



.....the practical approach



Clinical Evaluation of Medical Devices

Europe - Amsterdam (HQ) | USA - Boston - San Francisco | China - Nanjing



Contents

Introduction	3
1. Scoping the clinical evaluations	4
2. Literature review	4
3. Clinical Investigation	4
Our Clinical services:	
1. Clinical study objectives and plan	5
2. Clinical site selection	5
3. Ethics committee approval and notification of regulatory authorities	5
4. Clinical site training and study initiation	6
5. Clinical investigation monitoring	6
6. Data Management & Statistics	6
7. Writing the final clinical investigation report	6
Updating CER with Post-Market Clinical Data	7

Introduction

Clinical Evaluation is the final validation of a medical device to confirm that the device performs as intended and can safely be used in patients in accordance with its instructions for use.

Worldwide regulatory requirements prescribe how such Clinical Evaluation needs to be completed. Specific regulatory requirements regarding Clinical Evaluation exist for example, in the US, EU and China. Key principles of Clinical Evaluation are the same in the different regulatory regions.

Clinical Evaluation includes the following steps:

1. Scoping the clinical evaluation

Developing a Clinical Evaluation Strategy that is specific to the risks and claims of the medical device, and in line with the regulatory requirements, and factor in marketing requirements- reimbursement.

2. Literature review

Collecting and reporting on existing clinical data regarding equivalent devices, available in the public domain.

3. Clinical investigation

When deemed necessary, performing a clinical investigation to collect new clinical data to support claims or to mitigate newly identified risks.

The Qserve approach is tailored to the needs of the device, preventing any loose ends.

These steps will have to be repeated during the product's lifecycle. For that reason Clinical Evaluation can best be understood as the continuing process of assessing and reporting of clinical data regarding a medical device. The Clinical Evaluation report should reflect the current understanding of the benefits and risk of a medical device.

Qserve supports medical device manufacturers with their Clinical Evaluation during distinct phases of product development, underpinned by risk management activities.



1. Scoping the Clinical Evaluation

The specific regulatory requirements to be addressed as well as the relevant clinical research question(s) need to be identified in a Clinical Evaluation plan or strategy.

From there a review of existing clinical data is performed to establish if additional clinical data need to be generated to address the clinical research question through gathering of new clinical data (i.e., a clinical investigation).

Qserve has experts (many of whom were former regulators) who are very familiar with identifying the correct regulatory requirements to be addressed, as well as the developing appropriate research question(s) required to fulfill the regulatory requirements.

2. Literature Review

The evaluation of existing clinical data regarding a medical device is essential in understanding the benefit and risk determination of a medical device. Clinical literature- and safety data available in the public domain are assessed and reported on.

Review of clinical literature data is key to estimate baseline risk associated with the device, and to identify potential knowledge gaps that will need to be addressed during the Clinical Evaluation, possibly including clinical investigation of a medical device.

Qserve has a dedicated staff with key competences in setting the objectives and scope for a literature review. In case there are no gaps the Clinical Evaluation can be completed based on existing clinical data only and no additional clinical data is necessary.

3. Clinical Investigation

If the Clinical Evaluation Strategy identifies the need to collect new (additional) clinical data, Qserve can continue to perform the clinical investigation on behalf of the manufacturer.

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Our Clinical services includes:



1

Clinical study objectives and plan

A clear determination of the purpose of the clinical investigation will have to be established. The overall study strategy and design, determination of endpoints, number of patients, and the translation of the study design into a feasible clinical investigation plan or protocol (CIP) will be completed in close collaboration with the customer.

Identification of optimal study sites and specialists will be done in parallel.

2

Clinical site selection

When deciding in what countries the clinical investigation will be conducted a number of factors need to be considered. Do you want to involve key opinion leaders in the field of the intended use of your device? Are there regional regulatory or reimbursement considerations that weigh into the decision what sites will be included?

Qserve facilitates site selection and acceptability of the clinical investigation protocol.

3

Ethics committee approval and notification of regulatory authorities

Clinical investigation cannot be performed without the necessary ethical and regulatory approvals. Patients that are requested to participate in a clinical trial need to be fully aware of the risks that are involved.

Qserve's medical writing and clinical submission experience will serve in completing this critical step in the clinical investigation process.

4

Clinical site training and study initiation

Before the clinical investigation can be started the clinical site needs to undergo training to ensure that the investigation will be completed in line with the regulatory requirements and the instructions in the protocol. Instructions regarding clinical data capture will have to be provided to the site. Clinical data capture is elementary to clinical investigation and governed by the rules of Good Clinical Practice following ISO 14155. These rules apply to Electronic Data Capture (EDC) systems as well as clinical data capture using paper-based Case Report Forms (CRF).

Initiation of the study at a specific site can take place after site training has been completed, medical ethical/ regulatory approvals have been received, and the logistic process regarding clinical trial supplies has been completed.

5

Clinical investigation monitoring

The sponsor of the clinical investigation has to assure clinical trial oversight. This oversight should ensure patients safety and wellbeing and a high quality of the clinical data that is being captured. Monitoring of the clinical investigation site should be done to achieve these goals. The extent of the monitoring activities can be considered in relation to the experience of the clinical investigator and the clinical site's staff. Monitoring of the site is directed by a monitoring plan. This monitoring plan will cover clinical investigation activities from trial initiation to final closure of the clinical investigation.

Qserve staff has the experience to develop and execute adequate clinical monitoring, appropriately and in a risk based manner.

6

Data management & statistics

Qserve does provide direction of data management and analysis, and can develop data management and statistical analysis plans.

In addition, Qserve can provide a fully configured Data Management System in line with applicable regulations.

7

Writing the final clinical investigation report

After analysis of the data the results of the clinical investigation need to be reported in accordance with Good Clinical Practice. The clinical investigation results will have to be included in the Clinical Evaluation report (CER).

Qserve has a team of experienced staff from different medical device background. Writing of clinical reports (and publications) is considered a key competence.

Updating CER with Post-Market Clinical Data

According to the EU and US regulatory requirements (i.e. PMCF per Annex X section 1.1c and MEDDEV 2.12.2 rev 2) medical device manufacturers need to consider post marketing clinical follow-up as part of their Post Market Surveillance Plan. Clinical data gathered in the pre-market phase (literature review and clinical investigation) may be too limited to identify rare events or incidents. A post market clinical follow-up strategy is crucial to identify new and unknown risks.

Results of the PMCF, as well as vigilance and complaints will have to be analyzed by the manufacturer in an updated CER at periodic intervals in the post-market phase, as well as analyzed for input to the risk management process.

Setting up a PMCF within the overarching system of post market surveillance will increase the robustness of the post market surveillance system.

In close collaboration with the manufacturer, Qserve will determine the PMCF strategy for your device. Qserve will assist in factoring in marketing considerations (such as country specific reimbursement requirements, for example) into the PMCF plan. This will also allow manufacturers to assess if there are competitive advantages for the device. This can should also be considered already during initial product development.

Qserve has extensive experience with setting up PMCF clinical investigations, which are in fact run similar as any clinical investigation project.

The results of these investigations are to be reported in an updated Clinical Evaluation Report. In doing so the Clinical Evaluation report will reflect the current understanding to the benefits and risk of a medical device.

If you are interested in one of our clinical services, please send your request to: info@qservegroup.com

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Global Medical Device Regulatory Compliance Consultants



Clinical
Evaluation



Regulatory
Compliance



Global
Registration



Training



Quality
Assurance



Auditing