FAES
FOUNDATION FOR ADVANCED EDUCATION IN THE SCIENCES

MEDI 501: Principles of Preclinical Translational Science: A Case Study from Cancer Drug Discovery and Development

1 credit

Summer 2020 (Online)

Draft Syllabus

Instructors: Jessica M. Faupel-Badger, PhD, MPH and Amanda L. Vogel, PhD, MPH
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Virtual Office Hours: by appointment, please email to schedule a time

Preferred Method of Communication: email for both instructors

Course Information:

Prerequisites: None

Course Description: Translation is the scientific work of accelerating the application of observations from the laboratory, clinic and community into interventions that improve the health of individuals and the public. Translational research typically involves a team of collaborators whose expertise spans multiple levels of analysis, disciplines, and fields who work together to advance the science toward human applications.

But what approaches are needed for scientists, who are typically trained in a specialized subfield of research, to work together to accomplish this successfully? What are the varied roles of academic faculty and institutions, industry, and government agencies in advancing translation? What scientific, technical, and operational knowledge and skills are essential to the functioning of these collaborations? What administrative and legal issues must be addressed?

This course will introduce students to "Translational Science," an emerging field of research that aims to answer these questions, and provide evidence-based scientific and operational principles that can be applied to a wide variety of translational research collaborations. Students will learn key principles of translational science by way of a case study of a highly successful translational research partnership involving the National Center for Advancing Translational Sciences (NCATS) and the National Cancer Institute (NCI) of the US National Institutes of Health, Northwestern University, and the University of Kansas. It produced a promising potential drug shown to inhibit metastasis in animal models and that will be examined in a first-in-human clinical trial in 2020.

Course Website (Canvas): faes.instructure.com

This is an online course. It is expected students will access the website multiple times each week view all course lectures, access course readings and resources (i.e., short videos websites), take mini-quizzes, and post to the discussion boards. Course materials are organized in modules with one module corresponding to each week of class. Each module will open at 11:59 PM EDT on Sunday of that week.

Learning Materials:

Required and Recommended Texts: None

Required Readings and Resources: A list of course readings and resources with embedded links to PDFs, website, and videos, is supplied in the Canvas site. There is an overall Readings and Resources document for the entire course along with assigned readings/resources for specific weeks of the course.

Course Goals:

When you complete the course, you will be able to:

- Compare and contrast the definitions and goals of translational research and translational science
- Recognize there are preclinical translational science principles that can be applied across many different research projects
- Identify a range of both scientific and operational preclinical translational science principles that can be applied to one's future work
- Describe the research process and collaborations (inter-agency, and team-based) necessary to enable a scientific discovery to lead to an effective compound that can be used in humans

Structure of the Course:

The course Canvas site operates according to the US eastern time zone (Washington DC).

- The weeks in this course run **Monday – Sunday**.
- Each week's content will consist of multiple lectures, required readings, a mini-quiz, and a discussion board for posting questions for course speakers. Lectures are typically 15-20 minutes each and total 1-1.5 hours for each week.
- Weeks 3 and 6 also have an additional discussion board assignment.
- Unless otherwise indicated in the weekly announcement, min-quizzes quizzes must be submitted by 11:59 PM eastern time on Sunday (i.e., the end of the week). Discussion Board posts have multiple parts and will follow this timeline:
    - Posting due on Tuesday of the week
    - Question/comment to two other classmates due by Thursday of the week
    - Reply to question/comments received by Sunday of the week

Important Dates:

Drop deadline: June 26, 2020

Audit and withdrawal deadline: July 10, 2020

Holidays: July 4, 2020

Course Communication:

- **Weekly Canvas Announcements:** On Monday of each week, a weekly announcement will be posted in Canvas outlining all assignments and other important course information for that week. The weekly announcements are typically lengthy and detailed – please read them carefully, as they will help keep you on top of your coursework. *Additionally, if we need to make any modifications or updates to the course, such as adding or deleting an assignment or changing the due dates for an assignment, we will notify you of these changes in the weekly announcements.* In general, the weekly announcements will not be emailed, so be sure to check Canvas early each week (ideally, every Monday).

- **Other Canvas Announcements:** In addition to the weekly announcement, we will also periodically post mid-week announcements when we have important updates and reminders to share with you. It is a good habit to check the Announcements area in Canvas whenever you access the course.

- **Email:** You are strongly encouraged to contact Dr. Jessica M. Faupel-Badger (badgerje@mail.nih.gov) or Dr. Amanda L. Vogel (vogela@mail.nih.gov) with questions about the course policies, course material, and anything else.

Policies:

Academic Policies:

This course adheres to all FAES policies described in the academic catalog and student handbook, including the Academic Integrity policy listed on page 11 of the academic catalog and student handbook. Be certain that you are knowledgeable about all of the policies listed in this syllabus, in the academic catalog and student handbook, and on the FAES website. As a student in this program, you are bound by those policies.

Copyright:

All course materials are the property of FAES and are to be used for the student's individual academic purpose only. Any dissemination, copying, reproducing, modification, displaying, or transmitting of any course material for any other purpose is prohibited, will be considered misconduct, and may be cause for disciplinary action. In addition, encouraging academic dishonesty by distributing information about course materials or assignments which would give an unfair advantage to others may violate the FAES Academic Integrity policy. Course materials may not be exchanged or distributed for commercial purposes, for compensation, or for any

purpose other than use by students enrolled in the course. Distributions of course materials may be subject to disciplinary action.

Guidelines for Disability Accommodations:

FAES is committed to providing reasonable and appropriate accommodations to students with disabilities. Students with documented disabilities should contact Dr. Mindy Maris, Assistant Dean of Academic Programs.

Dropping the Course:

Students are responsible for understanding FAES policies, procedures, and deadlines regarding dropping or withdrawing from the course or switching to audit status.

Harassment:

FAES adheres to the NIH's harassment policies, which can be found at the following link:

https://hr.nih.gov/working-nih/civil/statement-workplace-harassment

Faculty and students in FAES courses are responsible for being familiar with the NIH's harassment policies and adhering to them.

Attendance and Participation Expectations:

• As this is an online course, there are no absences. You are expected to complete assignments by the specified due dates, and late work will not be accepted unless alternative arrangements are made *ahead of time*. As previously mentioned, due dates for assignments will be indicated in the weekly Canvas announcements, but if you have any confusion about when something is due, then please ask.

• Consistent, active participation will enable you to achieve the highest levels of success in this course. Although there is, in general, considerable flexibility in terms of when course materials can be viewed, when readings can be completed, and when assignments can be submitted within a given week, it is recommend that you develop the habit of logging onto the course Canvas site at multiple intervals throughout the week (at least three evenly-spaced intervals; e.g., Monday, Wednesday, and Saturday) in order to participate in the course.

• It is understood that illnesses, work or family obligations, and other unexpected issues may occur. If you have an issue that will cause you to be unable to submit an assignment on time or is impacting your ability to participate actively in the course, please notify the course instructors by email as early as possible so that we can work out alternative arrangements.

Grading:

The following assignments will determine you course grade

Mini-quizzes (7 total, 1 each week)	70% (10% for each quiz)
Self-reflection (week 3 and week 6)	30% (15% for each reflection)

Mini-quizzes (70% of course grade):

Each weekly unit includes an online, non-comprehensive quiz. The quizzes are designed to sample your learning gains – not to exhaustively assess every principle from the course material (which you will do more thoroughly in the discussion board-based assignments and in your projects). The quizzes are meant to be formative learning experiences – that is, to enable you to learn from the experience of taking the quizzes as opposed to simply providing a measure of your understanding at a single point in time. Therefore, you may use any resources – *except for other people* – on the quizzes. Additionally, you have two attempts to take each quiz, and your highest scoring attempt will be recorded. The kinds of question formats that you will encounter on the quizzes may include multiple-choice, true/false, and matching. Mini-quizzes will open on Wednesday of each week and you will have until Sunday (the end of the module/week) to complete them.

Self-reflection (30% of course grade):

There will be two self-reflections completed in the Discussion Board Posts in week 3 and week 6. Prompts for these posts will be available closer to the week they are due. This post will have multiple parts. You will post your own reflection. You will then post a comment or question to two other members of the class and reply to the comments and questions you receive. Posts are expected to be brief (~250 words or less) and will follow the schedule below:

- Posting due on Tuesday of the week
- Question/comment to two other classmates due by Thursday of the week
- Reply to question/comments received by Sunday of the week

Grading Scale:

A+	97-100
A	94-96
A-	90-93
B+	87-89
B	84-86
B-	80-83
C	70-79
D	69-60
F	59 and below

Weekly Schedule:

Reading assignments, discussion board-based assignments, and other assignments will be posted in the course Canvas site.

Week	**Dates and Activities**	**Topics***
1	June 15-21, 2020 Mini-quiz due by June 21	Overview of the Course, Translational Science, and Initiation of this Project
2	June 22-28, 2020 Mini-quiz due by June 28	Optimizing Efficiency and Effectiveness in Translational Research: Infrastructure, Teams and Partnerships, and Scientific Approaches

Week	Dates and Activities	Topics*
3	June 29-July 5, 2020 Q&A with speakers 1-2pm on July 2 Holidays: July 3-4, 2020. No assignments are due on these dates. Self-reflection #1 Mini-quiz due by July 5	Medicinal Chemistry to Advance Preclinical Translational Research
4	July 6-12, 2020 Mini-quiz due by July 12	Partnering for Success: Cross-agency Research Alliances and Interdisciplinary Science Teams
5	July 13-19, 2020 Mini-quiz due by July 19	Advancing Along the Translational Spectrum: Predictive Models in Drug Development; Pharmacology and Toxicology Testing in the Preclinical Research Project
6	July 20-26, 2020 (Q&A with speakers TBD) Self-reflection #2 Mini-quiz due by July 26	Target Identification
7	July 27-August 2, 2020 Mini-quiz due by August 2	Regulated Clinical Trials and Course Wrap-Up

***Please see the brief syllabus with topics for each lecture and speaker bios under the syllabus section on the Canvas site.**