Argus to Oracle Clinical SAE Reconciliation

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Agenda

- Background: SAE Reconciliation

- Benefits of Clinical Data Systems and Safety Data System Integration

- SAE Reconciliation with Oracle AERS

- SAE Reconciliation with Argus Safety

- Integration strategies

- Future Suggestions

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Background: SAE Reconciliation

- ## Purpose

  - Difference in time frames for reporting/data entry of SAE data to the Safety and Clinical systems leads to inconsistencies in safety data
  - Difficult to control changes
  - Consistent Safety data required for further statistical analysis and regulatory submission
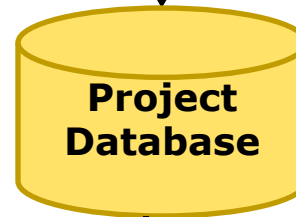 - Potential queries generation

- ## Common fields to be reconciled

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Background: SAE Reconciliation
Current Approach

Investigator Site

Site records SAE

SAE Report

CRF

Sponsor

Safety Database

Project Database

No Further Action Required ← Data Consistent — Reconciliation — Data Inconsistent → Queries raised for discrepant data

A

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Background: SAE Reconciliation Current Approach

Investigator Site

A

Site responds to the query

| No action required Acceptable discrepancy | Safety Database needs to be updated | Both the Databases need to be updated | Project Database needs to be updated |

Sponsor

Safety Database

Project Database

Reconciliation

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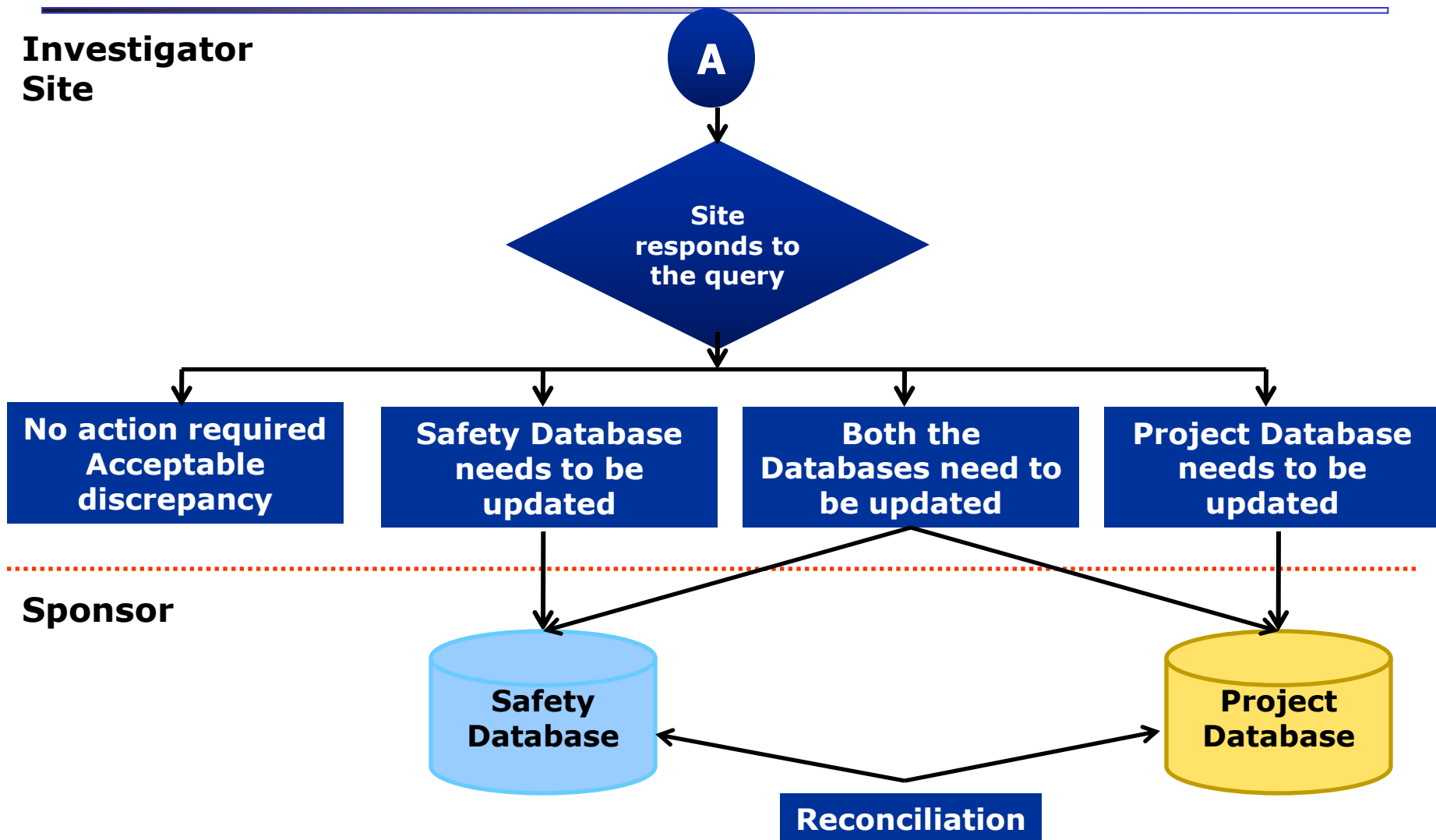
Background: SAE Reconciliation Difficulties with current Approach

- Complex process
- Manual process
- Higher costs than expected
- Time expenditure is more during manual reconciliation and its documentation
- Tracking of discrepancies is difficult
- Duplicate queries may get generated for site

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Benefits of Integration

| Clinical Data Management System | Integration | Safety Data Management System |

- Real time reconciliation

- Comparisons can be done more frequently

- Can help in effectively identifying records with discrepancies

- Tracking the reconciliation records

- Audit trail available for monitoring

SAE Reconciliation – Oracle AERS

Upload Clinical Data File, Format file and Column mapping file to the Clinical Data Files Folder in AERS Folders

Import- Clinical Extract by selecting the file. Also save Format file and column Mapping file

Run First Pass Reconciliation Report in Oracle AERS to get hard copy output

Run Reconciliation report in Oracle AERS to get hard copy output as well as discrepancy entries to the discrepancy module

Clinical Data Extract File: The extract program extracts data from the clinical database.

•**Format file:** The Format file defines the position of the fields for each record type.

• **Column Mapping file:** The Column Mapping file maps fields in the Extract file to columns in the RCN tables

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SAE Reconciliation – Oracle AERS and Oracle Clinical

Key Points:

- In Oracle AERS SAE reconciliation can be controlled through defined user roles

- Case level tracking of reconciliation status is possible

- Tracking of last reconciliation with details of User and date

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SAE Reconciliation – Oracle Argus Safety and Oracle Clinical

- The Argus Safety Reconciliation module enables user to configure and edit/reconcile records as per requirements.

- The interactive reconciliation report helps to visually identify data discrepancies

SAE Reconciliation – Oracle Argus Safety and Oracle Clinical

- **Source Database Verification:**
  - Source DB Definition screen enables user to define the mapping of the Reconciliation databases to the Common Interface of the Oracle Clinical.
  - This can be edited as per requirements at study level.
  - Reconciliation database connection can be established.
  - Reconciliation Match-up Configuration enables match up of reconciliation fields.

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SAE Reconciliation – Oracle Argus Safety and Oracle Clinical

- **Interactive Reconciliation screen:**
  Interactive Reconciliation screen enables user to view and configure an interactive reconciliation report.

SAE Reconciliation – Oracle Argus Safety and Oracle Clinical

Key Points:

- Automatic extraction of data from Clinical database

- Intuitive and user-friendly graphical interface

- Generation of advanced, interactive reconciliation report

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Future Suggestion for Integration

- Integration of the Oracle Argus Safety/AERS with Oracle Clinical to send Safety reconciliation discrepancies (such as missing data, specific variables discrepancies and inconsistent correlations between recorded narratives) to Oracle Clinical-Discrepancy Management Module.

  This will help in faster resolution of Safety discrepancies. Also tracking, managing will be easy and can avoid sending duplicate Safety discrepancies to the site.

- An Alert can be sent to the systems whenever new data related to SAE gets entered into either of the systems

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Bio:

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Questions?

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Thank you!!

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