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24 February 2023

Submission of comments on ICH M11 Template (EMA/CHMP/ICH/778801/2022)

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:
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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 or individual*	Line from* (line Nr or 0 for general comment)	Line to* (line Nr or 0 for general comment)	Section 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)
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)	0	0		ACRO notes that the Template reflects the standard requirements for protocol contents as noted in Part D of Annex I of the EU Clinical Trial regulation.	
ACRO (Association of Clinical Research Organizations)	0	0		ACRO would welcome provision of an editable version of the template for ease of implementation.	
ACRO (Association of Clinical Research Organizations)	370	405	2.2	The EMA Recommendation Paper on decentralised elements in clinical trials, December 2022, makes reference to including a specific and documented risk benefit assessment. The Recommendation Paper states that "This risk benefit assessment as well as any risk mitigation action taken should be clearly described in the clinical trial protocol or other protocol related document as part of the clinical trial application to the MS." ACRO suggest including provision for this within section 2.2 of the Protocol Template and the associated section of the Technical Specification.	Line 398. Add "Include risk benefit assessment and any risk mitigation for decentralised clinical trial (DCT) elements proposed for use in the study."
ACRO (Association of Clinical Research Organizations)	1119	1119	10.1	The "Note for guidance on Coordinating Investigator signature of Clinical Study Reports" CPMP/EWP/2747/00 dated Oct 2001" includes guidance that "The co-ordinating investigator or the process of designating the signatory co-ordinating investigator should be defined in the protocol". ACRO suggest including provision for this within section 10.1 of the Protocol Template and the associated section of the Technical Specification.	Line 1119. Add "Coordinating Investigator responsibilities should be included under Investigator Responsibilities"

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