Application of CDISC Standard in developing Risk-Based Quality Management(RBQM) system

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Meet the Speaker

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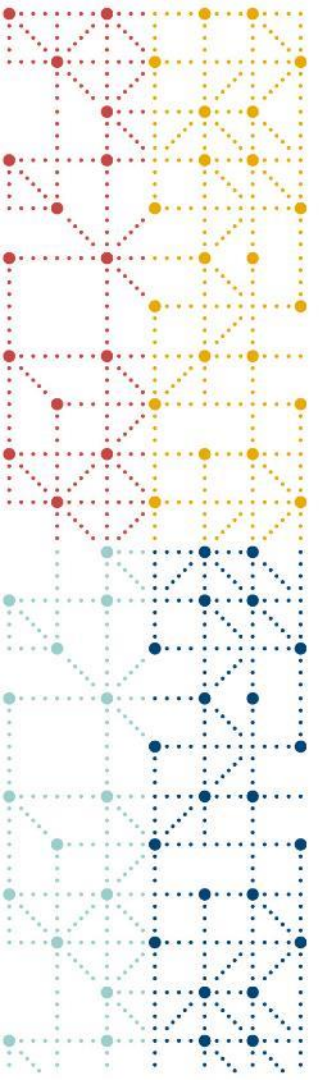
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Organization: Tigermed Co., Ltd.

Yi Lu is Senior RD Analyst from Tigermed. With more than 5-year focus on the CDISC standards and data automation, Yi has variety experience for the CDISC submission, RBQM solutions, and other automation system development.

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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

Background

What, Why and How RBQM (Risk-Based Quality Management)

RBQM (Risk-Based Quality Management)

▸ RBM (Risk-Based Monitoring): An adaptive approach to clinical trial monitoring that directs monitoring focus and activities to the evolving areas of greatest need which have the most potential to impact subject safety and data quality.

▸ RBQM (Risk-Based Quality Management):
  ◦ Extend the Risk-Based Approach from Monitoring (CO) to whole Quality Management (CO+DM+MM+PV+SA+QA+…)

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Why RBQM

Clinical Trial Quality Faces

STUDIES MORE COMPLEX:

- More data source
- More management systems
- Larger teams
- More geographical locations (MRCT)

RISKS on:

- Subject rights
- Clinical trial data quality

NEED:

- Consistently comprehensive risk assessment
- More valuable work
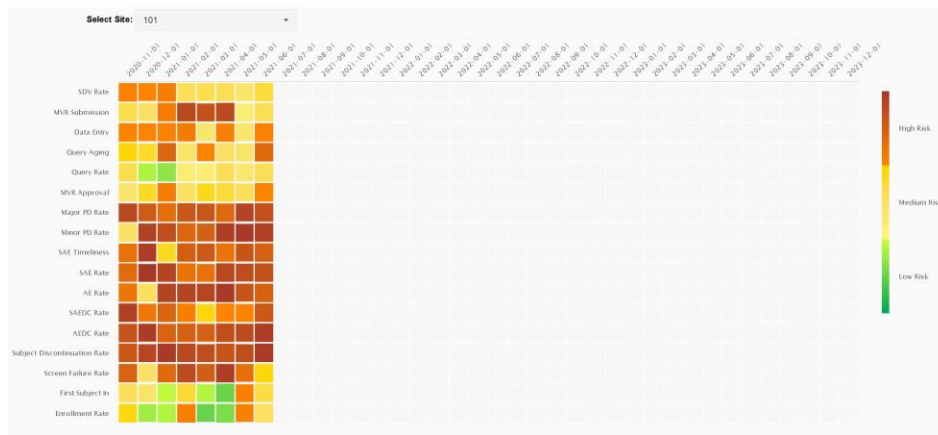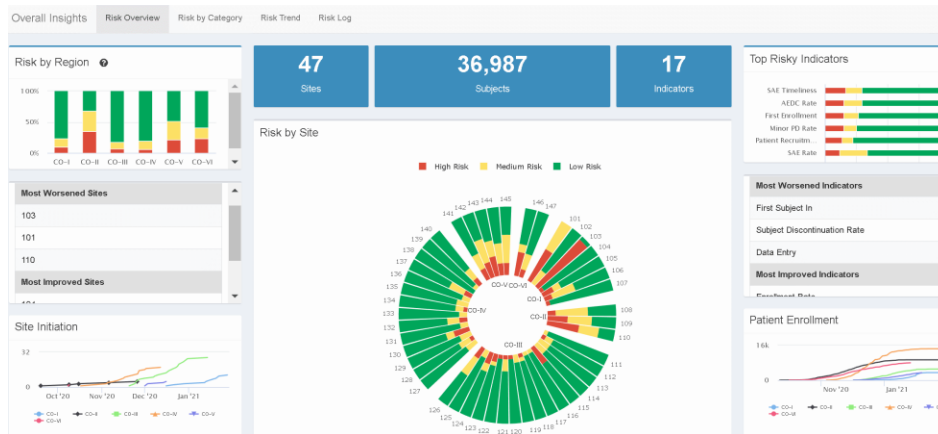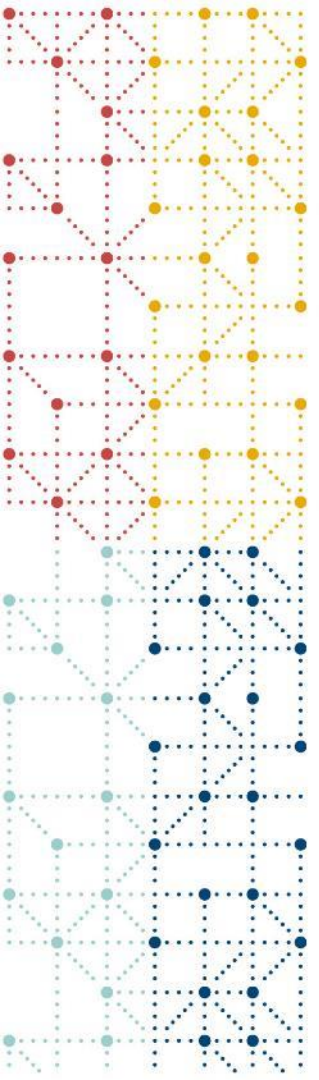- More effective than 100% SDV

Regulatory and ICH/GCP Requirements

- 2013 FDA: <Guidance for industry>
- 2013 EMA: <EMA: Reflection paper on RBQM>
- 2016 CFDA: GCP
- 2019 FDA: <FDA: Guidance for industry Q&A>
- 2020 NMPA: GCP
- 2021 CDE: <Centralized Monitoring Guidance>

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RBQM System

Risk visualization

- Overview
- Cross Check
- Risk Trend

CDISC Standard Application

Key Risk Indicator Visualization Challenge
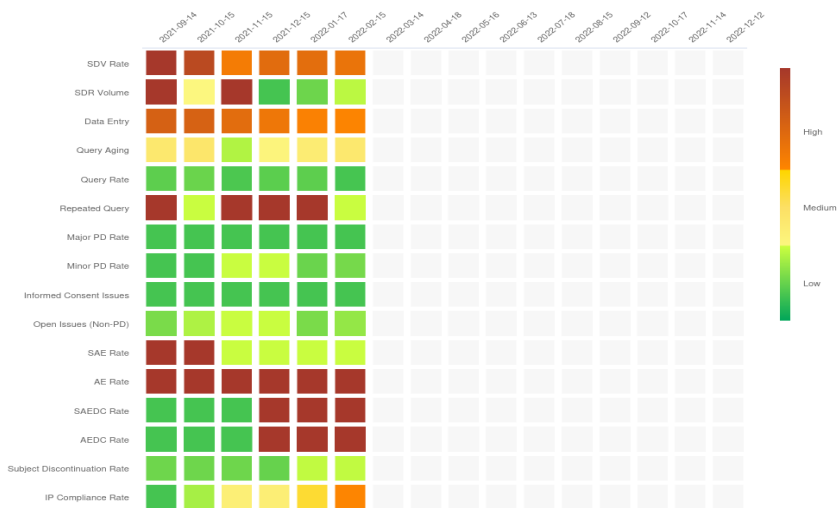
Data Integration using CDASH

KRI, Key Risk Indicator

Data Sources

- Clinical Management Data ———————→ CTMS
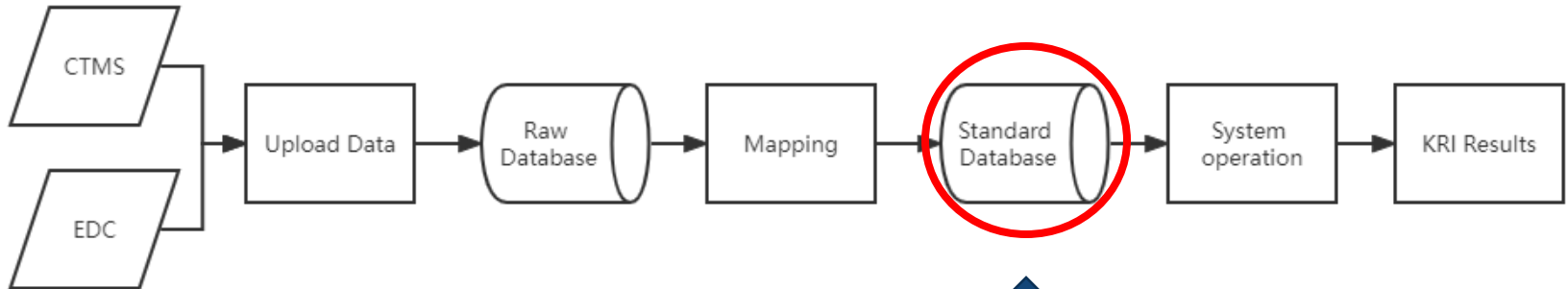- Clinical Trial Data ———————→ EDC

Data Styles

- sas7bdat
- xlsx,xls

Key Risk Indicator Visualization Challenge

Stable Algorithms vs Unstable Data ⟶ **Data Integration**

KRI Data Flow

CTMS

EDC

Upload Data → Raw Database → Mapping → Standard Database → System operation → KRI Results

CDASH Standard for EDC Data

Why CDASH?

- Clinical Data Acquisition Standards Harmonization Implementation Guide for Human Clinical Trials---Industry Development Trend
- Huge mapping history library
- Risk monitoring through the whole process of the trial

Fewer adjustments

More precise mapping

Non-CDISC CRF

Non-CDISC Database

Different therapeutic

CDASH Standardized
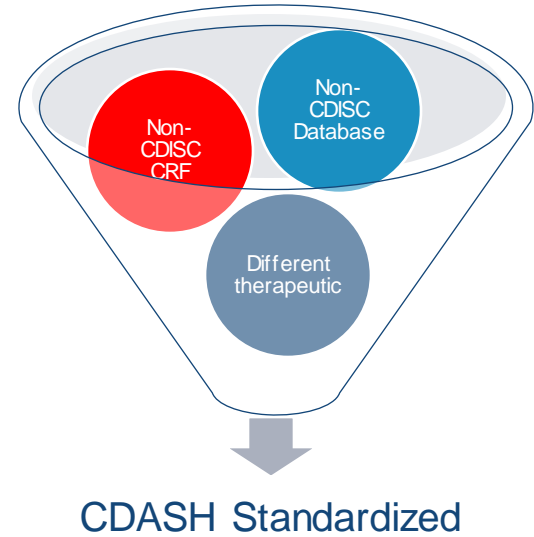
Risk Indicator Library

Select KRI from library or add new ones
BY STUDY DESIGN

❖ **Based CDASH Standard risk indicators**

- 3 categories

  Investigational Product

  Safety

  Subject Recruitment and Discontinuation
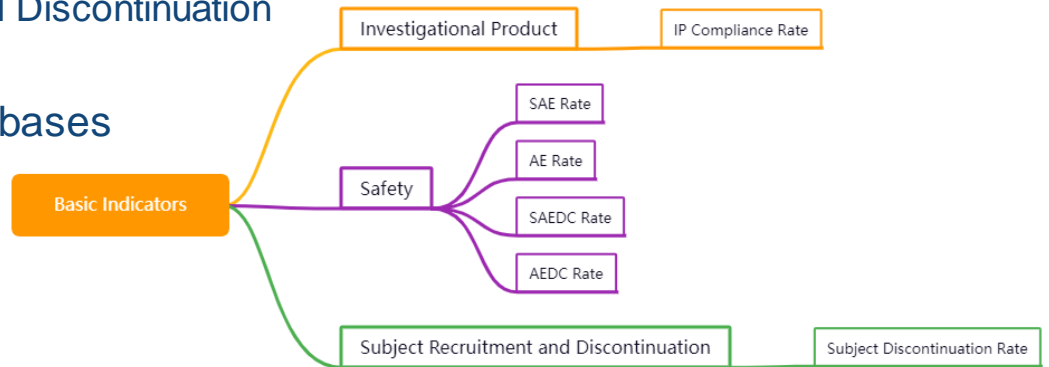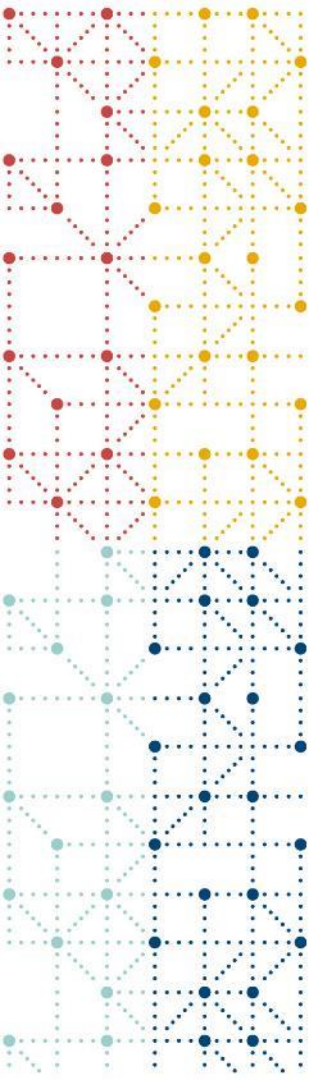
- 5 CDASH Standard Databases

  DM

  AE

  EX

  SV

  DS

Data Integration Solutions

Dataset Mapping + Variable Mapping

Automated mapping

Set KRI – SAE Rate

风险分析设置   ✕

* 风险名称   SAE Rate

* 分类   安全性 ⌄   * 风险   Over reporting of SAEs

* 定义   Number of serious adv   * 单位   # of events/month
          erse events per total

* 风险影响等级 高 ⌄   * 触发分析 30 days after FPI

* 数据源系统 EDC ⌄   * 数据源系统供应商 Tigermed

* 阈值方法 排序比较   ⌄

高风险	
阈值	Above the value of 95th percentile from the study
缓解措施(供参考)	1. CRA trains investigators on the characteristics and common a dverse reactions of the IMP, reminds the investigators of the r

确认   取消

Link to Standard Library AE

Link to Standard Library AE

字段名称 Variable Name	字段标签（英） Variable Label (EN)	字段标签（中） Variable Label (CN)	类型 Type	可否为空 Is NULL?
STUDYID	Study Identifier	研究标识符	Char	
SITEID	Study Site Identifier	研究中心标识符	Char	
SUBJID	Subject Identifier for the Study	研究受试者标识符	Char	
AEYN	Any Adverse Event	任何不良事件	Char	
AECAT	Category for Adverse Event	类别	Char	
AESCAT	Subcategory for Adverse Event	子类	Char	
AETERM	Reported Term for the Adverse Event	不良事件报告名称	Char	
AEOCCUR	Adverse Event Occurrence	是否发生	Char	Y
AEPRESP	Pre-specified Adverse Event	预设	Char	Y
AESTDAT	Adverse Event Start Date	开始日期	Date	
AESTTIM	Start Time of Adverse Event	开始时间	Time	
AEENDAT	Adverse Event End Date	结束日期	Date	Y

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Link to Standard Library AE

字段名称 Variable Name	字段标签（英） Variable Label (EN)	字段标签（中） Variable Label (CN)	类型 Type	可否为空 Is NULL?
AEENTIM	End Time of Adverse Event	结束时间	Time	Y
AESEV	AE Severity/Intensity	严重程度	Char	
AETOXGR	AE Standard Toxicity Grade	毒性分级	Char	
AESER	AE Serious Event	严重事件	Char	
AESDTH	Results in Death	死亡原因	Char	Y
DTHDAT	Death Date	死亡日期	Date	Y
AEDIS	AE Caused Study Discontinuation	导致研究终止	Char	Y
AESI	Adverse Event of Special Interest	特别关注的不良事件	Char	Y
AEDECOD	AE DictionaryDerived Term	标准化名称	Char	
AESOC	AE Primary System Organ Class	主系统器官分类	Char	

Mapping Solutions

Two Steps:

Dataset Mapping

Variable Mapping

Dataset Mapping

• Function:

Multi-table splicing

(Set + Merge)

Mapping Solutions

Variable Mapping

- Function:
    - Set
    - Assign
    - Conditional assign
    - Retype
    - Transpose
    - Text/Num/Date Processing
    - etc.

Mapping Library Management

Mapping History saved by Study Level with (Sponsor + Compound) information

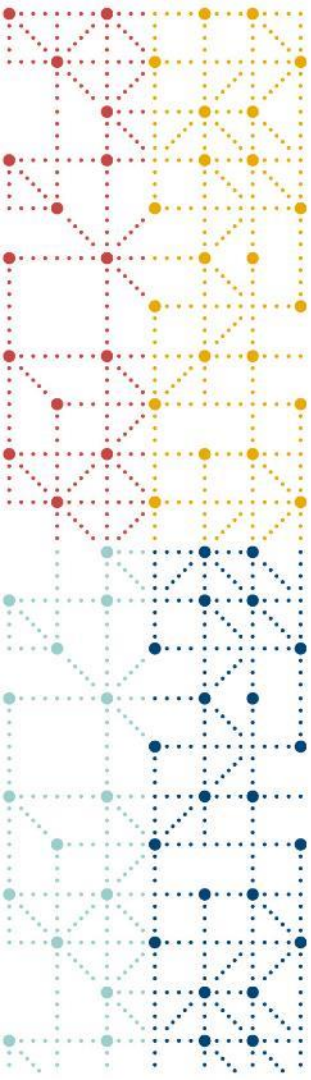**Intelligent Recommendation**
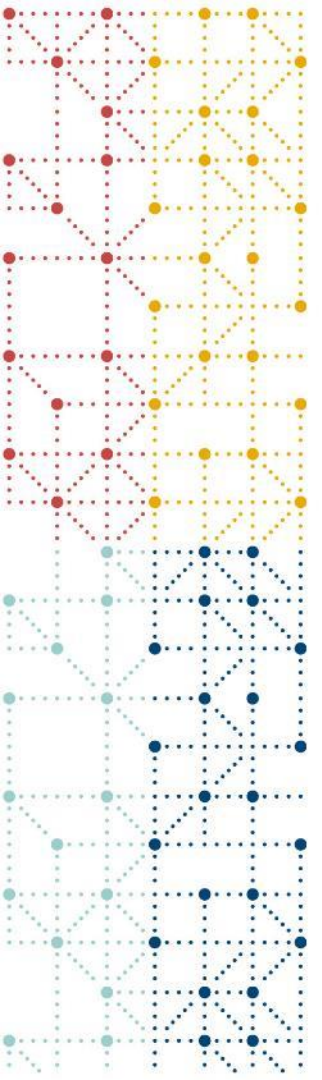
Conclusion

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1. RBQM System is **an efficient way** to implement RBQM.

2. Data preprocessing is **an important step** for system stability.

3. CDASH Mapping + Interface operation = User friendly + Efficient.

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Thank You!

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