Writing a compliant and effective Clinical Study Report

Monday, **16 September** 2019 - Milan

110 € Early Bird discount
for enrolment by **2nd September 2019**

Course Language: English

Hotel Melià

Via Masaccio 19

20149– Milan

Monday, 16 September 2019

09:00-18:00

*A portion of the proceeds from this course are donated to the **Vase of Flowers** project*

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Introduction

The Clinical Study Reports (CSRs) are the critical documents by which regulators can assess the outcome of clinical studies. CSRs also include Clinical Trial Reports - the new EU terminology for CSRs when the study report pertains to an interventional (rather than non-interventional) trial.

CSRs are scientific documents addressing efficacy and safety, not a sales or marketing tool. But the sponsoring company's goal is to sell a drug, biologic, or device. Sponsors want to showcase a product and the problem it solves, and they want regulators to focus on the forest, not the trees, to weave key messages with important study findings that are repeated throughout the marketing application. In the CSRs, key messages are found in the synopsis at the beginning and are reiterated in the body of the document as topic sentences, in summaries of sections or subsections, and in the conclusions. Sponsors hone key messages thoughtfully, selecting words and ideas to convey desired nuances. Although study findings determine key messages, messages may be influenced by other factors such as results of prior studies and characteristics of competing products.

CSRs for submission to the Health Authorities are also required to be in compliance with the International Conference on Harmonization (ICH) standards and must meet high quality standards. Participants will learn the elements of the CSRs and the appendices, methods for turning the protocol and statistical outputs into one cohesive document, the basics of writing and preparing a document for submission, and the guidance's to follow for reference. The course will provide latest strategies for preparing such clear, well organized, ICH-compliant CSRs in a more efficient way.

Who is the course aimed at?

This one-day course is intended for professional's researchers and medical doctors in the biomedical field, including, but not limited to employees of Biotech and/or Medical Device companies, Pharmaceutical companies, CROs, Consultants, Research hospitals, Universities, as:

- Medical Affairs Professionals
- Regulatory Professionals
- Clinical Operations Professionals
- Clinical Study Managers
- Biostatisticians
- Physicians
- Medical Writers
- Scientific Communications Professionals
- Medical Communications Professionals
- Scientists
- Investigators
- Representatives of academia running clinical trials

who are involved in clinical research and need to write clinical study reports.

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Programme

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- Welcome and objectives
- Introduction
- What is medical writing
- Regulatory requirements - CSRs
- Study Documents I Read Before Writing a Clinical Study Report
- The structure of CSR
- Title page, abbreviations, definition of terms, ethics, investigators
- Introduction, study objectives, investigational plan, study patients, efficacy evaluation, safety evaluation
- Discussion, overall conclusions, tables, figures, graphs, appendices
- The synopsis
- Workshop: where are infos?
- Closing remarks

Agenda

9:00 - 9:30		Participants registration
9:30		Course commences
11:00 - 11:15		Coffee Break
13:00		Lunch
15:45 - 16:00		Coffee Break
18:00		Q&A and conclusion

Required Experience

The course is designed for anyone who knows the basics of clinical research and scientific publishing being interested in presenting their results to regulatory authorities.

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Teaching methods

Interactive workshop

Lecturer's Bio

Andrea **Rossi,** *Medical Writer - European Medical Writers Association*

Andrea Rossi has a degree in Biology from Florence University. After a brief spell at the University, he started working in the Italian Affiliate of Eli Lilly as a Clinical Research Associate. In the years that followed he was responsible for Statistics, Health Outcomes and Medical Information. Andrea has been working in Medical Writing since 2003 and is Senior Medical Writer Manager at Fresenius Kabi SwissBioSim.

He is author of more than 350 publications and acknowledged for his contribution in several others. From 2007 to 2009 he was on the coordination board of BIAS (Biometristi Italiani Associati) and has been an European Medical Writers Association (EMWA) member since 2004. Andrea leads workshops for and is past-president of EMWA.
Andrea acted as trainer for statistics and medical writing in some Italian schools for specialization in medicine, and has been a speaker at national and international conferences.

At the end of the training, you will be able to:

- ✓ Recognize key regulatory requirements for clinical study reports
- ✓ Understand the relationship of the clinical study report to the clinical study protocol
- ✓ Develop a comprehensive and easily reviewable clinical study report

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TO REGISTER FOR THE COURSE YOU CAN FILL IN AND SEND **THE REGISTRATION FORM**

OR DIRECTLY **REGISTER ONLINE:** https://clinicalreport-2019.lsacademyevents.it/orders/new

REGISTRATION FEES:

- ☐ Early bird: **€ 750,00 *** until 02/09/2019
- ☐ Ordinary: **€ 860,00***
- ☐ Freelance – Academy – Public Administration: **€ 460,00***

***For Italian companies: + 22% VAT**

The fee includes: tuition, teaching materials, lunches and coffee 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**

Banco BPM - Filiale di Carobbio Degli Angeli

IBAN: **IT81 F 05034 53960 000000003450**

SWIFT CODE: **BAPPIT21AY5**

For additional information:

Secretarial office LS Academy	**Phone** +39 (0)35.515684	**Fax** +39 035.4501262	**Mail** training@LSacademy.com

Please fill in and send: **(+39) 035.4501262** | **training@LSacademy.com** 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 _____ **Invoice recipient code** _____

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.

In accordance with the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016, we inform you that EasyB S.r.l. (with headquarter in Via Roma 20, Alzano Lombardo, Bergamo, Italy, VAT number IT03633040161) will use your personal data voluntarily provided by you only with the consent and in compliance with the principles dictated by the European Regulations on the protection of personal data for sending newsletters, for marketing purposes (sending advertising material, market research and commercial communication) and for communication purposes to third parties (lecturers), also for marketing goals. You can read the complete information, including your rights and the procedures for the exercise of the same, following this link.

LSACADEMY.com **Date** _____ **Signature** _____