Paper DS01

CDISC 360i: Implementing the CDISC Roadmap Connecting Standards from Design to Analysis

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ABSTRACT

CDISC has put forward a vision and roadmap to expand and enable standards driven automation across the end-to-end study information lifecycle from study design through results. Several years ago we initiated 360, a proof of concept where we successfully proved out several key concepts of end-to-end standards and identified missing pieces in our normative standards. As part of our strategic goal, we are transitioning from the previous 360 project to 360i the implementation where we will close the gaps in our standards, redefine how we develop standards by connecting the standard from design through analysis, and focus on delivering ready to use and technology enables standards. This presentation will provide an overview of our 360i implementation plan, what we plan to achieve in 2025, and share with the community how you can engage in accelerating this work.

INTRODUCTION

Clinical research today faces major challenges with systems that are fragmented and operational functions that don't connect well leading to isolated data, time-consuming manual processes, and higher risk of mistakes. While standards are available, they aren't consistently applied and gaps in meaning exist within and across the standards, often requiring deep expertise that limits the ability to enable automation and collaboration. As science progresses, research data and standards are becoming more intricate, and current systems and workflows struggle to keep up. This makes it harder to maintain traceability, integrate information, and respond to modern research needs. These inefficiencies slow down decision-making, increase costs, and delay access to life-saving therapies.

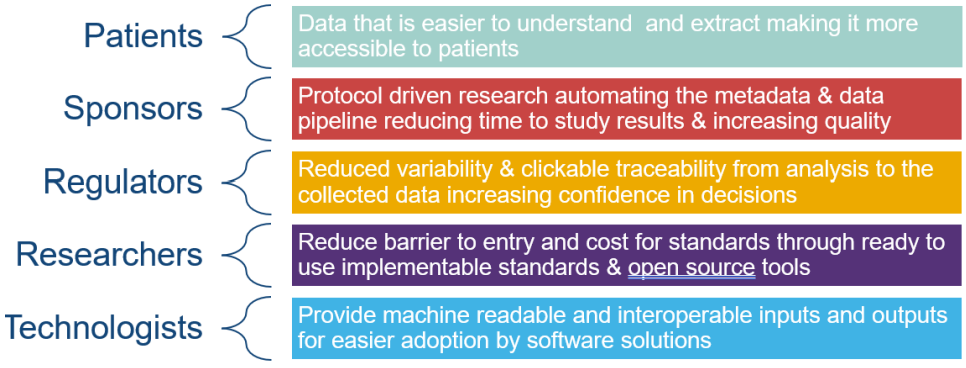
In a time when speed, precision, and innovation are critical, the current approach simply isn't sustainable. To fully unlock the potential of clinical research, the industry must adopt standards that support smart and seamless automation that drives efficiency, accuracy, and innovation to achieve better outcomes for patients.

As CDISC embarks on the 360i program, the overall goal is to break down the silos between company functions and the CDISC standards and reconnect the information to enable the end to end automation of the clinical data. Lifecycle.

BENEFIT OF CONNECTED STANDARDS

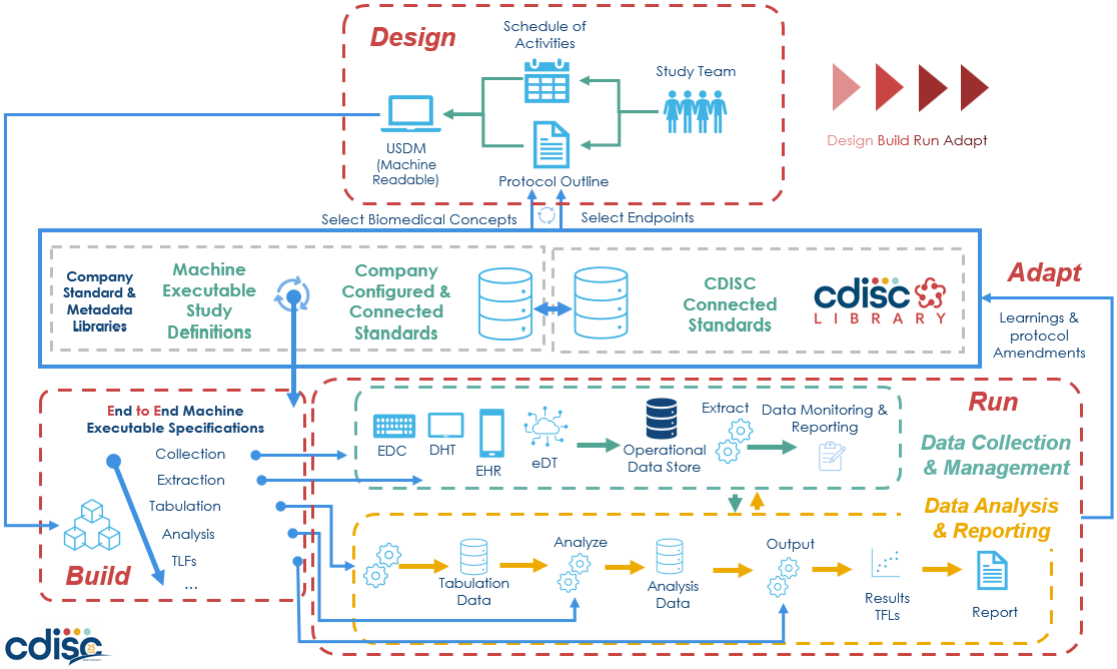
As we consider the challenge we face today with standards in silos and missing key meaning within and between standards, we are limited in realizing the true benefits of using standards to drive automation. The goal of 360i is to define the current CDISC content with more granularity adding key semantic meaning to the standards driving the end to end definition of a concept versus the vertical silos we have today. For a simple example, for the endpoint "Change from Baseline for Systolic Blood Pressure" we need to define what the Systolic Blood Pressure concept is, how it is collected, how it is transformed, and finally how it is analyzed downstream. By defining this endpoint from design to analysis we are creating a linked standard that enables interoperability and drives automation.

By connecting this information, we create connected and ready to use implementable standards. The diagram below provides the high level value proposition of connected standards for each of the key stakeholders.



END TO END 360I VISION

The diagram below defines the process of whowe can enable automation of the clinical information and data lifecycle.



First, study design needs to drive the process from the beginning. We need to allow study teams to continue to leverage their creativity while at the same time guiding them through a digital workflow allowing them to build the digital information required to leverage the systems and processes downstream. The definition of study is the foundation for everything else in the lifecycle. The CDISC USDM model can help drive the digital workflow entering information once and driving the downstream systems and processes. The digital study design process must be fed by a well-defined set of endpoints and connected concepts. The CDISC standards will be connected from the definition of an endpoint to the schedule of activities to the corresponding concepts that support it and so on with the metadata required for downstream aggregation of the data and the generation of the analysis and reports.

Each company will leverage these connected standards off the shelf to generate most of the artifacts they need with minimal additional effort. But there will be times when they need to extend and configure those standards within their own library of information to meet their scientific needs. The framework for the connected standards must be robust enough to allow this flexibility. These connections will enable the definition of executable study definitions that can be leveraged downstream in systems and processes to enable the automation we all want to see from standards. We have our traditional artifacts we currently generate but this approach will support many other use cases across R&D requiring executable metadata.

As we know, the variability of our data sources has grown exponentially and continues to every day. The next step is to leverage this metadata to extract the data from the from these different data sources, bringing it together into a common data store. Every company has their own flavor of an operational data store, and the metadata provided will help support populating and extracting from that source to support activities like the data monitoring and reporting that is needed during the study.

Once we have the connected metadata, we can support the automation of our traditional use case creating tabulation and analysis data, generating analyses and reports as well as many other use cases. And then most importantly, we adapt and learn from this process feeding back into the standards and company information enhancing and improving future studies.

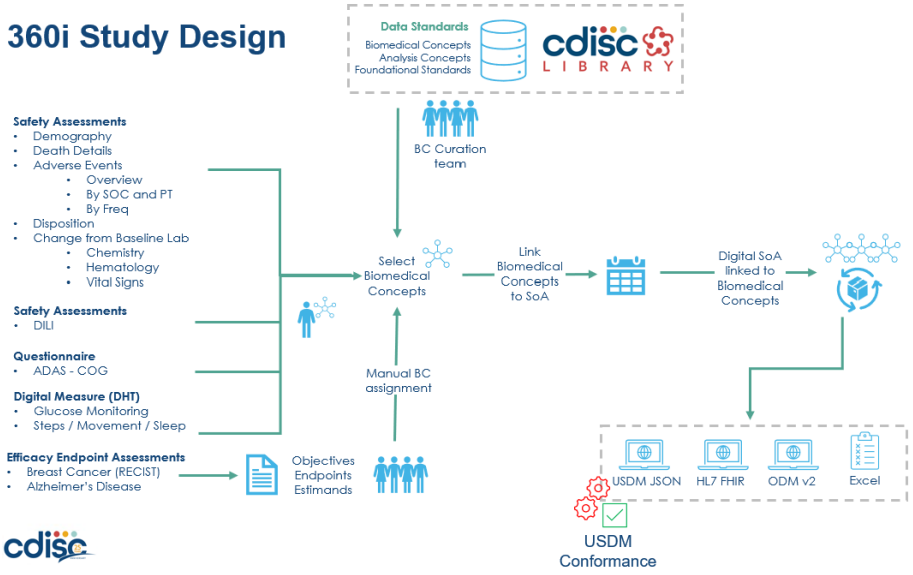
360I PHASE 1

360i will kick off this year with a focus on connecting study endpoints to the schedule of activities in a protocol while enabling the downstream creation of SDTM specifications and automation of the SDTM data. The goal of 360i is to deliver three key artifacts we transform the wat we develop and use standards.

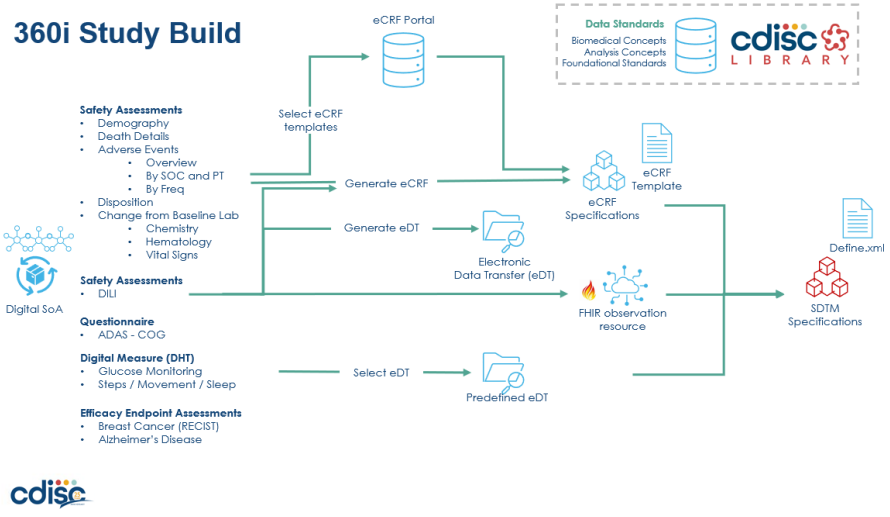
- Standards Packages: Linked and executable metadata from the study endpoint to the analysis that can be used to drive systems and processes. Packages of packages can be used to build your necessary artifacts while allowing many other use cases
- Implementation Cookbooks: Set of instructions for how to build and extend packages for your standards needs as well as how to implement those standards within your systems and processes to more easily enable automation
- Example Implementations: Community curated and published technical solutions that shows the industry how these packages are implemented within tools providing the community a playbook for how to leverage the executable metadata

360i will focus on the design, build and run aspects of the clinical trial defining the semantic metadata once and leveraging in downstream activities.

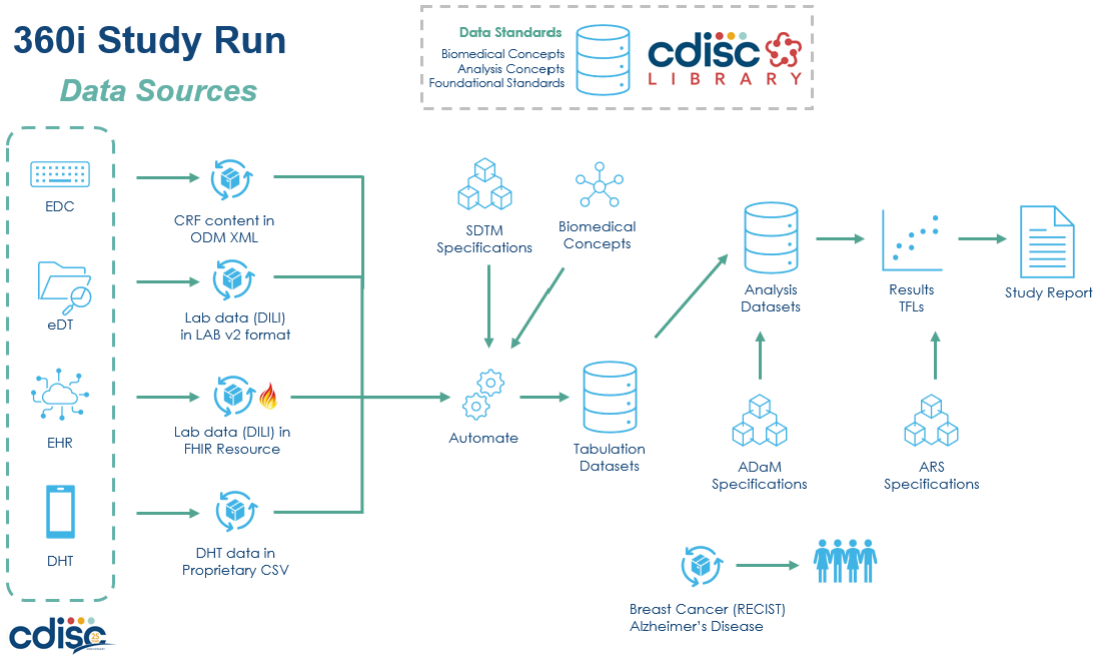
First we will focus on leveraging the digital protocol to define our endpoints and schedule of activities through the USDM model and link that information to concepts. This initial connection will be the foundation of the other activities downstream. The content scope on the left of the diagram below is where we will start and then continue to curate more content as the community learns and engages in the development process.



Second, we will drive the generation of executable specifications for CRFs, electronic data transfers, configurations of real world data connectors, and other data and analysis sources all built from the digital schedule of activities and the connected standards. These 'specifications' will be both human readable but more importantly machine consumable to drive the automation of the data lifeccle.



Finally, now that we have developed a robust set of connected metadata and machine executable specifications, we can extract the data using this metadata and trigger the downstream generation of the data sets analyses skipping a lot of previous manual and error prone steps we have today. In the first phase of 360i we plan to build and show this end-to-end workflow with a subset of our standards content. Once we develop the playbook for how this will work, we will ask our community to help us curate and accelerate the generation of the rest of our standards content.



CONCLUSION

360i will kick off this year with a focus on connecting study endpoints to the schedule of activities in a protocol, generating machine executable specifications, and showing we can automate the data flow to generate SDTM data. But this is only step 1. The next series of steps will include expanding the repository of metadata to broaden the scope of content as well as defining the downstream analysis concepts and linking those into the workflow. As we continue to build out the metadata required we will start to see enablement of a wide range of use cases that will the significant value of connected standards.

We would love to have you and your company join us on this journey. CDISC can't tackle this large transformation without the input and energy of our community. You can join the team and contribute to the 360i initiate but going to this link (Sign in/Sign up | CDISC), signing up, and selecting 360i once you log in.

RECOMMENDED READING

We suggest you listen to both the 360i vision webinar and the 360i kickoff webinar to gain a better understanding of the goals of this transformation.
CDISC 360i - Moving from Proof of Concept to Implementation | CDISC
360i Program Kickoff: Enabling Standards Driven Automation from Study Design Through Results | CDISC

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