



UNIVERSITY OF
CALGARY

CUMMING SCHOOL OF MEDICINE
GRADUATE COURSE OUTLINE

COURSE TITLE:			
Course Name and Number	MDGE 606 – Clinical Trials		
Pre/Co-Requisites	No defined pre-requisites or co-requisites. All students must be registered in the MBT graduate program, or have special permission from the Course Coordinator.		
Faculty	Cumming School of Medicine, Graduate Science Education		
Instructor Name(s)	Rachel Syme	Email	rmsyme@ucalgary.ca
Office Location	HMRB 372	Office Hours	By Appointment
Instructor Email Policy	Email is the best way to get a hold of the instructor (rmsyme@ucalgary.ca). Emails are typically responded to within 2-3 working days.		
Telephone No.	403-210-7204		
TA Name		Email	
Class Term, Days	Winter, January 14, 21, 28 February 4, 11, 25; March 4, 11, 18, 25		
Class Times	11:00-12:20 pm		
Class Location	Zoom and Lecture Hall TBD – synchronous BLENDED		

For online courses:

This course will take place mostly synchronously on-line via D2L and Zoom. A few classes will be held in person (as per the course schedule). When unable to participate live inform the instructor in advance.

COURSE INFORMATION/DESCRIPTION OF THE COURSE

This module is required for students in the Masters in Biomedical Technology (MBT) graduate program. It is intended to provide an overview of the area of clinical trials, their oversight and the clinical trials landscape in Canada.

LEARNING RESOURCES/REQUIRED READING



COURSE OBJECTIVES/LEARNING OUTCOMES

To provide a general understanding and appreciation of clinical trials and how they are regulated. An emphasis will be placed on regulatory obligations and current trends. Students will be given an opportunity to hear from experts in the field and apply what they have learned.

Communication:

Please discuss how you will communicate with your students (including how you provide link to online classes)

D2L is located on the University of Calgary server and will be used extensively for communication with Students. A link to the zoom classes will be provided on D2L. It is the student's responsibility to ensure that they receive all posted communications and documents and that they receive emails sent by instructors or fellow students through D2L. Only your @ucalgary.ca e-mail address maybe linked to D2L. Please ensure that you are regularly checking your @ucalgary.ca account.

Learning Technology Requirements

In order to successfully engage in learning experiences at the University of Calgary, students taking online, remote and blended courses are required to have reliable access to the following technology:

- A computer with a supported operating system, as well as the latest security and malware updates;
- A current and updated web browser;
- Webcam (built-in or external);
- Microphone and speaker (built-in or external), or headset with microphone;
- Current antivirus and/or firewall software enabled;
- Broadband internet connection

Most current laptops will have a built-in webcam, speaker and microphone.

Please see the following for a detailed explanation of the minimal required technology for online learning

<https://elearn.ucalgary.ca/technology-requirements-for-students/>

A laptop, desktop, tablet or mobile device is required for D2L access. If you need help accessing or using D2L, please visit the Desire2Learn resource page for students: <http://elearn.ucalgary.ca/d2l-student/>.

The University of Calgary Cumming School of Medicine would like to acknowledge the traditional territories of the people of the Treaty 7 region in Southern Alberta, which includes the Blackfoot Confederacy (comprising the Siksika, Piikani, and Kainai First Nations), as well as the Tsuut'ina First Nation, and the Stoney Nakoda (including the Chiniki, Bearspaw, and Wesley First Nations). The City of Calgary is also home to Métis Nation of Alberta, Region III.

CUT POINTS FOR GRADES



This course adheres to the grading system outlined in the University of Calgary, Faculty of Graduate Studies Calendar. Grades of A+ and A are not distinguished in the calculation of GPAs. Percentage/letter grade conversion used for this course is as follows

Grade	Grade Point Value	Percentage Conversion	Graduate Description
A+	4.00	95-100	Outstanding
A	4.00	85-94	Excellent – superior performance showing comprehensive understanding of the subject matter
A-	3.70	80-84	Very Good Performance
B+	3.30	75-79	Good Performance
B	3.00	70-74	Satisfactory Performance
B-	2.70	65-69	Minimum Pass for Students in the Faculty of Graduate Studies
C+	2.30	55-64	All grades below ‘B-’ are indicative of failure at the graduate level and cannot be counted toward Faculty of Graduate Studies course requirements
C	2.00	50-54	

Assessment Components: The University policy on grading related matters is outlined in the [2019-2020 Calendar](#).

Assessment Methods	Description	Weight %	Due Date and Time
Certificate completion	TSCPS2 CORE Tutorial or CITI-Canada GCP Course	10	January 28 th 12:20 pm
In class presentation/written assignment	Team Clinical Trial Case Study in-class presentation and one page summary of the case study. Each student presents one case study as part of a team and is evaluated on their presentation and the team’s summary of their case.	30	January 21 to March 25, 2021 (on-line/in class))
Written Assignment	Clinical Trial Protocol/Informed Consent form by each team will be worth 50 points	50	April 1, 2021 midnight
Quiz	Clinical Trial Acronym Quiz	5	Feb 25 th 12:20 pm



Participation	Students are expected to attend class on weekly basis and to actively participate in the group learning activities and games, and be prepared share their thoughts and ask questions during the case studies.	5	Ongoing
---------------	---	---	---------

ASSESSMENT AND EVALUATION INFORMATION
<p>ATTENDANCE AND PARTICIPATION EXPECTATIONS:</p> <p>Students are expected to attend class on weekly basis and to actively participate in the In-class group learning activities and games, and be prepared share their thoughts and ask questions during the case studies.</p> <p>GUIDELINES FOR SUBMITTING ASSIGNMENTS:</p> <p>Assignments will be sent to the instructor via email by the dates outlined.</p> <p>FINAL EXAMINATIONS:</p> <p>N/A</p> <p>EXPECTATIONS FOR WRITING:</p> <p>LATE AND/OR MISSING ASSIGNMENTS:</p>

Is a passing grade on a particular component essential to pass the course as a whole?

Yes, the Clinical Trial Protocol

COURSE TIMETABLE			
Course Schedule Date	Topic & Reading	Instructor	Assignments/Due Dates & Times
2021/01/14	Introduction History of Clinical Trials & Case Study Example (on-line)	Syme	
2021/01/21	Getting your Clinical Trial Started – Health Canada the FDA and CTAs - Regulations today, ICH-GCP (on-line)	Syme	CASE STUDY 1

2020/01/28	Role of REB / TCPS (on-line)	Page/Syme	CASE STUDY 2 Training Certificate Due (12:20 pm)
2020/02/04	Protocol Preparation (on-line)	Syme	
2020/02/11	Safety in Clinical Trials SAEs/AEs Monitoring/Audits/Inspections DSMB (in class)	David/Syme	CASE STUDY 3
2020/02/25	Clinical Trial Recruitment (in class)	Syme/David	CASE STUDY 4 Acronym Quiz Due (12:20 pm)
2020/03/04	Clinical Trial Design/Protocol development/ Stats (on-line)	Faris/Syme	
2020/03/11	Legal aspects of Clinical Trials Contracts CDAs 9 (on-line)	Syme	CASE STUDY 5
2020/03/18	Post Marketing Surveillance/ Canadian Initiatives (on-line)	Syme	CASE STUDY 6
2020/03/25	Pragmatic/Innovative Clinical Trials Clinical Trials in Action (in class) LAST DAY OF CLASS	Syme	CASE STUDY 7 Clinical Trial Protocol/Informed Consent form Due April 1, 2021 (12:00 pm)

Guidelines for Zoom Sessions

Zoom is a video conferencing program that will allow us to meet at specific times for a 'live' video conference, so that we can have the opportunity to meet each other virtually and discuss relevant course topics as a learning community.

To help ensure Zoom sessions are private, do not share the Zoom link or password with others, or on any social media platforms. Zoom links and passwords are only intended for students registered in the course. Zoom recordings and materials presented in Zoom, including any teaching materials, must not be shared, distributed or published without the instructor's permission.



The use of video conferencing programs relies on participants to act ethically, honestly and with integrity; and in accordance with the principles of fairness, good faith, and respect (as the Code of Conduct). When entering Zoom or other video conferencing sessions, you play a role in helping create an effective, safe and respectful learning environment. Please be mindful of how your behaviour in these sessions may affect others. Participants are required to use names officially associated with their UCID (legal or preferred names listed in the Student Centre) when engaging in these activities. Instructors/moderators can remove those whose names do not appear on class rosters. Non-compliance may be investigated under relevant University of Calgary conduct policies. If participants have difficulties complying with this requirement, they should email the instructor of the class explaining why, so the instructor may consider whether to grant an exception, and on what terms. For more information on how to get the most out of your zoom sessions visit: <https://elearn.ucalgary.ca/guidelines-for-zoom/>.

If you are unable to attend a Zoom session, please contact your instructor to arrange an alternative activity (where available). Please be prepared, as best as you are able, to join class in a quiet space that will allow you to be fully present and engaged in Zoom sessions. Students will be advised by their instructor when they are expected to turn on their webcam (such as for group work, presentations, etc).

The instructor may record online Zoom class sessions for the purposes of supporting student learning in this class – such as making the recording available for review of the session or for students who miss a session. Students will be advised before the instructor initiates a recording of a Zoom session. These recordings will be used to support student learning only.

Conduct During Lectures

The classroom should be respected as a safe place to share ideas without judgement - a community in which we can all learn from one another. Students are expected to frame their comments and questions to lecturers in respectful and appropriate language, always maintaining sensitivity towards the topic. Students, employees, and academic staff are also expected to demonstrate behaviour in class that promotes and maintains a positive and productive learning environment.

As members of the University community, students, employees and academic staff are expected to demonstrate conduct that is consistent with the University of Calgary Calendar, the Code of Conduct and Non-Academic Misconduct policy and procedures, which can be found at <https://www.ucalgary.ca/policies/forms/title>.

Equity, Diversity and Inclusion

The Cumming School of Medicine recognizes that equity, diversity, and inclusion benefits and strengthens all communities, including the medical community and those served by it. We aim to actively engage all learners, particularly those from equity seeking groups including women, Indigenous peoples, visible/racialized minorities, persons with disabilities, and LGBTQ+. While our faculty continues to learn about more equitable, diverse, and inclusive approaches to education, we welcome and appreciate suggestions to help us ensure that all learners are well served by our courses.



To help cultivate learning environments that support diverse and inclusive perspectives and lived experiences, learners are invited to let instructors know if:

- they have names and/or pronouns they would prefer to use that differ from those that appear on official records
- scheduled class meetings conflict with religious events so that alternative arrangements can be made

If they are not already, learners are also encouraged to become familiar with the various opportunities for diverse engagement, learning, and support on campus, including, but not limited to the following resources:

The Office of Equity, Diversity and Inclusion

<https://www.ucalgary.ca/equity-diversity-inclusion>

The Q Centre

<https://www.su.ucalgary.ca/programs-services/student-services/the-q-centre/>

The Writing Symbols Lodge

<https://www.ucalgary.ca/student-services/writing-symbols/home>

INTERNET AND ELECTRONIC COMMUNICATION DEVICE INFORMATION

Cell phones must be turned off in class unless otherwise arranged with the instructor.

The use of laptop and mobile devices is acceptable when used in a manner appropriate to the course and classroom activities. Students are to refrain from accessing websites that may be distracting for fellow learners (e.g. personal emails, Facebook, YouTube). Students are responsible for being aware of the University's Internet and email use policy, which can be found at

<https://www.ucalgary.ca/policies/files/policies/acceptable-use-of-electronic-resources-and-information-policy.pdf>

MEDIA AND RECORDING IN LEARNING ENVIRONMENTS

Media recording for lesson capture

Please refer to the following statement on media recording of students: https://elearn.ucalgary.ca/wp-content/uploads/2020/05/Media-Recording-in-Learning-Environments-OSP_FINAL.pdf

The instructor may use media recordings to capture the delivery of a lecture. These recordings are intended to be used for lecture capture only and will not be used for any other purpose. Although the recording device will be fixed on the Instructor, in the event that incidental student participation is recorded, the instructor will ensure that any identifiable content (video or audio) is masked, or will seek consent to include the identifiable student content to making the content available on University approved platforms.

Media recording for assessment of student learning



The instructor may use media recordings as part of the assessment of students. This may include but is not limited to classroom discussions, presentations, clinical practice, or skills testing that occur during the course. These recordings will be used for student assessment purposes only and will not be shared or used for any other purpose.

Media recording for self-assessment of teaching practices

The instructor may use media recordings as a tool for self-assessment of their teaching practices. Although the recording device will be fixed on the instructor, it is possible that student participation in the course may be inadvertently captured. These recordings will be used for instructor self-assessment only and will not be used for any other purpose.

Student Recording of Lectures

Audio or video/visual recording of lectures is prohibited except where explicit permission has been received from the instructor.

UNIVERSITY OF CALGARY POLICIES AND SUPPORTS

ACADEMIC ACCOMMODATIONS

Students seeking an accommodation based on disability or medical concerns should contact Student Accessibility Services; SAS will process the request and issue letters of accommodation to instructors. For additional information on support services and accommodations for students with disabilities, visit www.ucalgary.ca/access/. Students who require an accommodation in relation to their coursework based on a protected ground other than disability should communicate this need in writing to their Instructor. The full policy on Student Accommodations is available at www.ucalgary.ca/policies/files/policies/student-accommodation-policy.pdf

IMPORTANT INFORMATION

Any research in which students are invited to participate will be explained in class and approved by the appropriate University Research Ethics Board

INSTRUCTOR INTELLECTUAL PROPERTY

Course materials created by professor(s) (including course outlines, presentations and posted notes, labs, case studies, assignments and exams) remain the intellectual property of the professor(s). These materials may NOT be reproduced, redistributed or copied without the explicit consent of the professor. The posting of course materials to third party websites such as note-sharing sites without permission is prohibited. Sharing of extracts of these course materials with other students enrolled in the course at the same time may be allowed under fair dealing

COPYRIGHT LEGISLATION

All students are required to read the University of Calgary policy on Acceptable Use of Material Protected by Copyright www.ucalgary.ca/policies/files/policies/acceptable-use-of-material-protected-by-copyright-policy.pdf and requirements of the copyright act (<https://laws-lois.justice.gc.ca/eng/acts/C-42/index.html>) to ensure they are aware of the consequences of unauthorised sharing of course materials (including instructor



notes, electronic versions of textbooks etc.). Students who use material protected by copyright in violation of this policy may be disciplined under the Non-Academic Misconduct Policy

ACADEMIC INTEGRITY

The Cumming School of Medicine expects intellectual honesty from its students. Course participants should be aware of University policies relating to Principles of Conduct, Plagiarism and Academic Integrity. These are found in the printed Faculty of Graduate Studies Calendar, or online under Academic Regulations in the Faculty of Graduate Studies Calendar, available at [Faculty of Graduate Studies Academic Regulations](#)

ACADEMIC MISCONDUCT

For information on academic misconduct and its consequences, please see the University of Calgary Calendar at www.ucalgary.ca/pubs/calendar/current/k.html

EMERGENCY EVACUATION AND ASSEMBLY POINTS

Assembly points for emergencies have been identified across campus. The primary assembly points for South Campus (Health Science Centre (HSC); Health & Research Innovation Centre (HRIC); Heritage Medical Research Building (HMRB) and Teaching, Research and Wellness (TRW)) are:

- HSC and HMRB: HRIC Atrium (alternate assembly point is Parking Lot 6)
- HRIC: HMRB Atrium (alternate assembly point is Parking Lot 6)
- TRW: McCaig Tower (alternate assembly point is HMRB – Atrium)

APPEALS

If there is a concern with the course, academic matter or a grade, first communicate with the instructor. If these concerns cannot be resolved, students can proceed with an academic appeal, as per Section N of the Faculty of Graduate Studies Calendar. Students must follow the official process and should contact the Student Ombuds Office (www.ucalgary.ca/student-services/ombuds) for assistance with this and with any other academic concerns, including academic and non-academic misconduct

THE FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY (FOIP) ACT

This course is conducted in accordance with the Freedom of Information and Protection of Privacy Act (FOIP) and students should identify themselves on written assignments (exams and term work.) by their name and ID number on the front page and ID on each subsequent page. Assignments given by you to your course instructor will remain confidential unless otherwise stated before submission. The assignment cannot be returned to anyone else without your expressed permission to the instructor. Grades will be made available on an individual basis and students will not have access to other students' grades without expressed consent. Similarly, any information about yourself that you share with your course instructor will not be given to anyone else without your permission

WELLNESS AND MENTAL HEALTH RESOURCES

The University of Calgary recognizes the pivotal role that student mental health plays in physical health, social connectedness and academic success, and aspires to create a caring and supportive campus community where individuals can freely talk about mental health and receive supports when needed. We encourage you to explore the excellent mental health resources available throughout the university community, such as counselling, self-help resources, peer support or skills-building available through the SU Wellness Centre, at



www.ucalgary.ca/wellnesscentre/services/mental-health-services and the Campus Mental Health Strategy website at www.ucalgary.ca/mentalhealth/

SUPPORTS FOR STUDENT LEARNING, SUCCESS, AND SAFETY

Student Ombudsman: The Student Ombuds' Office supports and provides a safe, neutral space for students. For more information, please visit www.ucalgary.ca/ombuds/ or email ombuds@ucalgary.ca

Student Union: The SU Vice-President Academic can be reached at (403) 220-3911 or suvpaca@ucalgary.ca; Information about the SU, including elected Faculty Representatives can be found here: www.su.ucalgary.ca/

Graduate Student's Association: The GSA Vice-President Academic can be reached at (403) 220- 5997 or gsa.vpa@ucalgary.ca; Information about the GSA can be found here: gsa.ucalgary.ca

SAFEWALK

Campus security will escort individuals, day or night, anywhere on campus (including McMahon Stadium, Health Sciences Centre, Student Family Housing, the Alberta Children's Hospital and the University LRT station). Call 403-220-5333 or visit www.ucalgary.ca/security/safewalk. Use any campus phone, emergency phone or the yellow phone located at most parking lot pay booths. Please ensure your personal safety by taking advantage of this service.