15 April 2021
EMA/176509/2021

Agenda – Joint HMA/EMA Workshop on Artificial Intelligence in Medicines Regulation - 19-20 April 2021 (Virtual)

Day 1 - 19 April 2021 (15:00-18:50 CET)

Introduction

14:45-15:00	***Joining and technical checks***	*15'*
	Welcome to the workshop	
	Peter Arlett, EMA	
15:00-15:05	**Opening remarks from the EMA Executive Director**	5'
	Emer Cooke, Executive Director, EMA	
15:05:15:10	**Opening remarks from the HMA Chairperson**	5'
	Karl Broich, Chairperson, BFARM, HMA	
15:10-15:20	**European Commission policy initiatives in AI**	10'
	Andrzej Rys, Director - Health Systems, Medical Products and Innovation, DG SANTE	

Scene setting: AI – a paradigm-shifting technology in healthcare

Moderator: Nikolai Brun, DKMA

15:20-15:40	**AI to improve the lives of patients**	15'
	Andre Dekker, Maastricht University	
	Discussion	5'
15:40-16:00	**Putting machine learning into real-world practice: patient-level prediction development and validation in observational data**	15'

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	Peter Rijnbeek, Erasmus MC	5’
	Discussion	
16:00-16:20	**AI, Digital Twins and the promise of personalised medicine**	15’
	Liesbet Geris, Universities of Liège and KUL	
	Discussion	5’
16:20-16:50	**Translating a Trillion Points of Data into Real World Evidence and Enabled Intelligence for Medicine**	20’
	Atul Butte, USCF	10’
	Discussion	

Applications of AI in Medicines and Medicines Regulation

Moderator: Zaide Frias, EMA

16:50-17:10	**Novel methods in pharmacovigilance: use cases in VigiBase**	20’
	Lucie Gattepaille, WHO-UMC	
17:10-17:30	**AI and Digitalisation at EMA**	20’
	Joaquim Berenguer Jornet & Florence Butlen-Ducuing, EMA	
17:30-17:50	**AI in Therapeutic Development – A Policy Perspective**	20’
	Khair El Zarrad, FDA	
17:50-18:10	**AI in Medical Devices and Digital Healthcare Applications – the BfArM perspective**	20’
	Wolfgang Lauer, BFARM	
18:10-18:30	**Company experience of using AI to aid drug development**	20’
	Boris Braylyan, Pfizer	
18:30-18:50	**Discussion and end of day 1**	20’

Day 2 - 20 April 2021 (15:00-18:00 CET)

Introduction to second day

14:45-15:00	***Joining and technical checks***	*15’*
15:00-15:05	**Opening remarks**	5’
	Peter Arlett, EMA	

AI Transformation in Medicines Regulation: recommendations for action

Moderator: Jesper Kjaer, DKMA		
15:05-15:25	**European medicines agencies network strategy to 2025 - Strategy for Digital transformation** Jesper Kjaer, DKMA	20’
15:25-15:45	**Big Data Taskforce Recommendations and Regulatory Science Strategy on AI** Gianmario Candore, EMA	20’
15:45-15:55	**ICMRA AI Recommendations** Agnes Saint-Raymond, EMA	10’
15:55-16:05	**Big Data Training Survey** Jörg Zinserling, BFARM	10’

16:05-16:20	**Break**	15’

Discussion on Recommendations

Moderator: Anthony Humphreys, EMA

Rapporteur: Luis Pinheiro, EMA

16:20-17:45	**Round table discussion** • Inspectors - Lisbeth Bregnhøj, DKMA • Researchers - Peter Rijnbeek, Erasmus MC • Academia - Mark Lawler, Queen’s University Belfast, FEAM • Consumers - Jelena Malinina, BEUC • MedTech - Danny van Roijen, COCIR • Patients Organisation - Marilena Vrana, European Heart Network • Healthcare professional Organisation - Ioana Agache, EACCI • Pharmaceutical Industry - Kelly Zou, Viatris • Industry - Douglas Gregory, BMS, Digital Europe • European Innovation Network - Larry O’Dwyer, HMA	85’

Summary of the workshop and conclusion

17:45-18:00	**Concluding remarks** Nikolai Brun, DKMA	15’

Abbreviations

BFARM – Bundesinstitut für Arzneimittel und Medizinprodukte – Federal Institute for Drugs and Medical Devices

BEUC - The European Consumer Organisation

BMS – Bristol Myers Squibb

COCIR – European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

DKMA – Danish Medicines Agency

EAACI - European Academy of Allergy and Clinical Immunology

EHN – European Heart Network

EMA – European Medicines Agency

FDA – Food and Drug Administration, United States

FEAM – Federation of European Academies of Medicine

HMA – Heads of Medicines Agency

UCSF – University of California San Francisco

WHO-UMC – Uppsala Monitoring Centre - World Health Organization Collaborating Centre for International Drug Monitoring

List of documents and links

Documents with recommendations

Joint HMA/EMA Big Data Taskforce

EMA Regulatory Science Strategy to 2025

European medicines agencies network strategy to 2025

Links to organisations

International Coalition of Medicines Regulatory Authorities

Documents of National Competent Authorities

Questions to critical GxP AI/ML applications