

# Tooling Up and Rounding Out Biometrics

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Your Biometrics team is experienced and focused on the pivotal studies and ISE; however, this is their first CDISC submission and the team is overwhelmed. There are legacy studies to be converted to SDTM for the integrated summaries, and documentation to be assembled for the eCTD. Perhaps they have just started to think about the ISS. Whatever the case, they don't just need extra hands — they need experienced professionals who can integrate themselves into Biometrics operations and be accountable for their deliverables.

To support the Biometrics team through this difficult period PharmaStat collaborates with the company and its vendors to craft a strategy for the filing: Which studies need to be supported with data? Which study databases should be in SDTM? Which ones should be in Item 11 format? We help them define the eCTD deliverables for each study and offer services to fill in the gaps on their team. We can model SDTM, perform conversions, and verify SDTM databases against legacy reports. The company might need us for the integrated summaries as well. Where needed, we apply our expertise to the specific needs of our partner.

With a good partnership, this type of project can move rapidly. Nonetheless, the planning should start 18 months in advance, and, together with the company, we should start locking down deliverables six to nine months before the 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 (<http://www.pharmastat.com/services/biostatistics-and-statistical-programming>)
- Evaluation of ADaM Data and Documentation (<http://www.pharmastat.com/services/data-evaluation-services#adam>)
- 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>)

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## Featured Case Studies:

- CDISC Implementation for eCTD (<http://www.pharmastat.com/case-studies/small/cdisc-implementation-for-ectd/>)

- To view all Small Pharma/Biotech case studies, click here. (<http://www.pharmastat.com/case-studies/small/>)
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