



Industry
Life Sciences



Environment
5 continents
Tens of thousands
of Global Databases
Decentralized
computing



Analytics
Challenges
Manual spreadsheet-
based approach was
slow, inefficient and
error prone
Automated solution was
too inflexible to support
the end-to-end process



Key Benefits
Faster and more
accurate regulatory
compliance reporting
Flexibility, consistency,
and accuracy
throughout the entire
clinical trial lifecycle
Slashed development
lifecycles by 4X



CLINICAL DATA STANDARDS MANAGEMENT



SIMPLIFY AND SPEED COMPLIANCE WITH FEDERAL
AND INTERNATIONAL REGULATORY MANDATES



SUMMARY

A leading global pharmaceutical company was struggling to comply with the recent federal and international mandates for clinical data standards. The company had previously implemented an automated solution, but after years of effort the company was still not meeting its goals. Recently, the company implemented an automated solution based on Anzo®

and within five months was successfully achieving its goals, including proper regulatory compliance, faster and higher quality trial setups, reduced data management issues during data collection and analysis and reporting across the suite of clinical systems, and the ability to enable exploratory analytics across multiple clinical trials.



THE CHALLENGE

The company had been managing hundreds of global clinical trial data standards through the use of spreadsheets and manual processes. Due to the inefficiencies, manual effort, and associated errors, the company initially attempted to automate the process with an alternative solution. After years of effort, the company determined that the rigid architecture of the

solution was resulting in multi-year development cycles, difficulty supporting all of the different representations required by downstream clinical systems, and a lack of flexibility to support changes to the data, especially changes “on the fly” from downstream systems that needed to be reflected in the standards compliant data model with the proper governance and lineage.



THE SOLUTION

This industry leader is addressing these shortcomings with an end-to-end solution using the powerful and flexible Anzo, implemented in less than five months, four times faster than the previous approach. The company is currently extending the full production solution to support their entire global clinical teams. Anzo implementation is providing the

company with key capabilities including metadata consultation support, metadata specification library management, clinical trial metadata setup and monitoring, change request management workflow, standards up-version, audit traceability and reporting, and downstream clinical systems integration with bi-directional change propagation with no duplication of data.

ABOUT CAMBRIDGE SEMANTICS

Cambridge Semantics Inc., The Smart Data Company®, is an enterprise analytics and data management software company. Our software, Anzo®, allows IT departments and their business users to semantically link, analyze and

manage diverse data whether internal or external, structured or unstructured, with speed, at big data scale and at the fraction of the implementation costs of using traditional approaches.

The company is based in Boston, Massachusetts. For more information, visit: www.cambridgesemantics.com or follow us on:

