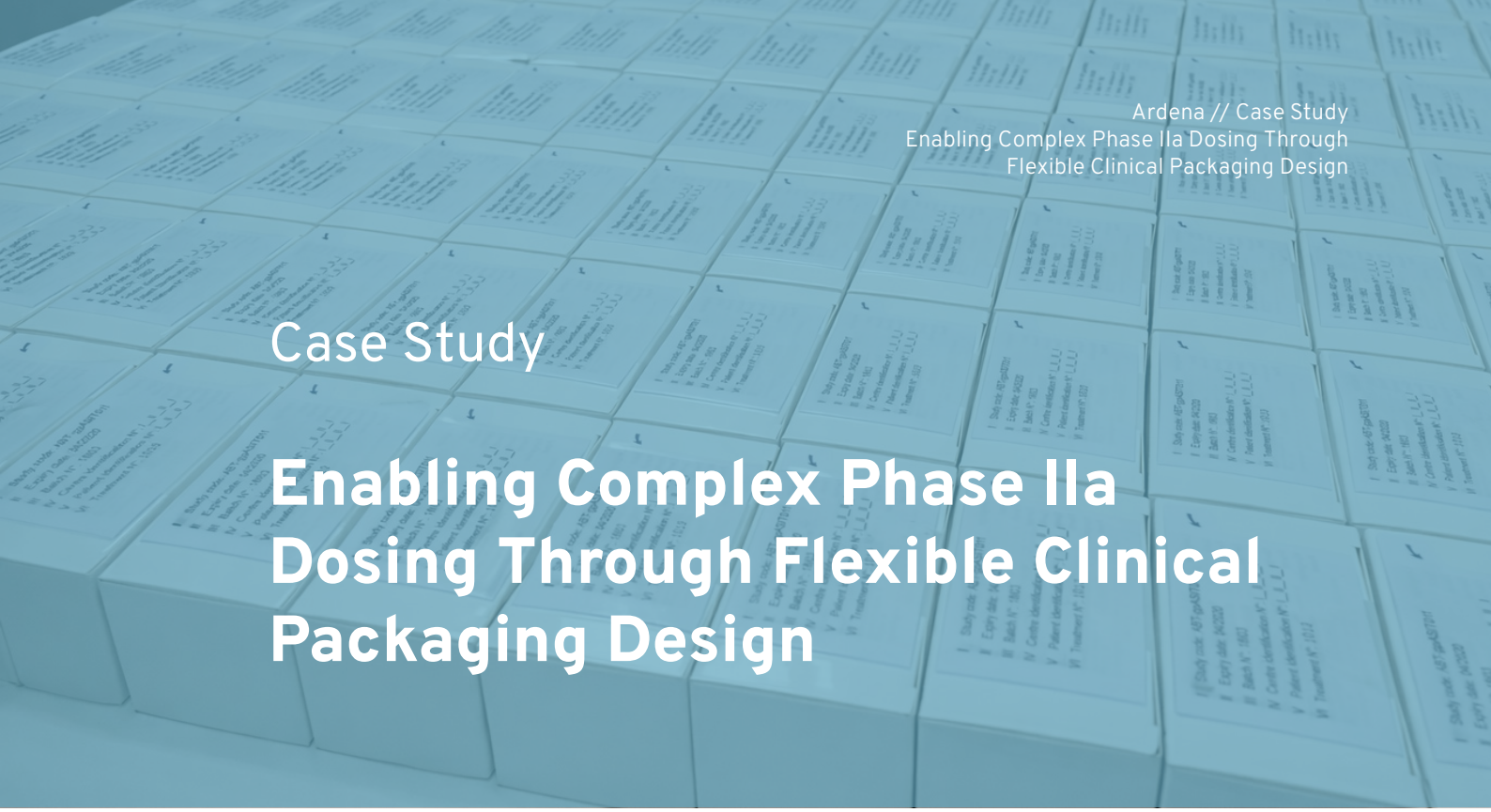


Case Study

Enabling Complex Phase IIa Dosing Through Flexible Clinical Packaging Design

Introduction

A Korean biotech developing a small molecule candidate for Phase IIa required a compliant and patient-centric clinical packaging solution. As the study design evolved, increasing complexity in dosing and treatment arms introduced additional requirements for packaging configuration, traceability, and patient usability.

Situation

Ardena was engaged early to design and implement a patient-friendly medication system while maintaining rigorous clinical and regulatory standards. The project began with stability assessment and a preliminary blister design containing five capsules.

At this stage, the clinical trial design had not yet been finalized, with only two treatment arms under consideration: placebo and a 200 mg dose. Once the clinical protocol was established, the study expanded into a randomized, double-blind, four-arm trial including placebo, 200 mg, 400 mg, and 600 mg dose levels.

This introduced a more complex dosing regimen in which each administration required patients to take one capsule from multiple blisters. The existing primary packaging, designed for a simpler study setup, was no longer aligned with these updated requirements, creating a clear mismatch between available materials and the finalized clinical protocol.

Challenge

The primary challenge was to support a multi-arm, multi-dose clinical study using an existing blister configuration without introducing delays or additional development work. Operationally, the dosing scheme introduced key constraints:

- Each patient required three blisters per dose
- For each administration, one capsule from each blister had to be taken
- Each dose level had to be clearly differentiated while maintaining blinding

Redesigning the blister and performing an additional stability study would have been costly and time-consuming, with a significant impact on the Phase IIa timeline.

Solution

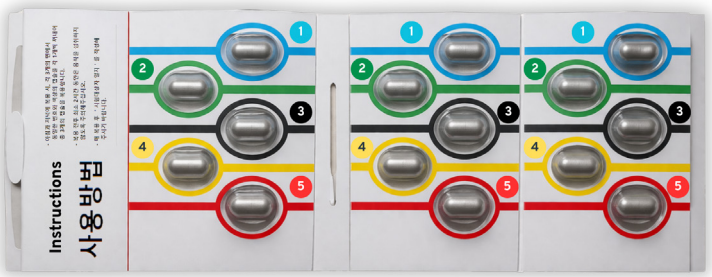
Ardena designed a GMP-compliant secondary packaging concept to integrate the existing blister configuration into the revised clinical design. The solution was based on a modular wallet system capable of holding three blisters per dosing unit. This enabled the required dosing scheme to be implemented without modification of the primary packaging.

Key elements of the solution included:

- Color and numeric coding for clear visual identification of capsules at each dosing event
- An external product label with a randomization code linking to the assigned treatment
- Integrated patient instructions to guide correct dosing and support adherence

As the full treatment required four wallets per patient, Ardena designed a compact outer carton to hold all units. This ensured:

- Patients could conveniently manage and transport the complete treatment
- Randomization codes remained consistent across both the outer carton and individual wallets
- The final system remained compact, intuitive, and user-friendly.



To support reliable execution, Ardena also defined and implemented robust assembly and quality control procedures. These ensured correct configuration of multi-component medication units, accurate labeling and placement of each dose in line with randomization requirements, and consistent quality across all finished products prior to release.

Results

The secondary packaging strategy enabled efficient execution of a complex Phase IIa study without introducing additional development or regulatory burden.

- No modification of primary packaging, avoiding additional stability studies
- Maintenance of the clinical timeline despite increased protocol complexity
- Reliable implementation of a multi-arm, multi-dose regimen
- Clear and intuitive dosing system supporting patient compliance
- Full traceability and control across all packaging components

Operationally, the defined assembly and quality control processes ensured consistent product quality and minimized the risk of labeling or configuration errors.

Conclusion

By designing a flexible and GMP-compliant secondary packaging strategy, Ardena enabled a seamless transition from a simple study design to a more complex Phase IIa protocol. The approach preserved existing development work while ensuring compliance, traceability, and patient usability. This case demonstrates Ardena's ability to support clients from early development stages, anticipate evolving clinical requirements, and deliver practical, cost-effective solutions without compromising quality or timelines.