

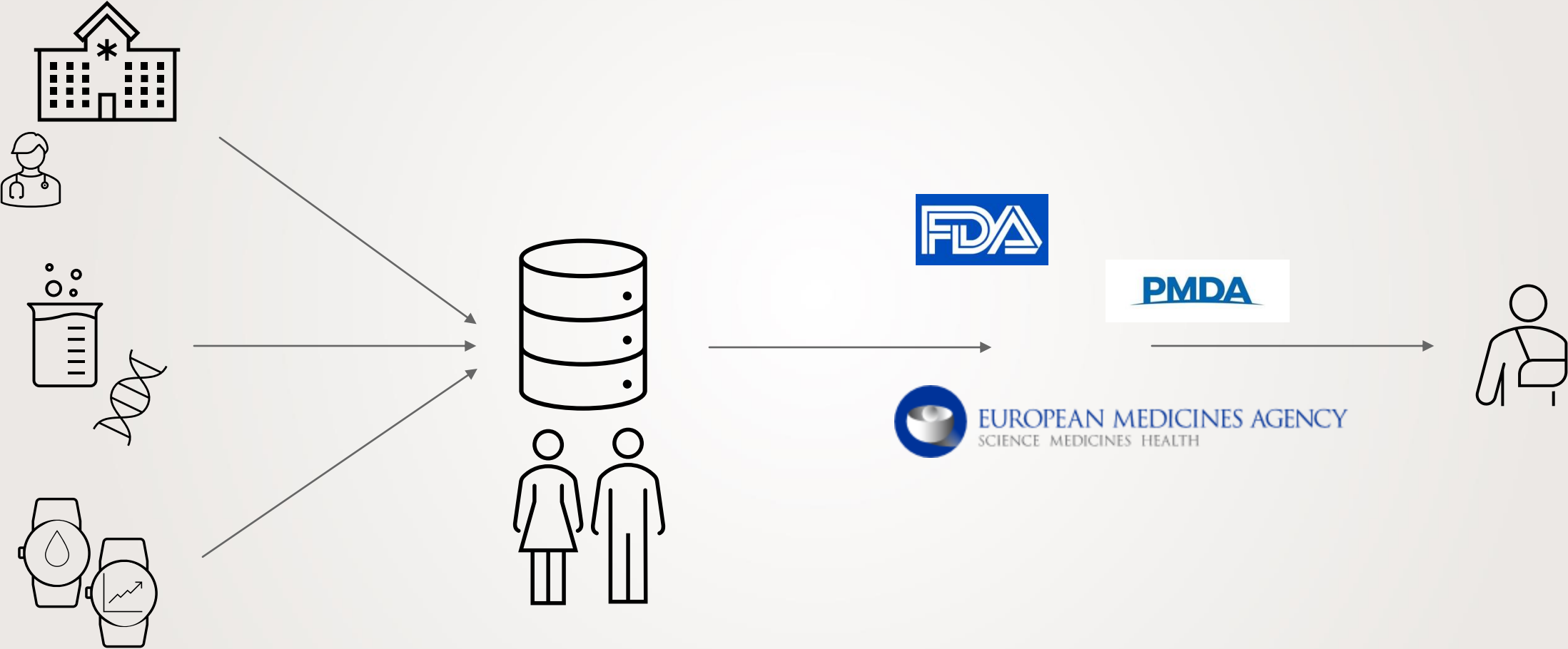
The Value of Clinical Trial Data: From Submission to Innovation

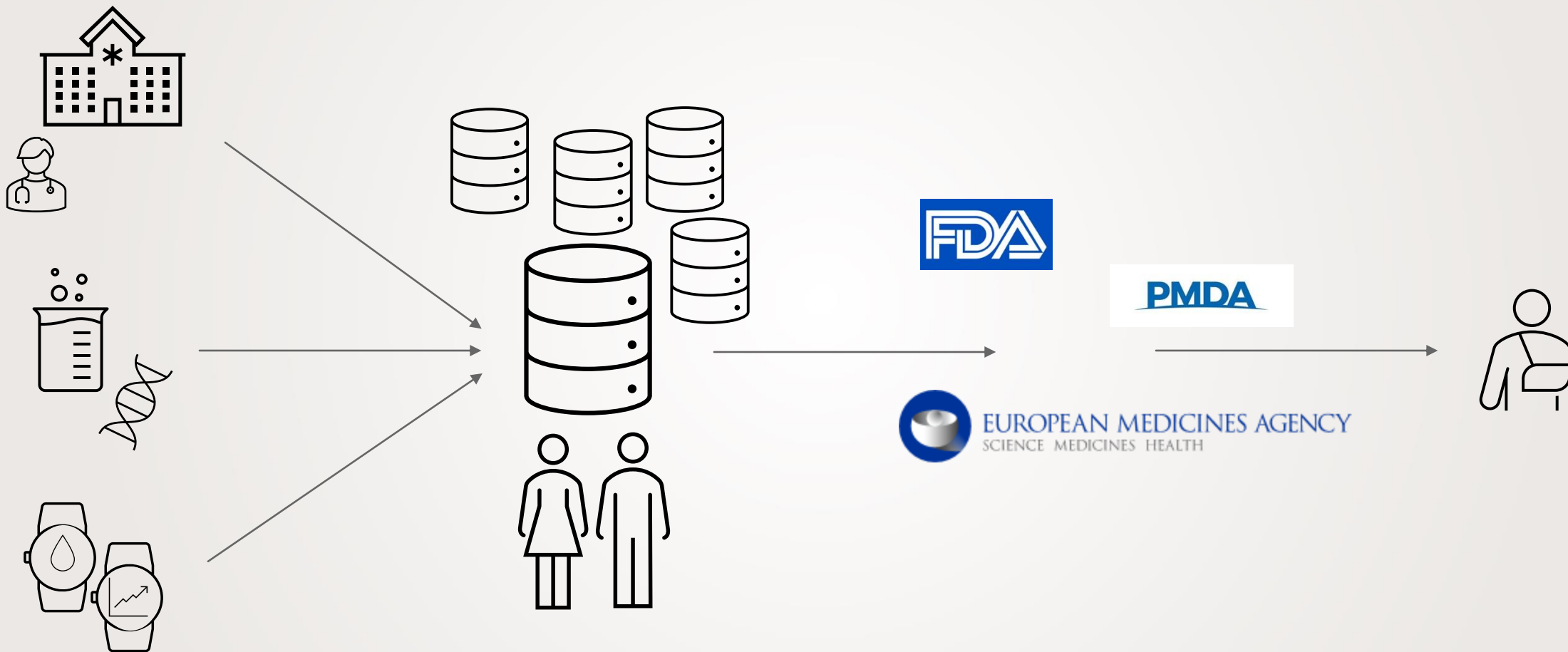
DH02 – PHUSE EU Connect 2025
Anne Katrine Alsing (akag@novonordisk.com)

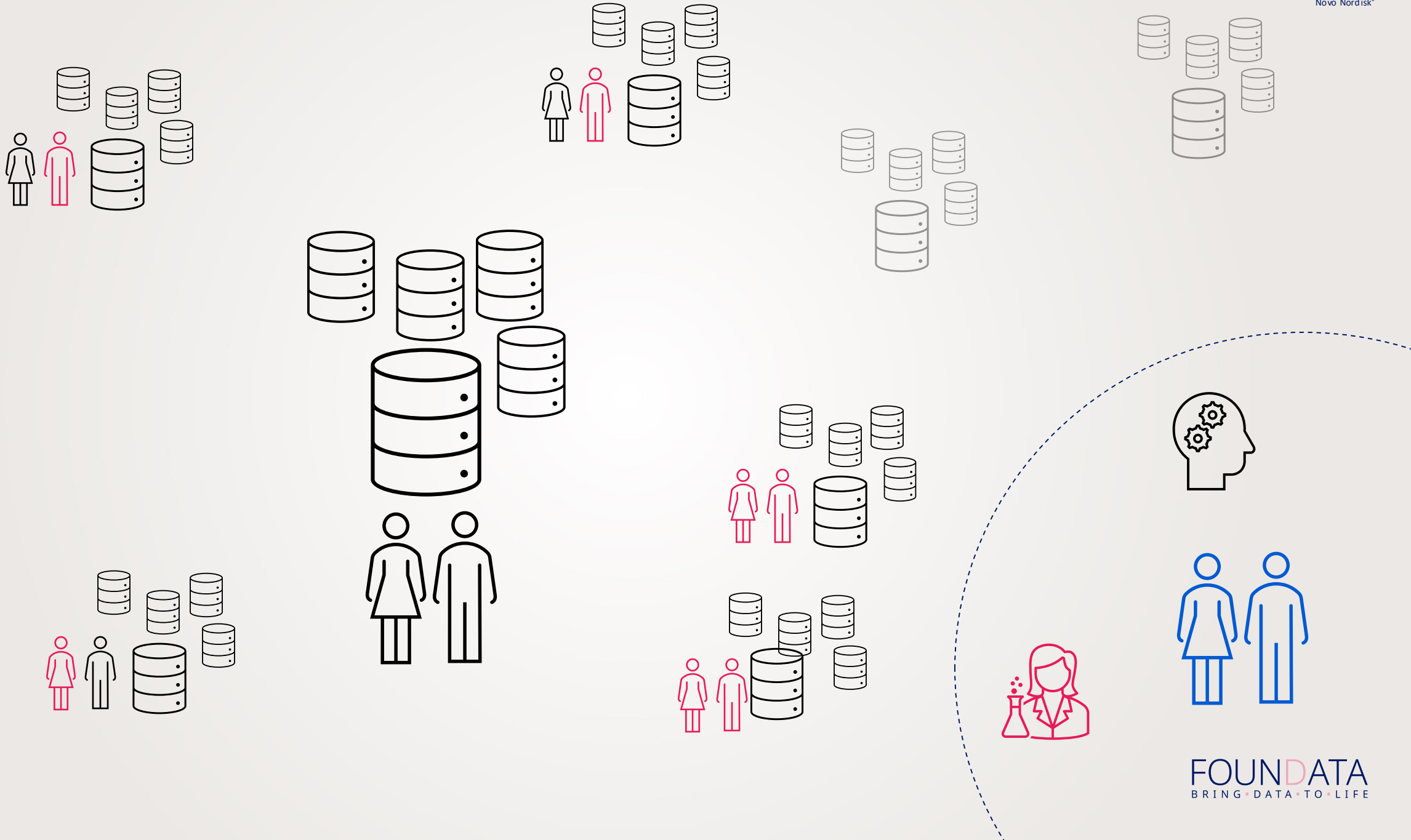
Disclaimer

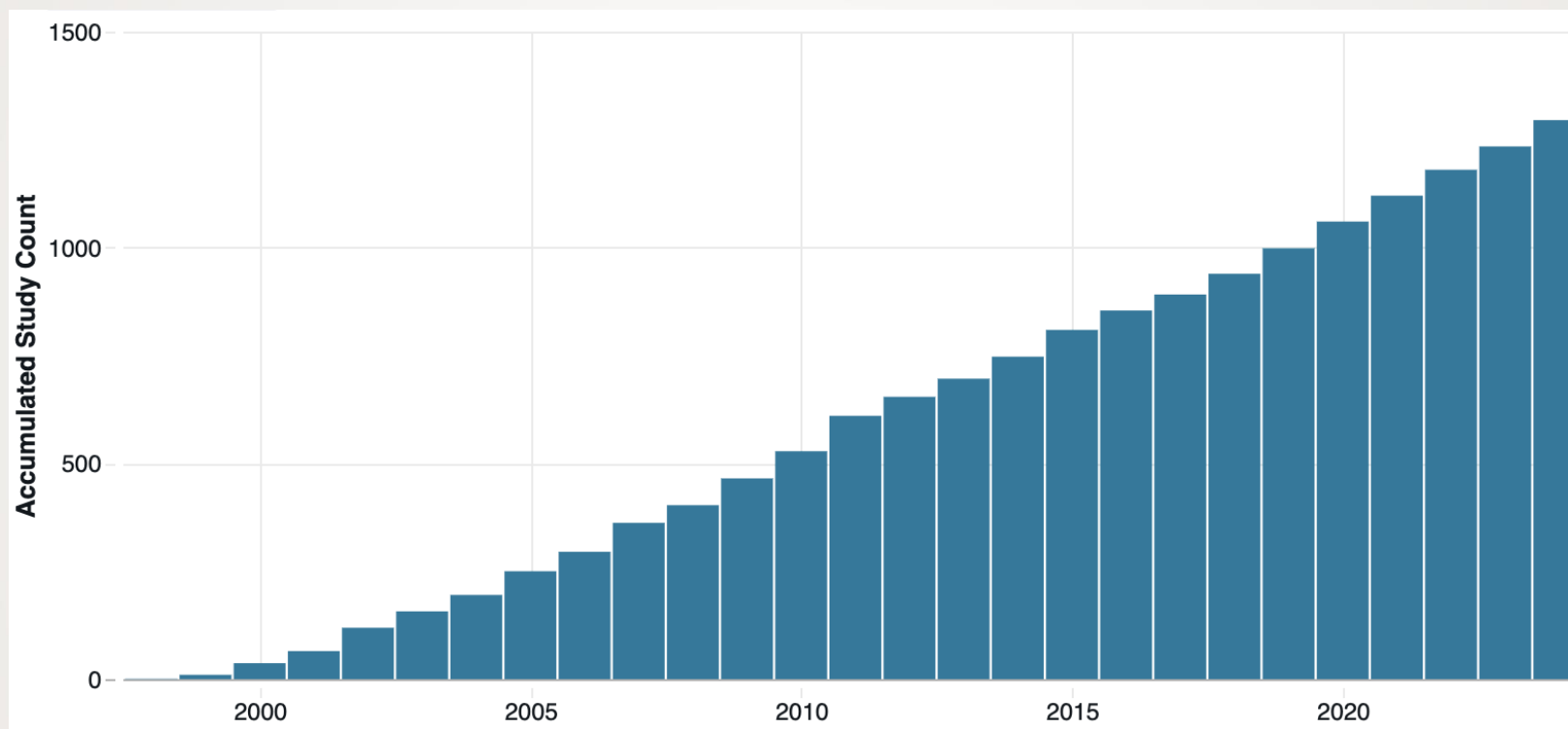
Views and opinions expressed are solely those of the presenter and do not necessarily reflect the official Novo Nordisk opinion. Information presented is based on personal expertise and experience.

Please do not take photos or recordings of the presentation.





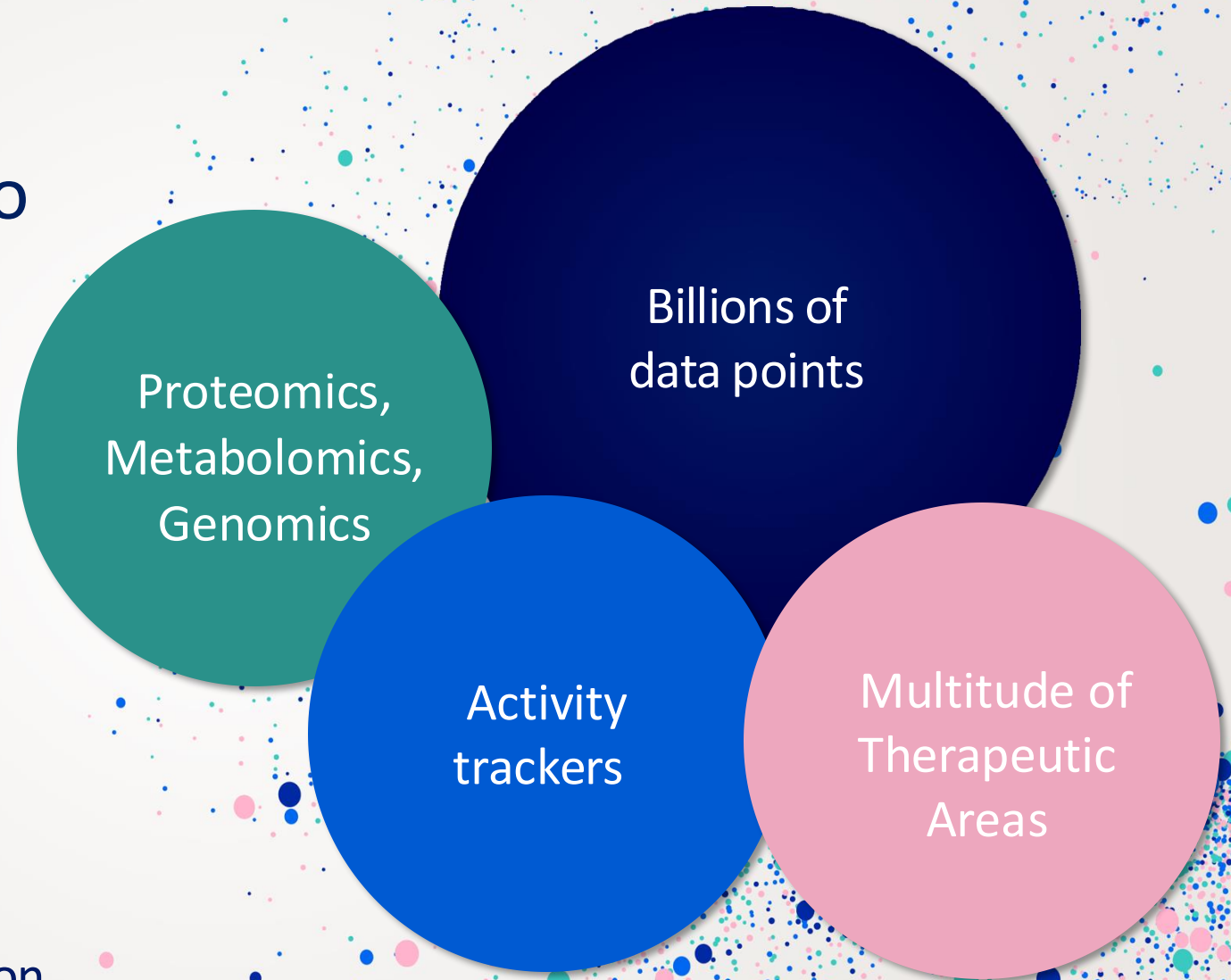




Why? | Increasing data complexity and volume creates an opportunity to create life-changing insights

It's time to:

- Democratised access
- Empower insight generation
- Enable collaborative value creation





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Sign in here

Apply for access

Want to know more about FounData? [Go to Sharepoint](#)




Home


Find


Request


Access


Support



Find

Actions: + Add to request (0) Compare protocols (0)

View:  

Studies: 14 Subjects: 3,260

☐	STUDY ID	STUDY ACRONYM	THERAPEUTIC AREA	PHASE	GENERIC NAME	
☐	NN9536-4373	STEP 1	Obesity	IIIA	SEMAGLUTIDE	View details >
☐	NN9536-4374	STEP 2	Obesity	IIIA	SEMAGLUTIDE	View details >
☐	NN9536-4375	STEP 3	Obesity	IIIA	SEMAGLUTIDE	View details >
☐	NN9536-4376	STEP 4	Obesity	IIIA	SEMAGLUTIDE	
☐	NN9536-4378	STEP 5	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-4379	STEP 7	Obesity	IIIA	SEMAGLUTIDE	
☐	NN9536-4382	STEP 6	Obesity	IIIA	SEMAGLUTIDE	
☐	NN9536-4451	STEP TEENS	Obesity	IIIA	SEMAGLUTIDE	
☐	NN9536-4576	STEP 8	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-4578	STEP 9	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-4706	STEP12	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-4707	STEP 11	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-4734	STEP 10	Obesity	IIIB	SEMAGLUTIDE	
☐	NN9536-7545	STEP UP T2D	Obesity	IIIB	SEMAGLUTIDE	


Home


Find


Request


Access


Support



Filters

Applied filters:

NN9536 X PHASE IIIA TRIAL X

PHASE IIIB TRIAL X Male X

Project & study

IDs & names

Dates & milestones

Drug information

Find

Actions: + Add to request (14) Compare protocols (14)

Demographics

Vital signs

Adverse events

Lab parameters

Medical history

Age

Demographics

Number of subjects

Under 18

18 to 24

25 to 34

35 to 44

45 to 54

55 to 64

65 and ab...

Age

Country

Demographics

Grouped by: None

Filters

Applied filters:

NN9536 X PHASE IIIA TRIAL X

PHASE IIIB TRIAL X Male X

Project & study

IDs & names

Dates & milestones

Drug information

Attributes

Subject

Demographics

Medical history

Adverse events

Lab parameters

Vital signs

Omic

Clear all filters



FIND



ACCESS



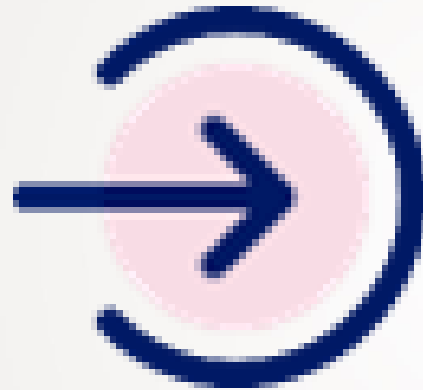
CONNECT



SOLVE



FIND



ACCESS
+ GOVERNANCE



CONNECT



SOLVE

Ethical considerations and legislation on secondary use

Consulting the Informed Consent: It is imperative to have a clear alignment between the informed consent and the desired secondary purpose. As the complexity of consent forms can vary over time, we have centralized this effort to relief the burden from the individual users and align assessments.

Data Ownership: Clearly defined roles within the data management hierarchy are essential. Each data product should have designated data owners and stewards who determine the appropriate usage of the data. Understanding ownership will also address potential issues related to company disclosure, ensuring that internal access to data is managed responsibly.

Conforming to legislation: Use of clinical trial data for secondary use will often be associated with constraints coming from external legislation or internal ethical requirements. It is essential to govern this in a general fashion to enable data users equal and correct access and guidance.





FIND



ACCESS



CONNECT



SOLVE



FIND



FIND STUDIES



FIND SUBJECTS

Find View 14 Subjects: 3,280

Actions: [Add to request \(0\)](#) [Compare protocols \(0\)](#)

STUDY ID	STUDY ACRONYM	INDICATED AREA	PHASE	STATUS NAME	View details
NNOV36-4372	STEP 1	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4374	STEP 2	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4375	STEP 3	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4376	STEP 4	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4378	STEP 5	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-4379	STEP 7	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4382	STEP 6	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4401	STEP 7EENS	Obesity	IIA	SENAGLUTIDE	View details
NNOV36-4576	STEP 8	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-4578	STEP 9	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-4760	STEP12	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-4767	STEP 11	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-4734	STEP 10	Obesity	IIIB	SENAGLUTIDE	View details
NNOV36-7545	STEP UP 12D	Obesity	IIIB	SENAGLUTIDE	View details

[Clear all filters](#)

Filters 14 Subjects: 3,280

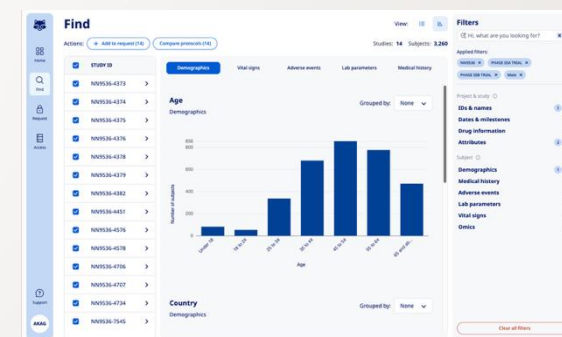
Applied filters: [Clear all](#) [Save filters](#) [Share filters](#)

Project & study +

- IDs & names +
- Dates & milestones +
- Drug information +
- Attributes +

Subject +

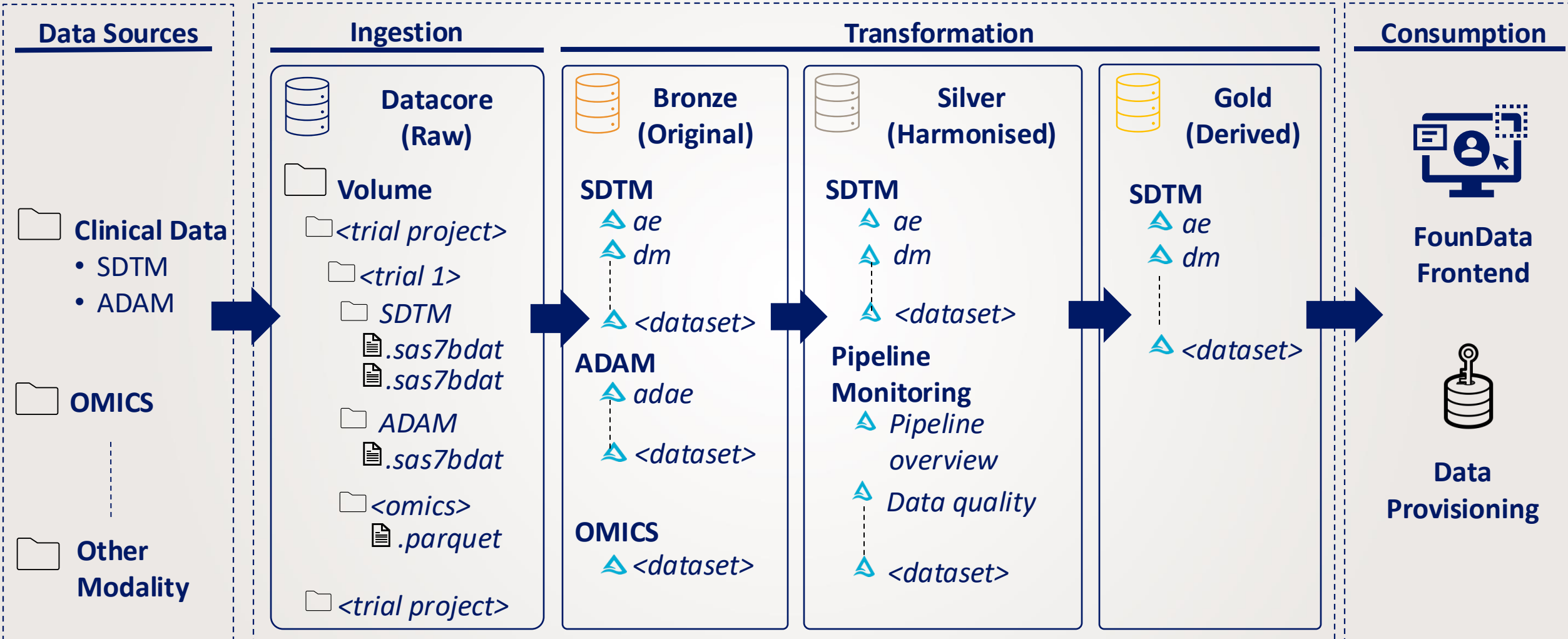
- Demographics +
- Medical history +
- Adverse events +
- Lab parameters +
- Vital signs +
- Genetics +



Stack the Data – Embark on harmonisation

	USUBJID	LBTEST	LBDTC	LBSTRESN	REF_NO	DT_COL	RES_NUM
Trial 1	NN-1111	ALBUMIN	01-2020	2.1 (g/L)			
Trial 2	NN-1112	Alb_test		1.1 (g/L)		05-2021	
Trial 3	NN-1113	Albumin	2020-01		1		0.5 (mmol/L)
Trial 4	NN-1114	ALBUMIN		0.2 (mmol/L)			
Trial 5	NN-1115	ALB_1	2020-05-24	0.3 (mmol/L)			POS

Data Products Process overview



Configuration files control data transformation

	USUBJID	LBTEST	LBDC	LBSTRESN	LBSTRESU	REF_NO	DT_COL	RES_NUM
Trial 1	NN-1111	ALBUMIN	01-2020	2.1	g/L			
Trial 2	NN-1112	Alb_test		1.1	g/L		05-2021	
Trial 3	NN-1113	Albumin	2020-01			1		0.5

LBTEST	LBTESTCD	LBSPEC	LBSTRESU	mapped_LBTEST	mapped_LBTESTCD	mapped_LBSPEC	mapped_LBSTRESU
ALBUMIN	ALB	BLOOD	g/L	Albumin	ALB	BLOOD	g/dL
Alb_test	ALB	SERUM	g/dL	Albumin	ALB	SERUM	g/dL
Albumin_serum	ALBS			Albumin	ALB	SERUM	g/dL
ALBUMIN	ALB	URINE	mg/L	Albumin	ALB	URINE	mg/L
ALB_1	ALB1	SERUM		Albumin	ALB	SERUM	g/dL

Derivations to increase speed to first insights

	USUBJID	LBTEST	LBDTC_IMP	LBSTRESN	SEX	LBSTRESN_BAS E	LBSTRESN_CHG _BASE
Trial 1	NN-1111	ALBUMIN	2020-01-15	0.1 (mmol/L)	F	0.1 (mmol/L)	0.0 (mmol/L)
Trial 2	NN-1112	ALBUMIN	2021-05-15	0.7 (mmol/L)	F	0.5 (mmol/L)	0.2 (mmol/L)
Trial 3	NN-1113	ALBUMIN	2020-01-15	0.5 (mmol/L)	M	0.1 (mmol/L)	0.4 (mmol/L)
Trial 4	NN-1114	ALBUMIN	2019-03-15	0.2 (mmol/L)	F	0.2 (mmol/L)	0.0 (mmol/L)
Trial 5	NN-1115	ALBUMIN	2020-05-24	0.3 (mmol/L)	M	0.1 (mmol/L)	0.2 (mmol/L)

Controlled release of code and configurations





FIND



ACCESS



CONNECT

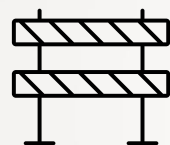


SOLVE

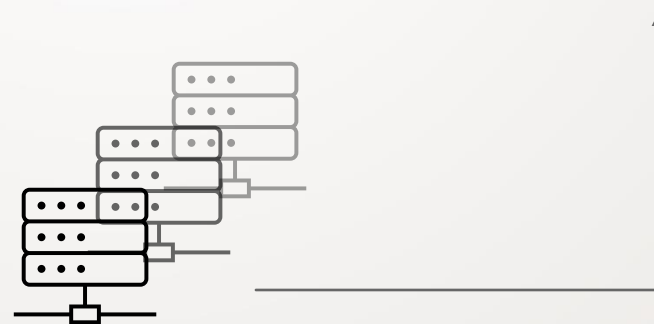
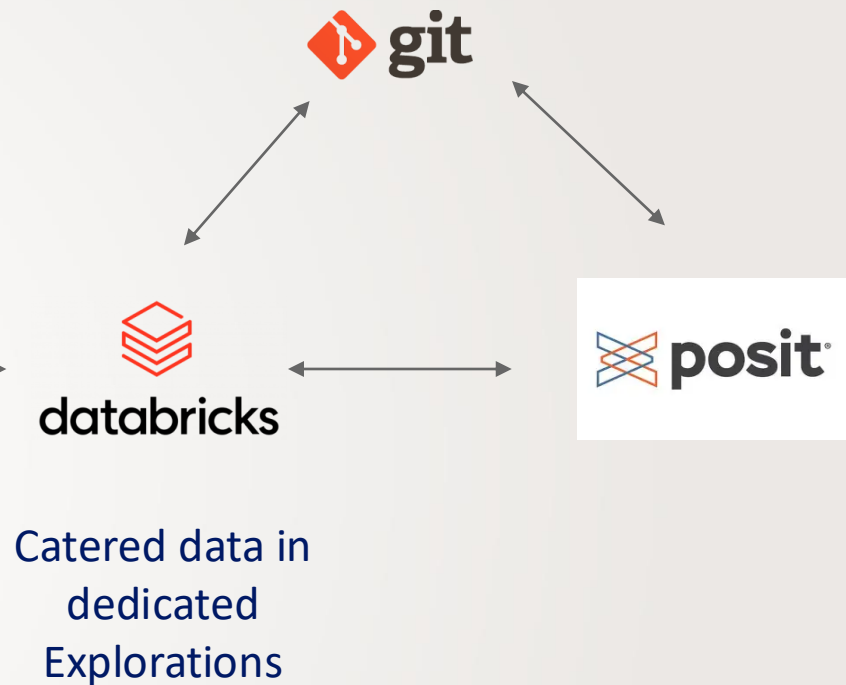
Connecting to data

STUDY ID	STUDY ACCESS	STUDY TYPE	DATA	STATUS	REQUEST ID
NOV-001-001	STUDY 1	Observational	SA	NOV-001-001	NOV-001-001
NOV-001-002	STUDY 2	Observational	SA	NOV-001-002	NOV-001-002
NOV-001-003	STUDY 3	Observational	SA	NOV-001-003	NOV-001-003
NOV-001-004	STUDY 4	Observational	SA	NOV-001-004	NOV-001-004
NOV-001-005	STUDY 5	Observational	SA	NOV-001-005	NOV-001-005
NOV-001-006	STUDY 6	Observational	SA	NOV-001-006	NOV-001-006
NOV-001-007	STUDY 7	Observational	SA	NOV-001-007	NOV-001-007
NOV-001-008	STUDY 8	Observational	SA	NOV-001-008	NOV-001-008
NOV-001-009	STUDY 9	Observational	SA	NOV-001-009	NOV-001-009
NOV-001-010	STUDY 10	Observational	SA	NOV-001-010	NOV-001-010
NOV-001-011	STUDY 11	Observational	SA	NOV-001-011	NOV-001-011
NOV-001-012	STUDY 12	Observational	SA	NOV-001-012	NOV-001-012
NOV-001-013	STUDY 13	Observational	SA	NOV-001-013	NOV-001-013

Find Data by
STUDYID

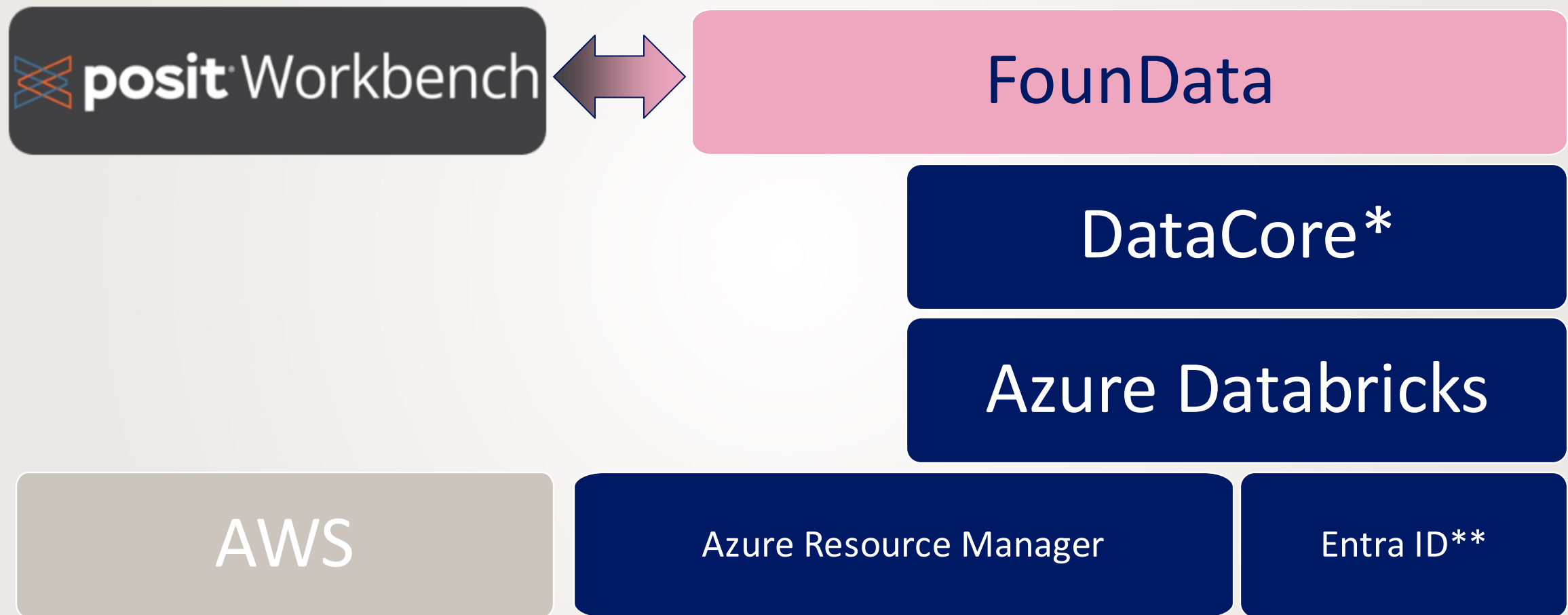


Request Access



Data releases

FounData is integrated into a Broader Ecosystem



* Central data repository for Research and Development in Novo Nordisk

** Centralized access management

1st layer access

Access to FounData front-end is open to Novo Nordisk employees via NovoAccess

The screenshot displays the FounData front-end interface. On the left, a sidebar contains the Novo Nordisk logo, a search bar, and navigation links for 'Find', 'Request', 'Access', and 'Support'. The main content area is titled 'Find' and shows a table of search results for obesity studies. The table has columns for Study ID, Study Acronym, Therapeutic Area, Phase, and Generic Name. A sidebar on the right contains filters for 'Applied filters', 'Project & study', 'IDs & names', 'Dates & milestones', 'Drug information', 'Attributes', 'Subject', 'Demographics', 'Medical history', 'Adverse events', 'Lab parameters', 'Vital signs', and 'Omics'. The table lists 14 studies with 3,260 subjects.

STUDY ID	STUDY ACRONYM	THERAPEUTIC AREA	PHASE	GENERIC NAME	View details
NN9536-4373	STEP 1	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4374	STEP 2	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4375	STEP 3	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4376	STEP 4	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4378	STEP 5	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-4379	STEP 7	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4382	STEP 6	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4451	STEP TEENS	Obesity	IIIa	SEMAGLUTIDE	View details
NN9536-4576	STEP 8	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-4578	STEP 9	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-4706	STEP 12	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-4707	STEP 11	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-4734	STEP 10	Obesity	IIIb	SEMAGLUTIDE	View details
NN9536-7545	STEP UP T2D	Obesity	IIIb	SEMAGLUTIDE	View details

2nd layer access

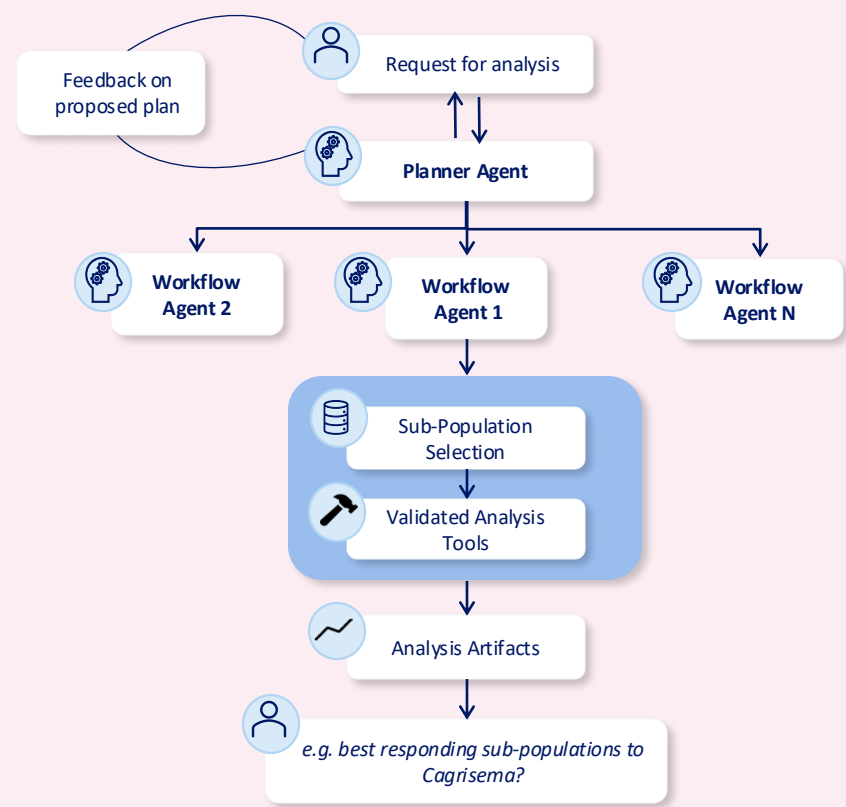
Access to FounData Analytical Environment follows a risk-based data access framework



A multi-agent AI chatbot | Optimising clinical trials and refining asset strategy



AGENTIC AI PROCESS FLOW



Actor: Data source system Agent Person Agent tools Artifacts

ZOOM IN ON AI AGENT



AI Capability: Full Agentic workflow for analytics

Thank You

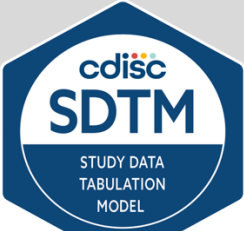
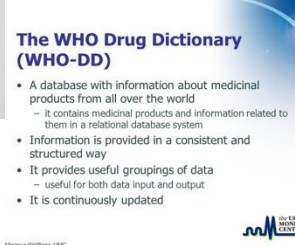
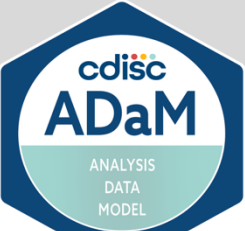
DH02 – PHUSE EU Connect 2025
Anne Katrine Alsing (akag@novonordisk.com)



Appendix

04

Overview of data standards

 SDTM A standard structure for <i>tabulating study data</i> to be submitted as part of a product application. <i>This will be the GST-1 version (previous)</i>	 CT <i>Controlled terminology</i> is a <i>set of standard values</i> used throughout the clinical research process <i>from data collection through analysis and submission</i>. <i>This will be the GST-1 version (previous)</i>	 MedDRA Medical dictionary for <i>registration, documentation and safety monitoring</i> in the biopharmaceutical industry. <i>This will be the most up to date standard</i>	 WHO-DD Dictionary to <i>identify drug names and evaluate medicinal product information</i>. <i>This will be the most up to date standard</i>	 ADaM Standards that support <i>efficient generation and replication</i> of statistical analyses and results. <i>This will be the available source standard</i>	 ISO <i>Global standards for trusted goods and services to define what good looks like.</i> <i>This will be static ISO8601 date format and ISO 3166-1 alpha-3 country codes unless new requirements are defined</i>
https://www.cdisc.org/standards/foundational/sdtmig	https://datascience.cancer.gov/resources/cancer-vocabulary/cdisc-terminology	https://www.meddra.org/how-to-use/support-documentation/English	https://who-umc.org/whodrug/whodrug-global/	https://www.cdisc.org/standards/foundational/adam	https://www.iso.org/home.html

These are the standards that we will be using

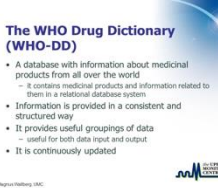
You *can't share data* in a meaningful and efficient way without addressing each of the above aspects.

***Glossary**

MedDRA: Medical Dictionary for Regulatory Affairs
ADaM: Analysis Data Model
ISO: International Organization for Standardization

GST: Global Standard Team
SDTM: Study Data Tabulation Model
CT: Controlled Terminology

FounData strategy of implementation of standards

	 SDTM <i>GST-1 version (previous)</i>	 CT <i>GST-1 version (previous)</i>	 MedDRA <i>The most up to date standard</i>	 WHO Drug Dictionary <i>The most up to date standard</i>	 ADaM <i>The available source standard</i>	 ISO <i>Static ISO8601 date format and ISO 3166-1 alpha-3 country codes unless new requirements are defined</i>
Why	We utilise the latest Global Standards Team version -1 in FounData to incorporate historical trials. The standards team has already conducted an impact assessment of newer standards, alleviating the need for repetition. Our primary objective is to harmonise data. However, exceptions can be made to accommodate specific use cases requiring the latest version.	We utilise the latest Global Standards Team version -1 in FounData to incorporate historical trials. The standards team has already conducted an impact assessment of newer standards, alleviating the need for repetition. Our primary objective is to harmonise data. However, exceptions can be made to accommodate specific use cases requiring the latest version.	The Medical History and Adverse Events domains play a crucial role in monitoring and modelling safety-related elements within a clinical trial. The latest version, where the MedDRA team has impact assessed changes, ensures seamless browsing of events and supports the linkage of terms for structured medical queries (SMQs) used to study adverse events.	The use of WHO-DD in the CDISC CM domain involves integrating ATC codes. The latest version, where the WHO-DD team has impact assessed changes, supports consistent and accurate representation of pharmaceutical data in clinical research and healthcare settings.	The reason for not having a standards strategy for ADaM data is that it is created for specific needs and requires a clear definition of analysis criteria before dataset development. This specificity makes migration to different versions challenging, as the dataset is tailored to meet precise analytical requirements.	Given the static nature of ISO8601 standards, we will avoid alterations unless new standards are widely adopted by the industry. Furthermore, we will maintain the use of ISO 3166-1 alpha-3 country codes, aligning older versions with these standards unless significant industry-wide changes occur.
Examples	<i>The latest version of the Global Standards team is version SDTM IG 3.3. Data products is currently using version 3.2</i>	<i>The latest version of the Global Standards team is version 2024-03-29. Data products is currently using version 2023-06-30</i>	<i>As of 1 March 2024, the English MedDRA Version 27.0 is available</i>	<i>Latest WHO Drug global Version is available from 1 March 2024</i>	<i>The available ADaM IG version of the Global Standards team are version 1.1, 1.2 & 1.3.</i>	<i>The static ISO8601 date format and ISO 3166-1 alpha-3 country codes unless new requirements are defined</i>

FounData cadence for implementation of standards strategy

Standards	Activity	Cadence	Description	Attendees
SDTM	Handshake Meeting	Twice a year 45 mins	Impact assessment of SDTM and CT standards, master model	Data Products: SJTK, QJDN, SDMT, NN GST: CKJS, KPDI
Controlled Terminology (CT)	Handshake Meeting	Twice a year 45 mins	Impact assessment of SDTM and CT standards, master model	Data Products: SJTK, QJDN, SDMT, NN GST: CKJS, KPDI
MedDRA	Review	April and October 45 mins	Terminology and impact assessment	FounData Data products
WHO Drug Dictionary	Review	April and October 45 mins	Terminology and impact assessment	FounData Data products
ADaM	No review Using the available source standard	NA	NA	NA
ISO	No review Using static ISO8601 date format and ISO 3166-1 alpha-3 country codes unless new requirements are defined	NA	NA	NA
Study metadata	No review Using static ISO8601 date format and ISO 3166-1 alpha-3 country codes unless new requirements are defined	Twice a year 45 mins	Review and identification of missing data	FounData Data products

Glossary

MedDRA: Medical Dictionary for Regulatory Affairs
ADaM: Analysis Data Model
ISO: International Organization for Standardization

GST: Global Standard Team
SDTM: Study Data Tabulation Model
CT: Controlled Terminology

Why do we use SDTM?



Background and Context

SDTM (Study Data Tabulation Model) is a standardised format used to organise and present clinical trial data. Developed by CDISC, it ensures consistency, quality, and interoperability of data for regulatory submissions and research. Its adoption promotes transparency and efficiency within the clinical research community.



Resolution in FounData platform

In the context of historic clinical trial harmonisation on FounData, the utilisation of SDTM (Study Data Tabulation Model) provides a standardised framework for organising and integrating data from various historical clinical trials. This approach ensures consistency, quality, and ease of data analysis across different studies, supporting the harmonisation and integration of diverse datasets within the FounData environment.

In FounData, we incorporate historical trials using the latest Global Standards Team version -1. The standards team has already assessed the impact of newer standards, eliminating the need for redundant assessments. Our main goal is to harmonise data, while allowing for exceptions to address specific use cases that require the latest version.

Why do we use controlled terminology?



Background and Context

Controlled terminology is utilised to ensure standardised and consistent representation of specific concepts, variables, and values within clinical trial data. This standardisation facilitates clear communication, data quality, and regulatory compliance across diverse studies and organisations.

Background and Context: Controlled terminology is employed to establish a common language for describing variables such as adverse events, medical history, and concomitant medications across clinical trials. It provides a predefined set of terms and codes, enhancing data quality, interoperability, and comparability. This approach supports the consistent capture, analysis, and reporting of data, ultimately aiding in the interpretation and review of clinical trial results.



Resolution in FounData platform

In FounData, we utilise controlled terminology for content harmonisation in historic trials. Currently, the latest version used by the Global Standards team is version 2024-03-29. Our Data Products team is currently using version 2023-06-30, as the Global trial team has already conducted an impact assessment. This approach avoids duplicative efforts on impact assessment and ensures alignment with the latest standards.

Why do we use MedDRA?



Background and Context

Medical History and Adverse Events domains are valuable to monitor and model safety related elements from a clinical trial. Due to regulatory requirements, the Adverse Events are generally very well harmonised and aligned to Medical Dictionary for Regulatory Affairs (MedDRA). Less emphasis is placed on MH. Alignment to MedDRA helps users browse through events of interest in a seamless manner and supports linkage of the terms for structured medical queries (SMQs) that are used to study adverse events.



Resolution in FounData platform

We developed a simple routine that standardises all the Adverse Event and Medical History terms to a common dictionary version of MedDRA allowing scientists to seamlessly find and browse through the events captured in the clinical trial. We have summarised our analysis of the **10 Dolfineous trials** to showcase the quality enhancements through MedDRA harmonisation. We use latest version as MedDRA as impact assessment of previous version and use cases may benefit from it.

Domain	Total Unique Terms	Unmapped before Harmonisation	Unmapped after Harmonisation	% Mapped
AE	16034	10-20%	1	99.9%
MH	23383	30-40%	65	99.72%

*This process can also be applied to WHO Drug Standardisation <https://who-umc.org/whodrug/whodrug-global/>

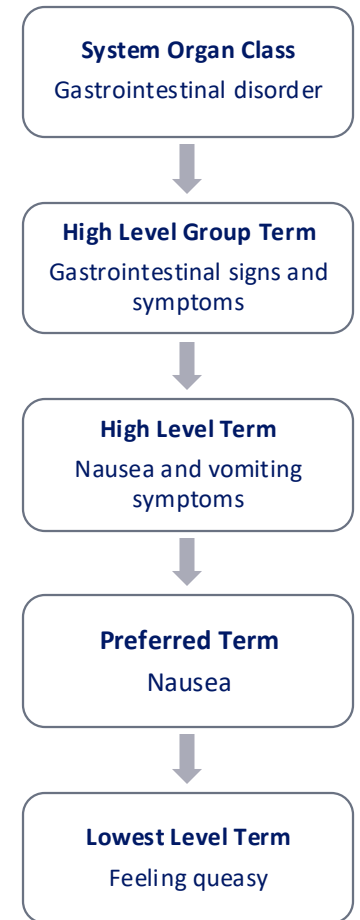


Figure 1: Typical MedDRA hierarchy

Why do we use WHO-DD?



Background and Context

The use of WHO-DD (World Health Organisation Drug Dictionary) in CDISC (Clinical Data Interchange Standards Consortium) CM (Clinical Data Acquisition Standards Harmonisation) domain involves the integration of ATC (Anatomical Therapeutic Chemical) codes. These codes are maintained by the WHO Collaboration Centre for Drug Statistics Methodology and are provided by the Uppsala Monitoring Centre. This collaboration ensures standardised and globally recognised drug coding within the clinical data domain, facilitating consistent and accurate representation of pharmaceutical data in clinical research and healthcare settings.

A **ALIMENTARY TRACT AND METABOLISM**

A10 **DRUGS USED IN DIABETES**

A10B **BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS**

A10BX **Other blood glucose lowering drugs, excl. insulins**

ATC code	Name	DDD	U	Adm.R	Note
A10BX07	liraglutide	1.2	mg		P



Resolution in FounData platform

In FounData, we utilise the most recent version of WHO-DD to access up-to-date and comprehensive drug information. This ensures that our data reflects the latest global standards and classifications for pharmaceutical products, supporting accurate and consistent representation within our system. We use latest version as WHO DD as impact assessment of previous version and use cases may benefits from it .

Found 13 entries containing 'acetylsalicylic'.

A01AD05 [acetylsalicylic acid](#)
 B01AC06 [acetylsalicylic acid](#)
 N02BA01 [acetylsalicylic acid](#)
 N02BA01 [acetylsalicylic acid](#)
 N02BA01 [acetylsalicylic acid](#)

USUBJID	CMTRT	CMMODIFY	CMDECOD	CMCLAS	CMCLASCD
AB-21-01	Asprina 03	Aspirina 03	Acetylsalicylic acid; Aluminium glycinate; Magnesium hydroxide	Platelet aggregation inhibitors excl. heparin	B01AC

*This process can also be applied to WHO Drug Standardisation <https://who-umc.org/whodrug/whodrug-global/>

Why do we use ADaM?



Why do end users ask for ADaM data?

- A lot of the initial users of the **FounData** platform will be teams who are used to working with clinical trial data
- These users are generally data engineers and data scientists who can derive imputations and flags for their analysis
- They are used to ADaM data as it is typically only one or two steps away from their analysis needs and hence prefer using it as a starting point over SDTM data



Benefits

- ADaM data is prepared for tabulation and visualisation of the data
- It captures the study design considerations and clinical end points from clinical trials



Challenges

- ADaM data is created for specific needs, and needs clear definition for analysis criteria prior to develop of the dataset
- There is limited user-friendly documentation to help describe the analysis dataset, making it hard for users who are unfamiliar with the data to work with the data
- The standards defined for analysis dataset allow for flexibility in the naming convention of variables leading to a lot of variety in the description of columns containing the same information.



Considerations for using ADaM datasets as a data product

- During the FounData project, we decided to provide stacked ADaM data as is to the scientists without much transformation
- We also provided as much documentation as possible for the data and worked closely with the users to understand the needs for deriving additional information in the dataset

Why do we use ISO standards?



Background and Context

We use the ISO8601 date format and ISO 3166-1 alpha-3 country codes in CDISC for standardised representation of dates and times, as well as for consistent identification of countries. This ensures uniformity and interoperability across different systems and datasets, facilitating efficient data exchange and analysis



Resolution in FounData platform

In FounData, As ISO8601 standards have remained static for a considerable period so we will refrain from making alterations unless there is industry-wide adoption of new standards. Additionally, we will adhere to using ISO 3166-1 alpha-3 country codes, ensuring that any older version country codes are migrated to align with these standards, unless significant industry-wide changes are adopted.