AGINKO Research

Preclinical - Clinical - Regulatories

Medical device clinical trials require a host of resources that many companies do not have in house. As a full-service contract research organization (CRO) focused on the osteoarticular medical device industry, AGINKO Research is uniquely able to support you through all phases of clinical trial development and testing.

Working with your team, we will help you to design and implement a clinical trial that will best meet your business needs, whether you need clinical data to support a regulatory pre-market submission, drive product adoption, support product reimbursement, or monitor post-market product use.

Strategic Advice

AGINKO Research can be your clinical partner, providing comprehensive assistance from IND to post-submission activities, or supporting you in specific areas when an extra hand is needed.

AGINKO Research assists its clients by providing strategic advice on many aspects of their drug development and medical devices programs.

This includes:

- Clinical study design
- Advice on regulatory strategy
- Selection of the best countries in which to conduct a clinical development program
- Obtaining advice from both EMEA and FDA
- Organizing clinical expert groups

Strategic advice is provided by in-house personnel supplemented by our network of external consultants as appropriate.

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Data Management

AGINKO Research offers complete data management services to meet your specific project needs.

From database design to data analysis, AGINKO Research assists clients in achieving reliable, verifiable statistical results:

- Flexible design
- EDC or paper solutions
- Fast database lock
- Cost effective data solutions
- Data Entry
- CRF Design and Annotation
- Database Design and Validation
- Electronic Edit Checks
- Tracking, Query Processing

Medical Writing

AGINKO can be your medical writing partner, whatever documentation you require. We have prepared protocols, as well as New Drug and Product Licensing applications, including clinical, statistical, safety and efficacy summaries, CPMP dossiers, expert reports, and clinical procedure write-ups. We have also written investigator brochures, SOPs and annual reports, designed case record forms, and drafted manuscripts and monographs.

After completion of the clinical and data work, the success of your project rests upon the way in which that work is explained and described. To gain regulatory approval, it is essential to make the most compelling case for your project, and we have the experience to help you achieve that. Our team of medical and technical writers is integrated within the regulatory affairs department offering particularly strong expertise in complex and demanding medical therapeutic areas such as bone and inflammatory diseases.