ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

ECRIN Scientific Board eligibility criteria for Access to Services

Declaration for submissions to the ECRIN

I acknowledge that access to ECRIN services requires compliance with the following eligibility criteria.

ELIGIBILITY CRITERIA

1 Multicentre trial run in at least two ECRIN-ERIC member or observer countries

2 Rules for transparency:

a) Commitment to register the trial in a public register before inclusion of the first participant. +

b) Commitment to post trial results in a public register one year after the trial is completed, i.e. last follow up of the last patient for the primary outcome. +

c) Commitment to publish results irrespective of findings.

d) Commitment to make raw anonymised data sets available to the scientific community upon request. *

e) Declaration of conflicts of interest.

+ according to the WHO ICTRP or ICMJE recommendations, for example on EudraCT or Clinicaltrials.gov.
* unless documented justification.

3 Commitment to fairly describe the contribution of ECRIN and its national partners in the publications.

I DECLARE THAT

- the current version of the protocol does not comply with <u>all the eligibility criteria</u> and cannot be changed at this stage. Therefore, I commit to include them on the occasion of the earliest protocol amendment. ☐

- <u>all the eligibility criteria</u> are already met and addressed in the current version of the study protocol. ☐

....., ...
date signature of the Coordinating Investigator

The Coordinating Investigator should also consider the following evaluation criteria and recommendations.

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 extensive and up-to-date review and analysis of relevant clinical and preclinical data. *
Suitable overall trial design appropriate to the clinical question
Clinical relevance for patients and public health
RECOMMENDATIONS
Relevant patient population (inclusion and exclusion criteria), setting, and duration of treatment and follow up.
Randomised superiority design is preferable for benefit assessment, rather than non-inferiority.
Use of the best available comparator.
Primary outcome measure most suitable for patient and public health's interests. Outcome measures for efficacy and safety clinically meaningful for the patient.
Adequate sample size with supporting calculation. Sample size calculation based on the primary outcome measure, and power calculation for secondary outcomes.
Adequate recording of adverse events.
Adequate strategies to reduce or control possible biases, for example central randomisation; blinding of all parties (at least assessors whenever possible, and the statisticians); intention-to-treat analysis for efficacy in superiority trial; blinded conclusions drawn before breaking the allocation code; and interpretation of, and decision to publish results, independent of funding source.
Adequate strategies to reduce the risks of random error ("play of chance"), i.e. problems with multiplicity due to multiple outcome comparisons and sparse data.
Description of potential risks and how to handle them, including involvement of and charter for independent data monitoring and safety committee.
Description of governance structure of the project including responsibility for coordination, data analysis, and independent monitoring.
Involvement of pertinent patient organisation (if available) or patient representatives in the protocol design.
Plan to make raw anonymised datasets available to the scientific community upon request.

* In essence this aims to ensure that the study hypothesis addresses an open clinical question, meaning a question never addressed or convincingly answered before, which only justifies the involvement (and possibly the randomisation) of patients in the study. This mainly applies to comparative phase III or IV trials.