Service Scope and Description

Safety Reporting Service

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Enterprise Architecture Specification Team

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Document Version	**Author**	**Changes**
0.0.1	Paul Baumgartner	Initial Draft as a separate service – initially safety reporting was included in the Adverse Event Service.
0.0.2	Paul Baumgartner	Incorporated feedback provided from the ESST.
0.0.3	Paul Baumgartner	Clarified support for report notifications.
0.0.4	Paul Baumgartner	Updated per feedback in the AE Management Service CIMSS.

TABLE OF CONTENTS

1 Introduction

Safety reporting, as it pertains to the cancer clinical trial and cancer clinical care spaces, is the process of communicating the occurrence of harmful or potentially harmful events that may have some relation to the clinical trial or care. Safety reports can include nearly any type of harmful or potentially harmful events, including but not limited to adverse events and product problems. Safety reporting may be required based upon criteria included in varied sources such as protocol documents, legal regulations, and institutional policies, among others. Additionally, safety reporting may be performed on a voluntary basis. Potential recipients of safety reports include, but are not limited to, clinical trial sponsors, regulatory agencies, drug safety monitoring boards, institutional review boards and ethics committees.

The purpose of the Safety Reporting Service is to provide a standard set of interfaces to create, manage, and submit safety reports. This service will enable the searching, analysis, sharing, and data mining of these reports. Additionally, this service will provide the ability to evaluate harmful or potentially harmful events against criteria to determine appropriate reporting requirements. This service will also facilitate the interaction and interoperability between systems that require and provide safety reports. As a result of this interoperability, this service will potentially improve the quality and availability of safety reports and improve the monitoring of safety on cancer clinical trials and in cancer clinical care.

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 Brian McIndoe Ram Chilukuri Vinay Kumar	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)	

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 reporting of safety issues.

4 Service Description

The Safety Reporting Service will provide the following functionality:

- The ability to create safety reports.
- The ability to update safety reports.
- The ability to submit safety reports.

- The ability to amend safety reports.
- The ability to withdraw safety reports.
- The ability to associate and disassociate data to safety reports including, but not limited to: adverse events, patient information and records, lab values, study interventions, and hospital records.
- The ability to evaluate harmful or potentially harmful events against criteria (or rules) to determine if safety reporting is required, and if so, which reports are required, when they are due, and to whom they must be submitted.
- The ability to create, update, and delete the criteria (or rules) used to evaluate harmful or potentially harmful events and determine the appropriate safety reporting requirements.
- The ability to create, update, and delete the report definition used for each safety report.
- The ability to provide an audit log of all create, update, and delete activity pertaining to a safety reporting record
- The ability to search for and retrieve safety reports using a variety of search criteria based on study, subject/patient, organization(s), personnel, and adverse event attributes.
- The ability to notify defined stakeholders regarding the status of a safety report.
- The ability to route safety reports for review and comment by study personnel.

5 Service Scope

The scope of the Safety Reporting Service is limited to providing the ability to create, manage, submit, query, and retrieve safety reports within the cancer clinical trial space and cancer care delivery space. This service doesn't explicitly exclude non-cancer utilities. Additionally, this service does not explicitly support federated adverse event data management.

6 Service Interactions

The Safety Reporting Service will be used by the following systems and services:

1. **Regulatory Systems:** Primarily to record a safety report or perform other safety report management operations.
2. **Adverse Event Management Service:** To evaluate adverse events against criteria to determine appropriate reporting requirements.
3. **Master Problem List Service:** To update problems associated with patients.
4. **Electronic Health Records / Clinical Data Management Systems:** To evaluate adverse events against criteria to determine appropriate reporting requirements.

The Safety Reporting Service will in turn use the following systems and services:

1. **Adverse Event Management Service:** To obtain adverse event records for inclusion on a safety report.
2. **Protocol Abstraction Service:** To perform a lookup to ensure that the protocol (study) is valid and active, obtain current protocol information, and obtain protocol specific criteria for safety reporting.
3. **Subject Registration Service:** To ensure that the subject is enrolled in the study
4. **Scheduled Calendar Service:** To obtain relevant patient treatment history, including course/cycle information.
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. **Electronic Health Records / Clinical Data Management Systems:** To obtain relevant patient medical history.
8. **History and Physical Service:** To obtain relevant patient medical history.
9. **Discharge Summary Service:** To obtain information regarding a discharge related to the reported event.
10. **Consult Note Service:** To obtain relevant patient medical history.
11. **Procedure History Service:** To obtain relevant patient medical history.
12. **Image Management Service:** To obtain relevant patient images.
13. **Medication Service:** To obtain relevant patient medication history.
14. **Laboratory Management Service:** To obtain relevant patient laboratory results.
15. **Disease Service:** To obtain relevant study disease information.
16. **Drug Service:** To obtain relevant drug information.
17. **Agent Service:** To obtain relevant study agent information.
18. **Allergy Service:** To obtain relevant patient allergy information.

7 Assumptions and Risks

None

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