Case Study

Pharma Sponsor Enlists Cenduit to Rescue a Multi-Country, Multi-Site Oncology Study

Achieves Seamless Transition to Cenduit IRT Mid-Study Execution, while Maintaining Study Timelines

Study overview

The sponsor assessed the safety and tolerability of escalating oral doses of one drug, when combined with the standard dosing of another, in patients with advanced solid malignancies.

The client was a global pharmaceutical group focused on developing prescription drugs that target unmet medical needs in numerous indications including oncology.

Challenge

ADAPTIVE DESIGN

- **A key factor:** the legacy system's medication management algorithm could not support the required flexibility in the supply chain. The trial included an adaptive cohort design, requiring dose level and flexible patient populations to be defined during study execution; previously unmanageable within the original IRT tool.
- **After go-live,** the sponsor learned its study **did not fit the existing IRT solution**, affecting data quality, timelines, and drug supply shipments. Following an RFP, the sponsor asked Cenduit to build a rescue study.

Results

Cenduit delivered a high-quality study achieved through innovation, close client collaboration, and expert project management.

Navigating Change Amid Complexity: A rescue is not a typical build. Migrating data is complex, and each study presents unique considerations. An IRT provider's team must have proven experience to manage, organize and deliver the transition seamlessly. Previous systems must remain live until the precise moment of changeover, so patients can continue receiving the correct medicines in accordance with the protocol visit schedule.

Solution

Cenduit's innovative IRT platform is highly configurable and customizable. Flexible technology and personalized service consultation can be applied quickly to an existing study, using proven processes that identify and manage risks and opportunities.

For the client, **rescue study build processes** included:

- **Setting a protocol for effective, completely transparent risk management**, via proactive identification, analysis and control processes from the outset and throughout the project lifecycle. Cenduit demonstrated the viability of transitioning IRT systems, mid-study.
- **Building clear lines of communication** among the sponsor's stakeholders, previous eClinical technology provider, CRO, drug distribution vendor, and the Cenduit team to foster collaboration.
- **Creating a study-specific project management plan** that outlined task ownership and due dates.

Transparent risk management

Clear lines of communication

Study-specific project management plan

An effective import strategy ensures data capture over the study lifecycle

With the previous IRT system replaced mid-study, Cenduit had to ensure that data associated with the earlier conduct of the trial was transferred and captured accurately, without interrupting inventory supply to sites and patients.

To accomplish this: Cenduit worked closely with all trial stakeholders to document roles, responsibilities, and timing of activities related to data transition.

Documented data import requirements and associated plan: Including the agreed transition approach, and mapping different patient/material statuses from the previous system, as well as the detail regarding roles, responsibilities, and risks associated with this import.

System validation performed via testing the data import script, and mapping against the documented requirements. Additional testing was completed using a variety of scenarios from legacy data, and for individual patient records, by ensuring that the next transaction completed to the correct expected outcome within the Cenduit IRT test environment.

Managing the transition – stakeholder communication: Cenduit, the sponsor, and all trial stakeholders collaborated to identify a suitable time point for managed trial activities during the identified transition window. A key activity in the data upload process into Cenduit's IRT: transformation of data values from the previous IRT system into a compatible format. Sites were also trained to use the Cenduit IRT prior to the system transition.

To ensure all data capture, pre-Go-Live: Ensuring data was immediately ready for use for all ongoing patient visits, the sponsor limited activity within the previous IRT system, to ensure source data stability. After the last import was provided by the sponsor, historic data was uploaded into the Cenduit IRT as part of Go-live activities. From that point, no further transactions within the previous IRT system occurred.

"In any clinical study, and particularly in a rescue, it is vital that the eClinical technology provider deliver the highest possible level of oversight, experience and quality to ensure that the sponsor can meet timelines, and that patients receive their medicines on time. We've been very pleased with the level of professionalism, innovation and leadership Cenduit's entire team has demonstrated. Not only is their work of the highest quality; they've also kept the study running within the original schedule."

– Quote from Senior Clinical Trial Supply Manager, pharmaceutical sponsor

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This case study describes an oncology rescue study – achieving Go-Live within the original timeframe, and exceeding expectations in navigating trial complexity. Cenduit would welcome the opportunity to speak with your organization about how our unparalleled approach in building clinical programs founded on quality, innovation and expertise can improve your organization's clinical programs.

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