What we do

Phase I-III

We will manage your studies from conception to study reporting, with our adaptable approach. Incorporating on the knowledge of our senior team members, who have nearly 20 years industry experience, we are able to reduce your risk while satisfying your needs. Our robust CDMS and IT infrastructure allows our clients the peace of mind that their data will be captured and validated in compliance with FDA regulations via various means.

Phase IV, Late stage and Post Marketing

A multifaceted approach is required for the efficient execution of late phase research. Our team operates as an extension of your team to understand your study objectives and data requirements.

Observational/Disease Registry

It takes experience to manage and capture real-world economic, humanistic, and safety data on drugs or devices used in actual medical practice. Our team is experienced in balancing the cleaning of data while understanding the sensitivities of working with real practices, and still maintaining high quality reliable data.

Cloud Data Centre

QA Data understands that sometimes outsourcing data management is not the solution everyone is looking for and therefore offers a 'cloud' service to our Investigational sites. This way you (the site) manage the data and we manage the technical details in a secure and regulatory industry compliant environment.

Services offered

QA Data's services cover the full spectrum of clinical data management

- Project Management
- Double Data entry (Paper)/ EDC
- Protocol / Report writing
- Case report form (CRF) design / guidelines
- Statistical Consultation (Sample size/protocol input/analysis)
- Medical Coding (MedDRA) and Medication Coding (MDR, WHODDE)
- Electronic loading of external data (ie Laboratory)

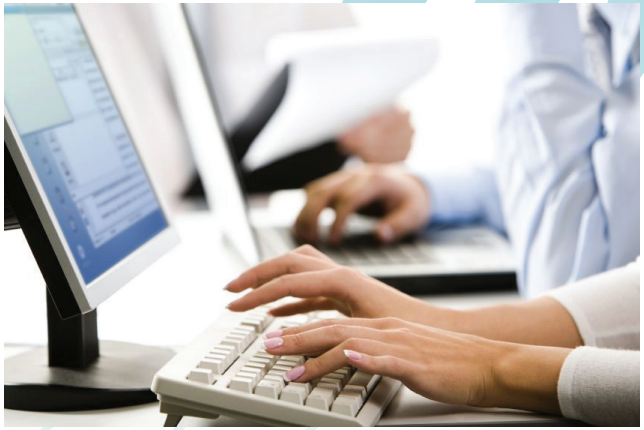
How we do it

Standards and Systems

QA Data utilises a Sybase server-based data management system, interfacing with SAS. **QA Data** utilizes a data management system specifically designed for the clinical research industry. Our system and SOPs meet all the FDA guidelines for clinical data management allowing our clients the peace of mind that their data will be captured and validated in compliance with FDA regulations

Our IT infrastructure

Our IT infrastructure is designed to ensure the highest level of security to support our data-management and biostatistics services. In order to maintain the functionality of EDC, we have designed a multi-level network with multiple firewalls. Our internal IT environment has been developed to meet the FDAs requirements set forth by CFR Part 11 with our comprehensive SOPs governing all aspects of our IT processes from back-up, disaster recovery, system and software validation and change control.



Company Profile

QA Data was founded as a fully functional data management company in 2003, performing full data management services to the pharmaceutical, device, biotech industry and investigational sites.

QA Data is dedicated to providing an efficient and affordable data management service performed in accordance with the highest quality standards namely ICH Guidelines and FDA Regulations for registration purposes in the US and many European countries.

We have completed studies in varied therapeutic areas. **QA Data's** staff have been involved in the management, design and analysis of roughly 100 clinical studies, from small complex Phase 1 Oncology studies to large multi-national registration studies, with over 2500 subjects, to very large observational and disease registry studies.

QAData

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QAData

QA Data is a South African, full-service clinical research data-management company. We pride ourselves in offering an efficient and unique mix of high-quality, flexible data management services to the pharmaceutical, biotechnology, medical device and CRO industries while at the same time being cost-effective.