

Data Sharing Statement

Data

Data available: Yes

Data types: Deidentified participant data, Data dictionary

How to access data: These data will be under control of the sponsor and the data coordinating center, who can be reached via the PI: Annetine C. Gelijns, annetine.gelijns@mountsinai.org

When available: beginning date: 02-28-2025

Supporting Documents

Document types: None

Additional Information

Who can access the data: Qualified external researchers can request de-identified participant data to conduct research.

Types of analyses: Any Purpose

Mechanisms of data availability: Proposals will be reviewed and approved by the sponsor and the trial Steering Committee. After approval of a proposal, data can be shared through a secure online platform after signing a data access agreement

Any additional restrictions: These de-identified data will only be available for request after all patient follow-up is completed and a period of 12 months has elapsed after U.S. Food and Drug Administration approval.