# 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 capable 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 small to medium sized academic research groups that don't have dedicated IT support staff. Reserarch groups such as these typically require a customizable, easily managed, affordable and secure system.

The key 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 research 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 file access settings (user role definition)
7. Allow user authentication
8. Provide auditable logging
9. CFR 21 Part 11 compliance capable.
10. Encrypted communication

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:

4. google sheets

Consider each of the above design goals in turn.

Rapid setup.

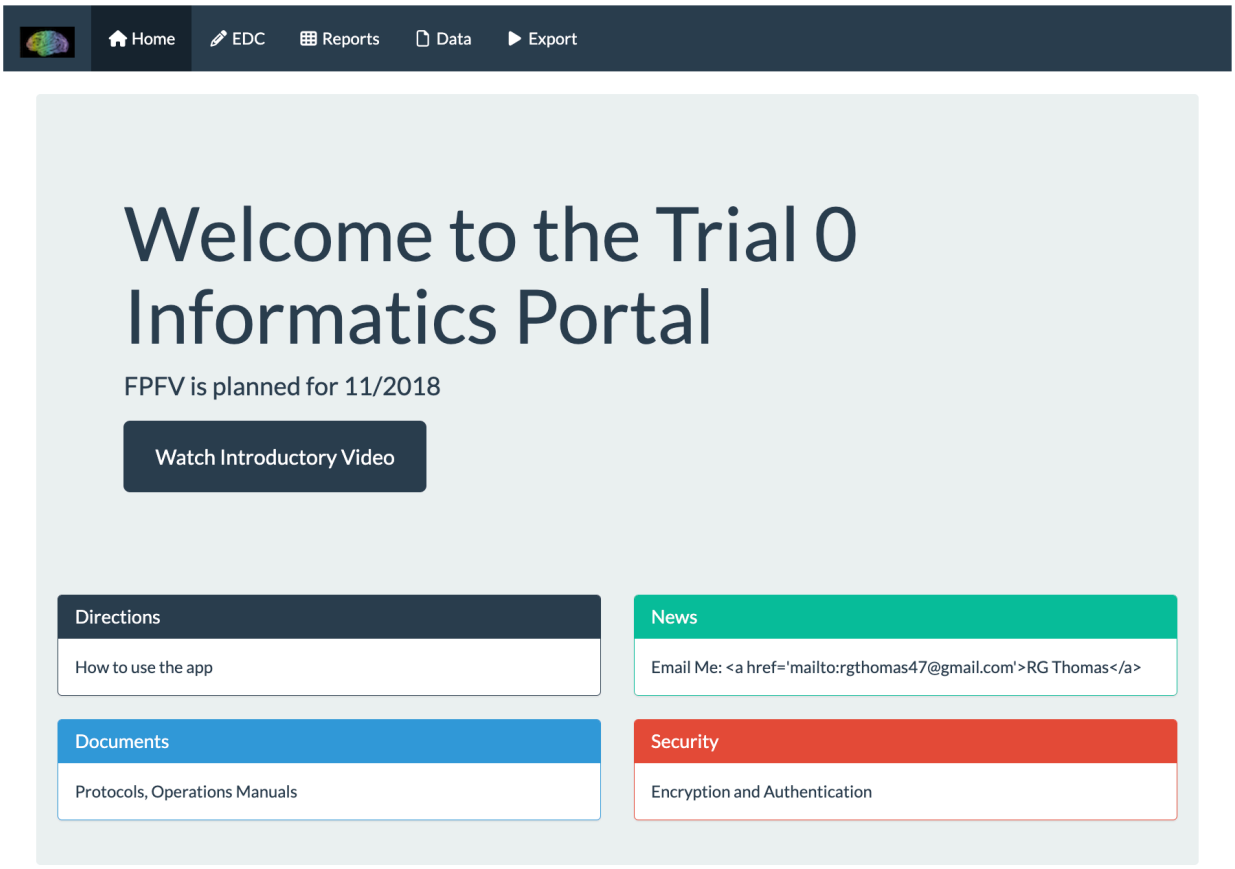
ICH guidelines compliant 1. Secure. EDC systems require flexible multilayer security. ideally at the part 11 level. This includes encryption and authentication as well as the use of secure servers.

## 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 User interfaces with Shiny" Granjon (2022)

## 3 Results

## 4 References

## 5 Appendix

Archive directories

~/sandbox/edc47

~/prj/c060/a32

~/prj/c060/a201

## 5.1 Prerequisites

In development

## 5.2 Step-by-Step Implementation

In development

## 5.3 Key Takeaways

In development

## 5.4 Further Reading

In development

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.