

A Partnership Approach for Electronic Data Capture in Small-Scale Clinical Trials

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Abstract

The data collection process for clinical trials can be a tedious and error-prone process, and even a barrier to initiating small-scale studies. Electronic Data Capture (EDC) software can meet the need for faster and more reliable collection of data, but these informatics solutions can also be difficult to for researchers to set up. Establishing a full-featured commercial Clinical Trials Management System (CTMS) ecosystem is not realistic due to current institutional resource constraints. As an alternative solution, our Biomedical Informatics core (BMI) provided the technical expertise to pilot each EDC system in partnership with research teams and performed a qualitative evaluation using criteria we had established with prior research.¹

When we began our pilot process, we assumed that each system's EDC functionality would be the most important aspect and we produced a whitepaper focused on functionality.² However, as we worked with various study teams it became clear they were willing to work around limitations since any web-based EDC software was a step up from paper forms.

In our evaluation we found that the design of the Catalyst Web Tools³ made it difficult to use for clinical trials. OpenClinica⁴ has the most advanced functionality, for example in site management and complex CRF design, but what documentation is available is written in less user-friendly technical language. REDCap⁵ had a very clear advantage due to its ease of use extensive tutorials, and online training materials.

In early 2010, BMI decided on REDCap as the preferred EDC software to support for small-scale studies. Since then usage has steadily increased. As of August 2010 there were 98 active REDCap users and 16 production studies at the University of Washington, Seattle Children's, Fred Hutchinson Cancer Research Center, and Bastyr University, with collaborators from many other institutions.

Post-evaluation, in addition to maintaining our installation of REDCap we are concentrating on future work in two areas: partnerships with investigators to enhance the local usage of REDCap, and informatics research to solve problems in data integration and interoperability. BMI members have contributed to the

Ontology of Clinical Research.⁷ Additionally through our i2b2 Cross-Institutional Clinical Translational Research (CICTR) project we have identified use cases for moving data between REDCap and i2b2.⁸ Lastly, in keeping with our "bottom up" philosophy we are applying lightweight data integration techniques to query across REDCap and other systems, such as freezer inventory.

Acknowledgements

Funded by ITHS grants UL1 RR025014, KL2 RR025015, and TL1 RR025016, and NLM training grant T15LM007442. Additionally we wish to acknowledge our pilot partner investigators and their grants: de Boer, Ian R01HL096875, Landau, Ruth NCT00799162. Ringold, Sarah, Seattle Children's Research Institute CCTR mentored scholar. Stevens, Anne, R01 AR051545. Walson, Judd, FWA00006878. Wennberg, Richard R21HD060901.

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