[redacted]

Unit B4 "Medical products – Quality, Safety and Innovation"
SANTE-B4-GL-risk-proportionate-approach@ec.europa.eu
European Commission
F101 08/058
B-1049 Brussels (Belgium)

Date 31 August 2016

[redacted]

Consultation document "Risk proportionate approaches in clinical trials"

Dear Sir or Madam

The [redacted] – has contacted [redacted] for feedback on the document "Risk proportionate approaches in clinical trials". Please find details of their replies in the following.

Comment	Reference text	Reference line
The definitions regarding low intervention trials und minimal additional risk or burden to the safety of the subject must be described in such a way that different persons and institutions come to the same evaluation result.		e.g. 121, 122
Not only the safety should be in the focus but also complexity, tolerability resp. wellbeing and the amount of burden, stress, discomfort, etc.		55
To reduce administrative burden for researchers it is essential to guarantee good education of all involved research personnel. A special focus should therefore be set on the documentation and control of certificates of training, work experience, awareness of responsibility, sufficient staff resources, etc. to guarantee high quality and legal compliance. This point is not sufficiently represented in the document so far.		197

[redacted]

Comment	Reference text	Reference line
To identify, evaluate, control, review and communicate as well as report risks resp. potential impact and likelihood of risk occurrence means in fact a high administrative obligation which could diminish the benefit of reduced administration burden due to low intervention.		168 ff.
Underlined parts should be defined or examples given. Centralized monitoring makes more sense in Multicenter Trials, as there is a comparison possible. In monocentric studies, reduced on-site monitoring should nevertheless be an option based on risk assessment. Description of risk assessment in the protocol might be sufficient in lower risk studies?	Centralized monitoring processes provide additional monitoring capabilities that can complement and justify adaptations to the extent and/or frequency of on-site monitoring or may replace them for some types of trial. On-site monitoring remains relevant in certain types of clinical trials, as it is instrumental for the verification of several critical aspects at the trial site, for e.g. the informed consent process, source data verification and IMP handling on site.	386 - 390

Those contributions can be directly published provided that my organisation remains anonymous (I consent to publication of any information in my contribution in whole or in part (which may include quotes or opinions I express) provided that this is done anonymously. I declare that nothing within my response is unlawful or would infringe the rights of any third party in a manner that would prevent publication).

With kind regards

[redacted]

[redacted]