EMWA Professional Development Programme

Writing Global Clinical Submission Dossiers Using the Common Technical Document

Drug Development Option – Advanced

Dr James Visanji
Trilogy Writing and Consulting GmbH

Workshop outline

Participant profile

The course is intended for medical writers with little or no experience of writing clinical submission dossiers. Participants should be familiar with the clinical development process, and ideally have some experience of writing clinical study reports.

Objectives

- To introduce participants to the preparation of clinical submission dossiers according to the CTD.
- To convey general principles and processes of summary writing.
- To facilitate understanding of the limits of the available regulatory guidance.

Workshop content (3:30 hours)

- Development and background of the CTD.
- Purpose and types of clinical summary documents.
- Group exercise.
- CTD Module 2.7 (Clinical Summary).
- CTD Module 2.5 (Clinical Overview).
- Data presentation in the CTD.
- Integrated summaries of efficacy and safety for the USA.

Pre-workshop assignment: Approximately 4 hours. Participants may need more or less time depending on their familiarity with the guidelines.

Post-workshop assignment: Approximately 4 hours.

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Needs analysis questionnaire

To ensure that the workshop corresponds to your needs, please complete this needs analysis form as part of the pre-workshop assignment.

Name:

Current job:

How much experience do you have of preparing clinical submission dossiers and clinical study reports?

What could you contribute towards this workshop?

Please rate each topic in terms of its importance to you. As far as possible, time during the workshop will be allocated to the items with highest scores.

1 = I do not want much time on this
2 = I do need some time on this
3 = I need lots of time on this

Topic	Score (tick appropriate box)		
	1	2	3
• Development and background to clinical modules			
• Purpose and types of summary documents			
• CTD Module 2.5: The Clinical Overview			
• CTD Module 2.7: The Clinical Summary			

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Pre-workshop assignment

Objectives

- Familiarity with the CTD guideline "Notice to Applicants".
- Familiarity with additional requirements for US submissions.
- Ensure that the issues which concern you most about the application of the guidelines are dealt with adequately during the workshop.
- Stimulate discussion of the guidelines during the workshop.

Content

- Study of the following sections only of the Notice to Applicants: Introduction and Modules 1, 2.2, 2.5, 2.7, 5.
- Study of two US "Guidance for Industry" documents.
- Completion of the needs analysis questionnaire.
- Preparation of one question or comment on the Notice to Applications sections and answering a question on clinical summary documents.

Assessment criteria

Participants attending the workshop for credit must complete the pre-workshop assignment and return it to me by the date specified below.

Instructions

1. As preparation for this workshop, study the documentation described above.
2. Complete the needs analysis questionnaire.
3. Prepare one question or comment on the materials studied. Please restrict your one question or comment to an issue connected with document preparation; questions connected with drug development plans, clinical trial design or regulatory submission procedures are outside the scope of this workshop.
4. Answer the question: "Why are clinical summary documents useful to reviewers of clinical submission dossiers?" - give three reasons.
5. Compile the answers to 2, 3, and 4 in a single Microsoft word document with the filename "Your surname_DDA1a 2018May.doc", and send by email to:

   emwa@visanji.com

Your assignment must reach me on or before

23 April 2018

if you are taking the workshop for credit.

Please send me a follow-up 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.

Material required

- Vol 2B Notice to Applicants.
- Guidance for Industry: Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.
- Guidance for Industry: Integrated Summary of Effectiveness.

Volume 2B	**ISS and ISE location**	**ISE guidance**
Adobe Acrobat Document	Adobe Acrobat Document	Adobe Acrobat Document

Time required

Approximately 4 hours. Participants may need more or less time depending on their familiarity with the guidelines.