Service Scope and Description

Adverse Event Management Service

Version 1.0

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Document Version	**Author**	**Changes**
0.0.1	Kalpesh Patel	Initial Draft
0.0.2	Kunal Modi	Additional content
0.0.3	Kalpesh S. Patel	Final Edits
0.0.4	Paul Baumgartner	Renamed to “Adverse Event Management” Service; removed safety reporting elements that will be moved into a separate scope document.
0.0.5	Paul Baumgartner	Incorporated feedback from the ESST.
0.0.6	Paul Baumgartner	Added support for federated adverse event data management.
0.0.7	Paul Baumgartner	Updated per changes made to the CIMSS for this service.
1.0	Paul Baumgartner	Submitted to the CAT.

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1 Introduction

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 oncology 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 this service, the Adverse Event Management Service, is to provide a standard set of interfaces to create and manage adverse event records. In addition, the service will enable the searching, analysis, sharing, and data mining of these records. 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.

2 Stakeholders

Stakeholder	**Individuals / Teams Name**	**Responsibility**
Executive/Business Representative	CGT	Approve the scope and effort and review the outcome
Subject Matter Expert	Mary Agnes Templeton Ann Setser Shanda Finnigan	Provide input regarding business processes and interaction with other areas that can initiate adverse events and provide knowledge for AE regulatory reporting needs
BAM Analyst	Michele Ehlman	Help facilitate SME interactions and provide help with development of initial story boards

SOA Analyst	Kalpesh Patel Ram Chilukuri Vinay Kumar Brian McIndoe	Review the business processes and develop the candidate interaction story boards and review with IO SIG
SOA Architect	Kunal Modi Srini Akkala	Develop CIM, PIM, PSM
Project Team Member	Paul Baumgartner Wesley Wiggins Biju Joseph Denis Krylov	Develop services.
Product Team	caAERS (including the Mayo Clinic Rochester, Wake Forest, and CALGB caAERS teams)	Define business processes and use cases.

3 Business Area

This service supports use cases from the Manage Subjects area under the Conduct Study Group in the BAM and also supports the Initialization of Safety Reporting System use case under Initiate Study in the BAM. It primarily focuses on the functionality related to the recording of adverse events.

4 Service Description

The Adverse Event Management service will provide the following functionality:

- The ability to create records of adverse events
- The ability to update adverse event records.
- The ability to delete or deactivate adverse event records.

- The ability to search for and retrieve adverse event records using a variety of search criteria based on study, subject/patient, organization, personnel, and adverse event attributes.
- The ability to provide an audit log of all create, update, and delete activity pertaining to an adverse event record.
- The ability to associate an adverse event record with a patient and/or a study subject.
- The ability to define, update, delete and search for solicited adverse events for a study.
- The ability to define, update, delete and search for expected adverse events for a study.
- The ability to route adverse events for review and comment by study personnel.
- The ability to find and associate adverse event terms from a terminology dictionary to an adverse event record.
- The ability to define, update, and get the data entry requirements for adverse event records.
- The ability to evaluate if an adverse event needs to be recorded for a study.

5 Service Scope

The scope of the Adverse Event Management Service is limited to providing the ability to record, manage, query, and obtain adverse event records within the cancer clinical trial space and cancer care delivery space. This service doesn't explicitly exclude non-cancer utilities. Additionally, this service will support federated adverse event data management activities.

6 Service Interactions

The Adverse Event Management Service will be used by the following systems and services:

1. **Lab System/EHR/CDMS/Clinical System:** To record an adverse event or performing other adverse event management operations.

2. **Safety Reporting Service:** To query existing adverse event records for reporting purposes.
3. **Patient Outcomes Data Service:** To query adverse event records for patient outcome purposes.
4. **Study Outcomes Service:** To query adverse event records for study outcome purposes.

The Adverse Event Management Service will in turn use the following services:

1. **Safety Reporting Service:** To evaluate adverse events against criteria to determine appropriate reporting requirements.
2. **Protocol Management Service:** To perform a lookup to ensure that the protocol (study) is valid and active.
3. **Subject Registration Service:** To ensure that the subject is enrolled in the study
4. **Scheduled Calendar Service:** To access Course/Cycle information and provide notifications with respect to adverse events.
5. **Person Service:** To associate the person(s) involved with recording the adverse event.
6. **Organization Service:** To associate the organization(s) involved with the adverse event.
7. **Lab Result Grading Service:** To obtain automated grading of lab based adverse events.

7 Assumptions and Risks

1. The patient and/or study subject exists.
2. The study exists with all necessary information.
3. The necessary patient and/or subject treatment information exists.

8 Glossary

Acronym	Definition
AE	Adverse event
BAM	Business Analysis Model
caAERS	The caBIG Adverse Event Reporting System

CIM	Computationally Independent Model
ESST	Enterprise Services Specification Team
PIM	Platform Independent Model
PSM	Platform Specific Model
SAE	Serious adverse event