30 August 2016

Public consultation on the revision of "Risk proportionate approaches in CTs"

Comments from:

Name of organisation or individual
[redacted]

1. General comment

The criteria for low interventional trials has been introduced and the trial specific risk assessment has been described in more detail in this paper. This is a new approach in the regulation and seems flexible. Even where study specific this approach needs more standards worked out to enhance the clarity and the transparency of this complex procedure.

Moreover, "If allowed in the concerned MS" type of statements means that the EU regulation would still allow unharmonized many important clinical trials related processes and an imbalanced review approach by different competent authorities in CTs in Europe. Therefore, either this wording is revised or a minimum set of criteria/items (as applicable) is added to all EU CT regulation guidelines in order to set a common and fairly balanced legal framework in all EU MSs.

Specific comments on text

Line number(s) of the relevant text	Comment and rationale; proposed changes
132	Approx. blood volume to be specified and added, as to better assess, when blood withdrawal is regarded as low intervention
196	Qualification of study personnel and site: is the same qualification as for studies Phase II to Phase IV? More information given here would be much appreciated
342	Labelling for use in a clinical trial according to local requirements is required (e.g. in order a compliance check can be done properly)? If no patient identification is on the labels, how will the monitor do a compliance check afterwards?
394	Does this exclude/include site selection / initiation and close out visits as well? No source data verification, no check of signed ICFs etc. Will sites be informed about the study via phone/e-mail (if there is no investigator meeting at all)?

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