■ COMPANY PROFILE



Marc Scull
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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 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 reach we offer the same reach and experience as larger CROs, but maintain the personal, attentive service our clients expect.

Experience in all major therapeutic areas.

Combining strong business perspective with clinical and medical expertise, our team goes beyond operational excellence, providing flexibility, guidance, and key strategies to successfully overcome drug development and regulatory procedures challenges.

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



Linical Europe GmbH

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BVMA member since 2015 Audits passed in 2015, 2018 and 2021





Services

Project Management

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

Clinical Monitoring

 Constantly trained on GCP, regulations, study indications

Clinical Regulatory Services

Submission to National and European authorities

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 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

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)



