



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 July 2020  
EMA/350890/2020

## Workshop on the General Data Protection Regulation (GDPR) and Secondary Use of Data for Medicines and Public Health Purposes

Meeting with Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures

29 September 2020 from 13h00 to 16h45, virtual meeting

### Objectives of the workshop

1. Provide an overview of the European Commission's (EC) work on the creation of the European Health Data Space for the use and re-use of health data for better healthcare, informed health policy-making and the development of new treatments, medicines, medical devices and services. The initiative aims to provide a clear legal and governance framework, interoperable technical infrastructure, quality health data and semantic interoperability and support capacity building in the Member States;
2. Discuss with medicines developers and EMA's network of research-performing and research-supporting academic infrastructures as well as data providers (payers, Health Technology Assessment bodies), the development of an EU-wide governance framework and a future code of conduct on the processing of personal data in the health sector;
3. For stakeholders who submitted feedback as part of EMA's targeted stakeholder consultation on the GDPR and the secondary use of health data for medicines and public health purposes, provide a platform to discuss their key questions;
4. Enable EMA to present an update on the drafting status of Questions and Answers (Q&As) on secondary use of data for medicines and public health purposes and next steps.

This workshop follows a dedicated meeting with the EMA Patient and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) to be held on 23 September 2020.

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# Workshop Draft Agenda

29 September 2020		
12:45	Connection to virtual room and technical checks	
13:00	<ul style="list-style-type: none"> <li>Welcome and introduction</li> <li>Workshop objectives</li> <li>Opening remarks</li> </ul>	Fergus Sweeney (EMA)
<b>Session 1: Towards the European health data space</b>		
<i>Chairs: Ioana-Maria Gligor (EC) and Peter Arlett (EMA)</i>		
13:15	<ul style="list-style-type: none"> <li>European Health Data Space</li> </ul>	Martin Dorazil (EC)
13:30	<ul style="list-style-type: none"> <li>Mapping of Member States' rules on health data</li> </ul>	Speaker (TBC)
13:45	<ul style="list-style-type: none"> <li>Joint Action to support work on the European Health Data Space</li> </ul>	Markus Kalliola, Senior Lead, IHAN – Human-driven data economy, SITRA
13:55	<ul style="list-style-type: none"> <li>Code of conduct initiative</li> </ul>	Martin Dorazil (EC)
14:05	Discussion	All
14:35 <b>Break</b>		
<b>Session 2: EMA's survey on GDPR secondary use of data for medicines and public health purposes</b>		
<i>Chairs: Peter Arlett and Stefano Marino (EMA)</i>		
<b>Session 2A: Summary of stakeholder input</b>		
14:45	<ul style="list-style-type: none"> <li>Medicines Developers</li> </ul>	Speaker(s) TBC
15:00	<ul style="list-style-type: none"> <li>Research-performing academia</li> </ul>	Speaker(s) TBC
15:15	<ul style="list-style-type: none"> <li>Research-supporting infrastructures &amp; data providers</li> </ul>	Speaker(s) TBC
<b>Session 2B: Development of Q&amp;As</b>		
15:30	<ul style="list-style-type: none"> <li>Highlights of the draft Q&amp;A and next steps</li> </ul>	Sabine Brosch and Orsolya Eotvos (EMA)
16:00	Discussion	Discussants: EC (TBC), Stefano Marino (EMA), Orsolya Eotvos (EMA)
16:30	Closing remarks	Peter Arlett (EMA)
16:45	<i>End of meeting</i>	

## Workshop session chairs and speakers list (confirmed)

Affiliation	Name	Function
European Medicines Agency (EMA)	Fergus Sweeney	Head, Clinical Studies and Manufacturing Task Force
EMA	Peter Arlett	Head, Data Analytics and Methods Task Force
EMA	Stefano Marino	Head, Legal Department, Data Protection Officer (acting)
European Commission (EC)	Ioana-Maria Gligor	Head of Unit - Directorate-General for Health and Food Safety - Deputy Director General for Health responsible for Directorates B and C - Health systems, medical products and innovation - European Reference Networks and Digital Health (SANTE.DDG1.B.3)
EC	Martin Dorazil	Deputy Head of Unit - Directorate-General for Health and Food Safety - Deputy Director General for Health responsible for Directorates B and C - Health systems, medical products and innovation - European Reference Networks and Digital Health (SANTE.DDG1.B.3)
The Finnish Innovation Fund Sitra	Markus Kalliola	Senior Lead Joint Action under the EU Health Programme, IHAN – Human-driven data economy, Finland
EMA	Sabine Brosch	Data Protection Coordinator
EMA	Orsolya Eotvos	Assistant Data Protection Officer