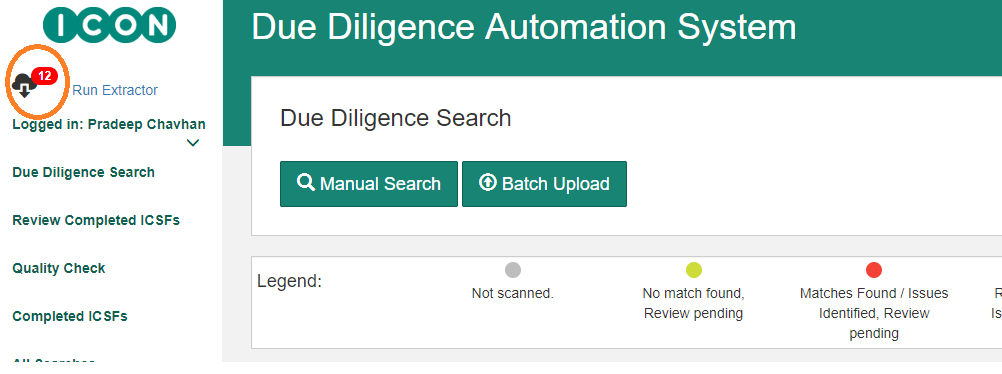
DDAS Troubleshoot Guide

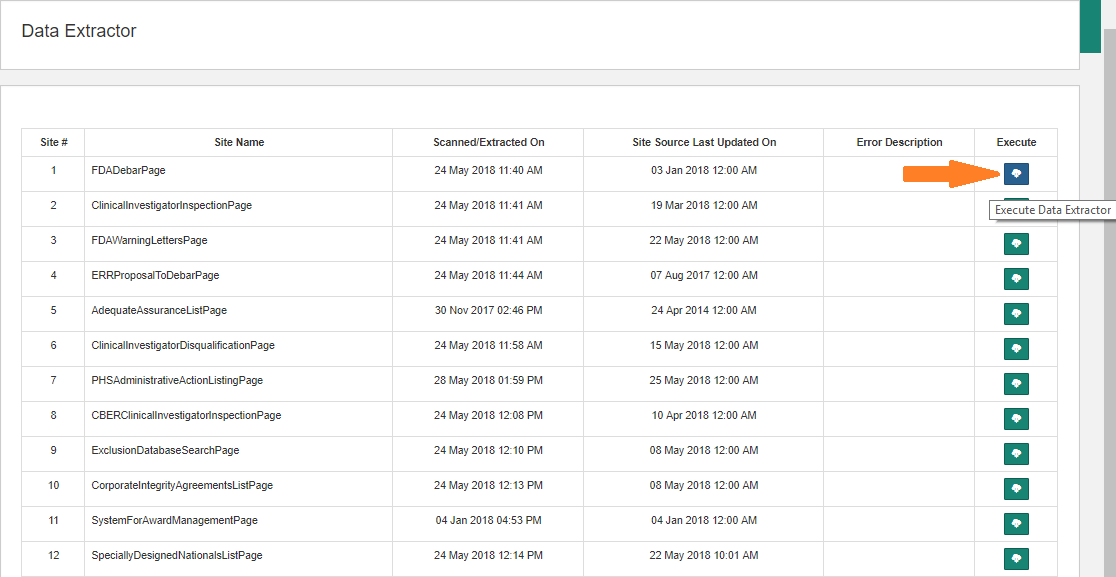
## Data Extraction Error:

DDAS application downloads/extracts data from 11 FDA sites every day. The download status of these websites provided in the application is shown below.

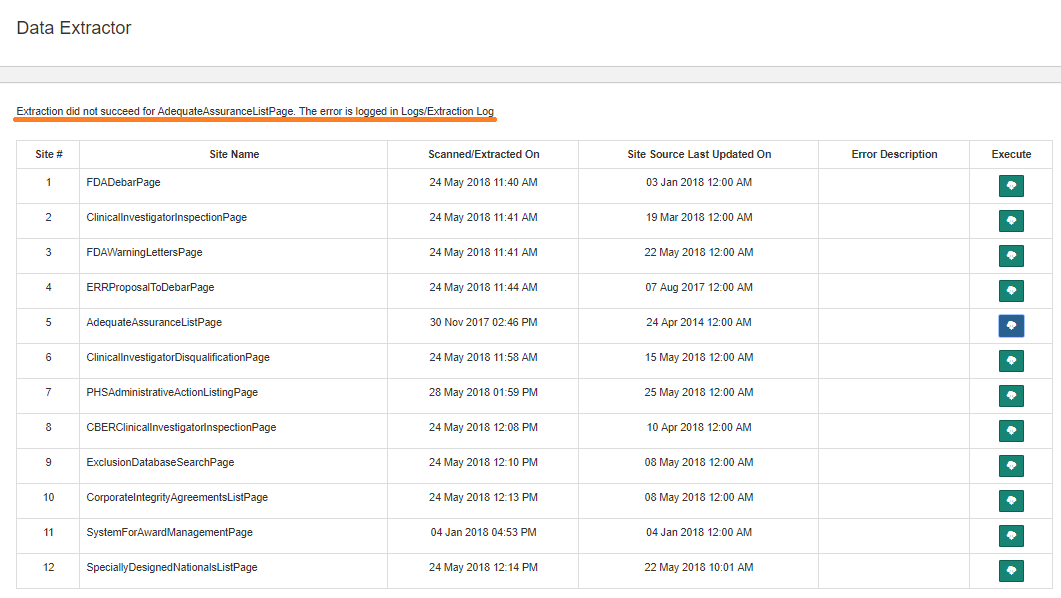
**Extractor Indicator**



**Data Extractor**



* As indicated in the above screenshot – **Extractor Indicator**, the number of sites for which the data has not been extracted is shown in red colour
* ‘**Run Extractor**’ link nextto the **Extractor Indicator** appears only for admin. This link will navigate to ‘**Data Extractor**’ page as per the above screenshot ‘**Data Extractor**’
* As indicated in ‘**Run Extractor**’ page, data can be extracted for any site. In case of success, the message is shown as below
* The extraction message in case of failure is shown as below



* If extraction fails, navigate to the site (refer **Annexture-1**) and check whether the site is accessible.

# Annexure:

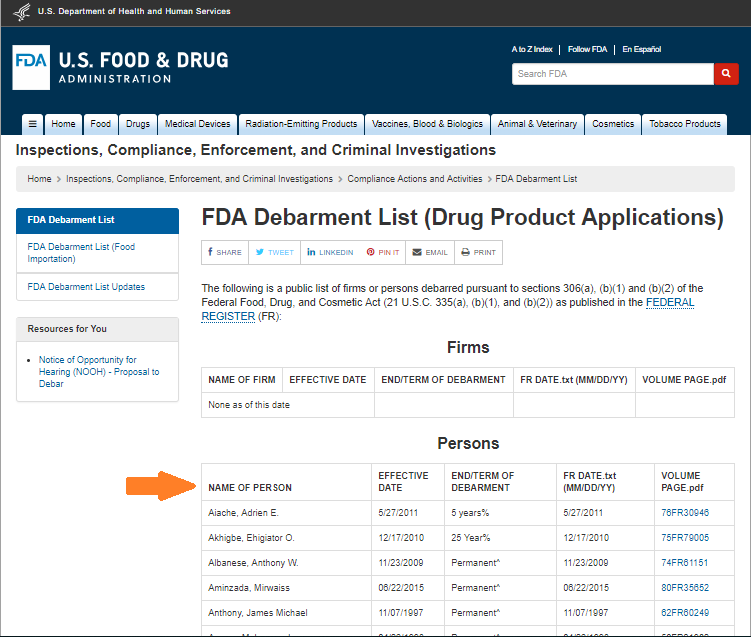
Below are the active links for the sites for which data extraction is carried out

|  |  |  |
| --- | --- | --- |
| **Serial Number** | **Site Name** | **Site Url** |
| 1 | FDA Debarment List | <http://www.fda.gov/ora/compliance_ref/debar/default.htm> |
| 2 | Clinical Investigator Inspection List (CLIL)(CDER) | <https://www.fda.gov/Drugs/InformationOnDrugs/ucm135198.htm> |
| 3 | FDA Warning Letters and Responses | <https://www.accessdata.fda.gov/scripts/warningletters/wlSearchResultExcel.cfm?qryStr>= |
| 4 | Notice of Opportunity for Hearing (NOOH) – Proposal to Debar | <http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadingRoom/ucm143240.htm> |
| 5 | Adequate Assurances List for Clinical Investigators | <http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm> |
| 6 | Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted) | <http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?sd=clinicalinvestigatorsdisqualificationproceedings&previewMode=true&displayAll=true> |
| 7 | Clinical Investigator Inspection List (CBER) | <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ComplianceActivities/ucm195364.htm> |
| 8 | PHS Administrative Actions Listing | <https://ori.hhs.gov/ORI_PHS_alert.html?d=update> |
| 9 | HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD | <https://oig.hhs.gov/exclusions/exclusions_list.asp> |
| 10 | HHS/OIG Corporate Integrity Agreements/Watch List | <http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp> |
| 11 | SAM/SYSTEM FOR AWARD MANAGEMENT | <https://www.sam.gov/portal/public/SAM> |
| 12 | LIST OF SPECIALLY DESIGNATED NATIONALS | <http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx> |

## 1. FDA Debarment List

Data File Downloaded: No

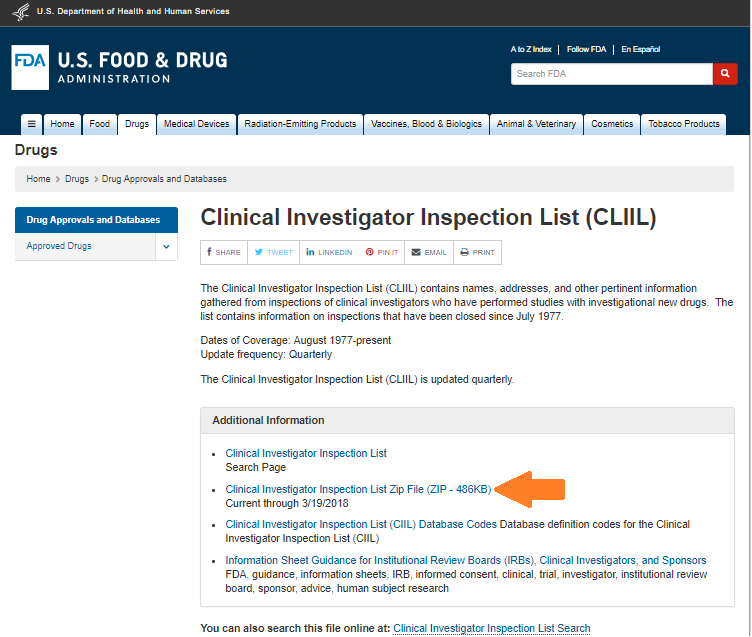
Contents in the table indicated below are extracted and saved into database



## 2. Clinical Investigator Inspection List (CLIL)(CDER)

Data File Downloaded: Yes

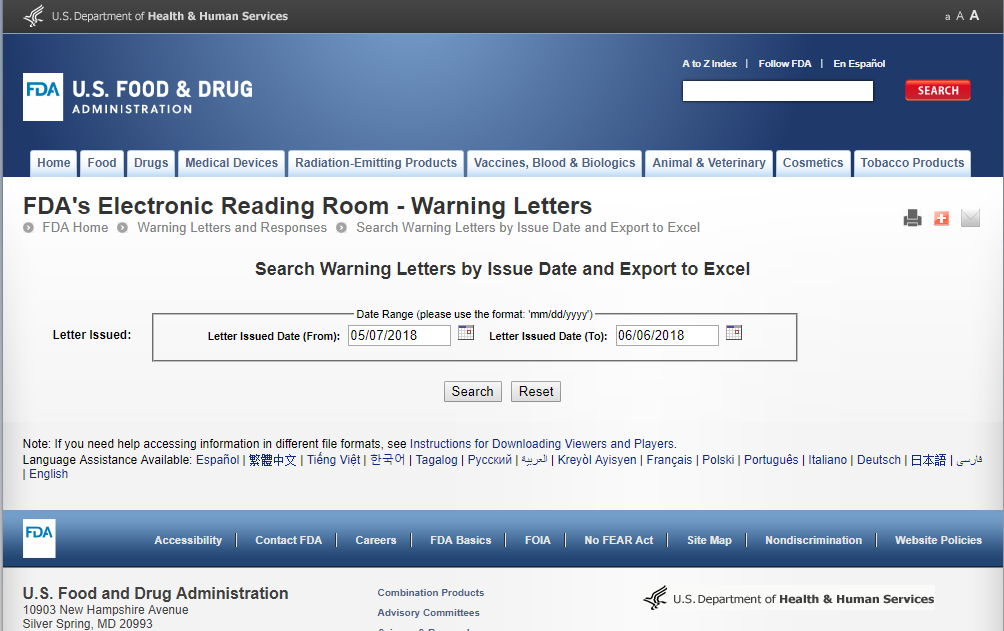
Data file is downloaded from the link indicated below and the data is saved into database



## 3. FDA Warning Letters and Responses

Data File Downloaded: Yes

The given link directly downloads the file. Data is then saved into database



## 4. Notice of Opportunity for Hearing (NOOH) – Proposal to Debar

Data File Downloaded: No

Contents in the table indicated below are extracted and saved into database



## 5. Adequate Assurances List for Clinical Investigators

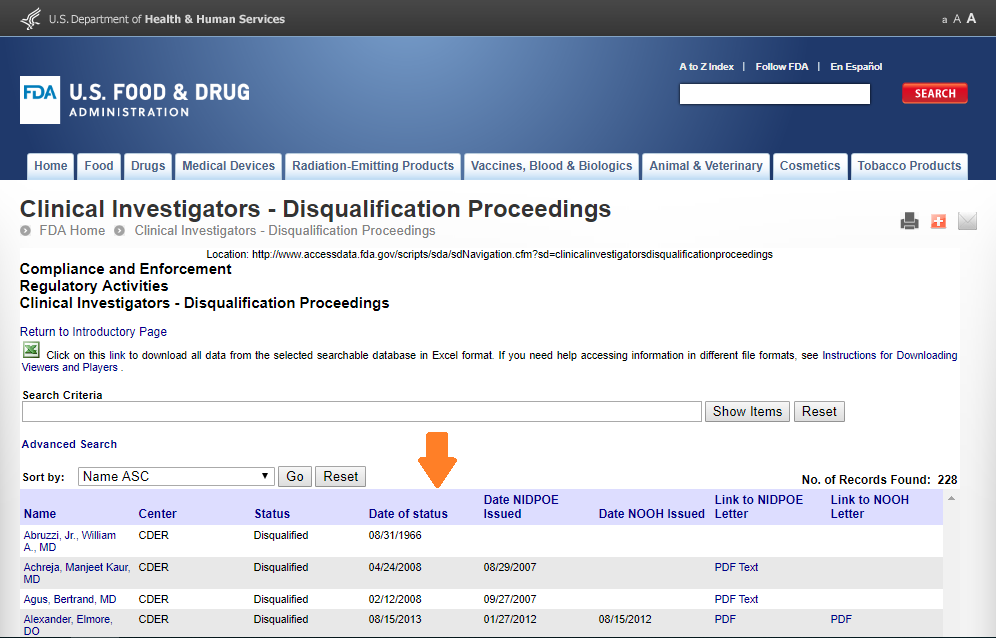
Data File Downloaded: No

Currently this site is down

## 6. Clinical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted)

Data File Downloaded: No

Contents in the table indicated below are extracted and saved into database

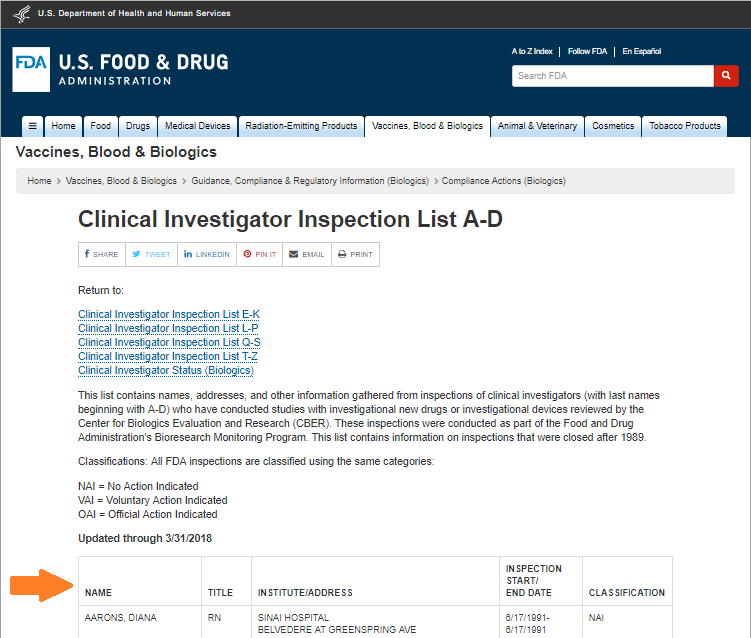


## 7. Clinical Investigator Inspection List (CBER)

Data File Downloaded: No

Contents in the table indicated below are extracted and saved into database

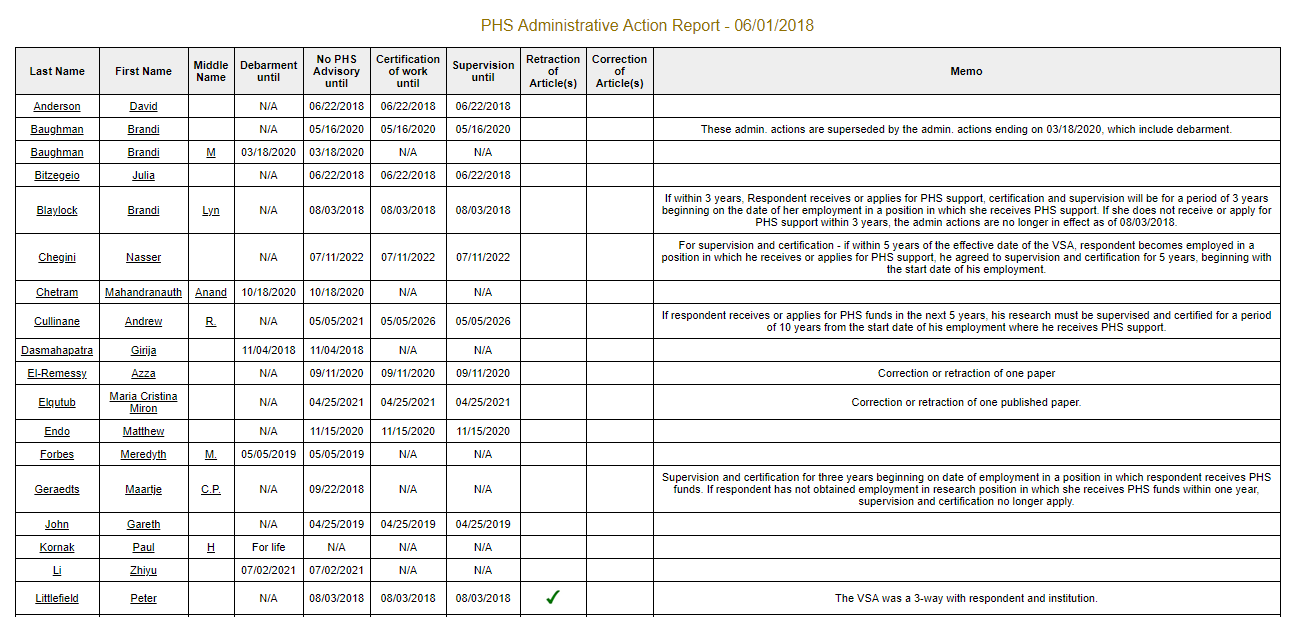
Data is extracted for all the lists: A-D, E-K, L-P, Q-S and T-Z



## 8. PHS Administrative Actions Listing

Data File Downloaded: No

Contents in the table below are extracted and saved into database



## 9. HHS/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD

Data File Downloaded: Yes

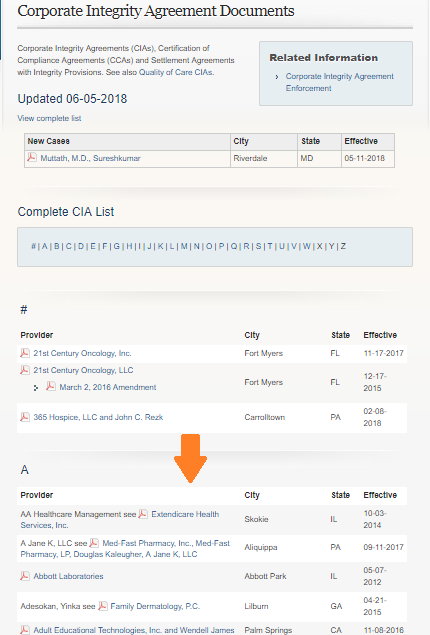
Data file is downloaded from the link indicated below and the data is saved into database



## 10. HHS/OIG Corporate Integrity Agreements/Watch List

Data File Downloaded: No

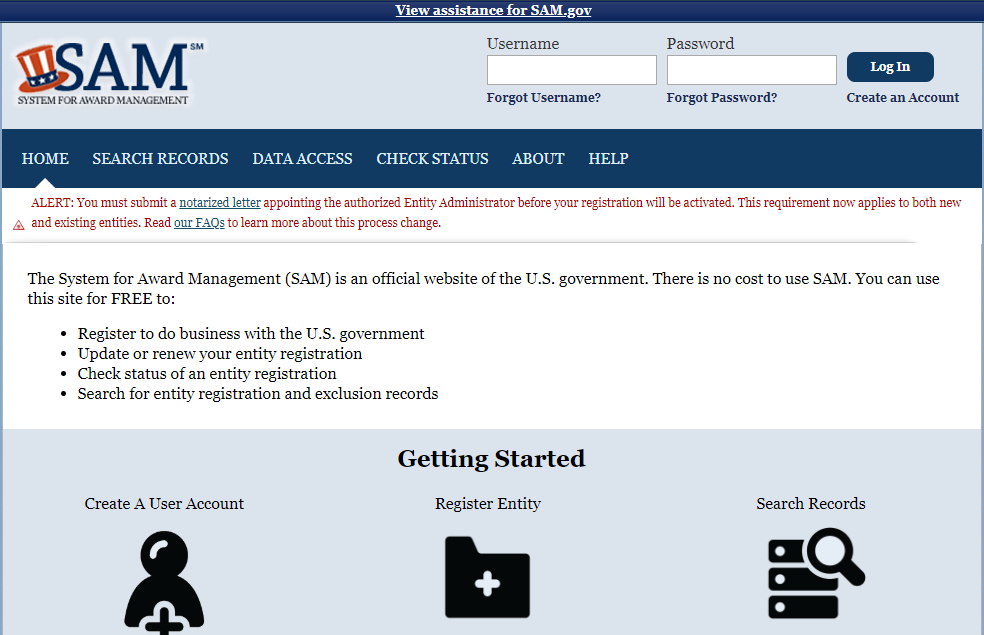
Contents in the table indicated below are extracted and saved into database (From A to Z)



## 11. SAM/SYSTEM FOR AWARD MANAGEMENT

Data File Downloaded: Yes

Below is the Home Page



Navigate to the ‘DATA ACCESS’ page. At the bottom of the page, ‘Exclusion Extract Data Package’ table is displayed, as shown below. This table contains past 7 days files of exclusion extract lists. Download the last file to get the most recent exclusion extract data as shown below



## 12. LIST OF SPECIALLY DESIGNATED NATIONALS

Data File Downloaded: Yes

Data file is downloaded from the link indicated below and the data is saved into database

