xShare

Transforming Health Data Access for Patients in Europe

The Yellow Button experience within the European Health Data Space

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Introduction to xShare project

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xShare…

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

xShare EHR Xchange Format

..Expanding the European **EHRxF** to

share and effectively use

health data within the **EHDS**

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The xShare three pillars

The “Yellow button”

Everyone can **share their health data** in EEHRxF with a “**click-of-a-button**”

The Hub

Build a **European EHRxF Standards and Policy Hub** sustainable by design.

The Industry label

Explore the **feasibility** and **value** of an EU xShare Industry label

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EHDS, the format, and xShare

xShare Vision: Everyone can share their health data in EEHRxF (the format) with a click-of-a-button in the European Health Data Space (EHDS)

Vision → Mission → Goals → Priorities

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

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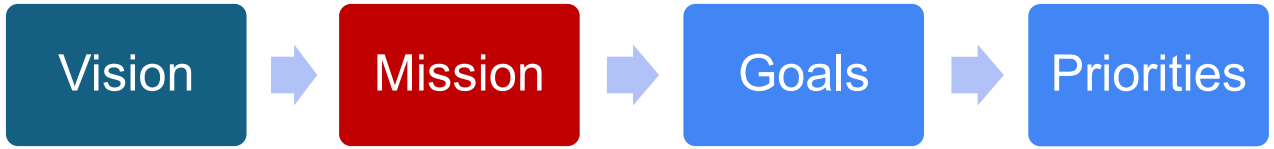
EHDS, the format, and xShare

xShare Mission: To experiment with evolving format specifications and identify future priority data categories, collaboratively preparing the digital health community for accelerated EHDS adoption.



EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

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EHDS, the format, and xShare

Vision → Mission → Goals → Priorities

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

- The **Button and API** (the yellow button): featured in apps and websites
- The **HUB** (the standards and policy HUB): brings global standards with industry and government to steward specifications and accelerate adoption
- The **Label** (the industry label): demonstrates the commitment and capability of the industry to implement the format

The Hub

GDHP
Global Digital Health Partnership

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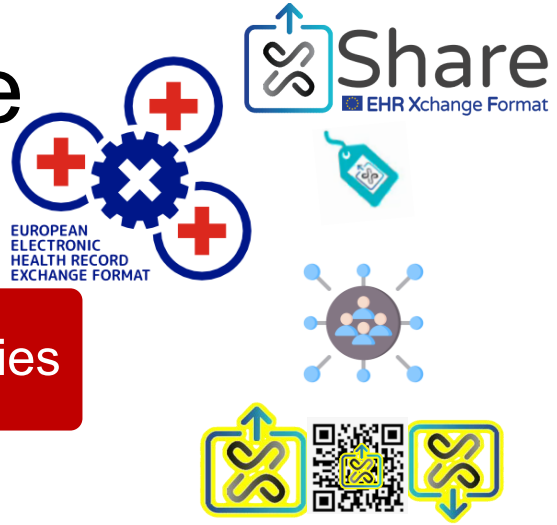
EHDS, the format, and xShare



Vision → Mission → Goals → Priorities

- Demonstrate the xShare impact on continuity of care, clinical research, and population health.
- Start with 8 adoption sites – 75+ ecosystem partners to accelerate adoption across Europe.
- Demonstrate safe, trusted, low-cost sharing of high-quality structured coded health data bridging healthcare, public/population health and clinical research
- Facilitate movement of digital health services across Europe and globally through standards.
- Drive Europe's competitive advantage for R&I in EHDS in the era of AI and big data.
- Incubate the Hub as an accelerator of global standards with the EEHRxF format.

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xShare "Yellow" Button Vision

xShare EHR Xchange Format

Click 'n share their health data in EEHRxF at click-of-a-button

- Download
- One-time share
- Linked options

EUROPEAN ELECTRONIC HEALTH RECORD EXCHANGE FORMAT

- Laboratory Report
- Hospital Discharge Report
- Patient Summary
- Imaging Report
- ePrescription/ Dispense
- IPS+R for Research
- Care Plans

Contact xShare: info@xshare-project.eu

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Introduction to the EEHRxF and xShare Yellow Button

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EHDS: What is it?

- EHDS is the European Health Data Space
  - It is a new EU Regulation that protects health data
  - You can think of it as something like the **GDPR of health data**

- *BUT: you may wonder: We already have GDPR. Why do we need EHDS?*

- Two main reasons:
- First: It enables **citizens** to **download their health data**
  - From all hospitals and laboratories they have visited
  - In a machine-readable format
- Second: it **accelerates research** in medicine!
  - Data collected for primary care can be utilized for **secondary purposes** as well
  - e.g. research for **new drugs**, for better health care, for early diagnosis…
  - Only with the **user consent**

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Citizens' rights in EHDS space

- Right to **access**
  - their personal electronic health data in the context of primary use free of charge
  - in an easily readable, … form.
- Right to **receive an electronic copy**
  - in the European electronic health record exchange format (EHRxF)
- Right to **insert** their electronic health data
  - in their own EHR
- Right to **request rectification**
  - through the electronic health data access services
- Right to **give access to**
  - a data recipient of their choice
- Right to **restrict access** of health professionals
  - to all or part of their electronic health data
- Right to **view access logs**
  - To obtain information on the healthcare providers… that have accessed their data

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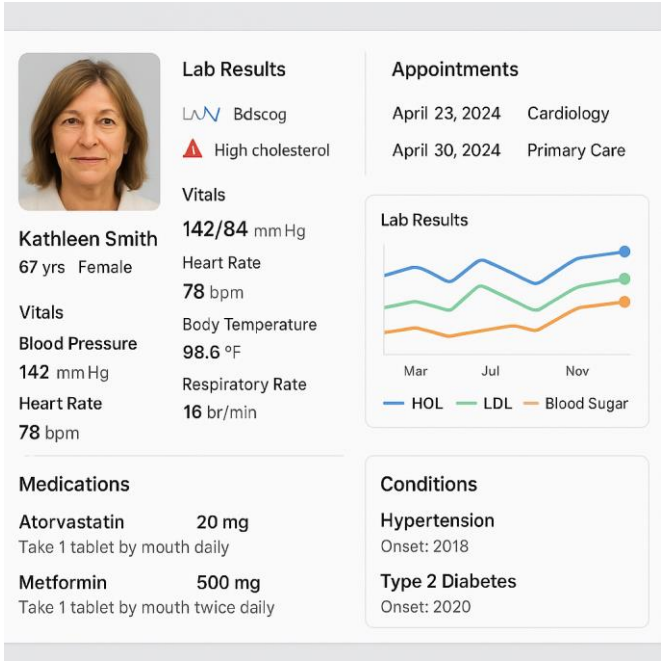
EHDS: Citizens can download their health data!

- For the **first time in history**
- Citizens can request **all their health data**
- From **all health care providers**
- In a **format** that can be read by computers
  - No more paper trails
  - No more hand-written notes
  - No more misplaced lab results
  - No more lock-in with a single hospital



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The Format: what is it?

- EHDS states that you should receive your data in a specific format called:
  - European Electronic Health Record exchange Format (EHRxF)
  - or simply … "The Format"
- It is based on existing standards
- Such as HL7 FHIR (FHIR is pronounced **fire**!)
- HL7 FHIR is **human-readable**
  - Simple ASCII text – people can read it
    - although it can be long – thousands of lines long…
- HL7 FHIR is **machine-readable**
  - **Computers** can read, process, and transfer it

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Frequently asked Questions (I)

→ *I can download my data from my hospital today - what more will the EHDS do for me?*

- EHDS enables users to download **all** their **health data from all providers**
- public, private, hospitals, diagnostic centers, labs, all of them!

→ *My hospital sends me my lab results in PDF - what more can EHDS do for me?*

- PDF (esp. scanned documents) **cannot be "understood" by computers**
  - **Computers cannot "extract" the health data** from the PDF document
    - PDF documents do not specify which text corresponds
      - to medical information (such as surgeries and lab tests)
- EHDS requires hospitals to give you your data in **machine-readable format**
  - **in HL7 FHIR!**

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Frequently asked Questions (II)

⟶ *OK – I downloaded my data in the format*

What can I do with it?

You can:

- visualize the **whole picture of your health**
- **compare and analyze your health data over time**: e.g.
  - how has my cholesterol changed over the past 10 years?
  - in 2024 I travelled a lot for work. How did this impact my cholesterol?
  - how much weight did I put on then?
  - Is my body weight related to my cholesterol?

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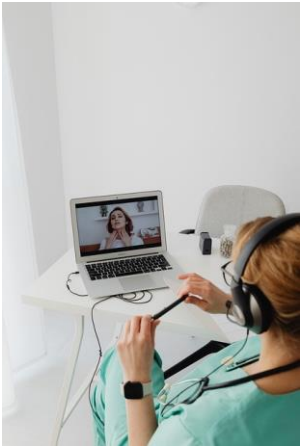
Frequently asked Questions (III)



→ *Anything else I can do with my data?*

Lots of things! You can:

- send the data to a specialist doctor abroad **for a second opinion**
  - the system can automatically translate it
  - if the doctor speaks a different language
- **avoid duplicate and expensive lab tests**
  - when you go to a new hospital and request more tests
- show a **prescription** to a **pharmacist translated to the local language**
  - in a different country and get the right medicine
- share your medical record with your family
  - For medical history purposes – genetic disorders etc.

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Frequently asked Questions (IV)

⟶ *OK – I downloaded my data in the format*

What ***future/futuristic uses*** *will this enable?*

You can:

- **Connect to wearables** and smart watches
  - Get a holistic picture of your health and fitness
- Use **AI health assistants**. They can
  - suggest **preventive care**
  - suggest exercise plans based on your health profile
  - Answer questions – provide **personalized answers**
  - Evaluate **alternative therapies** – which is more suitable for you?
- **Create a digital twin** – a personalized replica that assists in managing your health

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Frequently asked Questions (V)

→ *OK – I see. But is it secure?*

Yes. It is highly secure:

- It is fully **aligned with the General Data Protection Regulation (GDPR)**.
- You own your data and have the right to access, control, and limit its use.
- All data access and processing **activities are logged** and monitored.
- **You can see who accessed your data**, when, and why!!
  - For the first time in history!
- Secondary use (i.e. **research** using your data) happens only
  - After an application process (to health data access bodies)
  - Within a **secure processing environment**
  - Your data will be **anonymized**
  - You can opt-out of any secondary processing of your data

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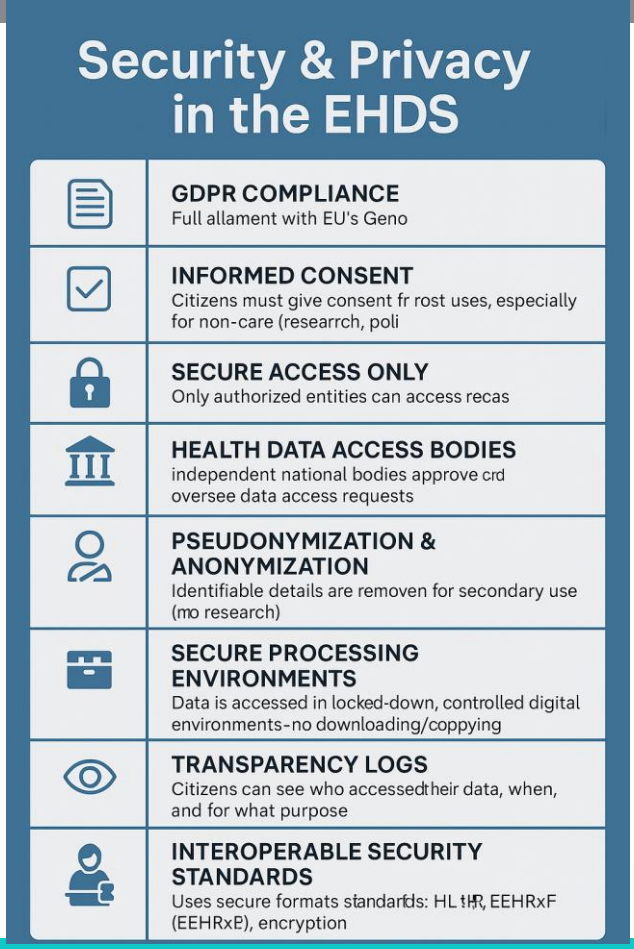
Frequently asked Questions (VI)

→ *I see. I hear, however, a lot about **ransomware**. Can my data be leaked from the hospital?*

- Hospitals will be safer than ever before.
- The EU is putting together
  - a **European action plan on the cybersecurity of hospitals and healthcare providers**
- that will significantly enhance cybersecurity
- **ENISA** plays a leading role in this activity with a new
  - Support Centre
- It will offer
  - a **ransomware recovery subscription service**
  - helping hospitals and healthcare providers
  - prepare recovery plans in advance



The perspective of the Citizen: Marina's story

- **Scene 1: Marina has high cholesterol**
  - **Marina**, a 40-year-old teacher, is struggling with **high cholesterol**
  - She takes care of herself, she eats healthy, she exercises
  - BUT she is **missing the full picture**:
    - Lab results in **paper documents are hard to process**
    - sometimes they are lost esp. during house moves
      - Lab results are **pieces of a puzzle**
      - She has a lot of pieces but not the full picture!
- **Scene 2: With the EHDS and the Yellow Button**
  - Marina is able to **download all her results in FHIR**
  - Marina can see her cholesterol levels over the years
  - Marina can consult foreign specialists for **second opinion**
  - Marina can join clinical trials
  - Marina is **truly in control of her health**

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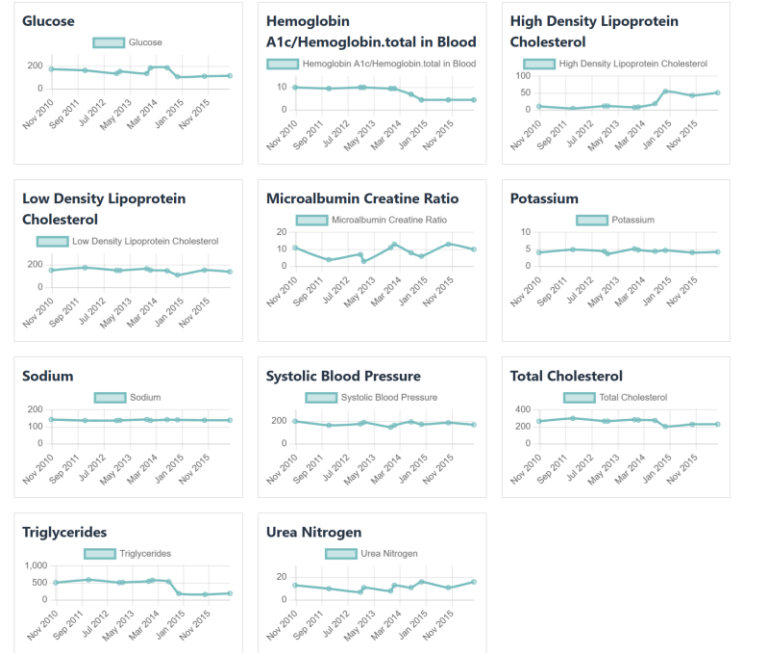
Marina on FHIR



- Using HL7 FHIR
- Marina **downloaded**
  - her lab results
  - her prescriptions
  - her medical tests
  - her procedures
  - In HL7 FHIR
- Marina is able to
  - view all them on a **Dashboard**
  - zoom and compare different tests
  - have the **Big Picture** of her health

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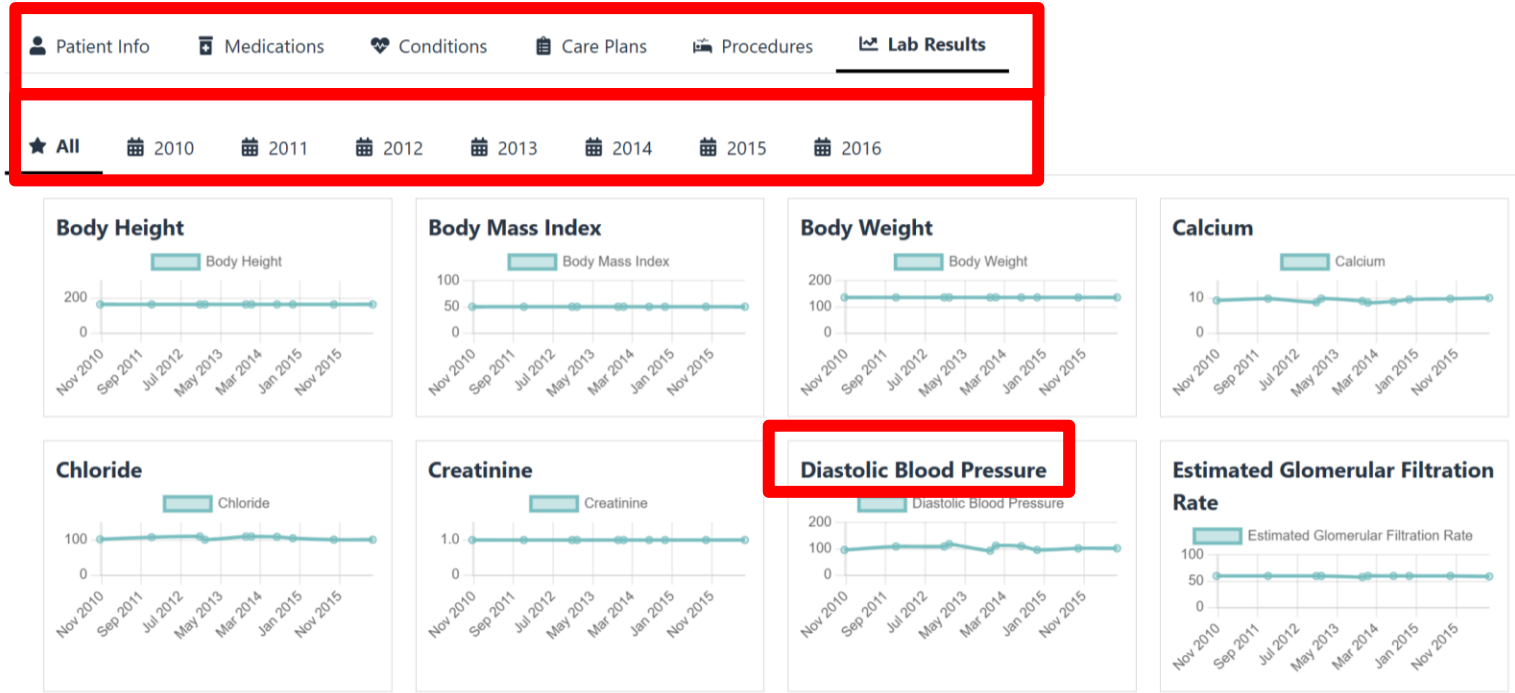
The Big Picture: Marina's health at a glance using HL7 FHIR



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Marina can translate to another language

From English

To Italian

e.g. to get a second opinion from a specialist in Italy

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Marina on FHIR

- Once Marina felt in control of her health
- She took the next step: **she became an active user** of her data
- She sent a (secure) link to her FHIR data to
  - a **doctor abroad asking for a second opinion**
  - She received a second opinion from a world-known specialist in the area
  - He also recommended a web portal specializing in her condition
  - In the web portal she found the latest scientific developments
  - She started attending monthly online meetings and lectures on her condition

Marina made the shift from

Following the instructions of her local doctor to

Having a deep understanding of

(I) how she needs to manage her condition

(ii) what she needs to do and (iii) why she needs to do it

Marina really on FHIR!

- Through the web portal Marina found online clinical trials in cholesterol
- She entered her (FHIR) data in a **clinical trials database**
  - Asking to participate in clinical trials related to cholesterol
  - She was selected to be screened for
    - a **clinical trial through her local hospital**
  - For a **new experimental drug**
    - that may lower cholesterol with less side effects

EHDS did not just give Marina the control over her data
EHDS empowered Marina to **reach her full potential** in the management of her health

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Marina really on FHIR! – caring for the family

- Marina has two children!
- Marina learned that high cholesterol may be related to **genetics**
- Marina talked to **her children** and had them tested as well
  - They started caring about their health from a very young age.
- They all start **exercising** regularly
- The portal provided recipes for **healthy meals**
- The portal gave advice for children and teenagers
  - with high cholesterol

Marina didn't just take charge of her own health—
she **became a champion for her entire family's well-being**.

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The first step – Click on the yellow button

- The first step in Marina's journey is the yellow button
- To get her data (in FHIR) Marina
  - Securely logs in her health system
  - Clicks on the yellow button
  - and gets a
    - link to her data in FHIR in a secure server

- Marina can now share this secure link
  - with another application or
  - with a doctor (for a second opinion)

- Marina can also download her data in her local computer
  - for later visualization
  - and processing

The journey of a thousand miles begins with a single step.
千里之行，始於足下
– Lao Tzu

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Are we there yet?

Help us understand the status quo of **hashtag#EEHRxF** uptake in the EU! Take our survey and let us know the status in your organisation! We assess the status of the Format, and related standards.

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Take the survey here: **https://lnkd.in/dB9P2jZR**

The xShare Consortium

xShare
EHR Xchange Format

Coordination

medcom
HL7 Europe

European EHRxF standards Hub (6 SDOs)

CEN Health Informatics TC251
HL7 Europe
DIGITALEUROPE
IHE Europe
IEEE
SNOMED International
cdisc
DNV

Action line #1 Data portability

gnomon informatics
UNINOVA

Action line #3 Clinical Research

iHD
EUCROF European CRO Federation

Action line #2 Population Health

EHTEL
CHARITÉ

X-Share Xbubbles: Demonstration & Scale up (9-11 countries)

Generalitat de Catalunya Departament de Salut
HAIKA
medcom
TicSalut
University of Cyprus
HSE
National eHealth Authority
Região Autónoma da Madeira Governo Regional
sciensano Belgian institute for health
DANISH HEALTH DATA AUTHORITY

SMEs (6) and Trade Associations (3+)

gnomon informatics
DIGITALEUROPE
MedTech Europe from diagnosis to cure
telemedicine technologies
CINECA
Datawizard
MEDIQ
EUCROF European CRO Federation

Monitoring & Evaluation

empirica

Capacity Building, Security & Privacy, Innovative Procurement

iscte
FORTH Institute of Computer Science

Stakeholder Engagement/ Expert Roster

ECHAlliance

Research Infrastructures & Registries

CINECA

Associated Partners

DANISH HEALTH DATA AUTHORITY
MedTech Europe from diagnosis to cure
Ministry of Health, Welfare and Sport
SANOFI
Gobierno de España Ministerio de Sanidad

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