eurofins

Global Infectious Disease Services. **Discover. Experience.**

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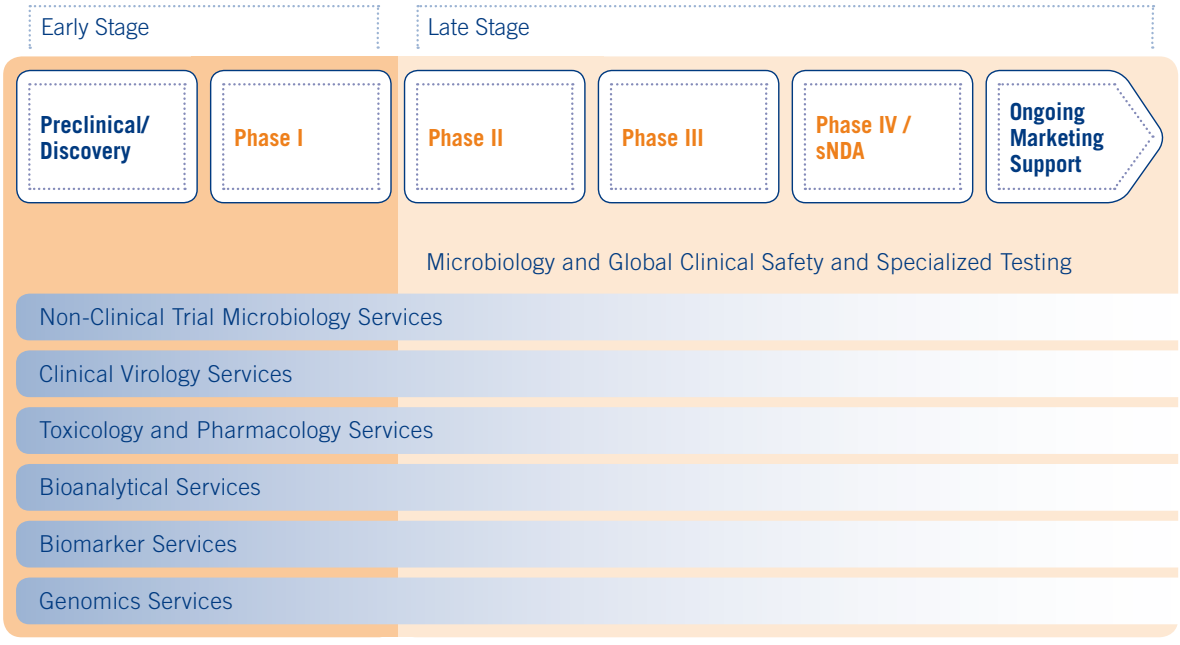
Your Global Partner for Anti-Infective Drug Development

Laboratory Testing Services

Eurofins Global Infectious Disease Services is a global leader in laboratory and consultative services that support the development of products for preventing, controlling, and treating infectious diseases throughout the world. Eurofins provides a full range of services to generate data required for regulatory submissions and post-approval studies for antibacterial, antifungal, antiviral, and vaccine products. Our anti-infective focus is fully supported by global central laboratory capabilities, seamlessly integrating toxicology, pharmacology, genomics, diagnostic virology, bioanalytics, and biomarker development that are used to support both early and late phase product development.

We offer a unique turn-key approach to support anti-infective development across all phases of drug development and commercialization. Our turn-key approach is founded on our unique ability to conduct all of the clinical trial and non-clinical trial based microbiology studies needed to support successful IND and NDA filings, as well as applications to other organizations such as EUCAST and CLSI.

Full Global Laboratory Services to Support Anti-Infective Drug Development



Non-Clinical Trial Microbiology Services include profiling, breakpoint development, resistance development, synergy, PAE, cidality, disk development, etc, all of which are required by the FDA for NDA submission.

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Non-Clinical Trial Microbiology
Such testing includes:
- Global and National Antimicrobial Surveillance
- Compound Screening and Profiling
- Bactericidal Assays
- Synergy, Antagonism, Post Antibiotic Effect (PAE)
- Disk and Breakpoint Development
- Tier 1, 2, and 3 QC Studies
- Regulatory Consultation

Global Clinical Safety and Specialized Testing
Full package of routine and non-routine laboratory testing, including:
- Bacteriology and Mycology
- Clinical chemistry
- Hematology
- Immunochemistry
- Urinalysis
- Coagulation testing
- Flow cytometry
- *Extensive testing menu available*

Clinical Trial Support Services
- Logistics support and courier management
- Import and export licenses consultancy for Asia-Pacific
- Investigator site support
- Multilingual regional helpdesk on three continents
- Sample management and storage
- Project management
- Data management
- Global LIMS
- Global QC and QA

Bioanalytical Services
- Method Development and Fit for Purpose Validations
- Compliant with Regulatory Guidances for Bioanalysis
- Metabolism- Analysis and Identification of Metabolites, Drug-Drug-Interactions, and IVIV Correlations
- PK/PD Analysis and Toxicokinetics
- Therapeutic Drug Monitoring
- Small Molecules, Large Molecules and Biotherapeutics

Biomarker Services
- Fit-for-purpose advanced validation and analysis of commercially available biomarker assays
- PK analysis of endogenous compounds (large molecules)
- Feasibility assessment and scientific consultancy

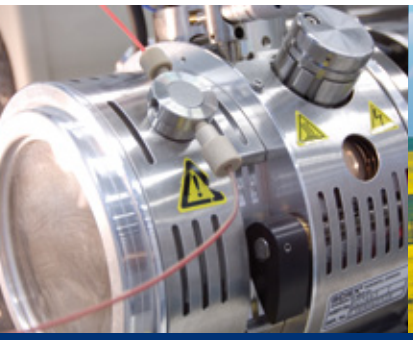
Clinical Virology
- Support global clinical trials for anti-virals, vaccines, and immunomodulating products
- Global real-time PCR technology
- Immunoassays to detect antigens and antibodies: HIV, HBV, HCV, HAV, CMV, HSV, EBV, Varicella, Rubella
- Nucleic Acid Detection and Quantification: HIV, HBV, HCV, HAV, CMV, HSV, EBV, Varicella, Parvovirus B19, BK
- Full sequencing
- Genotyping
- Therapeutic Drug Monitoring (LC/LC-MS)
- Cell Count via Flow Cytometry
- Viral Culture
- Biopsies
- Biomarker development

Genomic Services
- Genotyping
- Molecular Diagnostics
- Sequencing (Eucaryotic and Procaryotic)
- DNA and RNA Extraction/ Sequencing
- Gene Expression Profiling
- Gene Synthesis
- Pharmacogenetics

Pre-Clinical Services
- Pharmacology
- Toxicology

Eurofins is committed to providing the highest quality services, accurate, timely results capturing the planned completion date, and expert advice from our highly qualified team of experienced scientists. As data integrity is of paramount importance, we continually monitor both data quality and our laboratory operations to ensure the highest standards are maintained.

Eurofins Global Central Laboratory has earned various quality control accreditations and certifications, including ISO 15189, ISO 17025, CAP, CLIA, OECD GLP and our clinical laboratories are in compliance with GCP guidelines.

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