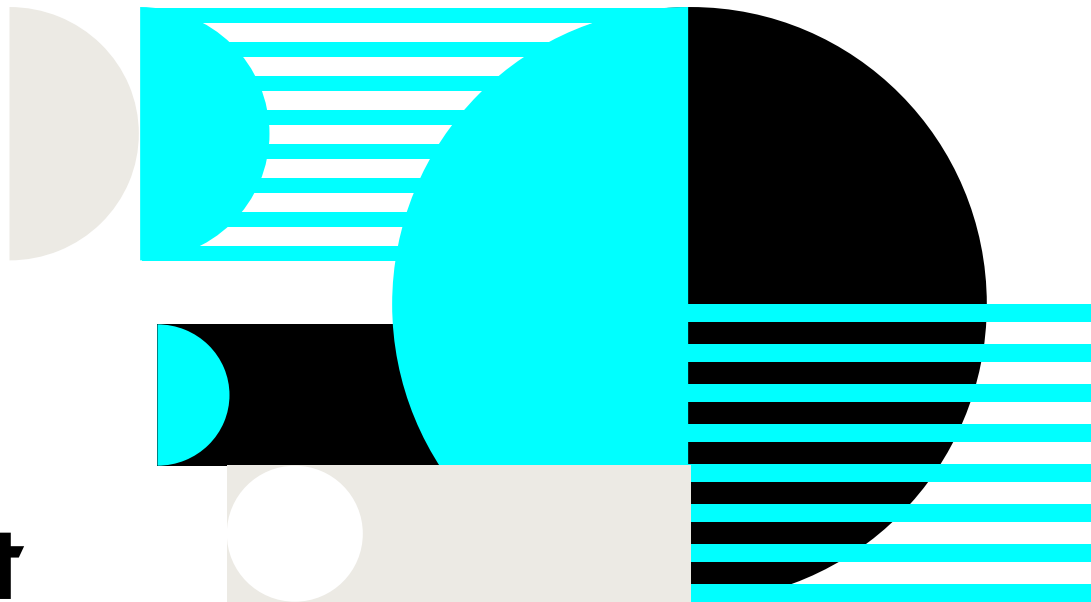# Datavant External Control Arms

December 2023

datavant

What is an external control arm?

An **external control arm** refers to the use of real-world data (RWD) to describe the progression of disease in a population that is not treated with the experimental drug candidate. External control arms can be used in single-arm clinical trials, in which all enrolled patients receive active treatment, often because a control arm is either infeasible or unethical.

Instead of enrolling patients and treating them with a placebo or Standard of Care, clinical researchers **analyze data from patients in the real world** to determine patient outcomes. They compare these real-world outcomes to outcomes for those patients treated with the experimental drug to assess efficacy and safety.

Why are external control arms important?

External control arms **enable a more ethical approach to clinical trials** by reducing or eliminating the need for a Standard of Care control group. This enables all patients in the study to be treated with the experimental therapy and to experience the potential benefits. Particularly when a disease lacks a good standard of care, providing all enrolled patients with the experimental therapy is a more ethical approach to development. An external control arm can also be a **powerful accelerant to clinical development**.

Save time by eliminating the need for a separate control group, enabling trial sponsors to recruit fewer patients overall.

Allow all patients to be treated with the experimental therapy, expanding the breadth of available response and outcomes data.

How Datavant powers external control arms

Datavant's ecosystem and technology enable you to connect real-world data and **create an external control arm with minimal friction:**

1 Find data partners

Use the Datavant ecosystem to connect and engage with all the sources of real-world data necessary to obtain required coverage.

3 Link and De-duplicate

Use Datavant tokens to determine the unique patients in each data source. Link outcomes records for these patients in a de-identified way to create your completed external control arm.
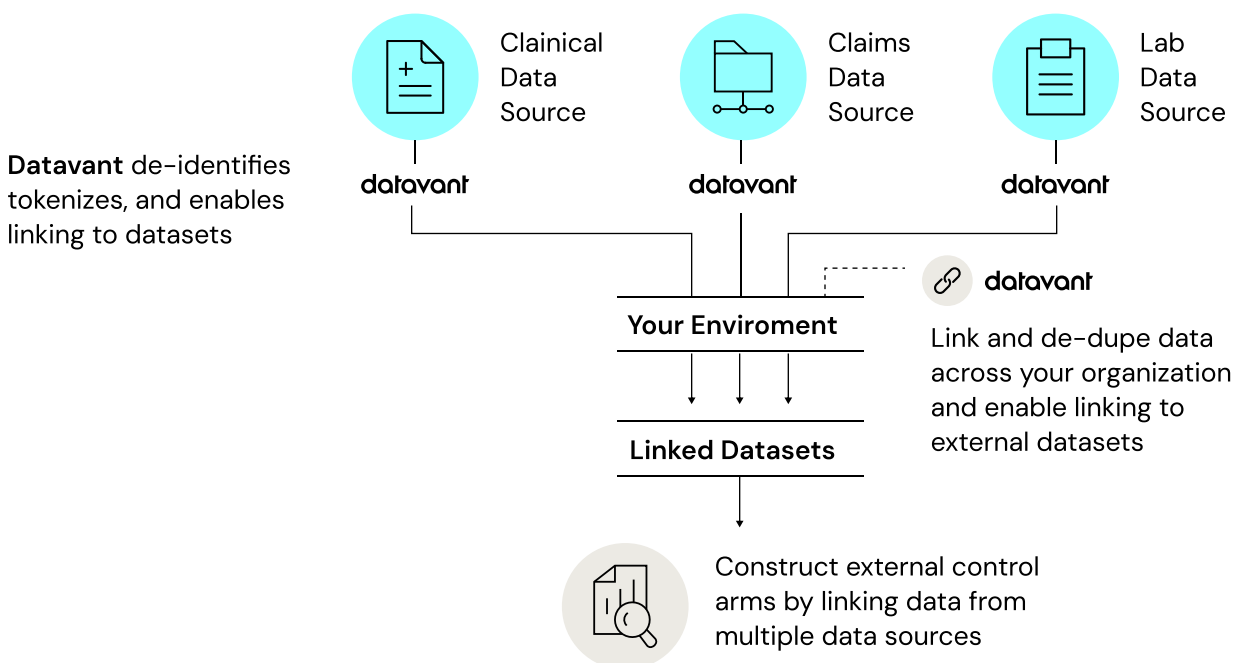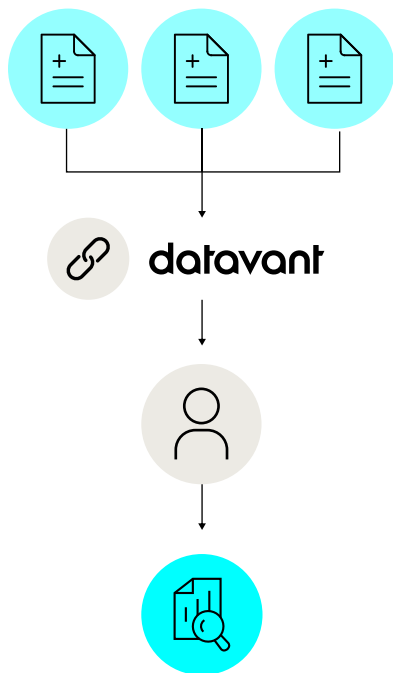
2 Tokenize and De-identify

Deploy Datavant software across all sources to tokenize, de-identify, and link data according to a common key. If a source isn't already in the Datavant ecosystem, we will install with them at no cost.

4 Analyze

Compare patient outcomes in the active treatment arm to real-world outcomes in the external control to assess the efficacy of your drug candidate and deliver treatments to patients sooner.

Datavant de-identifies tokenizes, and enables linking to datasets

Clainical Data Source

Claims Data Source

Lab Data Source

datavant | datavant | datavant

Your Enviroment

datavant

Link and de-dupe data across your organization and enable linking to external datasets

Linked Datasets

Construct external control arms by linking data from multiple data sources

Case Study: Creating an Oncology External Control Arm for a Top 5 Pharma

A top 5 pharma company sought to create an external control arm and support a clinical study for an experimental treatment in a solid tumor indication.

The company identified and engaged three sources of electronic medical records within the Datavant ecosystem to provide clinical outcomes data for the patients of interest. Together, these three data providers covered the necessary number of patients to power the clinical study.

Each data provider created Datavant tokens in their own environment, and securely sent those tokens to the pharma company. **The pharma company linked the tokens and matched them across the three datasets,** identifying unique patients and removing duplicates. They combined the certified de-identified records from each source to create a population of unique patients and their clinical outcomes.

Today, the **pharma company is analyzing the combined population of patients**, comparing their outcomes in the real-world to the outcomes of patients enrolled in the active arm of their clinical trial.

Their use of an external control arm enhanced the standard of care control arm, reducing the need and the number of patients required. This accelerated their trial recruitment and enabled the company to treat a greater number of patients with the experimental drug. The external control arm has put the treatment in more patients' hands, faster, and will continue to reduce the time to market.

To learn more contact us.
info@datavant.com.