Open Source Technology in Clinical Data Analysis

PHUSE

A significant amount of time and energy has been invested in recent years exploring the desirability (do we want it?), feasibility (can we do it?), and viability (is it worth it?) of integrating open source solutions into our clinical data pipelines which transform source data into clinical study reports and submission data packages.

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Preface

This is a Quarto book.

To learn more about Quarto books visit https://quarto.org/docs/books.

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1 OSTCDA

Open Source Technology in Clinical Data Analysis

A significant amount of time and energy has been invested in recent years exploring the desirability (do we want it?), feasibility (can we do it?), and viability (is it worth it?) of integrating open source solutions into our clinical data pipelines which transform source data into clinical study reports and submission data packages.

This repository will serve to collect and synthesize expert opinions and resources for a (hopefully) comprehensive set of questions which arise as organizations travel this journey.

The discussions will provide citable (and sometimes quotable) input from industry experts, resulting in a "state of the union"-style manuscript that will help us move past questions that have already been sufficiently addressed and focus on those that remain.

We invite you to navigate to the Discussions section section to provide your thoughts, resources, or perspectives that help address any or all of the questions. If we've overlooked a key question - start up a new discussion thread!

1.1 Purpose and Background

There are many questions around understanding and using open source for clinical data analysis. We want to create a comprehesive knowledge base about the "state of the union" and provide an overview and ideally also answers for core questions. We need and collect input from our community to compile the knowledge base, so please join the discussions to allow a broad and complete picutre.

If you like to know more, please join the R/Pharma talk "The State of Open Source Technology in Clinical Data Analysis, Reporting, and Submissions". The recording is here: 2023 R/Pharma presentation.

2 What is Open Source?

3 What is Open Source?

When someone says 'open source' - what does that mean to you?
What are the important characteristics of something that is regarded as 'open source'?

- Does the cost matter?
- Does the ability to review the code matter?
- Does the ability to reuse the code matter?
- Does the ability to modify the code matter?

3.1 Contribute

Contribute to the discussion here:
What is open source?

3.2 Guidance

- Provide your thoughts and perspectives

- Provide references to articles, webinars, presentations (citations, links)

- Be respectful in this community

3.3 Examples

Example 1: The Open Source Initiative provides a definition:

- Free distribution

- Available source code

- Derived works possible

Example 2: Merriam-Webster defines open source as "having the source code freely available for possible modification and redistribution".

4 Why Open Source?

5 What is the 'why' for using open source solutions in pharma clinical data analytics?

- What is the attraction to open source solutions?

- Why do users like open source solutions?

- Why are leaders of organizations in Data Management, Biostatistics, and Programming devoting resources toward the development, testing, and adoption of open source solutions?

5.1 Contribute

Contribute to the discussion here:
What is the 'why' for open source?

5.2 Guidance

- Provide your thoughts and perspectives

- Provide references to articles, webinars, presentations (citations, links)

- Be respectful in this community

6 Establishing Trust

7 Can an open source solution be trusted?

- How do we have confidence that an open source solution is accurate?

- What are the relevant considerations?

7.1 Contribute

Contribute to the discussion here:
Can an open source solution be trusted to be accurate?

7.2 Guidance

- Provide your thoughts and perspectives

- Provide references to articles, webinars, presentations (citations, links)

- Be respectful in this community

References