

## COMPANY PROFILE



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## History and Mission

**Passion for evidence. Since 1994!**

We are an experienced partner to the life science industry, obtaining reliable study results for the development of safe and innovative therapies.

## Highlights

- Owner-managed CRO.
- Established 1994 and located in Cologne, Germany.
- Successful conduct of more than 450 interventional (Phase I to IV), non-interventional and medical device studies.
- 35 + seasoned and technophile team members contribute to the success of your project.



## X-act Cologne Clinical Research GmbH

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BVMA member since 2017  
Audits passed in 2017, 2020 and 2023



<https://x-act-cologne.com>

## Services

### Biostatistical Services

- Statistical consulting, assuring that your scientific questions are answered.
- Delivering sample size determinations and statistical input to your study protocols.
- Development of a randomisation plan. Performing randomisation according to your study requirements.
- Developing Statistical Analysis Plans with a clear focus on the statistical programming of key results and analyses.
- SDTM and ADaM Mapping supporting the submission of your study results.
- Biostatistical reporting as part of your clinical study / investigational report, publication or dossier.

### Clinical Data Management

- Strategic consulting to find the best eClinical solution for your project.
- eCRF implementation according to CDSIC | CDASH supporting submission.
- Development of all essential DM documents for your successful project conduct.
- Implementing Good Clinical Data Management Practices throughout your project.
- The conduct of all DM activities is supported by the excellent procedures of our SOPs.
- Targeted data review and data cleaning in close collaboration with your CRA team.
- Benefit from expressive status reports providing transparency and overview to the study team.

**Curious about our special services?**

**Please contact:**

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