

IND Services



Prevalere draws on the extensive product development expertise of our core team of consultants to assist companies involved in the development of biologics. Prevalere offers expert guidance in non-clinical development for IND applications. Non-clinical programs are developed that maximize study designs to support the clinical program.

Our IND services include:

- The design and management of animal studies that are likely to be required to satisfy safety requirements prior to Phase I clinical studies
- Defining strategic decision points
- Preparation of requests for bids for non-clinical pharmacology studies
- Selection and GLP inspections of non-clinical sites conducting studies
- Development and validation of bioanalytical methods to support non-clinical studies
- PK/PD analysis of data to define dosing strategy for the clinic
- Review of draft and final study reports generated by study facilities
- Preparation of relevant sections of regulatory submissions (e.g., IND, NDA, BLA)

Prevalere provides our clients with a cost-effective alternative to the fixed costs associated with internal development. We also support early stage companies that may lack the resources to conduct many aspects of product development.

For further information or a price quotation, please contact Ms. Laura Newkirk.



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