30 September 2016

Submission of comments on ' Concept paper on the revision of the 'Guideline on strategies to identify and mitigate risks for first-in-human clinical trials with investigational medicinal products' ' (EMEA/CHMP/SWP/28367/07

Comments from:

Name of organisation or individual
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Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.

When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).

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1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	1. The paper would benefit from some discussion of pharmacogenomics. If there is a risk of differential behaviour as a result of genetic factors then the researchers should consider how to adapt the study to take this into account, either to mitigate risk or in an exploratory manner to understand what has happened.	
	2. Similarly immunogenicity should be addressed i.e. how to identify whether there are pre-existing antibodies to the therapeutic agent or if the therapeutic agent induces such antibodies and how to mitigate this.	
	3. Consideration might be given to how the recommendation in EMEA/CHMP/SWP/28367/07 that: "healthy subjects or patients should not be included in first-in-human clinical trials if they are in another clinical trial or have participated recently in another clinical trial unless justified. It is important to include clear exclusion criteria to prevent concomitant or immediate consecutive exposure to investigational medicinal products" might be facilitated. For example, In the UK, the HRA hosts The Over-volunteering Prevention System (TOPS) which aims to prevent participants from taking part too frequently in trials of new medicines. Volunteers are registered on TOPS when they attend a unit for a screening exam. Once the volunteer is registered on TOPS, other units using TOPS will be able to see that the volunteer has	

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	attended the unit and may be intending to participate in a study. It is a standard condition of ethical approval, as well as part of the MHRA accreditation scheme, that all Phase I studies using healthy volunteers register research participants onto TOPS and complete the record for each volunteer to specify whether they received a dose of the study medicine. It is free to all UK organisations undertaking Phase I trials in healthy volunteers.	

2. Specific comments on text

Line number(s) of the relevant text *(e.g. Lines 20-23)*	Stakeholder number *(To be completed by the Agency)*	Comment and rationale; proposed changes *(If changes to the wording are suggested, they should be highlighted using 'track changes')*	Outcome *(To be completed by the Agency)*
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	
		Comment: Proposed change (if any):	

Please add more rows if needed.