17 December 2021
EMA/MB/521726/2021 Adopted
Management Board meeting of 15-16 December 2021

Agenda for the 114th meeting of the Management Board

Held on 15 December 2021, Room 2A + Webex (15:00 – 18:30)

Held on 16 December 2021, Room 2A + Webex (09:00 – 16:00)

Chair: Christa Wirthumer-Hoche

Item		
1.	Draft agenda	For adoption, EMA/MB/521726/2021*
2.	Declarations of competing interests related to the current agenda	Oral report
3.	Minutes from the 113th meeting, held on 7 October 2021 adopted by written procedure	For information EMA/MB/571618/2021*
4.	COVID-19 • EMA Status Report • Update on lessons learned	 For information & discussion For information & discussion
A	**Points for automatic adoption/endorsement**	
A.1	Financial compensation and workload estimation of the NCA participation in the linguistic checking of product related information for 2022	For automatic endorsement, EMA/MB/94384/2021
A.2	Revision of budget remarks for budget 2022	For automatic endorsement, EMA/MB/254845/2021
B	**Points for discussion**	
B.1	Highlights of the Executive Director	Oral report
B.2	Report from the European Commission	Oral report
B.3	Programming 2022-2025 a) Technical amendment to procurement plan of programming document 2021-2023 b) Final programming document 2022-2024 c) Preliminary programming document 2023-2025	For adoption, EMA/MB/707273/2021 For information & adoption, EMA/MB/713342/2021; EMA/MB/591134/2021; EMA/MB/678773/2021; EMA/546314/2021

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

B.4	a) Amendment to audit plan 2021	For information & adoption EMA/MB/385281/2021; EMA/MB/434298/2020
	b) Audit strategy 2022-2024 and audit plan 2022	For adoption, EMA/MB/385166/2021
B.5	Review of activities of the Working Parties of the EMA Update from the Implementation Task Force	Oral report
B.6	Report to the Management Board on the implementation of EU IT systems required by the Clinical Trial Regulation	For information, EMA/MB/589223/2021
	a) Update on the Clinical Trials Information System (CTIS) Project for implementation of the Clinical Trial Regulation	For information, EMA/MB/589226/2021
	b) EU CTR Coordination Group Report following EU CTR meeting	For information, EXT/MB/712003/2021
	c) Communication plan endorsed by EU CTR Coordination Group	For information, EMA/708143/2021
B.7	Accelerating Clinical Trials in the EU (ACT EU), formerly known as Clinical Trials Transformation Initiative	For endorsement EMA/MB/714555/2021 EMA/715525/2021*
B.8	Agile transformation progress report	For information EMA/MB/720214/2021
B.9	EMA Cloud Strategy 2022	For endorsement EMA/MB/714597/2021 EMA/686675/2021*
B.10	Update on preparation for implementation of Veterinary Medicinal Products Regulation	Oral report
	• Expiry of the MUMS policy	For endorsement, EMA/MB/603352/2021; EMA/308411/2014-Rev.2*
	• Draft mandate of the future VMP-Reg systems improvement advisory group (VSI	For adoption, EMA/MB/654769/2021, EMA/555001/2021
	• Revised rules of procedure of CVMP	For adoption, EMA/MB/698644/2021, EMA/CVMP/422/04*
B.11	Joint Controllership Agreement under the Veterinary Medicinal Products Regulation	For endorsement, EMA/MB/715837/2021; EMA/366104/2021

B.12	Update on Big Data • Big Data Steering Group progress report • Data Standardisation Strategy	For information, EMA/MB/555173/2021 For endorsement, EMA/447502/2021*
B.13	Risk Management Plan (RMP) publication	For endorsement, EMA/MB/227679/2021
B.14	OPEN Pilot: one-year review and proposal for follow-up	Oral report
B.15	Annual report on the implementation of the EMA's Anti-Fraud Strategy	Oral report
B.16	Report on the implementation by EMA of the EU Data Protection Regulation	Oral report
C	**Points for information only****	
C.1	Updated Engagement framework: European Medicines Agency and patients, consumers and their organisations	For information, EMA/MB/649865/2021; EMA/649909/2021*
C.2	Report on EU Telematics	For information EMA/MB/709844/2021 EMA/693976/2021
C.3	Feedback from the Heads of Medicines Agencies	
C.4	Outcome of written procedures finalised during the period from 14 September 2021 to 24 November 2021	For information EMA/MB/717729/2021*
C.5	a) Summary of transfers of appropriations 2021 b) Summary report on implementation of assigned revenue	For information, EMA/MB/613491/2021* For information, EMA/MB/617640/2021
C.6	Ex-post evaluations to the building notifications and update on 30 Churchill Place	For information, EMA/MB/632403/2021; EMA/92059/2021; EMA/586800/2020; EMA/446490/2020

* Documents marked with a star * are intended for publication on the external website.
** Documents in *Additional documents for information* section are not intended for discussion unless specifically requested.