An agency of the European Union



Submission of comments on

24 February 2023



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 Excel format (not PDF), to the following address:

ICH@ema.europa.eu

All the cells with an asterisk (\*) should be filled in prior to completing the columns "Comment and rationale" and/or "Proposed changes / recommendation". For more details on how to use this template please refer to the tab "Manual for commenter".

Name of organisation	Line	Line	Section	Comment and rationale	Proposed changes / recommendation
or individual*	from* (line Nr or 0	to* (line Nr or 0 for general comment)		(to go to next line within the same cell use Alt + Enter)	(if applicable - to be used if you want to propose specific text changes)
ACRO (Association of Clinical Research Organizations)	0	0		The Association of Clinical Research Organizations (ACRO) represents the world's leading clinical research and technology organizations. Our member companies provide a wide range of specialized services across the entire spectrum of development for new drugs, biologics and medical devices, from pre-clinical, proof of concept and first-in-human studies through post-approval, pharmacovigilance and health data research. ACRO member companies manage or otherwise support the majority of all biopharmaceutical sponsored clinical investigations worldwide and advance clinical outsourcing to improve the quality, efficiency and safety of biomedical research.  ACRO welcomes the opportunity to comment on the ICH M11 Guideline	
ACRO (Association of Clinical Research Organizations)	4	6		ACRO welcomes the inention to have an internationally adopted stanadrd for the format and content of the clinical trial protocol to support consistency across sponsors. ACRO members work with multiple sponsors and harmonisation will enable efficiencies in clinical development.	
	35	42		ACRO notes the applicability of the protocol template across all phases of interventional clinical trials and all therapeutic areas. ACRO also notes the use of the term "medicinal product" to refer to any therapeutic, prophylactic, or diagnostic agent including pharmaceuticals, biologics, vaccines, cell or gene therapy products, as well as drug-device combination products when registered as a drug.	
ACRO (Association of Clinical Research Organizations)	69	71		ACRO notes the intention of the template to incorporate recommended and optional text to maintain flexibility. This will be important to ensure the specific needs of any particular clinical trial and/or geography can be sufficiently described.	
ACRO (Association of Clinical Research Organizations)	0	0		ACRO would welcome an additional section with guidance on a suitable transition period to use of the new template. This should cover guidance on ongoing clinical trials, those in set-up and new trials. Suggested timelines are given in column G.	Suggested additional new text: Clinical trials which are in set-up or ongoing, at the time of publication of the guidance may continue with existing protocol formats. Clinical trials to be submitted for regulatory approval from 1st January 2025 onwards should use the new template.

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			comment	comment			

Name of organisation or individual*	from*	to* (line Nr or 0 for general	number	Comment and rationale (to go to next line within the same cell use Alt + Enter)	Proposed changes / recommendation (if applicable - to be used if you want to propose specific text changes)