

Minimal EDC in Shiny

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12/14/23

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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 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 @Harris2009a, or the Lorris system @Das2011. These systems vary in design, and complexity and have differing requirements for the availability of professional support staff for development and maintenance. The system presented here is targeted at academic research groups who typically require a customizable, easily managed, secure yet affordable system.



Figure 1: purrr

This paper describes a data capture system designed and developed to meet the following requirements:

1. Secure
2. Fast project setup
3. Extensive use of open-source tools
4. Requires minimum to no programming for setup and maintainance. i.e. able to be managed by teams without dedicated programming staff
5. Fast project close-out and data export
6. Integrated reporting
7. Highly customizable validation definition
8. Auditable
9. CFR 21 Part 11 compliant
10. ICH guidelines compliant

An additional, secondary set of design goals includes

1. Quality support tools:
 1. tools for onsite monitoring
 2. tools for safety monitoring
 1. tools for AE coding
 3. tools for medication coding The open-source tools employed for this system are:
2. R
3. shiny
4. google docs
5. google sheets
6. sql-lite
7. rmarkdown

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.

2 Methods

3 Results

4 References

5 Appendix