



# **Due Diligence Automation System User Manual**

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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).

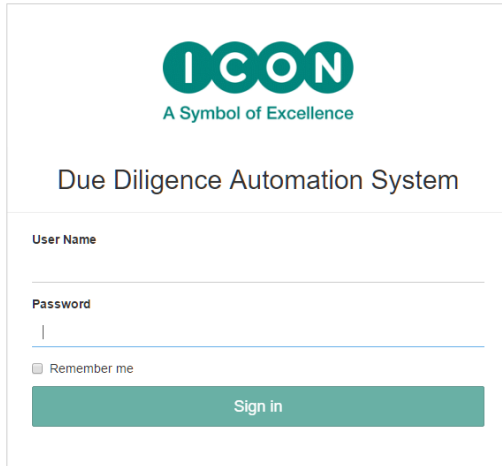
The application collects Investigator Compliance related data from various public sources. The application downloads this every 24 hours and converts it into data repositories.

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.

## Login

Navigate to DDAS via <http://ddas.claritytechnologies.com/> 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 input fields for 'User Name' and 'Password'. A 'Remember me' checkbox is located below the password field. A green 'Sign in' button is positioned at the bottom 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.

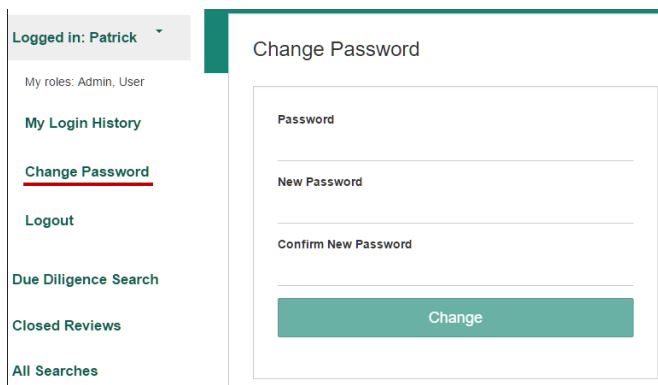
An e-mail will be sent to the user's e-mail address with the re-generated password.

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 the user is logged in as 'Patrick' and lists various options, with 'Change Password' highlighted. The main form area contains three input fields: 'Password', 'New Password', and 'Confirm New Password'. A green 'Change' button is located at the bottom of the form.

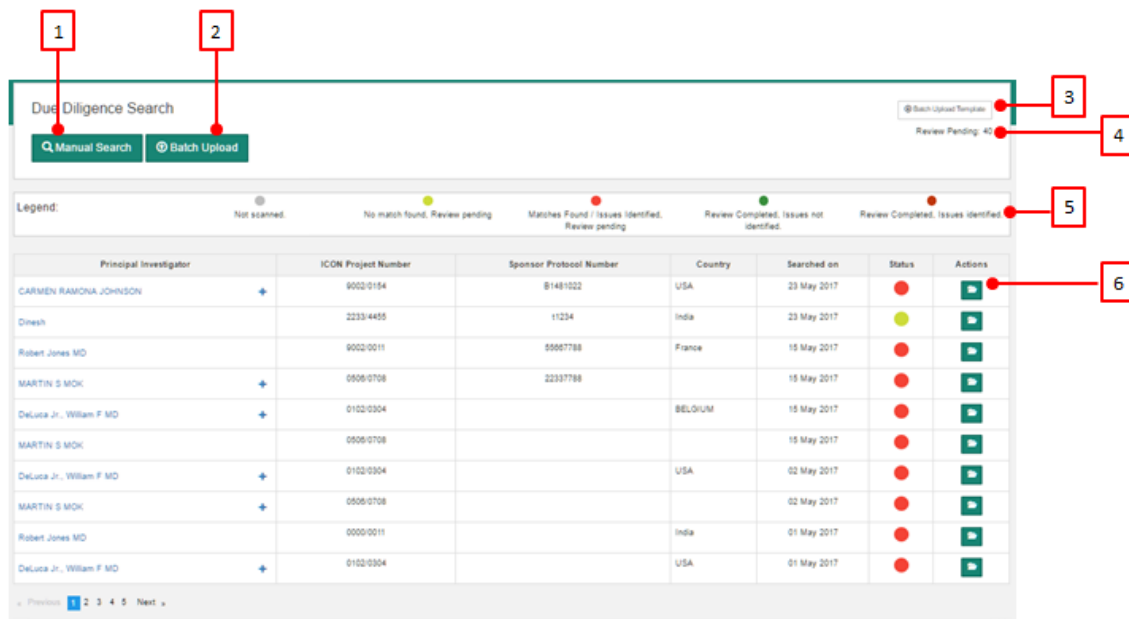
Click 'Change Password' to display this screen:

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.

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



The screenshot shows the 'Due Diligence Search' page. 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 five status categories: 'Not scanned' (grey circle), 'No match found, Review pending' (yellow circle), 'Matches Found / Issues Identified, Review pending' (red circle), 'Review Completed, Issues not identified' (green circle), and 'Review Completed, Issues Identified' (red circle). 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 entries with their respective details and status indicators (red or yellow dots). At the bottom, there is a pagination bar showing 'Previous', '1', '2', '3', '4', '5', 'Next'.

1. Manual Search
2. Batch Upload
3. Batch Upload Template
4. Pending for Review
5. Legend
6. Open Compliance Form for edit
7. Status of Compliance Form
8. Extraction Pending

## Compliance Form

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

1. General Info
2. Institute Findings
3. Investigators
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

Click on the Save button to save the Compliance Form. A search of all DB sites is carried out automatically for entries matching the given Investigator Name.



## General Info

### Investigator Compliance Search Form

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[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
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#### 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	<a href="#">Findings</a>
16	For Demo	0	<a href="#">Findings</a>
20	Belgium2 - RIZIV - Zoeken	0	<a href="#">Findings</a>

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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	Bhatkai		Yasim Bhatkai				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 across all the sites
3. User can make any investigator a PI/SI by using up/down arrows. The Investigators will appear in the same order in ICSF
4. User can delete an investigator
5. User can add an investigator to search, anytime



## 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.

By default, the page displays sites with the status 'Review Pending'.

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

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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	<a href="#">Adequate Assurances List for Clinical Investigators</a>	<input type="text"/> 	Institute	No	
18	<a href="#">Adequate Assurances List for Clinical Investigators</a>	27 Feb 2017	Pls	No	

Add

## Findings

This tab displays all the findings added for each investigator and Institute findings as well (if any)

The findings are listed in the following order:

1. Institute in ascending order,
2. And then by Source # in ascending order,
3. And then by Date of Inspection in descending order
4. And then by Investigator in the same order as the record appears on the Compliance Form,
5. And then by Source # in ascending order
6. And then by Date of Inspection in descending order.

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				

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[Save](#)

## 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

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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

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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

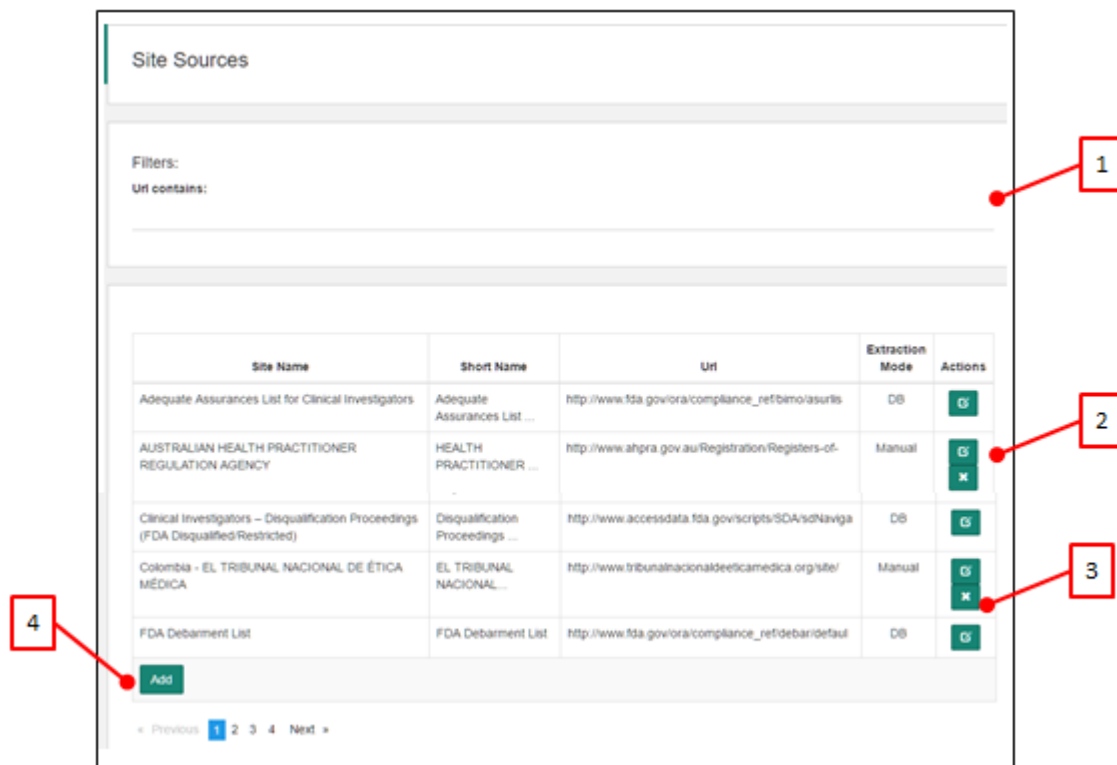


## Configurations








### 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' configuration page. It includes a filter section at the top, a table of site sources, and an 'Add' button at the bottom. Red callouts with numbers 1 through 4 point to specific features: 1 points to the 'Filters' section, 2 points to the 'Edit Record' icon (pencil), 3 points to the 'Remove Record' icon (trash), and 4 points to the 'Add' button.

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/asurils	DB	
AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY	HEALTH PRACTITIONER ...	http://www.ahpra.gov.au/Registration/Registers-of-	Manual	 
Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted)	Disqualification Proceedings ...	http://www.accessdata.fda.gov/scripts/SDA/sdNava	DB	
Colombia - EL TRIBUNAL NACIONAL DE ÉTICA MÉDICA	EL TRIBUNAL NACIONAL...	http://www.tribunalnacionaldeeticamedica.org/site/	Manual	 
FDA Debarment List	FDA Debarment List	http://www.fda.gov/ora/compliance_ref/debar/default	DB	

At the bottom of the table is an 'Add' button. Below the table is a pagination control: < Previous 1 2 3 4 Next >

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. PI SI
  - b. PI
  - 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 Institute. 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 Licese 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.

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