

# Web Services for Image Management and Analysis in OpenClinica



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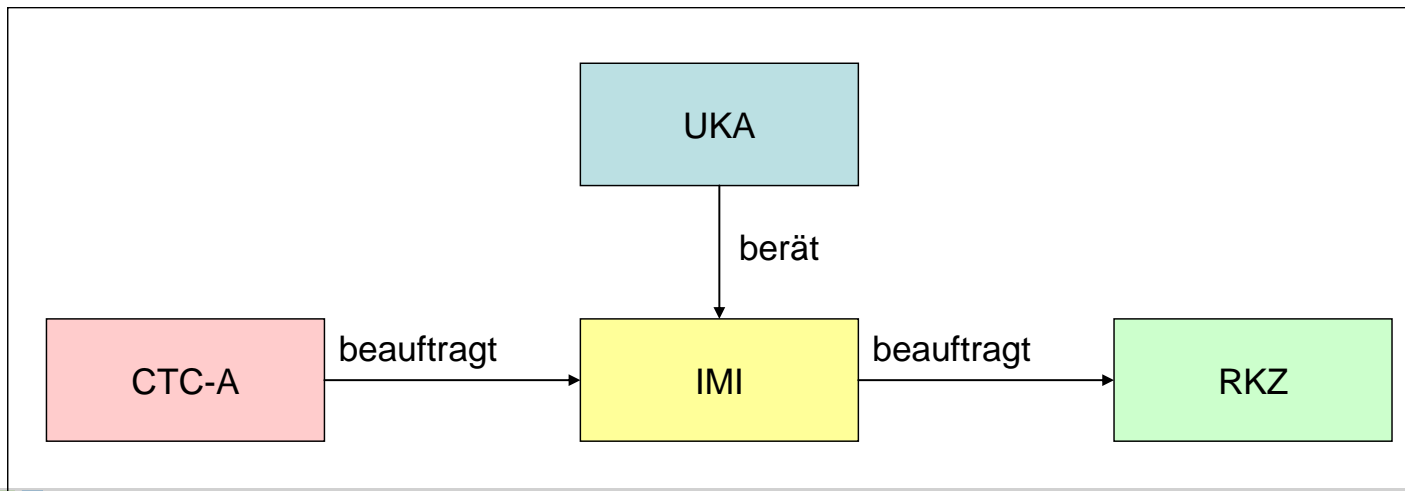
# Clinical Trial Center Aachen (CTC-A)

- Re-established (Nov. 2010)
  - Self standing unit  
RWTH Aachen University  
Medical School (Uniklinik)
- Mission
  - Improvement of study outcome (scientific, economic)
  - Support of investigator initiated trials (IIT)
  - Quality management
- Methods
  - Process re-structuring & controlling
  - Software (GWT, Dept. of Med. Informatics)

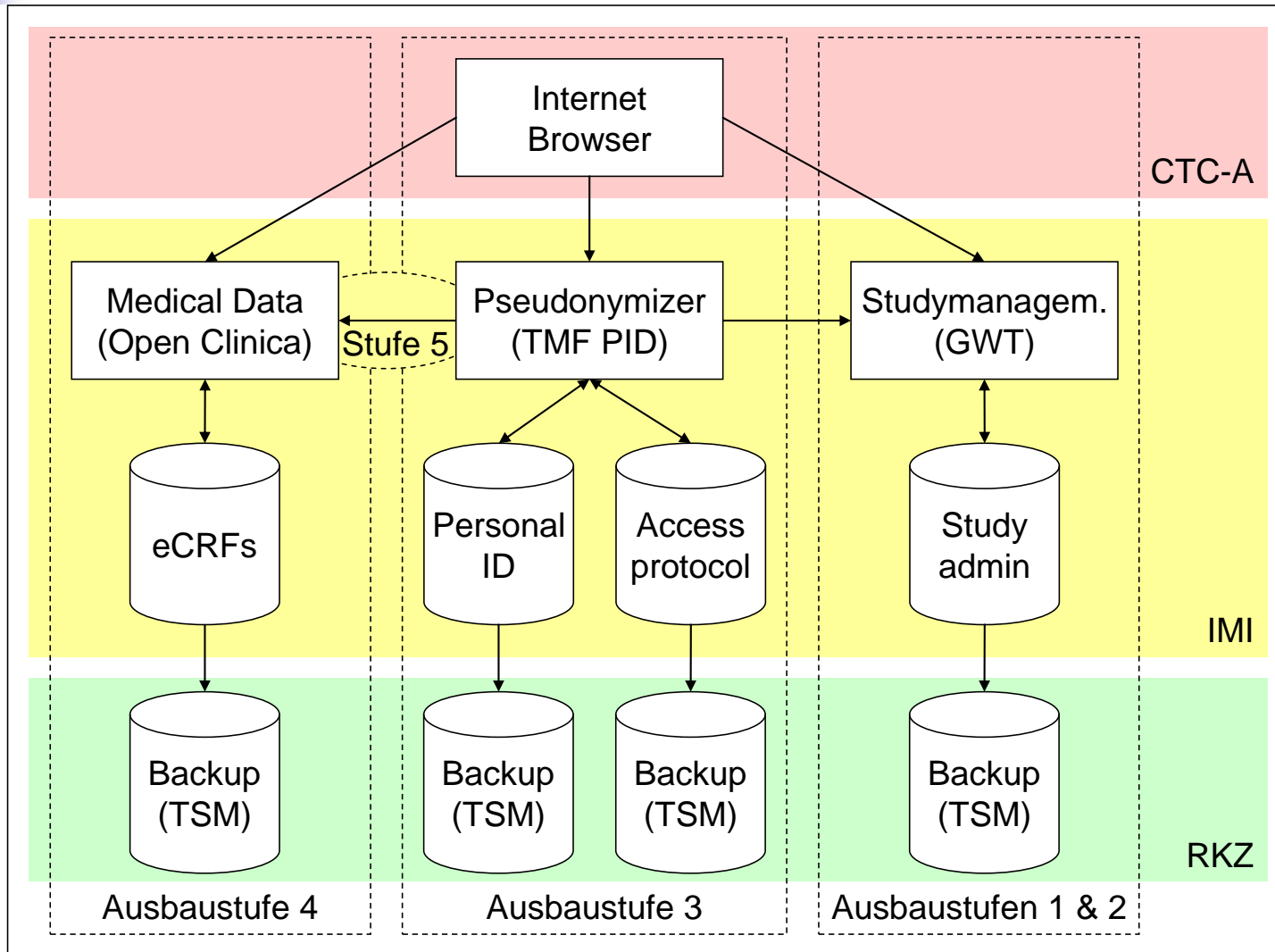


# Structure

- Uniklinik RWTH Aachen, Medical School
  - Clinical Trial Center Aachen (CTC-A)
  - Dept. Medical Informatics (IMI)
- Uniklinik RWTH Aachen, Hospital
  - IT Dept. (UKA)
- RWTH Aachen University
  - IT Dept. (RKZ)



# Structure



# CTC-A Study Management Tool

CTC-A Project Management Database - Mozilla Firefox

http://134.130.12.190:8080/StudyManagement\_20110923/

CTC-A Project Management ...

CTC-A 2.2.3

Study

Department: please select | Person: please select | Function: please select

Anzeige Eintrag 1 - 22 von 384

Shortname	CTCA-No	Sponsor	CRO	Status	Fonds	ClinTrial	EudraCT	Ethics-Ref.	AMG	MPG	BOANRW
Vortrag_ROC_Deserno	ML_001			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Leitung KKS vd	KKS-General-001	MK1		» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NeuroDB	IT-11-065	Neurologie		» Other					<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
OpenClinica	IT-11-062	CTC-A	IMI	» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
GWT-PMO	IT-10-045	CTC-A	IMI	» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NACHFOLGE MeDiNa	GB-FM-35	CTC-A		» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medizin.Technik.NRW	GB-FM-34			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ADHS-EEG	GB-FM-33			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PA-10-067	GB-FM-32			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Risk AGuA	GB-FM-31			» Other	360616				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Spende Eggermann	GB-FM-30			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
HUMTHAL	GB-FM-29			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DFG -Bei Wu	GB-FM-28			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
BRA 09/045	GB-FM-27			» Other	360456				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
MIF-Sekretion	GB-FM-26			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coburn-Baxter	GB-FM-25			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
YB-1	GB-FM-24			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Epiglu	GB-FM-23			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
DFG-Opländer	GB-FM-22			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Syntab	GB-FM-21			» Other					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
restless legs	GB-FM-20			» Other	374005				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Silk-Bladder	GB-FM-19			» Other	360602				<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>



# CTC-A Study Management Tool

CTC-A Project Management Database - Mozilla Firefox

http://134.130.12.190:8080/StudyManagement\_20110923/

CTC-A 2.2.3 Study details

Acronym: Therموال Funded by: Industry Validierung der klinischen Messgenauigkeit eines Dual-Mode Infrarot Fieberthermometers

Status: Completed Full Title:

Reference numbers

CTC-A: 10-018 01  
EudraCT:  
DIMDI:  
Ethics-Reference: 012/11 18  
Pharma-Ref.:  
BOB-Reference:  
ClinicalTrial.gov:

Functions

Sponsor: PHAG  
CRO: CTC-A  
PI-Finance: Krüger, Stefan

Function Principal investigator Person  
Project Manager Deserno, Ven  
Statistician Haselhuhn, Angelika  
Study-Nurse Main Thiele, Kathrin

Number of Patients

Timeline

67.02

Patients

No. planned: 105  
No. current: 148  
First in (FPI): 16.02.11  
Last out (LPO): 05.09.11

Guidelines

AMG  
GewebeG  
MPG  
BOÄNRW  
StriSchV  
RöV  
HealthClaimsV  
AWB

Track Status  
Track Finance  
Documents  
Add Effort  
Effort Statistic  
Help  
New Window  
Cancel  
Save & Exit

Fertig

# Primary Origins & Interchange

## CTC-A

### ■ Data

- Name of study
- Study sites
- Persons, roles, access levels
- Development of patients (FPI, LPO, History)

### ■ Function

- Image processing

### ■ Data

- Result images
- Result measurements

## OpenClinica

### ■ Data



←➤ ➤ Current number of patients

←➤ ➤ Images

### ■ Function

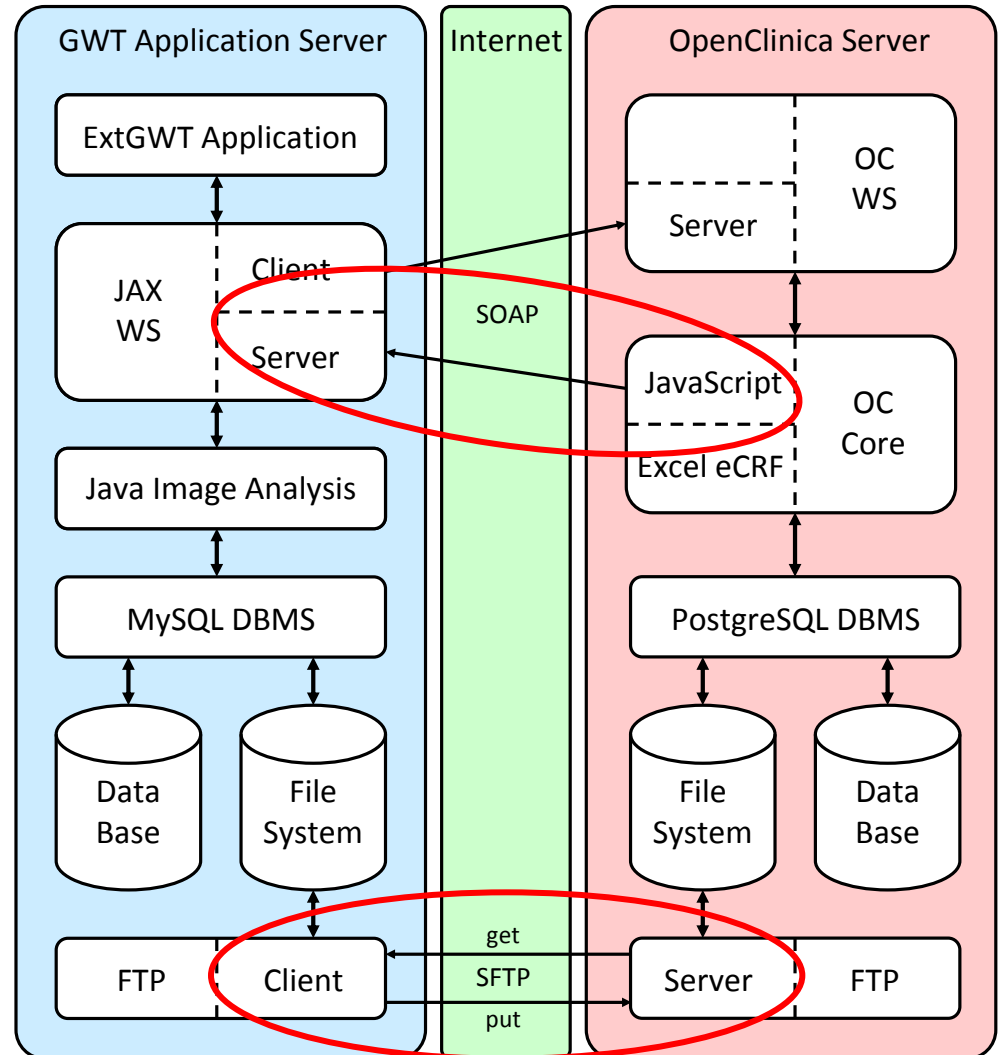
←➤ ➤ Call

### ■ Data



# Preferences

- Maintain OC code
  - Compatibility
  - Updates
- Full integration
  - Data
  - Function
- Automation
  - No user interaction
- Use standards
  - Communication
  - Data Interchange
- Data security







# OpenClinica Excel eCRF Definition

---

- Concept
  - JavaScript enhancement
  - Sends SOAP messages
- Problem
  - “Cross Domain Calls”
  - Not allowed to execute client JavaScript code on server
- Solution
  - PHP proxy server
  - Creates SOAP message
  - Calls OpenClinica web services



# Implementation

## ■ JavaScript

```
1 <script>
2
3 function callPHPProxy(){
4
5 // Prepare PHP proxy call
6 xmlhttp = new XMLHttpRequest();
7 xmlhttp.open('GET', 'http://oc-server/phpproxy.php?imageID=42', true);
8
9 // Send request
10 xmlhttp.send(null);
11 }
12 </script>
```

## ■ PHP Proxy

```
1 <?php
2
3 // Get parameters
4 $imageID = ($_POST['imageID']) ? ($_POST['imageID']) : ($_GET['imageID']);
5
6 // Create SOAP client
7 $client = new SOAPClient('http://gwt-server/image?wsdl');
8 $client->__setLocation('http://gwt-server/image');
9
10 // Invoke SOAP method
11 $client->startImageAnalysis(array('imageID' => $imageID));
12 ?>
```





# Image & Measure Transfer

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- JCraft Java secure channel library (JSch)
  - SFTP connection
  - Data transfer (get)
  - ... Java code execution
  - Data transfer (put)
- Web Service
  - OpenClinica Web Server
  - CTC-A Client
  - Well-formed XML file
  - Clinical Data Interchange Standards Consortium Object Data Module (CDISC ODM)



# Implementation

## ■ Java code

```
1 public String startImageAnalysis(String imageID){
2
3     // Create JSch SFTP object
4     JSch jsch = new JSch();
5
6     // Configure session
7     Session session = jsch.getSession("user", "oc-server");
8     session.setConfig("StrictHostKeyChecking", "no");
9     session.setPassword("password");
10    session.connect();
11
12    // Configure channel
13    Channel channel = session.openChannel("sftp");
14    channel.connect();
15    ChannelSftp sftpchannel = (ChannelSftp) channel;
16
17    // Get image
18    sftpchannel.get(filename, local_filename);
19
20    // Call Java module
21    callJavaImageAnalysis();
22
23    // Transfer result image back
24    sftpchannel.put(local_result_filename, result_filename));
25
26    // Close channel and session
27    sftpchannel.exit();
28    session.disconnect();
29
30    // Trigger JAX-WS to send SOAP message with results
31    sendSOAPResults();
32
33    return "Success!";
34 }
```

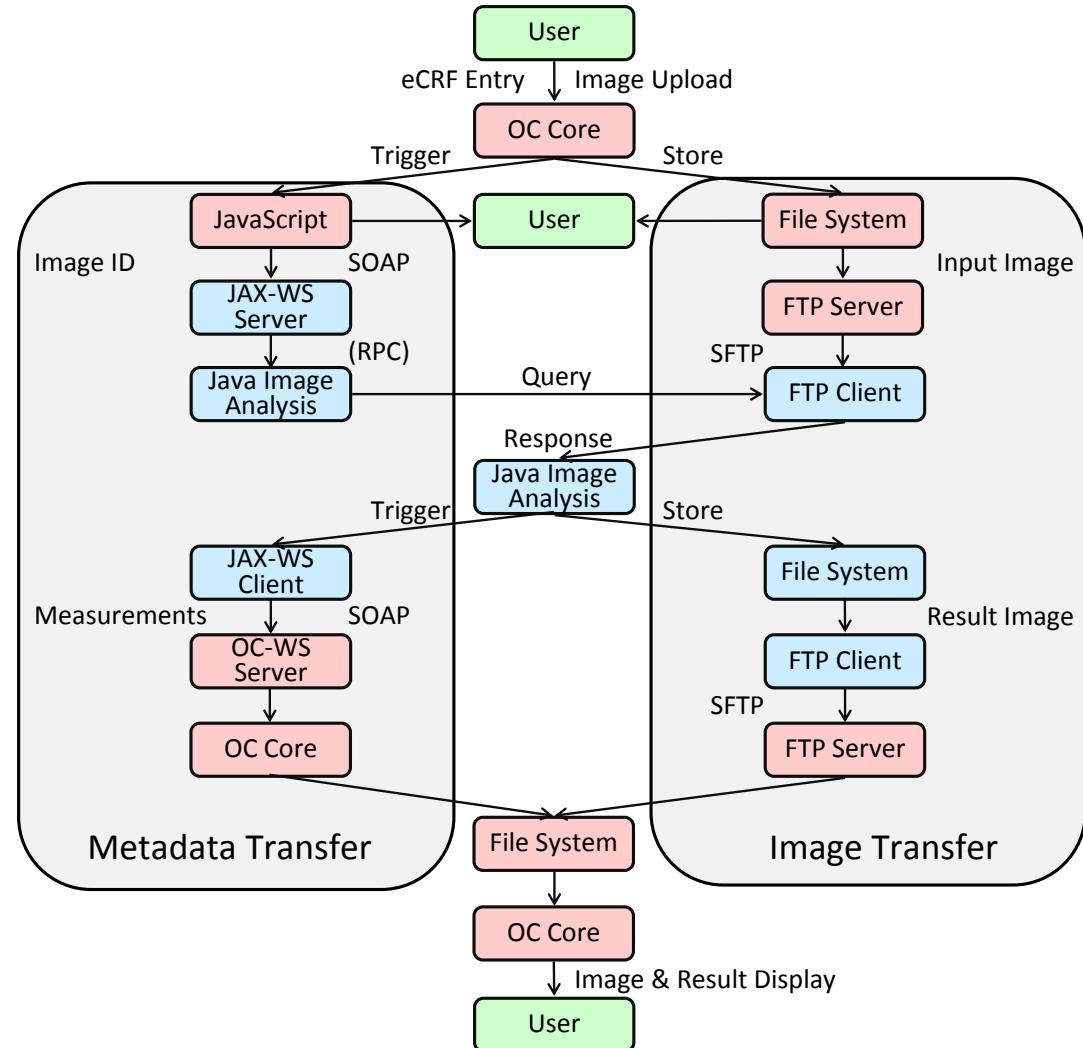
# Communication Protocols & Workflow

## ■ Color scheme

- Red: OpenClinica
- Blue: CTC-A
- Green: Internet Browser-based GUI

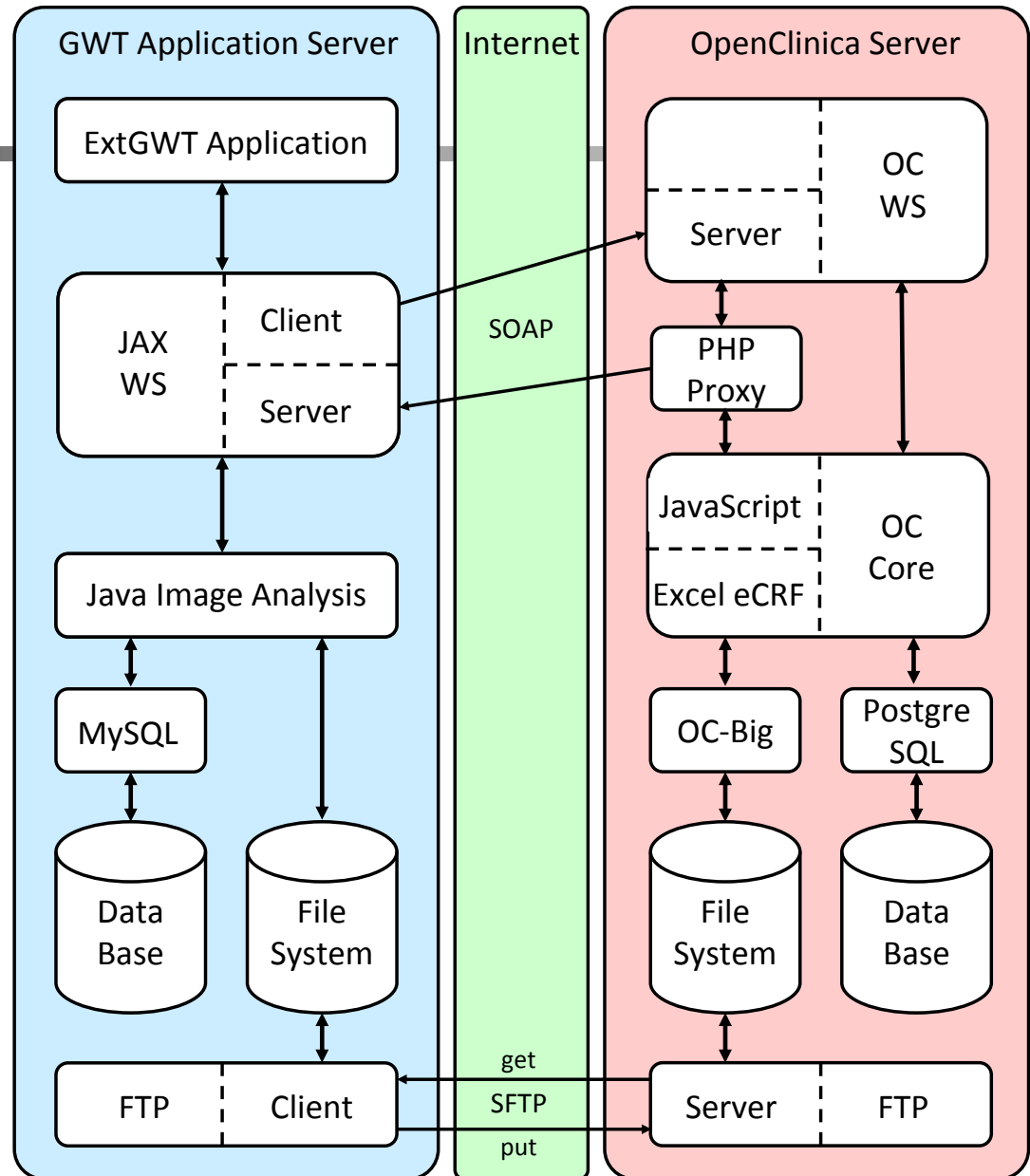
## ■ Example Workflow

- Conjunctival provocation test (CPT)



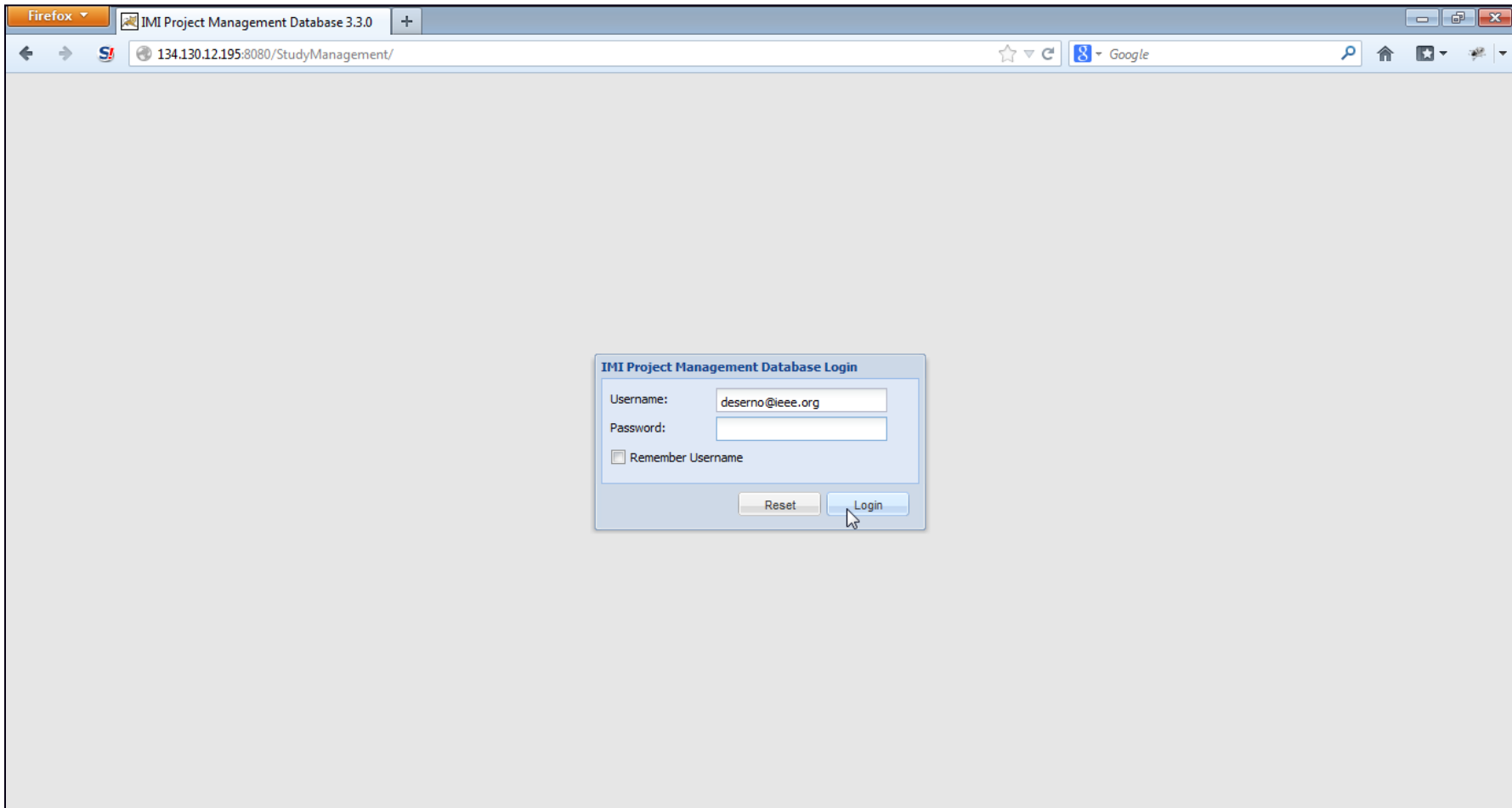
# Result

- Single-sign-on
- CTC-A
  - study selection
  - metadata transfer
  - Image processing
- OpenClinica
  - subject selection
  - CRF selection
  - Image upload
  - Image display
  - Processing results



# Result

## ■ 1. Single-sign-on authentication



The screenshot shows a Firefox browser window with the following details:

- Browser: Firefox
- Tab: IMI Project Management Database 3.3.0
- Address Bar: 134.130.12.195:8080/StudyManagement/
- Search: Google

The main content area displays the "IMI Project Management Database Login" form:

**IMI Project Management Database Login**

Username:

Password:

Remember Username



# Result

## 2. CTC-A: study selection

IMI 3.3.0

Department:  Clear

Person:  Clear

Function:  Clear

Anzeige Eintrag 1 - 23 von 749

Shortname	CTCA-No	Sponsor	CRO	Status	Phase	Fonds	Funded by	EudraCT	Ethics-Ref.	AMG	MPG	BOAN...	OpenClinica	Keywords
Carotis-Kurs	WS-03-12	Boston Scientific		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
2.Intensivkurs	WS-02-12	DGNR		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Workshop DGNR
Stroke Workshop	WS-01-12	DGNR		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Workshop DGNR
CPT	WS-0012			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Coil Retrieval	TV-02-12			» Other	Pre-clinical					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Aneurysma-Langzeitver...	TV-01-12			» Other	Pre-clinical					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
Tiertraining	TV-00-12			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Test vor Mittags-Deploy	test			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
NRAD-General-2012	NRAD-0000			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Vortrag_ROC_Deserno	MI_001			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Vollkostentool	IT-12-001	CTC-A		» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Datenschutz	IT-11-181	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
LapTop	IT-11-177	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
NeuroDB	IT-11-065	Neurologie	IMI	» Other	None		» Other			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
OpenClinica	IT-11-062	CTC-A	IMI	» Other	None		» Other			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
GWT-PMD	IT-10-045	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
RhePort21	GB-FM-99			» Other	None		NRW			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
P&G	GB-FM-98			» Other	None		» Other			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
ZIM Ritter	GB-FM-97			» Other	None		AiF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
In2WaK	GB-FM-96			» Other	None		BMBF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
TIM	GB-FM-95			» Other	None		NRW			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
MicSurf	GB-FM-94			» Other	None		AiF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SysmedIBA	GB-FM-93			» Other	None	360686	EU			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		



# Result

## 3. CTC-A: metadata transfer to OpenClinica

The screenshot shows the 'Edit Study' form in the IMI Project Management Database 3.3.0. The browser address bar shows '134.130.12.195:8080/StudyManagement/'. The form is titled 'Edit Study' and contains the following sections:

- Study Information:** Acronym: CPT, Status: Other, Full Title: Conjunctival Provocation Test. Buttons: Generate OC, Generate FCT.
- Reference numbers:** CTC-A: WS-0012, 06.02.13; EudraCT; DIMDI; Ethics-Reference; Pharma-Ref.; BOB-Reference; ClinicalTrials.gov; BFS No. (all with edit icons).
- Finance:** Fonds GB-FM; Budget: 0,00 €; Offered PPF: 0,00 €; per Pat. Fee (PPF): 0,00 €; Overhead: 0,0 %; Setup fee: 0,00 €; Budget summary: CTC-A: 0,00 € | Total: 0,00 €.
- Drugs:** No. drugs; Initialization; On stock; Random.: phys, pharm, none; Manufact.: zyto, recipe, none.
- Patients:** No. planned: 287; No. current; First in (FPI); Last out (LPO); Buttons: Add Patient, Patient Statistic.
- Functions:** Sponsor; CRO; PI-Finance: Aachen, CTC-A; Table with columns Function and Person (Data Manager, Deserno, Thomas); Buttons: New Line, Add Person, Add Dept.
- Keywords / Comments:** Keywords; Rich text editor.
- Guidelines:** List of checkboxes (AMG, GewebeG, MPG, BOÄNRW, StrISchV, RöV, HealthClaimsV); Phase: None; Buttons: Status (0), Finance (0), Docs (0), Add Effort, Effort Statistic, Help, New Window, Cancel, Save & Exit.

# Result

## 3. CTC-A: metadata transfer to OpenClinica

The screenshot shows the 'Edit Study' interface in the IMI Project Management Database 3.3.0. The main form contains the following fields:

- Acronym: CPT
- Funded by: [dropdown]
- Conjunctival Provocation Test
- Status: » Other
- Full Title: [text area]

Reference numbers section:

- CTC-A: WS-0012, 06.02.13
- EudraCT: [text area]
- DIMDI: [text area]
- Ethics-Reference: [text area]
- Pharma-Ref.: [text area]
- BOB-Reference: [text area]
- ClinicalTrials.gov: [text area]
- BFS No.: [text area]

Finance section:

- Fonds GB-FM: [text area]
- Budget: 0,00 €
- Offered PPF: 0,00 €
- per Pat. Fee (PPF): 0,00 €
- Overhead: 0,0 %

Drugs section:

- No. drugs: [text area]
- Initialization: [text area]
- On stock: [text area]
- Random.: phys, pharm, none
- Manufact.: zyto, recipe, none

Patients section:

- No. planned: 287
- Auto update: [checkbox]
- No. current: [text area]
- First in (FPI): [text area]
- Last out (LPO): [text area]

Functions section:

- Sponsor: [dropdown]
- CRO: [dropdown]
- PI-Finance: Aachen, CTC-A

Keywords / Comments section:

- Keywords: [text area]

Modal dialog: OpenClinica Connector

Do you really want to generate study details and user roles in OpenClinica?

Buttons: Ja, Nein

# Result

## 3. CTC-A: metadata transfer to OpenClinica

The screenshot displays the 'Edit Study' interface in the IMI Project Management Database 3.3.0. The browser window shows the URL '134.130.12.195:8080/StudyManagement/'. The main form is titled 'Edit Study' and contains several sections:

- Study Information:** Acronym: CPT, Status: Other, Full Title: Conjunctival Provocation Test.
- Reference numbers:** CTC-A: WS-0012, 06.02.13; EudraCT; DIMDI; Ethics-Reference; Pharma-Ref.; BOB-Reference; ClinicalTrials.gov; BFS No.:
- Finance:** Fonds GB-FM; Budget: 0,00 €; Offered PPF: 0,00 €; per Pat. Fee (PPF): 0,00 €; Overhead: 0,0 %.
- Drugs:** No. drugs; Initialization; On stock; Random.: phys, pharm, none; Manufact.: zyto, recipe, none.
- Patients:** No. planned: 287; No. current; First in (FPI); Last out (LPO); Add Patient; Patient Statistic.
- Functions:** Sponsor; CRO; PI-Finance: Aachen, CTC-A; Function: Data Manager; Person: Deserno, Thomas.
- Keywords / Comments:** Keywords; Rich text editor.
- Guidelines:** AMG, GewebeG, MPG, BOÄNRW, StrISchV, RöV, HealthClaimsV; Phase: None.

An 'OpenClinica Connector' modal window is overlaid on the Finance section, showing a 'Generating...' button. The browser window also shows a sidebar with navigation options like 'Study', 'Person', 'Department', etc., and a top navigation bar with 'Generate OC' and 'Generate FCT' buttons.

# Result

## 3. CTC-A: metadata transfer to OpenClinica

The screenshot displays the 'Edit Study' interface in the IMI Project Management Database 3.3.0. The browser address bar shows the URL '134.130.12.195:8080/StudyManagement/'. The interface is divided into several sections:

- Study Information:** Acronym: CPT, Status: Other, Full Title: Conjunctival Provocation Test.
- Reference numbers:** Fields for CTC-A (WS-0012), EudraCT, DIMDI, Ethics-Reference, Pharma-Ref., BOB-Reference, ClinicalTrials.gov, and BFS No.
- Finance:** Fields for Fonds GB-FM, Budget (0,00 €), Offered PPF (0,00 €), per Pat. Fee (PPF) (0,00 €), and Overhead (0,0 %).
- Drugs:** Fields for No. drugs, Initialization, On stock, and Manufact. (zyto, recipe, none).
- Patients:** Fields for No. planned (287), No. current, First in (FPI), and Last out (LPO).
- Functions:** Fields for Sponsor, CRO, and PI-Finance (Aachen, CTC-A).
- Keywords / Comments:** A text area for entering keywords and comments.
- Guidelines:** A list of checkboxes for various guidelines (AMG, GewebeG, MPG, BOÄNRW, StrISchV, RöV, HealthClaimsV).

A central dialog box titled 'Generation Completed' contains the message: 'Study, Users and Roles have been successful generated or updated.' with an 'OK' button.

# Result

## 4. Functional integration: switching to OpenClinica

IMI Project Management Database 3.3.0 ...  
134.130.12.195:8080/StudyManagement/

IMI 3.3.0  
CTC-A  
CLINICAL TRIALS CENTER AACHEN

Study  
Person  
Department  
Effort  
Patient  
Document  
SOP  
Report  
Chart  
Dashboard  
Help  
New Window  
Bug-Report  
Logout  
Change User  
Send E-Mail  
Search Pat.

Department: please select  
Person: please select  
Function: please select

Anzeige Eintrag 1 - 23 von 749

Shortname	CTCA-No	Sponsor	CRO	Status	Phase	Fonds	Funded by	EudraCT	Ethics-Ref.	AMG	MPG	BOAN...	OpenClinica	Keywords
Carotis-Kurs	WS-03-12	Boston Scientific		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
2.Intensivkurs	WS-02-12	DGNR		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Workshop DGNR
Stroke Workshop	WS-01-12	DGNR		» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		Workshop DGNR
CPT	WS-0012			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
Coil Retrieval	TV-02-12			» Other	Pre-clinical					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Aneurysma-Langzeitver...	TV-01-12			» Other	Pre-clinical					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
Tiertraining	TV-00-12			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Test vor Mittags-Deploy	test			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
NRAD-General-2012	NRAD-0000			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Vortrag_ROC_Deserno	MI_001			» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Vollkostentool	IT-12-001	CTC-A		» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Datenschutz	IT-11-181	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
LapTop	IT-11-177	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
NeuroDB	IT-11-065	Neurologie	IMI	» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
OpenClinica	IT-11-062	CTC-A	IMI	» Other	None					<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
GWT-PMD	IT-10-045	CTC-A	IMI	» Other	None		Own			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
RhePort21	GB-FM-99			» Other	None		NRW			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
P&G	GB-FM-98			» Other	None		» Other			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	oc	
ZIM Ritter	GB-FM-97			» Other	None		AiF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
In2WaK	GB-FM-96			» Other	None		BMBF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
TIM	GB-FM-95			» Other	None		NRW			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
MicSurf	GB-FM-94			» Other	None		AiF			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
SysmedIBA	GB-FM-93			» Other	None	360686	EU			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

# Result

## 4. Functional integration: OpenClinica in a new tab

The screenshot shows a Firefox browser window with two tabs: 'IMI Project Management Database 3...' and 'OpenClinica'. The address bar shows the URL '134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/MainMenu'. The page title is 'OpenClinica Community Edition'. The navigation menu includes 'Home', 'Subject Matrix', 'SDV', 'Notes & Discrepancies', and 'Tasks'. The user is logged in as 'deserno\_ieee\_org (Monitor) en' and can 'Log Out'. A search bar for 'Study Subject ID' is present.









The main content area displays a 'Welcome to CPT' message and 'Notes & Discrepancies Assigned to Me: 0'. Below this, there are two tabs: 'View By Event CRF' (selected) and 'View By Study Subject ID'. The 'Source Data Verification' section shows a table with 15 items, sorted by Event Date. The table has columns for SDV Status, Study Subject ID, Site ID, Event Name, Event Date, CRF Name / Version, SDV Requirement, CRF Status, and Actions. The current view shows no entries ('Keine Einträge gefunden.').

On the left sidebar, there are sections for 'Alerts & Messages' (welcome message for Thomas Deserno), 'Instructions', 'Other Info' (Study: CPT, Start Date: N/A, End Date: N/A, PI: Aachen, CTC-A), and 'Icon Key' (Statuses: Not Started, Scheduled, Data Entry).

# Result

## 5. OpenClinica: subject selection

The screenshot shows the OpenClinica web application interface. The browser address bar displays the URL: `134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/ListStudySubjects`. The page title is "Subject Matrix for CPT". The interface includes a navigation menu with options like "Home", "Subject Matrix", "SDV", "Notes & Discrepancies", and "Tasks". A search bar is present with the text "Study Subject ID" and a "Go" button. The main content area displays a table of study subjects.

Study Subject ID	Image Preview	Actions
IMG001	 x3	  
Test	 x2	  

Ergebnisse 1 - 2 von 2.

OpenClinica Portal | Help | Contact

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OpenClinica Community  
Version: 3.1-SNAPSHOT - Changeset: c4f62c5a9194+ \*2012-04-12 11:28 +0200\*

# Result

## 5. OpenClinica: CRF selection

The screenshot displays the OpenClinica web application interface. The browser window shows the URL `134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/MainMenu`. The page title is "Enter or Validate Data for CRFs in Image Preview".

**Alerts & Messages:** Welcome to OpenClinica, Thomas Deserno. You last logged in on 06-Feb-2013.

**Instructions:** If needed you may change the study/site or request access to a new study with a different role.

**Other Info:** Study: CPT, Start Date: N/A, End Date: N/A, PI: Aachen, CTC-A, Protocol Verification/IRB Approval Date:

**Icon Key:** Not Started, Scheduled, Data Entry

**Study Event Details:**

Study Subject ID	IMG001
Study Event	Image Preview
Location	N/A
Study Subject OID	SS_IMG001_9913
Start Date	22-Jan-2013
End Date/Time	
Subject Event Status	data entry started
Last Updated by	jgehlen (22-Jan-2013)

**CRFs in this Study Event:**

CRF Name	Version	Status	Initial Data Entry	Double Data Entry	Actions
IMG Button	1.2		jgehlen		

**Workflow:** Study Event Overview → Data Entry → Mark Event CRF Complete



# Result

## ■ 5. OpenClinica: image upload

The screenshot shows a web browser window with the following details:

- Browser: Firefox
- Tab: OpenClinica Initial Data Entry
- Address Bar: 134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/InitialDataEntry?eventCRFid=2&exitTo=ViewStudySubject?id=2
- Page Title: Conjunctival Provocation Test 1.0
- Page Content: A form titled "Patient Data" with the following fields:
  - 1 Name: Patient, Test
  - 2 Date of birth: 16-Aug-1972
  - 3 Sex: male
- Buttons: Save, Exit, Return to top



# Result

## ■ 5. OpenClinica: image upload

The screenshot shows a Firefox browser window with the OpenClinica Initial Data Entry interface. The page title is "Conjunctival Provocation Test 1.0" and the status is "Test". The interface includes a "CRF Header Info" section with a navigation bar showing "Patient...(3/3)", "Image U...(0/2)", and "Image A...(0/7)". A modal window titled "Image Upload" is open, displaying instructions and a form with two rows: "Control:" and "Response:". Each row has a text input field and a "Click to upload file" button. The modal also contains "Save" and "Exit" buttons at the bottom.

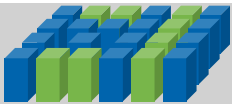


# Result

## 5. OpenClinica: image upload

The screenshot shows a Firefox browser window with two tabs: "IMI Project Management Database 3..." and "OpenClinica Initial Data Entry". The address bar displays the URL: "134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/InitialDataEntry?eventCRFid=2&sectionId=2&tab=2&exitTo=ViewStudySubject?id=2". The page content includes a title "Conjunctival Provocation Test 1.0" and a "Test" label. Below the title is a "CRF Header Info" section with a dropdown menu showing "Patient...(3/3)", "Image U...(0/2)", and "Image A...(0/7)". A modal dialog box titled "Image Upload" is open, displaying the following fields and buttons:

- Title: Image Upload
- Instructions:
- Page: Save Exit
- Control:  Click to upload file
- Response:  Click to upload file
- Return to top Save Exit

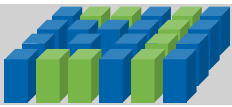


# Result

## 6. OpenClinica: image display

The screenshot displays a web browser window with the following details:

- Browser:** Firefox
- Page Title:** OpenClinica Initial Data Entry
- URL:** 134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/InitialDataEntry?eventCRFId=2&sectionId=2&tab=2&exitTo=ViewStudySubject?id=2
- Page Content:**
  - Section:** Conjunctival Provocation Test 1.0
  - CRF Header Info:** Image U...(2/2), Patient...(0/3), Image U...(0/2)
  - Form Title:** Image Upload
  - Instructions:** Please fill out all the questions and if an answer is unknown use the flag.
  - Fields:**
    - Control:** \_control20120806123838-0400.jpg (with Replace and Remove buttons)
    - Response:** \_response20120806123909-0400.jpg (with Replace and Remove buttons)
  - Buttons:** Save, Exit, Calculate, Return to top



# Result

## 7. OpenClinica: result images and measurements

The screenshot shows a web browser window with the URL `134.130.12.129/OpenClinica-web-3.1-SNAPSHOT/InitialDataEntry?eventCRFid=2&sectionId=2&tab=2&exitTo=ViewStudySubject?id=2`. The page title is "Conjunctival Provocation Test 1.0" and the status is "Test".

The form includes a "CRF Header Info" section with navigation buttons for "Patient... (0/3)", "Image U... (0/2)", and "Image ... (7/7)". Below this is a "Title: Image Analysis" section with instructions: "Please fill out all the questions and if an answer is unknown use the flag." The form also has a "Page:" section with a "Mark CRF Complete" checkbox, "Save", and "Exit" buttons.

Two eye images are displayed side-by-side. The left image is labeled "response:" and the right image is labeled "result:". Below the images is a table of measurements:

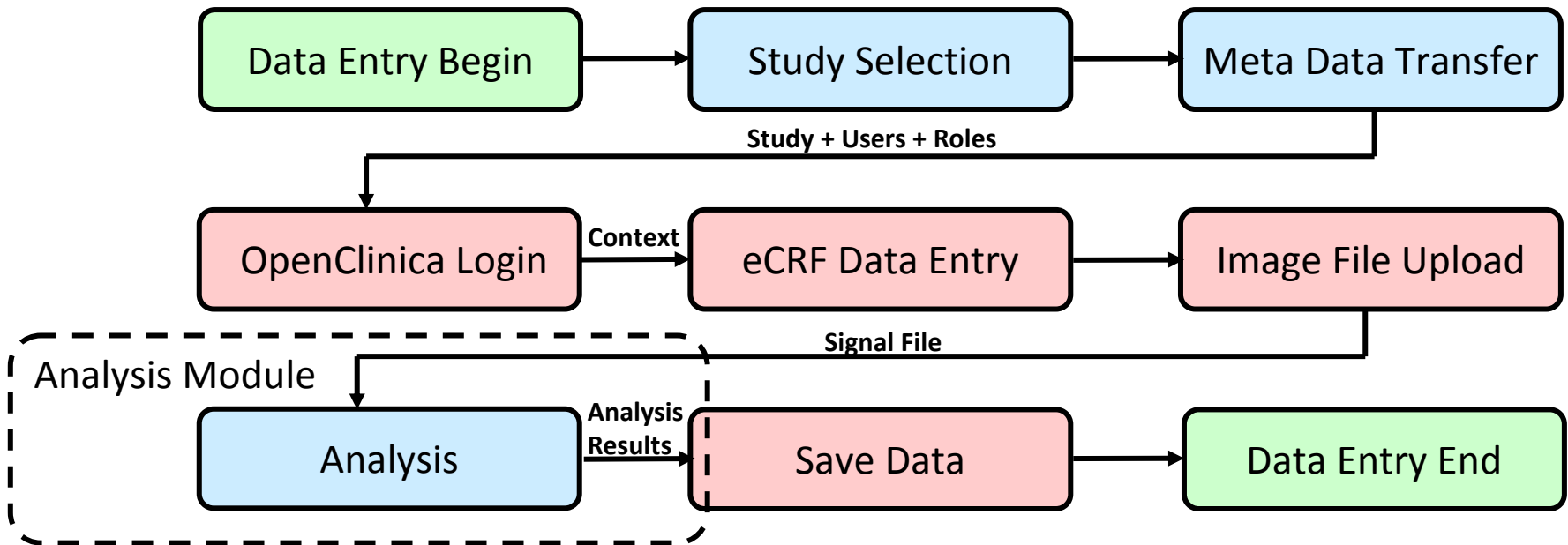
Field	Value	Unit
1 Image width	3648	Pixel
2 Image height	2736	Pixel
3 Control ROI	107333	%
4 Control redness	0.05255	Pixel
5 Responsive ROI	12.3183	%
6 Responsive redness	0.078512	Pixel
7 Relative redness	1.494	Pixel

At the bottom of the form, there is a "Return to top" link, a "Mark CRF Complete" checkbox, and "Save" and "Exit" buttons.

# Summary

## ■ Workflow

- Automatic
- Real-time ready

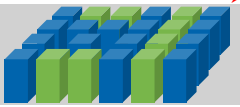




# Summary

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- Image analysis for controlled clinical trials
  - Java code for image processing
  - OpenClinica for eCRFs
- Data integration
  - Web services (SOAP)
  - CDISC ODM well-formed XML
- Functional integration
  - JavaScript
  - PHP proxy
- Workflow integration
  - Single sign on





# Future Work

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- Improvements

- Browser refresh
- Open / close after automatic eCRF fill
- Image processing runtime
  - ◆ Synchronous vs. asynchronous transfer

- Extensions

- RIS / HIS interface (HL7, CDISC-LAB)
- PACS interface (DICOM)
- Pseudonymization and randomization services

