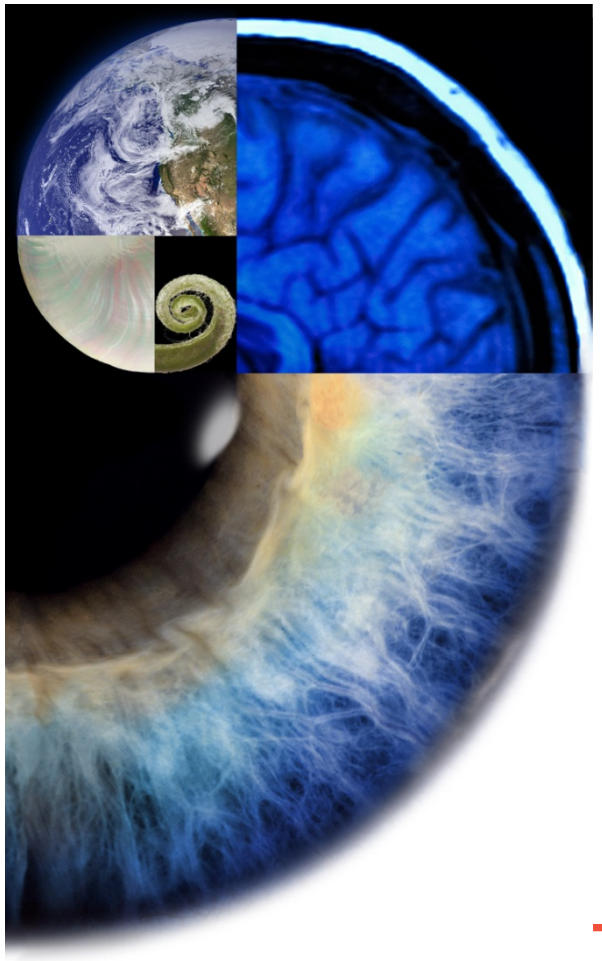


ISMPP Annual Meeting 2016

Conference Summary

MedComms Networking Event 4 May 2016

Dr Richard White
Commercial Director
Oxford PharmaGenesis

Oxford PharmaGenesis – the HealthScience Communicators™

- An independently owned consultancy, founded in 1998, with offices in Oxford, London, Basel and Philadelphia
  - Winners of the Queen's Award for Enterprise 2015
- Powerful thinking, dedicated to your success
  - 150 staff; 100 writers and consultants, over 90% with PhD/MD
- Acknowledged leaders in the publications field
  - Keynote presentations on publications for HEOR, RWE and patient outcomes studies at **ISMPP US**, **ISMPP Europe** and **TIPPA**

THE QUEEN'S AWARDS FOR ENTERPRISE: 2015

Richard White MA PhD – about the presenter

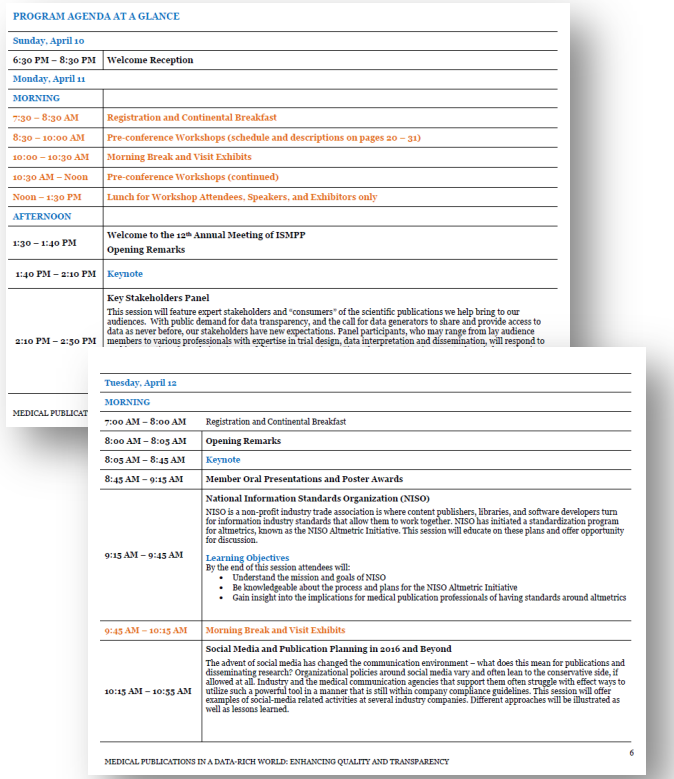
- Background
  - MA, PhD and Research Fellowship in Pharmacology, University of Cambridge, UK
  - International Marketing Program, INSEAD
  - Advanced Health Economic Modeling Program, University of Oxford
  - Honorary Research Fellow, Oxford Brookes University
- Oxford PharmaGenesis
  - Founder of the Value Demonstration Practice
    - Health economics and outcomes research (**HEOR**) and real-world evidence (**RWE**)
    - Training programmes, publication and communications plans
  - Award-winning speaker on HEOR and RWE publications at major international congresses
    - **ISMPP US**, **ISMPP Europe** and **TIPPA** meetings

ISMPP 2016: a well-attended event at an excellent venue

- More than 500 attendees from over 10 countries representing more than 170 organizations and more than 130 faculty (including medical journalists, medical fellows and patients)
- Effective mix of plenary presentations, panel discussions, workshops, poster sessions and roundtable discussions
  - 45 posters and 21 roundtable sessions

Emerging key topics of the meeting

- Clinical trial data disclosure and transparency
- ICMJE proposal for data sharing
- Whether the medical journal publishing model remains fit for purpose
- ‘Alternative metrics’ for measuring publication impact
- Social media and enhanced journal content for scientific publications
- Publication planning for RWE, HEOR, rare diseases and biosimilars



PROGRAM AGENDA AT A GLANCE

Sunday, April 10	
6:30 PM – 8:30 PM	Welcome Reception
Monday, April 11	
MORNING	
7:30 – 8:30 AM	Registration and Continental Breakfast
8:30 – 10:00 AM	Pre-conference Workshops (schedule and descriptions on pages 20 – 31)
10:00 – 10:30 AM	Morning Break and Visit Exhibits
10:30 AM – Noon	Pre-conference Workshops (continued)
Noon – 1:30 PM	Lunch for Workshop Attendees, Speakers, and Exhibitors only
AFTERNOON	
1:30 – 1:40 PM	Welcome to the 12th Annual Meeting of ISMPP Opening Remarks
1:40 PM – 2:10 PM	Keynote
2:10 PM – 2:50 PM	Key Stakeholders Panel This session will feature expert stakeholders and “consumers” of the scientific publications we help bring to our audiences. With public demand for data transparency, and the call for data generators to share and provide access to data as never before, our stakeholders have new expectations. Panel participants, who may range from lay audience members to various professionals with expertise in trial design, data interpretation and dissemination, will respond to

MEDICAL PUBLICAT

Tuesday, April 12

MORNING

7:00 AM – 8:00 AM	Registration and Continental Breakfast
8:00 AM – 8:05 AM	Opening Remarks
8:05 AM – 8:45 AM	Keynote
8:45 AM – 9:15 AM	Member Oral Presentations and Poster Awards
9:15 AM – 9:45 AM	National Information Standards Organization (NISO) NISO is a non-profit industry trade association is where content publishers, libraries, and software developers turn for information industry standards that allow them to work together. NISO has initiated a standardization program for altmetrics, known as the NISO Altmetric Initiative. This session will educate on these plans and offer opportunity for discussion. Learning Objectives By the end of this session attendees will: • Understand the mission and goals of NISO • Be knowledgeable about the process and plans for the NISO Altmetric Initiative • Gain insight into the implications for medical publication professionals of having standards around altmetrics
9:45 AM – 10:15 AM	Morning Break and Visit Exhibits
10:15 AM – 10:55 AM	Social Media and Publication Planning in 2016 and Beyond The advent of social media has changed the communication environment – what does this mean for publications and disseminating research? Organizational policies around social media vary and often lean to the conservative side, if allowed at all. Industry and the medical communication agencies that support them often struggle with effect ways to utilize such a powerful tool in a manner that is still within company compliance guidelines. This session will offer examples of social-media related activities at several industry companies. Different approaches will be illustrated as well as lessons learned.

MEDICAL PUBLICATIONS IN A DATA-RICH WORLD: ENHANCING QUALITY AND TRANSPARENCY 6

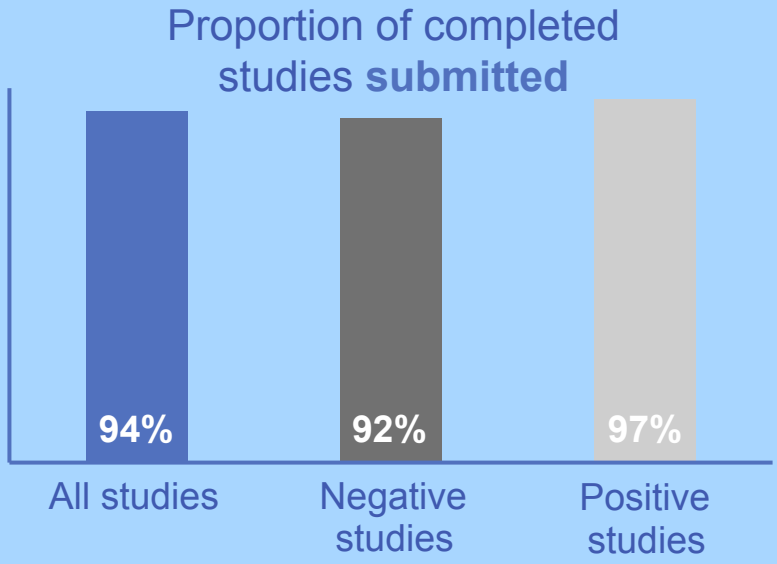
Data disclosure and transparency (1/2): publication of study data

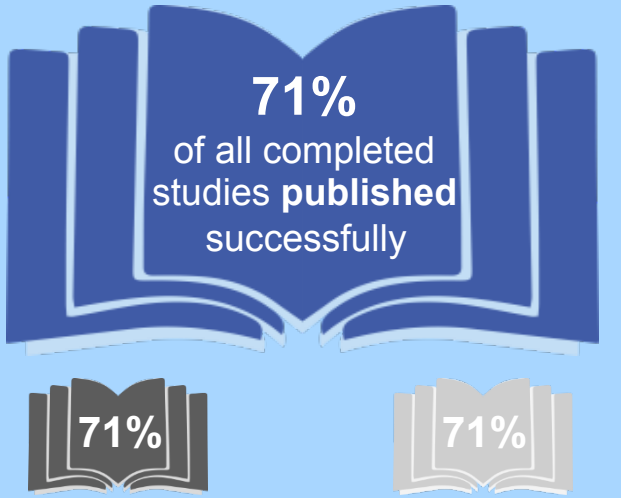
Jenny Sykes, VP Global Medical Platforms, GSK

- Summarized the principles of transparency
  - Expectations are not being met for timely access to clinical data by patients and healthcare professionals
- Defended GSK record on timely and transparent publication of clinical trial data …

"In a time of social media, standards are changing"

Over the past 5 years ...





Data disclosure and transparency (2/2): access to source data

Jenny Sykes, VP Global Medical Platforms, GSK

- GSK is the only pharma company signed up to AllTrials, and has established through www.clinicalstudydatarequest.com a process for access to anonymized patient data (since joined by 12 other companies)
  - Researchers submit research proposals
  - Proposals are reviewed by an independent panel (Wellcome Trust)
  - 123/136 proposals meeting requirements for submission have been accepted so far

- Other companies have similar but separate processes (e.g. YODA for Janssen company studies)
- Suggested that the ideal was **full data sharing**
  - No concern expressed over re-identification of 'anonymized' data

"This would be patient centric, and not affected by commercial interest"

ICMJE proposal on data sharing (1/2)

Panel discussion (ICMJE, pharma, academia)

- ICMJE proposal was stimulated by a recent IOM report and by forthcoming EU disclosure requirements
- Hundreds of comments have been posted and all will be reviewed
  - Finalization of the recommendations may therefore take longer than 6 months
- Key challenges identified during discussion
  - IP issues
    - Disclosing early-phase data could prevent subsequent patent
  - Risk of re-identification of patients
    - Responsibility may be with pharma as study sponsor
  - Concern whether analysts of data are qualified to do so
    - Original researchers should be involved in subsequent analyses
  - Multiple data repositories
    - A single source would be preferable
  - How timely data sharing will be policed
    - For example, could an article be retracted if data are not posted in 6 months?

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

Annals of Internal Medicine EDITORIAL

Sharing Clinical Trial Data: A Proposal From the International Committee of Medical Journal Editors

ICMJE proposal on data sharing (2/2)

Oxford PharmaGenesis position

- Oxford PharmaGenesis has submitted comment on the ICMJE proposal and has seven key recommendations – "time to put the patient first"
- http://icmje.org/news-and-editorials/sharing_clinical_trial_data_comments_feed.html

Our beliefs	Recommendations for action by the ICMJE
• Uncontrolled public access to individual-patient data is unethical	1 Make it clear that data sharing needs to be restricted to research purposes only
• Multiple analyses of individual-patient data could potentially distort the evidence base	2 Insist on registration and disclosure of all analyses
• The patient perspective has been largely ignored	3 Call for this perspective to be better studied and taken into account
• No method of de-identification is absolute and 'future-proof'	4 Make it clear that sharing of individual-patient data must be restricted to the minimum necessary
• Current informed consent is inadequate	5 Clarify what is required for genuinely informed consent
• Patients deserve to have access to the data they help to generate	6 Make a patient summary of results freely available in all ICMJE member journals
• The benefits and risks of data sharing are poorly characterized	7 Call on researchers to measure both intended and unintended consequences, and review ICMJE policy accordingly

Medical journals – is it time for something different? (1/3)

Richard Smith, former Editor of *BMJ*

Journals fulfil their intended role badly …

- Subjective ranking (out of 10) of the performance of medical journals

Medical journals – is it time for something different? (2/3)

Richard Smith, former Editor of *BMJ*

… the current medical publishing model is deeply flawed

- 12 major problems with the current journal model

Non-disclosure of source data	Publication bias	Poor-quality/ misleading research	Pointless research
Non-reproducible research	Fraud propagated, not corrected	Peer review process	Slow (months or years)
Lack of transparency	Lack of open access	Exploitation of scientists	Predatory journals

Medical journals – is it time for something different? (3/3)

Richard Smith, former Editor of *BMJ*

… the potential solutions are radical for everyone

- Any study should be justified by an open process based on:
  - a systematic literature review
  - broad consultation and publication of protocol
  - open-access publication in detail (not just a 3000-word summary)
  - source data disclosure (de-identified data)
  - critical assessment by wider society input, not closed peer review
- Q. Where would this leave journals?
  - With a role closer to that of the mass media – not actually disseminating the data but commenting, raising issues, campaigning, etc.
- Q. Where would this leave medical publications professionals?
  - With a role in working with researchers to communicate the data – turning poor writing into clear and engaging language, and organizing/curating data

Alternative metrics: going beyond impact factor (1/2)

Companies are trying these out …

- Altmetric and Plum Analytics are two major sources of alternative metrics data
- Pfizer has reviewed alternative metrics across all of their products and franchises over the past 2 years, assessing more than 400 articles
  - It is currently difficult to interpret metrics
  - Qualitative responses are more valuable than the overall metric alone

Alternative metrics: going beyond impact factor (2/2)

… but the tools need validating

- NISO is a not-for-profit industry organization that governs technical standards for information distribution
- NISO is developing technical standards for new forms of assessment of publications
  - Definitions and descriptions of use
  - Appropriate metrics and calculation methods for non-traditional outputs
  - Data quality, transparency and replicability, and accuracy of approaches to generate metrics
- Final recommendations to the draft standards are expected in June 2016, with final publication tentatively planned for 2017
- http://www.niso.org/topics/tl/altmetrics_initiative/

Social media and enhanced journal content (1/3)

Healthcare professionals are selective with social media …

- Preference is still to obtain new information from traditional sources
  - Printed material
    - Results of clinical trials
  - Industry websites
    - New product information
  - Surveys indicate suspicion regarding the veracity of social media sources of information
- Social media preference is for restricted online physician communities
  - SERMO, Doximity, etc. rather than Facebook and Twitter

QuantiaMD

doximity

SERMO
talk real world medicine

Social media and enhanced journal content (2/3)

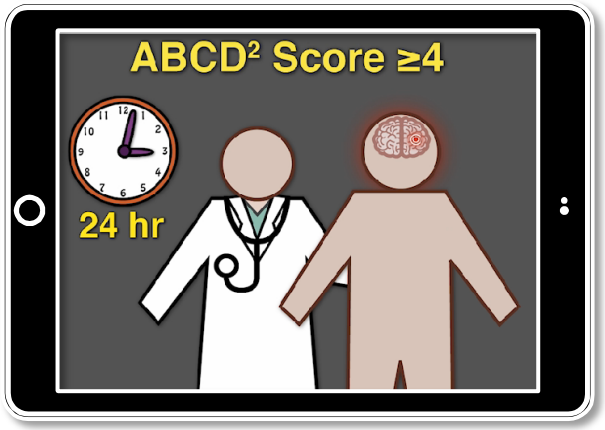
Pharma remains wary of social media …

- Pharma companies have strict policies on social media communication regarding their study publications
  - Stay within the scope of the publication
  - No additional interpretation
  - No identifiable patient information
  - Full disclosure of role of company
- Scientific publications are an accepted ‘safe harbour’ for scientific exchange, but Facebook, Twitter, etc. are not
  - Lack of control over dissemination and further discussion
  - Risk of inadvertent promotion to patients

Social media and enhanced journal content (3/3)

Rich media content and augmented reality are being trialled

- Journals are increasingly offering rich media content to supplement published articles, although uptake remains slow
  - Slide decks, interactive media, audio interviews, animations, interactive infographics (e.g. *NEJM* Quick Take http://www.nejm.org/multimedia/quick-take-video)
- Augmented reality is one approach to accelerate access to enhanced content
  - Pfizer has trialled the Blippar app for accessing rich media content by scanning a poster
  - Enhanced content could include multilingual audio or video abstracts, MoA videos, or additional tables and figures



Key workshop themes included RWE, HEOR, rare diseases and biosimilars

- The Oxford PharmaGenesis ISMPP-U on RWE publications was voted by ISMPP members as the best ISMPP-U of 2015
  - Workshop was subsequently presented at ISMPP 2016
- There was also considerable interest in workshops and roundtables on HEOR and biosimilar publications
- View the Oxford PharmaGenesis award-winning webinar on RWE publications online http://www.pharmagenesis.com/wp-content/uploads/2016/05/Oxford-PharmaGenesis-RWE-publications.pdf

Other themes are likely to increase in importance in the future

- Incorporating the patient voice into publications
  - Involving patients early on in the study development process, even in study design and outcomes selection
  - Including a section on patient involvement in publications
- Financial disclosure of ToV – the CONVEY system
  - Web-based repository of individual disclosures and ToV information, for ease of declaration (in journal articles, grant applications, etc.)
  - Created by the Association of American Medical Colleges and expected to go live in the USA within the next couple of months
- Predatory journals
  - The growth of these fake or 'pseudo' journals is of increasing concern, especially in India and other Asian countries
  - Greater awareness is needed of these predatory journals, which have the advantages of low price and short publication timelines but lack scientific rigour

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