

HOW to REGISTER

Two steps:

1) fill in the application form on the website:

www.xxxxx ;

2) upon acceptance, proceed to payment.

Registration will be effective **ONLY** when step 2 is completed.

Please note that: the maximum number of participants is 30. Applications will be considered in order of submission.

Eight places will be reserved to PhD students that provide a letter of the supervisor in step 1. The University of Milano-Bicocca might provide one scholarship for participation of a PhD student. Modalities for application are explained in the web page.

**DEADLINE for REGISTRATION is
15 January 2017**

FEE

Registration fee will be inclusive of teaching material, bus transfer, hotel accommodation, meals and insurance (from 19 to 23 March included).

General participant:	1400 €
PhD student:	1100 €
SISMEC member	1300 €

HOW to PAY

By credit card and bank transfer, after acceptance.

Please follow the information on the course webpage.

<http://www.xxxxxxx>

REGISTRATION CANCELLATION

It must be submitted to the secretariat by February 19, 2017 to receive a refund, less a 50 Euro processing fee. Refunds will not be granted after February 19.

OBJECTIVES of the COURSE

This course is designed to give a comprehensive introduction to clinical research on biomarkers and multivariate classifiers, addressing the entire spectrum from discovery to evaluation.

The goals of the course are:

- to understand how to conduct translational research on biomarkers and classifiers
- to be able to analyse data on biomarkers and classifiers and to interpret results.

The methods covered in the course have applications in diagnostic and therapeutic research.

The course will consist of lectures and tutorials.

COORDINATORS

Maria Grazia Valsecchi

Stefania Galimberti

Center of Biostatistics for Clinical Epidemiology

School of Medicine and Surgery

University of Milano-Bicocca

SECRETARIAT

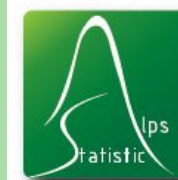
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**UNIVERSITY OF
MILANO-BICOCCA**
SCHOOL OF MEDICINE AND SURGERY
Center of Biostatistics for
Clinical Epidemiology



Statistic Alps

*Winter course on medical
statistics.....in the Alps*

7th Edition

**Biomarkers & Classifiers for
Diagnostic and Therapeutic Research:
Discovery, Study Design and Analysis**

Lisa McShane & Richard Simon

Biometric Research Program,
Division of Cancer Treatment and Diagnosis,
National Cancer Institute, Bethesda, USA

20 – 23 March 2017

PONTE DI LEGNO – BRESCIA, ITALY

With the endorsement of the



**Società Italiana di Statistica Medica
ed Epidemiologia Clinica**

PROGRAM

19 MARCH 2017

19.30 Registration
20.00 Welcome Dinner

1ST DAY – 20 MARCH 2017

9.00:13.00 Uses for biomarkers in drug development and clinical care
Kinds of validation (*Analytical, Clinical, Medical utility*)
Analytical validation (*Single analyte, Sequencing panels, Gene expression signatures*)
14.30:16.00 Introduction to case studies of prognostic single analyte biomarkers and biomarker scores
16.30:18.30 Statistical methods for development of prognostic scores (*Discriminant analysis, Shrunken centroids, Nearest neighbour methods, Support vector machines, Penalized logistic regression, Boosting, Random forests, Penalized proportional hazards model*)

2ND DAY – 21 MARCH 2017

9.00:13.00 Statistical methods for evaluation of prognostic scores (*Intended use of prognostic biomarker scores; Performance assessment; Internal validation methods; Hands on workshop on methods for development and evaluation of prognostic biomarker classifiers*)
14.30:16.00 Retrospective study designs (*Prospective-retrospective design with archived specimens; Efficient retrospective sampling (e.g., case-control, weighted); Sample size/power; Optimally splitting dataset*)
16.30:18.30 Prospective designs (*Considerations to establish medical utility; Trial examples: TAILORx, MINDACT, RxPONDER (also some predictive aspects), Sample size/power*)

3RD DAY – 22 MARCH 2017

8.30:12.30 Introduction to case studies of predictive biomarkers
Statistical methods for development of predictive scores/classifiers (*Score development methods*)
Statistical methods for evaluation of predictive scores (*Performance measures; Cross-validation for evaluation of predictive performance; Considerations in use of archived specimens; Special case sampling approaches in retrospective study designs*)

4TH DAY – 23 MARCH 2017

9.00:12.30 Hands on workshop on methods for development and evaluation of predictive biomarker classifiers
Evaluation of intermediate endpoint biomarkers (*Surrogate endpoints; Patient management biomarkers; Imaging biomarkers; Liquid biopsy based biomarkers*)
14.00-16.00 Biomarker driven clinical trial designs (*Basket design, Enrichment design, Umbrella design, Stratified all-comers design, Strategy design, Adaptive signature design, Adaptive threshold design, Adaptive enrichment designs*)

19.30 Course closure – Social Dinner

24 MARCH 2017

8.30 Departure from Hotel

A personal laptop with the most recent copy of R installed is required for tutorials.

PREREQUISITES

Knowledge of R programming.
Some knowledge of statistical methods for clinical trials.

TUTORS

P. Rebora, D. Bernasconi
Center of Biostatistics for Clinical Epidemiology
School of Medicine and Surgery
University of Milano-Bicocca

Participants will have the possibility to:

- Enjoy winter sports in the surrounding
- Spend time for individual study during the half day break.

COURSE VENUE

Ponte di Legno (BS)

COURSE WEB PAGE

www.statmed.medicina.unimib.it/xxxxxxx