Turning the Ship

Over the past two years, the FDA's expectations for eCTD content have been changing rapidly, as evidenced by the volume of new guidances, specifications and advisory documents. Add to that a company's first-ever submission based on CDISC standards and even large, established pharma companies may find themselves in uncharted territory. It can be like working on their very first submission.

PharmaStat helps these companies navigate obscure standards and complex process to achieve CDISC compliance and successfully deliver eCTD-ready data and documentation packages. PharmaStat's goal is to equip the company with the knowledge and experience to take the next project forward. Applicable services include:

- SDTM, ADaM, and Define.xml Workshops (http://www.pharmastat.com/services/sdtm-data-conversion-services#workshops)
- eCTD Submission Strategy (http://www.pharmastat.com/services/ectd-services#ectdsubmission)
- Production of Define.xml and Define.pdf (http://www.pharmastat.com/services/sdtm-data-conversion-services#defineproduction)
- QC Audit of Biometrics eCTD Deliverables (http://www.pharmastat.com/services/ectd-services#qcaudit)
- CDISC Implementation (http://www.pharmastat.com/services/sdtm-data-conversion-services/)

Featured Case Study:

- CDISC Implementation (http://www.pharmastat.com/case-studies/large/cdisc-implementation/)