Why a Health RDI system cannot afford to miss DIPoH

IACS Instituto Aragonés de Ciencias de la Salud

INFACT
Joint Action on Health Information

DIPoH

Distributed Infrastructure on **Population Health**

TEHDAS Joint Action

Towards the European Health Data Space

Towards the European Health DAta Space

SITRA

Building momentum for the European Health Data Space

Commission President von der Leyen, State of the Union address, 16/09/2020	• *"We need common data spaces - for example, in the energy or healthcare sectors. This will support innovation ecosystems in which universities, companies and researchers can access and collaborate on data."*
European Council, Summit Conclusions, 02/10/2020	• *"The Europe… strategic se… data space,*
Commission work programme 2021, 19/20/2020	• Plan: Legisl… assessment…
President von der Leyen, Statement after Covid-discussions, 29/10/2020	• *"I had five n… share compl…*
German EU Presidency's Conference on Digital Health 2020 – EU on the Move, 11/11/2020	• *"The Comm… work closely… research an…*
Commission Communication on building a European Health Union, 11/11/2020	• *"The set-up… European H…*
Commission proposal for a European Data Governance Act, 25/11/2020	• COM(2020)…

Council Conclusions on COVID-19 lesson learned in health,
09/12/2020:

"CALLS upon the European Commission, the Member States, and all relevant public and private stakeholders to jointly collaborate in order to deliver a functioning European Health Data Space, …"

"WELCOMES the close cooperation between Member States and the Commission in preparing the Joint Action for the European Health Data Space…"

2021 - Commission & Presidency joint press release on activities paving the way for better data-driven health care in Europe

Legal text on the European Health Data Space	• proposed by the Commission in Q4 of 2021
TEHDAS Joint Action	• to propose options on governance, infrastructure, data quality and data solidarity and empowering citizens with regards to secondary health data use in the EU
Investments to support the EHDS	• under the EU4Health programme, as well as common data spaces and digital health related innovation under Horizon Europe and Digital Europe programmes
Targeted Codes of Conduct	• for secondary health data use developed through engagement with relevant actors
A pilot project	• to demonstrate the feasibility of cross border analysis for healthcare improvement, regulation and innovation
Other EU funding opportunities	• for digital transformation of health and care available for Member States as of 2021 under Recovery and Resilience Facility, European Regional Development Fund, European Social Fund+, InvestEU.

Adapted from the joint press release 11/11/2020

Proposal for a Data Governance Act - European Health Data Space

- Proposal for DGA: adopted on 25 November
- General framework/minimum rules for the use of data in Europe
- Includes health, but will be supplemented by the *lex specialis* on European Health Data Space, which can add additional rules that will also apply
- European Health Data Space:
  - Health data – primary and secondary use of health data
    - governance, privacy, quality, portability and access to health data, interoperability, standards, infrastructures
  - Removing obstacles to the free movement of digital health services and products in the internal market.
  - Establishing clear liability rules fit for digital health, including AI in health.

Proposal DGA - EHDS

Pillar 1: re-use of sensitive data held by public sector bodies

- Multi-sector **single information point in each MS** that can orient towards
  - Public sector bodies holding the data
  - Competent bodies providing access to data (on behalf of data holders)
- MS must designate national body providing **support function** to public sector bodies/data holders
    - Secure processing environment
    - Advice on technical and legal aspects for disclosure of data

- EHDS:
  - Building on DGA, designated national competent bodies in health
    - Can provide access to health data
    - Offer a secure processing environment

Proposal DGA - EHDS

Pillar 2: notification of **data sharing intermediaries**

- Data sharing schemes for B2B and C2B (personal data spaces)
- Requirements of structural separation and acting not-for-profit

Pillar 3: **Data altruism**

- Register of data altruism organisations recognised in the Union
- EC will adopt template consent form(s) through ID

Pillar 4: **European Data Innovation Board**

- Coordination between sectors, representation of MS competent authorities (including sectoral bodies)
- Technical standardisation cross-sector

EHDS:

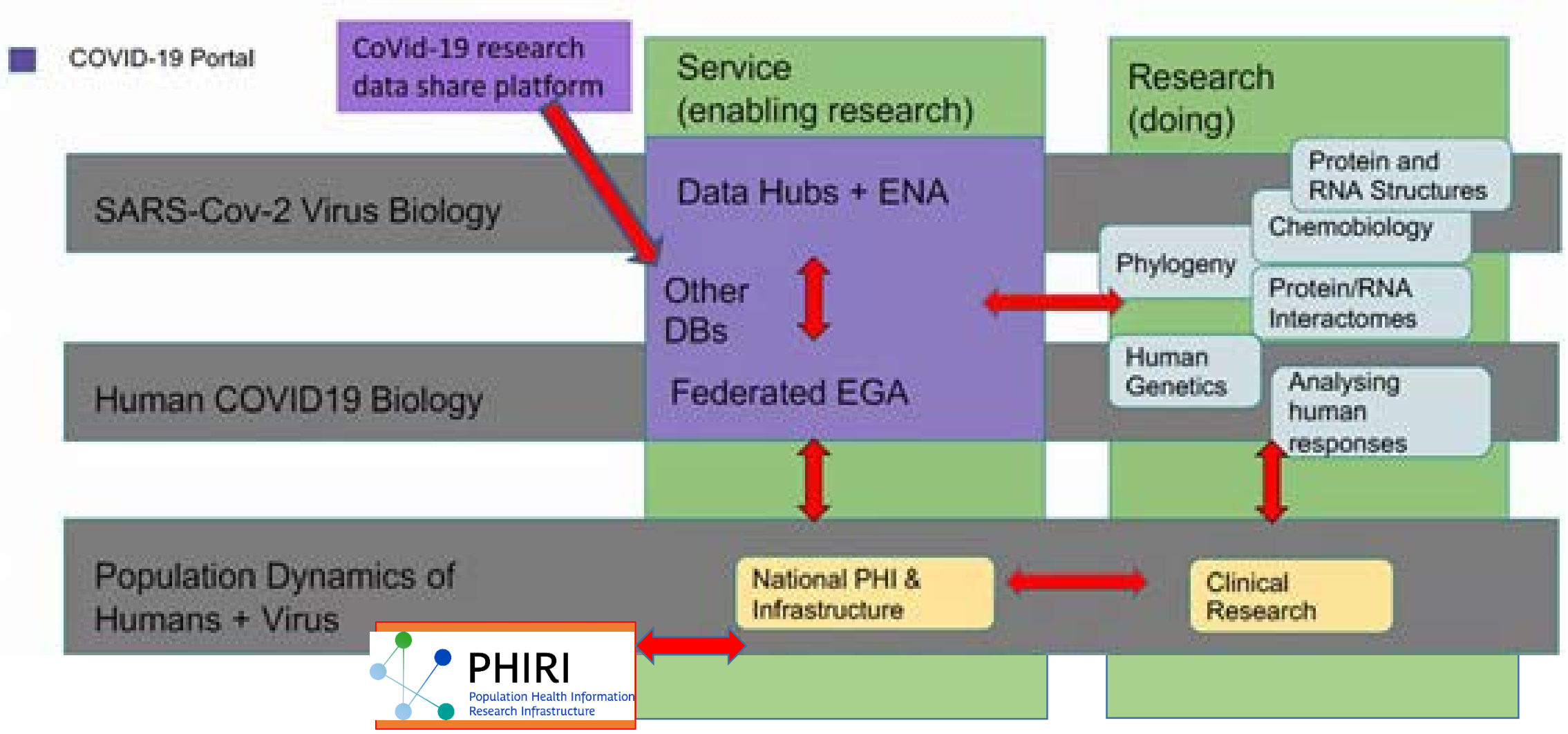
- Competent national digital health authorities to select appropriate standards and requirements for interoperability by data sharing intermediaries - and interoperability of data in health sector for primary and secondary use
- Competent national health authorities could manage data altruism scheme and obtain consent
- Tailor consent form to specificities of health

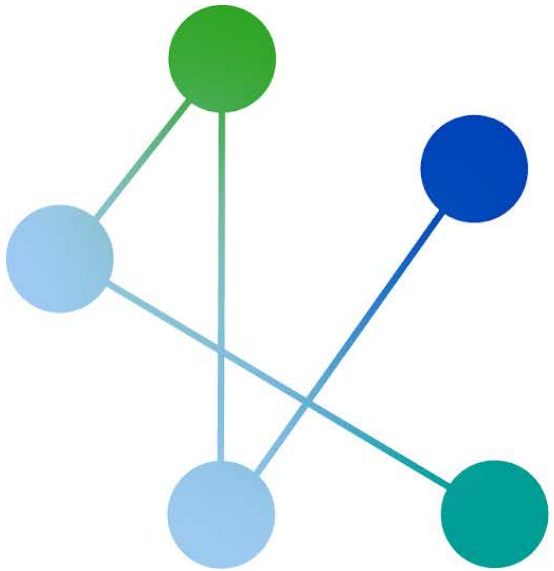
Proposal for DGA - EHDS

EHDS?

- Clarify the specificities for health data
- Categories of health data to which access should be facilitated/granted
- Interoperability of data within health sector (for primary and secondary use)
- Data access rules
- Role of competent support bodies in health
- Rules for EU level infrastructure and conditions for participating

COVID 19 Data Share Research Platform (EMBL- EBI/ELIXIR)





PHIRI

Population Health Information Research Infrastructure

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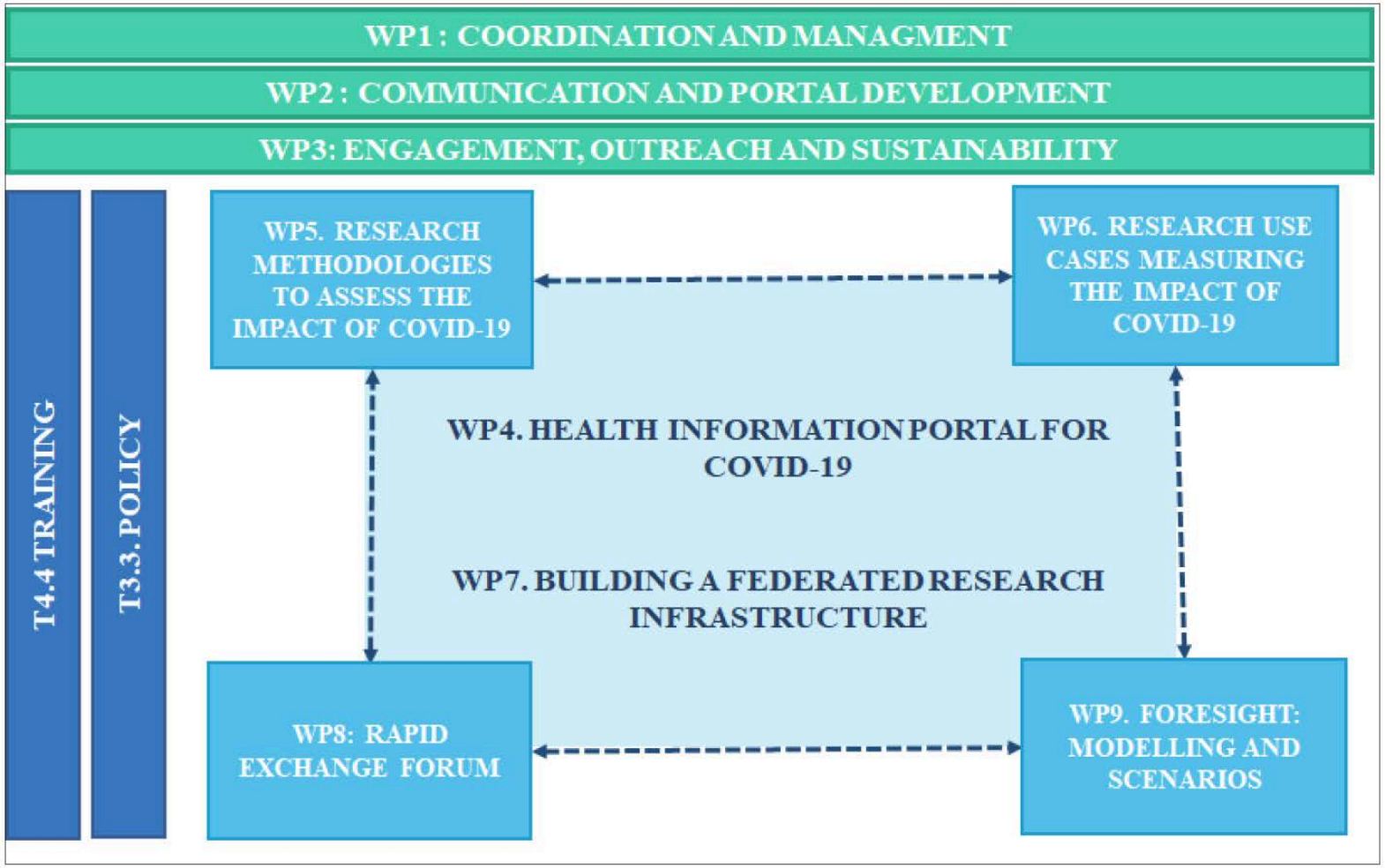
WORKPLAN


WP1 : COORDINATION AND MANAGMENT
WP2 : COMMUNICATION AND PORTAL DEVELOPMENT
WP3: ENGAGEMENT, OUTREACH AND SUSTAINABILITY
T4.4 TRAINING
T3.3. POLICY
WP5. RESEARCH METHODOLOGIES TO ASSESS THE IMPACT OF COVID-19
WP6. RESEARCH USE CASES MEASURING THE IMPACT OF COVID-19
WP4. HEALTH INFORMATION PORTAL FOR COVID-19
WP7. BUILDING A FEDERATED RESEARCH INFRASTRUCTURE
WP8: RAPID EXCHANGE FORUM
WP9. FORESIGHT: MODELLING AND SCENARIOS

DIPoH

Distributed Infrastructure
on **Population Health**

HEALTHYCLOUD
Health Research & Innovation Cloud

CSA Healthy Cloud:

a distributed e-infrastructure (“cloud”) for research with any kind of health data

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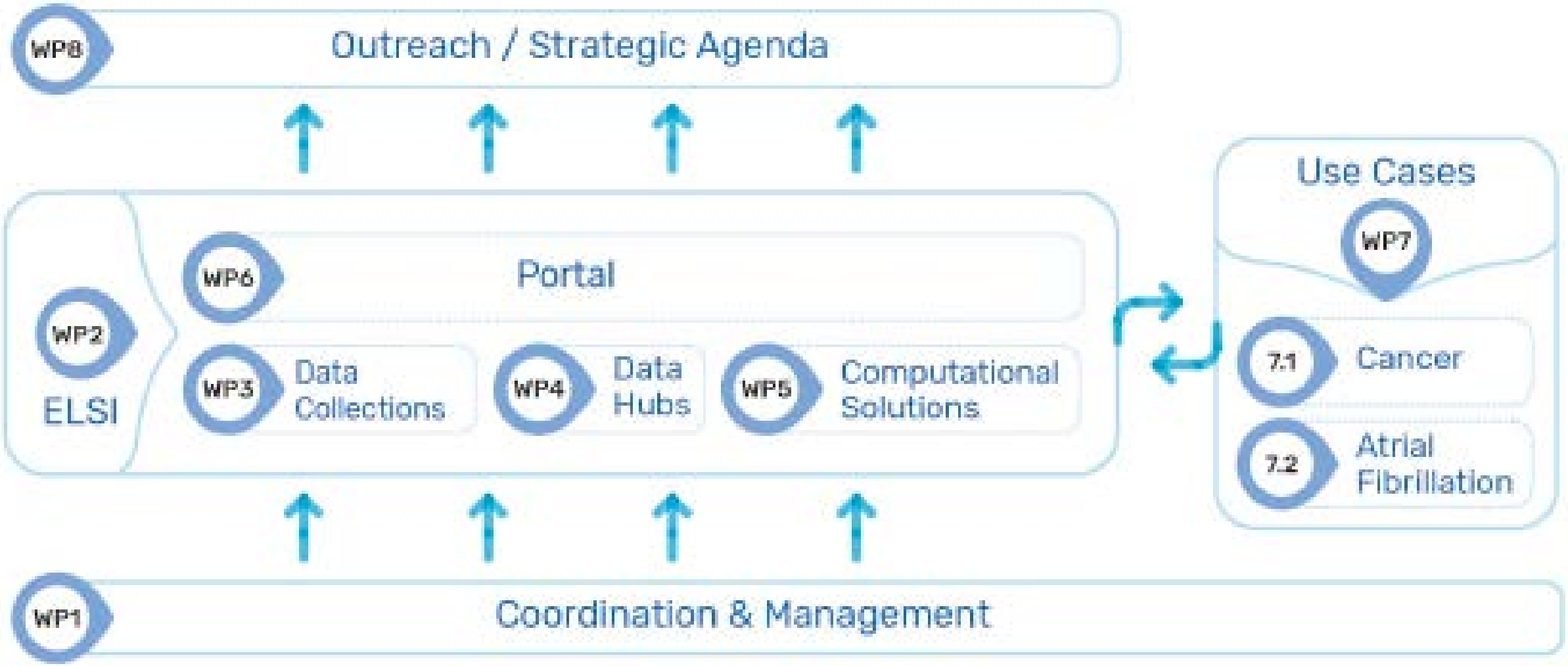
HEALTHYCLOUD
Health Research & Innovation Cloud



TECHNOLOGY DOMAIN