UPMC LIFE CHANGING MEDICINE

Clinical Research Services Regulatory Filing Transitions

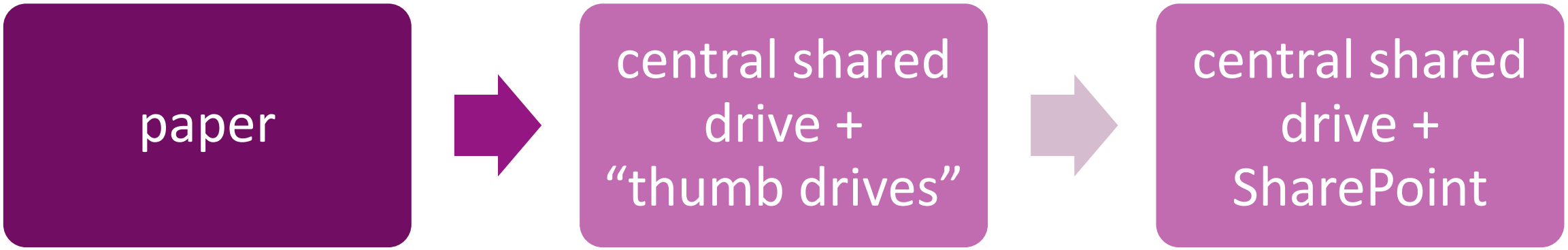
Brieana Marino, MA, Regulatory Manager

Deidre Cleary, BSN, RN, CCRC, Senior Director

Overview

- Transition from paper to hybrid systems
  - Paper
  - Central shared drive
  - SharePoint
- Successes and limitations

Paper to Hybrid Systems



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Scanning Project

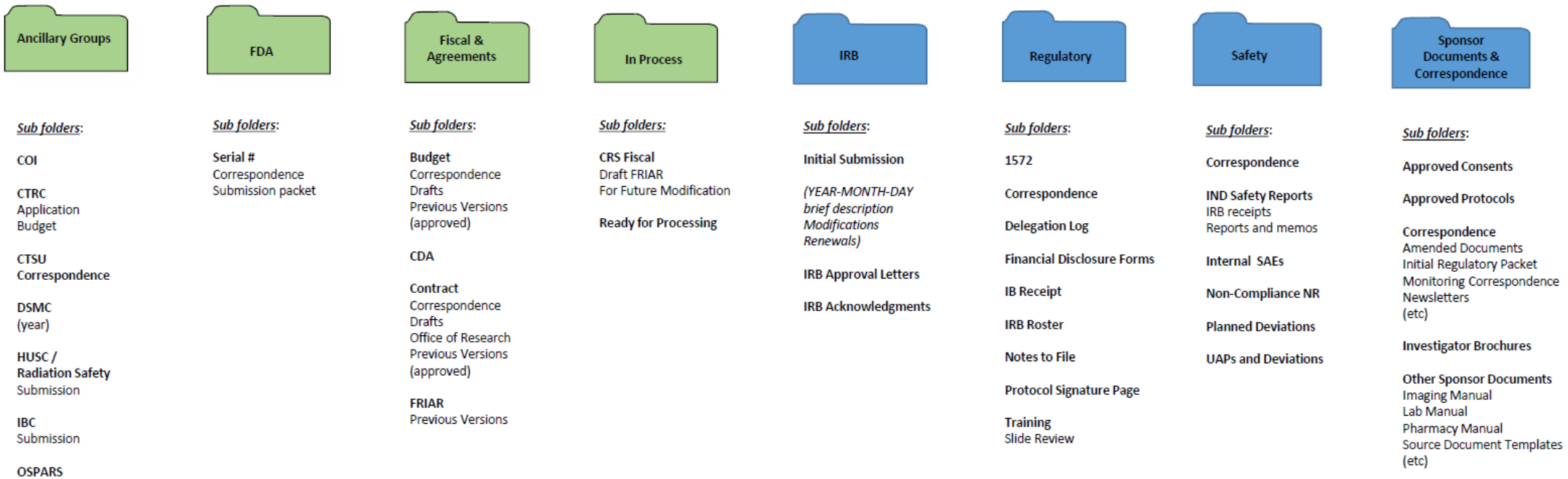
- Which studies will be transitioned?
  - pending / new, open to accrual, closed to accrual, long-term follow-up
- How will sponsors access the “electronic” files?
  - copy to “thumb drive”
- Which originals should be kept?
  - at minimum, any regulatory document with an original / wet signature

Scanning Project

- How will files be organized?

Internal Use Only

Monitored by Sponsor



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

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Clinical Research Services

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.

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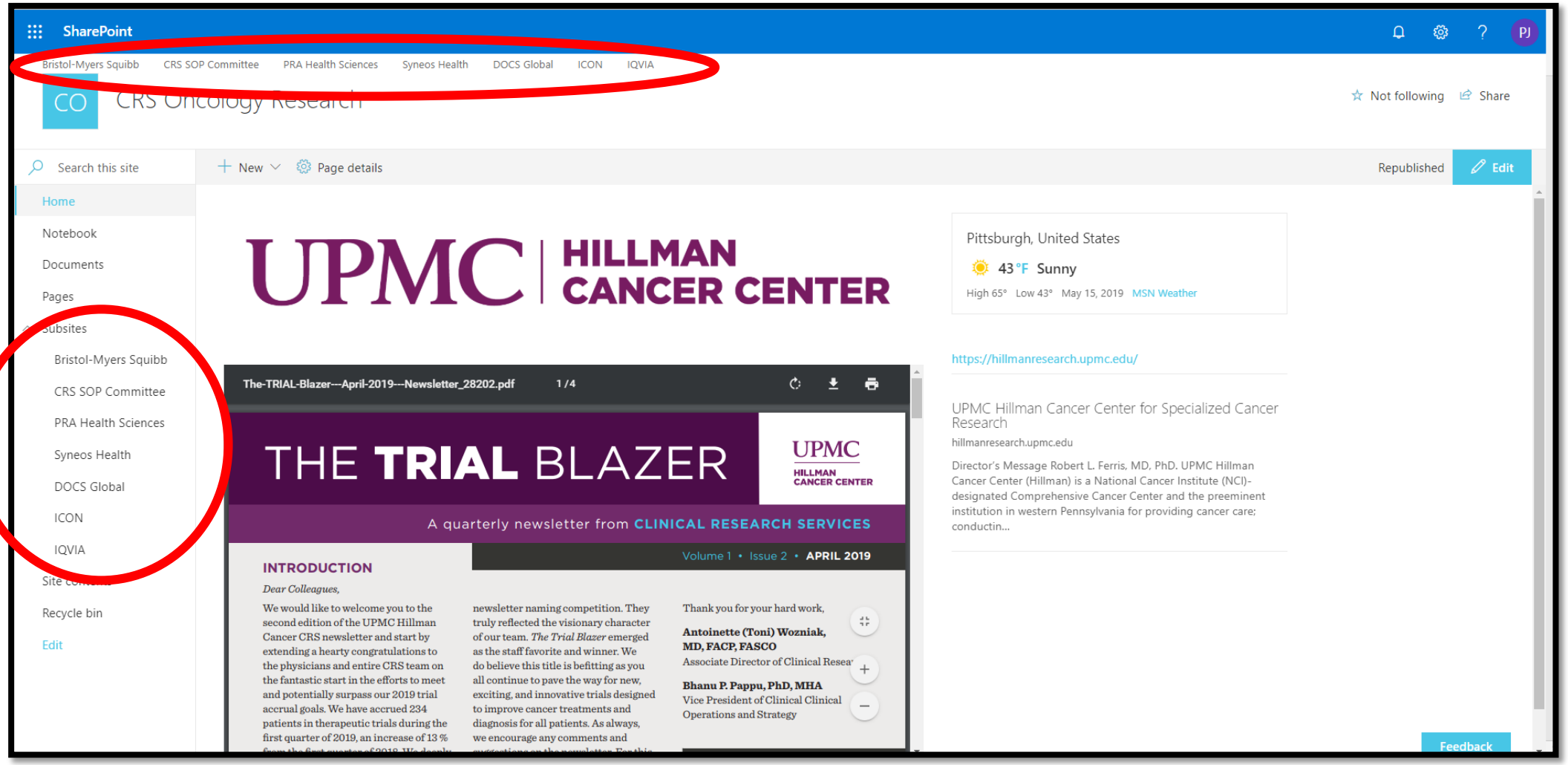
Shared Drive Successes

- 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



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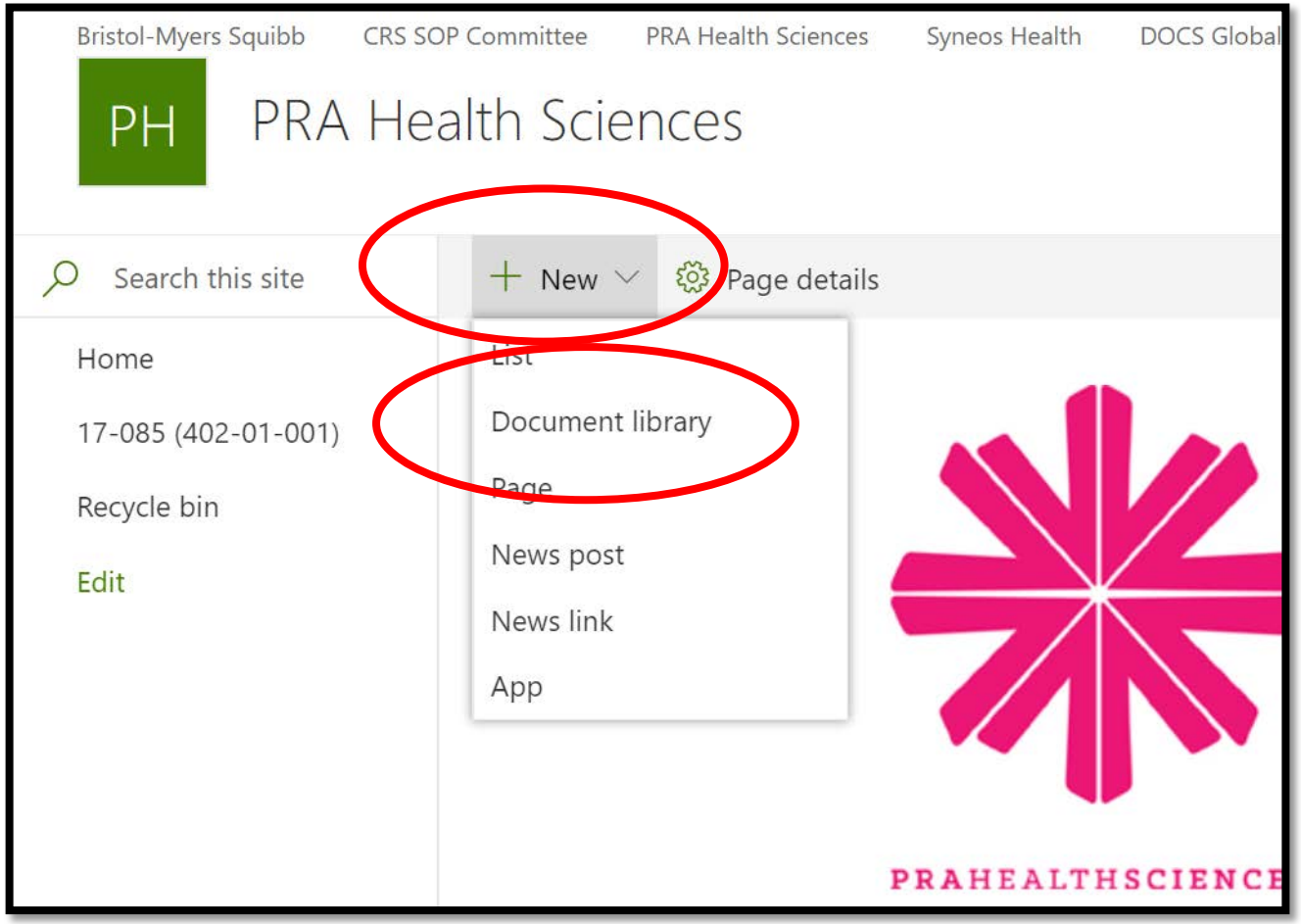

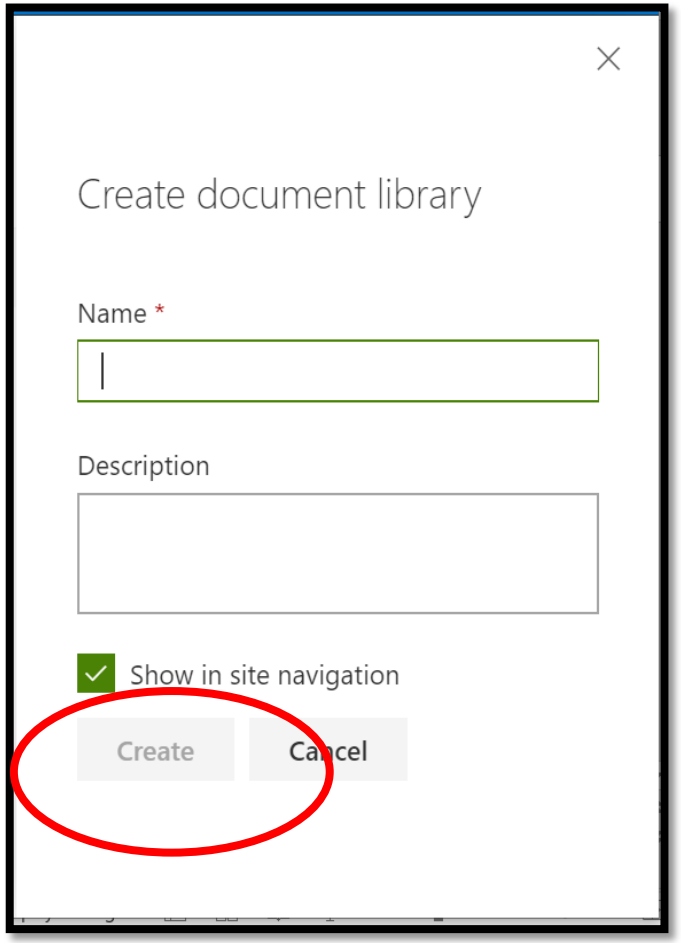

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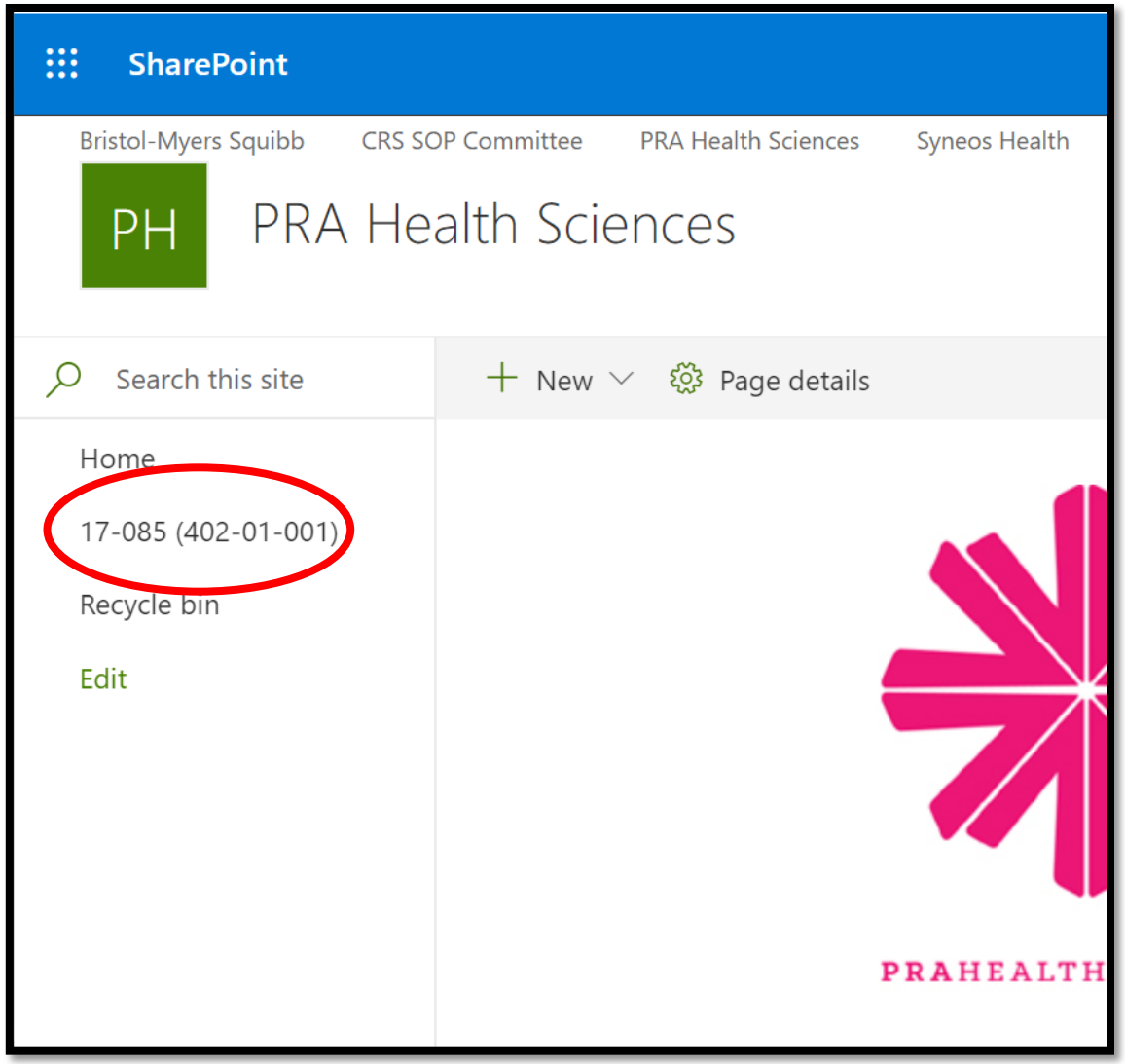

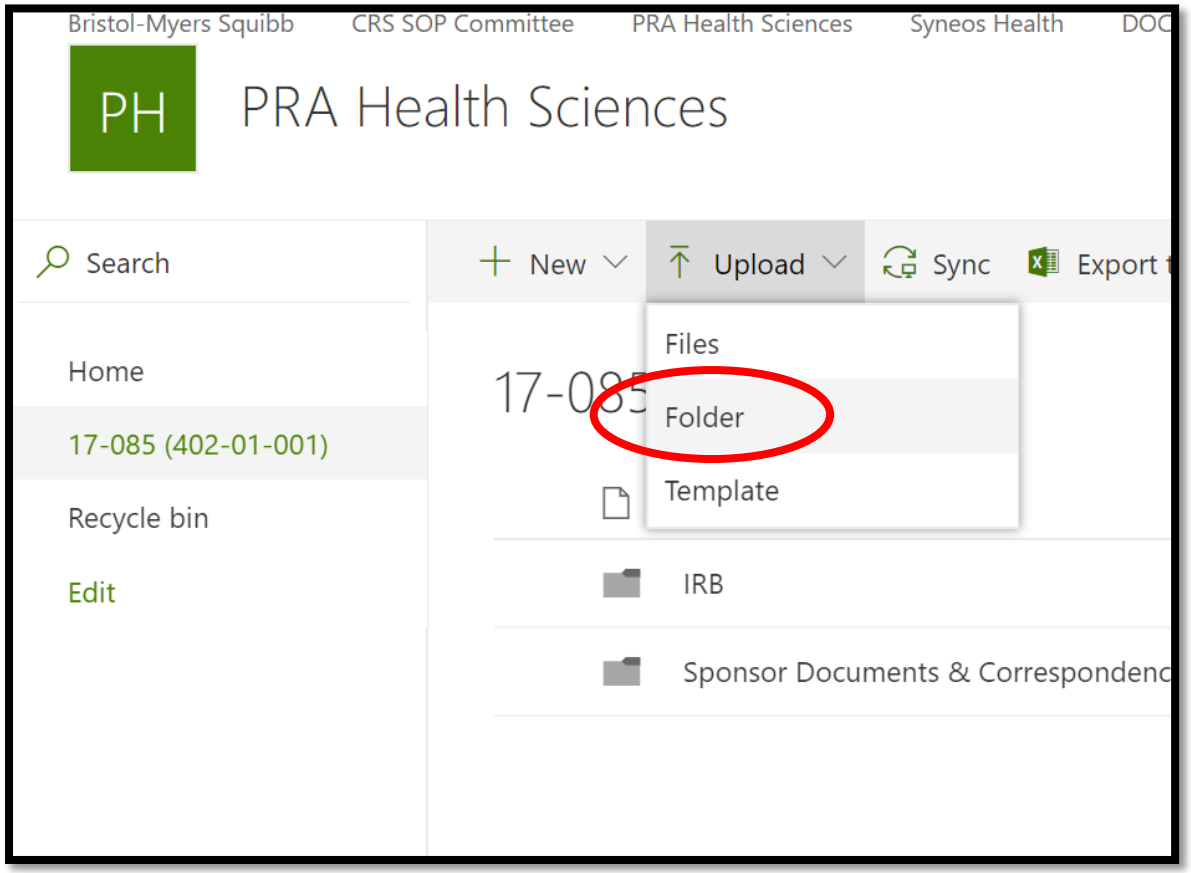

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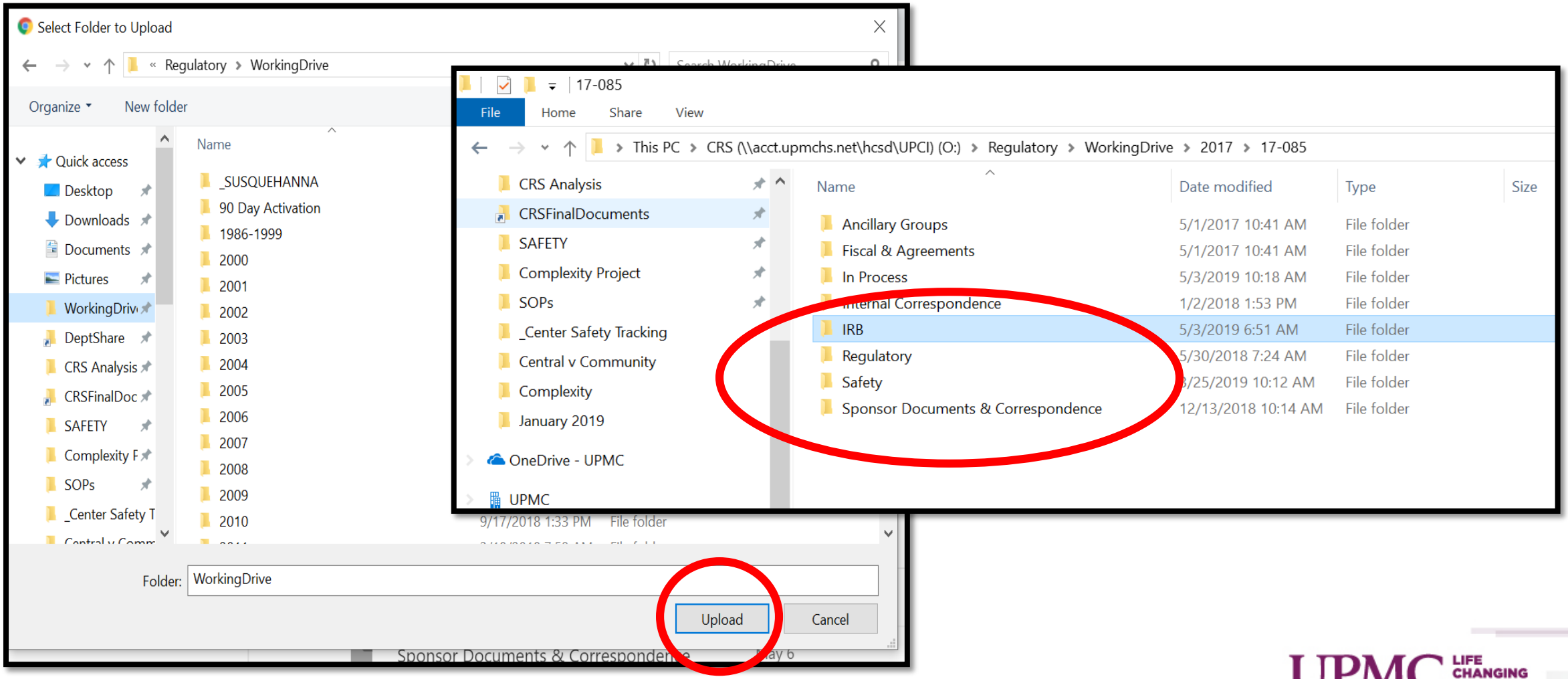

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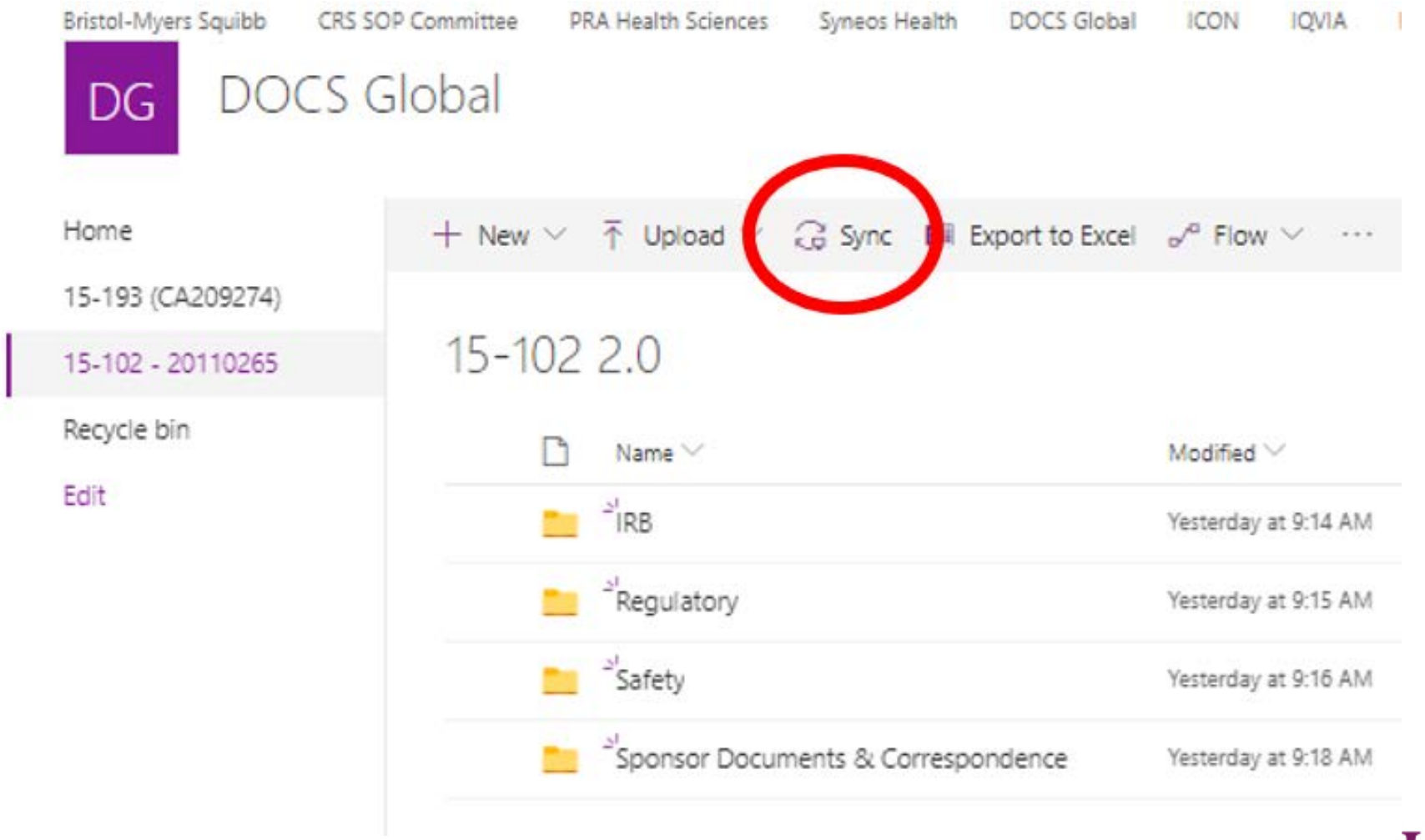
SharePoint: Ready for Sharing

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



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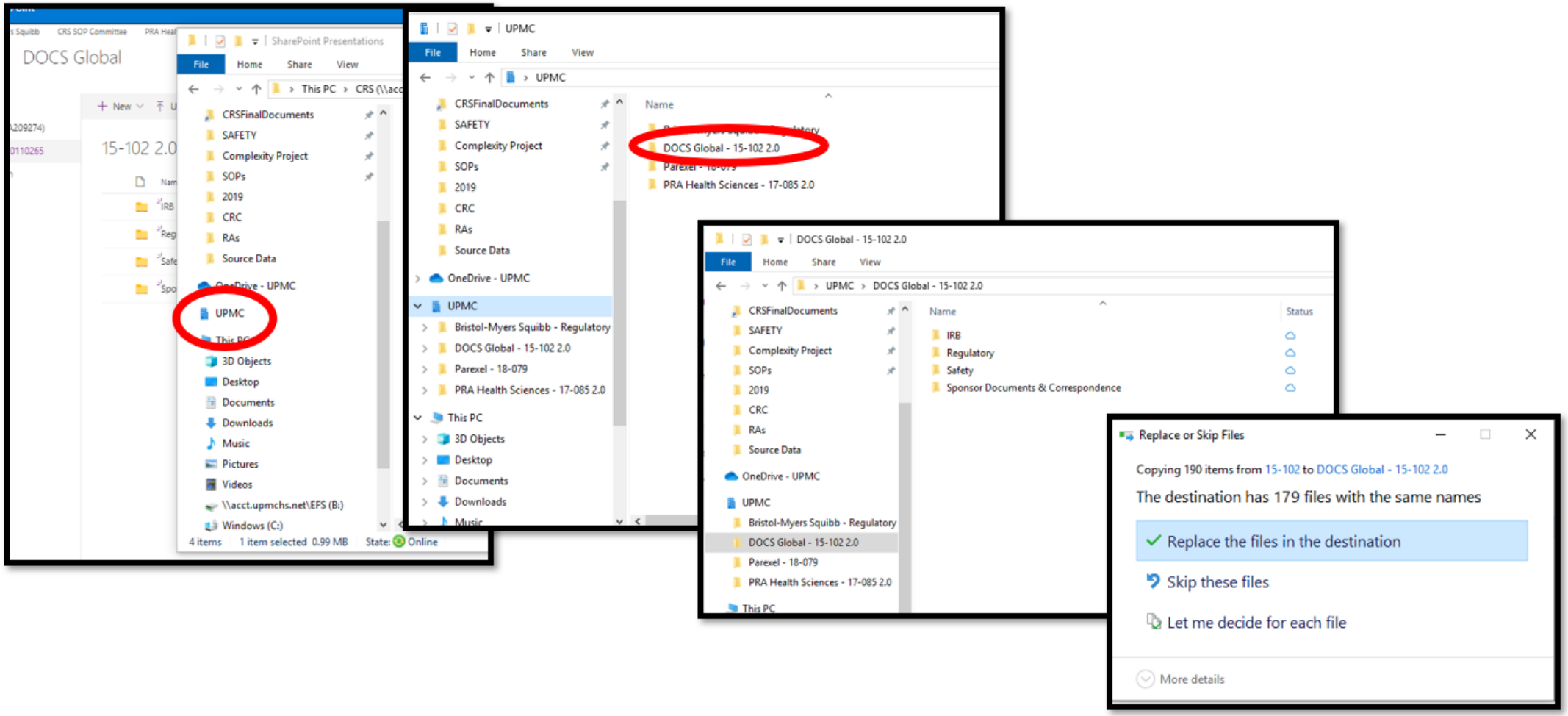

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SharePoint Successes

- 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

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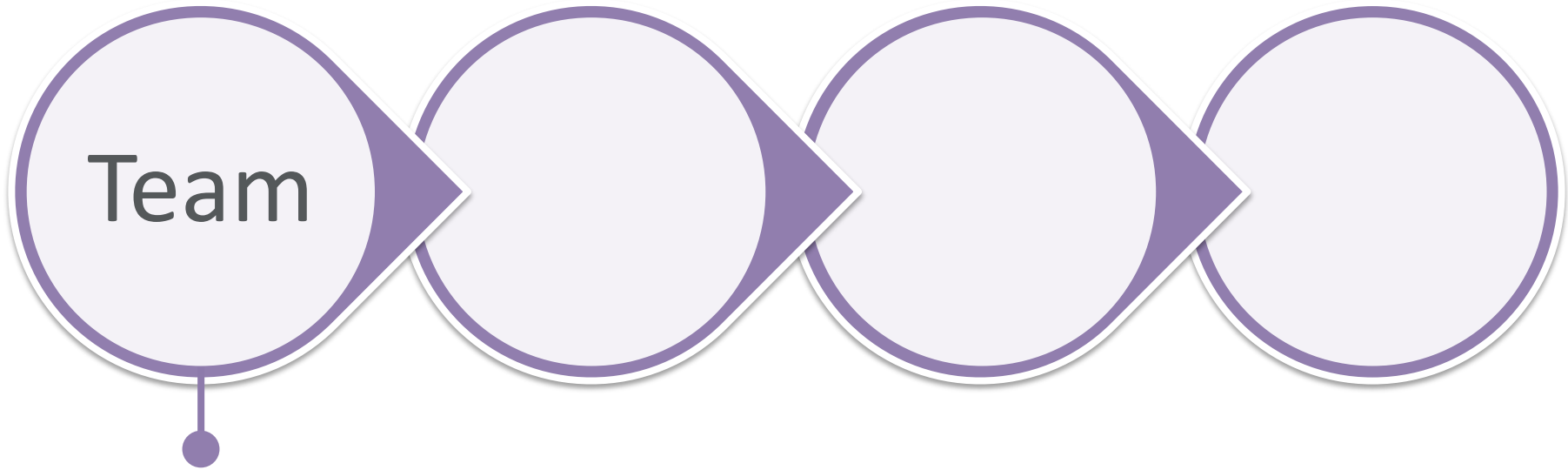
Considerations for e- Regulatory Binder

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



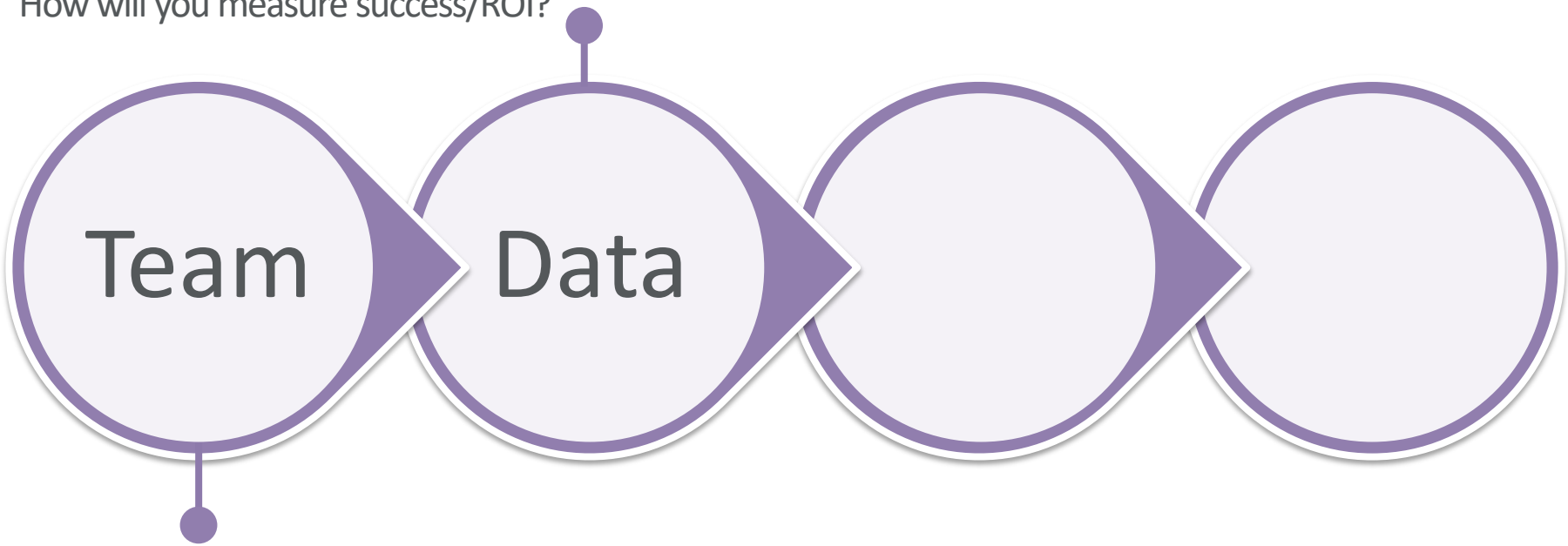
Assemble dedicated project team

- 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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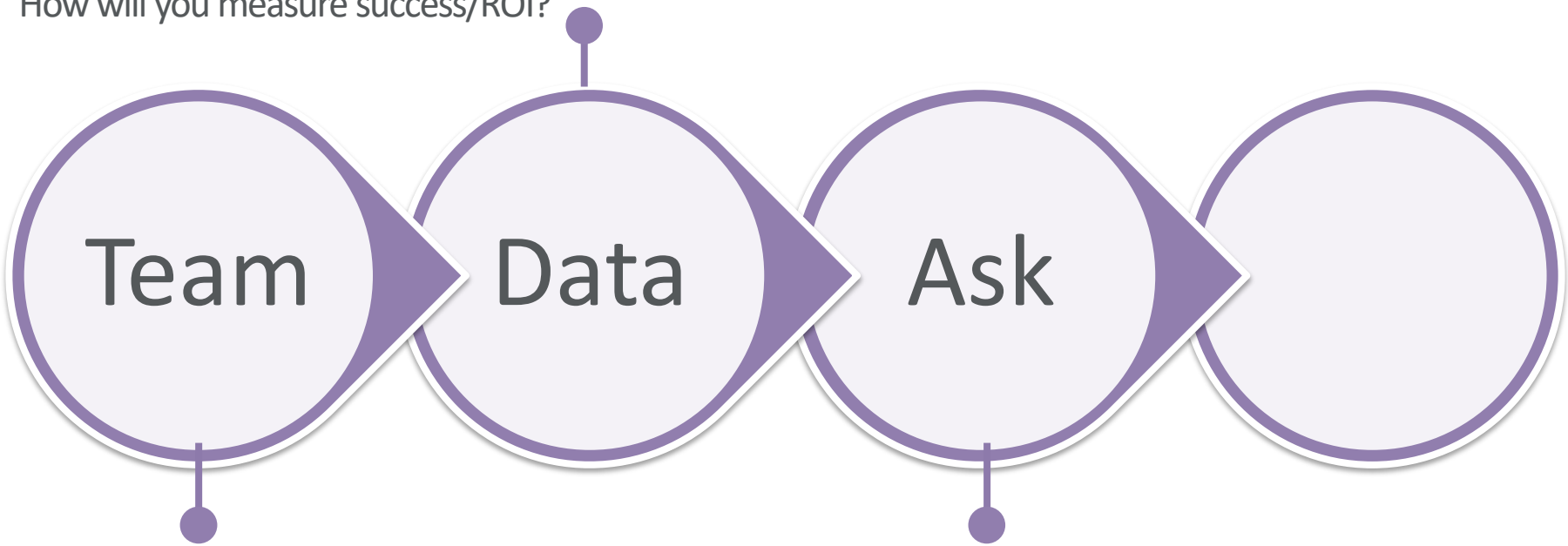

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- What format? (i.e. up front funding for platform, annual funding, # staff FTEs)
- How to quantify?

Building a Business Case

Quantify data

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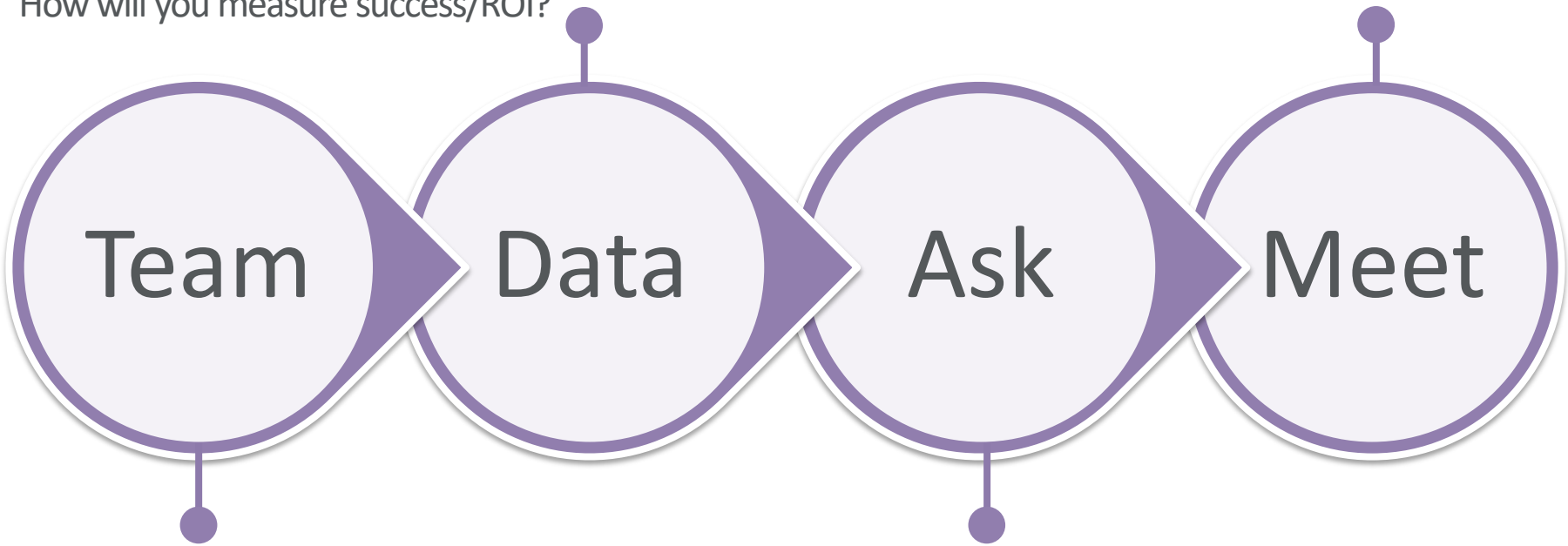
- How will you measure success/ROI?

Meet with senior leaders/executives

- Meetings important for context
- Get feedback before final "pitch"



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Building a Business Case

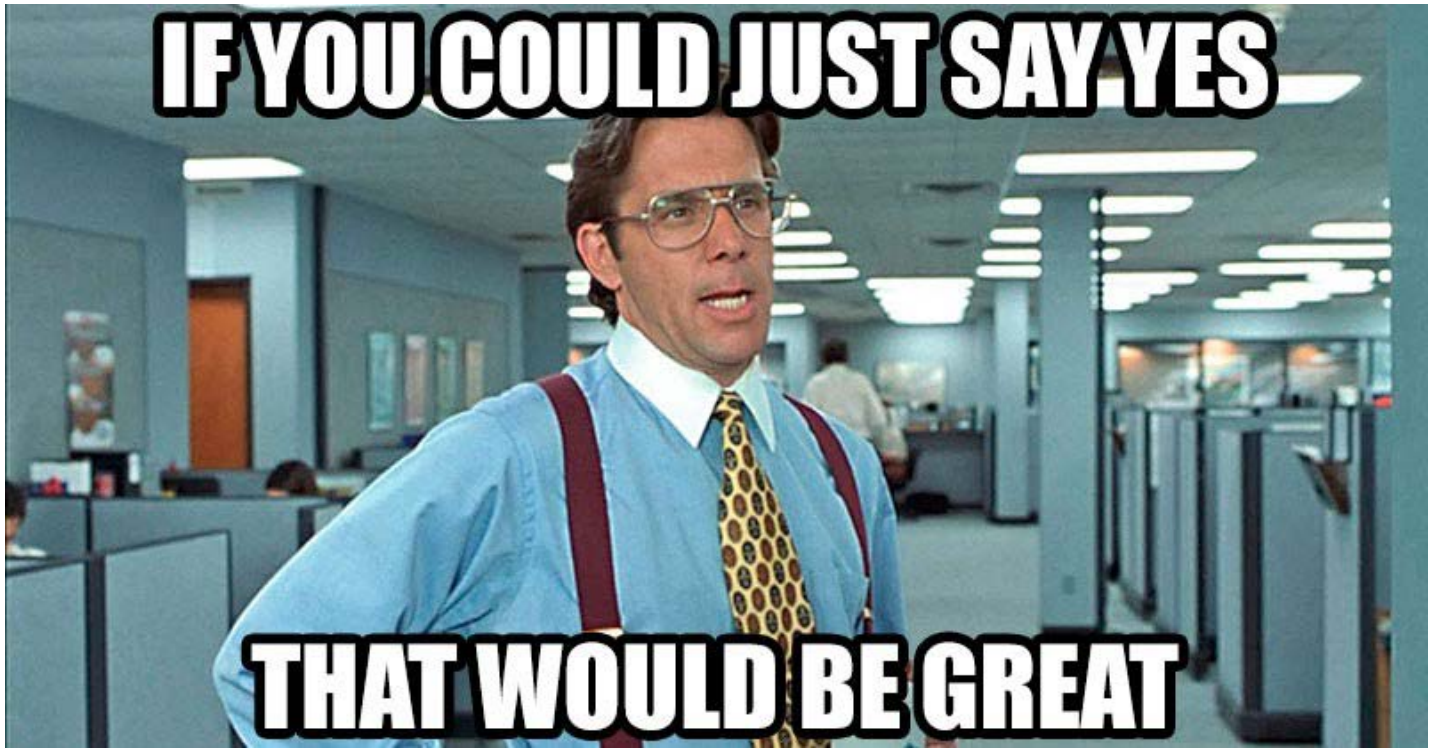
Focus on efficiency, security, and mitigating risk

PAST	PRESENT	FUTURE
		 
Paper	Shared Drive	Vendor Platform: Cloud-based system

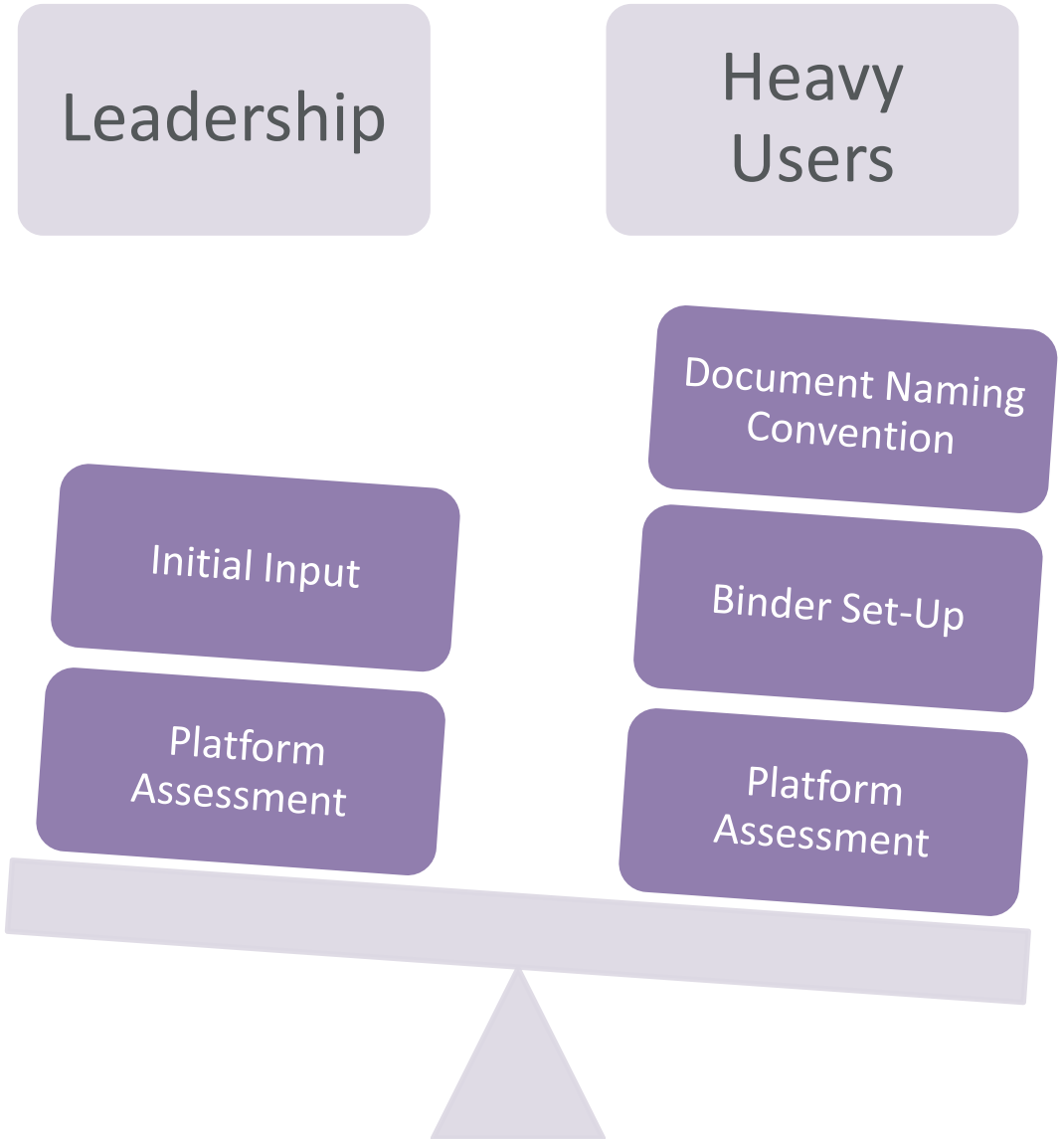
Building A Business Case/Funding Discussion

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

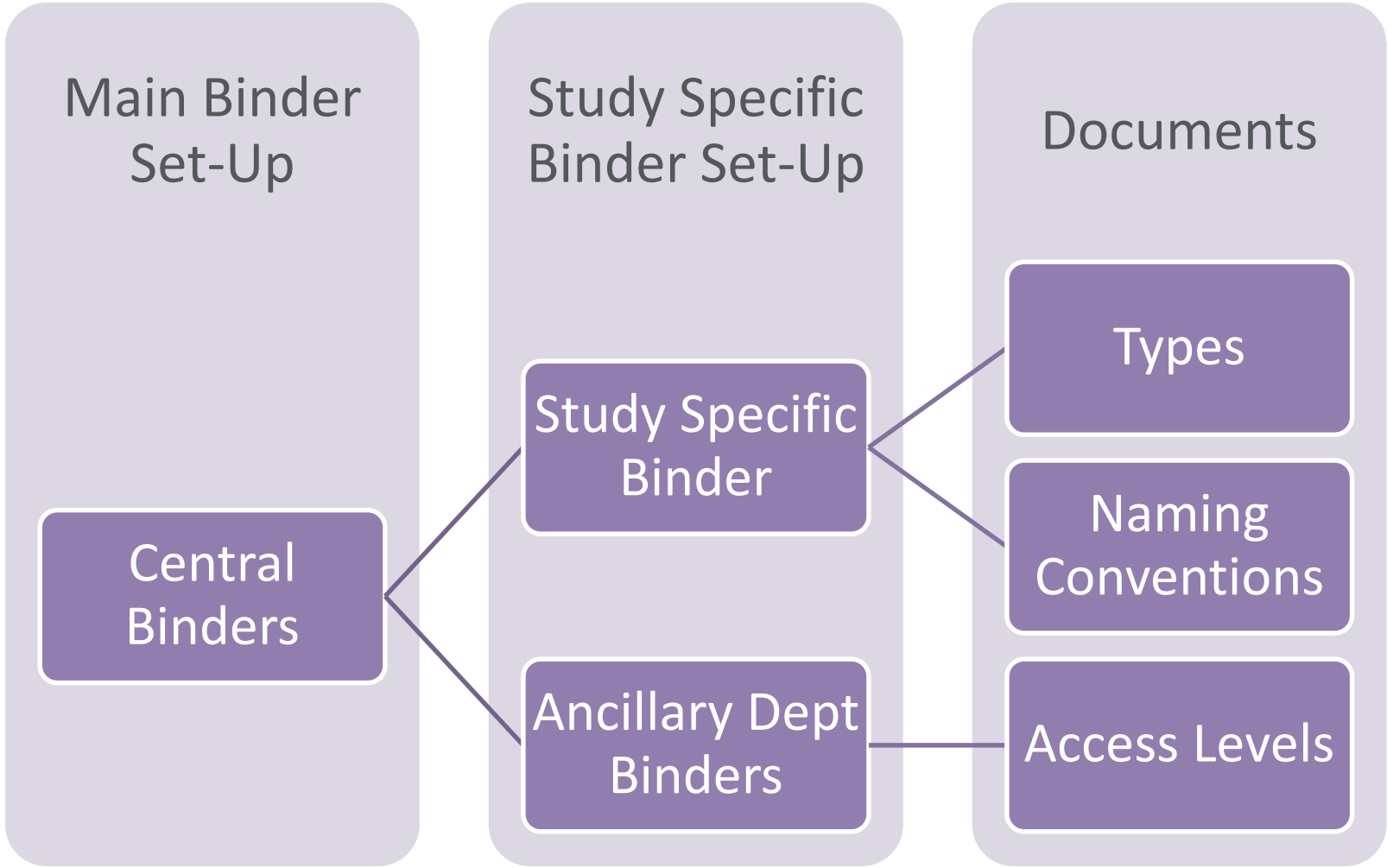
Building a Business Case



Initial Exploration Phase



Platform Chosen-Now What?

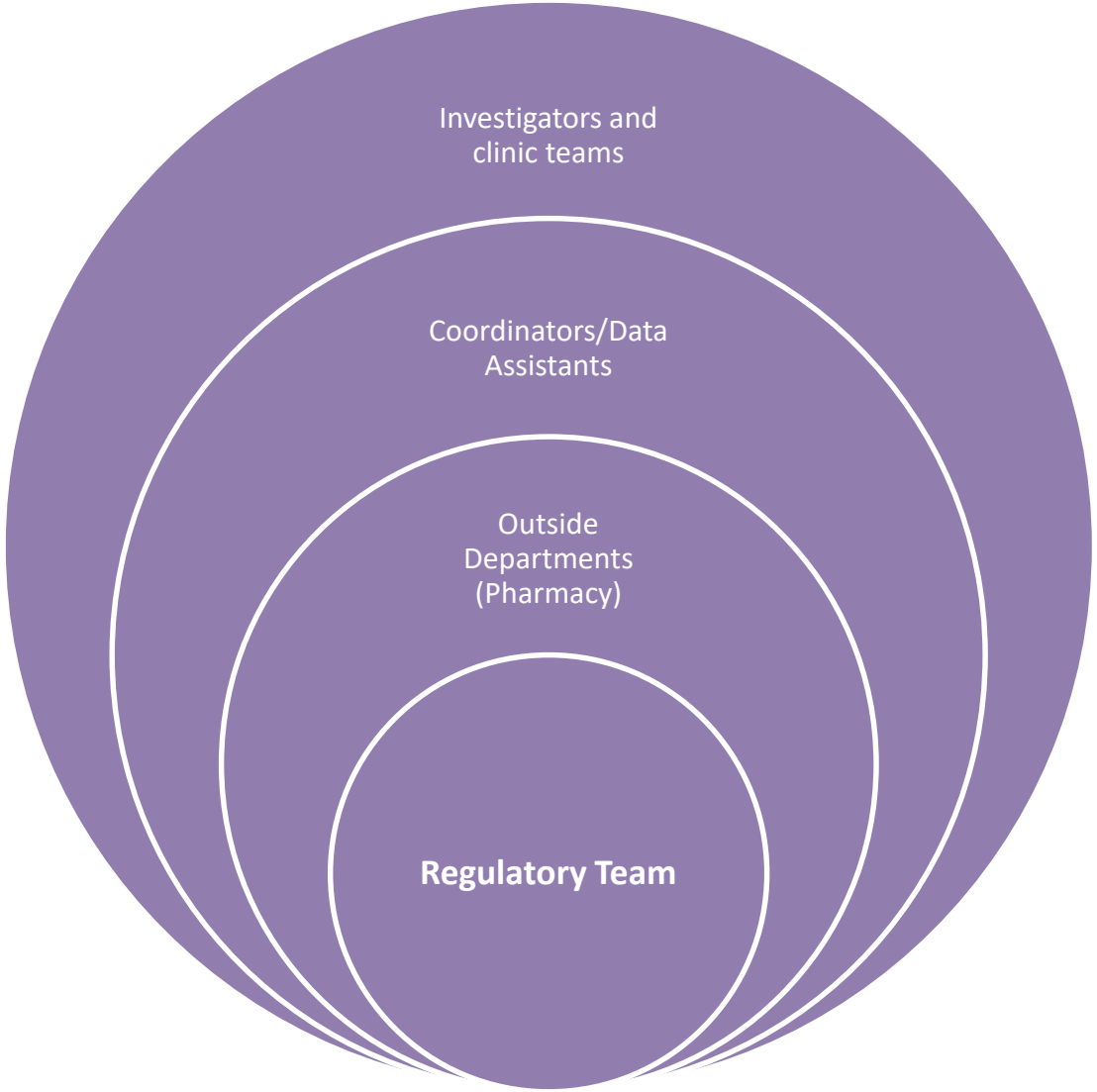


2 Most Important Words

VERSION CONTROL

Successful Implementation: Considerations

Team Characteristics and Workflow



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?

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Thank You

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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