Scientific Board - Criteria for Peer-Review Committee assessment

EVALUATION CRITERIA *Projects having already undergone scientific evaluation are invited to provide previous evaluation reports*
Rationale for the trial - including the choice of the experimental intervention and the comparator - based on a sound scientific review and analysis of relevant clinical and pre-clinical data *
Suitable overall trial design appropriate to the clinical question
Clinical relevance for patients and public health
RECOMMENDATIONS
Use international guidelines to design the protocol (SPIRIT, https://www.spirit-statement.org/spirit-statement/). Looking more generally at reporting guidelines should also help in framing the protocol (see https://www.equator-network.org/)
Relevant patient population (inclusion and exclusion criteria), setting, and duration of treatment and follow up
Non-inferiority/Equivalence design and margin should be fully justified
Use of the best available comparator, with appropriate description and justification
Primary outcome variable most suitable for patient and public health's interests is fully specified. Outcome variables for efficacy and safety are clinically meaningful for the patient.
Adequate sample size with supporting information, methods and results of the calculation. The sample size calculation should be based on the primary outcome variable. Power calculation should be considered for the key secondary outcomes variables
Adequate recording of adverse events and (pharmaco-/materio-) vigilance plan
Adequate strategies to reduce or control possible biases, for example central randomisation; blinding of all parties (at least assessors whenever possible, and statisticians); intention-to-treat analysis for efficacy in superiority trial; data analysis before breaking the allocation code; interpretation of results should be independent of funding source
Adequate strategies to reduce the risks of random error. Adequate methods to handle multiple testing problems
Description of potential risks (i.e. harm to patients; integrity of data) and how to handle them, including possible involvement of an independent data monitoring and safety committee
Description of governance structure of the project including responsibility for coordination, data management, and perspective for a data analysis plan and monitoring plan
Involvement of relevant patient organisation (if available) or patient representatives in the protocol design and selection of outcome variables
It is highly recommended to use an ECRIN-certified data centre and/or to take the ECRIN IT/DM*** standards into consideration
Establishment of a data sharing plan

** In essence this aims to ensure equipoise, and that the study hypothesis addresses an open clinical question, meaning a question never addressed or convincingly answered before. The recommendation for a systematic review and meta-analysis applies in particular to comparative effectiveness trials.** Reporting guidelines may also impact the protocol development, see CONSORT for trials (http://www.consort-statement.org/) or STROBE for observational studies (https://strobe-statement.org/index.php?id=strobe-home) ***IT/DM standards: Information Technology/Data Management standards*