Proposed Integrated Monitoring approach

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
- 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)

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

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.

Challenges
- 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 queried raised and resolved as soon as possible.