

Class REGULATORY SUBMISSION: STATISTICAL AND SAFETY REVIEW

Systems of Interest:
Compare Actual to Planned Treatment Progression

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Trigger

Regulatory Agency receives a Sponsor's study results that pair with a previously submitted study definition as per **Regulatory Submission:Submission:Transmit Study Protocol**

Primary Scenario

Regulatory Reviewer selects the study, study version associated study result data sets for analysis. The System extracts the select information from a USDM-compliant information stream and submitted Study Data sets. The Regulatory Reviewer compares planned treatment progression against actual treatment progression, formulates a set of questions based upon their review and forwards them to the Sponsor Regulatory Representative for further consultation.

Result

A list of questions regarding the the Sponsor's submission is returned to the Sponsor.

