Basic information

2022/0140(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
European Health Data Space **Subject** 1.20.09 Protection of privacy and data protection 2.80 Cooperation between administrations 3.30.06 Information and communication technologies, digital technologies 4.20 Public health 4.20.05 Health legislation and policy **Legislative priorities** Joint Declaration 2022 Joint Declaration 2023-24	

Key players

European Parliament

Joint committee responsible	Rapporteur	Appointed
ENVI Environment, Climate and Food Safety	SOKOL Tomislav (EPP)	31/01/2023
LIBE Civil Liberties, Justice and Home Affairs	TARDINO Annalisa (ID)	31/01/2023
	Shadow rapporteur ZARZALEJOS Javier (EPP) CERDAS Sara (S&D) VITANOV Petar (S&D) SOLÍS PÉREZ Susana (Renew) URIŠ NICHOLSONOVÁ Lucia (Renew) METZ Tilly (Greens/EFA) BREYER Patrick (Greens /EFA) KEMPA Beata (ECR) KOPCISKA Joanna (ECR) LIMMER Sylvia (ID) KONENÁ Kateina (The Left) ARVANITIS Konstantinos (The Left)	

Committee for opinion	Rapporteur for opinion	Appointed
BUDG Budgets	The committee decided not to give an opinion.	

	ITRE Industry, Research and Energy (Associated committee)	BUOI Cristian-Silviu (EPP)	09/06/2022
	IMCO Internal Market and Consumer Protection (Associated committee)	KOVATCHEV Andrey (EPP)	08/07/2022

Council of the European Union

Council configuration	Meetings	Date
Economic and Financial Affairs ECOFIN	4073	2025-01-21

European Commission

Commission DG	Commissioner
Health and Food Safety	KYRIAKIDES Stella

European Economic and Social Committee

Key events

Date	Event	Reference	Summary
03/05/2022	Legislative proposal published	COM(2022)0197	Summary
06/06/2022	Committee referral announced in Parliament, 1st reading		
16/02/2023	Referral to associated committees announced in Parliament		
16/02/2023	Referral to joint committee announced in Parliament		
28/11/2023	Vote in committee, 1st reading		
05/12/2023	Committee report tabled for plenary, 1st reading	A9-0395/2023	Summary
12/12/2023	Debate in Parliament	CRE link	
13/12/2023	Decision by Parliament, 1st reading	T9-0462/2023	Summary
13/12/2023	Results of vote in Parliament		
13/12/2023	Matter referred back to the committee responsible for interinstitutional negotiations		
09/04/2024	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	GEDA/A/(2024)001744 PE760.905	
24/04/2024	Decision by Parliament, 1st reading	T9-0331/2024	Summary
24/04/2024	Results of vote in Parliament		
21/01/2025	Act adopted by Council after Parliament's 1st reading		
11/02/2025	Final act signed		
05/03/2025	Final act published in Official Journal		

Technical information

Procedure reference	2022/0140(COD)

Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Rules of Procedure EP 59 Rules of Procedure EP 57_o Treaty on the Functioning of the EU TFEU 114 Treaty on the Functioning of the EU TFEU 016-p2
Mandatory consultation of other institutions	European Economic and Social Committee
Stage reached in procedure	Procedure completed
Committee dossier	CJ43/9/11202

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE742.387	10/02/2023	
Amendments tabled in committee		PE745.235	09/03/2023	
Amendments tabled in committee		PE745.175	17/03/2023	
Amendments tabled in committee		PE745.531	29/03/2023	
Amendments tabled in committee		PE745.532	29/03/2023	
Amendments tabled in committee		PE745.529	29/03/2023	
Amendments tabled in committee		PE745.530	29/03/2023	
Amendments tabled in committee		PE745.527	29/03/2023	
Amendments tabled in committee		PE745.528	29/03/2023	
Amendments tabled in committee		PE745.533	05/04/2023	
Amendments tabled in committee		PE745.471	05/04/2023	
Committee opinion	ITRE	PE742.310	23/05/2023	
Committee opinion	IMCO	PE740.773	25/05/2023	
Committee report tabled for plenary, 1st reading/single reading		A9-0395/2023	05/12/2023	Summary
Text adopted by Parliament, partial vote at 1st reading /single reading		T9-0462/2023	13/12/2023	Summary
Text agreed during interinstitutional negotiations		PE760.905	22/03/2024	
Text adopted by Parliament, 1st reading/single reading		T9-0331/2024	24/04/2024	Summary

Council of the EU

Document type	Reference	Date	Summary
Coreper letter confirming interinstitutional agreement	GEDA/A/(2024)001744	22/03/2024	
Draft final act	00076/2024/LEX	06/02/2025	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2022)0197	03/05/2022	Summary

Document attached to the procedure	SWD(2022)0131	04/05/2022	
Document attached to the procedure	SWD(2022)0132	04/05/2022	
Document attached to the procedure	SEC(2022)0196	04/05/2022	
Document attached to the procedure	SWD(2022)0130	04/05/2022	
Commission response to text adopted in plenary	SP(2024)394	08/08/2024	

National parliaments

Document type	Parliament /Chamber	Reference	Date	Summary
Contribution	CZ_CHAMBER	COM(2022)0197	27/06/2022	
Contribution	CZ_SENATE	COM(2022)0197	19/10/2022	
Contribution	PT_PARLIAMENT	COM(2022)0197	21/12/2022	
Contribution	FR_SENATE	COM(2022)0197	17/07/2023	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
CofR	Committee of the Regions: opinion	CDR3754/2022	08/02/2023	

Additional information

Source	Document	Date
EP Research Service	Briefing	15/09/2022

Meetings with interest representatives published in line with the Rules of Procedure

Rapporteurs, Shadow Rapporteurs and Committee Chairs

Name	Role	Committee	Date	Interest representatives
METZ Tilly	Shadow rapporteur	ENVI	14/03/2024	Stichting Onderzoek Multinationale Ondernemingen
METZ Tilly	Shadow rapporteur	ENVI	23/02/2024	European Patients' Forum (EPF)
METZ Tilly	Shadow rapporteur	ENVI	16/02/2024	Standing Committee of European Doctors
SOKOL Tomislav	Rapporteur	ENVI	06/02/2024	Cabinet of Commissioner Kyriakides
SOKOL Tomislav	Rapporteur	ENVI	23/01/2024	Brainlab AG
ZARZALEJOS Javier	Shadow rapporteur	LIBE	11/01/2024	Consejo General de Colegios oficiales de Médicos
ZARZALEJOS Javier	Shadow rapporteur	LIBE	21/11/2023	Farmaindustria
ZARZALEJOS Javier	Shadow rapporteur	LIBE	15/11/2023	Finnish Institute for Health and Welfare (THL)

SOKOL Tomislav	Rapporteur	ENVI	15/11/2023	Finnish Institute for Health and Welfare
SOKOL Tomislav	Rapporteur	ENVI	13/11/2023	Belgian Perm Rep
CERDAS Sara	Shadow rapporteur	ENVI	25/10/2023	GSK
SOKOL Tomislav	Rapporteur	ENVI	20/10/2023	European Association of E-Pharmacies
SOKOL Tomislav	Rapporteur	ENVI	03/10/2023	Czech Perm Rep
SOKOL Tomislav	Rapporteur	ENVI	03/10/2023	Koninklijke Philips
METZ Tilly	Shadow rapporteur	ENVI	26/09/2023	European Society of Cardiology
SOKOL Tomislav	Rapporteur	ENVI	21/09/2023	UnitedHealth Group
VITANOV Petar	Shadow rapporteur	LIBE	20/09/2023	Illumina, Inc.
TARDINO Annalisa	Rapporteur	LIBE	18/09/2023	Johnson & Johnson Meridian srl
SOKOL Tomislav	Rapporteur	ENVI	04/09/2023	Standing Committee of European Doctors
SOKOL Tomislav	Rapporteur	ENVI	01/09/2023	French Data Hub
SOKOL Tomislav	Rapporteur	ENVI	01/09/2023	European Patients' Forum (EPF)
SOKOL Tomislav	Rapporteur	ENVI	31/08/2023	Bruegel
SOKOL Tomislav	Rapporteur	ENVI	20/07/2023	European Pain Federation EFIC
VITANOV Petar	Shadow rapporteur	LIBE	12/07/2023	American Chamber
SOKOL Tomislav	Rapporteur	ENVI	11/07/2023	AmCham EU's Healthcare Committee
SOKOL Tomislav	Rapporteur	ENVI	29/06/2023	France Assureurs
DE BLASIS Elisabetta	Shadow rapporteur	ENVI	27/06/2023	European Society of Cardiology
SOKOL Tomislav	Rapporteur	ENVI	27/06/2023	Illumina, Inc.
GEESE Alexandra	Shadow rapporteur	IMCO	24/06/2023	Brainlab
SOKOL Tomislav	Rapporteur	ENVI	07/06/2023	EDPS
DE BLASIS Elisabetta	Shadow rapporteur	ENVI	31/05/2023	AstraZeneca PLC
SOKOL Tomislav	Rapporteur	ENVI	26/04/2023	United European Gastroenterology
ZARZALEJOS Javier	Shadow rapporteur	LIBE	12/04/2023	Consejo General de Colegios oficiales de Médicos
SOKOL Tomislav	Rapporteur	ENVI	30/03/2023	Dutch Parliament
CERDAS Sara	Shadow rapporteur	ENVI	27/03/2023	Associação Nacional de Médicos de Saúde Pública
SOKOL Tomislav	Rapporteur	ENVI	27/03/2023	EMA
SOKOL Tomislav	Rapporteur	ENVI	22/03/2023	The Holomedicine® Association
SOKOL Tomislav	Rapporteur	ENVI	22/03/2023	Centrum fur Eruopaische Politik
SOKOL Tomislav	Rapporteur	ENVI	22/03/2023	Allied for Startups asbl
VITANOV Petar	Shadow rapporteur	LIBE	16/03/2023	European Alliance of Medical and Biological Engineering and Science

SOKOL Tomislav	Rapporteur	ENVI	15/03/2023	MedTech Europe
SOKOL Tomislav	Rapporteur	ENVI	15/03/2023	EDPS
SOKOL Tomislav	Rapporteur	ENVI	14/03/2023	Johnson & Johnson
SOKOL Tomislav	Rapporteur	ENVI	14/03/2023	CMR Surgical
SOKOL Tomislav	Rapporteur	ENVI	09/03/2023	European Society of Cardiology
SOKOL Tomislav	Rapporteur	ENVI	09/03/2023	European Academy of Dermatology and Venereology
GEESE Alexandra	Shadow rapporteur	IMCO	09/03/2023	German Center for Neurodegenerative Diseases
SOKOL Tomislav	Rapporteur	ENVI	08/03/2023	ECDC
SOKOL Tomislav	Rapporteur	ENVI	08/03/2023	Flatiron
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	07/03/2023	Colegio Farmaceuticos
METZ Tilly	Shadow rapporteur	ENVI	07/03/2023	Health Data Hub / Plateforme des données de santé
ZARZALEJOS Javier	Shadow rapporteur	LIBE	07/03/2023	Consejo General de Colegios Farmacéuticos
SOKOL Tomislav	Rapporteur	ENVI	07/03/2023	Sciensano
SOKOL Tomislav	Rapporteur	ENVI	07/03/2023	European Pain Federation EFIC
SOKOL Tomislav	Rapporteur	ENVI	07/03/2023	Flanders institute for biotechnology
GLÜCK Andreas	Shadow rapporteur for opinion	ITRE	01/03/2023	Verband der Chemischen Industrie e. V.
ZORRINHO Carlos	Shadow rapporteur for opinion	ITRE	28/02/2023	MedTech Europe MSD Europe
ZORRINHO Carlos	Shadow rapporteur for opinion	ITRE	28/02/2023	BEUC
SOKOL Tomislav	Rapporteur	ENVI	28/02/2023	Doctolib
SOKOL Tomislav	Rapporteur	ENVI	28/02/2023	French health data hub
GEESE Alexandra	Shadow rapporteur	IMCO	24/02/2023	Deutsches Zentrum für Neurodegenerative Erkrankungen e.V.
METZ Tilly	Shadow rapporteur	ENVI	23/02/2023	Digital Health Network (DHN)
METZ Tilly	Shadow rapporteur	ENVI	22/02/2023	European Society of Cardiology
SOKOL Tomislav	Rapporteur	ENVI	15/02/2023	Label2Enable
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	14/02/2023	Spanish Ambassador
SOKOL Tomislav	Rapporteur	ENVI	14/02/2023	Spanish Perm Rep
TARDINO Annalisa	Rapporteur	LIBE	09/02/2023	Roche S.p.A
GLÜCK Andreas	Shadow rapporteur for opinion	ITRE	08/02/2023	Siemens Healthineers AG
BUOI Cristian-Silviu	Rapporteur for opinion	ITRE	08/02/2023	Siemens Healthcare NV
SOKOL Tomislav	Rapporteur	ENVI	08/02/2023	German Federal Ministry of Health
SOKOL Tomislav	Rapporteur	ENVI	08/02/2023	Siemens AG
KOVATCHEV Andrey	Rapporteur for opinion	IMCO	07/02/2023	EUROPEAN ORGANISATION FOR RARE DISEASES

CERDAS Sara	Shadow rapporteur	ENVI	03/02/2023	Agência de Investigação Clínica e Inovação Biomédica
CERDAS Sara	Shadow rapporteur	ENVI	03/02/2023	Direção Geral da Saúde
CERDAS Sara	Shadow rapporteur	ENVI	03/02/2023	Serviços Partilhados do Ministério da Saúde, EPE
DE BLASIS Elisabetta	Shadow rapporteur	ENVI	02/02/2023	Farmindustria
METZ Tilly	Shadow rapporteur	ENVI	02/02/2023	European Data Protection Supervisor (EDPS)
SOKOL Tomislav	Rapporteur	ENVI	02/02/2023	UnitedHealth Group
SOKOL Tomislav	Rapporteur	ENVI	02/02/2023	European Consumer Organisation
GLÜCK Andreas	Shadow rapporteur for opinion	ITRE	01/02/2023	Kassenärztliche Bundesvereinigung
METZ Tilly	Shadow rapporteur	ENVI	01/02/2023	MyData Global ry
METZ Tilly	Shadow rapporteur	ENVI	01/02/2023	European Consumer Organisation
KONENÁ Kateina	Shadow rapporteur	ENVI	01/02/2023	BEUC
CERDAS Sara	Shadow rapporteur	ENVI	30/01/2023	United Health Group
CERDAS Sara	Shadow rapporteur	ENVI	30/01/2023	France Digitale
GEESE Alexandra	Shadow rapporteur	IMCO	26/01/2023	European Social Insurance Platform AISBL
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	26/01/2023	Johnson & Johnson
METZ Tilly	Shadow rapporteur	ENVI	26/01/2023	European Social Insurance Platform AISBL
SOKOL Tomislav	Rapporteur	ENVI	26/01/2023	MedTech Europe
CERDAS Sara	Shadow rapporteur	ENVI	25/01/2023	Johnson & Johnson
NIINISTÖ Ville	Shadow rapporteur for opinion	ITRE	25/01/2023	The Finnish Innovation Fund Sitra
SOKOL Tomislav	Rapporteur	ENVI	25/01/2023	Merck Sharp & Dohme Europe Belgium SRL
SOKOL Tomislav	Rapporteur	ENVI	25/01/2023	European Social Insurance Platform AISBL
SOKOL Tomislav	Rapporteur	ENVI	25/01/2023	European Health Management Association asbl
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	24/01/2023	Ministry of Health - Spain
SOKOL Tomislav	Rapporteur	ENVI	24/01/2023	TEHDAS
METZ Tilly	Shadow rapporteur	ENVI	23/01/2023	European Consumer Organiation
METZ Tilly	Shadow rapporteur	ENVI	23/01/2023	Label2Enable
CERDAS Sara	Shadow rapporteur	ENVI	20/01/2023	European Federation of Pharmaceutical Industries and Associations
KONENÁ Kateina	Shadow rapporteur	ENVI	13/01/2023	European Patients' Forum (EPF)
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	12/01/2023	Merck Sharp & Dohme Europe Belgium SRL
SOKOL Tomislav	Rapporteur	ENVI	12/01/2023	CSL Behring
VITANOV Petar	Shadow rapporteur	LIBE	11/01/2023	EURORDIS
SOKOL Tomislav	Rapporteur	ENVI	11/01/2023	German Medical Association

SOKOL Tomislav	Rapporteur	ENVI	10/01/2023	Platform for Better Oral Health in Europe
SOKOL Tomislav	Rapporteur	ENVI	13/12/2022	European Federation of Pharmaceutical Industries and Associations
SOKOL Tomislav	Rapporteur	ENVI	08/12/2022	European Cancer Organisation
CERDAS Sara	Shadow rapporteur	ENVI	07/12/2022	Doctolib
CERDAS Sara	Shadow rapporteur	ENVI	07/12/2022	Bundesärztekammer
CERDAS Sara	Shadow rapporteur	ENVI	07/12/2022	European Association of E-Pharmacies
SOKOL Tomislav	Rapporteur	ENVI	07/12/2022	European Policy Centre
SOKOL Tomislav	Rapporteur	ENVI	07/12/2022	COCIR
CERDAS Sara	Shadow rapporteur	ENVI	05/12/2022	GSK
CERDAS Sara	Shadow rapporteur	ENVI	05/12/2022	European Patients' Forum (EPF)
CERDAS Sara	Shadow rapporteur	ENVI	01/12/2022	European Cancer Organisation
SOKOL Tomislav	Rapporteur	ENVI	01/12/2022	Align Technology, Inc.
SOKOL Tomislav	Rapporteur	ENVI	01/12/2022	European Patients' Forum (EPF)
VITANOV Petar	Shadow rapporteur	LIBE	30/11/2022	Bayer AG
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	30/11/2022	Bayer AG
SOKOL Tomislav	Rapporteur	ENVI	30/11/2022	Bayer AG
SOKOL Tomislav	Rapporteur	ENVI	29/11/2022	Kry International AB
CERDAS Sara	Shadow rapporteur	ENVI	28/11/2022	Merck Sharp & Dohme Europe Belgium SRL
SOKOL Tomislav	Rapporteur	ENVI	22/11/2022	European Pain Federation EFIC
SOKOL Tomislav	Rapporteur	ENVI	22/11/2022	European Association of E-Pharmacies
VITANOV Petar	Shadow rapporteur	LIBE	16/11/2022	BEUC
SOKOL Tomislav	Rapporteur	ENVI	15/11/2022	Bristol-Myers Squibb Company
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	10/11/2022	Amgen Inc
SOKOL Tomislav	Rapporteur	ENVI	10/11/2022	Centre for clinical research and prevention (Frederiksberg Hospital)
SOKOL Tomislav	Rapporteur	ENVI	10/11/2022	Novartis Denmark
SOKOL Tomislav	Rapporteur	ENVI	10/11/2022	Roche Denmark
SOKOL Tomislav	Rapporteur	ENVI	10/11/2022	Novo Nordisk A/S
SOKOL Tomislav	Rapporteur	ENVI	10/11/2022	Medicoindustrien MedTech Denmark
VITANOV Petar	Shadow rapporteur	LIBE	08/11/2022	ResMed
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	08/11/2022	ResMed
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	08/11/2022	BioMarin UK Limited
SOKOL Tomislav	Rapporteur	ENVI	08/11/2022	German Perm Rep

SOKOL Tomislav	Rapporteur	ENVI	08/11/2022	ResMed
CERDAS Sara	Shadow rapporteur	ENVI	07/11/2022	Standing Committee of European Doctors
CERDAS Sara	Shadow rapporteur	ENVI	07/11/2022	European Confederation of Pharmaceutical Entrepreneurs
SOKOL Tomislav	Rapporteur	ENVI	27/10/2022	ECDC
SOKOL Tomislav	Rapporteur	ENVI	27/10/2022	Biomedical Alliance in Europe
SOKOL Tomislav	Rapporteur	ENVI	26/10/2022	Merck Sharp & Dohme Europe Belgium SRL
SOKOL Tomislav	Rapporteur	ENVI	26/10/2022	Sequirus
KOVATCHEV Andrey	Rapporteur for opinion	IMCO	25/10/2022	EUROPEAN ORGANISATION FOR RARE DISEASES
SOKOL Tomislav	Rapporteur	ENVI	25/10/2022	Koninklijke Philips
SOKOL Tomislav	Rapporteur	ENVI	25/10/2022	EUCOPE
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	24/10/2022	CMR Surgical
CERDAS Sara	Shadow rapporteur	ENVI	20/10/2022	Seqirus
KOVATCHEV Andrey	Rapporteur for opinion	IMCO	20/10/2022	RELX
KOVATCHEV Andrey	Rapporteur for opinion	IMCO	19/10/2022	Doctolib
SOKOL Tomislav	Rapporteur	ENVI	18/10/2022	Doctolib
SOKOL Tomislav	Rapporteur	ENVI	12/10/2022	Standing Committee of European Doctors
SOKOL Tomislav	Rapporteur	ENVI	12/10/2022	EURORDIS
SOKOL Tomislav	Rapporteur	ENVI	11/10/2022	TEHDAS
CERDAS Sara	Shadow rapporteur	ENVI	10/10/2022	Seqirus
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	07/10/2022	EFPIA
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	07/10/2022	EuropaBio
SOLÍS PÉREZ Susana	Shadow rapporteur	ENVI	03/10/2022	Hanover Communications International
METZ Tilly	Shadow rapporteur	LIBE	26/09/2022	Agence e-Santé

Other Members

Name	Date	Interest representatives
SIPPEL Birgit	26/03/2024	MedTech Europe
SIPPEL Birgit	12/03/2024	Bundesministerium für Gesundheit
SIPPEL Birgit	27/02/2024	MedTech Europe
COLIN-OESTERLÉ Nathalie	21/02/2024	Dassault Systèmes
LIESE Peter	05/12/2023	Ärztin aus Deutschland
NIEBLER Angelika	01/12/2023	MedTech Europe
COLIN-OESTERLÉ Nathalie	08/11/2023	Illumina, Inc.
SIPPEL Birgit	12/09/2023	MedTech Europe
TRILLET-LENOIR Véronique	30/05/2023	Health Data Hub / Plateforme des données de santé

SIPPEL Birgit	09/05/2023	Bayerische Landesärztekammer
WÖLKEN Tiemo	24/04/2023	Deutsche Krankenhausgesellschaft e.V.
WÖLKEN Tiemo	21/04/2023	Bureau Européen des Unions de Consommateurs
SIPPEL Birgit	28/03/2023	Bundesärztekammer
WÖLKEN Tiemo	13/03/2023	Hanse-Office
WÖLKEN Tiemo	13/03/2023	Deepsight
DE LANGE Esther	07/03/2023	Meines Holla & Partners DocMorris
WÖLKEN Tiemo	01/03/2023	Doctolib
WÖLKEN Tiemo	22/02/2023	Bundesärztekammer
WÖLKEN Tiemo	08/02/2023	Bundesministerium für Gesundheit
WÖLKEN Tiemo	01/02/2023	Deutsche Sozialversicherung
WÖLKEN Tiemo	01/02/2023	Deutsche Krankenhausgesellschaft e.V.
WÖLKEN Tiemo	27/01/2023	Europäische Kommission – DG SANTE
LENAERS Jeroen	17/11/2022	Merck Sharp & Dohme Europe Belgium SRL
TRILLET-LENOIR Véronique	10/11/2022	European Federation of Public Service Unions
WÖLKEN Tiemo	20/05/2022	AOK Bundesverband
WÖLKEN Tiemo	16/05/2022	Gesundheitsregion EUREGIO

Final act	
Regulation 2025/0327 OJ OJ L 05.03.2025	Summary

European Health Data Space

2022/0140(COD) - 03/05/2022 - Legislative proposal

PURPOSE: to establish a European Health Data Space for people and science.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the COVID-19 pandemic has clearly shown the importance of electronic health data for policy-making in response to health emergencies. It has also highlighted the imperative of **ensuring timely access to personal electronic health data** for health threats preparedness and response, as well as for treatment, but also for research, innovation, patient safety, regulatory purposes, statistical purposes or personalised medicine.

However, the complexity of rules, structures and processes across Member States makes it **difficult to access and share health data**, especially cross-border. At present, individuals have difficulties in exercising their rights with regard to their electronic health data, in particular with regard to accessing and sharing their data nationally and across borders, despite the provisions of the General Data Protection Regulation (GDPR).

The European Health Data Space (EHDS) is the **first proposal for a common domain-specific European data space**. It will address health-specific challenges to electronic health data access and sharing and will be an integral part of building a European Health Union. EHDS will create a common space where natural persons can easily control their electronic health data. It will also make it possible for researchers, innovators and policy makers to use this electronic health data in a trusted and secure way that preserves privacy.

CONTENT: the proposed regulation has the following objectives:

- **to establish the European Health Data Space** (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data);

- **to improve the functioning of the internal market by establishing a uniform legal framework**, in particular for the development, marketing and use of electronic health record systems (EHR systems) in line with EU values.

Primary use of electronic health data

Under the proposal, natural persons should have the **right to access their personal electronic health data** processed in the context of primary use of electronic health data, immediately, **free of charge and in an easily readable, consolidated and accessible form**. They should easily share such data with other health professionals within and between Member States in order to improve the delivery of health care.

Member States should ensure that patient records, electronic prescriptions, medical imaging images and reports, laboratory results and hospital discharge reports are issued and accepted in a common European electronic health record exchange format. Categories of electronic health data could be added by means of delegated acts.

When processing data in electronic format, health professionals would have access to the electronic health data of their natural person patients, regardless of the Member State of affiliation and the Member State of treatment.

To safeguard citizens' rights, all Member States should designate **digital health authorities**. The Commission would set up a central platform for digital health (**MyHealth@EU**) to provide services to support and facilitate the exchange of electronic health data between Member States' national contact points for digital health.

Interoperability and security

The proposal provides for the implementation of a mandatory self-certification scheme for EMR systems, under which EMR systems must comply with essential interoperability and security requirements. Manufacturers of electronic health record systems will have to certify compliance with these standards. This will ensure that different electronic health record systems are compatible and allow for easy transmission of electronic health data between them.

Improving the use of health data for research, innovation and policymaking

The EHDS creates a strong legal framework for the use of health data for **research, innovation, public health, policy-making and regulatory purposes**. Under strict conditions, researchers, innovators, public institutions or industry will have access to large amounts of high-quality health data, crucial to develop life-saving treatments, vaccines or medical devices and ensuring better access to healthcare and more resilient health systems.

To access this data, researchers, companies or institutions would have to apply for authorisation from the body responsible for access to health data, which will have to be set up in each Member State. Access would only be allowed if the requested data are used for specific purposes, in closed and secure environments and without revealing the identity of individuals. Any attempt to use the data for any measures detrimental to the natural person, to increase insurance premiums, to advertise products or treatments, or develop harmful products should be prohibited.

Member States should designate **one or more health data access points responsible** for granting access to electronic health data for secondary use. The Health Data Access Bodies would be connected to the new EU decentralised infrastructure for secondary use of data (HealthData@EU), which will be set up to support cross-border projects.

BUDGETARY IMPLICATIONS: the fulfilment of the obligations by the Commission and associated support actions under this legal proposal will require EUR 220 million between 2023 and 2027 and will be funded directly from the EU4Health programme (EUR 170 million) and supported further from the Digital Europe Programme (EUR 50 million). In both cases, the expenditure linked to this proposal will be covered within the programmed amounts of these programmes.

European Health Data Space

2022/0140(COD) - 05/12/2023 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Environment, Public Health and Food Safety and the Committee on Civil Liberties, Justice and Home Affairs jointly adopted the report by Tomislav SOKOL (EPP, HR) and Annalisa TARDINO (ID, IT) on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The aim of the proposed regulation is to establish the European Health Data Space (EHDS) in order to:

- improve access to and control by natural persons over their personal electronic health data in the context of healthcare (**primary use** of electronic health data);

- better achieve as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (**secondary use** of electronic health data).

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

Rights of natural persons in relation to the primary use of their personal electronic health data

Access to EHR for primary use should be **strictly limited to healthcare providers**. Where they process data in an electronic format, health professionals should have access, based on the data minimisation and purpose limitation principles, to the electronic health data of natural persons under their treatment and exclusively for the purpose of that treatment, including relevant administration, irrespective of the Member State of affiliation and the Member State of treatment.

Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals should not be informed of the restricted content of the electronic health data without prior explicit consent the natural person.

Priority categories of personal electronic health data for primary use

The right of access should cover: patient records; electronic prescriptions; laboratory results; medical test results and other complementary and diagnostic results; discharge reports; patient discharge reports; medical directives of the natural persons and information about consent for substances of human origin and organ donations.

The patient summary should be **harmonised across Member States** and include a minimum data set that can be expanded to include disease-specific data. Prescription, dispensation and administration of current and past medications across the continuum of care, including, hospital and ambulatory/day hospitals.

The Commission should, by means of implementing acts, lay down the technical specifications for the priority categories of personal electronic health data. The Commission should ensure that those implementing acts contain the latest versions of healthcare coding systems and nomenclatures and that they are updated regularly in order to keep up with the revisions of the healthcare coding systems and nomenclatures.

Registration of personal electronic health data

When health data are registered or updated, electronic health records should identify the health professional, time and health care provider that carried out the registration or the update. Member States may provide for other aspects of data registration to be recorded.

Right to an effective judicial remedy against a health data access body

Without prejudice to any other administrative or non-judicial remedy, each natural or legal person should have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them. Proceedings against a health data access body should be brought before the courts of the Member States where the health data access body is established.

Conformity assessment of EHR systems

In order to certify the conformity of an EHR system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator should apply for a **conformity assessment procedure**. Only after an Union wide approval has been issued, may the CE marking be affixed, together with an identification number.

Minimum categories of electronic data for secondary use

Natural persons should have the **right to opt-out** of the processing of their electronic health data for secondary use. Member States should provide for an accessible and easily understandable **opt-out mechanism**, whereby natural persons should be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes.

Intellectual property rights and trade secrets for secondary use

Electronic health data entailing protected intellectual property and trade secrets from health data holders should be made available for secondary use. In this case, a specific procedure should apply.

Prohibited secondary use of electronic health data

Members call for rules to prohibit the processing of such data for the following purposes:

- taking decisions which are detrimental to an individual or a group of individuals and which are likely to have legal, economic or social effects;

- taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans;

- advertising or marketing activities;

- automated individual decision-making, including profiling.

Health data access body

Member States should need to designate one or more health data access bodies responsible for granting access to electronic health data for secondary use.

Member States should ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit, on the one hand, and for the reception and preparation of the data set, including anonymisation, pseudonymisation of the electronic health data.

Each health data access body should act with **full independence** in performing its tasks and exercising its powers in accordance with this Regulation. These bodies should decide on data access applications, including deciding on whether the data should be made accessible in **anonymised or pseudonymised form**, based on its own thorough assessment of any reasons provided by the health data applicant.

The data access body should only issue an **authorisation for data processing** if all the conditions set out in this Regulation are met.

Natural and legal persons should have the right to: (i) lodge a **complaint**, individually or, where relevant, collectively, with the health data access body; (ii) have the data processed by the health data access body reviewed.

Right to receive compensation

Any person who has suffered material or non-material damage as a result of an infringement of this Regulation should have the right to receive compensation. Where a natural person considers that their rights under this Regulation have been infringed, they should have the right to mandate a **not-for-profit body, organisation or association** to lodge a complaint on their behalf.

European Health Data Space

2022/0140(COD) - 24/04/2024 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 445 votes to 142, with 39 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

The aim of this Regulation is to establish the **European Health Data Space** ('EHDS') in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as to better achieve other purposes in the healthcare and care sector that would benefit society, such as research, innovation, policy-making, health threats preparedness and response including to prevent and address future pandemics, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).

Primary use of electronic health data

Natural persons should have the right to give access to or request a healthcare provider to transmit all or part of their electronic health data to another healthcare provider of their choice immediately, free of charge and without hindrance from the health care provider or from the manufacturers of the systems used by that healthcare provider. The Regulation should allow healthcare professionals to consult their patients' files with their consent, even from other EU countries.

The **priority categories** of personal electronic health data should be the following: patient summaries; electronic prescriptions; electronic dispensations; medical imaging studies and related imaging reports; medical test results, including laboratory and other diagnostic results and related reports; discharge reports.

Where electronic health data is processed for the provision of healthcare, healthcare providers should register the relevant personal health data falling fully or partially under at least the priority categories in the electronic format in an EHR system.

Member States should ensure that one or more proxy services are established as a functionality of health data access services enabling natural persons to authorise other natural persons of their choice to access their personal electronic health data.

Natural persons should have the **right** to: (i) insert information in their own HER; (ii) rectify their personal data; (iii) give access to or request a healthcare provider to transmit all or part of their electronic health data to another healthcare provider of their choice immediately, free of charge; (iv) restrict access of health professionals and healthcare providers to all or parts of their personal electronic health data; (v) obtain information, including through automatic notifications, on any access to their personal electronic health data; (vi) refuse to allow their health data to be consulted by practitioners (unless this is necessary to protect the vital interests of the person concerned or of another person).

Health professional access services

For the provision of healthcare, Member States should ensure that access to the priority categories of electronic health data is made available to health professionals, including for cross-border care, through health professional access services. These services should be accessible only to health professionals who are in possession of recognised electronic identification means. The electronic health data in the electronic health records should be presented in a user-friendly manner to allow for easy use by health professionals.

MyHealth@EU

The Commission should establish a central interoperability platform for digital health, MyHealth@EU, to provide services to support and facilitate the **exchange of personal electronic health data** between national contact points for digital health of the Member States.

Conformity assessment of EHR systems

This Regulation establishes a mandatory scheme of self-conformity assessment for EHR systems processing one or more priority categories of electronic health data should be established to overcome market fragmentation while ensuring a proportionate approach. Through this self-assessment, EHR systems will prove compliance with the requirements on interoperability, security and logging for communication of personal electronic health data established by the two mandatory EHR components harmonised by this Regulation, namely the 'European EHR systems exchange interoperability component' and the 'European logging component for EHR systems'.

The CE marking should be affixed before placing the EHR system on the market.

Secondary use of electronic health data

Data including health records, clinical trials, pathogens, health claims and reimbursements, genetic data, public health registry information, wellness data and information on healthcare resources, expenditure and financing, could be processed for public interest purposes, including research, statistics and policy-making (so-called secondary use).

Secondary use should **not be allowed for commercial purposes** including advertising, assessing insurance requests or making job market decisions or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans. Access decisions should be made by national data access bodies.

Natural persons should have the right to **opt-out** at any time and without stating reasons from the processing of personal electronic health data relating to them for secondary use under this Regulation. Member States should provide for an accessible and easily understandable opt-out mechanism to exercise this right, whereby natural persons should be offered the possibility to explicitly express their will not to have their personal electronic health data processed for secondary use.

European Health Data Space

2022/0140(COD) - 13/12/2023 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted by 516 votes to 95, with 20 abstentions, **amendments** to the proposal for a regulation of the European Parliament and of the Council on the European Health Data Space.

The matter was referred back to the committee responsible for interinstitutional negotiations.

The aim of the proposed regulation is to establish the European Health Data Space (EHDS) in order to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (**primary use** of electronic health data), as well as to better achieve as

well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data).

Access to and transmission of personal electronic health data for primary use

Natural persons should have the right to access, immediately, free of charge and in an easily readable, consolidated and accessible format, their personal electronic health data processed in the context of the primary use of electronic health data. They should have the right to request a health data holder in the health or social security sector, or in the reimbursement services, to transmit some or all of their electronic health data to a health data recipient of their choice in the health or social security sector, or in the reimbursement services, immediately and free of charge.

Access to EHR for primary use should be **strictly limited to healthcare providers**. Where they process data in an electronic format, health professionals should have access, based on the data minimisation and purpose limitation principles, to the electronic health data of natural persons under their treatment and exclusively for the purpose of that treatment, including relevant administration, irrespective of the Member State of affiliation and the Member State of treatment.

Where access to electronic health data has been restricted by the natural person, the healthcare provider or health professionals should not be informed of the restricted content of the electronic health data without **prior explicit consent** the natural person.

Priority categories of personal electronic health data for primary use

The right of access should cover: patient records; electronic prescriptions; laboratory results; medical test results and other complementary and diagnostic results; discharge reports; patient discharge reports; medical directives of the natural persons and information about consent for substances of human origin and organ donations.

Personal electronic health data of priority data categories should be delivered across the continuum of care. Member States may provide that individuals have a right to object to the recording of their personal health data in an EMR system.

Right to an effective judicial remedy against a health data access body

Natural and legal persons should have the right to lodge a complaint, individually or, where relevant, collectively, with the health data access body, where their rights are affected. Each natural or legal person should have the right to an effective judicial remedy against a legally binding decision of a health data access body concerning them. Proceedings against a health data access body should be brought before the courts of the Member States where the health data access body is established.

Conformity assessment of EHR systems

In order to certify the conformity of an EHR system with this Regulation, prior to placing an EHR system on the market, the manufacturer, its authorised representative, or any economic operator should apply for a **conformity assessment procedure**. Only after an EU wide approval has been issued, may the CE marking be affixed, together with an identification number.

Minimum categories of electronic data for secondary use

Natural persons should have the **right to opt-out** of the processing of their electronic health data for secondary use. Member States should provide for an accessible and easily understandable **opt-out mechanism**, whereby natural persons should be offered the possibility to explicitly express their wish not to have all or part of their personal electronic health data processed for some or all secondary use purposes. The amended regulation requires explicit consent to be obtained from a patient for the secondary use of certain sensitive data (e.g. genetic and genomic information).

Intellectual property rights and trade secrets for secondary use

Electronic health data entailing protected intellectual property and trade secrets from health data holders should be made available for secondary use. In this case, a specific procedure should apply.

In this case, health data access bodies should take measures necessary to preserve the confidentiality of such data and to ensure such rights are not infringed.

Prohibited secondary use of electronic health data

Members call for rules to prohibit the processing of such data for the following purposes:

- taking decisions which are detrimental to an individual or a group of individuals and which are likely to have legal, economic or social effects;

- taking decisions in relation to a natural person or groups of natural persons in relation to job offers or offering less favourable terms in the provision of goods or services, including to exclude them from the benefit of an insurance or credit contract or to modify their contributions and insurance premiums or conditions of loans;

- advertising or marketing activities;

- automated individual decision-making, including profiling.

Health data access body

Member States should designate one or more health data access bodies responsible for granting access to electronic health data for secondary use. They should also ensure that designated separate structures are set up within health data access bodies for the authorisation of the data permit.

Each health data access body should act with **full independence** in performing its tasks and exercising its powers in accordance with this Regulation. These bodies should decide on data access applications, including deciding on whether the data should be made accessible in **anonymised or pseudonymised form**, based on its own thorough assessment of any reasons provided by the health data applicant.

The data access body should only issue an authorisation for data processing if all the conditions set out in this Regulation are met.

Natural and legal persons should have the right to: (i) lodge a complaint, individually or, where relevant, collectively, with the health data access body; (ii) have the data processed by the health data access body reviewed.

Right to receive compensation

Any person who has suffered material or non-material damage as a result of an infringement of this Regulation should have the right to receive compensation. Where a natural person considers that their rights under this Regulation have been infringed, they should have the right to mandate a **not-for-profit body, organisation or association** to lodge a complaint on their behalf.

European Health Data Space

2022/0140(COD) - 05/03/2025 - Final act

PURPOSE: to improve cross-border access to EU health data.

LEGISLATIVE ACT: Regulation (EU) 2025/327 of the European Parliament and of the Council on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847.

CONTENT: the Regulation establishes the **European Health Data Space** (EHDS) to improve access to and control by natural persons over their personal electronic health data in the context of healthcare (primary use of electronic health data), as well as for other purposes that would benefit the society such as research, innovation, policy-making, patient safety, personalised medicine, official statistics or regulatory activities (secondary use of electronic health data). It provides for a health-specific data environment that will ensure cross-border access to digital health services and products within the EU.

Rights of individuals regarding the primary use of their personal electronic health data

Under the new rules, individuals will have **faster and easier access to personal electronic health data** such as patient record summaries, electronic prescriptions, medical imaging scans, medical examination results, and hospital discharge reports, whether they are in their home country or in another Member State. The Regulation will also allow **healthcare professionals** to access their patients' records with their consent, also from other EU countries.

Individuals will have **more control** over how this data is used. They will have the right to:

- add information to their own electronic medical record (EHR),

- request the rectification of their data,

- grant access to all or part of their electronic health data to a healthcare provider of their choice,

- restrict access by healthcare professionals and healthcare providers to all or part of their personal electronic health data,

- obtain information on data access;

- **refuse** to have their health data accessed by practitioners (unless this is necessary to protect the vital interests of the data subject or another person).

Member States will be required to establish a Digital Health Authority responsible for implementing the new provisions.

Secondary use

The EHDS will also allow **researchers and policymakers** to access specific types of anonymised and secure health data, including medical records, clinical trials, pathogens, health claims and reimbursements, genetic data, public health registry information, well-being data, and information on healthcare resources, expenditures, and financing, so that these data can be processed for purposes of **public interest**, such as research, statistics, and public policy development.

However, sharing of these data **will not be permitted** for commercial uses, such as advertising or making decisions regarding job offers or applying less favourable terms in the provision of goods or services, including excluding individuals from an insurance or credit contract or changing their contributions and premiums or loan terms.

Individuals will have the right to **object at any time** and without providing reasons to the processing of their electronic personal health data for secondary use. Member States must provide an accessible and easily understandable opt-out mechanism to exercise this right.

Each Member State will designate a national contact point for secondary use.

Trusted health data holders

To reduce administrative burden, Member States may designate trusted health data holders who can securely process requests for access to health data. Health data access bodies will make information on the conditions under which electronic health data are made available for secondary use **publicly available**, easily searchable through electronic means and accessible for natural persons.

Where a health data access body is informed by a health data user of a **significant finding** related to the health of a natural person, the health data access body will inform the health data holder about that finding.

Interoperability

The Regulation requires all electronic health record (EHR) systems to comply with the specifications of the **European electronic health record exchange format**, ensuring their interoperability at EU level. It establishes a mandatory conformity self-assessment system for EHR systems handling one or more priority categories of electronic health data to address market fragmentation.

The Commission will establish a **central interoperability platform for digital health**, MyHealth@EU, to provide services to support and facilitate the exchange of personal electronic health data between national contact points for digital health of the Member States. This will enable health data to be securely transferred to healthcare professionals in other EU countries through the platform, for example when citizens move to another state.

The Regulation requires all electronic health record (EHR) systems to comply with the specifications of the European electronic health record exchange format, ensuring that they are interoperable at EU level.

ENTRY INTO FORCE: 25.3.2025.

APPLICATION: From 26.3.2027.