

A microscopic view of blood cells, with two cells highlighted in red. The background is a textured, greyish surface.

# MEDICAL DEVICES

Ready for the diversity of the  
medical devices market

# 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



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