The Single Source Architecture x4T
(Exchange 4 Trials) to Connect Medical Documentation and Clinical Research

Philipp Dziuballe | Oral presentation at MIE Oslo, 30/08/2011
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Jens Lechtenbörger, Gottfried Vossen, Martin Dugas
Introduction

- Huge documentation efforts for clinical research
- Captured twice in two separated systems:
  - Routine medical data => EHR (Electronic Health Record)
  - Study documentation => CRF (Case Report Form) into EDC (Electronic Data Capture) system
- Time wasting & error-prone
- Physicians daily documentation time: ~ 25% - 33%\(^1,2\) a day
- 10% - 70%\(^3,4\) of EHR data is eligible for re-use in clinical research

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\(^1\)Ammenwerth E, Spötl HP. Methods Inf Med. 2009.
\(^3\)El Fadly A et. al. Stud Health Technol Inform. 2010.
Objective

- Development of an architecture that
  - allows the connection of EHR and EDC systems
  - uses available standards
  - fits into existing system landscape
  - re-uses medical routine documentation data for clinical research
Methods / Material

- **Analysis**
  - System landscape at University Hospital Münster
  - Amount of eligible EHR data for pre-filling in CRFs
  - SNOMED CT & NCI Thesaurus (mapping purposes)
  - CDISC ODM (Operational Data Model)
  - IHE RFD (Retrieve Form for Data Capture)

- **Development**
  - Apache Tomcat
  - Java Web Services
  - MySQL
  - eXist-DB with XRX (XForms-REST-XQuery)
Results - Analysis

- **EHR in Münster: ORBIS\(^1\) capabilities:**
  - Form implementation
  - Report generation
  - Proprietary formats
  - No semantic layer for standardised data access

- **CRF and EHR analyses**
  - 596 CRF items analysed in EHR
  - Amount of identified data: 47%

\(^1\)ORBIS from Agfa HealthCare
Results: x4T - Architecture

EHR system

Study docu form

UKM - Study Documentation

EHR DB

Web browser

Form engine/storage

eXist

Clinical Interface

ODM

Data Management

Mapping DB

Hospital

EDC

PDF

Single Source Architecture: x4T | MIE2011 Oslo | Philipp Dziuballe
UKM - Study Documentation

Please select a study from list and enter a valid pseudonym.

Study selection: Prias  Registered at: 18.07.2011
Pseudonym: x4t-pas  Excluded at: 
Comment: 

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<thead>
<tr>
<th>Form</th>
<th>Status</th>
<th>Documentation</th>
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</thead>
<tbody>
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<td>Call form</td>
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<tr>
<td>Adverse Events</td>
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<td>Vital Signs</td>
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<tr>
<td>Physical Exam</td>
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<td>Call form</td>
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**Results: Pre-filling process**

**ODM Study**

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<tr>
<th>Clinical data request</th>
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<tbody>
<tr>
<td>CS_Code</td>
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**Clinical Interface**

- **Lookup:** SQL-Queries
- **Mapping DB**

**EHR environment**
## Pre-filled x4T web-form

### PSA at diagnosis
- **ng/mL**: 2.30

### Prostatic volume (TRUS)
- **cc**
  - 2.00 (10th January, 2011, 14:28:32, Form: Prostatahistologie MS)
  - 2.00 (18th February, 2011, 12:23:55, Form: Prostatahistologie MS)
  - 2.30 (3rd March, 2011, 14:41:19, Form: Prostatahistologie MS)

### Method of detection
- - screen detection
- - clinically
- - uncertainly

### Comments

### Charlson score
Discussion

- **Advantages:**
  - Link between EHR and EDC
  - Pre-filling of CRFs items with EHR data values
  - Avoiding double data capture

- **System requirements**
  - EHR Study documentation form + DB extension
  - x4T server
  - Semantic annotation of EHR and CRF items with controlled terminologies
  - Connection to EDC

- **Further research:**
  - Evaluation of the prototype in ongoing studies
  - Terminology server (for cross-mapping and version control)
Thank you for your attention!

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