

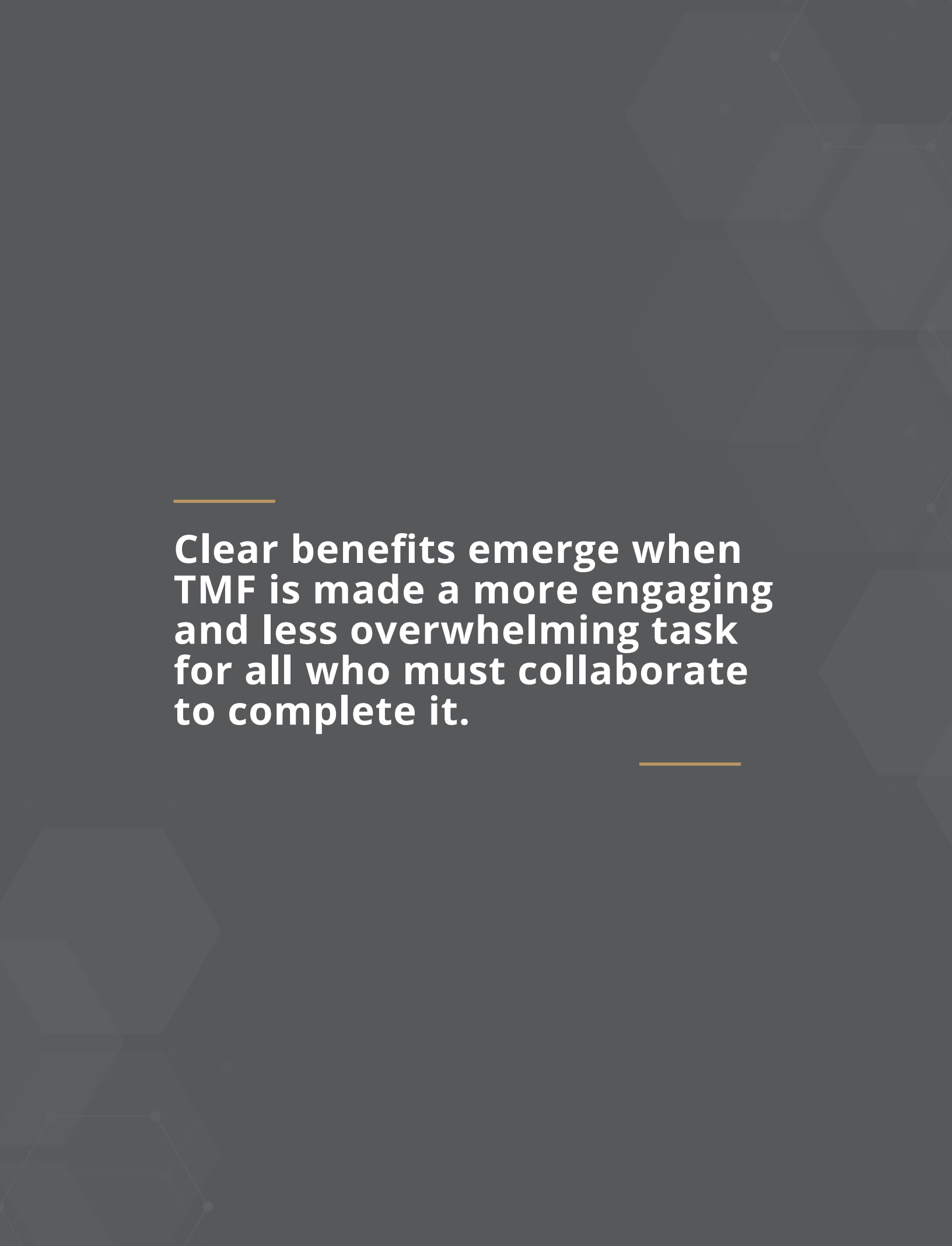


Restoring Business Trust and Confidence

inSeption

Modernize TMF Culture to Better Support Modern Clinical Trials

By **India Gardner**, inSeption Group



**Clear benefits emerge when
TMF is made a more engaging
and less overwhelming task
for all who must collaborate
to complete it.**



Modernize TMF Culture to Better Support Modern Clinical Trials

By **India Gardner**, inSection Group

To some, TMF stands for both “trial master file” and “too much fun!” But for others, preparing and managing the content within this vital repository can be an overwhelming process. Typically, the document management team overseeing the TMF embraces the work’s investigative elements. Most of their time is spent in the role of problem-solvers. But beyond that core team, enthusiasm for maintaining a clear and compliant TMF is much less consistent across many organizations and across the industry.

Clear benefits emerge when TMF is made a more engaging and less overwhelming task for all who must collaborate to complete it. This can be accomplished through a combination of

intuitive hiring, improved communication between stakeholder groups, and more meaningful, relevant TMF education. When these elements come together, the TMF becomes an integral part of the company’s work culture.

OBVIOUSLY, MAKE TMF AN ORGANIZATIONAL PRIORITY

Those who do not work directly in TMF, or document management, often feel little obligation as a TMF stakeholder, or do not recognize they are a stakeholder. They may have undergone general TMF training, and they still do not quite

understand their departmental role within the TMF. While dedicated TMF team members may be familiar with other departmental processes and requirements, they cannot be expected to be experts in those various departments. So, that team relies on stakeholders in each department to ensure completeness, timeliness, and quality in their TMF filings.

Without input or expertise from other functions, the TMF will be mediocre at best and incomplete at worst. Keeping it current is an ongoing activity that requires participation from all stakeholders. A key strategy to advance this viewpoint is establishing departmental SMEs or TMF resources who specifically monitor the department's TMF contributions to ensure compliance.

Usually, department heads are most appropriate to designate this person. It could be someone who has experience in the TMF or just someone who wants to learn more about TMF and becoming an SME. So, if no one in the department is proficient in the TMF (yet!), that should not be a deterrent to any of them being a TMF champion. It just means they need more guidance from TMF operations, allowing them to disseminate that information to the rest of their department. Still, the first qualification is interest. Anything can be taught, but you need invested participants willing to be the voice for a department and to help educate their peers.

Everyone on the study team should be trained on the TMF index, which acts as a road map for the study team, guiding them where and how to file all documents. They also should be reading and referencing TMF standard operating procedures (SOPs) and TMF work instructions (WIs). Still, even with these resources, compliance sometimes lags. Prioritizing this compliance starts with the head of each department.

When the department head makes TMF a priority and champions compliance, there is more engagement, more urgency about uploading

documents and completing TMF-related tasks in a timely manner, and more inquisitiveness. It is still the TMF team lead's responsibility to identify departments that are not as compliant as they could be and to strategize with those departments to improve the situation. But when leaders across the company are working together, the TMF becomes a smoother, more enjoyable experience for all involved.

GIVE STAKEHOLDER GROUPS A VOICE

Build a team focused on the TMF, involving at least one or two people from each department. They act as the hub where departmental personnel can share updates, concerns, and suggestions around the TMF. This ensures more voices are heard, creates a two-way flow of TMF information, and usually bolsters compliance.

The dynamic can be formalized by developing a charter documenting the departmental TMF team's purpose, setting expectations, and establishing a meeting schedule. Associated departmental TMF team members should have input into the charter's content and the document should be readily accessible. In addition to providing direction and clarity for departmental TMF efforts, the document helps inform others within the organization about the team's purpose.

For example, the company may be preparing for an upcoming inspection and needs evidence of how it approaches the TMF. The charter will help them explain to inspectors/auditors the effort and steps taken to keep TMF knowledge and understanding consistent across the company. It also helps the company's TMF team understand departments better — the pressures and burdens impacting how and when TMF documents are filed — allowing the TMF team to work with each department to accommodate them.

Also, bear in mind that the TMF often extends beyond the eTMF, encompassing data held in other repositories (such as electronic case report forms or the Argus platform) for various reasons. For example, the TMF system may not be designed for a certain document format, the file is too large to add to the TMF, or the file is confidential and must stay in a particular system.

Working across multiple systems can be burdensome and confusing for study personnel and can lead to TMF updates being forgotten, since the data is otherwise properly filed within the individual department's principal repository. Thus, it should be noted in the TMF index where each type of documentation or record is housed, so in the event a study is inspected or someone is reviewing the TMF index, the location of all data is clear.

Notably, a lot of training takes place when a study is newly created and finalized, or when certain trial elements have been updated. But sometimes, that training stays internal to the organizational TMF team; it does not necessarily reach other departments, creating gaps in knowledge and understanding. Ideally, the stakeholder group (e.g., departmental TMF teams and the organizational TMF team members) is assembled at this point to coordinate updates, either tailored to specific departments or relevant to all stakeholders.

PROMOTE TMF EDUCATION, NOT JUST TRAINING

TMF-specific training is always provided to TMF teams within their department, but how can it be made more relatable to those who do not work in the TMF daily? Training must speak directly to stakeholders. Individualizing TMF training may require more time and effort up front, but it can go a long way toward recognizing department-level needs and driving greater compliance.

TMF training for end users typically includes the TMF Plan and Index templates, as well as SOPs and WIs. TMF system end user training generally comprises system navigation, uploading documents, and managing various reports and dashboards. However, traditional training frequently lacks an opportunity for the trainee to ask exploratory questions, to question the training itself, or to provide their own expertise. As the saying goes, iron sharpens iron.

TMF education is not just teaching salient points and explaining the value to someone. It is also soliciting feedback that may contribute to the education process. With or without knowledge checks (e.g., a quiz at the end), training often advances personnel who do not fully grasp the instructions or concepts. For this reason, it is beneficial to have training calls or instructor-led sessions around massive documents like the TMF Index and the TMF Plan. Reviewing the TMF Plan and Index at a study level highlights TMF requirements and opens space for meaningful discussion. What is expected or ideal can be weighed, from a content perspective, against what departments consider to be feasible.

Progressing from there, departmental TMF training should take place, led by members of the organizational TMF team and designated departmental SMEs. Since every department contributes to the TMF differently, this training drills down into individual contributions that organizational TMF training can overlook. Every department needs to understand its specific contributions, as well as how to identify gaps in the TMF Index.

Expecting TMF proficiency from individuals whose training or support from department heads/management may be insufficient does not promote positive engagement with the TMF. However, an educated understanding of the TMF can render it (for the most part) an easy, quick-to-complete activity, compared with the experience of staring at a screen trying to figure out what should be uploaded or reviewed.

Accordingly, TMF filing guidance should be included in departmental SOPs/WIs. Each department contributes to the TMF by filing directly into the TMF or noting validated alternative locations where their documents are housed. Having guidance incorporated in departmental SOPs/WIs for known, oft-collected documents reduces confusion during TMF Index reviews and QCs. It also promotes buy-in from TMF resources on how to incorporate preferred verbiage.

SEEK PASSIONATE, EXPERIENCED PERSONNEL

Experienced, enthusiastic, and optimistic TMF leaders are instrumental to the success of changing a stagnant TMF culture. They are often the face and facilitator of the TMF, so those wanting to join any TMF team at any level need to understand the

weight of the responsibility that role bears and the amount of collaboration it requires. These individuals serve as accountability partners, driving collaboration within and between departments and letting it be known that everyone's involvement in TMF completeness is valued.

As the industry evolves and takes advantage of more advanced TMF systems and decentralized models, TMF operations will continue to be at the epicenter of company-wide collaboration. To learn more about how an enthusiastic TMF culture can benefit your study, contact the author and visit inseptiongroup.com.

To learn more, call:

Joseph Arcangelo Sr.
Co-Founder and Managing Partner
of **inSeption Group**
jarcangelo@inseptiongroup.com
267-498-5092

ABOUT THE AUTHOR



India Gardner is an Associate Director in TMF Operations at inSeption Group, LLC. She supervises TMF Managers and provides support and oversight for various projects. She has 10+ years' experience in clinical research, seven of those dedicated to TMF, spanning process improvement, SOP/WI writing, program oversight, people management, and training.

ABOUT INSEPTION GROUP

inSeption Group is a full-service, global outsourcing organization built on a foundational culture of exceptional service and quality. This culture attracts a subset of people who take a personal responsibility to deliver on what has been promised. inSeption Group's ability to custom-build teams with these experts, while providing valuable continuity, distinguishes our approach from traditional outsourcing options.