Case Study

Intelligent IRT Design Process for COVID-19 Trials Accelerates Digital Enablement at Sites

Supporting agility and accelerating time to first-patient-in for therapeutic and vaccine trials

Summary

Cenduit IRT study design teams took-on the challenges pressing biopharmaceutical industry sponsors as they worked to digitally enable sites and speed time to first-patient-in for COVID-19 therapeutic and vaccine trials.

What resulted included new intelligent design standards that launched seventeen COVID-19 studies rapidly, setting a new bar for accelerating study design by building flexibility into study design standardization.

Background

Even with innovations in IRT technology that support rapid build and delivery times, accelerating study design often remains a challenge for the biopharmaceutical industry.

The use of repeatable standards, modules and study design tools has advanced the bar for accelerated study delivery – setting it at 4 to 6 weeks. Cenduit IRT was at the forefront of the effort to develop standard processes for IRT study design and has been employing a design tool since 2018. As part of the effort to advance Cenduit's accelerated study design format, our team of design experts continue to develop best practices that employ modular design, accommodating unique study requirements and novel trial adaptations.

Delivering studies against unprecedented timelines, while building in flexibility and maintaining stringent quality guidelines.

Building the right standards

Cenduit has a history of collaborating with partners to develop standards for design that accelerate study timelines while also maintaining the quality standards and business processes unique to that partner.

Standardizing unique process and bespoke design was nothing new to Cenduit. Our study design team was ready to take on the unique challenges presented by COVID-19 trials; delivering studies against unprecedented timelines, while building in flexibility and maintaining alignment to WHO guidelines.

Case study: large pharmaceutical company partners with Cenduit to accelerate COVID-19 trial launch

SPONSOR CHALLENGE

Identify an **IRT solution** that met the organizations standards (processes and systems) and could also deliver a patient randomization and drug management platform within two weeks.

IRT solution needed to:

- **Go live within 2 weeks** and available for study drug shipments and recruitment
- Support flexible capping to **secure minimum recruitment rates** per region and strata, while also supporting custom recruitment capping by country group based on drug label groups to allow proactive monitoring of stocks, with alerts, early planning and forecasting to prevent stock-outs
- **Support flexible** drug supply strategy
- **Eliminate the need for unblinding** pharmacists and monitors – ensuring all study drug activities could be managed in the IRT, preventing manual procedures

PROCESS: DESIGNED TO GO LIVE IN 12 DAYS

DAY 1 TO 3

Kick off meeting to final and fully executed URS and Requirements Documents

DAY 6 TO 7

Randomization & system configuration completed, demo to Sponsor

DAY 8 TO 11

System validation and UAT prep

DAY 12

UAT execution, completion and system go live

Standard timelines for sponsor:
KOM to go live: 10 weeks/50 days

Actual timelines for this trial: 12 days

RESULTS

- **80% increase** in turn around and time saved
- **50% reduction in set-up costs** against standard study build
- **100% system flexibility** and required customization preserve

80%

80% increase in turn around and time saved

50%

50% reduction in set-up costs against standard study build

100%

100% system flexibility and required customization preserve

RISING TO THE GLOBAL COVID-19 CHALLENGE

In response to the COVID-19 crisis, the industry call-to-action required IRT study design teams to work fast, yet keep to stringent quality standards and guidelines. It also required a deep level of experience and design expertise.

Cenduit's response to this call-to-action was diligent study of the WHO guidelines as well as the functional aspect of what was most critical to study execution for this category of trial.

What resulted was a Cenduit IRT universal COVID-19 study design that could be scaled 'to need' quickly and efficiently.

CENDUIT'S COVID-19 SOLUTION

The Cenduit IRT's Universal COVID-19 Study maximized the use of configurability to reduce study design and delivery timelines, but also built in flexibility by designing for change and scale.

RAPID DELIVERY OF CENDUIT'S UNIVERSAL COVID-19 STUDY DESIGN FOR THERAPEUTIC AND VACCINE TRIALS

- Draft and finalize specification reduced from 3 weeks to 3 days
- UAT process trimmed from 1 week to 1 day
- Reduced build times from 4 – 6 weeks to 2 – 3 weeks, and in many cases much less
- Over seventeen COVID-19 studies delivered rapidly, and to scale using the universal COVID-19 design

RESULTS

- **Intelligent, rapid design capabilities** launched over seventeen COVID-19 studies at a critical time for patients around the globe
- **Flexible design** has allowed most of those studies to run with minimal customization
- **Ability to scale** according to study size and need has allowed the deployment of all COVID-19 studies to be done in a replicable, time-saving way
- **Integrated with critical systems** to improve efficiency and data integrity
- **Sites were activated and digitally enabled** in support of COVID-19 patients globally – delivering potentially life-saving treatment to patients – when they need it, where they need it
- **Multiple studies, managed by Cenduit**, were driven by government institutions that had a **significant impact on the country/region's therapeutics and vaccines**
- **Pre-validated design components built** for rapid design for other therapeutic areas and trial stages that expedite builds and speed trials along

NEXT STEPS

We would welcome the opportunity to talk with your organization about how Cenduit's innovative team of study design experts can help you digitally enable sites faster, improving your time to first-patient-in regardless of study size or design. **Contact us here.**

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