living and working in London, I didn't want the experience to be relegated to my photo albums. Joint EMWA/AMWA membership appears to offer a two-way, ongoing stream of new perspectives on the way medical writing is practiced. And since I'm an American drawn to European soil, I'm curious if the comparatively younger world of European freelance medical writing will adopt some creative US influences. I'd also like to see Copenhagen next year, so would you consider a seminar on Freelance Medical Writing -- American Style? If not, how about a sail around Cape Cod or whale watching if you ever visit Boston?

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From the President's Desk

by Gerold Wilson

Dear fellow EMWA members

As your new president, I intend to continue the tradition of communicating with you regularly, both in the EMWA Newsletter and at our website, to keep you informed about what the Executive Committee is doing. I hope that this will inspire you to contact me or any other member of the EC with your thoughts, ideas, and comments about our organisation. If you contact me, please use my e-mail address (either gerold.wilson@schering.de or 101632.2654@compuserve.com).

I hope that all of you who attended the conference in Madrid had an enjoyable time meeting with old and new friends, learning new skills, and taking advantage of all Madrid has to offer.

Now that the dust from the annual conference has settled this would be a good time (and place) to thank those who made the wonderful three days we spent together in sunny Madrid possible. First and foremost, I would like to thank Ben Young, who as programme manager, selected the venue and spent many hours working on the organisation of the conference at the hotel. Ben also arranged for the conference bags (how many of you noticed the dates??).

Fiona Swain was a whirlwind of activity in the early planning phase, scouring the continent for workshop leaders, pleading, twisting arms and bringing her considerable charm to bear. Her success in providing us with a superb slate of workshop leaders speaks for itself. Our thanks are also in order to the other members of the Executive Committee for their kind assistance, wise counsel, and much appreciated support.

Last, but not least, a special thanks to Phillipa Clow for the many hours of work and excellent, timely suggestions that helped make the conference work.

I received a few e-mails from members who felt that the business meeting in Madrid was not held in a manner that reflected the professional nature of our association. Those who wrote to me were, among other things, critical of the fact that there was no written agenda for the business meeting, that motions were not seconded (Have you ever attended a meeting where motions were not seconded?; after a while it becomes a contest - is it my turn to second?), and that the Executive Committee members did not give their reports before voting for new EC members.

If these are a widely held opinions, please accept my apologies. I will encourage those responsible for next year's conference in Copenhagen to prepare a written agenda in advance of the business meeting and I will pass the comments on to Geoff Hall so that he can give some thought as to the appropriate manner to conduct the business meeting in Copenhagen.

I have attended three EMWA annual conferences and three business meetings. So far, we have not used a set of formal rules to govern the meeting. I like to think that the business meeting is an opportunity for those interested in the day-to-day operation of EMWA and interested in EMWA's future to sit together and simply discuss those issues that have a bearing on who we are and where we are going. If this is no longer the case, so be it. But, I regret the passing of the "old" way of doing things.

The letters I received also discussed the timing of the business meeting. I have been directly involved in the planning of two of the last three conferences (Berlin 1996 - Programme Manager; Madrid 1998 - Conference Chairman). The timing of the business meeting is the single most discussed item in the planning of the conferences. There are pros and cons to each and every time slot proposed. One of the suggestions I received proposed holding the business meeting in the late afternoon of the first day (after the second workshop session and before the conference banquet). Personally, I do not agree with this schedule. I think a number of delegates would like to have some time to themselves after attending workshops all day, but I will pass the suggestions I received on to those responsible for planning the Copenhagen conference.

I look forward to working with this year's Executive Committee. I have worked with most of the members before and I know that they are a group of dynamic, forward-thinking professionals. I extend a hearty welcome to our three new members, Geoff Hall (Vice-President), Barbara Grossman (Treasurer), and Julia Cooper (Educational Development). From my conversations with them, I am positive that they, too, will make super additions to this fine team.

Barry Drees, in his first address to you, stated that he saw his upcoming year as president as being one of excitement. It certainly was and the excitement continues (and perhaps, always will). In the coming year, the Executive Committee has a year of change and challenge ahead of us. We hope to accomplish a number of things before the next conference in Copenhagen.

The approval of the constitution/by-laws at the business meeting in Madrid makes it possible for us to become an incorporated entity in the UK. The Executive Committee will begin action on this in the next few weeks. This important step will immeasurably add to the legitimacy of EMWA as an organisation and is the natural progression of our change from an AMWA chapter to an independent association. In conjunction with this, we will move our account to the UK in 1998 and try to set up the mechanisms to enable EMWA members to pay membership dues and conference fees with credit cards. Many members have asked about this in the past and I think this will greatly simplify financial transactions within the association.

Barry Drees and Jane Stock, our Public Relations Officer laid the groundwork last year for our corporate sponsorship initiative. This year, Jane, Debbie Jordan (who has agreed to continue to be the Membership Officer), and I will work more on this. We have every expectation that we can implement this programme this year. Corporate sponsorship will give EMWA a greater degree of financial latitude to offer the members wider educational opportunities, such as a second, perhaps 1-2 day workshop session per year. Also, with additional funds, we would be able to improve the newsletter format and appearance. I welcome your thoughts and ideas on this topic.

Continuing growth in membership is another issue that the Executive Committee will focus on this year. In this respect, I have already asked Jane and Debbie to work directly with me to develop some ideas as to how we can attract new members and what we can do to make EMWA more appealing to retain current members. I will keep you posted as work on this issue progresses.

As Tim Perrot reported to you at the business meeting, he and others are still collecting information for our proposal for a masters degree programme in medical writing. I have asked him to present his findings and a slate of options at the next Executive Committee meeting and to prepare a presentation (perhaps a poster) for the next annual conference. I suggest that we include this as a topic on the agenda for the next business meeting and make a decision about whether to pursue this or not. We were recently contacted by a group affiliated with a university in USA. This group is already starting a similar programme and wants to exchange ideas with EMWA. The Executive Committee will stay in contact with the group and report to the membership when more details are available.

Phillipa Clow has proven to be a real asset. Those of you who attended the conference in Madrid saw first hand the benefits of Phillipa's professionalism. We will continue to work with Phillipa and, to the extent that funds permit, we will increasingly call on her to help the Executive Committee provide as many services to you that we can.

At the conference in Edinburgh in 1997, the Executive Committee passed out questionnaires for the first time to those attending the conference. This was repeated in Madrid. I am sorry to say that from nearly 100 passed out, only 29 were returned. These questionnaires provide the Executive Committee with valuable information about the demographic makeup of the membership and insight into what members would like to see in the future. The organising committee for the annual conference has used information from the section of the questionnaire that asks about the workshops that members would like to see offered in the future to plan conferences. This information has already been passed on to Julia Cooper. She and Geoff will use it as a starting point to plan the workshops for Copenhagen. We will send another, similar questionnaire out to all members in the next few months. Please fill it out and return it. This is the only way we have to collect this information.

The results from the questionnaire we passed out in Madrid, reported elsewhere in this issue, are not remarkably different than those we saw last year.

Finally, let me give you an early glimpse at the next conference. At lunch one day in Madrid we (Susanne Wedderkopp, Hanne Anderson, Mary Ryan, Barry Drees, Ben Young, Gerold Wilson) had a meeting about the conference in Copenhagen. I was really impressed with how much work our colleagues at Novo Nordisk (Susanne, Hanne, Mary) have already put into the conference planning. The venue has been selected (and after the conclusion of the Madrid conference, confirmed). In 1999, the conference will be held at a conference center in the center of the city, within walking distance to a number of hotels in all price ranges (remember, Copenhagen is not an inexpensive city). The conference center has excellent facilities and I am sure that our requirements will be more than met. Currently, at least 12 workshops are planned (we are also looking at 14). In addition to the workshops, Susanne Wedderkopp put forth the brilliant idea of plenary sessions running parallel to the workshops. The topics at

the plenary sessions will complement workshop topics and, in the current state of planning, will probably be in the form of discussion groups or forums lasting for 1-3 hours. They will be designed so that participants can pop in and out according to their interests. The plenary sessions will also replace the panel discussion, leaving us most of the morning on Friday for the General Business Meeting (if the organisers plan the meeting for this time slot), which would mean that we could all eat lunch together before departing for home.

I am really excited and looking forward to what looks like our best conference yet. I hope that you can join us there!

Gerold Wilson

Berlin, April 1998

CONSORTing With a Quorum of MOOSES: What it takes to Report Medical Research

by Thomas A. Lang

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ALMOST AS DIFFICULT AS CONDUCTING MEDICAL research is reporting it in the scientific literature. (Indeed, if reporting medical research were easy, many medical writers and editors would be out of work.) The difficulty lies not just in how to write clearly and concisely but also in knowing what characteristics of the research need to be reported. As a result, many scientific articles, even well written ones, are actually of poor quality.

Although complaints about the poor quality of articles describing clinical research go back at least 50 years, serious efforts to address this problem have appeared only in the past few. Driven by the notion of evidence-based (read: literature-based) medicine and the increased use of systematic reviews and meta-analyses in medicine-both of which require accurate and complete research reports for their own validity-the movement to improve the quality of scientific reporting is now well underway.

In this article, I briefly describe some recent activities in the movement to improve the reporting of research and the guidelines that have come from these activities. In addition, I elaborate on the opportunities that this movement presents to medical writers and editors.

CONSORTing. . .

In late 1993, an international group called the Standards Of Reporting Trials (SORT) group began to develop a checklist for reporting randomized controlled clinical trials. This multi-disciplinary group of experts convened in Ottawa, Canada, to identify those characteristics of a clinical trial that evidence had shown could alter the conclusions of a trial if they were not reported accurately or completely. That is, the characteristics selected for reporting were evidence-based whenever possible and were not simply the opinions of a lone author or the consensus of a group of experts. These characteristics were then incorporated into a checklist of 32 items and a format for reporting trials.[1]
This checklist was applied to a published clinical trial for the first time by JAMA in 1994[2]. Each item on the checklist was cast as a subheading in the article in an attempt to provide "structured reporting" of the research. The result was an article that contained everything it should but that lacked continuity and was difficult to read. As a result, the structured format was not used again, although the checklist was retained, as described below.
In early 1994, independently of the SORT group, members of the Council of Biology Editors and the American Medical Writers Association met at the Asilomar Conference

Center in Monterey, California, to develop a checklist for the same purpose. This group-the Asilomar Working Group-consisted of journal editors, manuscript editors, biostatisticians, researchers, and information scientists. This group eventually published an initial checklist of 23 items with a call for comments[2] and, later, a final checklist of 39 items.[3] At the urging of the editors of JAMA, the SORT group and the Asilomar Working Group met and combined their recommendations into what has become the CONsolidated Standards Of Reporting Trials (CONSORT) checklist of 21 items (Table).[4]

Several dozen sets of guidelines for reporting clinical trials have been suggested by individual authors over the years, and the CONSORT checklist does not differ greatly from most of these guidelines. What makes the CONSORT checklist different is that it is being adopted as a requirement for publication by many medical journals.

As of January 1997, JAMA, the first journal to adopt the CONSORT checklist, has required authors submitting manuscripts reporting randomized clinical trials to include all the information on the checklist and to indicate on the checklist the manuscript page number on which each guideline is addressed. The checklist is sent to reviewers but is not published. The checklist provides authors with a means to assess the completeness of their reports before submittal, and journal editors and reviewers can now assess the adequacy of the trial more quickly by turning directly to the manuscript pages on which key
characteristics are described. The vast majority of letters received by JAMA regarding the checklist have been positive, and more than 80 journals worldwide have adopted or are considering adopting the checklist.[5]

...With a QUORUM. . .

Reports of clinical trials are the "data" from which systematic reviews and meta-analyses are created. A systematic review is a review article in which the articles to be reviewed are identified through a systematic and thorough search of the published (and often unpublished) literature on a topic and then selected for review according to a set of inclusion and exclusion criteria. Sometimes, the selected articles are combined and analyzed statistically in what is called a meta-analysis. In both systematic reviews and meta-analyses, the process by which the articles were identified and selected for review is (or should be) defined in advance and is reported fully in the Methods section of the review article. In contrast, in the traditional narrative review article, the articles are identified generally through an unsystematic and unspecified process, which increases the chance for bias in the identification and selection processes.
In 1996, a multi disciplinary group similar to the SORT group in composition and purpose convened as the QUality Of Reporting Meta-analysis group (QUORM) to develop guidelines for reporting systematic reviews and meta-analyses based on randomized controlled trials. The group has completed its checklist but will validate its utility before publishing it. The validity of the CONSORT checklist will also be tested in this trial (David Moher, MSc, personal communications, July 1997).
In yet another effort, a group of epidemiologists and biostatisticians met in Potsdam, Germany, as the Potsdam Consultation on Meta-Analysis.

Unfortunately, this group did not produce a useful acronym. However, it did produce a set of reporting requirements for meta-analyses of randomized controlled trials. The results of this meeting are published in the January 1995 issue of the Journal of Clinical Epidemiology. The last article of the issue is the set of guidelines proposed by this group.[6]

...Of MOOSES

Once guidelines had been developed for reporting randomized controlled clinical trials and for systematic reviews and meta-analyses based on randomized controlled trials, the next obvious step was to develop guidelines for reporting meta-analyses of observational trials. Thus was formed the Meta analysis Of Observational Studies in Epidemiology (MOOSE) group, which met in 1997 in Atlanta, Georgia, under the auspices of the Centers for Disease Control and Prevention. The issue here is that observational studies (primarily retrospective "case control" studies and prospective "cohort studies") are subject to more and different biases than are randomized controlled trials. Guidelines are needed to ensure that these biases and the heterogeneity of the studies to be combined have been adequately addressed in the meta-analysis.
These guidelines are still in development, but they are not expected to differ greatly from those for meta-analyses of randomized trials.

Implications for Medical Writers and Editors

The movement to set standards for reporting biomedical research offers medical writers and editors several opportunities: 1994.[7] Each item on the checklist was cast as a subheading in the article, in an

- We can improve our value added. As writers and editors, we are used to editing manuscripts to meet style and format requirements. We can do the same with scientific reporting requirements, a little study, and appropriate references.[1,4,5,7,8] To our current services of writing and editing we can add the ability to report or to edit research designs, methodologies, and statistical analyses (a service I refer to as "analytical editing," in contrast to copy editing and substantive editing.)
- We can improve the quality of the manuscripts that we write or edit. By assuring that research reports contain all the information they need to meet these new reporting standards, we improve the quality of these reports. We may call the authors' attention to errors or omissions before submittal and make manuscripts easier to review. These acts, in turn, may improve the likelihood of acceptance for publication and may lead to a better reception by readers after publication.
- We can establish a credibility that we have not had before. Many authors know little about the details of the design, statistical analysis, or reporting of biomedical research. By learning reporting requirements for these topics (a task quite different from learning how to design and analyze research studies), we can make unique and substantive contributions to the papers we prepare. In so doing, we become more credible, and with credibility comes professional respect and advancement.

In short, by involving ourselves in the standards movement, we can extend the

scope of our expertise beyond language, critical thinking, and communication skills; create new opportunities for professional growth, especially among senior writers and editors; improve our professional image and credibility; and generally help enhance scientific progress.

References

1. The Standards of Reporting Trials Group. A proposal for structured reporting of randomized controlled trials. JAMA 1994; 272(24): 1926-31.
   Correction: JAMA 1995; 273 (10):776.
2. Williams JW Jr, Holleman DR, Samsa GP, Simel DL. Randomized controlled trial of 3 vs 10 days of trimethoprim/ sulfamethoxazole for acute maxillary sinusitis. JAMA 1995; 273(13): 1015-21.
3. Working Group on Recommendations for Reporting Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature. Ann Intern Med 1994; 121(11): 894-5
4. The Asilomar Working Group on Recommendations for Reporting Clinical Trials in the Biomedical Literature. Checklist of information for inclusion in reports of clinical trials. Ann Intern Med 1996;124(8):741-3.
5. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials: The CONSORT Statement. JAMA 1996;276(8): 637-9.
6. Altman DG, Moher D, Rennie D. Authors' reply. BMJ: 1997; 314(7087): 1127. Response to Meade TW, Wald N, Collins R. CONSORT statement on the reporting standards of clinical trials. Recommendations are inappropriate for trial reports. BMJ: 1997; 314(7087): 1126.
7. Cook DJ, Sackett DL, Spitzer WO. Methodologic guidelines for systematic reviews of randomized control trials in health care from the Potsdam Consultation on Meta-Analysis. J Clin Epidemiol 1995;48(1):167-71.
8. Lang TA, Secic M. How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers. Philadelphia: American College of Physicians, 1997.

EMWA EDITOR'S NOTE: Readers interested in the CONSORT statement should should also see:

1. Meinert CL. Beyond CONSORT: need for improved reporting standards for clinical trials. JAMA 1998; 279: 1487-89.
2. Moher D. CONSORT: an evolving tool to help improve the quality of reports of randomized controlled trials. JAMA 1998; 279: 1489-91.

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Table. The CONSORT checklist of 21 items for reporting randomized controlled clinical trials[5]

☐ **TITLE:** Identify the study as a randomized trial

☐ **ABSTRACT:** Use a structured format

INTRODUCTION

☐ State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses

METHODS

Protocol: Describe the

- ☐ Planned study population, together with inclusion/exclusion criteria
- ☐ Planned interventions and their timing
- ☐ Primary and secondary outcome measure(s) and the minimum important difference(s), and indicate how the target sample size was projected
- ☐ Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis
- ☐ Prospectively designed stopping rules (if warranted)

Assignment: Describe the

- ☐ Unit of randomization (e. g., individual, cluster, geographic)
- ☐ Method used to generate the allocation schedule
- ☐ Method of allocation concealment and timing of assignment
- ☐ Method to separate the generator from the executor of assignment

Masking (blinding)

- ☐ Describe mechanism (e. g., capsules, tablets); similarity of treatment characteristics (e.g., appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful blinding among participants, person doing the intervention, outcome assessors, and data analysts

RESULTS

Participant Flow and Follow-Up

- ☐ Provide a trial profile (a figure) summarizing participant flow, numbers and timing of randomization assignment, interventions, and measurements for each randomized group

ANALYSIS

- ☐ State estimated effect of intervention on primary and secondary outcomes measures, including a point estimate and measure of precision (confidence interval)
- ☐ State results in absolute numbers when feasible (e.g., 10/20, not 50%)
- ☐ Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication
- ☐ Describe prognostic variables by treatment group and any attempt to adjust for them
- ☐ Describe protocol deviations from the study as planned, together with the reasons

COMMENT

- ☐ State specific interpretation of the study findings, including sources of bias and imprecision (internal validity), and discuss external validity, including appropriate quantitative measures when possible
- ☐ State general interpretations of the data in light of the totality of the available evidence

Website Update

'Privatisation' by Marian Hodges

Some members have commented that EMWA has been providing something for nothing by giving unlimited access to the EMWA website. So, from xx July* parts of the site will be accessible by members only.

The sections moving into the 'private' area will include Newsdesk, 'From the president's desk', the website links list, and Dialogue. The EMWA freelance list will remain on the 'open' section of the site, as will the 'Work available' section: job advertisements help to fund the site and advertisers will want to reach as large an audience as possible (and see their advert). However, EMWA members have the advantage of being able to receive immediate notification of new adverts (see below).

EMWA members will need a password to gain entry to the whole of the site. To obtain your password please email the website editor.

Job hunting?

If you are looking for a new work, or are just interested in keeping up-to-date with who's advertising, check out the 'Work available' section of the site. We can email EMWA members as soon as a new advert appears on the site. This is a confidential service (your name won't appear in a long 'cc' list at the top of the message!). To register for job advert notification email the website editor and state whether you are interested in permanent or freelance work, or both.

Calling all freelances

Do you know .....

- that you can add your name to the listing of freelance EMWA members on the EMWA website?
- that in the listing you can give a full description of the services you offer, with a link to your own website if you have one?
- that you don't have to be on the Internet to be included in the freelance list.
- that the website freelance list WORKS as a way of contacting new clients?

Inclusion in the list is open to all freelance EMWA members at an annual cost of only £10. BUT you don't need to wait until next year to sign up. Join now, for a 'special offer' fee of £5 for an entry to run until the end of the year.

Please contact the website editor for details.

Speak up

You can use the Dialogue page to air your views about issues to do with EMWA or medical writing in general, or to ask for help with a problem that has cropped up in your work. We hope that the move of the Dialogue section to the 'members only' part of the site will encourage more of you to participate.

Remember to bookmark the EMWA website at http://www.emwa.org

EMWA Webside Editor: Marian Hodges (details on page 24)

Meetings of Interest...

The following workshops, meetings, conferences, and courses are listed as a service to EMWA members. EMWA does not endorse these meetings in any way. Those having the [EMWA] symbol include presentations from EMWA members. For further information, contact Phillipa Clow at EMWA headquarters. If you would like to have something listed here to share with other members, please contact the editor, Barry Drees.

Date	Meeting/Sponsor	Location	
1998			
Sep 9-11	Foundation Course in Medical Writing Maxwell Courses	London, UK	
Sep 22	How to Write an Expert Report Rostrum Personal Development	London, UK	
Sep 24-25	Medical/Technical Writing & Associated Technologies Drug Information Association	Paris, France	**(EMWA)**
Oct 1	Medical Writing, Institüt for Management Forum	Frankfurt, Germany	**(EMWA)**
Oct 1-3	Third Tim Albert/BMJ Course for Editors of Peer-Reviewed journals	Wokingham, UK	
Oct 28-31	58th Annual Conference AMWA	Vancouver, Canada	**(EMWA)**
Nov 10-11	Understanding Pharmacokinetics Rostrum Personal Development	London, UK	
Nov 24-25	Understanding European Regulatory Requirements Rostrum Personal Development	London, UK	
Dec 12	Scientific and Technical Writing, Institüt for management Forum	Heidleberg, Germany	

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Coming next issue...(October)

The Changing Face of EMWA
Gerold Wilson and Barry Drees

A comparison of the results of the Madrid and Edinburgh conference questionnaires reveals whether and how member backgrounds and needs are changing.

The Role of Medical Writing in Scientific Citizenship
Carrie Nielson

Can medical writing save Western Civilisation? EMWA's academic ethicist presents her view on the vital role that technological writers (like us) have in bridging the dangerous gap between science and the public.

View from the South
Daleen Krige

Our series of articles from the farthest reaches of the sprawling EMWA universe takes you to the southern tip of the darkest continent, where we'll hear about medical writing in one of the newest and most exciting democracies on earth, South Africa.

Hopefully we will also have another article from the AMWA Journal, some responses to "A Ghostly Crew", and of course, we'll have our regular features (The Editor's Red Pencil and From the President's Desk) and perhaps a few new ones (Regulatory Matters, etc.). See you then.

Newsflash: EMWA mentioned in the journal "Nature"

Phillips H. The Write Stuff. Nature 1998: 393: 496-497

In the June 4th edition of the scientific journal *Nature*, there was a section about scientific careers, "Careers and recruitment" with an article about scientific writing entitled "The Write Stuff". Table 4 in this article, "Journalism and media information on the internet" listed seven websites, one of which was the EMWA website! One former academic is quoted in the article as saying that since becoming a medical writer she has "felt highly rewarded both intellectually and financially". Well, well!

Back Issues

Subject to availability, previous issues of the EMWA newsletter can be obtained for the cost of mailing by contacting Phillipa Clow at EMWA headquarters.

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