

# Developing a Commercialization Roadmap for Cell Therapy Operations

## INDUSTRY:



Cell Therapy

## PRODUCTS AND SERVICES:



Precision genetic medicines

# BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

This client is a clinical-stage biotechnology company developing precision genetic medicines for patients with serious diseases. The client is preparing to launch their first commercial autologous cell therapy in the U.S. within the next year.

As they move from clinical to commercial operations, the client needed to decide whether to outsource their commercial functions or build them in house. This decision would be based on their overall commercial strategy, high-level investment estimates, and the minimum capabilities needed to stay compliant and scale effectively over time. Senior leaders wanted a consulting partner who could provide guidance and develop capability roadmaps with associated resource needs for two different commercial models.

The client engaged Clarkston's commercialization and cell therapy experts to assess their current capabilities and determine which were needed to support commercialization. The evaluation covered commercial, patient operations, patient services, market access, clinical, safety, quality & regulatory, medical, supply chain & manufacturing, finance, and IT.

The Clarkston team delivered two commercialization roadmaps tailored to cell therapy operations. These roadmaps outlined prioritized capabilities, timelines for implementing systems aligned to launch milestones, and high-level cost estimates to support strategic planning.

## PRIMARY OBJECTIVES:

- Confirm the IT capabilities required for commercial operations for each of the commercial models under consideration
- Create a roadmap that includes a list of projects and a system implementation timeline aligned with the launch milestones
- Evaluate pros and cons for each capability, including timing impact for implementation
- Recommend potential software platforms with guidance on key decision criteria and considerations
- Deliver high-level cost estimates for capability implementation



## SOLUTION:

- Interviewed 36 stakeholders to understand business requirements across commercial operations, patient services, market access, clinical, safety, quality & regulatory, medical, supply chain, finance, and IT functional areas
- Synthesized interview themes into 70 business requirements that were then prioritized based on effort to implement, efficiency gains through technology, autologous cell therapy need, and risk mitigation
- Built the two roadmaps based on a set of assumptions around cell therapy operational requirements, an in-house or outsourced partner model, resource availability, regulatory requirements, and benchmarks from commercial cell therapy organizations
- Developed a detailed summary of current capabilities, required future state capabilities, considerations for scale, and rough order of magnitude estimates for each capability for each of the 11 functional areas
- Delivered a final report that included a capability prioritization, roadmaps, cost estimates, and overall recommendations to executive leadership for consideration as they made decisions about the commercial operating model for launch

## KEY BENEFITS:

- Guided executives on the baseline systems and reporting capabilities required to meet cell therapy commercial operations requirements
- Prioritized capabilities on two actionable roadmaps that could be leveraged to inform Market Authorization Holder (MAH) or non-MAH business model decisions
- Provided approximate cost estimates and implementation timeline for when capabilities should be enabled relative to DP PPQ, BLA submission, and commercial launch milestones



# KPIs

---

- Conducted interviews with 36 stakeholders across functional areas
- Prioritized 70 systems capabilities across 2 commercial model options based on system, data, and operational requirements
- Developed rough order of magnitude estimates for 22 systems capabilities considering directional implementation, headcount, and licensing costs based on vendor and Clarkston expertise