PhUSE Data Transparency Working Group

PhUSE Webinar
EU CSS Update
28 June 2017
Lukasz Kniola (Biogen)
The Group

Jean-Marc Ferran – Lead and Meeting Facilitator

20+ participants from industry, academia, vendors

3 EMA representatives (present for the duration of the meeting)
Objectives

Discuss and progress the blog on EMA policy

0070 CSR Anonymization Guidance:

– Review of Published Reports
– Data Utility
– Handling of Narratives
– Risk Determinations

• (Finalize the ADaM DelD standard)
Session 1 – Policy 0070: Where We Are (EMA Presentation)

- Target audience: patients, HCPs, researchers, drug developers,
- Total of 24 reports as of today, including 1024 published documents (rate to increase rapidly)
- 207 products in the back-log
- Survey is collecting views of users until end of August, 2017
- Good MAHs engagement, No non-compliance to date
- EMA TAG (Technical anonymization group) –
  - List of participants finalized, First meeting autumn 2017
- Annual report and Phase II – By end of 2017 and published early 2018
- Phase II in future – later stage- IPD
Session 2 – Review of published CSRs’ Anonymisation Reports

- Break-out session: Discussion on criteria used and potential other criteria to add
- Spreadsheet should be: Read-only, Subject to versioning, Reviewed independently, Updated quarterly
- Reviewer's should have the possibility to leave comments

- Volunteers: Lukasz (Lead) Alex, Beate, 1 more volunteer needed!

- EMA expects 50 – 60 publications during the course of 2017
- EMA is working on a tool summarizing information from the publication
### Data Transparency Working Group
Monday 19. June (3/3)

**Session 3 – Policy 0070 Interpretations / Data Utility**

- Break-out session: primary and other data recipients & attackers

<table>
<thead>
<tr>
<th>Intended recipients</th>
<th>Potential attackers</th>
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<tbody>
<tr>
<td>Patients</td>
<td>Hackers (demonstration attacks)</td>
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<tr>
<td>Doctors</td>
<td>Insurance Companies</td>
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<tr>
<td>Researchers</td>
<td>Employers</td>
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<td>Regulatory</td>
<td>Lawyers</td>
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<td>Uni/Students</td>
<td>Acquaintances</td>
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<td>Sponsors/Vendors</td>
<td>Recruitment agents</td>
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<td>Journalists</td>
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<td>Journalists</td>
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- Use of CSRs in academic research – presentation
Data Transparency Working Group
Monday 19. June

Extracurricular Session
Session 1.1 – Data Utility Levels – Considerations

- Discussion on ways to assess utility: levels (1-6) from no data utility to maximum utility (no information suppression)
- Initially 3 entities identified:
  Aggregated Data, Patient Listings, Narratives
- Each will need to be assessed separately (matrix)
- Number of levels may need reviewing
- Additional entity – subject ID retained
Session 1.2 – Policy 0070 Interpretations / Handling of Narratives

- Review of Narrative Subteam findings
- Retrospective anonymization of narratives
  (Manual vs. Automated with Software tools, Benefits and limitations)
- Prospective anonymization of narratives
  (Process changes, emergence of new standard for narratives that could both enable
  Pharmacovigilance to report on SAEs but also enable easier anonymization later
  on, Implementation features)

- Drive the topic forward until we meet again F2F.
Session 2 – Policy 0070 Interpretations / Risk Determination

• Break-out session
• Which population to use to measure the risk?
• Need better definition of “similar studies” in the context of risk determination
• Doesn’t just apply to Policy 0070, but to all data sharing initiatives and scenarios
Feedback from the WG members about the F2F Meeting

Outstanding feedback to break-out sessions as easier to contribute for more people

**Having EMA!!!**

- Idea sharing, Direct contact with experienced people,
- Open discussions, Wide viewpoint through variety of attendees
- Good to also fill the gaps in knowledge

Great to see progress, much has been achieved over the last years

- Good preparation by providing material and the agenda upfront
- Meeting very well organized and prepared

- Talking about future visions / confirming right direction
- Learning about the challenges the industry is facing

#PhUSE
Thanks