

# Increase Efficiency, Accelerate Timelines and Produce a Superior Quality Submission

In recent years the Quintiles Biostatistics team has completed more than 20 submissions globally for sponsors varying from emerging biotechs to large pharma companies. We provide formal CDISC SDTM Theory and Application training for all of our Biostatistics staff. We also have a large network of medical and regulatory experts who will collaborate with you and our statisticians in order to deliver the most effective submission possible.

Whatever your therapeutic area or regulatory requirements, our statisticians will work closely with you to make key strategic decisions — what studies should be included, which endpoints to analyze, and how best to present your data in the submission. These decisions are fully documented in an integrated Statistical Analysis Plan and a Data Integration Plan. We also understand the requirements for electronic Common Technical Documents (eCTDs) and how to successfully build your electronic submission.

## CASE STUDY

We recently teamed with three co-sponsors to convert, integrate, analyze, report and submit data from 30 studies in support of their first eNDA.

- > Quintiles Biostatistics handled the integration of legacy and current study data, conversion of data into CDISC SDTM standards (including PK data), creation of the eNDA submission, production of reviewer aids and training materials, and post-submission support.
- > Our strategic, multi-team approach reduced the timeline from end of Phase III to completed integrated analysis by nearly 50%.
- > Quintiles delivered the CDISC SDTM-compliant data files for all 30 studies with no requests from the FDA for changes or further information.



## Strategic Planning

We offer innovative thinking to develop your optimal statistical approach, detailed knowledge of regulatory requirements, and proactive planning of appropriately-timed regulatory meetings to start your submission on the right track.

## Efficient Data Analysis

Quintiles Biostatistics provides a proactive analysis strategy for integrated summaries utilizing a cumulative integration approach with ongoing analysis runs and systematic and collaborative reviews. Our goal is to achieve a shorter turnaround time from the end of last study to a completed submission.

## Complete Data Package Solution

From the start, we specialize in preparing your data to CDISC SDTM standards, with the thorough documentation that is required. Before actual submission, we engage in test data transfers to ensure any technical issues related to data acceptance are resolved.

## Post-Submission Strategy Planning

Our job does not end with your submission. We continue to support you with a “rapid response team” to address any questions or ad hoc requests from the regulatory agency, produce your post-submission safety updates and provide advisory committee support.

### CONSIDER THESE SUBMISSION ISSUES:

- > Did you know that Integrated Summaries of Safety and Efficacy may not be required if certain criteria are met by your submission?
- > How will you handle converting non-CDISC compliant legacy study data to meet CDISC SDTM standards?
- > Will recoding of adverse events, medications and medical histories be needed for your submission to ensure consistency across studies?
- > Do you have studies that need translation, and have you planned to handle the task concurrently with submission analyses to avoid any delays?

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