

Clinical Research:

DZHK-associated Clinical Studies, Registries or Cohort Studies

CR.1-D

(without DZHK funding)

- Guideline -

1. Purpose

The programme provides support for all prospective, interventional studies proceeded on humans with the aim of analyzing the effect of the intervention on the medical condition, as well as experimental and observational studies requiring study specific measures on humans and also includes clinical registries and cohorts.

Clinical studies, registries or cohorts which are in line with the strategic direction of the DZHK can be associated. The DZHK-association may foster the visibility in the researcher scene already during the recruiting stage of the study and, hence, forward recruitment.

2. Eligibility

Applications for the DZHK-association can be made by the respective principal investigator of the clinical study, registry or cohort. DZHK PI, DZHK scientists or external principal investigators are eligible to apply.

3. Application and decision process

- a) Applications for DZHK-association without funding may be submitted at any time to the main office of the DZHK.
- b) After checking whether all technical requirements are met, the main office of the DZHK will forward the grant applications to the members of the DZHK Clinical Study Group (CSG).
- c) The CSG will assess the application and will give a proposition to the Board of Directors.
- d) The RCC will decide on the final approval on the basis of the proposition of the Board of Directors.

4. Basic principles

- a) Studies can only be associated when they are already fully funded, when the study is sponsored by the investigators' clinical institution (investigator initiated trial) and when at least two DZHK partner sites are participating.
- b) The DZHK provides templates and accompanying instructions which are to be used for the submission of applications.
- c) The application must include an overview of financing of the clinical study.
- d) Use of the DZHK label is allowed on study print material as a sign for endorsement. The DZHK offers access to its researcher network and promotes the study on its website.
- e) If possible, the guidelines of the internal DZHK harmonization process (basic data set, standard operating procedures, etc.) should be considered. The DZHK 'Use and Access Policy' could be applied and the data management could be performed by use of the DZHK central data management. An individual agreement is then negotiated which can contain a chargeback for expenses, for example for use of DZHK-data storage.
- f) The rules of the DZHK Publication Policy will apply.
- g) The 'DZHK-association' does not constitute a basis for a legal claim to funding.

5. Contact partner

The application and approval process is coordinated by the DZHK main office.

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