3rd EORTC-NCI International Meeting on Cancer Molecular Markers
From Discovery to Clinical Practice:
An interactive workshop focused on practical methods for bringing promising prognostic and predictive markers from the research laboratory to the bedside

Brussels, Belgium, 18-20 April 2004

**FINAL PROGRAM**

**SUNDAY, APRIL 18**

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<td>5:00 pm – 5:30 pm</td>
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| 5:30 pm – 6:30 pm | **Keynote Address**
|                | Tyrosine kinase inhibitors: Successes, limitations, future directions |
|                | Carlos Arteaga, Vanderbilt University, Nashville, TN, USA            |
| 6:30 pm – 7:00 pm | Report on specimen sharing issues.                                   |
|                | Roger Aamodt, NCI, Bethesda, MD, USA                                |
|                | Alain Spatz, Gustave Roussy Institute, Villejuif, France             |
| 7:00 pm        | **WELCOME COCKTAIL**                                                |

**MONDAY, APRIL 19**

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| 8:30 am – 10:30 am | **Molecular Profiling in Cancer Diagnosis, Prognosis and Treatment Selection**
|                | Discovery and validation of potentially useful profiles, development of relevant clinical questions, statistical issues |
|                | Chairs: Martine Piccart, Jules Bordet Institute, Brussels, Belgium  |
|                | Bruce Johnson, Dana Farber Cancer Institute, Boston, MA, USA        |
|                | Expression profiling as a prognostic and predictive factor in breast cancer Laura van’t Veer, The Netherlands Cancer Institute, Amsterdam, The Netherlands |
|                | Gene expression profiling of human lung adenocarcinoma Matthew Meyerson, Dana Farber Cancer Institute, Boston, MA, USA |
|                | Statistical issues in molecular profiling studies Lisa McShane, NCI, Bethesda, MD, USA |
| 9.30 am -9.45 am | **COFFEE BREAK**                                                     |
|                | **Proffered abstract presentations**                                 |
|                | Gene expression profiling to predict prognosis in lymph node-negative (LNN) breast cancer John Fockens, Erasmus University Medical Center, Rotterdam, The Netherlands |
|                | Increasing the predictive ability of clinicopathologic markers for prostate cancer using biomarkers derived from high-throughput tissue microarray studies in a large retrospective cohort Ana Frolov, Baylor College of Medicine, Houston, TX, USA |
|                | Epigenetic signature predicts endocrine therapy response in patients with recurrent breast cancer John Martens, Erasmus University Medical Center, Rotterdam, The Netherlands |
10:30 am – 12:00 pm  Poster Tour
12:00 pm – 1:00 pm  LUNCH
1:00 pm – 1:30 pm  Critical Issues in Clinical Trials for Targeted Agents: Highlights of the AACR-NCI-EORTC Molecular Targets and Cancer Therapeutics Meeting 2003
Jaap Verweij, Erasmus University Medical Center, Rotterdam, The Netherlands
1:30 pm – 4:30 pm  Trial Design for Prospective Evaluation of Marker Utility
*Design of exploratory and confirmatory clinical experiments; evaluation of molecular profiles in the context of clinical treatment trials*
Chairs: Barbara Conley, NCI, Bethesda, MD, USA
Patrick Therasse, EORTC, Brussels, Belgium
Clinical trial designs for predictive marker validation in cancer treatment trials
Laurence Collette, EORTC, Brussels, Belgium
Design of the TRANSBIG/EORTC trial using molecular profiling as a prognostic factor
Martine Piccart, Jules Bordet Institute, Brussels, Belgium
Program for the Assessment of Clinical Cancer Tests (PACCT) – an NCI initiative using molecular profiling to assist treatment selection for node-negative breast cancer
Jeff Abrams, NCI, Bethesda, MD, USA
Discussion of trial designs
2.45 pm – 3.15 pm  COFFEE BREAK
Trial designs for clinical development of targeted drugs: molecular biomarkers and the pharmacological audit trail
Paul Workman, Institute of Cancer Research, Surrey, UK
Discussion of trial designs for targeted drug development
*Proffered abstract presentations*
Monitoring circulating tumor cell (CTC) levels to predict rapid progression in Metastatic Breast Cancer (MBC): a prospective, multi-institutional trial
Daniel Hayes, University of Michigan Cancer Center, Ann Arbor, MI, USA
Statistical considerations for immunohistochemistry panel development following gene expression profiling of human cancers
Rebecca Betensky, Harvard School of Public Health, Boston, MA, USA
4:30 pm – 5:30 pm  Poster Discussion Session: Session Chairs
7:00 pm  DINNER

**TUESDAY, APRIL 20**

8:00 am - 10:15 am  From the Research Lab to the Clinical Lab: When Does a Marker Become a Lab Test?
*What makes a marker/profile promising? What are the steps necessary to evaluate clinical utility and develop a test for clinical use?*
Chairs: Nadia Harbeck, Technical University of Munich, Munich, Germany
Soon Paik, NSABP, Pittsburgh, PA, USA
RT-PCR using paraffin sections for clinical patient management
Validation of a multi-gene RT-PCR assay of mRNA expression in fixed, paraffin-embedded tumor tissue to predict the likelihood of distant recurrence in node-negative, ER positive, Tamoxifen-treated breast cancer patients

“Aligning the Planets” to realize delivery of a successful *Theranostic uPA/PAI-1 for treatment decision making in breast cancer*

uPA and PAI-1 for treatment decision making in breast cancer: European view

Exploration and explanation of the relative difference in acceptance and utility of tumor biomarkers in Western Europe versus the United States

uPA/PAI-1 – NSABP Experience

**Discussion**

**Proffered abstract presentations**

Quality control for determination based on real time PCR: an Italian experience

Human kallikreins (hKs) as novel serum biomarkers for diagnosis, prognosis and monitoring of epithelial ovarian carcinoma

**Circulating Markers for Diagnosis and Monitoring Therapy.**

*Proteomics and single circulating markers for early diagnosis, drug development, prognosis and monitoring therapy.*

Chairs: Daniel F. Hayes, Univ. of Michigan Cancer Center, Ann Arbor, MI, USA
Julio E. Celis, Danish Cancer Society, Copenhagen, Denmark

Introductory remarks

Proteomic profiles in the assessment of disease etiology, diagnosis and therapeutic effectiveness

Serum HER-2 in patients with breast cancer

Circulating tumor cells and bone marrow micrometastasis

Concluding remarks

**Proffered abstract presentations**

Preliminary evaluation of the predictive significance of serum HER-2/neu, CA15-3 and EGFr in metastatic breast cancer HER-2/neu positive patients, enrolled in a Phase IIb study: paclitaxel (PCT) versus PCT + trastuzumab (T)

RT-PCR analysis of tyrosinase expression in the peripheral blood of melanoma patients: a clinical follow-up study in 514 patients at different clinical stages

Measuring tumor cell death in serum
12:30 pm – 1:30 pm  LUNCH

1:30 pm – 3:15 pm  Lessons Learned from Hematologic Malignancies: Markers for Diagnosis, Risk Stratification and Therapy Selection.
Progress in using diagnostics to classify cancers, select best treatment and monitor minimal residual disease.

Chairs:  Nils Brünner, Royal Veterinary & Agriculture Univ., Frederiksberg, Denmark
        Cheryl Willman, University of New Mexico, NM, USA

Molecular classification, outcome prediction and new therapeutic targets in acute leukemia through genomics

Gene expression, progression, and response in chronic myeloid leukemia

High post-operative plasma levels of tissue inhibitor of metalloproteinases 1 in colorectal cancer patients are indicative of minimal residual disease

Discussion

Proffered abstract presentations
Tumor budding detected by laminin-5 immunohistochemistry is of prognostic value in epidermoid anal cancer

Pure prognostic relevance of histological grade and of its components in node-negative breast cancer patients

Immunohistochemical overexpression of p16\textsuperscript{indk4A} and HPV infection in cervical intraepithelial neoplasias

3:15 pm – 3:30 pm  COFFEE BREAK

3:30 pm – 5:00 pm  Applying Diagnostic, Prognostic and Pharmacogenomic Markers in the Real World: Can We Individualize Cancer Treatment?
Are we ready to use these markers now? What is needed to assess prognosis and optimize treatment for individual patients? Panel discussion.

Chairs:  Sheila Taube, NCI, Bethesda, MD, USA
        Alexander Eggermont, Erasmus University Medical Center, Rotterdam, The Netherlands

Panel:  Richard L. Schilsky, University of Chicago, Chicago, IL, USA
        Cheryl Willman, University of New Mexico, NM, USA
        Martine Piccart, Jules Bordet Institute, Brussels, Belgium
        Nadia Harbeck, Technical University of Munich, Munich, Germany

Proffered abstract presentations
A pharmacogenomic approach to improving outcome of chemotherapy for advanced non-small cell lung cancer (NSCLC)

Sustained in vivo target modulation with CHIR258, a small molecule inhibitor of growth factor tyrosine kinase receptors, is associated with robust activity

Prediction of paclitaxel clinical response in advanced breast cancer patients: any role for β-tubulin alterations

5:00 pm – 5:30 pm  Overview

Richard L. Schilsky, University of Chicago, Chicago, IL, USA
Massimo Gion, Centro Regionale Indicatori di Tumore, Venice, Italy