CDISC Webinar Q&A Summary

Below is the complete Q&A transcript from the webinar. Questions are anonymized. Responses provided during the session are included. Additional responses may be added where noted.

Question 1

Joe Ben Clark (Feb 10, 2026 16:01):
Welcome everyone to the CDISC Webinar today. You can ask questions in the QnA section. We will answer questions at the end of the webinar.

- **CDISC Team (Feb 10, 2026 16:03):** am I the only one who can't hear Bill?
- **CDISC Team (Feb 10, 2026 16:07):** We cannot see slides
- **CDISC Team (Feb 10, 2026 16:11):** We cannot see slides
- **CDISC Team (Feb 10, 2026 16:11):** I can hear, but I am unable to see the slides
- **CDISC Team (Feb 10, 2026 16:11):** now they are up. Thank you!
- **CDISC Team (Feb 10, 2026 16:12):** i exited the meeting and rejoined and could see the slides better
- **CDISC Team (Feb 10, 2026 16:12):** yes
- **CDISC Team (Feb 10, 2026 16:17):** I hope this PPT will be shared with us.
- **CDISC Team (Feb 10, 2026 16:20):** the powerpoint will be added to the cdisc webinar archive with the video in a few days.
  Webinars - Public | CDISC

Question 2

Attendee (Feb 10, 2026 16:11):
Where can we find the adoption stories and use case library?

- **Bill Illis (Feb 10, 2026 16:32):** On this page you will find links to the adoption stories and use case library, Tools & Resources | Digital Data Flow

Question 3

Attendee (Feb 10, 2026 16:14):
Did you mention that 4.1 would be fully M11 aligned?

- **Bill Illis (Feb 10, 2026 16:34):** Yes, v4 is already >90% aligned, but there are some updates required based on the final M11 tech spec which was approved in Nov 2025 to achieve full alignment. USDM v4.1 will be released in the 2nd half of 2026.

Question 4

Attendee (Feb 10, 2026 16:18):

Will the recording of this webinar be available publicly later on?

- **CDISC Team (Feb 10, 2026 16:23):** the powerpoint will be added to the cdisc webinar archive with the video in a few days. Webinars - Public | CDISC

Question 5

Attendee (Feb 10, 2026 16:20):
Kindly share the recodings for future reference.

- **CDISC Team (Feb 10, 2026 16:23):** the powerpoint will be added to the cdisc webinar archive with the video in a few days. Webinars - Public | CDISC

Question 6

Attendee (Feb 10, 2026 16:20):
Having taken the CDISC USDM and Biomedical concepts trainings, I find that the training helped me embark on the journey to understand USDM. Are there plans for introducing more USDM or Biomedical Concepts related trainings to further strengthen our knowledge beyond the introductory trainings?

Response:

- **Julie Smiley (Feb 13, 2026):** CDISC has a USDM Onboarding Package that is tailored to your specific organization. I recommend checking into this education package.

Question 7

Attendee (Feb 10, 2026 16:21):
Please provide Youtube channel link for USDM providers

- **Bill Illis (Feb 10, 2026 16:26):** DDF Solution Showcase - YouTube

Question 8

Attendee (Feb 10, 2026 16:28):
Is the DDF Project Team or CDISC open to having discussions with sponsors who are actively looking into adopting USDM/Biomedical concepts to determine a good starting point?

- **Julie Smiley (Feb 10, 2026 16:35):** CDISC has a USDM Onboarding Package that is tailored to your specific organization. I recommend checking into this education package.
- **Bill Illis (Feb 10, 2026 16:39):** There are also some self-paced "getting started" material that you can access here, Getting Started | Digital Data Flow
- **Bill Illis (Feb 10, 2026 16:42):** This document is also helpful to launching a digital protocol project in your org. DDF_Practical_Approach_to_Implementation.pdf

Question 9

Attendee (Feb 10, 2026 16:29):
Are you using Open Source AI? Have you received any feedback on handling of proprietary information

- **Maxine Chan (Feb 10, 2026 16:53):** We use a combination of commercial and open-source AI components, depending on the use case. All models and services are deployed within a controlled environment with strict data-handling, access control, and security policies.
  We have received and incorporated feedback from customers and partners regarding the handling of proprietary information. As a result, we ensure that customer data is not used to train shared models, is processed in accordance with contractual and regulatory requirements, and is protected through technical and organizational safeguards.

Question 10

Attendee (Feb 10, 2026 16:35):
I wonder if you can share if any contestants tried to link USDM data elements into a CTMS system?

- **Julie Smiley (Feb 10, 2026 16:37):** Not that I recall with the challenge CDISC conducted, but I have seen this in other demos. I can't recall who they were from or where, but maybe Bill has some insights on this.
- **Julie Smiley (Feb 13, 2026):** At this time, we are not aware of any formal implementations specifically demonstrating integration of USDM with a Clinical Trial Management System (CTMS). We also reviewed recent challenge submissions and did not identify a focused CTMS-based use case.
  That said, integration of structured protocol metadata into downstream operational systems such as CTMS represents a compelling opportunity. As USDM adoption continues to expand, enabling seamless flow of digital protocol information into study planning, tracking, and operational execution systems is a natural and valuable next step.
  We would welcome input from the community on potential use cases involving CTMS integration. If there is interest, this could be considered as a focus area for a future innovation challenge or pilot initiative. We encourage organizations exploring this space to share their experiences and ideas.
- **Bill Illis (Feb 16, 2026):** You can also check our Solution Directory where technology providers list the features of their systems and the digital protocol use cases that they support. See here, [Digital Data Flow (DDF) Solution Directory | ddf-directory]

Question 11

Attendee (Feb 10, 2026 16:36):
Thank you for an interesting demo.
I'd like to ask what are output formats? Is it DITA XML or HL7 FHIR CDA, or other structured document?
What would be most optimal database to store these documents in your recommendation?
Thanks!

- **Maxine Chan (Feb 10, 2026 16:59):** We currently support JSON and .csv output formats for insights. XML and HL7 FHIR support are on our roadmap XML for EDC integration and HL7 FHIR

Question 12

Attendee (Feb 10, 2026 16:37):
Can you please also share any use cases, solutions of generating/automating SDTM domains from USDM?

- **Julie Smiley (Feb 10, 2026 16:40):** This particular use case wasn't addressed with the 2025 CDISC AI Innovation Challenge. However, we are working on what we will do this year and this use case is certainly one we will consider. Our goal is to roll out another AI Innovation Challenge aligned with our 360i Phase 2 plans in Apr/May timeframe.
- **Bill Illis (Feb 16, 2026): Recommend to search for "USDM and SDTM".** You will see a number of hits from prior talks and posts on this topic.

Question 13

Attendee (Feb 10, 2026 16:41):
Are the study designer, protocol writer and EDC builder validated ?

- **Maxine Chan (Feb 10, 2026 16:48):** Yes. Validation is critical across the entire workflow—including the study designer, protocol writer, and EDC builder. We apply both human-in-the-loop review and AI-based evaluation to ensure accuracy, consistency, and regulatory-grade quality. As AI agents are introduced, maintaining rigorous quality standards becomes even more essential.

Question 14

Attendee (Feb 10, 2026 16:43):
Are there any USDM use cases supporting generation of eSource at institutional sites for sponsor-based studies?

Response:

Bill Illis (Feb 16, 2026): USDM to eSource use cases have been recognized but there are no known implementations as of yet. We are working this year on establishing a collaborative project with clinical trial sites to demonstrate the integration of USDM digital protocols with site-based systems such e Source and site-CTMS.

Question 15

Attendee (Feb 10, 2026 16:45):
very impressive the Faro platform! however I wonder about the how mapping of authored Study protocol into Veeva would work when you (as frequently is the case) do not have a clear translation of study items into CDISC domains, codelists and metadata. Is there also an application of AI in this bridging of medcial concepts between protocol ideation and CRF design?

- **Julie Smiley (Feb 10, 2026 16:49):** CDISC is currently working on Biomedical Concept eCRF specializations, which will show how concepts that are selected in study design solutions and related to activities within the SoA are then implemented within data collection systems. We will be demonstrating this in CDISC 360i Phase 2, which we will launch on Feb 26 in a webinar.

- **Maxine Chan (Faro, Feb 17, 2026):** Yes, we map study items -specifically activities from your Schedule of Activities to CDISC domains (SDTM, CDASH, BC and Controlled Terminologies). Our metadata-enriched approach enables this mapping while supporting downstream use cases like Data Transfer Specification automation.

Question 16

Attendee (Feb 10, 2026 16:48):
Is the DDF team planning to have another in-person DDF Event this year? Please share the details.

- **Bill Illis (Feb 10, 2026 16:58):** Yes, we will have a one-day in-person event in Hyderabad India, May 13th, We plan an event in the fall in US and EU, dates TBD. You can follow us on LinkedIn for the announcements and registration information,. (62) Digital Data Flow (DDF): Posts | LinkedIn

Question 17

Attendee (Feb 10, 2026 16:49):
Thanks Maxine for such an impressive presentation. My question is If you had to replicate the use case with different tools in a non-Faro environment, what are the non-negotiable principles and design patterns you'd keep?

- **Maxine Chan (Faro, Feb 17, 2026):** In a non-Faro environment, we would still anchor the system in CDISC standards like the Biomedical Concept Library and the Schedule of Activities, enforce structured and computable design, maintain traceability, and ensure AI operates within a governed knowledge framework. The tools may change but those design principles are foundational to building scalable, regulator-ready, and AI-enabled clinical trial design.

Question 18

Attendee (Feb 10, 2026 16:52):
Impressive demos by Faro and Zifo. With JSONs generated from your solution, is it correct that in the future CDISC CORE can be used to validate conformance to USDM?

- **Bill Illis (Feb 10, 2026 16:53):** Yes, that is correct. Not in the future, this can be done now.
- **Julie Smiley (Feb 13, 2026):** In December, the CDISC Open Rules Engine (CORE) release v0.14.2 included the first set of executable conformance rules for the USDM (Unified Study Data Model). These rules support automated validation against USDM v3.0 and v4.0, enabling organizations to use USDM as part of quality checks and engineering flows.
  For reference, CDISC shared this announcement on LinkedIn when the release was published. This release represents an important step toward making USDM validation more accessible and automation-ready. If you are exploring USDM adoption, the CORE executable rules are available for evaluation and integration.

Question 19

Attendee (Feb 10, 2026 16:58):
is there a plan to allow the protocol writing directly in the tool with e.g. selecting the BCs in the SoA directly in the tool instead of importing PDFs?

- **Deepak Ananthan (Feb 10, 2026 17:00):** yes absolutely we are already working on it

Question 20

Attendee (Feb 10, 2026 16:58):
General standard question: how are managed concepts in CDISC standards that already are published in other controlled vocabularies, e.g. code systems to electronic CTD 4.0 standards?

Response:

- **Julie Smiley (Feb 13, 2026):** CDISC controlled terminology is managed and published through the NCI Enterprise Vocabulary Services (EVS), which serves as the authoritative source for CDISC terminology. When concepts are also defined in other standards or vocabularies, CDISC aligns to the authoritative source rather than redefining them.

  For example, the concept "Hematocrit Measurement" (NCIt Code C64796) is published in NCI EVS and references multiple other sources in the systems and abbreviations table.

Question 21

Attendee (Feb 10, 2026 17:00):
Will there be a record of the session?

Response:

- **Julie Smiley (Feb 13, 2026):** Yes, the slides will be added to the CDISC webinar archive with the video in a few days. Webinars - Public | CDISC