# Utilizing Finnish nationwide RWD to create an external control arm to a clinical trial

FUTURE CLINICAL TRIALS –
FROM TOMORROW TO 2030 –
WHY CHOOSE THE NORDICS

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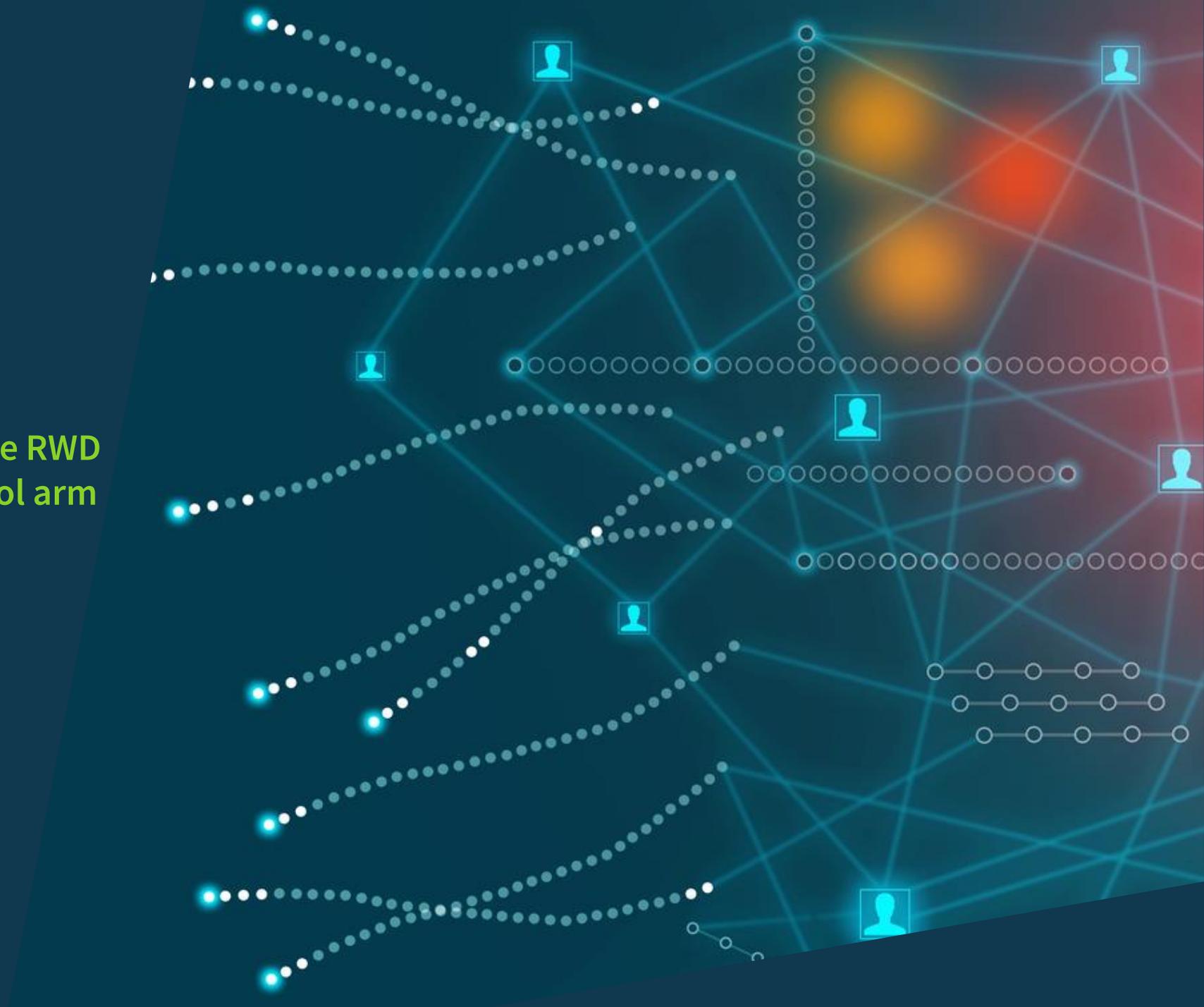
Future Clinical Trials Project

Expected duration: 2020 - 2024

// We develop unique

  // patient centric and
  // data driven solutions
    // to challenges in clinical trials today.

// With a potential to become global innovations

// Our core project team members work in global roles of Bayer's

// Data Science & Analytics

// Clinical Development Operations

// Oncology Development Operations

// R&D IT

// Integrated Evidence Generation in Medical Affairs

BUSINESS FINLAND

The Main Objectives of the Project (Data Science)

Trial 1

Trial 2

Trial 3

Trial 4

DATA INTEGRATION

Building capabilities for utilizing external RWD and internal legacy RCT data

PATTERN RECOGNITION

Design and implement data science methods to predict and manage the risks in clinical trials

RWE USE-CASES / EXTERNAL CONTROLS

Methodology for providing virtual or synthetic controls
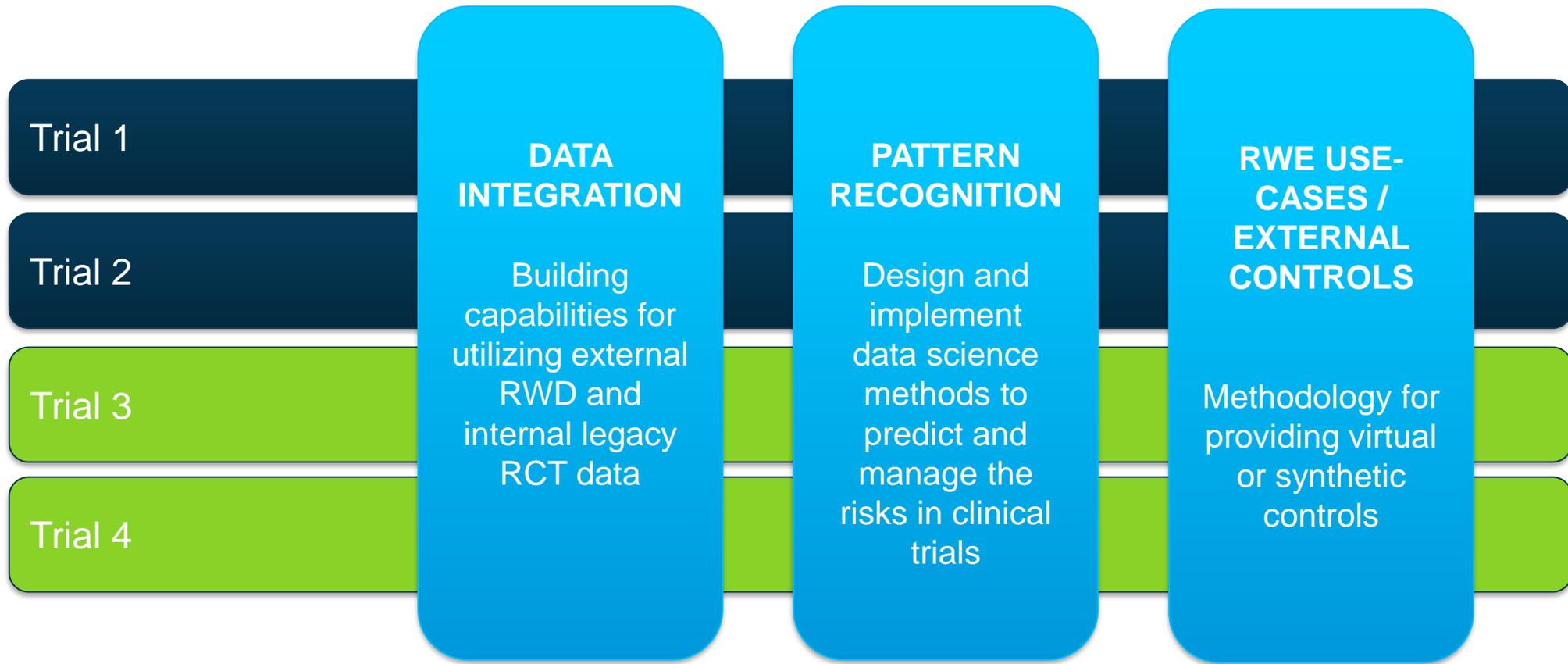
External Control Arm

// Process Flowchart

   // Data Access & Management

   // Data Sources

   // Data Curation & Analysis

// Summary

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Process Flowchart

FINDATA
Social and Health Data Permit Authority

Step 1: Feasibility assessment

- Assessment of availability of suitable patients and the required variables.

Step 2: Study preparation

- Preparation of the study plan in collaboration with the study team

Step 3: Study permit procedures

- Preparing and submitting data permit application to Findata

Step 4: Analysis of the pseudonymized data

- Data curation
- Matching with RCT data
- Preparation of TLFs defined in the protocol

Step 5: Analysis of the anonymized data

- Replication of TLFs and comparison to Step 4 analysis
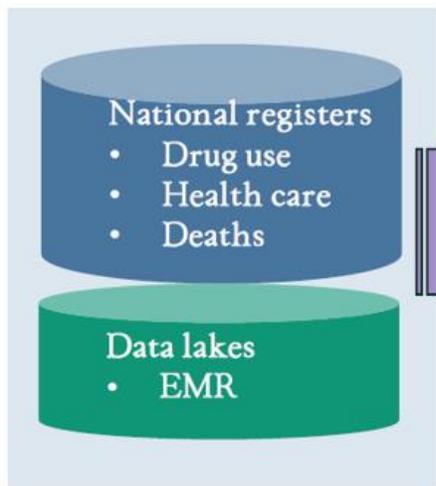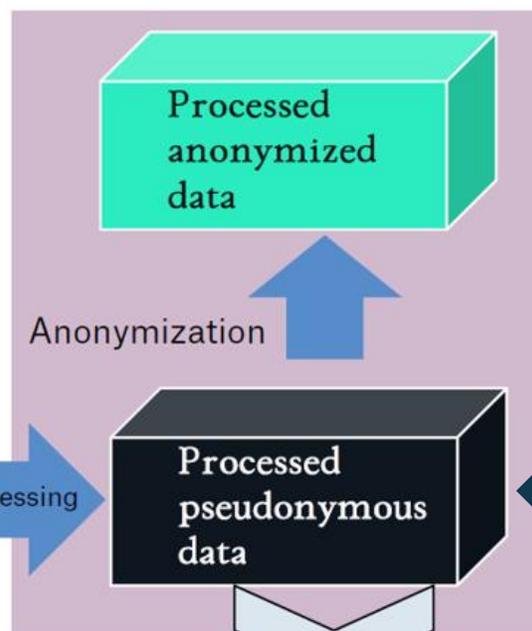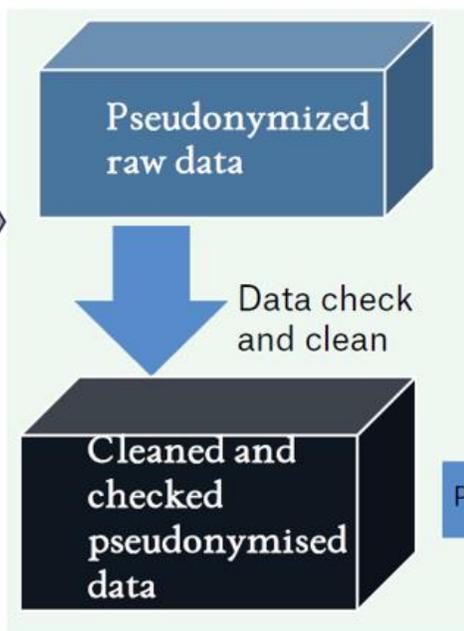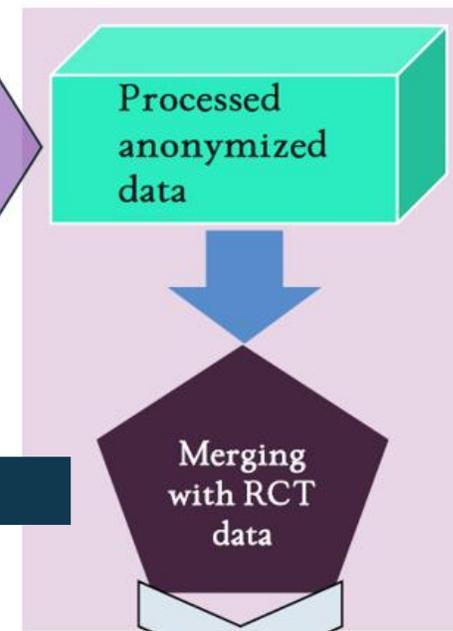
Data Access & Management

Data Sources
Electronic health records + National registries

Cancer Registry

Congenital malformations

DVV (Population Registry)

Statistics Finland, Causes of death

Drug reimbursements

Care Register for Health Care

Statistics Finland, Education and job occupation

Register of Social assistance

Medical Birth Register

Intensive care registry

Care Register for Social Welfare

Drug purchases

Infectious Diseases Register

Vaccination Register

Drug prescriptions

Primary Health Care

1990   2000   2010   2020

Statistics Finland, Causes of death, 1966–2025

Statistics Finland is a Finnish public authority that collects, combines, and stores data on society, and produces and releases statistics on a wide range of topics.

Statistics Finland – home

Data for FinRegistry: Time and causes of death.

- Examples of variables or variable types:
  - Date of death
  - The basic cause of death
  - The immediate cause of death
  - The contributing cause of death
- Data dictionary

https://www.finregistry.fi/finnish-registry-data

Data Curation & Analysis

Findata Secure Environment (remote connection)

RWD Sources → RWD Cohort (SDTM-) → Analysis dataset → TLFs

Real-world data

Clinical database → Trial baseline → Confounder dataset

Clinical trial data

Selected:
1. Demographic Information
2. Medical History (predefined terms in focus)
3. Concomitant Medications
4. Laboratory Results & Vital Signs
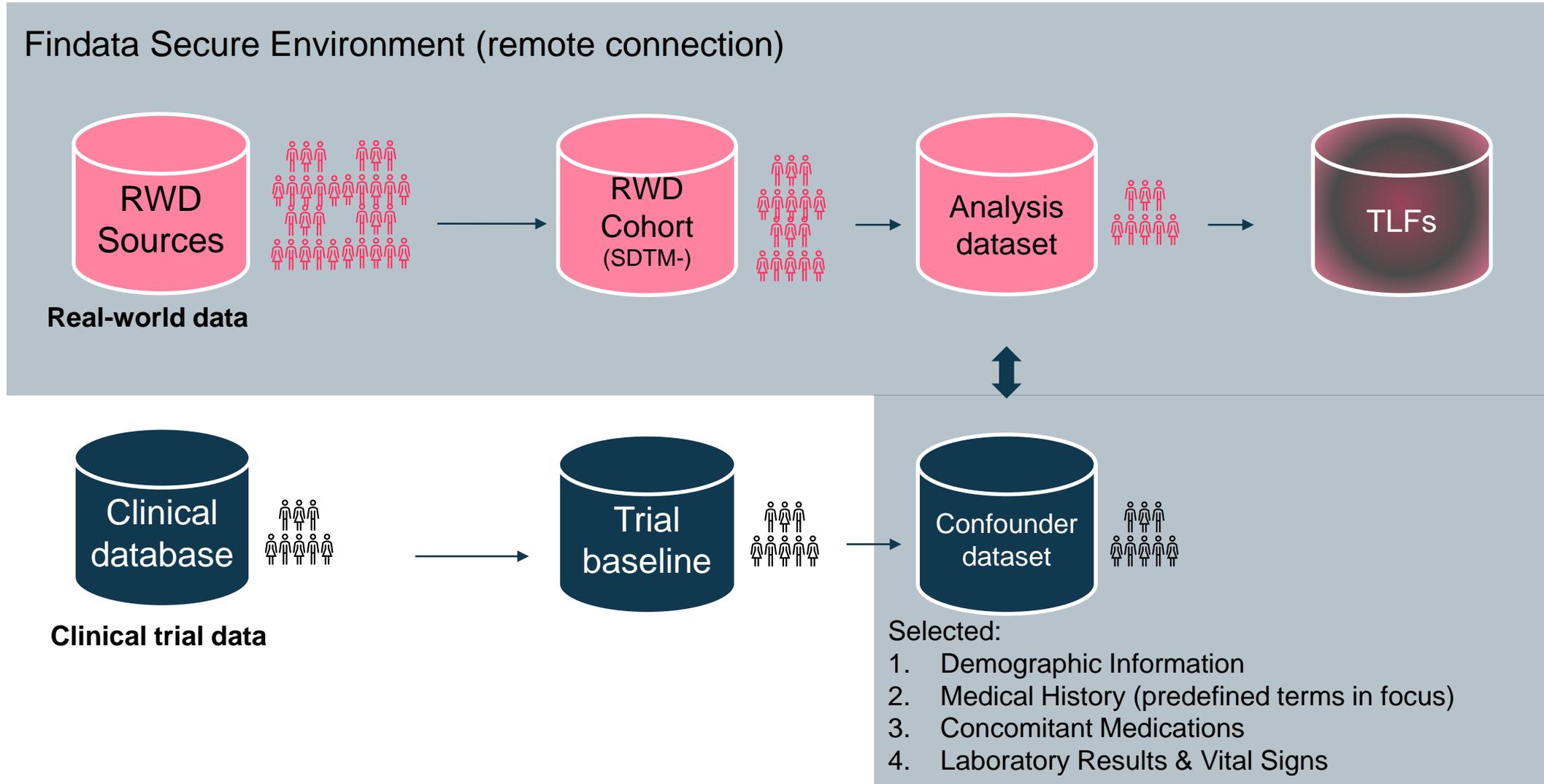
Mapping into SDTM-

Data model concept

SDTM- datasets consist of 3 set of variables:

- **Main variables** – can be harmonized across all raw datasets, e.g. MHTERM, MHSTDTC.

- **Source identification variables** – variables used to identify source data for the record, e.g. SRCDOM, SRCVAR, SRCID.

- **Supplemental variables** – other variables which are different across source datasets, e.g. additional visit information, type of service. Can be any kind of variables.

Hybrid of a relational (main variables + SRC variables) and document-oriented database (supplemental variables as JSON) which can still be stored as a plain SAS dataset.

Dataflow, broad picture
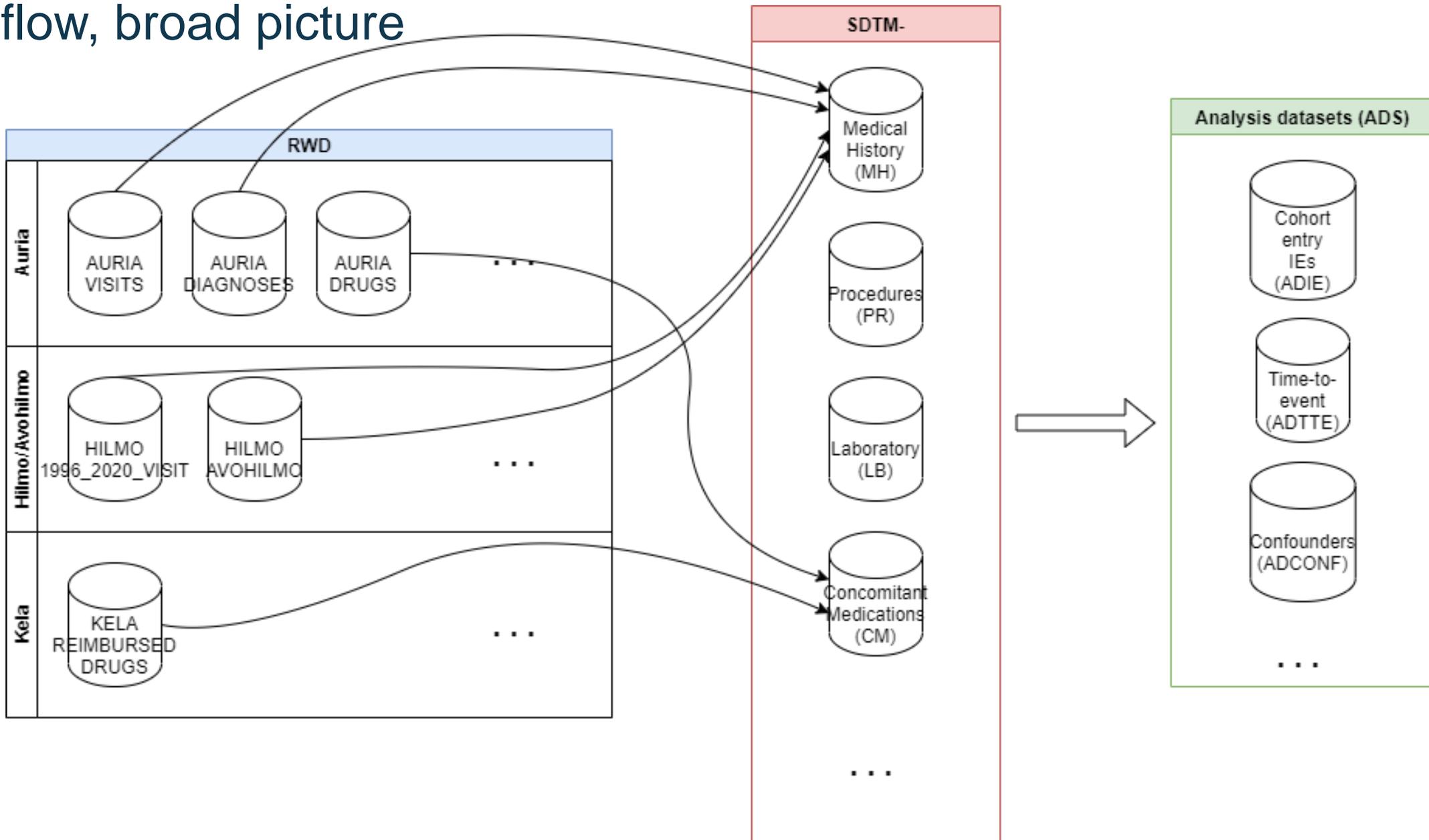
Example MH dataset

USUBJID	MHTERM	MHSTDTC	...	SRCDOM	SRC VAR	SRC ID	SUPP JSON
AAA-1234567	I12	2017-04-12		HILMO_1996_2020_VISIT	PDG0	17236	{ "serviceprovider": "R20", "typeOfContact": "inpatient", … }
AAA-1234567	I34	2019-12-31		AURIA_DIAGNOSES	DIAGNOSIS	213	…
AAA-1234567	I45	2016-17-12		HILMO_AVOHILMO	ICPC2_1	8136	{ "geoRegion": 73, "gender": "Male" }
…							

Summary

// Augmenting clinical trials with external controls can lead to greater patient diversity and a shorter duration of clinical trials with considerable potential savings involved

   // Estimated 10-20% cost & time savings

// Finland has implemented secondary use of health data legislation and biobank legislation to enable extensive data sharing with an industry friendly approach

// Nordic national registries, independently or combined with EHRs by unique personal IDs, can be used for reliable long-term tracking of outcome events and medication compliance

Investigated treatment: Investigational drug and control drug

Participants: 8,255 patients (RWD external control arm)

RWD Sources: Regional hospital data lake of Southwest Finland via Auria Clinical Informatics (study population identification and data collection); the nationwide healthcare registers — Care Registers for Healthcare (Hilmo and Avohilmo) by Finnish Institute for Health and Welfare (THL) (data collection); the nationwide cause of death register by Statistics Finland (data collection), ant the Prescription Centre and Drug Prescription Registry by Social Insurance Institution of Finland (Kela) (data collection).

Time span: 11/2020–

Funding: Bayer and Business Finland.

Partners: Bayer, MedEngine, Veil.AI

FINLAND – A TREASURE TROVE FOR REAL-WORLD EVIDENCE RESEARCH

Explore Finland's exceptional resources of health and social data, collections of biological samples, forerunning collaborators, and efficient operating environment for RWE research.

https://mediabank.businessfinland.fi/l/8DcLn5LqTKWP