

EMWA WEBINAR: 'The Core Reference Project – Value for the Global Regulatory MW community' 21 June 2023

00:15:26 Alison McIntosh (CORE Reference Team): Hi everyone- welcome to the webinar. If you have any questions please write them into the chat and we will try to answer at the end of the presentation. We will have some Q&A time at the end when we will address questions received in the chat as time allows.

00:20:19 Kamila Novak: Good morning, some years ago, I wrote a CSR following CORE Reference and the sponsor rejected it, asking me to re-write it taking E3 as a template. Seems many industry stakeholders do not know about CORE Reference at all. Are there any awareness boost initiatives? Thank you.

00:23:34 David Main: A linked question I think... in recently preparing an NDA it became clear that the FDA strictly requires granulated CSR components using the ICH E3 appendix numbering, which is a bit counter to the general notion that ICH E3 is 'not a template'. Has there been any consultation/discussions with FDA about either/both ICH E3 and CORE Reference?

00:27:53 Simone: The CORE Reference is great! Are there any plans to make a CORE reference for other Regulatory documents?

00:44:22 Andrea: The News Summaries are a lot and could be incredibly useful for MWs, but they are complex to navigate. Is a search engine or a browsing support (i.e. as for equator network) in the CORE reference website to simply seek what you're looking for?

00:44:40 Kamila Novak: In the light of ICH E6(R3), do you plan to update CORE Reference and eliminate "subject"?

00:51:27 Andrea: Is the CORE-commented CSR available for non-controlled studies, studies on devices, on animals, etc.? Why does the available one not have to be considered as a template?

00:54:04 Kamila Novak: Will the table Disclosure Landscape in Asia be made available as a resource?

00:56:27 Douglas Fiebig: Are you aware of any forthcoming ICH initiative to release a template for CSRs (hopefully similar in structure to TransCelerate), analogous to M11 for protocols?

00:59:41 Shelby Vale: Reacted to "Will the table Dis..." with 👍

01:03:38 David Main: To slightly broaden my earlier question re the FDA, I understand that FDA follows ICH M4, Table 6, Note 1 in requiring granulated CSRs, and as noted earlier, uses ICH E3 Section 16 structure strictly to define the granulation of the listing appendices. CORE Reference does not address this granulation issue at all (and in fact refers to the CSR as a 'single document'). Can/will this be addressed?

01:09:00 Monique Goldblatt: Replying to "A linked question I ..."

What about Transcelerate numbering?

01:10:56 Anne McDonough: I think the restriction on Section 16.2 has to do with eCTD publishing.

01:11:18 Douglas Fiebig: Replying to "A linked question I ..."

A solution I've seen in to have TransCelerate CSR Section 9 for appendices, and then within that section label the Appendices as 16.1, 16.2 etc. to concur with E3 and STF requirements

01:11:38 Vivien Fagan (CORE Reference Team): Replying to "Good morning, some y..."

Hi Kamila! Other than our workshops and events like this, no.

01:11:53 Anne McDonough: And does not necessarily apply to the main document

01:12:12 Monique Goldblatt: Replying to "A linked question I ..."

Obviously not ideal

01:12:35 Douglas Fiebig: Replying to "A linked question I ..."

...but practical!

01:12:46 Monique Goldblatt: Reacted to "...but practical!" with 👍

01:14:50 Padma: Good point about finding relevant webinars/Other

01:18:23 Beatrix Lehnert: Replying to "A linked question I ..."

Not sure that FDA really insists on the ICH E3 numbers as long as the content is halfway in line with ICH E3. e.g., we have included an additional 16.2 appendix in our CSRs, and so far FDA has never complained.

01:20:33 Sofia Poulou: Great presentation! Thank you all.

01:20:42 Desiree Douglas: Great that the chat will also be captured. Thank you!

01:20:44 Vivien Fagan: Reacted to "Great presentation! ..." with 👍

01:21:04 Sofia Poulou: Reacted to "Great that the cha..." with 👍

01:21:26 JoanaEnes: Thank you so much for your great work and presentation!

01:21:32 Vivien Fagan: Reacted to "Thank you so much fo..." with 👍

01:22:50 Vivien Fagan: Thank you everyone!

01:23:03 Zuo Yen Lee (CORE Reference Team): Replying to "Good morning, some y..."

Hi Kamila, I got asked similar questions of why certain sections were not following the E3 in a CSR that I prepared. I have provided the justifications, pointing them to the CORE Ref (CORE Ref includes the rationale in the comments) and even E3 is not a template. And so far I have not heard back from them asking to re-write the CSR. :)

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01:23:06 Silvia Reddehase: Thank you very much! Very helpful information, truly appreciated!

01:23:13 Simone: Thank you so much!

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