enhancing fraction and that in patients receiving VEGF inhibitors whose disease is progressing, the tumours manifest an increasing enhancing fraction. Together, these results highlight the potential of the vascular fraction as a potential predictive biomarker for VEGF inhibitors and we are now testing the additional information gathered by measuring imaging and blood borne biomarkers of angiogenesis.
Taken in conjunction with emerging imaging technologies (e.g. ASL) it is now appropriate to test the predictive value of imaging to determine which patients most benefit from anti-angiogenic agents.

Scientific Symposium (Wed, 23 Sep, 09:00−11:00) FLIMS Symposium and ECCO/EJC Young Investigators Award

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The FLIMS Workshop

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The 1st Annual Workshop "Methods in Clinical Cancer Research" was held in Flims, Switzerland in 1999 and was based on a similar training workshop held at Vail, USA. This Workshop had been borne out of a concern about the shortage of young clinical researchers and the increasing need to conduct clinical trials with new anticancer agents. The European Workshop was run under the auspices of FECS (now ECCO), AACR and ASCO). Funding was obtained from these organisations and a grant from NCI together with contributions from the pharmaceutical industry. Ten courses have been held with almost 800 graduates attending the Workshops. Each Workshop comprises 35 to 40 highly experienced international clinical investigators and several innovative techniques and teaching methods are utilised aimed at intensively guiding and supervising the students through the process of completing a protocol concept sheet and developing a finished protocol by the end of the Workshop week.
Four educational formats are used. Protocol development sessions involve small groups of students with at least 3 dedicated faculty members and this constitutes the core activity of the Workshop. Support is provided by Faculty members to each student so that the final protocol can be developed. Small group discussion sessions are held during the week to cover specialised topics relating to clinical trials development. Lectures and panel discussions are held on a daily basis to cover a variety of specific topics presented by experts in the field. These give an essential overview of the design and conduct of high-quality clinical trials. Where appropriate, lectures on related topics are followed by a panel discussion or round table sessions. One on one sessions are held during the week for individual counselling and advice on protocol and career development. The selection of participants is highly competitive and undertaken after submission by applicants of a trial concept sheet together with CV and letter of recommendation. International peer review is undertaken and successful candidates are selected following this. Constant monitoring of the success of the Workshop is undertaken. A set of objectives were determined at the outset of the Workshops in 1999 and, encouragingly all have been exceeded. Greater than 80% of protocols written during the Workshop were subsequently submitted, approved and funded for candidates in 2001, 2004, 2005 and 2006. Greater than 80% of protocols have subsequently been submitted and approved by Ethics Committees every year except 2001. The Workshop has proven extremely popular with universal positive feedback and the perception by many that this is one of the highlights of their careers. Several important trials have been developed at Flims and have been published in high impact journals.

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Presentation of a Flims study: The diagnostic value of PET/CT for primary ovarian cancer – a prospective study

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Background: To prospectively evaluate the diagnostic value of combined PET/CT for detecting a malignant tumor in patients with a pelvic mass and to identify PET/CT predictors of incomplete/suboptimal primary cytoreduction in advanced ovarian cancer patients.

Methods: From September 2004 to August 2007, 201 patients (median age=61 years, range=21–91 years) with a risk-of-malignancy index (RMI)>150 based on serum CA-125, ultrasound examinations, and menopausal state, underwent PET/CT within 2 weeks prior to standard surgery/debulking of a pelvic tumor. Histological diagnoses were compared to the PET/CT results to calculate the diagnostic value of PET/CT in differentiating between malignant and borderline/benign tumors. In 94 ovarian cancer patients the FIGO stage was compared with the stage indicated on PET/CT. Ten PET/CT features were identified and evaluated as predictors of cytoreduction in 66 patients with advanced ovarian cancer.
Results: The sensitivity of PET/CT for diagnosing a malignant pelvic tumor was 95% (107/113) and the specificity was 91% (80/88). FIGO stage IV was found in 11% (10/94) of ovarian cancer patients. In 44% (41/94) of ovarian cancer patients, PET/CT demonstrated areas of abnormally increased metabolic activity that indicated stage IV, metastatic disease. Complete cytoreduction (no macroscopic residual disease) was achieved in 38% (25/66) of patients with advanced ovarian cancer. Using univariate analysis, predictors of incomplete cytoreduction were large bowel mesentery implants (LBMI) ($P < 0.001$), peritoneal carcinosis ($P < 0.001$), pleural effusion ($P < 0.003$), ascites ($P < 0.01$) and small bowel mesentery implants ($P < 0.02$). Using multivariate analysis, LBMI was the only independent predictor of incomplete cytoreduction ($P = 0.004$).
Conclusion: Combined PET/CT demonstrated high diagnostic value in identifying primary ovarian cancer in patients with a pelvic mass of unknown origin and RMI>150. In patients with advanced ovarian cancer PET/CT located metastases unrecognised by standard staging procedures. In addition, PET/CT predictors of cytoreduction were found. However, those predictors should be used with caution until prospective randomised trials have clarified which subgroup of ovarian cancer patients benefits in terms of survival from neoadjuvant chemotherapy followed by interval debulking.

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Presentation of a Flims study: Randomized phase II study of docetaxel/oxaliplatin and docetaxel in previously treated non-small cell lung cancer patients

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The development of a research protocol is the core activity at the workshop on Methods in Clinical Cancer Research, sponsored by ECCO-AACR-ASCO and held annually in Flims, Switzerland. At the end of the workshop, the "Flims graduates" return to their home institution with an approved protocol to be implemented in the real world! Obtaining Ethics approval, granting financial support, having the study up and running can be challenging and the successful completion of the study up to a publication should not be taken for granted. This presentation will be given by an Italian Medical Oncologist who attended the Workshop in 2004 and whose life has definitely changed as a consequence of this experience. The talk will chronicle the development and implementation of her Flims protocol for a randomized phase II study evaluating the activity of docetaxel plus oxaliplatin in second-line non-small cell lung cancer (NSCLC); the comparator arm was single agent docetaxel. The study was designed as a one-stage, three-outcome phase II trial (Sargent et al, Control Clin Trials 2001) requiring 21 evaluable patients per arm; primary endpoint was response rate. The study was implemented at the student's home Institution with the support of the Alpe Adria Thoracic Oncology Multidisciplinary group (ATOM group). Fifty patients were enrolled at four Italian centers. It was a positive study: the level of activity for the combination docetaxel/oxaliplatin satisfied the pre-defined study primary endpoint, warranting further evaluation of this combination as second-line therapy for NSCLC. Final results have already been presented at International meetings and the manuscript is in preparation. This is only one of hundreds of trials designed during the Workshop since 1999. Without any doubt, the Flims Workshop is the best training opportunity to learn the essentials of clinical trials methodology: all young oncologists with a major interest in clinical cancer research should be encouraged to attend.

213 ECCO/EJC Young Investigators Award

The lessons that can be learned by studying the patterns of local recurrence after primary rectal cancer treatment

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Background: By determination of the subsite of locally recurrent rectal cancer on imaging and relating these to patient, treatment and tumor variables, the mechanisms of local relapse genesis can be reconstructed. The purpose of this study was to analyze the patterns of local recurrence