

Class REGULATORY SUBMISSION: SUBMISSION

Systems of Interest:
Transmit Study Protocol

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Trigger

Sponsor decides to share a study protocol with a Regulatory Agency

Primary Scenario

The Sponsor's regulatory representative selects the study and associated study version. The System extracts the corresponding study definition information from the USDM-Compliant Information stream and packages the information for transmission. The packaged study definition information is sent to the Regulatory Agency and stored in the Regulator's instance of an USDM-Compliant Information stream.

Result

The study definition, composed of all information to reconstitute the study protocol, is submitted to the Regulatory Agency.

