

Syllabus for CTM-5100

INTRODUCTION TO CLINICAL TRIALS RESEARCH AND DRUG DEVELOPMENT

COURSE DESCRIPTION

This course introduces students to the field of clinical research and provides an overview of the environment, Food and Drug Administration (FDA) approval processes and regulations, and various elements involved in the development and conduct of clinical trials.

COURSE OBJECTIVES

After completing this course, you should be able to:

- CO 1** Identify the history and principles of the drug development process and their application to the design and implementation of clinical research activities.
- CO 2** Identify the steps involved from discovery to market approval in the U.S.
- CO 3** Understand the role, responsibilities, and inter-relationships of regulatory agencies, sponsors, study personnel and other related groups in the clinical research process.
- CO 4** Understand the relevant ethical principles for the protection of human research subjects and the elements of informed consent.

COURSE MATERIALS

You will need the following materials to complete your coursework. Some course materials may be free, open source, or available from other providers. You can access free or open-source materials by clicking the links provided below or in the module details documents. To purchase course materials, please visit the [University's textbook supplier](#).

Required Textbook

- There is no required textbook.

Optional Texts/Reports:

- Fundamentals of Clinical Trials, 3rd Edition, Friedman, Fuberg, and DeMets C/O 1998 Springer-Verlag New York, Inc.
- Consider It Pure Joy...An Introduction to Clinical Trials, 3rd Edition, Raven, C/O 1997 Cambridge Healthcare Research LTD
- From Test Tube to Patient-Improving Health Through Human Drugs, Shalala, Henney, Woodcock, Trenter ed., US FDA Special Report
- Ethics of the Use of Human Subjects in Research, Shamoo AE, Khin-Maung-Gyi FA, C/O 2002 Garland Science Publishing London and New York

COURSE STRUCTURE

Introduction to Clinical Trials Research and Drug Development is a three-credit online graduate course, consisting of **ten** modules. Modules include an overview, topics, study materials, and assignments. Module titles are listed below.

- **Module 1: Introduction**
- **Module 2: Clinical Research Environment**
- **Module 3: Overview of the Drug Approval Processes**
- **Module 4: Understanding the Package Insert**
- **Module 5: Understanding the Protocol and its elements**
- **Module 6: Informed Consent Components and Processes**
- **Module 7: Institutional Review Boards**
- **Module 8: Clinical Trial Monitoring**
- **Module 9: Outcomes Research**
- **Module 10: Resources Used in Clinical Research**

ASSESSMENT METHODS

For your formal work in the course, you are required to participate in online discussion forums and

complete written assignments. See below for more details.

Consult the Course Calendar for assignment due dates.

Promoting Originality

One or more of your course activities may utilize a tool designed to promote original work and evaluate your submissions for plagiarism. More information about this tool is available in [this document](#).

Discussion Forums

This course requires you to participate in **nine** graded discussion forums. There is also an ungraded but required introductions forum in Module 1.

Online discussions provide an opportunity for you to interact with your classmates. During this aspect of the course, you respond to prompts that assist you in developing your ideas, you share those ideas with your classmates, and you comment on their posts. Discussion board interactions promote development of a community of learners, critical thinking, and exploratory learning.

Please participate in online discussions as you would in constructive face-to-face discussions. You are expected to post well-reasoned and thoughtful reflections for each item, making reference, as appropriate, to your readings. You are also expected to reply to your classmates' posts in a respectful, professional, and courteous manner. You may, of course, post questions asking for clarification or further elucidation on a topic.

For posting guidelines and help with discussion forums, please see the Student Handbook located within the General Information page of the course Web site.

Written Assignments

You are required to complete **seven** written assignments. The written assignments are on a variety of topics associated with the course modules.

For help regarding preparing and submitting assignments, see the Student Handbook located within the General Information page of the course Web site.

Note about research: The use of Wikipedia or other online encyclopedias for graduate-level papers is inappropriate. Aside from the uneven quality of the information that may be found in these sources, the real issue is that the information presented in these sources is "already digested." Use of such sources is an unacceptable shortcut for the graduate student. Students gathering information from these sites are essentially obtaining analyses done by someone else, not doing the work themselves. Rather than exploring the literature on a subject, such students are merely using the words of others who have

already taken this vital step in academic research. It is imperative that graduate students be able to search the more academically-oriented literature, sift through useful (and not so useful) information, analyze, synthesize, and report the results of their assignments. All of these steps are bypassed if information is cited from an online site such as Wikipedia. To sum up: Using information summarized or annotated by someone else is an unacceptable shortcut for a graduate student.

GRADING AND EVALUATION

Your grade in the course will be determined as follows:

- **Online discussions (9)**—20 percent
- **Written assignments (7)**—80 percent
 - **Written assignments 1-5 (10% each)**—50 percent
 - **Written assignments 6-7 (15% each)**—30 percent

All activities will receive a numerical grade of 0–100. You will receive a score of 0 for any work not submitted. Your final grade in the course will be a letter grade. Letter grade equivalents for numerical grades are as follows:

A	=	93–100	B	=	83–87
A–	=	90–92	C	=	73–82
B+	=	88–89	F	=	Below 73

To receive credit for the course, you must earn a letter grade of C or higher on the weighted average of all assigned course work (e.g., assignments, discussion postings, projects, etc.). Graduate students must maintain a B average overall to remain in good academic standing.

STRATEGIES FOR SUCCESS

First Steps to Success

To succeed in this course, take the following first steps:

- Read carefully the entire Syllabus, making sure that all aspects of the course are clear to you and that you have all the materials required for the course.
- Take the time to read the entire Online Student Handbook. The Handbook answers many questions about how to proceed through the course and how to get the most from your educational experience at Thomas Edison State University.
- Familiarize yourself with the learning management systems environment—how to navigate it and what the various course areas contain. If you know what to expect as you navigate the course,

you can better pace yourself and complete the work on time.

- If you are not familiar with Web-based learning be sure to review the processes for posting responses online and submitting assignments before class begins.

Study Tips

Consider the following study tips for success:

- To stay on track throughout the course, begin each week by consulting the Course Calendar. The Calendar provides an overview of the course and indicates due dates for submitting assignments, posting discussions, and scheduling and taking examinations.
- Check Announcements regularly for new course information.

COMMITMENT TO DIVERSITY, EQUITY, AND INCLUSION

Thomas Edison State University recognizes, values, and relies upon the diversity of our community. We strive to provide equitable, inclusive learning experiences that embrace our students' backgrounds, identities, experiences, abilities, and expertise.

ACCESSIBILITY AND ACCOMMODATIONS

Thomas Edison State University recognizes disability as a facet of diversity and seeks to advance access to its educational offerings. Students with disabilities may seek accommodations by contacting the Office of Student Accessibility Services via email at ada@tesu.edu or phone at (609) 984-1141, ext. 3415. Individuals who are deaf or hard of hearing may call the TTY line at (609) 341-3109.

ACADEMIC POLICIES

To ensure success in all your academic endeavors and coursework at Thomas Edison State University, familiarize yourself with all administrative and academic policies including those related to academic integrity, course late submissions, course extensions, and grading policies.

For more, see:

- [University-wide policies](#)
- [Undergraduate course policies and regulations](#)
- [Graduate academic policies](#)

- [Nursing student policies](#)
- [Academic code of conduct](#)