CDISC 360i Phase 2 Launch Webinar – FAQ

1. Can AI or automation be used in 360i, and can humans remain involved in the process?

Yes. While AI can assist with certain tasks, 360i focuses primarily on creating machine-readable and machine-executable standards that enable automation. These standards support human-in-the-loop workflows where users can review, configure, and adjust processes rather than relying solely on AI. Some AI Innovation Challenge solutions have also demonstrated converting unstructured protocols into machine-readable formats such as USDM.

Protocol Design and Schedule of Activities (SoA)

2. Can an existing protocol or Schedule of Activities be imported into 360i?

Yes. Some solutions demonstrated in the AI Innovation Challenge have shown that unstructured protocol documents can be converted into machine-readable USDM representations, which could then be imported into systems using CDISC standards.

3. What do "concept groups" in the Schedule of Activities represent?

Concept groupings are primarily a user experience feature that helps users quickly select related concepts in the SoA workbench. These groupings support efficient navigation and selection rather than serving as a strict ontology or taxonomy.

4. What happens if a test or measurement does not exist in controlled terminology or Biomedical Concepts?

Solutions can incorporate concepts from both CDISC repositories and sponsor-specific repositories. This means organizations can create custom Biomedical Concepts or reference internal libraries when a concept does not yet exist in CDISC standards.

CDASH, CRFs, and Data Collection

5. Will CDASH continue expanding to cover all SDTM domains?

Yes. The CDASH team plans to continue expanding content so that CDASH aligns with all domains defined in the SDTM Implementation Guide, including those that are currently missing.

6. Will 360i generate ODM-based CRFs and align with CDASH metadata?

Yes. During Phase 1, ODM-based CRFs were generated, and Phase 2 will further refine and expand this capability. CDISC also plans to generate CRFs that conform to CDASH and update the eCRF Portal. Tools used to generate these CRFs may also be released to the community.

7. Will 360i automatically recognize changes to CRFs when a study design changes?

The goal is for CRFs to become machine-readable digital assets generated dynamically from protocol metadata such as the SoA. If the study design changes, systems could regenerate impacted CRFs and downstream artifacts, allowing teams to review impacts before committing changes.

Automation and Data Generation

8. How will SDTM datasets be validated in 360i?

360i plans to use the CDISC Open Rules Engine (CORE) and open conformance rules to perform conformance checking. However, full validation processes are outside the scope of Phase 2.

EDC and Edit Checks

9. Will edit checks from EDC systems be supported in ODM or the eCRF portal?

This is a long-standing request in the ODM community. It is not currently in scope for Phase 2, partly because different EDC systems implement edit checks differently. However, CDISC is interested in exploring the topic further and potentially collaborating with EDC vendors in the future.

New Standards and Data Exchange

10. How does the new Data Transfer Agreement (DTA) standard relate to CDASH?

DTA is still in early development but is expected to function more like Biomedical Concepts with implementations across standards, rather than being directly embedded in CDASH. The concept model would likely support broader data exchange workflows across systems.

Clinical Operations and Future Use Cases

11. Could 360i standards support automation in clinical operations systems such as CTMS or TMF?

Potentially, yes. The machine-readable protocol metadata and digital scheduled activities created in 360i could enable automation across many parts of the study lifecycle. However, the current priority is establishing a strong foundation for protocol, study build, and analysis automation before expanding into operational systems. CDISC welcomes collaboration and experimentation from the community to explore additional use cases.

Applicability to Other Areas

12. Can these concepts apply to medical device studies?

Yes. The grouping capabilities being introduced in 360i are flexible and could support device-related concepts as well. For example, related device concepts could be grouped together to represent device-specific information within structured metadata frameworks.

Standards Delivery and Tools

13. Is 360i building software?

No. 360i's primary purpose is to create digital and connected standards, not to develop or market enterprise software products. The "Art of Possible" is an illustration of what future enterprise solutions people could build; it is not an indication that 360i intends to build it.

14. Will 360i release any open-source code or demonstration solutions?

Yes. Some 360i-related workstreams will include open-source code, demonstration tools, or reference implementations to illustrate how connected standards can be implemented in practice. These are intended to support continuous improvement and to broaden adoption.

15. Will standards still be delivered as PDFs?

Yes. PDFs will continue to be available, but they may increasingly be generated from structured metadata as part of the transition to digital standards.

Open Study Builder and Ecosystem Tools

16. Is Open Study Builder connected to 360i?

Open Study Builder will continue supporting 360i concepts, although development timelines may vary. Other initiatives, such as the SoA Workbench, may enable faster experimentation and development to support connected standards.

Participation and Volunteers

17. Do Phase 1 volunteers need to reapply for Phase 2?

Yes. Volunteers should submit the Phase 2 form so CDISC can match participants with the most relevant new opportunities.

18. What is the role of the AC/DC curation team?

The AC/DC curation team focuses on verifying and curating methods defined in the analysis concepts and derivation concepts library to ensure they are accurate and usable.

19. What experience is helpful for volunteers?

Volunteers do not need expertise in all areas. Relevant backgrounds may include CDASH, SDTM, EDC configuration, Define-XML, ODM, analysis programming, metadata-driven systems, system integration, and clinical data automation.