Course Outline BMDE-655
Clinical Trials and Business Models for Medical Devices

General Information

Course #: 655, **Section #:** 001, **Term:** Winter, **Year:** 2023, **Number of credits:** 3.
Course Schedule: Mondays 4:05 – 6:55 pm
Location: Room 321, Duff Medical Building. Some invited speakers' lectures will be over zoom.

Instructors Information

Name and Title: Ahmad Haidar, Associate Professor, Department of Biomedical Engineering
Email: ahmad.haidar@mcgill.ca
Office Location: Room 304, Duff Medical Building

Name: Michelle Hahn-Baker
Email: hahn-baker.michelle@mail.mcgill.ca

Name: Carina Sabourin
Email: carina.sabourin@mail.mcgill.ca

Calendar Course Description:
This course will train biomedical engineers to understand the clinical aspects of transferring a medical device idea into a commercial product. This course will cover different clinical trial designs, randomized controlled trials, statistical principles, hypothesis postulating, bias minimization, randomization methods, ethical and regulatory considerations for conducting clinical trials, and business models, as pertaining to medical devices.

Learning Outcomes By the end of this course, students will:

1. Understand different types of clinical trials based on their design, stage, and purpose.
2. Determine how to design a clinical trial based on the unique characteristics of the technology, the targeted patient populations, and the purpose of the trial.
3. Understand basic statistical principles and methods for clinical trial design, analysis, and reporting.
4. Understand the importance of good clinical practice and quality systems in clinical evaluations of medical technologies.
5. Appreciate the impact business models, reimbursement strategies, sales model on the commercial success and the adoption of medical technologies.

Course Material: Course material, prepared by the Lecturers, will be available via MyCourses.

Course Content/Outline

- **Week 1 (Jan 9; Instructor: Ahmad Haidar; in-person lecture):**
    - Introduction
    - Human trials purposes: regulatory (safety and effectiveness), reimbursement, and marketing purposes
    - Overview of safety and effectiveness requirements for medical devices

  Practicum part 1, GCP and SOP (due Jan 16, 4 pm eastern time).

  Practicum part 2: two to four hours of clinical observation.

- **Week 2 (Jan 16; Instructor: Claire Anne Magnussen; in-person lecture):**
    - Classification of clinical trials by design:
        - Observational studies
        - Case control studies
        - Prospective, randomized, controlled trials
    - Classification of clinical trials by stage:
        - Pilot studies (Phase I and II)
        - Pivotal trials (Phase III)
    - Post-marketing trials (Phase IV)

- **Week 3 (Jan 23; Instructor: Ahmad Haidar; in-person lecture):**
  Quiz 1 (week 2 material).
  Students' presentations: ~11 presentations (first round; material of week 1-2).

- **Week 4 (Jan 30; Instructor: Kristiana Salmon; lecture over zoom):**
  Students' presentations: ~4 students (first round; material of week 1-2).
    - Good clinical practice
    - Quality systems in clinical trials

  Assignment 1: Developing ICF based on a given protocol (due Feb 6, 4 pm eastern time).

Prospective, randomized, controlled trials (Weeks 4 to 7)

- **Week 5 (Feb 6; Instructor: Ahmad Haidar; in-person lecture):**
  Students' presentations: ~5 students (first round; material of week 1-2).
        - The null hypothesis and the alternative hypothesis
        - Crossover and parallel designs, pros and cons
        - Efficacy and effectiveness. Superiority, non-inferiority, and equivalence studies.

- **Week 6 (Feb 13; Instructor: Ahmad Haidar; in-person lecture):**
  Quiz 2 (week 5 material).
        - Randomization, bias, masking, allocation concealment, and trial registration
        - Study population, inclusion and exclusion criteria
        - Primary and secondary endpoints, efficacy and safety endpoints
        - Protocol development

- **Week 7 (Feb 20; Instructor: Ahmad Haidar; in-person lecture):**
  Quiz 3 (week 6 material).
    - Statistical power and sample size
    - Statistical analysis, p values, Type I/Type II error
    - Consolidated Standards of Reporting Trials (CONSORT) Statement
    - Data safety and monitoring board

  Assignment 2: Developing protocol (due April 3, 4 pm eastern time). This will be preceded with a pre-assignment.

- **Week 8 (March 6; Instructor: Ahmad Haidar; in-person lecture):**
  Quiz 4 (week 7 material).
  Students' presentations: ~11 students (second round; material of week 5-8).

- **Week 9 (March 13; Instructor: Alessandra Kobayati; in-person lecture):**
  Quiz 5 (week 7 material).
  Student's presentations: ~4 students (second round; material of week 5-8).
    - Patient-reported outcomes
        - Instruments, definitions, and validity of Instruments
        - Analyzing and reporting of patient-reported outcomes
        - Power calculations for patient-reported outcomes

- **Week 10 (March 20; Instructor: Stuart Kozlick; zoom lecture):**
  Quiz 6 (week 9 material).
  Students' presentations: ~4 students (second round; material of week 5-8)
  Students' presentations: ~2 students (third round; examples of studies/protocols).
    - Developing reimbursement strategy
    - Market and stakeholder analysis and strategy
    - Business models in medical devices
    - Competitive advantage and business strategy

  Assignment 3: Developing business plan (due March 27, 4 pm eastern time).

- **Week 11 (March 27; Instructor: Renaud Boulanger; in-person lecture):**
  Quiz 7 (week 11 material).
  Students' presentations: ~11 students (third round; examples of studies/protocols).
    - TBD: REB requirements, REB structure, patient protection, investigator requirement

- **Week 12 (April 3; Instructor: Joanna Rutkowski; in-person lecture):**
  Student's presentations: ~5 students (third round; examples of studies/protocols).
    - Health Canada Investigational Testing Authorization (ITA)
        - ITA approval process, responsibilities, application, reporting, labelling, and REB.

- **Week 13 (April 12; Instructor: Ahmad Haidar; in-person lecture):**
    - Final exam.

Assessment/Evaluation:

7 Quizzes: 28% (4% each), laptops are required for the quizzes
3 Assignments: 34% (6% for first, 23% for second, and 5% for third),
2 Practicums: 11% (7% for first, and 4% for second),
3 Presentations: 12% (4% per presentation),
Final Exam: 15%

McGill Policy Statements: McGill University values academic integrity. Therefore, all students must understand the meaning and consequences of cheating, plagiarism and other academic offences under the Code of Student Conduct and Disciplinary Procedures.

In accord with McGill University's Charter of Students' Rights, students in this course have the right to submit in English or in French any written work that is to be graded.

Delayed Submission Policy: Any assignment that is submitted late will be panelized 25% for each day late.