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|  | **Audit Trail Design Specification**  **For**  **Shared Investigator Platform**  **Release 2.1**  **V3.0** |
|  |

# Change Log

Please note that this table needs to be maintained even if separate Change item status log is maintained in the tool / document and the version history needs to be given here. But reference can be given to details of the changes if it is not given here.

|  |  |
| --- | --- |
|  | **Changes Made** |
| V 1.0 | Initial baseline created on 7 June 2016 |
| V 2.0 | Modified for R2.0 Changes on 03 May 2017 |
| V 3.0 | Modified for R2.1 Changes 09 October 2017 |

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# Introduction

The purpose of this Audit Trail design document is to describe how the audit trail will be implemented in the Shared Investigator Platform (SIP) for Release 2.0. The Shared Investigator Platform performs several regulated clinical activities. Having an audit trail is a requirement to ensure that SIP is compliant with regulatory rules for electronic records, including FDA 21 CFR Part 11.10(e) and EMA Annex 11 Paragraph 9 and GCP requirements, such as paragraph 5.5.3.c in the FDA Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.

Although seamless to end users, SIP is built upon several components. The primary application was created using Liferay Portal. The Learning Management System (LMS) functionality was built using SumTotal. Access to the application is provided by Exostar. Certain system data resides within the Investigator Registry (DrugDev) database. The complete audit trail captures data across these systems, with each system recording user actions performed within its area. The Audit Trail Reports combine information as appropriate from these systems and reports are generated from the SIP application.

This document will provide a high level technical explanation of how the audit trail records will be captured from these different systems, and how that data can be accessed and viewed by system users in the form of an Audit Trail Report.

# Scope

This document describes how the audit trail within the Shared Investigator Platform (SIP) for Release 2.0 functions. This document contains the list of the primary tables identified for audit trail, and also the corresponding tables for capturing the historical data. The document also describes how data changes will be captured in an audit trail table and how the Audit Trail Reports are generated. The specific process that Cognizant will follow to generate the Audit Trail Report is documented in Work Instruction: “Shared Investigator Platform Work Instruction for Audit Trail Report Generation” (SIP-WI-AT).

The Exostar related Audit Trail Report will follow the same process as it did in R1.0. It will be provided, upon request, through the SIP support helpdesk.

# References

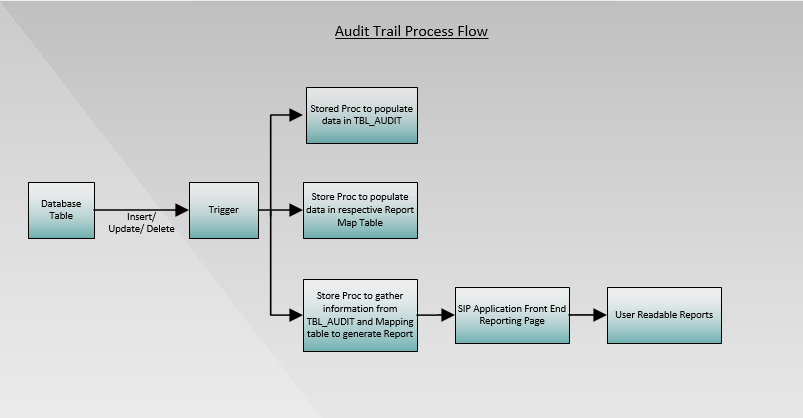
| **Sr. No** | **Document** | **Version** |
| --- | --- | --- |
|  | Functional Requirements Specification (SIP-FRS-S1-2.0) | 2.0 |
|  | Functional Requirements Specification (SIP-FRS-S2-2.0) | 2.0 |
|  | Functional Requirements in ALM  <https://almcognizant1221.saas.hpe.com/qcbin/start_a.jsp>  Domain: DEFAULT\_Cognizant  Project: SIP | NA |
|  | User Requirement Specification (SIP-URS-2.0) | 2.0 |

# Recording the Audit Trail

All audit trail requirements (see Section 4.1 detailed in the User Requirement Specification and Functional Requirement Specifications for Release 2.0) will be met by capturing the data changes in a primary table and storing this as historical data in an audit trail table (TBL\_AUDIT). The TBL\_AUDIT audit table will store audit entries in attribute name, old value and new value format along with some additional columns required for capturing the audit trail information. Details of the tables, the primary and the audit table structure, along with the process for capturing the data changes are detailed in the sections below.

Whenever data is affected due to Insert (Create), Update or Delete, a database trigger will be fired. Through these database triggers, all changed records will be stored in TBL\_AUDIT by specific stored procedures.

Each attribute of a table which has undergone the changes will be stored in Old Value and New value format in TBL\_AUDIT. All the related audit table structures are defined in Audit\_Tables\_Design.xlsx



Through the database trigger, several stored procedures are called to populate the data in the audit table and report mapping table. Report mapping tables are specific to each report category such as Study, Survey, Training credits, User, Facility etc., and stores audit mapping records for those attributes of the tables that have undergone changes in the form of Create, Update or Delete.

While retrieving the audit records from the audit and mapping tables, SIP will call a stored procedure, which will arrange the data in user readable format and display it via the report view screen. Pagination and sorting functionality is achieved through this stored procedure.

Details of the audit tables and stored procedures are provided in the below tables

| Tables | Description |
| --- | --- |
| TBL\_AUDIT | Contains the Records captured during CREATE, EDIT and DELETE operations across all tables |
| TBL\_STUDYAUDITREPORTMAP | Mapping of audit records for a particular Study and/or Study site. |
| TBL\_SURVEYAUDITREPORTMAP | Mapping of audit records for a particular Survey and/or Study. |
| TBL\_TRNGCREDITSREPORTMAP | Mapping of audit records for a particular Training credits record. |
| TBL\_DOCAUDITREPORTMAP | Mapping of audit records for a particular document related to user and/or Facility/Department. This table also stores data related to a user’s e-Signature |

| **Stored Procedure** | **Description** |
| --- | --- |
| SP\_SET\_AUDIT | This procedure inserts records into TBL\_AUDIT for the tables described in Section 3.0, in OLD value and NEW value format. |
| SP\_SET\_STUDYAUDITREPORTMAP | This procedure is called from the trigger to insert records in TBL\_STUDYAUDITREPORTMAP which capture only Study related changes |
| SP\_GET\_STUDY\_AUDIT | Procedure to retrieve the audit report data for Study attributes. |
| SP\_SET\_SURVEYAUDITREPORTMAP | This procedure is called from the trigger to insert records in TBL\_SURVEYAUDITREPORTMAP which capture only Survey related changes. |
| SP\_GET\_SURVEY\_AUDIT | Procedure to retrieve the audit report data for Survey attributes. |
| SP\_SET\_TRNGCREDITSATREPORTMAP | This procedure is called from the trigger to insert records in TBL\_ TRNGCREDITSREPORTMAP which capture only Training credits related changes. |
| SP\_GET\_TRNGCREDITS\_AUDIT | Procedure to retrieve the audit report data for Training credits related attributes. |
| SP\_SET\_DOCAUDITREPORTMAP | This procedure is called from the trigger to insert records in TBL\_ DOCAUDITREPORTMAP which capture only document related changes. |
| SP\_GET\_USERDOC\_AUDIT | Procedure to retrieve the audit report data for User documents related attributes. |
| SP\_GET\_FACDEPTDOC\_AUDIT | Procedure to retrieve the audit report data for Facility/Department documents related attributes. |
| SP\_USER\_ESIGNATURE\_REPORT | Procedure to retrieve records related to User’s e-Signature. |
| SP\_GET\_USER\_AUDIT | Procedure to retrieve audit records related to User profile which are stored in SIP Database. |
| SP\_GET\_FACILITY\_AUDIT | Procedure to retrieve audit records related to Facility profile which are stored in SIP Database. |

# Viewing Audit Trail Reports

## Requesting Audit Trail Reports

Sponsor Users generate Audit Trail reports by logging into the SIP application and selecting appropriate input filter conditions. Sponsor Users can generate the Audit Trail report in MS Excel (.xls) and in PDF (.pdf) format as per Release 2.0 User Requirement: UR-AT-03.

### Retrieving Data from SIP Database

All reports sourced from the SIP Database are retrieved through the following stored procedures

| **Stored Procedure** |
| --- |
| SP\_GET\_STUDY\_AUDIT |
| SP\_GET\_SURVEY\_AUDIT |
| SP\_GET\_TRNGCREDITS\_AUDIT |
| SP\_GET\_USERDOC\_AUDIT |
| SP\_GET\_FACDEPTDOC\_AUDIT |
| SP\_USER\_ESIGNATURE\_REPORT |
| SP\_GET\_USER\_AUDIT |
| SP\_GET\_FACILITY\_AUDIT |

Whenever a Sponsor User generates a report, the respective database stored procedures are called with specific input parameters as filters, and retrieved records are displayed in the report layout.

### Retrieving Data from IR

Some audit trail data is stored within the IR (DrugDev) database. When an SIP user generates an audit trail with data from IR, SIP requests the data from IR using the relevant IR endpoints (IR endpoints are: The API in which we pass the user defined search criteria as a request and fetch the required output result as a response from IR Database.). In the Portal screen, a user selects either User ID or Facility/Department ID, From Date and To Date. (Note: The Audit Trail Report cannot be generated without selecting a User ID or Facility/Department ID) Based on the defined filter criteria, an IR call to each endpoint and data regarding the selected User ID or Facility/Department is retrieved for the specified date range. Audit trail data from IR is displayed as is without any transformation, however IR labels are transformed to match with SIP screen. The design of the report is to call different IR audit endpoints to accumulate the result. The data is then accumulated in List and default sorting and pagination is implemented and the data is displayed on the screen.

### Retrieving Data from LMS (SumTotal)

Training Audit Trail Report is generated in a similar mechanism to that of IR provided reports. An API is called from the front end to pull records from SumTotal. The resultant records are displayed in the Training Audit Trail report. Only the Training Credit Audit Trail Report will be pulled from the SIP database.

### Retrieving Data from Exostar

Reports generated from Exostar will follow the same manual process as used in R1.0. A User request to generate the report is made to the SIP Support Helpdesk and the request will be communicated to Exostar. After getting the generated report from Exostar, the report will be sent to the Requester.

## Access to the Audit Trail

No SIP system user has direct access to edit the audit trail tables. This control meets User Requirement UR-AT-07 (“The audit trail records must be protected from modification and deletion by unauthorized users (for example, standard users and/or platform administrators)”).

The Audit Trail Reports are available to be viewed and generated from SIP User Interface only and can be generated by specific user groups like Study Administrator, Sponsor Administrator, etc. Audit Trail reports also can be generated in Excel and pdf format. Access to these functions is provided by user level security, verifying the access rights of the user before generating the Audit Trail Report.

# Tables Identified for Audit Trail

Below is the list of tables identified for capturing the data required to be tracked for specific audit reports

**Study Audit Trial Report**

| **Table Name** | **Description** |
| --- | --- |
| TBL\_STUDY | Stores information about the Study trials. |
| TBL\_STUDYCONTACT | Study Contact Information for a Study. |
| TBL\_STUDYCONTACTMAP | Multi Country mapping of a Study Contact to its Study. |
| TBL\_STUDYCOUNTRYMILESTONE | Table to store study countries |
| TBL\_STUDYCOMPOUND | Table to store study compounds |
| TBL\_DOCEXCHANGE | Study and Site Related Main Documents |
| TBL\_DOCEXCHANGEVERSION | Study and Site Related Document Versions of the Main Document |
| TBL\_DOCSTUDYMAP | Study Document Association |
| TBL\_POTENTIALINVESTIGATOR | Information Regarding Potential Investigators |
| TBL\_POTENTIALINVTITLES | Title List for Potential Investigators |
| TBL\_SITE | Stores information about a Site |
| TBL\_SITECONTACTMAP | Site Contact Association |
| TBL\_CONTACT | Contact related information |
| TBL\_ADDITIONALFACILITY | Additional Facility Details |
| TBL\_ADDLSITEMAPPING | Site and Additional Facility Association |
| TBL\_USERROLEMAP | User entity association with role |
| TBL\_USERPROFILES | User related information |
| TBL\_CONTACT | Stores contact information |
| TBL\_DOCSITEROLEMAP | Documents and Site Association |
| TBL\_USERROLEMAP | Site and Site Staff Association |
| TBL\_STUDYCENTRALIRB | Study and Central IRB Association |
| TBL\_STUDYCENTRALLAB | Study and Central LAB Association |
| TBL\_SITEIRBREGISTRATION | Site and IRB Registration |
| TBL\_SITEIRBMAP | Site and Central IRB Association |
| TBL\_SITELABMAP | Site and Central LAB Association |
| TBL\_SITELABACCREDITATION | Site and LAB Accreditation Association |
| TBL\_STUDYTHERAPEUTICAREA | Study and Therapeutic Area Association |
| TBL\_STUDYINDICATION | Study and Indication Association |
| TBL\_STUDYLABCOUNTRY | Study Lab and Country Association |

**Survey Audit Trial Report**

|  |  |
| --- | --- |
| **Table Name** | **Description** |
| TBL\_SURVEY | Surveys Detail information |
| TBL\_SURVEYSIPASSOCIATION | Survey and Study Association |
| TBL\_SURVEYUSERMAP | Survey and User Association |
| TBL\_SURVEYUSER | Survey Recipients Basic Information |
| TBL\_RECIPIENTLIST | Recipient List with respect to Survey |
| TBL\_RECIPIENTLISTMAP | Recipient List and Survey User Association |
| TBL\_REVIEWER | Survey Reviewers Basic Information |
| TBL\_REVIEWERMAP | Survey and Survey Reviewer Association |
| TBL\_REVIEWERRECIPIENTMAP | Survey Reviewer, Survey and Survey Users Association |
| TBL\_REVIEWERRESPONSEMAP | Reviewer Remarks for a Survey Question |
| TBL\_RESPONSEMANAGER | Response Managers Basic Information |
| TBL\_RESPONSEMANAGERMAP | Survey and Response Manager Association |
| TBL\_RESPONSEMANAGERQUESTIONMAP | Response Manager and Question Association |
| TBL\_RESPONSEMANAGERUSERMAP | Survey User Mapping to its Response Manager Association |
| TBL\_SURVEYQUESTION | All Survey Question Related Information |
| TBL\_SURVEYANSWER | Survey Question and Answer Title Association |
| TBL\_SURVEYMETADATATYPE | Type of Survey Metadata |
| TBL\_SURVEYMETADATA | Survey Metadata Information |
| TBL\_SURVEYSECTION | Different Sections of a Survey |
| TBL\_SURVEYVERSION | Different Versions of a Survey |
| TBL\_SURVEYRESPONSE | Response for Respective Survey |
| TBL\_SURVEYRESPONSEANSWER | Survey Question and Answer Mapping Information |
| TBL\_SURVEYRESPONSELIST | Survey Response List Information |
| TBL\_SURVEY\_COUNTRYMAP | Mapping information between survey and country |
| TBL\_SURVEY\_THERAPEUTICAREAMAP | Mapping information between survey and therapeutic area |
| TBL\_SURVEY\_COMPOUNDMAP | Mapping information between survey and compound |
| TBL\_SURVEY\_INDICATIONMAP | Mapping information between survey and indication |
| TBL\_SURVEY\_PROGRAMMAP | Mapping information between survey and program |
| TBL\_REASONLIST | Information of reason list |
| TBL\_SURVEYLOGICJUMP | Information of logic id and question answer |
| TBL\_SURVEYTEMPLATE | Information of survey template |
| TBL\_COMPLETEDELEGATIONMAP | Survey Delegated user's information |

**Training Credits Audit Trial Report**

| **Table Name** | **Description** |
| --- | --- |
| TBL\_TRNGCREDITS | Training Credits Information, Training Credit Request and Approver Mapping |

**User Documents, Facility Documents and User e-Signature Report:**

| **Table Name** | **Description** |
| --- | --- |
| TBL\_DOCUMENTS | User, Facility and e-Signature Related Information |
| TBL\_IRUSERLICENSEDOCUMENTMAP | Table to store user license document |
| TBL\_EXPORTUSERPROFILE | Table to store users document export details |

**User Profile Audit Report:**

| **Table Name** | **Description** |
| --- | --- |
| TBL\_CURRENTTHERAUSERMAPSIP | Table for storing User and Current Therapeutic Area Mapping |
| TBL\_TOTALCLINICALRESRCHEXPSIP | Table for storing Total Clinical Research Experience |
| TBL\_DOCUMENTS | Table for storing Documents |
| TBL\_CONTACT | Table for storing Contact |
| TBL\_USERDELEGATIONMAP | Table for storing User Delegation Mapping |
| TBL\_USERPROFILES | Table for storing User Profiles |
| TBL\_RESEARCHEXPTRIALTYPESIP | Table for storing Research Experience |
| TBL\_USEREDUCATIONSIP | Table for storing User Education |
| TBL\_TRNGCREDITS | Table for storing Training Credits |

**Facility Profile Audit Report:**

| **Table Name** | **Description** |
| --- | --- |
| TBL\_EQUIPMENT | Table to store equipment details |
| TBL\_DIGITALDIAGNOSTIC | Table to store digital diagnostic details |
| TBL\_COMPOPERATINGMAP | Table to store component mapping |
| TBL\_ADDITIONALFACILITYLABACC | Table to store additional facility |
| TBL\_IPSTORECONMAP | Table to store IP Storage mapping |
| TBL\_CONTACT | Table for storing Contact |
| TBL\_FACIPDETAIL | Table to store IP details |
| TBL\_CONANDTRGDETLS | Table to store |
| TBL\_SOURCEDOCUMENTATION | Table to store source document. |
| TBL\_THERAPETICAREAFACILITYMAP | Table to store therapeutic area. |
| TBL\_FACILITYPHASES | Table for storing Facility Phases |
| TBL\_FACILITYSPONSORTYPES | Table for storing Facility Sponsor Types |
| TBL\_FACILITIES | Table for storing Facility |
| TBL\_FACILITYDEMOGRAPHY | Table for storing Facility Demography |
| TBL\_ADDITIONALFACILITY | Table for storing Additional Facility |
| TBL\_ETHNICITYPERCENTAGE | Table for storing Ethnicity Percentage |
| TBL\_FACILITYEDSMAP | Table for storing Facility EDS Mapping |
| TBL\_FACILITYMONACCESSMAP | Table for storing Facility Access Mapping |
| TBL\_IRBREGISTRATIONMAP | Table for storing IRB Registration Mapping |
| TBL\_IRBGENERAL | Table for storing IRB General |

# Investigator Registry (IR) End Point for Audit Trail

| **End Pont** | **Description** |
| --- | --- |
| ${URL\_BASE}/audit/changelog?table\_name=person | Audit End Point for Person |
| ${URL\_BASE}/audit/changelog?table\_name=experience | Audit End Point for Person Experience |
| ${URL\_BASE}/audit/changelog?table\_name=currentresearch | Audit End Point for Person Current Research |
| ${URL\_BASE}/audit/changelog?table\_name=publication | Audit End Point for Person Publication |
| ${URL\_BASE}/audit/changelog?table\_name=presentation | Audit End Point for Person Presentation |
| ${URL\_BASE}/audit/changelog?table\_name=education | Audit End Point for Person Education |
| ${URL\_BASE}/audit/changelog?table\_name=licence | Audit End Point for Person Medical License |
| ${URL\_BASE}/audit/changelog?table\_name=personfacility | Audit End Point for Person Associated with Facility |
| ${URL\_BASE}/audit/changelog?table\_name=email | Audit End Point for Person Email |
| ${URL\_BASE}/audit/changelog?table\_name=telephone | Audit End Point for Person Telephone |
| ${URL\_BASE}/audit/changelog?table\_name=totalresearch | Audit End Point for Person Total Research |
| ${URL\_BASE}/audit/changelog?table\_name=facilityRole | Audit End Point for Persons Facility Role |
| ${URL\_BASE}/audit/changelog?table\_name=facility | Audit End Point for Facility |
| ${URL\_BASE}/audit/changelog?table\_name=contact | Audit End Point for Contact |
| ${URL\_BASE}/audit/changelog?table\_name=irbotherboard | Audit End Point for IRB |
| ${URL\_BASE}/audit/changelog?table\_name=localirb | Audit End Point for Local IRB |
| ${URL\_BASE}/audit/changelog?table\_name=locallab | Audit End Point for Local Lab |
| ${URL\_BASE}/audit/changelog?table\_name=address | Audit End Point for Address |
| ${URL\_BASE}/audit/changelog?table\_name=facilityrole | Audit End Point for Facility Role |
| ${URL\_BASE}/audit/changelog?table\_name=edcsystem | Audit End Point for EDC System |
| ${URL\_BASE}/audit/changelog?table\_name=Ethnicity | Audit End Point for Ethnicity |
| ${URL\_BASE}/audit/changelog?table\_name=TherapeuticArea | Audit End Point for Therapeutic Area |
| ${URL\_BASE}/audit/changelog?table\_name=phase | Audit End Point for Phase |
| ${URL\_BASE}/audit/changelog?table\_name=sponsortype | Audit End Point for Sponsor Type |

# Achievement Matrix

| URS Number | Requirement | Achievement | FRS Reference |
| --- | --- | --- | --- |
| UR-AT-01 | The platform must document an audit trail of platform activities (e.g. conducted within the platform).   1. User Profile 2. Study 3. Survey 4. Non-Sponsor specific 5. Facility/Department 6. Unauthorized Access 7. User e-Signature | Audit trail is created at Database level. This records the audit trail on the previously specified tables. User Profile and Facility/Department Profile will come from IR. Non-Sponsor specific reports such as: User Documents, Facility/Department Documents and Training Credits will come from database level. Though other training related audit trail will be captured in LMS. Unauthorized access records will be captured by Exostar. Please refer Section 4.0 and 5.0. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-02 | The platform must document following information in audit trail for action performed on the platform (e.g., add/delete/update files or data):   * Who updated the data * What data was changed (original and new) * Reason for change * When the changes were made. This time will be standardized across all locations   **Note:** Viewing a document/alert will not be considered as an action.  This audit trail will meet the requirements in 21 CFR Part 11.10(e) and Annex 11 Paragraph 9. | The audit trail captures the information as mentioned in the requirements. It captures the information like who captured the data, the date and time of the capture, and the reason for the changes (if any – and has been entered by the user in specific cases where front end provisions are given). | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-03 | The platform must provide access to the audit trail in Excel (xls) and pdf formats. | For all Audit Trail Reports links to export as an MS Excel and PDF file are provided just above the table. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-04 | The system must track / capture audit trail information for surveys which are delegated, forwarded and edited | This requirement is tracked through the audit trail being generated from the appropriate tables detailed in Section 3.0. (Please refer to section **Survey audit trail)** | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-05 | The platform must store the alerts and notifications history (i.e. those that have been distributed) along with the actual content. | All Alerts and Notification are getting stored in TBL\_ALERTSANDNOTIFICATION table. Reports are being generated from SOP. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-06,  UR-CFR-25 | The system must have the ability to export the audit trail in a human readable format. | This requirement was **cancelled**, and absorbed into UR-CFR-25. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-07,  UR-SR-02 | The audit trail records must be protected from modification and deletion by unauthorized users (for example, standard users and/or platform administrators). | The audit trail is only visible through a static report. No system user has the ability to modify the audit trail. No grants to audit trail tables to application users. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-08 | The platform must record unauthorized access attempts and log following information regarding it   1. Resource accessed 2. Timestamp 3. Accessing user 4. IP (IP Address of the computer from which the user is trying to access SIP. This may represent the IP Address of the terminal or that of the network as per the specific configuration of the user's machine / network.)   This functionality will meet the requirement in 21 CFR 11.300(d) | 1. Unauthorized access attempts - Login attempts with invalid username/password can be audited and it is populated in DBA\_AUDIT\_TRAIL in RETURNCODE column. 2. DBA\_AUDIT\_TRAIL also includes the Timestamp for all logins 3. Username, Hostname, OS\_USERNAME can be seen from DBA\_AUDIT\_TRAIL view. 4. IP will be used to identify machine name.   Please Note: All this activities are captured in Database level only. Reports can be generated by DBA, as on adhoc basis as and when requested. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-09. | SIP will have the following controls in place to ensure system security. These measures will:   1. Find data that has been changed by an unauthorized person. This will be accomplished through proper implementation of User level security (which prevents access) and SIP audit trail (which tracks all changes) 2. Detect unauthorized disclosure of sensitive or confidential information electronically, in paper form or verbally. This will be accomplished through the Acceptable Use and Privacy policy 3. Detect unauthorized Information access or use- Other compromise of user identity e.g. access to network or specific platform by unauthorized person. This will be accomplished through proper implementation of User level security 4. Prevent disclosure of logins to unauthorized people. This will be accomplished through the Acceptable Use and Privacy policy and the governing policies of the identity management provider 5. Prevent falsification of records and inappropriate destruction of records. This will be accomplished through both the Acceptable Use and Privacy policy and the audit trail   In addition, Cognizant will have processes in place to ensure the security of the SIP system. This will ensure that the SIP system:   1. Reports Information Security Incidents 2. Prevents accessing inappropriate material on the internet through SIP hardware 3. Prevents use of unapproved or unlicensed software on SIP hardware 4. Prevents SIP hardware from being infected by a virus or other malware, (for example spyware or adware) 5. Prevents SIP hardware from receiving and forwarding chain letters – Including virus warnings, scam 6. Provides warnings and other emails which encourage the recipient to forward onto others before sending though SIP hardware   **Note**: These reports will not be online and will be only tracked/monitored by infrastructure and security team. | 1. Can be achieved from DBA\_AUDIT\_TRIAL 2. This will be accomplished through the Acceptable Use and Privacy policy 3. This will be accomplished through the Acceptable Use and Privacy policy and the governing policies of the identity management provider. 4. This will be accomplished through the Acceptable Use and Privacy policy 5. This will be accomplished through both the Acceptable Use and Privacy policy and the audit trail 6. This will be covered by Cognizant’s Acceptable Use Policy. Specific reporting is performed by Cognizant GSSC. 7. This will be covered by Cognizant’s Acceptable Use Policy. Enforcement is provided at the Cognizant corporate level, which restricts access to web content through blacklisting objectionable web content. 8. This will be covered by Cognizant’s Acceptable Use Policy. Enforcement is provided at the Cognizant corporate level, which monitors the network and detects unauthorized software. 9. This will be covered by Cognizant’s Acceptable Use Policy. Enforcement is provided though anti-virus software. 10. This will be covered by Cognizant’s Acceptable Use Policy. Enforcement is provided at the Cognizant corporate level, which monitors the email and detects unauthorized content. 11. This will be covered by Cognizant’s Acceptable Use Policy. Enforcement is provided at the Cognizant corporate level, which monitors the email and detects unauthorized content.   **Note**: These reports will not be online and will be only tracked/monitored by infrastructure and esecurity team. | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-10 | The system must track / capture audit trail information for surveys which are delegated, forwarded and edited | Duplicate of UR-AT-04 in URS.1 | Appendix- I2.07 Study Audit Trail Report, 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-11 | The platform must allow the Sponsor user to download news and announcements. | Duplicate of UR-GE-07 | I2.07 Study Audit Trail Report, Appendix- 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, Appendix- 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-12 | The platform must store communications that the Sponsor user has identified as required for auditing purposes. | All communications are getting stored in Database. | I2.07 Study Audit Trail Report, Appendix- 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, Appendix- 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-13 | The platform must store audit trail of electronic records being created or modified in the platform | All Audit Trail records are getting stored in Database. | I2.07 Study Audit Trail Report, Appendix- 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, Appendix- 5.2.11 (Business Rule: RU 16.03) |
| UR-AT-14 | The platform must allow user to print Audit Trail Reports. | For all Audit Trail Reports links to print reports are provided just above the table. | I2.07 Study Audit Trail Report, Appendix- 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, Appendix- 5.2.11 (Business Rule: RU 16.03) |
| UR-CFR-13 | Outcome and meaning for electronic signatures must be captured on the Audit Trail Report | It is getting captured in TBL\_DOCUMENTS table. Column Name: NatureOfSignature. | Appendix- 5.2.11 (Business Rule: RU 16.03) |
| UR-DE-02 | The platform must allow Sponsors to generate reports | System will identify the User Type (Sponsor or Site) during log in and it will identify the role of the Sponsor users as well. Based on the Role of the Sponsor user system will allow the user to generate reports. | I2.07 Study Audit Trail Report, Appendix- 5.2.5, I2.02 Training Credit Request Audit Trail Report, I2.06 User and Facility Documents Audit Trail Report, Appendix- 5.2.11 (Business Rule: RU 16.03) |

# Report Data Sources

| # | Report Name | Data Source | FRS Reference |
| --- | --- | --- | --- |
| 1 | Study Audit Trail Report | SIP Database | I2.07 Study Audit Trail Report |
| 2 | Survey Audit Trail Report | SIP Database | Appendix 5.2.5 |
| 3 | Training Credit Request Audit Trail Report | SIP Database | I2.02 Training Credit Request Audit Trail Report |
| 4 | Training Audit Trail Report | LMS (SumTotal) | I2.03 Training Audit Trail Report |
| 5 | User Profile Audit Trail Report | IR (DrugDev) + SIP Database | I2.04 User Profile Audit Trail Report |
| 6 | Facility/Department Audit Trail Report | IR (DrugDev) + SIP Database | I2.05 Facility / Department Audit Trail Report |
| 7 | User and Facility Documents Audit Trail Report | SIP Database | I2.06 User and Facility Documents Audit Trail Report |
| 8 | User e-Signature Report | SIP Database | Appendix 5.2.11 |

# Limitations

N/A – There are no defined system limitations.

# Appendix 1: Database Objects

| **Sr. No.** | **Object Name** | **Object Type** | **Purpose** |
| --- | --- | --- | --- |
| 1 | TBL\_REPORT | Table | Master table for list of reports |
| 2 | TBL\_COLUMNFIELDMAP | Table | Master table for DB column-field/attribute  name mapping |
| 3 | TBL\_REPORTFIELDMAP | Table | Master table for report-field mapping |
| 4 | TBL\_AUDIT | Table | Main audit table to save audit entries in attribute  name, old value and new value format |
| 5 | TBL\_STUDYAUDITREPORTMAP | Table | Association table to maintain audit entry and  study report mapping |
| 6 | TBL\_SURVEYAUDITREPORTMAP | Table | Association table to maintain audit entry  and survey report mapping |
| 7 | TBL\_TRNGCREDITSAUDITREPORTMAP | Table | Association table to maintain audit entry  and Training Audit report mapping |
| 8 | TBL\_DOCAUDITREPORTMAP | Table | Association table to maintain audit entry  and User/Facility Document Audit report mapping |
| 9 | TBL\_USERAUDITREPORTMAP | Table | Association table to maintain audit entry  and User Profile Audit report mapping |
| 10 | TBL\_FACAUDITREPORTMAP | Table | Association table to maintain audit entry  and Facility Profile Audit report mapping |
| 11 | PKG\_AUDIT | Package | Package for audit report related procedures |
| 12 | PKG\_AUDIT.SP\_SET\_AUDIT | Procedure | Packaged procedure for saving audit entries in audit table in attribute name, old value and new value format |
| 13 | PKG\_AUDIT.SP\_SET\_STUDYAUDITREPORTMAP | Procedure | Packaged procedure to save mapping between  study report-audit entry |
| 14 | PKG\_AUDIT.SP\_GET\_STUDY\_AUDIT | Procedure | Packaged procedure to get study audit report data |
| 15 | PKG\_AUDIT.SP\_SET\_SURVEYAUDITREPORTMAP | Procedure | Packaged procedure to save mapping between  survey report-audit entry |
| 16 | PKG\_AUDIT.SP\_GET\_SURVEY\_AUDIT | Procedure | Packaged procedure to get survey audit report data |
| 17 | PKG\_AUDIT.SP\_SET\_TRNGCREDITSATREPORTMAP | Procedure | Packaged procedure to save mapping between  training credits-audit entry |
| 18 | PKG\_AUDIT.SP\_GET\_TRNGCREDITS\_AUDIT | Procedure | Packaged procedure to get training credits audit report data |
| 19 | PKG\_AUDIT.SP\_SET\_DOCAUDITREPORTMAP | Procedure | Packaged procedure to save mapping between  documents and audit entry. |
| 20 | PKG\_AUDIT.SP\_GET\_FACDEPTDOC\_AUDIT | Procedure | Packaged procedure to get facility/department audit report data |
| 21 | PKG\_AUDIT.SP\_GET\_USERDOC\_AUDIT | Procedure | Packaged procedure to get user audit report data |
| 22 | PKG\_AUDIT.SP\_GET\_USER\_AUDIT | Procedure | Packaged Procedure to retrieve audit records related to User profile which are stored in SIP Database. |
| 23 | PKG\_AUDIT.SP\_GET\_FACILITY\_AUDIT | Procedure | Packaged Procedure to retrieve audit records related to Facility profile which are stored in SIP Database. |

# Appendix 2: Table Design

| **Table Name** | **Field Name** | **Long Name/ Description** | **Data Type** | **Null/Not Null?** | **Constraints** | **Parent Tables** | **Comments/ Remarks** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **TBL\_REPORT** | **REPORTID** | **Report Id** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Report Id (Primary Key)** |
| REPORTNAME | Report Name | VARCHAR2(100) | NOT NULL |  |  | Report Name |
| REPORTDESCRIPTION | Report Description | VARCHAR2(500) | NOT NULL |  |  | Report Description |
| SOURCE | Source | VARCHAR2(30) | NOT NULL |  |  | Source |
| ISACTIVE | Active Flag | CHAR(1) | NOT NULL |  |  | Active Flag |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_COLUMNFIELDMAP** | **COLUMNFIELDMAPID** | **Column-Field Mapping ID** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Column-Field Mapping ID (Primary Key)** |
| TABLENAME | Table Name | VARCHAR2(30) | NOT NULL | **UK** |  | Table Name |
| COLUMNNAME | Column Name | VARCHAR2(30) | NOT NULL | **UK** |  | Column Name |
| FIELDNAME | Field Name | VARCHAR2(100) | NOT NULL |  |  | Field Name |
| ENTITY | Entity | VARCHAR2(50) | NOT NULL |  |  | Entity |
| ISACTIVE | Active Flag | CHAR(1) | NOT NULL |  |  | Active Flag |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_REPORTFIELDMAP** | **REPORTFIELDMAPID** | **Report Field Mapping ID** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Report Field Mapping ID (Primary Key)** |
| REPORTID | Report Id | NUMBER(10) | NOT NULL | **FK** | **TBL\_REPORT** | Report Id |
| COLUMNFIELDMAPID | Column-Field Mapping ID | NUMBER(10) | NOT NULL | **FK** | **TBL\_COLUMNFIELDMAP** | Column-Field Mapping ID |
| ISACTIVE | Active Flag | CHAR(1) | NOT NULL |  |  | Active Flag |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_AUDIT** | **AUDITID** | **Audit Id** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Audit Id (Primary Key)** |
| ENTITYREFID | Entity Reference Id | NUMBER(10) | NOT NULL |  |  | Entity Reference Id |
| TABLENAME | Table Name | VARCHAR2(30) | NOT NULL | **FK** | **TBL\_COLUMNFIELDMAP** | Table Name |
| COLUMNNAME | Column Name | VARCHAR2(30) | NOT NULL | **FK** | **TBL\_COLUMNFIELDMAP** | Column Name |
| OLDVALUE | Old Value | VARCHAR2(4000) | NULL |  |  | Old Value |
| NEWVALUE | New Value | VARCHAR2(4000) | NULL |  |  | New Value |
| OPERATION | Operation | VARCHAR2(10) | NOT NULL |  |  | Operation (Insert/Create, Update/Modify, Delete/Remove) |
| REASON | Reason | VARCHAR2(1000) | NULL |  |  | Reason |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_STUDYAUDITREPORTMAP** | **STUDYAUDITREPORTMAPID** | **Study Audit Report Map Id** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Study Audit Report Map Id (Primary Key)** |
| AUDITID | Audit Id | NUMBER(10) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| STUDYID | Study Id | NUMBER(38) | NULL | **FK** | **TBL\_STUDY** | Study Id |
| STUDYSITEID | Study Site Id | NUMBER(38) | NULL | **FK** | **TBL\_SITE** | Study Site Id |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_SURVEYAUDITREPORTMAP** | **SURVEYAUDITREPORTMAPID** | **Survey Audit Report Map Id** | **NUMBER(10)** | **NOT NULL** | **PK** |  | **Survey Audit Report Map Id (Primary Key)** |
| AUDITID | Audit Id | NUMBER(10) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| STUDYID | Study Id | NUMBER(38) | NULL | **FK** | **TBL\_STUDY** | Study Id |
| SURVEYID | Survey Id | NUMBER(38) | NULL |  |  | Survey Id |
| SURVEYNAME | Survey Name | VARCHAR2(200) | NULL |  |  | Survey Name |
| SURVEYRECIPIENTID | Survey Recipient Id | NUMBER(38) | NULL |  |  | Survey Recipient Id |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_TRNGCREDITSAUDITREPORTMAP** | **TRNGCREDITSAUDITREPORTMAPID** | **Training Credit Audit Report Map Id** | **NUMBER(38)** | **NOT NULL** | **PK** |  | **Training Credit Audit Report Map Id (Primary Key)** |
| TRNGCREDITSAUDITID | Audit Id | NUMBER(38) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| REQUESTID | Request Id | NUMBER(38) | NULL |  |  | Request Id |
| REQUESTEDBY | Requested By | NUMBER(38) | NULL | **FK** | **TBL\_USERPROFILES** | Requested By |
| REQUESTEDFOR | Requested For | NUMBER(38) | NULL |  |  | Requested For |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_DOCAUDITREPORTMAP** | DOCAUDITREPORTMAPID | **Document Audit Report Map Id** | NUMBER(38) | NOT NULL | **PK** |  | **Document Audit Report Map Id (Primary Key)** |
| DOCAUDITID | Audit Id | NUMBER(38) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| DOCUMENTID | Document Id | NUMBER(38) | NULL |  |  | Document Id |
| FACILITYID | Facility Id | NUMBER(38) | NULL | **FK** | **TBL\_FACILITIES** | Facility Id |
| USERID | User Id | NUMBER(38) | NULL | **FK** | **TBL\_USERPROFILES** | User Id |
| ISFORFACILITY | Is For Facility | VARCHAR2(1) | NOT NULL |  |  | Is For Facility |
| ISFORUSER | Is For User | VARCHAR2(1) | NOT NULL |  |  | Is For User |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_USERAUDITREPORTMAP** | USERAUDITREPORTMAPID | **User Profile Audit Report Map Id** | NUMBER(38) | NOT NULL | **PK** |  | **User Profile Audit Report Map Id (Primary Key)** |
| USERAUDITID | Audit Id | NUMBER(38) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| USERID | User Id | NUMBER(38) | NULL | **FK** | **TBL\_USERPROFILES** | User Id |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |
| **TBL\_FACAUDITREPORTMAP** | FACAUDITREPORTMAPID | **Facility Profile Audit Report Map Id** | NUMBER(38) | NOT NULL | **PK** |  | **Facility Profile Audit Report Map Id (Primary Key)** |
| FACAUDITID | Audit Id | NUMBER(38) | NOT NULL | **FK** | **TBL\_AUDIT** | Audit Id |
| FACILITYID | Facility Id | NUMBER(38) | NULL | **FK** | **TBL\_FACILITIES** | Facility Id |
| CREATEDDT | Created Date | DATE | NOT NULL |  |  | Created Date |
| CREATEDBY | Created By User | VARCHAR2(100) | NOT NULL |  |  | Created By User |
| MODIFIEDDT | Modified Date | DATE | NOT NULL |  |  | Modified Date |
| MODIFIEDBY | Modified By User | VARCHAR2(100) | NOT NULL |  |  | Modified By User |