2016 EUROPEAN MEETING OF ISMPP

PUBLICATION PLANNING IN PRACTICE: OVERCOMING CHALLENGES IN THE AGE OF TRANSPARENCY

19-20 January, 2016

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ISMPP International Society for Medical Publication Professionals™

DEAR COLLEAGUES:

To be effective, medical publication professionals must stay current with the continuous evolution of guidelines and regulations, occasionally make judgment calls on ethical "grey areas," and navigate a changing landscape while upholding good publication practices. To help members meet these challenges, this year's meeting dispenses with the theoretical and focusses on the practical skills that drive successful publication delivery.

Every year, we work hard to retain content that meets with favorable response, discard that which does not, and adapt educational offerings according to member feedback. Thus we have increased the number of roundtable options from two to three, and we are repeating and expanding the popular "speed research" session, where member authors are allowed a minimal amount of time to convey the highlights of their research. The importance of GPP3 cannot be overstated, but as it has been available on-line since August, we are taking a novel approach via relevant case studies and queries inspired by responses to a recent member survey.

We have designed content that reflects the meeting theme, ***Publication Planning in Practice: Overcoming Challenges in the Age of Transparency***, in the hope that attendees will leave the 2016 European Meeting of ISMPP with enduring messages and ideas they can apply the day they return to the office. This real-world approach will be carried out over two days of educational programming that covers GPP, RWE, data transparency, journal trends, metrics/altmetrics, peer review, authorship, plagiarism, fraud/redaction, pre-publication, and copyright, and features roundtables, poster and oral presentations, opportunities for collaborative exchange and networking, and exhibits.

We hope that these efforts and this year's emphasis on the fundamentals of medical publication meet with your approval. ISMPP members have the potential, the vision, the knowledge, the wherewithal and the experience to help ISMPP move successfully into the future. We trust that convening each year in this forum will go a long way toward keeping members proactive, engaged, and eager to help ISMPP shape the future of medical publications.

Sincerely,

Teresa L. (Terry) Peña, PhD, CQE
Executive Director, Global Medical Publications
Bristol-Myers Squibb
Chair, ISMPP Board of Trustees

Fiona Plunkett, PhD, ISMPP CMPP™
Client Services Director, Health Interactions
Chair, European Meeting Programme Committee

2016 EUROPEAN MEETING OF ISMPP

AGENDA

PUBLICATION PLANNING IN PRACTICE:
OVERCOMING CHALLENGES IN THE AGE OF TRANSPARENCY

ISMPP International Society for Medical Publication Professionals™

PROGRAMME AGENDA

Tuesday, 19 January 2016

MORNING

9:00–10:00	**Registration and Continental Breakfast**
10:00–10:15	**Welcome to the 2016 European Meeting of ISMPP** **Fiona Plunkett, PhD, ISMPP CMPP™** Chair, European Meeting Programme Committee
10:15–10:45	**2015: A Year in Review** A retrospective of key events and emerging issues in the medical publications space throughout the year **Faculty** **Iain Hrynaszkiewicz, PhD** Head of Data and Health & Social Sciences Publishing Nature Publishing Group/Palgrave Macmillan (UK) **Moderator** **John Gonzalez PhD, ISMPP CMPP™** Publications Director, AstraZeneca Pharmaceuticals (UK)

Tuesday, 19 January 2016

MORNING

10:45–11:45

GPP3: Member-Proposed Case Studies and Panel Discussion

A discussion of the key points included in the recent Good Publication Practice 3 (GPP3) publication and case-based presentations inspired by a recent ISMPP member survey, with a panel comprised of guideline authors, representatives from industry and agencies, and a journal editor

Faculty

Dan Bridges, MS, PhD, ISMPP CMPP™
Regional Director-Europe
Nucleus Global (UK)

Ana Marušić, MD, PhD
Professor of Anatomy; Chair, Department of Research in Biomedicine and Health, University of Split;
Editor in Chief, *Journal of Global Health* (Croatia)

Elizabeth Wager, MA, PhD
Publications Consultant
Sideview (UK)

Nicole Rapior, MS, PhD
Head of Global Scientific Publications
Boehringer Ingelheim Pharma GmbH & Co. KG (Germany)

Moderator
Dawn Lobban, PhD, ISMPP CMPP™
Director, Medical Strategy
Spirit Medical Communications (UK)

11:45-12:15

Real World Evidence and Publications

The relatively new discipline of real world evidence (RWE) is similar to traditional randomized clinical trial programs in that both use large datasets to determine performance of specific drugs. However, although clinical trials usually exclude participation of those not meeting precisely defined criteria, RWE utilizes observational data such as electronic medical records, claims information, and patient feedback to determine how health care professionals use medicines in diverse settings and how patients use them when not constrained by parameters of a controlled environment. Real-world observation offers valuable insights not obtainable via randomized controlled studies. This session explores the risks and benefits of planning and developing publications reporting results of real-world studies, and the similarities and differences vis-à-vis traditional publications stemming from clinical trials. Ample time for Q&A and audience input will conclude the session.

Faculty

Richard White, MA, PhD
Commercial Director, Oxford PharmaGenesis Ltd (UK)

12:15–13:15 **Lunch**

AFTERNOON

13:15-14:45 **Roundtables**

Utilizing case studies as a starting point and designed for optimal interaction, this year's roundtables provide the ideal setting for peer-to-peer engagement and expert-led consideration of issues fundamental to the role of publication professionals. In line with member recommendations, attendees will now be able to explore 3 different topics during the 90-minute session. Many qualify for CMPP recertification credit (check status on Meeting Day), with some especially targeted toward participants with 5 years or fewer of publication experience.

Table Topics/Moderators:

Best practice on authorship
Angela Cairns, ISMPP CMPP™
Ashfield Healthcare Communications
Elizabeth Wager, MA, PhD, Sideview

Data transparency & consistency
Fergus Sweeney, EMA
Laurence Rouxhet, ISMPP CMPP™, GSK

Devices/Diagnostics Publications
Patrice Becker, Medtronic

HEOR Publications: Why do we need them? (Introductory)
Jasim Uddin, PhD & Sean Walsh, PAREXEL Access Consulting

Industry-agency relationships (Introductory)
Tom Grant, PhD, Complete HealthVizion

Multidisciplinary working
Kay Koyander, AstraZeneca
Steve Winter, PhD, AstraZeneca

Patient lay summaries
Rachel Jones, PharmD, AstraZeneca
Richard Stephens, Patient Advocate/Blogger

Publication metrics based on social media
Ben McLeish, Altmetric
Tom Rees, MS, PhD, ISMPP CMPP™, PAREXEL International

Publications steering committees
TBC

Publications strategy (Introductory)
Ciara O'Donovan, MSc, PhD
Actelion
Jennifer Van Zwieten, MS, ISMPP CMPP™
Succinct Communications

Transfer of Value: The EU Perspective
Antonia Panayi, PhD, Shire
Andy Powrie-Smith, EFPIA

14:45–15:15 **Afternoon break and visit exhibits**

15:15-16:45 **Data and Financial Transparency Reporting**

Over the last few years, requirements for transparency and data reporting have become more widespread, with potentially substantial consequences for those responsible for scientific publication planning. Recently, the European Medicines Association (EMA) and European Federation of Pharmaceutical Industries and Associations (EFPIA) have implemented significant changes to existing rules and directives. This session features an in-depth discussion of these revised mandates and how they affect publication planning; representatives from EMA, EFPIA and industry will provide perspective. A panel discussion of key issues will conclude the session.

The faculty has asked that members familiarize themselves with the following background information on recent transparency initiatives before attending the session:
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/11/WC500099473.pdf

Faculty

Slavka Baronikova, PharmD, PhD, ISMPP CMPP™,
Publications Lead, Shire (Belgium)

Ana Marušić, MD, PhD
Professor of Anatomy; Chair, Department of Research in Biomedicine and Health University of Split
Editor in Chief, *Journal of Global Health (Croatia)*

Andy Powrie-Smith
Director of Communications, EFPIA

Laurence Rouxhet, ISMPP CMPP™
Head of Publications Management & Web Disclosures
GlaxoSmithKline Biologicals (Belgium)

Fergus Sweeney
Head of Inspections & Human Medicines
Pharmacovigilance Division
European Medicines Agency (EMA)

Moderator

Thomas Wicks
Chief Strategy Officer
TrialScope (USA)

AFTERNOON

16:45-17:00

ISMPP Update

It is a challenging time for the medical publications industry as ISMPP moves into its eleventh year of interpreting and applying evolving standards and guidelines for appropriate scientific exchange. As the society expands into new geographical regions during a time of global transformation, the hope is to continue to convene and bring together inspired publication professionals each year in forums like the 2016 European Meeting. Find out about ISMPP's 2015 journey, developments within the CMPP program, and aspirations for 2016 in this brief update.

Faculty

John Gonzalez, PhD, ISMPP CMPP™
Publication Director, Global Medical Affairs
AstraZeneca (UK)

Al Weigel, MEd, ISMPP CMPP™
President and COO, ISMPP

EVENING

17:00–18:30

ISMPP member poster presentation assembly and networking reception

Enjoy wine and hors d'oeuvres while catching up with old friends, making new contacts, and discovering the research of fellow ISMPP members.

Wednesday, 20 January 2016

MORNING

8:00–9:00 — **Registration and Continental Breakfast**

9:00–10:30

Publishing and Journals: Practical Considerations for Medical Publication Professionals in 2016

The models, publication offerings and concerns of journals and their publishers continue to evolve. Social media, altmetrics, digital offerings and mega-journals provide publication planners and authors with new features not available in the past. Open access and peer review models have been continuously enhanced and adapted. Many of these novel features are only possible because of the benefits associated with our new digital age. However, this digital era also brings its own challenges. Fraud and plagiarism are on the increase, and a new phenomenon – the "predatory journal" – has arisen in recent years. Additionally, authors now have the opportunity to communicate research online prior to publication. This session provides a practical guide for navigation of these often complicated issues. Part 1 offers an overview of factors to consider when choosing a journal in 2016. Part 2 is a discussion of key considerations affecting publishers/editors as we embark on the new year, with a focus on implications for medical publication professionals. The session will wrap up with an undoubtedly lively Q&A and panel discussion.

Faculty:

Amy Bourke-Waite
Senior Communications Manager
Springer Nature (UK)

Maria Kowalczuk, PhD
Biology Editor, Research Integrity Group
BioMed Central (UK)

Tom Rees, MS, PhD, ISMPP CMPP™
Scientific Strategy Advisor
PAREXEL International (UK)

Anna Sharman, PhD
Founder, Cofactor Ltd (UK)

Moderator:

Elizabeth Wager, MA, PhD
Publications Consultant, Sideview (UK)

10:30-11:00 — **Morning break and visit exhibits**

Wednesday, 20 January 2016

MORNING

11:00-Noon — **"Speed" Research**

An encore of last year's popular member presentation session, whereby authors of abstracts selected by blinded peer review must present their research in 8 minutes or less. Moderated Q&A follows each presentation.

Presenters:

Sana Eljamel
Costello Medical Consulting Ltd (UK)
Are we there yet? Does current practice in acknowledging professional medical writing support meet the requirements of GPP3?

Will Gattrell, PhD
Research Evaluation Unit, Oxford PharmaGenesisis Ltd (UK)
Department of Mechanical Engineering & Mathematical Sciences, Oxford Brookes University
Does professional medical writing support increase the impact of articles reporting randomized controlled trials?

Bernard Kerr
Succinct Medical Communications (UK)
Reporting of positive and negative clinical trial results in the age of mandatory clinical trial registration

Andrew Desson, MS, ISMPP CMPP™
Shire (Switzerland)

Christopher Winchester, PhD
Research Evaluation Unit, Oxford PharmaGenesis (UK)
Journal choice: Which factors do you value when submitting a manuscript?

Daniel Portsmouth
Boehringer Ingelheim Pharma GhbH & Co. KG (Germany)
Benchmarking of publicly disclosed clinical trial publication policies among pharmaceutical companies

Moderator:

Ryan Woodrow, ISMPP CMPP™
Director, Aspire Scientific Ltd (UK)

Noon-13:00 — **Lunch**

AFTERNOON

13:00-14:30 **Parallel Sessions: Other Guidelines and Regulations Impacting Publication Planners**

Attendees can choose 2 of 3 available topics that are of most interest and applicability to their publications roles: (1) Corporate Integrity Agreements, (2) Copyright, and (3) EQUATOR. Presenters will take a practical approach, sharing their personal experiences and using real-world examples to offer comprehensive definitions and evidence as to how and why publication professionals need to have more than a passing knowledge of each concept. Each session is 45 minutes long, with plenty of time for audience participation and Q&A.

Faculty:

Gina D'Angelo, MBA, PharmD, ISMPP CMPP™
Director, Global Scientific Publications, Shire (USA)

Jesper Konradsen, Candidatus magisterii
Global Publications Director
Novo-Nordisk Health Care AG (Switzerland)

Jackie Marchington, PhD, ISMPP CMPP™
Director of Operations, General Manager
Caudex (UK)

Ana Marušić, MD, PhD
Professor of Anatomy; Chair,
Department of Research in Biomedicine and Health
University of Split; Editor in Chief, *Journal of Global Health (Croatia)*

John McConnell
Editor, *The Lancet* (UK)

Abbie Pound
Head of Medical Communications
Sudler & Hennessy (UK)

Iveta Simera, PhD
Deputy Director, EQUATOR Network (UK)

Elizabeth Wager, MA, PhD
Publications Consultant, Sideview (UK)

Moderators:

Margaret Haugh, PhD, ISMPP CMPP™
President
MediCom Consult (France)

Sophie Inwood
Account Director, Client Services
Succinct Medical Communications (UK)

Laura McGovern, ISMPP CMPP™
Associate Editorial Director, Scientific Services
Cognito Medical (UK)

14:30-15:00 **Afternoon break and visit exhibits**

15:00-15:45 **Keynote Address: Publications: Where do we go from here?**

Vitek Tracz, Chairman of the Science Navigation Group, founder of BioMed Central

15:45-16:00 **Awards, exhibitor passport raffle**

16:00-16:10 **Closing comments, meeting adjourns**

Are clinical trial data published in a timely manner?
James Wallis, Amy MacLucas, & Nina C Kennard
iS LifeScience, Farnham, UK

Are we there yet? Does current practice in acknowledging professional medical writing support meet the requirements of GPP3?
Sana Eljamel & Simon Page
Costello Medical Consulting Ltd, Cambridge, UK

Benchmarking of publicly disclosed clinical trial publication policies among pharmaceutical companies
Daniel Portsmouth[a], David Haworth[b], & Elizabeth Ward[b]
[a]Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany; [b]Ashfield Healthcare Communications, Macclesfield, Cheshire, UK

Copyright infringement: A case study
Manon Boisclair[a], Robert Matheis[a], Keisha Peters[b], Adriana Stan[b], Niina Nuottamo[b], & Anna Georgieva[b]
[a]Celgene Corporation, Summit, NJ, USA; [b]Excerpta Medica, Amsterdam, The Netherlands

Current medical writing practices: Identifying the optimal model for effective and timely publications
Susan Pacconi[a] Dan Bridges[b], & Robert Matheis[a]
[a]Celgene Corporation, Summit, NJ, USA; [b]Nucleus Global, London, UK

Does professional medical writing support increase the impact of articles reporting randomized controlled trials?
William Gattrell[a,b], Paul Farrow[a], Elizabeth Costigan[a], Catherine Sheard[c], Richard White[a,b], & Christopher Winchester[a,d]
[a]Research Evaluation Unit, Oxford PharmaGenesis Ltd, Oxford, UK; [b]Department of Mechanical Engineering & Mathematical Sciences, Oxford Brookes University, Oxford, UK; [c]Department of Zoology, University of Oxford, Oxford, UK; [d]School of Medicine, Pharmacy & Health, Durham University, UK

Do patients have a voice in medical journals?
Amy MacLucas & Nina C Kennard
iS LifeScience, Farnham, UK

The impact of data extrapolation on publication plans for biosimilars
Holly Kramer, Tony Reardon, & Fiona Bolland
Spirit Medical Communications Ltd, Cambridge, UK

Is there a need for uniform poster presentation guidelines across conferences?
Kunbi Ayo-Okanlawon, Amy MacLucas, & Nina C Kennard
iS LifeScience, Farnham, UK

Journal choice: Which factors do you value when submitting a manuscript?
Noëlle L O'Regan[a], Andrew Desson[b], Catherine Hill[a], Antonia Panayi[b], Christopher Winchester[c,d], & Slavka Baronikova[b]
[a]Research Evaluation Unit, PharmaGenesis London, UK; [b]Shire, Nyon, Switzerland; [c]Research Evaluation Unit, Oxford PharmaGenesis, Oxford, UK; [d]School of Medicine, Pharmacy & Health, Durham University, UK

Journal preferences and changing views about open access: Results from the 2015 Author Insights survey
Neil Adams[a], Kathleen Lyons[a], Dan Penny[b], Katie Allin[b], & Alison Wrigley[b]
[a]Nature Publishing Group, New York, USA; [b]Nature Publishing Group, London, UK

Reporting of positive and negative clinical trial results in the age of mandatory clinical trial registration
Bernard Kerr[a], Elin Siddall[a], André da Luz[a], Veronique Buchanan[a], Radha Tailor[a], Rajpreet Grewal[a], Sara Black[a], & Rachel Spice[b]
[a]Succinct Medical Communications, Marlow, UK; [b]Succinct Medical Communications, London, UK

Systematic Literature Reviews in Oncology: A Cross-Sectional Analysis of Ambiguity in Publication Practice
Carole Jones[a], Robyn Fowler[a], Sadiq Lula[a], Rebecca McCracken[b], & Karen Smoyer[c]
[a]Envision Pharma Group, London, UK; [b]Envision Pharma Group, Southport, CT, USA; [c]Envision Pharma Group, Philadelphia, PA, USA

Systematic versus narrative reviews: How do they compare, and what does that tell us about their role in scientific exchange?
Tom Rees[a], Shweta Takyar[b], Debbie Sherwod[c], Shelley Lindley[a], & Manu Seghal[b]
[a]PAREXEL International Medical Communications, Worthing, UK, [b]PAREXEL HERON Commercialization, Chandigarh, India; [c]PAREXEL International Medical Communications, Uxbridge, UK

Use of reporting standards for consistent reporting in medical publications
Matthew Booth, Natalie Dennis, Leigh Prevost & Carol Richter
PAREXEL, Worthing, UK

Use of supplementary materials in the era of data transparency
Lynda Chang[a], Glynis Davies[b], Tom Grant[a], & Lianne Young[a]
[a]Complete HealthVizion, Glasgow, UK; [b]Complete HealthVizion, Macclesfield, UK

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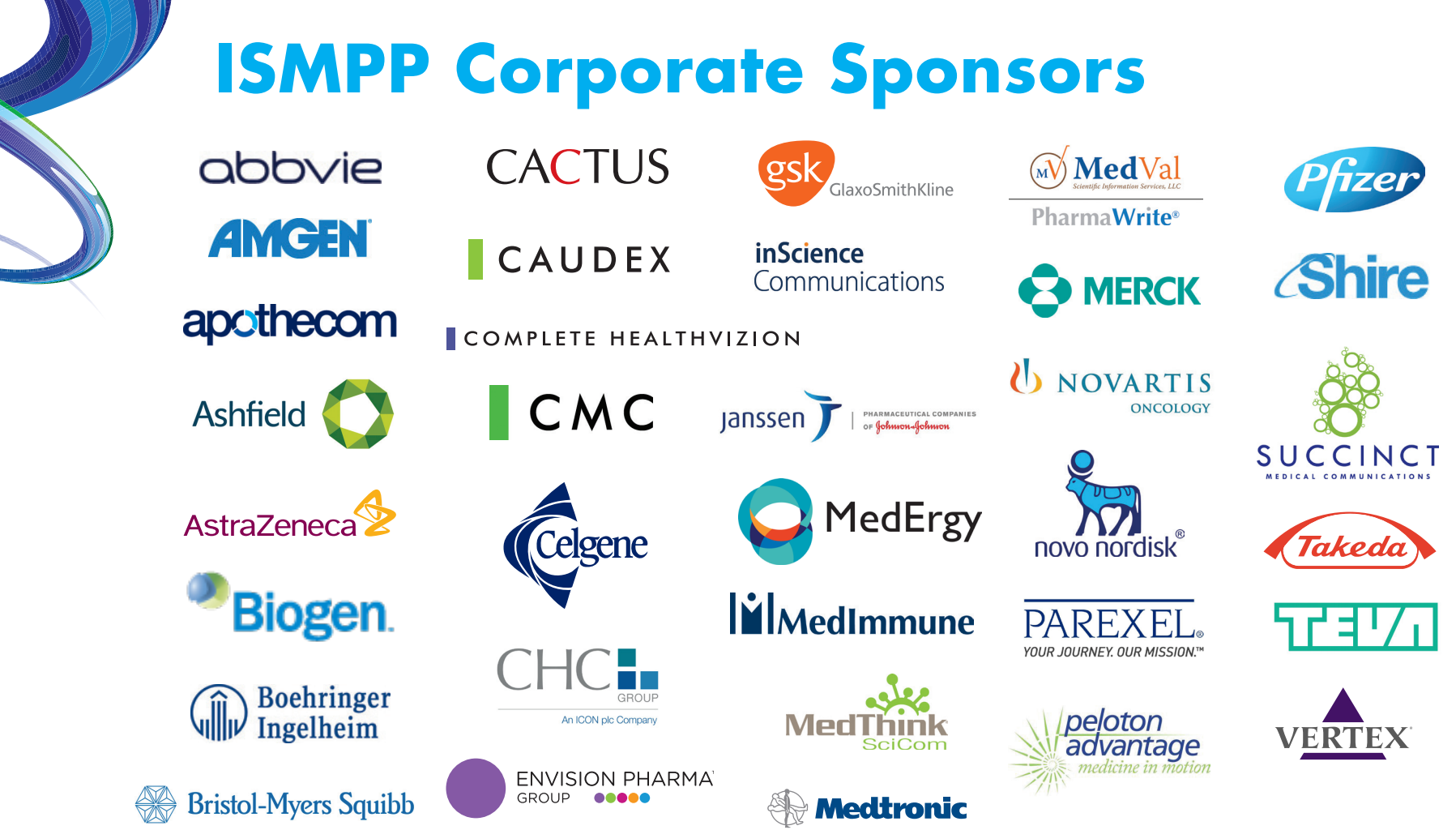

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ISMPP EXPRESSES ITS SINCERE APPRECIATION TO THE FOLLOWING, AND TO ALL OTHERS WHO HAVE PROVIDED SUPPORT FOR A SUCCESSFUL EUROPEAN MEETING.

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ISMPP also thanks its dedicated staff for their contributions to the 2016 European Meeting of ISMPP, and acknowledges the following:

Neil Thompson, Managing Director, Red White Blue Ltd. – overall meeting and logistic support
Creative Department, MedErgy – graphic support

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through our ISMPP LinkedIn Group!

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EXHIBITORS

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