Case Study

Clinical Supply Management Improved with Single IRT Solution

Service Areas: Supply Chain, Clinical Operations
Lifecycle Stage: Clinical

A cancer treatment company with a strong development pipeline had more than a dozen clinical studies in process and that number was growing. A lean team was managing everything and, like many emerging biotech companies, relied on CROs for many clinical operations activities.

As those programs progressed through development, our client was dealing with 3-4 CROs at any given time. Each CRO brought their own way of operating and their own proprietary/preferred IRT software solution for managing the trial materials supply and scheduling. IRT solutions ensure clinical material and ancillaries are available at the sites when needed, manage randomization of materials, and trigger replenishment and packaging runs for clinical product.

Our client was struggling to manage the growing complexity of having multiple IRT solutions across their portfolio of active studies with limited internal resources.

The team responsible for managing the trials looked for ways to reduce that complexity. With limited time, experience, and familiarity with IRT, they brought in Converge Consulting for access to clinical supply management experts. Working together, we quickly determined it was time to standardize their clinical processes around a single IRT solution.

Selecting the Clinical Supply Management Solution

Our client had 10+ studies in queue that would leverage the new IRT solution. They also had previous experience with several clinical supply management systems, so they knew some of what they did and did not like about those solutions.

We worked together to define core requirements and business needs. This informed an evaluation of leading IRT vendors, identification of a shortlist, and then a comparison between the finalist candidates.

The ultimate decision came down to some of the most critical differentiators for maintaining agility in the clinical supply chain: ease and cost of making system changes during active studies. These are important drivers because the clinical trial environment can be very dynamic with frequent protocol changes.

Bringing the IRT Systems Online

Once the solution partner was selected, we worked closely with the client to implement the new IRT solution, so it supported the upcoming study timelines.

IRT systems are different from many other software systems because they are implemented repeatedly. Each trial that a company runs typically requires a newly configured instance. Then, each installation goes through thorough validation and testing, as well as revalidation and/or retesting if there are any further significant changes.

One of the most challenging aspects to successful IRT implementation is the involvement of many parties across functional areas. Clinical Operations, Supply Operations, Biostatistics, Data Management, and Quality all play an integral role for configuration and data loading. This specification process is daunting for many clients.

The Converge team demystified the process and managed the internal communications crucial to cross-functional success. Our consultants' deep experience leads to asking the right questions at the right time, defining how each study would be performed by the clinicians, the supply planners, and clinical operations who would ultimately manage the study.

In addition, we translated the business and study requirements into language that made sense to the configuration specialists. Converge consultants and practitioners set up the software exactly as specified to accommodate the intended business needs, and efficiently brought the new solution online on a tight timeline with services that included:

- Guiding important decision-making to support the specification building process,
- Developing UAT test scripts for system testing,
- Supporting user testing with onsite support,
- Ensuring that reports are appropriate to fit the unique business needs,
- Conducting system user training,
- Facilitating go-live activity,
- Enhancing systems for post-go-live protocol amendments,
- Developing system standards, SOPs, and governance processes.

Status Today

Converge worked with the client's cross-functional specialists to implement the IRT for seven new clinical studies within a nine-month period. This included studies designed at short notice for potential COVID-19 benefit, requiring timelines to set up within three weeks. We also supported nine protocol-driven amendments or enhancements in that time.

Since then, we ensured that our client successfully initiated five additional clinical trials within the IRT. We also collaborated on standards that streamline the setup process and created a setup playbook for guiding their internal team. Most setup activity has now transitioned to that internal team for future studies.

Our relationship with this growing company and the IRT system vendor partner continues as we provide additional supply chain and logistics support services, and access to clinical supply management expertise.

Converge Consulting *serves the Life Sciences industry with strategy, operations, and execution expertise. We collaborate with biotech, pharmaceutical and cell/gene therapy companies to achieve important business objectives. The Converge approach focuses on bridging the gap between sound strategy and reliable execution. www.convergeconsulting.com*