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BVMA member since 2017  
 Audit passed in 2017

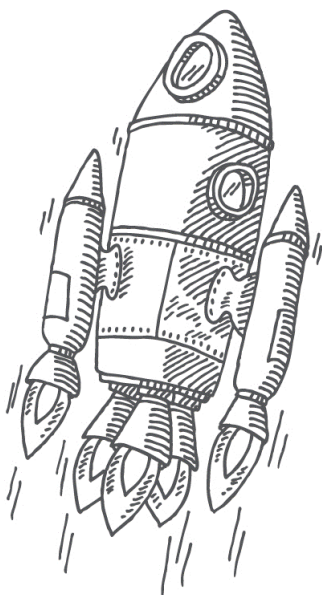


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## HISTORY AND MISSION

**PASSION. EFFICIENCY. QUALITY.** That's our mission since 1994. We performed more than 280 clinical studies phases I – IV, non-interventional studies, medical device studies as well as investigator initiated studies in over 25 therapeutic areas. Although our core competencies focus on clinical data management and biostatistics, many of these studies were performed as full-service together with our established partnerships.



## HIGHLIGHTS

**We are**  
 a team of seasoned as well as tech-savvy professionals providing valuable data management solutions and biostatistical services to the industry. Our wealth of experience enables us to tailor solutions matching your project specific requirements with budget-consciousness and creativity.

**Work with us**  
 because we are good! We are known for forward thinking, high quality and on-time delivery. You might be surprised by the benefits of working with us. Here are some reasons:

Expertise | Passion | Versatility | Planning Certainty | Quality | Stable Budgets | Reliable Results

## SERVICES

**We provide full-service in established partnerships!**

### X-act - Clinical Data Management

- ▷ Consulting on data management strategies
- ▷ (e)CRF design and database development | CDISC CDASH standards
- ▷ Integration of external study data
- ▷ Development of data management documents
- ▷ Data review and query management
- ▷ Coding of medical terms with MedDRA and WHO-Global
- ▷ SAE reconciliation
- ▷ CDISC SDTM mapping
- ▷ Lead data management on behalf of clients

### X-act - Biostatistical Services

- ▷ Statistical advice
- ▷ Sample size determination | Randomisation schedules
- ▷ Development of statistical analysis plan | Statistical evaluation with SAS™
- ▷ Implementation of CDISC ADaM standards
- ▷ SAS™ programming
- ▷ Reporting and interpretation of statistical results

### X-act - Medical Services

- ▷ Development of study protocol
- ▷ Safety narrative writing
- ▷ Clinical study report writing

### X-act - Quality Management

- ▷ Process analysis and improvement
- ▷ Independent system, process, or study audits on behalf of client