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Life Sciences

White Paper

The Clinical Trial Supplies Control Tower:

Gain End to End Visibility for your Clinical Supplies

About the Authors

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Yezhuvath Vinesh Balakrishnan works in the TCS Life Sciences vertical focusing on the supply chain management domain. He has over 22 years of experience in supply chain management, manufacturing, process excellence and IT management across pharmaceutical and chemical industries. An alumni of Birla Institute of Technology and Science (BITS Pilani), he holds a graduate degree in Chemical Engineering and a post-graduate degree in Mathematics. He combines process orientation and analytical abilities with an in-depth understanding of technology to develop IT solutions that drive productivity, efficiency and governance in the life sciences supply chain and manufacturing domains.

Vinesh is actively involved in numerous supply chain as well as outsourcing transformation initiatives. As a member of several groups within TCS as well as with client and partner and/or alliance organizations, he has helped conceptualize and develop innovative solutions, as well as enabled process optimization.

Abstract

According to industry reports,[1] the global clinical trial outsourcing market grew at a CAGR of 14%, indicating the increasing globalization of clinical trials, both in the pursuit of faster trials as well as market expansion. However, this trend is leading to more complexities in the trial process.

IMS Health estimates[(2)] that in order to eliminate the risk of avoidable design defects as well as patient recruitment issues, a sponsor spends USD 26 million on running 100 clinical trials a year. 60 percent of approximately USD 110 billion spent by the industry annually on global R&D, or 6.5 percent of the revenues is devoted to clinical trials.

The evolution of the Functional Service Model by clinical research organizations (CRO), which heralds the changing business models of engagements for clinical trial management, is adding increased nodes to the clinical trial supplies value chain.

Studies indicate that:

- 80 percent of all clinical trials are delayed by more than a month, leading to an estimated loss of USD 1 million.
- One in three of all investigative sites fails to enroll more than a single patient.
- There are roughly three amendments per protocol, a third of which could have been avoided.
- Each protocol amendment causes a delay in excess of 50 days.
- Recruitment difficulties along with protocol design flaws lead to 20% of such amendments

Clinical supply chains can be more responsive if there is an early indication of the probability of occurrence of such challenging situations. A modern control strategy for internal efficiency and effectiveness helps ensure that events are captured and analyzed in real time, enabling the supply chains to respond easily beyond time zone, geography and language barriers.

This paper highlights how the concept of the control tower can be leveraged to make the clinical supply chains more responsive if there is an early indication of the probability of occurrence of such challenging situations. A modern control strategy for internal efficiency and effectiveness helps ensure that events are captured and analyzed in real time, enabling the supply chains to respond easily beyond time zone, geography and language barriers.

[1] Tufts University, Tufts Center for the Study of Drug Development Impact Report, , Vol. 13, Number 5, 2011

[2] IMS Institute for Health Informatics(2012), The Global Use of Medicines: Outlook Through 2016, July 2012

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Contents

1. Introduction

Clinical trials are getting more global, complex, larger and focused, with CROs facing added pressure to complete them faster.

Figure 1 is a snapshot of the current operating environment in clinical trial supplies organizations. Key stakeholders in the ecosystem along with critical objectives and challenges of clinical trials define and influence this environment.

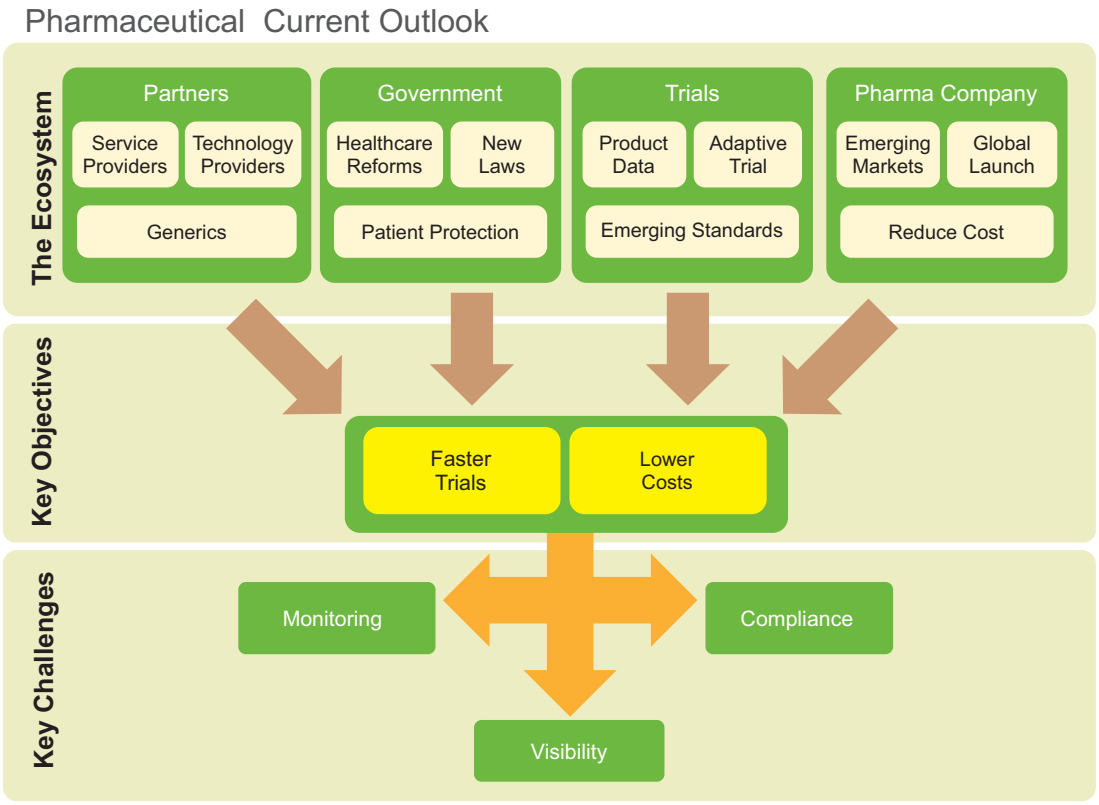

Figure 1: Several Influencers and Challenges affect the Operating Environment in a Clinical Trial Supply Chain

Pharmaceutical companies are expanding their clinical trial reach into new countries. They are also enhancing their portfolio in existing markets and introducing new products faster in the emerging markets, to reduce or contain costs. Clinical trials are also witnessing changes in terms of adoption of standards, adaptive clinical trials (or virtual clinical trials), and stringent labeling requirements for drugs.

The growing trend of outsourcing and the rise of specialist organizations mean that the permutations and combinations between trial sites, clinical materials and services offered are resulting in increasing number of supply chain nodes.

A few pressing challenges that contribute to increased uncertainty in the value chain include:

- Unpredictable trial duration and staggered subject recruitment.
- Processes relating to management of overage materials, monitoring of shelf life and expiry, controlled transportation, compliance with labeling requirements in global trial scenarios, and re-labeling can suffer - due to the lack of or limited real time visibility into clinical material location.
- Trade compliance, if not managed properly, leads to delays in customs clearance, impacting timelines and the ability to predict ETA (Expected Time of Arrival) accurately.
- Sub optimized and/or unreliable processes impact the drug reconciliation process, leading to trial closure delays and compliance issues.

2.The clinical trial ecosystem

The clinical trial supplies (CTS) value chain is subjected to the pulls and pressures of the operating environment that comprises elements such as internal trial objectives, operating laws, regulations and competitive forces. The CTS value chain and the ecosystem (illustrated in Figure 2) needs a foundation for end-to-end visibility to secure a tighter alignment of supply and demand planning while enabling faster decision making and execution .

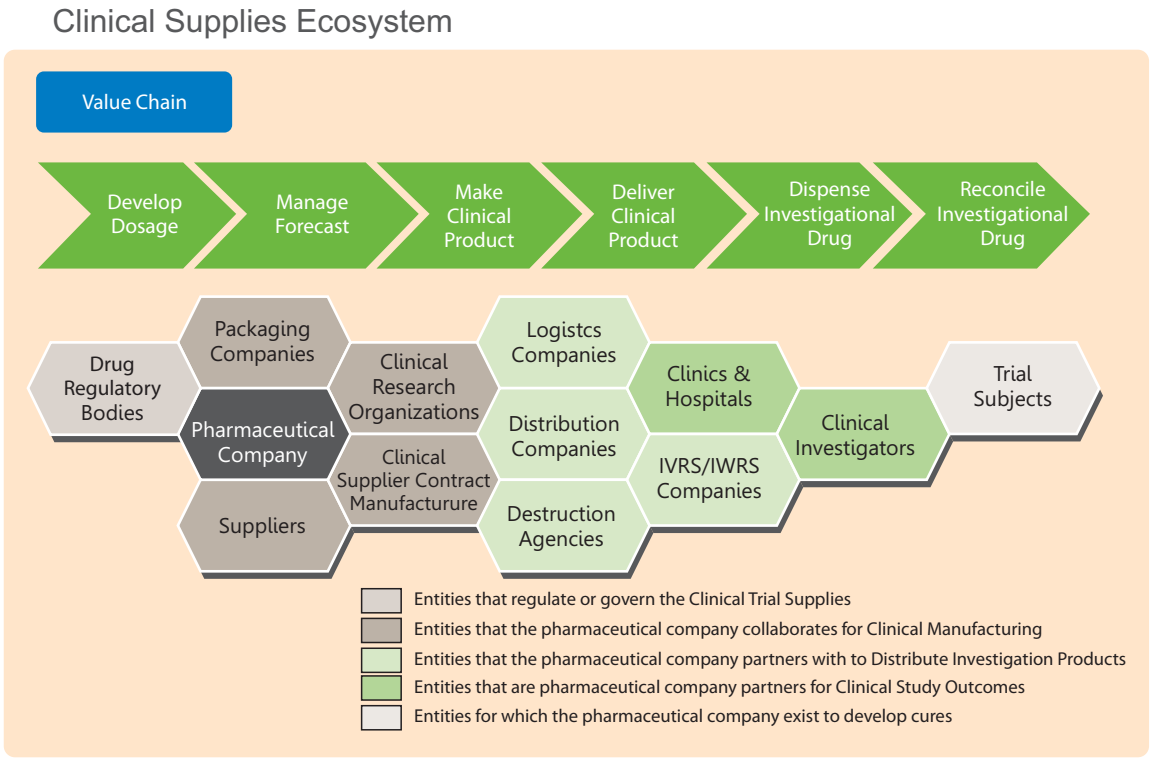

Figure 2: Comprising several stakeholders, the clinical trial supplies value chain and ecosystem is complex and dynamic.

Pharmaceutical companies collaborate with clinical research organizations (CROs), clinics/hospitals, technology platform vendors such as IVRS systems, packaging and clinical manufacturing units, labeling entities as well as simulation and modeling experts to make a drug therapy commercially feasible. Medicines or drug therapies are made in the clinical manufacturing sites of the pharmaceutical or its partner companies and transferred to clinical warehouses. These products are sometimes subjected to price negotiations, and price controls by group purchasing organizations, pharmacy benefit managers (PBMs), and government health programs. They are then delivered to clinical investigators, who dispense these items to trial patients. For smooth operations within this value chain, all stakeholders need to operate in compliance with regulations, guidelines and procedures defined by drug regulating agencies of all the countries they operate in.

3. Role of a Control Tower in the Clinical Supply Chain

The supply chain control tower, also referred to as operations center, supply chain radar or command center, is a location or central hub that provides visibility into the inbound and outbound material and information flows, and serves as an extended means for end-to-end visibility.

It provides a centralized view of the planning and execution systems across the extended enterprise for sensing, recognizing, and responding to changes in supply and demand. The 'control tower' approach offers visibility into supply chain events, and like a radar, enables quick identification, verification and control of situations that might disrupt desired results.

P&G Deploys Commercial Control Towers

P&G installed 'control towers' to handle distribution in its emerging markets. They allowed a comprehensive and complete view of inward and outward movement of goods - just like an airport control tower that directs the path of an airplane.

The control towers helped in delivering maximum truck fill for every kilometer travelled in the fastest possible time, in an ecologically friendly manner.

3.1.1Key Attributes of a Control Tower

The control tower is a technology driven concept. To be effective, all functions, organizations, and processes need to be combined with technology to provide strategic, tactical and operational level control for the clinical trial supplies value chain. Effective program governance, trading partner or ecosystem partner connectivity, strong analysis capabilities, and quick decision-making mechanism are the foundational elements of a reliable control tower design.

It can serve as a powerful navigation tool to control operations by:

- Enabling long term and short term decision-making in line with strategic goals and objectives.
- Bringing together data from different sources for analysis.
- Generating visual data for enhanced visibility to identify emerging risks
- Simulating consequences of the various decision options.
- Executing and tracking the decisions taken.

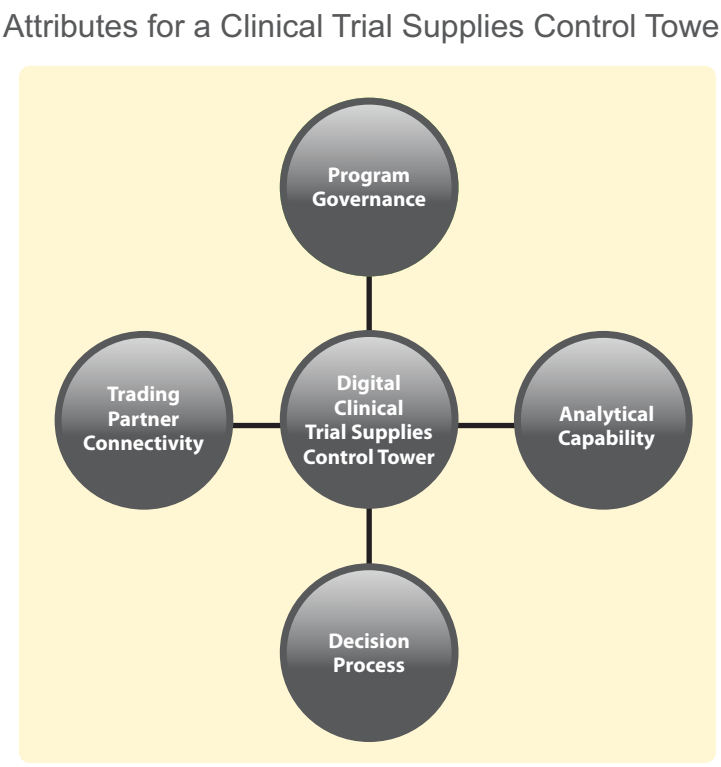

Figure 5: A Clinical Trial Supplies Control Tower Provides Several Strategic Benefits

3.1.2 Leveraging Control Tower for End-to-end Visibility

Visibility, although seemingly very simple, becomes enormous in the context of clinical materials, as it deals with information flow involving people, processes and technology. Visibility in clinical supply chains demands real time communication between the different nodes of the clinical trial network. From an IT perspective, it is the ability to collect and analyze distributed data, generate specific observations and recommendations, and provide insights and actionable information to make smart decisions.

Improvements in RFID technologies, advances in near field communication, and advances in packaging technologies along with the ubiquitous presence of mobile networks enable the design of 'smart cupboards'. These work with 'smart packaging' and 'smart labeling' to enable effective real time distribution of products, leading to better inventory management, as well as improved drug reconciliation. Another example is the use of mobile with a Bluetooth-enabled reader that can scan a previously barcoded drug and track movement and dispense to patients. The process facilitates automated capture of information that is linked to the patient, and used to update the case report form (CRF).What this also entails is a constant monitoring of sensors to ensure that the devices are operational for requisite event triggers.

The CTS Control Tower should provide this clear all round visibility of the clinical supplies movement, as well as the factors that influence that movement such as import clearances and temperature controls.

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4. Overview of the Clinical Trial Supply Chain

Clinical trial supply chain is large, complex and global comprising several stakeholders ranging from raw material providers, distributors, and marketers to customers. Two key characteristics of the supply chain include:

Figure 3: Clinical Trial Supply Chain comprises complex processes

- **Uniqueness and Complexity**

Key requirements such as patient safety, product tracking, short expiry cycles, varying regulations, as well as issues such as patient retention and data accuracy result in a complex and unique CTS ecosystem.

Its complexity is best illustrated with the help of an example. Consider a case of one active ingredient, leading to one Investigational New Drug (IND) involved in the clinical study arms - with four dosage forms, one placebo and one comparator, to be conducted in six countries across three continents. This results in a significantly large number of supply chain nodes for a relatively small quantity of materials that needs to be distributed across continents and sites over an extended period, under controlled conditions. This is to ensure that the right drug goes to the right subject at the right time in the right condition, every time a patient is enrolled.

Clinical trial supply chains are also characterized by differentiated networks, short response time, flexibility, transparency, and outsourcing competency. The chain must be equipped with well-defined flexible and adaptive strategies to support clinical study programs related to investigational drug, placebos and comparators.

- **Agility and Responsiveness**

While clinical trial supply chains need to be quick to respond to high expiration and low volume situations, the typical practice is to use anticipatory demand models created far ahead of the need. The factors that determine or drive the calculations are characterized by a high degree of uncertainty, and this is a cause for significant concern.

This apart, the advent of regulations related to cold chain, and the gradual acceptance of adaptive clinical trials demand transition from a 'build-to-stock' approach to a more responsive 'agile supply chain'. This constant pressure to achieve minimum lead time and the lowest possible cost also makes the life of a clinical supply manager more difficult as well as interesting.

All of this requires clinical supply chains to be supported by seamless visibility across geographically distributed sites and multiple channels of access, and integrated with varied applications. The critical factor is that the supply chain has to be operative in a controlled and flexible manner, through the adoption of best work practices to promote global utilization of resources.

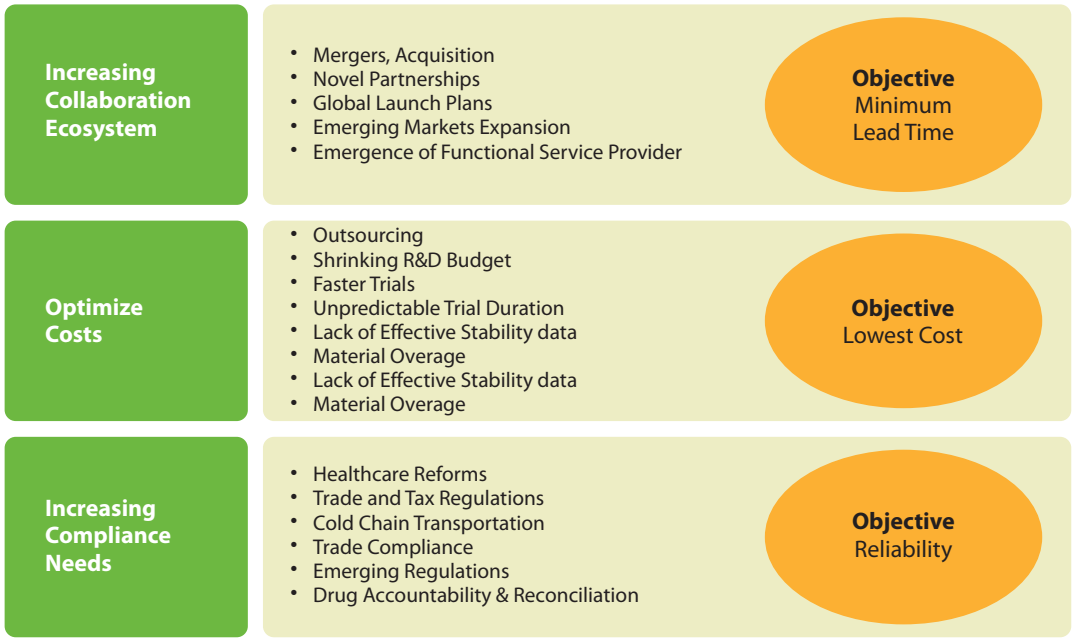

Figure 4: Minimum Lead Time, Low Cost, and Reliability are the Key Objectives of Clinical Supplies Companies

Figure 4 illustrates the three critical objectives of clinical supplies organizations. Therefore, the following issues need to be addressed effectively by the CTS control tower:

- How it plans to cope with the increasingly collaborative ecosystem
- How it can achieve a high degree of compliance
- How it intends to ensure the lowest possible trial supplies TCO
- How it proposes to exploit the advancements in smarter packaging

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These questions necessitate an increased (near) real-time supply chain visibility, multi-player monitoring and effective compliance, with a strong focus on the growing supply chain risk. Furthermore, new disruptive technologies like digital applications and the collaborative nature of specialized communities, along with the rise of the Internet of Things or sensor-based event applications provide an opportunity for improved outcomes. This scenario therefore demands a revisit of the goals and priorities of the clinical trial supply chain functions.

The clinical trial supply organization can meet the challenges through new processes, revamped skills matrix of its people and better organization and integration of systems with an innovative digital strategy. The clinical trial supply team needs to exercise complete control over their data and supporting tools to plan and manage the flow of materials between partners, subjects and investigators. Driving this initiative is the CTS Control Tower – the principal strategy tool for clinical trial operations.

5. Process of Building a Clinical Trial Supplies Control Tower

Creating an effective control tower requires consolidating information from several sources. This helps build a holistic two-tiered system that consists of the control tower, as well as unit towers for planning, tracking and decision-making.

5.1.1 Integration of Information

The clinical trial control tower is realized by integrating information residing in several systems within the extended ecosystem. Minute details of every transaction related to - placebo/comparator orders from a supplier, products manufactured across locations, documents created, shipments to and from a site, dispensation to subjects (patients) enrolled in a trial, payments due and paid to a site or investigator, and events in the chain – are captured, analyzed and acted upon.

The actions taken are recoded, communicated and tracked to closure. To achieve the anticipated results, the clinical trial supplies control tower needs to deal with the immediate real world logically and effectively.

5.1.2 Vision for the Control Tower

The vision for the control tower is envisaged as a two tier structure (see Figure 6.)– with the top tier providing a complete view of the clinical supplies organization, and the second tier comprising unit control towers for each of the key functions within the clinical supplies.

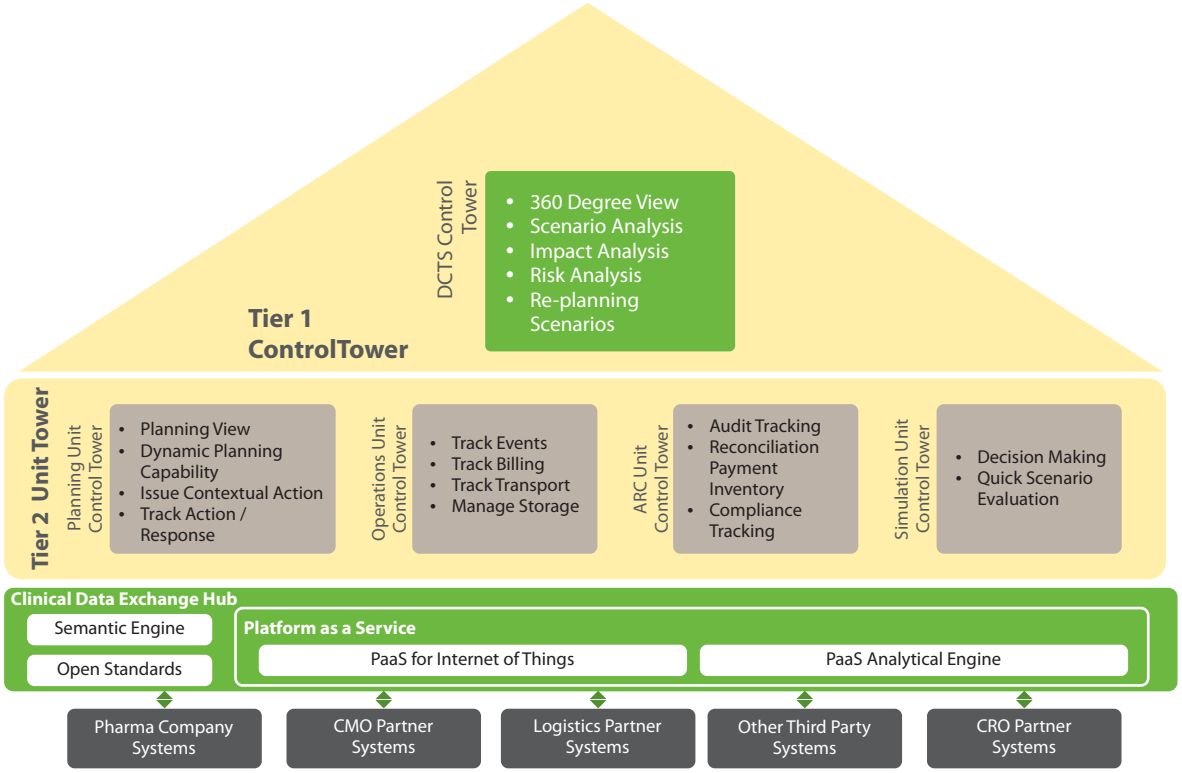

Figure 6: The Two Tiered Clinical Trial Supplies Control Tower Offers a Holistic Vision of the Clinical Trial Supply Chain Ecosystem

Pharmaceutical companies owned systems, and third party-systems owned by ecosystem partners are connected through a data exchange hub. This hub should be built using existing as well as emerging standards to support standardized information exchange with least disruption to the partner system.

CTS is best delivered as a hybrid Platform-as-a-Services. Existing technologies like RFID, barcode and emerging trends like Internet of Things/machine-to-machine should be utilized to provide faster and standardized information for logistics and documentary events. This can help strengthen CTS' capabilities to transfer and analyze vast amounts of data, as well as process and present the output as a continuous feed to individual control tower units. It can thus bring together elements of discrete event simulation, and ecosystem social collaboration to achieve greater visibility.

Control towers must be designed with end objectives of a clinical supplies company in mind. Key factors to be considered while designing the two-tier vision include:

- The Tier 1 units can be designed in line with organizational or assigned responsibility. They are not intended to replicate specific business process functionalities like forecasting, or manufacturing. For example the simulation unit is focused on simulation, forecasting and optimization of event statuses.

- It is essential to build an efficient ARC (Audit, Reconciliation and Compliance) unit, which keeps track of audit, reconciliation and compliance events. It issues the needs for compliance, as well as tracks the progress or adherence to key requirements. The ARC unit ideally generates alerts and events to ensure effective compliance with important requirements such as control temperature shipments. It also keeps track of the clinical supply costs.
- Control towers need to be customized based on organizational factors including the scope, processes, functions and geographic reach. A network of control towers using a central and a series of regional towers is yet another option.

6. Conclusion

Dynamic market changes demonstrate a need for more collaborative IT solutions that can address new risks across the clinical trials supply chain. The clinical trial supplies control tower provides for the execution of a modern control strategy built on a digital foundation.

The advent of Internet-of-Things, RFID enabled clinical supplies, controlled temperature shipping and technology advances in mobility have helped simplify the collection of data, and triggers event information to the control tower. The ecosystem in which the control tower should reside is already being created, and the sensor based application as a service further makes it a cost effective solution.

While the control tower provides for immediate action in real time or near real time, it also serves as a huge repository of information. The control tower builds up a huge accumulation of events and responses over a period of time, and the richness of this data lends itself to 'big data' based insights.

CTS control tower provides a strong digital strategy for clinical operations, and can be easily extended to the entire clinical trial operations environment. It comprises digital elements including event signals, pervasive computing, data velocity, seamless collaboration, cloud platform, enhanced security, and analytics that enable 'digital re-imagination'[3] for better business results.

[3] The Digital Enterprise: A Framework for Transformation, Perspectives, TCS Consulting Journal, http://www.tcs.com/perspectives/Pages/default.aspx

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We draw on our experience of having worked with 7 of the top 10 global pharmaceutical companies and 8 of the top 10 medical device manufacturers. Our commitment towards developing next-generation innovative solutions and facilitating cutting-edge research - through our Life Sciences Innovation Lab, research collaborations, multiple centers of excellence and Co-Innovation Network (COIN™) - have made us a preferred partner for the world's leading life sciences companies.

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