

This course is designed at an **advanced level** and is oriented towards medical doctors, specialists in oncology, experienced data managers, oncology nurses and those working in the pharmaceutical industry who are involved in cancer clinical trials (CCT).

The course will focus on the new aspects and methodological challenges of modern cancer clinical trials. The course will address new clinical trials features aimed at understanding the biology of the disease and document molecular determinants, whether host or disease related, which may be prognostic or predictive of patient outcome. As innovative approaches will be discussed, attendees are expected to already have a good understanding of the basis of clinical trial methodology.

TUESDAY 7 SEPTEMBER 2010

10.00 – 10.30	Registration	Challenges in Designing the Next Generation of CCT: Chair: R. Sylvester
10.30 – 10.45	Welcome by EORTC Director General <i>F. Meunier</i>	13.00 – 14.00 PFS as an end-point for Phase II / III trials - The clinician's point of view <i>J.Y Blay</i> - The statistician's point of view <i>M. van Glabbeke</i>
10.45 – 11.45	Key note: paradigm changes for cancer clinical research <i>J.Y. Blay</i>	14.00 – 14.45 Prognostic factors versus predictive factors <i>C. Fortpied</i>
11.45 – 12.00	Anatomy and objectives of the course <i>D. Lacombe, R. Sylvester</i>	14.45 – 15.30 Design / analysis of studies for the development of targeted agents <i>L. Collette</i>
12.00 – 13.00	Lunch	16.30 – 17.00 Practical questions/case study on Day 1 topics: presentation <i>R. Sylvester</i>

WEDNESDAY 8 SEPTEMBER 2010

08.30 – 09.00	Practical questions/case study on Day 1 topics: discussion <i>R. Sylvester</i>	Biomarkers: Chair: N. Harbeck
Multimodality Clinical Trials: Chair: D. Lacombe		12.55 – 13.25 Validation of a predictive biomarker for drug development <i>S. Tejpar</i>
09.00 – 09.30	Integrating surgery in multimodality clinical trials <i>C. Schuhmacher</i>	13.25 – 13.55 Development and cross validation of methods / platforms to validate biomarkers alongside clinical trials; <i>N. Harbeck</i>
09.30 – 10.00	Special considerations for radiotherapy trials <i>K. Haustermans</i>	13.55 – 14.25 Pitfalls in the development of gene signatures <i>T. Gorlia</i>
Surrogate Endpoints: Chair: L. Collette		14.25 – 14.55 What does molecular profile add to a clinical & pathological profile? <i>R. Sylvester</i>
10.50 – 11.50	Issues and challenges of surrogate endpoints - The clinician's point of view <i>D. Fennell</i> - The statistician's point of view <i>J. Bogaerts</i>	Biobanking: Chair: F. Cardoso
12.10 – 12.55	Lunch	15.45 – 16.15 Biobanking challenges for international cancer clinical trials <i>F. Cardoso</i>
		16.15 – 16.35 EORTC biobanking policy <i>J. Hall</i>
		16.55 – 17.10 Practical questions/case study on Day 2 topics: presentation <i>D. Lacombe, L. Collette, N. Harbeck, F. Cardoso</i>

THURSDAY 9 SEPTEMBER 2010

08.30 – 09.00	Practical questions/case study on Day 2 topics: discussion <i>D. Lacombe, L. Collette, N. Harbeck, F. Cardoso</i>	Safety: Chair: J. Flament
Imaging: Chair: S. Stroobants		13.00 – 13.30 Specific consideration for safety issues with targeted agents <i>A. Ravaud</i>
09.00 – 09.30	Integrating and validating markers / tracers in CCT <i>S. Stroobants</i>	13.30 – 14.00 Principles of safety monitoring in modern clinical trials <i>B. Penninx</i>
09.30 – 10.00	Imaging guidelines for clinical trials <i>R. Boellaard</i>	WORKSHOP 1 <u>Topic to choose from:</u>
10.30 – 11.00	Imaging response criteria/RECIST present & future <i>J. Verweij</i>	A. Implementing a multimodality, biobanking, imaging protocol in 2010
11.00 – 11.30	Selection of imaging methods for targeted agents <i>P. Flamen</i>	B. Implementing QA programs for radiotherapy clinical trials
11.30 – 11.50	EORTC Imaging platform <i>J. Flament</i>	17.00 – 17.15 Practical questions/case study on Day 3 topics: presentation <i>J. Flament, S. Stroobants</i>
12.15 – 13.00	Lunch	19.30 Course dinner (optional)

FRIDAY 10 SEPTEMBER 2010

08.30 – 09.00	Practical questions/case study on Day 3 topics: discussion <i>J. Flament, S. Stroobants</i>	WORKSHOP 2 <u>Topic to choose from:</u>
Regulatory / Legal Session: Chair: R. von Frenckell		C. Implementing tissue collection
09.30 – 10.00	The European regulatory environment for clinical trials <i>A. Negrouk</i>	D. Challenges for implementing & conducting European CCT
10.00 – 10.30	Specific considerations for tissue collection impact on biobanking agenda <i>G. Thomas</i>	Models of partnership Academia / Industry: Chair: R. von Frenckell
11.00 – 11.30	EMA perspective <i>F. Pignatti</i>	13.45 – 14.15 Academia perspectives <i>D. Lacombe</i>
12.00 – 12.45	Lunch	14.15 – 14.45 Industry perspectives <i>I. El Hariry</i>
		15.15 – 15.30 Closing remarks by Chairs

REGISTRATION FORM

Please complete and return this form by mail or by fax to the EORTC Education Office (see address below). Please type or write in CAPITAL LETTERS. Fill out one Registration Form for each participant.

(please tick) Prof Dr Ms Mr (Other) _____

Family name : _____
 First names : _____
 Institute : _____
 Department : _____
 Institute address : _____
 Town/Code : _____
 Country/ Phone : _____
 Fax : _____
 E-mail : _____

Speciality: surgery medical oncology epidemiology head of department
 radiotherapy nursing statistics secretariat
 radiology pathology data management senior assistant

Position: resident junior assistant senior assistant head of department

Sex (M) (F) _____ Year of birth: _____ Nationality: _____
 General hospital Cancer department in general hospital University
 Comprehensive cancer center Private company

I will attend:
 the Optional Dinner

Workshops Preference:
 Please indicate your workshop preference for

9 September (1 = first preference, 2 = second preference)
 Preference Topic
 A. Biobanking / Imaging
 B. QA radiotherapy

10 September (1 = first preference, 2 = second preference)
 Preference Topic
 C. Tissue collection
 D. Challenges European clinical trials

Please return this form to:
 Danielle Zimmermann (MS)
 Coordinator EORTC Education Office
 Avenue E. Mounier, 83/11
 1200 Brussels, Belgium