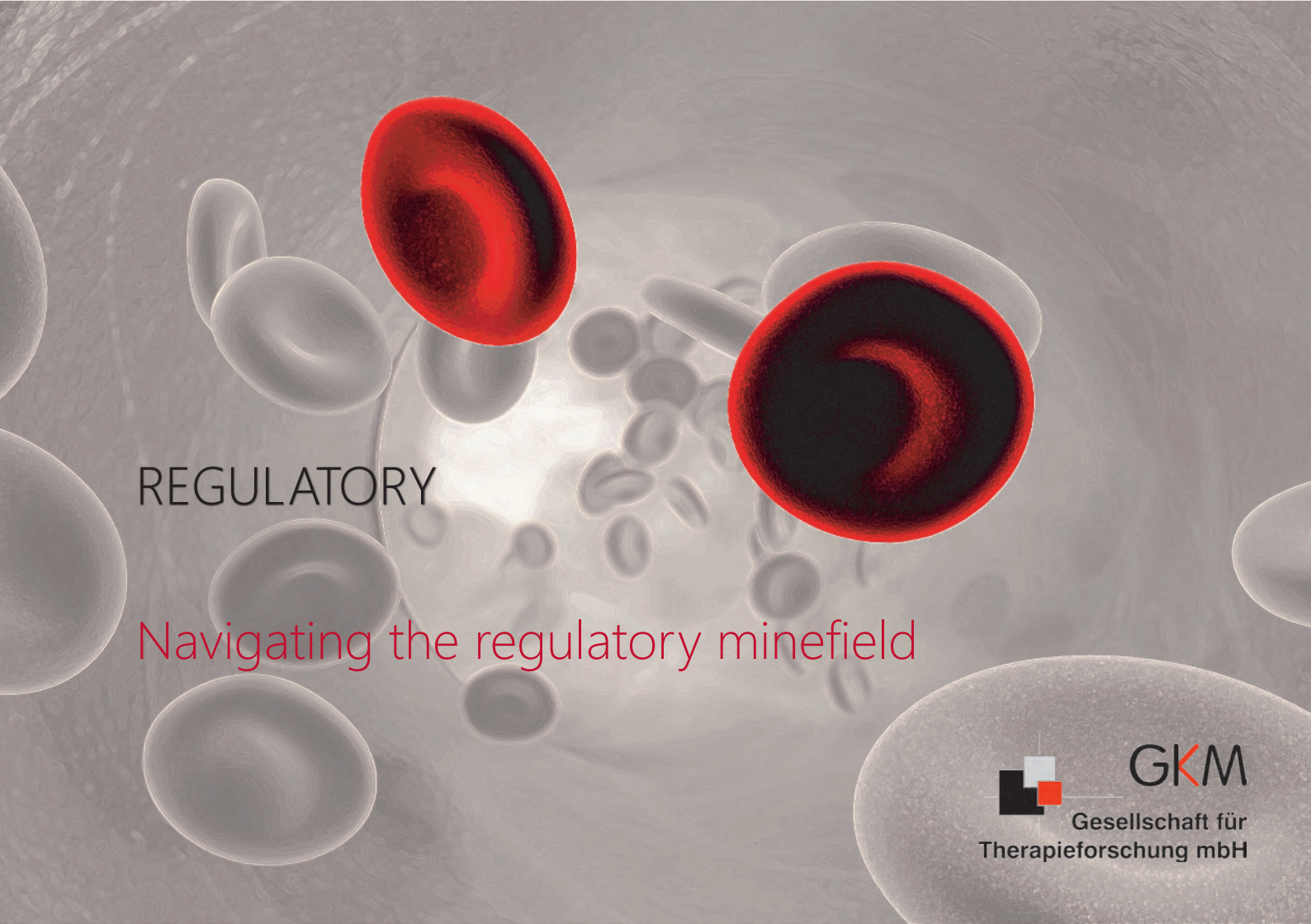

REGULATORY

Navigating the regulatory minefield

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Key Facts Regulatory

- extensive regulatory experience
- effective application and submission processes
- regulatory, medical or statistical support
- for national and international studies
- minimizing the risk of delays due to incomplete or inaccurate regulatory applications

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Services Regulatory

- obtaining of all required approvals for the conduct of clinical trials (e.g. Competent Authorities, Ethics Committees, Biobank, Radiation Committee)
- advice and notifications in the context of non-interventional studies (e.g. Ethics Committees, Competent Authorities, Federal Health Insurance Associations)
- notifications of study start, study progress and study end
- submission of substantial and notification of non-substantial amendments during the course of the study
- development and submission of study synopsis according to §42b (summary of study results)
- entry/review of necessary data into study registries (e.g. EudraCT)

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