ISMPP Annual Meeting 2016
Conference Summary
MedComms Networking Event 4 May 2016

Dr Richard White
Commercial Director
Oxford PharmaGenesis
Oxford PharmaGenesis – the HealthScience Communicators™

  - 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
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
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 …

Over the past 5 years …

<table>
<thead>
<tr>
<th>Proportion of completed studies submitted</th>
<th>71% of all completed studies published successfully</th>
</tr>
</thead>
<tbody>
<tr>
<td>All studies</td>
<td>94%</td>
</tr>
<tr>
<td>Negative studies</td>
<td>92%</td>
</tr>
<tr>
<td>Positive studies</td>
<td>97%</td>
</tr>
<tr>
<td>Negative studies</td>
<td>71%</td>
</tr>
<tr>
<td>Positive studies</td>
<td>71%</td>
</tr>
</tbody>
</table>
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?
Oxford PharmaGenesis has submitted comment on the ICMJE proposal and has seven key recommendations – “time to put the patient first”


### Our beliefs

<table>
<thead>
<tr>
<th>Recommendations for action by the ICMJE</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Make it clear that data sharing needs to be restricted to research purposes only</td>
</tr>
<tr>
<td>2. Insist on registration and disclosure of all analyses</td>
</tr>
<tr>
<td>3. Call for this perspective to be better studied and taken into account</td>
</tr>
<tr>
<td>4. Make it clear that sharing of individual-patient data must be restricted to the minimum necessary</td>
</tr>
<tr>
<td>5. Clarify what is required for genuinely informed consent</td>
</tr>
<tr>
<td>6. Make a patient summary of results freely available in all ICMJE member journals</td>
</tr>
<tr>
<td>7. Call on researchers to measure both intended and unintended consequences, and review ICMJE policy accordingly</td>
</tr>
</tbody>
</table>

- Uncontrolled public access to individual-patient data is unethical
- Multiple analyses of individual-patient data could potentially distort the evidence base
- The patient perspective has been largely ignored
- No method of de-identification is absolute and ‘future-proof’
- Current informed consent is inadequate
- Patients deserve to have access to the data they help to generate
- The benefits and risks of data sharing are poorly characterized
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

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Making money</td>
<td>10</td>
</tr>
<tr>
<td>Providing jobs</td>
<td>9</td>
</tr>
<tr>
<td>Agenda setting</td>
<td>9</td>
</tr>
<tr>
<td>Campaigning and reform</td>
<td>7</td>
</tr>
<tr>
<td>Investigating (e.g. corruption)</td>
<td>7</td>
</tr>
<tr>
<td>Promoting drugs of pharma companies</td>
<td>6</td>
</tr>
<tr>
<td>Leadership</td>
<td>5</td>
</tr>
<tr>
<td>Promoting science</td>
<td>4</td>
</tr>
<tr>
<td>Education</td>
<td>4</td>
</tr>
<tr>
<td>Forum for audience discussion</td>
<td>4</td>
</tr>
<tr>
<td>Informing what really matters</td>
<td>3</td>
</tr>
<tr>
<td>Entertaining the reader</td>
<td>2</td>
</tr>
<tr>
<td>Scoring performance of academics</td>
<td>2</td>
</tr>
<tr>
<td>Publishing science ranking</td>
<td>2</td>
</tr>
<tr>
<td>Quality assurance of the science</td>
<td>2</td>
</tr>
<tr>
<td>Organizing and curating the mass of knowledge</td>
<td>2</td>
</tr>
<tr>
<td>Reference to find everything we need</td>
<td>2</td>
</tr>
</tbody>
</table>
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

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


...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
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/

Alternative metrics: going beyond impact factor (2/2) … but the tools need validating
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
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
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
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
Contact

Richard White  MA PhD
Commercial Director

Oxford PharmaGenesis
Tubney Warren Barn
Oxford OX13 5QJ
UK

✉️ richard.white@pharmagenesis.com
📞 +44 1865 390 144
📞 +44 7833 433 210
💻 www.pharmagenesis.com

@OxPharmaGenesis  🌐 www.linkedin.com/company/oxford-pharmagenesis