TMF Completeness Check
The GSK Risk Based Approach to Inspection Readiness

Presented by Anne-Noëlle Charles
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Meet the Speaker

Anne-Noëlle Charles

Title: Director, Clinical Documentation Operations

Organization: GSK

Anne-Noëlle co-leads the GSK Clinical Documentation Operations team for the past 3 years. Prior to that, she was already a TMF Subject Matter Expert for the Clinical Data Management department.

As TMF Global Process Owner, her focus and points of attention in setting-up the TMF framework are the **TMF Performance Dialogue** and the **True Completeness Check** process enabling the confidence in the inspection readiness of our TMF, the **TMF RM governance** and how it supports the businesses to be accountable for their part, and the **Archiving** oversight and compliance, while at same time looking for opportunities to improve the TMF system/Process and user experience.

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The author(s) have no real or apparent conflicts of interest to report.

Agenda

1. The GSK TMF framework
2. Walk through the TMF Completeness Check process
3. Challenges and remediations

TMF at GSK ? A world in it-self!

63k active users

1850 active studies

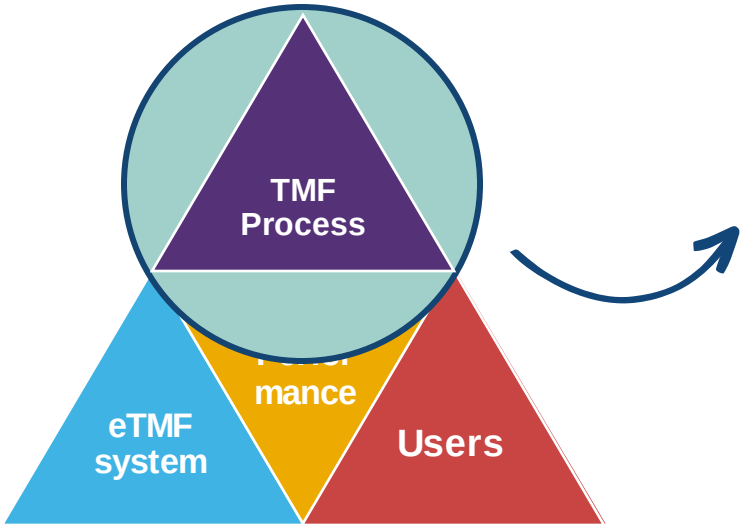
19k archived studies

~300k documents created per month

~30k documents QC per month

Can we be confident in our inspection readiness while maintaining so many records?

Study TMF is supported by People, Process, Technology



How is the GSK TMF Process designed, embedding risk-based concepts to target Inspection Ready any time?

Risk-based approach is embedded into TMF Process, within TMF Oversight and Completeness Check

Study TMF Inspection Readiness

TMF Oversight

TMF Completeness Check

Why and how we went FROM Periodic Review…

Check done on all documents

OR

Random sampling (%)

Performed centrally

Metadata driven

Focus on Expected Document List

Spot checks that verifies artefacts present in TMF

TMF Oversight is a set of *routine* activities performed throughout the study course

➢Define frequency and responsibilities upfront for each activity

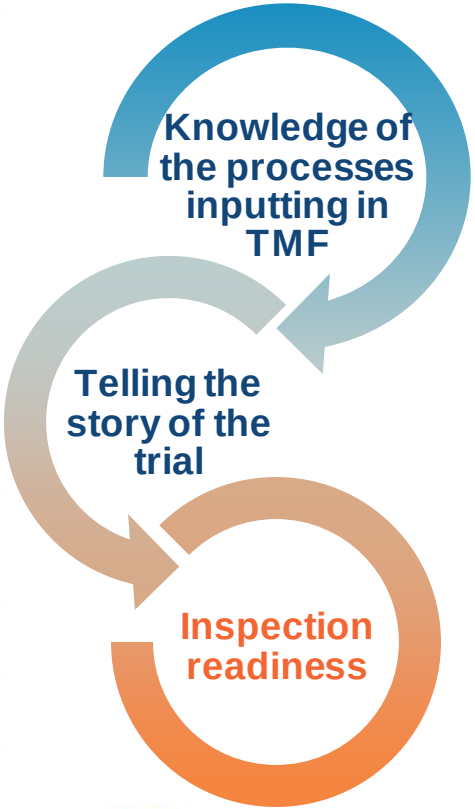
➢Check and act upon study metrics, reports, tools

- **Completeness**, Expected Documents List (EDL) maintenance…
- **Quality**, time to resolve Quality Issues, rejection reason…
- **Timeliness**, time to finalize artefacts after QC…

➢Focus on risky areas identified

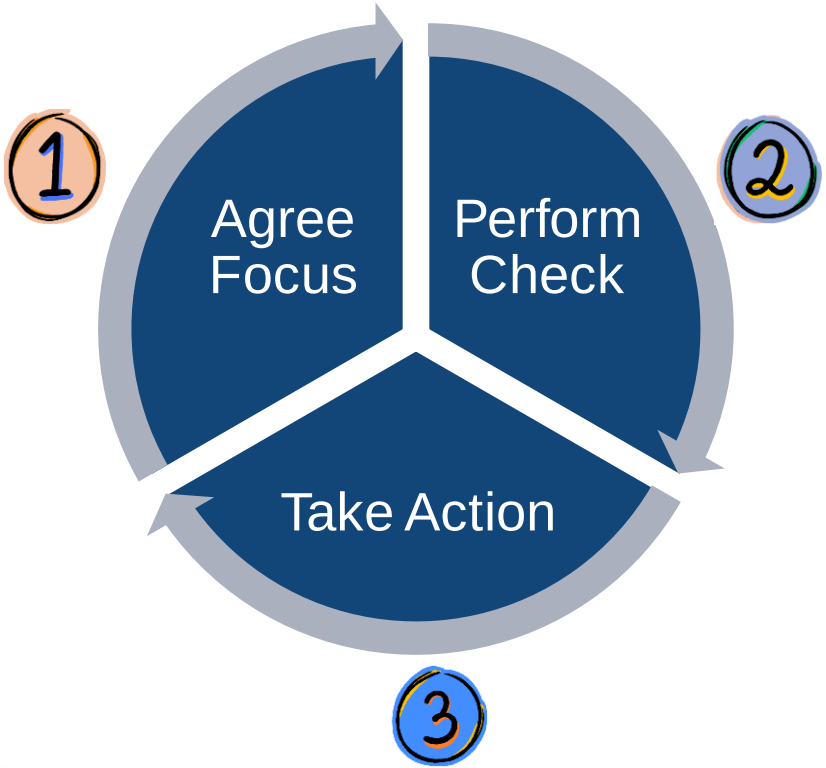
- Full Service Outsourced or Functional Service Provider settings
- New/Updated process
- History of issue within the study or from Audit/Inspection findings e.g. naming convention, country, process, certified copies, duplicates…

…*TO* TMF Completeness Check (TMF CC)



A risk-based review of the TMF Inspection Readiness
Leverage expertise and awareness of functional area that are most knowledgeable with the events of the study and the processes that occurred
Critical thinking exercise performed by functional area across all TMF locations (not just primary eTMF) to assure TMF allows for reconstruction of the study
Focuses reviews on documentation linked to significant events/issues/processes (i.e., the most likely targets during inspection and most critical to ensuring the TMF tells the story of the study)

TMF CC - A 3 steps process for a study team effort



To be performed at each important study milestone, prior to archiving and at least once a year

1 Agree Focus

DIALOGUE

- What happen in the study since start/last check?
- Which process/event occurred?
- Any issue raised?
- Any new risk?

AGREEMENT

- **Select the events/processes** based on **risk** and determine the scope **granularity**
  (e.g. criticality of the process, history trends from past audit, country/site,…)
- Define responsibilities for next steps based on expertise

Examples of study events to consider for TMF CC

- Analyses (Interim/final, ISRC, IDMC, SRT,…)
- Audits/inspections
- Temperature excursions
- Deviation(s) to business process(es)
- Electronic Data Capture update
- Investigational Product relabeling
- Management Monitoring findings
- Informed Consent approval/amendment
- Investigator Brochure distribution
- Engagement with Third party (contract, oversight plan)
- Patient death
- Protocol approval/amendments
- Serious quality incidents/breaches
- Site initiation/closure
- Statistical Analysis Plan amendment
- System migration
- Unexpected unblinding events
- Regulatory, EC submission/approval
- Investigational product shipment
- Process change

2 Perform Checks

EFFORT

Functional experts verify if

Can reconstruct the story of the event within the defined scope

Artefacts are ALCOA CCEA compliant

Report on Pass/Fail check status
Document the findings and needed corrective actions
Assign tasks or quality issues

➢ *True* TMF Completeness metric

3 Take Action

ACCOUNTABILITY

Artefact owners take corrective actions

Study Manager finalises the TMF Completeness Check Report

➢ TMF is Inspection Ready

Main challenges and remediations so far

❖ **Mindset and ways of working**

Lack of collaboration, lack of focus, still working as with previous process

➢ TMF Bootcamp (Engagement/Capability) with a focus in TMF Completeness Check and other engagement activities

❖ **Quality of the TMF CC performed**

In 2023 – 50% of studies didn't have enough specificity in the Agree Focus Step

e.g. no risk-based approach in the selection of events, practices not aligned from one study to another

➢ Capability building needs related risk-based and 'events'

➢ Specific support to Study Managers group to help them coordinating this activity and ensure alignment among them

❖ **Overdue TMF CC**

In 2023 – 33% of studies took > 3 months; some took > 8 months to complete single TMF CC

➢ New TMF CC KPI in place and improvement in guidance/requirements/TMF CC report template

Thank You!