*The committee agreed the application addressed an important need and was value for money. However, it was felt that the timescales were ambitious and 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. It was agreed that 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.*

*Changes to eudract to allow future updates*

*CTU survey, not Delphi*

*What formats currently used and existing systems at other CTUs.*

Research Plan

Stage 1 (2 months)

Project launch at the October 9th meeting of NIHR registered CTU statistics leads.

1. Collaboratively undertake a survey of UKCRC registered CTUs to review current practice, give guidance on the scope and detailed specifications, and obtain real-world testing data. Questions to give an overview of what data formats, and Eudract tools and processes are currently in place at other CTUs. (6-8 weeks)

2. Obtain Input from EMA as regards processes for change to XML schema.

3. Provide a formal specification and testing requirement documentation for the software tool, including for ongoing maintenance, service support, change requests. ~~Outputs to be reviewed using a Delphi survey method to obtain consensus across the stakeholders identified.~~

We will 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.

Stage 2 (3 months)

3. Implement the build and perform unit testing.

4. Develop manuals and training material.

Workshop??

Stage 3 (2 months)

5. Pilot the initial version of the tool at external CTUs, incorporating possible modifications based on feedback.

Stage 4 (5 months)

6. Perform User Acceptance Testing and evolve manuals and training material.

7. Provide open-access to software and documentation.

8. Provide dissemination using academic journals, conferences, workshops and online training resources.

-------------- Detailed steps

Letter back to NIHR 24th Aug, 5pm….

Internal roles: PV, monitors, Coords, DM, progs, stats – explain get feedback

PPI rep?

Contact with other CTUs (2 pilots, 2 UATs)

Survey questions – initial input internally, externally.

* What data format do you use
* How do you enter it into Eudract
* Any coputer tools
* What flavour stats software (R, SAS, stata, don’t min)
* Web-based interface, downloadable package, ?
* Help system
* Hcnage request
* Github

