IHE EUROPE EXPERIENCE DAY 13 SEPTEMBER 2022

EU-LEVEL POLICY DEVELOPMENTS ON DATA IN HEALTHCARE

IHE CONNECTATHON 2022 BUILDING THE BRIDGE MONTREUX+ATLANTA SEPTEMBER 12-16

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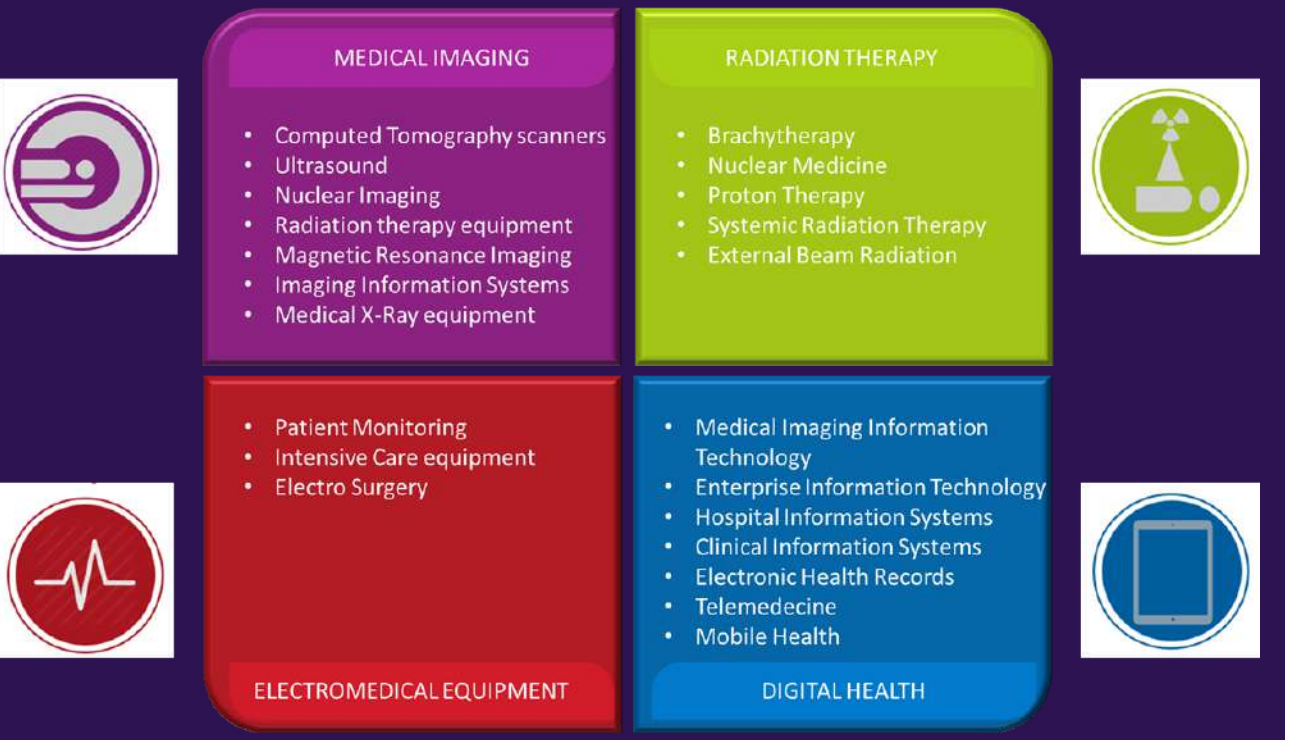
Introduction



- COCIR is a non-profit trade association, founded in 1959 and having offices in Brussels and China, representing the medical technology industry in Europe.
- Our Industry leads in state-of-art advanced technology and provides integrated solutions covering the complete care cycle
- COCIR covers 4 key industry sectors
  - Medical Imaging
  - Radiotherapy
  - Health ICT
  - Electromedical

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The digital transformation of our societies and economy in the EU

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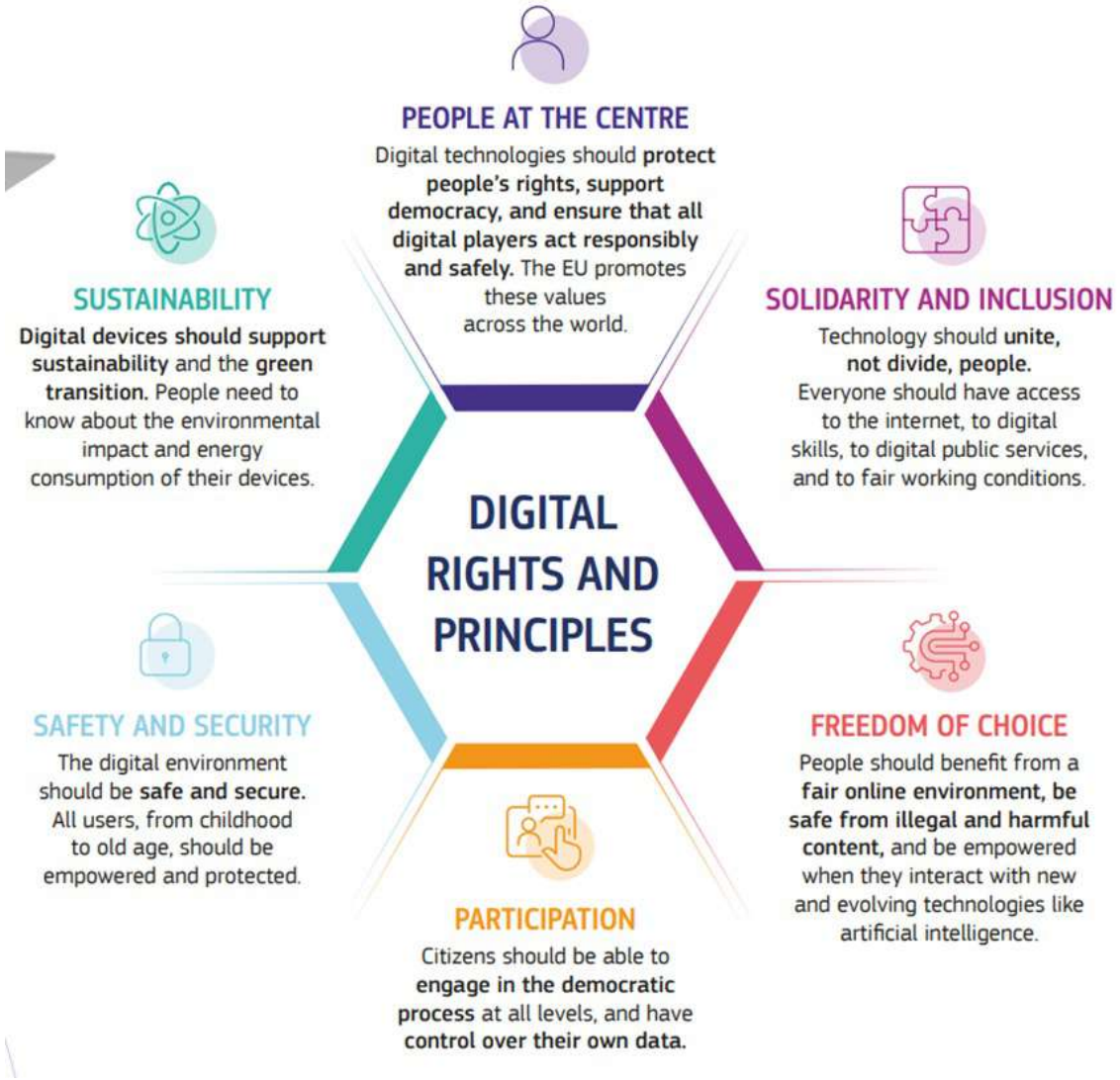
General context and challenges in healthcare

EC Declaration on European Digital Rights and Principles



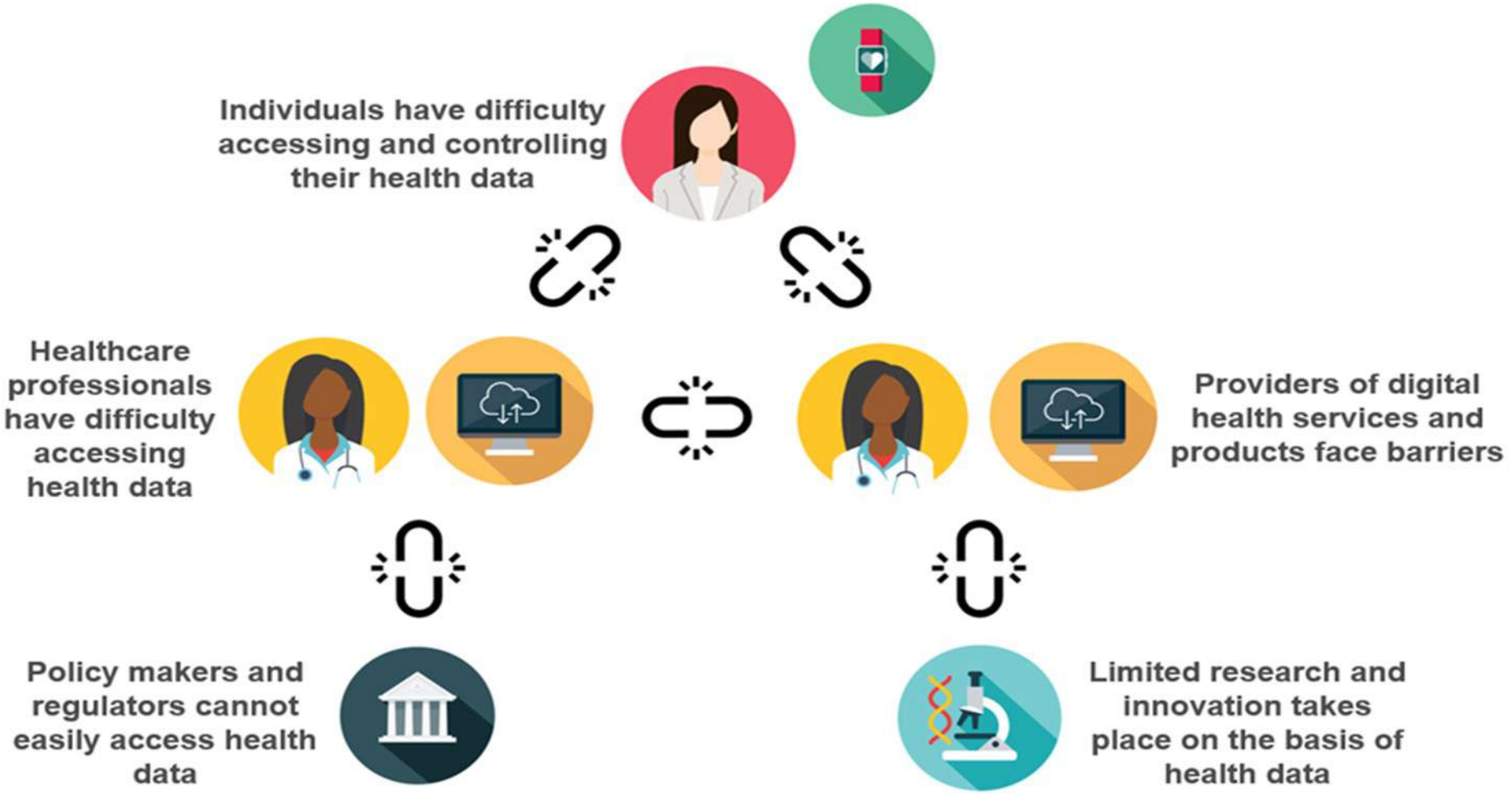
- **digital sovereignty**
- **inclusion**
- **equality**
- **sustainability**
- **resilience**
- **security**
- **trust**
- **improving quality of life**
- **respect of people' rights & aspirations**
- **dynamic, resource-efficient and fair economy & society**

Text of the Declaration

Digital transformation of health and care

- Citizen's **secure access to and sharing of health data** across borders
- **Better data** to advance research, disease prevention and personalised health and care
- **Digital tools for citizen empowerment and person-centred care**

Main challenges in harnessing the power of health data



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Game changer in healthcare. The EHDS

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Principles, aims and remaining challenges

European Health Data Space. Primary and secondary use of Data

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Primary use of Data

Single market for digital health products and services

Problems

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Areas of work

- Eliminate barriers to free movement
  - Labelling
  - Interoperability
  - Reimbursement
  - Liability

Primary use of Data

Access to health data for research, innovation, public health policy making

Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

Secondary use of Data

AI

Problems

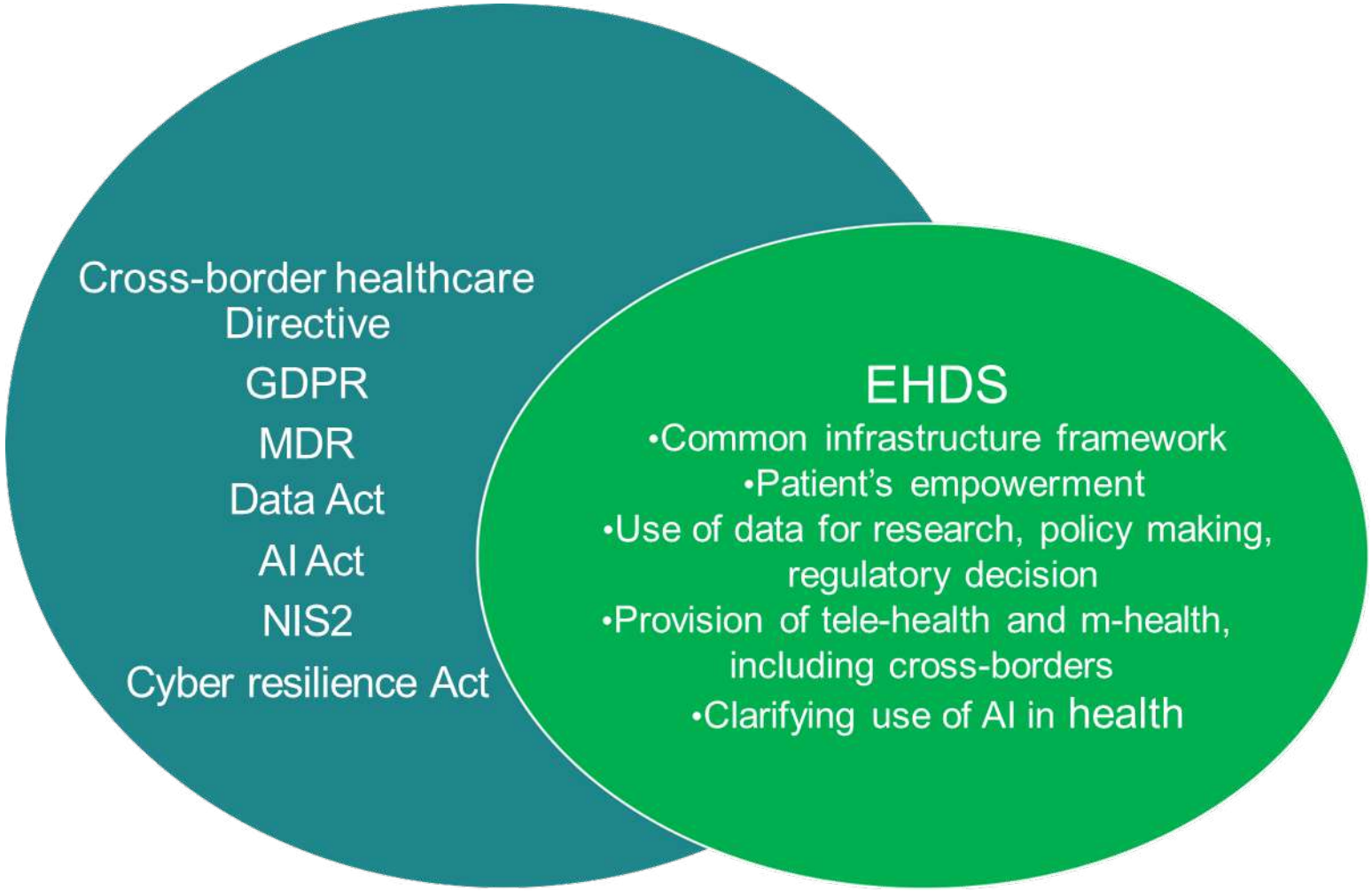
- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorythms
- Uncertainty on AI liability in health

Areas of work

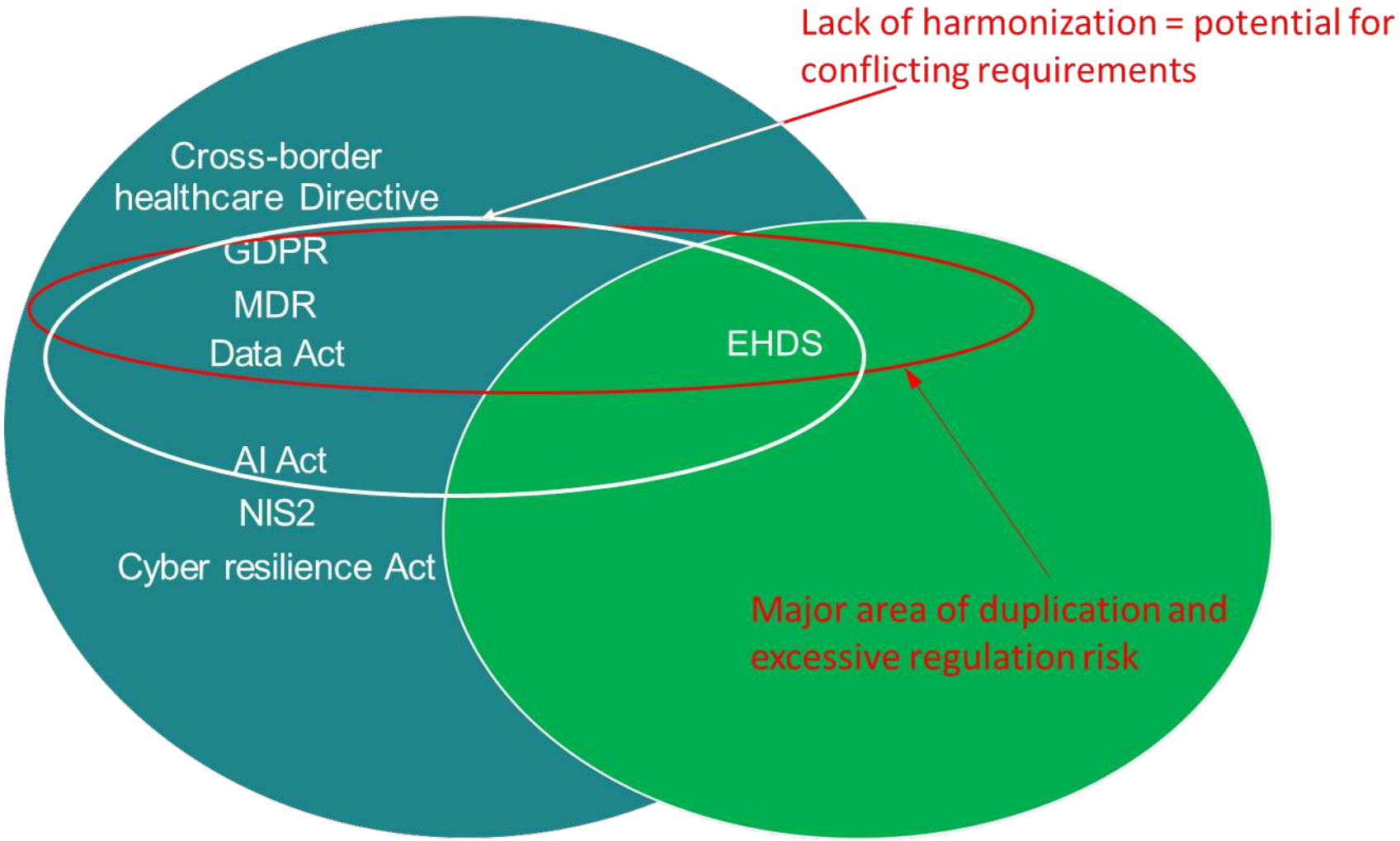
- Support for development and rollout of AI
- Data for AI
- Support for regulators

Secondary use of Data

EHDS in the context of EU regulatory framework for Medical Devices



Zones of major legislative contradictions & overlaps



Limitations of the targeted EHDS effect

Legal uncertainty	► **Not aligned with the GDPR, and the proposed Data Act.** This will create significant legal uncertainty and may lead to reduced security and privacy of the patients' personal data. ► **Insufficient distinction between data holder, user, and data recipient** should be better clarified as the (IoT) value chains. ► There is **no clarity as to the responsibilities** of healthcare professionals, healthcare providers, and third parties if any.
Risk management	► **Data interoperability cannot be governed by EU requirements only** but should be aligned with international standards. ► **The protection of IP rights and trade secrets and fair cost coverage is not properly secured** to preserve incentives for companies to invest into quality data collection. ► **Mechanisms for data provision for public interest are complicated** and may lead to subjective interpretations.
Potential fragmentation	► **Restrictions on non-personal data processing to third countries for secondary use purposes** aim to ensure data privacy. However, they **may pose significant unintended limitations to R&D in some cases**, for example, on rare diseases. ► Risks remain for **insufficient harmonization between national frameworks of the EHDS**.

EDPB &EDPS positions on EHDS and the Data Act

Joint_opinion_of_EDPB_and_EDPS_on_EHDS

EHDS proposal may weaken the protection of rights to privacy and protection, especially in the case of secondary use of data. The description of rights in not aligned with the GDPR.

Acknowledge that EHDs adds yet another layer to already complex multi-layered collection of provisions. Therefore, the interplay between those different pieces of legislation needs to be crystal clear, especially the interplay with GDPR and Member states laws.

Proposes that **wellness data should be subject to GDPR, as well as potentially e-Privacy directive**.

Strongly recommends to not extend the scope of GDPR exceptions regarding the Data subjects rights, in particular under Artc 38 (2)

It points that

wellness data should not be included in the secondary use of health data.

Calls to limit data storage in the EU/EEA.

Calls to clarify tasks, competencies and cooperation of the public bodies.

EDPB-EDPS_joint_opinion_22022_on_data_act_proposal

Additional safeguards are necessary as the rights to access, use and share data under the Proposal would likely extend to entities other than the data subjects, including businesses, depending on the legal title under which the device is being used. Second, the EDPB and EDPS are **deeply concerned by the provisions regarding the obligation to make data available to public sector bodies and Union institutions, agencies or bodies in case of "exceptional need".** Finally, the EDPB and the EDPS are concerned that the oversight mechanism established by the Proposal may lead to **fragmented and incoherent supervision.**

COCIR Recommendations for the EHDS

PRIMARY USE OF ELECTRONIC HEALTH DATA

6. The protection of IP rights and trade secrets and fair cost coverage should be secured to preserve incentives for companies to invest into quality data collection.
7. More simple and more standardized principle should be applied for data provision for the public interest to minimize subjectivity and ensure better comparability and transparency.
8. Ensure that obligations to collect, store and provide data (under Annexes II and III) are limited to information that is relevant to the intended purpose of the device or system.

COCIR Recommendations for the EHDS

EHR SYSTEMS AND WELLNESS APPLICATIONS

9. Article 16 should be elaborated to cover different scenarios of EHR system deployment and corresponding allocation of responsibilities between the manufacturer, the user and third-party deployer in case of its presence.
10. The difference between healthcare professionals and patients as users should be established.
11. The definition of EHR system should be adapted. The proposed broad definition may potentially encompass all medical devices which store, intermediate, import, export, convert, edit or view electronic health records. The delineation between EHR systems, medical devices and high-risk AI systems may be challenging.
12. Reference to the international state of the art standards should be introduced in Article 23 ad elaborated in Article 68.
13. Handling of risks posed by EHR systems and of serious incidents (Article 29) should be aligned to MDR/IVDR

COCIR Recommendations for the EHDS

SECONDARY USE OF ELECTRONIC HEALTH DATA

14. Data sharing for the secondary use purposes (Art 33) should be qligned with GDPR to avoid confusion which stakeholders are data holders under the EHDS.
15. More clarity on provision of electronic health data entailing protected intellectual property and trade secrets under the Article 34 should be provided.
16. Health-related private legal entities, including the developers of wellness applications should be ensured access to health data for secondary use when the request comply with the requirements under this Regulation.
17. Ensure proper cost coverage for data provision for secondary use and consider a different mechanism for deductions in fees for providing data under Article 42.

COCIR Recommendations for the EHDS

SECONDARY USE OF ELECTRONIC HEALTH DATA (cont.)

14. Restrictions on non-personal data movement to third countries for secondary use purposes should be proportionate to the objective risks and shall rely on clear criteria. Article 61 should be revised and more clarity on restriction criteria introduced.
15. National frameworks for implementing EHDS and safeguarding its performance compliance should be well aligned. Centralized principle for sanctions following the example set in the GDPR or the proposed AI Act for penalties upon the misconduct of stakeholders under the EHDS could prove to be more efficient.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Additional slides

Related guidance by TEHDAS & ENISA

TEHDAS deliverables in 2022

1. **Glossary** / reference for definitions which may underly interpretations of Data Act and EHDS
2. **Recommendations on Data Interoperability** / This document lists a number of interoperability standards on data discoverability (at data source and variable levels) and on standards for the development of common data models, and describes some basic features: typology of interest, utility and domain/s.
3. **Options to overcome Data barriers** / this report presents the perspectives of data users on secondary use of health data within the European Health Data Space (EHDS). It consolidates the results of the Report on secondary use of health data through European case studies, literature review, data sharing framework, stakeholder case studies and expert interviews. Addressing barriers to data sharing caused by semantic and legal interoperability was identified as a priority within the EHDS to ensure its success.
4. **European guidelines for Data Partnerships** / Guideline document for a peer-to- peer and cross-border partnership for the secondary use of health data proposes 6 major steps to follow to initiate a bi- or multilateral partnership agreement between structures wishing to share health data for secondary use.
5. **Funding options for secondary use of health Data** / The document gives a brief overview of the EU's funding instruments relevant to the secondary use in the periods of 2014-2020 and 2021-2027. Six existing EU health data sharing mechanisms are described in more detail.
6. **Minimum technical services for the European Health Data Space** / This document presents the options for the minimum services, understood as computing systems and software, required for the proper operation of the EHDS2
7. **Report on data Access processes in four countries** / demonstrates the importance of a one-stop shop for health data in national settings and the need to foster the implementation of national nodes and centralised health data access review processes / recommendations to address health data platforms related challenges: governance, ensuring a trustworthy approach for data holders and citizens, facilitating the data user journey by developing specific tools while continuing to work on guaranteeing data interoperability.

TEHDAS website

Cybersecurity Relevant Publications in 2022 by ENISA

ENISA report Data Protection Engineering

ENISA Pseudonymisation Healthcare

DATA PROTECTION ENGINEERING. From Theory to Practice

The report provides a concentrated summary of challenges of new technologies compatibility with GDPR. It points, that processing of personal data is often characterized by the absence of a predetermined purpose and by the discovery of new correlations between the observed phenomena, for example in the case of big data or machine learning. This modus operandi conflicts essentially with the principles of necessity and purpose limitation, as these are stipulated by the GDPR.

The report overviews legal and practical aspects of Data protection by design, touching on data protection engineering, connection with the Data Protection Impact Assessment (DPIA) and the role of a range of technologies that fall under the term of Privacy Enhancing Technologies (PETs), proposing possible categories of those technologies.

DEPLOYING PSEUDONYMISATION TECHNIQUES. The case of the Health Sector

This report demonstrates that there is not a single solution, but rather different solutions might provide equally good results in specific scenarios, depending on the requirements in terms of protection, utility, scalability, and others.

The report acknowledges that increasing processing of digitised medical data has also increased the risks, in terms of cybersecurity, data protection and the likelihood of data breaches. Yet it points that ddefining the goals and objectives of pseudonymization in each case and processing operation is really important.

It also reminds that in the General Data Protection Regulation (GDPR) pseudonymization is explicitly referred as a technique which can both promote data protection by design (Article 25 GDPR), as well as the security of personal data processing (Article 32 GDPR).