
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):	OTHER CODES:
r = outstanding refax request	- = missing page
? = unresolved Q&A note	x = registered in the lost data log
i = unresolved internal QC note	* = error status (missing keys)
+ = dirty but no unresolved QC notes	p = pending status (from iDataFax)
	NA = visit date is coded Not Available

ID	VISIT DATE	CRF PLATES
101	1 12/06/2009	10r 20? 30i 40+ 50- 60x 100* 110p 120NA 150
101	20 17/06/2009	70 81 110 125 170 175 185
101	30 25/06/2009	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      60: Day 6 or Discharge  
   Plate(s)   : 60,65,84,101,104,110-111,113,116,120,125,275-276,340,421  
   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 webserver
 - 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 ?