



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

23 September 2020  
EMA/350890/2020

## 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 Medicines Developers, Data Providers, Research-Performing and Research-Supporting Infrastructures

29 September 2020 from 13:00 to 17:00, 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, an 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 application of the 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 follows a dedicated meeting with EMA's Patient and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) to be held on 23 September 2020.



# Workshop Agenda

29 September 2020		
12:45	Connection to virtual room and technical checks	
13:00	<ul style="list-style-type: none"> <li><b>Welcome and introduction</b></li> <li>Opening remarks</li> <li>Workshop objectives</li> </ul>	Juan Garcia (EMA) Fergus Sweeney (EMA)
<b>Session 1: Towards the European Health Data Space (EHDS)</b>		
<i>Chairs: Ioana-Maria Gligor (EC) and Peter Arlett (EMA)</i>		
13:15	<ul style="list-style-type: none"> <li>Introduction to the EHDS</li> </ul>	Martin Dorazil (EC)
13:45	<ul style="list-style-type: none"> <li>Role of the EHDS in the German presidency</li> </ul>	Alina Brandes (BMG)
14:00	<ul style="list-style-type: none"> <li>Joint Action to support work on the EHDS</li> </ul>	Markus Kalliola (SITRA)
14:15	Discussion	All
14:35 <b>Break</b>		
<b>Session 2: EMA's survey on the General Data Protection Regulation (GDPR) and secondary use of data for medicines and public health purposes</b>		
<b>Session 2A: Highlights of stakeholders' input</b>		
<i>Chairs: Stefano Marino (EMA) and Peter Arlett (EMA)</i>		
14:45	<ul style="list-style-type: none"> <li>Brief introduction to the survey</li> </ul>	Sabine Brosch (EMA)
14:50	<ul style="list-style-type: none"> <li>Input from Medicines Developers</li> </ul>	Martijn ten Bloemendal (Abbvie)
15:10	<ul style="list-style-type: none"> <li>Input from Research-Performing Academia</li> </ul>	Paolo G. Casali (ESMO) Anton Ussi (EATRIS)
<b>Session 2B: Development of Questions &amp; Answers (Q&amp;As)</b>		
<i>Chairs: Stefano Marino (EMA) Peter Arlett (EMA)</i>		
15:30	<ul style="list-style-type: none"> <li>Key topics of Q&amp;As and next steps</li> </ul>	Orsolya Eotvos (EMA) Sabine Brosch (EMA)
15:50	<ul style="list-style-type: none"> <li>Panel discussion</li> </ul>	Panellists: Owe Langfeldt (EC) Isabelle Chatelier (EC) Sara Rafael Almeida (EC) Michaela Theresia Mayrhofer (BBMRI-ERIC) Chris Foremann (MSD Europe)
16:50	Closing remarks	Peter Arlett (EMA)
17:00	<i>End of meeting</i>	

## Workshop session chairs and speakers list

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)
Bundesgesundheitsministerium (BMG)	Dr. Alina Brandes	Referentin, Germany
The Finnish Innovation Fund Sitra	Markus Kalliola	Senior Lead Joint Action under the EU Health Programme, IHAN – Human-driven data economy, Finland
AbbVie	Martijn ten Bloemendal	Global Privacy Counsel, The Netherlands
European Society for Medical Oncology (ESMO)	Paolo G. Casali	Director of the Medical Oncology Unit 2 at the Istituto Nazionale Tumori, Milan, Italy
European infrastructure for translational medicine (EATRIS)	Anton Ussi	Operations & Finance Director
EMA	Sabine Brosch	Data Protection Coordinator, Clinical Studies and Manufacturing Task Force
EMA	Orsolya Eotvos	Assistant Data Protection Officer
EC	Owe Langfeldt	Legal and Policy Officer, Directorate-General for Justice and Consumers -

Affiliation	Name	Function
		Fundamental rights and rule of law - Data Protection (JUST.C.3)
EC	Isabelle Chatelier	Policy Officer, 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	Sara Rafael Almeida	Policy Officer, Directorate-General for Health and Food Safety - Deputy Director General for Health responsible for Directorates B and C - Health systems, medical products and innovation – Health systems, medicinal products and innovation – Medicines: policy (SANTE.DDG1.B.5)
BBMRI-ERIC	Michaela Theresia Mayrhofer	Interim Co-Director General, Head of ELSI Services & Research, Austria
Merck Sharp & Dohme (Europe) Inc.	Chris Foreman	Deputy Chief Privacy Officer