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Understanding the Humans of the TMF

Evaluating TMF stakeholder attitudes to achieve inspection readiness

The regulatory risk presented by the trial master file (TMF) continues to grow. Ironically, the implementation of the electronic TMF (eTMF), while overcoming many challenges associated with physical media, has introduced a new category of risk by increasing complexity and raising regulatory expectations. The TMF, once a periphery concern at the end of a clinical trial, has become an ongoing deliverable central to the trial's overall success.

TMF inspection readiness is no longer centered on a singular event, such as a pre-

and sponsors are struggling to adapt to this new paradigm. These TMF stakeholders recall that only fifteen years ago, the TMF was no more complex than a few rows of dusty papers in a filing cabinet.

Recent MHRA GCP inspection metrics confirm that the promises of eTMF digital transformation have not balanced the growing expectations of regulators. Comparing 2015-2016 GCP inspection metrics with 2016-2017 metrics shows that the finding category of "record keeping and essential documents" continues to

The TMF will require less of my time to manage in the future

Strongly disagree 9%
Strongly Agree 9%
Agree 24%
Neither agree nor disagree 31%
Disagree 27%
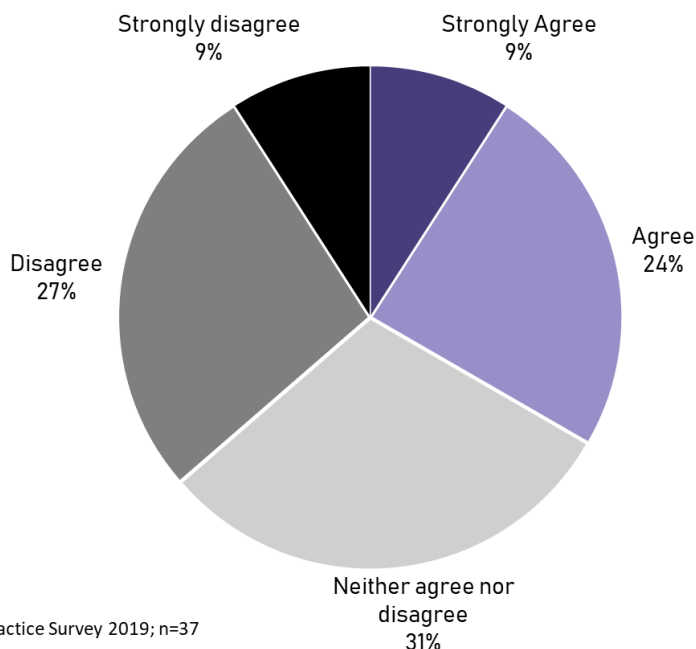
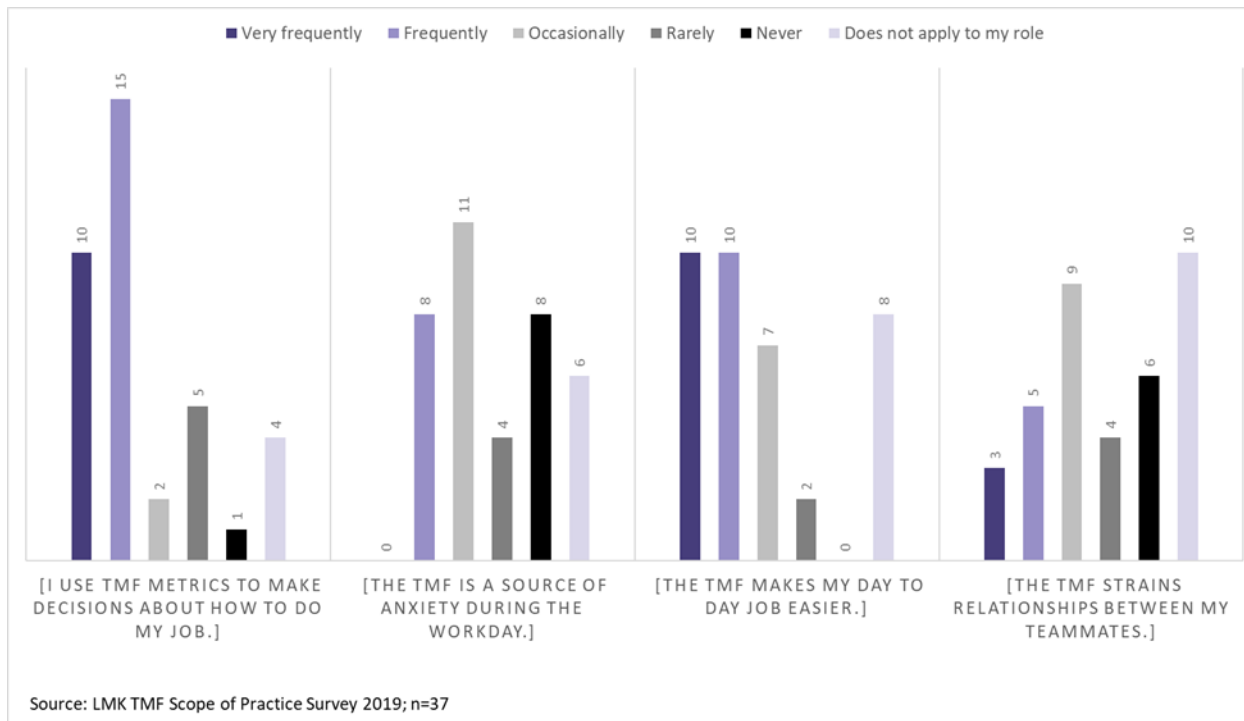Source: LMK TMF Scope of Practice Survey 2019; n=37

approval inspection, but instead requires a constant state of vigilance. This state of vigilance is now codified in regulation, including those of the MHRA, which state that "the master file shall at all times contain the essential documents relating to that clinical trial"[1]. Completeness, contemporaneousness, and accuracy are now expected from start-up to closeout. Trial sites, contract research organizations (CROs),

appear among the categories most frequently associated with major inspection findings for sponsors, CROs, and sites, often surpassing 15% of all major grade findings.[2,3]

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[1] http://www.legislation.gov.uk/uksi/2006/1928/pdfs/uksi_20061928_en.pdf

[2] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/631254/GCP_INSPECTIONS_METRICS_2015-2016__FINAL_21-07-17_.pdf

[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/706356/GCP_INSPECTIONS_METRICS_2016-2017__final_11-05-18_.pdf

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Legend: Very frequently | Frequently | Occasionally | Rarely | Never | Does not apply to my role

[I USE TMF METRICS TO MAKE DECISIONS ABOUT HOW TO DO MY JOB.]: 10, 15, 2, 5, 1, 4

[THE TMF IS A SOURCE OF ANXIETY DURING THE WORKDAY.]: 0, 8, 11, 4, 8, 6

[THE TMF MAKES MY DAY TO DAY JOB EASIER.]: 10, 10, 7, 2, 0, 8

[THE TMF STRAINS RELATIONSHIPS BETWEEN MY TEAMMATES.]: 3, 5, 9, 4, 6, 10

Source: LMK TMF Scope of Practice Survey 2019; n=37

The clinical trial industry has responded to the rising regulatory risk of the TMF, primarily, by pouring resources into eTMF adoption and migration projects. The explosive growth of these technological solutions, while succeeding in democratizing and globalizing many aspects of clinical research, has also overwhelmed TMF stakeholders in an avalanche of credentials, dashboards, trainings, workflows, and reports.

Even now, with the majority of migration work completed, industry struggles to utilize the technological solutions already put in place. Seeking to close this utilization gap, electronic solution providers have now shifted their focus from eTMF adoption and migration to the unification of the myriad of electronic platforms offered. Given the unique challenges of each clinical trial, users find that the electronic solutions often provided by third-party vendors cannot quickly pivot to respond to their changing needs. Unification, of electronic platforms, although an important step towards increasing efficiency and improving transparency, may still not address the foundational issues surrounding TMF inspection readiness.

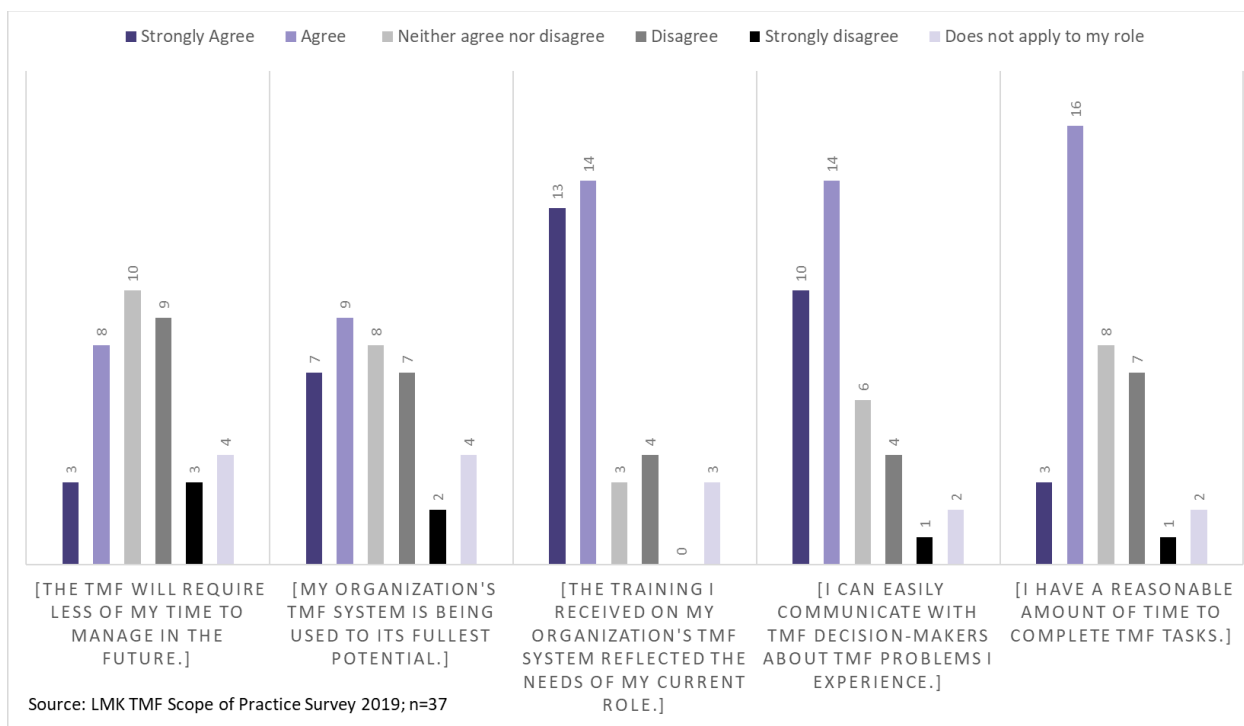Despite the increase of complexity, the central purpose of the TMF remains to, "permit evaluation of the conduct of a trial and the quality of the data produced"[4]. The TMF, regardless of technological changes, must serve the needs of the evaluators. Those evaluating the TMF, whether regulators, colleagues, or the public, continue to require a coherent, impartial, and persuasive narrative demonstrating the righteous conduct of a trial. Any potential solution to the problem of TMF inspection readiness, therefore, must consider more than just the hardware and software of the eTMF in isolation, but also consider how these tools augment the human roles, processes, and relationships that truly author the narrative within each TMF.

Starting a Dialogue

LMK Clinical Research Consulting's 2019 Scope of Practice Survey consisted of a survey instrument comprising of ten multiple-choice questions and two five-item matrix questions employing a Likert scale.

The survey instrument was broken into two main sections and one initial screening question

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[4]https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf

3

Legend: Strongly Agree · Agree · Neither agree nor disagree · Disagree · Strongly disagree · Does not apply to my role

[THE TMF WILL REQUIRE LESS OF MY TIME TO MANAGE IN THE FUTURE.]: 3, 8, 10, 9, 3, 4

[MY ORGANIZATION'S TMF SYSTEM IS BEING USED TO ITS FULLEST POTENTIAL.]: 7, 9, 8, 7, 2, 4

[THE TRAINING I RECEIVED ON MY ORGANIZATION'S TMF SYSTEM REFLECTED THE NEEDS OF MY CURRENT ROLE.]: 13, 14, 3, 4, 0, 3

[I CAN EASILY COMMUNICATE WITH TMF DECISION-MAKERS ABOUT TMF PROBLEMS I EXPERIENCE.]: 10, 14, 6, 4, 1, 2

[I HAVE A REASONABLE AMOUNT OF TIME TO COMPLETE TMF TASKS.]: 3, 16, 8, 7, 1, 2

Source: LMK TMF Scope of Practice Survey 2019; n=37

confirming the respondent's employment in the clinical research industry. The within-section order of questions, including the subitems of matrix questions, was randomized for each respondent in order to prevent order effects.

Section one attempted to identify a respondent's role within the clinical research industry, with questions like, "Do you manage individuals who conduct the day-to-day operations of clinical trials?" and "Is your main job responsibility TMF configuration, TMF maintenance, and/or TMF management?". Section one also contained a question intended to stratify respondents based on years of work experience in the clinical research industry (see figure on page five).

Section two included two five-item matrix questions intended to gauge a respondent's general attitude about eTMF implementation, eTMF training, interpersonal relationships among his or her TMF team, and TMF related workload/resourcing. Matrix question one asked respondents to designate the response that most correctly described their day-to-day work experience. For example, one subitem of matrix question one stated, "The TMF strains relationships between my teammates", and

allowed respondents to select their response via radio button on a Likert scale of, "Never", "Rarely", "Occasionally", "Frequently", "Very frequently", or, "Does not apply to my role".

Matrix question two asked respondents to mark the response that most correctly reflected their attitude about their role. For example , in response to the subitem statement, "My organization's TMF system is being used to its fullest potential", respondents were asked to choose a response via radio button on a Likert scale of "Strongly disagree", "Disagree", "Neither agree nor disagree", "Agree", "Strongly agree" , or, "Does not apply to my role".

The survey instrument was hosted on Google Forms. Promotion of the survey consisted of featured posts on LMK's LinkedIn page, emails to LMK Clinical Research Consulting staff, and direct email to LMK's promotional contact list. A public link to the survey instrument was made available on LMK's LinkedIn page and was imbedded in the various promotional emails. The survey was anonymous and no compensation was offered to participants. The survey was available via the public link to respondents for thirteen days. Thirty-seven responses were recorded.

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Although a representative cross section of clinical research professional respondents was desired, actual respondents are through to represent a niche group of experienced TMF specialists and clinical operations managers concerned with clinical documentation. Eighty-three percent of respondents had six or more years of clinical research industry experience. Seventy-eight percent of respondents reported that their main job responsibility was TMF configuration, maintenance, or management. This population is thought to closely mirror the demographic of subscribers to LMK's LinkedIn page, LMK's employees, and the employees of businesses that interact with LMK either professionally or on social media.

Same Goals, Different Perspectives

The pie chart on page two shows the proportion of respondents selecting each item when responding to the specific matrix subitem, "The TMF will require less of my time to manage in the future." This subitem was intended to investigate the validity of the justification for the capital expense of paper to eTMF migration: that eTMF adoption, whether through the elimination of paper or through functionality only possible in electronic format, will reduce the overall burden of eTMF management while still meeting regulatory expectations.
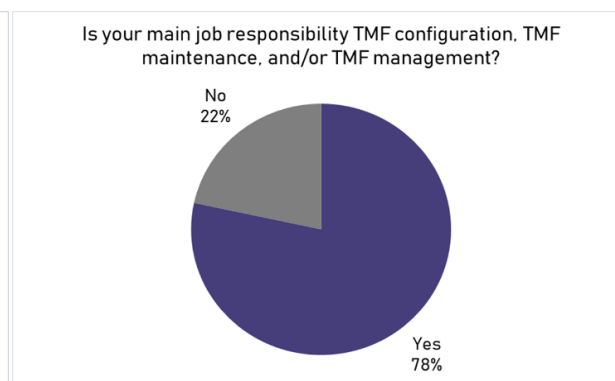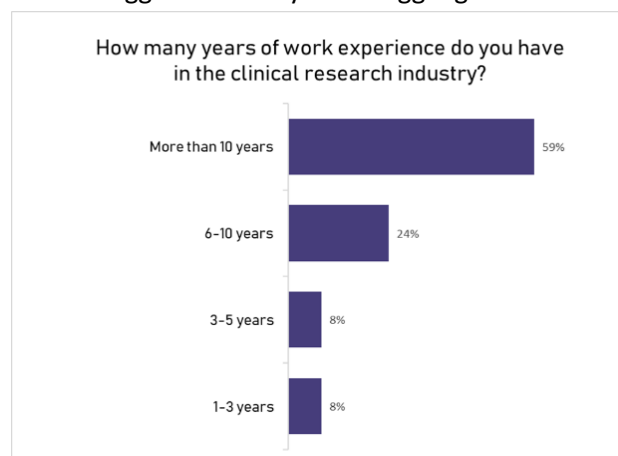
Only thirty-three percent of respondents, however, either agreed or strongly agreed with this statement. This data corroborates the previously discussed MHRA inspection metrics which suggest industry is struggling to meet their TMF compliance obligations regardless of the technological advances offered through a modern eTMF system.

Considering this evidence, and in order to provide further granularity of the diverse needs of TMF stakeholders, responses to the attitude-related questions of survey section two were separated in groups based on the responses to the stratifying questions in section one of the survey instrument. Responses to the two matrix questions were coded according to their five-point Likert scale value. For each of the two scales, the most negative value ("Never" or "Strongly disagree") were scored a value of one. The most positive values on the scale, ("Very frequently" or "Strongly agree") were scored a value of five.

Interesting mean score differences were identified between non-exclusive and exclusive eTMF adopter respondents, non-management and management respondents, non-TMF specialist and TMF specialist respondents, and respondents with greater than and less than ten years of experience. Although the statistical significance of each difference between the means was evaluated using a Student's t-test, given the small sample size and high variability between respondents, reproducibility is not assured. The data presented is selected for discussion value rather than statistical robustness.

Analysis of mean score differences between non-exclusive and exclusive eTMF adopters revealed significance differences between the groups regarding the statements "The TMF is a


How many years of work experience do you have in the clinical research industry?

More than 10 years — 59%
6–10 years — 24%
3–5 years — 8%
1–3 years — 8%

Is your main job responsibility TMF configuration, TMF maintenance, and/or TMF management?

No 22%
Yes 78%

Source: LMK TMF Scope of Practice Survey 2019; n=37

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source of anxiety during the workday", and, "My organization's TMF system is being used to its fullest potential". The large difference between non-exclusive eTMF adopters and exclusive eTMF adopters encouragingly suggests that the considerable effort and resources expended for migration from a paper TMF system to an electronic system does reduce the overall stress levels of TMF stakeholders. The reduced stress levels ideally contribute to increased performance and reduced TMF avoidance behavior, and ultimately increased TMF health.

The second comparison regarding the potential of the TMF system, although less robust sta-

Differences in attitudes about the statement "My organization's TMF is being used to its fullest potential" between eTMF adopters and non-adopters suggests that respondents utilizing eTMFs are able to, due to the functionality of their eTMF system, or other factors associated with eTMF adoption, leverage the TMF more effectively as a prospective trial management tool. Irrespective of the cause of this sense of TMF fulfillment, however, the shift from viewing the TMF as a static repository toward viewing the TMF as a contemporaneous risk management tool is a paradigm shift essential for achieving inspection readiness and meeting the

Mean Difference Between Non–Exclusive eTMF Adopters and Exclusive eTMF Adopters
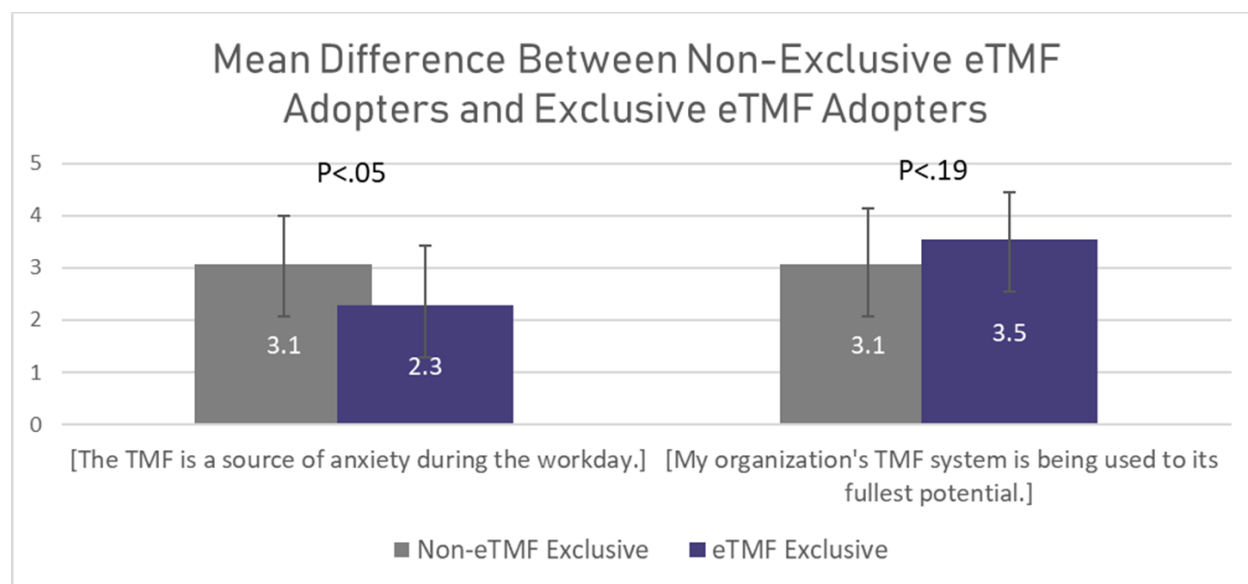
Source: LMK TMF Scope of Practice Survey 2019; n=37

tistically, further suggests that an investment in eTMF migration has palpable benefits for TMF stakeholders. Respondents whose organizations no longer employ paper TMFs for active projects were more likely to express that their TMF is being used to its fullest potential. Although individual conceptions of what qualifies a TMF being used to its fullest potential may vary, positive attitudes about this statement are thought to represent positive attitudes about TMF health, overall TMF competency, and satisfaction with the current TMF system, whether paper or electronic.

contemporary expectations of regulators.

Analysis of mean score differences between non-TMF specialists and TMF specialists also revealed differences in attitudes about the statement "My organization's TMF system is being used to its fullest potential", as well as differences in attitudes about metrics usage. A respondent was identified as a TMF specialist if the respondent answered affirmatively to the section one question, "Is your main job responsibility TMF configuration, TMF maintenance, and/or TMF management?" As above, positive attitudes about the statement, "My organization's TMF system is being used to its fullest

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potential", could suggest that the industry shift toward the utilization of TMF-specific teams and TMF-specialized staff has helped, on average, teams better access the potential of their TMF system. This potential benefit produced by TMF specialists could be the result of better TMF competency of TMF devoted staff, a net increase in TMF allocation because of dedicated TMF specialists, or increased performance of TMF specialists due to the elimination of competing priorities saddling general clinical operations staff. These potential benefits, however, should be considered in light of the resource

full one point difference, corresponding to one full item on the Likert scale, between those who are TMF specialists and those that are not. TMF specialist respondents therefore reported significantly greater frequency of metrics use compared to their non TMF-specialist peers.

Part of the difference between the score means of these two groups may be explained by the increased access to TMF data and reporting. Those with greater TMF responsibility also have great incentive to employ more efficient data-driven means of gauging TMF health as an alternative to the tedious manual generation of a
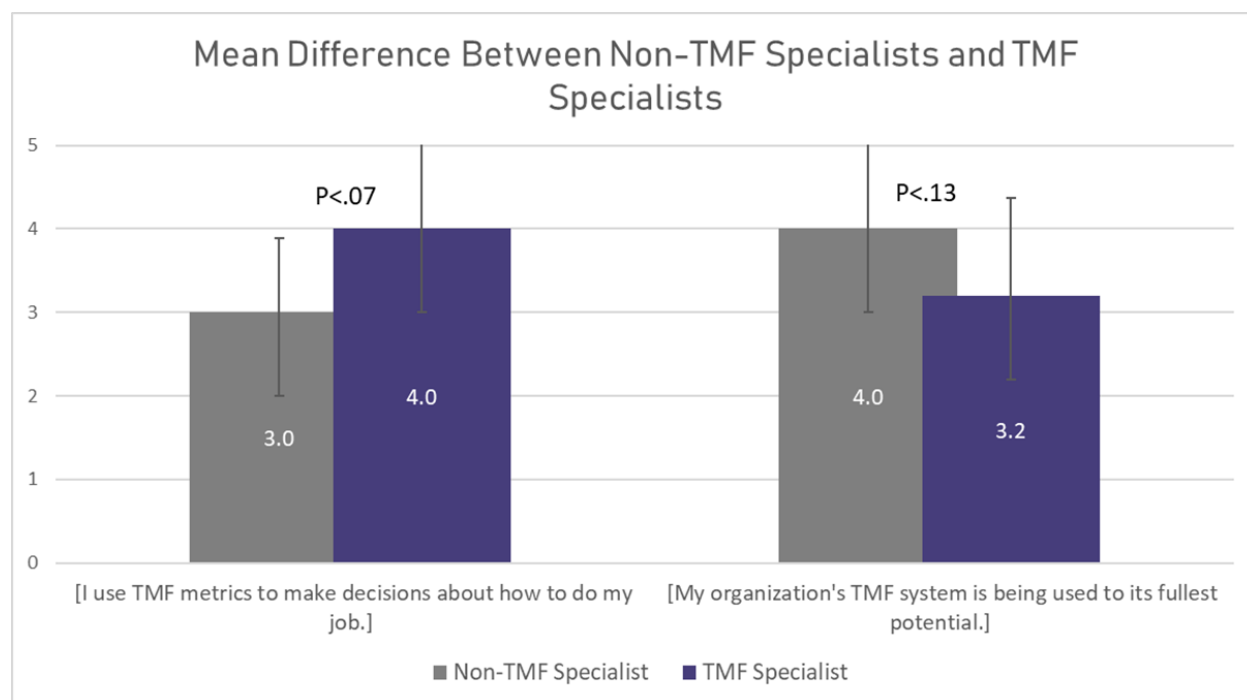
Source: LMK TMF Scope of Practice Survey 2019; n=37

and opportunity cost of these dedicated TMF roles.

The use of metrics for real-time decision-making is an essential component of both the digital transformation promises of eTMF solution vendors and the shift from passive to active TMF management mentioned above. For this reason, any differences in metrics usage between groups are of particular importance to better understanding the needs of TMF stakeholders. The comparison of group mean scores for the statement, "I use TMF metrics to make decisions about how to do my job", reveals a

complete document inventory.

Regulators, however, also increasingly emphasize the contemporaneousness of the TMF as important evidence of compliant trial management oversight. Due to the increasing imperative of adopting a data-driven risk-based trial management plan, it is concerning that TMF data appears to be siloed with TMF specialists.

Unexpectedly, TMF specialist respondents were less likely to affirm that their organization's TMF is being used to its fullest potential

despite, assumedly, a greater average level of TMF competency. Such a result suggests that those respondents who less frequently interact with the TMF may not be aware of the full functionality of the TMF, while those who do interact with the TMF more regularly have greater awareness to ongoing TMF health challenges and operational shortcomings.

Analysis of mean score differences between management and non-management respondents revealed significant differences between attitudes about how the TMF impacts relationships among teammates and, as above, attitudes about the statement "My organization's TMF system is being used to its fullest potential".

to the TMF disproportionately impacts the relationships of those TMF stakeholders in management roles. Although the increased incidence of relationship related stress reported by manager respondents could be, in part, due to the increased responsibility associated with management roles, the difference between managers and non-managers suggests that TMF engagement or expectations may not be consistent across teams or roles. Extrapolating further, managers may be more likely to be placed in situations where TMF expectation and TMF reality conflict, thus producing friction among teammates. In response to this difference be-
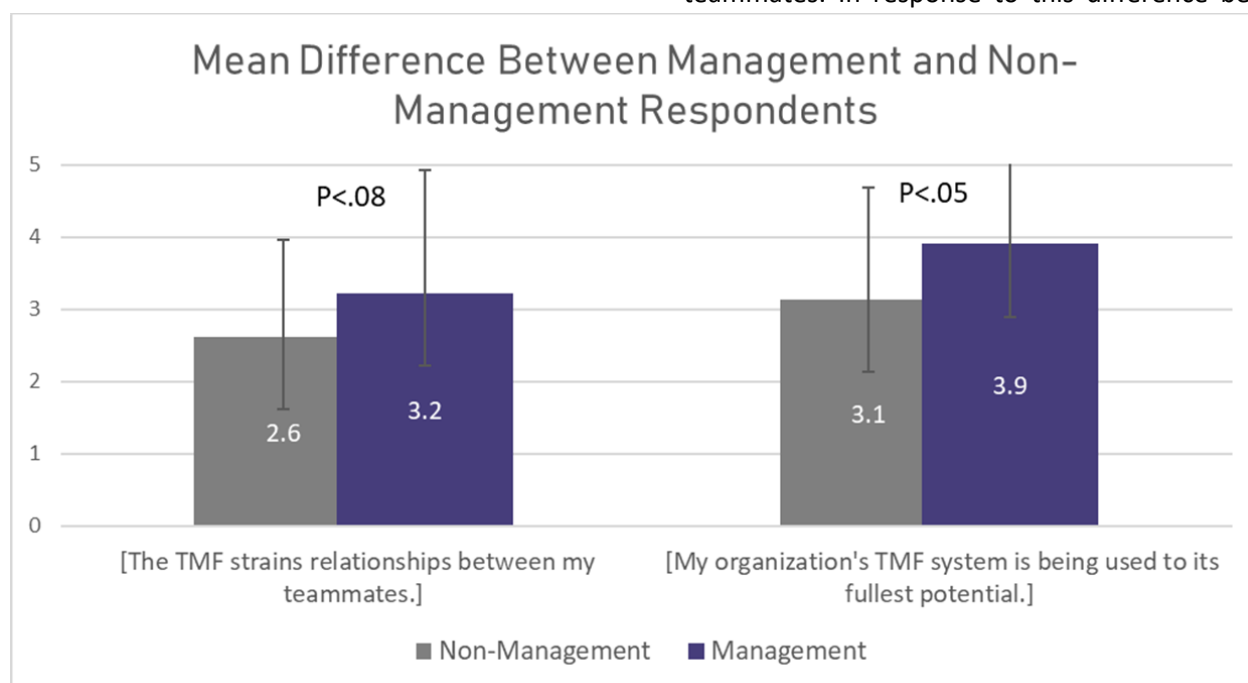
Mean Difference Between Management and Non-Management Respondents

P<.08

P<.05

Non-Management: 2.6 Management: 3.2
[The TMF strains relationships between my teammates.]

Non-Management: 3.1 Management: 3.9
[My organization's TMF system is being used to its fullest potential.]

■ Non-Management   ■ Management

tudes about the statement "My organization's TMF system is being used to its fullest potential". A respondent was identified as a manager if the respondent answered affirmatively to the section one question, "Do you manage individuals who conduct the day-to-day operations of clinical trials?" or "Is your current role a senior management, executive, and/or a director level position?"

The difference between management and non-management respondent mean scores regarding the statement about relationships between teammates suggests that stresses related

tween attitudes about the impact of the TMF on relationships, those making resourcing decisions should attempt to identify what aspects of the TMF are creating friction between teammates or teams in order to more equitably distribute the responsibility for addressing TMF challenges.

Manager respondents also reported a significantly more positive attitude about the statement regarding achievement of the full potential of the TMF system in use at their organization. Evaluation of this difference between managers and non-managers should be consid-

Pearson's Correlation Coefficient Heatmap of Matrix Question Subitems

	[I use TMF metrics to make decisions about how to do my job.]	[The TMF is a source of anxiety during the workday.]	[The TMF makes my day to day job easier.]	[The TMF strains relationships between my teammates.]	[The TMF will require less of my time to manage in the future.]	[My organization's TMF system is being used to its fullest potential.]	[The training I received on my organization's TMF system reflected the needs of my current role.]	[I can easily communicate with TMF decision-makers about TMF problems I experience.]
[I use TMF metrics to make decisions about how to do my job.]								
[The TMF is a source of anxiety during the workday.]	0.22							
[The TMF makes my day to day job easier.]	0.35*	0.35*						
[The TMF strains relationships between my teammates.]	0.08	0.61***	0.21					
[The TMF will require less of my time to manage in the future.]	0.21	0.09	0.52***	0.26				
[My organization's TMF system is being used to its fullest potential.]	0.19	-0.17	0.20	0.15	0.25			
[The training I received on my organization's TMF system reflected the needs of my current role.]	0.27	0.10	0.16	0.04	0.15	0.56***		
[I can easily communicate with TMF decision-makers about TMF problems I experience.]	0.25	-0.03	0.48***	-0.17	0.37*	0.39**	0.39***	
[I have a reasonable amount of time to complete TMF tasks.]	0.12	-0.05	0.44**	0.03	0.32*	0.53***	0.29	0.51***

***p<.001, **p<.01, *P<.05

Source: LMK TMF Scope of Practice Survey 2019; n=37

ered in tandem with the pervious comparison of TMF specialists and non-specialists regarding this statement.

Non-managers, presumably, have a day-to-day job experience that provides greater exposure to the granularity of trial conduct, including routine TMF administration tasks. Perhaps non-managers feel their TMF system is not being used it its fullest potential because of this greater TMF administrative burden.

It is also possible that non-managers are not sharing in the benefits of the TMF or eTMF (mainly increased oversight via reporting and

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automation) because their role is less likely to benefit from the robust reporting functionality of most eTMF systems. Conversely, a more pessimistic interpretation could be considered, where managers are overly optimistic about the utilization of the TMF because they are insulated from the weaknesses of their TMF system and/or processes by those who report to them. Regardless of the cause of these differences in attitudes between managers and non-managers, the divergence between these two groups should challenge teams to evaluate whether their TMF system and associated TMF processes produce implicit barriers to communication between those in decision-making and administrative roles.

Deeper Correlations

In addition to examining mean score differences between groups, a correlation matrix was created using data from matrix question subitem responses. Statistical significance was calculated for each pair of subitems. A heatmap was created from the correlation matrix and is included on page nine. Again, as discussed above, given the small sample size and high variability between respondents, reproducibility is not assured.

The decimal value listed each cell of the heatmap is the Pearson correlation coefficient between the two matrix question subitems in the corresponding horizontal and vertical headings. Values can range from -1 to +1. A value of zero indicates there is no linear association between the two variables. A positive value indicates a positive correlation where a negative value indicates an inverse correlation. In the heatmap, darker tones indicate a higher absolute value and therefore a stronger correlation. Many strong and moderate correlations were identified. The correlations discussed here are chosen for discussion value, not necessarily their statistical robustness.

The TMF makes my day to day job easier.

The statement "The TMF makes my day to day job easier" correlated strongly and signifi-

cantly with "The TMF will require less of my time to manage in the future". This correlation suggests that, as observed indirectly through the group mean score comparisons, TMF stakeholders that are positive about their current interactions with the TMF also tend to be optimistic about the future of the TMF.

"I can easily communicate with TMF decision-makers about TMF problems I experience" also correlated strongly and significantly with the above statement, implying that as also suggested by the group score mean comparisons above, attitudes about the TMF are shaped heavily by the openness of communication between administrative users and managers or decision-makers.

Finally, and to a slightly lesser extent, those who report positive attitudes related to the statement, "I have a reasonable amount of time to complete TMF tasks" also feel the TMF makes their daily job experience easier, underscoring the importance of proper resourcing for TMF stakeholder performance.

My organization's TMF system is being used to its fullest potential

The statement, "My organization's TMF system is being used to its fullest potential" correlated strongly and significantly with positive attitudes about "The training I received on my organization's TMF system reflected the needs of my current role". The correlation of positive attitudes about these two statements underscores the importance of a strong training program implemented along with any TMF system, whether paper, hybrid, or electronic. Although correlation does not equal causation, it follows that appropriately trained TMF stakeholder are able to fully leverage the features of a TMF system. An organization that uses its TMF to its fullest potential is also more likely to invest the resources necessary to tailor training to the roles of its employees.

"I have a reasonable amount of time to complete TMF tasks" also correlated strongly and significantly with "My organization's TMF sys-

tem is being used to its fullest potential". As discussed in the previous set of correlations, this matrix question subitem probes respondents' attitudes about their own workload and perceptions of their teams resourcing overall. The correlation of these two statements, therefore, positively suggests that organizations that fully leverage their TMF may actually increase the efficiency or reduce the workload of their TMF stakeholders. Conversely, the correlation could also indicate that employees that feel rushed when working with the TMF cannot use the TMF to its fullest potential. In either case, it is prudent to consider that clinical operations resourcing issues and TMF quality issues are likely synergistically linked.

I can easily communicate with TMF decision-makers about TMF problems I experience

Correlating moderately and significantly with several other statements, "I can easily communicate with TMF decision-makers about TMF problems I experience" emphasizes the importance of healthy relationships between TMF decision-makers and TMF stakeholders.

"I can easily communicate with TMF decision-makers about TMF problems I experience", correlates highly and significantly with "The TMF makes my day to day job easier." Although other factors contribute to individual satisfaction about one's job in the clinical research industry, the ability to easily communicate TMF problems with TMF decision-makers strongly correlated with several other positive TMF attitudes. It is therefore reasonable to assume that free communication across all levels of responsibility is fundamental to TMF health. Especially with the TMF, where remote work has become the norm, establishing lines of communication between global teams will become both more complex and critical.

"I can easily communicate with TMF decision-makers about TMF problems I experience" also correlates with "The TMF will require less of my time to manage in the future", "The training I received on my organization's TMF system reflected the needs of my current role", and as stated above, "My organization's TMF system is being used to its fullest potential". This relationship between a stakeholder's attitudes about lines of communication with management correlated more widely with the other available positive statements—more than statements related to metrics use or opinions about resourcing. Again, these correlations highlight how strong relationships between TMF managers and TMF stakeholders may very well directly influence perception of a stakeholder's day-to-day job. TMF decision-makers, therefore, should consider the establishment of a communication plan as essential to start-up as study or system-specific training. In the same manner, lack of communication between stakeholders and decision-makers could be considered an indication of more serious TMF health issues.

We are Different but the Same

Although eighty-three percent of respondents had over five years of clinical research experience, and thus are more likely to make trial management decisions in their roles, less than twenty-five percent of all survey respondents reported using metrics to make decisions frequently or very frequently. Of all the correlations presented in the heatmap above, "The TMF is a source of anxiety during the workday" and "The TMF strains relationships between my teammates" are the most strongly correlated for survey respondents. These statistics, and the figures above, even in light of the many unique perspective contained within, strongly argue that TMF systems, whether legacy or modern, are not conforming to the needs of users— precipitating in whole or part, the inspection readiness crisis we see today.

Creating a coherent narrative in order to "permit evaluation of the conduct of a trial and the quality of the data produced" grows more challenging in proportion to the opportunity offered with each new technological advancement. Complexity continues to increase. Every clinical trial is unique and therefore every TMF is different.

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Much like the TMFs they work with, TMF stakeholders are also a diverse group—even when considering the somewhat homogenous population of respondents to the survey. The radical change from paper TMF to eTMF has forever altered the day-to-day experience of the average clinical trial professional: TMF-dedicated staff have become the norm, managers are expected to make instant decisions about data dispersed across thousands of miles, and inspection readiness has become a demand as constant as the flow of data automatically harvested by digital platforms. The task of unifying the clinical systems we have created seems daunting, while the task of creating harmony between TMF stakeholders with these systems seems impossible.

But TMF stakeholders, who at a glance appear to have a myriad of unrelated needs, also have a shared human nature. Every TMF stakeholder has a voice that wants to be heard. Every TMF stakeholder desires a dialogue with those who make decisions about the TMF— whether the design team of an eTMF system or a line manager on the same clinical trial. Each wants to understand the requirements and limits of his or her role and have clear procedures to follow. An absence or excess of these underlying human elements, as suggested by the results of the survey presented here, impact the TMF as profoundly as a software crash or hardware failure. There are, however, signs, anecdotally, in the data presented here, and in data gathered by others, that electronic platforms in clinical research can reduce stress, increase efficiency, allow greater transparency, and enable communication between teams where communication once was not possible. Technology, though, still cannot fully produce the inspection-ready narrative expected within each TMF. So, until the day arrives when humans no longer evaluate the safety and efficacy of a clinical trial, it is in our best interest to try understand the humans of the TMF as well as we understand the TMF systems we've built to support them.

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