SDTM-based Centralized Statistical Monitoring

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Meet the Speaker

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Yingcong is Senior Data Science and Analytics at BeOne. She has 4 years of experience in Centralized Statistical Monitoring.

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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.*

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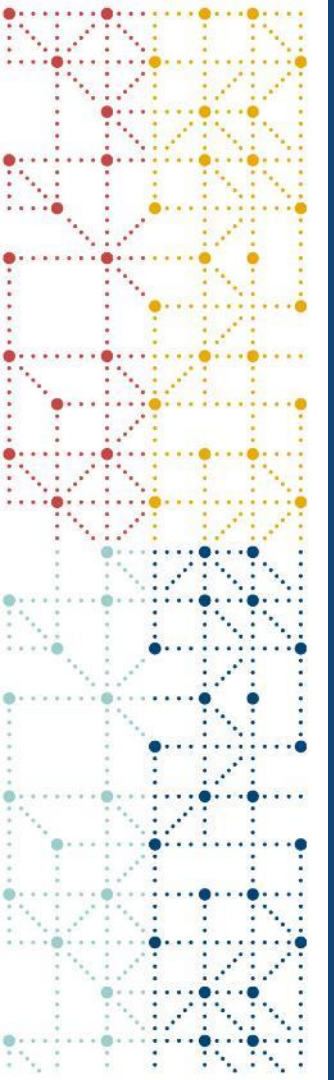
Agenda

1. Introduction of Central Statistical Monitoring
2. Real-time SDTM
3. Application and Benefits
4. Looking Ahead



Introduction of Central Statistical Monitoring

Risk-based Quality Management

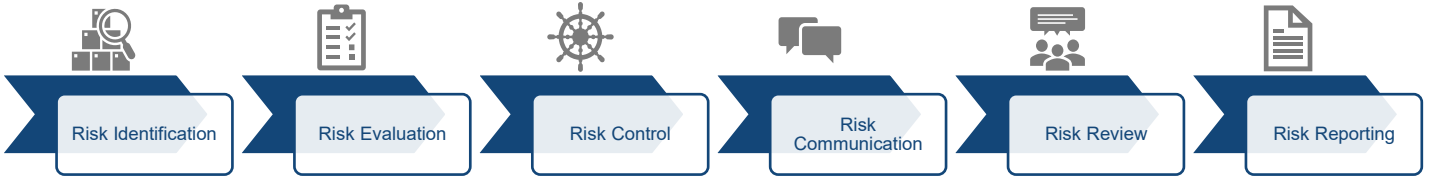
Regulatory Guidelines - Expectations Based on ICH E6 (R3)

3.10 Quality Management

The sponsor should implement an appropriate **system** to manage quality throughout **all stages** of the trial process.

Quality management includes the design and implementation of efficient clinical trial protocols, including tools and procedures for trial conduct (including for data collection and management), in order to ensure the protection of participants' rights, safety and well-being and the reliability of trial results.

The sponsor should adopt a proportionate and **risk-based** approach to quality management, which involves incorporating quality into the design of the clinical trial (i.e., quality by design) and identifying those factors that are likely to have a meaningful impact on participants' rights, safety and well-being and the reliability of the results (i.e., **critical to quality factors** as described in ICH E8(R1))



Monitoring Approaches in clinical trials

On-site Monitoring

- An activity that is performed at the sites at which the clinical trial is being conducted.

Off-site Monitoring

- Monitoring activities that occur away from the study site location, such as at a monitor's home or in a sponsor representative's office. This is also commonly known as remote monitoring.

Centralized Monitoring

- Centralized Monitoring is a remote evaluation of accumulating data, performed in a timely manner, supported by appropriately qualified and trained persons. Centralized monitoring process provide additional capabilities that can complement and reduce the extend and/or frequency of on-site monitoring and help distinguish between reliable data and potentially unreliable.

Risk-Based Monitoring (RBM) typically makes use of Centralized Monitoring to highlight risk, with various statistical methods and accumulating data to provide capabilities of:

- Identify missing and inconsistent data, outliers and unexpected lack of variability.
- Examine **data trends** such as the ranges, distribution and frequency.
- Optimize the overall efficiency and process improvements.
- Evaluate for **systematic or significant errors** in data collection and reporting at a site or across sites; or potential data reliability problems.
- Analyze site characteristics and performance metrics.
- Contribute to **selection sites** and processes for **targeted on-site monitoring**

Centralized Statistical Monitoring: While ICH was adopted by China regulation, **CDE** is evolving the approach and released **Guidance on Centralized Statistical Monitoring**.

CSM Analyses Type

Key Risk Indicator (KRI)

- Purpose to focus on critical data and other study variables to be assessed across program, protocol, country and site levels
- Use **operational data** and can be adjusted based on different factors such as enrollment, milestones, site performance
- Limited direct impact on subject safety and data integrity at the trial level
- Use thresholds - the level point or value associated with KRI that will trigger an action
- **Not reported in CSR**

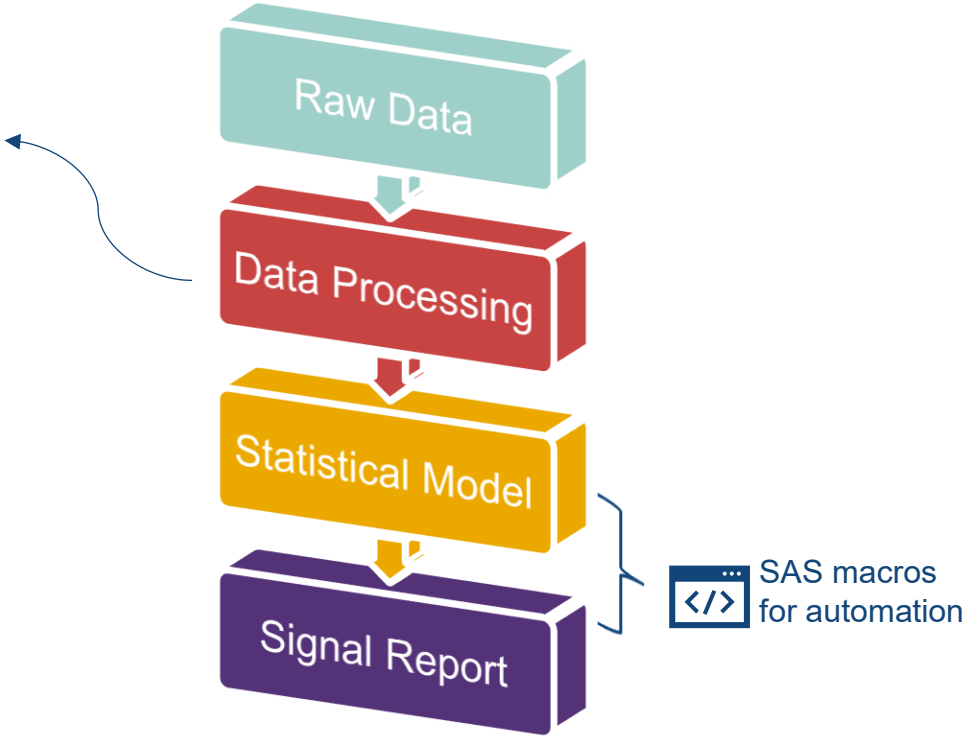
Quality Tolerance Limit (QTL)

- Purpose to **identify systematic issues** that can impact subject safety or reliability of trial results
- Established at the **trial level**
- Detection of deviations from the QTLs requires assessment
- Intent is to transparently demonstrate how subject safety was assured and how data quality was maintained through out the trial
- **Reported in the CSR**, including a summary of important deviations from QTLs and remedial actions

CSM Analyses Workflow

Challenges:

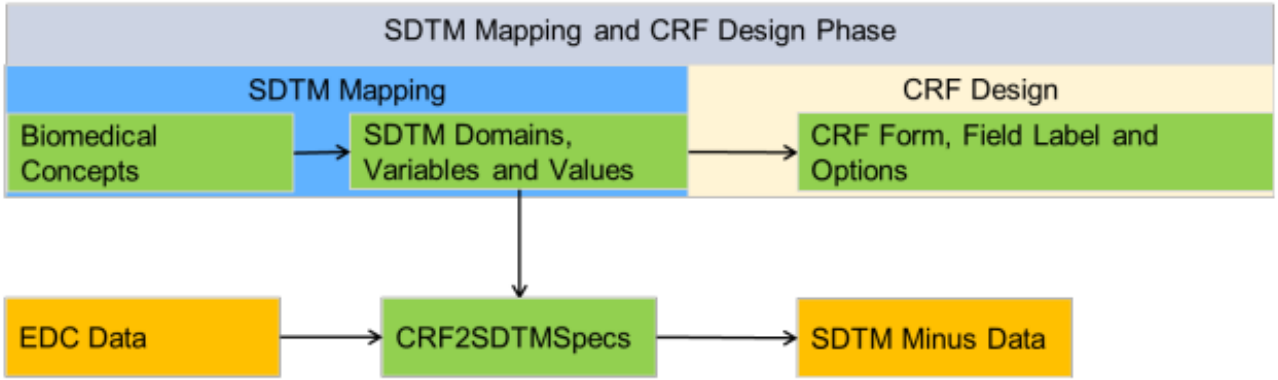
- Inconsistent Variable Naming Conventions
  - Different CRF design
- Data Heterogeneity
  - Various formats and structures
- Difficult to standardization
  - Time consuming



Real-time SDTM

SDTM Automation

- CRF Data SDTM Transformation



- SDTM Derived Data Full Automation

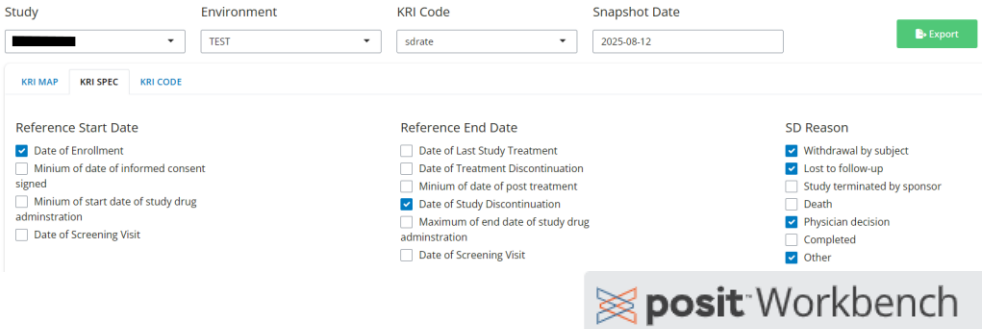
References
Chunpeng Zhao, 2025. "Re-designing SDTM Automation: Maximizing CDASH Process Values and Understanding Code-Specs Relationship" Pharmasug-China-2025-DS167.pdf

Application and Benefits

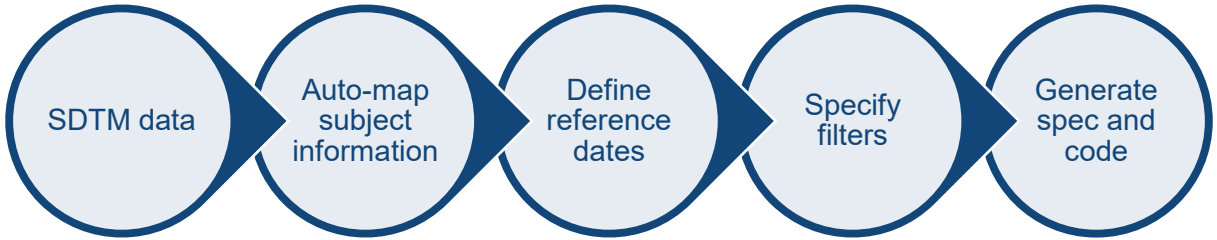
Standard KRI Analyses

Analysis Scope:

- Serious / Non-serious AEs
- Treatment Discontinuation
- Study Discontinuation
- …



Standardization facilitates Automation



Study Specific KRI & QTL Analyses

Application

Dose Compliance
- Consistent data formats for easy calculation

Missed Samples
- Structured data to integrate the sample collection process

Off-schedule
- Transformed study day for date comparison

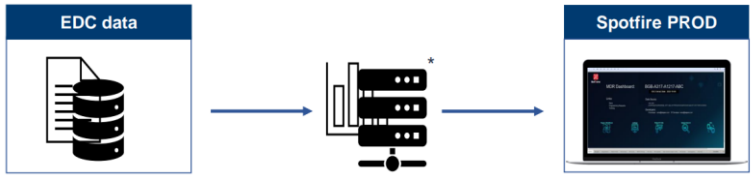
Benefits

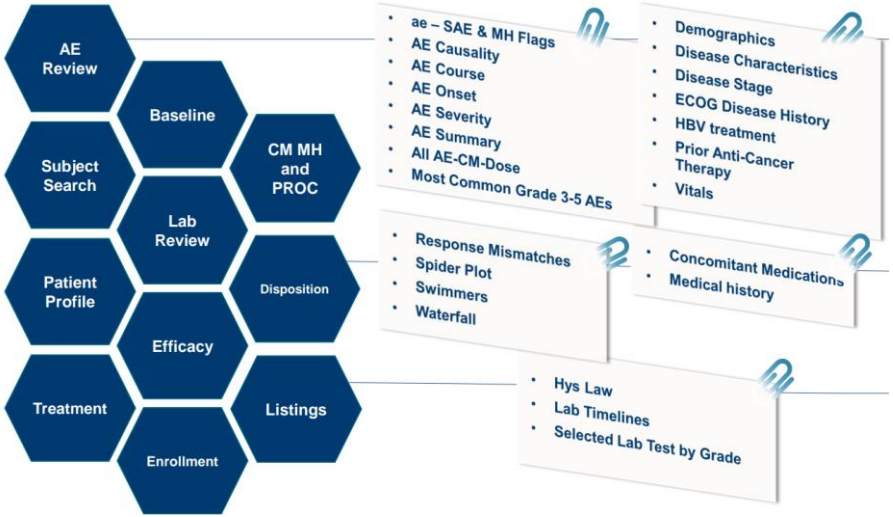
- Accuracy
  - Ensure consistent with CSR
- Consistency
  - Minor modification needed when CRF updated
  - Enable cross-study comparison and analysis
- Efficiency
  - Reduce FTE of standard KRI analyses by **80%**
  - Reduce FTE of study specific KRI & QTL analyses by **30%**

Medical Data Review

Medical Data Review (MDR) Dashboards are Web-based tool which makes every CRF in the EDC database available in near real-time.

- Help medical data reviewers **identify issues** in the data. The typical issues to look out for are described each study's IDRP (Integrated Data Review plan)
- Study visualizations – **Interactive Visualizations** in dashboard help identify high-level trends, outliers, and allow drill-down into the 'raw' source data.
- Application of SDTM data: **automation** of field mapping and coding





Looking Ahead

Future Enhancements

- Automation of commonly used study specific KRIs and QTLs
  - Need to handle discrepancies across different protocol versions
- Utilize real-time ADaM as a replacement for SDTM
  - Further enhance standardization and automation of data processing

Thank You!