

Developing a Commercial Systems Capability Roadmap for a Clinical-Stage Biotech Company

This client is a clinical-stage immune-oncology organization who focuses on developing therapeutics to address the unmet needs of patients with various forms of cancer. The client is based in Europe with several therapies in phase 1/2 trials with one therapy expected to launch in the U.S. within a year.

The client was evaluating whether to outsource commercial capabilities or build them in-house as they transition from clinical to commercial operations. The business model decision was informed by overall commercial strategy, financial return on investment, and minimal viable product (MVP) systems capability requirements to maintain regulatory compliance. The Senior leadership team was in the process of positioning their commercial model strategy with the Board of Directors and seeking a partner who could advise and develop capability roadmaps based on the commercial model scenarios that were in consideration.

The client engaged Clarkston's life sciences commercialization experts to assess existing requirements across business and IT functions and recommend which capabilities were required to implement based on their commercial model milestones, industry regulations, and capability needs. Functional areas evaluated included commercial operations, marketing, market access, patient services, medical, safety, accounting, supply chain, data and analytics, and regulatory.

Clarkston helped the client by developing commercialization roadmaps that prioritized capabilities required for Commercial Operations, documented a timeline for system implementation based on commercialization milestones, and presented the pros / cons for each capability decision based on compliance risk, level of effort, and scalability.

Life Sciences Case Study

PROJECT OVERVIEW



INDUSTRY:



Biotechnology

PRODUCTS AND SERVICES :



Oncology
Therapeutics

PRIMARY OBJECTIVES:

- Confirm the systems capabilities required to transition from clinical to commercial operations
- Create roadmaps for implementation of systems capabilities aligned to commercial milestones – one for an outsourced commercial partner model and one for managing capabilities in-house
- Evaluate pros and cons for each capability, including timing impact for implementation
- Provide recommendations on systems platforms and timing relative to data requirements – including data aggregation, reporting, integrations, and visualization

RESOLUTION:

- Conducted interviews with 20 stakeholders to understand business requirements across Commercial, Medical, Operations, and IT functional areas
- Synthesized interview themes into 50 business requirements, which were then prioritized based on effort to implement, efficiency gains through technology, and risk mitigation
- Developed two roadmaps to allow management to fully evaluate their options for systems capability investments from a cost-benefit perspective: one was a base-case scenario for an outsourced partner model and the other for an in-house model
- Built the two roadmaps based on a set of assumptions around the outsourced partner model, resource availability, regulatory requirements, and general best practices for commercial biotech organizations
- Generated a set of assumptions, functionality considerations, data requirements, potential risks, and open business decisions for each of the 10 functional areas
- Delivered the capability prioritization, roadmaps, and overall recommendations to executives across IT, Operations, and Commercial for consideration and input, as business decisions were made at the Board of Directors level

KEY BENEFITS:

- Provided actionable insights through capability prioritization and roadmap deliverables, which could be leveraged to inform business model decisions
- Guided executives on the MVP systems capabilities required to maintain ownership of data in an outsourced partner model
- Organized cross-functional business capability requirements into a cohesive roadmap that could be leveraged for stakeholder alignment and awareness as the business transitions into a commercial organization

KPIs

- **Conducted interviews with 20 stakeholders across functional areas**
- **Identified 25 challenges related to data, process improvements, and stakeholder alignment, which impact the capability roadmap**
- **Prioritized 36 systems capabilities across 4 commercial model options based on systems and data ownership requirements**