

Flims: Building the next generation of clinical researchers

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Conducting clinical trials is essential to the development of new cancer treatments, but there are many pitfalls, and it takes knowledge and experience to get it right. Where do Europe's young oncologists go to pick up the necessary skills? Until 1999, there was nowhere.

IN 1994 two leading US clinical oncologists, Daniel D von Hoff and Charles A Coltman Jr, realised that there was a serious shortage of translational / clinical investigators who could design and conduct the clinical trials necessary to assess new therapeutic agents under development.

They were concerned that not enough physician investigators were following careers in patient-oriented research. So they made proposals for a special course designed to train young clinical investigators in the fundamentals of clinical trials design.

In 1996 the American Association for Cancer Research (AACR) and the American Society of Clinical Oncology (ASCO) responded to their suggestions by creating the first Methods in Clinical Cancer Research Workshop, which was held in Park City, Utah, although all subsequent workshops have been held in Vail, Colorado.

In 1997, among the faculty members of the Vail Workshop was a certain Jean-Pierre Armand, from the Institut Gustave-Roussy in

Villejuif, France. He was impressed, and recognised the need for something similar in Europe. So he invited the Federation of European Cancer Societies (FECS) to take the lead in establishing a European equivalent. Together, FECS, ASCO and AACR saw a great opportunity for a parallel Methods in Clinical Cancer Research Workshop held in Europe, which, they reasoned, would allow additional highly qualified, highly motivated young clinical investigators to take the course and would increase interaction between US and European clinical researchers through direct contact at the Workshop.

So in 1999 FECS organised the first European Workshop (jointly sponsored by AACR and ASCO) in the town of Flims, Switzerland. It quickly established itself as one of Europe's leading educational oncology forums. The main aim of the Workshop is to develop a cadre of well-trained, experienced researchers whose expertise will foster better clinical trials design, thereby hastening the introduction of improved regimens for cancer therapy into everyday medical practice and patient care. The Workshop has a famously high academic standard, fostered by the involve-



The class of 2004.
Hopes for expanding
our knowledge
of cancer
and cancer therapies
over the coming
decades rest
on people like these

The great majority of Flims graduates become increasingly involved in clinical research

ment of a world-class, multi-disciplinary faculty encompassing leaders in the fields of clinical research, translational research and biostatistics. The core faculty consists of representatives of FECS, AACR and ASCO, ensuring that students receive guidance from both European and US perspectives. The Workshop is designed with a high faculty-to-student ratio so the students have ready access to their mentors, usually with groups of seven to ten students being mentored by two clinical investigators in conjunction with a biostatistician. This gives Workshop participants a full week of ready and uninterrupted access to the leaders in the field, ensuring an almost unequalled transfer of knowledge in a workshop setting, and helps to build long-term working relationships and friendships that enhance clinical trial design and implementation for the future.

BRAINSTORMING

The Workshop is structured to maximise the potential for students to apply the skills they learn in a practical setting following the completion of the course. For example, part of

the application procedure involves submitting, in advance, a concept for a prospective clinical trial to be developed during the Workshop. This concept must be new, ethical, and feasible and also be fully supported by the applicant's mentor in their home institute. During the Workshop the concept is developed into a scientifically sound clinical trial protocol that the student will subsequently endeavour to activate in their home institute. The development of this submitted concept into a clinical trial protocol forms the core of the Workshop. The design and refinement of each student's protocol is undertaken in small groups, which form highly interactive brainstorming sessions, and is also undertaken individually during sessions designed to allow the student to concentrate on their protocol, whilst calling on the available faculty experts for guidance on specific issues. To complement the clinical trial protocol development of the Workshops, students also receive specific training on how to get their protocol accepted, activated and sponsored. This guidance is

Students propose their own clinical trials and work in small groups to develop the designs and protocols



essential, given the complex regulation and bureaucracy involved in the activation of a trial.

Flims students also attend a range of lectures on all aspects of clinical trial design, covering biostatistics and ethical principles along with more detailed topics such as pharmacokinetics, tumour measurement, drug registration and clinical trial endpoints. These lectures, given by the faculty members, serve to provide a comprehensive theoretical background in all aspects of clinical trial design. The high level of support and mentoring that characterises the Workshop continues long afterwards: faculty members remain in close contact with their students, guiding them through the process of sponsoring and activating their protocol and maintaining an interest in their careers. This dedication by the faculty reflects the spirit of collaboration and commitment to education that the Workshop embodies.

The success of the Workshop lies in the combination of a world-class faculty, its unique format and the expectation of the transformation of a clinical concept into a real research protocol. The selection of Flims students has become a rigorous process designed to select a diverse group of young oncologists who will derive the greatest benefit from the experience and then successfully apply their knowledge to

clinical trial protocols at cancer research and treatment centres across the whole of Europe and throughout the world.

More than 500 students from 36 countries have participated in the Flims Workshop since it started six years ago. When added to the numbers who have participated in Vail, there are now more than 1,000 alumni from these Methods in Clinical Cancer Research workshops. This represents a considerable strength of clinical trial expertise, and the majority of these Flims alumni continue to be actively involved in patient-oriented research.

FROM PROTOCOL TO PRACTICE

A recent survey of Flims fellows revealed that the majority felt that participation in the Workshop had not only advanced their career, but had also stimulated them to continue working in clinical cancer research. Of those who have now been monitored for five years, the great majority have become increasingly active in clinical research and in advancing the field of cancer therapy. Specifically, the survey revealed that approximately 50% of protocols developed during the Workshop were submitted within two years to the local Ethics Review Committee. Of these protocols, 94% were approved by the Committees, with 76% of them

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being implemented at the student's home institution. Within a year of completing the Workshop, around 40% of the students had one protocol (and 30% had two or more protocols) submitted and implemented at their home institution. These figures reveal the extent to which the Workshop has a beneficial impact on clinical trials in Europe. So far, however, because of the relatively recent establishment of the Workshop, few of the implemented studies have come to maturity and been published or presented at conferences. This is set to change over the next few years.

FLIMS ALUMNI CLUB

Of the young oncologists who have attended the Workshop, a large number expressed the need for a forum where they could focus their continued involvement in clinical and translational research. To cater to this need, a group of past Flims participants started the Flims Alumni Club (FAC). Established in 2001, FAC has a wide range of aims, all intended to promote the active involvement of young cancer specialists in clinical and translational research. It provides a forum where young cancer specialists of all disciplines can develop collaborative networks, whilst encouraging a multidisciplinary approach and disseminating information on clinical cancer research. FAC has recently been accepted into FECS as an Affiliated Member, which means that FAC will have a representative on the FECS Council and will be entitled to have representatives on official FECS committees and other bodies including the Accreditation Council of Europe (ACOE).

Looking forward, FAC is keen to establish partnerships and synergies with other organisations that share its aim of teaching young European cancer specialists good research and

clinical practice. It has begun a collaboration with the European School of Oncology (ESO) in reaching out to promising young cancer clinicians. The two organisations will each encourage their members to make use of the educational opportunities available in their partners' programmes. FAC members will participate as tutors in the 2005 ESO Masterclass, and FAC will sponsor five travel grants for Masterclass participants from poorer countries. FAC also continues to sponsor participation in the Flims Workshop.

The Flims Workshop on Methods in Clinical Cancer Research is a valued and respected educational forum that adds strength and depth to the European oncology community, and helps to ensure that the future of clinical trials in Europe is secure. It is reassuring that so many young oncologists want to attend the Workshop, and reassuring too that so many Flims students manage to successfully activate their protocols and demonstrate a commitment to stay in patient-oriented research. The success of the Workshop is a testament to the vision of the founders.



High teacher-to-student ratios lead to lasting relationships