

Dear Colleagues,

Please find below comments/suggestions regarding the consultation document “Risk Proportionate Approaches in Clinical Trials”. [Link](#)

- Regarding “Risk Identification and Evaluation”, we propose that for low intervention clinical trials on medicinal products with Risk Management Plan (RMP) available, the RMP should be used as guidance/reference document.
- Row 262: typing error (adaptions: correct is adaptations)
- Rows 273-275: text as is now “particular, but not only, to marketed products, with a known safety profile, which are tested within the framework of low-intervention clinical trials. In this regard, the following situations apply”  
This sentence creates confusions as to whether all three statements in the sentence (i.e. marketed products / with a known safety profile / which are tested within [...]) should apply simultaneously i.e. marketed products with a known safety profile, which are tested within the framework of low-intervention clinical trials.  
If this is the case (i.e. all three statements should apply simultaneously) then we propose that it is rewritten as to remove the comma between “products, with”, i.e.:  
*“particular, but not only to to marketed products with a known safety profile, which are tested within the framework of low-intervention clinical trials”.*

Please be informed that the contribution is on behalf of Zeincro Hellas SA. The contribution can be directly published with my personal/organisation information (I consent to publication of all information in my contribution in whole or in part including my name/the name of my organisation, and 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).

We remain at your disposal.

Kind regards,



**Anastasia Sideri**

Safety Officer

Pharmacovigilance & Safety Department

**ZEINCRO HELLAS S.A.**

30 Anapafseos Street, 152 35, Vrilissia, Athens, Greece

Tel: +30 210 8047709 | Fax: +30 210 6134695

[www.zeincro.com](http://www.zeincro.com) | e-mail: [asideri@zeincro.com](mailto:asideri@zeincro.com)