Sarcouncil Journal of Engineering and Computer Sciences

ISSN(Online): 2945-3585

Volume- 04| Issue- 08| 2025

Research Article

Received: 08-07-2025| Accepted: 28-07-2025 | Published: 17-08-2025

Digital Enablement of Global Drug Launches: A Case Study of Enterprise IT Readiness for Lenacapavir (HIV-1 Capsid Inhibitor)

Joydip Basu

Independent Researcher, USA

Abstract: Bringing Lenacapavir to global markets revealed serious shortcomings in the manufacturer's computer systems. This innovative HIV-1 capsid inhibitor required a complete digital overhaul centered around SAP S/4HANA implementation. Before this change, product labels varied between countries, supply chains lacked transparency, and regulatory documentation moved through disconnected systems. The SAP integration eliminated these bottlenecks. As a result, patients - especially those with multidrug-resistant HIV infections - received this treatment significantly faster after regulatory approval without compromising safety standards. Unexpectedly, the technology platform built for Lenacapavir became valuable for launching other medications later. Different drug companies struggle with their specific problems, yet this case offers valuable insights about updating old computer systems. Yes, making operations run smoother saves money. But something far more important happens: sick people get life-changing medicines faster. This real-world example proves that smart technology choices help companies deal with complicated regulations without cutting corners on the scientific standards that patients depend on.

Keywords: Digital transformation, SAP S/4HANA, pharmaceutical commercialization, regulatory compliance, supply chain automation.

INTRODUCTION

Drug makers struggle to launch new medicines quickly due to complex regulations across global markets. When approvals take too long, both companies and patients suffer - one loses revenue, the other waits unnecessarily for potentially life-changing treatments (Hole, G. *et al.*, 2021). Bringing a new medicine to market now goes well beyond demonstrating safety and efficacy in clinical studies. Pharmaceutical firms must build complex computer networks that track products from factory to patient across dozens of regions worldwide. These systems must simultaneously satisfy countless regulatory requirements while adapting to vastly different local market conditions spanning multiple continents. Research shows companies that have invested in connecting their digital systems get medicines from approval to pharmacy shelves noticeably faster than those still using disconnected approaches (Hole, G. *et al.*, 2021; Shawon *et al.*, 2025). This problem grows even more serious for specialized medicines treating conditions with few existing options, like HIV/AIDS, where regulatory hurdles frequently delay global access.

Lenacapavir broke new ground as the first HIV-1 capsid inhibitor to reach patients. Developed through precise molecular design, this drug works unlike any previous HIV medication by targeting the virus's protein shell at multiple points during its lifecycle and requiring less frequent dosing. Studies showed it worked remarkably well even for patients whose HIV had developed resistance to most other available treatments (Dzinamarira, T. *et al.*, 2023). Getting this drug to patients worldwide required new approaches to traditional pharmaceutical operations. Each country maintains different approval processes, documentation standards, and distribution rules. Markets where supply chains had already undergone digital modernization consistently delivered Lenacapavir to patients faster than regions relying on conventional methods. This pattern underscores how digital transformation directly impacts patient access to innovative treatments (Dzinamarira, T. *et al.*, 2023).

This article examines the implementation of enterprise-wide digital transformation supporting Lenacapavir's global market introduction. Through SAP S/4HANA implementation as the core enterprise resource planning platform and orchestration of multiple digital systems through validated integration points, the pharmaceutical manufacturer achieved accelerated market entry while maintaining regulatory compliance across all jurisdictions (Hole, G. *et al.*, 2021). Though requiring substantial capital investment, the digital transformation initiative generated significant returns through accelerated revenue realization and operational efficiency improvements. The case demonstrates enterprise information technology readiness as a critical factor in contemporary pharmaceutical commercialization while offering insights applicable across similar initiatives within the industry, particularly given that relatively few

*Corresponding Author: Joydip Basu

DOI- https://doi.org/10.5281/zenodo.16889463

organizations currently maintain fully integrated digital platforms capable of supporting complex global therapeutic launches (Dzinamarira, T. *et al.*, 2023). Moreover, the initiative established a scalable digital foundation, reducing implementation timeframes for subsequent product introductions, creating a sustainable competitive advantage in delivering innovative therapies to patients globally.

ERP MODERNIZATION THROUGH SAP S/4HANA INTEGRATION

Legacy System Challenges

Before tackling the Lenacapavir launch, the pharmaceutical company struggled with disconnected computer systems that created major headaches for global commercialization efforts. Drug makers have historically fallen behind other industries in modernizing supply chain technology, with outdated systems causing significant operational problems (Gupta, M. *et al.*, 2025). The old technology environment split data across multiple regional ERP systems, forcing staff to spend countless hours manually reconciling information and delaying financial reporting cycles. This fragmentation made seeing the whole supply chain picture nearly impossible, compromising inventory tracking and production scheduling.

Staff managed regulatory paperwork through separate systems lacking centralized oversight, which slowed responses to health authority questions. Perhaps most troubling was how long it took to set up systems for new product launches - each market entry required months of preparation time. These shortcomings created real business dangers when launching medicines globally: potential market delays, compliance problems, and wasteful inventory practices. Creating modern, digital supply chains has become essential for pharmaceutical companies wanting to improve operational strength and launch readiness (Gupta, M. *et al.*, 2025).

S/4HANA Implementation Strategy

Instead of trying to change everything at once, the drug maker rolled out SAP S/4HANA in careful stages. This measured approach protected daily operations while building exactly what was needed to launch Lenacapavir successfully. Most tech projects in pharma face unique hurdles - regulatory agencies demand perfect documentation, and supply chains handle everything from raw ingredients to temperature-sensitive finished products, making careful planning necessary (Vrata Tech Solutions).

Work began with Core Finance Transformation, bringing together financial processes and master data to create a single, trusted information source. This phase cut month-end closing times and improved data accuracy through standardized global processes.

The new systems dramatically improved forecasting accuracy and inventory management worldwide. Next came the critical task of fixing regulatory information handling by linking compliance paperwork directly with product data. The integration established a unified repository for product specifications, manufacturing documentation, and regulatory submissions, eliminating previously fragmented information sources. For the concluding implementation phase, the team developed adaptable templates accommodating market-specific requirements. Rather than configuring each market deployment independently, these standardized frameworks allowed for efficient customization based on local regulatory requirements. This methodology substantially reduced implementation timeframes for subsequent market entries, accelerating patient access to Lenacapavir across global regions compared to historical product launches (Vrata Tech Solutions).

Regulatory-Driven System Design

What made this implementation special was putting regulatory compliance first in the system design, building requirements directly into the core architecture rather than adding them later. Life sciences supply chains need specialized capabilities to meet regulatory demands while maintaining efficiency (Gupta, M. *et al.*, 2025). Every system component underwent validation to GxP standards, using risk-based approaches that maintained thorough coverage of critical quality attributes.

The architecture connected electronic Common Technical Document (eCTD) submission capabilities directly with product data management, allowing seamless creation of regulatory submission content from trusted sources. Automatic tracking of regulatory commitments and safety monitoring obligations provided early warnings about upcoming deadlines, with compliance dashboards improving on-time completion rates. Quality management integration for handling complaints and adverse events ensured prompt capture, investigation, and

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reporting of product quality issues within required timeframes (Vrata Tech Solutions).

Regulatory inspections proceed with markedly improved efficiency under the new system architecture. Information requests during inspections receive prompt responses with comprehensive supporting documentation, including complete audit trails of relevant modifications. The architectural decision to incorporate compliance requirements as foundational elements rather than supplemental components established a robust platform for expedited market entry while maintaining stringent adherence to regulatory standards.

Table 1: S/4HANA Implementation Benefits for Pharmaceutical Launches (Gupta, M. *et al.*, 2025; Vrata Tech Solutions)

Performance Area	Improvement Level
Financial Closing	Significant Reduction
Regulatory Compliance	Zero Findings
Market Entry	Accelerated Timeline
Inventory Management	Enhanced Visibility
Launch Preparation	Reduced Effort

GLOBAL LABELING AND REGULATORY INFORMATION MANAGEMENT

Harmonized Labeling Strategy

The pharmaceutical company deployed a sophisticated global labeling platform to address complex regulatory requirements for Lenacapavir across diverse markets. Regulatory Information Management systems have become increasingly vital as pharmaceutical organizations seek operational efficiencies while ensuring compliance within intricate regulatory frameworks (Patel, S. 2024). This platform centralized core data sheet management with automated propagation to local labeling documents, maintaining consistency across markets while accommodating necessary regional variations. Such methodology preserved compliance with local regulations while minimizing discrepancies that might trigger regulatory concerns or compromise patient safety.

System architecture incorporated comprehensive revision tracking with complete audit histories suitable for regulatory inspections, providing full traceability of all labeling modifications along with documentation of approval decisions and scientific justifications. Translation management workflows with integrated validation controls ensured linguistic precision while preserving regulatory compliance across multiple languages and regions. The system enabled automated artwork generation with structured regulatory review processes, incorporating jurisdiction-specific requirements for packaging components while preserving brand consistency. Digital proofing and approval mechanisms replaced traditional paper-based reviews, substantially reducing approval cycle durations. This consolidated approach shortened labeling update cycles from months to weeks, facilitating rapid responses to evolving regulatory requirements and pharmacovigilance findings (Patel, S. 2024).

Regulatory Information Exchange

To enhance information exchange with global regulatory authorities, the pharmaceutical company implemented various digital capabilities aligned with emerging regulatory standards. Digital transformation initiatives in pharmaceutical regulatory affairs have yielded substantial benefits through streamlined regulatory processes and enhanced compliance outcomes (Ullagaddi, P. 2024). Implementation included a structured product information database conforming to the Identification of Medicinal Products standards, positioning the organization advantageously for compliance with evolving global regulatory requirements while establishing foundations for standardized data exchange.

The system checked submission packages automatically against each region's unique requirements, catching formatting errors and technical issues before filing. This meant fewer rejections and more first-time approvals. Managers could now see exactly where each submission stood with regulatory agencies in real time, while automatic alerts prevented missed deadlines and overlooked agency questions. Connecting directly to health authority portals streamlined how post-approval changes were handled, reducing paperwork while ensuring required modifications happened on schedule (Ullagaddi, P. 2024).

COMPLIANCE ANALYTICS AND REPORTING

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The company turned mountains of compliance paperwork into valuable business insights through sophisticated analytics tools. Keeping up with pharmaceutical regulations has grown nearly impossible without data-driven methods, especially as requirements multiply across global markets (Patel, S. 2024). Leadership could now see at a glance where Lenacapavir stood with regulators worldwide through specially designed dashboard screens, eliminating the previous guesswork about approval status. This clarity allowed managers to shift resources proactively before bottlenecks could delay launches.

The system analyzed historical approval patterns and past agency interactions to predict when approvals might occur, making launch planning more precise. Risk scoring identified which markets presented higher regulatory challenges, helping prioritize where extra attention was needed. Automatic scans detected labeling inconsistencies across countries before they became compliance problems during inspections. Digital approaches have proven particularly valuable in strengthening quality management and regulatory compliance through better automation, centralization, and data integration (Ullagaddi, P. 2024). The system also tracked post-approval commitments to ensure nothing fell through the cracks. Together, these capabilities gave executives clear visibility into Lenacapavir's regulatory status worldwide, supporting fact-based decisions throughout the launch sequence.

Table 2: Global Labeling and Regulatory Information Management Benefits (Patel, S. 2024; Ullagaddi, P. 2024)

Regulatory Area	Improvement Result
Labeling Updates	Weeks vs. Months
Submission Approvals	Higher Acceptance
Compliance Monitoring	Automated Detection
Regulatory Deadlines	Proactive Alerts
Risk Assessment	Data-Driven Scoring

SUPPLY CHAIN DIGITALIZATION AND AUTOMATION

End-to-End Supply Chain Visibility

The switch to SAP S/4HANA turned a murky supply chain into something managers could see and control. Drug companies face problems most businesses never encounter - fake products slipping into the supply chain, strict temperature requirements, and a maze of regulations that change with every border crossing (Jaberidoost, M. 2013). Once the new system went live, anyone with proper access could instantly check inventory at any factory, warehouse, or local market. This visibility wasn't just nice to have - it proved crucial during Lenacapavir's launch. When supplies were tight, the company could send the available medicine to markets where regulators had approved and where patients desperately needed this new treatment option.

Track-and-trace features did more than just satisfy regulations about serialization; they created a security barrier against counterfeiting that exceeded requirements. The old statistical forecasting methods couldn't compete with the new machine learning algorithms, which dramatically improved production planning and inventory placement. For the temperature-sensitive components, tiny IoT sensors kept constant watch during shipping and storage. If temperatures started drifting toward danger zones, the system sent alerts automatically - no human monitoring required. Supply disruptions that once caused panicked scrambling now trigger pre-planned emergency protocols immediately. These improvements let the company handle supply constraints more effectively while keeping just the right amount of inventory throughout the network, tackling the exact problems that typically plague pharmaceutical supply chains (Jaberidoost, M. 2013).

Manufacturing Integration

Digital transformation didn't stop at the factory door - it reached right onto the production floor. Modern pharmaceutical manufacturing simply can't function efficiently without digital systems, especially for complex medications with exacting quality standards (Kaneberg, E. *et al.*, 2025). Technical experts built digital bridges connecting SAP S/4HANA directly to factory floor systems throughout the manufacturing network. Information now moves seamlessly in both directions without anyone having to manually enter data. This eliminated countless errors that used to happen when staff mistyped numbers or misinterpreted handwritten notes, errors that

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frequently led to production holdups and documentation problems.

Paper batch records had always created headaches - signatures would be missing, pages would get damaged, and handwriting often proved indecipherable. Electronic documentation solved these problems through built-in compliance checks that verified each manufacturing step met requirements. The improvement in both efficiency and regulatory compliance was immediately apparent. This digital approach substantially improved both processing efficiency and regulatory adherence. This not only sped up reviews but caught process problems that humans might miss. Every manufacturing line got real-time monitoring with dashboards showing Overall Equipment Effectiveness metrics, making it obvious when lines weren't performing well. Quality testing results moved directly from lab systems into release workflows without retyping, cutting batch release times dramatically. Even equipment maintenance changed - sensors fed data to machine learning algorithms that could spot patterns suggesting upcoming failures, allowing repairs before unexpected breakdowns. All these manufacturing improvements meant the company could launch Lenacapavir in multiple markets simultaneously, quickly ramping up from small clinical trial production to full commercial volumes as approvals came in (Kaneberg, E. *et al.*, 2025).

Distribution Network Optimization

Old-style pharmaceutical supply chains moved in one direction like an assembly line. The new system created something more like a responsive network that could adapt on the fly to changing conditions. Getting specialty medicines like Lenacapavir to patients brings unique challenges - many need refrigeration, and all need careful handling to prevent tampering (Jaberidoost, M. 2013). Smart algorithms now continuously rebalance inventory across the network based on demand patterns, approval status, and where patient needs are most urgent. During the Lenacapavir launch, this meant patients with the most serious unmet medical needs got access first.

Customs paperwork - a notorious bottleneck - is now generated automatically, with each document tailored to specific country requirements. The right paperwork meant faster international shipments with fewer delays at borders. Third-party logistics partners connected directly to the system, providing real-time updates on products they handled. For the first time, managers could see all inventory regardless of which company physically held it or where it sat. Tracking didn't stop at delivery either - it extended to healthcare providers and specialty pharmacies. Product returns, once a logistical headache, now go through digital authentication automatically, eliminating a process that used to take weeks (Kaneberg, E. *et al.*, 2025). These distribution improvements ensured Lenacapavir reached priority markets when needed while tying up less working capital, solving key problems that pharmaceutical supply chain researchers have been highlighting for years.

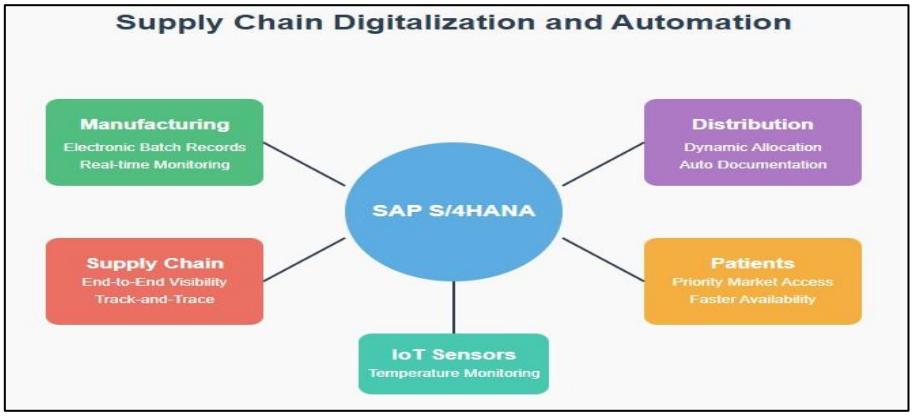

Fig 1: Integrated Digital Supply Chain for Pharmaceutical Launch Excellence (Jaberidoost, M. 2013; Kaneberg, E. *et al.*, 2025)

IMPLEMENTATION OUTCOMES AND PERFORMANCE METRICS

Launch Timeline Acceleration

The digital overhaul dramatically sped up how quickly Lenacapavir reached patients after receiving regulatory approvals. This success demonstrates how integrated computer systems can fundamentally change the pace of pharmaceutical commercialization. Digital transformation has evolved from a nice-to-have

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efficiency boost into a strategic necessity for companies wanting to stay competitive in today's market (Landwehr, K. 2015). Lenacapavir became available to patients much faster than previous drug launches across all markets, with especially striking improvements in countries where regulatory complexity had historically caused lengthy delays.

Setting up systems for each new market happened faster than ever before, thanks to standardized templates and automated validation tools. This approach allowed rapid adaptation to local market needs while keeping data consistent globally. The time needed to prepare regulatory submissions dropped significantly through automated document creation and validation. When health authorities asked questions, the company responded more quickly because all product and manufacturing information lived in one accessible place. Making changes to product labels - often a painfully slow process - happened faster through automatic updates that flowed from core data sheets to local market versions. These improvements meant patients gained access to this important HIV therapy sooner, perfectly aligning with the industry's growing focus on digital tools to speed up drug commercialization (Landwehr, K. 2015)

Compliance and Quality Metrics

The implementation produced exceptional compliance results, validating the strategy of building regulatory requirements directly into system design from the beginning. When pharmaceutical companies undertake digital transformation, prioritizing compliance and quality management must come first - both to reduce regulatory risks and to accelerate time-to-market (Deloitte). Despite launching a novel HIV medication with unique handling requirements and heightened regulatory scrutiny, Lenacapavir faced zero critical findings during regulatory inspections across all markets. Complete product traceability from manufacturing through distribution to patient dispensation became possible through integrated serialization and comprehensive tracking capabilities.

Quality issues during launch phases decreased notably through automated compliance verification and constant monitoring of critical manufacturing parameters. Data discrepancies virtually disappeared once a single, authoritative source of truth existed for all product and process information. The endless hours previously spent preparing compliance reports shrank dramatically through automated data collection and report generation. These results proved the value of embedding compliance considerations throughout the digital architecture rather than treating them as an afterthought. The stellar compliance performance positioned the company favorably for future interactions with regulatory agencies worldwide (Deloitte).

Business Impact

Beyond improving compliance, the digital transformation delivered substantial operational and financial benefits. Measuring return on investment for such initiatives requires looking at both concrete financial outcomes and strategic business capabilities (Deloitte). Inventory holding costs dropped significantly through improved visibility and smart allocation capabilities, optimizing inventory placement while ensuring product availability in all markets.

Monthly financial close processes, which historically demanded substantial manual intervention, were executed with significantly increased speed and precision through automated reconciliation functions and globally harmonized accounting methodologies. Forecast accuracy exhibited marked enhancement through the deployment of sophisticated analytical models and comprehensive market intelligence systems. These improvements enabled more judicious production planning decisions and optimized inventory deployment across the distribution network. A particularly significant efficiency gain emerged during subsequent product introductions, where validation requirements diminished considerably due to the established system templates and automated testing protocols developed during the Lenacapavir implementation. Overall, launch-related operating expenses came in lower compared to similar previous product introductions, creating a compelling financial case for digital transformation while simultaneously improving launch execution (Landwehr, K. 2015). These efficiencies created a sustainable model for future product launches, with each new introduction benefiting from the established digital foundation and accumulated organizational knowledge.

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Table 3: Digital Transformation Impact on Key Performance Indicators (Landwehr, K. 2015; Deloitte)

Performance Area	Measured Outcome
Launch Timelines	Dramatically Accelerated
Regulatory Inspections	Zero Findings
Product Traceability	Complete Visibility
Financial Closing	Significantly Faster
Operating Expenses	Lower Costs

CONCLUSION

The journey to bring Lenacapavir to HIV patients began in research laboratories but didn't end there. After breakthrough science delivered the first effective capsid inhibitor for treatment-resistant cases, a second phase of work began. How would this medicine navigate the complex path from factory to pharmacy across dozens of countries, each with unique regulatory demands? The digital transformation outlined here eliminated traditional obstacles that often delay medicines from reaching patients. By rebuilding systems around SAP S/4HANA and connecting previously isolated functions, the company delivered this breakthrough medicine to patients months sooner than traditional approaches would allow. What happens next? Smart analytics might help target medicines more precisely to populations with the greatest need. In markets where counterfeits endanger patients, secure tracking through technologies like blockchain could protect medicine integrity. The pharmaceutical world never stands still - new regulations appear constantly. But the Lenacapavir story offers a clear lesson about technology's role in modern drug launches: paper-based processes and disconnected computer systems create delays while integrated digital platforms get medicines to patients faster. For people waiting for life-changing treatments, that speed makes all the difference.

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Source of support: Nil; **Conflict of interest:** Nil.

Cite this article as:
Basu, J. "Digital Enablement of Global Drug Launches: A Case Study of Enterprise IT Readiness for Lenacapavir (HIV-1 Capsid Inhibitor)." *Sarcouncil Journal of Engineering and Computer Sciences* 4.8 (2025): pp 664-670.

Publisher: SARC Publisher