

---

## 2007 USER GROUP VENDOR AUDIT Clinical DataFax Systems, Inc.

Phil Kirsch  
Siwei Hong

John Raso  
Judy Casey



## Overview

---

- Purpose
- History
- Process
  - Plan
  - Reality
  - Results
- Highlights
- Conclusions
- Future



## Purpose

---

### User group audits ...

- Reduce the burden to the vendor
- Promote communication between
  - User Organizations
  - Quality and IT



## Purpose (2)

---

### Software vendor audits ...

- Do NOT remove the need for validation in a local environment
- Provide only a snapshot of the vendor
- Can be skewed by bias and miscommunication



---

## Purpose (3)

But, are required by regulatory agencies because they do provide important checks and balances.



---

## History

- This was the 3<sup>rd</sup> User Group Audit
  - January 2003
  - November 2004
  - May 2007 (with follow-up in August)



## Process

---

- **Announced**
  - At DFUG 2007 (Lake Tahoe)
  - On the DFUG mailing list
- **All interested parties were invited to participate on the basis that**
  - each company or individual would be responsible for his/her own expenses and that
  - the combined report would be freely available to any interested party.



## Audit Team

---

- **Phil Kirsch, Systems Administrator,**
  - Statistical Center for HIV/AIDS Research and Prevention at the Fred Hutchinson Cancer Research Center, Seattle, Washington, USA
- **John L. Raso, Systems Analyst,**
  - Population Health Research Institute, Hamilton, Ontario, Canada
- **Judy Casey, Manager, Clinical Data Management,**
  - Janssen-Ortho Inc., Toronto, Ontario, Canada
- **Siwei Hong, QA/Validation Project Manager,**
  - PDL Biopharma, Inc., Fremont, California, USA



## Plan

---

- Follow PDA Technical Report 32
- Draft report
- Include Vendor Response
- Publish



## Reality

---

- Not enough auditors to complete TR-32
- A narrower focus appeared productive
  - Observations from November 2004
  - Release process for DataFax 3.8
- Follow-up appeared to be in the interest of all parties



## Grading Guidelines for Observations

---

### CRITICAL

- Conditions, practices or processes which could adversely affect study integrity or data management operations and require corrective action.
- Considered unacceptable and require immediate attention.



## Grading Guidelines for Observations

---

### MAJOR

- Conditions, practices or processes, which indicate a high potential for an adverse effect on software integrity and require a corrective action plan.
- Current practices should be reviewed to assure corrective actions are implemented and to assure that practices do not jeopardize compliance status of studies.
- Observations categorized as “Major” may include those situations where there are patterns of deviations, including numerous “Minor” observations.



## Grading Guidelines for Observations

---

### MINOR

- Conditions, practices or processes, that while not expected to adversely affect the quality or integrity of software, are not in compliance with applicable regulations/guidelines and/or SOPs/ policies.
- Observations categorized as minor may become “Major” if not corrected.



## Grading Guidelines for Audit Findings

---

### COMMENTS

- These are suggestions on processes to improve quality, compliance, or procedures to reduce the potential for a deviation to occur.
- “Comments” are intended to enhance the overall quality within the compliance program.
- A response to comments is not required unless this has been specifically requested in the audit report.



## Grading Guidelines for Observations

---

# RESOLVED

Conditions, practices or process questioned by auditors in May 2007 which had been replaced, changed or otherwise corrected prior to the August visit.



## Results

---

- Eleven (11) observations in 8 areas were made during the course of this audit.
- After follow-up, one major and three minor observations remained; the others were resolved.



## Outstanding Finding #1 - Major

---

- There is no method for documenting SOP deviations.

CDSI agreed to revise SOP-PR002 and create a deviation report form by 30 Sep 2007



## Outstanding Finding #2 – Minor

---

In response to Finding #8 of the 2004 audit CDSI agreed to add a 'last review date and name' attribute to each SOP. SOP-PD001 [v1.32, dated 19 April 2007] changed this to indicate that SOP reviews would be noted on the SOP Approval log even if no change was required. However, the SOP log did not contain review dates for any SOP.



## Outstanding Finding #2 - Response

---

"SOP-PD001 was revised 19 April 2007 to include documentation of SOP Review, but implementation was not complete prior to this audit. All SOPs will be reviewed by 15 October, 2007 and the review will be documented in accordance with this SOP".



## Outstanding Finding #3 - Minor

---

- In response to Finding #9 of the 2004 audit which noted that it was unclear how an employee would identify the current, approved version of an SOP, CDSI created a script that publishes a list of approved SOPs. In the training logs there is evidence of an employee training on a draft SOP that was never approved; however, CDSI discovered a software error in that script that lead to this mistake and corrected it before this audit.



## Outstanding Finding #3 – Response

---

"In SOP-PR002 SOPs Training Procedure, we will clarify sections 4.1 and 4.2 (roles of employee and supervisor). We will also modify Table 1 "SOP applicability by department/job function" in section 4 to include the SOP version numbers. Staff can then simply scan the list and compare the version numbers to what's in their individual training logs. It looks like this was intended as the table heading refers to "[Version]", but this was never implemented. This will also make it necessary to revise and approve SOP-PR002 every time any SOP is revised, as the reference to it by version will have changed." To be implemented by 30 September 2007.



## Highlight 1: Security

---

- Physical and logical security is in place.
- Testing environments are separate from production environments.
- The disaster recovery architecture appears sufficient.



## Highlight 2: CRDS

---

- The Change Request Documentation System (CRDS) that runs on top of the Code Version Management System (CVS) provides a good change control and configuration management system with excellent change documentation.
- It integrates the testing, the change information, code information, and user requirements in a single comprehensive system.



## Audit Conclusion

---

- DataFax version 3.8 was developed and manufactured with adequate level of quality for application in clinical operations governed by
  - Good Clinical Practices (GCP),
  - Code of Federal Regulations, (CFR) Chapter 21 Part 11 (Electronic Records and Signatures),
  - and other applicable regulations, guidelines and standards listed in this report.



## You can get a copy from

---

- [www.DFquality.org](http://www.DFquality.org)
- Or by emailing any of the audit team members



## Questions for the Future

---

- **Purpose**  
How can we make the process more useful?
- **Schedule**  
When should the next audit be scheduled?
- **Audit Plan**  
Should we continue using TR-32?
- **Number of auditors**  
Are there suggestions for encouraging future participation by more organizations?



## Provide your feedback to

---

- Phil Kirsch - [phil@ssharp.org](mailto:phil@ssharp.org)
- John Raso = [rasojohn@phri.ca](mailto:rasojohn@phri.ca)
- Judy Casey - [jcasey1@joica.jnj.com](mailto:jcasey1@joica.jnj.com)

