

Class STUDY EXECUTION: SITE MONITORING

**Systems of Interest:
Verify Site Compliance**

Verify Site Compliance

Trigger

Study treatment progression data is made available to the Sponsor's Trial Data repository.

Primary Scenario

The System selects individual patient (study subject) data from the Trial Data Repository and the study Schedule of Activities (SOA) from a USDM-compliant information stream. The patient's treatment progression is evaluated against the SOA encounter and activity sequence to flag missed activities, procedures or other types of missing data. The timing of each encounter and activity is evaluated against the SOA timeline to flag any event that fails to meet timing criteria (e.g. occurred too early or late). All flags are reported to the Sponsor's trial site representative for additional follow-up.

Result

The Sponsor's trial representative confers with the Site Investigator on the findings.

