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Is TMF Really Too Much Fun? Challenging the TMF Culture Through Education and Collaboration

Presented by: India Gardner, Associate Director, TMF Operations,
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Meet the Speaker

India Gardner

Title: Associate Director, TMF Operations

Organization: inSection Group, LLC

I am India Gardner. I am an Associate Director in our TMF Operations department at inSection Group, LLC. In my current role, I oversee our TMF Managers as well as provide support and oversight for various projects. I have been in the clinical research industry for ten years, with seven of those dedicated to Trial Master File. During my time working in TMF, I've been able to gain a multitude of experience in process improvements, SOP/WI writing, program oversight, people management, and training. I consider myself a TMF-lifer as TMF has become a treasured passion of mine.



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- *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.*



Agenda

1. Changing the Way We Think
2. Relatable Education
3. TMF Stakeholder Groups
4. Passionate and Experienced Resources



Changing the Way We Think

Both perspectives!



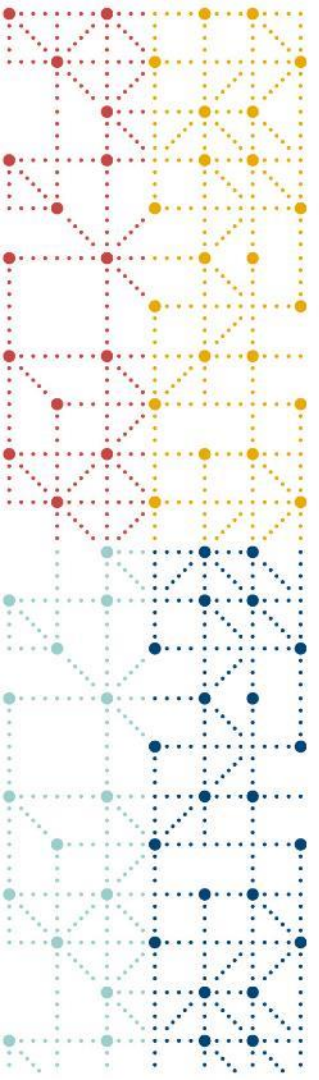
The Perfect Combo!

- **Perspective is Key**

- TMF Operations cannot solely create and maintain a complete TMF without the help of other stakeholders.
- Without input or expertise from other functions, the TMF will be mediocre at best.

- **Prioritization**

- Keeping the TMF current is an **ongoing activity** that requires participation from all stakeholders.
- There are times where study tasks may be more “important” than filing or reviews.
 - Establish departmental TMF SMEs or TMF Resources that specifically monitor the department TMF contributions to ensure compliance.
 - Create time, as TMF is just as important. It’s simple, no TMF – no proof.

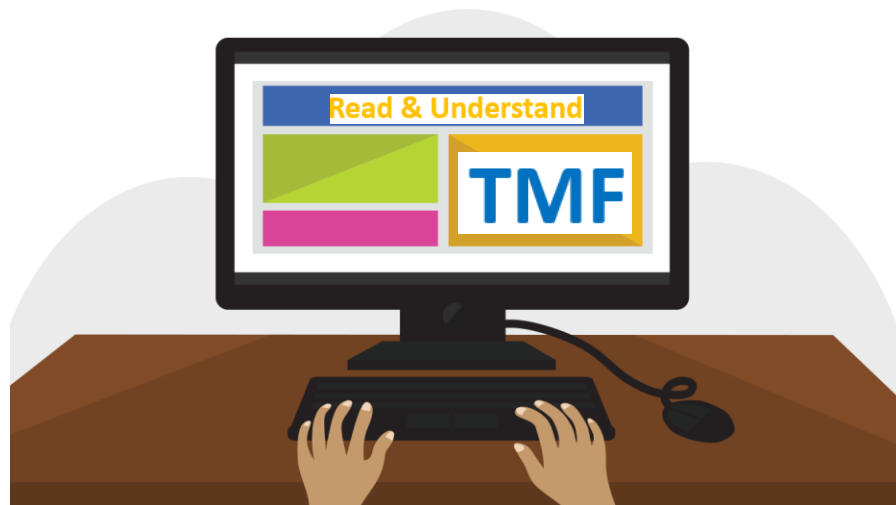


Relatable Education

The more you know!

The Basics

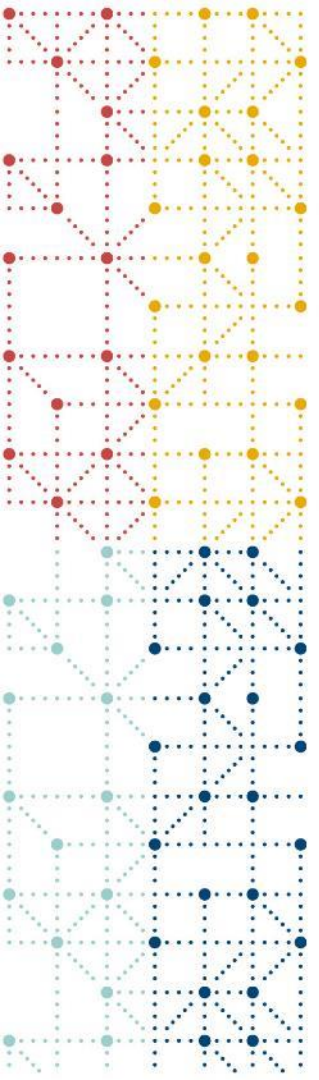
- General TMF Education
 - TMF Education for end users generally includes the following:
 - TMF Plan and Index templates
 - SOPs and WIs
 - System End User Training
 - Navigation
 - Uploading
 - Reports/Dashboards.
 - Training completion consists of an acknowledgment or a training certificate.





Going Beyond the Basics

- Departmental TMF Trainings
 - Understand that every department may contribute to the TMF differently.
 - General TMF Trainings do not cater to department needs.
 - Every department needs to understand their individual contributions.
- Study Team TMF Trainings
 - Each study may not have the same study requirements.
 - Reviewing the TMF Plan and Index on the study level highlights TMF requirements and opens space for questions and expectations.
- Incorporating TMF Filing Guidance in Departmental SOPs/WIs
 - Each department contributes to the TMF by filing directly into the TMF or noting other validated alternative locations their documents are housed.
 - Having guidance incorporated in departmental SOPs/WIs for known general/often collected documents, reduces confusion during TMF index reviews and QCs.
 - Get by-in from TMF resources on how to incorporate verbiage.



TMF Stakeholder Groups

Collaboration fun!

What are TMF Stakeholder Groups?

- A core team of TMF SMEs for their function, that will meet on a scheduled basis to provide feedback, best practices, updates, and departmental expertise to improve overall TMF involvement and compliance.



Create Your Team

- The creation of your team must start at the leadership level.
- The goal is to inform all leaders of the intent of the group and task them with selecting 1-2 people that they believe will contribute to the success of their department's TMF compliance.

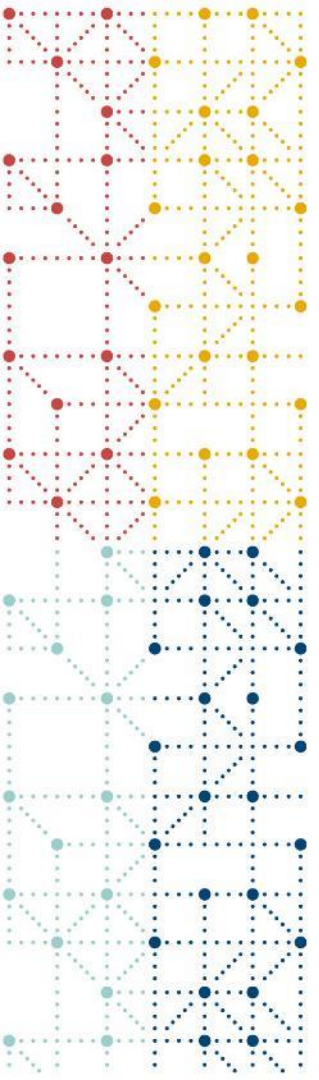
- Promotes information flow and a sense of inclusiveness across the board.
- Effectively updates everyone in real time on departmental process updates or changes.





Make it Official!

- Develop a Charter:
 - You should document the following:
 - Purpose
 - Expectations of the team
 - Meeting Schedule
 - Associated team members (by department).
 - The core team should all have input regarding the contents of the charter.
 - Charter should be signed off by core team leaders (usually TMF Leadership) and housed in a centralized location where all members can access it.



Passionate and Experienced Resources

You have to love what you do!

The Right People

- It takes a lot of work and a lot of heart to work within TMF in any capacity.
- TMF is not always fun, but these are times where good people with passion shine the most!



Characteristics of the Right People

- Experience

- While there are some TMF positions that can be performed by entry-level experience people, TMF management and oversight positions should not be classified as entry level.
- Those working in TMF should have an understanding and experience in the following:
 - The industry
 - Terminology
 - ICH GCP
 - Ability to identify and understand basic study documentation
 - All functional groups
 - TMF System
 - Various experiences in the most used/common EDMS
 - TMF related documentation
 - Critical thinking



Characteristics of the Right People

- Passion

- TMF can have its challenges, those with the right attitude and those that are passionate about TMF can overcome those challenges.
- Passion is understanding the bigger picture. It's not *just* about the TMF, it's more about the end goal – getting the drug to patients who need them.
- Passion is not using TMF as a stepping stone to other positions. Dedication is pivotal.

- Leadership

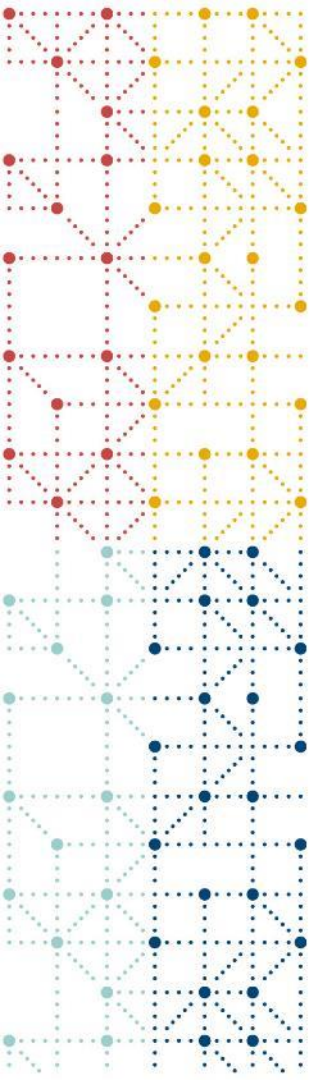
- With the amount of facilitation that it takes to get TMF tasks completed, one must possess leadership skills.
- Someone who has proven they can move the ball forward without nudges from management.
- Being innovative in your approach to collaboration.



Is TMF Really Too Much Fun?



...but only with collaboration, more robust TMF education, and passionate people.



Thank You!

Now, go make TMF Too Much Fun at your Organization!

