



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 September 2020  
EMA/307527/2020

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

Meeting with the EMA Patient and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP)

23 September 2020 from 09h00 to 13h00, 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 patients, consumers and healthcare professionals 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 application of GDPR in the health sector 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 will be followed by a dedicated meeting with medicines developers, data providers, research-performing and research-supporting infrastructures to be held on 29 September 2020.

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# Workshop Draft Agenda

**23 September 2020**

08:45	Connection to virtual room and technical checks	
09:00	<ul style="list-style-type: none"> <li>Welcome and workshop objectives</li> </ul>	Juan Garcia Burgos (EMA) Ioana-Maria Gligor (EC)
	<ul style="list-style-type: none"> <li>Opening remarks</li> </ul>	Kaisa Immonen (Co-Chair PCWP) Ulrich Jaeger (Co-Chair HCPWP)
<b>Session 1: Towards the European Health Data Space (EHDS)</b>		
<i>Chairs: Ioana-Maria Gligor (EC) and Peter Arlett (EMA)</i>		
09:15	<ul style="list-style-type: none"> <li>European Health Data Space</li> </ul>	Martin Dorazil (EC)
09:30	<ul style="list-style-type: none"> <li>Role of the EHDS in the German presidency</li> </ul>	Nick Schneider (BMG)
09:45	<ul style="list-style-type: none"> <li>Joint Action to support work on the European Health Data Space</li> </ul>	Markus Kalliola (SITRA)
09:55	<ul style="list-style-type: none"> <li>Code of conduct initiative</li> </ul>	Martin Dorazil (EC)
10:05	Discussion	
10:35	<i>Break</i>	
<b>Session 2: Update from the Big Data Steering Group</b>		
<i>Chair: Juan Garcia (EMA)</i>		
10:45	<ul style="list-style-type: none"> <li>Overview of Big Data Steering Group workplan</li> </ul>	Nikolai Brun (DKMA)
11:00	<ul style="list-style-type: none"> <li>Proposal for a Data Analytics and Real-World Interrogation Network (DARWIN)</li> </ul>	Peter Arlett (EMA)
11:15	<ul style="list-style-type: none"> <li>Patient/HCP representatives experience</li> </ul>	Marilena Vrana (EHN) Ioana Agache (EAACI)
11:30	Discussion	
<b>Session 3: 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>		
11:50	<ul style="list-style-type: none"> <li>Summary of stakeholder input</li> </ul>	Sabine Brosch (EMA)
12:10	<ul style="list-style-type: none"> <li>Highlights of the draft Q&amp;As and next steps</li> </ul>	Orsolya Eotvos (EMA)
12:30	Discussion	
12:55	Closing remarks	Peter Arlett (EMA)
13:00	<i>End of meeting</i>	

## Workshop session chairs and speakers list

Affiliation	Name	Function
<b>European Medicines Agency (EMA)</b>	Melanie Carr	Head, Stakeholders and Communication
	Juan García Burgos	Head, Public and Stakeholders Engagement
	Peter Arlett	Head, Data Analytics and Methods Task Force
	Stefano Marino	Head, Legal Department, Data Protection Officer (acting)
	Sabine Brosch	Data Protection Coordinator, Clinical Studies and Manufacturing Task Force
	Orsolya Eotvos	Assistant Data Protection Officer
<b>European Commission (EC)</b>	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.DDG 1.B.3)
	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.DDG 1.B.3)
<b>Danish Medicines Agency (DKMA)</b>	Nikolai Brun	Director of Division - Medical Evaluation and Biostatistics at DKMA. Chair HMA-EMA Taskforce on Big Data
<b>Federal Ministry of Health, Germany (BMG)</b>	Nick Schneider	Head of Division 511 - New technologies and data use
<b>The Finnish Innovation Fund (SITRA)</b>	Markus Kalliola	Senior Lead Joint Action under the EU Health Programme, IHAN – Human-driven data economy, Finland
<b>European Patients' Forum (EPF)</b>	Kaisa Immonen	Co-Chair, EMA's Patients' and Consumers' Working Party (PCWP)
<b>European Hematology Association (EHA)</b>	Ulrich Jaeger	Co-Chair, EMA's Healthcare Professionals' Working Party (HCPWP)
<b>European Heart Network (EHN)</b>	Marilena Vrana	Manager Patients and Research
<b>European Academy of Allergy and Clinical Immunology (EAACI)</b>	Ioana Agache	Member of EAACI's Executive Committee 2019-2021, Former president