

Preclinical Services

Supporting the early development of therapeutic antibodies

BioAcceleration includes progressing your antibody candidates seamlessly into Preclinical Development, which saves time and unnecessary cost. We do this by becoming an integral part of your program. We work with your internal team and provide guidance, leadership, and focus. Our expertise in development strategy, scientific design, implementation, and management of your company's programs ensure that you meet all regulatory requirements throughout the drug development process. In addition to our own internal team, we have partnered and managed third party experts who will conduct high quality studies in support of your preclinical development program. BioAtla has prequalified several service providers based on quality, cost, and historical performance. In addition, we have negotiated preferred pricing and priority for our clients within our Asian preclinical network.

Preclinical Program Planning Strategy

Defining and designing *in vitro* and *in vivo* studies to support your IND ensures that your objectives demonstrating efficacy and safety are met in a timely and cost effective manner. This program comprehensively evaluates the Pharmacology, Toxicology and Pharmacokinetics of your antibody and includes both timelines and budgets. This could include potential regulatory interfaces such as a pre-IND meeting with the FDA.

Preclinical Activities

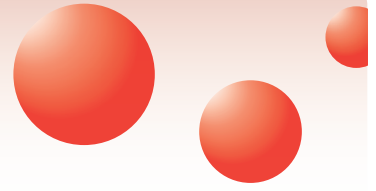
Design study protocols, initiate and monitor study, analyze data and issue progress and final reports. We work with clients on the evaluation and interpretation of the preclinical data such that all objectives have been met or addressed:

- 1) Pharmacology: *in vitro* such as affinity and functional binding, *in vivo* pharmacology studies to demonstrate that the reported mechanism of action results in the desired pharmacology,
- 2) Toxicology and Safety Studies: *in vivo* studies conducted in the appropriate species that are intended to characterize the safety and toxicity of your antibody. Animals are dosed with multiples of the expected therapeutic dose via the intended clinical route of administration. These studies include dose range finding studies and GLP IND-enabling studies which support the regulatory requirements,
- 3) Pharmacokinetics: These studies are designed to evaluate exposure and elimination of your antibody and are required for an IND.

IND Documentation

BioAtla will oversee the production of individual study reports and author the required IND summary documentation.

[Preclinical Services Chart >](#)



Protein Therapeutics

Preclinical Services

Assess Safety

- Show that product is safe enough for early human testing.
- Eliminate products with safety problems easily

Demonstrate Medical Utility

- Show benefits people
- Select appropriate candidate with high probability of effectiveness

Industrialization

Prototype: High quality product (physical design, characterization, specifications)



Basic
RESEARCH



Prototype Design or
DISCOVERY



Preclinical
DEVELOPMENT



Clinical
DEVELOPMENT

PH 1 / PH 2 / PH 3



US FDA
FILING/APPROVAL/LAUNCH
Preparation

Pre IND meeting with US FDA

Toxicology & Safety Studies

- Assay Development
- Dose range finding toxicity study in rats
- Dose range finding toxicity study in monkeys
- 2-12 week toxicity study in rats
- 2-12 week toxicity study in monkeys

Pharmacology

- in vitro* affinity and functional binding
- in vivo* confirmation of MOA

Pharmacokinetics

- Exposure
- Half-life