



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 DeID standard)~~





Data Transparency Working Group

Monday 19. June (1/3)

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





Data Transparency Working Group

Monday 19. June (2/4)

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

| Intended recipients | Potential attackers |
|---------------------|---------------------------------|
| Patients | Hackers (demonstration attacks) |
| Doctors | Insurance Companies |
| Researchers | Employers |
| Regulatory | Lawyers |
| Uni/Students | Acquaintances |
| Sponsors/Vendors | Recruitment agents |
| Journalists | Journalists |

- Use of CSRs in academic research – presentation





Data Transparency Working Group

Monday 19. June

Extracurricular Session





Data Transparency Working Group

Tuesday 20. June (1/3)

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





Data Transparency Working Group

Tuesday 20. June (2/3)

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.





Data Transparency Working Group

Tuesday 20. June (3/3)

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





Thanks

