

EORTC course on

# CLINICAL TRIAL STATISTICS FOR NON STATISTICIANS

15 - 18 JUNE 2010

BEST WESTERN PREMIER  
SODEHOTEL LA WOLUWE  
AVENUE E. MOUNIER, 5  
BE - 1200 BRUSSELS  
BELGIUM



# E O R T C

## CHAIRPERSONS

A. Bartolucci (US)  
L. Collette (BE)  
R. Sylvester (BE)

## Invited Faculty

A. BARTOLUCCI, University of Alabama, Birmingham AL, USA  
J. BOGAERTS, EORTC Headquarters, Brussels, Belgium  
C. COENS, EORTC Headquarters, Brussels, Belgium  
L. COLLETTE, EORTC Headquarters, Brussels, Belgium  
C. FORTPIED, EORTC Headquarters, Brussels, Belgium  
S. GEORGE, Duke University Medical Center, Durham NC, USA  
J. HALL, EORTC Headquarters, Brussels, Belgium  
C. LEGRAND, Université Catholique de Louvain, Louvain-La-Neuve, Belgium  
H. PUTTER, Leiden University Medical Centre, Leiden, The Netherlands  
R. SYLVESTER, EORTC Headquarters, Brussels, Belgium  
M. VAN GLABBEKE, EORTC Headquarters, Brussels, Belgium  
S. ZOHAR, Hôpital Saint-Louis, Paris, France

### Hotel and Course Venue

- **Hotel:** Participants requiring hotel accommodation should book directly with one of the mentioned hotels (see "Hotel Reservation")
- **Venue:** The course will be held at the Best Western Premier - Sodehotel La Woluwe, 5 avenue Emmanuel Mounier, 1200 Brussels, Belgium

### Registration

On-line registration is available at:  
<http://www.eortc.be/About/EducationOffice.htm>  
The registration site provides the guarantee of a secure on-line payment. Deadline for registration and payment is 28 May 2010. However the registration deadline for the optional course dinner is 30 April 2010. As the number of places in this course is limited, participants are encouraged to register as soon as possible.

Registration fees & Payment	Intro + Course + Dinner for payment received BEFORE 30 April	Intro + Course for payment received between 30 April and 28 May
Academics & non-profit organizations	145 + 715 + 40 Euros	165 + 825 Euros
For profit organizations & pharmaceutical industry representatives	230 + 1155 + 40 Euros	265 + 1320 Euros

Fees are net of all bank, exchange, tax and other charges. The fee includes the course book, coffees and lunches, but it does not include travel or hotel expenses.

**Advanced registration and payment are required.** Registration and corresponding payment should be received before the indicated deadlines. Confirmation of your participation will be sent to you only upon receipt of your complete registration data and payment. Registration forms submitted without full payment will not be processed. The language of the course is English.

### Cancellation policy

Cancellation of registration has to be faxed or e-mailed to the EORTC Education Office. If less than 2 month's notice of cancellation is given, 50% of the registration fee will be retained. If less than one month's notice of cancellation is given, no refund will be paid. Refunds will be processed by bank transfer after the course.

### For further information, please contact:

Ms Danielle Zimmermann, EORTC Education Office  
Av. E. Mounier 83, Bte 11 • 1200 Brussels, Belgium  
Phone: +32-2-774 16 02 • Fax: +32-2-772 62 33  
E-mail: [danielle.zimmermann@eortc.be](mailto:danielle.zimmermann@eortc.be)

## HOTEL RESERVATION

A limited number of rooms have been reserved for this event. Information and confirmation regarding hotel booking can be obtained directly with the hotel:

### Hotel Astrid

Place du Samedi 11  
BE - 1000 Brussels  
Phone: +32-2-219 31 19  
Fax: +32-2-219 31 70  
Single / Double: 107 / 130 Euros  
Deadline for booking: 14 May 2010

### Hotel Atlas

Rue du Vieux Marché aux Grains 30  
BE - 1000 Brussels  
Phone: +32-2-502 60 06  
Fax: +32-2-502 69 35  
Single / Double: 110 / 125 Euros  
Deadline for booking: 14 April 2010

### Best Western Premier Sodehotel

### La Woluwe

Avenue E. Mounier 5  
BE - 1200 Brussels  
Phone: +32-2-775 25 24  
Fax: +32-2-770 47 80  
Single / Double: 145 / 164 Euros  
Deadline for booking: 15 May 2010

## REGISTRATION FEE

**Academics and non-profit organizations:** the registration fee for the course is 715 €, or 860 € (incl. Optional Introduction) for payment received before 30 April 2010 (early rate), and 825 €, or 990 € (incl. Optional Introduction) for payment received between 30 April and 28 May 2010 (late rate).

**For profit organizations & pharmaceutical industry representatives:** the registration fee for the course is 1155 €, or 1385 € (incl. Optional Introduction) for payment received before 30 April 2010 (early rate), and 1320 €, or 1585 € (incl. Optional Introduction) for payment received between 30 April and 28 May 2010 (late rate).

**Social event:** All participants are welcome to attend the course dinner held on the **Thursday evening** (optional). The requested financial contribution is 40 Euros. The deadline for payment is **30 April 2010**.

**The registration fee is net of all bank, exchange, tax and other charges. This transaction is exempted according to Article 44 §2 4° of the Belgian VAT Code in connection with educational services.**

The total amount will be paid in € (Euro) as follows:

Visa  Eurocard/Master card

Card number

Expiry date:

CW/C (Card Verification Value/Code):

Owner's name: \_\_\_\_\_

Owner's signature: \_\_\_\_\_

Amount:     € Date: \_\_\_/\_\_\_/\_\_\_



Bank transfer: Fortis Banque SA, 14 av. de l'Astronomie, 1210 Brussels, Belgium  
Account No. 210-0510501-42; IBAN: BE77 2100 5105 0142; SWIFT: CEBABEBB  
Beneficiary: EORTC Education Office, 83/11 av. E. Mounier, 1200 Brussels, Belgium  
Message: Registration course "STATS - 2010" + Name of participant  
(Please add 13 € for bank transfers from outside the European Union)

Amount:     € Date: \_\_\_/\_\_\_/\_\_\_

Signature: \_\_\_\_\_

This course is designed as an introduction to the statistical principles which form the basis for the design and analysis of cancer clinical trials. It will concentrate on the philosophy and understanding of the statistical principles that are used on a day-to-day basis in conducting clinical trials and will not simply present statistical formulae in a cookbook fashion.

This course is aimed at non statisticians (medical doctors, data managers, etc.) who are already working in the field of clinical trials and who have had an introductory course in statistics, or at statisticians with little or no experience in clinical trials. For those persons who would like a review of the basic statistical concepts, an optional half day introduction to statistical methods has been organized.

### OPTIONAL INTRODUCTION

#### TUESDAY 15 JUNE 2010

13.30 – 14.00	Registration
14.00 – 17.00	Introduction to Statistical Methods <i>A. Bartolucci</i>

#### WEDNESDAY 16 JUNE 2010

08.30 – 08.50 Discussion of Homework from Tuesday  
*A. Bartolucci*

### COURSE

#### WEDNESDAY 16 JUNE 2010

08.30 – 09.00	Registration and welcome coffee	11.55 – 12.15	Morning Discussion
09.00 – 09.05	Welcome and Introduction		<i>S. Zohar, M. Van Glabbeke</i>
09.05 – 09.55	Design and Analysis of Phase I Cytotoxic Studies <i>S. Zohar</i>	13.15 – 14.15	Design of Phase III Trials <i>C. Fortpied</i>
09.55 – 10.45	Design and Analysis of Phase II Cytotoxic Studies <i>M. Van Glabbeke</i>	14.15 – 15.30	Sample Size for Phase III Trials <i>C. Legrand</i>
11.05 – 11.55	Early Development of Non-Cytotoxics <i>S. Zohar, M. Van Glabbeke</i>	15.50 – 16.50	Reporting and Interpreting Results <i>J. Bogaerts</i>
		16.50 – 17.15	Afternoon Discussion <i>C. Fortpied, C. Legrand, J. Bogaerts</i>

#### THURSDAY 17 JUNE 2010

08.30 – 09.30	Statistical Analyses: Basic Principles <i>L. Collette</i>	13.00 – 14.10	Interim Analyses and Early Stopping Rules (with discussion) <i>R. Sylvester</i>
09.30 – 10.15	Statistical Analyses: Binary Endpoints <i>A. Bartolucci</i>	14.10 – 15.10	Quality of Life (with discussion) <i>C. Coens</i>
10.35 – 11.45	Statistical Analyses: Time to Event Endpoints <i>H. Putter</i>	15.30 – 17.30	<u>Workshop</u> IDMC: What would you recommend?
11.45 – 12.00	Morning Discussion <i>L. Collette, A. Bartolucci, H. Putter</i>	<b>19.30</b>	<b>Course dinner (optional)</b>

#### FRIDAY 18 JUNE 2010

08.30 – 09.30	Reporting of Results: Practical examples <i>J. Bogaerts, C. Coens</i>	11.50 – 12.05	Morning Discussion <i>L. Collette, J. Hall</i>
09.30 – 11.10	Determination of prognostic and predictive factors (with break) <i>L. Collette</i>	12.50 – 14.00	<u>Workshops</u> Topics to choose from: - Phase I/II trials - Prognostic/Predictive Factors
11.10 – 11.50	Gene expression profiling <i>J. Hall</i>	14.00 – 15.15	Design and analysis of targeted agent studies <i>S. George</i>

## 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  chemotherapy  nursing  statistics  secretariat  
 radiology  pathology  data management  senior assistant

Position:  resident  junior assistant  senior assistant  head of department

Sex (M) (F) \_\_\_\_\_ Age: \_\_\_\_\_ Nationality: \_\_\_\_\_

Work sector  General hospital  Cancer department in general hospital  University  
 Comprehensive cancer center  Private company

#### I will attend:

the Optional Introduction and Course  
 the Course but not the Optional Introduction  
 the Optional Dinner

#### Workshops Preference:

Please indicate your workshop preference  
 (1 = first preference, 2 = second preference)

#### Preference Topic

..... - Phase I / II trials  
 ..... - Prognostic / Predictive factors

#### Please return this form to:

Danielle Zimmermann (MS)  
 Coordinator EORTC Education Office  
 Avenue E. Mounier, 83/11  
 1200 Brussels, Belgium