

Release Notes for the Shared Investigator Platform (v1.1.1 through 2.0.3.2)

Release Notes are designed to let SIP Site and Sponsor users understand the impact of any changes and defect fixes to the Shared Investigator Platform (SIP). All SIP training materials have been revised to reflect the new functionality and are available in the Online Help section of the application.

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SIP Help Desk Email: SIPHelp@Cognizant.com Telephone: See Help Desk	





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Release 2.0.3.2

Release Summary

Changes for Site Users

M3: Survey

 Survey Recipient Registration Status Report related DB Stored Procedure changes

SIP Modules Impacted

Survey

SIP Users Impacted

• Sponsor Users.

Release 2.0.3.1

Release Summary

Changes for Site Users

Configuration Change: Task List Report

• Task List Reports related configuration changes

SIP Modules Impacted

No functional changes on the core product SIP modules

Release 2.0.3

Release Summary

Changes for Site Users

Module 5: Training

- New Credit Request Wizard > Select Completed Course section
 - All mandatory fields should be filled to enable the Search button.
 - Button names and the process flow has been updated to ensure consistency in requests raised for self and others (Continue button is renamed to Submit. Reset button is removed. Add Completion Date button is renamed to Select Course and Add Completion Date)





SIP Modules Impacted

Training

SIP Users Impacted

All site users

Training Available

Following Training materials have been updated:

M5 - Training

- Site User Online Help Training Section
- Site User Job Aid (Manage Training)
- Site User FAQs (Manage Training)

Release 2.0.2.1

Release Summary

Integration: User Profile API 4.8

 Send user profile details along with their medical license using outbound API 4.8 to member company systems. The API will trigger correctly to provide the details when medical license(s) are added / updated or deleted by site users from their user profile in SIP

SIP Modules Impacted

• No functional changes on the core product SIP modules, however the integration API related to M2A: User Profile is being updated.

SIP Users Impacted

MC Sponsor users using integration API 4.8 to receive updated user profile information.

Release 2.0.2

Release Summary

Changes for Site Users

Module 1: Roles and Access Management

- Eliminate Zip/Postal Code Requirement from Exostar - Some countries do not have zip/postal codes. This field was previously required for completion of the Exostar registration process. Zip/Postal code has now been eliminated as a mandatory field in Exostar and SIP.
- Password Reset Change in Exostar Zip/Postal code was being used to request a password reset in Exostar. Users may now use their mobile phone to receive a password reset via text.

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Module 2A: User Profile

- Zip/Postal code is no longer a mandatory in the User Profile – Basic Details screen.
- Generate & eSign Abbreviated CV button is enabled only after all User Profile field mandatory fields for the CV have been completed by the Site User.
- Site Users and their User Profile Delegate can now preview the CV even if the mandatory user profile fields are not complete.

Module 5: Document Management

- When a site user searches for a sponsor user to whom a document related message will be sent, the system will display sponsor users with access to the study and study site. This includes following types of access:
 - Sponsor users assigned to the study or study site (Type 1 role)
 - Sponsor users with non-study specific/functional access to all studies (Type 2 and Type 3 roles) for example survey or training roles

SIP Modules Impacted

- Module 2A: User Profile
- Module 2B: Facility Profile
- Module 1: Roles and Access Management
- Module 5: Document Management

SIP Users Impacted

All Site Users

Deferred Defects

defect details for Release 2.0.2 is mentioned below

Defect Description	Functional Impact	Current Status	Justification
Not able to edit basic user profile information	Site users unable to edit the basic profile details that are stored in Exostar	 Exostar working on a temporary fix ASAP and a long term fix to come in their next release 	The basic details are stored in Exostar and can be updated directly from Exostar admin screens

Deferred Functionality

Module 2B: Facility Profile

Two "Save" buttons in Lo

 Two "Save" buttons in Local Lab section of Facility are repositioned on the screen to improve usability. One Save is for the entire Local Lab Section, the second Save button is save a new Local Lab added to the Facility.







Summary/Description	Module	Severity	Proposed Release
Study documents sent to sites appear to be duplicate (cannot determine recipients by site)	Document Management	Low	Future Release
Us a bility Enhancements - training credit requests and consistency across screens	Training	Low	Future Release
Enhancement: Add column to Review Training Credit Requests page	Training	Medium	Future Release
Enhancement: Add Columns to Training Status Report	Reports	Medium	Future Rel ease



Release 2.0.1.1

Module 8: General

 Enhance user experience when the users try to contact helpdesk - a sponsor or site user will be able to login to ServiceNow tool without having to enter separate login credentials i.e. access the ServiceNow tool with SSO enabled.

SIP Modules Impacted

General

SIP Users Impacted

- All Site Users
- All Sponsor Users

Release 2.0.1

Changes for Site Users

Module 2A: User Profile

 Update the specialty LOV's in the user profile education section to show new LOV which align IR's updated specialty LOV, The same LOV's also visible in user advanced search section and generated CV

Module 3: User Registration

• Show the country specific contact details when the user clicks on contact us link on the home page

SIP Modules Impacted

- User Profile module
- Facility Profile module
- General

SIP Users Impacted

- Site users
- Sponsor users

Deferred Defects

Defect Description	Functional Impact	Target Release	Justification
Only those individuals associated to the study should appear	Users who do not have study association and but Type 1 roles are also shown.	R2.0.2	The appropriate users along with some additional sponsor users are appearing. This is not breaking any functionality and acceptable to wait until target release.

Module 2B: Facility Profile

 Two questions related to the EMR/EHR systems to be removed as they are not facility related questions and in the current form these are misleading.



Release 2.0

Changes for Site Users

Module 1: Roles & Access Management

- Further Streamlined User Registration
- Enhanced Site User invitations
- Implemented new site user roles: Head of Facility, Head of Facility Delegate, Facility & Department Clinical Trial Contact (Partial Implementation)
 - Enhanced delegation capabilities for Site Users
 - User Profile
 - Facility Profile
 - Training Credit Requests

Module 2A: User Profile

- Simplify User Profile navigation and improve completion status indicators
- Implement ability to export full User Profile
- Implement enhanced User Profile form
- Implement "Confirm User" Warning Message when uploading User Profile Form
- Streamline Education section and added specialty
- Professional Experience section updated focus on Jobs held and timing (like a traditional resume)
- Streamlined Research Experience section and applied standard MeSH Terms for Therapeutic Area (Levels 1 and 2)
- Implemented new rules to prioritize CV content and meet 2-page guideline
- Updated CV History page
- Preview CV allowed for incomplete user profile
- Reminder task and email to eSign CV if not updated in 355 days
- CV that is generated within SIP is an abbreviated CV not the full profile

Module 2B: Facility Profile

- Enhanced Facility and Department search
- Reduced the risk of Facility/Department duplication
- Implement common Facility Search across User and Facility Profile
- Update Facility Search to separate Facility and Department workflows
- Reengineer Facility/Department creation workflows
- Streamlined Facility Profile content
- Improve Facility Profile roles and edit rights
- Added functionality to assign Site User to create the detailed Facility Profile
- Enable export of the Facility Profile
- Updated Facility Profile Form to improve upload of data into SIP
- Search Site users within a Facility to search by name
- Improve Site User search to allow Site users to send a "Facility Invitation" to other Site Users
- Revamp of IRB section to include new IRB types and streamline/improve questions
- Added Registering Body and Registration Number to IRB/ERB/Ethics Committees

Module 3: Survey

No change for Site Users





Module 2B: Facility Profile

 Standardized Therapeutic Area using two levels of MeSH terms

Module 3: Survey

Module 4: Study Enablement

- Improves messaging to ensure information is clearly linked to the 1572
- Supports entry of "Review Only" IRBs at the Study Site level
- Allows PI / delegate to select past year / historical dates as start dates while assigning site staff
- Allows assignment of Safety Contact and National Coordinating Investigator roles in Study Site Staff
- Provides general usability enhancements to improve the site user experience

Module 5: Training

- Greater number of courses available for completion in SIP – including Sponsor and Study Specific courses
- Simplified training credit request process which includes a wizard
- Simplified way to search Course Titles for Credit Requests
- A single view of all completed courses in SIP, Credits Requested, Credits Rejected and Credits Granted

Module 6&7: Document Exchange & Safety

- Common Documents
 - Allowing site users to access their user profile, mutually recognized training certificates and Facility documents in one single place
- Integration for Vault Site Exchange tasks to be displayed in SIP on Site User home page
- Email (immediate/daily/weekly digests) to be sent to user from SIP for Vault Site Exchange Tasks
- Single Sign On from SIP to Site Exchange from study documents and links in task and email
- Site user on-boarding and role management from SIP to Vault Site Exchange
- CV auto push as study document to all active study sites

Module 8A: Reports

Enhanced Reports

- Facility/Department Contact Details
- Site User Registration
- Training Status

Module 8B: General

- Enhance special/foreign characters set available a cross the platform (BL-552)
- Simplified Site User search for other Site Users within their Facility
- System announcement hyperlink enabled (BL-540)
- Implemented style guide a cross the application to improve us ability and a consistent user experience
 - Improved system messaging and on-screen text
 - Improved user warnings





Module 8A: Reports

Module 8B: General

- Ensure consistent terminology and use of acronyms
- Clarify who/what role can edit data if the user doesn't have access
 - Improved Screen Design for usability
 - Consistent use of "Breadcrumbs"
- Shorter screens
- Formatting of address fields
- Align expected text size to field character length and size of field on screen
- Text wrapping
- Navigation consistent buttons, wizards, new window vs. closing existing, consistent method for saving data
- Sorting Drop down lists, on screen tables, maintain sort across pages, across user sessions
- Scrolling Vertical and Horizontal
- Consistent sort of drop down lists
- Matching of field size to field length
- Increased use of Type Ahead on longdrop down lists
 - Enhance special characters set available across the platform
 - Simplified search for Site Users within a Facility

Changes for Sponsor Users

Module 1: Roles & Access Management

- New Sponsor Roles-Sponsor Document Administrator, Sponsor Training Administrator, Safety Admin, Study View Only & Full Access View Only
- Renamed of Study Manager role to 'Study Edit and View'

Module 2A: User Profile

- Improve Site User Pull CV functionality to allow Sponsors to better leverage the SIP User Profile data
- Location
- Program/Study
- GCP Training Status
- Research Experience
- SIP Activation Date Range
- CV Generated Date Range
- CV Generated (Yes/No)
- Facility/Department
- Professional Experience
- Education
- Specialty
- Removed unnecessary notification to sponsors when site user updates profile



Module 2B: Facility Profile

- Significant changes to data being collected in the Facility Profile including staff language capabilities, equipment details, investigational product and IRB details
- Improve Facility Search to allow Sponsors to better leverage the SIP Facility Profile data
 - Location
 - Facility/Department
 - Research Experience TA, Phase, Sponsor Type
 - Patient Population
 - Informed Consent Capability
 - Start-Up Timeline
 - IRB Type
 - Equipment
 - Investigational Product Capabilities
 - Language Capabilities
 - Facility Hours
 - PK/PD

Module 3: Survey

Enhance Reports

- Study Feasibility Survey Response Report Excel version
 - Add option to include User/Facility Profile data
 - Update layout to support analysis of survey outside SIP
- General Survey Response Report improve usability

Module 4: Study Enablement

- Allows capture of a primary compound and multiple compounds in the Study Workspace through manual set-up or through CTMS integration
- Allows set-up of planned countries for site identification
- Provides the ability to send compounds and planned country to the Document Management system for folder set up
- Enhanced Potential Investigator List Search Results
- Improves Potential Investigator list functionality
- Provides validations to ensure that Potential Investigators are part of planned countries, are registered in SIP, and have Facilities set up at critical points in the Site Selection process
- Improved usability by providing a hyperlink to the Department Profile
- Aligns the search in Study Enablement with User Profile and Facility Profile search enhancements
- Updates the study participation invitation & study site creation task messages to guide delegation of study site maintenance
- Provides a hyperlink to the user profile on the site staff

Module 5: Training

- Provides the ability to set up sponsor and study-specific training courses and course curriculums
- Provides Sponsor Training Admin with the ability to manage sponsor and study specific training catalogs, certificate templates, training expiration, retraining frequency, and training assignments
- Provides Sponsor Training Admin with the ability to create course assignments at "Sponsor" level, and also by Compound, program, study, site / role / user
- Simplified way to create a Course Assignment through a Wizard
- Ability to Grant Credits to site users without credit approval processes and invite unregistered site users as a part of the process
- Display of "ICH Version" on the credit approval screen
- Provides the ability to send training data to Sponsor LMS including MRT training courses



Module 6 & 7: Document Exchange and Safety Notifications

Common Documents

Allowing sponsor users to access all site user profile, mutually recognized training certificates and Facility documents of site users in one single place

- Enabling SIP Vault Site Exchange integration to manage study documents
- Single Sign On from SIP to Site Exchange from study documents
- Auto-creation of Study and Study Site in Vault Site Exchange from SIP

Module 8A: Reports

Enhance Reports

- Facility/Department Contact Details
- Site User Registration
- Training Status

Update Audit Trail Reports

- Study Audit Trail Report
- Training Credit Request Audit Trail Report
- Training Audit Trail Report
- User Profile Audit Trail Report
- Facility / Department Profile Audit Trail Report
- Us er and Facility Documents Audit Trail Report

Module 8B: General

- Implemented style guide a cross the application to improve us a bility and a consistent user experience
 - Improved system messaging and on-screen text
 - Improved user warnings
 - Ensure consistent terminology and use of acronyms
 - Clarify who/what role can edit data if the user doesn't have access
- Improved Screen Design for usability
 - Consistent use of "Breadcrumbs"
 - Shorter screens
 - Formatting of address fields
 - Align expected text size to field character length and size of field on screen
 - Text wrapping
 - Navigation consistent buttons, wizards, new window vs. closing existing, consistent method for saving data
 - Sorting Drop down lists, on screen tables, maintain sort across pages, across user sessions
 - Scrolling Vertical and Horizontal
 - Consistent sort of drop down lists
 - Matching of field size to field length
 - Increased use of Type Ahead on long drop down lists
- Enhances pecial characters set available a cross the platform
- Simplified search for Site Users within a Facility

Release Summary



SIP Modules Impacted

M1: Roles and Access Management

M2A: User Profile

• M2B: Facility Profile

M3: Survey

• M4: Study Enablement

M5: Training

• M6: Document Exchange

• M7: Safety Notifications

M8A: Reports

• M8B: General

SIP Users Impacted

All Sponsor Users

All Site Users

Deferred Defects

Defect Description	Functional Impact	Target Release	Justification
SumTotal Defect: As per the step, user should click on "Close" button to close the Completion Document window. However, that did not work for the user.	No functional impact as the user can close the window instead of using the close button.	2.1	This is a SumTotal product issue and a ticket is already raised with production team (SumTotal). No timelines received from SumTotal yet.
Platform notification is not received when Study Edit and View user is onboarded or associated with Study association through API.	The Users will not receive notification for onboarding or study association. The association will be reflected in SIP as well as source system. There is no other impact.	2.1	This notification issue will be addressed by enhancing API in R2.1
SumTotal Defect: Print, export and Close buttons are not working in the Certificate when user clicks on the Document present in the Completed Training tab (Both in Chrome and IE11 browser).	No functional impact as the user can close the window instead of using the close button. User is unable to print the record into PDF Format, which is of medium risk but the user can physically print a copy to a printer	2.1	This is a SumTotal product issue and a ticket is already raised with production team (SumTotal). No timelines received from SumTotal yet.
Veeva Defect: User is not able to eSign the documents in Veeva	E-signature workflow in Vault Site Exchange cannot be accomplished	2.1	E-signature workflow in Veeva is independently handled in Vault without SIP involvement, just like all the other document exchange workflows.



Defect Description	Functional Impact	Target Release	Justification
Veeva Defect: 30-minSessionTime- out	User will see Vault Site Exchange time out page when his/her session times out in Vault Site Exchange	Future Release	This is a Veeva issue (site exchange fix) that would be fixed 17R2 or 17R3 release of Veeva
Training Type Filter Doesn't Work	The filter works normal, except in the case where API data is sent to SIP. No change to requirements	R2.1	This will be addressed in R2.1 with other changes in Training
Requirement Field Due Date Field Not Populating when receiving data from IS	API-s pecific defect: Requirement Field, Due Date field. No change to requirements. A site user won't be able to see the due date of the training they have been assigned	R2.0.1	This is specific to API integration of one MC, and they agreed to wait for 2 weeks
Study Workspaces created by the integrations can't have their miles tone dates or their enrollment counts updated in the UI	If either of the dates are not provided from the API then user cannot edit the dates using SIP UI.	R2.0.1	This will be address in immediate patch before the Integrations are used by Sponsors
Copy Question Error Persists	When copying a question to a new survey if the selected survey is blank an error is shown. User can close the window and restart.	R2.1	This will be addressed in R2.1 with other changes in Survey
Requirement field value is not updated after editing course assignment	When requirement field is updated/edited from Required to recommend or vice versa the changes are not saved.	R2.0.2	Edit button before a course assignment is not working. The workaround for this is the Edit functionality after the course assignment is created
Wrong completion date appears in sip after launching a Trifecta course	API-specific defect: Completion Date. No change to requirements. A site user would see a discrepancy in the completed date after completing a course	R2.0.2	API issue for one MC. Date is being received correctly to SIP. It is an issue in the display, and hence is being deferred
Potential Investigator list does not match what is in SIP	Data in the system is correct but the report is not showing the right data.	R2.0.1	This will be addressed in R2.0.1
Site ID is showing as required for Prestudy invite	SIP behavior is as expected except for a validation message is being displayed to the user even though field is optional. This will be corrected in the next patch release	R2.0.2	Minor fix required to ensure that user is not given validation message for an optional field.
Survey create from previous	The summary only shows the questions and not the response options and the user can use the preview option that shows the	R2.1	This will be addressed in R2.1 with other changes in Survey





	sections, questions along with the response options		
Changes you made may not be saved dialogue box even though no changes made	User gets a wrong message that there were changes made when the user didn't make any changes	Future Release	As in the database, no actual changes were made, this can be addressed in a future release
Changes you made may not be saved appearing when making changes	User gets a wrong message that there were changes made when the user didn't make any changes	R2.1	This will be addressed in R2.1 with other changes in Reports
Style Guide - PDF Iconin Blue	Minor color standardization not present. No functionality impacted.	R2.1	This will be addressed in R2.1 with other changes in the screens

Deferred Functionality

Summary/Description	Module	Severity	Proposed Release
The system shall assign the Document Type 'Site and Staff Qualification Supporting Information' to all documents uploaded in 'Profile Attachments' section.	Module 2A: User Profile	Low	Future Release
This requirement would be made available when profile attachments are being passed on to document management system as study documents.			

Training Available

Following Training materials have been updated:

M1 - Roles and Access Management

- Site User Online Help Registration and Introductory Sections
- Site User Orientation Guide
- Site User Job Aid (User Registration)
- Site User Job Aid (Password Management)
- Sponsor User Online Help Introductory Sections
- User Registration and Password Management FAQs
- Sponsor User Orientation Guide
- User Registration and Password Management FAQs
- Manage OTP Job Aid

M2B - Facility Profile

• Site User Online Help - Facility Profile

M2A - User Profile

- Site User Online Help User Profile
- Site User Job Aid (Manage User Profile)
- Site User Demo Create User Profile
- Site User Demo Delegate Completion of User Profile
- Site User Demo Generate CV
- Sponsor User Online Help User Profile
- Site User FAQs User Profile

M3- Survey

• Site User Online Help - Surveys



Release Notes



- Site User Job Aid (Manage Facility Profile)
- Site User Demo Search for a Facility
- Site User Demo Create Facility/Department Profile
- Sponsor User Online Help Facility Profile
- Site User/sponsor User FAQs Facility Profile

M4- Study Enablement

- Site User Online Help Study Workspace
- Site User Job Aid (Manage Study Workspace)
- Sponsor User Online Help Study Workspace
- Sponsor User Job Aid (Manage Potential Investigator List)
- Sponsor User Job Aid (Manage Study Workspace)
- Sponsor User Demo Create Study Workspace
- Sponsor User Demo Create Potential Investigator List
- Sponsor User WBT Study Workspace
- Study Workspace/Study Site FAQs

M6- Document Exchange

- Site User Online Help Documents
- Site User Job Aid (Manage Documents)
- Sponsor User Online Help Documents
- Sponsor User Job Aid (Manage Documents)
- Sponsor User Demo Upload a Document
- Sponsor User Demo Search and Access a Document
- Sponsor User Demo Document Exchange Actions
- Sponsor User WBT Document Exchange
- Documents FAQs

- Site User Job Aid (Manage Surveys)
- Sponsor User Online Help Surveys
- Sponsor User Job Aid (Surveys: All Sponsor Users)
- Sponsor User Job Aid (Survey Creator)
- Sponsor User Job Aid (Survey Reviewer)
- Sponsor User Job Aid (Survey Response Manager)
- Sponsor User Demo Create a Survey
- Sponsor User Demo Design a Survey
- Sponsor User Demo Survey Review
- Sponsor User Demo Review a Survey Response
- Feasibility Surveys FAQs and Sponsor User Surveys FAQs

M5- Training

- Site User Online Help Training
- Site User Job Aid (Manage Training)
- Sponsor User Online Help Training
- Sponsor User Job Aid (Manage Training)
- Sponsor User Demo Assign a Training Course
- Sponsor User Demo Edit or Delete an Assigned Training Course
- Sponsor User Demo View Training Completion Status
- Sponsor User Demo Manage Training Credit Requests
- Sponsor User Demo Grant Credit
- Sponsor User Demo Upload Training Course
- Sponsor User WBT Training
- Training FAQs

M8- Reports and General

- Site User Online Help Reports
- Sponsor User Online Help Reports
- Sponsor User Job Aid (Reports)
- Reports FAQs



Release 1.4.3.0

Changes for Sponsor and Site Users

Release Summary

Module 4: Facility Profile

- Wrong information being shown in IP section if a Facility
- When a user looks at Investigational Product (IP) section of a Facility which has certain information and goes back to the same section of another Facility which has no information, the information of the of IP section from the first Facility is being be shown to the second Facility. This has caused misrepresentation of the information to the end users
- By fixing this defect, users will be able to view the
 accurate information of a Facility. If a certain Facility
 does not have any information in IP section, then user
 will not be able to view any details in that section while
 toggling between the facilities.

SIP Modules Impacted

Facility

SIP Users Impacted

- Sponsor users
- Site Users

Deferred Defects

None

Deferred Functionality

None

Training Available

NA



Release 1.4.0.2

Changes for Site Users

Release Summary

Module 4: Facility Profile

- View of attachments in Facility sections
- Facility Profile Attachments of a specific Facility are visible to other facilities [with no attachments] by a sponsor user. This issue will occur if a sponsor/site user opens a Facility details screen that has attachment(s) and later user goes back to Facility list and view another Facility which has no attachment, then the attachment(s) of the previous Facility will be visible from attachment section of second Facility as well. However, if both the Facilities have attachment(s), then the facilities will be viewed with correct set of attachment(s).

By fixing this defect, site users will be able to view the correct set of document as uploaded during Facility profile completion. If a certain Facility does not have any document attached then user will not be able to view any document for the Facility

Changes for Sponsor Users

Release Summary

Module 3: Survey

Sharing cross sponsor information in survey recipient list:

- When a same site user is added as a survey recipient by more than one sponsor organizations for different surveys, cross sponsor information is shared in Survey recipient list (Added BY field)
- By fixing this defect, each sponsor organization users will be able to view the correct details in the 'Added By' field and will not see details of sponsor users from another organization.





Module 4: Facility Profile

• View of attachments in Facility sections

Facility Profile Attachments of a specific Facility are visible to other facilities [with no attachments] by a sponsor user. This issue will occur if a sponsor/site user opens a Facility details screen that has attachment(s) and later user goes back to Facility list and view another Facility which has no attachment, then the attachment(s) of the previous Facility will be visible from attachment section of second Facility as well. However, if both the Facilities have attachment(s), then the facilities will be viewed with correct set of attachment(s).

By fixing this defect, Sponsor users will be able to view the correct set of document as uploaded during Facility profile completion. If a certain Facility does not have any document attached then user will not be able to view any document for the Facility

SIP Modules Impacted

- Survey
- Facility

SIP Users Impacted

- Sponsor users
- Site Users

Deferred Defects

None

Deferred Functionality

None

Training Available

NA



Release 1.4.0.1

Changes for Site Users

Release Summary

Module 4: Study Enablement

The following issue has been fixed:

- When a PI has added a site user as a site staff with a future date, and when the added site user successfully logs on to SIP prior to the future date, he/she gets a technical error due to which the main navigation bar is unavailable i.e. major functionality is not available.
- By the result of the fix, the user will be able to access the main navigation bar without the technical error, even if they log on to SIP prior to the future allocation date

SIP Modules Impacted

Study Enablement

SIP Users Impacted

• Site users who are associated as a site staff with a future date

Deferred Defects

None

Deferred Functionality

None

Training Available

Following Training materials have been updated

- Site User Job Aid
- Online Help





Release 1.4

Neicase 1.4

Changes for Site Users

Release Summary

Module 2: User and Facility Profiles

- Facility workflow has been simplified. If a user searched for Facilities and the search results yielded no existing Facility, the User is now provided with a button to create a new Facility.
- Us a bility improvements were made to ensure that users cannot leave the User Profile – Research Experience and Medical Education sections without saving their data.

Changes for Sponsor Users Release Summary

Module 2: User and Facility Profiles

 Site and Sponsor Users can now download and view training completion certificates from the User Profile.

Module 4: Study Enablement

 When a Sponsor User searches for a Potential Investigator the search results have been enhanced to include the address and city of the Facility to the Sponsor User can choose the appropriate location for the Study.





Module 5: Training

- When a Sponsor User is assigned as Training Credit Approver, all the pending tasks (including Training Credit Requests) are assigned to the new Training Credit Approver
- Any pending tasks sent to a Training Credit Approver will show as being "Assigned By" the actual requester.

SIP Modules Impacted

- User Profile
- Facility Profile
- Study Enablement
- Training

SIP Users Impacted

- Sponsor Users Survey Creators, Credit Approver
- All Site users.

Deferred Defects

None

Deferred Functionality

None

Training Available

Following Training materials have been updated

- Create Potential Investigator List Demo
- Sponsor User Job Aid Manage PI List
- Sponsor User Online Help



Release 1.3

Changes for Site Users

Release Summary

Module 1: Registration and General

- Simplified Registration Process: New Site Users will receive not two, but one email containing an account activation link and provide access immediately
 - Automated access to SIP for existing Exostar users without help desk involvement
 - No delay in access to SIP for both new and existing Exostar users
- Site User Orientation: New Site Users no longer need to complete a web-based training in order to access SIP for the first time. They can view the Site User Orientation PDF and provide an acknowledgment.
- Improved Usability of Drop-down Lists: Long drop-down lists (i.e. drop-down lists with substantially large numbers of items) are now provided with a type-ahead feature to improve usability. Examples include Country, State/Province/Region, Course Title, Time Zone, and Therapeutic Area.
- User Deactivation Process: This process continues to be managed by the SIP Administrator, but has been documented in an SOP
- Cross-Study Sponsor Roles: Sponsor roles have been updated to allow Personnel who have cross-study responsibilities with more applicable access to the application

Module 3: Surveys

 Survey Recipient List: An additional column, "Reference Code", is added to the Survey Recipient List, to allow Sponsor Users to capture notes and assign Survey Recipients to tiers

SIP Module Impacted

- Roles and Access Management
- User and Facility Profiles
- Surveys

Module 2: User and Facility Profiles

- User Profile Navigation: Cancel and Reset buttons have been removed from all sections of the User Profile
- Delegated User Profiles: The Delegate can now submit a training credit request on behalf of the User Profile Owner and Improve Delegator approval workflow
- Site User CV: Improved CV template
- Accepting/Rejecting Changes Made by Delegate
- Education Details: Education Details and Medical Education are now separate sections within the User Profile
- Attachments: Instead of the section Attachments, two sections
 Profile Attachments and Publications & Presentations are included
- CV History: Delegates can now view the CV History and CV download history of the User Profile Owner
- Facility Profile: It is no longer required to enter the central IRB information in the Facility Profile
- Facility Profile Navigation: Only the following navigation buttons are retained in the various sections of the Facility Profile – Previous Section, Next Section, and Save
- Facility/Department Profile Editability: Facility/Department Profile will remained itable even after creation/update

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SIP Users Impacted

• All Sponsor and Site users.

Deferred Defects

Defect Description	Functional Impact	Current Status	Justification
Reference code hyperlink not enabled.	Study Enablement	R2.x	Discussed and agreed with Member Companies that the defect will be addressed as part of future release.
In Medical License uploads ection, can the system guide the site user to provide a unique name to their uploaded medical license PDF document as its possible two people have saved it to their local with same name	User Profile Management	R2.x	Discussed and agreed with Member Companies that the defect will be addressed as part of future release.
As per the step, user should click on "Close" button to close the Completion Document window. However, that did not work for the user.	Training	R2.x	Discussed and agreed with Member Companies that the defect will be addressed as part of future release.
Phone number in IP Shipping screen does not accept '-'s or '+' (only numeric).	Facility Profile Management	R2.x	Discussed and agreed with Member Companies that the defect will be addressed as part of future release.
System would not allow me to create a Medical License record because the support dochad been used elsewhere.	User Profile Management	R2.x	Discussed and agreed with Member Companies that the defect will be addressed as part of future release.



Deferred Functionality

Summary/ Description	Module	Severity	Proposed Release
Observation - While completing site user profile, whenever user goes to the next section, the screen just scrolls up to the top instead of the exact section area. This should be taken as an enhancement as this is not a good user experience.	User Profile Management	2-Medium	R2.x
Observation - The tasks that training credit approver receives for approval has their own name on it. In our case, user Peggy Barnett has the role of Training Course Assigner and Training Credit Approver in the system. In her Tasks, she sees tasks where credit requests came from her but she never requested those.	Training	2-Medium	R2.x
Exostar email content - Reference to SMS text is not applicable until 3.3.4-remove content	Access Provisioning	1-Low	R2.x
Unable to create a facility from User Profile - After searching for a facility to associate with, a no results/create facility should appear	User Profile Management	4-Critical / Emergency	R2.x
Same person cannot be both Site Contact for CTs or FPM - Same person cannot be both Site Contact for CTs or FPM: BI: This could be the person.	Facility Profile Management	4-Critical / Emergency	R2.x
Questions are still required if Central IRB is checked - See screenshot, but 4 questions should still be available for facilities that have 'central' IRB checked. BI: these questions are still needed regardless, current users have these questions answered, removing them and bringing them back could impact current data in Facilities	Facility Profile Management	4-Critical / Emergency	R2.x
2 questions should remain if lab is answered no - IATA Training and attachment questions for labs hould still be displayed BI: Handling specimens are applicable regardless if a local or central lab is being used.	Facility Profile Management	2-Medium	R2.x
Missing message to "Create New Facility" - When creating a facility and performing a search to verify the current facility does not exist, there is no option to create a new facility from this screen.	Facility Profile Management	2-Medium	R2.x
User does not see all required fields of IRB section - Usability — I chose the "Central acting as a Local" option completed the required fields and then clicked saved and the checkmark never appeared because the IRB/ERB Ethics Committee is collapsed and there is no indication that there are required fields in that section	Facility Profile Management	2-Medium	R2.x
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Summary/ Description	Module	Severity	Proposed Release
Studies are not listed in any particular order - Managing study news and links (the dropdown for finding the targeted study to post news and links is to sort in any particular order).	Study Enablement	1-Low	R2.x
A study manager can post news/links to all studies regardless of assignment - a Study Manager should only have the ability to post study news and links for studies as assigned as a Study Manager	Study Enablement	1-Low	R2.x
Study News linkleads to a blank page - Study News linkis hyperlinked butleads to a blank page	Study Enablement	1-Low	R2.x
Additional information needs to be displayed in the Potential Investigator List - When searching for a Potential Investigator, there is not enough data in the results to a dequately select the correct investigator. A future requirement should be to also list the street, and city for the Facility	Study Enablement	2-Medium	R2.x
PI unable to edit Systems Access - When Study Site Creation occurs, PI is unable to edit the System Access fields. This same behavior occurs via study site creation in SIP and Study Site creation via integration	Study Enablement	2-Medium	R2.x
Ref Code text field when opened is not dismissed when you leave the screen, e.g., adding a new user, the child window is still open You must navigate back to the window and either cancel or add text or press cancel and/or add test and save.	Site Feasi bility Survey Management	2-Medium	R2.x
Researchs ortorder - Entered phase 1 first, but the list order sort seems random.	User Profile Management	1-Low	R2.x
Spacing and Grammar - spacing between phase. For; usually do not start a sentence with a preposition.	User Profile Management	1-Low	R2.x
Total Clinical Research Experience - List order seems random	User Profile Management	1-Low	R2.x
Word wrapping in PDF - additional fields need to be reviewed for word wrapping issues	User Profile Management	4-Critical / Emergency	R2.x
Consider rewording the Delegate message when pressing save - add clarification to the Delegate that the saved changes are viewable when they have completed and submitted the CV back to the delegator. Pressing Save and viewing the profile from the delegator account did not show the saved changes.	User Profile Management	1-Low	R2.x

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Summary/ Description	Module	Severity	Proposed Release
Delegator can still edit their profile after delegating their profile; changes are lost once the Delegate submits the profiles changes back to the delegator for approval record locking	User Profile Management	4-Critical / Emergency	R2.x
The delegator completed their CV (generated) but the task did not complete task management	User Profile Management	3-High	R2.x
Observation - User suggests that it will be a better experience if the font for the message can be made larger and in bold on the screen that site user gets after logging out from the system.	User Profile Management	1-Low	R2.x
"Clickhere to complete logout from your application".			
State is not carried over - Entered state of MN for 1st registration in Val2, state did not carry over in Val1 when registering	Access Provisioning	4-Critical / Emergency	Exostar Release 3.3.4
Special Characters (apostrophe) in User profile - When a delegate was completing the profile for a PI, and entering the data in the publications and Presentations section, the apostrophe, was not valid input for the location of the presentation.	User Profile Management	2-Medium	R2.x
Unable to retrieve a training certificate from the user profile - As a sponsor user in the Study Manager role, I navigated to the profile of Lisa Barnes. When navigating to the GCP Training area, there is no way to link to the training certificate attachment (no button, link, etc.).	User Profile Management	4-Critical / Emergency	I mmedia te Release
Research Experience not getting saved after delegate submits changes - When user clicks on submit changes there was no prompt to save the data before proceeding Option A - Prompt message Option B - Save implicit	User Profile Management	3-High	Immedia te Rel ease
Medical education Delegate updates lost for delegator - When the user removes the document Option A - Prompt message Option B - Save implicit	User Profile Management	3-High	Immedia te Rel ease

Training Available

Following Training materials have been updated

- Facility Profile Job Aid for Site User
- User Profile Job Aid for Site User
- Site User Online Help
- Sponsor User Online Help

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- User Registration Job Aid for Site User
- Survey Creator Job Aid for Sponsor User
- Create User Profile Demo
- Delegate Completion of User Profile Demo
- Edit Your Facility/Department Demo
- Generate CV Demo
- Create Facility Profile Demo
- Study Workspace WBT
- Create Potential Investigator List Demo
- Manage PI List Job Aid for Sponsor User
- Manage Reports Job Aid for Sponsor User



Release 1.2

Changes for All Users

Note: An earlier version of the Release Notes erroneously identified Release 1.2 as Release 1.1.4.

Release Summary

- In eSignature report, another column is added to include eSignature timestamp
- Debarment Statement is removed from the list of document types that the Sponsor User can send to the Site User.
- The system has been fixed to ensure that Local Lab information is saving and the status indicator will not change until each required field is populated
- Fix is being provided to ensure that the data entered by User in the Facility Profile is correctly reflected in Sponsor View and Export of the facility Profile
- Facility/Department will be created in Active status. Draft status has been removed.
- Fix made to ensure that all tasks forwarded by email are received by user recipient.

SIP Site User Modules Impacted

- User and Facility Profile
- Study Enablement
- Documents

SIP Sponsor User Modules Impacted

- Reports
- Documents

SIP Users Impacted

All Site & Sponsor users

Deferred Defects

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Defect Description	Functional Impact	Current Status	Justification
When the user requests association to Study- Site & the request is accepted & the user tries to see the notification if the user has access to that particular study site, a new page opened and an error appeared that stated: jsp.error.message-errorcode-Unknown_Code.	Intermittent issue. It worked fine the second time.	Deferred for R2.X release	Since this happens intermittently, it will be monitored to see if a fix is needed in the release stated.
While facility site user tries to create duplicate and draft Facility the table header for State/Province/Region listed. Result (State) does not appear	Intermittent issue. It worked fine the second time.	Deferred for R2.X release	Since this happens intermittently, it will be monitored to see if a fix is needed in the release stated.
MRT training is completed & expecting expiration reminder notification - Expired training notification was missing in SIP although earlier steps in the script confirmed that email notifications leading up to expiration and after expiration were received by site. Script did not ask for tester to check for site user notification in SIP (bell icon), but emails were received by site user as expected. Please also confirm that the SIP notification under the bell icon should also displayed to the site user.	Low functional impact as user is able to proceed with next steps	Deferred for R2.X release	Issue due to synchronization of time between Services and LMS servers. This should not occur in production since server times are synchronized. Even if this occurs this is minor in nature as it affects only sponsor user MRT
MRT training is completed & expecting expiration reminder notification - Email notification to sponsor after site GCP training expiration was not received.	Low functional impact as user is able to proceed with next steps	Deferred for R2.X release	Issue due to synchronization of time between Services and LMS servers. This should not occur in production since server times are synchronized. Even if this occurs this is minor in nature as it affects only sponsor user MRT
User trying to Create Facility by Online Option the Drop Down Menu Scroll Barfor country needs to be fixed	Minor UI issue	Deferred for R2.X release	Will be a nalyzed to see if this can be made intuitive to the user.



Defect Description	Functional Impact	Current Status	Justification
Training sponsor user and site administrator views training status report - Two training credit requests were submitted and Sync and Generate button was used to generate a report of most current training information. The credit requests just submitted were missing from the report. About an hour later, the Sync and Generate button was clicked again to confirm system behavior and on this try, system did display the requests for credit as expected. In order to confirm that the feature was working correctly, the steps for submitted new credit request and then immediately using Generate and then Sync and Generate to view reports were repeated. On this third try, the system was observed behaving as expected, i.e. after the new request was submitted with completion date 04-Nov-2016, it was not reflected on the report when Generate button		Deferred for R2.X release	Sync and Generate works when study site is not selected. Will be fixed in the next release.
was used and it was displayed on the report when Sync and Generate was used.			

Deferred Functionality

• No functionality planned for Release 1.2 has been deferred to a later release

Training Available

The SIP Help menu contains the links to the following Documentation on SIP.

- **WebHelp** Interactive and browser-based Online Help containing conceptual information as well as step-by-step guidance on tasks you can perform in SIP.
- Job Aids Printable documents containing step-by-step instructions on performing important tasks in SIP
- The following Training Materials are available to help impacted users:

Training	Description	
Online Help	The following sections have been updated:	
	Site User Online Help, Job Aids, Demos	
	Sponsor User Online Help, Job Aids, Demos	

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Web Based Trainings	The following WBTs have been updated:	
	Document Exchange WBT	
Demos	Site User Demos	
	Delegating Completion of User Profile	
	Create User Profile	
	Generate CV	
	Search for a Facility	
	Edit Your Facility or Department	
	Create Facility or Department	
	Sponsor User Demos	
	Document Exchange Actions	
	Search and Access	



Release 1.1.3

Changes for Site Users Release Summary

- The first time Login information for the newly Registered site users has been updated Newly registered users will receive a single email with the Account activation details
- Users will be reminded via email on 30th, 60th and 180th day of registration if the first time login is incomplete
- Login screen has been updated to accept Login ID first and then password in two successive pages
- First Time Login screens have been modified users will be redirected to the password set screen on clicking the activation link received via email
- Users can request the SIP Helpdesk for Resending the Activation Email in case they have not received or have misplaced the same. Service Provider Administrator can resend the Activation Email and Reset the password for the Site Users
- Site users will be notified in the registered email in case the SIP account is locked
- State/Province field updated with List of values containing state code
- Field Lengths extended for First Name, Last Name, Middle Name, Phone, Fax, Zip Code, Street Address 1,
 Street Address 2, Email, Job Title, City
- Users will receive proper error message on providing wrong credentials in Esign login screen

SIP Modules Impacted

- User Login module
- User Profile module

SIP Users Impacted

All Site users

Deferred Defects

Deferred defect details for Release 1.1.3 is mentioned below.

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Description	Functional Impact	Current Status	Justification
Missing content in the second email providing the SIP user with invitation code to activate account, in case the initial email was misplaced/not received. Missing Content:	The site users requesting for resending the activation Email will not receive the missing content	The defect is not getting fixed in the current release.	This defect to be fixed prior to the Usability Patch Release Dec 2016. The Help-Desk procedure currently in use is being updated to include a step that the User is to be advised as follows:
"NOTE: It may take up to 5 minutes for your application access to be active. If you cannot access the application right away, please wait for 5 minutes and re-attempt access.			a. It may take up to 5 minutes for your application access to be active. If you cannot access the application right away, please wait for 5 minutes and re- attempt access.
Please bookmark the following URL for accessing Shared Investigator Platform after account activation: https://sharedinvestigator.com/"			b. BookmarkSIPURL.



Deferred Functionality

• No updates to functionality planned for Release 1.1.3 has been deferred to a later release

Training Available

- The Online Help in SIP for Site Users and Sponsor Users have been updated to reflect changes made in this Release
- The following Training Materials are available to help impacted users:

Training	Description	
User Registration Job Aid for Site Users	All the sections have been updated	
Online Help for Site Users	The following sections have been updated:	
	Site User Orientation	
	Site User User Profile	
	Site User Facility Profile	
	Site User Study Workspace	
Online Help for Sponsor Users	The following sections have been updated:	
	Sponsor User Reports	
	 Sponsor User Documents Exchange 	
Site User		
FAQ's on User Registration for Site Users	The following sections have been updated:	
	How to Register	
	 Access Issues after Registration 	



Release 1.1.2

Changes for All Users Release Summary

• SIP users can now connect successfully from a desktop or laptop using Safari version 7 or above, including Safari 10.

SIP Modules Impacted

• User Login module

SIP Users Impacted

• All Sponsor and Site users

Deferred Defects

• No defects identified during Release 1.1.2 have been deferred to later releases.

Deferred Functionality

• No updates to functionality planned for Release 1.1.2 has been deferred to a later release.

Training Available

No changes were required to any Training Materials.

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Release 1.1.1

Changes for Site Users

Note: v1.1.1 was a patch on top of the v1.1 software release. V1.1 was never formally installed to the Production environment.

Module 1: Registration and General

- Site User Invitations: In order to register in S
 a site user must receive an invitation from a
 Sponsor or a nother Site User at their facility
- **Data Consent:** Data Consent is now directly displayed on the Terms and Polices screen.

Module 2: User and Facility Profiles

- User Profile: Add additional contact information, 24-hour number in addition to the main/daytime number
- Site User CV: Preview your CV before generating and e-signing it. The blank sections in the User profile will not appear in the preview or generated CV.
- Most Recent Research Experience: All "Most Recent Research Experience" entered and saved will be visible to the Site Users
- Facility Profile Manager (FPM):
 - All active Facility Profiles must have at least one Primary FPM, so that the Site can always edit the Facility and Users are able to associate to it
 - A Primary FPM cannot remove himself/herself without assigning the role to a nother Site User
 - For existing Facility Profiles that are orphaned (i.e. do not have a Primary FPM), the next FPM is assigned as the Primary FPM
 - On-screen help messages and navigation tips are added to clarify the process for Site Users
 - Department Profiles: Set up departments under a facility and maintain a department profile which can be re-used a cross SIP Sponsors and studies
 - Attachments in Facility Profile: Attach nonstudy specific documents in the IRB/ERB/EC, Local Lab, and Controlled Substances sections

Module 3: Surveys

• **Survey Delegation:** Improved delegation of surveys, sections of surveys, and questions to

Module 4: Study Workspace

- Registration invites to unregistered Users: Send SIP registration invitations when assigning site staff to a Study
- Sponsor Contacts: View Sponsor Contacts for a Study
- **Favorite Studies:** Create a list of Favorite Studies for easier navigation. Change a facility

Module 5: Training

- Request for Credit: Edit an already submitted credit request for mutually recognized training courses
- Training notifications: Receive notifications
 when training is expired or evertue.

Module 6: Document Management

- Document Title: Find documents easier with more descriptive System-generated document titles and new columns added to search results
- Document Personnel Name: Associate specific documents to site personnel
- Document Reminder Frequency: Set up reminders for overdue documents

Module 5: Reports

Facility/Department Report: Generate a
 Facility/Department report used by Facility
 Profile Managers to departments set up under a facility





Release Summary: Release 1.1.1 Changes for Sponsor Users

Module 1: SIP Roles and Access Management

- New CRO Roles: CRO users can now be provided with singlestudy access to the platform on behalf of their respective Sponsor Companies
- User Deactivation Process: This process continues to be managed by the SIP Administrator, but has been documented in an SOP
- Cross-Study Sponsor Roles: Sponsor roles have been updated to allow Personnel who have cross-study responsibilities with more applicable access to the application

Module 4: Study Workspace

- Study Workspace: Ability to create and edit information contained in the Study Workspace (manually and through integration)
- Simplified Invitation Process: When you add an unregistered user to the Potential Investigator list, they will a utomatically receive an invitation to register in SIP
- Spons or Contacts: Capability to add/edit Sponsor Contacts for a Study
- Favorite Studies: Capability to create a list of Favorite Studies for easier navigation
- Study Facility Change: Ability to receive a notification when a site user changes a facility for a study

Module 4: Study Workspace

- Study Workspace: Ability to create and edit information contained in the Study Workspace (manually and through integration)
- Simplified Invitation Process: When you add an unregistered user to the Potential Investigator list, they will automatically receive an invitation to register in SIP
- Spons or Contacts: Capability to add/edit Sponsor Contacts for a Study
- Favorite Studies: Capability to create a list of Favorite Studies for easier navigation
- Study Facility Change: Ability to receive a notification when a site user changes a facility for a study

Module 5: Training

 Training Expiration Notifications: Ability to send notifications about training expiration and track overdue training

Module 6: Document Management

- **Document Title:** Rule for system generated document title enhanced to be more descriptive
- Document Search Results screen: Columns File Name,
 Document Description, and Personnel added to ease searching
- Personnel: Personnel field introduced to identify the Site User(s) associated with the document
- Introduction of Reminder Frequency: Frequency at which the Site and Sponsor users will be reminded for documents that have not been accessed until the due date



Module 3: Surveys

- Survey Design: Ability to multi-select Indication,
 Therapeutic Area and Country, create Ranking questions and configure a list of reasons for declining participation in a feasibility survey
- Survey Recipient Lists: Ability to export and manage Survey Recipients
- Survey Recipients: Ability to send SIP registration invitations to Unregistered Survey Recipients
- Survey Response Manager: Ability to assign multiple
 Sponsor Personnel to manage responses for specific survey question(s)

Module 8: General

- News/announcements: Sponsors can now download any news and announcements posted on the Landing Pages in SIP
- Facility/Department Report: New report to view all existing Facilities and their associated Departments
- Audit Trail: New Audit Trail Reports for all SIP modules
- Configure News and Links: Sponsor Users are now allowed to configure Study News and Study Links from SIP

Training Available

The SIP Help menu contains the links to the following Documentation on SIP.

- **Web Help** Interactive and browser-based Online Help containing conceptual information as well as step-by-step guidance on tasks you can perform in SIP. The Sponsor User WebHelp also includes a keyword-based search and a Glossary of definitions of important terms relevant to SIP.
- Job Aids Printable documents containing step-by-step instructions on performing important tasks in SIP
- User FAQs Documents containing FAQs related to each module

To access the SIP Help menu, on the upper right corner of any page, click



Training Materials for Site Users	Training Materials for Sponsor Users
Site User Online Help	Sponsor User Online Help
Site User Job Aids	 Sponsor User Job Aids
- User Registration	- Manage Documents
- Password Management	- Manage Training
- User Profile	- Manage Study Workspace
- Facility Profile	- Manage Potential Investigator List
- Documents	- Manage Surveys: All Sponsor Users
- Training	- Create and Manage Surveys: Survey Creator
- Study Workspace	- Manage Surveys: Survey Reviewer
- Feasibility Surveys	- Manage Surveys: Survey Response Manager
- Site User Orientation Guide	- Manage Reports
Site User FAQs	- Sponsor User Orientation Guide
Site User Orientation Web-Based Training	- Sponsor User FAQs
	 Web-based Training (WBTs)
	Document Exchange Web-Based Training
	- Study Workspace Web-Based Training
	- Training Web-Based Training