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Standardized Data Sharing in a Paediatric Oncology Research Network

– A Proof-of-Concept Study

Nina Hochedlinger

Michael NITZLNADER, Markus FALGENHAUER, Stefan WELTE, Dieter HAYN, Lefteris KOUMAKIS,
George POTAMIAS, Manolis TSIKNAKIS, Davide SARACENO, Eugenia RINALDI, Ruth
LADENSTEIN, Günter SCHREIER

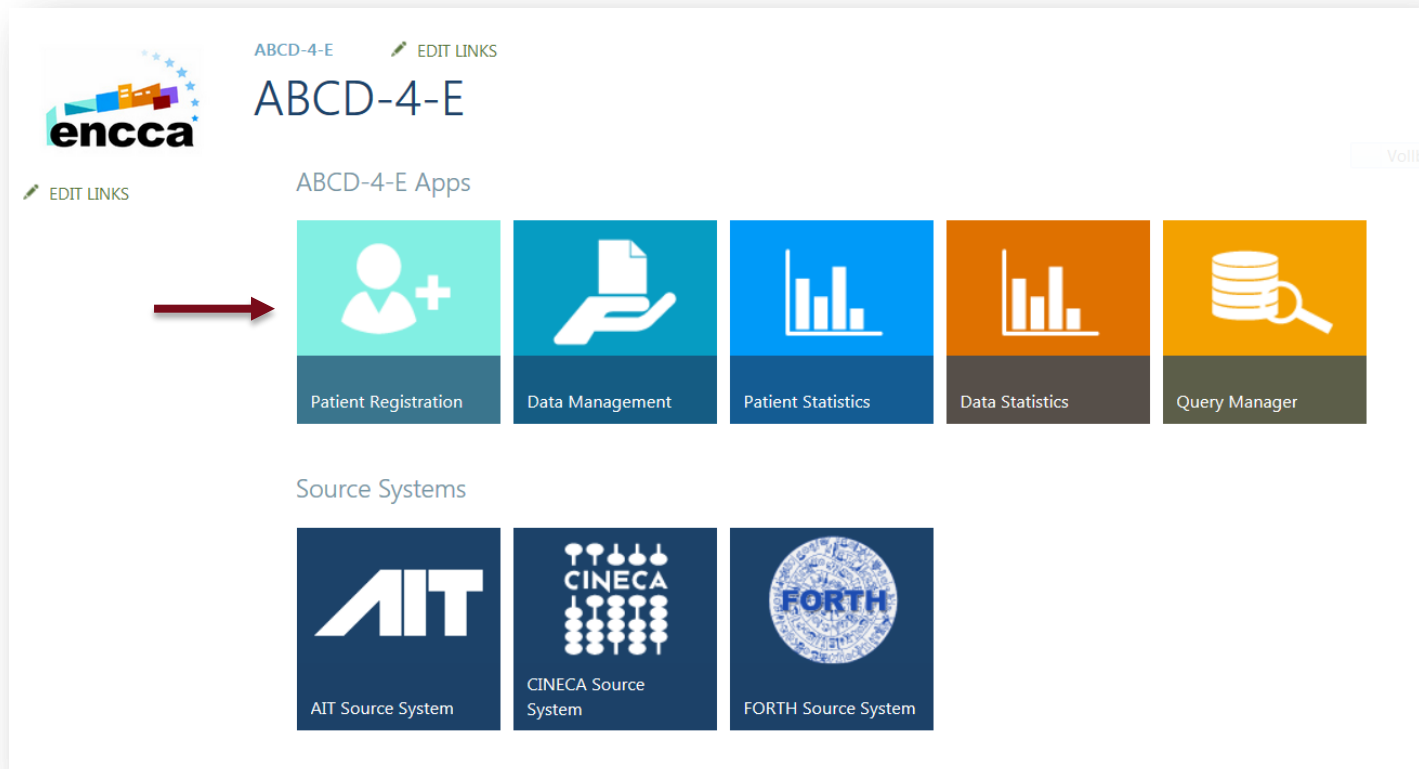
European Network for Cancer Research in Children and Adolescents

- Forschungsnetzwerk: 34 Partner aus 11 Länder
- Portal für Kollaboration:
Advanced Biomedical Collaboration Domain for ENCCA (ABCD-4-E)



ABCD-4-E

- Einheitliches Pseudonymisierungskonzept
ENCCA Unified Patient ID (EUPID)

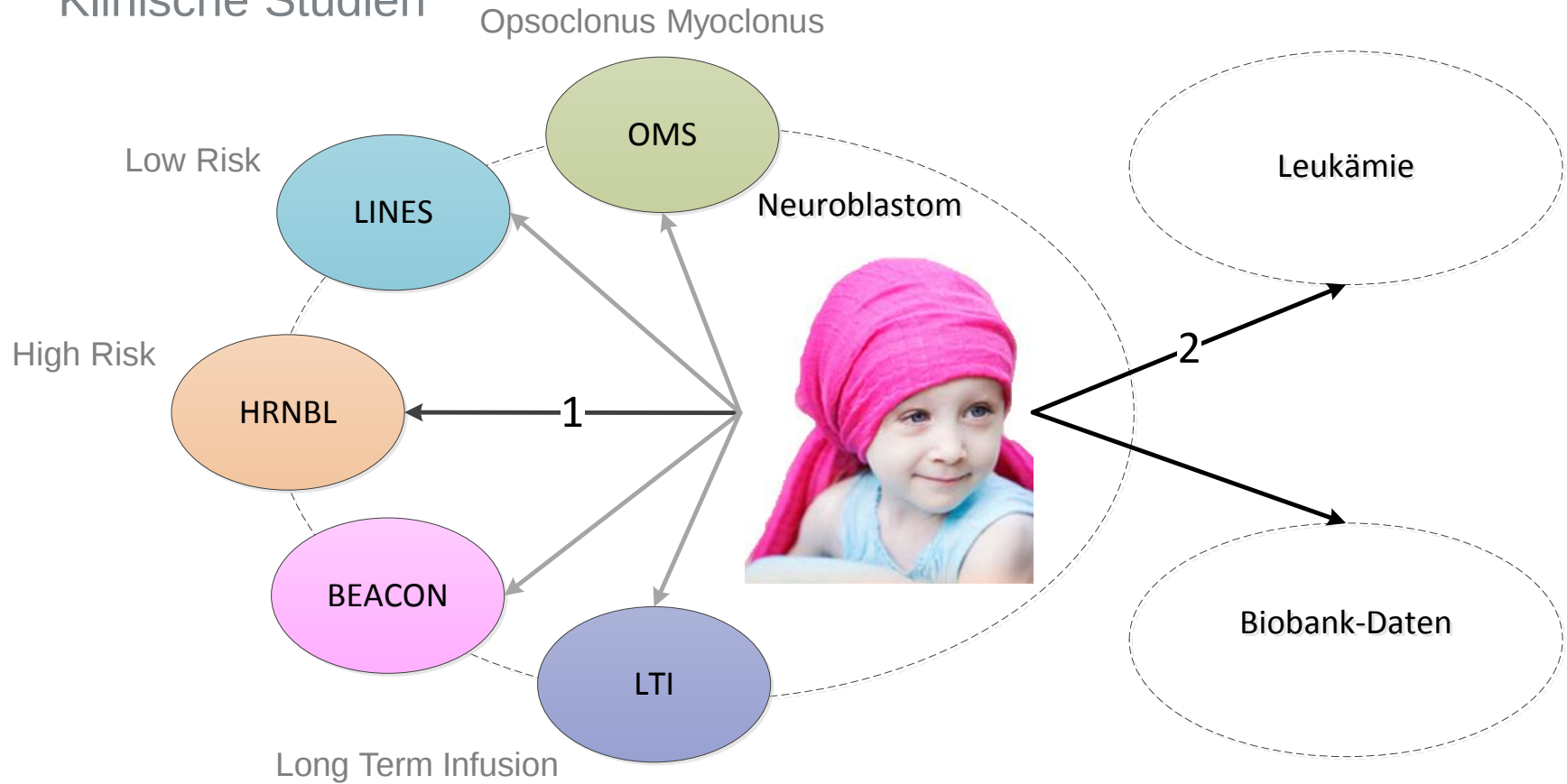


ABCD-4-E

- Data Management App
Verknüpfung von Daten aus unterschiedlichen Quellen



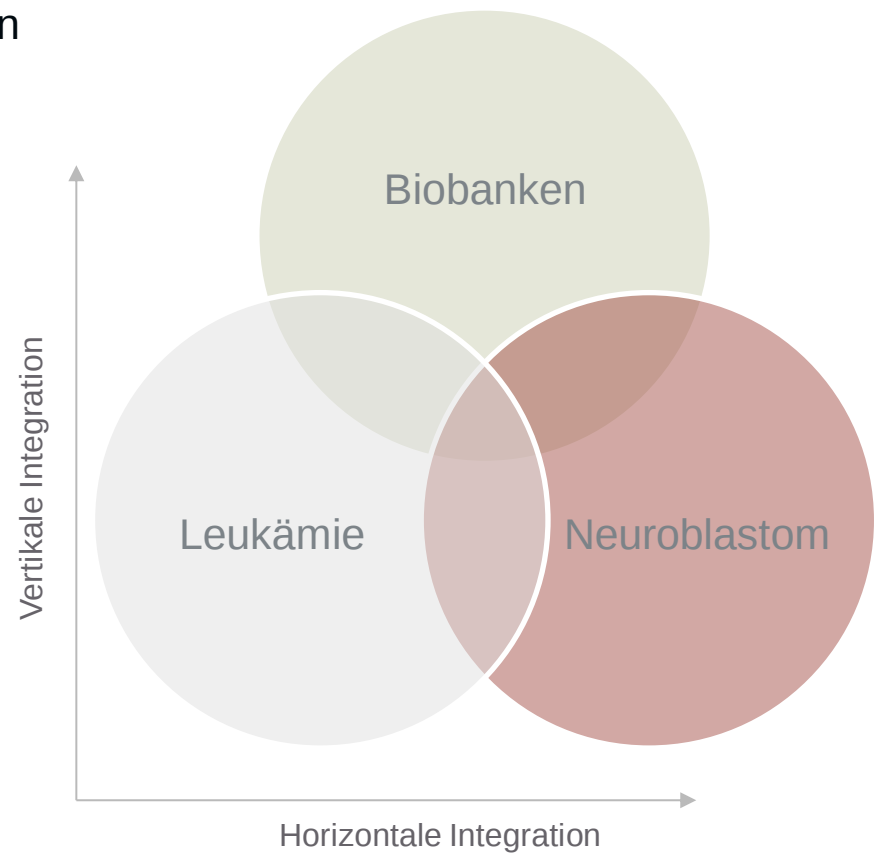
Klinische Studien



HRNBL ... High Risk Neuroblastoma Study

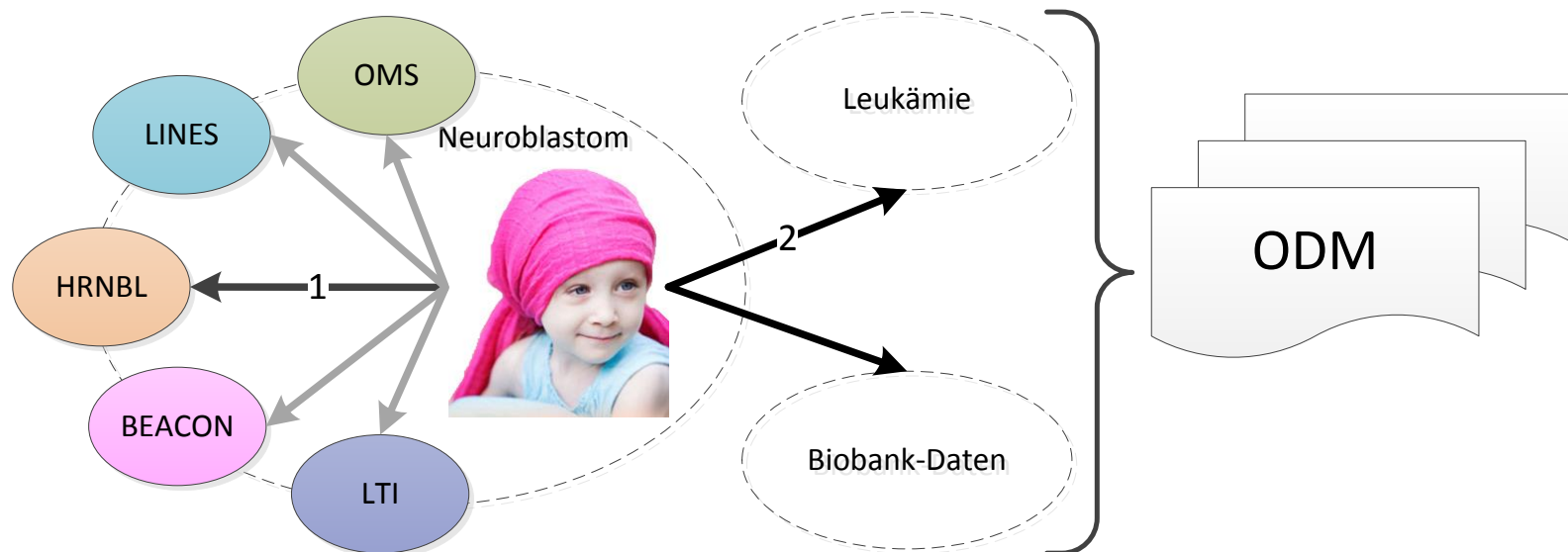
Horizontale und vertikale Integration

- Verknüpfung der klinischen Studiendaten
- Verknüpfung mit Daten aus Biobanken
- Secondary Use



Voraussetzung für horizontale und vertikale Integration

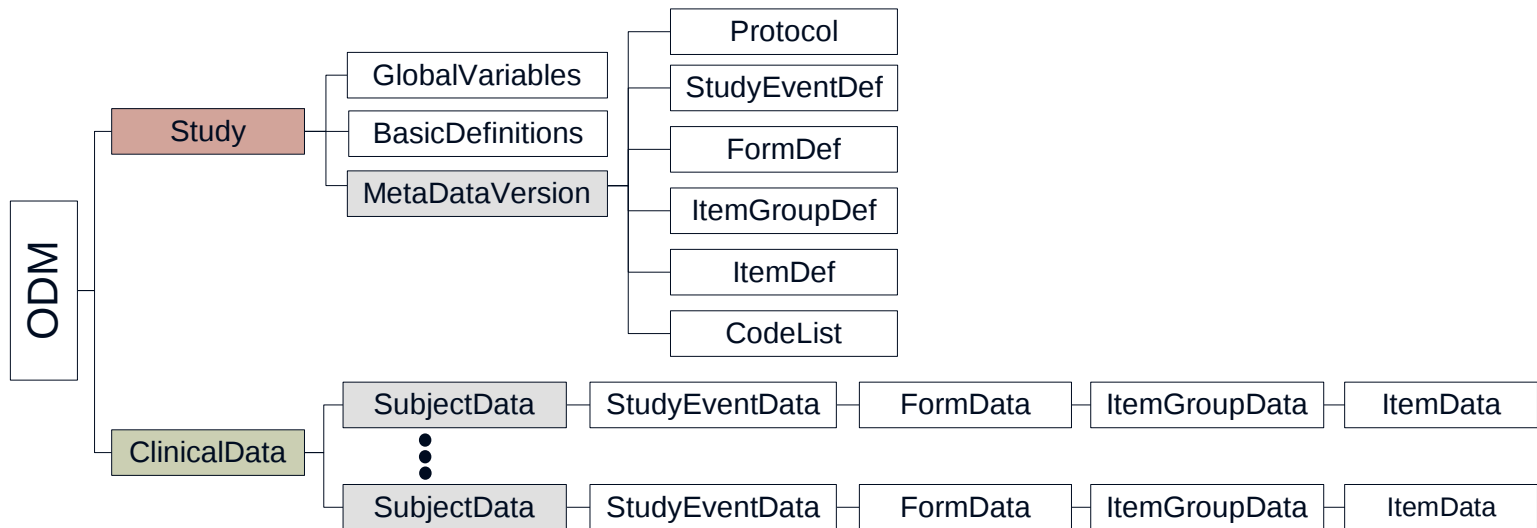
1. Einheitliche Struktur: Operational Data Model (ODM)





- CDISC – Clinical Data Interchange Standards Consortium
- Operational Data Model (ODM)
 - XML-basierter Datenstandard
 - Austausch
 - Archivierung
- Version 1.3.2
- www.cdisc.org

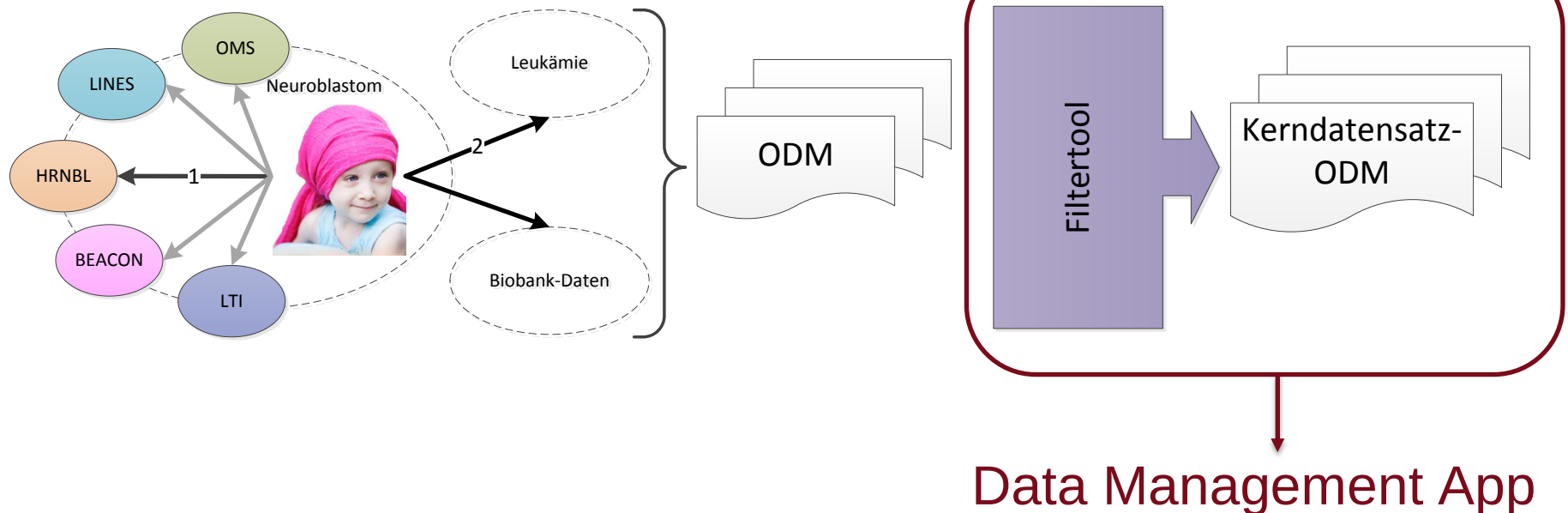
Operational Data Model (ODM)



- Study
 - Metadaten über Studie und Formulare
- ClinicalData
 - Studiendaten

horizontale und vertikale Integration

1. Einheitliche Struktur: Operational Data Model (ODM)
2. Einheitliche Semantik: ENCCA Kerndatensätze



Auszug aus ENCCA Kerndatensatz – Excel

Kerndatensatz für Klinische Studien

Item	Values	Description
Date of Birth		If date of birth cannot be provided in full, the next possible/available detail should be included
Sex at birth	1 = Male 2 = Female	
Initial Therapy	0 = None (observation) 1 = Surgery alone 2 = Conventionale-dose Chemotherapy plus surgery 3 = Intensive multi-modality therapy 4 = Intensive multi-modality therapy plus stem cell or bone marrow transplant 6 = other 9 = unknown	

Kerndatensatz Mapping – XML

Kerndatensatz Mapping-Datei für klinische Studien

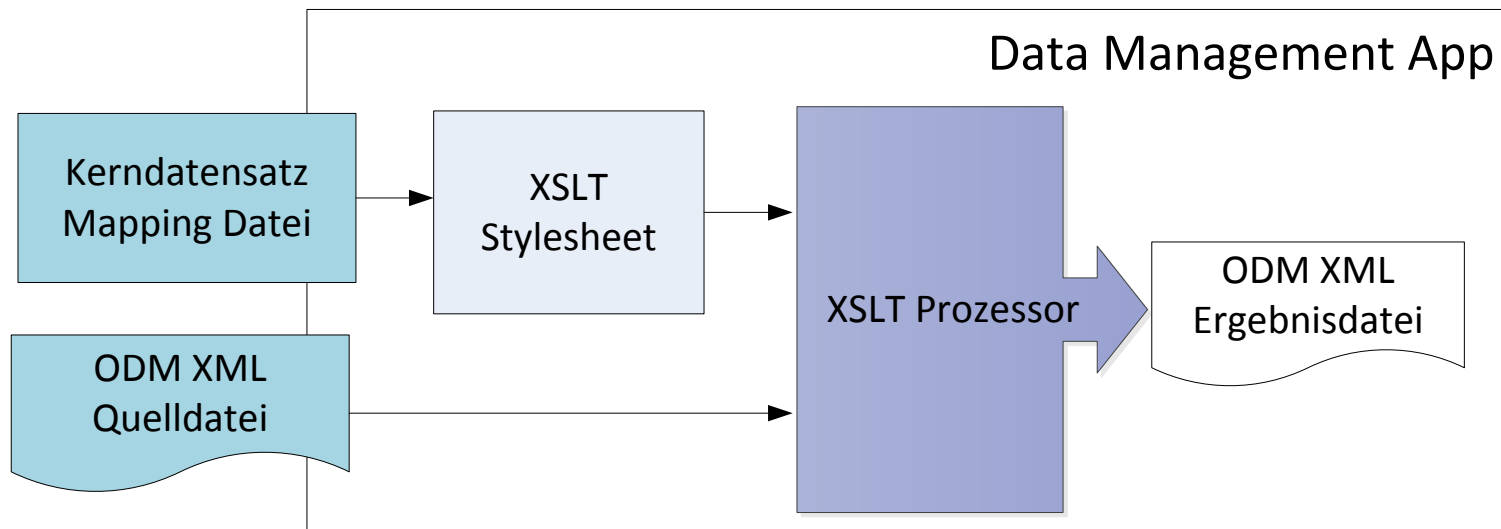
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    Item>
    <Item SourceItemID="sex" TargetItemID="Sex at birth" TargetFormat="integer">
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      Value>
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      Value>
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Quelldokument

Ergebnisdokument

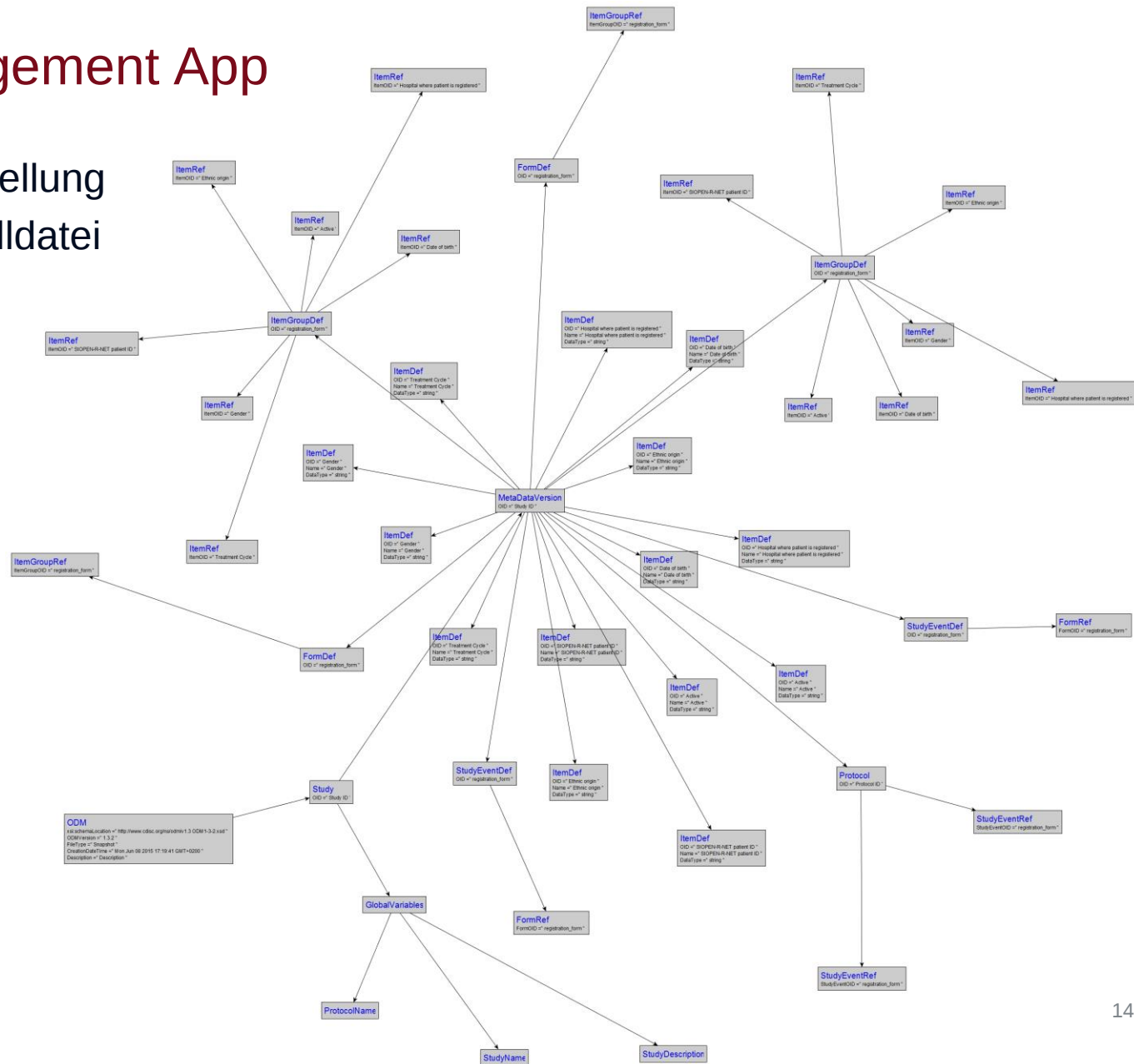
XSLT

- XSLT - Extensible Stylesheet Language Transformation
- Transformation von XML Dateien



Data Management App

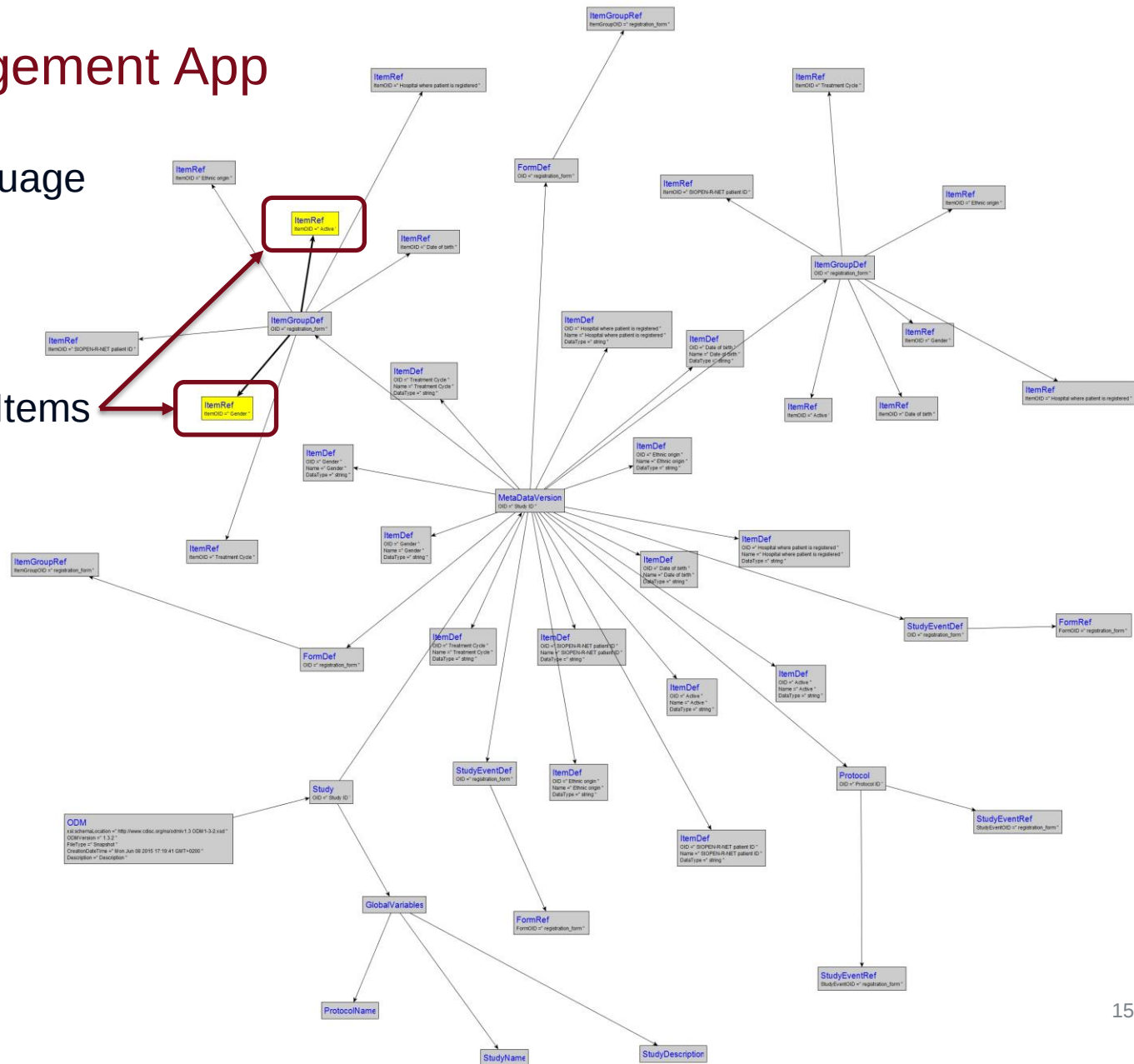
Grafische Darstellung ODM-XML-Quelldatei



Data Management App

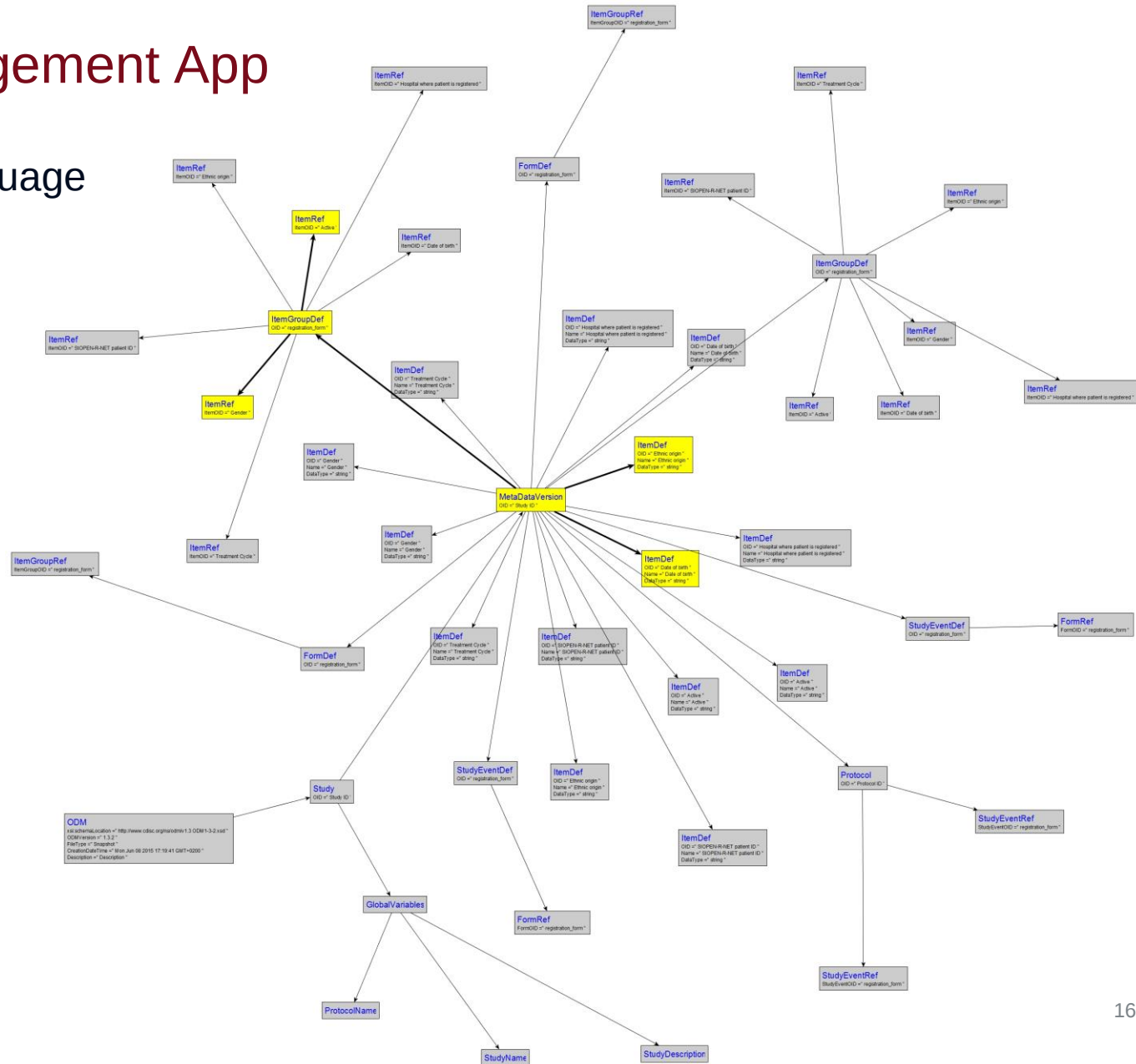
XML Path Language (XPATH)

Kerndatensatz-Items



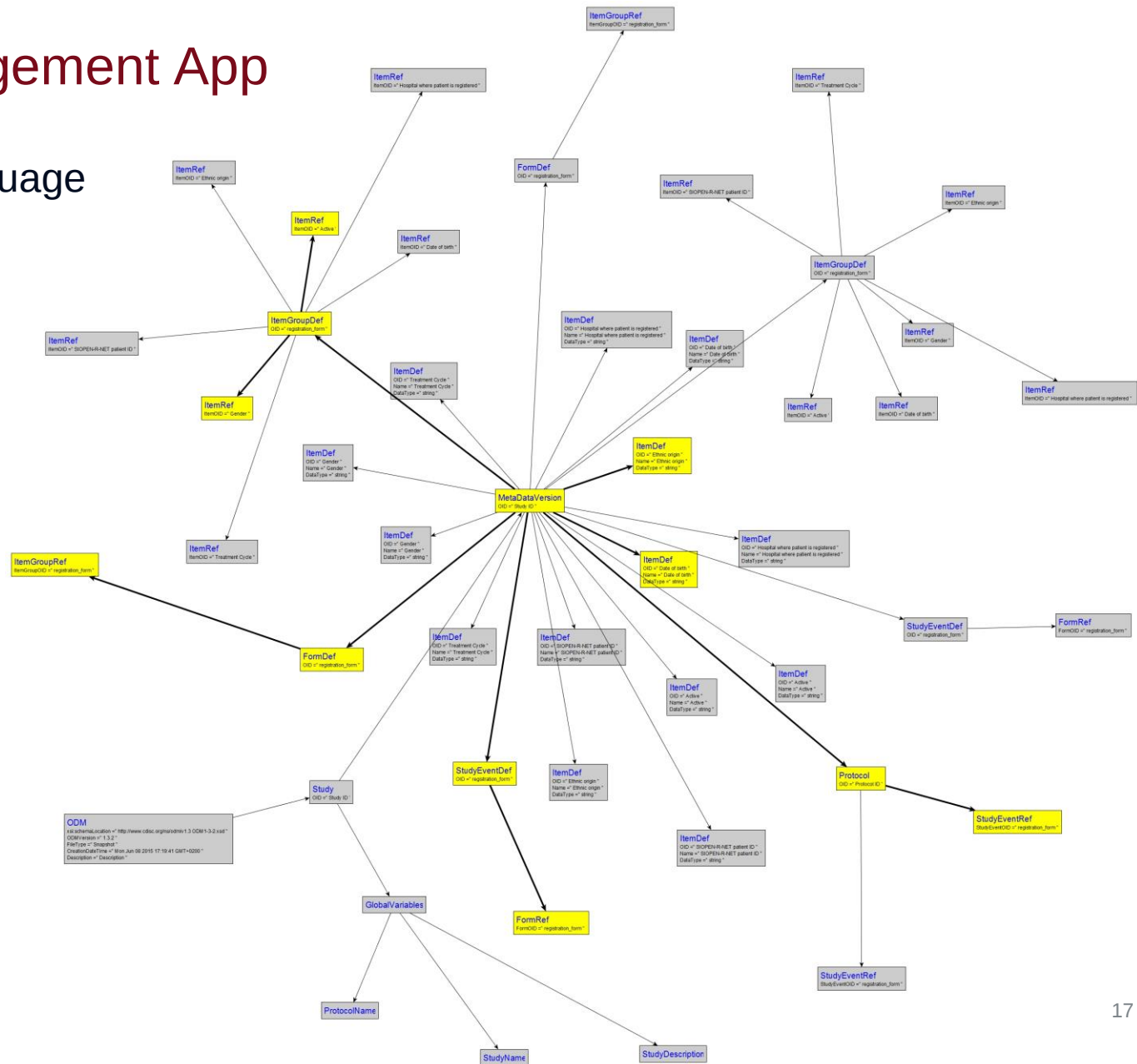
Data Management App

XML Path Language (XPATH)



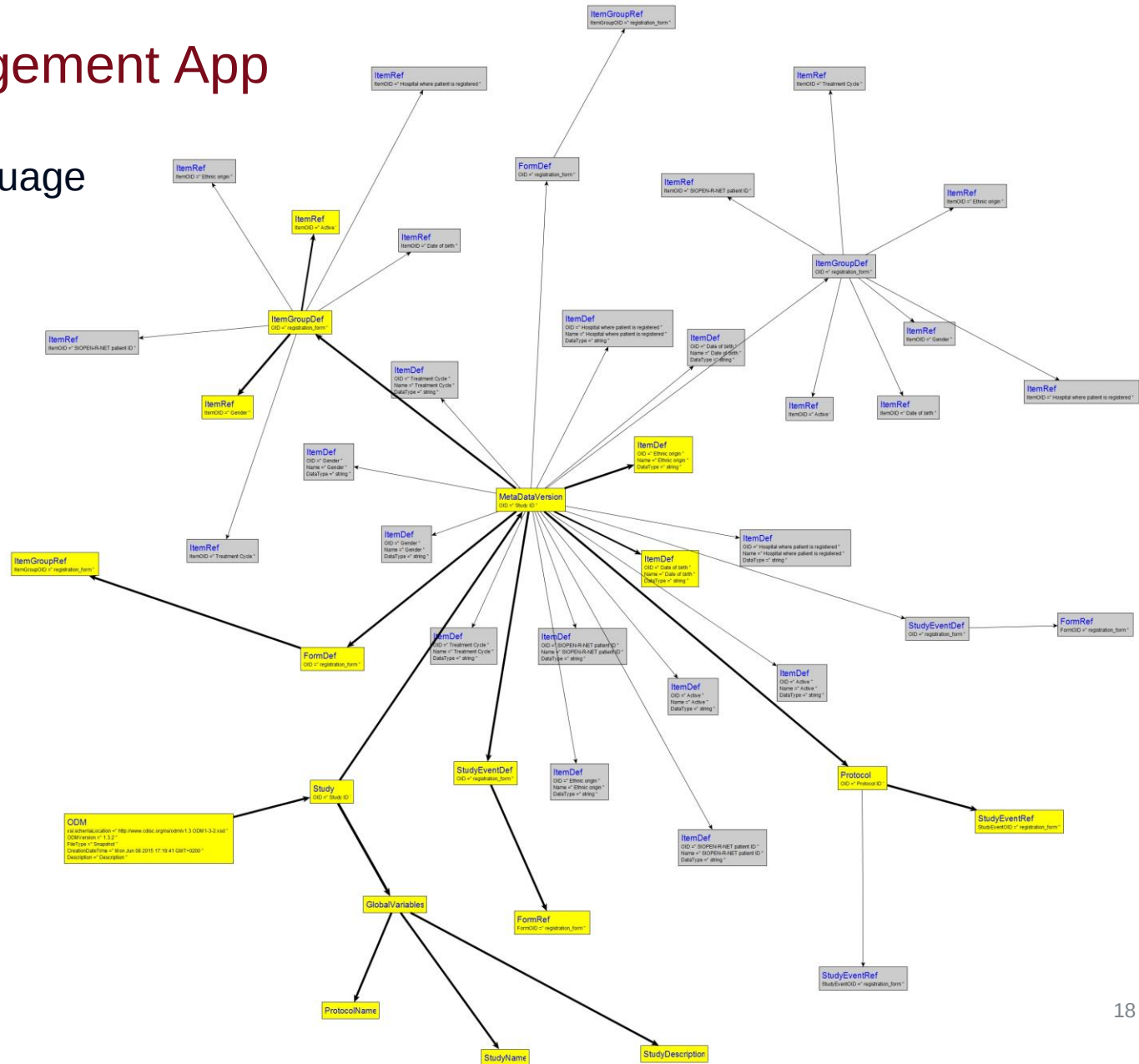
Data Management App

XML Path Language (XPATH)



Data Management App

XML Path Language (XPATH)



Data Management App

Transformation

Form

StudyEvent

ItemGroup

Item

Kerndaten-
satz

JA

Value-
Mapping

JA

Change

NEIN

Copy

SubjectData

Selected ☒

JA

Pseudonym

NEIN

Copy

JA

Change

Kerndaten-
satz

Warnings

Kerndatensatz-
Mapping-Datei

ODM-XML-
Quelldatei

Patientenliste

EUPID

NEIN

Pseudonym

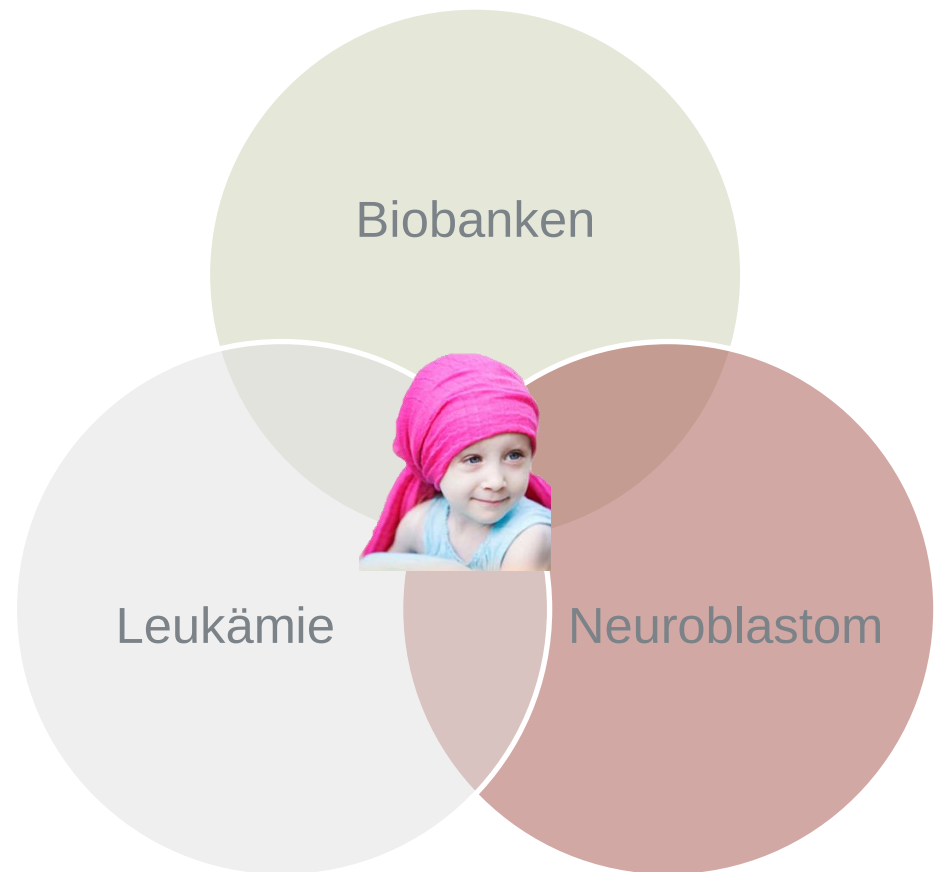
Showcase

- ENCCA General Assembly Meeting am 15.-16. Jänner 2015, Brüssel
- Data Management App Demonstration
- 3 ODM XML Quelldokumente + Kerndatensatz Mapping Datei

ENCCA IT Partner	origin of ODM-formatted source data sets	Type of Core Dataset
AIT	Neuroblastoma Clinical Trials Network	Clinical Trial
CINECA	Leukaemia Clinical Trials Network	Clinical Trial
FORTH	Biobank	Biosamples

Zusammenfassung

- Syntaktische Interoperabilität
- Semantische Interoperabilität
- Secondary Use
- Optimierung der Behandlung
- Verbesserte Lebensqualität



Vielen Dank

