Translational Research & Health Informatics

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Translational Research

- From bench to bedside
  - Laboratory outcome to clinical sites
  - Clinical findings to basic research

- CBMS evaluation in controlled clinical trials
Translational Research

- From bench to bedside:
  - Laboratory outcome to clinical sites
  - Clinical findings to basic research
- CBMS evaluation in controlled clinical trials

- Employees: 5,658 total, 900 physicians
- Patients: 44,768 stationary, 225,727 temporary
- Subjects: 9,482 enrolled, 2,526 PID generated
- Users: 921 total, 194 active
- Departments: 33 clinics, 25 research
- Trials: 1,358 monitored, 340 recruiting, 279 pre-clinical
Health Informatics

- System interconnection
  - Protocols & standards
  - Data interfaces
Systems in Clinical Research: CTMS

- Clinical trial management system
  - Actors
    - Sponsor, ethics, authorities, sites, investigators
  - Documents
    - Investigator’s brochure, study protocol, SOPs
  - Status
    - Stages, tracking, dashboards
  - Finances
    - Efforts, costs, billing
  - Reports
    - Adverse events (AE)
    - Serious adverse events (SAE)
Systems in Clinical Research: CTMS

Example

Effort Chart (CTC-A Study Management Tool)
Systems in Clinical Research: EDCS

- Electronic data capture system
  - Prospective trials
  - Retrospective registries & hybrids

- Electronic case report form (eCRF)
  - OpenClinica, REDCap, SecuTrial, BioClinica, …

**Example**
- Image integration
- Image analysis
- Measurement entry
Systems in Clinical Research: EDCS

- Example
  - Annotations

![Image of a clinical research form and a computer interface showing body regions for data entry.]

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Data Management & Services

- **Subjects**
  - De-identification
    - TMF (networked medical research in Germany)
  - Randomization
    - R-Project

- **Objects (measurements)**
  - Non-DICOM
    - Google Web Toolkit (GWT)
    - Sencha Ext GWT
  - DICOM
    - DCM4CHEE
    - Weasis
Data Management & Services

Example

➤ Workflow (state-of-the-art)

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System Integration

- **CTMS & EDCS**
  - SMT – Study Management Tool
  - OC – OpenClinica

- **EDCS & PACS**
  - OC Big
  - OC Dat

- **EDCS & mobility**
  - OC ToGo
  - OC Tab

Diagram:

- User
- Single Sign On
- Proprietary System Interfaces
- Google Web Toolkit
- Standard Query Language
- Web Service

CTMS & EDCS
- TMF PID
- C++
- SQL
- WS

OpenClinica
- Application Server
- Randomizor
- JRI
- SQL

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System Integration: CTMS & EDCS

Integration levels

- Data
- Function
- Presentation (Visual)
- Context

Web services

- ListAll (Study)
- GetMetaData (Study)
- Create (Study)
- AddUser (Study)
- Create (Site)
- Create (User)
- ListAll (User)
- ListAll (Patients)
System Integration: CTMS & EDCS
System Integration: EDCS & PACS

- General options
  - EDCS only vs. EDCS / PACS combination
  - EDCS vs. PACS is master system
  - Web-based vs. local viewer

Diagram:
- DICOM
- Bitmap Data
- Research PACS
- Standalone Viewer
- EDCS eCRF
- Web Viewer
- Patient
- Research Nurse
- Physician
Our suggestion

- EDCS / PACS combination
- EDCS is master system
- Web-based viewer
System Integration: EDCS & PACS

- **EDCS**
  - OpenClinica
  - OC-Big

- **PACS**
  - DCM4CHE

- **Viewer:**
  - WEASIS (Perennity, USA)
  - JiveX (Visus, Germany)

Data flows between the Patient, Nurse, Researcher, Physician, and the OpenClinica OC-Big, DCM4CHE, and Weasis components.
System Integration: EDCS & PACS
System Integration: EDCS & Mobility

Diagram:
- **OpenClinica** (Import) -> **OpenClinica (Incl. OpenClinica ext.)** (Export) -> **Converter** (Import)
- **Copy** -> **ODM (Model)**
- **Generate** -> **XRDF (View + Logic)**
- **Editor (optional)**
- **XRDF Runtime**
  - **HTML** (Load) -> **Rendering** -> **Processing** (Validation, Computations (XPath))
  - **Android**
  - **PDF**
- **User** (Input) -> **Controller** (Export via bindings)
- **Domain Specific (ODM)**
- **Study-Creator** (Modifies (optional))
Device-independent eCRF rendering

- Open Clinica
- HTML
- Android
- PDF
System Integration: EDCS & Mobility

- Mobile data entry & imaging
Summary

- State-of-the-art: Gap
  - Laboratory & Research
  - Clinics and health care system

- First narrowing attempts
  - Workflow optimization

- More research required
Selected References


- Jonas SM, Deserno TM, Buhimschi CS, Makin J, Choma MA, Buhimschi IA. Smartphone-based diagnostic for preeclampsia: an mHealth solution for administering the Congo Red Dot (CRD) test in settings with limited resources. *JAMIA* 2015