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
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.

Stefan Sleijfer

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Lee M. Ellis

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

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

WORKSHOP FACULTY

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
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Representing AACR
Lee M. Ellis
The University of Texas – MD Anderson Cancer Center, Houston, USA

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Johann de Bono
Royal Marsden NHS Foundation Trust and The Institute of Cancer Research, Sutton, United Kingdom

Victor Moreno
START Madrid FJD, Madrid, Spain

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

Representing Additional Faculty
Carina Belleu
Institut Bergonie, Bordeaux, France

Francoise-Germain Bidard
Institut Curie, Paris, France

Sarah Brown
University of Leeds, Leeds, United Kingdom

Laura Cheow
Johns Hopkins University School of Medicine, Baltimore, USA

Elizabeth de Vries
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Bettina Kray
Microsoft Research Laboratory, Cambridge, United Kingdom

Piotr Rutkowski
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Bettina Kray
Microsoft Research Laboratory, Cambridge, United Kingdom

Christian Michal Zwean
Emerence BC - Sophia Children’s Hospital, Rotterdam, Netherlands

Piotr Rutkowski
Maria Skłodowska-Curie Memorial Cancer Centre, Warsaw, Poland

Bettina Kray
Microsoft Research Laboratory, Cambridge, United Kingdom

Christian Michal Zwean
Emerence BC - Sophia Children’s Hospital, Rotterdam, Netherlands

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

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

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 lifetime experience where you will learn how to perform clinical research in a unique environment with highly motivated students and top clinical researchers.

Stefan Sleijfer
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

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.
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**

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>12:00 – 15:45</td>
<td>Registration</td>
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<tr>
<td>14:30 – 16:00</td>
<td>Independent Protocol Work</td>
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<tr>
<td>16:00 – 17:00</td>
<td>Welcome and Workshop Overview</td>
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<tr>
<td>16:30 – 17:00</td>
<td>Keynote Lecture</td>
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<td>17:00 – 17:30</td>
<td>Introductory Lecture Session Questions to ask yourself in designing a clinical trial</td>
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<tr>
<td>17:30 – 20:00</td>
<td>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.</td>
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**Sunday 17 June 2018**

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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>08:30 – 10:00</td>
<td>Lecture Session 1: Phase I trials of chemotherapy and targeted drugs Phase II trials (+ trials spanning phase I &amp; II) Phase III trials (+ trials spanning phase II &amp; III)</td>
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<td>10:15 – 12:15</td>
<td>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</td>
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<td>13:15 – 15:45</td>
<td>Protocol Development Session 2: Review of Concept Sheets &amp; Design Development Faculty guide students to complete their protocol concept sheets and develop an overall study design to meet the established objective.</td>
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<td>16:00 – 18:00</td>
<td>Small Group Discussion Sessions 1-8</td>
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<td>18:00 – 19:40</td>
<td>Meet your Expert Session 1</td>
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<tr>
<td>20:45</td>
<td>Independent Protocol Work</td>
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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 (Chemoradiation) – 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 Independent 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

Protocol development based on the outline with further details on eligibility criteria, evaluations schedule, treatment regimen and data/sample collection.

16:00 – 18:20 Independent Protocol Work

16:00 – 18:00 Small Group Discussion Sessions 9-15

18:00 – 19:20 Meet your Expert Session 4

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

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

18:00 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.

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

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 review.

Lizza Hendriks, Netherlands - Edition 19

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

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

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