

# REDCap Cloud adoption and implementation toolkit

## Abstract

REDCap Cloud (RCC) is a real-world Data capture and management platform which provides a comprehensive means to collect, collate, analyse and share health research data. It is marketed as having the flexibility to cost effectively run any type of study; proof of concept, outcomes, real world evaluation, registry, early phase through to phase III and medical devices. RCC is GCP, FDA CFR 21, HIPAA and ISO/IEC 27001:2013 certified and has been in development since 2016 with over 700 open studies world-wide.

In recent years there has been increased interest from academic CTUs in the UK in these types of data capture and management applications, with many CTUs looking either to move from bespoke in-house software development to a validated product, or to switch from the current main supplier in this space. Although still relatively new, RCC is feature-rich allowing such things as mobile device data entry, medical coding, file repositories, randomisation and API integration with other systems for data import/export or reporting. Although it uses a completely different codebase, RCC is built upon the twenty year history of development of the extremely popular REDCap system created at Vanderbilt University<sup>(1)</sup>.

This project was a collaboration between the five UK academic CTU RCC users with the aim of developing a toolkit for all future users of RCC as a guide to best practice, with quarterly meetings scheduled and an expected project duration of 12 months. The toolkit was intended to cover methodologies for developing SOPs, processes, standards and libraries to support EDC (electronic data capture) systems and module validation, subsequent system and module version control and validation, protocol review, CRF development, database design, testing, release, conduct and amendments.

It was recognised at the start of the project that all UK academic CTUs were very stretched in terms of resources especially in IT and data management roles, but it was hoped that the collaborative nature of this project would deliver a robust solution for CTUs far quicker than working alone. However no one could have predicted the impact that the Covid-19 pandemic would have on capacity within the CTUs to deliver this project.

## Introduction

The UK RCC User Group was set up in Autumn 2018 as a collaborative group of academic CTUs who were either UKCRC registered or aimed to be in the next registration round. The RCC User Group had representation from the five CTUs involved with this project from staff in IT, Data Management, Statistics and Quality Assurance. The CTUs involved were Manchester, Exeter, Hull Health Trials Unit, Peninsula and Swansea. The group met quarterly with the aim of sharing knowledge, developing best practice and acting as a collective voice to wield more influence with the vendor who engaged positively with the initiative. The group was completely independent of the vendor and received no funding or direction from them.

The UK RCC User Group proposed the development of version 1 of a toolkit for the adoption and implementation of RCC. The toolkit was intended to cover methodologies for developing SOPs, processes, standards and libraries to support EDC (electronic data capture) systems and module validation, subsequent system and module version control and validation, protocol review, CRF development, database design, testing, release, conduct and amendments.

All of the academic units involved in the project were new to RCC, with the most established having held a license for only 18 months and most in their first year. Whilst some work had already been undertaken by the earliest adopters e.g. establishing some SOPs and undertaking validation of elements of the system, other units were just beginning and all faced the same tasks. The proposal was that the collaborators meet to establish the scope of work required to develop a toolkit, identify and review what had been achieved and define and deliver what needed to be done to develop version 1 of the toolkit.

## Methods

It was intended to use a collaborative feasibility approach to complete this work over a 12 month period. Quarterly face-to-face meetings were scheduled to share ideas and progress, with the intention that user group members would return to their home CTU and initiate ideas. It was anticipated that the UK RCC user group membership would expand during the 12 month period as more CTUs considered the adoption and deployment of RCC.

Some academic units were further along in implementation and had established SOPs, documentation, processes and training. Other units had just adopted the system. At the initial user group meeting it was proposed the collaborators establish the scope of work, identify what had already been achieved and what needed to be done. To reduce impact on already stretched resources, elements relevant to each unit's existing work streams were adopted and developed by the collaborating units so that, once completed, work could be homogenised where applicable and an infrastructure library for current units and potential adopters developed.

The proposed roles of each CTU were defined as shown below:

- Manchester CTU (MCTU)
  - co-ordinating centre
  - host meetings and manage funding
  - contribute towards development
  - manage subsequent infrastructure library dissemination in collaboration with UK RCC User Group approval
- Exeter CTU (ExeCTU)
  - contribute towards development
- Hull Health Trials Unit (HHTU)
  - contribute towards development
- Peninsula CTU (PenCTU)
  - contribute towards development

- Swansea Trials Unit (STU)
  - contribute towards development

The objectives of the working group, the scope of the proposed work and the expected deliverables are detailed below and acted as terms of reference for the working group:

### **Objectives**

- Simplify the procurement process for prospective EDCs
- Increase understanding of the requirements for validation for potential adopters of cloud hosted EDCs
- Improve the efficiency of procuring, implementing and validating the adoption of a cloud hosted EDC
- Ensuring the integrity of ongoing trials through maintaining the validated state of the EDC

### **Scope**

- Review regulatory and associated guidance required for cloud hosted EDCs
- Develop a procurement guidance document
- Develop a guidance document on best practice in review of validation approaches
- Develop SOPs and templates to assist CTUs in all the steps involved in procuring, implementing and validating

### **Deliverables**

- A guide to assist in the analysis of master service agreements or contracts for suitability of the product and features in meeting the requirements of an EDC
- Templates for the user requirements specification with examples and checklist
- Templates for a risk assessment
- Templates for a validation plan
- Templates for configuration management
- SOP for validation and maintaining validated state

### **Results and Conclusion**

At the first meeting of the User group the objectives, scope and deliverables were defined and agreed as described in the methods section. Unfortunately shortly after the commencement of the project the Covid -19 pandemic escalated which refocused the priorities of many CTUs and resulted in most of the CTU staff involved being unable to collaborate on the project due to other more pressing priorities.

In addition during 2020 the future of Manchester CTU was reviewed by the University of Manchester and during the process of that review many staff left the CTU resulting in Manchester CTU no longer having the capacity to host the REDCap work. Arrangements were made to transfer hosting of the study to Hull Health Trials Unit,

however as the pandemic continued and the workload on CTUs grew Hull also decided they were unable to co-ordinate the work. With other CTUs in a similar position the REDCap project has now stalled.

During recent discussions with colleagues regarding the viability of continuing with the project the following issues were raised which further illustrate why the project has stalled:

- Significant work is needed to finish the content. The project was designed to pull together work from 5 CTUs covering different areas. Swansea are no longer using RCC, Manchester CTU are closing and Plymouth are losing their RCC expert who was the contributor. As such there is really only Hull and Exeter using RCC and this would place a significant burden of content writing on two CTUs. If there was commitment from other CTUs Hull and Exeter would be happy to complete their part of the project and help with the editing but this would still be problematic if they are not using the software.
- It is unclear whether there is still a great value to the output given the reduced number of users. When the project started we were building a community of CTUs who were using the product. This is now falling away.
- There is very limited capacity to do the work. All CTUs are stretched at the moment for staff and have a number of projects that the data teams need to work on and as such CTUs would be pressed to find resource without bringing more staff in, which most do not have the financial resource to do.

## **Dissemination**

Unfortunately there have been no tangible results for this project which were appropriate to disseminate.

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## **References**

1. <https://projectredcap.org/resources/community>

## **Appendices**

None

## **Conflict of interest declaration**

None declared