Achieving Efficiency in Clinical Data Management through OpenClinica Integration with a Patient Monitoring System

DNDi
Drugs for Neglected Diseases *initiative*

#OC15Europe

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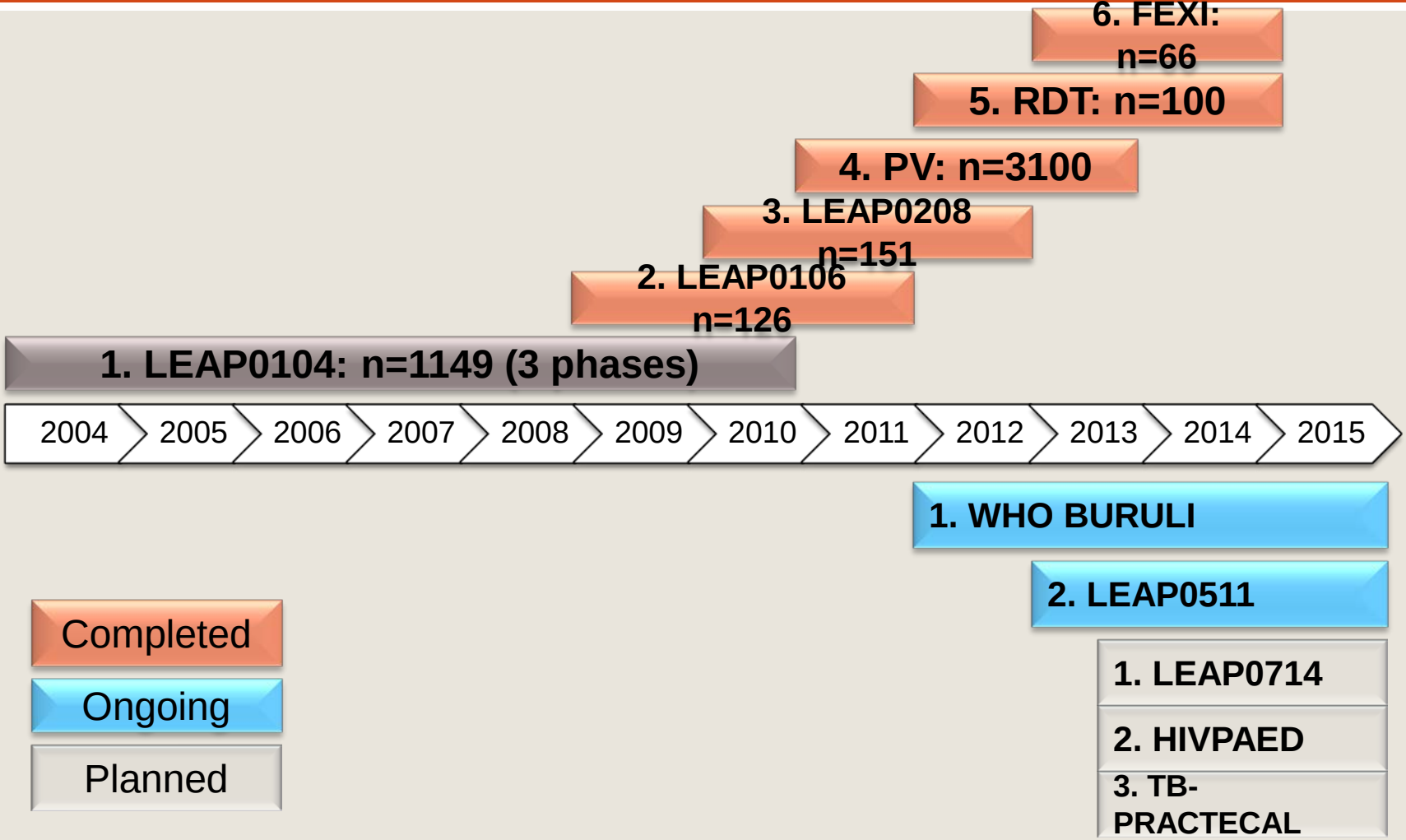
Presentation Outline

- Introduction
  - About DNDi DC
  - About PHPT
  - OpenClinica studies at DC
- OpenClinica integration with PMT
  - Need for integration
  - Methodology
  - Challenges
  - Conclusion

Introduction

- **DNDi** - A collaborative, patients' needs-driven, not-for-profit **Research and Development (R&D)** organization that develops safe, effective & affordable treatments for neglected diseases (www.dndi.org).
- **Data Centre** is a department within the DNDi Africa regional office
- Primary responsibility:
  - Data Management
  - Statistical Analysis
  - IT Support
- **PHPT** - The PHPT clinical research group in Thailand includes a network of over 50 public hospitals. Its coordination center in Chiang Mai is responsible for protocol development, training, monitoring of onsite activities, data processing and analysis, logistics, drug distribution and administration (www.phpt.org).

OpenClinica Studies at DC



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Need for integration

- In clinical trials (CTs), data monitoring is critical in assuring the integrity of any study.
- Clinical data management (CDM) which includes data collection and storage is equally important and both need to be performed in an efficient and reliable way to ensure;
  - timely production of results
  - And adherence to ICH-GCP principles.
- Using OpenClinica as a CDM system and a PMT as the study monitoring system, we have developed an integrated system with the two software;
  - allowing for easy monitoring by grouping related subject CRF data
  - Providing monitors with near real-time online access to patient data.

Integration objectives

- To determine the **turn-around time** gain to clean dataset by using an Integrated Data management and monitoring solution.
- To evaluate the **error rate change** between the traditional data management system and the integrated system.
- To determine **monitor's acceptance** of the integrated solution.

Related Questions

- What are the **success factors** to consider when transitioning from traditional monitoring to electronic monitoring in resource constrained settings?
- What are the **key features of an eCRFs** monitoring system for use in areas with poor telecommunication infrastructure?
- What are the **technological challenges** associated with implementation of eCRF monitoring solutions?

Methodology

- Review of Current DM approaches at DC
- Need for eMonitoring
- Proposed Integrated systems approach
- Discussion

Current DM approaches at DC

Paper CRF

- Paper CRFs collected by Monitors from sites
- Paper CRFs delivered to the DC by monitors
- DC Staff enters data into OpenClinica
- Queries raised in QMSPlus and sent to site

Hybrid eCRF

- Based on off-line implementation of OpenClinica
- Not purely EDC: Paper CRF also used as source document by the site
- A local installation of OC is done at the site computer-site investigators enter data into OC
- Site OC instance periodically synchronized with Main database at DC

Pure eCRF

- Purely EDC using OpenClinica
- Database hosted at the DC Server accessed at the site for data entry
- Query Management handled using OC Discrepancy management
- Site user training and intense DB testing is of high priority

Proposed Integrated Monitoring approach

- Using HIV Pediatrics Study (LIVING STUDY) as a case study.
- Need to know areas to concentrate on during the scheduled monitoring visits
- Need to reduce workload during monitoring visits so as to concentrate on review of critical data
- Need to identify areas that might go wrong way before the scheduled visits for corrective actions
- Need to reduce monitoring costs???

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OpenClinica integration with PMT

- Software Used;
  - OpenClinica –Clinical Data Management System
  - PMT – Clinical Monitoring software
  - OC Data Mart – Community DataMart availing data to the PMT

Patient Monitoring Tool

- Provides collated real-time view of study subject data in a single page for ease of monitoring.
- Originally developed in php language with mysql database back-end.
- Customized by PHPT team to access and display OpenClinica data via Community Data Mart
- Used alongside CRF Upload tool, Electronic document repository and SAE reporting Tool

PMT User Interface

S_DEFAULTS1 *LIVING study* | **DNDi-LIVING**

Monitoring by | Drop out

LV001	MO	Male	Height: 11 *cm*	Weight: 22 *kg*	
Born: 19-Feb-2015			Age: 0.3 year	Enrolled: 19-Feb-2015	End of Follow up
Select patient...			HIV stage: 1	Next visit: 09-Feb-2015	

Demog | Medic | CBC,Chem | CD4,VL | Treat | AE&CT | SAE | Com | CRFs | MENU | LOGOUT

Complete Blood Count (CBC)

Visit	Blood Draw Date	Blood Draw Time	Hemoglobin g/dL	Hematocrit	MCV fL	Platelets µL	WBC	Neutrophils		Lymphocytes		Monocytes		Basophils		Eosinophils		Comments
LAST VISIT	19-May-2015	17:05	15.0	43%	83.0	247	5.5	31%	1.84	49%	3.03	5%	0.31	0%	0.5	12%	0.65	OK
YEAR 3	19-Feb-2015	16:50	15.0	43%	83.0	267	6.5	31%	1.84	51%	3.03	5%	0.31	0%	0.5	12%	0.65	OK
MON 30	19-Aug-2014	17:45	15.0	43%	83.0	267	5.5	31%	1.84	49%	3.03	5%	0.35	0%	0.5	12%	0.65	ELEVATED PLATELETS
YEAR 2	19-Feb-2014	17:00	15.0	43%	83.0	247	6.5	31%	1.87	49%	3.03	5%	0.34	0%	0.5	12%	0.65	OK
MON 18	19-Aug-2013	17:00	15.2	43%	83.0	247	5.9	31%	1.84	49%	3.33	5%	0.31	0%	0.5	12%	0.65	NORMAL
YEAR 1	19-Feb-2013	17:15	15.4	43%	81.0	235	6.1	31%	1.84	49%	3.33	5%	0.35	0%	0.8	12%	0.65	OK
MON 6	19-Aug-2012	17:00	15.0	43%	83.0	247	5.9	31%	1.84	51%	3.03	5%	0.31	0%	0.5	11%	0.67	NORMAL
SCREENING: LABS	19-Feb-2012	16:00	15.0	43%	83.0	240	5.5	31%	1.84	51%	3.03	5%	0.35	0%	0.5	11%	0.65	RESULTS OK

Blood Chemistry

Visit	Blood Draw Date	Blood Draw Time	SGPT / ALT	SGOT / AST	Bilirubin		Albumin	Creatinine		Comment
LAST VISIT	19-May-2015	10:00	13.4	18.2	17.7	µmol/L		22.3	µmol/L	OK
YEAR 3	19-Feb-2015	10:00	13.4	18.2	17.7	mg/dL		17.7	mg/dL	NORMAL RESULTS
MON 30	19-Aug-2014	09:56	13.5	58.3	17.6	µmol/L	17	22.3	µmol/L	Abnormal AST
YEAR 2	19-Feb-2014	11:00	13.4	20.5	17.6	µmol/L	20	17.7	µmol/L	OK
MON 18	19-Aug-2013	10:15	15.1	20.5	17.7	µmol/L		17.7	µmol/L	OK
YEAR 1	19-Feb-2013	09:09	13.5	18.2	17.7	µmol/L		22.3	mg/dL	Normal Results
MON 6	19-Aug-2012	10:35	13.4	18.2	17.7	mg/dL		22.3	µmol/L	Normal Blood chemistry
SCREENING: LABS	19-Feb-2012	10:09	13.4	18.2	27.7	µmol/L		22.3	µmol/L	NORMAL RESULTS

Other PHPT Tools used with PMT

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Intranet tools for the clinical trial DNDi - LIVING


Transmission of scanned CRFs and laboratory results to Data Entry


Electronic documents repository


Patient Monitoring interface

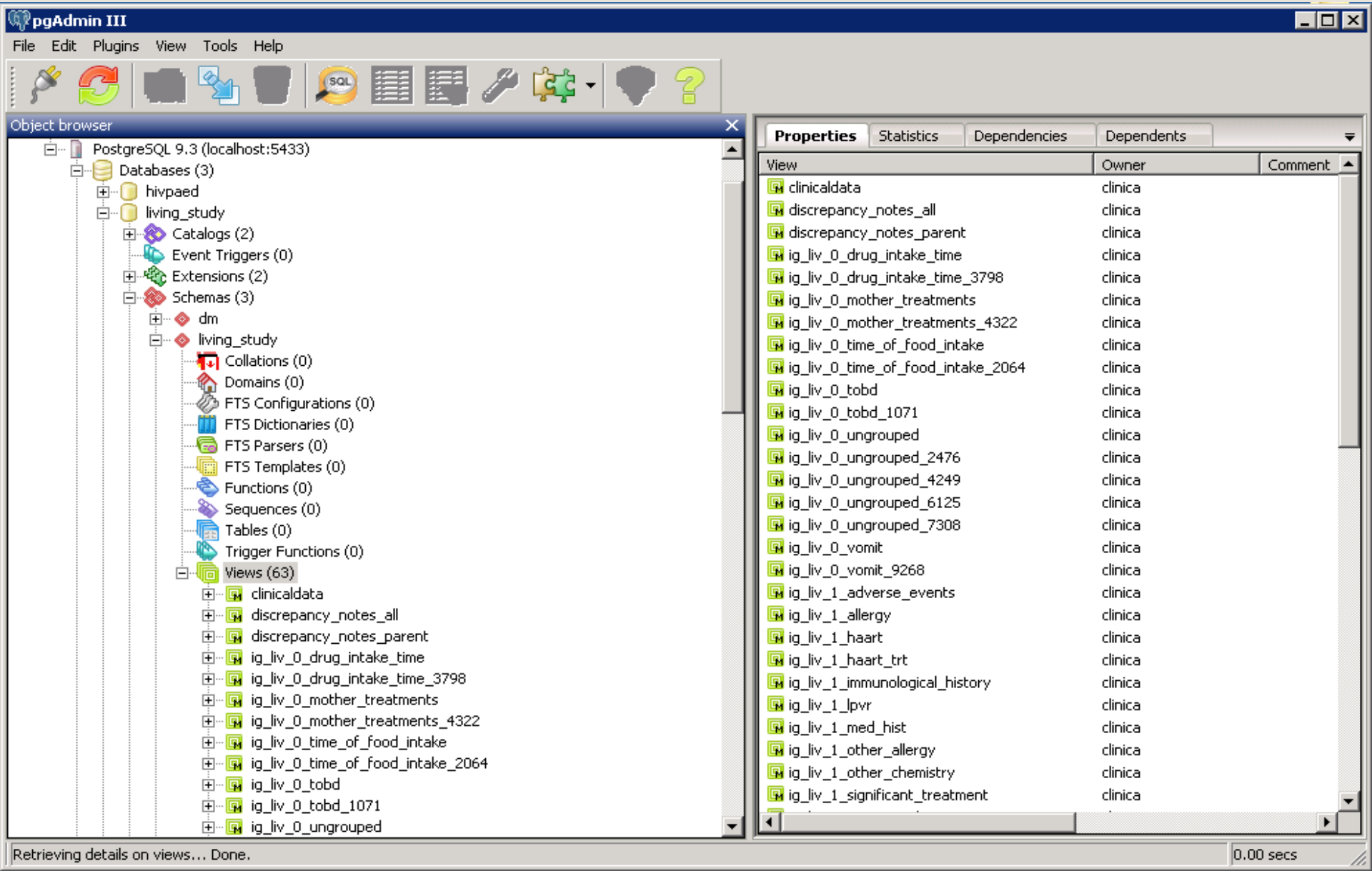

Tools for Expedited Adverse Event (EAE) reports

PHPT - October 2014

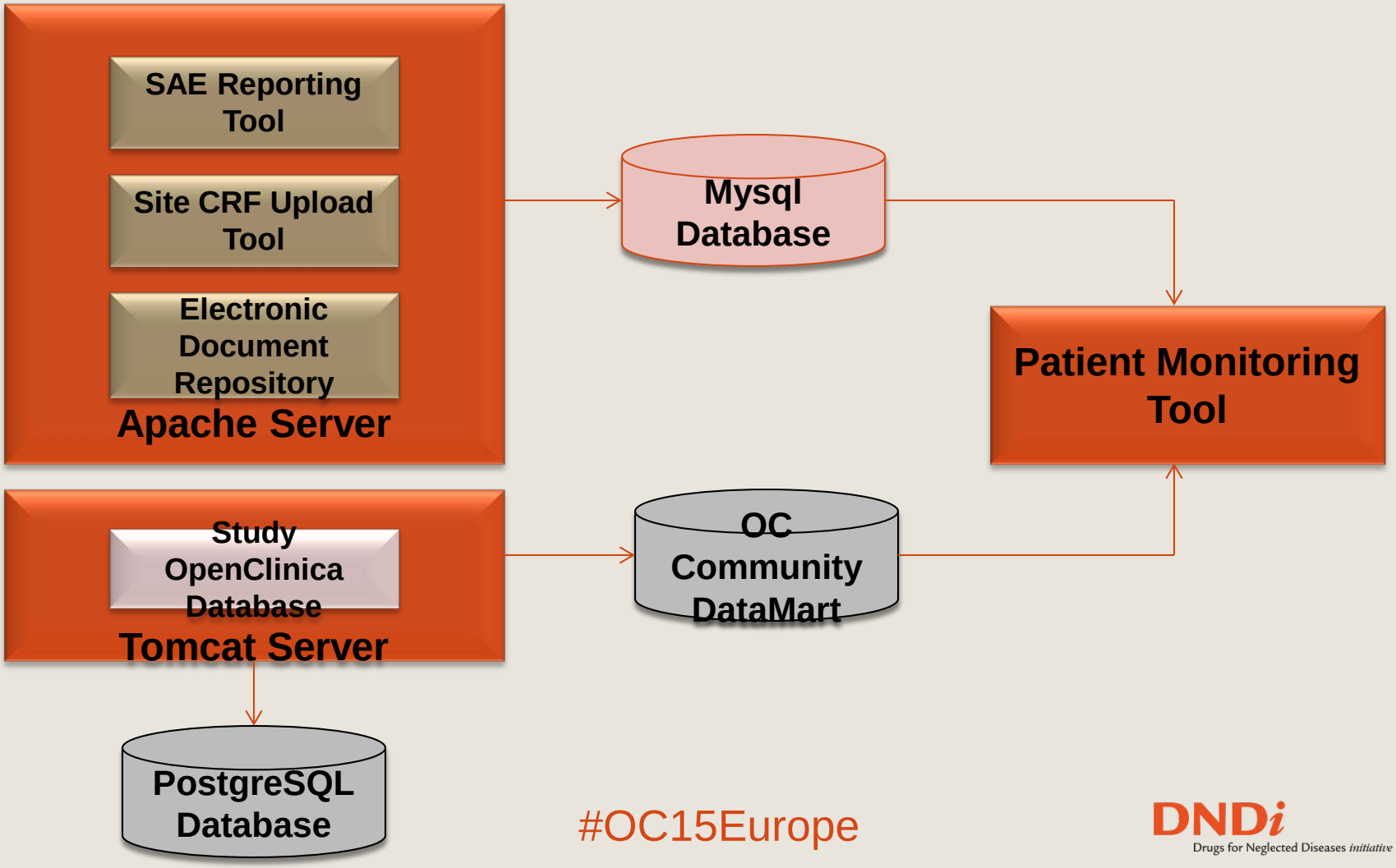
OC Community DataMart

- Developed by Lindsay Stevens and available from (https://github.com/lindsay-stevens-kirby/openclinica_sqldatamart)
- Dependencies
  - Windows OS (tested with Server 2008 R2, Server 2012 ,64-bit, and Windows 7)
  - Postgres (tested with 9.3, 64-bit)
  - Postgres ODBC drivers (tested with 9.02.0100, both 32-bit and 64-bit installed)

OC DataMart Views



OpenClinica Integration with PMT



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Integration overview

Site Activities

Scan and upload paper CRFs on to CRF Upload database

Data Center

- Enters CRF data into OC from electronics documents repository
- Allows for double data entry
- Raise Queries to site

Monitors

- Source data verification through PMT
- Have access to the scanned CRFs in the electronic document repository
- Flag discrepancies to site

Challenges

- Expected challenges include:
  - Changes to eCRF will not be automatically reflected on the PMT-
    - most part of the s/w is hard corded (work in progress).
  - Technological challenges such as internet reliability at sites.
  - Data entry from scanned CRFs into OpenClinica
    - new ways of doing things

Conclusion

- OpenClinica and PMT Integration presents an interesting Data Management and monitoring approach for the DNDi Africa.
- We hope that this approach will reduce the turn-around time for getting clean study dataset.
- The quality of data collected is expected to increase, with data errors reduced significantly as data is monitored as soon as recorded and queries raised and resolved as soon as possible.

Asante sana

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www.connect2fightneglect.org

www.dndi.org

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