Rules for the conduct of DZHK studies – study principal investigator/ sponsor delegated person

Fact sheet

Responsibilities

1. The study principal investigator normally assumes the overall responsibility for the study on behalf of the sponsor (member institution) according to the glossary of the ICH-GCP in conjunction with Chapter 3 ICH-GCP, cf. 'Grundsaetze und Verantwortichkeiten bei der Durchführung klinischer DZHK-Studien' (German Federal Ministry of Research, Technology and Space, 2025).
2. The reporting obligations (annual reports to the Funding Management Department, quarterly recruitment reports to the DZHK office, permanent and continuous communication) as well as the elaboration of a study-specific data protection concept and monitoring of study protocol compliance must be observed sustainably.
3. The Steering Committee of a multicentre study is supposed to bear co-responsibility for the performance of the study. It is expected that multicentre DZHK studies regularly appoint, next to the principal investigator, two or more local principal investigators from the DZHK into the Steering Committee of a study, who are obliged to recruit more than 10 percent of the necessary total number of participants (cf. Preparation instruction documents for full applications Point 17 Note 2). In order to make this commitment transparent the Steering Committee members shall be named in person in representations of the respective study.
4. The principal investigator is obliged to employ a study coordinator (ideally full-time, who is not integrated into clinical routine operations) for an efficient preparation and supervision of a study (budget for project management). The permanent, competent and reliable communication with the enrolling centres and the DZHK is essential to achieve the planned recruitment performance.

Study preparation

1. To prepare a DZHK study in the framework of the DZHK research platform the DZHK office provides a checklist for main study centres and a variety of information on the following website: https://service4studies.dzhk.de/wie-diese-seite-funktioniert/. The use of this information source is obligatory.
2. Pre-trial visits in potential local study centres for making arrangements and checking out the opportunities has proven to be a model of success and is obligatory. Personal interviews conducted by employees of the main study centre with inspection of the patient files and a joint perusal of the study protocol are instrumental in helping to estimate the actual recruitment potential. On this occasion go through all required steps together. Identify local places of contact with matching patients. Assess together the fulfilment of the conditions for the technical integration of a new study centre into the DZHK research platform (IT connection Fact Sheet) in

order to prevent a delay/problem at the initiation. Review the commitment submitted with the application (cf. Fact Sheet 'Commitments').
Reimburse the centre for this preparation time.

3. Please invariably integrate the local Clinical Staff of the DZHK centres involved in your study for
   - testing & improvement of the feasibility of the study and the commitments,
   - creation of the study protocol and definition of the inclusion and exclusion criteria,
   - eCRF creation,
   - writing SOPs and
   - pre-trial visits and initiation visits.

Study implementation

1. Milestones relating to the start of recruitment and recruitment success are part of the funding contract. The funds remain on hold until fulfilment. The principal investigator gives his/her approval to the milestones before closure of the funding contract. Usually the milestones are identical with (1.) the start of recruitment (a funds block is imposed after study preparation exceeds twice the length of time agreed by contract), and (2.) a recruitment success of 25% of the necessary number of participants (after more than 60% of the planned recruitment time a funds block will be imposed in this regard). Funds will be unblocked to the extent necessary to reach the next milestone, respectively.
2. The continuous supervision of the performance of each enrolling centre by the study coordination staff is indispensable.
3. Create simple inclusion checklists etc. for recruiters and have screening lists filled out.
4. Please include screening fees in the patient fee for successfully recruited patients in proportion to the effort required.
5. Please observe how the commitments stated in the application are handled and, if existent, any changes thereof (cf. Fact Sheet 'Commitments').
6. Initiations of centres must be performed by main study centre staff / the study coordinator in person. Instructions are given on the contents of the study, using of and technical integration into the DZHK research platform for conduction of the study.
7. Prioritise highly committed centres in initiations. Seek contact as early as possible because of matters related to submissions of the ethics committee or the study centre contract. Close tracking of the processes proves to be very important for a successful roll-out of a study and hence for a successful recruitment strategy.
8. Create incentives for the recruiting physicians at the enrolling centres: local study physicians who account for a recruitment contribution of over 10% in a study will be mentioned by name as top recruiters in representations of the study. That top recruiters (on work level) have the chance of becoming co-authors of study publications is regulated by the DZHK publication guideline. This is to be promoted by the principal investigator(s) accordingly.
9. Organise investigator meetings and meetings of study staff, e.g. on the side lines of conferences in which the principal investigator informs and motivates in person – promote communication and cooperation.
10. Study websites, regularly appearing newsletters, WhatsApp or Facebook groups etc. are effective methods to promote the communication between the decentral study staff and study coordination staff.

Trouble Shooting

1. In case of any problems or conflicts arising, please contact the DZHK main office or the Board of Directors to find a solution early.
2. A local enrolling study centre which – despite ongoing recruitments at the main study centre and other centres – has failed to recruit a patient six months after its initiation will be closed as a study centre for the respective study by the main study centre. The same applies if a centre has failed to recruit any further patient in six months' time. This provision is to be stipulated with every enrolling centre in the study centre contract.
3. In the event of a dissatisfactory recruitment performance of a DZHK study a consultation which is oriented toward finding a solution to the problem shall take place with the DZHK Board of Directors and the principal investigator within a period of a few months after the problems arose (e.g. in case of obvious deviations from the recruitment plan). The success of initiated measures shall be reviewed three to six months after this consultation.
4. Studies remaining distinctly below target, according to the milestones agreed upon in the funding contract, will be discontinued after a funds block has been imposed, unless a convincing concept to remedy the situation has been submitted.