

in.vent Clinical Services (ICS)

The One-Stop-Shop for IVD Validation

Before any IVD can be legally sold within the EU it needs to be CE-certified. To acquire a CE-certificate manufacturers must present **clinical evidence** that proves that the respective IVD fulfils European **performance and safety requirements**. In short, your assay needs to be **validated**.

The generation of the necessary **clinical data**, the compliance with all applicable **legal regulations** (e.g. IVDR 2017/746, Common Technical Specifications 2009/108/EC, ISO/FDIS 20916) and **ethical standards** (e.g. Declarations of Helsinki and Taipei) is a complicated process that can be a challenge even for large international companies.

We at **ICS** can solve this problem for you!

ICS is the newest expansion of our service portfolio. We have harnessed our 20 years of expertise in diagnostic studies to conceive a new level of IVD-services:
A complete all-round package covering every step of diagnostic **assay validation!**

With ICS you profit from our experience during the entire way towards CE-certification.

Planning and study design:

European law requires you to submit a **Performance Evaluation Plan**, illustrating every detail of your study design. We will develop and generate this plan for you, compliant to all applicable regulations.

Performance studies:

The main obstacles between you and the CE-mark are the **Analytical and Clinical Performance Studies**. Our experts will plan, conduct, and evaluate the challenging studies profiting from our company-owned Study Site.

Samples:

No study without samples! in.vent Diagnostica GmbH is the No.1 source for human biosamples in the EU. We can comply even with the highly demanding sample-requirements for Performance Evaluation.

Reporting:

Before issuing the CE-certificate a Notified Body will critically review all your clinical evidence, condensed in the **Performance Evaluation Report**. The report we write for you will guarantee a successful review!

Diagnostic Studies from A to Z



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Pricing:

We roughly stratify our price range into three categories: **simple, average, and complex** projects.

Simple:

starting at **80,000 €**

Average:

starting at **200,000 €**

Complex:

starting at **350,000 €**

Please note that these prices are only very rough estimations and by no means binding. Study design is a highly complex process and depends on a plethora of factors, such as the exact intended purpose of the IVD, whether residual samples can be used for the validation, whether an ethics committee needs to be consulted, etc.

Therefore: **Please enquire!**

We will provide you with a time and cost estimation for your individual validation project as quick as we can!



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