

BIOKINETICA



Your trusted partner in Biosimilars
and Early Phase Clinical Research

Phase 1 Unit

Who we are?

Biokinetica GmbH is a clinical research company headquartered in Berlin and operating its own Clinical Pharmacology Research Unit in Warsaw, Poland.

We specialize in Early Phase studies, including **First in Human (FiH)**, **Biosimilars**, **Proof of Concept**, and **Clinical Pharmacology** trials with Healthy Volunteers and Patients. Known globally, Biokinetica is recognized as an expert in conducting time- and cost-effective large Phase I Biosimilar projects with healthy volunteers.

Our outstanding phase 1 capabilities make us a preferred and trusted partner for the world's leading CROs as well as pharmaceutical and biotech companies.

The clinical trials are conducted at our FDA Inspected, state of the art Phase 1 Unit, connected to a specialized cardiology hospital. The unit is centrally located in the Warsaw area of Poland. This ensures excellent recruitment capabilities, thanks to direct access to a large population of healthy volunteers and patients with various diseases.

INHABITANTS

Poland 38 M

Warsaw region 5.5 M



Comprehensively equipped **Clinical Pharmacology Unit**



Area of 1,500 sq.m.



24/7 medical coverage



In-house Emergency Intensive Care Facilities with direct access to a Cardiac ECU



Ambulatory Examination Rooms



On-site Pharmacy



In-house Sample Processing Laboratory



Bio-storage room equipped with -80°C freezers



Subject Accommodation with a Capacity of 50 Hospital Beds



Advanced Medical Equipment, including full-scale emergency response capabilities



On-premise Modern Surgical Suite for study procedures under full anesthesia



Innovative Real-Time Cardiac Safety Monitoring System with cutting-edge technology and analytics



Outpatient Screening Facility

Due to its excellent location adjacent to the metro station and well-orchestrated organization, the clinic boasts a throughput exceeding 150 volunteers screened daily, including weekend days.

- Outpatient clinic in Warsaw with an area of 300 sq.m.
- General and Specialised Medical Examination Rooms, including ultrasound and gynecological facilities
- A Sample Processing Laboratory
- Reception & Waiting Area

Our Team

Biokinetica's highly qualified and robust team comprises of 70 staff members with an average 5 years of clinical trial experience:



- I** Investigators (Board Certified Specialists)
- N** Nurses
- L** Laboratory Diagnosticians & Technicians
- P** Pharmacists (Board Certified)
- PM** Project Managers & Study Coordinators
- R** Recruitment Team
- Q** Quality Assurance & Quality Control

Our specialized teams are dedicated to conducting early-phase studies with both healthy volunteers and patient populations across a diverse range of therapeutic areas.

Experience

by Type of Study

- First-in-Human
- Biosimilars
- Dose Escalation SAD/MAD
- Pharmacokinetics / Pharmacodynamics
- Proof of Concept
- Drug-Drug Interaction
- Food Effect
- Special populations (Renal and Hepatic impairment)

by Therapeutic Area

- Oncology
- Cardiology
- Neurology & Central Nervous System
- Respiratory & Pulmonology
- Immunology
- Gastroenterology
- Metabolic Disorders
- Infectious Diseases & Virology
- Women's Health

Our Mission & Goals

Customized Business Models for long term relationships

At Biokinetica, we understand that each client and project has unique needs and objectives. Our offer of unparalleled business flexibility is crafted to align with these objectives.

Our ambition is to establish and maintain long-term partnerships, aiming to be your preferred resource for your Early Phase Clinical Studies.

Whether you opt to collaborate with your selected qualified CRO or leverage our complementary partner CRO services, we are committed to building a long-lasting relationship that grows with your business needs.

Global Partnerships

Biokinetica is proud to collaborate with the world's premier CROs and add value to their portfolio of capabilities as a highly effective, high-quality EU-based Phase I Unit.

Swift and Effective Recruitment

Biokinetica's goal is to create value for our clients and partner CROs. Through highly effective recruitment campaigns, we are capable of swiftly and cost-effectively delivering large cohort Biosimilar studies to support global regulatory approvals and early market access. At Biokinetica we understand the importance of providing access to new, innovative, and cost-effective therapies for patients worldwide.

Scientific & Ethical Excellence

Our experienced medical and scientific team is eager to add value to our clients' strategic development plans by implementing innovative designs and early PoC endpoints.

We are steadfast in upholding the highest standards of quality and ethics, with subject safety positioned as our foremost priority.

Biokinetica

By Numbers



2

Clinics – Phase 1 Unit
and Satellite
Screening Facility

5K

Average annual
increase of healthy
volunteers in our DB
over the last 3 years

16K

Healthy Volunteers
and Patients
contacted over
the last 2 years

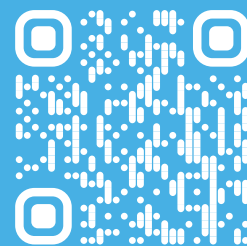
453

Largest Biosimilar
Study conducted
with Healthy
Volunteers

150

Monthly enrolment
rate in a single
Biosimilar study

BIOKINETICA



Get In Touch

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