

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

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Introduction

Need for Integration:

- In clinical trials, data monitoring is critical for assuring the integrity of any study.
- Clinical Data Management (CDM) is equally important and both need to be performed in an efficient and reliable way to ensure:
 - Timely production of results
 - Adherence to ICH-GCP principles
- Using OpenClinica as a CDM system and a Patient Monitoring Tool (PMT) as the study monitoring system, we have developed an integrated system:
 - 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.

Related Questions:

To determine **monitors' acceptance** of the integrated solution.

- What are the **success factors** in transitioning from traditional to electronic monitoring in resource constrained settings?
- What are the **key features of an eCRFs** monitoring system 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 the Data Centre
- Need for eMonitoring
- Proposed Integrated systems approach

Discussion

Current DM approaches at Data Centre

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 to focus on review of data
- Need to identify areas that might go wrong before the scheduled visits
- Need to reduce monitoring costs

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

The Patient Monitoring Tool

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

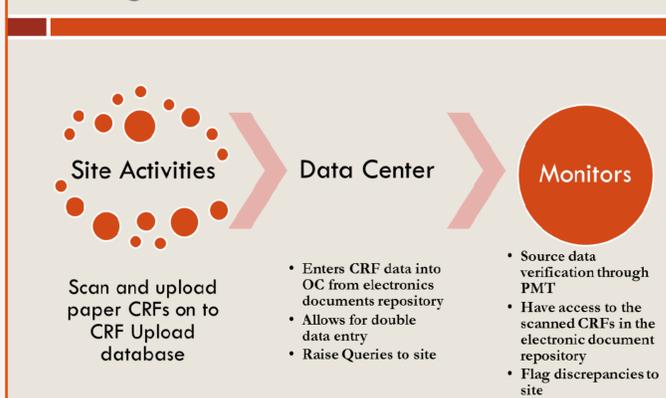
OpenClinica Community Datamart

Developed by Lindsay Stevens and available from (https://github.com/lindsay-stevens-kirby/openclinica_sqldatamart).

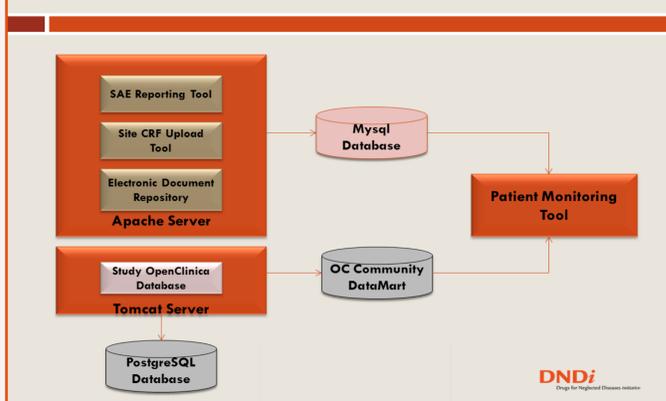
Dependencies:

- 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)

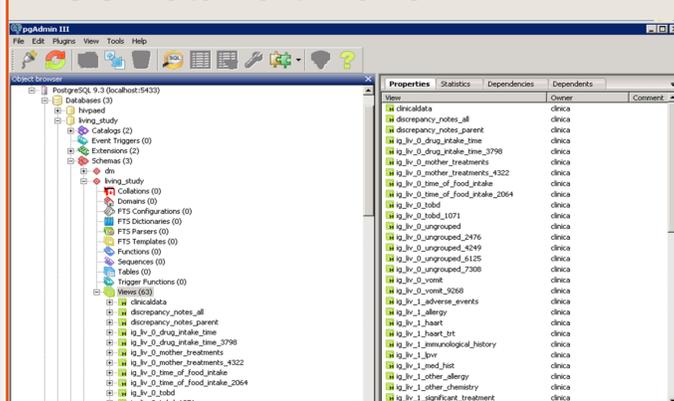
Integration overview



OpenClinica Integration with PMT



OC DataMart Views



PMT User Interface

Visit	Date	Time	Hemoglobin g/dL	Hematocrit %	MCV fL	Platelets μ L	WBC	Neutrophils %	Lymphocytes %	Monocytes %	Basophils %	Eosinophils %	Comments				
LAST VISIT	19-Feb-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	297	6.5	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 8	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	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

Challenges

Expected challenges include:

- Changes to eCRF will not be automatically reflected on the PMT- most part of the software is hard coded (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 DNDi Africa.
- We hope this approach will reduce the turn-around time for receiving clean study datasets
- 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.