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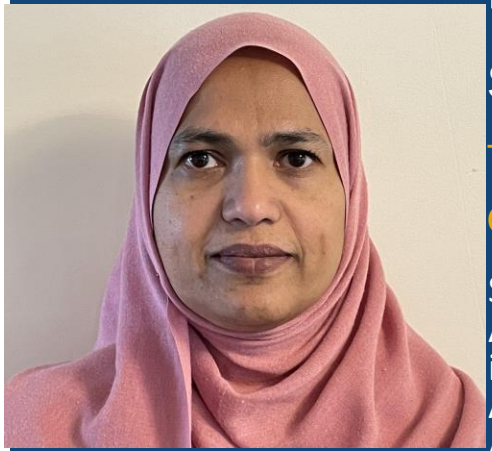
Trial Master File Reference Model – TMF Index Zone 11-Statistics Implementation Lessons Learned from a Statistical Programmer

Presented by Salma Ameen, Statistical Programming Associate Director
AstraZeneca



Meet the Speaker

Salma Ameen

Title: Statistical Programming, Associate Director

Organization: AstraZeneca

Salma is a Statistical Programming Associate Director at AstraZeneca, with 20 years of experience in the pharmaceutical industry. She has received her master's degrees in Business Administration and in Management Information System.
As the TMF Functional Process Expert for Statistics and Programming, Salma has utilized her expertise to train her colleagues and facilitate her department's TMF filings ensuring compliance with Completeness, Timeliness and Error Rate.
Salma has been with Early Oncology Programming at AstraZeneca since 2007.

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(s) has no real or apparent conflicts of interest to report.*

Agenda

1. Trial Master File Reference Model – Definition and History
2. TMF Index – Structure, Statistics Zone 11
3. TMF Compliance – Completeness, Timeliness, Approval Rate
4. Compliance Strategies – PQC, Trainings, Guidance Documents, Metrics, TMF Champions
5. Vendor Maintained TMF – Oversight, Periodic Quality Check

Trial Master File Reference Model

Definition and History

Trial Master File Reference Model

Definition

- A TMF is the collection of essential documentation needed to conduct a clinical study, ensure patient safety, the integrity of study data, and the compliance of the study with Good Clinical Practice.
- It forms the basis for an inspection to confirm compliance with regulatory requirements.
- As specified in the International Conference on Harmonization (ICH) Guideline for Good Clinical Practice E6, as well as applicable EU regulations and the US Food and Drug Administration 21 Code of Federal Regulations, the TMF must be in a state of Inspection Readiness at all times

Trial Master File Reference Model

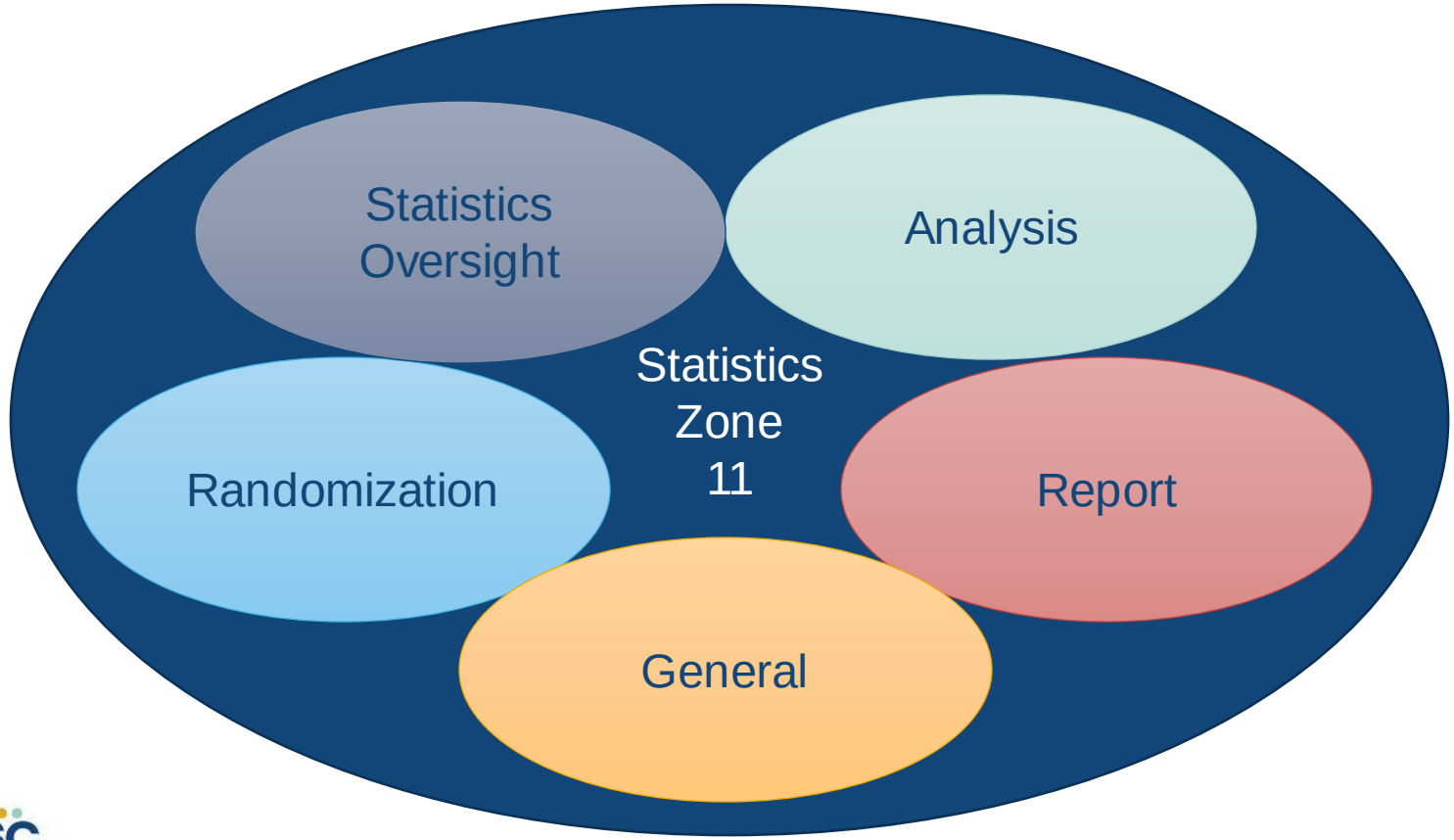
History

- TMF RM Group was formed in 2009 within the Documents and Records Management community of the Drug Information Association (DIA).
- The V1.0 TMF RM was released in June 2010, and organizations adapted it to fit their TMF filing needs.
- The current model being used is V3.3.1.
- The TMF Index is prepared based on the current model.

TMF Index

Structure, Statistics Zone 11

TMF Index – Structure



Analysis

Data Definitions for Analysis Datasets

Analysis QC Documentation

Subject Evaluability Criteria and Subject Classification

Interim Analysis Raw Datasets

Interim Analysis Program

Interim Analysis Datasets

Interim Analysis Outputs

Final Analysis Raw Datasets

Final Analysis Programs

Final Analysis Datasets

Final Analysis Outputs

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Statistics Oversight

- Statistical Analysis Plan
- Sample Size Calculation

Report

- Interim Statistical Reports
- Statistical Report

Randomization

- Randomization Plan
- Randomization Procedure
- Master Randomization List
- Randomization Programming
- Randomization Sign Off
- End of Trial or Interim Unblinding

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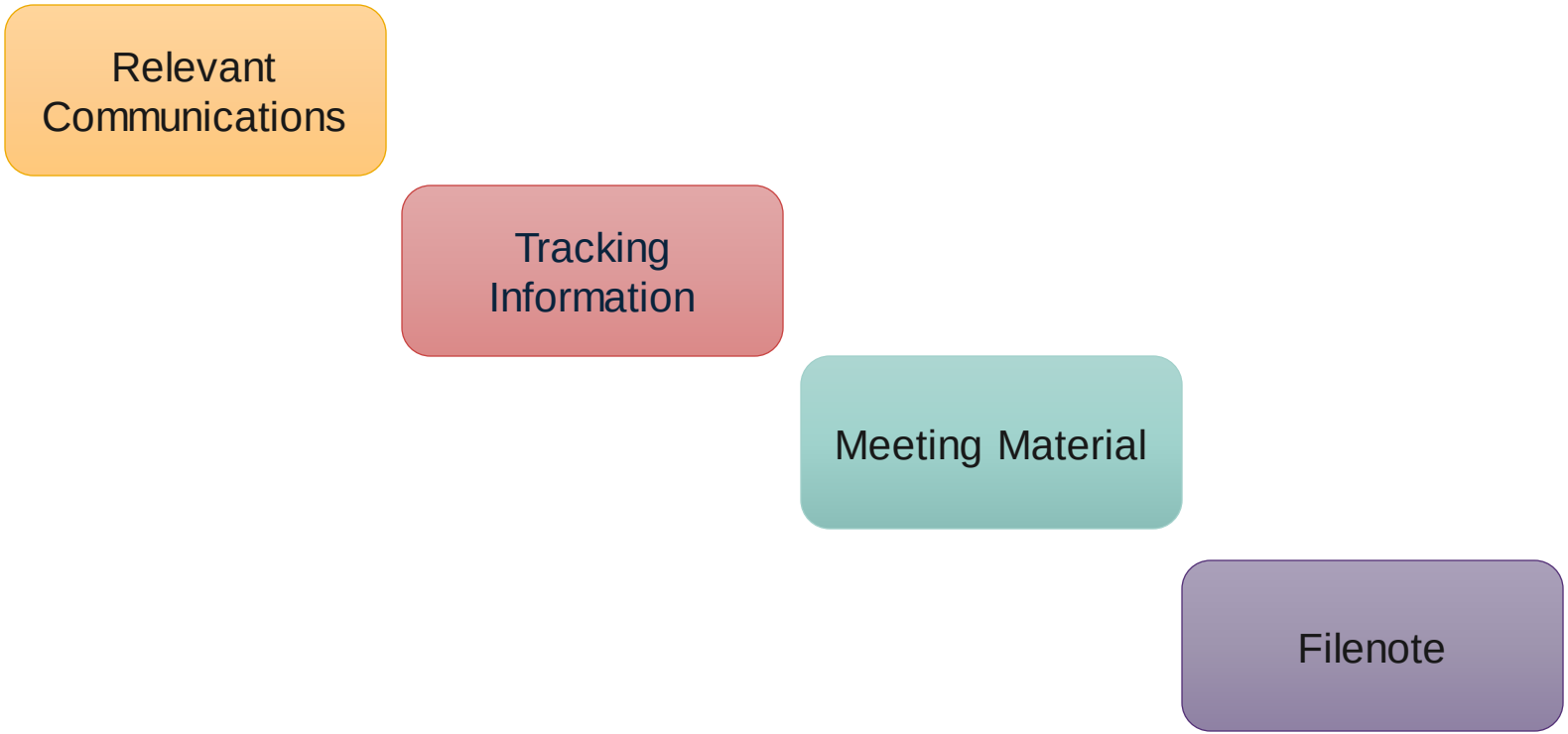
General


Relevant Communications
Tracking Information
Meeting Material
Filenote

TMF Compliance

Completeness, Timeliness, Approval Rate

TMF COMPLIANCE

Compliance Strategies

Periodic Quality Check

Trainings

Guidance Documents

Metrics

TMF Champions

COMPLIANCE STRATEGIES

WHAT & WHY?

Guiding Principles

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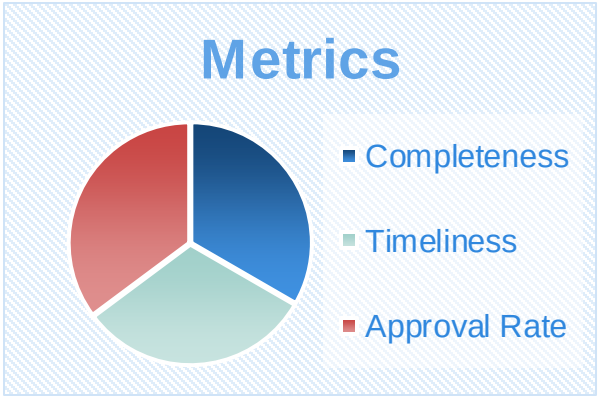
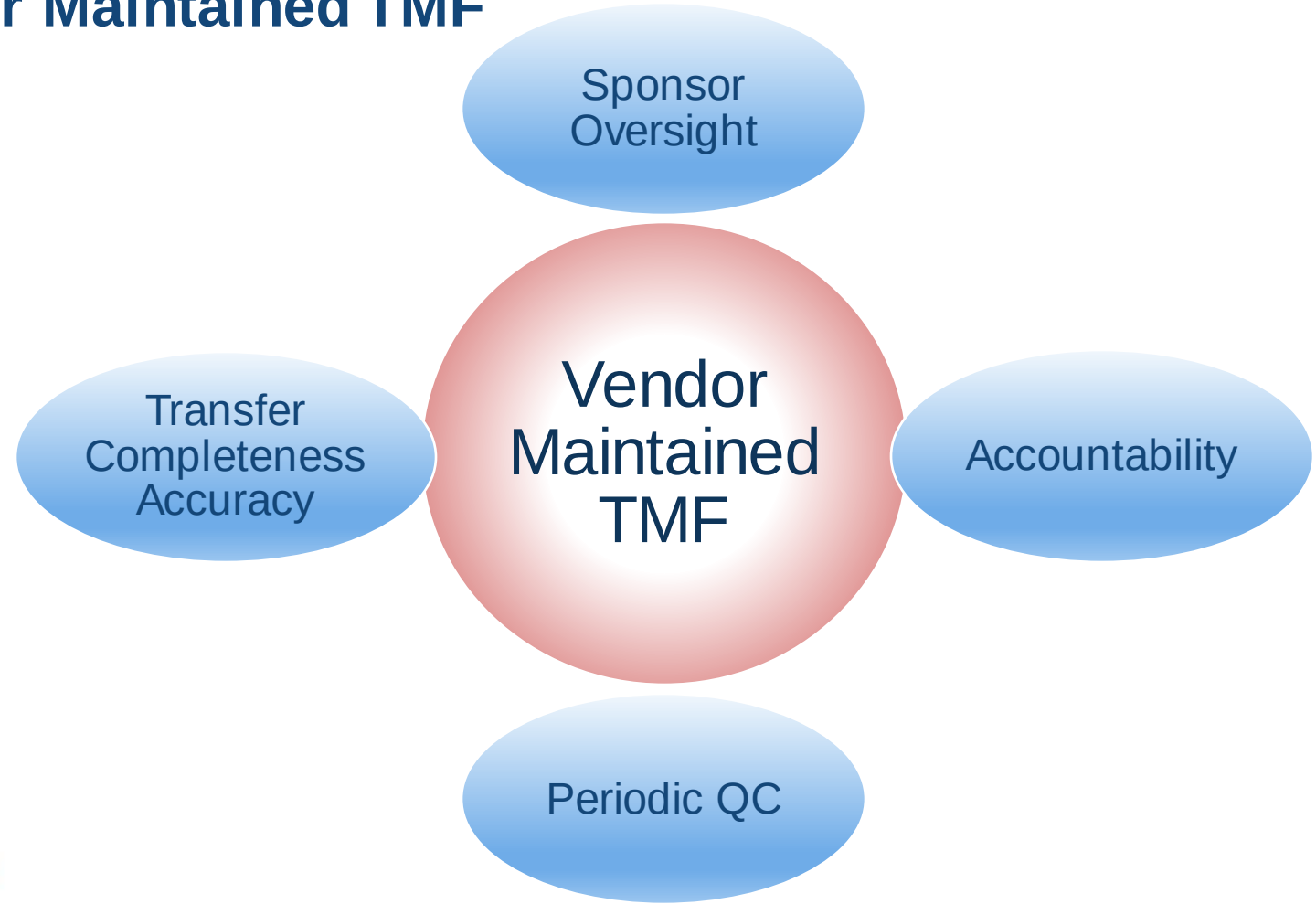


Vendor Maintained TMF

Oversight, Periodic Quality Check

Vendor Maintained TMF



Thank You!