Using assurance to overcome barriers to dynamic consent

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Dynamic consent provides ecosystem value

Hallmarks:
1. Options for consent can be presented and set through sustainable two-way communication between patients, healthcare professionals and researchers.
2. Patients have the option to modify their preferences over time if desired and when relevant.
3. The preferences set the basis for dynamic downstream clinical and data management actions.
Identifying barriers

Data collection

- Literature review
- Interviews

Analysis and synthesis

- Barriers to implementation
- Examples of approaches for overcoming the barriers

Dynamic consent in clinical genetics

Implementation barriers

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SAFER, SMARTER, GREENER
6 categories of barriers

**ETHICAL BARRIERS**
- Ensuring trust
- Autonomy versus information overload
- Sharing data
- Revoking previously consented data

**LEGAL AND REGULATORY BARRIERS**
- Regulation
- Use of data
- The GDPR

**KNOWLEDGE AND COMPETENCE BARRIERS**
- Consent comprehension
- Variable user backgrounds

**FINANCIAL BARRIERS**
- Investment versus gain

**CULTURAL AND ORGANISATIONAL BARRIERS**
- Stakeholder engagement and collaboration
- Cultural shift

**TECHNOLOGICAL BARRIERS**
- Security
- Traceability and transparency
- Interoperability
The ADA assurance framework

Iterative
Builds assurance over repeated cycles, starting simple and then evolving as more is learned.

Modular
Assures complex digital assets by breaking them into bite-sized fragments, and then assuring those and their connections.

Continuous
Builds and maintains assurance as assets are developed, deployed, and modified.

profile the digital asset

set goals

substantiate claims

plan

assess & adjust

execute
Pilot project: ADA on CTRL

- Partners recognize the complex landscape of dynamic consent
- Together pioneering the ADA approach on CTRL to:
  - identify and mitigate known and hidden risks
  - prioritize and capitalize on opportunities

Stage 1
- Documentation review, entity and data flow mapping
- Stakeholder interviews

WS1
- Risks and opportunities identification & prioritization

Stage 2
- High-priority risk identified
- Develop assurance case

WS2
- Evidence assessment and substantiation
Building assurance for dynamic consent

Data breach

Ethics breach

Unexpected consequences

Planning, evidence gathering, assessing
Systems approach to promoting trust and adoption of dynamic consent

- Dynamic consent solutions are implemented in complex ecosystems managed by complex organizations
- The processing of data is governed by explicit and implied security, privacy, ethics and governance requirements
- DNV’s Assurance of Digital Assets (ADA) framework is a flexible and extensible framework to provide trust in complex systems

Stage 1: 
- set goals
- plan
- assess & adjust
- execute

Stage 2: 
- substantiate claims

Profile the digital asset
Questions? Keen to know more?

Please get in touch!

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