

## COMPANY PROFILE



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## History and Mission

For more than 25 years on the pharma market, **Excelya Germany GmbH**, (former KOEHLER eClinical GmbH) has covered project management, data management, biostatistics, pharmacovigilance and medical writing for clinical trials.

Along with professional excellence and the newest technology, we are dedicated to performing value-added services for our customers.

## Highlights

With more than 40 experienced contracted biostatisticians Excelya is a major player in biostatistics, covering all aspects of the discipline.

The company operates its proprietary software VITESSA as a combined tool for EDC and clinical trial management. Tailor-made & customized eClinical solutions are a part of our services. For larger or more complex studies we are partnered with Veeva for use of their integrated state of the art software.

We are proficient in providing full service support for the local and international late phase clinical trials. The Excelya Group has over 800 professionals in Europe, and 4 offices in Germany.



## Excelya Germany GmbH

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BVMA member since 2012  
Audits passed in 2012, 2015, 2018  
and 2021

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excelling with care



[www.excelya.com](http://www.excelya.com)

## Services

### Full Service: Local NIS and Worldwide PMOS

- Central project management
- Regulatory setup
- Monitoring services

### Insourcing of Biostatisticians & SAS Programmers

- Ensures single point of contact, careful selection of candidates & on-boarding procedure
- Milestone management and oversight / project coordination

### eClinical Solutions

- VITESSA study platform: EDC, Web-randomisation, Trial Control System (TCS); Risk-Based Monitoring
- Real-time reporting with WEB2SAS®
- Software as a Service (SaaS)
- Wearable solutions for clinical studies
- Electronic Patient Reported Outcomes (ePRO)
- Tailor-made applications

### Data Management

- CDASH-conformed eCRF Design
- Database conversion into CDISC: SDTM, ADAM, define.xml
- External data integration
- Medical review, medical coding including data management consulting

### Biostatistics

- Study planning including Adaptive Design
- Randomisation
- Statistical analysis and reports
- DSMB preparation and statistical consultation

### Vigilance

- Pharmacovigilance, cosmetovigilance, medical device vigilance, veterinary and other
- Preparation of safety and regulatory documents
- Reporting and event processing
- Training