ISMPP EU, 23–24 Jan, 2018
Day 2 Summary

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aspire SCIENTIFIC

Disclosures

- Director of Scientific Communications at Aspire Scientific Ltd
- One of the team at thepublicationplan.com
- Presented a poster at ISMPP EU 2018

ISMPP EU day 2 agenda

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 Ciagllia

- 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

1

Witold Wiecek

- Increasing demand for RWE – RCTs no longer enough
- RWE build on evidence from RCTs
- RWE methods improving across drug lifecycle
- Growing role of RWE for regulators and payers – it's here to stay

2

Sajan Khosla

- RWE needed to mirror RCT data and fill knowledge gaps
- Industry / healthcare collaboration can easily generate large volumes of data
- Planning for RWE data can deliver evidence and build confidence in healthcare approaches

3

Richard White

- Lack of integration for RWE studies
- Uncertainty over availability of results
- Data keep coming – when do we stop?
- Flexible protocols / lack of CSR make pub planning difficult
- Lack of interest from publishers

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

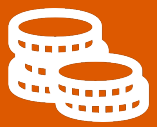
- Patient medicine packs supplied to and from EU – how do we ensure uninterrupted flow if free trade stops?

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

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