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BVMA Member since 2015  
Audit passed in 2015



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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 more than 700 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.

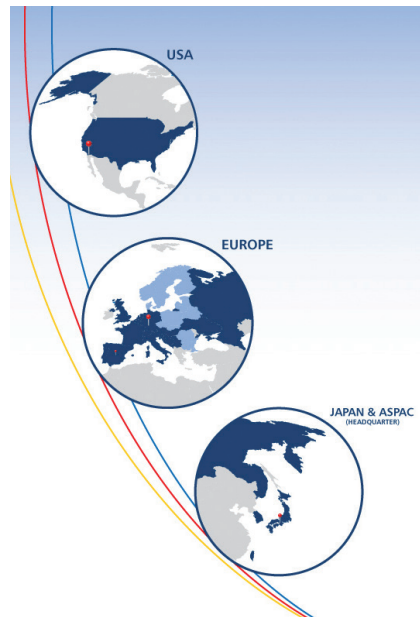
## HIGHLIGHTS

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 including medical devices.

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.



## 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

- ▷ Onsite visits and remote monitoring, site management
- ▷ 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 (Oracle AERS 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

### Biostatistics and Biostatistical Consulting

- ▷ All biostatistical services, CDISC, 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)

