

ISA Clinical Trials Solution

A BI solution from Cognos and ISA Consulting

In the race to produce new blockbuster drugs, pharmaceutical companies have been faced with numerous challenges in recent years. Regulatory requirements and global competition have led to a rise in clinical development costs. Organizations are now looking for efficiencies in their clinical development process that will bring new compounds to market more cost-effectively. This situation has led to an industry-wide push for tools to improve clinical development processes.

The clinical trials process represents one of the biggest direct-spend components in most pharmaceutical R&D budgets. It's also one of the most complex. Because of this complexity, the clinical development market has been slow to adopt technology such as performance management applications, data warehouses, or reporting tools. The hurdles for pharmaceutical companies include:

- **Data availability.** While other industries bemoan the difficulties of integrating disparate databases, in clinical trials, the databases may not exist. Data often resides in paper medical charts, spreadsheets, notebooks, and a variety of paper and electronic documents.
- **Human factors.** Scientists are accustomed to paper-based systems and often resist change—even though manual processes result in duplicated effort and multiple interpretations for the same data set. Time is lost determining whose numbers are correct, rather than focusing on how to use the results.
- **Complex measurements.** Even for trials that have electronic databases, clinical data consolidation needs to take into account equipment nature and calibration, and even subjective data such as interpretation of images.
- **Nature of drug development.** Scientists are more successful when they operate in an environment that fosters independence and innovation, and they can resent efforts to automate their work if it is not approached sensitively.

Although the clinical development industry may be slower than most to use available technologies, the situation is now changing. It is possible to make clinical R&D more productive, without compromising the role of the scientist. Data availability issues can be resolved, and the human and clinical factors can be addressed.

A strong partnership for proven results

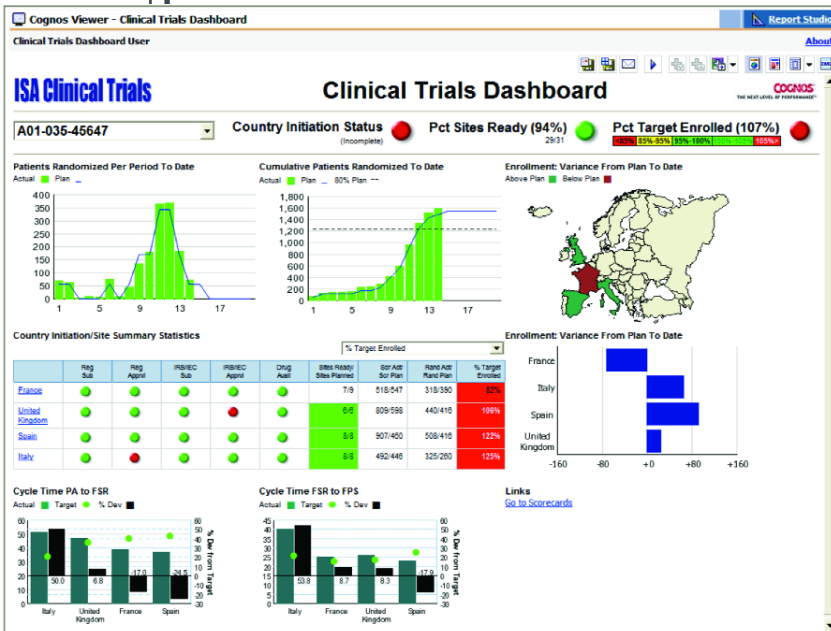
Cognos, an IBM company, is the world leader in business intelligence and corporate performance management software for the enterprise. By partnering with ISA Consulting, a leading professional services firm specializing in business intelligence and data warehousing, we have created a focused clinical trials solution.

Our combined experience in the pharmaceuticals industry can help you more efficiently manage your clinical trial processes. We offer more than the implementation of an electronic data capture (EDC) system, clinical trial management system (CTMS), or a new reporting application. Although the operational improvements delivered by these systems are important, a new priority has emerged: the examination of trial processes to improve overall clinical development performance.

The ISA Clinical Trials solution allows you to continually monitor clinical trials performance to alert you to situations needing attention, and provide the depth of understanding to correct issues at the source. ISA leverages IBM Cognos 8 Business Intelligence to create the ISA Clinical Trials solution, including:

- A Clinical Datamart, with pre-built data models
- Clinical Trials Dashboards and Reports
- A methodology and best practices to ensure superior performance and scalability.

The solution extracts data from existing CTMS, EDC, and ERP and systems to populate the data warehouse. Analytic pathways within the ISA Clinical Trials Dashboard bring important information to the surface and focus users' attention on high-priority areas. The user experience is maximized through multiple tables, charts, and prompts.



The right choice for pharmaceuticals

Pharmaceutical organizations worldwide choose Cognos for our unsurpassed expertise in delivering the information and insight they need to reduce costs, streamline processes, and increase profitability. Cognos has delivered solutions to 25 of the top 30 pharmaceutical firms, along with many leading life sciences and biotech companies.

With deep experience in the clinical trials process, ISA has enjoyed a 12-year relationship with Cognos as one of the first and strongest Cognos partners in North America, evident in its Platinum Reseller Partner status. Together we've worked with world-class pharmaceutical companies, enabling them to track worldwide clinical trials and understand how they are performing using key statistics like initiation, enrollment, and variances to plan. The combination of world-class performance management solutions, best practices, and experience with life sciences corporations is a powerful solution for our customers.

How the partnership works for you

Organizations that have implemented the ISA Clinical Trials solution with Cognos and ISA have benefited in many ways:

- An improved clinical trials process, including shorter cycle times
- Faster time to results through pre-built data models
- A Clinical Trials Dashboard application that allows thousands of worldwide users to access critical information relevant to their responsibilities
- Increased communication and collaboration worldwide
- Improved data quality as visibility to data increased

Pharmaceutical companies need the information to make critical R&D decisions earlier, reduce spending on failed compounds, and focus their companies' resources on the best candidates for success. A more strategic focus on clinical development processes reveals opportunities for efficiencies and making better decisions. Pharmaceutical companies are increasingly focusing on the overall conduct of investigators, sites, and CROs and looking for objective data on experiences to make decisions for future clinical research. The ISA Clinical Trials solution meets this need for reliable data, thoughtful analysis, and timely decisions.

About ISA Consulting

ISA Consulting specializes in helping companies turn data into information for competitive advantage—utilizing corporate data to increase efficiency, improve performance, and maximize profitability. ISA's mission is to help our customers adopt information-driven solutions to achieve their business objectives. Founded in 1995, ISA serves over 150 customers worldwide with offices in New York, NY, Blue Bell, PA, and Washington, DC.

About Cognos, an IBM company

Cognos, an IBM company, is the world leader in business intelligence and performance management solutions. It provides world-class enterprise planning and BI software and services to help companies plan, understand and manage financial and operational performance. Cognos was acquired by IBM in February 2008. For more information, visit <http://www.cognos.com>.

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Visit the Cognos Web site at www.cognos.com

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