FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

CLINICAL PHARMACOLOGY & CONSULTING

Preserve your study timelines with expert review and analysis of complex data

CASE STUDIES

The ability to predict reliable human response to investigational products by reviewing and cultivating minimal data sets requires unique and precise expertise. Such precision and expertise in a complex environment can only be accomplished by the most experienced and knowledgeable resources having familiarity with expectations set by regulatory agencies.

Our Clinical Pharmacology team helps bridge the gap between nonclinical and clinical data, leading to extrapolation of response into the larger population. We offer an experienced and knowledgeable team with extensive agency exposure to generate and support everything from program-level strategy, formulation of pharmacology documents, to plan operations and implementation.

Learn how three clients relied on Firma Clinical Pharmacology & Consulting to assess project data and deliver recommendations ahead of schedule.

REGULATORY APPROVAL BASED ON ANALYTICAL APPROACH

Client: Large, global pharma company

Project Focus: Pharmacological consulting

Request: Firma provided clinical pharmacological expertise in the development of a blockbuster CNS product within only one month timeframe.

Approach: Firma assigned two clinical pharmacologists to:

- ▷ Analyze data prior to an urgent agency meeting
- ▷ Review analysis of 1000+ data points

Result: The project was completed early allowing submission ahead of schedule by the client, with the regulatory body agreeing with the Firma-developed analysis approach.

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EXCEPTIONAL ASSESSMENT RESULTS IN FURTHER STUDY EVALUATION

Client: Medium-sized, US-based company

Project Focus: Pharmacological consulting for pediatric trial

Request: The client required expertise to help:

- ▷ Draft FDA question responses
- ▷ Develop concentration-exposure scenarios
- ▷ Determine optimal dosing regimen

Approach: Firma assigned two clinical pharmacologists to perform analysis and complex modeling. The project included reviews of:

- ▷ Literature
- ▷ Extrapolation analysis
- ▷ FDA collaboration

Result: Utilizing their experience and the available information, the Firma team provided an assessment that was labeled as "exceptional" by the client and resulted in further study evaluation and confident development progression.

EXTRAPOLATION AND ANALYSIS WITHIN TIMELINE

Client: Small, ex-US pharma company

Project Focus: Data analysis

Request: Client required a complex clinical pharmacological assessment with a focus on:

- ▷ Determining if a change in excipient had effect on PK properties for two different intravenous formulations
- ▷ Reviewing source reports and literature data

Approach: Firma assigned three clinical pharmacologists (two PhDs and one MD/PhD) to review and provide a written summary on the effect of excipient change on PK and toxicology properties. This involved the review of:

- ▷ Ex-US data
- ▷ Literature data
- ▷ Freedom of Information data

Results: Firma successfully completed the assessment within only one month of initiation, despite the project requirements of complex extrapolation and analysis. Based on our findings, the client moved forward with additional Phase 1 and Phase 2 studies, enabling them to focus their development investments into the most appropriate candidates.

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For more information on how we can preserve your study timelines with expert review and analysis of complex data, email **sales@firmaclinical.com** or visit **firmaclinical.com.**