Class STUDY START-UP: DEPLOYMENT

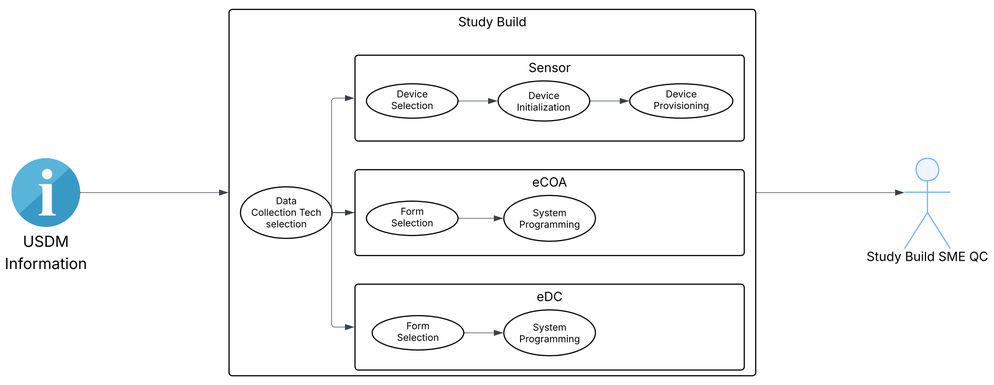
Systems of Interest:
Study Build
Central Analysis Services
Clinical Trial Materials
Interactive Response Technology
Clinical Trial Management

Study Build

Trigger
New digital study design information is approved (Note: this could be prior to an approved study protocol).

Primary Scenario
The System selects a study and study version from the Study Definition Respository, extracts the Schedule of Activities (SOA) and determines what data collection technology (e.g., eDC, eCOA, Sensor) is associated with each activity. The chosen data collection system is sent the activity information and uses associated Biomedical Concept (BC) structures to configure the system -- choosing from a library of existing forms/configurations -- or initialize the physical devices.

Result
The data collection systems are configured and ready for Quality Control checks prior to deployment.

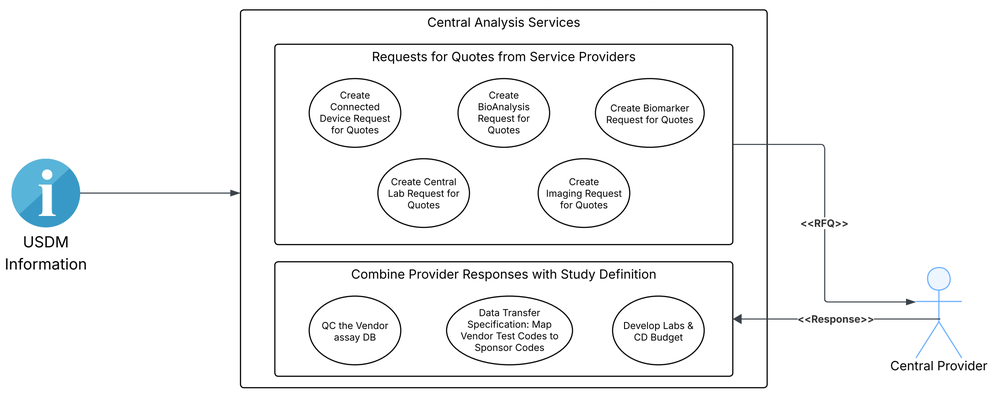


Central Analysis Services

Trigger
New digital study design information is approved (note: this could be prior to an approved study protocol) .

Primary Scenario
The System selects a study and study version to extract from a USDM-compliant information stream. The Schedule of Activities is used to draft Request For Quotes (RFQ) that, once reviewed, are sent to one ore more central analysis service Providers. The Provider responses are used to create detailed budgets for the study analysis (i.e., labs, imaging, bioanalysis, biomarkers, connected devices such as CGMs), map test codes between Provider & Sponsor, and initialize systems that control the quality of analysis results returned by the Provider during trial execution.

Result
Central analysis service providers are notified of the upcoming study and Sponsor needs. Sponsors received data required to initialize their analysis service budgets and QC functions.

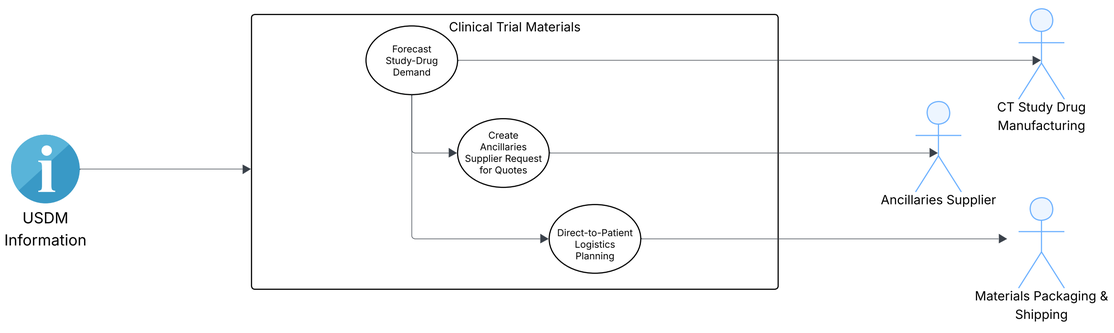


Clinical Trial Materials

Trigger
New digital study design information is approved (note: this could be prior to an approved study protocol) .

Primary Scenario
The System selects a study and study version to extract from a USDM-compliant Information Stream. The Schedule of Activities (SOA) is used to forecast overall demand for the Intervention materials (e.g. study-drug) and ancillary materials (e.g. test kits) as a function of time across trial execution. The Sponsor uses the forecasts to draft Request for Quotes (RFQ) that are sent to the suppliers of ancillary trial materials. Likewise, the SOA informs planning of any direct-to-patient materials needed during the study -- especially in cases of Community Based Research trials.

Result
Sponsor develops a model of materials demand during the study, ancillaries suppliers and materials packaging & shipping are informed of Sponsor's needs.

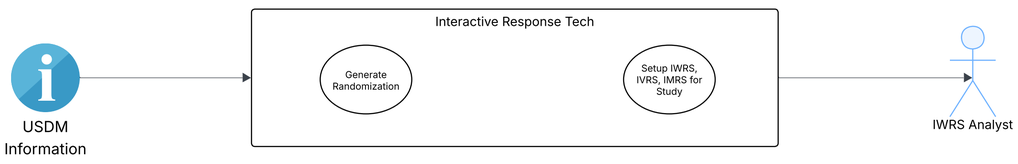


Interactive Response Technology

Trigger
New digital study design information is approved. (Note: this could be prior to an approved study protocol).

Primary Scenario
The System selects a study and study version to extract from a USDM-compliant information stream. The information (e.g. Schedule of Activities) is used to configure the Sponsor's Interactive response technologies (i.e. IWRS) -- including randomization parameters, dosing rules and visit schedules -- and to initialize built-in validation checks.

Result
Interactive response technologies are automatically configured for the study and ready for Quality Control review by an Analyst.



Clinical Trial Managment

Trigger
New digital study design information is approved. (Note: this could be prior to an approved study protocol).

Primary Scenario
The System selects a study and study version to extract from a USDM-compliant Information Stream. The digital study design information is used to create a new study record in the Clinical Trial Management System (CTMS) to serve as a container for all follow on information -- e.g. trial site information, milestones.

Result
Sponsor's CTMS is configured for the new study. Any downstream processes that rely on a new CTMS record are likewise configured.