

EMWA Professional Development Programme

Subject narratives for clinical study reports

Drug development option, 3.5 hours
Dr James Visanji
Trilogy Writing and Consulting GmbH

Abstract

Participant profile

This workshop is intended for medical writers who are familiar with the clinical development process but have no or limited experience in writing subject narratives for clinical study reports.

Objective

Participants will acquire a knowledge of the requirements and criteria for writing subject narratives within the framework of relevant ICH guidelines. They will obtain an understanding of the narrative writing process, including sources of data, presentation of information, important functional groups contributing to the narratives, and techniques for narrative generation. This will enable the writer to prepare high-quality narratives and optimize narrative writing activities.

Workshop content

The pre-workshop assignment will consist of reading relevant ICH guidelines (E2A, E3, E6) and a short exercise on narrative strategy.

The following topics will be discussed during the first part of the workshop:

- Relevant sections of the ICH guidelines, emphasizing the purpose of narratives
- Definition of narrative criteria and categories
- Content, including sources of information and data, the role of clinical trial and pharmacovigilance databases, recycling of information from CIOMS forms
- The narrative writing process, including formats, templates, use of programmed data, coordination with other functional groups, quality control, tips for handling narratives in large studies

During the second part of the workshop participants will be divided into groups and asked to write a simple narrative based on tables and listings. For the post-workshop assignment each participant will be asked to prepare a more complex narrative.

Pre-workshop assignment

2 hours

Post-workshop assignment

2 hours

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Drug development option, 3.5 hours

Dr James Visanji, Trilogy Writing and Consulting GmbH

Pre-workshop assignment

Objective

The aim of the pre-workshop assignment is to make sure that you are familiar with the guidance from the International Conference on Harmonization (ICH) that provides the regulatory basis for writing subject narratives. You are also asked to perform a short exercise on narrative writing strategy to start you thinking about the practicalities and processes involved.

Content

Please read carefully the following guidance on subject narratives:

- ICH E2A: Clinical safety data management: definitions and standards for expedited reporting
- ICH E3: Structure and content of clinical study reports (Section 12)
- ICH E6: Guideline for good clinical practice (Sections 5.16, 5.17, 6.8)

Clinical study reports come in a variety of shapes and sizes, and the strategy for writing subject narratives depends on several factors that include the study population, the underlying disease, and the study drug. The purpose of narrative writing is to bring the attention of the reviewer to clinically relevant, drug-related issues that have occurred in individual subjects.

Please submit the following as your pre-workshop assignment:

- 1: What would you consider to be the special challenges when writing subject narratives for a clinical study on 1000 terminally ill patients with metastatic colorectal cancer and a short life expectancy?
- 2: Please provide 3 suggestions for a strategy for preparing subject narratives that would allow a reviewer of the final report to identify clinically relevant, drug-related safety issues from the narratives.

Assessment criteria

I must receive your answers for the pre-workshop assignment by the date given below if you wish to qualify for workshop credit.

(Note: credit will only be given if the pre-workshop assignment, the workshop, and the post-workshop assignment are all completed satisfactorily).

Instructions

As preparation for this workshop, please study the ICH guidelines provided in the files attached below (also obtainable from the ICH web site

<http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>).

Then fill out the questionnaire below and prepare your response to the exercise.

Compile the questionnaire and your answers in a single Microsoft word document with the filename “DDF11a_2018May_Your name.doc”, and send by email to:

emwa@visanji.com

If you are taking the workshop for credit, your assignment must reach me on or before

23 April 2018

Please chase me by email if you have not received a receipt acknowledgement by

30 April 2018

Please bring a copy of your pre-workshop assignment with you as may need to refer it during workshop discussions.

Time required

About 2 hours.

ICH E2A	ICH E3	ICH E6
 Adobe Acrobat Document	 Adobe Acrobat Document	 Adobe Acrobat Document

Questionnaire and exercise

Subject narratives for clinical study reports

Name

Current job

How much experience do you have in writing subject narratives for clinical study reports?

Do you have any other relevant experience?

Which three questions would you most like to see answered during the workshop?

Exercise

What would you consider to be the special challenges when writing subject narratives for a clinical study on 1000 terminally ill patients with metastatic colorectal cancer and a short life expectancy?

Please provide 3 suggestions for a strategy for preparing subject narratives that would allow a reviewer of the final report to identify clinically relevant, drug-related safety issues from the narratives