



UniversityHospital Heidelberg

Facilitating Secondary Use of Medical Data by Using *openEHR* Archetypes

Christian Kohl^{1,3}, Sebastian Garde², Petra Knaup³

Coordination Center for Clinical Trials Heidelberg, Germany
Ocean Informatics Germany
Institute for Medical Biometry und Informatics



Introduction

Methods

Results

Discussion

Summary

Introduction

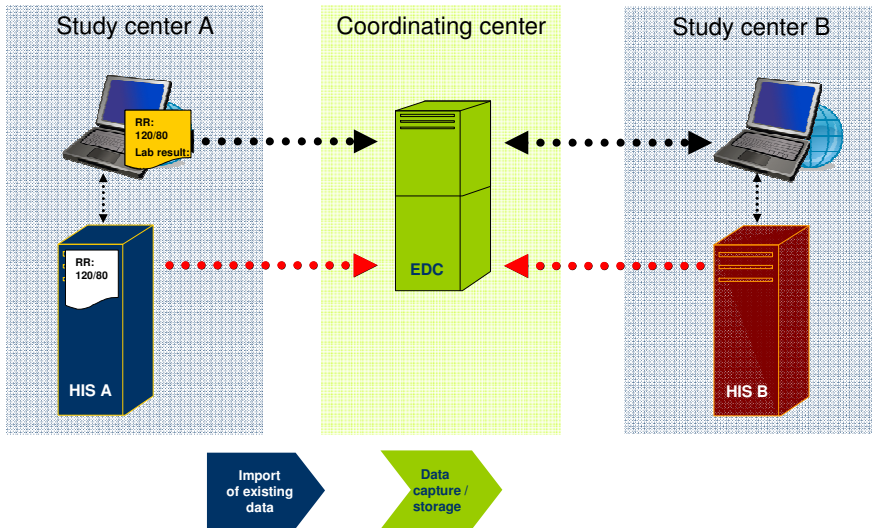
- Clinical trials are of high importance for medical research and progress.

Problem:

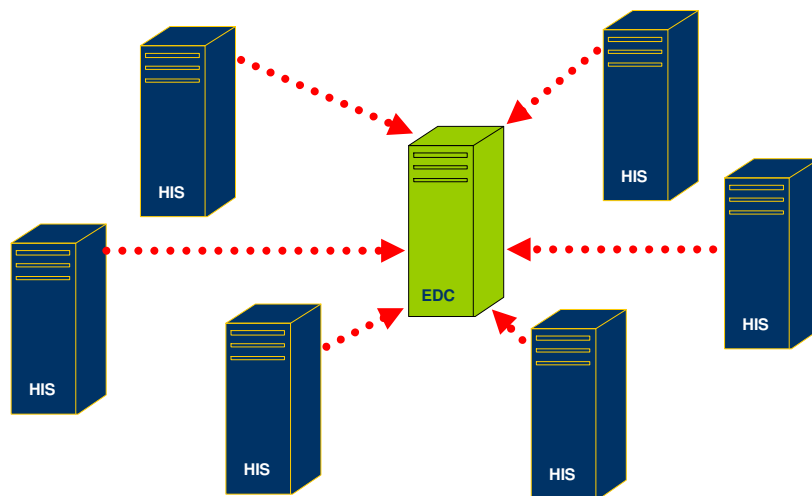
- Data collection in trials is a time consuming and expensive task.

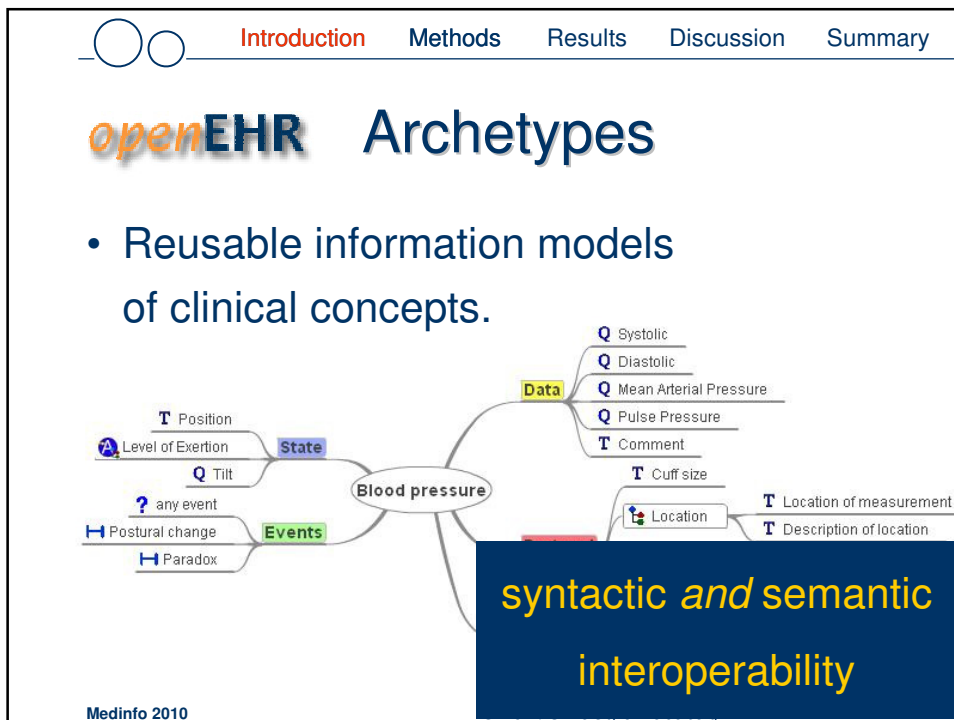
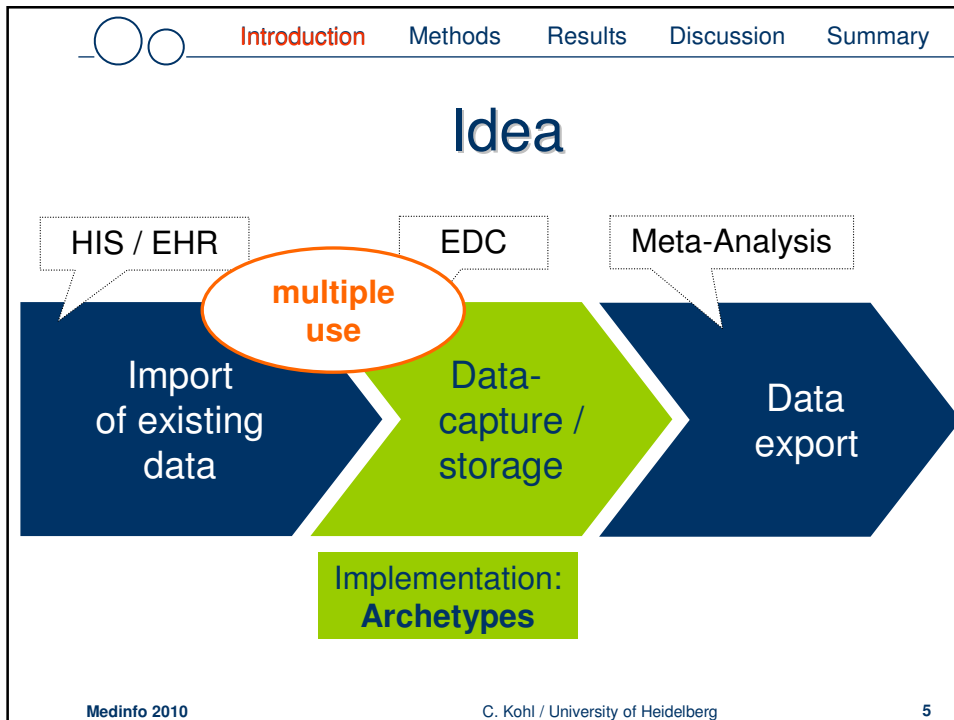


Problem



Problem: Multicenter Trials





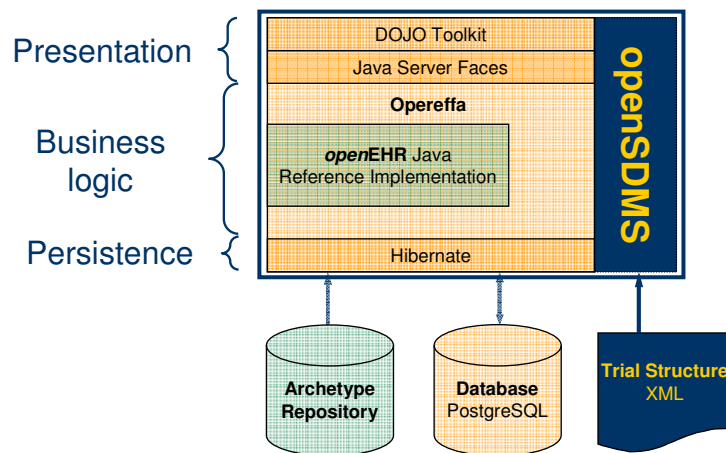


Goals

- ...to explore how a system for recording data in clinical trials can be built based on the *openEHR* approach.
- ...to facilitate reuse of existing medical data for clinical trials.



System Design





„Trial Data“

Trial

Meta-Data

- research question
- inclusion / exclusion criteria

Patient-Data

- sex
- age
- blood pressure ...

**EHR
archetypes**



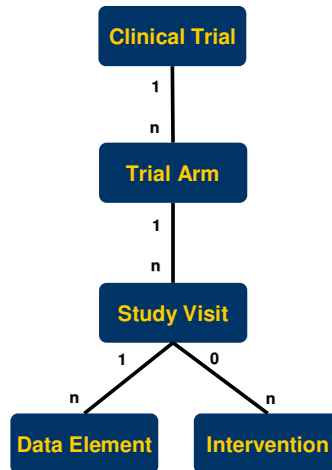
Archetypes: Study Meta Data

- 15 Archetypes
 - 3 COMPOSITIONS
 - 12 ADMIN_ENTRY
- which contain over 50 data items

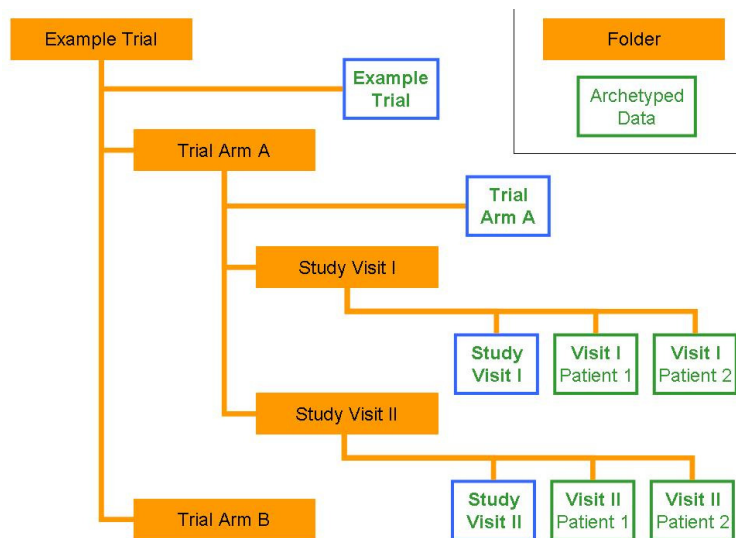
- openEHR-EHR-COMPOSITION.trial_visit.v1
- openEHR-EHR-COMPOSITION.trial_arm.v1
- openEHR-EHR-COMPOSITION.clinical_trial.v1
- openEHR-EHR-ADMIN_ENTRY.trial_visit_description.v1
- openEHR-EHR-ADMIN_ENTRY.trial_arm_description.v1
- openEHR-EHR-ADMIN_ENTRY.study_type.v1
- openEHR-EHR-ADMIN_ENTRY.study_state.v1
- openEHR-EHR-ADMIN_ENTRY.study_sponsor.v1
- openEHR-EHR-ADMIN_ENTRY.study_length.v1
- openEHR-EHR-ADMIN_ENTRY.study_identification.v1
- openEHR-EHR-ADMIN_ENTRY.study_ethics_committee_vote.v1
- openEHR-EHR-ADMIN_ENTRY.study_design.v1
- openEHR-EHR-ADMIN_ENTRY.study_content.v1
- openEHR-EHR-ADMIN_ENTRY.study_contact_data.v1
- openEHR-EHR-ADMIN_ENTRY.study_center.v1



Generic Trial Structure



Generic Trial Structure



Introduction Methods **Results** Discussion Summary

Mozilla Firefox / MI: Promotion - Vorbereitung Vortrag: 00:21:35 (Heute: 00:57:14) / Anwesenheit: 01:22:58

http://localhost:8080/Opereffa/pages/MainContainer.jsf#

UniversitätsKlinikum Heidelberg

Current Patient (Simpson, Homer - 1970-01-01)
Current Trial ()

openEHR

Observations

Clerking
Blood Pressure

Blood Pressure

Systolic:
Diastolic:
Comment:
Save

Edit

Systolic:
Diastolic:
Comment: 120/85

Instructions
Evaluations

Trial View

open Study Data Management System

http://localhost:8080/Opereffa/pages/MainContainer.jsf#

Introduction Methods **Results** Discussion Summary

Mozilla Firefox / MI: Promotion - Vorbereitung Vortrag: 00:28:12 (Heute: 01:03:51) / Anwesenheit: 01:29:35

http://localhost:8080/Opereffa/pages/MainContainer.jsf#

UniversitätsKlinikum Heidelberg

Current Patient (Simpson, Homer - 1970-01-01)
Current Trial (TEST : Interventionsgruppe)

openEHR

Visite 1
Visite 2

Clerking
Blood Pressure

Blood Pressure

Systolic:
Diastolic:
Comment:
Save

Use Data

Systolic:
Diastolic:
Comment: 110 / 90

EHR View

open Study Data Management System

Fertig

Introduction Methods **Results** Discussion Summary

Mozilla Firefox / MI: Promotion - Vorbereitung Vortrag: 00:38:03 (Heute: 01:05:42) / Anwesenheit: 01:31:26

http://localhost:8080/Opereffa/pages/MainContainer.jsf#

UniversitätsKlinikum Heidelberg

Current Patient (--- Edit Trial ---)
Current Trial (TEST) Help

Study Meta-Data

Study Meta-Data

Interventionsgruppe
Kontrollgruppe

Show patients

openEHR

Edit

Clinical Trial:
Study meta data
Trial ID :

Title of the study:
Test-Studie

Title abbreviation:
TEST

open Study Data Management System

Fertig

Introduction Methods Results **Discussion** Summary

Discussion

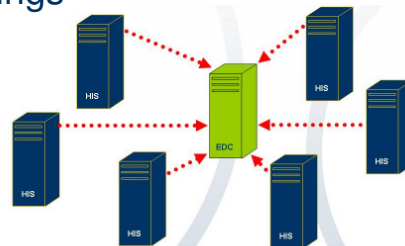
- *openEHR* / *Opereffa* proved as a good starting point.
- *openSDMS* is still a prototype
 - importing mechanisms for existing data
 - CDSIC / ODM-Export

Medinfo 2010 C. Kohl / University of Heidelberg 16

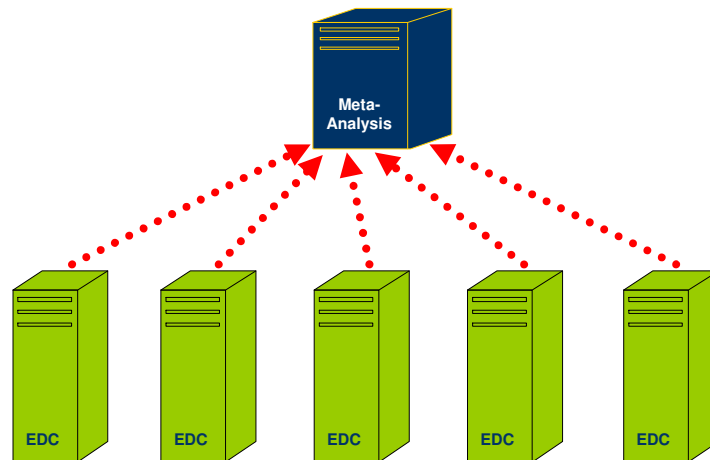


Conclusion and Perspective

- Benefits of using archetypes in EDC systems for clinical trials...
 - ...integration of existing data sets
 - ...multiple use of mappings
 - ...meta analysis.



Conclusion and Perspective





Thank you...

...Dr. Ian McNicoll

...Dr. Heather Leslie

...Seref Arikan



Heidelberg, Germany