ELECTRONIC SUBMISSION CHANGE REQUEST/Q&A FORM

Title[1]	

Contact Information

Organisation Name:	
Organisation Address:	
Contact Name:	
Address:	
Telephone Number:	
E-mail Address:	

Question or Change Request

Unique Id *(from the tracking table)*	
Category	*Business/Technical*
Level of urgency	*Low/Medium/High*
Summary	*This should be a short summary of the problem submitted including rationale.*
Submit Date	*Date you submit the change request (YYYY-MM-DD)*
Item to be Changed/ Question	*Reference to the Product Name of the specification to be changed (e.g., the eCTD DTD, the written specification, the M2 eCTD style sheet)*
Version Number and Date	*Indicate the specific version and date of the Specification or standard, system, guidance, etc., for which the change is proposed.*
Description	*Provide a detailed explanation of the problem, and steps on how to recreate the error, if applicable. If this is a new requirement or enhancement, please provide the reason for the requirement or enhancement and any known solutions. If you have any sample output, sample code or other examples to help clarify the description, attach the samples to this form. You should also provide a detailed description of any testing or research that was done to support the solution(s) being proposed and any advice on backward compatibility issues.*
Recommended solution, if any	*Provide a detailed explanation of any known solutions*
Preferred Implementation Date	*Following the level of urgency, provide the preferred implementation date*
Evaluation Assessment	*To be filled in by the Evaluation Committee. Provide additional information to clarify the description of the CR given by the change requestor if applicable.*
Implementation Proposal	*To be filled in by the Implementation Committee. Provide a summary of the proposed implementation.*

Submit a completed electronic copy of this form to esub.changerequests@ema.europa.eu.

Alternatively send it by post at the following address:

European Medicines Agency
Information and Communications Technology
7 Westferry Circus, Canary Wharf - UK - London, E14 4HB

[1] Title should specify the *Product Name* the CR or Q&A refers to, e.g. eCTD EU M1, eAF, EudraCT, RDM, Eudrapharm, etc.