



EU4Health & 2022 Work Programme Stakeholders' Targeted Consultation - Outcome

CRISIS PREPAREDNESS – Break out session

Housekeeping Rules



- **'Unmute' yourself only when invited to speak**
- **Switch off your video**
- Email SANTE-VISIO@ec.europa.eu for any technical issues



- **Indicate in full your organisation when joining Webex** (please reconnect in Webex and enter your details – organization, name)
- **Use the chat box** for any questions, remarks, or if you would like to speak **mentioning your organisation** clearly
- The **chat will be copied and workshop recorded** (if you do not wish to be recorded you can choose to listen and not intervene orally).

Breakout session – Crisis Preparedness

Moderator: Virginia Arnecci, Unit C3 Health Security

Rapporteur: Ana Burgos, EU4Health Task Force



PURPOSE OF THE SESSION: GATHER INPUT FROM STAKEHOLDERS ON:

- Orientations, priorities and needs for the 2022 work programme
- Possible solutions that could fall under the objectives of eu4health – with an EU added value.

STRUCTURE OF THE SESSION:

- Overview of the targeted consultation related to crisis
- Presentation of the most elaborated proposals / Q&A
- Coffee break
- Open discussion and additional proposals

EU4Health – Stakeholders’ Targeted Consultation

Overview Inputs from stakeholders

CRISIS PREPAREDNESS was considered an area with many needs to be addressed

- Protection of citizens from **cross-border health threats**, was considered the **4th most important** objective of EU4Health
- **Enhancing availability, accessibility & affordability** of medicinal products, medical devices and crisis-relevant products **was considered the 5th**.
- However, the **stockpiling** of essential crisis relevant products complementing national reserves, was considered **the least important objective** of EU4Health.



EU4Health – Stakeholders’ Targeted Consultation

Overview Inputs from stakeholders

CRISIS PREPAREDNESS contributions received touched upon:

- Antimicrobial resistance
- Building resilience into pharma and medical devices supply chain
- Monitoring the shortages and increase availability of medicines, medical devices and crisis relevant products
- COVID 19 vaccination strategy and immunisation programme
- Use of non-pharmaceutical intervention
- Global crisis response capacity and effectiveness
- Improve surveillance systems during health emergencies
- Increase awareness of the population and scientific communication during the crisis
- Strengthening EU preparedness for cross border health threats



EU4Health – Stakeholders' Targeted Consultation

Overview Inputs from stakeholders



THE MAIN NEEDS SHARED were:

- strengthening of the EU preparedness besides its regulatory angle;
- securing access to critical medical countermeasures as response to emergency situations for all EU citizens –including stockpiles;
- increasing resilience into the supply chain, including manufacturing capacity and to monitor the shortages of medicines;
- exchange of personal data to improve surveillance systems;
- improving scientific communication;
- supporting Europe-wide initiatives to prevent future (re)emerging pathogens zoonotic origin.

EU4Health – Stakeholders' Targeted Consultation

Most elaborated proposals

DIOGO NOGUEIRA AND NATASHA ALVES	INFARMED
SIBILIA QUILICI	Vaccines Europe
MARTIN FITZGERALD	GIRP - European Healthcare Distribution Association
PIKKA JOKELAINEN	One Health EJP
ISABELLE DE ZEGHER	MyData4Pandemics (thematic group from MyData Global)
ASK EIRIK STORSVE	Emergent BioSolutions



Webinar EU4Health Work Programme 2022

INFARMED's contribution

September 10, 2021

Diogo Nogueira Leite | Natasha Alves

Main challenges faced - crisis preparedness

- Lack of clear, succinct communication and information to the public
 - During the pandemic
 - Regarding the vaccines
- Public adherence to the rules set under the pandemic, such as face masks, social distancing, lockdowns, curfews, inability to travel
- Organisational architecture
 - Adopting a one-size-fits-all policy
 - Overwhelming pressure on public health structures
 - Lack of cohesiveness with different public health entities

Possible actions to be most effective in crisis preparedness

- Strengthen critical health infrastructure to cope with health crises:
 - Support the setup of tools for surveillance, forecast, prevention and management of outbreaks.
- Foster Union-wide health crisis prevention and preparedness:
 - Proactively upgrade Union and Member-State players' management skills and response capability;
- Promote upwards convergence of national systems' performance:
 - Development of health indicators analysis and knowledge brokerage;
 - Organise voluntary stress tests to national healthcare systems.

Proposed solutions to be more effective in crisis preparedness

- Bring together NCAs, government, and industry associations at EU and MS level;
- Use Union mechanisms and funding to leverage this network's capabilities, knowledge and insights to have a complete overview and identify opportunities beneficial for both companies and citizens;
- An EU monitoring system for early detection of possible health threats and infectious diseases;
- Integrated emergency response with coordination from the NCAs to create a disaster response agency. The preparedness needs to be closely coordinated with each country's health system, with collaboration with civil society groups such as military, community groups, that have clearly defined roles;
- A multilateral system that helps to improve national healthcare systems by increasing surge capacity and coordination through enhanced communication channels, data-driven approaches and mobile clinics.

Proposed solutions to be more effective in crisis preparedness

- Map manufacturing capabilities in pharma, PPE, digital health and biotech to increase crisis preparedness while strengthening both environmental sustainability and open strategic autonomy;
- Enhance information on needs, capabilities, available resources and loopholes, as well as flexibility within various supply chains;
- Use that info to inform public and private decision-making and extract synergies across countries and sectors while promoting digital and environmental transitions;
- Catalyse R&I within the EU, namely in biotech and synthetic biology;

EU4Health Programme Webinar

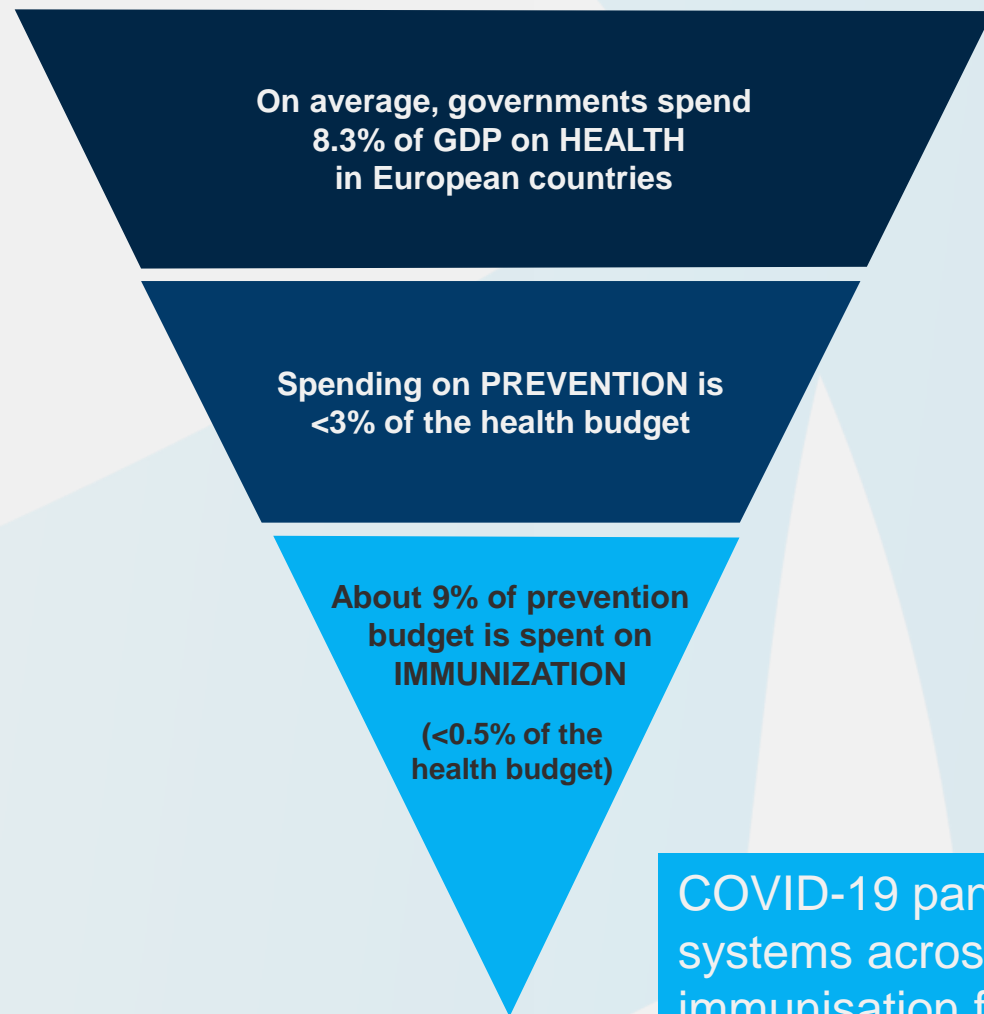
Sibilia Quilici, Executive Director,
Vaccines Europe

sibilia.quilici@vaccineseurope.eu

10 September 2021



Immunization programs have long been undervalued and underfunded



Short and long-term consequences:

- Difficulties in maintenance of routine vaccination services and population access during and outside pandemic
- Delay in access to novel vaccines
- Gaps and delays in the roll-out of COVID-19 vaccination
- Challenges in sustaining a high level of R&D and industrial capacities in the EU

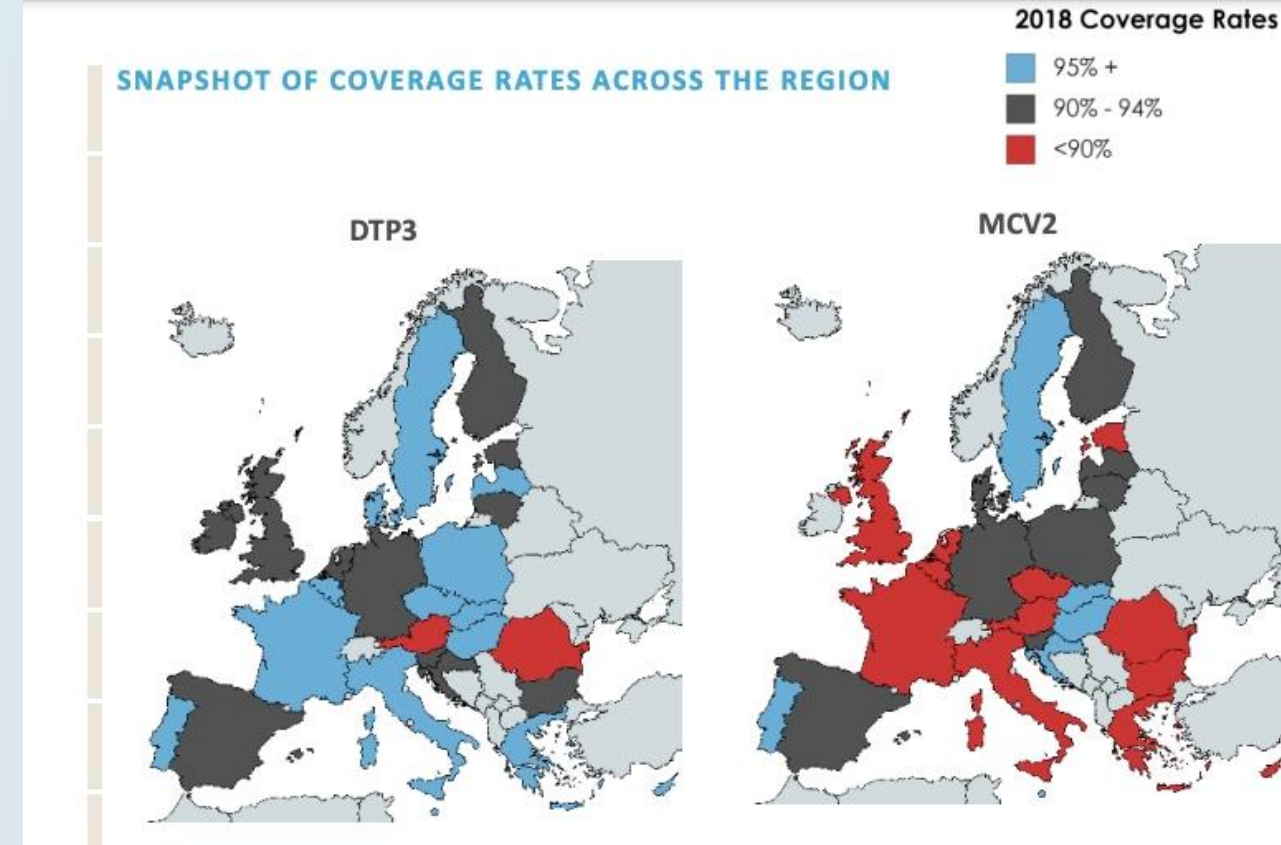
COVID-19 pandemic demonstrated the lack of resilience of immunisation systems across Europe and the urgent need for sustainable immunisation financing to improve the update of all routine vaccinations.



Vaccines recommendations varies across Europe and do not necessarily translate into funding neither uptake

VACCINES AVAILABLE THROUGH THE PUBLIC IMMUNIZATION PROGRAM						
Vaccine/Age	Greece	Netherlands	Poland	Romania	Spain	UK
DTP	X	X	X	X	X	X
Hib	X	X	X	X	X	X
HepA	X					
HepB	X	X	X	X	X	X
Herpes Zoster	X					X
HPV	X	X			X	X
Flu Ped	X					X
Flu Adult	X	X			X	X
MMR	X	X	X	X	X	X
Meningococcal C	X	X			X	X
PCV	X	X	X	X	X	X
PPV	X				X	X
Polio	X	X	X	X	X	X
Rota	X					X
Tb	X		X	X		X
Varicella	X		X		X	X

Source: ECDC



The EU4Health Programme as a turning point for sustainable immunisation financing across Europe

1. Report on the financing of immunization programmes in 27 EU Member States
EVIDENCE-BASE & BENCHMARK



2. Stakeholder platform on immunization programme financing and performance
LEARNING & EXCHANGE



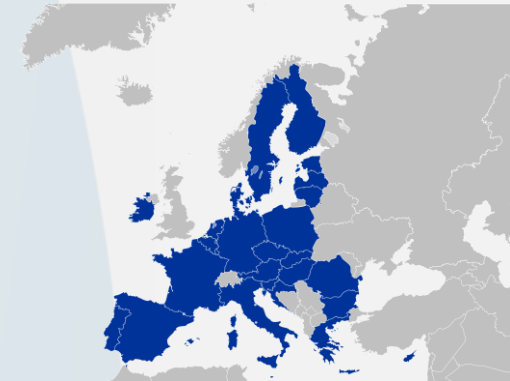
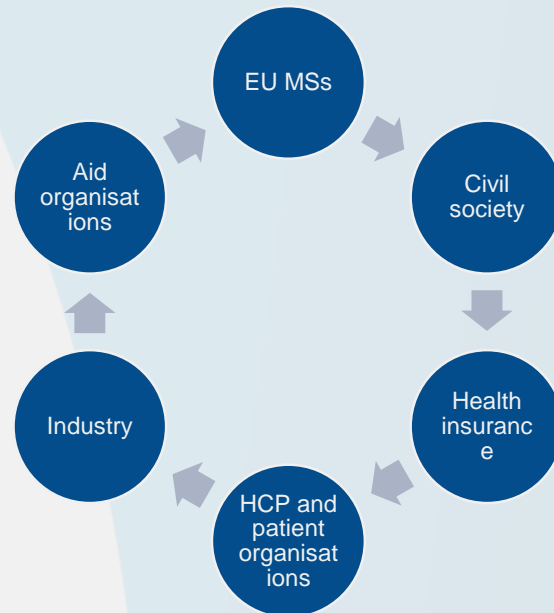
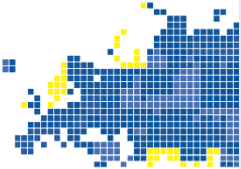
3. EU funding support in low-performing areas
FILLING THE GAP

STATE OF HEALTH IN THE EU 2019



The organization and delivery of vaccination services in the European Union

Prepared for the European Commission



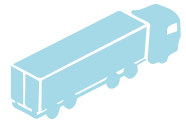
Objectives: To increase vaccination coverage rates, secure timely access to current and new vaccines by implementing effective solutions for driving sustainable immunization financing of current and novel vaccinations.



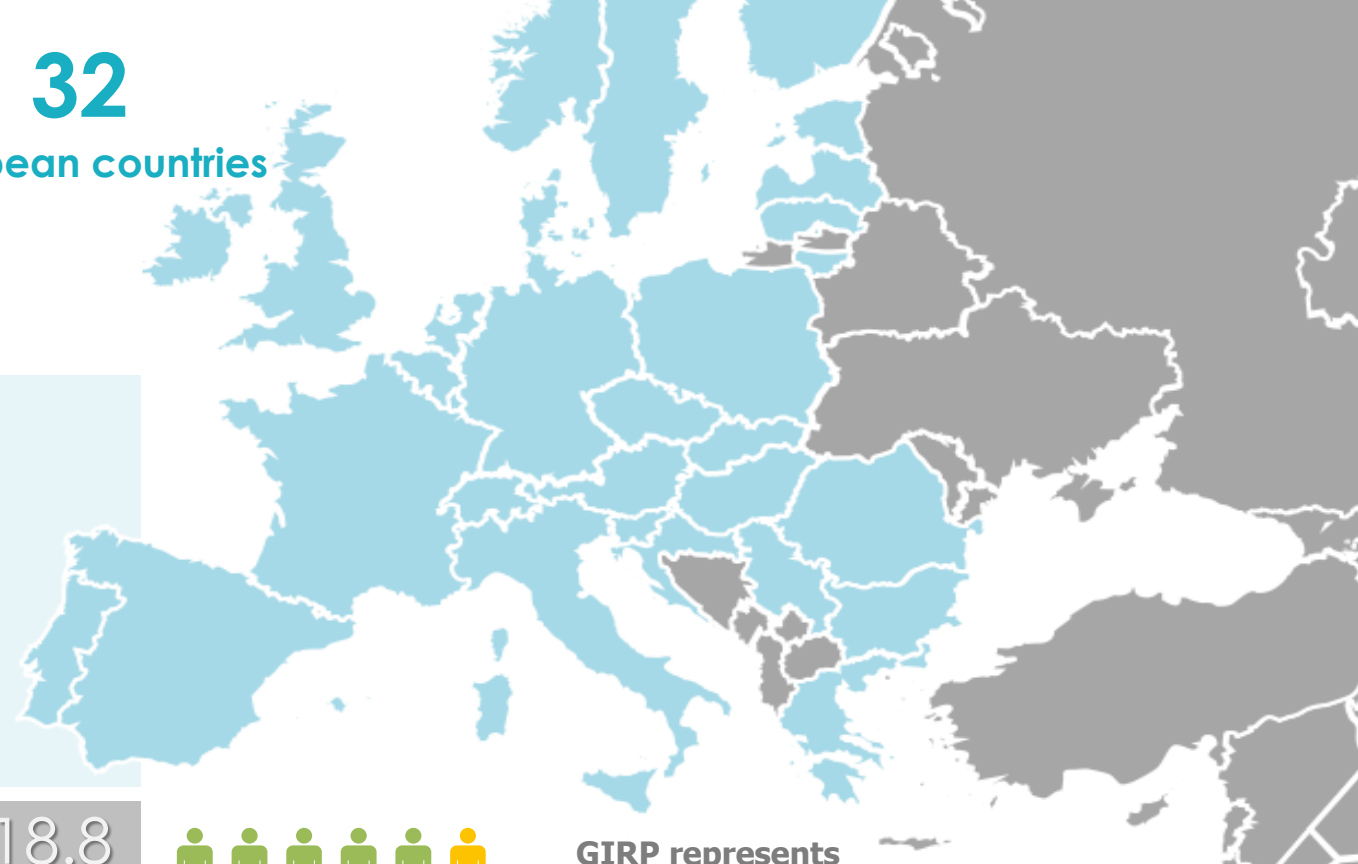
About GIRP

32

European countries



750+ pharmaceutical wholesalers
1,260 warehouses



Safe and sufficient supply of over **100,000 products**



15 bn packs of medicines/year
62 mio packs of medicines/day



From **3,500 manufacturers** to



200,000 pharmacies & healthcare professionals across Europe



2.5 h

Average delivery time



35

Products per delivery from stock of **100,000**



18.8

Different manufacturers per delivery



quality,
integrity,
excellence

GIRP members are trusted supply chain partners
the vital link in healthcare



EU Health Annual Work Programme 2022

ENSURING ACCESS TO HEALTHCARE FOR ALL EUROPEAN CITIZENS

1. Monitoring of medicines shortages at EU level

- Connect available national shortages monitoring systems which collect market signals from all supply chain stakeholders

2. Stockpiling of critical medicines

- Balance between European and national stocks
- Relying on existing infrastructure and expertise of full-service healthcare distributors
- Possibility to integrate emergency stockpile in buffer stocks held by full service healthcare distributors

3. Facilitating cross-border movement of medicinal products in crisis

- Pre-emptive framework for swift regulatory flexibility in licencing and labelling rules



One Health EJP input to EU4Health

Pikka Jokelainen
One Health EJP Project Management Team

September 10, 2021



One Health EJP



5 YEARS
2018-2022



HORIZON 2020
50% CO-FUNDED
€ 90 MILLION

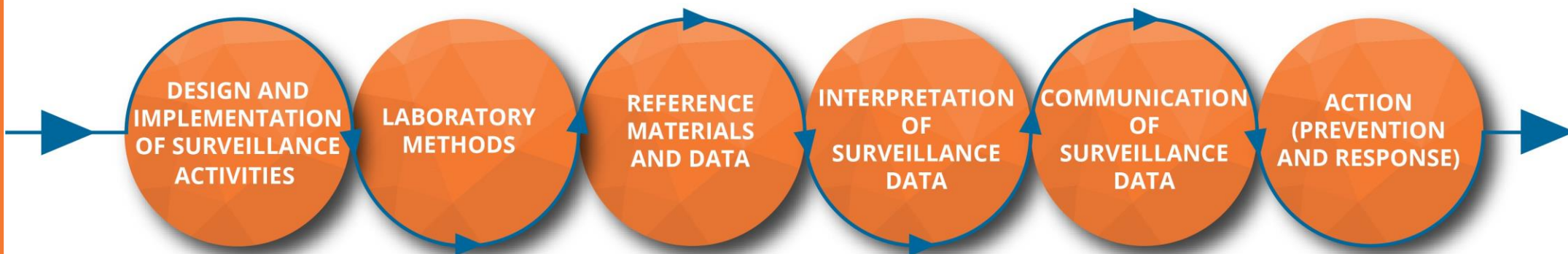


44 PARTNERS
ACROSS EUROPE





“a landmark partnership to strengthen collaboration and improve preparedness”

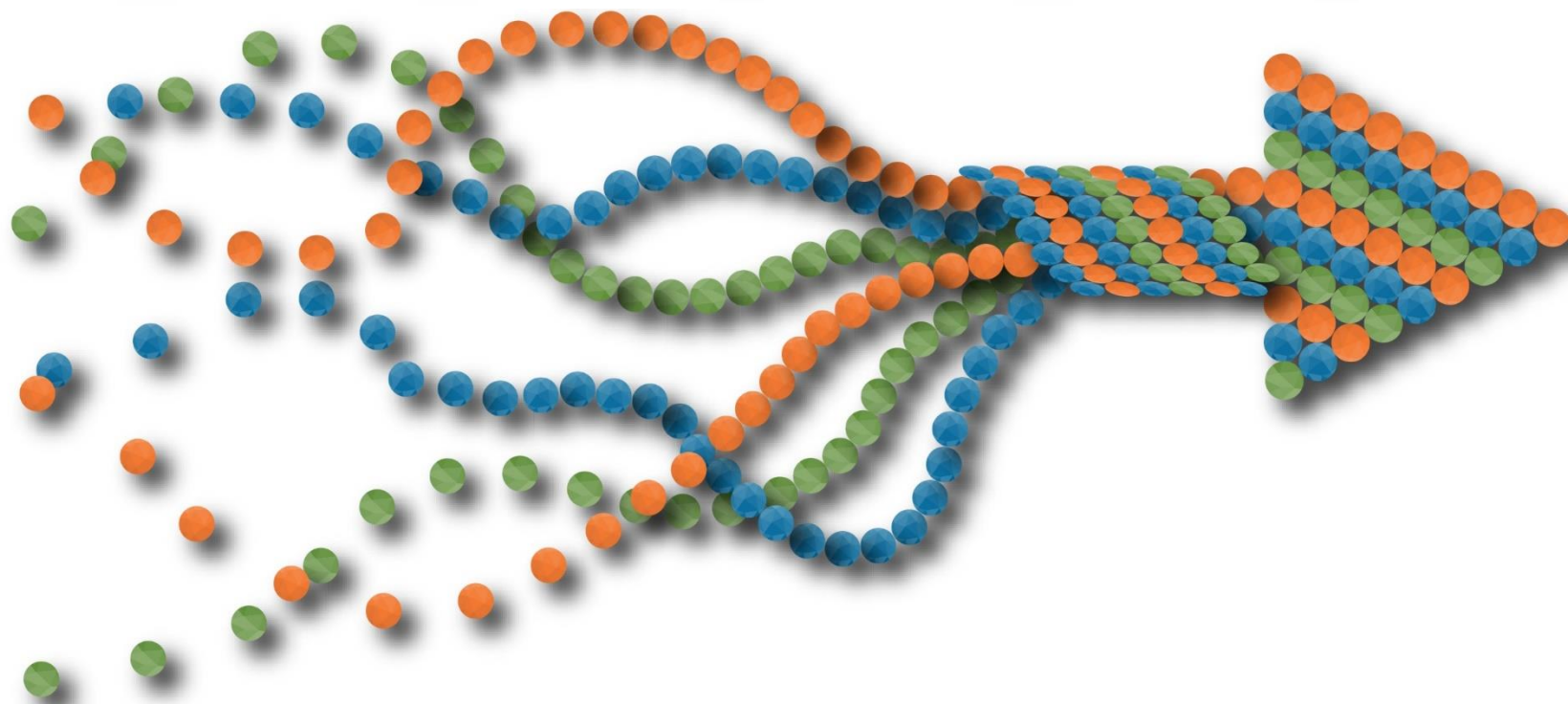


FOODBORNE
ZONOSIS

ANTIMICROBIAL
RESISTANCE

EMERGING THREATS

INTEGRATIVE
ACTIVITIES





One Health EJP input 1/3

1. Strong support to the European One Health Action Plan against **Antimicrobial Resistance**.



One Health EJP input 2/3

1. Strong support to the European One Health Action Plan against **Antimicrobial Resistance**.
2. Given also the **zoonotic** origin of most (re)emerging pathogens (e.g. SARS-CoV-2), strengthening human health systems requires collaboration with animal health and environmental surveillance systems.



One Health EJP input 3/3

1. Strong support to the European One Health Action Plan against **Antimicrobial Resistance**.
2. Given also the **zoonotic** origin of most (re)emerging pathogens (e.g. SARS-CoV-2), strengthening human health systems requires collaboration with animal health and environmental surveillance systems.
3. Collaborating with other initiatives for **a multi-disciplinary and cross-sector (One Health) approach** is essential to strengthen prevention, preparedness, risk assessment and response to cross-border health threats.



<https://onehealthjp.eu/>

Twitter icon | LinkedIn icon | My Events | Members | Groups

ne HEALTHEJP | European Union flag

About | Consortium | Projects | Training | Outcomes | ASM | News | Contacts | Search icon

One Health European Joint Programme

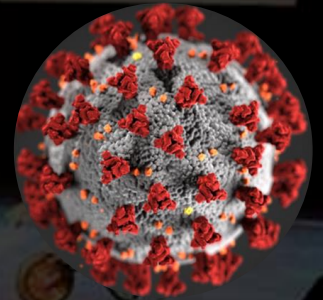
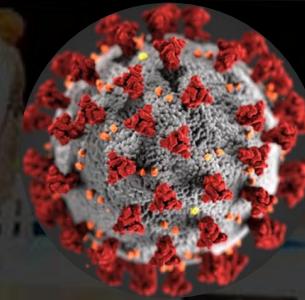
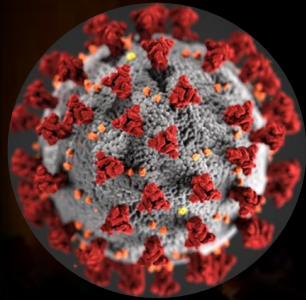
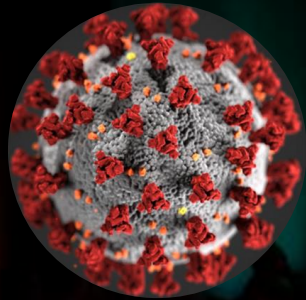
A landmark partnership between 44 partners, including acclaimed food, veterinary and medical laboratories and institutes across Europe and the Med-Vet-Net Association.

[LEARN MORE](#)

How to avoid a pandemic during the next outbreak, by empowering citizens

Isabelle de Zegher, MD, MSc (MyData Brussels, co-Lead MyData4Pandemics)

Frederik Linden (MyData Sweden, co-Lead MyData4Pandemics)



*Empowering citizens during the first months of an infectious disease outbreak
- before medications and vaccines are available -
will support development of targeted public health measures, and minimize the risk of pandemic,
while preserving human rights such as data privacy and freedom of movement.*

Table of Contents

A wheelbarrow filled with a bouquet of purple and red flowers, set against a dark background. The wheelbarrow is white with a green handle and a single large green wheel with a red hub. The flowers are a mix of purple and red, with green foliage. The background is dark, and the wheelbarrow is positioned in the lower right quadrant of the image.

- **Introduction: MyData & MyData4Pandemics**
- **Needs & Challenges**
- **Proposed Solution**

MyData



- ✓ **International** nonprofit, advocating for human rights & data privacy
- ✓ Founded in **2018**
- ✓ Headquartered in **Finland**
- ✓ **25** local hubs on **6** continents

- ✓ Over **600** members
... including over **90** organisations
... from over **50** countries
- ✓ International **thematic** groups – including **MyData4Pandemics**

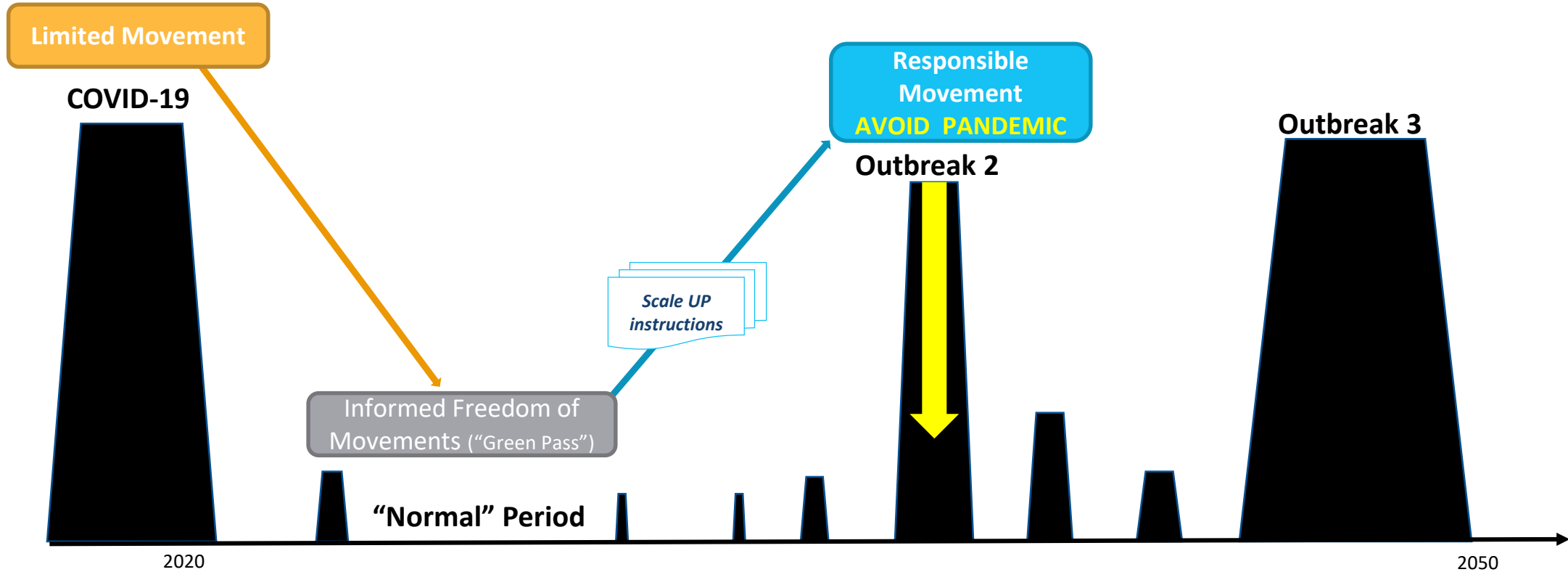
MyData4Pandemic's proposed solution was awarded an honourable mention in Sitra's "Fair Health Data Challenge" on June 9th, 2021. [Press release](#).



The judges remarked:

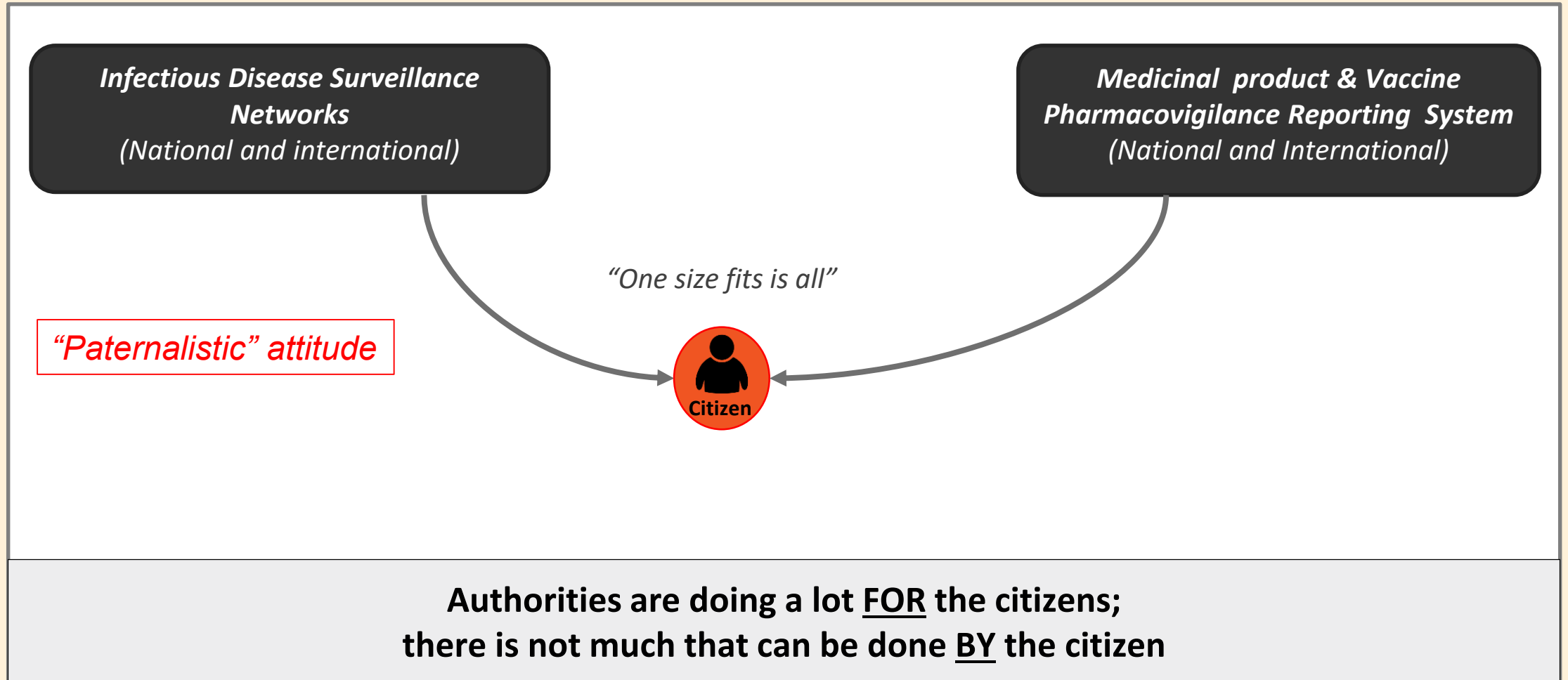
“In complex and difficult-to-manage crises, it is easy to forget the individual’s responsibility and perspective. This solution is exceptional in making them the starting point of all planning activities.”

As infectious disease outbreaks come and go we need to build Scalable Individual Centric Services...

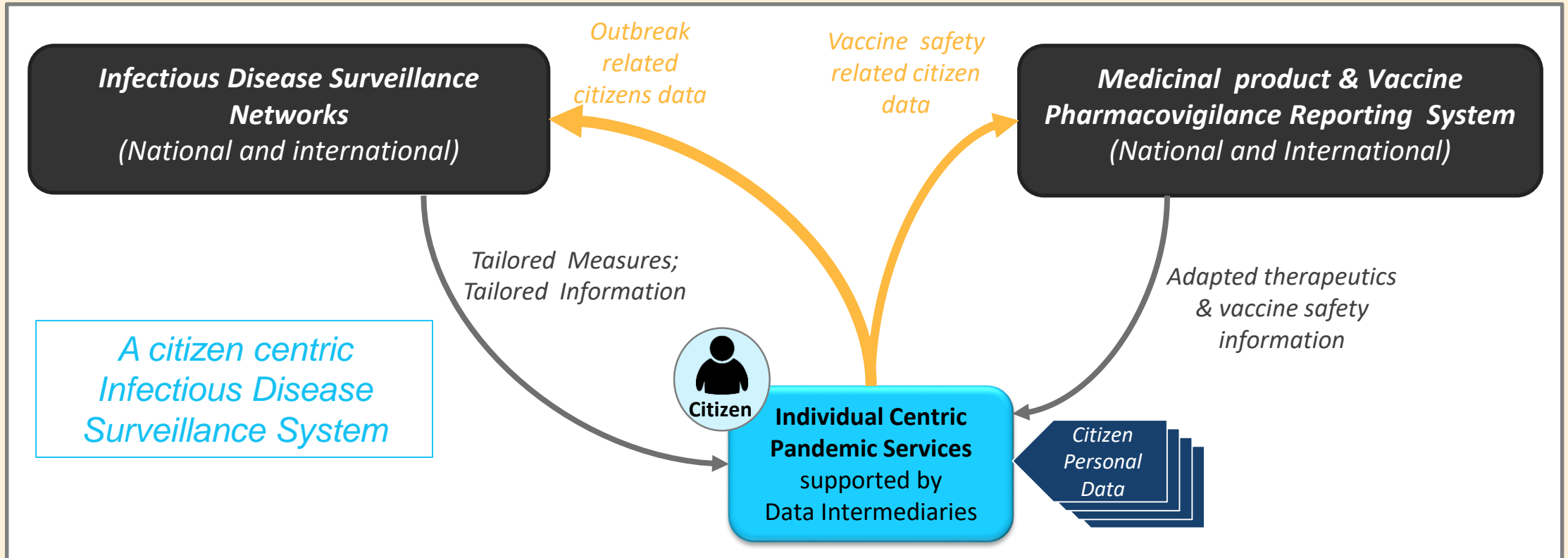


Responsible freedom of movements:
maximize respect of human rights and AVOID pandemics by enabling informed choice BY citizen.

... where citizens are not just being protected and “told” but....



...can share personal data with consent, and receive tailored feedback and information.



A Person Public Private Partnership (4P) for cross-border outbreaks enables data privacy compliant reuse of personal data & empowers citizens to act as responsible stakeholders

**As a Citizen,
in case of an
outbreak like
COVID19, ..**

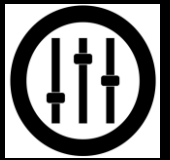


I need to have access to trustworthy information & understand what measures are of application and how/ why they apply to me and to others.



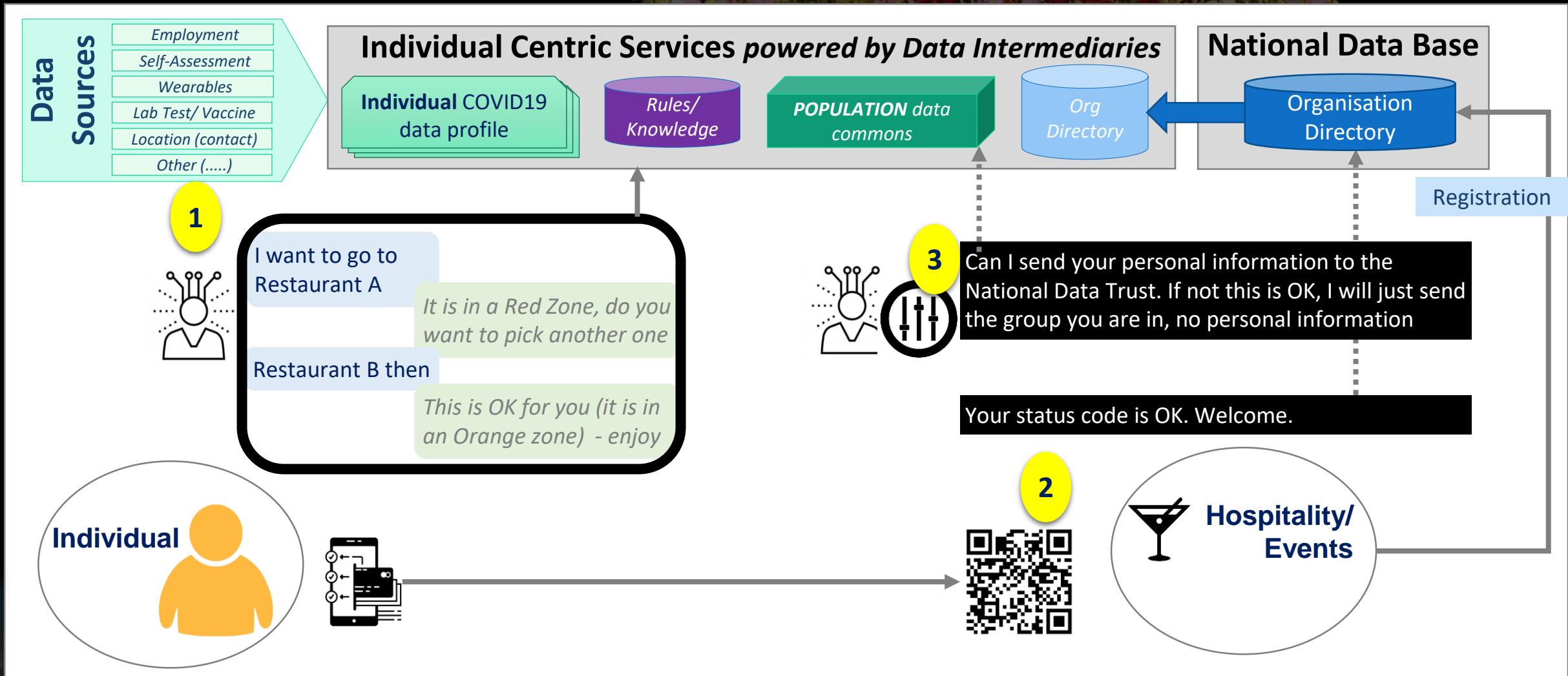
I want

- to maximize my freedom of movement
- while minimizing the risk of contagion for others and my own risk to become infected.

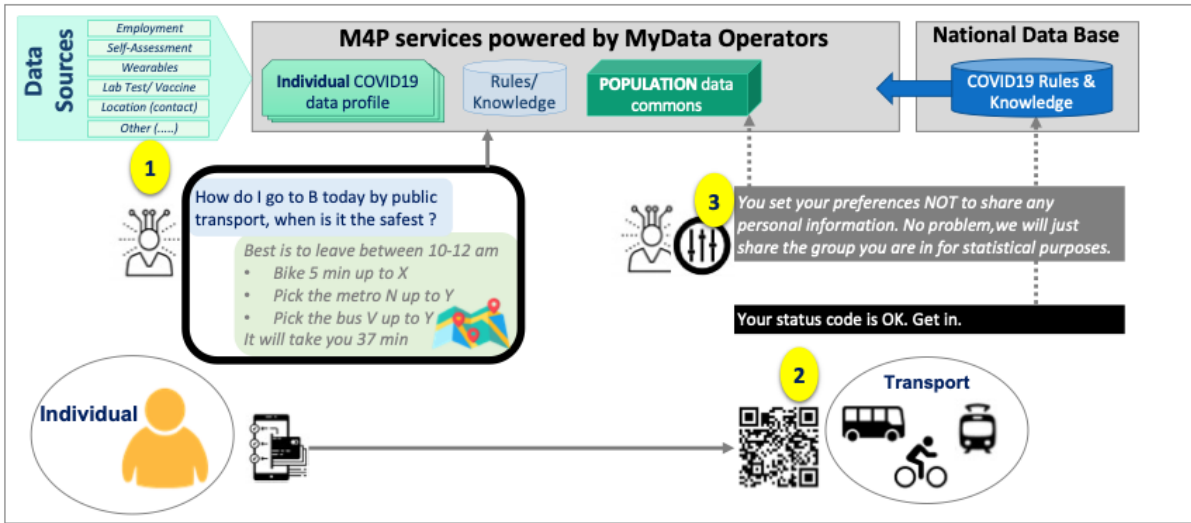


I am ready to share my data to an organisation I can trust to manage these data in a secure way, while ensuring data privacy and giving me control whenever relevant (less critical).

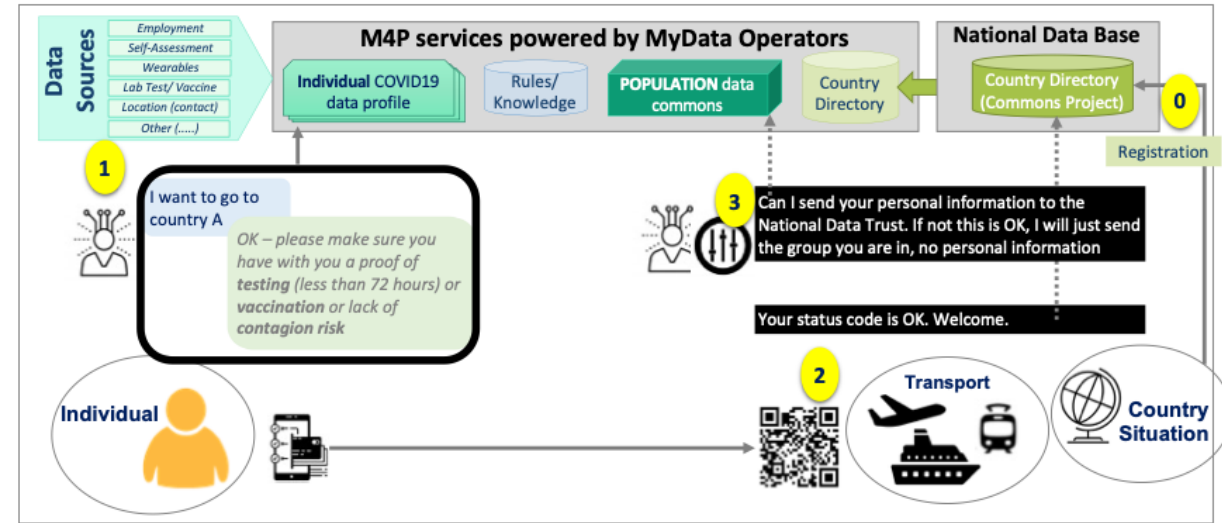
Use cases: Hospitality & Events Sector



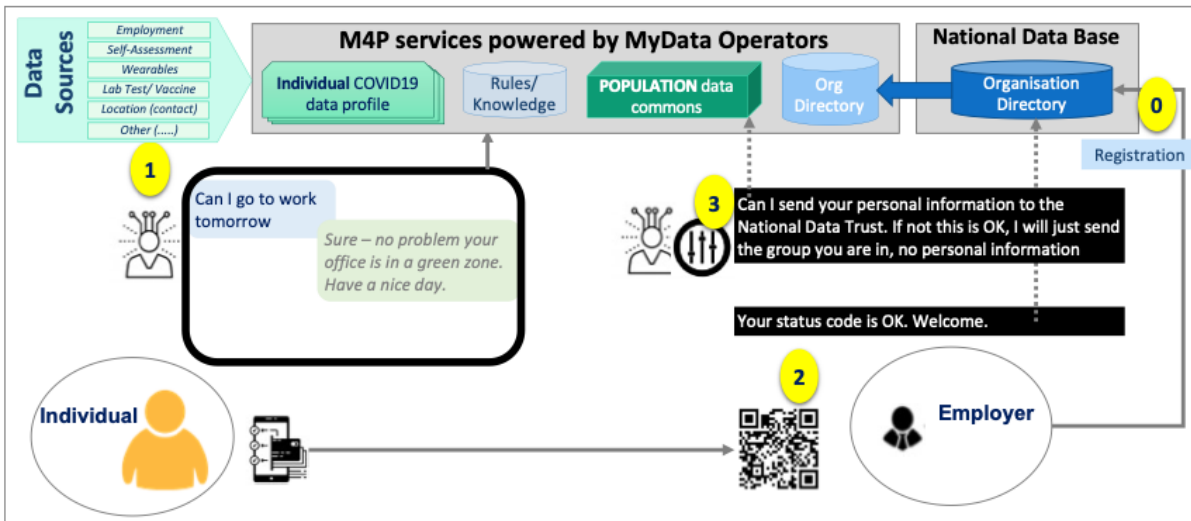
City transportation



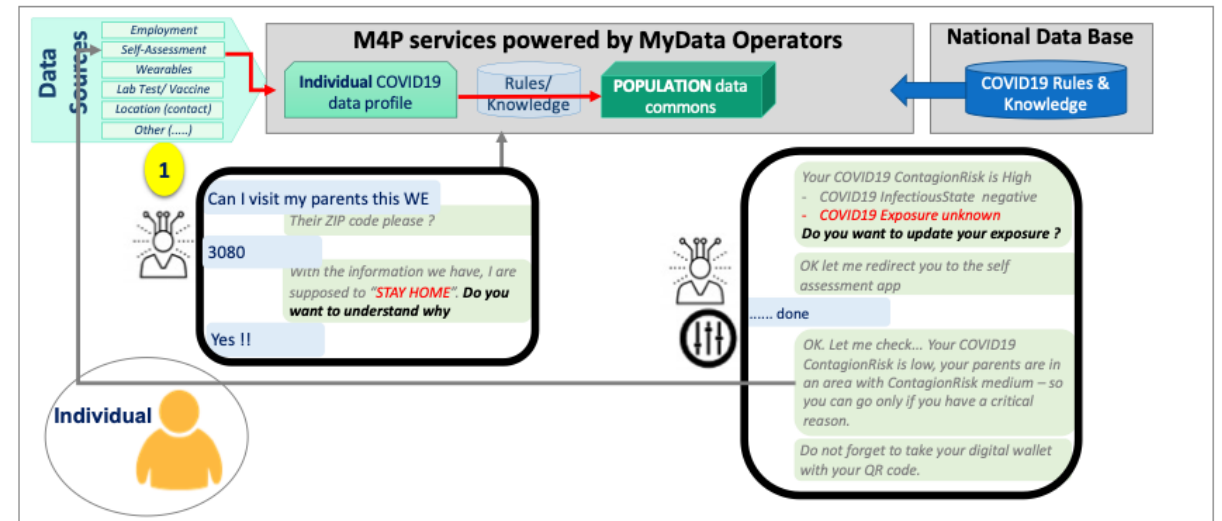
Travel



Going to work



Visiting family and friends



Defining the SOLUTION: Connecting the Dots

Digital
Initiatives
around
level

- e (unique identifier)
- Contact tracing interoperability

gateway
• Digital
• response measures

at national level
academic
contact & location
initiatives

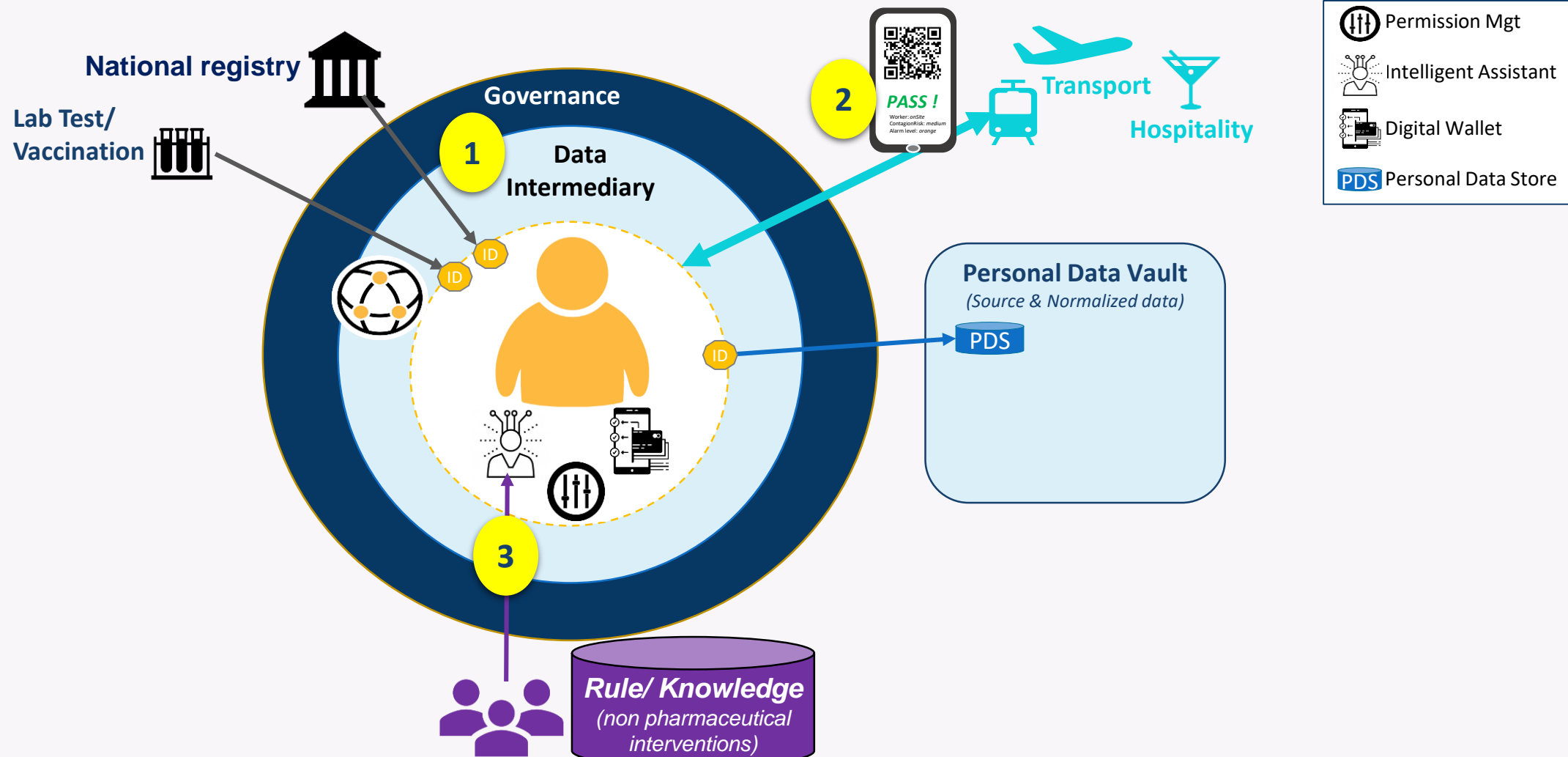
Data
Strategy
similar Data
Governance

- (Health) Data

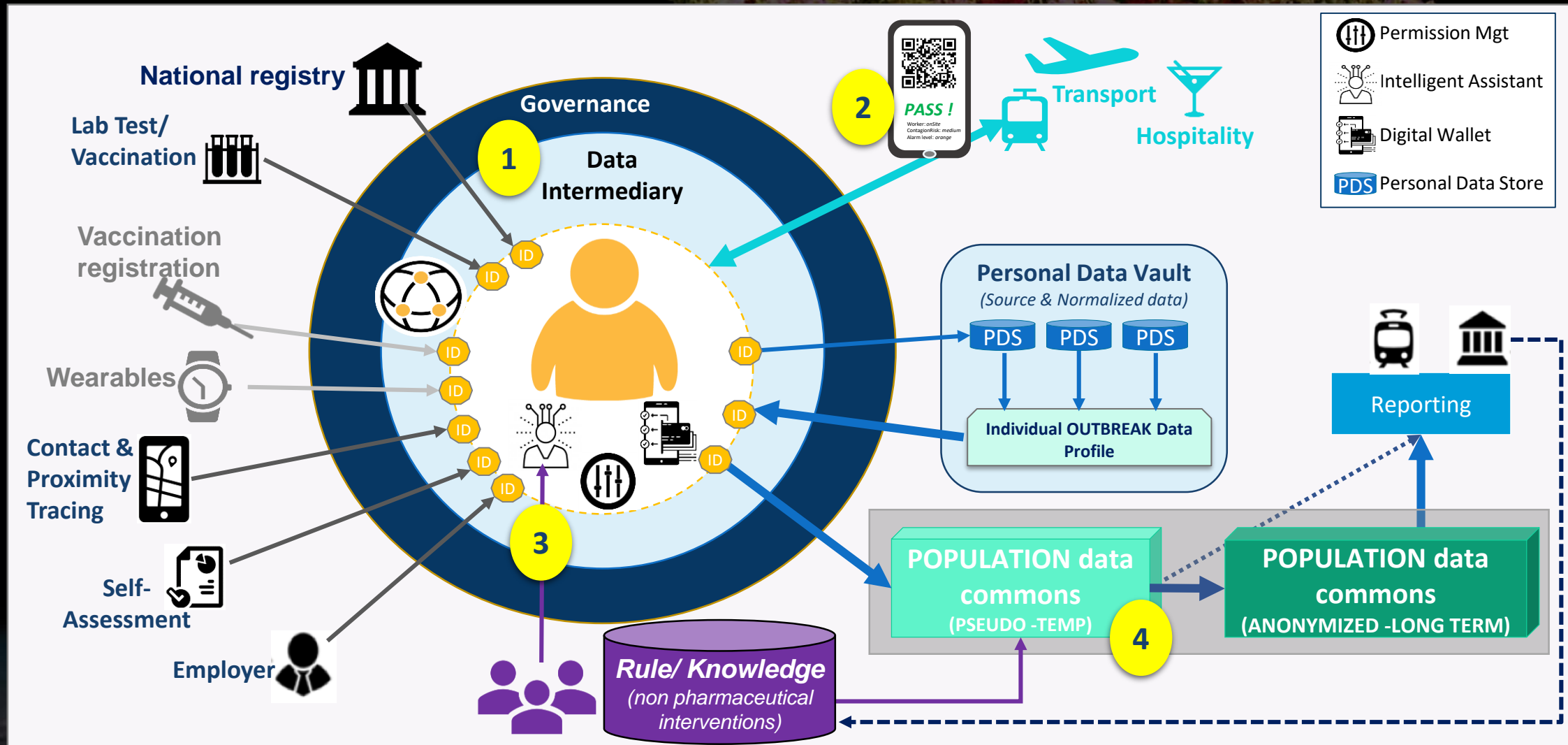
Intermediaries
Health
Director
Prevention, preparedness & response to cross-border health threats (Specific objective 2)
Data spaces
• Health Data
pace (Health)

Horizon
Europe
• Health

Existing Data Intermediaries Solutions - Minimum Services outside outbreaks



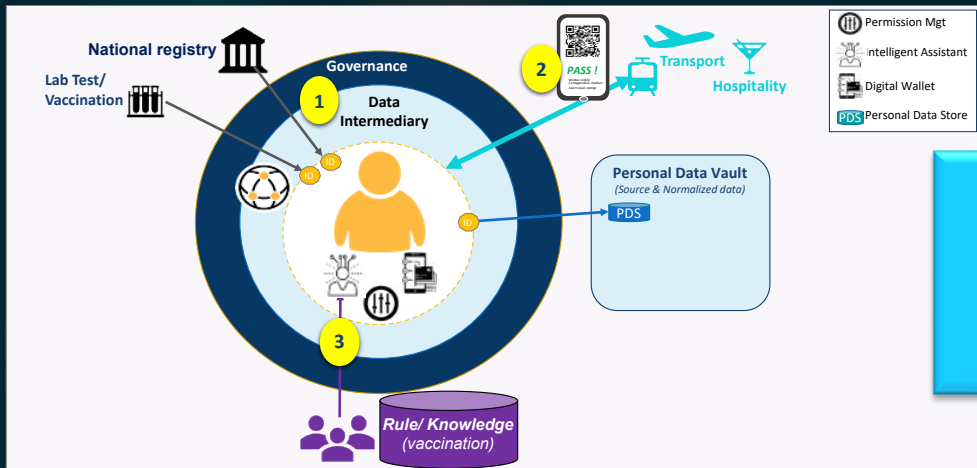
MyData4Pandemics - Additional Services during outbreaks



Crisis Preparedness Plan

From minimum to full solutions

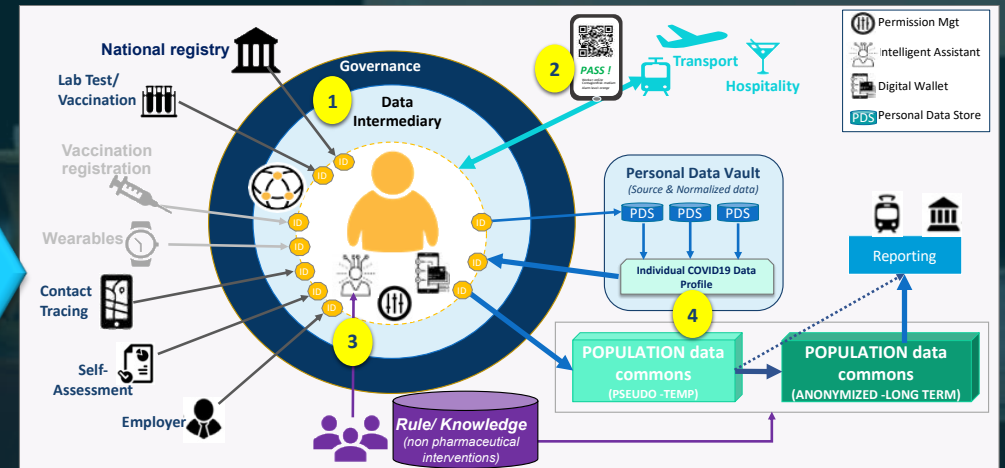
Minimum Services Outside Outbreaks: Vaccination pass in Digital Wallet



Scale up
1. Technology
2. Governance
3. Stakeholders

- Global rules (in Knowledge base) with national and global vaccination schemes
- Data Intermediaries with interoperable Digital Wallet
- Personal Intelligent Assistant

Full Services during an Outbreak Data Commons with Multiple credentials in Digital Wallet



- Update of Global rules (in Knowledge base)
- Data intermediaries add specific apps (*contact tracing, self-assessment,..*)
- Develop and integrate Data Commons
- Update Personal Intelligent Assistant

Crisis Preparedness Plan Stepped Approach

#	Description	Benefit
1	MVP of the Individual Centric solutions	Demonstrate it is possible to empower individuals and to bring high quality data to decision makers
2	MVP of the Pandemic Public Health Knowledge Base and the Intelligent Personal Assistant	Demonstrate value of machine readable form of public health measures , linked with adaptive virtual assistants:
3	Expand MVP to different Data Intermediaries and data sources, based on same standards	Demonstrate interoperability
4	Develop scale up instructions,	Be prepared for the next pandemics with sustainable and scalable services

Acknowledgement

Isabelle de Zegher (MyData Brussels)
Fredrik Lindén (MyData Sweden)
Hessie Jones (MyData Canada)
Iain Henderson (MyData Scotland)
Casandra Grundstrom (MyData Health - FI)
Davide Calvi (MyData London)
Dixon Siu (MyData Japan)
Sherry Chung (MyData Taiwan)
Adrian Gropper (MyData Health - US)

Contact: pandemics@mydata.org
isabelle.dezegher@mydata.org
frederik.linden@mydata.org





EU4Health Work Programme 2022

Ask Eirik Storsve
Head of European
Government Affairs
10 September 2021



Agenda

- 1) Objective Harmonise regulatory, legal, and logistical requirements.
Outcome Faster and more secure access to critical MCMs for the protection of EU citizens.
Added value Improved preparedness for EU citizens in response to CBRN emergency situations.

- 2) Objective Establish European strategic stockpile of MCMs able to respond to CBRN incidents – naturally occurring or man-made.
Outcome Supports maintenance of “know-how” and collective expertise.
Added value EU CBRN MCM stockpile complementary to MS stockpiles, avoiding duplication and strengthening EU preparedness for cross border health threats.

- 3) Objective Integrate EU procurement structures within global supply.
Outcome Mutually reinforcing and cost-effective global preparedness structures.
Sustainable and predictable framework for both government and global industry partners.
Added value Facilitated investment in less commercially profitable / niche products
Improved attractiveness of EU market.

Contact



Ask Eirik Storsve
StorsveA@ebsi.com

Coffee break

...we will start at 12:20

EU4Health – Stakeholders' Targeted Consultation

Open discussion and additional proposals

- Other proposals submitted in the targeted consultation can be presented
- Comments related to all proposals are welcomed

Please use the chat to ask for the floor
Only unmute when invited to speak

**Please return to the
plenary session**

...we will start at 13:00