



19 April 2021
EMA/MB/221593/2021
Extraordinary Management Board meeting of 21 April 2021

Draft Agenda for the Extraordinary Management Board meeting on CTIS audit

Held on 21 April 2021, Room 1C (13:00-17:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/221593/2021
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Welcome and order of proceedings	Oral report
B	Points for discussion	
B.1	Introduction by the Executive Director	Oral report
B.2	European Commission	Oral report
B.3	Introduction – EU Portal and Database (EUPD)	Oral report
	<i>KPMG Audit Manager and Lead Auditor join the meeting</i>	
B.4	Results of the EUPD independent audit	Oral report
	<i>KPMG Audit Manager and Lead Auditor leave the meeting</i>	
B.5	Project Release Plan for go-live and post-go-live	Oral report For discussion, EMA/MB/224749/2021 EMA/MB/216931/2021 EMA/MB/216922/2021 EMA/MB/62395/2021
B.6	Training and Communication	Oral Report



Item		
B.7	<p>Confirmation of EUPD functionality in accordance with Art 82(2) of Clinical Trial Regulation</p> <p>a) Functional Specifications</p> <p>b) In accordance with Article 82(2) of Regulation (EU) No 536/2014 the Board is invited to confirm it has verified on the basis of the independent audit report that the EU portal and the EU database have achieved full functionality and the systems meet the functional specifications drawn up pursuant to paragraph 1 of the same Article of Regulation (EU) No 536/2014</p> <p>c) Letter to EC DG SANTE - Confirmation of functionality of the EU portal and the EU database in accordance with Article 82(2) of Regulation (EU) No 536/2014</p>	<p>For information EMA/MB/224273/2021, EMA/42176/2014 Rev.1, Corr. * EMA/129363/2015, Final EMA/228383/2015, Endorsed EMA/MB/103780/2021</p> <p>For endorsement</p> <p>For information, EMA/MB/224771/2021, EXT/MB/44907/2021</p> <p>For information, EMA/MB/223838/2021, EMA/MB/210238/2021</p>
B.8	Next Steps	Oral report

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