



Due Diligence Automation System User Manual

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Developed by:
Clarity Information Technologies Pvt. Ltd.
Bangalore.
Tele: 080 - 2529 1698
Email: mail@claritytechnologies.com

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Introduction

DDAS is a Web Application and can be accessed through: [http:](http://...) on your web browser.

The main goal of the DDAS application is to aid the user to collate Investigator and Institute related Compliance Issues into Investigator Compliance Search Forms (ICSF).

The application collects Investigator Compliance related data from various public sources. The application downloads this every 24 hours and converts it into data repositories.

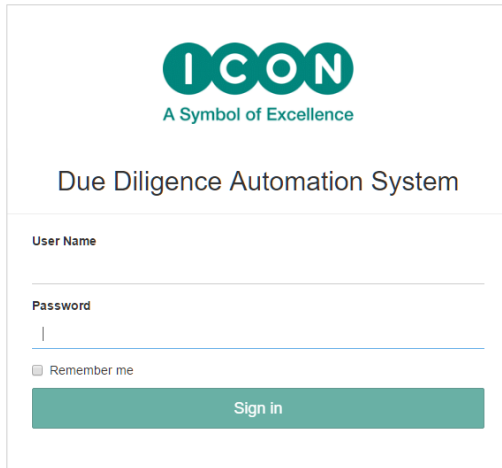
The application user inputs details such as Project Number, Name of Institute, Country, List of Investigators and their Role, Principal or Sub. The application scans through the latest version of the data repositories for suitable match of Investigator Name and presents the results to the user for recording observations.

The data is extracted from the following web sites –

1. FDA Debarment List
2. Clinical Investigator Inspection List (CLIL)(CDER)
3. FDA Warning Letters and Responses
4. Notice of Opportunity for Hearing (NOOH) – Proposal to Debar
5. Adequate Assurances List for Clinical Investigators
6. Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted)
7. Clinical Investigator Inspection List (CBER)
8. PHS Administrative Actions Listing
9. HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD
10. HHS/OIG Corporate Integrity Agreements/Watch List
11. SAM/SYSTEM FOR AWARD MANAGEMENT
12. LIST OF SPECIALLY DESIGNATED NATIONALS

Login

Navigate to DDAS via <http://> in your internet browser. Username and Password are mandatory fields for logging in.



The login form features the ICON logo at the top, followed by the title 'Due Diligence Automation System'. Below this, there are two input fields: 'User Name' and 'Password'. A 'Remember me' checkbox is located below the password field. A green 'Sign in' button is positioned at the bottom right of the form.

Forgot Password

Not implemented:

Forgotten passwords can be recovered using the 'Forgot Password' link on the login page.

Enter your username and e-mail address and click on 'Re-Generate Password' as shown below.

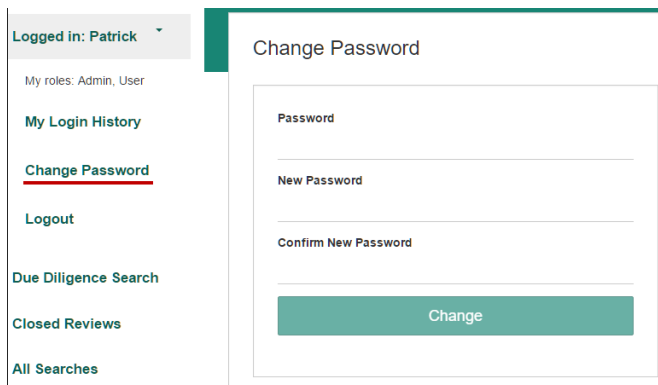
An e-mail will be sent to the user's e-mail address with the re-generated password.

In the event that the 'Re-generate password' link is not working please e-mail the DDAS Administrator mailbox: **xxxxxxxx** for assistance.

The re-generated password can be changed using the 'Change Password' link (see next section).

Change Password

The Change password link is accessible via the user menu on the top left-hand side of the screen.



The 'Change Password' form is displayed within a user menu. The menu on the left shows 'Logged in: Patrick' and a list of links: 'My roles: Admin, User', 'My Login History', 'Change Password' (highlighted with a red underline), 'Logout', 'Due Diligence Search', 'Closed Reviews', and 'All Searches'. The main form area has the title 'Change Password' and three input fields: 'Password', 'New Password', and 'Confirm New Password'. A green 'Change' button is at the bottom.

Click 'Change Password' to display this screen:

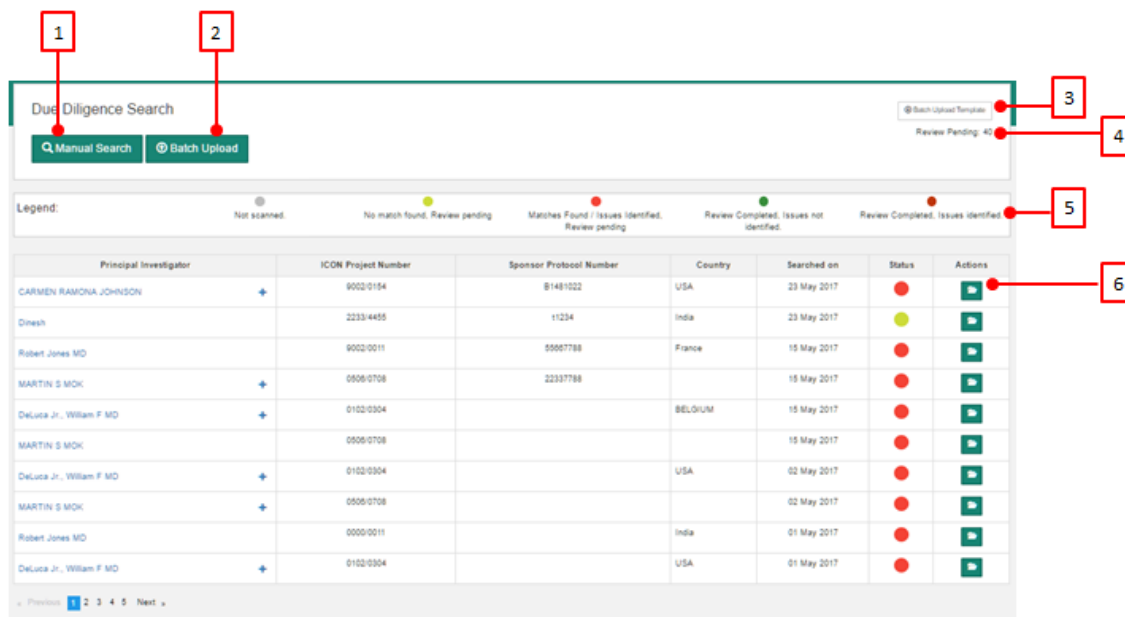
Complete all fields and click update to change the password.

Due Diligence Search

The Due Diligence Search page will be visible to the user immediately after login.

The user can carry out the following actions:

1. Create a Compliance Form and Carry out Manual Search
2. Batch Upload an excel file containing multiple data for Compliance Forms
3. Download a Compliance Form Template
4. Legend
5. Open a Compliance Form for Review



The screenshot shows the 'Due Diligence Search' interface. At the top, there are two buttons: 'Manual Search' (callout 1) and 'Batch Upload' (callout 2). To the right, there is a 'Batch Upload Template' link (callout 3) and a 'Review Pending: 40' indicator (callout 4). Below these is a legend (callout 5) with color-coded status indicators: Not scanned (grey), No match found, Review pending (yellow), Matches Found / Issues Identified, Review pending (red), Review Completed, Issues not identified (green), and Review Completed, Issues identified (dark red). The main table (callout 6) has columns: Principal Investigator, ICON Project Number, Sponsor Protocol Number, Country, Searched on, Status, and Actions. The table lists several investigators with their respective project and protocol numbers, countries, search dates, and status indicators (red, yellow, or green circles). The 'Actions' column contains icons for opening forms for review.

1. Manual Search

In this section, compliance form details are to be entered manually. Follow the below steps to create a compliance search form manually

- Fill up the details in 'General Info' tab
- Provide the investigator details in the 'Investigators' tab
- Name entered in the column 'Name to Search' will be taken up to search in the database
- Name provided under the column 'Name (for display)' will be displayed in the ICSF
- The application considers the first Investigator to be a 'Principal Investigator'
- Investigator name to be searched must have at least two components (first name, last name / last name, middle name / first name, middle name... etc)
- 'Investigator Id' and 'Member Id' will not be displayed in the ICSF. This information will only be available in the output file
- After filling up all fields, save the compliance form to carry out the search. The search is automatically carried out when the Compliance Form is saved. Repeat saving does not re-execute the search operation for the already searched Investigators, however search operation for the additional investigators will be executed.
- After the search, Status column indicates whether full/partial/no matches found for respective investigators

- Details of the search results can be viewed from 'Actions' column. Opening the investigator search results will display the 'Investigator Search Summary' screen
- Actions column also provides the functionality to move an investigator up/down. Any investigator in the first row is considered as Principal Investigator.
- Any investigator can be removed from the search

2. Batch Upload

Any number of investigator can be searched by uploading an excel template(downloading this template is covered in the next step)

- Fill up the details as per the excel file and upload into the application using 'Batch Upload' option
- Application validates the data in the file and carries to search operation in case of no errors, otherwise application will provide error details and the line number where error has occurred. User should update the file with valid data and upload again
- Application will display all the investigators uploaded from the excel template along with status of the investigators
- User can view/edit the search results from the actions column

3. Batch Upload Template

Download the template which is the only format the application accepts to perform searches on the given investigators. Template will be downloaded as 'DDAS_Upload_Template.xlsx'

4. Legend

Due Diligence Search

Manual Search
Batch Upload

Batch Upload Template

Review Pending: 2

Legend:

●

 Not scanned.

●

 No match found, Review pending

●

 Matches Found / Issues Identified, Review pending

●

 Review Completed, Issues not identified.

●

 Review Completed, Issues identified.

Principal Investigator	ICON Project Number	Sponsor Protocol Number	Country	Searched on	Status	Actions
PITISUTTIHUM Punnee	0000/0008	0102	Spain	15 Jun 2017	●	

Legend indicates the status of a compliance form/investigator. Application updates the status of a compliance form/investigator when a compliance form is created/updated.

Legend contains following statuses

- Not scanned – could not carry out the search
- No match found, Review pending – Completed search. No match found for any of the given investigators. Application marks all the sites for which data is extracted, as 'Review Completed' when there are no matches found. Additional sites are also marked as 'Review Completed', by default
- Matches Found / Issues Identified, Review pending –



- ❖ Matches Found - During search if there are any matches found (full/partial) the status is updated as 'Matches Found' for the given investigator
- ❖ Issues Identified - If user identifies any of the matches found as an issue, status of the respective investigator is updated to 'Issues Identified'
- Review Completed, Issues not identified
- Review Completed, Issues identified

5. Open Compliance Form for Edit

After the search is completed, compliance form details can be viewed or edited. Compliance form data is divided into 8 tabs, each of which are described in the next section.

Compliance Form

The information in the Compliance form is arranged in 8 tabs.

1. General Info
2. Institute
3. Investigators
 - a. Investigator Search Summary
 - i. Findings
4. Mandatory Sites
5. Additional Sites
6. Findings
7. Searched By
8. Summary

Investigator Compliance Search Form

9002/0154 - CARMEN RAMONA JOHNSON

Back

Save

Legend:

●

Not scanned.

●

No match found, Review pending

●

Matches Found / Issues Identified, Review pending

●

Review Completed, Issues not identified.

●

Review Completed, Issues identified.

General Info

Institute

Investigators (11)

Mandatory Sites (14)

Additional Sites (2)

Findings (0)

Searched By

Summary



General Info

Investigator Compliance Search Form

9002/0154 - CARMEN RAMONA JOHNSON

[Back](#) [Save](#)

Legend:	Not scanned.	No match found, Review pending	Matches Found / Issues Identified, Review pending	Review Completed, Issues not identified.	Review Completed, Issues identified.
---------	--------------	--------------------------------	---	--	--------------------------------------

[General Info](#) [Institute](#) [Investigators \(11\)](#) [Mandatory Sites \(14\)](#) [Additional Sites \(2\)](#) [Findings \(0\)](#) [Searched By](#) [Summary](#)

General Information:

ICON Project Number (1234/1234):

9002/0154

Address:

GAMBRILLS MD

Sponsor Protocol No:

B1481022

Country:

USA

[Back](#) [Save](#)

The fields are:

ICON Project Number

Format: dddd/ddd example: 1234/5678

The first 4 digits of the Project Number represent the sponsor.

Institute:

Address

Country

Institute

The Institute tab displays the Institute Name and the list of Site Sources where Search Applies to given Institute.

[General Info](#) | [Institute](#) | [Investigators \(1\)](#) | [Mandatory Sites \(14\)](#) | [Additional Sites \(7\)](#) | [Findings \(2\)](#) | [Searched By](#) | [Summary](#)

Institute

Institute:

#	Source Name	Issues Identified	Action
14	World Check for Institute	2	Findings
16	For Demo	0	Findings
20	Belgium2 - RIZIV - Zoeken	0	Findings

[Back](#) [Save](#)

Findings for Institute:
[Source: 14.World Check for Institute](#)

Findings:

Issue 1

Date of Inspection:

10 May 2017

X

[Remove](#)

Findings:

Issue 2

Date of Inspection:

11 May 2017

X

[Remove](#)

[Add A Finding](#)

[Back](#) [Save](#)

Investigators

Investigators added (with batch upload/manually using ‘Add an Investigator’ button) appear under this tab.

Investigator Compliance Search Form
9002/0154 - CARMEN RAMONA JOHNSON

Back Save

Legend:

Not scanned.
No match found. Review pending
Matches Found / Issues Identified. Review pending
Review Completed. Issues not identified.
Review Completed. Issues identified.

General Info
Institute
Investigators (5)
Mandatory Sites (14)
Additional Sites (2)
Findings (1)
Searched By
Summary

Investigators :

Name to search			Name	Med. Lic No.	Inv Id.	Member Id	Role	Status	Actions
First	Mid	Last	(for display)						
CARMEN	RAMONA	JOHNSON	CARMEN RAMONA JOHNSON	NA	SAM1		Principal		<div> <div></div> <div></div> <div></div> </div>
JANNY	JUANJUAN	LIAO	JANNY JUANJUAN LIAO	NA	SAM3		Sub		<div> <div></div> <div></div> <div></div> </div>
SHELDON	M.	SALANT	SHELDON M. SALANT	NA	SAM6		Sub		<div> <div></div> <div></div> <div></div> </div>
Yasim	Bhatkal		Yasim Bhatkal				Sub		<div> <div></div> <div></div> <div></div> </div>
WEI		PANG	WEI PANG	NA	SAM7		Sub		<div> <div></div> <div></div> <div></div> </div>

Add an Investigator

Back Save

1. Name entered in the column – Name (for display) , will be for display purpose and will be displayed in the ICSF
2. Name entered in the columns – First, Mid and Last will be taken up to search in all the sites
3. User can make any investigator a Principal Investigator/Sub Investigator by using up/down arrows. The Investigators will appear in same order in the ICSF
4. User can delete an investigator
5. User can add an investigator to search



Investigator Search Summary

This section displays all mandatory and additional sites (if any) along with full/partial/single component match counts after the search is completed.

Below are the actions user can perform on this screen -

- A Check box is provided to hide/show the sites along with the full/partial match counts.
- For a given investigator, when search does not return any matching records for a site(mandatory/additional), application marks the respective site as 'Review Completed'
- User can view all sites by unchecking the 'Hide Review Completed Sites' option
- User can add/update/remove findings which is described in the next section

Findings

Search result for an investigator includes – full/partial/single component matches along with status and Issues Identified flags.

When a match is found, application displays record details which user can add into the ‘Findings’ section.

User can also add ‘Additional Finding’ where, unlike matching records, the observation will have to be added manually without any matching record information.

Follow below steps to add a Finding -



1. Click on any of the matched record, if match is found (full/partial/single) or on ‘Review Matching Records’ button
2. Select any record and click on ‘Add to Findings’
3. Enter record details/any observation into the ‘observations’
4. ‘Date of Inspection’ is added by the application for ‘DB’ sites. User will have to add the Date of Inspection manually in case of additional/manual sites
5. ‘Is an Issue’ is checked by default, which indicates that the selected record is a positive match for the given search name. User can uncheck this option
6. To complete review for a site, User has to check the ‘Review completed’ option which indicates that the matched records (if any) have been checked
7. User can mark a site as ‘Review Completed’ by not identifying any issues, even when the application displays matched records. It is the user who decides whether a record can be added as an issue
8. In case of no matches found – user can add ‘Additional Findings’. User can provide observations, identify it as an issue and mark the site as ‘Review Completed’

Mandatory Sites

This section displays the sites that are part of the search by default. These sites cannot be modified.

General Info
Institute
Investigators (1)
Mandatory Sites (14)
Additional Sites (7)
Findings (5)
Searched By
Summary

Mandatory Sites participating in the search:

#	Source Name	Extraction Mode	Source Date	Applies To	Issues Identified
1	FDA Debarment List	DB	27 Feb 2017	PIs SIs	Yes
2	Clinical Investigator Inspection List (CLIL)(CDER)	DB	20 Mar 2017	PIs SIs	No
3	FDA Warning Letters and Responses	DB	09 May 2017	PIs SIs	No
4	Notice of Opportunity for Hearing - Proposal to Debar	DB	29 Nov 2016	PIs SIs	Yes
10	HHS / OIG Corporate Integrity Agreements / Watch List	DB	08 May 2017	PIs SIs	No
11	SAM System for Award Management	DB	12 May 2017	PIs SIs	No
12	List of Specially Designated Nationals	DB	11 May 2017	PIs SIs	No
13	World Check for PIs	Manual	<input type="text"/> 	PIs	No
14	World Check for Institute	Manual	<input type="text"/> 	Institute	Yes

Back
Save






Additional Sites

As a part of the search, In addition to mandatory sites, additional sites can also be added.

Note: (Applies to Mandatory and Additional Site)

Source Date is automatically generated for sites applicable to PIs and SIs and whose extraction mode is 'DB' .
For other sites, the Source Date is recorded by the user.

Additional Sites participating in the search:

#	Source Name	Source Date	Applies To	Issues Identified	Remove
16	Test Site Name	<input type="text"/> 	Pls SIs	No	
17	Adequate Assurances List for Clinical Investigators	<input type="text"/> 	Institute	No	
18	Adequate Assurances List for Clinical Investigators	27 Feb 2017	Pls	No	

Add

General Info	Institute	Investigators (1)	Mandatory Sites (14)	Additional Sites (7)	Findings (5)	Searched By	Summary
Findings (Issues identified):							
Investigator / Institute	Source #	Date of Inspection / Action	Description of Findings				
Indian Institute of Science	14	11 May 2017	Issue 2				
Indian Institute of Science	14	10 May 2017	Issue 1				
MARTIN S MOK	1	06 Mar 2013	Effective Date: 03/06/2013 End/Term Of Debarment: Permanent^ FR Date.txt: 03/06/2013				
MARTIN S MOK	4	06 Nov 2012	Date: 11/06/12 Issuing Office: Office of Regulatory Affairs				
MARTIN S MOK	18	06 Mar 2013	Effective Date: 03/06/2013 End/Term Of Debarment: Permanent^ FR Date.txt: 03/06/2013				

Searched By

This section displays the name of the user performing the search and the date search started on.

Investigator Compliance Search Form

0597/0092 - Khozema Palanpurwala

Back

Save

General Info

Investigators (1)

Mandatory Sites (13)

Additional Sites (0)

Findings (1)

Searched By

Summary

Search Performed By:

Searched By:

Nimisha

Searched On:

04 Apr 2017

Back

Save



Summary

This section displays summary of the compliance form added by any user.

Following details are displayed –

1. Name of the file uploaded by the user (Uploaded File can be downloaded, for reference)
2. Name of investigator
3. Search started on date and Review completed on for each investigator

Configurations

Site Sources

The Site Sources section displays all the sites available for use with Compliance Forms. The list contains 12 pre-defined Site Sources. The extraction mode for these sites is 'DB'. These records cannot be removed or modified.

Additional sites can be added to the Site Source list. The extraction mode for additional sites is automatically marked as 'Manual'

The screenshot shows the 'Site Sources' interface. At the top, there is a 'Filters:' section with a 'Url contains:' text box. Below this is a table with columns: Site Name, Short Name, Url, Extraction Mode, and Actions. The table lists five pre-defined sites, all with 'DB' extraction mode. Below the table is an 'Add' button. At the bottom, there is a pagination control showing 'Previous', '1', '2', '3', '4', and 'Next'.

Numbered callouts in the image:

- 1: Points to the 'Url contains:' filter text box.
- 2: Points to the 'Edit Record' icon (pencil) in the Actions column for the 'AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY' row.
- 3: Points to the 'Remove Record' icon (trash can) in the Actions column for the 'Colombia - EL TRIBUNAL NACIONAL DE ÉTICA MÉDICA' row.
- 4: Points to the 'Add' button below the table.

Site Name	Short Name	Url	Extraction Mode	Actions
Adequate Assurances List for Clinical Investigators	Adequate Assurances List ...	http://www.fda.gov/ora/compliance_ref/bimo/asurits	DB	[Edit]
AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY	HEALTH PRACTITIONER ...	http://www.ahpra.gov.au/Registration/Registers-of-	Manual	[Edit] [Remove]
Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted)	Disqualification Proceedings ...	http://www.accessdata.fda.gov/scripts/SDA/sdNaviga	DB	[Edit]
Colombia - EL TRIBUNAL NACIONAL DE ÉTICA MÉDICA	EL TRIBUNAL NACIONAL ...	http://www.tribunalnacionaldeeetamedica.org/site/	Manual	[Edit] [Remove]
FDA Debarment List	FDA Debarment List	http://www.fda.gov/ora/compliance_ref/debar/default	DB	[Edit]

1. Filters - 'Url contains' Filters records matching the text in the Url contains text box.
2. Edit Record - Applies to Manual sites. DB Sites cannot be edited.
3. Remove Record - Applies to Manual sites. DB Sites cannot be removed.
4. Add a new Site Source with the following values:
 - a. Site Name
 - b. Short Name
 - c. URL
 - d. Extraction Mode: Manual

Default Sites

The application maintains a list of Default Sites. The Site Sources listed under this section are added to the compliance form when the form is created.

The fields in the Default Site are:

1. Site Url: Selected from the list of Site Sources. Site Sources are managed in the Site Source section.
2. Order No: Defines the order in which the Site Sources have to appear in the Compliance Form.
3. Name: By default, the Site Name provided by the Site Source is applied. This can be modified.
4. Search Applies To options are:
 - a. Principal Investigator and Sub Investigator
 - b. Principal Investigator
 - c. Institute
5. Mandatory, Yes / No. Mandatory Site Sources are listed under the Mandatory section of the Compliance Form. Not Mandatory Site Sources are listed in the 'Additional Sites to Search' section of the Compliance form.
6. Extraction Mode: not editable. The Extraction Mode defined in the Site Source section is applied except in the case where the Search Applies To is Insitute. The Default Site Extraction Mode is marked as 'Manual' for all records that have 'Additional Sites To Search' as Institute.



Country Specific Site Sources

When a Compliance Form is created, the application will add applicable additional Site Sources as defined in this section.

The application matches the value in the Country field of Compliance Form inputs to the list of corresponding sites in the Country Specific Sites List and adds these sites to the Compliance Form.

Note: This functionality is available only when the Compliance Form is created through the Batch Upload mode.

Sponsor Specific Site Sources

When a Compliance Form is created, the application will add applicable additional Site Sources related to a Sponsor.

The application matches the first four digits in the Project Number field of Compliance Form inputs to the list of corresponding sites in the Sponsor Specific Site Sources and adds these sites to the Compliance Form.

Note: This functionality is available only when the Compliance Form is created through the Batch Upload mode.

Data Structures

Compliance Form Data Structure

Compliance Form

--Project Number, Sponsor Protocol Number, Institute, Address
 --Investigators
 |----Sites Searched
 --Site Sources
 --Findings

*UI = User input, AG = Application Generated









Field Name	Data Type	Size	*UI / AG	Validations	Comments
Project Number	text	9	UI	Required, dddd/ddd (1234/1234)	
SponsorProtocolNumber	text	100	UI	none	
Institute	text	100	UI	none	
Address	text	500	UI	none	
Country	text	100	UI	none	
AssignedTo	text	-	AG	none	
SearchStartedOn	date	-	AG	none	
UploadedFileName	text	-	AG	none	
ExtractedOn	date	-	AG	none	
FullMatchesFoundInvestigatorCount	number	-	AG	none	
PartialMatchesFoundInvestigatorCount	number	-	AG	none	
SingleMatchFoundInvestigatorCount	number	-	AG	none	
IssuesFoundInvestigatorCount	number	-	AG	none	
ReviewCompletedInvestigatorCount	number	-	AG	none	
Investigators	Collection	Min: 1, Max: no limit	UI	none	
Field Name	Data Type	Size	UI/AG	Validations	Comments
Name	text	100	UI	Required	
First Name	text	25	UI	Any two fields First, Middle or Last are required	
Middle Name	text	25	UI		
Last Name	text	25	UI		
Role	text	50	AG	Values: Principal / Sub	
Qualification	text	50	UI	none	
Medical License Number	text	50	UI	none	
InvestigatorId	text	50	UI	none	
MemberId	text	50	UI	none	
Sites_FullMatchCount	number	-	AG	none	
Sites_PartialMatchCount	number	-	AG	none	
Sites_SingleMatchCount	number	-	AG	none	
IssuesFoundSiteCount	number	-	AG	none	
ReviewCompletedSiteCount	number	-	AG	none	
Sites Searched	Collection		AG	none	
Field Name	Data Type	Size	UI/AG	Validations	Comments
Site Id	text	128	AG		

FullMatchCount	number	-	AG		
PartialMatchCount	number	-	AG		
SingleMatchCount	number	-	AG		
IssuesFound	number	-	AG		
ExtractionMode	Text, value: 'Manual', 'DB'	-	AG		
Site Sources		Collection	-	AG	-
Field Name	Data Type	Size	UI/AG	Validations	Comments
Display Position	number		AG		
SiteName	text		AG		
SiteUrl	text		AG		
Extraction Mode	text		AG		
SiteSourceUpdatedOn	number		AG		
SearchAppliesTo	number		AG		
IssuesIdentified	number		AG		
Findings		Collection	Min: 0, Max: no upper limit	AG	
Field Name	Data Type	Size	UI/AG	Validations	Comments
SiteId	text	128	AG		
Investigator Name	text		AG		
IsMatchedRecord	Yes/No		AG		
RecordDetails	text		AG		
Observation	text		AG		
IsAnIssue	Yes/No		AG		
Links	Collection		AG		

Closed Reviews

When a user marks all sites, mandatory and additional (if any), as 'Review Completed', the compliance form is moved under 'Closed Reviews' tab.

Closed Reviews

Legend:						
		Not scanned.		No match found, Review pending		Matches Found / Issues Identified, Review pending
		Review Completed, Issues not identified.		Review Completed, Issues identified.		
Principal Investigator	ICON Project Number	Sponsor Protocol Number	Country	Searched on	Status	Actions
Bansal, Padam C. MD	0102/0304	0102	Spain	15 May 2017		 

1. Compliance form can be downloaded
2. Open any compliance form to edit/modify

Manage Reassignments

All compliance forms, Review Pending/Review Completed, appear under this tab.

Below are the actions user can carry out in this section -

1. Compliance form can be assigned to any user
2. Compliance form can either be closed/opened for edit