

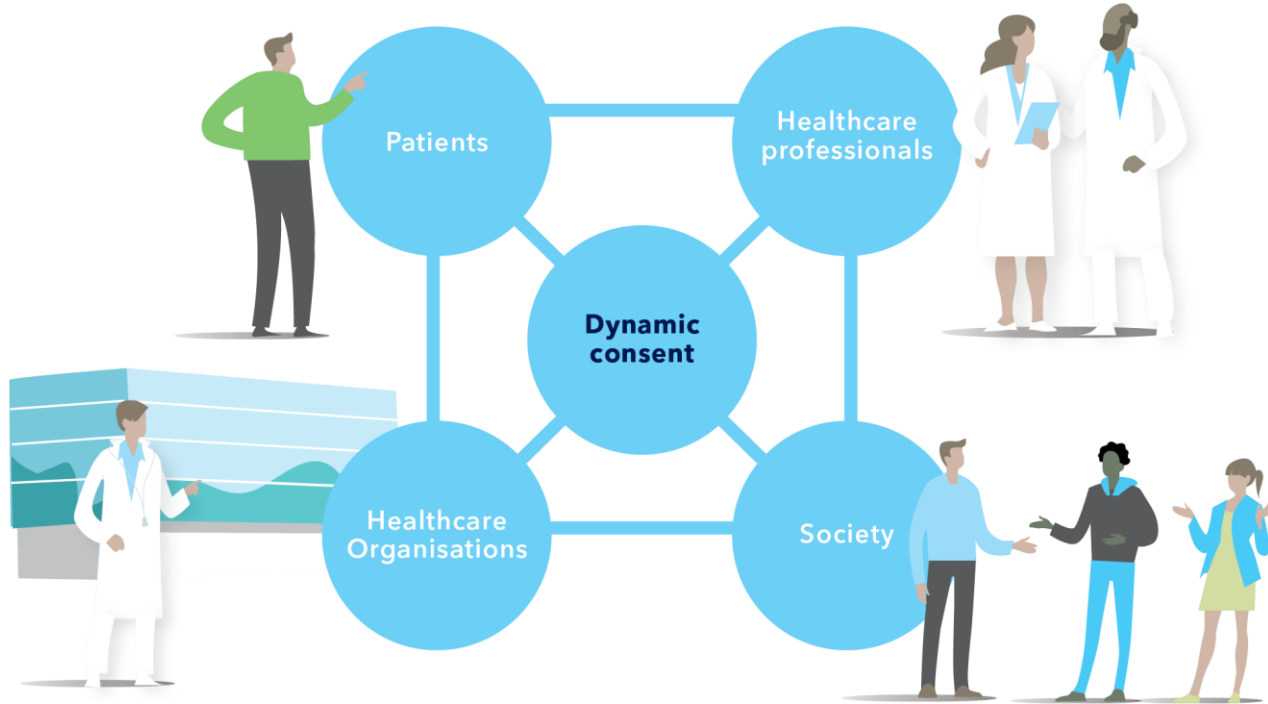
Using assurance to overcome barriers to dynamic consent

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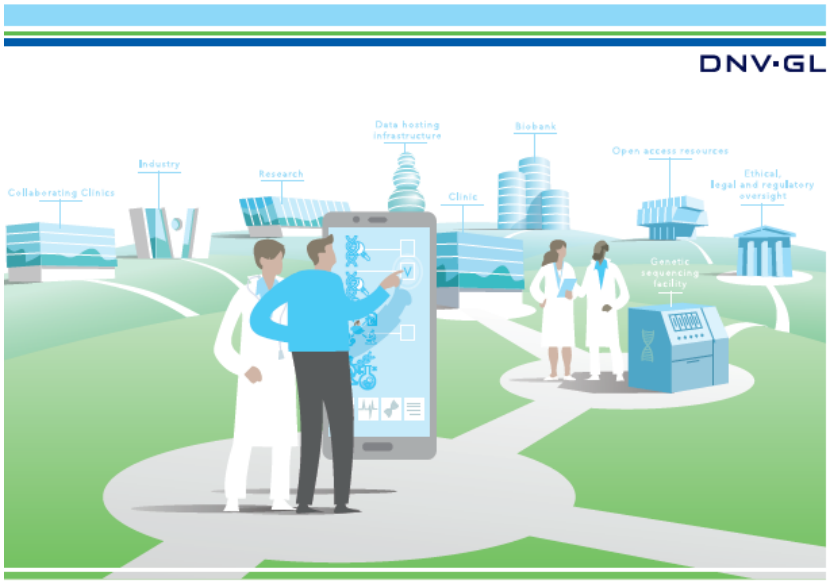
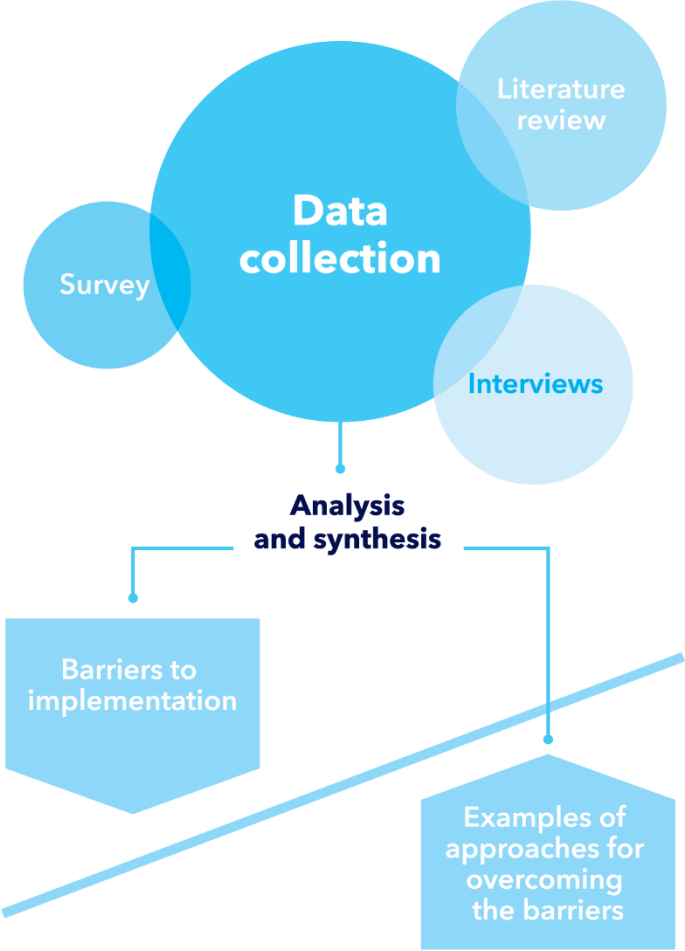
Dynamic consent provides ecosystem value



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



GROUP RESEARCH AND DEVELOPMENT, PRECISION MEDICINE, WHITE PAPER 2021

DYNAMIC CONSENT IN CLINICAL GENETICS

Implementation barriers

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

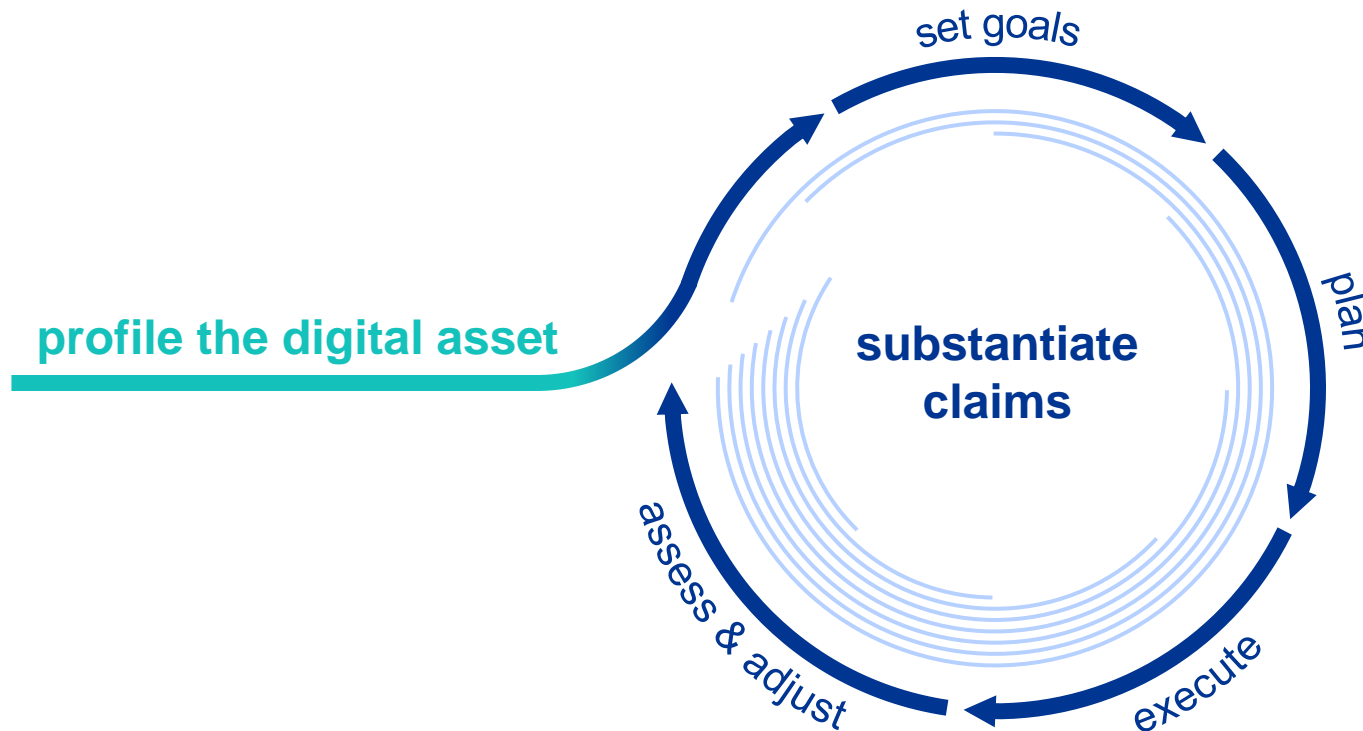
- Stakeholder engagement and collaboration
- Cultural shift



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

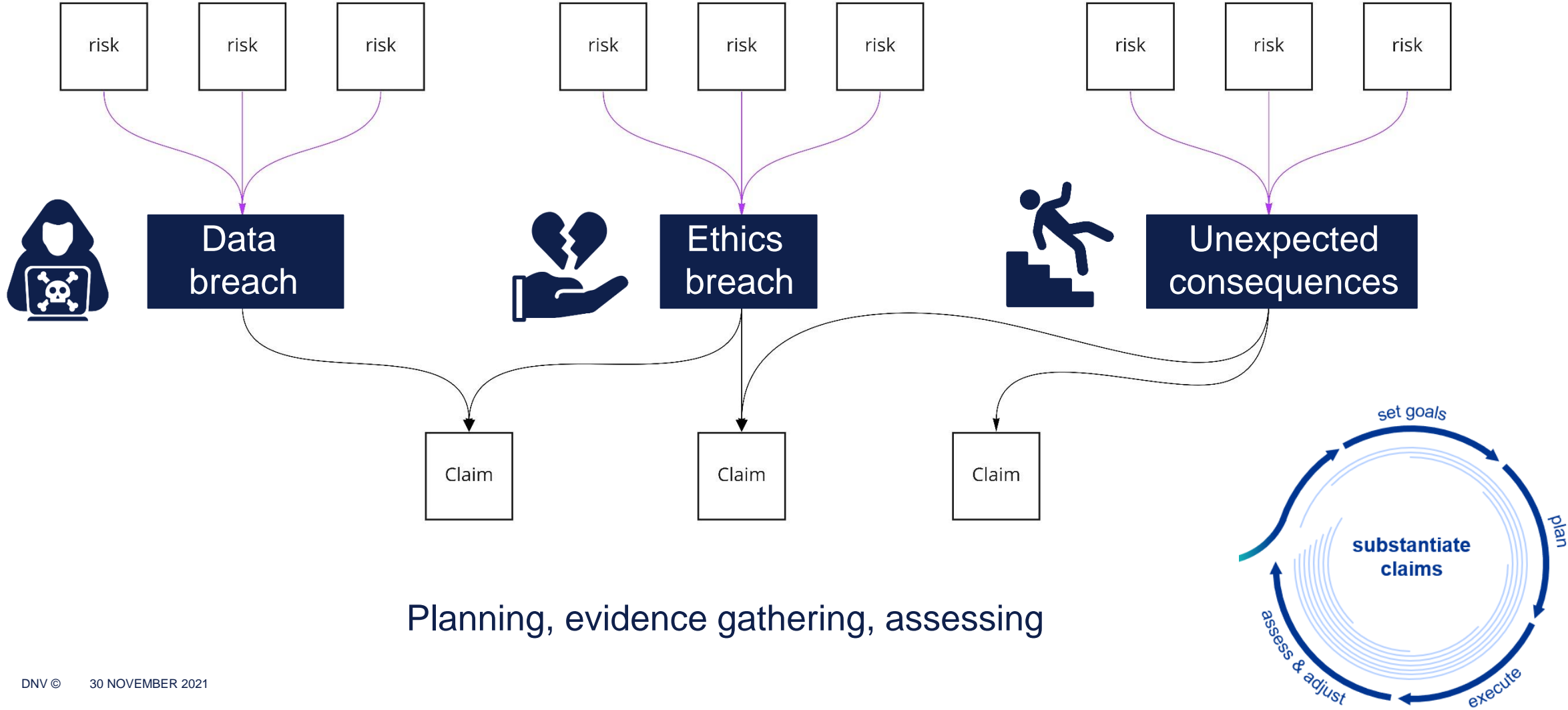
Builds and maintains assurance as assets are developed, deployed, and modified.

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

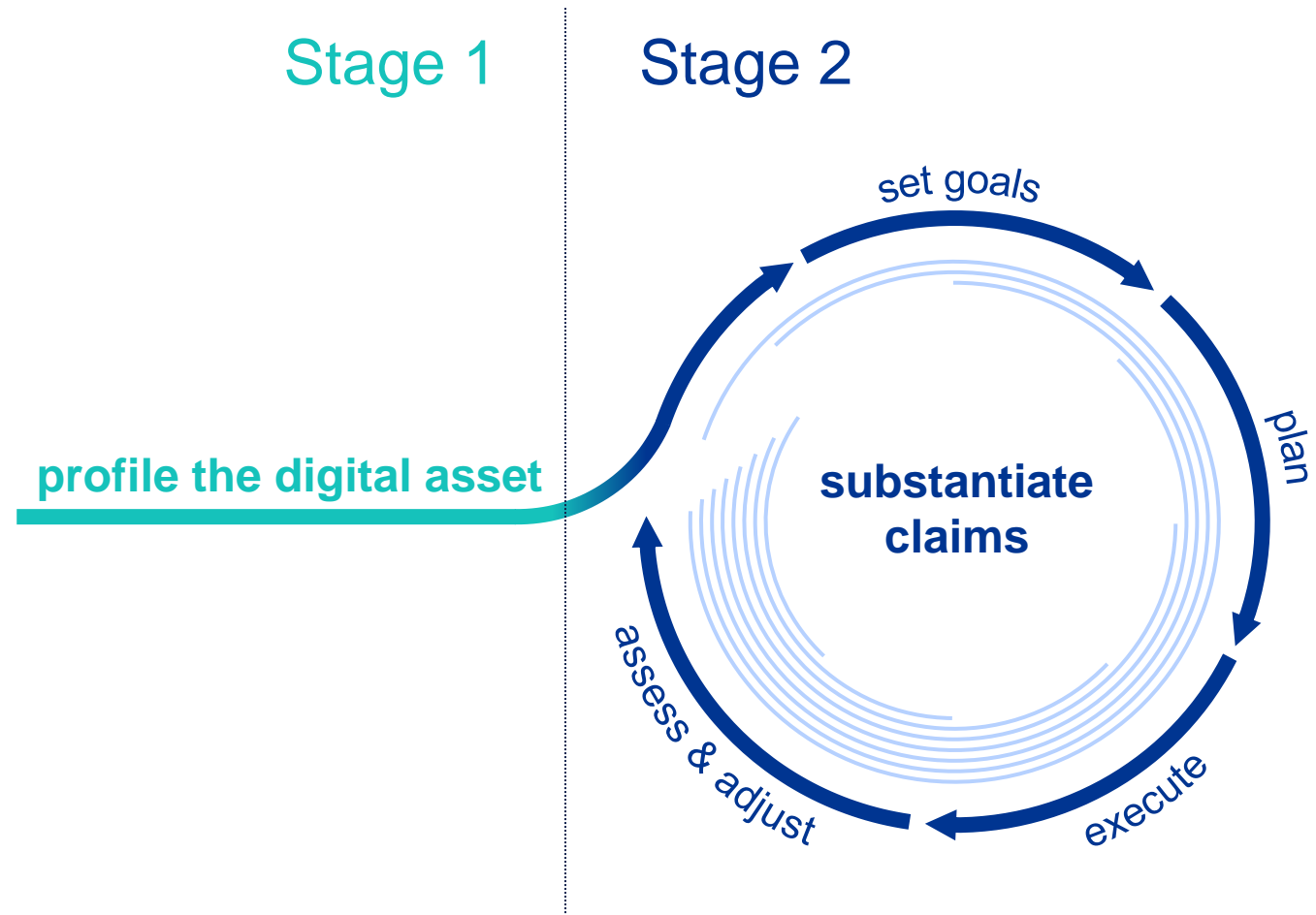


Building assurance for dynamic consent



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



Questions? Keen to know more?

Please get in touch!

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