



European Health Data Space

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Why?

To support:

- Patients, healthcare providers
- Policy makers, regulators
- Researchers, pharma, AI companies

For what?

- Access of patients to data and portability of data
- Access and continuity of health care
- Policy making, regulatory analysis, research

European Health Data Space

Legislative proposal 2021

Quality of data

Infrastructure

Capacity building and digital skills

Better Healthcare

Governance and rules, interoperability, infrastructure (primary and secondary use of health data)

Better Policy Making

Digital health services

Better Research and Innovation

Regulatory framework for AI and liability

Electronic Health Record Exchange Format

FAIR-ification of health data

MyHealth@EU
CPMS (ERNs)

1+mil genomes

European Health Data Space infrastructure

Pilot project 2021 (EMA, ECDC)

Digitalisation of healthcare systems

Trainings of public administration

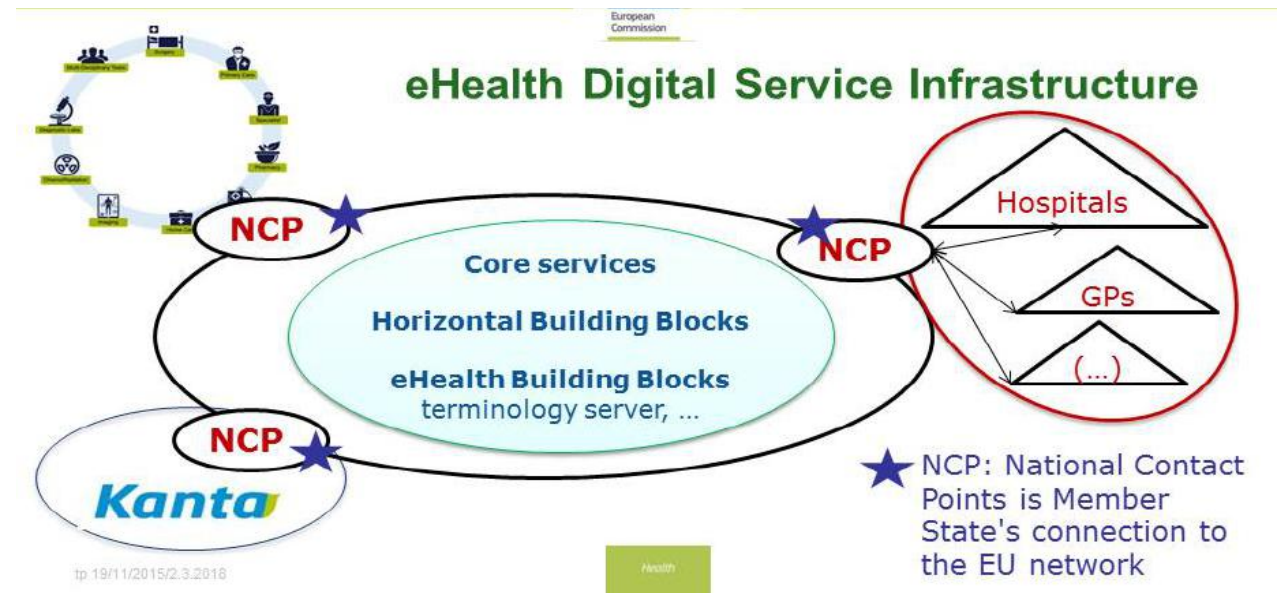
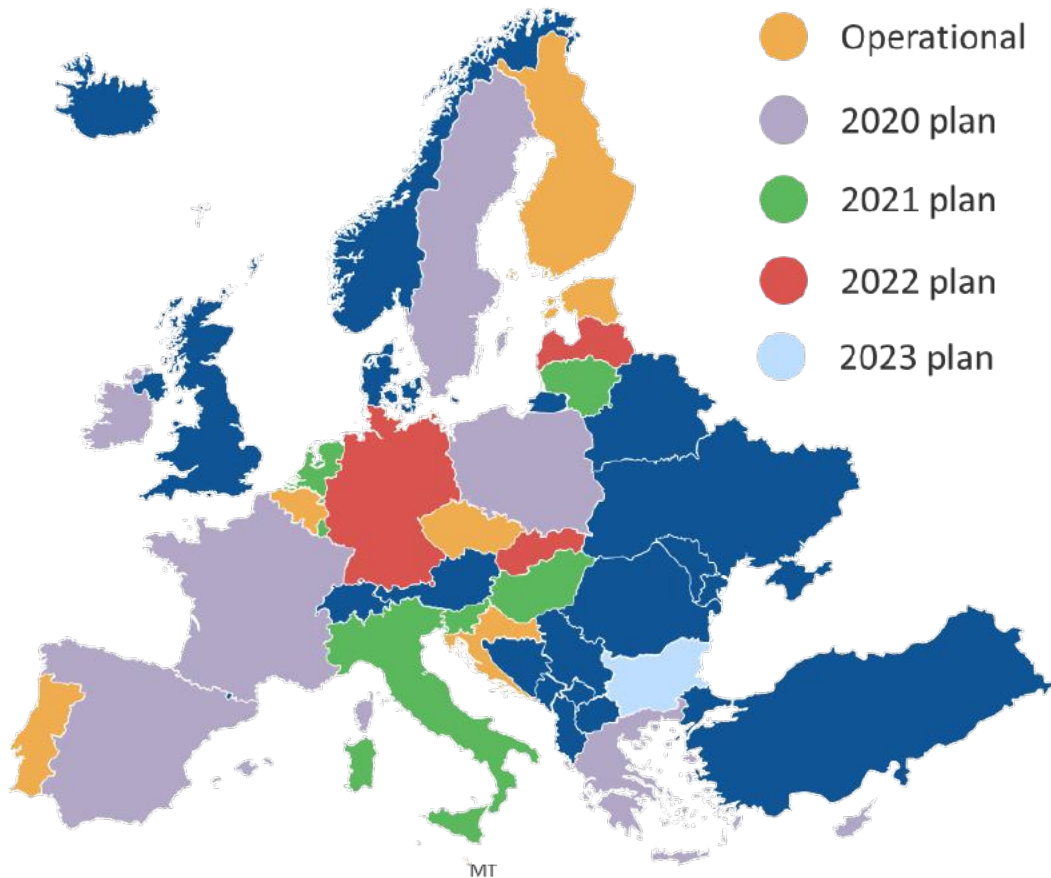
Digital skills

EHDS:

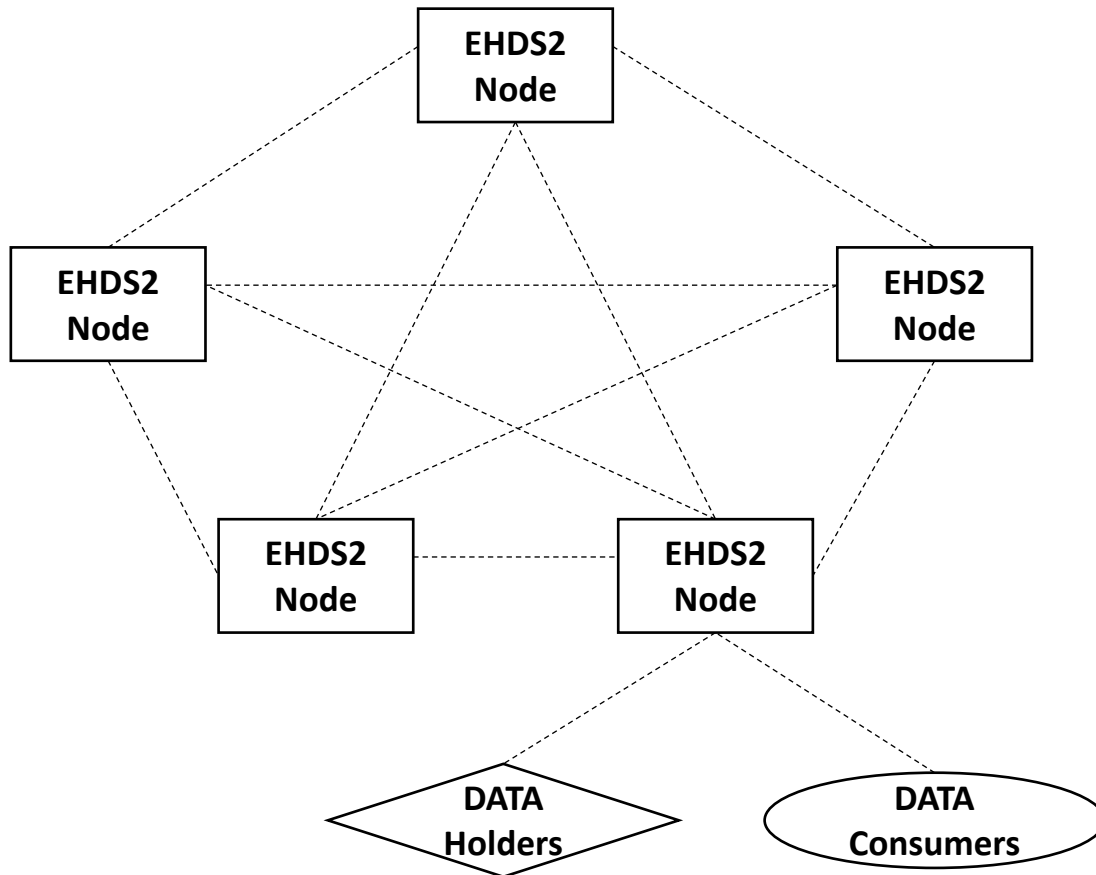
Health Data + Digital Health + AI in health

- From a legal perspective, we grouped the challenges in establishing the EHDS into three main pillars that interrelate to each other and need to work in harmony to provide concrete benefits to individuals. The three pillars are:
 - (1) Health data (governance, privacy, quality, portability and access to data, infrastructures, interoperability)
 - (2) Removing obstacles to the free movement of digital health services and products in the internal market.
 - (3) Establishing clear liability rules fit for digital health, including AI in health.

EHDS1: MyHealth@EU: cross-border exchange of patients' data



EHDS2: access to data for research and policy making (secondary use of health data)



EHDS2 NODEs are the entry point for stakeholders into the EHDS

EHDS2 NODEs can be established by National or Trans-national stakeholders

EHDS2 NODEs follow common policies and interoperability specifications

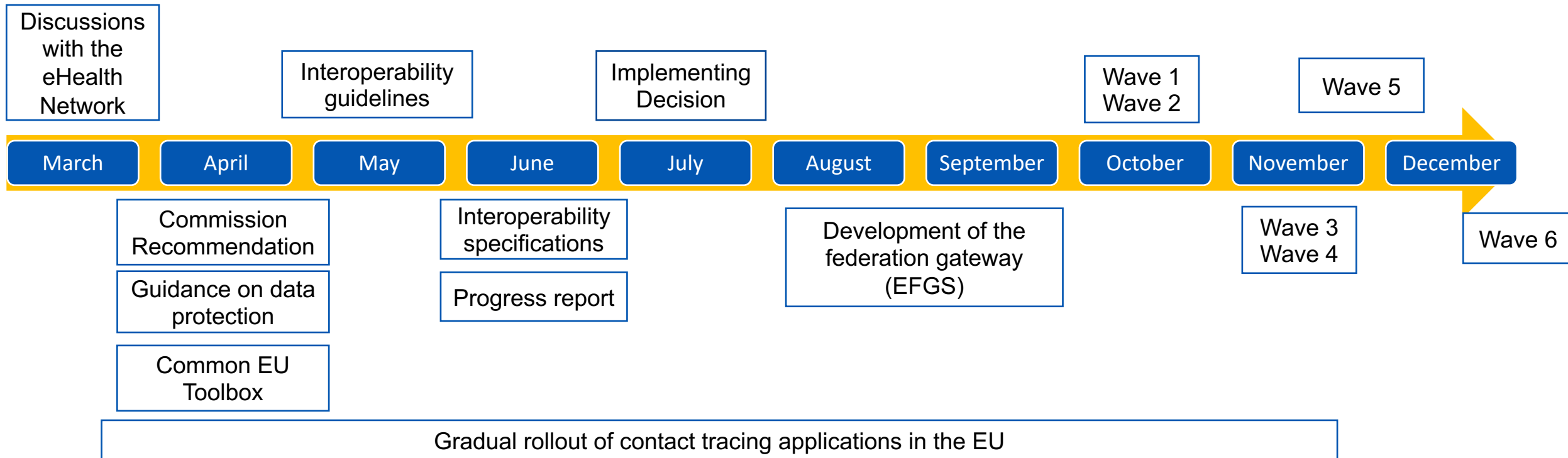
DATA Holders make health data available for secondary use

DATA Consumers further process data for research or policy making

Eliminate barriers to free movement of digital health services

- Tele-health, m-health
 - New evolutions, new products and services
 - New legislation in MS (telemedicine, m-health etc.)
- Evaluation of Directive 2011/24/EU
- What are the main barriers?
 - Authorisation
 - e-ID of patients and health professionals
 - Reimbursement
 - Interoperability
- What actions at EU level beyond the current Directive 2011/24/EU?

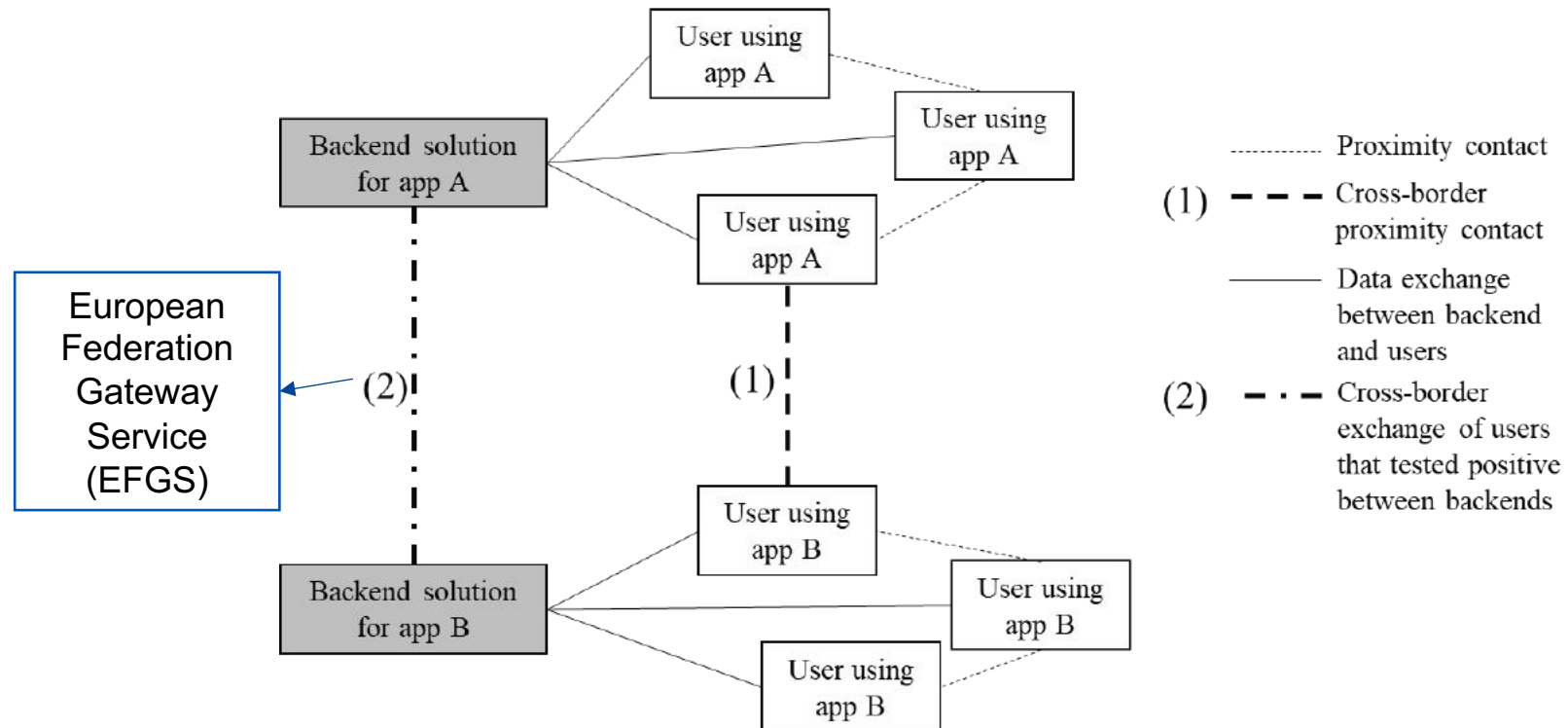
Contact tracing and warning apps- timeline



Building blocks of the common European approach

Legal	Organisational	Epidemiological/ Semantic	Technical
<ul style="list-style-type: none">• GDPR compliance and guidance• Clear modalities and responsibilities for cross-border exchange of data	<ul style="list-style-type: none">• Coordination of actions agreed in the eHealth Network• Collaboration with the Health Security Committee, ECDC, WHO	<ul style="list-style-type: none">• Epidemiological heuristics by ECDC• Common protocols for digital contact tracing	<ul style="list-style-type: none">• Common technical specifications• Common European infrastructure for interoperability (the gateway – EFGS)

European Federation Gateway Service (EFGS)



State of play (1)

More information:
See [Confluence](#)

	Decentralised	Centralised	TOTAL
Online	AT, IT, LV, DE, PL, DK, IE, HR, ES, NL, FI, EE, PT, MT, BE, CZ, SI, LT	FR, HU	20
Development	CY, NO, EL		3
TOTAL	21	2	23
To be confirmed	SK		1
Not planned	LU, SE, RO, BG		4

State of play (2)

**Joining the EFGS:
See Annex**

- **6 Member States are live (DE, IE, IT, ES, LV, DK)**
 - 5 Member States are in the process of joining (HR, CZ, PL, NL, CY)
 - 6 or more could join before Christmas (AT, FI, PT, BE, LT, SI)

Wave	Deadline for submission	Tentative go-live date	Countries	Count
Wave 1	05/10	19/10	DE, IE, IT	3
Wave 2	12/10	30/10	ES, LV, DK, HR	4
Wave 3	30/10	23/11	CZ, PL	2
Wave 4	06/11	30/11	NL, CY, PT?, FI, BE?, LT?, SI?	7
Wave 5	20/11	14/12	AT?	1
Wave 6 (tentative)	08/01/2021	25/01/2021		
Wave not determined			EE, NO, SK, MT, EL	5

State of play (3)

- Uptake of apps
- Every user counts

Member State	Countries	Downloads (since go-live)	Population (Eurostat)	Downloads as a percentage of population	Percentage of total downloads
Contact tracing app deployed	20	63.085.337	391.065.328	16%	100%
EFGS-compatible area	18	56.040.337	314.282.919	18%	89%
EFGS area (live with EFGS)	6	40.803.294	202.890.761	20%	65%

Questions?

Further information

eHealth Network

https://ec.europa.eu/health/ehealth/policy/network_en

All events

https://ec.europa.eu/health/ehealth/events_en#anchor0