



CLINICAL TRIAL SUPPLY CHAIN

Insights from the Industry





Introduction

Clinical Trial Supply Chains have always relied on unique technologies and highly specialized operators, with companies rising to meet highly complex and tailored demands to support the conduct of clinical trials at the cutting edge of pharmaceutical practice. The pandemic has shown the degree of disruption possible, and has motivated the industry to find new ways through which to build resilience in the field. Complicated geopolitical situations have further highlighted the need for increased collaboration and coordination to produce unified and meaningful responses to emergent situations. COVID-19, and the heterogeneity of responses to the pandemic - with some countries being more prone to enter additional lockdowns than others, present a challenge that the industry must overcome. Conflicts such as the war in Ukraine further complicate the picture, while regulatory and infrastructural fragmentation add new complexities for the industry to deal with. Additionally, new solutions to ensure compliance and increase transparency in supply chains that are often criticized for being too opaque are urgently needed. The current trends show that cooperation, both within industry and with regulators, will be needed to solve these systemic challenges.

The Editorial Team
Proventa International



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Challenges 2022: What Peers are Focusing on



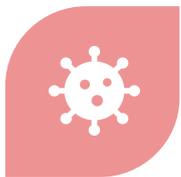
1 Collaboration

Increased collaboration with partners who can provide tailored solutions remains the key challenge for peers, particularly as they hope to select the right partners for global partnerships that can expand their own reach. Collaboration is also cited as the key to adapting with novel technologies, including Artificial Intelligence and supply chain Blockchains.



2 Flexibility

The effects of pandemic-related and geopolitical disruption have prioritized the need for flexibility, with peers seeking to future-proof their own supply chain solutions in the face of an increasingly unpredictable global climate. The need to adjust with the rise of Decentralized Clinical Trials and the supply models they require further add to calls for increased flexibility.



3 COVID-19

COVID-19 may have peaked, but its effects are expected to be lasting. Trial sponsors seek solutions that are compatible with the pandemic environment, while increasing redundancies to cope with the possibility of further lockdowns and policy changes.



4 Compliance and Chain Visibility

Regulators seek to improve standards across the industry, and many delegates are concerned about the opacity of their own supply chains. Peers cite the need for fully compliant solutions at every stage, in a bid to increase adherence to good practice and regulatory requirements and reduce dependency on providers they cannot hold accountable.



5 Talent Acquisition and Retention

A challenge that is common to many parts of industry subsequent to the COVID-19 pandemic, many delegates cited a challenge in attracting and retaining specialized talent. Firms seek solutions to this challenge by re-examining their own internal working environments as well as corporate culture. This need is exacerbated as firms look to incorporate experts in areas such as AI, which have not traditionally had a big talent base exclusive to the life sciences.



Blockchains in Pharma Supply Chains - Insights from PharmaFEATURES

Pharmaceutical manufacturing is a complex, burdensome, beast. The production of just one drug may involve complex chains of suppliers spanning different continents, while also necessitating large amounts of data management. This is so that the journey an agent has taken can be fully traced – not only for traceability and accountability, but also to weed out counterfeits amidst a growing black market. However, committing to a fully traceable life cycle when suppliers may have conflicting interests, can be rife with questions; blockchain is a technology that seeks to solve that.

While most people are familiar with the use of blockchain technology for cryptocurrencies, that is not its sole application. Blockchains are distributed ledger networks which can verify transactions or other information, without the need to have a centralized ledger holder that is privy to all the information. This ledger is held by all members of the decentralized network; when new blocks are added to the chain, they are added to all copies of the ledger, irreversibly. Tampering with one copy of the blockchain is ineffective; the rest of the blockchain will still show the genuine account of events.

This makes falsification of the information held extremely improbable. Due to their distributed nature, blockchains can also bring together different parties that would not entrust their open information to one another – a clear advantage. Blockchains display clear potential for the enforcement of the FDA’s new Drug Supply Chain Security Act rules, which all manufacturers must adhere to by 2023.

Global Partnerships

One of the most obvious applications for blockchains in supply chains is to authenticate returned products. The Healthcare Distribution Alliance estimates that over 60 billion units are returned annually; wholesalers face the enormous burden of tracking down the manufacturers of these products to verify their genuinity. Blockchains can simplify and vastly accelerate this process – from taking days to mere seconds, through the use of distributed, instantly verifiable databases.

A global consortium consisting of leading companies from the industries already aims to apply such technology: the MediLedger Network, which counts Pfizer, Gilead, Genentech, Amgen and others among its members. The network has completed a pilot scheme to show how blockchain can fulfill a further role of tracking changes of ownership across the supply chain with confidentiality, and in real-time. This allows products to travel with their own embedded, automatic “black box” to provide a paper trail of accountability, while concealing any business intelligence that may have otherwise been revealed, had more conventional ways of tracking been involved.

Other partnerships are also emerging in the area. CEVALogistics has partnered with Maersk and IBM to provide blockchain-enabled solutions across a variety of shipping areas, including pharmaceutical supply chains. Their solutions also highlight the need for digitized inserts that are usually included in product packaging. The need to correct or update leaflets and inserts can result in unnecessary and otherwise avoidable product recalls – 13% of recalls are estimated to be for packaging information. Similar issues are observed with cargo and shipping information, such as bills of lading – 10% of which are estimated to contain incorrect information. Blockchains aim to ameliorate such issues.



Commercial Applications

Blockchain technology is already being leveraged for the monitoring of the environmental conditions across the supply chain of pharmaceuticals. This has happened in a collaboration between OCEASOFT, which designs atmospheric monitors, and Chronicled, an American blockchain firm. The monitors track the levels of carbon dioxide, temperature and humidity throughout the supply chain and record them on a database managed by the blockchain. Should any unacceptable or denaturing changes happen to these conditions, a smart contract is in place to automatically identify the infringed parties and compensate them – and also recall any defective drugs.

Another company making waves through the use of blockchain has been VeChain. VeChain specializes in patient medical records, granting patients full control over their records and who they choose to share them with. In turn, this smart sharing can result in intelligent solutions such as NFC cards that can be used for identification on site, and improve the digitization – but also the security of records.



Their technology has been applied at the [Intelligent Tumour Center](#) in China and the [Mediterranean Hospital of Cyprus](#). VeChain is also in a partnership with Bayer for the co-development of [Csecure](#), which aims to bring blockchain technology to clinical trial supply chains.

Naturally, it may be tempting to consider the limitless applications of blockchain technology across vast numbers of areas in pharmacy. However, it is wise to remember that blockchains are an expensive, energy-intensive technology. Blockchains require nearly full connectivity of the entire supply chain to function properly – this comes with concomitant infrastructural costs. The cost that comes with storing information across hundreds of nodes – and the computing power expended in the processing of such data, makes blockchain a technology that is best applicable in areas where it displays very clear advantages over other technologies. Record-keeping, rules enforcement and data synchronization are two areas where this has become evident. Other areas may prove to be worth it in the future, as well.

Additionally, the cost of employing blockchain technologies itself may become drastically lower as we see increasing adoption and improvements in computing.

The future remains clearly promising for blockchain technology in the industry however. With regulators pursuing increasing guidelines for supply chain transparency, the technology can provide an invaluable tool for meeting these demands. Creative applications of the technology can lead to cost savings while improving compliance. Another effect that cannot be underestimated is the forging of closer bonds between trading partners in the industry. Trust may be in short supply through conventional collaboration methods for the track and trace of supply chains, but blockchains can improve on that through their distributed nature.

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Top Five Investment Areas

Proventa asked delegates at its events to speak about their investments for the coming year. Delegates cited a need to diversify and provide resilience to their own supply models while rising to meet the challenges presented by an increasingly uncertain world.

Cold Chains



Delegates are expanding their own investments in cold storage supply chains, with many novel therapeutic modalities requiring cold transportation. The subject was exacerbated with COVID-19 vaccines, which has put increasing pressure and strain on existing cold chain infrastructure, with peers investing to expand capacity.

Clinical Trial Logistics



Diversifying supply capabilities remains a key concern in the industry, particularly as clinical trials grow in complexity and vary in their protocols. With decentralization on the rise, suppliers will need to adjust to increased heterogeneity in supply models - with many embracing direct to patient, or fewer, more distant and varied sites.

Drug Storage & Distribution



Drug storage and distribution is becoming another pressing concern, particularly as trial sponsors increase demands for unique storage requirements to adhere with diversifying trial protocols and increased regulation. Distribution models are also experiencing rapid change as a result of the pandemic and the adaptations the industry has had to embrace to respond to it.

Packaging and Labelling



Solutions for increasingly complex packaging and labeling problems are another key area of investment, particularly as regulators seek to increase accountability in the supply chain. Many have embraced electronic labeling with distributed tracking and tracing to improve transparency, but solutions such as blockchains are also on the rise to ensure compliance.

Consulting

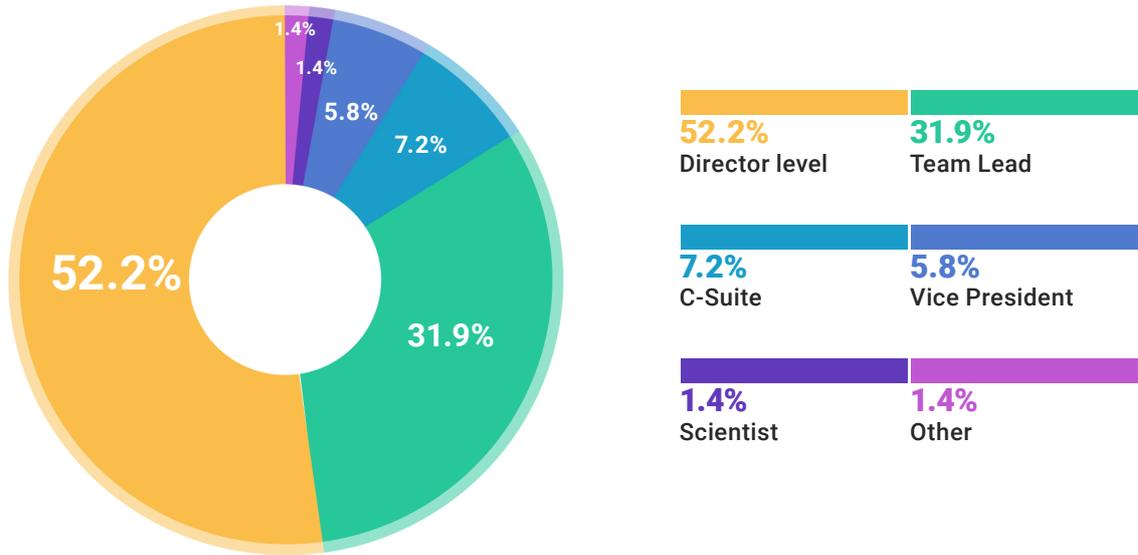


Delegates cited increased spending on consulting services as they seek to respond to multiple emergent situations and novel technologies across the globe, with the industry facing an unprecedented scale of change and pressure for adaptation. With new treatment modalities, novel trial design protocols and geopolitical concerns, this is likely to continue.

Delegate Breakdown:

Attendees at Proventa's 2022 Strategy Meetings

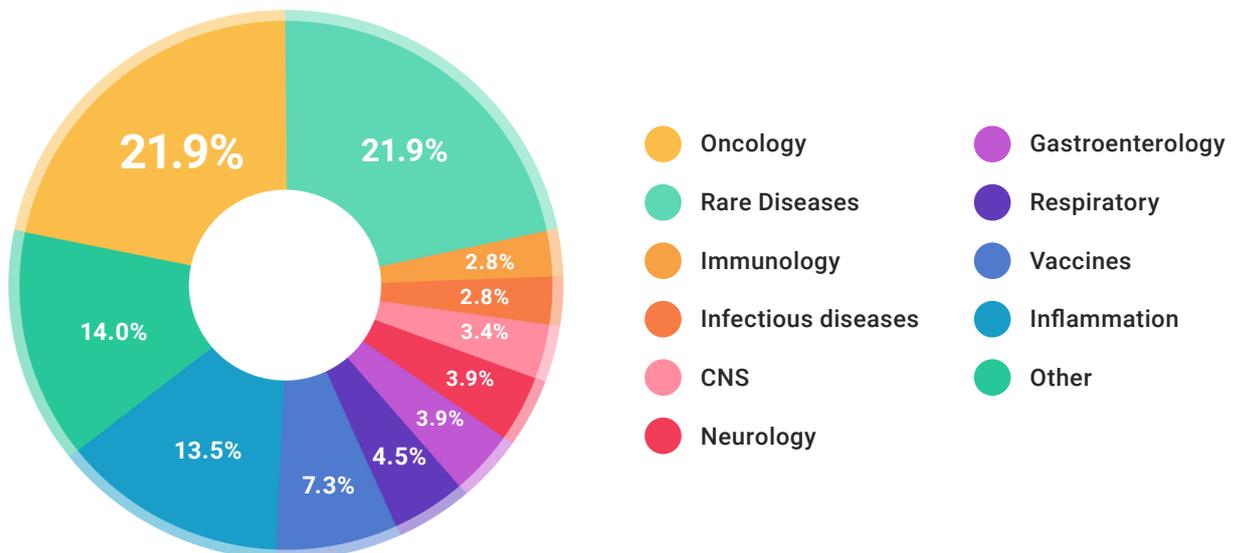
2022 Attendee Breakdown



Drug Development Stages



Therapeutic Areas



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