

# Translational Research & Health Informatics



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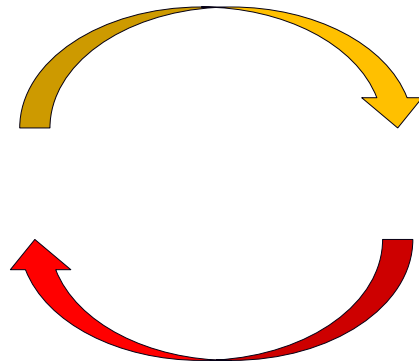


# Translational Research

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



Laboratory



Clinic

- CBMS evaluation in controlled clinical trials



# Translational Research

## ■ From bench to bed

- Laboratory Trials
  - 1.358 monitored
  - 340 recruiting
  - 279 pre-clinical
- Clinical Trials

Employees  
5.658 total  
900 physicians

**UNIKLINIK  
RWTHAACHEN**

Users  
921 total  
194 active



Departments  
33 clinics  
25 research

Subjects  
9.482 enroled  
2.526 PID generated

Patients  
44.768 stationary  
225.727 temporary

Laboratory

Clinic

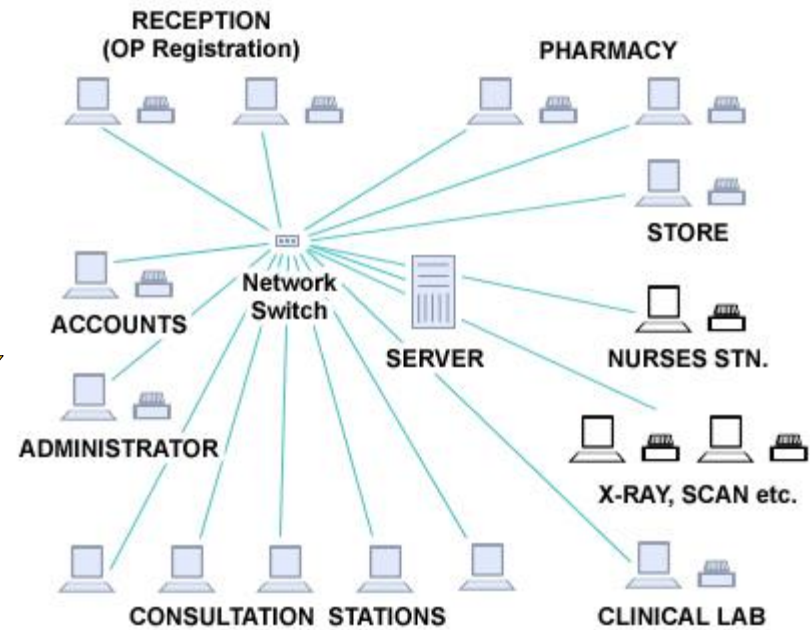
## ■ CBMS evaluation in clinical trials

# Health Informatics

- System interconnection
  - Protocols & standards
  - Data interfaces



Laboratory



Clinic





# Systems in Clinical Research: CTMS

## ■ Clinical trial management system

### ➤ Actors

- ◆ Sponsor, ethics, authorities, sites, investigators

### ➤ Documents

- ◆ Investigator's brochure, study protocol, SOPs

### ➤ Status

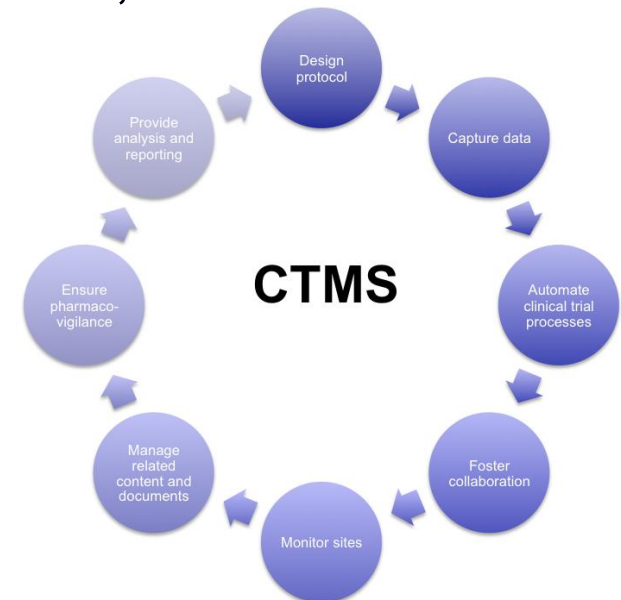
- ◆ Stages, tracking, dashboards

### ➤ Finances

- ◆ Efforts, costs, billing

### ➤ Reports

- ◆ Adverse events (AE)
- ◆ Serious adverse events (SAE)



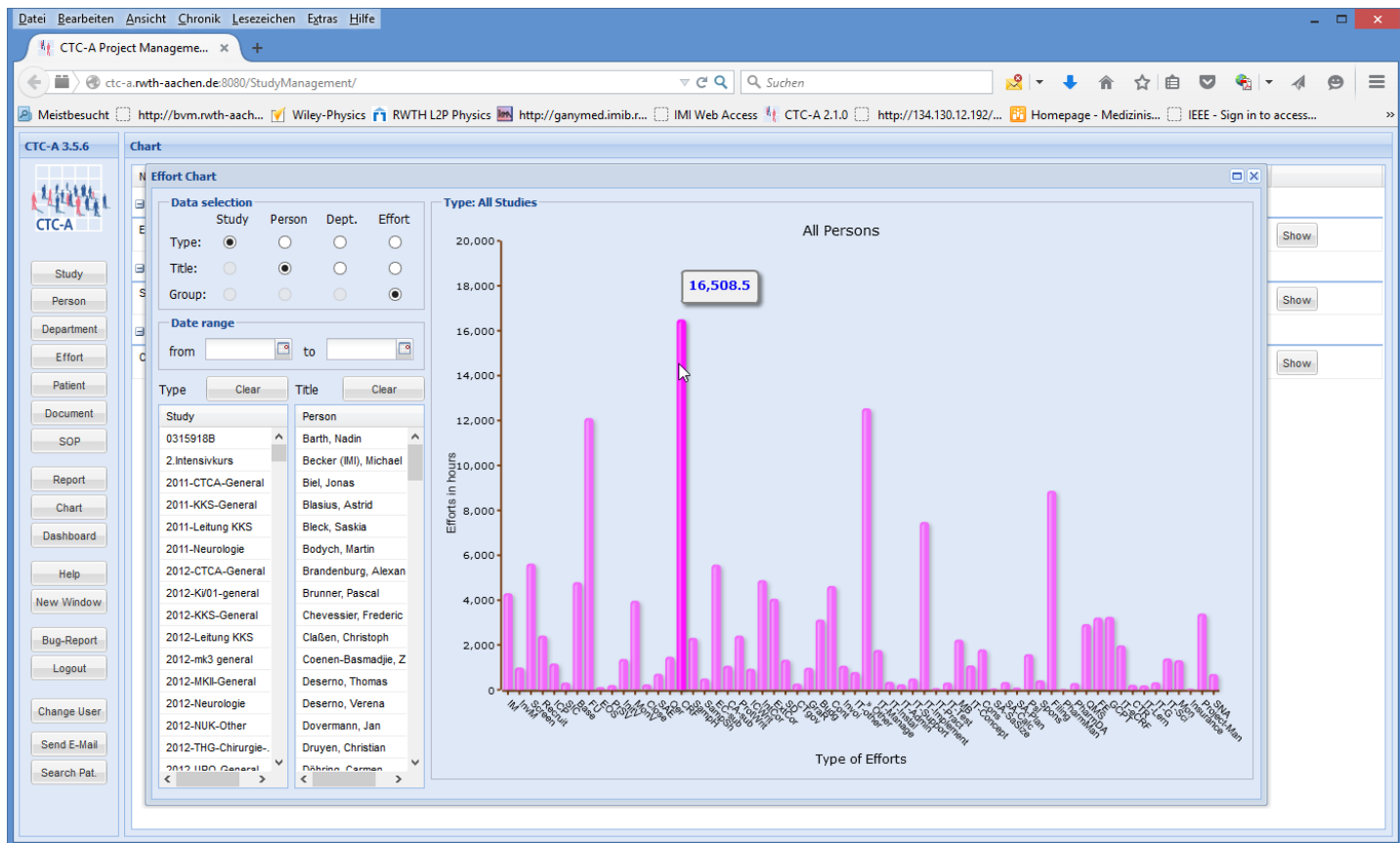
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# Systems in Clinical Research: CTMS

## ■ Example

### ➤ Effort Chart (CTC-A Study Management Tool)



# Systems in Clinical Research: EDCS

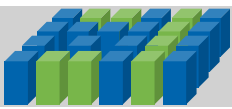
- Electronic data capture system
  - Prospective trials
  - Retrospective registries & hybrids
- Electronic case report form (eCRF)
  - OpenClinica, REDCap, SecuTrial, BioClinica, ...



- Example
  - Image integration
  - Image analysis
  - Measurement entry

Body system	Normal	Abnormal	Not done	Unknown
01 Skin	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
02 Head, eyes, ears, nose, throat	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
03 Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
04 Cardiovascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
05 Gastrointestinal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
06 Endocrine/metabolic	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
07 Genitourinary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
08 Neurological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
09 Hematological	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10 Musculoskeletal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
11 Other, specify:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Responses:	result	unit
1 Image width	3648	px (pixel)
2 Image height	2736	px (pixel)
3 Control ROI	10.7333	% (%)
4 Control redness	0.05255	px
5 Responsive ROI	12.9183	% (%)
6 Responsive redness	0.078512	px
7 Relative redness	1.494	px



# Systems in Clinical Research: EDCS

## ■ Example

### ➤ Annotations

Deutscher Schmerzfragebogen Seite 3

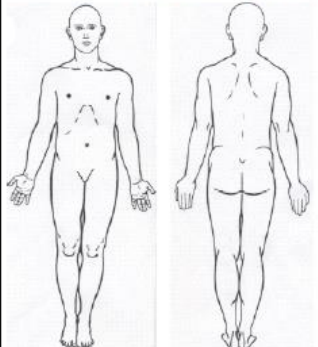
Patient: \_\_\_\_\_ Datum beim Ausfüllen: \_\_\_\_\_

1. Geburtsdatum: \_\_\_\_\_ Alter: \_\_\_\_\_ Jahre

2. Geschlecht: männlich  weiblich

3. Körpergröße (cm): \_\_\_\_\_ 4. Körpergewicht (kg): \_\_\_\_\_

5. Bitte zeichnen Sie im Körperschema ein, an welchen Körperstellen Ihre Schmerzen auftreten  
Bitte beschreiben Sie Ihre Schmerzen mit eigenen Worten:



6. Wegen welcher Schmerzen kommen Sie hauptsächlich zur Behandlung?

7. a) Seit wann bestehen diese Schmerzen?

weniger als 1 Monat <input type="radio"/>	1/2 Jahr bis 1 Jahr <input type="radio"/>	1 bis 2 Jahre <input type="radio"/>	2 bis 5 Jahre <input type="radio"/>	mehr als 5 Jahre <input type="radio"/>
1 Monat bis 1/2 Jahr <input type="radio"/>				

b) Gibt es ein genaues Datum, ab dem die Schmerzen aufgetreten sind? \_\_\_\_\_

OpenClinica Initial Data Entry

https://openclinica2.rwth-aachen.de/OC-demo/InitialDataEntry?event=...

Demo body regions V1.0 1.0 John Doe

CRF Header Info

Radiobu...(0/1) Checkbo...(0/1) ImageMap (1/1) -- Select to Jump --

Title: ImageMap with two columns

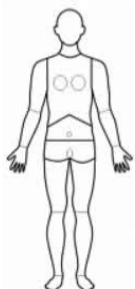
Instructions: Please answer all the questions, for any issues you can use the flag behind each question.

Page:  Mark CRF Complete Save Exit

By combining checkboxes with an image map a very sophisticated, user-friendly application is implemented. If the user is hovering over a certain area it will be highlighted. By clicking on this area it will be highlighted permanently. The corresponding checkbox will also be selected. Furthermore the checkbox can be used to select or deselect the desired areas. The image map will work both ways. There are three possible area shapes, circles, squares and polygons.

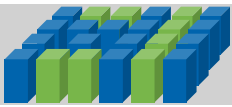
Using JQuery it is possible to split the checkboxes into two columns. Allowing the question, response options and a smaller overview image to be displayed in one row.

By adjusting the image map and response options the application can be modified for different purposes.

1. 

<input type="checkbox"/> n.a.	<input type="checkbox"/> Gastrointestinal tract
<input type="checkbox"/> Head	<input type="checkbox"/> Lower body
<input type="checkbox"/> Neck	<input type="checkbox"/> Genital area
<input type="checkbox"/> Thorax	<input type="checkbox"/> Bauchnabel
<input type="checkbox"/> Upper right arm	<input type="checkbox"/> Upper left arm
<input type="checkbox"/> Breast right	<input type="checkbox"/> Breast left
<input type="checkbox"/> Lower right arm	<input type="checkbox"/> Lower left arm
<input type="checkbox"/> Right hand	<input type="checkbox"/> Left hand
<input type="checkbox"/> Thigh right	<input type="checkbox"/> Thigh left
<input type="checkbox"/> Lower right leg	<input type="checkbox"/> Lower left leg
<input type="checkbox"/> Right foot	<input type="checkbox"/> Left foot

Return to top  Mark CRF Complete Save Exit





# 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

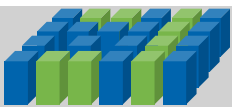
- ◆ DCM4CHEE
- ◆ Weasis



dc<sup>m</sup>4chee



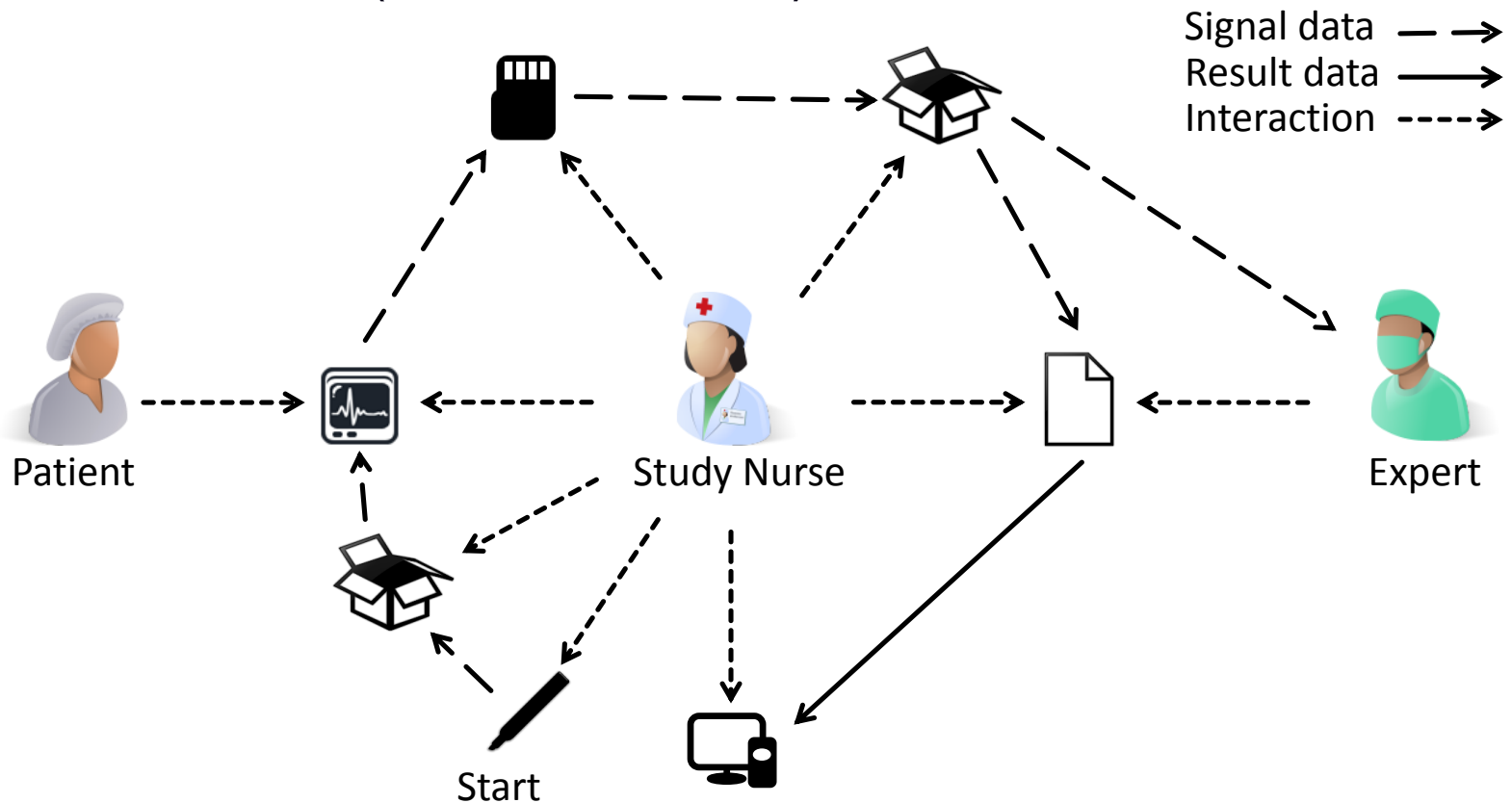
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# Data Management & Services

## ■ Example

### ➤ Workflow (state-of-the-art)



# System Integration

## ■ CTMS & EDCS

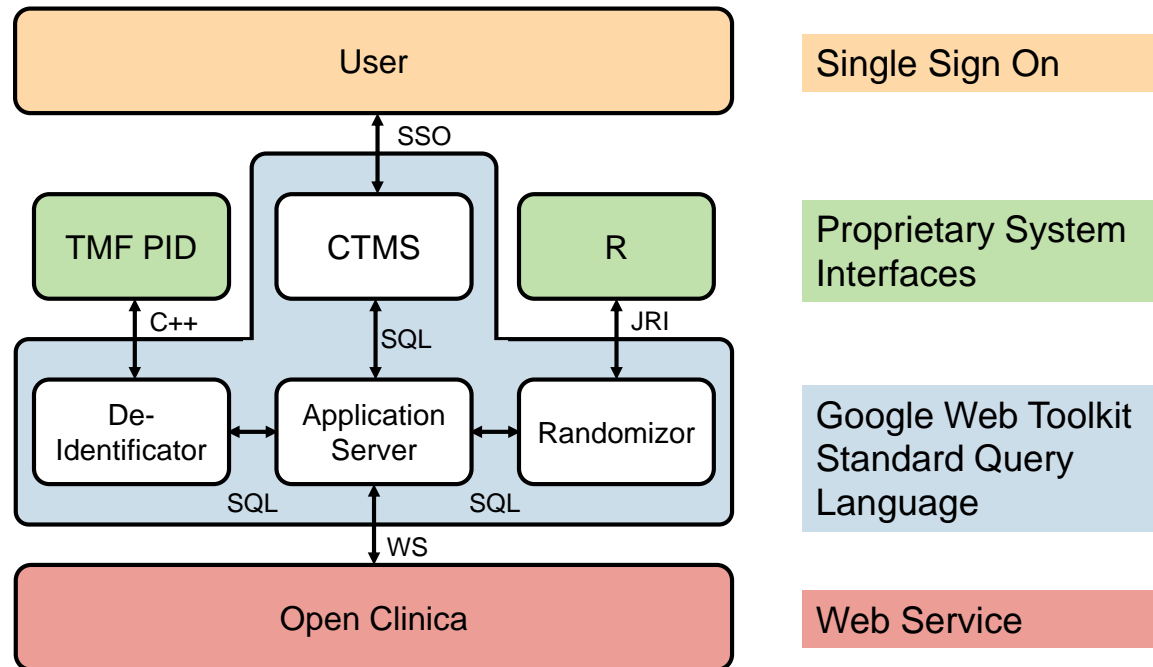
- SMT – Study Management Tool
- OC – OpenClinica

## ■ EDCS & PACS

- OC Big
- OC Dat

## ■ EDCS & mobility

- OC ToGo
- OC Tab



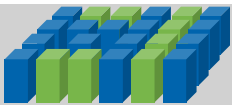
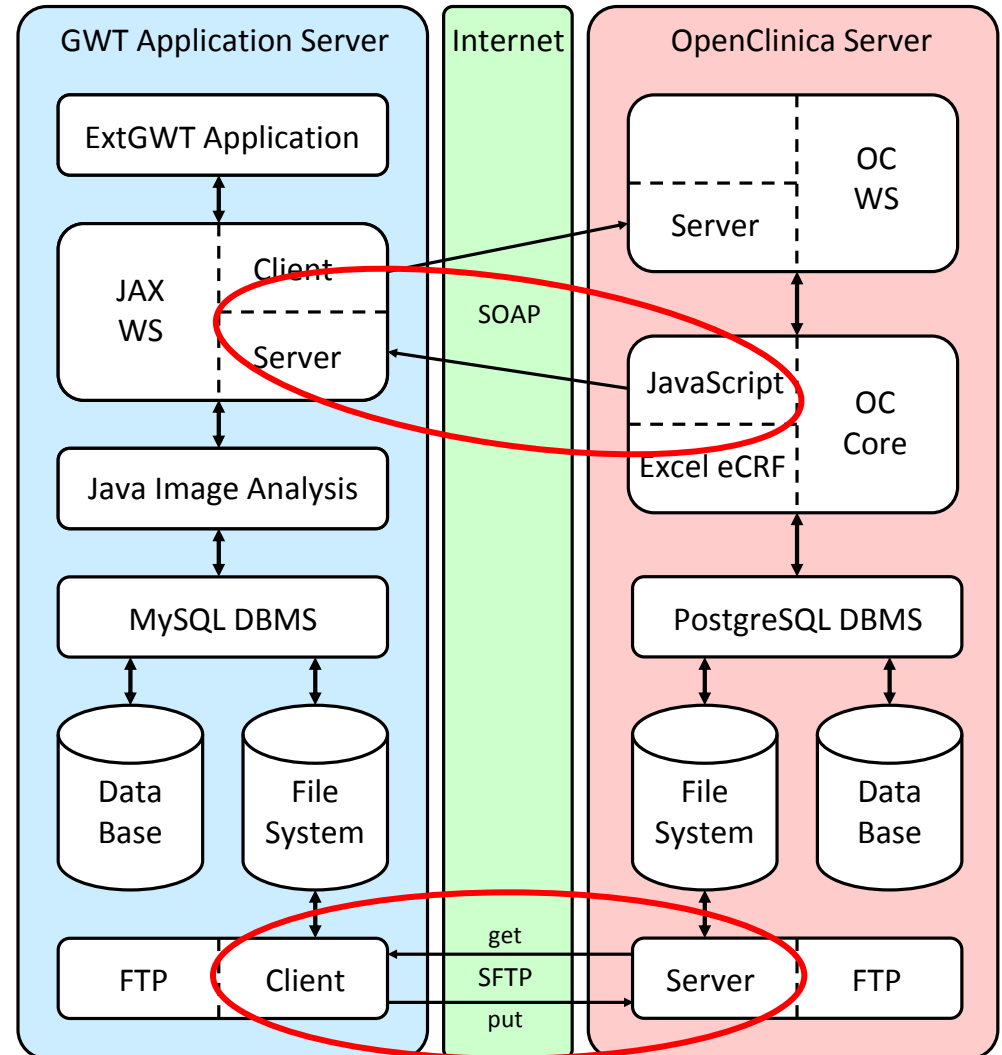
# System Integration: CTMS & EDCS

## Integration levels

- Data
- Function
- Presentation (Visual)
- Context

## Web services

- |   |          |
|---|----------|
| <ul style="list-style-type: none"> <li>■ ListAll (Study)</li> <li>■ GetMetaData (Study)</li> </ul>  | existend |
| <ul style="list-style-type: none"> <li>■ Create (Study)</li> <li>■ AddUser (Study)</li> <li>■ Create (Site)</li> <li>■ Create (User)</li> <li>■ ListAll (User)</li> <li>■ ListAll (Patients)</li> </ul> | new      |



# System Integration: CTMS & EDCS

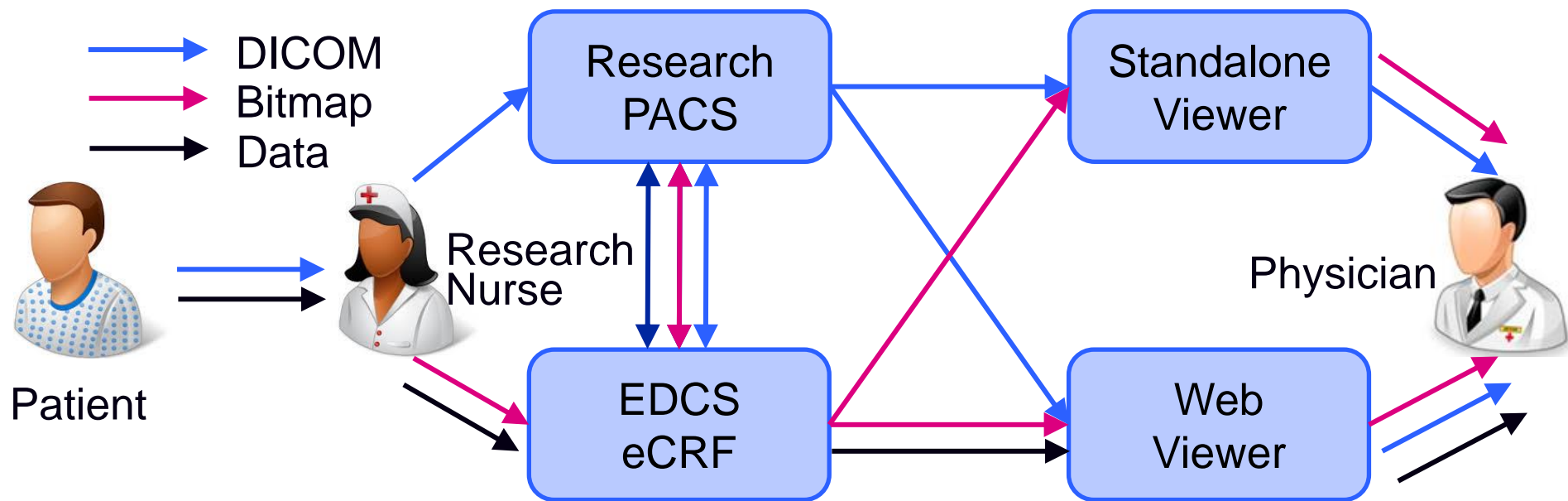
The screenshot displays the OpenClinica web application interface. The main window is titled "CTC-A Project Management" and shows a study management screen. The interface includes a navigation menu on the left with buttons for "Study", "Person", "Department", "Effort", "Patient", "Report", "Chart", "Dashboard", "Documents", "Help", "New Window", "Bug-Report", "Logout", "Change User", "Send E-Mail", and "OpenClinica" (circled in red). The main content area shows study details for "Thermal" (Acronym: Thermal, Status: Completed) and a "Patient Statistic" chart. The chart displays the "Number of Patients" over a "Timeline" from 03.11.2010 to 15.06.2014. The chart shows a green area representing the total number of patients and a red line representing the number of patients who have completed the study. The "Patients" panel on the right shows "No. planned: 105", "No. SMT: 151", "No. OC: 0", "First in (FPI): 16.02.11", and "Last out (LPO): 01.12.11". The "Guidelines" panel on the right shows a list of checkboxes for various guidelines, with "BOÄNRW" checked. The bottom of the screen displays copyright information: "© 2004-2011 OpenClinica, LLC and collaborators. The OpenClinica software for clinical research is provided AS IS, without warranty. Licensed under LGPLv2.1, you can redistribute it and/or modify it under the terms of the GNU General Public License version 2.1 as published by the Free Software Foundation. OpenClinica is a community project." The bottom right corner shows the "OpenClinica Community" logo.



# System Integration: EDACS & PACS

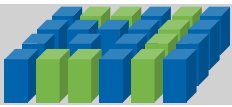
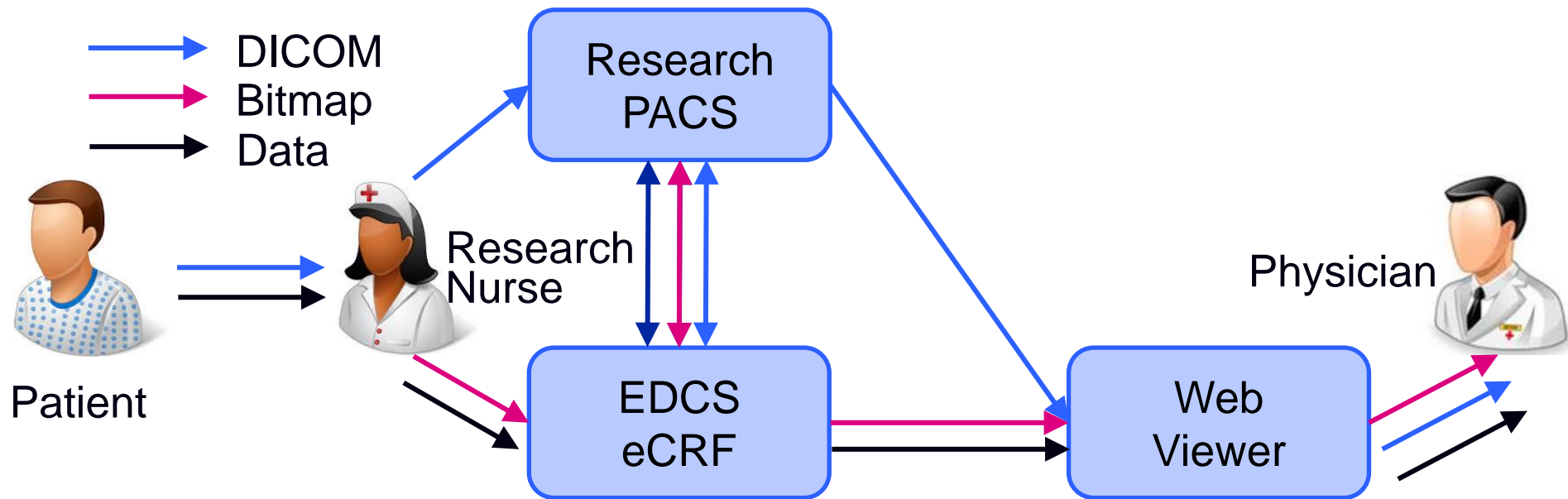
## ■ General options

- EDACS only vs. EDACS / PACS combination
- EDACS vs. PACS is master system
- Web-based vs. local viewer



# System Integration: EDACS & PACS

- Our suggestion
  - EDACS / PACS combination
  - EDACS is master system
  - Web-based viewer



# System Integration: EDCS & PACS

## ■ EDCS

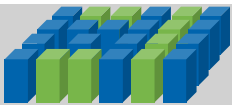
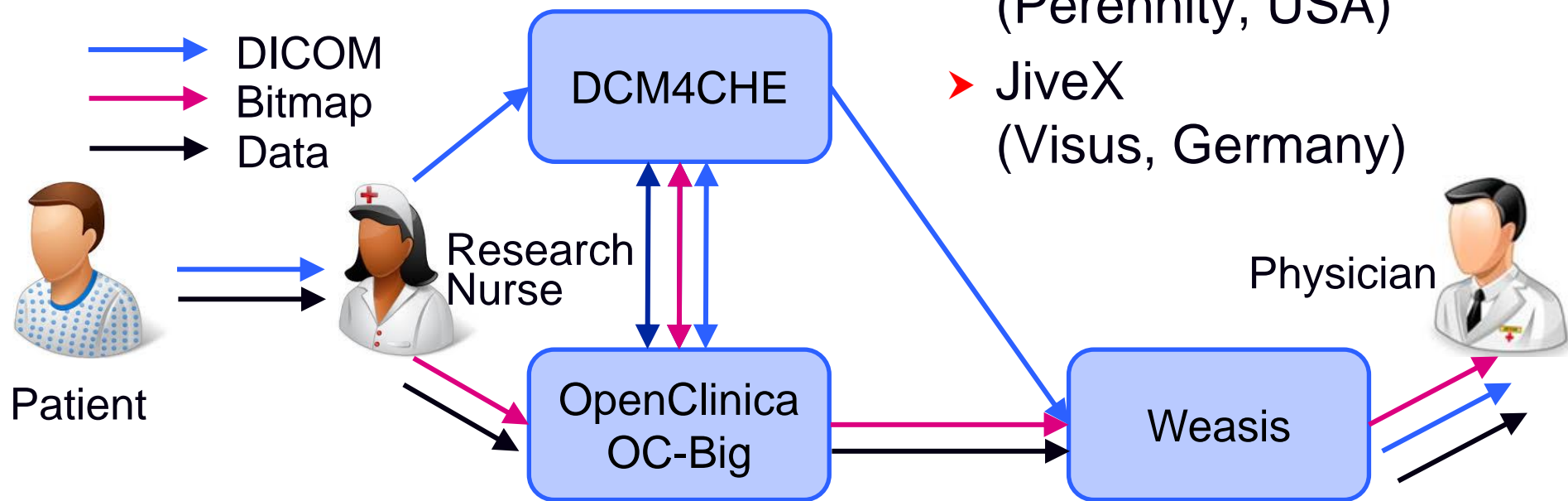
- OpenClinica
- OC-Big

## ■ PACS

- DCM4CHE

## ■ Viewer:

- WEASIS  
(Perennity, USA)
- JiveX  
(Visus, Germany)



# System Integration: EDCS & PACS

The screenshot displays the OpenClinica web application interface. The browser address bar shows the URL `https://openclinica2.rwth-aachen.de/openclinica/AddNewSubject`. The page title is "DICOM (DICOM) | Change Study/Site". The user is logged in as "cpage\_mi\_rwth\_aachen\_de (Data Entry Person)" and can click "Log Out".

The main content area is titled "DICOM: Add Subject" and includes a legend: "\* indicates required field." The form contains the following fields:

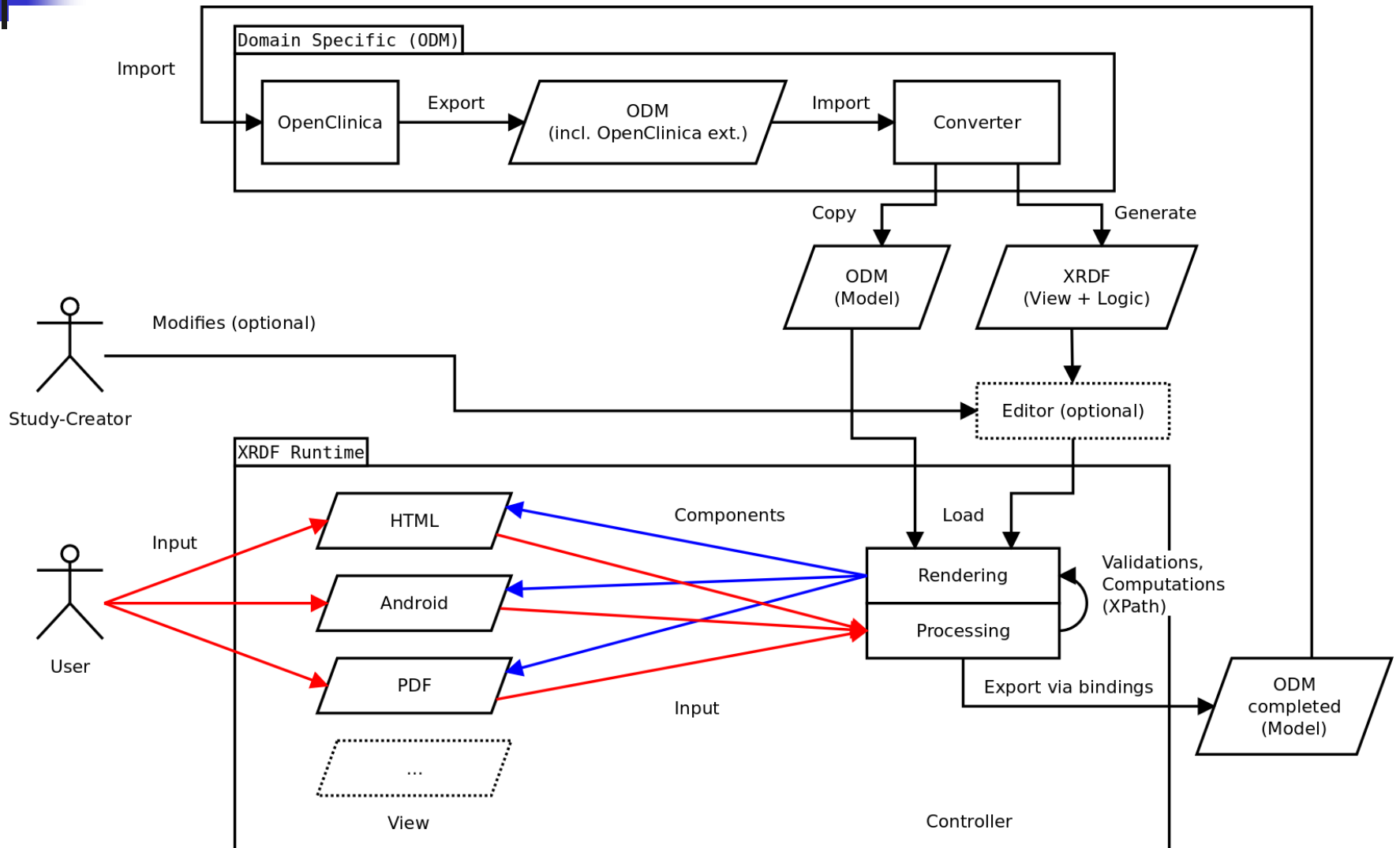
- Study Subject ID:
- Secondary ID:
- Date of Enrollment for Study DICOM:  (with a calendar icon)
- Sex:  (with a dropdown arrow)

Below the form are four buttons: "Save and Assign Study Event", "Save and Add Next Subject", "Save and Finish", and "Cancel".

A "Workflow" section at the bottom shows a sequence of steps: "Add New Subject" followed by "Add Study Event", connected by a right-pointing arrow.

On the right side of the desktop environment, a terminal window titled "134.130.12.48 - default\* - SSH Secure Shell" is open, showing a standard menu bar (File, Edit, View, Window, Help) and a toolbar with various icons.

# System Integration: EDCS & Mobility





# System Interconnection: EDCS & Mobility

## ■ Device-independent eCRF rendering

- Open Clinica
- HTML
- Android
- PDF

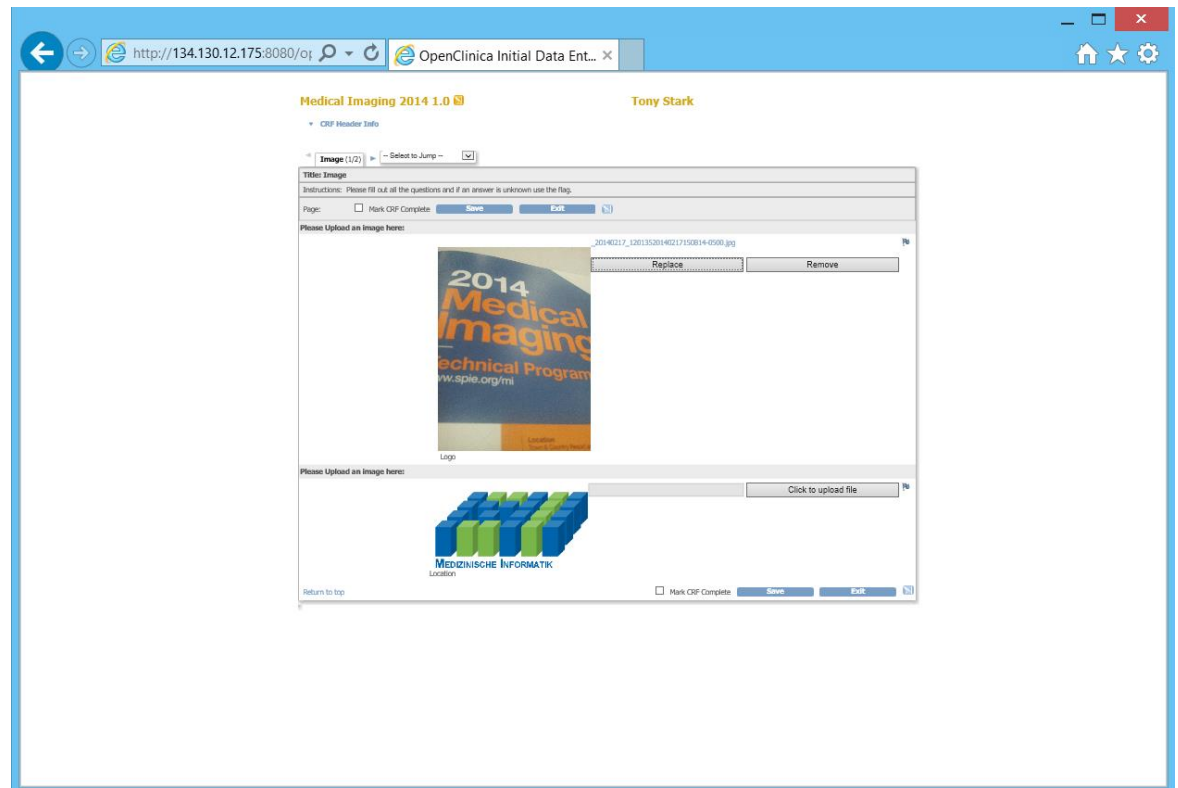
The screenshot displays a mobile application interface for an eCRF form. At the top, there are navigation buttons: 'LENGTH (0/3)', 'QUESTIO...(0/3)', 'OTHER (0/5)', and a dropdown menu '-- Select to Jump --'. Below these, there are tabs for '1) Model-XML' and '2) Form-XML', with sub-buttons for 'Datei auswählen', 'Artificial...\_model.xml', 'ArtificialT...1\_xrdf.xml', 'Validate', and 'Show Model'. The main content area shows the form for 'Other' properties. The form includes the following fields:

- Title: Other
- Subtitle: Other properties
- Instructions: You may play around with the input fields
- Required (ST)  \*
- Unit (ST)  (mg)
- Right item text (ST)  Here it is
- Header text
- Subheader text
- Headers (ST)
- Default value (ST)



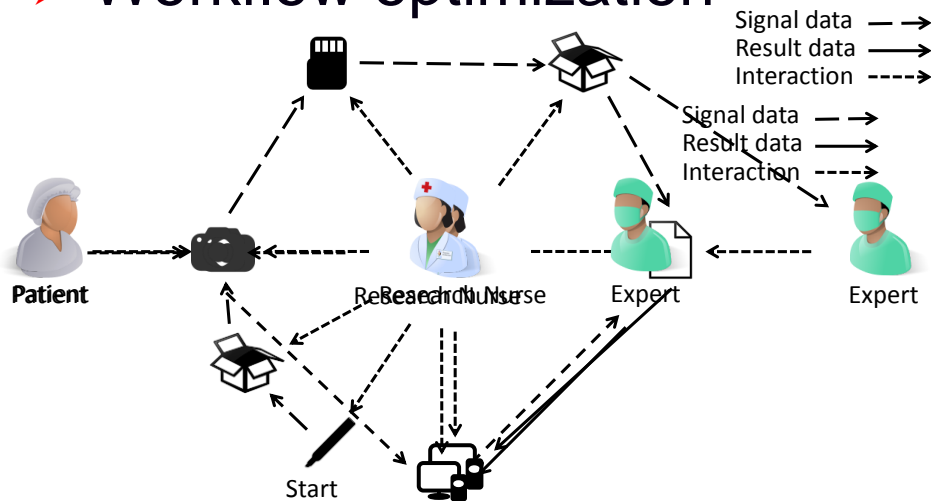
# System Integration: EDCS & Mobility

- 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



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Smartphone-based diagnostic for preeclampsia: an mHealth solution for administering the Congo Red Dot (CRD) test in settings with limited resources  
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