

OVERVIEW

The aim of this course is to explore the translational aspects of preclinical and clinical research covering all CIHR pillars of research. It is designed to help graduate students and medical residents to better understand translational research or even become effective translators of discovery and knowledge themselves.

Objectives of the whole program (MED 602-604-606-608)

I: Preclinical models: understand the principles of selecting optimal preclinical models of human disease and conducting preclinical research in a manner that promotes translation to early phase clinical trials. Understand the strengths and limitations of animal models of chronic diseases

II. Early-phase and large clinical trials: understand the challenges in the conduction of early-phase versus large clinical trials and the requirements for successful translation of preclinical research: traditional and novel trial designs, endpoints, statistical challenges, regulatory and funding challenges, structure of translational teams, knowledge translation.

III. Biomarkers: recognize the importance of established biomarkers for the conduction of clinical research, particularly early phase trials or clinical care at the population levels, as well as principles for the discovery of novel biomarkers at the preclinical and clinical level.

IV. Drug Development: Identifying candidate drug targets, along with drug design and validation of drug targets will be discussed at the cellular level, along with pre-clinical models and clinical studies.

While the clinical examples that will be used will mainly come from diseases related to metabolism, the emphasis will not be on the clinical aspects of these diseases. Rather, these diseases will often provide a platform in which some of the following research concepts will be developed:

- Identification of candidate drug targets in complex multifactorial diseases
- Economics and ethics of Drug Development
- Features of effective pre-clinical models (bench to bedside and bedside to bench)
- Strengths and weaknesses of large clinical trials
- Principles of designing small pilot studies and early phase trials
- Principles of knowledge translation in preclinical and clinical studies
- Communication skills (debating) and effective grant writing

OUTLINE OF A TYPICAL SESSION

Pre-session

All students will have access to and will be expected to read one or two provided reviews on the topic that will allow them to understand the basis of the clinical case discussed. In addition, these reviews will often offer some overview (without details) of the research challenges and future directions in the field. The student presenting will be expected to search the literature for support to the points he/she will present. Specific questions and tasks are given to the student for each session, as seen in the “weekly session schedule” attached. The student will also post the papers he/she will find most helpful in the program’s CLOUD, so all students could review or have access to them during the session. Students will interact with each other and with the presenting faculty member before (and after) the session as needed.

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Session

Sessions will feature 2 speakers, one presenting faculty member and a student – 15 min each: **The faculty member** will typically summarize the essentials of the clinical case discussed. This is not done with the intention to teach clinical medicine but only in order to provide the real-life clinical perspective in which the discussion will be based. The, he/she will answer the questions as outlined, according to their expertise and background. Overall the emphasis will be on the description of the basic or clinical research in their field, preparing the grounds for the discussion that would follow, in which solutions will be discussed. **The student** will follow with a 15 minute presentation in response to the task that he/she has been given. As can be seen in the listed tasks, the emphasis is not on the collection of facts. Rather, the student will be expected to use creativity and apply common logic in order to respond to the tasks, which are based on the learning of skills in applied translational research. Often the tasks are based on hypothetical research platforms and questions and do not require previous knowledge of the field or extensive review of the subject. Broad concepts should be presented emphasizing on research rationale, originality and creativity and not known facts.

Discussion and Post-Session

The main objective of the discussion is to synthesize the information presented and discuss an optimal pathway that is needed in order to optimize translation from preclinical to the clinical stage, focusing on a continuum of the molecule-animal-patient-populations-health services model. For example: “How is preclinical research and clinical trial design need to be modified to promote translation, what kind of teams need to be put in place in order to achieve this”, etc. A student will be assigned for each session and, after the discussion, will be called to draft a 250 word abstract / “executive summary”, post it on the CLOUD, discussed in the discussion forum and finalized a week later. Eventually the program will have these executive summaries for all the diseases discussed with the potential for subsequent publication of the curriculum.

EVALUATION

The following table summarizes how students will be evaluated for MED 602 – 608

Class Participation	Presentation	Final Examination
30%	30%	40%

***Note:** The final examination will be an in-class open book exam. It will focus on research concepts learned during the sessions, rather than on disease-specific details.

Presentation points will be based upon the student’s in-class presentation(s). Students are evaluated on organization of material into a clear and concise presentation, response to questions and articulation of the major issues in the field (see participation criteria below).

Class participation will be based upon demonstration of the student’s insight into the issues facing researchers in the topic areas, including successes and challenges of performing research in that area:

- “Successes” refer to recent major discoveries which have significantly changed thinking about the disease/field.

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- “Challenges” refer to methodologic, administrative or ethical issues which must be overcome in order to advance translation of findings from animal to human research or to health policies

All grades are reviewed by the Translational Medicine Steering Committee

COURSE MATERIALS

Graduate students will access all materials (including the recommended reading as shown in the attached weekly sessions schedule) through eClass

CHALLENGE EVALUATION

Graduate students must achieve a grade of at least a C+ (65-69%)

***Note:** Evaluation procedures and information for graduate students can be found through the Office of the Registrar at: <http://www.registrar.ualberta.ca/calendar/Regulations-and-Information/Academic-Regulation/23.4.html#23.4>)

“Policy about course outlines can be found in §[23.4\(2\)](#) of the University Calendar”.

“The University of Alberta is committed to the highest standards of academic integrity and honesty. Students are expected to be familiar with these standards regarding academic honesty and to uphold the policies of the University in this respect. Students are particularly urged to familiarize themselves with the provisions of the Code of Student Behaviour (online at www.governance.ualberta.ca) and avoid any behaviour which could potentially result in suspicions of cheating, plagiarism, misrepresentation of facts and/or participation in an offence. Academic dishonesty is a serious offence and can result in suspension or expulsion from the University.”