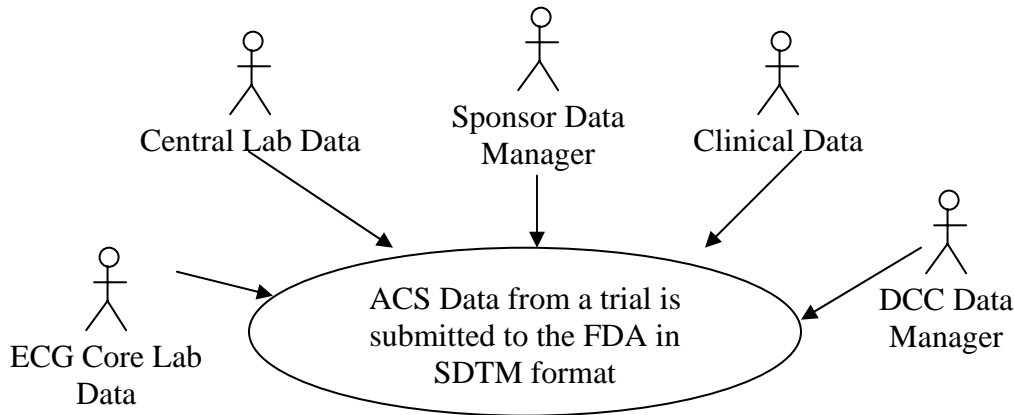


Use Case: Data from a Data Coordinating Center for an ACS trial is transmitted to the FDA

Use Case Description:

The purpose of this use case is to show how data for an acute coronary syndrome trial (ACS) is transmitted in study data tabulation module (SDTM) format from a Data Coordinating Center (DCC) to the sponsor to be merged with existing data from other trials. The merged data is then sent to the FDA.



Use Case Sequence of Steps:

1. Clinical data is entered into an electronic data capture (EDC) system for an ACS trial
2. Central lab data is transmitted and loaded into the DCC database
3. ECG Core lab data is transmitted and loaded into the DCC database
4. The DCC Data Manager writes the specifications for the data to be mapped to SDTM format.
5. The DCC programmer writes the program to map the data to SDTM format.
6. The DCC Data Manager validates the mapping program.
7. The DCC Data Manager uses the program to map the ACS data to SDTM format.
8. The DCC Data Manager sends the ACS data in SDTM format to the sponsor.
9. The sponsor Data Manager then merges this data with data from other studies in SDTM format
10. The sponsor Data Manager sends the merged data to the FDA

Story Board: Data from an ACS trial is sent to the FDA in SDTM Format

Actors:

Site:

Sally Study Coordinator

Data Management

Dana Data Manager-DCC
Donna Data Manager-Sponsor
Lula Lab Data Manager
Erica ECG Data Manager
Peter Programmer

Story Board: Data from an ACS trial is sent to the FDA in SDTM Format

Salley Study Coordinator from site 001 enters the clinical data for patients in the ACS Trial into an ECD system. Lula Lab Data Manager from the central lab transmits the lab data to Dana Data Manager at the DCC. She loads the data into the ACS database. Erica ECG Data Manager from the ECG core lab transmits the ECG data to Dana Data Manager at the DCC. She loads the data into the ACS database. Dana Data Manager writes the specifications for the data to be mapped in SDTM format. Peter Programmer develops the program to map the data to SDTM. Dana Data Manager validates the mapping program. Dana Data Manager uses the mapping program to map the ACD data to SDTM. Then Dana Data Manager sends the data in SDTM format to the sponsor. Donna Data Manager at the sponsor merges the data with other existing studies in SDTM format and sends the data to the FDA.

