

Bench-to-bedside Project: Drug development and clinical trials

Learning Outcomes:

At the completion of this project the student will be able to:

1. Demonstrate the ability to work collaboratively and effectively as part of a team in the small group setting to discuss contemporary topics in drug discovery and development
2. Demonstrate an understanding of the basic and translational science approaches used to investigate pathophysiological mechanisms and discover, develop and evaluate new drugs
3. Demonstrate an ability to identify, appraise and interpret the primary biomedical literature relevant to pre-clinical drug discovery and clinical drug development
4. Demonstrate an ability to identify any knowledge deficiencies that exist with regards to basic and clinical research and use the primary biomedical literature and other resources in order to adequately address those deficiencies
5. Demonstrate an ability to evaluate the credibility of online resources of scientific content
6. Demonstrate an ability to read a pharmacologically-relevant primary biomedical research paper and then discuss the rationale, design, conduct, results and significance of the published research with peers
7. Demonstrate the ability to synthesize complex basic science and clinical concepts and effectively explain them to individuals of diverse educational backgrounds
8. Create effective oral and written presentations capable of communicating the rationale, study design, major findings and significance of a scientific study

Assignment 2: Drug Development and Clinical Trials

Goal: *To gain insights into the process by which basic and translational research approaches are used to develop and evaluate new drugs*

Overview: You and your group will be provided with the name of a drug that is either currently in development, or has recently been approved, and will then be responsible for working collaboratively to research the drug and prepare a group presentation on the drug to be presented to the other three small groups present in your assigned SDL. In addition, you will be required to write a brief report (no more than 400 words) describing the drug, its indications, mode of action and relative benefits to a typical patient.

Dates: September 19th 10:30am-12:30pm – Online research of drug
September 25th 1:00pm - 3:00pm – Group oral presentations

1. At the first small group of this session on **September 19th (10:30am-12:30pm)** your group will be provided with the name of a drug that is either currently in development, or has recently been approved. You will then work collaboratively as a team to fully research the drug by taking advantage of appropriate online resources to identify the following information:

- a) Background on the disease that the drug is intended to treat and the rationale for developing the drug for this indication
- b) Description of the drug and its mechanism of action and physiological effects
- c) Review of any pre-clinical data supporting the development of the drug (e.g. in vitro and/or animal models)
- d) Review of clinical trial data including study design and protocol, results of clinical efficacy data and outcomes, and any significant safety issues (e.g. adverse effects/major drug-drug interactions).
- e) Pharmacological significance and future prospects for patient care

Note: Each of these pieces of information should be supported by the relevant primary literature, which will need to be appropriately listed in the accompanying written report (see below).

These small group discussions will be moderated by a faculty facilitator who will help guide the discussion and provide feedback, but should not be expected to serve as a content expert.

2. At the second small group of this session on **September 25th (1:00pm - 3:00pm)** your group will present their findings in the form of an informal presentation to the other small groups present in the SDL. These presentations should be in the form of a powerpoint presentation and should take no longer than 20 mins. Presentations should involve each member of the group. Each group should also be prepared to answer questions from both the faculty and other students.

Presentations should not aim to describe every last detail of the drug discovery and development (there likely will not be sufficient time and that is not the point of the exercise). Instead, you will be expected synthesize the most important points

that are essential for communicating the “essence” and significance of the drug development process. It is far more important that the presentation is logical and understandable, rather than full of highly technical jargon and data that “goes over the heads” of the audience.

3. At the completion of the assignment, each student should write a brief report (no more than 400 words) to explain the clinical use and significance of the drug to a **typical patient** who has asked you a question about the drug based on a piece they had read in a newspaper (i.e. what disease the drug is used to treat, how it works, how well does it work, and what, if any are its expected side effects). As part of this report, the student should also include the relevant references (including authors names, title, journal name and page numbers) for the manuscripts describing the drugs mechanism of action and clinical trial results. These reports should be completed on the Project report form available for download from the Pharm page web site and should be labeled with your name, room number and peer group number. Reports should represent your own original work and should not be copied from either other students or lifted from the assigned paper. Any evidence of plagiarism will result in the award of no points and a concern noted in your professionalism competency. Completed reports should be handed into the Pharmacology and Therapeutics Medical Education Coordinator, Jackie Greer (Rm 320) no later than **Friday October 13th**.

Note: The goal of this exercise is for you to provide an explanation that would be suitable to explain the major findings and clinical significance of the study to a typical patient. The premise is that a patient has perhaps seen a report of the drug in a newspaper or on television and is now asking you (his/her doctor) to explain it to them in terms they can understand. The goal is for you to demonstrate your ability to communicate complex biological concepts in language that is suitable for a typical patient to understand.

4. In addition to the written assignment you should also submit a Peer Group evaluation form (these will be provided to you during the session). Simply sign your signature against your name and then distribute 100 points amongst the members of your group to reflect the quality of their participation in the group activity. Points can be distributed in any manner you wish, except that students are not able to award points to themselves- attempts to do so will nullify all points awarded to the student by other members of the group.