



## Mandatory Sites

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

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"/> 	PIs 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	PIs	No	

Add

## Findings

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
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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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## 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 text box labeled 'Url contains:'. Below this is a table with columns: Site Name, Short Name, Url, Extraction Mode, and Actions. The table lists five sites: 'Adequate Assurances List for Clinical Investigators' (DB), 'AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY' (Manual), 'Clinical Investigators - Disqualification Proceedings (FDA Disqualified/Restricted)' (DB), 'Colombia - EL TRIBUNAL NACIONAL DE ÉTICA MÉDICA' (Manual), and 'FDA Debarment List' (DB). Each row has an 'Actions' column with icons for edit and delete. A red box with the number '1' points to the filter text box. A red box with the number '2' points to the edit icon for the 'AUSTRALIAN HEALTH PRACTITIONER REGULATION AGENCY' row. A red box with the number '3' points to the delete icon for the 'Colombia - EL TRIBUNAL NACIONAL DE ÉTICA MÉDICA' row. A red box with the number '4' points to the 'Add' button at the bottom left of the table. A pagination bar at the bottom shows 'Previous 1 2 3 4 Next'.

Site Name	Short Name	Url	Extraction Mode	Actions
Adequate Assurances List for Clinical Investigators	Adequate Assurances List ...	http://www.fda.gov/oc/compliance_ref/bmo/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/CDER/rdNavi	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/oc/compliance_ref/debardefault	DB	

[Add](#)

« 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 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 Insititute. 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.