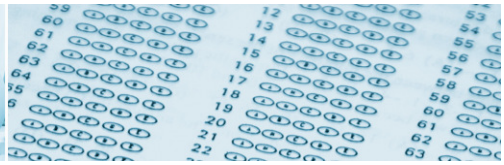
INTEGRATED SCIENTIFIC SERVICES
A MEDTECH COMPANY



CLINICAL EVALUATIONS ACCORDING TO MEDDEV 2.7/1 REV. 4

Revision 4 of the guideline MEDDEV 2.7/1, which has been in effect since June 2016, significantly restricts the scope for the creation of clinical evaluations, especially with regards to the use of data of other products and the justification for the waiver of clinical data for one's own product. It also further specifies the requirements concerning the qualification of the authors of an evaluation. With a well-developed team in place, ISS offers clinical evaluations according to MEDDEV 2.7/1 rev.4 and MDR

Your Advantage

Through our support you win time and assurance in your clinical evaluations. In addition, our process for the creation of a clinical evaluation offers you several options when defining the scope of work.

Our Services

Creation of a clinical evaluation in several steps

MEDDEV. 2.7/1 rev. 4 defines the clinical evaluation as a process in 5 phases (stages 0 through 4). Our approach and the associated templates are based on this phase model. We carry out the projects in phases in order to detect risks and weak data material early and to take appropriate measures. In stage 0, we work closely with the knowledge carriers of your company. Depending on the agreement, you have the possibility to conduct reviews in the following stages.

Clinical evaluation as a process according to MEDDEV. 2.7/1 rev. 4

Phase	*Activity*	*You receive:*
Stage 0	Scoping, Plan	Clinical Evaluation Plan
Stage 1	Data Identification	Search Report incl. Search History
Stage 2	Data Appraisal	Appraisal Plan and Report
Stages 3/4	Data Analysis, Clinical Evaluation	Clinical Evaluation Report

The aim of our, according to rev. 4, newly designed and modular creation process is to correctly and efficiently incorporate your expertise, the product history and technical details into the clinical evaluation in collaboration with you. Depending on the situation, individual sections can be provided by you.

Why choose ISS for clinical evaluations?

Experience

Our team currently of scientists (PhD), physicians and engineers. With its expertise in research techniques and biostatistics as well as the experience from more than 100 evaluations, which have been found compliant by various Notified Bodies, it meets the high requirements of rev. 4 with respect to the authors of clinical evaluations.

Medical expertise

We have a network of specialists from various disciplines. Currently we can cover the following medical specializations with our own medical experts: ophthalmology, odontology, traumatology, and orthopedics. We seek expert advice from other disciplines on a situational basis.

Efficiency

Thanks to our proximity to IT issues and software development, we can support the process with tools that ensure high efficiency in the creation of an evaluation.

Your contact

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