



Clinical Research:

## DZHK-associate Clinical Studies, Registries, or Cohort Studies (without DZHK financing)

- guideline -

### Purpose

Clinical studies<sup>1</sup> from within the scientific research area of the DZHK may apply for the status 'DZHK-associated'. Prerequisites are that the study is fully funded already, that it is sponsored by the investigators' clinical institution (investigator initiated trial; IIT), and that at least two DZHK-partner sites participate. This call addresses both DZHK-partner sites and external partners.

DZHK-association of such studies may foster their visibility in the researcher scene already during the recruiting stage of the study and, hence, forward recruitment. 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.

### Please note

- a) Applicant is the respective principal/coordinating investigator (either DZHK-PI, DZHK-scientist or external principal/coordinating investigator).
- b) The application for DZHK-association is the form 'Application Template for DZHK-Association'
- c) The application has to contain an overview of the complete study financing.
- d) The aims of a DZHK-associated study have to correspond to the research objectives of the DZHK (cf. [DZHK Statutes of the Association §2](#)). In brief, the research activities of the DZHK focus on three main topics which are particularly important for patients and for the health care system:
  - Prevention and treatment of heart attack,
  - Prevention and individualized treatment of cardiac insufficiency, and
  - Prevention of sudden cardiac death.
- e) If possible, DZHK-associated studies should regard guidelines of the internal DZHK harmonization process (basic data set, SOPs, etc.). They may apply the DZHK 'Use and Access Policy' and perform their data management via the DZHK central data management system (ZDM). The application form contains a free text box to propose configuration of the DZHK-association (e. g. application of DZHK-SOPs, of the DZHK Use and Access Policy, connection to the DZHK-ZDM etc.). An individual agreement is then negotiated which can contain a chargeback for expenses, for example for use of DZHK-data storage.
- f) Publications/manuscripts of the study have to point out the DZHK-association in the acknowledgement ('Endorsed by DZHK.').

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<sup>1</sup> 'Clinical studies' addresses 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 (also embraces clinical registries and cohorts).



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- g) All manuscripts for the publication of results, which emerge from the DZHK-associated research, conform to the rules of good scientific practice and are presented to the Board of Directors for approval prior to the first submission to a journal (via the DZHK main office at least 4 weeks in advance; please send to [clinicalstudies@dzhk.de](mailto:clinicalstudies@dzhk.de)).
- h) The status 'DZHK-associated' does not create any claim for financing by the DZHK.

Applications for DZHK-association without financing may be submitted anytime. The decision on DZHK-association is made by the DZHK Board of Directors after consulting the DZHK Clinical Study Group.

For contextual questions, please contact Alexandra Bayrak, coordinator for clinical research ([alexandra.bayrak@dzhk.de](mailto:alexandra.bayrak@dzhk.de)).