

Class REGULATORY SUBMISSION: REGULATORY REVIEW

Systems of Interest:
Review Study Protocol

Review Study Protocol

Trigger

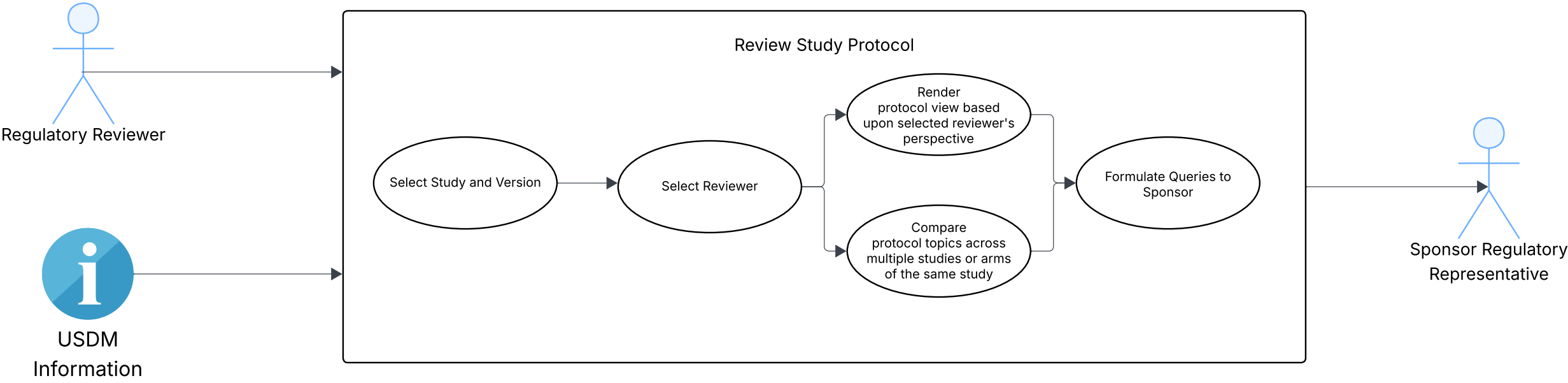
Regulatory Agency receives a study definition package that is the subject of a pre-submission or submission review as per **Regulatory Submission:Submission:Transmit Study Protocol**.

Primary Scenario

The Regulatory Reviewer selects the study and associated study version to review. The System extracts the study definition information from a USDM-compliant information stream, determines the reviewer's archetype and renders the corresponding view. The Regulatory Reviewer performs the review as per their archetype, optionally comparing the study information to similar studies or arms of the same study to understand differences. The Regulatory Reviewer 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 Sponsor's submission are returned to the Sponsor.



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