Reviewer’s report

Title: Development of a survey on the regulatory requirements for clinical research in the EU by the European Clinical Research Infrastructures Network (ECRIN) and suggestions for a clinical research classification

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Reviewer: Maurizio Bonati

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The paper report the followed trial to define the different national regulatory requirements for clinical research in a few EU countries. The aim and expected findings are useful to set up a common and essential variables characterizing different clinical research approaches.

In the present version the methodological phase concerning what done by the working group to define the major categories of clinical research is reported. This can be of interest for a few readers. However, a few findings should be shown, e.g. the main intercountry differences. On this subject a table can be added.

Discussion should be more critical and suggests potenzial hypotheses in the practice.

Nothing is said about clinical registries is and where available or used. This can be also a potential objective for ECRIN work in the practice: what is now an experimental survey, tomorrow should be a constant and systematic monitoring of clinical research in EU throughout common and shared instruments.

After all, the discussion between interventional or non-interventional study is a little fatuous. In the clinical practice is more useful to define a study as experimental or non-experimental denoting what is compliant to the routine or differs because is under assessment.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests