Paper PD04

From Fragmentation to Fusion: A Journey through Mergers and Acquisitions Data Integration Challenges

Xiao Huang, Pfizer, Cambridge, MA, USA
Ajay Aiyer, Pfizer, New York, NY, USA
Wenjian Xu, Pfizer, Collegeville, PA, USA

ABSTRACT

In today's dynamic pharmaceutical landscape, mergers and acquisitions (M&A) have become integral strategies for companies aiming to enhance their market presence, expand their pipelines, and drive innovation (McKinsey & Company, 2023). However, the seamless integration of data from acquired entities remains a significant challenge. This paper examines the multifaceted challenges that a statistical programming (SP) team may encounter during data integration following pharmaceutical acquisitions. Key topics explored include understanding acquired data, maintaining data quality, and harmonizing variations in company data management practices while ensuring compliance with both corporate and regulatory standards.

INTRODUCTION

The timing of mergers and acquisitions in the pharmaceutical industry varies depending on the strategic goals and circumstances of the companies involved. M&A can occur during the pre-clinical stage, clinical development, between regulatory approval and market launch, or post-market entry (McKinsey & Company, 2023). Recent trends indicate that pharmaceutical companies are increasingly focusing on mid- and late-stage acquisitions to enhance their portfolios (Cooley, 2024).

Late-stage clinical development aims to generate extensive trial data on the safety and efficacy of the IP before regulatory submission. Therefore, when an acquisition occurs before NDA submission, integrating acquired data to support the submission and address regulatory information requests presents a significant challenge for the statistical programming (SP) team. This paper discusses key challenges arising from late-stage M&A, including data migration, internalization, preparation for analysis and reporting (A&R), and special considerations for ongoing and completed studies.

DATA MIGRATION

Data migration is a crucial initial step in the data integration process, ensuring the accurate, complete, reliable, and compliant transfer of data essential for future analysis.

ASSESSING, PLANNING, AND MAPPING

Acquiring and acquired companies often use different systems for data and metadata storage, leading to variations in formats, structures, and schemas. Figure 2 provides an example of how the acquired and acquiring companies may differ in their data storage structures. A comprehensive planning and mapping strategy is critical to ensure successful and secure data migration. Key considerations include defining clear objectives and scope, assessing source data, selecting appropriate migration tools, and developing a data backup and rollback plan.

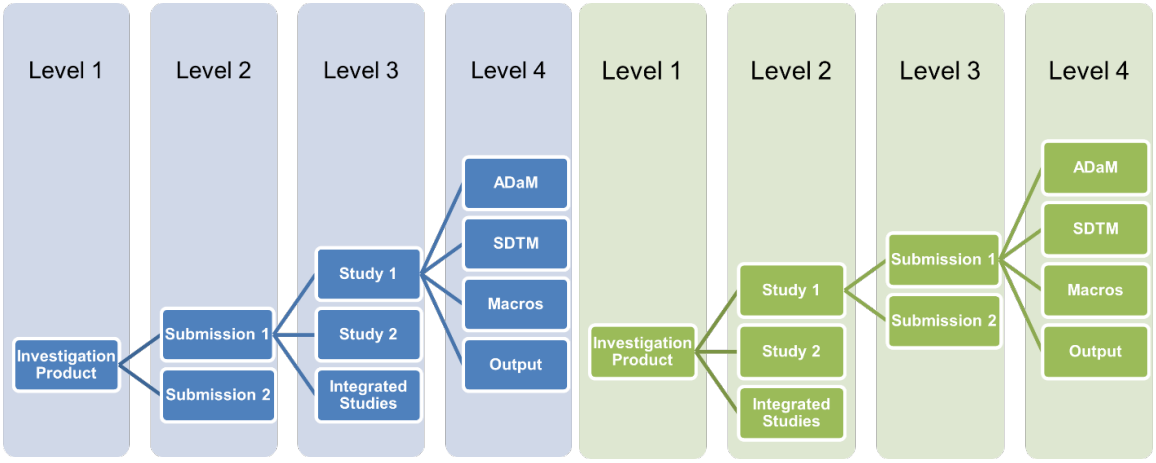

Figure 2. Acquiring company directory (left) vs. acquired company directory (right).

EXECUTION, VALIDATION, AND DOCUMENTATION

When M&A occurs during late-stage clinical development, both completed and ongoing studies may exist. Closed studies adhere to the acquired company's standard operating procedures (SOPs), while ongoing studies follow the acquiring company's SOPs. This necessitates stakeholder collaboration at various stages and requires extensive documentation to maintain transparency and consistency. To ensure successful data migration, the SP team can implement multi-level validation, including testing migration, full migration, validation, documentation, and go-live support.

EFFECTIVE COMMUNICATION AND COLLABORATION

Given the involvement of multiple functions across both companies, effective communication and collaboration are essential. Clear alignment on objectives, scope, responsibilities, timelines, and potential impacts facilitates smoother integration. Given the complexity and tight timelines associated with data migration, allocating additional resources and contingency planning for unforeseen challenges is advisable.

DATA INTERNALIZATION AND GETTING READY FOR A&R

One primary objective of M&A data integration is to use acquired data to support reporting events effectively. The SP team must investigate how data was previously utilized for submissions and determine how to harmonize it within the acquiring company's framework.

STARTING WITH PIVOTAL STUDIES

The initial phase involves reviewing pivotal study materials, including Clinical Study Reports (CSR), study protocols, statistical analysis plans (SAP), annotated case report forms (aCRF), lists of tables (LoT), mock shells, and specifications. This comprehensive review provides the SP team with a solid foundation for handling future complexities.

Challenges in this phase may also include retrieval of pertinent information and documents and adapting to variations in document formats and data structures between companies. Therefore, it is important to maintain a comprehensive log of identified issues, sources, key contacts, and resolutions. Focusing on pivotal studies ensures effective issue tracking and knowledge retention.

ADDRESSING THE INTEGRATED SUMMARY OF EFFICACY AND SAFETY (ISE/ISS)

Following the initial data review, the focus shifts to analyses that required derivation of new variables and varied analysis pools, including ISE and ISS. New variables typically include analysis pool flags, on-treatment flags, risk periods indicators, new treatment-emergent adverse event flags, and re-windowed visits based on integrated analysis and planning (iA&P).

Additional challenge associated with ISE/ISS may include the up-version of MedDRA or WHODrug dictionary terms and codes in corresponding datasets. A new data cut date may also be proposed in accordance with new analysis requests, which require data cleaning and remapping. Acquiring and acquired companies may have different approaches to address these circumstances, therefore decisions on how to harmonize the process for the new reporting events may require discussions from different stakeholders.

MAINTAINING THE QUALITY OF PROGRAMMING DELIVERABLES

SP team is responsible for meticulously reviewing and cross-checking past statistical analysis plans, dataset specifications, and related documents to maintain consistency across submissions. It is important for the team to understand the logic of prior statistical models and data structures and to be able to reproduce reports from past analyses before embarking on new ones. This strategic action improves efficiency and ensures data integrity.

FACILITATING KNOWLEDGE TRANSFER

Effective knowledge transfer is essential for a seamless transition and sustained efficiency. Engaging in structured discussions and documentation helps ensure clarity, particularly for deliverables involving complicated algorithms or variables. Prioritizing communication and documentation minimize confusion and rework, fostering a smoother integration process.

SPECIAL CONSIDERATIONS: ONGOING STUDIES VS COMPLETED STUDIES

Upon acquisition, both completed and ongoing studies must undergo data migration, investigation, and internalization process, as discussed in previous sections. Depending on the stage of study’s lifecycle, SP team may adopt different approaches.

For completed studies, SP team typically rely on pivotal CSR tables, listing and figures (TLFs) and reference codes to understand the data upon successful data integration. These stable sources provide a reliable foundation for analysis.

Conversely, ongoing studies present unique challenges due to multiple dataset versions corresponding to different reporting events and cutoff dates. This variability complicates direct comparisons among reporting events, as not all Study Data Tabulation Model (SDTM) or ADaM datasets are consistently present across versions. Additionally, each company’s SOPs may have slight variations in data collection, database review (DBR), and CSR preparation. To address these challenges, a hybrid approach—where certain elements continue under the acquired company’s SOPs while others transition to the acquiring company’s standards—is often necessary.

CONCLUSION

In the complex landscape of pharmaceutical M&A, data integration is a critical process requiring strategic planning, effective communication, and robust knowledge transfer. Challenges arise from differences in SOPs, data structures, and regulatory compliance requirements, particularly when integrating ongoing and completed studies. Successfully managing these challenges is essential to maintaining data integrity, ensuring regulatory compliance, and facilitating scientific advancements. This paper underscores the importance of a coordinated and strategic approach to data integration, reinforcing its role as both a technical and strategic necessity for pharmaceutical companies leveraging M&A for growth and innovation.

REFERENCES

Cooley. (2024). 2024 Life Sciences M&A Year in Review: M&A Slims Down in 2024 but Will Appetites Grow in 2025? Retrieved from https://cooleyma.com/2025/01/22/cooleys-2024-life-sciences-ma-year-in-review-ma-slims-down-in-2024-but-will-appetites-grow-in-2025.

McKinsey & Company. (2023). Life sciences M&A shows new signs of life. Retrieved from https://www.mckinsey.com/capabilities/m-and-a/our-insights/life-sciences-m-and-a-shows-new-signs-of-life.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Author Name: Xiao Huang, Ajay Aiyer, Wenjian Xu
Company: Pfizer
Email: xiao.huang@pfizer.com, ajay.aiyer@pfizer.com, wenjian.xu@pfizer.com