

TMF Metrics :

They aren't just for
marketing anymore!

Joanne Malia

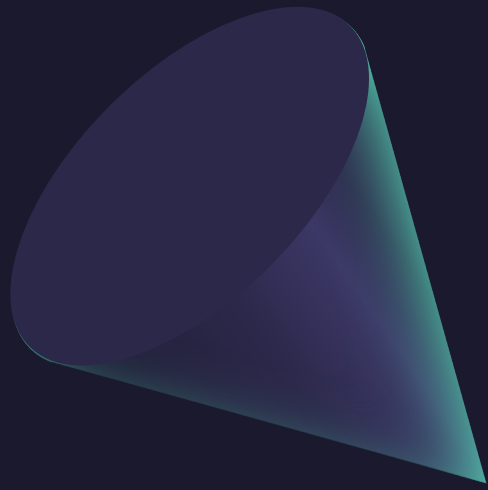
May 20, 2022





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Agenda

TMF Metrics Defined

Operationalizing Metrics

Metrics Program

Risk Reduction



TMF Metrics

Defined

TMF Compliance & Quality



- How to start?
- What do you want to measure?
 - What do you need to show your organization?
 - What are your challenges?
 - Are there metrics you need to manage your TMF study or operations?
 - What processes do you want to dig into, ensure get done etc.
 - How do you want to oversee your CROs and vendors?
 - What do you want to do with the metrics? Are they contractually based?



TMF Metrics

Typically include metrics on:

- Timeliness
- Quality
- Completeness

TMF Health = QTC



Quality

Error rates

% of documents approved on first pass

% of queries, duplicates, and expired documents



Timeliness

Time from finalization to entered into TMF

Time from entered into TMF to approved state

Time from query created to resolved

Possible metrics for TMF
Health (QTC)

Operational Metrics

01

Number of documents submitted per day, per month, per year

02

Number of Queries

- By study
- By Vendor / Department
- By Type

03

Time frame to get TMF or Placeholders set up

04

Time from document finalized to placed in TMF

05

Time from document in TMF to approved

06

Number of obsoletes / duplicates

Determining thresholds may be challenging

- Remember, you can always change if necessary
- Consult:
 - Industry resources
 - Vendors / CROs
 - Internal stakeholders

Should be a reasonable goal (not just a confirmation of what you are doing today)

Acceptable implication to the TMF?

Stakeholders' agreement is necessary

Thresholds

Oversight

Ultimately looking to

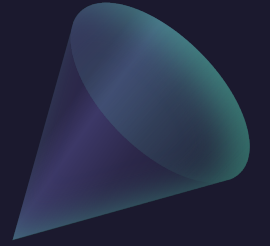
- Reduce risk
- Catch issues before serious
- Streamline inefficient processes
- Ensure activities are being conducted
- Evaluate vendor quality

May want to elevate:

- Key Quality Indicators
- Key Performance Indicators
- Contractual elements
- Individual Performance / Objectives / Accountability



How to Begin?



- You know what you want to do.
- How do you put it in place?



Operationalizing

Implementation Plan



Determine what your TMF can supply

Can your metrics be calculated ?

Are you capturing the proper information?

Do you need additional software such as visualization package?

Do you need IT resources?



Start small - plan to grow



Discuss with Shareholders (including Quality and Vendor Management)

May need to negotiate with those "being measured"

Metric definitions are key

Single source of metrics



Develop a plan with timelines

Following the plan

Draft the actual metrics and provide to stakeholders

Expect lots of discussion

What is in and what is out?

Establishment of trust

Frequency

Audience(s)

Various levels (study, functional areas, therapeutic area, organization, TMF)

Metrics Program

Socialize

Begin measuring

Look for improvement in the metric

May not be linear

May take time (behavior change)

Be prepared to show trends

Trend Analysis

Look at
metrics over
time

Are they
going up or
down

What does it
say?

Evaluate
compliance &
risk

Dig in to the
details

Develop
Action Plans

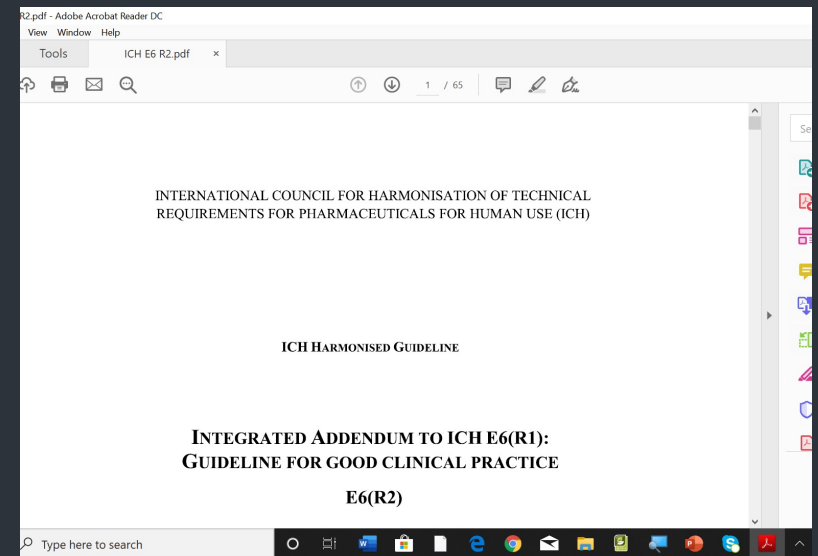
Alignment

Include	Include metrics review and discussion with vendors/CROs <ul style="list-style-type: none">• Study Teams• Functional Area (TMF group to TMF group)• Governance Boards & Quality -related meetings
Document	Document metrics & thresholds in study plans, CRO / vendor manuals, agreements
Align	Align with internal functional areas to improve metrics internally and with partners
Consider	Consider blinded reviews with all vendors/ CROs (peer pressure)
Work	Work with contracts group to include in CRO /vendor contracts

Risk Reduction

Regulatory Environment

- ▶ If it is not documented, it did not happen
- ▶ ICH E6 R2 focuses on building quality in and using properly tested tools and procedures
 - ▶ Risk management
 - ▶ Oversight
 - ▶ Essential documents
- ▶ EMA guideline on TMF focuses on an active TMF
 - ▶ Single TMF per study; Sponsor & ISF components
 - ▶ Direct access to TMF
 - ▶ Contemporaneous
 - ▶ Virtual TMF concept - pathway to associated documents



Inspection

- ▶ Always Inspection Ready
- ▶ The TMF is everyone's friend during the inspection...
- ▶ Shouldn't it be all the time?
- ▶ What can the metrics tell ?



Additional Expectations

TMF + Clinical Data base → Company Asset

Oversight of study and vendor partners

Review (Risk-based) and Metrics

- Decision- making
- Communication with team and management
- Focuses QC and attention to where needed

Continual improvement

Summary

- Metrics necessary for oversight and risk reduction
- Start small and grow the metrics
- Align and socialize metrics internally and externally



The way to get started is to quit talking and begin doing.

Walt Disney

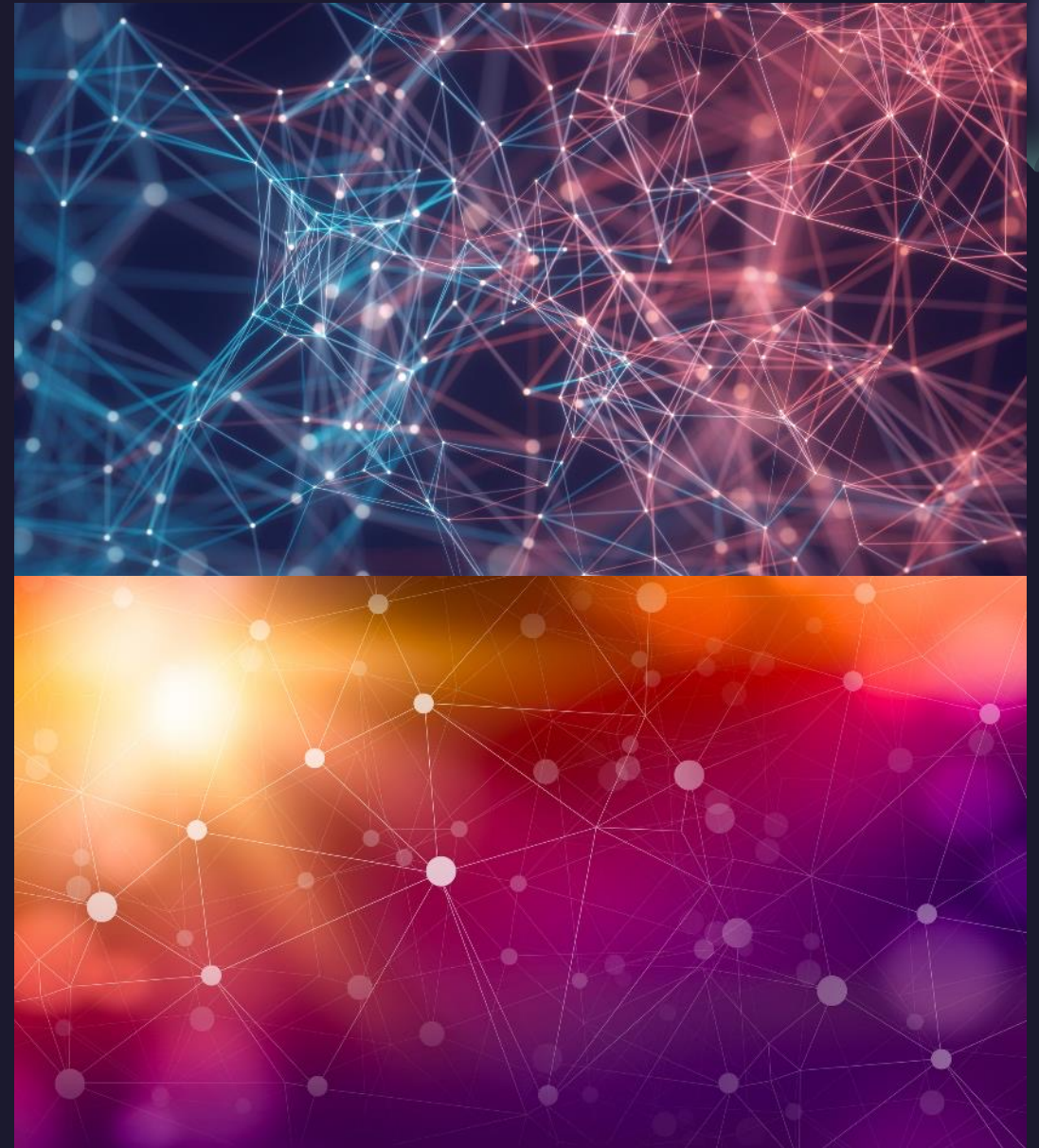


Thank You

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TMF

WEEK
2022

