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CHINA

INTERCHANGE

29-30 JULY | VIRTUAL EVENT

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

Presented by Yi Lu, RD Senior Analyst, Biometrics Business Unit, Tigermed Co., Ltd.

30Jul2022



Meet the Speaker

Yi Lu

Title: Senior R&D Analyst

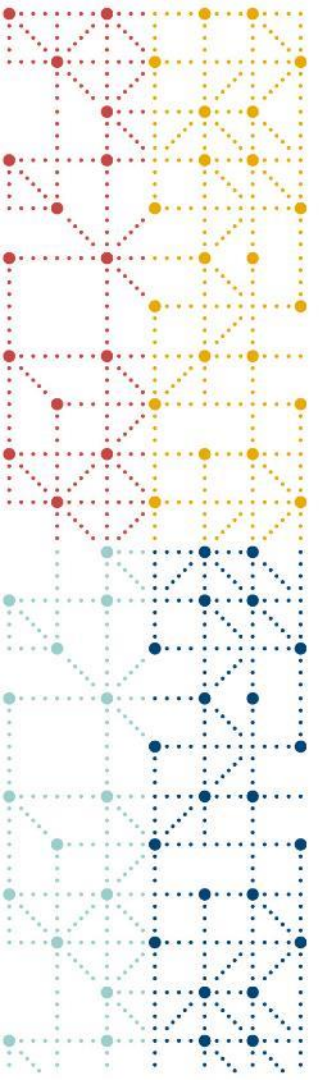
Organization: Tigermed Co., Ltd.

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.



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.*



Agenda

1. Background
2. CDISC Standard Application
3. Data Integration Solutions
4. Conclusion



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+...)

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

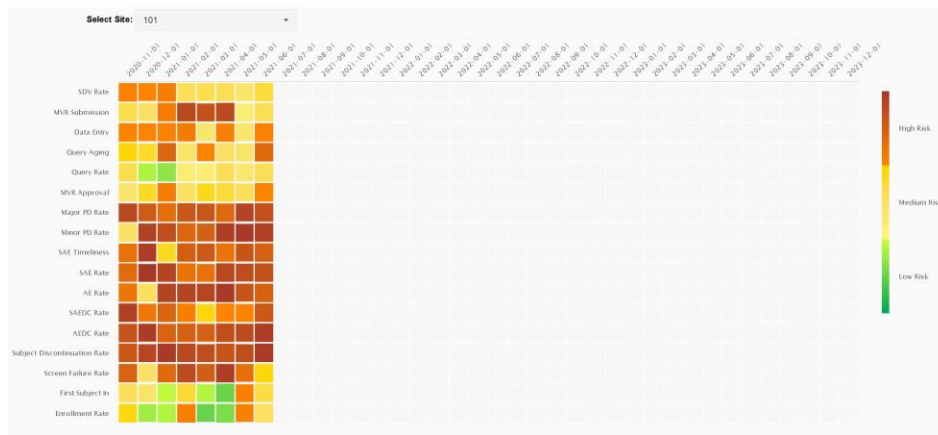
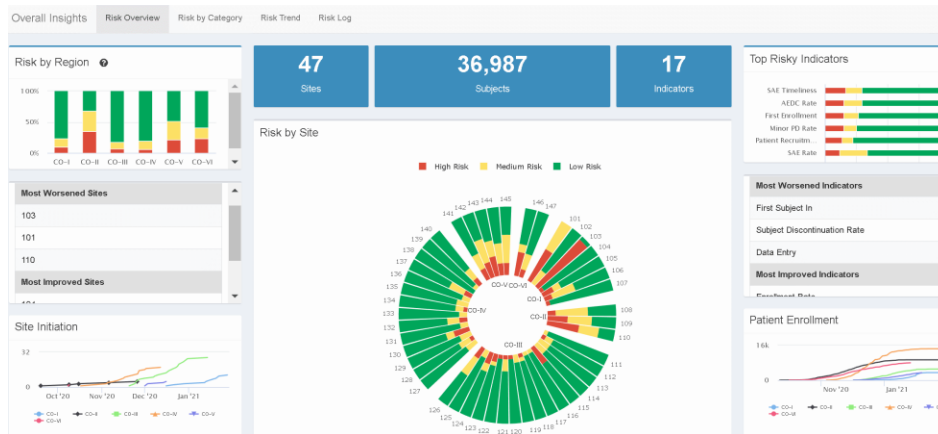
Regulatory and ICH/GCP Requirements

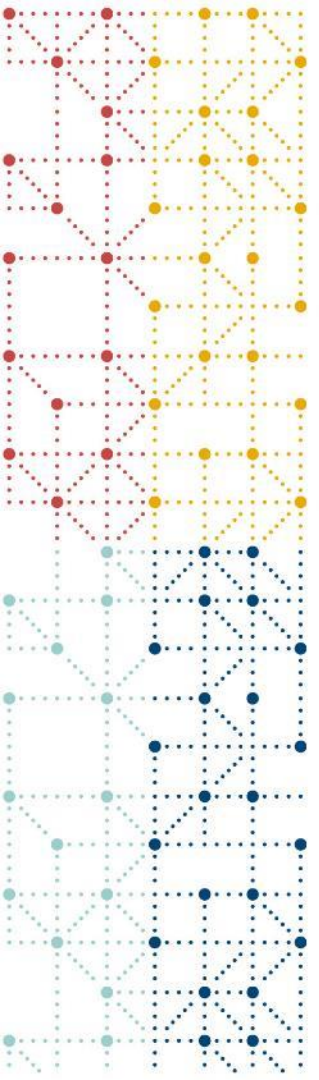
-
- 2013 FDA: <Guidance for industry>
-
- 2013 EMA: <EMA: Reflection paper on RBQM>
-
- 2016 CFDA: GCP
-
- 2019 FDA: <FDA: Guidance for industry Q&A>
-
- 2020 NMPA: GCP
-
- 2021 CDE: <Centralized Monitoring Guidance>
-

RBQM System

Risk visualization

- Overview
- Cross Check
- Risk Trend





CDISC Standard Application

Key Risk Indicator Visualization Challenge

Data Integration using CDASH

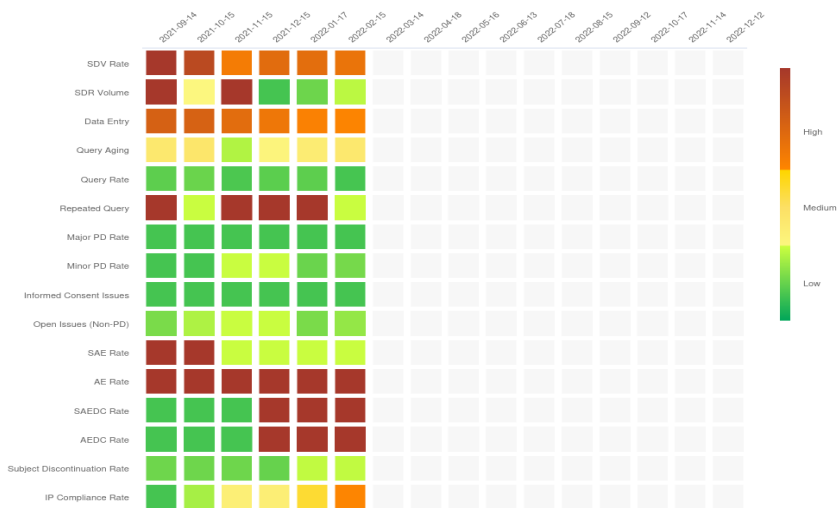
KRI, Key Risk Indicator

Data Sources

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

Data Styles

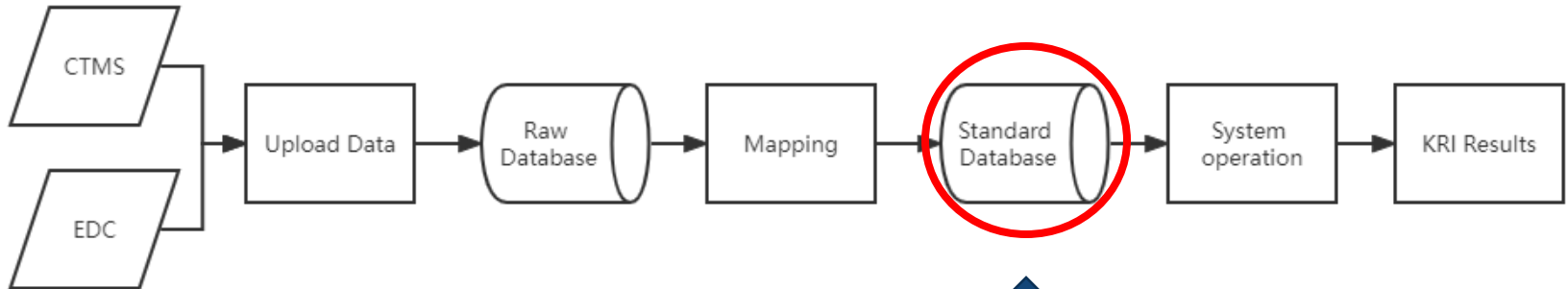
- sas7bdat
- xlsx,xls



Key Risk Indicator Visualization Challenge

Stable Algorithms vs Unstable Data → **Data Integration**

KRI Data Flow



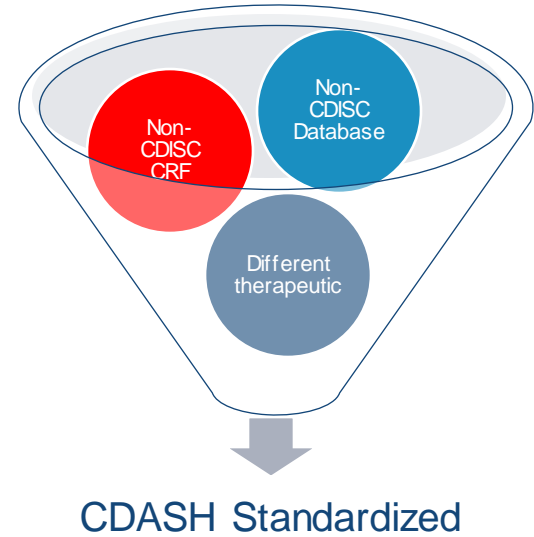
**CDASH
Standard
for EDC Data**

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



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

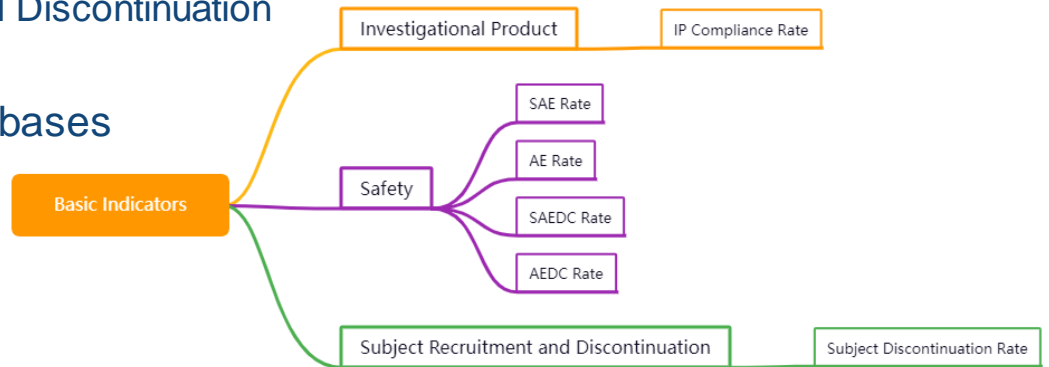
DM

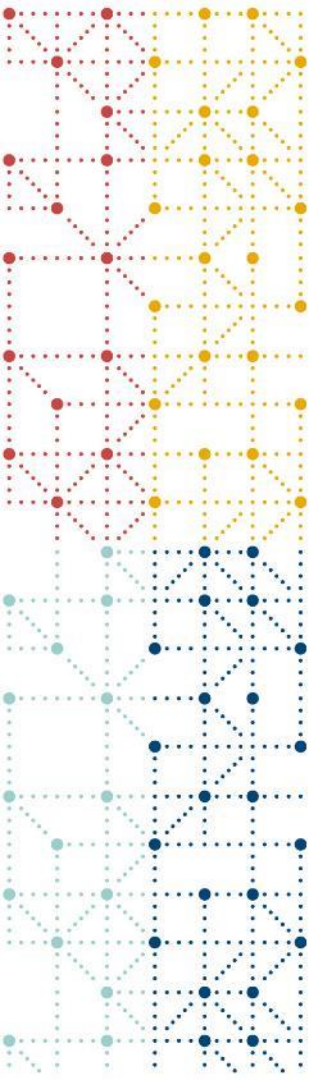
AE

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 adverse events per total	* 单位	# of events/month
* 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 adverse reactions of the IMP, reminds the investigators of the r

确认

取消

Link to Standard Library AE

系统管理

项目配置

项目

项目 标准数据库映射 ×

标准数据库映射 --- 关键风险指标

标准数据库: 风险因子: 映射状态:

标准数据库	原始数据库	风险因子	映射状态	更新时间	操作
AE	AE, SAE	SAE Rate	已完成	2022-06-31 23:12:00	编辑

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

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)

The screenshot displays a web-based interface for data preprocessing. The top navigation bar includes a search icon, a notification bell, and the user name 'Yi Lu'. The main content area is titled '数据预处理' (Data Preprocessing) and shows a configuration page for a project named 'AE (不良事件)'. The page is divided into two main sections: '标准数据库映射 --- AE (不良事件)' (Standard Database Mapping --- AE (Adverse Events)) and '数据预览' (Data Preview). In the mapping section, '原始数据库1' (Original Database 1) is set to 'AE' and '原始数据库2' (Original Database 2) is set to 'SAE'. There are buttons for '条件筛选' (Condition Selection), '合并关系' (Merge Relationship), '新增' (Add), and '保存' (Save). The '数据预览' section has a '预览' (Preview) button and a large empty area for displaying the mapped data.

Mapping Solutions

Variable Mapping

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

The screenshot shows a web-based interface for configuring variable mappings. On the left is a dark sidebar with navigation options: '系统管理' (System Management), '项目配置' (Project Configuration), and '项目' (Project). The main content area is titled '项目 AE变量映射' (Project AE Variable Mapping) and '标准变量映射 --- AE (不良事件)' (Standard Variable Mapping --- AE (Adverse Event)). It features a table with columns for '标准变量' (Standard Variable), '受控术语' (Controlled Term), '原始变量' (Original Variable), '设置' (Settings), and '值' (Value). The table lists various standard variables like STUDYID, SITEID, SUBJID, AEYN, AECAT, AESCAT, AETERM, AEOCCUR, AEPRESP, AESTDAT, AESTTIM, and AEENDAT, each with corresponding dropdown menus for configuration. To the right of the table is a '数据预览' (Data Preview) section with a '预览' (Preview) button.

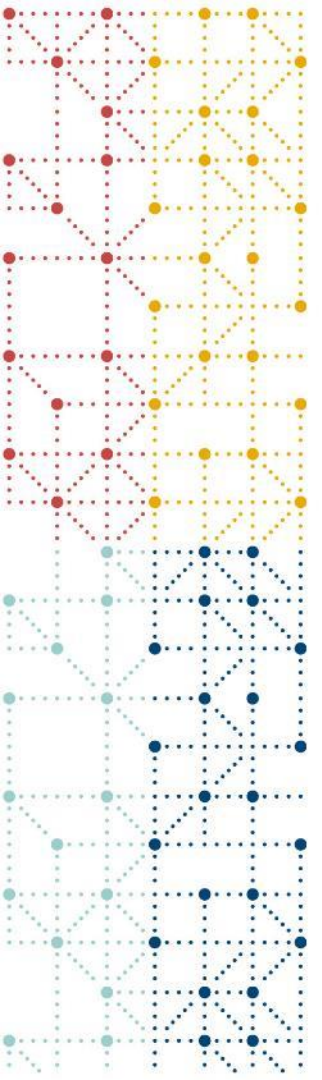
标准变量	受控术语	原始变量	设置	值
STUDYID		<input type="text"/>	赋值	"TEST123"
SITEID		sitenum	<input type="text"/>	
SUBJID		subject	<input type="text"/>	
AEYN	YN	aeyn	条件赋值	aeyn = Yes, 'Y' aeyn = No, 'N'
AECAT		<input type="text"/>	<input type="text"/>	
AESCAT		<input type="text"/>	<input type="text"/>	
AETERM		aeterm	<input type="text"/>	
AEOCCUR		<input type="text"/>	<input type="text"/>	
AEPRESP		<input type="text"/>	<input type="text"/>	
AESTDAT		<input type="text"/>	日期拼接	aestdat_yyyy, aes
AESTTIM		<input type="text"/>	<input type="text"/>	
AEENDAT		<input type="text"/>	日期拼接	aeendat_yyyy, aec

Mapping Library Management

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



Intelligent Recommendation

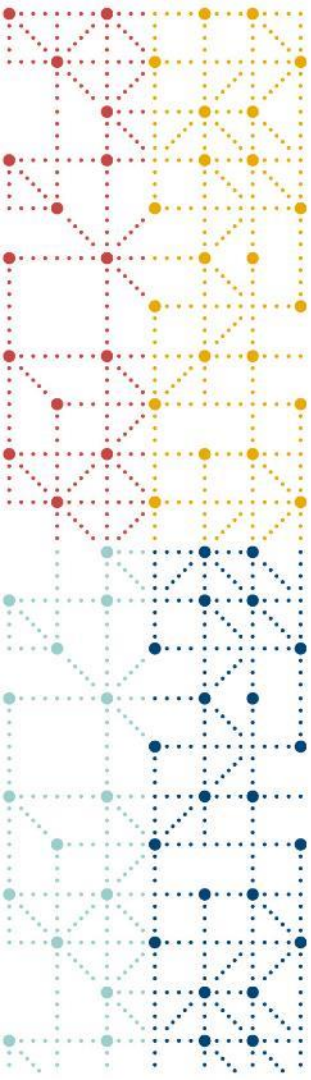


Conclusion



Conclusion

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.



Thank You!

cdisc