Course Outline BMDE-655
Biomed Clin Trials-Med Devices

General Information

Course #: 655

Section #: 001

Term: Winter

Year: 2018

Course Schedule: Tuesdays and Thursdays
1:00 – 2:30 pm

Number of credits: 3

Location: Room 321, Duff Medical Building
3775 University Street
Montreal, Quebec, H3A 2B4

Instructor Information

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Calendar Course Description:

This course will train biomedical engineers to understand the clinical and business aspects of transferring a medical device idea into a commercial product. This course provides an overview of the pre-clinical and clinical testing of medical devices, clinical trials, reimbursement systems, market analysis, sales models, and business models, as pertaining to medical devices. This course will also cover the design of randomized trials, including statistical principles, hypothesis postulating, bias minimization, and randomization methods.

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, good laboratory practice, and quality systems in pre-clinical and 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 Lecturer, will be available to registered students via MyCourses.

Reference Text: Yock, P.G., Zenios, S., Makower, J., Brinton, T.J., Kumar, U.N., Kurihara, C.Q., Denend, L., Krummel, T.M. and Watkins, F.J., 2015. **Biodesign: The Process of Innovating Medical Technologies**. Cambridge University Press.

Course Content/Outline

- **Week 1:**
    - Pre-clinical (animal and bench) and clinical phases of evaluation
    - Overview of pre-clinical evaluation, *in vitro* and *in vivo*
- **Week 2:**
    - Research ethics approval for animal testing
    - Good laboratory practice
- **Week 3:**
    - Human trials purposes: regulatory (safety and effectiveness), reimbursement, and marketing purposes
    - Overview of safety and effectiveness requirements for medical devices
        - US safety and effectiveness requirements under the US Food, Drug and Cosmetic Act
        - Health Canada safety and effectiveness requirements under the Medical Device Regulations
- **Week 4:**
    - Good clinical practice
    - IRB requirements, patient protection, Investigator requirements and potential conflicts
    - Quality systems in clinical trials
- **Week 5:**
    - 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)

Prospective, randomized, controlled trials (Weeks 6 to 9)

- **Week 6:**
    - The null hypothesis and the alternative hypothesis
    - Crossover and parallel designs, pros and cons
    - Efficacy and effectiveness studies. Superiority, non-inferiority, and equivalence studies.
- **Week 7:**
    - Randomization, bias, masking, allocation concealment, and trial registration
    - Study population, inclusion and exclusion criteria
    - Primary and secondary endpoints, efficacy and safety endpoints
- **Week 8:**
    - Statistical power and sample size
    - Statistical analysis, p values, Type I/Type II error
- **Week 9:**
    - Consolidated Standards of Reporting Trials (CONSORT) Statement
    - Data safety and monitoring board

- **Week 10:**
    - FDA Investigational Device Exemption (IDE)
        - IDE approval process, responsibilities, application, reporting, labelling, and IRB
    - Health Canada Investigational Testing Authorization (ITA)
        - ITA approval process, responsibilities, application, reporting, labelling, and REB
- **Week 11:**
    - Human factors considerations
    - Post-marketing trials
    - Post-marketing safety surveillance

- **Week 12:**
    - Reimbursement systems in US and Canada
    - Developing reimbursement strategy
    - Market and stakeholder analysis and strategy
    - Sales and distribution models
        - Indirect, direct, and hybrid sales and distribution models

- **Week 13:**
    - Business models in medical devices
        - Types of business models (disposable, reusable, implantable, capital equipment, service, etc.)
        - How to choose an appropriate business model
    - Competitive advantage and business strategy
        - First to market, IP management, capability-based advantages, distribution play, etc
        - Developing a statement of competitive advantage

Assessment/Evaluation:

Class Quizzes: 30%

Assignments: 40%

There will be four assignments each worth 10%.

Final Exam: 30%

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.