

Class STUDY START-UP: TRIAL REGISTRIES

Systems of Interest:
Upload Study to Registry

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Trigger

A Sponsor registers a new study with a Regulatory Agency.

Primary Scenario

The System selects a study and study version from the USDM-Compliant Information Stream, imports the digital study definition into its Clinical Trial Reporting System (CTRS), and populates a registry template. The template is uploaded to the Regulator's Trial Registry system and a Registry Record, along with any potential errors, is returned to the Sponsor.

Result

The Sponsor's Study Team reviews the Registry Record, along with any returned errors, to determine if the study's registry is as expected.

