Minimal EDC in Shiny

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1 Introduction

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:

1. Allow rapid project setup (Require minimum to no programming for setup and maintainance. i.e. must be able to be managed by teams without dedicated programming staff)
2. Built with open-source tools
3. Rapid project close-out and data export
4. Integrated reporting
5. Customizable validation definition (via google sheets or similar collaboration software)
6. Allow configurable access (user role setting)
7. Authentication
8. Auditable
9. CFR 21 Part 11 compliance capable.

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.

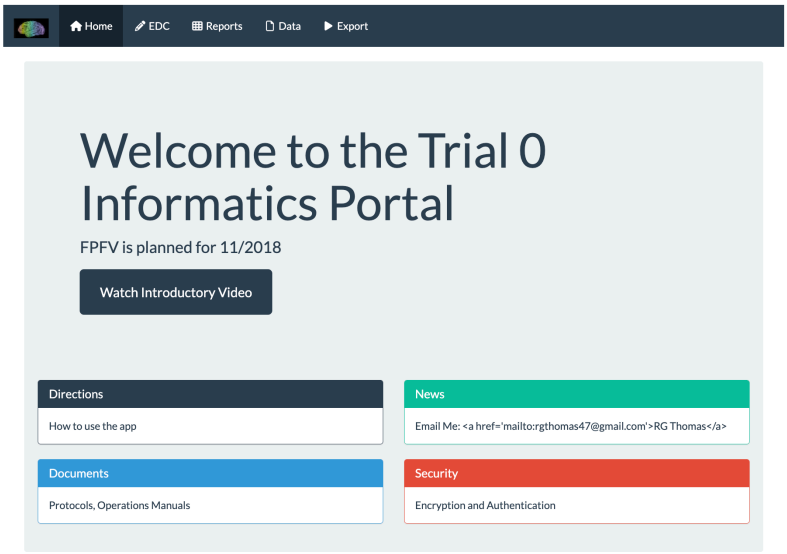
Rapid setup.

ICH guidelines compliant 1. Secure. EDC systems require flexible multilayer security. ideally at the part 11 level. This includes encryption and authentication as well as the use of secure servers.

2 Methods

Start in working directory /Users/zenn/prj/qblog/posts/minimalist_edc_app/working_from_c060_a201

Interface looks like this:



2.1 Polish the interface

Start with the online/CRC book "Outstanding shiny interfaces"
Granjon (2022)

3 Results

4 References

5 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.

Granjon, David. 2022. *Outstanding User Interfaces with Shiny*. CRC Press.

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.