Your Clinical Research Organization for Clinical Studies and Evaluations

As an international Contract Research Organization (CRO), we conduct clinical studies with medical devices, in vitro diagnostics (IVDs) and pharmaceuticals. In addition to full service, we also offer individual services such as the creation of databases (eCRFs), statistical evaluations and clinical monitoring for your study.

The Clinical Research Organization Dr. med. Kottmann has great expertise in clinical studies with medical devices. First-in-man studies are completed at a high level and the medical devices can be quickly CE-marked. Our Clinical Research Organization supports the entire product cycle of medical devices including PMCF studies and studies according to MPG §23b.

In drug studies, we are specialized in phases II to IV and can look back on many years of experience of our project managers and CRAs (Clinical Research Associates - clinical monitors) in almost all medical fields, thus ensuring comprehensive and individual support.

Our Clinical Research Organization also conducts non-interventional studies and Investigator Initiated Trials (IITs). The aim here is to create professional study designs with good interaction with the sponsors and study sites. In addition to rapid patient recruitment, the fulfillment of the requirements of the notified bodies and the MDR (Medical Device Regulation) for medical device studies is a priority.

As a matter of principle, the Clinical Research Organization Dr. med. Kottmann is responsible for the entire project management in clinical studies from study planning, writing of the observation plan / study protocol to database creation (creation of CRF or eCRF - e.g. with secuTrial), sample size calculation, statistical analysis, clinical monitoring and medical writing under the supervision of medical specialists.

In addition, our contract research organization also creates Clinical Evaluation Plans (CEP) and Clinical Evaluation Reports (CER) of medical devices according to MEDDEV 2.7.1/ rev. 4 and the MDR (Medical Device Regulation) or updates existing clinical evaluations.

The Clinical Research Organization Dr. med. Kottmann works strictly according to Good Clinical Practice (GCP) and, in addition to the Declaration of Helsinki, also observes the required laws such as the AMG or MPG and ISO 14155. Our contract research organization places great emphasis on high quality management, so that we are certified according to ISO 9001:2015 and ISO 13485:2016 and also have a data protection certificate.

Currently, it is a challenge to conduct clinical studies under the COVID pandemic. We have found professional solutions for this, e.g. to increasingly replace on-site monitoring by remote monitoring. Our Clinical Research Organization works according to the currently available regulatory guidelines and also consistently implements the requirements of the ethics commissions, the higher federal authorities (BfArM or PEI) and, if applicable, the notified bodies.

What can we do for you?