

Dear Sir/Madam,

Please find below the input on the public consultation on the above-mentioned document. This input is sent to you on behalf of the Nederlandse Vereniging van Farmaceutisch Geneeskundigen (NvFG, Dutch branch association).

Compliments on the thorough way the document is set up; in our view all main considerations are addressed. Some additional thoughts:

- 3. 'Low interventional trials'. Whether or not a study is considered 'low interventional' can vary per member state. Can you consider to allow a study risk management plan that varies per member state so that the mitigation of risks does not have to apply to countries with a low risk?
- 4.4 'Trial Management'. In this section is referred to implications on monitoring strategy based on study-specific risks. Please also refer to site-specific risks that are applicable (monitor needs to make site-specific risk plan and mitigate and continuously evaluate these risks to set out the monitoring strategy in addition to the overall study-specific risks) as this differentiation is very important on a monitoring level as well.
- And finally it will be very helpful if EMA could provide templates for the documents as mentioned in this document; eg risk management plan, mitigation plan).

I hope our input is helpful and clear. Should you have any questions, please let me know.

I consent to publication of all information in my contribution in whole or in part including my name/the name of my organisation (NvFG), 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).

Kind regards, Marianne Bertens on behalf of the NvFG (ClinOps charter)