



The European experiences of the Istituto Superiore di Sanità in Health and Digital sectors

Anna Ceccarelli, Research Coordination and Support Service



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SERVIZIO TECNICO-SCIENTIFICO
COORDINAMENTO E SUPPORTO
ALLA RICERCA

ISS

a constant commitment to public health

in 7 strategic research areas...

ISS is the main biomedical and public health research institute in Italy, and the leading technical and scientific body of the Italian National Health

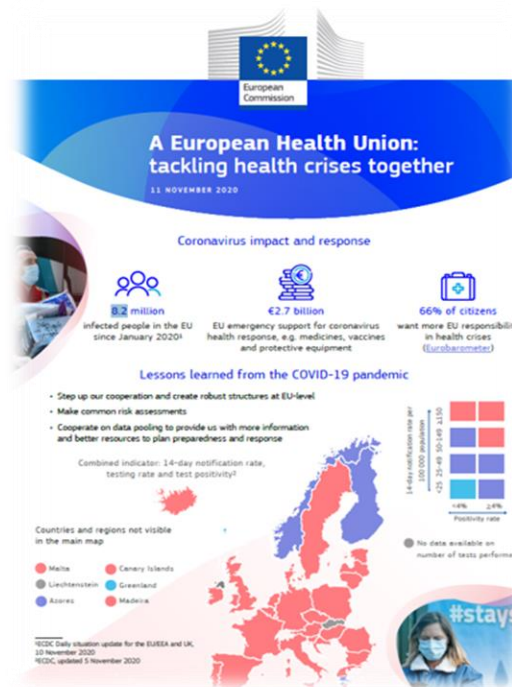


ISS 7 strategic research areas



Synergies with EU health initiatives

- The ISS strategy and governance is in synergy with European Union priorities supporting health.
- ISS actively participates, including with coordination roles, in actions promoted by the European Union in support of its priorities:
 - ✓ EU health working groups with its experts;
 - ✓ Joint Actions funded by the EU4Health programme;
 - ✓ European research and innovation projects and partnerships funded by Horizon Europe;
 - ✓ Projects and initiatives funded by the DIGITAL programme.



Participation in EU Programmes

EU4HEALTH

- 13 actions under WP 2021-2022
1 as coordinator
- 8 proposals (Joint Actions) submitted under WP 2022-2023
1 as coordinator

HORIZON EUROPE

- 17 projects under WP 2021-2022
1 as coordinator
- 17 proposals submitted under WP 2023 (first semester)

DIGITAL

- 1 project

CERV

- 1 project (as coordinator)

EUROPEAN DEFENCE

- 1 project

EURATOM

- 1 project (PIANOFORTE)

EU4HEALTH: overview of participation

Work Programme 2021

**CRISIS
PREPAREDNESS (CP)**
3 actions

**DISEASE PREVENTION
(DP)**
4 actions
(1 as coordinator)

**HEALTH SYSTEMS AND
HEALTHCARE WORKFORCE
(HS)**
4 actions

Work Programme 2022


**CRISIS
PREPAREDNESS (CP)**
1 action

**DISEASE
PREVENTION (DP)**
1 action



EU4HEALTH 2021: crisis preparedness

1.1 SUPPORT ACTION TO MITIGATE SHORTAGES OF MEDICINES AND IMPROVE THE SECURITY OF SUPPLY INCLUDING OF COVID-19 THERAPEUTICS

EU4H-2021-JA-06: Direct grants to Member States' authorities: availability of medicines, shortages and security of supply

Action	Field of science
 CHESSMEN <small>Commission and implementation of the existing systems against shortages of medicines - European Network</small>	Short supply of medicines; Public health; Medical care delivery; European Network



1.2. COMMUNICABLE DISEASES – SURVEILLANCE AND EARLY DETECTION

Action		Field of science
EU4H-2021-JA-13: Direct grants to Member States' authorities: Union and national surveillance systems		Pandemic preparedness; Law; Cross-border threats; ECDC framework; Surveillance; transferability of knowledge; Capacity building
EU4H-2021-PJ-20 Action grant to support a HERA laboratory network	 DURABLE <small>Research Network against Epidemics</small>	Pandemic preparedness; HERA Lab network; Medical countermeasures; One Health; Epidemiology; intelligence; Surveillance

EU4HEALTH 2021: disease prevention

2.1. HEALTH PROMOTION AND PREVENTION OF NON-COMMUNICABLE DISEASES AND RELATED RISK FACTORS


EU4H-2021-JA-08: Direct grants to Member States' authorities: implementation of best practices and research results on prevention of non-communicable diseases and risk factors

Actions	Field of science
 	Type 2 diabetes; Lifestyle treatment; Transfer of good practices; Pilot actions; Intensive care programme; After care programme

EU4HEALTH 2021: disease prevention


2.2. SAVING LIVES THROUGH SUSTAINABLE CANCER PREVENTION

EU4H-2021-JA-02: Direct grant to Member States' authorities: support to assist Member States to roll out large-scale human papillomavirus vaccination campaigns (Coordinated by ISS)

Action	Field of science
	HPV; Vaccination coverage; Cervical Cancer

2.4. CANCER: ENSURING ACCESS TO HIGH STANDARD CANCER CARE DIAGNOSIS AND TREATMENT




EU4H-2021-PJ-15: Action grants for 'Cancer Diagnostic and Treatment for All' including 'Genomic for Public Health

Action	Field of science
	Genomics; Public health research; Cancer; Next Generation Sequencing; Pathways

EU4HEALTH 2021: health systems and health workforce

3.3. STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS AND COOPERATION BETWEEN NATIONAL AUTHORITIES AND PROFESSIONAL SECTOR ASSOCIATIONS

EU4H-2021-PJ-05: Action grants on substances of human origin (SoHO) – increase resilience, ensure continuity of supply and access to safe and high quality therapies, in particular in times of crisis

Actions	Field of science
	Transplantation; Quality; Safety; Donation
	Plasma; PDMP; Covid-19; Donor; Strategic independence; SoHo; Best practice
	Blood; Tissues; Cells; Accessibility; Sufficiency; Harmonisation; Accreditation; Technical assistance

EU4HEALTH 2021: health systems and health workforce

3.3. STRENGTHENING THE IMPLEMENTATION OF THE LEGISLATION ON BLOOD, TISSUES AND CELLS AND ORGANS AND COOPERATION BETWEEN NATIONAL AUTHORITIES AND PROFESSIONAL SECTOR ASSOCIATIONS

EU4H-2021-PJ-17: Action grants to organise and collect data to understand the safety, quality and efficacy of therapies applied in the field of assisted reproduction and therapies based on haematopoietic stem cells

Action	Field of science
EuroTraCTOR	Clinical data; European registry; Quality; Donor/Patient safety; Efficacy; Cellular therapies; haematopoietic stem cell transplantation

EU4HEALTH 2022: health promotion and disease prevention

2.2. ADDRESSING MENTAL HEALTH CHALLENGES

EU4H-2022-PJ-03: Call for proposals on promoting mental health

Action	Field of science
Icehearts Europe	Mental health; Sport; Health; Youth

HORIZON EUROPE: overview of participation

PILLAR I. EXCELLENT SCIENCE

Research infrastructures: 1 project

PILLAR II. GLOBAL CHALLENGES AND EU INDUSTRIAL COMPETITIVENESS

Cluster Health: 13 projects (including 3 EU Partnerships)

Cluster Civil Security for Society: 1 project

Cluster Food, Bioeconomy Natural Resources, Agriculture and Environment:
1 project

Cluster Climate, Energy and Mobility: 1 project

Overview of participation in Cluster Health

Destination 2. Living and working in a health-promoting environment

- 1 Project coordinated
- 4 Projects as Beneficiaries
- 1 EU Partnership as Italian node

Destination 3. Tackling diseases and reducing disease burden

- 2 projects as Beneficiary
- 1 project as Affiliated Entity
- 1 EU Partnership as Affiliated Entity (ItaCRIN)

Destination 4. Ensuring access to innovative, sustainable and high-quality health care

- 1 EU Partnership as Affiliated Entity in support to Coordinator

Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society







- 1 project as Beneficiary

Destination 6. Maintaining an innovative, sustainable and globally competitive health industry

- 1 project as Beneficiary





HORIZON EUROPE: Cluster Health

Destination 2. Living and working in a health-promoting environment

Project	Field of science
 COORDINATOR	Artificial intelligence; Dementia; Pollution
 Blue Adapt	Public health; Climatic changes; Decision support tools
 CLIMOS	Ontology; Big Data; Climatic changes; Zoonosis
 INQUIRE	Data science; Air pollution engineering; Sensors; Pollution; Machine learning
 NextGEM	Electromagnetism; Radio frequency; Law
 PARC <small>Partnership Assessment Risks Chemicals</small>	Public health; Crisis management; Chemicals (EU Partnership)

HORIZON EUROPE: Cluster Health (cont)

Destination 3. Tackling diseases and reducing disease burden

Project	Field of science
	Infectious diseases; Pandemic preparedness; Public health
	Artificial intelligence; Pneumology; sensors
	Infectious diseases; Bacterial and viral respiratory pathogens; Vaccines
	Public health; Cardiovascular diseases; Nanomedicine; Nutrition; Clinical trials (EU Partnership)

HORIZON EUROPE: Cluster Health (cont)

Destination 4. Ensuring access to innovative, sustainable and high-quality health care

Project

Field of science



Public health; sustainability; Policy dialogue; Priority setting; Capacity building; Good practice transferability (EU Partnership)

Destination 5. Unlocking the full potential of new tools, technologies and digital solutions for a healthy society

Project

Field of science

LEOPARD

Organ transplantation; Artificial intelligence

Destination 6. Maintaining an innovative, sustainable and globally competitive health industry

Project


Field of science




Mhealth; Law; Quality

HORIZON EUROPE: other clusters


Cluster Civil Security for Society

Project	Field of science
 SUNRISE	Access control; Pandemics; Coronaviruses; Climatic changes; Machine learning

Cluster Food, Bioeconomy Natural Resources, Agriculture and Environment

Project	Field of science
 CoDiet	Social inequalities; Nutrition; Machine learning

Cluster Climate, Energy and Mobility

Project	Field of science
 HEALTHY SAILING	Pandemics; Coronaviruses; Naval engineering

The European experiences of the Istituto Superiore di Sanità in Health and Digital sectors

Digital Technologies in support of Innovation

Mauro Grigioni

Director of National Center for Technology Innovation in Public Health



<https://www.iss.it/centro-nazionale-per-le-tecnologie-innovative-in-sanita-pubblica>
National Center for Innovative Technologies in Public Health

“Synergies across the EU Funding Programmes managed by the European Health and Digital Executive Agency (HaDEA)”

A **toolkit** for dynaMic health Impact analysis
to **predicT** disability-Related costs in the
Aging population based on 3 case studies of
steel-industry exposed areas in europe

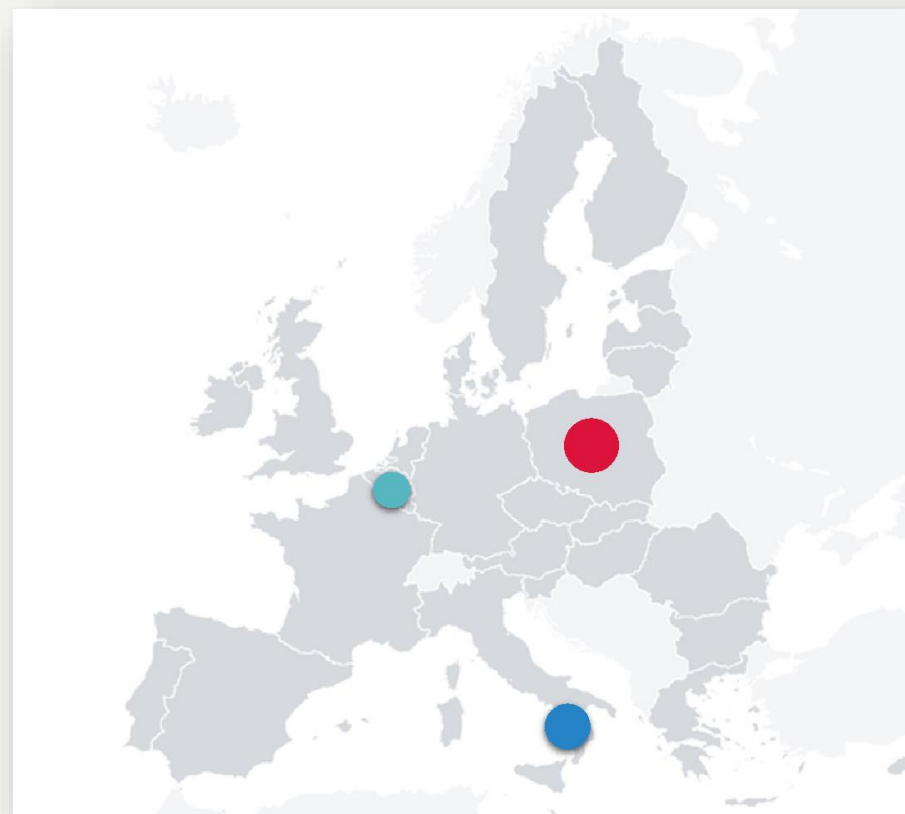


mistral

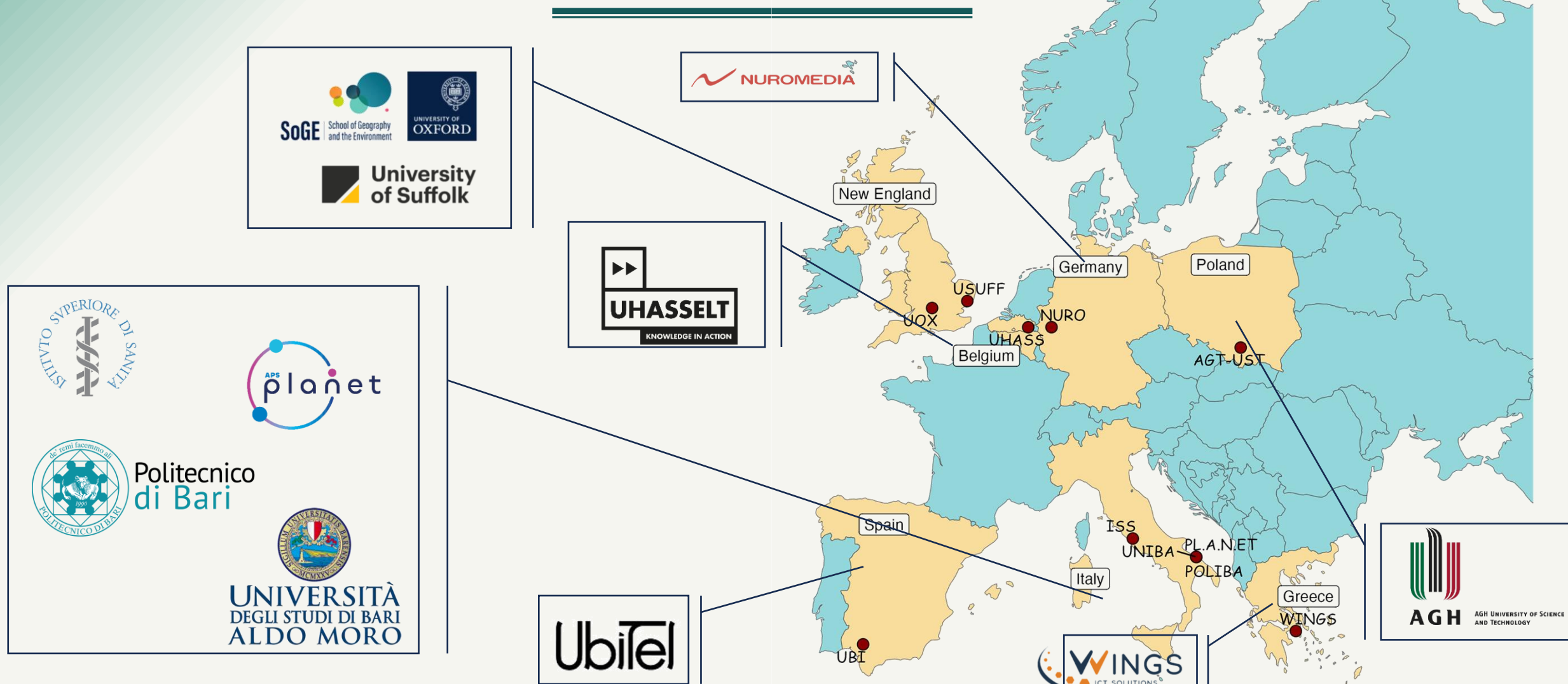
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National Center for Innovative Technologies in Public Health

MISTRAL Aim

Development of a **web-based platform** interfaced with an immersive visualization **dashboard** capable of handling all **health impact assessment (HIA) tools**, allowing access to deterministic data (case studies of three European cities impacted by pollution) and **predictive models** based on machine learning, simulating "**in-silico**" **scenarios of intervention** with **health protection policies**



MISTRAL Consortium

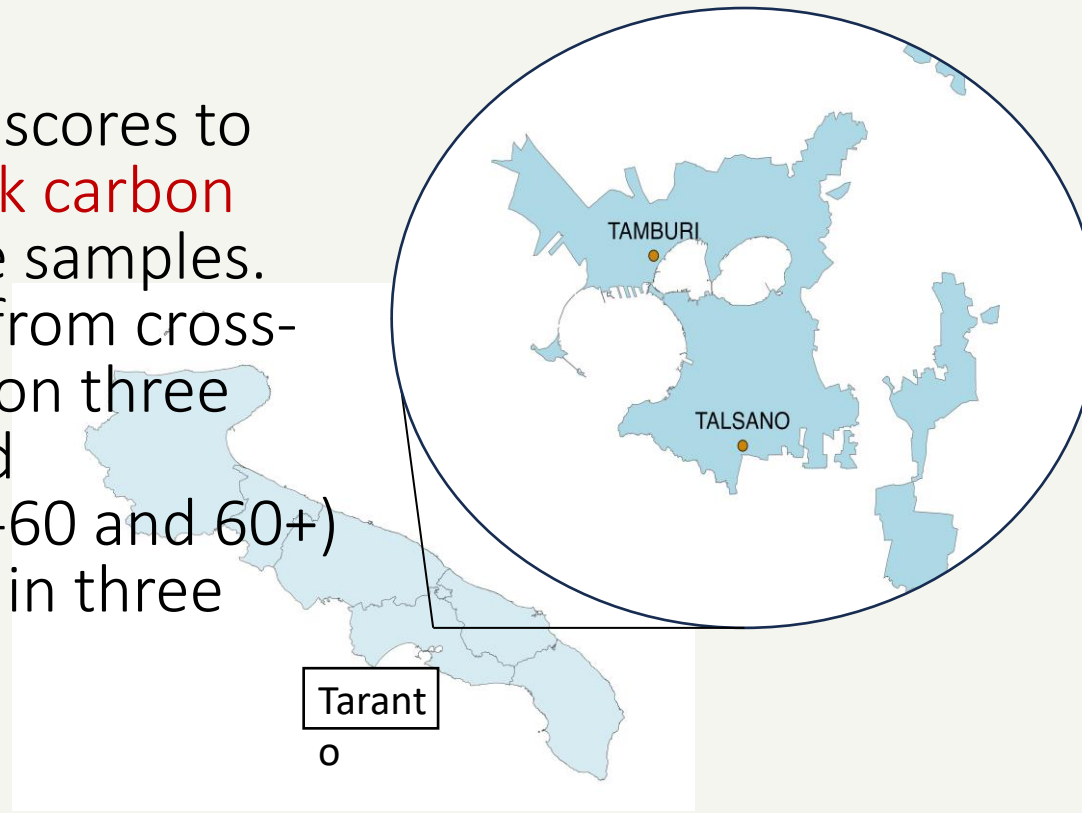


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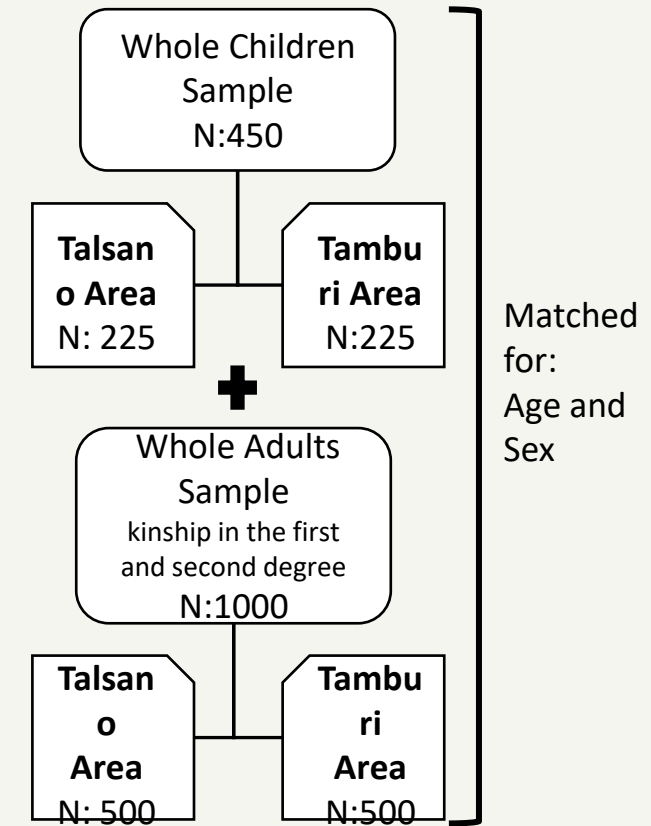
National Center for Innovative Technologies in Public Health

MISTRAL Zephyr Study

To create AI-driven multidimensional risk scores to predict **QALY** and **black carbon concentration** in urine samples. The model will come from cross-sectional survey data on three different age-stratified populations (4-15, 16-60 and 60+) exposed to pollutants in three different countries.



Clustered Sampling Scheme



MISTRAL Tramontana Study

To **test, validate, and calibrate** multidimensional risk scores generated on cross-sectional data and other mortality-related health measures (e.g., DALYs) in a **retrospective cohort study**, in the general populations of the three countries (Italy-Taranto, Poland-Rybnik, Belgium-Hasselt) **observed over the past 10 years**

Whole Sample
N:10 000

Cases
N:3000

Specific Deaths according
to ICD10 for:

- COPD (N:1000)
- Stroke (N:1000)
- Dementia (N:1000)

Control
N:7000

Primary AIM

Evaluation DALY,
YYL, YYD

Evaluation

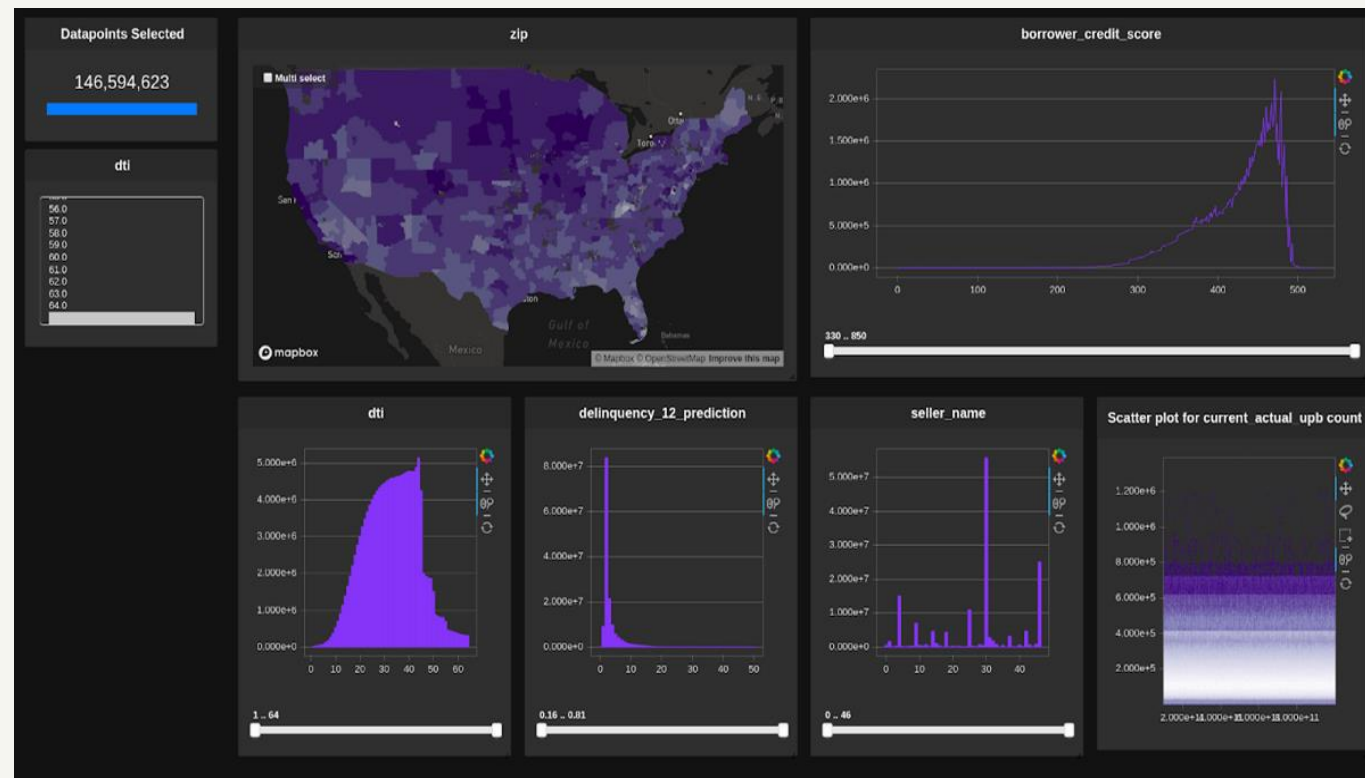
- Clinical Assessment
- Enviromental exposure
- Social Background
- Occupational Exposure

Inclusion Criteria:

- Over 50 years
- Residents in Taranto

MISTRAL TOOL

- To develop **interactive** and **immersive dashboards** to **manage models and data** using counterfactual explainable AI architectures,
- Enabling **policy makers** to create **simulated target scenarios** in terms of **health economic outcomes**



MISTRAL Aim in detail

The MISTRAL aim is:

- to **create an electronic tool**, based on AI prediction and classification algorithms,
- to **model the health and economic impact** of non-communicable diseases with a high disability impact (CHD, Dementia, COPD, and Stroke),
- using **big data** from different age populations and individual sources,
- recording **lifestyle, socio-economic status, environmental and geographical** conditions, and **health status**
- in areas of **high pollution exposure** (Steel Industry).
- To support the data exploration and sensemaking,
- **Immersive Analytics** will be adopted to promote **collaboration among groups of dedicated experts**,
- implementing expertise with sophisticated data analysis tools

Clustering in EU

EU funded Environment and Health Research and promoted the implementation of the **Methods for assEssing health-related costs of Environmental stressORs (METEOR)** Cluster consisting of the 5 projects resulting from the Horizon Europe call HORIZON-HLTH-2022-ENVHLTH-04-01

to optimize synergies,

avoid overlaps and

increase the impact of the projects



METEOR Cluster

Projects

■ BEST-COST ● MARCHES ▲ Mistral ◆ UBDPOLICY ● VALESOR



BEST-COST

SCI (lead), VITO, LMU, DTU, TAI, THL, CSTB, SpF, RIVM, NIPH, EM, UP, EHNet, CHAIN, STPH, IHME (USA)



MARCHES

AU (lead), UMY, UTARTU, CU, MENON, ISG, ISP, BSC, GEUS, EERC, NIBIO



UBDPOLICY

ISGlobal (lead), UU, STPH, LIN, HEAL, UCAM



MISTRAL

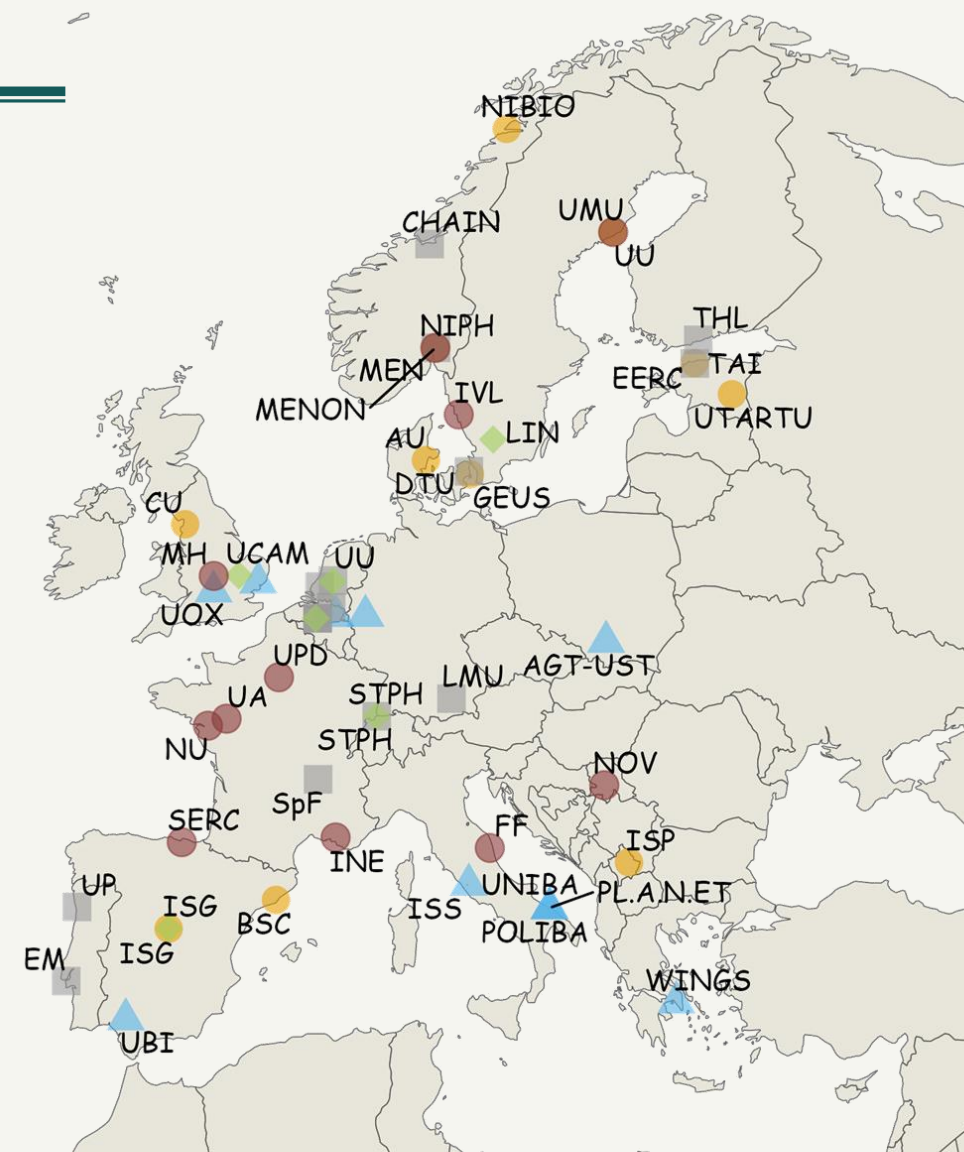
ISS (lead), PL.A.N.ET, UNIBA, POLIBA, USUFF, UHASS, AGH-UST, UOXF, UBI, NURO, WINGS



VALESOR

UA (Lead), NU, IVL, INE, MEN, UPD, UU, SERC, MH, FF, NOV

IHME (USA)
BEST-COST



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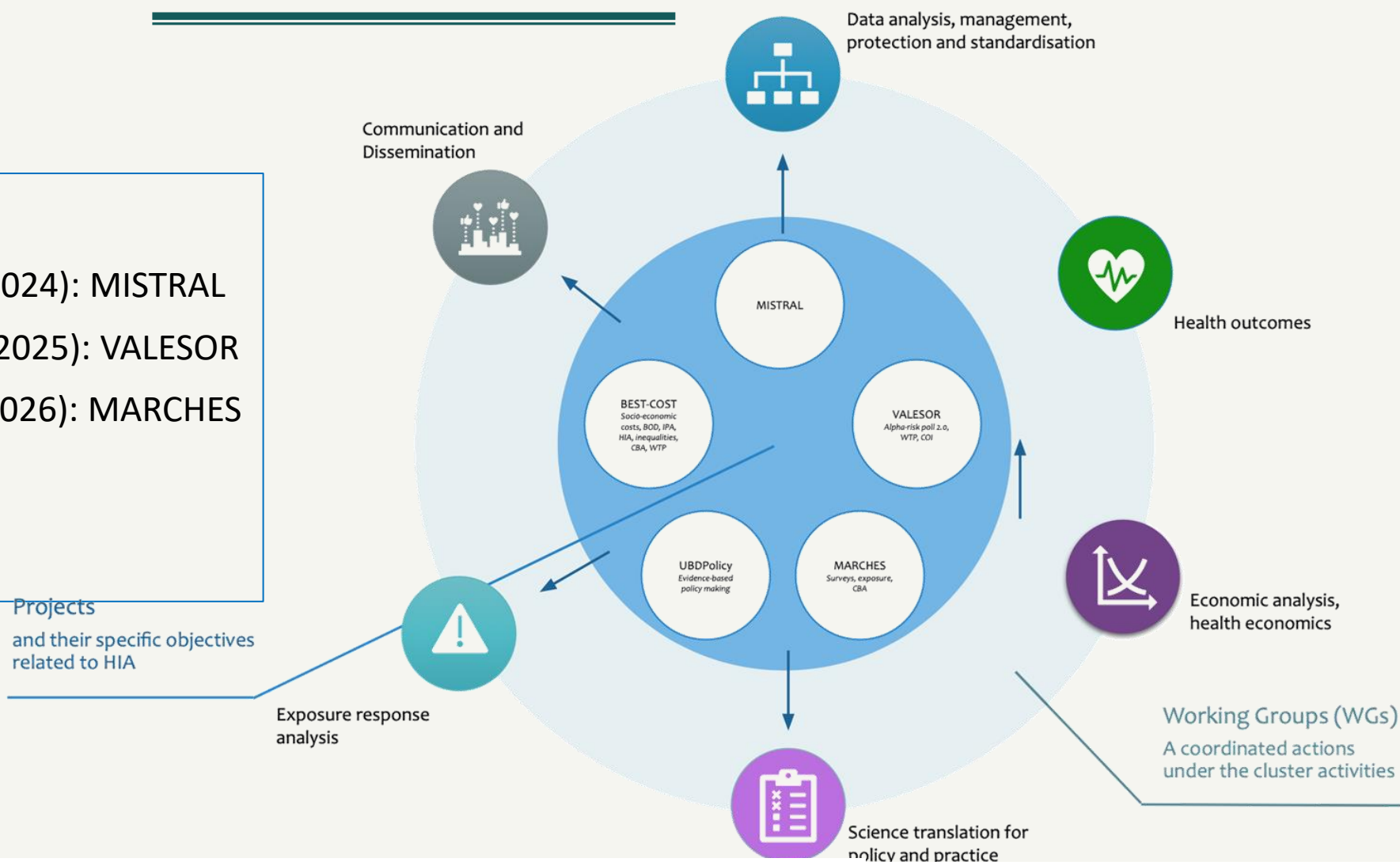


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IN SANITÀ PUBBLICA

METEOR Working Groups

Governance

- 1st period (Jan 2023 - June 2024): MISTRAL
- 2nd period (July 2024 – Dec 2025): VALESOR
- 3rd period (Jan 2026 – Dec 2026): MARCHES



Label2enable

Title: Adopting CEN-ISO/TS 82304-2 and a trusted EU mHealth label for a single market that enables patients, citizens, health professionals, systems and authorities to benefit from a healthy supply of useful apps.

Duration: June 2022 – May 2024

Instrument: Horizon Europe

Type: Coordination and Support Action

Grant Agreement number: 101057522

Budget: 1,999.957.50 EUR

Partners:



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Label2Enable operates within the context of the EU policy

Digital Health and Care



TRANSFORMATION OF HEALTH AND CARE IN THE DIGITAL SINGLE MARKET - Harnessing the potential of data to empower citizens and build a healthier society

European health challenges

- ⊗ Ageing population and chronic diseases putting pressure on health budgets
- ⊗ Unequal quality and access to healthcare services
- ⊗ Shortage of health professionals

Potential of digital applications and data to improve health

- ✍ Efficient and integrated healthcare systems
- ✍ Personalised health research, diagnosis and treatment
- ✍ Prevention and citizen-centred health services

What EU citizens expect...



Support European Commission:

1 Secure access and exchange of health data

Ambition:

Citizens securely access their health data and health providers (doctors, pharmacies...) can exchange them across the EU.

Actions:

- eHealth Digital Service Infrastructure will deliver initial cross-border services (patient summaries and ePrescriptions) and cooperation between participating countries will be strengthened.
- Proposals to extend scope of eHealth cross-border services to additional cases, e.g. full electronic health records.
- Recommended exchange format for interoperability of existing electronic health records in Europe.

2 Health data pooled for research and personalised medicine

Ambition:

Shared health resources (data, infrastructure, expertise...) allowing targeted and faster research, diagnosis and treatment.

Actions:

- Voluntary collaboration mechanisms for health research and clinical practice (starting with "one million genomes by 2022" target).
- Specifications for secure access and exchange of health data.
- Pilot actions on rare diseases, infectious diseases and impact data.

3 Digital tools and data for citizen empowerment and person-centred healthcare

Ambition:

Citizens can monitor their health, adapt their lifestyle and interact with their doctors and carers (receiving and providing feedback).

Actions:

- Facilitate supply of innovative digital-based solutions for health, also by SMEs, with common principles and certification.
- Support demand uptake of innovative digital-based solutions for health, notably by healthcare authorities and providers, with exchange of practices and technical assistance.
- Mobilise more efficiently public funding for innovative digital-based solutions for health, including EU funding.



Updated 24/04/2018

Choosing a 'good' health app is difficult

The sheer number of health apps makes choosing them confusing

37%

I am not sure health apps will help me

32%

I prefer face-to-face consultations with doctor/nurse

31%

I know of no health apps relevant to me

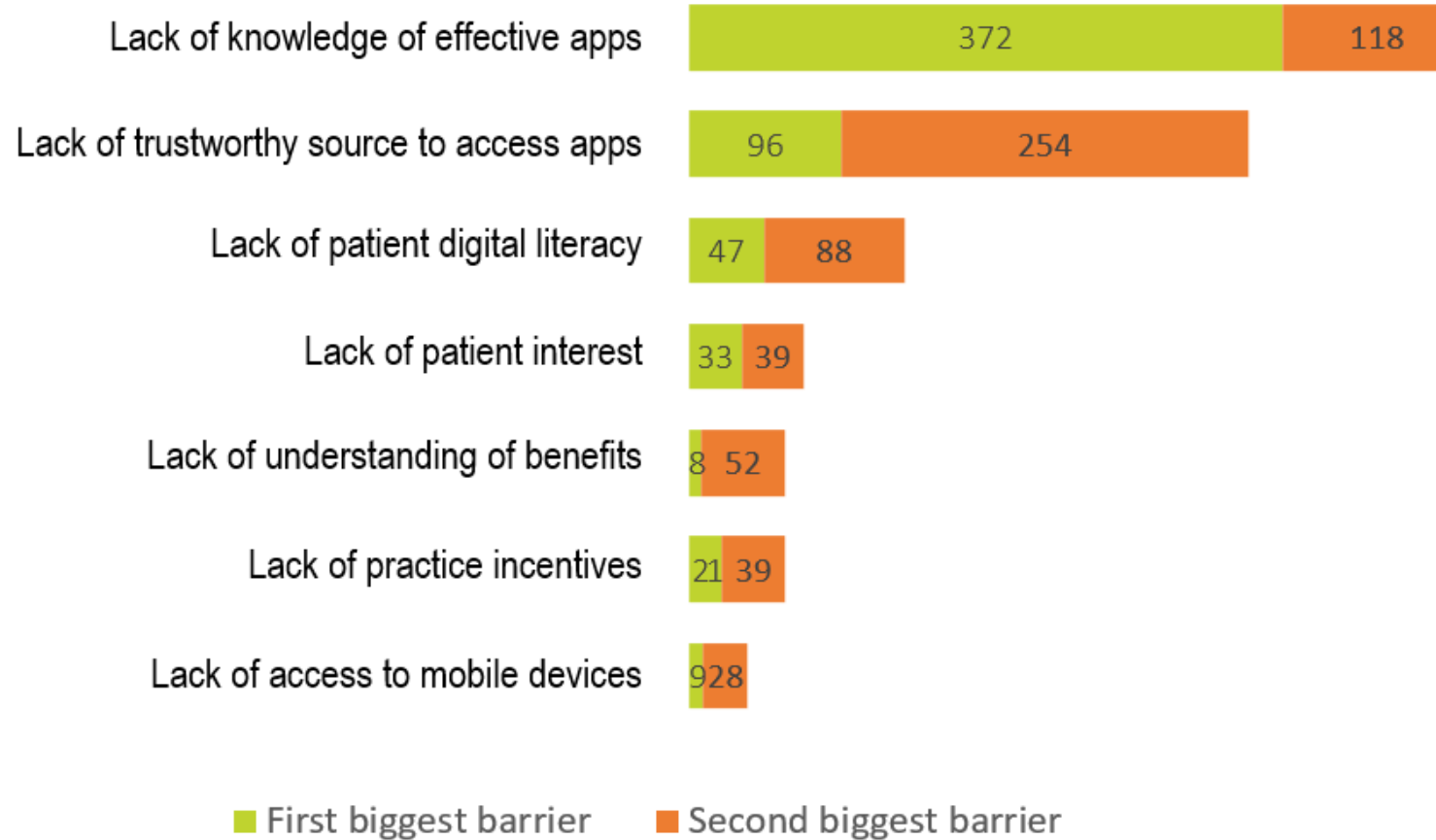
30%

I am suspicious of health apps, because I don't know who makes them

27%

Get-ehealth.eu (2015) What do patients and carers need in health apps – but are not getting? Global survey of 1,120 patients and carers

Choosing a 'good' health app is difficult



Byambasuren et al (2019) Current knowledge and adoption of mobile health apps among Australian General Practitioners: Survey study

EU policy context

The EU moves towards a common transparent assessment of health apps:

Label2Enable: Horizon Europe project creates EU certification scheme CEN-ISO/TS 82304-2

- The *Green Paper on mobile health* (2014) addresses the potential benefits and risks of health apps, questioning **how to verify or ensure the efficacy of health apps** (e.g. certification schemes) and **how to better inform users** on the quality and safety of these apps
- The *Communication on enabling the digital transformation of health and care in the Digital Single Market* (2018) highlights “digital tools and data for citizen empowerment and person-centred care” as a key priority and proposes **common principles and certification** to facilitate supply of these tools, also by Small and Medium-sized Enterprises
- **CEN-ISO/TS 82304-2:2021** (*health and wellness apps – quality and reliability*), an assignment from the European Commission to the European Committee for Standardization (**CEN**), International Organization for Standardization (**ISO**) and the International Electrotechnical Commission (**IEC**), delivers a **common health app assessment framework and label**
- The Proposal for a *Regulation on the European Health Data Space* (2022) calls for **voluntary labelling of wellness apps** (Article 31) and a **cascading effect in medical devices** that aim to be interoperable with Electronic Health Record systems

L2E: CEN-ISO/TS 82304-2:2021 helps choose apps

Main AIM: framework CEN-ISO/TS 82304-2:2021 experimentation on stakeholder to assess App quality (wellness & Health)

Comprehensive For wellness and medical device apps, not duplicating notified bodies

Evidence-informed EU energy level recognised and used by 85% EU consumers

Inclusive Label tested by people with low health literacy

Informative Displayed as a score – accompanying report provides more details

Proportionate At most 81 questions, of which at most 67 score-impacting yes/no questions

Testable Yes-answers require evidence to be assessed by accredited app assessors

Relevant Founded in a Delphi study with 83 experts from 8 stakeholder groups

Global Quality Indicator

Flag or logo Health app quality label

App icon App name

Platform icons

Name app manufacturer

Benefit of the app

With this app [intended users] can [intended use] / With this app [x in 10] [intended users] [health effect] [if use]

Check [here] when app requires approval from a health professional before use

Healthy and safe

Easy to use

Secure data

Robust build

Overall health app quality score

App checked on [date]

CEN-ISO/TS 82304-2:2021

Who can benefit from CEN-ISO/TS 82304-2:2021?

App manufacturers who seek to **deliver quality apps**



Patients, citizens, and carers who seek to **use** health apps



Health and care systems and authorities who seek to **review/reimburse apps**



Health care providers and professional societies who seek to **recommend** apps



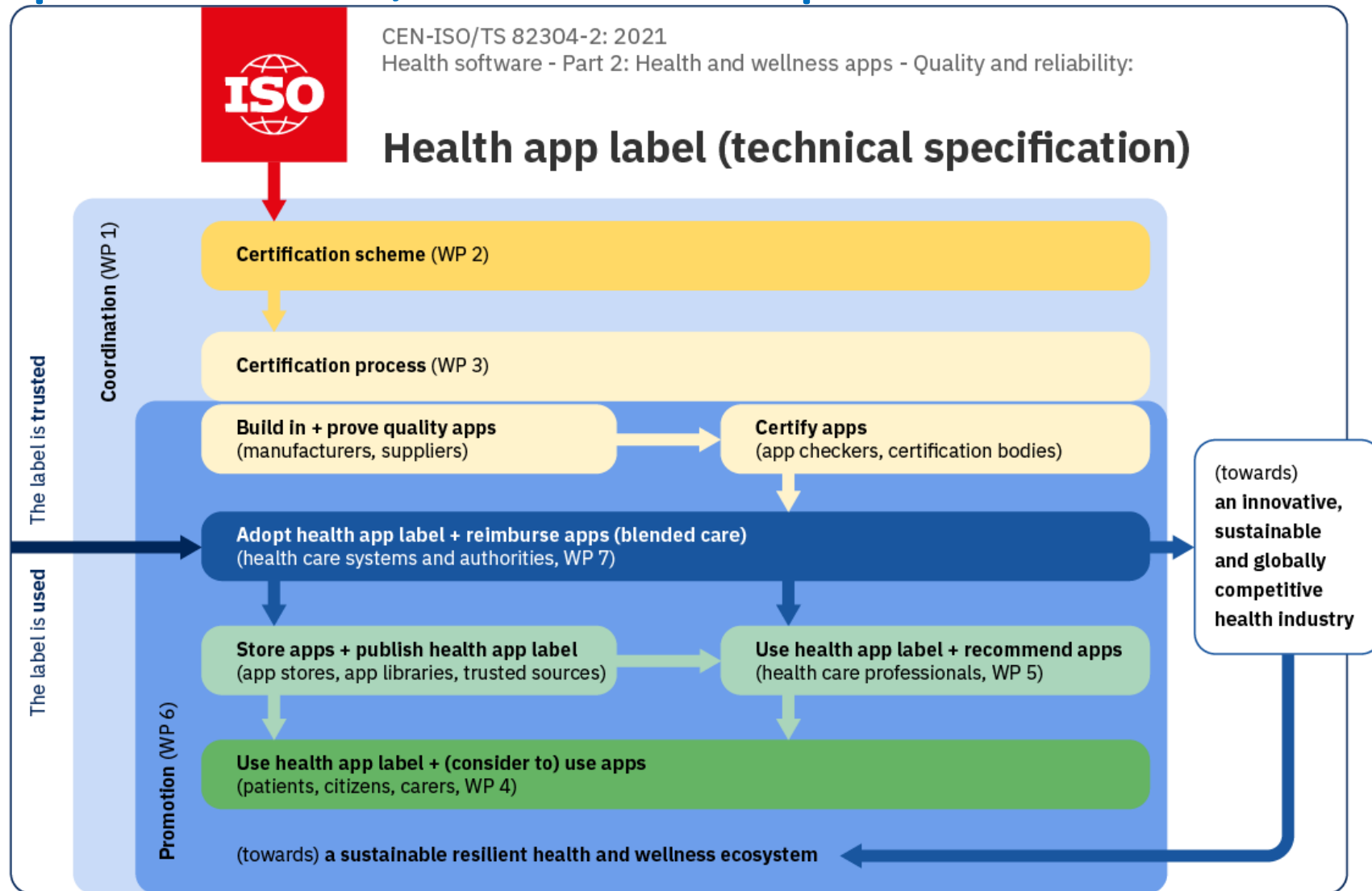
Health App assessment organisations who seek to use a **trusted, globally recognised assessment** framework



App stores and libraries who seek to help their customers make **informed decisions** on health apps



L2E: Project pillars: trust, use and adoption



TRUST

Test handbook for accredited health app assessors

Co-create the trusted **EU certification scheme** (**handbook for accredited health app assessment**):

- Test scheme with 24 manufacturers and 5 app assessment organisations for **consistency and efficiency**
- Align **assessment methods** and **pass/fail** with **EU legislation, EU values** and **stakeholder trust**
- Analyse **business models** for app assessment and existing **label legislations** for applicability

USE

Addressing citizens' and health care professionals' needs

Co-create the communication citizens and health care professionals need:

- Survey whose recommendations on health apps **citizens trust** and what **health professionals need** to recommend health apps
- Test how to introduce the label with people with **limited health literacy**
- Propose level of detail **health app quality report**
- Test **label display** in app stores, app libraries and trusted sources

ADOPTION

Promoting uptake by health care authorities and systems

Co-create a single market (**cross country recognition of EU certification scheme**):

- **Involve relevant stakeholders** through various channels
- Document '**use stories**' of pilots with CEN-ISO/TS 82304-2 in Italy, Catalonia, the Netherlands, Norway, ..
- Explore with health insurers and health technology assessment bodies how the ISO assessment framework can **help in decision-making on reimbursement of health apps**

Project SUNRISE

Mission: Facilitate active collaboration of EU critical Infrastructure



SUNRISE

Improving critical infrastructures through collaboration, strategy and technology

SUNRISE aims to ensure greater availability, reliability, and continuity of critical infrastructures including transport, energy, water, and healthcare to safeguard Europe's lifeline services in pandemics and other major threats.

ISS CI: Covid – 19
Surveillance by GIS
Application for Wastewater
plants network in Italy used
to find Virus genomic copies
and Variants



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Project SUNRISE

Partner	Country
ATOS (C)	ES
INTRASOFT INT.	LU
XLAB	SI
UPM	ES
INSIEL	IT
SQUAREDEV	BE
IMA	CZ
ADDITESS	CY
AIT	AT
Hermes Bay	IT
ICS	SI
HZI	DE
HER	DE
Univ of Warwick	UK
LISER	LU
Inst Adv Studies	AT
Carr Comms.	IE

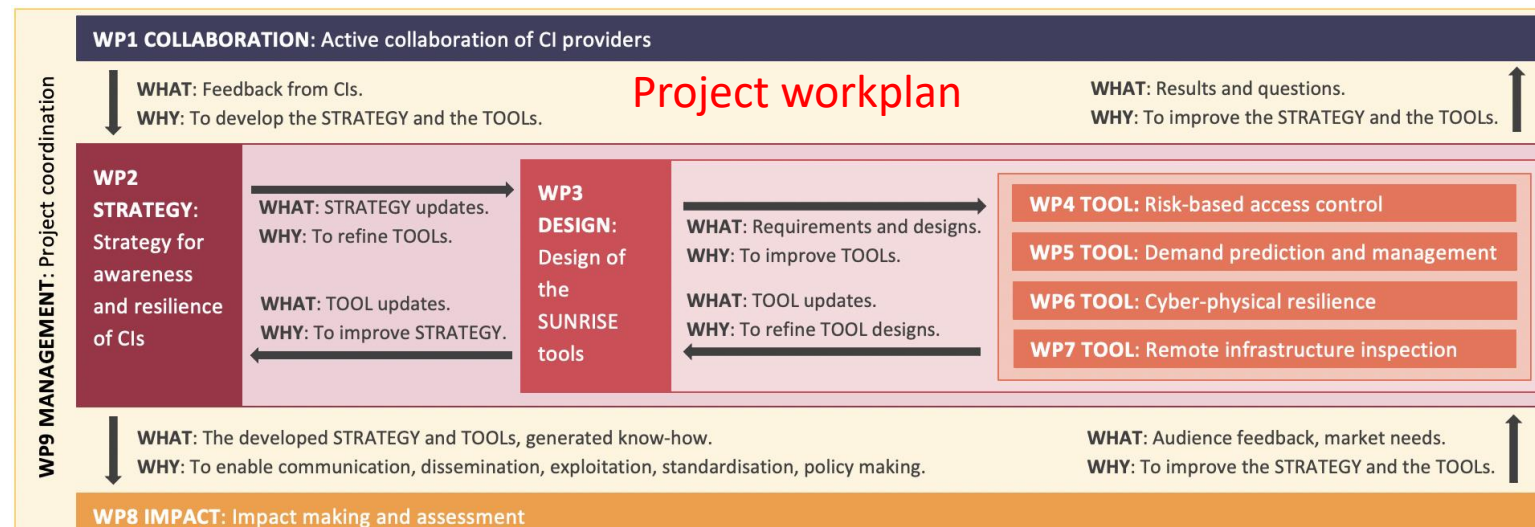
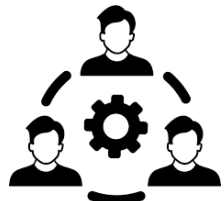
Partner	Country
Ministry Infrastr	SI
Univ. Med. Cent	SI
Teleko Slovenije	SI
ELES (Electr. Op.)	SI
Sloven. Railway	SI
S.Railway Infrastr	SI
Inst Traffic Trans	SI
Plinovodi (Gas O.)	SI
Ministry Interior	ES
Quironsalud instit	ES
IDCQ Hospitals	ES
Telefónica	ES
Pub Tran Madrid	ES
Acosol (Water O.)	ES
Regional Gov	IT
Istit Sup. Sanità	IT
Hydro Dolomiti	IT

Partner	Country
Trieste Transport	IT
CAFC (Water Op)	IT
Elec Coor Center	RS
Munic Jerusalem	IL
Port Maritime Bordeaux	FR
Estonian Supply Chain PROLOG	EE



Project SUNRISE OBJECTIVES:

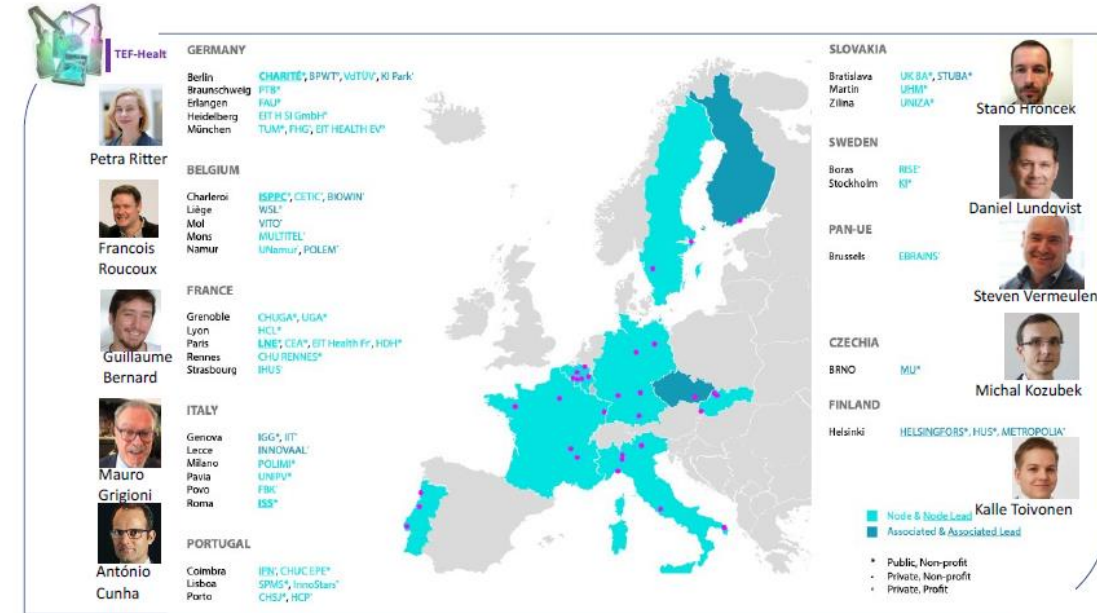
- Facilitate active collaboration among CIs within and across European borders, within and across different sectors, between public and private stakeholders
- Identify pandemic-specific vital services and CIs in Europe, their interactions and dependencies, the risks and cascading effects among them, and effective countermeasures at European level.
- Develop a comprehensive strategy and a set of mature technologies for CI resilience and business continuity in a pandemic.
- Pilot the new strategy and technologies in real-world conditions across Europe.
- Enhance knowledge, awareness, and capacities for unity and resilience in Europe.



TEF Health

Testing and Experimentation Facilities for Health AI and Robotics

(Promote services for SME)



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TEF-Health develops a reference testing and experimentation facility (TEF) with a threefold Objective:

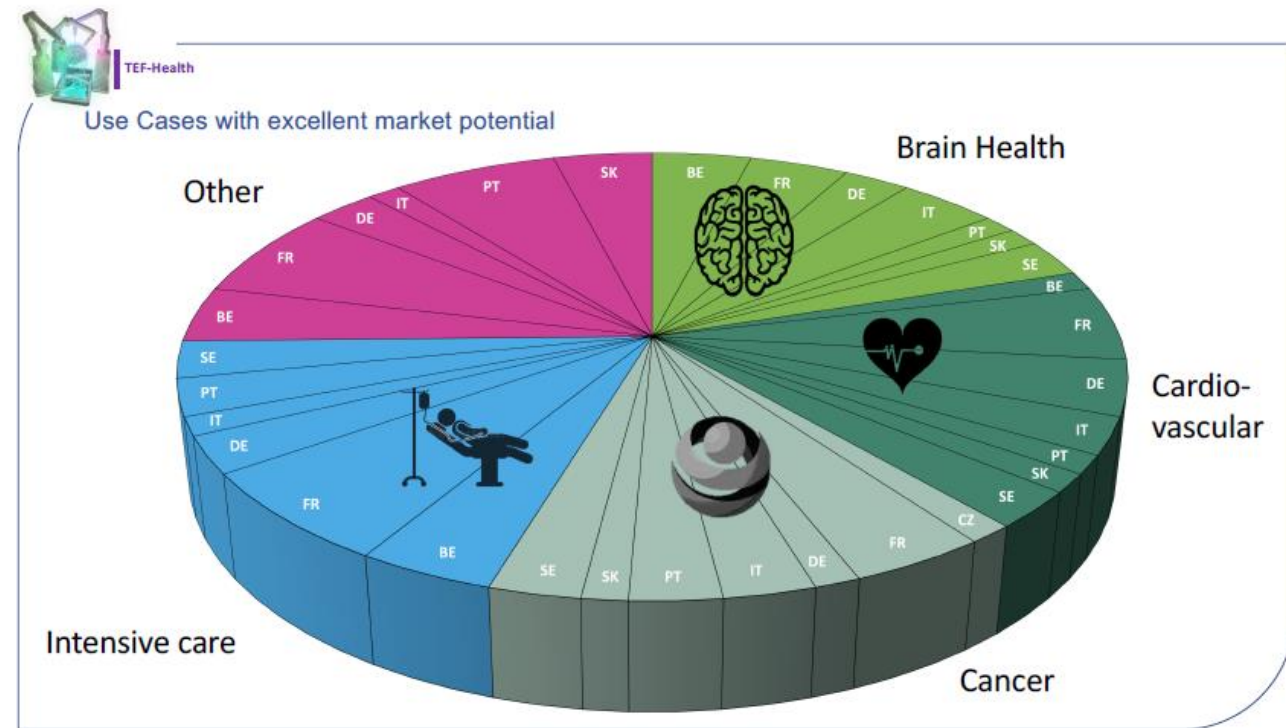
- (1) Carrying out **tests and experiments** of AI solutions in real or **realistic environments**;
- (2) Implementing **evaluation activities** to facilitate market access for trustworthy intelligent technologies considering regulatory requirements (certification, standardization, code of conduct), and ensuring easy access to these resources (link with digital innovation hubs); and
- (3) Optimizing investments by capitalizing on past investments.

TEF-Health will generate Impact by increasing effectiveness, resilience, sustainability of health systems, reduce inequalities; and ensure compliance with legal, ethical, quality and interoperability standards.

TEF Health

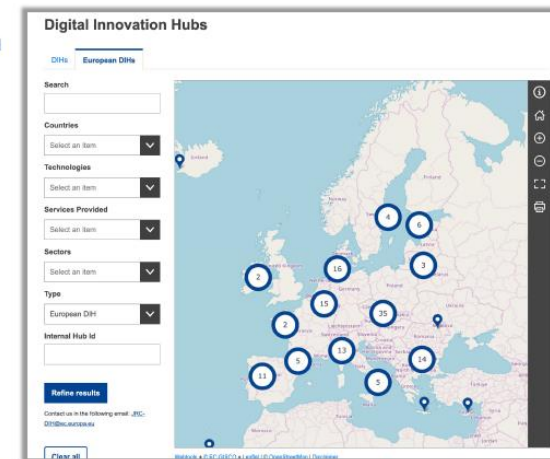
Outcome and KPIs

- Foster state of the art AI and robotics in healthcare
- KPIs:
 - Number of TEF **users** served (target: N500, 80% SMEs)
 - Percentage of cross boarder participation (target: 70%)
 - Number of **solutions** tested (target: N500)
 - At least started **CE marking procedure** or certification (target 50%=N250)
 - Brought to market (target 2% = N5)
 - Adopted by health providers (target 2% = N5)
 - Added value for end users



Partner with European Digital Innovation Hubs (EDIH)

EIDH



<https://s3platform.jrc.ec.europa.eu/>

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 National Center for Innovative Technologies in Public Health



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