Overview

• Transition from paper to hybrid systems
  – Paper
  – Central shared drive
  – SharePoint

• Successes and limitations
Paper to Hybrid Systems

paper → central shared drive + “thumb drives” → central shared drive + SharePoint
Scanning Project

• Which studies will be transitioned?
  – pending / new, open to accrual, closed to accrual, long-term follow-up

• How will sponsors access the “electronic” files?
  – copy to “thumb drive”

• Which originals should be kept?
  – at minimum, any regulatory document with an original / wet signature
Scanning Project

• How will files be organized?
Scanning Project

• How will files be named?
  – general format: YYYY-MM-DD Title_HCC #
    • date = version / IRB approval / distribution / signature
    • depends on file type and location

• Ensure availability of high speed scanner
  – save at “moderate” quality to avoid slowing the process

• Contract in advance with document shredding company
Scanning Project

- Set a hard date for transition to avoid parallel / inconsistent regulatory folders
- Spreadsheet to track the process and location / type of each regulatory folder
- Save scanned documents to appropriate electronic study folder in real time using naming convention
- Batch scan email correspondence by topic
Scanning Project

• Long-term follow-up studies and others with minimal ongoing monitoring:
  – batch scan regulatory documents by type (1572, FDFs, etc.)

• Implement a double-check system to make sure all relevant documents are scanned prior to destruction

• Create an SOP on the new electronic process
  – notify sponsor of the transition at next monitoring visit
UPMC HCC CLINICAL RESEARCH SERVICES POLICY AND PROCEDURE MANUAL

POLICY: HCC-CRS-REG-110
SUBJECT: Electronic Regulatory Files

I. POLICY

It is the policy of UPMC Hillman Cancer Center (UPMC HCC) Clinical Research Services (CRS) that all regulatory files (with the exception of documents containing a wet signature) are saved electronically.

II. PURPOSE/SCOPE

This policy describes the process for generating an electronic regulatory file for all trials managed by CRS.

III. PROCEDURE

A. All study regulatory documents are saved to a CRS departmental drive which resides on central servers backed up on a nightly basis according to the UPMC corporate Information Services Division (ISD) procedures. Access to the CRS drive for editing purposes is limited to only regulatory and management staff. Additional designated research staff will have “read only” access.

B. Documents with original signatures will be scanned, saved electronically, and named per the CRS Document Naming Convention, and then filed in the study paper file. Electronic documents needed for auditing and monitoring purposes may also be copied to a study specific jump-drive or cloud drive. Per request, electronic files can be printed for review by FDA auditors.

C. Regulatory files containing documents with original signatures will be saved per study requirements. Electronic files are saved indefinitely.
Shared Drive Successes

• Limited amount of paper on site
  – paper regulatory file contains wet signature documents and monitoring logs
• Save documents directly from distributions
• Reduction in filing and monitoring visit preparation time
• Central location for CVs, medical licenses, lab ranges and certifications
Shared Drive Limitations

• Not truly electronic
  – wet signatures required
    • time spent obtaining signatures, corrected documents (sponsor QA issues)
  – scan signed documents into regulatory files

• Cost of “thumb drives”

• UPMC encryption requirements

• Monitor issues:
  – against company SOP to accept external drives
  – computers incompatible with “thumb drives”
SharePoint Setup
SharePoint Setup
SharePoint Setup
SharePoint Setup
SharePoint: Ready for Sharing

17-085 (402-01-001)

- IRB
- Sponsor Documents & Correspondence
SharePoint: Monitor Access

- Monitors receive an email invitation to access the SharePoint for a given study
  - create a password-protected account
- Multiple studies (for the same monitor) are accessed via the same sign-in
- Unlimited access to the regulatory files
SharePoint: Updating Libraries
SharePoint: Updating Libraries
SharePoint Successes

• Monitors maintain access to folders at all times
  – reduction in on-site regulatory monitoring time and space
  – reduction in emailing documents to monitors
• Elimination of SOP / compatibility issues
• Reduction of “thumb drive” costs
  – used only when there are expected or prolonged difficulties with SharePoint site
SharePoint Limitations

- Still not truly electronic
  - maintain (small) paper regulatory file
- Folders require updating for each monitoring visit
  - sync is not automatic
  - importing CVs, medical licenses, lab ranges and certifications to each study folder (or emailing to sponsor)
Continued Limitations of Hybrid System

• Routine study file maintenance
• Staff compliance with filing system and naming convention
• Time spent on paperwork and clerical tasks
  – work from home staff: limited opportunities to obtain signatures
• Training documentation
  – volume of physicians and trials
  – obtaining email responses from study staff
  – sponsor requirements
Summary

• Shared central drive and SharePoint greatly reduce amount of paper and time spent on filing and monitoring visit preparation

• SharePoint permits monitors unlimited access to regulatory files

• Benefits outweigh the negatives, but hybrid systems do not solve the problems of paper systems
Considerations for e- Regulatory Binder

Cary Passaglia, MSRC, CCRP
Administrative Director, Clinical Research
Robert H. Lurie Comprehensive Cancer Center
Overview

- Building a Case
- Exploration
- Platform Implementation
- Platform Adoption
Building a Business Case

Team

Assemble dedicated project team

• Regular, recurring meetings
• Interdisciplinary
Building a Business Case

Quantify data

- Time spent on obtaining signatures and filing
- Potential Efficiencies Added
- How will you measure success/ROI?

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Determine ultimate executive ask
- What format? (i.e. up front funding for platform, annual funding, # staff FTEs)
- How to quantify?
Building a Business Case

**Quantify data**
- Time spent on obtaining signatures and filing
- Potential Efficiencies Added
- How will you measure success/ROI?

**Meet with senior leaders/executives**
- Meetings important for context
- Get feedback before final “pitch”

**Team**
Assemble dedicated project team
- Regular, recurring meetings
- Interdisciplinary

**Data**

**Ask**
Determine ultimate executive ask
- What format? (i.e. up front funding for platform, annual funding, # staff FTEs)
- How to quantify?
Building a Business Case

Focus on efficiency, security, and mitigating risk

PAST
Paper

PRESENT
Shared Drive

FUTURE
Vendor Platform: Cloud-based system
### Building A Business Case/Funding Discussion

<table>
<thead>
<tr>
<th></th>
<th>Current State</th>
<th>Future State</th>
<th>Required Decisions</th>
</tr>
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<tr>
<td><strong>Format</strong></td>
<td>Paper Binders</td>
<td>e-Regulatory</td>
<td>Shared Drive vs. Cloud Based Platform</td>
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<td><strong>Investment</strong></td>
<td>Current, minimal funds</td>
<td>Portion of required funds</td>
<td>Full requested funds</td>
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<tr>
<td><strong>Impact</strong></td>
<td>Will need to develop:</td>
<td>Will need to develop:</td>
<td>Will need:</td>
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<tr>
<td></td>
<td>• More efficient way to obtain wet ink signatures</td>
<td>• Binder Set-Up</td>
<td>• Staff support of shared drive or cloud based system implementation</td>
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<tr>
<td></td>
<td>• Storage solution for open trials</td>
<td>• Document Naming Conventions</td>
<td>• Support for cost of cloud based platform</td>
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<tr>
<td></td>
<td>• Scanning and storage solutions for closed trials</td>
<td>• Version Control</td>
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<td></td>
<td></td>
<td>• Access</td>
<td></td>
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<tr>
<td><strong>Risks</strong></td>
<td>• Loss of essential Reg docs</td>
<td>• Version Control with Shared Drive</td>
<td>• Not full buy-in/ adoption therefore efficiency not maximized</td>
</tr>
<tr>
<td></td>
<td>• Incomplete Trial Master File/Audit findings</td>
<td>• Part-11 Compliance</td>
<td>• System not end user friendly</td>
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<td></td>
<td>• Inefficient study maintenance</td>
<td>• Recurrent discussion as efficiency decreases and risk increases without eReg Platform</td>
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</tbody>
</table>
Building a Business Case

IF YOU COULD JUST SAY YES

THAT WOULD BE GREAT
Initial Exploration Phase

Leadership

Heavy Users

- Initial Input
- Platform Assessment
- Document Naming Convention
- Binder Set-Up
- Platform Assessment
Platform Chosen-Now What?

Main Binder Set-Up
- Central Binders

Study Specific Binder Set-Up
- Study Specific Binders
- Ancillary Dept Binders

Documents
- Types
- Naming Conventions
- Access Levels
2 Most Important Words

VERSION CONTROL

You leave out version control........
everyone starts losing their minds!
Successful Implementation: Considerations

Team Characteristics and Workflow

- Investigators and clinic teams
- Coordinators/Data Assistants
- Outside Departments (Pharmacy)
- Regulatory Team

Big teams-light users vs. Small teams-heavy users
Successful Implementation Considerations

Roll Out Phases

- **Early Phase**: Hands on training with heavy users
- **Late Phase**: Basic Intro to System/Demonstrations with all teams
- **Ongoing**: 1:1 with Lighter Users
Adoption Considerations

- Once Go-Live date established, stick to it.
- Do not use old platform/formats for new studies past Go-Live
- Track Metrics of Adoption:
  - How many documents uploaded by month
  - How many/what type of users logged in
  - Number of e-Signatures per month
Successful Adoption
Lessons Learned

- Create team-based user groups before roll-out.
- To achieve buy-in, take the time to understand current workflows of different teams and consider how to demonstrate benefit to them.
- Consider incentivizing the rollout process with prizes for teams with largest compliance.
- Plan ahead how and when to measure and track adoption using appropriate metrics – for instance at roll-out, 6, 12 and 24 months.
Summary

- Collect necessary data to present case to leadership for eReg platform
- Consider current workflow and determine who heavy end users will be
- Get input from all relevant teams
- Document decisions as you make them
- Version Control is Key
- Successful Adoption involves a roll-out plan with multiple training formats
Questions?
Thank You
We will now take questions for our presenters. Please use the question box on the lower right to submit a question. Questions will be answered as time permits.

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Please send further questions to Kate Shaw at kathryn@aaci-cancer.org