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Rescue Studies – Ensuring a Smooth Transition

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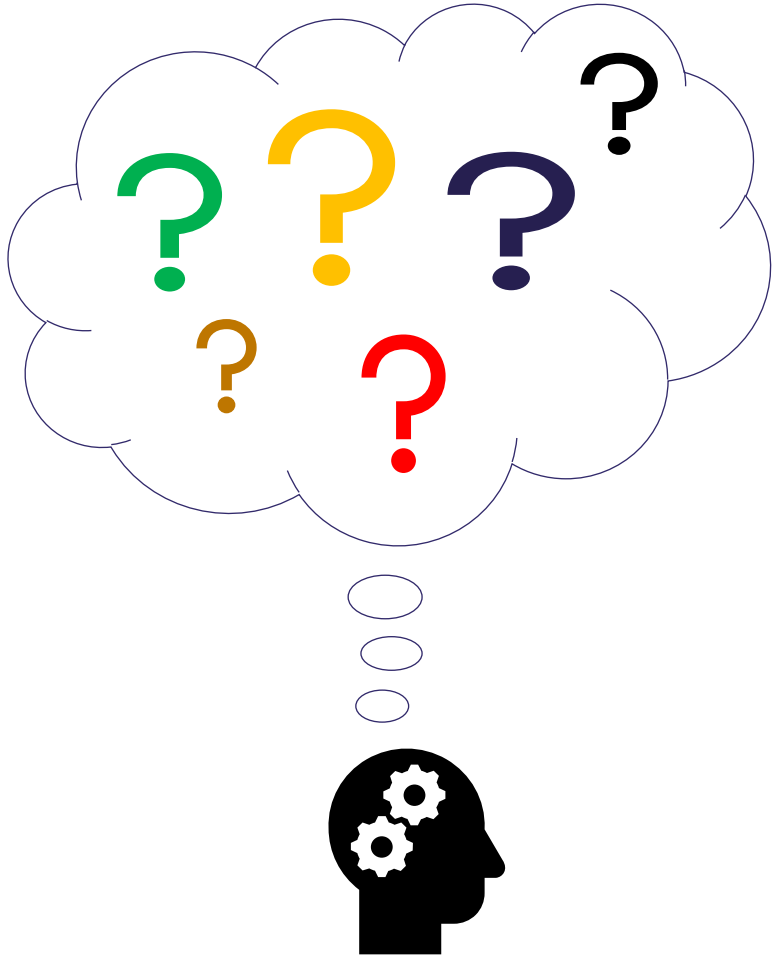
Rescue: What and Why

- What:
  - A study rescue is moving a study from one Medidata URL to another Medidata URL
- Why:
  - Study buyout
  - Sponsor acquired
  - Strained CRO relationship

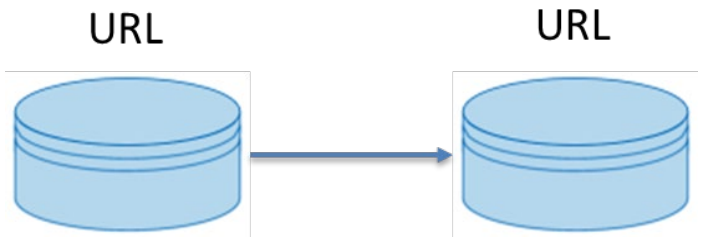
Challenges of a Rescue

- Anxiety
- Amount of data
- Study down time
- Timeframe
- Document procurement

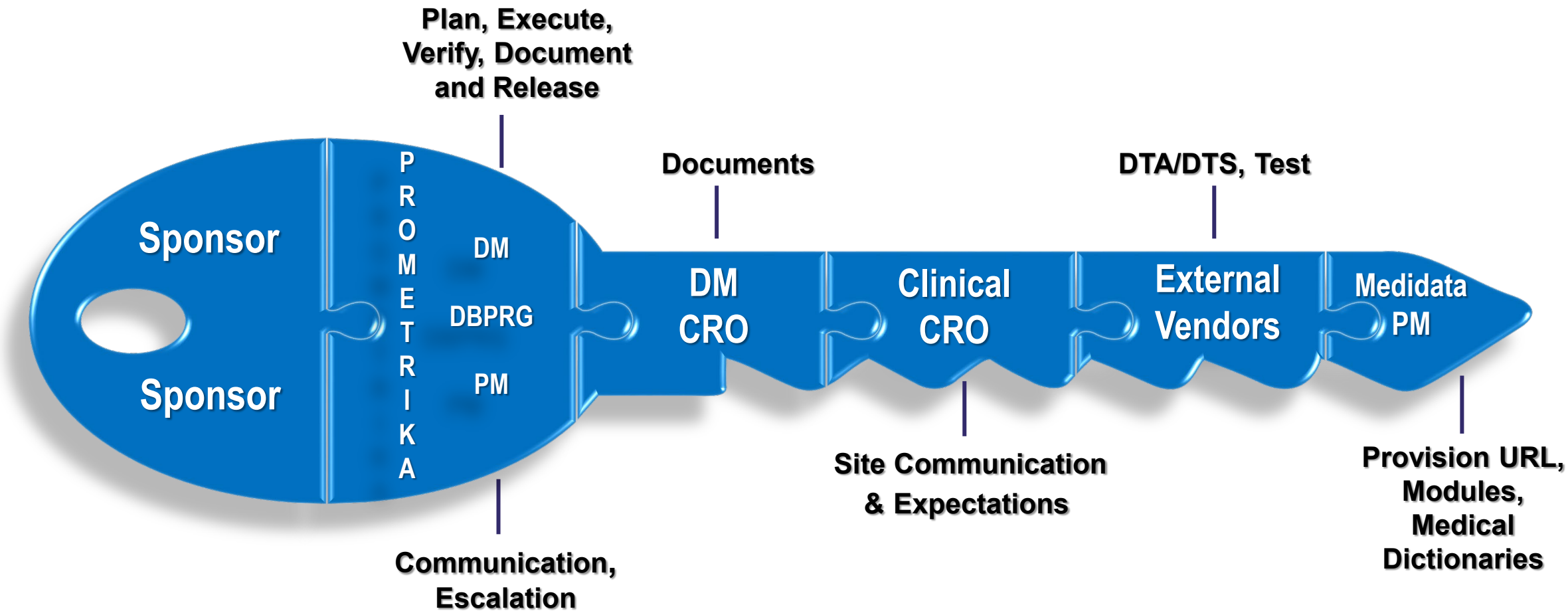


Case Study

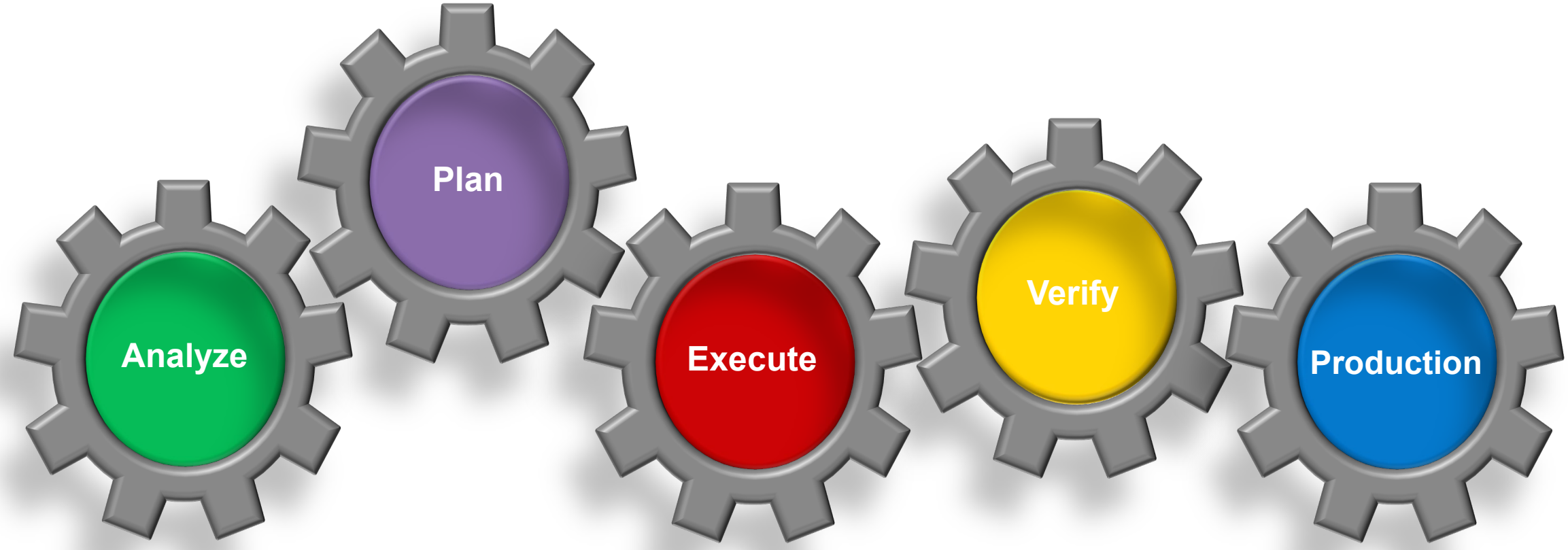
- Production study
  - Rare oncology, Phase I
  - Dose escalation and Expansion study
- Sponsor-owned URL
- Move to new sponsor URL
- 8 weeks from KOM to production live



Collaboration is Key



Study Rescue Process



Technical Analysis

- Critical document review and analysis
  - Protocol
  - Core Configuration
  - Architect Loader Specification (ALS)
- Review will determine
  - Medidata modules
  - External integrations
  - Other build documents

External Data Integration(s)

- Data Transfer Specification
- RWS configuration
- UAT of external integration(s)
- Capabilities of external vendor
  - Subjects
  - Data

Data Analysis

- Number of Subjects
- Number of Forms - total
- Number of Queries
  - Open and Answered
  - Canceled and Closed – only appear in Audit Trail
- Number of Forms
  - SDVed
  - DM Reviewed
  - Signed

Configuration Plan

- Develop Study Configuration Plan
- Develop Study Configuration Checklist

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<study name> Study Configuration Plan
<sponsor> URL to <sponsor> URL
Version 1.0

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Task	Resource	Dependency
Create new URL <sponsor>.mdsol.com	Medidata	
Upload Medical Dictionaries	Medidata	<sponsor> send license agreements to Medidata
Configure URL - Upload Core Configuration - Configure Cloud Admin Roles - Configure Rave Coder - Upload eLearnings	Medidata	
Create <study name> study - Create the <study name> study on the new <sponsor> URL	PROMETRIKA	Need Study Creation form from DM
Configure Synonym Lists - Download/Obtain the <study name> Synonym Lists from old <sponsor> URL - Create the <study name> Synonym Lists on the new <sponsor> URL - Upload old <sponsor> Synonym Lists to new <sponsor> Synonym Lists	PROMETRIKA	Need Synonym List spec from DM
Lab Admin - Download/Obtain the <study name> PROD site export from old <sponsor> URL - Upload <study name> site expor to new <sponsor> DEV/UAT/PROD/MIG/Other - Download.Obtain Lab Loader from old <sponsor> URL - Remove <other study(s)> local lab ranges from the AnalyteRanges/Lab tab - Upload updated Lab Loader to new <sponsor> URL	PROMETRIKA	Need Site Creation forms from DM
Spreadsheet Compare Lab Admin Loader - Download the Lab Admin Loader from the new <sponsor> URL - Run spreadsheet compare on - the <study> Lab Loader from the old <sponsor> URL - the <study> Lab Loader from the new <sponsor> URL	PROMETRIKA	

UAT Plan

- Develop re-configuration UAT Plan
  - Testing approach
  - Requirements
  - Test Plan
  - Risk Assessment
  - Issues Reporting and Tracking
  - Summary Report

Data Plan

- Develop Study Data Plan

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<study name> Data Management Re-entry Plan
<sponsor> Study Reconfiguration on the <sponsor> URL
Version 1.0

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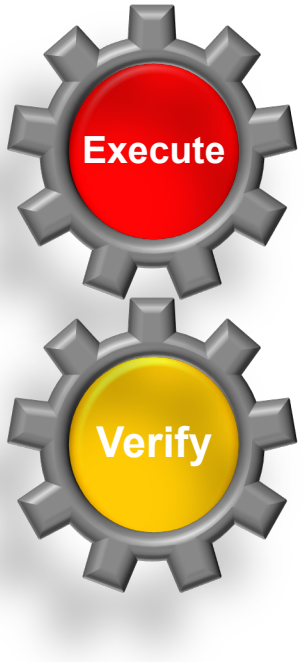
Data Plan

- Clinical Data
  - Data re-entry Guidelines
  - Data Entry team trained on re-entry guidelines
  - Sites/Subjects assigned
  - Re-Entry Tracker and Data Issues Tracker
  - No Change to SDV and DM Review
- Queries
- Query Tracker
    - Open
    - Answered

Execute & Verify Configuration Plan

- Medidata provision
  - URL, eLearning, Reports
  - Medical Dictionaries
- Execute the Study Configuration Checklist
- Verification by independent database programmer
- Write Configuration Summary Report



Execute & Verify Data Plan

- Execute the Study Data Plan
- Clinical Data
- Queries
  - Open
  - Answered
- Run SAS PROC COMPARE by subject

Production Live

- Upload production user export file from previous URL
- Remove users from previous URL

Rescue Result

- New URL and Dictionaries provisioned in 10 days
- Study running on new URL in 4 days
- UAT complete in 5 days
- Data entry complete in 7 days
- Study production live < 6 weeks from KOM

Thank You

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