EURONANOMED

JOINT TRANSNATIONAL CALL FOR PROPOSALS (JTC2020) FOR "EUROPEAN INNOVATIVE RESEARCH & TECHNOLOGICAL DEVELOPMENT PROJECTS IN NANOMEDICINE"

GUIDELINES FOR PRE-CLINICAL AND CLINICAL STUDIES

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GUIDELINES FOR THE EXPERIMENTAL DESIGN OF PRECLINICAL STUDIES

A. Methodological approach

- Describe the rationale behind the study and, the use of animals
- please explain how and why the animal species and model being used can address the scientific objectives and the relevance to human biology. Elaborate on the type of animal that is the subject of study (strain, pathogen free, genetic modification status, source, age, developmental stage, weight, sex) and the housing and husbandry (type of facility, type of cage or housing, bedding material, number of cage companions, type of food, access to food and water, environmental enrichment etc.)
- Primary and secondary (experimental) outcomes
- Describe the experimental and control groups and the experimental procedures: type, duration, frequency and time points of the measurements and the equipment that will be used
- Proposed sample size(s) / power calculations: Specify the N of each experiment and each condition and how this N was arrived at with power calculations including justification of the effect size. Where power calculations are not appropriate (for example in exploratory research), explicitly explain why. Statements as 'this N has been used in previous publications' are not acceptable
- Strategies to minimise the effects of bias (e.g. randomization, blinding, order of assessment), or an explanation why these are not relevant
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- please describe the methods directed to authenticate the validity and identity of specific biological and chemical resources, such as cell and animal lines, chemicals, antibodies, biological samples and other specific reagents used in your research. Please also describe the controls you are planning to apply to validate key biological and chemical resources in the research (e.g. how you intend to confirm the genotypes of animals used, authenticate cell lines, etc.). This does not apply to common reagents or chemicals.

B. Statistical analysis

- Describe the details of the statistical methods used for each (subgroup) analysis and the methods used to assess whether the data met the assumptions of the statistical approach
- Describe the dataset that will be used for the analyses and the number of replications (if applicable)
- Details of any statistical advice sought (seeking advice is strongly recommended)

GUIDELINES FOR THE EXPERIMENTAL DESIGN OF CLINICAL STUDIES

A. Methodological approach

- *Describe the rationale behind the study and, the use of patient, human cohort sample(s)/group(s) for this specific study*
- *please elaborate on the prevalence, incidence, mortality and burden of the disease, the expected improvement of the therapy/measure or impact of the study and patient participation*
- *Primary and secondary (experimental) outcomes*
- *Describe the experimental and control groups and the experimental procedures: type, duration, frequency and time points of the measurements and the equipment that will be used*
- *Proposed sample size(s) / power calculations: Specify the N of each experiment and each condition and how this N was arrived at with power calculations including justification of the effect size. Where power calculations are not appropriate (for example in exploratory research), explicitly explain why. Statements as 'this N has been used in previous publications' are not acceptable*
- *Strategies to minimise the effects of bias (e.g. randomization, blinding, order of assessment), or an explanation why these are not relevant*
- *List recruiting centres, describe inclusion/exclusion criteria and elaborate on the feasibility of recruitment / evidence that intended recruitment rate is achievable.*
- *Please specify "stopping rules" / "discontinuation criteria" for*

  a) the individual subject / patient (stopping the trial early) / sample,

  b) participating / recruiting centres, which fail to include the estimated number of subjects / patients,

  c) for the whole study.

B. Statistical analysis

- *Describe the details of the statistical methods used for each (subgroup) analysis and the methods used to assess whether the data met the assumptions of the statistical approach*
- *Describe the dataset that will be used for the analyses and the number of replications (if applicable)*
- *please include Information on interim analyses specifying what interim analyses will be carried out and listing of time points, any planned adjustment of the significance level and timing of final analysis.*
- *Details of any statistical advice sought (seeking advice is strongly recommended)*