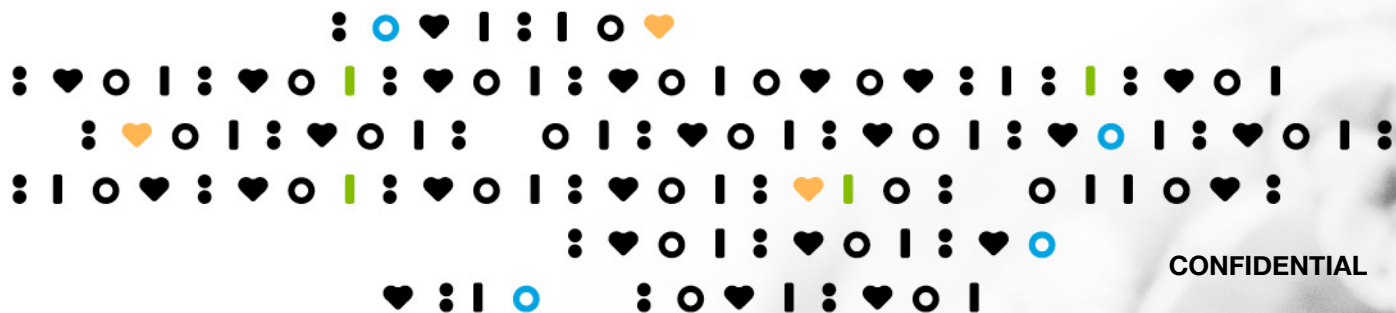# TAYSHA
GENE THERAPIES

TMF WEEK 2022

No budget, no team, no buy-in:
How to TMF without everything you need

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Introduction

Belinda Mabe, Director TMF Operations @ Taysha Gene Therapies
Belinda has over 30 years of CRO, Pharma, TMF Vendor and TMF Consulting experience in Clinical Operations, Project Management, Quality Management and Records and Information Management. Belinda has extensive knowledge of the TMF (implementation through archive), inspection readiness and clinical operations. Belinda is passionate about all things TMF and loves helping others understand that the TMF is the representation of the work we all do, every day for **our patients**! Let the TMF tell the story by itself.

Disclaimer

The views and opinions expressed in this presentation are my own and not representative of Taysha Gene Therapies.

No Budget, No Team , No Buy In

No Problem!

No Budget, No Team , No Buy In – The Landscape

- It has become apparent through conferences, forums and consultations that the lack of resources and budgets for TMF oversight is a common hurdle in our industry.

- Financial constraints is the reality for startups, niche or boutique companies in today's landscape. Sponsors and CROs may limit investment in an infrastructure like TMF ops, these constraints are justifiable until there is evidence of stability and growth in the organization.

- For TMF professionals this brings challenges, risks and choices we need to make as we balance finances, resources ,growth of our department and inspection readiness.

- In this session I would like to explore some of the impacts & risks we need to consider and ultimately how we can overcome them to strive for inspection readiness.

No Budget, No Team , No Buy In – The Potential Impacts & Risks

Potential Impact of no budget:

- Technology - No in house TMF ,Tracking difficulties, Limited access to Dashboards and Reports

- Resources - Insufficient team to build an infrastructure and perform TMF activities, without technology manual effort is required which takes time and people

- Buy in - if you don't have budget, you may not have the buying power with vendors (low revenue stream for vendor)

- Processes /SOPs – Lack of funding affects access to necessary resources, both human and technological to efficiently produce and implement needed processes

- Lack of Inspection Readiness

- Lack of early investment in TMF could result in documents lost, gaps in defending decisions made or documented especially in young organization with all studies in start up and no infrastructure /TMF oversight as all energies are focused on start up , patient enrollment etc. and documentation may be an after thought.

Potential Impact of no team or being under resourced

- Lack of knowledge and diversity in skills

- Lack of growth ,support, constant juggling and re prioritizing

- Lack of work that can be completed

Potential Impact of no buy in

- Risk as there is little to no support or understanding of how critical TMF is

- Difficulty in building relationships cross functionally

- Hard decisions, choices need to be made about what can be accomplished

- May not be involved or proactively looped in, always after thought

- Potential for a negative perception of unnecessary work with no value due to the aforementioned issues

No Budget, No Team , No Buy In - The Assessment

Utilize free resources – TMF Reference Model, Regulatory sites, Blogs/free resources from example TMF vendors and consulting companies. Sign up on websites and follow-on LinkedIn, get to know thought leaders and follow them many will keep you updated in latest developments in our industry. Paid resources – add subscriptions to your budget if needed.

Crucial as TMF professionals that we **document our assessment** of our situation:

- The decisions we took, alignments we gained, priorities made especially in recognition of potential gaps in regulations or industry recommendations.

- Rationale for any Risk based approaches taken which can be detailed in TMF and or oversight plans.

- Particular attention should be given to vendors, ensure strong contractual verbiage, detailed operational plans defining type of documents, accountability for filing, frequency, storage location, access and inspection readiness activities

- Build your department structure roadmap – resources, processes, implementation plan for TMF systems, migrations etc. Proactively investigate cost associated with your roadmap(wish list) to be ready for decisions to be made if/when budget becomes available. Consider both outsourced versus In house – the structure and cost would differ.

- Get executive buy-in early and continuously revisit to take small steps to build your TMF empire.

No Budget, No Team , No Buy In - No Problem: Here is what can be achieved

Develop a TMF plan and/or Develop a Sponsor Oversight Plan (dependent on resources/structure)

- Define where TMF content is housed, and who the responsible party/owning function is – include vendors!

- Document when periodic reviews are expected and performed, and confirm evidence of these activities,

- Include a RACI, be clear on what you/your team will check and when and what the expectation is for external/internal teams

- Metrics – define your expectations and clearly communicate them

- Risk based considerations - Add a rational to oversight /TMF plan etc. make certain to document why, for example, you only reviewed 1 site or 1 zone or only confirmed 2 functional areas had their oversight evidence filed. Set the expectation of what can be accomplished with the tools and people you have in advance.

- Data Integrity checks – audit trails and access

Outsourced CRO TMF and Sponsor content housed on Sharepoint, BOX – attempt to separate content for control, put a structure in place (index) as well as an access control process.

- Understand the pros/cons and risks of a systems if eTMF is not an option. Document the comparison using regulations or guidance like ICH GCPE6R2 .Use this for justifications for your decision but also to highlight risk.

If there is no CTMS, clinical tracking, or eTMF - implement an excel (or similar) storyboard (always recommended).

- Do not duplicate content, link to content but let the storyboard serve as the source of truth. Consider Multi use of a storyboard (be flexible if resourcing is issue across the board) – example: perhaps 1 tracker to record study content for file reviews, can also serve as knowledge transfer for transitions or new team members onboarding in other functional areas. EDL , sponsor oversight activities and metrics for example can be added and utilized cross functionally. It helps build relationships, align on one source of truth and gives visibility into what you are doing and inspection preparation activities.

No Budget, No Team , No Buy In - No Problem: Here is what can be achieved

Metrics

If no eTMF or only CRO TMF - utilize excel to develop an EDL. It can be as elaborate or simple as needed dependent on resources. If you have access to Power BI or Smartsheet's you can build these out and then generate dashboards and visuals for reporting out /oversight capabilities. Consider multipurpose – example: combine your EDL and file reviews (if manual) in the same tracker for easy retrieval of data points for dashboards/visualizations which can be provided to vendors, CRO and leadership. Plan on a regular documented review of metrics – this is crucial to demonstrating sponsor oversight. Expect to see contemporaneous filing, documents processed in timely manner for example.

SOPs/WI

While it is desired and recommended it may not be practical to have a dedicated suite of TMF Ops SOPs. Document and plan for it with rationale and risks but in the absence of TMF specific SOPs be sure all activities related to start up, file reviews, sponsor oversight, access, training, data integrity checks, closeout, archiving, PHI etc. are captured in the TMF or Oversight plan . It is possible to include some content in other SOPs -This is not ideal, but you can work towards extracting this as resources/budget permits

TMF Ops Structure on Box/SharePoint or like tohouse

- Storyboards

- TMF Ops Department Implementation roadmap

- Best practices /links to guidance/FAQ/QRGs

- Current processes & training if applicable

Buy In

Gained by achievement of above, opportunities to build relationships by looking at cross functional pain points and adapting as needed. Ensure visibility of department roadmap and achievement. Set clear expectations on what can be achieved singularly versus with support if available cross functionally. Start small and continually look for opportunities to insert TMF operations.

Thank you Montrium for hosting these sessions.

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