caBIG® Platform Specific Model and Service Specification

Adverse Event Management Service

Grid Service

Version 1.0

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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 Adverse Event Service. For its representation of the Adverse Event 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 Adverse Event 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 Adverse Event Management Service profiles described in the platform independent model (PIM).

2.3 Semantics

This Service implements the BRIDG V3.0.2-based adverse event management 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."

Platform-specific representation of a few important classes is detailed in the following sections.

2.3.1 Adverse Event Semantics

This service directly implements the semantics of Adverse Event as referenced here: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.2 Study Semantics

This service directly implements the semantics of Study as referenced here: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.3 StudySubject Semantics

This service directly implements the semantics of StudySubject as referenced here: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.4 Document Identifier Semantics

This service directly implements the semantics of Document Identifier as referenced here:

https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.5 Document Semantics

This service directly implements the semantics of Document as referenced here: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.6 PerformedActivity Semantics

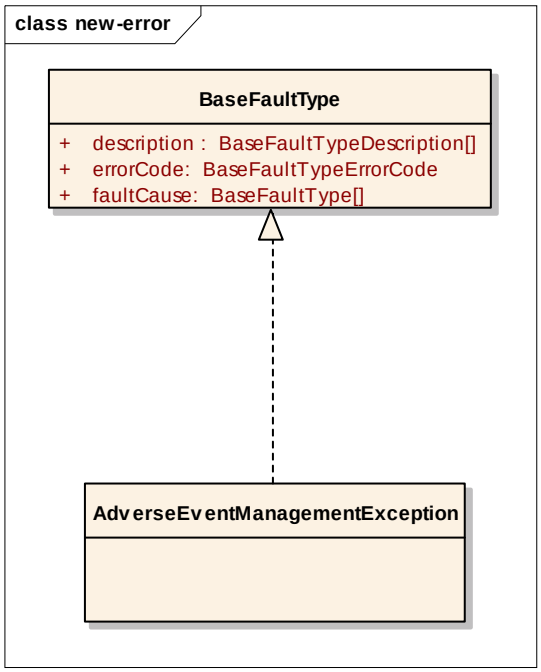
This service directly implements the semantics of PerformedActivity as referenced here: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd. The referenced "ISO" package contains ISO 21090 data types and is omitted for brevity. The element and type names in the XML directly correspond to the types in PIMSS.

2.3.7 Return Value Semantics

Any SOAP reply that does not contain a fault and contains HTTP 200 OK code is to be considered a successful acknowledgement of the service operation. Any service operation that does not return a SOAP reply is to be considered successfully executed if it returns HTTP 200 OK or 202 Accepted status code.

2.3.8 Error Handling Semantics

At the logical level described in PIMSS, the Adverse Event Management Service throws a single exception AdverseEventManagementException with attributes for description, errorCode, and faultCause.



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.

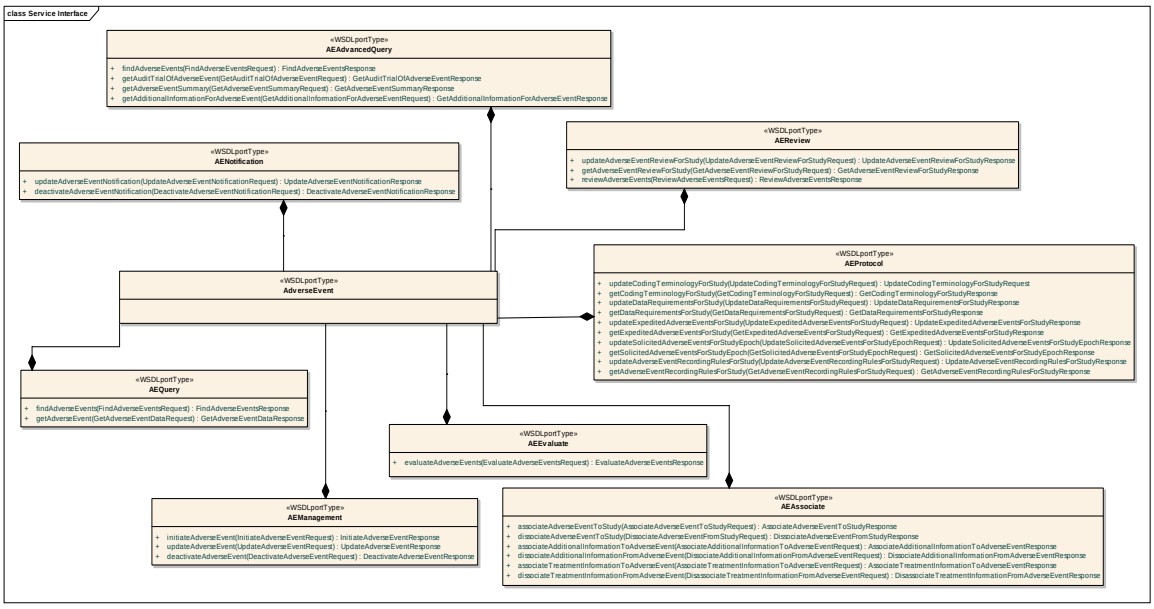
3.2 Assumptions

Assumption	Affects

caGrid1.3	This Service is deployed in the caGrid 1.3 environment.
This Service will require the following supporting services to be in place in order to provide all functionality: • Person • Organization • Protocol Abstraction	If one or more of these dependencies is not met, the Adverse Event Service interface cannot be used.

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 Adverse Event Grid Service. The purpose of a service context is to provide operations for a given context.

Description	URL
Adverse Event Service WSDL (Primary Service)	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/AdverseEventService.wsdl
AE Query Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Query.wsdl
AE Advanced Query Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/AEAdvancedQuery.wsdl
AE Associate Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/AEAssociate.wsdl
AE Evaluate Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Evaluate.wsdl
AE Management Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Management.wsdl
AE Notification Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Notification.wsdl
AE Protocol Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Notification.wsdl
AE Review Service Context WSDL	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/Review.wsdl
Adverse Event Service XML Schema	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/AE-PSM.xsd
ISO 21090 Healthcare Data Types	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/xsd-1.0/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/docs/DesignDocs/essn/AdverseEventService/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 Query Service Context

This interface provides operations to find and retrieve adverse events.

3.4.1.1 AE-INF1-OP1 : findAdverseEvents

Behavior Description	Query by Example model of querying and will retrieve all adverse events that match the input AdverseEvent attributes with search limit offset.
Pre-Conditions	
Security Conditions	The requestors • Must be an AE reporter
Inputs	FindAdverseEventsRequest is a wrapper object that contains a BRIDG:AdverseEvent which may be a fully or partially populated instance of an AdverseEvent object. This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	FindAdverseEventsResponse is a wrapper object that contains a BRIDG:AdverseEvent[ ] which is a collection of Adverse Event objects matching the specified criteria. This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	No
Exception Conditions	• Values of all mandatory attributes for the Adverse Event Class have not been provided • Invalid Adverse Event

Additional Details	Empty collection will be returned if no adverse events are found
Notes	

3.4.1.2 AE-INF1-OP2 : getAdverseEventData

Behavior Description	Retrieves an entire adverse event based on the specified adverse event identifier(s)
Pre-Conditions	Adverse events exists
Security Pre-Conditions	The requestors • Must be an AE reporter
Inputs	GetAdverseEventDataRequest is a wrapper that contains DSET<ISO:II> which is an array of Adverse Event identifiers. These identifiers are defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	GetAdverseEventDataResponse is a wrapper that contains a BRIDG:AdverseEvent[ ] which is an array of Adverse Event objects matching the specified criteria This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier
Additional Details	Only adverse event objects for matched identifiers are returned
Notes	

3.4.2 Management Service Context

This interface facilitates functionality for managing the adverse events.

3.4.2.1 AE-INF2-OP1 : initiateAdverseEvent

Behavior Description	Allows initiation of adverse event and associates with study and subject
Pre-Conditions	BRIDG:StudySubject object exists
Security Pre-Conditions	The requestors • Must be an adverse event reporter
Inputs	InitiateAdverseEventRequest is a wrapper object which contains the following objects: • BRIDG:AdverseEvent and instances of its aggregation/composition classes with the mandatory attributes filled and desired optional attributes provided. • ISO : II which is the StudySubject identifier. This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	InitiateAdverseEventResponse is a wrapper object that contains a BRIDG: AdverseEvent instance of adverse event class. This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditio	An adverse event is initiated and the business process is started to report the

ns	adverse event
Exception Conditions	Invalid Study protocol Invalid Study participant Invalid Adverse Event Subject not found for the given identifier **Study not found for the given identifier**
Additional Details	Not all attributes of the AdverseEvent class need to be provided to initiate an adverse event
Notes	

3.4.2.2 AE-INF2-OP2 : updateAdverseEvent

Behavior Description	Allows updating adverse event attributes
Pre-Conditions	Adverse event exists
Security Pre-Conditions	The requestors • Must be an adverse event reporter
Inputs	UpdateAdverseEventRequest is a wrapper object that contains a BRIDG:AdverseEvent object and instances of its associated classes with required attributes filled and with optional attributes filled optionally. Identifier is required for update. NOTE: You will need to provide values for all the existing attributes along with the changed ones to avoid them from being nullified This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	UpdateAdverseEventRequest is a wrapper object that contains a BRIDG:AdverseEvent updated instance of adverse event. This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-

	PSM.xsd.
Post-Conditions	Adverse event is updated
Exception Conditions	Invalid Adverse Event Adverse event is not found for the given identifier
Additional Details	If identifier is unique, only one adverse event should be found.
Notes	

3.4.2.3 AE-INF2-OP3 : deactivateAdverseEvent

Behavior Description	Deactivates adverse event
Pre-Conditions	Adverse event exists
Security Pre-Conditions	The requestors • Must be an adverse event reporter
Inputs	DeactivateAdverseEventRequest is a wrapper object that contains an ISO : II (AdverseEvent Identifier)
Outputs	DeactivateAdverseEventResponse is a wrapper object that contains a BRIDG:AdverseEvent This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	Adverse Event is deactivated and the status flag is updated from ACTIVE to INACTIVE
Exception Conditions	If adverse event is already inactive, no action is taken. Adverse event is not found for the given identifier Invalid AdverseEvent

Additional Details	Update adverse event status flag
Notes	

3.4.3 Associate Service Context

This interface provides operations to associate multiple adverse events together for study purpose and dissociate multiple events that were previously associated.

3.4.3.1 AE-INF3-OP1 : associateAdverseEventToStudy

Behavior Description	Associates an adverse event record to a study
Pre-Conditions	• Specified adverse event exists • Specified study exists
Security Pre-Conditions	The requestor • Must be a clinical data coordinator or some equivalent associated with the study
Inputs	AssociateAdverseEventToStudyRequest is a wrapper object that contains the following: • ISO : II (adverse event identifier) • ISO : II (study protocol identifier)
Outputs	AssociatedAdverseEventToStudyResponse is a wrapper object that contains no content.
Post-Conditions	Adverse event is associated to study
Exception Conditions	Adverse event is not found for the given identifier Study not found for the given identifier Invalid Adverse Event Identifier Invalid Study Identifier * If AE is already associated to Study , No action taken .

Additional Details	
Notes	

3.4.3.2 AE-INF3-OP2 : dissociateAdverseEventFromStudy

Behavior Description	Removes association between an adverse event record and a study
Pre-Conditions	• Specified adverse event exists • Specified study exists • Adverse event record is associated to the study
Security Pre-Conditions	The requestor • Must be a clinical data coordinator or some equivalent associated with the study
Inputs	DissociateAdverseEventFromStudyRequest which is a wrapper object that contains the following: • ISO : II (adverse event identifier) • ISO : II (study protocol identifier)
Outputs	DissociateAdverseEventFromnStudyResponse which is a wrapper object that contains no content.
Post-Conditions	Adverse event is dissociated from study
Exception Conditions	• Adverse event is not found for the given identifier Invalid Study protocol
Additional Details	
Notes	

3.4.3.3 AE-INF3-OP3 : associateAdditionalInformationToAdverseEvent

Behavior Description	Associates an adverse event to additional information
Pre-Conditions	Specified adverse event exists
Security Pre-Conditions	The requestor • Must be a clinical data coordinator or some equivalent associated with the study
Inputs	AssociateAdditionalInformationToAdverseEventRequest is a wrapper object which contains the following: • ISO : II (AdverseEvent Identifier) • AE : Additional Information This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	AssociateAdditionalInformationtoAdverseEventResponse which is a wrapper object that contains no content.
Post-Conditions	Additional information is associated to adverse event
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.4.3.4 AE-INF3-OP4 : dissociateAdditionalInformationFromAdverseEvent

Behavior Description	Removes association between an adverse event and additional information

Pre-Conditions	• Specified adverse event exists • Association with specified AdditionalInformation exists
Security Pre-Conditions	The requestor • Must be a clinical data coordinator or some equivalent who are associated with the study
Inputs	DissociateAdditionalInformationFromAdverseEventRequest is a wrapper object that contains the following: • ISO: II (adverse event identifier) • ISO: II (additional information identifier)
Outputs	DissociateAdditionalInformationFromAdverseEventResponse is a wrapper object that contains no content.
Post-Conditions	AdditionalInformation is dissociated from adverse event
Exception Conditions	• Adverse event is not found for the given identifier Association not found for the specified adverse events
Additional Details	
Notes	

3.4.3.5 AE-INF3-OP5 : associateTreatmentInformationToAdverseEvent

Behavior Description	Creates the association between the adverse event and the information regarding what the subject was treated with in relation to the presentation of the adverse event.
Pre-Conditions	• Specified adverse event exists • Treatment information exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	AssociateTreatmentInformationToAdverseEventRequest is a

	wrapper object that contains the following: • ISO : II (BRIDG:AdverseEvent Identifier) • ISO : II (BRIDG:Activity.identifier)
Outputs	AssociateTreatmentInformationToAdverseEventResponse is a wrapper object that contains no content.
Post-Conditions	TreamentInformation is associated to adverse event
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier * No action taken if associated already exists .
Additional Details	
Notes	

3.4.3.6 AE-INF3-OP6 : disassociateTreatmentInformationFromAdverseEvent

Behavior Description	Removes the association between an adverse event and the subject treatment information
Pre-Conditions	• Specified adverse event exists • The association exists between the subject treatment information and the adverse event record
Security Pre-Conditions	The requestor • Must be an adverse even reporter
Inputs	DissociateTreatmentInformationFromAdverseEventRequest is a wrapper object that contains the following: • ISO : II (AdverseEvent Identifier) • ISO : II (Activity.identifier)

Outputs	DissociateTreatmentInformationFromAdverseEventResponse is a wrapper object that contains not content.
Post-Conditions	Treatment information is dissociated from adverse event
Exception Conditions	• Adverse event is not found for the given identifier Association not found for the specified adverse events • Invalid Identifier
Additional Details	
Notes	

3.4.4 Notification Service Context

This interface provides operations to notify other systems and services based upon updates to adverse events.

3.4.4.1 AE-INF4-OP1 : updateAdverseEventNotification

Behavior Description	Updates the notification rule (adverse event criteria on which a notification should be triggered)
Pre-Conditions	
Security Pre-Conditions	The requestor • Must be a study data manager
Inputs	UpdateAdverseEventNotificationRequest is a wrapper object that contains the following: • AERule This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	UpdateAdverseEventNotificationResponse is a wrapper object that contains the following: DSET<BRIDG : AdverseEvent >

Post-Conditions	• A rule is created • Trigger notification service when adverse event meets notification criteria
Exception Conditions	
Additional Details	Will leverage caAERS rules engine
Notes	

3.4.4.2 AE-INF4-OP2 : deactivateAdverseEventNotification

Behavior Description	Deactivates notification rule (adverse event criteria on which a notification should be triggered)
Pre-Conditions	Notification rules exists
Security Pre-Conditions	The requestor • Must be a study data manager
Inputs	DeactivateAdverseEventNotificationRequest is a wrapper object that contains the following: • AERule.Identifier (II)
Outputs	DeactivateAdverseEventNotificationResponse is a wrapper object that contains the following: • ISO : BL (Rule Status)
Post-Conditions	Rule deactivated
Exception Conditions	Notification rule not found
Additional Details	Will leverage caAERS rules engine
Notes	

3.4.5 Review Service Context

This interface provides operations for other systems, services, and users to manage and execute the adverse event review process.

3.4.5.1 AE-INF5-OP1 : updateAdverseEventReviewProcessForStudy

Behavior Description	Updates the workflow process that must be followed for reviewing adverse event records
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be a study data manager
Inputs	ReviewServiceContextRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier) ESS-AE:ReviewProcess This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	ReviewServiceContextResponse is a wrapper object that contains the following:
Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.5.2 AE-INF5-OP2 : getAdverseEventReviewProcessForStudy

Behavior Description	Retrieves the workflow process that must be followed for reviewing adverse event records
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be a study data manager
Inputs	GetAdverseEventReviewProcessForStudyRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier)
Outputs	GetAdverseEventReviewProcessForStudyResponse is a wrapper object that contains the following: • AE-ESS : ReviewProcess This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	None
Exception Conditions	• Study not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.4.5.3 AE-INF5-OP3 : reviewAdverseEvent

Behavior Description	Review adverse events
Pre-Conditions	Specified adverse event exists
Security Pre-Conditions	The requestor • Must be a healthcare provider
Inputs	ReviewAdverseEventRequest is a wrapper object that contains the following: • ISO : II (adverse event identifier) • AE-ESS: ReviewProcess This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	ReviewAdvereEventResponse is a wrapper object that contains the following: • BRIDG:AdverseEvent
Post-Conditions	None
Exception Conditions	Invalid adverse event identifier
Additional Details	
Notes	

3.4.6 Protocol Service Context

This interface provides operations to manage adverse events contain ed within a protocol.

3.4.6.1 AE-INF6-OP1 : updateCodingTerminologyForStudy

Behavior Description	Updates the terminology system to be used for encoding adverse events on a study
Pre-Conditions	• Specified study exists • Adverse event terminology exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	UpdateCodingTerminologyForStudyRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier) • ISO : OID (StudyProtocolVersion.aeCodingSystem)
Outputs	UpdateCodingTerminlogyForStudyResponse is a wrapper object that contains no content.
Post-Conditions	None
Exception Conditions	• Study not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.4.6.2 AE-INF6-OP2 : getCodingTerminologyForStudy

Behavior Description	Retrieves the terminology system used for encoding adverse events on a study
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter

Inputs	GetCodingTerminologyForStudyRequest is a wrapper object that contains the following: • ISO : II (Study Protocol Identifier)
Outputs	GetCodingTerminologyForStudyResponse is a wrapper object that contains the following: • ISO : OID
Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.6.3 AE-INF6-OP3 : updateDataRequirementsForStudy

Behavior Description	Updates the mandatory, optional, and not applicable (disallowed) attributes for adverse event records on a study
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	UpdateDataRequirementsForStudyRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier) • AE : DataRequirement This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	UpdateDateRequirementsForStudyResponse is a wrapper object that contains not content.

Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.6.4 AE-INF6-OP4 : getDataRequirementsForStudy

Behavior Description	Retrieves the mandatory, optional, and not applicable (disallowed) attributes for adverse event records on a study
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	GetDataRequirementsForStudyRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier)
Outputs	GetDataRequirementsForStudyResponse is a wrapper object that contains the following: • AE : DataRequirement This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier

Additional Details	
Notes	

3.4.6.5 AE-INF6-OP5 : updateExpectedAdverseEventsForStudy

Behavior Description	Updates the expected adverse event records associated to a study
Pre-Conditions	• Specified adverse event term(s) exists • Specified study exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	UpdateExpectedAdverseEventsForStudyRequest is a wrapper object that contains the following: • DSET<ISO : ANY> (Adverse Event Term or Verbatim) • ISO : II (Study Protocol Identifier) • ISO : OID (Adverse Event Coding Terminology)
Outputs	UpdateExpectedAdverseEventsForStudyResponse is a wrapper object that contains no content.
Post-Conditions	Any expected adverse events that were previously associated to the study will be removed
Exception Conditions	Study not found for the given identifier Terminology not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.6.6 AE-INF6-OP6 : getExpecteddverseEventsForStudy

Behavior Description	Retrieves the expected adverse events associated to a study
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	GetExpectedAdverseEventsForStudyRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier)
Outputs	GetExpectedAdverseEventsForStudyResponse is a wrapper object that contains the following: • DSET<BRIDG : AdverseEvent > This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	
Exception Conditions	Study protocol identifier is invalid
Additional Details	
Notes	

3.4.6.7 AE-INF6-OP7 : updateSolicitedAdverseEventsForStudyEpoch

Behavior Description	Updates the solicited adverse event records associated to a study epoch

Pre-Conditions	• Specified adverse event term(s) exists • Specified study exists • Specified epoch exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	UpdateSolicitedAdverseEventsForStudyEpochRequest is a wrapper object that contains the following: • DSET<ISO: ANY> (adverse event term or verbatim) • ISO : II (study protocol identifier) • ISO : ST (epoch name)
Outputs	UpdateSolicitedAdverseEventsForStudyEpochResponse is a wrapper object that contains no content.
Post-Conditions	Any solicited adverse events that were previously associated to the study epoch will be removed.
Exception Conditions	• Study not found for the given identifier • Invalid Identifier * Invalidates even one Object in the list is not valid .
Additional Details	
Notes	

3.4.6.8 AE-INF6-OP8 : getSolicitedAdverseEventsForStudyEpoch

This operation allows obtaining the solicited adverse event records associated to a study epoch.

Behavior Description	Retrieves the solicited adverse event records associated to a study epoch.

Pre-Conditions	• Specified study exists • Specified epoch exists
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	GetSolicitedAdverseEventsForStudyEpochRequest is a wrapper object that contains the following: • ISO : II (study protocol identifier) • ISO : ST (study epoch name)
Outputs	GetSolicitedAdverseEventsForStudyEpochResponse is a wrapper object that contains no content. • DSET<ISO : ANY >
Post-Conditions	
Exception Conditions	• Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.6.9 AE-INF6-OP9 : updateAdverseEventRecordingRulesForStudy

Behavior Description	Updates/creates rule against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Pre-Conditions	
Security Pre-Conditions	The requestor • Must be an adverse event reporter
Inputs	UpdateAdverseEventRecordingRulesForStudyRequest is a wrapper object that contains the

	following: • AERule • BRIDG : II (StudyProtocolVersion Identifier) These classes are defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	UpdateAdverseEventRecordingRulesForStudyResponse is a wrapper object that contains the following: • ISO : II (AERule Identifier)
Post-Conditions	Rule is created
Exception Conditions	Study not found for the given identifier Rule not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.6.10 AE-INF6-OP10 : getAdverseEventRecordingRulesForStudy

Behavior Description	Retrieves rules against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Pre-Conditions	
Security Pre-Conditions	The requestor • Must be an adverse event reporter

Inputs	GetAdverseEventRecordingRulesForStudyRequest is a wrapper object that contains the following: • BRIDG : II (StudyProtocolVersion Identifier)
Outputs	GetAdverseEventRecordingRulesForStudyResponse is a wrapper object that contains the following: • DSET<AERule > This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	
Exception Conditions	Rule not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.4.7 AdvancedQuery Service Context

This interface provides operations to find and retrieve adverse events, audit trail of adverse events, and associated adverse events.

3.4.7.1 AE-INF7-OP1 : queryAdverseEvents

Behavior Description	Query by search criteria (caAERS) model of querying and will retrieve all adverse events that match the input search criteria with search limit offset.
Pre-Conditions	
Security Conditions	The requestor • Must be an adverse event reporter
Inputs	QueryAdverseEventsRequest is a wrapper object that contains the following:

	• CAAERS : AdverseEventQuery • AE : LimitOffset These classes are defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	QueryAdverseEventsResponse is a wrapper object that contains the following: • DSET<BRIDG:AdverseEvent> This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	No
Exception Conditions	• Minimum and mandatory attributes of search criteria have not been provided, especially identifier or key term • Invalid data type or code value for any attribute • Inputs fail validation specified under **Behavior Description** above
Additional Details	
Notes	

3.4.7.2 AE-INF7-OP2 : getAuditTrailOfAdverseEvent

Behavior Description	Retrieve an audit trail of all changes that have been made to an adverse event record based on an adverse event identifier and month worth of data from provided date
Pre-Conditions	
Security Pre-Conditions	The requestors • Must be a study QA manager
Inputs	GetAuditTrailOfAdverseEventRequest is a wrapper object that contains the following:

	• ISO : II (Adverse Event Identifier) • ISO : TS.DATETIME (date)
Outputs	GetAuditTrailOfAdverseEventResponse is a wrapper object that contains the following: • DSET<AE : AuditTrial> This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	
Exception Conditions	• Invalid start date • Invalid adverse event identifier
Additional Details	
Notes	

3.4.7.3 AE-INF7-OP3 : getAdverseEventSummary

Behavior Description	Retrieves summarized information regarding adverse event records based on provided search criteria (caAERS)
Pre-Conditions	
Security Pre-Conditions	The requestors must be a principal investigator
Inputs	GetAdverseEventSummaryRequest is a wrapper object that contains the following: • CAAERS : AdverseEventQuery This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.

Outputs	GetAdverseEventSummaryResponse is a wrapper object that contains the following: • DSET<CAAERS : AdverseEventSummary> This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Post-Conditions	
Exception Conditions	
Additional Details	
Notes	

3.4.7.4 AE-INF7-OP4 : getAdditionalInformationForAdverseEvent

Behavior Description	Retrieves the additional information records associated to an adverse event
Pre-Conditions	Specified AdverseEvent exists
Security Pre-Conditions	The requestor must be an adverse event reporter
Inputs	GetAdditionalInformationForAdverseEventRequest is a wrapper object that contains the following: • ISO : II (AdverseEvent Identifier)
Outputs	GetAdditionalInformationForAdverseEventResponse is a wrapper object that contains the following: • DSET<AE:AdditionalInformation> This class is defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-

	PSM.xsd.
Post-Conditions	
Exception Conditions	Invalid adverse event identifier
Additional Details	
Notes	

3.4.8 Evaluate Service Context

This interface provides operations that evaluate adverse events against recording rules.

3.4.8.1 AE-INF8-OP1 : evaluateAdverseEvents

Behavior Description	Evaluate an adverse event against the criteria that must be satisfied in order for an adverse event to be considered an appropriate record for associating to a study.
Pre-Conditions	
Security Conditions	The requestor must be an adverse event reporter.
Inputs	EvaluateServiceContextRequest is a wrapper object that contains the following: • BRIDG : AdverseEvent • ISO : II (StudyProtocolVersion Identifier) These classes are defined in: https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/AE-PSM.xsd.
Outputs	EvaluateServiceContextResponse is a wrapper object that contains the following: • ISO : BL (adverse even meets the criteria or not)
Post-Conditions	

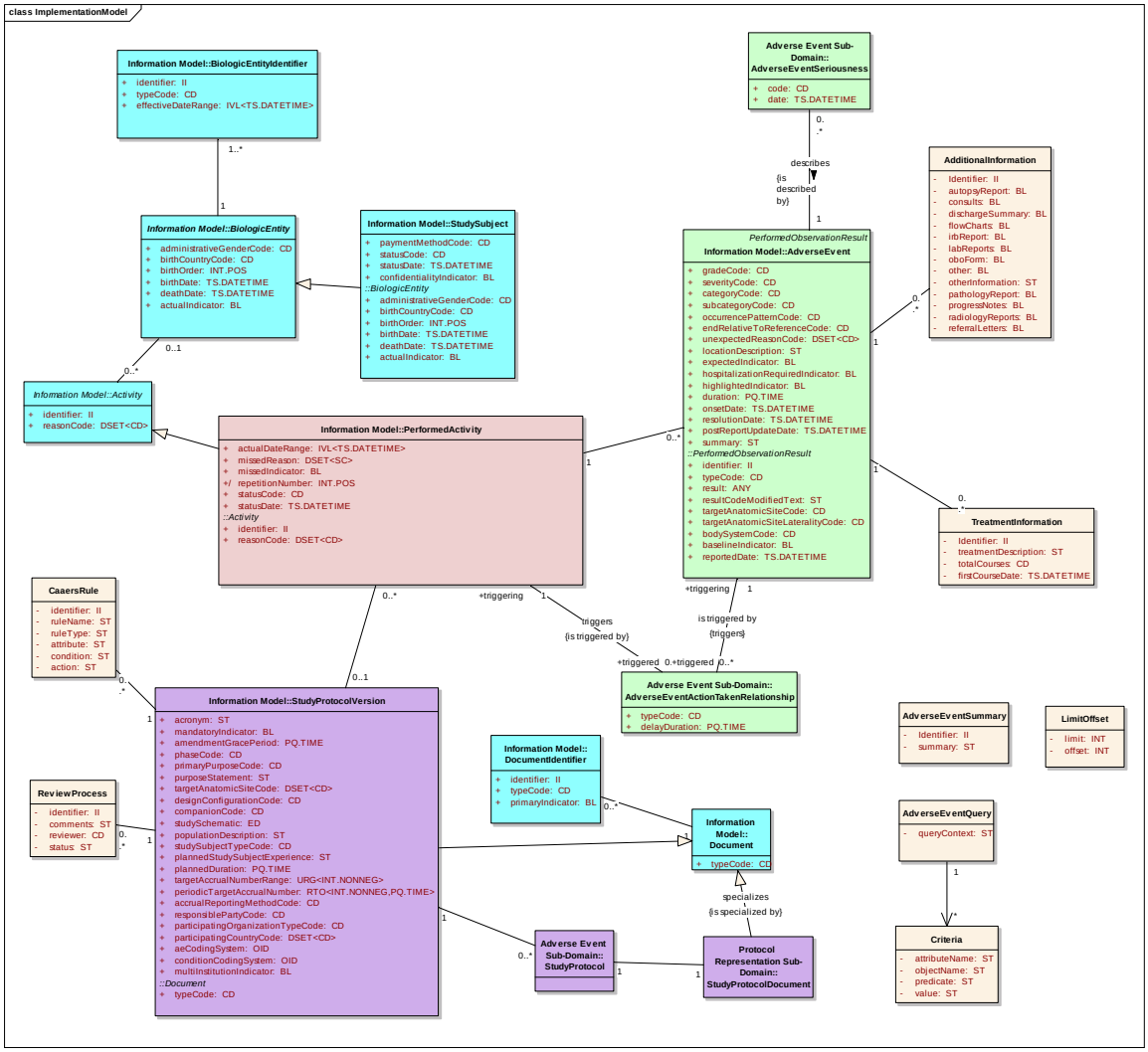
Exception Conditions	• Study not found for the given identifier • Rules not found on specified study
Additional Details	Validates the adverse event against rules
Notes	

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 Information	Adverse Event Service relies on Protocol 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	
Cryptography	

Does the Service require encryption of data transmitted to and from it?	Yes
If *Yes*, 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 *yes*, is it at risk from any external threats or vulnerabilities?	No
If *Yes*, 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 *Yes*, 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 *Yes*, then provide the following in detail:SSL	

3.7.2 Auditing

Operation Name	Auditing Details
Create/Update/ Delete	All operations will be audited using the AdverseEvent Management Service. Each table has four audit columns: • 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

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

	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 Biomedical Research Integrated Domain Group (BRIDG) has developed a comprehensive domain analysis model representing biomedical/clinical research.
COPPA	NCI's Enterprise Services of Correlation, Organization, Person and Protocol Abstraction.