Life Sciences Case Study

PROJECT OVERVIEW

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Commercialization Launch Readiness Roadmap for an Emerging Oncology Biopharma



INDUSTRY

Life Sciences

PRODUCTS AND SERVICES

Targeted Oncology Therapies

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

An emerging oncology biopharma was advancing toward a targeted U.S. commercial launch, and leadership needed a clear view of the technology and data capabilities required for launch readiness. The company also needed to define the IT resource model that could support the business as it scaled.

The company had a solid technology baseline, including Veeva for regulated processes and NetSuite for finance. Established security and cloud platforms supported the environment, alongside early commercial tools. However, launch readiness required faster decision-making and tighter integration across commercial and medical functions, as well as safety and regulatory. Planning also needed to account for product supply and finance, with data requirements and IT support incorporated across functions.

Several core decisions needed to be made before major platform investments or buildouts could move forward. These included commercial customer relationship management (CRM) and healthcare provider/healthcare organization (HCP/HCO) master data. Leadership also needed to define patient services hub (HUB) and specialty pharmacy (SP) visibility requirements, along with GTN revenue management. Additional considerations included partner data feeds from third-party logistics (3PL) providers and contract manufacturing organizations (CMOs), as well as specialty pharmacies. Validation capacity and the IT support model also needed to be defined.

The client engaged Clarkston to assess its technology environment and translate commercialization drivers into IT requirements. The team then developed an executive roadmap that distinguished launch-critical priorities from post-launch enhancements.

PRIMARY OBJECTIVES

- Assess current-state technology readiness across launch-relevant capabilities, distinguishing foundational platforms from areas requiring additional configuration or integration
- Identify capabilities that may require new development or configuration, along with integration or replacement
- Validate the three- to five-year commercialization roadmap against launch timing, cross-functional dependencies, business ownership, implementation capacity, and the launch-readiness phase gate
- Translate commercial, medical, safety, regulatory, supply, finance, and data requirements into a capability-based roadmap rather than a system-by-system project list

PRIMARY OBJECTIVES

- Identify critical decisions and sequencing gates, along with support model expectations required before major platform investments
- Recommend a future-state IT organization and partner capacity model to support launch readiness and hypercare, with room to scale after launch

SOLUTION

- Reviewed source materials and current-state inputs across the technology stack, including the previous roadmap; Finance, Human Resources Information System (HRIS), and General & Administrative (G&A) launch considerations; meeting notes; and draft IT commercialization planning
- Organized the newly created roadmap around Level 1 and Level 2 business capabilities across four domains: Commercial Launch; Medical/Safety/Regulatory; Product Supply/Regulated Operations; and Enterprise Enablement
- Assessed system health to distinguish foundational systems from launch-readiness requirements as well as identify automation and replacement needs
- Defined extensive, limited, and post-launch/scale-triggered implementation requirements
- Sequenced decision-making and build activities, followed by proof and scale phases, with launch-critical targets
- Developed decision gates and business triggers for the following workstreams:
  - CRM
  - HUB/SP
  - HCP/HCO master data management (MDM)
  - Commercial Data Warehouse (CDW)/Business Intelligence (BI)
  - GTN/government pricing
  - NetSuite material requirements planning (MRP) and order-to-cash (O2C), along with cost of goods sold (COGS)
  - TraceLink
  - Procure-to-pay (P2P)/contract lifecycle management system (CLMS)
  - Veeva release governance and security
  - Field enablement
  - Application managed services (AMS)/managed service provider (MSP) support
- Recommended a future-state IT accountability model with in-house ownership of roadmap, architecture, data governance, AI governance, vendor oversight, and business accountability, supported by specialist partners

KEY BENEFITS

- Provided an executive-level roadmap that aligned application decisions with commercialization capabilities and launch timing
- Confirmed that the client's technology baseline was strong, while launch risk was concentrated in ownership, data rights, partner feeds, revenue controls, validation capacity, and support model readiness
- Clarified which capabilities needed to be operational before the launch-readiness gate and which could remain limited, manual, outsourced, or deferred until scale triggers emerge
- Established decision gates and dependencies to help leadership avoid premature tool selection and reduce rework from unresolved operating model decisions
- Created a shared planning view of future-state IT roles, partner pods, commercial service desk needs, validation support, data and AI governance, and launch hypercare

KPIs

- 3- to 5-year roadmap aligned to launch readiness
- 4 cross-functional capability domains reviewed and sequenced
- 3 launch-readiness tiers defined



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Glossary

Acronym	Full Name	Case Study Context
3PL	Third-Party Logistics Provider	Partner supporting warehousing and distribution, including order fulfillment.
AI	Artificial Intelligence	Technology capability requiring controlled enablement and approved use cases, with governance for regulated use.
AMS	Application Managed Services	Partner-provided application support and release management.
BI	Business Intelligence	Reporting and analytics capabilities used to monitor performance.
CDW	Commercial Data Warehouse	Centralized repository for commercial reporting data, including information from partners.
CLMS	Contract Lifecycle Management System	System supporting contract workflows from request through renewal.
CMO	Contract Manufacturing Organization	External manufacturing partner.
COGS	Cost of Goods Sold	Inventory costing and related cost-accounting treatment.
CRM	Customer Relationship Management	System supporting HCP/HCO engagement and field activity management.
G&A	General and Administrative	Corporate support functions and launch considerations outside core commercial or regulated operations.
GTN	Gross-to-Net Revenue Management	Estimating and reconciling net revenue after applicable deductions.
HCO	Healthcare Organization	Hospital, practice, integrated delivery network, oncology network, academic center, or other organization.
HCP	Healthcare Provider	Individual clinician, prescriber, investigator, or other professional stakeholder.
HRIS	Human Resources Information System	Core HR employee data, onboarding, role, and reporting platform.
HUB	Patient Services Hub	Patient support operation covering access and reimbursement processes.
KPI	Key Performance Indicator	Agreed metric used to monitor readiness or performance.
MDM	Master Data Management	Governance and tooling for consistent master data, including HCP/HCO records and account hierarchies.

Glossary

Acronym	Full Name	Case Study Context
MLR	Medical, Legal, Regulatory	Cross-functional review of promotional and certain medical or scientific materials before use.
MRP	Material Requirements Planning	Material planning functionality; confirm the intended NetSuite scope.
MSP	Managed Services Provider	Partner providing ongoing operational support.
O2C	Order-to-Cash	End-to-end process from order capture through payment collection.
P2P	Procure-to-Pay	End-to-end business process of acquiring goods and services.
SP	Specialty Pharmacy	Pharmacy partner that dispenses specialty products and may provide patient-status or dispensing data.