FACTORY CRO FOR MEDICAL DEVICES & IVDs

CLINICAL EVIDENCE

CLINICAL EVALUATION

A clinical evaluation is performed by the manufacturer to **confirm compliance** with the essential requirements (93/42/EEC) throughout the lifetime of the product. It may include pre-clinical study data, **clinical study data** of the evaluated product, and/or clinical study data from equivalent devices, identified through a systematic literature review.

Factory's expert team of medical writers can perform the clinical evaluation for you, or support you in this clinical evaluation process.

To ensure a high level of safety and performance, demonstration of compliance with the general safety and performance requirements should be based on clinical data that is sourced from **clinical investigations**, carried out under the responsibility of a sponsor.

PREMARKET

The clinical demonstration of safety and performance of your device is an essential premarket conformity assessment specified under Annex I, 93/42/EEC. The results of a premarket clinical investigation are an important section of your technical documentation which you will build under the **CE-marking process**.

Factory CRAs are experienced pre-market consultants and have the expertise to support you in the efficient and smooth performance of premarket trials.

POST-MARKET

The upcoming Medical Device Regulation shows increased requirements for post market surveillance (PMS). It has been proposed that the **post-market clinical follow-up** shall be part of the manufacturer's PMS plan, and to this end proactively collect and evaluate clinical data with the aim of confirming safety and performance throughout the expected lifetime of a device.

Factory's experience and expertise provide the support for your post-market surveillance strategy and perform the required post-market clinical follow-up trials.

Factory Europe
Contact:
Dirk Meijer
d.meijer@factory-cro.com
+31 302292727

Factory US
Contact:
Joris Bannenberg
j.bannenberg@factory-cro.com
+1 6093752485

Global Coverage

www.factory-cro.com