



2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

Risk-Based Flight Plans for TMF Migration: Ensuring a Safe Landing During Acquisitions

Presented by Nita Whyte, Sr. Manager, Clinical Records & Info Management at
Gilead and Marion Mays, CEO/Principal Consultant at Jerion Consulting

Agenda

1. Introduction to Risk Based Acquisitions and Mergers
2. Establishing Risk-based approach to Acquisitions and Mergers
3. Engaging the Flight Crew
4. Charting the Flight Identifying Storms and Navigating Turbulence
5. Safe Landing & Post Flight Check (identify key things to check after the landing)
6. Q & A

Speakers



Nita Whyte

Sr. Manager, Clinical Records & Info Management
Gilead Sciences



Marion Mays

Principal Consultant – On assignment with Gilead Sciences
Jerion Consulting Group

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 speaker's employers or CDISC.*
- *Speakers have no financial relationship or conflict of interest relevant to this presentation*
- *Artificial Intelligence was used to generate graphics*

#ClearDataClearImpact



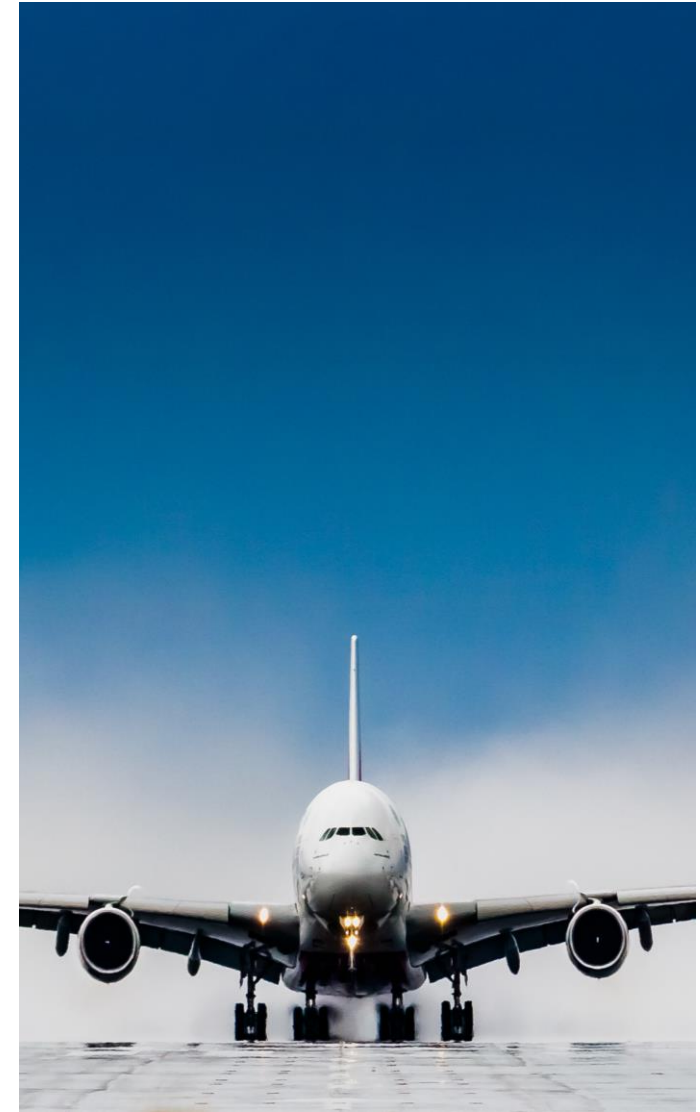
Introduction to Risk Based Acquisitions and Mergers

This should be simple, right?

Have you ever been asked to support the transfer of TMF ownership – from a CRO, a partner, or during a merger or divestment – and thought, “*This should be simple*”?

TMF transfers often look straightforward on paper, but they rarely are.

Today, we’ll walk through how a **risk-based approach** helps anticipate challenges, guide decision-making, and keep TMF transfers inspection-ready – so when turbulence hits, you’re prepared to stay on course and land safely.



What is Risk-Based TMF Migration & Why It Matters

- Risk-based TMF migration is an approach to transferring Trial Master File content from one system to another or location to another that prioritizes effort based on the regulatory and operational risk associated with the records being moved rather than treating all records equally.
- Risk-based migration drives earlier cross-functional alignment, reducing rework and preventing ad-hoc decisions that can create gaps in the TMF record
- It decreases downstream impact: focusing checks on critical content preventing last-minute QC spikes and reducing the likelihood of audit/inspection findings when options & remediation resources are limited
- It avoids “lift-and-shift” – simply moving problems instead of resolving them



Establishing Risk-based Approach to Acquisitions and Mergers

Identifying your team and need for experts

Establishing The Framework

Risk-Based TMF Transfer Purpose

Ensures patient safety, data integrity, and regulatory compliance while avoiding disproportionate controls.

Regulatory Framework Emphasis

ICH E6(R2) and E6(R3) promote quality by design and proportionate oversight in TMF management.

Focus on Critical records

Prioritizes essential records like protocol, consent forms, and safety reports for thorough review.

Defensible Risk-Based Decisions

Supports clear rationale for review depth, sampling, and exclusions based on documented risk assessments.

Tip: Each acquisition is going to be different, adjustments at the project and study level will be needed.

What is your Risk Mitigation Strategy

- Think about where you might have Risk
 - Taxonomy & Meta Data – Classification of content
 - Accessibility to content (lost, duplicated, corrupted content)
 - Chain of custody, audit trail, traceability – Regulatory compliance
 - Positioning for regulatory submissions – Inspection Readiness
 - Maintaining the value of the asset to the organization - Completeness
 - Business continuity and Long-term continuation of product line (usable data)

TIP: Build a Risk Register and Define clear Go/No-Go criteria

Navigating Turbulent Zones – High Risk Content Areas

Turbulence Zones are TMF content areas where migration defects are most likely, and where the impact to inspection readiness is highest.

Focus on what matters:

- Map and validate high-risk zones
- Use targeted QC checks and sampling, weighted by risk type rather than 100% QC
- Checking Pre-Migration / Post Migration of content



Adopting a Flight Plan Mindset

We don't just react to acquisitions – we plan for them.

- Every acquisition begins with a defined mission and a clear destination
- Roles and responsibilities are assigned before the journey begins
- The route is mapped; milestones, timelines and handoffs are established upfront
- Contingencies are built in (known risks are identified and planned for while still on the ground)
- Checkpoints are scheduled throughout to ensure the flight stays on course
- The crew should be fully briefed, so no one is surprised in-flight
- Adjustments may happen but the destination remains the same
- Inspection readiness isn't the finish line – it's weaved into the flight plan from the start



Engaging the Flight Crew

Identifying your team and need for experts

TMF During Mergers & Acquisitions

Members of the Acquisition Flight Operations Team

- Alliance Management: Finds and negotiates the transaction
- Legal: Governs information sharing boundaries
- Project Management: Drives alignment and keeps stakeholders informed
- Therapeutic Area: Vested interest in success of the merger/acquisition
- Functional Area(s): Identify what they need to understand the acquired content
- Clinical Records: Trying to make sure we have all of the TMF components (some which are managed/controlled by other Functional Areas)
- Various Records Groups (i.e., Information Governance): Each main area has records teams who are looking to support content

Establishing TMF Migration Flight Crew and Roles



Having the right skills is essential

- Migration Lead
- System Specialist
- TMF Compliance Specialist
- TMF Structure SME
- Study Team – Functional Groups

Engaging the Flight Crew Early for Success

- To ensure all key teams are aligned before wheels up, all are to be working from the same playbook
- Communication channels established early
- A well-briefed crew = a smoother flight and safer landing
- Role clarity upfront prevents missteps mid-flight
- Each FA shapes the flight plan
- Conduct due diligence assessment of systems and studies; share findings – no surprises at cruising altitude
- Conducting Risk Assessment - risks identified on the ground are easier to manage than in-flight turbulence

Charting the Flight Plan

Identifying how to best move the records



Planning the Course: Collect TMF Current State Info

Intake and standardize the information needed to plan and execute the study transfer and related study records/systems transfer.

This helps the receiving/transfer team:

- identify the right contacts and stakeholders
- define the scope (studies, systems, records, vendors like CROs)
- capture study details needed for planning (status, countries, sites/patients, timeline, PHI considerations, records outside TMF)
- align on project dates and risks so the transfer can be scheduled, resourced, and governed appropriately.

All are required to develop the Migration Plan

Planning the Course: The Migration Plan

Before we can fly the route, we need to know exactly what we're carrying.

- Understanding the full make-up of the study(ies) is the foundation of every migration plan.
- What studies are included? What are the therapeutic areas, phases, and statuses?
- Not all studies are on the radar. If the divesting company owns additional products or studies beyond the initial scope, those come with the deal too!
- What does the TMF look like? Is it complete, partial, or in need of remediation?
- What systems were used? Can they be mapped to our eTMF structure and how will it be done?

Planning the Course: The Migration Plan

Before we can fly the route, we need to know exactly what we're carrying.

- Does content exist that needs to be filed in an ancillary system?
- Are there active studies still generating records or have the studies closed?
- What are the regulatory obligations tied to these studies?
- Gaps and risks identified during due diligence directly inform the migration route. Confirm remediation owners/timelines before migration starts.
- The migration plan is the flight plan – it tells us where we're starting, how we're getting there, and what we need to land safely.
- Draft the plan with continuous status checks and team check-ins

Planning the Course: Establishing Integration Timelines

The check starts before the deal closes – timing is everything...

- Integration timelines are directly tied to the acquisition closing date
- Anticipated Inspections drive urgency and set the pace
- Expiring CRO contracts create hard deadlines for access and support
- Studies held by the divesting organization have a window – act before it closes
- Knowledge transfer must be prioritized before key personnel are gone
- System access and data availability have expiration dates
- Regulatory submissions and study milestones must be mapped to the timeline
- Every dependency is a checkpoint – missing one delays the entire route



Identifying Storms and Navigating Turbulence

What could go wrong and how to influence the outcome

Risk Control & QC Strategy

TMF Migration Risk Control – What to Get Right



System Validation and Compliance

Validated systems with robust audit trails and access controls reduce transfer risks and ensure regulatory compliance.

Metadata Consistency and Mapping

Consistent metadata and one-to-one field mapping between source and target systems minimize data transfer issues and risks.

Risk Mitigation Strategies

Identifying system gaps allows use of supplemental documentation and manual verification to manage transfer risks effectively.

Documentation of System Capabilities

Clear documentation of system capabilities and limitations is essential for demonstrating risk awareness and control.

Determine Risk-Based QC Approach (High/Medium/Low Risk Records)



High-Risk Record Controls

High-risk records require 100% detailed quality control including presence, completeness, and version accuracy checks.

Medium-Risk Sampling Approach

Medium-risk records can use statistically justified sampling based on error rates and pilot results.

Low-Risk System Reconciliation

Low-risk records are verified through system-level checks like record counts and folder completeness.

Risk-Driven Quality Decisions

Quality control is guided by documented risk assessments, ensuring resource allocation is effective and justified.

Apply Risk Tiers based on Record Criticality and Regulatory Impact (High/Medium/Low Risk Records)



High-Risk Records

These records are crucial for subject protection and trial integrity, often reviewed in regulatory inspections.

Medium-Risk Records

Support sponsor oversight and compliance, with moderate impact on safety and governance if issues arise.

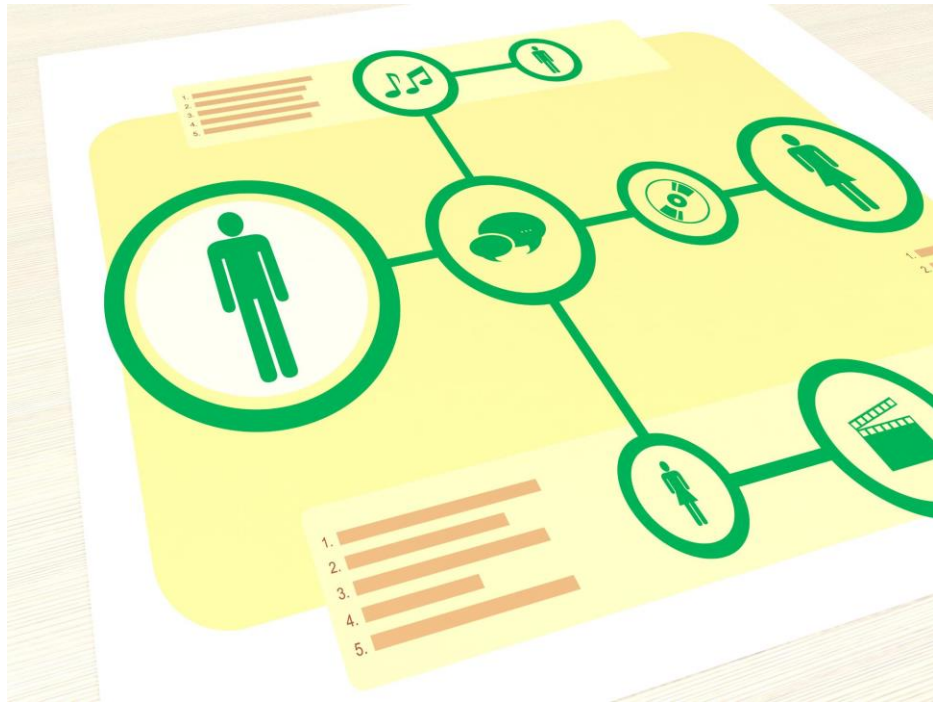
Low-Risk Records

Primarily administrative materials with minimal direct impact on patient safety or regulatory compliance.

Risk-Based Transfer Strategy

Applies stringent controls and verification for high-risk records while sampling lower-risk categories.

Consider Transfer Methods and Associated Risk



Automated Transfers

Automated transfers use validated tools, lowering risk by reducing manual errors and ensuring traceability but still require validation and checks.

Semi-Automated Transfers

Semi-automated methods involve tools plus human steps, increasing risk and necessitating more quality control for accuracy.

Manual Transfers

Manual transfers carry the highest risk due to human error, misclassification, and omissions during individual record handling.

Risk-Based Quality Control

A risk-based strategy matches quality control depth to transfer method risk and records rationale in the TMF Transfer Plan.

Read the Runway: Consider Study Stage, Timing, and Risk



Impact of Study Stage on Risk

Risk varies significantly with study stage; archived studies present lower risk than ongoing studies.

Critical Milestones Elevate Risk

Transfers near milestones like database lock or regulatory submission increase risk due to record sensitivity.

Risk-Based Control Strategies

Adjusting controls like parallel system access and content freezing manages risks during TMF transfer.

Documentation Supports Readiness

Documenting transfer rationale and mitigations ensures proactive risk management and inspection readiness.

Turbulence on the Horizon: Challenges that can be identified Upfront

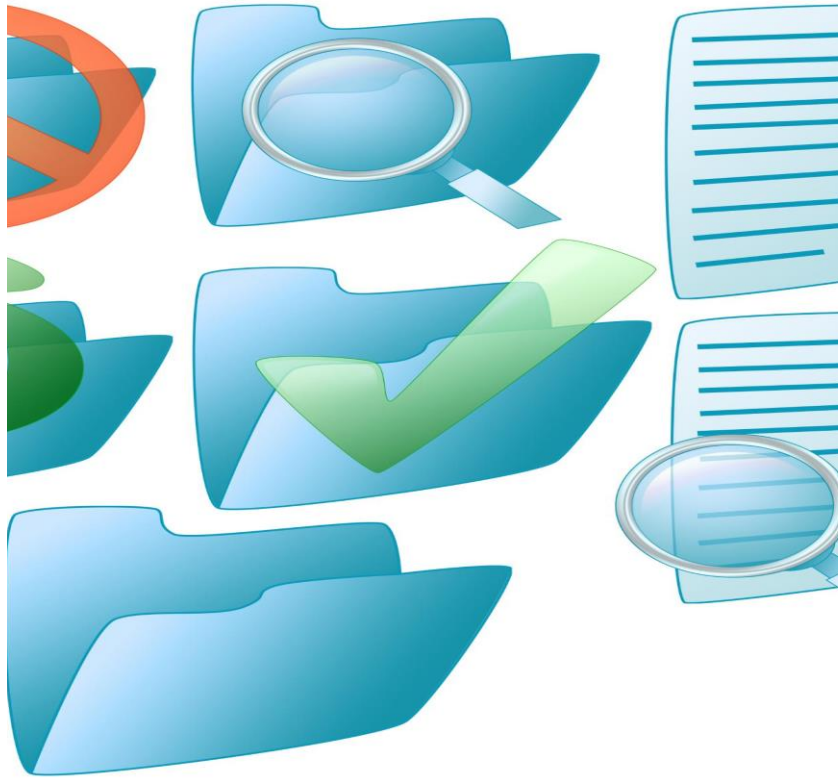
- Tight timelines driven by acquisition and integration deadlines
- Inspections occurring during transfer planning or execution
- High and competing stakeholder expectations
- Limited resources during the integration period
- Competing priorities across functions and workstreams
- Data integrity and version control risks
- Managing study team access during the transfer window
- Identifying and resolving duplicate content
- Ensuring completeness of file transfer and associated metadata
- Multiple CROs and vendors supporting different studies
- Use of disparate systems, repositories, and storage locations
- Inconsistent file naming conventions and organizational structures
- Need to map and reconcile content across multiple platforms
- Differences in system validation status and audit trail capabilities
- Chain of custody documentation gaps or inconsistencies
- Limitations in preserving historical audit trails across systems



Preflight Check and Take Off

Getting ready to fly

Objectives and Success Criteria for a TMF Transfer



Record Integrity Assurance

Ensure no records or metadata are lost, altered, or inaccessible during the TMF transfer process.

Continuity of TMF Oversight

Maintain sponsor and stakeholder visibility and control over the TMF throughout the system transition.

Regulatory Alignment

Align the transfer process with EMA and ICH guidelines to ensure regulatory compliance and audit readiness.

Measurable Success Criteria

Define measurable criteria such as 100% verification and user acceptance testing to confirm transfer success.

Required: Documentation and Traceability



Risk Assessment Documentation

Maintain a TMF Transfer Risk Assessment to identify, evaluate, and mitigate key risks with residual risk acceptance.

Transfer Plan Execution

Develop and implement a TMF Transfer Plan covering scope, responsibilities, quality control, and exceptions.

Traceability Artifacts

Use transfer logs, reconciliation reports, and exception registers to provide evidence of controls and issue resolution.

Accountability and Oversight

Ensure clear ownership and approval of records to reinforce accountability and oversight in the TMF transfer.

Ready to Fly

Taking Off.....and In the Air

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)
1. Continuously monitoring progress is everything landing without incident – soft approach
 2. Maintaining log of any issues/unexpected actions, decisions made in flight, and pivots/course corrections made in transit
 3. Assessing and monitoring risk – including the potential for downstream effects (it is about inspection)



This Photo by Unknown Author is licensed under CC BY-SA

Safe Landing and Post Flight Check

Lessons learned and Key take aways



Safe Landing your TMF

- TMF Content (regardless of what system it goes into) is complete and accessible for Inspection
- Key Factors to consider:
 - Knowing what has moved
 - Documenting where it is now
 - Checking the quality and content
- Making sure you don't have Non-Official repositories also holding content (Maintain Source of Truth)

Navigating the Weather – Lessons Learned



[This Photo](#) by Unknown Author is licensed under [CC BY](#)

**Prepare,
prepare,
prepare...**

Identify issues
before they
became critical
– risk mitigation

Do on-gong
assessments

Review your
Risk
Management
Plan

Determine
cause

Mobilized team
for resolution

Make team
aware of the
situation and
course of action

Getting back on
course – not
landing in the
jungle

Finding our way
back after the
long journey

The aftereffects
– what we are
learning now



Post-Flight & Q&A

What will we do

Common Pitfalls and Key Takeaways

Common Pitfalls in TMF Transfer

Risk-based TMF transfers often fail due to undocumented risk assessments and unjustified sampling. Avoid one-size-fits-all quality controls that overlook risk differentiation.

Inspection Concerns

Be cautious of prioritizing cost or speed over compliance, emphasizing the importance of thorough and justified processes.

Key Takeaways for Readiness

Ensure risk-based decisions are evidence-based, documented, and consistently applied with clear explanations suited to study context and system capabilities.

Benefits of Proper Implementation

Thoughtful risk-based TMF transfers show strong quality culture, effective oversight, and meet regulatory expectations.



Lessons from the Skies



- 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 and content is always necessary



Questions?

