

Integration of Heterogeneous Data and Evidence towards Regulatory and HTA Acceptance (IDERHA)

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IDERHA Goals

1. A **federated data infrastructure** architecture which permits existing platforms to integrate and connect with (new) data sources in health data spaces.
2. Optimised **AI/ML algorithms, validated on EU data sets**, to support more efficient and accurate risk profiling, malignancy risk prediction, diagnosis, and prognosis on **Lung Cancer**.
3. A **digital application to remotely monitor the individual patient post-discharge health status**.
4. Extension of the **OMOP** common data model.
5. Enabling **personal health data environment**, bridging the gaps in the current standards and **FAIRification** framework including necessary extensions of standards.
6. Subject's **specific health data connected, and accessible** under dynamic consent for secondary use.
7. Consensus on **policy recommendations** for the development of **laws, guidelines and policies** adapted to the current and future states of digitalisation, and consistent with **secondary use of health data for research and innovation**, as well as acceptability of **RWD for regulatory** and **HTA decision making**.

IDERHA aligns with the European Data Space Principles

Health-specific ecosystem

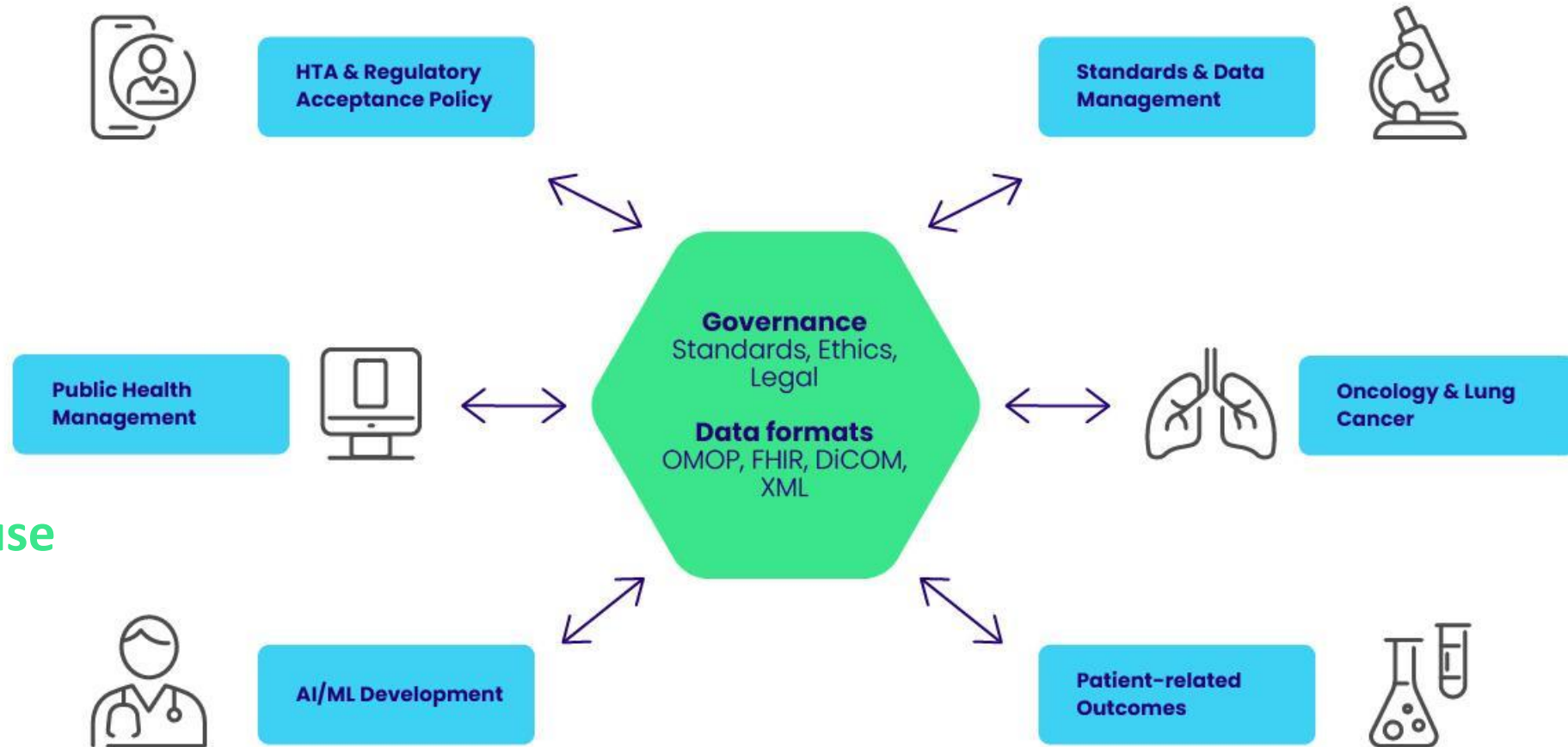
- Rules
- Common standards + practices
- Infrastructures
- Governance framework

Empowers individuals

- Increased access and control
- Support free movement
- Market for EHRs

Enables health data reuse

- Consistent
- Trustworthy
- Support innovation
- Policy making
- Regulatory activities

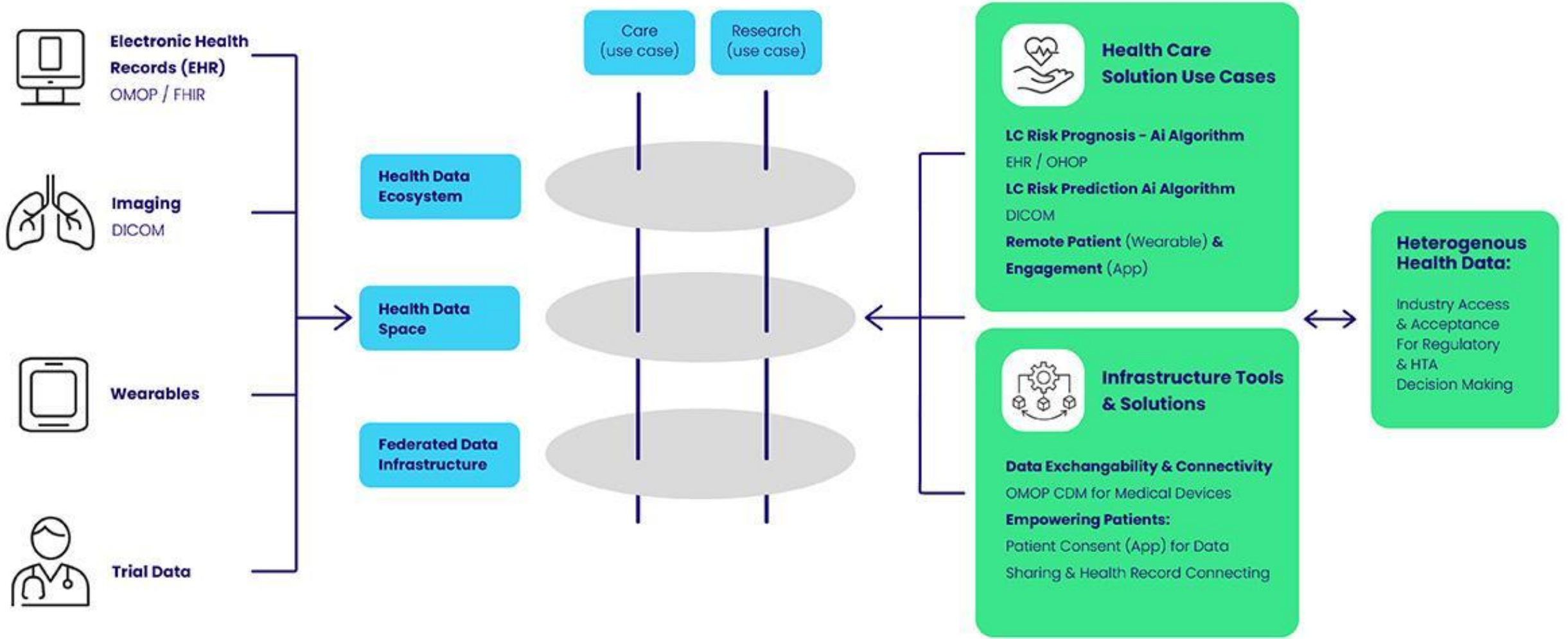


1. Access to diverse data at scale

2. Further develop a scalable, open platform

3. Tools focused on needs of Patients, Clinicians & Research

4. Shape Policy



Partner Synergetic Interconnectivity

IMI Projects



EU Data Standards



EU Health Data Space Public Partner



33 Leading Expert Partners from 10 Countries in Europe, plus strong non-EU support

academia & research & public



industry & SME



associated



affiliated





Synergies Among Health Data Projects with Cancer Use Cases based on Health Standards

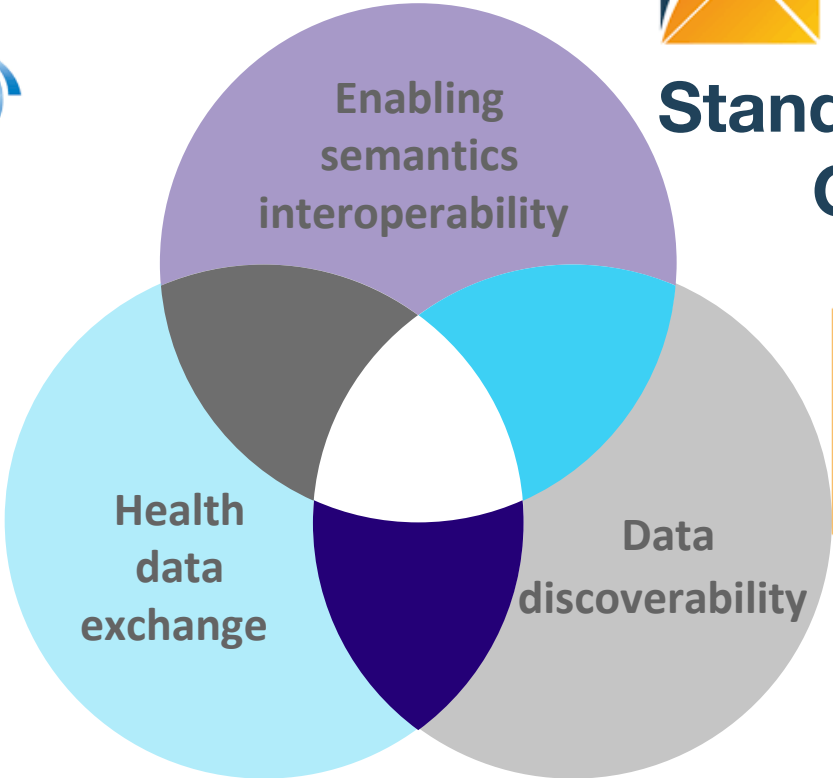
Synergies among EU Projects - Cancer Use Cases



TEHDAS Recommended Standards



**Standardized Data: The OMOP
Common Data Model**



**HealthData@EU pilot
Health extension to
the DCAT-AP
"HealthDCAT-AP"**

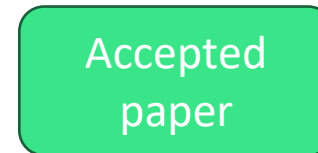
Study on health standards used in Health Data Space Projects

Projects related to cancer/ Standards	HL7 FHIR	DICOM	OMOP	ISO TC 215 CEN TC 251 Health Informatics Standards	Other Standards	Knowledge Graph (KGs)/Ontology Technologies W3C DCAT-AP
IDERHA/ Lung Cancer	HL7 FHIR	DICOM	OMOP	ISO TC 215 (Planned)		DCAT-AP: HealthDCAT-AP (Planned)
Bigpicture / Kidney	-	In use for all Whole Slide Images in the repository	-	Medical laboratories — Part 2: Digital pathology and artificial intelligence (AI)- based image analysis	-	-
EUCAIM Cancer Images	-	DICOM	OMOP	Image preparation, data processing, harmonization, segmentation and AI model predictions	-	-
iHELP Pancreatic Cancer	HHR based on FHIR	-	OMOP	Mapper transformation for data harmonization	ISO 27799:2016	SNOMED, LOINC
ASCAPE Breast and Prostate Cancer	HL7 FHIR	-	-	ISO/CEN 13606	-	LOINC, SNOMED
HealthData@EU Colorectal cancer, etc.	Does not work on actually implementing data standardization based on common guidelines but rather observes and collects standardization efforts undertaken by research teams to help them in their research/work. DCAT-AP, Importance of FHIR Profiles.					

Synergies among Alliances and Other Projects

Some synergies are being done with impactful alliances working on those topics, such as AIOTI Health WG, and data space alliances such as BVDA, GAIA-X, etc.

- **AIOTI Health WG** released a White Paper IoT/Edge Computing and Health Data and Data Spaces Release 1.0 AIOTI WG Health March 2024, where IDERHA and HealthData@EU pilot projects are cited among use cases.
- **Big Data Value Association (BDVA)** published the European Health Data Space white paper in July 2023.



Conclusion and Future Work

- Creating synergies among European Health Data Space projects
 - IDERHA, ASCAPE, iHELP, EUCAIM, Bigpicture, HealthData@EU pilot project
 - Thanks to the HSBOOSTER EU Project
 - By focusing on the health standards usage.
- Focus on **semantic interoperability** by studying the usage of **health ontologies**.
- **Need for tools** to support standards and help users choose the one fitting their needs to reduce the time-consuming task of comparing health standards, nomenclatures, data formats, etc. such as HL7 FHIR, OMOP, DICOM, etc.
- **Future work:** investigate the usage of health ontologies, and devices used to produce health data.

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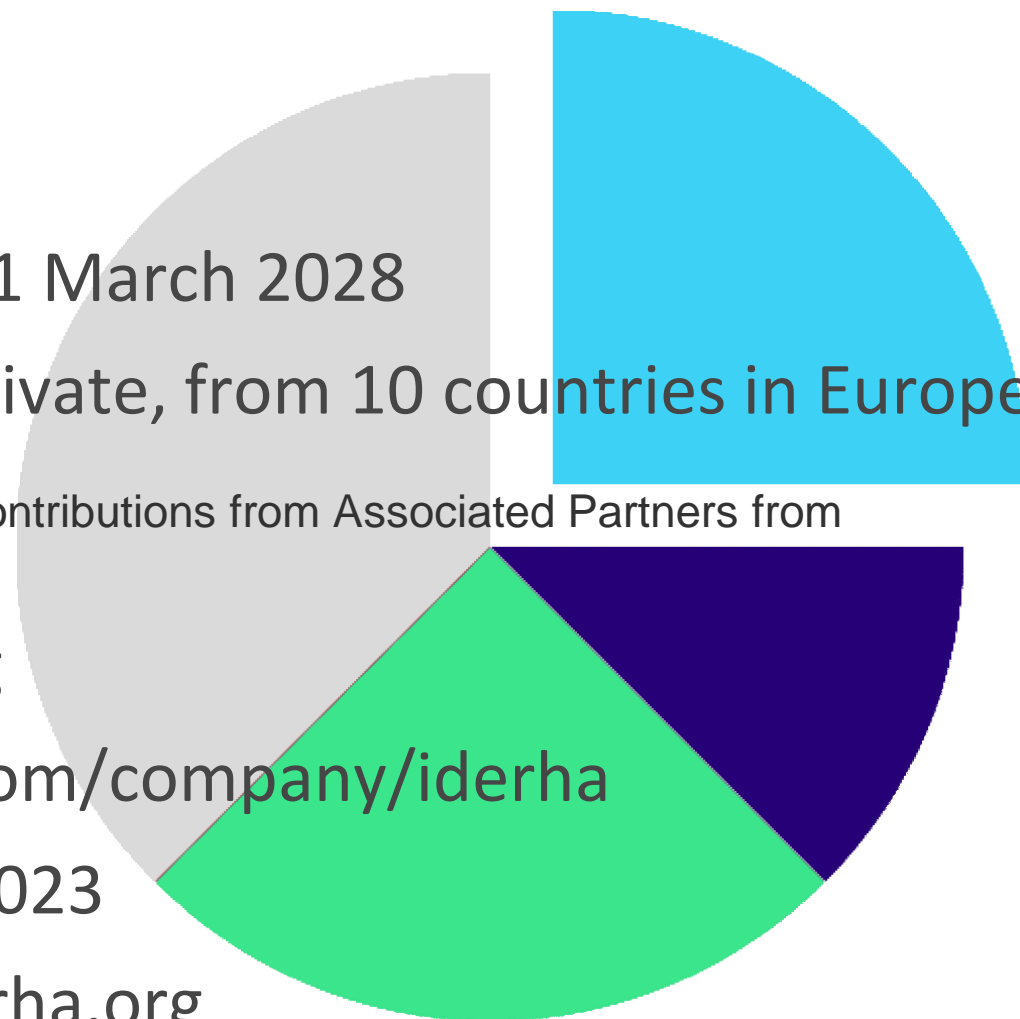
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Co-funded by
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Key Facts

- **Timeline:** 1 April 2023 – 31 March 2028
- **Partners:** 32 public and private, from 10 countries in Europe
- **Budget:** € 42.7 mln (plus contributions from Associated Partners from Switzerland and the UK)
- **Website:** www.iderha.org
- **LinkedIn:** www.linkedin.com/company/iderha
- **X (formerly Twitter):** x.com/iderha_2023
- **Contact address:** communications@iderha.org
- **IHI grant number:** 101112135





‘We aim to improve
clinical decision-making
and enhance patient access
to health innovations
through better use of
health data’

