

CREATING AND APPLYING KNOWLEDGE IN ELECTRONIC HEALTH RECORD SYSTEMS

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www.transformproject.eu

- €7.5M European Commission
- March 2010-May 2015
- Funded under the Patient Safety Work Program of FP7
 - To support clinical diagnosis
 - To support clinical trials
 - As part of a 'Rapid Learning Healthcare System'



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21 Partners from 10 EU Member States



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Aims of TRANSFoRm

- To develop methods, models, services, validated architectures and demonstrations to support THE LEARNING HEALTH SYSTEM:
 - Epidemiological research using primary care records, including genotype-phenotype studies and other record linkages
 - Research workflow embedded in the EHR
 - Decision support for diagnosis





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Use case 2: Gastro-oesophageal reflux disease (GORD)

- Research Question: What gives the best symptom relief and improvement in Quality of Life: continuous or on demand Proton Pump Inhibitor use?
- **Design:** Randomised Controlled Trial (RCT)
- Data: Collection through EHR & web based questionnaire – electronic case report forms AND mobile Patient Related Outcome Measures
- Provenance and security



Limitations of existing CDISC standards for clinical trials

- Operational Data Model operates as a holder and can contain a wide variety of content.
- Therefore clinical meaning and context can vary between clinical and research domains in unpredictable ways.
- CDASH offers a means of assembling libraries of welldefined forms, but does not implicitly translate to a clinical setting



Approach to Meaning

- TRANSFoRm uses common data models expressed as ONTOLOGIES to maintain meaning across the Learning Health System
- Archetypes are used to link 'meaning' as a reference to the ontologies (Research and clinical meaning) at individual data element level



Approach to Heterogeneity

- Source/Target data structures are mapped locally to the common models
- Terminologies are mapped using a common reference the Unified Medical Language System (UMLS)
- Systems are communicated with using a DATA NODE CONNECTOR locally



Standards used by TRANSFoRm

- UMLS
- CDISC SDM, ODM
- Reference Terminologies
- Ontologies RDF
- Archetypes and Archetype Definition Language

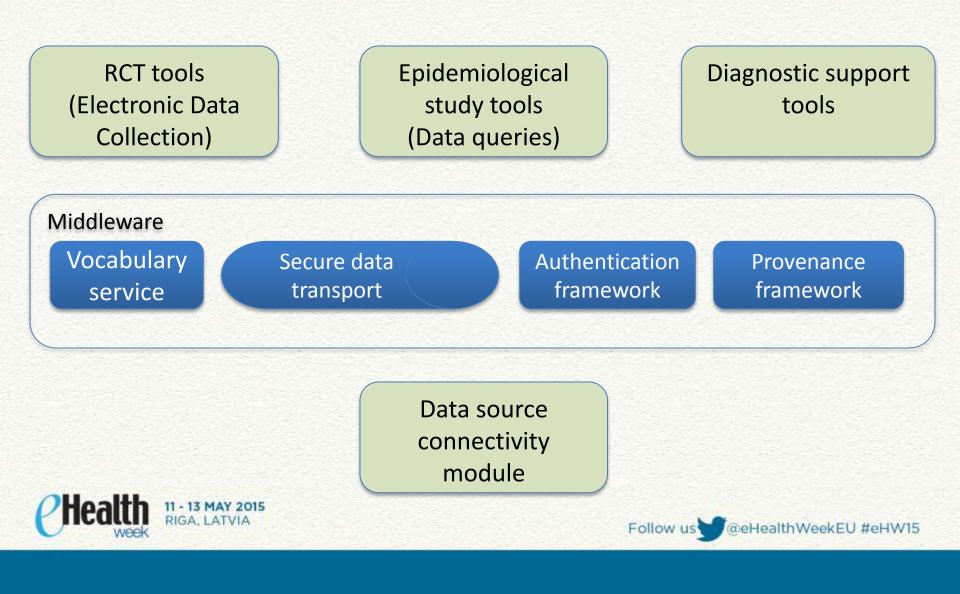


A software platform for the Learning Health System is built using tools to author, exchange and act upon these basic information constructs. It serves all three use cases.



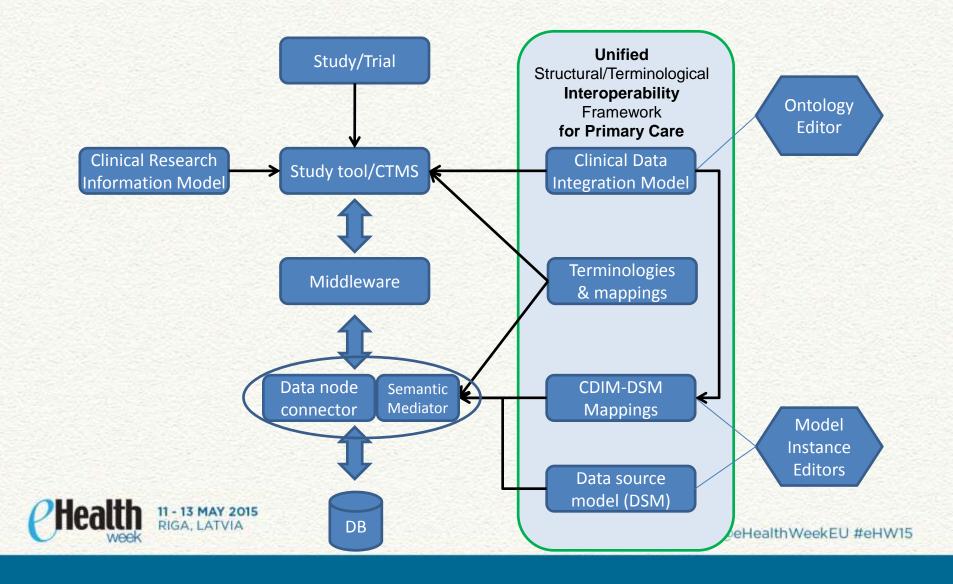


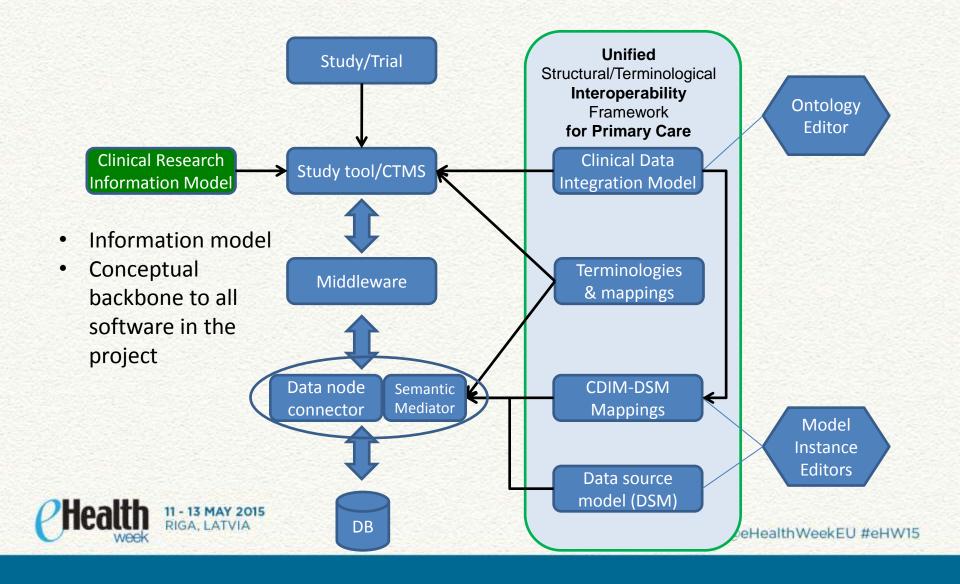
TRANSFoRm software highlevel overview

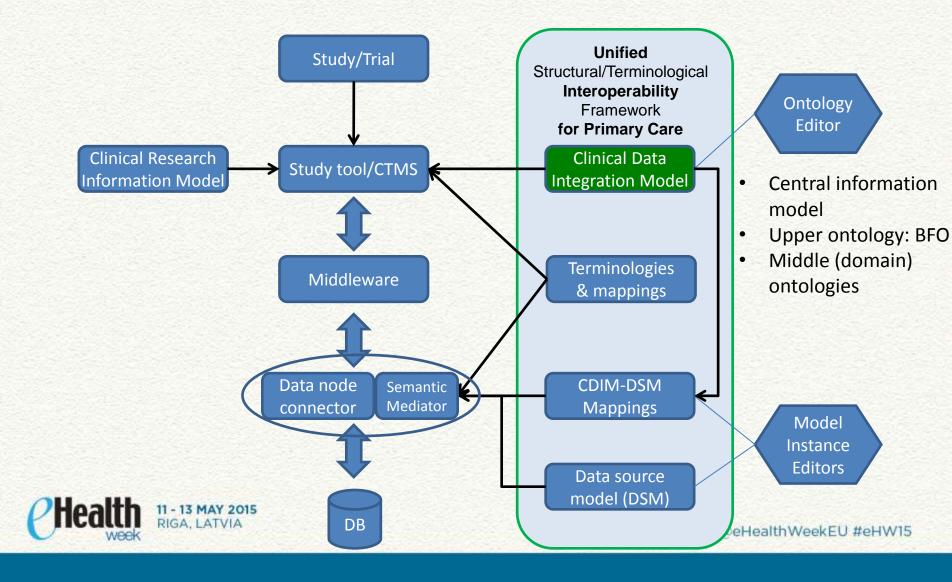


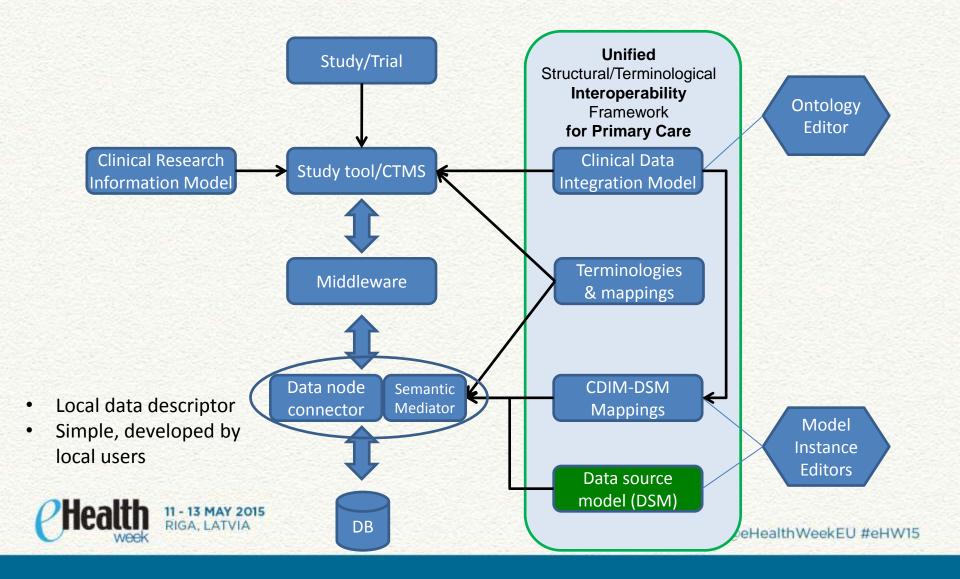
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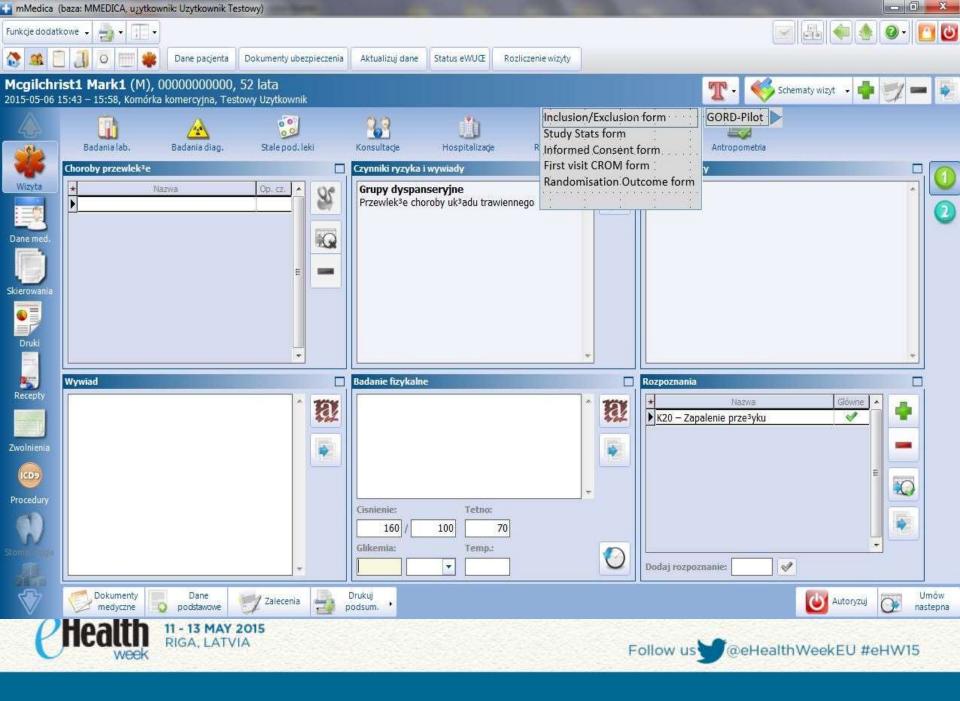


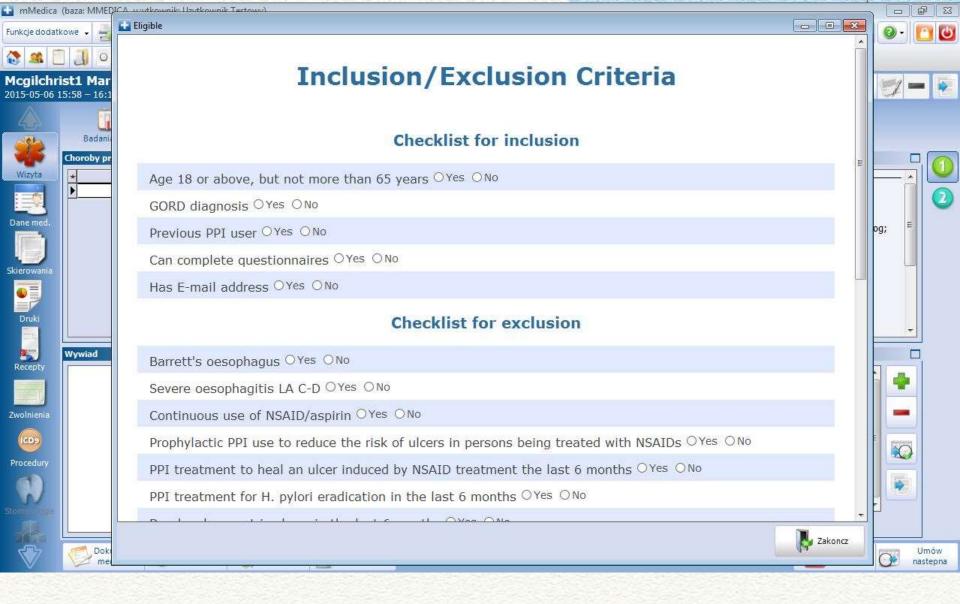
Four points of eCRF/EHR integration

- Extracting study data from the EHR to facilitate data entry
- Asking physician to complete the study data that are not present in the eHR
- Presenting all study data to the physician for approval before sending to the research databasein order to increase control and data quality
- Adding care-relevant study data to the EHR, so that the physician needs to fill out the information only once









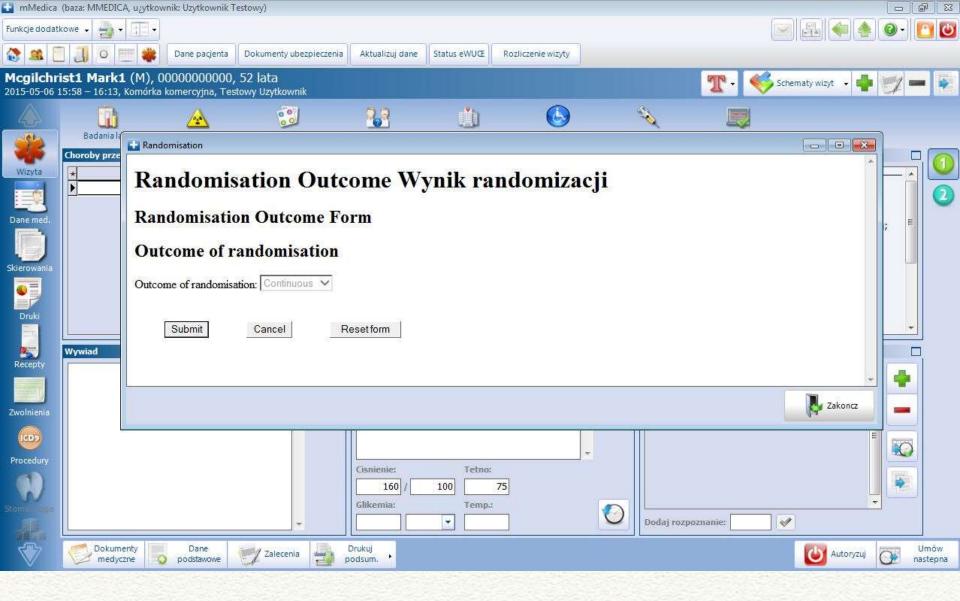


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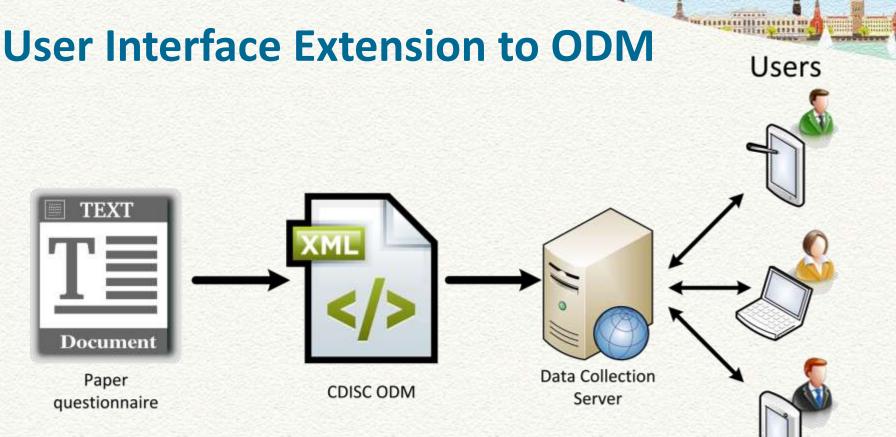


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- ODM extended with GUI elements
- When an ODM is created, the QuestionType attribute is added to every ItemDef object in ODM
- Platform-agnostic, rendered appropriately for each device



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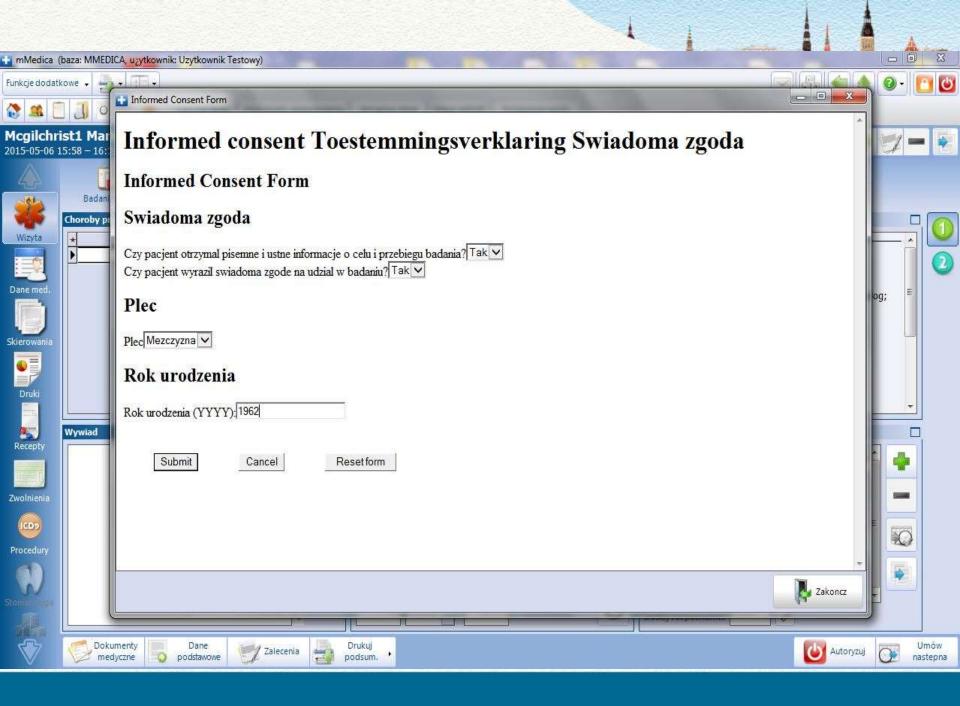
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