

Large Submission, Fully-Outsourced

The sponsor is preparing for its first submission, or perhaps it has been a few years since the previous one. Although the team members are all experienced, this may be their first submission as a unit. Not only has the regulatory landscape changed, but the company has neither the established processes nor the resources to produce the work products. Instead, it has made a strategic decision to rely on vendors to accomplish its submission goals.

PharmaStat's role in this kind of project is to help the client manage its vendors and optimize reliability and efficiency. We fill in the gaps in the process, provide tools and support to help the vendors succeed, and produce and/or package the final submission-ready deliverables for regulatory publishing.

This type of project should begin at least nine months — but preferably 12 to 14 months — in advance of the target submission date. Services may include:

- Vendor Support (<http://www.pharmastat.com/services/ectd-services#vendor>)
- SDTM Conversion (<http://www.pharmastat.com/services/sdtm-data-conversion-services/>)
- Biostatistics (<http://www.pharmastat.com/services/biostatistics-and-statistical-programming/>)
- 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>)
- Evaluation of ADaM Data and Documentation (<http://www.pharmastat.com/services/data-evaluation-services#adam>)

Featured Case Study:

- Vendor Support and Data Review (<http://www.pharmastat.com/case-studies/small/vendor-support-and-data-review/>)
 - To view all Small Pharma/Biotech case studies, click here. (<http://www.pharmastat.com/case-studies/small/>)
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