IDDI

PASSION. SCIENCE. EXPERIENCE.

EXPERT STRATEGIC CONSULTING

Clinical and Statistical Expert Services from dose findings to confirmatory trials

OPTIMIZING YOUR CLINICAL DEVELOPMENT STRATEGY

LEVERAGE IDDI STATISTICAL KNOWLEDGE OF THE REGULATORY APPROVAL PROCESS TO OPTIMIZE YOUR CLINICAL DEVELOPMENT STRATEGY

REGULATORY STATISTICS & APPROVAL-OPTIMIZATION STRATEGIES

From dose finding to confirmatory trials

- Streamlined clinical development paths.
- Robust statistical knowledge of regulatory guidances and process ensure data quality and increases the chances of regulatory approval.
- A methodologically sound trial design enhances the credibility of data submitted for regulatory approval. IDDI's expert consultants team helps you determine the right sample size, appropriate endpoints, and effective randomization techniques.

COMPREHENSIVE SERVICES TO HELP WITH YOUR CLINICAL DEVELOPMENT STRATEGY

- CLINICAL INPUT FOR DEVELOPMENT PLANS
- TRIAL DESIGN
  - Conventional, adaptive, biomarker-based design, complex & innovative designs
  - Frequentist, Bayesian methods
  - Sample-size calculation and simulations
  - PK/PD analysis: Non-compartemental analysis (NCA), Population pharmacokinetics (PK), Modeling
- REGULATORY SUPPORT
  - Regulatory guidance for IND and NDA submissions
- INPUT IN LICENSING DEALS & PORTFOLIO MANAGEMENT
- ADVANCED BUOSTATISTICS
  - Validaton of surrogate endpoints, Generalized Pairwise Comparisons (GPC)

IDDI's expert consultants have the medical expertise, biostatistical acumen and profound knowledge of the regulatory environment that are required to design and launch clinical trials that ask the right questions regardless of the trial phase.

EUROPE HQ
1341 Ottignies-Louvain-la-Neuve, Belgium
Tel.: +32 10 61 44 44

USA OFFICE
Raleigh • NC 27617
Tel.: +1 984 227 8599

MORE INFO?
info@iddi.com
IDDI.COM