

Project Case Summary
Global Drug Development Strategy and Special Protocol Assessments
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Client:	<i>Small U.S. company</i>
FDA Reviewing Division:	<i>Division of Oncology Drug Products</i>
Project Profile:	<i>Intravenous Solution and Capsule</i>

Beckloff Associates became involved after client submitted IND to FDA, with one Phase 1/2 clinical trial in progress.

1. Planned drug development strategy with client, including indications, CMC, nonclinical, and clinical development plans for U.S. and ex-U.S. countries
2. Managed all regulatory affairs activities, including regularly scheduled project meetings with client
3. Interacted with the FDA on the client's behalf, led meetings with FDA, prepared Meeting Requests and Information Packages, and prepared the client for the meetings
4. Provided guidance and training regarding CGMP manufacturing guidelines
5. Reviewed and evaluated drug product and drug substance CMC data, including formulation, stability studies, packaging, manufacturing methods, and Certificates of Analyses
6. Prepared, reviewed, and submitted an additional new IND to FDA
7. Prepared, reviewed, and submitted documentation to FDA on client's behalf including IND Information Amendments, Protocol Amendments, expedited Safety Reports, Annual Reports, and General Correspondence
8. Reviewed, evaluated, and revised Investigator's Brochure (IB) on annual basis
9. Reviewed, evaluated, and revised new protocols and protocol amendments
10. Reviewed, evaluated, and revised Informed Consent Forms for compliance with guidelines and corresponding protocol
11. Reviewed, evaluated, and revised Case Report Forms for consistency with corresponding protocol
12. Reviewed, evaluated, and revised Standard Operating Procedures (SOPs) and project specific SOP plans based on involvement of CROs
13. Reviewed, evaluated, and revised Safety Monitoring Plans

14. Performed, reviewed, and evaluated clinical site audits and audit reports
15. Established and coordinated activities including safety management, clinical data management, and clinical site management for global trials
16. Prepared communication flowcharts for corresponding CROs and participated in clinical study monitoring meetings
17. Reviewed regulatory documents and approval of study drug shipment
18. Prepared, reviewed, and evaluated clinical study documents and reports
19. Prepared three U.S. Orphan Drug Designation requests (approved)
20. Prepared U.S. Fast Track Designation request (approved)
21. Prepared single patient IND requests on behalf of physicians approved to treat patients with drug (compassionate use)
22. Assisted with preparation of pivotal protocols for two lead indications and negotiated with FDA for Special Protocol Assessment Agreement on both protocols (approved)
23. Participated in meetings with EMEA on the client's behalf including preparation of meeting materials
24. Prepared, reviewed and evaluated documentation to ex-U.S. regulatory authorities including two Orphan Drug Designation requests (both approved), Requests for Scientific Advice, and General Correspondence
25. Prepared special protocol assessment for pivotal clinical protocol
26. Prepared IMPDs for ex-U.S. regulatory/ethics commissions
27. Maintained file of ex-U.S. regulatory documentation

Outcome:	<i>Orphan Drug Designations approved, U.S. Fast Track Designation approved, Single Patient IND requests approved, Special Protocol Assessment Agreements approved, clinical studies in progress</i>
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