eHAction WP5 Workshops “Common governance principals for the re-use of health data”

EHTEL

Collaborating for Digital Health and Care in Europe

PITCH: Towards a European Trust Architecture

Re-use enablers and broad consent

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„Fit for EHDS“ / EHDS Data flows and enabling factors / consent

Real World Data

- Wellness/ Monitoring Data
- Primary Care Data
- Specialist and Hospital Data
- Disease and Population Registries

Data Features/Quality

- Free Text
- Structured and coded data
- Controlled Natural language

*Data altruism / **Consent***

- Consent limited to indiv. treatment
- C. limited to predefined research
- Broad Consent
- Unlimited Data Donation

EHDS Enablers

- *Data Transport Enablers*
  - National EHR
  - Regional HIE
  - Local Data Integration Centres
- *Data IOp Enablers*
  - EHR Architecture
  - Syntax and APIs
  - Coding / Nomenclature
  - National Language Processing
- *Legal/Policy Enablers*
  - GDPR
  - Patient Rights/Ownership
  - Legislation Sec. Data Use incl. Data Donation
- *Governance Enablers*
  - FAIR Data Governances
  - Health Data-Ecosystems

- *EU-wide **Secondary** Data Use*
  - Clinical Research
  - Innovation
  - Public Health Reporting / Planning
  - Pharmacovigilance
  - Big Data
  - AI / Machine learning

- **MyHealth@EU**
  Cross-border Primary Data use
  - Cross-border ePrescriptions
  - Cross-border Medication History
  - Cross-Border Patient Summary
  - Cross-Border Discharge, Lab, Images

EHDS: GDPR conformant data lakes and Consent Management

Developing and implementing GDPR conformant data lakes

- Joining forces by Member States and healthcare providers.
- Address fragmentation of 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- Consent can be withdrawn (implementation of withdrawal)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to be shared, the healthcare systems uses such data in an ethical manner and ensure that the **given consent can be withdrawn at any time**.

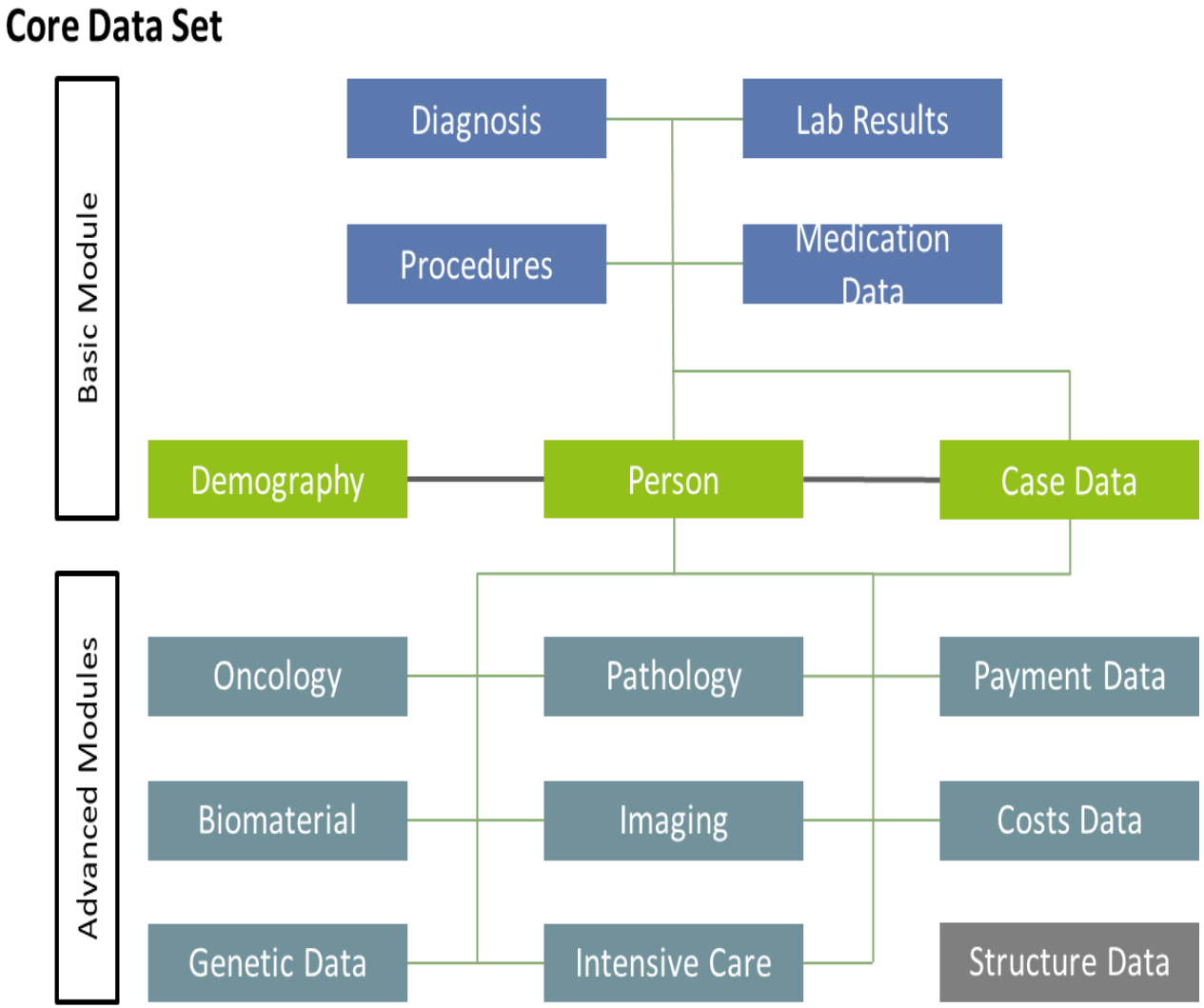
Understanding of „Broad Consent“ by Article 29 Working Party

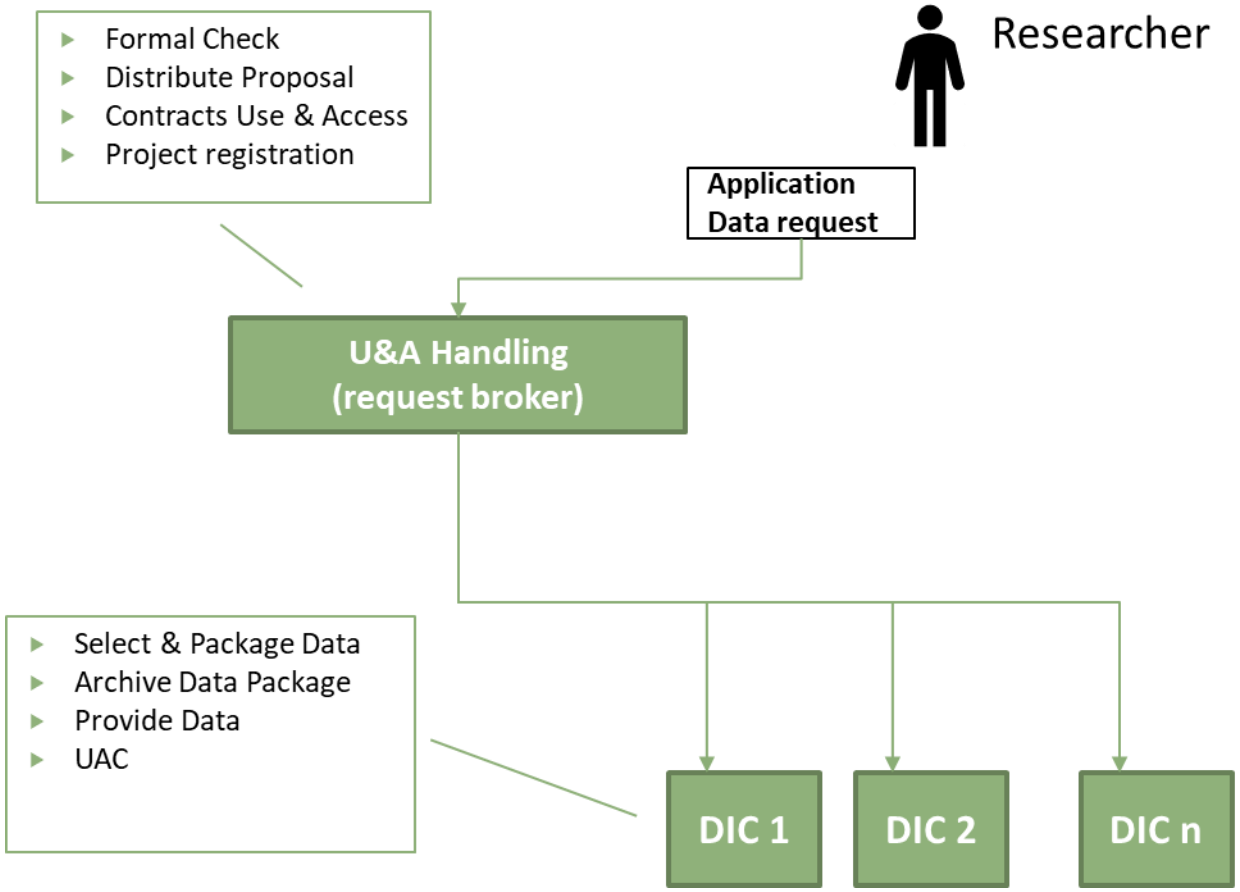
- **“…the GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked. …**

- **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.

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





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

Tool: IHE Advanced Patient Privacy Consents (APPC)

- **The APPC Profile defines a structural representation of a patient-specific Privacy Policy, based on the patient's choices or other circumstances.**
- **The Privacy Consent Document is designed to allow an unspecified enforcement mechanism, potentially within an existing access control system, to use the structured policy representation contained within the consent document to automatically determine and enforce those policies.**
- **Patient Privacy Policy Domains give patients choices that are more granular by creating access rules that add constraints on top of an underlying Patient Privacy Policy.**
  - *A patient may not want to give all physicians access to her/his clinical documents and may therefore limit the Patient Privacy Policies to only apply to a specific healthcare provider organization or to a specific episode of care.