Comment to consultation document

Risk proportionate approaches in clinical trials

The German scientific society Arbeitsgemeinschaft Angewandte Humanpharmakologie (AGAH) strongly supports the approach of risk proportionate approaches in clinical trials. Taking into account the risk study participants are confronted with in a clinical trial in regard to applicable approval processes is highly encouraged and very meaningful.

So far the consultation document encourages the classification as low intervention clinical trials if the following conditions are fulfilled:

(a) the investigational medicinal products, excluding placebos, are authorised;

(b) according to the protocol of the clinical trial, the investigational medicinal products are used in accordance with the terms of the marketing authorisation; or the use of the investigational medicinal products is evidence-based and supported by published scientific evidence on the safety and efficacy of those investigational medicinal products in any of the Member States concerned; and

(c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned

However, according to our understanding this definition does not cover any type of pharmacokinetic, bioavailability and / or bioequivalence studies in healthy subjects, as these studies do not follow the marketing authorisation.

Thus, our recommendation is to extend the classification criteria by studies investigating low-risk drugs in healthy subjects for PK/PD/BA/BE assessments. Low-risk drugs for example could be simply defined as OTC drugs as long as the total dose does not exceed the OTC approval.

Such an extension would be very much appreciated and does not result in any increased risk for study participants.

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