

Introduction to Clinical and Translational Research - From Bench to Bedside

Time: 9:00-9:50 am

Course director: Mark de Caestecker Mark.de.caestecker@vanderbilt.edu

Co-director: Abigail Brown Abigail.brown@vanderbilt.edu

Teaching Assistants: Jennifer Battle and Payam Fathi

Syllabus:

<u>Day</u>	<u>Date</u>	<u>Topic</u>	<u>Speaker</u>
Friday	20-Mar	Course Introduction	Brown & deCaestecker
Monday	23-Mar	Overview of Translational & Clinical Research	deCaestecker
Wednesday	25-Mar	Human Clinical Trials	Loretta Byrne & Colleen Lawrence
Friday	27-Mar	Discussion: Clinical & Translational Research	Mark & Abby
Monday	30-Mar	Cancer Drug Development & Regulation	Vicki Keedy
Wednesday	1-Apr	Drug Development & Regulation	Matt Luther
Friday	3-Apr	FDA committee	Jamie Dwyer
Monday	6-Apr	Discussion - heart failure paper	Mark & Abby
Wednesday	8-Apr	Drug discovery process	Dan Foster
Friday	10-Apr	Discussion - AD paper	Mark & Abby
Monday	13-Apr	Biorepositories, Electronic Medical Records, & Use of Human Samples in Research	Robert Carroll
Wednesday	15-Apr	Data Safety Monitoring Boards for Clinical Trials	Harvey Murff
Friday	17-Apr	Discussion - informatics paper	Mark & Abby
Monday	20-Apr	IRB & Ethical considerations in human subjects research	Todd Rice
Wednesday	22-Apr	Discussion: Ethics of Human Subjects Research	Mark & Abby
Friday	24-Apr	no class	

To attend the course via zoom, consult the schedule above and click on the appropriate link below:

- **Lectures** (dates with white background): <https://vanderbilt.zoom.us/j/607961135>
- **Discussions** (dates with gray background):
Abby's group: <https://vanderbilt.zoom.us/j/342705619>
Mark's group: <https://vanderbilt.zoom.us/j/285831402>

Discussion groups and reports: Five of the classes will be dedicated to the student-led journal article discussions. Students presenting the paper should be prepared to ask questions of and answer questions from the audience. All students will receive a grade for their journal article presentation. All students not presenting a paper will be expected to ask thoughtful, insightful questions and email a report on the journal article before the start of class which will be graded according to the criteria outlined below. For the discussion groups without formal journal presentations, you will also be given some preparatory literature to read and will need to write a brief report, as outlined below.

1. **Journal article presentations (dates: April 6, 10, 17):** The class will be divided into two groups (Group A with de Caestecker; Group B with Brown). For each journal article discussion, 3-4 students from each group will work together to prepare one of the papers for presentation to the rest of the class (see group presentation assignments under each paper citation below). Each student will participate in preparing and presenting the paper. The presentation should last no more than 30 minutes. Each student will be given a grade and personal feedback by the organizers at the end of their presentation. Mark and Abby will help moderate each of the groups and make sure there is even discussion involving all of the students. *Each of you will be graded for your participation during discussion of the paper. Along with the other discussion groups (see below), this will represent 40% of your grade based on your involvement in the discussion, understanding of and insights into the paper.*

Journal Articles:

- **Date April 6:** [Combination of isosorbide dinitrate and hydralazine in blacks with heart failure.](#) Taylor AL, Ziesche S, Yancy C, Carson P, D'Agostino R Jr, Ferdinand K, Taylor M, Adams K, Sabolinski M, Worcel M, Cohn JN. African-American Heart Failure Trial Investigators. N Engl J Med. 2004 Nov 11; 351(20):2049-57.
 - **Presenters:**
 - **Group A:** Contreras Panta, Favret, Glass
 - **Group B:** Collins, Evans, Gil
- **Date April 10:** [Reduced efficacy of anti-A \$\beta\$ immunotherapy in a mouse model of amyloid deposition and vascular cognitive impairment comorbidity.](#) Weekman EM, Sudduth TL, Caverly CN, Kopper TJ, Phillips OW, Powell DK, Wilcock DM. The Journal of Neuroscience. 2016 Sept 21; 36(38):9896-9907.
 - **Presenters:**
 - **Group A:** Guevara, Kim, McNamara, Riedmann
 - **Group B:** Graves, Hargrove-Wiley, McClanahan, Nation
- **Date April 17:** [Genome- and phenome-wide analyses of cardiac conduction identifies markers of arrhythmia risk.](#) Ritchie MD, Denny JC, Zuvich RL, Crawford DC, Schildcrout JS, Bastarache L, Ramirez AH, Mosley JD, Pulley JM, Basford MA, Bradford Y, Rasmussen LV, Pathak J, Chute CG, Kullo IJ, McCarty CA, Chisholm RL, Kho AN, Carlson CS, Larson EB, Jarvik GP, Sotoodehnia N; Cohorts for Heart and Aging Research in Genomic Epidemiology (CHARGE) QRS Group, Manolio TA, Li R, Masys DR, Haines JL, Roden DM. Circulation. 2013 Apr 2;127(13):1377-85.
 - **Presenters:**
 - **Group A:** Stanley, Taylor, Zhang

- **Group B:** Sensoy, Stark, Thomas

2. **Other discussion groups (date(s) March 27, April 22):** These sessions will not have presenters, but will be moderated discussions covering general issues (March 27), and ethical issues with examples (April 22). It is important that you prepare for these by reading the literature we will give you in advance and by writing your reports. You will be expected to participate in the discussions with thoughtful questions / comments, and Abby and Mark will try to encourage everyone to participate as best we can. As per above, *each of you will be graded for your participation during discussion of the paper. Along with the other journal discussion groups (see above), this will represent 40% of your grade based on your involvement in the discussion, understanding of and insights into the paper.*

- **Date March 27:**

- [Engaging basic scientists in translational research.](#) Hobin JA, Galbraith RA. FASEB J. 2012 Jun; 26(6):2227-30.
- Raising standards for pre-clinical cancer research. Begley CG, Ellis LM. Nature 2012, 29th March; 483: 531-533
- [The cultural divide: exploring communication barriers between scientists and clinicians.](#) Restifo LL, Phelan GR. Dis Model Mech. 2011 July; 4(4): 423-426.

- **Date April 22:**

- Emanuel E, Abdoler E, Stunkel L. (n.d.) [Research Ethics: How to Treat People who Participate in Research.](#) [brochure] Bethesda, MD: Clinical Center Department of Bioethics, National Institutes of Health.

3. **Journal article and discussion group reports:** Two different kinds of reports have to be generated at five of the classes:

a. **Journal article reports (April 6, 10, 17).** Students will write a brief report (~1-page report) on the journal article and email it to your discussion group leader before the beginning of class. The student speakers for the week will be excused from writing a report. Each paper summary should contain: 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 use spell check and grammar check.*** Reports will be graded by Mark and Abby and written feedback will be given on these reports each week.

b. **Discussion group reports (March 27, April 22).** For both sessions you will be expected to read some relevant literature that we will give you and which will be used as part of the discussion. You will need to write a one-page report about this which is different from the journal reports and email it to your discussion group leader before the beginning of class. For this report, you should outline key elements of these reviews/commentaries and present some ideas that these reviews/commentaries provoke with you for discussion (this part is the most important).

Journal and discussion reports together represent 40% of your grade. However, if you do not email either the journal club or discussion group reports before the beginning of

class and have not emailed or spoken to Abby or Mark, you will be given zero for these assignments.

Grading

- 1) Weekly journal or discussion group report (40%)
- 2) Journal Presentation (20%)
- 3) Class Participation (40%)