



Auditing eGxP vs Paper

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20 October 2009

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Why focus on eGxP vs Paper?

Industry move to EDC and eClinical
(ePro, eTMF, eCRF etc.)

- Survey 83% of respondents use EDC
- 50% said EDC will increase by >50% over next 2 years
- Infrastructure and technology is available and expanding

*EDC survey conducted by Phoenix Data Systems/PharmaVOICE with more than 6,000 industry professionals



Why focus on eGxP vs Paper?

Attractive solution providing features like:

- Rapid data acquisition and reporting
- Automatic acquisition of measured data
- Integration with other systems
- Less error prone
- Live query management
- Remote access, configurable access
- Increased mobile computing

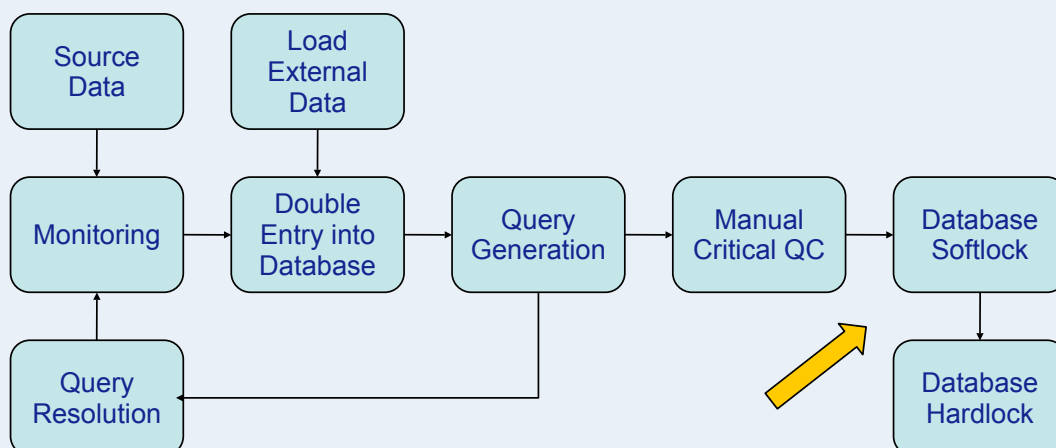


Objectives

- Identify key differences between eGxP and Paper
- Identify some restrictions and benefits of eGxP in auditing
- Identify an overall strategy for eGxP auditing (when, where, how)
- Develop efficient, accurate, risk-based audit scope



Example Paper Study



Audit Approach (Paper)

- Protocol, Data Management Plan, CRF Completion Guidelines
- When? Soft lock stage
- Where? Office where Clinical Data Management is performed
- What? Paper CRFs, DCFs and DM Plan, Sample QC of data
- Who? DM and Clinical Experienced QA

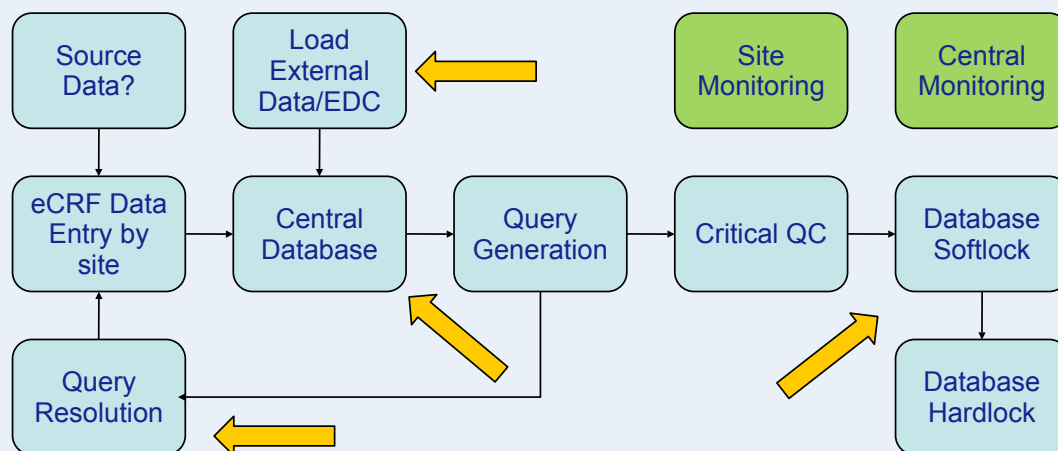


Audit Approach (Paper)

- Review test transfers of external data
- Review electronic lab data results
- QC listings of statistical sample
- Time required approx 5 days
- Limited time for corrective actions due to looming Database Lock



Example eCRF Study



Audit Approach (eCRF/EDC)

- Protocol, Data Management Plan, CRF Completion Guidelines
- When? Live data, several audits, any time
- Where? Office where Clinical Data Management is performed, remote or at Investigator Site



Audit Approach (eCRF)

- What? Processes, Data Transfers, Validation, System integration (EDC), Hybrid, Data, Access
- Who? DM, Clinical and CSV Experienced QA?
- System or Data Audits?
- Ongoing monitoring of Quality System instead of one-off audit



Audit Approach (eCRF)

System Audits

- Site audits
- Vendor audits
- Internal audits
- Part of routine System Audit Plan



Audit Approach (eCRF)

Data Audits

- Best done on site (location of source)
- Percentage of subject records
- Review data changes (audit trail)
- Physical and system security, controlled access to data
- Combine regular data auditing with site audits?



Things to keep in mind

- Harder to detect fraud?
- More focus on validation?
- Calibration of instruments, ECG, Spirometry, Holters etc.
- Electronic Records and Signatures
- Intensive on-site monitoring required?
- Natural home for EDC is Phase I
- Use of eSource is key to efficiency



Things to keep in mind

- Helpdesk available to troubleshoot issues – all issues
- 24x7 availability for global implementation – multilingual
- Ease of use can determine compliance
- Backup processes (manual if systems fails)



How we're coping

- Vast increase in electronic systems, GCP, PV, Lab etc.
- Re-organised and focused Quality Assurance
- TACQA and GSQA
- Maintain inventory of electronic systems
- Conduct combined audits, process and validation



How we're coping

- Audit report distribution to business and application owner
- Atmosphere for constant interaction within QA
- Establish mindset change away from uncontrolled systems
- Sudden increase in findings, expecting to level out



Summary

- Technology should be used as tool and will only increase
- Ongoing vigilance and oversight is a benefit to be utilised
- Principles remain same, but approach is different
- Starts with assessing site and personnel for competency and technical compliance



Summary

- Human error still remains
- Better oversight does not necessarily mean more audits
- Example was eCRF but principles can be applied to all eGxP systems

