Patient centric European electronic patient records – from promise to delivery?

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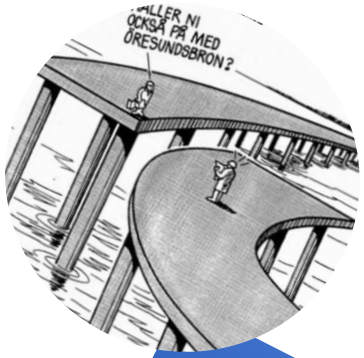
10-year Journey of laying the foundations



2008-2016
epSOS, CALLIOPE, EXPAND

CEF 2016-2020,
eIDAS, GDPR, NIS

Beyond CEF 2020

Optimizing Multi-Stakeholder Value Chains
CEF eHDSI (infrastructure)
Value Generation Flow

CEF eHDSI Funders

- MS and Regions
- EC
- Public/private payers
- Potential competitors

Providers of CEF eHDSI

- National Competence Centers
- EC
- ICT industry
- SDOs, etc.
- Scientific Associations

Users of eHDSI

- National Infrastructures
- Cross border eHealth services providers

Beneficiaries of eHDSI

- Enabled cross border services
- SDOs

Capturing Value → **Creating Value** → **Delivering Value**

Optimizing Multi-Stakeholder Value Chains

CEF services (cross border ePr, PS)

Value Generation Flow

CEF services Funders

- MS and Regions
- EC
- Public/private payers
- Potential Competitors

Providers of CEF services

- National Competence Centers and EC
- Health Providers, care networks
- EC (ERN portal)

Users of CEF services

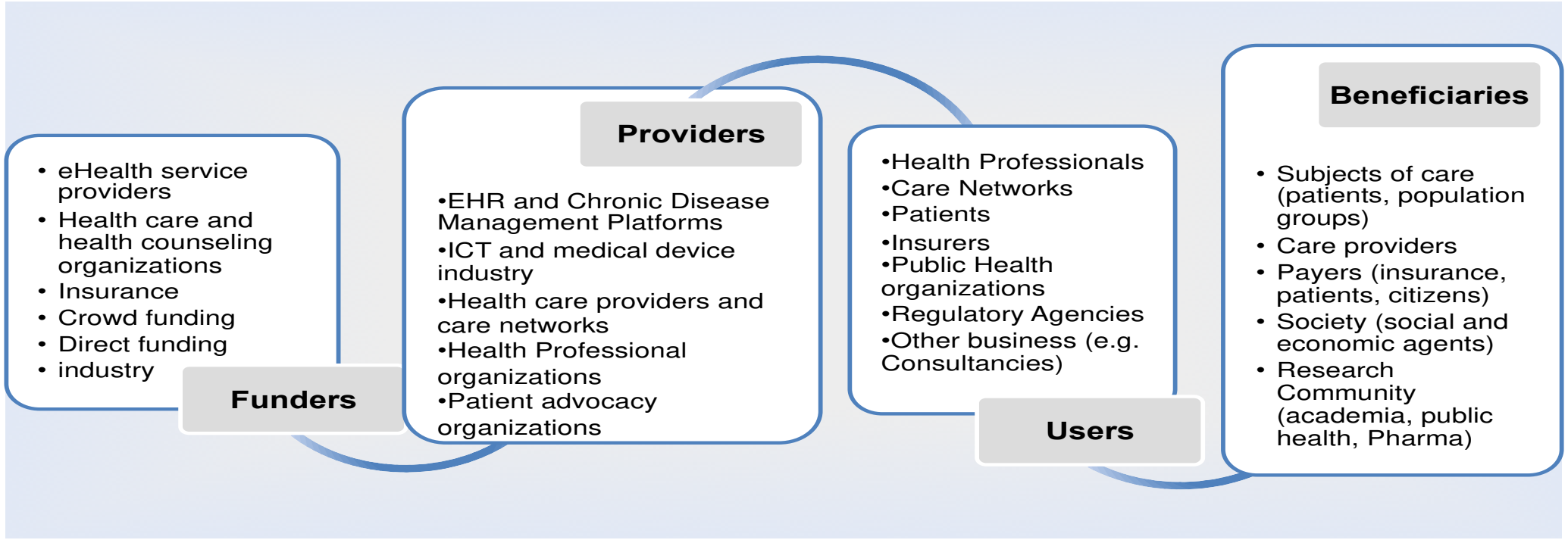
- HPs and HCPs
- Patients
- Insurers

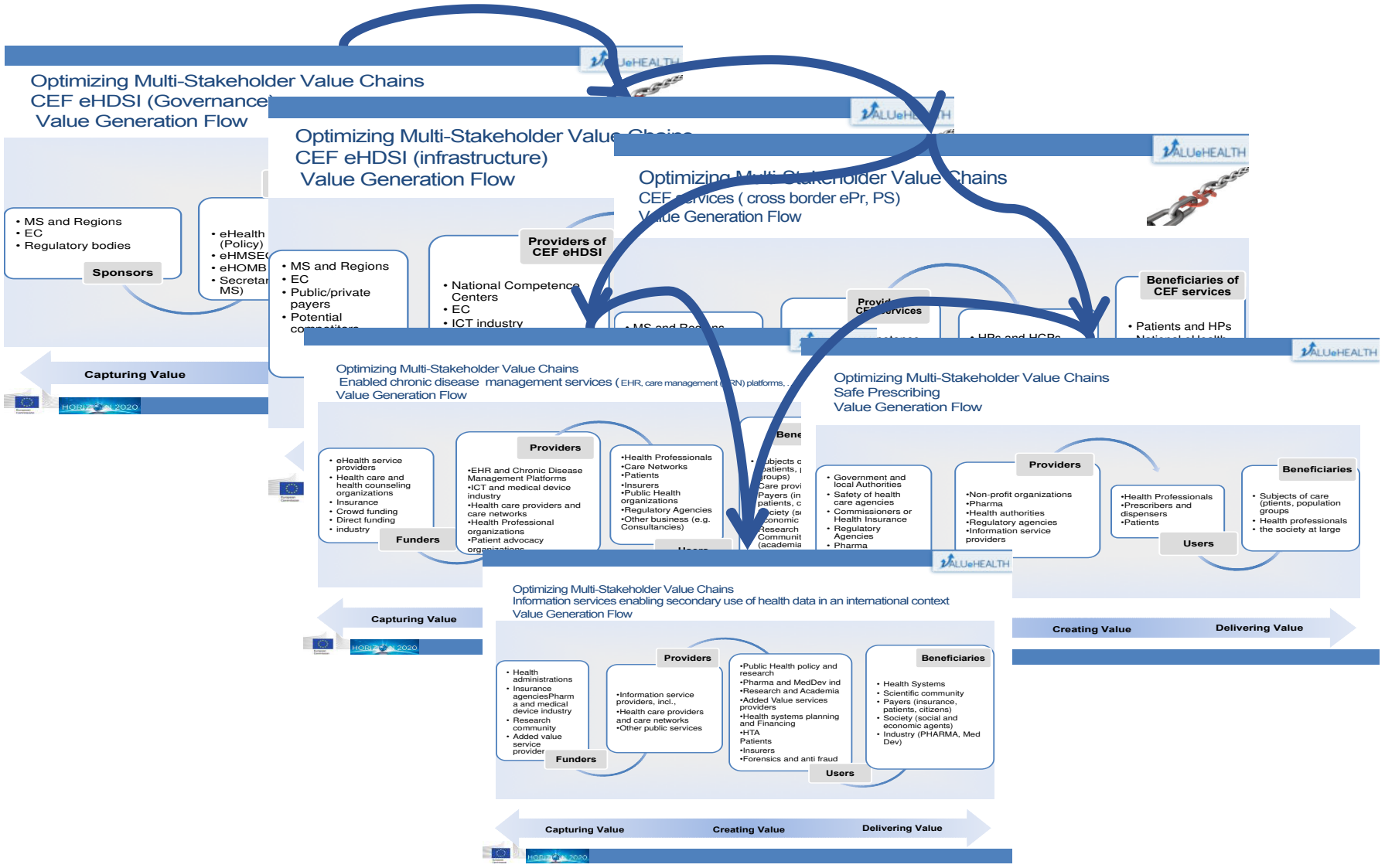
Beneficiaries of CEF services

- Patients and HPs
- National eHealth Systems
- National health service and ICT industry
- Health Service Providers

Capturing Value → **Creating Value** → **Delivering Value**

Optimizing Multi-Stakeholder Value Chains
Enabled chronic disease management services (EHR, care management (ERN) platforms, . . .)
Value Generation Flow




Optimizing Multi-Stakeholder Value Chains
CEF eHDSI (Governance)
Value Generation Flow
• MS and Regions
• EC
• Regulatory bodies
Sponsors
• eHealth (Policy)
Capturing Value
Optimizing Multi-Stakeholder Value Chains
CEF eHDSI (infrastructure)
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• MS and Regions
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Optimizing Multi-Stakeholder Value Chains
Enabled chronic disease management services (EHR, care management
Value Generation Flow
• eHealth service providers
• Health care and health counseling organizations
• Insurance
• Crowd funding
• Direct funding
• industry
Funders
Providers
•EHR and Chronic Disease Management Platforms
•ICT and medical device industry
•Health care providers and care networks
•Health Professional organizations
•Patient advocacy
•Health Professionals
•Care Networks
•Patients
•Insurers
•Public Health organizations
•Regulatory Agencies
•Other business (e.g. Consultancies)
Optimizing Multi-Stakeholder Value Chains
Safe Prescribing
Value Generation Flow
• Government and local Authorities
• Safety of health care agencies
• Commissioners or Health Insurance
• Regulatory Agencies
• Pharma
Providers
•Non-profit organizations
•Pharma
•Health authorities
•Regulatory agencies
•Information service providers
•Health Professionals
•Prescribers and dispensers
•Patients
Users
Beneficiaries
• Subjects of care (ptients, population groups
• Health professionals
• the society at large
Capturing Value
Optimizing Multi-Stakeholder Value Chains
Information services enabling secondary use of health data in an international context
Value Generation Flow
• Health administrations
• Insurance agenciesPharma and medical device industry
• Research community
• Added value service provider
Funders
Providers
•Information service providers, incl.,
•Health care providers and care networks
•Other public services
•Public Health policy and research
•Pharma and MedDev ind
•Research and Academia
•Added Value services providers
•Health systems planning and Financing
•HTA
Patients
•Insurers
•Forensics and anti fraud
Users
Beneficiaries
• Health Systems
• Scientific community
• Payers (insurance, patients, citizens)
• Society (social and economic agents)
• Industry (PHARMA, Med Dev)
Capturing Value
Creating Value
Delivering Value
Creating Value
Delivering Value

Foresight exercise – CEF 2020 and beyond

Iria Acosta in need of unplanned treatment/medication while in another country

- *Iria Acosta is a financial analyst of 33 years old. She lives in Portugal and for the past 3 weeks, has been working on a short-term assignment for the Portuguese branch of an international bank located in the London Financial District. … In order to stay fit, Iria enjoys exercising.*
- *Iria has Type 1 diabetes and was diagnosed at the age of 10. … She has started using a mobile application to help her manage her diabetes. …*
- *Iria experiences an emergency situation while jogging out in cold weather and having left her medication behind..*

eHDSI for Iria - today

The mobile health solutions have empowered Iria to build her own health profile, and to share her self-monitoring health data (glycaemia levels, weight, etc.) with the health professionals involved in her care plan (endocrinologist, GP, pharmacist and nutritionist) through secured access rights.

Possibly, Iria's health data is captured and stored in a way that makes it possible to share amongst different physicians of different disciplines within Portugal. **However,**

1. Scope Limitation: *only what is part of her patient summary can be exchanged across borders.*

The smartphone has immediately and automatically transmitted Iria's glycaemia values to the OCC, which also provides real-time access to her patient summary contained in her electronic health record (EHR) based in Portugal.

….. a UK-based on duty emergency physician at a London clinic near to Iria's location is immediately contacted by the OCC in Portugal. Iria's current glycaemia values are then assessed in relation to her diabetes medical summary, prescriptions and recent care/monitoring data that are on file in Portugal…

It is quite likely that at national level, Iria has provided informed and specific consent for her care team to have access to her electronic health record that can be meaningfully read by all HPs in her care team **BUT**

2. Access Limitations

- *Sharing data with a treating physician in an emergency situation in another country is possible only with the patient on site*

As Iria is too confused to remember her insulin regimen, thanks to the real-time consultation system enabled by her EHR, the UK physician is able to confirm her last insulin regimen, thus ensuring safe prescribing in accordance with her medication profile in Portugal. The doctor is also able to place an e-referral with Iria's endocrinologist in Portugal asking him to reassess Iria's insulin dosage upon on return to Portugal the following week, in order to reflect her more active life style. Iria is sent home, perfectly fine, an hour later.

3. Geographical limitations

The current cross border scenario will be activated (if both UK and PT have deployed cross border eHealth services)

- *Iria will be "identified" by the HP and will provide on-site consent*
- *The request for access will be mediated by the two NCPs*
- *The PS will be retrieved and converted to EU format and presented in English*
- *An emergency "break glass" procedure is also possible*

Later, back in Portugal, upon filling out Iria's new prescription, her pharmacist checks that both the new insulin dosage and administration schedule are recorded in the patient mobile e-diary that Iria uses to record her daily activities and health status, so that she can also get auto-reminders to refill her prescription….

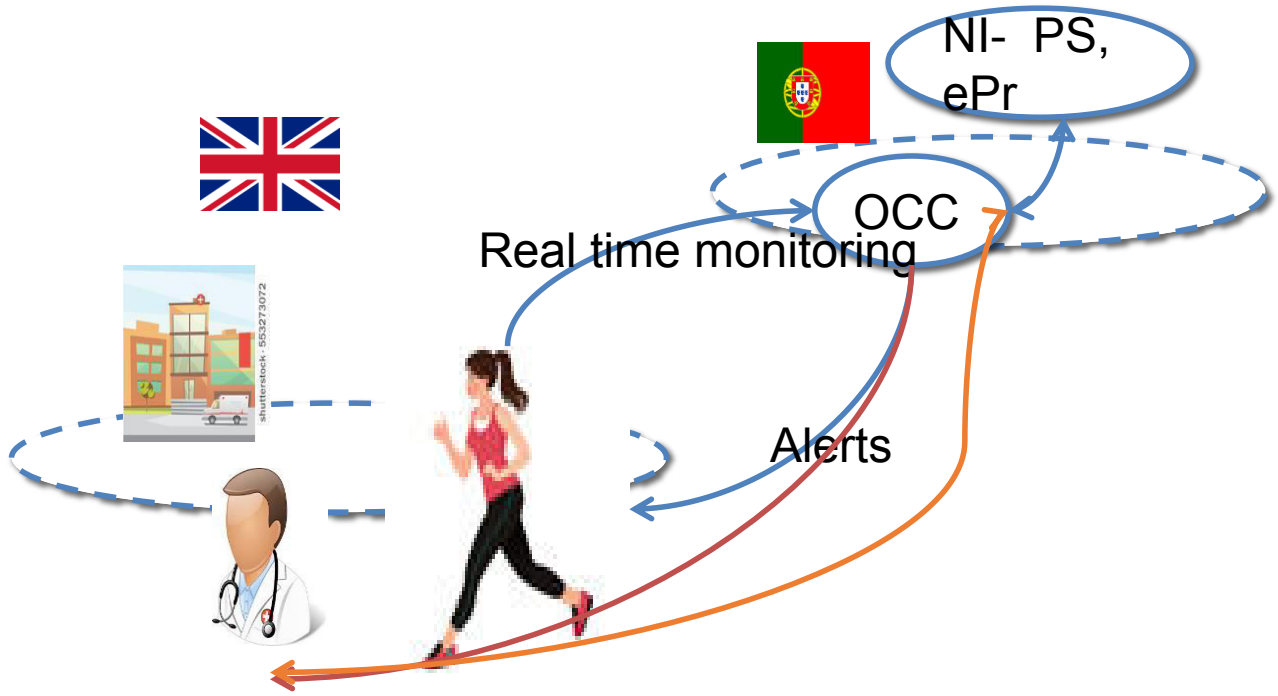
If Iria had medication dispensed in London, an e-dispensation message will be sent back to the Portuguese national ePrescription infrastructure and the relevant active e-prescription list will be updated accordingly. **However,**

4. Continuity limitation

none of the information, referrals and e-prescriptions originating from this encounter will appear in the national systems.

What are the road blocks today?

- Geographical Coverage
  - Political will and priorities
- Current Scope of CBeHIS
  - Scalability?
  - Enabler for Innovation
- Patient as an active node
  - Provider and consumer of information
  - Determining access to own health data
- Networked care
  - ERN is an example
  - Wide applicability solution



A new Governance paradigm

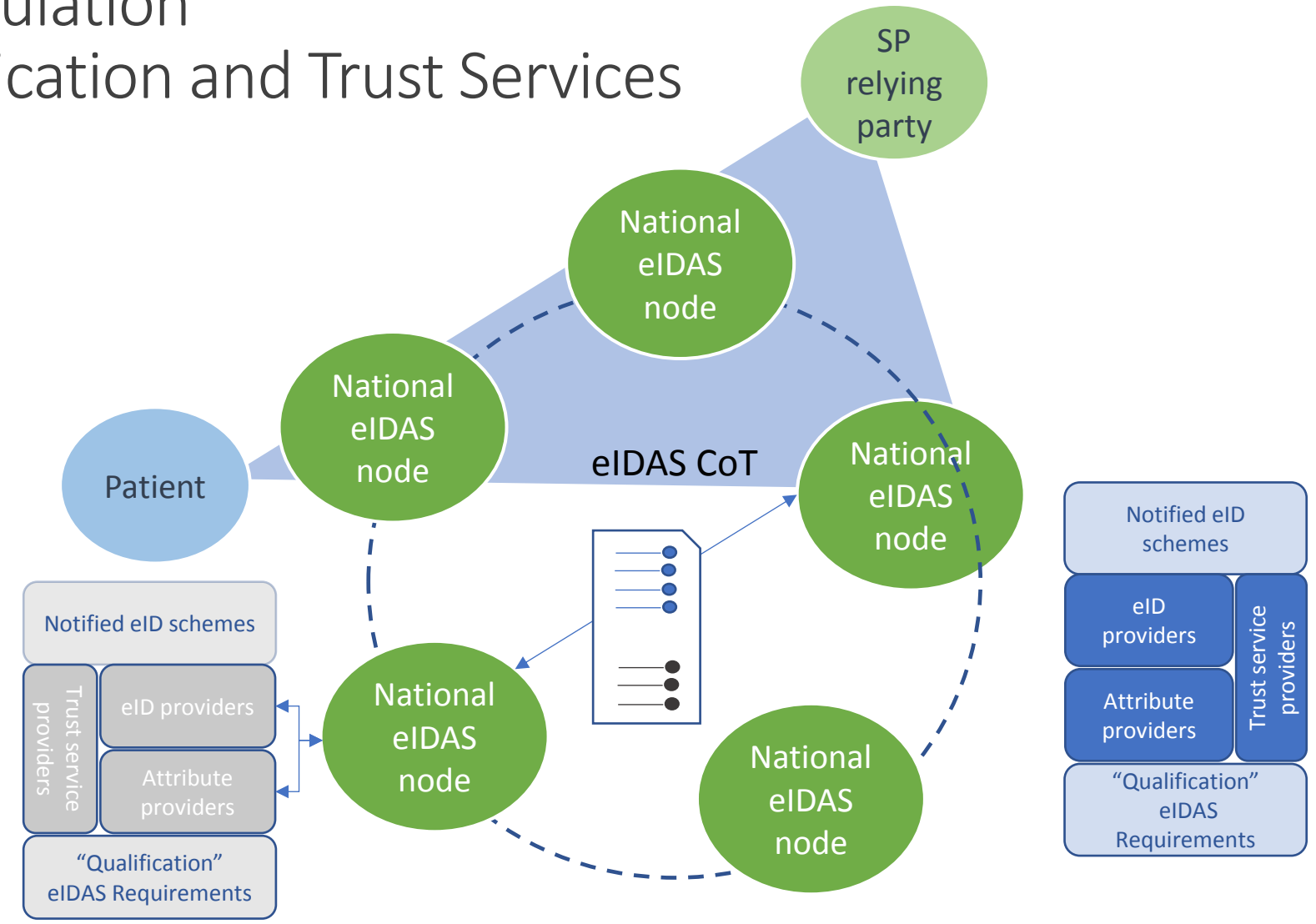
Enabling EU legislation

eIDAS, GDPR, NIS Directive

What if ….. - patient as an active node

- Would be identified and authenticated within and across border
  - At an appropriate Authentication level
  - Within a non-discriminating system
  - In a legally secure environment – incl. liability
- Be provided Interfaces for interacting with the eHR systems
  - For managing consent
  - For accessing data
  - For enabling access to it by his trusted parties

eIDAS Regulation
e-Indentification and Trust Services



EU coverage – What if

- All Iria's health data custodians could share data
  - Within border and cross border
  - Through secure infrastructures – e-delivery, GWs, Connectors, Platforms
  - Meeting predefined criteria – legal effects
- Both public and private players
- On-boarding a scalable health care community

Qualified electronic registered delivery service

Associated legal effect to the qualified e-registered delivery service

- Non-discrimination as evidence in court vis-à-vis paper equivalent
- **Data sent and received enjoy the presumption of**:
  - the integrity of the data,
  - the sending of that data by the identified sender,
  - the receipt of the data by the identified addressee
  - the accuracy of the date and time of sending and receipt of the data.

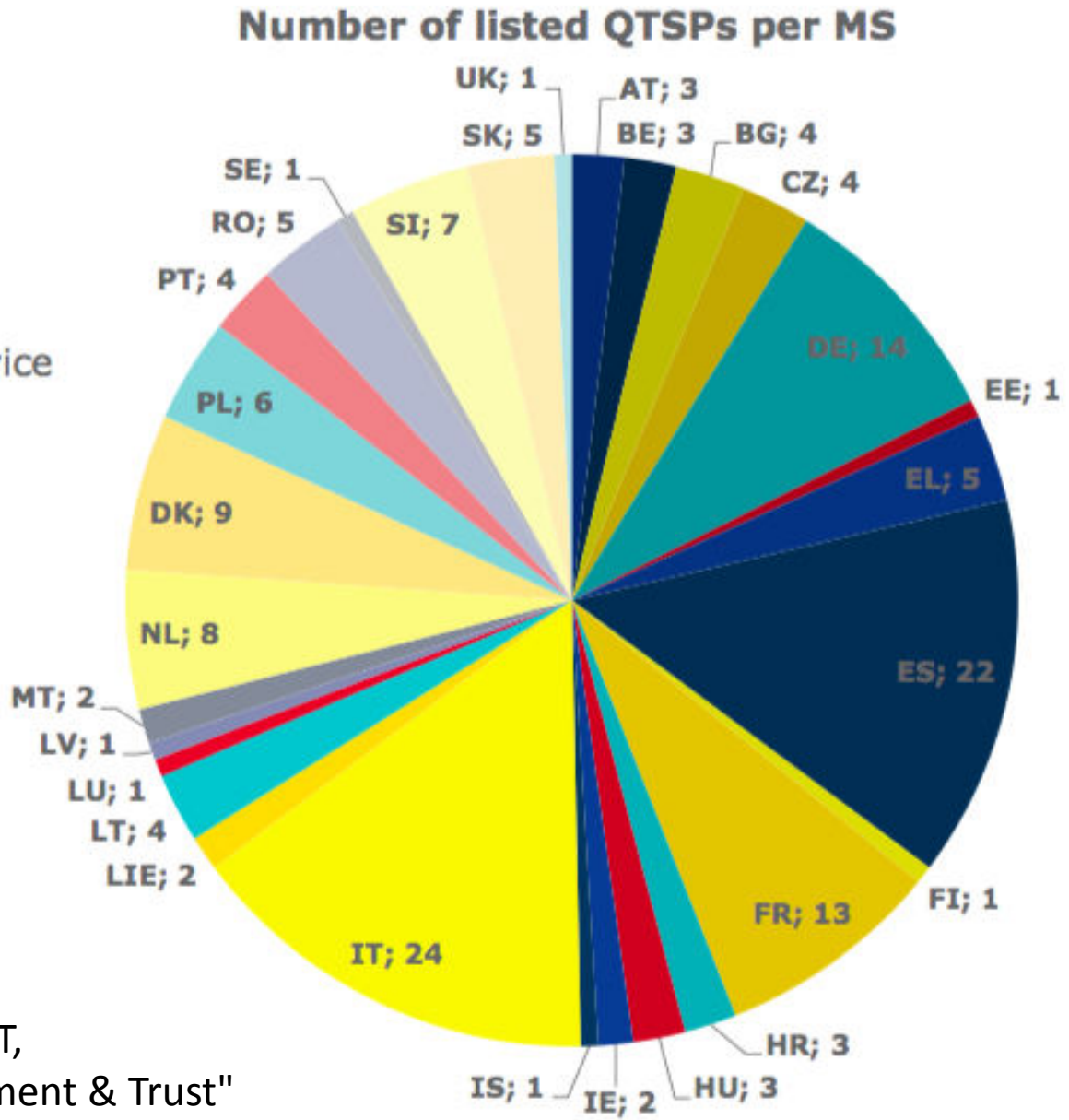
SOURCE: Andrea Servida, DG CONNECT, European Commission Unit "eGovernment & Trust"

European Commission

Trust services: where we stand

Electronic trust services

- Electronic signatures
- Electronic seals
- Time stamping
- Electronic registered delivery service
- Website authentication



SOURCE: Andrea Servida, DG CONNECT,
European Commission Unit "eGovernment & Trust"

What if ….. scalability

- Onboard public and private health care providers
  - Sharing lab data, imaging…omics, life long records, detailed instances
- Onboard key partners
  - Competence centers, App providers, VASPs, SDO's….
- Create networks of care….
- For EU citizens
- Around transparently governed eHR Platforms

Is the future of European eHRs really here?

Major legal enablers

- From eHealth Strategies to Innovation Strategies
- From today's institutional culture to a governance culture
  - Making the best use of the new legislative framework

but also outstanding eHealth Challenges

- semantic interoperability, data quality,
- clinical governance, clinical liability
- an empowered patient culture

Thank you!

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