

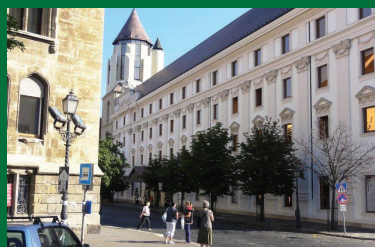
38th EMWA Conference



EUROPEAN
MEDICAL
WRITERS
ASSOCIATION

13–17 May 2014

The Hilton, Budapest, Hungary



www.emwa.org



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EMWA Head Office

Tel: +44 (0)1625 664 534

Email: info@emwa.org or emwaconference@emwa.org

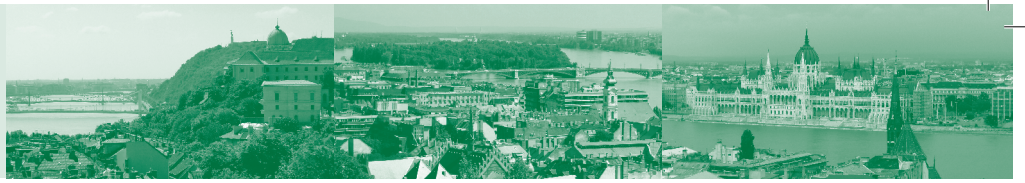


Remember to download the EMWA conference app





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Message from the

EMWA Executive Committee

Dear Colleagues,

We are delighted to invite you to the 38th EMWA Conference in Budapest, Hungary, from 13–17 May 2014.

EMWA conferences offer an unparalleled training and networking programme covering all aspects of medical writing and related topics. You can benefit from attendance in many ways, whether you are a freelancer or salaried employee, or a beginner or a professional with many years of experience:

- Stay up to date with the latest developments in medical writing at our lunchtime and early evening seminars, and at the 1-day Symposium, which now forms an integral part of EMWA's Spring Conferences.
- Gain credits towards EMWA foundation and advanced professional development certificates at credit workshops.
- Enjoy this powerful platform for networking with colleagues and making new contacts. No other event in Europe brings together so many medical writing professionals.
- Continue exchanging ideas and networking at our evenings social events, which have been chosen to enable you to experience something of the special atmosphere that Budapest has to offer.

The theme of the conference and the EMWA Symposium in Budapest is:

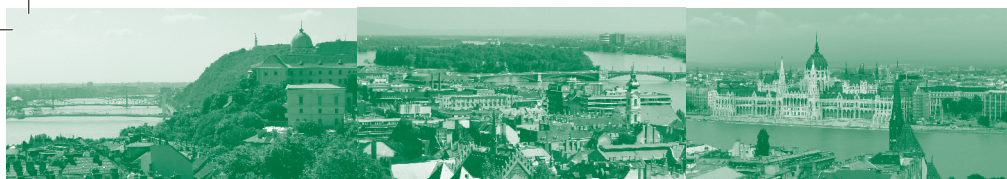
Transparency of clinical trial data – where do medical writers fit in?

The first step in the implementation of the EMA transparency act will be concerned with the publication of clinical study reports redacted as appropriate and the definition of a standard format for the submission of data. This will inevitably affect the work of medical writers and it is likely that their workload will increase now that greater levels of transparency are required. This topic also has implications for the areas of disclosure and publications. We will be bringing together representatives of the European Medicines Agency, European Federation of Pharmaceutical Industries and Associations, the European Patient's Forum and experienced medical writers and panellists to discuss the implications of this hotly debated topic for medical writers and communicators at our 1-day Symposium. This event is included in the full conference registration fee, or can be booked separately.

It is worth booking early, as spaces at workshops and seminars are limited and many fill up quickly. Early-bird registration carries an attractive discount on the regular registration fee.

We look forward to welcoming you to the conference in Budapest!

EMWA Executive Committee



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EMWA Professional Development Programme

The EMWA Professional Development Programme (EPDP) provides high-quality training for medical writers through workshops and homework assignments. All workshops are taught by leaders with hands-on expertise in the topic, and are approved by the EMWA Professional Development Committee.

EMWA workshops have both a pre-workshop exercise or pre-reading, and an assessed post-workshop assessment. Attendees who complete both are awarded an EMWA professional development credit for the workshop. The element of assessment ensures that EMWA credits represent a real attainment, and are a valuable addition to your curriculum vitae. Credits are added to your personal professional development record, which you can access through the EMWA website.

By gaining credit for eight workshops, participants can obtain an EMWA professional development certificate, as described below. Those not wanting credits can attend workshops without doing the assignments, and will receive a certificate of attendance.

Registration is limited to four credit workshops per conference. There is no limit on registration workshops or seminars that are not part of the EPDP.

Advanced workshops: There are no formal prerequisites for attending advanced workshops. However, there will not be time during advanced workshops to recap the basics of the subject for attendees who do not fit the profile in the workshop description.

Note: All workshops except not-for-credit workshops and seminars have pre- and post-workshop assignments.

Gaining EPDP credits

To receive credit for a workshop, you must:

- Download your pre-workshop assignments from the Members' only area of the EMWA website after registering for the conference.
- Complete the pre-workshop assignment (usually up to 2 hours), and submit it to the workshop leader by the deadline given, if applicable.
- Attend the workshop itself.
- Complete the post-workshop assignment (up to 3 hours) to a satisfactory standard, and submit it by the deadline given.

The times required to complete the assignments are a general guide only.

Late registrants: if you register for the conference after the deadline for the pre-workshop assignment, you should submit the assignment as soon as you can if you wish to obtain credit. Pre-workshop assignments cannot be accepted after the workshop.

Please note: it is no longer necessary to enrol for the EPDP. Instead, an administration fee will be charged for the issuing of certificates. Members who have previously paid the EPDP enrolment fee will be exempt from this for the 5 years from their date of enrolment.



EPDP certificates

The EPDP is divided into six subject areas: Drug Development, Language and Writing, Medical Communication, Medical Science, Professional Techniques, and Soft Skills.

There are two levels of certificate: Foundation and Advanced.

An EMWA Foundation Certificate is awarded for eight credits from foundation workshops as follows:

- At least five workshops in a single subject area to qualify for a specialised certificate in that option.
- Workshops in at least two subject areas but no more than four workshops per area for a multidisciplinary certificate.

Members may obtain more than one specialised Foundation Certificate after completing the appropriate requirements for each certificate.

An EMWA Advanced Certificate is awarded for credits in any eight advanced workshops. Advanced Certificates are limited to one per member. A Foundation Certificate is not a pre-requisite for an Advanced Certificate.

General

Workshops are available at EMWA conferences only. Workshops offered will depend on the availability of the workshop leaders. For the full list of EMWA workshops, see the EPDP brochure on the EMWA website (www.emwa.org).

We welcome ideas for new workshops. If you are interested in developing a workshop, please contact the Education Officer, Jo Whelan (education@emwa.org).



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Fees and Registration

Non-Members and New Members

Conference attendance is only available to members of the European Medical Writers Association. If you are not a member, you can still register online where you will be asked to create a unique account and your membership fee will be added to your registration fee. The annual fee is €130 for members living in Europe and €145 for members living outside Europe.

You do not have to be a member to attend the one-day Symposium (see below) or the Introduction to Medical Writing Seminar, but you must join EMWA if you wish to attend any of the other events at the conference.

EMWA Member Conference Registration

Register for the conference by logging in to the EMWA website at www.emwa.org. You will need your EMWA membership number and password. Registration fees are presented below. The full registration fee includes free attendance at the EMWA Symposium.

Early Registration				Regular Registration				Late Registration			
Before Monday 14 April 2014				Before Tuesday 6 May 2014				From Tuesday 6 May 2014			
Full*	2 days**	1 day	Symposium only	Full*	2 days**	1 day	Symposium only	Full*	2 days**	1 day	Symposium only
€580	€460	€230	€230	€695	€555	€280	€230	€1015	€800	€400	€230

*includes Symposium

** can include Symposium

Registration fees include conference materials, the opening networking event and welcome reception, Annual Meeting, Freelance Business Forum, Introduction to Medical Writing seminar, any lunchtime and early evening seminars, and lunches and coffee breaks on the days for which you have registered.

Registration fees are payable in advance. Full payment is due by Tuesday 6 May 2014. EMWA reserves the right to refuse admission to the conference if payment has not been received and to request payment on-site at the late registration rate.

Workshop fees

Foundation Workshop	€150
Double Foundation Workshop	€300
Advanced Workshop	€230
Seminar or Soft Skills Workshop	€110

Symposium – Non-Member Registration

The Symposium is open to members and non-members. The fees for non-members are shown below and include lunch and all refreshments.

Registration	Late Registration
Before Tuesday 6 May 2014	From Tuesday 6 May 2014
€300	€350

Changes to registration: An administration fee of €20 will be charged for changes to registration, e.g. change of workshop choice or cancellation of a workshop. There is no fee for adding workshops or social events to your registration.

Cancellation of attendance: A refund, less an administration fee of €100, will be made for written cancellations of attendance received before Monday 14 April 2014. No refunds will be made after this date, and FULL payment is due.

Payment methods: The preferred payment method is on-line by credit or debit card at the time of registration. If this is not possible, an invoice can be requested and payment made by bank transfer.

Registered accompanying persons: Accompanying persons who would like to attend the opening networking event and welcome reception, other free-of-charge events and to join the EMWA lunch and coffee breaks must be registered for the conference by the EMWA member they are accompanying. The fee for registered accompanying persons is €200 (4 days), €110 (2 days) and €60 (1 day).

Social events: Details and fees for all social events are provided in the social events section of the brochure. EMWA members, invited speakers, registered and non-registered accompanying persons are welcome to attend social events on payment of the event fee.



Conference Overview

For full workshop abstracts and leader profiles please visit the [online conference planner](#).

[Online conference planner](#)

Note: all workshops except for not-for credit workshops and seminars have pre- and post-workshop assignments

Tuesday 13 May

16:00 onwards	EMWA Registration desk opens
17:30-18:45	<p>Opening session, welcome lecture and presentation of the Geoff Hall Scholarship Award</p> <p>Budapest - What a good place to do Medical Writing, Prof András Váradi Nature was generous to Budapest putting her in a spectacular geographic situation - just go to the top of Gellért Hill and look down - but the historical buildings are not that grandiose as in Vienna to which the city is often compared. There are many layers of Budapest and everyone who is open-minded can find their own. I'll give you an example: about 10 years ago "ruin pubs" started to open. They are located in the inner courtyards of unused buildings on the Pest side. They became extremely popular as student hangout places, some of them are open till early morning, some of them run open air cinema, others offer live music each night. What a great place to do Medical Writing if you like to do so in loud music. Next day you can enjoy silence visiting the Museum of History of Medicine on the Buda side.</p> <p>Deconstructing Goulash - An irreverent look at a national favourite, Suzann Johnson We've all heard the expression, "You are what you eat." So what does the national dish of Hungary, Goulash, or Gulyas, reveal about its people? This fiery dish has been enjoyed for well over one thousand years. Journey through the history of this culinary treasure with a nutritionist and long-time friend of EMWA.</p>
18:45-20:45	Welcome Reception

Wednesday 14 May

08:45-12:15 DDF1	<p>Writing Clinical Study Reports using ICH E3 (Drug Development — Foundation) Stephen de Looze (Freelance)</p>
08:45-11:45 DDF23	<p>Drug Safety for Medical Writers Part 2: Laboratory Data (Drug Development — Foundation) Wendy Kingdom (Freelance) Gillian Pritchard (Sylexis Limited)</p>
08:45-11:45 MCF1	<p>Introduction to Manuscript Writing (Medical Communication — Foundation) Julia Forjanic Klapproth (Trilogy Writing & Consulting) Phil Leventhal (4Clinics)</p>
08:45-11:45 PTF3	<p>Using Statistics in Medical Writing (Professional Techniques — Foundation) Barry Drees (Trilogy Writing & Consulting)</p>
08:45-12:15 DDF11a	<p>Subject Narratives for Clinical Study Reports (Drug Development — Foundation) James Visanji (Trilogy Writing & Consulting)</p>
08:45-11:45 MSF5c	<p>Medical Writing for Vaccines (Medical Science — Foundation) Julia Donnelly (Freelance) Luise Kalbe (GlaxoSmithKline Vaccines)</p>
08:45-12:15 PTA10	<p>Effective Reporting of Scales, Questionnaires and VAS (Professional Techniques — Advanced) Thomas Wagner (Trilogy Writing & Consulting)</p>



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Conference Overview (continued)

08:45-12:15 DDA18	Medical Writing for Healthy Volunteer Studies (Drug Development — Advanced) Anne McDonough (McDonough Clinical Research Ltd)
08:45-12:15 MSA1	Advanced Epidemiology (Medical Science — Advanced) Rita Wellens (Wellens Clinical Research Consulting)
08:45-12:15 DDF26	Introduction to Writing for Medical Devices (Drug Development — Foundation) Claudia Frumento (ICiMT International Communication in Medicine and Technology)
09:30-11:30	Introduction to Medical Writing (Short Seminar — Not for credit) Helen Baldwin (Scinopsis)

This seminar is provided free-of-charge and is aimed at those considering a career in medical writing. It is open to conference delegates and members of the general public. It will also be interesting to those who have recently joined the profession who would like to know more. In addition to a presentation covering all aspects of medical writing, the seminar leader will act as a facilitator to optimise exchange of experience between participants, as well as providing insight based on her expertise in this area.

10:00-10:45	Refreshment break and exhibition viewing in the Ballroom foyer
12:00-13:30	Lunch Lunch will be held in the hotel restaurant
12:45-13:15	Vitamin D - an update on it's relevance for medical writers (Short seminar - Not for credit) Kathy Thomas - Urban (Freelance)
13:30-15:30	EMWA Editorial Board Meeting
13:30-16:30 PTF18	Writing for the Internet (Professional Techniques — Foundation) Jo Whelan (Textpharm Ltd)
13:30-16:30 DDF7	Introduction to Pharmacokinetics (Drug Development — Foundation) John Carpenter (Freelance)
13:30-17:00 DDA22	Summarising Clinical Safety Data for a New Drug Application (Drug Development — Advanced) Peggy Boe (Nightingale Medical Writing)
13:30-16:30 MCF5	Overcoming Publication Hurdles: Dealing with Biomedical Journals (Medical Communication — Foundation) Elise Langdon-Neuner (Freelance editor and publications consultant in biomedical sciences)
13:30-17:00 PTA6	Scheduling and Proposal Writing: The Clinical Study Protocol and Report (Professional Techniques — Advanced) Sam Hamilton (Sam Hamilton Medical Writing Services Ltd)
13:30-16:30 DDF30	Writing Risk Management Plans (Drug Development - Foundation) Tizana von Bruchhausen (Safetywriting)
13:30-17:00	Quality Awareness in Clinical Study Report Development





Conference Overview (continued)

DDF21	(Drug Development — Foundation) Nicky Dodsworth (Premier Research Group Limited)
13:30-16:30 DDF6b	From Protocol to Study Report: What's In-between? (Drug Development — Foundation) Franziska Pirkel (Kantar Health, Clinical Research)
13:30-16:30 PTF14	Time Management for Medical Writers (Professional Techniques — Foundation) Debbie Jordan (Freelance)
13:30-17:00 LWA14	The Medical Journal Article: Section-Specific Distractions (Language and Writing — Advanced) Michael L Schneir (Herman Ostrow School of Dentistry of University of Southern California)
13:30-16:30 YWLF	Workshop Leaders' Forum (By invitation)
14:45-15:30	Refreshment break and exhibition viewing in the Ballroom foyer
17:15-17:55	EMA Presentation - details to be confirmed Inga Abed, EMA
18:00-19:00	Annual Meeting



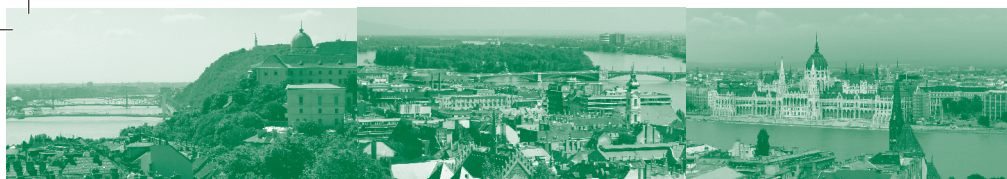
The official EMWA administrative meeting takes place once per year at the Spring Conference. In addition to formal matters of association business that require consultation of the membership (which are kept to a minimum to maximise time for other matters) this is the opportunity for members to make their opinions heard on a formal level. If you have any ideas you want to make known or want your voice to be heard, this is the place to do it. To request items to be put on the agenda, contact Lynne Fletcher at info@emwa.org. The Annual Meeting also marks the beginning and end of the President's term of office and those of other officers following the preconference electronic elections. It is also one of the few times that the entire EC and the membership come together in person, so please come along and use this opportunity to put some names to some faces and make your presence felt. We need you and want to hear what you have to say!

20:00-23:00	EMWA Spring Dinner The Castle Museum The dinner venue is a short walk from the hotel. Please meet in the lobby of the hotel at 19:45
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Thursday 15 May

09:30-16:30	2nd EMWA Symposium – see pages 15 for further details
08:45-16:30 LWF13+14	Editing and Proofreading Essentials (Double Workshop) (Language and Writing — Foundation) Barbara Grossman (Hawkeye Medical Limited) Marian Hodges (National Institute for Health and Care Excellence)
08:45-11:45 PTF19	An Introduction to Marketing for Medical Writers (Professional Techniques — Foundation) Diarmuid De Faoite (AO Foundation)
08:45-12:15 MCA4	Manuscript Writing: from Good to Excellent (Medical Communication — Advanced) Kari Skinningsrud (Limwric as)





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Conference Overview (continued)

10:00-10:45	Refreshment break and exhibition viewing in the Ballroom foyer
12:00-13:30	Lunch Lunch will be held in the hotel restaurant
13:30-16:30 MCF7	Targeting your Audience (Medical Communication — Foundation) Lisa Chamberlain James (Trilogy Writing & Consulting) Julia Forjanic Klapproth (Trilogy Writing & Consulting)
13:30-16:30 PTF13	Critical Appraisal of Medical Literature (Professional Techniques — Foundation) Adam Jacobs (Dianthus Medical Limited)
14:45-15:30	Refreshment break and exhibition viewing in the Ballroom foyer
17:15-18:45	Freelance Business Forum Sam Hamilton (Sam Hamilton Medical Writing Services Ltd) Kathryn White (Cathean Limited Medical Writing Consultancy)

This is an open forum for freelance medical writers. The aim is to share experience of dilemmas and solutions. It is an opportunity to find out how other freelancers approach the business of medical writing, to pass on any tips you might have for newcomers, and find out what freelance writers can do for, and expect from, EMWA.

19:00	Social Activities For further details see pages 19 & 20
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Friday 16 May

08:45-12:15 DDA21	Writing Clinical Evaluations for Medical Devices (Drug Development — Advanced) Claudia Frumento (ICiMT International Communication in Medicine and Technology)
08:45-11:45 DDF4	The Patient Information Leaflet (Drug Development — Foundation) Wendy Kingdom (Freelance)
08:45-12:15 PTA4	Data Presentation II: Advanced Data Presentation (Professional Techniques — Advanced) Barry Drees (Trilogy Writing & Consulting)
08:45-12:15 DDF18	Good SOP Practice: Processes and Authoring (Drug Development — Foundation) Tracy Farrow (PPD) Sam Hamilton (Sam Hamilton Medical Writing Services Ltd)
08:45-11:45 MSF6	Why do Drugs and Medicines have Adverse Effects? (Medical Science — Foundation) John Carpenter (Freelance)
08:45-12:15 MCF8	From Clinical Study Report to Manuscript (Medical Communication — Foundation) Helen Baldwin (Scinopsis)
08:45-12:15 DDF17a	Ethical Issues in Clinical Trials (Drug Development — Foundation)





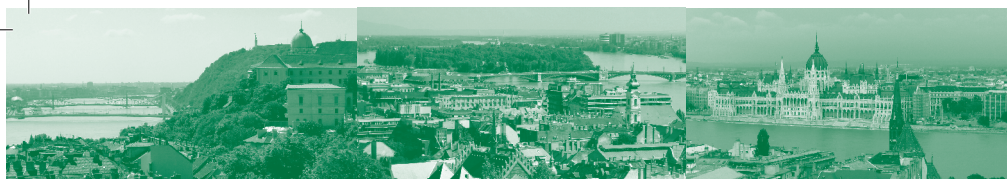
Conference Overview (continued)

	Art Gertel (TFS, Inc.)
08:45-12:15 DDA3	The CTD Clinical Summary (Drug Development — Advanced) Debbie Jordan (Freelance)
08:45-12:15 DDF28	Paediatric Clinical Trials (Drug Development — Foundation) Klaus Rose (klausrose Consulting)
08:45-12:15 DDA9	Medical Writing and Observational Studies (Drug Development — Advanced) Thomas Wagner (Trilogy Writing & Consulting)
09:00-17:00	Executive Committee Meeting
10:00-10:45	Refreshment break and exhibition viewing in the Ballroom foyer
12:00-13:30	Lunch Lunch will be held in the hotel restaurant
12:30-13:30	How to work more efficiently on your business (Short Seminar - Not for credit - Free to attend) Kathryn White (Cathean Limited Medical Writing Consultancy)

This seminar is free-of-charge and is primarily for freelance medical writers who have to juggle client demands with those of their business. Many freelancers struggle to find time to manage their personal and business needs whilst meeting client demands and deadlines. This seminar will introduce and explore the concepts of working 'on your business' as well as 'in your business', describing processes, systems and practices which may be implemented to help freelancers manage their business more efficiently while managing their clients more effectively.

13:30-17:00 DDA10	Introduction to the Paediatric Investigation Plan Application (Drug Development — Advanced) Wolfgang Thielen (CSL Behring GmbH) Douglas Feibig (Trilogy Writing & Consulting GmbH)
13:30-17:00 DDA14a	Periodic Benefit-Risk Evaluation Reports (Drug Development — Advanced) Alison Rapley (Parexel)
13:30-16:30 PTF5	Medical Writing and Quality Control of Documents Entering the Public Domain: Manuscripts and Abstracts (Professional Techniques — Foundation) Alison McIntosh (AAG Medical Writing)
13:30-17:00 PTA8	Statistical Analysis of Binary Data (Professional Techniques — Advanced) Adam Jacobs (Dianthus Medical Limited)
13:30-17:00 DDA23	Summarising Clinical Efficacy Data for a New Drug Application (Drug Development — Advanced) Peggy Boe (Nightingale Medical Writing) Thomas Schindler (Boehringer Ingelheim)
13:30-17:00 DDA19	Pharmacokinetic and Pharmacodynamic Modelling: an Overview for Medical Writers (Drug Development — Advanced) Graham Blakey (GBPK Consulting)
13:30-17:00	Master Class: Taxonomic Analysis of Medical Writing





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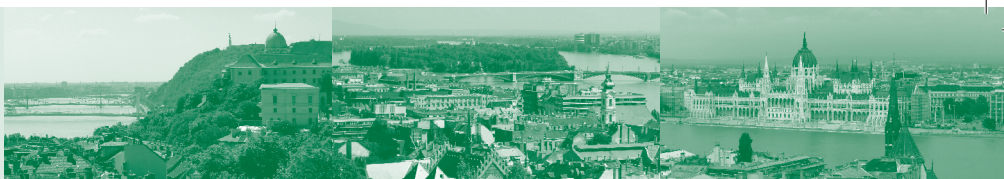
Conference Overview (continued)

LWA12	(Language and Writing — Advanced) Michael L Schneir (Herman Ostrow School of Dentistry of University of Southern California)
13:30-16:30 DDF10c	European Regulatory Procedures for Medical Writers (Drug Development — Foundation) Susan Bhatti (Premier Research Germany Ltd) Viola Hoffmann (YES Pharmaceutical Development Services GmbH)
13:30-16:30 DDF29	Protocol Amendments (Drug Development — Foundation) Walther Seiler (Bayer HealthCare AG)
13:30-17:00 DDA16	Clinical Trial Disclosure for Medical Writers: Results Posting (Drug Development — Advanced) Uma Swaminathan (GlaxoSmithKline Biologicals, Belgium) Tatjana Poplazarova (GlaxoSmithKline Biologicals, Belgium)
17:15-17:45	Seminar - to be confirmed
17:45-18:30	The Rising Tide of Plagiarism in Medical Writing Jonathan Bailey (CopyByte) (Seminar - free to attend)



Plagiarism has long been a growing issue in the medical writing field, with both incidents of retraction and incidents of rejection on the rise. The ramifications of plagiarism can reach far beyond the page and can have an impact not just on the researchers and journals facing allegations, but also on the doctors who depend on receiving high-quality research to treat their patients. In this talk, we will examine just how much the problem of plagiarism is growing in the medical writing field, what its implications are and what can be done to stop or slow its spread, including looking at plagiarism detection tools and other evaluation techniques.

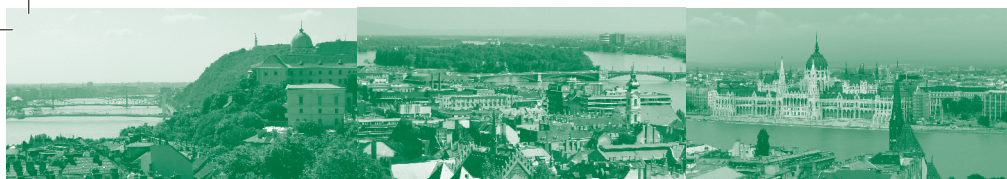
14:45-15:30	Refreshment break and exhibition viewing in the Ballroom foyer
19:00	Social Activities For further details see pages 19 & 20



Conference Overview (continued)

Saturday 17 May

08:45-11:45 MCF13	Management of Translation Projects (Medical Communication — Foundation) Laurence Auffrett (CINETIQUE Translations)
08:45-12:15 LWF8	Sharpen Up Your Writing Skills (Language and writing — Foundation) Jo Whelan (Textpharm Ltd)
08:45-12:15 PTF20	Introduction to Health Economics (Professional Techniques — Foundation) Stuart Mealing (Oxford Outcomes (ICON Plc))
08:45-12:15 DDA20	Risk Management Plans (Drug Development — Advanced) Tiziana von Bruchhausen (Safetywriting)
08:45-12:15 DDA7	Serving Two Masters: Comparing and Contrasting US and EU Regulatory Submissions and Processes (Drug Development — Advanced) Susan Bhatti (Premier Research Germany Ltd) Art Gertel (TFS, Inc.)
08:45-12:15 MSA3	Pharmacogenomics (Medical Science — Advanced) Andrea Palluch (Inpharmmedia)
08:45-12:15 LWA10	Adverbs (Language and Writing — Advanced) Susanne Geercken (Pfizer Pharma GmbH) Alistair Reeves (Ascribe Medical Writing and Translation)
09:00-12:00	EPDC Meeting
10:00-10:45	Refreshment break in the Ballroom foyer
12:00-13:30	Lunch Lunch will be held in the hotel restaurant
13:30	Delegate departure



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Conference venue and accommodation

Hilton Budapest
Hess András tér 1-3
1014 Budapest
Hungary

Tel: +36 1 889 6600
www.budapest.hilton.com



Accommodation – conference venue

Set in the heart of the Royal Castle District – a UNESCO World Heritage Site – this Budapest hotel is on the Buda side of the city, just a few steps away from Matthias Church and Fisherman's Bastion.

EMWA has reserved a number of rooms at the Hilton Budapest at the special conference rate of €59.00 per standard single room including VAT and city tax at the current rate of 22%, breakfast, and free internet access in all bedrooms and public areas. This specially negotiated rate is available for the 4 conference nights only – Tuesday 13 May to Friday 16 May inclusive.

The hotel has also agreed to offer a reduced rate of €175.00 for a standard single room for guests who wish to extend their stay in Budapest before or after the event.

A link to a dedicated EMWA booking site for the Hilton Budapest is available below.

<http://www.hilton.com/en/hi/groups/personalized/B/BUDHITW-GEMWA-20140513/index.jhtml>

The conference rate will be available until 20 March, after which the hotel reserves the right to offer rooms subject to availability at the prevailing rate.

Getting to the Hilton Budapest from the airport

Budapest airport provides a hotel minibus service that departs every 15 to 20 minutes from the airport stopping at a number of hotels, as required by the passengers. Details of this service can be found by clicking on the link below.

<http://www.airportshuttle.hu/en/>

Alternatively a taxi from the airport will take between 30 and 50 minutes depending on traffic and will cost approximately €35 to €40. Taxis can also be pre-booked via the hotel concierge for a fixed price by calling +36 1 889 6922.

With public transportation you can take bus NR200, change to metro NR3 at Kobánya Kispest and take bus NR16 at Deák Ferenc square.

<http://www3.hilton.com/en/hotels/hungary/hilton-budapest-hotel-BUDHITW/maps-directions/index.html>



Conference venue and accommodation (continued)

Accommodation – alternative hotels

With the help of our local agent we have identified 3 alternative hotels a short walk or short taxi ride away from the conference hotel. Details of these are given below. Please note that EMWA does not offer a recommendation for the accommodation quality or customer service for these alternative hotels.

To book any of these hotels at the specially negotiated rate, please remember to quote EMWA Conference and include this in the email subject line when booking.

Buda Castle Fashion Hotel: (Located approximately 5 minutes walk from the conference venue)

Úri utca 39.
1014 Budapest,
Hungary
Telephone: +36 1 224 7900
Email: info@budacastlehotel.eu
www.budacastlehotelbudapest.com

Rates (including taxes and buffet breakfast)

Single room	€105.00 per room per night plus city tax at 4%
Double/Twin room	€118.00 per room per night plus city tax at 4%

BUDAPEST ART'OTEL: (Located approximately 10 minutes walk from the conference venue)

1011 Budapest
Bem rakpart 16-19,
Hungary
Telephone: +36 1 487 9487
Email: budapest@artotel.hu
www.artotels.com/budapest-hotel-hu-h-1011/hunbuart/

Rates (including taxes and buffet breakfast)

Single room	€109/room/night
Double/Twin room	€129/room/night

HOTEL CASTLE GARDEN: (Located approximately 15 minutes walk from the conference venue)

1012 Budapest,
Lovas út 41.
Hungary
Telephone: +36 70 967 1226
Email: hotel@castlegarden.hu
<http://en.hotelcastlegarden.com/>

Rates (including taxes and buffet breakfast)

Single room	€82/room/night
Double room	€100/room/night



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EMWA 2nd Symposium

Transparency of clinical data - where does medical writing fit in?

Clinical trial disclosure and 'Transparency of clinical trial data' are terms familiar to those working on documentation for clinical trials and peer-reviewed publications based on clinical trials. These terms represent requirements imposed by law that demand greater transparency of drug development. Regardless of the sponsor, details of trial protocols and results disclosure of completed studies must be made available on a publicly accessible Internet site. These are independent and legally-binding requirements made by the USA, EU, and several countries worldwide. The topic is evolving fast, with transparency of clinical trial information taking on new dimensions, including demands seeking the release of clinical trial participant-level data in a format that can be used to re-evaluate the data by independent external experts. It is not yet clear how – and how far – this will affect medical writers. This symposium will explore in depth the immediate and future implications for medical writing.

Morning

09:30 - 09:40 **Welcome and Introduction**

09:40 - 10:20 **The Medical Writer's Perspective**

Kathy B. Thomas, Independent medical writing consultant, Meersburg, Germany

This presentation will focus on introducing the topic of Clinical Trial Disclosure, highlighting the role of medical writers in this area. A brief summary will be made of the requirements for Clinical Trial Disclosure in the USA and especially in the EU, where this topic is the subject of a great deal of activity at present. Registration of clinical study protocols for new and ongoing studies and disclosure of results for completed studies will be clarified for these two geographic regions.

Medical writers have the best skills to prepare documents based on information from clinical studies. The documents include study protocols, patient information, study results, lay language summaries of study results, and peer-review publications of clinical studies. Medical writers are well aware of the internal and external partners who are in the supply chain of information for these documents. Thus, medical writers play an essential gate-keeping role to ensure clarity as well as consistency and alignment across all documents that are based on information from clinical studies. Furthermore, medical writers with their knowledge of document structures are eminently suitable to ensure that retrospective clinical studies, which also fall under the legislation, are presented in a compliant manner for transparent and consistent sharing of information on public databases, while respecting the relevant privacy laws.

10:25 - 11:00 **The European Medicines Agency Perspective**

A speaker from the EMA has been confirmed and will also be acting as a panel member throughout the day.

11:00 - 11:20 **Panel discussion**

11:20 - 11:40 **Coffee and refreshments**

11:40 - 12:20 **The Industry Perspective**

Hans-Jürgen Lomp, Global Head of Statistics, Boehringer Ingelheim, Germany; Co-Chair of the Boehringer Ingelheim Transparency Initiative

The presentation will focus on the (already available) options to gain access to analysable patient-level clinical trial data for any well-justified research proposals. This will allow interested



professional researchers from academia and competitor companies to verify the original sponsor analysis as well as to perform secondary analysis - at the trial level, across-trial level and even across-project level. The necessary framework and the challenges in setting up this new opportunity will be presented. Using existing examples of secondary research proposals, we will discuss the potential impact of the expected “wave” of secondary analysis. One key topic is that standards for Good Statistical Practice and Good Document Writing Practice for such secondary research have not been agreed upon. Another topic is the impact on document writing standards for the original clinical documents, which now will have a potentially broader audience than just regulatory reviewers.

12:20 - 12:40 **Panel discussion**

12:45 - 14:00 **Lunch**

Afternoon Session

Moderator: Kathy B. Thomas

14:00 - 14:10 **Introduction**

14:10 - 14:45 **The Association Perspective**

Susan Forda, Vice-President, Global Regulatory Affairs International, Lilly UK, European Federation of Pharmaceutical Industries and Associations

The area of transparency of clinical data is currently under review by regulators worldwide and it is not clear what the industry can expect from the final EMA policy on ‘publication and access to clinical trial data’ to be issued in March 2014. This presentation will cover the industry response to the final EMA policy, guidance on how to interpret and implement the requirements in the context of industry-generated initiatives, and how medical writers might be involved in this process.

14:45 - 15:05 **Panel discussion**

15:10 - 15:45 **The Patient Perspective**

Transparency and beyond - the changing role of the patient
David Gilbert, Co-Chair, Centre for Patient Leadership, London, England

Consumerist expectations have helped fuel recent moves towards disclosure of data, including patients having access to their own medical records and receiving high quality evidence-based information about treatment options. But, in the patient’s relationship with medical professionals, regulators and policy making, the patient is still viewed as a passive recipient of information, rather than as an equal partner in health care decision making. Drawing on recent work in the UK that sees patients as leaders - people who seek to influence change by working in partnership with professionals - David will explore the role of the patient in the changing health care policy environment. By shifting the debate, he will outline some possible future roles for patients, within their own individual care, and at strategic level. This reframing has significant implications for regulators, the pharmaceutical industry and policy makers. It is important that professionals involved in drug development, including medical writers, are aware of these new initiatives so that they can take account of them when preparing the documentation required.

15:45 - 16:05 **Panel Discussion**

16:05 - 16:30 **Wrap-up and closing remarks**

Kathy B. Thomas



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Seminar and Symposium Speaker profiles

Jonathan Bailey

Plagiarism Today

Jonathan Bailey is a plagiarism and copyright consultant and is the author of Plagiarism Today, a site dedicated to covering plagiarism issues both online and off. In the past he has spoken at the International Plagiarism Conference, the American Medical Writer's Association Annual Conference, The European Journalism Centre Innovation Journalism Conference, SXSWi and many other tech-oriented conferences. He resides in New Orleans and operates the consulting firm CopyByte.

Helen Baldwin PhD

Scinopsis

Helen is a pharmacologist with over 25 years of experience in the biomedical field. As a research scientist in academia and the pharmaceutical industry, she authored 30 publications in scientific journals. She then spent 5 years as project leader of European clinical trials in a CRO. In 1999 she started working as a freelance medical writer in the South of France. Then in 2006 she set up Scinopsis, a service company with a small team of medical writers. Her expertise includes writing of CSRs, protocols, CTD clinical summaries and overviews, manuscripts, and biomedical translations. Helen served on the EPDC from 2006 to 2007 and held the posts of EMWA Vice President from 2007 to 2009 and President from May 2009 to May 2010.

Susane Forda

Eli Lilly

Sue trained as a pharmacist. After completing a PhD in neuropharmacology, she worked as a post-doctoral research fellow at St George's Hospital Medical School, University of London. She later joined Beecham, subsequently SmithKline Beecham Pharmaceuticals, as a regulatory associate in their Worldwide Regulatory Affairs Department where she held different positions for 9 years. Eighteen years ago she joined the Lilly European Regulatory Group and became its director in 1997. She is now responsible for all International regulatory aspects of Lilly's current and future products. In May 2003, she was awarded an MSc in the Economic Evaluation of Healthcare. Sue participates in industry association regulatory initiatives and has been Chair of the European Federation of Pharmaceutical Industries and Associations (EFPIA) "Scientific, Regulatory Manufacturing Policy Committee" since 2004.

David Gilbert

David was a consumer activist, with Health Action International and the Consumers Association in the UK helping to campaign for openness in pharmaceutical

licensing and against over-promotion of medicines. He was a consumer representative at the EMEA and UK Medicines Control Agency. He then focused on supporting national and local organisations in the UK to better engage with patients and the public, and worked at the Commission for Health Improvement (the UK inspectorate), the Kings Fund and founded the NHS Centre for Involvement. In 2006, he founded InHealth Associates, a network of engagement specialists, before teaming up with Mark Doughty three years ago to form the Centre for Patient Leadership (www.cpl-uk.com) that supports patients as influential partners and agents of change.

Sam Hamilton PhD

Sam Hamilton Medical Writing Services Ltd

Sam is a postdoctoral virologist with a multidisciplinary clinical research background since 1994. Sam has specialised in medical writing since 1998, writing extensively for regulatory authorities, and most recently managing the UK Medical Writing group for the 5th largest CRO globally before going freelance in 2006. In October 2007, Sam co-founded the regular freelance feature section 'Out on Our Own' in Medical Writing, is a section editor and regular contributor to the publication and guest-edited the March 2009 edition of TWS on the theme of regulatory writing. Sam and her team run the Freelance Business Forum at EMWA conferences and further support the EMWA freelance contingent throughout the year. Sam has been involved in content development for the past five EMWA spring conferences.

Inga Abed, Medical Writer

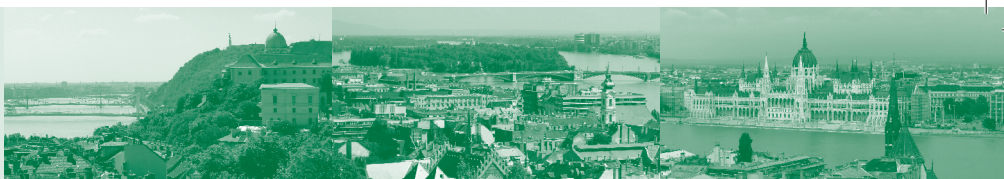
European Medicines Agency

Inga began her career as a clinical pharmacist in the NHS. She joined the European Medicines Agency in 2009 as a medical writer. In this role she writes and edits documents for patients, healthcare professionals and the general public, including question-and-answer (Q&A) documents describing the outcomes of procedures and evaluations by the Agency's scientific committees.

Suzann Johnson

Suzann is a registered dietitian with a master's degree in Nutrition and Communications who has dedicated the majority of her 30+-year career to furthering preventive medicine issues within business and industry. She has held positions with major consumer and pharmaceutical companies with the common mission of developing behavior-change programs to support the company's drugs, medical devices, or services.

Suzann has enjoyed 22 years of service with



Seminar and Symposium Speaker profiles

Johnson & Johnson, where she currently serves in Global Enrollment Strategies for Janssen Research & Development. In this position, Suzann is focusing her attention on applying behavior-change strategies to clinical trials to facilitate patient recruitment and retention.

In her “off hours,” Suzann enjoys practicing the esoteric sport of competitive carriage driving.

Hans-Jürgen Lomp

Hans-Jürgen has more than 20 years of pharma industry experience as a statistician. He worked for 10 years for Hoechst, now Sanofi, as a project statistician on diabetes and cardiovascular projects, and was also a statistics manager. He switched to Boehringer Ingelheim (BI) to become Group Head Statistics, covering all statistical aspects from basic research, non-clinical development, pharma production development, clinical development, and medical affairs support. He chaired the Statistics Leader Group in the VFA (Association of German researched-based pharma companies) for several years. In 2013, he was appointed Global Head of Statistics for BI worldwide. He is co-chair of the BI Transparency Initiative.

Tatjana Poplazarova

GlaxoSmithKline Biologicals, Belgium

Tatjana is currently Head of Medical Governance and Bioethics at GSK Biologicals and leads a team of experts promoting industry-leading medical governance and bioethical excellence for GSK. Previously, as Director of Scientific and Public Disclosure at GSK Biologicals, Tatjana was heading an international team with representatives in Asia-Pacific, Europe and the USA which was involved in both Regulatory submissions (writing of protocols, study reports, clinical study summaries) and disclosure activities (both web based disclosure and publications). Tatjana is one of the founders of the disclosure team at GSK Biologicals and spearheads both strategic and operational aspects related to Disclosure of Human Subject Research. Tatjana is also the Biologicals representative at the GSK decision making body on disclosure activities.

András Váradi

Is the head of one of the leading laboratories of ABC protein research, especially in basic biochemistry of these type of transporters. His research group has been organized in the Institute of Enzymology of Budapest in 1989 focusing on the molecular mechanism of active transport proteins. In 2001 he initiated a project to study the function of ABCC6 protein; mutations in the ABCC6 gene are associated

with two genetic diseases with arterial calcification symptoms. They found that mutations causing disease are mostly missense frequently resulting in incorrect cellular localization. Currently, he is working on preclinical projects to correct the cellular localization of mutant forms of the protein thus providing allele-specific intervention in the two disorders. Dr. Váradi has been elected to be member of Academia Europaea in 2013. Beside his scientific activity he writes short fiction stories and critical reports on art photography.

Keith Veitch

Since giving up academic biochemical research 18 years ago, Keith has been working on medical communications in the vaccine industry for several of the leading manufacturers, leading and creating publication groups at GSK Bio, Sanofi Pasteur and Novartis Vaccines, located in different countries up and down Europe. He recently set up his own company to provide consultancy and writing services to the industry. Throughout his career he has been involved in monitoring and responding to the various aspects of data disclosure as they have developed, from trial registration to patient-level data sharing.

In his time, Keith has served in EMWA, from writing the Newsletter back in the days when EMWA was simply a chapter of AMWA, to being EMWA President in 2000-2001. He has also served on the board of TIPPA, on committees in ISMPP, and advised on the CBI Publications and Disclosure conferences.

Kathryn White

Cathean Limited Medical Writing Consultancy

Kathryn worked as a clinical research manager and medical writer in the pharmaceutical industry for over 15 years, before embarking on a freelance career. Since becoming a freelancer, Kathryn has successfully worked alongside international business coach, Elaine Bailey, to improve her own work-life balance and business processes, systems and practices. This included attendance at Elaine's Business Retreat in November 2011. Kathryn has experienced first hand the significant effects this has on work-life balance and your business. In summer 2012, Kathryn initiated the first UK medical writers' retreat for freelancers with Elaine Bailey's support. She provided group coaching including concepts discussed in her seminar. The retreat was well attended and received very positive feedback.



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Social programme

Gala dinner: Wednesday 14th May 2013 from 19:00

€70 per person including all food and drinks

The gala dinner will take place in the beautiful Baroque Hall courtyard, part of the Budapest History Museum. Guests will enjoy a four-course meal prepared by Restaurant Alabárdos, one of Hungary's top ten restaurants. Guests will be treated to some traditional Hungarian music during the evening.



Social activities: Thursday 15th May 2013 from 19:00

OPTION 1: Széchenyi Bath

from 19:00 (3 hours including transfer times)

€60 per person, includes transfers, bath kit and English speaking guide

Maximum per tour 15

The Széchenyi Bath is located on the Pest side, in the City Park. It is the biggest bathing complex in Europe. The spa, housed in a Neo-Baroque building, was constructed in 1909. In addition to the usual indoor thermal pools, it also boasts outdoor thermal and swimming pools complete with sun terraces. With the hottest spa-water in the city, reaching the surface at a temperature of 75° C (180° F), the outdoor thermal pool is popular even in the depths of winter.



The springs, rich in minerals, are distinguished by their alleged healing properties. They are recommended for treating rheumatism and disorders of the nervous system, joints and muscles.

OPTION 2: Walking tour with Secret Military Hospital

Thursday 15th May and Friday 16th May 2013 from 19:00 (approx. 2 ½ hours)

€28 per person (includes English speaking guide, entry to the Fisherman's Bastion and Secret Military Hospital)

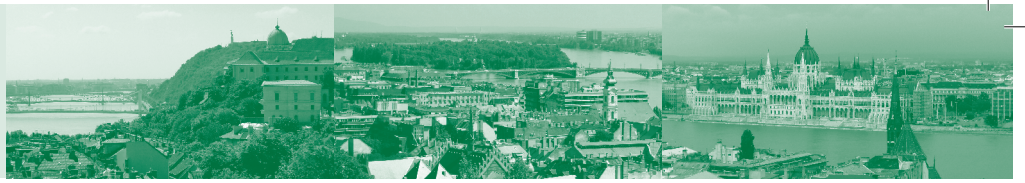
Maximum per tour 25.

One of the most historic parts of Budapest is the World Heritage area known as the Castle District. The Castle Hill is a 1 ½ kilometre long flat crag, packed with houses. The tour begins with a visit to the Secret Military Hospital and Atomic Bunker where you will see parts of the buildings that were built and extensively used during the Second World War and the siege of Budapest. This tour provides a truly remarkable, intense visual experience that really moves the visitor.

The tour continues at the Royal Palace which was totally demolished in the 16th-17th century. The construction of the "new building" that can be seen today started in the 18th century, but was heavily damaged again during World War II. Today, it houses three large museums and the national Széchényi Library. Magnificent views of the River Danube can be seen from the Palace.

The tour continues to the heart of the district and on to the Matthias Church and the Fishermen's Bastion. The Fishermen's Bastion is a lookout terrace with five round towers and a main tower with several floors.





Social programme (continued)

OPTION 3: Hungarian Wine Tasting

Thursday 15th May from 19:00 (2 hours)

€50 per person including tasting and nibbles

Maximum per tour 30



Listed as one of the top ten restaurants in Hungary and highly recommended by Michelin, Restaurant

Alabárdos will host a wine tasting evening in their 700 year old historic wine cellar below the restaurant. Guests will have the opportunity to sample 5 different Hungarian wines led by the restaurant's Sommelier.

The tasting will be accompanied by small gourmet bites to compliment each wine.

OPTION 4: Hungarian folk dance demonstration & workshop

Thursday 15th May 2013 from 19:00 – 21:00 (2 hours including dancing lessons and a live show)

€45 per person including drinks

Maximum 30 dancers

Founded in 1992, the Angyalföldi Vadrózsa Ensemble dance group have discovered how their ancestors danced at the beginning to middle of the 20th century. Hungarian folk dance is a rich, well researched and lively aspect of Hungarian culture. Guests will learn some of the Hungarian dances of the Carpathian Basin. Drinks will be available.





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FUTURE EVENTS

39th EMWA Conference

6–8 November 2014

The Grand Mediterraneo Hotel, Florence, Italy

40th EMWA Conference

5–9 May 2015

The DoubleTree Hotel, Dublin, Ireland

41st EMWA Conference

5–7 November 2015

The Bel Air Hotel, The Hague, Netherlands

42nd EMWA Conference

10–14 May 2016

The Sheraton Hotel, Arabella Park,
Munich, Germany

39th EMWA Conference



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6–8 November 2014

The Grand Mediterraneo Hotel, Florence, Italy



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