Big Data and B2B Platforms: the next big opportunity for Europe

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GRIMALDI STUDIO LEGALE

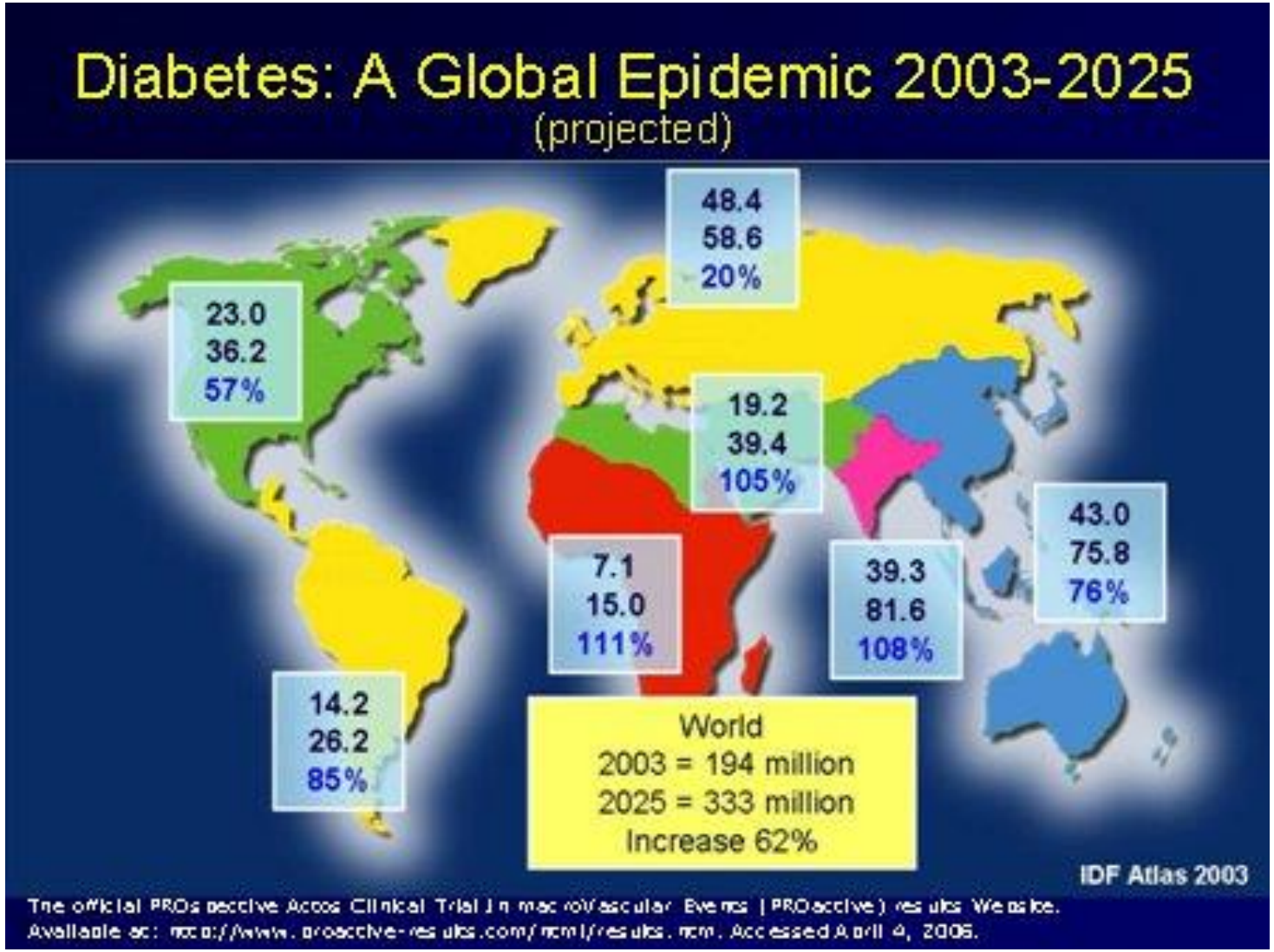
4th Workshop
Infrastructure of health databases in T2D

Big Data and B2B platforms: the next big opportunity for Europe

EASME/COSME/2018/004

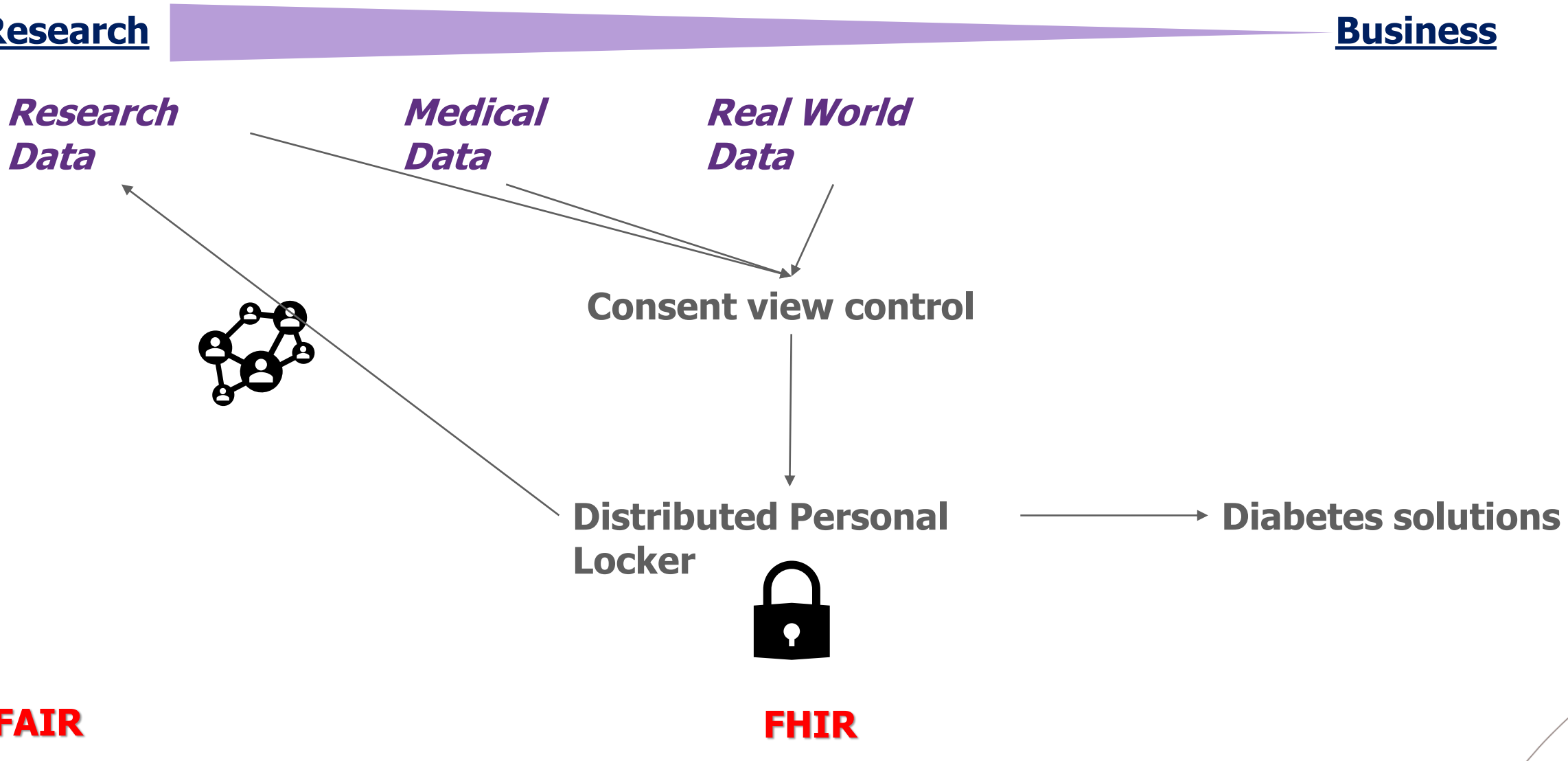
7 October 2020

Diabetes type 2: an Epidemic problem

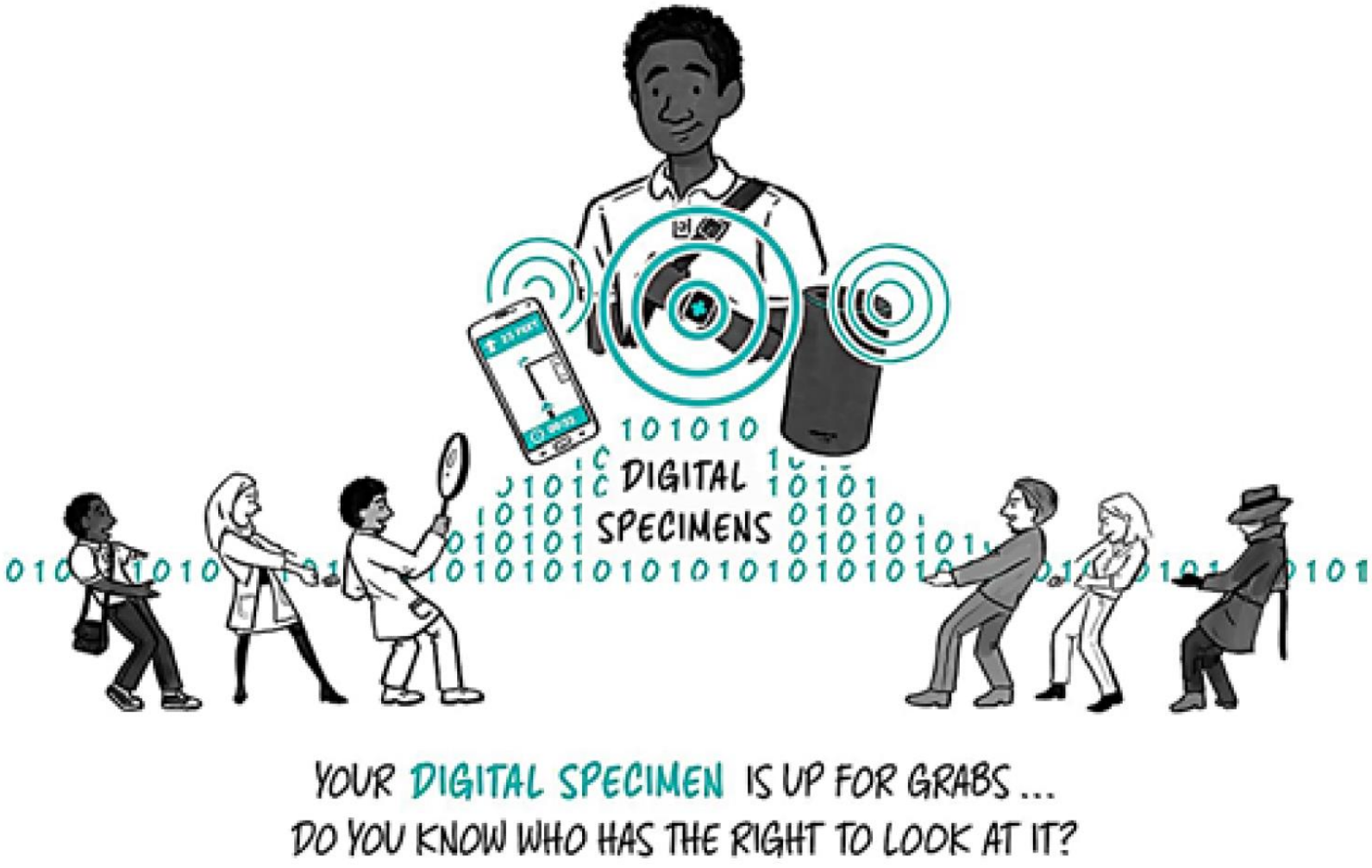


Data silo’s

Diabetes FAIRPOrt: Global idea of the infrastructure



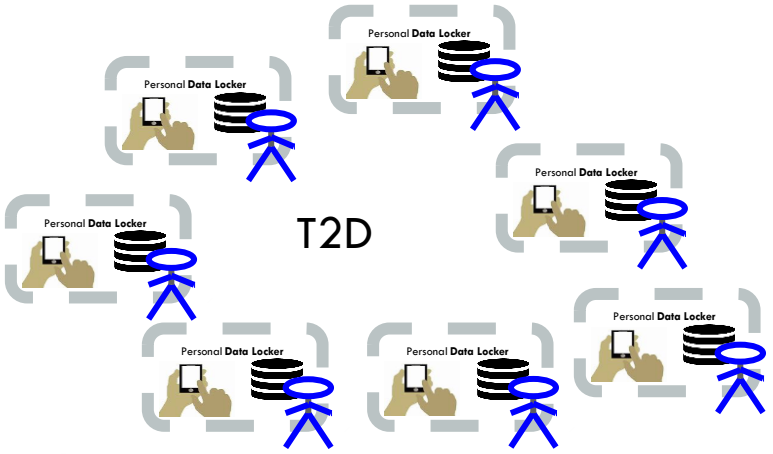
Who owns and controls your data?



Fair-trade of health data

Governance of health data

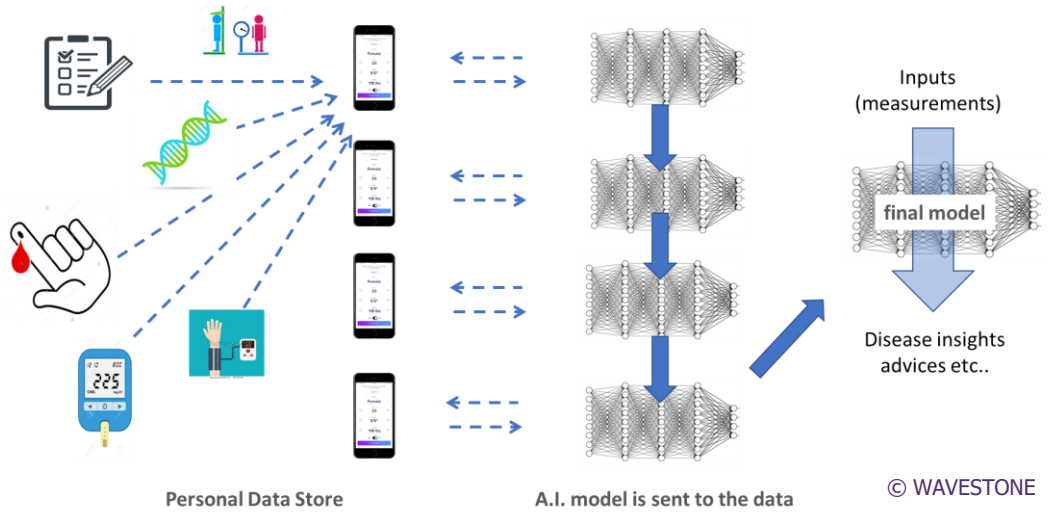
*data **stewardship**
*data **privacy – trust –transparency**
***security**
***dynamic consent**
*responsible and explainable A.I.
*agency over data



Technical needs

***data standardization (FAIR)**
***decentralized** personal data stores
*personal Health Train (**PHT**) approaches
*dynamic **consent** management tools

A privacy-by-design, trust and transparency framework



General goal of the T2D pilot

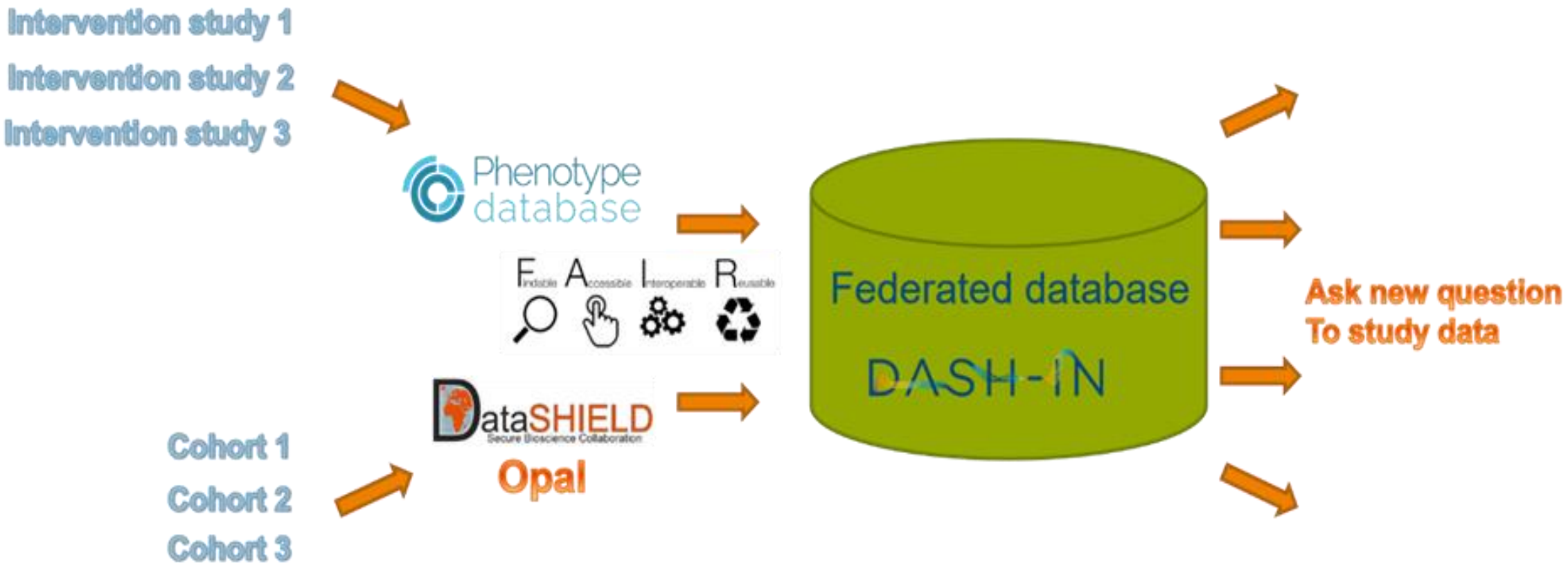
Test and further develop a **federated infrastructure** that connects and unlocks data from different research sources (including omics data) and Real World Data

Two use cases

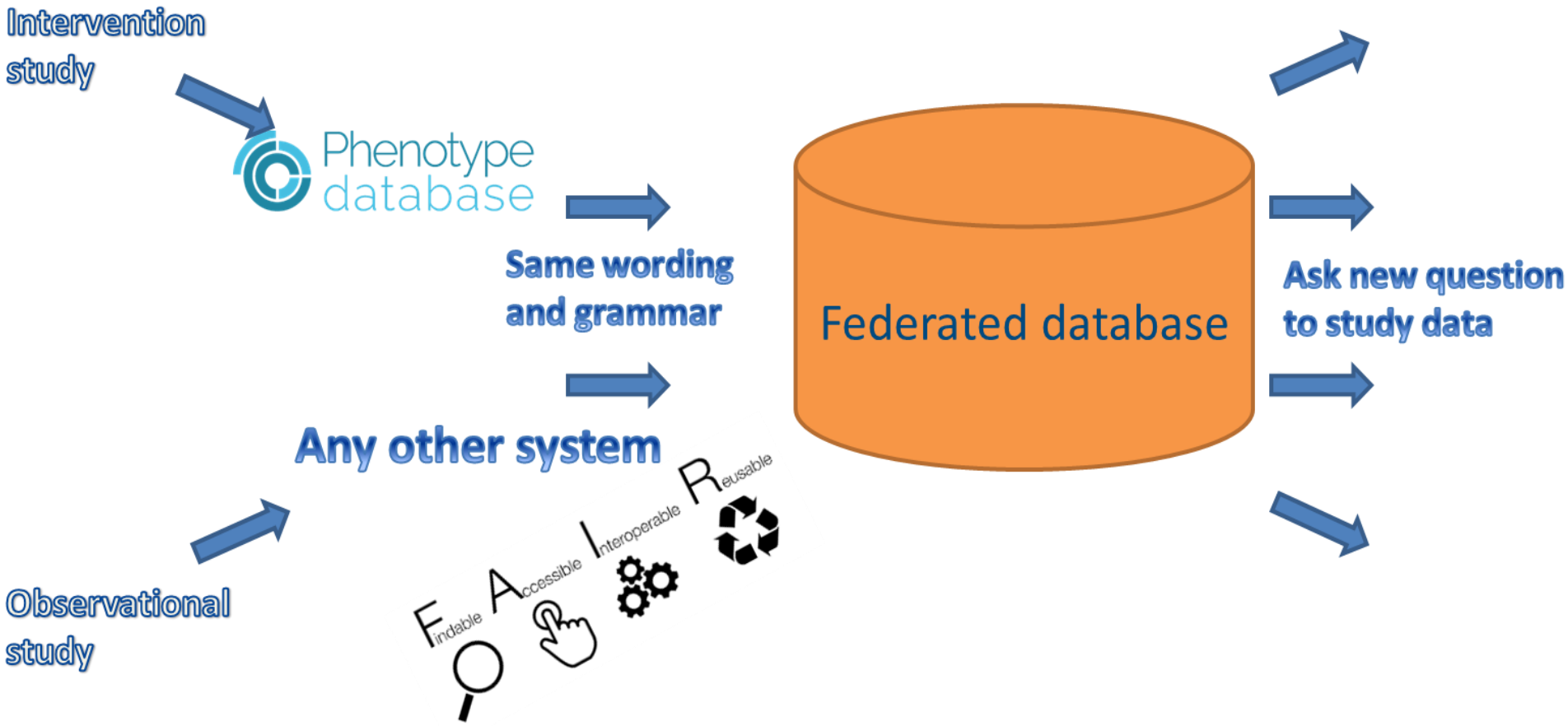
- To **extract and exploit data sets** from both, **'omics' profiling and other biomarkers** from key European and national research projects or prospective **cohorts related to T2D**. These data could be used to develop a comprehensive biomarker package that quantifies the relevant processes of the metabolic flexibility system and determines an individual's metabolic health trajectory and predisposition to certain conditions.

- To **combine such data repository** with **Real World Evidence (RWE)** data. RWE is defined as healthcare information that is derived from multiple sources outside the typical clinical research setting.

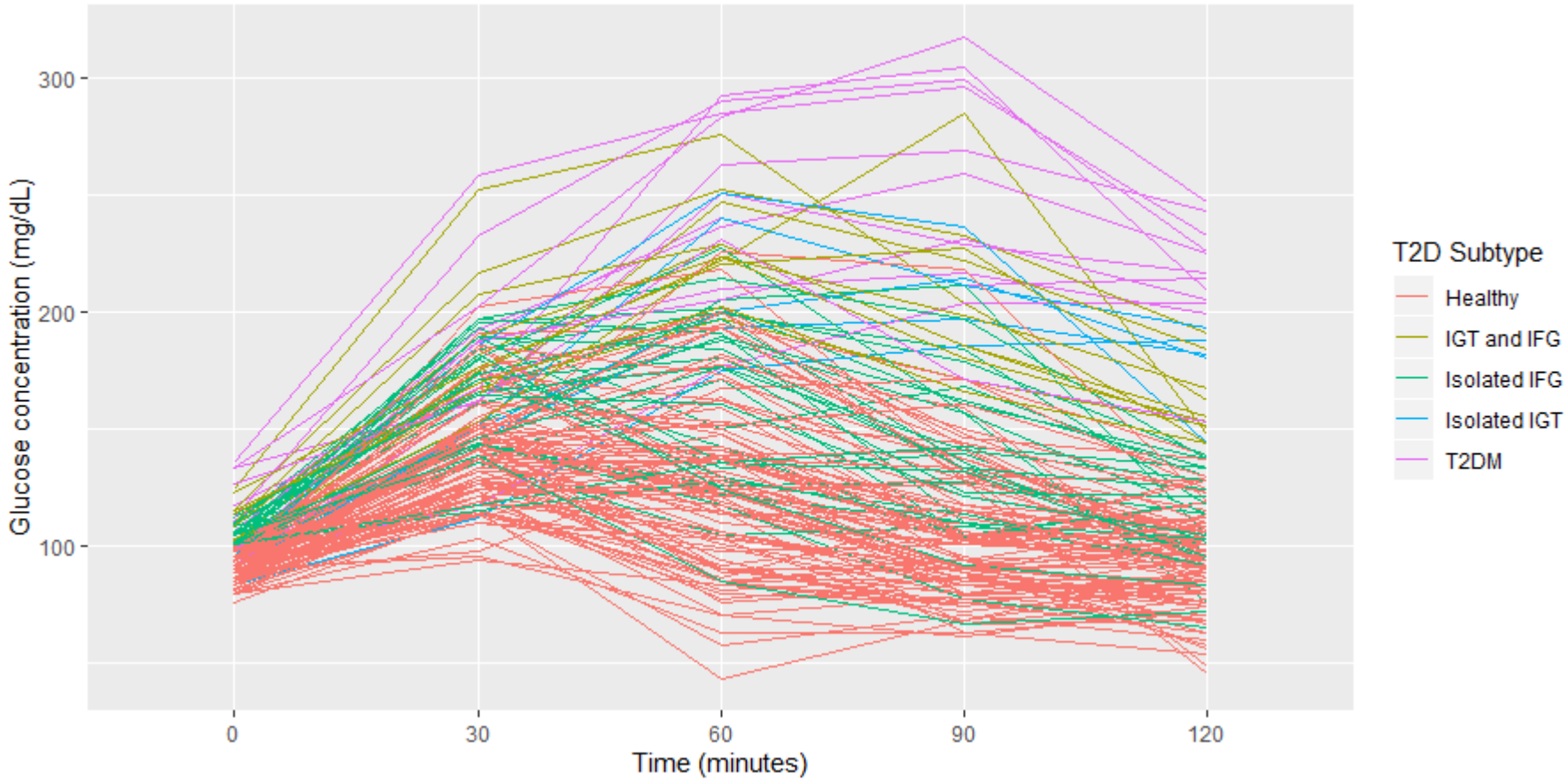
Initial plan for FAIRPOINT, using DataShield



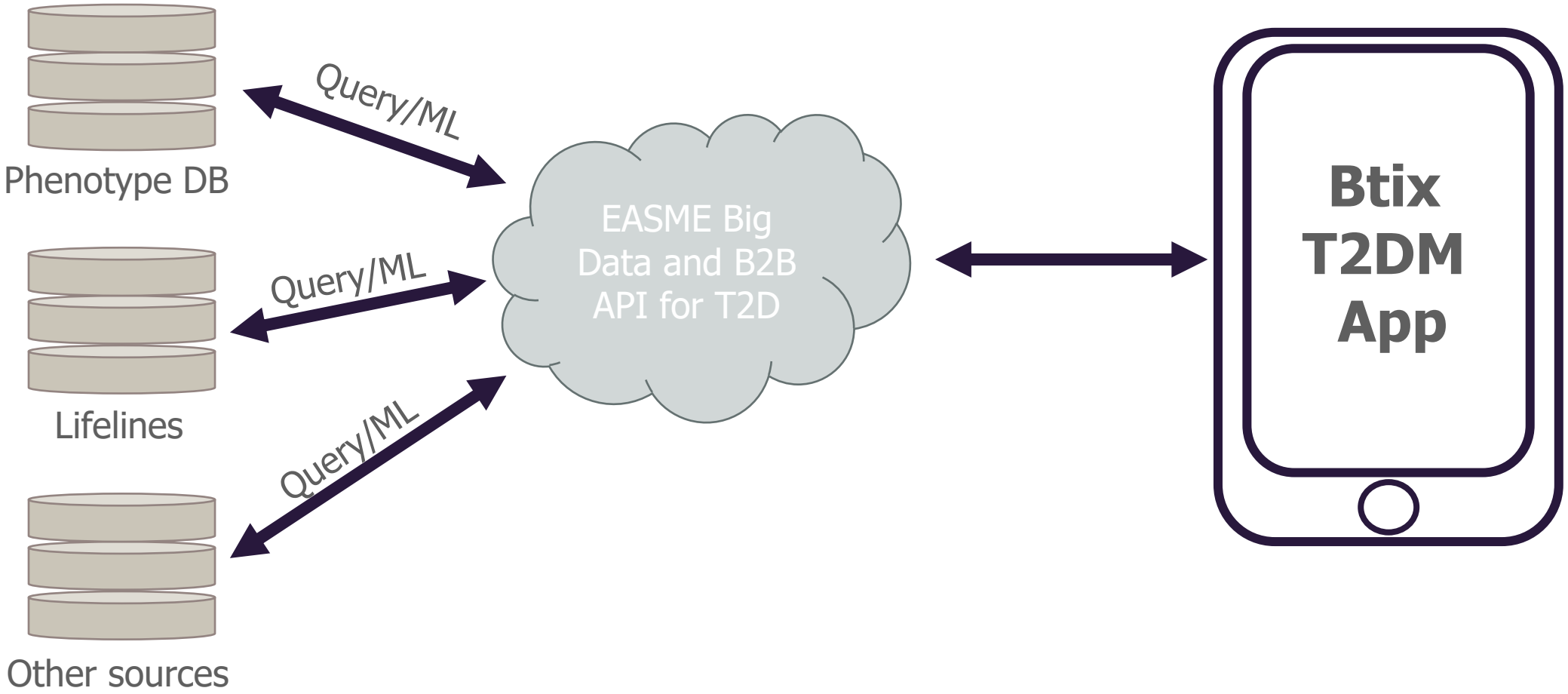
Adapted plan: still privacy-by-design and independent of source database



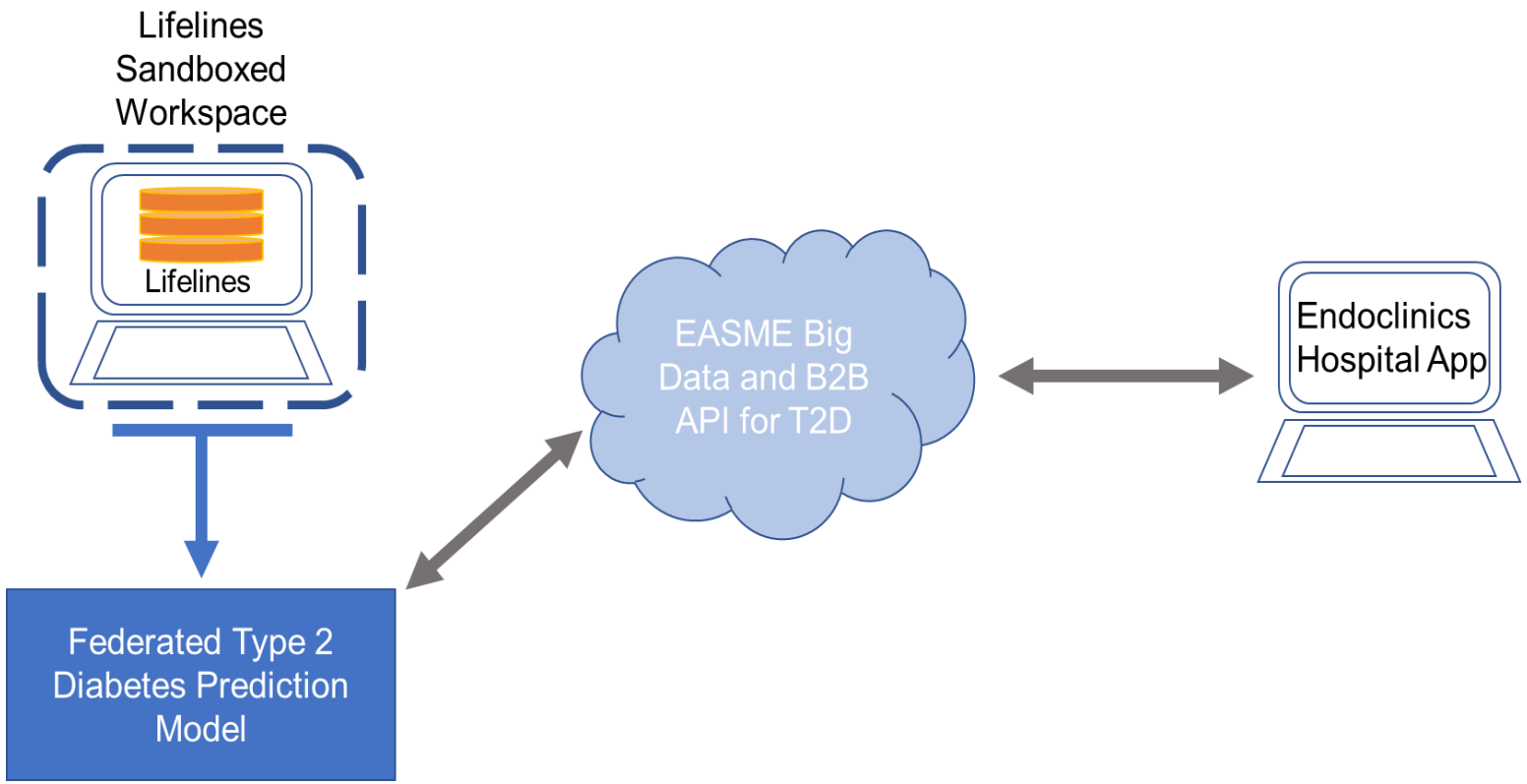
Demo1: Direct calculation of insulin subtypes for all (accessible) studies



Demo2: connecting research data to real world data
Glucose level that one measures at home, would it be possible to estimate insulin levels



Demo3: connecting research data to real world data
Prediction of diabetes onset

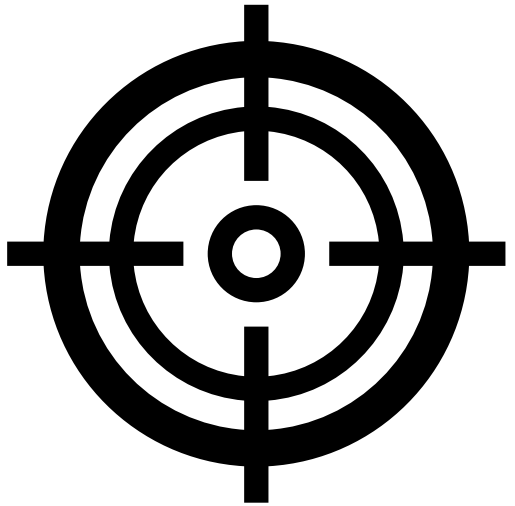


Summary Workshop 3

- We have shown that federated analysis is possible
- Portal: https://dashin.eu/ft2d/login/ and please sign up on this website (source code of portal is stored in a private Github repository)
- Scripts (Github, if licenses are OK): The scripts are currently stored and versioned in an internal version of Gitlab
- Demo mobile-app: Open-sourced on Github (https://github.com/TNO/ft2d-mobile-app) Glucose level that one measures at home, would it be possible to estimate insulin levels
- Prediction of diabetes onset, first they will obtain access to the data in the pilot. Afterwards, using their API token, they can request pretrained model parameters to make the prediction
- An ontology mapper was developed to make it possible to connect additional databases and make them FAIR

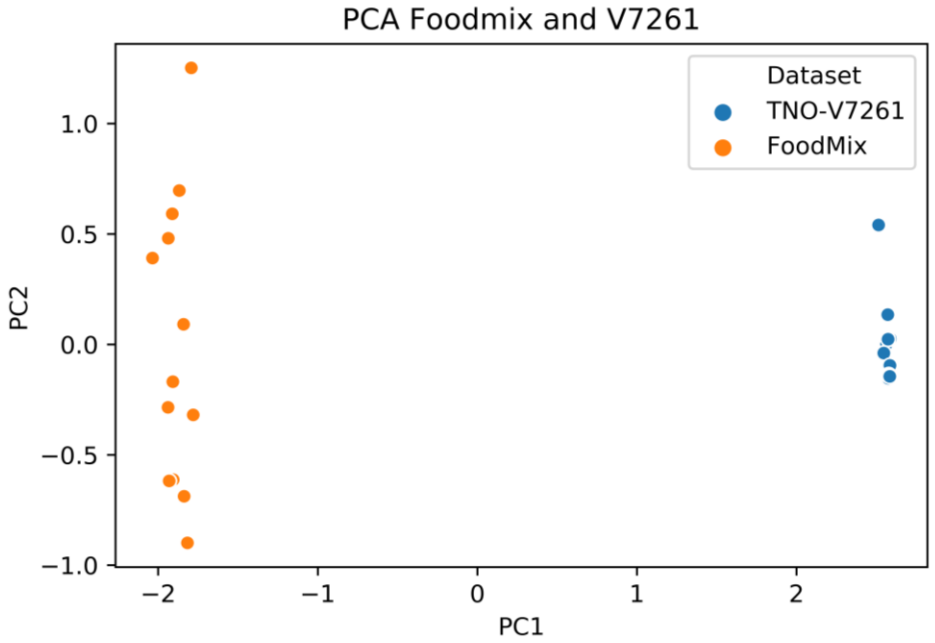
Goals today

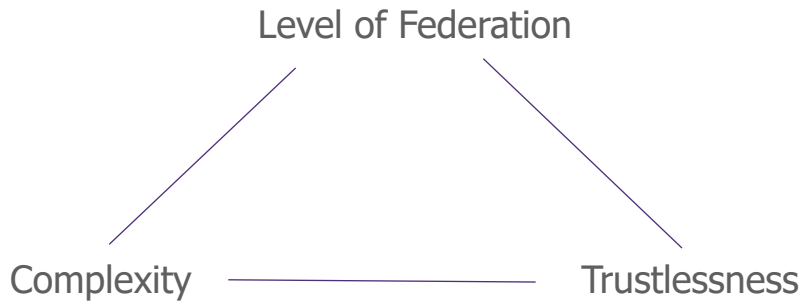
- Review the outcomes of the Pilot: focus on the omics use case and a tutorial of how participants can access the data
- Discuss on the functionality of the system, and on the usability of the interface
- Presentation the Hyve: From the point of view of SMEs, what are the barriers and next steps
- Presentation of the policy recommendations to support data sharing in the healthcare sector
- Discussion on market deficiencies and regulatory barriers and related policy recommendations with participants



Lessons learned from the pilot (Technical Perspective)

- Technical experts are in high demand
- Efforts such as the ontology mapper are essential to creating a sort of 'minimum' level of standardization
- Standardize standards – When there are a hundred standards, there is no standard
- Guidelines for privacy
- Privacy-by-design implementations exist on a continuum. There is no 'one size fits all' solution. The level of security required to access data is essential to determine use-case specific roadmaps





Lessons learned from the pilot in general

- Privacy-by-design technology can give access to individual data for aggregated analysis, but (not yet) GDPR compliant
  - Biomarker calculation can be done in a federated way (using data of other subjects)
  - Disease prediction can be done with federated analysis
  - Omics profiles can be compared to research studies/cohorts
- Individual health data dynamics can be processed automatically
- Data access remains an issue
  - Psychological issues: *the data is mine….*
  - Legal issues: *for every data access the contract has to be negotiated and data is often proprietary*
  - Ethical issues: *Can personal medical data even be used in a commercial setting?*
  - Technical issues: *Insufficient software available for privacy-aware data analysis and federated learning*
- Data interoperability
  - Data and metadata over different sources need to refer to the same terms: we made an ontology mapper
  - Ontologies are community dependent, we started with enriching the current diabetes ontologies
- For diabetes eHealth tools the diabetes ICHOM (outcome measure) is important → value-based health care

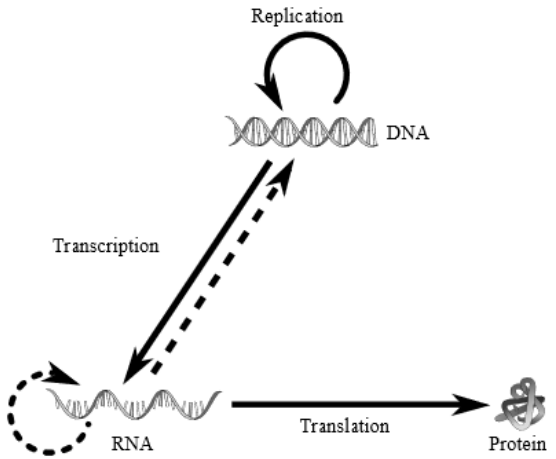
DEMO- use case 2

https://dashin.eu/ft2d/tutorial

Tutorial

In this tutorial, we will try to get some information about β cell dysfunction based on transcriptomics data available in FT2D.

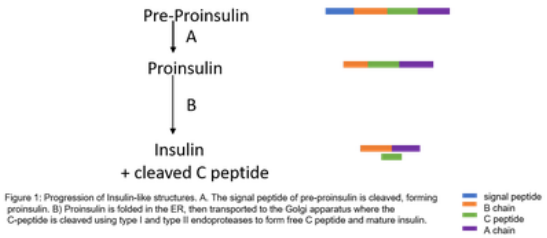
What is transcriptome?



RNA is synthesized from DNA. This process is called transcription. Afterwards proteins or peptides are synthesized using the RNA sequence. This process is called translation. (source: Wikimedia Commons)

Transcriptome is defined as the collection of RNA (transcripts) collected from individual or population of cells. RNA is synthesized from DNA and it contains the genetic sequence that is necessary to synthesize proteins or peptides.

What are β cells?



Insulin synthesis (source: Wikimedia Commons)

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Thank you for your time

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European Commission

7 October 2020

4th Workshop
Infrastructure of health databases in T2D

Big Data and B2B platforms: the next big opportunity for Europe

Dr. C.E. Chideock

7 October 2020

Goal of this session

Findings from Delphi survey process on draft policy recommendations

- What the surveys tell us:
  Relative importance
  Relative urgency of action
- Four areas for final debate
  - How to move forward OR
  - What's needed to reach consensus?

Background

- Significant opportunities for improving healthcare outcomes through data-driven services.
- Requires an ecosystem that allows data flow, within a trust framework supported by all stakeholders.
- At present a series of barriers exist to data sharing to enable this.
- These barriers can be overcome. In a nutshell, the actual and potential barriers identified are:

/ the requirements applicable across the EU for the protection of personal data, and health data in particular;

/ the uncertainty around who is held liable in case of damages stemming from data-driven services and how the quality of the data should be ensured in a marketplace;

/ the need for accountability and trust for sustaining a data-sharing framework;

/ the need to ensure that data can flow seamlessly supported by interoperable and standardized systems and processes;

/ the potential strategic barriers to accessing data; and

/ the need for digital literacy and skills.

To explore these barriers and find possible solutions, we undertook a series of surveys

- Three rounds of surveys sent to 12 experts from different stakeholder groups. (July through September)
- Findings from first survey summarised, anonymised and recirculated for comment.
- Second survey produced some consensus, but minimal further comment.
- Third survey asked 2 main questions – timescale for implementation and relative importance of the policies.

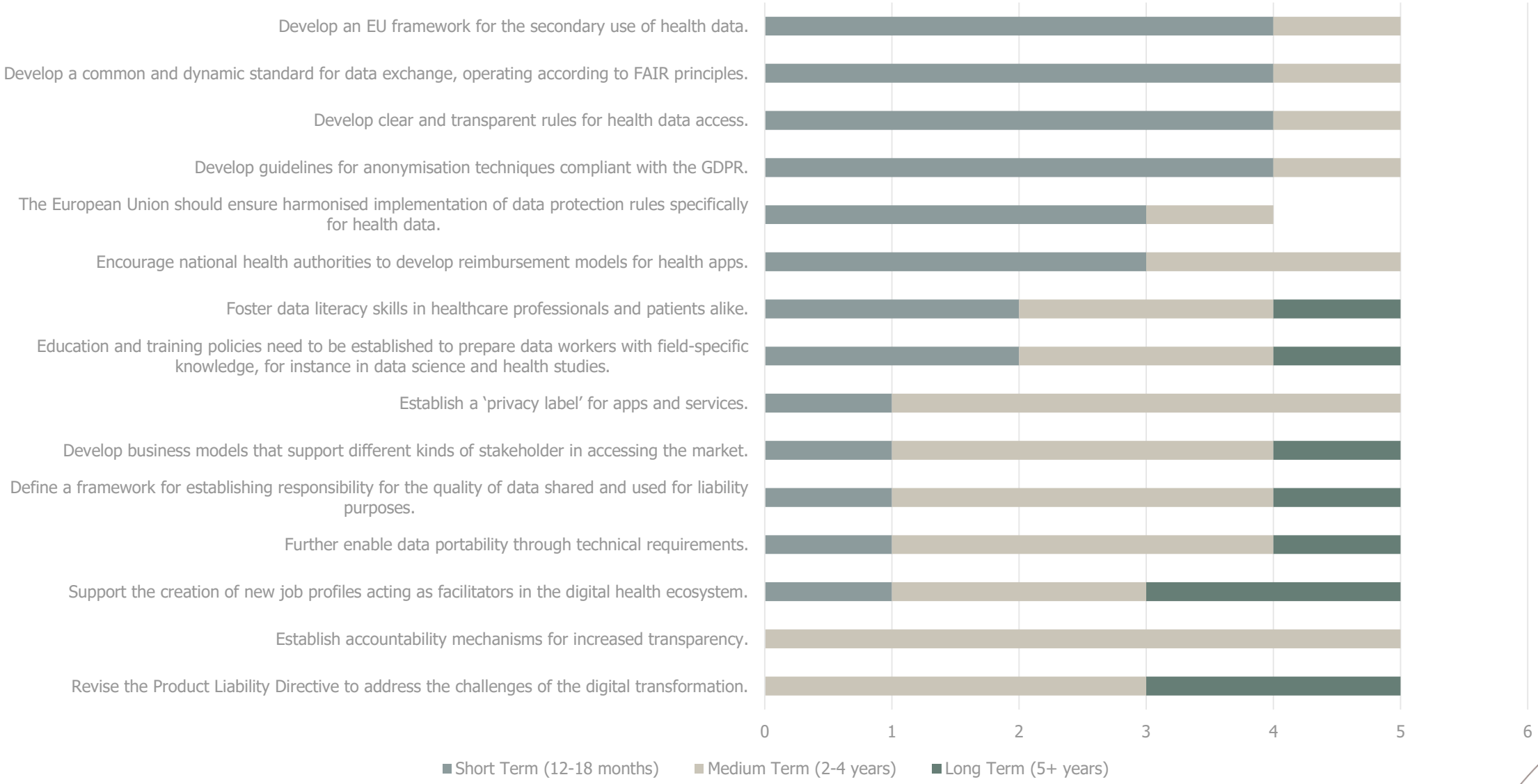
To note:

/ Small groups of people. Response rate was around 50% (7 in first survey, 6 in second survey, 5 in third survey) – probably due to the time of year.

/ In the first survey in particular, most recommendations were rated as important – average of all grades given was 4, only two 1s and six 2s for all statements. Most people think most recommendations are important!

Experts commented on the relative importance of recommendations

And on possible timelines for implementation



Policy recommendations can now be categorised into three groups

Consensus – move forward on detail	Debate – dig deeper	Relatively lower in importance/ low debate
The European Union should ensure harmonised implementation of data protection rules specifically for health data	**Establish a 'privacy label' for apps and services**	Support the creation of new job profiles acting as facilitators in the digital health ecosystem.
Encourage national health authorities to develop reimbursement models for health apps	Address fragmentation of liability rules due to diverging national approaches by overseeing their evolution and promoting a coherent approach to enable cross-border data exchanges.	Establish accountability mechanisms for increased transparency.
Develop guidelines for anonymisation techniques compliant with the GDPR	Develop a common and dynamic standard for data exchange, operating according to FAIR principles.	Further enable data portability through technical requirements.
Foster data literacy skills in healthcare professionals and patients alike.	**Develop an EU framework for the secondary use of health data.**	Support research demonstrating the benefits of T2D lifestyle apps in partnership with patient advocacy organisations
Develop clear and transparent rules for data access	Revise the Product Liability Directive to address the challenges of the digital transformation	Define a framework for establishing responsibility for the quality of data shared and used for liability purposes.
Education and training policies need to be established to prepare data workers with field-specific knowledge, for instance in data science and health studies.		Develop business models that support different kinds of stakeholder in accessing the market.

‘Ensure harmonized implementation of data protection rules specifically for health data’

- GDPR has helped to create a foundation for governance and regulation of data, but implementation has led to differences in application in Member States.
- The European Data Protection Board’s remit includes issuing guidelines/ best practice and ensuring consistency of application, particularly on cross-border cases.
- Feedback from experts suggests that inconsistency remains an issue.
- Highest ranked recommendation in Delphi 1, 4th highest in Delphi 3.

Key questions :
- How should harmonization happen?
- If guidelines are not the answer – how should this dialogue take place?
- *Should this be about harmonization or a reduction in over-implementation?*

A harmonized set of regulations will **reduce the legal and compliance burden on SMEs.** [SME]

A harmonization of regulations between is **crucial for the implementation of a functioning marketplace**. [Industry Association]

There is little discussion at the EDPB-level meaning dissenting voices get drowned out by the majority. Harmonization needs to happen through **new means of dialogue with member states, researchers, healthcare providers, data protection experts and industry, and not through EDPB guidelines.**

‘Encourage national health authorities to develop reimbursement models for health apps’

- In Europe, health apps are rarely covered by health insurance services.
- This leads to low uptake, and limits start-up activity for health apps in Europe.
- Reimbursement models could help make tools and apps affordable for T2D patients.
- Second highest ranked recommendation in Delphi 1, 5th highest in Delphi 3.

Key questions for today:

- Reimbursement models would need to be implemented on a country by country basis – suggestions for how to manage this?
- Are there models in some countries that experts would recommend?
- What is the role of scientific evidence?
- What is balance between preventive and medical support? (how is the funding model now for prevention in your country?)

Data protection business: The only way to boost innovation in healthcare and provide solutions for unmet needs is to provide means for start-ups and companies to develop sustainable business models. The current reimbursement system is the core issue that keep the innovation landscape for healthcare on hold.

SME Data user: Clear and unified reimbursement models would provide much needed guarantees for companies in this market.

‘Develop guidelines for anonymisation techniques compliant with the GDPR’

- While anonymised data is not subject to the GDPR, significant uncertainty remains about what is considered anonymised data and what anonymisation techniques should be employed to comply with GDPR.
- Specific guidance on their application and the accompanying regulatory implications lacking.
- 3rd ranked recommendation in Delphi 1 and Delphi 3, clear consensus.

Key questions for today:
- How far can anonymization guidelines be created?
- What are SMEs looking for exactly?

SME: There should be guidelines that balance the degree of anonymisation with the level of permission gained from the data owner.

Industry Association: There is an urgent need for practical and technical clarification to what extent data needs to be anonymised in a health context to ensure it is no longer considered personal data, while also trying to preserve the value and meaningfulness of the health data.

'Establishing Trust: Establish a 'privacy label' for apps and services'

- A 'privacy label' for health apps could be developed along the lines of nutrition labels, containing information about the underlying technology and the level of privacy the application provides.
- Can also act as a self-regulatory measure, allowing developers to distinguish themselves in the market.
- 9th in importance in Delphi 1, 11th in Delphi 3, ranges in importance from 5 to 3.
- Range of disagreement shown in Delphi 2 - key points
  - / Who or what should be in the lead for developing a privacy label?
  - / Does a label risk over-simplifying for consumer?

SME: The market will decide... The law should not dictate this. [SME * 2 disagreed, industry association disagreed]

Industry Association: We… question whether labelling would be the most effective instrument to address such a complex issue. [SME *2 disagreed, other industry association disagreed, standards association disagreed]

Company – data protection: The use of such a label will provide a simple and accessible way to improve awareness and educate consumers. Privacy policies and legal terms are too often too complicated for the general public to understand.

Key questions for today:
- How should we encourage the development of trust in the secondary use of health data?
- Who would develop and implement the privacy label?
- How would compliance with the requirements be audited?
- Should the market or EU be in the lead?
- Is labelling over simplistic?
- (although not an alternative) would a feedback loop work to increase trust?

Develop an EU framework for the secondary use of health data.

- There is a lack of clear rules for the secondary use of health data for applications such as research and wider public health considerations.
- The Finnish national law on the secondary use of health data is an example of policy action that supports legitimate developments in this field.
- Introducing a framework for the secondary use of health data at the EU level, building on the example of the Finnish law in this field, can bolster research and innovative data-based applications.
- 6th ranked recommendation in Delphi 1, polarisation on importance (four 5s, three 3s), 1st ranked recommendation in Delphi 3,

Key questions for today:
- Would this framework add value at the EU level?
- How would this model adapt to national or regional contexts?
- Is this simply about consent from the original owner of the data?
- What would scope and purpose look like?

Public sector: The Finnish law is a valuable tool at national level, but it is questionable whether such a framework would add value at the EU level. What would the framework do? It is such a broad concept so the framework might as well encompass many of the recommendations put forward in this document. [SME disagrees, SME agreed]

Industry Association: A certain level of adaptability may be required to ensure such initiatives (Frameworks) are well-adjusted to the national or regional context.

SME: The important issue here is the permission to trade in a secondary market. Does the original owner of the data give explicit permission and take part in the economics as is the case with all other IP? [Industry Association x 2 disagrees, data user disagrees]

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EASME/COSME/2018/004

European Commission

7 October 2020

Big Data and B2B platforms: the next big opportunity for Europe Online meeting – 7 October 2020 - 09:00 – 13:15				
9:00	9:05	5 min	Welcome & practicalities General information about the workshop	Wavestone/CEPS
09:05	09:15	10 min	Goal setting Recap on the objectives and aims of this study under WP2 "Explore the feasibility of, pilot, promote and stimulate strategic investment in high-impact healthcare related projects" What did we do and why? What did we learn? What should be changed in the set-up of data exchange infrastructures?	TNO Jildau Bouwman
09:15	09:45	30 min	Final presentation of the pilot Demonstration of the 1st and 2nd use case and presentation of the status of the infrastructure development as well as the outcomes collected during the last workshop. What did we learn? What does it mean for the future? (ref. COVID, European Open Science Cloud (EOSC))	TNO Serdar Özsezen Andrew Berdard
09:45	10:25	40 min	Break-out 1: Lessons learned from the pilot infrastructure and use cases Input from the experts on the lessons learned and future developments (using Mentimeter as a tool for discussion). Participants will be asked for extensive review and feedback on the pilot infrastructure and the use-cases.	TNO team
10:25	10:30	5 min	Break - Bring your own tea/coffee	
10:30	11:00	30 min	Presentation from an invited speaker From the point of view of SMEs, what are the barriers and next steps to bring this initiative further. What lessons did the SME learn and what policies could be helpful and supporting successful implementation. What are the important issues to solve?	Kees van Bochove, CEO of The Hyve
11:00	11:30	30 min	Break-out 2: lessons learned discussion based on SME experience Discussion on all lessons learned from the project on technical, legal and ethical issues and needed policies and related to the practical experience from the SME presentation.	TNO team
11:30	11:50	20 min	Break - Bring your own tea/coffee	
11:50	12:05	15 min	Presentation of the recommendations to the EU and national policy makers to create a unified EU-wide diabetes related data platform Presentation of the policy recommendations to support data sharing in the healthcare sector, focusing on the urgency of action and the role of stakeholders. Results from the regulatory barriers study and input from experts during the Delphi study on needed policies will be presented.	TNO Cass Chideock
12:05	12:35	30 min	Break-out 3: discussion on market deficiencies and regulatory barriers with proposed associated policy recommendations Participants will be invited to share their opinion on where they see potential market deficiencies and regulatory barriers and how they prioritize the suggested policies and their practical roll out. Aiming at some concrete recommendation to the EU.	TNO team
12:35	12:50	15 min	Break - Bring your own tea/coffee	
12:50	13:10	20 min	Wrap-up of the day Focus on policy recommendations related to the topics discussed in the breakout sessions. Q&A will follow the presentation	TNO André Boorsma/ Jildau Bouwman
13:10	13:15	5 min	Give your feedback and thank you for the participation This time will be dedicated to fill-in the satisfaction survey on the workshop day.	Wavestone

Thank you