# Clinical Study Reports – a 360° Perspective

## Planning and Authoring CSRs in Accordance with Public Disclosure Requirements

| Type | Date | Language | Location |
|---|---|---|---|
| Online Training - Limited number | 27 and 29 September 2021 | English | Online |

## ABOUT

This virtual course in 2 sessions covers scheduling, managing and authoring of clinical study reports (CSRs) for modern design clinical studies. It discusses the stages of preparation of CSRs in the context of precursor documents including the clinical study protocol (CSP), the statistical analysis plan (SAP), and the incorporation of study data. Components of the integrated CSR include narratives and appendices, and the preparation of these sections of the CSR will also be covered. Scheduling an achievable reporting timeline for this complex and multi-component document will be explained.

The practical use of CORE Reference for writing integrated CSRs is demonstrated. Open access CORE Reference (www.core-reference.org/) launched in 2016, provides interpretational guidance on CSR authoring that incorporates ICH, regional (EU and US) guidances and real-world insights. CORE Reference helps writers to author CSRs that share clinical trial data responsibly, and in accordance with current public disclosure requirements.

At the end of this course participants should understand the resources and have gained the knowledge to schedule, manage, write and deliver draft through final version CSRs that are of the highest quality, and are fully ICH compliant. By completing the course, participants will also gain insight into the public disclosure requirements that a CSR must fulfil.

## PROGRAMME

***MODULE 1***
General Introduction

- Meeting agenda
- Getting to know each other

**Part 1: Process Overview, Components and Stages of Preparation of the Integrated CSR**

- Background and Overview of CSR Writing
- Shell CSR
- Draft CSR
- Final CSR

**Part 2**

- CSR Appendices
- CSR Narratives
- Overnight quiz

***MODULE 2***

**Part 1: CSR Authoring Using a 'State of the Art' Tool**

- Quiz answers
- Introduction to CORE Reference
- CORE Reference web tour www.core-reference.org
- Common areas of confusion in ICH E3 – group discussions

**Part 2: CORE Reference: 'CLARITY' in clinical study reporting**

- How CORE Reference solves inconsistencies in areas of ICH E3 confusion; selected examples
- CORE References appendices and annexes
- Added value – results posting efficiencies

**Part 3: CORE Reference 'OPENNESS' in clinical study reporting**

- Transparency and disclosure environment
- Public disclosure requirements
- CORE Reference approach
- EMA, Health Canada – publicly disclosed CSRs
- Changing concepts and culture

**Part 4: Close**

- Closing remarks; are expectations met and any remaining questions not covered through the modules

- Feedback forms reminder

## WHO SHOULD ATTEND

Regulatory medical writers working in the contract research organisation or pharmaceutical company environment who write or review clinical study reports (CSRs).
Medical writing managers who oversee regulatory medical writers and who wish to ensure that they are incorporating industry standards into their regulatory writing process would also benefit from attending. Participants will be expected to complete a 'needs analysis ' form prior to the course to provide the course leader with insights to allow for an optimal teaching and learning experience.

### Participant experience

Participants must have written at least one CSR or reviewed several and have working knowledge of International Council for Harmonisation (ICH) reporting guidelines.

## TEACHING METHODS

This online course will be highly interactive with discussion and questions encouraged throughout the two virtual sessions. In each session there will be an opportunity for participants to actively participate. Participants are asked to bring a hat or cap to the sessions to facilitate their on-screen participation.

## LECTURERS

### Sam Hamilton

**Subject Matter Expert in Regulatory Medical Writing**

Sam Hamilton is a postdoctoral virologist, currently Global Head of Medical and Regulatory Writing and Public Disclosure for the CRO, Clinipace www.clinipace.com. Sam has over 25 years in clinical and regulatory medical writing roles in the pharmaceutical industry and is an expert in writing and managing clinical-regulatory documentation for medicines licensing. Sam is an internationally recognised expert and speaker in the area of public disclosure of clinical-regulatory documents as Chair of the EMWA-AMWA group who delivered open-access www.core-reference.org in May 2016. Sam is long-time supporter of her professional association, the European Medical Writers Association (EMWA) www.emwa.org serving in various roles over 12 years, notably as Freelance Advocate; Editorial Board member for Medical Writing (MEW) (journal); Workshop Leader; Expert Seminar Series (ESS) Chair; and Vice President and President of the Executive Committee (EC). Sam was elected an EMWA Lifetime Fellow in 2018 for her services to the association. Currently, Sam is MEW Section Editor for the "Regulatory Public Disclosure" Section and serves on the Advisory Panel of the EMWA Regulatory Public Disclosure Special Interest Group.

## AT THE END OF THE TRAINING, YOU WILL BE ABLE TO

- Demonstrate the knowledge and skills required to author or review fit-for-purpose CSRs that belong in the modern drug development arena
- Understand the stages involved in authoring CSRs allowing you to make a valuable contribution to your organisation's process improvement activities
- Be better equipped to manage stakeholder expectations with regard to efficient, effective and realistic CSR scheduling

## USEFUL INFORMATION

**Online training – 2 modules**

| | |
|---|---|
| September 27th, 2021 | 2.30 pm – 5.30 pm CET |
| September 29th, 2021 | 2.30 pm – 5.30 pm CET |

After the registration, you will receive all details about the connection.

**The course will proceed with a minimum number of participants. Should this number not be reached the registered participants will be notified one week prior to the commencement of the course.**

## REGISTRATION FEE

**Early Bird**: **€ 660,00*** (until 6 September 2021)

**Ordinary**: **€ 780,00***

**Freelance – Academy – Public Administration****: **€ 430,00***

* for Italian companies: +22% VAT

**Early Bird discount not applicable to Freelance – Academy – Public Administration fee

**The fee includes:** tuitions, organizational office assistance, teaching materials and attendance certificate that will be sent after the training via e-mail.

## SEDE DEL CORSO

Online interactive training on Zoom platform.
*LS Academy will provide the access link to the virtual platform a few days before the training.*