caBIG® Platform Independent Model and Service Specification

Adverse Event Management Service

1.0

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Version Number	Date	Contributor	Description
0.0.2		Harsh Marwaha	Updated based on changes to the CFSS.
0.0.3		Kunal Modi Harsh Marwaha	Updated based on the 0.1.4v of AE CFSS
0.0.4		Harsh Marwaha Kunal Modi	Updated based on review with caAERS team and Michele Ehlman. Also removed the retrieveExpectedAdverseEvents method.
0.1.0	01/13/2010	Kunal Modi	Converted to new Template
0.1.1	01/22/2010	Kunal Modi	Incorporated changes to the Reporting Section for CTEP Requirements
0.1.2	01/22/2010	Kunal Modi	Added Update AE Report based on input from Paul Baumgartner
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0.1.4	02/03/2010	Kunal Modi	Updated after review with caAERS team and also to reflect changes to the CFSS
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0.5.1	11/18/2010	Paul Baumgartner	Minor modifications made
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0.5.3	12/23/2010	Srini Akkala	Modifications made in response to changes to the PSMSS.
0.5.4	01/13/2011	ESST	Modifications made regarding inputs and output standards.

0.5.5	01/19/2011	Srini Akkala	Modifications made in response to ESST review.
0.5.6	02/21/2011	Paul Baumgartner	Modifications made in response to ESST review.
1.0	03/07/2011	Paul Baumgartner	Submitted to the CAT.

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

Adverse Event Service Platform Independent Model and Service Specification

1 Introduction

1.1 Overview

The Adverse Event Management Service provides a standardized set of interfaces to record, manage, query, and obtain adverse event records within the clinical trial space and healthcare delivery space. For its representation, it uses a constrained AdverseEvent class from the NCI version of BRIDG 3.0.2 (http://gforge.nci.nih.gov/frs/?group_id=342) and ISO 21090 data types (http://gforge.nci.nih.gov/frs/download.php/3819/ISO_21090_20080317.pdf). Thus, the semantics of the Adverse Event Management Service's AdverseEvent representation are directly conformant to the BRIDG 3.0.2 and ISO 21090 data types.

1.2 Relationship to Standards

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

1.3 Relation to the Adverse Event Management Conceptual Functional Service Specification

Conceptual Functional Service Specification Name	Conceptual Functional Service Specification Version	Description & Link to the Conceptual Functional Service Specification
Adverse Event Conceptual Functional Service Specification	0.5.0	https://ncisvn.nci.nih.gov/svn/caaersappdev/docs/DesignDocs/essn/AdverseEventService/docs/CFSS/CFSS_Adverse_Event_Management_Service.doc

Deviation from the Conceptual Functional Service Specification	Reason for Deviation
None	

1.3.1 Conformance and Compliance

Conformance Profile No.	AE-CP1	
Conformance Profile Name	BRIDG Based Entire AE Conformance Profile	
Functional Profiles	Functional Profile No.	Functional Profile Name
	AE-FP1	AE Query
	AE-FP2	AE Management
	AE-FP3	AE Associate
	AE-FP4	AE Notification
	AE-FP5	AE Review
	AE-FP6	AE Protocol
	AE-FP7	AE Advanced Query
	AE-FP8	AE Evaluate
Semantic Profiles	Semantic Profile No.	Semantic Profile Name
	AE-SP1	BRIDG V3.0.2 Adverse Event

2 Platform Independent Model and Service Specification

2.1 Overview and Architecture

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

Eight interfaces have been defined:

1. **Query** includes all read-only operations to find and retrieve adverse events, audit trail of adverse events, associated adverse events.

2. **Management** includes all operations that initiate, update, and deactivate adverse events.

3. **Associate** includes all operations that associate adverse events to a study and dissociate adverse events from a study. Associate additional information, subject treatment information to study and dissociate additional information, subject treatment information from study.

4. **Notification** includes all operations that update and deactivate adverse event notifications.

5. **Review** includes all for other systems, services, and users to manage and execute the adverse event review process.

6. **Protocol** includes operations that manage adverse events contained with in a protocol.

7. **Advanced Query** includes operations that find and retrieve adverse events, audit trail of adverse events, associated adverse events.

8. **Evaluate** includes operations that evaluate adverse events against recording rules.

2.2 Implementation Considerations

Implementation Consideration	Impact
ISO data types may need to be constrained for the implementation	The Service developed might not be fully compliant with ISO 21090

2.2.1 Assumptions

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

2.2.2 Deployment Considerations

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

### 2.2.3 Jurisdictional Domains

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

2.3 Information Model

2.3.1 AdverseEvent Type

class Adverse Event Sub-Domain

Common Sub-Domain:: InvestigativeSubject

+performed · is a function performed by · +involved
· +performing {ns as} · ticipated in by · {participates in}
· 0..1 · 0..*

Common Sub-Domain:: BiologicEntity
+ administrativeGenderCode: CD
+ birthCountryCode: CD
+ birthOrder: INT.POS
+ birthDate: TS.DATETIME
+ deathDate: TS.DATETIME
+ actualIndicator: BL
0..1

specializes
{is specialized by}

Common Sub-Domain:: Activity
+ identifier: II
+ reasonCode: DSET<CD>

Common Sub-Domain:: StudySubject
+ paymentMethodCode: CD
+ statusCode: CD
+ statusDate: TS.DATETIME
+ confidentialityIndicator: BL

specializes
{is specialized by}

+identified · 1
identifies
{is identified by}
+identifying 0..*

Common Sub-Domain:: BiologicEntityIdentifier
+ identifier: II
+ typeCode: CD
+ effectiveDateRange: IVL<TS.DATETIME>

AdverseEventSeriousness
+ code: CD
+ date: TS.DATETIME
0..*
describes
{is described by} · 1

PerformedObservationResult
AdverseEvent
+ gradeCode: CD
+ severityCode: CD
+ categoryCode: CD
+ subcategoryCode: CD
+ occurrencePatternCode: CD
+ endRelativeToReferenceCode: CD
+ unexpectedReasonCode: DSET<CD>
+ locationDescription: ST
+ expectedIndicator: BL
+ hospitalizationRequiredIndicator: BL
+ highlightedIndicator: BL
+ duration: PQ.TIME
+ onsetDate: TS.DATETIME
+ resolutionDate: TS.DATETIME
+ postReportUpdateDate: TS.DATETIME
+ summary: ST
+ status: BL
::PerformedObservationResult
+ identifier: II
+ typeCode: CD
+ result: ANY
+ resultCodeModifiedText: ST
+ targetAnatomicSiteCode: CD
+ targetAnatomicSiteLateralityCode: CD
+ bodySystemCode: CD
+ baselineIndicator: BL
+ reportedDate: TS.DATETIME

Study Conduct Sub-Domain::PerformedActivity
+ actualDateRange: IVL<TS.DATETIME>
+ missedReason: DSET<SC>
+ missedIndicator: BL
+/ repetitionNumber: INT.POS
+ statusCode: CD
+ statusDate: TS.DATETIME
::Activity
+ identifier: II
+ reasonCode: DSET<CD>

+executed 0..* · +triggering 1 · +triggering 1
triggers
{is triggered by}
is triggered by
{triggers}

was executed under
{is the version for}

+version 0..1

+triggered 0 +triggered 0..*

AdverseEventActionTakenRelationship
+ typeCode: CD
+ delayDuration: PQ.TIME

Protocol Representation Sub-Domain::StudyProtocolVersion
+ acronym: ST
+ mandatoryIndicator: BL
+ amendmentGracePeriod: PQ.TIME
+ phaseCode: CD
+ primaryPurposeCode: CD
+ purposeStatement: ST
+ targetAnatomicSiteCode: DSET<CD>
+ designConfigurationCode: CD
+ companionCode: CD
+ studySchematic: ED
+ populationDescription: ST
+ studySubjectTypeCode: CD
+ plannedStudySubjectExperience: ST
+ plannedDuration: PQ.TIME
+ targetAccrualNumberRange: URG<INT.NONNEG>
+ periodicTargetAccrualNumber: RTO<INT.NONNEG,PQ.TIME>
+ accrualReportingMethodCode: CD
+ responsiblePartyCode: CD
+ participatingOrganizationTypeCode: CD
+ participatingCountryCode: DSET<CD>
+ aeCodingSystem: OID
+ conditionCodingSystem: OID
+ multiInstitutionIndicator: BL

Common Sub-Domain:: DocumentIdentifier
+ identifier: II
+ typeCode: CD
+ primaryIndicator: BL

+identifying
0..* identifies
{is iden...} +identified · 1

Common Sub-Domain:: Document
+ typeCode: CD

specializes
{is specialized by}

1
StudyProtocol
0..* · 1 · 1

Protocol Representation Sub-Domain:: StudyProtocolDocument

AdverseEvent and its associated classes used by Adverse Event Services

Attribute Name	Type	Type
categoryCode	CD	A coded value specifying a classification of the adverse event; for example, bleeding, hypoglycemia. NOTE: Theoretically speaking, the category should be derivable from the subcategory; however, if there may only be a category and not a subcategory, then both attributes must be present in the model.
duration	PQ.TIME	The length of time of an adverse event. For example, one day, two hours. NOTE: This is used only when duration is collected on the CRF and not derived from start and end date/times.
endRelativeToReferenceCode	CD	A coded value specifying when this adverse event ended with respect to the sponsor-defined reference period; for example, before, during, during/after, after, etc. NOTE: If the reference period is computably represented, AdverseEvent.endRelativeToReferenceCode is conceptually derivable based on the reference period and the resolution date of the adverse event. Sponsors should define the reference period in the study metadata, which may be populated when a start date is not.
expectedIndicator	BL	Specifies whether the specificity (nature), frequency, or severity of an adverse event is consistent with the applicable study documentation (e.g., investigator's brochure, protocol document, or consent document) or product labeling (package insert).
gradeCode	CD	A coded value specifying the level of injury suffered by the subject for whom the event is reported. For example, the gradeCode could be three if the CTCAE coding system is being used.
highlightedIndicator	BL	Specifies whether the adverse event or reaction term is a major concern or reason for reporting the adverse event.
hospitalizationRequiredIndicator	BL	Specifies whether the subject requires hospitalization as a result of the adverse event.
occurrencePatternCo	CD	A coded value specifying the time recurrence by which

de		an adverse event occurs; for example, intermittent.
onsetDate	TS.DATE TIME	The date (and time) on which an adverse event began. NOTE: Must be at least a full date (8 digits) but could contain a time (14 digits).
postReportUpdateDate	TS.DATE TIME	The date (and time) an adverse event was updated after it had been submitted.
resolutionDate	TS.DATE TIME	The date (and time) when the adverse event ends or returns to baseline.

NOTE: Must be at least a full date (8 digits) but could contain a time (14 digits). |
| severityCode | CD | A coded value specifying the intensity of the event; for example, moderate could be used to describe acne. |
| subcategoryCode | CD | A coded value specifying a subdivision within a larger category of an adverse event; for example, neurologic.

NOTE: Theoretically speaking, the category should be derivable from the subcategory; however, if there is only a category and not a subcategory, then both attributes must be present in the model. |
Summary	ST	A description of the adverse event and the treatment of the event.
unexpectedReasonCode	DSET<CD>	A coded value specifying the representation of the criteria for determining whether an adverse event (experience or reaction) is considered unanticipated for example, severity, frequency, or specificity from what has been previously documented.
status	BL	Specifies if the adverse event is active or inactive.

2.3.2 Adverse Event Implementation Model

AdverseEvent class and its associations are derived from BRIDG information model. The Enterprise Architect Project for the Adverse Event Implementation Model can be found at http://gforge.nci.nih.gov/frs/?group_id=342. The class diagram of the Adverse Event Implementation Model is shown below:
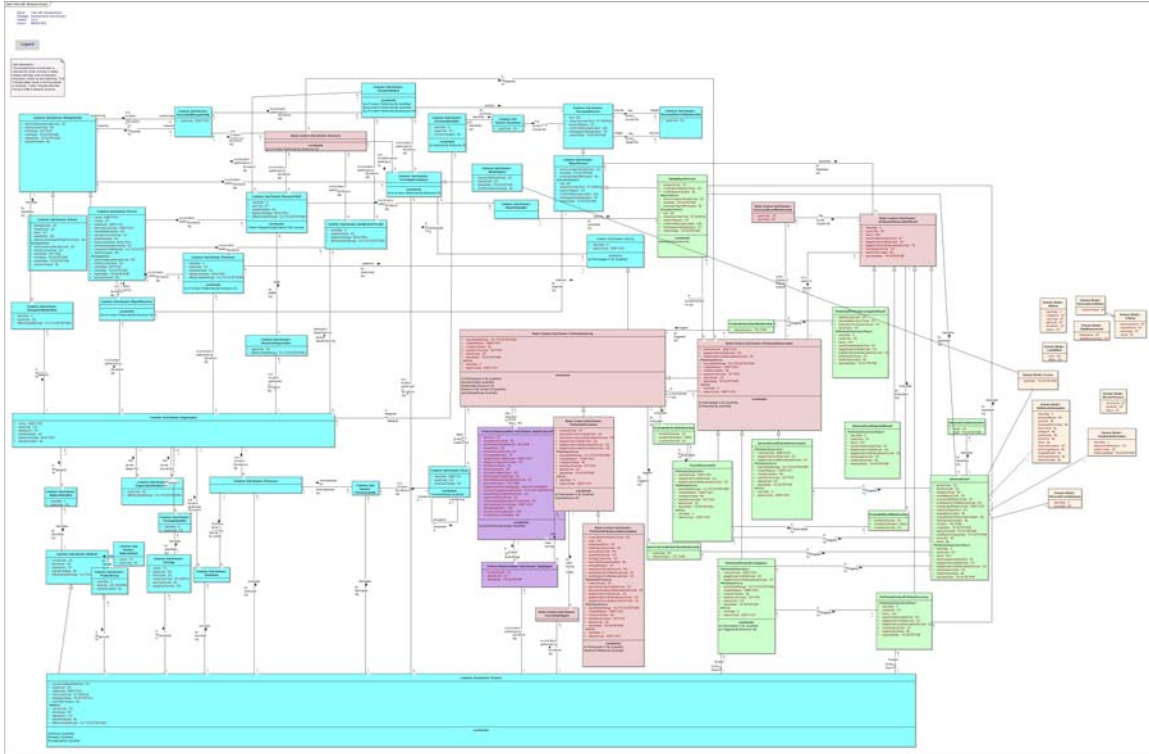
Adverse Event – Implementation Model derived from BRIDG3.0.2 Information Model

Additional classes were defined in the Adverse Event Implementation Model. These classes are not derived from the BRIDG 3.0.2 model. These classes are used for control

parameters for searching, subscribing and reporting adverse events. The class diagram below shows these classes:
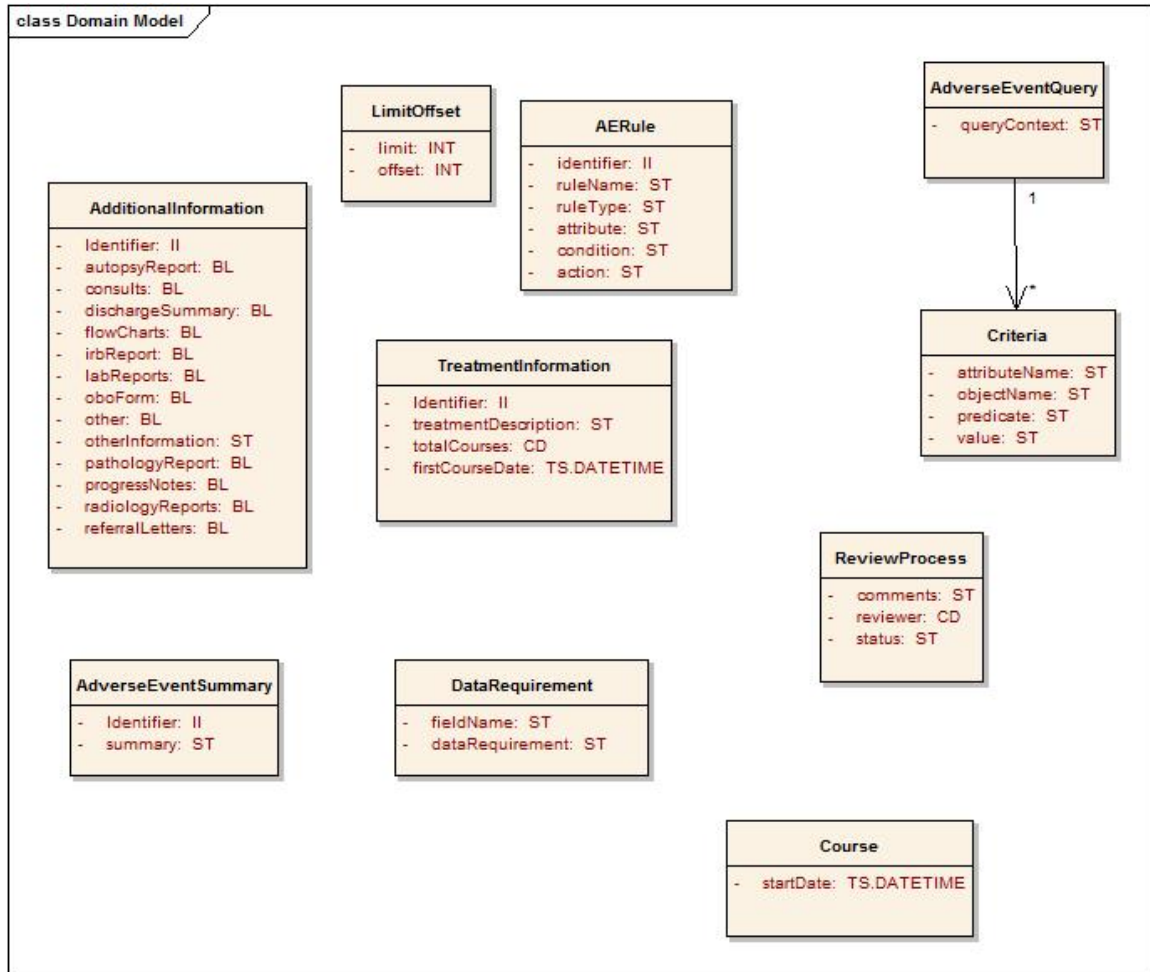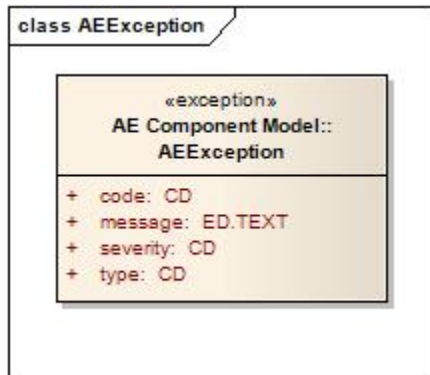

Adverse event implementation classes not derived from BRIDG

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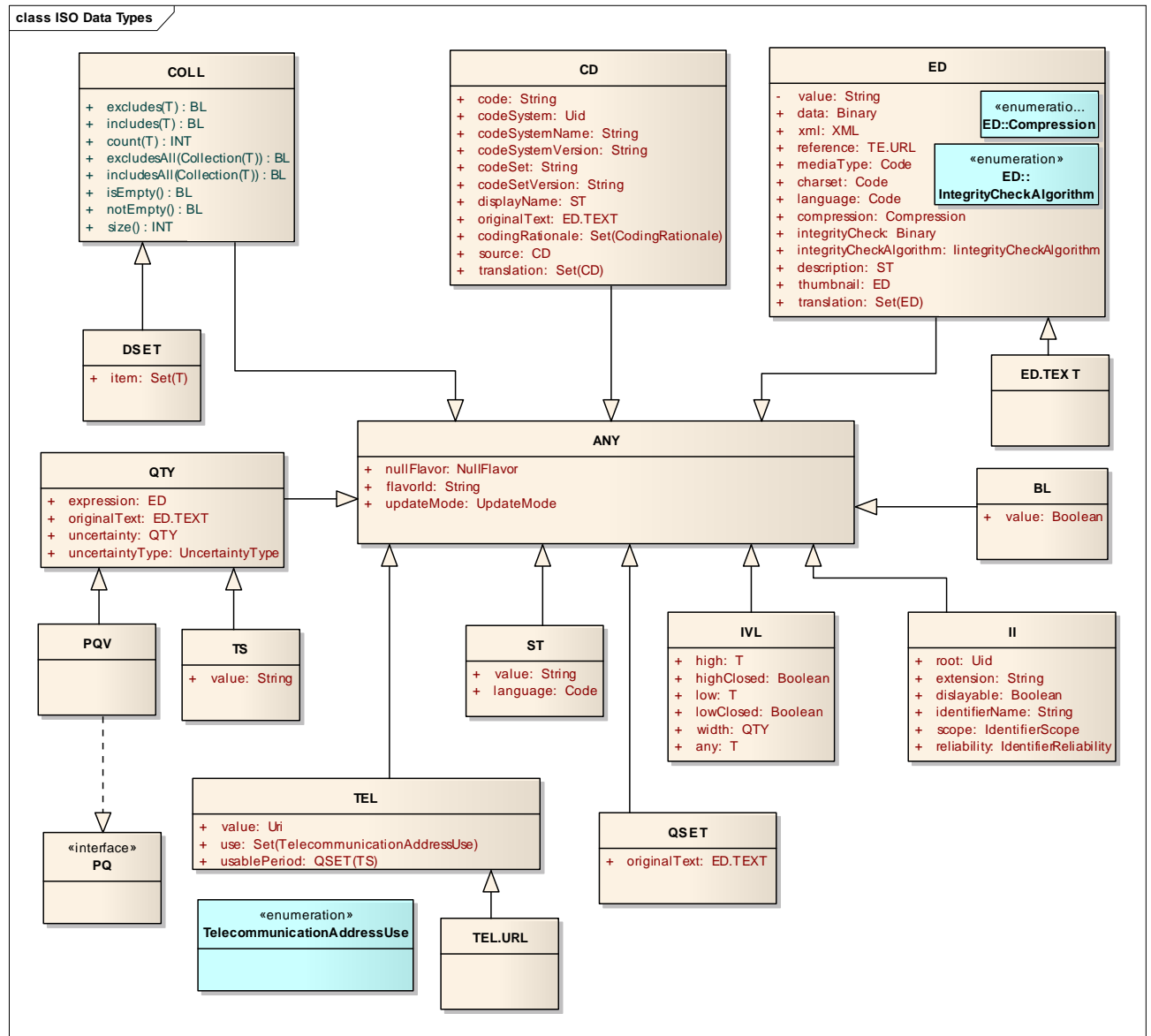
ISO 21090 data types used by the Adverse Event Service

2.3.3 Error Implementation Model

Attribute Name	Type	Attribute Description
code	CD	The actual error code which the Exception class represents
message	ED.TEXT	The detailed error message
severity	CD	The severity of this error, which can be "FATAL", "HIGH", "MEDIUM" or "LOW"
type	CD	Indicates what type of error has occurred; for example, business or system

2.4 Control Data Type Definitions

2.4.1 Status/Return Values/Exceptions

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

2.4.2 Error Codes

Error Code	Error Condition	Error/Exception Description
AEE10100	Major	Values of all mandatory attributes for <Object> have not been provided
AEE10101	Fatal	Invalid <Object>
AEE10102	Minor	Adverse event is not found for the given identifier
AEE10103	Major	More than one adverse event found
AEE10104	Minor	Invalid data type or code value for any attribute
AEE10105	Minor	Association not found for the specified adverse events
AEE10106	Minor	Minimum and mandatory attributes of search criteria have not been provided, especially identifier or key term
AEE10107	Minor	No boundaries provided for find/search operation
AEE10108	Minor	Not all required parameters provided
AEE10200	Fatal	One of the dependent systems of adverse management system is unavailable momentarily and hence the given operation failed
AEE10203	Minor	Study protocol cannot be verified
AEE10204	Minor	Study participant cannot be verified
AEE10203	Minor	Subject not found for the given identifier
AEE10302	Minor	Minimum and mandatory attributes of report criteria have not been provided, especially identifier or key term
AEE10303	Minor	Study not found for the given identifier
AEE10304	Minor	Rule not found for the given identifier

AEE10305	Minor	Rules not found on specified study
AEE10306	Minor	Terminology not found for the given identifier

3 Interfaces

3.1 UML Model of Interfaces

Interface ID	Interface Name	Interface Description
AE-INF1	AEQuery	This interface provides operations to find and retrieve adverse events.
AE-INF2	AEManagement	This interface facilitates functionality for managing the adverse events.
AE-INF3	AEAssociate	This interface provides operations to associate multiple adverse events together for study purpose and dissociate multiple events that were previously associated.
AE-INF4	AENotification	This interface provides operations to notify other systems and services based upon updates to adverse events.
AE-INF5	AEReview	This interface provides operations for other systems, services, and users to manage and execute the adverse event review process.
AE-INF6	AEProtocol	This interface provides operations to manage adverse events contained within a protocol.
AE-INF7	AEAdvancedQuery	This interface provides operations to find and retrieve adverse events, audit trail of adverse events, associated adverse events.
AE-INF8	AEEvaluate	This interface provides operations to evaluate adverse events against recording rules.

The following is the Interface Model for the Adverse Event Service:
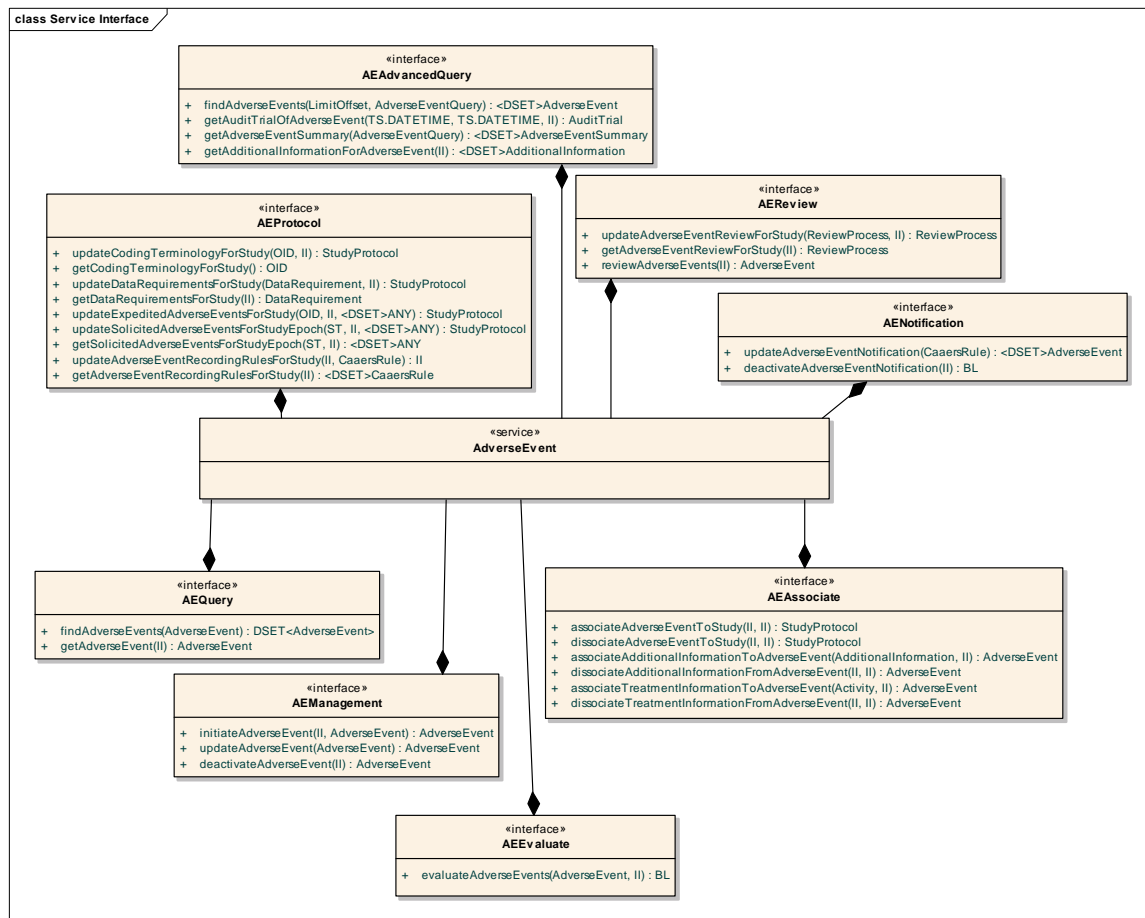
Adverse Event Services Interface Model

3.2 Operations (Enumeration)

Operation ID	Operation Name	Interface Name
AE-INF1-OP1	findAdverseEvents	AEQuery
AE-INF1-OP2	getAdverseEventData	AEQuery
AE-INF2-OP1	initiateAdverseEvent	AEManagement
AE-INF2-OP2	updateAdverseEvent	AEManagement
AE-INF2-OP3	deactivateAdverseEvent	AEManagement
AE-INF3-OP1	associateAdverseEventToStudy	AEAssociate
AE-INF3-OP2	dissociateAdverseEventToStudy	AEAssociate
AE-INF3-OP3	associateAdditionalInformationToAdverseEvent	AEAssociate
AE-INF3-OP4	dissociateAdditionalInformationFromAdverseEvent	AEAssociate
AE-INF3-OP5	associateTreatmentInformationToAdverseEvent	AEAssociate
AE-INF3-OP6	dissociateTreatmentInformationFromAdverseEvent	AEAssociate
AE-INF4-OP1	updateAdverseEventNotification	AENotification
AE-INF4-OP2	deactivateAdverseEventNotification	AENotification
AE-INF5-OP1	updateAdverseEventReviewProcessForStudy	AEReview
AE-INF5-OP2	getAdverseEventReviewProcessForStudy	AEReview
AE-INF5-OP3	reviewAdverseEvents	AEReview
AE-INF6-OP1	updateCodingTerminologyForStudy	AEProtocol
AE-INF6-OP2	getCodingTerminologyForStudy	AEProtocol
AE-INF6-OP3	updateDataRequirementsForStudy	AEProtocol

AE-INF6-OP4	getDataRequirementsForStudy	AEProtocol
AE-INF6-OP5	updateExpectedAdverseEventsForStudy	AEProtocol
AE-INF6-OP6	getExpectedAdverseEventsForStudy	AEProtocol
AE-INF6-OP7	updateSolicitedAdverseEventsForStudy Epoch	AEProtocol
AE-INF6-OP8	getSolicitedAdverseEventsForStudyEpo ch	AEProtocol
AE-INF6-OP9	updateAdverseEventRecordingRulesFor Study	AEProtocol
AE-INF6-OP10	getAdverseEventRecordingRulesForStud y	AEProtocol
AE-INF7-OP1	queryAdverseEvents	AEAdvancedQuery
AE-INF7-OP2	getAuditTrailOfAdverseEvent	AEAdvancedQuery
AE-INF7-OP3	getAdverseEventSummary	AEAdvancedQuery
AE-INF7-OP4	getAdditionalInformationForAdverseEve nt	AEAdvancedQuery
AE-INF8-OP1	evaluateAdverseEvents	AEEvaluate

3.3 Operation Behavior Descriptions

3.3.1 AEQuery Interface

This interface provides operations to find and retrieve adverse events.

3.3.1.1 **AE-INF1-OP1: findAdverseEvents**

Behavior Description	Query by Example model of querying and will retrieve all adverse events which match the input AdverseEvent attributes with search limit offset
Pre-Conditions	
Security	The requestor

Conditions	• Must be assigned the AE Query privilege role for the studies and organizations of interest.
Inputs	• BRIDG : AdverseEvent
Outputs	ISO:DSET<BRIDG:AdverseEvent>
Post-Conditions	No
Exception Conditions	• Values of all mandatory attributes for the Adverse Event Class have not been provided • Invalid Adverse Event
Additional Details	
Notes	

3.3.1.2 AE-INF1-OP2: getAdverseEventData

Behavior Description	Retrieves an entire adverse event based on the specified adverse event identifier(s)
Pre-Conditions	Adverse event exists
Security Pre-Conditions	The requestor • Must be assigned the AE Query privilege role for the studies and organizations of interest.
Inputs	BRIDG:AdverseEvent.Identifier
Outputs	ISO:DSET<BRIDG:AdverseEvent>
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.3.2 AEManagement Interface

This interface facilitates functionality for managing the Adverse Events.

3.3.2.1 AE-INF2-OP1: initiateAdverseEvent

Behavior Description	Allows initiation of adverse event and associates with study and subject
Pre-Conditions	BRIDG:Study exists BRIDG: Subject exists Course Exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	• BRIDG:AdverseEvent and instances of its aggregation/composition classes with the mandatory attributes filled and desired optional attributes provided • BRIDG:Subject.Identifier • BRIDG:StudyProtocolVersion.Identifier • ISO:TSDateTime (Course Start Date)
Outputs	BRIDG: AdverseEvent
Post-Conditions	An adverse event is initiated and the business process is started to report 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	

3.3.2.2 AE-INF2-OP2: updateAdverseEvent

Behavior Description	Allows updating adverse event attributes
Pre-Conditions	Adverse event exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	BRIDG:AdverseEvent class 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.
Outputs	BRIDG:AdverseEvent
Post-Conditions	Adverse event is updated
Exception Conditions	Invalid Adverse Event Adverse event is not found for the given identifier
Additional Details	When more than one adverse event is found, some means is necessary to identify the exact adverse event to be updated, which may necessitate matching on other key mandatory attributes.
Notes	

3.3.2.3 AE-INF2-OP3 : deactivateAdverseEvent

Behavior Description	Deactivates adverse event
Pre-Conditions	Adverse event exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.

Inputs	ISO : II (AdverseEvent Identifier)
Outputs	BRIDG:AdverseEvent
Post-Conditions	Adverse event is deactivated
Exception Conditions	Adverse event is not found for the given identifier Invalid AdverseEvent
Additional Details	Update adverse event status flag
Notes	

3.3.3 AEAssociation Interface

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

3.3.3.1 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 assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	• ISO : II (Adverse Event Identifier) • ISO : II (Study Protocol Identifier)
Outputs	
Post-Conditions	None
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

Additional Details	
Notes	

3.3.3.2 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 assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	- ISO : II (Adverse Event Identifier) - ISO : II (Study Protocol Identifier)
Outputs	
Post-Conditions	None
Exception Conditions	Adverse event is not found for the given identifier Invalid Study protocol
Additional Details	
Notes	

3.3.3.3 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 assigned the AE Reporter privilege role for the studies

	and organizations of interest.
Inputs	• BRIDG:AdverseEvent.identifier • AE : AdditionalInformation
Outputs	
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.3.3.4 AE-INF3-OP4 : dissociateAdditionalInformationFromAdverseEvent

Behavior Description	Removes association between an adverse event and additional information
Pre-Conditions	• Specified adverse event exists • Association with specified AdditionInformation exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	• BRIDG:Adverse Event.identifier • AE:AdditionalInformation.identifier
Outputs	
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier Association not found for the specified adverse events
Additional Details	

Notes	

3.3.3.5 AE-INF3-OP5 : associateTreatmentInformationToAdverseEvent

Behavior Description	Creates the association between the adverse event and the information regarding what the subject was treated within relation to the presentation of the adverse event.
Pre-Conditions	• Specified adverse event exists • Treatment information exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	• BRIDG:AdverseEvent.identifier • BRIDG:Activity.identifier
Outputs	
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.3.3.6 AE-INF3-OP6: disassociateTreatmentInformationFromAdverseEvent

Behavior Description	Removes the association between an adverse event and the subject treatment information.
Pre-Conditions	• Specified adverse event exists • Association exists between the subject treatment

	information and the adverse event record
Security Pre-Conditions	The requestor • Must be assigned the AE Reporter privilege role for the studies and organizations of interest.
Inputs	• BRIDG:AdverseEvent.identifier • BRIDG:Activity.identifier
Outputs	
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier Association not found for the specified adverse events • Invalid Identifier
Additional Details	
Notes	

3.3.4 AENotification Interface

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

3.3.4.1 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 assigned the AE Notification Manager privilege role for the studies and organizations of interest.
Inputs	AERule
Outputs	ISO:DSET<BRIDG : AdverseEvent>
Post-Conditions	• A rule is created

	• Trigger notification service when adverse event meets notification criteria
Exception Conditions	
Additional Details	
Notes	

3.3.4.2 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 assigned the AE Notification Manager privilege role for the studies and organizations of interest.
Inputs	AERule.Identifier (II)
Outputs	ISO : BL (Rule Status)
Post-Conditions	Rule deactivated
Exception Conditions	Notification rule not found
Additional Details	
Notes	

3.3.5 AEReview Interface

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

3.3.5.1 AE-INF5-OP1: updateAdverseEventReviewForStudy

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 assigned the AE Review Manager privilege role for the studies and organizations of interest.
Inputs	• BRIDG:StudyProtocol.identifier • AE:ReviewProcess
Outputs	
Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.3.5.2 AE-INF5-OP2: getAdverseEventReviewForStudy

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 assigned the AE Reviewer privilege role for the studies and organizations of interest.
Inputs	BRIDG:StudyProtocol.identifier
Outputs	AE : ReviewProcess
Post-Conditions	None
Exception	• Study not found for the given identifier

Conditions	• Invalid Identifier
Additional Details	
Notes	

3.3.5.3 AE-INF5-OP3: reviewAdverseEvent

Behavior Description	Review adverse events
Pre-Conditions	Specified adverse event exists
Security Pre-Conditions	The requestor • Must be assigned the AE Reviewer privilege role for the studies and organizations of interest.
Inputs	• BRIDG:AdverseEvent.identifier • AE : ReviewProcess
Outputs	BRIDG:AdverseEvent
Post-Conditions	None
Exception Conditions	Adverse event is not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.3.6 AEProtocol Interface

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

3.3.6.1 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest.
Inputs	• BRIDG:StudyProtocol.identifier • BRIDG:StudyProtocolVersion.aeCodingSystem
Outputs	
Post-Conditions	None
Exception Conditions	• Study not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.3.6.2 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest, or • Must be assigned the AE Reporter privilege role for the studies of interest.
Inputs	BRIDG:StudyProtocol.identifier
Outputs	BRIDG:StudyProtocolVersion.aeCodingSystem
Post-Conditions	None

Exception Conditions	Study not found for the given identifier
	Invalid Identifier
Additional Details	
Notes	

3.3.6.3 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest.
Inputs	- BRIDG:StudyProtocol.identifier - AE : DataRequirement
Outputs	
Post-Conditions	None
Exception Conditions	Study not found for the given identifier
	Invalid Identifier
Additional Details	
Notes	

3.3.6.4 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest, or • Must be assigned the AE Reporter privilege role for the studies of interest.
Inputs	BRIDG:StudyProtocol.identifier
Outputs	AE : DataRequirement
Post-Conditions	None
Exception Conditions	Study not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.3.6.5 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest.
Inputs	• ISO:DSET<ISO : ANY>(Adverse Event Term or Verbatim) • BRIDG:StudyProtocol.identifierBRIDG:StudyProtocolVersion.aeCodingSystem
Outputs	
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	

3.3.6.6 AE-INF6-OP6: getExpectedAdverseEventsForStudy

Behavior Description	Retrieves the expected adverse event associated to a study.
Pre-Conditions	Specified study exists
Security Pre-Conditions	The requestor • Must be assigned the Supplemental Study Information Manager privilege role for the studies of interest, or • Must be assigned the AE Reporter privilege role for the studies of interest.
Inputs	BRIDG:StudyProtocol.identifier
Outputs	ISO:DSET<BRIDG : AdverseEvent >
Post-Conditions	
Exception Conditions	Study not found for the given identifier
	Invalid Identifier
Additional Details	
Notes	

3.3.6.7 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest.
Inputs	• ISO:DSET<ISO: ANY> (Adverse Event Term or Verbatim) • BRIDG:StudyProtocol.identifierBRIDG:Epoch.name
Outputs	
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
Additional Details	
Notes	

3.3.6.8 AE-INF6-OP8: getSolicitedAdverseEventsForStudyEpoch

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

Behavior Description	
Pre-Conditions	• Specified study exists • Specified epoch exists
Security Pre-Conditions	The requestor • Must be assigned the Supplemental Study Information Manager

	privilege role for the studies of interest, or • Must be assigned the AE Reporter privilege role for the studies of interest.
Inputs	• BRIDG:StudyProtocol.identifierBRIDG:Epoch.name
Outputs	ISO:DSET<ISO : ANY>
Post-Conditions	
Exception Conditions	• Study not found for the given identifier • Invalid Identifier
Additional Details	
Notes	

3.3.6.9 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 assigned the Supplemental Study Information Manager privilege role for the studies of interest.
Inputs	• AE : AERule • BRIDG:StudyProtocolVersion.identifier
Outputs	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	

3.3.6.10   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 assigned the Supplemental Study Information Manager privilege role for the studies of interest, or • Must be assigned the AE Reporter privilege role for the studies of interest.
Inputs	BRIDG : StudyProtocolVersion.identifier
Outputs	ISO:DSET<AE:Rule>
Post-Conditions	
Exception Conditions	Rule not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.3.7 AEAdvancedQuery Interface

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

3.3.7.1 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 assigned the Data Analyst privilege role for the studies of interest.
Inputs	• AE: AdverseEventQuery. • AE: LimitOffset.
Outputs	ISO:DSET<BRIDG:AdverseEvent>
Post-Conditions	No
Exception Conditions	• Minimum and mandatory attributes of search criteria have not been provided, especially identifier or key term •
Additional Details	
Notes	

3.3.7.2 AE-INF7-OP2: getAuditTrailOfAdverseEvent

Behavior Description	Retrieve an audit trail of all changes that have been made to an adverse event record based on the adverse event identifier and month worth of data from provided date
Pre-Conditions	
Security Pre-Conditions	The requestor • Must be assigned the Data Reader privilege role for the studies of interest.
Inputs	• BRIDG:AdverseEvent.identifier) • ISO : TS.DATETIME (date)

	•
Outputs	ISO:DSET<AE : AuditTrail>
Post-Conditions	
Exception Conditions	• Adverse event is not found for the given identifier • Invalid start date
Additional Details	
Notes	

3.3.7.3 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 requestor • Must be assigned the Data Analyst privilege role for the studies of interest.
Inputs	AE: AdverseEventQuery.
Outputs	ISO:DSET<AE : AdverseEventSummary>
Post-Conditions	
Exception Conditions	
Additional Details	
Notes	

3.3.7.4 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 assigned the Data Analyst privilege role for the studies of interest.
Inputs	BRIDG:AdverseEvent.identifier)
Outputs	ISO:DSET<AE:AdditionalInformation>
Post-Conditions	
Exception Conditions	Adverse event is not found for the given identifier Invalid Identifier
Additional Details	
Notes	

3.3.8 AEEvaluate Interface

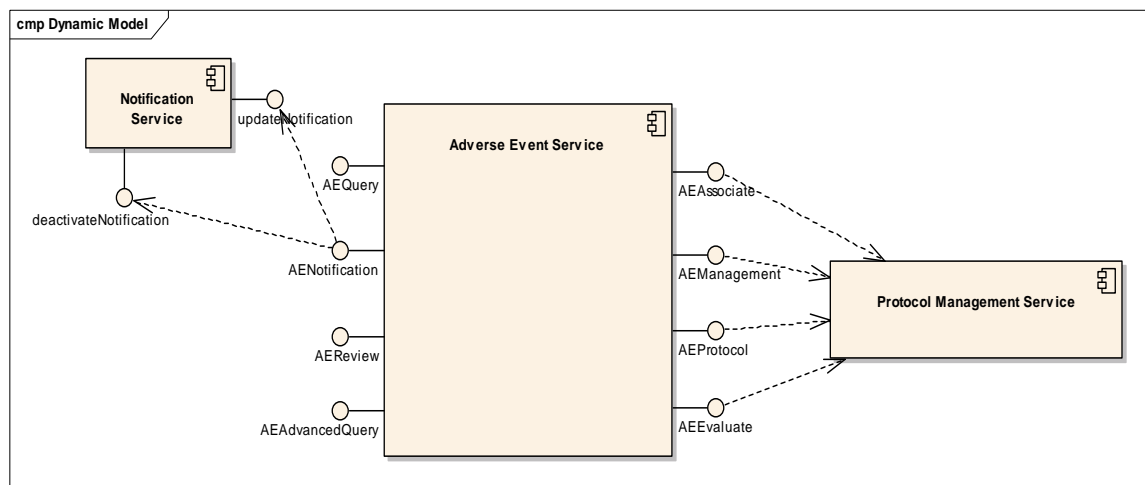This interface provides operations that evaluate adverse events against recording rules

3.3.8.1 AE-INF8-OP1: evaluateAdverseEvents

Behavior Description	Evaluate an adverse event against the criteria, which 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 assigned the AE Reporter privilege role for the studies of interest.
Inputs	• BRIDG : AdverseEvent • BRIDG:StudyProtocolVersion.identifier
Outputs	ISO : BL (adverse event 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 the rules
Notes	

4 Dynamic Model

The Adverse Event Service is a core service with a fairly simple dynamic model that can be used in many contexts and thus should be illustrated in context of the Clinical Trials business process. The following architecturally significant component diagram should sufficiently demonstrate the dynamics of the Adverse Event Service.
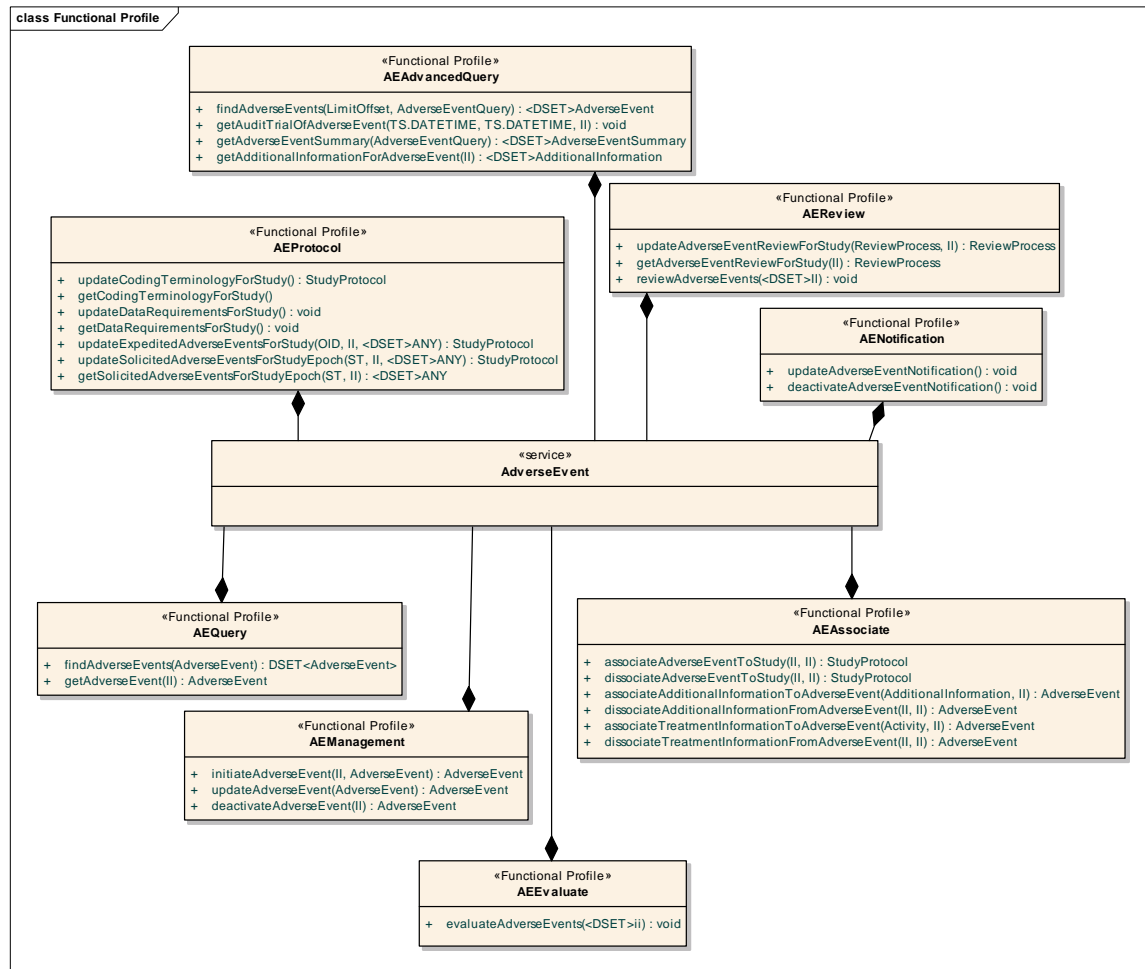
5 Profiles

5.1 Functional Profiles

Profile No.	Profile Name	Profile Description
AE-FP1	AE Query	The query functional profile provides an encapsulation boundary for the commissioner of the query to be guaranteed that the information provided by a given query is correct and complete.
AE-FP2	AE Management	The management series of capabilities details the complete encapsulation boundary behind which the adverse event object may be managed.
AE-FP3	AE Associate	The association functional profile provides for a series of capabilities to connect an adverse event record with other information, whether that association happens across system or organizational boundaries.
AE-FP4	AE Notification	The notification functional profile provides a series of functional capabilities for other systems, services, and users to manage the notifications that shall be triggered based upon updates to adverse event records and the associations to those records.
AE-FP5	AE Review	The AE review functional profile provides a series of functional capabilities for other systems, services, and users to manage and execute the adverse event review process
AE-FP6	AE Protocol	The AE protocol functional profile provides a series of functional capabilities for other systems, services, and users to manage the adverse event specific information contained within a protocol.
AE-FP7	AE Advanced Query	The advanced query functional profile provides an encapsulation boundary for the commissioner of the query to be guaranteed that the information provided by a given query is correct and complete. This functional profile provides functionality beyond that provided in the AE query functional profile.
AE-FP8	AE Evaluate	The AE evaluate functional profile provides a series of functional capabilities for other systems, services, and users to evaluate if an adverse event should be recorded.

Interface Operation No.	Interface Operation Name	Profile No.	Profile Name
AE-INF1-OP1	findAdverseEvents	AE-FP1	AE Query
AE-INF1-OP2	getAdverseEventData	AE-FP1	AE Query
AE-INF2-OP1	initiateAdverseEvent	AE-FP2	AE Management
AE-INF2-OP2	updateAdverseEvent	AE-FP2	AE Management
AE-INF2-OP3	deactivateAdverseEvent	AE-FP2	AE Management
AE-INF3-OP1	associateAdverseEventToStudy	AE-FP3	AE Associate
AE-INF3-OP2	dissociateAdverseEventToStudy	AE-FP3	AE Associate
AE-INF3-OP3	associateAdditionalInformationToAdverseEvent	AE-FP3	AE Associate
AE-INF3-OP4	dissociateAdditionalInformationFromAdverseEvent	AE-FP3	AE Associate
AE-INF3-OP5	associateTreatmentInformationToAdverseEvent	AE-FP3	AE Associate
AE-INF3-OP6	dissociateTreatmentInformationFromAdverseEvent	AE-FP3	AE Associate
AE-INF4-OP1	updateAdverseEventNotification	AE-FP4	AE Notification
AE-INF4-OP2	deactivateAdverseEventNotification	AE-FP4	AE Notification
AE-INF5-OP1	updateAdverseEventReviewProcessForStudy	AE-FP5	AE Review
AE-INF5-OP2	getAdverseEventReviewProcessForStudy	AE-FP5	AE Review

| AE-INF5-OP3	reviewAdverseEvent	AE-FP5	AE Review
AE-INF6-OP1	updateCodingTerminologyForStudy	AE-FP6	AE Protocol
AE-INF6-OP2	getCodingTerminologyForStudy	AE-FP6	AE Protocol
AE-INF6-OP3	updateDataRequirementsForStudy	AE-FP6	AE Protocol
AE-INF6-OP4	getDataRequirementsForStudy	AE-FP6	AE Protocol
AE-INF6-OP5	updateExpectedAdverseEventsForStudy	AE-FP6	AE Protocol
AE-INF6-OP6	getExpectedAdverseEventsForStudy	AE-FP6	AE Protocol
AE-INF6-OP7	updateSolicitedAdverseEventsForStudyEpoch	AE-FP6	AE Protocol
AE-INF6-OP8	getSolicitedAdverseEventsForStudyEpoch	AE-FP6	AE Protocol
AE-INF6-OP9	updateAdverseEventRecordingRulesForStudy	AE-FP6	AE Protocol
AE-INF6-OP10	getAdverseEventRecordingRulesForStudy	AE-FP6	AE Protocol
AE-INF7-OP1	findAdverseEvents	AE-FP7	AE Advanced Query
AE-INF7-OP2	getAuditTrailOfAdverseEvent	AE-FP7	AE Advanced Query
AE-INF7-OP3	getAdverseEventSummary	AE-FP7	AE Advanced Query
AE-INF7-OP4	getAdditionalInformationForAdverseEvent	AE-FP7	AE Advanced Query
AE-INF8-OP1	evaluateAdverseEvents	AE-FP8	AE Evaluate

Profile view of the Operations of Adverse Event Service

5.2 Semantic Profiles

Semantic Profile No.	Semantic Profile Name	Semantic Profile Description

AE-SP1	BRIDG V3.0.2 Adverse Event	NCI's version of BRIDG v3.0.2-based semantic profile

6 Relationship with other services

The following diagram illustrates the positioning of the Adverse Event Service within the Clinical Trials business process (at a logical level). The full set of interactions depicted here are beyond the scope of this specification, but the overall intent is to convey the interoperability from adverse event management.
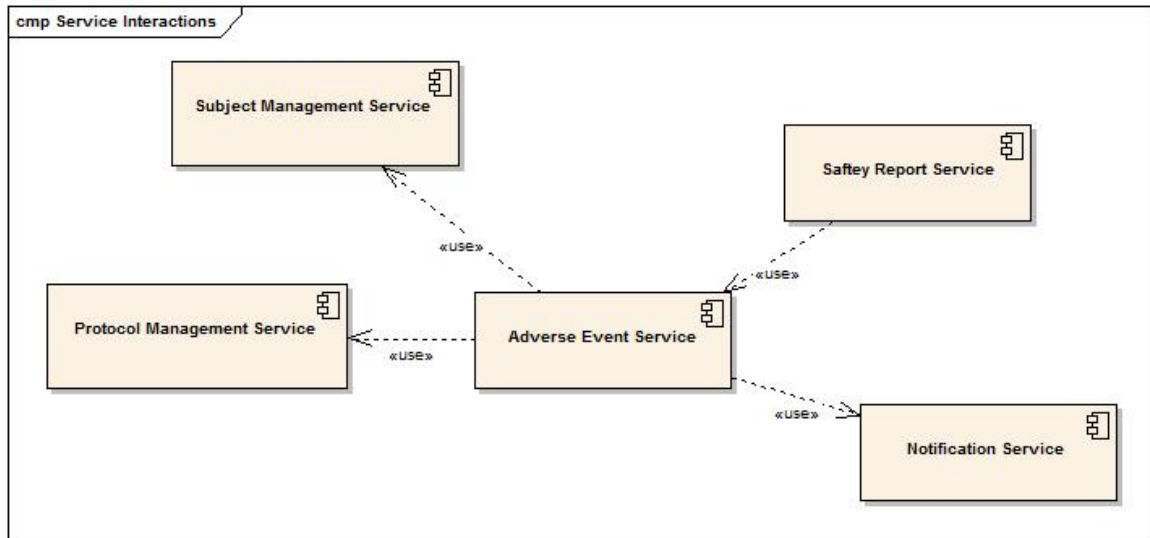
Adverse Event Management Component and Dependency Model

Service / System / Actors Name	Dependant / Depends	Data	Description
Protocol Management	Dependant	Study Information	AE Service relies on Protocol Management Service to retrieve study information and ensure that the study exists
Subject Registration Service	Dependant	Subject Information	AE Service relies on Subject Registration Service to retrieve subject information and verify that subject is registered on the study
Safety Report Service	Depends	Report Information	Safety Report Service relies on AE Service to report adverse event data
Notification Management Service	Dependant	Notifications	AE Service relies on Notification Management service to trigger notifications based on

			modifications to adverse events

7 Conformance Statements

No	Name	Type	Viewpoint	Description	Test method
1	Query Performance	Obligation	Engineering	The AE query profile should provide a response within 0.5 seconds to support a synchronous UI-based client	Test cases to include performance testing
2	Multiple Jurisdictions	Obligation	Enterprise	The AE Service will span jurisdictional boundaries and will need to support a federated data model	Test cases include multiple domain scenarios
3	Secured Access	Obligation	Engineering	The AE service should have access control mechanism in place to restrict access to the secured data	Design review Test cases to be defined for security
4	Additional Functionality	Permission	Computational	The AE service can provide additional functionality other than specified in these specifications	Design Review
5	Semantic Model	Obligation	Informational	The AE service must support NCI's version of BRIDG 3.0.2 model adverse event class.	Design Review
6	Functional Profiles	Obligation	Computational	Functional profiles shall be deployed as functional wholes. Ignoring or omitting functional behavior defined within a functional profile is not permitted, nor is diverging from the detailed functional specifications provided in Section 4.	Design Review Test cases

No	Name	Type	Viewpoint	Description	Test method
7	Functional Profiles	Obligation	Computational	A conformant implementation of this specification must deploy at least one functional profile. If that functional profile has dependencies on other profiles, then those dependencies must be deployed as well to support the provenance of that service instance.	Design Review Test cases
8	ISO Data types	Obligation	Information	Implementers are obligated to support ISO 1090 data types in all operations	Test cases
9	Auditing	Obligation	Engineering	Designers/implementers are obligated to decide on and document the approach for logging or auditing operation calls.	Design Review

8 Appendix A - References

Name	Description	Location
NCI's BRIDG v3.0.2	NCI's BRIDG model used for modeling the AE Service	http://gforge.nci.nih.gov/frs/download.php/8831/BRIDG_Release_3.0.2_Package.zip
caAERS Use Case Document	Document containing use cases for the caAERS application	https://wiki.nci.nih.gov/display/CTMS/Use+Cases+-+caAERS

9 Appendix B - Glossary

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

10 Appendix C - Cross Reference Tables

10.1 Interface to Profile Mapping

Interface No.	Interface	Profile No.	Profile
AE-INF1	AEQuery	AE-FP1	AE Management
AE-INF2	AEManagement	AE-FP2	AE Associate
AE-INF3	AEAssociate	AE-FP3	AE Publication
AE-INF4	AENotification	AE-FP4	AE Report
AE-INF5	AEReview	AE-FP5	AE Query
AE-INF6	AEProtocol	AE-FP6	AE Protocol
AE-INF7	AEAdvancedQuery	AE-FP7	AE Advanced Query
AE-INF8	AEEvaluate	AE-FP8	AE Evaluate

10.2 Interface Operations to Profile Operations

Operation No.	Operation Name	Capability No.	Profile Capability
AE-INF1-OP1	findAdverseEvents	AE-CPB1	Find Adverse Event
AE-INF1-OP2	getAdverseEventData	AE-CPB2	Get Adverse Event Details
AE-INF2-OP1	initiateAdverseEvent	AE-CPB3	Initiate Adverse Event
AE-INF2-OP2	updateAdverseEvent	AE-CPB4	Update Adverse Event
AE-INF2-OP3	deactivateAdverseEvent	AE-CPB5	Deactivate Adverse Event
AE-INF3-OP1	associateAdverseEventTo Study	AE-CPB6	Associate Adverse Event to Study
AE-INF3-OP2	dissociateAdverseEventTo Study	AE-CPB7	Dissociate Adverse Event from Study

AE-INF3-OP3	associateAdditionalInformationToAdverseEvent	AE-CPB8	Associate Additional Information to Adverse Event
AE-INF3-OP4	dissociateAdditionalInformationFromAdverseEvent	AE-CPB9	Dissociate Additional Information from Adverse Event
AE-INF3-OP5	associateTreatmentInformationToAdverseEvent	AE-CPB10	Associate Treatment Information To Adverse Event
AE-INF3-OP6	dissociateTreatmentInformationFromAdverseEvent	AE-CPB11	Dissociate Treatment Information from Adverse Event
AE-INF4-OP1	updateAdverseEventNotification	AE-CPB12	Update Adverse Event Notification
AE-INF4-OP2	deactivateAdverseEventNotification	AE-CPB13	Deactivate Adverse Event Notification
AE-INF5-OP1	updateAdverseEventReviewProcessForStudy	AE-CPB14	Update Adverse Event Review Process for Study
AE-INF5-OP2	getAdverseEventReviewProcessForStudy	AE-CPB15	Retrieve Adverse Event Review Process for Study
AE-INF5-OP3	reviewAdverseEvent	AE-CPB16	Review Adverse Events
AE-INF6-OP1	updateCodingTerminologyForStudy	AE-CPB17	Update Adverse Event Coding System for Study
AE-INF6-OP2	getCodingTerminologyForStudy	AE-CPB18	Retrieve Adverse Event Coding System for Study
AE-INF6-OP3	updateDataRequirementsForStudy	AE-CPB19	Update Adverse Event data requirements for Study
AE-INF6-OP4	getDataRequirementsForStudy	AE-CPB20	Retrieve Adverse Event data requirements for

			Study
AE-INF6-OP5	updateExpectedAdverseEventsForStudy	AE-CPB21	Update expedited Adverse Events associated to Study
AE-INF6-OP6	getExpectedAdverseEventsForStudy	AE-CPB22	Retrieve expedited Adverse Events associated to Study
AE-INF6-OP7	updateSolicitedAdverseEventsForStudyEpoch	AE-CPB23	Update solicited Adverse Events associated to Study
AE-INF6-OP8	getSolicitedAdverseEventsForStudyEpoch	AE-CPB24	Retrieve expedited Adverse Events associated to Study
AE-INF6-OP9	updateAdverseEventRecordingRulesForStudy	AE-CPB25	Update Adverse Event Study rules
AE-INF6-OP10	getAdverseEventRecordingRulesForStudy	AE-CPB26	Retrieve Adverse Event Study rules
AE-INF7-OP1	findAdverseEvents	AE-CPB27	Find Adverse Events by Advanced Query model
AE-INF7-OP2	getAuditTrailOfAdverseEvent	AE-CPB28	Retrieve Audit Trial Information of Adverse Event
AE-INF7-OP3	getAdverseEventSummary	AE-CPB29	Retrieve Summarized Information of Adverse Event
AE-INF7-OP4	getAdditionalInformationForAdverseEvent	AE-CPB30	Retrieve Additional Information of Adverse Event
AE-INF8-OP1	evaluateAdverseEvents	AE-CPB31	Evaluate Adverse Events