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Krom YD[1,5], Hoek R[1], Houwen-van Opstal S[2,5], van de Velde NM[1,5], Ikelaar N[1,5], van der Holst M[3,5], Snijder RR[4], Niks EH[1,5]

[1]Department of Neurology, Leiden University Medical Center, Leiden, the Netherlands
[2]Department of Rehabilitation, Donders Centre of Neuroscience, Radboud University Nijmegen Medical Center, Nijmegen, the Netherlands
[3]Department of Orthopaedics, Rehabilitation and Physiotherapy, Leiden University Medical Centre, Leiden, the Netherlands
[4]Biobank Organization, Leiden University Medical Centre, Leiden, the Netherlands
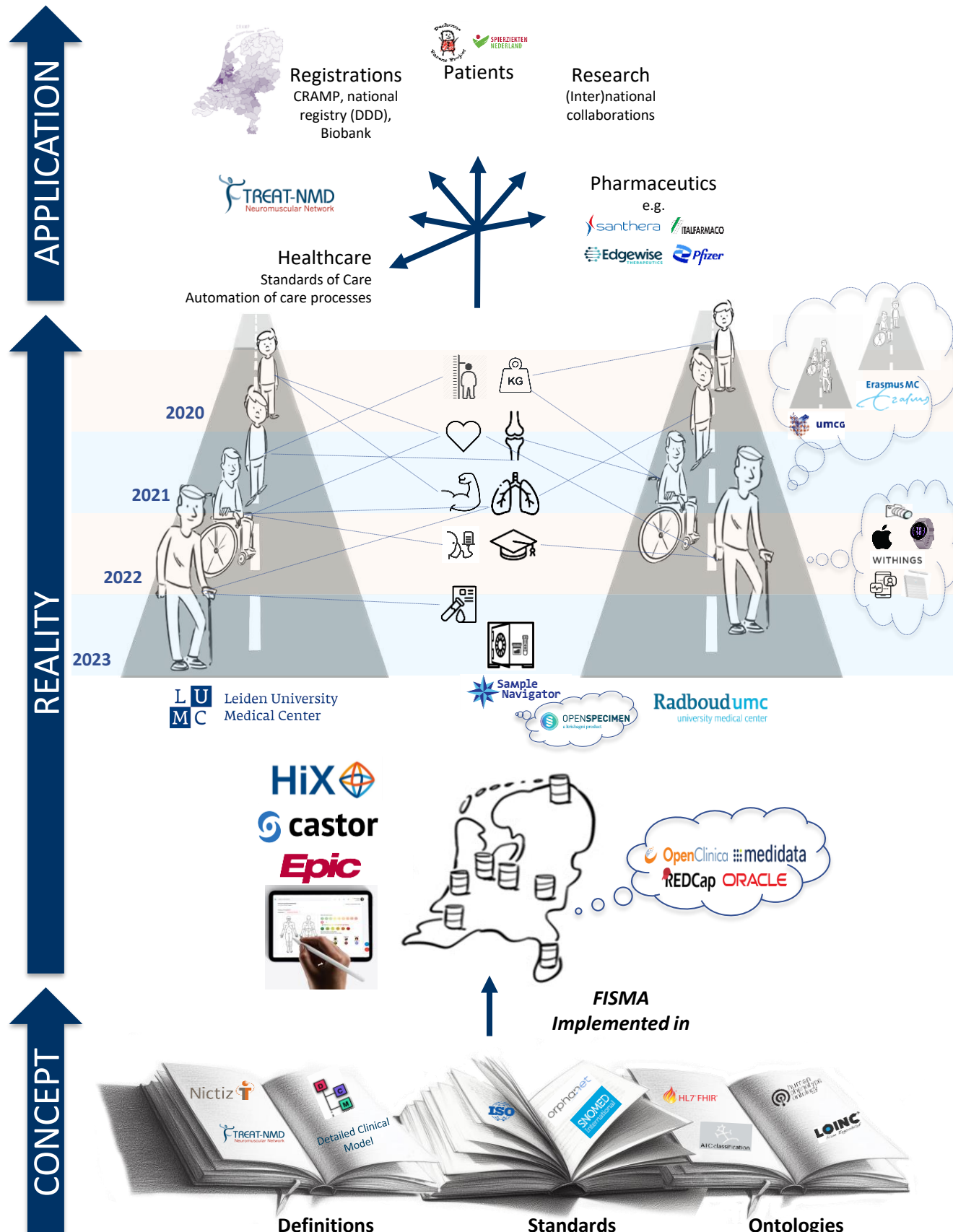[5]Duchenne Center Netherlands

# FISMA for high quality and interoperable real-world data on Dystrophinopathies
# FAIR from the start: From concept to reality

## CONCLUSION
Duchenne Center Netherlands has developed and adopted a conceptual framework, FISMA, that allows capturing real-world data as relevant, re-usable and semantically interoperable data. FISMA is drafted with expansion in mind: both within the field of dystrophinopathies (Duchenne and Becker muscular dystrophy), as beyond, to other neuromuscular diseases. Our national Biobank demonstrates that FISMA allows exchange and pooling of data between participating centers and has thus achieved IR from FAIR (Findability, Accessibility, Interoperability, and Reusability).



**APPLICATION**

Registrations
CRAMP, national registry (DDD), Biobank

Patients

Research
(Inter)national collaborations

Pharmaceutics
e.g. santhera, ITALFARMACO, Edgewise Therapeutics, Pfizer

Healthcare
Standards of Care
Automation of care processes

**REALITY**

2020
2021
2022
2023

WITHINGS

**CONCEPT**

FISMA Implemented in

Definitions    Standards    Ontologies

### READY for the future - the proof is in the pudding
FISMA was developed with many lessons learned in mind: it should be organic and robust enough to allow modification and expansion as clinical insights progressed. Already during the finalization of FISMA Duchenne/Becker 1.0, we modified and extended the framework to accommodate patient reported outcome measures (PROMS) without breaking existing implementations and minimal disruption of operations. Wearables, apps and even different neuromuscular diseases are on the table, or even in very early stages of development

### collection of REAL-WORLD DATA
Being system-independent, FISMA can be implemented in locally available source systems to capture data. FISMA thus allows the collection of *all* clinically relevant information, in *every* participating center, from *all* patients, in *every* stage of life - *fully* interoperable and exchangeable for a variety of purposes.

### FISMA: FAIR from the start
**F**ramework for **I**nformation **S**pecification, **M**odelling and **A**rchitecture has a multi-faceted approach with several underlying principles:
- Data-elements embedded in their clinical context (Real-World Data)
- Registered once (at the source) in a clinical setting (integration of research and healthcare)
- Unambiguously defined with internationally adopted ontologies, standards
- System-independent, allowing implementation in any data capture solution
- Data is reusable for multiple purposes
- Expandable without disrupting existing implementations.
- Expandable to other neuromuscular diseases