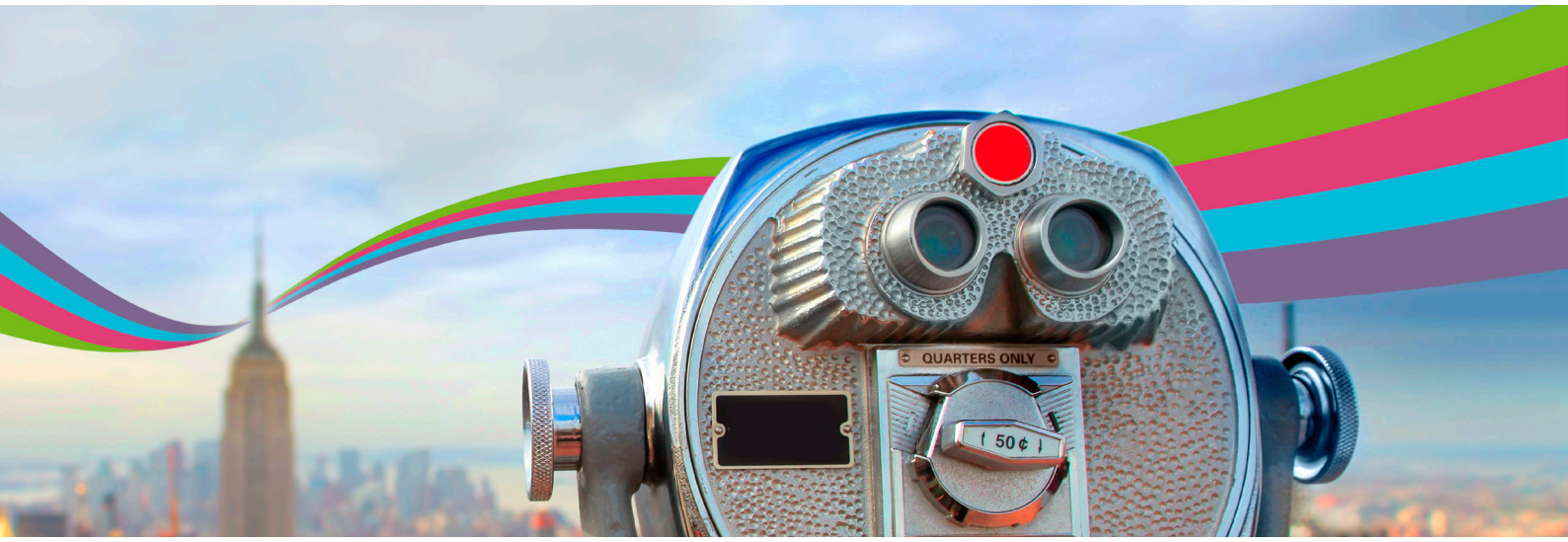
CDISC Data Standardization Challenges and Solutions



Utilizing 20 Life Sciences subject matter experts, Navitas Life Sciences deployed a flexible team that ensured performance excellence in a distributed delivery environment

Navitas Life Sciences deployed the right number of resources and coordinated with key stakeholders, both internal and external.

Customer Profile

A mid-sized pharmaceutical company outsourced a large-scale SDTM conversion project to Navitas Life Sciences. The project involved conversion of legacy and ongoing clinical trials data to CDISC SDTM standards, creation of stackable datasets, and delivering Define.XML for submission.

The project involved 39 Phase I –III legacy and ongoing studies. Ten of the clinical studies were conducted in Japan and the data collected were in Japanese. The data was to be submitted to the FDA, requiring it to be translated into English. The trials were conducted over a period of several years, and all Adverse Events and Medications were to be coded to a single dictionary version (up-coding). The project also involved Define. XML generation for the studies included as part of submission.

The Challenge

- Studies were conducted for over a decade by multiple CROs worldwide. Source data collected was produced under different standards and many studies were true legacy with no standards at all
- Non-standard Case Report Forms with individual studies coded using different versions of the dictionaries
- Some of the legacy studies were conducted 10-15 years earlier, so gathering complete data and having any questions answered was a huge challenge
- Translation of Japanese strings to English language text
- Very aggressive submission timelines

The Solution:

Converting 39 studies under tight time restrictions is a difficult task in itself, but there were additional complexities that occurred, such as translating Japanese text to English language, working with translation agencies, the handling of ongoing studies and data by different vendors, and up-coding AE & Medications to a singular dictionary version. With all this workload being performed simultaneously, the challenges soon grew to be enormous. On top of all of this, Navitas Life Sciences had to coordinate with another CRO who was working on our deliverables for the ISS/ISE analysis.

All communication with the sponsor and other vendors, project management, coding and QA activities were performed from our US offices and the bulk of programming from our offshore office

A team of 20 people, comprised of Programmers, CDISC Standards Analysts, SDTM Consultants, Bio-statisticians, Medical coders and Project Managers, both on-shore and offshore, were deployed by Navitas Life Sciences to complete this project on time. SDTM Analysis and authoring of logical mapping specifications to map the non-standard raw data to SDTM standards were done in the United States, while implementation and double programming were done off-shore. All communication with the sponsor and other vendors, project management, coding and QA activities were performed from our US offices, while the bulk of programming was enacted from our offshore office. This deployed the ideal mix of talent, while ensuring quality deliverables to the client in a cost-effective and timely manner.

A consistent SDTM model was used across all the studies, which avoided iterations.

Customer success factors were:

- Having deep domain expertise and the Subject Matter Experts (SMEs)
- Flexibility and the ability to coordinate and perform well in a distributed delivery environment, enabling the project team to meet demanding timelines
- Navitas Life Sciences deployed the right number of resources and coordinated with all the key stakeholders of the project, both internal & external

Having the right mix of people from various CDISC industry standards group such as SDS & CDASH teams and access to such members enabled the project team to make the correct decisions and come up with a single interpretation of data. A consistent SDTM model was used across all the studies, which avoided iterations. In-house Automated tools such as Define.XML generator, Validator and various other conversion utilities also helped accelerate the process and produce high quality deliverables much faster.

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About Navitas Life Sciences

Navitas Life Sciences brings together the proven strengths of its legacy brands Navitas, Ecron Acunova and Intelent to serve as a strategic partner to global Life Sciences companies. Navitas life Sciences leverages its industry insights and domain expertise to develop and implement consulting, technology and functional services across the spectrum of Clinical, Regulatory and Safety, to innovative and create value to address the needs of the industry uniquely.

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