

Biometrics Submission Support

Biometrics Submission Support for a Clinical Company

It's the sponsor's first submission. The clinical team is experienced and they have regulatory support, but all the Biometrics tasks are outsourced. As a result, no one within the company has the background to evaluate Biometrics deliverables or answer vendors' questions. This is a frequent scenario in projects that PharmaStat takes on. Our role depends on the capacities of existing vendors and their ability to serve the company. We help our client configure its vendors to maximize their reliability and efficiency. We fill in the process gaps and provide technical support to the vendors. PharmaStat consultants frequently take responsibility for tasks related to integrated summaries, such as producing a consolidated SDTM database, writing SAPs, and conducting analyses. We frequently verify reports from other vendors and prepare, or audit, the final submission-ready deliverables for regulatory publishing. Depending on the number and duration of studies involved, this type of project should begin at least nine months— but preferably 12 to 14 months — before the target submission date. Services typically include:

- eCTD Submission Strategy (<http://www.pharmastat.com/services/ectd-services#ectdsubmission>)
- SDTM Conversion (<http://www.pharmastat.com/services/sdtm-data-conversion-services/>)
- Biostatistics (</services/biostatistics-and-statistical-programming>)
- Vendor Support (<http://www.pharmastat.com/services/ectd-services#vendor>)
- Production of Define.xml and Define.pdf (<http://www.pharmastat.com/services/sdtm-data-conversion-services#defineproduction>)
- Statistical Programming (<http://www.pharmastat.com/services/biostatistics-and-statistical-programming#statisticalprogramming>)
- Integrated Safety Summary (ISS) (<http://www.pharmastat.com/services/biostatistics-and-statistical-programming#iss-ise>)
- QC Audit of Biometrics eCTD Deliverables (<http://www.pharmastat.com/services/ectd-services#qcaudit>)
- Preparation of Biometrics eCTD Deliverables (<http://www.pharmastat.com/services/ectd-services#biometrics>)

Featured Case Studies:

- eCTD Prep with Biometrics Support (</case-studies/small/ectd-prep-with-biometrics-support/>)
 - To view all Small Pharma/Biotech case studies, click here. (</case-studies/small/>)
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