

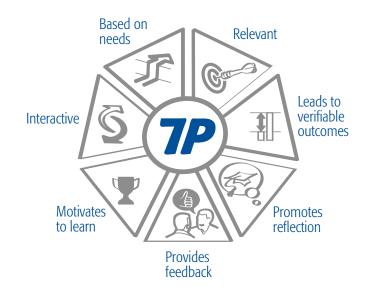
### AOPEER course program

# Principles of Clinical Research

November 9-10 2019 BMO Education and Conference Centre, Toronto, Canada



## 7 Principles of education



### Dear course participant

I am excited to welcome you to the AOPEER Course 'Principles of Clinical Research' organized and supported by the AO Foundation.

Clinical studies are the foundation of evidence-based medicine and are critical for developing management strategies to improve outcomes for patients. However, conducting clinical studies is a challenging and multifaceted task. This course will provide you with the practical tools, including tips and pitfalls, to help you develop a framework that will ensure you successfully complete your clinical study.

This course will cover literature reviews, basic statistics, trial design, conducting a clinical study, the art and science of writing a high-impact publication, and study management. The content learned during this course will be invaluable to you as you design your next clinical study.

We look forward to welcoming you to Toronto for this unique course!



Michael G. Fehlings MD PhD FRCSC FACS

Professor of Neurosurgery Vice Chair Research, Department of Surgery University of Toronto

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### Mandatory precourse activities for participants

- Think of factors that make a clinical problem suitable as a starting point for a clinical study.
- Watch recorded lecture about "study designs" and read through the presentation with specific study design examples
- Read the article of Guo et al and complete the related tasks.
- Complete 2 eLearning modules "Statistics for surgeons"

### Course structure

1.5 days face-to-face including interactive discussions, workshops, preceded by online preparatory activities.

## Goal of the course

The goal of this course is to introduce the principles of clinical research, including skills and knowledge on why and how to do research, how to build a good research environment, and where to find additional resources, tools, and reference packages to support a research project.

## Target participants

This course is targeted at individuals who want to learn or improve the skills for conducting clinical research and publishing results and also at those with a general interest in research and documentation of clinical cases.

### Course description

Participants will learn about the importance of research and evidence-based medicine (EBM), the relevant ethical considerations and guidelines for Good Clinical Practice (GCP) with a focus on the formulation of a clinical research question.

In addition to practicing some of the skills related to critical literature review, this course offers support in working with a statistician, and navigating the AO Program for Education and Excellence in Research (AOPEER) to help make their research project a success.

For more information, please visit www.aopeer.org. Access is free for all members of an AO Clinical Division.

## Learning objectives

At the end of this course, participants should be able to:

- Explain the importance of doing research and the link to evidence-based medicine.
- Apply the basic principles of literature search and critical appraisal.
- Follow GCP guidelines and adhere to ethical requirements, eg, informed consent.
- Identify a clinical problem, formulate a clinical research question, and select the study design.
- Collaborate with a statistician to perform sample size calculation and basic statistical analyses.
- Describe the principles of medical writing.
- Utilize available research environment, resources, and tools.

### Teachers

## Course organization

### **AO Clinical Investigation and Documentation**

Stettbachstrasse 6 8600 Dübendorf, Switzerland Phone +41 44 200 24 77 Fax +41 44 200 24 60

### **University Health Network (UHN)**

60, Leonard Ave, Toronto, ON M5T 2R1 Canada

## Saturday, November 9, 2019 (Start 01:30pm)

TIME	AGENDA ITEM	WHO
	LOCATION	
01:00 PM	REGISTRATION	
Module 1:	Importance of research	
01:30-01:45	Welcome	
01:45-02:00	Why is research important in your daily practice? Plenary discussions	
02:00-02:15	Evidence-based medicine (EBM): Why is it important? Lecture	
02:15-02:45	<b>What can EBM do for you?</b> Small group discussions	
Module 2:	Basics of Good Clinical Practice	
02:45-03:15	<b>Ethical imperatives</b> Introduction and plenary discussions	
03:15-03:25	Guidelines of Good Clinical Practice Lecture	
03:25-03:55	BREAK	
03:55-04:05	<b>Importance of ethics committee</b> Plenary discussions	
04:05-04:25	Informed consent process Lecture	
04:25-05:10	Ethical approval case studies Practical exercise	
Module 3:	Study question	
05:10-05:50	<b>How to identify a clinical problem for research</b> Small group discussions (follow-up from homework)	

End of Day 1

## Sunday November 10, 2019 (Start 08:30am)

TIME	AGENDA ITEM	WHO
08:30-09:20	<b>PICOT and formulating a structured clinical research question</b> Introduction and practical exercise	
09:20-09:35	Study designs Lecture	
Module 4:	Literature review	
09:35-10:15	<b>Literature search</b> Introduction / demonstration	
10:15-10:45	BREAK	
10:45-11:35	<b>Critical appraisal</b> Practical exercise	
Module 5:	Research environment	
11:35-11:45	Roles of research team Lecture	
11:45-12:15	Accessing and finding your way around a research environment Small group discussions	
12:15-01:15	LUNCH	
Module 6:	Basics of statistical thinking	
01:15-01:25	How to work with a statistician Lecture	
01:25-01:45	<b>Basics of statistics</b> Lecture: Confidence intervals, hypothesis testing, <i>P</i> value	
01:45-02:05	Sample size calculation Lecture	
02:05-02:25	Most typical flaws in statistics Plenary discussion	
Module 7:	Basics of medical writing	
02:25-03:10	Bad practice in publishing Plenary discussion and lecture	
03:10-03:25	BREAK	
03:25-04:45	Review a paper section by section Practical exercise - Abstract - Introduction: Describe the clinical question - Methods: Explain the study design - Results: Reporting the findings of the study - Discussion: How are the results interpreted? - Conclusion: Lessions learned	

## Sunday, November 10, 2019 (cont.)

TIME	AGENDA ITEM	WHO
04:45-04:55	Medical writing tips: Manuscript maker Demonstration	
04:55-05:05	Reference management Demonstration	
Module 8:	Make your research project a success	
05:05-05:15	Use the AOPEER platform Demonstration	
05:15-05:20	What's next for your research education Lecture	
05:20-05:30	<b>Conclusions and feedback</b> Plenary discussion	
05:30	END OF COURSE	

## Course information

### **Course fee**

USD 600 for non-AO members USD 480 for members of any AO division USD 480 for residents and employees of the University of Toronto USD 540 for any other non-for-profit organizations

Your registration fee includes:

- Attendance of all lectures/practical sessions
- Teaching material for the course
- Coffee breaks and lunch

### **Course certificate**

The course certificates will be available at the end of the course.

#### **Evaluation guidelines**

All AOCID courses apply the same evaluation process with paper and pencil questionnaires. This will help AOCID to ensure that we continue to meet your training needs.

#### **Intellectual property**

Course materials, presentations, and case studies are the intellectual property of the course faculty. All rights are reserved. Check hazards and legal restrictions on www.aofoundation.org/legal.



Recording, photographing, or copying of lectures, practical exercises, case discussions, or any course materials is strictly forbidden. Participants violating intellectual property will be dismissed. The AO Foundation reserves the right to film, photograph, and audio record during their events. Participants must understand that in this context they may appear in these recorded materials. The AO Foundation assumes participants agree that these recorded materials may be used for AO marketing and other purposes, and made available to the public.

#### Security

Security checks will be conducted at the entrance of the building. Wearing of a name tag is compulsory during lectures, practicals, and discussion groups.

#### No insurance

The course organization does not take out insurance to cover any individual against accidents, thefts or other risks.

#### Use of mobile phones

Use of mobile phones is not allowed in the lecture rooms and in any other facilities during educational activities. Please be considerate of others by turning off your mobile phone.

#### Dress code

Business casual

#### **Travel and hotels**

Participants are responsible for their own travel and hotel arrangements.

### Course venue

BMO Education and Conference Centre – University Health Network (UHN) 60, Leonard Ave, Toronto, ON M5T 2R1

## Notes

## Notes

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