InteropEHRate

EHR in people's hands across Europe

Enabling citizen-centred health ecosystems

Activating Citizens Through the Power of Data & Technology

FRANCESCO TORELLI
Engineering Ingegneria Informatica SpA

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106

Traditional (almost) waterfall medicine process

Information flows linearly from medical research to medical practice:

- Controlled clinical trials produce validated medical knowledge;
- Medical knowledge is exploited to define evidence based clinical guidelines;
- HCPs apply clinical guidelines;
- Patients follow doctors' prescriptions.

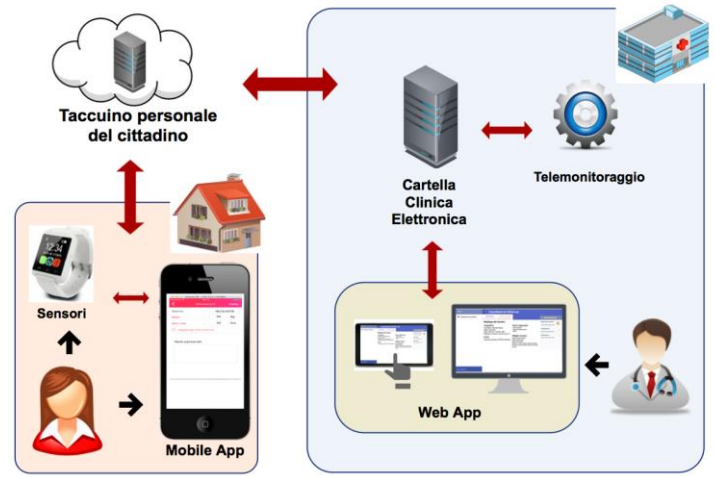
Patients are mainly **receivers** of healthcare **treatments.**

Knowledge comes mainly from **controlled clinical data.**

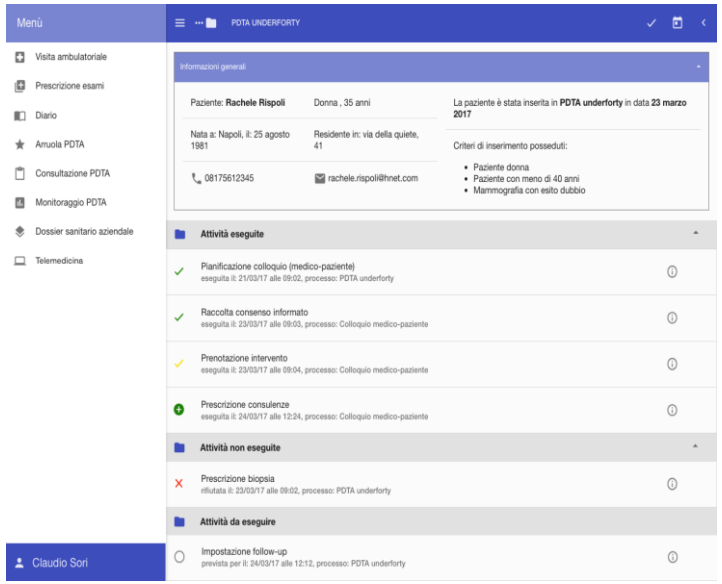
Data is mainly **controlled by healthcare providers.**

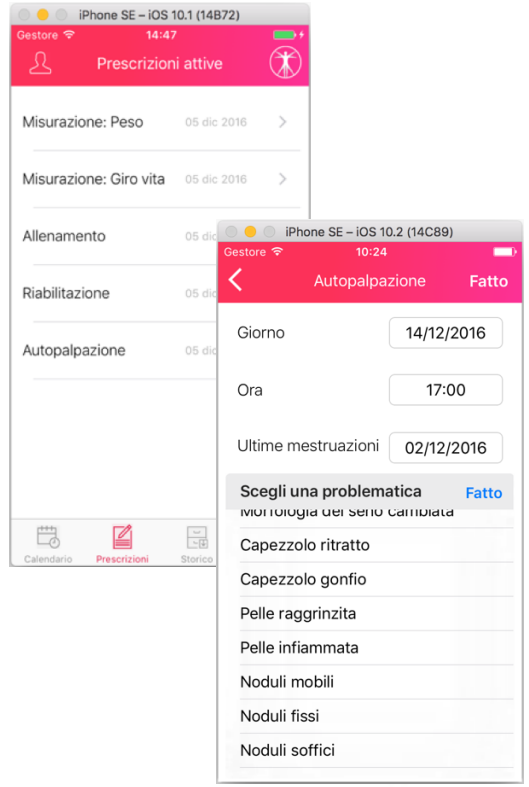
Digital wellness and healthcare

Applications to support diagnosis, therapy and follow-up supported by AI and IoT.



- Mobile Personal Health Record
- CDSS based on clinical practice guidelines
- Telemonitoring





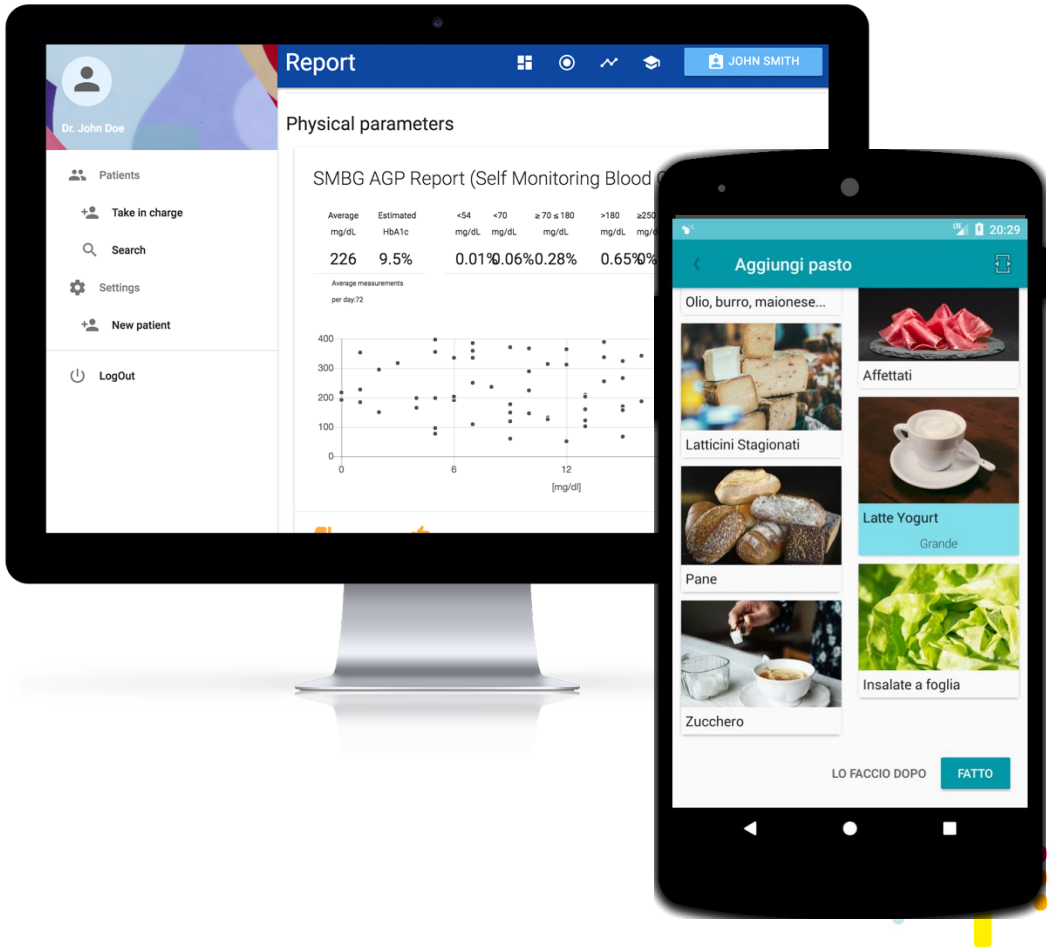
Clinical theme

- Breast cancer treatment and follow-up

Digital wellness and healthcare

Personalised coaching on healthy lifestyle. Hospital Information Systems integrated with multi-sensor devices for detection of physiological parameters (e.g., temperature, activity, stress).

- Remotely monitoring nutrition, physical activity, and anthropometric parameters
- Motivating the user to adopt a healthy lifestyle through personalised feedbacks
- Preventing and managing the pathology in the long term through the patient's empowerment and clinician's monitoring



Clinical theme

- Patients at risk or diagnosticated with Type 2 Diabetes

Digital learning health systems

Information flows circularly and continuously from research to practice to research:

- Clinical practice produce real world clinical data (also from IoT);
- Controlled clinical trials produce controlled clinical data (also about DTx);
- Researchers extract medical knowledge from clinical data;
- Medical knowledge is exploited to define evidence based guidelines, including usage of DTx;
- HCPs apply guidelines.

People receive (also **digital**) **prevention** and treatment healthcare.

Knowledge comes from **any clinical data.**

Data is **controlled by healthcare and digital platform providers.**

Open citizen-centred health AI ecosystems

- **Information flows automatically** from people to AI to people (Researchers, Patients, HCPs):
  - HCPs support people in their health management;
  - People produce Real World (RW) holistic data (also by IoT and DTx);
  - People contributes to RW Evidence Trials and Controlled Clinical Trials with holistic data;
  - AI extracts computable medical knowledge from holistic data;
  - Researchers review/refine computable medical knowledge;
  - AI (computable medical knowledge) supports HCPs and Persons in healthcare.

- People **self manage their health** and are **supported by both HCPs and AI**;
- Knowledge comes from **holistic data** and is **produced and consumed by AI**;
- **People control** their data and **may boost medical knowledge** important to them.

A challenging journey 1/2

- **A citizen-centred health ecosystem powered by AI is possible only by a gradual and regulated evolution.**

- **Without regulation, we risk to move from healthcare-centred to platforms-centred systems:**
  - *Limited citizens' privacy*: our full life exposed to IT platform providers;
  - *Limited citizens' power*: our decisions driven by the IT platforms;
  - *Safety risks*: people relying too much on AI, tools based on non validated knowledge;
  - *Inequalities*: health solutions perform poorly for less remunerative customers.

A challenging journey 2/2

Key steps for EU wide citizen-centred healthcare

- Regulations to protect the users (e.g. GDPR, MDR, upcoming **EHDS** regulation, AI regulation);
- Open specifications to avoid vendor lock-in and guarantee interoperability (**InteropEHRate**);
- Certification of products for trust (DTx, mobile apps, CDSS, cloud services …);
- EU e-services for interoperability and trust (e.g. for certification check, eID, data conversion, translation).

Openness, trustworthy AI and privacy will help to engage more citizens in more ways. E.g.:

- Detect subtle unhealthy behavioural patterns that the person is unable to identify, so to receive better suggestions from the HCP or by the AI;
- Proactively inform about local social and health services suitable to the subject;
- Receive anonymous specialistic or emotional/experiential support from certified HCPs and/or from similar Patients;
- Help to use drugs, interpret diagnostic reports, reduce health risks, self plan and achieve health goals.

Proposed EHDS Regulation - Article 3

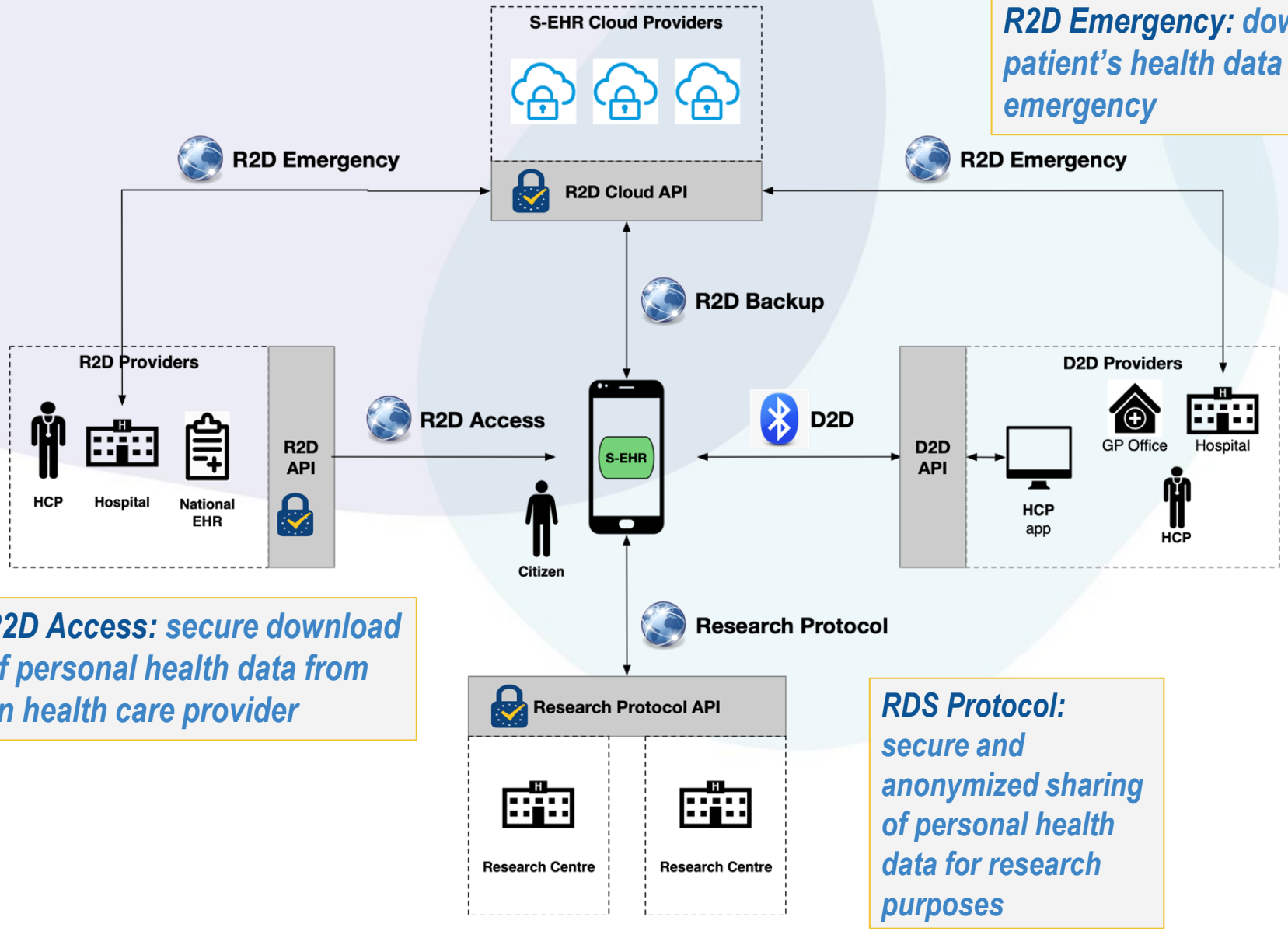
Rights of natural persons

*2. Natural persons shall have the right to **receive an electronic copy**, in the **European electronic health record exchange format** referred to in Article 6, of at least their electronic health data in the priority categories referred to in Article 5.*

Strengthen GDPR:

- *articles 16 (right of access by the data subject)*
- *article 20 (right to data portability)*

INTEROPEHRATE ARCHITECTURE



R2D Emergency: *download of patient's health data in emergency*

D2D: *secure sharing of personal health data during a medical visit*

R2D Access: *secure download of personal health data from an health care provider*

RDS Protocol: *secure and anonymized sharing of personal health data for research purposes*

R2D Backup: *periodic backup of smartphone's health data*

Why to adopt the InteropEHRate open protocols

Pros of Citizen centred, decentral data exchange

- ***Complement*** *healthcare centred approach.*
- *Citizens and HCPs may consult health data also* ***offline****.*
- *Citizens have high* ***privacy & control*** *and are more health aware.*
- *Researchers may obtain* ***more data*** *more easily, both clinical data and wellness ones.*

Pros of InteropEHRate protocols

- ***Open*** *protocols free Citizens and organisations from vendor lock.*
- *Citizens may receive digital copy of health data produced in* ***foreign countries****.*
- *eIDAS allows Citizens to login with same account* ***across different EU states****.*
- *Common FHIR profiles support* ***reliable translation*** *in different natural languages.*
- ***Data provenance is digitally traced****.*

How InteropEHRate relates to EHDS? 1/3

The InteropEHRate FHIR profiles (healthcare IG) provide to EHDS a proposal for the EU data **format** and **API**:

Data minimisation

to exchange not only documents but also more fine grained health data (FHIR resources) so to better minimise the data exchange.

Metadata

- for translation
- For trustable provenance information
- to represent research protocols

How InteropEHRate relates to EHDS? 2/3

According to the proposed EHDS regulation:

> *“ ‘data holder’ means any **natural** or legal **person**, which is an entity or a body in the health or care sector ”*

The data subjects are the main natural persons in health sector!

InteropEHRate provides a model for natural persons (the data subjects) that are **data holders** and that not rely on third party data processors**.**

The **S-EHR app** is a **Secure Processing Environment (SEP)** fully running at the edge on the citizen’s personal mobile device.

How InteropEHRate relates to EHDS? 3/3

What kind of services and mobile apps will participate to EHDS?

The S-EHR conformance levels define a process to classify (and certify) S-EHR apps w.r.t. 5 aspects.

Documentation

1. Obtain the SW and the related contractual documentation
2. Identify the declared InteropEHRate requirement
3. Identify any additional (non-standard) SW requirement

Interoperability

4. Verify the compliance of the InteropEHRate requirements

Completeness

5. Determine the functional level (**completeness**)

Privacy & security

6. Determine the security level
7. Assign the conformance levels
8. Check if the declared conformance level is compatible
9. Analyse non-standard behaviours
10. Verify the fulfilment of all InteropEHRate constraints

Transparency

11. Check the transparency of the processing activities
12. Communicate the assessment result

Thank you.

Happy to answer your questions!

Further information

Web site

www.interopehrate.eu

Videos:

www.youtube.com/channel/UC7eROgmxBoqIG-snjFA47eg

@interopehrate

Contact

info@interopehrate.eu

InteropEHRate

EHR in people's hands across Europe

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106