



HDA

Agenda

- 01** Introduction
- 02** Our work in Europe
- 03** HDA in Belgian context

01

Introduction- Why creating the HDA

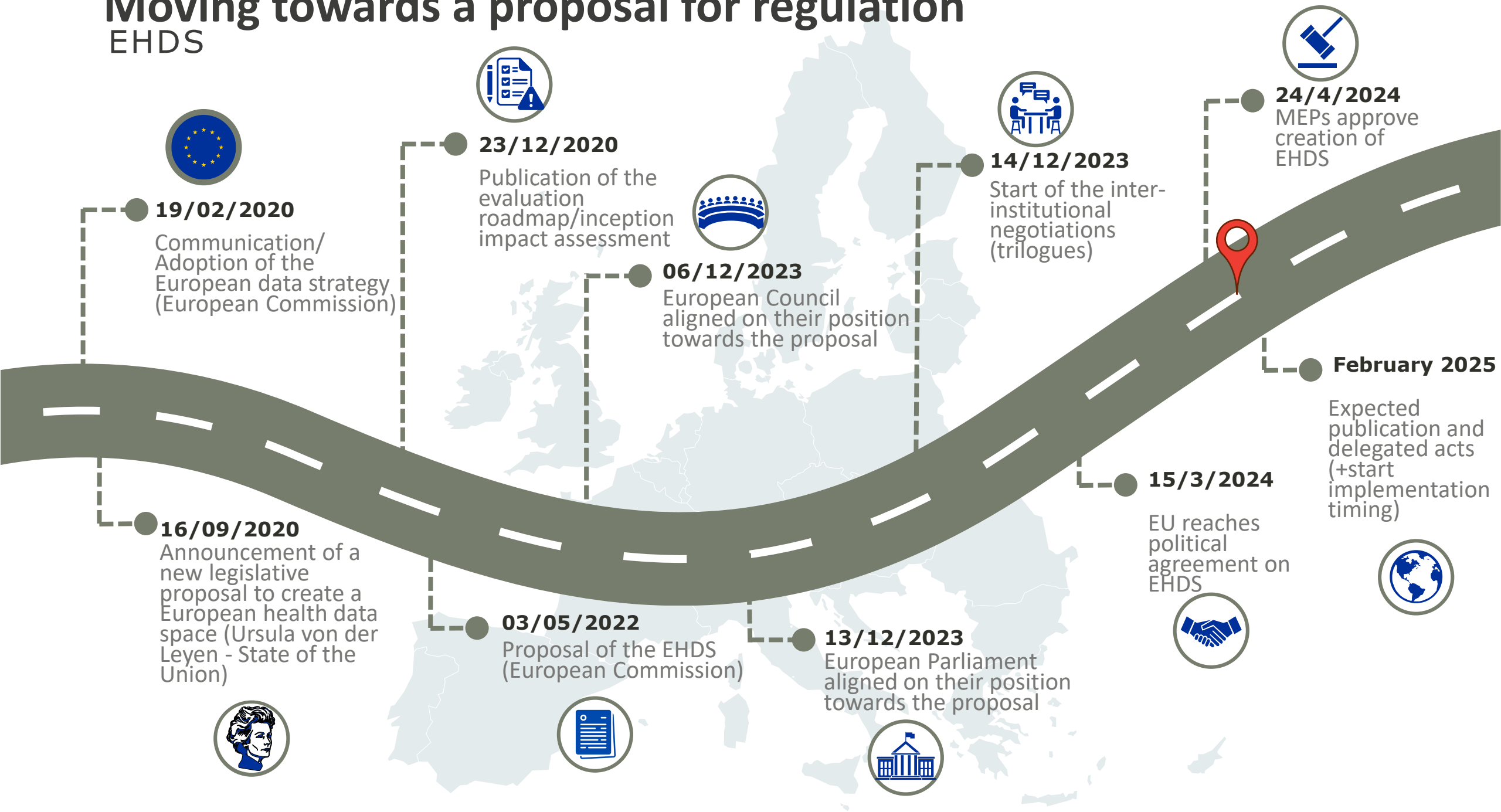
A photograph of the European Union flag, featuring twelve yellow stars on a blue field, waving in front of a modern glass and steel building. The flag is on a tall pole, and several other poles are visible in the foreground.

European Context

- A Europe “**fit for the digital age**” as a priority of the Commission for 2019-2024
- **EU's digital strategy** provides for the establishment of the **European Health Data Space (EHDS)**
- The **EU Data Governance Act**, approved on May 30, 2022
- **EU recovery plan**

Moving towards a proposal for regulation

EHDS



Belgian Context

- Numerous healthcare data, but fragmented and scattered across organizations and systems.
- Need for an integrated federal initiative on (re)use of these data.
- October 28, 2021: Coalition agreement and Health Policy Note foreseeing the establishment of the Belgian Health Data Agency (HDA)
- March 14, 2023: Law establishing the HDA



Context behind the creation of the HDA

PRIMARY USE

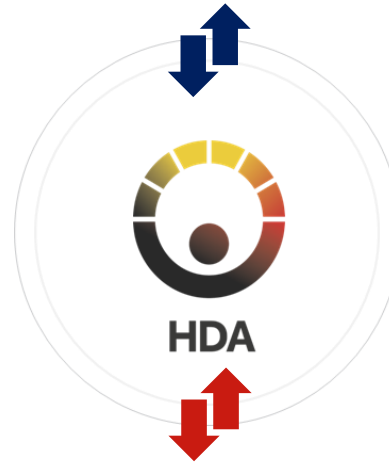
Empowering individuals through increased digital access and control of their electronic personal health data

Myhealth@EU

SECONDARY USE

Providing a consistent, trustworthy and efficient set-up for the use of health data for research, innovation, policy-making

Healthdata@EU



02

HDA in European context

EU Dataset Records

Formats [?]

Catalogues [?]

Keywords [?]

Data scope [?]

Licences [?]

Health Data Access Body [?]

 [EU Dataset Records](#)[EU Dataset Catalogues](#)[Last modified](#)[Relevance](#)[Name ascending](#) 

4 dataset records found

[Adapted] Antimicrobial resistance in the ECDC atlas

Data covering EU/EEA countries, currently from 2000 and onward, and collected by the European Antimicrobial Resistance Surveillance System (EARSS), and later, from 2010 by the European Centre for Disease Prevention and Control (ECDC) through the European Antimicrobial Resistance Surveillance Network (EARS-Net...

[Excel XL](#)[HTML](#)

Updated: 09 October 2024

Created: 22 September 2022



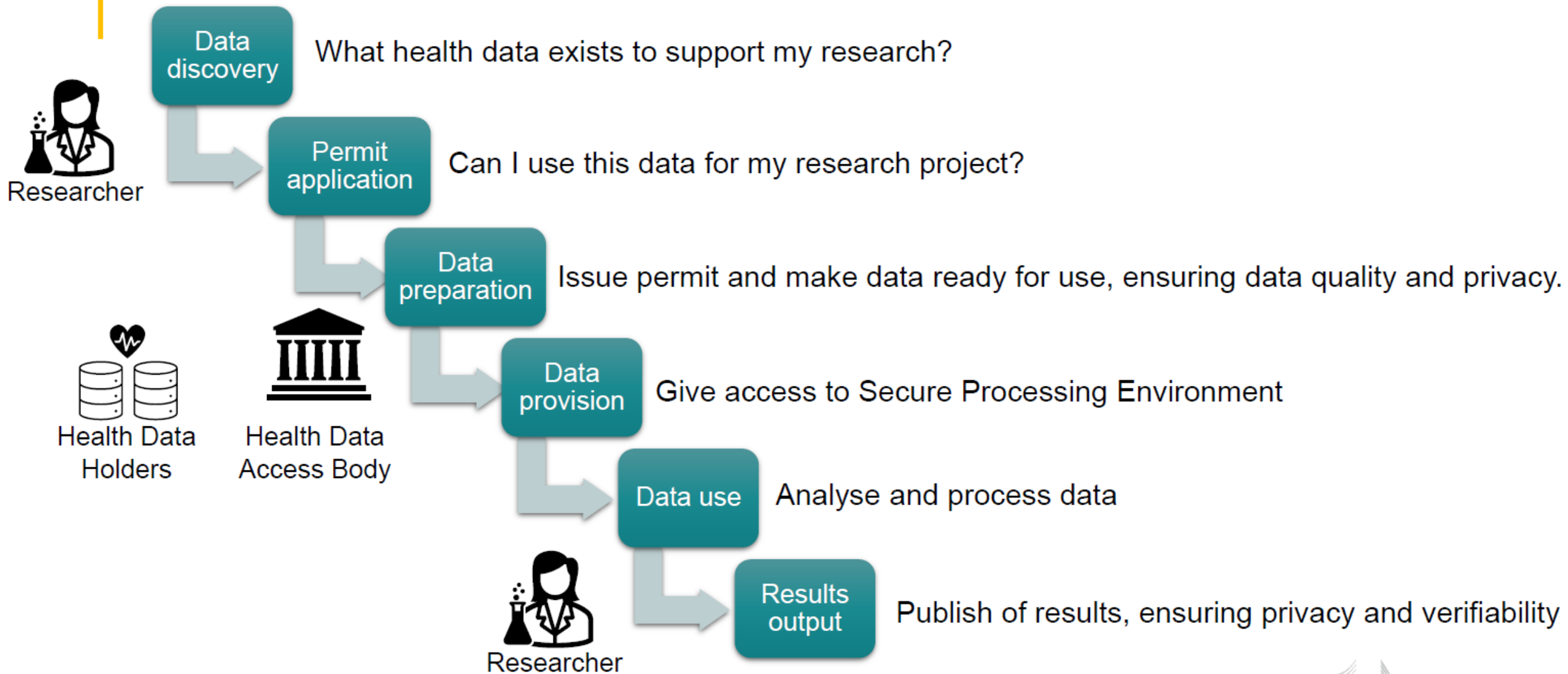
[Test] EU datasets

[Adapted] Linking of registers for COVID-19 vaccine surveillance

The LINK-VACC project links selected variables from existing registries for COVID-19 vaccine surveillance, in order to ensure the monitoring of COVID-19 vaccines in the phase following their marketing authorization (post-authorization

[CSV](#)

Overview of a generic data access approval process for secondary use under EHDS proposal



Implementing and Delegated Acts

Implementing acts

1. Principles for fees policies
2. Architecture of IT tool for transparency on enforcement measures
3. **Templates for applications, requests, decisions**
4. EHDS logo
5. **Requirements for SPEs**
6. Template controller-processor agreements
7. Connecting third countries
8. **Requirements and specs for HealthData@EU**
9. Decisions to let authorised participants join
10. **Elements to be provided for data catalogue**
11. **Details for data quality and utility label**
12. High impact datasets
13. Reciprocity decisions

Delegated acts

1. Changing data quality and utility label elements
2. DGA protective measures for third-country transfers of non-personal data

Bold = deadline for adoption by entry into force plus 2 years



European Projects – EHDS implementation for secondary use – role of HDA



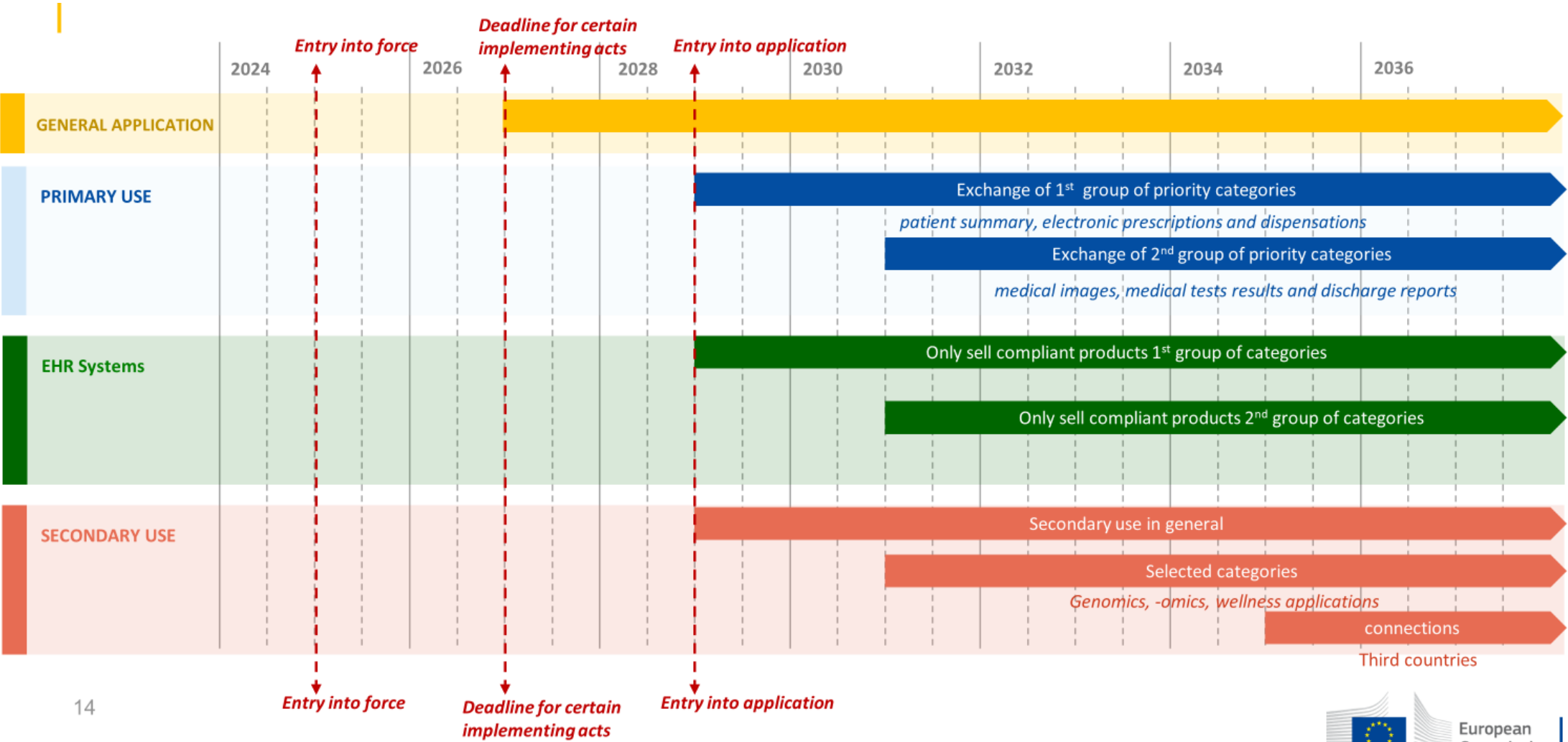
SHAIPED



- The **Healthdata@EU pilot** project will test European data sharing in practice. Current recommendations slowly being published and being prepared for further work in Tehdas2
- The results of the joint action **Tehdas 2** will be valuable for all organisations implementing the EHDS regulation including the European Commission, which will prepare the implementing acts to accompany the regulation.
- **Quantum** aims to create a common quality and utility label for Europe that will allow its use in all countries for scientific and health innovation purposes.
- **SHAIPED** will support the synergetic implementation of EHDS regulation with the AI regulation

NEW

Timeline for implementation



03

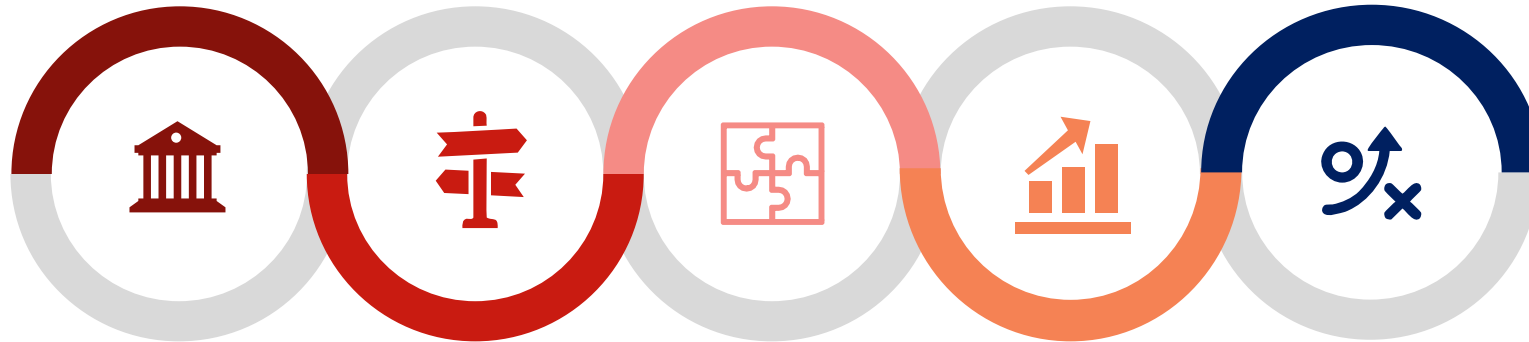
HDA in Belgian context

What will the HDA do?

Health Data Access Body

Facilitate the FAIRification
of data

Support data requests

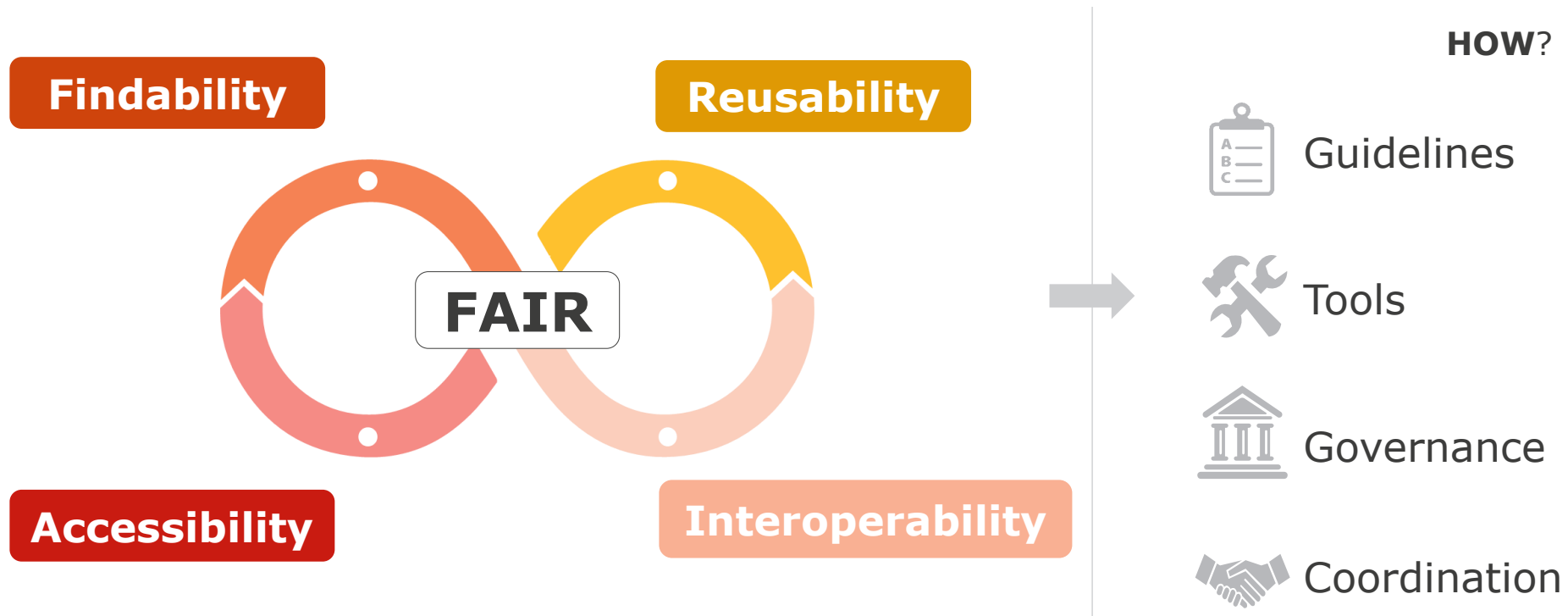


Facilitate access to the
data via the metadata

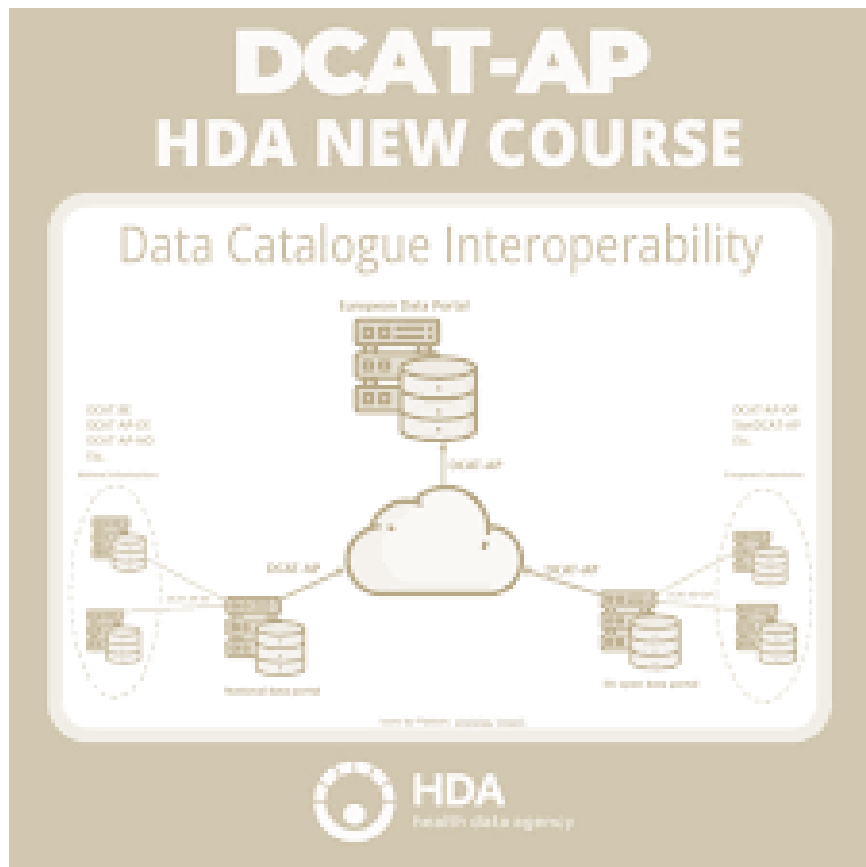
Increase the data literacy
in the ecosystem

FAIRification of data

Facilitate **FAIRification** of health data

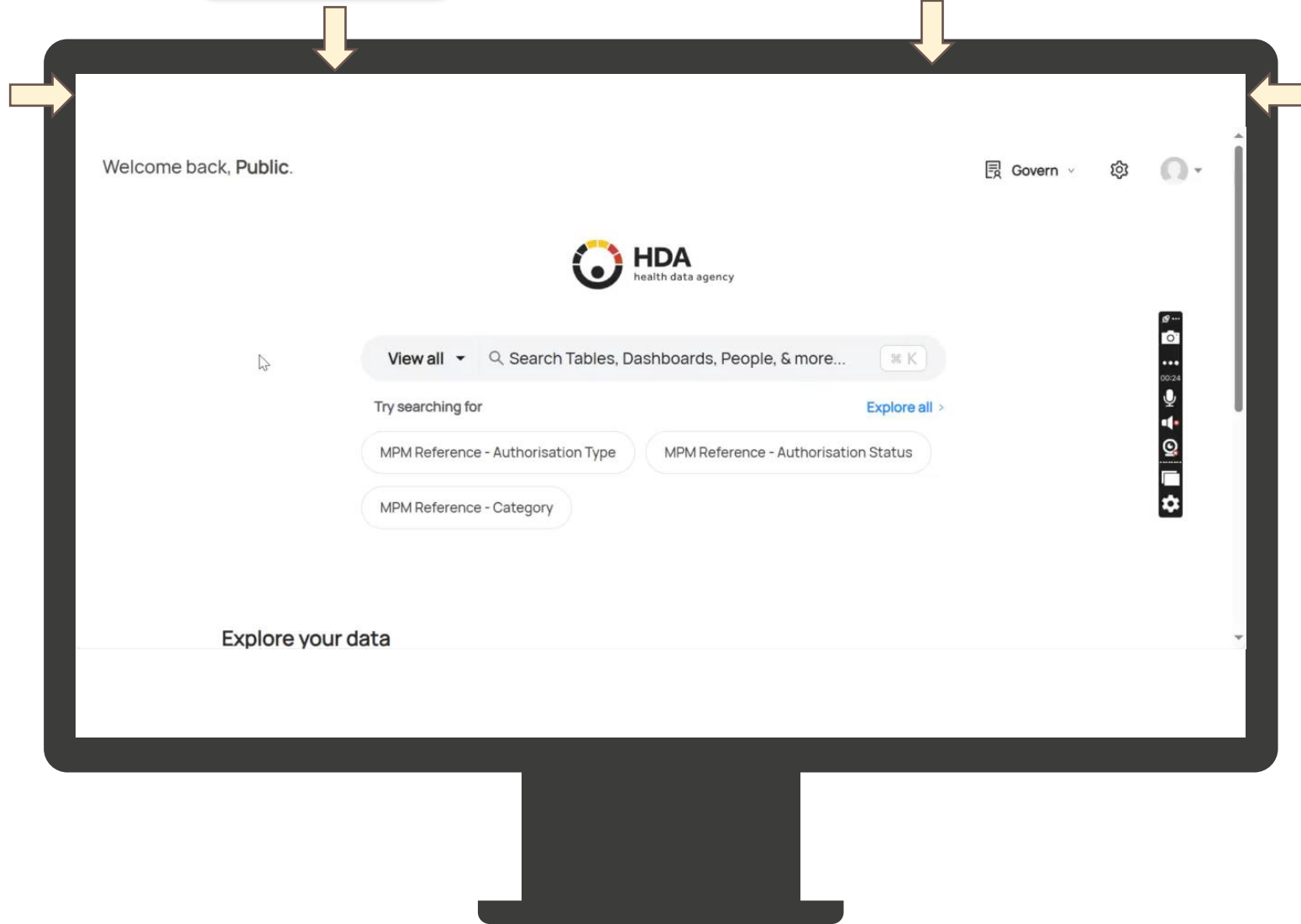


Health DCAT-AP

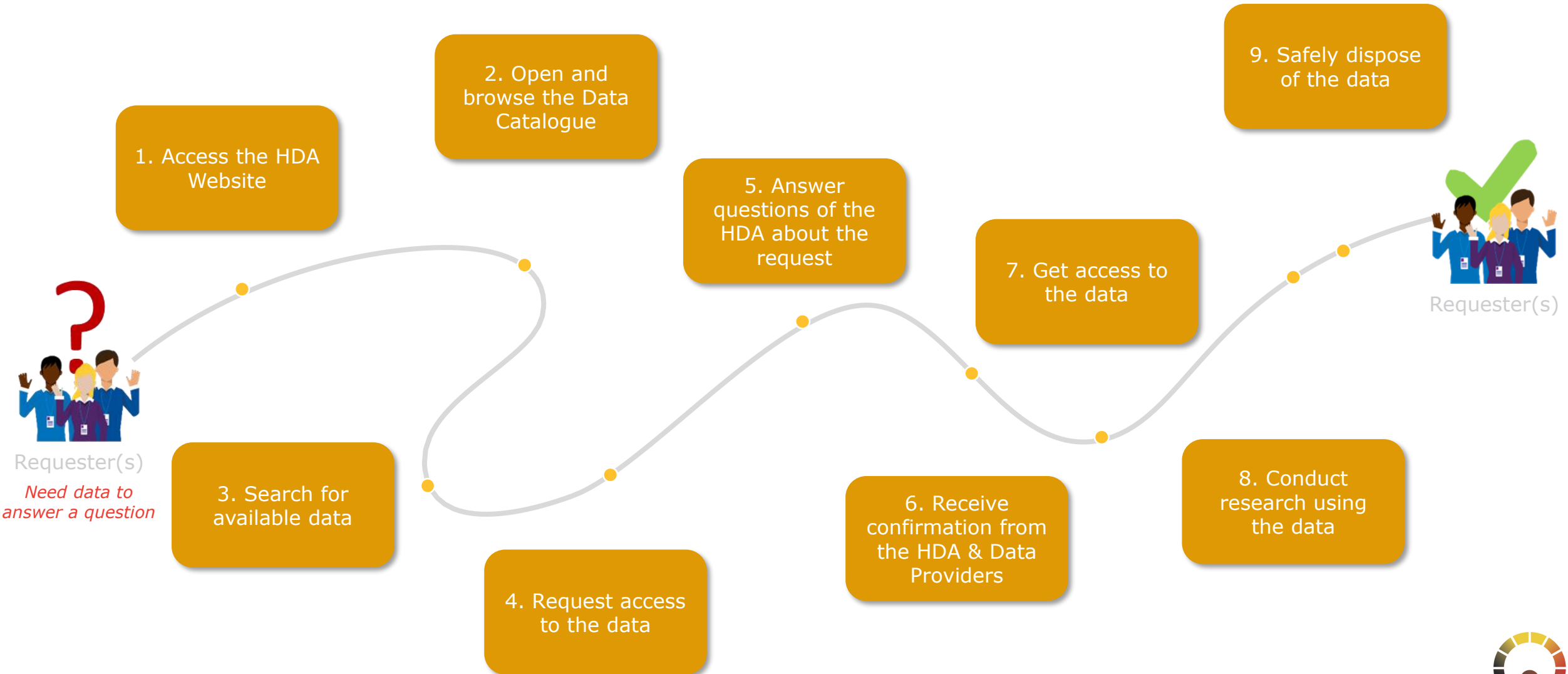


- A working data catalog filled with 246 datasets is publicly available (www.catalog.hda.belgium.be)
- The metadata are compliant with the DCAT-AP standard with regards to the properties/variables
- Values & controlled vocabularies are still work in progress

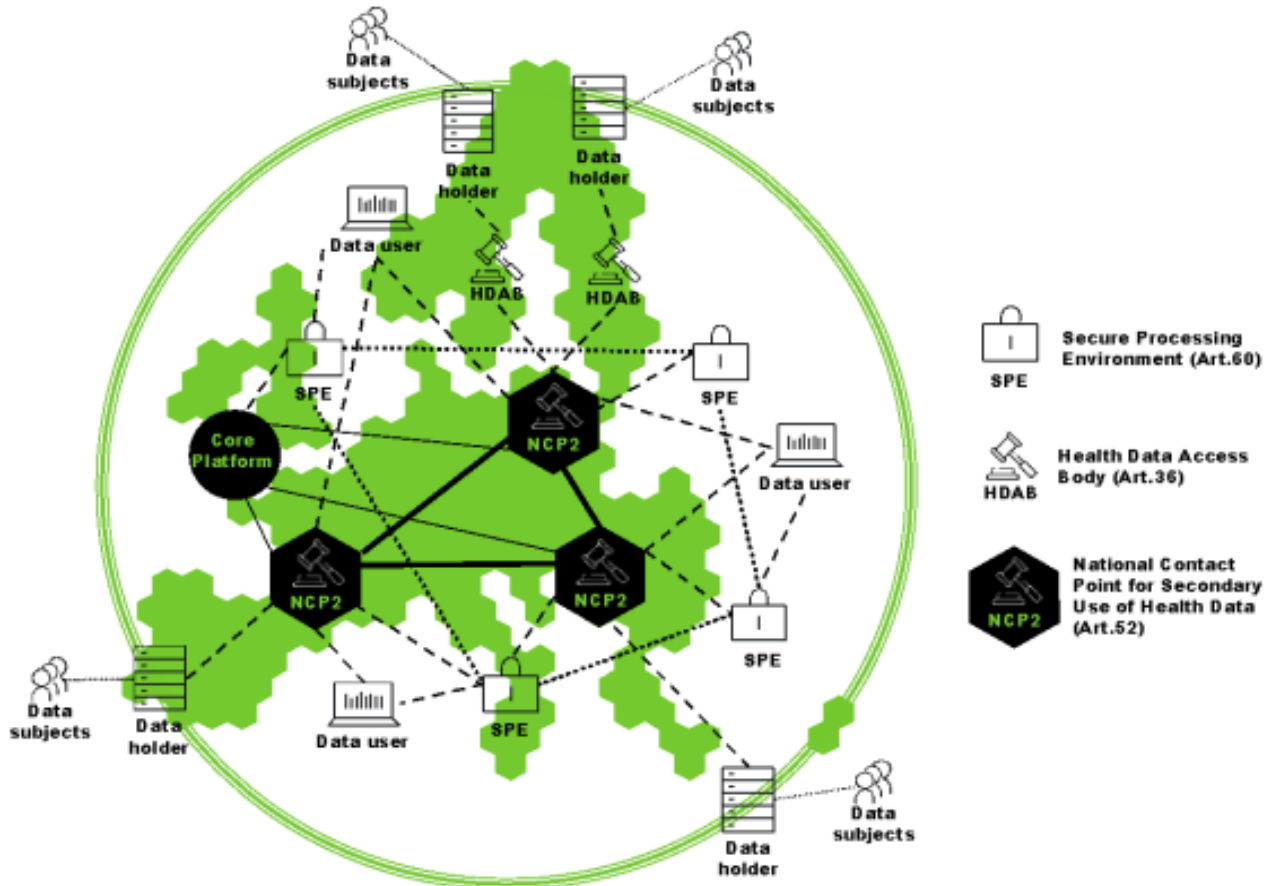
HDA Data Catalogue



Data request process



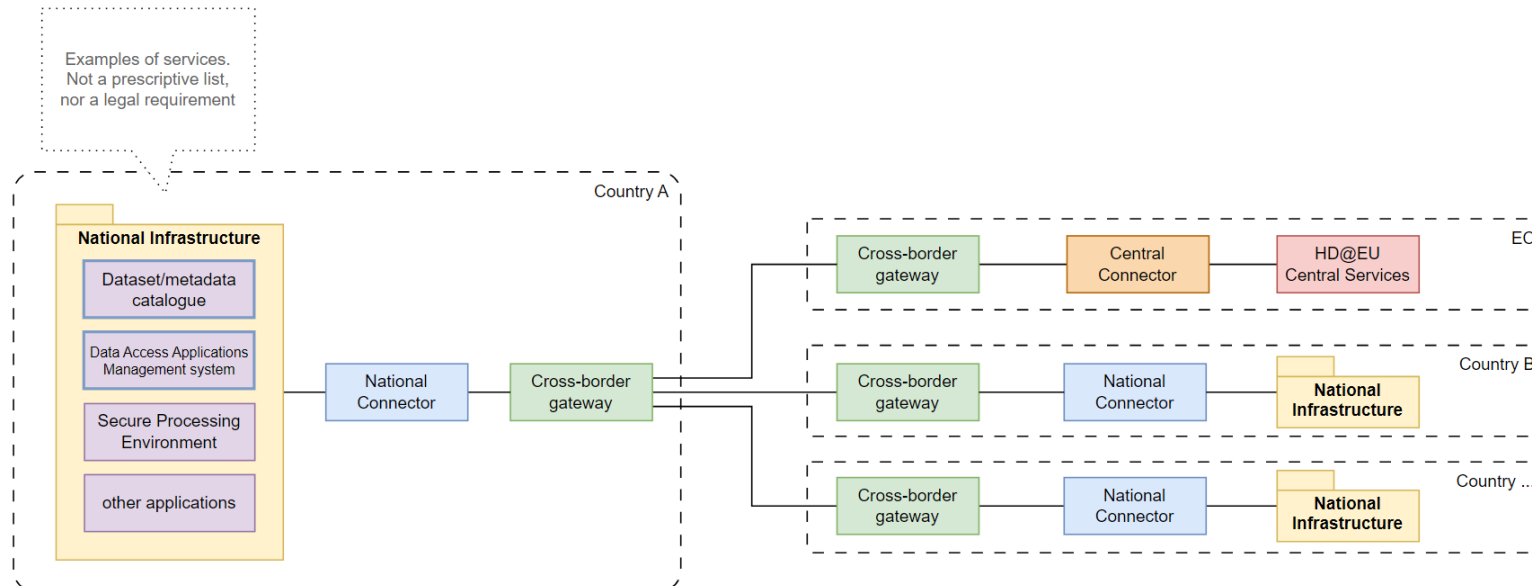
Secure Processing in Belgium



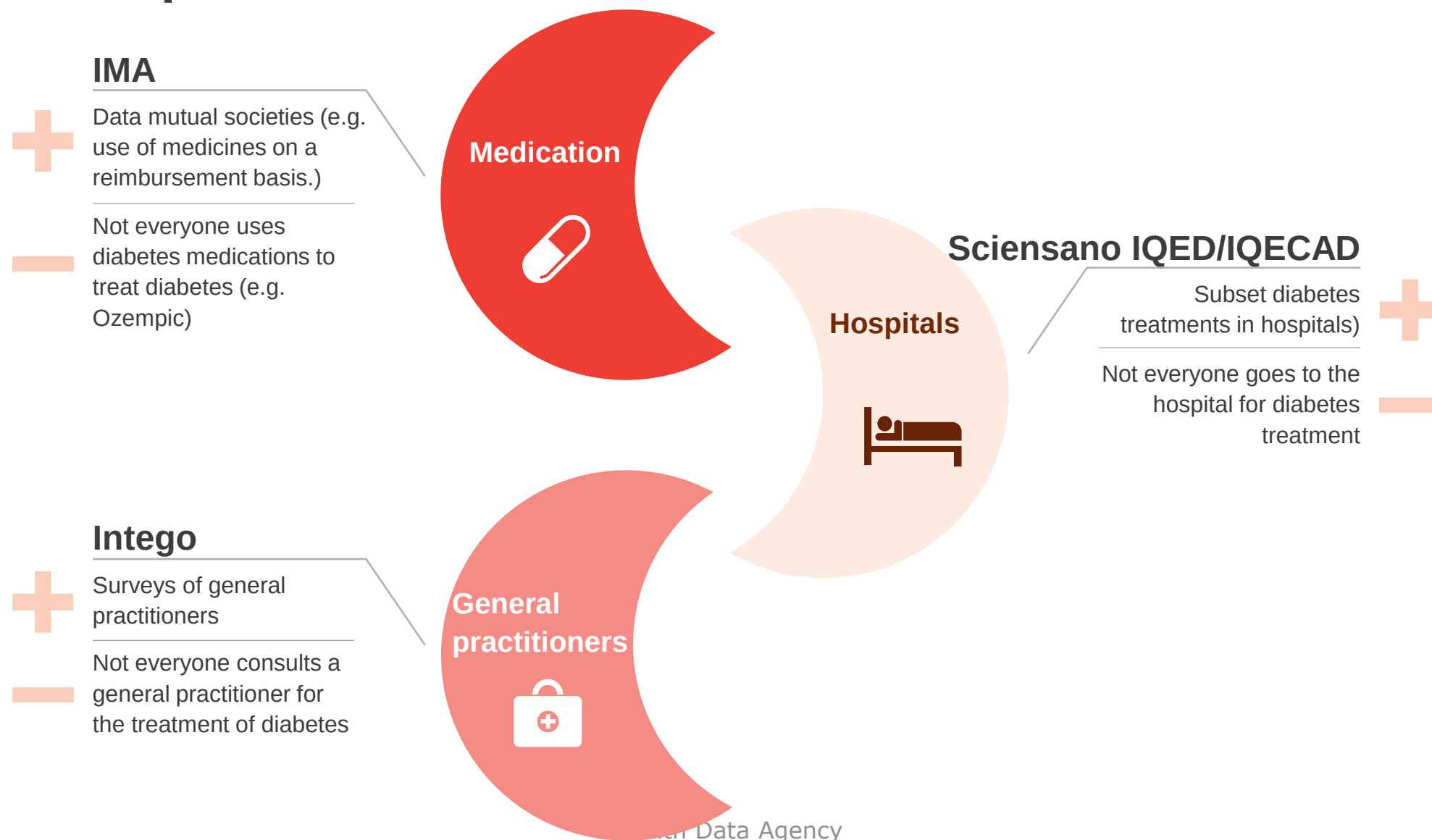
- Location for the SPE(s) to be defined
- Currently listing the major functional requirements for the SPE (in HeDERA)
- Choice between a centralized approach, a distributed approach, client-server deployment or hybrid to be taken
- Art 8 data act - national contact point

Cross-border gateways

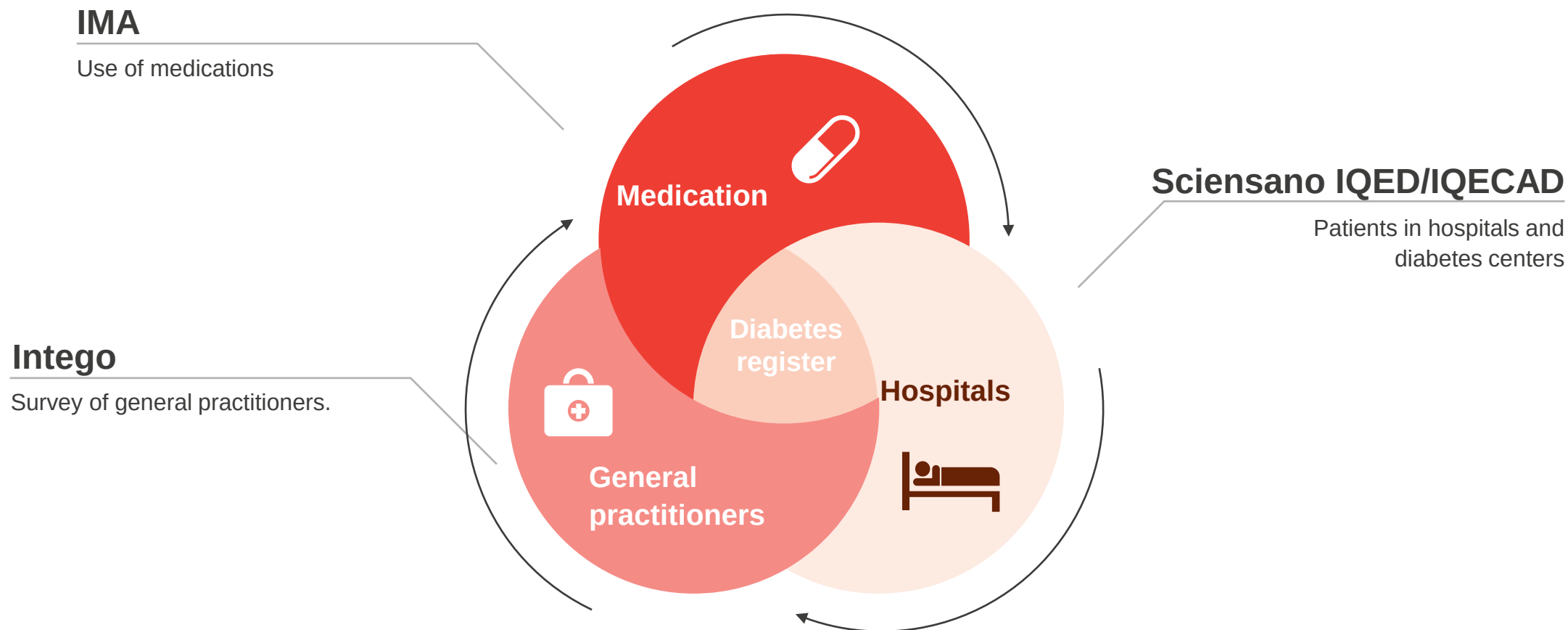
- Official delivery of EHDS Architecture Definition Document in process
- Following outcome of the CoP , practical application after delivery (via HeDERA)



Example: Diabetes case



Actors in the diabetes case



How did the HDA assist?

Gegevens Aanvraag Nederlands

* Vereist

Informatie & context over aanvraag

8. Wat voor soort vraag heeft u?

Let op dat een specifieke vraag betekent dat u een rechtstreeks antwoord nodig heeft in plaats van toegang tot gegevens. Bijvoorbeeld: een specifieke vraag is "hoeveel patiënten lijden aan ziekte X" en het directe antwoord is een getal.

☐ Ik heb een specifieke vraag

☐ Ik zou graag bijkomende gegevens opvragen bij een eerdere aanvraag

☐ Ik zou graag gegevens opvragen

☒ Ik wil ondersteuning aanvragen voor het proces van het IVC (Informatieveiligheidscomité)

9. Licht de context van de ondersteuning toe voor het proces van het IVC (Informatieveiligheidscomité). *

Voer uw antwoord in

Initial application with the HDA

Analysis of the request and collection of the necessary information

HEALTH DATA AGENCY: Data Request – Diabetes

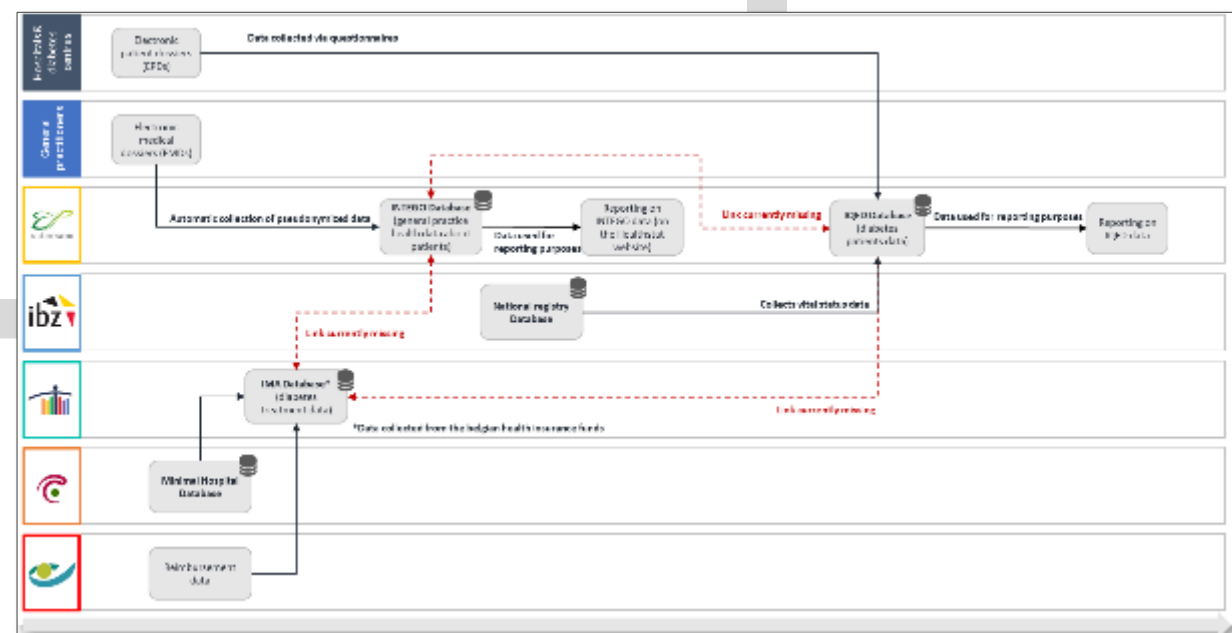
FACTSHEET	CONTEXT	DATA FLOWS	PLAN FORWARD	DOCUMENTATION	TO DO's												
CONTACT DETAILS REQUESTER <table border="1"> <tr> <td>Name</td> <td>Astrid Lavens</td> </tr> <tr> <td>Capacity</td> <td>Researcher</td> </tr> <tr> <td>Organization</td> <td>Sciensano</td> </tr> <tr> <td>Mail</td> <td>astrid.lavens@sciensano.be</td> </tr> </table>		Name	Astrid Lavens	Capacity	Researcher	Organization	Sciensano	Mail	astrid.lavens@sciensano.be	MAIN & SUB QUESTIONS - Can the HDA help in setting up a Federal Diabetes Registry? Ultimately the data gathered should make it possible to solve more elaborate questions and allow for further research, e.g.: - How many people in Belgium are living with diabetes? - What types of diabetes do these people have? - Which type of diabetes is the most recurring?		LEGAL, SECURITY, ETHICAL & DEONTOLOGY Currently there is no known legal basis to create a federal diabetes registry. <table border="1"> <tr> <td>Is there an obligation to publish?</td> <td>No</td> </tr> <tr> <td>Is there an obligation to have a central registry?</td> <td>Yes</td> </tr> </table>		Is there an obligation to publish?	No	Is there an obligation to have a central registry?	Yes
Name	Astrid Lavens																
Capacity	Researcher																
Organization	Sciensano																
Mail	astrid.lavens@sciensano.be																
Is there an obligation to publish?	No																
Is there an obligation to have a central registry?	Yes																
CURRENT DATA STATUS There is a lot of data available with regards to diabetes. But this data is spread across different institutes and not easily linkable. <table border="1"> <tr> <td>Is there data available?</td> <td>Yes</td> </tr> <tr> <td>Is the data available for this specific case?</td> <td>No</td> </tr> <tr> <td>Is there meta data available?</td> <td>No</td> </tr> <tr> <td>Is the data publicly available?</td> <td>No</td> </tr> </table>		Is there data available?	Yes	Is the data available for this specific case?	No	Is there meta data available?	No	Is the data publicly available?	No	FACTS & FIGURES No facts & figures have been collected for this data request.							
Is there data available?	Yes																
Is the data available for this specific case?	No																
Is there meta data available?	No																
Is the data publicly available?	No																

How did the HDA assist?

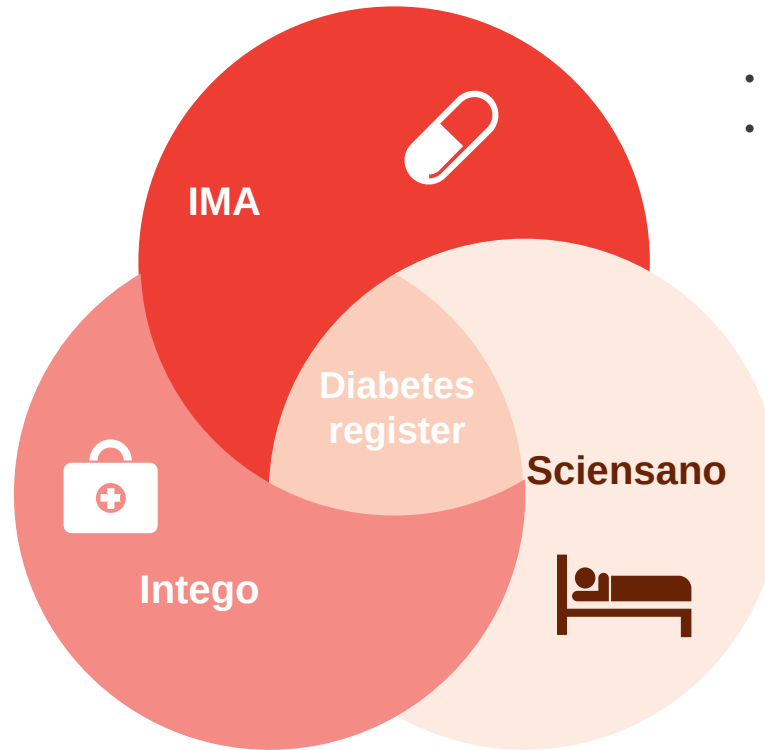
AANVRAAG TOT HET VERLENEN VAN EEN BERAADSLAGING DOOR HET INFORMATIEVEILIGHEIDSCOMITÉ	
1. Algemeen	9 reeds uit, een van de
1. Informatie over de aanvrager: benaming, volledig adres en contactinlichtingen (eventueel te vermelden per aanvrager, <u>indien</u> er meerdere aanvragers zijn)	e die de
2. Type aanvraag	geds het uit, een van de
☐ Nieuwe beraadslaging ☐ Wijziging van een bestaande beraadslaging De aanvraag heeft betrekking op de wijziging van de beraadslaging nr. .../... (referentienummer) van ... (datum). De aanvrager kan een WORD-versie van de meest recente versie van deze beraadslaging verkrijgen bij het secretariaat van het informatieveiligheidscomité (ivc@mail.fgov.be). Hij voert zelf in de meest recente versie van deze beraadslaging de door hem gewenste wijzigingen door (met het systeem van <i>track changes</i>) en verschaft daarover een omstandige toelichting (dit document moet dan niet verder worden ingevuld).	van primair instelling penbare federale sector
3. Beschikt de aanvrager reeds over beraadslagingen of protocollen met betrekking tot de verwerking van persoonsgegevens?	gevens
Specificaties:	es

Assistance in the drafting the IVC file

Facilitation of the discussions within the diabetes working group



conclusion

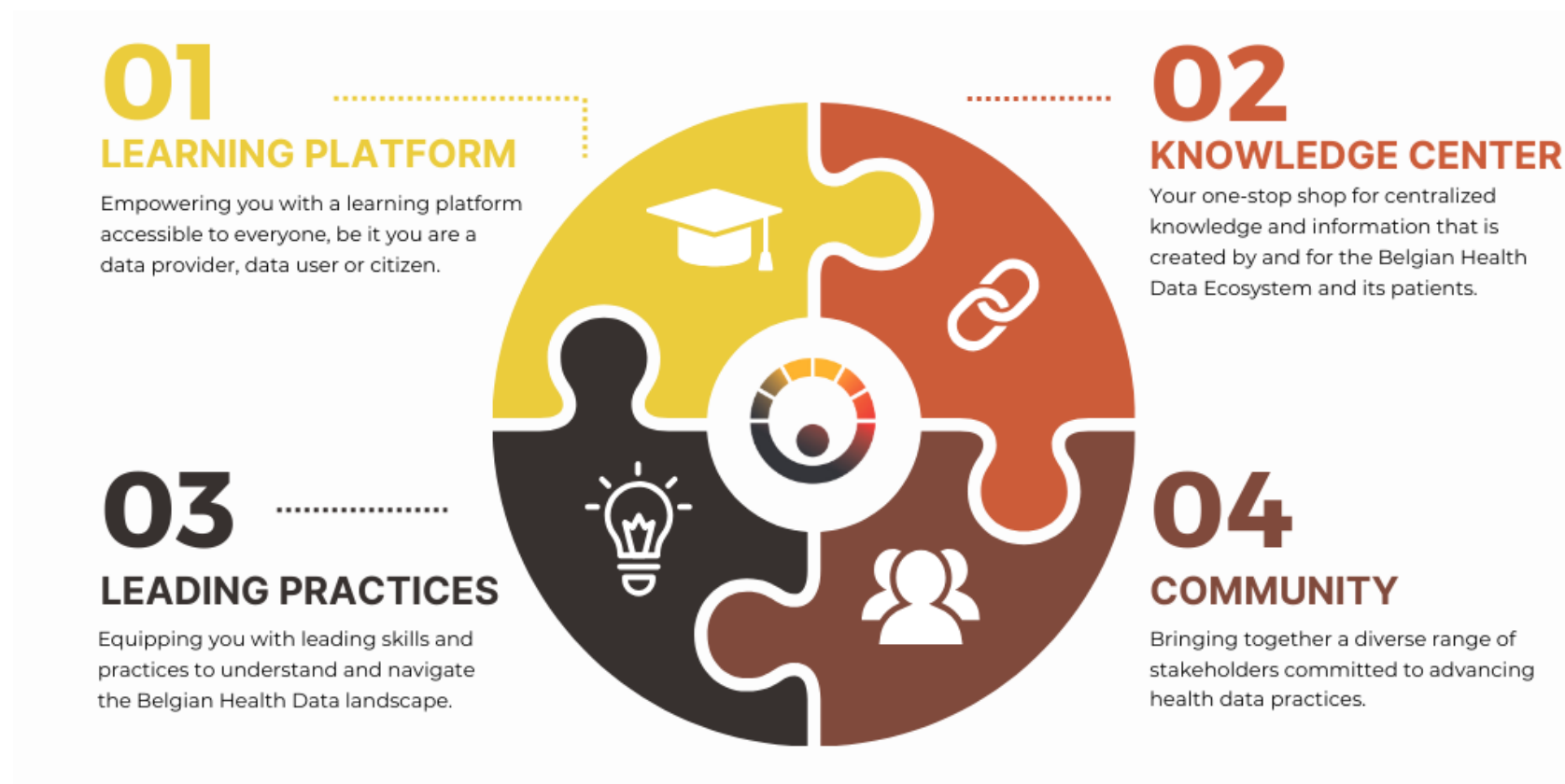


Approval

- The file has been approved
- The data can be cross-referenced and made available to the three actors

HDA Academy

HDA Academy to increase literacy of the Belgian Health Data Ecosystem



13 Available e-learnings

1. What is the HDA? A basic introduction (FR & NL)
2. What is the EHDS? A basic introduction (EN)
3. How to navigate the data catalogue? (FR & NL)
4. Ethical considerations when using health data (FR & NL)
5. Foundations of HDA (FR & NL)
6. Health data, what do you need to know? (FR & NL)
7. Health data in the era of artificial intelligence
8. What is open data? (EN)
9. The journey of requesting data to the HDA (EN)
10. FAIR Federated Data Infrastructures for Better Health Care (EN)
11. How to assess your organisation's data maturity (EN)
12. Proposal regulation on the European Health Data Space (EN)
13. Privacy Rights and Protection, the key principles to consider when working with health data (EN)

3 New Learnings Coming Soon

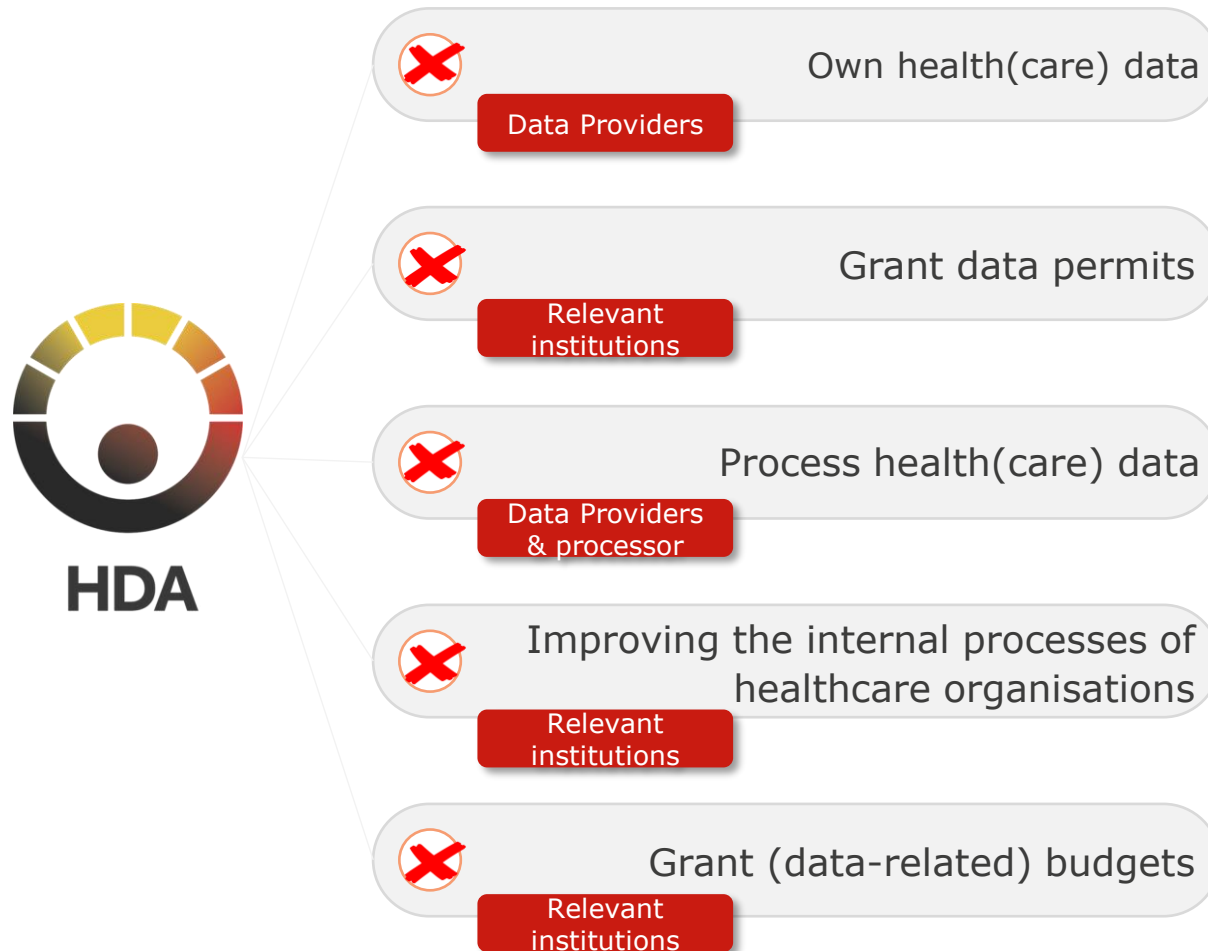
 Comment naviguer dans le catalogue de données? HDA Services	 Considérations éthiques lors de l'utilisation ... Health Data Landscape	 De oprichting van de GDA, in welke context kwam ... Legal Frameworks & Policies	 Les fondations de l'ADS, dans quel contexte ... Legal Frameworks & Policies	 Privacy Rights and Protection, the key ... Legal Frameworks & Policies	 Proposal Regulation on the European Health Data ... Legal Frameworks & Policies
 Données de santé, ce que vous devez savoir Health Data Landscape	 Ethische overwegingen bij het gebruik van ... Health Data Landscape	 FAIR Federated Data Infrastructures for Better ... (Meta)Data	 The Journey of Requesting Access to Data ... HDA Services	 What is Open Data? (Meta)Data	 What is the EHDS? A Basic Introduction Health Data Landscape
 Gezondheidsdata, wat je moet weten Health Data Landscape	 Health Data in the Era of Artificial Intelligence Analytics & AI	 Hoe navigeer je door de data catalogus? HDA Services	 What is the HDA? A Basic Introduction Health Data Landscape	 How to assess your organization's data maturity? (Meta)Data	
[Placeholder] What is metadata? Coming soon	[Placeholder] FAIRification of health data Coming soon	[Placeholder] DCAT-AP Coming soon			

CONCLUSION

We have started with the Basic Topics which aim to explain and promote what the HDA is and does. We are currently planning additional initiatives to create further awareness but the LT Learning Plan will contain expert topics that deep dive in specific topics.

13

What does (actually) the HDA not do?



Thank you!

Contact

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