



Fact Sheet on the DZHK Clinical Research Platform (CRP)

1. Introduction

The use of the clinical research platform is mandatory for studies predominantly funded by the DZHK (DZHK studies). This fact sheet lists the services of the DZHK clinical research platform (CRP). Services which are not listed here, but which have to be fulfilled according to legal/data protection/GCP or ethical requirements, or which are necessary in connection with the individual needs of the study, have to be taken over by the sponsor and, if necessary, funds have to be applied for within the scope of the study. In case of uncertainty, we always ask to contact the respective subprojects of the DZHK CRP at an early stage to clarify the financial calculation of the study. All contact persons can be found [here](#).

2. Ethics coordination (contact: [Monika Kraus](#))

The Ethics Coordination (EC), located at the Helmholtz center Munich, supports you in the submission processes and all questions regarding the ethics documents of your study (patient information and consent). In close coordination with the independent trusted third party (TTP) the content-related and administrative formatting of the documents is ensured in order to guarantee implementation in the IT system. Central to this is the adequate representation of the DZHK CRP. This enables the subsequent use of data and biospecimens for further biomedical research projects, which represents a central added value of the DZHK.

Tasks of the EC as a service for DZHK studies (study preparation phase and amendments):

- DZHK sample documents for patient information and consent
- consultation and coordination on data protection and ethical issues within the study; agreements with the TTP and other CRP project partners
- support in the preparation of study-specific patient documentation (CRP-related processes; adequate presentation)
- final approval of the documents prior to submission to the ethics committee(s) (lead/local)
- where appropriate, assistance with ethics submission;
if necessary, correspondence with ethics committees (national)
- archiving of ethics votes (if necessary, harmonized revision for multicenter studies)
- if applicable, in case of international recruitment: support in communication/coordination with the (international) CRO(s) in the field of ethics (e.g. preparation of a requirements paper, support in discussion on possibilities of harmonization; possibly support in preparation of a German/English master document)
- possibly training of study personnel in the use of ethics documents

The EC portfolio does not include the following services in particular:

- translation of consent forms
- checking the conformity of German/English master consent forms to national consent versions in other languages



- 24/7 availability

3. Trusted third party (contact: [Dana Stahl](#))

The trusted third party (TTP), located at the University Medicine Greifswald, centrally manages the personal identifying data (e.g. name, date of birth) of all persons participating in DZHK studies. Depending on the study, one or more pseudonyms are generated by the TTP for each participating person (pheno_lims_idms_pseudonym). Furthermore, the consent forms of the participants are a) managed electronically as an image in the database and as a scan of the paper consent or b) entered completely digitally (via tablet) into the system of the TTP.

Tasks of the TTP as a service for DZHK studies:

- a) During the study preparation phase:
 - consultation and coordination on data protection and ethical issues (in cooperation with the EC) within the study
 - support of the technical connection of the main study center and other study centers
 - technical implementation of the agreed and by the ethics committee positively voted consent form
 - (optional) initial training to prepare the study staff for TTP relevant processes as well as operation of the web interfaces
- b) During the active study phase:
 - implementation of new versions of consent forms after they have been positively voted by the ethics committees
 - technical connection of study centers participating in the study
 - follow-up and refresher trainings for study staff
 - monthly mailing of the TTP feedback report with the aggregated figures of the data managed in the TTP
 - regular review of the consent form for correctness and completeness of the information provided, and resulting monthly mailing of IC review reports
 - implementation of a reminder process regarding consent forms that need to be corrected, with sending of summary reports to the study coordinators for follow-up at the study centers; if applicable, block or deletion of individual records after consultation if consent is not legally valid for TTP
 - contact for the administration of revocations, study exclusions, contact blocks and the processing of persons for whom more than one patient account has been created
- c) Upon completion of the study:
 - compilation of all open cases in the IC review and assist in closing the cases
 - follow-up on open revocation, study exclusion, and contact blocking processes

The portfolio of the TTP does not include the following services in particular:

- translation of consent forms
- checking the conformity of German master consent forms to national (non-German) consent versions
- creation and coordination of study-specific data protection concepts with data protection officers
- allocation of SecuTrial® user access



- 24/7 availability

4. Data handling (contact: Sabine Hanß)

The data handling management (DH), located at the department of medical informatics of the university medical center Göttingen, provides the study database. For this purpose, the GCP-compliant software SecuTrial® is used and study-relevant processes are embedded in a quality management system.

Tasks of the DH as a service for DZHK studies:

a) During the study preparation phase:

- provision of the item catalog and advice on the design of the electronic case report forms (eCRF, electronic case report forms)
- implementation of the visit plan structure, as well as the data entry forms in accordance with the study protocol and in consultation with the chief investigators
- deposition of value range checks and rules in the data entry forms according to the specifications of the study management/the study protocol
- (optional) implementation of randomization and blinding according to the study protocol and in consultation with the responsible biometry
- conduct final system testing prior to start the productive operation mode

b) During the active study phase:

- administration of centers and user access
- providing and programming of reports to support the main study center and the DZHK main office (e.g. patient inclusion figures)
- execution of automated data discrepancy checks based on the originally defined value ranges and rules
- execution of center changes and revocations
- performing adjustments to the eCRF
- first-level-support for users of the study database

c) Upon completion of the study:

- preparation and participation in data review meetings
- closing of the study database
- export and transfer of data to the responsible biometrics
- transfer of data for archiving and subsequent use in accordance with usage regulations

The portfolio of the DH does not include the following services in particular:

- preparation of paper-based data entry forms
- (provision of software for) drug supply management
- (quality) control of the entered data and/or performing monitoring
- follow up, answering and closing of queries (query management)
- any form of reporting of (Severe) Adverse Events ((S)AEs)
- 24/7 availability



5. Biobanking (contact: [Ivonne Wallrabenstein](#), [Christian Schäfer](#))

In the DZHK Clinical Study Units, the central DZHK-LIMS (CentraXX) is used to document the biospecimen data, in external study centers the clinical data platform SecuTrial® is used. In external study centers, the bio sample data must be documented not only digitally, but also analogically, and the storage location of the biospecimen must be kept locally. At the end of the DZHK study, the collected biospecimen must be sent together with the analog documentation to the main study center. The main study center must document reception and re-storage accordingly in the DZHK-LIMS. For external study centers, the required consumables for biobanking are sent as a sample set by the Institute of Clinical Chemistry and Laboratory Medicine (ICCL) in Greifswald.

Biobanking is coordinated by the DZHK main office in Berlin (in terms of content and organization). Technical support is provided by the LIMS operator in Greifswald.

Tasks of the Biobanking-office as a service for DZHK studies:

- a) During the application phase:
 - general advice on mandatory DZHK-biobanking (DZHK Heart Bank)
 - general advice on optional study biobanking, incl. feasibility of special settings (study-specific bio-sampling)
 - general advice on cost planning/financing of biobanking
- b) During the study preparation phase:
 - consulting on the implementation/scheduling of the DZHK biobanking system
 - consulting on the implementation/scheduling of the study biobanking system
 - if required: establishment of contact to the ICCL
 - support in the preparation of study initiation documents for DZHK Clinical Study
 - support in the preparation of documents for study initiation at external study centers
 - provision of documentation of biosample data in DZHK-LIMS
- c) During the active study phase:
 - administration of user access to the DZHK-LIMS
 - training of study staff at the DZHK Clinical Study Units in the use of the DZHK-LIMS
 - IT support in case of error messages in the DZHK-LIMS
 - data transfer from SecuTrial® to the central DZHK-LIMS
 - quality control of biosample data for DZHK-biobanking
 - consulting for the accounting of the DZHK-biobanking

The portfolio of the TTP does not include the following services in particular:

- quality control biosample data for study biobanking
- storage of samples
- shipping of samples
- analysis of samples
- training DZHK SOPs for biosample collection and biosample processing
- 24/7 availability



6. Image data management (Kontakt: Jens Schaller, Roberto Lorbeer)

For the image data management system (IDMS), the TrialComplete system with technical service is provided. It complements the existing systems for capturing study data in DICOM format and forms the transfer platform from the study centers to the CoreLabs. Synchronization is used to synchronize eCRF data from the data management system to IDMS. For the CoreLabs of the studies it is the central working tool to receive image data and eCRF data and to enter new evaluation data into the study database.

The coordination is carried out by specialized project staff in Berlin (technical) and Munich (quality management).

Tasks of the IDMS as a service for DZHK studies:

- a) During the study preparation phase:
 - adoption of eCRF study design from data management
 - implementation of study-specific automated quality checks based on DICOM header values
 - implementation of a final system test prior to start the productive operation mode
 - initial training for chief investigators and CoreLab user
 - know-how transfer for higher data quality in study planning
 - contact person for the study directors during the conception of the imaging procedures in the studies including the evaluation planning
- b) During the active study phase:
 - management of user access
 - providing and programming of reports to support the main study center
 - performing automated data discrepancy checks based on the original value ranges and rules for the CoreLab-eCRF
 - adoption of adjustments to eCRF forms
 - follow-up and refresher training for study staff
 - helpdesk for IDMS user with 09:00 am -17:00 pm availability of the IDMS Team
 - feedback in case of deviations from defined quality criteria due to DICOM header values
 - providing imaging related reports (e.g. available image data uploads, quality criteria)
- c) Upon completion of the study:
 - closing of the image database
 - long-term archiving and subsequent use in compliance with usage regulations

The portfolio of the IDMS does not include the following services in particular:

- preparation of paper-based capture sheets
- acceptance of image data on data carriers or others
- tracking, answering and closing of queries (query management)
- collection of image data at the study centers or evaluation of image data
- assumption of costs for evaluation including possible special software
- 24/7 availability