Data Governance and Management Overview for Althaia Data Space

1. Data Source Governance

The Althaia Data Space is managed by Fundació Althaia, a healthcare provider and research institution with established data governance and security frameworks. The data is transformed into the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) to ensure harmonization and interoperability.

Oversight of the data source is provided our Institutional Data Governance Committee, which defines policies for data access, quality control, and ethical compliance in alignment with national and EU data protection regulations (e.g., GDPR).

Althaia Data Space has been developed in partnership with IOMED, a company that operate a Data Space Platform powered by AI, created to enable Data Spaces and mediate health data for secondary use, ensuring compliance.

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2. Data Capture and Management

The source data originates from electronic health records as well as transactional data from pharmacy, lab and Rx software, collected routinely as part of healthcare delivery. Data extraction, transformation, and loading (ETL) into the OMOP CDM is performed following standardized procedures, including:

- **Routine ETL process documentation and version control**
- **Periodic updates** reflecting newly available data
- **Data lineage tracking** to ensure auditability

Data storage and processing environments comply with institutional and legal data protection standards.

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3. Data Quality Check and Validation

Before each data release, in collaboration with our technological partner IOMED we perform multi-level data quality assessment using the **OHDSI Data Quality Dashboard (DQD)** and **ACHILLES** tools. These checks cover:

- **Conformance:** Structural alignment with OMOP CDM specifications
- **Completeness:** Assessment of missingness and population coverage
- **Plausibility:** Evaluation of data consistency and medical logic

Validation results are reviewed by the internal data quality team and documented for traceability.

4. Data Access and Utilization for Research

Access to the OMOP CDM instance for research purposes is governed by a **formal review and approval process**. Researchers must submit:

- A **well-structured research protocol** (including study objectives, study design, data requirements, and analysis plan)
- **Ethical approvals** (if applicable)
- **Data use agreements (DUA)** or **collaboration agreements**, specifying data use terms

Data access is only granted to approved users, under strict data protection measures. Data transfer follows predefined contractual and regulatory pathways.

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5. Contact Person

For governance, access requests, and technical inquiries related to the OMOP CDM data source, please contact:

Name: Alfons Hervàs
Position: Director Quality and Knowledge
Institution: Fundació Althaia
Email: ahervas@althaia.cat

Version: June 30, 2025