Clinical Research:  
DZHK-associated Clinical Studies,  
Registries or Cohort Studies

CR.2-D

(without DZHK funding)

- Application template -

# Study synopsis

|  |  |
| --- | --- |
| 1. Applicant/ Coordinating investigator | First name, last name, academic title  Institution and department (complete name)  Postal address  Telephone  E-mail address |
| 1. Date of application | Please enter the text here. |
| 1. Title of study | Please enter the date here. |
| 1. Medical condition | Please enter the text here. |
| 1. Objectives | Please enter the text here. |
| 1. Interventions | Experimental intervention / index test:  Please enter the text here.  Control intervention / reference test:  Please enter the text here.  Follow-up per patient:  Please enter the text here.  Duration of intervention per patient:  Please enter the text here.  Experimental and/or control off label or on label in Germany: (*if applicable)*  Please enter the text here. |
| 1. Key inclusion and exclusion criteria | Key inclusion criteria:  Please enter the text here.  Key exclusion criteria:  Please enter the text here. |
| 1. Outcome(s) | Primary efficacy endpoint:  Please enter the text here.  Key secondary endpoint(s):  Please enter the text here.  Assessment of safety:  Please enter the text here. |
| 1. Study type | Please enter the text here. |
| 1. Statistical analysis | Efficacy / test accuracy:  Please enter the text here.  Description of the primary efficacy / test accuracy analysis and population:  Please enter the text here.  Safety:  Please enter the text here.  Secondary endpoints:  Please enter the text here. |
| 1. Sample size | To be assessed for eligibility (n = …): Please enter the number here.  To be allocated to trial (n = …): Please enter the number here.  To be analysed (n = …): Please enter the number here. |
| 1. Trial duration | First patient in to last patient out (months): Please enter the number here.  Duration of the entire trial (months): Please enter the number here.  Recruitment period (months): Please enter the number here. |
| 1. Participating centres | To be involved (n): Please enter the number here.  Signed agreement to participate (n):Please enter the number here. |

## Summary

Please enter the text here.

## Key words

Please enter the text here.

## Intervention scheme/Trial flow

Please enter the text here.



## Frequency and scope of study visits

Please enter the text here.

# The medical problem

## Evidence

Please enter the text here.

## Impact of the clinical study

Please enter the text here.

# Justification of design aspects

## Controls/Comparators

Please enter the text here.

## Inclusion and exclusion criteria

Please enter the text here.

## Outcome measures

Please enter the text here.

## Methods against bias

Please enter the text here.

## Proposed sample size/Power calculations

Please enter the text here.

## Feasibility of recruitment

Please enter the text here.

# Statistical analyses

What is the proposed strategy of statistical analysis?

Please enter the text here.

What is the strategy for analysing the primary outcome?

Please enter the text here.

If interim analyses are planned, please specify. Are there any subgroup analyses?

Please enter the text here.

What are the methods for calculating test reproducibility in diagnostic trials?

Please enter the text here.

# Ethical considerations

Please enter the text here.

# Trial management

## Key participants

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial sponsor** | | | | |
|  | | | | |
| **Key participants** | | | | |
| # | **Name** | **Affiliation** | **Responsibility/Role** | **Signature** |
| 1 |  |  | Principal/Coordinating investigator |  |
| 2 |  |  | Trial statistician |  |
|  |  |  |  | |
|  |  |  |  | |

## Supporting facilities

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Trial Supporting facilities** (central laboratories, pharmacies etc.) | | | | |
| # | Name | Affiliation | Responsibility/Role | |
|  |  |  |  | |
|  |  |  |  | |
| **Recruiting centres** (Signatures have to be provided ) | | | | |
| # | Name | Affiliation | | Expected number of patients recruited for the complete trial |
|  |  |  | |  |
|  |  |  | |  |
| **Total sum of recruited patients** | | | | Σ = |

# Financing

## Financial summary

|  |  |
| --- | --- |
| **Item** | **Total funding period (€)** |
| Administrative/organisational trial management (incl. quality management, data management, travel costs, fees and insurance, etc.) |  |
| Case payments |  |
| Materials (e.g. trial drug, etc.) |  |
| Other: *please specify* |  |
| **Total** |  |

## Outline of cost coverage

Please enter the text here.

## Intellectual property status

For pharmacological interventions: Trial drug is covered by intellectual property rights  no  yes, until Please enter the date of expiry.

For interventions with medical devices: The device is CE-marked  no  yes

## Commercial interest

Please enter the text here.

# Match of DZHK and trial aims

## Matching of scientific aims

Please enter the text here.

## Advantages linked to the trials DZHK association for the DZHK

Please enter the text here.

## Expectations related to DZHK-association of the trial

Please enter the text here.

## Suggestions for merging the trial into DZHK infrastructure

Please enter the text here.

# Bibliography

Please enter the text here.

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