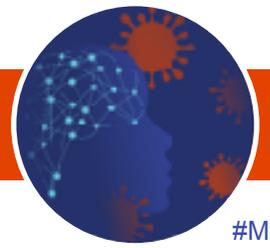


Data Sharing: Good practices

Prof Dipak Kalra
President of i~HD

FLAMES Annual Meeting 2021



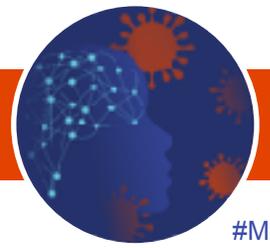
Mission

To support people affected with MS, healthcare professionals and researchers during the pandemic

Objective 1: Scale-up COVID-19 data collection efforts

Objective 2: Achieve insights to support care during the pandemic

Objective 3: Act as stimulus to steer ongoing and future scientific research



A list of variables that can be the common denominator across all initiatives

Approach consensus building:

Step 1: Prepare draft recommendations for a COVID-19 core dataset

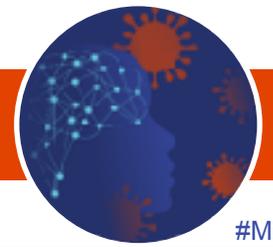
- 1. Compare several initiatives that were already pioneering COVID-19 data collection in MS**
e.g. Italian MuSC-19 Case Reporting platform, UK MS Register substudy protocols, Australia and New Zealand COVID19 Data Set, ...
- 2. Aligning with more generic COVID-19 data collections**
e.g. LEOSS register for hospitalized COVID-19 patients, World Health Organization's recommendations, ...

Step 2: Consensus-building global task force agreeing upon the final list of variables

Wednesday 25th of March 2020

Task force: Liesbet M. Peeters (MSDA), Clare Walton (MSIF), Nick Rijke (MSIF), Tina Parciak (MSDA), Robert McBurney (iConquerMS), Rod Middleton (UK MS Registry), Anneke Van Der Walk (Australia and New Zealand COVID19 Data Set & MSBase Registry), Maria Pia Sormani and Marco Salvetti (Italian MuSC-19 Case Reporting platform), Giancarlo Comi (ECF), Jan Hillert (Swedish MS Registry), Bruce Bebo (US National Society), Alberto Asherio (Harvard University), Alexander Stahmann (German MS Registry)

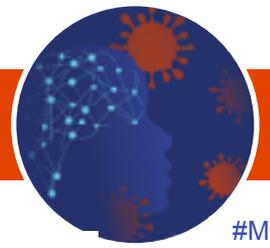
COVID-19 & MS Global Data Sharing Initiative : Current data partners



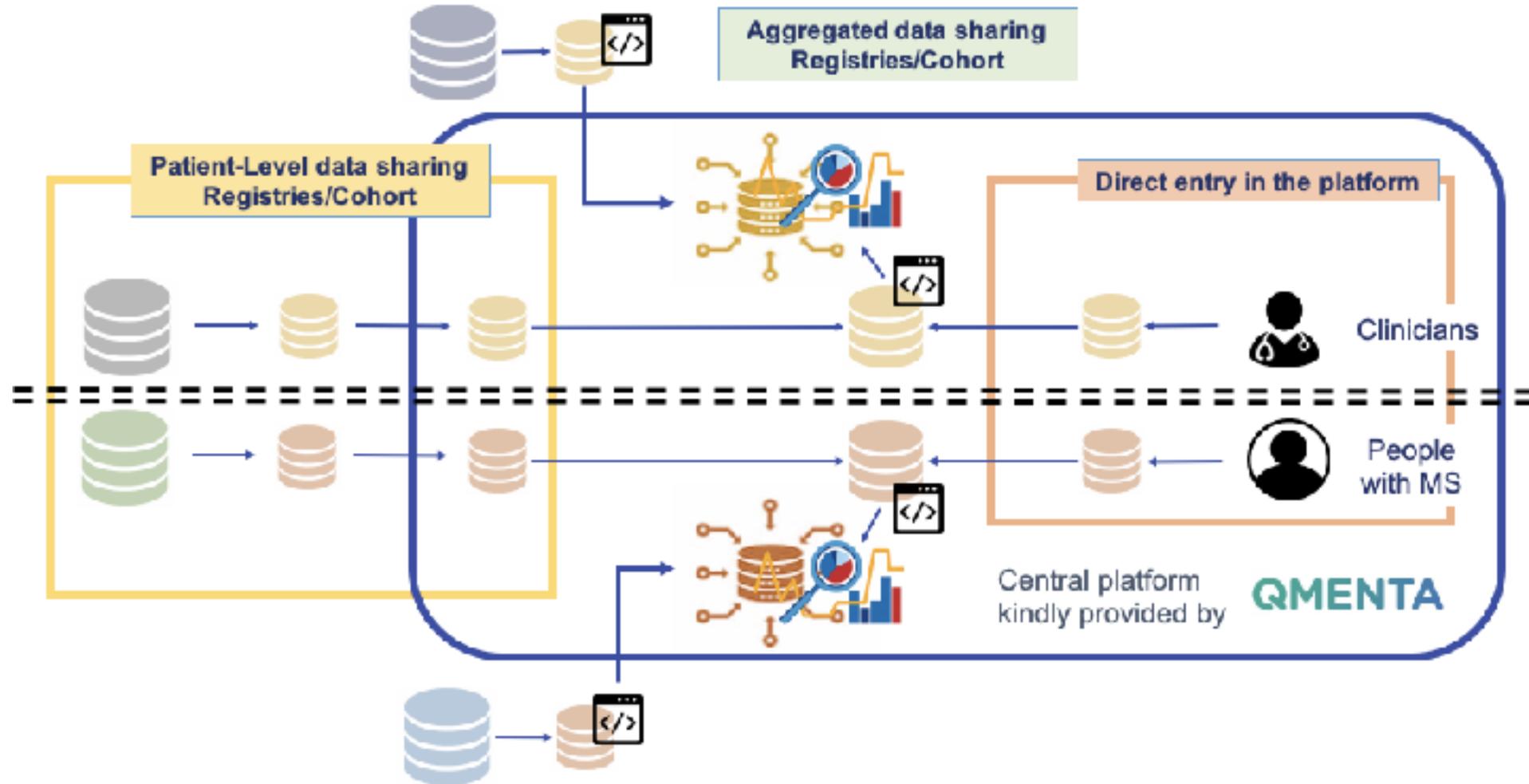
#MSCOVID19

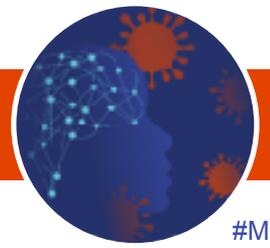


How does the Global Data Sharing Initiative work?



#MSCOVID19





+50%
increase in the
number of
participating
registries from 12 to
18



+48%
increase in the
number of
records from
5727 to 8484



- 75%
reducing time
needed for (!)
weekly data
wrangling

MULTIPLE
SCLEROSIS
JOURNAL

MSJ

Future Perspectives

COVID-19 in people with multiple sclerosis: A global data sharing initiative

Liesbet M Peeters¹, Tina Parciak, Clare Walton, Lotte Geys, Yves Moreau, Edward De Brouwer, Daniele Raimondi, Ashkan Pirmani², Tomas Kalincik, Gilles Edan, Steve Simpson-Yap³, Luc De Raedt, Yann Dauxais, Clément Gautrais⁴, Paulo R Rodrigues, Landon McKenna, Nikola Lazovski, Jan Hillert, Lars Forsberg, Tim Spelman⁵, Robert McBurney, Hollie Schmidt, Arnfin Bergmann, Stefan Braune, Alexander Stahmann, Rodden Middleton⁶, Amber Salter⁷, Bruce F Bebo, Juan I Rojas, Anneke van der Walt⁸, Helmut Butzkueven, Ingrid van der Mei, Rumen Ivanov, Kerstin Hellwig, Guilherme Sciascia do Olival, Jeffrey A Cohen⁹, Wim Van Hecke, Ruth Dobson¹⁰, Melinda Magyari, Doralina Guimarães Brum, Ricardo Alonso, Richard Nicholas, Johana Bauer, Anibal Chertcoff, Jérôme de Sèze, Céline Louapre, Giancarlo Comi and Nick Rijke

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The spectrum of data use: from care to research

Individual level health data

EHR systems, apps, sensors, genomics, Clinical Decision Support, AI

Used for:

- Health status monitoring
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness

Population level health data

EHR systems, regional & national eHealth infrastructures

Reused for:

- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

Big health data

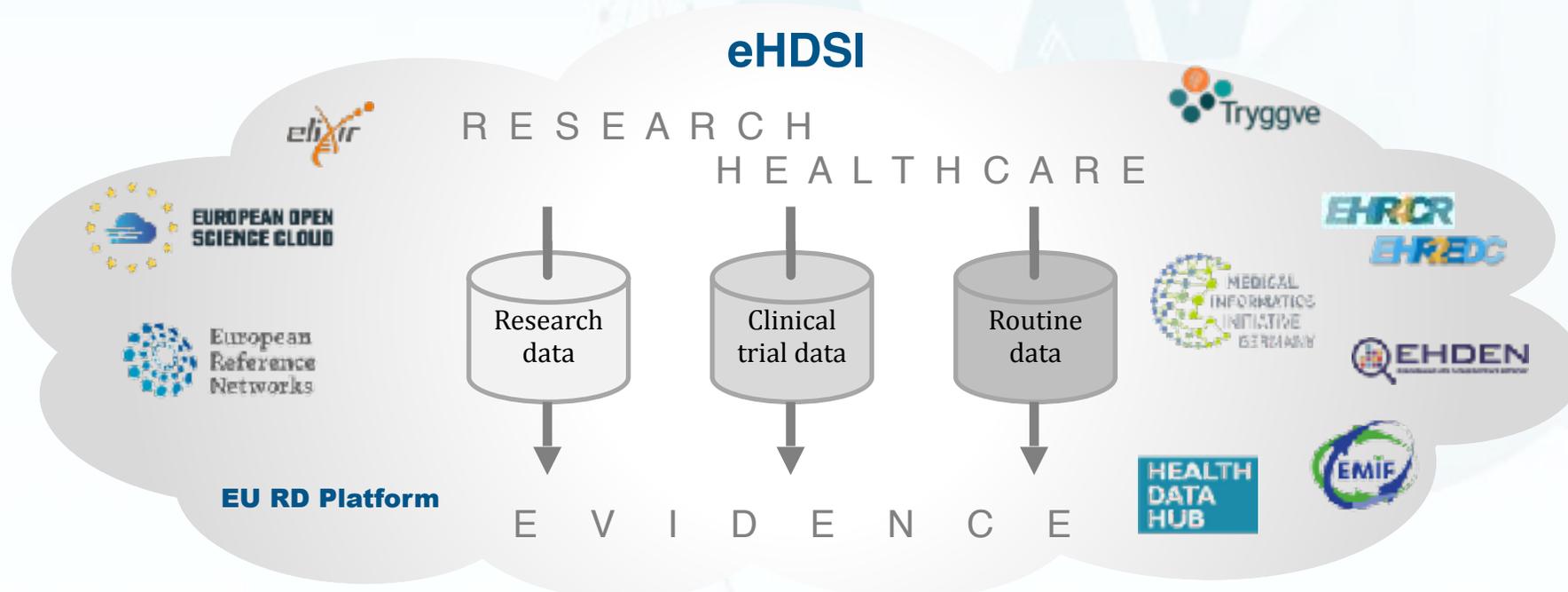
national & international research infrastructures, federated query platforms + cross-sectoral services

Reused for:

- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and bio-marker research
- Diagnostics development
- Drug development
- Disease understanding and stratification

Big health data sharing initiatives

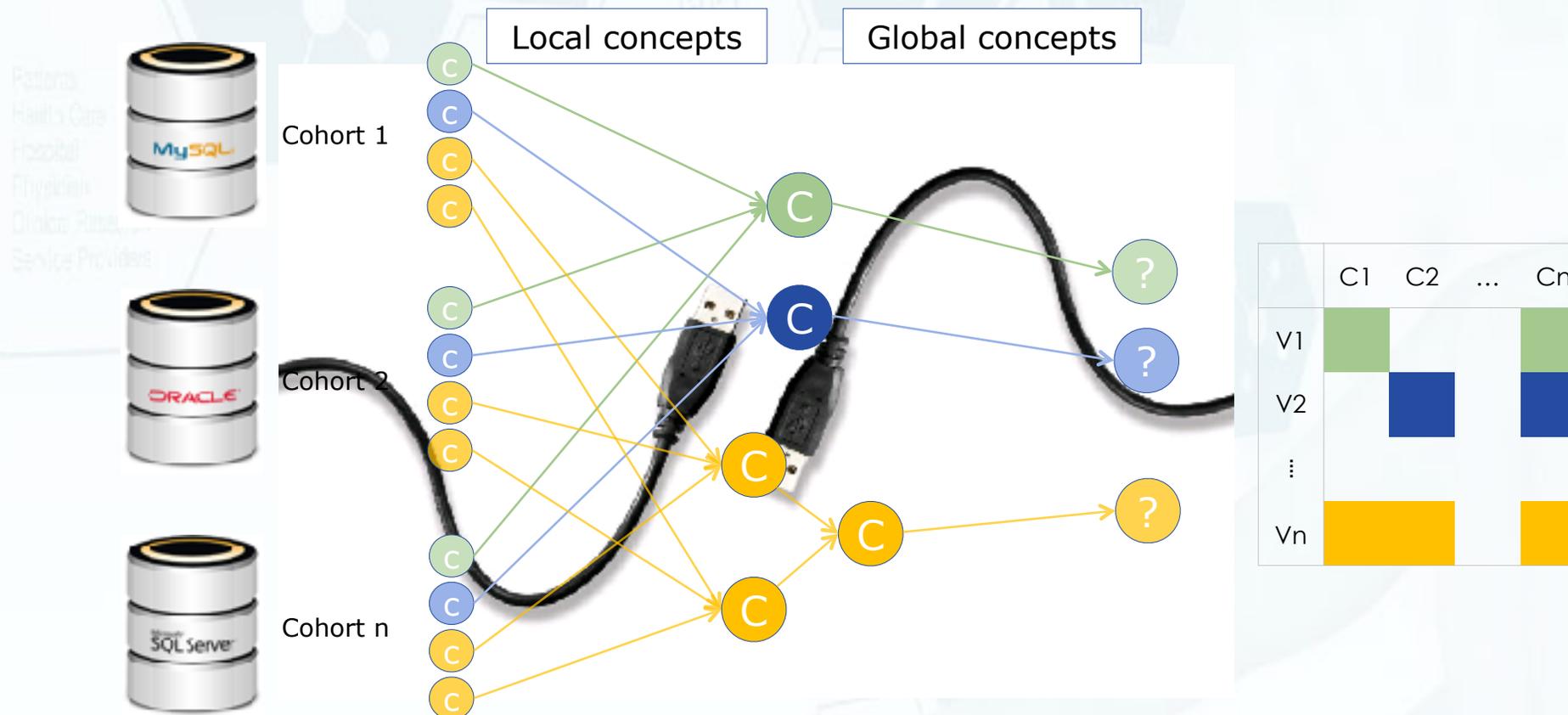
- Myriad of initiatives to share health data across jurisdictional, institutional and domain borders:
 - Sharing data for cross-border care, e.g. eHDSI, ERN
 - Sharing data for research, e.g. EH DEN, EHR2EDC, French Health Data Hub, German MI Initiative
- Emerging paradigm for analysing personally-identifiable health data:
 - federated infrastructure model: network of repositories with an overarching governance and interoperability layer



The FAIR principles: a commitment by data sources

- Data must be **Findable**
 - a searchable method to discover resources, with standardised metadata and a repository identifier
- Data must be **Accessible**
 - retrievable metadata, and potentially retrievable data via appropriate protocols and controls
- Data must be **Interoperable**
 - metadata is standardised, data conforms to relevant published standards
- Data must be **Reusable**
 - there is transparency about the terms under which the data may be reused

Data harmonisation



Common Data Models
Standardised Clinical Models

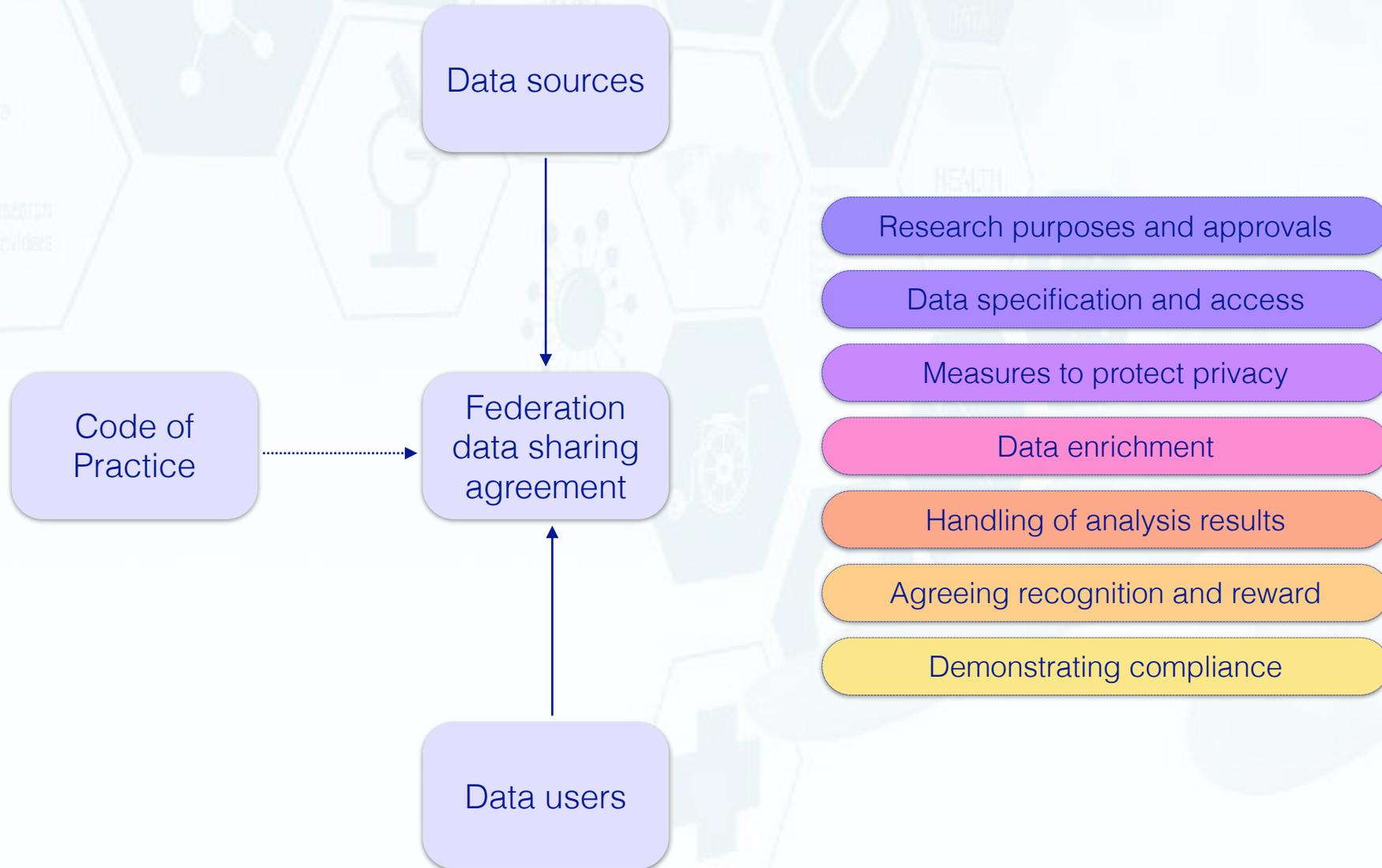
Data custodians

- Identify local concepts
- Specify mappings
- Define security

Community

- Specify global and derived concepts
- Define research groups

Data sharing agreements protect all parties



The challenge with gaining public acceptance of health data reuse

Individual level health data

EHR systems, apps, sensors, genomics, Clinical Decision Support, AI guidance

Used for:

- Health status monitoring
- Continuity of care (including the patient and caregivers)
- Care pathway tracking, clinical workflow management
- Real-time feedback and guidance to patients and clinicians
- Personalised medicine
- Disease interception, prevention and wellness
- Healthcare provider reimbursement

Population level health data

EHR systems, regional & national eHealth infrastructures

Reused for:

- Healthcare provider performance and planning
- Quality and safety, care pathway optimisation
- Medical device and algorithm refinement
- Pharmacovigilance
- Public health surveillance
- Public health strategy
- Health services and resource planning

Big health data

national & international research infrastructures, federated query research platforms + cross-sectoral infrastructures & services

Reused for:

- Disease understanding and stratification
- Digital innovation: devices, sensors, apps
- AI development
- Personalised medicine and bio-marker research
- Diagnostics development
- Drug development

Decreasing public understanding of why and how data are used

Increasingly unfamiliar data users

Increasing distance of data results from the patient

Increasing time from data use to demonstrated value

Perceived lessening choice and greater cybersecurity risk = harder to trust

We now urgently need a consistent European data use landscape

- The growing European data infrastructures are set up quite differently
 - adopting different data standards and data dictionaries, may lead to inconsistency in defining data minimisation, consent & transparency wording
 - different permitted uses and users, different access terms
 - different approaches to GDPR compliance, may lead to compliance which isn't adequate and causes IG issues later
- Multiple public attitude surveys are generating mixed messages (not all surveys are framed well), perhaps confusing public opinion
- COVID-19 has highlighted the value of sharing intelligence across countries, but introduced approaches that might only be temporarily acceptable e.g. location tracking
- Europe is revealing variable interpretations of GDPR compliance when it comes to health data use and reuse

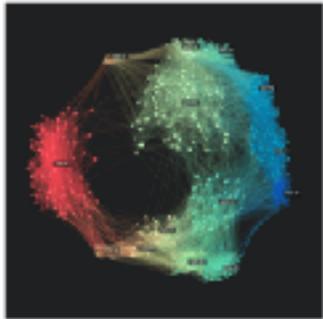
Defining “acceptable” research

- Its objective must be to discover new knowledge intended for the public good and to be made publicly accessible
 - new knowledge includes the corroboration of, or the challenge to, existing knowledge as well as completely new discoveries
- The public are generally accepting of commercially productised research, provided that downstream access to it is equitable (e.g. affordable across health systems)

Examples of research organisations usually considered to be acceptable to the public

- Health and social care provider
- Academic research organisation (e.g. university)
- Public health organisation
- Healthcare funder (health ministry, commissioning group, health insurer)
- Patient association or charity
- Regulatory body (e.g. EMA, HTA)
- Pharma company, biotech company, AI company
- Manufacturers of medical devices, appliances, systems etc.
- ICT (software, platform) developer or service provider, digital therapeutics

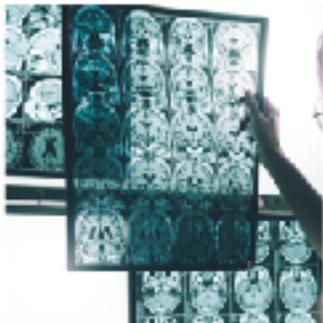
i~HD has provided examples to Data Saves Lives



Big Data' used for the early identification of other diseases associated with cancer

A novel computer programme to help doctors and scientists to better understand which other diseases are likely to occur in patients with cancer.

[Learn more](#)



Helping the Fight Against Alzheimer's

Discovering a test to detect those at risk of developing Alzheimer's Disease

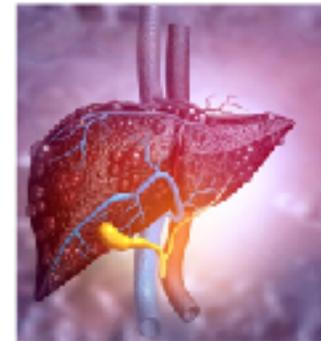
[Learn more](#)



Early Detection of a Cancer Killer

Helping identification of people at high risk of colorectal cancer from an existing blood test

[Learn more](#)



Using health data to explore a link between Body Mass Index and non-alcoholic fatty liver disease

Analysis of over 2 million anonymous patient records to establish how increasing body weight approaching obesity increases the risk of developing liver disease

[Learn more](#)

How do we reach societal acceptability?

- Data protection regulations prioritise the **rights of the individual** to privacy
- Clinical research can bring important benefits **to society**
- Many surveys indicate **patients are in favour** of their data being re-used for research
 - But the GDPR hype sometimes breeds fear (public, DPOs, CEOs...)
- The public need **greater transparency** about why and how health data are used, safeguarded, and the benefits of that use

We need to find the right balance between the rights of the individual and the benefits for society