MEDICAL DEVICE KNOWLEDGE TEAM

Post Market Surveillance

The MEDICAL DEVICE KNOWLEDGE TEAM takes over all steps of the post market surveillance for you. This allows you to concentrate fully on your company and not have to manage several external teams.

Familiarize

with the existing device documentation.

STEP 01

STEP 02

Gap analysis

and identification of the missing clinical data supporting existing claims.

Study design

Development of the PMS study design to address existing gaps and to collect relevant clinical data.

STEP 03

Clinical investigational plan (CIP)

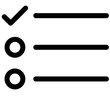
development, defining patient population, sample size, inclusion/exclusion criteria, primary and secondary endpoints, statistical

STEP 04

Regulatory

Regulatory (Ethics) submission and approval.

STEP 05



STEP 06

Preparation

Study site selection, contracting, and training.

Project management

Communication with study site team and site management.

STEP 07

STEP 08

Monitoring

Site monitoring, identification of possible deviations, corrective actions.

Data Analysis

Data collection, data cleaning and database lock. Statistical analysis and final study report development.

STEP 09

STEP 10

Documentation

Assembly of the whole set of the documents (including primary documentation) to the one file (TMF) and transition of these documents to the client.

MD-KT.com

Your Hands-on Consultants

Dr. Veit Otto

Dr. Yuriy Lebed

Dr. Michaela Hajek

We are not consultants who stand by and just tell you what you should do differently. We pitch in so you can keep your focus on your business: Leave the study design, the technical documentation and also everything else to us **we ensure the approval of your product.**

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