



20 February 2017
Information Management
EMA/86223/2017

Draft Agenda – EU IDMP/SPOR Task Force

10 March 2017, 9:00 to 17:00 (UK time), EMA, meeting room 2A

Co-chairs: Isabel Chicharo (EMA), Joris Kampmeijer (Netherlands), John Kiser (EFPIA)

Item		Action ¹	Speaker	Mins
1.	Welcome <ul style="list-style-type: none">Adoption of the draft agendaReview of EU IDMP/SPOR TF actions logMembership update	Adoption / Discussion	ALL ALL	15 m
2.	Updates	Information	FPF	15 m
3.	SMS Implementation plan <ul style="list-style-type: none">Business cases supported by Iteration 1Scope: what classes/types; what data fieldsApproach: how data will be migrated; completed, usedConstraints	Information / Discussion	ICH	60 m
<i>Coffee break (10:30-11:00)</i>				
4.	SMS Target Operating Model (TOM) <ul style="list-style-type: none">SLAs and need for provisional substancesEU/US RegistrationNCA checks on proceduresChanges to Substance details and need for variations	Information / Discussion	ICH	45 m
5.	SMS High Level Business Plan <ul style="list-style-type: none">Change requestsTranslationsOther	Information / Discussion	ICH	45 m
<i>Lunch break (12:30 – 13:30)</i>				
6.	PMS Target Operating Model (TOM) <ul style="list-style-type: none">MAA application & Art.57: integrated or not	Information / Discussion	PA	90 m

¹ Adoption, Decision, Discussion, Information



Item	Action ¹	Speaker	Mins
<ul style="list-style-type: none"> • TOM scenarios • Process by 2019 • Messaging by 2019 • ID generation • "O" data variations • Data Quality framework and involvement of NCAs various TOM scenarios • Approach for legacy data 			
<i>Coffee break (15:00- 15:30)</i>			
7.	PMS High Level Business Plan / Implementation Plan <ul style="list-style-type: none"> • P Submissions based on the various TOM scenarios and the various product lifecycles • User Registration and training for P module • Data publication • Recommendation for TOM • Recommendation for the High Level Business Plans 	Information / Discussion	PA 60 m
8.	Communication <ul style="list-style-type: none"> • Update • Endorsement process – next steps and timelines 	Information	AL 20 m
9.	A.O.B	Discussion	ALL 10 m