



Clinical Trials Unit Freiburg (ZKS)

The Clinical Trials Unit (ZKS) is a central research infrastructure of the University Medical Center Freiburg. Founded in 1997, it was one of the first Coordination Centers for Clinical Trials in Germany, initially funded by the Federal Ministry of Education and Research (BMBF).

The ZKS is committed to science-driven clinical research and to the sustainable strengthening of Freiburg as a research location: With more than 70 employees, the ZKS supports the researchers of the University Medical Center Freiburg in planning, financing, applying for funding, conducting, evaluating and publishing clinical trials (Investigator Initiated trials).

Personnel expertise, GCP-compliant processes, digital equipment and an excellent IT infrastructure are available for this purpose across the areas of project development and management, biometry and data management, pharmaco vigilance/vigilance for medical devices, monitoring and site management.

In addition to advice on drug trials, the ZKS also offers support for the evaluation of medical devices or psychotherapeutic approaches, surgical procedures or data registries.

In doing so, the ZKS is committed to international standards for the conduct of clinical trials (including ICH-GCP) as well as the rules on compliance and quality management of the University Medical Center Freiburg. Compliance with these standards has been attested to the ZKS in various audits and expert reports (e.g. ECRIN certified data center). The ZKS supports trials in compliance with the German Drug Act and the Medical Device Regulation. All processes are performed according to regularly updated Standard Operating Procedures (SOPs) - this guarantees compliance with harmonized quality standards such as ICH-GCP and the ISO standard DIN EN ISO 14155:2020.

The ZKS is a founding and steering board member of the International Clinical Trials Center Network (ICN) and member of the German Network of Trial Centers (KKS Netzwerk e.V.).

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