



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## Joint HMA/EMA Big Data Steering Group AI Workshop – Smart regulation on a rapidly evolving world

### AGENDA

#### MONDAY, 20 NOVEMBER - FIRST DAY OF WORKSHOP

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12:30-12:45	<b>Joining and technical checks (for online)</b>	15'
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#### Opening session

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12:45-12:50	<b>Welcome to the workshop</b> Peter Arlett, EMA	5'
12:50-12:55	<b>Opening remarks from the EMA Executive Director</b> Emer Cooke, Executive Director, EMA	5'
12:55-13:00	<b>Opening remarks from the HMA Chairperson</b> Karl Broich, Chairperson, BfArM, HMA	5'
13:00-13:05	<b>Opening remarks from European Commission</b> Rainer Becker, DG SANTE, EC	5'

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#### Introduction to the workshop

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13:05-13:15	<b>Scene-setting and goals of the workshop</b> Peter Arlett, EMA and Jesper Kjaer, DKMA	10'
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#### State of AI: The promise of AI to transform the medicines lifecycle

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	<b>Introduction to the session</b>	5'
	<b>Moderators:</b> (TBC)	
13:20-14:20	<b>Industry presentation</b> Thomas Brookland, Roche, EFPIA	20'
	<b>Artificial Intelligence in Drug Discovery - Towards Virtual Drug Discovery and Safety Assessment</b> Gerard van Westen, Leiden University	20'
	<b>Using AI to generate insights from real world big data</b>	20'

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	PJ Noble, Liverpool University	
14:20-14:45	<b>Discussion</b>	25'

### European legislative and policy ecosystem on AI

	<b>Introduction to the session</b>	5'
	<b>Moderators:</b> George Paliouras, BDSG and TBC	
14:50-15:50	<b>Ethics of AI in healthcare</b>	20'
	Andreas Reis, WHO	
	<b>Comparative worldwide regulatory approaches to AI</b>	20'
	Elisabetta Biasin, KU Leuven	
	<b>The AI legislative ecosystem</b>	20'
	Olga Solomon, DG SANTE	
15:50-16:15	<b>Summary and Interactive Discussion</b>	25'
16:15-16:45	<b>Coffee-Break</b>	30'

### European medicines regulatory network's initiatives to prepare for AI

16:45-16:50	<b>Introduction to the session</b>	5'
	<b>Moderators:</b> Gabriel Westman, MPA and Joaquim Berenguer-Jornet, EMA	
16:50-17:10	<b>An overview of regulatory interactions on AI in medicines lifecycle</b>	20'
	Joerg Zinserling, BfArM	
17:10-17:50	<b>Change management: training and upskilling in the European network</b>	10'
	TBC	
	<b>Collaborations: building communities to extract greater value from AI</b>	10'
	Pierpaolo Moscariello, EMA	
	<b>Experimentation: designing responsible ways to explore and integrate AI</b>	20'
	Anne-Marie van Nederkassel, EMA and Jakub Hasiec, EMA	
17:50-18:10	<b>Discussion</b>	20'

### First day wrap-up

18:10-18:20	<b>Summary and close of first day</b>	10'
	Peter Arlett, EMA and Jesper Kjaer, DKMA	

## TUESDAY, 21 NOVEMBER - SECOND DAY OF WORKSHOP

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08:45-09:00	Joining and technical checks (for online)	15'
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### Introduction to the second day of the workshop

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09:00-09:10	Opening remarks	10'
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Peter Arlett, EMA and Jesper Kjaer, DKMA

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### Smart regulation of AI in Medicines' lifecycle – introduction and round table

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09:10-09:40	HMA/EMA's AI reflection paper – promoting trustworthy AI for public health	30'
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Gabriel Westman, Head of AI, MPA

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09:40-11:00	Moderators: Kit Roes, MWP and TBC	80'
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Round-table discussion with stakeholders

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11:00-11:20	Coffee-Break	20'
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### Smart regulation of AI in Medicines' lifecycle – Panel discussion

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11:20-12:00	Moderators: Kit Roes, MWP and TBC	40'
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Panel discussion (with audience surveyed views)

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### The next four years: An AI roadmap

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12:00-12:05	Introduction to the session	5'
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Moderators: Hilmar Hamann, EMA and Joerg Zinserling, BfArM

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12:05-12:15	AI Roadmap	10'
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Luis Pinheiro, EMA

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12:15-12:45	Discussion	30'
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### Summary of the workshop and conclusion

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12:45-13:00	Concluding remarks and closure of workshop	15'
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Peter Arlett, EMA and Jesper Kjaer, DKMA

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