



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

**Submission of comments on 21.08.17**

**Submission of comments on Guideline for the notification of serious breaches of Regulation (EU) No 536/2014 or the clinical trial protocol EMA/430909/2016**

## Comments from:

Name of organisation or individual

### **EUROPEAN INDUSTRIAL PHARMACISTS GROUP (EIPG)**

*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).*



## 1. General comments

Stakeholder number <i>(To be completed by the Agency)</i>	General comment (if any)	Outcome (if applicable) <i>(To be completed by the Agency)</i>
	<p><b>Appendix 1 page 8 (IMP) sentence on detail of breach:</b> "5) Due to an interactive response technologies (IRT) malfunction 50% of subjects assigned to one arm were unblinded in a blinded trial, furthermore this information was submitted to all trial staff at all investigator sites participating in the trial"</p> <p>Obviously this was a systematic issue that impacts the robustness and reliability of the data but please clarify why this could potentially affect the safety of trial subjects.</p>	
	<p><b>General comment on the document:</b></p> <p>Trial subjects take many risks, and must be given the opportunity to play an active role in safeguarding their own interests, including the ability to report SAEs or SUSARs directly.</p> <p>The document should state that when a serious breach is considered to impact the safety of trial subjects, all subjects in the trial should receive information on the breach.</p>	

## 2. Specific comments on text

Line number(s) of the relevant text <i>(e.g. Lines 20-23)</i>	Stakeholder number <i>(To be completed by the Agency)</i>	Comment and rationale; proposed changes <i>(If changes to the wording are suggested, they should be highlighted using 'track changes')</i>	Outcome <i>(To be completed by the Agency)</i>
Lines 87-90		Comment: Clarify with examples.  Proposed change (if any):	
		Comment:  Proposed change (if any):	
		Comment:  Proposed change (if any):	