gaia-x

Health Data Space Event

4 APRIL 2022

10:00 - 12:00 - Chapter 1: General Session

We will start in 2min

1. Welcome & Opening

- **Ulf Nehrbass,** CEO of the Luxembourg Institute of Health
- **Bert Verdonck,** Philips & Gaia-X Health Domain

2. Introduction

- **Francesco Bonfiglio,** CEO, Gaia-X
- **Jeroen Tas,** Member Board of Directors, Gaia-X

3. Video - Citizen perspective

- **Karl Wouters,** medinet.tv

The citizen perspective

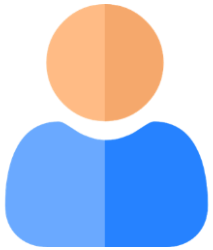
gaia-x

4. The Health Data Hub : a unique gateway to health data for research & innovation

- **Emmanuel Bacry,** Chief Scientific Officer, Health Data Hub

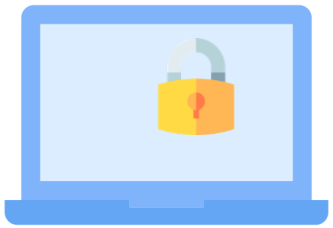
The Health Data Hub, an institution aiming to facilitate access to health data in France …

Created late 2019, the Health Data Hub guarantees easy, unified, transparent, and secure access to health data to improve the quality of care and patient support



A **unique gateway** to health data in France

A **collection of databases**, including one of the largest medico-administrative database in the world



A **state-of-the-art** and **secure technological platform**

In a nutshell: a growing demand for data access and an even greater challenge to support project leaders

+300

projects submitted to the CESREES each year

#520

projects submitted to the CNIL since HDH creation

from various types of actors

- **43 %** Hospitals
- **24 %** Health industry
- **15 %** University & research institutes
- **5 %** Health consultancies and insurance companies
- **4 %** Administration
- **4 %** Associations
- 5 % Other

The HDH role is to **create the simplest possible user journey** to **enable the maximum number of projects to access health data**

More than **60% of the projects require access to the National Health Data System (SNDS)**, the highly solicited database **for which the HDH is authorised to make available**, **which will be effective soon**.

35 % of projects need linkage of other databases to the SNDS

… by providing access to the large medico-administrative database of National Health Insurance Fund…

- ✓ The SNDS is a **compilation of pre-existing databases fed by data flows**
- ✓ **These databases are already linked to each other** to enhance opportunities for research and innovation
- ✓ **We can link external databases with data from the SNDS***

The SNDS is made available on the National Insurance Fund portal, after a positive opinion from the CESREES scientific and ethics committee and authorisation from the CNIL.

3 main databases

SNIIRAM
DCIR

All data linked to health insurance reimbursement since 2006

PMSI

French hospitals discharge database allows to define the activity of hospitals, both from the public and private sector, for the initial purpose of hospital budget planning allocation

CépiDc

Medical Cause of Death Database to be matched with SNIIRAM. *The database does not contain any name.*

*SNDS : National Health Data System

…and making existing databases of interest available to project leaders

gaia-x

DGS

SIDEP : Covid-19 National Population Screening Information System

SIVIC : Hospital data for the COVID-19 pandemic

Covid Vaccine Information System

Thoracic Scanner for the diagnosis of Coronavirus 19 pneumonia (**STOIC**)

National Bank for Rare Diseases (**BNDMR**)

Inserm

HEPATHER : Cohort of patients infected with hepatitis B or C virus

DREES

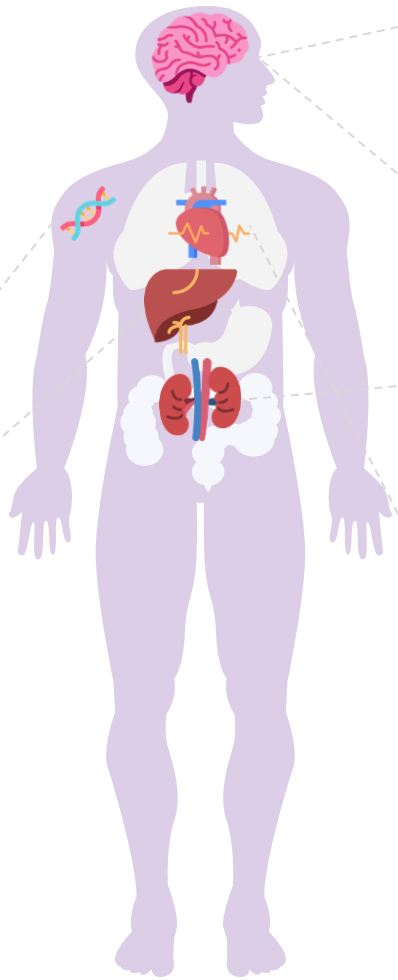
EPICOV : National survey on the Covid-19 epidemic

DÉPISTAGE DES CANCERS Centre de coordination Occitanie

Base e-sis : SI for the complete paperless management of breast cancer screening

Roche

Base ATU : Database collected as part of early access



BNA : Alzheimer's National Bank

I-Share : A multidisciplinary study to assess health status and explore risk factors for specific health problems among students

Memento : cohorte de patients ayant des signes pouvant évoquer une forme débutante de la maladie d'Alzheimer ou une maladie apparentée

UroCCR : French Research Network on Kidney Cancer

OSCOUR : Organisation of coordinated emergency monitoring

MDO : List of mandatory diseases

E-must : Prospective collection of information concerning myocardial infarction

ESME : Epidemiological and economic strategy for breast cancer

CANTO : improve the quality of life for women with breast cancer

DGOS

université de BORDEAUX

CHU BDX

Santé publique France

ars

unicancer

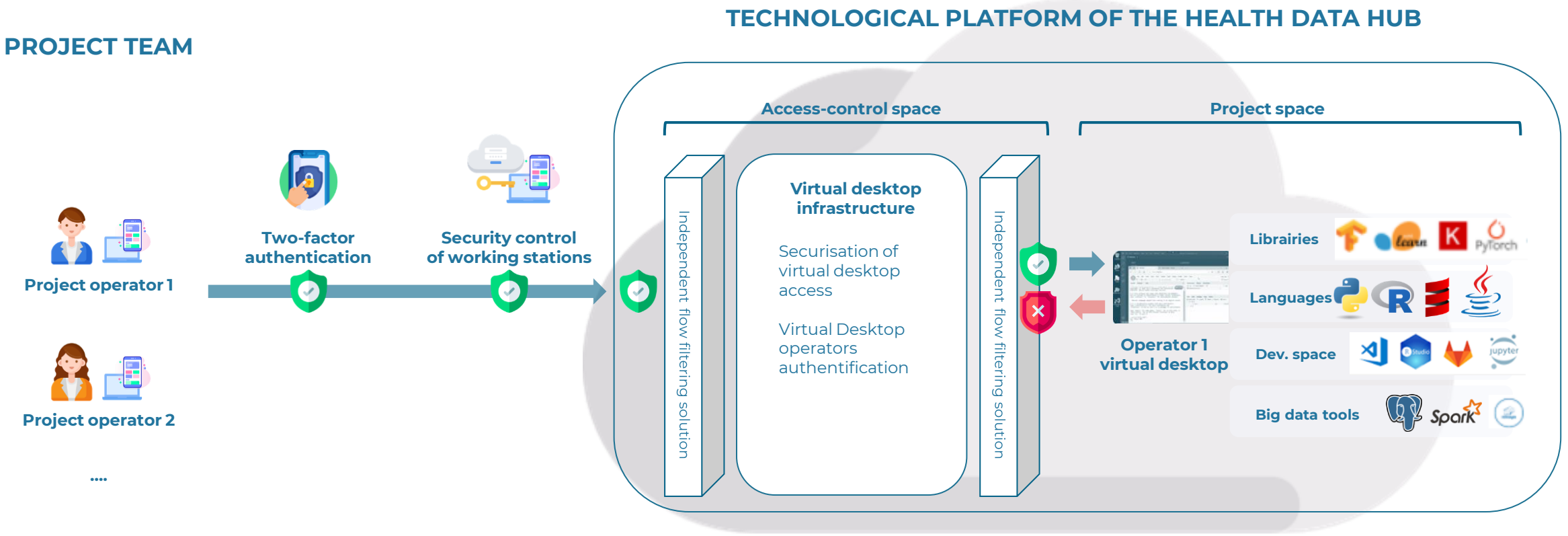
HEALTH DATA HUB | List of bases identified for the 1rst version of the catalogue

Covid-19 related databases

Catalogue HEALTH DATA HUB

Core database L'Assurance Maladie HEALTH DATA HUB

Once authorisations are granted and the data prepared, project leaders can start their study on the platform



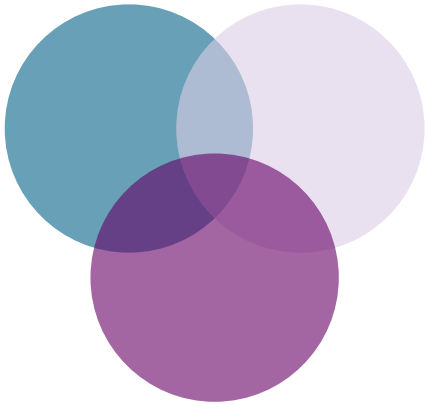
In 2022, the Health Data Hub will continue to **implement its software offer** for project developers and to **develop functionalities for operators or citizens** who would like to exercise their rights.

The Health Data Hub, leader of a candidate consortium for the EHDS pilot project

gaia-x

A major consortium to answer the European commission call for project…

National platforms
(France, Finland, Germany, Belgium, Denmark, Hungary, Croatia, Norway)



European agencies
(EMA, ECDC)

International research infrastructures and associations
(BBMRI, Elixir, eBrains)

… to concretely test the EHDS in practice

- A **network of data platforms** at European level
- Cross-border research **use cases**
- **Recommendations** for the future EHDS regulation

IACS Instituto Aragonés de Ciencias de la Salud · sciensano · orphanet · FINDATA · HEALTH DATA HUB · elixir · EBRAINS · CROATIAN INSTITUTE OF PUBLIC HEALTH · EUROPEAN MEDICINES AGENCY · BBMRI-ERIC · ecdc · Bundesinstitut für Arzneimittel und Medizinprodukte · The Norwegian Directorate of eHealth · DANISH HEALTH DATA AUTHORITY · EESZT National eHealth Infrastructure

5. Video – An industry point of view

- **Cecilia Bonefeld-Dahl,** Director-General, DIGITALEUROPE

An industry point of view

gaia-x

- **Cecilia Bonefeld-Dahl,** Director-General, DIGITALEUROPE

6. Challenges and trends in Healthcare

- **Cristina Bescos,** Director of Innovation, EIT Health

EIT Health is a vibrant community of some of the world's leading health innovators backed by the European Union.

Co-funded by the European Union

A. What are the big challenges in healthcare?

- Patient-centric and personalized medicine is needed to improve treatment of disease
- Chronic diseases are a growing burden on health systems
- Prevention and healthy living should be the primary goal of healthcare
- Strong pressure on health systems to cater to growing elderly population
- Working-age populations experience the most years of life lost due to poor health
- Healthcare costs are continuing to rise
- Shortfall of healthcare workers
- Inequity in access to healthcare
- Antimicrobial resistance & pandemic mitigation
- Fragmentation of healthcare in Europe

eit Health

Co-funded by the European Union

B. What are key trends affecting the demand-side of healthcare?

Patients taking greater ownership and having greater demands for their own care

Consumers becoming more digitally mature, with increasing needs for data access and ownership

Investors attracted to digital health technologies

Communication gap between healthcare innovators and practitioners

Reimbursement guidelines shifting to account for new models of care

Governments play a key role in instigating system-wide changes

Fragmented patient experiences evolving into seamless journeys

Providers focusing on operational improvements

Mental health diseases growing at faster rates than others

Changing profiles of Healthcare workforce

C. What are key trends affecting the supply-side of healthcare?

Data is becoming more available, accessible and useable

AI and big data analytics finding more applications in healthcare and life sciences

Wearables and connected devices becoming ubiquitous

Automation and robotics are transforming healthcare operations

Digital therapeutics and digital health solutions providing new modes of care

E-pharmacies and DTC medication platforms supporting patient access to medication

RWE is enabling a more rounded understanding of therapeutic interventions

Telemedicine and virtual care are now becoming standard practice

Shift from hospital to out of hospital and patient-led self-care

Challenges for public health systems to meet and prioritize budget towards demand

eit Health

Co-funded by the European Union

What are some potential solution ideas that would allow EIT Health to make a meaningful impact?

Pan-EU genomics database

An integrated European-wide database of genomic information which can be used to help in the identification, diagnosis, classification and treatment of disease

Digital health ecosystem for chronic disease

Map out what a “digital health ecosystem” for chronic care could look like and then orchestrate collaboration across companies to make this a reality

Pan-EU knowledge platform

Cross-EU platform which can be used to share knowledge consolidated by EIT Health as well as help with training of healthcare workers and lifelong learning goals

EU health data repository

Developing a central repository for longitudinal health data from across the EU, with potential to form a non-profit organisation to hold and govern the data as well as set access rules, license agreements etc.

Healthy city ranking

Establish a “healthy city ranking” of European cities and municipalities and foster health & wellbeing programs on municipality level

New payment models for elderly care

Develop framework for new financing/payment models to increase the ability of elderly citizens to remain in their home for longer, possibly enabled by digital technologies

eit Health

Co-funded by the European Union

7. Video
Needs from EU university hospitals

- **Martin Hirsch, CEO, AP-H**

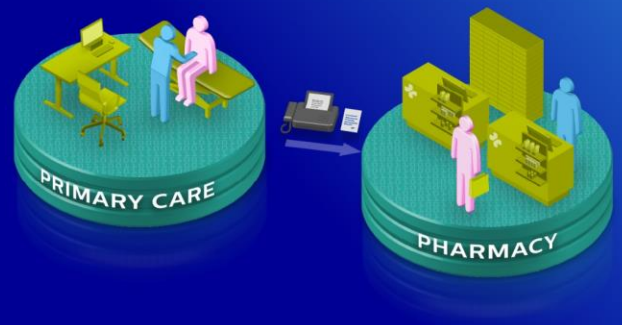
ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

8. From today – To the future of health

- **Bert Verdonck,** DSBC leader for the Gaia-X health domain

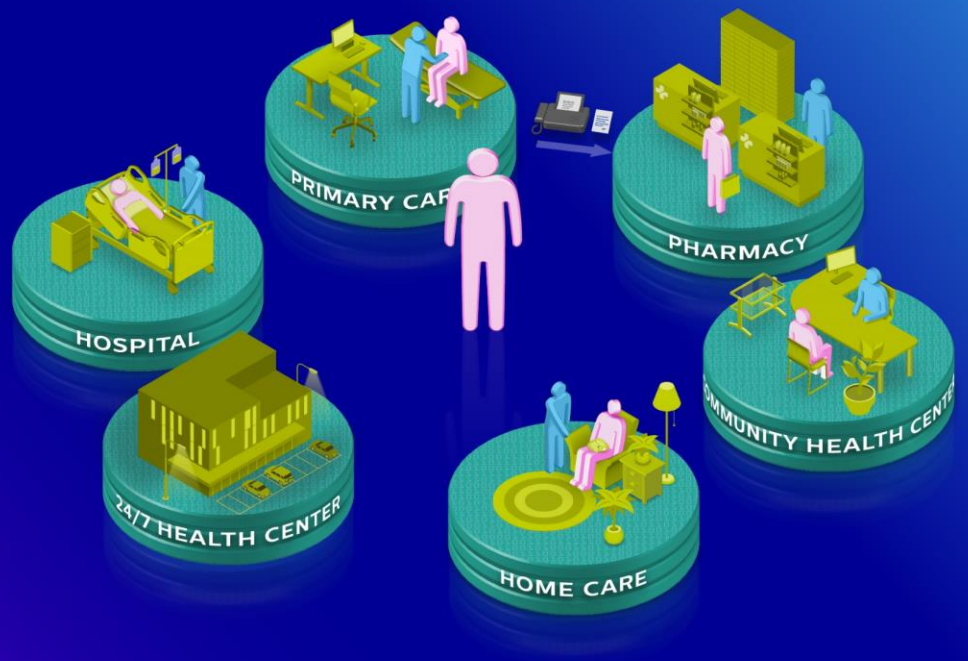
Today

aia-x



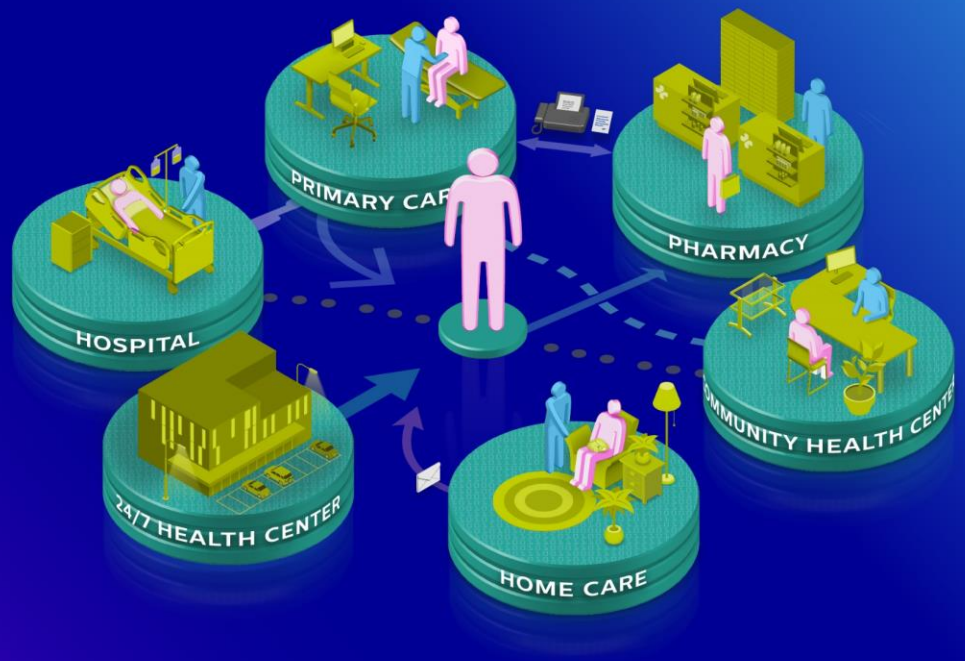
Today

aia-x



Today

aia-x



Today

aia-x


GOVERNMENT
ACADEMIC RESEARCH
PHARMA INDUS
MEDDEV INDUSTRY
HEALTH INSTITUTE
PRIMARY CA
PHARMACY
DEVICE CLOUD SERVICE
HOSPITAL
DIAGNOSTIC LAB
24/7 HEALTH CENTER
HOME CARE
A.I. SERVICE PROVIDER
PHYSIOTHERAPIST
IMAGING CENTER
PAYER
DENTIST

Today

aia-x


GOVERNMENT
ACADEMIC RESEARCH
PHARMA INDUS
MEDDEV INDUSTRY
HEALTH INSTITUTE
PRIMARY CA
PHARMACY
DEVICE CLOUD SERVICE
HOSPITAL
?
DIAGNOSTIC LAB
24/7 HEALTH CENTER
MMUNITY HEALTH CENTE
A.I. SERVICE PROVIDER
HOME CARE
IMAGING CENTER
PHYSIOTHERAPIST
PAYER
DENTIST

Future

aia-x

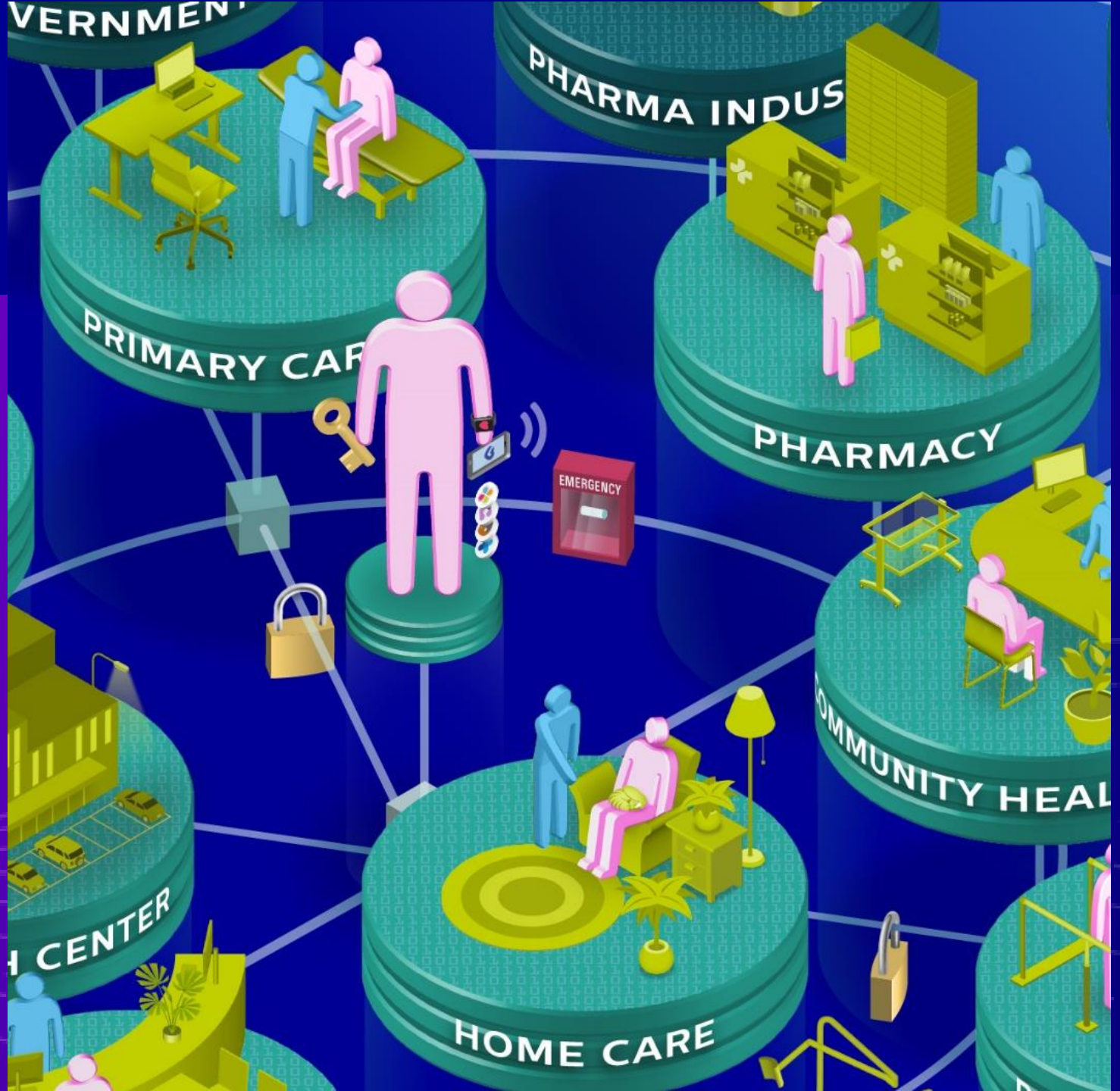

GOVERNMENT
ACADEMIC RESEARCH
PHARMA INDUS
MEDDEV INDUSTRY
HEALTH INSTITUTE
PRIMARY CAR
PHARMACY
DEVICE CLOUD SERVICE
HOSPITAL
DIAGNOSTIC LAB
24/7 HEALTH CENTER
HOME CARE
A.I. SERVICE PROVIDER
IMAGING CENTER
PAYER
DENTIST
PHYSIOTHERAPIST

Future

gaia-x

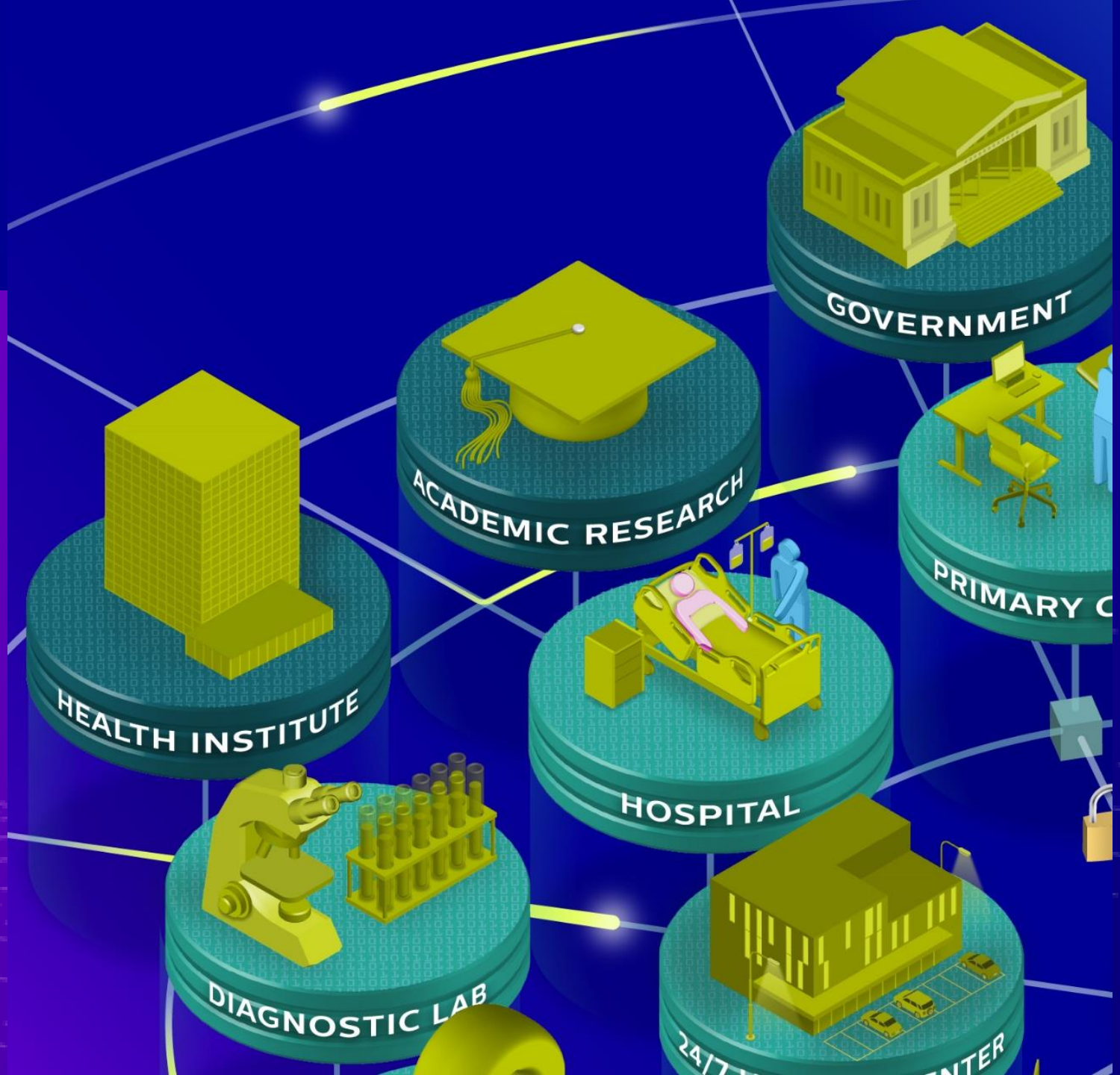
Future

gaia-x



Future

gaia-x



Future

aia-x


GOVERNMENT
ACADEMIC RESEARCH
PHARMA INDUS
MEDDEV INDUSTRY
HEALTH INSTITUTE
PRIMARY CAR
PHARMACY
DEVICE CLOUD SERVICE
HOSPITAL
DIAGNOSTIC LAB
24/7 HEALTH CENTER
HOME CARE
A.I. SERVICE PROVIDER
IMAGING CENTER
PAYER
DENTIST
PHYSIOTHERAPIST

Future

aia-x


GOVERNMENT
ACADEMIC RESEARCH
PHARMA INDUS
MEDDEV INDUSTRY
HEALTH INSTITUTE
PRIMARY CAR
PHARMACY
DEVICE CLOUD SERVICE
HOSPITAL
DIAGNOSTIC LAB
24/7 HEALTH CENTER
HOME CARE
A.I. SERVICE PROVIDER
PHYSIOTHERAPIST
IMAGING CENTER
PAYER
DENTIST

9. Video interview

- **Jeroen Tas,** Member Board of Directors, Gaia-X
- **Maurice van den Bosch,** CEO of OLVG Hospital Amsterdam - the future, more virtual hospital perspective

In conversation with Maurice van den Bosch

CEO OLVG Hospital Amsterdam

10. Panel and Q&A

Summarize all multi-disciplinary needs and opportunities, cross-fertilize research – clinical domain – industry

- **Ulf Nehrbass, Jeroen Tas, Francesco Bonfiglio, Dipak Kalra**

11. Data* Acts and EHDS

- **Thomas Hellebrand,** Manager for Digital Transformation Policy, DIGITALEUROPE

We represent over 36,000 businesses across Europe

The voice of digitally transforming industries

- pharmaceutical businesses,
- medical devices manufacturers,
- tests and vaccine developers,
- consumer healthcare,
- insurance companies,
- platform services,
- data analytics,
- software,
- hardware,
- telecoms,
- semiconductors,
- cloud technology

DIGITALEUROPE

European Health Data Space

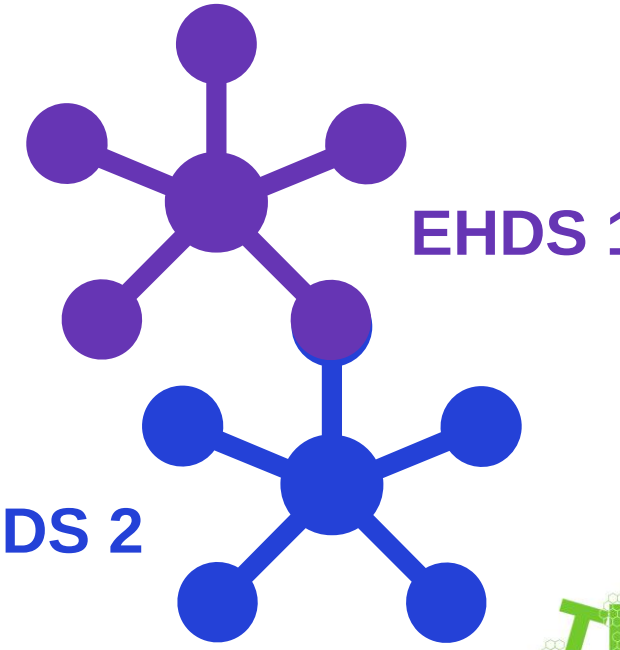
What to expect

GDPR

Data Governance Act

Data Act

My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union



EHDS 1

EHDS 2

DIGITALEUROPE

European Health Data Space

What to expect

GDPR 2016

- **General Data Protection Regulation**
- Rights and obligations personal data
- EDPB guidance
  - Research (Q&A)
  - Pseudo- and anonymisation

Agreement Nov 2021

- **Data Governance Act**
- Reuse of publically held sensitive data
- Data spaces
  - Competent bodies
  - Secure processing environments
- Conditions for non-personal data to third countries

Proposed Feb 2022

- **Data Act**
- B2B data sharing
- B2G data sharing
- Interoperability data spaces
- Smart contracts
- Conditions for non-personal data to third countries

Expected May 2022

- **European Health Data Space**
- EHDS 1 (+authorities)
- EHR certification
- EHDS 2 (+bodies)
  - Secure processing environments
- Conditions for non-personal data to third countries

12. TEHDAS status of investigations

- **Tapani Piha,** Senior Advisor for Sitra and the Ministry of Social Affairs and Health

TEHDAS and the European Health Data Space

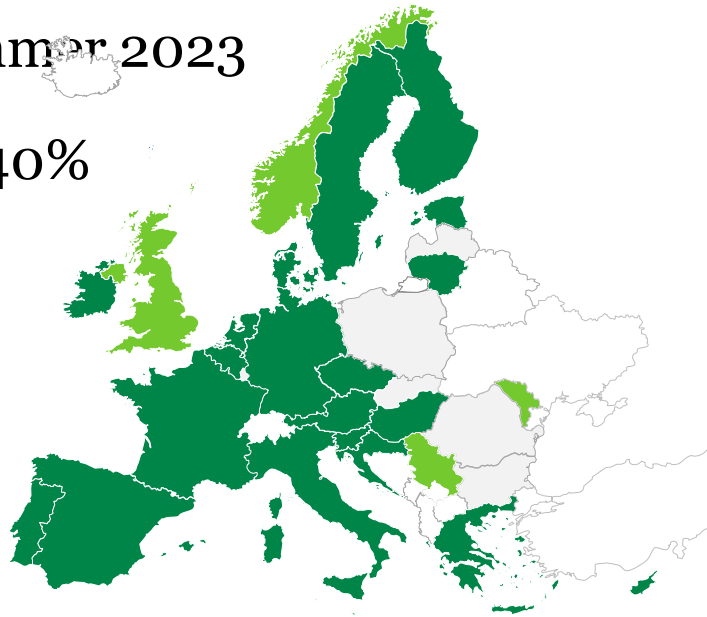
4 April 2022

Tapani Piha, Senior Advisor
For Sitra and the Ministry of Social Affairs and Health

Co-funded by
The Health Programme
of the European Union

Joint Action Towards the European Health Data Space – TEHDAS

Joint Action	Collaborative project by Member States to develop, share and test tools and approaches to a specific health issue and engage in capacity building.
Participants	Nominated authorities from 25 European countries
Duration	30 months from February 2021 – Summer 2023
Co-funding	€4 million - EU 60%, Member States 40%
Project coordinator	Sitra, Finnish Innovation Fund

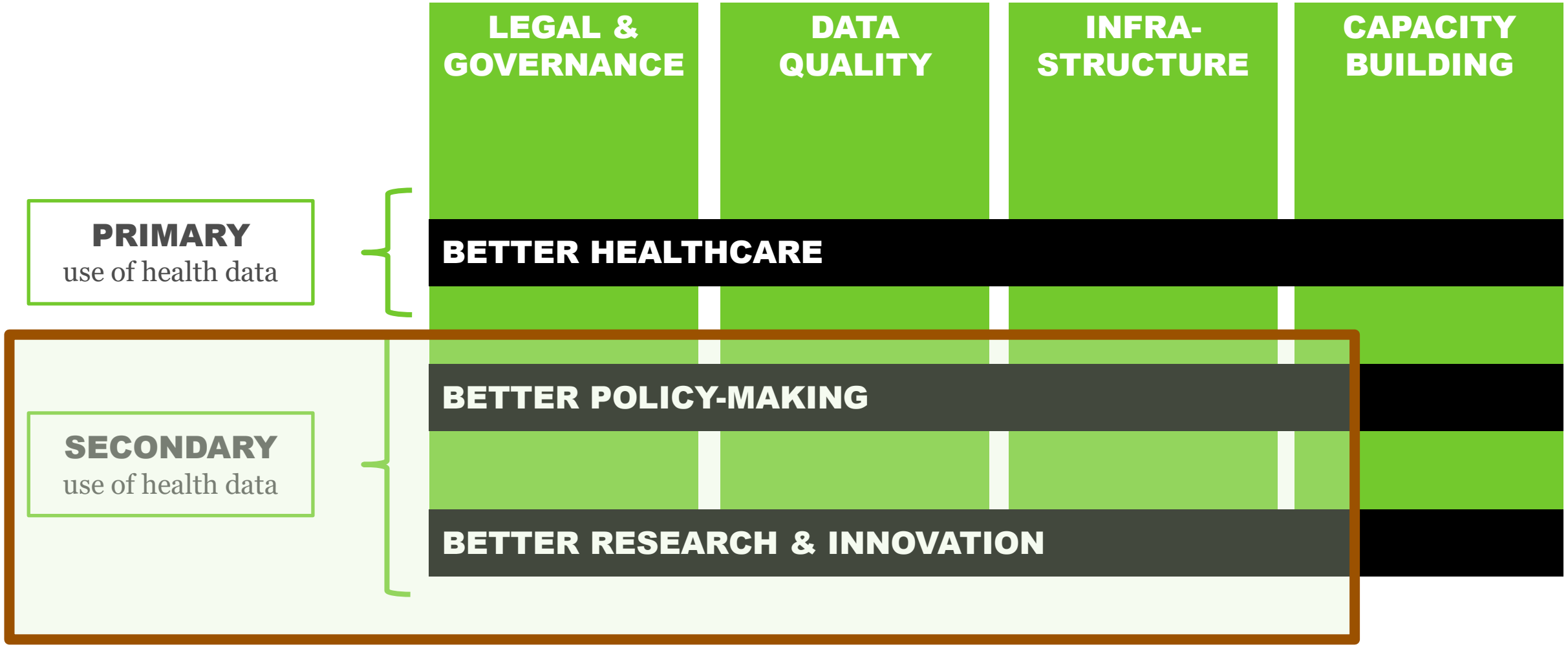


Co-funded by
The Health Programme
of the European Union

The TEHDAS Joint Action helps
the Members States and the Commission by
developing and promoting concepts
for sharing of data in secondary use
for citizens' health, public health, as well as
health research & innovation in Europe.

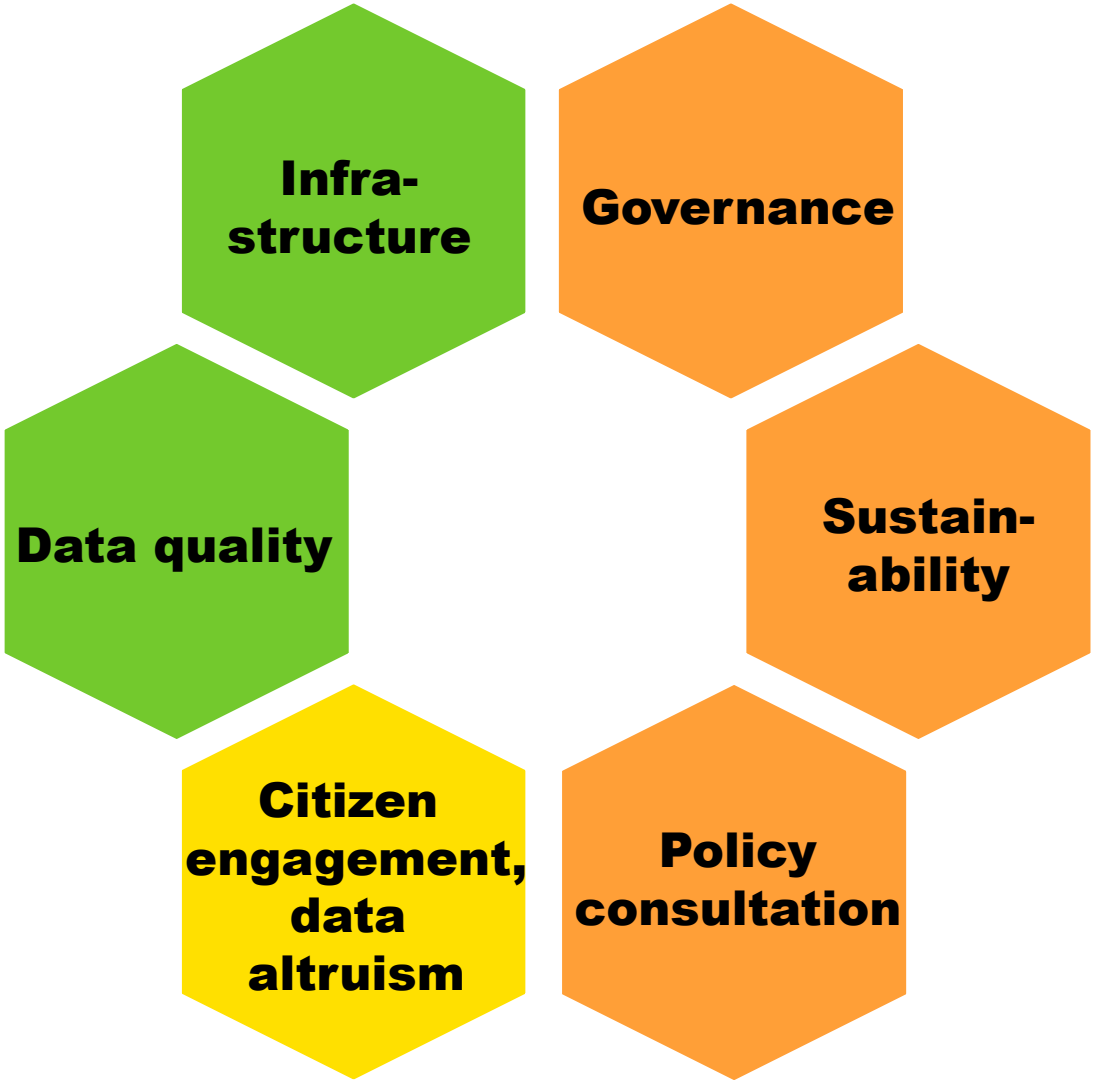
Co-funded by
The Health Programme
of the European Union

Four pillars of the European Health Data Space



Co-funded by
The Health Programme
of the European Union

Technical and semantic



Policy

People

Co-funded by
The Health Programme
of the European Union

A flow of results scheduled for 2021-2023

01.04.2022 WP 4 Outreach, engagement and sustainability

RESULTS: TEHDAS identifies funding options for secondary use of health data

31.03.2022 WP 5 Sharing data for health

RESULTS: TEHDAS establishes European guidelines for data partnerships

www.tehdas.eu

03.02.2022 WP 6 Excellence in data quality

RESULTS: TEHDAS provides recommendations on data interoperability

09.12.2021 WP 7 Connecting the dots

RESULTS: TEHDAS proposes European Health Data Space services

Co-funded by
The Health Programme
of the European Union

TEHDAS Stakeholder Forum
14 June 2022 in Helsinki

Register

www.tehdas.eu

Join the dialogue about the European Health Data Space!

Newsletter

www.tehdas.eu

Twitter
@tehdas

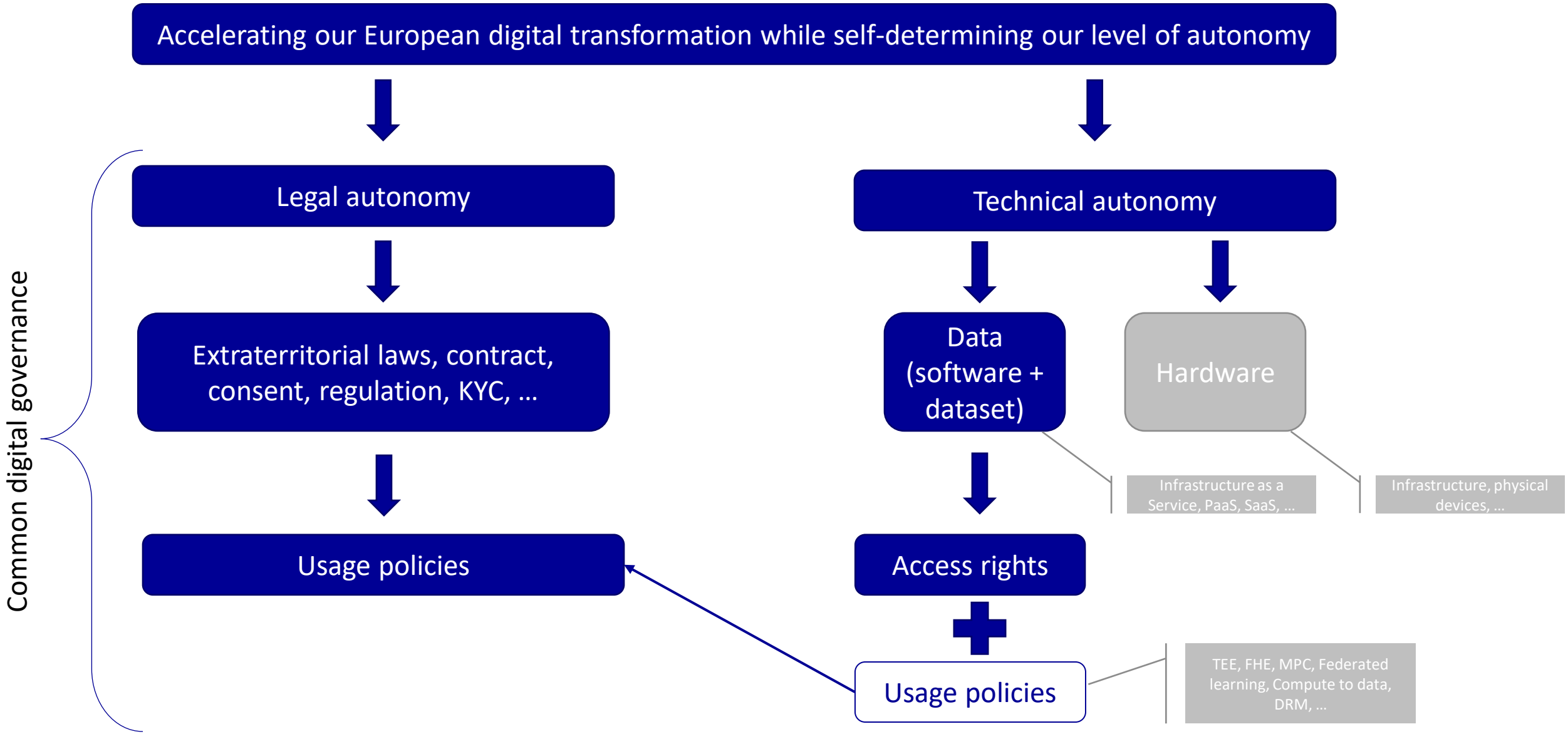
Hashtags
#TEHDAS
#HealthData

Co-funded by
The Health Programme
of the European Union

13. Gaia-X Infrastructure & Data ecosystem - trust framework

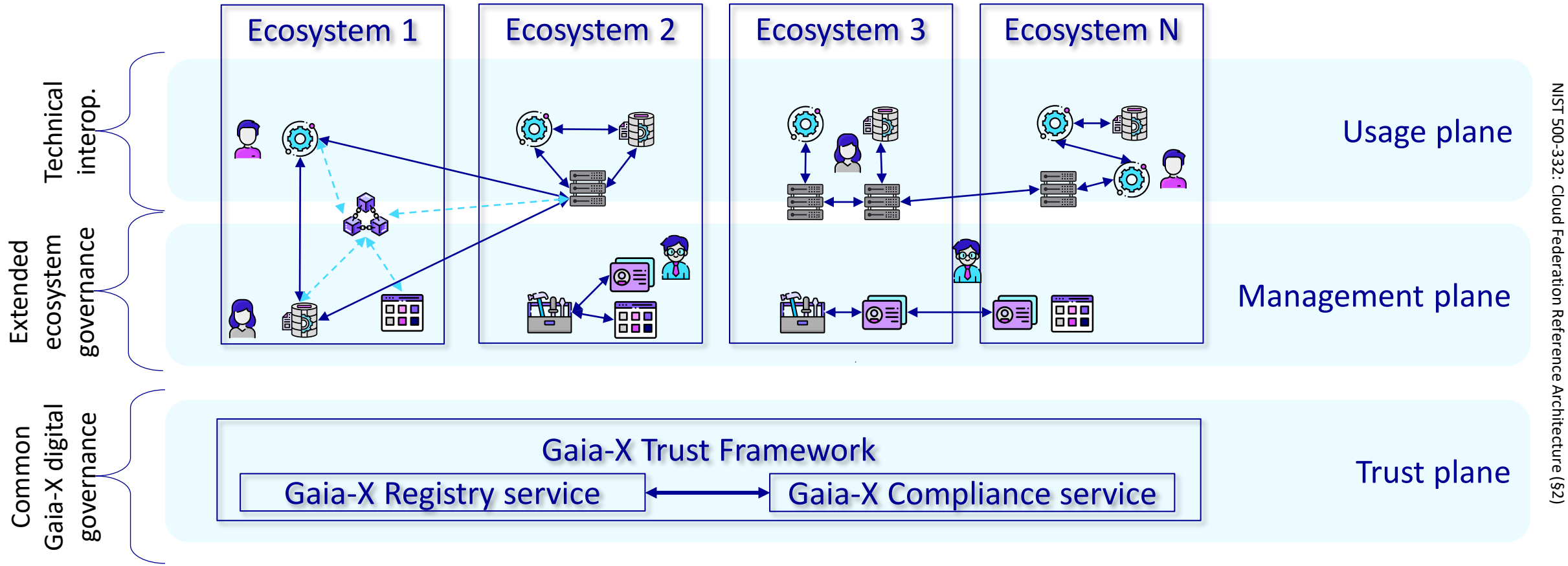
- **Pierre Gronlier,** CTO, Gaia-X

Gaia-X mission



One **Gaia-X Ecosystem,** federating **interoperable autonomous ecosystems.**

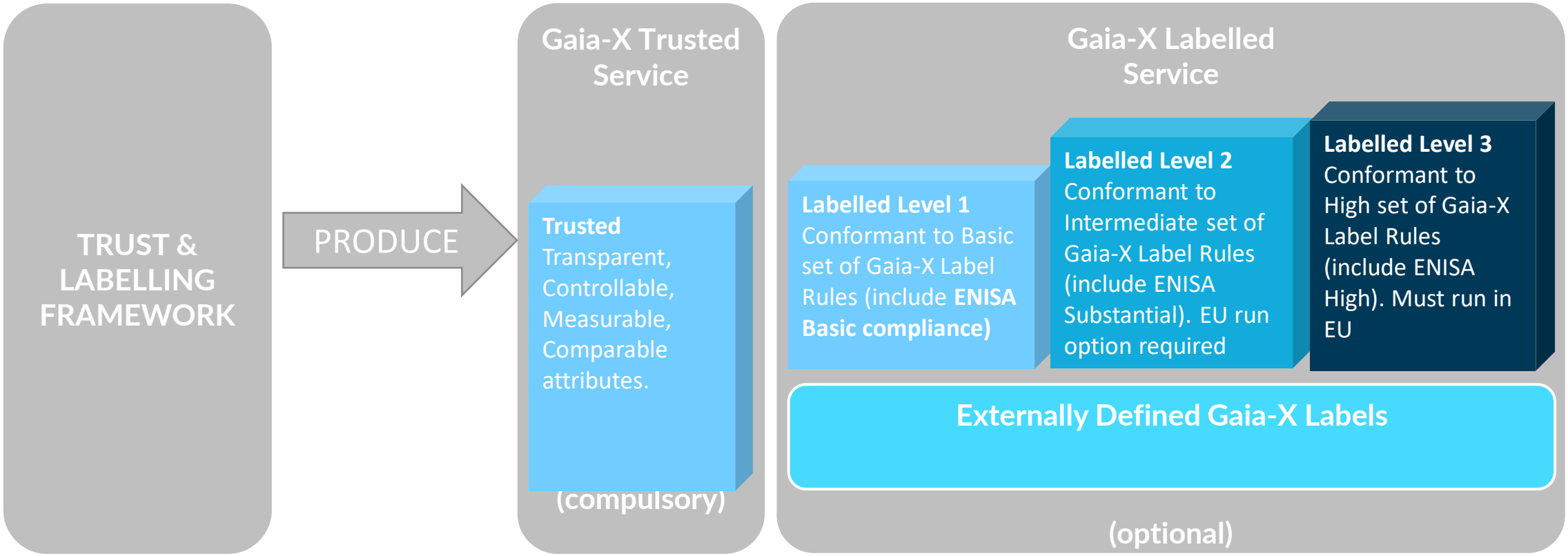
- **Gaia-X Ecosystem:** the virtual set of Participants, Service Offerings, Resources fulfilling the requirements of the **Gaia-X Trust Framework.**



NIST 500-332: Cloud Federation Reference Architecture (§2)

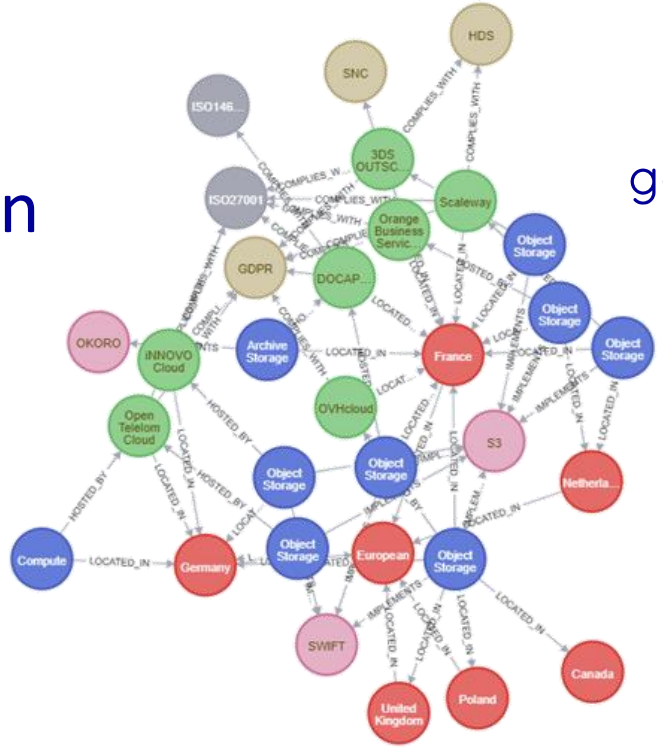
Today’s status

Gaia-X Trust & Labelling Framework

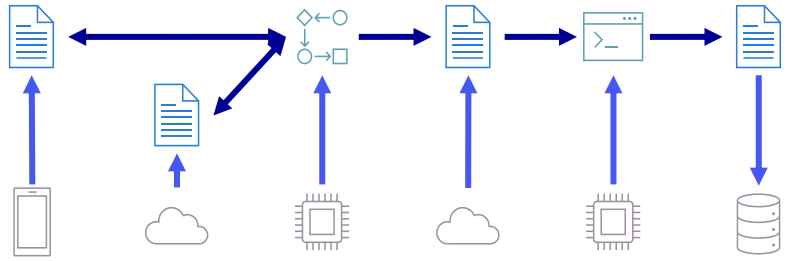


Gaia-X Trust Framework 1/2
from fragmented market to service composition

- Enable the creation of more complex composite services from atomic or elementary services as well as complex services.
- Ensuring composability and hence substitution
- Creates **Transparency** with portability across providers and hosting platform



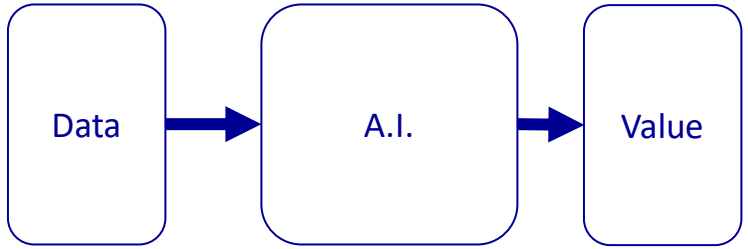
Knowledge graph of verifiable and composable signed claims
(Catalogue demonstrator - March 2020)



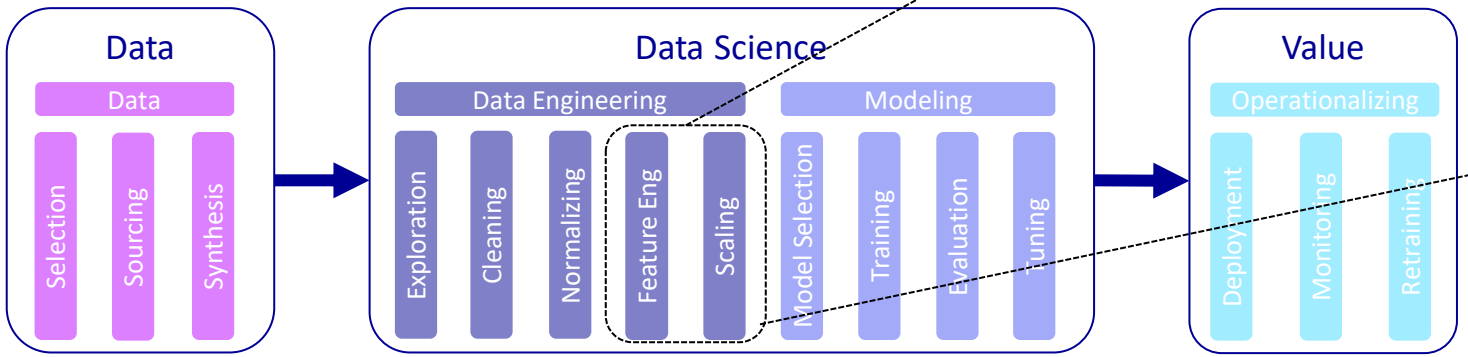
Data pipeline example, from edge (mobile) to cloud

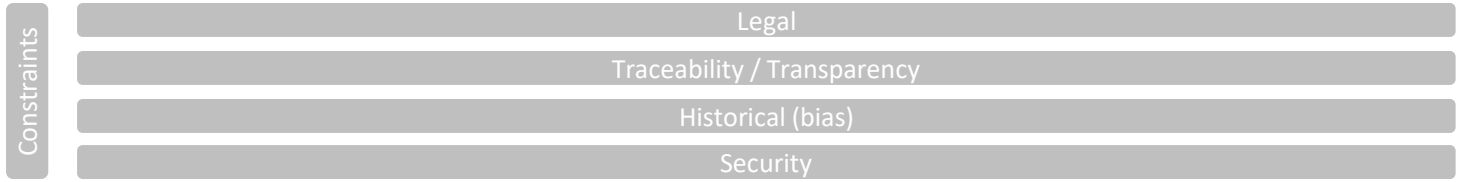
Data Exchange services

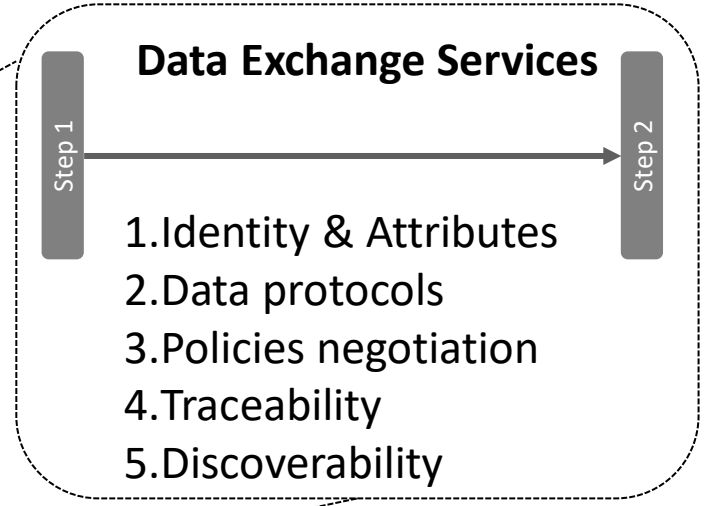
What most think A.I. and data processing looks like



How it actually looks like





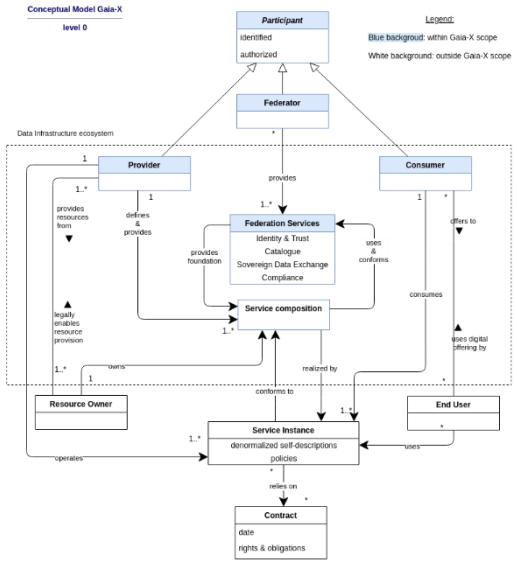


Gaia-X Trust Framework 2/2

To ensure **Trust** the Gaia-X Trust Framework is:

- Automated by Gaia-X specific components part of decentralized technology framework
- Versioned, i.e. bound to a specific version in time of the Compliance rules set
- Applied to the self-description file of all entities implied in the Gaia-X conceptual model (*)
- Aimed to verify the existence and veracity of the attributes and not judging their value

(*) as defined as part of the Gaia-X Conceptual model described in the Gaia-X Architecture document



The content
Verify if the mandatory attributes are filled in and if the values are verified.

Set of claims

attribute: value
attribute: value
attribute: value
.....

The envelop
Verify the keypair issuers and cryptographic signatures

Claims
Machine readable or plain English

- Trust Framework example:
  - All cars must have a color
  - All Datasets must have a location
  - All Services must identify their provider with its legal country of jurisdiction.
- Label examples:
  - cars level 1 are red, cars level 2 are blue, …
  - My dataset must be located in EU
  - My services must be non-subject/immune to non-EU laws

Gaia-X Trust Framework summary

- Measurable & Comparable – **Gaia-X Trust Index** as a function of service composition and signature's identity.
- Doesn't take decision for the user – 2nd order rule
- Enforce **transparency**
- Enable **portability** – service composition
- Enable **traceability** – consent aggregation and policies attenuation
- **Automatable** – machine readable
- **Secure** – Zero-Knowledge-Proof principle
- **Scalable** – Web semantics
- **Cost efficient** – SMEs included
- Include **Remediation** / Penalties

gaia-x

Question ?

https://www.gaia-x.eu

https://members.gaia-x.eu

14. Health use cases – overview

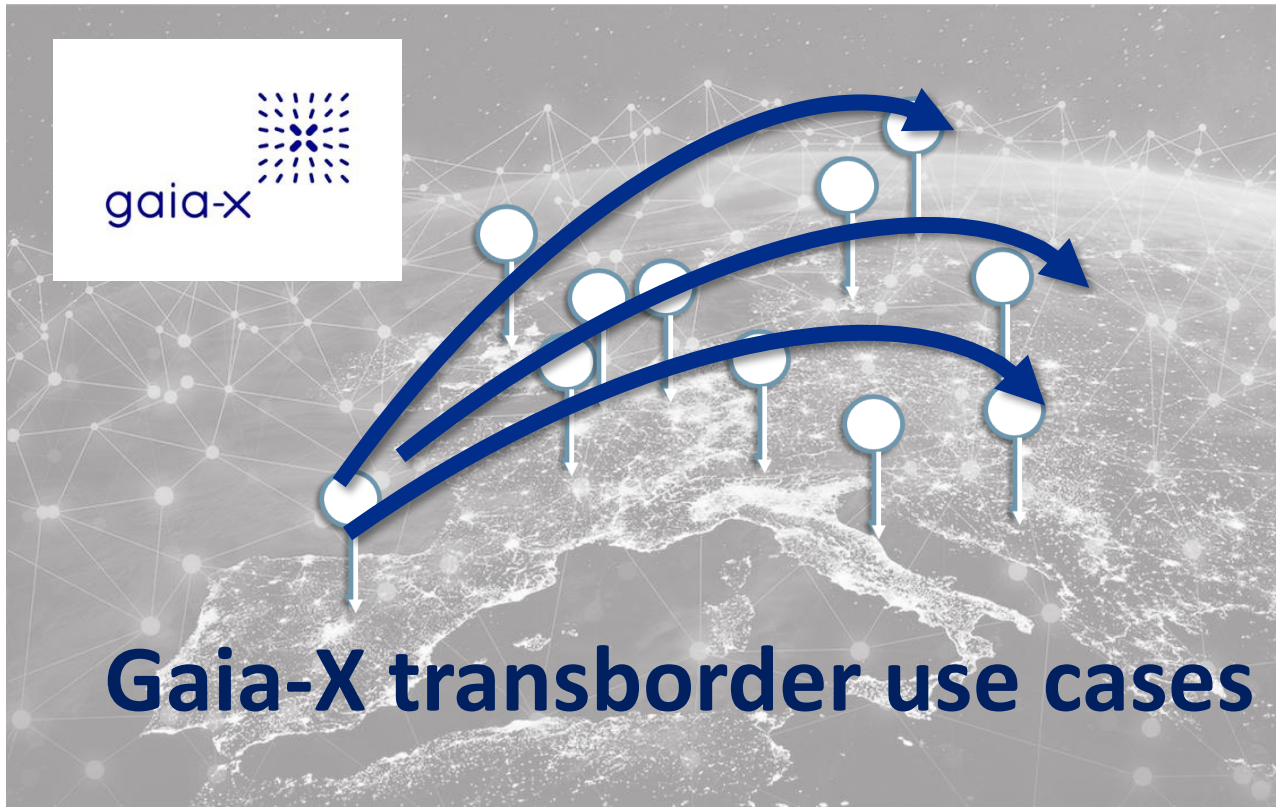
- **Ulf Nehrbass,** CEO of the Luxembourg Institute of Health

Coordination team

Coordination Team Defined!

- The coordination team should help the coordinator in realizing objectives and deliverables
- The coordination team is constituted with 2 members each of Germany and France as well as Finnland, Belgium and Luxembourg
- In addition, TEHDAS representatives have joined the coordination team to ensure alignment between these initiatives

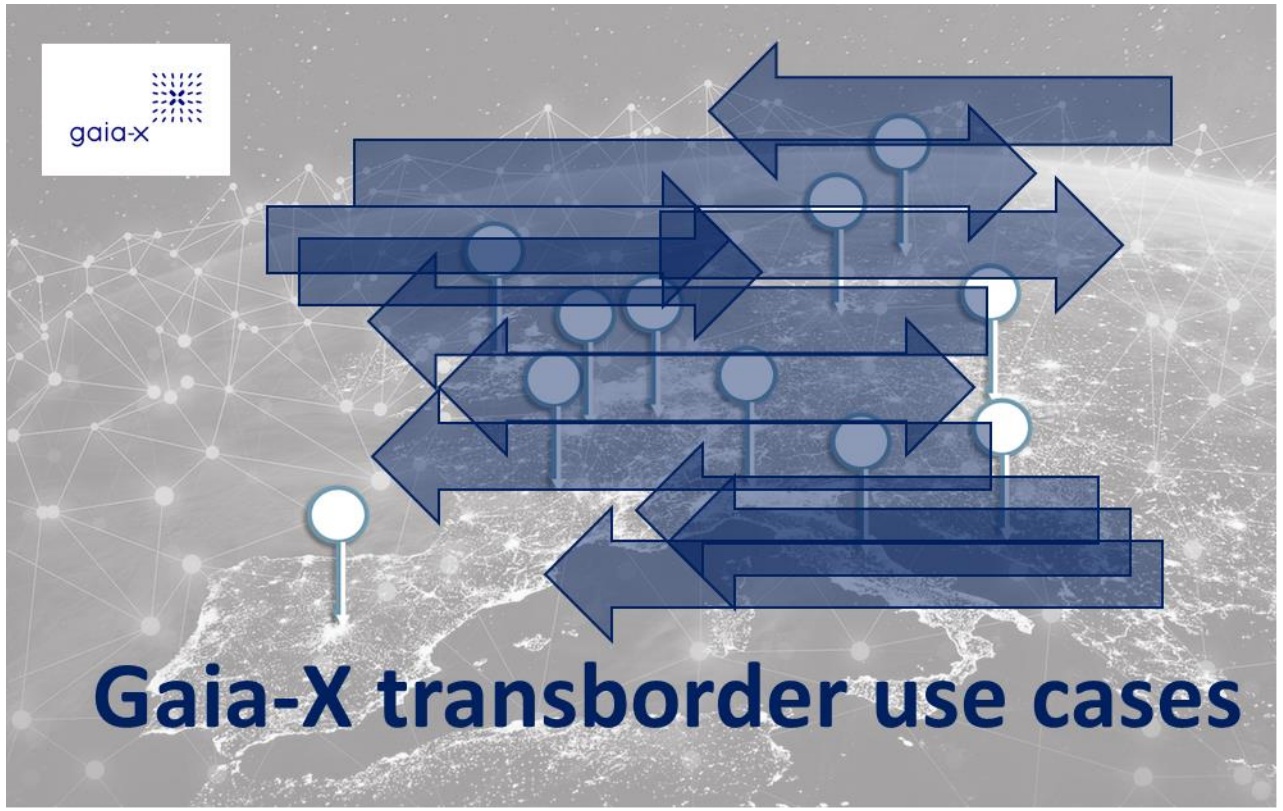
Trans-border use cases



Trans-border use cases

- Trans-border use cases aim at stress-testing and aligning critical enablers on a European level
- Straight forward and/or already funded programs should be included to provide a rapid proof-of-concept
- Trans-border cases are important to mobilize EU-decision takers in the short term

Trans-border use case themes identified

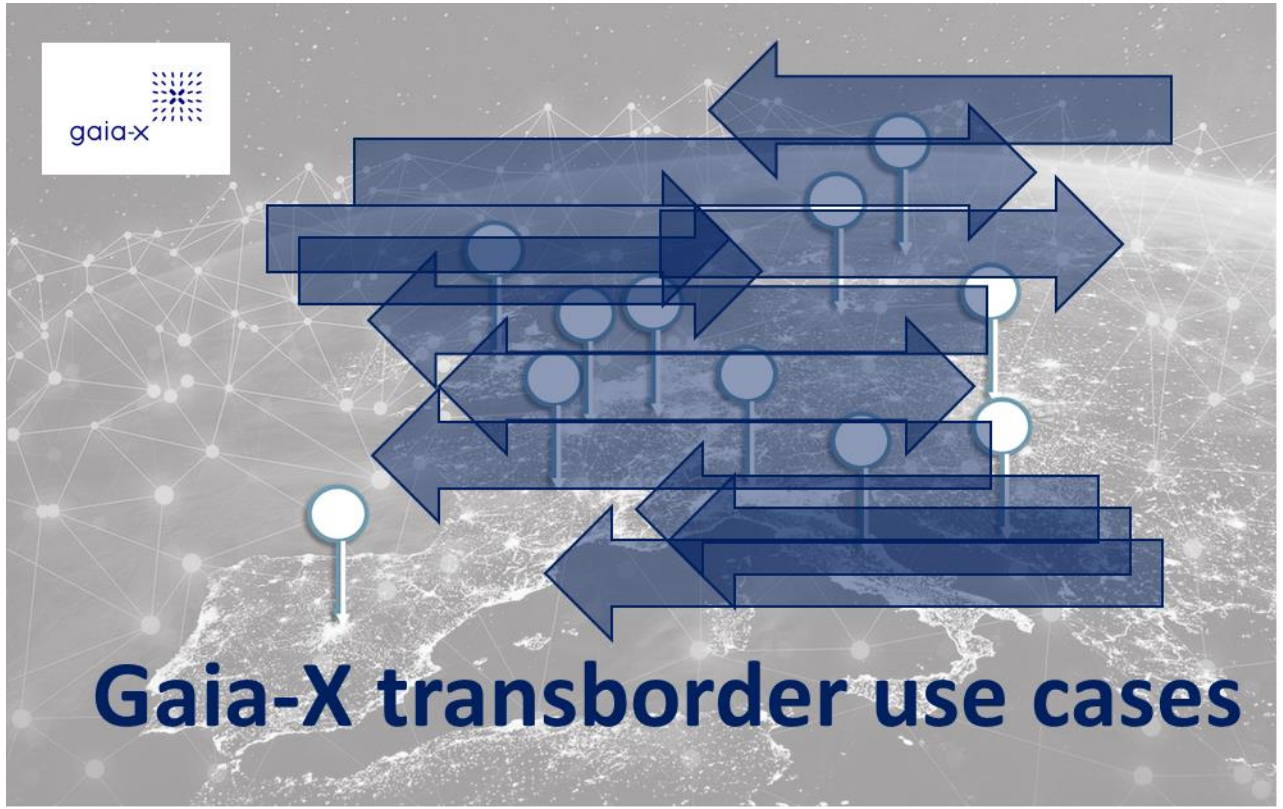


Genomics and imaging data for cancer care and rare diseases: make this data available at a large, cross-country scale, for study, and for improving diagnosis and treatment. Make the data-driven findings available at the point of care, in applications useful for the treating physician as well as to the patient.

Patient driven measurements and outcomes: bring the infrastructure in place to learn from patient centric observations at a massive scale, and to deploy smart patient applications using that data using this same infrastructure.

Longitudinal patient journey: enable patients to get access to their medical records collected at different providers, and enable patients to provide access to their integral, longitudinal health record in a controlled manner to their doctor of choice or to a clinical study of choice.

Trans-border use cases identified



Genomics and imaging data for cancer care and rare diseases

Rare diseases/cancer: Germany, France

Patient driven measurements and outcomes

DiHa: Germany, France, Luxembourg

Clinnova: Luxembourg, France, Germany

DataLoft/TEAM-X: Germany

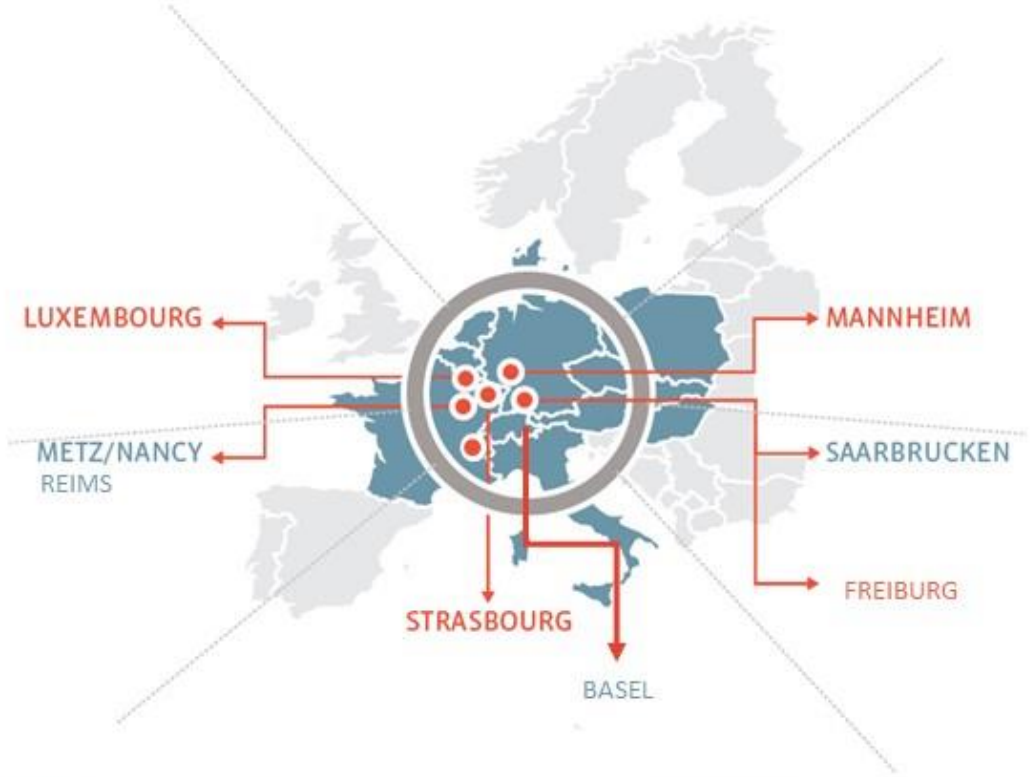
Longitudinal patient journey

Diabetes: Finland, Denmark, Germany

Gastric cancer: Latvia, Germany

Clinnova partner network

gaia-x



nd rare

KTBW KOORDINIERUNGSSTELLE TELEMEDIZIN Baden-Württemberg

miracum

UMM UNIVERSITÄTSMEDIZIN MANNHEIM

Medizinische Fakultät Mannheim der Universität Heidelberg

Universitätsklinikum Mannheim

DFKI Deutsches Forschungszentrum für Künstliche Intelligenz GmbH

UNIVERSITÄTS KLINIKUM FREIBURG

uni.lu

CHL Centre Hospitalier de Luxembourg

HÔPITAUX ROBERT SCHUMAN

CNS d'Gesondheetskeess

Fonds National de la Recherche Luxembourg

LE GOUVERNEMENT DU GRAND-DUCHÉ DE LUXEMBOURG Ministère de l'Enseignement supérieur et de la Recherche

CHU DE REIMS

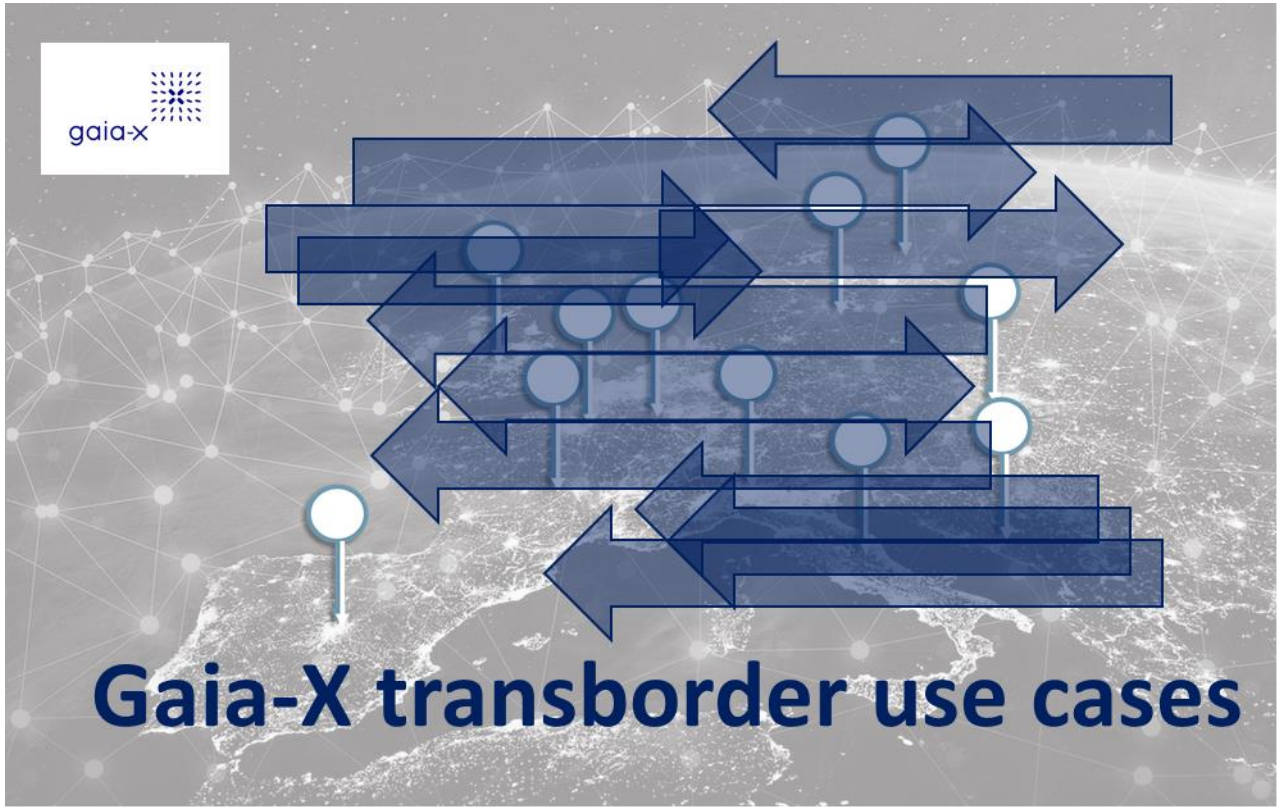
CHRU NANCY

Les Hôpitaux Universitaires de STRASBOURG

ihu STRASBOURG

Universität Basel

Funding



How can funding for Gaia-X Health be obtained

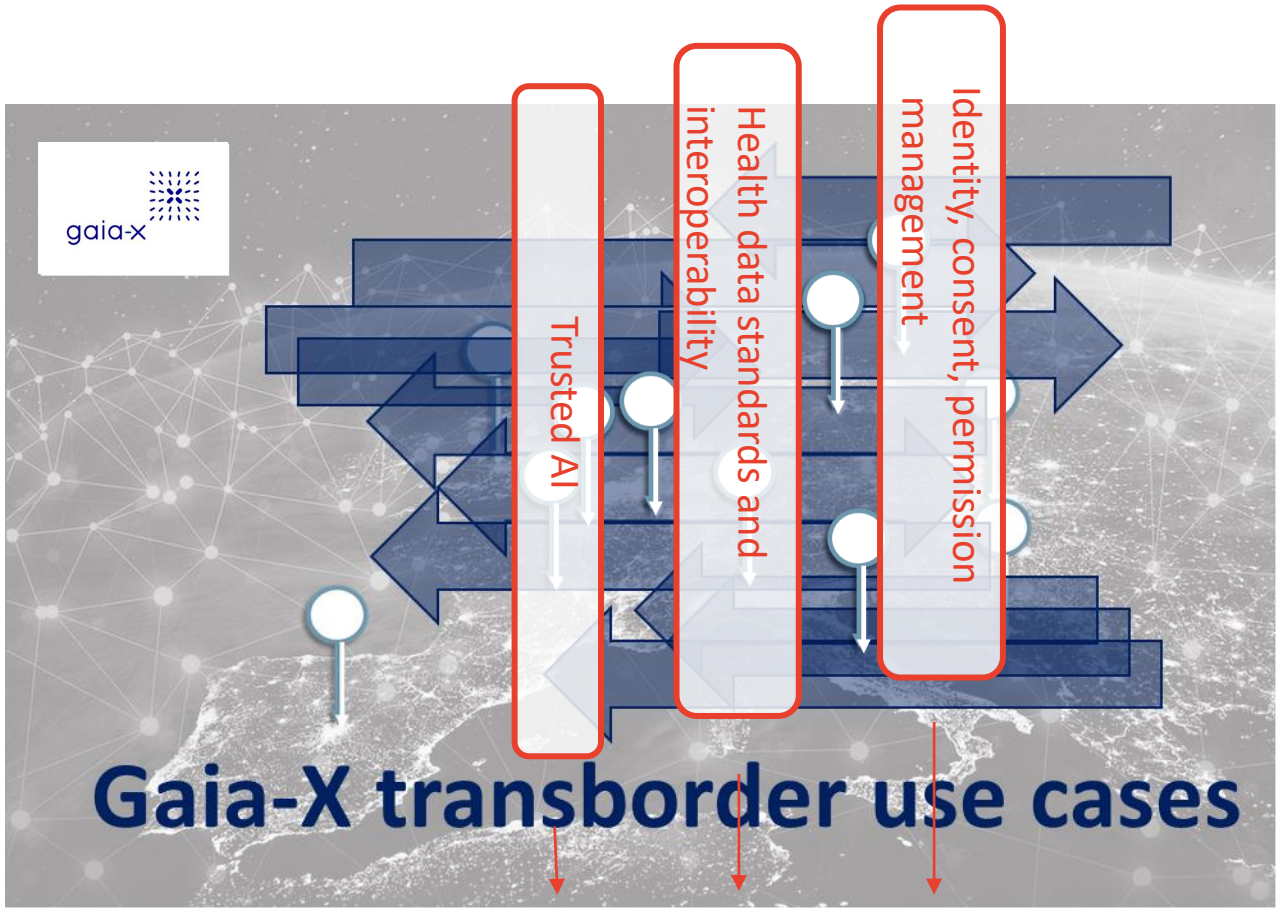
Recovery fund?

- Considered plausible by Coordination team members, in particular when matching projects can trigger coordinated Recovery funding from collaborating countries.
- Important to provide project managers (Finland and /or Luxembourg) to build these trans-border models.
- Recovery fund availability to be checked on the German side

Horizon Europe?

- Considered useful, but long-term
- How can we reach out to policy/decision makers to discuss options?
- It has been pointed out by the AISBL leadership that national funding sources are more accessible in the short and medium term (see Recovery funds)

Working groups



"enabler"-specific transversal working groups

In order for the trans-border use cases to further Gaia-X, they should be probed by working groups for specific enablers

- **Each working group should be constituted by specialists around a given enabler**
  - From the countries participating in the use case
  - From other member countries interested in the use case/subject
  - From AISBL «HQ» a specialist closest to the enabler
- **Types of transversal working groups:**
  - Identity, consent, permission mgt
  - Health data standards and interoperability
  - Trusted AI
- Eventually, common solutions for enablers should be elaborated and proposed to AISBL

15. Common building blocks

- **Bert Verdonck**, Philips & Gaia-X Health Domain

On top of the Gaia-X trust framework, the Health Domain needs common building blocks:

- **Identity, consent and trust**:
  - Enable trust and sovereign control
  - Federated identity management
  - Interoperable consent management

- **Data standardization:**
  - Harmonization of competing standards
  - Semantic interoperability
  - Simplify adoption
  - Automated conversion wherever possible

- **Trusted AI:**
  - Ethical principles
  - Anonymization and synthetic data generation
  - Explainable AI without discriminatory bias

16. Panel and Q&A

How to make it work, converge existing and emerging new initiatives, Gaia-X, Ignite-X

- **Bert Verdonck, Jeroen Tas, Francesco Bonfiglio, Dipak Kalra**

1h Break

See you at **13:00** in the session **Chapter 2a: Breakout Use cases**
**select and join only one session when the breakout rooms open*

- #1 Cancer & Rare Disease
- #2 Patient Driven Measurements and Outcomes
- #3 Longitudinal Patient Records Exploration
- #4 Enabler Identity, Consent & Trust
- #5 Data standards, the key to enable a European Health Data Space
- #6 Enabler trusted AI