ISS
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY

CLINICAL RESEARCH ORGANISATION C R O

WE SUPPORT YOUR MEDICAL DEVICE DEVELOPMENT THROUGH THE CLINICAL PHASE

The importance of clinical data as a prerequisite for market access of a medical device is reflected in the increasing demand for services related to the conduct of clinical investigations. Integrated Scientific Services (ISS AG) has decades of cumulative technical experience in providing supportitive services to companies performing clinical investigations. ISS can help drive the project from commencement 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 are all fully supported by ISS AG.

Your Benefit

The services covered by ISS experts include the analysis of a product's life cycle and overseeing a wide range of tasks that focus on the clinical trials. our highly experienced Services range from required engineering work, to fully compliant technical documentation of medical devices, and 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 before the commencement of clinical trials and according to ISO 14155. ISS services are more often utilized by smaller enterprises and start-ups that are typically focused on the product development and often lack the adequate resources to manage the regulatory and clinical investigations and documentation.

Our Services

Gap analysis of the technical documentation with an emphasis on clinical trials
ISS services also include feasibility studies, pilot project studies, technical documentation (TD) of the medical device, needed to fulfill regulatory requirements. The experts of the ISS AG create a gap analysis of the TD and help in completing TD for the regulatory agencies.

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

CRO Activities: Support of your clinical investigation up to the final report
Clinical Investigations managed by ISS take into account the strategic objectives of our clients as well as any operational, ethical, regulatory and statistical requirements. We offer a value for our customers from a first draft design, negotiation with potential sites, key opinion leader contact, clinical investigation plan, monitoring, data management, statistics to the final clinical investigation report. Clinical investigations include Feasibility or Pilot Investigations, Confirmatory Clinical Investigations for CE certification or Post Market Investigations. A full compliment of services are typically provided for the customer but single analysis and support activities may be provided at the customers' request.

Your Contact

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