

SDTM to ADaM

Trigger

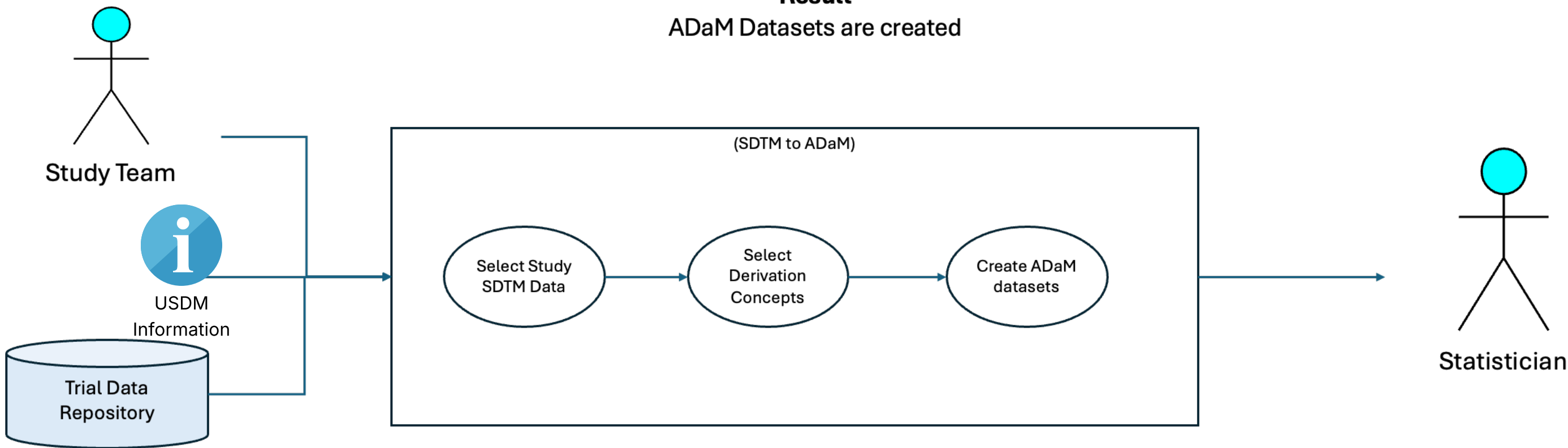
SDTM Data Domains exist with targeted number of subjects to be able to make Interim analysis for a study
or
Final SDTM Data Domains and randomization code has been broken

Primary Scenario

Sponsor has a final version of SDTM and selects Derivation Concepts from a USDM-compliant Information Stream
and execute the Derivation Concepts to produce ADaM datasets

Result

ADaM Datasets are created



Perform Study Analysis

Trigger

ADaM datasets are available

Primary Scenario

Sponsor selects ADaM datasets and selects the study configured Analysis Concepts from a USDM-compliant Information Stream
and execute the Analysis Concepts to produce Analysis Results Data

Result

Analysis Result Data is produced

