Introduction to Translational Research (IGP 8002-17)
Time: 10:00 to 10:50 am
March 6th-April 27th
Course directors
Mark de Caestecker: Mark.de.caestecker@vanderbilt.edu
Chris Wilson: Christopher.s.wilson.2@vanderbilt.edu
Teaching Assistants
Bryce Thomas: Bryce.a.thomas@vanderbilt.edu
Olivia Kelly: Olivia.kelly@vanderbilt.edu
Teams
Mark/Bryce
Chris/Olivia

Day	Date	Topic	Speaker	location
Friday	March 6	#1 Course Introduction	Mark/Chris	LH 415
Monday	March 9	#1 Overview	Mark	LH 415
Friday	March 13	#1 Discussion: Translation research discussion	Mark/Chris	2 rooms – LH 415
Monday	March 16	#4 Using electronic health records linked to DNA biobanks in research	Megan Shuey	LH 415
Friday	March 20	#2 FDA Committee	Matt Luther/Julia Lewis	LH 415
Monday	March 23	#2 Discussion: Journal presentation-Preclinical drug development (COVID vaccine)	Mark/Chris	2 rooms – LH 415
Friday	March 27	#2 Tech Transfer	Alan Bentley	LH 415
Monday	March 30	#3 Human Clinical Trials	Colleen Lawrence	LH 415
Friday	April 3	#2 Drug Discovery Process	Colleen Niswender	LH 415
Monday	April 6	#4 Discussion: Journal Presentation-Informatics in clinical trials	Mark/Chris	2 rooms – LH 415
Friday	April 10	#3 Drug Development & Regulation	Matt Luther	LH 415
Monday	April 13	#3 Data Safety Monitoring Boards for Clinical Trials	Mona Mashayekhi	LH 415
Friday	April 17	#5 IRB & Ethical Considerations in Human Subject's Research	Todd Rice	LH 415
Monday	April 20	#3 Discussion: Journal presentation-Clinical Trial Design (GLP1 agonist)	Mark/Chris	2 rooms – LH 415
Friday	April 24	#5 Discussion: Ethics discussion	Mark/Chris	2 rooms – LH 407
Monday	April 27	#3 Cancer Drug Development & Regulation	Vicki Keedy	LH 415

Classes will be in person unless something unexpected arises and the class needs to be held remotely. In that event, the course directors will notify the class by email before 8am that morning. For remote classes, you will receive a zoom link via email.

Grading

1) Discussion group reports (50%)
2) Journal Presentation (20%)
3) Class Participation (30%)

Discussion group reports: Three classes will be dedicated to student-led journal article discussions. All students not presenting a paper will be expected to ask thoughtful, insightful questions in class and submit a report on the journal article before the start of class. For the discussion groups without formal journal presentations, you will read relevant literature and write a brief report, as outlined below.

Absences:
Students may have no more than **one unexcused absence**. To receive an excused absence, please email the instructors in advance of the session. Excused absences do not apply to scheduled experiments.

1. **Journal article presentations (March 23rd, April 6th, and April 20th):** For each journal article discussion, a number of pre-assigned students from each group will work together to present a summary of the paper (no more than 30 minutes) to the rest of the class. Group presentation assignments are under each paper citation below. Each presenter will participate equally in preparing and presenting the paper. Presenters should be prepared to pose questions to and answer questions from the audience. *Each presenter will be graded for their presentation and the rest of the class will be graded for their participation during discussion of the paper.* The presenters are expected to read around the paper-reviews/follow up for background and context, and be sure to check out any supplemental data they may have published

Journal Articles:

- **3/23/2026: Pre-clinical drug development.** Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates. Corbett KS et.al. N Engl J Med. 2020 Oct 15;383(16):1544-1555. doi: 10.1056/NEJMoa2024671. Epub 2020 Jul 28. PMID: 32722908 (be sure to look at supplemental data for this presentation)

    - **Presenters:**
        - **Chris/Olivia group:** Huang/Maitland
        - **Mark/Bryce group:** Ayres/Cervantes

- **4/6/2026: Informatics in target discovery.** Multiomics Mendelian Randomization Study Investigating the Impact of PCSK9 and HMGCR Inhibition on Type 2 Diabetes across Five Populations. 2025; 74(1): 120–130. https://doi.org/10.2337/db24-0451

- **Additional reading:**

- Using Mendelian Randomization to Improve the Design of Randomized Trials. Ference B. et al. Cold Spring Harb Perspective in Med 2021;11:a040980. doi: 10.1101/cshperspect.a040980

- **Presenters:**
  - **Chris/Olivia group:** Martin/Sela
  - **Mark/Bryce group:** Chen/Cramer/Fuentes

- **4/20/2026: Clinical Trial Design for a GLP1 agonist.** Cardiovascular and Renal Outcomes with Efpeglenatide in Type 2 Diabetes. Gerstein H. et al. N Engl J Med 2021;385:896-907. DOI: 10.1056/NEJMoa2108269

  - **Presenters:**
    - **Chris/Olivia group**: Xue/Yin
    - **Mark/Bryce group:** Goswami/Hill

2. **Other discussion groups (March 13th, and April 24th).** These sessions will be moderated discussions covering general issues and/or ethical issues with examples. It is important that you prepare for these by reading the assigned literature in advance and by writing your reports. You will be expected to participate in the discussions with thoughtful questions / comments, and the session moderators will try to encourage everyone to participate as best we can. *Each of you will be graded for your participation during discussion of the paper.*

   - **3/13/2026 (Mark/Bryce and Chris/Olivia groups separate)**
     - Hobin JA, Galbraith RA. FASEB J. 2012 Jun; 26(6):2227-30.
     - Begley CG, Ellis LM. Nature 2012, 29th March; 483: 531-533
     - Restifo LL, Phelan GR. Dis Model Mech. 2011 July; 4(4): 423-426
   - **4/24/2026 (Mark/Bryce and Chris/Olivia groups separate)**
     - Emanuel E, Abdoler E, Stunkel L. Bethesda, MD: Clinical Center Department of Bioethics, National Institutes of Health

3. **Journal article and discussion group reports: Two distinct kinds of reports must be generated at five of the classes:**

   a. Journal article reports **(March 23rd, April 6th, and April 20th):** Students will write a brief report (~1-page report) and post it on Brightspace before the beginning of class. The student speakers for the week will be excused from writing a report. Each paper summary should contain four labeled sections: a) a brief summary; b) comments about the single most important piece of data (figure or table); c) major criticisms; d) ideas generated by reading the paper and how the findings impact human health and disease. ***Make sure that you use 11-point font and spell check and grammar check.***

   b. Discussion group reports **(March 13th, and April 24th)**. For both sessions you will be expected to read relevant literature that will be used as part of the discussion. You will need to write a one-page report (different from the journal reports) and post it on Brightspace before the beginning of class. These reports should each be divided into two labeled sections: a) an outline of key elements of the article and b) ideas that the articles provoke with you for discussion (this part is the most important).

4. **<u>AI Use:</u> If students use any AI tools in generating assignments (including presentations), they are required to: (1) cite all text that the AI generated (even if you edited it) with a bibliography / footnote entry that includes the name and version of the AI tool that you used, (2) the date and time it was used, and (3) include the exact query or prompt that you used to get the results. Any failure to properly cite AI usage is a violation of the Vanderbilt University Honor Code and will be referred to the Honor Council.**

   Journal and discussion reports together represent 50% of your grade. However, if you do not email either the journal club or discussion group reports before the beginning of class <u>and</u> have not emailed or spoken to Mark, Chris, Oliva, & Bryce you will be given zero for these assignments.