

Analysis Concepts

– Initial perspectives from the CDISC working group

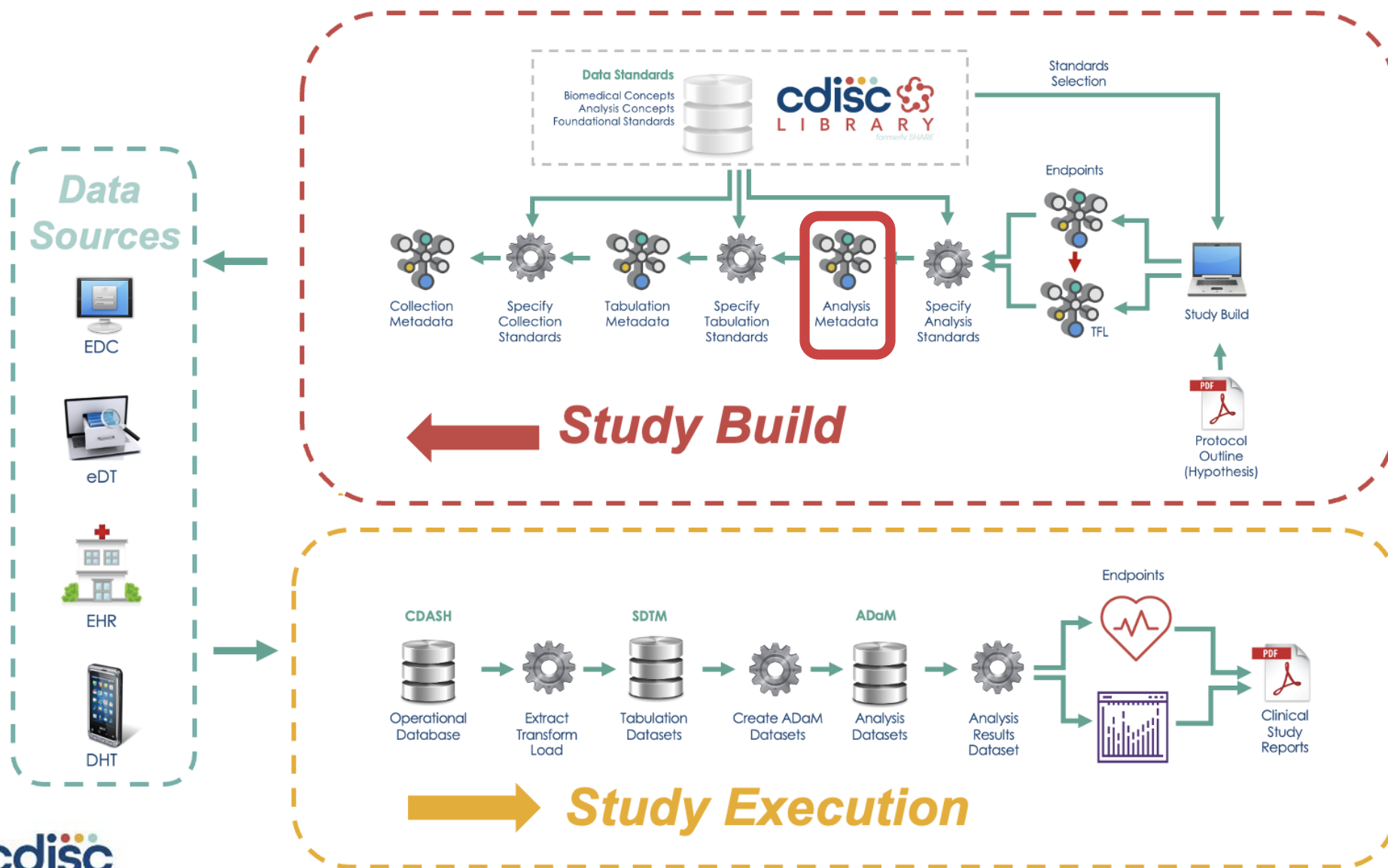
Bess LeRoy

Head of Standards Development, CDISC

05-September-2025



Standardizing Analysis Metadata



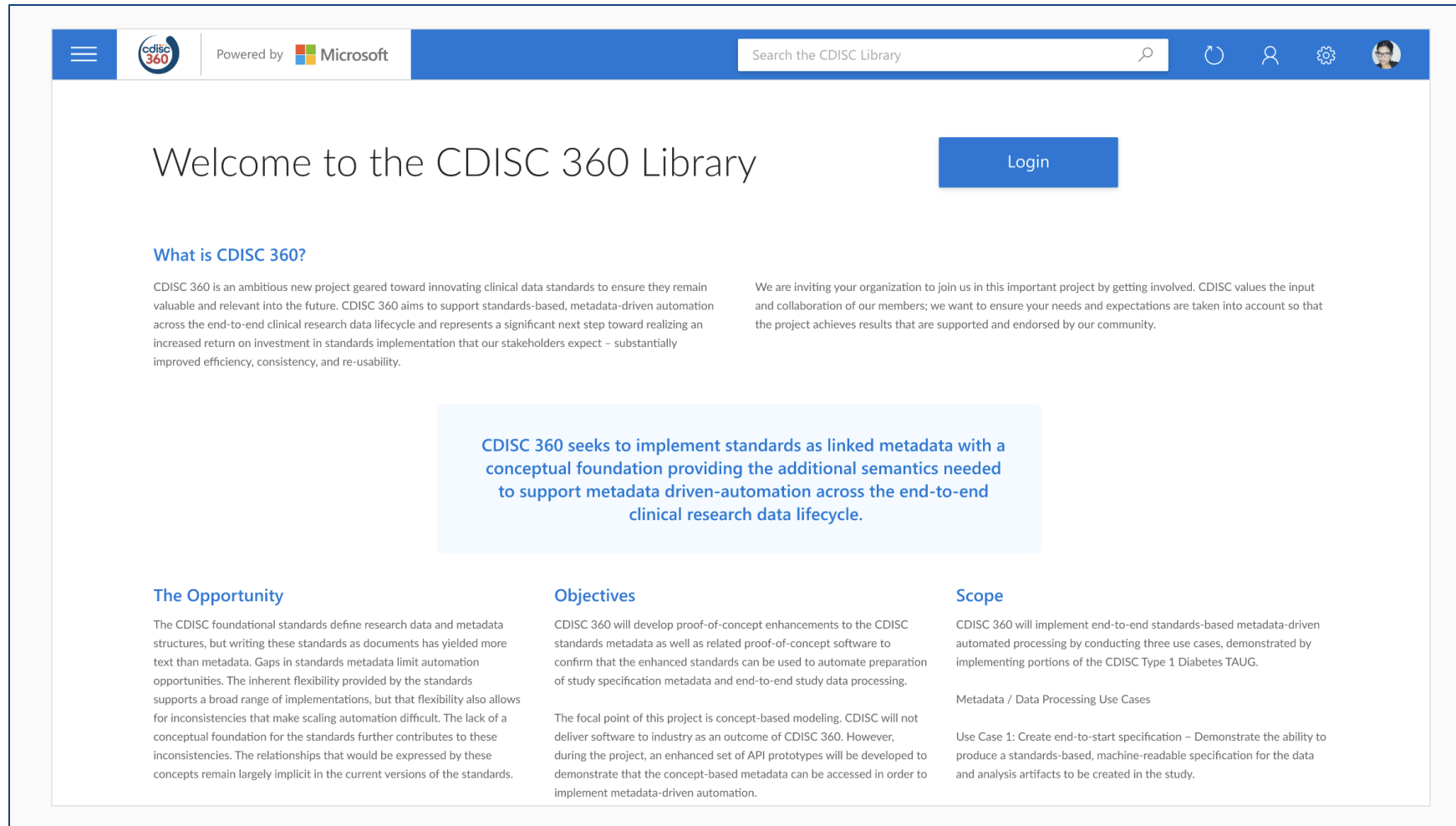
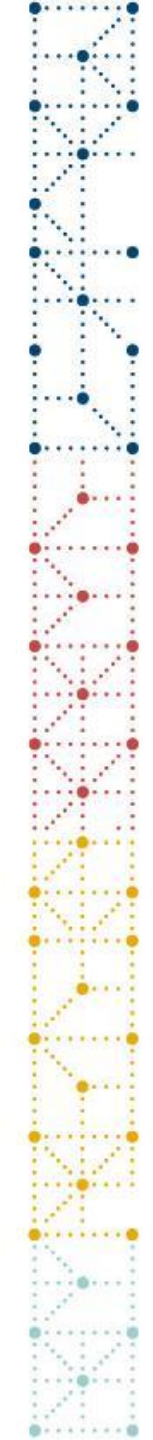
CDISC 360

- CDISC 360 was a proof of concept that sought to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata-driven automation across the end-to-end clinical research data lifecycle.
- This will enable software developers to develop new tools (proprietary and open source) that consume this novel metadata to ease standards' implementations, while increasing data processing efficiencies.
- Reduce unnecessary variation and lower the barrier to adoption.

White Paper: https://www.cdisc.org/sites/default/files/2021-06/CDISC_360_Project_White_Paper.pdf



CDISC 360: The Art of the Possible



The screenshot shows the CDISC 360 Library homepage. The header includes the CDISC 360 logo, 'Powered by Microsoft', a search bar, and user icons. The main content area features a 'Welcome to the CDISC 360 Library' message with a 'Login' button. Below this is a section titled 'What is CDISC 360?' with two columns of text. A central light blue box contains a key message about implementing standards as linked metadata. At the bottom, there are three columns: 'The Opportunity', 'Objectives', and 'Scope', each with descriptive text.

Welcome to the CDISC 360 Library [Login](#)

What is CDISC 360?

CDISC 360 is an ambitious new project geared toward innovating clinical data standards to ensure they remain valuable and relevant into the future. CDISC 360 aims to support standards-based, metadata-driven automation across the end-to-end clinical research data lifecycle and represents a significant next step toward realizing an increased return on investment in standards implementation that our stakeholders expect – substantially improved efficiency, consistency, and re-usability.

We are inviting your organization to join us in this important project by getting involved. CDISC values the input and collaboration of our members; we want to ensure your needs and expectations are taken into account so that the project achieves results that are supported and endorsed by our community.

CDISC 360 seeks to implement standards as linked metadata with a conceptual foundation providing the additional semantics needed to support metadata driven-automation across the end-to-end clinical research data lifecycle.

The Opportunity

The CDISC foundational standards define research data and metadata structures, but writing these standards as documents has yielded more text than metadata. Gaps in standards metadata limit automation opportunities. The inherent flexibility provided by the standards supports a broad range of implementations, but that flexibility also allows for inconsistencies that make scaling automation difficult. The lack of a conceptual foundation for the standards further contributes to these inconsistencies. The relationships that would be expressed by these concepts remain largely implicit in the current versions of the standards.

Objectives

CDISC 360 will develop proof-of-concept enhancements to the CDISC standards metadata as well as related proof-of-concept software to confirm that the enhanced standards can be used to automate preparation of study specification metadata and end-to-end study data processing.

The focal point of this project is concept-based modeling. CDISC will not deliver software to industry as an outcome of CDISC 360. However, during the project, an enhanced set of API prototypes will be developed to demonstrate that the concept-based metadata can be accessed in order to implement metadata-driven automation.

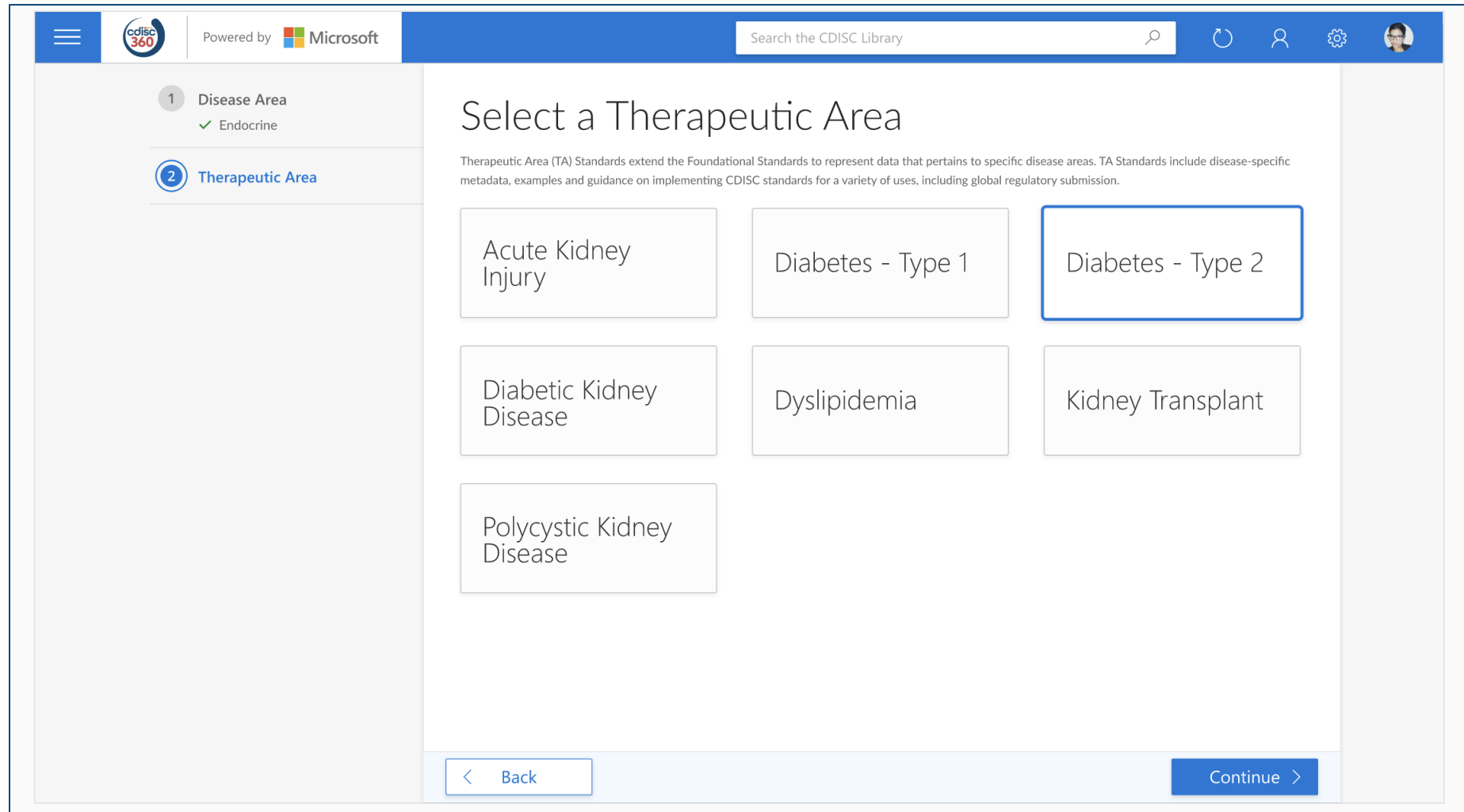
Scope

CDISC 360 will implement end-to-end standards-based metadata-driven automated processing by conducting three use cases, demonstrated by implementing portions of the CDISC Type 1 Diabetes TAUG.

Metadata / Data Processing Use Cases

Use Case 1: Create end-to-start specification – Demonstrate the ability to produce a standards-based, machine-readable specification for the data and analysis artifacts to be created in the study.

CDISC 360: The Art of the Possible



The screenshot displays the CDISC 360 web application interface. The top navigation bar is blue and contains the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and icons for refresh, user profile, settings, and a user avatar. On the left side, there is a sidebar with two steps: "1 Disease Area" with a green checkmark and "Endocrine" selected, and "2 Therapeutic Area" which is the current step. The main content area is titled "Select a Therapeutic Area" and includes a paragraph explaining that Therapeutic Area (TA) Standards extend Foundational Standards to represent data for specific disease areas. Below this, there are seven selectable boxes for therapeutic areas: "Acute Kidney Injury", "Diabetes - Type 1", "Diabetes - Type 2" (which is highlighted with a blue border), "Diabetic Kidney Disease", "Dyslipidemia", "Kidney Transplant", and "Polycystic Kidney Disease". At the bottom of the main content area, there are two buttons: "Back" and "Continue >".

cdisc 360

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Search the CDISC Library

1 Disease Area
✓ Endocrine

2 Therapeutic Area

Select a Therapeutic Area

Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

Acute Kidney Injury

Diabetes - Type 1

Diabetes - Type 2

Diabetic Kidney Disease

Dyslipidemia

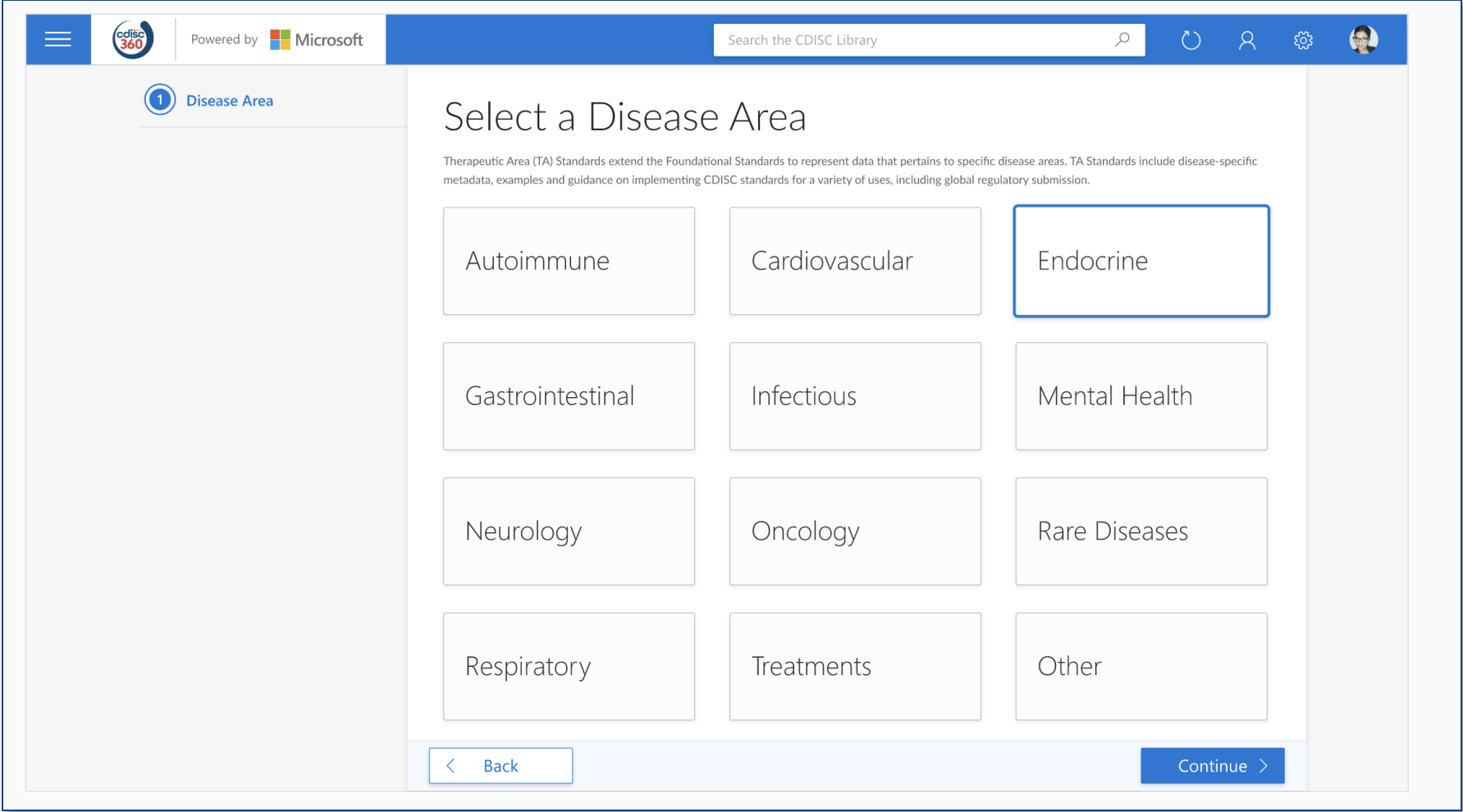
Kidney Transplant

Polycystic Kidney Disease

< Back

Continue >

CDISC 360: The Art of the Possible



The screenshot displays the CDISC 360 web application interface. The top navigation bar is blue and contains the CDISC 360 logo, the text "Powered by Microsoft", a search bar labeled "Search the CDISC Library", and icons for refresh, user profile, settings, and a user avatar. On the left, a sidebar shows a "Disease Area" section with a blue circle containing the number "1". The main content area is titled "Select a Disease Area" and includes a paragraph explaining that Therapeutic Area (TA) Standards extend Foundational Standards to represent data for specific disease areas, including disease-specific metadata and guidance for regulatory submission. Below this, there is a 4x3 grid of buttons for selecting a disease area. The "Endocrine" button in the top-right position is highlighted with a blue border. At the bottom of the grid, there are two buttons: "Back" with a left arrow and "Continue" with a right arrow.

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Search the CDISC Library

1 Disease Area

Select a Disease Area

Therapeutic Area (TA) Standards extend the Foundational Standards to represent data that pertains to specific disease areas. TA Standards include disease-specific metadata, examples and guidance on implementing CDISC standards for a variety of uses, including global regulatory submission.

Autoimmune	Cardiovascular	Endocrine
Gastrointestinal	Infectious	Mental Health
Neurology	Oncology	Rare Diseases
Respiratory	Treatments	Other

< Back

Continue >

CDISC 360: The Art of the Possible

1 Disease Area
✓ Endocrine

2 Therapeutic Area
✓ Diabetes - Type 2

3 Standards Focus
✓ Study Endpoint

4 Study Endpoint
✓ Analysis of Glycated Hemoglobin

5 Standard Analyses

Select from Standard Analyses

HbA1c Longitudinal Repeated Measures Analysis

Parameter	Mean (SD)	Mean (SD)	Mean (SD)
Baseline	7.0 (1.0)	7.0 (1.0)	7.0 (1.0)
Week 1	6.8 (1.0)	6.8 (1.0)	6.8 (1.0)
Week 2	6.5 (1.0)	6.5 (1.0)	6.5 (1.0)
Week 3	6.3 (1.0)	6.3 (1.0)	6.3 (1.0)
Week 4	6.1 (1.0)	6.1 (1.0)	6.1 (1.0)
Week 5	5.9 (1.0)	5.9 (1.0)	5.9 (1.0)
Week 6	5.7 (1.0)	5.7 (1.0)	5.7 (1.0)
Week 7	5.5 (1.0)	5.5 (1.0)	5.5 (1.0)
Week 8	5.3 (1.0)	5.3 (1.0)	5.3 (1.0)
Week 9	5.1 (1.0)	5.1 (1.0)	5.1 (1.0)
Week 10	4.9 (1.0)	4.9 (1.0)	4.9 (1.0)
Week 11	4.7 (1.0)	4.7 (1.0)	4.7 (1.0)
Week 12	4.5 (1.0)	4.5 (1.0)	4.5 (1.0)
Week 13	4.3 (1.0)	4.3 (1.0)	4.3 (1.0)
Week 14	4.1 (1.0)	4.1 (1.0)	4.1 (1.0)
Week 15	3.9 (1.0)	3.9 (1.0)	3.9 (1.0)
Week 16	3.7 (1.0)	3.7 (1.0)	3.7 (1.0)
Week 17	3.5 (1.0)	3.5 (1.0)	3.5 (1.0)
Week 18	3.3 (1.0)	3.3 (1.0)	3.3 (1.0)
Week 19	3.1 (1.0)	3.1 (1.0)	3.1 (1.0)
Week 20	2.9 (1.0)	2.9 (1.0)	2.9 (1.0)
Week 21	2.7 (1.0)	2.7 (1.0)	2.7 (1.0)
Week 22	2.5 (1.0)	2.5 (1.0)	2.5 (1.0)
Week 23	2.3 (1.0)	2.3 (1.0)	2.3 (1.0)
Week 24	2.1 (1.0)	2.1 (1.0)	2.1 (1.0)
Week 25	1.9 (1.0)	1.9 (1.0)	1.9 (1.0)
Week 26	1.7 (1.0)	1.7 (1.0)	1.7 (1.0)
Week 27	1.5 (1.0)	1.5 (1.0)	1.5 (1.0)
Week 28	1.3 (1.0)	1.3 (1.0)	1.3 (1.0)
Week 29	1.1 (1.0)	1.1 (1.0)	1.1 (1.0)
Week 30	0.9 (1.0)	0.9 (1.0)	0.9 (1.0)
Week 31	0.7 (1.0)	0.7 (1.0)	0.7 (1.0)
Week 32	0.5 (1.0)	0.5 (1.0)	0.5 (1.0)
Week 33	0.3 (1.0)	0.3 (1.0)	0.3 (1.0)
Week 34	0.1 (1.0)	0.1 (1.0)	0.1 (1.0)
Week 35	-0.1 (1.0)	-0.1 (1.0)	-0.1 (1.0)
Week 36	-0.3 (1.0)	-0.3 (1.0)	-0.3 (1.0)
Week 37	-0.5 (1.0)	-0.5 (1.0)	-0.5 (1.0)
Week 38	-0.7 (1.0)	-0.7 (1.0)	-0.7 (1.0)
Week 39	-0.9 (1.0)	-0.9 (1.0)	-0.9 (1.0)
Week 40	-1.1 (1.0)	-1.1 (1.0)	-1.1 (1.0)
Week 41	-1.3 (1.0)	-1.3 (1.0)	-1.3 (1.0)
Week 42	-1.5 (1.0)	-1.5 (1.0)	-1.5 (1.0)
Week 43	-1.7 (1.0)	-1.7 (1.0)	-1.7 (1.0)
Week 44	-1.9 (1.0)	-1.9 (1.0)	-1.9 (1.0)
Week 45	-2.1 (1.0)	-2.1 (1.0)	-2.1 (1.0)
Week 46	-2.3 (1.0)	-2.3 (1.0)	-2.3 (1.0)
Week 47	-2.5 (1.0)	-2.5 (1.0)	-2.5 (1.0)
Week 48	-2.7 (1.0)	-2.7 (1.0)	-2.7 (1.0)
Week 49	-2.9 (1.0)	-2.9 (1.0)	-2.9 (1.0)
Week 50	-3.1 (1.0)	-3.1 (1.0)	-3.1 (1.0)
Week 51	-3.3 (1.0)	-3.3 (1.0)	-3.3 (1.0)
Week 52	-3.5 (1.0)	-3.5 (1.0)	-3.5 (1.0)
Week 53	-3.7 (1.0)	-3.7 (1.0)	-3.7 (1.0)
Week 54	-3.9 (1.0)	-3.9 (1.0)	-3.9 (1.0)
Week 55	-4.1 (1.0)	-4.1 (1.0)	-4.1 (1.0)
Week 56	-4.3 (1.0)	-4.3 (1.0)	-4.3 (1.0)
Week 57	-4.5 (1.0)	-4.5 (1.0)	-4.5 (1.0)
Week 58	-4.7 (1.0)	-4.7 (1.0)	-4.7 (1.0)
Week 59	-4.9 (1.0)	-4.9 (1.0)	-4.9 (1.0)
Week 60	-5.1 (1.0)	-5.1 (1.0)	-5.1 (1.0)
Week 61	-5.3 (1.0)	-5.3 (1.0)	-5.3 (1.0)
Week 62	-5.5 (1.0)	-5.5 (1.0)	-5.5 (1.0)
Week 63	-5.7 (1.0)	-5.7 (1.0)	-5.7 (1.0)
Week 64	-5.9 (1.0)	-5.9 (1.0)	-5.9 (1.0)
Week 65	-6.1 (1.0)	-6.1 (1.0)	-6.1 (1.0)
Week 66	-6.3 (1.0)	-6.3 (1.0)	-6.3 (1.0)
Week 67	-6.5 (1.0)	-6.5 (1.0)	-6.5 (1.0)
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Week 70	-7.1 (1.0)	-7.1 (1.0)	-7.1 (1.0)
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Week 72	-7.5 (1.0)	-7.5 (1.0)	-7.5 (1.0)
Week 73	-7.7 (1.0)	-7.7 (1.0)	-7.7 (1.0)
Week 74	-7.9 (1.0)	-7.9 (1.0)	-7.9 (1.0)
Week 75	-8.1 (1.0)	-8.1 (1.0)	-8.1 (1.0)
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Week 77	-8.5 (1.0)	-8.5 (1.0)	-8.5 (1.0)
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Week 79	-8.9 (1.0)	-8.9 (1.0)	-8.9 (1.0)
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Week 81	-9.3 (1.0)	-9.3 (1.0)	-9.3 (1.0)
Week 82	-9.5 (1.0)	-9.5 (1.0)	-9.5 (1.0)
Week 83	-9.7 (1.0)	-9.7 (1.0)	-9.7 (1.0)
Week 84	-9.9 (1.0)	-9.9 (1.0)	-9.9 (1.0)
Week 85	-10.1 (1.0)	-10.1 (1.0)	-10.1 (1.0)
Week 86	-10.3 (1.0)	-10.3 (1.0)	-10.3 (1.0)
Week 87	-10.5 (1.0)	-10.5 (1.0)	-10.5 (1.0)
Week 88	-10.7 (1.0)	-10.7 (1.0)	-10.7 (1.0)
Week 89	-10.9 (1.0)	-10.9 (1.0)	-10.9 (1.0)
Week 90	-11.1 (1.0)	-11.1 (1.0)	-11.1 (1.0)
Week 91	-11.3 (1.0)	-11.3 (1.0)	-11.3 (1.0)
Week 92	-11.5 (1.0)	-11.5 (1.0)	-11.5 (1.0)
Week 93	-11.7 (1.0)	-11.7 (1.0)	-11.7 (1.0)
Week 94	-11.9 (1.0)	-11.9 (1.0)	-11.9 (1.0)
Week 95	-12.1 (1.0)	-12.1 (1.0)	-12.1 (1.0)
Week 96	-12.3 (1.0)	-12.3 (1.0)	-12.3 (1.0)
Week 97	-12.5 (1.0)	-12.5 (1.0)	-12.5 (1.0)
Week 98	-12.7 (1.0)	-12.7 (1.0)	-12.7 (1.0)
Week 99	-12.9 (1.0)	-12.9 (1.0)	-12.9 (1.0)
Week 100	-13.1 (1.0)	-13.1 (1.0)	-13.1 (1.0)
Week 101	-13.3 (1.0)	-13.3 (1.0)	-13.3 (1.0)
Week 102	-13.5 (1.0)	-13.5 (1.0)	-13.5 (1.0)
Week 103	-13.7 (1.0)	-13.7 (1.0)	-13.7 (1.0)
Week 104	-13.9 (1.0)	-13.9 (1.0)	-13.9 (1.0)
Week 105	-14.1 (1.0)	-14.1 (1.0)	-14.1 (1.0)
Week 106	-14.3 (1.0)	-14.3 (1.0)	-14.3 (1.0)
Week 107	-14.5 (1.0)	-14.5 (1.0)	-14.5 (1.0)
Week 108	-14.7 (1.0)	-14.7 (1.0)	-14.7 (1.0)
Week 109	-14.9 (1.0)	-14.9 (1.0)	-14.9 (1.0)
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Week 112	-15.5 (1.0)	-15.5 (1.0)	-15.5 (1.0)
Week 113	-15.7 (1.0)	-15.7 (1.0)	-15.7 (1.0)
Week 114	-15.9 (1.0)	-15.9 (1.0)	-15.9 (1.0)
Week 115	-16.1 (1.0)	-16.1 (1.0)	-16.1 (1.0)
Week 116	-16.3 (1.0)	-16.3 (1.0)	-16.3 (1.0)
Week 117	-16.5 (1.0)	-16.5 (1.0)	-16.5 (1.0)
Week 118	-16.7 (1.0)	-16.7 (1.0)	-16.7 (1.0)
Week 119	-16.9 (1.0)	-16.9 (1.0)	-16.9 (1.0)
Week 120	-17.1 (1.0)	-17.1 (1.0)	-17.1 (1.0)
Week 121	-17.3 (1.0)	-17.3 (1.0)	-17.3 (1.0)
Week 122	-17.5 (1.0)	-17.5 (1.0)	-17.5 (1.0)
Week 123	-17.7 (1.0)	-17.7 (1.0)	-17.7 (1.0)
Week 124	-17.9 (1.0)	-17.9 (1.0)	-17.9 (1.0)
Week 125	-18.1 (1.0)	-18.1 (1.0)	-18.1 (1.0)
Week 126	-18.3 (1.0)	-18.3 (1.0)	-18.3 (1.0)
Week 127	-18.5 (1.0)	-18.5 (1.0)	-18.5 (1.0)
Week 128	-18.7 (1.0)	-18.7 (1.0)	-18.7 (1.0)
Week 129	-18.9 (1.0)	-18.9 (1.0)	-18.9 (1.0)
Week 130	-19.1 (1.0)	-19.1 (1.0)	-19.1 (1.0)
Week 131	-19.3 (1.0)	-19.3 (1.0)	-19.3 (1.0)
Week 132	-19.5 (1.0)	-19.5 (1.0)	-19.5 (1.0)
Week 133	-19.7 (1.0)	-19.7 (1.0)	-19.7 (1.0)
Week 134	-19.9 (1.0)	-19.9 (1.0)	-19.9 (1.0)
Week 135	-20.1 (1.0)	-20.1 (1.0)	-20.1 (1.0)
Week 136	-20.3 (1.0)	-20.3 (1.0)	-20.3 (1.0)
Week 137	-20.5 (1.0)	-20.5 (1.0)	-20.5 (1.0)
Week 138	-20.7 (1.0)	-20.7 (1.0)	-20.7 (1.0)
Week 139	-20.9 (1.0)	-20.9 (1.0)	-20.9 (1.0)
Week 140	-21.1 (1.0)	-21.1 (1.0)	-21.1 (1.0)
Week 141	-21.3 (1.0)	-21.3 (1.0)	-21.3 (1.0)
Week 142	-21.5 (1.0)	-21.5 (1.0)	-21.5 (1.0)
Week 143	-21.7 (1.0)	-21.7 (1.0)	-21.7 (1.0)
Week 144	-21.9 (1.0)	-21.9 (1.0)	-21.9 (1.0)
Week 145	-22.1 (1.0)	-22.1 (1.0)	-22.1 (1.0)
Week 146	-22.3 (1.0)	-22.3 (1.0)	-22.3 (1.0)
Week 147	-22.5 (1.0)	-22.5 (1.0)	-22.5 (1.0)
Week 148	-22.7 (1.0)	-22.7 (1.0)	-22.7 (1.0)
Week 149	-22.9 (1.0)	-22.9 (1.0)	-22.9 (1.0)
Week 150	-23.1 (1.0)	-23.1 (1.0)	-23.1 (1.0)
Week 151	-23.3 (1.0)	-23.3 (1.0)	-23.3 (1.0)
Week 152	-23.5 (1.0)	-23.5 (1.0)	-23.5 (1.0)
Week 153	-23.7 (1.0)	-23.7 (1.0)	-23.7 (1.0)
Week 154	-23.9 (1.0)	-23.9 (1.0)	-23.9 (1.0)
Week 155	-24.1 (1.0)	-24.1 (1.0)	-24.1 (1.0)
Week 156	-24.3 (1.0)	-24.3 (1.0)	-24.3 (1.0)
Week 157	-24.5 (1.0)	-24.5 (1.0)	-24.5 (1.0)
Week 158	-24.7 (1.0)	-24.7 (1.0)	-24.7 (1.0)
Week 159	-24.9 (1.0)	-24.9 (1.0)	-24.9 (1.0)
Week 160	-25.1 (1.0)	-25.1 (1.0)	-25.1 (1.0)
Week 161	-25.3 (1.0)	-25.3 (1.0)	-25.3 (1.0)
Week 162	-25.5 (1.0)	-25.5 (1.0)	-25.5 (1.0)
Week 163	-25.7 (1.0)	-25.7 (1.0)	-25.7 (1.0)
Week 164	-25.9 (1.0)	-25.9 (1.0)	-25.9 (1.0)
Week 165	-26.1 (1.0)	-26.1 (1.0)	-26.1 (1.0)
Week 166	-26.3 (1.0)	-26.3 (1.0)	-26.3 (1.0)
Week 167	-26.5 (1.0)	-26.5 (1.0)	-26.5 (1.0)
Week 168	-26.7 (1.0)	-26.7 (1.0)	-26.7 (1.0)
Week 169	-26.9 (1.0)	-26.9 (1.0)	-26.9 (1.0)
Week 170	-27.1 (1.0)	-27.1 (1.0)	-27.1 (1.0)
Week 171	-27.3 (1.0)	-27.3 (1.0)	-27.3 (1.0)
Week 172	-27.5 (1.0)	-27.5 (1.0)	-27.5 (1.0)
Week 173	-27.7 (1.0)	-27.7 (1.0)	-27.7 (1.0)
Week 174	-27.9 (1.0)	-27.9 (1.0)	-27.9 (1.0)
Week 175	-28.1 (1.0)	-28.1 (1.0)	-28.1 (1.0)
Week 176	-28.3 (1.0)	-28.3 (1.0)	-28.3 (1.0)
Week 177	-28.5 (1.0)	-28.5 (1.0)	-28.5 (1.0)
Week 178	-28.7 (1.0)	-28.7 (1.0)	-28.7 (1.0)
Week 179	-28.9 (1.0)	-28.9 (1.0)	-28.9 (1.0)
Week 180	-29.1 (1.0)	-29.1 (1.0)	-29.1 (1.0)
Week 181	-29.3 (1.0)	-29.3 (1.0)	-29.3 (1.0)
Week 182	-29.5 (1.0)	-29.5 (1.0)	-29.5 (1.0)
Week 183	-29.7 (1.0)	-29.7 (1.0)	-29.7 (1.0)
Week 184	-29.9 (1.0)	-29.9 (1.0)	-29.9 (1.0)
Week 185	-30.1 (1.0)	-30.1 (1.0)	-30.1 (1.0)
Week 186	-30.3 (1.0)	-30.3 (1.0)	-30.3 (1.0)
Week 187	-30.5 (1.0)	-30.5 (1.0)	-30.5 (1.0)
Week 188	-30.7 (1.0)	-30.7 (1.0)	-30.7 (1.0)
Week 189	-30.9 (1.0)	-30.9 (1.0)	-30.9 (1.0)
Week 190	-31.1 (1.0)	-31.1 (1.0)	-31.1 (1.0)
Week 191	-31.3 (1.0)	-31.3 (1.0)	-31.3 (1.0)
Week 192	-31.5 (1.0)	-31.5 (1.0)	-31.5 (1.0)
Week 193	-31.7 (1.0)	-31.7 (1.0)	-31.7 (1.0)
Week 194	-31.9 (1.0)	-31.9 (1.0)	-31.9 (1.0)
Week 195	-32.1 (1.0)	-32.1 (1.0)	-32.1 (1.0)
Week 196	-32.3 (1.0)	-32.3 (1.0)	-32.3 (1.0)
Week 197	-32.5 (1.0)	-32.5 (1.0)	-32.5 (1.0)
Week 198	-32.7 (1.0)	-32.7 (1.0)	-32.7 (1.0)
Week 199	-32.9 (1.0)	-32.9 (1.0)	-32.9 (1.0)
Week 200	-33.1 (1.0)	-33.1 (1.0)	-33.1 (1.0)
Week 201	-33.3 (1.0)	-33.3 (1.0)	-33.3 (1.0)
Week 202	-33.5 (1.0)	-33.5 (1.0)	-33.5 (1.0)
Week 203	-33.7 (1.0)	-33.7 (1.0)	-33.7 (1.0)
Week 204	-33.9 (1.0)	-33.9 (1.0)	-33.9 (1.0)
Week 205	-34.1 (1.0)	-34.1 (1.0)	-34.1 (1.0)
Week 206	-34.3 (1.0)	-34.3 (1.0)	-34.3 (1.0)
Week 207	-34.5 (1.0)	-34.5 (1.0)	-34.5 (1.0)
Week 208	-34.7 (1.0)	-34.7 (1.0)	-34.7 (1.0)
Week 209	-34.9 (1.0)	-34.9 (1.0)	-34.9 (1.0)
Week 210	-35.1 (1.0)	-35.1 (1.0)	-35.1 (1.0)
Week 211	-35.3 (1.0)	-35.3 (1.0)	-35.3 (1.0)
Week 212	-35.5 (1.0)	-35.5 (1.0)	-35.5 (1.0)
Week 213	-35.7 (1.0)	-35.7 (1.0)	-35.7 (1.0)
Week 214	-35.9 (1.0)	-35.9 (1.0)	-35.9 (1.0)
Week 215	-36.1 (1.0)	-36.1 (1.0)	-36.1 (1.0)
Week 216	-36.3 (1.0)	-36.3 (1.0)	-36.3 (1.0)
Week 217	-36.5 (1.0)	-36.5 (1.0)	-36.5 (1.0)
Week 218	-36.7 (1.0)	-36.7 (1.0)	-36.7 (1.0)
Week 219	-36.9 (1.0)	-36.9 (1.0)	-36.9 (1.0)
Week 220	-37.1 (1.0)	-37.1 (1.0)	-37.1 (1.0)
Week 221	-37.3 (1.0)	-37.3 (1.0)	-37.3 (1.0)
Week 222	-37.5 (1.0)	-37.5 (1.0)	-37.5 (1.0)
Week 223	-37.7 (1.0)	-37.7 (1.0)	-37.7 (1.0)
Week 224	-37.9 (1.0)	-37.9 (1.0)	-37.9 (1.0)
Week 225	-38.1 (1.0)	-38.1 (1.0)	-38.1 (1.0)
Week 226	-38.3 (1.0)	-38.3 (1.0)	-38.3 (1.0)
Week 227	-38.5 (1.0)	-38.5 (1.0)	-38.5 (1.0)
Week 228	-38.7 (1.0)	-38.7 (1.0)	-38.7 (1.0)
Week 229	-38.9 (1.0)	-38.9 (1.0)	-38.9 (1.0)
Week 230	-39.1 (1.0)	-39.1 (1.0)	-39.1 (1.0)
Week 231	-39.3 (1.0)	-39.3 (1.0)	-39.3 (1.0)
Week 232	-39.5 (1.0)	-39.5 (1.0)	-39.5 (1.0)
Week 233	-39.7 (1.0)	-39.7 (1.0)	-39.7 (1.0)
Week 234	-39.9 (1.0)	-39.9 (1.0)	-39.9 (1.0)
Week 235	-40.1 (1.0)	-40.1 (1.	

CDISC 360: The Art of the Possible

1 Disease Area
✓ Endocrine

2 Therapeutic Area
✓ Diabetes - Type 2

3 Standards Focus
✓ Study Endpoint

4 Study Endpoint
✓ Analysis of Glycated Hemoglobin

5 Standard Analyses
✓ Mean Change from Baseline in HbA1c (%) Over Time

6 Selection Summary
Endocrine
Diabetes - Type 2
Study Endpoint
Analysis of Glycated Hemoglobin
Mean Change from Baseline in HbA1c (%) Over Time

Selection Summary

Study Endpoint

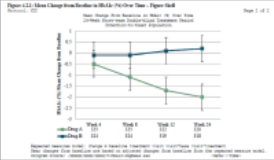
Analysis of Glycated Hemoglobin

Analysis of the continuous clinical endpoint of HbA1c. Example: a Phase III, parallel-group study designed to determine efficacy of Drug A for patients with Type II diabetes. The primary endpoint defined as the change in HbA1c from baseline.

[View details](#)

Analysis

Mean Change from Baseline in HbA1c (%) Over Time



Provides a visual display of the information in the "HbA1c Longitudinal Repeated Measures Analysis" table. Includes additional weeks beyond those in that table. The mean changes shown are based on adjusted changes from baseline from the repeated measures model.

[View details](#)[View analysis results metadata](#)

Analysis Datasets

ADSL

Analysis Data Subject Level

[View analysis dataset metadata](#)[View sample analysis data](#)[View analysis dataset structure](#)

ADHBA1C

DBS - Structured Dataset

[View analysis dataset metadata](#)[View sample analysis data](#)[View analysis dataset structure](#)

[< Back](#)

[Save Selection](#)

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2 Therapeutic Area
✓ Diabetes - Type 2

3 Standards
✓ Analysis

4 Study
✓ Analysis

5 Analysis Results Metadata

Selection Summary

Study Endpoint

Analysis

Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Metadata Field

Metadata

DISPLAY IDENTIFIER

Table 4.2.1/Figure 4.2.1

DISPLAY NAME

Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week

RESULT IDENTIFIER

Period, Intention-to-treat Population

PARAM

Treatment difference results (LSMean, confidence interval, p-value)

PARAMCD

HbA1c (%)

ANALYSIS VARIABLE

HbA1C

ANALYSIS REASON

CHG (Change from baseline)

ANALYSIS PURPOSE

SPECIFIED IN SAP

ANALYSIS DATASET

PRIMARY OUTCOME MEASURE

SELECTION CRITERIA

ADHBA1C

DOCUMENTATION

ITITFL="Y" and PARAMCD="HBA1C" and CHG ne . and ANL01FL="Y" and DTTYPE=""

PROGRAMMING STATEMENTS

See SAP Section XX for details. Program: t-hba1c-repm-sas LS means and 95% CIs are based on planned treatment, baseline HbA1c value, avisit, avisit*baseline and avisit*treatment interaction.

[SAS version 9.2]

PROC MIXED DATA = ADHBA1C;

WHERE ITITFL="Y" and PARAMCD="HBA1C" and CHG ne . and ANL01FL="Y" and DTTYPE="";

CLASS TRTP AVISIT;

MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / DDFM=KR;

LSMEANS TRTP / CL DIFF; REPEATED usebjid / subject = USUBJID TYPE=ON;

RUN;

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4 Study
✓ Analysis

5 Analysis Dataset Metadata

Selection Summary

Study Endpoint

Analysis

Analysis Datasets

Table 4.1.1: ADHBA1C Analysis Dataset Metadata

Keys

Location

Documentation

UDYID, USUBJID,

ADHBA1C.xpt

ADHBA1C.SAS/SAP

PARAMCD, AVISIT, ADY

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✓ Diabetes - Type 2

3 Standards
✓ Analysis

4 Study
✓ Analysis

5 Sample Analysis Data

Selection Summary

Study Endpoint

Analysis

Analysis Datasets

Table 4.1.1: ADHBA1C Analysis Dataset

Row	STUDYID	USUBJID	PARAM	PARAMCD	VISIT	AVISIT	AWTARGET	ADY	TRTP	ITITFL	ABLFL	BASE	AVAL	CHG	ANL01FL	CRITI	CRIT1FL	DTTYPE	LSSEQ
1	XYZ	XYZ-001-001	HbA1c (%)	HBA1C	Visit 2	Baseline	1	1	Drug A	Y	Y	9.2	9.2		Y	<7%	N		23456
2	XYZ	XYZ-001-001	HbA1c (%)	HBA1C	Visit 3	Week 4	28	28	Drug A	Y		9.2	8.5	-0.7	Y	<7%	N		45325
3	XYZ	XYZ-001-001	HbA1c (%)	HBA1C	Visit 4	Week 8	56	56	Drug A	Y		9.2	7.3	-1.9	Y	<7%	N		24768
4	XYZ	XYZ-001-001	HbA1c (%)	HBA1C	Visit 5	Week 12	84	84	Drug A	Y		9.2	6.8	-2.4	Y	<7%	Y		76553
5	XYZ	XYZ-001-001	HbA1c (%)	HBA1C	Visit 6	Week 24	168	168	Drug A	Y		9.2	6.3	-2.9	Y	<7%	Y		65678
6	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 2	Baseline	1	1	Drug B	Y	Y	8.6	8.6		Y	<7%	N		90874
7	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 3	Week 4	28	28	Drug B	Y		8.6	8.7	0.1	Y	<7%	N		23454
8	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 4	Week 8	56	56	Drug B	Y		8.6	9.6	1.0	Y	<7%	N		56744
9	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 5	Week 8	56	61	Drug B	Y		8.6	9.5	1.1	Y	<7%	N		67543
10	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 5.1	Week 12	84	84	Drug B	Y		8.6	9.5	1.1	Y	<7%	N	LOCF	67543
11	XYZ	XYZ-001-002	HbA1c (%)	HBA1C	Visit 6	Week 24	168	168	Drug B	Y		8.6	9.5	1.1	Y	<7%	N	LOCF	67543

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Save Data Standards

CDISC Foundational Standards

Example CDASH Report

CDASH (Clinical Data to Analysis Standard Headers) is a standard for clinical trial data collection. It defines a common set of data elements and their relationships, ensuring consistency and interoperability across different clinical trial systems.

The CDASH report shows a detailed view of a clinical trial data collection form, including fields for patient information, study details, and various clinical measurements.

Data Collection
CDASH



Row	STUDYID	DOMAIN	USUBID	CSEQ	CRCAT	CETERM	CDISCID	CDISCPR	CDISCCUR	CDISCSTC	CDISCSTY
1	XYZ	CR	XYZ-001-001	1	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
2	XYZ	CR	XYZ-001-001	2	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
3	XYZ	CR	XYZ-001-001	3	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
4	XYZ	CR	XYZ-001-001	4	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
5	XYZ	CR	XYZ-001-001	5	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
6	XYZ	CR	XYZ-001-001	6	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
7	XYZ	CR	XYZ-001-001	7	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
8	XYZ	CR	XYZ-001-001	8	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL
9	XYZ	CR	XYZ-001-001	9	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL	HYPOHYPOHOL



ObsID	ObsDate	ObsTime	ObsTimeSec	ObsTimeMin	ObsTimeSec	ObsTimeMin	ObsTimeSec	ObsTimeMin	ObsTimeSec	ObsTimeMin	ObsTimeSec
1001	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1002	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1003	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1004	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1005	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1006	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1007	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1008	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1009	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100
1010	2011-08-24T08:48	100	100	100	100	100	100	100	100	100	100

Analysis
ADaM



Table 4.2.1: RMA: Longitudinal Repeated Measures Analysis - Table Shell

Protocol: XYZ

Table (A) Longitudinal Repeated Measures Analysis
24-Week Short-term Double-blind Treatment Period
Intention-to-treat Population

		Drug A	Drug B
BASELINE	Mean (SD)	100 (10)	100 (10)
WEEK 4	Mean (SD)	100 (10)	100 (10)
WEEK 12	Mean (SD)	100 (10)	100 (10)

Change from baseline: Mean (SD)

Adjusted change from baseline: Mean (SD)

95% Confidence interval for adjusted mean

Difference vs. Drug B (SE)

95% Confidence interval for difference

P-value vs. Drug B

Results
???

CDISC Analysis Result Standards – Released April 19, 2024!



Analysis Results Standard (ARS) v1.0



Large trials generate many analysis results in the form of tables, figures, and written reports, yet these results are rarely output in a form that is machine-readable. Previously, there has been no standard way of describing and organizing these results, making it difficult to automate their generation, make them reproducible, trace their origin, or enable them to be reused in other outputs.

To address these inefficiencies, CDISC has developed the [Analysis Results Standard \(ARS\)](#), which aim to facilitate automation, reproducibility, reusability, and traceability of analysis results data.

Features of ARS v1.0

- A Logical Data Model that describes analysis results and associated metadata.
- A User Guide to illustrate and exercise the model with common safety displays.



<https://cdisc-org.github.io/analysis-results-standard/>

Class	Description
NamedObject	An object with a name
ReportingEvent	A set of analyses and outputs created to meet a requirement...
ListOfContents	A structured list of analyses and outputs

Date	Version
2024-04-19	Final

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<https://wiki.cdisc.org/display/ARSP/Analysis+Results+Standard+User+Guide+v1.0>

Analysis Results Key Objectives

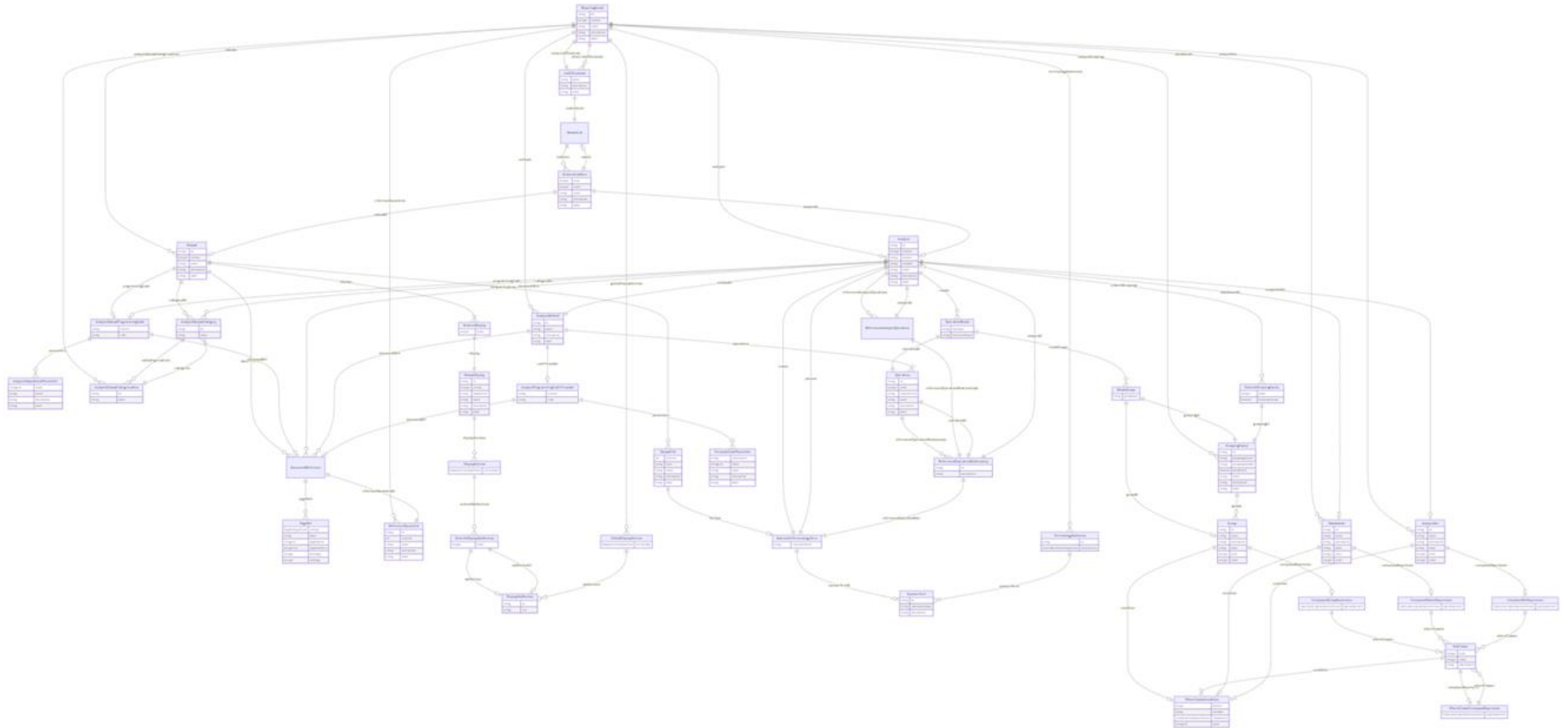


Leverage analysis results metadata to drive the automation of results



Support storage, access, processing, traceability and reproducibility of results

ARS Logical Model Schema Diagram



Today's specification of analysis

- Written in plain text
 - not machine readable
- Some details are left out
 - often (at best) retrievable from the analysis executable program/define.xml
 - reason why regulators requires SAS programs to be submitted
- Specifications are not software agnostic
 - SAS versus R syntax
 - different set of options

*know the document is old, but very likely the same is seen in newer documents

<i>Primary analysis from CDISC pilot study*</i>	Issue
<i>The primary analysis of the ADAS-Cog (11) at Week 24 will use the efficacy population with LOCF imputation for any missing values at Week 24.</i>	define.xml revealed that it was Change from baseline (CHG) that was analysed.
<i>An ANCOVA model will be used with the baseline score, site, and treatment included as independent variables.</i> <i>Treatment will be included as a continuous variable, and results for a test of dose response will be produced.</i> <i>Interaction terms will not be investigated.</i>	The define.xml specifies how the analysis is done in SAS, but how to translate to R or other programming language?
<i>If the test for dose response is statistically significant, pairwise comparisons among the 3 groups will be performed and evaluated at a significance level of 0.05.</i>	Pairwise estimates made – but test for dose response was significant (p < 0.05)

Why Develop Analysis Concepts?

- Reduces ambiguity
 - Analysis Concepts with standardized metadata structure enforce precision in specifying analysis settings and assumptions
- Enables machine-readable analysis plans
 - Analysis Concepts structured as metadata rather than narrative text, can be directly linked to statistical programming code
- Supports traceability
 - Analysis Concepts help maintain clear linkage between protocol objectives, endpoints, and the specific analytical methods applied
- Streamlining collaboration
 - Analysis Concepts provide a common language between statisticians, clinicians, data managers, and other stakeholders

Analysis Concepts – scope of CDISC 360i

**360i Journey: Ideas → Implementation →
Common Practice**



Define and digitize E2E standards



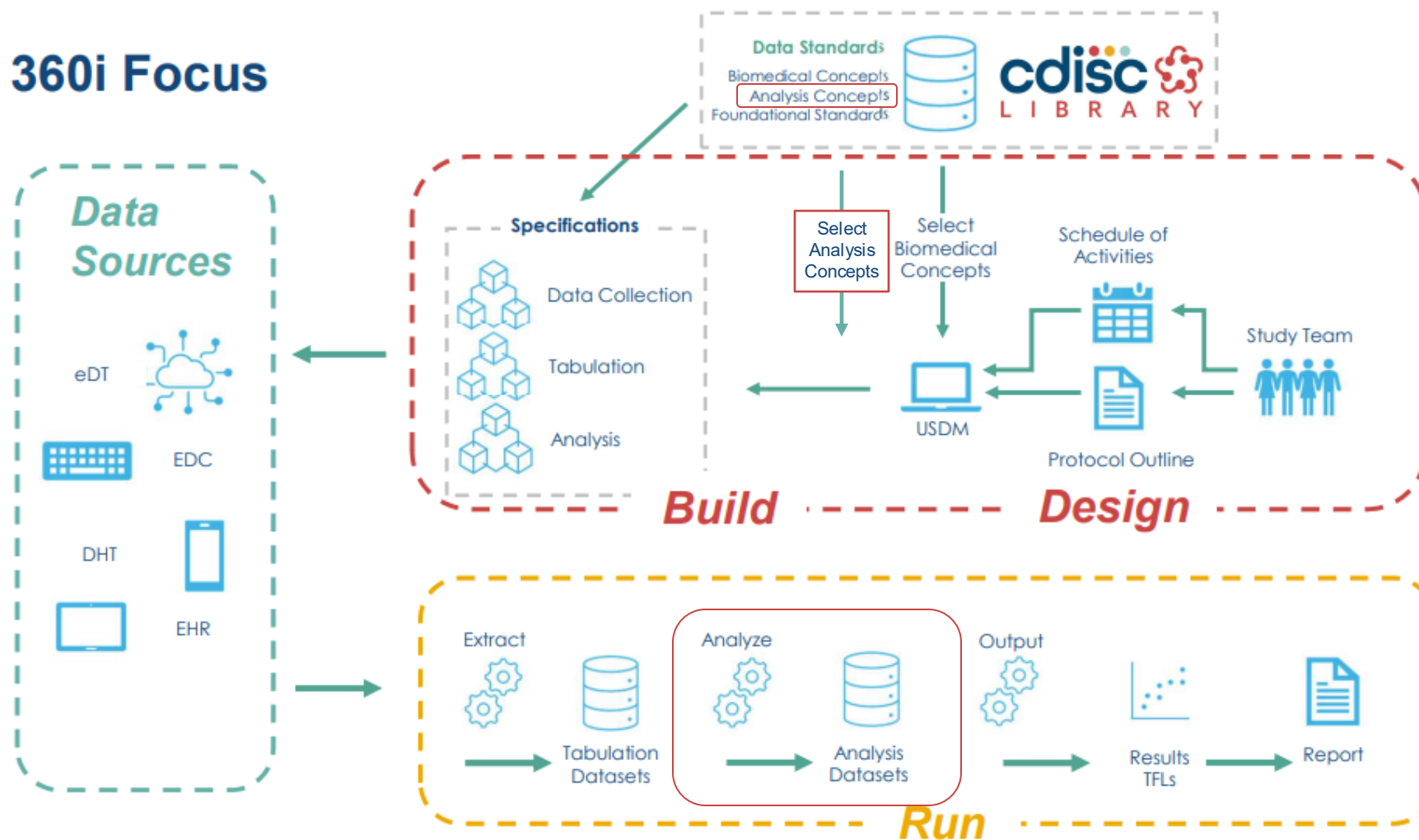
Accelerate study design and build through digitized standards



Demonstrate automated data flow from design to analysis

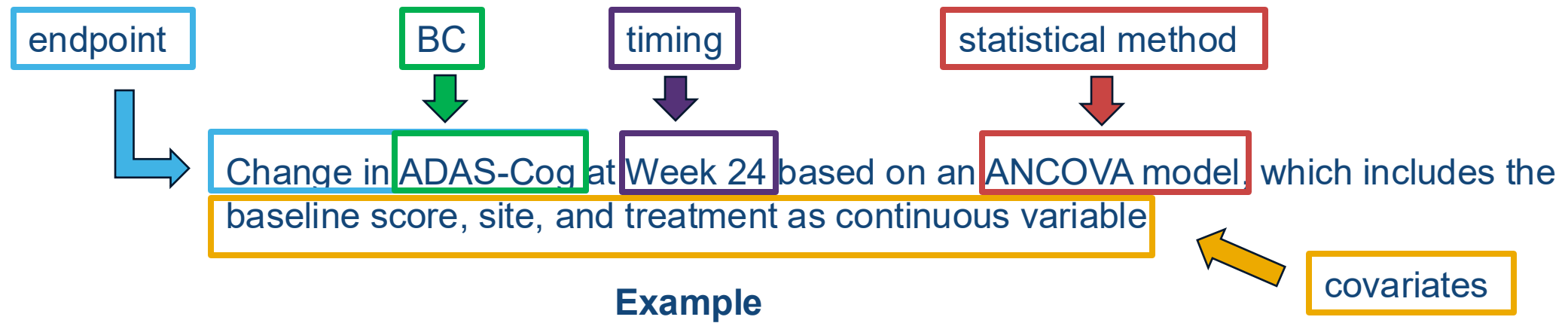
From 360i-Program-Kickoff webinar – 2025-FEB-18

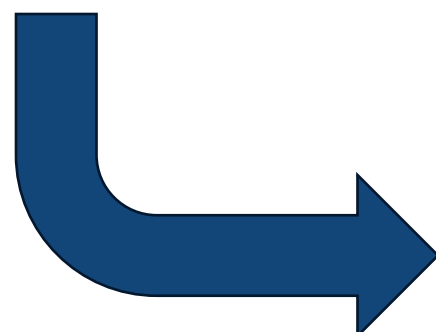
Analysis Concepts in 360i: Use for Downstream Automation



Analysis Concepts

- What is an Analysis Concept?
 - Collection of standardized configurable elements & methods that are needed to describe a final output or answer a clinical question
 - Standard definitions in a digital statistical analysis plan
- What is the purpose of an Analysis Concept?
 - Supports configuration and automation of analysis
 - Informs what needs to be collected to answer the clinical question





AC ⚡ DC

	Analysis Concept (AC)	Derivation Concept (DC)
Purpose	Examines existing data or information to draw conclusions, identify patterns, or test hypotheses	Generates new derived values from raw or derived data
Direction	Typically works with completed measurements or observations to extract meaning	Transforms or processes data to create new representations
Process	Involves applying statistical methods, critical thinking, and interpretative frameworks to understand data	Uses mathematical operations, formulas, or algorithms to calculate new quantities
Outcome	Produces insights, conclusions, or evaluations based on the data - aggregated data (not subject-level)	Creates derived data (subject level) that serve as inputs for subsequent analysis or derivations
Example 1	The p-value (from Type III Sums of Squares for treatment dose), based on linear model analysis of CHG for dose response; using randomized dose and site group in model.	CHG: Change from Baseline to Week 24 in ADAS Cog (11). Use LOCF if missing value at week 24.
Example 2	Mean value of CHG by visit	CHG: Change from BASELINE in ADAS Cog (11) by visit BASELINE = 'Y' if ADAS Cog (11) at visit 2

Approaches Considered

- Top-Down
 - What are the element covered across sample SAPs?
 - What element are covered across standards?
- Bottom-up
 - Build a picture of an analysis concept using the most common statistical analyses

SAP Coverage Matrix — Comprehensive Look

SAP Element	USDM v4	Define JSON	ARS LDM	OMOP CDM	SDMX	Notes
Study Objectives	■	×	■	×	▲ metadata concept	OMOP lacks study context
Endpoints	■	×	■	▲ via observation domain	■ concept-level metadata	SDMX can describe statistical variables
Hypotheses (null, alt)	×	×	▲ test in method	×	×	Not modeled anywhere
Stratification Factors	×	×	×	▲ via covariates	×	OMOP lacks explicit stratification
Sample Size Calculations	×	×	×	×	×	Missing everywhere
Multiplicity Control	×	×	▲ noted in ARS	×	×	-
Randomization Info	▲	×	×	×	×	USDM may include some design details
Analysis Populations	▲ (Origin, Role)	×	×	▲ cohorts	▲ metadata groups	OMOP cohorts approximate populations
Population Criteria / Rules	×	×	▲ test only	▲ cohort definitions	▲ concept mappings	OMOP cohorts share parsable logic
Change-from-Baseline Logic	■ (Method/Expression)	▲ test method	▲ test method	×	▲ calculation metadata	SDMX can hold computations
Time-to-Event Definition	×	▲ test method	▲ test method	▲ via observation periods	▲ event-step metadata	Partial support
Consenting/Failure Event Definition	×	▲ test method	▲ test method	▲ death, loss to follow-up flags	▲ event metadata	-
Visit Windowing Rules	▲	×	▲ method test	▲ VISIT_occurrence period	▲ time-series metadata	OMOP dates available
Data Derivations	×	■ (Method, Expression)	▲ AnalysisVariable.derivation	▲ limited SQL logic	▲ computed datatables	SDMX supports formula metadata
Missing Data Handling	×	▲ test in derivation	▲ method test	▲ via flags or data source	▲ metadata notes	-
Simple Imputation	×	■ (via Expression)	▲ method test	▲ Can create derived flags	▲ formula metadata	-
Advanced Imputation (MI, MCMC)	×	▲ test only	▲ test only	×	×	Not structured
Shell Definitions (TFLs)	×	×	■ AnalysisIdDisplay	×	■ SDMX structure for outputs	SDMX can define output tables
Table Titles, Shells	×	×	×	×	■	ARS focused, SDMX more abstract
Denominator Definitions	×	▲ footnote/comment	■	×	×	-
Programming Notes	×	▲ comment	×	×	×	-
Disposition Summaries	×	×	×	×	×	-
Early Termination Analysis	×	×	×	×	×	-
Programming Conventions	×	▲ via comments	▲ notes	×	×	-
Statistical Methods	▲ test	■ via Method	■ AnalysisIdEffect	×	×	-
Expressions/Calculations	×	■ Expression	▲ test only	×	×	-
Code References/Attachments	×	▲ links	×	×	×	-
External References / Docs	×	▲	■	×	×	-
Analysis Variables	×	×	■	×	×	-
Endpoint Dataset Mapping	×	■ (Identifier)	■ (AnalysisIdTable)	×	×	-
Visit Windows / Interpolation Rules	×	×	×	×	×	-
Repeated Measures Models	×	▲ test	▲ test	×	×	-
Responder Definitions	×	▲ test	▲ test	×	×	-
Subject Status (OMOP-like)	×	×	×	×	×	-
Formal AE Groupings/Categories	×	■ via CodeList	■	×	×	-



Analysis Data Model (ADaM) Examples in Commonly Used Statistical Analysis Methods

Prepared by the
CDISC Analysis Data Model Team

Development Plan

Subset SAPs

Use a script to download and parse SAPs

Extract the primary analysis description

Tokenization and Pattern Recognition

Tokenize text into meaningful components

Identify common patterns

Visualize relationships

Iterative Modeling

Build generalized model of analysis concepts using tokenized elements

Refine based on new feedback and examples

Compare and validate against existing models (USDM, ARS)

Template Development

Common analyses

Software agnostic

Important that the statistical community see the vision and benefits

- 'Automation' stakeholders

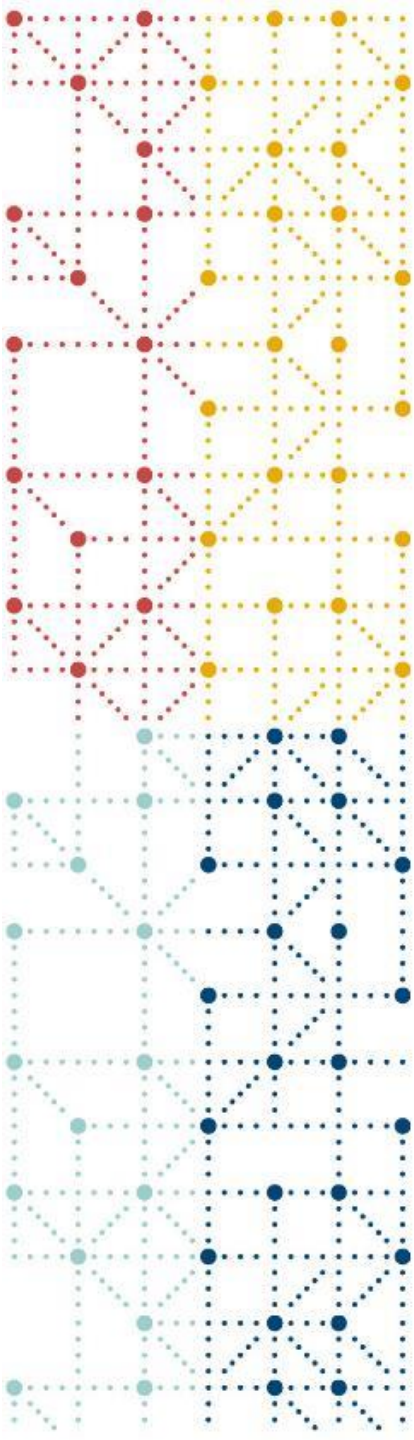
- CDISC
- PHUSE
- USDM dev team
- TCB / Pharma-Biotech
- CRO's
- Vendors

- 'Scientific' stakeholders

- Regulators
 - FDA, EMA, PMDA
- Statistical communities
 - United States
 - Society for Clinical Trials (SCT) - <https://www.sctweb.org/>
 - Statistical Analysis and Modelling in Clinical Development (SAMCD) - <https://community.amstat.org/biop/home> (Part of the ASA Biopharmaceutical Section)
 - Drug Information Association (DIA) - <https://www.diaglobal.org/>
 - Europe
 - European Federation of Statisticians in the Pharmaceutical Industry (EFSPI) - <https://www.efspi.org/>
 - Statisticians in the Pharmaceutical Industry (PSI) - <https://www.psiweb.org/>
 - European Clinical Research Infrastructure Network (ECRIN) - <https://ecrin.org/>

Challenges

- Defining the 80 percent (80/20 rule)
- Defining the boundaries between USDM, Analysis Results Standard, Biomedical Concepts, and Analysis Concepts
- How and if to leverage existing ontologies such as STATO
- How and if to leverage Statistical Data and Metadata eXchange (SDMX)
 - Set of technical standards designed to describe statistical data and metadata (ISO 17369)
- How do we make this relatable to the CDISC community?
 - Creation of an eSAP?
- Limited volunteer time



Thank You!

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