

OBSERVATIONAL CLINICAL RESEARCH FOR REAL WORLD EVIDENCE

A two days intensive course to learn the most important and successful factors involved in the planning and design of observational clinical research, with particular emphasis on the choice of the best study design in relation to methodological, regulatory and organizational constraints.

Monday, **18** and Tuesday **19 September** 2017



Training course

210 € Early Bird discount
for enrolment by **21th August 2017**

H10 Urquinaona Plaza

Plaça Urquinaona, 2
E-08010-Barcelona, Spain

Monday 18 and Tuesday 19
September 2017

09:00-17:30

For additional information:



+39 (0)35.515684



training@LSacademy.eu

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easyB

Training Course: Observational Clinical Research for Real World Evidence

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Introduction

Observational clinical research has become a fundamental tool for the development of new health technologies through the observation of what happens in actual clinical practice. Observational studies are extremely heterogeneous since they include very different designs and aims. Unfortunately this type of study is only partially regulated, both at a local and international level. This causes some difficulties in the planning of the ethical and authorisation process, and in the conduction of the study. Designing and carrying out an observational study requires, besides a depth knowledge of legal constraints and of the legislative framework, specific methodological and epidemiological skills. The use of the traditional operative models borrowed from controlled clinical trials is not the solution. To identify the right solutions it is important to adapt to every single project the huge amount of available techniques and instruments.

Who should attend?

The course is aimed at everyone who works in biomedical or pharmaceutical companies and needs to plan and design an observational clinical study.

Attendees' experience

Experience in Medical Affairs, Clinical Development or of Late Phase Clinical Research. Specialists from Market Access and from Health Economics and Outcome Research (HEOR) are also welcomed.

Teaching method

Lessons with case studies and classroom exercises.

At the end of the course the participant will be able to...

...identify the key success factors that characterize the design and the outcome of an observational study.

IN COMPANY TRAINING - "Tailor-Made" Training

LS Academy can offer in company tailor-made training courses to meet specific learning needs.

Contact us to design your training course:

Tel: +39 (0)35. 515684 **Fax:** +39 (0)35.4501262 **Email:** training@LSacademy.eu

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Course subjects:

18 September: Definition, applications and regulations

- Clinical Observational Research and the need of Real World Evidence
- Post marketing studies (Registries, PASS / PAES, DUS, etc.)
- Pre marketing studies (disease, epidemiological, etc.)
- Regulations and international standards
- EMA (European Medicines Agency) Guidelines
- References for the treatment of personal data

Course subjects:

19 September: How to design a study?

- Why design and conduct an observational study?
- Strategic approaches to Real World Data
- How to define the "Research Question"
- Advantages and Disadvantages of the main Study Designs
- How to deal with Confounders
- Communication of the results of an observational study

Agenda

Day 01

9:00 - 9:30		Participants registration
9:30		Course commences
11:00 - 11:15		Coffee Break
12:45 - 13:45		Lunch
15:30 - 15:45		Coffee Break
17:30		End of day 1

Day 02

09:00		Course commences
11:00 - 11:15		Coffee Break
12:30 - 13:30		Lunch
15.30 - 15.45		Coffee Break
17:00		Q&A and Conclusion

Participants will get a **10% discount** for the registration to the European Epidemiological Forum 2017 – October 9th 2017 – www.epiforum.eu



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Lecturers

The course will be taught by two senior consultants of MediNeos Observational Research under the scientific responsibility of Giovanni Fiori.

MediNeos is specialized in the design and management of multicenter, international observational studies and patients registries for the Life Sciences Industries.



Giovanni Fiori, Managing and Scientific Director

A PhD in Human Population Biology research (Bologna University) Fiori has also a Master degree in Public Health from the Catholic University "Sacro Cuore" (Rome). He has participated in epidemiological researches in Italy and managed numerous research campaigns abroad as part of International cooperation programs promoted by the University of Bologna. Since 2005 he has been coordinating the "Observational Studies" Working Group of SSFA (Società di Scienze Farmacologiche Applicate) where he has twice been a member of the Board of Directors. He is in charge of the EUCROF (European CRO Federation) "Late Phase" working group and an active member of SISMEC (Società di Statistica Medica e Epidemiologia Clinica), SIF (Società Italiana di Farmacologia), ISPE (International Society of Pharmacoepidemiology) and ISPOR (International Society for Pharmacoeconomics and Outcomes Research). He has authored or co-authored over one hundred scientific papers and articles at National and International level.

MediNeos Senior Consultants:



Simona Sgarbi
Real World Data Senior Advisor



Stefano Viaggi
Director of Real World Data Solutions



Lucia Simoni
Clinical Data Management and Biostatistics Unit Manager

Short biographies are available on the website

MediNeos strives for constant improvement in the application of proper epidemiological methods geared to collecting reliable and significant health data in both pre and post marketing phases, covering the most important therapeutic areas. With a track record of over 100 successful observational studies managed since 2003, MediNeos has developed a vast and specific experience in Real World Data collections performed with a variety of prospective, retrospective and hybrid designs.

Course language English

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND THE REGISTRATION FORM OR DIRECTLY REGISTER ONLINE:

<https://2017-observational-clinical-research-es.eventify.it/orders/new>

REGISTRATION FEES:

- Early bird: **€ 1460,00** (before 21/08/2017)
- Ordinary: **€ 1670,00**
- Freelance – Academy – Public Administration: **€ 770,00**

The fee includes: tuition, teaching materials, lunches breaks, organizational office assistance, attendance certificate.

Methods of payment

The full amount must be paid on registration to EasyB s.r.l by bank transfer or by credit card. If paying by bank transfer please attach proof of payment to the registration form. Bank transfer payable to:

EasyB S.r.l.

Via Roma, 20 - 24022 Alzano Lombardo (BG)
P. IVA **03633040161**
BPM - Filiale di Carobbio Degli Angeli
IBAN: **IT81 F 05034 53960 000000003450**
SWIFT CODE: **BAPPIT21AY5**



For additional information



Secretarial office **LS Academy**

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Please fill in and send:  **(+39) 035.4501262**

 **training@LSacademy.eu**

or register [online](#)

Surname _____ **Name** _____
Company _____ **Job title** _____
Address _____
City _____ **Post code** _____
Tel. _____ **Fax.** _____
E-mail _____
Special Dietary Requests _____

INVOICING DETAILS

Company name _____
Address _____
Mail address (If different) _____ **Post code** _____
City _____
Vat number _____

Terms & Conditions

Terms of payment The registration fee must be paid at the time of registration. Confirmation of course admission will be given on receipt of payment. EasyB reserves the right to refuse late registrations or additional registrations above the maximum accepted number of participants

Cancellation Please note that refunds (70% refund of the registration fee) will only be given if cancellation is received at least one week before the course date. Cancellations will only be valid if made in writing. Transfer of registrations (or name changes) are allowed and should be made in writing within 7 days prior to the event. EasyB reserves the right to postpone or cancel an event, to change the location of an event or to alter the advertised speakers for an event. EasyB is not responsible for any loss or damage as a result of substitution, alteration, postponement or cancellation of an event due to causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade of industrial disputes, terrorism, or hostilities

LS Academy reserves the right not to accept registrations not compatible with the event's target audience.

The course will proceed with a minimum of 8 participants.

Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.

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Date _____

Signature _____

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