



PhUSE Data Transparency Working Group

Detailed Agenda
London CSS
19-20 June 2017

Jean-Marc Ferran, WG Lead





Participants

Lukasz Kniola (Biogen)	Sherry Meeh (Johnson & Johnson)	Nick De Donder (Business & Decisions Life Sciences)
Stephen Bamford (Johnson & Johnson and PhUSE)	Iain Humphreys (PRA Health Sciences)	Jennifer Chin (EISAI)
Beate Hientzsch (HMS Analytical Software)	Sven Wichmann (HMS Analytical Software)	Hazel Nicholls (Privacy Analytics)
Alex Hughes (Roche)	Kelly Mewes (Roche)	Ralf Gessenich (Grunenthal)
Jean-Marc Ferran (Qualiance and PhUSE)	Shafi Chowdhury (Shafi Consultancy)	Matthew Gale (Bayer)
Alexandra Marquart (Boehringer Ingelheim)	Gertjan van Maaren (Nutricia Research)	Khaled El Emam (Privacy Analytics)
Karen Quigley (EMA)	Yvonne Moores (GCE & PhUSE)	Ada Adriano (EMA)
Jules van der Zalm (OCS Consulting)	Sarah Nevitt (Liverpool University & Cochrane)	James McDermott (Ab Tartarus)
Radu Popescu (EMA)		





Data Transparency Working Group

Monday 19. June

Time (UK)	Topic
09:00-10:30	Welcome & Keynote Speaker Crystal Allard (FDA/CDER): How PhUSE Collaborations Assist Regulatory Review Trish Groves (The BMJ): Why Data Sharing from Clinical Trials Really Matters?
10:30-11:00	Coffee Break
11:00 – 12:30	Session 1: EMA presentation on Policy 0070 followed by Q&A
12:30 – 13:30	Lunch
13:30 – 15:00	Session 2: Review of Published CSR Anonymization Overview
15:00 – 15:30	Coffee Break
15:30 – 17:00	Session 3: Policy 0070 Interpretations / Data Utility
17:00 - 20:00	Reception drinks at the venue for all CSS participants
20:00 - ...	Working Group Dinner at Cafe Spice Namaste: https://www.cafespice.co.uk/





Data Transparency Working Group

Tuesday 20. June

Time (UK)	Topic
09:00 – 10:30	Session 4: Policy 0070 Interpretations / Handling of Narratives
10:30 – 11:00	Coffee Break
11:00 – 12:30	Session 5: Policy 0070 Interpretations / Risk Determination
12:30 – 13:30	Lunch
13:30 – 14:30	Panel Discussion: Navigating Regulatory Guidance – Separating Fact From Fiction – Regulatory & Industry Panelist
14:30 – 15:00	Wrap-Up & Closing Remarks
15:30	Conference close





Roles on the day

- For each session
 - 4 Facilitators: Lukasz, Khaled, Stephen and Jean-Marc
 - 1 Note taker: Beate
 - 1 Time keeper: Nick





Objectives / Next Steps

- Finalize blog on EMA policy 0070 CSR Anonymization Guidance:
 - Review of Published Reports
 - Data Utility
 - Handling of Narratives
 - Risk Determinations
- (Finalize the ADaM DeID standard)





Session 2: Review of Published CSRs' Anonymization Reports

Item	Description
Time slot	Monday 19. June, 11:00-12:30
Duration	90 min
Pre-read material	<ul style="list-style-type: none">• Draft Overview Spreadsheet• “An Analysis of Anonymization Practices in Initial Data Releases Pursuant to EMA Policy 0070”: http://www.appliedclinicaltrials.com/analysis-anonymization-practices-initial-data-releases-pursuant-ema-policy-0070• Anonymization Reports published on EMA website• PhUSE standard paper: http://www.phusewiki.org/docs/Conference%202015%20DH%20Papers/DH01.pdf
Topics	<ul style="list-style-type: none">• Assess PhUSE criteria for classifying published CSRs and Anonymization Reports• Discuss and capture group comments on what has been released so far in terms of anonymization practice and data utility





Session 3: Policy 0070

Interpretations / Data Utility

Item	Description
Time slot	Monday 19. June, 13:30-15:00
Duration	90 min
Pre-read material	<ul style="list-style-type: none">• Data Utility Subteam Draft Paper• Maund 2014: http://www.bmj.com/content/348/bmj.g3555• Maund 2014: http://nordic.cochrane.org/sites/nordic.cochrane.org/files/public/uploads/ResearchHighlights/considering_benefits_and_harms_of_duloxetine_for_treatment_of_stress_urinary_incontinence_a_meta-analysis_of_clinical_study_reports.pdf
Topics	<ul style="list-style-type: none">• Comment on Data Utility Draft Paper• Refine list of primary and other data recipients & attackers• Itemize potential analyses and reviews from anonymized CSR• Discuss Maund papers and use of narratives for secondary analysis purpose





Session 4: Policy 0070 Interpretations / Handling of Narratives

Item	Description
Time slot	Monday 19. June, 15:30-17:00
Duration	90 min
Pre-read material	<ul style="list-style-type: none">Narratives Subteam Draft Paper
Topics	<ul style="list-style-type: none">Comment on Narratives Subteam Draft PaperRetrospective 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)





Session 5: Policy 0070 Interpretations / Risk Determination

Item	Description
Time slot	Tuesday 20. June, 11:00-12:30
Duration	90 min
Pre-read material	<ul style="list-style-type: none">• Kniola 2016: http://www.phusewiki.org/docs/Conference%202016%20DH%20Papers/DH09.pdf• Scaiano 2016: http://www.sciencedirect.com/science/article/pii/S1532046416300697
Topics	<ul style="list-style-type: none">• Which population to use to measure the risk?• Which patients and QIs to consider between the CSRs and the full analysis set?• Which metrics to use?• Which quasi/direct identifiers from CSRs to consider?• Which criteria to consider to adjust the threshold?

