

■ COMPANY PROFILE



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History and Mission

Linical Europe, headquartered in Frankfurt/Main, Germany and its further major offices in Madrid, Spain and Paris, France has more than two decades of track records in successfully conducting clinical trials. With corporate headquarters in Osaka, Japan and 1,000 employees globally Linical directly covers more than 20 countries in Europe, the US and Asia-Pacific with its own staff. Linical is listed in the prime segment of the Tokyo Stock exchange, and dedicated to serve its client as a true partner in development.

Highlights

As a midsize CRO with global coverage we provide flexible solutions for clinical research and drug development customized to the clients' needs and project specifications through all phases of clinical development.

Experience in all major therapeutic areas.

Linical is active in all markets relevant for the drug development and market access including Europe, US, and Asia-Pacific including Japan.

Linical can provide flexible sourcing solutions through its Pharma Resourcing Solutions business unit.



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BVMA member since 2015
Audits passed in 2015 and 2018



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Services

Project Management

- Clinical Trial planning, management and control
- Scientific background, experience in various therapeutic areas

Clinical Regulatory Services

- Submission to National and European authorities

Clinical Monitoring

- Constantly trained on GCP, regulations, study indications

Medical Consulting and Medical Management

- Development plan- and protocol design
- DSMBs, advisory boards, medical monitoring, patient eligibility review

Pharmacovigilance Services

- Full service PV-capabilities (ArisGlobal database and dedicated PV team)
- Our PV team and medics are Eudravigilance-certified

Clinical Data Management

- All Data Managers SCDM certified, experienced team (20+ years)
- Oracle Silver partner, 21 CFR Part 11 compliant, full GCDMP implementation
- Medidata Rave certified

Biostatistics and Biostatistical Consulting

- All biostatistical services, CDISC and data conversion

Medical Writing

- Preparation of CSP and CSR, SAE narratives, IB, IMPD, Informed Consents

Pharma Resourcing Solutions

- Flexible sourcing solutions (single staff, entire team or function)