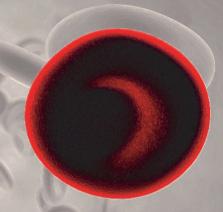


MEDICAL DEVICES







Key Facts Medical Devices

- medical devices expert group: experience, know-how and practical recommendations on how to gather and evaluate high-quality clinical data
- regulatory, statistical and medical expertise
- clinical and post-marketing follow-up studies
- medical devices of all classes
- regulatory know-kow: in accordance with national and international regulations
- support with German method assessment according to §137h SGB V (a necessity for reimbursement of novel, high-risk diagnostic or therapeutic devices and procedures)



Services Medical Devices

scientific and medical advice

study planning

medical device vigilance

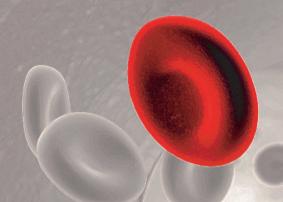
clinical trials with medical devices in the context of clinical evaluation (pre-market authorization)

clinical trials and observational studies in the context of post-market clinical follow-up (PMCF)

support with preparation of assessment according to §137hSGB V

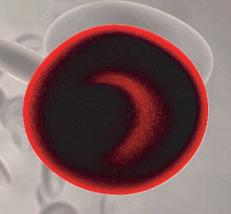
- systematic literature and study register searches
- selection of relevant endpoints
- transparent presentation of available evidence
- consulting regarding suitable study designs





Your personal contact:

Dr. Kathrin Hagl Manager Business Relations k.hagl@gkm-therapieforschung.de +49 89 20 91 20-855





Lessingstraße 14 D-80336 München Phone +49 (0)89 20 91 20-0 www.gkm-therapieforschung.de