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EARLY PHASE INSTITUTE

Trusted for safety, chosen for speed, recognized for quality.



## A RELIABLE PARTNER FOR HIGH-PRECISION EARLY-PHASE DEVELOPMENT

**Confident early-phase execution driven by regulatory strength, hospital-based safety, and operational speed.**



Biokinetica is a European early-phase clinical research institute supporting CROs, pharma, and biotech companies.

We operate through a dual-country model: an operational hub at the Academic Hospital Groningen (NL) and a hospital-based, FDA-inspected Phase 1 Unit in Warsaw (PL).

We deliver safe, high-quality, and fast early-phase execution, powered by strong recruitment, scientific rigor, and a regulatory track record that includes multiple FDA inspections with no actions indicated.

# INFRASTRUCTURE DESIGNED FOR COMPLEX PROTOCOLS

**Hospital-based capability that ensures safety, precision, and uninterrupted execution.**



## Hospital-based, FDA-inspected Phase 1 Unit:

- ◆ 1,500 sq.m. clinical area
- ◆ 50-bed accommodation
- ◆ 24/7 medical coverage
- ◆ In-house fully-equipped surgical room
- ◆ 5-bed in-house ECU with direct access to cardiac ECU
- ◆ In-house CSF sampling
- ◆ In-house pharmacy, sample processing lab, and -80°C biostorage
- ◆ Dedicated screening unit, Warsaw





## TESTED CAPABILITIES FOR HIGH-QUALITY EXECUTION

Biokinetica is trusted for early-phase designs requiring precision, safety, and scientific depth:

- ◆ First-in-Human, SAD/MAD, PK/PD, DDI projects
- ◆ Biosimilar Phase 1 programs
- ◆ QTc studies and cardiac safety assessments
- ◆ CSF sampling
- ◆ Precision monitoring for complex study designs

Therapeutic focus on:

- ◆ oncology
- ◆ cardiovascular
- ◆ immunology

Additional experience in: CNS, Respiratory, Infectious Diseases, Gastroenterology, Metabolic Disorders, Women's Health, and more.

**Expertise where early-phase precision matters most.**

# DUAL COUNTRY MODEL FOR SPEED & SCALE

**Start fast in the Netherlands.**  
**Scale reliably in Poland.**

- ◆ Accelerated regulatory approval in the Netherlands
- ◆ Deep experience working with Dutch regulatory authorities
- ◆ Fast study start-up in the Netherlands with a 42-day approval cycle
- ◆ Exceptional patient and healthy study participants recruitment potential in Poland
- ◆ Smooth cohort continuation between countries



# RECRUITMENT POWER THAT DELIVERS

**High-volume, reliable enrollment that keeps  
early-phase timelines on track.**

- ◆ 150+ volunteers screened weekly
- ◆ Access to both healthy study participants and patient populations
- ◆ Proven recruitment performance across oncology, cardiology, immunology, and more
- ◆ Optimized enrollment process
- ◆ High retention strategy
- ◆ Dedicated recruitment and retention team

# QUALITY & COMPLIANCE: INSPECTION READY BY DESIGN

Biokinetica's quality systems are independently validated through rigorous external oversight:

- ◆ 2 FDA inspections across 3 studies — no actions indicated
- ◆ 20+ sponsor audits in the last 5 years
- ◆ Consistent compliance with international regulatory standards
- ◆ GCP-aligned SOPs and inspection-ready documentation

This regulatory strength is a major competitive advantage — especially for biosimilar and FIH programs requiring global submission readiness.

**Regulatory excellence validated by FDA, demonstrating the quality of our data and the strength of our processes.**



# BUILT FOR EARLY-PHASE SUCCESS

**Experience, quality, speed, and partnership — the foundation of confident early-phase development.**

## Experience That Builds Confidence

Our track record enables informed decision-making in complex early development stages.

## Quality Through Regulatory Excellence

This regulatory strength supports global submissions and biosimilar development programs.

## Speed Through Efficient Operations

By combining regulatory speed with scalable operations, Biokinetica shortens development timelines without compromising quality.

## Partnership as a Principle

We work as an extension of our sponsors' teams — flexible, responsive, and focused on shared success.

## BIOKINETICA BY NUMBERS

**2** strategic locations: Groningen (NL) and Warsaw (PL)

**2** FDA inspections in 3 studies — no actions indicated

**5,000+** annual increase in study participants in our database

**16,000+** study participants contacted in the last 2 years

**453** participants — largest single-site biosimilar study

**150** monthly enrollments in a single-site biosimilar study

# BECAUSE WE CARE

Behind every dataset is a person who trusted us with their time and wellbeing.

We care for our study participants with the same dedication we bring to scientific excellence — ensuring they feel informed, respected, and safe at every step.

Their experience shapes how we design our processes, how we train our teams, and how we deliver studies that sponsors can rely on.



Let's Advance Early-Phase  
Development Together

## CONTACT

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