



2024 CDISC + TMF
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TMF Completeness Check **The GSK Risk Based Approach to Inspection Readiness**

Presented by Anne-Noëlle Charles
Director, Clinical Documentation Operations
GSK



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 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.

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



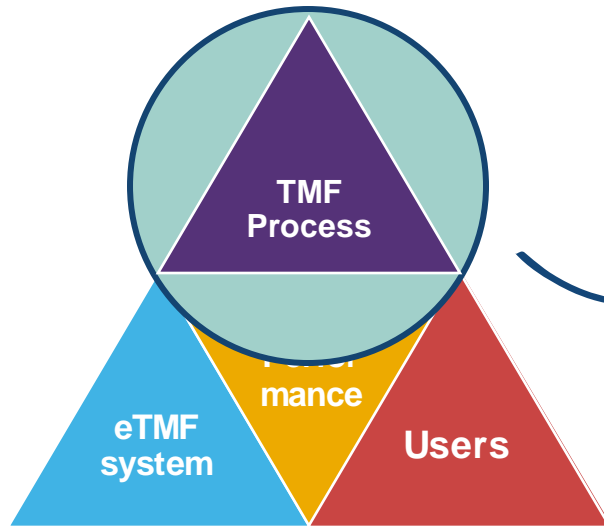
~30k documents
QC per month



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

Confidential - GSK proprietary - NOT FOR SHARING

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

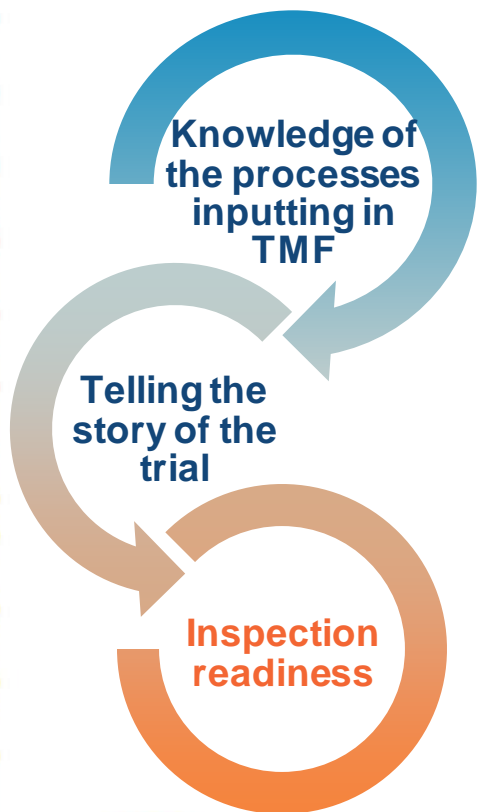
Spot checks that verifies artefacts present in TMF



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)



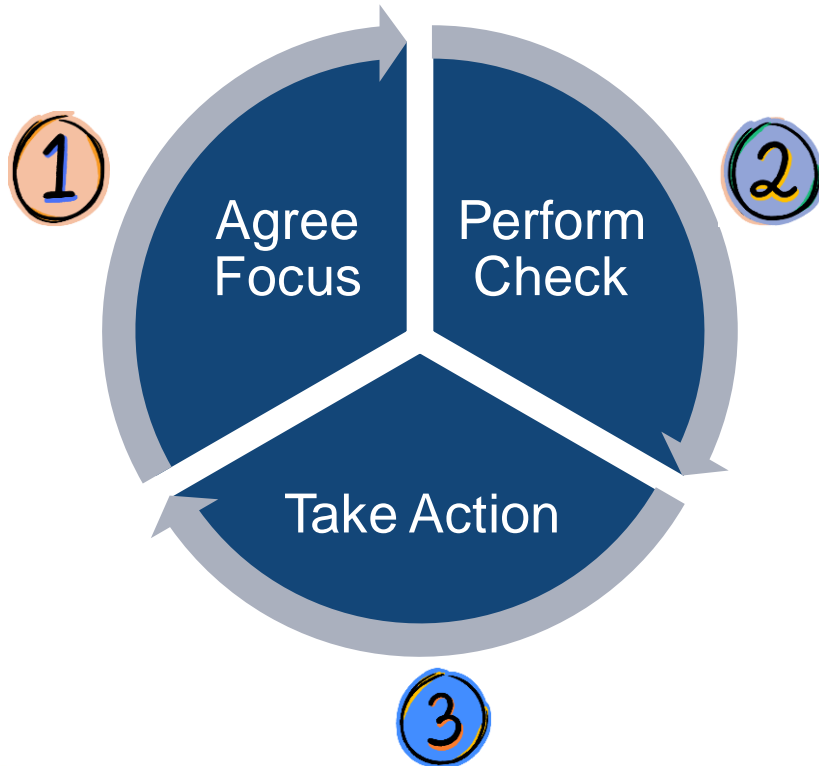
A risk-based review of the TMF Inspection Readiness

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

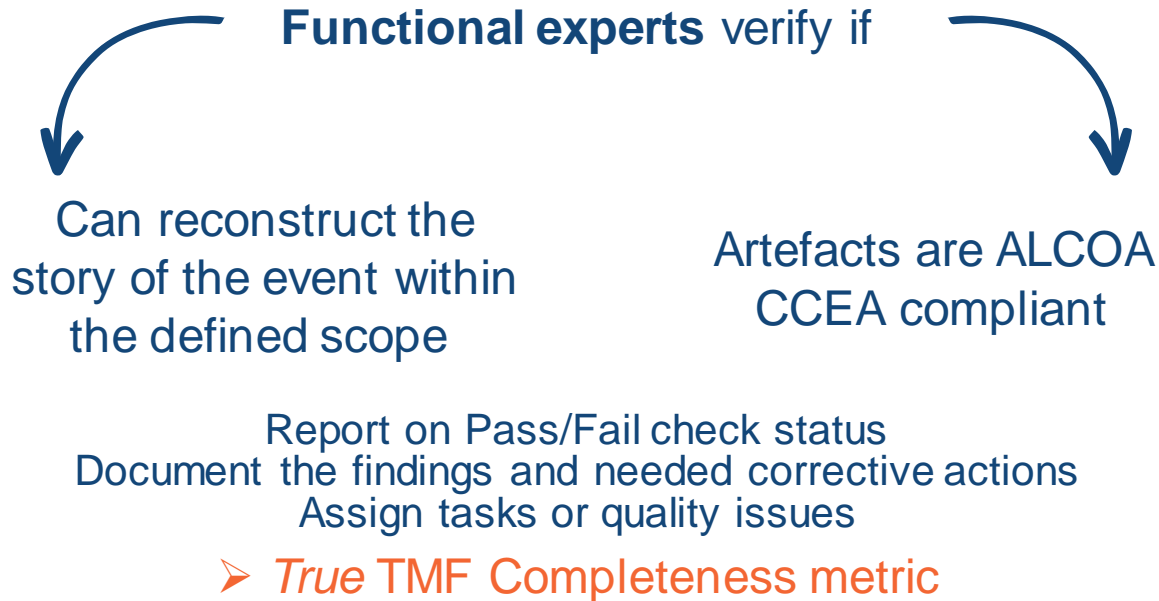
Regulatory, EC submission/approval

Investigational product shipment

Process change

2 Perform Checks

EFFORT





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

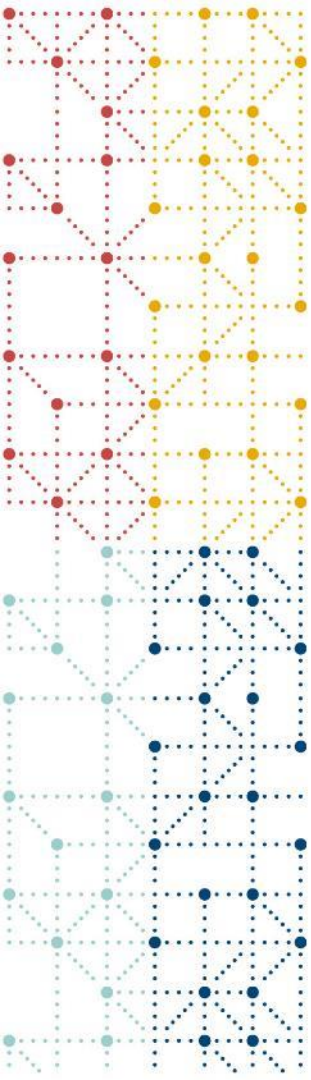
e.g. no risk-based approach in the selection of events, practices not aligned from one study to another

- 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!

