In focus:

- **Leverage the value of Big Data and Artificial Intelligence by overcoming barriers to data reuse**

- **European Policies and governance principles for data re-use**

- **Frameworks for patient centric data sharing and consent**

- **Health data re-use by national and regional eHealth competence centres**

EHTEL
Collaborating for Digital Health and Care in Europe

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and next steps (Save the date ..)
ELO CoChair Vesa Jormanainen, THL, Finland

@ehtel_ehealth

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and <mark>**Vesa Jormanainen, THL, Finland**</mark>

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and next steps (Save the date ..)
ELO CoChair Vesa Jormanainen, THL, Finland

The following controllers will provide access to data specified in the Act through Findata

FINDATA

- Social Insurance Institution (Kela)
- National Institute for Health and Welfare (THL)
- Social and health care operating units
- Finnish Centre for Pensions (ETK)
- National Supervisory Authority for Welfare and Health Valvira
- Finnish Medicines Agency Fimea
- Regional State Admin. Agencies
- Data saved in Kanta services
- Statistics Finland
- Population Register Centre
- Finnish Institute of Occupational Health

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
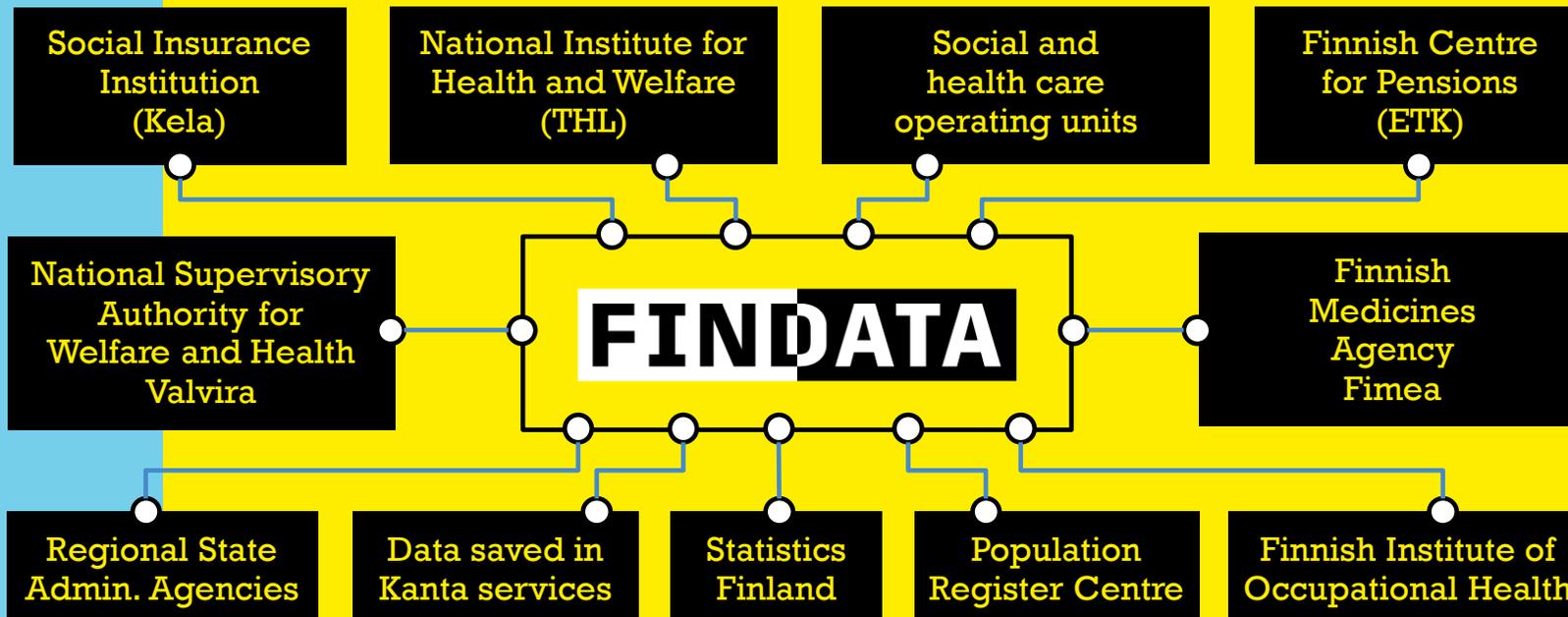Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and next steps (Save the date ..)
ELO CoChair Vesa Jormanainen, THL, Finland

#Imagining2029

EHTEL
Collaborating for Digital Health and Care in Europe

@ehtel_ehealth

European Strategy for data and perspectives towards (Health) Data Spaces

- **Ceri Thomson** (Deputy Head of Unit DG CONNECT) illustrated how today's rapid **increase in digital health services data volume leads to increased data sharing, boosting storage solutions and helping citizen to better control their own data**, e.g. by building new **infrastructures** and finding an **appropriate data sharing** model.

- To move forward, the **European Strategy for Data** aims to overcome these barriers:

  - **Not enough data available for reuse**

  - **No real user empowerment / imperfect data portability mechanisms**

  - **Skills shortage and low data literacy**

  - **Fragmentation of the single market**

  - **Lack of European data processing & storage solutions**

  - **Absence of comprehensive data governance approaches**

EHTEL
Collaborating for Digital Health and Care in Europe

Matrix of the EHDS – European Health Data Space

	Governance	Quality of Data	Infrastructure
Better Healthcare	Legislative and non-legislative measures on governance and rules for primary and secondary use of data, respecting GDPR	Uptake and develop the EEHRxF	MyHealth@EU ERN-CPMS 1+mil genomes
Better Policy Making			Darwin (regulators) Link different repositories (eg registries: cancer, ERN, transplantation)
Better Research and Innovation	AI Framework (incl AI&liability)	FAIR-ification of health data for primary and secondary use	Images database Research infrastructures

EU Data strategy related ELO Survey - **Lessons learned for health and care**

- Following from the **European Strategy for Data** (published Feb. 2020) the European Commission launched a **public consultation on the proposed strategy.**

- EHTEL contributed to help **feeding future EC initiatives on access to and re-use of data**.

- EHTEL submitted **Annexes** providing insights **beyond the limited scope** of the consultation.

Annex 1 – Synthesis from **survey of eHealth Competence Centre views on the health domain**

- Sufficiently **accommodate health and care in the implementation** of the Eur. Strategy for Data

- Identify **key purposes** for enabling meaningful re-use of data in health and care.

- Reflect **lessons learned in deploying cloud infrastructures** for health providers.

Annex 2 – Synthesis of EHTEL healthcare sector ambassador survey in OPEN DEI project

Annexes to be published at www.ehtel.eu/imagining-2029/getting-ready-for-european-health-data-space-s.html

EHTEL Members / eHealth Competence Centre views on the **health domain**

Priority recommendations for data re-use in health and care

- Health data need to be **more open/available to every stakeholder** (e.g., industry, governments at national & regional level, hospitals)

- To assure **trust for all actors** in health data re-use, privacy (GDPR) and (cyber)security most be guaranteed.

  - "For any widely shared data, a **Pan-European patient consent** would be highly instrumental to overcome the limitations of country-specific consent."

- Full benefits of health data re-use rely on **meaningful real world data sources** and thus establishing **EU-wide interoperability**.

European Data Spaces and EHDS - view from cross-sector perspective

- **Sven Meister** (International Data Spaces Association, IDSA and Open DEI project compared data to the "**new blood**". He emphasised how important it is to maintain **health data sovereignty** and to have **decentralized medical data spaces**. He also focused on the role of business and on legal and ethical implications of data-sharing**.**

0110 01101 00 011
011   1001
011

0110 01101
011 101 0
              1001

0110 01101   00
              011
0 1001

SMART HEALTH   SMART HOME   SMART INDUSTRY
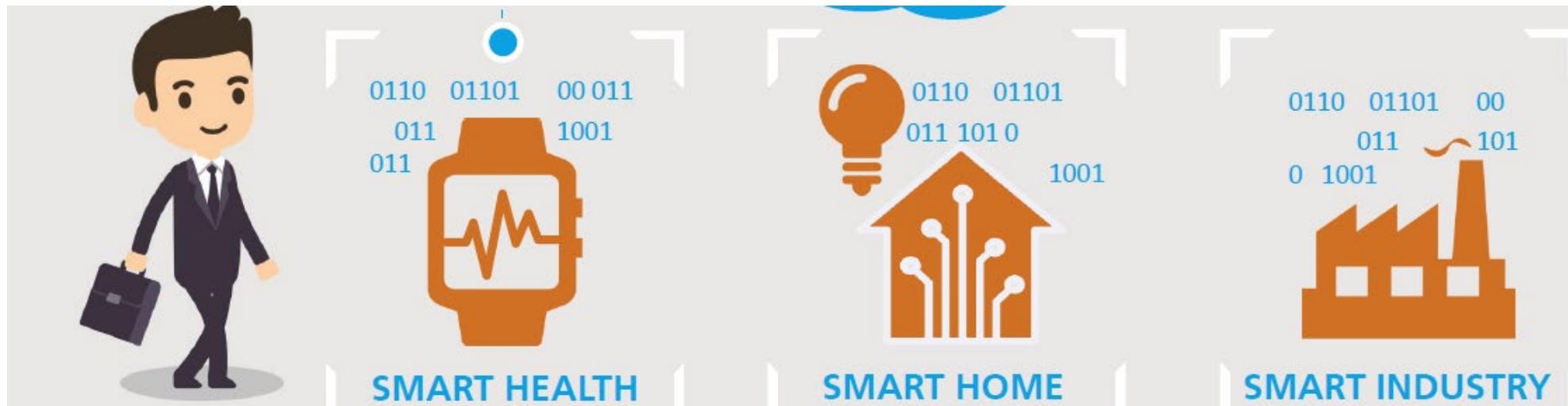
DAWID (data-centered value creation platform for interactive-assisted service systems)

EHTEL
Collaborating for Digital Health and Care in Europe

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and next steps (Save the date ..)
ELO CoChair Vesa Jormanainen, THL, Finland

#Imagining2029

EHTEL
Collaborating for Digital Health and Care in Europe

@ehtel_ehealth

EHTEL's Imagining 2029 webinar

Getting ready for

European Health Data Space(s)

Making real-world data fit for EHDS:
Enablers for meaningful data re-use
Monday, 29 June 2020

WP 5 – Innovative Use of Health data

eHAction
Joint Action supporting
the eHealth Network

JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data

István Csizmadia (NHSC, HU)

Márton Kis (SU, HU)

What shall we speak about?

1. *eHAction – WP5*
2. *Focus Group Meetings with SHs*
3. *Fine-tuning principles*
4. *Wrap-up*

What shall we speak about?

1. eHAction – WP5

2. Focus Group Meetings with SHs

3. Fine-tuning principles

4. Wrap-up

- eHAction, eHN MWP
- Work Package 5
- WP5 outcomes, deliverables
- Focus
- Root causes of challenges

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

18

eHAction – Joint Action supporting the eHealth Network

A.
EMPOWERING PEOPLE

B. INNOVATIVE USE OF HEALTH DATA

MAIN AREAS AND PRIORITIES OF eHN MWP 2018-2021

C.
ENHANCING CONTINUITY OF CARE

D.
OVERCOMING IMPLEMENTATION CHALLENGES

Expected Outcomes of the MWP 2018-2021

- Synergetic and coherent approach to patient access, sharing, and reuse of health data in the EU
- Common vision and priorities for innovative use of data in healthcare
- Common principles to facilitate the development of innovative use of data projects at European Level

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

19

eHAction – WP5 will deliver

- *common principles for*

  – *practical governance of big data / innovative use of health data*

  – *implanting available relevant recommendations and use cases*

- *guidance for the implementation of the principles*

New **JA-04-2020**

- Data governance model

Code of Conduct

- Ironing out differences in GDPR

eHAction

- Principles + Guidance on innovative use of data

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017
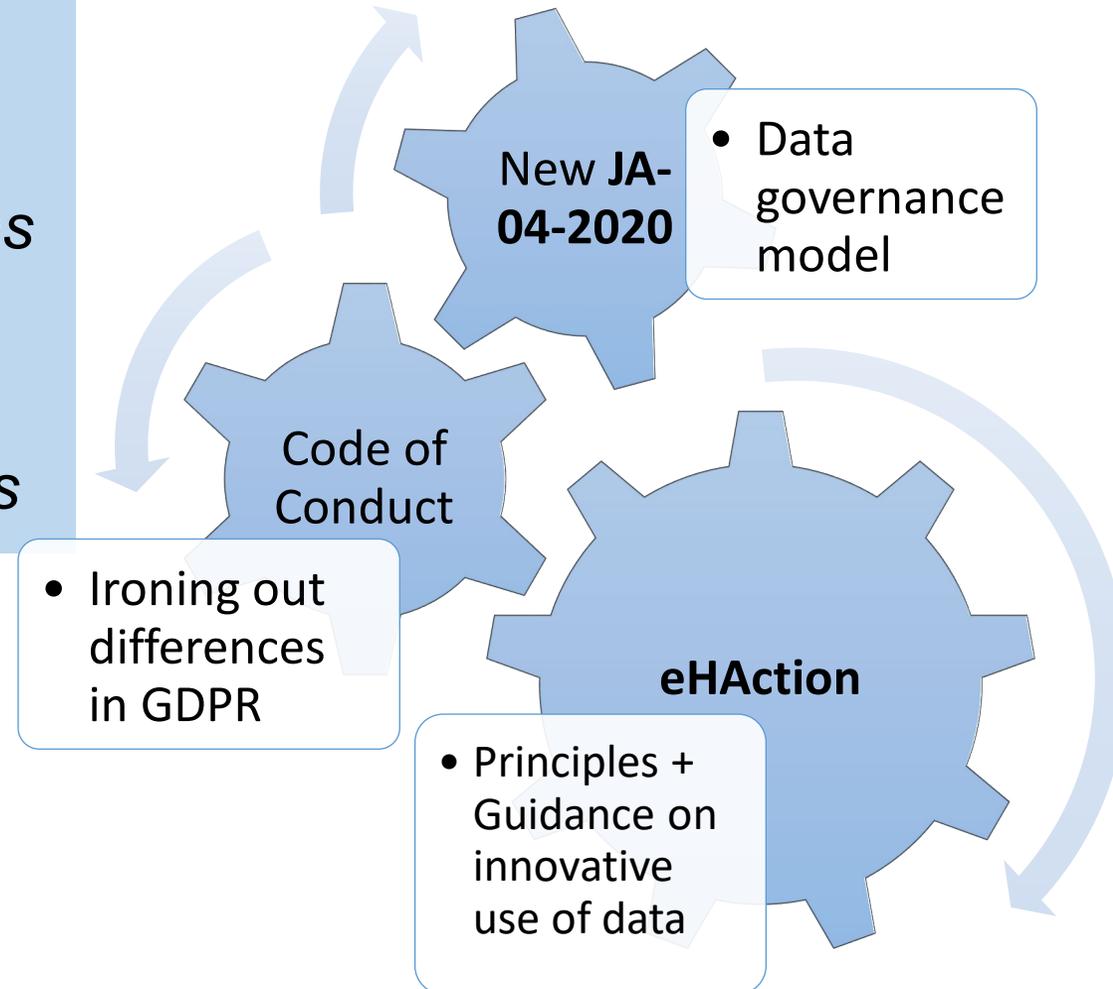
eHAction – Wide focus (not only research)

- *common principles for*
  - *practical governance of big data / innovative use of health data*
  - *implanting available relevant recommendations and use cases*

- *guidance for the implementation of the principles*

D5.3 –Guidance for the implementation of common principles for practical governance of big data
 with a special focus on data to be used (and the implementation of data access and use) in public health, research and quality assurance in healthcare on a European scale

Governance of data re-use shall focus on:

- assisting academic and sponsored research

- providing tools and evidence in public health

- strengthening quality assurance in healthcare:
  - supporting institution management and system governance
  - improving patient care by assisted decision making, diagnostic analytics, robots (software and equipment), smart devices, teleHealth, mHealth and remote care
  - reducing (hospital) re-admission rate
  - forecasting patient demand, attitude, behaviour and need
  - predicting outbreaks and spread of the epidemics
  - optimising administration, finance, procurement, inventory, infrastructural capacities, workforce management and investment
  - etc.

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

21

Root causes of challenges faced in the governance of data re-use

The result of mapping challenges showed that three general obstacles appeared as reasons slowing down or hampering translation of policy-level recommendations into actions:

1. lack of trust,

2. legal uncertainties, and

3. lack of funding and financial resources.

Looking for common policy level principles and guidance which can assist MS/C to eliminate or mitigate against root causes of challenges faced in the governance of data re-use (National + Xborder contexts)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

22

What shall we speak about?

1. *eHAction – WP5*

2. **Focus Group Meetings with SHs**

3. *Fine-tuning principles*

4. *Wrap-up*

- *23-25 June 2020: 101 participants*
- *Introduction of principles (1st draft)*
- *Prioritized principles (online voting)*
- *Learnings from the pitches*
- *Learnings from the discussions*

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

23

eHAction FGM on common governance principles for the re-use of health data

101 Participants from 26 countries

19 Pitches
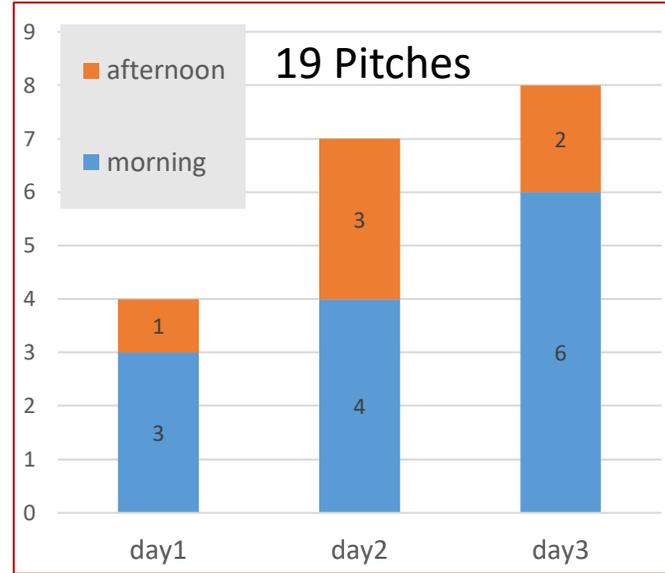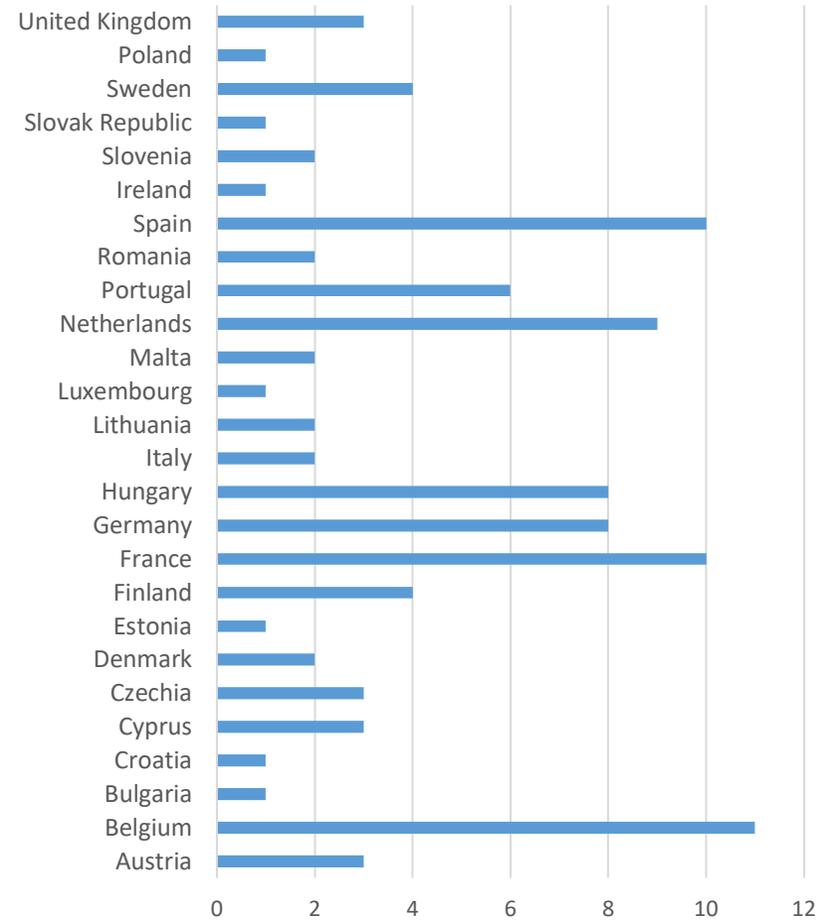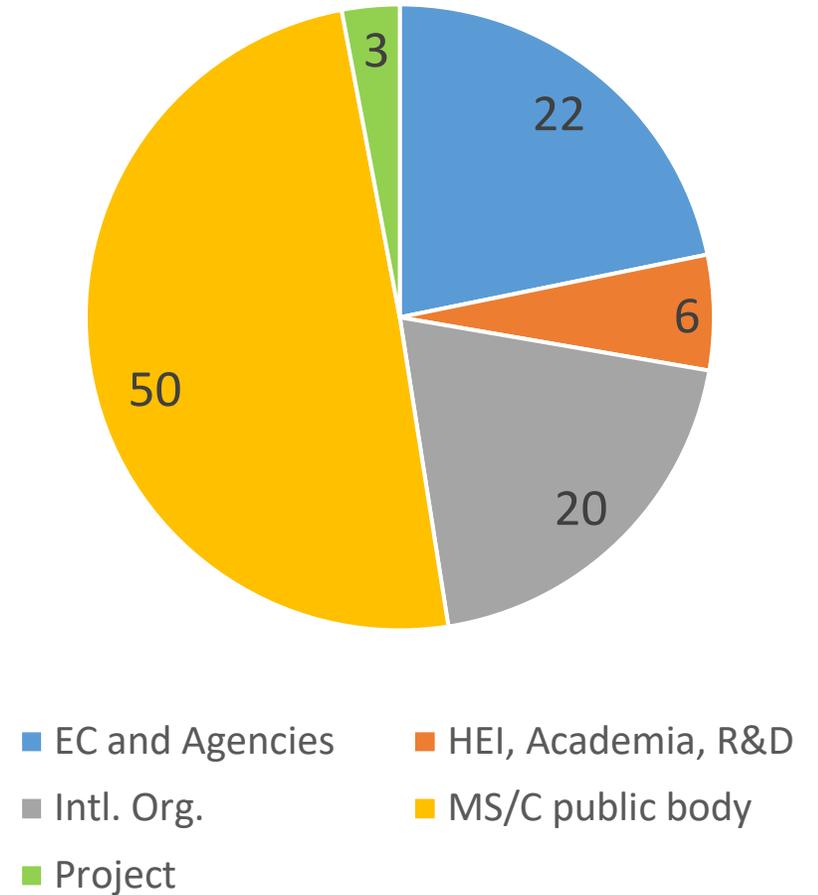
101 Participants

DAY 1. Technology and Interoperability
Tuesday, 23 June 2020

DAY 2. Public Health and Research
Wednesday, 24 June 2020

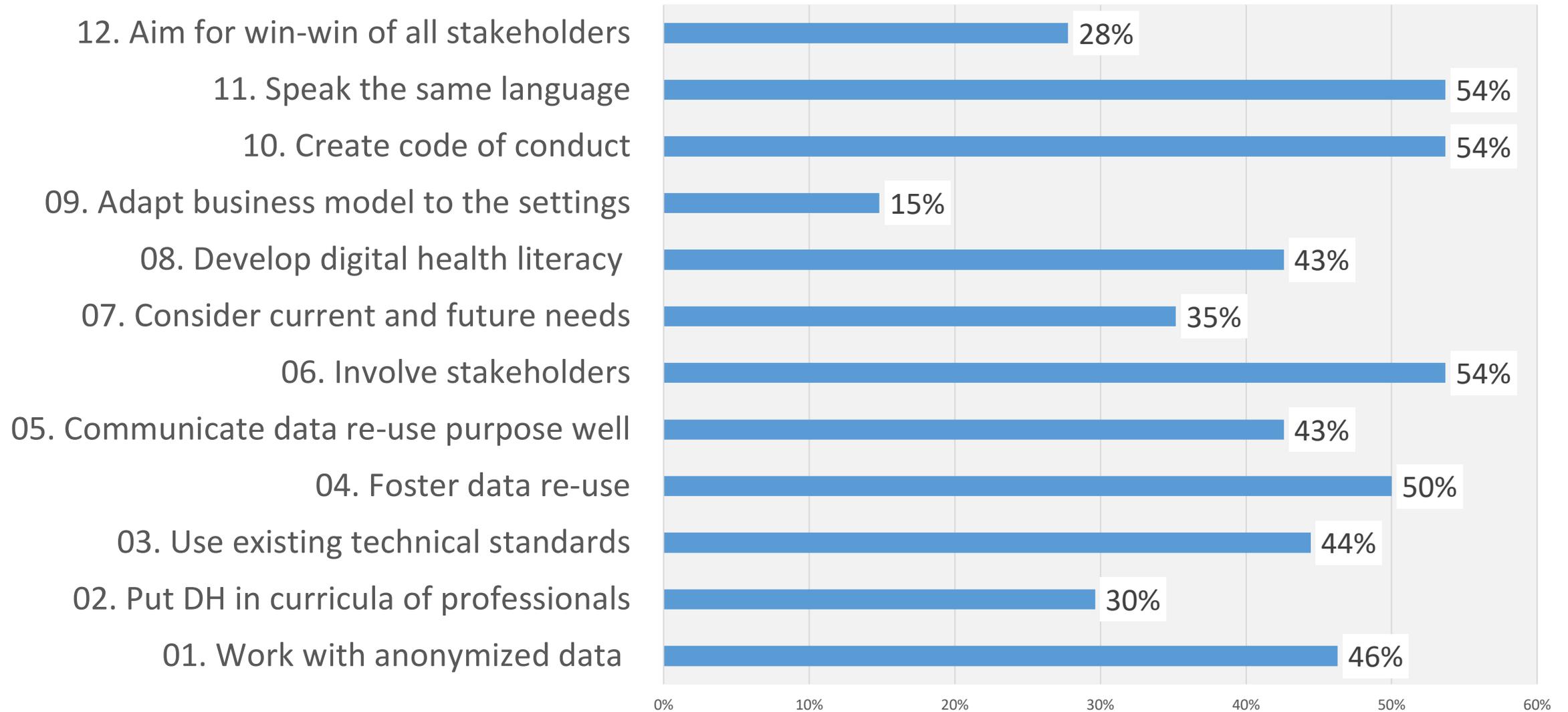**DAY 3. Policy and Regulation**
Thursday, 25 June 2020

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

24

eHAction FGM on common governance principles for the re-use of health data

Principle short names (used at poll for prioritizing)	Principle names (first draft version)
01. Work with anonymized data	Work with anonymized data as far as possible for the purpose of secondary use of data and big data.
02. Put DH in curricula of professionals	Curricula of health professionals should be adapted to include digital health literacy + big data in all EU countries.
03. Use existing technical standards	Avoid evolution of new technical standards, but use already existing ones and maintain "zero trust".
04. Foster data re-use	Choose the right customers, users and beneficiaries of the business model for open data and data sharing to foster data reuse.
05. Communicate data re-use purpose well	Communicate socially acceptable purpose to reuse data.
06. Involve stakeholders	Involve stakeholders in the reuse of data and creating value.
07. Consider current and future needs	Learn current and future stakeholder needs (incl. non-negotiables, differentiators and dissatisfiers → *'How to Get Ecosystem Buy-In' by Martin Ihrig and Ian MacMillan, HBR, March–April 2017 Issue*)
08. Develop digital health literacy	Develop digital health literacy of stakeholders to strengthen empowerment and adherence to data sharing and re-use.
09. Adapt business model to the settings	Treat health challenges in the urban environment with a special business model for data management & data governance.
10. Create code of conduct	Create international terms of data ownership, sharing, exchange and access to mitigate risks regarding sensibility and privacy.
11. Speak the same language	Share common vocabulary to avoid misunderstandings and lead to exploit the value of data.
12. Aim for win-win of all stakeholders	Measure, manage, engineer and communicate worth of the customers, users and beneficiaries of data sharing and access.

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

25

Importance - What percentage of participants has considered the directive important?

- 12. Aim for win-win of all stakeholders — 28%
- 11. Speak the same language — 54%
- 10. Create code of conduct — 54%
- 09. Adapt business model to the settings — 15%
- 08. Develop digital health literacy — 43%
- 07. Consider current and future needs — 35%
- 06. Involve stakeholders — 54%
- 05. Communicate data re-use purpose well — 43%
- 04. Foster data re-use — 50%
- 03. Use existing technical standards — 44%
- 02. Put DH in curricula of professionals — 30%
- 01. Work with anonymized data — 46%

Learnings from the pitches (1)

1. Public investment in a management and coordination tool (terminology server) is essential.

2. The investment in semantic resources related to coding of data for clinical use (in support of continuity of care in particular) must receive priority in terms of public investment.

3. Use the potential of data to elevate efficiency and quality of care

4. Member states to orchestrate standards deployment - Standards are the solution, but there is much to choose from

5. The practical: Data processing – show me your reasons!

6. Building-up trust by co-designing digital tools with health professionals, managers, researchers, patients. - The co-design process is a good instrument to maintain everyone engaged, and to "find time" to align the working processes with the system.

7. Europeans' attitudes towards the use of personal data - Data leaks have affected the way people behave - Trust is built through actions. "I want to be able to accept and deny the selling of my data to third parties."

8. Research in Digital Times … is no longer restricted to traditional research organisations like universities or research labs, … could be defined very broadly, … has a habit of "early publishing"

Learnings from the pitches (2)

7. Plethora of legal stipulations (Fundamental Rights, EU-Treaty, GDPR or Open Data Directive (Academic freedom, European research area, Derogations relating to public interest or research and statistics)

8. Lack of certainty and different GDPR implementation regimes amongst Member States in connection with health data can inhibit secondary use of data.

9. Confusion regarding role of ethics committee

10. Interoperable digital health eco-system is pre-requisite for big data and AI - LEGAL, ORGANISATIONAL and SEMANTIC INTEROPERABILITY → TECHNICAL INTEROPERABILITY

11. De–identification standards

12. Data altruism / Consent - limited to individual treatment, predefined research

13. Broad Consent - Not all future research goals are known at the time the data are captured / Unlimited Data Donation

14. eHealth agencies need to work with cybersecurity agencies to create guidance (no new regulation)

Learnings from the pitches (3)

15. EPF → Data Saves Lives - build awareness and trust in responsible health data sharing through a European Health Data website + a 'Health Data Community' + a network of health data ambassadors at national level

16. Trust is built (and lost) at local, regional or Member States level / Education/communications about benefits of health data use

17. Governance model needs to address data lifecycle and data actors + Transparency and engagement about data use and benefits

18. Data strategy for a national health system - Data governance: shaping population health and precision medicine in the big data era

19. HDH-FR → public interest group created by the law providing documented data catalogue / entry point facilitating access to health data for research at the highest level of security for networking to bring together key stakeholders

Choose the right governance model

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

29

Some learnings from the discussions (breakout rooms)

➢ Group, chop and combine some principles as a whole or partly.

➢ Data ownership? - GDPR doesn't provide definition (only for data subject and controller). Important to clarify!

➢ Assess needs for and possibilities of the use of anonymised/pseudonymised data

    ↘ Especially in big data it is often useless.

    ↘ It requires proper legal basis, aim and guarantees

➢ Work in federated data can be proposed, too:

    ↘ Establish a common data model and facilitate the tools to deploy **federated (distributed) networks** of analysis **where data stays where it is generated** in the custody of their owners and knowledge and analysis are provided in a rigorous, auditable and reproducible way enabling data owners to contribute to the research effort by deploying the study's design and analytic scripts within their systems and sharing results and insights generated by those analyses.

➢ 2020 ZERO TRUST PROGRESS REPORT, ©2020 Cybersecurity Insiders, surveyed more than 400 cyber security decision makers, and

    ↘ found that 72% of organisations plan to assess or implement Zero Trust capabilities in some capacity in 2020 to mitigate growing cyber risk.

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

30

What shall we speak about?

1. *eHAction – WP5*

2. *Focus Group Meetings with SHs*

3. **Fine-tuning principles**

4. *Wrap-up*

- *Domains and uses cases, principles, root causes*

- *12 draft principles in 3 sets*

- *Chop, re-phrase and integrate some*

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

31

Uses cases and challenges

USE CASES	Problems (EU Data Strategy)
1. Forecasting patient demand, attitude, behaviour and need	Not enough data available for reuse
2. Hospital re-admission reduction	
3. Public health, surveillance and prediction of health threats and diseases	No real user empowerment
4. Clinical decision support, assisted diagnostic analytics and robots	
5. Personalised medicine	Lack of European data processing and storage solutions
6. Robots, smart devices, teleHealth, mHealth and remote care	
7. Administration, finance, inventory and investment optimisation	Absence of comprehensive data governance approaches (legal & technical barriers)
8. Prediction of procurement demand and workforce needs	
9. Big Data assisting legislation, governance and regulatory activities (eg. Disease epidemiology or Product related)	Skills shortage and low data literacy
10. Hidden citizen behaviour patterns analysis	
11. Insight and evidence for policy-making and investments	Fragmentation of the single market
12. Prediction of health and health related needs, expenditure and costs	
13. Academic, clinical and translational research and sponsored research	Healthcare systems are separated, what is not the case in other systems
14. Provision of tools and evidence	

Domains and uses cases, principles, root causes

Policy + Governance

Education + Training

Legal, Ethical and Regulatory Issues

Interoperability + Technical Standards

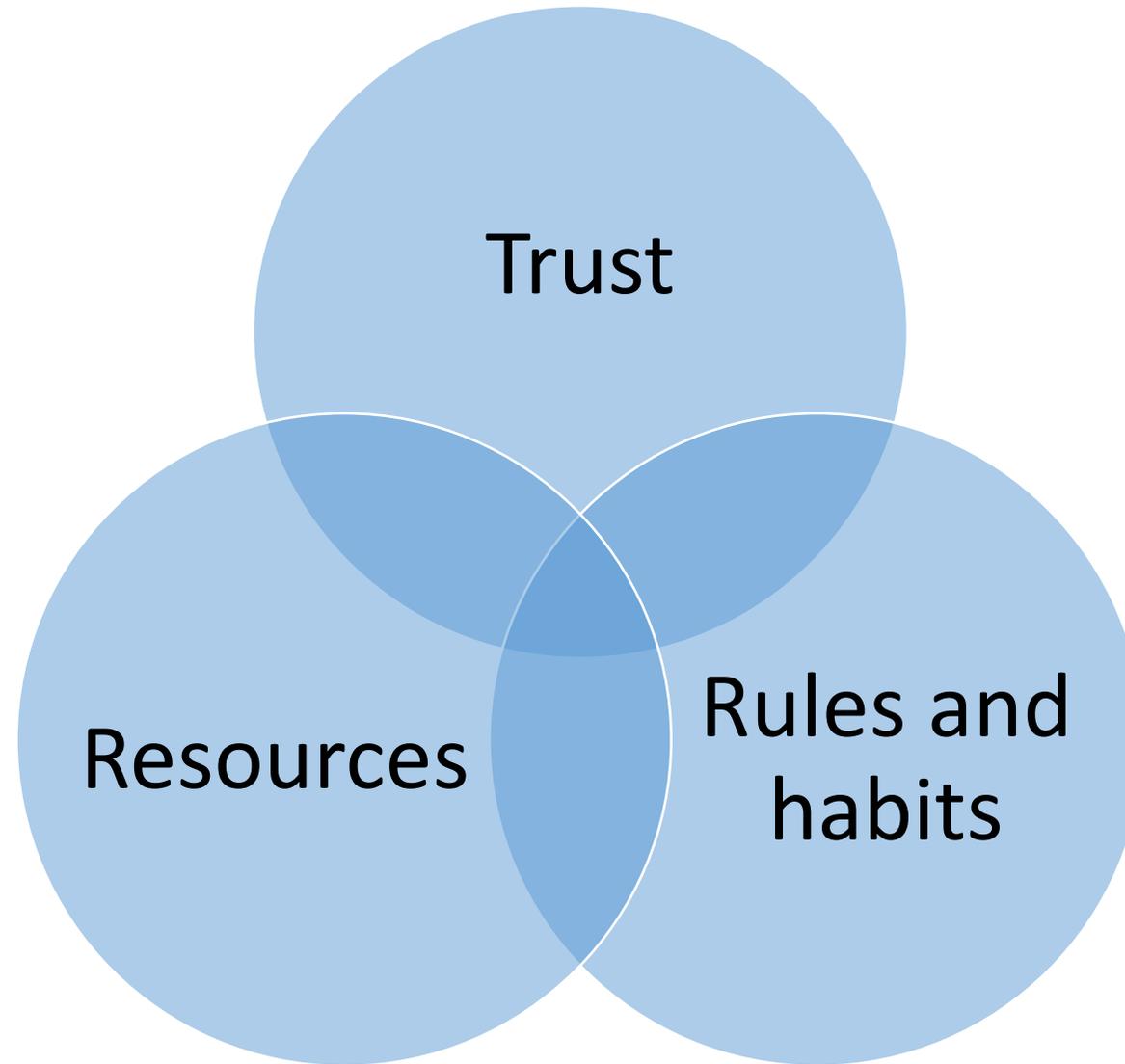Dissemination + Stakeholder Involvement

USE CASES and CHALLENGES
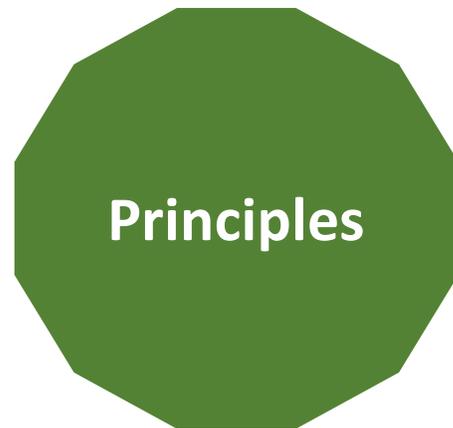
Principles

Targeting on root causes

lack of funding and financial resources

Lack of trust

legal uncertainties

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

33

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

34
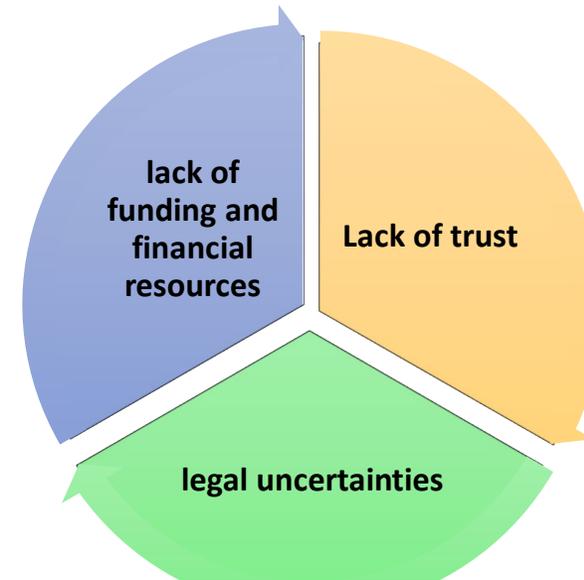
Principles – group 1: Increase trust in privacy protection and cyber security

Work with anonymized (or pseudonymised data - if national laws allow) as far as possible for the purpose of secondary use of data and big data.

- **Work with anonymized data ①**
- **Countries shall aim to have health-related data in machine readable format**
  → Can be switched to 3/a
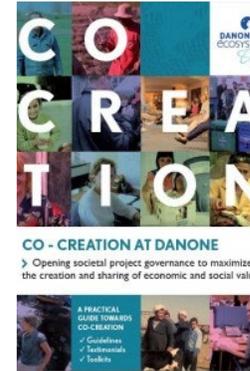
Identify and involve stakeholders in the reuse of data and creating value.

- **Involve stakeholders in co-creation ⑥**
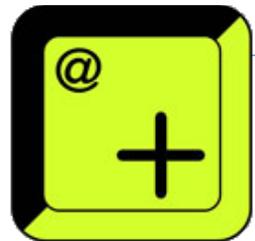
Identify, communicate and disseminate socially acceptable purpose to reuse data

Communicate in a socially acceptable and timely manner the purpose to re-use data.

- **Disseminate data re-use purpose well ⑤**

Do everything possible to reduce the risk and avoid attacks and misuse or abuse.

maintain "zero tolerance".

- **Put high efforts in secure and protect data ③ (3/b)**

eHAction
Joint Action supporting the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European Union's Health Programme (2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

35

Principles – group 2: Increase efficiency of using funds and financial resources

Curricula of health professionals, healthcare managers and other stakeholders should be adapted to include digital health literacy (eSkills / eAbility) + big data in all EU countries *to develop digital health literacy of stakeholders to strengthen empowerment and adherence to data sharing and re-use.*

- **Develop DHL, DB, AI and start teaching at >14 years ② + ⑧**

Choose the right customers Address the right decision makers, users and beneficiaries of the business model for open data and data sharing to foster data re-use.

Include data to support the decision making process.

- **Foster data re-use ④ + ⑬**

Learn and systematically integrate current, emerging and future stakeholder needs (incl. non-negotiables, differentiators and dissatisfiers) 'How to Get Ecosystem Buy-In' by Martin Ihrig and Ian MacMillan, HBR, March–April 2017 Issue

- **Consider current and future needs ⑦**
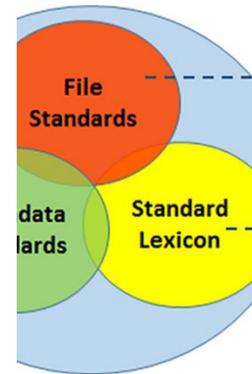
Foster to find, select and use existing technical standards, and avoid evolution of new ones when not justified, but use already existing ones and maintain "zero tolerance".

- **Use existing technical standards ③ (3/a)**

Principles – group 3: Rules and habits
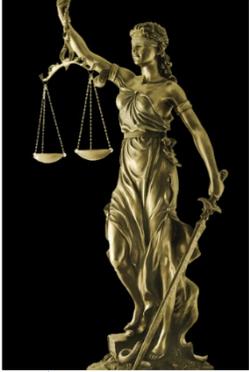
Create international terms/alignment of data control, data ownership [?], sharing, exchange and access to mitigate risks regarding sensitivity and privacy.

- **Create Code of Conduct** ⑩

Share common vocabulary and meta-data to avoid misunderstandings and lead to exploit the value of data.

- **Speak the same language** ⑪

Measure, understand, ~~manage, engineer~~ and communicate why stakeholders ~~worth of the customers, users and beneficiaries~~ of data sharing and access are important to each other, as well as their value for them.

- **Aim for win-win of all stakeholders** ⑫
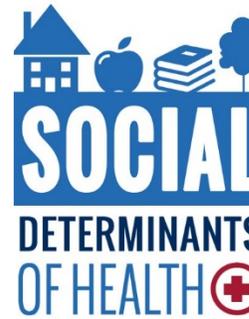
Treat health, health-related and non-health data ~~challenges in the urban environment~~ with a special use case / ~~business~~ model for data management & data governance.

- **Adapt model to the settings** ⑨

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

37

Average values of the replies to our short survey

Principle	Value
01. Work with anonymized data	25
02. Put DH in curricula of professionals	16
03. Use existing technical standards	24
04. Foster data re-use	27
05. Communicate data re-use purpose well	23
06. Involve stakeholders	29
07. Consider current and future needs	19
08. Develop digital health literacy	23
09. Adapt business model to the settings	8
10. Create code of conduct	29
11. Speak the same language	29
12. Aim for win-win of all stakeholders	15

Work Package 5 – Innovative Use of Health data
VIRTUAL WORKSHOPS ON COMMON GOVERNANCE PRINCIPLES FOR THE RE-USE OF HEALTH DATA - DAY 2.
Policy and Regulation - Thursday, 25 June 2020

Please help us further fine tune our principles!

Please find vote link in the chat:
https://directpoll.com/v?XDVhEtdVO8bR7oD9uH4QxPaAS1nN1Tt

Pick your 5 preferred principles please!

- Prioritize principles using poll (Putting principles in order of importance, so that you can deal with the most important first)

- Did something change?

- Proposal to add/eliminate principle(s) - optional

DirectPoll

Pick your 5 preferred principles pls!

- 01. Work with anonymized data
- 02. Put DH in curricula of professionals
- 03. Use existing technical standards
- 04. Foster data re-use
- 05. Communicate data re-use purpose well
- 06. Involve stakeholders
- 07. Consider current and future needs
- 08. Develop digital health literacy
- 09. Adapt business model to the settings
- 10. Create code of conduct
- 11. Speak the same language
- 12. Aim for win-win of all stakeholders

VOTE

eHAction Joint Action supporting the eHealth Network JA-05-2017

Project ID:801558 Co-funded by the European Union's Health Programme (2014-2020)

Work Package 5 – Innovative Use of Health data
VIRTUAL WORKSHOPS ON COMMON GOVERNANCE PRINCIPLES FOR THE RE-USE OF HEALTH DATA - DAY 2.
Policy and Regulation - Thursday, 25 June 2020

39

What shall we speak about?

1. *eHAction – WP5*

2. *Focus Group Meetings with SHs*

3. *Fine-tuning principles*

4. **Wrap-up**

- *Conclusions*
- *Next steps*

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

40

Wrap-up – Conclusions

How to further develop principles?

❖ Principles shall be designed for policy makers – Policy/macro level + Best practices

❖ Principles shall support policy makers to offer win-win data re-use governance model for their key stakeholders – Interoperable and aligned with stakeholders' principles and programmes (e.g. Data Saves Life)

❖ Principles shall be easy to start and implement - Low hanging fruits

❖ Principles shall be effective – Eliminate or mitigate root causes of challenges

❖ Principles shall be efficient – Effective + no side effects + minimized costs

eHAction
Joint Action supporting
the eHealth Network
JA-05-2017

Project ID:801558
Co-funded by the European
Union's Health Programme
(2014-2020)

EU eHealth Network proceedings for governance principles for re-use of health data, EHTEL, Monday, 29 June 2020
István Csizmadia (AEEK-HU)) and Márton Kis (SU-HU)

41

Thank you for your attention!

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and next steps (Save the date ..)
ELO CoChair Vesa Jormanainen, THL, Finland

EHTEL
Collaborating for Digital Health and Care in Europe

APPROACH AND OPEN PROTOCOLS

MAKING REAL WORLD DATA FIT EHDS – JUNE 29TH 2020

ALESSIO GRAZIANI
Engineering Ingegneria Informatica SpA - R&D Lab

InteropEHRate

Research and Innovation action
Grant Agreement N.: 826106
Budget: €7,192,592.50

- **Start**: 1st January 2019
- **End**: 30th June 2022
- **Duration**: 42 months

16 Partners

- Engineering - Ingegneria Informatica S.p.A. (Italy)
- A7 Software (Belgium)
- EHTEL - European Health Telematics Association (Belgium)
- DTCA Hygeia – Diagnostic and Therapeutic Centre of Athens (Greece)
- University of Trento (Italy)
- University of Vienna (Austria)
- EFN - European Federation of Nurses Associations (Belgium)
- FTGM - Toscana Gabriele Monasterio per la Ricerca Medica e di Sanità Pubblica (Italy)
- CHU de Liège - Centre Hospitalier Universitaire de Liège (Belgium)
- UBITECH Limited (Cyprus)

- UPRC - University of Piraeus Research Center (Greece)
- SCUBA - «Bagdasar-Arseni» Clinical Emergency Hospital of Bucharest (Romania)
- SIVECO Romania S.A. (Romania)
- Fraunhofer ISST - Institute for Software and Systems Engineering (Germany)
- ISA - Iatrikos Syllogos Athinon (Greece)
- Byte Computer S.A. (Greece)

cross-border exchange of health data

EHDSI APPROACH

Top-down approach
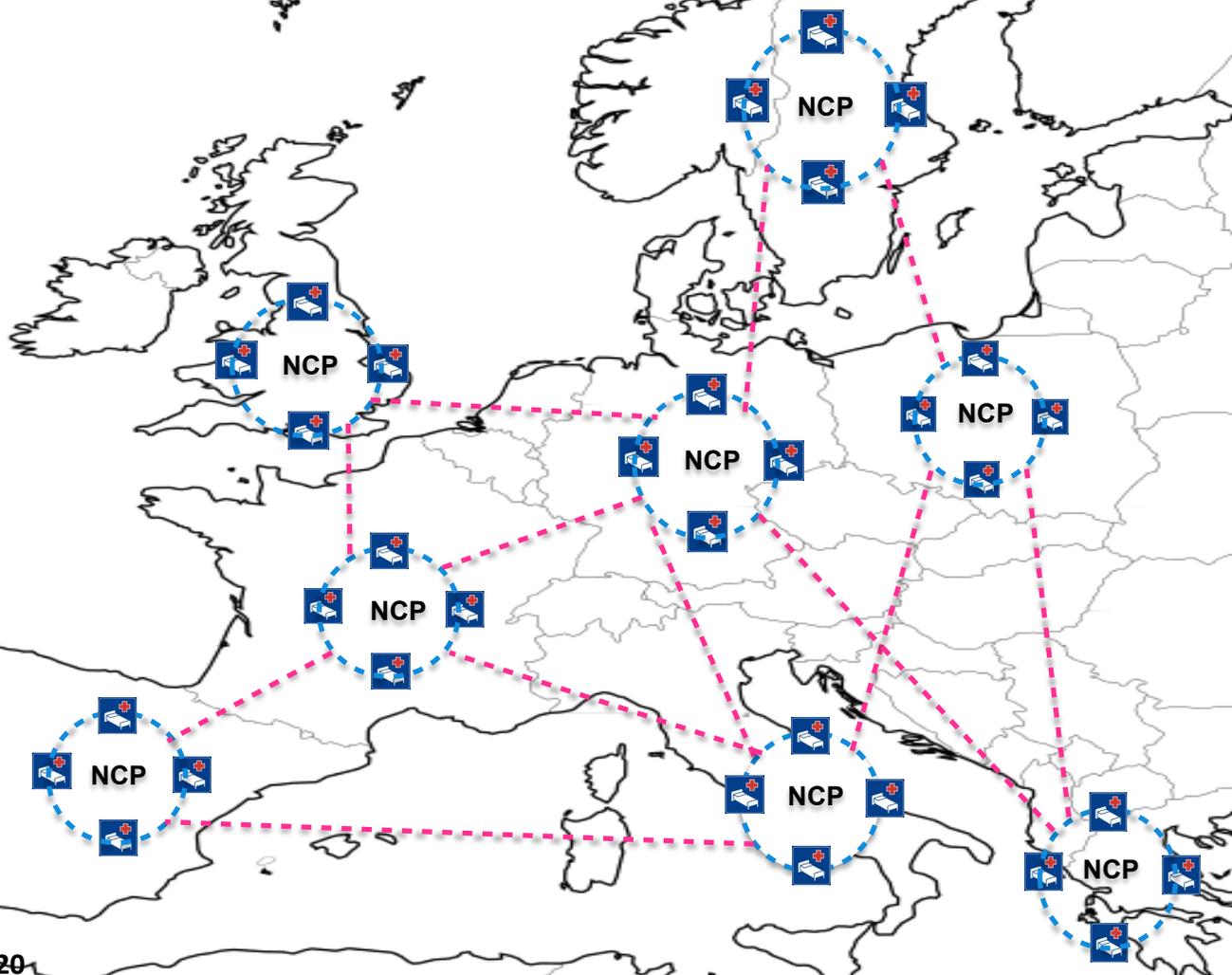
NEW CROSS-BORDER INTEROPERABILITY UNDER TESTING IN EU

With **eHDSI**

- Every EU country will expose NCPeH (National Contact Points for eHealth) to offer to other countries the cross border exchange of ePrescriptions and Patient Summaries

Limits:

- HCPs **cannot access** to health data produced in foreign countries **without network**
- Citizens **cannot access** to health data produced **in foreign countries**
- Citizens have **no control on** health data exchange
- There is limited support for translation
- Limited query capabilities (Document Based)

InteropEHRate GOAL

*To complement **eHDSI Architecture***

*to support **cross-border exchange** of*

personal health data

between Citizens and Institutions

HOW

Define, validate and promote an **open specification** to securely store health data on personal mobile apps (**S-EHRs**) and exchange health data between Citizens and HCPs or Researchers of different countries using **InteropEHRate protocols**.

INTEROPEHRATE APPROACH

Top-down approach
+
Bottom-up approach

IEHR Open specifications
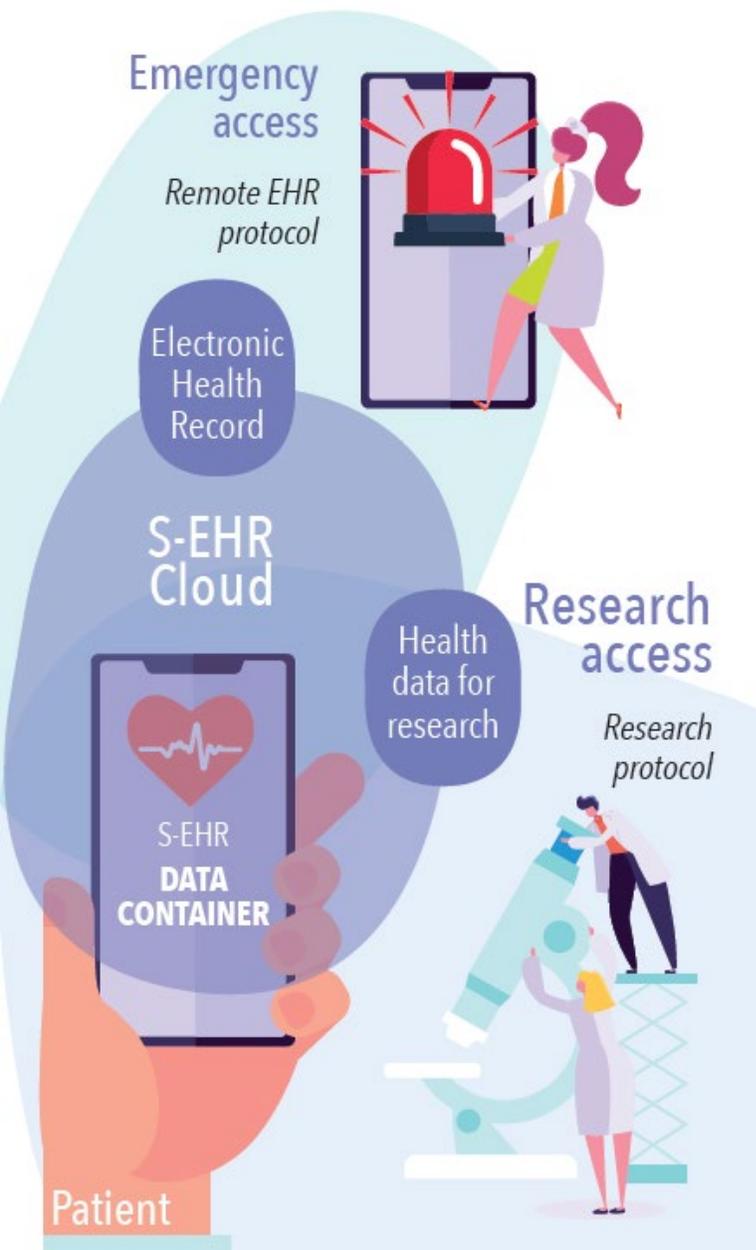
1. *D2D protocol – applied to* Medical visit abroad
Exchange of health data without internet connection

2. R2D protocol – *applied also to* Emergency access
Remote access to HRs sources and back-up on personal cloud

3. *Research protocol – applied to* Health Research study

D2D protocol

IEHR Protocols

S-EHR Cloud Providers

R2D Emergency

R2D Cloud API

R2D Emergency

R2D Backup

R2D Providers

HCP · Hospital · National EHR

R2D API

R2D Access

S-EHR

Citizen

D2D

D2D API

D2D Providers

HCP app · GP Office · Hospital · HCP

Research Protocol

Research Protocol API

Research Centre · Research Centre

29/06/2020
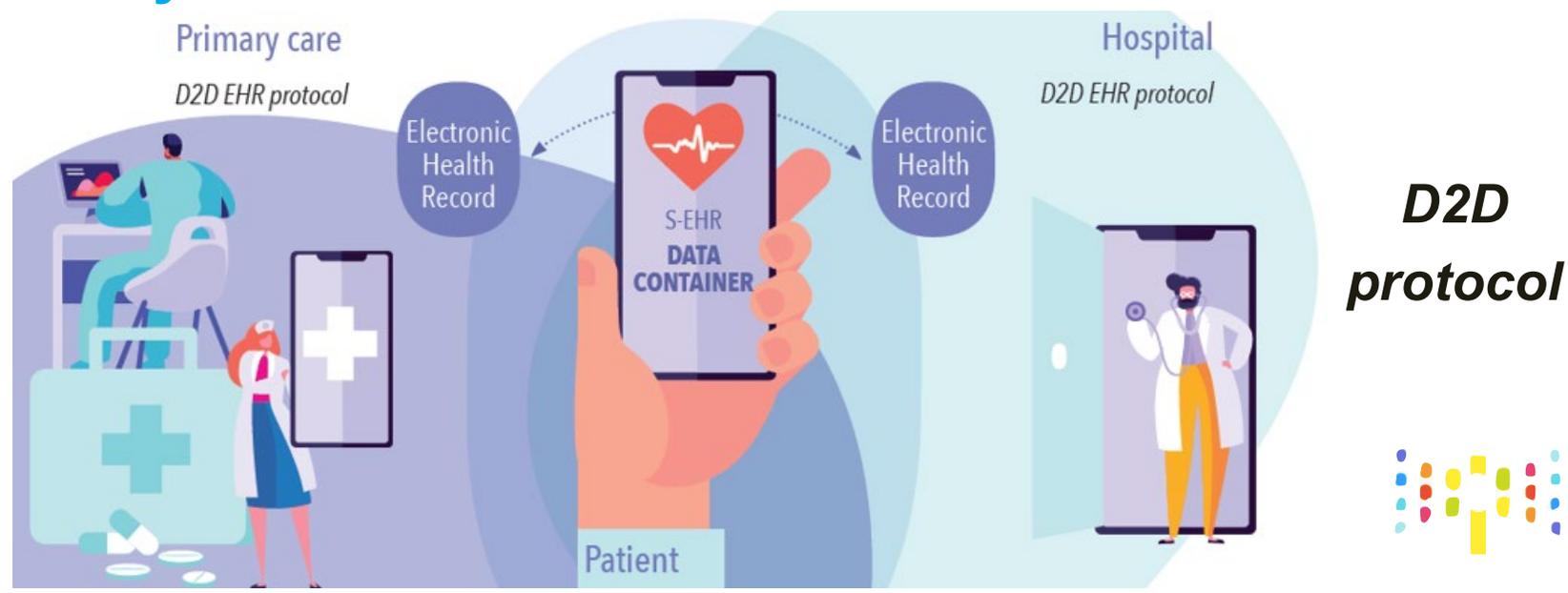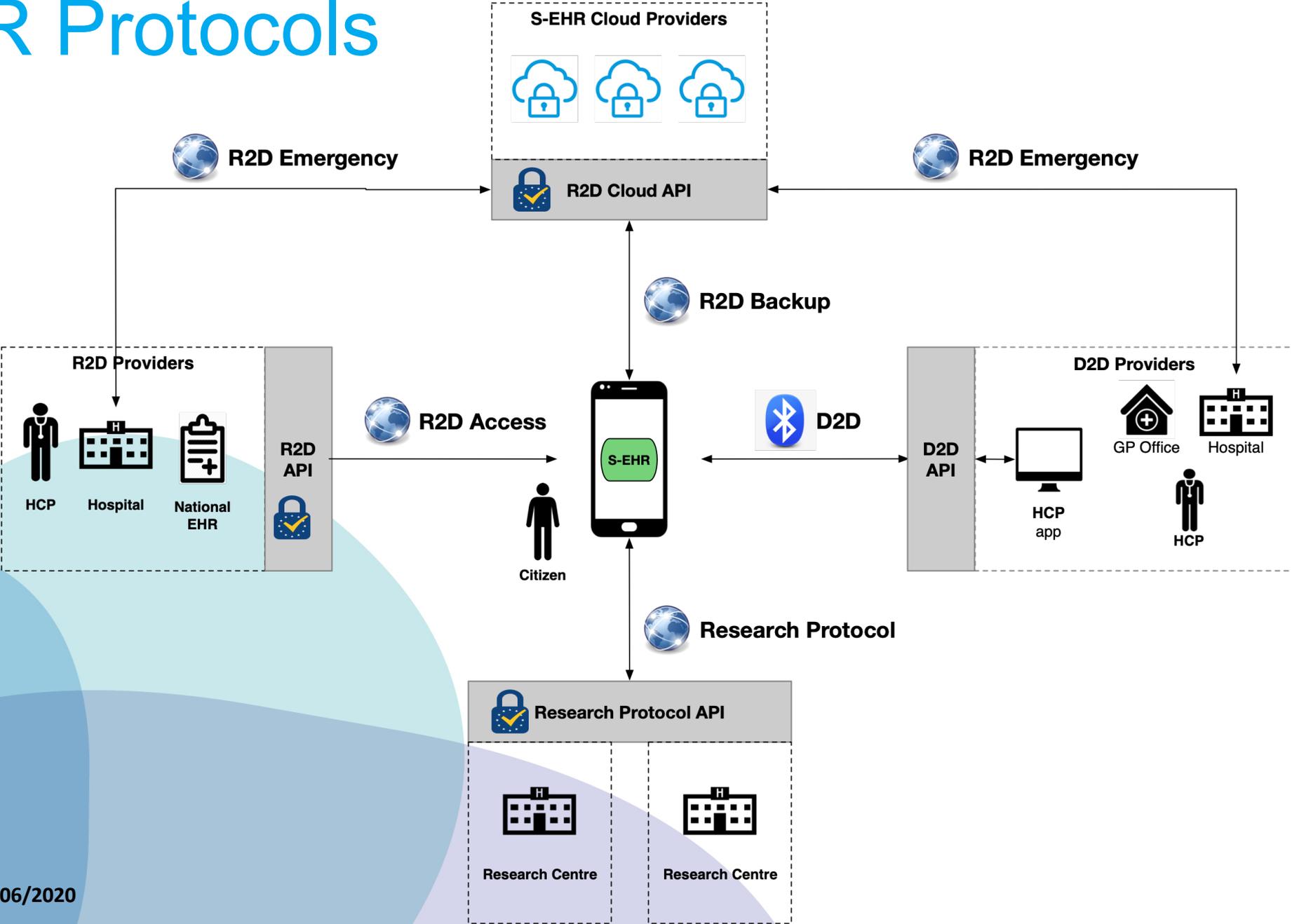
INTEROPEHRATE OPEN SPECIFICATIONS

1. FHIR profiles for EHR interoperability

Leverage
- *HL7 FHIR*
- *CEN IPS*

2. S-EHR conformance levels
constraints and guidelines that S-EHRs and cloud storage must fulfil.

Leverage
- *GDPR*
- *Security standards*

3. D2D protocol for healthcare
exchange among two near devices, on encrypted short range channel (Bluetooth).

4. R2D protocol for healthcare
health data exchange between S-EHR, S-EHR Cloud;

Leverage
- *eIDAS / CEF eID*

5. Remote protocol for Research
exchange of health data, on internet, between a S-EHR and Research Centres.

Improvement in interoperability & patient empowerment

- **Non proprietary protocols free Citizens, HCPs and Researchers from specific vendors.**

- Citizens are **in control** of health data exchange, give\retract **specific usage consents**.

- Citizens may use (EIDAS) **same credentials** for accessing every health data source.

- With **Remote protocol**

  o Citizens may **import** their health data at distance **into their preferred (S-EHR) mobile app**.

  o HCPs may access to health data stored in Citizen's S-EHR Cloud in **emergency**.

- With **D2D protocol** Citizens and HCPs can exchange health data without internet.

- With **Research protocol** Citizens can **share certified health data** to researchers **across Europe**.

PILOTS

Pilot site	Country	Medical Visit	Emergency	Research
FTGM (FONDAZIONE TOSCANA GABRIELE MONASTERIO PER LA RICERCA MEDICA E DI SANITA PUBBLICA)	**Italy**	X	X	X
CHU Liege (CENTRE HOSPITALIER UNIVERSITAIRE DE LIEGE)	**Belgium**	X	X	X
DTCA Hygeia (DIAGNOSTIKON KAI THERAPEFTIKON KENTRON ATHINON YGEIA ANONYMOS ETAIREIA)	**Greece**	X		X
SCUBA (SPITALUL CLINIC DE URGENTA BAGDASAR-ARSENI)	**Romania**		X	X

AN EU ROADMAP FOR EHR EXCHANGE MEDIATED BY CITIZENS

1. Open specifications;
   a. FHIR based APIs covering Citizens' requirements
   b. FHIR profiles integrating standards (also for digital consents)

2. Vendors and standardisation bodies engagement;

3. EU endorsement of open specifications;

4. EU Certification of SW products (mobile apps, services, systems);

5. EU Services (e.g. for official translation of standard terminologies);

ACHIEVEMENT: Reliable cross border exchange of health data.

Thank you!

Q&A time.

SCENARIOS AND DATA RE-USE FOR RESEARCH

STEFANO DALMIANI - FTGM

MAKING REAL-WORLD DATA FIT FOR EHDS:

ARCHITECTURES AND PROCESSES ENABLING DATA RE-USE

SCENARIO 3 - RESEARCH PROTOCOL
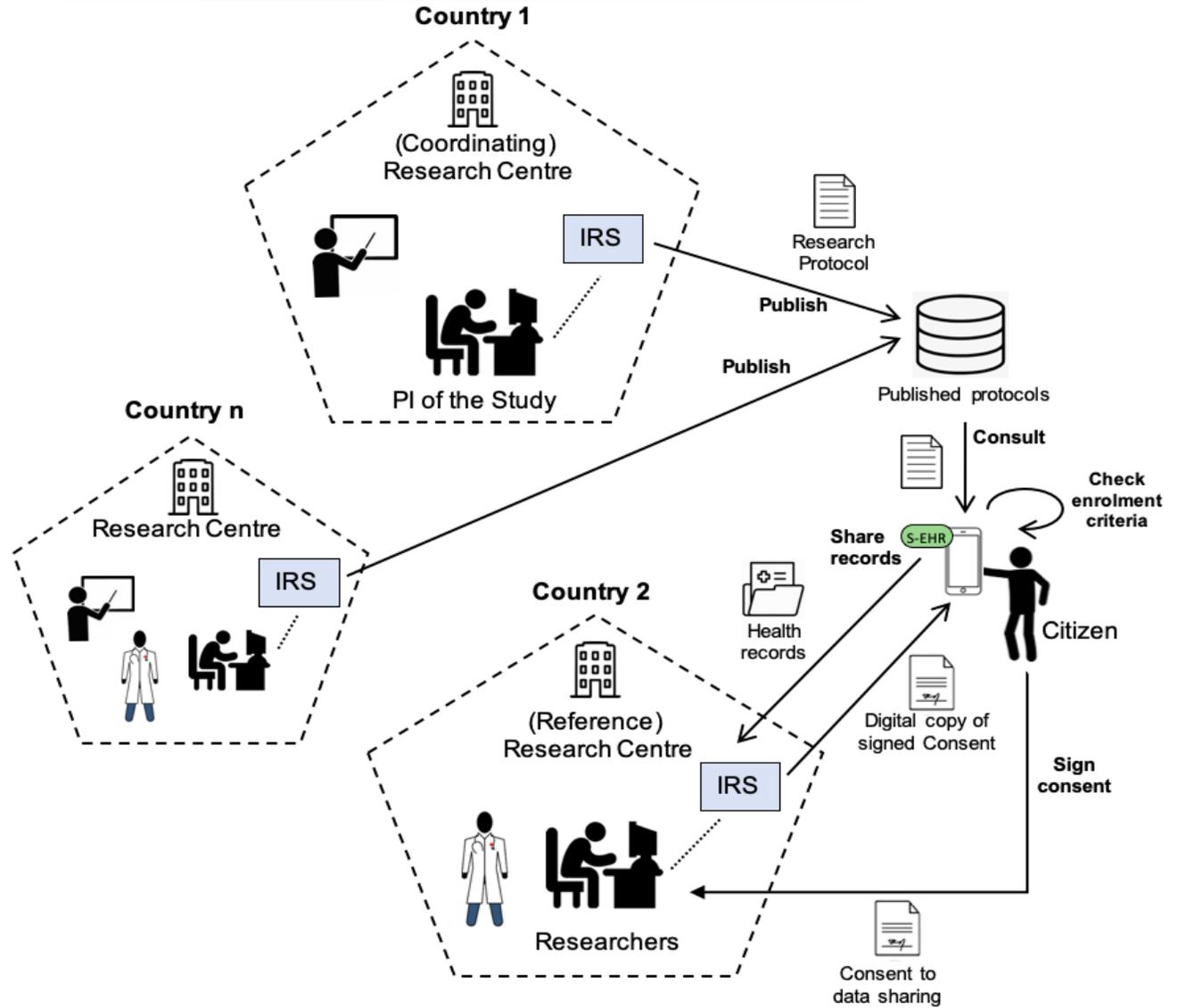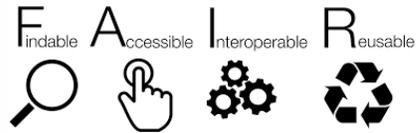
RESEARCHERS FOCUS GROUP: ORGANIZATION

- **The researchers focus group was formed by professionals performing clinical research in different settings, such as pulmonology, cardiology, gynaecology, neurosurgery, and cardiac surgery:**

  - *BAGDASAR-ARSEN EMERGENCY CLINICAL HOSPITAL (SCUBA): 5 researchers physicians.*
  - *ATHENS DIAGNOSTIC AND TREATMENT CENTERS (HYG): 7 researchers.*
  - *GABRIELE MONASTERIO TUSCANY FOUNDATION (FTGM): 5 researchers.*
  - *UNIVERSITY HOSPITAL CENTER OF LIEGE (CHU): 5 researchers.*

- **Different types of health research, e.g.:**

  - *Epidemiological studies (Retrospective, Retrospective+Prospective)*
  - *Experimental trials of drugs/devices/etc., cohorts studies (Prospective, Retrospective+Prospective)*

RESEARCHERS FOCUS GROUP: RESPONSE

- **Most researchers like very much the idea of getting their data directly from patients.**
  - *especially if these data are certified by hospitals, and do not use manually entered data.*
  - *they fear that elderly patients would not adhere to this solution.*

- **They like the possibility of allowing patients to apply for a research study using a personal app**
  - *This represent an effective way of increasing, in a simple manner, the number of participants in the study.*

- **Some Epidemiological studies do not need to manage a local population**
  - *They work with large anonymous cohorts of patients*

- **Experimental trials need a population with a real follow-up**
  - *consider important to perform studies on a local population, suitable for performing instrumental control examinations at regular intervals with direct contacts with the patients*

Thank you!
Stefano Dalmiani
FTGM - Monasterio Foundation Research Hospitals
Q&A time.

www.interopehrate.eu

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | **Welcome and Introduction to the second EHTEL ELO Virtual Meeting**
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

11:05 – 11:10 | **Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data**
Stephan Schug, EHTEL

11:10 – 11:30 | **EU eHealth Network proceedings for governance principles for re-use of health data**
István Csizmadia, AEEK Hungary and Márton Kis, Semmelweis University, Hungary (both: eHAction WP5)

11:30 – 11:50 | **InteropEHRate approach to patient-centric data sharing and enabling data altruism**
InteropEHRate Approach and open sharing protocols, Alessio Graziani, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | **Flashlight contributions on enabling "European consent in support of the EHDS"**
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | **Q&A and Interactive Round Table for Webinar Audience**
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | **Conclusions and next steps (Save the date ..)**
ELO CoChair Vesa Jormanainen, THL, Finland

EHTEL
Collaborating for Digital Health and Care in Europe

Imagining 2029 ELO Webinar II   **29 June**   **64**   @ehtel_ehealth

EHDS: GDPR conformant data lakes and consent management

Developing and implementing GDPR conformant data lakes

- Joining forces by Member States and healthcare providers.

- Agree on governance models for accessing data and digital health services.

Consent Management

- **No use without consent**

- Ethical guidance

- **Consent can be withdrawn (implementation of withdrawal)**

Based on Communication 2020(66) "A European Strategy on Data" – Annex 4: Citizens also need to be reassured that, once they have given **consent** for their data to be shared, the healthcare systems uses such data in an ethical manner and ensure that the **given consent can be withdrawn at any time**.

Limitations inherent in consent by Article 29 Working Party

- "…the GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked. …

- When research purposes cannot be fully specified, a controller must seek other ways to ensure the essence of the consent requirements are served best, for example, to allow data subjects to consent for a research purpose in more general terms and for specific stages of a research project that are already known to take place at the outset. *As the research advances, consent for subsequent steps in the project can be obtained before that next stage begins."*

Article 29 Working Party "Guidelines on consent under Regulation 2016/679"
Adopted on 28 November 2017, as last Revised and Adopted on 10 April 2018.

@ehtel_ehealth

DE Use Case: Medical Informatics Init.: **Access to Data**

Core Data Set
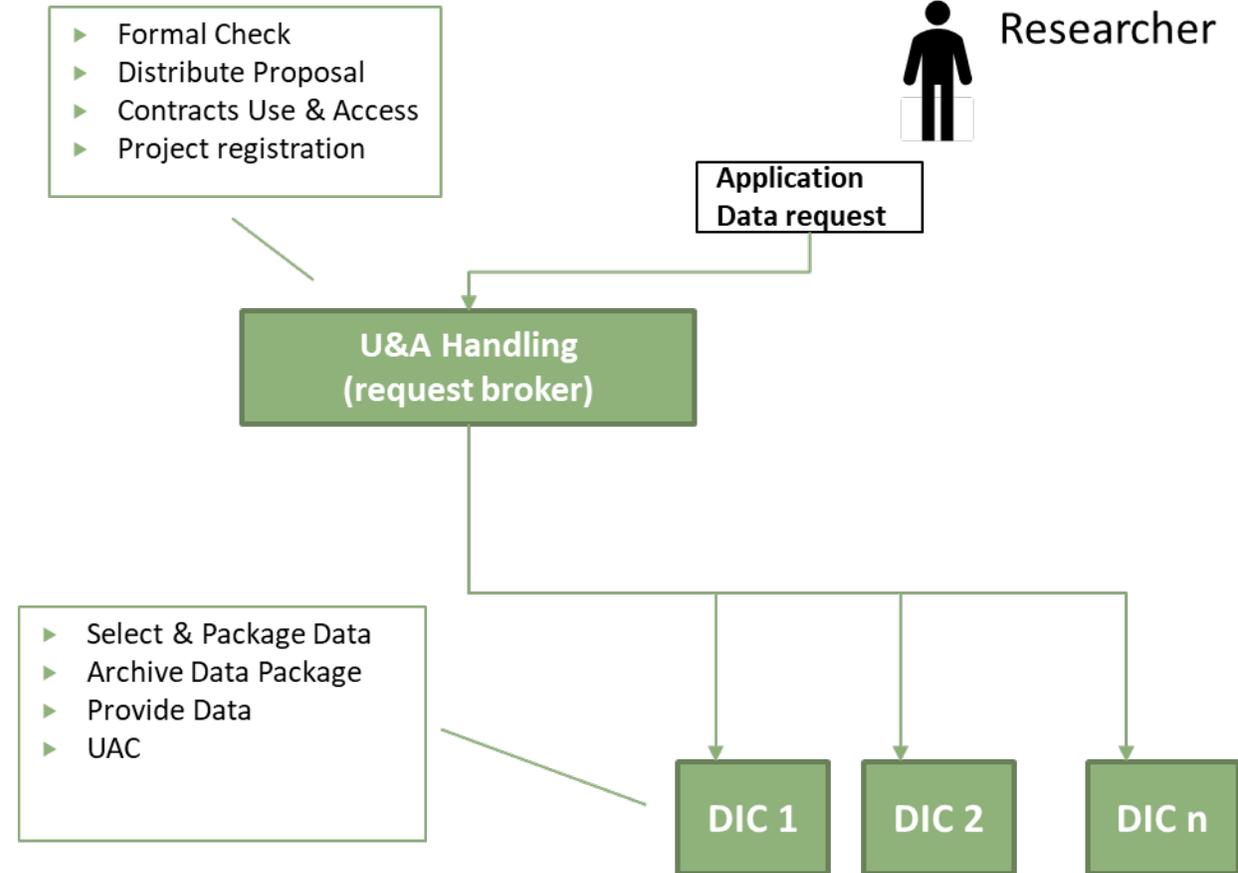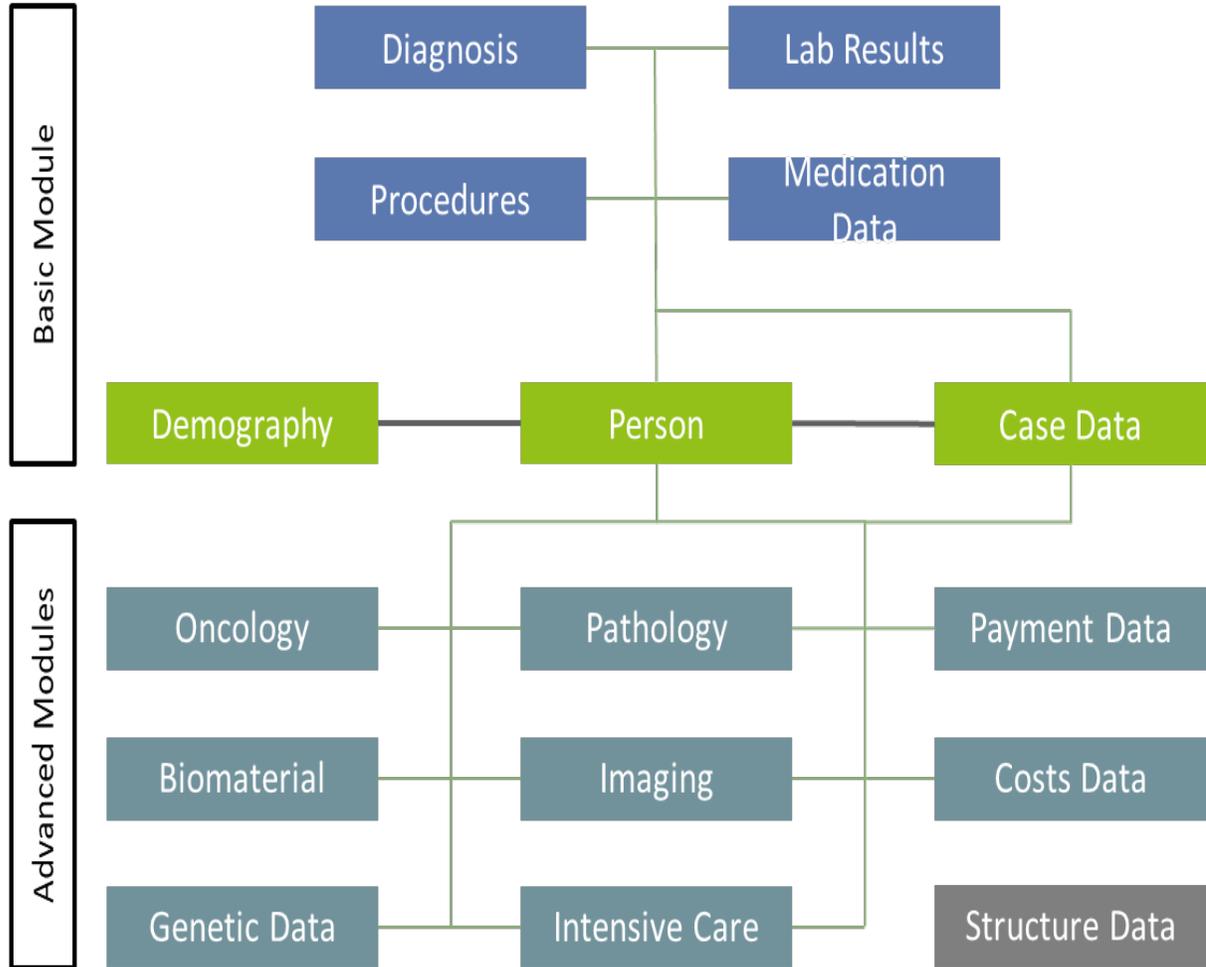
Medical Informatics Initiative **Template for Broad consent**

Scope

- **Not all future research goals are known at the time the data are captured.**
- Describe potential future use of data for research and healthcare in very general terms when a patient/participant declares consent **(broad consent).**

Achievements

- **Uniform template text agreed** by relevant actors, such as the Biobanks Working Group of the Medical Ethics Committee and the Data Protection Working Group of the TMF.

- **The Conference of Independent Data Protection Commissioners of the Federal Government and the German federal states approved template text 15 April 2020**.

- An English translation of the template text and the patient handbook is currently being implemented and will be available in the coming weeks (was announced for early May)

Source: https://www.medizininformatik-initiative.de/en/template-text-patient-consent-forms

PRIVATE MODEL EXAMPLE :

"MADANA's goal to allow data producers, data analysis buyers, and plug-in providers to participate in the data market in a, fair, anonymous and privacy-protecting way."
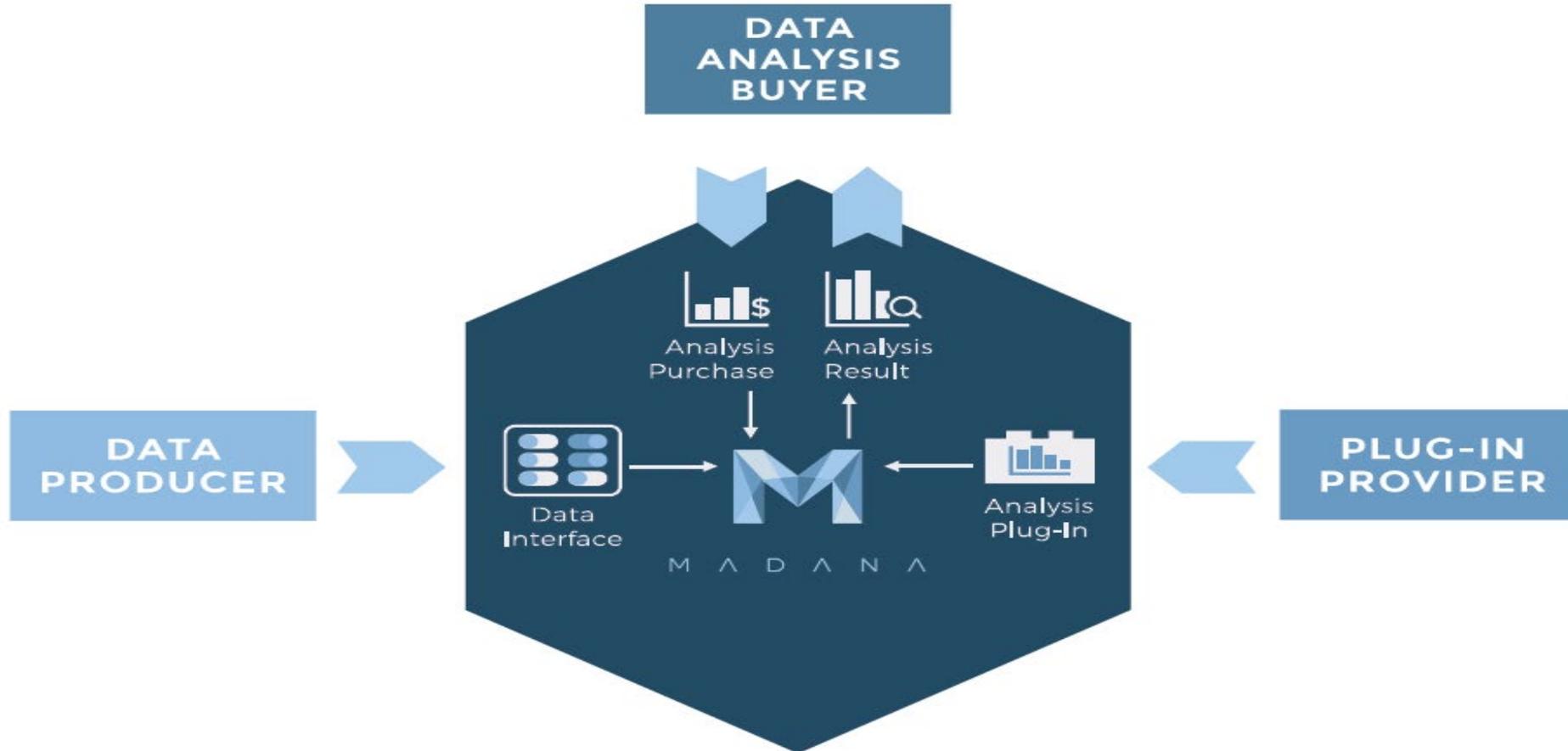
Which ecosystem ?

Data Producers can be:

➢ End-users
➢ Data Collecting Devices
➢ Applications
➢ IoT Devices
➢ Companies
➢ Public Databases

Data analysis buyers can be:

➢ Companies
➢ Institutions
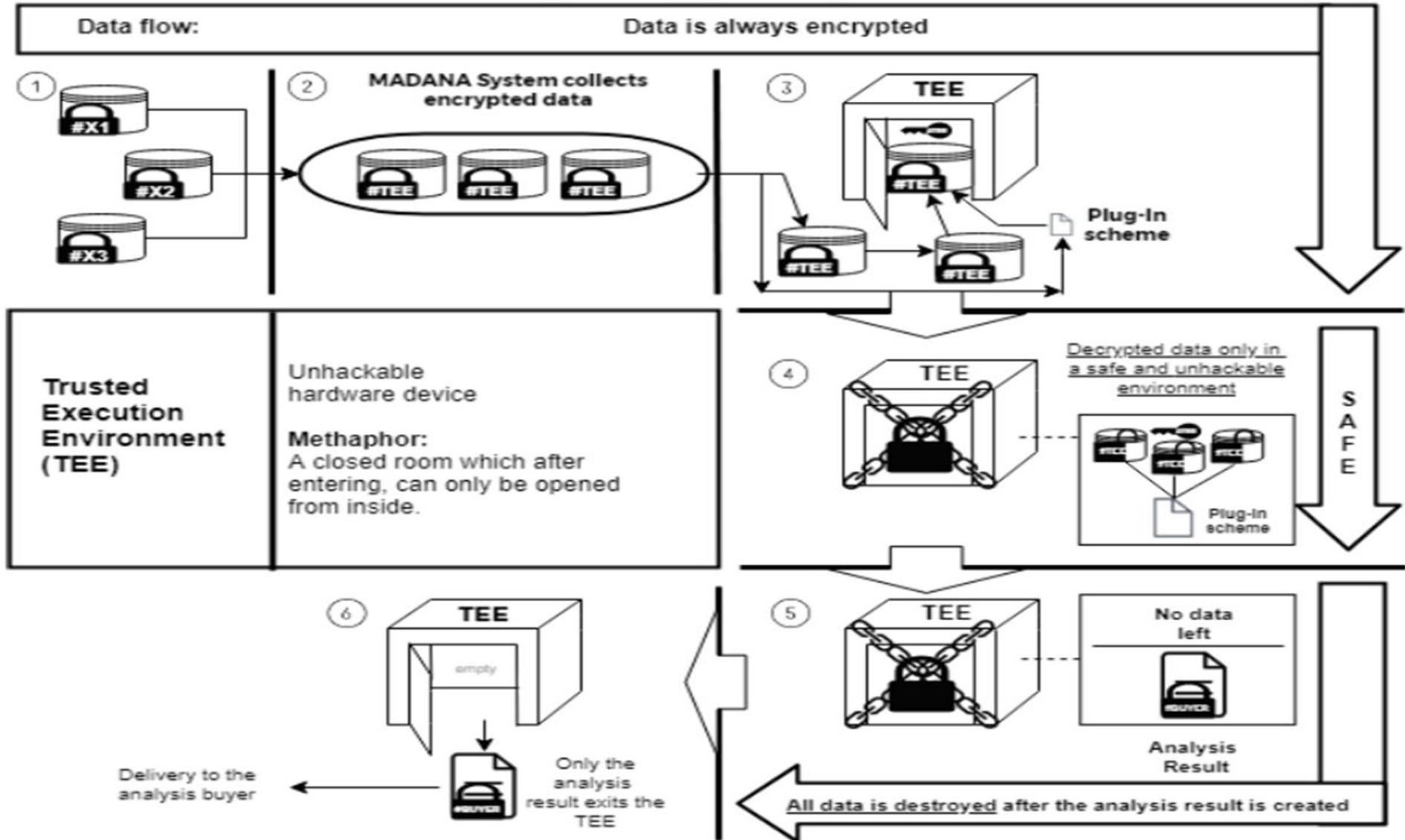➢ Market Research Institutes
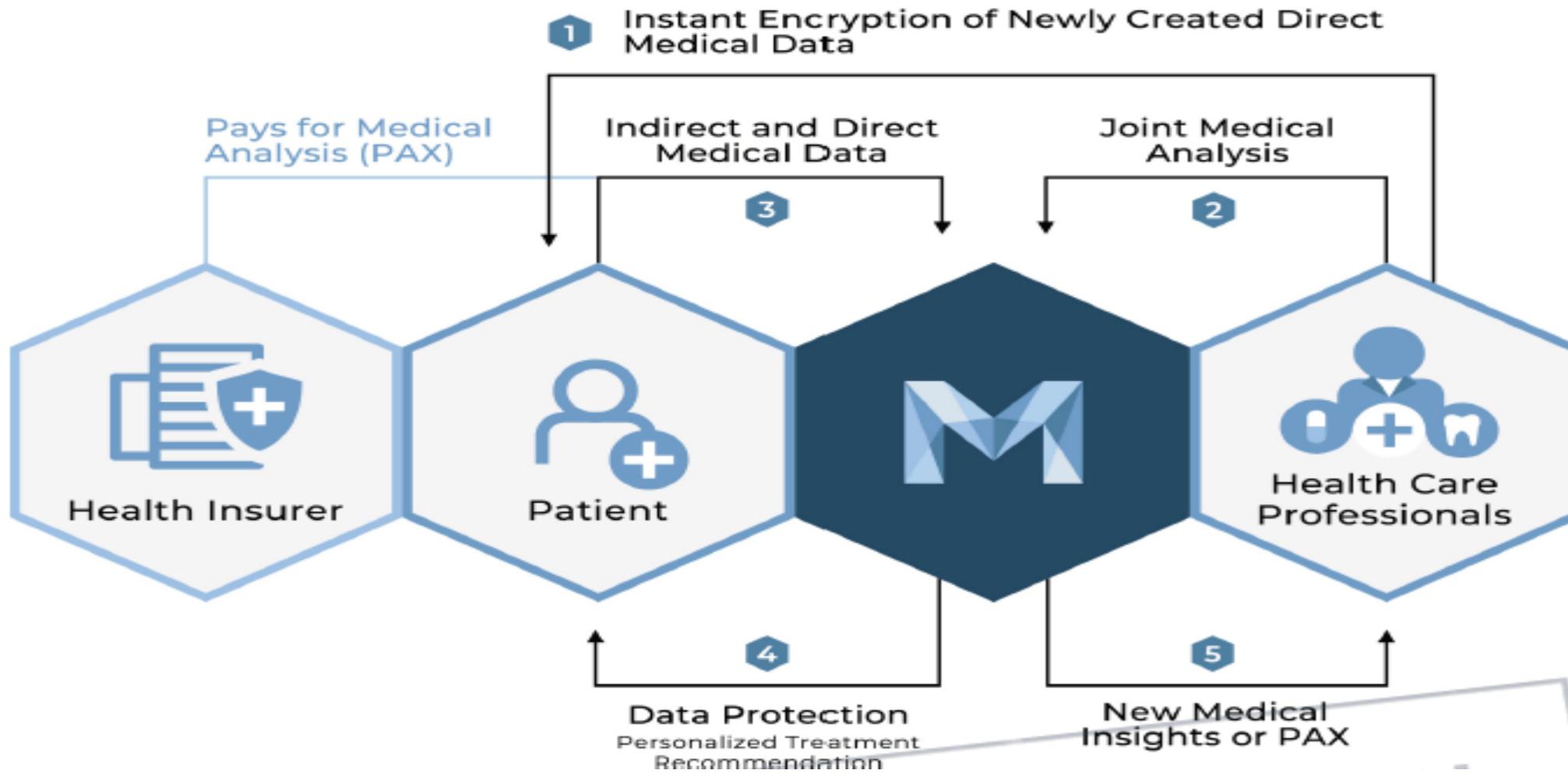➢ Every Data Analyst Professional

Plug-in Providers can be:

➢ Freelancers
➢ Developers
➢ Data Scientists
➢ Analytics companies
➢ Market research Institutes

EHTEL
Collaborating for Digital Health and Care in Europe

@ehtel_ehealth

Data Privacy by MADANA's Design

Mandana whitepaper

Public/private initiative:
Estonian eHealth Fundation/Guardtime
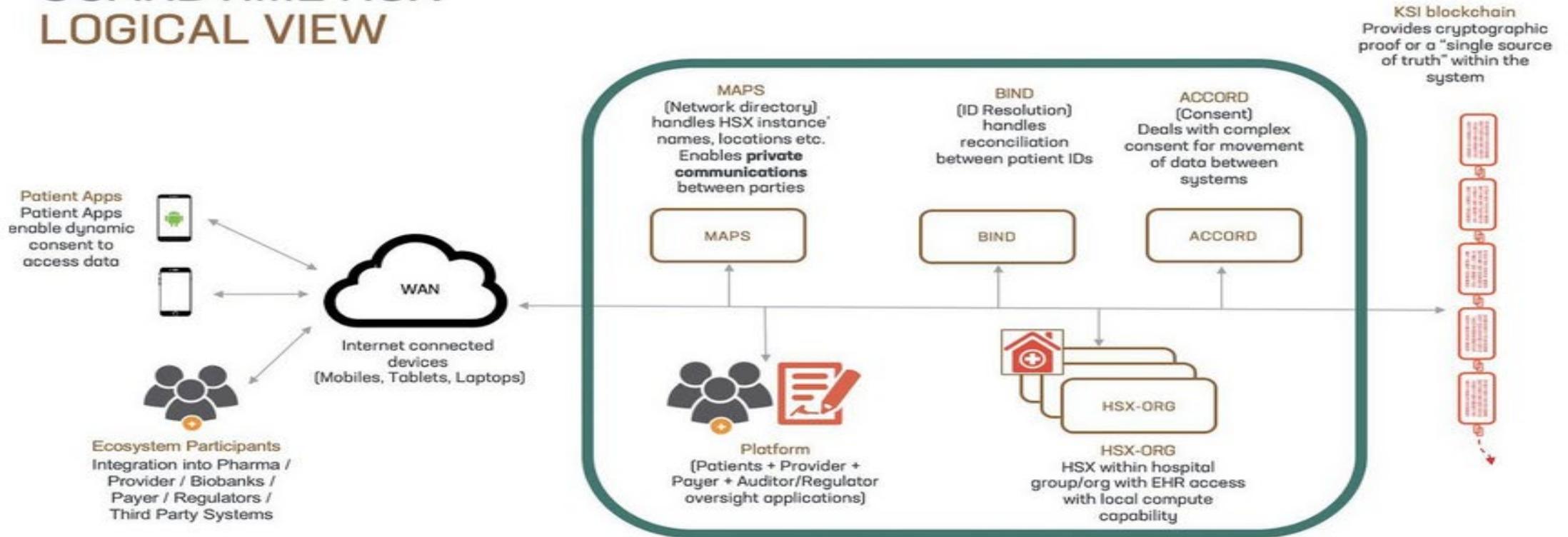
A FOCUSED ECOSYSTEM
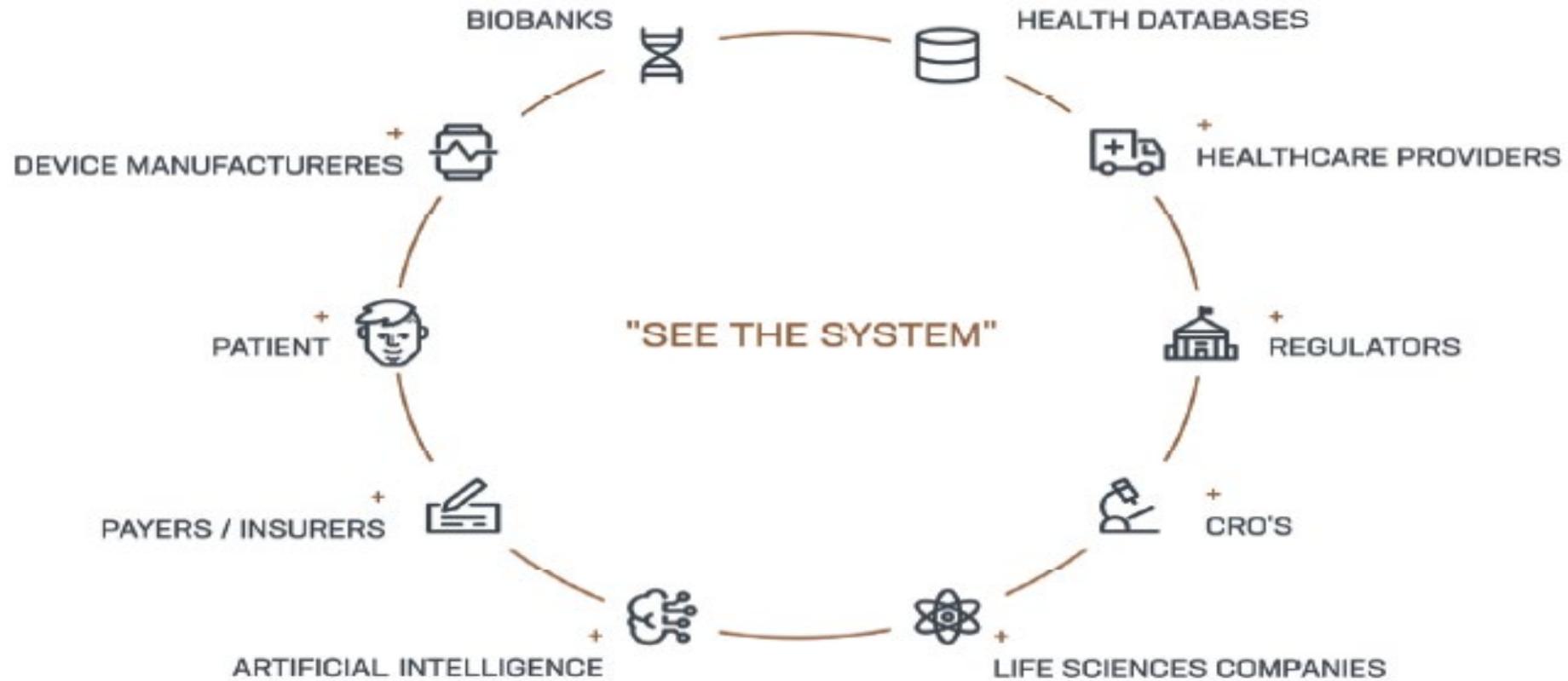
Dynamic consent API

- **Consent:**
  - The consent API enables developers to implement consent in their applications **without needing to understand how consent maps to GDPR** regulations.
  - At its most basic the API provides a predefined **set of consent types; associated consent reasons and how long consent is being granted** so developers just need to choose or match these to their customer requirements and then integrate the API into their application. If **more complex** consent is required the API is **fully configurable**, allowing consent chains to be built quickly just by choosing how many consent types should be bound to an individual.

Main Use case: Assured Medical AI

- **Assured AI provides different institutions a method to offer <u>reliability testing of artificial intelligence algorithms before they are used</u> in medicine. In particular, security and transparency ensuring that <u>all incoming data is reliable and unbiased</u>, outputs are controlled to ensure the protection of personal health data, and that data is processed end-to-end only for the agreed purposes.**
- **<u>Monitor changes</u> in the patient medical record in a real-time mode**

Guardtime Whitepaper

EHTEL
Collaborating for Digital Health and Care in Europe

@ehtel_ehealth

Data fit for EHDS - Architectures and processes enabling data re-use

11:00 – 11:05 | Welcome and Introduction to the second EHTEL ELO Virtual Meeting
ELO CoChairs Andreas Grode, Gematik GmbH, Germany and Vesa Jormanainen, THL, Finland

#Imagining2029

11:05 – 11:10 | Setting the Scene – Lessons from 1st ELO webinar – European Strategy on data
Stephan Schug, EHTEL

11:10 – 11:30 | EU eHealth Network proceedings for governance principles for re-use of health data
Presenter: István Csizmadia, AEEK Hungary and eHealthAction WP5 lead

11:30 – 11:50 | InteropEHRate approach to patient-centric data sharing and enabling data altruism
InteropEHRate Approach and open sharing protocols, Francesco Torelli, Engineering, Italy
InteropEHRate Scenarios and data re-use for research, Stefano Dalmiani, FTGM, Pisa, Italy

11:50 – 12:00 | Flashlight contributions on enabling "European consent in support of the EHDS"
Concept of "broad consent" (Medical Informatics Initiative, Germany): Stephan Schug, EHTEL
Public & private initiatives for operationalising decentralised data spaces: Luc Nicolas, EHTEL

12:00 – 12:25 | Q&A and Interactive Round Table for Webinar Audience
Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

12:25 – 12:30 | Conclusions and Next Steps

Interactive Q&A and Interactive Round Table for Webinar Audience

Facilitator: Prof. Henrique Martins, Digital Health Systems, Portugal

... some elements from webinar presentations

1. Purposes (public health, research, AI) and willingness for data altruism

2. How to organise the re-use of data?

3. When to provide data lakes and when to enable algorithms travelling to the data?

4. How to operationalise GDPR compliant patient consent fit for data re-use

@ehtel_ehealth

Save the date – Next steps

Series of upcoming webinars

- Early September 2020:   **EHTEL Innovation Initiative**
  Digital therapeutics and interacting with human beings

- September 2020:   **Digitally integrated care task force**
  Health data ecosystems for integrated care

- September/October 2020:   **ELO Network Virtual Meeting**
  Investments and regulations for better data sharing and data re-use

Workstreams and Events: https://www.ehtel.eu/imagining-2029.html
Webinar Documentation and Recording: https://www.ehtel.eu/activities/webinars.html

@ehtel_ehealth