FIRMA
CLINICAL RESEARCH
Expert Insights | Quality Outcomes

CLINICAL PHARMACOLOGY & CONSULTING

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

The ability to predict reliable human response to investigational products by reviewing and cultivating minimal data sets requires unique and precise expertise. 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.

25+
Analyses defended in front of regulatory bodies

25+
Small molecule and biologic trials completed

20+
PK analysis plans prepared

Uniting science and medicine

Drive timely, accurate results in a cost-efficient manner with our full-service and consulting options. Our extensive relationships with a large network of study sites across the country allows us to supplement support where needed.

Critical scientific thinking for your nonclinical and clinical drug development projects

We will work closely with you to develop an optimal research strategy and plan to address:

- Nonclinical and clinical development support including pharmacology, toxicology, pharmacokinetic studies, biopharmaceutical, and ADME programs
- Bridging support between nonclinical and clinical data sets
- Extrapolating minimal data into human response prediction
- Calculating proper dosing and sampling
- Defending exposure-response modeling in front of global regulatory bodies
- Strategizing program management of your small molecule, biologic, and immunoresponse clinical trials
- Writing specialized pharmacokinetics/pharmacodynamics publications, protocol design, biopharmaceutics summaries, briefing books, and all related study documents

BRING A LEVEL OF CONFIDENCE AND STRATEGY TO YOUR PROJECTS

As expert strategists in the delivery of translational medicine and clinical development, our goal is to address your key objectives and help your compound progress successfully through the trial process. How can our expertise benefit you?

Regulatory approval based on analytical approach

Leveraging clinical pharmacological expertise to analyze data can drive submissions ahead of schedule and agreement by regulatory bodies.

Exceptional assessment results in further study evaluation

Proven industry experience can result in further study evaluation and confident development progression.

Extrapolation and analysis within timeline

Complete assessments within timelines, despite project requirements of complex extrapolation and analysis.

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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.**