CASE STUDY
An Innovative Solution to Flexibly Meet Unique Primary Packaging Requirements

Executive Summary
A customer enlisted Catalent to support their child-resistant blister packaging requirements for a global Phase III study. Initially tasked with the packaging design for a smaller study, Catalent created a flexible design with an integrated blister card that could also support larger study requirements of 1.9 million monthly dosing cards. Through customized commercial blistering equipment Catalent provided a solution that would accommodate the customer’s growing demands for clinical supplies.

Using 3D rapid prototyping, Catalent worked directly with the customer to quickly vet multiple physical designs as clinical requirements shifted while accommodating varying dosing regimens and sizes of investigative and comparator products in uniform packaging. Through ongoing collaboration with the customer, Catalent created an integrated blister card design which virtually eliminated the need for conventional wallets. This novel approach saved the customer an estimated $1 million in material, labor and ancillary storage costs.

The Challenge
The customer required a design that would meet the study requirements for two separate protocols. With a global study spanning 20 countries and using comparator products from unique, in-country manufacturers, the blister package had to accommodate both DBAA and DBAA-elongated capsules. During development of the primary packaging solution, the customer’s requirements for dosing changed and the design evolved from 64 small tablets to 70. This seeming small change of adding just 6 additional tablets significantly increased the complexity of project due to equipment limitations. In addition, Catalent needed to create a flexible design that could be used for both child resistant (CR) and non-CR packaging configurations.

The Catalent Solution
Anticipating the possibility of further changes, the Catalent team worked to design an innovative and flexible solution in the form of a card that could easily adjust to shifting requirements while maintaining the customer’s tight schedule. Catalent
mocked-up several designs with cavities that would work for different-sized products and allowed appropriate space for the multi-lingual product label.

As part of an ongoing effort to involve the customer and incorporate crucial feedback during development, Catalent provided a three dimensional (3D) virtual model which allowed the customer to manipulate it on their computer screen allowing a full visual of the proposed design. From 12 design iterations, six were produced using a 3D printer to deliver physical samples of the designs and gather feedback within just a few days. This user-centric process of rapid prototyping allowed the customer’s clinical team and quality person (QP) to incorporate their comments into the solution proposed for use throughout the study.

To meet the requirements of a uniform product that could be both child-resistant and non-CR, the Catalent team added a rivet to the corner of the package to give the customer the option of incorporating an Ecoslide-Rx® sleeve which carries a F=1 Child Resistance rating, the highest possible. Manufacturing was then performed using a customized Uhlmann UPS1030ET commercial blistering platform to produce the clinical packages. With its commercial format components, the Uhlmann offered a unique solution for high-throughput clinical supplies that would accommodate the index of the monthly card.

Given the non-standard approach and very tight tolerances involved, Catalent’s packaging design team also consulted with technical experts from Uhlmann to ensure that the equipment modifications would produce the desired results. The Catalent team was excited to be able to offer the customer a packaging solution that would meet their current and future needs in one flexible design that many considered to be impossible.

FIGURE 1 The final package designed in collaboration with the customer to flexibly meet the needs for both child-resistant (CR) and non-CR requirements.

The flexible design of the packaging includes an option with and without a rivet for use of the child-resistant Ecoslide-Rx® feature, along with an area for the label and pre-printed material for patient compliance.
Conclusion

As part of Catalent’s proactive efforts to incorporate user feedback and involve the customer in important design decisions, the innovative packaging solution satisfied a wide range of requirements and met the needs of both patients and the clinical sites. Catalent delivered the initial product on time and with a $1 million cost reduction and gave the customer the crucial ability to scale to support larger volumes, ultimately producing nearly 2 million blister packs for the global Phase III study.