

Enhancing Quality of External Data

Pascale Youinou

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AGENDA

- Introduction
- Case scenario 1
- Case scenario 2
- Conclusion



#Data #DataDriven
#DataStrategy #DataIntegration
#DataViz #DataStandards
#DataScience #Datagovernance
#HealthCare #DataAnalysis
#ClinicalTrials
#ArtificialIntelligence
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#ClinicalResearchLifeCycle
#MedicalWriting
#MedicalInformation
#MedicalReview #SDTM
#ADaM #CDISC #Innovation
#RegulatorySubmissions
#Protocol #Coding

INTRODUCTION



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Data Management is a crucial process in clinical research. DM is ensuring that **high quality, reliable and accurate data** is available for the statistical analysis.



INTRODUCTION

- Significant amounts of data are collected to support study endpoints.
- The structure of the Clinical Database (CDB) is designed to collect and store all data required by the protocol.
- Variety of sources:
 - ✓ Electronic Data Capture (EDC) systems
 - ✓ Interactive Response Technology (IRT) systems
 - ✓ Electronic Clinical Outcome Assessment (eCOA)
 - ✓ External vendor databases (ECG, Lab, Imaging,...)

INTRODUCTION

- Involvement of Clinical Data Management (CDM) CRO
- Involvement of additional vendors
- Challenges related to data integration



How will data from external sources (beyond the CDB) be collected, stored, transferred and integrated?

STUDY SET-UP



Sponsors face strategic decisions regarding external data integration into CDB through:

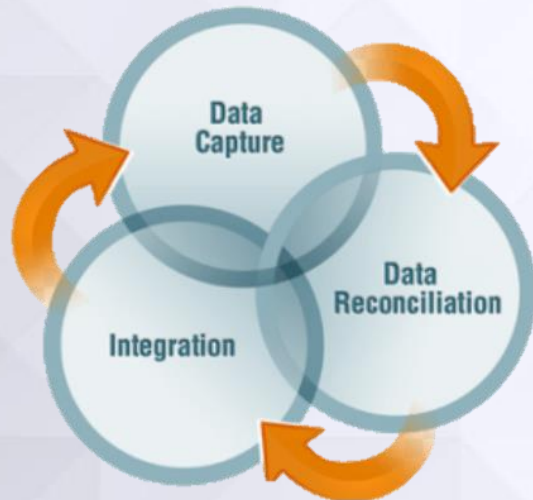
- **Integrated Databases:** Data are synchronized automatically every few minutes through API and are directly accessible into EDC (IWRS, Coding tool, etc.). This approach streamlines data flow and ensures consistency.
- **Regular Uploads:** Through sFTP server into EDC system (ex: eCOA), data are transmitted electronically on a regular basis, and EDC data are refreshed with external data on same windows (ex: daily). This simplifies data management.
- **Late Reconciliation:** Databases are transferred outside the EDC system, reconciled at a later stage and then merged with the clinical database. This approach allows flexibility but requires careful coordination. Ex: Pharmacokinetics (PK) Data.

STUDY SET-UP

Each strategy has its advantages and disadvantages, impacting data quality, efficiency, and overall study success.

In this presentation, we will share our experiences, **as CRO**, with two similar biometrics projects that involved EDC and external vendor databases.

Case 1: INTEGRATION, UPLOAD AND RECONCILIATION



Case 2: RECONCILIATION ONLY



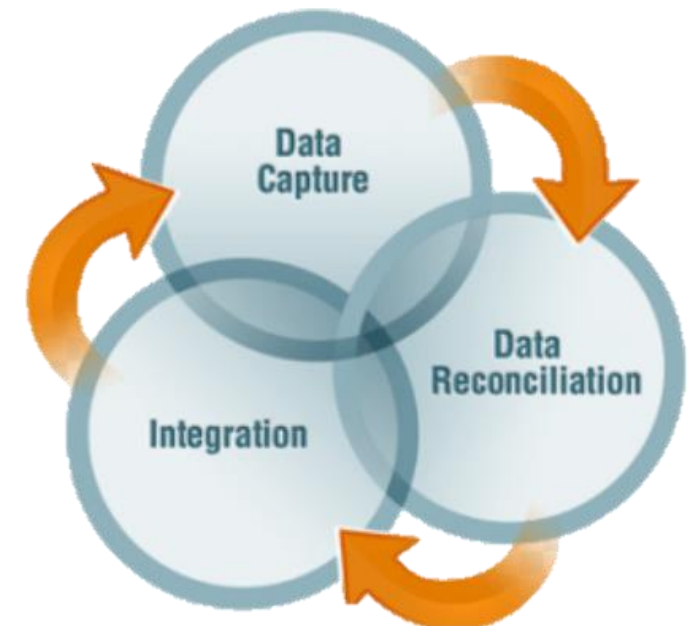
CASE SCENARIO 1



CASE SCENARIO 1

INTEGRATION, UPLOAD AND RECONCILIATION

- Integration: IWRS into the EDC system
- Regular Uploads: eCOA into the EDC system
- Reconciliation of other databases (e.g., ECG, PK)
- Strategic position: Involving all relevant parties during study initiation and later alignment stages



CASE SCENARIO 1



KEY CONSIDERATIONS

- Sponsor Set-up supervision: All parties involved on revision of User Requirement Specifications (URS) and Data Transfer Specifications (DTS)
- Timelines and Vendor Peculiarities:
 - Understanding each vendor's processes & DB specificities for accurate data integration, upload and reconciliation
 - Parallel systems UATs
 - Synchronized UATs: EDC go-live with IRT and eCOA systems integrated
- Defining Unique Key Variables:
 - ✓ Unique identifiers, age/birth dates, visit identifiers
 - ✓ Ensuring consistent format between clinical and vendor databases
 - ✓ Consistent Timepoints: nomenclature between clinical and vendor databases

CASE SCENARIO 1



ADVANTAGES OF EARLY ALIGNMENT

- **Effective Communication:** Clear communication and regular meetings
- **Efficient Data Reconciliation:** A smooth integration during system's go-live phase
- **Consistency on Critical Variables:** Maintaining a consistent format across all databases
- **Timelines:** Aligning vendor processes avoid going back and forth
- **Quality:** Ensuring global data quality throughout the study until final analysis

CASE SCENARIO 1

CHALLENGES – COMMUNICATION & TECHNICAL LIMITATIONS

- **Multiple Vendors:**

- ✓ Managing parallel database setups
- ✓ Regular meetings

- **Settings Configuration:**

- ✓ Integration environment
- ✓ API or sFTP interface set-up
- ✓ Data transmission issues

- **Global Time zones:**

- ✓ Logistical challenges
- ✓ Time zone Etiquette

- **Strict Timelines:**

- ✓ Clear communication
- ✓ Flexibility



YOUR LIFE SCIENCES DATA EXPERTS



CASE SCENARIO 2



CASE SCENARIO 2

NO INTEGRATION, ONLY RECONCILIATIONS

- No integration of vendor data into the EDC system
- External data transfers: ECG, Lab, MRI, IWRS, PK...
- Strategic position: Role of subject matter experts (SMEs):
 - Sponsor SMEs assigned to each provider team
 - Separate set-up of EDC, IRT, and other vendor systems
 - Knowledge expertise
- Reconciliation Process:
 - All systems in production
 - Separate agreements
 - Regular reconciliation of vendor data with EDC data after GO LIVE

CASE SCENARIO 2



ADVANTAGES OF LATE RECONCILIATION

- **Efficient Set-Up:** Rapid deployment of all systems
- **Flexibility:** Adjustments after system's go-live in data collection
- **Expertise:** SME knowledge in specific medical area
- **Study Picture at Cut-off date:** Capturing study data for interim analysis

CASE SCENARIO 2



CHALLENGES

- **Vendor & EDC DB Incompatibilities**

- Vendor database documentation not shared with the CRO responsible for the EDC DB
- Vendor URS not properly reviewed by Sponsor SME (format or field inconsistencies with EDC)

→ Some expected visits were not included in the vendor DB, despite being essential according to EDC requirements

Visit Name (EDC)	Visit Name (ECG)	Visit Name (Lab)
VISIT 1- SCREENING		
VISIT 2 - VISIT 1	VISIT 2	FIRST VISIT
VISIT 3 - SAFETY FOLLOW-UP	VISIT 3	SAFETY FOLLOW-UP
VISIT 4 – VISIT 2		SECOND VISIT
VISIT 5 – SAFETY FOLLOW-UP		SECOND SAFETY FOLLOW-UP
	UNSCHEDULED VISIT	UNSCHEDULED VISIT

CASE SCENARIO 2



CHALLENGES

- **Discrepancies in Data Collection and Protocol Understanding:** Variations in data collection methods and interpretation
- **Variables Mismatch:** Problems with keys variables not matching between DB

→ Specific rules were established for reconciliation

For patients ≥ 17 years and < 18 years: Do not consider month of birth during reconciliation. Check the flagged cases and put status to 'CONFIRMED' once checked and ok, else submit query.
For patients ≥ 2 years and < 17 years: Post query into EDC when difference ≥ 1 month asking site investigator to clarify EDC age and vendor Date of Birth.
For patients < 2 years, exact match (complete Date of Birth) expected.

EDC	VENDOR
Adult patient: Age (in years): _ _ _ _ Pediatric patient: Age: _ _ and _ _ Years and Months For pediatric patient under 2 years old (from birth to 23 months of age): Date of Birth: _ _ _ / _ _ _ / _ _ _ _ Day Month Year	Date of birth For subjects with Age>17, only year of birth is required. Enter 01 for day (DD) and JAN for the month (MMM). (eg:01-JAN-1989) For subjects with Age≥ 2 and ≤ 17, both month (MMM) and year (YYYY) are required and enter 01 for day (DD) (eg:01-AUG-2014) For subjects with Age < 2, full date of birth is required (eg: 17-JUN-2022)

CASE SCENARIO 2



CHALLENGES

- **Lack of communication:** Misalignment between sponsor and vendors
- **Multiple DTS updates:** Frequent revisions and test transfer issues
- **Deviations:** Timing of reconciliation affecting protocol deviations detection
- **Discrepancies management by external vendors:**
 - Challenges with external vendor database updates
 - CDM access to external vendor portals

CONCLUSION



CONCLUSION

CASE 1

-  • **Technical limitations of integration interfaces**

- Variables consistency
- Efficient Data integration
-  • Data Quality

CASE 2

- **Data & structures Inconsistencies**

- Efficient systems Set-Up
- Flexibility
- Expertise

CONCLUSION

- **Impact of Sponsor Approaches:** Influence on data quality and timelines
- **Vendor Selection and Data Management:** Considerations for integration vs. reconciliation
- **Proactive Planning:** Importance of planning, clear communication and attention to details
- **Enhancing Data Quality:**
 - Additional efforts required for late reconciliation
 - Impact on analysis
- **Stakeholder Processes:** Understanding and aligning different processes

**COMMUNICATION
IS   KEY**



THANK YOU FOR YOUR ATTENTION
Q&A

CONTACT



Kimberly Devis

Lead Data Manager

Kimberly.devis@businessdecision.be



Pascale Youinou

Project Manager

Pascale.youinou@businessdecision.be