Class ANALYSIS AND REPORTING: SDTM

Systems of Interest:
SDTM Trial Domains
SDTM Data Domains

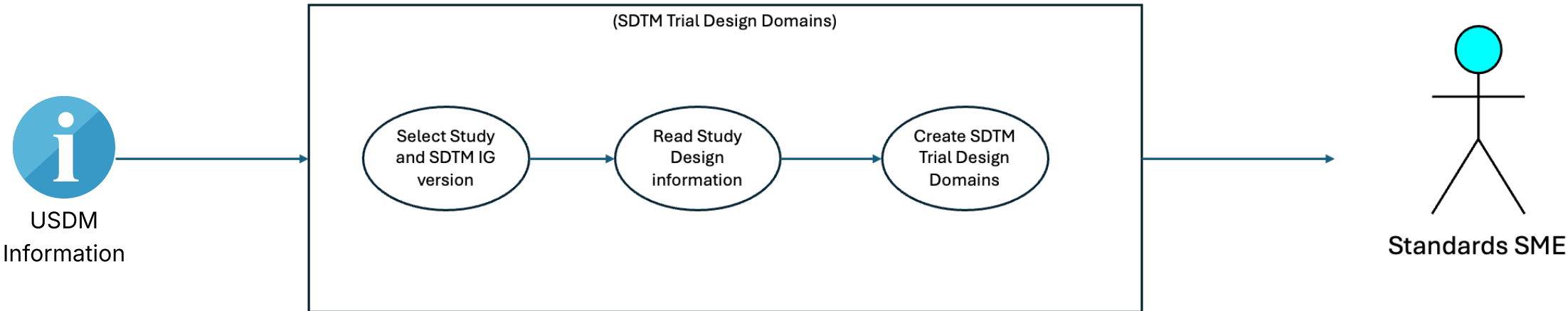### SDTM Trial Design Domains

Trigger
A final study design exists for a study
or
Sponsor initiates preparation for submission

Primary Scenario
Sponsor selects a study and study version from a USDM-compliant Information Stream, retrieves the study design information from USDM for the STDM Trial Design domains: Trial Arms, Trial Elements, Inclusion/Exclusion Criteria, Trial Visits, Trial Summary.

Result
Trial Design datasets are created

SDTM Data Domains

Trigger
The Schedule of Activities, including Biomedical Concepts, for a Study Design has been finalized and data is available for study

Primary Scenario
Sponsor selects target version of SDTM Implementation Guide and produces mapping specifications and programs for submission datasets.

Result
SDTM Mapping Specification created