Leiden University
Medical Center

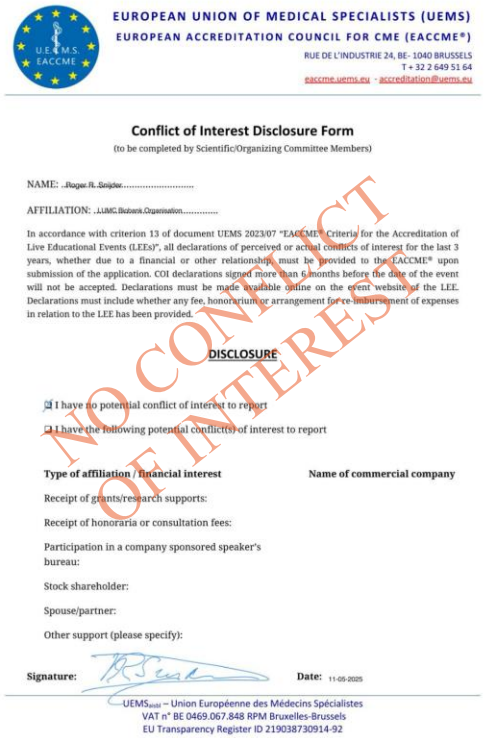
Curated registration at the source yields RWD for many purposes

- Protocols.io
- Open Terminology server

Practical application of FISMA in the Duchenne/Becker Biobank

Roger R. Snijder
LUMC Biobank Facility

Conflict of Interest



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(to be completed by Scientific/Organizing Committee Members)

NAME: ..Roger R. Snijder.....

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☑ I have no potential conflict of interest to report

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Stock shareholder:	
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Other support (please specify):	

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UEMS$_{AISBL}$ – Union Européenne des Médecins Spécialistes
VAT n° BE 0469.067.848 RPM Bruxelles-Brussels
EU Transparency Register ID 219038730914-92

More information?
Linktr.ee/RWD_NL

Crucial colleagues and key figures

My two fellow **authors -** Duchenne Center Netherlands

- Erik Niks, senior neurologist
- Yvonne Meijer-Krom, coordinator

Framework for **I**nformation **S**pecification, **M**odelling, and **A**rchitecture

Primary principles

- Registration and *curation* at the source = reusable RWD
- Context is key!

Open Terminology Server

- Dirk Hupperts

More information?
Linktr.ee/RWD_NL

… as well as esteemed peers from BBMRI.QM

A special shout-out to

- Peter Riegman
- Niina Eklund

Self-assessment tool for biobank data quality capabilities

BBMRI.QM has developed a new tool for biobanks seeking to confirm the quality of the organisational framework for data management and governance. The Data Quality Self Assessment Survey (DQ SAS) provides a structured checklist to verify that the organisational requirements are in place.

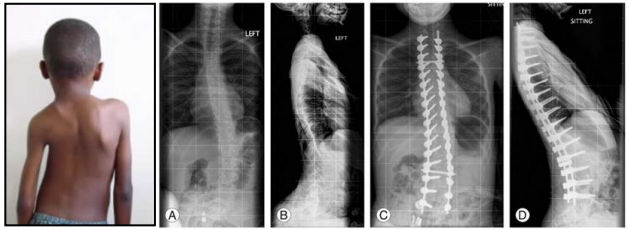
More information?
Linktr.ee/RWD_NL

Duchenne MD is a progressive, fatal disease

1st manifestation of muscle weakness: 1,5-3 y/o

decrease in muscle strength: >6-7 y/o

scoliosis: 15jr



4-6 y/o: Diagnosis

12-14 y/o: loss of ambulation

Loss of muscle strength in arms

>18 y/o : cardiac and respiratory issues

More information?
Linktr.ee/RWD_NL

When (Circulating) Cell-free DNA isn't (c)cfDNA

Scoring evidence challenges after 44 articles – GRADE

Small sample sizes (n<10, 50%)

- No statistics / inconsistency

No uniform approach, e.g centrifuge settings

- 1st centrifuge step 36 unique combinations
- 2nd centrifuge step 32 unique combinations

Underreportage

- Temperature, time, pooled samples (n=2), brakes (n=3)

Outcome measures variation

- Variable extraction methods
- Variable yield/integrity/mutation measurements

1st centrifugation step combinations
300g 20m
380g 20m
800 g 10m
800g 10m
820g 10m 4d
820g 10m RT
900g 7m RT
1300g
1300g 20m RT
1350g 12m
1370g 10m 4d
1500g 10m
1500g 10m RT
1600g 10m
1600g 10m 4d
1600g 10m RT
1600g 15m RT
1600g 20m
1600g 20m RT
1700g 10m
1700g 5m
1900g 10
1900g 10m 4d
1900g 7m
2000 rpm 15m 4d
2000g
2000g 10m
2000g 10m 4d
2000g 10m RT
2500 rpm 10m 4d
2500g 10
2500g 10m 4d
2500g 10m RT

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Erasmus MC

More information?
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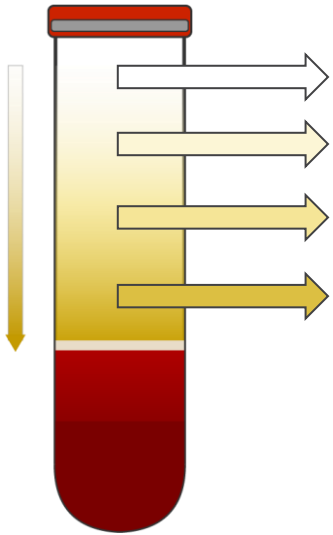
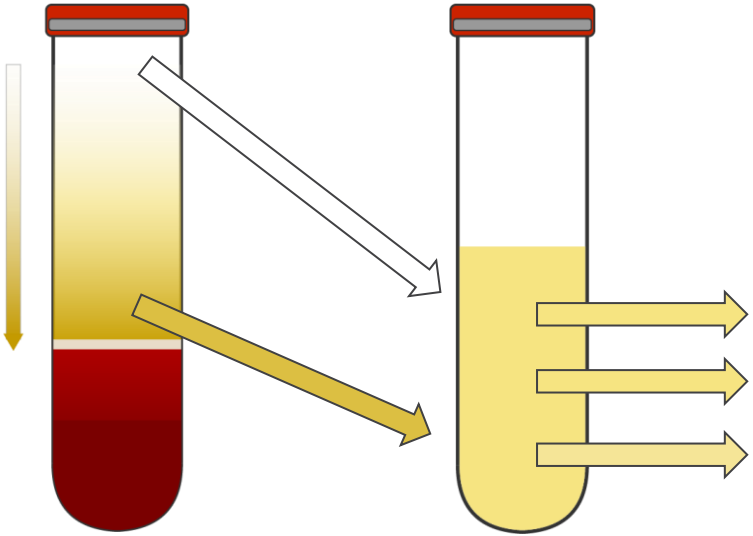
Lessons learned over the years

National protocol



SERUM

LUMC protocol >2022



ALSO SERUM

More information?
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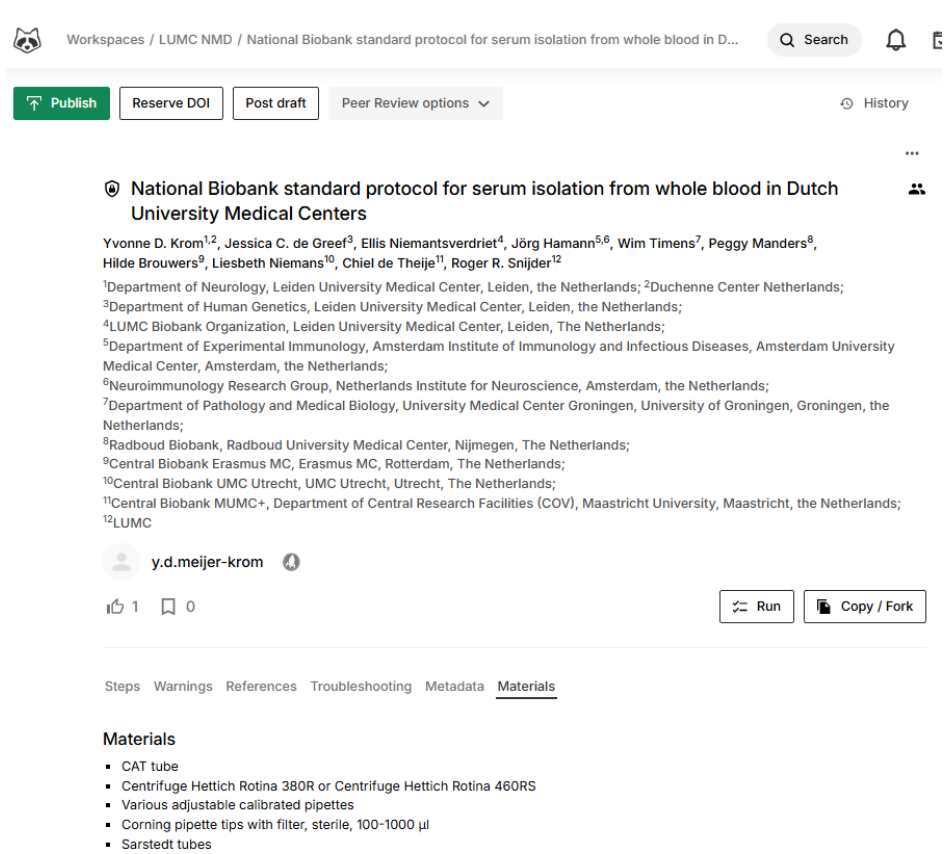
Making biomaterials FAIR – protocols.io

protocols.io



More information?
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Making biomaterials FAIR – protocols.io 2

Steps Warnings References Troubleshooting Metadata Materials

Abstract

As of 2007, the 8 Dutch University Medical Centers (UMCs) have agreed to collaborate in, and exchange knowledge regarding, setting up local biobanks, where materials for a wide variety of diseases were collected under the same protocol. These nation-wide protocols are, to a large extent, still in place for most materials collected in the extant 7 UMC biobanks. Materials collected comprise blood derivates, DNA, urine, and tissue samples.

All materials and data are handled in accordance with GDPR (AVG) and Bioba request human body material and/or clinical data.

At LUMC, the protocols to collect and store biomaterials according to nationa the years, for example, through technology improvements in sample proc carried out in the Biobank information management system, Sample Naviga assigned a unique code that cannot be traced to the donor without access to LUMC IT department under supervision of the LUMC Biobank Facility.

All pre-analytical deviations are systematically documented at the sampl high-quality downstream data use. Deviations are recorded using predef metadata and optional free-text clarification. This enables traceability, supp assess potential impact on biomarker analyses or clinical interpretation.

This protocol describes the procedure for isolating serum from whole blood,

Procedure

1 Whole blood is collected in a commercially available CAT tube. If the donor is over 12 years of age, a standard 10 ml tube is used; otherwise, a 4 ml tube is used.

2 The CAT tube is processed within 4 hours after collection.

Before initiating sample processing (and within 4 hours after collection), the CAT tube is inspected for pre-analytical deviations. The following deviation categories are captured for the tube, each accompanied by a free-text field for additional notes:

- Hemolytic material
- Lipemic material
- Icteric material
- Incorrect tube type used
- Incorrect storage temperature prior to processing
- Deviated storage duration prior to processing

3 The CAT tube is then spun at 2350 RCF for 10 minutes at 20°C to remove cells and platelets.

4 Next, the supernatant is collected by pipetting without disturbing the red pellet on the bottom of the CAT tube.

5 2-3 aliquots (from 4 ml tube) or 5 aliquots (from 10 ml tube) of serum (500 µl each) are distributed in Sarstedt tubes.

6 The Sarstedt tubes with serum are then stored at -20°C until 5 pm, at which time the tubes are stored in a UHT freezer at -80°C.

After centrifugation and completion of the storage procedure, additional pre-analytical deviations related to the processing phase are recorded. The following deviation categories are captured for the sample, each with a free-text field for additional notes:

- Deviation during centrifugation
- Storage incident

External link

https://openbioresources.metajnl.com/articles/10.5334/ojb.23

Manuscript citation

Please remember to cite the following publication along with this protocol

Manniën, J., Ledderhof, T., Verspaget, H.W., Snijder, R.R., Flikkenschild, E.F., van Scherrenburg, N.P.C., Stolk, R.P. and Zielhuis, G.A. 2017 The Parelsnoer Institute: A National Network of Standardized Clinical Biobanks in the Netherlands. Open Journal of Bioresources 4: 3, DOI: https://doi.org/10.5334/ojb.23

Keywords

serum from whole blood | processing serum | processing of serum | whole blood sample | serum | whole blood | processing | blood | standard operating protocol | protocol | biobank of Dutch academic centers | Dutch academic centers | biobank

Widget

Widget code will become available once this protocol is published

QR Code

protocols.io

Created

May 18, 2026

Last Modified

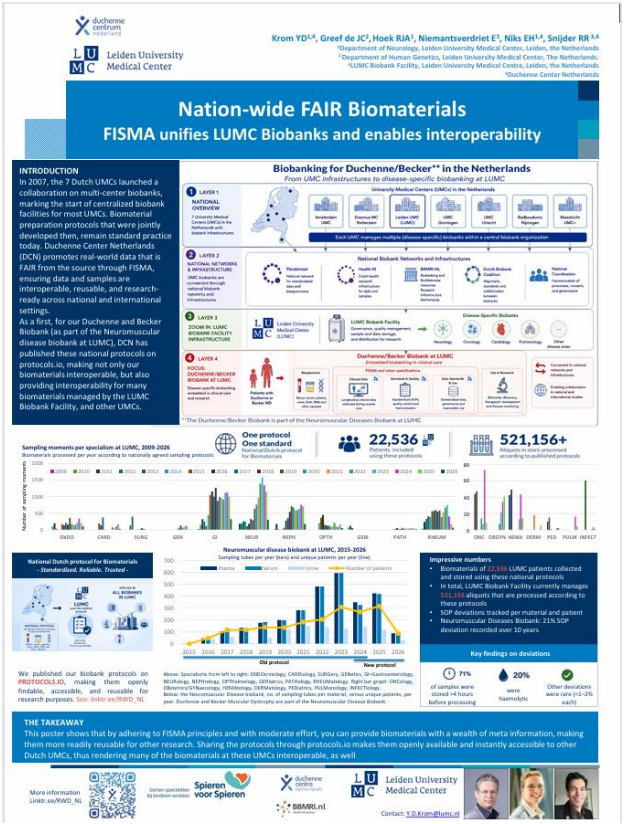
May 20, 2026

Protocol Integer ID

317251

More information?
Linktr.ee/RWD_NL

The proof of the pudding is in the eating



More information?
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Simply lost for words…

Danish

•*Hygge*: A concept of cozy, comfortable conviviality, contentment, and well-being, often with loved ones or simple pleasures.

Dutch

•*Gezelligheid*: Similar to hygge, but broader; a feeling of coziness, togetherness, fun, and warmth in social situations.

German

•*Fernweh*: A yearning for distant places, a feeling of being homesick for somewhere you've never been.

•*Waldeinsamkeit*: The feeling of being alone in the woods, a sense of solitude and connection to nature.

Japanese

•*Komorebi*: The scattered light filtering through the leaves of trees.

•*Wabi-sabi*: Finding beauty in imperfection and transience.

Welsh

•*Hiraeth*: A deep longing for a home that might not exist or a romanticized past.

Portuguese

•*Saudade*: A deep, melancholic longing for something or someone absent, often with a bittersweet quality.

Finnish

•*Sisu*: A combination of grit, perseverance, and resilience in the face of extreme adversity.

French

•*L'appel du vide*: The sudden, intrusive urge to jump from a high place.

•*Flâner*: To wander aimlessly through a city, observing life.

Italian

•*Abbiocco*: The drowsy, satisfied feeling after a large meal.

Spanish

•*Sobremesa*: The time spent lingering and chatting at the table after a meal.

More information?
Linktr.ee/RWD_NL

FISMA principles applied to biomaterials (*draft*)

Element	Definition	Value [domain] (*example*)	Coding	Cardinality	requirement	Note
ID of participant			data type II	1		
Cohort	local descriptor collection or study	REMICADEPIB4002: A multicentre, prospective, long-term registry of paediatric patients with Crohn's disease: an EU-specific registry protocol (zie ook P10.0XX)	data type ST	0..1		**Meta information**, may be implied by cohort/protocol
Centre of collection	hospital where material is collected	LUMC | OLVG endoscopy centre | etc	OID (https://www.hl7.nl/actuele-hl7-nl-oid-register.html)	1		**Meta information** for centre
DateTime of collection	Date time when material was extracted from participant	23-01-2023 11:30 GMT	date time + timezone	1		
Specimen				1..N		
Unique ID of specimen			data type II	1		
ID of parent specimen			data type II	0..1	where status of material <> unprocessed	
Status of material	*Derived from protocol (collection protocol or processing protocol)*	*raw/unprocessed | processed*	*derived*	*1*		*Pseudo-element*
Centre (or lab) of processing	centre/ lab where material is processed	LUMC | OLVG endoscopy centre | etc	OID (https://www.hl7.nl/actuele-hl7-nl-oid-register.html)	1		**Meta information** for centre
DateTime of processing	Start date time when material was processed according to protocol	23-01-2023 11:30 GMT	date time + timezone	1	where status of material <> unprocessed	protocol may call for additional datetime stamps as observations
DateTime of storage	Start date time when material was stored according to protocol	23-01-2023 11:30 GMT	date time + timezone	1	where status of material <> unprocessed	protocol may call for additional datetime stamps as observations
Type of material	material as collected / processed	[Venous|arterial|capillary] blood | tissue | biopsy | CSF | Synovial fluid | etc	Snomed CT	1		may be derived from protocol, CD to be provided at a later date
Body site of material	location of collection on body	Structure of palm of left hand (body structure) SCTID: 789216008 Descending colon structure (body structure) SCTID: 32622004	Snomed CT	1	where type of material <> blood AND where status of material = unprocessed	may be derived from protocol
Nature of material	as macroscopically assessed by relevant health professional	healthy | diseased | malignancy | neoplasm | inflamed | etc	Snomed CT	0..1		
Indication for collection	working diagnosis, procedure, in accordance with cohort protocol etc	################	ID in Diagnosis, Treatment, or both	0..1		**Meta information**, may be derived from protocol (eg biopsy of malignancy during mastectomy)
collection consumable, descriptor	the container used to collect/store material	EDTA, 9 ml'	Snomed CT	1		may be derived from protocol may be derived from type of material
collection consumable reference	reference to entry in consumables repository	################		0..N		may be derived from protocol
Protocol	protocol used for collecting / processing material	################	ID in protocol repository	1		may be supplied in study protocol
protocol deviations / observations				1..N		
DateTime of observation / deviation	Date time when material when an observation was made / deviation was reported	23-01-2023 11:30 GMT	date time + timezone	1		
observed / deviated element	protocol element where deviation was observed / observation was made	################	dependent on protocol repository	1		coding is proprietary, based on protocol repository
deviation	value of deviation / observation	TBA	PQ / Num / INT	1		coding is proprietary, based on protocol repository
end protocol deviations						
End Specimen						

More information?
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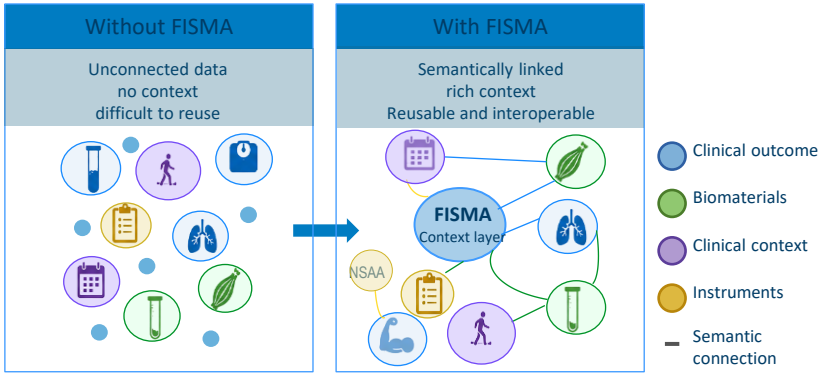
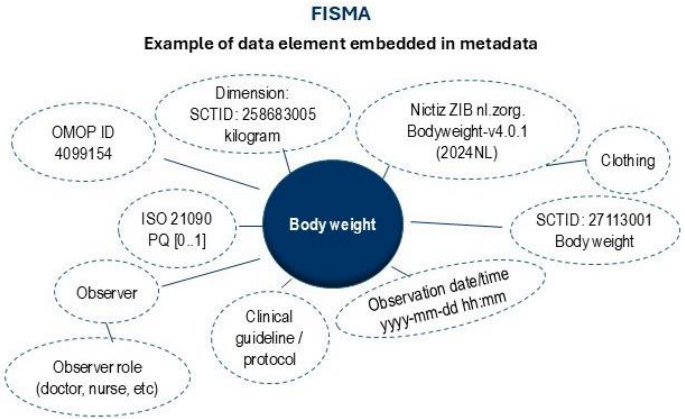
FISMA dictates every step of the process

FISMA governs every step of RWD collection, from implementation to distribution.



From unconnected data to data richly embedded in its context with FISMA.



More information?
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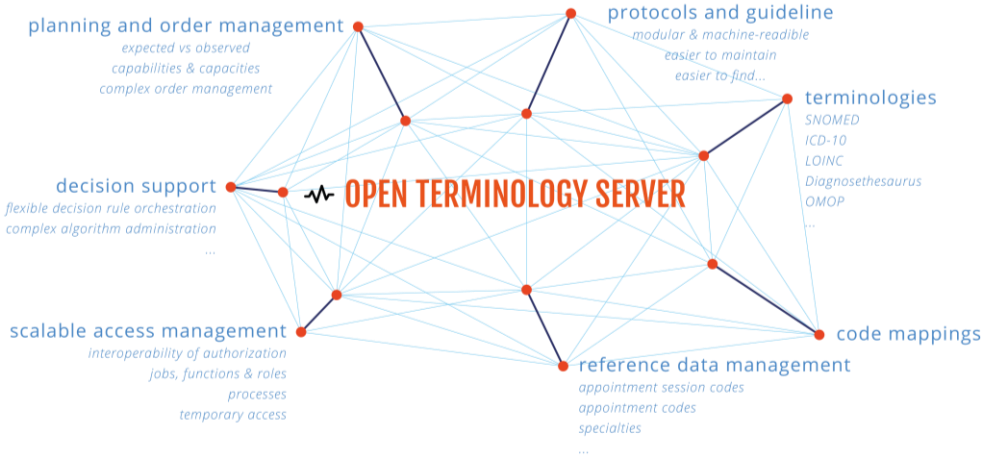
A new home for FISMA

OPEN TERMINOLOGY SERVER



More information?
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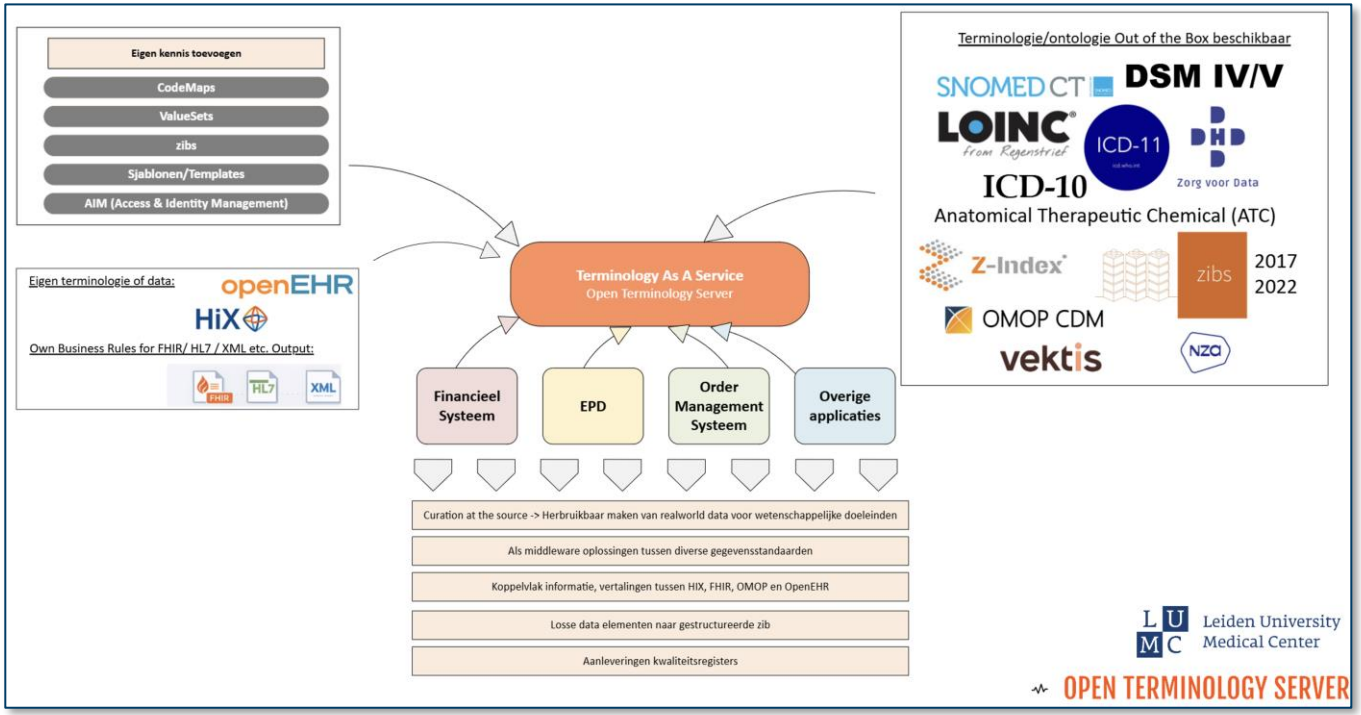
A synthesis of knowledge and standards



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More information?
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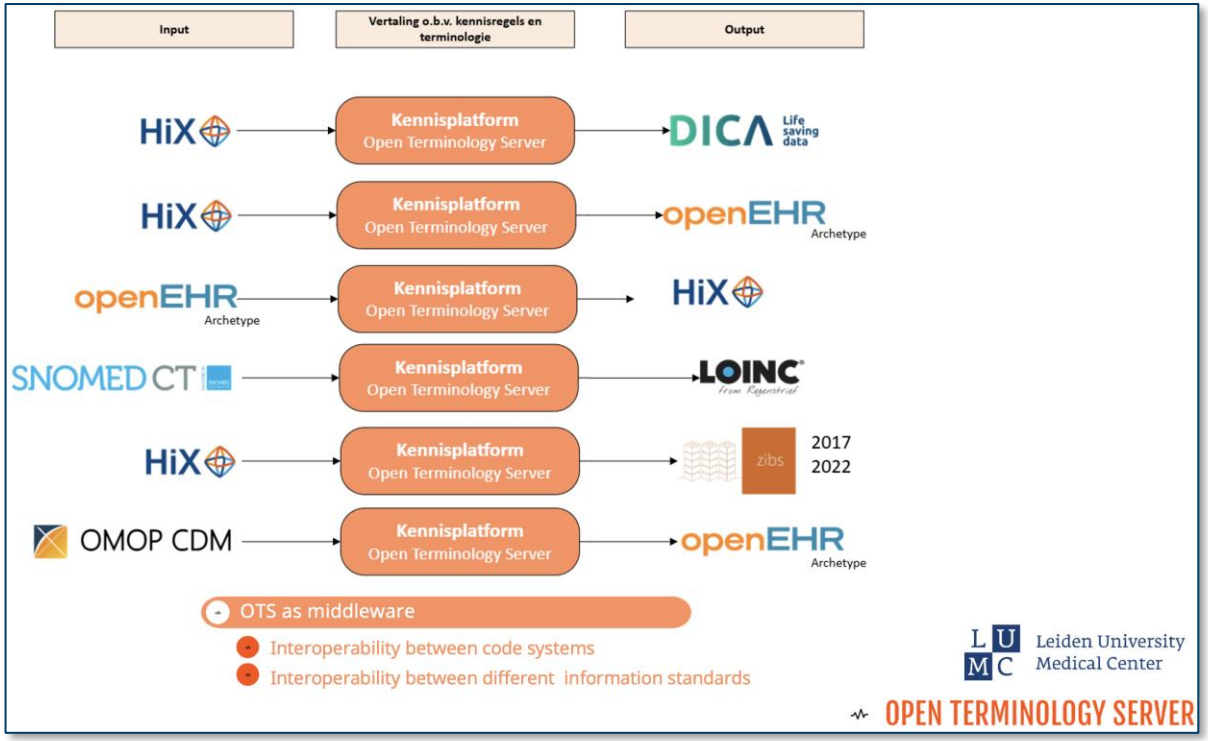
A modern-day Rosetta Stone



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More information?
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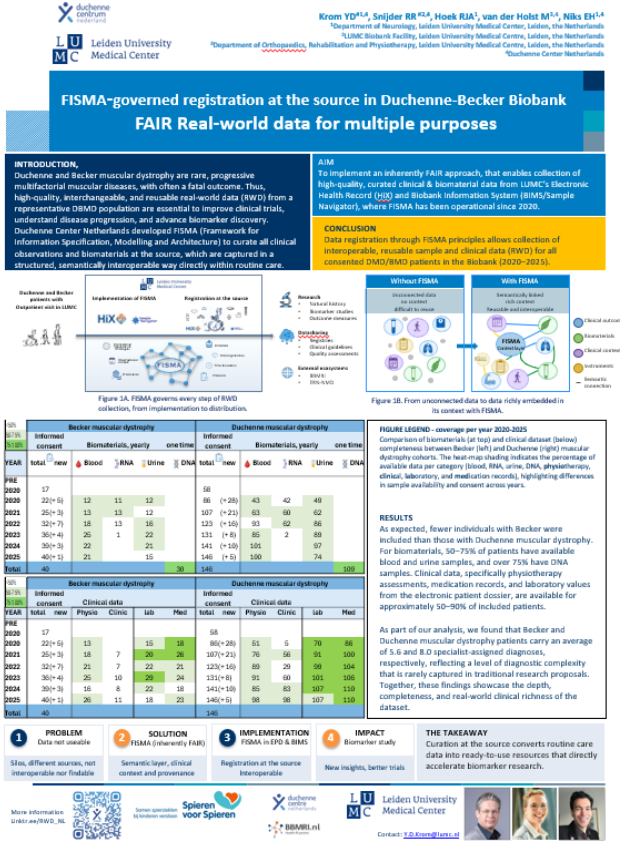
Some room left for *more* pudding?



More information?
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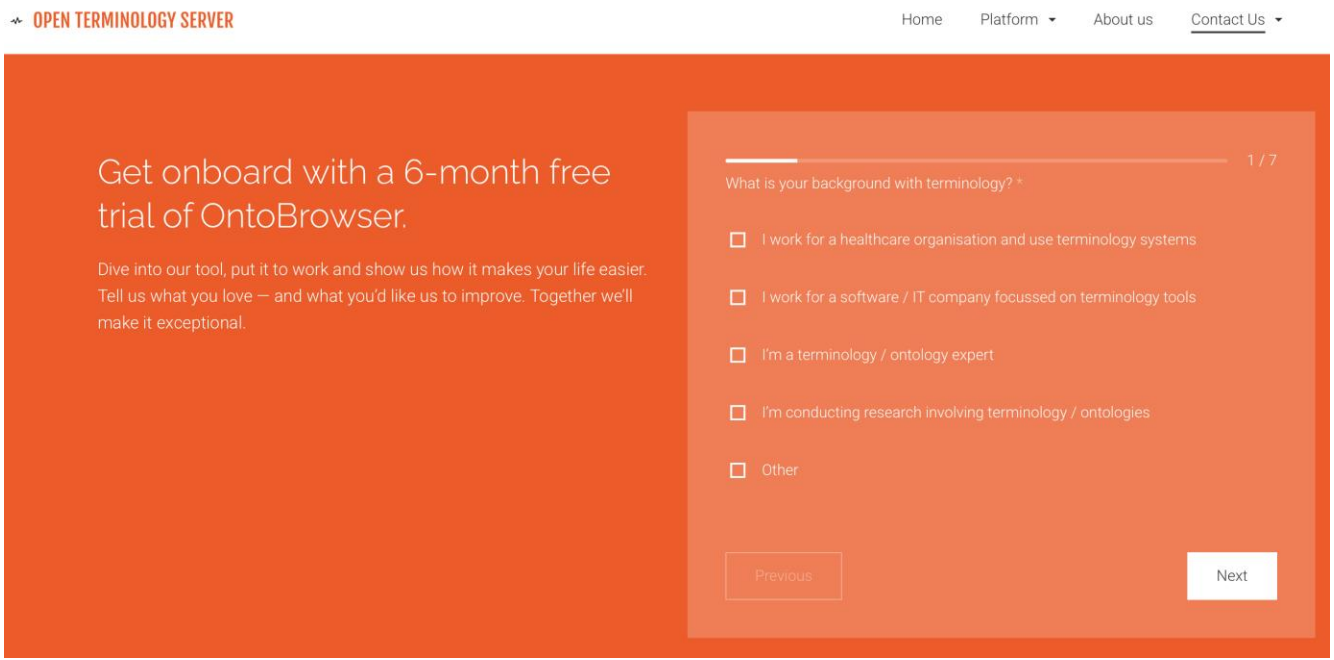
Are you in for an adventure?

Curious? Give it a whirl for free. The link is in our linktree!



More information?
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