

Small Pharma/Biotech Companies

PharmaStat was built on referrals and repeat business. We don't take on projects beyond our capabilities. Instead, we offer what we do best. A few case studies illustrate our expertise and how we bring value to the drug development process.

(<https://www.pharmastat.com/case-studies/small/ectd-prep-with-biometrics-support/>)

eCTD Prep with Biometrics Support (<https://www.pharmastat.com/case-studies/small/ectd-prep-with-biometrics-support/>)

A small pharma company contacted PharmaStat for help in the midst of preparing an eCTD. Two vendors were already engaged in producing CDISC data but their interpretations varied and their databases were different. PharmaStat consultants wrote specifications and conducted reviews to coordinate the work of the two CROs. New Biometrics tasks were added: we revised...
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(<https://www.pharmastat.com/case-studies/small/cdisc-implementation-for-ectd/>)

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

A small biotech company with their first product came to PharmaStat with Phase 2 studies in an orphan indication. The product looked promising and an NDA was planned in 18 months. PharmaStat developed a plan for the submission, enabling the sponsor to scope it and assign resources. We then prepared the company for a CDISC...
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(<https://www.pharmastat.com/case-studies/small/full-biometrics-support/>)

Full Biometrics Support (<https://www.pharmastat.com/case-studies/small/full-biometrics-support/>)

A pharmaceutical company with Clinical and Regulatory departments — but no in-house Biometrics department — needed post-submission support for their first NDA one month after filing. They had lost confidence in their CRO and approached PharmaStat and one of our partners for statistics and regulatory expertise to cover the review period. The review resulted in...
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(<https://www.pharmastat.com/case-studies/small/vendor-support-and-data-review/>)

Vendor Support and Data Review (<https://www.pharmastat.com/case-studies/small/vendor-support-and-data-review/>)

A small pharmaceutical company operating with outsourced Biometrics found themselves in trouble nine months before their NDA filing was due. The company had engaged seven data management and biostatistics vendors and they were producing data in all flavors of SDTM. The company was referred to PharmaStat late — just as decisions were needed on the...
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