MEDS Synthetic Control Database™: Mitigating the Patient Data Scarcity Challenge in Clinical Research

Overcome data scarcity

Improve disease understanding to promote precision medicine

Facilitate exploratory data analysis

The ability to efficiently study a medical product is enhanced by a thorough understanding of the natural history of a disease. The expected safety and efficacy outcomes overall or in specific subgroups can be obtained from previous clinical trial experience in the indication of interest. To bridge knowledge gaps, biostatisticians/biometricians, epidemiologists, therapeutic area heads, and pharmacovigilance leads are dependent on existing literature, their own previously run trials, and emerging real-world data (RWD).

These resources have shortfalls that hinder researchers' ability to make data-driven decisions.

- Published literature is static and surfaces only a few data elements about one trial at a time.
- RWD, although voluminous, lacks systematic data collection and defined endpoints, is often limited to only a few geographies, and may represent an inherently different type of patient than a patient likely to enroll in a clinical trial.
- A sponsor's own historical clinical trial data is limited in scope and variety to their own work in the disease area and is laborious to standardize for meta-analysis.

To mitigate these challenges and make clinical data actionable, a large pool of standardized clinical data from multiple sponsors and geographies needs to be made available. Enter Medidata Solutions.

Medidata has helped sponsors run clinical trials for over 20 years, accumulating a large clinical trial data repository collected from millions of patients and thousands of trials. Medidata is now making that industry-unique data store fit for purpose so that advanced analytics can generate new clinical and business insights. MEDS Synthetic Control Database™ (SCD) makes patient data available, actionable and consumable to improve decision-making in trials from design through submission.

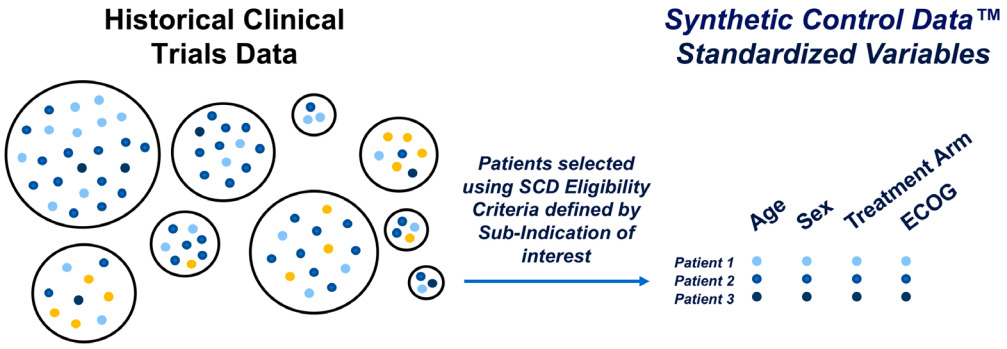
MEDS Synthetic Control Database™

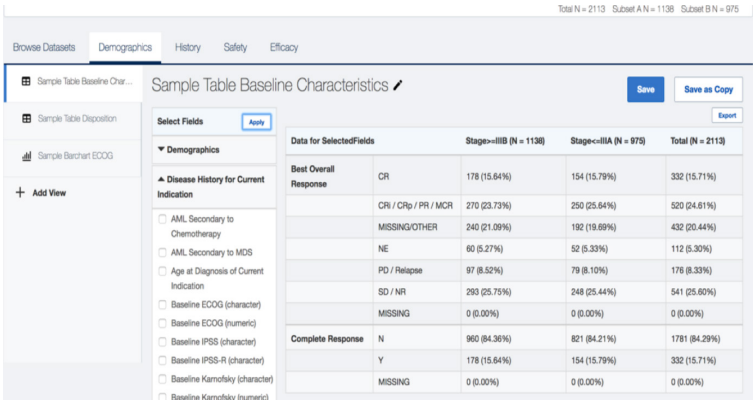
SCD is a visualization application with over 100 patient-level standardized variables populated with data that has been aggregated and de-identified from a variety of trials and sponsors, across geographies and time periods. The dynamic application allows researchers unbounded exploration of available data in the disease area of interest. Researchers can now explore questions like:

- How can I improve sample size calculations to reduce costs and still have adequate statistical accuracy?
- Who are the disease/patient subpopulations most likely to benefit from a particular class of treatments?
- What is the natural history of the disease and the expected efficacy outcomes?
- What is the normal background rate for serious adverse events in my trial?
- Can I discover endpoint correlations to better understand how early phase trials with short-term endpoints (e.g., complete response) can predict results of later confirmatory studies (e.g., overall survival)?

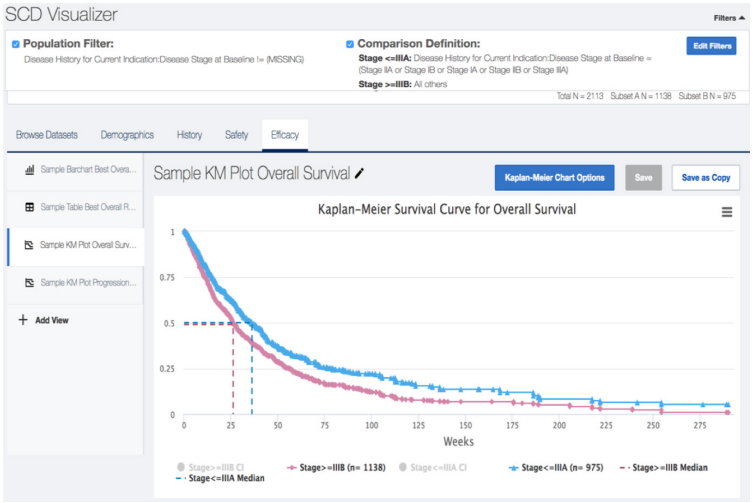
How Medidata Builds a Synthetic Control Database™

SCD starts with queries of the Medidata Enterprise Data Store (MEDS) for relevant studies in a sub-indication. Patient data from these studies is then standardized and harmonized into over 100 patient-level variables. Data is quality reviewed by biostatisticians and with proprietary machine learning algorithms that automatically detect errors in the data. Finally, the analytical data is surfaced in a visualization tool that presents familiar biostatistical views and is designed to facilitate exploratory analyses. Patient privacy and sponsor intellectual property are protected within the tool through de-identification and aggregation.

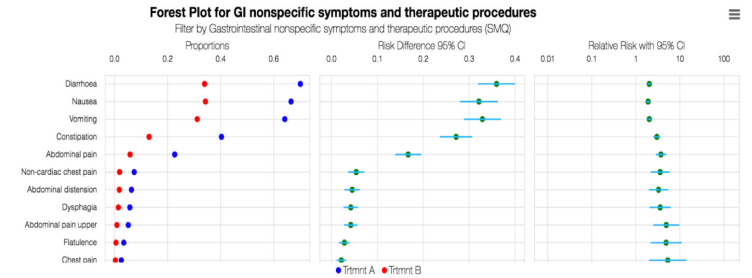




Drill-down on subpopulation and get a detailed historical population provided where none existed before.



Output is dynamically updated based on the parameters selected.



	Trtmnt A TOTAL N = 1224		Trtmnt B TOTAL N = 889			
Variable	Count	Incidence	Count	Incidence	Difference (95% CI)	Adj Relative Risk (95% CI)
Diarrhoea	859	0.7018	303	0.3408	0.3603 (0.31996, 0.40059)	2.0575 (1.86, 2.27)
Nausea	816	0.6667	306	0.3442	0.3218 (0.28097, 0.36271)	1.9354 (1.75, 2.14)

Gain insight into risk factors between custom comparator groups via forest plots. Explore a variety of graphical comparisons of data conformed to industry standards such as: Meddra and WHOdrug.

SCD Visualization Tool Features

- Browse statistical views of the contents of all database variables.
- Create sub-population filters and custom comparison groups on-the-fly.
- Build data tables using any of the standardized variables within the database.
- Use a variety of visualization types for representing the intended comparison; easily layer in new data, or build a specific filtering/stacking option.
- SCDs are updated quarterly with newly completed study data and features.

Available SCD Indications

Medidata currently has SCDs available in several oncology subindications and is continually building more. If interested in discussing further, please email Medidata at info@mdsol.com.

Leveraging Synthetic Controls to Improve Trials with No or Compromised Concurrent Control

A sister product to SCD named MEDS Synthetic Control Arm (SCA) allows the additional capability of statistically matching patients in the SCD to a target trial that needs additional controls, such as an early-phase single arm trial or a trial where the randomized control has been compromised by availability of the experimental product outside the trial. This can provide much higher confidence for decisions on under or non-controlled trials. **To learn more about SCA, read our whitepaper here.**

About Medidata Solutions

Medidata is leading the digital transformation of life sciences with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by #1 ranked industry experts, the Intelligent Platform for Life Sciences helps pharmaceutical, biotech, medical device companies and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata serves more than 1,000 customers and partners worldwide and empowers more than 100,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: **www.mdsol.com**

info@mdsol.com | +1 866 515 6044