CLINICAL
INVESTIGATION
SUPPORT

CIS Clinical Investigation Support

CIS GmbH

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„QUALITY IS OUR EXPERIENCE“

CIS was founded in 1990 and is located in Vienna.

Our experience is based on more than 19 years' practical work. Sponsors benefit from our well-trained team of professionals and our sophisticated Quality Assurance system.

We set great store by continuous training and improvement, from both the scientific and workflow point of view.

SPEED, QUALITY & PRECISION

CEO Andreas Nahler

1990	*Foundation of CIS „Clinical Investigation Support“*
1994	*Launching of the office in Brussels / Belgium*
2002	*Concentration of the core business: Quality Assurance, Clinical Development up to Marketing Authorisation*
2007	*Transfer of all activities from Brussels to Vienna*

MANAGEMENT AND QUALITY

CIS's services cover consulting and project management services, starting from the switch preclinical-to clinical development up to submission for marketing authorisation.

This includes also "coaching" of projects or staff-training "on the job" in case of temporary shortages of resources of the client.

CIS offers full services on quality assurance in clinical research and development. This includes regulatory-, monitoring- and biometric- QA support, for projects of phase I-IV, including post-marketing surveillance studies, but also development, review and consultancy for standard operating procedures (SOP) and vendor audits.

Dr. Dr. Gerhard Nahler, General Management

Quality is doing a job right the first time. The function of quality assurance (QA) is to detect deviations from accepted standards and weaknesses in order to improve systems, quality of work and cost-effectiveness.

CIS has experiences in the auditing of data bases, electronic clinical trials, e-systems used (e.g., e-Data Capture, IVRS), central laboratories and GMP-aspects of clinical trials.

The primary goal of CIS is not just enumerate deficiencies but consult for improving systems and procedures in order to increase quality and streamline activities, therefore saving time and costs of projects. Recommendations for corrective and preventive actions are an integral part of our job.

Roland Krammer, Quality

OUR SERVICES

CIS IS A CONTRACT RESEARCH ORGANIZATION
WE OFFER SERVICES IN THE AREA OF:

preparation/adaption of Standard Operating Procedures (SOP),
training of project leaders,
training of auditors,
training of monitors (GCP),
training of investigators (GCP),
feasibility analysis of projects or clinical trials,
integrated medical-statistical reports (ICH),
CDT medical parts (2.5, 2.7 and 5), Expert Reports,
Quality Assurance, GxP.

CIS Clinical Investigation Support has a broad experience in conducting audits in all major areas of clinical research. CIS has performed audits in more than 30 different European and non-European countries. CIS considers quality assurance services not only as an instrument to increase or maintain quality but also to reduce costs.

Quality Assurance

CIS has performed or is performing quality assurance activities for more than 20 companies, most of which have trusted CIS repeatedly with various projects.

Management Support

References for Management Support in R&D,
Consulting for Drug Development, Protocols, CRFs, Reports, etc.) for more than 30 international companies.

Integrated Medical-Statistical Reports (ICH), Application for Clinical Trial Authorization and Expert Reports for more than 20 companies.

Registration Support has been performed for more than 10 international companies.

Company-Training incl. Training on the Job as on Good Clinical Practice, monitoring, auditing, logistics/organization of trials, protocol and CRF design, codification, randomization, statistics, blinding and Investigator-Training, as well as Lectures and Seminars for several companies and institutes.

More than 20 years experience in planning and managing of clinical Phase-I studies.

Risk management and pharmacovigilance.