

Advancing Pharma-Grade, GxP-Compliant Digital Labeling with a Strategic Innovation Framework

INDUSTRY:



Pharma

PRODUCTS AND SERVICES:



Pharmaceuticals, Biologics,
Advanced Therapies

BUSINESS TRANSFORMATION STORY & BUSINESS CHALLENGE

A leading global pharmaceutical company co-developed a pharma-grade, GxP-compliant digital label technology. This is a rewritable electronic label that enables NFC- and SAP-driven updates to drug packaging, including expiration dates, language, and protocol numbers, without physical reprinting or repackaging. Following a successful clinical pilot, the company faced a critical decision on how to advance the technology without relying on traditional capital ROI frameworks that are poorly suited to early-stage innovation.

High unit costs associated with a single-source vendor, uncertain drug savings, and an incomplete economic model made a full-scale business case premature. The company engaged Clarkston Consulting to develop a strategic narrative that positioned the Digital Label as a phase-gated innovation, clarified a path to value realization, and established decision criteria to scale, pause, or exit the initiative.

PRIMARY OBJECTIVES

- Reframe the investment from a traditional capital evaluation to a phase-gated innovation model with milestone-based funding and clearly defined pivot persevere or exit criteria
- Synthesize clinical pilot outcomes to establish a proof-of-concept baseline and identify gaps that must be addressed before committing to scale
- Evaluate the vendor and supply chain ecosystem to articulate the strategic value of the co-development partnership while identifying constraints to unit cost reduction
- Define two parallel 2026 workstreams focused on use case validation and unit cost reduction to support development of a defensible business case through targeted learning
- Deliver a structured options analysis to support executive decision-making on whether to advance, pause, or discontinue the program





SOLUTION

- Developed a strategic narrative positioning the label technology as an innovation investment, including innovation-appropriate hurdle rates, separation of cost to learn versus cost to operate, and milestone-based 2026 funding tranches
- Designed a four-phase validation framework covering proof of technology, feasibility and value, adoption and viability, and launch and scale, aligned to technology readiness, use case complexity, and volume scale
- Synthesized clinical pilot results, highlighting a 27-day cycle time reduction, 80% user satisfaction, and successful SAP and NFC integration in a GxP environment, while identifying remaining gaps in drug savings and reusability infrastructure
- Evaluated the technology ecosystem to document vendor dependencies, unit cost constraints, and strategic advantages including first mover position, co-development intellectual property, and influence over the vendor roadmap
- Developed a three-option strategic framework with financial implications and tradeoffs to evaluate discontinuation, targeted validation, or pause and restart, culminating in a recommendation to pursue focused validation
- Defined two concurrent 2026 workstreams focused on priority use case validation and unit cost reduction through vendor negotiation, ecosystem expansion, and reusability partnerships

KEY BENEFITS

- Equipped executive leadership with a structured framework to evaluate the label technology as an innovation investment, replacing premature ROI pressure with milestone-driven decision criteria and clear go or no-go gates
- Preserved first mover advantage and co-development intellectual property by reinforcing the strategic case for continued vendor ecosystem engagement during a critical technology maturation period

- Translated a complex, multi-variable investment decision into a clear options analysis with defined financial implications, enabling confident executive decision-making
- Established a focused 2026 learning agenda that concentrated investment on the most critical uncertainties, including drug savings, operational efficiency, and unit costs, prior to any scale commitment
- Created a reusable innovation investment framework applicable beyond label technologies, enabling evaluation of future emerging technologies using appropriate success metrics

KPIs

- Cycle time reduction per study (days)
- User satisfaction score (%)
- Use cases validated per quarter
- Technology unit cost reduction (%)
- Drug material savings from expiry extension studies