

## Analysis Concepts Role within the CDISC 360i Vision

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### ABSTRACT

Since January 2025, a CDISC working group has been working on defining a model for Analysis Concepts to address a gap in enabling the end-to-end linking, automation, and interoperability envisioned by the CDISC 360i initiative.

Just as biomedical concepts (BC) serve as an essential semantic framework that connects and aligns various foundational standards in clinical research, analysis concepts can provide a similar semantic framework that not only extends into analysis and reporting components but also ensures a clear link to the protocol (as represented by the Unified Study Definition Model (USDM)) as well as the existing BC library.

Analysis Concepts aim to:

- Provide a standardized, configurable framework for expressing how clinical questions are translated into analytical outputs
- Enhance the statistical consideration component of the USDM (eProtocol) & support creation of a digital, machine-readable Statistical Analysis Plan (eSAP)
- Inform both data collection needs and programming logic for analysis.

Importantly, this work is being developed in alignment with other CDISC standards including USDM, CDASH, SDTM, ADaM, and the new Analysis Results Standard (ARS). Analysis Concepts focus on the clinical intent and analytical approach, which is then realized in these different standards.

Using a breast cancer use case, we will demonstrate how analysis concepts are being applied to enhance data exchange and foster cross-disciplinary collaboration, paving the way for more efficient and transparent clinical research.

This paper will share the following:

- The overall scope and vision of CDISC 360i, including
  - The key gap that Analysis Concepts is seeking to fill
  - The linkages to USDM, BC, CDASH, SDTM, ADaM, and ARS
- Early model and draft controlled terminology developed by the working group
- Breast Cancer use case
- Future directions for standardizing analysis planning and enabling traceable, automated pipeline

### INTRODUCTION

The clinical research data lifecycle is now reinforced by a suite of standards designed to facilitate end-to-end automation, moving the industry toward a “digital data flow”. This starts with the Unified Study Definition Model (USDM) which uses Biomedical Concepts (BC) to create the digital representation of the study protocol. This serves as the digital backbone for the study lifecycle, providing machine-readable representations of the clinical study protocol which ensures a link to downstream systems.

Then, the data representation itself begins at CDASH and the CRF Portal for data collection through SDTM for tabulation and finally moves into ADaM for analysis-ready datasets. Data is captured, tabulated, and prepared for analysis using robust standards which facilitate faster review cycles.

Analysis proceeds and has Analysis Results Standards (ARS) and Analysis Results Data (ARD) standards available to follow traceability of analysis through to each output. The eTFL portal is ready-for-use to create ARS-compliant reporting templates.

This checks most of the boxes we need through the study as seen in Display 1.



**Display 1. Protocol to CSR scope**

Many of these pieces have current standards to use within CDISC 360i. However, there is a hole in this: standardizing the information about *how* we are analyzing the data. In other words, how do we standardize the Statistical Analysis Plan (SAP) which informs ADaM and ARS? Enter: Analysis Concepts (AC).

## ANALYSIS CONCEPTS: BUILDING BLOCKS FOR THE DIGITAL SAP

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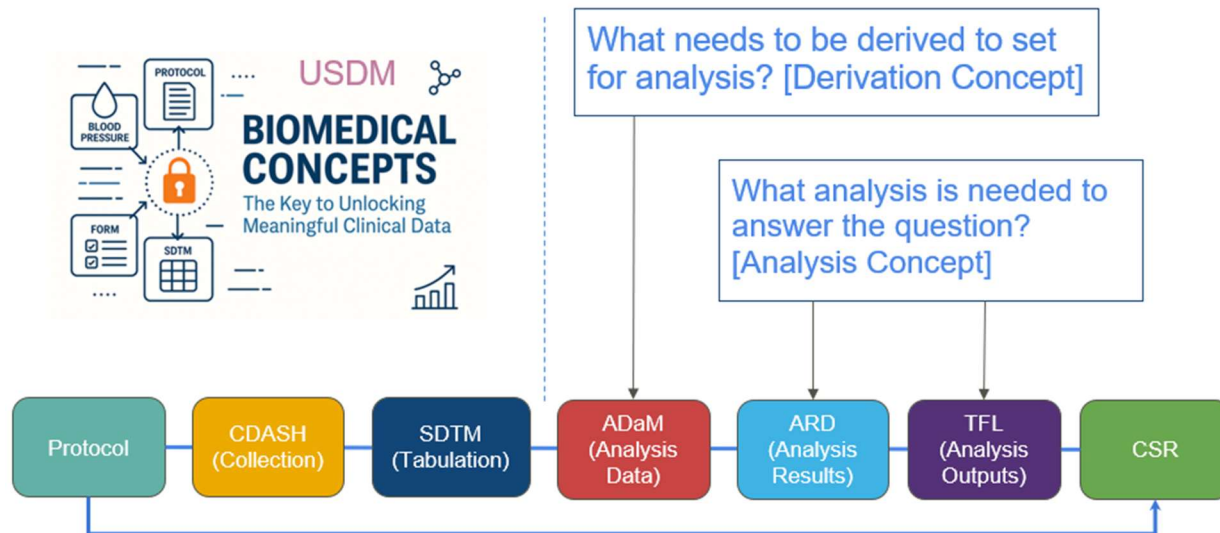
## ANALYSIS VERSUS DERIVATION CONCEPTS (AC/DC)

Within the Analysis Concepts framework that has been in development, two concepts have been identified: the analysis concept (AC) itself which describes how an endpoint will be analyzed, and the derivation concept (DC) which describes how observed data will be used in calculations to be ready for analysis. This is described further in Table 1 and Display 2.

Table 1 compares analysis concepts to derivation concepts:

	<b>Analysis Concept (AC)</b>	<b>Derivation Concept (DC)</b>
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

**Table 1. Analysis Concepts versus Derivation Concepts**



**Display 2. Protocol to CSR: Standards-Driven Conceptual Mapping**

To ensure that the model for Analysis Concepts is truly fit for purpose, the team has developed a series of user stories for various potential users of Analysis Concepts.

## USER STORIES

### Accelerating Study Start-up

**As a study statistician, I want to** select from a library of Analysis Concepts **so that I can** quickly draft the digital Statistical Analysis Plan (SAP) and identify needed datasets and variables. Pre-specified codelists and options **allow me** to make a robust SAP with all of the necessary information for reproducible result and **gives my team** the information they need to create all outputs.

### Automating Standard Analyses Across Studies

**As a statistical programmer, I want to** use pre-defined Analysis Concepts **so that I can** automate the generation of standard TFLs across studies without recreating logic each time.

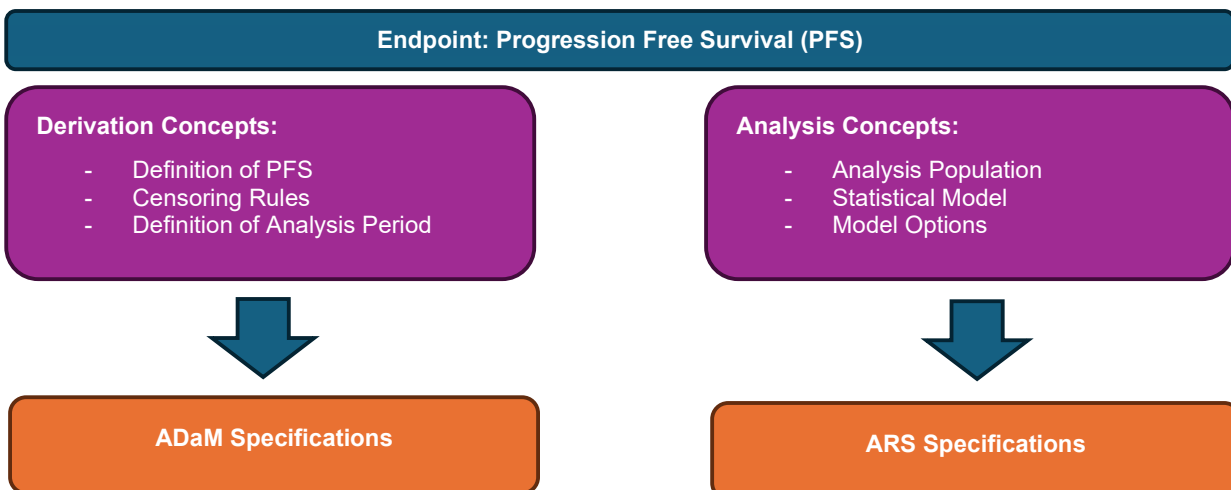
### Enabling Metadata-driven Automation

**As a clinical data standards expert, I want to** build a structured repository of Analysis Concepts **so that** downstream automation tools (e.g., ADaM specifications generator, TFL code generators, validation scripts) can use them as inputs.

## BREAST CANCER USE CASE

The BC, USDM, and Analysis Concepts teams are utilizing the Breast Cancer Therapeutic User Guide to test-drive these new standards. Transforming the TAUG to use a BC and USDM will automate the necessary SDTMs for the study based on the selected BCs specified. Similarly, this will work in conjunction with Analysis Concepts, feeding the chosen endpoints through to the eSAP where the derivation concepts will be defined, and the analysis required for the endpoints will be chosen and described in their entirety.

The eventual bi-products of using Analysis Concepts is then the ability to make the basis for ADaM specifications and ARS Specifications with the information contained within the Analysis Concept standards. Through the process of creating the Analysis Concepts model, the metadata required for both ADaM and ARS will be mostly if not entirely defined enough to output the specifications directly. This facilitates key pieces of making a fully end-to-end standard.



**Display 3. Implementation of Analysis Concepts for Progression Free Survival**

## NEXT STEPS

The Analysis Concepts team is still in the early stages of development. There is a long road ahead which must be developed to get to a usable standard. However, the team is progressing together through many key pieces.

- A data model needs to be created, determining which key sections are needed to define in an eSAP, then developing the standardized concept and tools to use each section.
- The boundaries and flow between USDM, Analysis Results Standard, Biomedical Concepts, and Analysis Concepts need to be determined. Pieces from each are pulled from the prior standard, and the overlap, give, and take needs to be defined.
- Investigations must be made to existing ontologies such as STATO to leverage their definitions within CDISC controlled terminology.
- Determination of the relatable-ness and useability for the CDISC community
- Gaining buy-in from the statistician community (whose members are often not familiar with CDISC standards), the CDISC standards community, and end-users such as statistical programmers and regulatory agencies is perhaps the key piece for this effort and will answer the questions: Is it worth it? Is it functional? Is it sustainable?

## CONCLUSION

Analysis concepts will play an integral part in deploying a true end-to-end CDISC 360i model applied to enhance data exchange and foster cross-disciplinary collaboration, paving the way for more efficient and transparent clinical research. It allows for automation, standardization, and easily-attainable improvements of the quality of analysis plans.

## ACKNOWLEDGMENTS

We acknowledge the work of the CDISC Analysis Concepts workstream.

## RECOMMENDED READING

- [CDISC 360i](#)
- [STATO: Statistics Ontology](#)

## CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Analysis Concepts Role within the CDISC 360i Vision, continued

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