Minimal EDC in Shiny

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1 Introduction

2 2/7/24 main task is to resurrect previous work.

2.1 working directories are

2.1.1 ~/prj/qblog/minimalist_edc_app/working

2.1.2 ~/sandbox/edc47

One of the essential tools for the conduct of a randomized clinical trial (or any scientific experiment involving the collection of data) is the availability of a high quality electronic data capture (EDC) system.

Numerous software systems have been developed over the past 30 plus years, both commercial and open-source, that provide a platform for scientific data capture e.g. the RedCap system Harris, Taylor, and Thielke (2009), or the Lorris system Das et al. (2011). These systems vary in design, and complexity and require different levels of professional support for development and maintenance. The system presented here is targeted at academic research groups without dedicated IT support staff, who typically require a customizable, easily managed, affordable and secure system.

The design goals for the system are as follows:

2. Allow rapid project setup (Requires minimum to no programming for setup and maintainance. i.e. able to be managed by teams without dedicated programming staff)
3. Built with open-source tools
4. Rapid project close-out and data export
5. Integrated reporting
6. Customizable validation definition (via google sheets)
7. Secure
8. Auditable
9. CFR 21 Part 11 compliant
10. ICH guidelines compliant

The open-source tools employed for this system are:

1. R
2. shiny
3. sqllite
4. rmarkdown

Also, the system makes use of the propriatary but free to use tools from google:

3. google docs
4. google sheets

   Consider each of the above design goals in turn.

   1. Secure. Any EDC system connected to the internet must be secure at the part 11 level at a minimum. This includes encryption and authentication as well as the use of secure servers.

3 Methods

4 Results

5 References

6 Appendix

Archive directories

~/sandbox/edc47

~/prj/c060/a32

~/prj/c060/a201

Das, Samir, Alex P Zijdenbos, Jonathan Harlap, Dario Vins, and Alan C Evans. 2011. "LORIS: a web-based data management system for multi-center studies." *Frontiers in Neuroinformatics* 5 (January): 37. https://doi.org/10.3389/fninf.2011.00037.

Harris, PA, R Taylor, and R Thielke. 2009. "Research electronic data capture (REDCap)—a metadata-driven methodology and workflow process for providing translational research informatics support." *Journal of Biomedical ….* http://www.sciencedirect.com/science/article/pii/S1532046408001226.