The Journey So Far and the Road Ahead Webinar Q&A

General responses applicable to multiple questions:

1. CDISC will not deliver any software systems as an outcome of the CDISC 360 proof-of-concept project. CDISC, as a standards development organization, plans to use the CDISC 360 project learnings to subsequently develop and deliver enhanced, concept-based standards.
2. The intention of CDISC 360 is to provide as much transparency as possible regarding the approaches, learnings, and prototypes used during the project. In this spirit, the CDISC 360 team will determine, at the end of the project in October 2020, to what extent and in what manner the prototype software and other work products of the project will be shared.
3. Some survey responses contained similar questions which have been merged as one.
4. The CDISC 360 team regrets that it was unable to provide a response to some of the questions submitted because they were either insufficiently clear or too general.

Project Definition

1. Please explain, in layman's terms, what the CDISC 360 project is including its purpose and benefits.	The current CDISC Foundational Standards describe the structure and nomenclature of clinical research data, but not the full data meaning, which includes the relationships among the various data. Further, the standards today do not describe the transformations and derivations among the data that will enable automation. Additionally, the inherent flexibility provided by the standards today supports a broad range of implementations, but that flexibility also allows for inconsistencies that make scaling automation difficult. Finally, the standards today are published as text instead of machine-readable content with machine-executable transformation and derivation algorithms. The intent of the CDISC 360 project is to create and store standards as concepts, which contain the additional semantics that provide the full data meaning. The added semantics include description of the data transformations and derivations, and other added content to allow a single unified implementation by users. The further project intent is to publish the concept-based standards electronically as linked metadata. CDISC 360 will develop concept-based standard definitions, and test and demonstrate their use in end-to-end automation of study specification, data processing, and analysis through use cases. The project will prepare prototype software to execute the use cases but will not deliver any software solutions to industry. Rather, following successful project conclusion, CDISC intends to develop and deliver a library of concept-based standards, for industry (including the software technology community) to use in enhanced automated clinical research systems.

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Availability

1. Once CDISC 360 goes into production, how will the Industry benefit from this?	There are many benefits expected from concept-based standards, as discussed during the webinar presentations. CDISC will be able to address this question better and in more detail following completion of the CDISC 360 project. See also general responses #1 and #2.
2. Is CDISC planning to facilitate a software build in collaboration with IT industry partners to implement these models post POC?	CDISC plans to collaborate with commercial and open source software vendors interested in developing tools to implement the CDISC 360 models post POC.
3. Will the code for the Shiny app be made available?	Please see general responses #2.
4. Is CDISC 360 going to be a free to download software or for purchase?	Please see general response #1.
5. Will this be free to University Cancer Centers to utilize in 6 months?	Please see general response #1.
6. Could you provide more detail or examples of the CDASH output from the study design specifications (i.e., to automate EDC design)?	Please see general response #2. We anticipate releasing an ODM representation of the CDASH metadata as part of what we share at project end.
7. Will the CDISC 360 project be accessible to CDISC members for free? Or should each company pay a license to use it?	Please see general response #1.

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8. Would it be possible to have read-only access to CDISC 360 MS Azure application?	Currently the MS Azure environment used by the CDISC 360 project is restricted to CDISC 360 volunteers. Please also see general response #2.
9. Would it be possible to share an example of semantic model for SDTM and in in future ADaM?	After the 2020 US Interchange, the CDISC 360 team will author a white paper describing the models and their use in the project. Please also see general response #2.
10. Would there be any templates (SDTM or ADaM) available for the concept-based standards?	As part of the POC, templates are being developed to support the implementation of CDASH, SDTM, and ADaM using biomedical and analysis concepts. Please also see general response #2.
11. Study Designer looks so good. Will it be available to the public?	Please see general responses #1 and #2. Additional comment: Currently the POC prototype is available to the CDISC 360 participants, and some of the documentation to all CDISC volunteers. We will consider how the design, data models and source code for the prototype can be shared (per general response #2). The goal is to inspire software vendors to build great tools that can work with the CDISC Library API as well as the future TransCelerate DDF API. We will also deliver additional presentations on the POC prototype to share the design and learnings publicly.
12. When will the project deliver something which CROs can use and incorporate into their systems?	The CDISC 360 project is a proof-of-concept only. Following CDISC 360, CDISC will have a better understanding of what implementation steps it will take. CDISC anticipates implementing concept-based standards in iterative releases that provide increasing value to industry.
13. Will detailed presentations or white papers be made available that detail the information presented in the SDTM/ADaM POCs?	After the 2020 US Interchange, the CDISC 360 team will author a white paper describing the models and their use in the project. Please also see general response #2.

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Project process, scope, effort

1. If I get partial dates in SDTM, how can I impute the date values during the code?	The imputation rule can be specified in the METHODS table for the associated variable or it could be incorporated as part of the script used to generate date variables.
2. Is PHUSE RDF Semantic project leveraged within CDISC 360? And would some examples same be published eventually?	The initial PHUSE RDF work was used as a pre-cursor to the current CDISC Library model, but the more recent PHUSE RDF project work has not been leveraged within the CDISC 360 POC. We have incorporated RDF into the processing of biomedical concepts.
3. What is the interaction with the HL7 FHIR team and standards?	After the completion of the CDISC 360 POC, CDISC plans to demonstrate the use of HL7 FHIR as a source of RWD that flows into the automated data processing. Currently, CDISC is working on a FHIR-to-CDISC standard.
4. When automating the mapping from EDC to SDTM, how to handle the mapping from external transferred lab to SDTM?	Standardized external data transfer specifications is not in scope for CDISC 360, but is a future CDISC goal. However, today, sponsors should work on defining specific standards for external transferred lab data. Further, sponsors can work on building study-specific standards for the external data during the study design phase and load them into a Study Metadata Library. The idea is to make those metadata available so it can be ingested by the SDTM automation engine.
5. How could the tools discussed during the presentations interact with a study electronic data system like Medrio?	The CDISC 360 POC will demonstrate the automated generation of CDASH-based CRFs in ODM and SDTM and ADaM-based datasets in Define-XML. We will not load the CRFs into an EDC system as part of the CDISC 360 POC. The additional metadata that results from the CDISC 360 work will be available for EDC vendors to use.
6. For the SDTM automation part, how the excel metadata is generated from the concept map? Or is it manually created?	The Excel metadata complements the metadata generated from the concept maps and was created manually for the webinar demonstrations. We do not anticipate using Excel as a metadata authoring tool after the POC has been completed, and we plan to generate most of the metadata currently included in Excel.

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7. For the TLF section, which tools, software will be used for semantic model?	While we have used R Shiny to build the user interface for the TFL automation engine POC, we are hoping to use Neo4j to store TFL metadata semantics and consume it downstream by the TFL automation engine.
8. Has CDISC 360 developed a Biomedical Concept model?	The biomedical concept model development is in-progress during the CDISC 360 project and will be an outcome of the project.
9. Has CDISC 360 identified specific gaps in the current standards development process?	The current CDISC standards development process is working well; however, CDISC anticipates that its standards development process may need to be adjusted to facilitate the creation of concept-based standards.
10. Do you think that this will affect the market in a way that specialists such as DM and SAS Programmer will not be needed?	We anticipate that Data Management and Statistical Programming expertise will remain critical going forward, and that the focus of this skillset will shift more to the new science rather than today's repetitive, standardizable tasks.
11. How many working hours were needed to bring the ADaM/TLF automation that far?	It is difficult to quantify working hours as we have multiple people working on this on a volunteer basis.
12. How many working hours were needed to bring the SDTM automation that far?	It is difficult to quantify working hours as we have multiple people working on this on a volunteer basis.
13. Has CDISC 360 defined a standards development process for biomedical concept driven CDISC standards?	During the CDISC 360 project, the team is developing information that will inform a process definition for developing biomedical concepts. CDISC expects to apply these learnings to define the development process at the end of the project.

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14. What is the tool/programming language that is used to create the study designer app?	The web application is developed in the Python-Django framework, running on an Azure Cloud App Service. The database is based on the Neo4j labeled property graph database. These tools have been selected to support a rapid prototype application development that utilize linked graph data models - but the solution could be implemented in many different ways using different technologies.
15. Is this use for any study design?	The current CDISC standards can be used for all study designs. CDISC does not anticipate this to change when implementing concept-based standards after the CDISC 360 project.
16. Is the use of a template construct with respect to standards and study specification part of CDISC 360 or was it just an example use?	In many ways the current CDISC standards are structural standards that can be applied in different ways – thereby, by nature, template like standards. Similarly, we anticipate that concept-based standard definitions will be produced as instantiations of standard concept templates. The instances will grow over time and be shared. For us this is the realistic approach to standards (i.e., imagining that all possible endpoints will be specified within a TA is not realistic, but a number of endpoint templates and sample instantiations of these are realistic and will bring a lot of value to our community).
17. Will CDISC 360 be using the BRIDG model?	There are no plans for the CDISC 360 project to directly implement the BRIDG model at this time. The BRIDG model may be used as a reference to inform the development of biomedical concepts.
18. Is it planned to integrate checks for CDISC compliance (like P21 validation)?	Yes, we plan to execute P21 validation against the study data and metadata produced as part of the proof-of-concept.
19. How will the annotated CRF be created during that process? Will it be submission compliant?	The team is yet to work on this use case. However, yes, the concept is to generate an aCRF, which is submission compliant (bookmarking is not in scope of this use case). We are hoping the needed elements for the annotation are available in the enriched ODM-XML and then using the XML and associated style sheet, we can render the CRF, along with the associated SDTM annotation. We think with proper development of an XML style sheet, it can be made submission compliant.

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20. The Neo4j slide represented metadata lineage. Is lineage of data also being looked at?	Yes, we would like to show the specified data lineage in the metadata. The key part of this lineage is a Unique Resource Identifier (URI) for the Biomedical Concept (BC) - this will be part of the metadata specification - and it can also be 'tagged' to the subject level data, thereby driving the data lineage. Exactly how this will be implemented is a work in progress, and one of our main focus areas for the remaining part of the project.
21. How CDISC 360 will be connected with the different EDC Systems or it will collect the data as an EDC System?	The CDISC 360 POC will demonstrate the automated generation of CDASH-based CRFs in ODM and SDTM and ADaM-based datasets in Define-XML. We will not load the CRFs into an EDC system as part of the CDISC 360 POC. The additional metadata that results from the CDISC 360 work will be available for EDC vendors to use.
22. How with this integrate with existing EDC systems?	Integrating with EDC systems is not in scope for CDISC 360; we do plan to generate CDASH-based ODM CRFs that could be imported into an EDC system that supports ODM.
23. Is some kind of import/export from the EDC Systems needed and will there be new requirements for them?	The additional metadata that results from the CDISC 360 work will be available for EDC vendors to use. The CDISC 360 project plans to demonstrate the use of ODM and Define-XML to drive the transformation of CDASH data into SDTM. EDC vendors that support ODM would benefit by using this approach to generate SDTM-based datasets for their customers.
24. Are there any plans to include Machine Learning in CDISC 360?	The CDISC 360 team is not incorporating Machine Learning; we may opt to use Machine Learning to support the development of biomedical concepts and templates as we move into the implementation phase.
25. Will derivations be able to be modified? (for example, baseline flag directly assigned to screening visit)	We anticipate that the concept-based standard definitions will contain implementation options (e.g., common and alternate ways to derive the baseline flag); however, there will always be need for study-specific adjustments for non-standardized situations, and clinical systems designed to use the concept-based standards will need to allow for this.
26. Is there an interest in or coverage of natural language processing to either text-to-data or data-to-text?	The CDISC 360 team is not using NLP as part of the proof-of-concept.

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27. Will SAP also be in the library in the foreseeable future?	CDISC anticipates standardizing analysis results and analysis endpoint in the future, and that this standards metadata will highly contribute to creation of a machine-readable SAP. The timeline for developing these standards is not available today.

Timeline/Status

1. The presentation seemed largely based on hypotheses and wireframes of what great would look like, where are we in reality?	The wireframes were created to illustrate what great could look like when enabled by concept-based standards. In addition, during the project, the CDISC 360 team has, and continues to, develop prototype concept-based standards metadata and prototype software to demonstrate the concept and value of concept-based standards.
2. During the webinar it was mentioned that this project would have a milestone in October 2020, so will this project end then?	The CDISC 360 project will end in October of 2020. CDISC is currently considering how it will implement the results of CDISC 360 following the project end.
3. Is there ANY sort of timeline or intermittent deadlines past the initial 18-months of "sprints"?	The CDISC 360 proof-of-concept project will end after the current 18-month period. CDISC is currently developing its post-360 implementation plan for developing and delivering concept-based standards to industry. This plan will include a timeline.

Volunteer

1. How can I volunteer / contribute to the CDISC 360 project?	CDISC 360 Project volunteer opportunities are restricted to employees of CDISC member companies. To determine if your organization is a member of CDISC, please visit the CDISC Membership page. If your organization is not a member of CDISC, we invite you to join us. If you are an employee of a CDISC member and wish to volunteer on the CDISC 360 project, please complete the CDISC Volunteer Form (you must log in to your account on the CDISC website or create an account to access the form)