CSG

Demonstrating Value

Conclusive clinical and observational studies

Innovative approaches and efficient solutions for accessing the German and European market

CSG, the CRO that doesn't lose sight of the big picture

- ✓ We stay on top of things –
  thanks to profound market expertise
- ✓ We have a great network –
  in close cooperation with IGES experts
- ✓ We are flexible –
  in synergistically working project teams
- ✓ We work accurately –
  with experience and diversity of methods

Safety for your product

Our clients benefit from the flexibility of an expert CRO. As part of the IGES Group, CSG ensures synergies with complementary fields of research. This results in an excellent knowledge of the market, its players and developments. In connection with the broad range of methods, more options arise for actions for tailor-made project results.

Our employees pursue a consistent advisory approach. From the project idea through to the report we keep the study's goal in mind.

A holistic perspective and high accuracy are a matter of course in standardized study processes just as in challenging constellations.

This makes CSG a CRO that doesn't lose sight of the big picture.

Profound expertise in proof of benefit

For more than 15 years, CSG as an independent contract research organization has been supporting clients from the pharmaceutical sector, the fields of biotechnology and medical device manufactoring in planning, implementing and analyzing clinical-scientific studies. Due to our long-term experience and our employees' know-how as well as the usage of state-of-the-art technologies, CSG ensures the cost- and time-effective implementation of projects. The focus lies on the following study types:

Clinical trials for pharmaceuticals

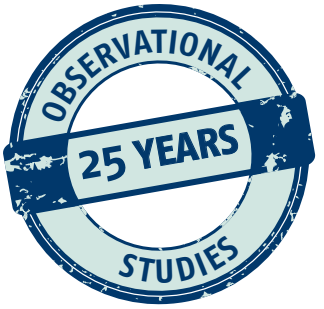
The implementation of clinical trials to assess the effectiveness and safety of pharmaceuticals before, during and after authorization is subject to strict and constantly changing statutory, regulatory and ethical requirements. As competent partner, CSG supports clients in the successful implementation of the following studies:

- → Phase II and III trials
- → Phase IV trials
- → Non-commercial trials
  (IITs – Investigator Initiated Trial)

Non-interventional studies of pharmaceuticals

An evidence-based proof of benefits of pharmaceuticals is of major importance for the use and reimbursement of such products. In addition to clinical testing, well-planned trials of authorized pharmaceuticals can provide important insights under routine conditions. CSG offers tailor-made concepts for the implementation of the following studies:

- → Observational studies
  (PMS – Post-Marketing Surveillance)
  - Prospective cohort studies
  - Retrospective case-control studies
  - Cross-sectional studies
- → Safety evaluations
  (PASS – Post-Authorization Safety Study)



Clinical trials for medical devices

Due to the growing statutory requirements in the framework of the clinical assessment for the authorization and the proof of benefits of a medical device, the implementation of clinical trials is gaining in importance. CSG assists clients successfully when implementing the following studies:

- → Interventional studies (§§19-23a MPG)
- → Non-interventional studies (§23b MPG)
- → Non-commercial trials (IITs – Investigator Initiated Trial)

Biomarker studies

The development of new biomarkers for the diagnosis of diseases and the prognostic estimation for potential individual treatment strategies increasingly gained importance in the course of the last years. Scientific studies to identify and validate biomarkers are governed by specific regulatory and data protection requirements. Subject to the adherence to the good clinical practice, CSG offers competent concepts for the implementation of such studies:

- → Regulatory requirements for sample collection studies
- → Data collection in sample collection studies
- → Logistics for sample collection studies
- → Data protection / data trusteeship at biobanks

Decisive advantages due to the affiliation to the IGES Group

With CSG, the clinical research has been an own independent work area within the IGES Group for 15 years:

- → **IGES Institute**
  Research and consulting for infrastructure and health care
- → **CSG Clinische Studien Gesellschaft**
  Clinical research
- → **AiM Assessment in Medicine**
  Analysis and consulting for medical technology
- → **IMC clinicon**
  Analysis and consulting for hospitals

CSG as full-service CRO supplements the services offered by the IGES Group synergistically when primary data is required as proof of benefits or safety.

Thanks to the interaction of the conceptional strategic competence of the overall IGES Group with CSG's implementation competence, it is possible to plan and implement studies that are successful in the market.

IMC clinicon

Targeted support before and after market access

Clinical trials

During project planning, implementation and reporting, CSG ensures

- → High efficiency based on the advantages of a small CRO structure with short decision paths and cost-efficient processes
- → High quality due to an interdisciplinary team of experienced, qualified and highly motivated employees
- → Tailor-made solutions and individual support.

CSG uses the certified technology of the Oracle Clinical database with EDC system for secure data keeping and processing (21CRF Part 11 compliant) and has a MedDRA license.

CSG project managers are in the focus of activities and are always informed about all study processes. Their work is characterized by focusing on the project goal and forward-looking consultation.

Patient recruitment

Thanks to IMC clinicon's (IGES Group) data analysis capacities, CSG is able to identify test centers, accurately estimate the number of cases and to search for clinical constellations.

As a result, the significance of feasibility studies is improved, costs are optimised and the implementation is realised on time. CSG data analyses allow for targeted measures to achieve recruitment targets.

Non-interventional studies (NIS)

Studies investigating the use of pharmaceuticals or medical devices under real routine conditions represent a necessary addition to classic clinical trials. The latter observe strictly selected patient groups and can only provide limited insights due to their experimental and thus artificial approach. Effects in special patient segments (with comorbidities or concomitant therapies), rare effects and the influence of health care settings can be investigated under real life conditions. With methodically high-quality, pragmatic study approaches also in connection with cost-benefit analyses, the benefit of new therapy approaches can be substantiated in observational studies with the highest possible efficiency.

Together with the IGES Institute, CSG has available comprehensive knowledge resources and is able to contribute all relevant perspectives of the health market when planning tailor-made NIS concepts.

CSG knows the different prescriber, user and cost unit groups and is aware of their specific health care reality.

CSG has an overview on who receives study results when and how, and is thus able to provide customized results for an evidence-based market management. Also under changing constellations, the project goal remains in focus.

IGES health service research – 35 years of real life evidence

Routine data analyses can beforehand and in addition answer questions regarding patient care and frequency of clinical and therapeutic constellations.

IGES regards health service research as an analysis of health care under every-day conditions based on routine data and thus as an important complement of clinical research. IGES provides long-standing competence in the health care reality. IGES knows the health care settings, is aware of the incentive structures and is familiar with the subject and sector interfaces. Furthermore, IGES offers a broad range of methods.

Together with CSG, real life evidence can also be gained based on primary data collection.

Full-service CRO

Our services cover the entire range applied in the planning, implementation and analysis of interventional and non-interventional clinical studies with pharmaceuticals or medical devices. Thereby, we always follow our clients' needs in order to find optimal, practical solutions for the respective issue, which we implement cost- and time-effectively. To meet the highest quality standards, our experienced and highly qualified employees work according to SOPs (standard operating procedure) which correspond to the applicable legal requirements and standards.

→ **Study planning and preparation**
Careful planning is decisive for the successful implementation of a study. Thanks to the CSG experts' and even the IGES Group's long-standing experience, we are able to chose an optimal study design for our clients and support them during adequate implementation of the testing and monitoring plans and CRFs (case report forms). CSG provides all necessary study documents (primary / secondary endpoints, study design, etc.).

→ **Project management**
CSG project managers are the central interface in the study team. Comprehensive understanding of our clients' needs and identification with the project form the basis for our cooperation. The project managers coordinate all activities, monitor the study's progress and thus ensure that all planned project goals are realized within the scheduled time and cost framework and in highest quality.

→ **Regulatory affairs**
CSG checks and clarifies the respective regulatory requirements for the different study projects. Correct submission of the study for approval by the respective higher federal authority and for approving assessment by the ethics committees form part of our services just as the reporting of studies to authorities, associations and study registers.

→ **Data management**
Based on the integrated technology platform, CSG offers a comprehensive range of implementation options for data collection – always targeted to our clients' needs: electronic and / or paper-based data collection (eCRF, pCRF), data base creation with Oracle Clinical 4i RDC or SQL (provision of data in CDISC).

→ **Monitoring**

Need-based monitoring is essential to ensure the protection of patients as well as the quality and integrity of the collected data. In addition to the realization of feasibility surveys and the selection of suitable study centers, SDV (source data verification) and data reviews for completeness, correctness and plausibility belong to the CSG monitors' tasks. In doing so, the reasonable combination of center visits, remote monitoring and risk-based approaches play an important role.

→ **Statistics**

Already at an early study planning stage, statistical aspects are decisive in order to collect data during the study, which is relevant for the subsequent analysis. Our statisticians accompany and offer advice during the qualified elaboration of review and monitoring plans and draw-up a statistical analysis plan. The results of the statistical analysis are provided in all common formats upon the client's request.

→ **Pharmacovigilance**

CSG offers 24/7 readiness to receive messages of undesired events and ensures immediate processing by our Drug Safety team. Our services comprise the recording and processing of cases (incl. case narratives), on-time reporting of SUSARs (suspected unexpected serious adverse reaction) to authorities and ethics committees, reconciliation of data bases and draw-up of PSURs (periodic safety update report) and DSURs (development safety update report).

→ **Medical writing**

CSG offers the qualified draw-up of review and monitoring plans, the patients' declarations of content, CRFs and integrated final study reports. Our medical writers together with the statistics and data management experts form a well-functioning team.

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