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**Course Syllabus**

**CTS 015 Real World Evidence**

**Spring 2024**

**Course Director/s:**

Name: David Kent, MD, MS

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Name: William Crown, PhD
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**Discussion Board Facilitator:**

Name: Angie Rodday, PhD, MS

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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:**

This is an entirely remote class that will primarily take place as weekly asynchronous lectures with weekly discussion board participation on Canvas. Lectures will be released Monday morning of each week, and may be viewed at any time during that week. There will be 2-3 guest speakers throughout the course; these will primarily be synchronous with recordings available for students unable to attend synchronously. At the end of the course, student pairs will give synchronous final presentations.

**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:**

Grades will be based on how well you perform compared to the stated course learning objectives through the assessments listed below.

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

Discussion board participation: 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 11:59pm each Sunday. Students are then expected to respond to at least one post from another student by 11:59pm 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 will receive a template to guide their presentation, which will be based on HARPER/ISPE/ISPOR. 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 15-30 minutes to discuss their final project proposal. More details about the assignment will be posted on Canvas.

Guest Speakers: There will be guest speakers throughout the course. The speakers are experts in the field of RWE and will present on relevant topics. These will primarily be synchronous with recordings available for students unable to attend synchronously. These sessions are not mandatory, but students are encouraged to attend and engage in discussion with the guest speakers.

**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” synchronous guest lecture 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 (3/4) | -Introduction -Real World Data and Real World Evidence  | -Discussion board post-Primary reading: Duke-Margolis 2018 -Suppl reading: Madigan 2013  | D KentW Crown |
|  | Pre-recorded guest speaker: Tools to Increase Transparency, Reproducibility, and Validity of RWE Studies | -Suppl reading: Wang 2022 | Shirley Wang, PhD |
| 2 (3/11) | - RWE & Study Designs: Pragmatic vs. Explanatory Trials - RWE & Study Designs: RCTs vs. Observational Studies  | -Discussion board post-Primary reading: Thorpe 2009 | D Kent |
| 3 (3/18) | -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 |
| 4 (3/25) | -Propensity Score Methods -Instrumental Variables | -Discussion board post-Primary reading: D’Agostino 1998 -Suppl reading: Desai 2019 -Suppl reading: Greenland 2000  | W Crown |
| 5 (4/1) | -Differences in Differences and Regression Discontinuity Models | -Discussion board post-Primary reading: Cowger 2022-Suppl reading: Jacob 2012, Schuler 2016.  | W Crown |
| 6 (4/8) | -Introduction to Predictive Modeling  | -Discussion board post-Primary reading: Steyerberg 2014-Suppl reading: Collins/TRIPOD 2014 | D Kent |
| 7 (4/15) | -Heterogeneous Treatment Effects-RWE & Machine Learning | -Discussion board post-Primary reading: Kent 2018, Obermeyer 2016  | D KentW Crown |
| 8 (4/22) | Final presentation |  |  |

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

**UNIVERSITY AND GSBS POLICY**

**Diversity, Equity, and Inclusion for all Tufts Community Members:**

It is our commitment that students from all diverse backgrounds and perspectives be well served by this course, that students’ learning needs be addressed, and that the diversity that students bring to this class be viewed as a resource, strength and benefit. It is our intent to present materials and activities that are respectful of diversity in all forms, including but not limited to: gender, sex, sexual orientation, disability, age, socioeconomic status, national origin, ethnicity, race, color, religion, culture, and the intersectionality of identities. Please let us know ways to improve the course for you personally or for other students or student groups. Please see the Tufts University [Non-Discrimination Policy](https://oeo.tufts.edu/wp-content/uploads/NonDiscriminationPolicy_September-2022.pdf) for more information.

**Requesting Reasonable Religious or Disability-related Accommodations at Tufts University**

Both university policy and Massachusetts law provides that students unable to attend classes, participate in required course or lab activities, or take a scheduled examination because of religious observance will be provided with reasonable opportunity to make up the course work without adverse effects. The University’s Disability and Religious Reasonable Accommodations Policy and other policies are available at <https://oeo.tufts.edu/policies-procedures/accommodation-policies/>. Students requiring an accommodation should contact the course director prior to the requested dates to work out suitable accommodations.

Tufts University is also 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 Michael T. Chin: michael.chin614279@tufts.edu at GSBS. You can also request a reasonable accommodation for either a disability-related or a religious reason at <https://oeo.tufts.edu/accommodations/>.

**Decolonization**

The course director and lecturers acknowledge the damage done to BIPOC communities by generations of systemic racism within academia. The director also acknowledges that this is a particularly difficult time to be students, and that the political, medical, economic, and personal stresses that have been amplified in the past few years disproportionately affect already marginalized students. This course enthusiastically supports the University’s stated anti-racist goal (<https://gsbs.tufts.edu/about/diversity-equity-and-inclusion>) and in pursuit of this, will abide by the following policies.

1. The director and lecturers will seek and use course resources that are inclusive of race, socio-economic standing, gender, sexuality, disability, immigration status, English language learning status, and first-generation status.
2. Microaggressions, along with any other racist remarks, actions or behaviors will not be tolerated.
3. Students experiencing challenges are encouraged to reach out to Michael T. Chin: [michael.chin614279@tufts.edu](file:///%5C%5Ctitan.tufts.ad.tufts.edu%5Ctusm_sackler%24%5CCurriculum%5CSyllabi%5CCurrent%20Templates%5Cmichael.chin614279%40tufts.edu%20) or to whom they feel comfortable talking to at GSBS to discuss solutions. Students who want to file a formal complaint can do so with the [Tufts Office of Equal Opportunity](https://oeo.tufts.edu/) or through the online portal at [Tufts-OEO.ethicspoint.com](http://tufts-oeo.ethicspoint.com/).

Students are encouraged to reach out to the course director with any suggestions for adjustments or further course guidelines.

**Course Expectations**

In addition to the course specific late work and remediation policies detailed above, students, course director and lecturers acknowledge the following:

1. The director accepts responsibility to notify students early if expectations regarding learning, attendance or participation are not being met.
2. The course director will make themselves available by multiple avenues of communication and if needed, will work with students to find mutually convenient times to meet.
3. Opportunities may be available, upon request, to retake missed or late work. If a student falls behind, the director may provide opportunities for that student to catch up. If a student is struggling to understand the material, the course director will work with the student on strategies to better understand the material.
4. Mistakes are expected and respected, and the director will make conscious efforts to prevent them from biasing their opinion of students. The director acknowledges that graduate level biological science material is difficult, and the best way to learn it is by engaging at the limits of your knowledge. If done well, this inevitably will lead to mistakes being made.

**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 the [Office of Equal Opportunity](https://oeo.tufts.edu/) who can help you find appropriate resources and discuss your options before you decide if you want to formally file. Anonymous reporting is available through the third party online reporting tool called [Ethicspoint](http://tufts-oeo.ethicspoint.com/) which also has an option to report anonymously. Students may also obtain free confidential counseling through Talk One2One at 1-800-756-3124. Campus police may be contacted at 6-6911 in an emergency.
* ***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/student-life/student-handbook-0>).
* ***Disclosing Conflicts of Interest***: The course director and lecturers, including guest lecturers, are expected to disclose any significant financial interests or conflicts of interest that might undermine, appear to undermine, or have the potential to undermine the objectivity of their lecture content and assigned reading materials.

Revised December 2023