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novineon CRO & Consulting Ltd
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Germany

Your Advantage

MEDDEV 2.7.1 requires the clinical evaluation to be performed by a **qualified and independent expert.** novineon CRO as an external consultant offers you **long-standing experience** in clinical evaluation. As an independent company, our expertise includes the evaluation of medical devices in **various fields of application.**

Your existing collaborations with physicians with regards to testing your product can of course be integrated into the work of novineon CRO.

As our client, you are involved in all process steps and relevant aspects of the evaluation.

If necessary, we can provide **additional support** in implementing the clinical evaluation's findings on risks and usage issues into your risk management documentation. Furthermore, we offer assistance in the creation and revision of user documents.

At the end of the process, you will receive the **final clinical evaluation** including **all documentation.** Due to their systematic structure, novineon CRO clinical evaluations can be **easily updated** and adjusted to the current state of the art and development stage of your product.

We are always focused on finding the best solution for our clients and offer you **swift, professional services and support** regarding all aspects of your clinical evaluation.

Profile

novineon CRO & Consulting Ltd is a private consulting and research company operating in the field of medical technology.

We are an **international service provider** and act as an interface between science and industry. In our contract research division, novineon CRO (Contract Research Organisation), we provide a wide range of services for manufacturers of medical products in **all areas of pre-clinical and clinical research** as well as in **product registration.**

An **international network** of leading medical institutions together with our professional staff gives us a competitive advantage.

Our clients are international healthcare companies as well as small and medium enterprises and start-ups.

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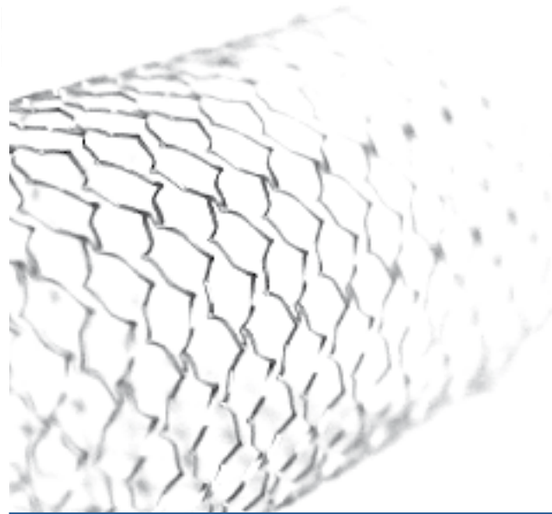
Additional information is available from:

www.clinicalevaluation.com

novineon cro



Clinical evaluation

of medical devices
according to MEDDEV 2.7.1

General Information

Efficiency is crucial for medical devices and procedures – and requirements are growing continuously. As the industry is driven by innovation, companies with a strong focus on research and development have excellent opportunities to increase their market share with **innovative products.**

Clinical evaluation plays a key role in the **approval process, product launch** and **market surveillance** of medical products.

According to the European Medical Device Directive 93/42/EEC, suitability for the intended use must be established for all medical products.

For this, a clinical evaluation based on data from scientific literature, research and testing or clinical studies has to be submitted.

The clinical evaluation analyses available clinical data as well as product and procedure-related risks. This analysis then forms the basis for a **critical assessment of risks and benefits** as well as an evaluation of the advertised product features. This includes an assessment of whether future users are sufficiently informed about remaining risks in the instructions for use and product warnings.

The clinical evaluation is **part of the technical file.** It is submitted to the notified body as part of the official approval process, regardless of the product's risk category.

Our Services

According to MEDDEV guideline 2.7.1, a clinical evaluation can be based on **published scientific data about equivalent devices** and clinical indications. This literature route requires the equivalence of a new and an already approved product to be established. This option should be considered thoroughly, especially for devices derived from existing product lines. novineon CRO can evaluate whether your product meets all requirements and carry out the complete process of clinical evaluation for you.

In case you already have **clinical data from your own studies** or through collaboration with physicians, we offer a comprehensive analysis and discussion of the results in context of the relevant scientific literature. This will serve as the **basis of a clinical evaluation.**

As part of the clinical evaluation, we conduct **literature research** on the **clinical and technical properties** of your product with information from the following sources:

- **scientific publications**
- **guidelines of medical associations**
- **information issued by government agencies**
- **manufacturer's clinical data, un-published data**

Methodology

Our method includes the assessment of your product's **relevant user documents** such as instructions for use and training materials as well as the analysis of your risk management file.

We perform a **comprehensive analysis** of data available through market surveillance by public authorities and product registries and also assess related and competing products. This enables us to perform a context-based analysis of your product's features relevant to the clinical application.

On this basis we make a **neutral assessment** of your product's clinical benefits, its application as well as potential risks.

Regardless of whether the data used come from clinical studies or scientific literature, a clinical evaluation by novineon CRO provides a conclusive document based on a **solid foundation** and accurately analyses both the **risks and clinical benefits** of your medical device.

We are certified according to ISO 9001:2008 for pre-clinical and clinical contract research in the field of medical technology.

Reply card

Please contact me:

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