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**Course Syllabus**

**CTS 0150 Real World Evidence**

**Fall 2021**

**Course Director/s:**

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**Discussion Board Facilitator:**

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**Course Information:**

Credit/s: To be determined by the Registrar based on class contact hours: 15 contact hours

Grading Option (select: A-F or S/U): A-F

Required or Elective: Required

**Course Contact Hours, Meeting Schedule, and Location:**

Classes will take place primarily as weekly asynchronous lectures with weekly discussion board participation on Canvas. Lectures will be released each week, and may be viewed at any time during that week. There will be 3-4 synchronous, remote case presentations throughout the course. At the end of the course, there will be an in-person event for final student presentations and socializing with faculty and students.

**Brief Course Description:**

This course serves as an introduction to topics in the use of real world evidence (RWE) to inform healthcare decision making. While randomized controlled trials remain the gold standard for establishing treatment efficacy, RWE offers many advantages including the availability of timely data at reasonable cost, large sample sizes that enable analysis of subgroups and rare outcomes, and increased generalizability to real-world clinical practice and more representative patients. Enthusiasm for RWE is tempered by concerns including those related to misclassification or data quality, the lack of randomization and other biases, and spurious data-driven findings. This course will introduce the foundational study designs and analytic approaches that are integral to the valid and efficient analysis of RWE, including those relevant to “big data.” RWE frameworks and approaches to be discussed will include limiting bias in observational big data, harnessing RWE for predictive analytics, identification of heterogeneity of treatment effects, pragmatic trial designs and the role of RWE for various stakeholders, including regulators. The potential role of RWE for the regulatory approval of novel therapies will also be discussed. Topics will be illustrated through the use of contemporary case studies representing both the promise and limitations of using RWE to inform healthcare decision making.

**Learning Objectives:**

At the conclusion of the course students should be able to:

1. Consider how to address a healthcare problem using RWE approaches
2. Interpret RWE studies to identify strengths, limitations and clinical significance
3. Anticipate the problems and biases that can invalidate RWE studies, and identify possible remedies
4. Appreciate the role of RWE for various stakeholders including patients, healthcare professionals, policy-makers, regulators and those working in the life sciences

**Course Texts and Materials:**

Course material, including lecture videos, lecture slides, discussion boards, assignments, and additional readings, will be posted on the course website (Canvas).

**Assignments and Grading:**

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| --- | --- |
| **Assignments** | **Grading Weight** |
| Discussion board participation | 50% |
| Final project/presentation | 50% |
| Total: | 100% |

Discussion board: The Discussion board is an important venue for interaction between students and faculty. Students will contribute using the “Discussions” feature of the course website (Canvas) each week. Students are expected to submit their own post by 5pm each Sunday. Students are then expected to respond to at least one post from another student by 5pm the following Sunday. There will be a total of 7 Discussion boards throughout the course, so each student will complete 14 posts (7 of their own posts, 7 responses to other students’ posts). Most Discussion boards will include prompts from the instructor about a specific topic or reading. Student comments on the Discussion board will be evaluated in terms of quality and not just length.

Throughout the semester, there will also be an ongoing “question & answer” Discussion for any questions related to the course. Although not mandatory, students are encouraged to post questions there and review other students’ questions.

Final project/presentation: The final project will be a 15-minte presentation at the end of the course. Students will work in pairs with another student from the class; they should form pairs early during the course. For the final presentation, students will propose a comparative effectiveness research project using RWE on a topic of their choosing. Students should use the ISPE/ISPOR template to guide their presentation. The presentation should include clearly stated objectives, significance of the project, study design used, a brief analytic plan, and a discussion of the strengths and limitations of the proposed study, with a particular focus on the opportunities and caveats introduced by the use of RWE.

At the mid-point of the course, student pairs will have the option to meet with the course faculty for 30 minutes to discuss their proposal.

**Expectations:**

* View the lecture videos
* Read the assigned articles
* Write a weekly discussion board post and reply to another student’s post
* Attend and participate in “live” remote case presentations (or view recordings afterwards)
* Work with a partner to give a 15-minute final presentation

**Penalties for late or incomplete assignments:**

Credit will not be given for late assignments without prior permission from the instructor.

**Remediation Policy:**

Remediation is generally not offered. Reach out to the instructors if you think you are at risk of failing the course*.*

**Course and Assignment Schedule:**

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| --- | --- | --- | --- |
| **Week**  | **Topic or class title** | **Assignments & activities** | **Lecturer(s)** |
| 1 (10/25) | -Introduction-Real World Data and Real World Evidence | -Discussion board post-Primary reading: Duke-Margolis 2018 -Suppl reading: Madigan 2013  | D KentW Crown |
| 2 (11/1) | - RWE & Study Designs: Pragmatic vs. Explanatory Trials- RWE & Study Designs: RCTs vs. Observational Studies | -Discussion board post-Primary reading: Thorpe 2009 | D Kent |
|  | Case Presentation on ISPE/ISPOR template (Shirley Wang, 7-8:15p ET on Tues 11/2) |  |  |
| 3 (11/8) | -Emulating Trials: Time related biases-Emulating Trials: Statistical Methods for Causal Inference with Observational Data | -Discussion board post-Primary reading: Franklin 2021-Suppl reading: Petersen 2014  | W Crown |
|  | Case Presentation on RWE & Regulatory Approval (Marc Berger, 7-8:15p ET on Tues 11/9) | -Primary reading: FDA 2021 Guidance -Suppl reading: Duke-Margolis 2017-Suppl reading: FDA 2018 Framework |  |
| 4 (11/15) | -Propensity Score Methods -Instrumental Variables | -Discussion board post-Primary reading: D’Agostino 1998 -Suppl reading: Desai 2019 -Suppl reading: Greenland 2000  | W Crown |
| 5 (11/22) | -Differences in Differences and Regression Discontinuity Models | -Discussion board post | W Crown |
|  | Case Presentation (Rozalina McCoy, 7-8:15p ET on Tues 11/23) |  |  |
| 6 (11/29) | -Introduction to Predictive Modeling | -Discussion board post-Primary reading: Steyerberg 2014 | D Kent |
| 7 (12/6) | -Predictive Modeling II (logistic regression & model performance) | -Discussion board post-Primary reading: Steyerberg 2010-Suppl reading: Collins/TRIPOD 2014 and Wolff/PROBAST 2019-Suppl reading: Kent 2018  | D Kent |
| 8 (12/13) | Final presentation |  |  |

*This schedule is subject to modifications at the discretion of the course director.*

**Important University Policies:**

* ***Sexual Misconduct Policy:*** Tufts is committed to providing an education and work environment that is free from sexual misconduct. If you or someone you know has been harassed or assaulted, please contact Dan Volchok, the GSBS Sexual Misconduct Reporting Liaison, at 6-6767 or daniel.volchok@tufts.edu. He can help you find appropriate resources and discuss your options. Anonymous reporting is available through the Tufts anonymous Incident Report Form: (<https://tuftsuniversity.ethicspointvp.com/custom/tuftsuniversity/oeo/form_data.asp>). Students may also obtain free confidential counseling through Talk One2One at 1-800-756-3124. Campus police may be contacted at 6-6911.
* ***Americans with Disabilities Act Policy:*** Tufts University is committed to providing reasonable accommodations for qualified individuals with disabilities. If you are interested in seeking accommodations in courses or in a laboratory setting, please contact Dan Volchok, the GSBS Disability Officer, at 6-6767 or at daniel.volchok@tufts.edu.
* ***Tufts Information Stewardship Policy*** outlines the actions all members of the Tufts community are expected to follow when working with institutional data and systems (<https://it.tufts.edu/ispol>).
* ***Academic Conduct:*** All students are responsible for compliance with all academic standards and policies, including plagiarism and academic integrity, as outlined in the Graduate School of Biomedical Sciences Student Handbook (<https://gsbs.tufts.edu/studentLife/StudentHandbook>).