

Class STUDY EXECUTION: SITE SUPPORT

Systems of Interest:

Populate Trial Site Data Systems

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Trigger

A trial site joins a study or a protocol amendment results in an updated study definition.

Primary Scenario

The System selects a study and study version from the USDM-compliant information stream. The Schedule of Activities (SOA) is extracted, packaged for transport and sent to the site where it is ingested into the site CTMS and/or EHR.

If the trial site supports local lab procedure analysis (i.e. Local Labs) then the Sponsor designates the lab procedures to be performed at the trial site, creates a payload of the designated lab procedure records and sends it to the trial site for ingestion into the site CTMS and/or EHR.

Result

The site data systems (CTMS and/or EHR) are updated with the latest SOA and Local Lab procedure information.

