A microscopic view of red blood cells. Most are shown in grayscale, but two are highlighted in a vibrant red color. One is positioned in the upper left, and the other is larger and more prominent in the center-right. The background is a textured, light gray.

VIGILANCE

We give safety our full attention

Key Facts Vigilance

- AE/SAE management and reporting services for clinical and non-interventional studies with medicinal products or medical devices
- from complete end-to-end solutions to selected services
- team of experienced clinical safety staff members, mostly medical doctors
- continuous training on novel regulations and sponsor's vigilance SOPs
- training of in-house staff and CRAs on unique vigilance requirements of the project


Services Vigilance

vigilance management

- fully customised vigilance management
- SAE/AE/incidence handling (documentation, follow-up, reporting)
- medical vigilance-related analysis
- SAE/AE/incidence data management (tracking, line listings, data entry, query management)
- free text check for potentially unreported SAE/AE/incidences
- spontaneous adverse event reporting
- medical coding of events
- reconciliation between sponsor safety database and study database

reporting & writing

- e(S)AE reporting – direct report generation from the eCRF
- medical writing (narratives, CIOMS, annual safety reports)
- safety and SUSAR reporting to investigators, Ethics Committees, Authorities
- literature services (search, review, summaries)

A microscopic view of blood cells, including several red blood cells and a few white blood cells, set against a grey, textured background.

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