

Class STUDY START-UP: TRIAL BUDGETS

Systems of Interest:

Draft Study Budget

Draft Site-Level Budgets

Draft Study Budget

Trigger

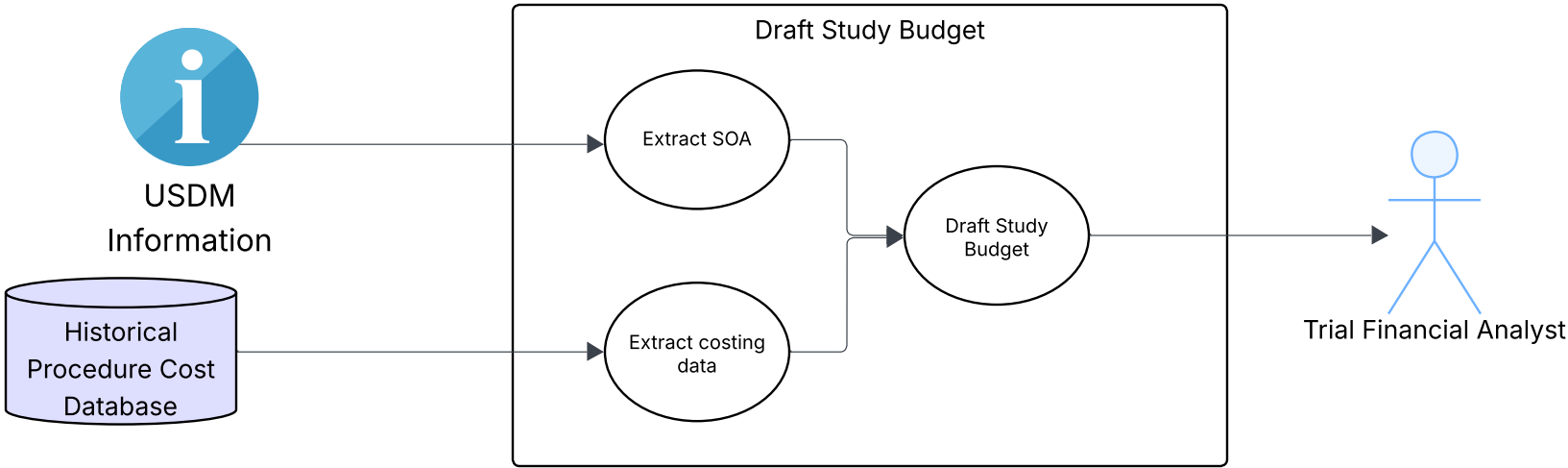
A new study protocol is approved.

Primary Scenario

The System selects a study and study version from a USDM-compliant information stream, analyzes the relevant design elements, and pulls historical costing data for the associated medical activities and analysis procedures on geographical region and analysis supplier(e.g. Labs, Imaging) basis. The geographical-level and supplier-level costing data is used to draft a study-level budget -- taking into account the regions in scope for site recruitment and the desired patient enrollment per region.

Result

A Draft Study budget is created. The Sponsor's Financial Analyst reviews the draft budgets and makes changes as required.



Draft Site-Level Budgets

Trigger

A new study trial site is identified for use in the study.

Primary Scenario

The System selects a study and study version from a USDM-compliant information stream, analyzes the relevant design elements, and pulls Fair Market Value costing data for the associated medical activities on per-market and per-geographical region basis. The FMV data is used in conjunction with the overall study budget to construct drafts of individual trial site budgets, in preparation for site activation, as sites are identified for use in the study.

Result

A draft Study budget at the Site level is created. The Sponsor's Financial Analyst reviews the draft budgets and makes changes as required.

