Federation of European Cancer Societies (FECS)

American Association for Cancer Research (AACR)

American Society of Clinical Oncology (ASCO)

Jointly organise

METHODS IN CLINICAL CANCER RESEARCH

The 3rd intensive workshop for European junior clinical oncologists of all disciplines to learn the essentials of clinical trials design

Supported by a grant from the U.S. Department of Health and Human Services, National Cancer Institute

23 - 28 June 2001
Park Hotel Waldhaus, Flims, Switzerland

PROGRAMME COMMITTEE

Chairpersons
Jean Pierre Armand (FECS), Daniel D. Von Hoff (AACR), Elizabeth A. Eisenhauer (ASCO)

FECS - AACR - ASCO representatives on the core faculty
Otis Brawley (USA), Gary M. Clark (USA), Otilia Dalesio (NL), Elisabeth de Vries (NL), S. Gail Eckhardt (USA), Alex Eggermont (NL), Didier Frappaz (F), Ian Hart (UK), W. Gillies McKenna (USA), Mace L. Rothenberg (USA), Pierre Scalliet (B), Patrick Therasse (B), Jacob Verweij (NL)

APPLICATION DEADLINE 15 FEBRUARY 2001

APPLICATION PROCEDURE

1 **Complete the attached application form.**

2 **Submit a one-page description of the clinical therapeutic trial protocol** you intend to write during the workshop. This description should contain all of the following elements:

a. Title: Example: "Will an antisense to HER-2/*neu* increase the antitumor activity of cisplatin?"
b. Background: No more than 2 sentences explaining why the trial should be undertaken.
c. Proposed design: No more than one paragraph describing the elements of the trial. A schematic diagram may be used instead of a narrative.
d. Proposed endpoints: No more than two sentences explaining how the results of the trial will be evaluated.

These responses will be used to assign participants to appropriate faculty advisors. Please note that only feasible protocols will be considered.

3 **Submit a letter explaining why you wish to participate in this workshop.** Be sure that your letter provides the following information:

a. Please indicate the date you finalised your specialty training (month, year) and give a description of your previous research background.
b. The nature of the programme in which you are scheduled to participate for the next two years.
c. A description of the kind of programme in which you would like to be working in five years.
d. An explanation of how participation in the workshop will help you to design and conduct the trial to be outlined in your protocol (see Item 2., above).
e. A commitment to participate in the long-term evaluation of this workshop by maintaining contact with the organisers and responding to questionnaires when requested.

4 **Submit a copy of your personal C.V.**

5 **Submit a letter from your Supervisor/Department Head** in support of your application for this workshop.

This letter should include the following:

a. A description of the length of time and the capacity in which the writer has known the applicant.
b. An assessment of the quality of the applicant's performance in his or her current programme.
c. A commitment to make every reasonable effort to enable the candidate to conduct a clinical trial based on the protocol produced at the workshop.
d. A commitment to participate in the long term evaluation of this workshop by reporting the results of the trial conducted by the candidate to the organizers and by responding to questionnaires that may be submitted by the organisers.

1 Applications will not be considered unless they contain all documents described above, i.e. your application form, the one-page description of your proposed protocol, your letter of application, the letter of support from your supervisor/ department head and your personal C.V.

2 Please submit 5 copies of the application package.

3 The deadline for receipt of applications in the FECS office is **15 February 2001.**

GOALS OF THE WORKSHOP

Errors made in the design and conduct of a clinical trial can make it impossible for the trial to provide a definitive answer about the effectiveness of a new approach. Poor design can thus lead to the abandonment of promising avenues of research that are based on sound basic scientific work and to delays in the introduction of new treatments into the general practice of medical oncology. FECS, AACR and ASCO have responded to this problem by designing jointly a programme that will:

1. Introduce junior clinical oncologists in any oncology subspecialty to the principles of good clinical trials design; i.e., give them the tools they need to conduct clinical trials that will yield clear results which investigators can use to proceed to the next level of research.
2. Expose junior clinical scientists to the full spectrum of challenges in clinical research, from conventional antineoplastic agents and multidisciplinary treatment regimens to gene therapy, in the expectation that they will then want to devote all or a portion of their future careers to some aspect of clinical research.
3. Develop a cadre of well-trained, experienced researchers whose expertise will foster better clinical trials design and thereby hasten the introduction of improved regimens for cancer therapy and prevention into everyday medical practice and patient care.

SCIENTIFIC SESSION FORMATS

The workshop scientific programme will consist of three types of activities to serve a variety of didactic needs:

▶ **Protocol development sessions** during which each participant develops a concept sheet for a clinical trial protocol and, through extensive mentoring, designs and completes the writing of the protocol before the end of the workshop. These sessions constitute the core activity of the workshop and allow students to apply the lessons being learned in the workshop to their own programmes and to receive detailed critiques of their proposals from experienced scientists.

▶ **Parallel group discussion sessions** on special topics. These sessions treat topics that are either essential to the success of many different kinds of clinical trials or offer an opportunity for students to discuss the intricacies of a particular type of trial in a small group session. These sessions will be limited in size to maximise information exchange.

▶ **Lectures on specific topics** presented by experts in the field. These talks give participants a necessary overview of the design and conduct of high-quality clinical trials. Where appropriate, lectures on related topics are followed by a panel discussion during which faculty and students can explore issues raised during the talks in greater depth.

CHAIRPERSONS

Jean Pierre Armand	Institut Gustave-Roussy Villejuif, France
Elizabeth A. Eisenhauer	Queen's University Kingston, Ontario, Canada
Daniel D. Von Hoff	Arizona Cancer Center Tucson, USA

WORKSHOP FACULTY

Søren M. Bentzen	Gray Laboratory Cancer Research Trust Middlesex, United Kingdom
Georges R. Blackledge	AstraZeneca Cheshire, United Kingdom
Otis W. Brawley	National Cancer Institute Rockville, USA
Marc Buyse	International Institute for Drug Develop Brussels, Belgium
Gary M. Clark	Breast Cancer Center Baylor College of Medicine Houston, USA
Charles A. Coltman Jr	Cancer Therapy & Research San Antonio, USA
Otilia Dalesio	The Netherlands Cancer Institute Amsterdam, The Netherlands
Elizabeth G. E. de Vries	University Hospital Groningen, The Netherlands
Gail Eckhardt	University Hospital Denver, USA
Alex M.M Eggermont	Rotterdam Cancer Institute Rotterdam, The Netherlands
Margareth Foti	American Association for Cancer Research Philadelphia, USA
Didier Frappaz	Centre Léon Berard Lyon, France
Ian R. Hart	Richard Dimbleby Department of Cancer Research London, United Kingdom
Ian Judson	Institute of Cancer Research Sutton, Surrey, United Kingdom
Andrew Kramar	Centre Val d'Aurelle Montpellier, France
Ferdy J. Lejeune	Centre Hospitalier Univ Vaudois Lausanne, Switzerland
Anthony Man	Novartis Pharma AG Basel, Switzerland
Gillies W. McKenna	University Hospital of Pennsylvania Philadelphia, USA
John O'Quigley	University of California San Diego La Jolla, France
Elaine Rankin	University of Dundee Dundee, United Kingdom
Mace Rothenberg	Vanderbilt University Nashville,USA
Pierre Scalliet	UCL Clinique Universitaire St.Luc Brussels, Belgium
Hans J. Schmoll	Martin Luther Universität Halle,Germany
Alberto Sobrero	Universita di Udine Udine, Italy
Baudouin Standaert	Health Economics Europe, AMGEN Brussels, Belgium
Richard Sylvester	EORTC Data Center Brussels, Belgium
Ian Tannock	Princess Margaret Hospital Toronto, Canada
Patrick Therasse	EORTC Data Center Brussels, Belgium
Valter Torri	Istituto Mario Negri Milan, Italy
Martine Van Glabbeke	EORTC Data Center Brussels, Belgium
Jacob Verweij	Dr. Daniel den Hoed Cancer Center Rotterdam, The Netherlands
Steve Weitman	Institute for Drug Development San Antonio, USA

WORKSHOP PROGRAMME

Day 1 — Saturday 23 June 2001

12.00 - 16.00	Faculty meeting / Registration
16.00 - 17.00	Pretest
17.00 - 18.45	Welcome and Lecture Session 1 • Introduction to FECS - AACR - ASCO and the workshop • Lecture 1: CaBOOM: Pitfalls of clinical trials • Lecture 2: Translating basic science into new therapeutic strategies
19.00 - 20.00	Protocol development session 1 (What is your primary question?)
20.15 - 22.00	*Dinner*

Day 2 — Sunday 24 June 2001

08.30 - 12.00	Lecture session 2 • Lecture 3: Basic biostatistics for the clinical trialist • Lecture 4: Pre-clinical data for clinical trials • Lecture 5: Phase I trials • Lecture 6: Clinical pharmacology and pharmacodynamics
12.00 - 13.00	*Lunch*
13.00 - 15.30	Protocol development session 2 (Endpoint/design)
15.30 - 18.30	Team building session = informal networking
19.30 - 20.30	*Dinner*
20.45 - 23.00	Work on protocols • in parallel: Small Round Table sessions = informal question period

Day 3 — Monday 25 June 2001

08.30 - 12.00	Lecture Session 3 • Lecture 7: Phase II trials • Lecture 8: Phase III trials • Lecture 9: Design of clinical trials related to biological agents • Lecture 10: Statistical review on clinical trial design
12.00 - 14.30	Protocol development session 3 (Prepare protocol) *Lunch*
15.00 - 16.30	Work on protocols Small Discussion Groups – in parallel
17.00 - 18.30	Work on protocols Small Discussion Groups – in parallel
19.30	*Dinner*
20.30 - 22.00	Round Table discussion Ethical principles in the conduct of clinical trials

Day 4 — Tuesday 26 June 2001

08.30 - 10.00	Lecture Session 4 • Lecture 11: Unique aspects of trials in surgical oncology • Lecture 13: Unique aspects of trials in radiation oncology
10.30 - 12.00	Protocol development session 4 (Review of first protocol draft)
12.00 - 13.00	*Lunch*
13.00 - 14.30	Work on Protocols Small Discussion Groups – in parallel
15.00 - 16.30	Work on Protocols Small Discussion Groups – in parallel
17.00 - 19.00	Protocol development session 5 (Work on protocols)
20.30 - 22.00	Round Table discussion Practical issues of implementation of clinical trials: what a principal investigator should know.

Day 5 — Wednesday 27 June 2001

08.30 - 10.30	Lecture Session 5 • Lecture 13: Treatment of intra-epithelial cancer • Lecture 14: Functional imaging: challenges and opportunities
10.30 - 12.30	Protocol development session 6 (Funding and implementation and final protocol)
12.30 - 13.30	*Lunch*
13.30 - 15.00	Work on protocols
13.30 - 16.00	Faculty meeting
15.00 - 16.00	Posttest
18.00	Final protocol due
19.30	Reception and dinner

Day 6 — Thursday 28 June 2001

Departure

TOPICS OF PARALLEL DISCUSSION GROUPS

- Quality of life - clinical benefit
- Special problems in clinical trial design: cytostatic agents, angiogenesis inhibitors, growth factors
- Laboratory correlates and pharmacodynamics
- Special considerations for radiation oncology trials
- Special considerations for surgical oncology trials
- Special considerations for clinical trials with children
- The meta-analysis concept
- Statistical problems
- How to make your research memorable - presentation and publication skills

GENERAL INFORMATION

Selection of participants

The Organising Committee will review all the applications and accept a maximum of 75 participants from applications received. Preference will be given to those who are close to the end of their Residency/Fellowship training and to junior staff within 5 years of completion of their training. The Committee will base its decisions mainly on the quality of the proposed protocol and on the letters submitted by the applicant and the Supervisor/ Department Head. These documents will be scrutinized both for the information they supply about the candidate and the assurances they provide about the participation of the candidate and his or her supervisor in the long-term evaluation of the workshop. The Committee will seek a group of 75 trainees who have made outstanding progress in their medical training, who have displayed an interest and competence in clinical cancer research, and who will come from a diverse group of training institutions and personal backgrounds in Europe. Those accepted for the workshop will begin with a concept for a clinical trial and leave with a finished protocol. They should have the support of their Department/Institution to carry out the clinical trial after attending the workshop. Only feasible therapeutic trial protocols will be considered.

Applicants will be notified of their status by early April 2001.

Applicants are informed that the official language of the workshop is English and that all protocols should be written in English. A basic computer knowledge (Word, Excel) will be required to develop your protocol on site.

Fellowships

The Committee will award the selected participants with a fellowship. This group will not be required to pay any registration fee for the workshop. They will also receive hotel accommodation in Flims for the nights of 23 June through 27 June, inclusive, and complimentary meals throughout the workshop with the exception of dinner on Tuesday 26 June. Participants receiving a fellowship will be required to share sleeping rooms with other awardees. An activity fee of 100 EUR will be imposed on all participants to offset the costs of social events and a group photo. The 75 participants will receive a restricted travel grant to cover part of the travel expenses.

Workshop materials

All faculty members will contribute material to the workshop syllabus to be distributed to all participants at the workshop. For each lecture and small group discussion section the syllabus will contain the instructional objectives of the presentation, an outline of the topics to be covered, and a bibliography of relevant articles and texts.

Workshop site

Workshop sessions will take place at the Park Hotels Waldhaus, Flims, Switzerland. Workshop participants will be able to use the open air and indoor swimming pools and the tennis courts of the hotel as well as a variety of other recreation facilities.
The organisers will arrange for complimentary shuttle bus transport for workshop participants between Zurich airport and the Park Hotels Waldhaus in Flims on Saturday morning 23 June, and again on Thursday 28 June 2001. Participants will receive the schedule of the shuttle buses. Apart from the shuttle bus service no other complimentary transport between Zurich and Flims will be provided.

Workshop housing

All applicants accepted to the workshop should reside at the Park Hotels Waldhaus for the duration of the workshop and participate in all group meals. Fellows will receive complimentary accommodation at the hotel on the basis of a room to be shared with one other Workshop participant. Fellows requesting a single room accommodation should pay a supplement of 50 EUR per night/per person.

APPLICATION FORM
METHODS IN CLINICAL CANCER RESEARCH WORKSHOP

23-28 June 2001 - Park Hotels Waldhaus, Flims, Switzerland

Title (Please tick as appropriate): ❑ Prof ❑ Dr ❑ Mr ❑ Mrs ❑ Ms ❑ Other : .....

Family name

First name

Institute/company

Department

Address

Postal code City

Country

Phone (International)

Fax (International)

e-mail address

Have you attended a related or similar course or workshop?

❑ Yes ❑ No If yes, please describe:

Education

(Begin with baccalaureate or other initial professional degree)

Degree	Institution	City	Country	Year
Degree	Institution	City	Country	Year
Degree	Institution	City	Country	Year
Degree	Institution	City	Country	Year

Assurances and signatures

This form must be signed where indicated by both the applicant and the supervisor submitting a letter of recommendation.

Applicant: I certify that the above statements are true and complete to the best of my knowledge. If admitted to the workshop, I agree to attend all scheduled sessions and afterwards to participate as requested in the long-term evaluation of this programme.

Signature ..... Date

Supervisor or Department Head of Applicant: I recommend this applicant for the FECS/AACR/ASCO Workshop on Methods in Clinical Cancer Research. I certify that the above statements are true and complete to the best of my knowledge. If the applicant is admitted, I agree to make every reasonable effort to enable the candidate to conduct a clinical trial based on the protocol concept sheet developed at the workshop and to participate as requested in the long-term evaluation of this programme.

Signature ..... Date

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