# TMF Risk Management: Developing a plan for mitigating risk identified by the CDISC Risk Tool


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# Meet the Speakers

## Marion Mays

Title: CEO / Principal Consultant
Organization: Jerion Consulting Group

Over 30 years of experience supporting organizations through GCP regulatory inspections with FDA, MHRA, EMA, and PMDA. My experience working for sponsors, CROs, software vendors as well as directly helping sponsors manage inspections uniquely positions me to offer valuable insights into managing risk and the process of implementing Risk-Based programs.

## Sarah Hitching

Title: Director
Organization: Hedian Records Management

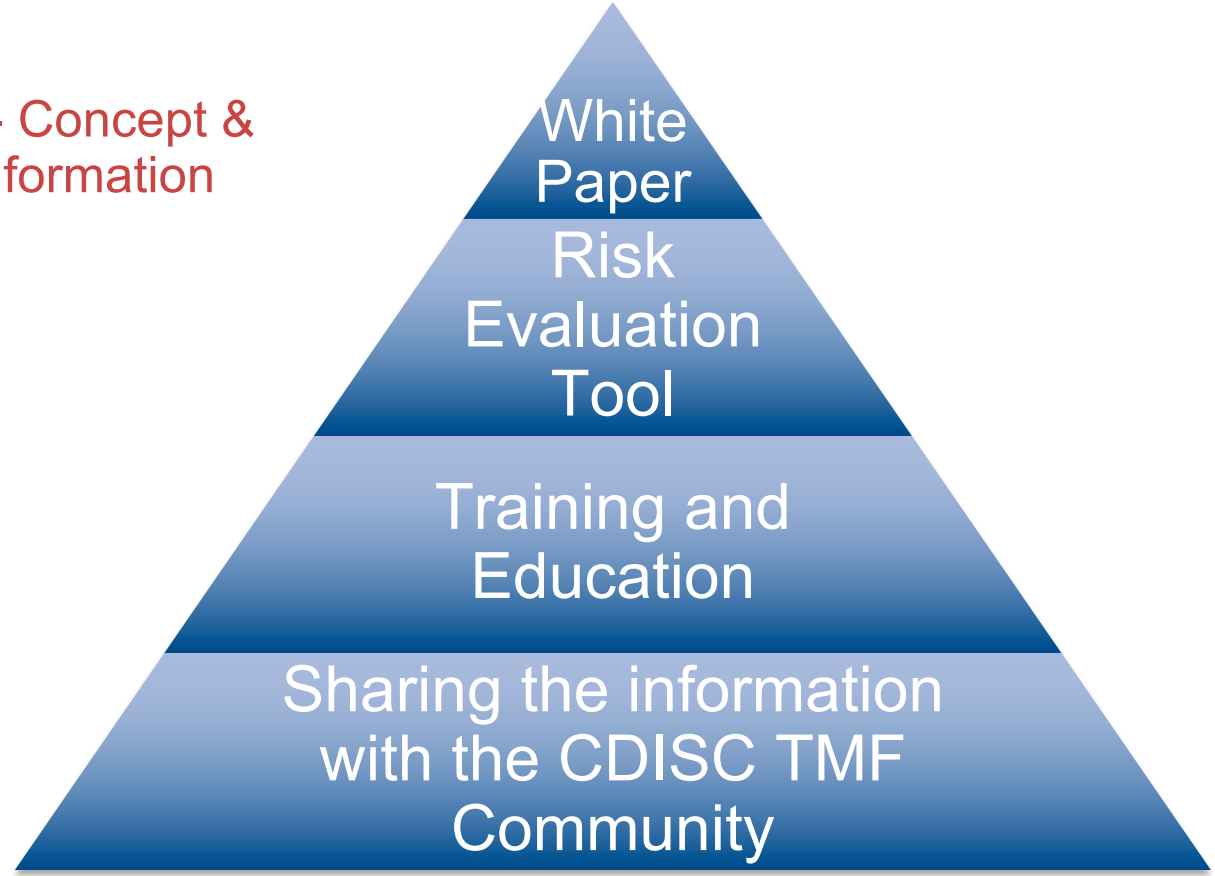
A highly experienced clinical trials expert who set up Hedian Records Management (HRM) in 2018. HRM provides expertise and TMF contract staff, particularly in relation to Inspection Readiness for pharmaceutical companies with little or no TMF experience.  Sarah has worked in a GCP environment for more than 30 years as a CRA, Project Manager/ Director then specialising in TMFs from 2005.

# Agenda

- Overview of the CDISC TMF Risk Tool….sneak preview
- How does the tool work……let's delve a bit deeper?
- What will the tool mean for me…..be prepared to give input
- How can I mitigate the identified risks?
- Q&A

# Timeline of the CDISC TMF Risk Initiative

2023 - Concept & Team formation



# CDISC Risk-Based Approach Concept

Whitepaper to establish best practice and provide context to establishing a Risk-Based Approach.

A Toolkit to help you evaluate your risk and support your approach to a sold Risk Based process.

Training that can support the activities to create and implement a Risk-Based approach to managing TMF Records.

# Overview of the CDISC TMF Risk Tool Journey

## Workshop 2 – Developing The Tool

- Leads: Rebecca Reel (Biogen), Ramya Iyer (Regeneron), Marion Mays (Jerion Consulting)
- Team Members: Initially 26 on the team, special thanks to Albert Cheng, Kelley Robinson, and Melissa Miller who were huge contributors.
- Deliverable: Design and build a tool that can support the evaluation for Risk in managing TMF
- Action: Over the past year several scenarios were discussed and developed. The tool needed to be user friendly and not require additional or bespoke software.
    - Team members developed the tabs you see today based on experience, lessons learned, and industry knowledge.
- Output: The team agreed on Excel as the best tool which was universal. Developed targeted sections to support key areas of risk associated with managing TMF content

# How does the tool work

Each of the tabs in the Workbook support specific areas to consider when looking at Risk of the TMF

- Start Here: Instruction on how to maximize the use of the tool
- Final Scores
- General Considerations
- Study Start Up
- Oversight of Internal Resources
- QC
- Software Checklist
- Service Providers
- Study Closeout and Archiving
- Study Specific

Depending on your approach to managing TMF, review and rate your compliance to the statement

# How does the tool work

- Depending on your approach to managing TMF, review and rate your compliance to the statement
- Review each tab or select those that you would like to evaluate your risk
  - Guidance and consideration for each of the statements is also included
- Each response will indicate a risk level
    - Impact
    - Probability
    - Compliance
- Each tab will provide an overall risk level for that section
- Once you have completed the tabs, you will be able to see areas you may have risk
- The Final Score tab will provide a summary of your responses

# How does the tool work

| A | B | C | D | E | F | G | H |
|---|---|---|---|---|---|---|---|
| **Statement** | **Additional Considerations** | **Your Answer** | **Impact (1 = Low, 2 = Medium, 3 = High)** | **Probability (1 = Low, 2 = Medium, 3 = High)** | **Compliance Risk (1 = Low, 2 = Medium, 3 = High)** | **Risk Rating** | **Action Plan/ Mitigations** |
| My organization uses a service provider's eTMF | If with a vendor, what kind of access do you have, direct?<br>If with a vendor, do you have any limitations on the access (such as running reports or other visibility to record status).<br>If using CSP's eTMF system, do you have direct interaction with teams responsible for filing documents?<br>If using CSP's eTMF system, do you train CSP staff on your organization's TMF Process and SOPs?<br>If CSPs SOPs are being used, has the sponsor's project team trained on the SOPs?<br>Is there any concern with giving/getting actual copies of the SOPs (full text) rather than just the List of SOPs? Training on SOPs: is read/understand level training enough? | | | | | | |
| My organization has used this provider before and this is not a priority study. | Does that impact how you manage the clinical service provider (CSP)? What about things like low-risk studies? Does things you say are low-risk still merit the same type of oversight? And if you're asking for the clinical service provider to operationalize this study does that impact how you oversight the CSP? | | | | | | |
| The contractual outsourcing plan/agreements include TMF and TMF services as an essential part of the document. | Have you considered when your risk 're-assessments' should happen during the life of the study? (e.g. ... you get into a study and then it is terminated/shelved, does that change your level of oversight of a service provider?)<br>Has the priority of the study changed over time/ is this a "rescue" situation | | | | | | |

# What will the tool mean for me?

Support your efforts in mitigating risk with the TMF

Bring rational and reason to how you are managing your TMF

Provide a format of how to approach the TMF from a risk based view point

Produce a document to support requests for improvements to process or staff etc for senior management

Provides a process to share with regulators on how risk was evaluated

# DEMO

Take a look at ‘Start Here’

Show how the tabs are set up by looking at ‘General Considerations’

Work in ‘Study Start Up’ to show how the tabs work. Audience input required!

# Case Study – Study Start Up

Medium sized pharma

600 employees

Based in Europe

10 marketed products

10 clinical studies

€7.8m Revenue

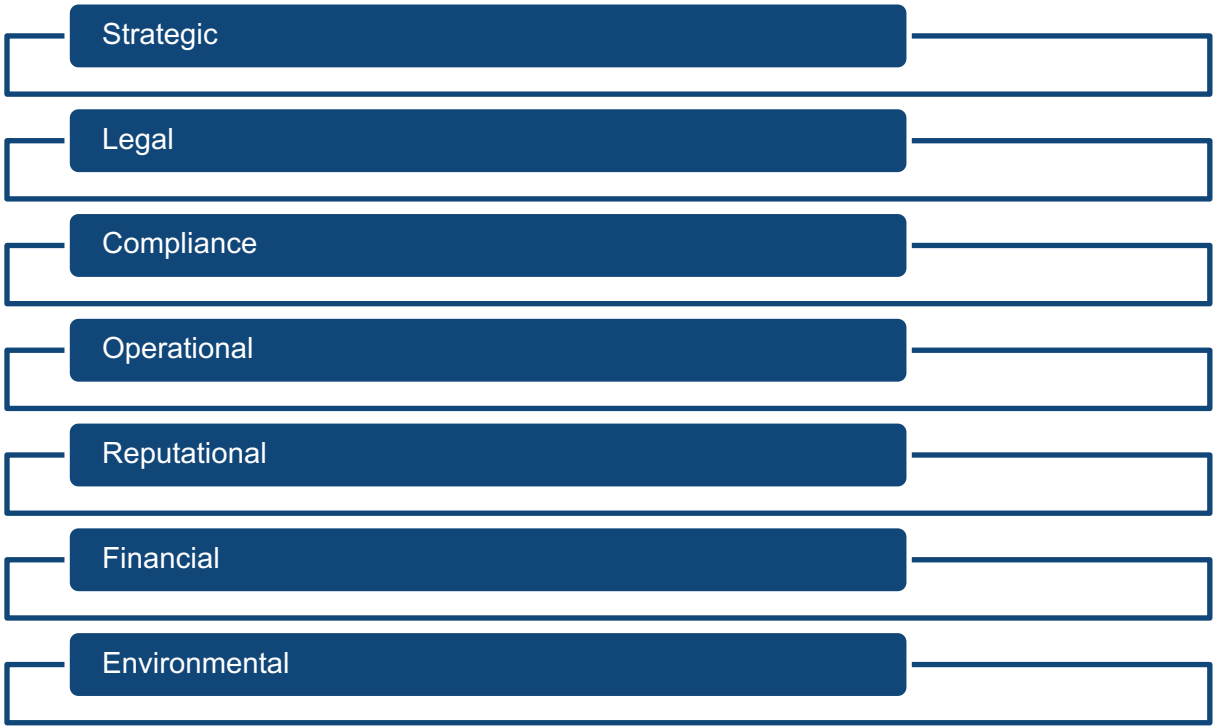
Use two CROs

Various phase studies

Multi-Country

Various in-house / commercial systems

# Mitigation of the identified risks – identify type



# Mitigation of the identified risks – approaches

| | |
|---|---|
| Transfer | • To service provider<br>• e.g. TMF or TMF provider |
| Accept | • Short or long term if cannot be avoided<br>• e.g. no dedicated TMF staff |
| Avoid | • Where possible<br>• e.g. use of two TMF providers |
| Reduce | • Take steps to lessen impact<br>• Most common approach |

# Q&A