

The German Study Centre for
Otorhinolaryngology, Head and Neck
Surgery (DSZ-HNO) is a joint project of



UNIVERSITÄTSMEDIZIN GÖTTINGEN **UMG**
Studienzentrum



The GSC-ENT is sponsored by

German Society of Oto-Rhino-Laryngology,
Head and Neck Surgery e. V.

German Association of Ear, Nose and Throat
Professionals e. V.



Deutsches Studienzentrum für
HNO-Heilkunde, Kopf- und Hals-Chirurgie

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**German Study Centre for
Otorhinolaryngology,
Head and Neck Surgery
(GSC-ENT)**



Study Center for Otorhinolaryngology, Head and Neck Surgery, DSZ-HNO

The pre-condition of evidence-based acting in patients' care and research are reliable data retrieved from clinical trials. The lack of controlled multicenter trials in the field of Otorhinolaryngology, Head and Neck Surgery is obvious. With this background, the executive committees of the German Society of Otorhinolaryngology, Head and Neck Surgery, and the Professional Association of German Otolaryngologists founded a common study center.

The focus of this institution is the support of selected prospective studies regarding all special fields of this discipline.

Scope of the German Study Center for Otorhinolaryngology, Head and Neck Surgery

The ENT Study Center provides support in the context of planning, implementation, and publication of selected investigations. Among other aspects, also consulting regarding clinical trials such as financing, data collection, or on site visits of trial sites is provided by the German ENT Study Center.

The ENT Study Center focuses in particular on national and international multicenter studies with clinical or translational approach. Also surgical questions and projects of healthcare research will be accompanied. By closely associating the ENT Study Center to the Clinical Trial Unit of the University Medical Center Göttingen, the already existing interdisciplinary expertise is beneficially used.

ENT studies become visible

A prospective registration in this WHO register fulfills the criteria of publication of a study in biomedical journals issued by the International Committee of Medical Journal Editors (ICMJE).

Hence, every ENT-specific study registered in the German Register of Clinical Studies (www.drks.de) is also visible on an international scale. Through registration in the German Register by the principal investigator, the study is automatically labeled as an ENT study. In the future, every study performed in Germany in the discipline of otorhinolaryngology can be displayed prominently on the websites of the German Society of Otorhinolaryngology (www.hno.org) and the Professional Association of German Otolaryngologists (www.hno-aerzte.de). In this way, specialists, patients and all other people in healthcare services as well as the general public may be informed.

Investigator Database

The GSC-ENT has set up an investigator database for ENT physicians in Germany who are interested in clinical research. The aim is to help study directors from academia or the pharmaceutical industry to plan a multicenter, clinical study in the field of ENT-adequate test centers GSC-ENT.



GCP Trainings

The GSC-ENT offers individual study-related basic and advanced courses according to GCP, which correspond to the recommended curriculum of the German Medical Association. Proof of successful participation in these courses is a prerequisite for working as a member in a study group or as a principal investigator to conduct a clinical trial.



The German Study Center is a competent partner

- Consulting of the Steering Committee regarding the selection of clinical studies and support by preparing, coordinating, and implementing the selected studies.
- Contact partner for physicians in medical offices and hospitals
- Consulting of investigators before initiating studies
 - Elaboration of cost and financing estimates
 - Statistical, regulatory, and organizational consultation
- Support of the review process
- Support in the context of external funding
- Central and decentralized support of the investigators
 - Regarding the recruitment of trial sites
 - Regarding national and international study cooperations
 - Regarding applications to regulatory agencies and ethical committees
 - Regarding negotiations and elaboration of contracts and agreements with industrial partners
 - Regarding the registration of the studies
- Contact partner for patient representatives and self-aid groups regarding the inclusion in studies
- Implementation and maintenance of an ENT specific trial register
- Public relations work