



**Your Partner of Choice for Projects in  
Bone and Joint Diseases**



**AGNKO Research**  
The Osteoarticular CRO

# The Most Appropriate Models Complying with Regulations are Chosen to Fulfill our Customers' Needs



## Our Expertise

Our scientific networks integrate researchers and clinicians, resulting in an efficient process from lab bench to clinic and reducing time to market, for pharmaceutical, biotechnology and medical devices companies.

**AGINKO Research** is an osteo-articular and inflammation focused preclinical and clinical research organization with an unrivaled reputation for conducting global preclinical and clinical development programs of the highest integrity.

Pharmaceutical, biotechnology and medical device companies look to **AGINKO Research** for a complete range of customized preclinical and clinical programs in bone, cartilage, spine, inflammation and pain therapeutic areas.

In these areas in particular, we offer broad study experience and direct knowledge of

study requirements, risk management, and best practice implementation.

We offer effective study design and management services, multi-service integration, and an efficient process that reduces delays and gives clients confidence and peace of mind.

By combining the **AGINKO Research** methodology with therapeutic expertise, sponsors can decide with confidence due to improved information about drugs and device development.

**AGINKO Research's** headquarters are situated in Marly, Fribourg, SWITZERLAND.

# Cutting Edge Research and Services



AGINKO Research provides a wide range of services for companies seeking to contract preclinical and clinical testing. Whether you are a large pharmaceutical company in need of a trustworthy CRO focused on the osteoarticular system, a smaller company or bio-tech requiring program guidance and management, or a device company searching for surgical, behavioral and model development expertise, AGINKO has the people and systems that will ensure preclinical and clinical program success.

## In Vitro and In Vivo validated models:

- Broad portfolio of in vitro testing systems
- Medical and surgical animal models

## Portfolio of disease models:

- Joints: ligaments, cartilage, meniscus, bone regeneration and reconstruction
- Spine: disc replacement and fusion
- Osteoarthritis
- Rheumatoid arthritis
- Osteoporosis
- Orthopaedic medical devices
- Dental implants
- Pain models

AGINKO Research's facilities are designed to conduct cutting edge orthopaedic procedures. Our facilities are suitable for small rodents to large animals. The projects are either performed by our very experienced and skilled in-house orthopaedic and veterinary surgeons or the sponsors themselves. Based on our expertise, the most appropriate models complying with regulations are chosen to fulfill our clients' needs.



# CRO and Regulatory Consulting for the Entire Medical Device Life Cycle



Our scientific networks integrate researchers and clinicians, resulting in an efficient process from lab bench to clinic and reducing time to market for developers of pharmaceutical biotechnology.

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 use.

## **Strategic Advice**

**AGINKO Research** assists its clients by providing strategic advice on many aspects of their drug development and medical device programs. Strategic advice is provided by in-house personnel supplemented by our network of external consultants as appropriate.

## **Medical Writing**

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.



## Preclinical

Functional and toxicology assays

De-/Re-differentiation models

Destructive and non-destructive mechanical testing

Biomechanical and molecular biology assays, including a broad variety of biomarkers

Histology of all soft and hard tissue:

- Paraffin embedding
- Plastic embedding in MMA
- Groud section slides
- Immunohistochemistry
- Histomorphometry

Imaging:

- MicroCT
- DEXA, MRI, CT with 3D reconstruction
- Biomarkers



## Clinical Design/Clinical Trial

If your clinical protocol is not yet developed, or is partially developed, Aginko can assist in its completion.

- Study protocol & budget development
- Literature searches & analysis
- Investigator selection
- Retrospective clinical data compilation
- Biostatistics
- Data management/database
- Site qualification/Site management
- Study management and administration
- Clinical monitoring
- Study closeout
- Analysis
- Final Clinical Report

## Regulatory & Additional Advisory Research Services

AGINKO Research develops and executes regulatory strategies for manufacturers of medical devices, biologics and combination products. We provide regulatory support in multiple ways:

- ad hoc hourly consultation and advice
- Submission support:
- Functioning as a virtual regulatory/QA department
- Emergency response to Official Agencies concerns, warnings or decisions



## Partnering with Clients



### AGINKO offers you:

- A team of experienced professionals, adapted to each project
- Direct contact with the study director of your project
- Direct access to key opinions in osteoarticular diseases
- Step by step follow-up of your study
- High quality report delivered on time
- Intermediate results and customized reports

The company is committed to providing exceptional services beyond client expectations and is flexible in meeting clients specific needs. Dedicated service groups assist clients from beginning to end, from project planning to final review together with the client's project management team. Clients choose **AGINKO Research** because of our commitment to high quality and prompt results within budget.

**AGINKO Research** is dedicated to assisting the pharmaceutical, medical device and biotech industries in the pursuit of their drug discovery programs and product development requirements. While the specific needs vary across industries, all share a common requirement: to make accurate decisions

and draw the right conclusions based on the best available and most reliable data.

**AGINKO Research** recognizes that the single most important element of data collection and analysis is accuracy. To this end, executing studies in a prescribed and thorough manner, as well as interpreting the data using the most appropriate methodologies are standard operating procedures.

At **AGINKO Research**, our top priority for every experiment we conduct is scientific integrity. To achieve this goal, we are committed to making experimental design and analysis recommendations based strictly on a scientific rationale.





# Quality Reporting

## Quality Assurance

The management of **AGINKO Research** is highly supportive of QA and has adopted a philosophy that is based on the concept of total quality. Management, study directors, and scientific support staff work together using sound scientific procedures to produce studies that meet the needs of our customers. The QA staff ensures the quality and regulatory compliance of these studies.

## On Schedule Report Submission

The commitment of our dedicated writing staff allows **AGINKO Research** to meet your requirements for deadlines and submissions. All draft reports receive a full review by the Study Director prior to report audits performed by **AGINKO Research's** Quality Assurance Unit.

## Standard Electronic Formats

**AGINKO Research** prepares data and documents in the format you need for submission. Our standard report format is Microsoft WORD document. We also implement Adobe Acrobat file created from the native file which includes bookmarks and hyperlinks according to the formats suggested by EPA, OECD and FDA for electronic submissions.

## Customized Reports

Although we maintain standard report formats for all study types, **AGINKO Research** will produce client-specific, customized study reports upon request.

**AGINKO Research** constantly monitors the regulatory environment to provide up-to-date information and guidance for our clients.



**AGINKO Research**, the unique service provider in osteoarticular diseases and inflammation



# AGINKO Research

The Osteoarticular CRO

Route de l'Ancienne Papeterie  
1723 Marly 1  
Switzerland

Tel: +41 31 331 76 79

Fax: +41 41 560 80 53

Email: [info@aginko.com](mailto:info@aginko.com)

[www.aginko.com](http://www.aginko.com)

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