EUREGHA

1° Meeting

Digital Transformation Working Group

Online – 22 September 2022

Agenda

I. **Welcome and meeting introduction by EUREGHA Director (5')**

I. **Tour de table (10')**

- Members introduction. Suggested focus: expectations from the Working Group, brief description of members' interest in the field of Digital Transformation.

I. **Presentation on the key elements of the EHDS framework (15')**

- Recap of EHDS early reaction from EUREGHA (Public Consultation response 2021)
- Presentation key elements EHDS based on EC information.

I. **Roundtable EUREGHA members current engagement and reactions on EHDS (60')**

- Presentation from Region Östergötland about response to national consultation on EHDS (10')
- Tour de table to collect members' reactions, covering, where possible, the key points suggested below:

Goal → Collect early views on the European Health Data Space (EHDS), in particular to understand the current level of engagement with the initiative and, in general, on health data.

i. With regards to the EHDS, it will be particularly interesting to collect views on: Technical preparedness (infrastructure, interoperability, etc). Ecosystem preparedness (e.g., citizens' digital literacy, healthcare professionals' skills, etc.), Main challenges and hurdles, including at cross-border level, Needs (e.g., investments), Active projects or initiatives of interest.

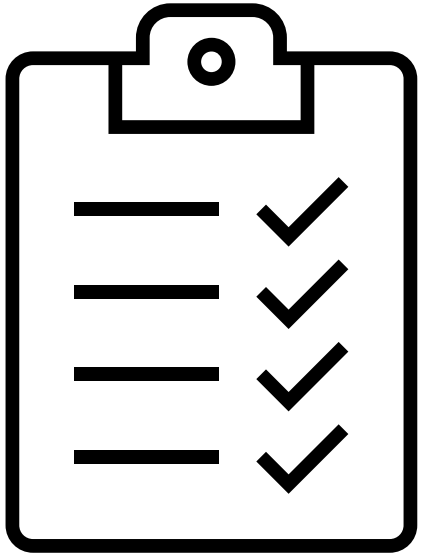
I. **Collection of additional inputs/best practices in the field of Digital Transformation, not necessarily linked to EHDS (10')**

- Tour de table to collect inputs/best practices presentations from members, covering topics not necessarily related to the EHDS.

I. **Discussion on potential activities and focus for Working Group (15')**

- Members to provide inputs on potential activities, future meetings (e.g., invitation of guest speakers), for the Working Group.

I. **Wrap up and End of Meeting (5')**



2. Tour de Table

- Members introduction.
- Suggested focus: expectations from the Working Group, brief description of members' interest in the field of Digital Transformation.

3. Presentation on the key elements of the EHDS framework

- Recap of EHDS early reaction from EUREGHA (Public Consultation response 2021)
- Presentation key elements EHDS based on EC information.

3. Recap of EHDS early reaction from EUREGHA

- Essential to put the willingness and needs of the patient at the centre of this ambitious initiative. Patient's right to privacy and choices about the use of their data must be safeguarded

Data governance and rules for data exchange

- Consider the legislative **fragmentation and the structural and infrastructural capabilities and obstacles of local administrations** to implement potential solutions in the EHDS framework.
- to encourage regional authorities to respond and contribute effectively to the setup of a European framework, it is necessary to emphasise the potential benefits of this project in terms of local economic development and growth.
- **active involvement of regional authorities** must take place not only on the level of European political planning but also on the operational level using the **European Structural and Investment funds** to support the implementation the EHDS..
- citizens' engagement in the data governance model functioning is fundamental. **Regional and local authorities, being the government level closer to citizens, should have an instrumental role in the citizen engagement in this domain**

https://www.euregha.net/wordpress/wp-content/uploads/2018/11/EUREGHA-Contribution-to-the-public-consultation-on-a-EHDS.pdf

3. Recap of EHDS early reaction from EUREGHA

Data quality and interoperability

- **Setting standards for high-quality data represents a vital step**. There is a need to have a straightforward and common direction in the definition of high standards and pool standards and technical requirements together.
- efforts of **international standard bodies should be coordinated with digital health bodies that work at the national and regional levels.**
- **identification and use of countries' and regional existing legislative frameworks may be beneficial to certify, apply and enforce those standards**, fostering a wide adoption as well as facilitating health interoperability within and between countries.
- **Ensuring interoperability** is instrumental not only to foster a European framework f**or re-use of health data but also to improve its primary use in the cross-border healthcare provision cooperation**
- Concerning **interoperability**, the thrust of the European Union in this regard must **take into account the differences of regional health systems**, intercepting their weaknesses and **supporting local authorities** in bridging existing gaps, for example, in data collection and sharing techniques.

https://www.euregha.net/wordpress/wp-content/uploads/2018/11/EUREGHA-Contribution-to-the-public-consultation-on-a-EHDS.pdf

3. Recap of EHDS early reaction from EUREGHA

Infrastructure and technology

- EUREGHA recognises the **potential leading role of the European Union on data-driven technologies and on eliminating barriers to digital health services** in accordance with the GDPR and standards and protocols established within the EHDS framework.
- **EU regulations consider AI as a medical device** and, as such, similar existing approaches apply. In this framework, **AI systems should always represent a tool to support healthcare professionals** in making their decisions, through transparency and guidelines.
- **education and transferring skills tools will be required not only among cross-border national healthcare systems but also among regions.**
- **Regional authorities can significantly contribute to spreading digital literacy, building public understanding of and trust** in how health data is used in research for the benefit of the overall European community.

https://www.euregha.net/wordpress/wp-content/uploads/2018/11/EUREGHA-Contribution-to-the-public-consultation-on-a-EHDS.pdf

3. Presentation on the key elements of the EHDS framework

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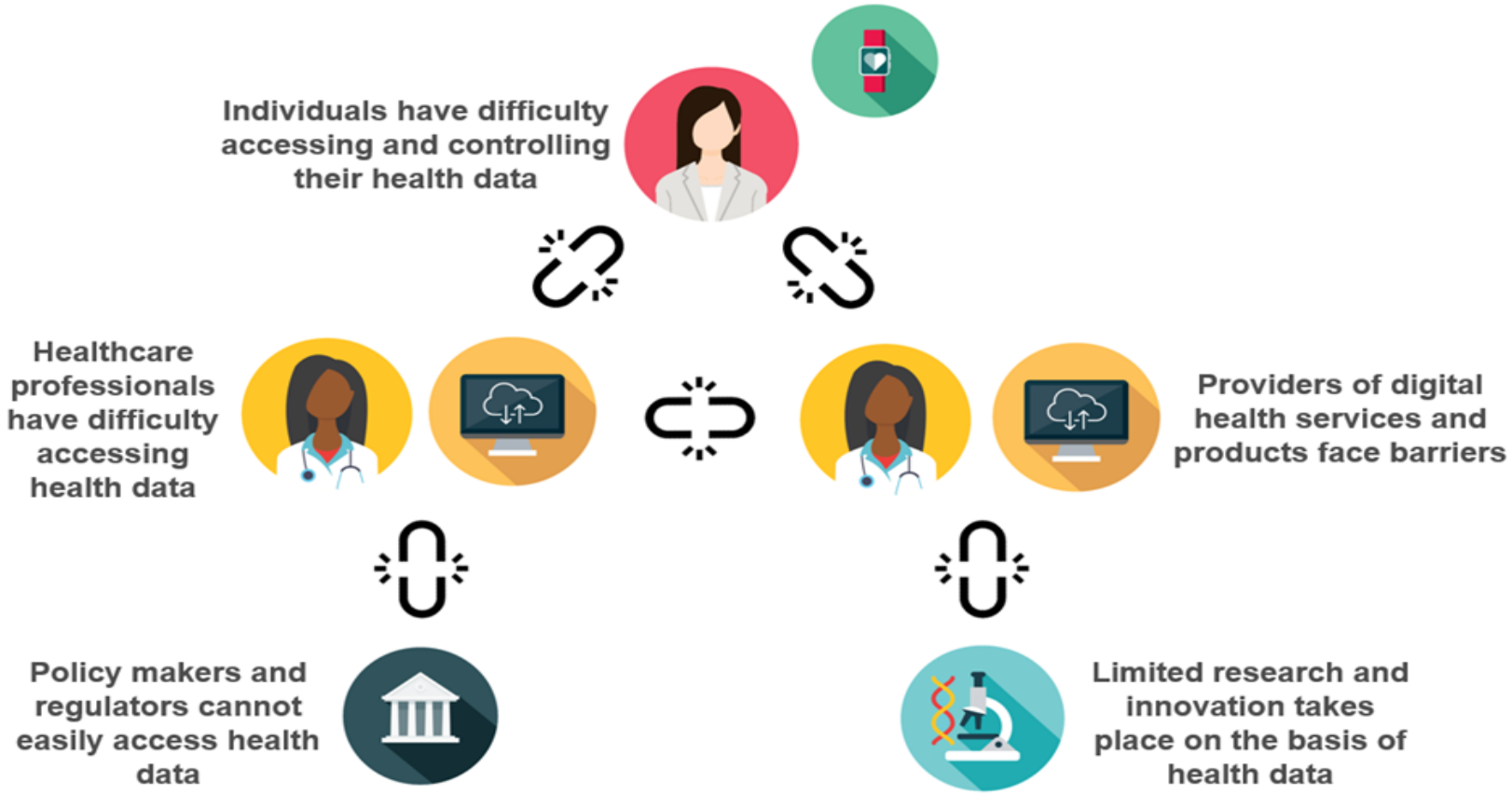
3. Presentation on the key elements of the EHDS framework

- **The 2020 European Strategy for Data** announced the Commission's plans for European data spaces, including EHDS
- The COVID-19 pandemic has clearly demonstrated **the importance** of digital services in the health domain, and has triggered **an important acceleration in the uptake** of digital tools.
- The European Digital Covid Certificate – positioned the EU as a **global leader and standard setter in digital health**

Source: European Commission

Main challenges in harnessing the power of health data

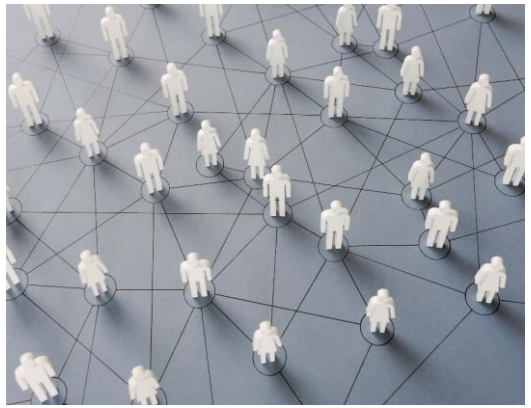


Source: European Commission

Proposal for a Regulation on the European Health Data Space

It sets out rules, common standards, infrastructures and a governance framework for the use of electronic health data for healthcare, research, innovation and policy making

Empower individuals to access and control their personal health data

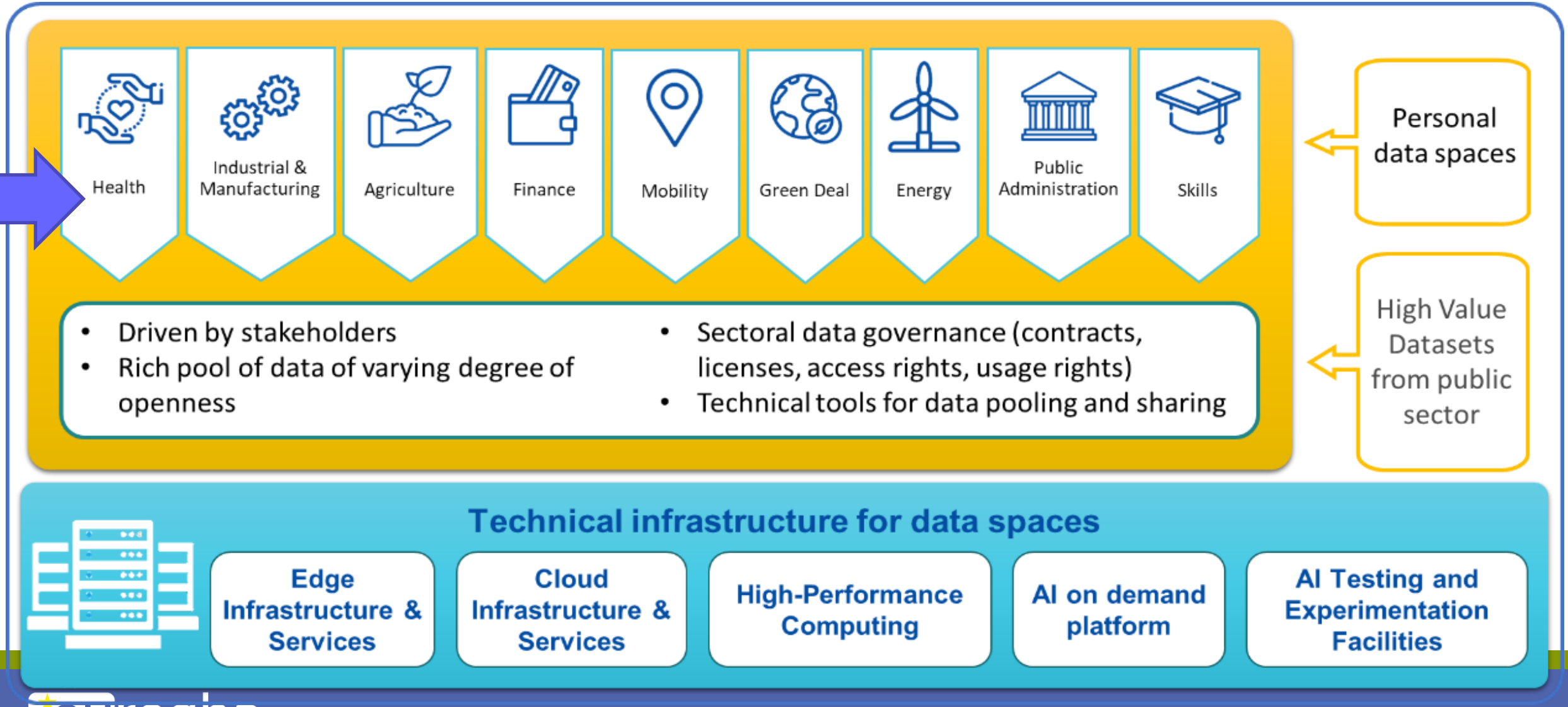


Ensure a consistent framework for the use of individuals' health data for research, innovation, policy-making and regulatory activities

Unleash the data economy by fostering a genuine single market for digital health services and products (EHR systems)

Source: European Commission

EHDS – **the first** sector specific European Data Space



Source: European Commission

EHDS – links with other legal proposals and initiatives

GDPR

EHDS builds upon GDPR rights and further develops some of them

European Health Union

EHDS will boost the work of EU Cancer plan, HERA, Pharmaceutical Strategy for Europe

Data Governance Act, Data act

EHDS complements and provides more tailor-made rules for the health sector

EU cybersecurity framework (NIS directive)

EHDS complements and provides more tailor-made rules for the health sector

Artificial Intelligence Act

EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality

Medical Device Regulations

If manufacturers claim interoperability of devices with EHR systems –EHDS requirements apply

Source: European Commission

European Health Data Space (EHDS)

OBJECTIVES

Effective use of health data

SCOPE & EXPECTED IMPACT

Use of health data (primary, MyHealth@EU)	• Empower individuals to control their data • Standardization and mandatory certification of EHR systems • Voluntary labelling of wellness apps • European Electronic Health Record Exchange Format	Single market for health data, data protection, free movement of people, digital goods and services
Re-use of health data (secondary, HealthData@EU)	• Health data access bodies • Purposes for use and forbidden use • Data permits, secure environments, no identification	Facilitated Research & Innovation Better Policy Making

MEANS

- **Legal / Governance**
- Quality of data
- Infrastructure
- Capacity building/digitalisation (MFF)

The scope of EHDS

Strengthens the rights of individuals in relation to greater control over their electronic health data:

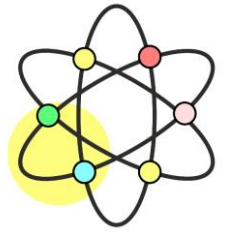
Access, share health data with health professionals nationally or cross-border, add information, rectify errors, restrict access, know what health professional accessed data, issue and accept health data in a common European format, strengthen interoperability.

Rules for electronic health record systems (EHR systems)

Rules and mechanisms supporting the secondary use of electronic health data

Mandatory cross-border infrastructures for primary and secondary use of health data

- **MyHealth@EU**
- **HealthData@EU**



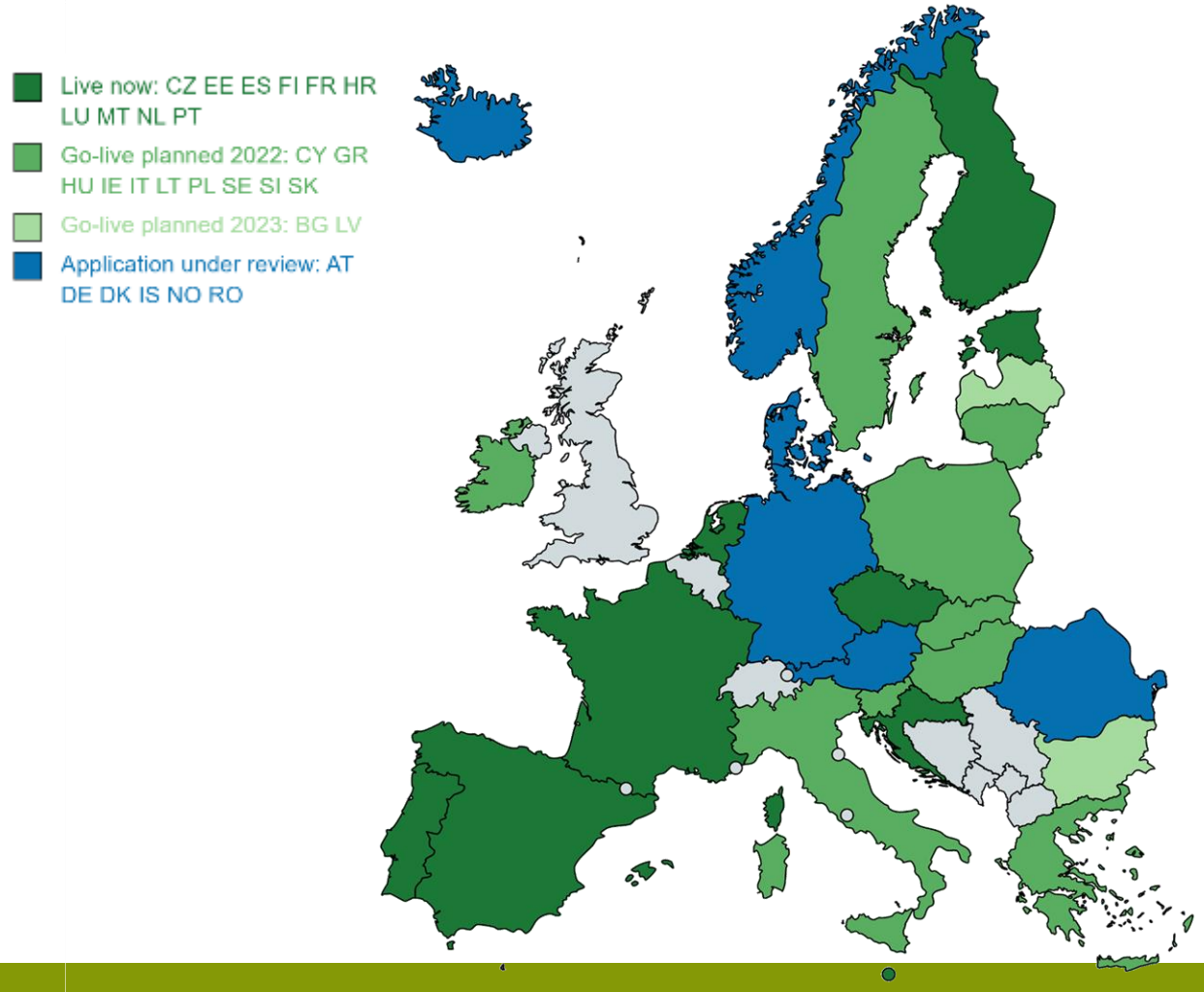
Source: European Commission

Chapter II Primary use of electronic health data

- Develops **additional rights** of individuals to complement the rights provided under the GDPR in relation to their electronic health data (Art. 3)
- Sets out the provision for the **access by health professionals** to personal electronic health data (Art. 4)
- **Identifies** some type of electronic health data **as a priority** to be integrated in the EHDS in a staged process (Art.5) with deferred application (art 72)
- **Member States shall: establish one or more electronic health data access services at national, regional or local level (Art.5)**
- Introduces **European electronic health record exchange format** (Art. 6)
- Requirements **for the registration** of personal electronic health data and **identification management** (Art. 7 and Art. 9), non discrimination for provision of **telemedicine** (Art. 8)
- Set up a **digital health authority** and its tasks (Art.10) and right to lodge a complaint with the authority (Art 11)
- **Mandatory** participation in common infrastructure **MyHealth@EU** (Art. 12)
- **Supplementary services** to MyHealth@EU, including **interoperability with third countries and international organisations** (Art 13)

Source: European Commission

MyHealth@EU



- Currently 10 Member States are live
- The number of connected Member States will grow rapidly in the years ahead - there are plans for all Member States to join **MyHealth@EU until 2025.**
- Currently there are 2 services: Patient Summary and ePrescription
- This is being expanded to include Medical images, Laboratory results, Discharge letters, Rare disease data and other health information categories
- A Pilot project will explore Patient Access to their health data in MyHealth@EU

Source: European Commission

Chapter III EHR systems and wellness applications

- Implementing **a mandatory self-certification scheme** for EHR systems, relation with medical devices and high risk AI systems (Art. 14 – 16)
- **The obligations** of each economic operator of EHR systems (Art. 17 – 22)
- The **requirements** related **to the conformity** of such EHR systems (Art 23 - 27)
- **Market surveillance authorities** for EHR systems (Art.28 – 30)
- Provisions on the **voluntary labelling** of wellness applications (Art. 31)
- **EU database** for certified EHR systems and labelled wellness applications (Art. 32)

Source: European Commission

Chapter IV Secondary use of health data I

- Defines **a set of minimum categories** of electronic data **for secondary use** that can be used for defined **purposes** (supporting policy making, regulatory activities, research, innovation and development of health products, training of AI algorithms eg for medical devices). Defines **prohibited purposes** (eg use of data against persons, commercial advertising, increasing insurance, develop dangerous products) (Art. 33, 34, 35)

- Set up a **health data access body/bodies** for secondary use of electronic health data (Art. 36) – *building upon the Data Governance Act*

- **The tasks and obligations** of the health data access body, the data holders and the data users (Art. 37, 38, 39)

- Implementation of **data altruism** in health (Art.40)

- Sets **the duties for data holders (**Art. 41)

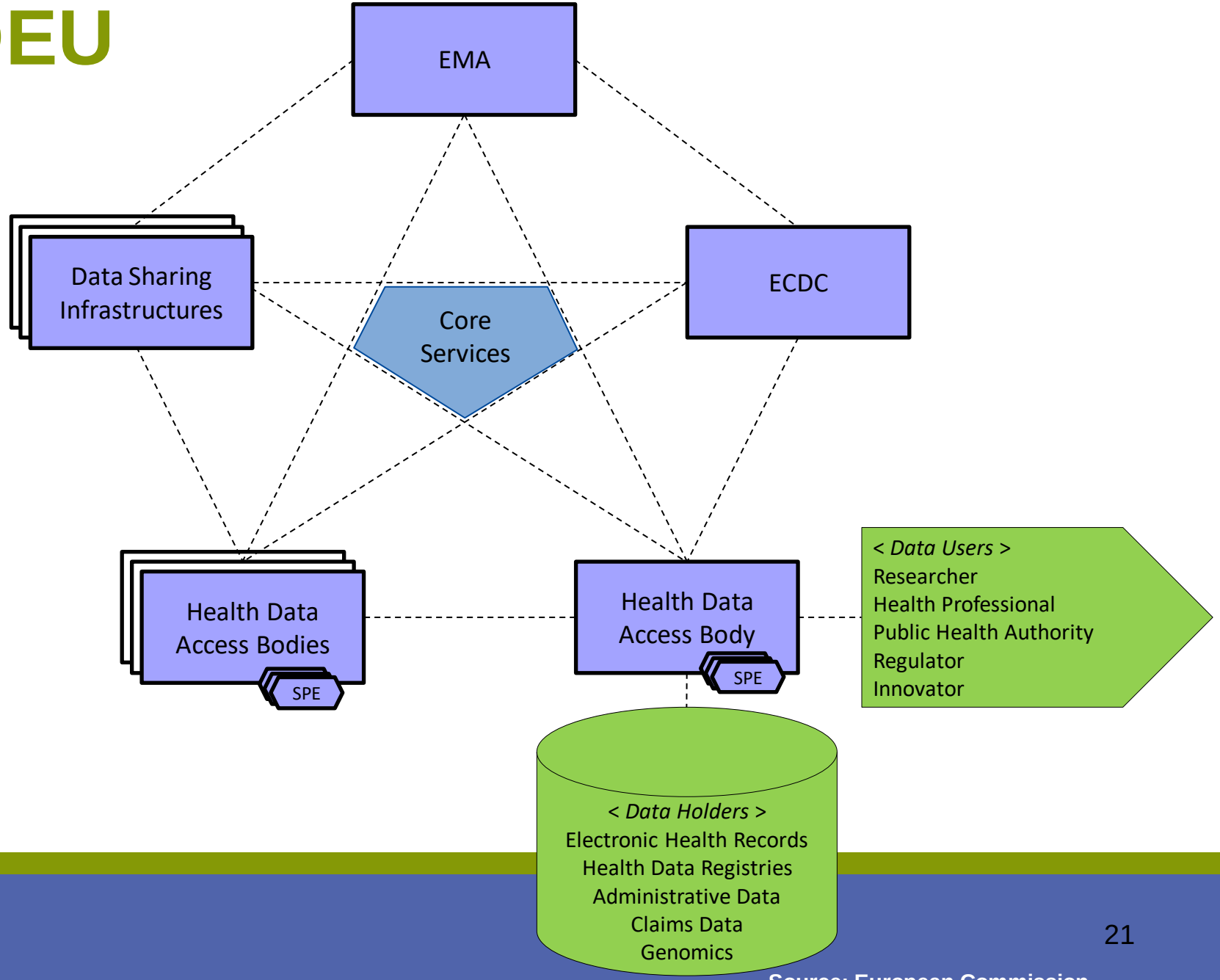
Source: European Commission

Chapter IV Secondary use of health data II

- General provisions on transparency and structure **of fees calculation (**Art. 42), building upon Data Governance Act
- **Penalties** by health data access bodies (Art. 43)
- The conditions and requirements **for data permit for the secondary of** electronic health data (data minimization, data access, incl. access to data for public and EU institutions, access to data from a single data holder, data permit, data request, secure processing environment) (Art. 44 – Art.51)
- Development of the **new decentralised EU cross-border infrastructure** for secondary use **(HealthData@EU)** (Art. 52)
- **Provisions** on setting up and fostering **cross-border access** to electronic health data and mutual recognition (Art 53, 54)
- **Provisions** related **to dataset description** and their **quality,** establishment of **EU Dataset Catalogue** (Art. 55, 56, 57)

Source: European Commission

HealthData@EU



Source: European Commission

Chapter V Additional actions

- Other measures to promote **capacity building** by the Member States (Art.59)
- Sets the **additional requirements for public procurement** and **Union funding** to comply with **EHDS** rules (Art. 60)
- **Third country transfer** of non-personal electronic health data (Art.61)
- **The provisions of the international access and transfer** for non-personal and personal data in the EHDS (Art.62, 63)

Source: European Commission

Governance (Chapter VI and VII)

- Current situation – eHealth Network is **voluntary**, soft cooperation – **not binding** decisions, not addressing the needs of secondary use of health data.

- EHDS is proposing:
  - **Article 14** of Directive 2011/24/EU **is deleted** (Art. 71)
  - **a new European Health Data Space Board (***high level representatives of digital health authorities (primary) and new health data access bodies (secondary) from all the Member States, the Commission, observers etc*). The Commission will chair these meetings. Among other tasks, it will assist Member States in coordinating practices, issue written contributions and to exchange best practices, facilitate cooperation of Member States etc

Source: European Commission

Governance (Chapter VI and VII)

- **comitology committee** (*both for primary and secondary*) – to provide an opinion on draft implementing acts (*now – more than 20 empowerments for implementing acts in the text*). They include one representative from every EU country and are chaired by a Commission. The rules and procedures applicable to committees are set out in **Regulation 182/2011**. The committee will adopt its rules of procedure on the basis of standard rules of procedure which have been published in Official Journal.

- **expert groups** (*both for primary and secondary*) - the Commission will prepare and adopt **binding** delegated acts (*now - more than 10 in the text)* after consulting these experts groups, composed of representatives from each EU country. It is a commitment under the Interinstitutional Agreement on Better Law-Making from 2016 that the Commission consults experts designated by the Member States on draft delegated acts.

- **joint controllership groups -** for two cross-border digital infrastructures (one for primary and another one for secondary uses of health data). The composition, organisation, functioning and cooperation of the sub-groups shall be set out in the rules of procedure adopted by those groups. The Commission is secretariat.

Source: European Commission

Chapter VIII Miscellaneous

- Provisions **on penalties for future infringements of data regulation (**Art. 69**)**
- **After 5 years** from the entry into force of this Regulation, the Commission shall carry out a targeted evaluation of this Regulation especially with regards to Chapter III (*EHR systems and wellness apps*). The evaluation shall include an assessment **of the self-certification of EHR systems** (Art. 70)
- **After 7 years** from the entry into force of this Regulation, the Commission shall carry out **an overall evaluation of this Regulation**, and submit a report on its main findings (Art. 70)

Source: European Commission

Entering into force

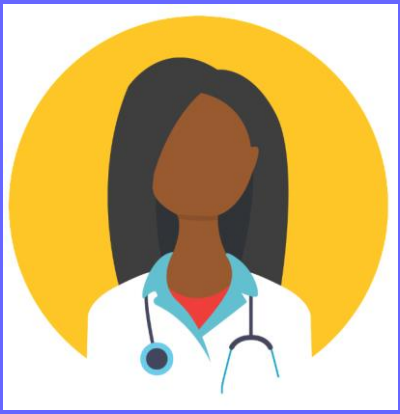
- The Regulation will start applying **one year** after its adoption following the negotiations between co-legislators.
- However, the proposal foresees **several transitional periods** for the application of different elements of the proposal, especially related to the primary use of health data (*1 year from the entry into application of the Regulation for patient summaries and ePrescriptions and 3 years for images and image reports, laboratory results and discharge reports*)
- At the same time, all the Member States, as well as Norway and Iceland have applied under CEF and EU4Health **to connect to MyHealth@EU** and most of them intend to connect **by end of 2025**

Source: European Commission

Benefits

Individuals

- Accessing and sharing health data
- More efficient healthcare
- Avoid unnecessary tests
- Support medical decisions
- Improve health outcomes



Healthcare providers

- Savings in hospital expenditure, improved decision making, better patient care
- Remote care and advice via telemedicine

Researchers, policy makers, regulators

- Access to more data
- Better decision making
- Research and development

Industry

- Access to data
- Research, development
- Larger markets for EHR systems

Individuals: strengthened security

Primary use

- Builds upon EU-cybersecurity legislation
- Security/interoperability criteria for EHR systems + CE marking
- Security audits for the MyHealth@EU (primary use) infrastructure
- Strong authentication for patient and health professionals
- Only persons entitled to access the data can get access to individual's data

Secondary use

- Data processed in secure processing environments, compliant with high standards of privacy and (cyber)-security.
- No personal data can be downloaded
- Users cannot identify individuals
- Audits of participants in HealthData@EU

Funding

Overall funding for EHDS and its infrastructures	Earmarked funding: € 330 mil	Complementary funding: ≥ € 480 mil	Funding for national investments
• Around € 800 mil	• EU4Health: € 280 mil • DEP: € 50 mil	• DEP: €140 mil • CEF: €130 mil • HE: € 210 mil	• RRF: € 12 bn • ERDF • InvestEU

Next steps

- The Regulation negotiated with the Council of the EU and European Parliament (**EP lead ENVI + LIBE committee**).
  - *Swedish EU Presidency 1st Semester 2023*
- Presentation to ministers in EPSCO
- EDPS & EDPB opinion

4. Roundtable EUREGHA members current engagement and reactions on EHDS

- Presentation from Region Östergötland about response to national consultation on EHDS (10')
- Tour de table to collect members' reactions, covering, where possible, the key points suggested below:

Region Östergötland Position on EHDS

Response to the Swedish consultation

22 September 2022

Region Östergötland

Process

- Spring 2021 – EU consultation
- May 2022 – EHDS proposal published and national consultation disseminated
- Internal processes
- Consultation conferences by national innovation agency, SALAR etc.
- Professions included
- Coordinated response mid August by three regions (Östergötland, Jönköping and Kalmar)

General comments on the proposal

- Welcome the initiative and overall ambition
- Lacking details; delegated acts an issue
- Beneficial to have legislation harmonized in this area but question of EU competency
- Regulation vs Directive
- Harmonization with current national legislation

General comments cont.

- Opportunity for precision medicine
- Primary vs secondary use of data
- Administrative burden
- Harmonization of standards/definitions etc.
- National agencies responsible for enforcement

Region Östergötland

Examples of specific comments

- Cost assessment – too optimistic
- Data submitted by patient
- Electronic records already on the market

4. Roundtable EUREGHA members current engagement and reactions on EHDS

- Tour de table to collect members' reactions

Goal → Collect early views on the European Health Data Space (EHDS), in particular to understand the current level of engagement with the initiative and, in general, on health data.

With regards to the EHDS, it will be particularly interesting to collect views on:

1. **Technical preparedness** (infrastructure, interoperability, etc).
2. **Ecosystem preparedness** (e.g., citizens' digital literacy, healthcare professionals' skills, etc.)
3. **Main challenges and hurdles**, including at cross-border level.
4. **Needs** (e.g., investments)
5. **Active projects or initiatives of interest**.
6. Any questions?

5. Collection of additional inputs/best practices in the field of Digital Transformation

- Tour de table to collect **inputs/best practices presentations from members**, covering topics not necessarily related to the EHDS.

6. Discussion on potential activities and focus for Working Group

- Members to provide **inputs on potential activities, future meetings** (e.g., invitation of guest speakers), for the Working Group.
- Planning 2nd Meeting

DT4REGIONS Award

Your solution for digital transformation

DT4REGIONS is a European Parliament Preparatory Action supported with European Funds

Aim of the Award

The DT4REGIONS Award gives visibility to the best solutions (such as initiatives and technological applications) based on Artificial Intelligence and Big Data currently in use by public administrations in Europe

DT4REGIONS is a European Parliament Preparatory Action supported with European Funds

Who can participate?

01 Civil Servants

02 Representative of public administration

03 Members of European regional and national authorities

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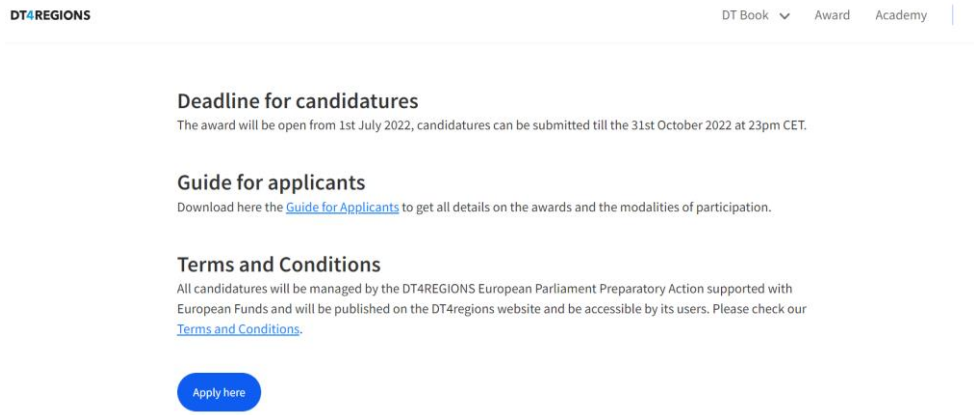
How to participate?

Apply under https://dt4regions.eu/award

- Each entrant can candidate one or more initiatives, applications or solutions providing all data to its best knowledge.
- It is possible to candidate initiatives belonging to one's own region, city, nation or public administration
- …but each entrant can also candidate initiatives of which he/she is aware of, belonging to other countries or public administrations.



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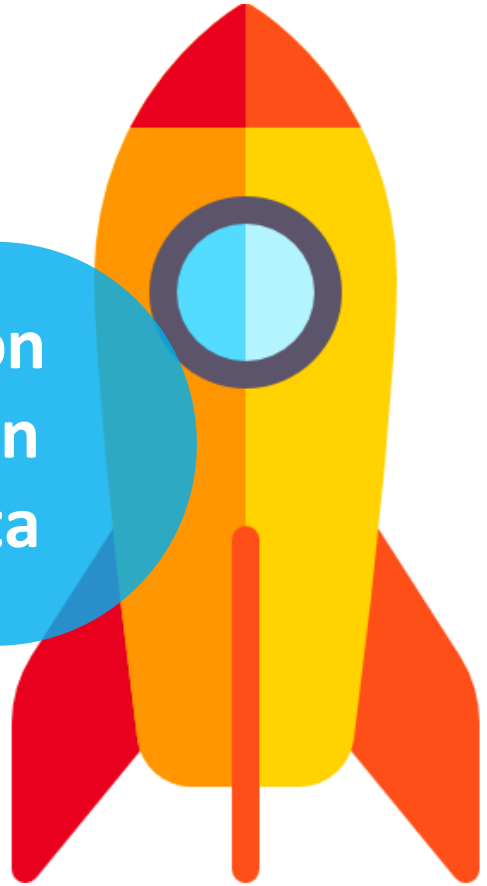
Prizes

Most Innovative Solution for public administration based on AI and Big Data

Selected and awarded by an expert jury



Public's favourite

Selected and awarded by the DT4regions' platform users

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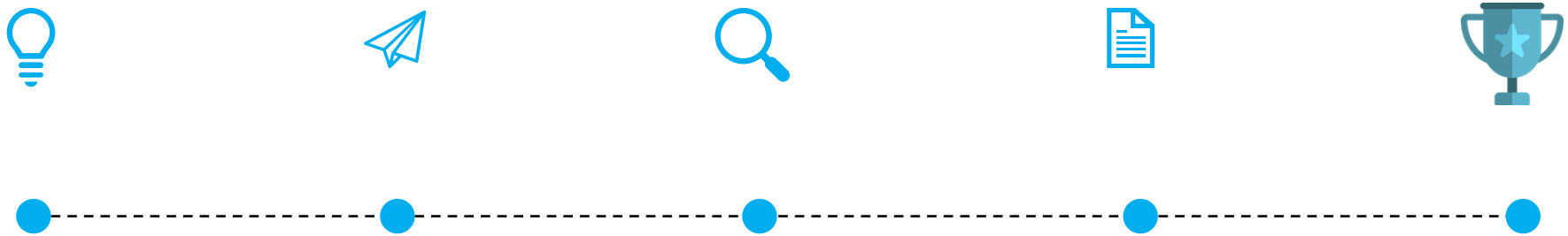
Timeline for the Award



Opening of Award

1st July 2022

Submission Deadline

31st October 2022 at 23pm CET

Pre-selection of Jury

By January 2023

Publication of pre-selected solutions

By March 2023

Public voting and Prizes

April 2023

DT4REGIONS is a European Parliament Preparatory Action supported with European Funds

Share your digital transformation solution now!

Thank you for your attention!

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DT4REGIONS

7. Wrap up and end of meeting

Thank you for your attention!

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