Conceptual Functional Service Specification

Adverse Event Management

1.0

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1 Overview and Business Case

1.1 Name of Service

The service discussed in this specification will be known as the Adverse Event Management Service or AEMS for short.

1.2 Service Description and Purpose

An adverse event is any undesirable medical experience associated with the use of a product or procedure on a person. Adverse events are identified and recorded during the conduct of clinical trials and as a part of clinical care. Adverse events can be identified through a combination of several mechanisms such as patient self-reporting, clinical observation, or quantitative measurements (i.e. laboratory results). Likewise, adverse events can be recorded by patients or clinical trial subjects, clinical researchers, health care delivery professionals, and the systems that support clinical care (e.g. laboratory systems)

The purpose of the Adverse Event Management Service is to provide a standard set of interfaces to record, manage, query, and obtain adverse event records within the cancer clinical trial space and cancer care delivery space. The common, reusable set of interfaces provided by this service will facilitate the interaction and interoperability between systems that require and provide adverse event data. As a result of this interoperability, this service will likely improve the quality and availability of adverse event information while likely reducing the cost of providing this information. This service is not intended to facilitate to reporting of adverse events to regulatory agencies and oversight committees, such as the Food and Drug Administration (FDA) and Institutional Review Boards (IRBs), respectively. The aforementioned functionality is within the scope of the Safety Reporting Service.

1.3 Scope

Items	Scope / Out of Scope	Source
Provide the ability to record, manage, query, and obtain adverse event records within the cancer clinical trial space and cancer care delivery space.	Scope	Adverse Event Management Service Scope Document
Provide support for utilization by other authorized systems and services.	Scope	Adverse Event Management Service Scope Document
Provide support for federated adverse event data management.	Scope	Adverse Event Management Service Scope Document
Provide an audit log of all create, update, and delete activity pertaining to an adverse event record.	Scope	Adverse Event Management Service Scope Document
Provide the ability to associate an adverse event record with a patient and/or a study subject.	Scope	Adverse Event Management Service Scope Document
Provide the ability to define, update, delete and search solicited adverse events for a study	Scope	Adverse Event Management Service Scope Document
Provide the ability to define, update, delete and search for expected adverse events for a study.	Scope	Adverse Event Management Service Scope Document
Provide notification message to user that SAE reporting is required (Note: This will be addressed by the Notification Service)	Out of Scope	

1.4 Assumptions

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

the study.	future Coding service could be developed for this.	

2 Business Storyboards

2.1 Primary Actors

The following actors are used in the storyboards below.

2.1.1 People Actors

Name	Role	Notes
Dr. David Jones	Healthcare Provider	The treating physician for a study subject or a patient.
Lucy Taylor	AE Reporter	The person responsible for recording adverse events. Common synonyms are Research Nurse, Study Coordinator, Clinical Research Associate, Clinical Research Coordinator
Mike Sweet	Patient	Patient undergoing clinical care outside the scope of a clinical trial.
Jerry Carlos	Study Subject	A participant on a clinical trial. Also know as Study Participant.
Dr. Linda Lu	Principal Investigator	A subscriber to notifications regarding adverse events.
John Miller	Laboratory Technician	A person responsible for performing laboratory tests.
Patty Higgs	Supplemental Study Information Manager	A person responsible for abstracting information from the clinical trial protocol.
Alabama Adams	Clinical Data Coordinator	A person who participates in adverse event data entry and data management activities.
May Cooper	Study Data Manager	A person responsible for managing data on the entire study.
Peter Porter	Statistician	A person responsible for analyzing the data on a study.

Joshua Daniels	Quality Assurance Auditor	A person responsible for ensuring the adherence to standard operating procedures.

2.1.2 System Actors

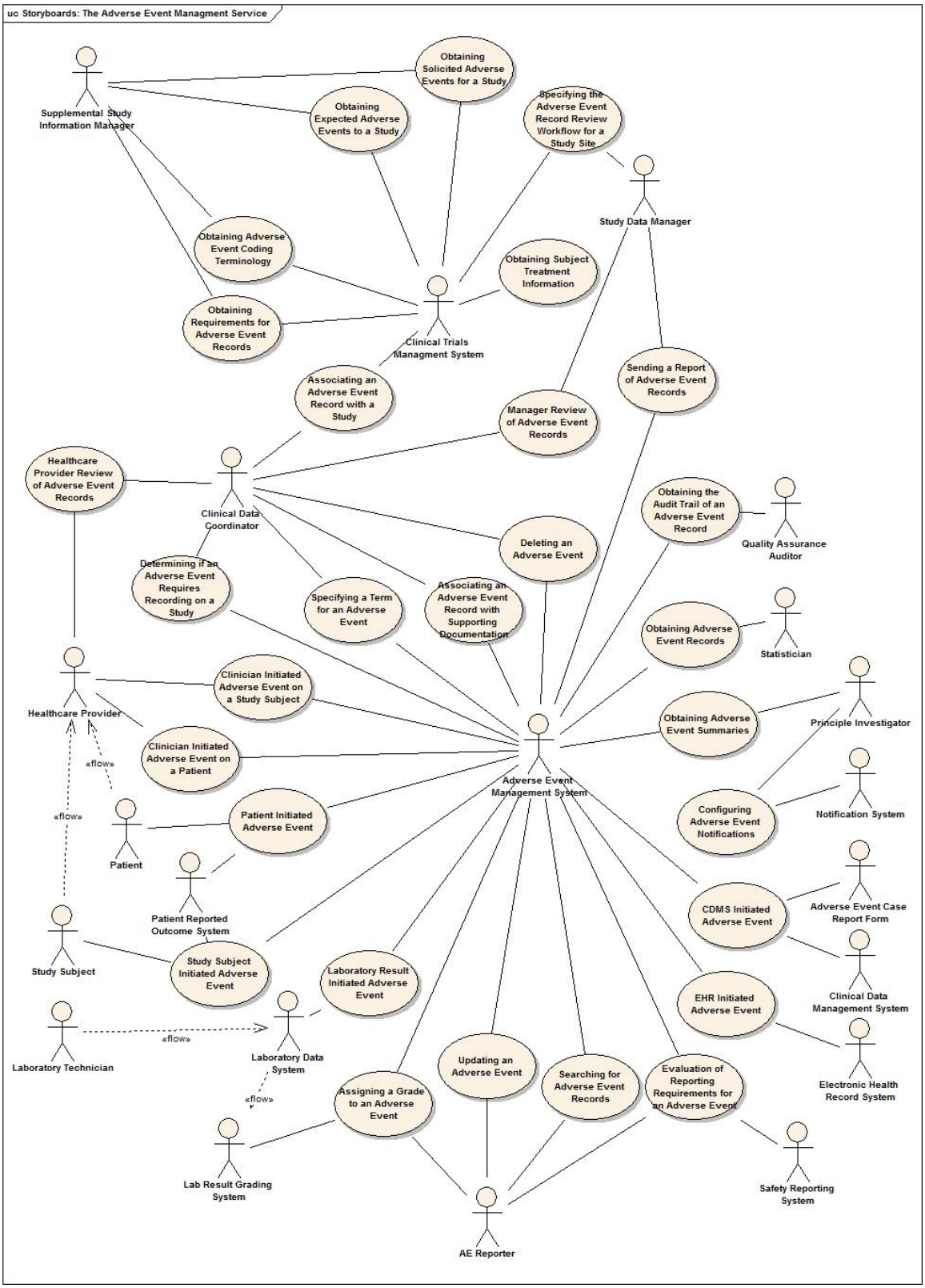
Name	Notes
Adverse Event Management System	A system used to record adverse events.
Clinical Trials Management System (CTMS)	The system used to store the information regarding protocols, people, organizations, and subjects, and schedules that are needed to conduct a clinical trial.
Laboratory Data System	The system used to store the results of laboratory tests.
Lab Result Grading System	Used to obtain automated grading of lab based adverse events.
Notification System	Used to provide notifications regarding adverse event management activities.
Safety Reporting System	Used to evaluate adverse events against criteria to determine appropriate reporting requirements.
Electronic Health Record (EHR) System	The system which houses the clinical data associated with the conduct of routine clinical care.
Adverse Event Case Report Form (AE-CRF)	The form, either paper or electronic, used to record the adverse events observed on a study-subject.
Patient Reported Outcome	The system used to record

(PRO) System	adverse symptoms (events) directly from subjects/patients.
Clinical Data Management System (CDMS)	The system which houses the clinical data associated with the conduct of a clinical trial.

2.2 Story Boards

2.2.1 Overview

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


uc Storyboards: The Adverse Event Managment Service
Supplemental Study Information Manager
Obtaining Solicited Adverse Events for a Study
Obtaining Expected Adverse Events to a Study
Specifying the Adverse Event Record Review Workflow for a Study Site
Study Data Manager
Obtaining Adverse Event Coding Terminology
Obtaining Subject Treatment Information
Obtaining Requirements for Adverse Event Records
Clinical Trials Managment System
Associating an Adverse Event Record with a Study
Sending a Report of Adverse Event Records
Manager Review of Adverse Event Records
Healthcare Provider Review of Adverse Event Records
Clinical Data Coordinator
Obtaining the Audit Trail of an Adverse Event Record
Quality Assurance Auditor
Deleting an Adverse Event
Determining if an Adverse Event Requires Recording on a Study
Specifying a Term for an Adverse Event
Associating an Adverse Event Record with Supporting Documentation
Obtaining Adverse Event Records
Statistician
Healthcare Provider
Clinician Initiated Adverse Event on a Study Subject
Principle Investigator
Obtaining Adverse Event Summaries
Clinician Initiated Adverse Event on a Patient
«flow»
Adverse Event Management System
«flow»
Configuring Adverse Event Notifications
Notification System
Patient
Patient Initiated Adverse Event
Patient Reported Outcome System
CDMS Initiated Adverse Event
Adverse Event Case Report Form
Study Subject
Study Subject Initiated Adverse Event
Laboratory Result Initiated Adverse Event
EHR Initiated Adverse Event
Clinical Data Management System
Laboratory Technician
«flow»
Laboratory Data System
Updating an Adverse Event
Searching for Adverse Event Records
Evaluation of Reporting Requirements for an Adverse Event
Electronic Health Record System
«flow»
Assigning a Grade to an Adverse Event
Lab Result Grading System
Safety Reporting System
AE Reporter

2.2.2 AE-SB1 – Clinician Initiated Adverse Event on a Study Subject

Outline	An adverse event is identified by a Healthcare Provider during the clinical exam of a Study Subject who is participating on a clinical trial.
Detail	During a scheduled clinical exam for the clinical trial, Dr. Jones (Healthcare Provider) observes that Jerry Carlos (Study Subject) is experiencing an adverse event. Dr. Jones describes the adverse event in Jerry Carlos' chart. Lucy Taylor (AE Reporter) later reviews the chart and enters the adverse event information onto the Adverse Event Case Report Form (AE-CRF) for the study after which it is entered into the Adverse Event Management System.

2.2.3 AE-SB2 – Clinician Initiated Adverse Event on a Patient

Outline	An adverse event is identified by a Healthcare Provider during the clinical exam of a Patient as part of clinical care.
Detail	During a clinical exam, Dr. Jones (Healthcare Provider) observes that Mike Sweet (Patient) is experiencing severe headache after taking a prescribed medication. Dr. Jones describes the headache in Mike Sweet's chart. Lucy Taylor (AE Reporter) later reviews the chart and enters "headache" as an adverse event into the Adverse Event Management System.

2.2.4 AE-SB3 – Study Subject Initiated Adverse Event

Outline	A Study Subject directly reports an adverse symptom and it is initiated as an adverse event.
Detail	As part of the study he is participating on, Jerry Carlos (Study Subject) completes a weekly questionnaire regarding symptoms that he is experiencing. Jerry Carlos records these symptoms into the Patient Reported Outcome (PRO) system. The PRO system sends these symptoms to the Adverse Event Management System used for this clinical trial and an adverse event record is created.

2.2.5 AE-SB4 – Patient Initiated Adverse Event

Outline	A Patient directly reports an adverse symptom and it is initiated as an adverse event.
Detail	Dr. David Jones (Healthcare Provider) provides his patients with access to a Patient Reported Outcome (PRO) system that can be used by the patient to report any side-effects they are having as part of a treatment. Mike Sweet (Patient) has recently been treated by Dr. Jones for headaches. Since the treatment for his headache Mike Sweet has experienced bouts of dizziness. Mike Sweet records his dizziness symptom into the Patient Reported Outcome (PRO) system. The PRO system sends this symptom to the Adverse Event Management System and an adverse event record is created.

2.2.6 AE-SB5 – Laboratory Result Initiated Adverse Event

Outline	An out-of-range laboratory result is initiated as an adverse event.
Detail	During a routine visit Jerry Carlos has a blood sample drawn as part of the treatment. His sample is analyzed by John Miller, the lab technician at the laboratory and it is found that the potassium level is well beyond normal range. The lab system electronically reports this lab to the Adverse Event Management System and an adverse event record is created.

2.2.7 AE-SB6 – CDMS Initiated Adverse Event

Outline	An AE Reporter reviews a subject's medical chart, identifies an adverse symptom, and records it onto an AE-CRF. A Data Coordinator then reviews the AE-CRF and enters the symptom into the CDMS after which an adverse event record is created in the Adverse Event Management System.
Detail	Lucy Taylor (AE Reporter) is reviewing the clinical notes from Jerry Carlos' routine visit. She notices a note that Mr. Carlos was experiencing headaches. Lucy Taylor enters "headache" as an adverse symptom onto the Adverse Event Case Report Form (AE-CRF). Alabama Adams (Clinical Data Coordinator) reviews the AE-CRF and then enters the AE into the CDMS. The CDMS electronically sends this symptom to the Adverse Event

	Management System used for this clinical trial where a record for the adverse event is created.

2.2.8 AE-SB7 – EHR Initiated Adverse Event

Outline	An adverse symptom is identified by a Healthcare Provider during the clinical exam of a Patient and the symptom is entered into the Patient's Electronic Health Record (EHR) after which an adverse event record is created in the Adverse Event Management System.
Detail	During a clinical exam, Dr. Jones (Healthcare Provider) observes that Mike Sweet (Patient) is experiencing an adverse symptom. Dr. Jones describes the adverse event in Mike Sweet's EHR. The EHR electronically sends this symptom to the Adverse Event Management System where a record for the adverse event is created.

2.2.9 AE-SB8 – Updating an Adverse Event

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

2.2.10 AE-SB9 – Evaluation of Reporting Requirements for an Adverse Event

Outline	An adverse event is assessed to determine if it needs to be reported in an expedited manner.
Detail	Lucy Taylor (AE Reporter) needs to know if Jerry Carlos' (Study Subject) recent headache needs to be reported to the sponsor in an expedited manner. She finds the adverse event in the Adverse Event Management System and asks the system if further reporting is required. The Adverse Event Management System sends

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

2.2.11 AE-SB10 – Configuring Adverse Event Notifications

Outline	A Healthcare Provider specifies the conditions under which they will receive a notification regarding adverse events records.
Detail	Dr. Linda Lu (Principal Investigator) would like to receive an email notification when an adverse event of grade 4 or higher is entered on study NCI00234. A grade 4 adverse event record is entered into the Adverse Event Management System for study NCI00234 and subsequently an email is sent to Dr. Lu regarding this adverse event.

2.2.12 AE-SB11 – Assigning Grade to an Adverse Event

Outline	An adverse event is graded.
Detail	A grading of severity is needed for the potassium adverse event that was created due to an elevated potassium lab result for Jerry Carlos (Study Subject). A request to grade this lab-based adverse event is sent to the Lab Result Grading System along with any information required to determine the grade. The Lab Result Grading System responds with the appropriate grade(s) for the lab-based adverse event. The Adverse Event Management System associates the grade with the lab-based adverse event. If multiple grade options are returned, then the Adverse Event Management System will provide the grading options for review and selection by Lucy Taylor (AE Reporter).

2.2.13 AE-SB12 – Obtaining Subject Treatment Information

Outline	Treatment information for a study subject at the time of an adverse event occurrence is obtained.
Detail	Information is required about the study treatment that Jerry Carlos

	(Study Subject) was undergoing at the time his headache adverse event presented. A request for this information is sent to the Clinical Trials Management System (CTMS). The CTMS responds with the requested information. The Adverse Event Management System associates this information with the adverse event. Any missing information is identified by the Adverse Event Management System for review by Lucy Taylor (AE Reporter).

2.2.14 AE-SB13 – Searching for Adverse Event Records

Outline	Search criteria are provided and adverse event records satisfying the search criteria are identified.
Detail	Lucy Taylor (AE Reporter) needs to find certain adverse event records for Jerry Carlos (Study Subject). She enters the search criteria into the Adverse Event Management System. The Adverse Event Management System identifies the records which satisfy the search criteria.

2.2.15 AE-SB14 – Obtaining Adverse Event Records

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

2.2.16 AE-SB15 – Obtaining Adverse Event Summaries

Outline	Adverse event records of interest are identified, the attribute(s) on which to summarize the records are specified, along with method of summarization, and the requested summaries are provided

Detail	Dr. Lu (Principal Investigator) would like to summarize a collection of adverse event records by severity grade and study ID. In the Adverse Event Management System she identifies the adverse event records in her collection of interest, provides the attribute(s) upon which she would like to categorize the collection (in this case, severity grade and study ID), and provides the method of summary (e.g. % of total). The Adverse Event Management System processes the request and returns the summary information.

2.2.17 AE-SB16 – Obtaining Adverse Event Coding Terminology

Outline	An AE Reporter obtains the terminology to be used for adverse event recording for a specific study.
Detail	Lucy Taylor (AE Reporter) is preparing to record adverse events for study NCI00234. She reviews the protocol and identifies the CTCAE v3.0 as the adverse event terminology to use for the study and MedDRA v12 as the terminology to use for "Other, specify" terms. She enters adverse events into the Adverse Event Management System using the appropriate terminologies.

2.2.18 AE-SB17 – Obtaining Requirements for Adverse Event Records

Outline	An AE Reporter obtains the requirements for adverse event records on a specific study.
Detail	Lucy Taylor (AE Reporter) is preparing to record adverse events for study NCI00234. She reviews the protocol and identifies the mandatory, optional, and not applicable attributes for adverse event entry. She also identifies that "verbatim" must be entered prior to assigning a CTCAE v3.0 term. She enters adverse events into the Adverse Event Management System according to these requirements.

2.2.19 AE-SB18 – Obtaining Solicited Adverse Events for a Study

Outline	An AE Reporter obtains the adverse events that should always be evaluated during certain epochs of a study.
Detail	Lucy Taylor (AE Reporter) is preparing to record adverse events for a treatment epoch on study NCI00234. She reviews the protocol and identifies the adverse events to be evaluated during each treatment cycle. She enters the observations for these solicited adverse events into the Adverse Event Management System.

2.2.20 AE-SB19 – Obtaining Expected Adverse Events for a Study

Outline	An AE Reporter obtains the adverse events that are expected to occur on a study.
Detail	Lucy Taylor (AE Reporter) is preparing to record adverse events for study NCI00234. She reviews the protocol and identifies the adverse events that should be considered expected. She enters this information into the Adverse Event Management System.

2.2.21 AE-SB20 – Obtaining the Audit Trail of an Adverse Event Record

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

2.2.22 AE-SB21 – Specifying the Adverse Event Record Review Workflow for a Study Site

Outline	The Study Data Manager for the study specifies the workflow that should be followed for reviewing adverse event records for a study

	site.
Detail	May Cooper (Study Data Manager) defines the mandatory and optional steps that should be followed for reviewing an adverse event record. This workflow is provided to Patty Higgs (Supplemental Study Information Manager) who enters this information into the Adverse Event Management System.

2.2.23 AE-SB22 – Healthcare Provider Review of Adverse Event Records

Outline	A Clinical Data Coordinator sends one or more adverse event records to a Healthcare Provider for review. The Healthcare provider then reviews the record(s).
Detail	Alabama Adams (Clinical Data Coordinator) identifies several adverse event records for study NCI00234 and sends them to Dr. David Jones (Healthcare Provider) for review. Dr. Jones is notified of a pending adverse event record review. He then reviews the records, provides comments and/or updates the record, and completes his review.

2.2.24 AE-SB23 – Manager Review of Adverse Event Records

Outline	A Clinical Data Coordinator sends one or more adverse event records to a Study Data Manager for review. The Study Data Manager then reviews the record(s).
Detail	Alabama Adams (Clinical Data Coordinator) identifies several adverse event records for study NCI00234 and sends them to May Cooper (Study Data Manager) for review. May is notified of a pending adverse event record review. She reviews the records, provides comments and/or updates the record, and completes her review.

2.2.25 AE-SB24 – Sending a Report of Adverse Event Records

Outline	A Study Data Manager identifies adverse event records and sends those records as a report.
Detail	May Cooper (Study Data Manager) has identified, through an adverse event search, the adverse event records from study

	NCI00234 that are ready to be reported to the sponsor. She obtains those records and/or summaries of those records and sends them to the sponsor.

2.2.26 AE-SB25 – Associating an Adverse Event Record with a Study

Outline	A Clinical Data Coordinator links an adverse event record from a Patient to the study(s) on which the patient is participating as a Study Subject.
Detail	Jerry Carlos (Study Subject) is participating on study NCI00234. During the weekend, Mr. Carlos was seen at the emergency room for a high fever. The attending physician in the emergency room documented the fever as an adverse event in Mr. Carlos' electronic medical record (EMR). Alabama Adams (Clinical Data Coordinator) looks up Mr. Carlos' patient records and identifies the fever adverse event record as needing to be recorded for study NCI00234. She links the adverse event record to the study.

2.2.27 AE-SB26 – Associating an Adverse Event Record with Supporting Documentation

Outline	A Clinical Data Coordinator links an adverse event record from a Study Subject to information related to the adverse event.
Detail	Jerry Carlos (Study Subject) is seen in clinic by Dr. David Jones (Healthcare Provider). Dr. Jones describes, in narrative form, the symptoms exhibited by Mr. Carlos. Alabama Adams (Clinical Data Coordinator) abstracts the adverse events from this narrative. Ms. Adams links the abstracted adverse events to the narrative dictated by Dr. Jones.

2.2.28 AE-SB27 – Determining if an Adverse Event Requires Recording on a Study

Outline	An AE Reporter evaluates an adverse event to determine if it needs to be associated with a study.
Detail	Lucy Taylor (AE Reporter) is preparing to record adverse events for study NCI00234. She reviews the protocol and identifies the

	criteria regarding which adverse events should be recorded for the study. She evaluates each adverse event against this criteria and records the appropriate events into the Adverse Event Management System.

2.2.29 AE-SB28 – Specifying a Term for an Adverse Event

Outline	A Clinical Data Coordinator specifies the adverse event term from an adverse event terminology that should be associated to an adverse event record.
Detail	Jerry Carlos (Study Subject) has presented with an adverse event that has initially been recorded with the verbatim of "sick to stomach." Alabama Adams (Clinical Data Coordinator) references the CTCAE v4.0, which is the adverse event terminology for the study. She finds the CTCAE v4.0 term "nausea" as appropriate and specifies this as the term for the adverse event.

2.2.30 AE-SB29 – Deleting an Adverse Event

Outline	The adverse event record needs to be deleted.
Detail	Alabama Adams (Clinical Data Coordinator) accidentally entered an adverse event on Jerry Carlos (Study Subject) that actually occurred on a different Study Subject. She deletes the adverse event from Jerry Carlos' records.

3 Detailed Functional Model

3.1 Structure of the Service

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

Capability	Description
Initiate Adverse Event	Provides the capability to initiate an adverse event record from any source.
Update Adverse Event	Provides the capability to update an adverse event record.
Find Adverse Event Terms	Provides the ability to search an adverse event terminology system and find adverse event terms that match the search string.
Deactivate Adverse Event	Provides the ability to change the state of an adverse event to effectively delete the event.
Associate Adverse Event to Study	Provides the capability to link an adverse event record to a study.
Dissociate Adverse Event from Study	Provides the capability to remove the link between an adverse event and a study.
Update Expected Adverse Events for a Study	Provides the capability to specify and alter the expected adverse event records associated to a study.
Get Expected Adverse Events for a Study	Provides the capability to request and obtain the expected adverse event records associated to a study.
Update Solicited Adverse Events for a Study Epoch	Provides the capability to specify and alter the solicited adverse event records associated to a study epoch.
Get Solicited Adverse Event for a Study Epoch	Provides the capability to request and obtain the solicited adverse event records associated to a study epoch.
Associate Additional Information to an Adverse Event	Provides the capability to link an adverse event with additional information.
Dissociate Additional Information from an Adverse Event	Provides the capability to remove the link between an existing adverse event and specified additional information.
Find Additional Information Associated to an Adverse Event	Provides the capability to find the additional information associated to an existing adverse event.
Get Additional Information Associated to an	Provides the capability to retrieve the additional information associated to an existing adverse event.

Adverse Event	
Associate Subject Treatment Information to an Adverse Event	Provides the capability to create 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.
Dissociate Subject Treatment Information from an Adverse Event	Provides the capability to remove the link between the adverse event and information regarding what the subject was treated with prior to the adverse event.
Find Adverse Events	Provides the ability to search for adverse events matching search criteria.
Get Adverse Event Data	Provides the ability to request and retrieve adverse event record details.
Get Adverse Event Summary Data	Provides the ability to request and retrieve summarized information regarding adverse event records.
Get an Audit Trail of an Adverse Event Record	Provides the ability to request and retrieve an audit trail of all changes that have been made to an adverse event record.
Update Adverse Event Coding Terminology for a Study	Provides the capability to specify and alter the specific terminology system to be used for encoding adverse events on a study.
Get Adverse Event Coding Terminology for a Study	Provides the capability to request and obtain the specific terminology system to be used for encoding adverse events on a study.
Update Adverse Event Data Requirements for a Study	Provides the ability to specify and alter the mandatory, optional, and not applicable (disallowed) attributes for adverse events recorded for a specific study.
Get Adverse Event Data Requirements for a Study	Provides the ability to request and obtain the data entry requirements regarding the mandatory, optional, and not applicable (disallowed) fields for adverse event records associated to a study.
Update Adverse Event Recording Rules for a Study	Provides the capability to specify and alter the criteria against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Get Adverse Event Recording Rules for a Study	Provides the capability to request and obtain the criteria against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Evaluate an Adverse Event Against Recording Rules	Provides the capability to 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.
Update Adverse Event	Provides the capability to specify and alter the workflow

Review Process for a Study	process that must be followed for reviewing adverse event records.
Get Adverse Event Review Process for a Study	Provides the capability to request and obtain the workflow process that must be followed for reviewing adverse event records.
Review Adverse Events	Provides the capability to review adverse event records.
Update Adverse Event Notification	Provides the capability to specify and alter the criteria that will trigger notifications regarding adverse event records.
Deactivate Adverse Event Notification	Provides the capability to delete a notification trigger.

3.2 Detail of the Capabilities

Name [M]	Initiate Adverse Event
Description [M]	Enables a client system to create an adverse event record in the Adverse Event Management System with all fields required for adverse event creation. If successful, a properly formed Adverse Event object with an identifier is returned as an acknowledgement that the Adverse Event is initiated.
Pre-Conditions [M]	A Patient or Study Subject exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: AdverseEvent.result (verbatim and/or term) SubjectIdentifier.identifier (Patient or Study Subject identifier) Optional: AdverseEvent.comment AdverseEvent.onsetDate AdverseEvent.resolutionDate

	AdverseEvent.locationDescription AdverseEvent.expectedIndicator AdverseEvent.gradeCode AdverseEvent.reportedDate AdverseEvent.hospitalizationRequiredIndicator AdverseEvent.postReportUpdateDate AdverseEventSeriousness.date AdverseEventSeriousness.code
Outputs [M]	An Adverse Event object with an identifier
Post-Conditions [O]	An Adverse Event is initiated on the system
Exception Conditions [M]	Invalid Adverse Event Object representation Specified Patient or Study Subject is invalid Invalid data type or code value for any attribute
Aspects left for Technical Bindings [O]	Where identifier is not part of the input, some means is necessary to identify potential duplicates. This may necessitate matching on other key attributes
Notes [O]	The data entry requirements for the optional inputs will need to utilize the capability “Get Adverse Event Data Requirements for a Study.”

Name [M]	Update Adverse Event
Description [M]	Enables updating an existing Adverse Event record.
Pre-Conditions [M]	The Adverse Event record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	Mandatory: The Adverse Event record identifier Optional:

	AdverseEvent.result (verbatim and/or term) AdverseEvent.comment AdverseEvent.onsetDate AdverseEvent.resolutionDate AdverseEvent.locationDescription AdverseEvent.expectedIndicator AdverseEvent.gradeCode AdverseEvent.reportedDate AdverseEvent.hospitalizationRequiredIndicator AdverseEvent.postReportUpdateDate AdverseEventSeriousness.date AdverseEventSeriousness.code A description of the reason for the update.
Outputs [M]	Return an instance of the updated Adverse Event object. A properly formed and returned Adverse Event object with the updated data is an acknowledgement that the Adverse Event is updated.
Post-Conditions [O]	Adverse Event is updated
Exception Conditions [M]	Adverse Event Identifier is invalid Invalid data type or code value for any attribute Invalid Adverse Event Object representation
Aspects left for Technical Bindings [O]	The way by which interfaces are realized between Dependent Systems
Notes [O]	This operation depends on AE Query Profile to retrieve the Adverse Event object in order to allow a service consumer to update it This operation requires the entire Adverse Event object consisting of both the existing as well as the changed attributes to be passed. External Systems can use the Query Operation to obtain the latest Adverse Event object and update it and pass it as parameter to this operation.

	Failure to pass in an existing attribute will change that attributes value to NULL. Updating the Patient or Study Subject to which the Adverse Event is associated is not a supported operation. Updates to this association will require an Adverse Event to be deactivated and the re-initiated with an association to the correct Patient or Study Subject. The data entry requirements for the optional inputs will need to utilize the capability “Get Adverse Event Data Requirements for a Study.”

Name [M]	Find Adverse Event Terms
Description [M]	Provides the ability to search an adverse event terminology system and find adverse event terms that match the search string.
Pre-Conditions [M]	An adverse event terminology system is available to reference.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	AdverseEvent.result (verbatim or term) StudyProtocolVersion.aeCodingSystem
Outputs [M]	A list of adverse event terms (AdverseEvent.result) from the requested terminology system (StudyProtocolVersion.aeCodingSystem) that are possible matches or synonyms for the string searched (AdverseEvent.result).
Post-Conditions [O]	Initiate a request to update AdverseEvent.result for a specified record
Exception Conditions [M]	Invalid StudyProtocolVersion.aeCodingSystem Improperly formatted AdverseEvent.result
Aspects left for Technical Bindings	

[O]	
Notes [O]	

Name [M]	Deactivate Adverse Event
Description [M]	Provides the ability to change the state of an adverse event to effectively delete the event.
Pre-Conditions [M]	The Adverse Event record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. A description of the reason for the deactivation [O]
Outputs [M]	An instance of the deactivated Adverse Event object along with the identifiers of all studies (DocumentIdentifier.identifier) from which the adverse event was dissociated.
Post-Conditions [O]	
Exception Conditions [M]	The Adverse Event Identifier is invalid The user of the capability is not authorized to dissociate the adverse event from the associated studies.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Associate Adverse Event to Study
Description [M]	Provides the capability to link an adverse event record to

	a study.
Pre-Conditions [M]	The Adverse Event record exists. The Study exists to which an association is being made. The Patient is a Study Subject on the Study to which an association is being made.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The Adverse Event record identifier. DocumentIdentifier.identifier (the study identifier)
Outputs [M]	Return an acknowledgement that the adverse event record was successfully associated to the specified study.
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid The study identifier is invalid The Patient is not registered as a Study Subject on the specified study. The user of the capability is not authorized to associate the adverse event to the specified study.
Aspects left for Technical Bindings [O]	Format or data type of the acknowledgement
Notes [O]	

Name [M]	Dissociate Adverse Event from Study
Description [M]	Provides the capability to remove the link between an adverse event and a study.
Pre-Conditions [M]	The adverse event record exists. The study exists.

	The adverse event record is associated to the study.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. The identifier of the study to be dissociated from the adverse event record (DocumentIdentifier.identifier). A description of the reason for the dissociation [O]
Outputs [M]	Return an acknowledgement that the adverse event record was successfully dissociated from the specified study.
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid The study identifier is invalid The adverse event record was not associated to the specified study. The user of the capability is not authorized to dissociate the adverse event from the specified study.
Aspects left for Technical Bindings [O]	Format or data type of the acknowledgement
Notes [O]	

Name [M]	Update Expected Adverse Events for a Study
Description [M]	Provides the capability to specify and alter the expected adverse event records associated to a study.
Pre-Conditions [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.

Inputs [M]	The verbatim and/or adverse event terms considered expected (AdverseEvent.result) for the study. The identifier of the study to which expected adverse events are being associated (DocumentIdentifier.identifier). The adverse event coding terminology associated with the provided adverse event term (StudyProtocolVersion.aeCodingSystem) [O].
Outputs [M]	Return an acknowledgement that the expected adverse events were successfully associated to the specified study.
Post-Conditions [O]	Any expected adverse events that were previously associated to the study will be removed.
Exception Conditions [M]	Invalid representation of the adverse event term/verbatim (AdverseEvent.result) Specified study identifier is invalid The specified coding terminology is invalid. The specified adverse event term is invalid for the specified coding terminology.
Aspects left for Technical Bindings [O]	
Notes [O]	Expected adverse event terms for a study are typically derived based on the adverse events expected for the study interventions (e.g. the pharmaceutical being used as the study treatment). The derivation of the expected adverse events based on the study interventions is beyond the boundaries of this service and will need to be obtained elsewhere.

Name [M]	Get Expected Adverse Events for a Study
Description [M]	Provides the capability to retrieve the expected adverse event records associated to a study.

Pre-Conditions [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The identifier of the study to which expected adverse events have been associated (DocumentIdentifier.identifier). The adverse event coding terminology that the expected adverse event terms should be returned using (StudyProtocolVersion.aeCodingSystem) [O]. The ID(s) of the specific study agent(s) for which expected adverse events are sought (Product.identifier) [O]. The name(s) of the specific study agent(s) for which expected adverse events are sought (Product.name) [O].
Outputs [M]	The verbatim and/or adverse event terms considered expected (AdverseEvent.result) for the study. The identifier of the study to which expected adverse events are being associated (DocumentIdentifier.identifier). The adverse event coding terminology associated with the provided adverse event term (StudyProtocolVersion.aeCodingSystem) [O]. The ID(s) of the specific study agent(s) for which the provided adverse events are expected (Product.identifier) [O]. The name(s) of the specific study agent(s) for which the provided adverse events are expected (Product.name) [O].
Post-Conditions [O]	
Exception Conditions [M]	The specified study identifier is invalid. The specified coding terminology is invalid. The specified agent(s) are invalid for the study.
Aspects left for	

Technical Bindings [O]	
Notes [O]	

Name [M]	Update Solicited Adverse Events for a Study Epoch
Description [M]	Provides the capability to specify and update the solicited adverse event records associated to a study epoch.
Pre-Conditions [M]	The study exists. The study epoch exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The verbatim and/or adverse event terms (AdverseEvent.result) for which observations will be solicited during the conduct of the study. The identifier of the study to which solicited adverse events are being associated (DocumentIdentifier.identifier). The name of the study epoch to which solicited adverse events are being associated (Epoch.name). The adverse event coding terminology associated with the provided adverse event term (StudyProtocolVersion.aeCodingSystem) [O].
Outputs [M]	Return an acknowledgement that the solicited adverse events were successfully associated to the specified study epoch.
Post-Conditions [O]	Any solicited adverse events that were previously associated to the study epoch will be removed.
Exception Conditions [M]	Invalid representation of the adverse event term/verbatim (AdverseEvent.result) The study identifier is invalid. Specified study epoch name is invalid

	The specified coding terminology is invalid. The specified adverse event term is invalid for the specified coding terminology.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Solicited Adverse Events for a Study Epoch
Description [M]	Provides the capability to obtain the solicited adverse event records associated to a study epoch.
Pre-Conditions [M]	The study exists. The study epoch exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The identifier of the study to which solicited adverse events are being associated (DocumentIdentifier.identifier). The name of the study epoch to which solicited adverse events are being associated (Epoch.name).
Outputs [M]	The verbatim and/or adverse event terms (AdverseEvent.result) for which observations will be solicited during the conduct of the study. The adverse event coding terminology associated with the provided adverse event term (StudyProtocolVersion.aeCodingSystem) [O].
Post-Conditions [O]	
Exception Conditions [M]	The study identifier is invalid. Specified study epoch name is invalid
Aspects left for	

Technical Bindings [O]	
Notes [O]	

Name [M]	Associate Additional Information to an Adverse Event
Description [M]	Provides the capability to link an adverse event to additional information.
Pre-Conditions [M]	The adverse event exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier to which additional information is to be associated. The additional information to associate to an adverse event. A description of the additional information being associated to the adverse event.
Outputs [M]	Return an acknowledgement that the association was successfully created and an identifier for the association.
Post-Conditions [O]	Adverse events are associated with the additional information.
Exception Conditions [M]	The adverse event identifier is invalid
Aspects left for Technical Bindings [O]	Format or data type of the additional information. Format or data type of acknowledgement
Notes [O]	

Name [M]	Dissociate Additional Information from an Adverse Event

Description [M]	Provides the capability to remove the link between an existing adverse event and specified additional information.
Pre-Conditions [M]	The adverse event exists. The association between the adverse event and the additional information exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier from which additional information is to be dissociated. The identifier of the association that should be dissociated.
Outputs [M]	Return an acknowledgement that the association was successfully removed.
Post-Conditions [O]	The adverse event is dissociated from the additional information.
Exception Conditions [M]	The adverse event identifier is invalid. The identifier of the association is invalid.
Aspects left for Technical Bindings [O]	Format or data type of the additional information association identifier. Format or data type of acknowledgement
Notes [O]	

Name [M]	Find Additional Information Associated to an Adverse Event
Description [M]	Provides the capability to find the additional information associated to an existing adverse event.
Pre-Conditions [M]	The adverse event exists.

Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier.
Outputs [M]	Returns the association identifiers for the additional information associated to the adverse event. Also returns the description of the additional information associated to the adverse event.
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid.
Aspects left for Technical Bindings [O]	Format or data type of the additional information association identifier. Format or data type of acknowledgement
Notes [O]	

Name [M]	Get Additional Information Associated to an Adverse Event
Description [M]	Provides the capability to retrieve the additional information associated to an existing adverse event.
Pre-Conditions [M]	The adverse event exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. The identifier of the association between the adverse event and the additional information [O].
Outputs [M]	Returns the additional information associated to the adverse event. If the identifier of the association between the adverse event and the additional information is not provided, then all additional information associated to the

	adverse event will be returned along with the identifiers for the associations.
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid. The identifier of the association between the adverse event and the additional information is invalid.
Aspects left for Technical Bindings [O]	Format or data type of the additional information. Format or data type of acknowledgement
Notes [O]	

Name [M]	Associate Subject Treatment Information to an Adverse Event
Description [M]	Provides the capability to create 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 [M]	The adverse event exists. The subject treatment information exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. The subject treatment information identifier.
Outputs [M]	Return an acknowledgement that the association was successfully created.
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid.

	The subject treatment information identifier is invalid. The adverse event and subject treatment information are not associated to the same subject.
Aspects left for Technical Bindings [O]	Format or data type of acknowledgement.
Notes [O]	The subject treatment information must already exist.

Name [M]	Dissociate Subject Treatment Information from an Adverse Event
Description [M]	Provides the capability to remove the association between an adverse event and the subject treatment information.
Pre-Conditions [M]	The adverse event record exists. The association exists between the subject treatment information and the adverse event record.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. The subject treatment information identifier.
Outputs [M]	Returns an acknowledgement that the subject treatment information was successfully dissociated
Post-Conditions [O]	
Exception Conditions [M]	The adverse event identifier is invalid. The subject treatment information identifier is invalid.
Aspects left for Technical Bindings [O]	Format or data type of acknowledgement.
Notes [O]	

Name [M]	Find Adverse Events
Description [M]	Provides the ability to search for Adverse Events matching search criteria.
Pre-Conditions [M]	Search criteria are provided
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The search criteria for adverse event records in the form of a query. The input would specify the criteria needed to search on (e.g. get all AEs with grade >= 3). The search criteria for any associated element upon which the search should be restricted.
Outputs [M]	Returns the identifiers for adverse event records matching search criteria. Indicates pagination if search found bulky results
Post-Conditions [O]	Returns no results if there is no match
Exception Conditions [M]	Invalid data type or code value for any attribute. Mandatory search criteria not provided.
Aspects left for Technical Bindings [O]	Format or data type of acknowledgement. The mandatory search criteria. The associated objects available for inclusion in the search. The pagination standard.
Notes [O]	Default boundary checks are enforced to avoid system/service failures.

Name [M]	Get Adverse Event Data

Description [M]	Provides the ability to request and retrieve the adverse event record details.
Pre-Conditions [M]	The adverse event record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifiers. The child element objects to which the output should be constrained [O].
Outputs [M]	Returns the entire adverse event record, including all specified child element objects, for all records identified in the input. If no child elements are specified in the input, all child element objects are returned. Indicates pagination if search found bulky results
Post-Conditions [O]	
Exception Conditions [M]	The adverse event record identifier is invalid.
Aspects left for Technical Bindings [O]	The pagination standard.
Notes [O]	

Name [M]	Get Adverse Event Summary Data
Description [M]	Provides the ability to request and retrieve summarized information regarding adverse event records.
Pre-Conditions [M]	
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	One or more of the below filter criteria.

	Two or more adverse event identifiers. One or more study identifiers One or more patient and/or study subject identifiers
Outputs [M]	A collection object containing the results
Post-Conditions [O]	Returns data
Exception Conditions [M]	Invalid study identifier Invalid adverse event record identifier Invalid data type or code value for any attribute Invalid patient and/or study subject identifier
Aspects left for Technical Bindings [O]	Format or data type for the returned summary
Notes [O]	

Name [M]	Get Audit Trail of an Adverse Event Record
Description [M]	Provides the ability to request and retrieve an audit trail of all changes that have been made to an Adverse Event record.
Pre-Conditions [M]	The adverse event record exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. Date range for which audit trail is desired [O]
Outputs [M]	Return audit trail of the adverse event record, within the desired date range, if applicable. The audit trail shall include: The date of any change (create, update, delete) to

	the adverse event record or to any association to the adverse event record. The identifier of the user who performed the change. The code or description that describes the reason for the change (where applicable).
Post-Conditions [O]	Returns audit trail information
Exception Conditions [M]	Invalid data type or code value for any attribute Invalid adverse event record identifier.
Aspects left for Technical Bindings [O]	Format or data type of the audit trail information.
Notes [O]	

Name [M]	Update Adverse Event Notification
Description [M]	Provides the capability to specify and alter the criteria that will trigger notifications regarding adverse event records.
Pre-Conditions [M]	None
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The search criteria for adverse event records for which a notification is being defined in the form of a query. The input would specify the criteria needed to search on (e.g. get all AEs with grade >= 3). The search criteria for any associated element upon which the search should be restricted. The notification identifier, if the desired activity is to

	update an existing notification. [O]
Outputs [M]	Return a notification object with its identifier.
Post-Conditions [O]	A notification is created or updated.
Exception Conditions [M]	Invalid data type or code value for any attribute.
Aspects left for Technical Bindings [O]	The data type and format of the notification
Notes [O]	

Name [M]	Deactivate Adverse Event Notification
Description [M]	Provides the capability to delete a notification trigger.
Pre-Conditions [M]	The notification exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The notification identifier.
Outputs [M]	Returns and acknowledgement that the specified notification was deactivated.
Post-Conditions [O]	Subscribers to the notification are notified of the deactivation.
Exception Conditions [M]	Invalid notification identifier.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Adverse Event Coding Terminology for a Study
Description [M]	Provides the capability to specify and alter the terminology system to be used for encoding adverse events on a study.
Pre-Conditions [M]	The study exists The adverse event terminology exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier) The adverse event coding terminology identifier (StudyProtocolVersion.aeCodingSystem).
Outputs [M]	Returns an acknowledgement of the successful assignment of the adverse event coding terminology to the study.
Post-Conditions [O]	
Exception Conditions [M]	The study identifier is invalid. The adverse event coding terminology identifier is invalid.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Adverse Event Coding Terminology for a Study
Description [M]	Provides the capability to request and obtain the specific terminology system to be used for encoding adverse events on a study.
Pre-Conditions [M]	The study exists The adverse event terminology exists

Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier)
Outputs [M]	Returns the adverse event terminology identifier for the study.
Post-Conditions [O]	
Exception Conditions [M]	The study identifier is invalid.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Adverse Event Data Requirements for a Study
Description [M]	Provides the ability to specify, for a specific study, the mandatory, optional, and not applicable (disallowed) attributes for adverse event records.
Pre-Conditions [M]	The study exists
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier)
Outputs [M]	Returns an adverse event object with each attribute identified as mandatory, optional, or not applicable.
Post-Conditions [O]	The mandatory, optional, and not applicable fields are applied when using the Initiate Adverse Event capability.
Exception	The study identifier is invalid

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

Name [M]	Update Adverse Event Recording Rules for a Study
Description [M]	Provides the capability to specify and alter the criteria against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Pre-Conditions [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier) An adverse event object with each attribute containing the criteria which must be satisfied in order to record the adverse event.
Outputs [M]	Returns a confirmation containing the study identifier and an adverse event object with each attribute containing criteria which must be satisfied in order to record the adverse event.
Post-Conditions [O]	
Exception Conditions [M]	The study identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Get Adverse Event Recording Rules for a Study
Description [M]	Provides the capability to request and obtain the criteria against which an adverse event record should be evaluated to determine if it is an appropriate record for associating to a study.
Pre-Conditions [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier)
Outputs [M]	Returns an adverse event object with each attribute containing criteria which must be satisfied in order to record the adverse event.
Post-Conditions [O]	
Exception Conditions [M]	The study identifier is invalid
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Evaluate an Adverse Event Against Recording Rules
Description [M]	Provides the capability to 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 [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this

	capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier). An adverse event object.
Outputs [M]	Returns a Boolean true / false indication of whether or not the adverse event recording criteria for the study were satisfied.
Post-Conditions [O]	A true response will result in the adverse event being associated to the study.
Exception Conditions [M]	The study identifier is invalid. The format of the adverse event object is invalid.
Aspects left for Technical Bindings [O]	
Notes [O]	

Name [M]	Update Adverse Event Review Process for a Study
Description [M]	Provides the capability to specify and alter the workflow process that must be followed for reviewing adverse event records.
Pre-Conditions [M]	The study exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier). A review process object.
Outputs [M]	Returns an acknowledgement that the review process was associated to the study.
Post-Conditions [O]	
Exception	The study identifier is invalid.

Conditions [M]	The format of the review process object is invalid.
Aspects left for Technical Bindings [O]	The format of the review process object. The format of the acknowledgement.
Notes [O]	

Name [M]	Get Adverse Event Review Process for a Study
Description [M]	Provides the capability to request and obtain the workflow process that must be followed for reviewing adverse event records.
Pre-Conditions [M]	The study exists. A review process object is associated to the study.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The study identifier (DocumentIdentifier.identifier).
Outputs [M]	Returns the review process object associated to the study.
Post-Conditions [O]	An adverse event is routed along the prescribed review process as defined by the returned review process object.
Exception Conditions [M]	The study identifier is invalid.
Aspects left for Technical Bindings [O]	The format of the review process object. The format of the acknowledgement.
Notes [O]	

Name [M]	Review Adverse Events
Description [M]	Provides the capability to review adverse event records.

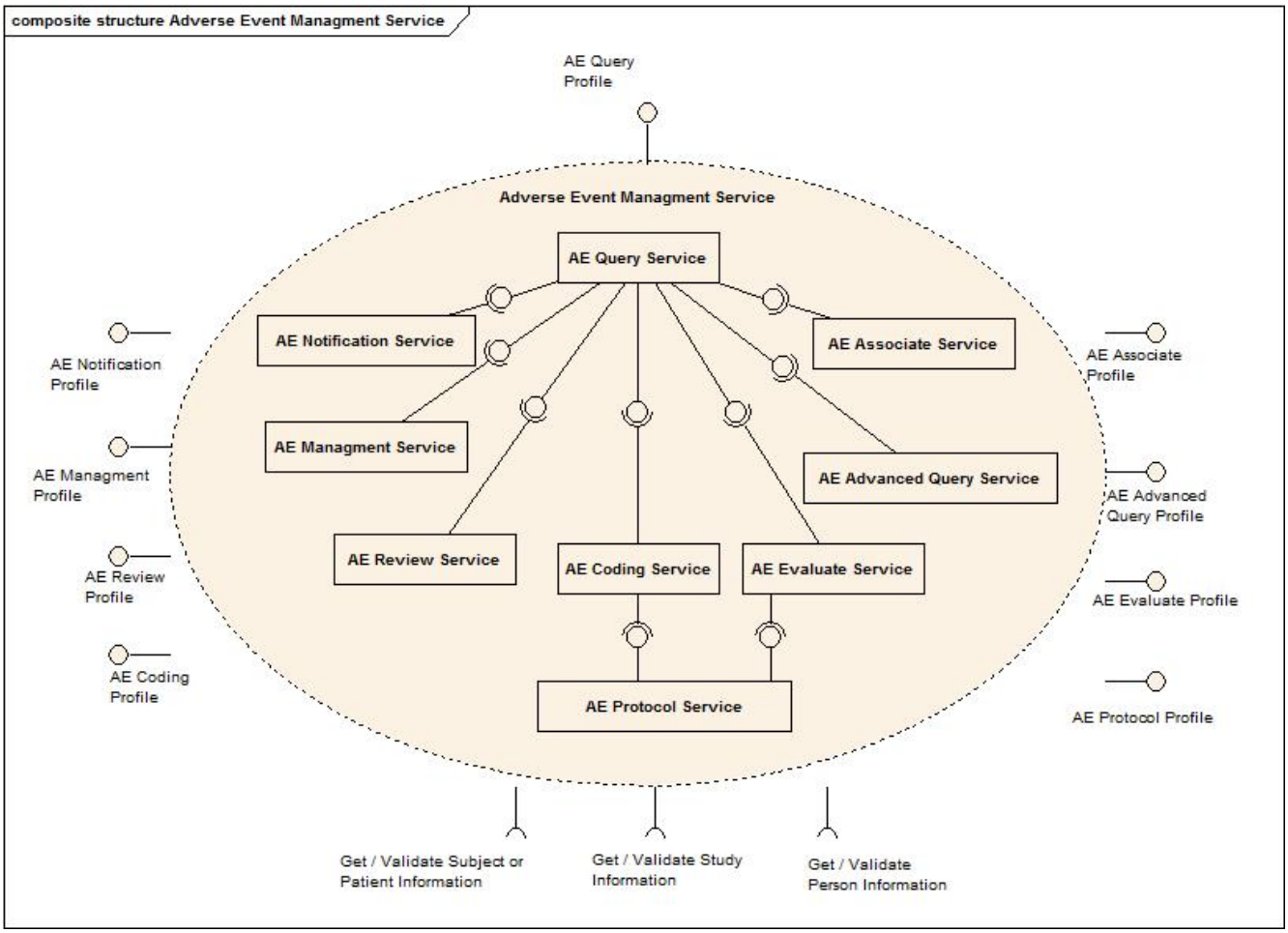
Pre-Conditions [M]	The adverse event record exists.
Security Pre-Conditions [M]	Access control mechanisms need to be in place to ensure that the client has valid privileges to exercise this capability.
Inputs [M]	The adverse event record identifier. The review object containing Comments regarding the review of the adverse event record [O]. An indication of the change in review state of the adverse event record.
Outputs [M]	Returns a confirmation of the review including all comments and review state changes.
Post-Conditions [O]	An adverse event is routed along the prescribed review process as defined by the returned review process object.
Exception Conditions [M]	The adverse event identifier is invalid.
Aspects left for Technical Bindings [O]	The format of the review object. The format of the acknowledgement.
Notes [O]	

4 Profiles

4.1 Functional Profiles

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

4.1.1 Service Composite Structure



4.1.2 Functional Profile Details

Functional Profile No.	Functional Profile Name	Functional Profile Description	Capability Name

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.	• Find Adverse Events • Get Adverse Event Data
AE-FP2	AE Management	The Management series of capabilities details the complete encapsulation boundary behind which the Adverse Event object may be managed.	• Initiate Adverse Event • Update Adverse Event • Deactivate Adverse Event
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.	• Associate Adverse Event to Study • Dissociate Adverse Event from Study • Associate Additional Information to an Adverse Event • Dissociate Additional Information from an Adverse Event • Associate Subject Treatment Information to an Adverse Event • Dissociate Subject Treatment Information

			from an Adverse Event
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.	• Update Adverse Event Notification • Deactivate Adverse Event Notification
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.	• Update Adverse Event Review Process for a Study • Get Adverse Event Review Process for a Study • Review Adverse Events
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.	• Update Adverse Event Coding Terminology for a Study • Get Adverse Event Coding Terminology for a Study • Update Adverse Event Data Requirements for a Study • Get Adverse Event Data

			Requirements for a Study • Update Expected Adverse Events for a Study • Get Expected Adverse Events for a Study • Update Solicited Adverse Events for a Study Epoch • Get Solicited Adverse Events for a Study Epoch • Update Adverse Event Recording Rules for a Study • Get Adverse Event Recording Rules for a Study
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.	• Get Audit Trail of Adverse Event • Get Adverse Event Summary Data • Find Additional Information Associated to an Adverse Event • Get Additional Information Associated to an Adverse Event

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.	• Evaluate an Adverse Event Against Recording Rules
AE-FP9	AE Coding	The AE Coding Functional Profile provides a series of functional capabilities for other systems, services, and users to find coded adverse event terms that are appropriate for an adverse event record.	• Find Adverse Event Terms

4.2 Semantic Profiles

Semantic Profile No.	Semantic Profile Name	Constrained Information Model	Semantic Profile Description
AE-SP1	BRIDG V3.0.2 Adverse Event	BRIDG V3.0.2	• Initiate Adverse Event • Update Adverse Event • Find Adverse Event Terms • Deactivate Adverse Event

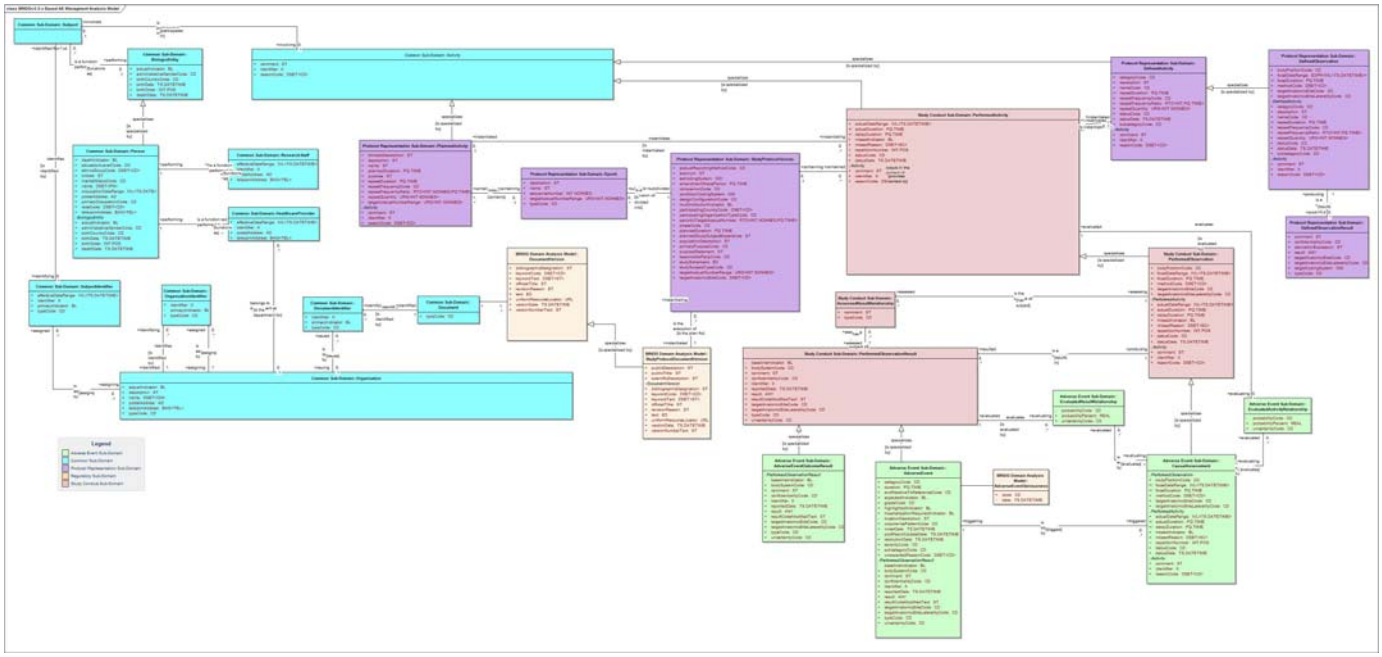
			• Associate Adverse Event to Study • Dissociate Adverse Event from Study • Update Expected Adverse Events for a Study • Get Expected Adverse Events for a Study • Update Solicited Adverse Events for a Study Epoch • Get Solicited Adverse Events for a Study Epoch • Associate Additional Information to an Adverse Event • Dissociate Additional Information from an Adverse Event • Find Additional Information Associated to an Adverse Event • Get Additional Information Associated to an Adverse Event • Associate Subject

			Treatment Information to an Adverse Event • Dissociate Subject Treatment Information from an Adverse Event • Find Adverse Events • Get Adverse Event Data • Get Adverse Event Summary Data • Get an Audit Trail of an Adverse Event Record • Update Adverse Event Coding Terminology for a Study • Get Adverse Event Coding Terminology for a Study • Update Adverse Event Data Requirements for a Study • Get Adverse Event Data Requirements for a Study • Update Adverse Event Recording

			Rules for a Study • Get Adverse Event Recording Rules for a Study • Evaluate an Adverse Event Against Recording Rules • Update Adverse Event Review Process for a Study • Get Adverse Event Review Process for a Study • Review Adverse Events • Update Adverse Event Notification Rule • Deactivate Adverse Event Notification

4.1.1 BRIDG Information Model

The Adverse Event Management Service binds and complies with semantics of BRIDG V3.0 information model. The subset of this model applicable for this service is displayed below.



4.3 Conformance Profiles

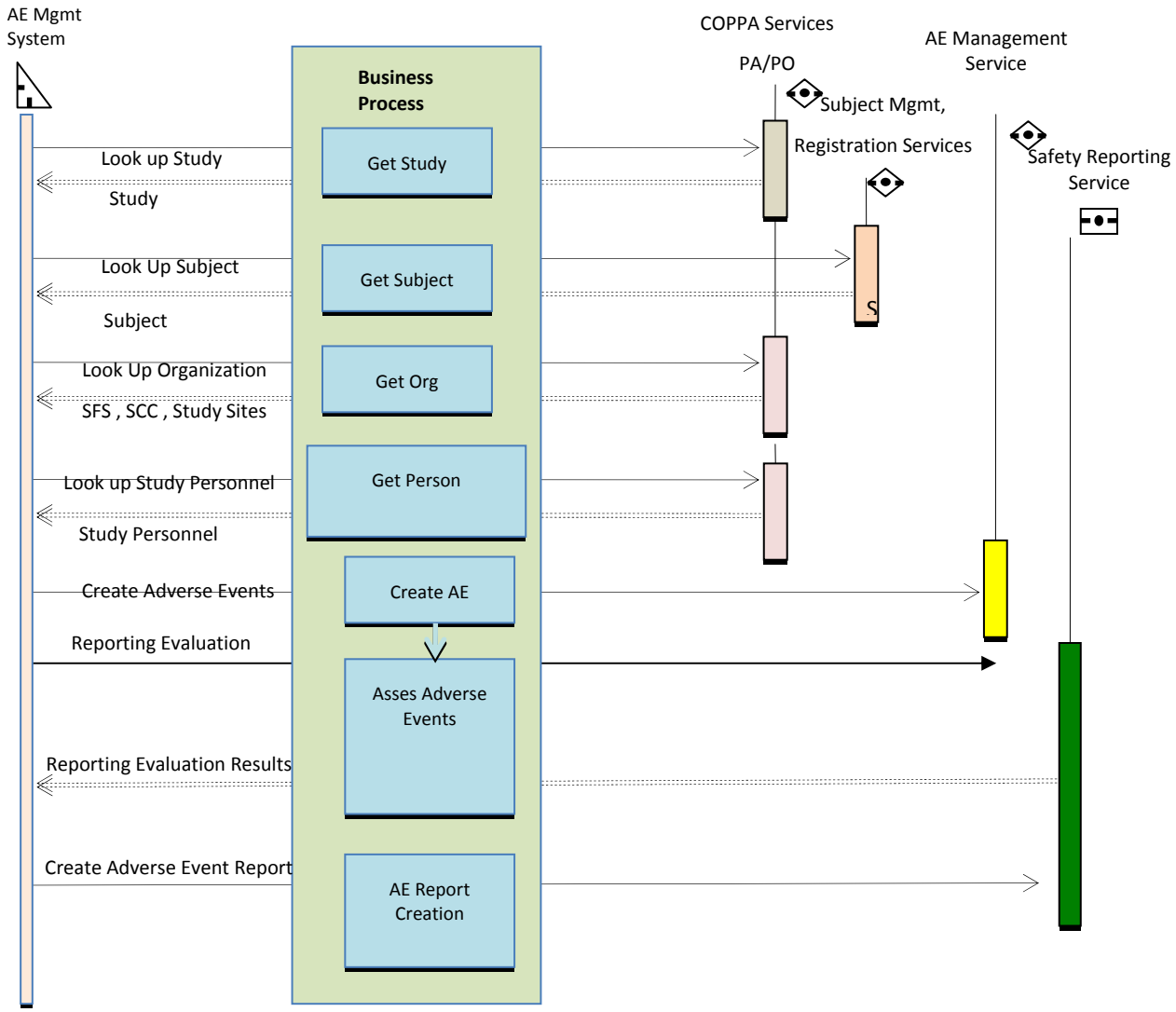
Conformance No	AE-CP1
Conformance Name	BRIDG based Entire AE Conformance Profile
Description	This is the conformance profile defines the entire functionality for the Adverse Event Management Service using BRIDG based semantics
Usage Context	This profile would be used by a study administrator or equivalent that has responsibility for all aspects of adverse event data collection and data management.
Mandatory	No
Functional Profile(s)	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, AE-FP9: AE Coding
Semantic Profile(s)	AE-SP1 : BRIDG V3.0 Adverse Event

Conformance No	AE-CP2
Conformance Name	BRIDG based Essential AE Conformance Profile
Description	This is the conformance profile defines the essential functionality for creating, reading, updating, finding, and deleting adverse event records using BRIDG based semantics
Usage Context	This profile would be used by a user or system that has responsibility for adverse event record creation and management.
Mandatory	Yes
Functional Profile(s)	AE-FP1: AE Query, AE-FP2 : AE Management, AE-FP3 : AE Associate
Semantic Profile(s)	AE-SP1 : BRIDG V3.0 Adverse Event

5 System Implementation Details

5.1 System Runtime Interactions

The following diagram shows interaction between Adverse Event Management system and other participants.



5.2 Implementation/Deployment Considerations

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

6 Conformance and Compliance

6.1 Compliance and Conformance Statements

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

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

7 Appendix A – Relevant Standards

Name	Description	Location
BRIDG v3.0	BRIDG model used for modeling the AE Service	http://gforge.nci.nih.gov/frs/?group_id=342
HL7v3	Health Level 7 version 3	http://www.hl7.org/implement/standards/v3messages.cfm

8 Appendix B – References

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

9 Appendix C - Glossary

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

10 Appendix D – Cross Reference Tables

10.1 List of Storyboards

#	Storyboard	Description	Source
AE-SB1	Clinician Initiated Adverse Event on a Study Subject	An adverse event is identified by a Healthcare Provider during the clinical exam of a Study Subject who is participating on a clinical trial.	caAERS Use Cases
AE-SB2	Clinician Initiated Adverse Event on a Patient	An adverse event is identified by a Healthcare Provider during the clinical exam of a Patient as part of clinical care.	caAERS Use Cases
AE-SB3	Study Subject Initiated Adverse Event	A Study Subject directly reports an adverse symptom and it is initiated as an adverse event.	caAERS Use Cases
AE-SB4	Patient Initiated Adverse Event	A Patient directly reports an adverse symptom and it is initiated as an adverse event.	caAERS Use Cases
AE-SB5	Laboratory Result Initiated Adverse Event	An out-of-range laboratory result is initiated as an adverse event.	caAERS Use Cases
AE-SB6	CDMS Initiated Adverse Event	An AE Reporter reviews a subject's medical chart, identifies an adverse symptom, and records it onto an AE-CRF. A Data Coordinator then reviews the AE-CRF and enters the symptom into the CDMS after which an adverse event record is created in the Adverse Event Management System.	caAERS Use Cases
AE-SB7	EHR Initiated Adverse Event	An adverse symptom is identified by a Healthcare Provider during the clinical exam of a Patient and the symptom is entered into	caAERS Use Cases

		the Patient's Electronic Health Record (EHR) after which an adverse event record is created in the Adverse Event Management System.	
caAERS Use Cases AE-SB8	Updating an Adverse Event	The adverse event record is updated with new information.	caAERS Use Cases
AE-SB9	Evaluation of Reporting Requirements for an Adverse Event	An adverse event is assessed to determine if it needs to be reported in an expedited manner.	caAERS Use Cases
AE-SB10	Configuring Adverse Event Notifications	A clinician or researcher receives notifications regarding adverse events records.	caAERS Use Cases
AE-SB11	Assigning a Grade to an Adverse Event	An adverse event is graded.	caAERS Use Cases
AE-SB12	Obtaining Subject Treatment Information	Treatment information for a study subject at the time of an adverse event occurrence is obtained.	caAERS Use Cases
AE-SB13	Searching for Adverse Event Records	Search criteria are provided and adverse records satisfying the search criteria are identified.	caAERS Use Cases
AE-SB14	Obtaining Adverse Event Records	Adverse event records of interest are identified, the information to be returned from those records is specified, and the requested information is provided.	caAERS Use Cases
AE-SB15	Obtaining Adverse Event Summaries	Adverse event records of interest are identified, the attribute(s) on which to summarize the records are specified, along with method of summarization, and the requested summaries are provided	caAERS Use Cases

AE-SB16	Obtaining Adverse Event Coding Terminology	An AE Reporter obtains the terminology to be used for adverse event recording for a specific study.	caAERS Use Cases
AE-SB17	Obtaining Requirements for Adverse Event Records	An AE Reporter obtains the requirements for adverse event records on a specific study.	caAERS Use Cases
AE-SB18	Obtaining Solicited Adverse Events to a Study	An AE Reporter obtains the adverse events that should always be evaluated during certain epochs of a study.	caAERS Use Cases
AE-SB19	Obtaining Expected Adverse Events to a Study	An AE Reporter obtains the adverse events that are expected to occur on a study.	caAERS Use Cases
AE-SB20	Obtaining the Audit Trail of an Adverse Event Record	A Quality Assurance Auditor requests to view the audit trail of create, update, and delete operations associated with a specific adverse event record.	caAERS Use Cases
AE-SB21	Specifying the Adverse Event Record Review Workflow for a Study Site	The Study Data Manager for the study specifies the workflow that should be followed for reviewing adverse event records for a study site.	caAERS Use Cases
AE-SB22	Healthcare Provider Review of Adverse Event Records	A Clinical Data Coordinator sends one or more adverse event records to a Healthcare Provider for review. The Healthcare provider then reviews the record(s).	caAERS Use Cases
AE-SB23	Manager Review of Adverse Event Records	A Clinical Data Coordinator sends one or more adverse event records to a Study Data Manager for review. The Study Data Manager then reviews the	caAERS Use Cases

		record(s).	
AE-SB24	Sending a Report of Adverse Event Records	A Study Data Manager identifies adverse event records and sends those records as a report.	caAERS Use Cases
AE-SB25	Associating an Adverse Event Record with a Study	A Clinical Data Coordinator links an adverse event record from a Patient to the study(s) on which the patient is participating as a Study Subject.	caAERS Use Cases
AE-SB26	Associating an Adverse Event Record with Supporting Documentation	A Clinical Data Coordinator links an adverse event record from a Study Subject to information related to the adverse event.	caAERS Use Cases
AE-SB27	Determining if an Adverse Event Requires Recording on a Study	An AE Reporter evaluates an adverse event to determine if it needs to be associated with a study.	caAERS Use Cases
AE-SB28	Specifying a Term for an Adverse Event	A Clinical Data Coordinator specifies the adverse event term from an adverse event terminology that should be associated to an adverse event record.	caAERS Use Cases
AE-SB29	Deleting an Adverse Event	The adverse event record needs to be deleted.	caAERS Use Cases

10.2 Storyboards to Capabilities Mapping

#	Storyboard	Capabilities	Functional Profiles
AE-SB1	Clinician Initiated Adverse Event on a Study Subject	• Initiate Adverse Event	AE-FP2 : AE Management

AE-SB2	Clinician Initiated Adverse Event on a Patient	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB3	Study Subject Initiated Adverse Event	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB4	Patient Initiated Adverse Event	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB5	Laboratory Result Initiated Adverse Event	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB6	CDMS Initiated Adverse Event	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB7	EHR Initiated Adverse Event	• Initiate Adverse Event	AE-FP2 : AE Management
AE-SB8	Updating an Adverse Event	• Find Adverse Events • Get Adverse Event Data Requirements for a Study • Update Adverse Event	AE-FP1 : AE Query AE-FP2 : AE Management AE-FP6 : AE Protocol
AE-SB9	Evaluation of Reporting Requirements for an Adverse Event	• Find Adverse Events • Get Adverse Event Data	AE-FP1 : AE Query
AE-SB10	Configuring Adverse Event Notifications	• Update Adverse Event Notification	AE-FP4 : AE Notification
AE-SB11	Assigning a Grade to an Adverse Event	• Find Adverse Events • Update Adverse Event	AE-FP2 : AE Management
AE-SB12	Obtaining Subject Treatment Information	• Associate Subject Treatment Information to an Adverse Event • Dissociate Subject	AE-FP3 : AE Associate

		Treatment Information from an Adverse Event	
AE-SB13	Searching for Adverse Event Records	• Find Adverse Events	AE-FP1 : AE Query
AE-SB14	Obtaining Adverse Event Records	• Find Adverse Events • Get Adverse Event Data	AE-FP1 : AE Query
AE-SB15	Obtaining Adverse Event Summaries	• Find Adverse Events • Get Adverse Event Summary Data	AE-FP7 : AE Advanced Query
AE-SB16	Obtaining Adverse Event Coding Terminology	• Get Adverse Event Coding Terminology	AE-FP6 : AE Protocol
AE-SB17	Obtaining Requirements for Adverse Event Records	• Get Adverse Event Data Requirements for a Study	AE-FP6 : AE Protocol
AE-SB18	Obtaining Solicited Adverse Events for a Study	• Get Solicited Adverse Events for a Study Epoch	AE-FP6 : AE Protocol
AE-SB19	Obtaining Expected Adverse Events for a Study	• Get Expected Adverse Events for a Study	AE-FP6 : AE Protocol
AE-SB20	Obtaining the Audit Trail of an Adverse Event Record	• Find Adverse Events • Get an Audit Trail of an Adverse Event Record	AE-FP7 : AE Advanced Query
AE-SB21	Specifying the Adverse Event Record Review Workflow for a Study Site	• Update Adverse Event Review Process	AE-FP5 : AE Review

AE-SB22	Healthcare Provider Review of Adverse Event Records	• Find Adverse Events • Get Adverse Event Data • Get Adverse Event Review Process • Review Adverse Events	AE-FP1 : AE Query AE-FP5 : AE Review
AE-SB23	Manager Review of Adverse Event Records	• Find Adverse Events • Get Adverse Event Data • Get Adverse Event Review Process • Review Adverse Events	AE-FP1 : AE Query AE-FP5 : AE Review
AE-SB24	Sending a Report of Adverse Event Records	• Find Adverse Events • Get Adverse Event Data • Retrieve Adverse Event Summary Data	AE-FP1 : AE Advanced Query
AE-SB25	Associating an Adverse Event Record with a Study	• Associate Adverse Event to Study • Dissociate Adverse Event from Study	AE-FP3 : AE Associate
AE-SB26	Associating an Adverse Event Record with Supporting Documentation	• Find Adverse Events • Associate Additional Information to an Adverse Event • Dissociate Additional Information from an Adverse Event	AE-FP1 : AE Query AE-FP3 : AE Associate

AE-SB27	Determining if an Adverse Event Requires Recording on a Study	• Find Adverse Events • Get Adverse Event Data • Get Adverse Event Recording Rules for a Study • Evaluate Adverse Event Against Recording Rules • Associate Adverse Event to Study • Dissociate Adverse Event from Study	AE-FP1 : AE Query AE-FP6 : AE Protocol AE-FP3 : AE Associate AE-FP8 : AE Evaluate
AE-SB28	Specifying a Term for an Adverse Event	• Find Adverse Events • Get Adverse Event Coding Terminology • Find Adverse Event Terms • Update Adverse Event	AE-FP2 : AE Management AE-FP6 : AE Protocol AE-FP9: AE Coding
AE-SB29	Deleting an Adverse Event	• Find Adverse Events • Deactivate Adverse Event	AE-FP2 : AE Management

10.3 Actors

Actors	Type	Description
Healthcare Provider	Person	The treating physician for a study subject or a patient.

Site Investigator	Person	A Healthcare Provider participating as an investigator on a study.
AE Reporter	Person	The person responsible for recording adverse events. Common synonyms are Research Nurse, Study Coordinator, Clinical Research Associate, Clinical Research Coordinator
Patient	Person	Patient undergoing clinical care outside the scope of a clinical trial.
Study Subject	Person	A participant on a clinical trial. Also know as Study Participant.
Principal Investigator	Person	A subscriber to notifications regarding adverse events.
Laboratory Technician	Person	A person responsible for performing laboratory tests.
Supplemental Study Information Manager	Person	A person responsible for abstracting information from the clinical trial protocol.
Clinical Data Coordinator	Person	A person who participates in adverse event data entry and data management activities.
Study Data Manager	Person	A person responsible for managing data on the entire study.
Statistician	Person	A person responsible for analyzing the data on a study.
Quality Assurance Auditor	Person	A person responsible for ensuring the adherence to standard operating procedures.
Adverse Event Management System	System	A system used to record adverse events.

Clinical Trials Management System (CTMS)	System	The system used to store the information regarding protocols, people, organizations, and subjects, and schedules that are needed to conduct a clinical trial.
Laboratory Data System	System	The system used to store the results of laboratory tests.
Lab Result Grading System	System	Used to obtain automated grading of lab based adverse events.
Notification System	System	Used to provide notifications regarding adverse event management activities.
Safety Reporting System	System	Used to evaluate adverse events against criteria to determine appropriate reporting requirements.
Electronic Health Record (EHR) System	System	The system which houses the clinical data associated with the conduct of routine clinical care.
Adverse Event Case Report Form (AE-CRF)	System	The form, either paper or electronic, used to record the adverse events observed on a study-subject.
Patient Reported Outcome (PRO) System	System	The system used to record adverse symptoms (events) directly from subjects/patients.
Clinical Data Management System (CDMS)	System	The system which houses the clinical data associated with the conduct of a clinical trial.