Zelta

merative

Rapidly building dependable clinical studies

How Southern Star Research was empowered to build its own studies

Southern Star Research, a leading Asia-Pacific full-service contract research organization (CRO) based in Sydney, Australia, wanted to build a technology platform that would allow its data managers to rapidly develop and deploy clinical studies without the help of IT staff and programmers. Although CROs still conduct paper-based clinical studies, well over half are now initiated electronically.

For this majority of studies, electronic data capture (EDC) systems form the core of study data management. When digital server technology is hosted and maintained by the CROs themselves, a large amount of extra technical resources is required. Building a single study could take an organization weeks, if not months.

For many clinical studies, data collection relies on extensive technical activities such as software upkeep and programming, adding time and expense to the building of studies. When these technical requirements are minimized or eliminated, data is captured more efficiently and studies are launched more quickly. Increasingly, cloud-based technology is becoming the home where clinical data can flow rapidly, securely and accurately.

To build a dependable clinical study, Southern Star Research needed to integrate data from disparate sources. Information from subjects, sites, laboratories, devices and agencies is expected to become part of the clinical study report. Technical staff may be needed to import and export files, add fields to questionnaires, perform edit checks, validations, and testing, and more. eClinical systems hosted at such organizations demand constant attention and time from in-house or contracted experts.

When the different requirements of a study are divided among multiple external services, it becomes challenging to provide uniformity and consistency in the processing and flow of data — and by extension, in the user experience. The latter is especially essential when permissions are expected for a variety of eClinical users, from clinical research associates to external adjudication committee members.

“We basically built a complete database, including edit checks, within one week. I think this was phenomenal.”

Director of Biometrics
Southern Star Research

Effective data capturing

Capturing timely and accurate information is at the core of clinical research. For any given study, the case report form (CRF) — paper or electronic — is a mechanism for collecting study data that is stored in a database or EDC system. The data reflects the protocol of the clinical research and the statistical analysis plan. The availability and integrity of the data contribute to the research findings.

Merative's Zelta™ created a brief and accelerated study-build program that provided Southern Star Research with a unified system for EDC and comprehensive training in building clinical studies. The Zelta clinical trials platform, a software-as-a-service (SaaS) EDC solution, requires no user infrastructure or programming experience.

Designed to be intuitive and easy to navigate, users access all study data and platform functions through a centralized, password-protected web interface.

The Zelta platform offers comprehensive solutions that help streamline clinical trial processes. From electronic patient-reported outcome (ePRO) to Randomization and Trial Supply Management (RTSM) and more, Zelta helps clinical research teams launch and complete studies efficiently, bringing needed tools to patients sooner. Used by clinical professionals worldwide, the platform lets users capture, manage, analyze and report study data across any therapeutic area and trial type.

Uncomplicating the mechanics

Following implementation, Southern Star Research could create a new set of case report forms, launch a study, and receive the necessary resources and credentials for deploying future studies in under a week. The solution from Zelta provided a security-rich and intuitively rendered cloud-based EDC that supports advanced data integration, medical coding, reporting and analytics for clients.

The mechanics of building a single study need not be complicated, costly or time-consuming. By implementing the Zelta cloud-based EDC system and obtaining instruction on basic and advanced technical features, Southern Star Research was able to deploy an actual study in four days and can launch other studies independently in the future.

The four-day program trains new users to create studies, and it began with the organization accessing the core EDC of the Zelta platform and implementing a clear and focused agenda using the client's own clinical trial protocol. The program culminated with Southern Star Research building a complete study in less than a week and gaining trainee certification.

Instead of using a sample protocol, Zelta used the actual trial protocol from Southern Star Research for the study-build. The solution thoroughly addresses the mechanics of startup, process, build, deployment and closeout. It also gives specific attention to revisions, code lists, pages, queries, visits, reports and languages. The rapid and complete nature of this study-build exceeded the team's expectations.

About Southern Star Research

Southern Star Research is a full-service, contract research organization based in Sydney, Australia. It specializes in providing clinical research services for pharmaceutical, medical device and biotechnology clinical trials in Australia and New Zealand.

About Zelta

Zelta by Merative is a clinical trials solution business that includes both a clinical data management and acquisition platform and consulting, enablement, and extension services. Zelta's unified cloud-hosted platform supports all phases and complexities of research, including more than 450 phase III trials.

Learn more at merative.com/clinical-development

About Merative

Merative provides data, analytics, and technology for healthcare and government social services. With focused innovation and deep expertise, Merative works with providers, employers, health plans, governments, and life sciences companies to improve decision-making and performance.

Learn more at www.merative.com.

Merative
100 Phoenix Drive
Ann Arbor, MI 48108

Produced in the United States of America, June 2023.

MCD-3062039499 Rev 4.0