Beyond the TMF Plan & TMF Index: Harmonizing Sponsor & CRO Expectations in Outsourced TMF Management

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Presented by Katie Hoover, Founder, Vital GxP Consulting LLC

Meet the Speaker

Katie Hoover

Title: Founder

Organization: Vital GxP Consulting LLC

A leading Clinical Trial Master File (TMF) consultant with deep expertise in clinical systems strategy, regulatory compliance, and process optimization. As the Owner and Principal Consultant of Vital GxP Consulting, she specializes in eTMF implementation, inspection readiness, and risk-informed quality management systems, ensuring clinical trial sponsors meet global regulatory standards.

Ms. Hoover has successfully led eTMF system configurations, TMF gap analyses, migrations, and compliance driven process improvements across multiple organizations. She has developed and delivered comprehensive training programs to enhance TMF best practices and operational efficiency.

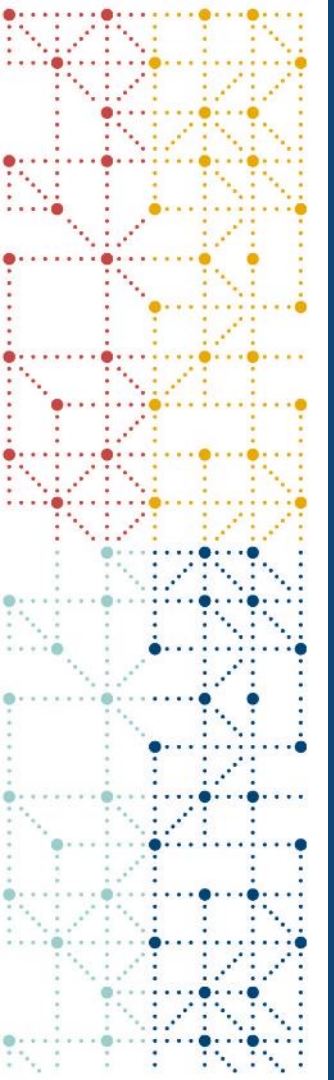
Holding a B.S. in Biology and B.A. in English from Virginia Tech, along with PMP and Lean Six Sigma Green Belt certifications, Ms. Hoover combines strategic insight with a meticulous approach to streamline TMF operations and drive clinical trial efficiency.

Disclaimer and Disclosures

- *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.*

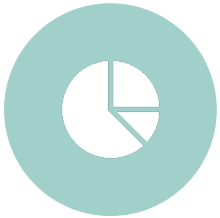
Agenda

1. TMF Oversight vs. TMF Management
2. Common Scenario
3. Set Expectations - Internal
4. Set Expectations - External
5. Common Scenario with Improvements
6. Key Takeaways
7. Q&A



TMF Oversight vs. TMF Management

TMF Management is Study Management



PRIOR TO START

DURING

END

ICH E6 R3, Appendix C, C.2.5 "The sponsor…should ensure that the essential records are collected and filed in a timely manner, which can greatly assist in the successful management of the trial. Some essential records should generally be in place prior to the start of the trial and may be subsequently updated during the trial."

ICH E6(R3) - Essential Records Table

- 54 lines of essential record types
- 30 of 54 lines contain “*”

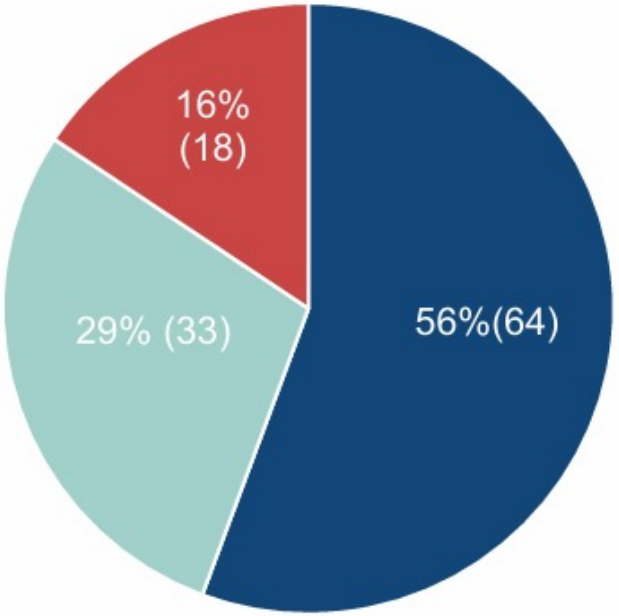
This table is not an exhaustive list, and other trial records may also be consider essential by the sponsor or the investigator.

C.3.3 For some trial records listed in the Essential Record Table, their presence and natu are dependent on the trial design, trial conduct and risk proportionate management the trial and may not be produced.

Essential Records Table If these trial records are produced, they are considered essential and should be retained (see sections C3.1 an C3.2). *Note: An asterisk (*) identifies those essential records that should generally be in place prior to the start of the trial (see section C2.5).*
Investigator’s Brochure or basic product information brochure (e.g., summary of product characteristics, package leaflet or labelling)*
Signed protocol* and subsequent amendments during the trial
Dated, documented approval/favourable opinion of IRB/IEC of information provided to the IRB/IEC*
IRB/IEC composition*
Regulatory authority(ies) authorisation, approval and/or notification of the protocol* and of subsequent amendments during the trial (where required)
Completed signed and dated informed consent forms
Completed participant identification code list and enrolment log

If you are a Sponsor, do you utilize your own eTMF or do you use CRO's eTMF?

- Use our own eTMF solution and require CRO to use our eTMF
- Use our own eTMF solution only for sponsor-generated records and CRO eTMF for CRO / site-generated records
- We don't have an eTMF so use the CRO eTMF

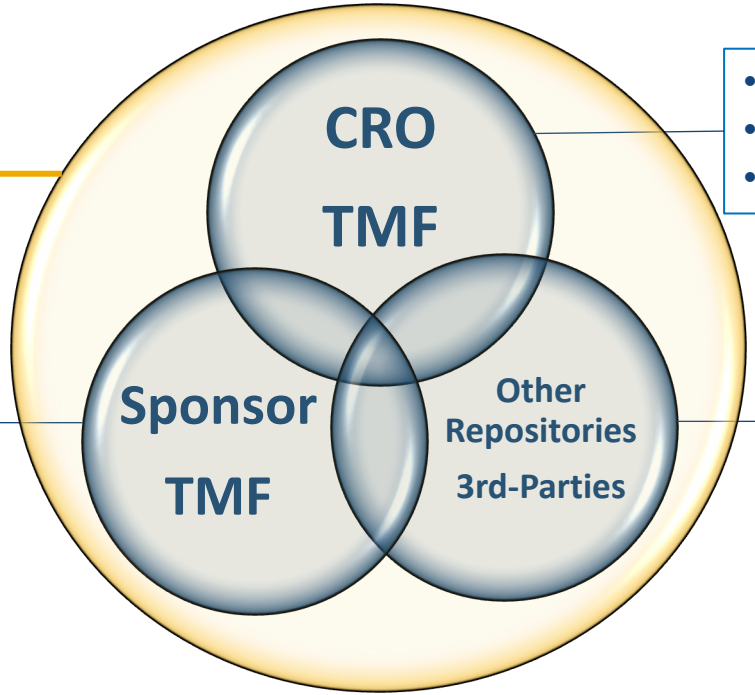


Source: CDISC TMF Survey June 2022, 115 Sponsor Respondents

Before & During Trial – Many Repositories

While CRO & Third Parties may *manage* elements of TMF,
Sponsor is responsible for *oversight* of all essential records.

Sponsor Oversight



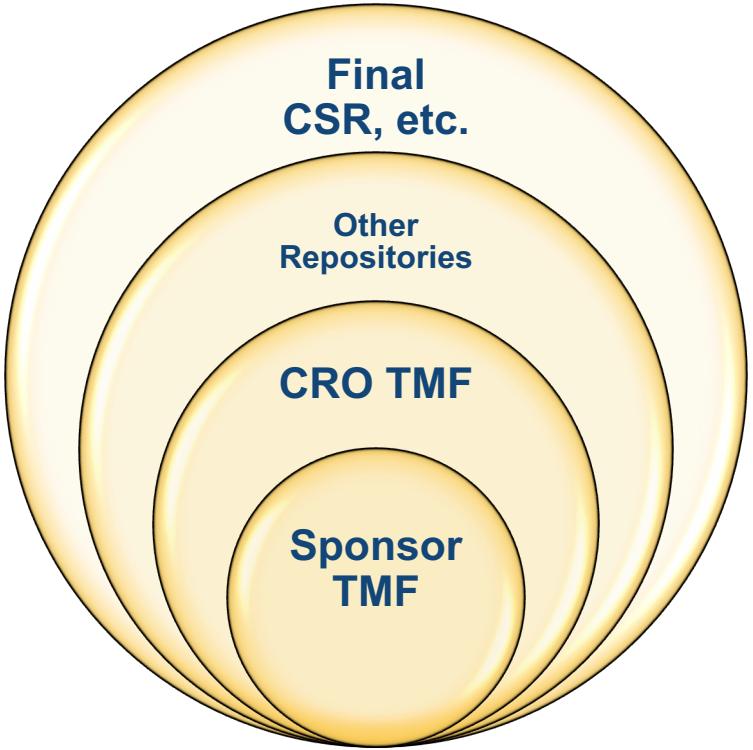
- Protocol & Amendments
- Monitoring Reports
- Relevant communications

- Proof of Insurance
- Contracts
- Regulatory Filings

- Safety Database
- Laboratory Results
- Patient Data

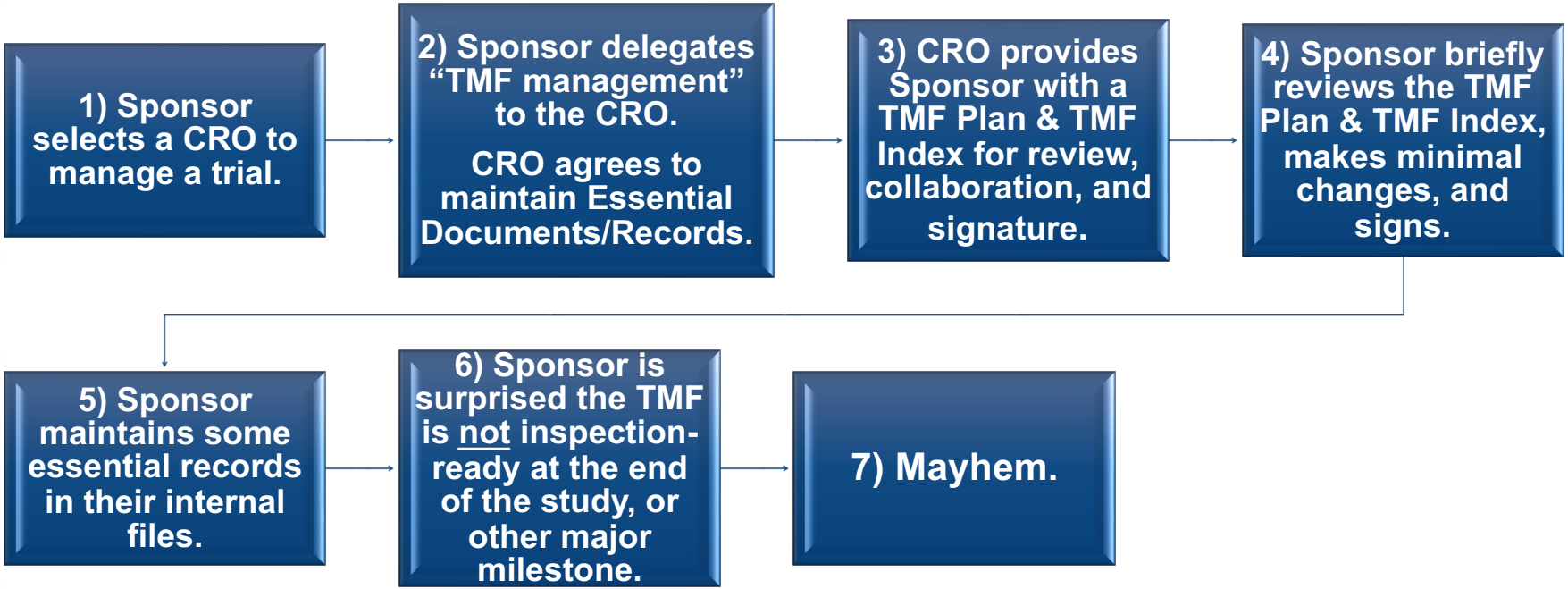
Combine to Archive

- Combine repository content and metadata at closeout

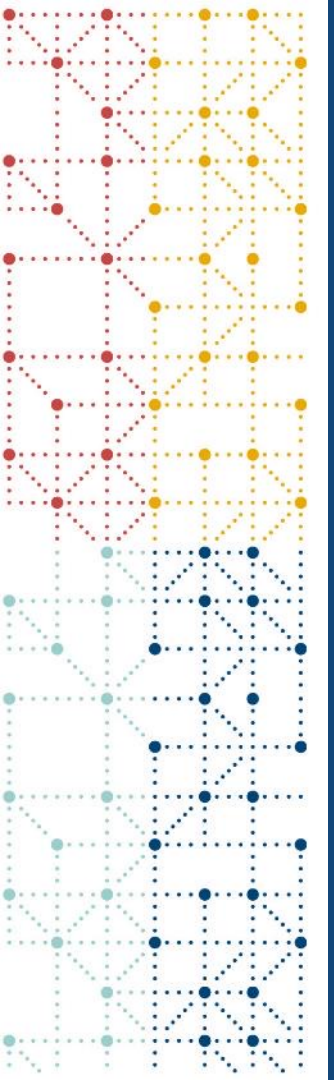


- GxP Compliant System and Process
- Required Retention Period

Common Scenario




This will cause delays
We are
Missing Record s
You wa to man
IP records are part of TMF?
Too Much Frustration
Who is responsib le?



Set Expectations - Internal

Leadership Awareness

Sponsor's Leadership should be aware that TMF Oversight has evolved to be central to Study Management.

They should be aware of the resources required to maintain risk-based compliance.

A compliant TMF generally requires early and periodic attention from the Sponsor and cannot wait until the end of the trial.

Sponsor's Business Tools & Processes

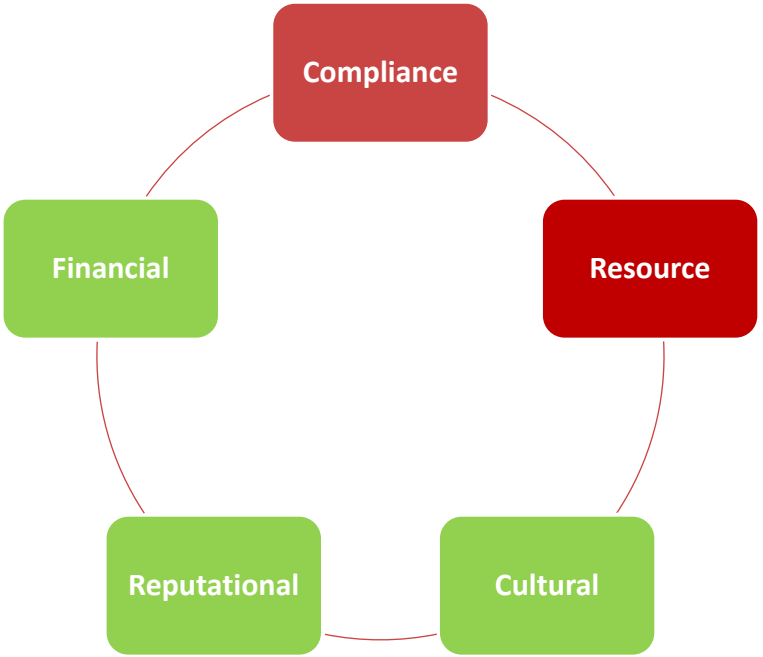
- Risk Assessments
  - Study Team, Program, Executive Level
  - Risks of Inadequate TMF Oversight Program
- Develop TMF Oversight Program
- Vendor Selection Process
  - Request for Proposal (RFP)
- Job Descriptions
  - Clin Ops & TMF
  - Study Team Function Leaders (e.g., Safety, DM, Biostats)

Risk Assessment Focus

Risks of Inadequate TMF Oversight Program

- Study Team Level
- Program Level
- Executive Level

- Risk
- Risk Type
- Impact
- Mitigation



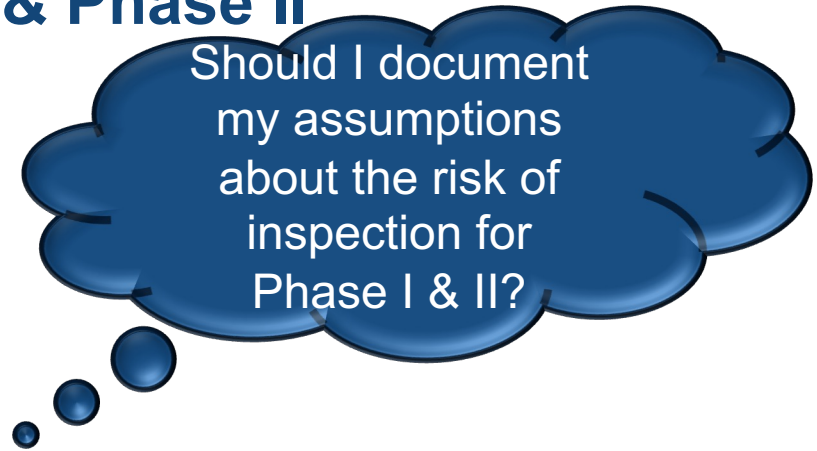
Risk of Inspection for Phase I & Phase II

LOW RISK OF INSPECTION

- MOST ARE LOW RISK OF INSPECTION

HIGH RISK OF INSPECTION

- RARE DISEASE
- BREAK THROUGH DESIGNATION
- USE DATA IN THE FUTURE
  - SPONSOR
  - PARTNER
  - BUYER

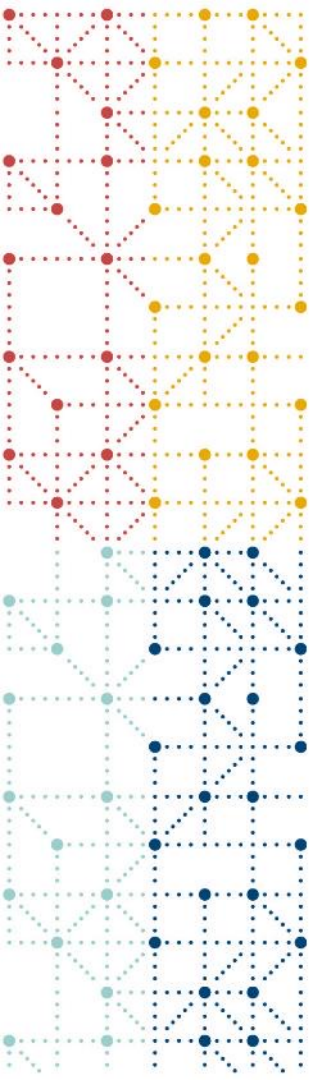


Document assumptions, rationale, and decisions in Executive Level risk assessment. RA will help you decide when to change your mind and when to bolster TMF Oversight.
In the future, you may: raise more money, change your mind about the risk of inspection, have a potential buyer in mind, experience TMF "Trauma"

Elements of Sponsor's TMF Oversight Program

- Business Risk Assessments
- All TMF Repositories
- Sponsor's Risk-based TMF Review Process
- Equivalence of CRO & Sponsor Metrics, Reports & Outcomes
- Defined Escalation Pathway
- Included in Periodic Governance Meetings

Job Descriptions



Set Expectations - External

Study Management Collaboration Tools

- Contracts & Budgets
  - Scope of work, change orders
- Project Plan and Study Timeline
  - Include time for sponsor review and remediation
- Governance
  - Emerging risks, Escalation Path, Solutions planning
- TMF Plan & Index

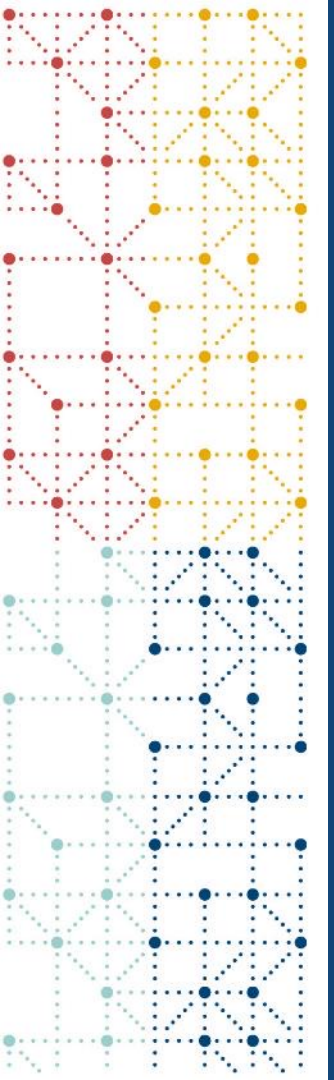
Make it Your Cozy Blanket

TMF PLAN

- One master plan that covers Sponsor, CRO, and third parties
- All repositories
- Responsible company and sponsor department
- Agree upon criteria for document quality, completeness, and timeliness
- Clarify, agree upon, and document the meaning of KPI's, metrics, and reports

TMF INDEX

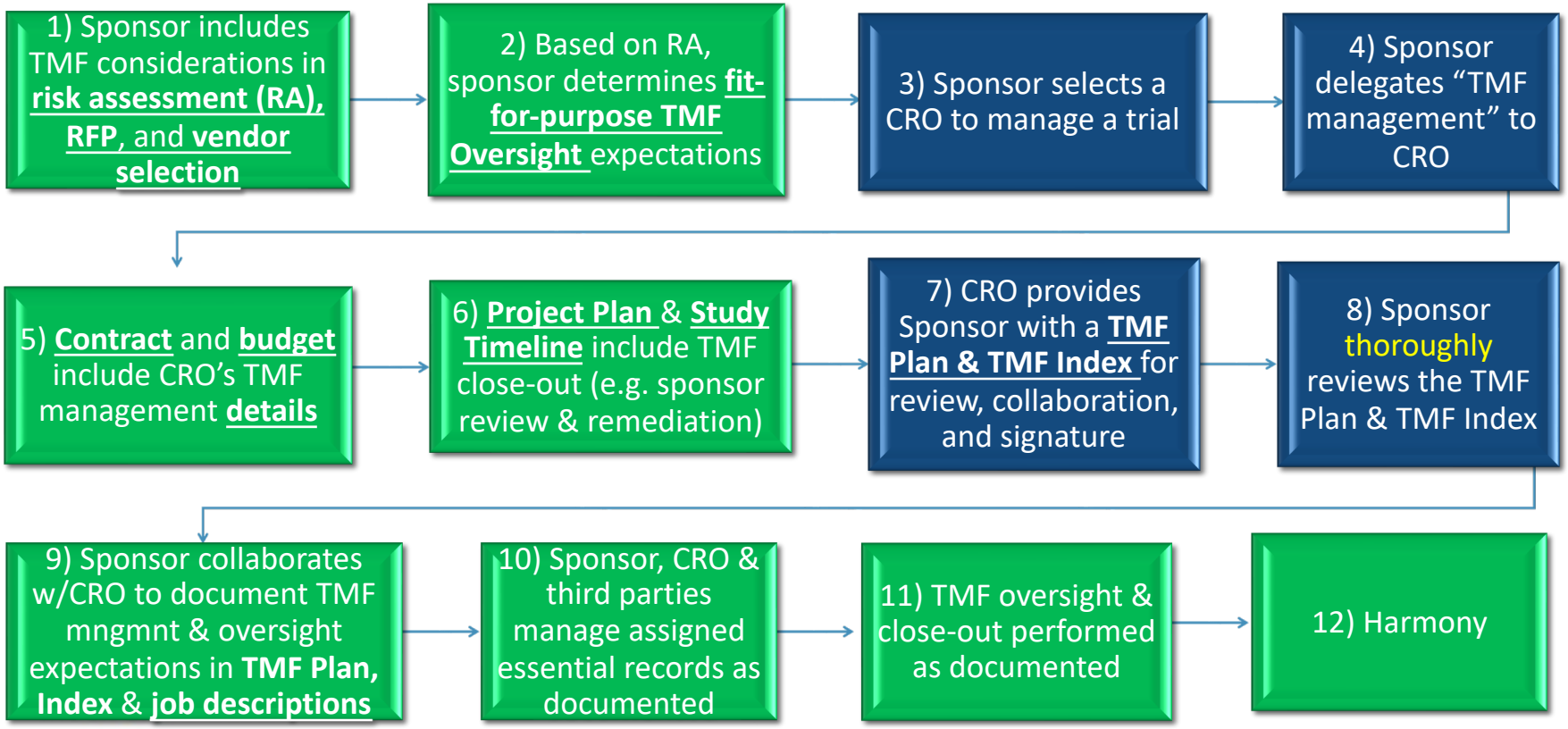
- Which records are essential?
- When should they be filed?
- Where should they be filed? By which organization? Which repository?
- Who is responsible for the content of each zone/artifact at the sponsor?
- Consider the same questions re: before, during, and after the trial



Common Scenario with Improvements

Use Study Management Tools to Harmonize

Common Scenario with Improvements



Too Much Fun!

Key Takeaways

Add TMF considerations to Trial Management tools, starting with risk assessments.

Document expected documents/records, filing responsibility, and quality criteria.

Start sponsor oversight reviews early, (e.g., after First Patient In).

Add TMF responsibilities to sponsor study team members job descriptions and goals.

Define an escalation pathway and link TMF to governance meetings.

Thank You!

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