

Investigational New Drug Reporting

Eliminating hurdles to drug development by reducing regulatory burden



Challenge · The National Cancer Institute (NCI) was searching for a faster and more efficient way to generate Investigational New Drug (IND) reports for annual submission to the Food and Drug Administration (FDA). The time lag for producing these submissions was attributable to the myriad of tables and narratives that comprise the reports, as well as the large quantities of investigational data that must be compiled from NCI's clinical data management system

SOLUTION · Xcalibur created an efficient, user-friendly and highly accurate annual reporting system for FDA submissions. Users can generate fully-formatted MS Word documents with real-time data directly from NCI's enterprise data system. Users construct the document by accessing a library of templates, which can be used to produce different sections such as abstracts, indexes, and toxicity tables. With one click, the system automatically generates comprehensive reporting documents; all within the matter of a few minutes.

Complex sections such as those containing toxicity data often consist of hundreds of thousands of data points embedded within several hundred pages. Rather than reinvent the wheel each time this data needs to be updated, the initial document creation enables information to update regularly from the database at any time.

CHALLENGE · Xcalibur met NCI's challenge to create an application that can generate IND reporting documents and FDA submissions efficiently and accurately. Furthermore, the system delivers several additional benefits:

+ Eliminates manual cut and paste procedures to increase efficiency and accuracy.

- + Utilizes MS Office software suite, a standard of NCI's desktop, for easy learning and effective use.
- + Employs a familiar layout, so users can edit reports simply and at anytime.
- + Provides flexibility within the application; resulting in time savings in subsequent reporting years since data can be "refreshed" instantly to produce next year's submission.

Today, NCI has an IND reporting application that has increased efficiency and accuracy in reporting, and dramatically reduced delays in FDA submissions.

Xcalibur performed this effort with its Teaming Partner, Capital Technology Information Services, Inc., as a task order in support of their 6 year, \$66 million Technical Services Contract with the NCI.

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