

1 May 2018

Agenda - HMA-EMA Joint Big Data Taskforce Workshop Regulatory Solutions for Big Data Challenges

4 May 2018 Meeting Room 2/A

Time: 08:30 – 16:15

Chairs: Nikolai Brun and Alison Cave

Item	Topic	Speaker	Time
1	Welcome, and update on work of the HMA/EMA Joint Big Data Task Force on Big Data	Nikolai Brun & Alison Cave	8:30-08:50
2	Lessons learnt from the EMA patient registries initiative	Patricia McGettigan EMA	08:50-09:10
3	Big Data makes regulatory science work	Bert Leufkens Utrecht University	09:10-09:40
4	Building bridges: Turning big data into value	James Kugler EFPIA	09:40-10:10
Coffee break			10:10-10:25
5	Managing, sharing and integrated analysis of large-scale life science data: researcher needs, emerging solutions and opportunities for regulatory science	Niklas Blomberg Elixir	10:25-10:55
6	Big Data Utilization in Japan – Regulatory experiences in utilizing real world data	Mari Shirovani PDMA, Japan Mariko Tsukuda MHLW, Japan	10:55-11:25
7	Real World Data and Evidence at the US FDA	David Martin FDA	11:25-11:55

Item	Topic	Speaker	Time
8	Summary and introduction to break-out sessions	Nikolai Brun & Alison Cave	11:55-12:00
Lunch and Coffee			12:00-13:00
9	Break-out sessions (please note that these break-out sessions will not be broadcast) 1. Regulatory Solutions 2. International Solutions 3. Stakeholder Solutions		13:00-14:30
	Break-out Group 1 - Regulatory Solutions Example questions: <ul style="list-style-type: none"> Should EU regulators analyze (big) data for regulatory purposes? How do we disentangle the complex opportunities that big data offers and how do we prioritize its utilization? How do we maintain expertise within the regulatory network? What are the best mechanisms for collaborating with academics/other third parties? How can regulators influence the collection, storage and accessibility of data? 	Moderated by: Didier Meulendijks HMA-EMA Joint Big Data Taskforce	
	Break-out Group 2 - International solutions Example questions: <ul style="list-style-type: none"> What are the opportunities for international harmonisation? In what areas are international guidelines and standards needed? What are the specific challenges around implementation? What are the solutions for access and technical obstacles? 	Moderated by: Marjon Pasmooij HMA-EMA Joint Big Data Taskforce	
	Break-out Group 3 – Stakeholder solutions Example questions: <ul style="list-style-type: none"> How can a data sharing culture be encouraged? How can sharing of in house data be facilitated, recognizing commercial and academic sensitivities? How can regulators influence the collection and storage of data? What are the barriers for standardization of assays and implementation of common formats and quality especially in the area of diagnostics and biomarkers? 	Moderated by: Hans Ovelgönne HMA-EMA Joint Big Data Taskforce	
10	Coffee All groups return to 2A. Moderators provide any summary slides to be shown.		14:30-14:45
11	Feedback from the break-out sessions General Discussion Summary and closing remarks	15 mins/group All Nikolai Brun & Alison Cave	14:45-15:30 15:30-16:00 16:00-16:15