

Due Diligence Automation System Troubleshooting Guide

Revision 2 21-June-2018

Developed by: Clarity Information Technologies Pvt. Ltd. Bangalore.

> Tele: 080 - 2529 1698 Email: mail@claritytechnologies.com



Table of Contents

Re	evisio	on History	.3
In	trodu	uction	.3
1	Аp	plication Environment	.4
	1.1	Application Architecture	4
	1.2	Application Servers	5
	1.3	Database Servers	5
	1.4	System Functions and or Services	E
	1.5	Backups/Restores	E
2	Su	pport Procedures	
	2.1	Common Problems/Troubleshooting	6
	Data	Extraction Error:	7
Αı	nnex	ure:	.9
	1. FD	A Debarment List	10
	2. Clir	nical Investigator Inspection List (CLIL)(CDER)	11
	3. FD	A Warning Letters and Responses	11
	4. No	tice of Opportunity for Hearing (NOOH) – Proposal to Debar	12
	5. Ad	equate Assurances List for Clinical Investigators	13
	6. Clir	nical Investigators – Disqualification Proceedings (FDA Disqualified/Restricted)	13
	7. Clir	nical Investigator Inspection List (CBER)	14
	8. PH	S Administrative Actions Listing	14
	9. HH	S/OIG/ EXCLUSIONS DATABASE SEARCH/ FRAUD	14
	10. H	HS/OIG Corporate Integrity Agreements/Watch List	15
		AM/SYSTEM FOR AWARD MANAGEMENT	
	12. LI	ST OF SPECIALLY DESIGNATED NATIONALS	17

1

¹ Test Foot Note



Revision History

Date	Version	Section	Description	Author
19-June-2018	1.0	All	Initial	Pradeep / Johnly
21-June-2018	2.0	Application Architecture	Updated	Pradeep / Johnly
21-June-2018	2.0	Header	ICON Logo – replaced.	

Introduction

DDAS is a Web Application and can be accessed through: http://ddas.iconplc.com and http://ddastest.iconplc.com

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

The application collects Investigator Compliance related data from various pubic 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, Prinicpal or Sub. The application scans through the latest version of the data repositories for suitable match of Invesigator Name and presents the results to the user for recording observations.

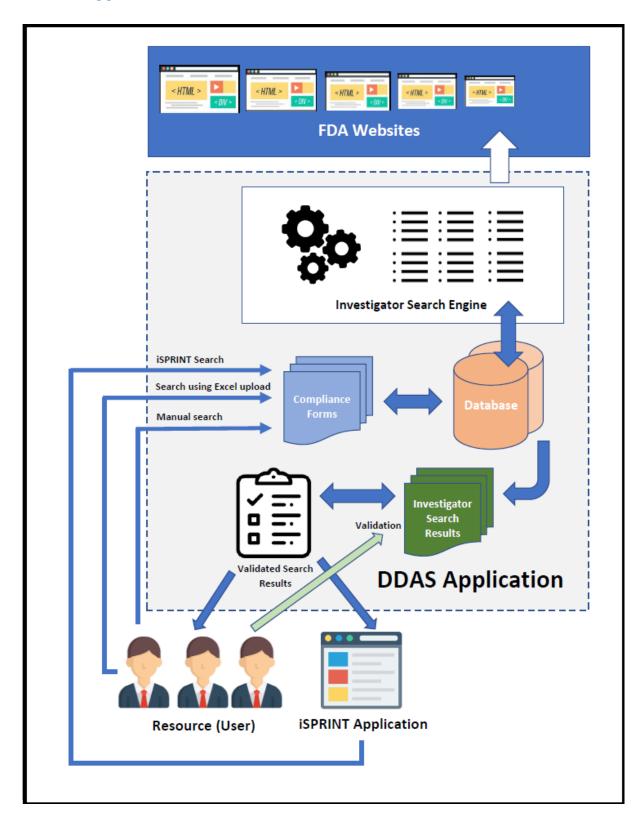
The data is extracted from the following web sites -

- 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



1 Application Environment

1.1 Application Architecture





Application Servers

Web Servers

Function	IP Address	Server Name	Physical Location	Software	Version
Prod	10.11.103.145				
Test	10.11.103.149				

Folder Structure

Path	Notes
\DataFiles\Attachments	Files attached while requesting QC are
	saved in this folder
\DataFiles\Downloads\CIILFolder	Files extracted for CIIL source are saved
\DataFiles\Downloads\ExclusionDatabase	Files extracted for Exclusion database
	source are saved
\DataFiles\Downloads\FDAWarningLetters	Files extracted for FDA Warning Letters
	source are saved
\DataFiles\Downloads\SAM	Files extracted for SAM source are saved
\DataFiles\Downloads\SDN	Files extracted for SDN source are saved
\DataFiles\Downloads\ErrorScreenCapture	Errors occurred during data extraction
	process are saved
\DataFiles\Downloads\OutputFileFolder	Output files generated by the application
	are saved
\DataFiles\Downloads\Templates	Templates used in the application are
	saved (Input, Output template and user
	manual)
\DataFiles\Downloads\Uploads	Compliance forms uploaded using input
	excel template are saved

1.2 Database Servers

Database Servers

Function	IP Address	Server	Physical	Software	Version
		Name	Location		
Prod	10.11.103.154	eu-duedilp-	-		
		d001			
Test	10.11.103.156	eu-duedilt-	-		
		d001			
Dev	10.11.103.156	eu-duedilt-	-		
		d001			

Database Instances

Function	Server	Instance	Notes
Prod	eu-duedilp-d001	ddasprod	
Test	eu-duedilt-d001	ddastest	
Dev	eu-duedilt-d001	ddasdevp	



1.3 System Functions and or Services

Batch Schedulers

Type: Scheduled Task

File Path: bin\DDASDataExtractor.exe

Frequency: Scheduled to run at 1 am everyday

Description: The scheduled task extracts data from the data sources (refer to

Annexure), downloads files and saves data into the database

1.4 Backups/Restores

Handled by ICON IT

2 Support Procedures

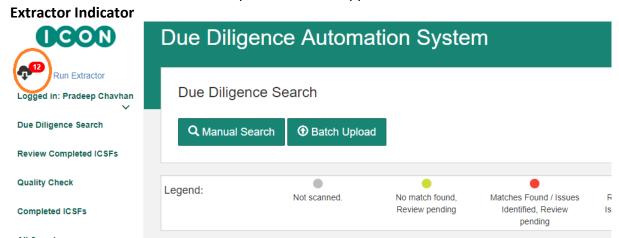
2.1 Common Problems/Troubleshooting

Data Extraction Errors

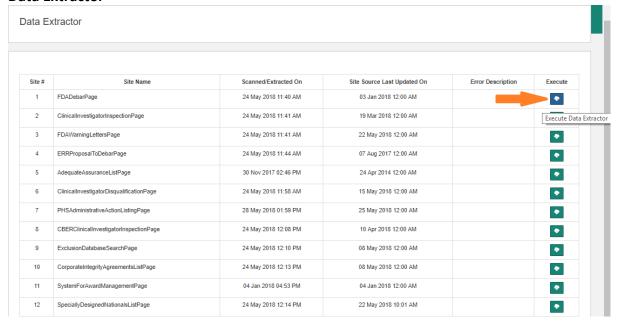


Data Extraction Error:

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



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 next to 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

(On successful data extraction)



Data Extractor

Extraction successful for ERRProposalToDebarPage

Site #	Site Name	Scanned/Extracted On	Site Source Last Updated On	Error Description	Execute
1	FDADebarPage	01 Jun 2018 12:05 PM	03 Jan 2018 12:00 AM		•
2	ClinicalInvestigatorInspectionPage	24 May 2018 11:41 AM	19 Mar 2018 12:00 AM		•
3	FDAWarningLettersPage	24 May 2018 11:41 AM	22 May 2018 12:00 AM		•
4	ERRProposalToDebarPage	18 Jun 2018 05:40 PM	07 Aug 2017 12:00 AM		•
5	AdequateAssuranceListPage	30 Nov 2017 02:46 PM	24 Apr 2014 12:00 AM		•
6	ClinicalInvestigatorDisqualificationPage	24 May 2018 11:58 AM	15 May 2018 12:00 AM		•
7	PHSAdministrativeActionListingPage	01 Jun 2018 12:07 PM	31 May 2018 12:00 AM		*
8	CBERClinicalInvestigatorInspectionPage	24 May 2018 12:08 PM	10 Apr 2018 12:00 AM		•

(On failure)

Data Extractor

Extraction did not succeed for AdequateAssuranceListPage. The error is logged in Logs/Extraction Log

Site #	Site Name	Scanned/Extracted On	Site Source Last Updated On	Error Description	Execute
1	FDADebarPage	24 May 2018 11:40 AM	03 Jan 2018 12:00 AM		•
2	ClinicalInvestigatorInspectionPage	24 May 2018 11:41 AM	19 Mar 2018 12:00 AM		•
3	FDAWarningLettersPage	24 May 2018 11:41 AM	22 May 2018 12:00 AM		•
4	ERRProposalToDebarPage	24 May 2018 11:44 AM	07 Aug 2017 12:00 AM		•
5	AdequateAssuranceListPage	30 Nov 2017 02:46 PM	24 Apr 2014 12:00 AM		•
6	ClinicalInvestigatorDisqualificationPage	24 May 2018 11:58 AM	15 May 2018 12:00 AM		•
7	PHSAdministrativeActionListingPage	28 May 2018 01:59 PM	25 May 2018 12:00 AM		•
8	CBERClinicalInvestigatorInspectionPage	24 May 2018 12:08 PM	10 Apr 2018 12:00 AM		•
9	ExclusionDatabaseSearchPage	24 May 2018 12:10 PM	08 May 2018 12:00 AM		•
10	CorporateIntegrityAgreementsListPage	24 May 2018 12:13 PM	08 May 2018 12:00 AM		•
11	SystemForAwardManagementPage	04 Jan 2018 04:53 PM	04 Jan 2018 12:00 AM		•
12	SpeciallyDesignedNationalsListPage	24 May 2018 12:14 PM	22 May 2018 10:01 AM		•

• 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

	ı	for the sites for which data extraction is carried out
Serial	Site Name	Site Url
Number		
1	FDA	http://www.fda.gov/ora/compliance_ref/debar/default.htm
	Debarment	
	List	
2	Clinical	https://www.fda.gov/Drugs/InformationOnDrugs/ucm135198.ht
	Investigator	<u>m</u>
	Inspection	
	List	
	(CLIL)(CDER)	
3	FDA Warning	https://www.accessdata.fda.gov/scripts/warningletters/wlSearc
	Letters and	hResultExcel.cfm?qryStr=
	Responses	
4	Notice of	http://www.fda.gov/RegulatoryInformation/FOI/ElectronicReadi
	Opportunity	ngRoom/ucm143240.htm
	for Hearing	
	(NOOH) –	
	Proposal to	
	Debar	
5	Adequate	http://www.fda.gov/ora/compliance_ref/bimo/asurlist.htm
	Assurances	
	List for	
	Clinical	
	Investigators	
6	Clinical	http://www.accessdata.fda.gov/scripts/SDA/sdNavigation.cfm?s
	Investigators	<u>d=clinicalinvestigatorsdisqualificationproceedings&previewMode</u>
	_	<u>=true&displayAll=true</u>
	Disqualificati	
	on	
	Proceedings	
	(FDA	
	Disqualified/	
_	Restricted)	
7	Clinical	http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianc
	Investigator	eRegulatoryInformation/ComplianceActivities/ucm195364.htm
	Inspection	
	List (CBER)	
8	PHS	https://ori.hhs.gov/ORI_PHS_alert.html?d=update
	Administrativ	
	e Actions	
	Listing	
9	HHS/OIG/	https://oig.hhs.gov/exclusions/exclusions list.asp
	EXCLUSIONS	

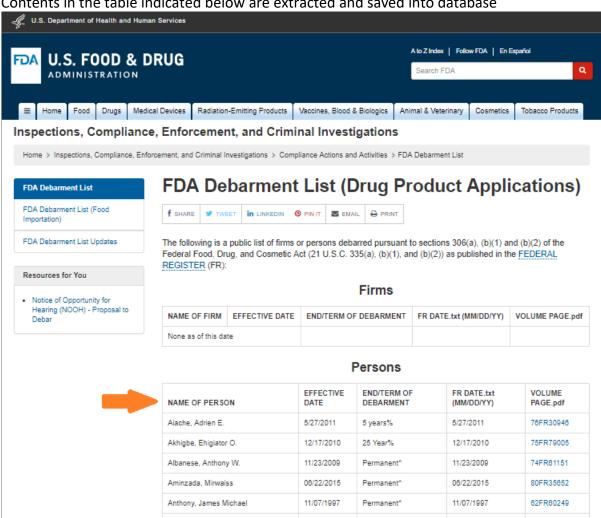


	DATABASE	
	_	
	SEARCH/	
	FRAUD	
10	HHS/OIG	http://oig.hhs.gov/compliance/corporate-integrity-
	Corporate	agreements/cia-documents.asp
	Integrity	
	Agreements/	
	Watch List	
11	SAM/SYSTEM	https://www.sam.gov/portal/public/SAM
	FOR AWARD	
	MANAGEME	
	NT	
12	LIST OF	http://www.treasury.gov/resource-center/sanctions/SDN-
	SPECIALLY	<u>List/Pages/default.aspx</u>
	DESIGNATED	
	NATIONALS	

1. FDA Debarment List

Data File Downloaded: No

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

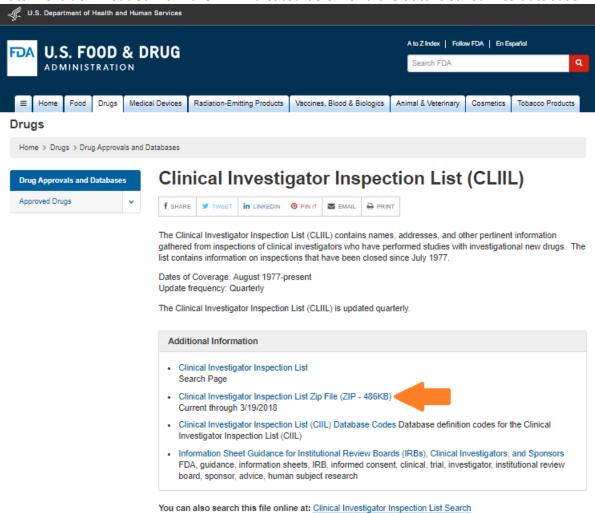




2. Clinical Investigator Inspection List (CLIL)(CDER)

Data File Downloaded: Yes

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

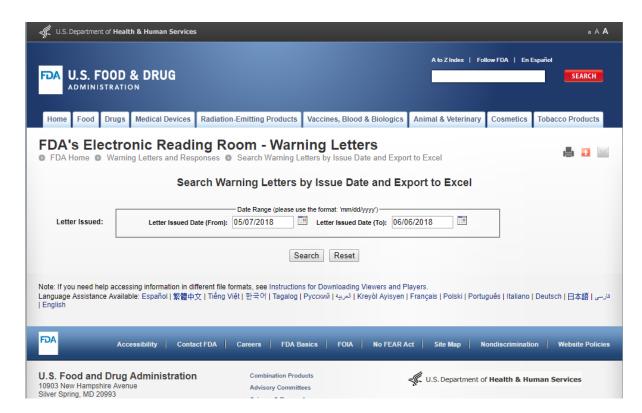


3. FDA Warning Letters and Responses

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





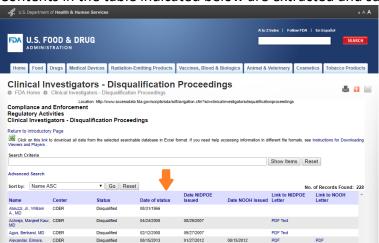
5. Adequate Assurances List for Clinical Investigators

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



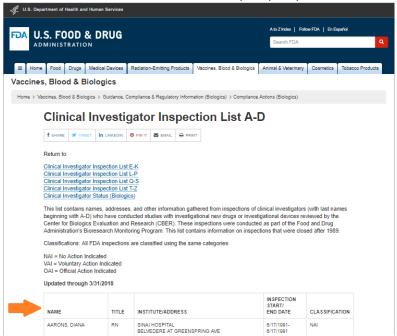


7. Clinical Investigator Inspection List (CBER)

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

PHS Administrative Action Report - 06/01/2018

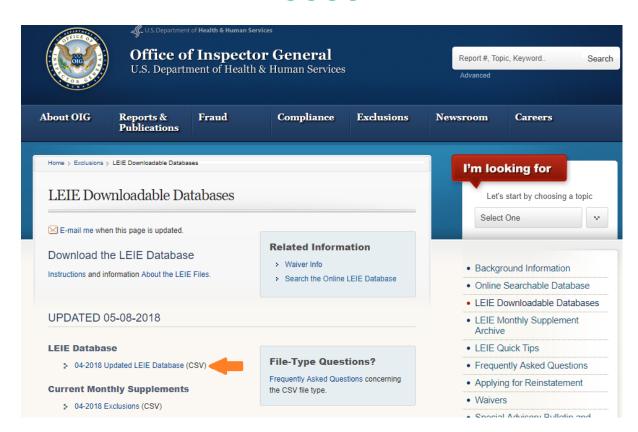
Last Name	First Name	Middle Name	Debarment until	No PHS Advisory until	Certification of work until	Supervision until	Retraction of Article(s)	Correction of Article(s)	Memo
Anderson	David		N/A	06/22/2018	06/22/2018	06/22/2018			
<u>Baughman</u>	Brandi		N/A	05/16/2020	05/16/2020	05/16/2020			These admin. actions are superseded by the admin. actions ending on 03/18/2020, which include debarment.
Baughman	<u>Brandi</u>	M	03/18/2020	03/18/2020	N/A	N/A			
<u>Bitzegeio</u>	<u>Julia</u>		N/A	06/22/2018	06/22/2018	06/22/2018			
Blaylock	Brandi	<u>Lyn</u>	N/A	08/03/2018	08/03/2018	08/03/2018			If within 3 years, Respondent receives or applies for PHS support, certification and supervision will be for a period of 3 years beginning on the date of her employment in a position in which she receives PHS support. If she does not receive or apply for PHS support within 3 years, the admin actions are no longer in effect as of 080/32018.
Chegini	Nasser		N/A	07/11/2022	07/11/2022	07/11/2022			For supervision and certification - if within 5 years of the effective date of the VSA, respondent becomes employed in a position in which he receives or applies for PHS support, he agreed to supervision and certification for 5 years, beginning with the start date of his employment.
<u>Chetram</u>	Mahandranauth	Anand	10/18/2020	10/18/2020	N/A	N/A			
Cullinane	Andrew	<u>R.</u>	N/A	05/05/2021	05/05/2026	05/05/2026			If respondent receives or applies for PHS funds in the next 5 years, his research must be supervised and certified for a period of 10 years from the start date of his employment where he receives PHS support.
<u>Dasmahapatra</u>	<u>Girija</u>		11/04/2018	11/04/2018	N/A	N/A			
El-Remessy	Azza		N/A	09/11/2020	09/11/2020	09/11/2020			Correction or retraction of one paper
Elgutub	Maria Cristina Miron		N/A	04/25/2021	04/25/2021	04/25/2021			Correction or retraction of one published paper.
Endo	Matthew		N/A	11/15/2020	11/15/2020	11/15/2020			
<u>Forbes</u>	<u>Meredyth</u>	<u>M.</u>	05/05/2019	05/05/2019	N/A	N/A			
Geraedts	<u>Maartje</u>	<u>C.P.</u>	N/A	09/22/2018	N/A	N/A			Supervision and certification for three years beginning on date of employment in a position in which respondent receives PHS funds. If respondent has not obtained employment in research position in which she receives PHS funds within one year, supervision and certification no longer apply.
<u>John</u>	Gareth		N/A	04/25/2019	04/25/2019	04/25/2019			
Kornak	Paul	H	For life	N/A	N/A	N/A			
<u>Li</u>	<u>Zhiyu</u>		07/02/2021	07/02/2021	N/A	N/A			
Littlefield	Peter		N/A	08/03/2018	08/03/2018	08/03/2018	1		The VSA was a 3-way with respondent and institution.

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



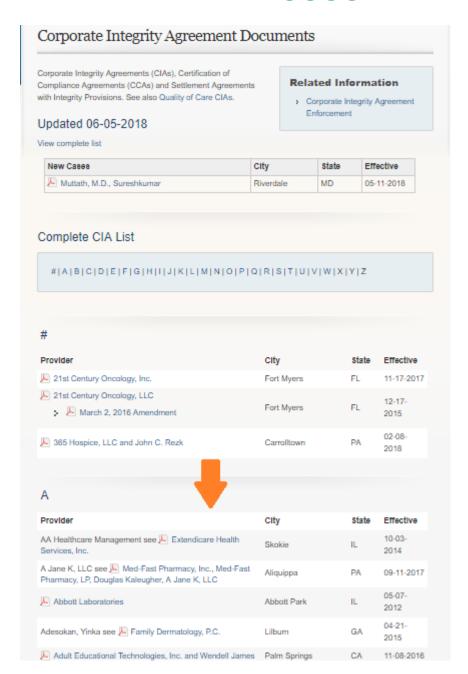


10. HHS/OIG Corporate Integrity Agreements/Watch List

Data File Downloaded: No

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

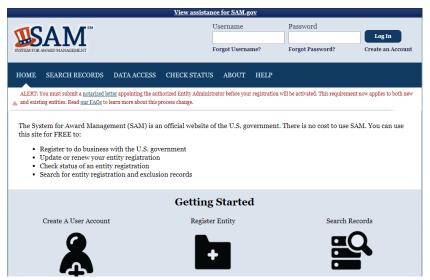




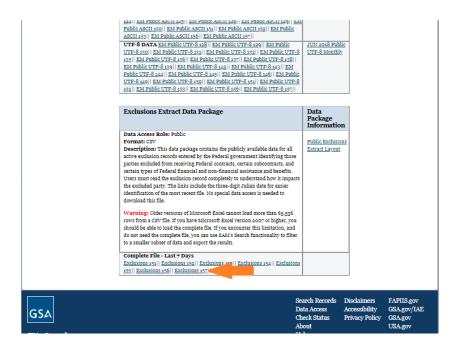
11. SAM/SYSTEM FOR AWARD MANAGEMENT

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



