

Data Protection, GDPR and Rare Diseases: Learning from the coal face

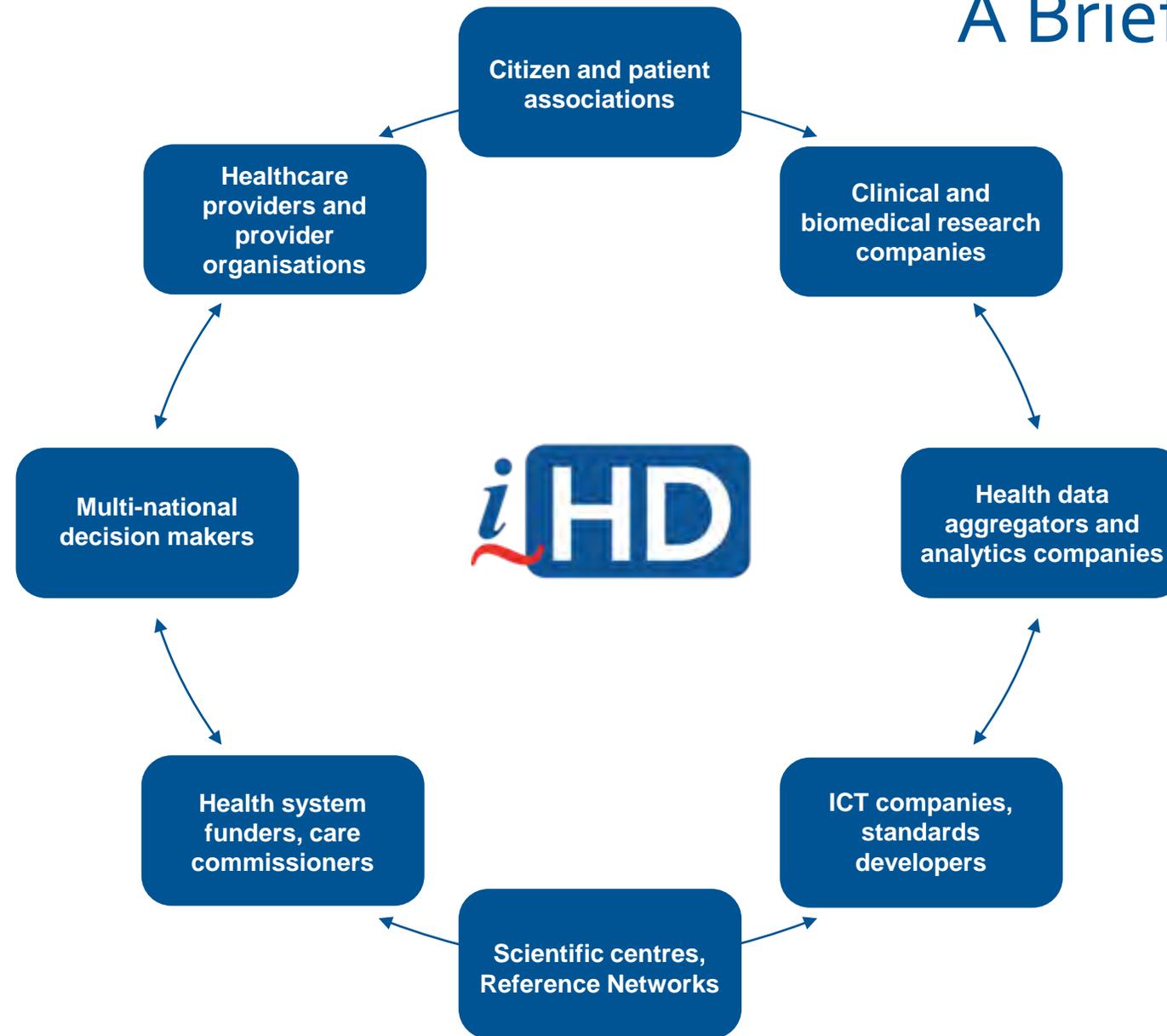
Maria Christofidou, PhD researcher, i~HD

Dr. Nathan Lea , Governance Lead and DPO, i~HD



A Brief Introduction

- Created as an outcome of European IMI and H2020
- Address needs confirmed by multiple healthcare and research stakeholders
- Co-create solutions for:
 - The capture and sharing of better quality health data
 - Its efficient research trustworthy use for smarter health care



EU funded training network

Academics and non-academic partners

Engaged in various European projects –
working alongside Early Stage Researchers
(ESRs)

A trans-sectoral and interdisciplinary
programme

HELICAL Innovative Training Network

Health Informatics, data protection within
the clinical context

Data protection and governance
Research governance

Projects in 8 different EU countries

Analysis of large biological datasets (gene
sequencing, genomics)



Using autoimmune vasculitis as a paradigm

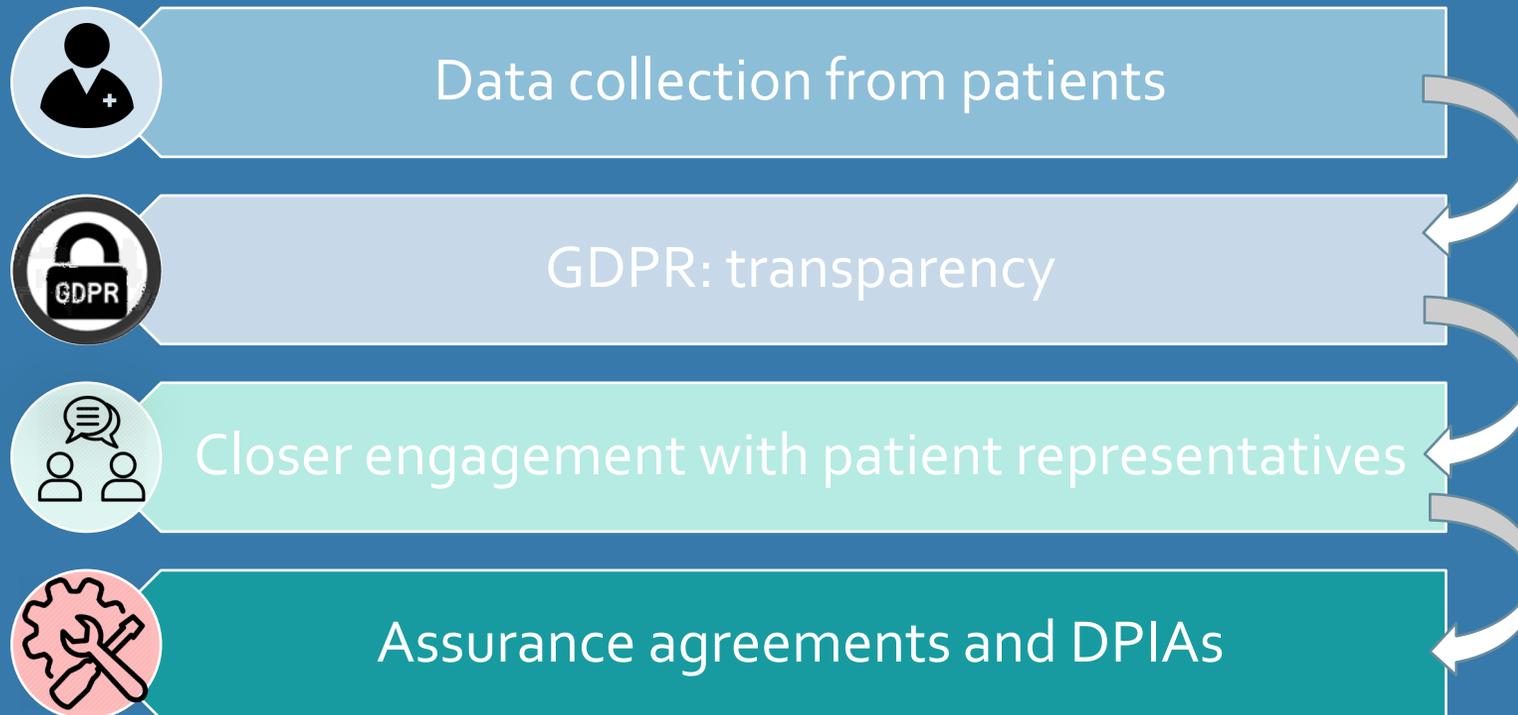
To provide state of the art training for 15 PhD
students

Demonstrating value from the use of health data



Rare Disease Patients Outlook

An Interdependent Process



Exchanges with Patient Representatives



- Part of the RITA European Reference Network (ERN)
- A support group set up for patients of all the Vasculitis diseases, their carers and interested healthcare professionals in Ireland
- Aims include support to those affected by Vasculitis and awareness raising



- The GDPR, information security and the need for better education to patients
- What patients are asked to agree to when participating in research
- The aspects of research on which patient input should be more strongly included during the design stage

Key Takeaways

GDPR, information security and patients

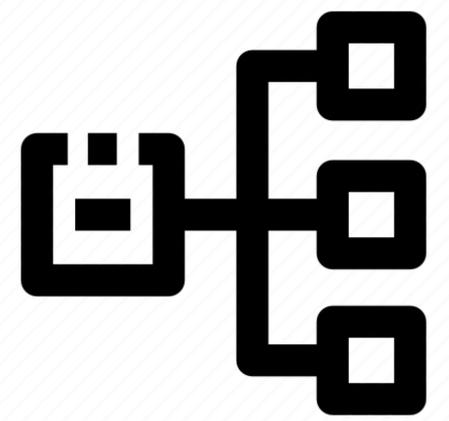
- Need for better education - various levels of understanding on what the GDPR entails and the rights of patients
- Lack of clarity on 'personal data' and how these can be protected

What patients are asked to agree to

- Projects should be better explained and patients should receive feedback during the study
- Favourable views for outreach/education pieces to be circulated. Unanimous opinion for more involvement of patients in the creation of materials

Patient input during the design stage

- Lack of a full understanding of what is requested from patients
- Opportunity to be contacted in the future and provide the means to do so
- Keep patients in the loop as to how and when their personal data is utilised

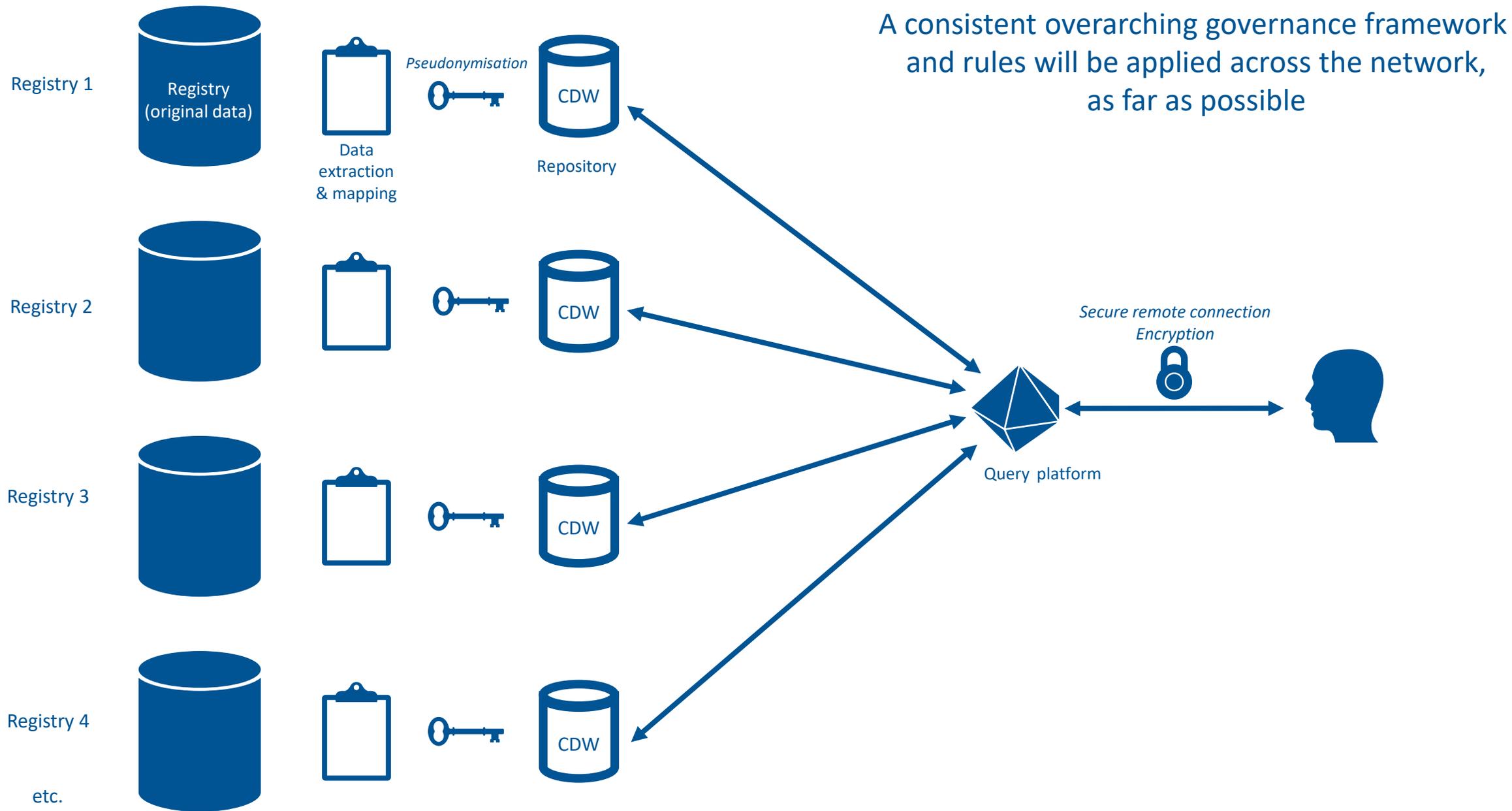


Understanding data flows and how to govern them

Data Protection Impact Assessments (DPIAs)

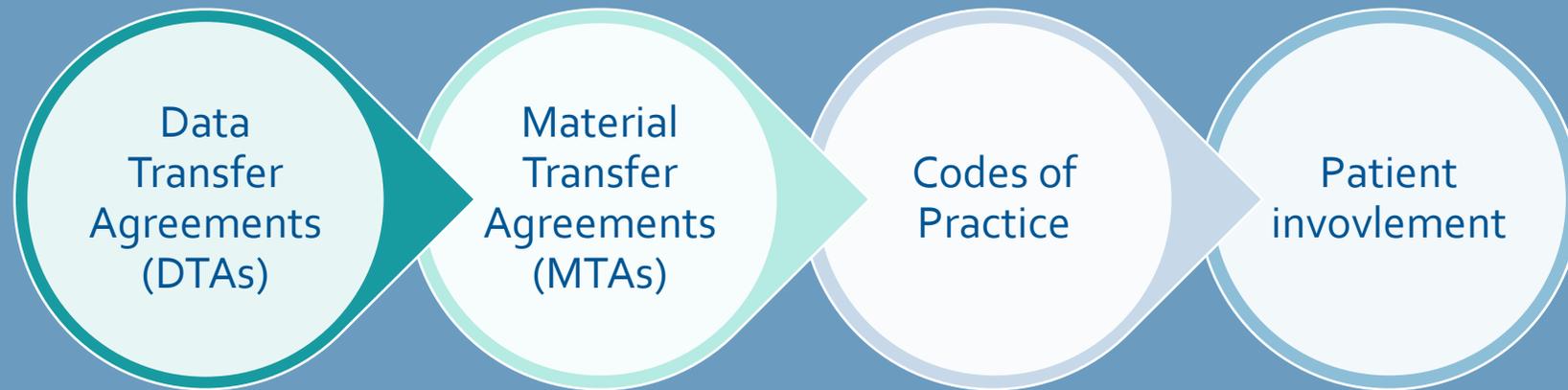
- Tools help to manage risk by:
 - Lawfulness and consent
 - Accountability, necessity and accuracy
 - Security (data safe havens and encryption processes)
 - Transparency
- In order to apply these tools correctly, we need to firstly understand the data flows
- GDPR data protection design and default approach: using a DPIA, one of the risk assessment tools, aids to understand data flows, intricacies and the DP designs in them





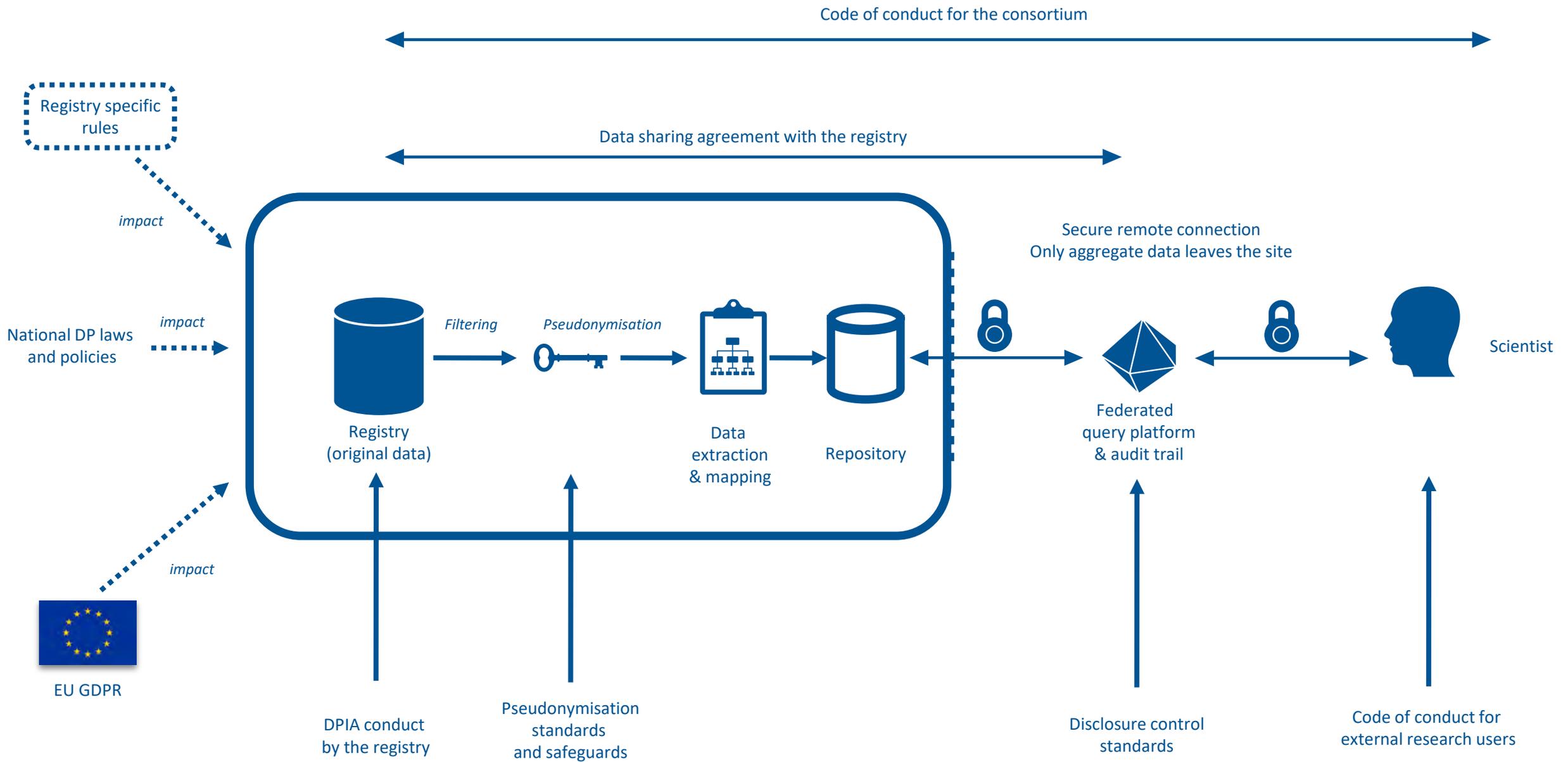
A consistent overarching governance framework and rules will be applied across the network, as far as possible

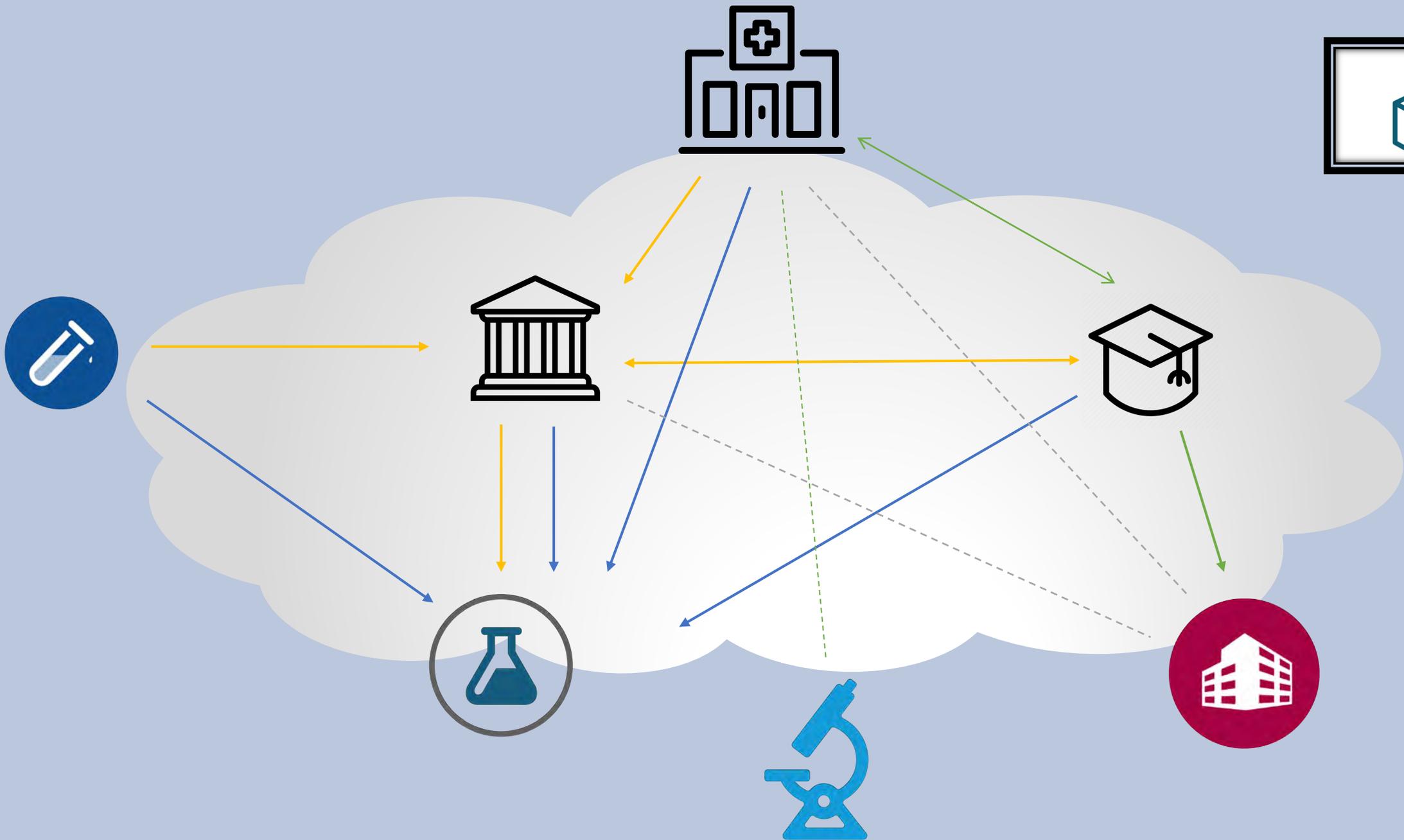
THE TOOLS



DPIA helps us to truly understand how these are best used in the particular research project

Rare Disease Registries: Challenges and Solutions







Learnings Discovered

GDPR contributes in mapping out the complexities of data flows and aspects that need to be governed

Principles, codes, data protection tools and security controls

GDPR to be applied in a holistic way, ensuring patient involvement

A suggested approach

Engagement and consultation on various steps of the research process
Public consultations on perceptions, preferences, priorities

Consistent understanding of data flows across all partners

Communication, transparency and consistent DPIAs and relevant updates

The creation of a GDPR Observatory

Highlight outstanding challenges and uncertainties that should be addressed
Incorporate patient voice
Aid in compliance with GDPR in the reuse of data for research and other forms of knowledge discovery
Provide a transparent view of emerging recommendations and approaches across Europe



QUESTIONS AND COMMENTS