Pharmbiotest Poland LTD
tel.: +48736335818
Mieszka I 5, 86-300 Grudziądz
contact@pharmbiotest.pl

PHARMBIOTEST Poland LTD

Contract Research Organization

Full Range Services in Phase I clinical trials

Pharmbiotest Poland

Who we are

PHARMBIOTEST Poland is a contract research organization (CRO) with its own clinical and bioanalytical facilities, providing a broad range clinical trials services for pharmaceutical, generic drug and healthcare companies. Our headquarters are in Grudziadz, Poland.

Pharmbiotest Poland LTD
tel.: +48736335818
Mieszka I 5, 86-300 Grudziądz
contact@pharmbiotest.pl

Our services

PHARMBIOTEST Poland offers comprehensive Phase I clinical trials, specializing in pharmacokinetic, bioavailability, and bioequivalence studies. In addition, we conduct R&D activities, including the development of generic drugs, offering expertise from early formulation to clinical trial.

BA/BE STUDY

PHASE I STUDY

CLINICAL TRIAL DOCUMENTS DEVELOPMENT

BIOSTATISTICS & BIOANALYTICAL SERVICES

THERAPEUTIC DRUG MONITORING

Pharmbiotest Poland LTD
tel.: +48736335818
Mieszka I 5, 86-300 Grudziądz
contact@pharmbiotest.pl

Our Clinical Trials Services

- ✓ Study planning and development of study documents
  - Study protocol, Information for volunteers/Informed Consent Form (ICF), case report form (CRF), Randomization
- ✓ Regulatory Authority
  - CTIS submission
  - CTIS study progress maintenance
- ✓ Clinical part
  - recruitment of volunteers, initial medical check-up, screening procedures
  - laboratory check-up
  - hospitalization/catering
  - clinical procedures, PK sampling
- ✓ Project Management
  - project management, data management, storage of IMP in clinic, storage of plasma samples, archiving and storage of study documents (25 years)
- ✓ Bioanalysis
  - LC/MS-MS development and validation of analytical method according to M10 ICH
  - LC/MS-MS analysis
- ✓ Statistics
  - statistical analysis plan (BE/BA)
  - pharmacokinetic evaluation
  - statistical evaluation
  - statistical / pharmacokinetic report (BA/BE)
- ✓ Study reporting
  - final report
  - CTIS study results publication
- ✓ Quality Assurance
  - QA of study protocol, CRF and other subject documentation, analytical results, reports
- ✓ Insurance
  - Subject insurance (Clinical Trials Compensation Fund)
  - Sponsor and Investigator insurance

Pharmbiotest Poland LTD
tel.: +48736335818
Mieszka I 5, 86-300 Grudziądz
contact@pharmbiotest.pl

Types of Phase I clinical trials we conduct

- ✓ First-In-Human (FIH) Studies - Single-Ascending Dose (SAD) and Multiple-Ascending Dose (MAD)
- ✓ Food-Effect Studies
- ✓ Dose Escalation Studies
- ✓ Drug-Drug Interaction Studies
- ✓ Bioavailability / Bioequivalence (BA/BE) Studies
- ✓ Steady-State Studies (Multi-Dose Drug Administration Study)
- ✓ Biosimilarity Studies

We offer both full-service solutions and individual service modules for Phase I clinical trials — tailored to your needs.

Our advantages

- Over 30 successful Phase I studies
- A full range of Phase I studies (turnkey studies)
- Clinical unit & Bioanalytical laboratory (GLP- certified) in one facility
- Any complexity of bioanalytical methods
- Staff trained in accordance with GLP and certified in GCP
- Wide experience in difficult designs (full-replicate, two-stage etc.)

We look forward to partnering with you!

Our contact information:

Mieszka I 5, Grudziądz 86-300

contact@pharmbiotest.pl

+48 736 335 818

www.pharmbiotest.com