



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



**drs. Roger R. Snijder, BBA**

- Senior staff advisor LUMC Biobank Facility / Information architect
- Senior consultant / information architect integration research & academic care / FAIR for Health RI (main architect for LUMC node)
- Information architect Research for collaboration EMC | LUMC | UMCU
- Information architect for Duchenne Center Netherlands
- Chair Research in EHR working group (HiX Standard Content)

# Conflict of Interest



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## Conflict of Interest Disclosure Form

(to be completed by Scientific/Organizing Committee Members)

NAME: J. Rogier, R. Sijpe

AFFILIATION: UEMS, Business Organization

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### DISCLOSURE

I have no potential conflict of interest to report

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Type of affiliation / financial interest      Name of commercial company

Receipt of grants/research supports:

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More information?  
[Linktr.ee/RWD\\_NL](https://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](https://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](https://linktr.ee/RWD_NL)



# Duchenne MD is a progressive, fatal disease

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



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

4-6 y/o: Diagnosis

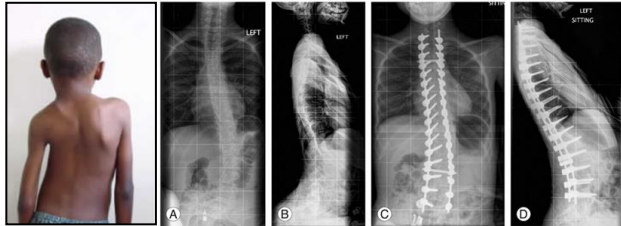
12-14 y/o: loss of ambulation



scoliosis: 15jr

Loss of muscle strength in arms

>18 y/o : cardiac and respiratory issues



More information?  
[Linktr.ee/RWD\\_NL](https://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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Hilde Brouwers – da Silva

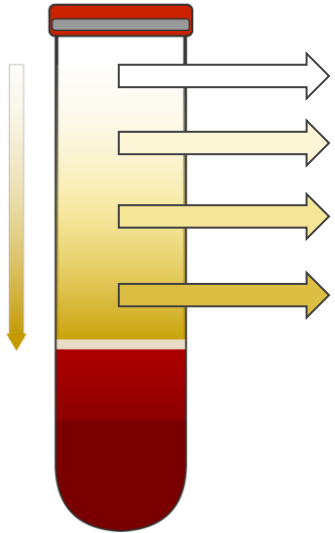


More information?  
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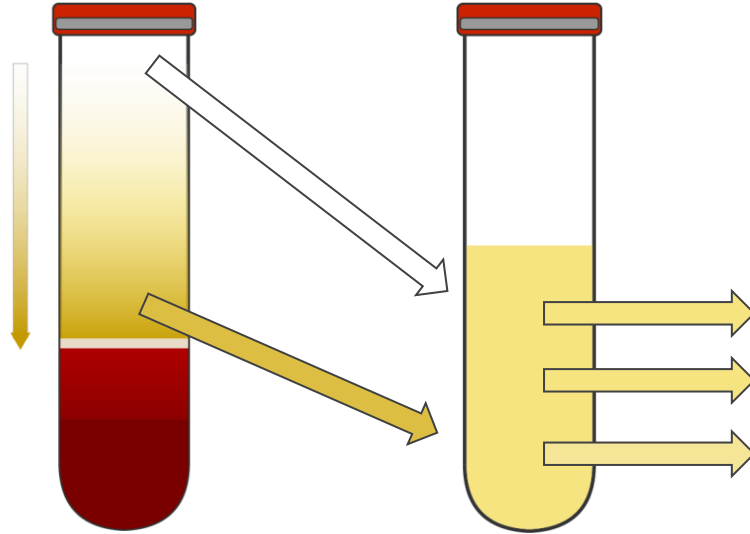
# Lessons learned over the years

National protocol



**SERUM**

LUMC protocol >2022

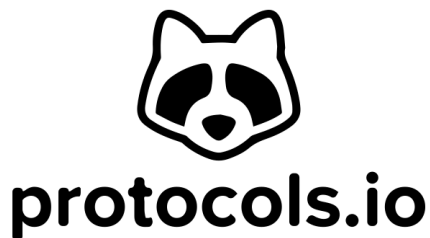


**ALSO  
SERUM**

More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# Making biomaterials FAIR – protocols.io



Workspaces / LUMC NMD / National Biobank standard protocol for serum isolation from whole blood in D...

Search



Publish

Reserve DOI

Post draft

Peer Review options

History

## National Biobank standard protocol for serum isolation from whole blood in Dutch University Medical Centers

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<sup>10</sup>Central Biobank UMC Utrecht, UMC Utrecht, Utrecht, The Netherlands;

<sup>11</sup>Central Biobank MUMC+, Department of Central Research Facilities (COV), Maastricht University, Maastricht, the Netherlands;

<sup>12</sup>LUMC



y.d.meijer-krom

1 0

Run

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Steps Warnings References Troubleshooting Metadata Materials

### Materials

- CAT tube
- Centrifuge Hettich Rotina 380R or Centrifuge Hettich Rotina 460RS
- Various adjustable calibrated pipettes
- Corning pipette tips with filter, sterile, 100-1000 µl
- Sarstedt tubes

More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# 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 nationwide protocols are, to a large extent, still in place for most materials collected in the extant 7 UMC biobanks. Materials collected comprise blood derivatives, 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 prede 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., Filkkenschild, 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



## Created

May 18, 2026

## Last Modified

May 20, 2026

## Protocol Integer ID


317251

More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# The proof of the pudding is in the eating





**LUMC**  
Leiden University  
Medical Center

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<sup>3</sup>LUMC Biobank Facility, Leiden University Medical Center, Leiden, the Netherlands  
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## Nation-wide FAIR Biomaterials

### FISMA unifies LUMC Biobanks and enables interoperability

**INTRODUCTION**

In 2007, the 7 Dutch UMCS launched a collaboration on multi-center biobanks, marking the start of centralized biobank facilities for most UMCS. Biomaterial preparation protocols that were jointly developed then, remain standard practice today. Duchenne Center Netherlands (DCN) promotes real-world data that is FAIR from the source through FISMA, ensuring data and samples are interoperable, reusable, and research-ready across national and international settings.

As a first, for our Duchenne and Becker Biobank (as part of the Neuromuscular disease biobank at LUMC), DCN has published these national protocols on protocols.io, making not only our biomaterials interoperable, but also providing interoperability for many biomaterials managed by the LUMC Biobank Facility, and other UMCS.

**Biobanking for Duchenne/Becker\*\* in the Netherlands**

Each UMCS manages multiple (disease specific) biobanks with a central biobank organization

**LAYER 1 NATIONAL OVERVIEW**

**LAYER 2 NATIONAL NETWORK & INFRASTRUCTURE**


**LAYER 3 DUCHENNE/BECKER BIOPROTOCOLS AT LUMC**

**LAYER 4 DUCHENNE/BECKER BIOPROTOCOLS AT LUMC**

**One protocol. One standard. One standard for Biomaterials.**

22,536 biomaterials using these protocols

521,156+ publications according to published protocols



**National Dutch protocols for Biomaterials - Standardized, Reliable, Trusted!**

**Neuromuscular disease biobank at LUMC, 2015-2026**

Sampling tubes per year (black) and donor patients per year (blue)


**Key findings on deviations**

- 11% of samples were stored > 14 hours before processing
- 20% were from non-patients
- Other deviations were rare (0-2% each)


**THE TAKEAWAY**

This poster shows that by adhering to FISMA principles and with moderate effort, you can provide biomaterials with a wealth of meta information, making them more readily reusable for other research. Sharing the protocols through protocols.io makes them openly available and instantly accessible to other Dutch UMCS, thus rendering many of the biomaterials at these UMCS interoperable, as well!


More information: [linktr.io/RWD\\_NL](mailto:linktr.io/RWD_NL)




Spielen voor Spieren




Duchenne Center Netherlands



LUMC Leiden University Medical Center



Contact: [Y.D.Krom@lumc.nl](mailto:Y.D.Krom@lumc.nl)



More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# 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](https://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.hi7.nl/actuele-hi7-nl-oid-register.html)	1	Meta information for centre
Date/Time of collection	Date/Time when material was extracted from participant	23-01-2023 11:30 GMT	date time + timezone	1	
<b>Specimen</b>				1..N	
Unique ID of specimen			data type II	1	where status of material <>
ID of parent specimen			data type II	0..1 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.hi7.nl/actuele-hi7-nl-oid-register.html)	1	Meta information for centre
Date/Time of processing	Start date/Time when material was processed according to protocol	23-01-2023 11:30 GMT	date time + timezone	1 unprocessed	where status of material <> protocol may call for additional date/Time stamps as observations
Date/Time of storage	Start date/Time when material was stored according to protocol	23-01-2023 11:30 GMT	date time + timezone	1 unprocessed	where status of material <> protocol may call for additional date/Time 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 as macroscopically assessed by relevant health professional	Structure of palm of left hand (body structure) SCTID: 789216008 Descending colon structure (body structure) SCTID: 32622004	Snomed CT	1 unprocessed	where type of material <> blood AND where status of material = may be derived from protocol
Nature of material		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
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
<b>protocol deviations / observations</b>				1..N	
Date/Time 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
<b>end protocol deviations</b>					
<b>End Specimen</b>					



More information?  
Linktr.ee/RWD\_NL

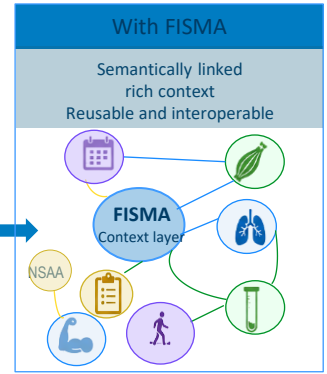
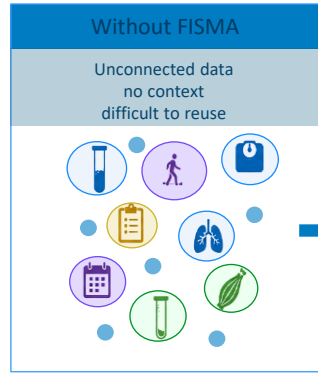
# FISMA dictates every step of the process



Duchenne and Becker patients with Outpatient visit in LUMC



- Research**
  - Natural history
  - Biomarker studies
  - Outcome measures
- Datasharing**
  - Registries
  - Clinical guidelines
  - Quality assessments
- External ecosystems**
  - BBMRI
  - ERN-NMD



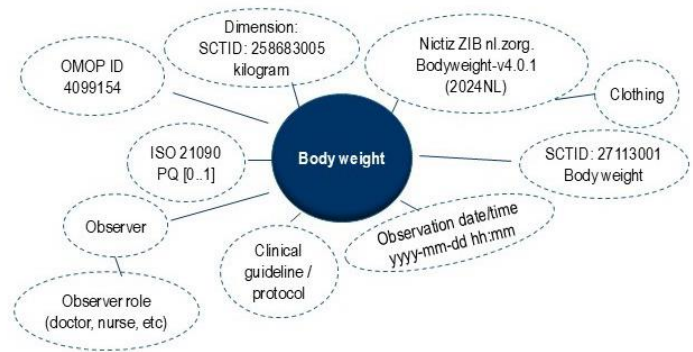
- Clinical outcome
- Biomaterials
- Clinical context
- Instruments
- Semantic connection

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

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

## FISMA

Example of data element embedded in metadata



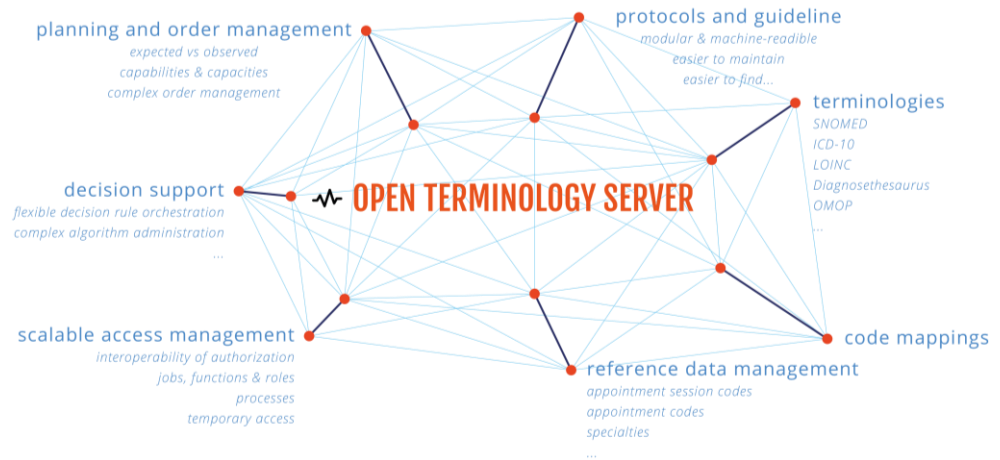
More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# A new home for FISMA



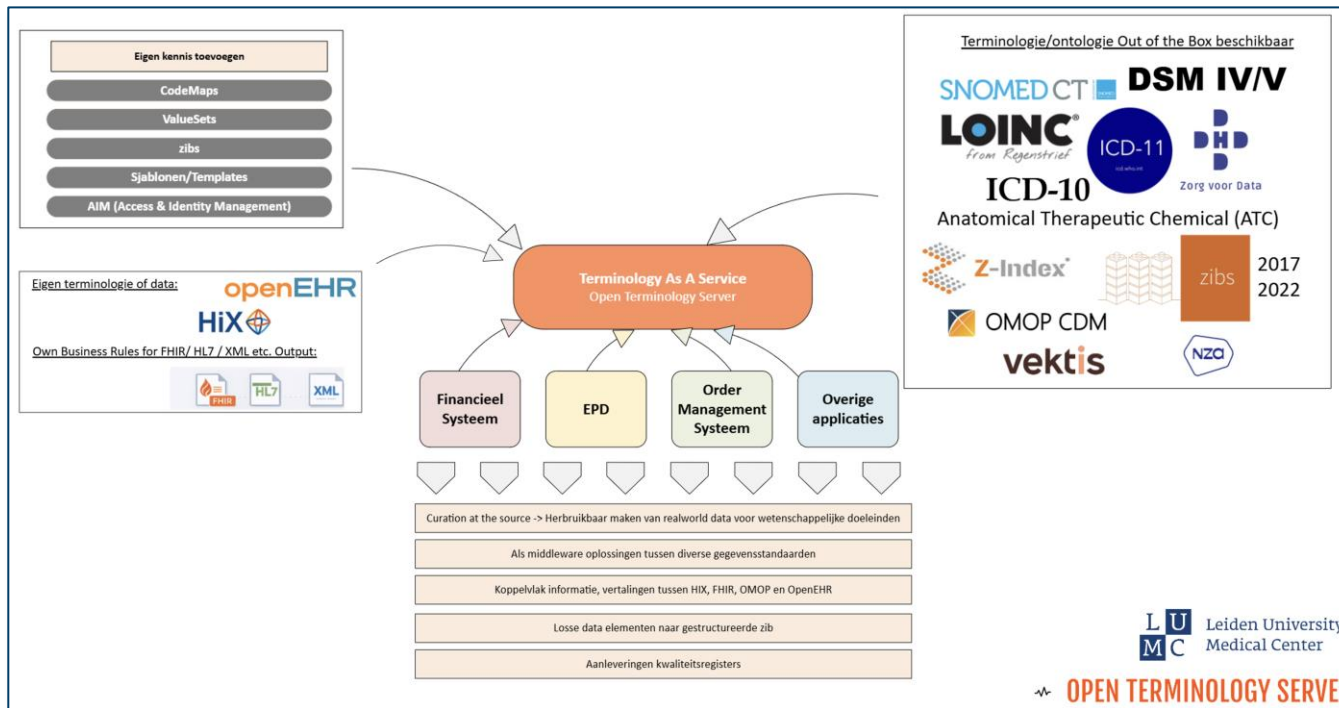
# OPEN TERMINOLOGY SERVER



More information?  
[Linktr.ee/RWD\\_NL](https://linktr.ee/RWD_NL)



# A synthesis of knowledge and standards

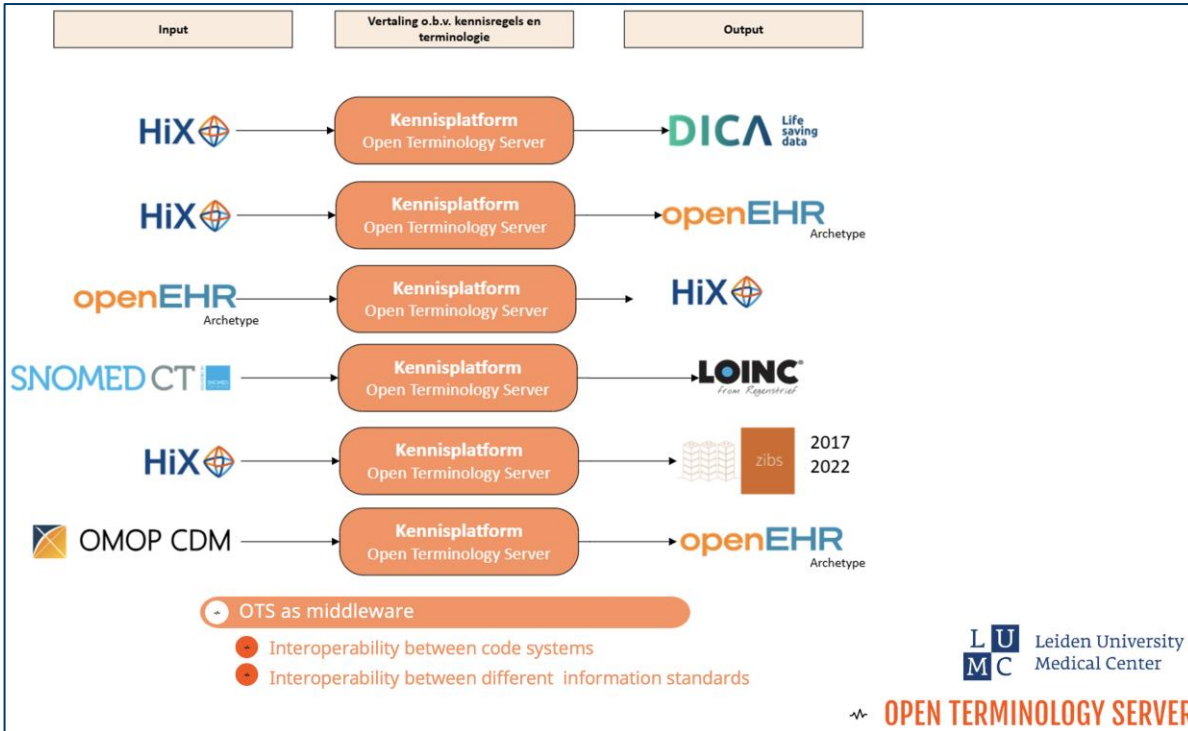


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# A modern-day Rosetta Stone



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



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## FISMA-governed registration at the source in Duchenne-Becker Biobank FAIR Real-world data for multiple purposes

### INTRODUCTION

Duchenne and Becker muscular dystrophy are rare, progressive multifactorial muscular diseases, with often a fatal outcome. Thus, high-quality, interchangeable, and reusable real-world data (RWD) from a representative DMD population are essential to improve clinical trials, understand disease progression, and advance biomarker discovery. Duchenne Center Netherlands developed FISMA (Framework for Information Specification, Modelling and Architecture) to curate all clinical observations and biomaterials at the source, which are captured in a structured, semantically interoperable way directly within routine care.

### AIM

To implement an inherently FAIR approach, that enables collection of high-quality, curated clinical & biomaterial data from LUMC's Electronic Health Record (EHR) and Biobank Information System (BIMS) (Sample Navigator), where FISMA has been operational since 2020.

### CONCLUSION

Data registration through FISMA principles allows collection of interoperable, reusable sample and clinical data (RWD) for all consented DMD/BMD patients in the Biobank (2020-2023).



Figure 3A. FISMA governs every step of RWD collection, from implementation to distribution.



Figure 3B. From unconnected data to data-richly embedded in its context with FISMA.

Year	Becker muscular dystrophy						Duchenne muscular dystrophy					
	total	new	Blood	RNA	Urine	DNA	total	new	Blood	RNA	Urine	DNA
2020	17						68	(+28)	43	42	49	
2021	25(+3)	13	13	13			107	(+13)	63	68	62	
2022	32(+7)	18	13	16			123	(+16)	93	62	66	
2023	36(+4)	25	1	22			131	(+8)	85	2	89	
2024	38(+3)	32		25			143	(+12)	101		97	
2025	40(+2)	21		15			146	(+3)	100		74	
<b>Total</b>	<b>40</b>			<b>58</b>	<b>38</b>	<b>146</b>					<b>100</b>	<b>100</b>

Year	Becker muscular dystrophy					Duchenne muscular dystrophy				
	total	new	Physio	Clinic	Lab Med	total	new	Physio	Clinic	Lab Med
2020	17					68				
2021	25(+3)	13		15	18	106(+28)	55	5	70	66
2022	32(+7)	18	7	20	25	117(+13)	70	56	74	108
2023	32(+7)	21	7	22	21	123(+16)	80	29	90	104
2024	36(+4)	25	10	20	24	131(+8)	91	60	101	100
2025	38(+3)	18	8	22	18	141(+16)	85	83	100	110
2026	40(+2)	26	11	18	23	146(+1)	88	98	107	116
<b>Total</b>	<b>40</b>									

Year	Becker muscular dystrophy				Duchenne muscular dystrophy			
	total	new	Physio	Clinic	total	new	Physio	Clinic
2020	17				68			
2021	25(+3)	13			107			
2022	32(+7)	21	7		123			
2023	36(+4)	25	10		131			
2024	38(+3)	18	8		141			
2025	40(+2)	26	11		146			
<b>Total</b>	<b>40</b>							

Year	Becker muscular dystrophy				Duchenne muscular dystrophy			
	total	new	Physio	Clinic	total	new	Physio	Clinic
2020	17				68			
2021	25(+3)	13			107			
2022	32(+7)	21	7		123			
2023	36(+4)	25	10		131			
2024	38(+3)	18	8		141			
2025	40(+2)	26	11		146			
<b>Total</b>	<b>40</b>							

Year	Becker muscular dystrophy				Duchenne muscular dystrophy			
	total	new	Physio	Clinic	total	new	Physio	Clinic
2020	17				68			
2021	25(+3)	13			107			
2022	32(+7)	21	7		123			
2023	36(+4)	25	10		131			
2024	38(+3)	18	8		141			
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- I work for a software / IT company focussed on terminology tools
- I'm a terminology / ontology expert
- I'm conducting research involving terminology / ontologies
- Other

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