Class STUDY EXECUTION: AMENDMENTS

Systems of Interest:
Report Protocol Changes

Report Protocol Changes

Trigger
Sponsor makes a decision to change a study protocol that has been previously submitted and/or approved by a Regulatory Authority as per **STUDY-EXPERIMENTAL CONCEPT: ANALYTICS, STUDY DESIGN** and/or **PROTOCOL AUTHORING**.

Primary Scenario
The protocol changes result in a new study version in a USDM-Compliant Information stream. The System extracts information from the USDM-Compliant Information stream corresponding to the new and previously approved study definition and performs a comparison to identify changes. The changes are encapsulated as a Study Protocol Delta and sent to one or more subscribing stakeholders.

Result
Stakeholders are notified of the Amendment changes relative to the previous Study protocol version.

USDM Information

Report Protocol Changes
- Compute differences between Study Protocol Versions
- Populate a Study Protocol Delta Data Structure
- Encapsulate Delta Data Structure into exchange payloads

Investigator

Trial Site EHR/CTMS

USDM-Compliant Regulatory Authority Ingest

Regulatory Authority Representative