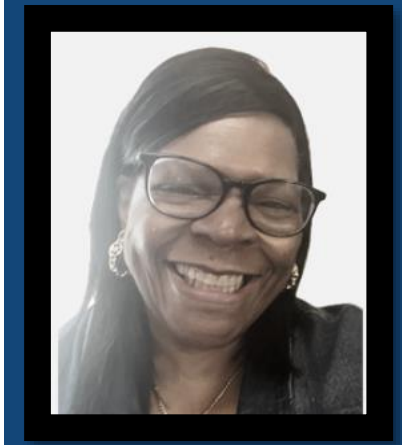
Acquisition Migrations
Weathering the Storm on the Voyage to TMF Ownership

Presented by Nita Whyte, Sr. Manager, Clinical Records and Info Management
Marion Mays, Principal Consultant, Clinical Records & Info Management

Meet the Speakers

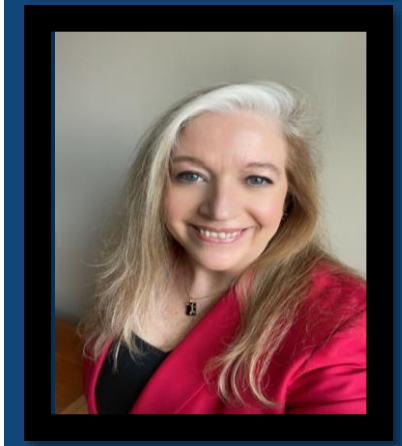


Nita Whyte

Title: Sr. Manager, Clinical Records & Info Management

Organization: Gilead Sciences

A seasoned professional with unique insights into the end-to-end clinical trial process and compliance. Nita brings nearly two decades of comprehensive experience in the pharmaceutical industry, having served in roles that developed expertise in inspection readiness, TMF management, and TMF migrations. With hands-on experience, Nita brings valuable perspective on industry best practices, operational efficiency, and quality management in clinical records management.



Marion Mays

Title: Principal Consultant - On assignment with Gilead Sciences

Organization: Jerion Consulting Group

A leader in the Life Sciences space with 30 years of experience. She has extensive experience in Inspection Readiness and supports clients in their efforts to become fully inspection prepared. A trusted advisor to sponsors in support of regulatory inspections, TMF Management, and Clinical Operations. Offering a unique combination of both strategic and operational abilities combined with creative thinking.

Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *No financial relationship or conflict of interest relevant to this presentation*
- *The author(s) have no real or apparent conflicts of interest to report.*

Acquisition Migrations:

Weathering the Storm - The Voyage to TMF Ownership

Agenda

1. Introduction
2. Engaging the Crew
3. Charting the Course
4. Identifying Storms on the Horizon
5. Getting Ready to Sail
6. Navigating Rough Seas – Weathering the Storm
7. Reaching Safe Harbor
8. Q & A

Topic Introduction

Weathering the Storm on the Voyage to TMF Ownership

- Have you ever been asked to support the transfer of ownership of a TMF?
- Have you ever received a TMF from a CRO?
- Have you ever been part of an acquisition or maybe a divestment activity involving the movement of TMF content?

- If you have or have not, this is a story you want to hear……
- Just when you thought it was going to be smooth sailing or maybe just a simple day task thinking “What could go wrong”

    - We are going to walk you through one of the most thought out, collaborative, planned transfers that did not go at all as planned!

TMF Migration Team and Roles

Our Crew

- Debbie Sefton – Admiral
- Nita Whyte – Captains
- Marion Mays – Captains
- Clarissa Tam – Chief Mate
- FSP – Chief Stewarts
- Clinical Systems / Veeva SME
- Clin Ops – Chief Engineers
- Asset Management – Boatswain
- Alliance Management - Charter Company

Divesting Organization

- SME for Indication
- Clinical Operations – Director
- Clinical Operations – TMF Manager
- Coordinating Project Manager - Support
- Regulatory Operations - Director
- Archiving / Off-Site Storage - Contact
- IT - Director
- Many - Ordinary seamen

Engaging the Crew

Engaging the Crew

Organizational Prep / Stakeholder Alignment

- Build the crew starting with resource and stakeholder identification.
- Introduce and inform the crew prior to setting sail. This is critical for ensuring a smooth transitional voyage and maintaining study integrity.

Early engagement should consist of:

- Risk assessment and mitigation planning
- Strategic planning (migration plan)
- Agree on risk mitigation efforts and potential remediation
- Align with priorities and timelines
- Due dilligence and assessment

There are many moving parts in Clinical trials.

To ensure cohesive progress, everyone needs to be working from the same playbook.

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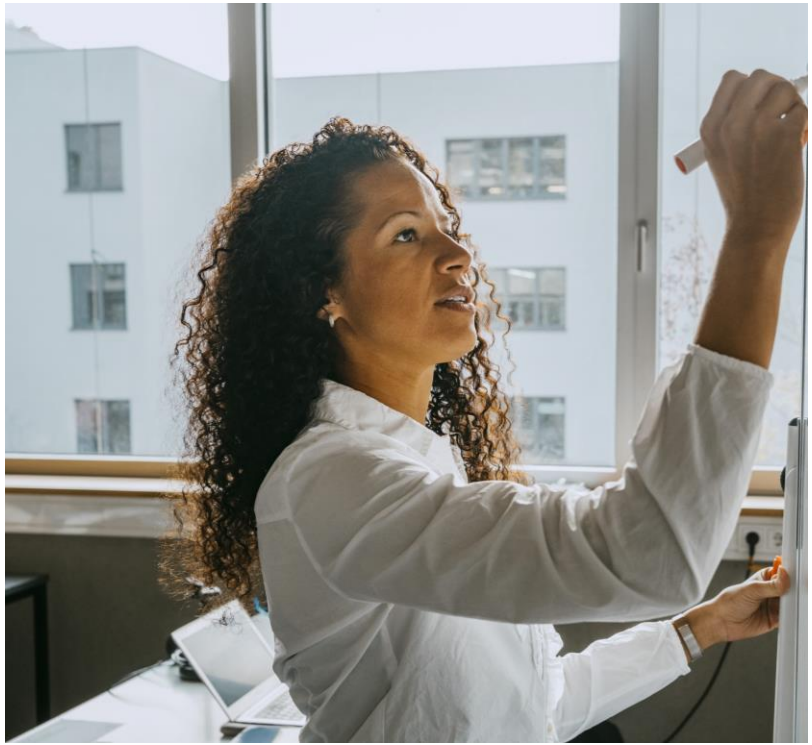
Why Success Mattered

Successful TMF migration was critical to the deal for:

- Maintaining the value of the asset to the organization
- Positioning for regulatory submissions
- Business continuity for ongoing and planned studies
- Risk mitigation for potential regulatory inspections
- Long term continuation of product line

Charting the Course

Charting the Course



Step 1: Evaluating the Manifest

The manifest included our passengers (5 studies). It was used to facilitate the efficient movement of each from one point to the other.

Each passenger had different baggage and health issues:

- 1 closed study – CRO 1 (familiar player)
- 2 ongoing studies in different stages of life – CRO 1
- 1 study in close-out – CRO 2 (new Player)
- 1 study in progress – CRO 3 (new Player)

No stow aways in sight.....

Charting the Course with the Migration Plan

Step 2: Understanding the make-up of each study

a) To establish the best process for transfer, we had to determine:
   - Volume
   - Format & Structure
   - Timelines & Effort
   - Technology requirements & limitations
   - Risks

b) Include continuous status checks and team check-ins as part of the plan

Charting the Course

Step 3: Establishing Integration Timelines

a) Directly tied to acquisition closing dates

b) Anticipated inspections

c) Success criteria established for each migration phase, i.e., ***keeping studies operational during the transition***

d) Expiring contracts with CROs holding the studies

Charting the Course

Step 3: Establishing Integration Timelines (cont'd)

e) Influenced by dependencies on other integration workstreams

- Availability of staff
- IT infrastructure (i.e. target servers and network establishment; access controls; network connectivity between sites).
- User integration – user accounts and permissions, access provisioning requires training/onboarding)
- Legal and Compliance - Regulatory approvals needed before files can be transferred; data transfer agreements

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Charting the Course

Step 4: Reading the Waters (Navigation Charts) – Developing Final Destination Path

As the captains, we were responsible for understanding the current state of each study to establish migration plan

Appraisal: What are the current weather conditions (i.e. is the water clear, what direction is the wind blowing, what ports are we stopping at)?

Finalize Migration Plan from information gathered about the acquisition, such as:

- Acquiring & divesting company roles and responsibilities with contact information
- Type of acquisition – Product, Trial
- Source system/location, accessibility, format, blinding, prior migrations
- Activities and Timelines

Charting the Course

Step 4: Reading the Waters (Navigation Charts) – Developing Final Destination Path (Cont'd)

Planning: Based on the information gathered, we determined the best process for transfer (i.e., manual transfer, technology enabled, or both)

The ask and the waters were clear - or so we thought …

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Identifying Storms on the Horizon

Storms on the Horizon

Challenges identified upfront

Different CROs and Vendors used for studies

- Different Systems and File Structures
- Different file naming conventions and organizational structures
- Multiple platforms & repositories requiring mapping & reconciliation

Regulatory Validation and Audit Trail Requirements

- Maintaining chain of custody documentation
- Historical audit trail preservation across systems

Storms on the Horizon

Challenges Identified Upfront (cont'd)

Timeline Pressures from Acquisition Deadlines

- Inspection during transfer preparation
- Stakeholder expectations
- Resource constraints during integration period
- Competing priorities

Data Integrity and Version Control

- Managing study team access during transfer process
- Identifying and resolving duplicates
- Ensuring completeness of file transfer and metadata

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Getting Ready to Sail

Getting Ready to Sail

Pre-work

- Set-up / prep – Divesting company prepared the records for transport while we prepared to accept the records
- Determine Migration Priority to ensure data integrity and regulatory compliance:
  - Staged migration approach used to minimize business disruption
    - Phase 1: Active studies with regulatory deadlines
    - Phase 2: Recently completed study under regulatory review

Ready to Sail

Leaving Port…..

Establish Data Integrity Checks to ensure chain of custody is maintained and metadata / timestamps / version history is retained.

Determine Points of Validation and Verification:

- Pre-migration (source system integrity)
- Transfer validation (accurate mapping)
- Post-migration (transfer completeness)

Sailing – Open Waters

Ongoing Risk Mitigation

- Evaluating the status of each study in the portfolio to determine when to move it
- Complexity of system housing the study
- Urgency for study team access to the eTMF
- Impact to on-going inspection
- Timeline of acquisition activities - knowledge transfer loss
- Access to the other systems – Loss of access due to them being decommissioned

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Sailing towards our destination…..

Knowing we were going to be:

1. Continuously monitoring progress
2. Maintaining log of any issues/unexpected actions, and pivots/course corrections
3. Assessing and monitoring risk – including the potential for downstream effects

Navigating Rough Seas – Weathering the Storm

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Riding the Waves – Unexpected Challenges, Divesting Organization

- 30+ legacy studies added to the transfer pool
- Studies stopped then restarted with different CROs
- pTMFs lacking inventories
- Off-site storage listings were insufficient
- Password protected portable media provided without passwords available
- Information provided difficult to validate
- Lack of consistency in transfer of records (personnel extracting and transferring records were not knowledgeable in the process – i.e., they did not correctly generate a "clean" manifest for transfer)

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Navigating Rough Seas – Weathering the Storm

Riding the Waves – Additional Challenges, Gilead Side

CTMS entry for active studies

- Confusion with site numbers - Number in eTMF not matching the number on site documents
- Misfiling of records and QC findings resulting from the above

CTMS entry for legacy studies

- Data required for CTMS set-up (i.e., PI contact information) not available
- Internal Communications
- Lack of communication between functions

eTMF

- Customization of Master Index Reference Model caused confusion when mapping (i.e., split single artifact into multiple subcategories)

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Navigating Rough Seas – Weathering the Storm

Managing the Challenges

Understanding and looking at issues holistically – **Stop, Drop & Roll**

- Regular meetings to discuss issues & wide-scale potential solutions to be applied
- Having access to experienced collaborators
- Documented Risk-based approaches & developed relevant processes
- Communications – ensuring overall team awareness of status
- Increased collaboration with internal teams

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Navigating Rough Seas – Weathering the Storm

Crisis Management

Prepare, prepare, prepare…

- Identified issues before they became critical – risk mitigation
- Determine cause
- Mobilized team for resolution
- Made team aware of the situation and course of action
- Getting back on course – not getting lost at sea
- Finding our way back after the long journey
- The aftereffects – what we are learning now

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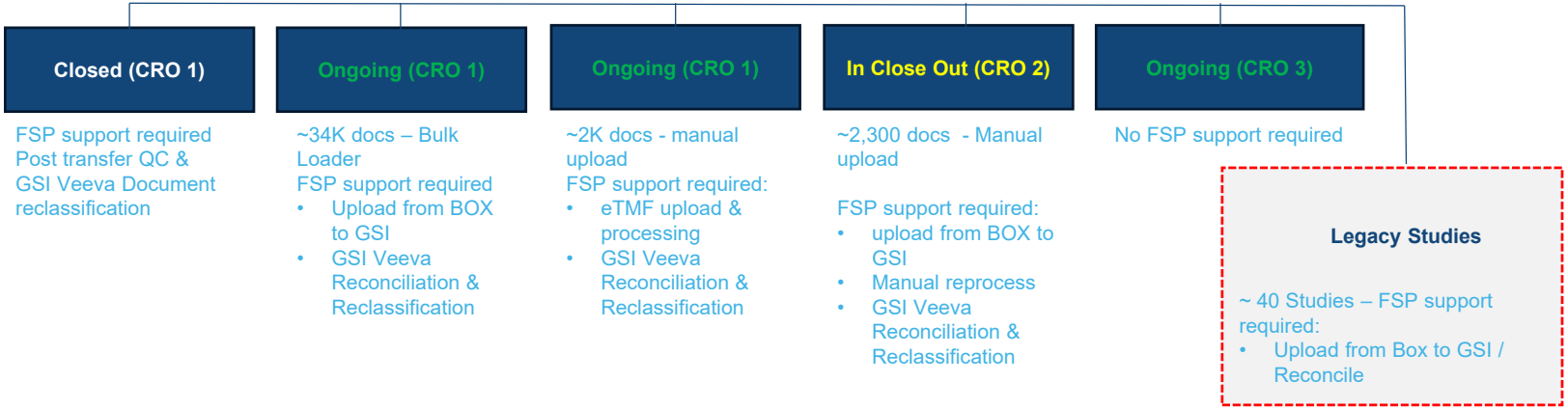
Reaching Safe Harbor

Reaching Safe Harbor

Where we ended…



Lessons from the Deep

- Not all Sponsors interpret Reference Model artifacts the same
- While expanding on the TMF Reference Model may be beneficial to a Sponsor, it sets the stage for confusion when acquiring compounds/studies.
- Migration of attached and zipped files requires extra work and clearly defined processes through user access
- Teasing out records that are housed in other systems is tedious and time-consuming
- Cleaning up metadata

Post-Voyage Process Improvements

- Built stronger relationships internally (alliance management, information governance, study teams, etc.)
- Adding long term electronic archive for files
- Identified potential opportunities for improvement during acquisition phase
- Developed a Playbook for future transfers
- Updates to study intake questionnaire – expanded now know what to ask –
- Having our life preservers handy – Developing tools to support future transfers
- Eventually we did make it back home.....well not yet, we see land

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Charting Future Waters – Long-term Vision

To seamlessly integrate trial master files during acquisitions through flawless migrations that safeguard research investment and accelerate development timelines.

How?

- Have knowledgeable and experienced teams to support migrations
- Build risk mitigation actions (example: how to handle Zip files)
- Partner with Alliance Management (the Acquisition team)
- Wish List: Better integration tools/systems that talk to each other/AI assistance with metadata

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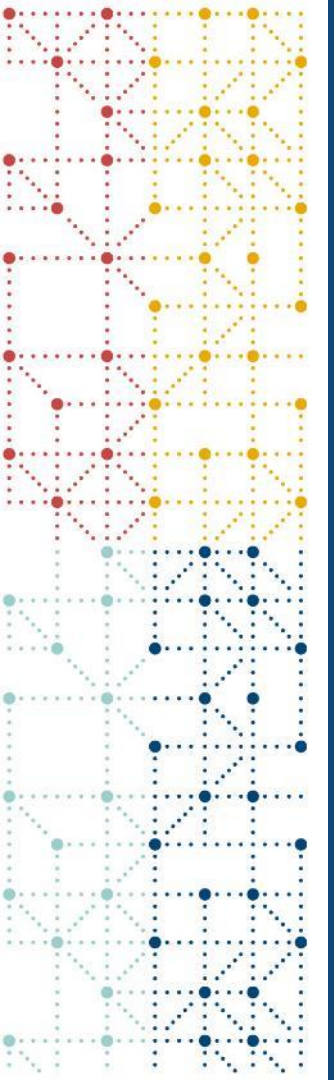

Q & A

Thank You!