

Platform Specific Service Specification

caBIG®

Safety Reporting Service

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1 Executive Summary:

1.1 Service Description and Purpose

The Service provides a standardized set of interfaces for managing and exposing the Safety Reporting Service. For its representation of the Safety Reporting Service, it uses constrained classes from NCI's version of BRIDG 3.0.2 expressed as XML. The semantics are directly conformant to BRIDG 3.0.2.

1.2 Scope

The scope of this document is limited to the specification of the Safety Reporting Service as a grid service using the WSDL 1.1 standard.

1.3 Relationship to Standards

1.3.1 Domain Standards

Domain Standards	Description
BRIDG v3.0.2	https://cabig.nci.nih.gov/inventory/infrastructure/bridg
HL7v3	http://www.hl7.org
ISO 21090	Health Informatics – Harmonized data types for information interchange

1.3.2 Technology Standards

Standards	Description
Globus Toolkit 4.0.3	GTK is used to develop this WSRF compliant grid service
caGrid 1.3	caGrid version 1.3 for grid service development
XML Schema 1.0	XML schema version 1.0 will be used to define types used to interact with the web service
WSDL 1.1	Web Services Description Language 1.1 will be used to describe the web service.

2 Conformance to Platform Independent Model

2.1 Conformance Profile

This Service implements the BRIDG 3.0.2 conformance profile and the ISO 21090 data type conformance profile.

2.2 Functional Profiles

This Service implements the Safety Reporting Service profiles described in the platform independent model (PIM).

2.3 Semantics

This Service implements the BRIDG V3.0.2-based safety reporting semantic profile from the Platform Independent Model (PIM). The referenced “ISO” package contains NCI’s version of ISO 21090 data types. The element and type names in the XML directly correspond to the types in the Platform Independent Model (PIMSS). The complete WSDL can be located in “3.3.2 WSDL Messages and Port Types.”

3 Platform Specific Model

3.1 Overview

This section details the service payload model and the service interface contract. Schemas for the service message payloads are included. The service interface is described using WSDL snippets and the complete WSDL is in the appendix. This section also provides guidelines for implementing this service.

Standards	Description
NCI’s BRIDG v3.0.2	The service specifications will be based on NCI’s version of the BRIDG model.
NCI’s implementation of ISO 21090 data types	The service specifications will be based on NCI’s restricted implementation of ISO 21090 data types.

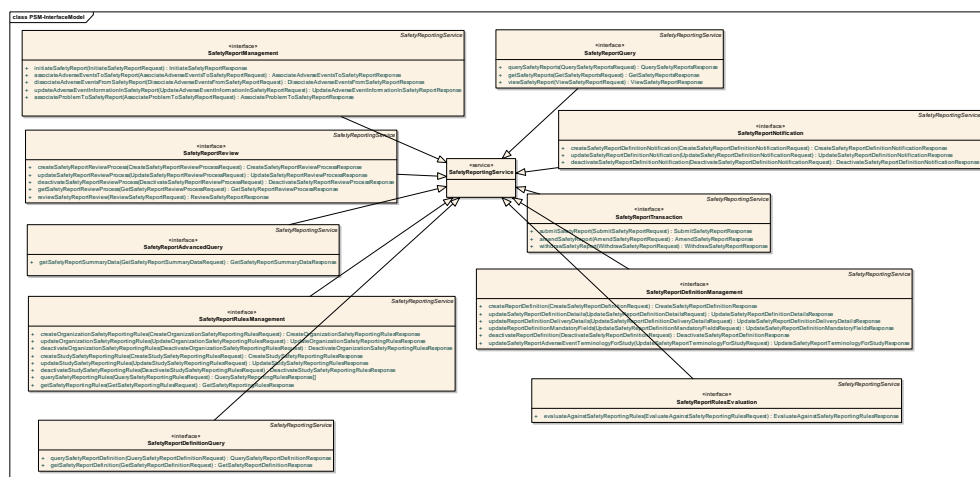
3.2 Assumptions

Assumption	Affects
caGrid1.3	This Service is deployed in the caGrid 1.3 environment.

<p>This Service will require the following supporting services to be in place in order to provide all functionality:</p> <ul style="list-style-type: none"> • Person • Organization • Protocol Abstraction • Adverse Event Management 	<p>If one or more of these dependencies is not met, the Safety Reporting Service interface cannot be used.</p>
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3.3 Service Interface

3.3.1 Interface Model



This service interface consists of all the interfaces and its operations. The service interface details are provided in the following sections.

3.3.2 WSDL Messages and Port Types

The Service shall conform to the messages and port types defined in the WSDL located at the following URLs. Each interface in PIM is represented as service context in the Safety Reporting Grid Service. The purpose of a service context is to provide operations for a given context.

Description	URL
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Safety Reporting Service WSDL (Primary Service)	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportingEnterpriseService.wsdl
Safety Report Query Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportAdvancedQuery.wsdl
Safety Report Management Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportManagement.wsdl
Safety Report Transaction Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportTransaction.wsdl
Safety Report Definition Management Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportDefinitionManagement.wsdl
Safety Report Rules Management Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportRulesManagement.wsdl
Safety Report Notification Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportNotification.wsdl
Safety Report Review Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportReview.wsdl
Safety Report Advanced Query Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportAdvancedQuery.wsdl
Safety Report Rules Evaluation Service Context	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/

WSDL	schema/SafetyReportingEnterpriseService/SafetyReportRulesEvaluation.wsdl
Safety Report Definition Query Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SafetyReportDefinitionQuery.wsdl
Safety Reporting Service XML Schema	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/SR-PSM.xsd
ISO 21090 Healthcare Data Types	https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/ISO_datatypes_Narrative.xsd

3.4 Operations Details

All classes named with the prefix ISO: are defined in the ISO 21090 health care data types which can be found here at:

https://ncisvn.nci.nih.gov/svn/caaersappdev/trunk/caAERS/software/grid/introduce/SafetyReportingEnterpriseService/schema/SafetyReportingEnterpriseService/ISO_datatypes_Narrative.xsd

All other inputs and outputs in this section are described in the XSD document referred to in the operation's input and output table entries.

3.4.1 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]	QuerySafetyReportsRequest is a wrapper object which contains.

	- BRIDG:SafetyReportVersion
Outputs [M]	QuerySafetyReportsResponse is a wrapper object contains DSET_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]	GetSafetyReportsRequest is a wrapper object contains : - DSET_II (BRIDG:DocumentIdentifier.identifier)
Outputs [M]	GetSafetyReportsResponse wrapper object contains DSET_SafetyReportVersion
Post-Conditions [O]	
Exception Conditions [M]	Safety Report Identifier is invalid
Aspects left for Technical Bindings [O]	

Notes [O]	
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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]	ViewSafetyReportRequest is a wrapper object contains <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:ST (Desired Viewing Format)
Outputs [M]	ViewSafetyReportResponse is a wrapper object contains 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]	

3.4.2 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

	<p>safety report creation.</p> <p>If successful, a properly formed Safety Report object with an identifier is returned as an acknowledgement that the Safety Report is initiated.</p>
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]	<p>ISO:II (BRIDG:StudyVersion.identifier)</p> <p>ISO:II (BRIDG:Subject.identifier)</p> <p>ISO:II (Patient Identifier)</p> <p>DSET<ISO:II> (BRIDG:AdverseEvent.identifier)</p> <p>DSET<ISO:II >(BRIDG:PerformedProductInvestigationResult.identifiedIdentifier)</p>
Outputs [M]	BRIDG:SafetyReportVersion
Post-Conditions [O]	A safety report is initiated on the system
Exception Conditions [M]	<p>The Report Definition Identifier is invalid.</p> <p>Any of the optional inputs are invalid.</p> <p>The Subject Identifier is invalid for the provided Study Identifier.</p> <p>The Subject Identifier is invalid for the provided Patient Identifier.</p>
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	Safety Report Identifier is invalid

Conditions [M]	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.
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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: <ul style="list-style-type: none"> - 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.
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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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) Conditional: <ul style="list-style-type: none"> - 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

	<p>on the report.</p> <p>Patient Identifier is invalid</p> <p>Person Identifier is invalid</p>
Aspects left for Technical Bindings [O]	
Notes [O]	<p>This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.</p>

Name [M]	dissociateStudyFromSafetyReport
Description [M]	Provides the capability to dissociate a study from a safety report.
Pre-Conditions [M]	<p>The Safety Report record exists.</p> <p>The Study is associated to the Safety Report.</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:StudyVersion. Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - ISO:ST (Reason for the dissociation)
Outputs [M]	BRIDG:SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Study Identifier is invalid</p>
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: <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:Person.identifier) Optional: <ul style="list-style-type: none"> - 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - 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]	<p>Safety Report Identifier is invalid.</p> <p>Adverse Event Identifier is invalid.</p> <p>Production Problem Identifier is invalid.</p>
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: <ul style="list-style-type: none"> - 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-	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: <ul style="list-style-type: none"> - 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 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]	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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:Person.identifier or BRIDG:StudySubject Identifier or BRIDG:Person Identifier) Optional: <ul style="list-style-type: none"> - BRIDG:PerformanceClinicalResult.result (Baseline Performance) - BRIDG:PerformanceCLinicalResult.result (Height) - BRIDG:PerformanceCLinicalResult.result (Weight)

Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Patient Identifier is invalid</p> <p>Study Subject Identifier is invalid</p> <p>Report Person Identifier is invalid</p> <p>Clinical Attributes are invalid</p> <p>Clinical Attribute Values are invalid</p>
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]	<p>The Safety Report record exists.</p> <p>The Patient is associated to the Safety Report.</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:Person.identifier) <p>Optional:</p> <ul style="list-style-type: none"> - BRIDG:PerformedDiagnosis <p>(Disease History Attributes (i.e. primary disease, primary site of disease, initial date of diagnosis, metastatic sites of disease, pre-existing conditions))</p>

	Disease History Attribute Values)
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Report Patient Identifier is invalid</p> <p>Disease History Attributes are invalid</p> <p>Disease History Attribute Values are invalid</p>
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]	<p>The Safety Report record exists.</p> <p>The Patient is associated to the Safety Report.</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (BRIDG:Person.identifier (Report Patient Identifier)) <p>Optional:</p> <ul style="list-style-type: none"> - 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]	<p>Safety Report Identifier is invalid</p> <p>Report Patient Identifier is invalid</p> <p>Concomitant Medication Attributes are invalid</p> <p>Concomitant Medication Attribute Values are invalid</p>
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]	<p>The Safety Report record exists.</p> <p>The Patient is associated to the Safety Report.</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II BRIDG:Person.identifier (Report Patient Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - 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]	<p>Safety Report Identifier is invalid</p> <p>Report Patient Identifier is invalid</p> <p>Prior Therapy Attributes are invalid</p> <p>Prior Therapy Attribute Values are invalid</p>
Aspects left for Technical Bindings [O]	
Notes [O]	<p>This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.</p>

Name [M]	updatePatientDemographicsInSafetyReport
Description [M]	Provides the capability to update patient demographics in the safety report.
Pre-Conditions [M]	<p>The Safety Report record exists.</p> <p>The Patient, Study Subject, or Report Person is associated to the Safety Report.</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II BRIDG:Person.identifier (Report Patient Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - BRIDG:Person <p>(Patient Demographic Attributes (i.e. sex, race, ethnicity, DOB)</p> <p>Patient Demographic Attribute Values)</p>

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: <ul style="list-style-type: none"> - 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]	<p>This operation depends on Safety Report Query Profile to retrieve the Safety Report object in order to allow a service consumer to update it.</p> <p>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.</p>

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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:HealthcareProvider
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Healthcare Provider Identifier is invalid</p> <p>Healthcare Provider Attributes are invalid</p> <p>Healthcare Provider Attribute Values are invalid</p>

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

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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:ReportSubmitter
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Submitter Identifier is invalid</p> <p>Submitter Attributes are invalid</p> <p>Submitter Attribute Values are invalid</p>
Aspects left for	

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

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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - BRIDG:PerformedProductInvestigationResult
Outputs [M]	BRIDG: SafetyReportVersion.
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Product Problem Identifier is invalid</p> <p>Product Problem Attributes are invalid</p> <p>Product Problem Attribute Values are invalid</p>
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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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-	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this

Conditions [M]	capability.
Inputs [M]	Mandatory: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.

3.4.3 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: <ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (ReportDefinition Identifier) -
Outputs [M]	
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]	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: <ul style="list-style-type: none"> - 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.
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Name [M]	withdrawSafetyReport
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]	<ul style="list-style-type: none"> - ISO:II (BRIDG:DocumentIdentifier.identifier) - ISO:II (ReportDefinition.Identifier) -
Outputs [M]	
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Withdrawer Identifier is invalid</p>
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.

3.4.4 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Safety:ReportDefinition (Safety Report Definition Object with all basic detail attributes and values to update)
Outputs [M]	

Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Definition Identifier is invalid</p> <p>Safety Report Definition Basic Detail Attributes are invalid</p> <p>Safety Report Definition Basic Detail Attribute Values are invalid</p>
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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - Safety:ReportDefinition (Safety Report Definition Object with all delivery detail attributes and values to update)
Outputs [M]	
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Definition Identifier is invalid</p> <p>Safety Report Definition Delivery Attributes are invalid</p> <p>Safety Report Definition Delivery Attributes Values are invalid</p>
Aspects left for	Determination of method for Safety Report Definition

Technical Bindings [O]	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: <ul style="list-style-type: none"> - 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (Safety:ReportDefinition.Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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.

3.4.5 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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Safety:ReportingRule (populated Safety Reporting Rules Object) - ISO:II (BRIDG: Organization Identifier)
Outputs [M]	<ul style="list-style-type: none"> - 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - BRIDG:Organization.identifier (Safety Reporting Rules Organization Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - ISO:ST (Reason for deactivating the Safety Reporting Rules)
Outputs [M]	<ul style="list-style-type: none"> - 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
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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: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - Safety:ReportingRule (populated Safety Reporting

	Rules Object) <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - ISO:II (BRIDG:StudyVersion Identifier) ISO:II (BRIDG:Organization Identifier)Optional: <ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - 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]	

3.4.6 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 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: <ul style="list-style-type: none"> - 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (Safety: SafetyReportDefinitionNotification.Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - 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.

3.4.7 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - Safety:SafetyReportReview - ISO:II (Safety:SafetyReportDefinition Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:Organization Identifier) - ISO:II (BRIDG:StudyVersion Identifier)
Outputs [M]	<ul style="list-style-type: none"> - Safety:SafetyReportReview
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Review Object is invalid</p> <p>Safety Report Definition Identifier is invalid</p> <p>Organization Identifier is invalid</p> <p>Study Identifier is invalid</p>
Aspects left for Technical Bindings [O]	<p>Method of identification of Safety Report Definition.</p> <p>Method of identification of Safety Report Review Process.</p>
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: <ul style="list-style-type: none"> - Safety:SafetyReportReview Optional: <ul style="list-style-type: none"> - ISO:II (BRIDG:Organization Identifier) - ISO:II (BRIDG:StudyVersion Identifier)
Outputs [M]	<ul style="list-style-type: none"> - Safety:SafetyReportReview
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]	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: <ul style="list-style-type: none"> - ISO:II (Safety:SafetyReportReview.Identifier) Optional: <ul style="list-style-type: none"> - ISO:ST(Reason for deactivation)
Outputs [M]	<ul style="list-style-type: none"> - 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: <ul style="list-style-type: none"> - ISO:II (Safety:SafetyReportReview. Identifier) -
Outputs [M]	<ul style="list-style-type: none"> - 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]	
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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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (Safety:SafetyReportReview.Identifier) - ISO:ST (Review Disposition) - ISO:II (BRIDG:Person(Reviewer) Identifier) - ISO:TsDateTime(Date / Time of Review) <p>Optional:</p> <ul style="list-style-type: none"> - ISO:ST (Comments regarding review)
Outputs [M]	<ul style="list-style-type: none"> - Safety:SafetyReportReview <p>.</p>
Post-Conditions [O]	
Exception Conditions [M]	<p>Safety Report Identifier is invalid</p> <p>Review Disposition is invalid</p> <p>Reviewer Identifier is invalid</p> <p>Date / Time of Review is invalid</p> <p>Review comments are invalid</p>
Aspects left for Technical Bindings [O]	
Notes [O]	

3.4.8 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: <ul style="list-style-type: none"> - 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]	

3.4.9 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]	<p>Mandatory:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:Adverse Event Identifier or - Product Problem Identifier) <p>Optional:</p> <ul style="list-style-type: none"> - ISO:II (BRIDG:StudyVersion Identifier) - ISO:II (BRIDG:Organization Identifier)
Outputs [M]	Safety:ReportDefinition[]
Post-Conditions [O]	
Exception Conditions [M]	<p>Adverse Event Identifier is invalid</p> <p>Product Problem Identifier is invalid</p> <p>Study Identifier is invalid</p> <p>Organization Identifier is invalid</p>

3.4.10 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]	

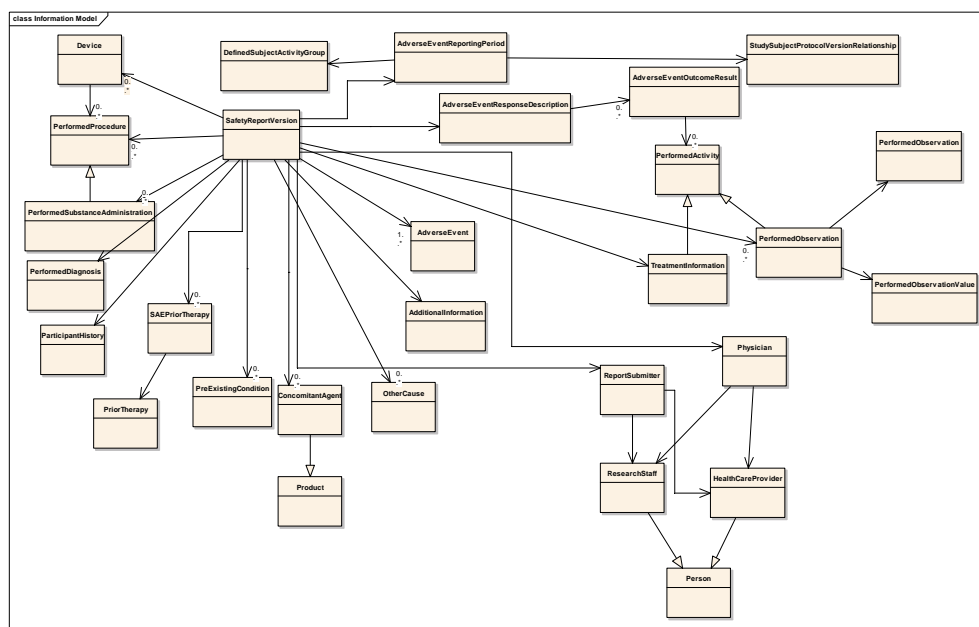
Name [M]	getSafetyReportDefinition
Description [M]	Provides the capability to get a safety report definition.
Pre-Conditions [M]	The Safety Report Definition record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise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

3.5 Message Information Model

Communication protocol of the Referral Service is chosen to be SOAP 1.1, so all messages of the service will contain appropriate SOAP envelope and will conform to this protocol standard.

3.5.1 Information Model

The platform for this PSM is chosen to be Java, thus Platform Independent Model presented in the PIMSS specification document is transformed into the Java Platform Specific Model. The Java PSM class diagram is shown in the following diagram.



3.6 Service Interactions

The Adverse Event Service interacts with other enterprise services.

3.6.1 Interaction Details

Service / System / Actors Name	Dependent / Depends	Data	Description
Protocol Management	Dependent	Study	Adverse Event Service relies on Protocol

		Information	Management Service to retrieve study information and ensure that the study exists
Subject Registration Service	Dependent	Subject Information	The Adverse Event Service relies on the Protocol Management Service to retrieve subject information and that subject is registered with the study
Coding Service	Dependent	Coding Information	The Adverse Event Service relies on the Coding Service for automatic coding of the adverse events
CDMS	Depends	AE Information	CDMS initiated adverse event, which will be stored in the Adverse Event Service
Lab Management Systems	Depends	AE Information	Lab Management Systems initiated adverse event, which will be stored in the Adverse Event Service
Patient Care Systems	Depends	AE Information	Patient Care Systems initiated adverse event, which will be stored in the Adverse Event Service
NCI (CTEP)	Depends	AE Reports	The Adverse Event Service provides adverse event-related reports for NCI (CTEP) reporting
FDA	Depends	AE Reports	The Adverse Event Service provides adverse event-related reports for FDA reporting
IRB	Depends	AE Reports	The Adverse Event

			Service provides adverse event-related reports for IRB reporting
Sponsor	Depends	AE Reports	The Adverse Event Service provide adverse event-related reports for sponsor reporting

3.7 Implementation Considerations

3.7.1 Security

The Service will be deployed in a secure https environment. Thus, client/server communication itself will be secured. Also, the Service will be deployed on a caGrid container that requires caBIG-style authentication.

Access Control	
Does the Service require the access control mechanism to be in place to restrict access to only authenticated users or systems?	Yes
If Yes, then provide the following in detail:	
1) Users need to get provisioned by an IdP in the production trust fabric 2) caGrid X509 certificates	
Application (Service) Security [Access Policy]	
Does the Service incorporate any security controls (authorization) to ensure that access to information is granted to only the authorized users / systems?	Yes
If Yes, then provide the following in detail: Under lying implementation uses caAERS authorization , more information can be found here https://wiki.nci.nih.gov/display/caAERS/Security++Content+Filtering+Design ,	

Comment [BG1]: Provide information describing how this will be accomplished.

Cryptography	
Does the Service require encryption of data transmitted to and from it?	Yes
If <i>Yes</i> , then provide the following in detail:	
1) Use standard caGrid encryption	
Information Security and Risk Management	
Is the information served by the Service confidential or privileged? And if <i>yes</i> , is it at risk from any external threats or vulnerabilities?	No
If <i>Yes</i> , then provide the following in detail:	
Legal, Regulations, Compliance and Investigations	
Does the information served by the Service fall under any legal / regulatory compliance either at federal, state, local or institutional level ?	No
If <i>Yes</i> , then provide the following in detail:	
Telecommunications and Network Security	
Does the Service need any network or transport level security such as SSL, Firewall protection, etc.?	Yes
If <i>Yes</i> , then provide the following in detail:SSL	



3.7.2 Auditing

Operation Name	Auditing Details
Create/Update/Delete	<p>All operations will be audited using the AdverseEvent Management Service. Each table has four audit columns:</p> <ul style="list-style-type: none"> • Create by • Date created • Updated by • Date last updated

3.7.3 Privacy

CTRP / NES does not contain any information that is consider Personally Identifiable Information (PII). Clinical investigators who conduct NIH-supported clinical research and their research administrative designees will be asked to register online and provide work related information. They will be assigned a unique identifier in order to search and view clinical trial details. The system was designed to retrieve an investigator's name, but the name does not link to any personally identifiable information. An HHS Privacy Impact Assessment performed on the NIH NCI Clinical Trials Reporting Program determined that there is no PII in the system; therefore, the Privacy Act does not apply to CTRP data collection.

The CTRP PIA is available at

[https://gforge.nci.nih.gov/svnroot/coppa/trunk/documents/project_management/CTRP_program_management/Policy/PIA/06_1HHS Privacy Impact Assessment-NIH NCI Clinical Trials Reporting Program CTRP.doc](https://gforge.nci.nih.gov/svnroot/coppa/trunk/documents/project_management/CTRP_program_management/Policy/PIA/06_1HHS%20Privacy%20Impact%20Assessment-NIH%20NCI%20Clinical%20Trials%20Reporting%20Program%20CTRP.doc)

As confirmation, the NIH Privacy Act Officer issued a memo to John Speakman, Product Owner of CTRP, stating that the Privacy Act does not apply.

The memo is available at

https://gforge.nci.nih.gov/svnroot/coppa/trunk/documents/project_management/CTRP_program_management/Policy/PIA/CTRP-Privacy-Memo.doc

3.7.4 Error Handling

Subclasses of Globus BaseFaultType are instantiated and thrown in case of errors along with user-friendly error messages. Java exceptions are translated into SOAP faults correspondingly by globus runtime.

3.8 Deployment Details

Deployment Details	Impact
Deployment Modes	caGrid 1.3 environment

3.8.1 Performance

The table below lists, per operation, the maximum average performance conformant implementations must meet, under the load given in the next section. Times are expressed in seconds and should be measured using clients on networks local to the deployed services. Roundtrip times are for full message delivery but do not include network latency or client serialization/de-serialization overhead.

Operation	Maximum Average Roundtrip
CRUD operations	< 5.0s
Query Operations	< 30s

3.8.2 Scalability

Conformant services will support the performance metrics described in the previous section under a sustained maximum load of two requests per second. The requests should be a random mix of the available operations.

3.8.3 Discovery

The service posts all specifications in a WSDL and is accessible via web service endpoints. There will be global and local registries, such as globus Index service, that list available service providers in the context of further metadata aiding the discovery of relevant services. Clients can invoke the web service via caGrid service client.

3.8.4 Uptime

The expected uptime for this service is to be 99.9% during the local business hours for the deployment context.

3.8.5 Failover

Failover should be provided for endpoints in the case of failing server software (servlet container, database) or hardware. Recommended is a second server (hardware) that can either be switched in when the primary hardware fails or concurrently deployed in a load balancing setup.

3.9 Constraints

Constraints	Impact
None	

4 Recommendations for Conformance and Compliance

4.1 Conformance Assertions

	Type	Viewpoint	Description	Test method
NCI's Version of BRIDG 3.0.1 Conformant	Obligation	Informational	The semantics of the adverse event representation are directly conformant to BRIDG 3.0.1.	1. Design Review 2. Inspection of WSDL and XSD
ISO 21090 Data Type Conformant	Obligation	Informational	The attributes of the adverse event class use ISO 21090 data types as defined in the referenced PIM_21090 document, as represented by the ISO 21090 XSD.	1. Design Review 2. Inspection of WSDL and XSD
Observable Behavior	Prohibition	Computational	Service clients are prohibited from making any assumptions based on the internal implementation details of the Service. As a corollary, all observable behavior must be made explicit in the Service specification.	1. Design Review 2. Change of implementation does not affect clients
Functional Profile	Obligation	Computational	All functional profiles must be implemented.	1. Design review 2. Inspection of WSDL and XSD
Operations Required	Obligation	Computational	Designers/implementers are obligated to implement all of the operations of both identified functional profiles.	1. Test cases include all identified operations
Information Model Conformance	Obligation	Information	The Information Model representation will conform to the Information Model provided in Section 3.5.1.	1. Design Review 2. Test cases to be defined to test specified Information Model

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	Type	Viewpoint	Description	Test method
				conformance
Multiple Jurisdictions	Obligation	Enterprise	Implementers will provide an implementation that supports multiple jurisdictional domains to support different coordinating centers and sites, as well as multi-site trials.	1. Test cases include multiple domain scenarios
Query Performance	Obligation	Enterprise	The performance of the query operations operation should be within 0.2 second to return a single record from the underlying database.	1. Test cases to include performance testing
Auditing	Obligation	Engineering	Designers/implementers are obligated to decide on and document the approach for logging or auditing of operation calls.	1. Design Review

5 Appendix A - Relevant Standards

Name	Description	Location
NCI's BRIDG v3.0.2	NCI's BRIDG model used for modeling the AE Management Service	http://gforge.nci.nih.gov/frs/download.php/8831/BRIDG_Release_3.0.2_Package.zip
Use Case Document	Document containing use cases for the caAERS application	Please add Links.
Adverse Event Service PIMSS	Platform Independent Model and Service Specification for Adverse Event Service	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/docs/PIMSS/PIMSS_Adverse_Event_Service_0.5.3.doc
PIM_21090.doc	ISO 21090 data types	https://gforge.nci.nih.gov/svnroot/coppa/trunk/documents/analysis_and_design/PIM_21090.doc

6 Appendix B – Relevant Standards

Please refer to the Section **Error! Reference source not found.** of this document.

7 Appendix C – Glossary

Please refer to the caBIG shared glossary located at <https://wiki.nci.nih.gov/display/Suite/10+-+Glossary+v2.2>.

Appendix B - Glossary

Term	Description
BRIDG	The <u>B</u> iomedical <u>R</u> esearch <u>I</u> ntegrated <u>D</u> omain <u>G</u> roup (BRIDG) has developed a comprehensive domain analysis model representing biomedical/clinical research.
COPPA	NCI's Enterprise Services of <u>C</u> orrelation, <u>O</u> rganization, <u>P</u> erson and <u>P</u> rotocol <u>A</u> bstraction.