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TMF Health Management through fit for purpose tools beyond Completeness-Timeliness-Quality (Expert Level)

Presented by Susan Homminga
Clinical Documentation Manager
Global Clinical Operations

GSK

Meet the Speaker

Susan Homminga

Title: Clinical Documentation Manager

Organization: GSK

Susan is part of the Clinical Documentation Operations Team in GSK and leading the TMF Performance Lead network, consisting of representatives of departments contributing to TMF. The goal of the network is to improve TMF metrics from a departmental perspective via the TMF performance dialogue and by engaging users and their leadership teams.

Before joining the TMF team, Susan was part of the Clinical Quality Assurance Team and among others, involved in the implementation of new eTMF system.

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.*

- *The author has no real or apparent conflicts of interest to report.*

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Agenda

1. Setting the scene – TMF @GSK
2. TMF Metrics Tools @GSK
3. TMF Stakeholders with a focus on the Functional Perspective
4. TMF Health Management through fit for purpose Tools beyond Completeness-Timeliness-Quality
5. Take Home Messages

Setting the scene – TMF @ GSK

TMF at GSK ? A world in it-self!

63k active users

1850 active studies
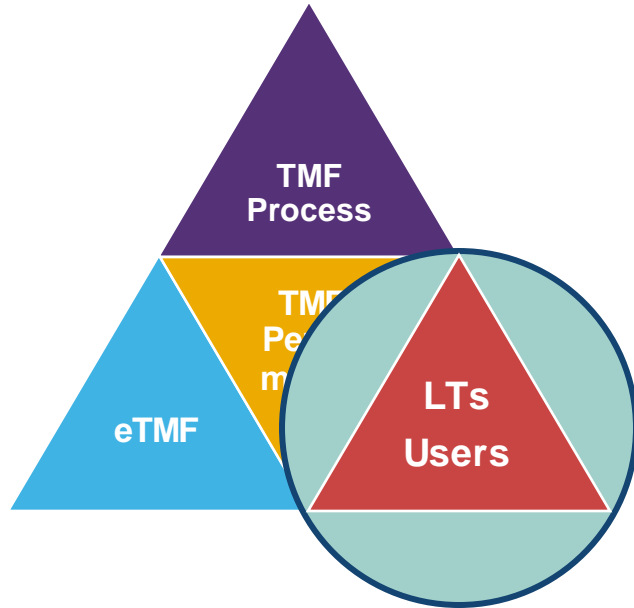
19k archived studies

~300k documents created per month

~30k documents QC per month

Can we be confident in our inspection readiness while maintaining so many records?
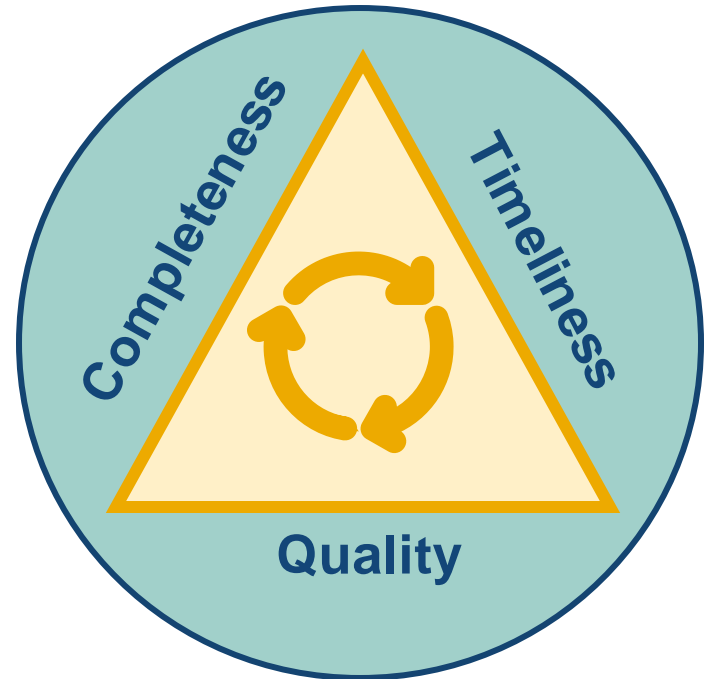
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Study TMF is supported by People Process Technology

TMF Process

eTMF

TMF People management

LTs Users

TMF Health Composite Score

the 'average' of the 3 main TMF metrics

Completeness

Timeliness

Quality
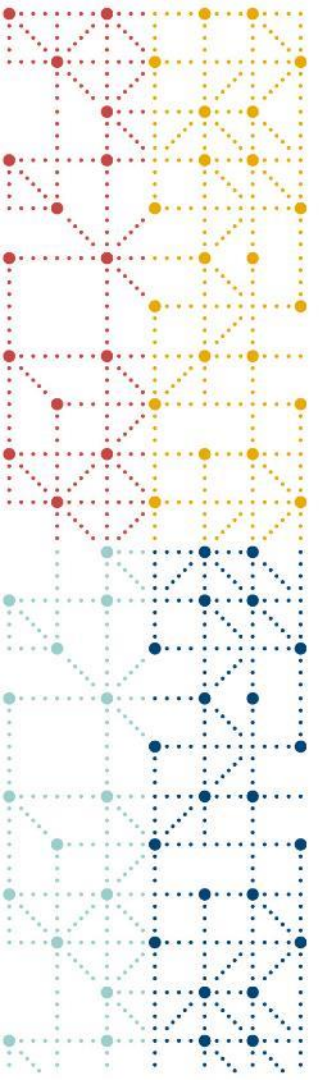
TMF Metrics Tool @ GSK

TMF metrics tools available at GSK
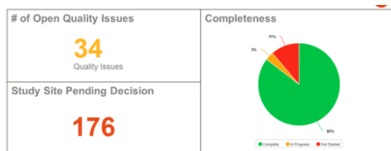
Excel tool

- Initial tool
  - right set-up achieved by gathering requirements and needs
- Possibility to **link to** individual documents in **eTMF**
- More possibilities in filtering (to tailor to needs of analysis)
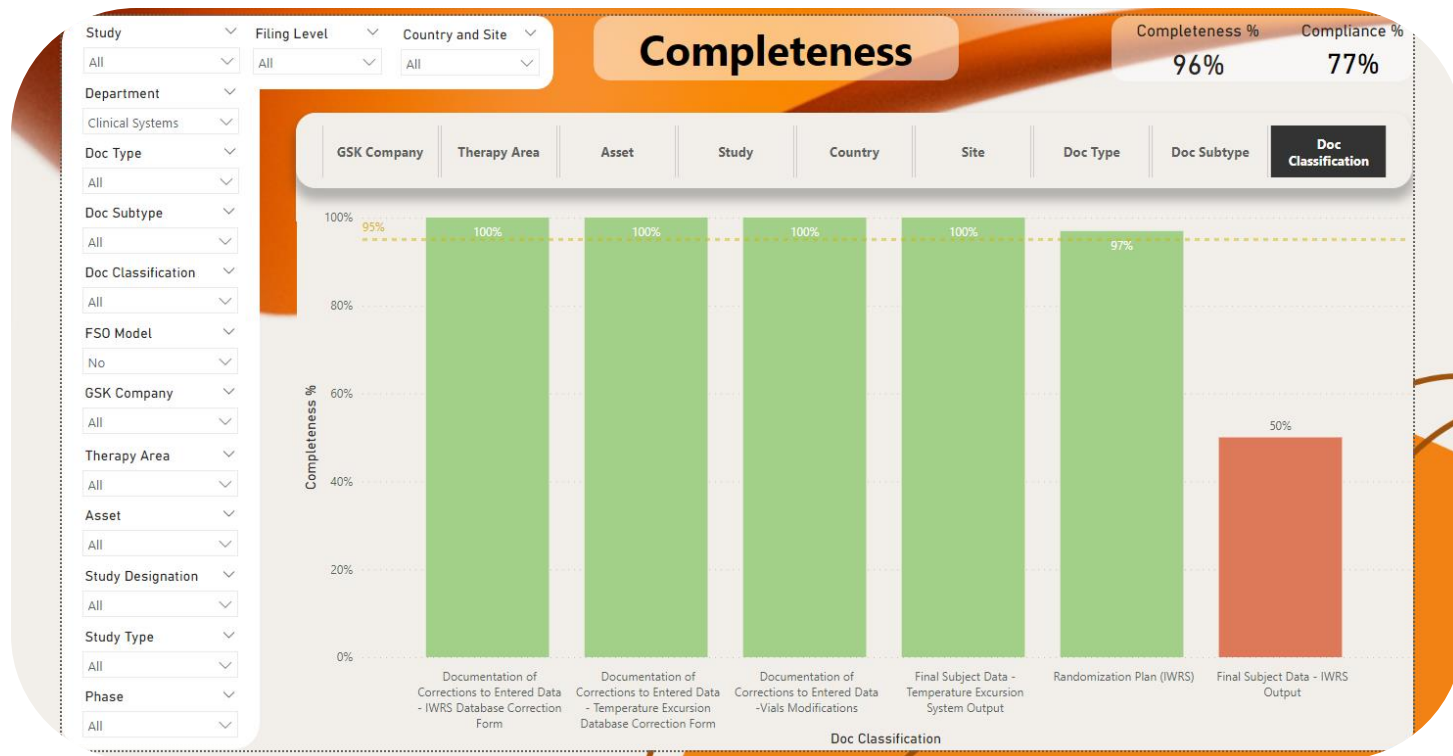
Power BI dashboard

- User-friendly
  - Easy filtering
  - Ease to visualize data by immediate creation graphs
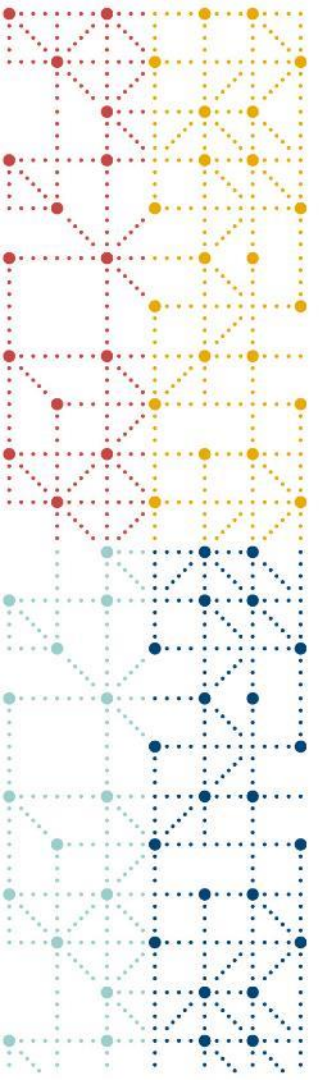- Access to all

eTMF – available data and reports

- Less preferable, as different calculation of metrics
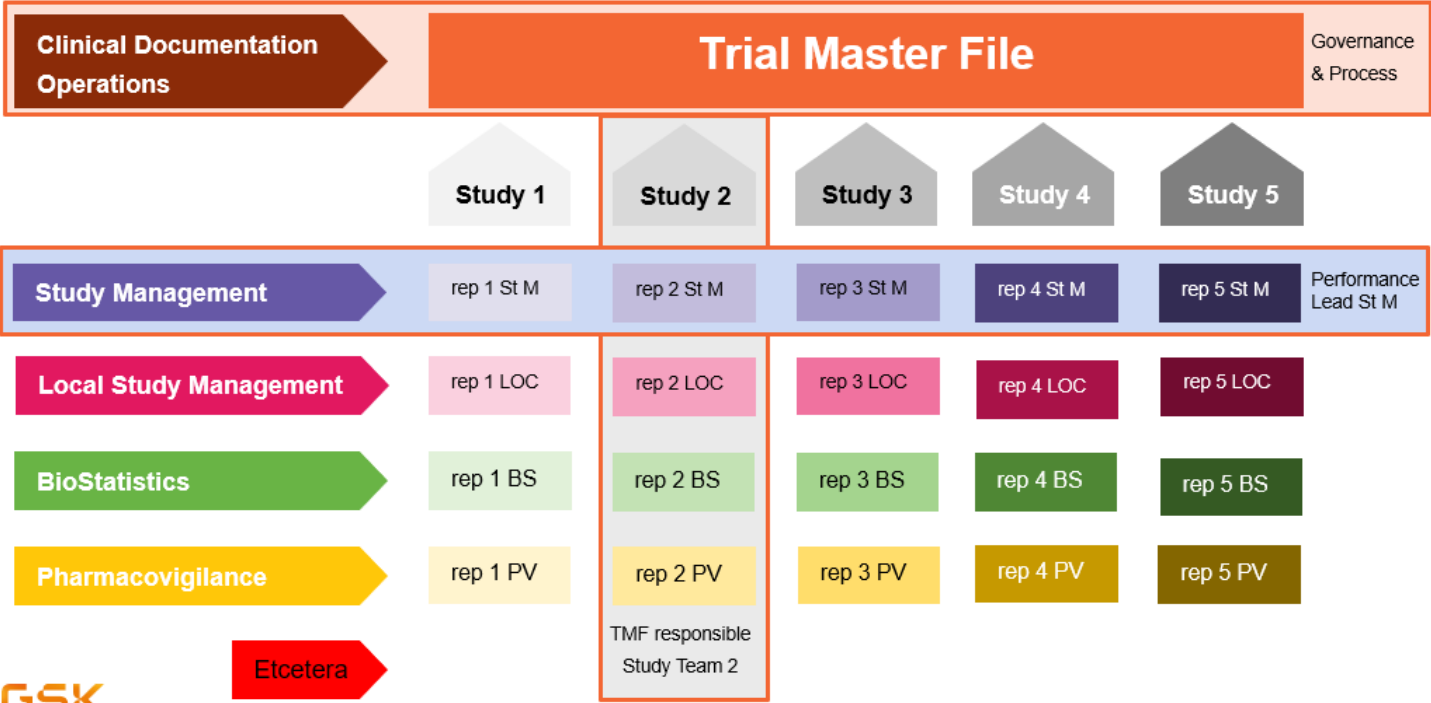
TMF Dashboard increased simplicity and accessibility

TMF Stakeholders

With a focus on the Functional Perspective

Different TMF stakeholders

Clinical Documentation Operations	Trial Master File					Governance & Process
		Study 1	Study 2	Study 3	Study 4	Study 5
Study Management		rep 1 St M	rep 2 St M	rep 3 St M	rep 4 St M	rep 5 St M	Performance Lead St M
Local Study Management		rep 1 LOC	rep 2 LOC	rep 3 LOC	rep 4 LOC	rep 5 LOC
BioStatistics		rep 1 BS	rep 2 BS	rep 3 BS	rep 4 BS	rep 5 BS
Pharmacovigilance		rep 1 PV	rep 2 PV	rep 3 PV	rep 4 PV	rep 5 PV

TMF responsible Study Team 2

Etcetera

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Engagement, interaction with SMEs and Performance Dialogue are the responsibilities of Performance Leads
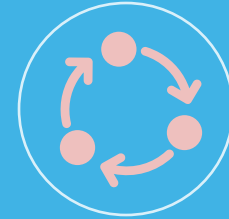
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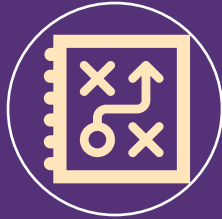
Manage Departmental Engagement Activities
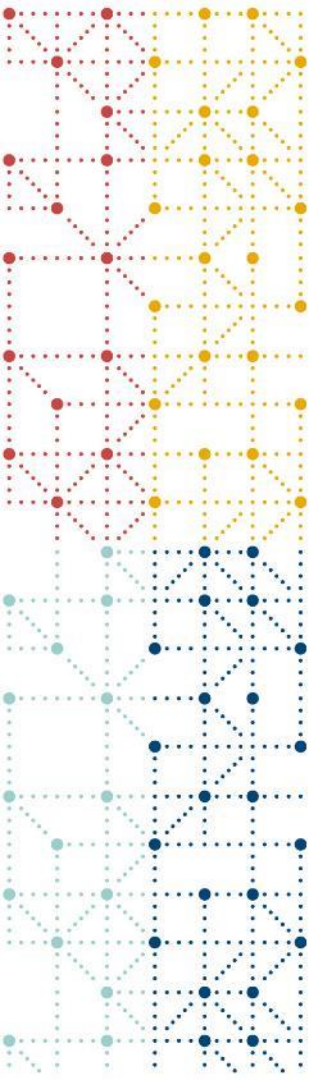
Interact with TMF SMEs:

LeadershipTeam, Risk Managers, Reference Model SMEs, etc.

Drive Performance Dialogue

Establish KPIs, track and analyze them, Indicate actions

Improve TMF Performance from Departmental Perspective

TMF Health Management
# beyond Completeness-Timeliness-Quality

Through fit for purpose Tools

Filters to choose from to tailor to perspective

Perspective	Example of filters to be used
Individual local study contributor	Study number, site level documents, plus selecting country

Please note:
the possibility to **filter** on

- Owning Department
- Doc Type
- Doc Subtype
- Doc Classification
- And more:
  - FSO model
  - Therapy Area
  - Study Type
  - Phase
  - Etcetera
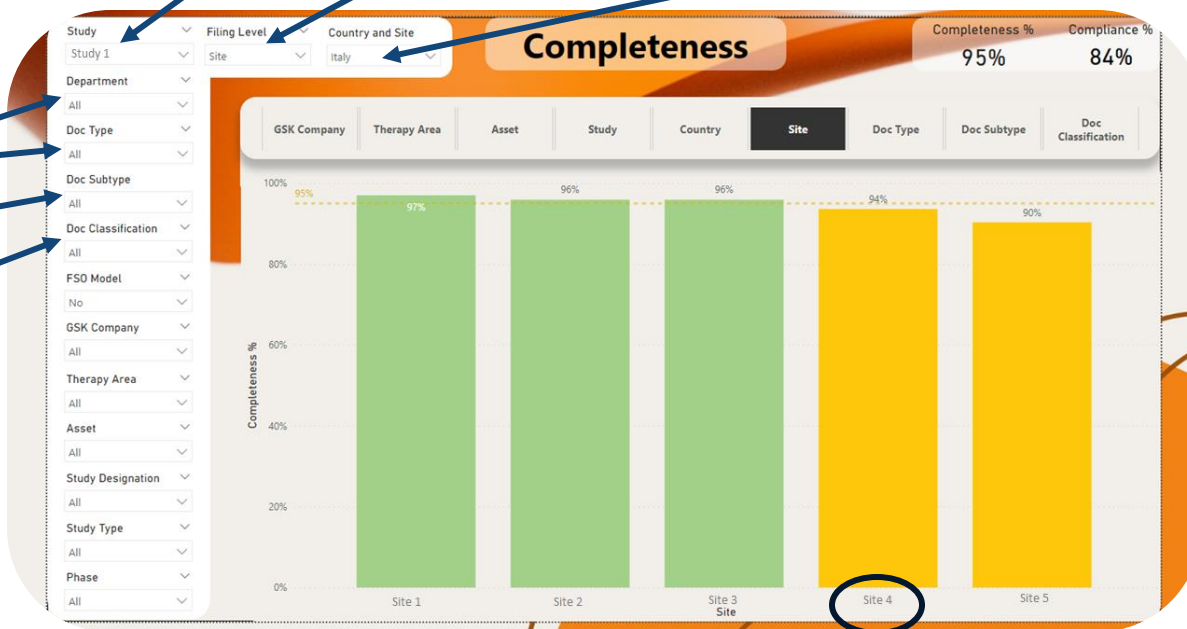
Review metrics from different perspectives

Perspective	Example of filters to be used
Functional Performance Lead	All studies, owning department, all levels ⟶ Deep-dive of Functional TMF metrics
Study Lead	Study number, all levels ⟶ Review study TMF metrics
Leadership Team Department Z	Owning department, study level documents, FSO = No ⟶ Review key TMF metrics Department Z is responsible for
Therapeutic Area Head ABC	Compound A, B and C, all studies, all levels ⟶ Review study TMF metrics for Therapeutic Area ABC
Country Line Manager	Country X, country and site level, studies 1, 2, 3 ⟶ Review TMF performance of direct reports

Knowing TMF Health Status requires a Set of Metrics
Compare with how to describe an apple

- To describe the 'health' of an apple, you could use metrics on the appearance, like color, shape, the condition of the peel.

- Compare with the TMF standard metrics are **Completeness, Timeliness and Quality**.

- To know the quality of the apple in more detail, it could be helpful to know the taste, juiciness

- Similar for TMF: **a full set of metrics** to have a more **complete understanding of TMF Health** and to make the metrics **actionable.**

Reliability of Completeness is based on the management of EDLs

Completeness:

Number of final documents versus expected documents as required per EDL
(=Expected Document List) for achieved inspection readiness milestones and not third party managed

Complementary metric:

• **Number of pending decisions** in the EDL to support completeness

Finding:

• High number of pending decisions
• Thus, EDLs are not being managed
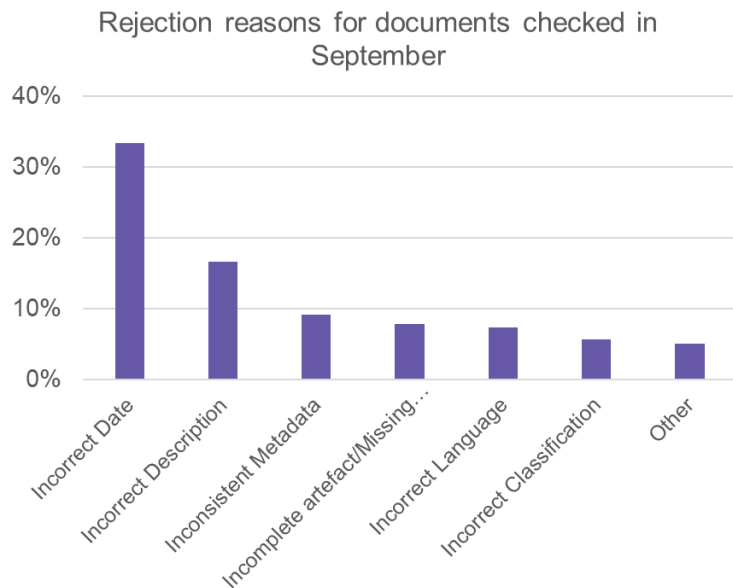• Meaning reliability of completeness metric is low

Conclusion based on **using set of metrics**

• Explain **importance of EDL management**
• **Request** study teams **to maintain EDLs**

When Quality metric is low – need to understand the reason

Quality: % of Quality Checked documents without Quality Issues

Ideally verify **Quality of all documents**, including
- Quality Issues of documents not undergoing QC
- Self-discovered Quality Issues

Complementary metrics:
- **Reasons for Rejections:** which metadata is causing the rejection of the quality check?
- **Time to resolve Quality Issues:** average time between creation of Quality Issue and closure date
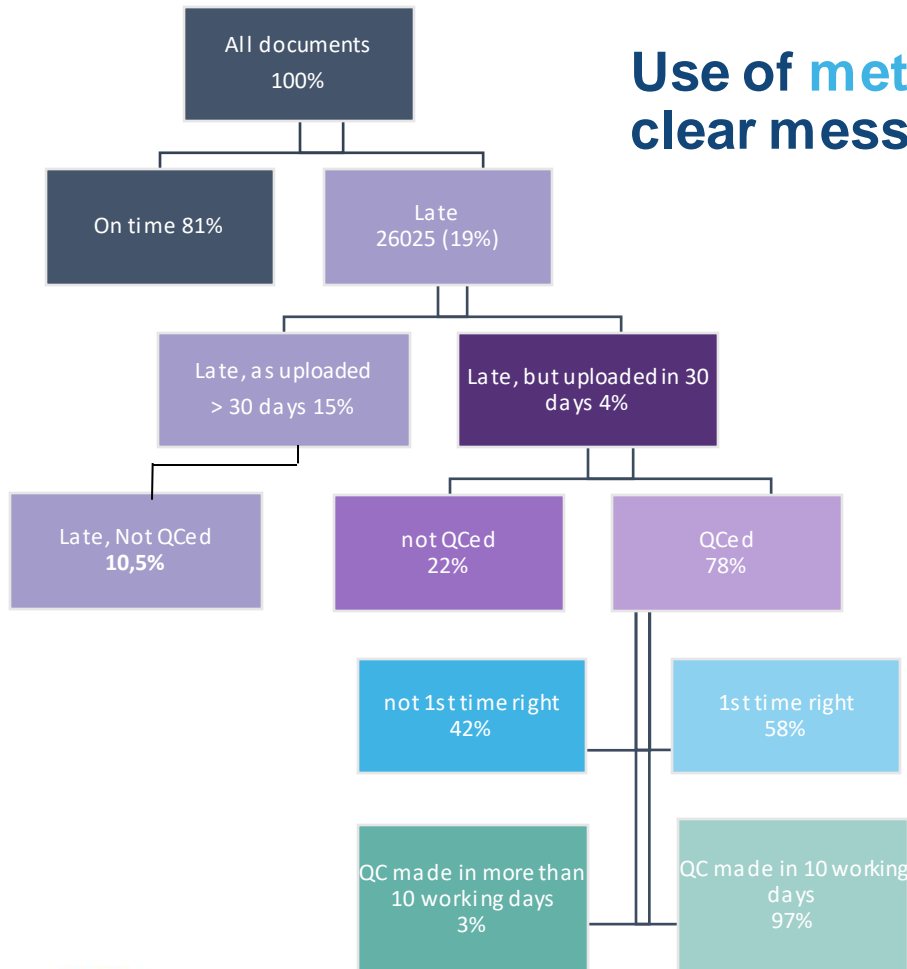
Finding:
- Over 30% of documents undergoing QC were rejected because of incorrect date
- Artefacts that were quality rejected were on hold too long

Conclusion based on **using set of metrics**
- **Create guidance** on the **right document date**
- **Send message** to end-users: **if document is QC rejected, resolve it** and resend for QC workflow

Rejection reasons for documents checked in September

Use of metrics plus data results in a clear message to end-user

Deep-dive on Timeliness

- Timeliness
  - # days to upload
- Quality (1st time right)
  - Need for QC (yes/no)
  - # days to do quality check

Finding:

- 10,5% of total number of documents are late
- Only 3% of documents uploaded late, required more than 10 working days for the Quality Check

Conclusion of metrics + data

Clear message to TMF Users
Upload and finalize documents instantly
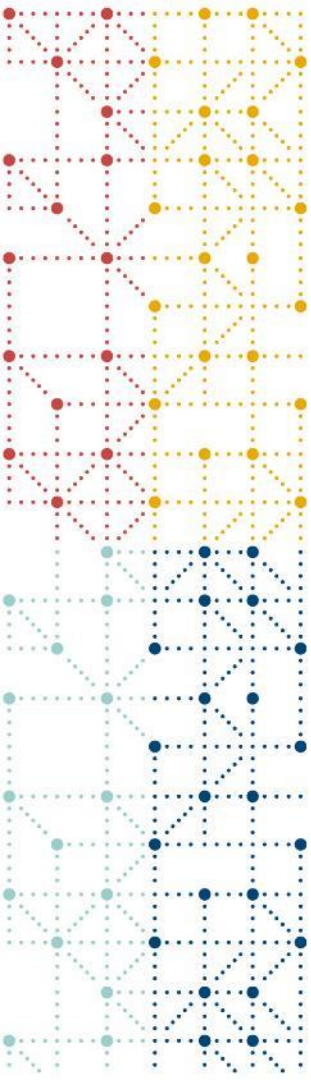
Take Home Messages

Take Home Messages

Target Stakeholder(group)s to review metrics
use study, country, departmental or any level

Use Completeness, Timeliness and Quality in
conjunction with complementary metrics and data

Review Metrics, do Root Cause Analysis,
Identify clear Actions and Communicate to Users

Stay curious and keep searching for Improvement

Thank You!
Good luck with making your metrics actionable