



Lesson Learned from Integrating OpenClinica with Other IT Systems

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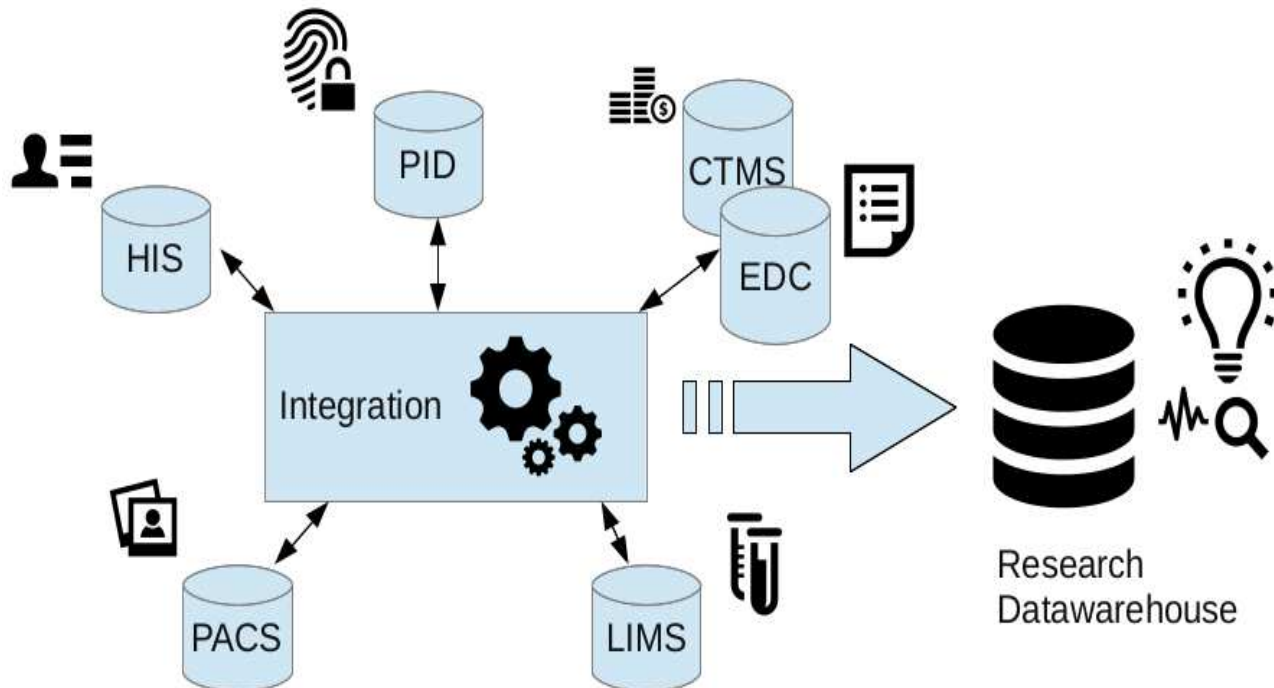
- German Consortium for Translational Cancer Research
 - Building efficient translational research units focused on cancer research
 - CCP (Clinical Communication Platform) in DKTK handles recruitment of uniquely annotated and stratified cancer patients into translational research projects and trials

- **RadiationDosePlan-Image/Biomarker-Outcome** platform provides sustainable radiotherapy specific IT infrastructure
 - Large scale clinical trials
 - Collection of imaging data and treatment plans

Why healthcare systems integration



- Create a uniform layer which connect federated clinical and non-clinical IT systems so they can:
 - Leverage each other functions
 - Exchange and use each other data



Integration and interoperability



- Interoperability
 - Syntactic = ability to exchange data
 - Semantic = ability to meaningfully interpret data and use it
- What makes it tick:
 - Protocols (HTTP, ...)
 - Services (REST, SOAP, ...)
 - Data formats (XML, JSON, ...)
 - Terminologies, ontologies, data elements and information models (ICD10, UMLS, CDASH, CDISC ODM)



Common integration artifacts

- SingleSignOn (SSO): unify user credentials
- Enterprise service bus (ESB): unify communication
- Common identifiers (patients, specimens, ...)
 - Global IDs
 - ID list services
- Reverse proxy: hide the complexity of underlying infrastructure = one public IP, one domain, one identity
- Common systems in clinical research IT environment:
 - HIS, Pseudonym generator, CTMS & EDC, PACS, LIMS...

OpenClinica integration abilities



- LDAP users
- SOAP web services
- REST
 - Web services
 - RESTful URLs
- eCRFs enhancement (HTML + JavaScript)
- Alternate ways
 - Program web access with HTML document parsing
 - Direct access to OC database

SingleSignOn



- LDAP users feature: make SSO possible BUT!!!
 - LDAP user can not use SOAP web services
- Solution 1:
 - Standard OC user as the primary account
 - OC SOAP study ws (listAll) for authentication or,
 - OAuth OC REST services
- Solution 2:
 - Auto-generated OC user account
 - Navigation to OC from external system (auto-login)
 - POST user credential

OC Web services - SOAP



- Reliable and secure
- Deployed as separate web app
- Limited set of features
- REST seems to be the future direction
- Some features not working e.g.
 - Secondary ID field ignored in subject creation
 - StudySubjectID generation properties ignored
 - Auto StudySubjectID: empty string required
 - Gender property always mandatory

Web services REST



- Originally designed for OC Designer
 - *designer is freshly open sourced :)
- Currently very limited features
- RESTful URLs
 - POST/GET approach (user credential, JSON/XML formatted CDISC ODM clinical data)
 - User credentials in clear text

```
import requests
```

```
session=requests.Session()
```

```
loginData={"j_username": "ocuser", "j_password" : "pass"}
```

```
r=session.post("http://server/OpenClinica/j_spring_security_check", loginData)
```

```
r=session.get("http://server/OpenClinica/rest/clinicaldata/json/view/S_DEFAULTS1/SS_XXY/*/*?includeDNs=y&includeAudits=y")
```

eCRFs enhancement



- JavaScript make it possible to
 - Programmatically work with data from eCRF
 - Trigger external web service/ web application
- Make any eCRF data field easily navigable:
 - `RIGHT_ITEM_TEXT (<div id="uniqueIdentifier"> </div>)`

```
var fieldRow = document.getElementById(divFieldName).parentNode.parentNode;  
var input = fieldRow.getElementsByTagName('input')
```
- Domain specific annotations of eCRF fields
 - E.g. in external DB
 - When reliable access to data needed

Alternate ways



- Whatever a user can see a program can see
 - Program access to OC and parsing of HTML DOM tree
 - *not very sustainable (depending on generated HTML)
 - OK for administration usage

- Direct access to OC DB
 - *can be a security issue
 - *can slow down the production DB performance
 - Read only please (bypassing OC application logic)

- Use only as a last resort

Common identifier

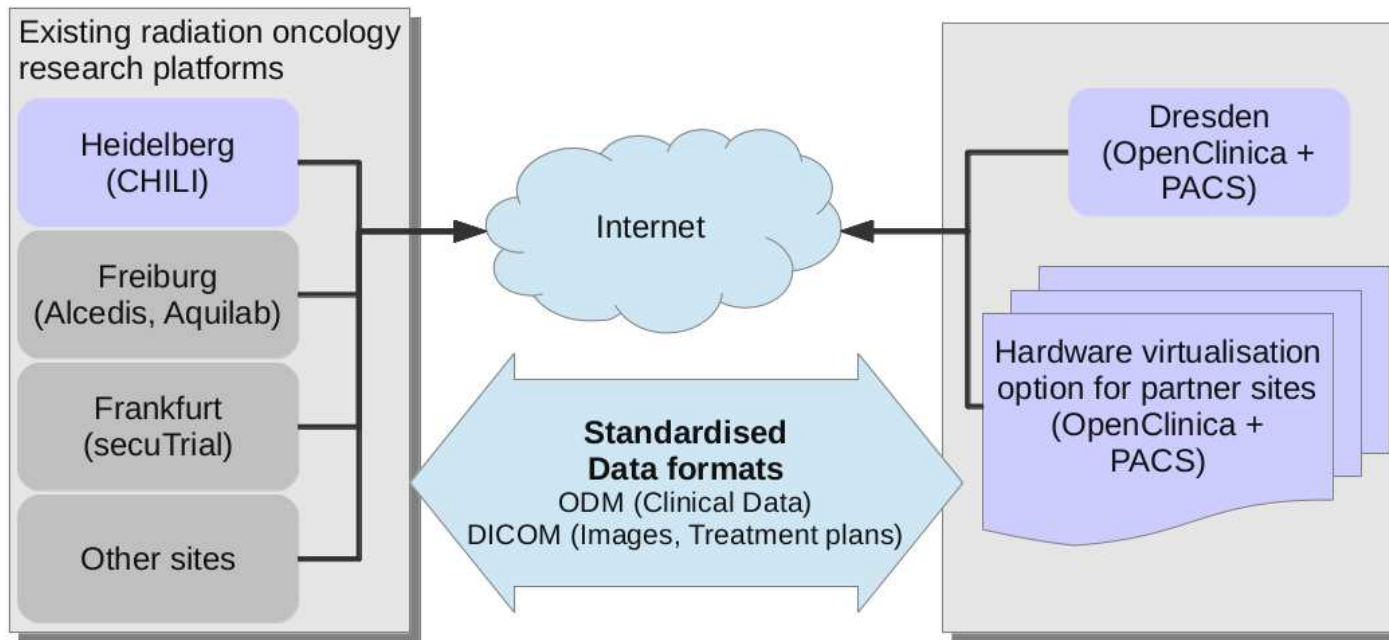


- StudySubject
 - Tracking patient across studies: Person ID (pseudonym)
 - Merging patient data from another system (e.g. HIS)
 - StudySubject secondary ID
 - Merging patient data from multiple systems
 - PatientID List service (keep the links between IDs separate)
- Saving IDs from different systems in eCRF
 - Make sure data fields are annotated
 - PHI flag if not exportable

Example: RadPlanBio platform



- Sustainable IT solution focused on clinical/ preclinical trials
- Radiotherapy specific study features: treatment plans and imaging data
- Multi-centre data exchange and collection (national and international translational projects)

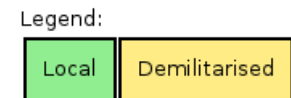
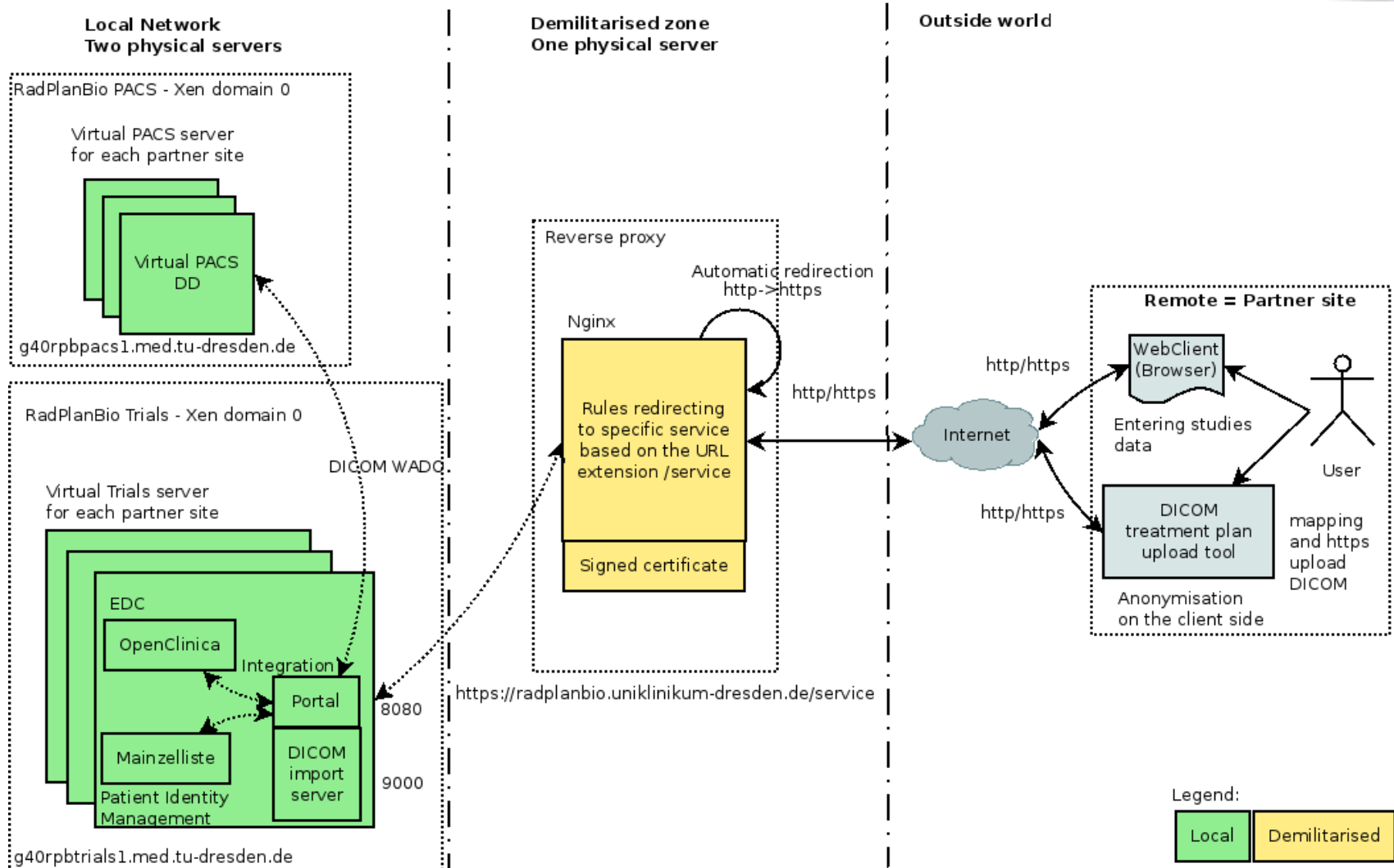


RadPlanBio components



- Highlighted features:
 - Virtual server infrastructure with partitioned secured areas for each partner site
 - Imaging data base on DICOM and DICOM RT standards
 - Support for randomisation in clinical trials (Randi2)
 - OpenSource
 - Deployment: web access, hosting, local installation
- Main components:
 - EDC & CTMS: OpenClinica
 - Patient identity management service: Mainzelliste
 - PACS server & DICOM viewer: Conquest, DWV
 - Desktop client: DICOM data upload
 - Portal: integration & single access point

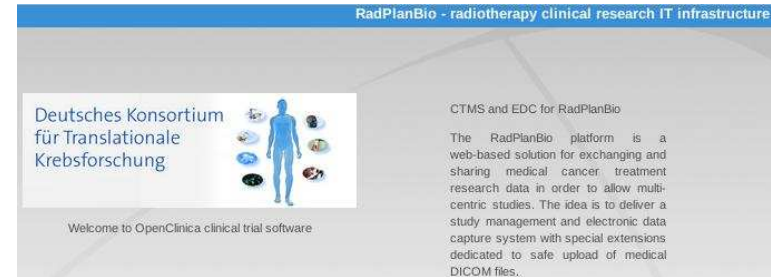
Deployment example



Integration portal



- Platform infrastructure database
 - Enable systems communication
- Unify access web access
 - Single URL + SSO
- Integrate RadPlanBio components
 - OC, Conquest, Mainzliste
- Extra features
 - Randomisation based on Randi2



Use case: patient registration



- Separate database of patient identities
 - Patient => PID (pseudonym)
 - DB per site

- PID generation
 - 8 character string
 - (read-write fault tolerant)

- Record linkage
 - phonetic code matching
 - configurable for many languages
 - (hear-write fault tolerant)

- Technology: REST Mainzliste + SOAP OpenClinica



Create a new study subject

Generate PID for patient subject with PID generator:	<input checked="" type="checkbox"/>
Selected study: *	PETra
Selected partner site: *	STR-PETra-2013
Secondary label:	<input type="text"/>
Enrollment date: *	05.05.2014 <input type="button" value="📅"/>
Gender: *	<input checked="" type="radio"/> Male <input type="radio"/> Female
PID generator (pseudonymise the patient):	http://g40rbtrials1.med.tu-dresden.de:8080/mainzlisteDD-1.1/
First name: *	<input type="text" value="Tomas"/>
Last name: *	<input type="text" value="Skripcak"/>
Maiden name:	<input type="text"/>
Birth date: *	09.04.1986 <input type="button" value="📅"/>
Place of residence:	<input type="text" value="Trnava"/>
ZIP code:	<input type="text"/>
Generated patient PID:	0003Y0WZ
<input type="button" value="Generate"/>	
<input type="button" value="Submit"/> <input type="button" value="Reset"/>	

Use case: DICOM data upload



- Desktop client
 - SSO – OC ws SOAP
 - Study/subject/event/item browse
 - DICOM clinical trial deidentification
 - Utilisation of patient PID
 - DICOM suppl. 142
 - DICOM ROI harmonisation
 - Standard organ naming
 - Uploading DICOM data
 - Auto import to PACS
 - Import DICOM eCRF
- Technology:
 - REST + SOAP OpenClinica
 - eCRF enhancement

The screenshot displays the RadPlanBio Desktop Client interface. A large black arrow points upwards from a server icon, indicating data upload. The main window shows patient and study details, and a dialog box for mapping ROI names.

Selected DICOM Study

DICOM patient:

ID: radicals1 -> 0003YOWZ
Name: Aarhus1 -> XXX
Gender: -> -
DOB: -> 19000101

DICOM study:

Study type: TreatmentPlan
Description: -> -

DICOM study series

Filter: -

Modality	Original description	New description
1 RTSTRUCT		
2 RTPLAN		
3 RTDOSE		
4 CT		

ROIs mapping:

Mapping ROI names

	Original Name	Assigned Name
1	BODY	Bone
2	Rectum	Rectum
3	CTV	CTV
4	PTV	PTV
5	Bladder	Bladder
6	o PTV	PTV
7	o Rectum post	Rectum
8	o Bladder	Bladder

Use case: PACS integration



- Conquest
 - PACS extensions with Lua scripts
 - Querying PACS server
 - JSON formatted DICOM study
 - ZIP and download
- Configurable DICOM viewers
 - Communication over WADO
 - HTML5 = DWV
 - Java = Weasis
- Technology:
 - Lua
 - REST
 - eCRF enhancement
 - WADO



portal Dresden adminidd Logout Home

[DICOM patient studies overview](#)

Patient PID:

DICOM Studies | DICOM Study Series

Print Help

List of study series within selected study in PACS Search all fields:

Instance UID	Time	Description	Modality	
274944458998193203269749210242360216737	000000.000000		CT	Via
7157544831935593499368188534137816			RTSTRUCT	Via
1458633447635710007057118760519708			RTPLAN	Via
2647362904167963026204240018754690			RTDOSE	Via

There are 4 DICOM series in selected study.

Wish list - now



- Unification of web services strategy
 - REST base
 - Migrate all services from SOAP (study subject, data import)
 - Preferred OAuth 2.0 authentication
 - Side effect: LDAP fully usable
- Direct support for semantic annotation in CDISC ODM
 - E.g. `<Alias Context="UMLS" Name="C1880229">` aka DICOM Study
- Randomisation as a first class citizen
 - Subject group class
 - E.g. Randi2

Wish list - future



- Direct support for controlled terminology
 - ICD 10, ICD-O-3, ...
- Pluginable architecture for OC
 - Advanced OC modularisation
 - Dynamic loading/unloading of plugins
 - Spring-plugin...
- User changeable localisation
- Reporting
 - Custom reports

Thanks for your attention...



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