DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Checklist "Preparation (and execution) of DZHK clinical studies" - for enrolling study centers

The checklist contains all relevant work steps that must be performed to connect an enrolling study center prior to the start of recruitment. Study centers include subjects for the respective study and can be located at DZHK facilities as well as at external institutions.

For work steps marked in gray, templates, (digital) forms or information sheets are available. Please make sure to always use the current and valid version of each document, which you can find in the corresponding submenu item on the Service4Studies homepage.

The contact details of the addressees mentioned in this checklist can be found in the document "DZHK contact persons", which is also available for download. In addition, this document lists the main areas of responsibility of the respective contact persons.

List of abbreviations

IDMS	Image Data Management System
DH	Data handling
EC	Ethics coordination
FMD	Funding Management Department
CRP	Clinical research platform
ICH-GCP	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) – Good Clinical Practice
ICCL	Institute for clinical chemistry and laboratory medicine, UM Greifswald
LIMS	Laboratory information and management system
TTP	Trusted third party

Work Blocks

Completed	work steps	Task of	Addressee
1. Templates for contracts (in German)			
☐	a. Conclusion of study center contract	Study center	Main study center
2. Ethics			
	a. Reconciliation/release patient records for local submission(s)	Study center	EC
☐	b. Submission of the local ethics application	Study center	Local ethics committee of the study center
☐	c. Submission of the local ethics vote	Study center	Main study center, forwarding to: ☐ TTP ☐ EC ☐ DZHK main office
3. DZHK clinical research platform (CRP)			
☐	a. Sending the form „Study center activation notification“ (in German)	Study center/ main study center	☐ CRP via Infrastruktur@dzhk.de ☐ ICCL
☐	b. Sending the form „Authorized persons at the study center“ (in German)	Chief investigator	Person to be auhtorized at the main study center (Forwarding to: Infrastructure/ICCL)
☐	c. Sending the form „Application for Registration, Re-registration or Deregistration of a User Access for the DZHK-IT infrastructure“	Study center	CRP via Infrastruktur@dzhk.de
☐	d. Retrieving the client certificate and password, installing the client certificate	Applicant	TTP
☐	e. DH, LIMS and IDMS send user access	CRP	Applicant
	a. Withdrawal of a study participant (see DZHK-SOP-P-05-Recording Revocation and Study Exclusion)	Study center	TTP
	b. Exclusion of a participant from a study	Study center	TTP

DZHK
DEUTSCHES ZENTRUM FÜR
HERZ-KREISLAUF-FORSCHUNG E.V.

Completed	work steps	Task of	Addressee
4. Biobanking (LIMS)			
☐	a. Dispatch of the form "Request for collecting sets (biobanking)" (form is in German)	Study center	☐ ICCL ☐ Main study center