

PROVIDER PROFILE

Name of the organisation	Coordination Centre for Clinical Trials (KKS); Koordinierungszentrum für Klinische Studien (KKS)
Type of the organisation	Open to all
Contact email(s)	steffen.luntz@med.uni-heidelberg.de
Offering website	www.kks-hd.de
Service language(s)	German, English
Target group	Principal Investigators, Researchers, Companies
Type of the support	Consulting, Training, Guidance (e.g. document templates), Support and handling of all regulatory tasks in clinical trials
Short support description	The Coordination Centre for Clinical Trials (KKS) Heidelberg (Head: Dr. Steffen Luntz, MD, approx. 80 employees) is a leading clinical trials competence center in Germany, associated with the University Hospital Heidelberg. It has established a professional infrastructure for clinical studies with the aim to ensure the highest level of scientific quality, to ensure patients safety and integrity of the clinical data. Main task of the KKS during the trial will be project management (incl. regulatory matters), biometrics, validated data management, independent clinical monitoring and medical device vigilance. All tasks will be performed according to Standard Operating Procedures (SOPs) of KKS Heidelberg which are based on ICH-GCP guidelines and current laws, e.g. for drugs or medical devices.

This profile is part of the [Comprehensive Inventory \(CI\)](#) provided by the [STARS project](#).

Purpose of the CI is to assist European academic drug developers in finding support on regulatory affairs. The inventory lists various support services provided by national competent authorities, public actors and private entities.

For information about the STARS project please visit www.csa-stars.eu or contact CoordinationSTARS@bfarm.de.