IND-Enabling Study Planning & Execution

The Challenge

Early-stage biotechnology company had conducted early exploration of an NCE, but struggled with how to achieve clinical stage quickly and efficiently.

Our Approach

Built a RAPIDD™* team of PhD and MD Subject-Matter Experts, each averaging 25+ years of experience in the industry.

Value Added

Working closely with the client:

Developed an IND-enabling regulatory-compliant study plan to ensure speed & efficiency, advised on therapeutic approach, and provided evidence-based recommendations for TPP and potential development innovations.

Specifics

- ✓ Executed IND-enabling studies plan.
- ✓ Managed RFP process end-to-end.
- ✓ Determined optimal regulatory pathway.
- ✓ Prepared FDA INTERACT meeting materials.

**Resources Assembled to Plan IND-Enabling Data Dossier

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