eCTD Services

PharmaStat works on enough submissions that we always have a few in review at the FDA at any given time. We work closely with the FDA review divisions to solve their issues so that our clients avoid the fire hose of requests that can set back their PDUFA date by months. Most importantly, we help our clients strategize the content of their submission to deliver exactly what the review division needs, no more and no less. This planning yields two benefits: it eliminates noise and distractions in the submission, and it saves our clients money by eliminating work that they may have thought necessary.

Once the submission strategy is in place, PharmaStat has the processes, tools and templates to produce, audit and validate the entire range of Biometrics documentation for an eCTD submission.

eCTD Submission Strategy

PharmaStat consultants confer with Biometrics staff in planning for the eCTD. We have provided strategic input to more than 20 submissions in the last 5 years. We share our experience, recommend processes, provide templates and procedures, and develop related documentation as needed.

Preparation of Biometrics eCTD Deliverables

FDA specifications request define.xml for SDTM databases in eCTD submissions. Though not specified for ADaM databases, the expectation is generally the same. However, you need more than just define.xml to create a reviewable documentation package. You will also need a Study Data Reviewer's Guide and annotated CRF for the SDTM (or Item 11) source database, and an Analysis Data Reviewer's Guide for the ADaM (or other analysis) database. You may also need define.pdf depending on the version of define.xml you are using. If you are submitting programs, you'll also need an index of analysis programs. The Module 1 Reviewer's Guide may be mostly the work of Clinical and Regulatory, but it will need a Biometrics contribution as well. We have the tools, templates and experience to produce the entire range of documents you'll need.

Vendor Support

Some companies rely on vendors to conduct their studies, and may not have their own biometrics team. For these clients we act as members of the in-house team by contributing our expertise in

- Project planning
- Defining timelines and specifications for deliverables
- Negotiating vendor timelines and milestones
- Ensuring that timelines are met and deliverables are on schedule
- Documenting processes and procedures
- Reviewing study data and documents
- Specifying analysis methods
- Providing feedback on deliverables

In addition, we help your vendors resolve data and analysis issues when they arise, so that projects can stay on schedule.

QC Audit of Biometrics eCTD Deliverables

In our experience evaluating vendor deliverables, 33% of all eCTD study packages and 75% of all phase III packages are missing datasets or other eCTD components. Such deficiencies may pose the risk of a Refusal to File. PharmaStat's procedure for auditing Biometrics eCTD deliverables ensures that they're submission-ready. It verifies that every component of the eCTD is accounted for and meets our client's quality standards. Our operational documents facilitate the audit and ensure its accuracy and completeness. We provide you with templates and instructions for the content of these documents.