

Streamline Your FDA Submissions: Cut Costs and Optimize Efficiency

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ABSTRACT

From concept to marketing of medical products be it a drug, device or a combination, is a complex endeavor that requires in-depth understanding of the multifaceted regulatory pathways. Evidence suggests that these pathways require collaboration of clinicians, investigators, researchers, quality assurance and regulatory, industry sponsors and regulators. The clear bottleneck in the whole process is regulators – domestic or worldwide. This is where critical expertise is required. Many highly worthy researchers fail due to two reasons: 1) Not able to effectively deal with regulators due to knowledge gap end to end, and 2) Project becomes cost prohibitive. Regulatory Affairs Team of experts from Stanford Center for Clinical Research (SCCR) has the experience to lead academic researchers and industry-sponsored projects alike through this arduous process and saves you significant amount of money along the way.

RESULTS AND DISCUSSION

We gathered data on IND/IDE costs from external regulatory sources, consultants, and online searches. Costs varied widely, typically ranging from \$25,000 to over \$100,000. Additionally, most services charged inflexible, high hourly rates, unlike SCCR, which offers additional support without extra fees. See Table below:

Task	Consultant Costs	SCCR Cost
Pre-IND/IDE Meeting/Package:	\$20,000	\$16,000
IND/IDE Application		
1. Simple (established)	1. \$25,000	1. \$25,000
2. Complex CMC	2. \$100,000	2. \$35,000
Pre-clinical study support		
1. Toxicology studies	1. \$5,000-\$15,000	1. \$7,000
2. Pharmacokinetic studies	2. \$25,000 - \$200,000	2. 10,000

KEY TAKEAWAYS

- Our model leverages expertise across therapeutic areas, from infectious diseases to cell and gene therapy.
- We offer flexible, comprehensive support—addressing patient safety, adjudication, DSMB, and monitoring—serving as a one-stop shop.
- Additionally, we are 50-70% more cost-effective than external consultants and understand the unique needs of Principal Investigators within the School of Medicine

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