

# Data Science Workflow for Clinical Trial Data Syllabus

Document under construction  
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**Important Note:** This syllabus is subject to change

## Course Information

### Instructor Information

**Instructor:** James C Slaughter

### Course Information

**Course Description:** The course provides learners with a hands-on experience for successfully working with data collected during a randomized clinical trial. The course will teach (1) the role of the data scientist during a clinical trial, (2) steps for ensuring that high-quality data are collected during the trial, (3) how to use R and R markdown to prepare interim analysis report for a data safety monitoring board and (4) how to conduct the most common types of analyses needed for final publication in major medical journals.

**Prerequisite:** Successful learners will have some programming experience and an interest in learning best practices for working with randomized clinical trial data. While a basic introductory statistics course is helpful for maximizing the content of this course, much of the course assumes a limited statistical background.

### Instructor Responses and Discussion Forums

Learners will post any questions they have in discussion forums that will be monitored by instructors. Instructors will reply in the forums so that others can benefit from the questions and replies.

### Textbook & Course Materials

**Required Text:** None

**Recommended Texts & Other Readings:** Freely available online resources will be made available on the course page

### Course Technology Requirements

- A stable internet connection of sufficient speed to watch videos

- Installation of R and R studio

## Course Structure

This course will be delivered entirely online through Coursera.

## Student Expectations

In this course you will be expected to complete the following types of tasks.

- communicate via discussion board
- complete basic internet searches
- download and upload documents
- read documents online
- view online videos
- complete auto-graded quizzes online
- work independently on course materials

## Course Learning Outcomes

Primary learning objectives

- Understand the role of a data scientist in the clinical trial team
- Learners will be able to understand and work with the type of data commonly collected in clinical trials
- Learners can conduct interim checks to ensure actively collected data are of high quality and free from error
- Learners can create interim analysis reports suitable for presentation to data safety monitoring boards
- Learners will be able to conduct the most common type of analyses need for final publication of clinical trial endpoints
- Learners will be able to use R markdown to create reproducible analysis reports

You will meet the outcomes listed above through a combination of the following activities in this course:

- Watch online videos created by the instructor and hosted by Coursera
- Complete assignments and quizzes
- Participate in online discussions

## Topic Outline/Schedule

- **Major Topic 1: Introduction to Clinical Trials Data**

- o Course information
- o Fundamentals of clinical trial design
- o Role of the data scientist in an ongoing clinical trial
- o Randomization of treatment group and blinding
- o Databases, including Redcap databases
- **Major Topic 2: Monitoring the collection of clinical trial data**
  - o Continual evaluation of data quality and consistency
  - o Monitoring for adverse events
  - o Keeping track of subjects who dropout of the study
- **Major Topic 3: Interim reports to data safety monitoring boards**
  - o Purpose of a data safety monitoring board (DSMB)
  - o Reproducible reports using R markdown for clinical trials data
- **Major Topic 4: Analysis of primary endpoints needed for manuscript submission**
  - o Review the types of analyses expected by major medical journal for clinical trials data (e.g. JAMA)
  - o Perform descriptive analyses by randomization group
  - o Analysis of continuous outcomes by randomization group
  - o Analysis of binary outcomes by randomization group

## Evaluation Policies

Coursera courses are designed for learners to enroll at a time of their choosing and to proceed through the course at their own pace. As such, there are no specific due dates for assignments or quizzes. All quizzes will be auto graded and provide immediate feedback while taking the course.

## Course Policies

### Netiquette Guidelines

Netiquette is a set of rules for behaving properly online. Your instructor and fellow students wish to foster a safe online learning environment. All opinions and experiences, no matter how different or controversial they may be perceived, must be respected in the tolerant spirit of academic discourse. You are encouraged to comment, question, or critique an idea but you are not to attack an individual. Working as a community of learners, we can build a polite and respectful course community.

The following netiquette tips will enhance the learning experience for everyone in the course:

- Do not dominate any discussion.
- Give other students the opportunity to join in the discussion.
- Do not use offensive language. Present ideas appropriately.
- Be cautious in using Internet language. For example, do not capitalize all letters since this suggests shouting.
- Popular emoticons such as 😊 or / can be helpful to convey your tone but do not overdo or overuse them.
- Avoid using vernacular and/or slang language. This could possibly lead to misinterpretation.
- Never make fun of someone's ability to read or write.
- Share tips with other students.
- Keep an "open-mind" and be willing to express even your minority opinion. Minority opinions have to be respected.
- Think and edit before you push the "Send" button.
- Do not hesitate to ask for feedback.
- Using humor is acceptable

Adapted from:

Mintu-Wimsatt, A., Kernek, C., & Lozada, H. R. (2010). *Netiquette: Make it part of your syllabus*. *Journal of Online Learning and Teaching*, 6(1). Retrieved from [http://jolt.merlot.org/vol6no1/mintu-wimsatt\\_0310.htm](http://jolt.merlot.org/vol6no1/mintu-wimsatt_0310.htm)

Shea, V. (1994). *Netiquette*. Albion.com. Retrieved from: <http://www.albion.com/netiquette/book/>.

## **Commit to Integrity**

As a student in this course, you are expected to maintain high degrees of professionalism, commitment to active learning and participation in this class and also integrity in your behavior in and out of the classroom.