



## CASE STUDY

# Expediting Path to Clinic With OptiForm® Total Supply

## Integrating Early-Phase Development Clinical Supply Manufacturing & Distribution

### OPTIFORM® TOTAL SUPPLY

Integrated Development,  
Manufacturing & Clinical  
Supply Solution

**OptiForm® Total Supply** helps clinical sponsors simplify development, accelerate their timeline and reduce risk through the integration of:

- Development formulation
- Clinical manufacturing
- Demand forecasting and clinical supply management
- Clinical packaging, labeling, storage and distribution (Phase 1-3)

### Executive Summary

MGB Biopharma (MGB), a biotech company based in Scotland, U.K., is developing a new class of anti-infective medicine based on Minor Groove Binder compounds. MGB-BP-3, a novel small molecule is currently in Phase 2a in the U.S. and Canada. The drug is being developed for the treatment of Clostridium difficile-associated diarrhea. The Catalent sites located in San Diego, CA and Kansas City, MO offered a tablet formulation as a solution to MGB's needs, in the form of OptiForm® Total Supply, allowing the integration of formulation development, clinical trial material (CTM) manufacturing, and supply and distribution to patients. Within five months, the first clinical trial kits were successfully delivered to MGB's patients.

### The Challenges

MGB requested an expedited formulation and optimization development program from Catalent to allow the first patient to be dosed in their Phase 2a clinical study in a timely manner. Furthermore, as a start-up company, MGB has limited resources and experience to handle a complex supply chain with multiple vendors. Tight timelines dictated the need for development steps, manufacturing, and CTM supply to be executed in parallel.

### The Catalent Solution

The Catalent San Diego site was used for early-phase development while the Kansas City site was used for clinical supply services. To meet the aggressive timeline, the Catalent team offered an integrated development, manufacturing and clinical supply service. In addition, the team offered support in import and export logistics management. Catalent's expedited timeline allowed delivery of MGB-BP-3 clinical kits to MGB Biopharma.



DEVELOPMENT



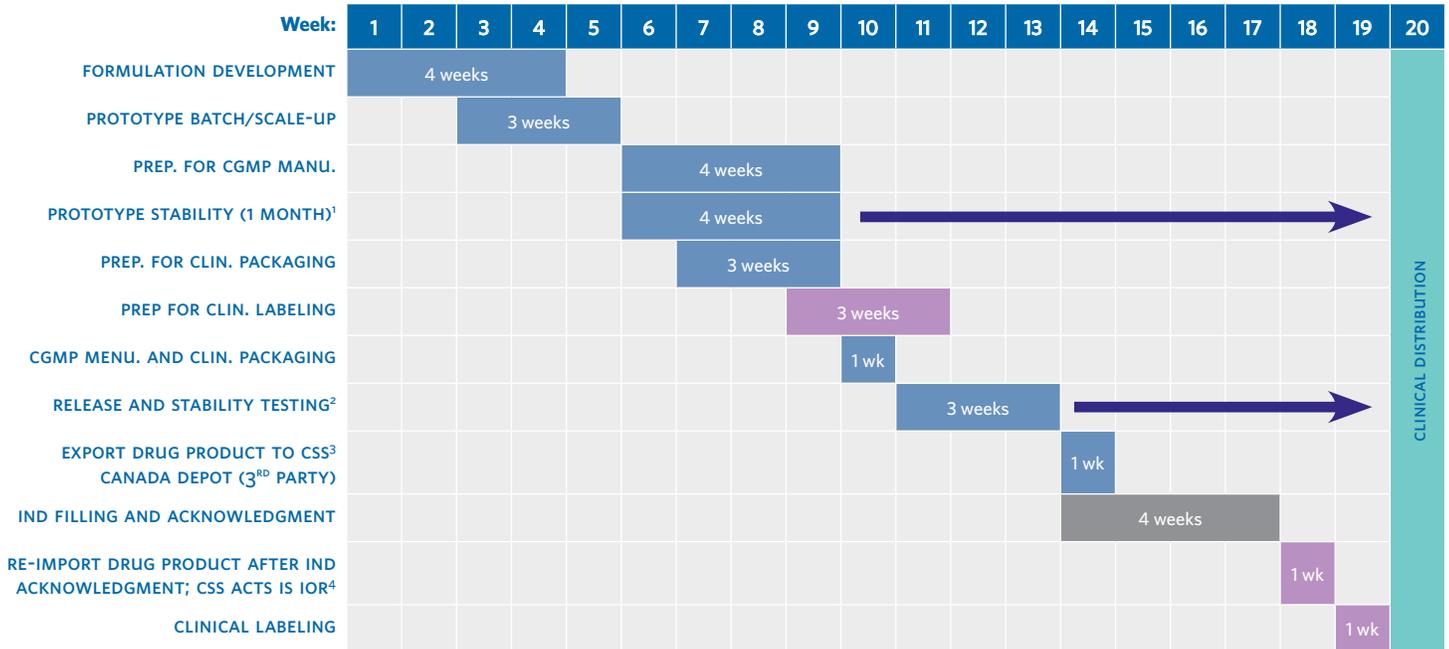
DELIVERY



SUPPLY

The chart below demonstrates how each step was completed to expedite the path to clinic.

### OPTIFORM® TOTAL SUPPLY PROCESS



- Ongoing prototype stability after Week-4 gate
- Ongoing stability storage after release & stability testing
- CSS: Clinical Supply Service (Catalent's business unit)
- IOR: Importer of Record

■ Performed at San Diego site    
 ■ Performed at Kansas City site    
 ■ Performed outside of Catalent

- In just one month, Catalent completed an expedited API developability assessment and developed a new dose form, a roller-compacted enteric coated tablet
- The Catalent sites operated in parallel to deliver flexible options for labelling and packaging, and cGMP manufacturing and clinical supply distribution
- Throughout the entire process, MGB Biopharma had a single point of contact with Catalent that enabled efficient communication and simplified project management

## Conclusion

OptiForm® Total Supply, an integrated formulation, screening and development solution for CTM manufacturing, packaging, labeling and distribution, provided a simplified and accelerated path to clinic, and minimized the risks involved in transferring projects between multiple vendors. With Catalent's broad global capabilities, OptiForm® Total Supply is specifically designed for small and innovative companies who prefer to work with a single service provider.

more products.  
better treatments.  
reliably supplied.™

Discover more solutions at [www.catalent.com](http://www.catalent.com)  
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