Business challenge

Southern Star Research needed a technology platform that allowed its data managers to rapidly build and deploy clinical studies without the help of IT staff and programmers.

Transformation

Southern Star Research needed a technology platform that would allow its data managers to rapidly build and deploy clinical studies without the help of IT staff and programmers. Teaming up with IBM® Watson Health™, the organization successfully built a comprehensive and ready-to-launch study in four days using the IBM Clinical Development platform's solutions and services.

Results

Builds a comprehensive study in four days
delivering a reliable and complete study and exceeding expectations

Accelerates training
so team members can deploy studies quickly and autonomously

Provides a security-rich, cloud-based EDC system
that supports advanced data integration, reporting and analytics

Southern Star Research

Rapid and instructive building of dependable clinical studies

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.

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

—Director Biometrics, Southern Star Research

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Costly and time-consuming studies

Southern Star Research, a leading Asia-Pacific full-service contract research organization (CRO) based in Sydney, Australia, looked 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, EDC systems form the core of study data management. When digital server technology is hosted and maintained by the CROs themselves, a great deal 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 are 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, to add fields to questionnaires, to 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.

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 are 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.

Watson Health 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 IBM Clinical Development 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 IBM Clinical Development 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, IBM 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. Watson Health's solution 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 Watson Health's cloud-based EDC system and providing 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 IBM Clinical Development 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, Watson Health 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. In addition to the knowledge acquired by the Southern Star team during training, the resulting study was ready in four days. The rapid and complete nature of this study-build exceeded the team's expectations.

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About Watson Health
For more than a century, IBM has been creating innovations that matter. And with Watson Health, we are committed to help build smarter health ecosystems. This means working with you to help you achieve simpler processes, better care insights, faster breakthroughs, and improved experiences for people around the world. Our core strengths combined—deep industry expertise in health, data and analytics, actionable insights, and our reputation for trust and security—can enable us to deliver support for our clients. Together with our clients and partners, IBM is putting smart to work. For more information, visit https://www.ibm.com/watson-health