

Class STUDY-EXPERIMENTAL CONCEPT: ANALYTICS

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

Systems of Interest:
 Optimization Scores
 Enrollment Forecasting
 Resourcing and Cost Predictions
 Country and Site Selection
 Timeline Forecasting

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Trigger

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

Primary Scenario

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.

Result

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

