Disclosures

• Director of Scientific Communications at Aspire Scientific Ltd

• One of the team at thepublicationplan.com

• Presented a poster at ISMPP EU 2018
Evolving transparency requirements in a complex multi-stakeholder environment

**09.05** Evolving transparency requirements in a complex multi-stakeholder environment

**11.00** Speed research: Part 2
- Reporting Delphi Methods to achieve consensus on guidelines in rare diseases
- Should we consider patients in communication plans?
- Patient involvement... or not? Analysis of ‘patient involvement’ statements in clinical trial publications in the BMJ

**11.30** Keynote address: Mohammad Al-Ubaydli
- Patients know best

**13.15** Parallel sessions
- Patient involvement in research and communication: opportunities and challenges
- The growing importance of RWE: what does it mean for publication professionals
- Facing the challenges of publishing unfavourable, negative, equivalence or non-confirmatory data

**15.15** Keynote address: Andy Powrie-Smith
- The Impact of BREXIT
Evolving transparency requirements in a complex multi-stakeholder environment – Trish Groves

Open Science

- Manuscripts AND data AND methods AND review
- Failure to share wastes research investment through duplication

ICMJE / industry recognition of data sharing

- “Data dumps” are not the answer – context is needed
- EU science cloud will begin to address sharing for EU-funded studies

BMJ open consensus statement

- Promote discoverability and reuse of data
- “As open as possible, as closed as necessary”
Evolving transparency requirements in a complex multi-stakeholder environment – Andy Powrie-Smith

Shifting cultural considerations
• Loss of public confidence
• Desire for self-directed investigation
• …yet conflicting calls for action

EFPIA-PhRMA principles
• Most data access requests approved
• Relatively low uptake – mostly focusing on novel analyses

“No reverse gear for transparency”
• We’re not going to retreat from this
• Collaboration, confidentiality and consistency will be key to ensure meaningful progress
Evolving transparency requirements in a complex multi-stakeholder environment – Anne-Sophie Henry-Eude

Outlining EMA data policies

- Focus on clinical data publication policy
- Journey to approval, documents collected / available
- Aim to improve public confidence in drug approvals

Data downloads

- >3,500 registered users
- >80,500 downloads
- Clear enthusiasm for data access

Redaction

- EMA recognizes the need to protect patient anonymity or sensitive company information
- ...yet requested redaction is often actually unnecessary
Evolving transparency requirements in a complex multi-stakeholder environment – Katherine Tucker

Trial registration is now standard...
- ...disclosure of patient-level data is not
- Fragmented ecosystem of reporting databases and a lack of standardization has frustrated reuse / meta-analysis

Roche perspective
- Challenges in retrospectively identifying information
- Commitment to FAIR (Findable, Accessible, Interoperable, Reusable) principles

Historically poor data sharing
- Improving, but industry must move to build-in transparency to the core of research
- Consider all eventual uses and audiences
Evolving transparency requirements in a complex multi-stakeholder environment – Rafal Swierzewski

Data created by patients, should be for patients
- Many stakeholders...
- ...require complex range of health data...
- ...to meet different analytical needs / capabilities

No clear route for patient access
- Call for transparency and ease of patient access

“Nothing about us, without us”
- Shocking lack of patient involvement or even acknowledgement in clinical trial reporting
Speed research: Part 2

**Reporting Delphi Methods to achieve consensus on guidelines in rare diseases - Henrike Resemann**
- Literature review of Delphi method reporting in publications
- Key details from the AGREE checklist are often omitted or not reported
- Variation in study design
- Lack of RCTs in rare diseases means consensus guidelines are particularly important – rigorous reporting is therefore particularly pertinent

**Should we consider patients in communication plans? - Anna Georgieva**
- Survey of patients and caregivers with atopic dermatitis
- Almost half were familiar with and used medical journal articles, but found them impenetrable and unrelatable
- Publication professionals have a responsibility to present understandable data

**Patient involvement… or not? Analysis of ‘patient involvement’ statements in clinical trial publications in the BMJ - Ann-Clare Wadsworth**
- BMJ introduced patient involvement statement in 2014
- Quarter of studies had no patient involvement – or even acknowledgement
- Rates of patient involvement in study design and conduct were low (<20%)
Keynote address: Mohammad Al-Ubaydli
Patients know best

Improve patient access – improve collaboration
• Access to personal health records
• Controlled behind secure NHS N3 network

Who knows most about the individual patient?
• The patient is the only one present at every consultation
• Empower patient to use this data, and actively manage

Easier sharing and integration
• With healthcare services, researchers, charities, patient advocacy groups, devices – overcoming legal issues

A shift in power
• Allowing patients to edit and view their digital care plan may increase patient engagement and adherence
Parallel sessions: Patient involvement in research and communication: opportunities and challenges

1. Karen Woolley
   • 1/52 clinical trials published in 2015-2016 had patient co-author
   • Outperformed others in tweets and Altmetrics
   • Patients should affect publications
   • Time and resources needed to engage and earn trust of patients

2. Antonio Ciaglia
   • Patients not just users, data supplies or beneficiaries
   • Early and late engagement equally important
   • Requires cross stakeholder effort

3. Rachel Jones
   • Duty of pharma to help patients piece together clinical information
   • Patients involvement in pubs and research can feed back into strategic planning
   • Patients can better inform pharma and reduce costs…
   • …but lack of clarity around patient engagement

4. Sophie Cook
   • BMJ patient partnership strategy
   • Patients and carers included on BMJ editorial team
   • Involvement in both unsolicited and commissioned articles
   • Provides valuable new perspectives
**Parallel sessions:**
The growing importance of RWE: what does it mean for publication professionals

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Witold Wiecek</td>
<td>Sajan Khosla</td>
<td>Richard White</td>
</tr>
<tr>
<td>• Increasing demand for RWE – RCTs no longer enough</td>
<td>• RWE needed to mirror RCT data and fill knowledge gaps</td>
<td>• Lack of integration for RWE studies</td>
</tr>
<tr>
<td>• RWE build on evidence from RCTs</td>
<td>• Industry / healthcare collaboration can easily generate large volumes of data</td>
<td>• Uncertainty over availability of results</td>
</tr>
<tr>
<td>• RWE methods improving across drug lifecycle</td>
<td>• Planning for RWE data can deliver evidence and build confidence in healthcare approaches</td>
<td>• Data keep coming – when do we stop?</td>
</tr>
<tr>
<td>• Growing role of RWE for regulators and payers – it’s here to stay</td>
<td></td>
<td>• Flexible protocols / lack of CSR make pub planning difficult</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Lack of interest from publishers</td>
</tr>
</tbody>
</table>
Parallel sessions:
Facing the challenges of publishing unfavourable, negative, equivalence or non-confirmatory data

1. Karen Mittleman
   - Difficult data is not the same as bad data
   - Ethical obligation to publish
   - Push for commitment to report ALL studies
   - Hurdles include:
     - Lack of interest (even among investigators)
     - Confidentiality affecting timing
     - Consider publication bundling?

2. Danielle Sheard
   - Rare disease research valuable, but hard-to-publish
     - Small sample sizes
     - Unconventional designs
     - Limited knowledge and reviewer pool
   - Tips
     - Realistic journal choices
     - Honesty upon submission

3. Jan Seal-Roberts
   - Planning should include contingencies for difficult data
   - Confirm with investigators in advance
   - Be transparent with journal editors
     - Avoid trying to ‘fudge’ analyses
Keynote address: Andy Powrie-Smith
The impact of BREXIT

**Regulation**
- UK sponsored trial regulation?
- UK market authorisations ↔ EU market authorisations

**Trade and supply**
- Patient medicine packs supplied to and from EU – how do we ensure uninterrupted flow if free trade stops?

**People**
- Science and medicine depend on free movement
- Recruitment issues?

**Research**
- UK is large recipient of EU research funding
- Loss of funding = loss of talent?

**Intellectual property**
- Current IP and investment framework allows investment in new medicines across EU
Thank you

Duncan.Campbell@aspire-scientific.com

For written reports on the ISMPP EU meeting see: ThePublicationPlan.com