



20th MCCR WORKSHOP

METHODS IN CLINICAL CANCER RESEARCH

Zeist, Netherlands

A Workshop for junior oncologists in any clinical research specialty area, to learn the essentials of clinical trial design

16 - 22
JUNE
2018

www.ecco-org.eu/workshop

CELEBRATING
20
EDITIONS

Having attended the Workshops several times as a faculty member, I noticed that everyone experiences this course as I did as a student in 2004. This is a once in a life time experience where you will learn how to perform clinical research in a unique environment with highly motivated students and top clinical researchers.

Stefan Sleijfer

WORKSHOP DIRECTORS

Representing ECCO

Stefan Sleijfer



Erasmus University Medical Centre, Rotterdam, Netherlands

Representing AACR

Lee M. Ellis



The University of Texas – MD Anderson Cancer Center, Houston, USA

Representing EORTC

Corneel Coens



EORTC Headquarters, Brussels, Belgium

Representing ESMO

Emiliano Calvo



START Madrid, Centro Integral Oncologico Clara Campal, Madrid, Spain

Being a mentor in the Workshops has been the highlight of my career. There is nothing more gratifying than helping young, smart trainees put forth their best efforts to improve the lives of patients with cancer. Being a mentor at this Workshop is a true privilege.

Lee M. Ellis

It is always gratifying to see a former student return as faculty member. It means we are succeeding in training the next generation of cancer clinical researchers and provide them the necessary network.

Corneel Coens

MCCR Workshop will become one of the most educational and fruitful weeks for most of the participants. It is a golden opportunity for those who wish to pursue an academic career in clinical cancer research.

Emiliano Calvo

WORKSHOP FACULTY

The listed Faculty are from the 2017 Workshop. Please visit www.ecco-org.eu/workshop for updates on Faculty for the 2018 Workshop.

Representing ECCO

Stefan Sleijfer	Erasmus University Medical Centre, Rotterdam, Netherlands
Nadia Harbeck	University of Munich, Munich, Germany
Emiel Rutgers	Netherlands Cancer Institute, Amsterdam, Netherlands
Jan Bussink	Radboud University Medical Centre, Nijmegen, Netherlands

Representing AACR

Lee M. Ellis	The University of Texas – MD Anderson Cancer Center, Houston, USA
Robert G. Maki	Monter Cancer Center, Northwell Health and Cold Spring Harbor Laboratory, New York, USA
Charles R. Thomas	Oregon Health Sciences University, Portland, USA

Representing EORTC

Corneel Coens	EORTC Headquarters, Brussels, Belgium
Vassilis Golfopoulos	EORTC Headquarters, Brussels, Belgium
Saskia Litière	EORTC Headquarters, Brussels, Belgium

Representing ESMO

Emiliano Calvo	START Madrid, Centro Integral Oncológico Clara Campal, Madrid, Spain
Johann de Bono	Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, Sutton, United Kingdom
Jordi Rodón	The University of Texas – MD Anderson Cancer Center, Houston, USA

Additional Faculty

Carine Bellera	Institut Bergonié, Bordeaux, France
Francois-Clement Bidard	Institut Curie, Paris, France
Sarah Brown	University of Leeds, Leeds, United Kingdom
Laura Chow	University of Washington – Seattle Cancer Care Alliance, Seattle, USA
Angelo De Marzo	Johns Hopkins University School of Medicine, Baltimore, USA
Elisabeth de Vries	University Medical Centre Groningen, Groningen, Netherlands
Chaitanya Divgi	Columbia University Medical Center, New York, USA
Elizabeth Garrett-Mayer	Medical University of South Carolina, Charleston, USA
Viktor Grünwald	Medical University Hannover, Hannover, Germany
John Haanen	Netherlands Cancer Institute, Amsterdam, Netherlands
Emma Hall	The Institute of Cancer Research, Sutton, United Kingdom
Paul Haluska	Merck Research Laboratories, Rahway, USA
Susan Hilsenbeck	Baylor College of Medicine, Houston, USA
Michail Ignatiadis	Institut Jules Bordet, Brussels, Belgium
Michael Lahn	Incyte, Geneva, Switzerland
Gwénaél Le Teuff	Institut Gustave Roussy, Villejuif, France
Martijn Lolkema	Erasmus University Medical Centre, Rotterdam, Netherlands
Victor Moreno	START Madrid FJD, Madrid, Spain
Vicki Morrison	University of Minnesota, Minneapolis, USA
David Olmos	Spanish National Cancer Research Centre (CNIO), Madrid, Spain
Piotr Rutkowski	Maria Skłodowska-Curie Memorial Cancer Center, Warsaw, Poland
Bettina Ryll	Melanoma Patient Network Europe, Uppsala, Sweden
Daniel Sabanés Bové	F. Hoffmann-La Roche Ltd., Basel, Switzerland
Matthew Sydes	University College London, London, United Kingdom
Christian Michel Zwaan	Erasmus MC - Sophia Children's Hospital, Rotterdam, Netherlands

WORKSHOP OVERVIEW

The ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research is an educational programme that introduces junior clinical oncologists in any oncology subspecialty to the principles of good clinical trial design. Beginning in 1999, this well-recognised and CME accredited Workshop progressed with each subsequent edition to reinforce its value.

WHY DO WE NEED A WORKSHOP?

The presence of a strong research base is essential to the future of good quality cancer care. Clinical scientists who are able to set up and run high-quality clinical trials are vital to the advancement of new therapies. The ultimate goal is to develop a robust, expanding base of well-trained clinical researchers by providing them with the essential training to conduct better clinical and translational trial designs.



KEY BENEFITS OF ATTENDING THE WORKSHOP

- Exclusive access to and mentoring by up to 40 highly experienced clinical experts in the field of oncology from Europe and North America
 - Exceptional opportunity to meet and network with an elite group of up to 80 junior clinical oncologists from all over the world
 - Outstanding educational experience in a unique setting conducive to professional relationship building, learning and development
 - Access to a variety of educational tools designed to enable participants to develop their initial protocol proposal into a complete protocol
 - Active promotion of productive dialogues between young cancer specialists and the European and non-European Cancer Societies
 - Establishment of a network for educational exchanges between young cancer clinicians worldwide
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SESSION OVERVIEW

The Scientific Sessions have been specially formulated to cater for all learning needs and will use one of the following four formats:



Protocol Development Group Sessions

These sessions form the core activity of this Workshop and allow students to complete the writing of their protocol by applying the knowledge acquired during the Workshop. Students will receive extensive feedback on their trial concepts from designated faculty within assigned groups comprising a maximum of ten students.



Meet your Expert Sessions

One-to-one sessions where students will have access to experts providing individual counselling on protocol related issues and advice on career development.



Small Group Discussion Sessions

Sessions that focus on topics that are essential to the success of clinical trials and facilitating discussion on and around the difficulties and challenges of a particular type of trial. Attendance to these sessions is limited to maximise interaction and information exchange.



Lectures and Panel Discussions

Presentations by key experts on specific topics will provide participants with an overview of the design and implementation of high-quality clinical trials. This will be followed by a panel discussion during which Faculty and students can explore issues raised during the talks in greater depth.

PRELIMINARY WORKSHOP PROGRAMME

Session topics and schedule are subject to change;
please visit www.ecco-org.eu/workshop for updates.

Saturday 16 June 2018

- 12:00 – 15:45 **Registration**
- 14:30 - 16:00 **Independent Protocol Work**
- 16:00 - 16:30 **Welcome and Workshop Overview**
- 16:30 – 17:00 **Keynote Lecture**
- 17:00 – 17:30 **Introductory Lecture Session**
Questions to ask yourself in designing a clinical trial
- 17:30 – 20:00 **Protocol Development Session 1:
Protocol Presentation**
Students present their study concept. Faculty and students discuss the protocol concept sheet and the single key question for each study concept.

Sunday 17 June 2018

- 08:30 – 10:00 **Lecture Session 1**
Phase I trials of chemotherapy and targeted drugs
Phase II trials (+ trials spanning phase I & II)
Phase III trials (+ trials spanning phase II & III)
- 10:15 – 12:15 **Lecture Session 2**
Basic biostatistics for the clinical trialist (part I)
Basic biostatistics for the clinical trialist (part II)
Choosing and measuring endpoints in clinical trials
Immunotherapy trials
- 13:15 – 15:45 **Protocol Development Session 2:
Review of Concept Sheets & Design
Development**
Faculty guide students to complete their protocol concept sheets and develop an overall study design to meet the established objective.
- 16:00 – 18:00 **Small Group Discussion Sessions 1-8**
- 18:00 – 19:40 **Meet your Expert Session 1**
- 20:45 **Independent Protocol Work**

Monday 18 June 2018

- 08:30 – 10:00 **Lecture Session 3**
Integrating surgery in multi-modality trials – implications for design, endpoints and quality control
Special considerations in combined treatment trials (Chemo-radiation) – implications for design, endpoints and quality control
Imaging biomarkers – implications for design endpoints and quality control
- 10:15 – 11:45 **Lecture Session 4**
Prognostic and predictive markers for patient selection
Liquid biopsies and CTCs
Biomarkers & adaptive clinical trial design
- 13:15 – 15:45 **Protocol Development Session 3: Study Outlines**
Study concepts translate into a short study outline detailing trial objectives, statistical design, target population, biomarkers and translational research opportunities.
- 18:15 - 19:45 **Team Building Activity**
- 20:45 **Interdependent Protocol Work**

Tuesday 19 June 2018

- 08:30 – 09:30 **Lecture Session 5**
Role of pharmacokinetics & pharmacodynamics in clinical trials
Overview of dose finding designs for phase I clinical trials
- 09:45 – 11:15 **Lecture Session 6**
Ethics and patient participation in cancer clinical trials
Patient-oriented endpoints/QoL
Pragmatic vs non-pragmatic trials: Addressing economic aspects of clinical trials
- 13:15 – 15:45 **Protocol Development Session 4: Protocol Development**
Protocol development based on the outline with further details on eligibility criteria, evaluations schedule, treatment regimen and data/sample collection.
- 16:00 – 19:20 **Independent Protocol Work**
- 16:00 – 18:00 **Small Group Discussion Sessions 9-15**
- 18:00 – 19:20 **Meet your Expert Session**
- 20:30 **Independent Protocol Work**

Wednesday 20 June 2018

- 08:30 – 09:30 **Lecture Session 7**
Research integrity and its effects on drug development
Data and safety monitoring and independent study review - regulatory and other practical issues
- 10:00 – 11:00 **Lecture Session 8**
Common errors in statistics
Practical implementations of a clinical trial
- 13:15 – 15:45 **Protocol Development Session 5: Challenges and Feasibility**
Protocol finalisation and discussion on challenges, feasibility and informed consent.
- 17:00 – 19:00 **Meet your Expert Session 4**
- 20:00 **Independent Protocol Work**

Thursday 21 June 2018

- 08:30 – 09:00 **Closing Lecture Session**
Translating cancer research into targeted therapeutics
- 09:45 – 12:45 **Protocol Development Session 6: Post-Protocol Management**
Final protocol discussions about various post-protocol implementation aspects. If possible, students present their final protocols to other PDG Faculty (mock IRB review).
- 13:45 – 18:00 **Independent Protocol Work**
- 18:00 **Workshop evaluations & final protocol due**

Friday 22 June 2018

Departure

KEY DATES

- **5 DECEMBER 2017** - Application submission opens
- **5 FEBRUARY 2018** - Application submission deadline
- **16-22 JUNE 2018** - 20th MCCR Workshop

ONLINE APPLICATION PROCEDURE

Applications to participate in the ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research can only be submitted electronically.

For the online application please go to the MCCR Workshop website at www.ecco-org.eu/workshop and follow the instructions on the screen.

MINIMUM SELECTION CRITERIA

Candidates must have completed one year of clinical training at the time of application and be within five years of completion of Residency/Fellowship training in one of the following disciplines:

- Junior physician specialising in oncology;
- Junior clinical professional managing cancer patients (i.e. dermatologist, gynaecologist, haematologist, neuro-oncologist, urologist);
- Junior radiologist or pathologist with a strong involvement in cancer care.

Have a major interest in clinical research and intend to develop a career in that field.

Aim to write and conduct a clinical protocol for a study not previously performed, nor written, which is also considered feasible within the institutional setting and the time of completion of the candidate's clinical training.

Have support of the Direct Supervisor/Mentor and sustained commitment in the years following the Workshop.

Be fluent in written and spoken English and have good computer skills.

GENERAL INFORMATION & CONDITIONS OF PARTICIPATION

Selection of Participants

Participation to the MCCR Workshop is limited to 80 participants.

The Workshop Review Committee will evaluate the applications and base its decision on a number of factors including:

- Quality and feasibility of the proposed protocol concept and the letters of commitment submitted;
- Individual career path in medical training and competence in clinical cancer research;
- Support of relevant departments and/or institutions to help conduct the clinical trial.

The selection of applications is at the sole discretion of the Workshop Review Committee. Whilst feedback on the application process and selection is welcome, the Workshop Review Committee will not enter into any discussions regarding the final decision.

For further details on application requirements, the selection criteria and process, please visit: www.ecco-org.eu/workshop

Workshop Materials

As of May 2018, selected participants will have access to the MCCR Workshop portal, an online resource platform for all educational Workshop material. The portal will also be used as a message centre and as a platform for all organisational aspects of the Workshop.

Participation Fee

In order to attend the MCCR Workshop, all selected participants will be required to pay the Workshop Participation Fee of 2.800 EUR (including local VAT).

The Workshop Participation Fee includes:

- Exclusive access to and mentoring by highly experienced clinical experts in oncology;
- Access to Workshop portal, the online resource platform for all Workshop material;
- Accommodation at the Workshop venue from 16-22 June 2018;
- Food and beverages throughout the duration of the Workshop;
- Round-trip travel arrangements from closest home airport to Amsterdam or travel reimbursement as specified in the Workshop Reimbursement Policy for trips arranged by the participant;
- Shuttle bus service from Amsterdam airport to the Workshop venue on Saturday 16 June 2018;
- Shuttle bus service from the Workshop venue to Amsterdam airport on Friday 22 June 2018.

Please note: This Workshop is supported by generous grants from national, European and international cancer organisations and educational grants from corporate sponsors.

TESTIMONIALS

The MCCR Workshop provides the necessary tools one needs to conduct clinical trials that yield clear results and have the potential to impact patient care.

Katarzyna Kozak, Poland - Edition 19

Lecture sessions, interactive discussions, daily “meet your expert” sessions, constant networking with faculty members and other fellows contribute to your learning and asking the right questions to be addressed in your research protocol.

Claudia Cardone, Italy - Edition 19

The MCCR Workshop provides an invaluable and rare opportunity to receive close guidance from world-class mentors and sage, experienced statisticians – all of whom were generous with their time and experience.

Aly-Khan Lalani, USA - Edition 19

I now truly understand the basis of clinical trial protocol development and implementation. I arrived with an outline and went home with a protocol that is almost ready for regulatory review.

Lizza Hendriks, Netherlands - Edition 19



Flims Alumni Club
www.ecco-org.eu/workshop

Flims Alumni Club Membership is free and open solely to young professionals and Faculty who have participated in the ECCO-AACR-EORTC-ESMO Workshops on Methods in Clinical Cancer Research.



Workshop Venue

Woudschoten Hotel & Conferentiecentrum
Woudenbergseweg 54
3707 HX Zeist
Netherlands

16-22
JUNE
2018

Application submission opens: 5 December 2017
Application submission deadline: 5 February 2018

Workshop Secretariat

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