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

Michael Ochieng, Raymond Omollo, 1st June 2015

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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

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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](http://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](http://www.phpt.org)).

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OpenClinica Studies at DC

1. LEAP0104: n=1149 (3 phases)
   - 2004
   - 2005
   - 2006
   - 2007
   - 2008
   - 2009
   - 2010
   - 2011
   - 2012
   - 2013
   - 2014
   - 2015

2. LEAP0106: n=126
3. LEAP0208: n=151
4. PV: n=3100
5. RDT: n=100
6. FEXI: n=66

Completed
Ongoing
Planned

1. WHO BURULI
2. LEAP0511
1. LEAP0714
2. HIVPAED
3. TB-PRACTECAL

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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.

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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

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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???
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

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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

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## PMT User Interface

### Complete Blood Count (CBC)

<table>
<thead>
<tr>
<th>Visit</th>
<th>Date</th>
<th>Time</th>
<th>Hemoglobin (g/dL)</th>
<th>Hematocrit</th>
<th>MCV [fl]</th>
<th>Platelets [x10^9/L]</th>
<th>WBC [x10^9/L]</th>
<th>Neutrophils</th>
<th>Lymphocytes</th>
<th>Monocytes</th>
<th>Basophils</th>
<th>Eosinophils</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAST VISIT</td>
<td>19-May-2015</td>
<td>17:05</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>247</td>
<td>5.5</td>
<td>31%</td>
<td>1.84</td>
<td>49%</td>
<td>3.03</td>
<td>5%</td>
<td>0.31</td>
</tr>
<tr>
<td>YEAR 3</td>
<td>19-Feb-2015</td>
<td>16:50</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>267</td>
<td>6.5</td>
<td>31%</td>
<td>1.84</td>
<td>51%</td>
<td>3.03</td>
<td>5%</td>
<td>0.31</td>
</tr>
<tr>
<td>MON 30</td>
<td>19-Aug-2014</td>
<td>17:45</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>267</td>
<td>6.5</td>
<td>31%</td>
<td>1.84</td>
<td>49%</td>
<td>3.03</td>
<td>5%</td>
<td>0.35</td>
</tr>
<tr>
<td>YEAR 2</td>
<td>19-Feb-2014</td>
<td>17:00</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>247</td>
<td>6.5</td>
<td>31%</td>
<td>1.87</td>
<td>49%</td>
<td>3.03</td>
<td>5%</td>
<td>0.34</td>
</tr>
<tr>
<td>MON 18</td>
<td>19-Aug-2013</td>
<td>17:00</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>247</td>
<td>6.5</td>
<td>31%</td>
<td>1.84</td>
<td>49%</td>
<td>3.33</td>
<td>5%</td>
<td>0.31</td>
</tr>
<tr>
<td>YEAR 1</td>
<td>19-Feb-2013</td>
<td>17:15</td>
<td>15.4</td>
<td>43%</td>
<td>81.0</td>
<td>235</td>
<td>8.0</td>
<td>31%</td>
<td>1.84</td>
<td>49%</td>
<td>3.33</td>
<td>5%</td>
<td>0.35</td>
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<tr>
<td>MON 6</td>
<td>19-Aug-2012</td>
<td>17:00</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>247</td>
<td>6.5</td>
<td>31%</td>
<td>1.84</td>
<td>51%</td>
<td>3.03</td>
<td>5%</td>
<td>0.31</td>
</tr>
<tr>
<td>SCREENING: LABS</td>
<td>19-Feb-2012</td>
<td>16:00</td>
<td>15.0</td>
<td>43%</td>
<td>83.0</td>
<td>240</td>
<td>5.5</td>
<td>31%</td>
<td>1.84</td>
<td>51%</td>
<td>3.03</td>
<td>5%</td>
<td>0.35</td>
</tr>
</tbody>
</table>

### Blood Chemistry

<table>
<thead>
<tr>
<th>Visit</th>
<th>Date</th>
<th>Time</th>
<th>SGPT / ALT</th>
<th>SGOT / AST</th>
<th>Bilirubin [umol/L]</th>
<th>Albumin [g/dL]</th>
<th>Creatinine [mg/dL]</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>LAST VISIT</td>
<td>19-May-2015</td>
<td>10:00</td>
<td>13.4</td>
<td>18.2</td>
<td>17.7</td>
<td>22.3</td>
<td>1.7</td>
<td>OK</td>
</tr>
<tr>
<td>YEAR 3</td>
<td>19-Feb-2015</td>
<td>10:00</td>
<td>13.4</td>
<td>18.2</td>
<td>17.7</td>
<td>22.3</td>
<td>1.7</td>
<td>NORMAL RESULTS</td>
</tr>
<tr>
<td>MON 30</td>
<td>19-Aug-2014</td>
<td>09:56</td>
<td>13.5</td>
<td>58.3</td>
<td>17.6</td>
<td>22.3</td>
<td>17.0</td>
<td>Abnormal AST</td>
</tr>
<tr>
<td>YEAR 2</td>
<td>19-Feb-2014</td>
<td>11:00</td>
<td>13.4</td>
<td>20.5</td>
<td>17.8</td>
<td>22.3</td>
<td>17.0</td>
<td>OK</td>
</tr>
<tr>
<td>MON 18</td>
<td>19-Aug-2013</td>
<td>10:15</td>
<td>15.1</td>
<td>20.5</td>
<td>17.7</td>
<td>22.3</td>
<td>17.0</td>
<td>OK</td>
</tr>
<tr>
<td>YEAR 1</td>
<td>19-Feb-2013</td>
<td>09:09</td>
<td>13.5</td>
<td>18.2</td>
<td>17.7</td>
<td>22.3</td>
<td>17.0</td>
<td>Normal Blood chemistry</td>
</tr>
<tr>
<td>MON 6</td>
<td>19-Aug-2012</td>
<td>10:35</td>
<td>13.4</td>
<td>18.2</td>
<td>17.7</td>
<td>22.3</td>
<td>17.0</td>
<td>Normal Blood chemistry</td>
</tr>
<tr>
<td>SCREENING: LABS</td>
<td>19-Feb-2012</td>
<td>10:09</td>
<td>13.4</td>
<td>18.2</td>
<td>27.7</td>
<td>22.3</td>
<td>17.0</td>
<td>NORMAL RESULTS</td>
</tr>
</tbody>
</table>
Other PHPT Tools used with PMT

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

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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)
OpenClinica Integration with PMT

Apache Server
- SAE Reporting Tool
- Site CRF Upload Tool
- Electronic Document Repository

Tomcat Server
- Study OpenClinica Database

PostgreSQL Database

Mysql Database

Patient Monitoring Tool

OC Community DataMart

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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

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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.
Thank You to All Our Partners & Donors

www.connect2fightneglect.org  www.dndi.org