Audience Questions and Panelist Responses

Question: How are your standards / machine executable content aligned to the TEFCA data elements / standards?

Answer: CDISC Standard define the data elements that are collected, derived, analyzed and reported in clinical research trials. We collaborate with HL7 on the use of CDISC standards as they relate to healthcare environment and the clinical care providers. CDISC is providing the standards metadata in a machine-readable format to be implemented by solutions that would comply with the Trusted Exchange Framework and Common Agreement (TEFCA).

Question: Is CDISC working with the WHO? In particular, I'm thinking about the WHO trial registry network and standards.

Answer: CDISC collaborates with WHO on a number of projects including standards to be used as part of a trial registry. Most recently CDISC collaborated with WHO on Vaccine Administration standards.

Question: Are there plans to add safety terms to the glossary (i.e., common definitions for neutropenia, tumor lysis syndrome, etc.).

Answer: Right now we are mostly focused on clinical research terms more generally but open to learning how we can grow in the future

Question: As part of the CDISC partnership, will the terms be mapped to existing (non-plain language) standards for clinical or medical terms?

Answer: Great to see you on this webinar. Yes, CDISC/MRCT Terminology will include the necessary mappings.

Question: Will a recording of this be available after? Some of our colleagues here would be interested in the discussion.

> **Answer:** Yes! We will send out a link to a web page of resources including the recording, slides, panelist info, and public review details.

Question: I heard in the previous presentation, that CDISC is working to standardize all eCRF. Can you talk a little bit about that

> **Answer:** CDISC eCRFs consists of ready-to-use, CDASH-compliant, annotated eCRFs, available in PDF, HTML and XML, to use as is or import to an EDC system for customization. The eCRFs are examples and are not meant to imply that any particular layout or collection plan is preferable over another. CDISC is expanding the eCRF templates into additional data collection areas and therapeutic indication. The CDISC eCRF Portal is located at:
> https://www.cdisc.org/kb/ecrf

Question: Thank you for the amazing work that this team has created and for this detailed webinar. Are there any issues with us sharing the glossary on an IRB resource page?

> **Answer:** Please feel free to share and use our glossary at any time! We just ask that you please credit the MRCT Center. When there are updates, we will notify users via our social media channels and on the website itself.

Question: Some of these definitions are really good already even if they will change can they be used now?

> **Answer:** Yes! Please feel free to start using the MRCT Center Clinical Research Glossary definitions now.

Question: There is a myriad of online readability software, which vary wildly in how they interpret readability. Are there any plans to develop a standardized readability software for clinical trials?

> **Answer:** This is a great suggestion! While there are no plans at the moment, we are open to exploring creating such a resource.