4G CLINICAL

Supply Chain Optimisation

Investigator Sponsored Trials (IST)

Knowledge Sharing Series

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Supply Chain Optimisation

Leveraging RTSM/IRT Systems to Avoid Wasted Supply, Enable Drug Pooling and Accurately Project Demand

Purpose

Unlike industry-sponsored trials focused on regulatory approval of new medications, Investigator Sponsored Trials (ISTs) are developed and executed under the direction of third-party clinical investigators who are physician researchers, often within an academic institution. The investigator or affiliated study sponsor, working in an academic medical centre, is responsible for study conception, design, operational execution, data handling, and data analysis and interpretation, along with subsequent publication. **Source: www.centerwatch.com/articles/15646**

ISTs are a beneficial method to better understand the potential risks, safety and additional uses that can improve patient health. Participating in ISTs, from a biopharma point of view, however, does present challenges with supply chain management. This white paper addresses the common challenges faced by biopharma organisations with regards to supply chain management and offers insight into solutions by leveraging the RTSM/IRT.

Investigator Sponsored Trials *– Process Overview*

At the pharmaceutical company, ISTs are usually run by the Medical Affairs department, not Clinical Operations
The pharmaceutical company is the manufacturer and supplies the drug directly to the Investigator sites.
The site is responsible for writing the study protocol and sends to Medical Affairs at the sponsor. Medical Affairs determines whether to approve the protocol and study, and subsequently provides approval for the sponsor to supply the drug to support the protocol. The Investigator is responsible for submission and approval of the protocol with the regulatory authorities. During study conduct, the site runs the study and re-supply of IP is typically handled by the Clinical Supply Operations function at the sponsor. As a result, Clinical Operations is left out of the loop with regards to planning, setup, tracking of enrollment and overall execution of these studies.

IST Supply Chain **Challenges**

Lack of Transparency into Supply Demand

For many sponsors, ISTs are managed on a local or regional level while the global Medical Affairs group approves the overall structure. This complicates both supplies demand and aggregation significantly as the local Medical Affairs teams are disconnected from the broader company/compound strategy.

There is very little transparency on how much drug will be needed to support ISTs. A typical sponsor can have hundreds of ISTs running at any given time, and when an IST has multiple sites, it can become quite complex. Project too much demand, you run the risk of wasting expensive drug. Project too little, you may not have enough drug to cover both ISTs and the company-sponsored studies.

ISTs Pull from Both Commercial and Clinical Supply

Many ISTs are managed with commercial SKUs as the drug may not yet be submitted or approved in that country, or when blinding is needed, clinical supplies are used. As a result, the company is facing demand from both commercial and clinical SKUs for the same program/product. Supply originates from separate manufacturing sources with different decision makers on capacity and commitments to product availability. This presents a unique challenge for sponsor supply teams in projecting demand for study drug, allocating supply at the program level, scheduling production to maintain adequate inventory and management of distribution to sites.

IST Supply Chain **Challenges**

Compliance with Sunshine Reporting

Manufacturers also must track drug given to the sites for sunshine reporting. The Sunshine Act is a section of the Patient Protection and Affordable Care Act of 2010 that requires pharmaceutical and medical device companies to report to the federal government certain payments and other transfers of value that they make to US physicians and teaching hospitals. For ISTs, the PIs are not paying the manufacturer for the drug, but rather have an arrangement to share data and report findings together. Therefore, the value of the drug given to the PI becomes subject to sunshine reporting requirements.

Traditionally, tracking ISTs for both supply and sunshine reporting purposes is done manually. The site will send a form to the manufacturer requesting a certain amount of drug and it is up to Clinical Supply Operations to determine whether the request is legitimate based on information obtained from either Medical Affairs or the site directly regarding enrollment.

Some sites may ask for several years of drug supply, without taking expiry into consideration. Other sites may request more supply overage to account for planned enrollment versus actual patients on study. This often results in wasted drug. From the manufacturer point of view, how do you know how much drug supply to send? How can you keep track of all the ISTs, project demand, avoid waste and accurately account for the value?

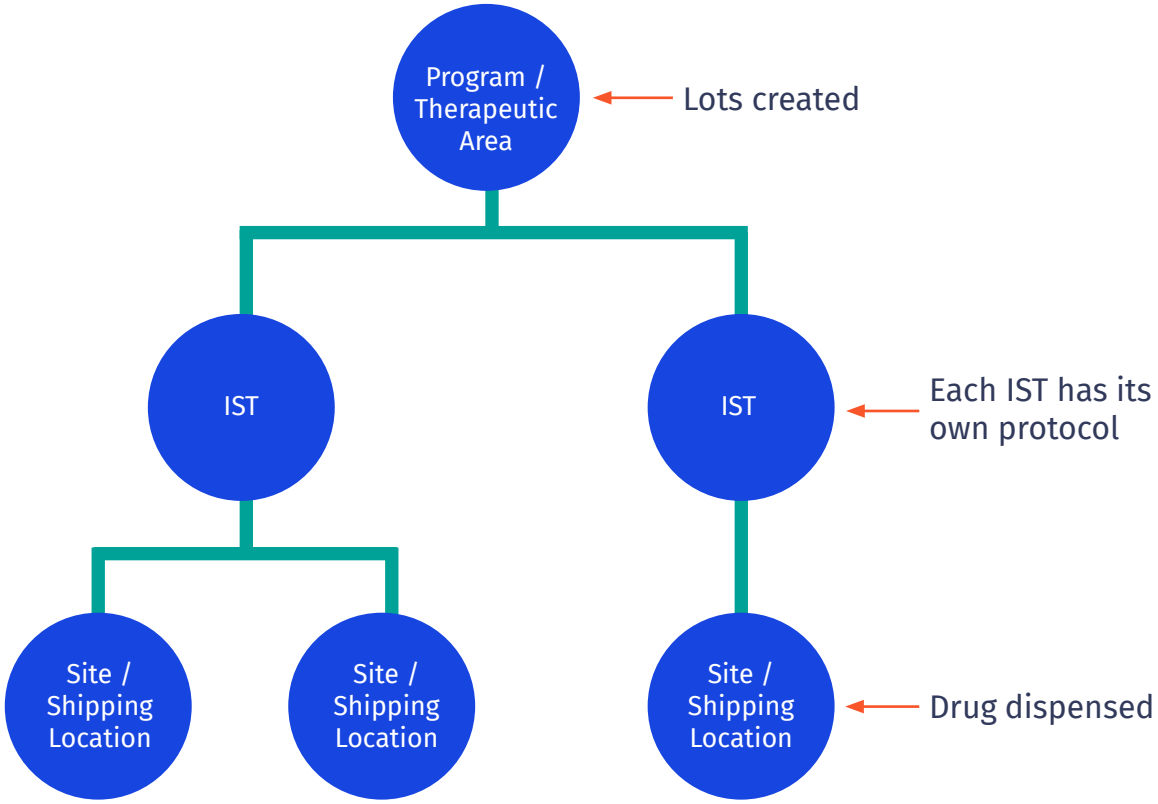
The **Solution**

Leverage the RTSM/IRT to Track IST Supply and Project Demand

While not traditionally used for ISTs, a modern and flexible randomisation and trial supply management (RTSM) system can solve some of these challenges.

The RTSM must be configured to adapt to the different terminology required for an IST. One way configuration can accommodate ISTs, the "Sponsor" designation changes from the pharma company to the Investigator site. The "Study" can now capture information at the program level and "sites" can be used as the shipping locations. This is just one of many ways an RTSM can be configured to meet the needs of an IST program.

IST Study Architecture



The **Solution**

The RTSM can also be set up so that sites are able to order drug directly through the RTSM. When they enter the order request, the RTSM can require a site to enter justification for the quantity they want such as number of patients, how many months of supply that represents, etc. Any automated resupply depends on the site doing one of two things – entering the demand (i.e. number of patients) or entering the total consumption over time.

If the sites add patients and enter visits, the system can perform simple dispensing. If the preference is to have sites track consumption by entering the quantity consumed at the patient level or site level, just as site inventory would be marked as lost or damaged in the RTSM for a regular clinical study, the system can be configured to change inventory status to consumed. With this type of setup, minimum/maximum settings are used to automatically trigger resupply (once they are below x kits on hand, we send them y – the minimum is the x, the maximum is the y).

Manufacturers also can use the RTSM to pool supply across multiple ISTs and shipping locations. If the site can add patients to the RTSM, the manufacturer can easily project future visits, upcoming demand and track supplies used for a given IST.

Although not traditional, using a modern, flexible RTSM for ISTs provides the sponsor with several key benefits. Manual management of the IST supply is not scalable, so with an increasing number of ISTs, automation of this process is critical. Other key benefits include avoiding waste, pooling supply across all ISTs in that program, transparency of IST status and maintaining a record of shipments to facilitate sunshine reporting.

Most importantly, an RTSM system helps sponsors track and project demand for all manufacturer sponsored studies and ISTs, accounting for the use of both commercial and clinical drug product.

The caveat? For this approach to work, sponsors must work collaboratively with sites to ensure the system is used properly. There needs to be a clear communication strategy, and possibly retraining, with the sites on this new approach.

Interested in learning more or discussing various IST approaches?

Contact us at
www.4gclinical.eu

Meet **Kathleen Greenough**

About the Author

Kathleen Greenough, Director of Client Solutions at 4G Clinical, has 16 years of experience in life sciences spanning Clinical Operations, Finance, and IT. Her wide range of solutions implementation expertise includes RTSM, CTMS, trial costing tools, OLAP financial suites and patient enrollment planning.

Kathleen has also spent many years as a Clinical Financial Planner and Analyst at a major biotech in Cambridge, MA, gaining a broad and deep understanding of the challenges inherent in Clinical Development. Specialising in software adoption and a frequent speaker at industry conferences, Kathleen is most in her element when working within a user community to facilitate solutions that are insightful and truly helpful.

Curious to hear more?
Explore our Resource Center

Still have questions?
Contact us today to start a conversation.

About 4G Clinical

We reduce the time it takes to commercialise vital medications by delivering validated, easily extendable RTSM capabilities to Pharma and CROs faster than anyone in the world.

4G Clinical is driven by a single purpose: bring crucial medicines to those who need them, faster. 4G Clinical believes that the way to accelerate clinical research is by disrupting the way trials are executed. That's why we have revolutionised RTSM (randomisation and trial supply management) and supply forecasting capabilities and services from the ground up.

4G Clinical is committed to helping sponsors and CROs follow the science, wherever it may lead, as quickly and as safely as we can. While we will not discover the next novel compound in the lab, we are doing our part by leveraging our extensive experience and technological innovations to bring speed and agility to clinical trials.

Prancer RTSM®

Our 100% configurable and agile RTSM is built for the clinical trials of today and tomorrow.

4G's RTSM platform, Prancer RTSM®, utilises natural language processing alongside integrated clinical supplies forecasting and management functionality to slash development timelines, increase operational efficiencies and offer exceptional quality.

Bringing crucial medicines to those who need them, ***faster.***

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