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EHDS provides a new framework for collaboration on eHealth

Expansion of services: adding Lab results, Medical images, Hospital discharge letters, Vaccination Card, European Social Security Pass, etc.



Some common goals of MyHealth@EU



To support continuity of care when people exercise their right of freedom of movement



To provide appropriate and usable tools to health professionals and to patients



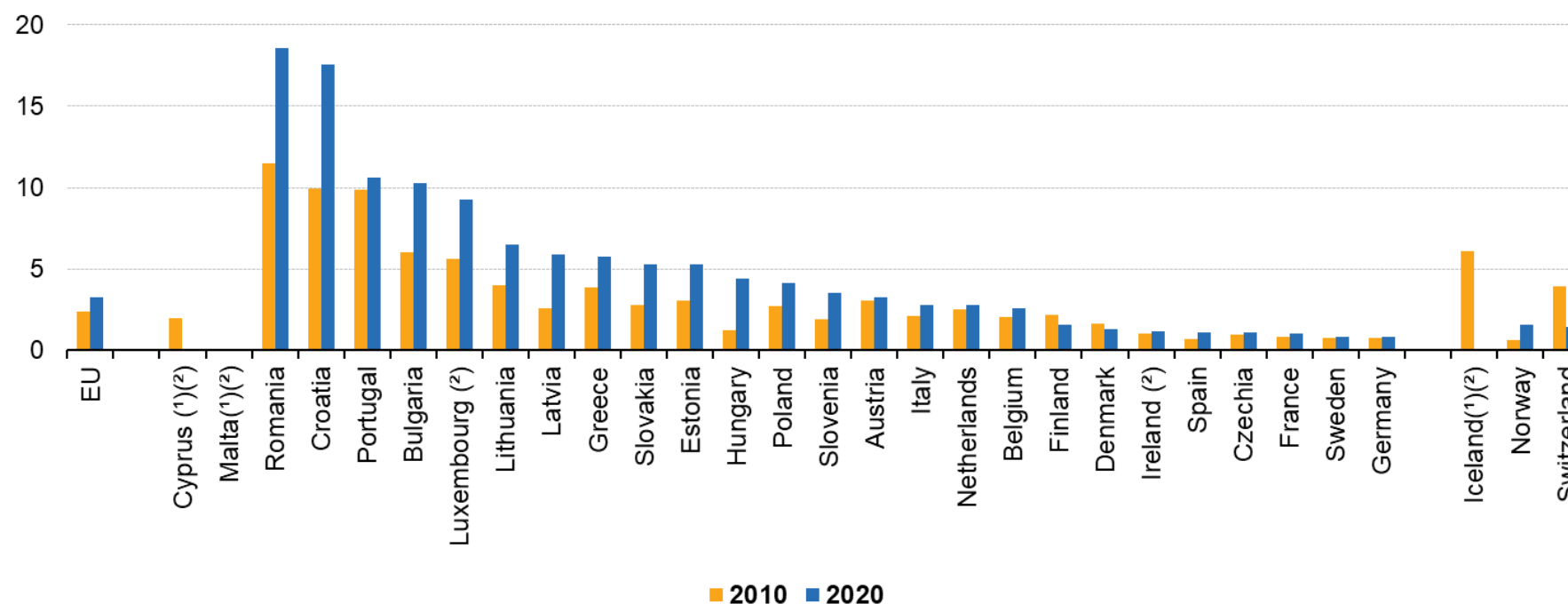
To ensure data protection and security



To ensure stability and further development of services, and make people aware of them

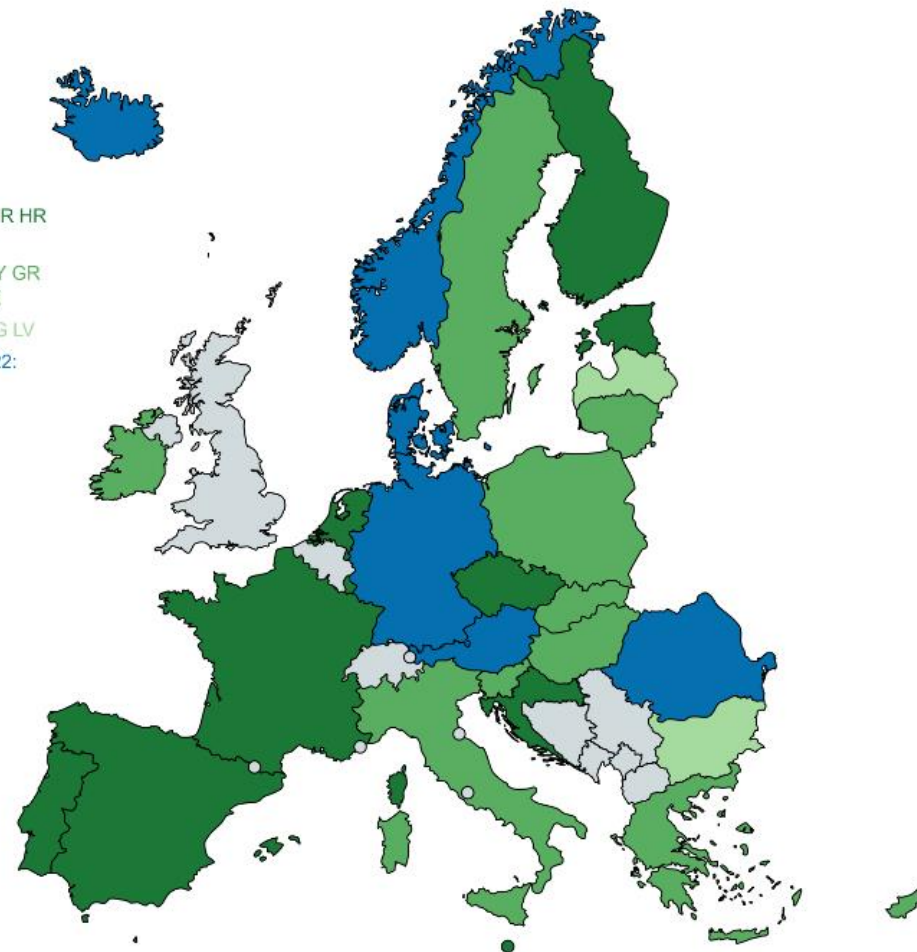
What is the scale?

EU mobile citizens of working age (20-64) by country of citizenship, % of their home-country resident population



MyHealth@EU

- Live now: CZ EE ES FI FR HR
LU MT NL PT
- Go-live planned 2022: CY GR
HU IE IT LT PL SE SI SK
- Go-live planned 2023: BG LV
- Application expected 2022:
AT DE DK IS NO RO



MyHealth@EU is the existing infrastructure that connects healthcare providers in 10 Member States. It allows them to exchange health data such as Patient Summaries and ePrescription. These services will be expanded to include lab results and other types of health data.

Services that are live:

- PS-A in CZ, ES, HR, MT, PT (5)
- PS-B in CZ, ES, FR, HR, LU, MT, NL (7)
- eP-A in EE, FI, HR, PT (4)
- eP-B in EE, FI, HR, PT (4)

Grants to join:

- PS-A in BG, CY, EE, EL, FI, IE, IT, LT, LU, LV, SI, SK (+12)
- PS-B in BG, CY, EE, EL, FI, HU, IE, IT, LT, LV, SI (+11)
- eP-A in BG, CY, CZ, EL, ES, HU, IE, IT, LT, LV, PL, SE, SI (+13)
- eP-B in BG, CY, CZ, EL, ES, HU, IE, IT, LT, LV, PL, SE, SI (+13)

Key Performance Indicators:

- Number of eP transactions since 2019: 26.098
- Number of PS transactions since 2019: 426
- Number of Hospitals connected (PS-B): 3.207
- Number of Pharmacies connected (eP-B): 24.981
- Citizens able to benefit from MyHealth@EU: 5.749.635

* Data are from the KPI's Q4 2021

Coverage of HCPs in the MS

MS	Hospitals	Pharmacies	Other POC
CZ	15%		
EE		100%	
ES	3.4%		
FI		100%	
FR	100%	100%	100%
HR	100%	100%	100%
LU	100%		
MT	94%		
PT	2%	0.03%	

EUROPEAN HEALTH DATA SPACE
Use of data for healthcare (primary use of data)

Give citizens **better access** to their **health data**, everywhere in EU



My Health @ EU
eHealth Digital Service Infrastructure
A service provided by the European Union



X-eHealth

Exchanging Electronic Health Records
in a common framework



From 2019 exchange of:

ePrescriptions

Patient Summaries

Access by health professionals in
their native language

From 2022
exchange of:

**Original Clinical
Documents**

From 2024 exchange of:

Laboratory results and reports

Medical images and reports

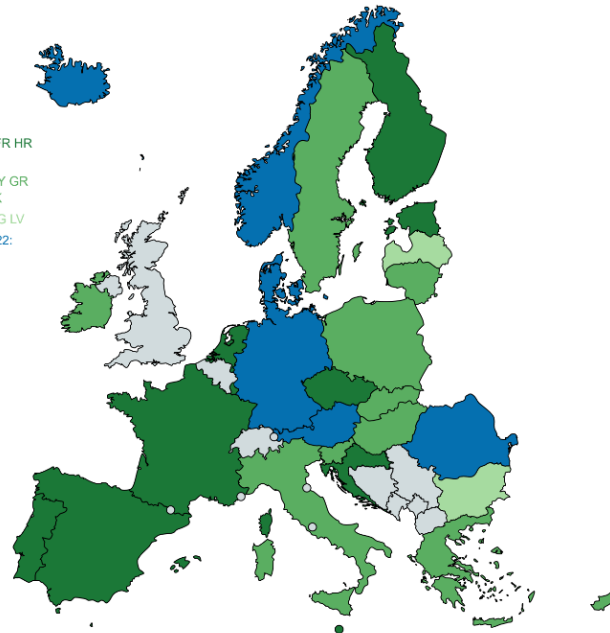
Hospital discharge reports

in health professional's language

As in Recommendation on an
Electronic Health Record exchange
format

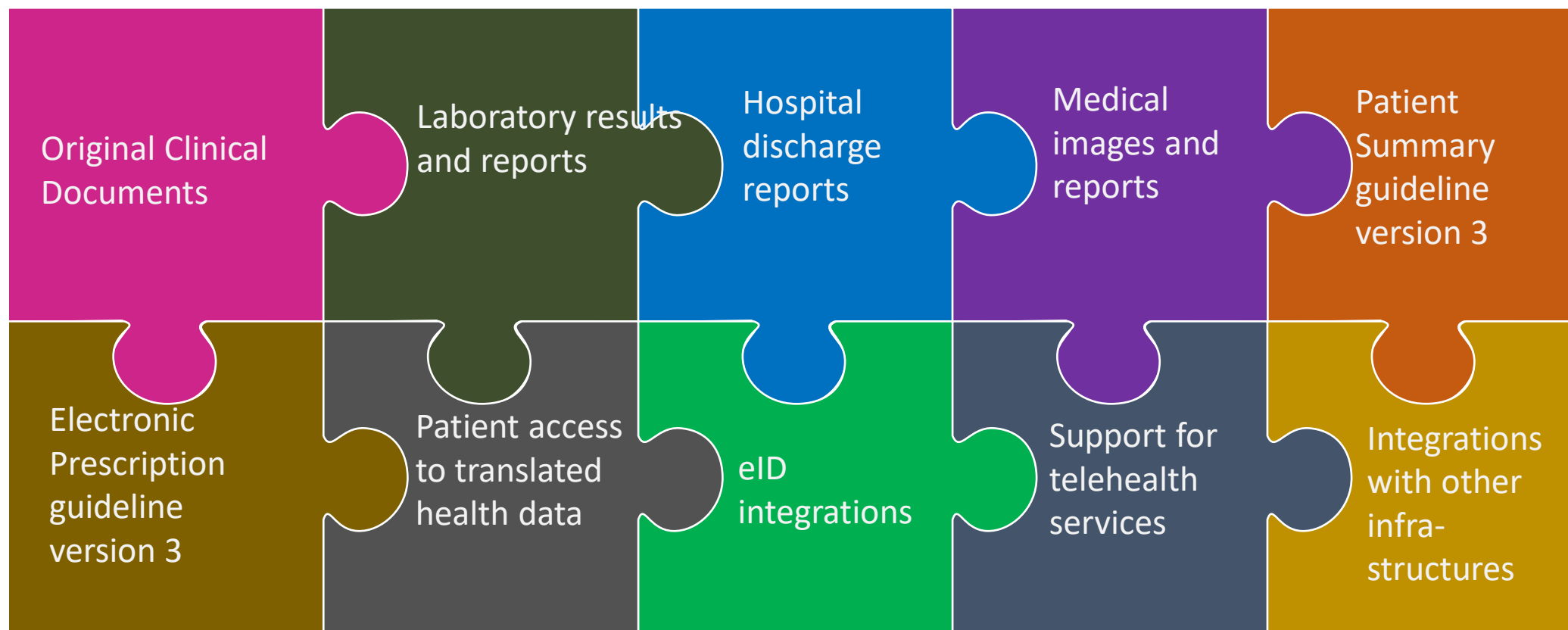
in cooperation with DG CNECT

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From 2022: pilot on
Patients' access to their translated
health data

Next possible steps for MyHealth@EU



Additional elements that could or should be considered

Further mobile elements

- Patient Access on mobile
- eID Wallet or Citizen wallet integrations



Use of non-structured data

- Extensions to Original Clinical Documents
- Links from PS to underlying data

Quicker development

- Further streamlining of testing arrangements



Ethical principles

- Ensure sufficient coverage of existing services
- Children and elderly not to be forgotten

European Health Data Space

Primary use of health data

Sharing of health data for healthcare

Problems

- Limited control of patients over their health data
- Limited interoperability between health care providers

Areas of work

- Control of patients over their data
- Interoperability
- Role of e-health agencies
- Reinforced EU governance (eHealth Network)
- Reinforced MyHealth@EU

Single market for digital health products and services

Problems

- Uneven national legislative frameworks
- Uneven quality framework
- Uneven procedures for prescriptions, reimbursement, liability

Areas of work

- Eliminate barriers to free movement
- Labelling
- Interoperability
- Reimbursement
- Liability

Secondary use of health data

Access to health data for research, innovation, public health policy making

Problems

- Low re-use of health data
- Cumbersome cross-border access to health data
- Fragmented digital infrastructures

Areas of work

- Governance and rules for access to health data
- Data FAIR-ification
- Digital infrastructure (EHDS2)

Artificial Intelligence

Problems

- Limited provision of data for training of AI
- Difficulties for regulators to evaluate AI algorithms
- Uncertainty on AI liability in health

Areas of work

- Support for development and rollout of AI
- Data for AI
- Support for regulators



1	9:30	Opening by the French Ministerial eHealth Delegation and by ParisSanté Campus; <i>Ouverture par la Délégation ministérielle du Numérique en Santé et par ParisSanté Campus</i>	15'	<ul style="list-style-type: none"> • Antoine Tesniere – ParisSanté Campus – France • Laura Létourneau – French ministerial eHealth Delegation – France
2	9:45	The European commission eHealth roadmap; <i>La feuille de route en e-santé de la commission européenne</i>	20'	<ul style="list-style-type: none"> • Konstantin Hyppönen, Hugo van Haastert – European Commission
3	10:05	EU Digital covid certificate : How Europe joined forces for eHealth during the COVID-19 crisis ? <i>Comment l'Europe a-t-elle unit ses forces pour une meilleure e-santé Durant la crise du covid-19 ?</i>	20'	<ul style="list-style-type: none"> • Vincent Van Pelt – Nictiz – Netherlands • Achille Lerpinière – Ministry of Health – France
4	10:30	Speeding up the digital shift in healthcare : European state of play end 2021 <i>Accélérer le virage numérique européen : l'état des lieux à fin 2021</i>	20'	<ul style="list-style-type: none"> • Nihal Filali, Loïc Chabanier - EY
	10:50	Break Pause	15'	
5	11:05	MyHealth@EU use cases deployment: Member States' updates <i>Les cas d'usages MaSanté@UE : Etat des lieux des états membres</i>	60'	<ul style="list-style-type: none"> • Eamon Coyne, Klara JIRAKOVA – eHMSEG • Ines ANTUNES – SPMS – Portugal • Alexander ZLOTNIK – Ministry of Health – Spain • Heiko ZIMMERMANN, Olivier LEPANTO - Agence e-Santé – Luxembourg • Antoine DE MARASSE – ANS – France
6	12:05	X-eHealth (laboratory results, imaging) and rare diseases updates <i>Présentation du projet X-eHealth (résultats de laboratoire, imagerie, lettres de sortie) et réflexion sur les maladies rares</i>	25'	<ul style="list-style-type: none"> • Cátia Sousa Pinto – SPMS – Portugal • Ana Rath - ORPHANET



Vincent VAN PELT

*Co-chair, eHealth Network Subgroup on
Technical Interoperability
Senior Advisor International, Nictiz (NL)*

Nictiz



Achille LERPINIÈRE

*Head of IT and support
Division*

**French General
Directorate for Health**



**MINISTÈRE
DES SOLIDARITÉS
ET DE LA SANTÉ**

*Liberté
Égalité
Fraternité*



Ask your questions on the chat !



MyHealth@EU Webinar
April 7th, 2022
#EU2022FR

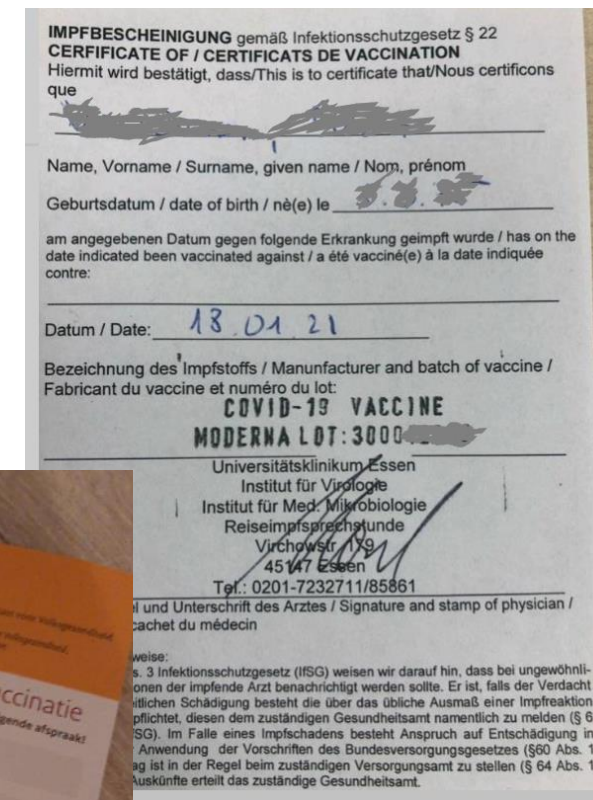
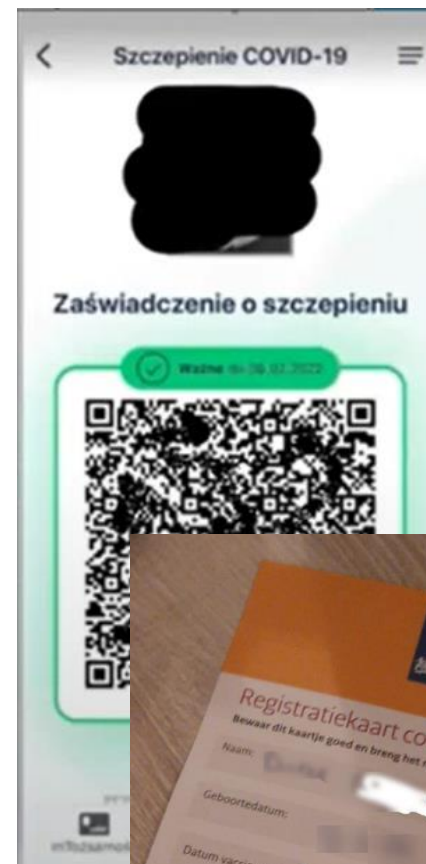
Vincent van Pelt
MS Co-chair,
eHN Subgroup on
Technical Interoperability



Ask your questions on the chat !

December 2020

- Each MS has different vaccination/test proofs
- No agreements on acceptance of the proofs
- Different restrictions for different countries
- Language problems, different naming conventions
- Possible fraud and forgeries
- No standardised data format
- No automated verification possible





EU requirements

- Free travel of EU citizens, non-discriminatory (vaccination/test/recovery)
- Private by design and by default (data minimization, purpose limitation)
 - legislation: GDPR, national laws
- Secure by design and by default
 - signed certificates, off-line verification, acceptance rules, revocation
- User-friendly, robust, inclusive (digital and paper)
- Interoperable (open standards, no language barriers, global scope)
- Modular, adaptable (acceptance rules, additional use cases)



EU collaboration

- December 2020: first plans for harmonisation (just before start of vaccinations in EU)
- eHealth Network Subgroup on Semantics specifies the minimal data set (vaccination, test and recovery), Subgroup on Technical Interoperability defines the Trust Framework.
- January 2020: eHealth Network develops Guideline for vaccination certificates, for medical purpose
- February 2020: switch to travel purpose
- June 2021: publication of the EU DCC [Regulation](#) (PE/25/2021/REV/1)
- June 2021: first EU DCC in production

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on a framework for the issuance, verification and acceptance of interoperable certificates on vaccination, testing and recovery to facilitate free movement during the COVID-19 pandemic (EU COVID Card/Digital Green Certificate)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 21(2) thereof,

Having regard to the proposal from the European Commission,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) Citizenship of the Union confers on every citizen of the Union the right to move and reside freely within the territory of the Member States, subject to the limitations and conditions laid down in the Treaties and by the measures adopted to give effect to them. Directive 2004/38/EC of the European Parliament and of the Council⁹ lays down detailed rules as regards the exercise of that right.
- (2) On 30 January 2020, the Director-General of the World Health Organization (WHO) declared a public health emergency of international concern over the global outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes



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eHN SG on Technical Interoperability - approach

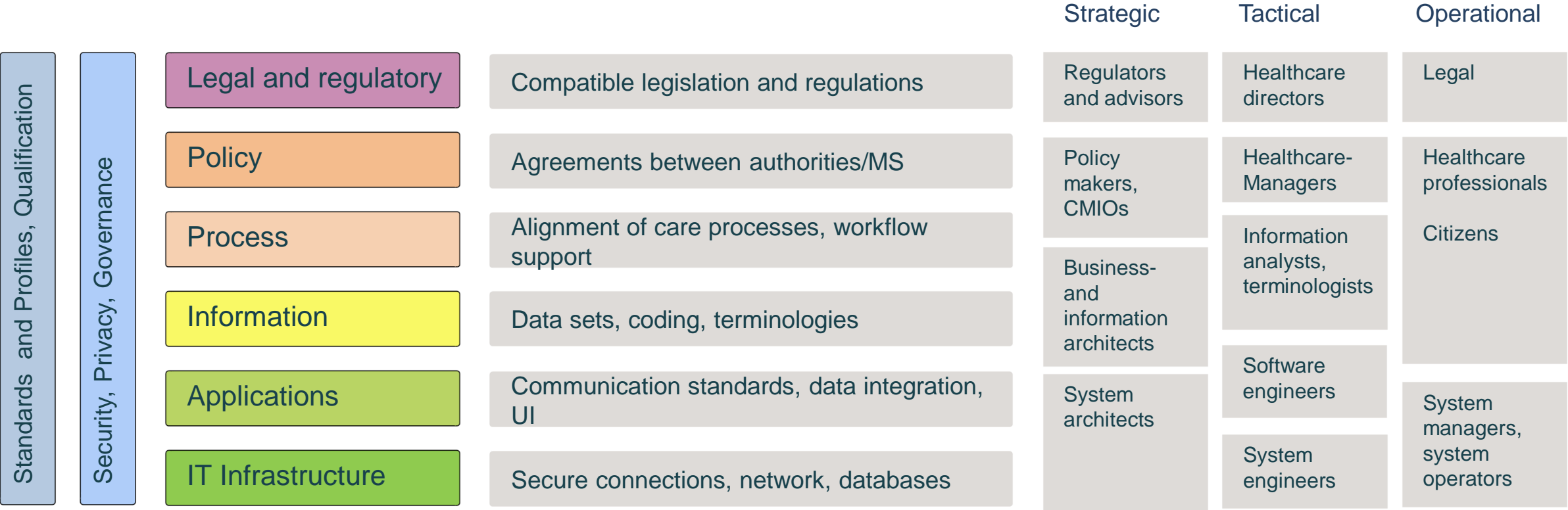
- Top experts from the EU
- Up to 175 participants, meetings almost daily
- Stakeholders:
 - 27 Member States
 - DG CNECT, DG SANTE, DG MOVE, DG HOME, DG JUST
 - WHO, ECDC, JRC, HSC, EDPB
 - ICAO, IATA, A4E, Schiphol/Frankfurt/Paris Airport
 - HL7, IHE, Apple, Alphabet, Microsoft
- Agile, quick but not dirty, look for the most elegant solution
- Room for opinions but respect for knowledge and each other
- Task Forces, open process, open source and free software



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Approach for interoperability - domains, stakeholders

Refined eHealth European Interoperability Framework



ReEIF interoperability model

Alignment between organisations, on all layers of the model

Involve all stakeholders, at different levels and for different tasks



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EU DCC framework components

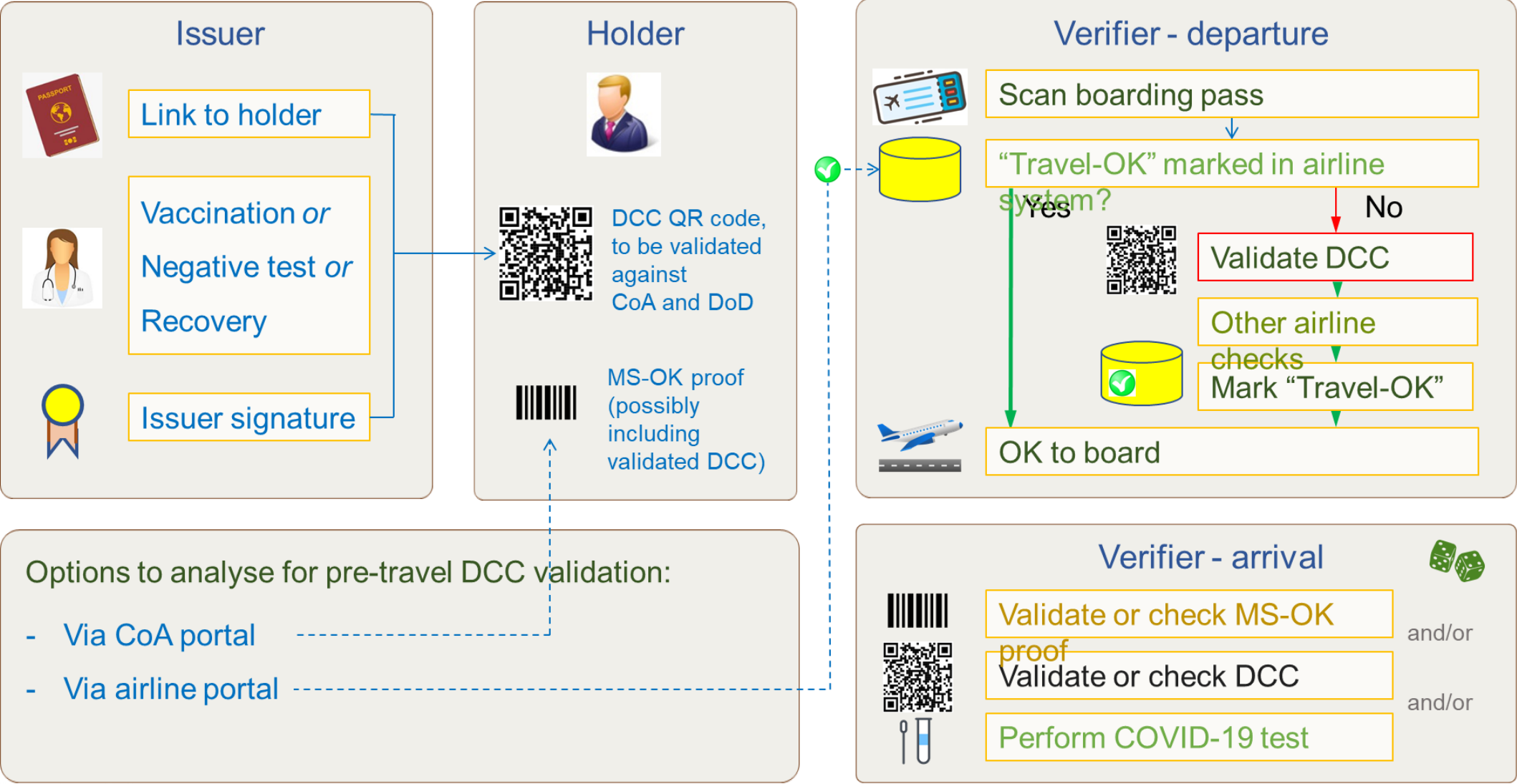


Legal and regulatory	Legal foundation	EU Regulation (GDPR), eHN adoption, MS legislations
Policy	Harmonisation	Discussions on alignment with ICAO, WHO, third countries. Scoping, conformance, acceptance rules
Process	Use cases	Different realisation scenarios (pre-boarding, border patrol, spot checks, wallet app)
Information	Minimum data set	Data minimisation, purpose limitation. Data definition + value sets
Applications	QR code	Authenticity, safety, size limitations. JSON Schema, CBOR, COSE, zlib, Base45, QR code
Applications	Technical rules	JSON schema, JSON Logic (BR), technical validity checks, UI, UX, mapping strategies
IT Infrastructure	Architecture	Off-line verification. Configuration updates. QR creation, DCC Gateway, DCC validation, revocation
Security, Privacy	Configuration	Daily updates of signatures, acceptance rules, revocation lists and value sets
Qualification	Testing and qualification	Onboarding procedure, testing of the different components, verifier apps, wallet apps



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Basic workflow

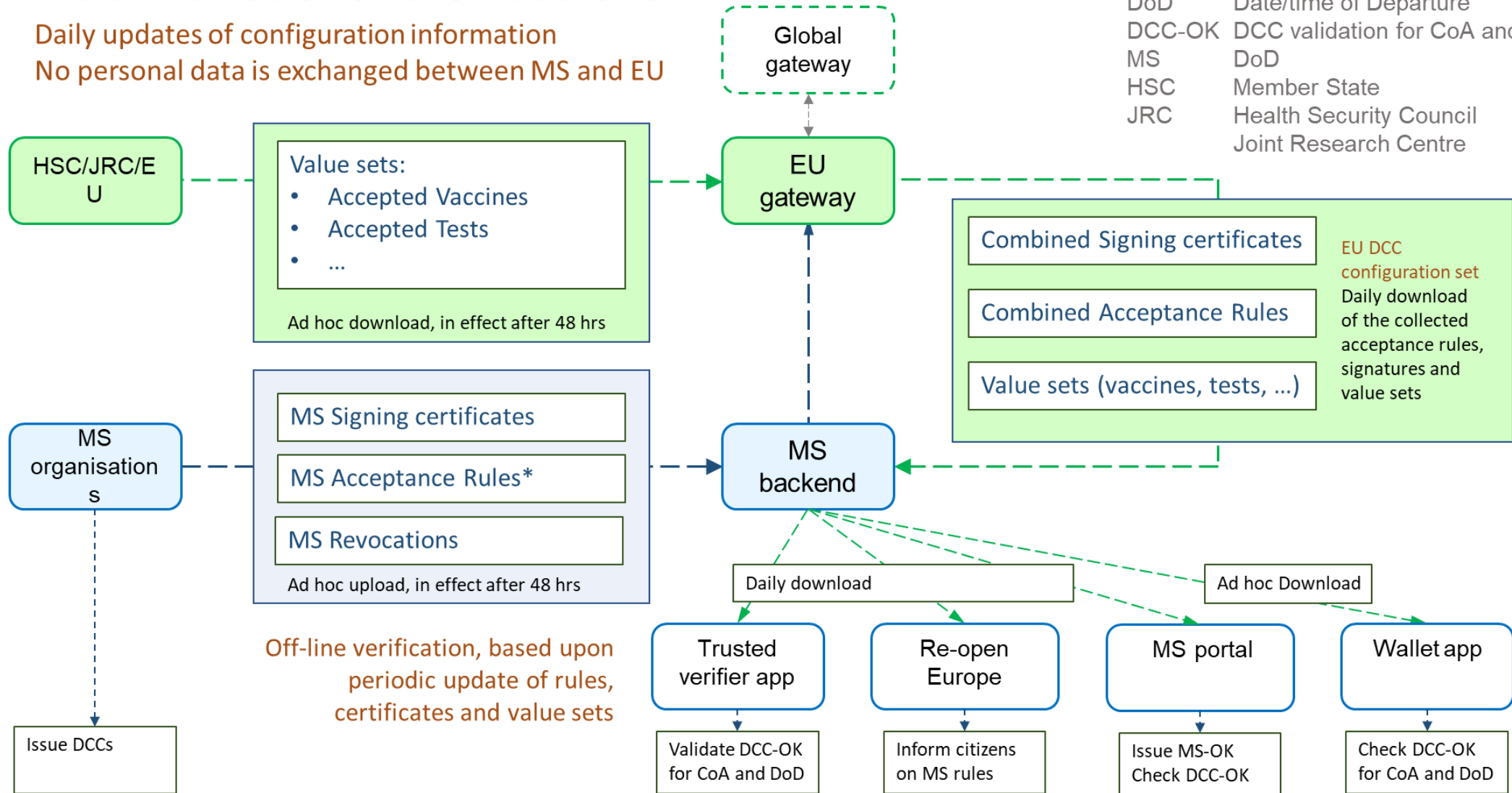


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DCC - functional architecture

Daily updates of configuration information
No personal data is exchanged between MS and EU

Legend		
Ad hoc		when update is needed
CoA		Country of Arrival
DoD		Date/time of Departure
DCC-OK		DCC validation for CoA and DoD
MS		Member State
HSC		Health Security Council
JRC		Joint Research Centre



Off-line verification, based upon periodic update of rules, certificates and value sets

* These may include possible other MS accepted vaccines



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Minimum data set

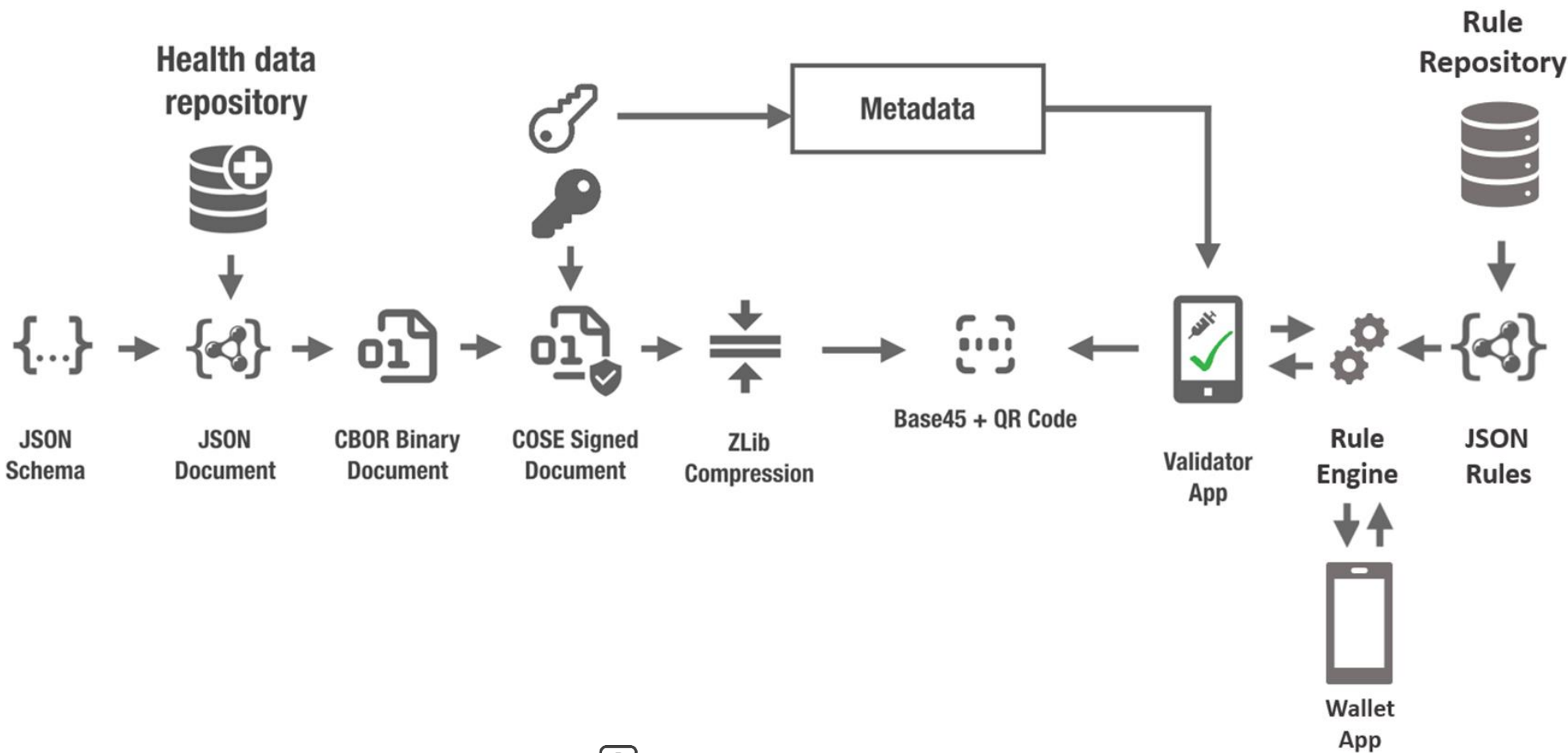
- As defined by the eHN SG on Semantics and adopted by the eHN
- The list of data fields is defined by the hCert Schema

Data Field	Abbreviation	Type
Certificate Issuer	is	Vac/Test/Rec
Certificate Valid Until	du	Rec
Country of Test	co	Test
Country of Vaccination	co	Vac
Date of Vaccination	dt	Vac
Date/Time of Sample Collection	sc	Test
Date/Time of Test Result	dr	Test
Dose Number	dn	Vac
ISO 8601 Date of First Positive Test Result	fr	Rec
ISO 8601 Date: Certificate Valid From	df	Rec
Marketing Authorization Holder	ma	Vac
NAA Test Name	nm	Test
RAT Test name and manufacturer	ma	Test
Target Disease Agent	tg	Vac/Test/Rec
Test Result	tr	Test
Testing Centre	tc	Test
Total Series of Doses	sd	Vac
Type of Test	tt	Test
Unique Certificate Identifier: UVCI	ci	Vac/Test/Rec
Vaccine medicinal product	mp	Vac
Vaccine or Prophylaxis	vg	Vac



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Not your average QR code



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In the press

Date: 26 August 2021

IATA Backs European Digital Covid Certificate as Global Standard



Geneva - The International Air Transport Association (IATA) has backed the European Digital COVID Certificate (DCC) for its leadership and speed in delivering the EU make it their global standard for digital vaccine

"The DCC was delivered in record time to help in the absence of a single global standard for digital vaccine, and other nations looking to implement digital vaccine to reap associated economic benefits," said Conrad C

The EU DCC meets several key criteria which help ensure the vaccination certificate is to be effective:

- **Format:** the DCC has the flexibility to be used in both paper and digital format
- **QR code:** The DCC QR code can be included in both digital and paper format. It contains essential information to ensure the certificate is authentic.
- **Verification and authentication:** The European Commission has built a gateway through which the digital certificate signatures can be distributed across the EU. The gateway can be also used by other issuers. The EU has also developed a specification for machine readable Validation



Tourism Manifesto

EUROPE'S TRAVEL & TOURISM SECTOR WELCOMES ADOPTION OF EU DIGITAL COVID CERTIFICATE

Brussels, 26th May 2021.

The European Tourism Manifesto alliance of more than 60 travel and tourism organisations warmly welcomes the adoption of the "EU Digital COVID Certificate" (DCC) Regulation and urges its speedy implementation by Member States.

Less than three months after the publication of the Commission's proposal, the European Parliament's LIBE committee and the Council have approved the

EU Digital COVID Certificate goes live a month early

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Milestones and current status

Milestones EU DCC

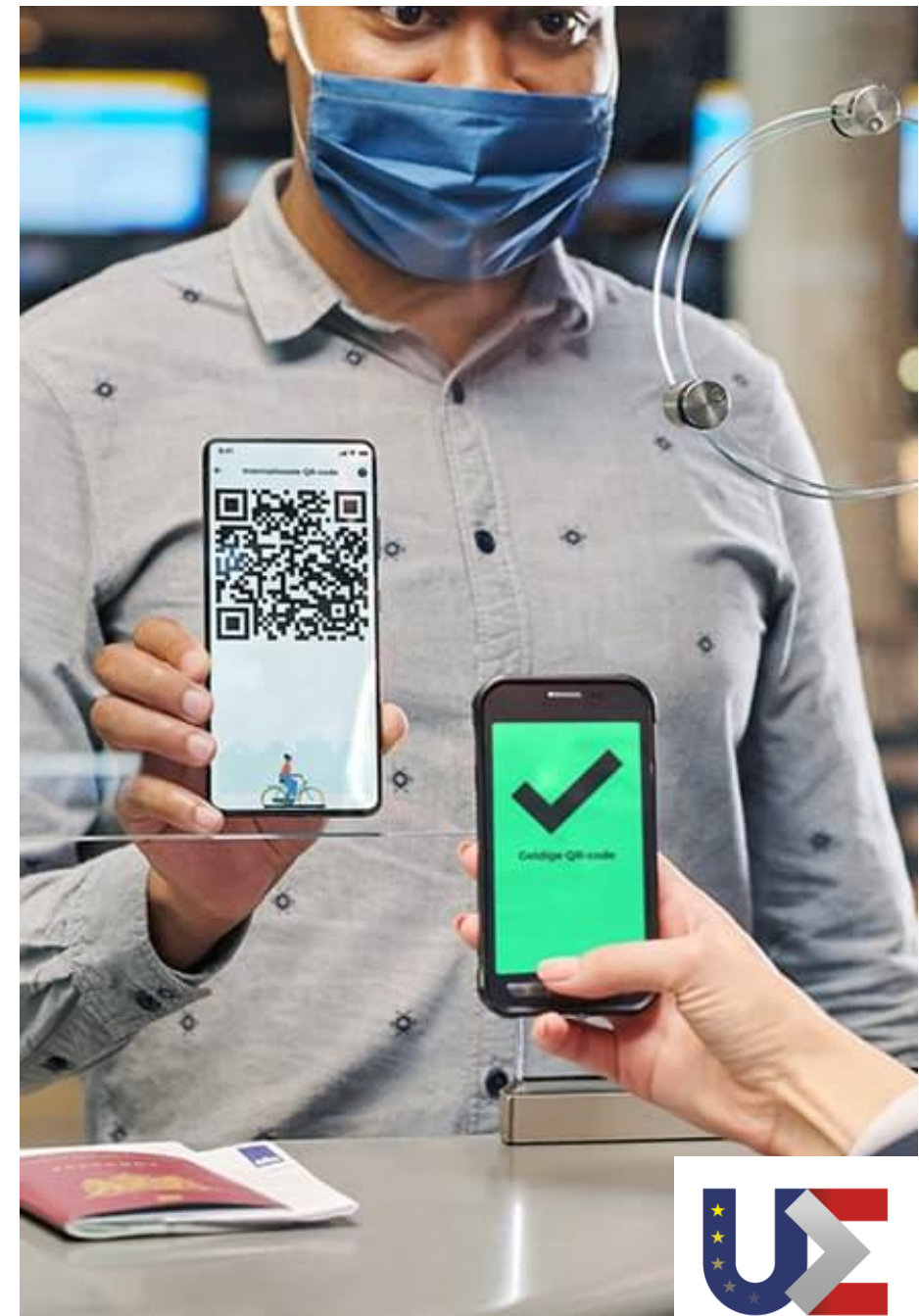
- First assignment: December 2020
- First go-live: June 2021
- From first idea to fully standardised implementation in 6 months

Current status

- Currently implemented in 64 countries, 27 in the pipeline
- More than 1,7 billion certificates issued
- No security breaches (and revocation for fraud and errors)



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Lessons learned

- Shared goal
- Sense of urgency
- Top experts from all MS
- Positive atmosphere
- Flexibility, room to manoeuvre
- Focus - Task Forces
- Quick but not dirty
- Strength through diversity
- Inspirational approach, way of working, results
- From first idea to standards-based implementation in six months!



Current health IT landscape

Shared sense of urgency

Similar challenges

Similar solution directions

Let's join forces!