

Note: this Class consists of five interrelated Systems of Interest that use existing information to extrapolate performance characteristics for a new study design

Optimization Scores
Enrollment Forecasting
Resourcing and Cost Predictions
Country and Site Selection
Timeline Forecasting

A Study Designer initiates a design for a new clinical trial.

The Study Designer inputs an initial Therapeutic Area (TA) and basic study design parameters -- i.e. inclusion/exclusion criteria, endpoints, objectives, & schedule of activities. The system queries the Protocol Store for previous studies matching the given inputs and initiates a series of analytics. The Study Designer iterates on the initial inputs and analytic parameters, making tradeoff decisions across the entire set of analytical scores until the final set of analytics parameters are generated.

Note that several of the analytics require operational information from previous studies (e.g. budgets, site performance, milestones) in addition to the Protocol Store information.

The Study Designer uses the analytics parameters in subsequent design phases. See **STUDY-EXPERIMENTAL CONCEPT: STUDY DESIGN**.

