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AI-Powered Patient Recruitment & Data Acquisition

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Proposal Concept related Strategic Objective 5 (Enable development of new and improved methodologies and models for a comprehensive assessment of the added value of innovative and **integrated** healthcare solutions)

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Challenges and Objectives

- Only 5% (or less) of eligible patients are actually recruited in clinical trials
- The main reason for clinical trial failure is due to insufficient recruitment
- Acquisition of data from incomplete, heterogeneous health records is time-consuming (transformation/curation) and error-prone (manual copy)

We aim to develop and evaluate AI-powered solutions to **improve patient recruitment** and **data acquisition in clinical trials**. Based on the findings, recommendations will be issued for implementing European Health Data Space (EHDS).

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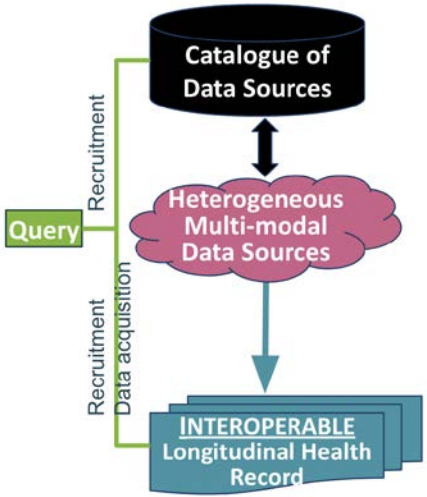
Proposed Solution

1. **Comparative analysis of 2 AI-powered solutions**



1. **(lower complexity) : AI generated query to public/standard catalogue of data sources**
   - Metadata on available data (e.g.Finnish catalogue)
   - Metadata on population (DCAT-AP per EHDS)
2. **(higher complexity): AI generated query to interoperable longitudinal patients record**
   - Knowledge graph compliant with reference ontology
   - Requires AI based curation (per AIDAVA HE project)

2. **Recommendations for implementation within EHDS**

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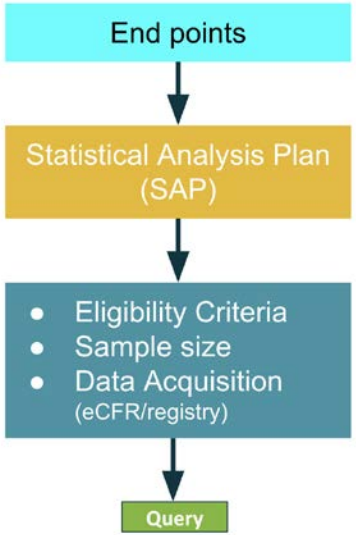
Proposed Approaches



- AI generated **synthetic data** (e.g.,Synthia) for
  - Catalogue of Data Sources
  - Interoperable longitudinal patient record,RDF format (PHKG*)
- AI supported **generation of protocol** (statistical and data management components) from end points
- AI generated **query** for
  - **eligibility check** of Catalogue of Data Sources, and PHKG
  - **data acquisition** from PHKG & **transformation** into CDISC CDASH or registry format
- Execution and assessment
- Recommendations

*PHKG = Personal Health Knowledge Graph, aligned with reference ontology

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Outcome and Impact

This project proposes a more consistent, efficient way to identify eligible patients, reduce trial delays, and manage data compliantly across healthcare systems.

It will **tackle a recurrent bottleneck** in clinical trials and solves a problem that directly impacts the pharmaceutical and biotech industries by delivering

1. **Proof of concepts** that deliver value to the pharma industry on a recurring problem
2. **Recommendations on EHDS implementation** to EU authorities that would benefit both health organisation, patients and research organisations

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Expertise and resources

- **Maastricht University**
  - Founder of FAIR principles
  - Synthetic data generation and evaluation (REALM HE, PI)
  - AI based curation (AIDAVA HE, technical coordination)
  - Privacy-preserving health data sharing and analysis
  - Personal knowledge graphs
- **b!loba**
  - 25+ years experience in pharma development
  - AI based curation (AIDAVA HE, clinical coordination)
- **Additional partners to be identified**
  - Generative AI experience in health applications
  - Clinical partner for Data Catalogue, PHKG Generation

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