

KEY INFORMATION ABOUT US

Location: Grenoble, France

Core expertise: Eurofins Optimed is a Contract Research Organization (CRO) and a Clinical Unit specialised in early-phase clinical development, with more than 35 years of experience.

Clinical :

- Dedicated on-site Clinical Trial Unit
- 60-bed clinical pharmacology unit equipped for early-phase trials
- On-site medical, nursing, laboratory and safety teams
- Access to a large database of volunteers for timely recruitment

Compliance & quality:

- Good Clinical Practice (ICH-GCP)
- Inspections by the French Medicines Agency (ANSM) and regional health authorities
- Internal and external audits
- Compliance with EMA, FDA and international regulatory requirements
- Comprehensive SOP framework and quality documentation

CLINICAL TRIAL CONCEPTION

- Scientific & methodological support
- In-house multidisciplinary experts

REGULATORY AFFAIRS

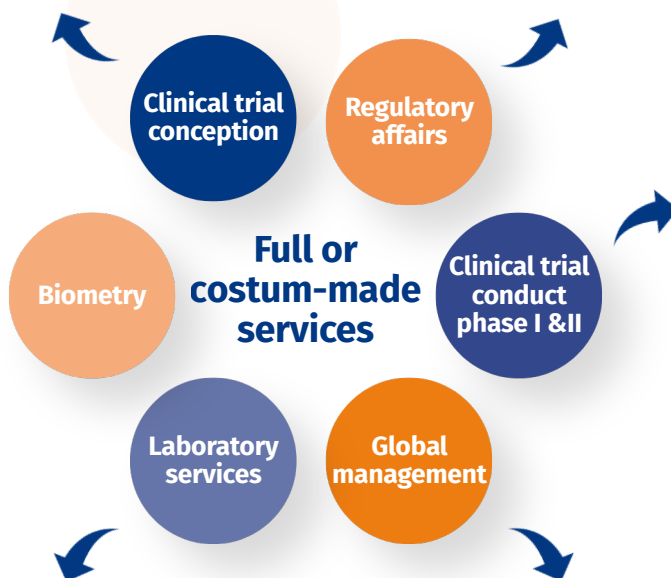
Development, review and submission of regulatory documents (IMP/IB, CRF, ICF...) – **CTIS platform**

BIOMETRY

- Data management
- Statistics
- FDA compliant
- CSR

TYPE OF STUDIES

- First-in-Human
- PHASE I & II
 - QT Assessment
 - Bioequivalence
 - PK/PD
 - Food effect
 - Drug/drug interaction



LABORATORY SERVICES

- Kit and sample logistics
- Bioanalysis (PK/PD)
- Biomarkers
- IMP manufacturing and labeling

GLOBAL MANAGEMENT

- Site set-up & management
- Local regulatory submissions
- Monitoring
- Project management
- Recruitment follow-up
- Pharmacovigilance

EUROFINS OPTIMED

1 rue des Essarts, 38610 Gières – France

+33(0) 6 83 29 60 05 - OptimedSales@ba.eurofinseu.com