



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 October 2018  
EMA/579507/2017  
European Medicines Agency

## Agenda – 1<sup>st</sup> meeting of the Technical Anonymisation Group (TAG)

29 and 30 November 2017 - Meeting room 03-M

### Wednesday, 29 November 2017 – 13h30 to 17h30

Item	Topic	Presenter
1.	Welcome and introductory remarks	M. Dias
2.	Adoption of draft Agenda	All
3.	Introductions from TAG members	All
4.	TAG mandate and Rules of Procedure	A. Spina
5.	EMA External guidance on the anonymisation of clinical reports for the purpose of publication in accordance with EMA Policy 0070	K. Quigley
6.	Analysis of clinical reports published in the context of Policy 0070 (review performed by EMA on published AnRs in first year)	A. Adriano
7.	Analysis of clinical reports published in the context of Policy 0070 (review performed by PhUSE)	J-M. Ferran/ L. Kniola
8.	Experience from Pharmaceutical Industry with the anonymisation of clinical reports for the purpose of publication in accordance with EMA Policy 0070	C. Fletcher/ L. Kniola
9.	Anonymisation report: How to improve the quality of the reports	A-S. Henry-Eude



**Thursday, 30 November 2017 – 08h30 to 12h00**

<b>Item</b>	<b>Topic</b>	<b>Presenter</b>
10.	Quantitative methods to measure the risk of re-identification: methodology review	B. Malin
11.	Review of the scientific utility of the data published as a function of the methodology used	S. Nevitt/ J-M. Ferran
12.	Data environment (data available that can be cross-linked with trial data) and plausible attacks on the data	K. El Emam
13.	Legal issues with the anonymization of clinical reports: state-of-play and GDPR evolution	N. Orlandi/ L. Parker
14.	Anonymisation of clinical reports by CROs: impact from the GDPR	U. Fiedler
15.	Next steps	M. Dias
16.	A.O.B.	All

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## List of participants

### EMA participants:

Monica Dias, Policy and Crisis Management (Chair)  
Ada Adriano, Document Access and Publication Service  
Alison Cave, Surveillance & Epidemiology Service  
Anne-Sophie Henry-Eude, Head of Document Access and Publication Service  
Frank Pétavy, Head of Biostatistics and Methodology Support (*ad interim*)  
Karen Quigley, Document Access and Publication Service  
Jeanne Riqué, Policy and Crisis Management  
Alessandro Spina, Legal Department

### TAG Members:

Giuseppe D'Acquisto, Italian Data Protection Authority (DPA)  
Khaled El Emam, Privacy Analytics Inc.  
Jean-Marc Ferran, Qualiance Aps  
Uwe Fiedler, Parexel  
Christine Fletcher, Amgen Ltd  
Cathal Gallagher, d-Wise  
Lukasz Kniola, Biogen  
Bradley Malin, Vanderbilt University  
Sarah Nevitt, University of Liverpool  
Nicola Orlandi, Novartis  
Lee Parker, Biogen International GmbH  
Frank Rockhold, Duke Clinical Research Institute  
Kristian Svendsen, Tromsø Hospital  
Rafal Swierzewski, European Cancer Patient Coalition (ECPC)

### Observer:

Kostoula Kampouraki, European Data Protection Supervisor (EDPS)