

## COMPANY PROFILE



**Dr. Antal Hajos**  
Chief Executive Officer  
ahajos@excelya.com



**Michael Pfitzenmaier**  
Chief Executive Officer  
mpfitzenmaier@excelya.com

## History and Mission

Since more than 25 years on the pharma market, **KOEHLER eClinical GmbH** is a niche CRO, covering project management, data management, biostatistics and medical writing for clinical trials. After a merger with clinIT AG in 2013, the company inherited and successfully operated the web-based technology platform as well as the eClinical solutions.

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

## Highlights

With more than 30 experienced contracted biostatisticians, **KOEHLER eClinical** 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.

We are proficient in providing full service support for the local and international late phase clinical trials with a network of more than 20 monitoring CROs worldwide.



## KOEHLER eClinical GmbH

A member of Excelya Group  
Hornusstrasse 18  
79108, Freiburg, Germany

Tel. +49 0761 50318-0  
Fax +49 0761 50318-30

Info.de@excelya.com

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



[www.koehler-eclinical.com](http://www.koehler-eclinical.com)  
[www.excelya.com](http://www.excelya.com)

## Services

### Full Service: Local NIS and Worldwide PMOS

- Central project management
- Network of 20 CROs worldwide

### 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