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Dear Professor Walley,

We would like to thank yourself and the CTU Standing Advisory Committee for your positive and helpful review of our application titled "Eudract Safety Data Input Software Tool" that was submitted to the funding call "NIHR Clinical Trials Unit Support Funding Opportunity – Supporting efficient / innovative delivery of NIHR research."

Dealing with the points raised:

potential changes to Eudract had not been considered. The importance of developing a tool which would allow future updates was acknowledged, with the ability to change data fields if required.

We have made initial contact with EMA regarding the likelihood of potential changes, and the response was a definite negative. Nonetheless, we will include within the specifications of the tool an ability to make change requests, to perform a timely review of any such requests, and to effect their subsequent implementation. This would definitely include the potential to change data fields.

the tool would need to work with different formats and applicants needed to explore systems used by units. The committee noted that a survey through the UKCRC CTU Network (rather than a Delphi) would be a good way of achieving this.

We agree that a survey directly aimed at the UKCRC CTU Network will be incorporated into the proposal, with no subsequent cycles of review and revision. The scope of formats and systems used by units around the UK will be a topic of the questions posed in this survey. Preliminary contact has been made with the administration of the UKCRC Registered CTU Network as to the practicalities of running such a survey.

The proposed revised time line is below.

October 2018	Project launch at the October 9th meeting of NIHR registered CTU statistics leads.	
	Survey 6-8 weeks	review current practice

		give guidance on the scope and detailed specifications
		obtain real-world testing data
		an overview of what data formats
		Eudract tools and processes are currently in place at other CTUs
November	Obtain Input from EMA as regards processes for change to XML schema.	
	Analyse the survey results and feedback to participants	
December	Provide a formal specification and testing requirement documentation for the software tool, including for ongoing maintenance, service support, change requests	
	Invite 2 CTUs to pilot the initial version of the software and 2 CTUs to perform the User Acceptance test. These CTUs will be selected at Stage 1 based on their involvement of the project	
January – February 2019	Implement the build and perform unit testing.	
	Develop manuals and training material	
March -April	Pilot the initial version of the tool at external CTUs, incorporating possible modifications based on feedback.	
May	Perform User Acceptance Testing and evolve manuals and training material	
June – September	Provide open-access to software and documentation	
	Provide dissemination using academic journals, conferences, workshops and online training resources	

Yours Sincerely,

Professor Ian Wilkinson
Director of CCTU