

Introduction to Clinical and Translational Research - From Bench to Bedside

Time: 9:00-9:50 am

Location: 412 Light Hall

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

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

Teaching Assistants: Yvonne Latour and Breanne Gibson

Syllabus:

<u>Day</u>	<u>Date</u>	<u>Topic</u>	<u>Speaker</u>
Friday	22-Mar	No class	
Monday	25-Mar	Overview of Translational & Clinical Research	Mark deCaestecker
Wednesday	27-Mar	Discussion: Clinical & Translational Research	Brown: 412 LH De Caestecker: 411A-B LH
Friday	29-Mar	FDA committee	Jamie Dwyer
Monday	1-Apr	Discussion - AD paper	Brown: 412 LH De Caestecker: 411A-B LH
Wednesday	3-Apr	Biorepositories, Electronic Medical Records, & Use of Human Samples in Research	Kelsey Mayo
Friday	5-Apr	Drug Development & Regulation	Matt Luther
Monday	8-Apr	IRB & Ethical considerations in human subjects research	Todd Rice
Wednesday	10-Apr	Data Safety Monitoring Boards for Clinical Trials	Harvey Murff
Friday	12-Apr	Discussion - informatics paper	Brown: 412 LH De Caestecker: 512 LH
Monday	15-Apr	Human Clinical Trials	Loretta Byrne & Colleen Lawrence
Wednesday	17-Apr	Cancer Drug Development & Regulation	Vicki Keedy
Friday	19-Apr	Discussion - heart failure paper	Brown: 412 LH De Caestecker: 419A-B LH
Monday	22-Apr	Drug discovery process	Rocco Gogliotti
Wednesday	24-Apr	Tech Transfer	Tom Utley
Friday	26-Apr	Discussion: Ethics of Human Subjects Research	Brown: 412 LH De Caestecker: 415A-B LH

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 hand

in a report on the journal article at the end of that 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. For all discussions, the class will be divided into two groups (Group A with de Caestecker; Group B with Brown).

*****Journal and discussion reports together represent 40% of your grade. However, if you do not hand either the journal club or discussion group reports at the end of class and have not emailed or spoken to Abby or Mark, you will be given zero for these assignments.**

1. Journal articles (dates: April 1, 12, 19):

- **Journal Article Presentations:** 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 article reports (April 1, 12, 19).** Students will write a brief report on the journal article to be handed in at the end of the class (1 page report). 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.
- **April 1:** [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:** Battle, Bindeman, Bunn, Trinh
 - **Group B:** Bergdorf, Bullock, Davies
- **April 12:** [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:** Francis , Kassel, Schwartz
 - **Group B:** Green, Piazza, Rivera

- **April 19:** [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:** Stephens, White, Xu
 - **Group B:** Shelton, Volk, Walker

2. **Other discussion groups (date(s) March 27, April 26):** These sessions will not have presenters, but will be moderated discussions covering general issues (March 27), and ethical issues with examples (April 26). 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.*

- **Discussion group reports** (March 27, April 26). 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 hand it in at the end 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).
- **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.
- **April 26:**
 - 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.

Grading

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