

Class STUDY-EXPERIMENTAL CONCEPT: STUDY DESIGN

Systems of Interest:

Design Study

Design Study

Trigger

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

Primary Scenario

The Study Designer inputs the same initial Therapeutic Area (TA) and study structure provided by **STUDY-EXPERIMENTAL CONCEPT:ANALYTICS** to query the Protocol Store and populate the starting potential set of digital study design elements (e.g. SOA, Inclusion/Exclusion). The Study Designer applies the analytics output from the above referenced Class to refine the digital study design elements until a final, optimal set of design elements is constructed.

The Study Designer consults with the Study Team on the draft design and iterates as necessary, revisiting **STUDY-EXPERIMENTAL CONCEPT:ANALYTICS** to generate new analytics parameters and update the study design elements. Iterations continue until the Study Designer and Study Team agree on the final set of study design elements.

Secondary Scenario

The Study Designer and Study Team agree upon the completeness of individual design elements at different times during the design process. For example, the SOA is considered complete before the Inclusion/Exclusion criteria. In this scenario iteration continues on the incomplete design elements while the completed design elements are released for export.

Result

The study design elements are reviewed by the Study Team and exported as a USDM compliant information stream for subsequent use.

