From EU projects to value sets - an overview

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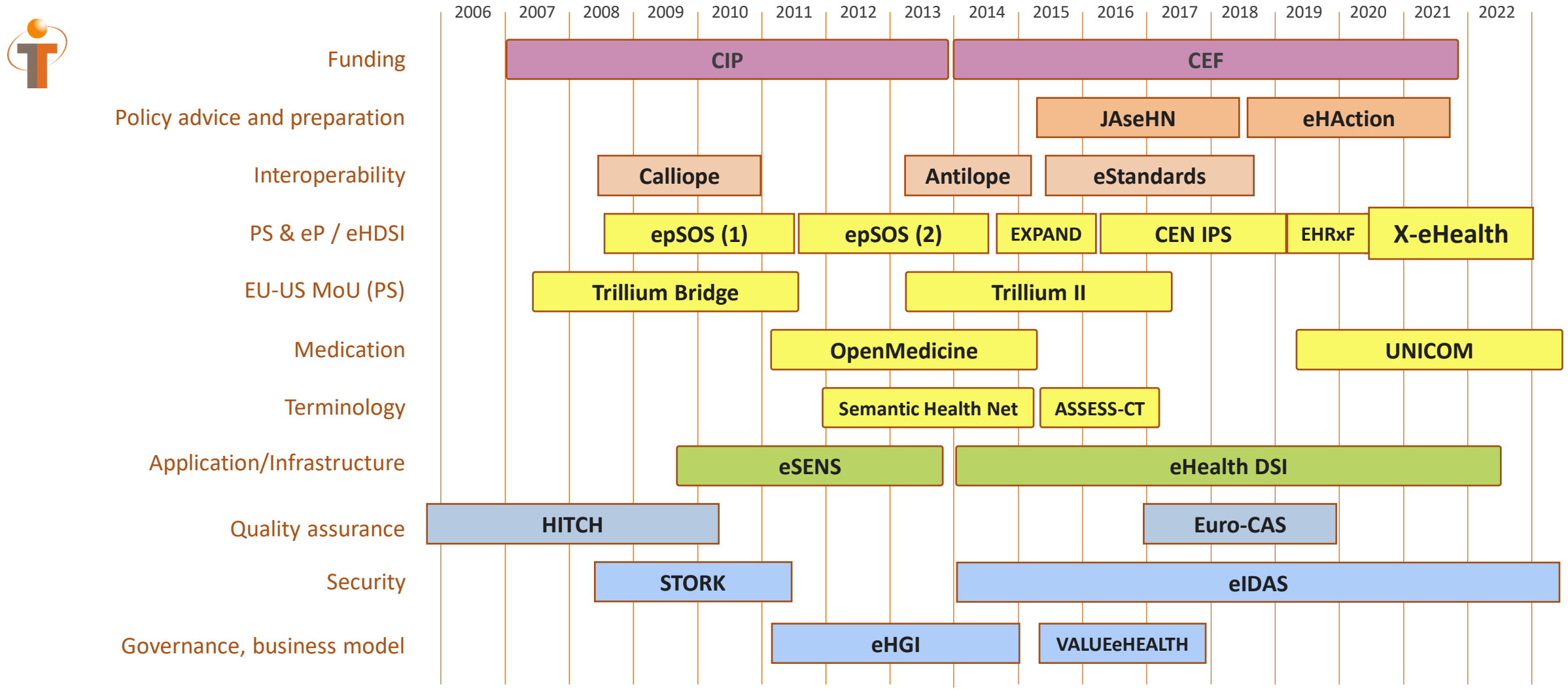
- Chair, eHealth Network Subgroup on Technical Interoperability

October 12th, 2022, KlasifiKon Prague

EU Healthcare IT Projects (Dutch perspective)



X-eHealth

Towards an eHealth Community in Europe

Exchanging EHR in a common framework:

the European EHR Exchange Format (EEHRxF)

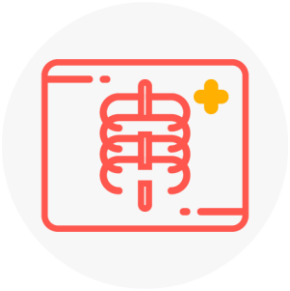
Co-funded by the European Union's Health Programme (2014-2020)

X-eHealth
Exchanging Electronic Health Records in a common framework

X-eHealth Project Scope

X-eHealth
Exchanging Electronic Health Records in a common framework

X-eHealth's purpose is to develop the foundations for a common framework for medical imaging, discharge letters, laboratory results and rare diseases to in addition to the already existing Patient Summary and ePrescription cross-border information exchange.



Medical Imaging

Discharge Letters

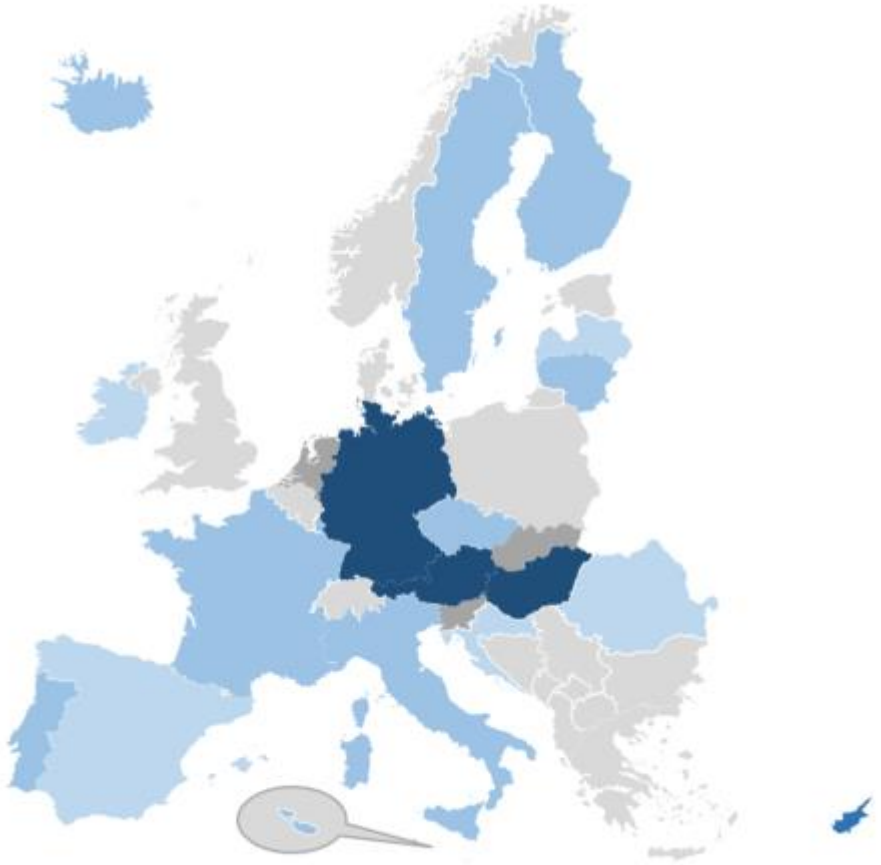
Laboratory Results

Rare Diseases

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant. Agreement Nº 951938

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

Plans to implement structured laboratory results exchange



Application in:

2022-2023: CY, HU, AT, DE

2024-2025: CZ, LU, FR, PT, HR, MT, IT, SE, LT, IS

2026-2027: ES, IE, LV, RO, FI

Unlikely: NL, SI, SK

08/09/2021

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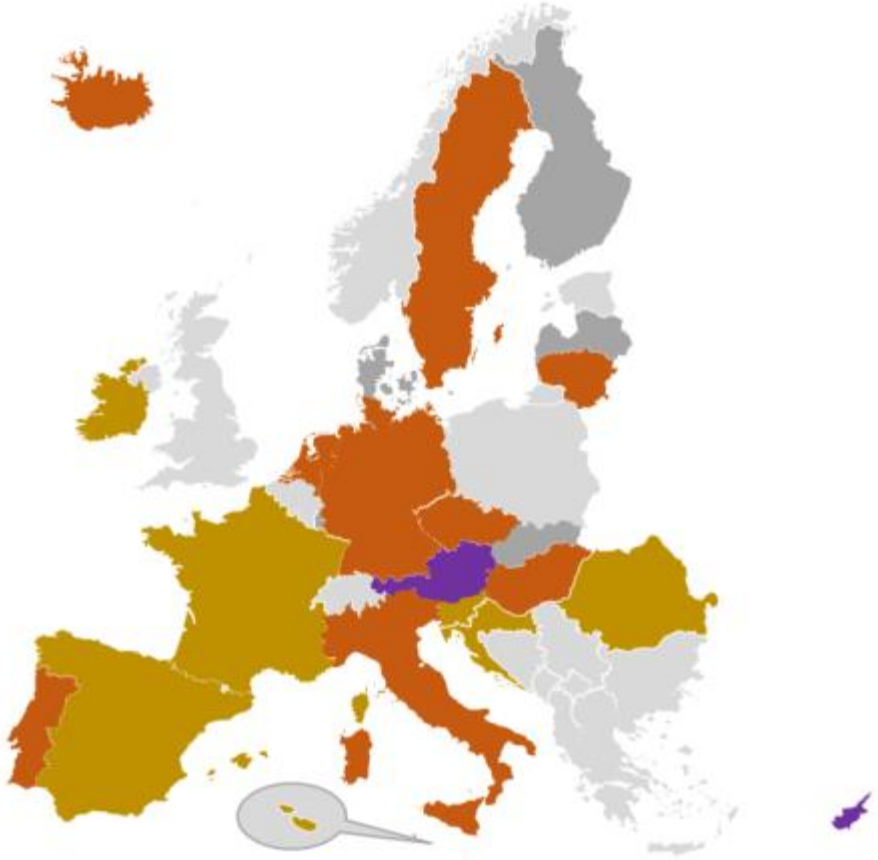
Plans to implement structured medical images/ images reports exchange



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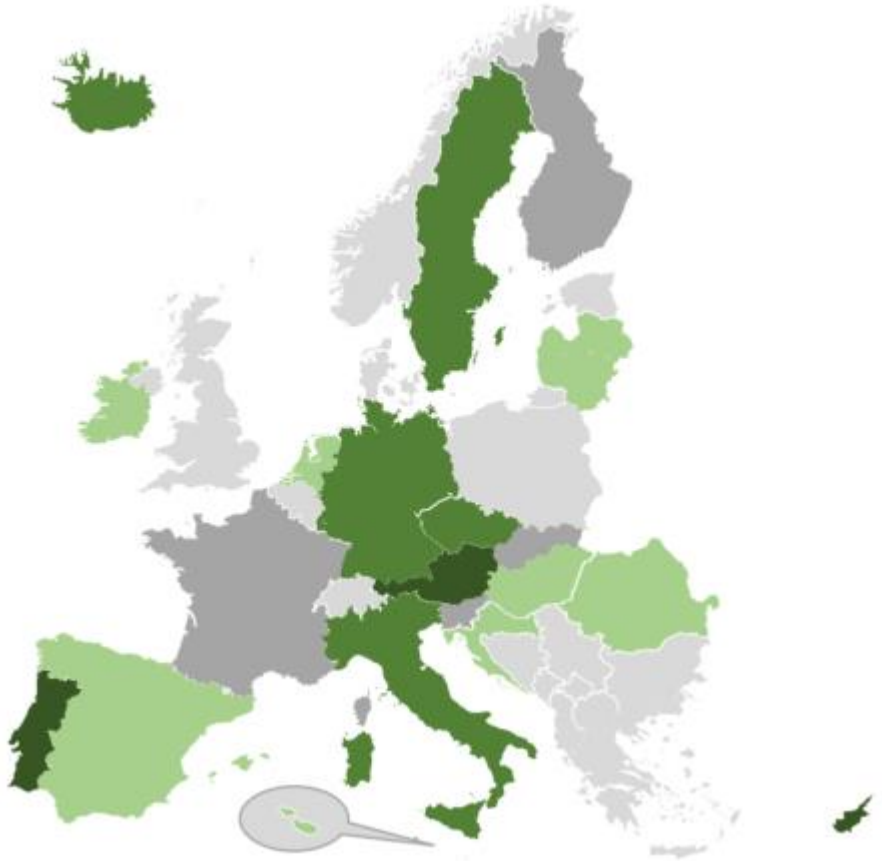
Plans to implement structured hospital discharge letters exchange



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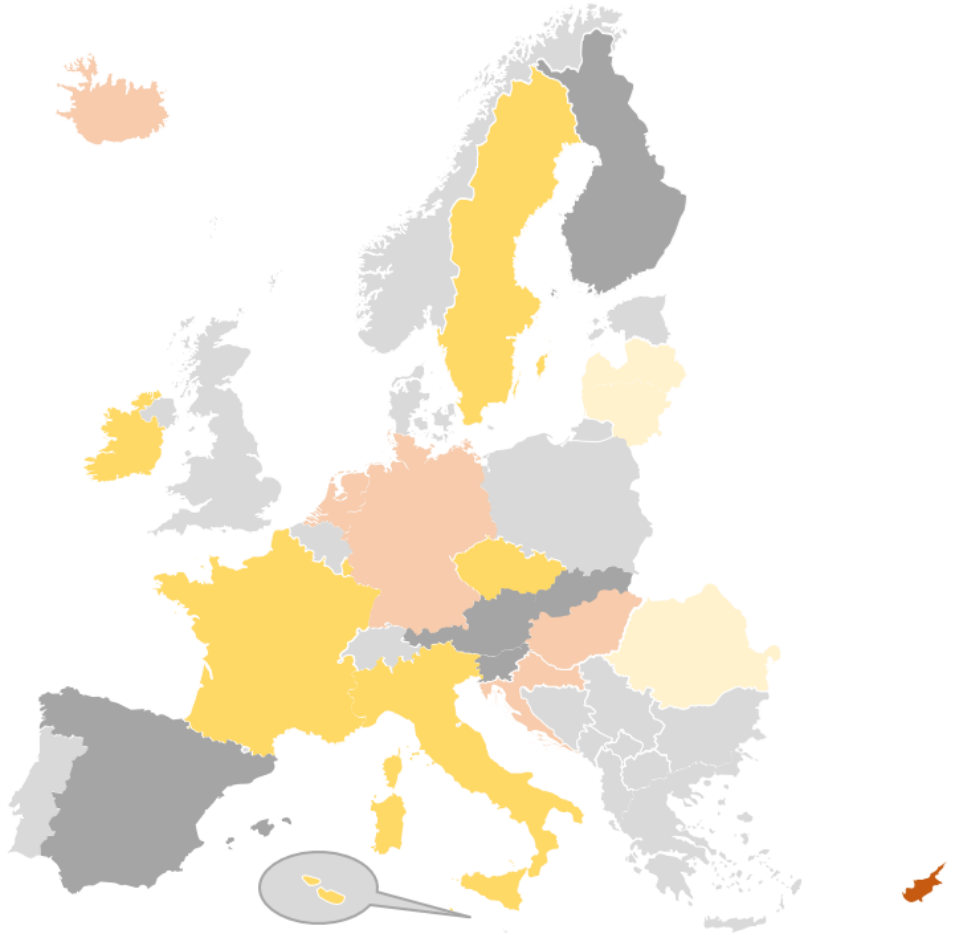
Plans to implement Original Clinical Documents



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08/09/2021

Approach for the evolution of the EEHRxF

X-eHealth
Exchanging Electronic Health Records in a common framework

- Choice of domains: from generic to specific (sunflower model)
- Standardisation approaches
  - Start with the basic Interoperability Framework: ReEIF
  - From functional to technical to implementation specifications - standardisation life cycle
  - From document to paragraph to concept level
    - Document level: metadata
    - Paragraph level: reusable "containers"
    - Concept level: reusable information building blocks (ISO 13972)
- Working methodology
  - Iterative process
  - Involve all stakeholders during the entire process

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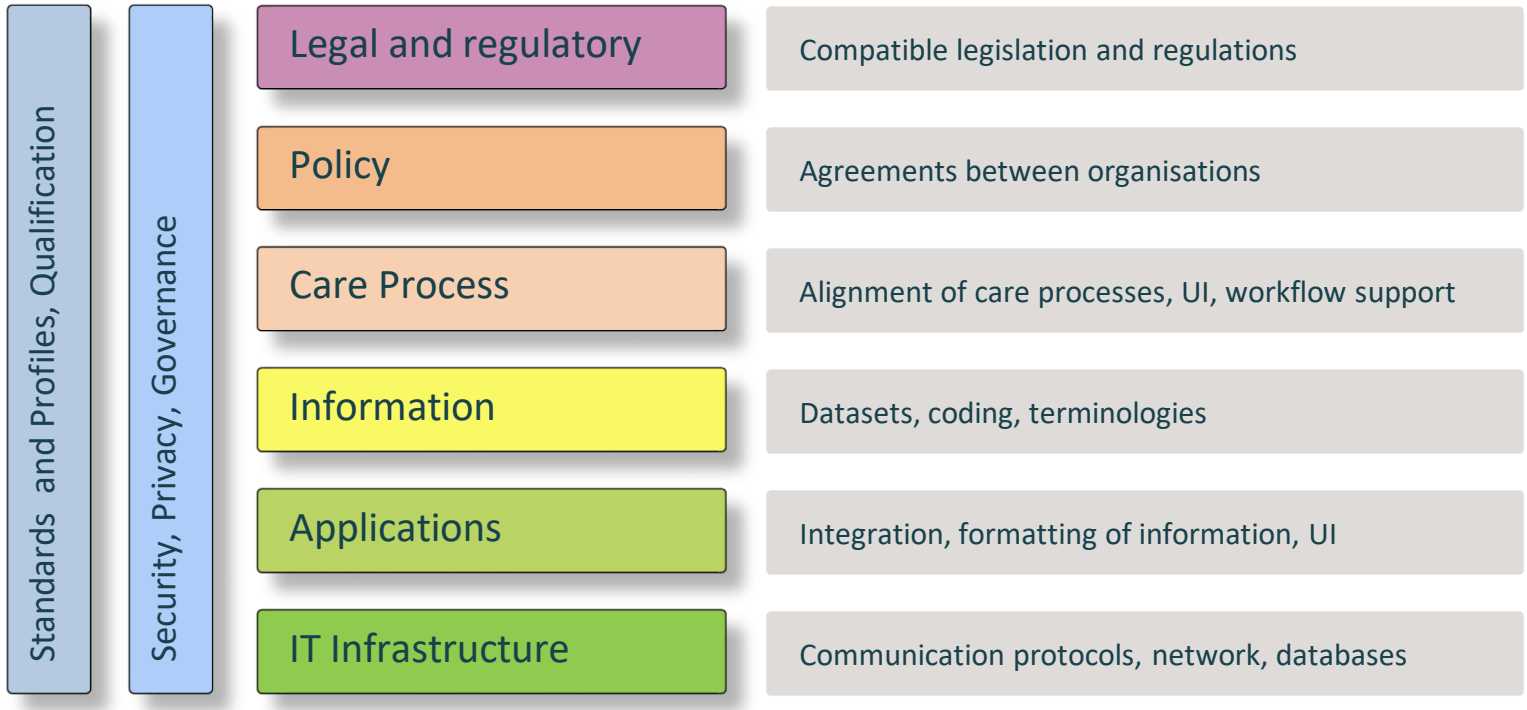
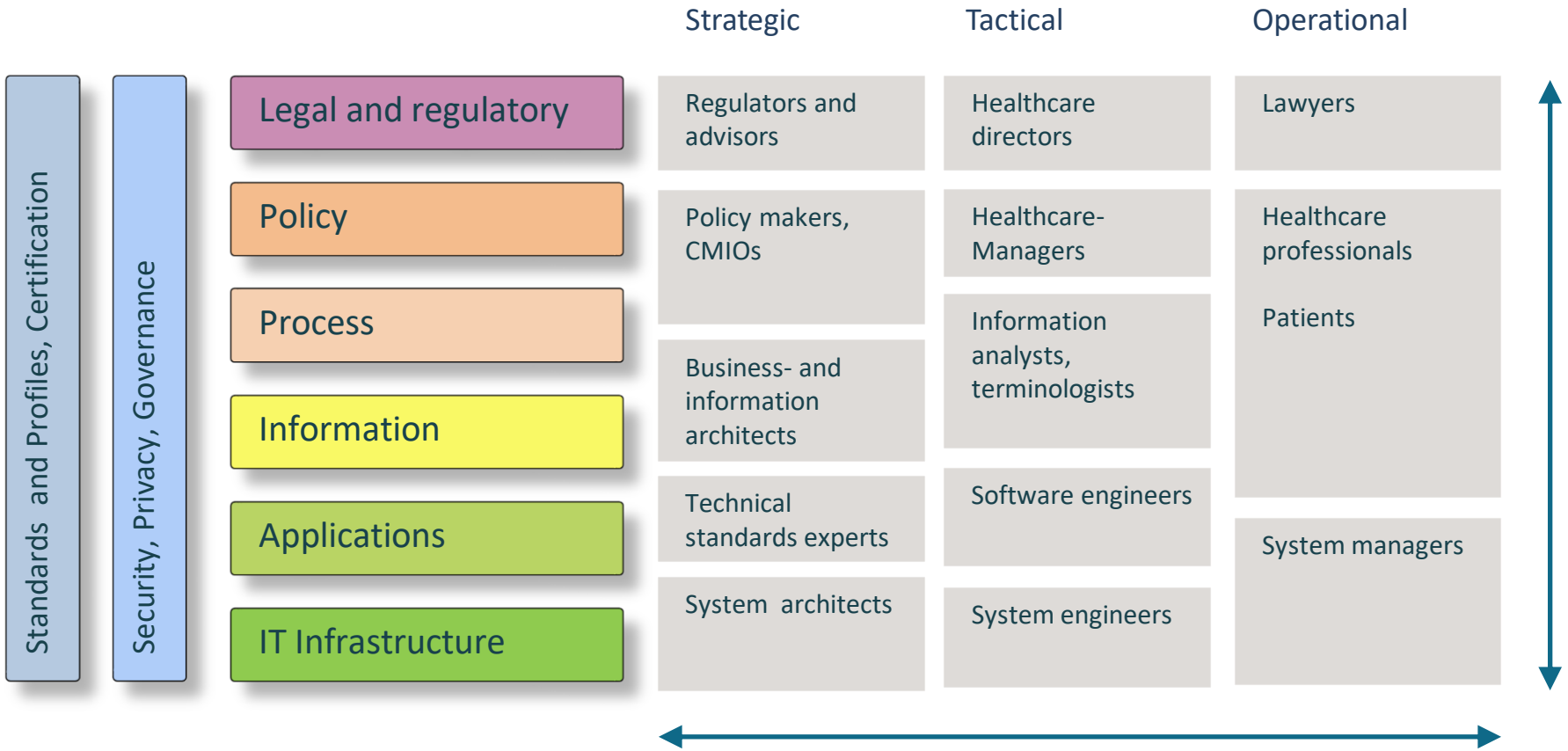
Refined eHealth European Interoperability Framework

- ✓ All aspects of interoperability
- ✓ Flexible
- ✓ Non-technical



Requirement for success: involve all stakeholders

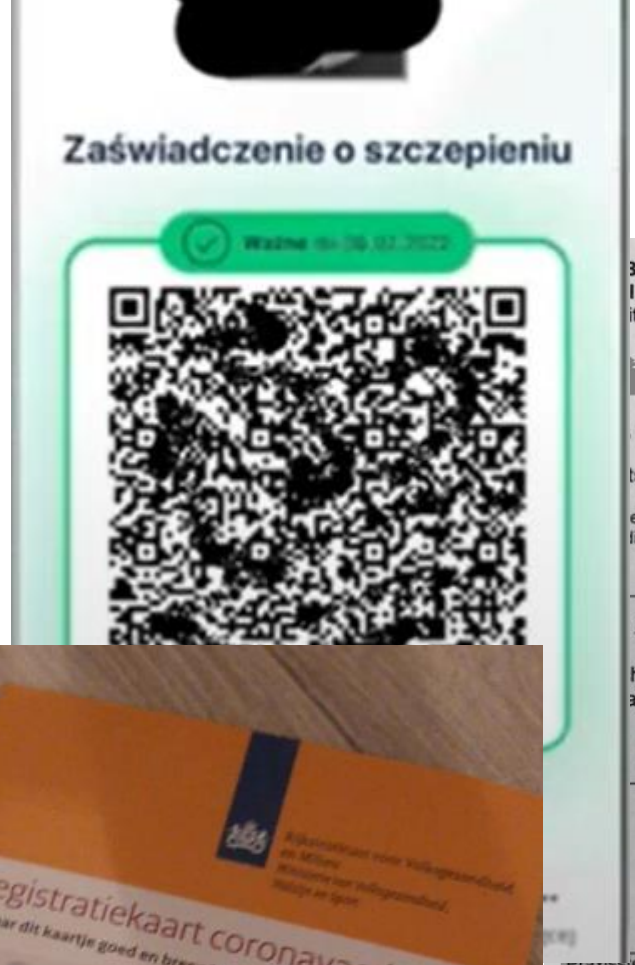


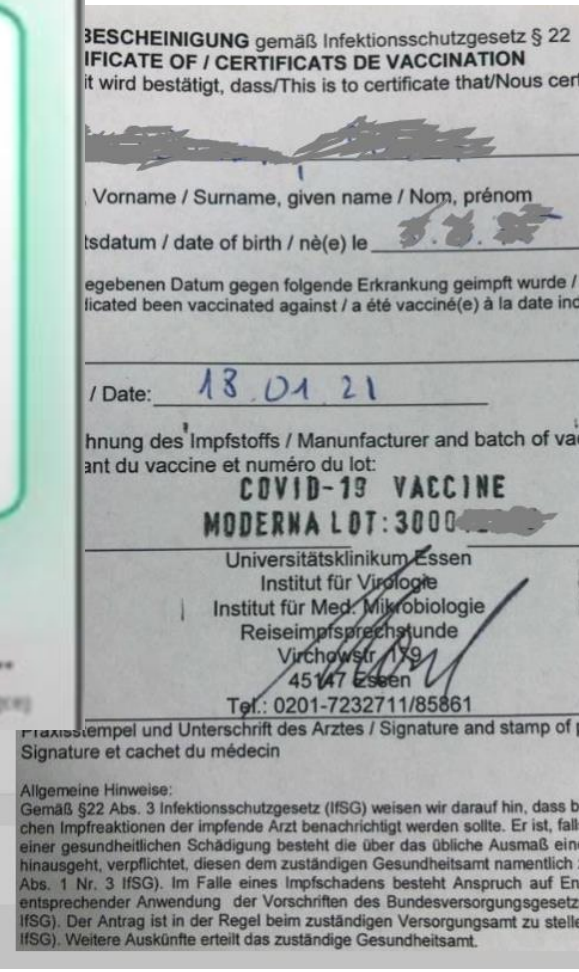
Examples of the use of the ReEIF

- X-eHealth
- EU Digital COVID Certificate
- Your next project

COVID-19 - December 2020

- Each MS had 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





European Commission

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 and private 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 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

eHN SG on Technical Interoperability - the work

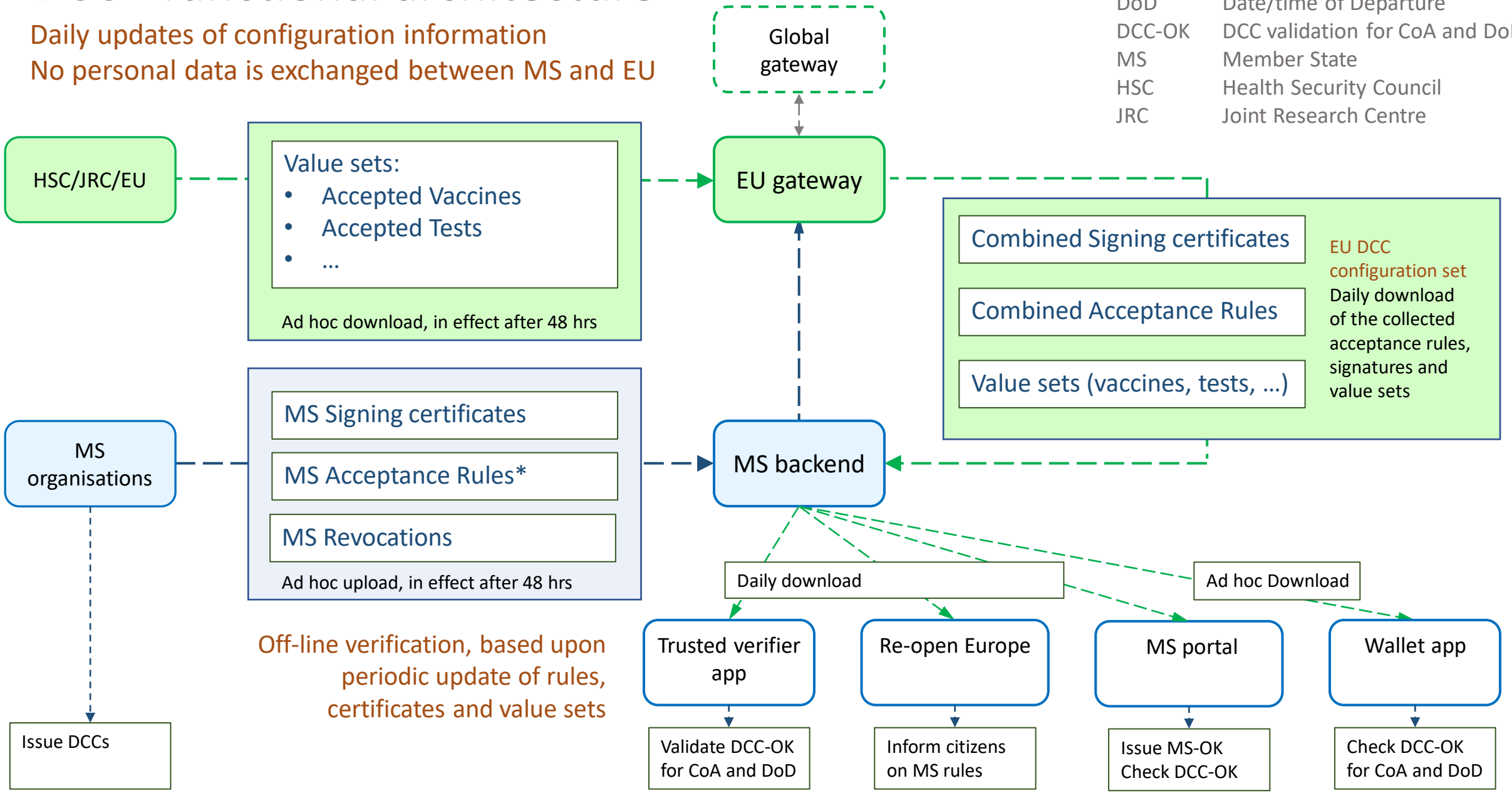
- Top experts from the EU
- Up to 175 participants, meetings almost daily
- Stakeholders:
  - 27 Member States
  - DG CNECT, DG SANTE, DG MOVE, DG HOME, DG JUST
  - WHO, ECDC, JRC, HSC, EDPB
  - ICAO, IATA, A4E, Schiphol/Frankfurt/Paris Airport
  - HL7, IHE, Apple, Alphabet, Microsoft
- Agile, quick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

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



* These may include possible other MS accepted vaccines

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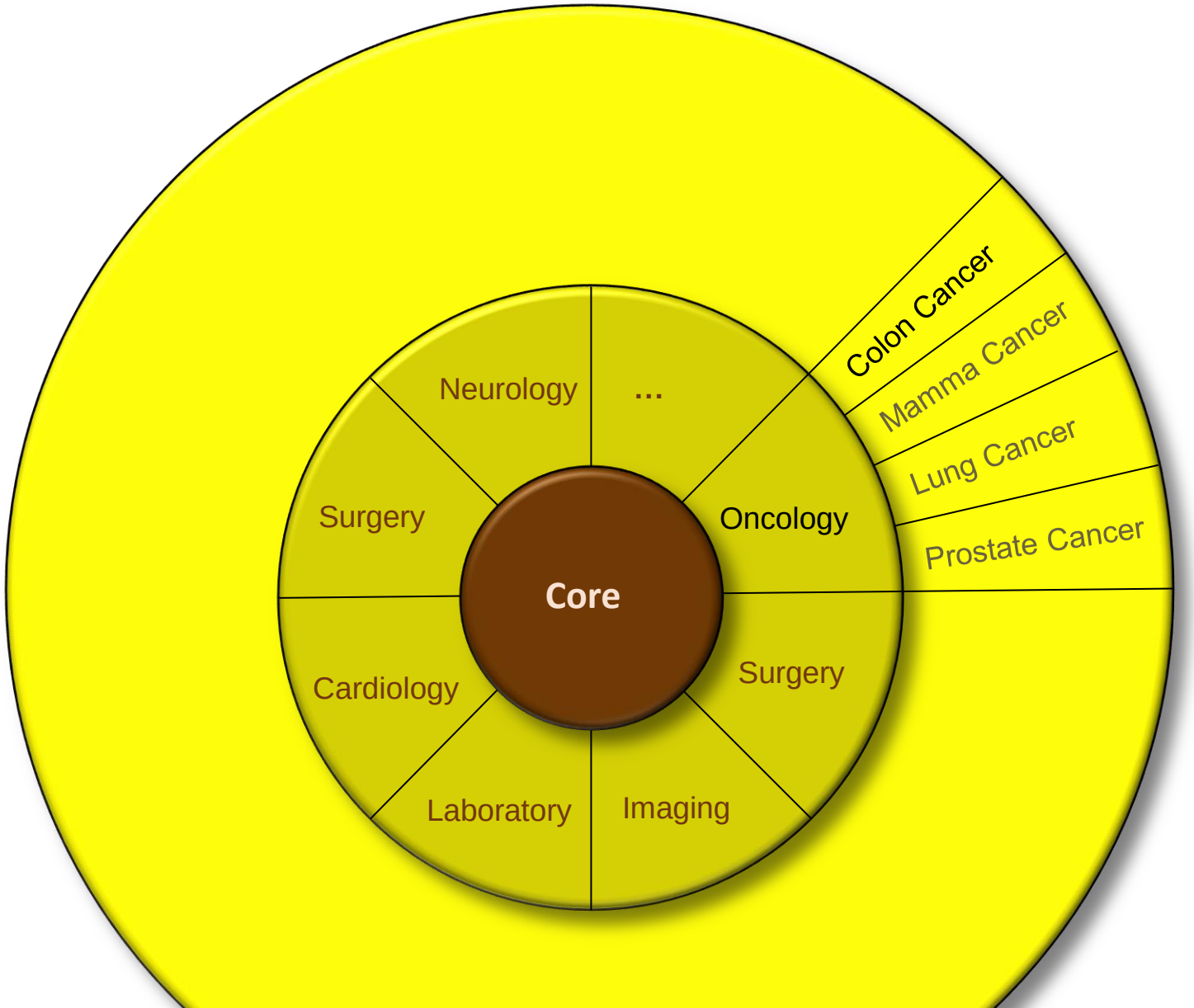
Choice of domains - from generic to specific - the sunflower model

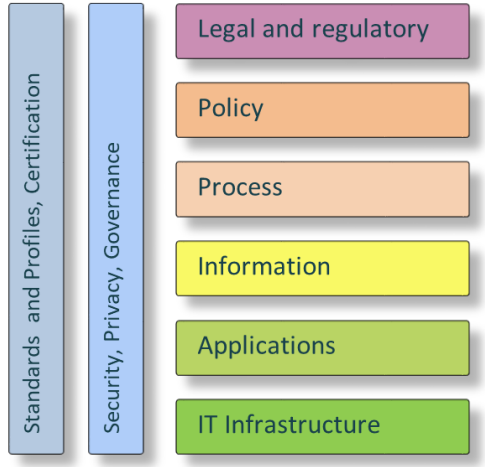


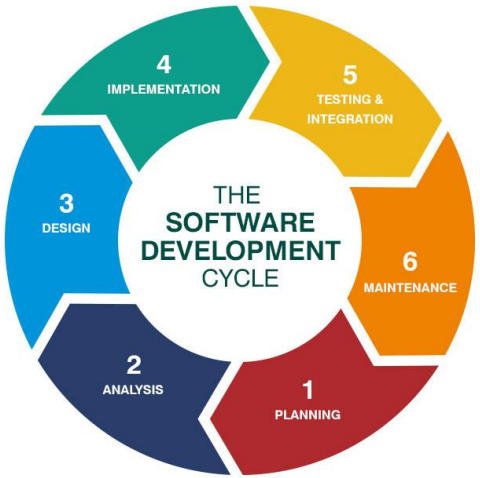
1. Healthcare generic (“Core”)
2. Domain / specialism generic
3. Problem / disease generic

Information standardisation development life cycle

Business need and goals	Legal boundaries, business goals, end user requirements, funding
Organisation policy	Ambition, organisations, stakeholder commitment, contracts
Process analysis	Protocols and procedures, workflow, information exchange
Use case	Process analysis, process steps, information exchange
Functional specification	Data sets, valuesets, data modelling, terminology binding
Technical specification	Constraints, cardinality and conformance, technical format
Implementable specifications	Development, integration, configuration
Testing and qualification	Quality assurance, technical and acceptance testing
Implementation and integration	Usability, ergonomics, applicability, completeness
Evaluation, version management	Change proposals, version management, innovation

ReEIF





Level of detail- the Matryoshka model

1. Document
   2. Paragraph
      3. Concept / value

Different levels of detail provide context to the information

1. Start at the document level

- Green field, blue ocean: start big, end small
- Use metadata to filter, group, sort, order, select
- Basis for content-driven authorisation and consent
- Quick access to the right information at the right moment

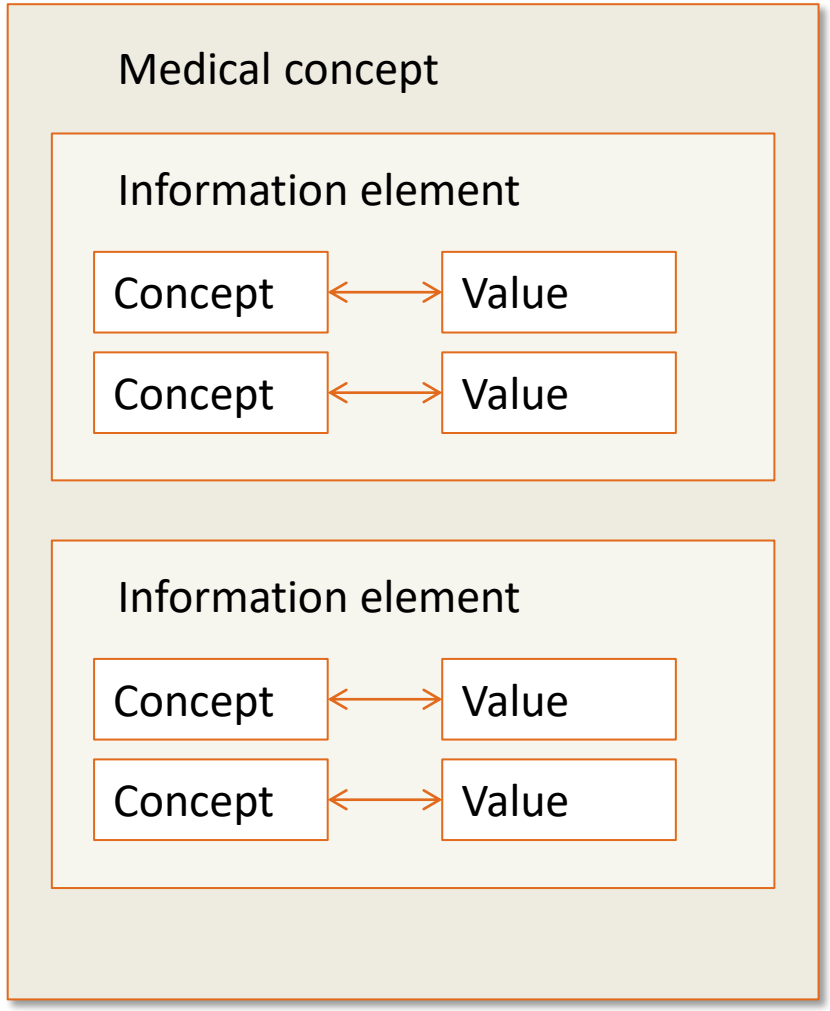
2. Create some document structure at the paragraph level

- Brings structure to the report / document, impact not too big
- Possibility for automatic retrieval of the ‘Conclusion’ part into a discharge report

3. Specify the separate information elements

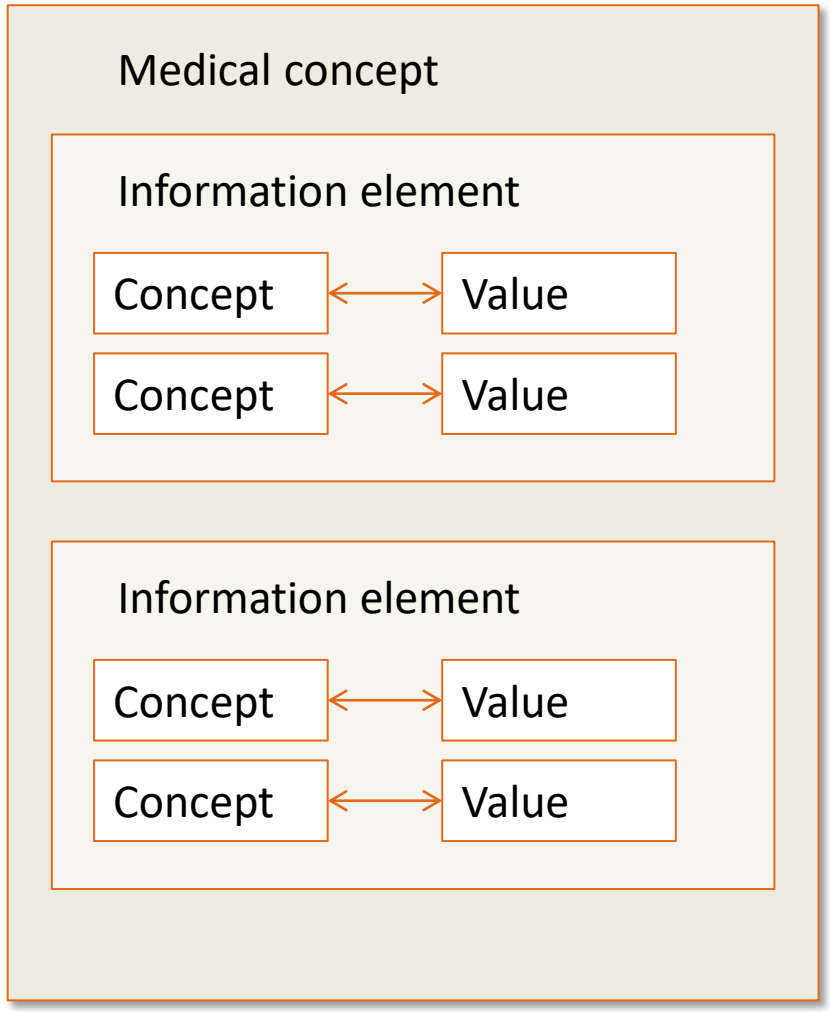
- Basis for information reuse, better quality and efficiency of healthcare
- Specification of medical concepts, linking to terminologies

Concept - value level - information building blocks



- Identify a medical concept
- Identify the constituting components (data modelling)
- Specify both concepts and values
- Bind them to terminologies (where relevant)

Information building blocks



Main value types

- Numerical (with Unit of Measurement)
- Datetime (flexible)
- Boolean
- Coded list (binding to terminology)
- Free text

Thank you!

Betere zorg
door betere informatie
Nictiz

Legal and regulatory	Compatible legislation and regulatory guidelines define the boundaries for interoperability across borders, but also within a country or region. Implementation guidelines on how to implement legislation.
Policy	Contracts and agreements between organisations. Trust and responsibilities between the organisations are formalized on the Policy level.
Care process	Cooperating organisations specify shared or aligned care processes, resulting in integrated care pathways and shared workflows. Use cases, tracking and management of workflow processes on a non-technical level.
Information	The functional description of the data model, the data elements (concepts and possible values) and the linking of these elements to terminologies define the interoperability of the data elements.
Applications	The technical specification of how information is transported is at this level (communication standards). The information systems must be able to export and import these communication standards. Also, interfaces between applications are described at this level (APIs).
IT Infrastructure	The generic communication and network protocols and standards, concerning storage, backup and the database engines. This layer contains mostly “generic” interoperability standards and protocols.