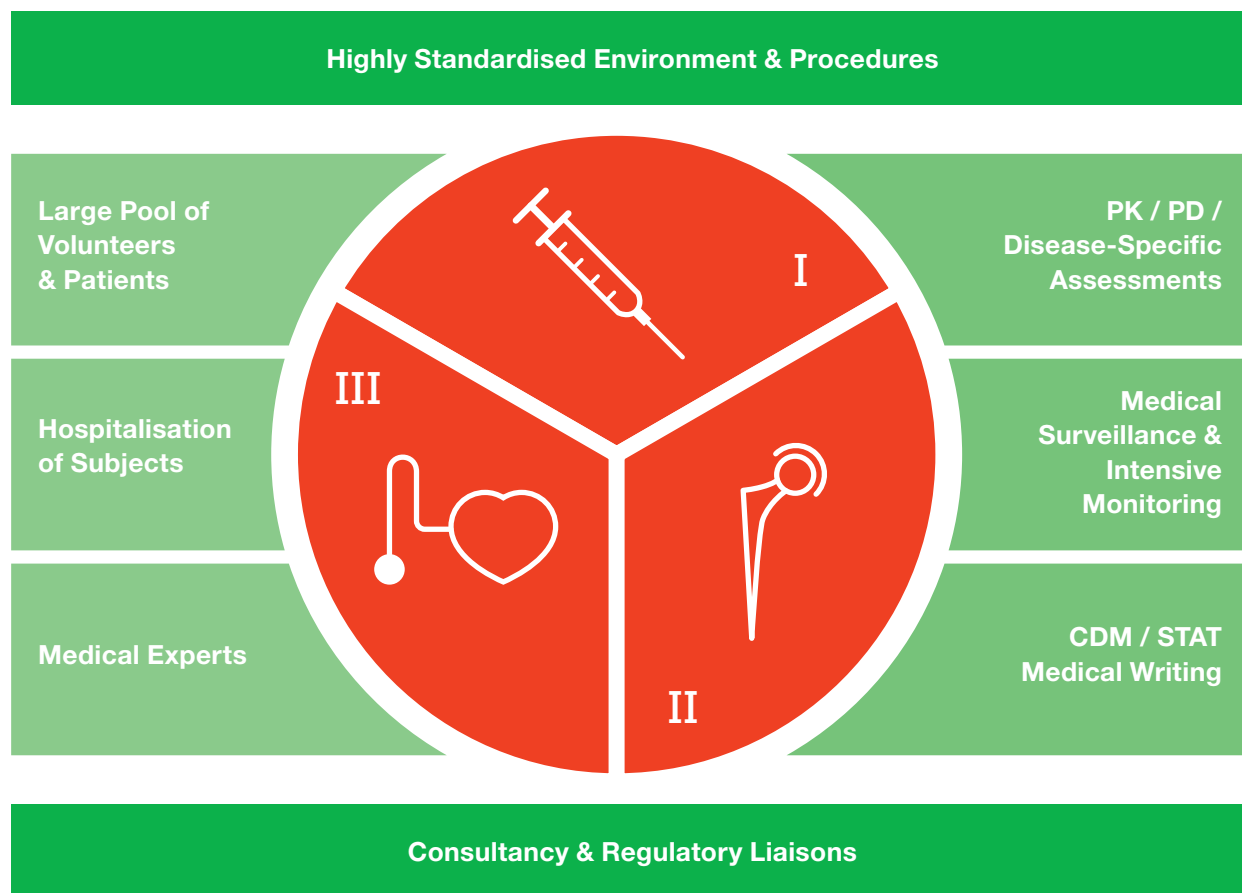


Your Medical Device - Clinical Investigation Is Our Business

Full-Service By CRS



Requirements during Medical Device Development depend on the class of device, the therapeutic area and specific regulatory demands.

It is strongly recommended for developers of Medical Devices to seek the support of Phase-I professionals when requirements of their trials include any of the services illustrated in the graph above.

Moreover, CRS offers fast and cost-efficient provision of human blood and / or tissue samples for in-vitro diagnostic device assessments and the conduct of clinical investigations of in-vitro diagnostics.

CRS Experience

CRS was established in 2006 as a merger of three German Phase-I CROs having more than 35 years of experience in clinical research. Clients from various sectors of the healthcare industry profit from the comprehensive service portfolio offered by CRS. Furthermore, diverse therapeutic areas can be covered through the recruitment of respective patients for clinical trials due to the strategic location of the CRS clinics in densely populated areas.

Medical Devices & Combination Products Experience includes:

- ▶ Apheresis / dialysis studies inhouse in healthy volunteers and multicentric in dialysis patients
- ▶ Intrauterine devices
- ▶ Needle free injection systems
- ▶ Inhaler studies in respiratory and other therapeutic areas
- ▶ Implantable devices for continuous drug release
- ▶ Laser perforation for transdermal application

Specific Therapeutic Area Experience includes among others:

- ▶ Respiratory
- ▶ Renal Impairment
- ▶ Hepatic Impairment
- ▶ Gynecology
- ▶ Cardiovascular

Consultancy For Clinical Trials With Medical Devices

Regulatory Know-how

The first step during CE marking is the classification of a Medical Device according to the classification criteria of the Directive of Active Implantable Medical Devices (90/385/eec), the Medical Devices Directive (93/42/EEC), and the Directive of In Vitro Diagnostic Medical Devices (98/79/ec):

- ▶ **Class I: Low Risk Devices**
- ▶ **Class IIa and Class IIb: Medium Risk Devices**
- ▶ **Class III: High Risk Devices**

The second step is to define in detail which data for a conformity assessment are required. The third step is to clarify whether such conformity requirements need clinical trials in order to generate the requested data. These first three steps in the process of marketing authorisation application for a Medical Device are the crucial ones.

When dealing with authorities, the realisation of the previous mentioned steps requires both, a profound medical understanding and a comprehensive expertise and knowledge. Those factors will help to precisely define authorities' requirements and to gain their acceptance in a cost-effective way.

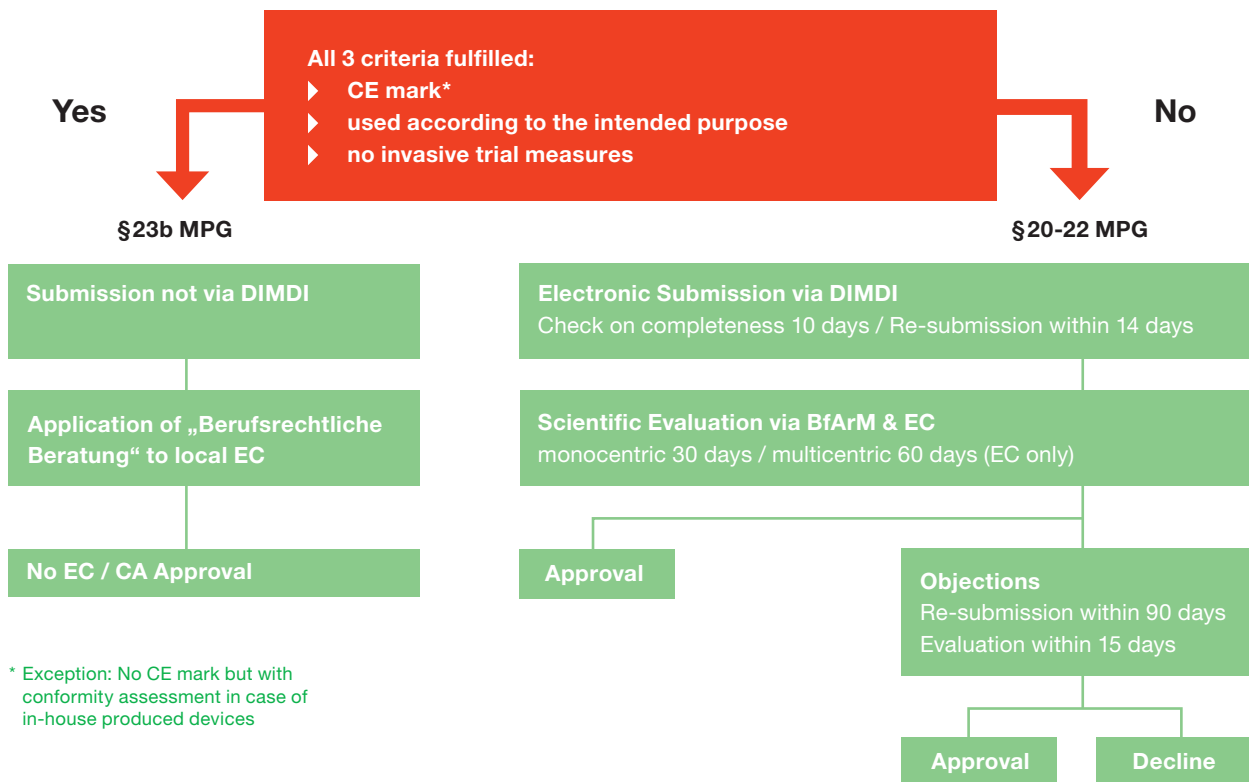


Figure: Regulatory submission process acc. to the German Medicinal Products Law (MPG).

CRS - The Specialist For Your Products

As a consultant for your project, your CRS team will

- ▶ brief, support and accompany your team during liaisons with authorities (BfArM, EMA, FDA),
- ▶ support you in the set-up of study concepts,
- ▶ manage the cooperation between you and the involved CRS departments Medical Writing, Statistics, Data Management and Clinics,
- ▶ precisely define the specific regulatory, documentary and device safety requirements,
- ▶ ensure an efficient subject recruitment and smooth study conduct as well as the handling of study data to the final product: the Integrated Clinical Study Report.