caBIG® Platform Independent Model and Service Specification

Safety Report Service

0.1.0

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0.0.1		Srini Akkala	Initial Draft

T A B L E   O F   C O N T E N T S

Adverse Event Service Platform Independent Model and Service Specification

1 Introduction

1.1 Overview

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.

For its representation, it uses a constrained SafetyReportVersion Class from the NCI version of BRIDG 3.0.2 (https://gforge.nci.nih.gov/plugins/scmsvn/viewcvs.php/BRIDG/?root=ent-resources) and ISO 21090 data types (http://gforge.nci.nih.gov/frs/download.php/3819/ISO_21090_20080317.pdf). Thus, the semantics of the Safety Reporting Services' Safety Report representation are directly conformant to the BRIDG 3.0.2 and ISO 21090 data types.

The scope of potential usage of this service is unbounded within the health care environment, where safety reporting is needed and the BRIDG forms the basis of the implemented Information Model, and computable semantic interoperability is a goal.

1.2 Relationship to Standards

Standards	Description
BRIDG v3.0.2	Service conforms to NCI's version of BRIDG v3.0.2
HL7v3	The service conforms to NCI's HL7V3 RIM
ISO 21090	The service conforms to NCI's version of ISO 21090 data types

1.3 Relation to the Safety Reporting Conceptual Functional Service Specification

Conceptual Functional Service Specification Name	Conceptual Functional Service Specification Version	Description & Link to the Conceptual Functional Service Specification
Safety Reporting Conceptual Functional Service Specification	0.6	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/SafetyReportingService/docs/CIMSS/CIMSS_Safety_Reporting_Service.doc

Deviation from the Conceptual Functional Service Specification	Reason for Deviation
None	

1.3.1 Conformance and Compliance

Conformance Profile No.	SR-CP1	
Conformance Profile Name	BRIDG based Entire SR Conformance Profile	
Functional Profiles	**Functional Profile No.**	**Functional Profile Name**
	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 Profiles	**Semantic Profile No.**	**Semantic Profile Name**
	SR-SP1	BRIDG V3.0.2 Adverse Event

2 Platform Independent Model and Service Specification

2.1 Overview and Architecture

The sections below fully describe the operations and behavior of the interfaces provided by the Safety Reporting Service. It is important to note that the structure of interfaces is specifically defined for the Service provider. These are effectively distinct to the groupings of capabilities defined in Functional Profiles that form the basis for conformance and for consumption of the service by Clients. In some cases, the functional profiles may approximate or match the interface structure.

Ten interfaces have been defined:

1. **SafetyReportQuery**: Interface provides capability to perform query operations to retrieve Safety Report data.
2. **SafetyReportManagement** : Interface provides capability to manage Safety Report.
3. **SafetyReportTransaction** : Interface provides capability to perform transactions required for Safety Reporting.
4. **SafetyReportDefinitionManagement** : Interface provides capability to manage Report Definition .
5. **SafetyReportRulesManagement** : Interface provides capability to manage Safety Reporting Rules.
6. **SafetyReportNotification** : Interface provides capability to manage notifications triggered based on updates to adverse event and associations of those records.
7. **SafetyReportReview** : Interface provides capability to manage and execute the safety report review process..
8. **SafetyReportAdvancedQuery** : Interface provides capability to perform query operations to retrieve Safety Report Summary and Audit data..
9. **SafetyReportRulesEvaluation** : Interface provides capability to evaluate if a safety report is required.
10. **SafetyReportDefinitionQuery** : Interface provides capability to find and obtain a safety report definition.

2.2 Implementation Considerations

Implementation Consideration	Impact
ISO datatypes may need to be constrained for the implementation	The service developed might not be fully complaint with ISO 21090

2.2.1 Assumptions

Assumptions	Affects
Audit & Logging is assumed to be handled by supporting infrastructure	As a result it is not explicitly referenced in individual operations and assumed to be done automatically
Authorization checks are enforced	Only authorized users will be allowed access

2.2.2 Deployment Considerations

Deployment Consideration	Impact
Local Deployment Mode	Service should be able to run locally in the same container as the client application
Remote Deployment Mode	Service should run remotely and be able to support remote client
Inter domain / Inter Enterprise	The Safety Reporting Service provides inter-domain or inter-enterprise access by multiple applications / services from remote domains and enterprises.

2.2.3 Jurisdictional Domains

Jurisdictional Domains	Boundary
NCI's OCIO	The service will be deployed within NCI network
Institutional IRB	The service will be deployed at various institutions and will be subject to the management procedures and policies within their jurisdictional boundaries

2.3 Information Model

2.3.1 SafetyReportVersion Type
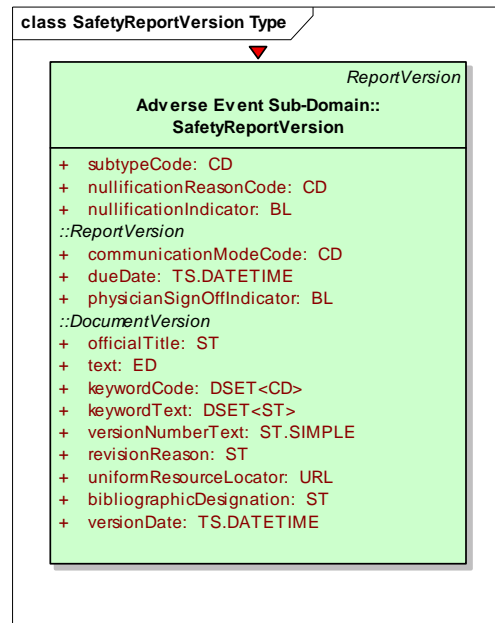
SafetyReportVersion Class used by Safety Report Service

Attribute Name	Type	Type
subTypeCode	CD	A coded value specifying a further classification of type.
nullificationReasonCode	CD	A coded value specifying the reason why the safety report report is nullified.
nullificationIndicator	BL	Specifies whether the report cancels a previously sent adverse event.
communicationModeCode	CD	A coded value specifying the form in which the report is transmitted.
dueDate	TS.DATETIME	The date (and time) on which the report is expected or scheduled to be submitted.
physicianSignOffIndicator	BL	Specifies whether the physician has reviewed and signed off on a version of a report.
officialTitle	ST	The formal title of the document.
versionNumber	ST.SIMPLE	A character string that identifies a given collection of

Text		content of a document at a point in time.
revisionReason	ST	The reason why the document is revised.
uniformResourceLocator	URL	A complete reference to a website (including http://) from which the document contents can be retrieved.
bibliographicDesignation	ST	A text block containing publishing and authoring information that allows receivers of this document version to refer appropriately to this document version.
versionDate	TS.DATETIME	The date (and time) on which the document is versioned.

2.3.2 SafetyReport Implementation model

SafetyReportVersion class and its associations are derived from BRIDG information model. The Enterprise Architect Project for the Safety Report Implementation Model can be found here (https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/models/Services/BRIDGv3.0.2_based_DAM_for_caAERSv2.2.EAP). The class diagram the Safety Report implementation model is shown below:
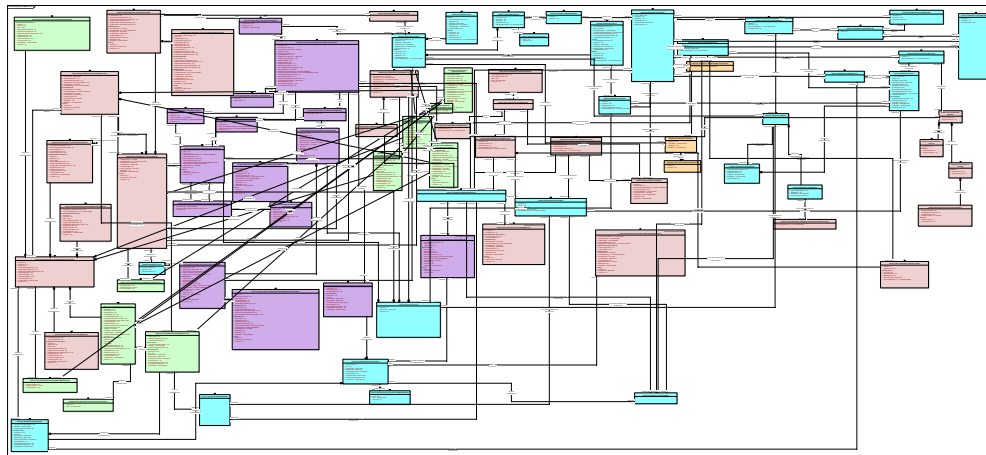
Safety Reporting - Implementation Model derived from BRIDG Information Model
Diagram is BRIDG 3.0.2 compliant.

Additional classes were defined in the Safety Reporting implementation model. These classes are not derived from the BRIDG 3.0.2 model. The class diagram below shows these classes:
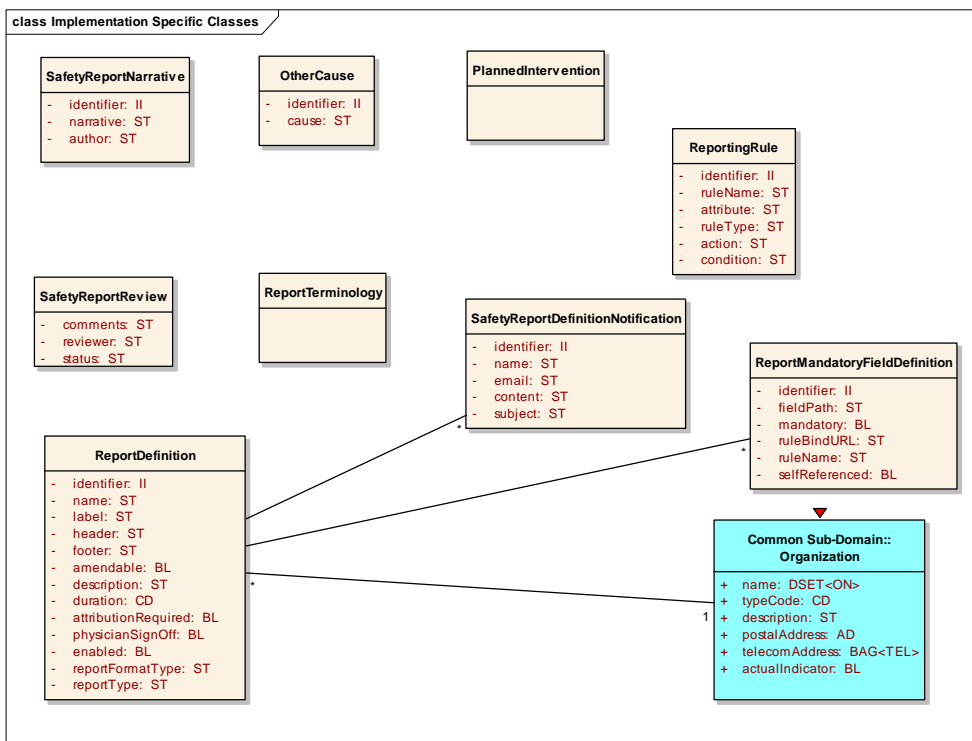
Safety Report implementation classes not derived from BRIDG

Since BRIDG uses ISO 21090 data types, which are HL7 V3 RIM R2 compliant,
Adverse Event Service uses the following ISO 21090 Data Types:

class ISO Data Types

COLL
+ excludes(T) : BL
+ includes(T) : BL
+ count(T) : INT
+ excludesAll(Collection(T)) : BL
+ includesAll(Collection(T)) : BL
+ isEmpty() : BL
+ notEmpty() : BL
+ size() : INT

CD
+ code: String
+ codeSystem: Uid
+ codeSystemName: String
+ codeSystemVersion: String
+ codeSet: String
+ codeSetVersion: String
+ displayName: ST
+ originalText: ED.TEXT
+ codingRationale: Set(CodingRationale)
+ source: CD
+ translation: Set(CD)

ED
- value: String
+ data: Binary
+ xml: XML
+ reference: TE.URL
+ mediaType: Code
+ charset: Code
+ language: Code
+ compression: Compression
+ integrityCheck: Binary
+ integrityCheckAlgorithm: IintegrityCheckAlgorithm
+ description: ST
+ thumbnail: ED
+ translation: Set(ED)

«enumeratio...»
ED::Compression

«enumeration»
ED::IntegrityCheckAlgorithm

DSET
+ item: Set(T)

ED.TEXT

ANY
+ nullFlavor: NullFlavor
+ flavorId: String
+ updateMode: UpdateMode

QTY
+ expression: ED
+ originalText: ED.TEXT
+ uncertainty: QTY
+ uncertaintyType: UncertaintyType

BL
+ value: Boolean

PQV

TS
+ value: String

ST
+ value: String
+ language: Code

IVL
+ high: T
+ highClosed: Boolean
+ low: T
+ lowClosed: Boolean
+ width: QTY
+ any: T

II
+ root: Uid
+ extension: String
+ dislayable: Boolean
+ identifierName: String
+ scope: IdentifierScope
+ reliability: IdentifierReliability

TEL
+ value: Uri
+ use: Set(TelecommunicationAddressUse)
+ usablePeriod: QSET(TS)

QSET
+ originalText: ED.TEXT

«interface»
PQ

«enumeration»
TelecommunicationAddressUse

TEL.URL

ISO 21090 Data Types used by Safety Reporting Service

2.3.3 Error Implementation Model
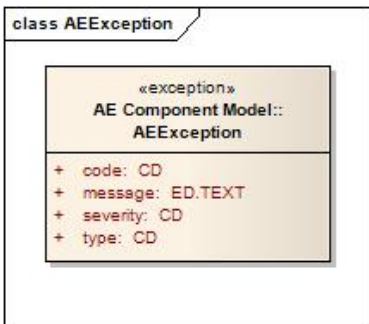
Attribute Name	Type	Attribute Description
code	CD	The actual error code which is Exception class represents
message	CD	The detailed error message
severity	CD	The severity of this error. It can be "FATAL", "HIGH", "MEDIUM" or "LOW"
type	CD	Indicates what type of error has occurred. E.g. Business, System etc.

2.4 Control Data Type Definitions

2.4.1 Status/Return Values/Exceptions

Data Type	Type (Status / Return Value / Exception)	Data Type Description
SafetyReportException	Exception	Exception thrown when there is an error in the operation of Safety Reporting Service methods

2.4.2 Error Codes

Error Code	Error Condition	Error/Exception Description
SRE10100	Major	Safety Report Identifier is invalid

SRE10101	Major	Safety Report Identifier is invalid
SRE10102	Major	View Format is invalid
SRE10103	Major	The Report Definition Identifier is invalid
SRE10104	Major	The Subject Identifier is invalid for the provided Study Identifier
SRE10105	Major	The Subject Identifier is invalid for the provided Patient Identifier.
SRE10106	Major	Adverse Event Identifier is invalid
SRE10107	Major	The Adverse Event record is invalid for the Subject or Patient on the Safety Report
SRE10108	Major	Problem Identifier is invalid
SRE10109	Major	Additional Information Identifier is invalid
SRE10110	Major	Patient Identifier is invalid
SRE10111	Major	Person Identifier is invalid
SRE10112	Major	Study Subject Identifier is invalid
SRE10113	Major	Regulatory information for Intervention is invalid
SRE10114	Major	Intervention Identifier is invalid
SRE10115	Major	Lab Test is invalid
SRE10116	Major	Other Cause Identifier is invalid
SRE10117	Major	Report Person Identifier is invalid
SRE10118	Major	PerformanceClinicalResult is invalid

SRE10119	Major	Disease History is invalid
SRE10120	Major	Concomitant Medication is invalid
SRE10121	Major	Prior Therapy is invalid
SRE10122	Major	Healthcare Provider is invalid
SRE10123	Major	Submitter is invalid
SRE10124	Major	Report Patient is invalid
SRE10125	Major	Safety Report Narrative is improperly formatted
SRE10126	Major	Safety Report Identifier is invalid
SRE10127	Major	Treatment is invalid
SRE10128	Major	Amendment Identifier is invalid
SRE10129	Major	Withdrawer Identifier is invalid
SRE10130	Major	Safety Report Definition is invalid

3 Interfaces

3.1 UML Model of Interfaces

Interface No	Interface Name
SR-INF1	SafetyReportQuery
SR-INF2	SafetyReportManagement

SR-INF3	SafetyReportTransaction
SR-INF4	SafetyReportDefinitionManagement
SR-INF5	SafetyReportRulesManagement
SR-INF6	SafetyReportNotification
SR-INF7	SafetyReportReview
SR-INF8	SafetyReportAdvancedQuery
SR-INF9	SafetyReportRulesEvaluation
SR-INF10	SafetyReportDefinitionQuery

Following is the Interface model for Safety Reporting Service:

class Interface Model

«interface»
SafetyReportRulesManagement
+ createOrganizationSafetyReportingRules() : void
+ updateOrganizationSafetyReportingRules() : void
+ deactivateOrganizationSafetyReportingRules() : void
+ createStudySafetyReportingRules() : void
+ updateStudySafetyReportingRules() : void
+ deactivateStudySafetyReportingRules() : void
+ querySafetyReportingRules() : void
+ getSafetyReportingRules() : void

«interface»
SafetyReportNotification
+ createSafetyReportDefinitionNotification() : void
+ updateSafetyReportDefinitionNotification() : void
+ deactivateSafetyReportDefinitionNotification() : void

«interface»
SafetyReportTransaction
+ submitSafetyReport() : void
+ amendSafetyReport() : void
+ withdrawSafetyReport() : void

«interface»
SafetyReportReview
+ createSafetyReportReviewProcess() : void
+ updateSafetyReportReviewProcess() : void
+ deactivateSafetyReportReviewProcess() : void
+ getSafetyReportReviewProcess() : void
+ reviewSafetyReportReview() : void

«interface»
SafetyReportQuery
+ querySafetyReports(BRIDG:SafetyReportVersion) : BRIDG:SafetyReportVersion []
+ getSafetyReports(ISO:II) : BRIDG:SafetyReportVersion
+ viewSafetyReport(ISO:ST, ISO:II) : Safety:SafetyReportFormat

«service»
SafetyReportingService

«interface»
SafetyReportAdvancedQuery
+ getAuditTrailForSafetyReport() : void
+ getSafetyReportSummaryData() : void

«interface»
SafetyReportDefinitionManagement
+ createReportDefinition() : void
+ updateReportDefinition() : void
+ updateReportDefinitionDeliveryDetails() : void
+ updateReportDefinitionMandatoryFields() : void
+ deactivateReportDefinition() : void
+ updateSafetyReportAdverseEventTerminologyForStudy() : void

«interface»
SafetyReportDefinitionQuery
+ querySafetyReportDefinition() : void
+ getSafetyReportDefinition() : void

«interface»
SafetyReportRulesEvaluation
+ evaluateAgainstSafetyReportingRules() : void

«interface»
SafetyReportManagement
+ initiateSafetyReport(ISO:II, ISO:II, ISO:II, ISO:II, ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ associateAEToSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ associateProblemToSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ dissociateAEFromSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ dissociateProblemFromSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ updateAdverseEventInformationInSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ updateProblemInformationInSafetyReport(ISO:II, BRIDG:PerformedProductInvestigationResult) : BRIDG:SafetyReportVersion
+ associateStudyToSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ associateAdditionalInformationToSafetyReport(ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ associateSubjectToSafetyReport(ISO:II, ISO:II, ISO:II) : BRIDG:SafetyReportVersion
+ dissociateStudyFromSafetyReport(ISO:II, ISO:II, ISO:ST) : BRIDG:SafetyReportVersion
+ dissociatePersonFromSafetyReport(ISO:II, ISO:II, ISO:ST) : BRIDG:SafetyReportVersion
+ updateAdverseEventInformation() : BRIDG:SafetyReportVersion
+ updateAttributionInSafetyReport(ISO:II, ISO:II, ISO:II, ISO:ST, ISO:ST) : BRIDG:SafetyReportVersion
+ updateInterventionInSafetyReport(ISO:II, ISO:II, BRIDG:RegulatoryApplication) : BRIDG:SafetyReportVersion
+ updateLabTestResultsInSafetyReport(ISO:II, BRIDG:PerformedClinicalResult) : BRIDG:SafetyReportVersion
+ updateOtherPossibleCausesInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientClinicalMeasurementsInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientDiseaseHistoryInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientConMedsInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientPriorTherapiesInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientDemographicsInSafetyReport() : BRIDG:SafetyReportVersion
+ updateReporterInSafetyReport() : BRIDG:SafetyReportVersion
+ updateHealthcareProviderInSafetyReport() : BRIDG:SafetyReportVersion
+ updateSubmitterInSafetyReport() : BRIDG:SafetyReportVersion
+ updateProductProblemInformationInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePatientStatusInSafetyReport() : BRIDG:SafetyReportVersion
+ updatePlannedInterventionInformationInSafetyReport() : BRIDG:SafetyReportVersion
+ updateSafetyReportNarrative() : BRIDG:SafetyReportVersion
+ updateTreatmentInformationInSafetyReport() : BRIDG:SafetyReportVersion

Safety Reporting Services Interface Model

3.2 Operations (Enumeration)

Operation No.	Operation Name	Interface Name
SR-INF1-OP1	querySafetyReports	SafetyReportQuery
SR-INF1-	getSafetyReports	SafetyReportQue

OP2		ry
SR-INF1-OP3	viewSafetyReport	SafetyReportQuery
SR-INF2-OP1	initiateSafetyReport	SafetyReportManagement
SR-INF2-OP2	associateAEToSafetyReport	SafetyReportManagement
SR-INF2-OP3	associateProblemToSafetyReport	SafetyReportManagement
SR-INF2-OP4	dissociateAEFromSafetyReport	SafetyReportManagement
SR-INF2-OP5	dissociateProblemFromSafetyReport	SafetyReportManagement
SR-INF2-OP6	updateAdverseEventInformationInSafetyReport	SafetyReportManagement
SR-INF2-OP7	updateProblemInformationInSafetyReport	SafetyReportManagement
SR-INF2-OP8	associateStudyToSafetyReport	SafetyReportManagement
SR-INF2-OP9	associateAdditionalInformationToSafetyReport	SafetyReportManagement
SR-INF2-OP10	associateSubjectToSafetyReport	SafetyReportManagement
SR-INF2-OP11	dissociateStudyFromSafetyReport	SafetyReportManagement
SR-INF2-OP12	dissociateSubjectFromSafetyReport	SafetyReportManagement
SR-INF2-	updateAdverseEv	SafetyReportManagement

OP13	entInformation	
SR-INF2-OP14	updateAttributionInSafetyReport	SafetyReportManagement
SR-INF2-OP15	updateInterventionInSafetyReport	SafetyReportManagement
SR-INF2-OP16	updateLabTestResultsInSafetyReport	SafetyReportManagement
SR-INF2-OP17	updateOtherPossibleCausesInSafetyReport	SafetyReportManagement
SR-INF2-OP18	updatePatientClinicalMeasurementsInSafetyReport	SafetyReportManagement
SR-INF2-OP19	updatePatientDiseaseHistoryInSafetyReport	SafetyReportManagement
SR-INF2-OP20	updatePatientConMedsInSafetyReport	SafetyReportManagement
SR-INF2-OP21	updatePatientPriorTherapiesInSafetyReport	SafetyReportManagement
SR-INF2-OP22	updatePatientDemographicsInSafetyReport	SafetyReportManagement
SR-INF2-OP23	updateReporterInSafetyReport	SafetyReportManagement
SR-INF2-OP24	updateHealthcareProviderInSafetyReport	SafetyReportManagement
SR-INF2-OP25	updateSubmitterInSafetyReport	SafetyReportManagement
SR-INF2-	updateProductProblemInformatio	SafetyReportManagement

OP26	nInSafetyReport	
SR-INF2-OP27	updatePatientStatusInSafetyReport	SafetyReportManagement
SR-INF2-OP28	updatePlannedInterventionInformationInSafetyReport	SafetyReportManagement
SR-INF2-OP29	updateSafetyReportNarrative	SafetyReportManagement
SR-INF2-OP30	updateTreatmentInformationInSafetyReport	SafetyReportManagement
SR-INF3-OP1	submitSafetyReport	SafetyReportTransaction
SR-INF3-OP2	amendSafetyReport	SafetyReportTransaction
SR-INF3-OP3	withdrawSafetyReport	SafetyReportTransaction
SR-INF4-OP1	createReportDefinition	SafetyReportDefinitionManagement
SR-INF4-OP2	updateReportDefinition	SafetyReportDefinitionManagement
SR-INF4-OP3	updateReportDefinitionDeliveryDetails	SafetyReportDefinitionManagement
SR-INF4-OP4	updateReportDefinitionMandatoryFields	SafetyReportDefinitionManagement
SR-INF4-OP5	deactivateReportDefinition	SafetyReportDefinitionManagement
SR-INF4-OP6	updateSafetyReportAdverseEventTerminologyFor	SafetyReportDefinitionManagement

	Study	
SR-INF5-OP1	createOrganizationSafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP2	updateOrganizationSafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP3	deactivateOrganizationSafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP4	createStudySafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP5	updateStudySafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP6	deactivateStudySafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP7	querySafetyReportingRules	SafetyReportRulesManagement
SR-INF5-OP8	getSafetyReportingRules	SafetyReportRulesManagement
SR-INF6-OP1	createSafetyReportDefinitionNotification	SafetyReportNotification
SR-INF6-OP2	updateSafetyReportDefinitionNotification	SafetyReportNotification
SR-INF6-OP3	deactivateSafetyReportDefinitionNotification	SafetyReportNotification
SR-INF7-OP1	createSafetyReportReviewProcess	SafetyReportReview
SR-INF7-OP2	updateSafetyReportReviewProces	SafetyReportReview

	s	
SR-INF7-OP3	deactivateSafety ReportReviewPr ocess	SafetyReportRe view
SR-INF7-OP4	getSafetyReport ReviewProcess	SafetyReportRe view
SR-INF7-OP5	reviewSafetyRep ortReview	SafetyReportRe view
SR-INF8-OP1	getAuditTrailFor SafetyReport	SafetyReportAd vancedQuery
SR-INF8-OP2	getSafetyReportS ummaryData	SafetyReportAd vancedQuery
SR-INF9-OP1	evaluateAgainstS afetyReportingR ules	SafetyReportRu lesEvaluation
SR-INF10-OP1	querySafetyRepo rtDefinition	SafetyReportDe finitionQuery
SR-INF10-OP2	getSafetyReport Definition	SafetyReportDe finitionQuery

3.3 Operation Behavior Descriptions

3.3.1 SafetyReportQuery Interface

Name [M]	querySafetyReports
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: - BRIDG:SafetyReportVersion Object with attributes populated to support a query by example operation.
Outputs [M]	DSET<BRIDG:SafetyReportVersion>
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]	getSafetyReports
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: - DSET<ISO:II> (BRIDG:DocumentIdentifier.identifier)
Outputs [M]	DSET<BRIDG:SafetyReportVersion>
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	viewSafetyReport
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:
	
	   - ISO:II (BRIDG:DocumentIdentifier.identifier)
	
	   - ISO:ST (Desired Viewing Format)

Outputs [M]	Safety:SafetyReportFormat
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid View Format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

3.3.2 SafetyReportManagement Interface

Name [M]	initiateSafetyReport
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]	ISO:II (BRIDG:StudyVersion.identifier) ISO:II (BRIDG:Subject.identifier) ISO:II (Patient Identifier) DSET<ISO:II> (BRIDG:AdverseEvent.identifier) DSET<ISO:II >(BRIDG:PerformedProductInvestigationResult.identifier) Safety:AdverseEventReportingPeriod
Outputs [M]	BRIDG:SafetyReportVersion
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]	associateAdverseEventsToSafetyReport
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: 　　　ISO:II (BRIDG:DocumentIdentifier.identifier) 　　　DSET<ISO:II>　　　　　　(BRIDG:AdverseEvent 　　　Event.identifier]
Outputs [M]	BRIDG:SafetyReportVersion
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]	associateProblemToSafetyReport
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: 　　　ISO:II (BRIDG:DocumentIdentifier.identifier) 　　　ISO:II 　　　(BRIDG: 　　　PerformedProductInvestigationResult.identifier)
Outputs [M]	BRIDG:SafetyReportVersion
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]	dissociateAdverseEventsFromSafetyReport
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:
	    ISO:II (BRIDG:DocumentIdentifier.identifier)
	    DSET<ISO:II> (BRIDG:AdverseEvent.identifier.)

Outputs [M]	BRIDG:SafetyReportVersion
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]	dissociateProblemFromSafetyReport
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:
	    ISO:II (BRIDG:DocumentIdentifier.identifier)
	    ISO:II
	    (BRIDG:
	    PerformedProductInvestigationResult.identifier)

Outputs [M]	BRIDG:SafetyReportVersion.
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]	updateAdverseEventInformationInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier). - BRIDG:AdverseEvent 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]	BRIDG:SafetyReportVersion.
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]	updateProblemInformationInSafetyReport
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: ISO:II (BRIDG:DocumentIdentifier.identifier) BRIDG: PerformedProductInvestigationResult

Outputs [M]	BRIDG:SafetyReportVersion
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]	associateStudyToSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:StudyVersion.identifier)
Outputs [M]	BRIDG:SafetyReportVersion
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]	associateAdditionalInformationToSafetyReport
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:

	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	- ISO:II (AE:AdditionalInformation.Identifier)
Outputs [M]	BRIDG:SafetyReportVersion.
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]	associateSubjectToSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) Conditional: - ISO:II (BRIDG:StudySubject.Identifier) - ISO:II (BRIDG:Person.identifier)
Outputs [M]	BRIDG: SafetyReportVersion.
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]	dissociateStudyFromSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:StudyVersion. Identifier) Optional: - ISO:ST (Reason for the dissociation)
Outputs [M]	BRIDG:SafetyReportVersion.
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]	dissociatePersonFromSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:Person.identifier) Optional:

	- ISO:STReason for the dissociation
Outputs [M]	BRIDG:SafetyReportVersion.
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]	updateAttributionInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:AdverseEvent) - ISO:II (BRIDG:PerformedProductInvestigationResult Identifiers) - ISO:ST (The cause of the Adverse Event or Product Problem) - ISO:ST (and the degree of causation.)
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateInterventionInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG: PerformedSubstanceAdministration.Identifier) - BRIDG: RegulatoryApplication
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateLabTestResultsInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:PerformedClinicalResult (Lab Test Identifier , Lab Test Attributes ,Lab Test Attribute Values)
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception	Safety Report Identifier is invalid

Conditions [M]	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]	updateOtherPossibleCausesInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - Safety:OtherCause.identifier
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid 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]	updatePatientClinicalMeasurementsInSafetyReport
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:

	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	- ISO:II (BRIDG:Person.identifier
	or BRIDG:StudySubject Identifier or BRIDG:Person Identifier)
	Optional:
	- BRIDG:PerformanceClinicalResult.result (Baseline Performance)
	- BRIDG:PerformanceCLinicalResult.result (Height)
	- BRIDG:PerformanceCLinicalResult.result (Weight)
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid
	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]	updatePatientDiseaseHistoryInSafetyReport
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:
	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	- ISO:II (BRIDG:Person.identifier)
	Optional:
	- BRIDG:PerformedDiagnosis
	(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]	BRIDG: SafetyReportVersion.
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]	updatePatientConMedsInSafetyReport
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:
	
	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	
	- ISO:II (BRIDG:Person.identifier (Report Patient Identifier))
	
	Optional:
	
	- BRIDG:PerformedSubstanceAdministration
	
	  (Concomitant Medication Attributes (i.e. name, date(s), description)
	
	  Concomitant Medication Attribute Values)

Outputs [M]	BRIDG: SafetyReportVersion.
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]	updatePatientPriorTherapiesInSafetyReport
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:
	
	   - ISO:II (BRIDG:DocumentIdentifier.identifier)
	
	   - ISO:II BRIDG:Person.identifier (Report Patient Identifier)
	
	Optional:
	
	   - BRIDG : PerformedMedicalHistoryResult
	
	(Prior Therapy Attributes (i.e. name, date(s), agents)
	
	Prior Therapy Attributes Values)

Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid 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]	updatePatientDemographicsInSafetyReport
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:
	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	- ISO:II BRIDG:Person.identifier (Report Patient Identifier)
	Optional:
	- BRIDG:Person
	(Patient Demographic Attributes (i.e. sex, race, ethnicity, DOB)
	Patient Demographic Attribute Values)
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateReporterInSafetyReport
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:
	- ISO:II (BRIDG:DocumentIdentifier.identifier)
	- BRIDG:DocumentAuthor
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateHealthcareProviderInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:HealthcareProvider
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateSubmitterInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:ReportSubmitter
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateProductProblemInformationInSafetyReport
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:

	- ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:PerformedProductInvestigationResult
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updatePatientStatusInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:Person
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updatePlannedInterventionInformationInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - Safety:PlannedIntervention
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateNarrativeInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - Safety:SafetyReportNarrative
Outputs [M]	BRIDG: SafetyReportVersion.
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]	updateTreatmentInformationInSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:PerformedActivity
Outputs [M]	BRIDG: SafetyReportVersion.
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.

3.3.3 SafetyReportTransaction Interface

Name [M]	amendSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (ReportDefinition Identifier)
Outputs [M]	

Post-Conditions [O]	
Exception Conditions [M]	Safety Report 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]	submitSafetyReport
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: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG ReportDefinition.identifier) - ISO:DEST_TEL (additionalRecipientEmails) -
Outputs [M]	.
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]	withdrawSafetyReport
Description [M]	Provides the capability to withdraw a safety report.
Pre-Conditions [M]	The Safety Report record exists.
Security Pre-	Access control mechanisms need to be in place to ensure

Conditions [M]	that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (ReportDefinition.Identifier) -
Outputs [M]	
Post-Conditions [O]	
Exception Conditions [M]	Safety Report 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.

3.3.4 SafetyReportDefinitionManagement Interface

Name [M]	createSafetyReportDefinition
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:ReportDefinition (Safety Report Definition Object with attributes/values to initiate)
Outputs [M]	
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]	updateSafetyReportDefinitionDetails
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:ReportDefinition (Safety Report Definition Object with all basic detail attributes and values to update)
Outputs [M]	
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]	updateSafetyReportDefinitionDeliveryDetails
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:ReportDefinition (Safety Report Definition Object with all delivery detail attributes and values to update)
Outputs [M]	
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]	updateSafetyReportDefinitionMandatoryFields
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:ReportDefinition (Safety Report Definition Object with all mandatory field attributes and values to update)
Outputs [M]	
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]	deactivateSafetyReportDefinition
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:

	- ISO:II (Safety:ReportDefinition.Identifier) Optional: - ISO:ST (Reason for deactivating the Safety Report Definition)
Outputs [M]	
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]	updateSafetyReportTerminologyForStudy
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:
	
	    - ISO:II (Safety:ReportDefinition Identifier)
	
	    - ISO:II (BRIDG:StudyVersion.Identifier)
	
	    - ISO:II (Safety:ReportTerminology.Identifier)

Outputs [M]	
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.

3.3.5 SafetyReportRulesManagement Interface

Name [M]	createOrganizationSafetyReportingRules
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:ReportingRule (populated Safety Reporting Rules Object) - ISO:II (BRIDG:Organization.Identifier)
Outputs [M]	Safety:ReportingRule
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]	updateOrganizationSafetyReportingRules
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:ReportingRule (populated Safety Reporting Rules Object) - ISO:II (BRIDG: Organization Identifier)
Outputs [M]	- Safety:ReportingRule
Post-Conditions [O]	
Exception	Improperly formatted Safety Reporting Rules Object

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

Name [M]	deactivateOrganizationSafetyReportingRules
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: - BRIDG:Organization.identifier (Safety Reporting Rules Organization Identifier) Optional: - ISO:ST (Reason for deactivating the Safety Reporting Rules)
Outputs [M]	- Safety:ReportingRule
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rules Organization Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	createStudySafetyReportingRules
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:ReportingRule (populated Safety Reporting Rules Object) - ISO:II (BRIDG:StudyVersion Identifier)

	- ISO:II (BRIDG:Organization Identifier)
Outputs [M]	- Safety:ReportingRule
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]	updateStudySafetyReportingRules
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:ReportingRule (populated Safety Reporting Rules Object) - ISO:II (BRIDG:StudyVersion Identifier) - ISO:II (BRIDG:Organization Identifier)
Outputs [M]	Safety:ReportingRule
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]	deactivateStudySafetyReportingRules
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:

	- ISO:II (BRIDG:StudyVersion Identifier) ISO:II (BRIDG:Organization Identifier)Optional: - ISO:ST (Reason for deactivating the Safety Reporting Rules)
Outputs [M]	Safety:ReportingRule
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]	querySafetyReportingRules
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:ReportingRule (Safety Reporting Rules object with attributes properly populated to support a query by example operation.)
Outputs [M]	Safety:ReportingRule [ ]
Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rule Object format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	getSafetyReportingRules
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: - ISO:II (Safety:ReportingRule.Identifier)
Outputs [M]	Safety:ReportingRule.

Post-Conditions [O]	
Exception Conditions [M]	Safety Reporting Rule Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

3.3.6 SafetyReportNotification Interface

Name [M]	createSafetyReportDefinitionNotification
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: - Safety: SafetyReportDefinitionNotification (The Safety Report Definition Notification Object populated with attributes requiring initialization) - ISO:II (BRIDG:SafetyReportDefinition Identifier.)
Outputs [M]	
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Definition Notification Object format is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	updateSafetyReportDefinitionNotification
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: - Safety: SafetyReportDefinitionNotification (The Safety Report Definition Notification Object with

	populated with attributes requiring update.)
Outputs [M]	
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]	deactivateSafetyReportDefinitionNotification
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:
	- ISO:II (Safety: SafetyReportDefinitionNotification. Identifier)
	Optional:
	- ISO:ST (Reason for deactivation the Safety Report Definition Notification.)
Outputs [M]	
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.

3.3.7 SafetyReportReview Interface

Name [M]	createSafetyReportReviewProcess
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:SafetyReportReview - ISO:II (Safety:SafetyReportDefinition Identifier) Optional: - ISO:II (BRIDG:Organization Identifier) - ISO:II (BRIDG:StudyVersion Identifier)
Outputs [M]	- Safety:SafetyReportReview
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]	updateSafetyReportReviewProcess
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:SafetyReportReview Optional: - ISO:II (BRIDG:Organization Identifier) - ISO:II (BRIDG:StudyVersion Identifier)
Outputs [M]	- Safety:SafetyReportReview
Post-Conditions [O]	
Exception	Safety Report Review Process Identifier is invalid

Conditions [M]	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]	deactivateSafetyReportReviewProcess
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:
	
	   - ISO:II (Safety:SafetyReportReview.Identifier)
	
	Optional:
	
	   - ISO:ST(Reason for deactivation)

Outputs [M]	- Safety:SafetyReportReview
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]	getSafetyReportReviewProcess
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:
	
	   - ISO:II (Safety:SafetyReportReview. Identifier)
	
	   -

Outputs [M]	- Safety:SafetyReportReview
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]	reviewSafetyReport
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: - ISO:II (Safety:SafetyReportReview.Identifier) - ISO:ST (Review Disposition) - ISO:II (BRIDG:Person(Reviewer) Identifier) - ISO:TsDateTime(Date / Time of Review) Optional: - ISO:ST (Comments regarding review)
Outputs [M]	- Safety:SafetyReportReview .
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]	

3.3.8 SafetyReportAdvancedQuery Interface

Name [M]	getSafetyReportSummaryData
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]	

Comment [BWM1]: Would they want to summarize by Study? PB: Yes Or by Site? PB: Yes

Methods of Summarization needs to be defined in the Info Model. PB: The methods of summarization will be defined in an implementation, if not at run-time. May need more discussion on if / how to incorporate this into the Info Model.

3.3.9 SafetyReportRulesEvaluation Interface

Name [M]	evaluateAgainstSafetyReportingRules
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: - ISO:II (BRIDG:Adverse Event Identifier or - Product Problem Identifier) Optional: - ISO:II (BRIDG:StudyVersion Identifier)

	- ISO:II (BRIDG:Organization Identifier)
Outputs [M]	Safety:ReportDefinition[ ]
Post-Conditions [O]	
Exception Conditions [M]	Adverse Event Identifier is invalid Product Problem Identifier is invalid Study Identifier is invalid Organization Identifier is invalid

3.3.10   SafetyReportDefinitionQuery Interface

Name [M]	querySafetyReportDefinition
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:ReportDefinition (Safety Report Definition Object for query by example operation.)
Outputs [M]	Safety:ReportDefinition [ ]
Post-Conditions [O]	
Exception Conditions [M]	Improperly formatted Safety Report Definition Object
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	getSafetyReportDefinition
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: - ISO:II (Safety:ReportDefinition.Identifier)
Outputs [M]	Safety:ReportDefinition
Post-Conditions [O]	

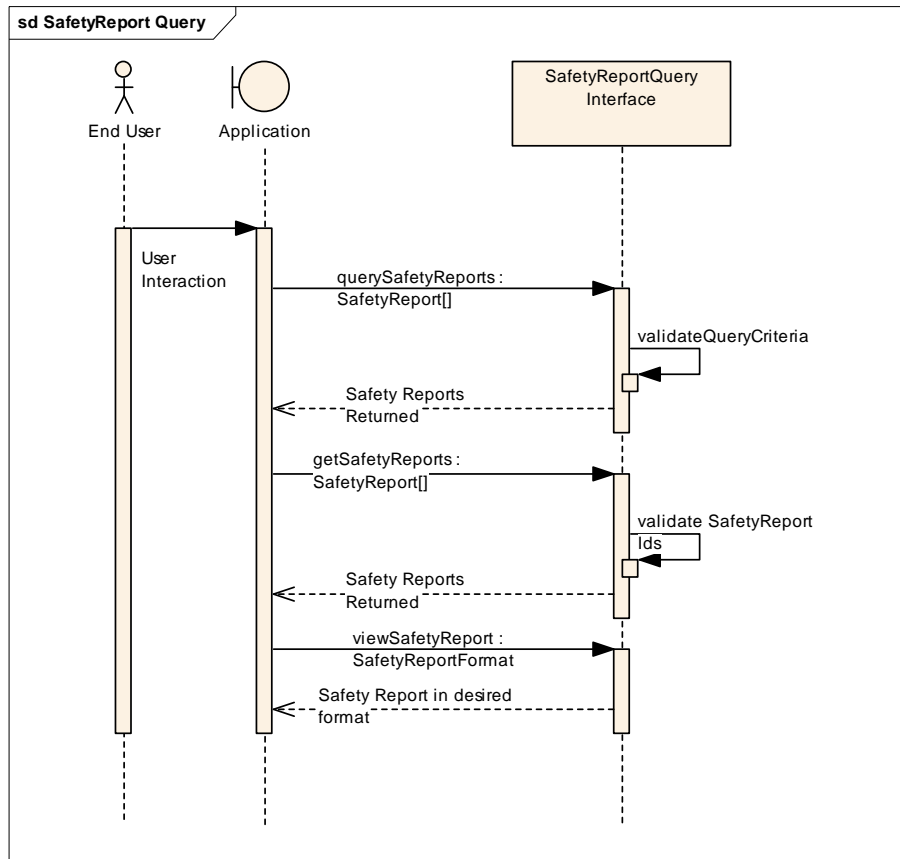| Exception Conditions [M]	Safety Report Definition Identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

4 Dynamic Model

The following architecturally significant sequence diagrams should sufficiently demonstrate the dynamics of the Safety Reporting Service.
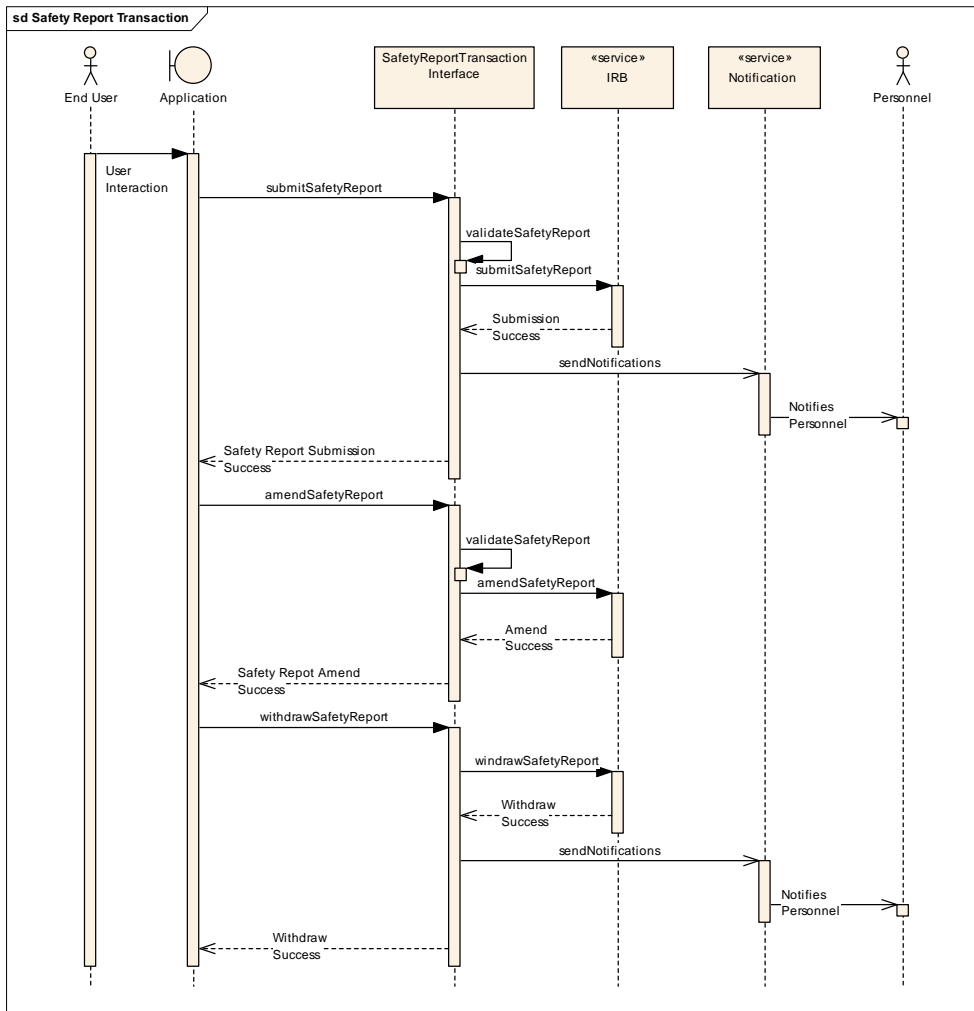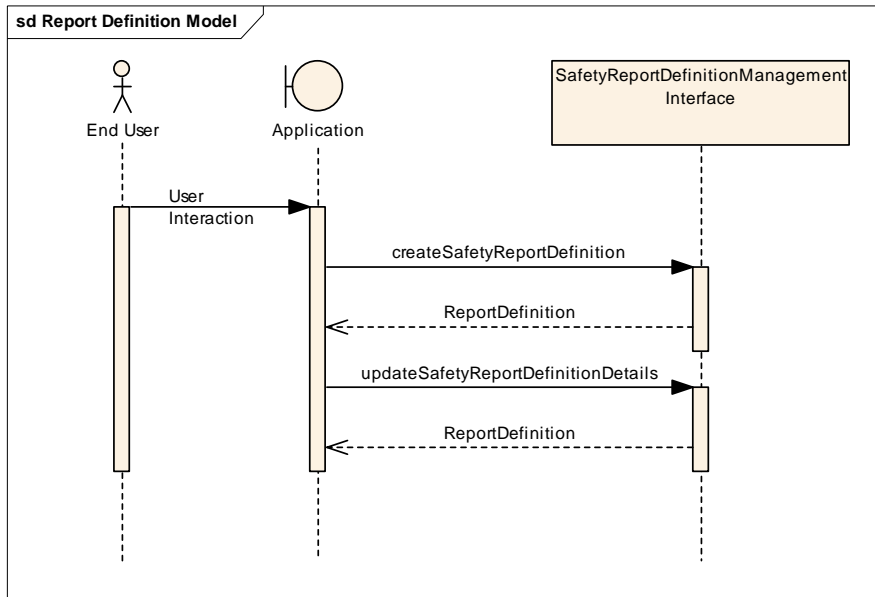
4.1 Safety Report Management
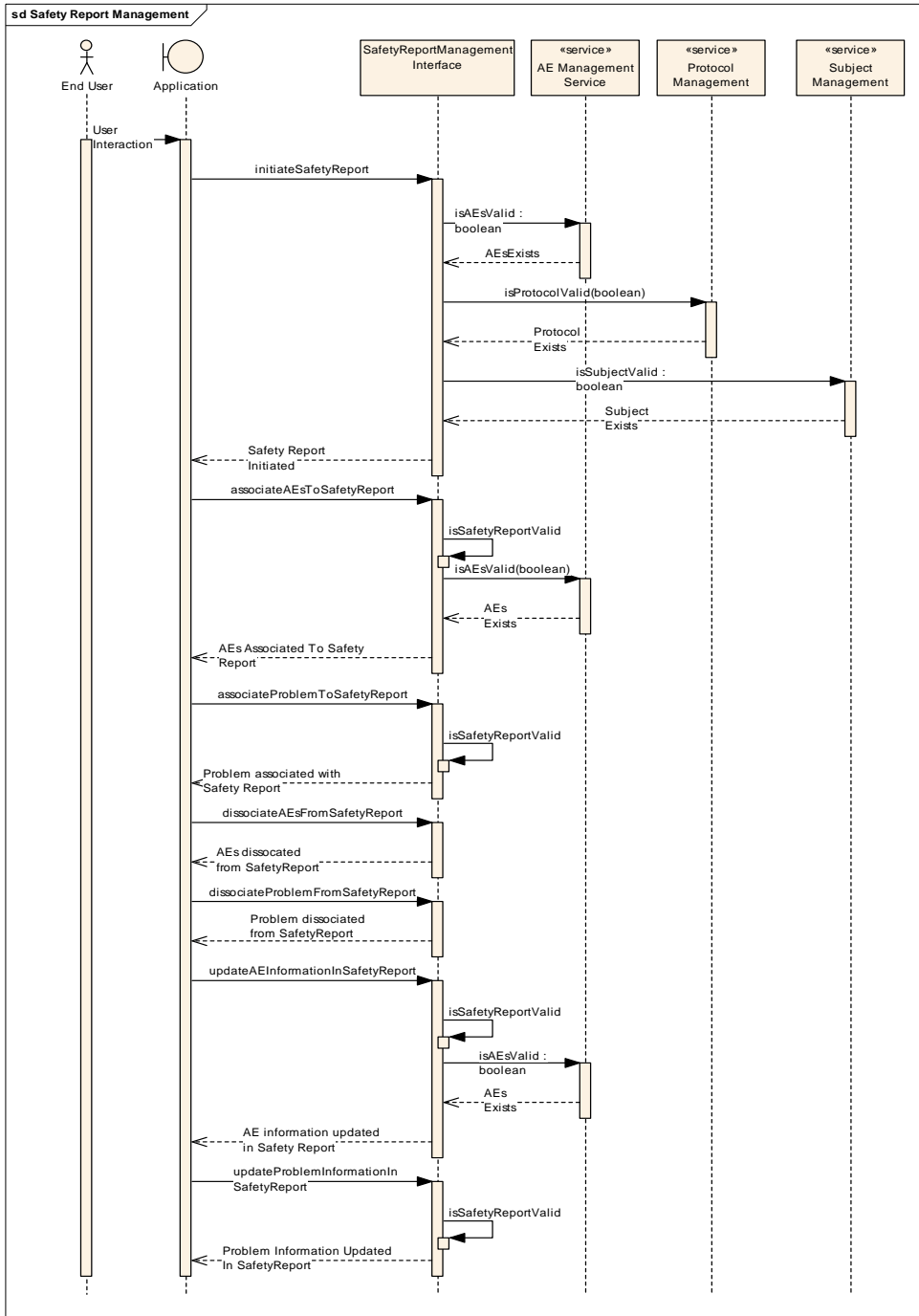
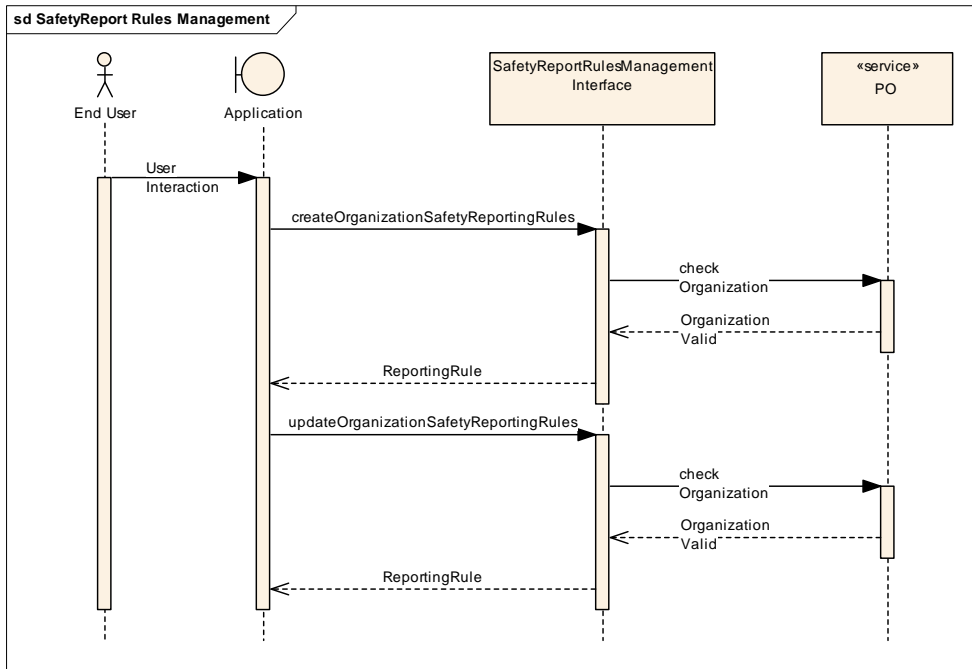## 4.2 Safety Report Query

4.3 Safety Report Transaction

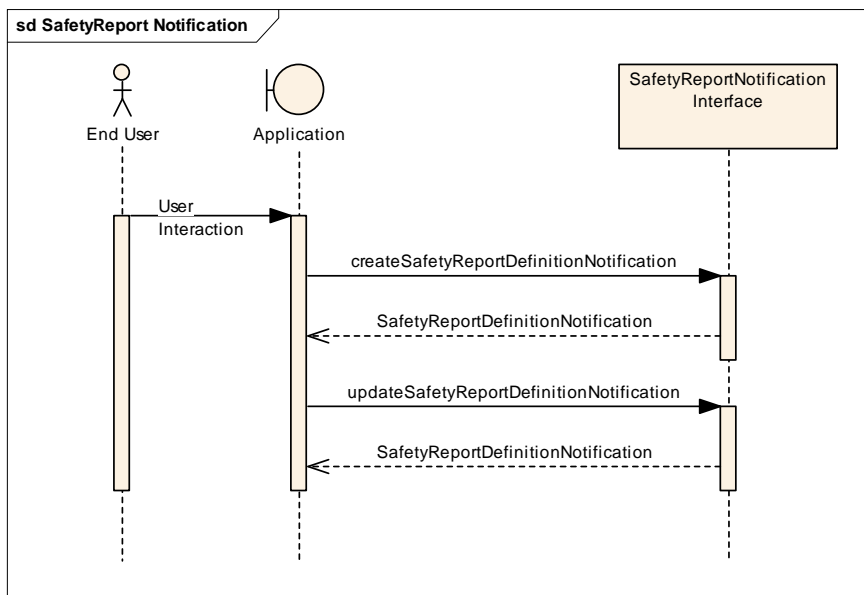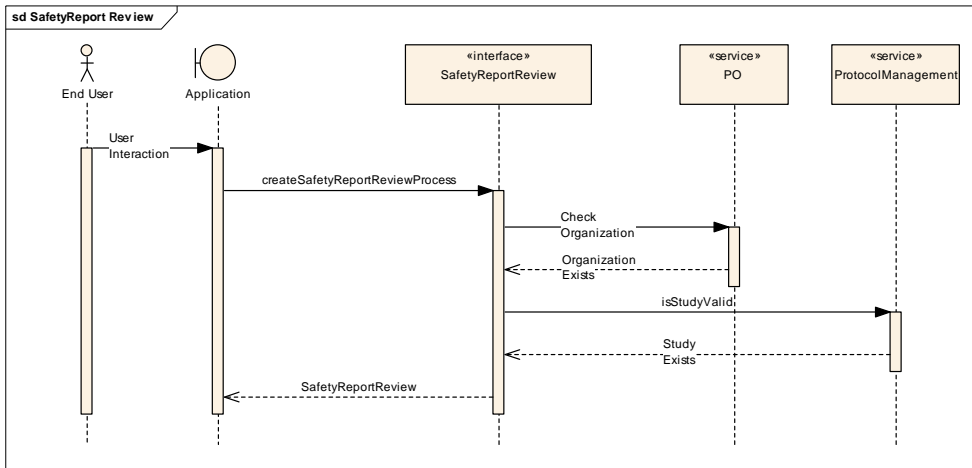## *4.4 Safety Report Definition Management*

4.5 Safety Report Rules Management

4.6 Safety Report Notification

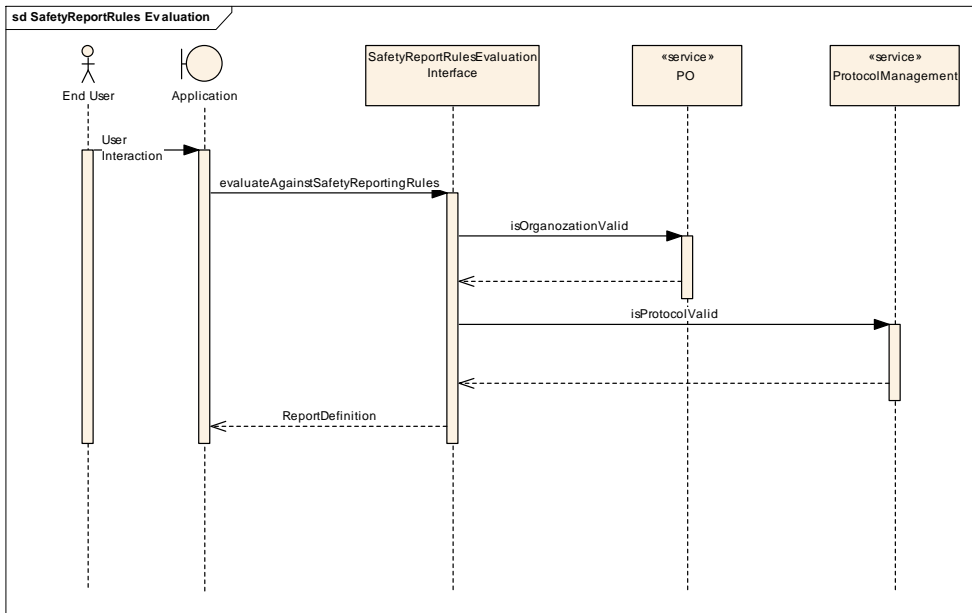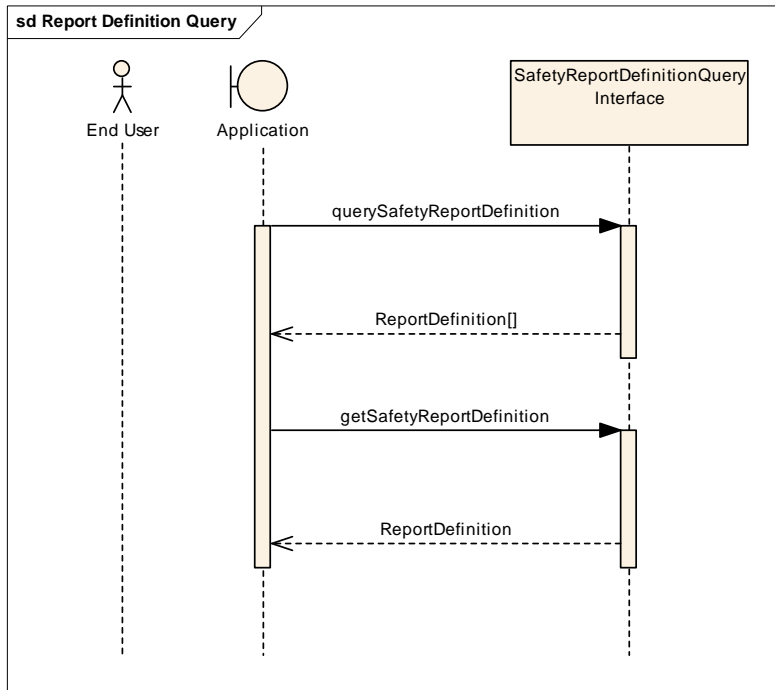## 4.7 Safety Report Review

4.8 Safety Report Advanced Query

4.9 Safety Report Rules Evaluation

4.10 Safety Report Definition Query

5 Profiles

5.1 Functional Profiles

5.1.1

Functional Profile No.	Functional Profile Name	Functional Profile Description
SR-FP1	Safety Report Query	The Safety Report 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.
SR-FP2	Safety Report Management	The Management series of capabilities details the complete encapsulation boundary behind which the Safety Report object may be managed.
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.
SR-FP4	Safety Report Definition Management	The Safety Report Definition functional profile provides the complete encapsulation boundary behind which the Safety

|		Report Definition may be managed.
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.
SR-FP6	Safety Report Notification	The Notification functional profile 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.
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.
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 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.
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.

5.2 Semantic Profiles

Semantic Profile No.	Semantic Profile Name	Constrained Information Model
SR-SP1	BRIDG V3.0 Safety Report	BRIDG V3.0.2

6 Relationship with other services

The following diagram illustrates the positioning of the Safety Report Service within the Clinical Trials business process (at a logical level). The full set of interactions depicted here are beyond the scope of this specification, but the overall intent is to convey the interoperability from safety reporting.
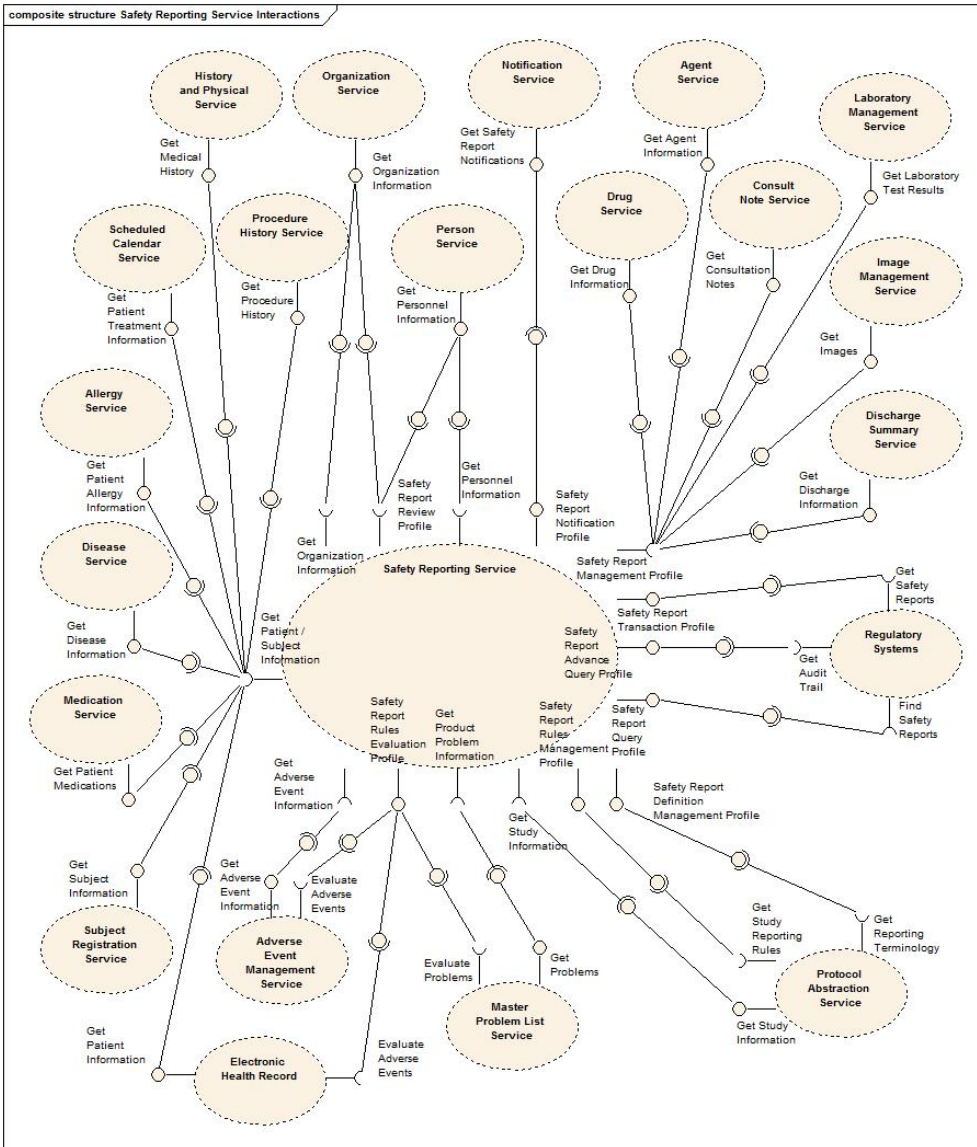
Safety Reporting Component and Dependency Model

Service / System / Actors Name	Dependant / Depends	Data	Description

7 Conformance Statements

No	Name	Type	Viewpoint	Description	Test method
1	Query Performance	Obligation	Engineering	The Safety Report Query Profile should provide a response within 0.5 seconds to support a synchronous UI based client	Test cases to include performance testing.
2	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.
3	Secured Access	Obligation	Engineering	The Safety Reporting service should have access control mechanism in place to restrict access to the secured data	Design review Test cases to be defined for security
4	Additional Functionality	Permission	Computational	The Safety Reporting service can provide additional functionality other than specified in these specifications	1. Design Review
5	Semantic Model	Obligation	Informational	The Safety Reporting service must support NCI's version of BRIDG 3.0.2 model Adverse Event class.	Design Review
6	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 specifications provided in Section 4.	Design Review Test cases

No	Name	Type	Viewpoint	Description	Test method
7	Functional Profiles	Obligation	Computational	A conformant implementation of this specification must deploy at least one Functional Profile. If that Functional Profile has dependencies on other profiles, then those dependencies must be deployed as well to support the provenance of that service instance.	Design Review Test cases
8	Associate Functional Profile	Obligation	Computational	If deployed, the Associate Functional Profile may associate foreign identifiers with local identifiers. Local identifier can be either MRN or any other identifiers which can be used to identify any additional information associated with the Adverse Event such as a specimen, an image or a chart etc.	Test cases
9	Boundary	Obligation	Computational	Implementations of the Management and Query profiles shall be authoritative within an organization's boundaries only, and are not intended to provide an encapsulation boundary that supports different rules or policies regarding the management and access to information regarding a given adverse event focal object.	Test cases
10	Information Authority	Obligation	Computational	Implementations of other profiles may provide access to information external to a given organization's boundary. This shall not imply authority for that information except transitively, and supporting that authority is expected to be supported directly by conformance statements at the	Test cases

No	Name	Type	Viewpoint	Description	Test method
				Platform Independent and Platform Specific levels.	

8 Appendix A - References

Name	Description	Location
NCI's BRIDG v3.0	NCI's BRIDG model used for modeling the AE Service	https://gforge.nci.nih.gov/frs/download.php/7606/BRIDG_Release_3.0_Package.zip
caAERS Use Case Document	Document containing use cases for the caAERS application	https://wiki.nci.nih.gov/display/CTMS/Use+Cases+-+caAERS

9 Appendix B - Glossary

Term	Description
BRIDG	The Biomedical Research Integrated Domain Group (BRIDG) has developed a comprehensive domain analysis model representing biomedical/clinical research.

10 Appendix C - Cross Reference Tables

10.1 Interface to Profile Mapping

Interface No.	Interface	Profile No.	Profile
SR-INF1	SafetyReportQuery	SR-FP1	Safety Report Query
SR-INF2	SafetyReportManagement	SR-FP2	Safety Report Management
SR-INF3	SafetyReportTransaction	SR-FP3	Safety Report Transaction
SR-INF4	SafetyReportDefinitionManagement	SR-FP4	Safety Report Definition Management
SR-INF5	SafetyReportRulesManagement	SR-FP5	Safety Report Rules Management
SR-INF6	SafetyReportNotification	SR-FP6	Safety Report Notification
SR-INF7	SafetyReportReview	SR-FP7	Safety Report Review
SR-INF8	SafetyReportAdvancedQuery	SR-FP8	Safety Report Advanced Query
SR-INF9	SafetyReportRulesEvaluation	SR-FP9	Safety Report Rules Evaluation
SR-INF10	SafetyReportDefinitionQuery	SR-FP10	Safety Report Definition Query