INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

ISS AG, THE MEDTECH CRO BASED IN SWITZERLAND

WE SUPPORT YOUR CLINICAL MEDICAL DEVICE DEVELOPMENT

The importance of clinical data as a prerequisite for market access of a medical device is not only reflected in the new MDR but also in the increasing demand for services related to the conduct of clinical investigations.
ISS AG, Integrated Scientific Services has decades of cumulative technical experience in providing supportive services to companies performing clinical investigations. ISS AG can help drive the project from the start in a highly efficient manner to maintain scheduled deadlines and budget constraints. Clinical studies for market access, feasibility or pilot studies and post marketing studies (PMCF) are all fully supported by ISS AG.

ISS GCP processes are audited by the BVMA.

Your Contact

Dr. Michel Weber
Division Leader Clinical Services

T +41 32 513 67 80
michel.weber@iss-ag.ch

Your Benefit

Our services range from engineering work, over fully compliant technical documentation up to and including the traditional services of a Contract Research Organization (CRO).
The proximity of our engineers to the product provides an understanding of the normative requirements necessary for conducting a clinical investigation according to ISO 14155. Thus, the technical documents in the submission process exactly fit the health authorities' requirements and timelines can be dramatically accelerated.

Our Services

Gap analysis of the technical documentation with an emphasis on clinical trials
For a successful and timely submission of a clinical investigation, complete and correct technical documents are critical. ISS AG supports the set-up of the technical documentation (TD) of your medical device needed to fulfill regulatory requirements. The experts of ISS AG create a gap analysis of the TD and help with completing the TD for the regulatory agencies.

Compilation of the submission dossier for approval of a clinical investigation
The standard ISO 14155, the new MDR as well as the competent authorities and ethics committees specify the content of the dossier. The experts of ISS AG will assist you to strategically plan and drive a clinical study, create the proper supporting documentation or critically review your documentation prior to submission.

Experience of ISS AG as a CRO
Our CRO has been externally audited on GCP and is a member of BVMA. We have experience with pre- and post-market clinical studies (PMCF) in the indication of dermatology, drug delivery, ophthalmology, orthopedics, dentistry etc.

CRO Activities: Support of your clinical investigation up to the final report
Clinical investigations managed by ISS AG take into account the strategic objectives of our clients as well as any operational, ethical, regulatory scientific and statistical requirements. The value we offer to our customers varies from a first draft design over negotiation with potential sites, key opinion leader contact, clinical investigation plan, monitoring, data management, statistics to the final clinical investigation report. Clinical Investigations managed by ISS AG include feasibility or pilot investigations, confirmatory clinical investigations for CE certification or Post Market Clinical Follow-up investigations (PMCF). Typically, a full range of services is provided to the customer. However, at your request we can also provide isolated modules.

Network
ISS AG has built up its own network of clinical specialist throughout Europe. In the following countries we have selected CRAs at our services: Germany, Austria, Switzerland, France, Spain, Italy, Belgium Netherlands, UK, and Hungary. Depending on your needs we have good contacts into other countries and can facilitate your planned clinical project in other countries of the world.