

COMPANY PROFILE



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History and Mission

Clinical data is our passion!

Whether in interventional phase I-IV studies, non-interventional or medical device studies. Our team is passionate about processing your data in all major therapeutic areas, driven by our dedication to quality, efficiency, and improvement.

Highlights

- Established 1994
- 400+ interventional studies
- 120+ non-interventional studies

As client of an owner-managed SME, you benefit from short decision-making paths, direct communication, and motivated employees. The wealth of experience of our tech-savvy and seasoned employees makes a decisive contribution to the success of your projects.



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BVMA member since 2017
Audits passed in 2017 and 2020



www.x-act-cologne.com

Services

Full Service

Realise your project from the planning phase to the final submission together with us in one of our successfully established CRO partnerships or contract (individual) services from our core service portfolio.

Monitoring Services

- Monitoring visits (on-site and remote) including, site initiation, interim monitoring and close-out visits, source document review and source data verification, site management. Focus on academically driven, oncologic trials (IITs).

Clinical Data Management

- Setup of e-clinical solutions such as eCRF with ePRO, external data integration and other functionalities, data entry, SAS™ programming, data review, discrepancy and query management, SAE reconciliation, medical coding, and electronic data transfer.

Biostatistical Services

- Statistical advice, sample size estimations, development of study protocols and investigational plans, randomization, CRF review, data review, statistical analysis plans and mock shells for tables, figures and listings, statistical analysis with SAS™, SAS™ programming, study reports, publications, Analysis files (CDISC format), and merging of data from different studies.