Overview

Increasingly, cloud-based technology is becoming the home where clinical data can flow rapidly, securely, and accurately.

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

The solution
IBM Watson Health delivered to Southern Star Research a cloud-based EDC and study-build training using its own clinical trial protocol. Intuitive drag-and-drop features enabled Southern Star Research to create clinical study reports quickly and independently.

The result
Southern Star Research acquired a new clinical data management system and built a reliable, complete study in 4 days. It also gained the ability to rapidly launch other studies and train its team members to deploy studies quickly and autonomously in the future.

“We basically built a complete database including edit checks within 1 week. I think this was phenomenal.”

Director Biometrics | Southern Star Research
In activating Watson Health’s cloud-based EDC system and providing instruction on basic and advanced technical features that help to launch studies in a time-sensitive manner, Watson Health enabled Southern Star Research to deploy an actual study in four days and to launch other studies independently in the future.

The four-day program to train new users to create studies began with Southern Star Research accessing the core EDC of IBM Clinical Development and continued with IBM 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, the actual trial protocol from Southern Star Research was used for the study-build. The mechanics of startup, process, build, deployment and closeout were thoroughly addressed. Specific attention was also given to revisions, code lists, pages, queries, visits, reports, and languages. From design attributes to visit rules to file transfers, IBM Watson Health covered all aspects of this clinical study that led to a fully executable clinical research endeavor.

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.

Southern Star Research built a clinical study in less than a week
Effective data capture is central to building clinical studies

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.

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.

Clinical researchers are often faced with technological obstacles

Although paper-based clinical studies are still conducted today, 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 clinical research institutions themselves, a great deal of extra technical resources is required. Building a single study might take an organization weeks, if not months.

To build a dependable clinical study, researchers must 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 important when permissions are expected for a variety of eClinical users, from clinical research associates to external adjudication committee members.

As processes such as randomization, safety reporting, medical coding, endpoint adjudication, and ePRO are unified within one EDC, as they are with IBM Clinical Development, data may flow and undergo analyses with speed and precision. Likewise, efficiency is achieved when each of these processes are hosted in a web-based service cloud and contain navigation tools and functions that enable all users to work with ease and uniformity.

**IBM Watson Health clients acquire speed and autonomy through cloud-based EDC and study-build training**

Watson Health has created a succinct and accelerated study-build program that provides clients with a unified system for electronic data capture and comprehensive training in building clinical studies. During the span of a week or less, clients can build a new set of case report forms, launch a study, and receive the necessary resources and credentials for deploying future studies.

The mechanics of building a single study need not be complicated, costly or time-consuming. IBM Watson Health has repeatedly provided clients with a secure and intuitively rendered cloud-based EDC that supports advanced data integration, medical coding, reporting and analytics, among other solutions. Additionally, IBM’s experienced instructors are skilled in transferring knowledge that is applicable to each trainee’s role and leaves trainees with a sense of independence going forward.
About IBM Clinical Development
IBM Clinical Development, a solution-as-a-service (SaaS) electronic data capture (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.

IBM Clinical Development offers comprehensive solutions that help streamline clinical trial processes. From ePRO to 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.

Why Watson technology?
IBM solutions — from data capture to endpoint adjudication — are the groundwork for new ventures and directions. With IBM Watson technology, support for greater patient engagement is at hand.

Watson can retrieve volumes of data from many medical sources, including electronic health records and insurance claims data. It can also work to help protect patient privacy, allowing clinical, research and social health information to be aggregated, analyzed and shared in a security-rich IBM cloud that complies with government regulations and industry standards.

Combined with the cognitive computing ability of Watson to rapidly derive meaning from voluminous networks of data, there are technological solutions and enhancements underway at IBM to help enrich patient care.

Next steps
To learn more about IBM Clinical Development from Watson Health, please contact your IBM representative or IBM Business Partner, or visit ibm.com/clinical-development

About IBM Watson Health
Each day, professionals throughout the health ecosystem make powerful progress toward a healthier future. At IBM Watson Health, we help them remove obstacles, optimize efforts and reveal new insights to support the people they serve. Working across the landscape, from payers and providers to governments and life sciences, we bring together deep health expertise; proven innovation; and the power of artificial intelligence to enable our customers to uncover, connect and act — as they work to solve health challenges for people everywhere.

For more information on IBM Watson Health, visit ibm.com/watsonhealth