GUIDE FOR INSTRUCTORS
Fundamental of Clinical Trial Design, Conduct and Analysis

WELCOME

This module is intended for graduate students who are interested in learning about the design and execution of clinical trials in Canada. This module pulls together many resources already widely available and leads the learner through the structure of a clinical trial protocol. The learner will be provided with additional resources to review to increase mastery of knowledge and will have the opportunity to apply newly developed skills through novel assessments and activities. Some background in research methodology is advantageous but not mandatory as this module will review some basics to 'anchor' the landscape in the world of study designs.

WHAT/ WHY

The goal of the *Fundamental of Clinical Trial Design, Conduct and Analysis* module is to provide an introduction to clinical trial methodology using a contextual framework of actual studies and their role in drug development and regulatory approval.

After completing *Fundamentals of Clinical Trial Design, Conduct and Analysis*, students will be able to:

1. use appropriate terminology to describe and differentiate between common types of clinical trial study designs;
2. identify sources of bias, and explore methods used to prevent and minimize bias in Randomized Control Trials (RCTs);
3. explain the statistical methods commonly used in the analysis of Phase I, II and III clinical trials;
4. reference the regulatory and ethical framework of clinical research in Canada;
5. participate in the development of a methodologically sound research protocol; and
6. critically appraise the validity of relevant published literature.

WHO

This module is applicable to students in a variety of learning situations, including online or on-campus courses that offer a range of graduate level foundational topics relevant to Research Methods and Analysis.

WHEN/ WHERE

Self-paced module with interactive elements intertwined to help students engage with the concepts and build skills in discerning information that will accompany learning. This module can be integrated as part of online or on-campus courses, as a tool to help students develop the skills required to complete a course assignment(s). The duration of this module is the equivalent of 20% of a full credit course.

HOW IT WORKS

Supported Formats

To facilitate easy LMS implementation, the Clinical Trials Module has been pre-exported into the following formats:

- **Sharable Content Object Reference Module (SCORM) package:** this format is supported by most major LMS systems and can be uploaded as a .ZIP file. For information on uploading a SCORM package, please visit your LMS's support page.
- **HTML Web Distribution**: This format is typically used outside of the LMS and is hosted on a webserver. Web packages are typically published to a website via an FTP client. For more information, please visit the Articulate Publishing and Sharing page.

Both formats support Adobe Flash and HTML5 allowing for the module to be viewed on most computers.

Changing/Editing Content

All content within the Clinical Trials Module has been created with a Creative Commons License. All content may be changed or edited. The module was created using Articulate Storyline 2.

- If you are interested in editing the existing module, the Storyline file may be downloaded from http://www.queensu.ca/artsci_online/additional-resources/Clinical Trials/Clinical_Trials_Development_Package.zip . If your institution does not have a Storyline 2 license, a free trial may be downloaded from Articulate's website. For information on using Articulate Storyline 2, please consult the Storyline 2 User Guide.
- Raw multimedia content (images, video) that was used to create the module has been included in the development package

The complete module may be viewed from the Arts and Science Online Learning Support page.
Please contact Continuing and Distance Studies if you have any questions regarding the module.