



**EUROPEAN  
CANCER  
ORGANISATION**



# METHODS IN CLINICAL CANCER RESEARCH

The 14th intensive Workshop for junior clinical oncologists in any clinical research specialty area, to learn the essentials of clinical trial design

**Waldhaus Flims, Switzerland**

Applications Open: 14 December 2011  
Applications Close: 13 February 2012

**23-29  
JUNE  
2012**

[www.ecco-org.eu](http://www.ecco-org.eu)

The most stimulating, interactive and multidisciplinary educational activity on clinical trial methodology in oncology. Outstanding, top-ranking international faculty. Highly motivated, selected workshop participants with very heterogeneous clinical, scientific and cultural background. A unique, once-in-a-lifetime opportunity for young clinical cancer researchers.



## WORKSHOP DIRECTORS

### Representing ECCO

Patrick Schöffski

University Hospital Gasthuisberg, Leuven, Belgium

### Representing AACR

Stephen M. Hahn

University Hospital of Pennsylvania, Philadelphia, USA

### Representing EORTC

Jan Bogaerts

EORTC Headquarters, Brussels, Belgium

### Representing ESMO

Johann de Bono

Royal Marsden Hospital, Sutton, United Kingdom



A unique and stimulating environment optimising interactions between leading international faculty and young oncologists. An exceptional place for the next generation of cancer clinical researchers to build from their peers the foundations of the 21st century cancer treatment therapeutic strategies.

I have worked over the years with fellows and junior faculty members who have attended the Flims course and have found them to be exceptionally well-prepared to perform high quality clinical research.

I attended Flims in 1999 and it changed my career and my understanding of cancer research.

## Workshop Faculty

### Representing ECCO

Peter Naredi  
Riccardo Riccardi

University Hospital Umeå, Umeå, Sweden  
Catholic University of the Sacred Heart, Rome, Italy

### Representing AACR

Patricia M. LoRusso  
Ignacio Wistuba

Barbara Ann Karmanos Cancer Institute, Detroit, USA  
The University of Texas, MD Anderson Cancer Center, Houston, USA

### Representing EORTC

Sandrine Marreaud  
Stefan Sleijfer

EORTC – European Organisation for Research and Treatment of Cancer, Brussels, Belgium  
Erasmus University Medical Center, Daniel den Hoed Cancer Center, Rotterdam, The Netherlands

### Representing ESMO

Christian Dittrich  
Chris H. Takimoto

Ludwig Boltzmann Institute for Applied Cancer Research, Vienna, Austria  
Ortho Biotech Oncology Research and Development, Radnor, Pennsylvania, USA

### Additional Faculty

Powel H. Brown  
Susan Percy Ivy  
Yolande Lievens  
Lara Lusa  
David Machin  
Xavier Paoletti  
Lesley K. Seymour  
Sally Stenning  
Stefan Michiels  
Piotr Rutkowski

MD Anderson Cancer Center, Houston, Texas, USA  
National Cancer Institute, Bethesda, Maryland, USA  
Leuven Cancer Institute, University Hospital Gasthuisberg, Leuven, Belgium  
Institute of Biomedical Informatics, Ljubljana, Slovenia  
University of Leicester, Leicester, United Kingdom  
Institut Curie, Paris, France  
Queen's University, Kingston, Canada  
MRC Cancer Trials Unit, London, United Kingdom  
Institut Bordet, Brussels, Belgium  
Oncology Centre Warsaw, Poland

Additional Faculty will be announced. Faculty disclosures will be provided in the Workshop Syllabus



## WORKSHOP OVERVIEW

*The ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research, better known as the 'Flims' Workshop, is an educational programme that introduces junior clinical oncologists in any oncology subspecialty to the principles of good clinical trial design. Since 1999, this extremely successful joint Workshop has taken place in the small town of Flims, nestled in the Swiss Mountains.*



## 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. This Workshop was established to reverse the decline in numbers of clinical scientists. The ultimate goal: to develop a robust, expanding base of well-trained clinical researchers by providing them with the training they need to conduct better clinical/translational trial designs.*

**Very impressive expertise.**

Guilhem Roubaud

## 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 the U.S.A;
- Exceptional opportunity to meet and network with an elite group of 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.

*It's so fantastic to have a patient representative at FLIMS, especially one with clinical trial participation, support group and advocacy experience.*

Alysa Fairchild



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



#### Protocol Development 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 detailed critiques of their proposals from the experts in the field in small groups comprising a maximum of 10 people.

#### Meet Your Expert Sessions

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



#### Small Group Discussion Sessions

These sessions focus on topics that are essential to the success of clinical trials as well facilitating discussion on and around the difficulties and challenges of a particular type of trial. They are limited in size to maximise exchange of information.

#### Lectures and Panel Discussions

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



## PRELIMINARY WORKSHOP PROGRAMME

The workshop starts on **Saturday 23 June 2012** so participants are asked to arrive in Flims no later than **04.00pm** as the workshop will start with a mandatory pre-test at 04.00 p.m

### Saturday 23 June 2012

12:00 – 16:00	Registration
16:00 – 17:00	Pre-test (mandatory for all fellows)
17:00 – 17:35	<b>Welcome and Workshop overview</b>
17:35 – 18:15	<b>Introductory lecture:</b> Questions to ask yourself in designing a clinical trial
18:30 – 20:30	<b>Protocol development session 1</b>



THE best lecture I have heard on statistics! Normally is rather dry... very good.

Caroline Michie

### Sunday 24 June 2012

08:30 – 10:00	<b>Lecture session 1</b> <ul style="list-style-type: none"><li>Basic biostatistics for the clinical trialist I</li><li>Basic biostatistics for the clinical trialist II</li><li>Common errors in statistics</li></ul>
10:15 – 11:30	<b>Small Discussion Groups - session 1</b>
11:30 – 12:30	<b>Small Discussion Groups - session 2</b>
13:30 – 15:30	<b>Protocol development session 2</b>
16:00 – 17:00	<b>Small Discussion Groups - session 3</b>
17:15 – 18:15	<b>Small Discussion Groups - session 4</b>
18:15 – 19:30	Individual work on protocols
20:45	Individual work on protocols
20:45 – 22:45	<b>Meet-your-expert session</b> (office hours)

## Monday 25 June 2012

- 08:15 – 09:15 **Lecture session 2**
- Special considerations in trials of radiation therapy – implications for design, endpoints and quality control
  - Special considerations in combined treatment trials (Chemo-radiation) – implications for design, endpoints and quality control
- 09:15 – 10:15 **Lecture session 3**
- Integrating surgery in multi-modality trials – implications for design, endpoints and quality control
  - Design of studies with immunological agents
- 10:30 – 11:30 **Lecture session 4**
- Prognostic and predictive markers for patient selection
- 11:30 – 15:00 Individual work on protocols
- 15:00 – 17:00 **Protocol development session 3**
- 17:00 Group activity
- 21:00 Individual work on protocols

Excellent.  
Taught me what  
I need to know  
in a short time  
period.

Alastair Greystoke

## Tuesday 26 June 2012

- 08:00 – 09:30 Individual work on protocols
- 09:30 – 11:00 **Protocol development session 4**
- 11:00 – 12:30 **Lecture session 5**
- Role of pharmacokinetics in clinical trials
  - What can imaging contribute to your trial?
  - CRM & Bayesian designs – practical aspects of implementation
- 13:30 – 14:30 **Lecture session 6**
- Ethical principles in the conduct of clinical trials
  - Patient-oriented endpoints / Quality of Life
  - Round table – Ethical issues and informed consent - a case-based discussion
- 14:45 – 16:45 **Meet-your-expert session** in parallel with Small Discussion Group sessions and individual work on protocols
- 14:45 – 15:45 **Small Discussion Groups - session 5**
- 15:45 – 16:45 **Small Discussion Groups - session 6**
- 17:00 – 19:00 Individual work on protocols
- 20:30 – 21:30 **Meet-your-expert session** (continued)

## Wednesday 27 June 2012

- 08:00 – 09:00 Individual work on protocols
- 09:00 – 10:00 **Small Discussion Groups - session 7**
- 10:00 – 11:00 **Lecture session 7**
- Reading the literature with a critical eye
  - Data and safety monitoring and independent study review
- 11:15 – 12:30 **Lecture session 8:** “Barriers to successful implementation”
- Regulatory and other practical issues
  - Improving patient participation in cancer clinical trials
  - Panel discussion
- 13:30 – 15:30 **Protocol development session 5**
- 15:45 – 19:00 Individual work on protocols
- 20:15 Individual work on protocols



## Thursday 28 June 2012

- 08:30 – 10:00 **Lecture session 9**
- Molecular targeting and the prevention-therapy convergence
  - Translating cancer research into targeted therapeutics
  - Haematology as a role model for drug development
- 10:15 – 11:00 **Small Discussion Groups - session 8**
- 11:15 – 13:15 **Protocol development session 6**
- 14:15 – 16:00 Individual work on protocols
- 16:00 – 17:00 Post-test (mandatory for all fellows)
- 18:00 **Final protocol due**
- 20:00 Reception and dinner

## Friday 29 June 2012

Departure

Although I'm not a radiation oncologist, I enjoyed this lecture. I learnt about the difference between radiation oncology study and medical oncology study.

Ogita Shin

## ONLINE APPLICATION PROCEDURE

Applications to participate in the ECCO-AACR-EORTC-ESMO Workshop on Methods in Clinical Cancer Research can **only** be **submitted electronically**. Paper submissions will NOT be accepted.

For the online application please go to Workshop website at: [www.ecco-org.eu](http://www.ecco-org.eu) (select 'Education>Flims>Flims 14') and follow the instructions on the screen.

Deadline for receipt of applications: Monday 13 February 2012.

## MINIMUM SELECTION CRITERIA

1. Candidates must be in at least the 2nd year of training and within 5 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. urologist, gynaecologist, neuro-oncologist, haematologist);
  - Junior radiologist or pathologist with a strong involvement in cancer care.
2. Have a major interest in clinical research and intend to develop a career in that field.
3. 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.
4. Be fluent in written and spoken English and have good computer skills.
5. Have support from the Supervisor/ Head of Department and sustained commitment in the years following the Workshop.

## GENERAL INFORMATION & CONDITIONS OF PARTICIPATION

### Selection of Participants

Participation to the 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 Workshop Review Committee's decision is final and whilst we welcome your feedback about the application process, 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](http://www.ecco-org.eu)

### Workshop Materials

As of May 2012, selected participants will have access to the Flims Intranet, an online resource platform for all educational Workshop material. The Flims Intranet 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 Workshop, all selected participants will be required to pay the Workshop Participation Fee of 2.000 EUR (local VAT incl.).

Applicants from countries with limited resources may apply for an exemption of the Workshop Participation Fee. Each application will be assessed on a case-by-case basis in accordance with the evaluation criteria.

The Workshop Participation Fee offsets only part of the actual Workshop costs per student, which includes the following:

- Round-trip travel arrangements from closest home airport to Zurich or travel reimbursement as specified in the Workshop Reimbursement Policy for trips arranged by the participant;
- Shuttle bus service from Zurich airport to the Workshop Venue on Saturday 23 June 2012;
- Shuttle bus service from the Workshop Venue to Zurich airport on Friday 29 June 2012;
- Accommodation in the Workshop Venue from 23-29 June 2012 (for single room accommodation a supplement applies)
- Food and beverages (5 meals/day) throughout the duration
- Access to Flims Intranet, the online resource platform for all Workshop material.

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

## Flims Alumni Club

<http://www.ecco-org.eu/Flims>

The Flims Alumni Club (FAC) is a non-profit organisation and an Advisory Member of ECCO, the European CanCer Organisation. It was established in 2001 and is open solely to young professionals and Faculty who have participated in the ECCO-AACR-EORTC-ESMO Workshops on 'Methods in Clinical Cancer Research' in Flims, Switzerland.

The FAC responds to the interests and needs of highly driven junior clinical oncologists by offering an expanding range of benefits exclusive to its Members. These include access to the FAC Members Directory and a direct networking opportunity via the Flims Alumni Club LinkedIn Group. Through these channels the FAC aims to develop a sense of community by fostering interactions amongst its members and also promote a productive dialogue between young cancer specialists and the European and non-European Cancer Societies.





**EUROPEAN  
CANCER  
ORGANISATION**



## Workshop Venue

Waldhaus Flims Hotel  
Via dil Parc  
7018 Flims  
Switzerland  
[www.waldhaus-flims.ch](http://www.waldhaus-flims.ch)

23-29  
JUNE  
2012

## Workshop Secretariat

ECCO – the European CanCER Organisation  
Avenue E. Mounier 83  
1200 Brussels  
Tel.: +32 (0) 2 775 02 01  
Fax: +32 (0) 2 775 02 00  
E-mail: [samira.essiaf@ecco-org.eu](mailto:samira.essiaf@ecco-org.eu)

[www.ecco-org.eu](http://www.ecco-org.eu)