Five ways digital technologies boost clinical supply chain performance

Imperative for change

Over the past four years, Deloitte has engaged with the clinical supplies leadership of major biopharmas as part of an industry forum, the Clinical Supplies Working Group (CSWG). Forum activities include benchmarking capabilities and maturities, discussing current topics of interest on a quarterly basis, and holding in-person workshops. A combination of CSWG forum activities, Deloitte’s clinical supplies projects, and life sciences industry research informs our perspectives for this piece.

The accelerating shift toward personalized medicine, greater drug portfolio complexity, and efforts to speed up clinical development in today’s ultracompetitive biopharmaceutical industry are raising the stakes for companies trying to extract the greatest business and clinical value from their research and development (R&D) investments. However, Deloitte’s ongoing analysis of 12 large biopharma companies reveals that R&D spending on innovative new drugs is not producing a commensurate return on investment (ROI).

- In 2018, the average cost of developing a new drug and bringing it to market topped $2.1 billion—up $362 million from 2017, and almost double the average cost in 2010, according to Deloitte’s most recent research.¹

- The 12 companies’ R&D spending grew by an average of 15 percent; however, their ROI fell from 10.1 percent in 2010 to 1.9 percent in 2018—the lowest percentage we have seen since we started tracking it.²
To help reverse ROI's downward trajectory, biopharma companies of all sizes are reorganizing their clinical operations and reconfiguring clinical trials to increase efficiency, reduce cost, and better connect with patients. These actions are an important step forward; however, they may escalate cost pressures and create operational and regulatory challenges for companies’ clinical supply chains, especially when viewed in the context of current industry trends including clinical supply traceability, regulatory complexity, growing reliance on external partners, unique and evolving requirements of next-generation cell/gene therapies, and increasing cost pressures (see figure 1). Some of these trends are disruptive to current practices; for example, cell and gene therapies, which often have a supply chain of one patient–one drug, create a potential future scenario where the clinical supply chain mirrors the production supply chain.

Digital considerations for change
This article examines five technology-powered capabilities that improve clinical supply chain performance by enabling increased agility and improved results (see figure 2). These capabilities can contribute substantial value in efficiency, agility, investigator and regulatory improvements, and in clinical trial outcomes.

Figure 1. Biopharma industry trends create challenges for clinical supply chains

<table>
<thead>
<tr>
<th>Full traceability of clinical supplies</th>
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<tr>
<td>End-to-end finished goods traceability is needed at the trial, program, CMO, and geography levels</td>
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<tr>
<th>Regulatory complexity and varied trial designs</th>
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<tr>
<td>Regulatory changes, import/export rules, and expiry date requirements create regional complexities to manage and adapt operations</td>
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<tr>
<th>Increased externalization</th>
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<tr>
<td>Increased reliance on external partners drives integration and standardization challenges required for achieving orchestration capabilities</td>
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<th>Next-gen advanced therapies</th>
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<tr>
<td>New drug modalities, including gene and cell therapy, create additional implications due to their unique and evolving requirements</td>
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<tr>
<th>Increasing cost pressures</th>
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<tbody>
<tr>
<td>Cost management expectations exceed capabilities for managing and continually improving cost performance</td>
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Evolving trial models, such as direct-to-patient, adaptive designs, and the push to faster trials drive additional clinical supply requirements.
Five ways digital technologies boost clinical supply chain performance

Figure 2. Digital clinical supply chain

Cloud-enabled digital core
- Integrated planning and execution solution or data hub model to enable leading capabilities, practices, and insights

Analytics-driven performance
- Insights lead to actions: Orchestrate activities across the value chain; align performance and status to KPIs

Blockchain-based product track and trace
- Secure insight to product movement at the finished good and batch level, and audit trail to enhance regulatory compliance

Optimized trial supply

Faster trial outcomes

Enhanced regulatory compliance

IoT-powered, real-time quality monitoring
- Constant monitoring during shipping and storage to provide temperature excursion alerts and patient adherence information

Mobile-centric digital patient experience
- Simplify and streamline clinical label management and allow for improved patient experience and insights
Cloud-enabled digital core

Solution and data integration across the clinical supply chain provides the backbone to enable planning excellence, operational efficiencies, and third-party orchestration.

A digital core uses a single, trusted data source—typically, a robust application or a data aggregation solution sometimes referred to as a data hub—to house all relevant data in a repository that keeps it accurate and up to date (see figure 3). A digital core gives a clinical supply organization the ability to operate more efficiently, rapidly understand the current state, make informed decisions, better plan activities, and streamline processes. Biopharma organizations looking to integrate their various clinical supply chain management systems can be further aided by cloud-enabling their digital core.

In addition to enabling mission-critical planning and operational functions, digital core assets can form the foundation for future digital capabilities built on standardized, accurate data and end-to-end business processes. Cloud-enablement of the digital core, either through cloud-based access and interoperability or through a data hub hosted on the cloud, further expands information accessibility, increases information timeliness, and eases integration with third-party data sources.

Potential value delivered

**Improved process cycle time**
- Ability to trust the data leads to faster decision making and improved business flow
- Common, integrated solution enables continual process improvements

**Reduced cost and waste**
- Better information and processes help improve KPIs
- Full inventory and demand visibility helps drive planning improvements and optimized supply levels

**Enhanced regulatory compliance**
- Single source of truth for regulatory and quality information improves compliance
- Integrated solution allows quality and regulatory activity monitoring (shelf life, lot expirations, genealogy) alongside inventory transactions

Figure 3. Cloud-enabled digital core

Building and reexamining the digital core for global clinical supplies transformation

Ten years after making a significant investment to build clinical supplies-specific capabilities into its corporate-wide ERP solution, a global biopharma company is currently considering how to refresh its digital core to address increasing clinical supply chain complexities and take advantage of new digital technologies. While evaluating whether to further customize the existing digital core or to integrate it with powerful new external solutions, one thing is clear: By continuing to operate with its existing capabilities and architecture, the company likely will be unable to achieve the transformation necessary to manage an increasingly complex and digital clinical supply chain.
Analytics-driven performance

Clinical supply analytics provide increased visibility, generate actionable insights, and optimize supply and inventory management.

Providing near-perfect delivery performance for complex study designs across multiple countries and their trial sites is the day-to-day complexity of clinical supply forecasting and planning. The supply chain needs to be agile to react to all kinds of changes during clinical trial execution. The confluence of three factors—aggregated data in a digital core; other cloud-based third-party data sets; and new analytics and visualization tools—is prompting biopharmas to invest in clinical supply analytics to help them make better decisions faster and meet the evolving needs of new trial designs (see figure 4).

The business value of using analytics to support clinical supply management can be considerable: On-demand access to clinical supply information and self-service analytics can help clinical supply managers address the complexity of large, geographically distributed trials, react quickly and accurately to change, and meet the evolving needs of new trial designs. Furthermore, companies may see non-direct improvements in areas such as site selection and third-party activity management.

The primary challenges to achieving these benefits reside in the data upon which the analytics capability depends. Ever-increasing data volumes, disparate data sources, undisciplined data feeds (even, sometimes, manual data integration), and the inability to reliably structure the data add complexity to producing the robust data necessary for trusted analytics results.
Potential value delivered
Increased forecasting and planning accuracy
- Create automatic forecast updates to reflect changes per the trial protocol (e.g., enrollment forecast actuals, plan adjustments, additional countries)
- Generate dashboards with drill-down capabilities and ability to track performance to KPIs

Reduced supply disruption risk
- Provide insight to prioritize supply to clinical trial sites
- Increase supply chain flexibility for long lead-time items

Improved transparency and collaboration
- Maintain optimized inventory levels to avoid stock-outs and reduce planned waste
- Generate a single dashboard view across all clinical trials
- Improve collaboration by providing demand visibility to clinical operations teams, manufacturing, and third parties
- Collaboratively adjust the plan to ensure supply continuity

Figure 4. Analytics-driven performance
Clinical supply analytics
IoT-powered, real-time quality and adherence tracking

IoT-enabled sensor technology captures and records drug, environmental, and patient adherence data in real time, allowing rapid insights and evaluation.

Temperature monitoring and excursion management are regulatory mandates and safety imperatives for clinical supply organizations. Existing methods of collecting and manually assessing temperature data are labor-intensive and time-consuming; a delay in temperature excursion analysis may lead to supply chain disruption and impact patient safety.

Internet-connected sensors capture and record investigational drug temperature data in real time to enable rapid and accurate product quality evaluations. Using this technology opens the door for future possibilities in configuring product-specific adjudication algorithms and recording site performance for knowledge-driven improvements in future clinical trials (see figure 5).

Beyond temperature monitoring and alerts, another sensor-driven capability that biopharmas are investigating and deploying is smart packaging, which allows delivery of sensor-driven product information at the patient level. This information can be used to track adherence, leverage mobile reminders to patients, and gather and analyze granular information for dosage tracking. The IoT sensor marketplace has multiple vendors offering solutions; conducting concurrent pilots is common for assessing solution suitability and value.

Figure 5. IoT-powered, real-time quality monitoring
Potential value delivered

**Improved patient safety**
- Detect temperature excursions earlier
- Determine next actions to prevent supply disruption and ensure patient safety
- Understand patient-level drug consumption

**Optimized trial supply**
- Provide more data points to validate or adjust predetermined excursion criteria
- Support a more robust and justifiable product evaluation approach
- Minimize discarding of drug supply that may, in fact, remain viable

**Enhanced regulatory compliance and patient-centricity**
- Automate temperature monitoring and reporting
- Provide auditable data history
- Gain insights into packaging suitability

Managing site temperature excursions with technology along with a business model change

A leading biopharma is using a combination of technology (temperature sensors, software, Internet connectivity) and operating model changes to tackle the challenge of site-based temperature excursions. As part of an ongoing prototype, the biopharma and two solution partners are changing the existing temperature sensor and recording model from a manual log per sponsor/per storage area that might be checked once per day to a 24/7 streaming data feed available for all companies using the study site per a subscription model.

Each company will have alarm limits per drug storage area, so any temperature excursion outside of these limits triggers escalating alerts, thereby reducing the severity and duration of any site temperature excursions. The streaming data will feed into a cumulative time out-of-condition tracking process by linking the temperature storage data to the existing in-transit monitoring program. Among the solution’s anticipated benefits are increased patient safety, easier onsite IP temperature monitoring, more reliable results, and lower drug sponsor operating and technology costs.

Additional technology improvements in the works include mining historical data around transport product exposure versus external temperature exposure, and using machine learning to better predict which packaging solution is most appropriate based on weather conditions at the shipping point of origin and destination.
Blockchain-based product track and trace

Clinical supply blockchain tracks product and data movement among partners and across sites, and provides transparency and auditability to fulfill regulatory mandates.

Today’s clinical supply chain often relies heavily on third-party documentation, manual processes, disparate systems, and numerous intermediaries to facilitate the movement of clinical drug supplies around the globe. The lack of end-to-end transparency leads to information distortion in the supply chain and produces asynchronous information among supply chain partners. Among blockchain’s benefits are increased trust and reduced intermediary reliance, making this fertile ground for blockchain-enabled technology solutions. Specific to clinical supplies management, blockchain can improve material traceability, reduce losses from waste, and enable better compliance around outsourced manufacturing and inventory operations (see figure 6).

Through the use of blockchain, the digitization of the clinical supply movement process can help facilitate secure information sharing throughout the supply chain. As such, some organizations are exploring how blockchain can provide a viable alternative to the biopharma’s intermediary-reliant and technologically siloed infrastructure used to share information and enable institutionalized trust.

Potential value delivered

Enhanced regulatory compliance
- Provide a single source of data integrity through time-stamped and tamper-proof transactions
- Track and record destruction of unused or expired products

Optimized trial supply
- Track and trace product movement and inventory level in real time at each supply node
- Redirect shipments to satisfy surging patient enrollment or supply shortages
- Provide integrated product information and demand requests to facilitate expiry date control
- Support the ability to operate the supply chain more efficiently in direct-to-patient situations

Streamlined information flow
- Track and report clinical trial results to improve efficiency
- Manage consent information across sites, systems, and protocols to use in future research
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Figure 6. Blockchain-based product track and trace

- **Blockchain** enables product tracking to trace items and data across the end-to-end supply chain
- **All stakeholders** can access product history and data, authenticate items, and prove compliance in real time
- **Product** is registered on the blockchain and custody is recorded as the product is transferred from node to node

Legend:
Blockchain-enabled track and trace
Mobile-centric digital patient experience

Digital technologies support patient engagement during the clinical trial.

Mobile digital engagement technologies have changed the way organizations across all industries communicate, deliver products and services, and meet their customers’ needs and expectations. Biopharmas, for example, have been creating companion apps for their drugs to better support patients and care providers. Potential use cases include issuing drug adherence reminders, recording health data, and providing patients with important drug information.

The clinical supply chain can play a role in improving the clinical patient experience by replacing traditional paper-based drug labels with electronic labels (eLabels). What benefits can eLabels achieve? In aggregate, the cost to print booklet-size paper labels to meet language and regulatory requirements can be significant. Print label production may be further complicated when introducing expiry date management and other evolving regulatory requirements. Finally, paper-based labels often present information in a way that is difficult for patients to read and understand. eLabeling, in contrast, provides information in a more structured, visible, and user-friendly format (see figure 7).

Figure 7. Mobile-centric digital patient experience

<table>
<thead>
<tr>
<th>Universal label</th>
<th>eLabel</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal content on physical label to identify material and ensure patient safety</td>
<td>Fully regulatory-compliant label that can be viewed by scanning a 2D barcode using a mobile app</td>
</tr>
</tbody>
</table>
While the eLabel application is a game-changing clinical patient engagement improvement, its importance is further magnified by its likely being the first major digital application to gain broad acceptance with the clinical patient. With this, it will then serve as the information and application gateway for further engagement using the same technical infrastructure to feed content to the clinical patient’s mobile device and to gain important insights into patient adherence and study feedback throughout the trial.

**Potential value delivered**

**Increased patient engagement**
- Access key product information through a digital solution by patients and site personnel
- Leverage the eLabel process and application for further direct digital communication and interactions with the clinical trial patients

**Reduced cost and waste**
- Minimize waste produced by printed label updates
- Increase inventory agility through the ability to reroute drug supplies more efficiently

**Decreased label cycle time**
- Provide a real-time method to update labels per changing product information or regulatory requirements
- Increase supply agility by reducing label development cycle time

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**Developing a platform for digital clinical patient engagement**

One biopharma envisioned making its clinical operations and clinical supplies capabilities more patient-centric; it identified a series of digital connections that would improve both the patient experience and a clinical trial’s effectiveness and speed. Achieving the company’s digital vision depended on increasing the ease, timeliness, and utility of information being delivered to the patient. The biopharma selected eLabeling as the core digital patient use case and developed a platform solution that leverages a cloud-based, secure information portal for hosting eLabel content and future digital information exchanges, such as adherence reminders, drug administration videos, and e-diaries. The program is well underway, with the development of the eLabel patient application as its first completed solution component. Also under consideration is an operating model change that would produce a nonbranded industry mobile application to drive better adoption and reduce complexity for site personnel.
Digital technologies such as the ones in this article can help transform how biopharma companies approach clinical supplies management by incorporating valuable insights from multiple sources of data, radically improving the patient experience, enhancing clinical trial productivity, and increasing the amount and quality of data collected in trials. So why aren’t more organizations incorporating technology-enabled capabilities into their clinical supply chain and other functions? Capitalizing on specific opportunities requires a level of digital maturity—an overall strategy, culture of collaboration and experimentation, and supportive leadership—which many biopharma companies have not yet attained.

Deloitte and MIT Sloan Management Review’s fourth annual study on digital maturity shows that biopharma ranks somewhere in the middle of industries in digital maturity and adoption of flexible and adaptable leadership and learning models. While many biopharma companies are experimenting with digital, most are yet to make consistent, sustained, and bold moves to take advantage of the new capabilities. Most biopharma companies that responded to the Deloitte and MIT survey are either in early stages of the journey (25 percent) or developing their capabilities (55 percent); only 20 percent report themselves to be maturing.

Even though most biopharmas are still developing their digital capabilities, 58 percent say that digital is a top management priority and 79 percent expect to realize the value of digital initiatives within the next five years. And because differing maturity levels typically have specific capability needs, companies are taking various paths to close their digital maturity gap—most start with the digital core and leverage its collective end-to-end data to build out from there (see figure 8).

### Figure 8. The biopharma digital maturity journey

<table>
<thead>
<tr>
<th>Digitally integrated</th>
<th>Digital orchestration</th>
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<tbody>
<tr>
<td>Internally focused</td>
<td>Externally focused</td>
</tr>
<tr>
<td><strong>Demand-driven</strong></td>
<td><strong>Patient value-driven</strong></td>
</tr>
<tr>
<td>Build and extend capabilities to drive value chain collaboration</td>
<td>Joint value, outcome-focused performance management</td>
</tr>
<tr>
<td>- Robust collaboration</td>
<td>- End-to-end patient response</td>
</tr>
<tr>
<td>- Prescriptive analytics</td>
<td>- Targeted marketing</td>
</tr>
<tr>
<td>- Real-time information and insights</td>
<td>- Clinically connected value chain</td>
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</table>

<table>
<thead>
<tr>
<th>Efficiency-focused</th>
<th>Execution-focused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrate and consolidate business process infrastructure</td>
<td>Acquire, merge, partner with business units and functions</td>
</tr>
<tr>
<td>- Standardization</td>
<td>- Fragmented solution</td>
</tr>
<tr>
<td>- Network rationalization</td>
<td>- Basic integration</td>
</tr>
<tr>
<td>- Global ERP &amp; business process management</td>
<td>- Local/Point solutions</td>
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Moving forward

Thus far, the biopharma industry has been slow to digitize its end-to-end clinical development processes. Even the most advanced organizations are still piloting technologies in different areas, or focusing on point solutions and new tools to support existing processes.⁶ Our research and client experience suggest that understanding current clinical supply chain inefficiencies, identifying an organization’s digital maturity level, and focusing on specific capability needs can aid in deciding which technologies should be implemented, and in what order to move the process forward.
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Endnotes


2. Ibid.


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