

1<sup>st</sup> Planning meeting

# **Joint Action for the European Health DAta Space**

18 June 2020

Markus Kalliola, The Finnish Innovation Fund



# Agenda

## 1. 13:00 Welcome

2. 13:05 Introduction of participants
3. 13:50 Objectives of the Joint Action
4. 14:10 Application creation practicalities

14:30 BREAK

6. 14:40 Work Package planning
7. 15:40 Working title for the JA
8. 15:50 AOB
9. 15:55 Next Meeting
10. 16:00 Closing

# Objectives for this meeting

- discuss the objectives of the Joint Action and the possible Work Packages
- set up a provisional planning team for each Work Package;
- map key questions to tackle during the planning process;
- find a date for a virtual meeting before the summer break to take the planning forward as a joint effort of 26 Competent Authorities;
- draft a timetable of work over the summer break;
- agree on a working title for the Joint Action and provisional working methods (communication channels and file repositories).

In short: the objective is to get started on the planning!

# What this meeting is not about

- Decide on budget or WP leaders
- Decide on WP deliverables
- Discuss JA project management

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## BREAK

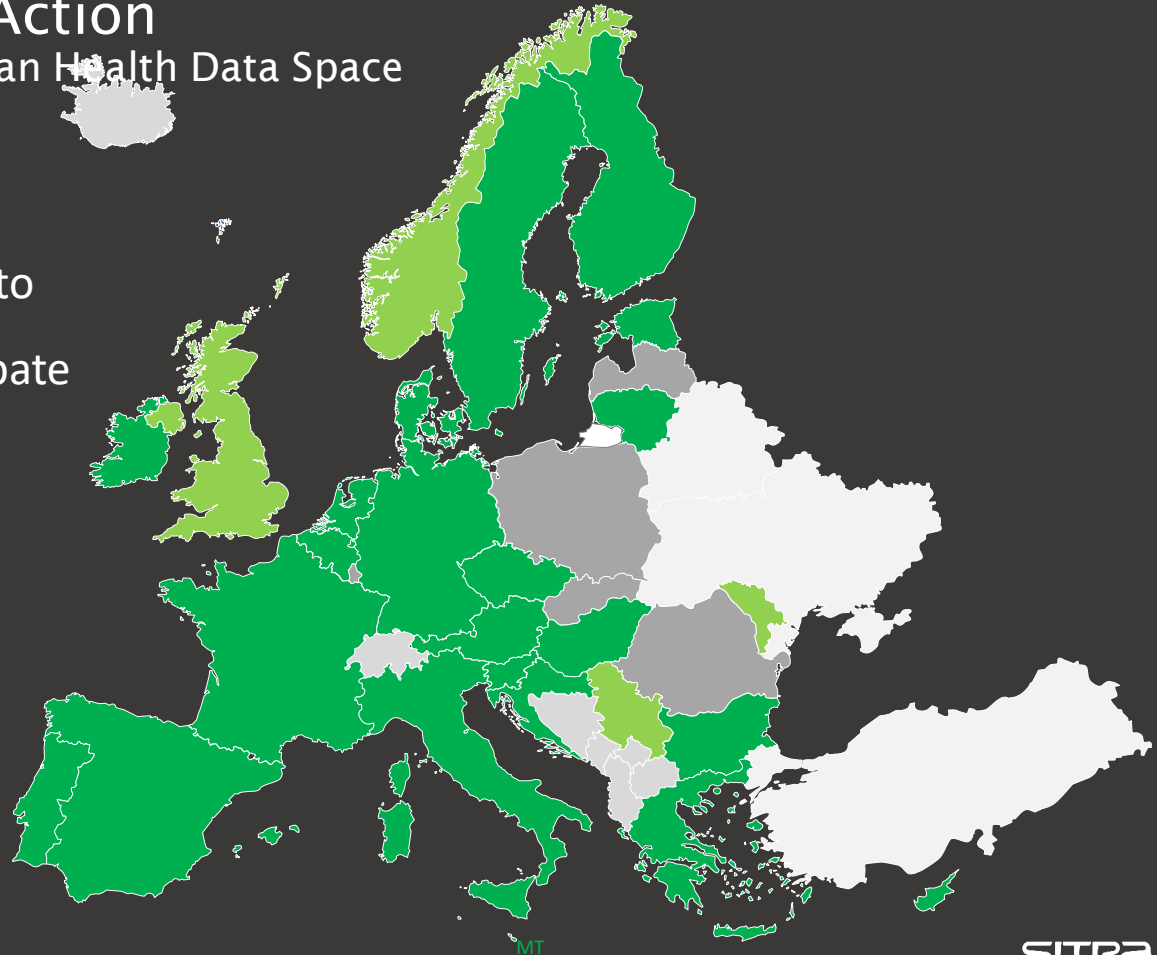
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# TEHDAS Joint Action

## Towards the European Health Data Space

-  Member States interested to participate
-  Other Interested to participate
-  Not participating
-  Not participating



Austria	BUNDESMINISTERIUM FÜR SOZIALES, GESUNDHEIT, PFLEGE UND KONSUMENTENSCHUTZ	ATNA
Belgium	Federal Public Service Health, Food Chain Safety and Environment	FPS Health
Bulgaria	Ministry of Health	MoH
Croatia	CROATIAN HEALTH INSURANCE FUND (HRVATSKI ZAVOD ZA ZDRAVSTVENO OSIGURANJE)	CHIF (HZZO)
Cyprus	MINISTRY OF HEALTH CYPRUS	MOH CY
Czechia	The Ministry of Health of the Czech Republic	MZCR
Denmark	Danish Ministry of Health	SUM
Estonia	Ministry of Social Affairs	MSAE
Finland	Finnish Innovation Fund Sitra	Sitra
France	French HEALTH DATA HUB	FR-HDH
Germany	Forschungsdatenzentrum, Bundesinstitut für Arzneimittel & Medizinprodukte / Bundesministerium für Gesundheit	BMG / BfArM
Greece	6th HEALTH REGION OF PELOPONNESE, IONIAN ISLANDS, EPIRUS AND WESTERN GREECE	6th Y.PE.
Hungary	National Healthcare Service Center	NHSC
Ireland	Department of Health	DoH
Italy	MINISTERO DELLA SALUTE	MINSAL
Lithuania	Ministry of Health of the Republic of Lithuania	SAM LT
Malta	Directorate Health Information and Research - Ministry for Health	DHIR
Moldova	Transplant Agency of the Republic of Moldova,	ATRM
Netherlands	Directorate Information Policy of the Ministry of Health, Welfare and Sports	VWS
Norway	Norwegian Ministry of Health	MoH
Portugal	Shared Services of the Ministry of Health, EPE (Serviços Partilhados do Ministério da Saúde)	SPMS
Serbia	Institute of Public Health of Republic of Serbia "Dr Milan Jovanovic Batut"	IPHS "Batut"
Slovenia	National Institute of Public Health	NIJZ
Spain	Instituto Aragonés de Ciencias de la Salud	IACS
Sweden	Swedish e-Health Agency (E-hälsomyndigheten)	(E-hälsomyndigheten)
United Kingdom	National Health Service X	NHSX

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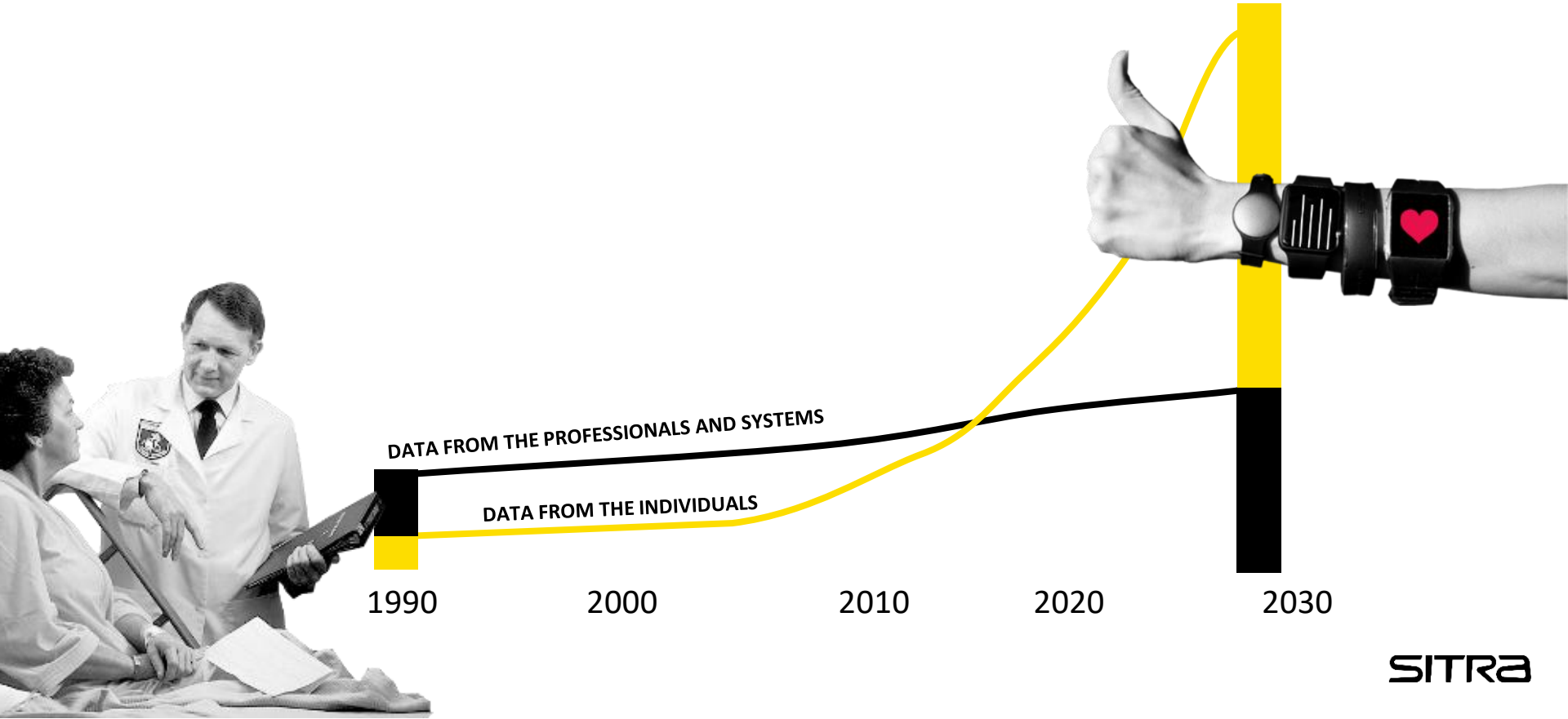


## Mission statement

**The Joint Action helps Members States and the Commission in developing **sharing of health data** for citizen's health, public health, treatment, research and innovation in Europe.**

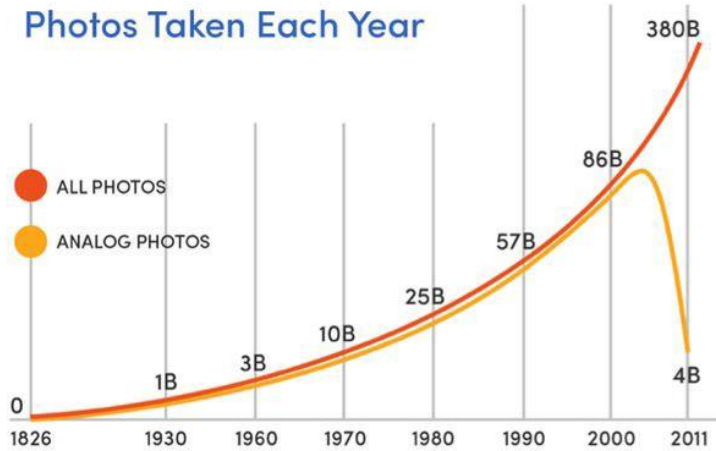
**In the future Europe, citizens, communities and companies benefit from a **protected and secure access to seamless health data** available regardless where it is stored.**

# Vision: It's Going to Get a Lot More Personal



# Vision: Home diagnostics

## Photos Taken Each Year



# Provisional names of Work Packages

Mandatory

- WP 1 Coordination of the project
- WP 2 Dissemination of the project
- WP 3 Evaluation of the project
- WP 4 Sustainability and links to other EU actions

Thematic

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

# Survey results 1/5

Sitra presented a provisional structure of the JA on Monday 8 June. It included 8 work packages. Please indicate which WP you are interested in contributing and participating. You can select as many as you want.

	n	Percent
WP 2: Dissemination	5	26,32%
WP 3: Evaluation	4	21,05%
WP 4: Sustainability	9	47,37%
WP 5: Sharing data for health	19	100%
WP 6: European Excellence	13	68,42%
WP 7: Connecting the dots	9	47,37%
WP 8: iCitizen	8	42,11%

# From the survey: General

**Do you think that these Work Packages provide a good basis for our discussions or would you like to suggest some other topics. If so, please describe your ideas.**

“We would like to see a greater focus on cybersecurity across all WP:s.”

“European Open Science Cloud should be mentioned”

“Liaison-wise a discussion with other EU sectoral data spaces”

**Would you like to give any other feedback on the WPs or the JA in general?**

“Would it be possible to have lead and co-lead for the WP:s?”

“Are all WPs necessary? We could merge WPs and focus on main deliverables.”

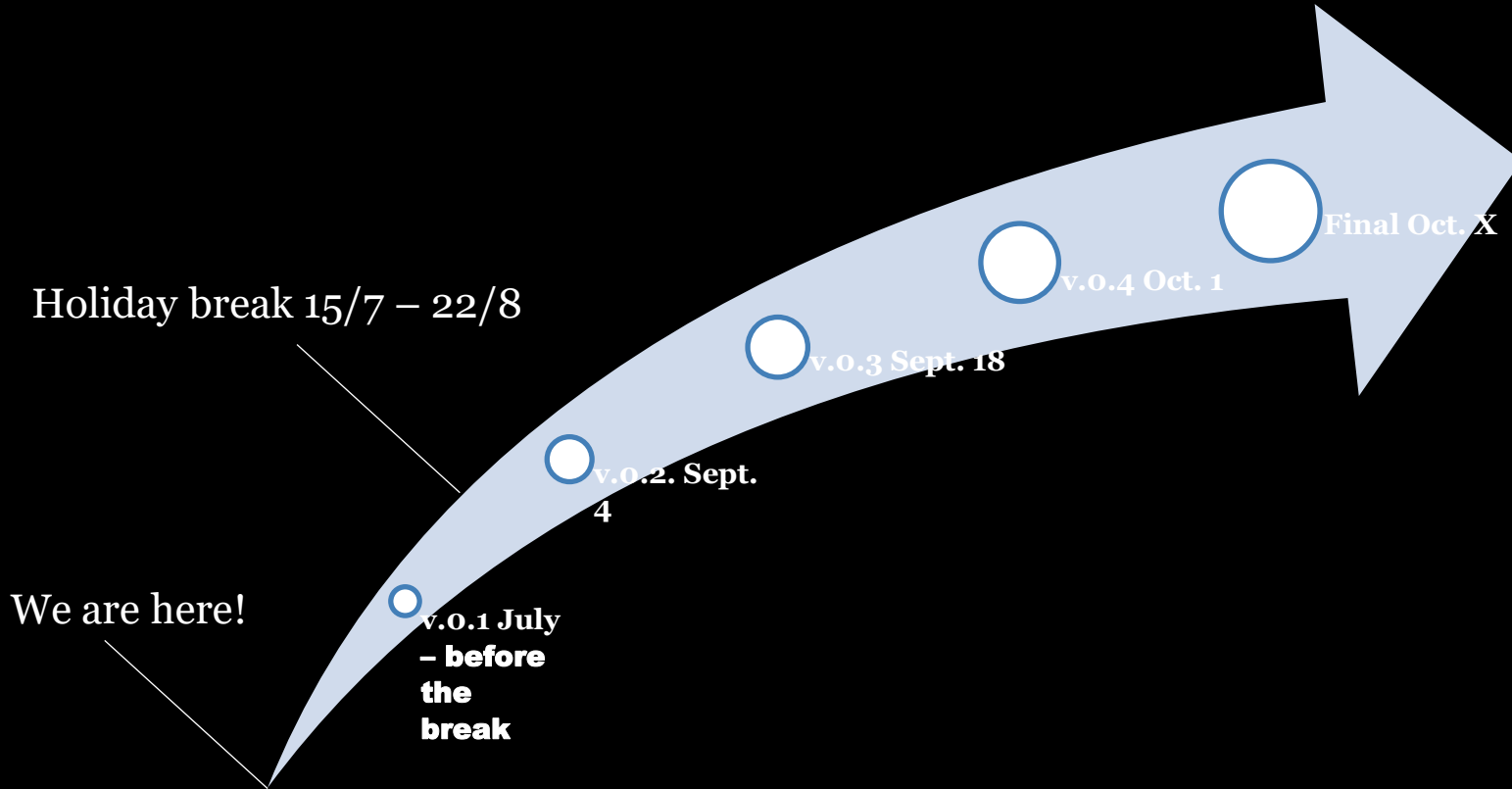
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# Countdown from today to October





# Common planning meetings – all CAs

- Today is the first such meeting
- Tasks:
  - Provide a forum for all CAs to discuss and contribute to all WPs and follow their progress in general
  - At the end of the process, to take decisions on the final documents
  - Select WP leaders
  - Administrative matters, including the budget discussions
  - What else we need to discuss commonly?
- How often would you like to meet?
  - Next meeting?
  - Can we share your contact details within this JA?

# Common work space

- Technology: Teams
- General stream and stream for each WP
- Discussion and documents

We want a live demo



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# WP Planning – What needs to be done?

- We need to start drafting WP descriptions immediately in order to hit the deadline
- The first version is needed before the summer break, so that we can continue at full speed after the break
- Thus the Coordinator suggests that we have the first version of description of action (DoA) for each WP before the break in July
- -> Coordinator puts v.o.1 of the whole project plan together as soon as possible for circulation to all CAs

# WP Planning – suggested way of working

- Interested CAs form a planning team for each WP today
- Common working practises
  - All drafts put into TEAMS
  - Discussion should take place in TEAMS, not by email
  - Invitations to calls (virtual meetings) by EMAIL
- Each planning team to hold a planning call every two weeks
  - Starting next week
  - Coordinator sends invitation to the first meeting
- What other practicalities and common working methods you would like to discuss now?

# First WP planning meeting

- Based on the provisional WP structure, CAs can indicate which WP planning they would like to participate. You can do that now or by 26 June EOB by email to Sitra. We also take into account the survey results.
- Sitra will send on 29 June the list of CAs for each WP to all CAs
- Sitra will send invitations to first planning meeting for each WP on 29 June
- In the first planning meeting CAs will choose among them who starts leading the planning work
- The next WP planning meetings will be convened by the chosen leader
  
- -> Quick recap on WP descriptions (Time permitting)

# First WP planning meeting (Sitra invites)

- The first planning meetings will take
  - WP5 Tuesday 30 June 10:00 - 12:00 CEST
  - WP6 Tuesday 30 June 13:00 - 15:00 CEST
  - WP7 Wednesday 1 July 10:00 – 12:00 CEST
  - WP8 Wednesday 1 July 13:00 – 15:00 CEST
  - WP4 Thursday 2 July 10:00 – 12:00 CEST
  - WP3 Thursday 2 July 13:00 – 15:00 CEST
  - WP2 Friday 3 July 10:00 – 12:00 CEST
  - WP1 no meeting



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# Working title?

- Towards the European Health DAta Space Joint Action – TEHDAS JA
- European Health Data Space Joint Action – EHDS JA
- Joint Action addressing differences in national General Data Protection Regulation (GDPR) implementation in the health sector, including the European Health Data Space and the health data use
- Other?

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**Thank you!**



**SITRA**

# **WORK PACKAGE SLIDES**

# **WP 5: SHARING DATA FOR HEALTH**

Needed skills: Legal, organisational

Sharing health data for the 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.



# From the survey: WP5

“Deliverable in WP5 (or its own WP) regarding code of conduct for GDPR implementation, both primary and secondary use.”

“The Description of work should outline in more detail the use cases that are envisaged. What kind of data sharing and for whom? What has to move in order to achieve what?”

“D5.1 / D5.1.5: should include a handbook for policy makers in the Member States how to achieve a national interoperable digital health infrastructure that is capable of sharing data with other organisations within the country and also outside the country for purpose of primary and secondary use of health data”

“A clarification regarding primary and secondary use. Different member states might have different views on the meaning of primary and secondary use of data.”

## **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:
- D 5.2. Options to harmonise GDPR implementation

# WP 5: Ideas for deliverables / milestones

- 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 5: Ideas for deliverables / milestones

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  - 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 and interoperability?

# From the survey: WP6, WP7 and WP8

“D6.1 Please include study of functional requirements and functional specifications, technical specifications, standards and profiles that are currently commonly used by the Member States”

“D6.2 The analysis should include recommendations for policy makers of the Member States as well giving them guidance on which business models to use”

“D 7.1 and in particular M 7.1.1: Please include here to also look at the current digital health infrastructures used on the level of Healthcare Providers and in hospitals”

“M 7.2.1 Should it really be the intention to provide options by the Joint Action FOR the European Commission? Or is it the intention to provide options for the Member States as kind of a guidance from which programmes to obtain funding for building for instance necessary interoperable health infrastructure?”

“WP8: relates to the discussions around data donation, where there are important ethical and socio-economical questions involved; the ethics part is missing a bit in general in the proposal”

# 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 health systems need billions of new investments, in the Member States and at EU level. The proposed EU4Health, together with other EU level instruments, would bring the new impetus to building infrastructures in the EU.



# 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 healthcare or professionals?

## Deliverables for Work Package 8 : iCitizen

Suggested by Sitra

**Deliverables**

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

**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?*

**HDH's suggestions for additional deliverables**

- A set of recommendations tackling citizen involvement in the reuse of data and creating value.
- Recommendations for citizen engagement mechanisms / involvement in governance
- ....

# 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 and track future epidemics

# WP 4 Sustainability and links to other EU actions

- 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 Linking to other actions

## EU priorities and strategies

- A Europe fit for the digital age
- A European Strategy for Data
- eHealth Network
- 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 (1+MG)
- International Consortium for Personalised Medicine
- European Reference Networks (ERNs)
- European Research Infrastructures
- Human Brain Project
- Joint Actions, e.g. IPAAC (Cancer)
- DARWIN

# WP 3 Evaluation

- Evaluation methodology
- Internal evaluation of the project deliverables

# WP 2 Dissemination

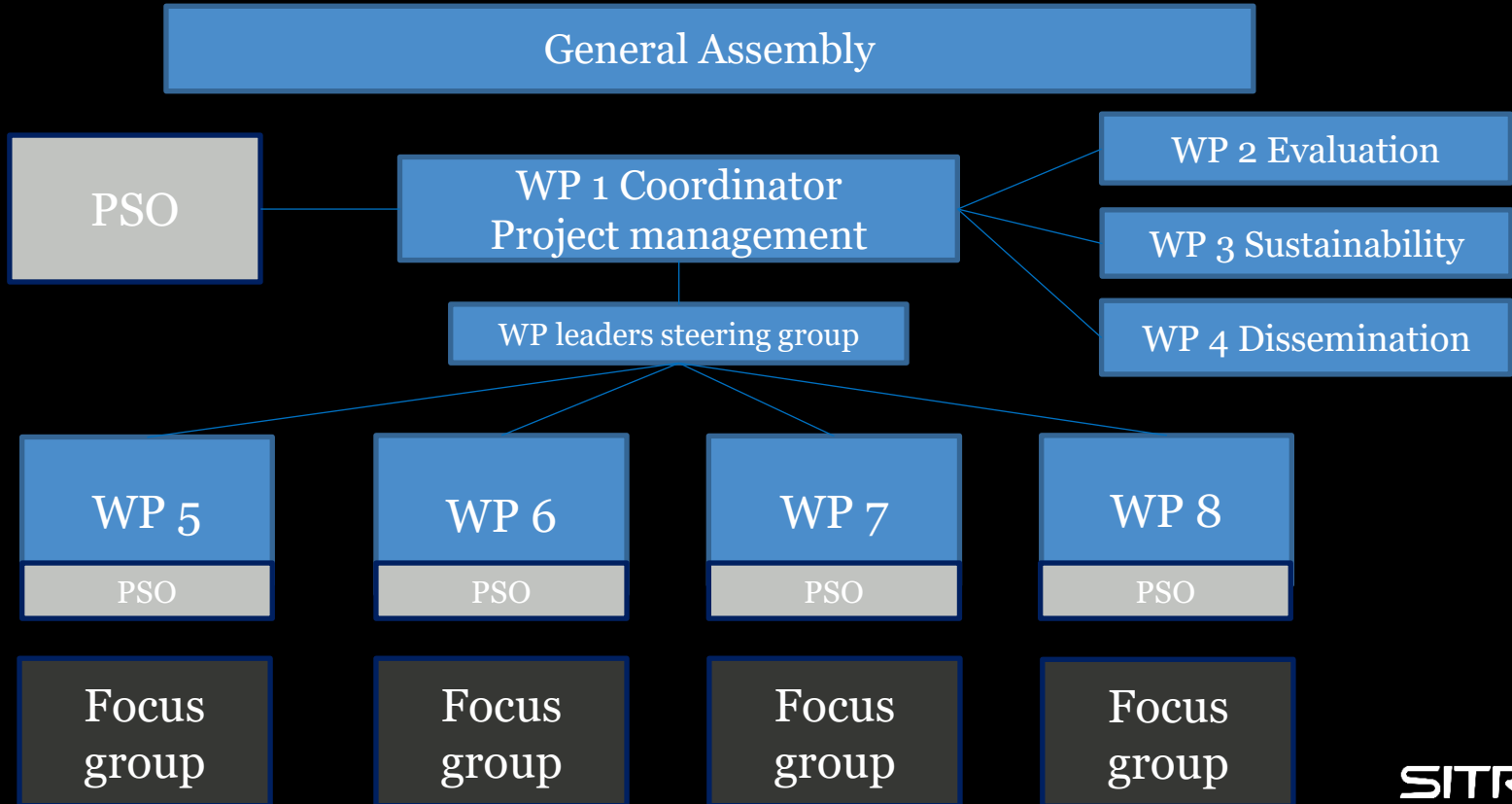
- Communication plan
- Public dissemination including website etc.
- Social media
- Raises awareness of target stakeholders of the deliverables
- Active communication and stakeholder engagement throughout the lifetime of JA



# WP 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

# 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