

Ideas for

Joint Action for the European Health DAta Space

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Potential name with acronym

**Towards the European Health DAta Space –
TEHDAS**

Mission statement

The Joint Action helps the Member States and the Commission in developing sharing of health data for public health, treatment, research and innovation in Europe.

TEHDAS - Provisional Structure

TEHDAS consists of eight Work Packages (WPs): four mandatory and four thematic WP's.

Mandatory

- WP 1 Coordination of the project
- WP 2 Dissemination of the project
- WP 3 Evaluation of the project
- WP 4 Sustainability

Thematic

- WP 5 Sharing data for health
- WP 6 European Excellence
- WP 7 Connecting the dots
- WP 8 iCitizen
- WP 9 ...?

Better health

**Better policy
making**

Better R&D&I

WP.1 Coordination

WP.2 Dissemination

WP.3 Evaluation

WP.4 Sustainability

WP.5 Sharing data for health

WP.6 European Excellence

WP.7 Connecting the dots

WP.8 iCitizen

Deliverables

WP 1 Coordination

- General management
- Coordination of the project
- Project management including financial and administrative monitoring and reporting
- EC/Chafea communication
- Main contact point for external stakeholders and public presence
- Steering meetings management
- General assembly organization

WP 2 Dissemination

- Communication plan
- Public dissemination including website etc.
- Social media
- Raises awareness of target stakeholders of the deliverables
- Active communication and stakeholder engagement throughout the lifetime of JA

WP 3 Evaluation

- Evaluation methodology
- Internal evaluation of the project deliverables

WP 4 Sustainability

- Sustainability plan
- How to sustain deliverables and make impact
- Interlink between other ongoing initiatives
- Requires good knowledge of ongoing initiatives and European policies

WP 4 Sustainability - Liaison

EU priorities and strategies

- A Europe fit for the digital age
- A European Strategy for Data
- EU presidencies (DE, PT, SL, FR, CZ, SE)

Existing EU Programmes and funded projects, e.g. 3rd Health Programme & Horizon2020 (2014-2020)

- Joint Actions
- Digital health Europe (digitalhealthurope.eu)
- European mHealth Hub (mhealth-hub.org/)
- Infact (<https://www.inf-act.eu/>)

Future EC Funding (MFF 2021-2027)

- 4th Health Programme (EU4HEALTH - CHECK)
- Digital Europe Programme ~9,2 Billion Euros 2021-2027
- New Horizon Europe Programme ~100 Billion Euros 2021-2027
- eHealth network

Other initiatives

- 1 Million genomes initiative
- International Consortium for Personalised Medicine,
- the European Reference Networks,
- the European Research Infrastructures,
- the Human Brain Project
- Joint Actions: eHAction, IPAAC (Cancer)

Deliverables consists of

- Study: Material collection and review
 - Analysis: Analysis of specific topic
 - Guidance: Overall guidance how to improve a specific topic
 - Options: Provide alternative options for a specific actor to move forward
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- M = Milestone
 - D = Deliverable

WP 5: SHARING DATA FOR HEALTH

Needed skills: Legal, organisational

Sharing health data for care of citizens as well as for public health, research, development an innovation is increasingly important. The work package will develop options for next steps in EU policy by building on existing initiatives and mobiliseng new ideas from the Member States.

WP 5: Ideas for deliverables

- D 5.1. Options for governance models including functions and responsibilities for cross-border collaboration in the secondary use of health data taking into account use cases:
 - M 5.1.1 A network of national authorities responsible for the secondary use of health data
 - M 5.1.2 Scientific research
 - M 5.1.3 Statistics
 - M 5.1.4 Development and innovation activities
 - M 5.1.5 Steering and planning activities of national authorities
 - M 5.1.6 Data quality governance
 - M 5.1.7 Teaching
 - M 5.1.8 Public health surveillance
 - M 5.1.9 Open data
- D 5.2. Options to harmonise GDPR implementation
 - M 5.2.1 Study of national GDPR implementation in secondary use of health data
 - M 5.2.2 Analysis of the differences in national GDPR implementation concerning the secondary use of health data

WP 6: EUROPEAN EXCELLENCE

Needed skills: Quality, semantics, interoperability, economics

What can we do and how to incentivize quality?

WP 6: Ideas for deliverables

- D 6.1. Data quality framework
 - M 6.1.1 Study of currently used data exchange formats and common data models (Patient Summary, OMOP, i2b2)
 - M 6.1.2 Study of current means to harmonise EHR data from multiple sources commercial and non-commercial (TrinetX, BC Platforms, Darwin etc.)
 - M 6.1.3 Analysis of data exchange formats and best practises used in the markets to harmonise data
 - M 6.1.4 Analysis of the fairification of health data, how to make data FAIR, Findable, Accessible, interoperable and reusable. (Metadata catalogues, federated availability queries etc.)
 - M 6.1.5 Study of health data categories (identifiable, pseudonymised, anonymised, syhthetic, fabricated)
- D 6.2 Analysis of economic models of data exchange

WP 7: CONNECTING THE DOTS

Needed skills: Technical, architecture, investments

The Commission said health systems need €70 billion of extra investments. The new EU4Health is €9,4 billion.

WP 7: Ideas for deliverables

- D 7.1. Technical framework
 - M 7.1.1 Study of the potential of current infrastructures to support European wide collaboration on the secondary use of health data (eHDSI, ERN CPMS, EMA Darwin, EMBL Covid19dataportal.org, EWRS etc.)
 - M 7.1.3 Analysis of centralised, decentralised, federated architectures models usage in health
 - M 7.1.4 Guidance How to benefit from cross-sectoral infrastructures in health (Gaia-X etc.)
 - M 7.1.5 Guidance How to take into account EU cross-border exchange and EU secondary use of health data when investing into healthcare IT
 - M 7.1.6 Options how to build European Health Data Space to facilitate AI/Big data innovations
- D 7.2 Investment framework
 - M 7.2.1 Options for the European Commission to fund in
 - Horizon Europe
 - Digital Europe and
 - The next health programme

WP 8: iCITIZEN

Needed skills: Home diagnostics, citizen science, personal medical devices, consent

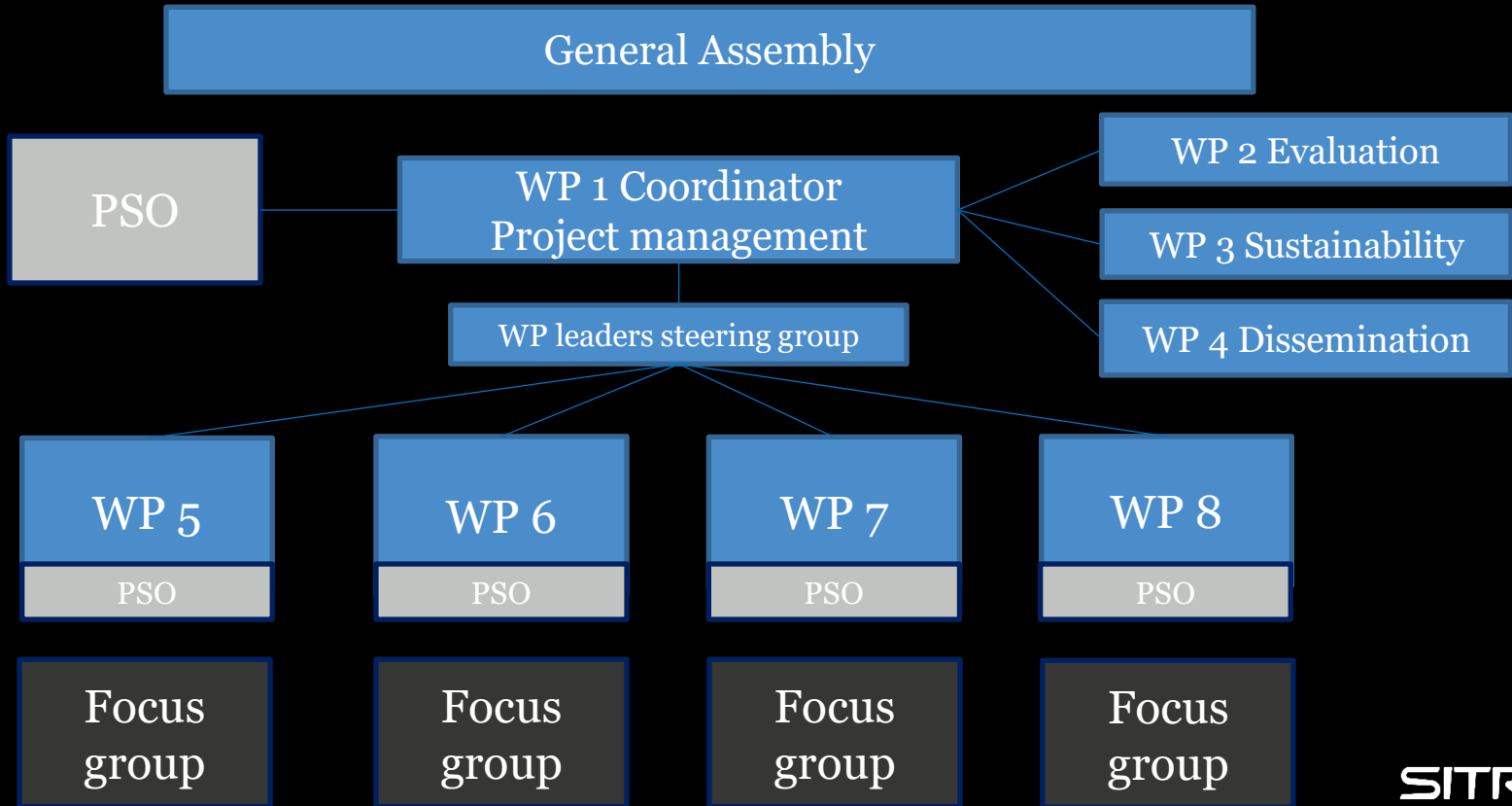
What happens when data is not in the hands of the authorities, healthcare or professionals?

WP 8: Ideas for deliverables

- D 8.1 Options for the European Commission to move forward to create a European Health Data Space where citizens are active participants
 - M 8.1.1 Study of current market where health data is out of reach for authorities
 - M 8.1.2 Analysis of current means to access the data or grant access to the data
 - M 8.1.3 Guidance on how to use citizen controlled health data to prevent/track future epidemics

TEHDAS PROJECT MANAGEMENT

Extended Structure



Project Support Office, PSO

- PSO
 - Organises meetings, agenda, meeting minutes
 - Keeps track of deliverables, timelines, consultation comments
 - Maintain collaborative space for WP members and Focus group members
 - Does not make decisions on the substance
- Budget
 - From Coordinator budget

External stakeholders

- ✓ External stakeholders must be included in the substance work
 - ✓ Not the same as commenting draft documents
- ✓ Use of focus groups?
 - ✓ Focus groups are permanent, same experts to follow work throughout the lifecycle
- ✓ Members from industry, NGOs, Patient representatives etc.
- ✓ Common workshops

Interest in participating in different work packages?

- Expressions of interest to participate in different work packages sent to the Coordinator by 15 June
 - Name and contact information
- Ideas on proposed or other work packages sent to the Coordinator by 15 June
- First meeting to look at the proposals in June – week 25
 - Decision on the provisional structure
 - Work plan to develop the proposal
 - Time table of work and meetings to hit the deadline of October
 - Proposal for the tools to be used
- At least one face-to-face meeting needed



Joint Action Timeline (26th May 2020)

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|---|--|
| Invitation to Member States to nominate Competent Authorities: | Send out on 05 March 2020 - Nomination Platform |
| Deadline for nomination of competent authorities | 28 May 2020 (Extended deadline due to COVID-19 crisis) |
| Webstreamed Infoworkshop for nominated Competent Authorities | 03 June 2020 (nominated competent authorities will be invited and notified about the agenda and access details) |
| Invitations to nominated Competent authorities to submit proposals | June 2020 |
| Deadline for applications: | October 2020 |
| Evaluation: | November 2020 |
| Information on evaluation results: | December 2020 |
| Grant agreement signature: | February 2021 |
| Starting date: | March 2021 |
| Duration: | 2 years |
| Budget: | € 2.500.000.000 (€ 1.500.000 EC, € 1.000.000 MS) |

Let's do this



SITRA