Web-Reporting of DataFax Study Data: The Why, the How and the Demo
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WYAS (Why Yet Another System) ?

• Use existing DataFax Reports?
• Existing Graphics tools did not cut it
  – SAS
  – dfRTools
  – Java Programs
• Web-based Study-Portal
  – Covers user-restricted access and content
  – Access by all Parties in a Trial
  – Easy to implement and maintain
Study-Portal Demo

• What is Study-Portal?
  – SAAS-based generic solution to exchange information with all Trial participants and enhance collaboration
  – Secure environment using SSL; User Authorization based on Role-based access per Project
  – Dynamic content filtering per Role per Project: Site will see different content than a Sponsor
  – Fully customizable: create own menu-options and content; Portal Design is customized per client
  – Content can be re-used over Projects
  – Intuitive to use: can be used to communicate with Trial Patients (Blog, Forum)

Sources of Information

• DataFax Meta Files
  – Setup Files (Study Schema)
  – Visit Map
  – Page Map
  – Centers DB

• DataFax Data Files & Reports
  – QC Notes
  – DF_PTCrfs
  – DF_PTVisits
  – DF_PTunexpected
  – DF_PTmissing
Practical issues

• Meta information is ASCII:
  – Many clients each write own ‘import’ programs
  – No direct interface capability
  – Error-prone and time-consuming

• Files contain different ‘sets’ of information:
  – Page Map: VISITS.shortname and PAGES.pagelabel
  – Visit Map: VISITS.fields & PAGES.fields
  – QC notes: DFQCCRT is ‘creation date’ + user
  – DFcenters: CENTERS.fields & Patient_Center Links

Transfer Process

• Automated Script on DF server copies/renames files to webserver
  – Using SFTP
  – To a Secured directory on webserver

• Daemon process on webserver imports files
  – Data imported into set of MySQL Tables
  – Using study reference in filename to include field ‘DFSTUDY’
  – Errors written to log-file
Study-Portal’s ‘DF structure’

- Set of ‘normalized’ Tables & Views, e.g.
  - DFcenters in: DFCENTERS & PTS_CENTERS
  - DF_PTcrfs in: PTS_VISITS & ERRORS

- Linking Studies and Centers
  - Table links:
    - DFSTUDY to PROJ_ID
    - DFcenterno to USER_ID
  - Study-Portal user authorization ensures proper access to Projects (=DF studies)
  - And filters data for any matching USER_ID as found in Table ‘LINKS’ (e.g. filters data ‘by Center’)

DataFax Reports

- Meta Information ‘pulled out’ of reports

EXCERPT FROM DF_PTcrfs:

QC CODES (ordered by priority):
- r = outstanding refax request
- i = unresolved internal QC note
- + = dirty but no unresolved QC notes

OTHER CODES:
- = missing page
- k = registered in the lost data log
- * = error status (missing keys)
- p = pending status (from iDataFax)
- NA = visit date is coded Not Available

<table>
<thead>
<tr>
<th>ID</th>
<th>VISIT DATE</th>
<th>CRF PLATES</th>
</tr>
</thead>
</table>
| 101| 12/06/2009 | 10x 20 30 40 50 60 x 100 x 110 x 120 | 100 x 120
| 101| 17/06/2009 | 7 81 110 125 170 175 189 |
| 101| 28/06/2009 | 80 110 170 175 185 |

Record in PTS_VISITS for each Patient Visit
Record in PTS_PAGES for each Page per Visit
Record in ERRORS for each Missing Page
Merging Information

• Merging Report Information
• Both ‘DF_Ptunexpected’ and ‘DF_Ptmissing’ update ERRORS Table

EXCERPT FROM DF_Ptunexpected:
2 Visit 61: Day 6 or Discharge
Plate(s) : 60,85,86,101,104,110-111,113,116,120,125,275-276,340,421
Problem : unexpected visit; excluded by visit condition 1

EXCERPT FROM DF_Ptmissing:
PATIENT ID VISIT PROBLEM
101 20 Missing Plates: 70 81 110
102 30 Missing Plates: 100 103 112

• Single source of Information facilitates Reporting

Reporting Tool

• Our Requirements:
  1. Available for Apache on Solaris/Linux
  2. Able to access MySQL
  3. Allow embedding in Study-Portal website
  4. Flexibility to filter content by Project/User/Role
  5. Reporting and Graph capabilities
  6. Ability to drill-down
  7. Ability to create Printable version (e.g. .PDF)
  8. Cost-effective
### Reporting Tool (2)

- **Final Choice: i-net Crystal Clear**
  - Java based, wide range of platforms; Database independent
  - Reports can be developed on PC and transferred to webservice
  - Dynamic Reporting (filter by Parameter)
  - Dynamic Formatting (QCnote overdue turns Red if > x days overdue)
  - Dynamic Content (Skip sections)
  - Flexible output: Java, PDF, HTML
  - Multi-language reports (based on Browser or System Language)
  - (Compatible with Crystal reports)

### DataFax Reporting Demo

- Graphical presentation of DF_PT* report content
- QC Note reporting
- Data Quality Graphs
- Patient Recruitment Graphs
EOP

- Questions ?