1 June 2016

Submission of comments on ' Guidance on format of the risk management plan (RMP) in the EU – in integrated format' (EMA/PRAC/613102/2015 Rev.2 accompanying GVP Module V Rev.2)

Comments from:

Name of organisation or individual
ACRO (Association of Clinical Research Organizations)

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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Send a question via our website www.ema.europa.eu/contact

1. General comments

Stakeholder number *(To be completed by the Agency)*	General comment (if any)	Outcome (if applicable) *(To be completed by the Agency)*
	The Association of Clinical Research Organizations (ACRO) represents the world's leading, global clinical research organizations (CROs). Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices – from discovery, pre-clinical, proof of concept and first-in-man studies through post-approval and pharmacovigilance research. With more than 110,000 employees engaged in research activities around the world (including more than 30,000 in Europe), ACRO advances clinical outsourcing to improve the quality, efficiency and safety of biomedical research. Each year, ACRO member companies conduct more than 9,000 clinical trials involving nearly two million research participants in 142 countries. On average, each of our member companies works with more than 500 research sponsors annually. ACRO welcomes and supports the draft revision of the guidance on format of the risk management plan (RMP) in the EU – in integrated format accompanying the draft GVP Module V Rev.2. ACRO especially welcomes the clarity provided by the explanatory notes within the template, and the emphasis on the need for a high level and brief summary that should provide an interpretive,	

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	high level view of the available information, avoiding detailed discussion, with the prime focus on the European patient population.	

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)*
235		Comment: ACRO recommends that table SII.1 should also include a summary of important drug interactions identified in non-clinical studies. Proposed change (if any): Include important drug interactions identified in non-clinical studies in table SII.1.	
382 - 394		Comment: ACRO recommends that, to avoid confusion, the guideline should state clearly that the basic definition of terms is as stated in GVP Annex 1 and that the terminology is further clarified within the context of risk management planning by GVP Module V (R2) as stated. Proposed change (if any): State clearly that the basic definition of terms is as stated in GVP Annex 1 and that the terminology is further clarified within the context of risk management planning by GVP Module V (R2) as stated.	
646 - 729		Comment: ACRO recommends adding “Non-imposed PASS” to these sections of the template so that they provide a complete overview of additional pharmacovigilance activities, whether or not individual studies are mandated. Proposed change (if any): Add “Non-imposed PASS” to these sections of the template.	

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)*
		ACRO thanks the Agency for this comment opportunity. Please do not hesitate to contact ACRO if we can provide additional information (knoonan@acrohealth.org)	

Please add more rows if needed.