Increase Transparency for Clinical Trials to Improve Public Trust

The Issue
Regulatory authorities, researchers and the AllTrials clinical trial data transparency campaign (among others) are placing pressure on the life sciences industry to voluntarily provide access to patient-level data and results from clinical trials on which regulatory decisions are based. Momentum is gaining on data sharing, but if ignored, regulatory authorities may require full public disclosure of clinical trials information - which doesn’t limit access to researchers conducting valid scientific inquiry. In this scenario, exposure of proprietary information to competitors is a concern for biopharmaceutical organizations.

Clinical trial data transparency enables qualified researchers to verify clinical trial results, improve the efficiency of clinical trials and advance medical knowledge. In addition, data sharing has the potential to improve public health, while also increasing public trust in clinical research and the life sciences industry.

The SAS® Approach
SAS Clinical Trial Data Transparency provides researchers with a globally available, secure clinical trials data repository with easy access to SAS Analytics for valid research purposes. Our software and services deliver:

- A secure clinical trials data repository. Give authorized researchers controlled access to the clinical trial data they need for research projects. Researchers can access data sets and information from participating sponsor companies, and analyze it using statistical routines to reconfirm the analyses performed, combine data across a series of studies, and explore medical questions.
- Analytics for research. SAS empowers researchers with the leading analytic tools for clinical research. Because analytic technologies are embedded into the system, researchers can confidently generate new medical knowledge, improve the efficiency of clinical trials, verify trial results and improve health care. SAS provides authorized researchers the power and flexibility to access data and produce presentation-ready statistical analyses.
- Rapid, flexible implementation. SAS provides the rapid and flexible implementation and support sponsors require for data transparency initiatives. SAS can support a single company in its own standalone solution, or provide a shared solution that will support access to clinical trials data from multiple participating sponsor companies.

Business Impact

“In sharing our data with worldwide researchers, we hope to further scientific research and increase understanding about our medicines. Our goal is to transition to a broader system allowing researchers to access data from trials conducted by multiple organizations.”

Senior Vice President for Science and Innovation
Top 10 Pharmaceutical Company

Challenges

- Public disclosure by regulators. Some key regulatory authorities favor mandatory data sharing policies that could include full public disclosure.
- Public trust in clinical trial results. Sharing clinical trial results with authorized researchers allows validation of regulatory decisions to boost confidence in results.
- Inaccurate conclusions. Some meta-analyses have produced negative or inaccurate conclusions because of limitations in the data the researchers could access. Increased data transparency allows researchers to access the information they need for more accurate medical conclusions.
The SAS® Difference: Power and flexibility to access data and produce presentation-ready statistical analyses

Through a secure clinical trials data repository with SAS, you can give authorized researchers access to the data and our powerful analytics.

- With SAS, you can take advantage of more than three decades of industry experience. SAS is globally recognized as the de facto industry standard for clinical trial data analysis and reporting and is the industry leader in business analytics. And we bring all that expertise to you.
- SAS Analytics is widely accepted as the gold standard for the analysis and reporting of safety and efficacy in clinical trials. Researchers prefer to utilize proven, trusted technologies like SAS to ensure the success of their projects.
- SAS offers the flexibility to support researcher access to the clinical trial data of a single company or multiple companies. In a multicompany configuration, each company’s clinical trial data is securely separated from access by the other companies; yet approved researchers can access and analyze data from multiple sponsor companies for their projects.
- As a trusted business partner in life sciences clinical research, SAS has hosted secure clinical analytics solutions in the cloud for over a decade for both leading and emerging life sciences companies.

SAS is the market leader in clinical trials data transparency initiatives. We make it possible for researchers to analyze data across a series of studies from multiple sponsors – helping them to benefit patients and develop better medicines.

Case Study: A top 10 pharma data transparency initiative

Situation

Regulatory authorities and other stakeholders are pushing for increased transparency into the results of clinical trials. In response, a top 10 pharmaceutical company wanted to provide authorized scientific and medical researchers with a repository of clinical trials data and the appropriate analytical tools. The company needed to control uploads and exports of content, and make the environment as self-service as possible. It also had a very aggressive implementation time frame.

Solution

SAS provided a secure analytical data repository – easily accessible to authorized researchers – in addition to ongoing system monitoring and support.

Results

SAS provided this top 10 pharmaceutical company with a rapid implementation of a data sharing system that allows approved researchers to access and analyze clinical trial data. The research completed in this data transparency environment benefits health care by delivering additional insights into clinical study results, how medicines work and how they can be further enhanced. In addition, the company was able to enhance its reputation as a good corporate citizen.

What if you could …

What if you could securely share clinical trial data with authorized researchers? What if authorized researchers could apply SAS Analytics to improve health care and the efficiency of clinical trials? What if researchers could access clinical trial data from multiple sponsor companies? You can. SAS gives you THE POWER TO KNOW®.

SAS Facts

- SAS is the de facto industry standard for clinical trial data analysis and reporting.
- For more than three decades, life sciences companies have trusted SAS to derive greater insight from information.
- Today, SAS has customers at more than 65,000 sites worldwide.

Learn more about SAS software and services for life sciences at: sas.com/lifesciences.