AGINKO Research

The Osteoarticular CRO

Your Partner of Choice for Projects in Bone and Joint Diseases

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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.

The most appropriate models complying with regulations are chosen to fulfill our customers' needs.

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.

AGINKO Research is headquartered in Zug, SWITZERLAND, with operational offices in Bern, Fribourg and

Singapore

In these areas in particular, we offer broad study experience and direct knowledge of study requirements, risk management, and best practice implementation.

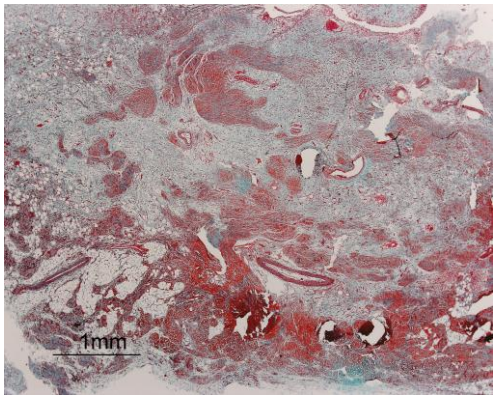
We offer effective study design and management services, multi-service integration, and an efficient process that reduces delays and gives clients confidence and peace of mind.

Combining the AGINKO Research methodology and therapeutic expertise leads sponsors to more confident, better-informed drug and device development decisions.

AGINKO Research

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
- Customized safety and efficacy studies
- 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's needs.

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

CRO and Regulatory Consulting for the Entire Medical Device Life Cycle

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 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.

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.

Our services include:

- Investigator Brochures
- Operating Manuals
- Presentation Files
- Protocols
- Final Reports
- Expert Reports
- Publications

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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 biomakers

Histology of all soft and hard tissue:

- Paraffin Embedding
- Plastic Embedding in MMA
- Ground Section Slides
- Immunohistochemistry
- Histomorphometry

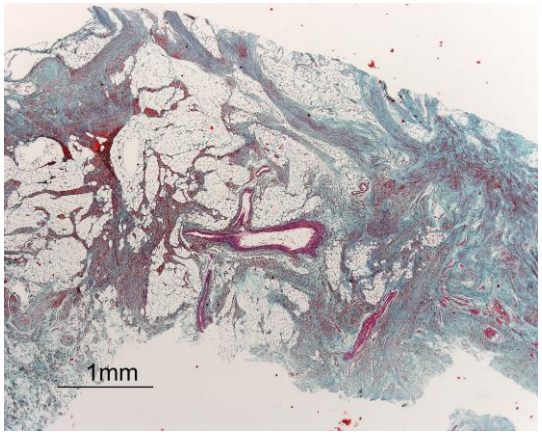
Imaging:

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

Clinical Design / Clinical Trial Conduct

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, selection and initiation activities
- 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

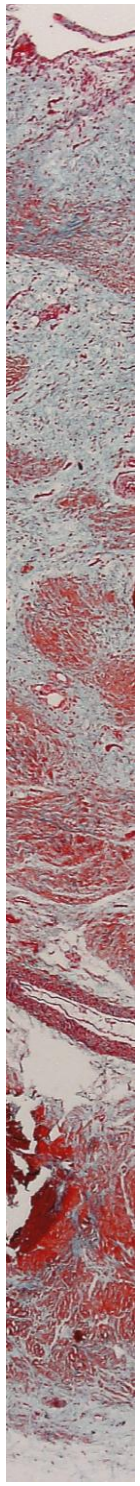
The integration of those three pillars makes AGINKO Research unique as a service provider in Osteoarticular diseases and inflammation.

Partnering with Clients:

The company is committed to provide exceptional service beyond client expectations and is flexible in meeting client specific needs. Dedicated service groups assist clients from beginning to end, starting with project planning and finishing with a review with client's projects management team. Clients choose AGINKO Research for our commitment to providing high quality, prompt result within budget.

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 opinion leaders in osteoarticular diseases
- Step by step follow - up of your study through secure tools
- High quality report delivered on time by regulatory experts
- Intermediate results and customized reports



AGINKO Research is dedicated to assist 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, and 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.

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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 to our clients. AGINKO Research follows Good Laboratory Practice guidelines within our research services.

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