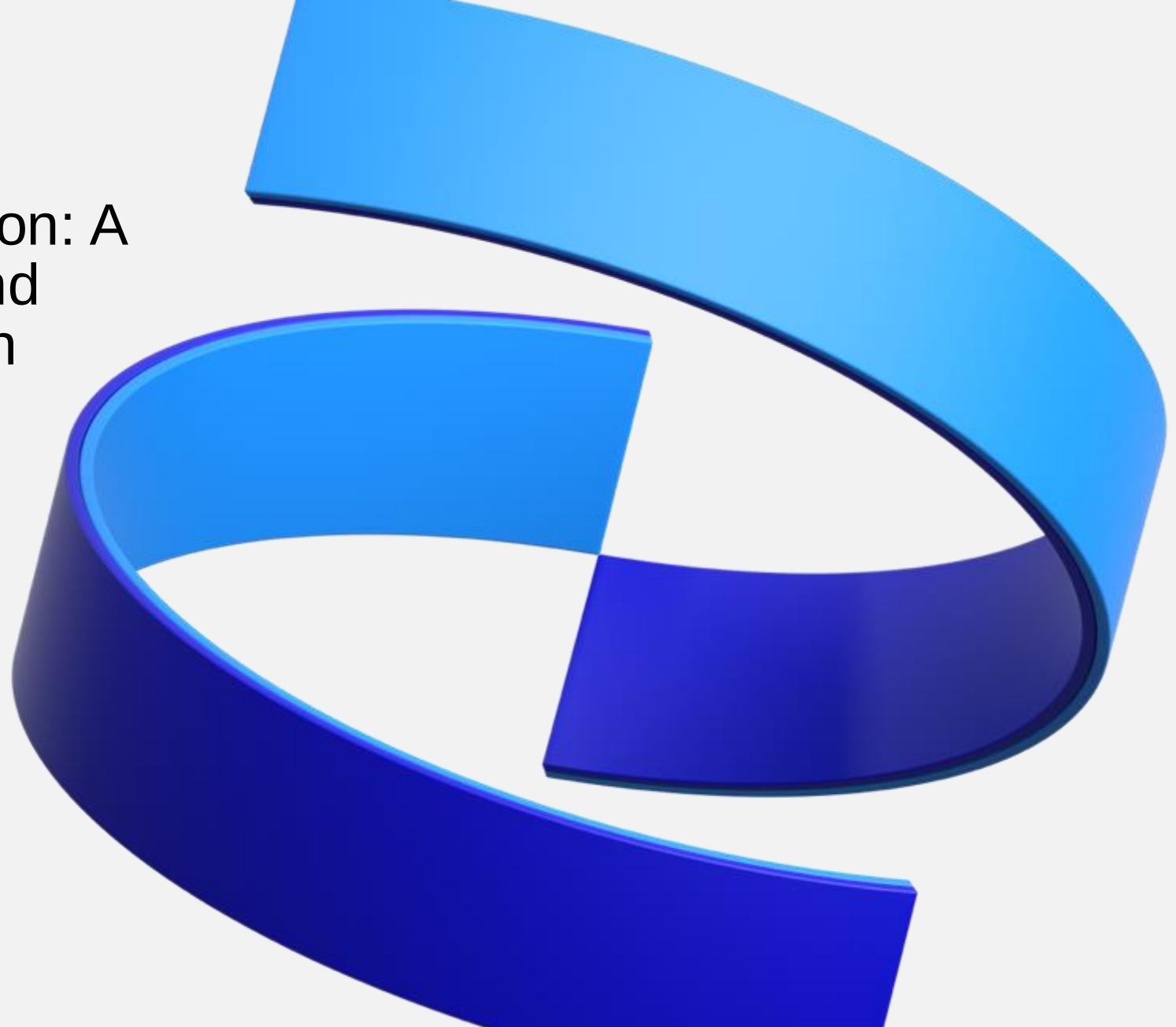




From Fragmentation to Fusion: A Journey through Mergers and Acquisitions Data Integration Challenges

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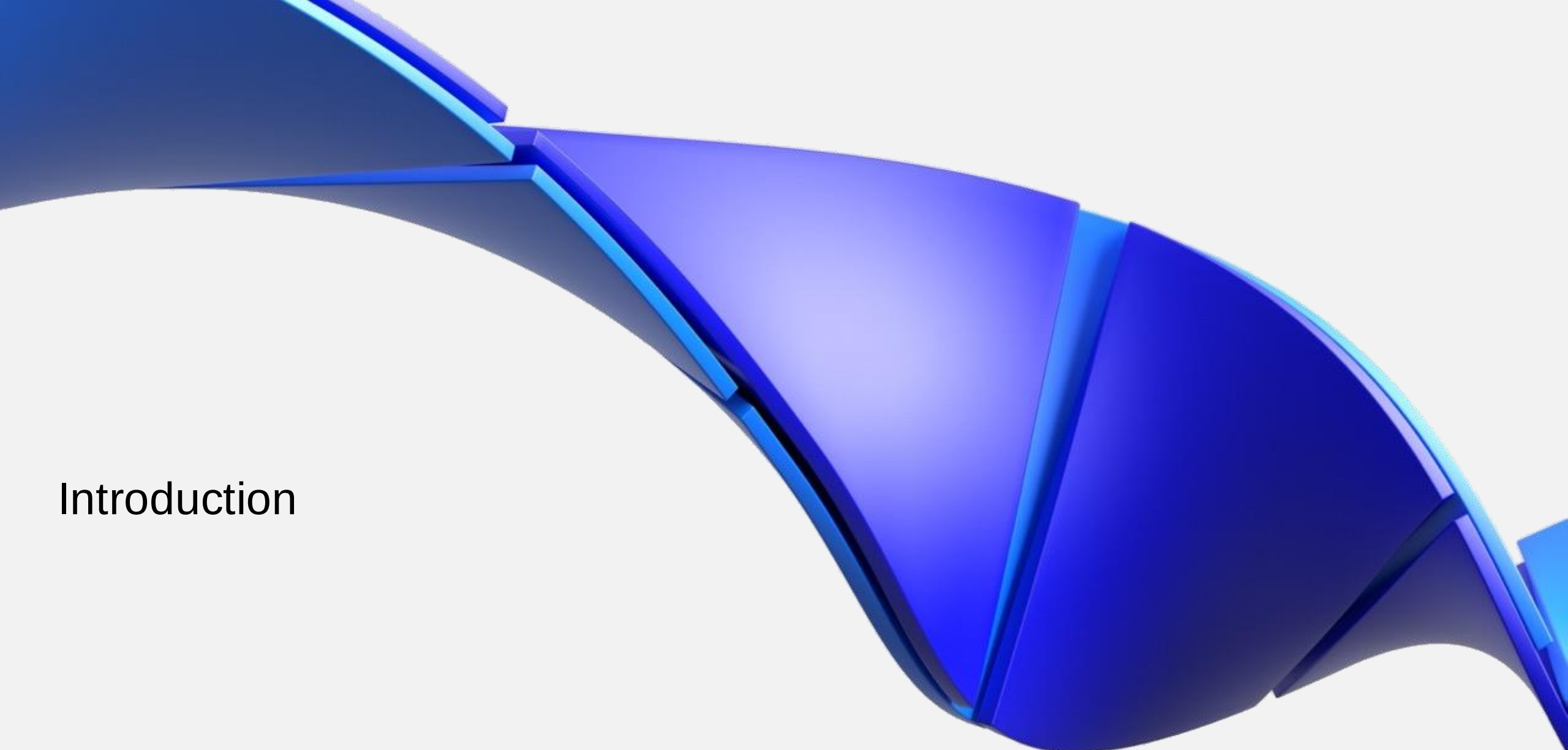
Mar 17, 2025
PHUSE US Connect 2025





Agenda

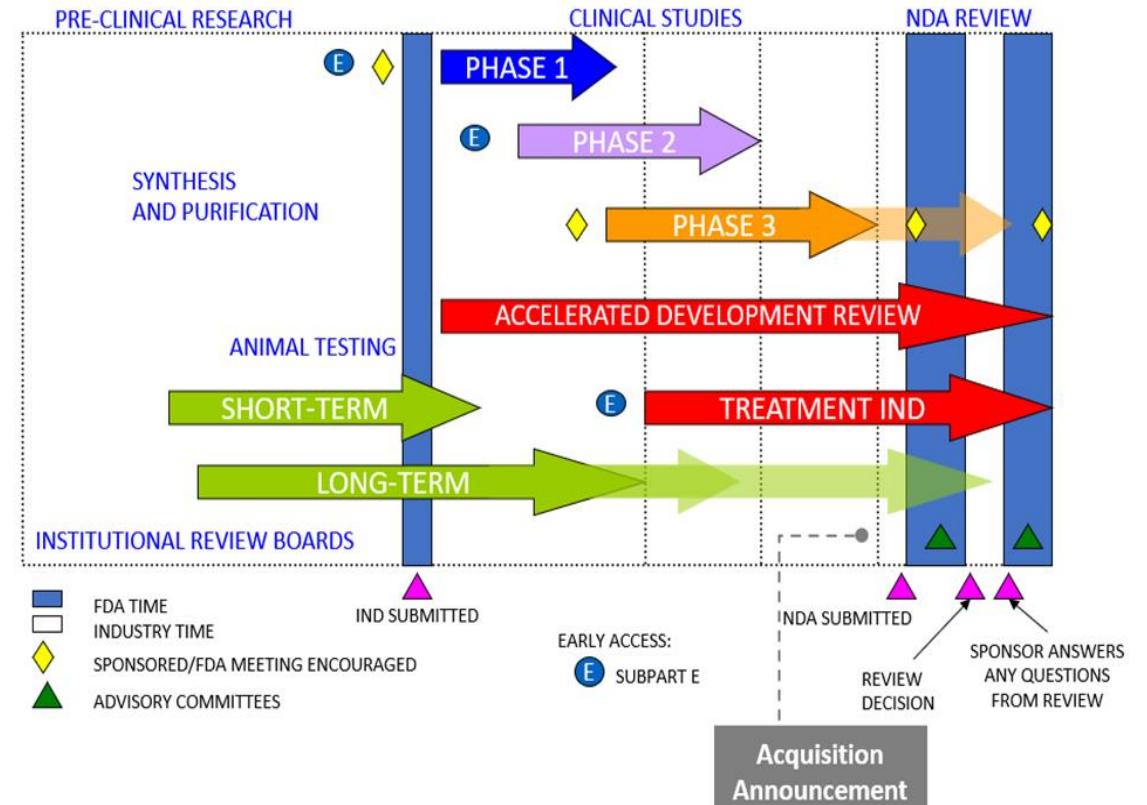
1. Introduction
2. Challenges
 - Data migration
 - Data internalization for analysis & reporting
 - Special considerations: ongoing studies vs. completed studies
3. Conclusion
4. Q&A

A large, abstract graphic composed of several overlapping, curved, and faceted planes in various shades of blue and purple. The shapes create a sense of depth and movement, resembling a stylized wave or a series of connected segments. The lighting is soft, highlighting the edges and surfaces of the planes.

Introduction

Introduction

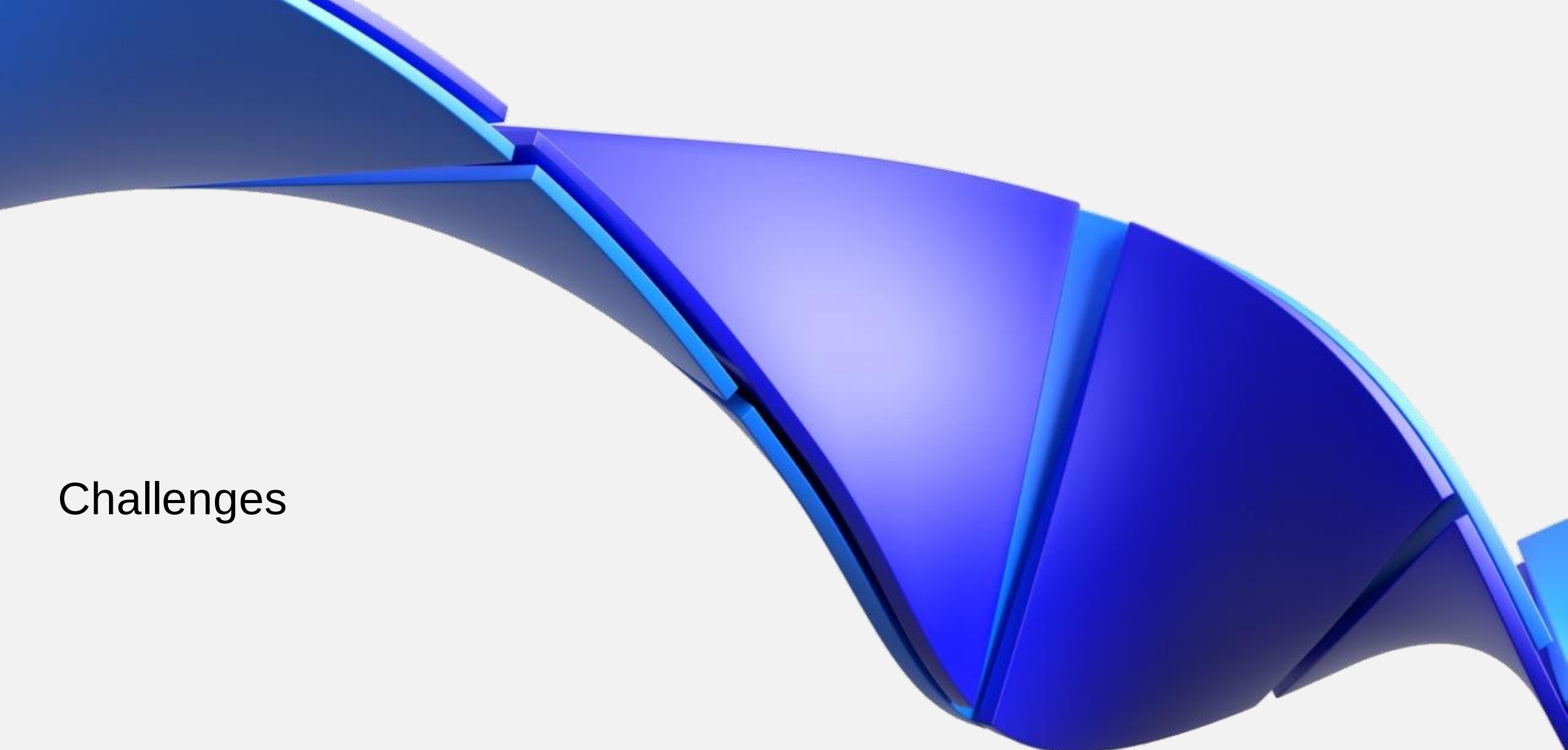
- Mergers and acquisitions (M&A) are key strategies in the pharmaceutical industry.¹
 - They can occur during pre-clinical stage, during clinical stages, between regulatory approval and market launch, or even after a drug has been launched.^{1 2}
- Recent trends indicate that pharmaceutical companies are increasingly focusing on mid- and late-stage acquisitions to enhance their portfolios.³
- Data integration is crucial for seamless operations and regulatory compliance, presenting unique challenges, especially during late-stages.



¹ Figure: U.S Food and Drug Administration (FDA). (2023). The New Drug Development Process: Steps from Test Tube to New Drug Application Review. Retrieved from <https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/new-drug-development-and-review-process>.

² 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>.

³ 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://cooley.com/2025/01/22/cooleys-2024-life-sciences-ma-year-in-review-ma-slims-down-in-2024-but-will-appetites-grow-in-2025>.

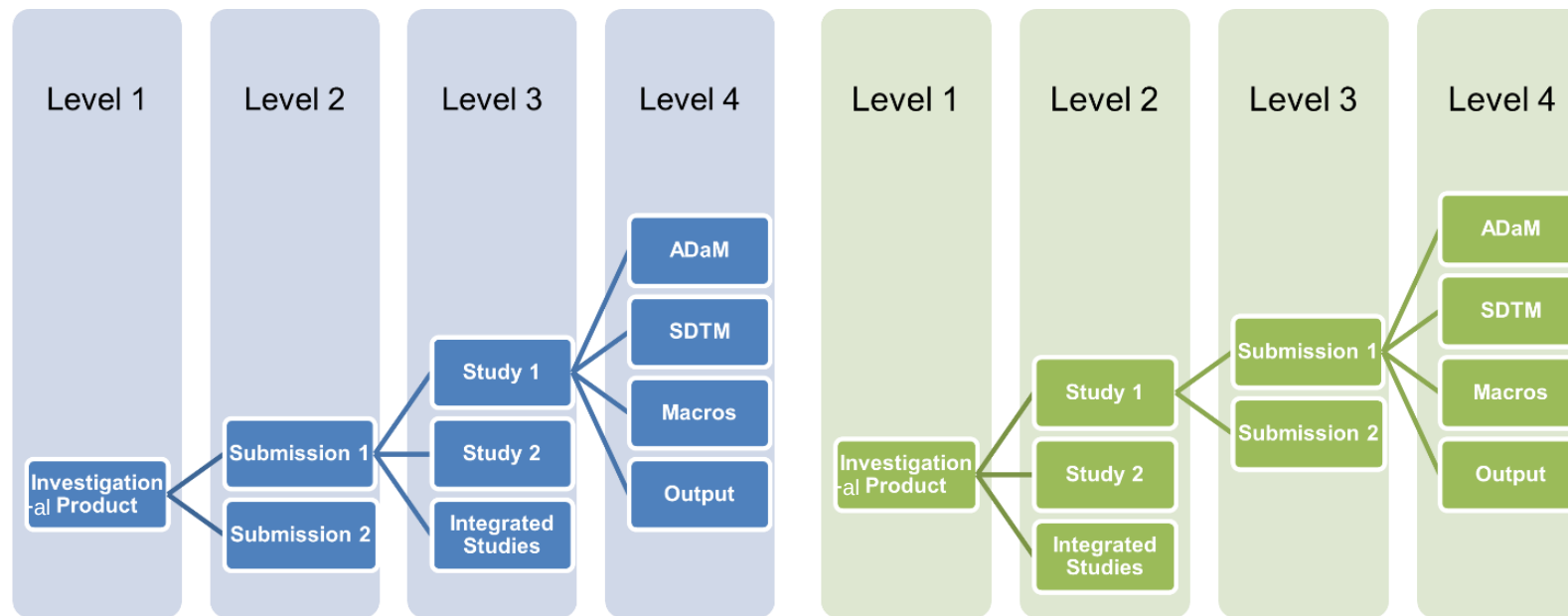
An abstract, three-dimensional graphic composed of several overlapping, curved blue planes. The planes are arranged in a way that creates a sense of depth and movement, with some planes appearing to rise and others to fall. The color of the planes transitions from a lighter blue on the left to a darker blue on the right. The overall shape is reminiscent of a stylized wave or a series of connected arches.

Challenges

Challenges

Data Migration

- Assessing, planning, and mapping
 - Assess and plan to accommodate stakeholders' differences in system formats, structures, and schemas.¹
 - Key considerations: objectives and scope definition, source data assessment, migration tools selection, data backup and rollback plan.



¹ Acquiring company directory (left) vs. acquired company directory (right).



Challenges

Data Migration (continued)

- Execution, validation, and documentation
 - Perform step-wise and multi-level validation and thorough documentation.
 - Ensure transparency and consistency.
- Effective communication and collaboration
 - Encourage proactive communication and collaboration
 - Align stakeholders on objectives, scope, responsibilities, timeline, and potential impact.

Challenges

Data Internalization for Analysis & Reporting

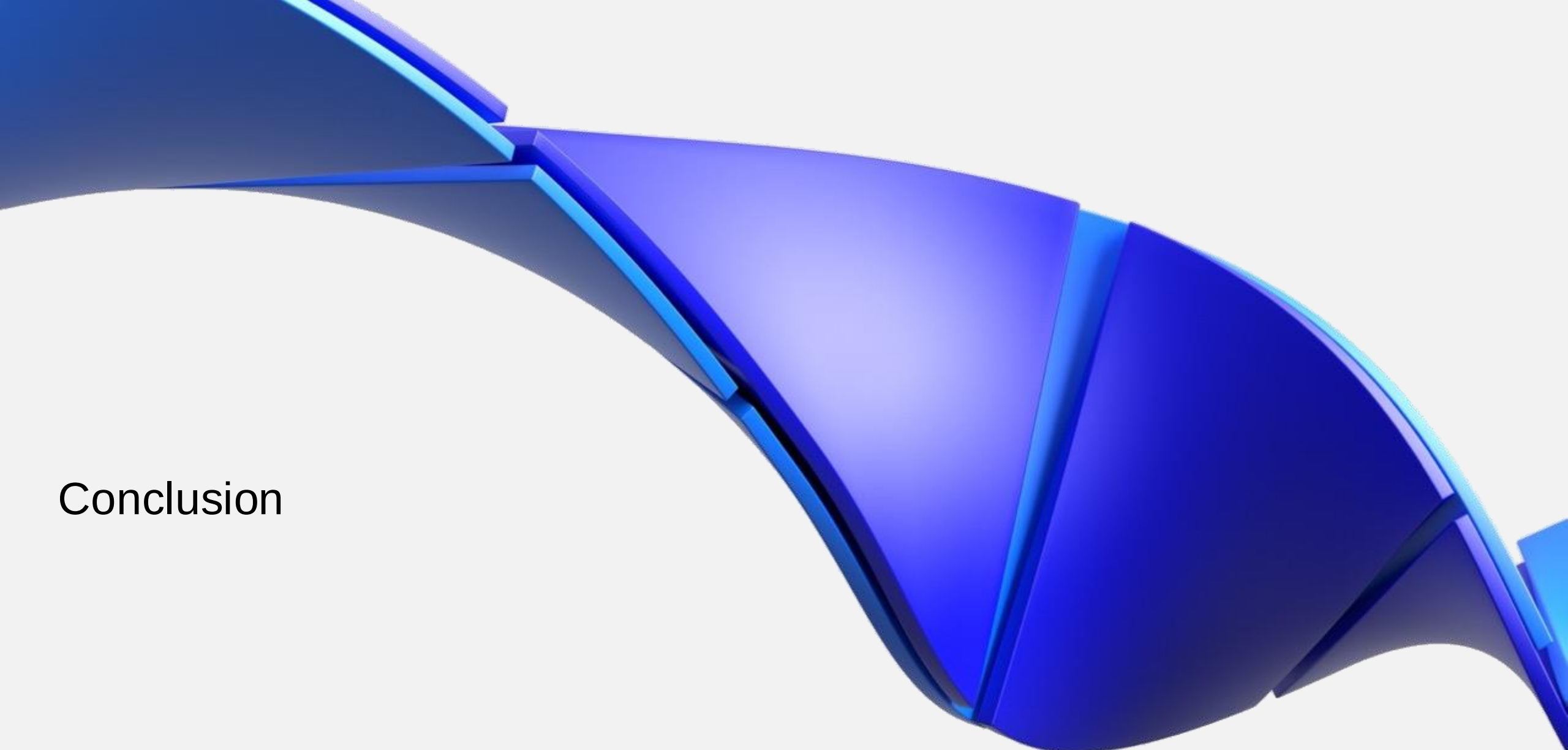
- Start from pivotal studies to understand study design and statistical considerations
 - Retrieve documents and information from different stakeholders' resources.
 - Maintain an issue log to record detailed issues, sources, key contacts, and resolutions.
- Address the integrated summary of efficacy and safety (ISE/ISS)
 - Understand new variables, analysis pools, visit windowing, etc.
 - Up-version of MedDRA/WHODrug dictionary terms and codes.
- Maintain the quality of programming deliverables
 - Ensure consistency across submissions.
- Facilitate knowledge transfer
 - Prioritize open and effective communication.
 - Document key resolutions and insights.



Challenges

Special Considerations: Ongoing Studies vs Completed Studies

- Completed studies
 - Use stable sources, such as CSR tables and reference codes.
- Ongoing studies
 - Address variabilities in dataset versions, SOPs, mock shells, and other study documents.
 - Adopt hybrid approaches for smooth transitions.

An abstract, three-dimensional graphic composed of several overlapping, curved, blue and purple planes. The planes are arranged in a way that creates a sense of depth and movement, with some planes appearing to be in front of others. The colors transition from a deep blue to a lighter purple. The overall shape is organic and flowing, resembling a stylized wave or a series of connected segments.

Conclusion



Conclusion

Data integration in M&A is a strategic imperative that supports pharmaceutical growth and innovation. The process involves:

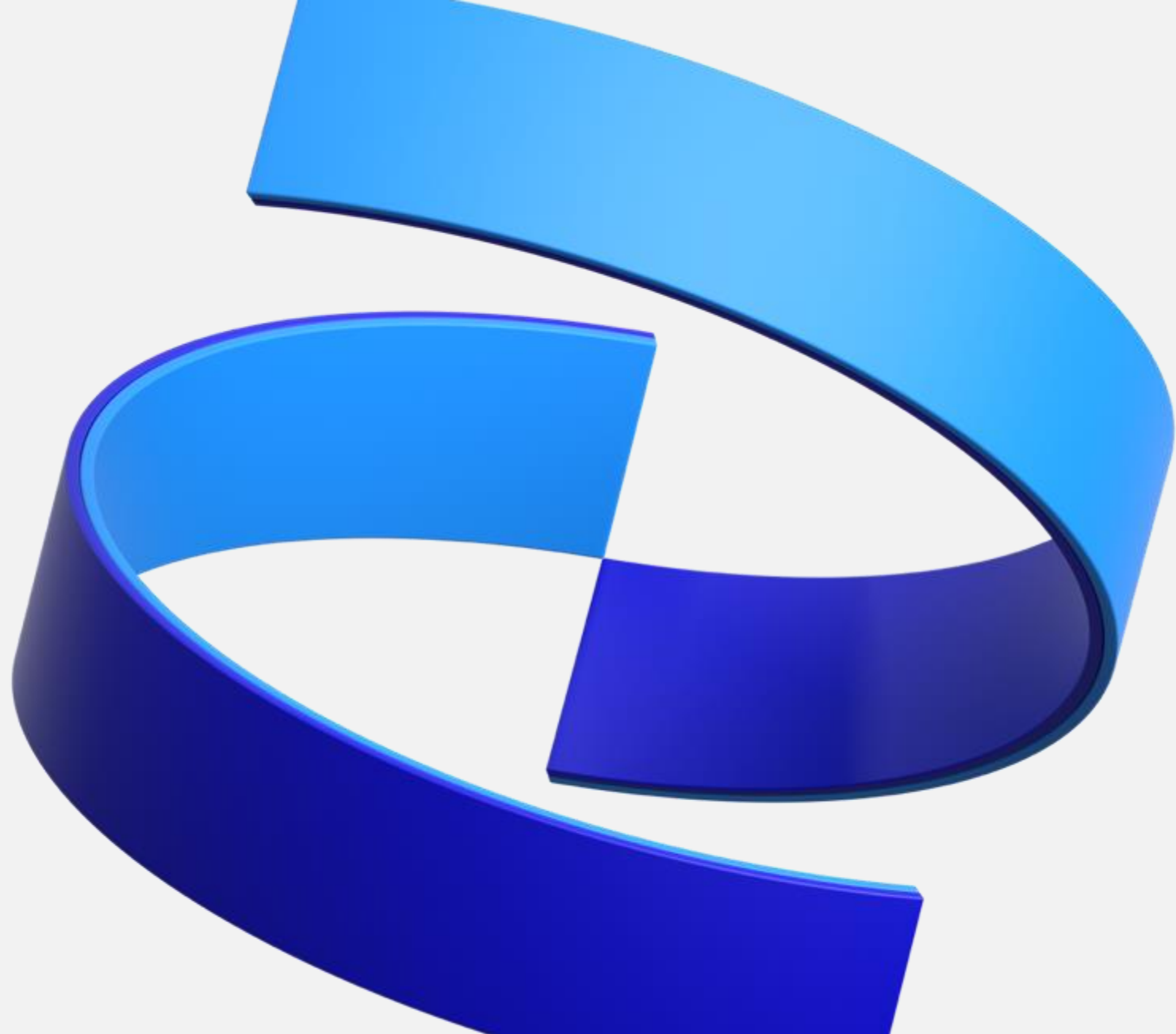
The process involves:

- Effective data migration strategies, including mapping, validation, and collaboration.
- Seamless data internalization and readiness for analysis and reporting.
- Maintaining the quality and consistency of programming deliverables through meticulous reviews.
- Ensuring knowledge transfer to preserve insights and enhance efficiency.
- Tailored approaches for both completed and ongoing studies to align with new SOPs.

A coordinated, strategic approach ensures data integrity, regulatory compliance, and sets the stage for future advancements.



Questions?





Thank You

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Breakthroughs that change patients' lives