Computationally Independent Model and Service Specification

Safety Reporting

0.6

12/23/2010

Document Version	Date	Author	Changes
0.1	10/06/2010	Paul Baumgartner	Initial draft.
0.2	11/23/2010	Paul Baumgartner	Updated draft based upon caAERS team review.
0.3	11/24/2010	Paul Baumgartner	Incorporated additional feedback.
0.4	11/29/2010	Paul Baumgartner	Incorporated feedback from Ram Chilukuri.
0.5	11/30/2010	Paul Baumgartner	Incorporated additional feedback from reviewers.
0.6	12/16/2010	Paul Baumgartner	Incorporated additional feedback from the ESST.

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1 Overview and Business Case

1.1 Name of Service

The service discussed in this specification will be known as the Safety Reporting Service.

1.2 Service Description and Purpose

Safety reporting, as it pertains to the cancer clinical trial and cancer clinical care spaces, is the process of communicating the occurrence of harmful or potentially harmful events that may have some relation to the clinical trial or care. Safety reports can include nearly any type of harmful or potentially harmful events, including but not limited to adverse events and product problems. Safety reporting may be required based upon criteria included in varied sources such as protocol documents, legal regulations, and institutional policies, among others. Additionally, safety reporting may be performed on a voluntary basis. Potential recipients of safety reports include, but are not limited to, clinical trial sponsors, regulatory agencies, drug safety monitoring boards, institutional review boards and ethics committees.

The purpose of the Safety Reporting Service is to provide a standard set of interfaces to create, manage, and submit safety reports. This service will enable the searching, analysis, sharing, and data mining of these reports. Additionally, this service will provide the ability to evaluate harmful or potentially harmful events against criteria to determine appropriate reporting requirements. This service will also facilitate the interaction and interoperability between systems that require and provide safety reports. As a result of this interoperability, this service will potentially improve the quality and availability of safety reports and improve the monitoring of safety on cancer clinical trials and in cancer clinical care.

1.3 Scope

The scope of the Safety Reporting Service is limited to providing the ability to create, manage, submit, query, and retrieve safety reports within the cancer clinical trial space and cancer care delivery space. This service doesn't explicitly exclude non-cancer utilities.

Items	Scope / Out of Scope	Source
Provide the ability to create safety reports	Scope	Safety Reporting Service Scope

		Document
Provide the ability to update safety reports.	Scope	Safety Reporting Service Scope Document
Provide the ability to submit safety reports.	Scope	Safety Reporting Service Scope Document
Provide the ability to amend safety reports.	Scope	Safety Reporting Service Scope Document
Provide the ability to withdraw safety reports.	Scope	Safety Reporting Service Scope Document
Provide support for utilization by other authorized systems and services.	Scope	Safety Reporting Service Scope Document
Provide support for federated safety reporting.	Scope	Safety Reporting Service Scope Document
Provide an audit log of all create, update, and delete activity pertaining to a safety report record.	Scope	Safety Reporting Service Scope Document
Provide the ability to associate and disassociate data to safety reports including, but not limited to: adverse events, patient information and records, lab values, study interventions, and hospital records.	Scope	Safety Reporting Service Scope Document
Provide the ability to evaluate harmful or potentially harmful events against criteria (or rules) to determine if safety reporting is required, and if so, which reports are required, when they are due, and to whom they must be submitted.	Scope	Safety Reporting Service Scope Document

Provide the ability to create, update, and delete the criteria (or rules) used to evaluate harmful or potentially harmful events and determine the appropriate safety reporting requirements.	Scope	Safety Reporting Service Scope Document
Provide the ability to create, update, and delete the report definition used for each safety report.	Scope	Safety Reporting Service Scope Document
Provide the ability to search for and retrieve safety reports using a variety of search criteria based on study, subject/patient, organization(s), personnel, and adverse event attributes.	Scope	Safety Reporting Service Scope Document
Provide the ability to notify defined stakeholders regarding the status of a safety report.	Scope	Safety Reporting Service Scope Document
Provide the ability to route safety reports for review and comment by study personnel.	Scope	Safety Reporting Service Scope Document

1.4 Assumptions

Assumption	Affects	Source
The patient and/or study subject exists.	Initiation of a safety report	Safety Reporting Service Scope Document
The study exists with all required	Initiation of a safety	Safety Reporting

information.	report, associating a safety report to a study.	Service Scope Document
The patient and/or subject treatment information exists.	Associating a safety report to the treatment information for a patient and/or study subject.	Safety Reporting Service Scope Document
There will be multiple sources of data for a safety report. For example, a safety report may use data from a Lab System, information regarding the treatment of the event may be sent via an electronic health record, and the course on which the event occurred may come from a participant calendar system.	Initiation and updating of a safety report.	Safety Reporting Service Scope Document
Service users (human and system) must be authorized to access the study and/or subject / patient to which they are attempting to perform an action on.	A security mechanism that can limit users by study and action needs to be in place.	
The event sent to the Safety Reporting Service may be sent using the Safety Reporting coding terminology specified for the study.	The event needs to be coded appropriately.	

2 Business Storyboards

2.1 Primary Actors

The following actors are used in the storyboards below.

2.1.1 People Actors

Name	Role	Description
Dr. David Jones	Healthcare Provider	The treating physician for a study subject or a patient.
Lucy Taylor	Safety Reporter	The person responsible for completing the safety report.
Alaska Greer	Safety Report Submitter	The person responsible for submitting the safety report.
Taylor Smith	AE Reporter	The person responsible for recording adverse events.
Mike Sweet	Patient	Patient undergoing clinical care outside the scope of a clinical trial.
Jerry Carlos	Study Subject	A participant on a clinical trial. Also know as Study Participant.
Dr. Linda Lu	Principal Investigator	A subscriber to notifications regarding adverse events.
Ricky Higgs	Report Definition Manager	A person responsible for maintaining the definition of safety reports.
Patty Smith	Reporting Rule Manager	A person responsible for maintaining safety reporting rules.
Alabama Adams	Clinical Data Coordinator	A person who participates in adverse event data entry and data management activities.
May Cooper	Study Data Manager	A person responsible for managing the data on the study.
Ray Potter	Study Safety Monitor	A person responsible for monitoring the

		safety of the study.
Peter Porter	Statistician	A person responsible for analyzing the data on a study.
Joshua Daniels	Quality Assurance Auditor	A person responsible for ensuring the adherence to standard operating procedures.
IRB	Institutional Review Board	A committee responsible for reviewing, monitoring, and approving all investigations at an organization involving human subjects.
PharmaX	Study Sponsor	An organization sponsoring a clinical study.

2.1.2 System Actors

Name	Description
Safety Reporting System	A system used to manage safety reports.
Adverse Event Management System	A system used to manage adverse event records.
Safety Report	The form, either paper or electronic, used to record and report the safety issue.
Clinical Trials Management System (CTMS)	The system used to store the information regarding protocols, people, organizations, and subjects, and schedules that are needed to conduct a clinical trial.
Notification System	Used to provide notifications regarding Safety Reporting activities.
Electronic Health Record (EHR) System	The system which houses the clinical data associated with the conduct of routine clinical care.
Clinical Data Management System	The system which houses the clinical data associated with the conduct of a clinical trial.

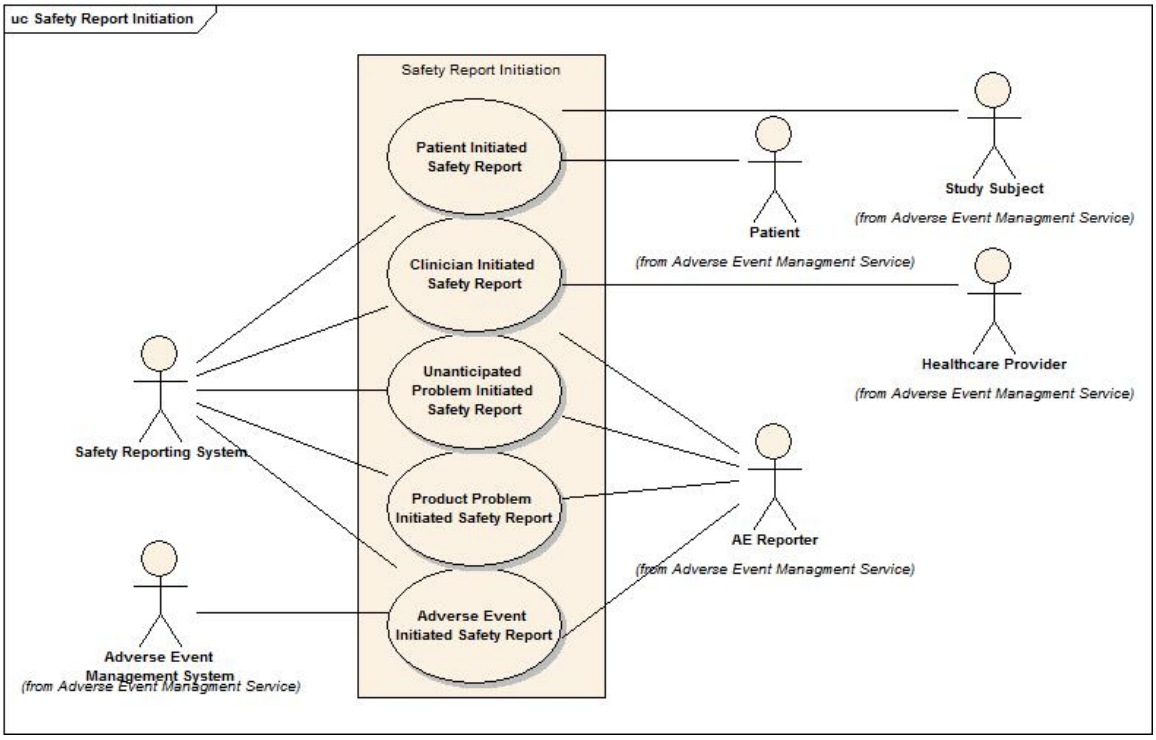
(CDMS)	

2.2 Storyboards

The storyboards for this service have been developed largely through the analysis of the use cases developed for the caBIG® Adverse Event Reporting System (caAERS). These use cases are available at the following url: https://wiki.nci.nih.gov/display/caAERS/Use+Cases+-+caAERS.

The storyboards have been grouped into (7) general categories: Safety Report Initiation, Safety Report Updates, Safety Report Transactions, Search and Retrieve Safety Reports, Safety Report Rules, Safety Report Definitions, and Safety Report Review. These seven storyboard categories are described in depth below.

2.2.1 Safety Report Initiation



2.2.1.1 SR-SB1 – Clinician Initiated Safety Report

Outline	An adverse event requiring safety reporting is identified by a Healthcare Provider during the clinical exam of a Patient as part of clinical care.

Detail	During a clinical exam, Dr. Jones (Healthcare Provider) observes that Mike Sweet (Patient) is experiencing severe headache after taking a prescribed medication. Dr. Jones determines this adverse event should be reported in the safety report and initiates a safety report. Lucy Taylor (Safety Reporter) subsequently completes the safety report and submits it to the proper recipient(s).

2.2.1.2 SR-SB2 – Patient Initiated Safety Report

Outline	A Patient directly reports an adverse symptom and it is initiated as a safety report.
Detail	Mike Sweet (Patient) has recently been treated by Dr. Jones for headaches. Since the treatment for his headache Mike Sweet has experienced severe bouts of dizziness and nausea. Mike Sweet records his dizziness and nausea symptoms onto a safety report and submits it to the appropriate recipient(s).

2.2.1.3 SR-SB3 –Adverse Event Initiated Safety Report

Outline	An adverse event requiring safety reporting to the Study Sponsor is observed on a Study Subject.
Detail	During a scheduled clinical exam for the clinical trial, Dr. Jones (Healthcare Provider) observes that Jerry Carlos (Study Subject) is experiencing an adverse event that requires safety reporting to PharmaX (Study Sponsor). Dr. Jones describes the adverse event in Jerry Carlos' chart. Lucy Taylor (Safety Reporter) reviews the chart and enters the adverse event information onto the safety report.

2.2.1.4 SR-SB4 – Product Problem Initiated Safety Report

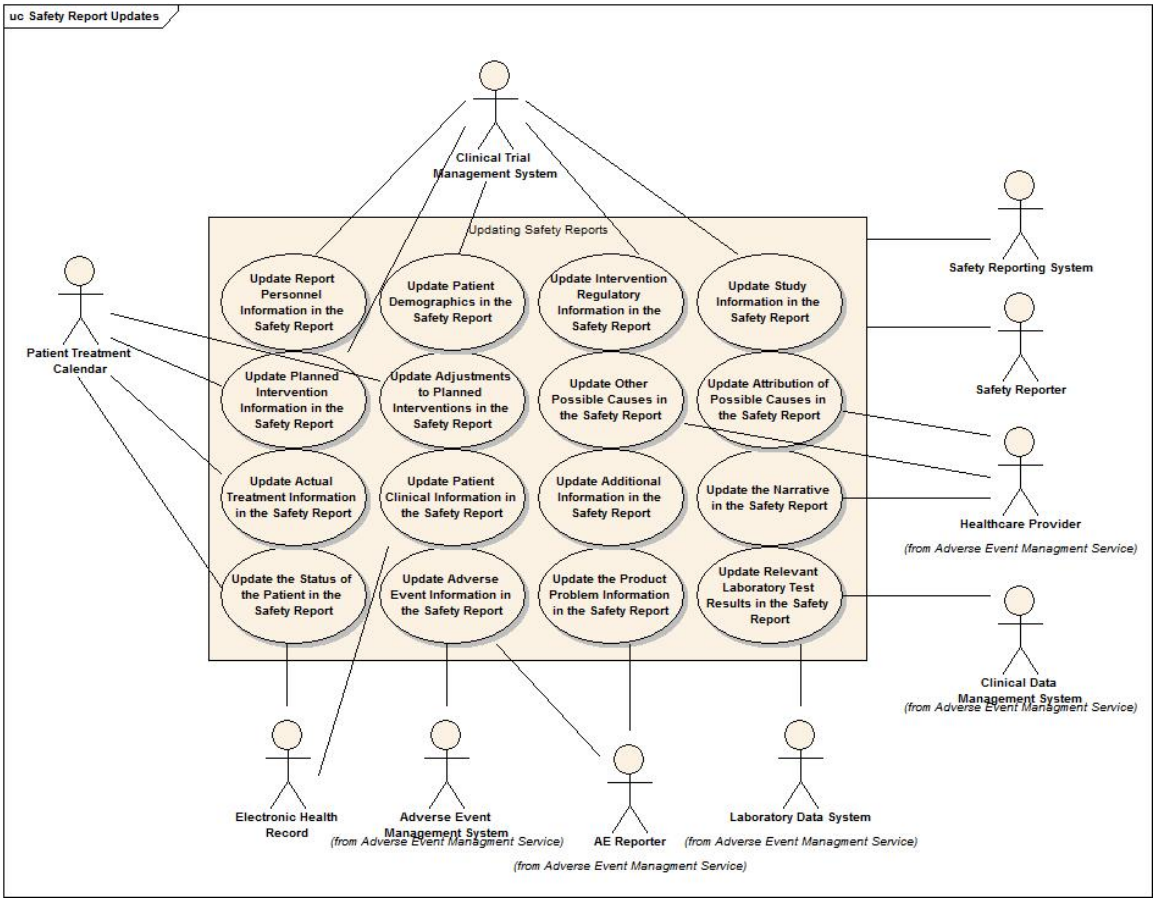
Outline	A product problem requiring safety reporting to the Study Sponsor is observed on a Study Subject.
Detail	Prior to implanting an investigational device used to treat Jerry Carlos' (Study Subject) prostate cancer, Dr. Jones (Healthcare Provider) observes that the device appears to be dirty. He

	determines that this is a safety issue that should be reported to PharmaX (Study Sponsor). The dirty device product problem is then described on the Safety Report and subsequently submitted to PharmaX.

2.2.1.5 SR-SB5 – Unanticipated Problem Initiated Safety Report

Outline	An unanticipated problem occurs on a study and requires reporting to the IRB.
Detail	During the conduct of a clinical trial, a laptop is lost which contains protected health information (PHI) including patient diagnoses and social security numbers. Dr. Linda Lu (Principal Investigator) determines that the losing the laptop with PHI was unexpected, was related to the study, and places study subjects at an increased level of risk not previously disclosed in the informed consent. Dr. Lu reports this unanticipated problem to the Institutional Review Board (IRB).

2.2.2 Safety Report Updates



2.2.2.1 SR-SB6 – Update Report Personnel Information in the Safety Report

Outline	The contact information for the named personnel responsible for completing, approving, and submitting the safety report is updated in the safety report.
Detail	Lucy Taylor (Safety Reporter) enters all required and any optional information in the safety report regarding her contact information as the person completing the safety report. She also enters all required and appropriate optional contact information regarding Dr. David Jones (Healthcare Provider), the responsible physician named on the safety report. During the report submission, Alaska Greer (Safety Report Submitter) enters in the Safety Report all required and appropriate optional information regarding her contact

	information as the submitter of the safety report.

2.2.2.2 SR-SB7 – Update Study Information in the Safety Report

Outline	The safety report is updated with the basic information regarding the clinical trial.
Detail	Lucy Taylor (Safety Reporter) updates the safety report with the required information and any other pertinent optional information regarding the study, including but not limited to the Study ID, Study Title, Study Phase, Principal Investigator, and Study Sponsor.

2.2.2.3 SR-SB8 – Update Adverse Event Information in the Safety Report

Outline	The Safety Report is updated with new adverse event information.
Detail	The adverse event experienced by Jerry Carlos (Study Subject) has been included in the Safety Report. This adverse event eventually resolves and the date of resolution is recorded in Jerry Carlos' medical chart. Lucy Taylor (Safety Reporter) reviews the patient chart and identifies that the adverse event resolved. Lucy Taylor then searches the Adverse Event Management System for the adverse event record and updates the record with the resolution date. Lucy Taylor (Safety Reporter) is then prompted to update the Safety Report with the resolution date of the adverse event.

2.2.2.4 SR-SB9 – Update the Product Problem Information in the Safety Report

Outline	A Safety Report is updated with new product problem information.
Detail	The details of the contaminated vaccine are updated onto the

	Safety Report by Lucy Taylor (Safety Reporter).

2.2.2.5 SR-SB10 – Update the Narrative in the Safety Report

Outline	The Safety Report is updated to include a clinical narrative describing the entire event.
Detail	Dr. David Jones (Healthcare Provider) describes in-depth all of the relevant information regarding the presentation, progression, treatment, and resolution of the adverse event experienced by Jerry Carlos (Study Subject). He enters this narrative onto the Safety Report.

2.2.2.6 SR-SB11 – Update the Status of the Patient in the Safety Report

Outline	The Safety Report is updated with the information regarding the status of the Patient or Study Subject at the time of the report, with respect to the adverse event.
Detail	Dr. David Jones (Healthcare Provider) annotates the Safety Report with the information that Jerry Carlos (Study Subject) is still recovering from the adverse event.

2.2.2.7 SR-SB12 – Update Planned Intervention Information in the Safety Report

Outline	The Safety Report is updated with the information regarding the planned interventions that a Study Subject was supposed to receive.
Detail	Lucy Taylor (Safety Reporter) looks up the Jerry Carlos' (Study Subject) records in the Clinical Trials Management System (CTMS) to obtain the information regarding the study treatments that Jerry Carlos was supposed to receive.

2.2.2.8 SR-SB13 – Update Actual Treatment Information in the Safety Report

Outline	The Safety Report is updated with the information regarding the actual interventions that a Study Subject received.
Detail	Lucy Taylor (Safety Reporter) looks up Jerry Carlos' (Study Subject) records in the Clinical Data Management System (CDMS) to obtain information regarding the study treatments Jerry Carlos actually received.

2.2.2.9 SR-SB14 – Update Adjustments to Planned Interventions in the Safety Report

Outline	The Safety Report is updated with the information regarding the adjustments to the planned interventions that were made because of the adverse event.
Detail	Lucy Taylor (Safety Reporter) examines the planned interventions for Jerry Carlos (Study Subject) and compares them to the actual treatments he received. She notices a discrepancy between the two and identifies a comment in the CDMS that indicates the intervention was reduced due to the adverse event. She updates the Safety Report with this information.

2.2.2.10 SR-SB15 – Update Intervention Regulatory Information in the Safety Report

Outline	The Safety Report is updated with the information regarding the regulatory status of the relevant study interventions.
Detail	Lucy Taylor (Safety Reporter) queries the Clinical Trials Management System (CTMS) for regulatory information regarding the study interventions administered to Jerry Carlos (Study Subject). She finds that one of the study drugs is investigational. She obtains the information regarding the holder of the investigational drug application and updates the Safety Report with this information.

2.2.2.11 SR-SB16 – Update Patient Demographics in the Safety Report

Outline	The Safety Report is updated with information regarding the Patient's demographics.
Detail	Lucy Taylor (Safety Reporter) queries the Electronic Health Record (EHR) for Michael Sweet (Patient) and obtains basic demographic information including, but not limited to, his age, sex, ethnicity, and race. Lucy Taylor then updates the Safety Report with this information as appropriate.

2.2.2.12 SR-SB17 – Update Patient Clinical Information in the Safety Report

Outline	The Safety Report is updated with relevant clinical information regarding the Patient.
Detail	Lucy Taylor (Safety Reporter) queries the Electronic Health Record (EHR) for Michael Sweet (Patient) and obtains basic clinical information including, but not limited to, his height, weight, concomitant medications, prior therapies, pre-existing conditions, diseases, and metastatic sites of disease. Lucy Taylor then updates the Safety Report with this information as appropriate.

2.2.2.13 SR-SB18 – Update Other Possible Causes in the Safety Report

Outline	The Safety Report is updated with information regarding any possible causes of the problem not already identified.
Detail	Dr. Linda Lu (Principal Investigator) is reviewing the Safety Report and notices that the car accident Jerry Carlos (Study Subject) was involved in is not identified as a possible cause of Mr. Carlos' severe neck pain. Dr. Lu updates the Safety Report with this information.

2.2.2.14 SR-SB19 – Update Attribution of Possible Causes in the Safety Report

Outline	Likely cause(s) of each adverse event or problem is documented on the Safety Report.
Detail	Dr. Linda Lu (Principal Investigator) is reviewing the Safety Report and assigns the likely cause(s) of each adverse event.

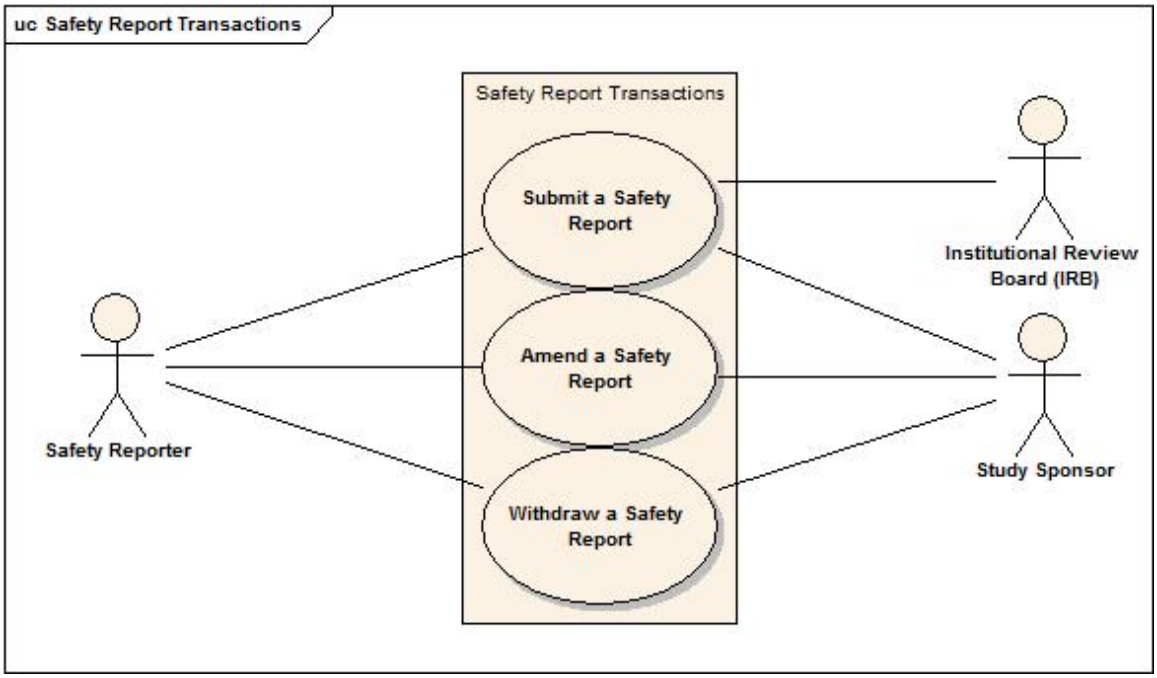
2.2.2.15 SR-SB20 – Update Relevant Laboratory Test Results in the Safety Report

Outline	Relevant laboratory tests are documented on the Safety Report.
Detail	Lucy Taylor (Safety Reporter) updates the Safety Report with laboratory test results relevant to the presentation, progression, and resolution of the severe fatigue adverse event exhibited by Mike Sweet (Patient).

2.2.2.16 SR-SB21 – Update Additional Information in the Safety Report

Outline	Relevant supporting documentation is linked to the Safety Report.
Detail	Lucy Taylor (Safety Reporter) updates the Safety Report with links to the CT scan results and radiology consults related to the adverse event experienced by Jerry Carlos (Study Subject).

2.2.3 Safety Report Transactions



2.2.3.1 SR-SB22 – Submit a Safety Report

Outline	The Safety Report is submitted to the appropriate recipient(s).
Detail	Lucy Taylor (Safety Reporter) submits the safety report to the PharmaX (Sponsor) and the Institutional Review Board (IRB). The Notification System sends out a notification to Dr. Linda Lu (Principal Investigator) and Dr. Jones (Healthcare Provider) informing them that the Safety Report has been submitted.

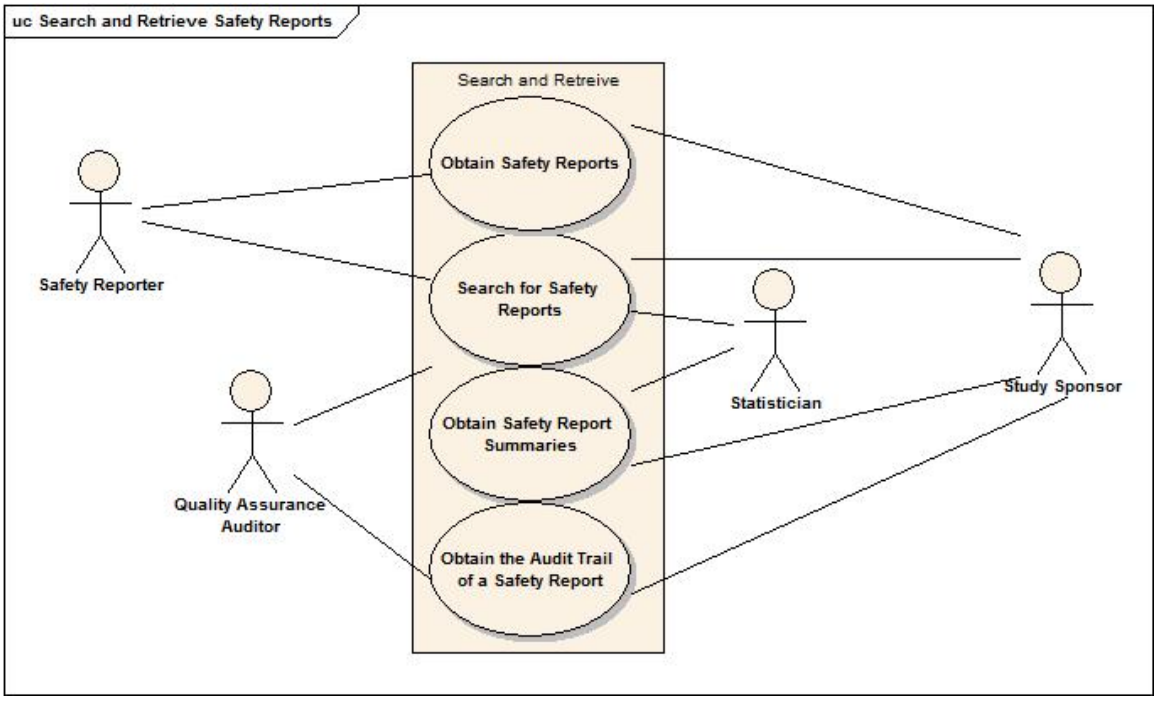
2.2.3.2 SR-SB24 – Withdraw a Safety Report

Outline	A submitted Safety Report is withdrawn.
Detail	Lucy Taylor (Safety Reporter) identifies that the Safety Report recently submitted was submitted in error. She submits a request to the Safety Reporting System to withdraw the Safety Report. The Safety Report is subsequently withdrawn and notifications are sent by the Notification System to inform appropriate personnel of the report withdraw.

2.2.3.3 SR-SB24 – Amend a Safety Report

Outline	A submitted Safety Report is amended.
Detail	Lucy Taylor (Safety Reporter) identifies an update required to be made to a submitted Safety Report. She amends the submitted Safety Report, updates the appropriate information, and submits the updated Safety Report.

2.2.4 Search and Retrieve Safety Reports



2.2.4.1 SR-SB25 – Search for Safety Reports

Outline	Search criteria are provided and Safety Report records satisfying the search criteria are identified.
Detail	Lucy Taylor (Safety Reporter) needs to find certain Safety Report records for Jerry Carlos (Study Subject). She enters the search criteria into the Safety Reporting System. The Safety Reporting System identifies the records which satisfy the search criteria.

2.2.4.2 SR-SB26 – Obtain Safety Reports

Outline	Safety Report records of interest are identified, the information to be returned from those records is specified, and the requested information is provided.
Detail	Peter Porter (Statistician) needs to obtain specific information on certain Safety Report records for Jerry Carlos (Study Subject). He sends a request to the Safety Reporting System that identifies both the Safety Report records he is interested in and the information he would like to obtain from these records. The Safety Reporting System retrieves the specified information on the specified records and returns the requested information to Peter Porter.

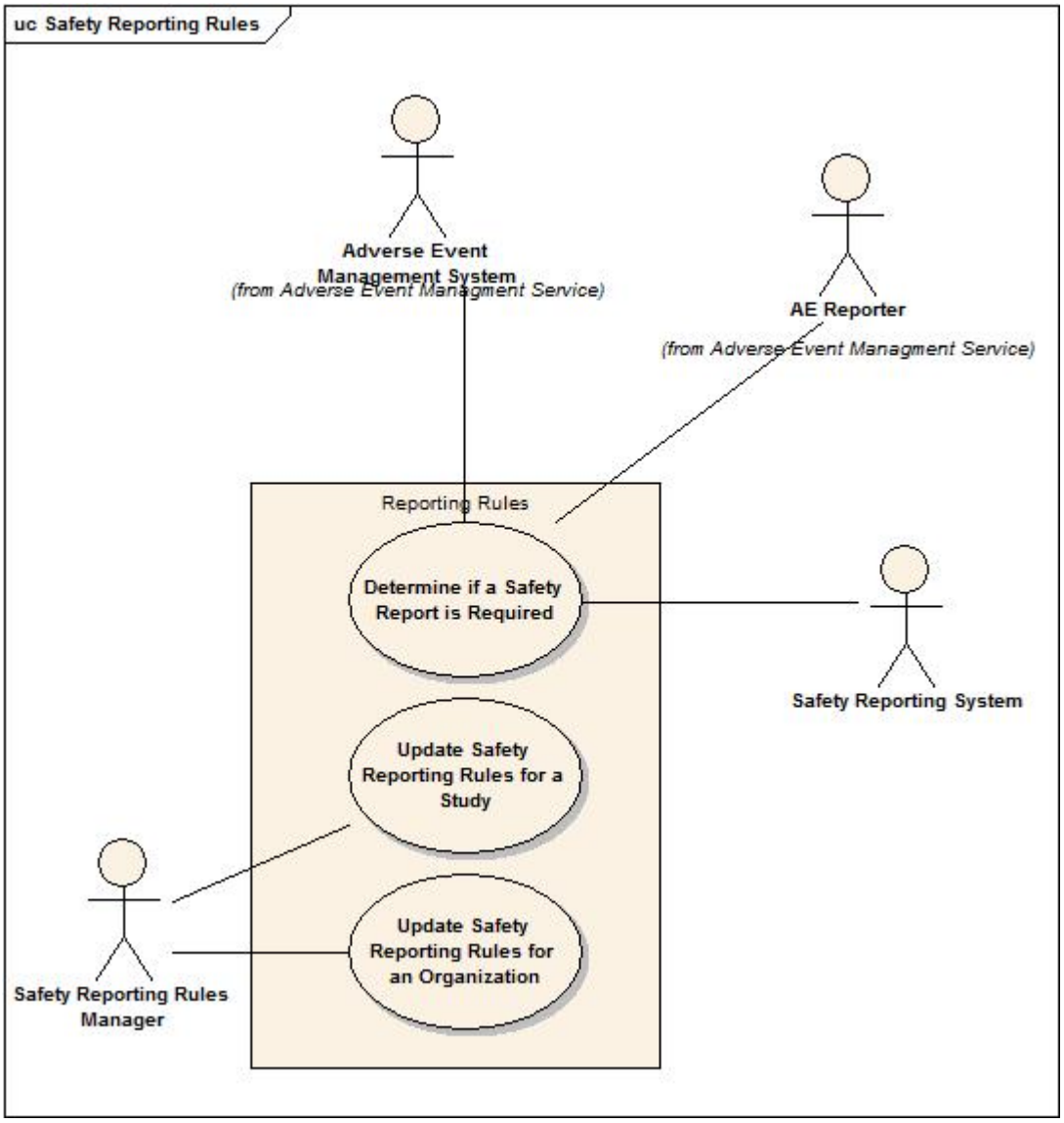
2.2.4.3 SR-SB27 – Obtain Safety Report Summaries

Outline	Safety Report records of interest are identified, the attribute(s) on which to summarize the records are specified, along with method of summarization, and the requested summaries are provided
Detail	Dr. Lu (Principal Investigator) would like to summarize a collection of Safety Report records by the regulatory application number (i.e. IND #) to which they are associated. In the Safety Reporting System she identifies the Safety Report records in her collection of interest, provides the attribute(s) upon which she would like to categorize the collection (in this case, IND #), and provides the method of summary (e.g. frequency count). The Safety Reporting System processes the request and returns the summary information.

2.2.4.4 SR-SB35 – Obtain the Audit Trail of a Safety Report

Outline	A Quality Assurance Auditor requests to view the audit trail of create, update, and delete operations associated with a specific safety report.
Detail	Joshua Daniels (Quality Assurance Auditor) is performing an audit of the safety data for study NCI00234. He identifies a safety report for which he would like to view the audit trail of all create, update, and delete operations. This information is requested to and returned by the Safety Reporting System.

2.2.5 Safety Reporting Rules



2.2.5.1 SR-SB28 – Determine if a Safety Report is Required

Outline	An adverse event is assessed to determine if it needs to be reported in the safety report.
Detail	Taylor Smith (AE Reporter) needs to know if Jerry Carlos' (Study Subject) recent headache needs to be reported to the sponsor in an expedited manner. She finds the adverse event in the Adverse

	Event Management System and asks the system if further reporting is required. The Adverse Event Management System sends information about the headache adverse event to The Safety Reporting System where it is evaluated against the reporting rules. The results of the evaluation are sent back to the Adverse Event Management System and displayed to Taylor Smith instructing her which reports are needed and when they are due.

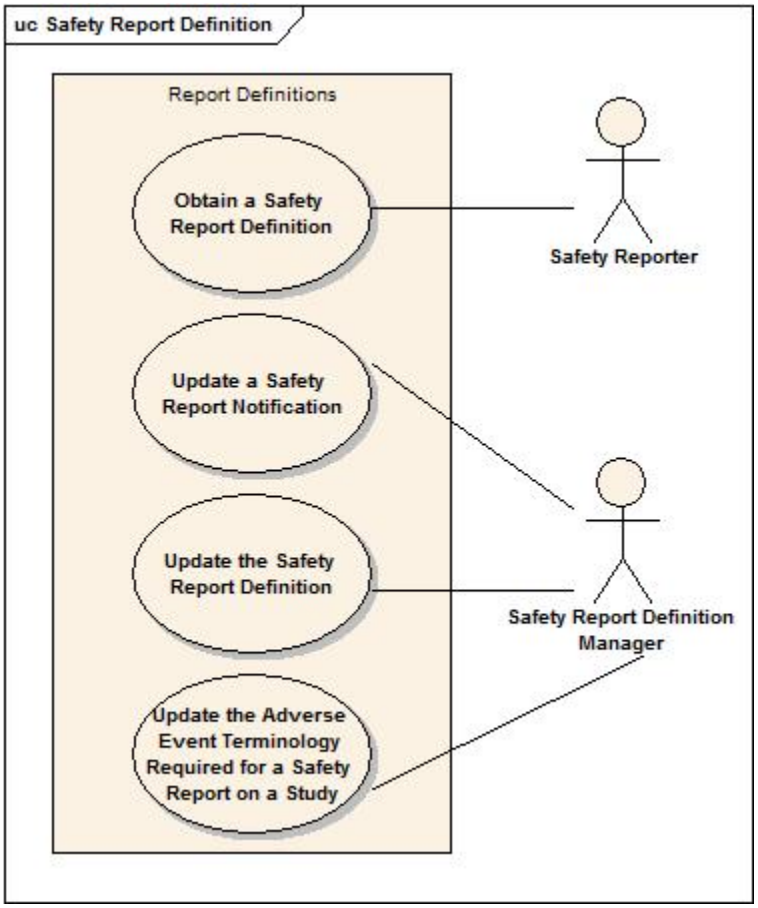
2.2.5.2 SR-SB29 – Update Safety Reporting Rules for a Study

Outline	The criteria for the study are updated against which an adverse event is assessed to determine if it needs to be reported in the safety report.
Detail	Patty Smith (Reporting Rule Manager) reviews the study protocol document and identifies the conditions under which certain safety reports should be completed. She enters these criteria in the Safety Reporting System where they will be available for reference by AE Reporters to evaluate when safety reporting is required.

2.2.5.3 SR-SB30 – Update Safety Reporting Rules for an Organization

Outline	The criteria for the study organization are updated against which an adverse event is assessed to determine if it needs to be reported in the safety report.
Detail	Patty Smith (Reporting Rule Manager) is provided with the criteria under which the IRB requires a safety report to be submitted to them. She enters these criteria in the Safety Reporting System where they will be available for reference by AE Reporters to evaluate when safety reporting to the IRB is required.

2.2.6 Safety Report Definitions



2.2.6.1 SR-SB31 – Update the Safety Report Definition

Outline	A Report Definition Manager specifies the requirements for a specific safety report.
Detail	Ricky Higgs (Report Definition Manager) identifies the mandatory, optional, and not applicable attributes for a Safety Report. He enters this information into the Safety Reporting System where it will be available for reference by AE Reporters to determine the requirements for completing a given Safety Report.

2.2.6.2 SR-SB32 – Update a Safety Report Notification

Outline	A Healthcare Provider specifies the conditions under which they will

	receive a notification regarding a safety report.
Detail	Dr. Linda Lu (Principal Investigator) would like to receive an email notification when a safety report is submitted on study NCI00234. After a safety report is entered into the Safety Reporting System for study NCI00234 an email is subsequently sent to Dr. Lu regarding this report.

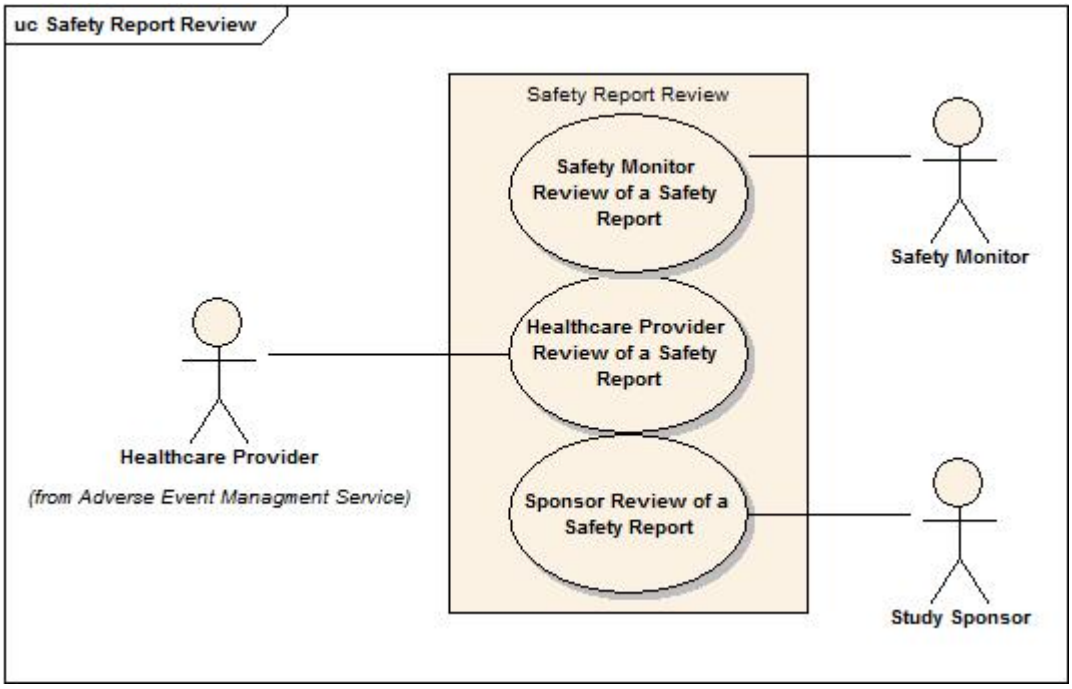
2.2.6.3 SR-SB33 – Obtain a Safety Report Definition

Outline	A Safety Reporter obtains the requirements for completing a safety report.
Detail	Lucy Taylor (Safety Reporter) is preparing to generate a safety report. She reviews the requirements of the safety report and identifies the mandatory, optional, and not applicable attributes for the safety report.

2.2.6.4 SR-SB34 – Update the Adverse Event Terminology Required for a Safety Report on a Study

Outline	A Report Definition Manager updates the terminology to be used for safety reporting for a specific study.
Detail	Ricky Higgs (Report Definition Manager) is preparing to update the report definitions for use on study NCI00234. He reviews the protocol and identifies the CTCAE v3.0 as the adverse event terminology to use for safety reports on this study and MedDRA v12 as the terminology to use for “Other, specify” terms. He updates the report definitions with the appropriate terminologies for use on this study.

2.2.7 Safety Report Review



2.2.7.1 SR-SB36 – Update the Safety Report Review Workflow

Outline	The Study Data Manager for the study specifies the workflow that should be followed for reviewing safety reports for a study site.
Detail	May Cooper (Study Data Manager) defines the mandatory and optional steps that should be followed for reviewing a specific Safety Report. This workflow is provided to Ricky Higgs (Report Definition Manager) who enters this workflow information into the Safety Reporting System and associates the workflow with the appropriate report definition.

2.2.7.2 SR-SB37 – Healthcare Provider Review of a Safety Report

Outline	A Safety Reporter sends a Safety Report to a Healthcare Provider for review. The Healthcare provider then reviews the safety report.
Detail	Lucy Taylor (Safety Reporter) completes most of a safety report and sends it to Dr. David Jones (Healthcare Provider) for review. Dr. Jones is notified of a pending safety report review. He then reviews the report, provides comments and/or updates the report,

	and completes his review.

2.2.7.3 SR-SB38 – Safety Monitor Review of a Safety Report

Outline	A Safety Reporter sends a Safety Report to a Study Safety Monitor for review. The Study Safety Monitor then reviews the report.
Detail	Lucy Taylor (Safety Reporter) completes most of a safety report and sends it to Ray Potter (Study Safety Monitor) at the Coordinating Center for review. Ray is notified of a pending safety report review. He reviews the records, provides comments and/or updates the report, and completes his review.

2.2.7.4 SR-SB39 – Sponsor Review of a Safety Report

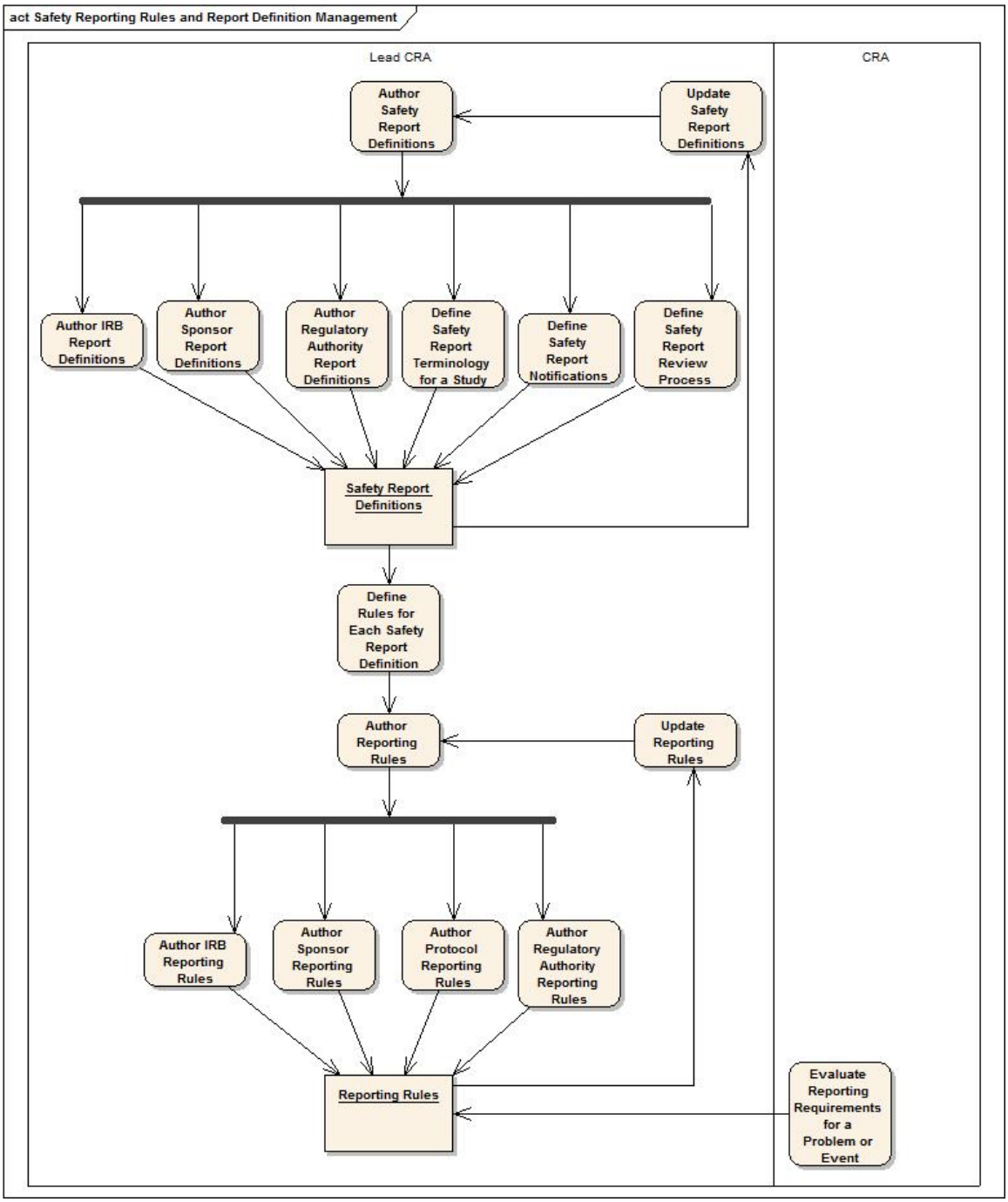
Outline	A Safety Reporter sends a Safety Report to a Sponsor for review. The Sponsor then reviews the report.
Detail	Lucy Taylor (Safety Reporter) completes most of a safety report and sends it to PharmaX (Sponsor) for review. PharmaX is notified of a pending safety report review. PharmaX reviews the records, provides comments, and completes the review.

2.3 Safety Reporting Activity Diagrams

The activity diagrams below describe the actions associated with two (2) critical activities that will be supported by this service.

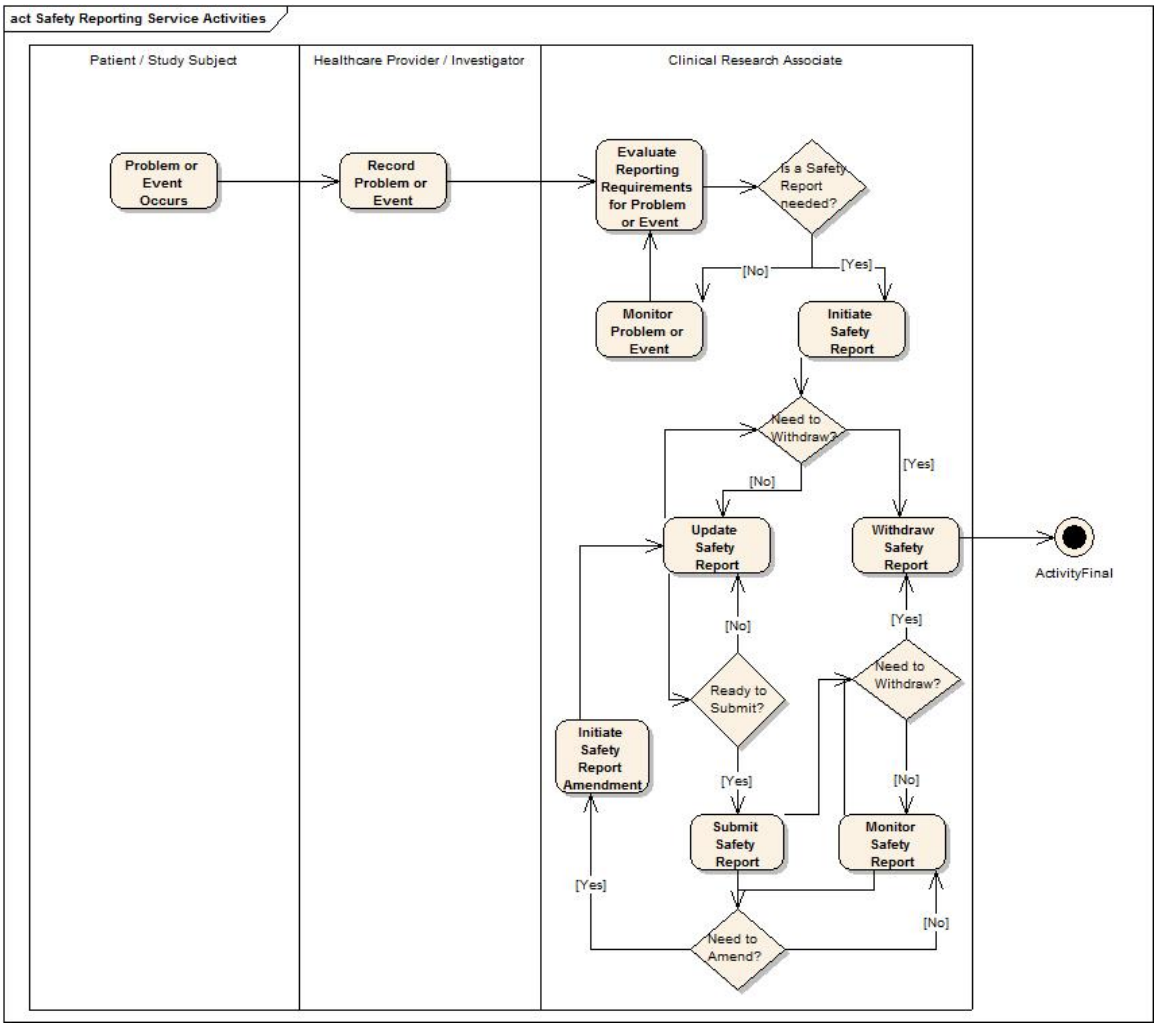
2.3.1 Safety Report Definition and Rules Managment Activities

The below diagram describes the actions involved with managing safety report definitions and safety reporting rules. This activity would be considered required set-up prior to being able to initiate and complete a safety report.



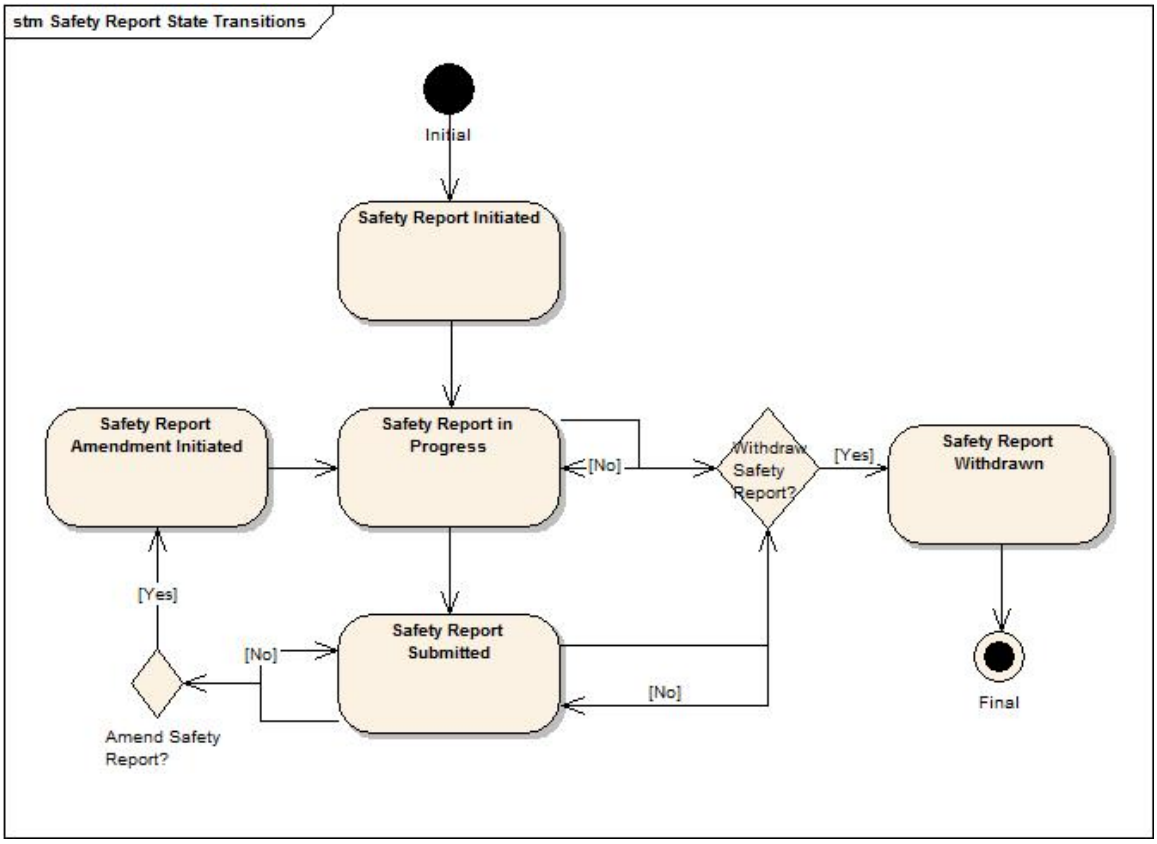
2.3.2 Safety Report Management Activities

The below diagram describes the actions associated with initiating and completing a safety report and sending the safety report through any appropriate transition.



2.4 Safety Report State Transitions

The below diagram describes the state transitions that a safety report may undergo.


stm Safety Report State Transitions
Initial
Safety Report Initiated
Safety Report Amendment Initiated
Safety Report in Progress
[No]
Withdraw Safety Report?
[Yes]
Safety Report Withdrawn
[Yes]
[No]
Safety Report Submitted
[No]
Amend Safety Report?
Final

3 Detailed Functional Model

3.1 Structure of the Service

The following list of capabilities was created from an analysis of the storyboards.

Capability	Description
Initiate Safety Report	Provides the capability to initiate safety report.
Associate Adverse Event to a Safety Report	Provides the capability to associate adverse event to a safety report.
Associate Problem to a Safety Report	Provides the capability to associate problem to a safety report.
Dissociate Adverse Event from a Safety Report	Provides the capability to dissociate adverse event from a safety report.
Dissociate Problem from a Safety Report	Provides the capability to dissociate problem from a safety report.
Update Adverse Event Information in the Safety Report	Provides the capability to update adverse event information in the safety report.
Update Problem Information in the Safety Report	Provides the capability to update problem information in the safety report.
Associate a Study to a Safety Report	Provides the capability to associate a study to a safety report.
Associate Additional Information to a Safety Report	Provides the capability to associate additional information to a safety report.
Associate Subject to a Safety Report	Provides the capability to associate a person to a safety report who is the subject of the report.
Dissociate a Study from a Safety Report	Provides the capability to dissociate a study from a safety report.
Dissociate Subject from a Safety Report	Provides the capability to dissociate a Subject from a safety report.
Update Attribution in the Safety Report	Provides the capability to update attribution in the safety report.
Update Intervention Regulatory Information in the Safety Report	Provides the capability to update intervention regulatory information in the safety report.
Update Laboratory Test Results in the Safety Report	Provides the capability to update laboratory test results in the safety report.
Update Other Possible Causes in the Safety Report	Provides the capability to update other possible causes in the safety report.
Update Patient Clinical Measurements in the Safety	Provides the capability to update basic patient clinical measurements in the safety report.

Report	
Update Patient Disease History in the Safety Report	Provides the capability to update patient disease history in the safety report.
Update Patient Concomitant Medications in the Safety Report	Provides the capability to update patient concomitant medication information in the safety report.
Update Patient Prior Therapies in the Safety Report	Provides the capability to update patient prior therapy information in the safety report.
Update Patient Demographics in the Safety Report	Provides the capability to update patient demographics in the safety report.
Update Reporter in the Safety Report	Provides the capability to update the reporter in the safety report.
Update Healthcare Provider in the Safety Report	Provides the capability to update the healthcare provider in the safety report.
Update Submitter in the Safety Report	Provides the capability to update submitter in the safety report.
Update Product Problem Information in the Safety Report	Provides the capability to update product problem information.
Update the Patient Status in the Safety Report	Provides the capability to update the patient status in the safety report.
Update the Planned Intervention Information in the Safety Report	Provides the capability to update the planned intervention information in the safety report.
Update the Narrative in the Safety Report	Provides the capability to update the safety report narrative
Update Treatment Information in the Safety Report	Provides the capability to update treatment information in the safety report.
Amend a Safety Report	Provides the capability to amend a safety report.
Submit a Safety Report	Provides the capability to submit a safety report.
Withdraw a Safety Report	Provides the capability to withdraw a safety report.
Create Safety Report Definition	Provides the capability to create a safety report definition.
Update Safety Report Definition Details	Provides the capability to update the basic details in a safety report definition.
Update Safety Report Definition Delivery Details	Provides the capability to update the delivery details in the safety report definition.
Update Safety Report	Provides the capability to update the mandatory

Definition Mandatory Fields	fields in the safety report definition.
Create Safety Report Definition Notification	Provides the capability to create a notification template in the safety report definition.
Update Safety Report Definition Notification	Provides the capability to update a notification template in the safety report definition.
Deactivate Safety Report Definition Notification	Provides the capability to deactivate a notification template in the safety report definition.
Deactivate Safety Report Definition	Provides the capability to deactivate a safety report definition.
Query Safety Report Definition	Provides the capability to find safety report definition.
Get Safety Report Definition	Provides the capability to get a safety report definition.
Update Safety Report Terminology for a Study	Provides the capability to update the safety report terminology to be used for a study.
Create Organization Safety Reporting Rules	Provides the capability to create safety reporting rules for an organization.
Update Organization Safety Reporting Rules	Provides the capability to update safety reporting rules for an organization.
Deactivate Organization Safety Reporting Rules	Provides the capability to deactivate safety reporting rules for an organization.
Create Study Safety Reporting Rules	Provides the capability to create safety reporting rules for a study.
Update Study Safety Reporting Rules	Provides the capability to update safety reporting rules for a study.
Deactivate Study Safety Reporting Rules	Provides the capability to deactivate safety reporting rules for a study.
Query Safety Reporting Rules	Provides the capability to find safety report rules.
Get Safety Reporting Rules	Provides the capability to get a safety reporting rules.
Evaluate Against Safety Reporting Rules	Provides the capability to evaluate an adverse event or problem against safety reporting rules.
Query Safety Reports	Provides the capability to find safety reports.
Get Safety Reports	Provides the capability to get safety reports.
View Safety Report	Provides the capability to view a safety report in a specific report definition template.
Get Audit Trail of a Safety Report	Provides the capability to get audit trail of a safety report.
Get Safety Report Summary Data	Provides the capability to get safety report summary data.
Create Safety Report	Provides the capability to create a safety report

Review Process	review process.
Update Safety Report Review Process	Provides the capability to update a safety report review process.
Deactivate Safety Report Review Process	Provides the capability to deactivate a safety report review process.
Get Safety Report Review Process	Provides the capability to get safety report review process.
Review Safety Report	Provides the capability to review safety report.

3.2 Detail of the Capabilities

Name [M]	Initiate Safety Report
Description [M]	Enables a client system to create a safety report record in the Safety Reporting System with all fields required for safety report creation. If successful, a properly formed Safety Report object with an identifier is returned as an acknowledgement that the Safety Report is initiated.
Pre-Conditions [M]	The Report Definition Exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Report Definition Identifier Optional: Study Identifier Subject Identifier Patient Identifier Adverse Event Identifier Product Problem Identifier
Outputs [M]	A safety report object with an identifier
Post-Conditions [O]	A safety report is initiated on the system

Exception Conditions [M]	The Report Definition Identifier is invalid. Any of the optional inputs are invalid. The Subject Identifier is invalid for the provided Study Identifier. The Subject Identifier is invalid for the provided Patient Identifier.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Associate Adverse Events to a Safety Report
Description [M]	Provides the capability to associate adverse events to a safety report.
Pre-Conditions [M]	The Safety Report record exists The Adverse Event record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Safety Report record identifier. The Adverse Event record identifiers.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Adverse Event Identifier is invalid The Adverse Event record is invalid for the Subject or Patient on the Safety Report

Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Associate Problem to a Safety Report
Description [M]	Provides the capability to associate a problem to a safety report.
Pre-Conditions [M]	The Safety Report record exists The Problem record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Safety Report record identifier. The Problem record identifier.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Problem Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Dissociate Adverse Event from a Safety Report
Description [M]	Provides the capability to dissociate an adverse event from a safety report.
Pre-Conditions [M]	The Safety Report record exists The Adverse Event record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Safety Report record identifier. The Adverse Event record identifier.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Adverse Event Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Dissociate Problem from a Safety Report
Description [M]	Provides the capability to dissociate a problem from a safety report.
Pre-Conditions [M]	The Safety Report record exists

	The Problem record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Safety Report record identifier. The Problem record identifier.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Problem Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Adverse Event Information in the Safety Report
Description [M]	Provides the capability to update the adverse event information in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Adverse Event is associated to the Safety Report
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier.

	- Adverse Event Identifier. Optional: Adverse Event attribute(s) that should be updated on the Safety Report along with the new values to which the attribute(s) will be updated.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Adverse Event on the Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Adverse Event Identifier is invalid Adverse Event attributes are invalid or improperly formatted
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Problem Information in the Safety Report
Description [M]	Provides the capability to update the problem information in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Problem is associated to the Safety Report
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Safety Report record identifier.

	The Problem record identifier. Optional: Any information related to the problem.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	The Problem on the Safety Report is updated
Exception Conditions [M]	Safety Report Identifier is invalid Problem Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Associate a Study to a Safety Report
Description [M]	Provides the capability to associate a study to a safety report.
Pre-Conditions [M]	The Safety Report record exists. The Study exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Study Identifier
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid. Study Identifier is invalid.
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Associate Additional Information to a Safety Report
Description [M]	Provides the capability to associate additional information to a safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Additional Information Identifier
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Additional Information Identifier is invalid
Aspects left for Technical Bindings [O]	

Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Associate Subject to a Safety Report
Description [M]	Provides the capability to associate a person to a safety report who is the subject of the report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier Conditional: - Study Subject Identifier - Patient Identifier - Person Identifier
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Study Subject Identifier is invalid Study Subject Identifier is not valid for the Study Identifier on the report. Patient Identifier is invalid Person Identifier is invalid
Aspects left for Technical Bindings [O]	

Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Dissociate a Study from a Safety Report
Description [M]	Provides the capability to dissociate a study from a safety report.
Pre-Conditions [M]	The Safety Report record exists. The Study is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Study Identifier to dissociate Optional: - Reason for the dissociation
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Study Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Dissociate Person from a Safety Report
Description [M]	Provides the capability to dissociate person from a safety report.
Pre-Conditions [M]	The Safety Report record exists. The Person is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Person Identifier to dissociate Optional: - Reason for the dissociation
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Person Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Attribution in the Safety Report

Description [M]	Provides the capability to update attribution in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Adverse Event or Product Problem Identifiers - The cause of the Adverse Event or Product Problem and the degree of causation.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid. Adverse Event Identifier is invalid. Production Problem Identifier is invalid.
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Intervention Regulatory Information in the Safety Report
Description [M]	Provides the capability to update intervention regulatory information in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this

	capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Intervention Identifier - Regulatory information for Intervention
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Intervention Identifier is invalid Regulatory information for Intervention is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Laboratory Test Results in the Safety Report
Description [M]	Provides the capability to update laboratory test results in the safety report.
Pre-Conditions [M]	The Safety Report record exists. Lab Test for patient/subject exist
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Lab Test Identifier

	- Lab Test Attributes - Lab Test Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Lab Test Identifier is invalid Lab Test Attributes are invalid Lab Test Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Other Possible Causes in the Safety Report
Description [M]	Provides the capability to update other possible causes in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Other Cause Identifier
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception	Safety Report Identifier is invalid

Conditions [M]	Other Cause Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it. The Other Cause Identifier may be the name of the other cause.

Name [M]	Update Patient Clinical Measurements in the Safety Report
Description [M]	Provides the capability to update basic patient clinical measurements in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Patient is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Patient Identifier or Study Subject Identifier or Report Person Identifier Optional: - Baseline Performance - Height - Weight
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception	Safety Report Identifier is invalid

Conditions [M]	Patient Identifier is invalid Study Subject Identifier is invalid Report Person Identifier is invalid Clinical Attributes are invalid Clinical Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Patient Disease History in the Safety Report
Description [M]	Provides the capability to update patient disease history in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Patient is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Report Patient Identifier Optional: - Disease History Attributes (i.e. primary disease, primary site of disease, initial date of diagnosis, metastatic sites of disease, pre-existing conditions) - Disease History Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid Report Patient Identifier is invalid Disease History Attributes are invalid Disease History Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Patient Concomitant Medications in the Safety Report
Description [M]	Provides the capability to update patient concomitant medications in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Patient is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Report Patient Identifier Optional: - Concomitant Medication Attributes (i.e. name, date(s), description) - Concomitant Medication Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid Report Patient Identifier is invalid Concomitant Medication Attributes are invalid Concomitant Medication Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Patient Prior Therapies in the Safety Report
Description [M]	Provides the capability to update patient prior therapies in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Patient is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Report Patient Identifier Optional: - Prior Therapy Attributes (i.e. name, date(s), agents) - Prior Therapy Attributes Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception	Safety Report Identifier is invalid

Conditions [M]	Report Patient Identifier is invalid Prior Therapy Attributes are invalid Prior Therapy Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Patient Demographics in the Safety Report
Description [M]	Provides the capability to update patient demographics in the safety report.
Pre-Conditions [M]	The Safety Report record exists. The Patient, Study Subject, or Report Person is associated to the Safety Report.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Report Patient Identifier Optional: - Patient Demographic Attributes (i.e. sex, race, ethnicity, DOB) - Patient Demographic Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid Report Patient Identifier is invalid Demographic Attributes are invalid Demographic Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Reporter in the Safety Report
Description [M]	Provides the capability to update the reporter in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Reporter Identifier Optional: - Reporter Attributes and Attribute Values specific to the Safety Report.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Reporter Identifier is invalid

	Reporter Attributes are invalid Reporter Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it. The safety report may require or provide the option to detail additional information about the reporter that may not be associated directly to the reporter. Examples of such additional information could include a cell phone number to be used as a contact detail for the specific safety report.

Name [M]	Update Healthcare Provider in the Safety Report
Description [M]	Provides the capability to update the healthcare provider in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Healthcare Provider Identifier Optional: - Healthcare Provider Attributes and Attribute Values specific to the Safety Report.
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid Healthcare Provider Identifier is invalid Healthcare Provider Attributes are invalid Healthcare Provider Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it. The safety report may require or provide the option to detail additional information about the healthcare provider that may not be associated directly to the healthcare provider. Examples of such additional information could include a cell phone number to be used as a contact detail for the specific safety report.

Name [M]	Update Submitter in the Safety Report
Description [M]	Provides the capability to update the submitter in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Submitter Identifier Optional: - Submitter Attributes and Attribute Values specific to the Safety Report.

Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Submitter Identifier is invalid Submitter Attributes are invalid Submitter Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it. The safety report may require or provide the option to detail additional information about the submitter that may not be associated directly to the submitter. Examples of such additional information could include a cell phone number to be used as a contact detail for the specific safety report.

Name [M]	Update Product Problem Information in the Safety Report
Description [M]	Provides the capability to update product problem information.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier

	- Product Problem Identifier - Product Problem Attributes - Product Problem Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Product Problem Identifier is invalid Product Problem Attributes are invalid Product Problem Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update the Patient Status in the Safety Report
Description [M]	Provides the capability to update the patient status in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Report Patient Identifier - Patient Status Attributes - Patient Status Attribute Values

Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Report Patient Identifier is invalid Patient Status Attributes are invalid Patient Status Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update the Planned Intervention Information in the Safety Report
Description [M]	Provides the capability to update the planned intervention information in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Planned Intervention Identifier - Planned Intervention Attributes - Planned Intervention Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	

Exception Conditions [M]	Safety Report Identifier is invalid Planned Intervention Identifier is invalid Planned Intervention Attributes are invalid Planned Intervention Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update the Narrative in the Safety Report
Description [M]	Provides the capability to update the safety report narrative.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Safety Report Narrative Optional: - Safety Report Narrative Author
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Safety Report Narrative is improperly formatted
Aspects left for	

Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Update Treatment Information in the Safety Report
Description [M]	Provides the capability to update treatment information in the safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Treatment Identifier - Treatment Attributes - Treatment Attribute Values
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Treatment Identifier is invalid Treatment Attributes are invalid Treatment Attribute Values are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a

	service consumer to update it.

Name [M]	Amend a Safety Report
Description [M]	Provides the capability to amend a safety report.
Pre-Conditions [M]	The Safety Report record exists and is in a submitted state.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Amendment Identifier Optional: - Reason for the amendment
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Amendment Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Submit a Safety Report
Description [M]	Provides the capability to submit a safety report

Pre-Conditions [M]	The Safety Report record exists. The Safety Report is complete and adheres to all business rules required for report submission.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Submitter Identifier Optional: - Additional Recipient Identifiers
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Submitter Identifier is invalid Additional Recipient Identifiers are invalid The Safety Report is incomplete or improperly formatted for submission.
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Withdraw a Safety Report
Description [M]	Provides the capability to withdraw a safety report.
Pre-Conditions [M]	The Safety Report record exists.

Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - Withdrawer Identifier Optional: - Reason for the Safety Report Withdraw
Outputs [M]	Return an instance of the updated Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Withdrawer Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Create Safety Report Definition
Description [M]	Provides the capability to create a safety report definition.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Object with all attributes to initiate

	- Safety Report Definition Attribute Values
Outputs [M]	Return an instance of the created Safety Report Definition object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Attributes are invalid Safety Report Definition Attributes Values are invalid
Aspects left for Technical Bindings [O]	Determination of method for Safety Report Definition identification.
Notes [O]	This operation may depend on the Query Safety Report Definition capability to search for an existing Safety Report Definition.

Name [M]	Update Safety Report Definition Details
Description [M]	Provides the capability to update the basic details a safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Object with all basic detail attributes and values to update
Outputs [M]	Return an instance of the updated Safety Report Definition object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Identifier is invalid Safety Report Definition Basic Detail Attributes are invalid

	Safety Report Definition Basic Detail Attribute Values are invalid
Aspects left for Technical Bindings [O]	Determination of method for Safety Report Definition identification.
Notes [O]	This operation may depend on the Query Safety Report Definition capability to search for an existing Safety Report Definition.

Name [M]	Update Safety Report Definition Delivery Details
Description [M]	Provides the capability to update the delivery details in the safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Object with all delivery detail attributes and values to update
Outputs [M]	Return an instance of the updated Safety Report Definition object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Identifier is invalid Safety Report Definition Delivery Attributes are invalid Safety Report Definition Delivery Attributes Values are invalid
Aspects left for Technical Bindings [O]	Determination of method for Safety Report Definition identification.

Notes [O]	This operation may depend on the Query Safety Report Definition capability to search for an existing Safety Report Definition.

Name [M]	Update Safety Report Definition Mandatory Fields
Description [M]	Provides the capability to update the mandatory field requirements in the safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Object with all mandatory field attributes and values to update
Outputs [M]	Return an instance of the updated Safety Report Definition object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Identifier is invalid Safety Report Definition Mandatory Field Attributes are invalid Safety Report Definition Mandatory Field Attribute Values are invalid
Aspects left for Technical Bindings [O]	Determination of method for Safety Report Definition identification.
Notes [O]	This operation may depend on the Query Safety Report Definition capability to search for an existing Safety Report Definition.

Name [M]	Deactivate Safety Report Definition
Description [M]	Provides the capability to deactivate a safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Identifier Optional: - Reason for deactivating the Safety Report Definition
Outputs [M]	Return an instance of the deactivated Safety Report Definition object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.

Name [M]	Query Safety Report Definition
Description [M]	Provides the capability to find safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists.

Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Object for query by example operation.
Outputs [M]	Returns identification of Safety Report Definition objects satisfying the query by example criteria.
Post-Conditions [O]	
Exception Conditions [M]	Improperly formatted Safety Report Definition Object
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Safety Report Definition
Description [M]	Provides the capability to get a safety report definition.
Pre-Conditions [M]	The Safety Report Definition record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Identifier
Outputs [M]	Return the entire Safety Report Definition object requested.
Post-Conditions [O]	
Exception	Safety Report Definition Identifier is invalid

Conditions [M]	
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Safety Report Terminology for a Study
Description [M]	Provides the capability to update the safety report terminology to be used for a study.
Pre-Conditions [M]	The Safety Report Definition record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Definition Identifier - Study Identifier - Safety Report Terminology Identifier
Outputs [M]	Returns a confirmation that the specified terminology will be used when completing the given safety report definition on the given study.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Identifier is invalid Study Identifier is invalid Safety Report Terminology Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	In the event that the safety report terminology for a study is updated after a safety report has already been initiated,

	the elements using the previous terminology will not automatically be re-coded to the new terminology.

Name [M]	Create Organization Safety Reporting Rules
Description [M]	Provides the capability to create safety reporting rules for an organization.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Object including o Attributes o Attribute Values - Organization Identifier
Outputs [M]	Return an instance of the created Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Improperly formatted Safety Reporting Rules Object Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Organization Safety Reporting Rules
Description [M]	Provides the capability to update safety reporting rules.

Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Object including o Attributes to update o Attribute Values to update - Organization Identifier
Outputs [M]	Return an instance of the updated Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Improperly formatted Safety Reporting Rules Object Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Deactivate Organization Safety Reporting Rules
Description [M]	Provides the capability to deactivate the safety reporting rules for an organization.
Pre-Conditions [M]	The Organization Safety Reporting Rules record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Organization Identifier

	Optional: - Reason for deactivating the Safety Reporting Rules
Outputs [M]	Return an instance of the deactivated Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rules Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Create Study Safety Reporting Rules
Description [M]	Provides the capability to create safety reporting rules for a study.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Object including o Attributes o Attribute Values - Study Identifier - Organization Identifier
Outputs [M]	Return an instance of the created Safety Reporting Rules object.
Post-Conditions [O]	

Exception Conditions [M]	Improperly formatted Safety Reporting Rules Object Study Identifier is invalid Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Study Safety Reporting Rules
Description [M]	Provides the capability to update safety reporting rules for a study.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Object including o Attributes o Attribute Values - Study Identifier - Organization Identifier
Outputs [M]	Return an instance of the updated Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Improperly formatted Safety Reporting Rules Object Study Identifier is invalid Organization Identifier is invalid
Aspects left for	

Technical Bindings [O]	
Notes [O]	

Name [M]	Deactivate Study Safety Reporting Rules
Description [M]	Provides the capability to deactivate the safety reporting rules for a Study.
Pre-Conditions [M]	The Study Safety Reporting Rules record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Organization Identifier - Safety Reporting Rules Study Identifier Optional: - Reason for deactivating the Safety Reporting Rules
Outputs [M]	Return an instance of the deactivated Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rules Organization Identifier is invalid Safety Reporting Rules Study Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Query Safety Reporting Rules

Description [M]	Provides the capability to find safety report rules.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules object with attributes properly populated to support a query by example operation.
Outputs [M]	Return Identifiers of the Safety Reporting Rules objects satisfying the query by example criteria.
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rule Object format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Safety Reporting Rules
Description [M]	Provides the capability to get a safety reporting rules.
Pre-Conditions [M]	The Safety Reporting Rules record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Reporting Rules Identifier

Outputs [M]	Return an instance of the requested Safety Reporting Rules object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rule Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Evaluate Against Safety Reporting Rules
Description [M]	Provides the capability to evaluate an adverse event or problem against safety reporting rules.
Pre-Conditions [M]	The Safety Reporting Rule record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Adverse Event Identifier or - Product Problem Identifier Optional: - Study Identifier - Organization Identifier
Outputs [M]	Returns the Safety Report Definition(s), if any, that are recommended for completion.
Post-Conditions [O]	
Exception Conditions [M]	Adverse Event Identifier is invalid Product Problem Identifier is invalid

	Study Identifier is invalid Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Create Safety Report Definition Notification
Description [M]	Provides the capability to create a notification template in the safety report definition.
Pre-Conditions [M]	The Safety Report Definition exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - The Safety Report Definition Notification Object populated with attributes requiring initialization - The Safety Report Definition Identifier.
Outputs [M]	Return an instance of the updated Safety Report Definition Notification object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Notification Object format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Safety Report Definition Notification
Description [M]	Provides the capability to update a notification template in the safety report definition.
Pre-Conditions [M]	The Safety Report Definition Notification exits
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - The Safety Report Definition Notification Object with populated with attributes requiring update.
Outputs [M]	Return an instance of the updated Safety Report Definition Notification object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Notification Object format is invalid Safety Report Notification Identifier is invalid
Aspects left for Technical Bindings [O]	Method of identification of Safety Report Definition Notification. Method of identification of Safety Report Definition.
Notes [O]	

Name [M]	Deactivate Safety Report Definition Notification
Description [M]	Provides the capability to deactivate a notification template in the safety report definition.
Pre-Conditions [M]	The Safety Report Definition Notification record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.

Inputs [M]	Mandatory: - Safety Report Definition Notification Identifier Optional: - Reason for deactivation the Safety Report Definition Notification.
Outputs [M]	Return an instance of the deactivated Safety Report Definition Notification object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Notification Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	This operation depends on Safety Report Definition Query Profile to retrieve the Safety Report Definition object in order to allow a service consumer to deactivate it.

Name [M]	Query Safety Reports
Description [M]	Provides the capability to find safety reports.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Object with attributes populated to support a query by example operation.
Outputs [M]	Returns identifiers instance Safety Report object satisfying the search criteria of the query by example

	operation.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Safety Report Object is improperly formatted.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Safety Reports
Description [M]	Provides the capability to retrieve safety reports.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifiers
Outputs [M]	Returns the complete objects of the requested Safety Reports.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	View Safety Report
Description [M]	Provides the capability to retrieve safety reports.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier - View Format (e.g. MedWatch 3500A pdf)
Outputs [M]	Returns the requested Safety Report in the requested viewable format.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid View Format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Audit Trail of a Safety Report
Description [M]	Provides the capability to get audit trail of a safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier

	Optional: - Operation type(s) - Date range - User ID
Outputs [M]	Returns detailed records of all create, read, update, and delete operations performed on the Safety Report object, or a subset of operations based upon the optional filter criteria.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid The Operation type(s) are invalid The Date range is invalid The User ID is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Safety Report Summary Data
Description [M]	Provides the capability to get safety report summary data.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifiers - Safety Report Attributes to summarize - The methods of summarization for the Safety

	Report Attributes
Outputs [M]	Returns the summarized Safety Report objects.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Safety Report Attributes to summarize are invalid The methods of summarization for the Safety Report Attributes are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Create Safety Report Review Process
Description [M]	Provides the capability to create a safety report review process.
Pre-Conditions [M]	The Safety Report Definition exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Review Object - Safety Report Definition Identifier Optional: - Organization Identifier - Study Identifier
Outputs [M]	Returns an instance of the created review process for the specified Safety Report Definition with a Safety Report Review Identifier

Post-Conditions [O]	
Exception Conditions [M]	Safety Report Review Object is invalid Safety Report Definition Identifier is invalid Organization Identifier is invalid Study Identifier is invalid
Aspects left for Technical Bindings [O]	Method of identification of Safety Report Definition. Method of identification of Safety Report Review Process.
Notes [O]	

Name [M]	Update Safety Report Review Process
Description [M]	Provides the capability to update a safety report review process.
Pre-Conditions [M]	The Safety Report Review Process exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Review Process Identifer - Safety Report Review Process Object with attributes and values to update. Optional: - Study Identifier - Organization Identifier
Outputs [M]	Returns an instance of the updated review process.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Review Process Identifier is invalid

	Safety Report Review Object is invalid Organization Identifier is invalid Study Identifier is invalid
Aspects left for Technical Bindings [O]	Method of identification of Safety Report Review Process.
Notes [O]	

Name [M]	Deactivate Safety Report Review Process
Description [M]	Provides the capability to deactivate a safety report review process.
Pre-Conditions [M]	The Safety Report Review Process exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Review Process Identifier Optional: - Reason for deactivation
Outputs [M]	Returns an instance of the deactivated review process.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Review Process Identifier is invalid
Aspects left for Technical Bindings [O]	Method of identification of Safety Report Review Process.
Notes [O]	

Name [M]	Get Safety Report Review Process
Description [M]	Provides the capability to get safety report review process.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - Safety Report Identifier
Outputs [M]	Returns an instance of the review process for the specified Safety Report.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Safety Report Review Process does not exist for this report
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Review Safety Report
Description [M]	Provides the capability to review safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory:

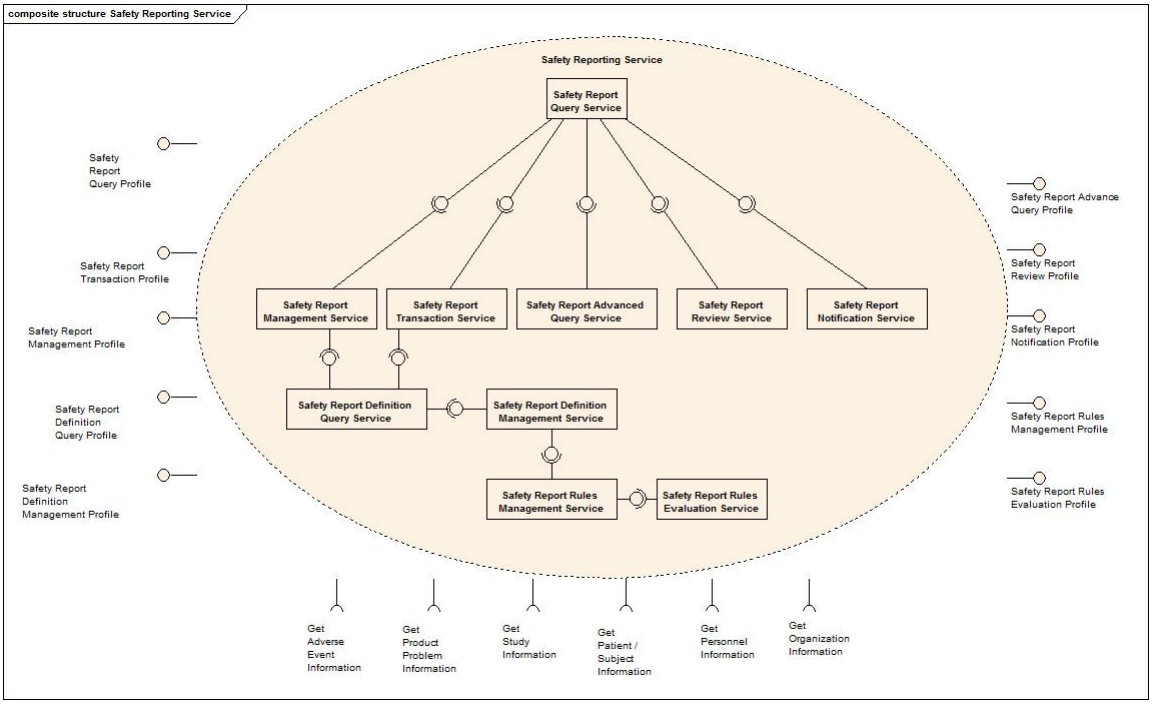
	- Safety Report Identifier - Review Disposition - Reviewer Identifier - Date / Time of Review Optional: - Comments regarding review
Outputs [M]	Returns an instance of the reviewed Safety Report object.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid Review Disposition is invalid Reviewer Identifier is invalid Date / Time of Review is invalid Review comments are invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Profiles

3.3 Functional Profiles

Functional Profiles are intended to be deployed as a collection of operations that have been designed to provide coherent and consistent access to capabilities. The functional profiles allow service provider to gradually implement and comply with this specification.

3.3.1 Service Composite Structure



3.3.2 Functional Profile Details

Functional Profile No.	Functional Profile Name	Functional Profile Description	Capability Name
SR-FP1	Safety Report Query	The Safety Report Query functional profile provides an encapsulation boundary for the commissioner of the	• Query Safety Reports • Get Safety Reports • View Safety Report

		query to be guaranteed that the information provided by a given query is correct and complete.	
SR-FP2	Safety Report Management	The Management series of capabilities details the complete encapsulation boundary behind which the Safety Report object may be managed.	• Initiate Safety Report • Associate Adverse Event to a Safety Report • Associate Problem to a Safety Report • Dissociate Adverse Event from a Safety Report • Dissociate Problem from a Safety Report • Update Adverse Event Information in the Safety Report • Update Problem Information in the Safety Report • Associate a Study to a Safety Report • Associate Additional Information to a Safety Report • Associate Subject to a Safety Report • Dissociate a Study from a Safety Report

			• Dissociate Subject from a Safety Report • Update Adverse Event Information • Update Attribution in the Safety Report • Update Intervention Regulatory Information in the Safety Report • Update Laboratory Test Results in the Safety Report • Update Other Possible Causes in the Safety Report • Update Patient Clinical Measurements in the Safety Report • Update Patient Disease History in the Safety Report • Update Patient Concomitant Medications in the Safety Report • Update Patient Prior Therapies in the Safety Report • Update Patient Demographics in the Safety Report

			• Update Reporter in the Safety Report • Update Healthcare Provider in the Safety Report • Update Submitter in the Safety Report • Update Product Problem Information • Update the Patient Status in the Safety Report • Update the Planned Intervention Information in the Safety Report • Update the Safety Report Narrative • Update Treatment Information in the Safety Report
SR-FP3	Safety Report Transaction	The Safety Report Transaction functional profile provides for a series of capabilities to perform the transactions required for safety reporting.	• Submit Safety Report • Amend Safety Report • Withdraw Safety Report
SR-FP4	Safety Report Definition Management	The Safety Report Definition functional profile provides the complete encapsulation	• Create Safety Report Definition • Update Safety Report

		boundary behind which the Safety Report Definition may be managed.	Definition Details • Update Safety Report Definition Delivery Details • Update Safety Report Definition Mandatory Fields • Deactivate Safety Report Definition • Update Safety Report Adverse Event Terminology for a Study
SR-FP5	Safety Report Rules Management	The Safety Report Rules functional profile provides the complete encapsulation boundary behind which the Safety Report Rules may be managed.	• Create Organization Safety Reporting Rules • Update Organization Safety Reporting Rules • Deactivate Organization Safety Reporting Rules • Create Study Safety Reporting Rules • Update Study Safety Reporting Rules • Deactivate Study Safety Reporting Rules • Query Safety Reporting Rules • Get Safety Reporting Rules
SR-FP6	Safety Report	The Notification functional profile	• Create Safety Report

	Notification	provides a series of functional capabilities for other systems, services, and users to manage the notifications that shall be triggered based upon updates to adverse event records and the associations to those records.	Definition Notification • Update Safety Report Definition Notification • Deactivate Safety Report Definition Notification
SR-FP7	Safety Report Review	The Safety Report Review functional profile provides a series of functional capabilities for other systems, services, and users to manage and execute the safety report review process.	• Create Safety Report Review Process • Update Safety Report Review Process • Deactivate Safety Report Review Process • Get Safety Report Review Process • Review Safety Report
SR-FP8	Safety Report Advanced Query	The Advanced Query functional profile provides an encapsulation boundary for the commissioner of the query to be guaranteed that the information provided by a given query is correct and complete. This functional profile provides functionality beyond	• Get Audit Trail of Safety Report • Get Safety Report Summary Data

		that provided in the Safety Report Query functional profile.	
SR-FP9	Safety Report Rules Evaluation	The Safety Report Rules Evaluation functional profile provides a series of functional capabilities for other systems, services, and users to evaluate if a safety report is required.	• Evaluate Against Safety Reporting Rules
SR-FP10	Safety Report Definition Query	The Safety Report Definition functional profile provides a series of functional capabilities for other systems, services, and users to find and obtain a safety report definition.	• Query Safety Report Definition • Get Safety Report Definition

3.4 Semantic Profiles

Semantic Profile No.	Semantic Profile Name	Constrained Information Model	Semantic Profile Description
SR-SP1	BRIDG V3.0 Safety Report	BRIDG V3.0.2	• Initiate Safety Report • Associate Adverse Event to a Safety Report • Associate Problem to a Safety Report • Dissociate Adverse

			Event from a Safety Report • Dissociate Problem from a Safety Report • Update Adverse Event Information in the Safety Report • Update Problem Information in the Safety Report • Associate a Study to a Safety Report • Associate Additional Information to a Safety Report • Associate Subject to a Safety Report • Dissociate a Study from a Safety Report • Dissociate Subject from a Safety Report • Update Adverse Event Information in the Safety Report • Update Attribution in the Safety Report • Update Intervention Regulatory Information in the Safety Report

			• Update Laboratory Test Results in the Safety Report • Update Other Possible Causes in the Safety Report • Update Patient Clinical Measurements in the Safety Report • Update Patient Disease History in the Safety Report • Update Patient Concomitant Medications in the Safety Report • Update Patient Prior Therapies in the Safety Report • Update Patient Demographics in the Safety Report • Update Reporter in the Safety Report • Update Healthcare Provider in the Safety Report • Update Submitter in the Safety Report • Update Product

			Problem Information in the Safety Report • Update the Patient Status in the Safety Report • Update the Planned Intervention Information in the Safety Report • Update the Narrative in the Safety Report • Update Treatment Information in the Safety Report • Amend a Safety Report • Submit a Safety Report • Withdraw a Safety Report • Create Safety Report Definition • Update Safety Report Definition Details • Update Safety Report Definition Delivery Details • Update Safety Report Definition

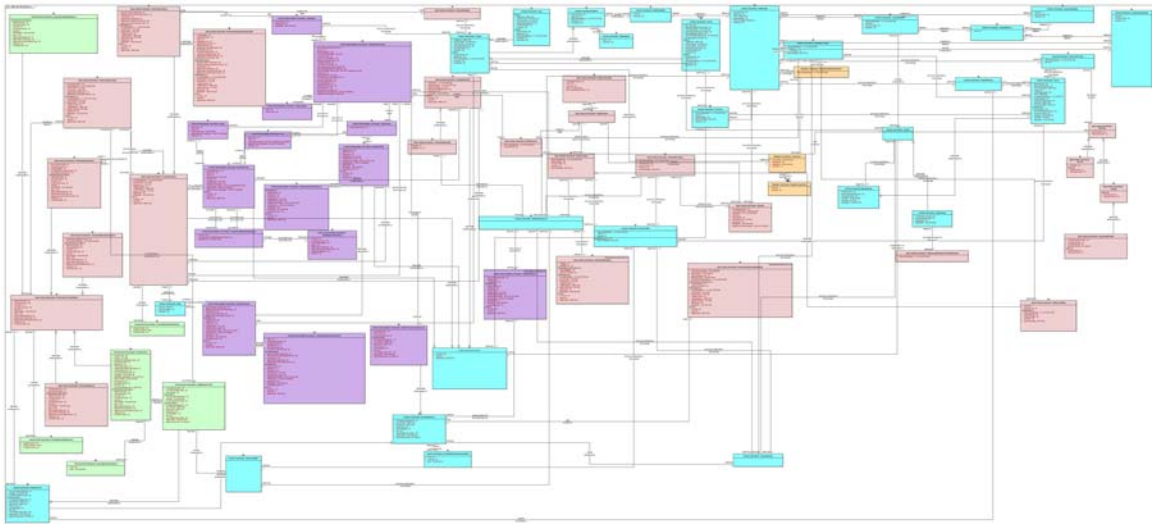
			Mandatory Fields • Create Safety Report Definition Notification • Update Safety Report Definition Notification • Deactivate Safety Report Definition Notification • Deactivate Safety Report Definition • Query Safety Report Definition • Get Safety Report Definition • Update Safety Report Terminology for a Study • Create Organization Safety Reporting Rules • Update Organization Safety Reporting Rules • Deactivate Organization Safety Reporting Rules • Create Study Safety Reporting Rules

			• Update Study Safety Reporting Rules • Deactivate Study Safety Reporting Rules • Query Safety Reporting Rules • Get Safety Reporting Rules • Evaluate Against Safety Reporting Rules • Query Safety Reports • Get Safety Reports • View Safety Report • Get Audit Trail of a Safety Report • Get Safety Report Summary Data • Create Safety Report Review Process • Update Safety Report Review Process • Deactivate Safety Report Review Process • Get Safety Report

			Review Process • Review Safety Report

4.1.1 BRIDG Information Model

The Safety Reporting Service binds and complies with semantics of BRIDG V3.0.2 information model. The subset of this model applicable for this service is displayed below.



3.5 Conformance Profiles

Conformance No	SR-CP1
Conformance Name	BRIDG based Entire Safety Report Conformance Profile
Description	This is the conformance profile defines the entire functionality for the Safety Reporting Service using BRIDG based semantics
Usage Context	This profile would be used by a study administrator or equivalent that has responsibility for all aspects of safety report management.
Mandatory	No

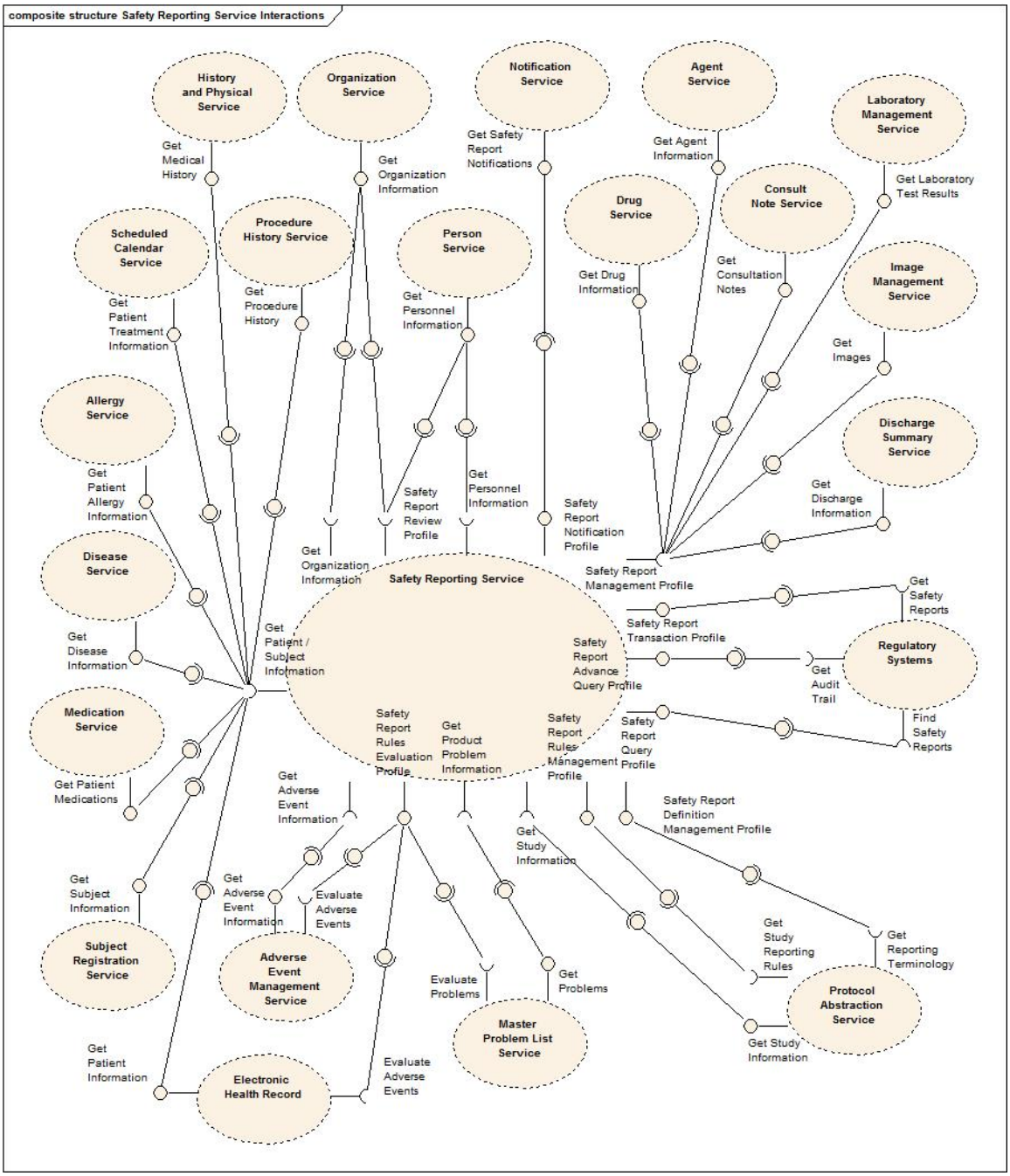
Functional Profile(s)	SR-FP1: Safety Report Query SR-FP2: Safety Report Management SR-FP3: Safety Report Transaction SR-FP4: Safety Report Definition Management SR-FP5: Safety Report Rules Management SR-FP6: Safety Report Notification SR-FP7: Safety Report Review SR-FP8: Safety Report Advanced Query SR-FP9: Safety Report Rules Evaluation SR-FP10: Safety Report Definition Query
Semantic Profile(s)	SR-SP1 : BRIDG V3.0.2 Safety Report

Conformance No	AE-CP2
Conformance Name	BRIDG based Essential Safety Report Conformance Profile
Description	This is the conformance profile defines the essential functionality for initiating, updating, completing, and finding safety reports using BRIDG based semantics
Usage Context	This profile would be used by a user or system that has responsibility for safety report management.
Mandatory	Yes
Functional Profile(s)	SR-FP1: Safety Report Query SR-FP2: Safety Report Management SR-FP3: Safety Report Transaction SR-FP10: Safety Report Definition Query
Semantic Profile(s)	SR-SP1 : BRIDG V3.0.2 Safety Report

4 System Implementation Details

4.1 System Runtime Interactions

The following diagram shows interaction between Safety Reporting Service and other participants.



4.2 Implementation/Deployment Considerations

Implementation Considerations	Impacts
This specification is intended to support both local and federated adverse event data management where multiple local deployments would interact together to form a larger whole.	The system may have to be configured such that specific profiles are served by different processes.

5 Conformance and Compliance

5.1 Compliance and Conformance Statements

Name	Type	Viewpoint	Description	Test method
Query Performance	Obligation	Engineering	The Safety Reporting Service should provide a response capable of supporting a synchronous UI based client	Test cases to include performance testing.
Multiple Jurisdictions	Obligation	Enterprise	The Safety Reporting Service will span jurisdictional boundaries and will need to support a federated data model.	Test cases include multiple domain scenarios.
Secured Access	Obligation	Engineering	The Safety Reporting Service should have access control mechanism in place to restrict access to the secured data	1. Design review 2. Test cases to be defined for security
Additional Functionality	Permission	Computational	The Safety Reporting Service can provide additional functionality other than specified in these specifications	Design Review
Semantic Model	Obligation	Informational	The Safety Reporting Service must support NCI's version of BRIDG 3.0.1 model Adverse Event class.	Design Review
Functional Profiles	Obligation	Computational	Functional Profiles shall be deployed as functional wholes. Ignoring or omitting functional behavior defined within a functional profile is not permitted, nor is diverging from the detailed functional	1. Design Review 2. Test cases

Name	Type	Viewpoint	Description	Test method
			specifications provided in Section 4.	
Functional Profiles – Conformant Implementation	Obligation	Computational	A conformant implementation of this specification must deploy at least the BRIDG based Essential Safety Reporting Conformance Profile.	1. Design Review 2. Test cases

6 Appendix A – Relevant Standards

Name	Description	Location
BRIDG v3.0.2	BRIDG model used for modeling the Safety Reporting Service	http://gforge.nci.nih.gov/frs/?group_id=342
HL7v3	Health Level 7 version 3	http://www.hl7.org/implement/standards/v3messages.cfm

7 Appendix B – References

Name	Description	Location
BRIDG v3.0.2	BRIDG model used for modeling the AE Service	http://gforge.nci.nih.gov/frs/?group_id=342
caAERS Use Case Document	Document containing use cases for the caAERS application	https://wiki.nci.nih.gov/display/caAERS/Use+Cases+-+caAERS
Safety Reporting Domain Model	BRIDG v3.0.x based Safety Reporting Domain Model	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/Services/BRIDGv3.0.1_based_AEServices_analysis.EAP
caAERS Design Model	Design model for caAERS	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/caAERS_model.eap

8 Appendix C - Glossary

Term	Description
adverse event	An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care.
AdEERS	The Adverse Event Expedited Reporting System used by the NCI Cancer Therapy Evaluation Program (CTEP) for safety reporting.
BRIDG	The Biomedical Research Integrated Domain Group (BRIDG) has developed a comprehensive domain analysis model representing biomedical/clinical research.
caAERS	Cancer Adverse Event Reporting System
clinical trial	A scientific investigation (or study) utilizing human subjects.
CTCAE	Common Terminology Criteria for Adverse Events
MedDRA	Medical Dictionary for Regulatory Activities
expected adverse event	A safety report that has been previously demonstrated to have a probability of occurring as a result of certain medical treatment.
epoch	A characterization of a type of period during a clinical trial.
grade	The degree of severity of the adverse event.
protocol	The written document detailing the materials and methods for a clinical trial.
reporting period	A defined period during a clinical trial.
solicited adverse event	A safety report for which an evaluation is prompted and actively sought.

9 Appendix D – Cross Reference Tables

9.1 List of Storyboards

#	Storyboard	Description	Source
SR-SB1	Clinician Initiated Safety Report	An adverse event requiring safety reporting is identified by a Healthcare Provider during the clinical exam of a Patient as part of clinical care.	caAERS Use Cases
SR-SB2	Patient Initiated Safety Report	A Patient directly reports an adverse symptom and it is initiated as a safety report.	caAERS Use Cases
SR-SB3	Adverse Event Initiated Safety Report	An adverse event requiring safety reporting to the Study Sponsor is observed on a Study Subject.	caAERS Use Cases
SR-SB4	Product Problem Initiated Safety Report	A product problem requiring safety reporting to the Study Sponsor is observed on a Study Subject.	caAERS Use Cases
SR-SB5	Unanticipated Problem Initiated Safety Report	An unanticipated problem occurs on a study and requires reporting to the IRB.	caAERS Use Cases
SR-SB6	Update Report Personnel Information in the Safety Report	The information regarding the clinical personnel and reporting points-of-contact are updated on the safety report.	caAERS Use Cases
SR-SB7	Update Study Information in the Safety Report	The safety report is updated with the basic information regarding the clinical trial.	caAERS Use Cases
SR-SB8	Update Adverse Event Information in the Safety Report	The Safety Report is updated with new adverse event information.	caAERS Use Cases
SR-SB9	Update the Product Problem Information in the Safety Report	A Safety Report is updated with new product problem information.	caAERS Use Cases

SR-SB10	Update the Narrative in the Safety Report	The Safety Report is updated to include a clinical narrative describing the entire event.	caAERS Use Cases
SR-SB11	Update the Status of the Patient in the Safety Report	The Safety Report is updated with the information regarding the status of the Patient or Study Subject at the time of the report, with respect to the adverse event.	caAERS Use Cases
SR-SB12	Update Planned Intervention Information in the Safety Report	The Safety Report is updated with the information regarding the planned interventions that a Study Subject was supposed to receive.	caAERS Use Cases
SR-SB13	Update Actual Treatment Information in the Safety Report	The Safety Report is updated with the information regarding the actual interventions that a Study Subject received.	caAERS Use Cases
SR-SB14	Update Adjustments to Planned Interventions in the Safety Report	The Safety Report is updated with the information regarding the adjustments to the planned interventions that were made because of the adverse event.	caAERS Use Cases
SR-SB15	Update Intervention Regulatory Information in the Safety Report	The Safety Report is updated with the information regarding the regulatory status of the relevant study interventions.	caAERS Use Cases
SR-SB16	Update Patient Demographics in the Safety Report	The Safety Report is updated with information regarding the Patient's demographics.	caAERS Use Cases
SR-SB17	Update Patient Clinical Information in the Safety Report	The Safety Report is updated with relevant clinical information regarding the Patient.	caAERS Use Cases

SR-SB18	Update Other Possible Causes in the Safety Report	The Safety Report is updated with information regarding any possible causes of the problem not already identified.	caAERS Use Cases
SR-SB19	Update Attribution of Possible Causes in the Safety Report	Likely cause(s) of each adverse event or problem is documented on the Safety Report.	caAERS Use Cases
SR-SB20	Update Relevant Laboratory Test Results in the Safety Report	Relevant laboratory tests are documented on the Safety Report.	caAERS Use Cases
SR-SB21	Update Additional Information in the Safety Report	Relevant supporting documentation is linked to the Safety Report.	caAERS Use Cases
SR-SB22	Submit a Safety Report	The Safety Report is submitted to the appropriate recipient(s).	caAERS Use Cases
SR-SB24	Withdraw a Safety Report	A submitted Safety Report is withdrawn.	caAERS Use Cases
SR-SB24	Amend a Safety Report	A submitted Safety Report is amended.	caAERS Use Cases
SR-SB25	Search for Safety Reports	Search criteria are provided and Safety Report records satisfying the search criteria are identified.	caAERS Use Cases
SR-SB26	Obtain Safety Reports	Safety Report records of interest are identified, the information to be returned from those records is specified, and the requested information is provided.	caAERS Use Cases
SR-SB27	Obtain Safety Report Summaries	Safety Report records of interest are identified, the attribute(s) on which to summarize the records are specified, along with method of summarization, and the requested summaries are provided	caAERS Use Cases

SR-SB28	Determine if a Safety Report is Required	An adverse event is assessed to determine if it needs to be reported in the safety report.	caAERS Use Cases
SR-SB29	Update Safety Reporting Rules for a Study	The criteria for the study are updated against which an adverse event is assessed to determine if it needs to be reported in the safety report.	caAERS Use Cases
SR-SB30	Update Safety Reporting Rules for an Organization	The criteria for the study organization are updated against which an adverse event is assessed to determine if it needs to be reported in the safety report.	caAERS Use Cases
SR-SB31	Update the Safety Report Definition	A Report Definition Manager specifies the requirements for a specific safety report.	caAERS Use Cases
SR-SB32	Update a Safety Report Notification	A Healthcare Provider specifies the conditions under which they will receive a notification regarding a safety report.	caAERS Use Cases
SR-SB33	Obtain a Safety Report Definition	A Safety Reporter obtains the requirements for completing a safety report.	caAERS Use Cases
SR-SB34	Update the Adverse Event Terminology Required for a Safety Report on a Study	A Report Definition Manager updates the terminology to be used for safety reporting for a specific study.	caAERS Use Cases
SR-SB35	Obtain the Audit Trail of a Safety Report	A Quality Assurance Auditor requests to view the audit trail of create, update, and delete operations associated with a specific safety report.	caAERS Use Cases
SR-SB36	Update the Safety Report Review Workflow	The Study Data Manager for the study specifies the workflow that should be	caAERS Use Cases

		followed for reviewing safety reports for a study site.	
SR-SB37	Healthcare Provider Review of a Safety Report	A Safety Reporter sends a Safety Report to a Healthcare Provider for review. The Healthcare provider then reviews the safety report.	caAERS Use Cases
SR-SB38	Safety Monitor Review of a Safety Report	A Safety Reporter sends a Safety Report to a Study Safety Monitor for review. The Study Safety Monitor then reviews the report.	caAERS Use Cases
SR-SB39	Sponsor Review of a Safety Report	A Safety Reporter sends a Safety Report to a Sponsor for review. The Sponsor then reviews the report.	caAERS Use Cases

9.2 Storyboards to Capabilities Mapping

#	Storyboard	Capabilities	Functional Profile
SR-SB1	Clinician Initiated Safety Report	- Initiate Safety Report	Safety Report Management
SR-SB2	Patient Initiated Safety Report	- Initiate Safety Report	Safety Report Management
SR-SB3	Adverse Event Initiated Safety Report	- Initiate a Safety Report - Associate Adverse Event to a Safety Report - Dissociate Adverse Event from a Safety Report - Update Adverse Event Information in the Safety Report	Safety Report Management
SR-SB4	Product Problem Initiated Safety Report	- Initiate a Safety Report - Associate Problem	Safety Report Management

		to a Safety Report - Dissociate Problem from a Safety Report - Update Problem Information in the Safety Report	
SR-SB5	Unanticipated Problem Initiated Safety Report	- Initiate a Safety Report - Associate Adverse Event to a Safety Report - Dissociate Adverse Event from a Safety Report - Update Adverse Event Information in the Safety Report - Associate Problem to a Safety Report - Dissociate Problem from a Safety Report - Update Problem Information in the Safety Report	Safety Report Management
SR-SB6	Update Report Personnel Information in the Safety Report	- Initiate a Safety Report - Update Reporter in the Safety Report - Update Healthcare Provider in the Safety Report - Update Submitter in the Safety Report	Safety Report Management
SR-SB7	Update Study Information in the Safety Report	- Initiate a Safety Report - Associate a Study to a Safety Report - Dissociate a Study from a Safety Report	Safety Report Management
SR-SB8	Update Adverse Event	- Update Adverse	Safety Report

	Information in the Safety Report	Event Information	Management
SR-SB9	Update the Product Problem Information in the Safety Report	- Update Product Problem Information	Safety Report Management
SR-SB10	Update the Narrative in the Safety Report	- Update the Safety Report Narrative	Safety Report Management
SR-SB11	Update the Status of the Patient in the Safety Report	- Update the Patient Status in the Safety Report	Safety Report Management
SR-SB12	Update Planned Intervention Information in the Safety Report	- Update the Planned Intervention Information in the Safety Report	Safety Report Management
SR-SB13	Update Actual Treatment Information in the Safety Report	- Update Treatment Information in the Safety Report	Safety Report Management
SR-SB14	Update Adjustments to Planned Interventions in the Safety Report	- Update Treatment Information in the Safety Report	Safety Report Management
SR-SB15	Update Intervention Regulatory Information in the Safety Report	- Update Intervention Regulatory Information in the Safety Report	Safety Report Management
SR-SB16	Update Patient Demographics in the Safety Report	- Update Patient Demographics in the Safety Report - Associate Person to a Safety Report - Dissociate Person from a Safety Report	Safety Report Management
SR-SB17	Update Patient Clinical Information in the Safety Report	- Update Patient Clinical Measurements in the Safety Report - Update Patient Disease History in the Safety Report - Update Patient Concomitant Medication in the	Safety Report Management

		Safety Report - Update Patient Prior Therapies in the Safety Report	
SR-SB18	Update Other Possible Causes in the Safety Report	- Update Other Possible Causes in the Safety Report	Safety Report Management
SR-SB19	Update Attribution of Possible Causes in the Safety Report	- Update Attribution in the Safety Report	Safety Report Management
SR-SB20	Update Relevant Laboratory Test Results in the Safety Report	- Update Laboratory Test Results in the Safety Report	Safety Report Management
SR-SB21	Update Additional Information in the Safety Report	- Update Additional Information in the Safety Report	Safety Report Management
SR-SB22	Submit a Safety Report	- Submit a Safety Report	Safety Report Transaction
SR-SB24	Withdraw a Safety Report	- Withdraw a Safety Report	Safety Report Transaction
SR-SB24	Amend a Safety Report	- Amend a Safety Report	Safety Report Transaction
SR-SB25	Search for Safety Reports	- Query Safety Reports	Safety Report Query
SR-SB26	Obtain Safety Reports	- Get Safety Reports - View Safety Report	Safety Report Query
SR-SB27	Obtain Safety Report Summaries	- Get Safety Report Summaries	Safety Report Advanced Query
SR-SB28	Determine if a Safety Report is Required	- Evaluate Safety Reporting Rules	Safety Reporting Rules Evaluation
SR-SB29	Update Safety Reporting Rules for a Study	- Create Study Safety Reporting Rules - Update Study Safety Reporting Rules - Deactivate Study Safety Reporting Rules	Safety Reporting Rules Management
SR-SB30	Update Safety	- Create Organization	Safety

	Reporting Rules for an Organization	Safety Reporting Rules - Update Organization Safety Reporting Rules - Deactivate Organization Safety Reporting Rules	Reporting Rules Management
SR-SB31	Update the Safety Report Definition	- Create Safety Report Definition - Update Safety Report Definition Details - Update Safety Report Definition Delivery Details - Update Safety Report Definition Mandatory Fields - Deactivate Safety Report Definition	Safety Report Definition Management
SR-SB32	Update a Safety Report Notification	- Create Safety Report Definition Notification - Update Safety Report Definition Notification - Deactivate Safety Report Definition Notification	Safety Report Notification
SR-SB33	Obtain a Safety Report Definition	- Query Safety Report Definition - Get Safety Report Definition	Safety Report Definition Query
SR-SB34	Update the Adverse Event Terminology Required for a Safety Report on a Study	- Update Safety Report Adverse Event Terminology for a Study	Safety Report Definition Management
SR-SB35	Obtain the Audit Trail of a Safety Report	- Get Audit Trail of a Safety Report	Safety Report Advanced Query
SR-SB36	Update the Safety Report Review	- Create Safety Report Review	Safety Report Review

	Workflow	Process - Query Safety Report Review Process - Get Safety Report Review Process - Update Safety Report Review Process - Deactivate Safety Report Review Process	
SR-SB37	Healthcare Provider Review of a Safety Report	- Get Safety Report Review Process - Review Safety Report	Safety Report Review
SR-SB38	Safety Monitor Review of a Safety Report	- Get Safety Report Review Process - Review Safety Report	Safety Report Review
SR-SB39	Sponsor Review of a Safety Report	- Get Safety Report Review Process - Review Safety Report	Safety Report Review

9.3 Actors

Actor	Type	Description
Healthcare Provider	Person	The treating physician for a study subject or a patient.
Safety Reporter	Person	The person responsible for completing the safety report.
Safety Report Submitter	Person	The person responsible for submitting the safety report.
AE Reporter	Person	The person responsible for recording adverse events.
Patient	Person	Patient undergoing clinical care outside the scope of a clinical trial.
Study Subject	Person	A participant on a clinical trial. Also know as Study Participant.

Principal Investigator	Person	A subscriber to notifications regarding adverse events.
Report Definition Manager	Person	A person responsible for maintaining the definition of safety reports.
Reporting Rule Manager	Person	A person responsible for maintaining safety reporting rules.
Clinical Data Coordinator	Person	A person who participates in adverse event data entry and data management activities.
Study Data Manager	Person	A person responsible for managing the data of the entire study.
Study Safety Monitor	Person	A person responsible for monitoring the safety of the entire study.
Statistician	Person	A person responsible for analyzing the data on a study.
Quality Assurance Auditor	Person	A person responsible for ensuring the adherence to standard operating procedures.
Institutional Review Board	Person	A committee responsible for reviewing, monitoring, and approving all investigations at an organization involving human subjects.
Study Sponsor	Person	An organization sponsoring a clinical study.
Safety Reporting System	System	A system used to manage safety reports.

Adverse Event Management System	System	A system used to manage adverse event records.
Safety Report	System	The form, either paper or electronic, used to record and report the safety issue.
Clinical Trials Management System (CTMS)	System	The system used to store the information regarding protocols, people, organizations, and subjects, and schedules that are needed to conduct a clinical trial.
Notification System	System	Used to provide notifications regarding Safety Reporting activities.
Electronic Health Record (EHR) System	System	The system which houses the clinical data associated with the conduct of routine clinical care.
Clinical Data Management System (CDMS)	System	The system which houses the clinical data associated with the conduct of a clinical trial.