

15 June 2016 Information Management EMA/47181/2016

Agenda - EU IDMP/SPOR Task Force meeting

30 June 2016, 15:00 – 18:15 and 1 July 2016, 09:00-16:00 EMA, meeting room 2A

Co-chairs: Ilaria Del Seppia (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Item	Preliminary draft agenda	Action ¹	Initials	Mins			
Day 1: 30 June 2016; 15:00-18:15							
1	 Welcome & announcements Adoption of draft agenda Introduction of new members and observers Terms of Reference update and adoption Review of open actions log 2017 meeting dates 	Adoption Discussion	All	40			
2	 SPOR for Veterinary Draft Veterinary regulation and SPOR Feedback from the Veterinary SPOR Webinar (22 June) Status of Veterinary SPOR and way forward 	Information/ Discussion	JO	45			
coffee break 16:25-16:35							
3	 Feedback on meetings: Joint IT Directors/HMA ISO Plenary and HL7 Working Group 	Information/ Discussion	FPF PAL/PT	15 15			
4	 EU Implementation Guides SPOR benefits for variations Feedback from Industry workshop on EU IGs developments and planning 	Information/ Discussion/ Adoption	RM GT GT	70			

 $^{^{\}mathrm{1}}$ Adoption, Decision, Discussion, Information

Item	Preliminary draft agenda		Action ¹	Initials	Mins
		End of Day 1			

Item	Preliminary draft agenda	Action ²	Initials	Mins			
Day 2: 1 July 2016; 9:00-16:00							
5	 MedDRA -SNOMED- ICD 10 mapping Feedback on MedDRA Management Board on 12 June 2016 	Information/ Discussion	David Lewis	45			
6	 Referentials sub-group Status update and next steps 	Information/ Discussion	JG	60			
coffee break 10:45-11:05							
6	 Organisations sub-group Status update and next steps Products & Substances sub-group Report on current activities Progress report on Business case for PMS Iteration 1 scope 	Information/ Discussion	KA IDS	60 25			
Lunch break 12:30-13:30							
7	• Status update	Information	PAL/PM/ JK	60			
8	 Communication & Change management Plan Status update & Change Liaisons Survey report Change Management Plan EU IGs consultation and sign off processes 	Information	AL	60			
9	A.O.B		All	30			
End of Day 2							

² Adoption, Decision, Discussion, Information