EMWA Professional Development Programme

Addressing safety in Medical writing of Clinical Study Protocol

Proposed category Professional techniques – Advanced

Duration - 3 hours

Siddharth Chachad

Pre-workshop assignment

Objective

The objective of the assignment is to ensure that all attendees have basic understanding of the clinical study protocol content and structure format, as well as drug development process so that this knowledge can be built on during the workshop for designing the safety section of the study protocols appropriately.

Content

Attendees should be familiar with "ICH Guideline E6 (R2) Guideline for good clinical practice https://www.ema.europa.eu/documents/scientific-guideline/ich-e-6-r1-guideline-good-clinical-practice-step-5_en.pdf. This guideline provides basic structure for writing clinical study protocols. In particular, section 6.8 will be relevant to this workshop.

Assessment criteria

There will be no formal assessment.

Instructions

You must complete following needs assessment questionnaire and provide a copy to the workshop leader prior to the workshop.

Resources and materials

Attendees will need access to the internet in order to obtain the guidance document needed for this workshop.

Time required

1 hour

Needs assessment questionnaire

To ensure that the workshop corresponds to your needs, please complete this questionnaire.

Name:

Educational Qualifications:

Current company:

Current job profile (in brief):

What is your level of understanding of clinical development process? (Please tick appropriate box)

Basic ☐

Intermediate ☐

Advanced ☐

How much experience do you have in medical writing?

< 5 years ☐

5 - 10 years ☐

> 10 years ☐

Have you written clinical study protocols? If yes, how many years of experience do you have specifically in writing study protocols?

If not, have you taken basic workshop on the clinical study protocol: content & structure?

Have you received any trainings recently in drug safety or medical writing? If so, please provide details below.

Are you attending this workshop to get credit towards your certificate?

Yes: **No:** **Undecided:**

What specific issues do you have in preparing the safety sections of clinical study protocols?

Please return to Siddharth Chachad at siddharthchachad@gmail.com at least two weeks prior to the workshop.