



Central Drugs Standard Control Organization (CDSCO)

User Manual

For

SAE reporting (Serious Adverse Event)

On SUGAM portal

Version 1.0

Centre for Development of Advanced Computing

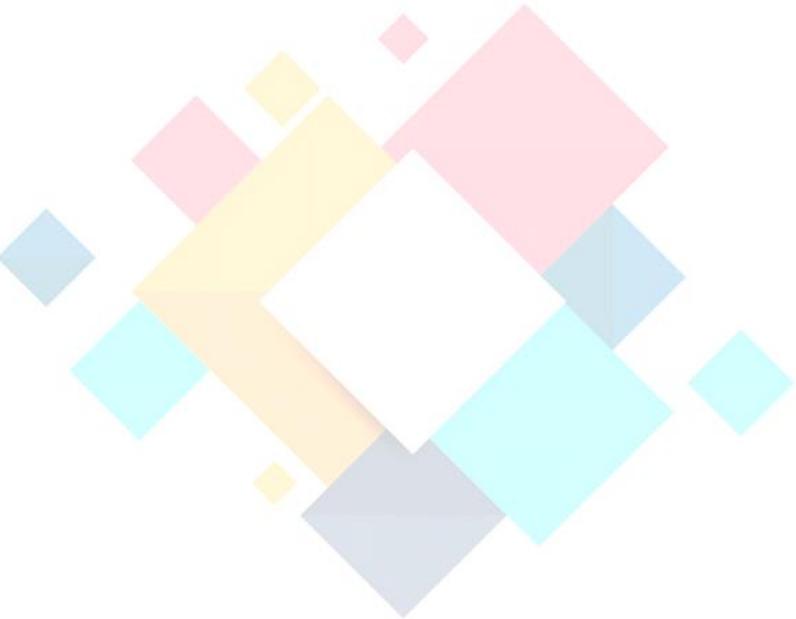
(A Scientific Society of the Ministry of Electronics and Information Technology, Govt. of India)

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Chapter-1

Serious Adverse Events



1.1 What is a Serious Adverse Event

A Serious Adverse Event (SAE) is defined as any adverse drug event (experience) occurring at any dose that in the opinion of either the investigator or sponsor results in any of the following outcomes:

- 1) Death
- 2) Life-threatening adverse drug experience
- 3) Inpatient hospitalization or prolongation of existing hospitalization (for >24 hours)
- 4) Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- 5) Congenital anomaly/birth defect
- 6) Important Medical Event (IME) that may not result in death, be life threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon medical judgment, it may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

It is important to remember that all SAEs are adverse events, but not all adverse events are SAEs

A “Life Threatening Adverse Drug Experience” defined as

Any adverse experience that places the subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, or it is suspected that the use or continued use of the product would result in the patient’s death.

“Congenital Anomaly” defined as

Exposure to a medical product prior to conception or during pregnancy resulting in an adverse outcome in the child.

1.2 General SAE Reporting Policy

A Serious Adverse Event report must be submitted on any event which meets the reporting criteria occurred during conduct of a clinical trial in India.

1.2.1 Timeframe for initial SAE reports submission

The investigator shall report all serious adverse events to the Central Licensing Authority (CDSCO), the sponsor or its representative and the Ethics Committee within twenty-four hours of their occurrence and after due analysis to the Central Licensing Authority, Ethics Committee and the head of the institution within fourteen days of the knowledge of occurrence of serious adverse event.

The sponsor or its representative shall report all serious adverse events to the Central Licensing Authority (CDSCO), head of the institution and Ethics Committee within fourteen days of the knowledge of occurrence of serious adverse event.

The Ethics Committee shall forward its report on serious adverse event within a period of thirty days of receiving the report of the serious adverse event from the investigator.

1.2.2 Recipients of SAEs reports

Site Principal Investigators (PI), who confirmed that SAEs occurred in their trial, are required to report the SAEs to CDSCO and also to their Trial Sponsor and Ethics Committees.

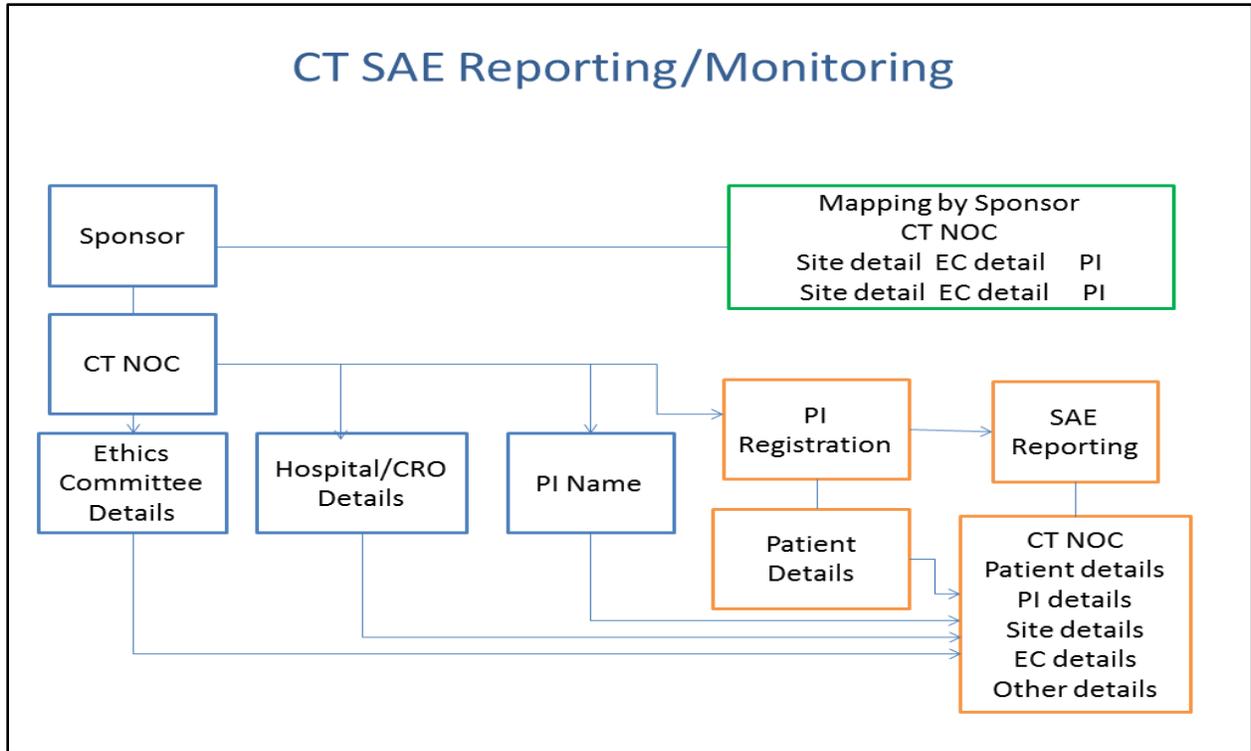


Figure 1: CT SAE Reporting/Monitoring

Figure1 above depicts the Mapping of PI with Site.

1.3 Process Flow for SAEs Reporting

After obtaining CT-NOC from CDSCO and registering at Clinical Trials Registry-India (CTRI), the sponsor may initiate trial and shall monitor the clinical trial in all the participating sites. To report SAE on SUGAM portal, sponsor shall mandatorily follow the below mentioned steps to build-up the database and for proper linking of data.

- Add Site Investigator
- Site Investigator Mapping
- Initiate Clinical Trial
- SAE Reported

To accomplish above steps, the Sponsor may login into the SUGAM portal and then click on CLINICAL TRIALS tab under MENU from their dashboard.

Step 1: Add Site Principal Investigator

As the Sponsor/Applicant, when receives CT NOC, it only contains details of trial sites (i.e. Hospital), Ethics committee and PI name (but not PI details and each PI has to register themselves in the portal to report SAE).

After login into the portal, click on “Add Site Investigator” tab under “Clinical Trials” in Menu as shown in below figure.

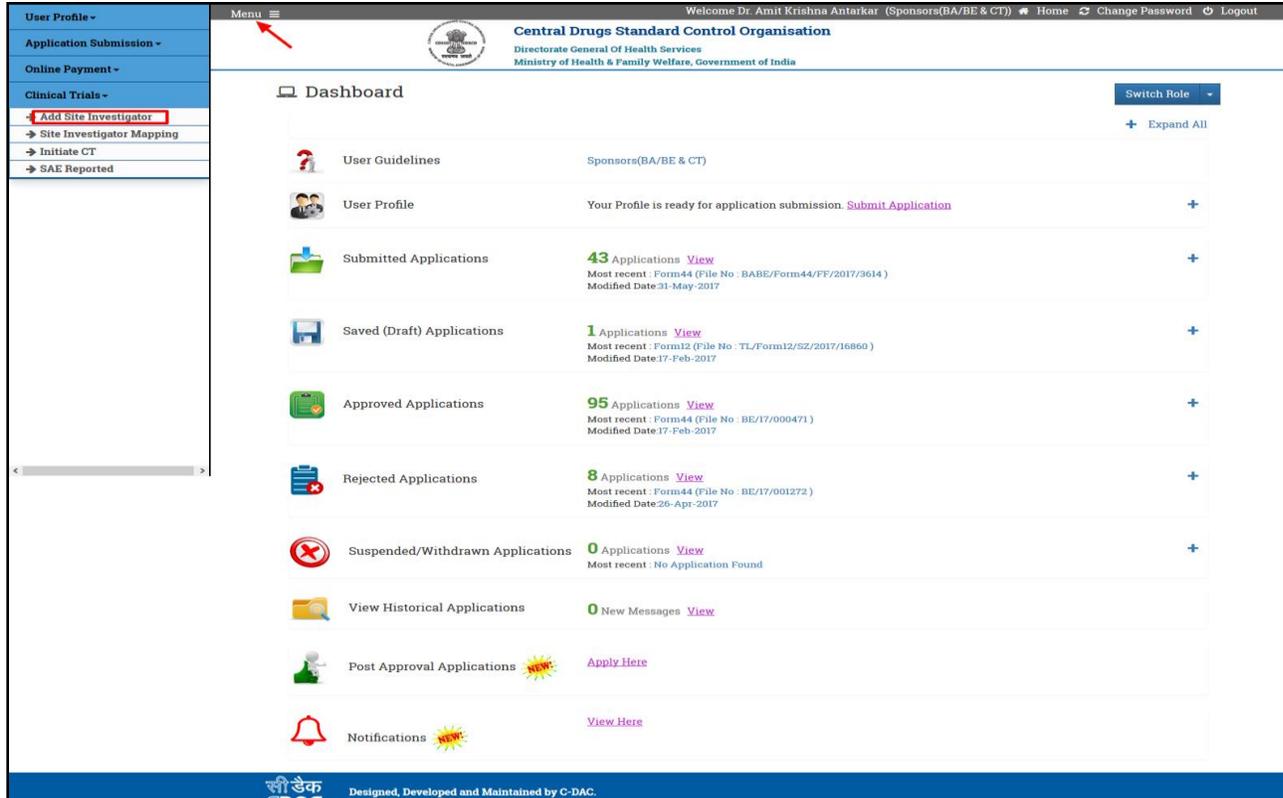
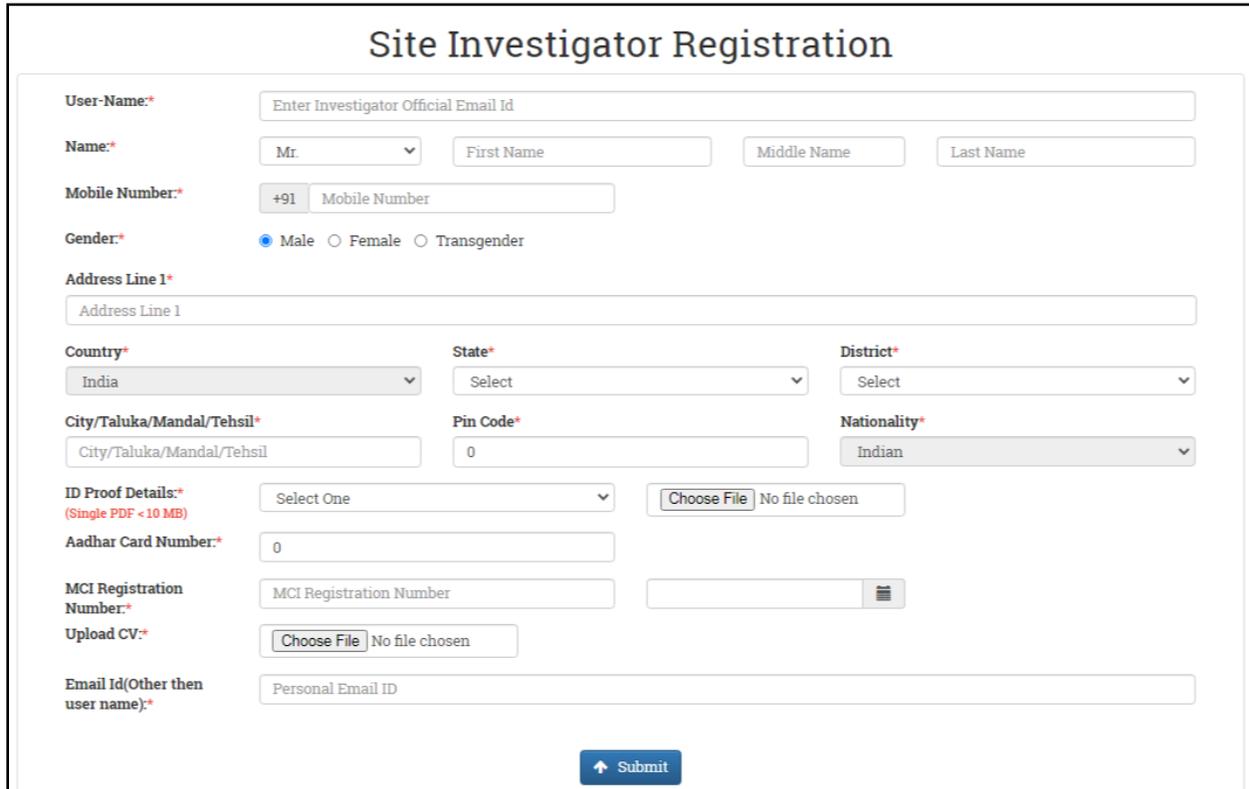


Figure 2: Sponsor Dashboard

After that a new window will open as shown in below figure. Sponsor has to enter the Investigator’s basic details and click on “Submit” button. He must add all the investigators mentioned in the CT-NOC.



The screenshot shows a web form titled "Site Investigator Registration". The form contains the following fields and controls:

- User-Name*:** A text input field with the placeholder "Enter Investigator Official Email Id".
- Name*:** A dropdown menu with "Mr." selected, followed by three text input fields for "First Name", "Middle Name", and "Last Name".
- Mobile Number*:** A text input field with "+91" in a small box and "Mobile Number" as a placeholder.
- Gender*:** Radio buttons for "Male" (selected), "Female", and "Transgender".
- Address Line 1*:** A text input field with "Address Line 1" as a placeholder.
- Country*:** A dropdown menu with "India" selected.
- State*:** A dropdown menu with "Select" as the placeholder.
- District*:** A dropdown menu with "Select" as the placeholder.
- City/Taluka/Mandal/Tehsil*:** A text input field with "City/Taluka/Mandal/Tehsil" as a placeholder.
- Pin Code*:** A text input field with "0" as a placeholder.
- Nationality*:** A dropdown menu with "Indian" selected.
- ID Proof Details* (Single PDF <10 MB):** A dropdown menu with "Select One" and a "Choose File" button with "No file chosen" text.
- Aadhar Card Number*:** A text input field with "0" as a placeholder.
- MCI Registration Number*:** A text input field with "MCI Registration Number" as a placeholder and a small icon to its right.
- Upload CV*:** A "Choose File" button with "No file chosen" text.
- Email Id(Other then user name)*:** A text input field with "Personal Email ID" as a placeholder.

At the bottom center of the form is a blue "Submit" button with an upward-pointing arrow.

Figure 3: Site Investigator Registration

On clicking Submit button, an e-mail link will be sent to Investigator for confirming and creating his login credentials. Once the investigator clicks the e-mail link, a window will open as shown in figure below:

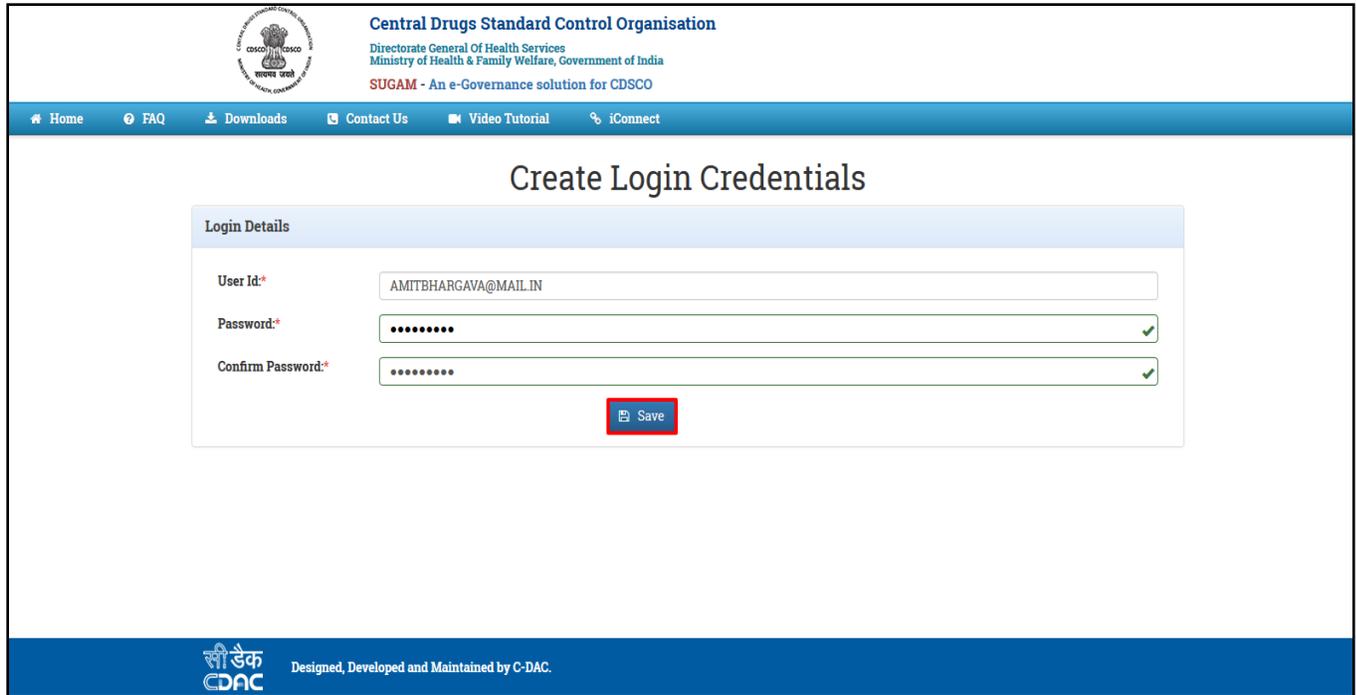


Figure 4: Login Credential Window

The User Id is auto fetched (i.e. same as entered by applicant/sponsor), investigator needs to enter only Password and Confirm Password. After clicking on “Save” button a message will pop-up as shown in figure below:

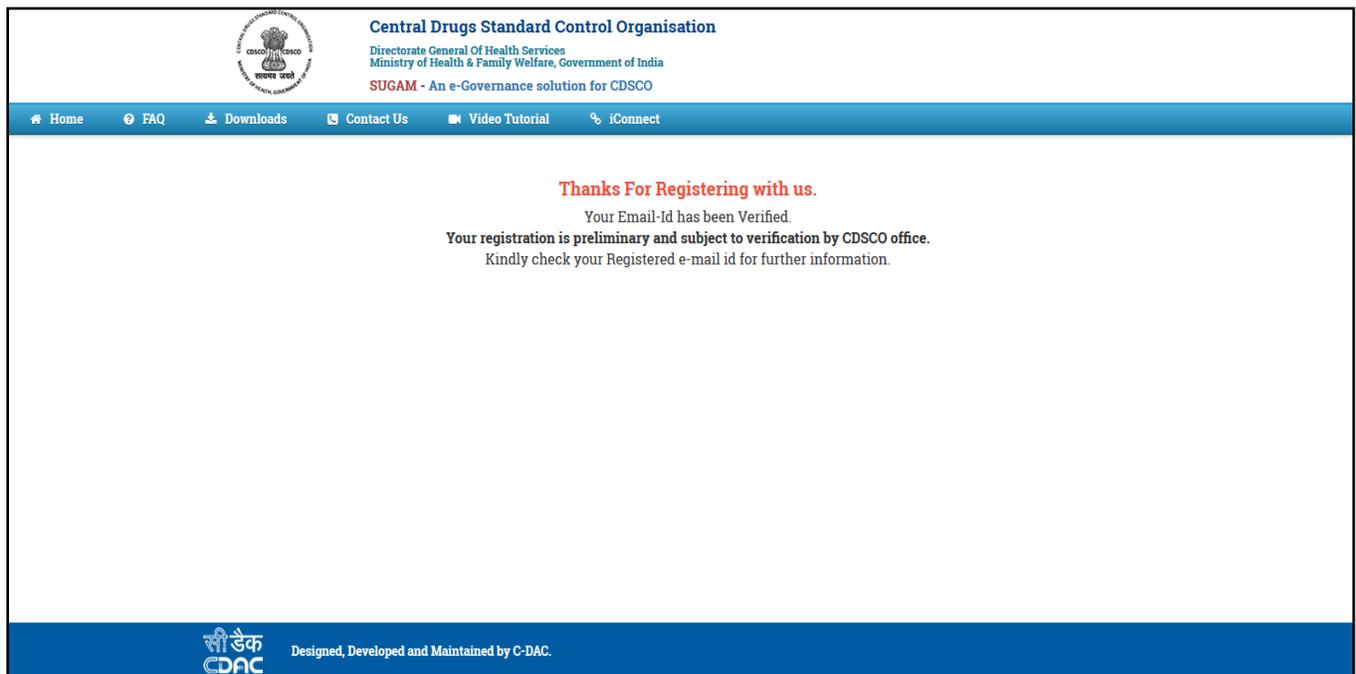


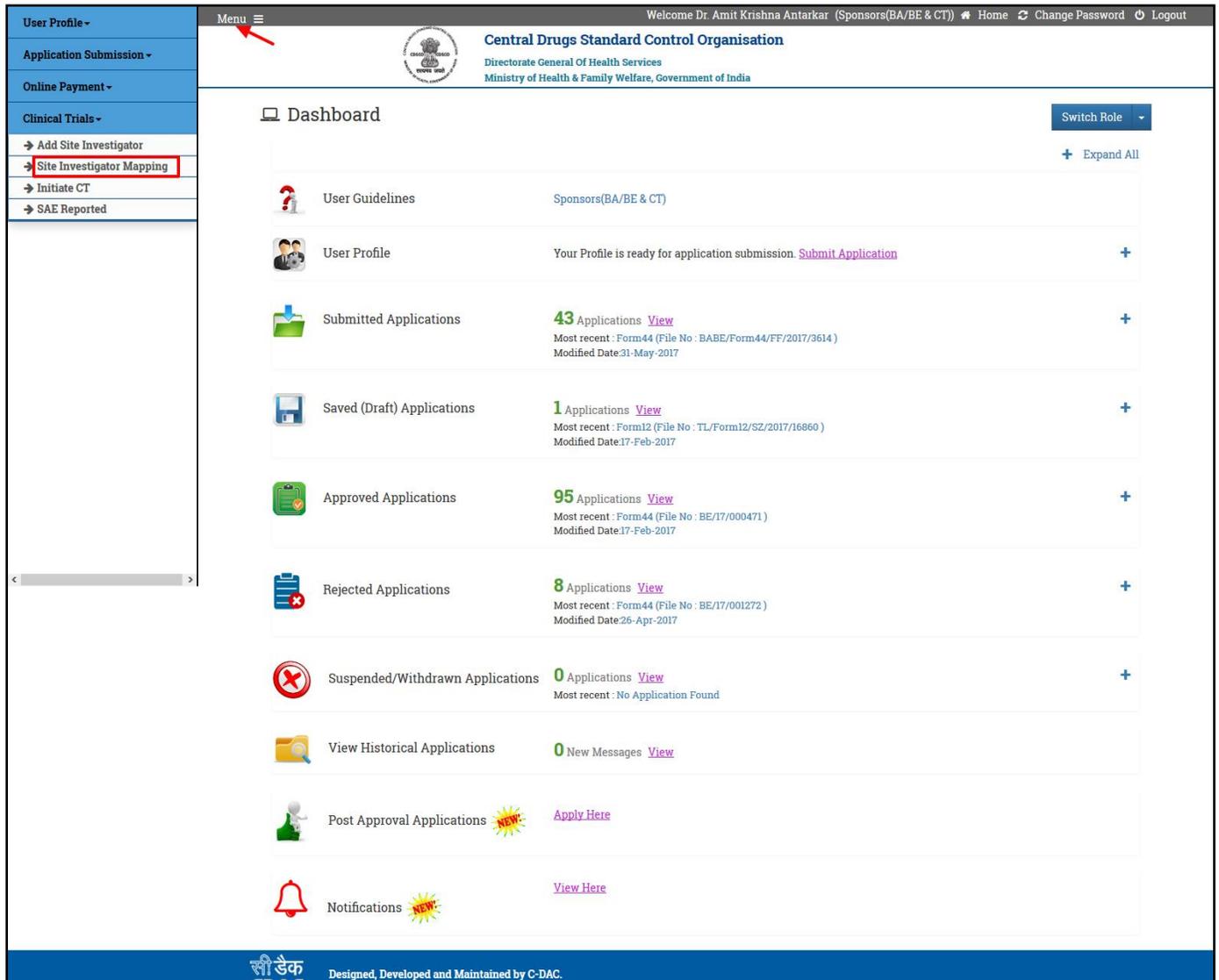
Figure 5: Successful Registration Pop-up

Once the login credentials of Investigators are created meanwhile, they must login into the SUGAM portal to complete their user profile and send request for **Approval of User Profile**.

Step 2: Site Investigator Mapping

After approval of Investigator’s User Profile, Applicant/Sponsor will map them with the trial Site/Hospital from his dashboard.

Click on “Site Investigator Mapping” tab under “Clinical Trials” in Menu as shown in figure below:



The screenshot displays the Sponsor Dashboard for the Central Drugs Standard Control Organisation. The left sidebar menu includes options like 'User Profile', 'Application Submission', 'Online Payment', and 'Clinical Trials'. Under 'Clinical Trials', the 'Site Investigator Mapping' option is highlighted with a red box. The main dashboard area shows a list of application categories with their respective counts and 'View' links. A 'Menu' icon is also visible at the top left of the dashboard area.

Category	Count	Action
User Guidelines	Sponsors(BA/BE & CT)	
User Profile	Your Profile is ready for application submission.	Submit Application
Submitted Applications	43 Applications	View
Saved (Draft) Applications	1 Applications	View
Approved Applications	95 Applications	View
Rejected Applications	8 Applications	View
Suspended/Withdrawn Applications	0 Applications	View
View Historical Applications	0 New Messages	View
Post Approval Applications	NEW!	Apply Here
Notifications	NEW!	View Here

Figure 6: Sponsor Dashboard

After that a new window will open as shown in figure below. Applicant/Sponsor has to select the BE/CT application, a list of sites mentioned in the CT-NOC will get displayed. Just select the site investigator from drop down and check the checkbox (as highlighted) and click on “Save” button.

Central Drugs Standard Control Organisation

Directorate General Of Health Services
Ministry of Health & Family Welfare, Government of India

Application Investigator Mapping Form

NOTE :

- If you are **unable to find Site Investigator name in dropdown list** then inform the respective PI to kindly register on SUGAM portal <https://cdsconline.gov.in/CDSCO/homepage>
- After saving the data, kindly inform the respective PIs to login on SUGAM portal and enter the data of patients enrolled for Clinical Trial.

* All fields are mandatory

Select BE / CT Application: * CT/17/000013

CT Site Mapping Details

☐	Site ⇅	Proposed Site Investigator ⇅	Select Site Investigator ⇅
<input checked="" type="checkbox"/>	✚ All India Institute of Medical Sciences Ethics Committee, All India Institute of Medical Sciences, Room No. 102, 1st Floor, Old O.T. Block, Ansari Nagar, , New Delhi, Not Available, Delhi	Name: Dr Shalimar	TEST@YOPMAIL.COM
<input checked="" type="checkbox"/>	✚ Government Medical College Dept of Pharmacology , Govt Medical College, Nagpur, Not Available, Maharashtra	Name: Dr Sudhir Gupta	SITEINVESTIGATOR@CDSCO.IN
<input checked="" type="checkbox"/>	✚ S.M.S. Medical College and Attached Hospitals, Jaipur First Floor, Dhanvantri OPD Block, S.M.S. Hospital, J.L.N. Marg, Jaipur, Not Available, Rajasthan	Name: Dr Sandeep Nijhawan	<div style="border: 1px solid gray; padding: 2px;"> <input type="text"/> </div> <div style="background-color: #0056b3; color: white; padding: 2px;">Select</div> <div style="border: 1px solid gray; padding: 2px;"> AMITBHARGAVA@MAIL.IN MUNEESHGARG@MAIL.IN ----- NEETU.PI@YOPMAIL.COM SITEINVESTIGATOR@CDSCO.IN TEST@YOPMAIL.COM </div>
<input type="checkbox"/>	✚ SR Kalla Memorial Gastro and General Hospital 78, Dhuleshwar Garden, Behind HSBC Bank, sardar Patel Marg C-Scheme, Jaipur, Not Available, Rajasthan	Name: Dr Ramesh Roop Rai	Select
<input type="checkbox"/>	✚ Global Hospital Ethics Committee, Global Hospital situated at Room No.: 214, Global Hospital, Dr. E Borges Road, Hospital Avenue, Opp. Shirodakar High School, Parel, , Mumbai, Not Available, Maharashtra	Name: Dr Samir Shah	NEETU.PI@YOPMAIL.COM SITEINVESTIGATOR@CDSCO.IN TEST@YOPMAIL.COM
<input type="checkbox"/>	✚ Institutional Ethics committee Global Hospitals B-1-1070/1 TO 4, LAKDIKAPUL , Hyderabad, Not Available, Telangana	Name: Dr Dharmesh Kapoor	Select
<input type="checkbox"/>	✚ VGM Hospital institutional ethics committee VGM Hospital No-2100, Trichy Road , Coimbatore, Not Available, Tamil Nadu	Name: Dr V G Mohan Prasad	Select
<input type="checkbox"/>	✚ Deccan college of medical sciences and allied Hospitals PO, Kanchanbagh, DMRL 'X' Road, Santosh Nagar, , Hyderabad, Not Available, Telangana	Name: Dr Mohd Aejaz Habeeb	Select
<input type="checkbox"/>	✚ Ethics Committee Midas Multispeciality Hospital Ethics Committee Midas Multispeciality Hospital Pvt.Ltd situated at Midas Maharashtra, Nagpur, Not Available, Maharashtra	Name: Dr Shrikant Mukewar	Select
<input type="checkbox"/>	✚ Sir Ganga Ram Hospital Ethics Committee Room No 1496. IV Floor , Old Building ,Old Rajinder Nagar, New Delhi, Not Available, Delhi	Name: Dr Anil Arora	Select

« < 1 2 > »

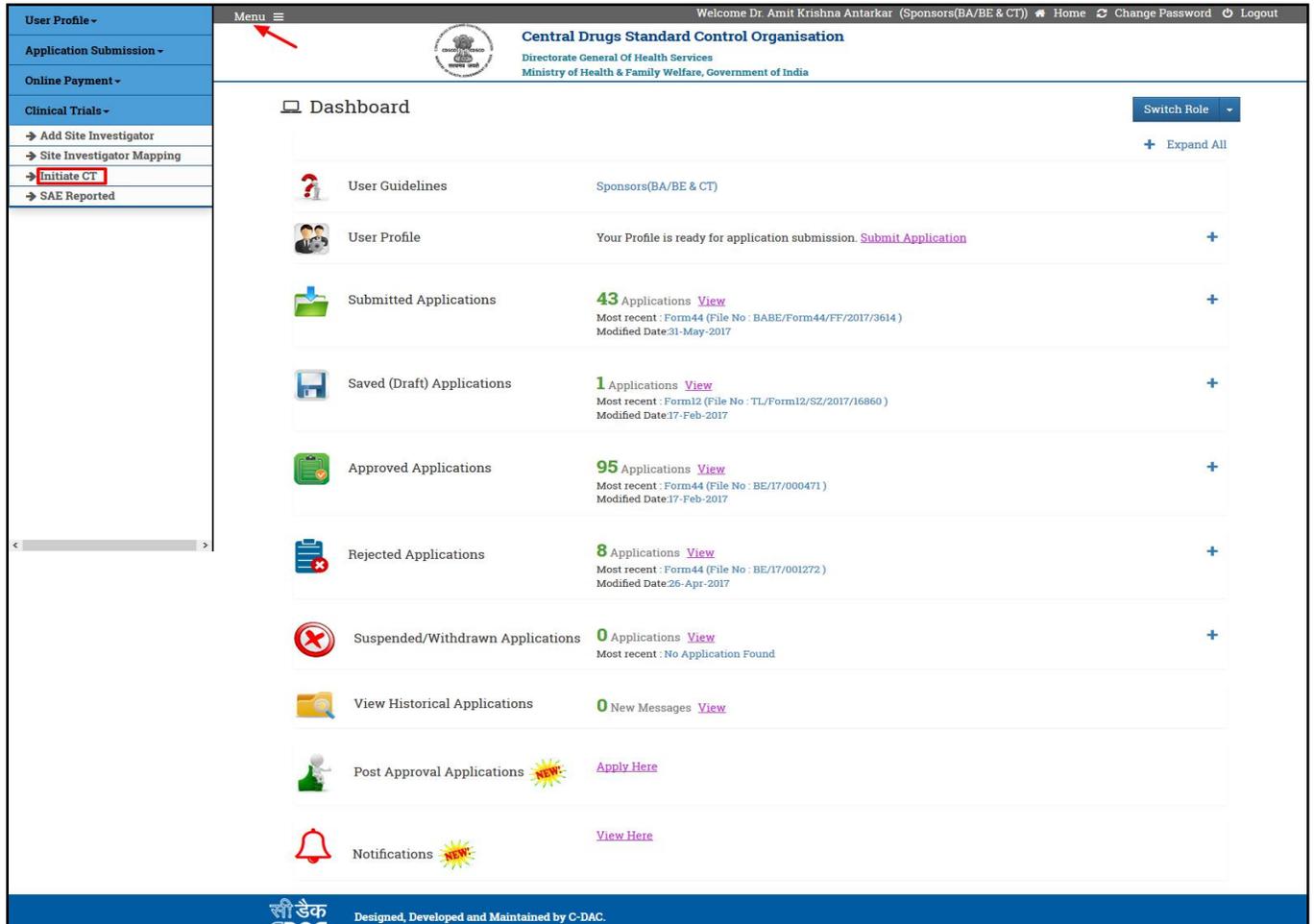
➔ Save

Figure 7: Application Investigator Mapping Form

Step 3: Initiate Clinical Trial

Once the Site Investigator mapping is done for any BE/CT application, the applicant/sponsor can initiate the trial.

Click on “Initiate CT” tab under “Clinical Trials” in Menu as shown in figure below:



The screenshot displays the 'Sponsor Dashboard' interface. On the left, a navigation menu is visible with the following items: User Profile, Application Submission, Online Payment, Clinical Trials (with sub-items: Add Site Investigator, Site Investigator Mapping, **Initiate CT**, and SAE Reported), and a scrollable area. The main dashboard area is titled 'Dashboard' and includes a 'Switch Role' button and an 'Expand All' link. The dashboard content is organized into several rows, each representing a different application status:

- User Guidelines:** Sponsors(BA/BE & CT)
- User Profile:** Your Profile is ready for application submission. [Submit Application](#)
- Submitted Applications:** 43 Applications [View](#). Most recent: Form44 (File No : BABA/Form44/FF/2017/3614) Modified Date:31-May-2017
- Saved (Draft) Applications:** 1 Applications [View](#). Most recent : Form12 (File No : TL/Form12/SZ/2017/16860) Modified Date:17-Feb-2017
- Approved Applications:** 95 Applications [View](#). Most recent : Form44 (File No : BE/17/000471) Modified Date:17-Feb-2017
- Rejected Applications:** 8 Applications [View](#). Most recent : Form44 (File No : BE/17/001272) Modified Date:26-Apr-2017
- Suspended/Withdrawn Applications:** 0 Applications [View](#). Most recent : No Application Found
- View Historical Applications:** 0 New Messages [View](#)
- Post Approval Applications:** [Apply Here](#) (marked with a 'NEW' badge)
- Notifications:** [View Here](#) (marked with a 'NEW' badge)

The footer of the dashboard contains the CDAC logo and the text: 'Designed, Developed and Maintained by C-DAC.'

Figure 8: Sponsor Dashboard

After that, a new window will open as shown in figure below. Applicant/Sponsor has to select the BE/CT application and enter the CTRI Registration Number, then click on “Save” button.

To Initiate Clinical Trial

* All fields are mandatory

Select BE / CT Application: *

CTRI Registration No: *

Details:

Search:

Sr.No. ↕	CTRI No. ↕	CDSKO File No. ↕
1	CTRI001166	BE-EXPORT/20/001166

Figure 9: Initiate Clinical Trial Window

Step 4: SAE Reported

After the initiation of the clinical trial SAE occurring at any trial site has to be reported by investigator, sponsor and ethics committee involved in that particular clinical trial.

An applicant/sponsor can view the list of all reported SAEs, for that, just Click on “SAE Reported” tab under “Clinical Trials” in Menu as shown in figure below:

The screenshot shows the 'Sponsor Dashboard' interface. On the left, a sidebar menu is visible with the following items: User Profile, Application Submission, Online Payment, Clinical Trials (with sub-items: Add Site Investigator, Site Investigator Mapping, Initiate CT, and SAE Reported), and a search bar. The 'SAE Reported' item is highlighted with a red box. The main dashboard area displays various application status cards: User Guidelines, User Profile, Submitted Applications (43), Saved (Draft) Applications (1), Approved Applications (95), Rejected Applications (8), Suspended/Withdrawn Applications (0), View Historical Applications (0), Post Approval Applications, and Notifications. The top navigation bar includes the user's name, role, and options for Home, Change Password, and Logout.

Figure 10: Sponsor Dashboard

After that a new window will open as shown in figure below. Applicant/Sponsor can view or report SAEs by clicking on options available under 'Action' button (as highlighted).

CDSCO Online Application Submission System for Licensing

Mr. Rahul Nijhawan

List of Serious Adverse Events Reported by Site Investigator

14D Reporting | 24Hr Reporting

Search:

BE or CT NOC No.	Application File No.	CTRI Registration No.	SAE Terminology	SAE Type	Sponsor's created Subject Id	Status	Processing Status	Action
+ CT/18/000059	CT/SAE-ND-7/2020-115(14Days-Sponsor)	test123	test	Other than Death	13.0	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ CT/18/000059	CT/SAE-ND-1/2020	test123	sae test	Other than Death	salman01	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ BE/18/002491	CT/SAE-D-6/2020-110(14Days-Sponsor)	TESTINGDEEPSHIKHA	corona	Death	salman01	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ BE/18/002491	CT/SAE-ND-4/2020-102(14Days-Sponsor)	TESTINGDEEPSHIKHA	test	Other than Death	kat01	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ BE-EXPORT/19/002168	CT/SAE-ND-53/2020-226(14Days)	AbhiBE2504	Hyperglycemia	Other than Death	rohit/54/001	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ CT/18/000059	CT/SAE-ND-5/2020	test123	test	Other than Death	2015/54/002	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ BE/16/000707	CT/SAE-D-20/2020-138(14Days-Sponsor)	CTAbhi0606	Death	Death	123456.0	SAE14 Day Report Submitted by Sponsor	Query Responded	
+ BE/18/002491	CT/SAE-ND-54/2020	TESTINGDEEPSHIKHA	fever	Other than Death	T patient 1	SAE14 Day Report Submitted by Sponsor	Order Issued	
+ BE/17/001134	CT/SAE-ND-21/2020-143(14Days-Sponsor)	CT03062020Abhi	Acute Gastritis	Other than Death	sati/54/002	SAE14 Day Report Submitted by Sponsor	Inprocess	
+ BE/17/002122	CT/SAE-ND-23/2020	CT11052020Abhi	Seizures	Other than Death	123456.0	SAE14 Day Report Submitted by Sponsor	Inprocess	

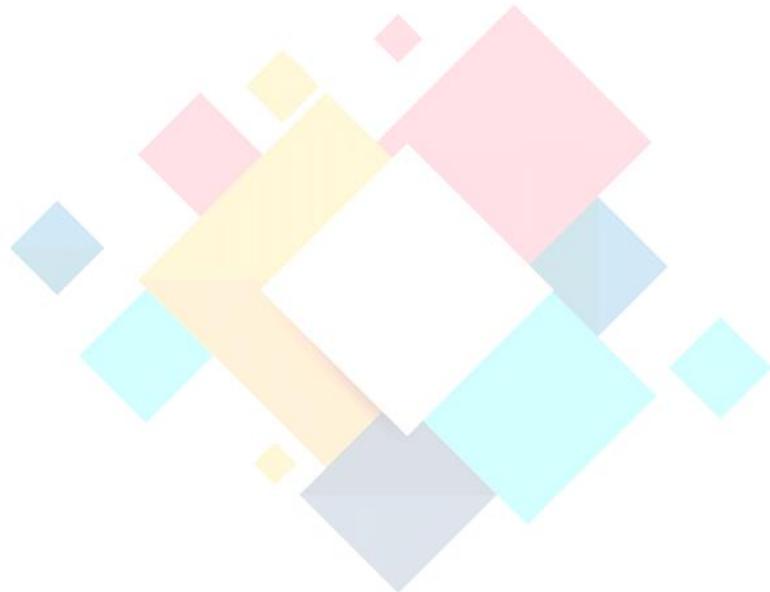
1 2 3 4

Figure 11: List of SAEs reported by Site Investigator



Chapter- 2

SAE Reporting



To report serious adverse events (SAE), there are three types of forms:

- SAE Reporting (24-hour Report by PI)
- SAE Reporting (14th Day Due Analysis Report by PI and Sponsor)
- SAE Reporting (30th Day Report by Ethics Committee)

While SAE reporting all the data (Sponsor/CRO details, Ethics committee details, Hospital/Site details, PI details) will be fetched automatically based on BE/CT NOC number and rest details will be entered depending on the form.

2.1 SAE Reporting (24 Hours)

Investigator will fill the *SAE Reporting* form with the following details:

- **Administrative Information**
 - SAE report of death or non-death **(to be filled)**
 - Sponsor/CRO details (Auto fetch from CT NOC)
 - Clinical Site details (Auto fetch from CT NOC)
 - Investigator details (from PI registration)
 - Ethics Committee details (Auto fetch from CT NOC)
- **Clinical Study/BE Study details**
 - Study title & Protocol No. (Auto fetch from CT NOC)
- **Patient/Subject details**
 - Unique Identifier (Initials/Subject No.)
 - Gender
 - Date of birth and age at the time of SAE
 - Height & Weight
- **SAE(s) Details**
 - SAE(s) Term**(to be filled)**
 - Start date of SAE**(to be filled)**
 - Stop date of SAE/ongoing
 - Table-5**(Upload)**

Ethics Committee Details

Name of the Ethics Committee: IBIOME Independent Ethics Committee

EC Registration No. provided by CDSCO: ECR/40/Indt/GJ/2013/RR-19

Address: Nirmal Ashram Deepmala Pagarani Public School ,Shyampur
PO. Satyanarayan Rishikesh (India) - 249204

Contact No. :

Email ID :

Clinical Study/BE Study Details

Study Title: Single dose oral bioequivalence study of Oxcarbazepine XR Tablets 600mg and OXTELLAR XR™ (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fasting conditions.

Protocol No.: CIB00314

Clinical Study/BE Study Details

Study Title: Single dose oral bioequivalence study of Oxcarbazepine XR Tablets 600mg and OXTELLAR XR™ (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fed conditions.

Protocol No.: CIB00315

SAE(s) Details

Expectedness of SAE Expected Unexpected

SAE report of Death or other than Death * Death other than Death

SAE(s) Terminology *

Brief description of the SAE *

Start Date of SAE(s) 

SAE Stop or Ongoing?*

TABLE 5 (24 hr. Report submitted)*
(Single Pdf File < 10 MB) No fil_.hosen

EC Registration Certificate copy obtained from CDSCO*
(Single Pdf File < 10 MB) No fil_.hosen

Copy of Clinical Trial permission/ BE-NOC obtained from CDSCO*
(Single Pdf File < 10 MB) No fil_.hosen

Figure 12: SAE Reporting Form 24 hours

After final submission of 24Hrs SAE reporting, a unique file number will be generated for future reference as shown inFigure.



Figure 13: File Number for 24Hour Reporting

2.2 SAE Reporting (14th Day due Analysis Report)

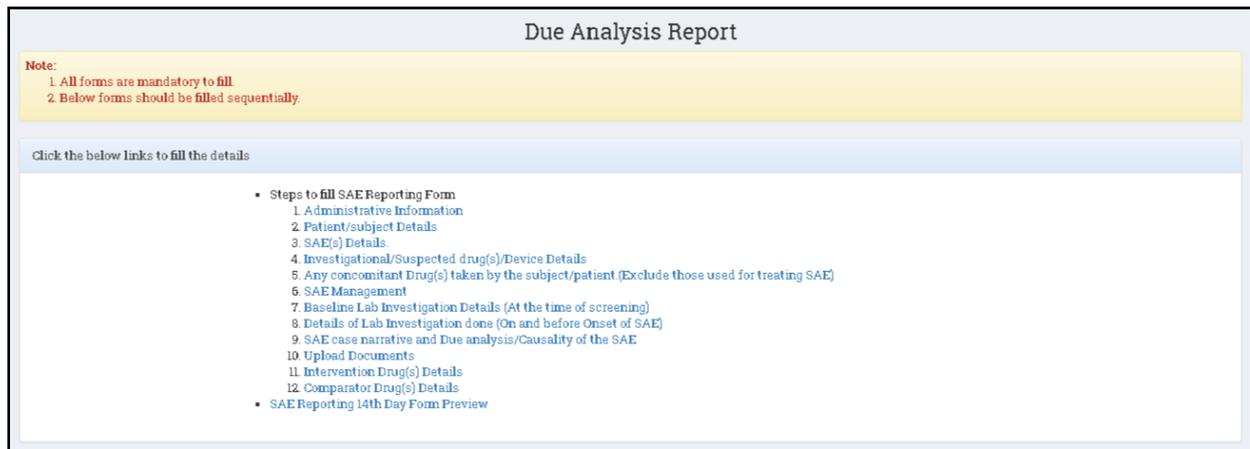
After 24-hour SAE report is submitted, investigator may proceed to fill the Due Analysis Report. This form is divided into several parts. A report may be submitted only after all the parts of the form are completed. Before clicking the SUBMIT button Investigator may verify the filled data from preview page.

Investigator shall fill the *SAE Reporting* form with the following details:

- **Administrative Information**
 - SAE report of death or other than death(**to be filled**)
 - Type of Report (**to be filled**)
 - Sponsor/CRO details (Auto fetch from CT NOC)
 - Clinical Site details(Auto fetch from CT NOC)
 - Investigator's details (Auto fetch from PI registration)
 - Ethics Committee details(Auto fetch from CT NOC)
- **Clinical Study/BE Study details**
 - Study title & Protocol No.(Auto fetch from CT NOC)
- **Patient/Subject details**
 - Unique Identifier (Initials/Subject No)(Auto fetch from 24-hour report)
 - Gender (Auto fetch from 24-hour report)
 - Date of birth and age at the time of SAE(Auto fetch from 24-hour report)
 - Weight & Height(Auto fetch from 24-hour report)
 - Previous disease/medical history(**to be filled**)
- **SAE(s) Details**
 - SAE(s) Term (Auto fetch from 24-hour report)
 - SAE Management Setting (**to be filled**)
 - Start date of SAE (Auto fetch from 24-hour report)
 - Stop date of SAE (Auto fetch from 24-hour report)

- Re challenge/De challenge Details (to be filled)
- Investigational/Suspected drug(s)/Device Details (to be filled)
- Any concomitant Drug(s) taken by the subject/patient.(Exclude those used for treating SAE) (to be filled)
- SAE Management (to be filled)
- Baseline Lab Investigation Details (At the time of screening) (to be filled)
- Details of Lab Investigation done (On and before Onset of SAE) (to be filled)
- SAE case narrative and Due analysis/Causality of the SAE (to be filled)

As figures below:



Due Analysis Report

Note:

1. All forms are mandatory to fill
2. Below forms should be filled sequentially

Click the below links to fill the details

- Steps to fill SAE Reporting Form
 1. Administrative Information
 2. Patient/subject Details
 3. SAE(s) Details
 4. Investigational/Suspected drug(s)/Device Details
 5. Any concomitant Drug(s) taken by the subject/patient (Exclude those used for treating SAE)
 6. SAE Management
 7. Baseline Lab Investigation Details (At the time of screening)
 8. Details of Lab Investigation done (On and before Onset of SAE)
 9. SAE case narrative and Due analysis/Causality of the SAE
 10. Upload Documents
 11. Intervention Drug(s) Details
 12. Comparator Drug(s) Details
- SAE Reporting 14th Day Form Preview

Figure 14: 14 days Due Analysis Report Form List

Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)
(14th day report, Initial and Subsequent Follow-Up)

Administrative Information

Expectedness of SAE * Expected Unexpected
 SAE report of Death or other than Death * Death Other than Death

CT/BE Permission No. (Copy to be attached) BE- EXPORT/20/001166 dated 26-AUG-2020
 CTRI Registration No. CTRI001166

Sponsor/CRO Details

Name: M/s. Shanghai Aucta Pharmaceuticals Co., Ltd
 Address: Building 10, Lane 100 Banxia Road Pudong New Area Shanghai Shanghai (China) - 201318
 Mobile No. : 862158585606
 Landline No. :
 Email ID. :

Clinical Site Details

Name: M/s. Cliantha Research Ltd.,
 Address: M/s. Cliantha Research Ltd., Opp. Pushparaj Towers, Nr. Judges Bungalows, Bodakdev, Ahmedabad
 Contact No. :
 Email ID. :

Investigator Details

Name : Ms. Deepshikha Singh
 Site Address:
 Email ID. : deepshikha@gmail.com

Ethics Committee Details

Name of the Ethics Committee: IBIOME Independent Ethics Committee
 EC Registration No. provided by CDSCO: ECR/40/Indt/GJ/2013/RR-19
 Address: Nirmal Ashram Deepmala Pagarani Public School ,Shyampur PO. Satyanarayan Rishikesh (India) - 249204
 Contact No. :
 Email ID. :

Clinical Study/BE Study Details

Study Title: Single dose oral bioequivalence study of Oxcarbazepine XR Tablets 600mg and OXTELLAR XR TM (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fasting conditions.
 Protocol No.: C1B00314

Clinical Study/BE Study Details

Study Title: Single dose oral bioequivalence study of Oxcarbazepine XR Tablets 600mg and OXTELLAR XR TM (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fed conditions.
 Protocol No.: C1B00315

Study Status * Ongoing Completed

Is subject/patient Continued or Withdrawn from the Study * Continued Withdrawn

← Previous

Save

Reset

Figure 15: 14th day Due Analysis Report (Administrative Information)

Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)
(14th day report, Initial and Subsequent Follow-Up)

Patient/Subject Details

Patient Unique Identifier (Subject Id/Randomization ID)		Patient 1/Pat sub id01			
Gender:	Female	Date of Birth:	25-Dec-1998	Age at the time of SAE:	40.0
Weight (in Kg):	65.0	Height (in cms):	250.0	Monthly Income(INR):	50000.0
Qualification:	Btech	Occupation:	Developer		

Disease Condition/Diagnosis	Since (Year)(YYYY)	Duration (Years/Months)
<input type="text" value="Enter Disease Condition"/>	<input type="text" value="0"/>	<input type="text" value="15 Years or 6 months"/>

Social History

[← Previous](#)
[+ Save](#)
[↻ Reset](#)

Relevant previous Disease/Medical History

↕	Disease Condition/Diagnosis ↕	Since (Year) ↕	Duration (Years/Months) ↕	Social History ↕	Delete ↕

Figure 16: 14th day Due Analysis Report (Patient/Subject Details)

SAE Details

Fill SAE Details

SAE(s) Term(s)	sae term		
SAE Management Setting: *	<input type="text" value="Select"/>	Date of Awareness of SAE by the Site Personnel(s): *	<input type="text"/>
Start Date of SAE(s):	15/09/2020	Stop Date of SAE(s):	Sae Ongoing <input type="text" value="SAE Stop date"/>
Information on recovery and any sequelae *		Other Informations *	
Information on recovery and any sequelae, Results of specific tests and/or treatment that may have been conducted		Anything relevant to facilitate assessment of the case, such as medical history including allergy, drug or alcohol abuse, family history	
For a fatal outcome*			
Cause of death and a comment on its possible relationship to the suspected reaction or any post-mortem findings			

Re challenge/De challenge Details

Whether Re-challenge/De-challenge was done? *	<input type="text" value="Yes"/>	Date of Re-challenge	<input type="text"/>	Date of De-challenge	<input type="text"/>
(a) Did Reaction abate after discontinuation or dose reduction? *	<input type="text" value="Select"/>				
(b) Did reaction re-appear after re-introduction of the drug? *	<input type="text" value="Select"/>				
How was drug regimen altered in response to the event? *	<input type="text" value="Select"/>				

Outcome of the Event

Outcome of the Event at the time of the Report dated *	<input type="text"/>	Please Select *	<input type="text" value="Select"/>
---	----------------------	------------------------	-------------------------------------

← Previous
Save
Reset

Figure 17: 14th day Due Analysis Report (SAE Details)

Investigational/Suspected drug(s)/Device Details

Note:

- * All fields are mandatory to fill.
- Click on **Edit Icon** to add details for each table row.
- If below Drug Details table is not visible then kindly Refresh the page by pressing F5 button.

Fill the following details

Generic Name: *	<input type="text" value="Generic Name"/>	Strength: *	<input type="text"/>	Units: *	<input type="text" value="Select"/>
Route of Administration: *	<input type="text" value="Select"/>	Dosing Frequency: *	<input type="text"/>	Indication for use: *	<input type="text"/>
Start Date & Time:	<input type="text"/>		<input type="text" value="Enter start time e.g. 11:15am"/>		
Stop Date & Time:	<input type="text"/>		<input type="text" value="Enter stop time e.g. 01:45pm"/>		
Therapy Duration:	<input type="text"/>		Suspected: *	<input type="text" value="Select"/>	
Date of Last dose taken prior to the SAE *	<input type="text"/>		Whether Study regimen altered in response to the SAE? *	<input type="text" value="Select"/>	
Pharmacology of Drug					
Pharmacokinetics (ADME)/Pharmacodynamics*	<input type="text" value="Enter Pharmacokinetics (ADME)/Pharmacodynamics"/>				
Elimination t1/2 *	<input type="text" value="Enter Elimination"/>				
Mechanism of Action *	<input type="text" value="Enter Mechanism of Action"/>				

Figure 18: 14th day Due Analysis Report (Investigational/Suspected drugs/Device details)

Concomitant Drug Details

Note:

- * All fields are mandatory to fill.
- If any Concomitant Drug(s) is not taken by the subject/patient then no need to save data for this section.
- If selected Yes then multiple drug details can be saved by click on 'Add Drug' button for each drug.
- After all drug details are added click on 'Submit Form' button.

Fill the following details

Any Concomitant Drug(s) taken by the subject/patient.(Exclude those used for treating SAE)			<input type="text" value="Yes"/>		
Generic Name: *	<input type="text" value="Generic Name"/>	Strength: *	<input type="text"/>	Units: *	<input type="text" value="Select"/>
Dosing Frequency: *	<input type="text"/>	Route of Administration: *	<input type="text" value="Select"/>	Indication for use: *	<input type="text"/>
Start Date:	<input type="text"/>		<input type="text" value="Enter start time e.g. 11:15am"/>		
Stop Date:	<input type="text"/>		<input type="text" value="Enter stop time e.g. 01:45pm"/>		
Therapy Duration:	<input type="text"/>		Suspected: *	<input type="text" value="Select"/>	

Figure 19: 14th day Due Analysis Report (Concomitant Drug Details)

SAE Management

Note:

- * All fields are mandatory to fill
- If selected Yes then multiple drug details can be saved by **click on 'Add Drug'** button for each drug.
- After all drug details are added, fill rest data in form and **click on 'Submit Form'** button.

Fill the following details

Date of Hospitalization (Admission Date)

Date of Discharge Available?*

Please upload related documents

Copy of Discharge Summary available?*

Copy of Death Certificate available?

Copy of Autopsy report available?

Details about Drugs/treatment used in SAE Management

Any Drugs/treatment used in SAE Management *

Figure 20: 14th day Due Analysis Report (SAE Management)

Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)
(14th day report, Initial and Subsequent Follow-Up)

Baseline Lab Investigation Details (At time of screening)

Note:

- To add details in this section download the given template and upload the Lab Investigations details excel sheet only in given format.
- Please read Guidelines to Fill Lab Investigations Details in Excel Sheet.

Lab Test Details

Guidelines to Fill Lab Investigations Details in Excel Sheet

<p>Upload Lab Investigations Sheet * <small>(Single Excel File < 10 MB)</small></p> <p><input type="button" value="Choose File"/> No file chosen</p>	<p>Download and Fill this Excel sheet Template and Upload the same here</p>	
<p>Upload Scan Report (Single Pdf File < 10 MB)</p> <p><input type="button" value="Choose File"/> No file chosen</p>	<p>Upload Histopathology report (Single Pdf File < 10 MB)</p> <p><input type="button" value="Choose File"/> No file chosen</p>	

Figure 21: 14th day Due Analysis Report (Baseline Lab Investigation Details)

Due Analysis Report

(To be filled by Investigators/Sponsors/CROs)
(14th day report, Initial and Subsequent Follow-Up)

Details of lab investigations done during clinical trial and SAE

Note:
1. To add details in this section download the given template and upload the Lab Investigations details excel sheet only in given format.
2. Please read Guidelines to Fill Lab Investigations Details in Excel Sheet.

Lab Test Details

Guidelines to Fill Lab Investigations Details in Excel Sheet

<p>Upload Lab Investigations Sheet * (Single Excel File < 10 MB)</p>	<input type="button" value="Choose File"/> No file chosen	Download and Fill this Excel sheet Template and Upload the same here	
<p>Upload Scan Report (Single Pdf File < 10 MB)</p>	<input type="button" value="Choose File"/> No file chosen	<p>Upload Histopathology report (Single Pdf File < 10 MB)</p>	<input type="button" value="Choose File"/> No file chosen

Figure 22: 14th day Due Analysis Report (Lab Investigation done during clinical trial)

Due Analysis Report
(To be filled by Investigators/Sponsors/CROs)
(14th day report, Initial and Subsequent Follow-Up)
Due analysis/Causality of the SAE

SAE case narration

SAE case narrative should cover following points. *

1. Date of Screening and Date of Randomization
2. Medical history of the subject at the time of entry/randomization to the study
3. Date of first dose of study drug, concomitant medications etc.
4. Lab tests reports / values at the time of enrollment
5. Detailed description of the SAE and lab investigations reports at the time of the SAE
6. Medical management of the SAE
7. Probable causes of the event
8. Description of different Study Drugs
9. Description of different Concomitant Drugs

1. Date of Screening *  Date of Randomization 

2. Medical history of the subject at the time of entry/randomization to the study *

3. Date of first dose of study drug  Date of first dose of concomitant medications 

4. Remarks on lab tests reports/ values at the time of enrolment *

5. Detailed description of SAE *

6. Medical management of the SAE *

7. Probable causes of the event *

8. Description of different Study Drugs

9. Description of different Concomitant Drugs

Figure 23: 14th day Due Analysis Report (Due Analysis/Causality of the SAE (Part 1))

Causality Analysis

Adverse effect of investigational product(s) *

Violation/Deviation of the approved protocol, scientific misconduct or negligence by the Sponsor or his representative or the investigator *

Failure of investigational product to provide intended therapeutic effect where, the required standard care or rescue medication, though available, was not provided to the subject as per clinical trial protocol *

Use of placebo in a placebo-controlled trial [where, the standard care, though available, was not provided to the subject as per clinical trial protocol] *

Adverse effects due to concomitant medication excluding standard care, necessitated as part of the approved protocol *

Adverse effect on a child in-utero because of participation of the parent in the clinical trial *

Any other procedures involved during the clinical study *

Assessment

SAE Assessment by Investigator with Reasoning for Relatedness/Un Relatedness as per criteria under Rule 41 of New Drugs & Clinical Trial Rules, 2019. *

Reason for not submitting SAE due analysis report by Investigator within timeline as per Rule 42 of New Drugs & Clinical Trial Rules, 2019.

← Previous Save Reset

Figure 24: 14th day Due Analysis Report (Due Analysis/Causality of the SAE (Part 2))

Upload Documents

SAE(s) Details

1. Copy of Signed Informed Consent Form of the Subject/Patient*
(Single Pdf File < 10 MB)

No file chosen

2. Copy of Protocol version on which the subject was at the time of occurrence of SAE-death/injury *
(Single Pdf File < 10 MB)

No file chosen

3. Upload Updated Table 5 *
(Single Pdf File < 10 MB)

No file chosen

4. Upload Standard of Care given *
(Single Pdf File < 10 MB)

No file chosen

5. Upload CIOMS
(Single Pdf File < 10 MB)

No file chosen

Figure 25: 14th day Due Analysis Report (Upload Document)

Intervention Drug Details

Note:

- * All fields are mandatory to fill
- Multiple drug details can be saved by click on 'Add Drug' button for each drug.

Fill the following details

Generic Name: *	<input type="text" value="Generic Name"/>	Strength: *	<input type="text"/>	Units: *	<input type="text" value="Select"/>
Dosing Frequency: *	<input type="text"/>	Route of Administration: *	<input type="text" value="Select"/>	Indication for use: *	<input type="text"/>
Start Date & Time:	<input type="text"/>		<input type="text" value="Enter start time e.g. 11:15am"/>		
Stop Date & Time:	<input type="text"/>		<input type="text" value="Enter stop time e.g. 01:45pm"/>		
Therapy Duration:	<input type="text"/>				

Figure 26: 14th day Due Analysis Report (Intervention Drug Detail)

Comparator Drug Details

Note:

- * All fields are mandatory to fill
- If any Comparator Drug(s) is not taken by the subject/patient then no need to save data for this section.
- If selected Yes then multiple drug details can be saved by **click on 'Add Drug' button** for each drug.
- After all drug details are added **click on 'Submit Form' button**.

Fill the following details

Is there any comparator drug ?		<input type="text" value="Yes"/>	
Generic Name: *	<input type="text" value="Generic Name"/>	Strength: *	<input type="text"/>
Dosing Frequency: *	<input type="text"/>	Route of Administration: *	<input type="text" value="Select"/>
Start Date:	<input type="text"/>	Enter start time e.g. 11:15am	<input type="text" value="Select"/>
Stop Date:	<input type="text"/>	Enter stop time e.g. 01:45pm	<input type="text"/>
Therapy Duration:	<input type="text"/>	Suspected: *	<input type="text" value="Select"/>

← Previous
+ Add Drug
↺ Reset

Figure 27: 14th day Due Analysis Report (Comparator Drug Detail)

After filling all forms of 14Day due Analysis Report, PI have to submit it by clicking on “SAE Reporting 14Day form Preview” link as shown in Figure below:

Due Analysis Report

Note:

- All forms are mandatory to fill
- Below forms should be filled sequentially.

Click the below links to fill the details

- Steps to fill SAE Reporting Form
 - 1. Administrative Information ✓
 - 2. Patient/subject Details ✓
 - 3. SAE(s) Details ✓
 - 4. Investigational/Suspected drug(s)/Device Details ✓
 - 5. Any concomitant Drug(s) taken by the subject/patient (Exclude those used for treating SAE) ✓
 - 6. SAE Management ✓
 - 7. Baseline Lab Investigation Details (At the time of screening) ✓
 - 8. Details of Lab Investigation done (On and before Onset of SAE) ✓
 - 9. SAE case narrative and Due analysis/Causality of the SAE ✓
 - 10. Upload Documents ✓
 - 11. Intervention Drug(s) Details ✓
 - 12. Comparator Drug(s) Details ✓
- SAE Reporting 14th Day Form Preview

Figure 28: Filled Form List of 14D Report by PI

After final submission of 14th Day SAE report, a unique file number is generated for future reference as shown in Figure below:



Figure 29: File number for 14Day report by PI

List of Serious Adverse Events Reported by Site Investigator

Search:

BE or CT NOC No.	Application File No.	CTRI Registration No.	SAE Terminology	SAE Type	Sponsor's created Subject Id	Status	Processing Status	Action
+ BE-EXPORT/19/002135	CT/SAE-ND-82/2020-278(24Hours)		Test SAE	Other than Death	XYZ1	SAE 24 Hour Report Submitted by Investigator	Inprocess	
+ BE-EXPORT/19/002135	CT/SAE-ND-82/2020-279(14Days)		Test SAE	Other than Death	XYZ1	SAE 14 Day Report Submitted by Investigator	Inprocess	

Figure 30: List of SAEs reported by Site Investigator

2.3 SAE Reporting (14th Day Report by Sponsor)

After 14-day report submitted by Investigator, the file will be displayed on Sponsor’s dashboard as shown in Figure below:

List of Serious Adverse Events Reported by Site Investigator

14D Reporting | 24Hr Reporting

Search:

BE or CT NOC No.	Application File No.	CTRI Registration No.	SAE Terminology	SAE Type	Sponsor's created Subject Id	Status	Processing Status	Action
+ BE-EXPORT/19/002168	CT/SAE-ND-53/2020-226(14Days)	AbhiBE2504	Hyperglycemia	Other than Death	rohit/54/001	SAE 14 Day Report Submitted by Investigator	Inprocess	

Figure 31: List of SAEs reported by Site Investigator at Sponsor

After clicking on “SAE Reporting 14th Day Form Preview” link, Sponsor can see the preview details entered by Pland have to enter their remarks and submit 14 days report as shown in figure below:

Due Analysis Report

Note:

1. All forms are mandatory to fill
2. Below forms should be filled sequentially.

Click the below links to fill the details

- Steps to fill SAE Reporting Form
- SAE Reporting 14th Day Form Preview

Figure 32: List of SAEs forms by Sponsor

Analysis

Pre-Existing/underlying Disease (Specify the disease condition) [qwewqe](#)

Due to Study drug (Specify the drugs related to SAE with reasoning) [qwqw](#)

Due to Concomitant Medication (Specify the details) [asdasd](#)

Protocol Violation (Specify) [asdasd](#)

Medical Mismanagement (Specify) [qwqwqe](#)

Others (eg. Accident, New or current illness) (Specify) [asdas](#)

SAE Assessment by Investigator with Reasoning for Relatedness/Un Relatedness as per criteria under Rule 41 of New Drugs and Clinical Trials Rules. [asdasd](#)

Sponsor Remarks

SAE Assessment by Sponsor/CRO with Reasoning for Relatedness/Un Relatedness as per criteria under Rule 41 of New Drugs and Clinical Trials Rules.

Copy of Investigator Brochure*
(Single Pdf File < 10 MB)

Choose File

 No file chosen

Filled copy of CRF/Patient admission records *
(Single Pdf File < 10 MB)

Choose File

 No file chosen

Compensation paid Before(If Yes upload Document)
(Single Pdf File < 10 MB)

Choose File

 No file chosen

CIOMS
(Single Pdf File < 10 MB)

Choose File

 No file chosen

Submit Form

Figure 33: SAE 14 days Due Analysis Report Form by Sponsor

After final submission of 14th Day SAE report by Sponsor, a unique file number will be generated for future reference as shown in Figure below:

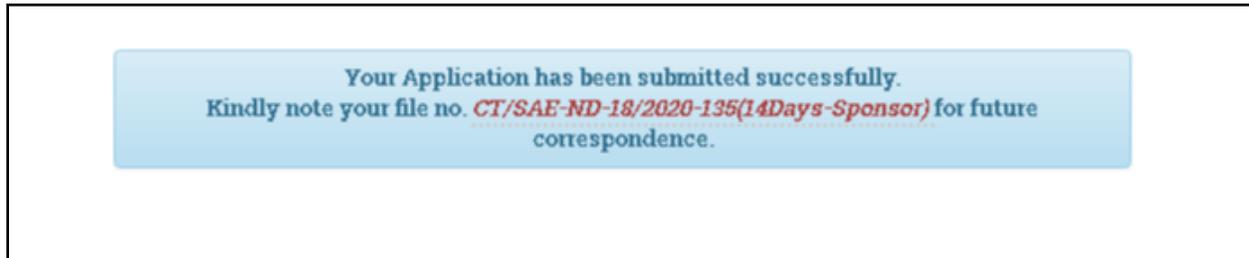


Figure 34: File number for 14D report by Sponsor

After submitting 14 days report by sponsor, the status of this file will be changed on Sponsor’s dashboard and this file will be visible to Ethics committee to submit its 30 Day report as shown in Figure.

List of Serious Adverse Events Reported by Site Investigator

30D Reporting
24Hr Reporting

Search:

BE or CT NOC No. ⌵	Application File No. ⌵	CTRI Registration No. ⌵	SAE Terminology ⌵	SAE Type ⌵	Sponsor's created Subject Id ⌵	Status ⌵	Processing Status ⌵	Action ⌵
+ BE-EXPORT/19/002168	CT/SAE-ND-53/2021-287(14Days-Sponsor)	AbhiBE2504	Hyperglycemia	Other than Death	rohit/54/001	SAE 14 Day Report Submitted by Sponsor	Inprocess	

Figure 35: List of SAEs reported by Sponsor at EC

2.4 SAE Reporting (30th Day Report)

After 14th day SAE report is submitted by investigator and sponsor, the ethics committee may proceed to fill its 30th day SAE Report.

Step 1 - First map ethics committee form shown as figure: -

Figure 36: Ethics Committee Mapping Form

Step 2 - After mapping the form, EC go to SAE Reported option as shown figurebelow:

Figure 37: SAE Reported option in the dashboard

Step 3 - EC can see the preview of submitted 24th and 14th day reports and fill the 30th days form: -

List of Serious Adverse Events Reported by Site Investigator

30D Reporting 24Hr Reporting

Search:

BE or CT NOC No. ↓	Application File No. ↓	CTRI Registration No. ↓	SAE Terminology ↓	SAE Type ↓	Sponsor's created Subject Id ↓	Status ↓	Processing Status ↓	Action ↓
+ BE-EXPORT/19/002168	CT/SAE-ND-53/2021-287(14Days-Sponsor)	AbhiBE2504	Hyperglycemia	Other than Death	rohit/54/001	SAE 14 Day Report Submitted by Sponsor	Inprocess	<div style="border: 2px solid red; padding: 5px;"> View SAE Report(24 Hour) Preview View SAE Report(14th Day) Preview 30th day SAE Reporting </div>

Figure 38: List of SAEs reported by Site Investigator at EC

Step 4 –30days form will open in new window and it looks as below: -

Menu ☰ Welcome Dr. Anand Patel (Ethics Committee) Home Change Password Logout

Central Drugs Standard Control Organisation
 Directorate General Of Health Services
 Ministry of Health & Family Welfare, Government of India

SAE Reporting

(30 Day)
(To be Filled by Ethics Committee)

Patient/Subject Details

Patient Unique Identifier (Initials/ Subject No.) AA/2016/54/144

Gender Male Date of Birth 05-Jan-2001 Age at the time of SAE in Yrs

Administrative Information

Sponsor/CRO Details

Name: M/s. Alembic Pharmaceuticals Limited

Address: Alembic Road Vadodara Vadodara Gujarat (India) - 390 003

Mobile No. : 91-265-3007590

Landline No. :

Email ID. :

Clinical Site Details

Name: M/s. Cliantha Research India Ltd.

Address: M/s. Cliantha Research India Ltd., 1st floor Silver Arcade, Near Ashwamegh-III, Samrajya, Mujmahuda Road, Akota, , Vadodara, Vadodara, Gujarat- 390020

Figure 39: SAE Reporting (Part 1)

EC have to fill following details: -

1. SAE(s) details
2. Upload Minutes of Meetings.
3. Chairman Details
4. Due analysis report

Study Title:	A Randomized, Double-Blind, Multicenter, Three arm, Active and Placebo Controlled, Parallel Study to Evaluate the Bioequivalence (with clinical endpoint) of Adapalene and Benzoyl Peroxide Gel, 0.3%/2.5% (Cadila Healthcare Ltd, India) to EPIDUO? FORTE (Adapalene and Benzoyl Peroxide) Gel, 0.3%/2.5% (Galderma Laboratories, L.P, USA) in Subjects with Acne Vulgaris.		
Protocol No.:	CRL031816		

SAE(s) Details

SAE report of Death or other than Death * Death other than Death

SAE(s) Terminology *

Start Date of SAE(s) * 29/03/2020 Stop Date of SAE(s)

Table-5 (24 hr. Report) * [Download](#) Updated Table-5 (14day Report) * [Download](#)

Minutes of Meetings for review of SAE.

Upload Minutes of Meeting * No file chosen
(Single PDF File < 10 MB)

Chairman Details

Chairman Name:* ✖
Chairman Name is required and cannot be empty

Chairman Address:* ✖
Chairman Address is required and cannot be empty

Due analysis report/ assessment report of SAE duly signed by Chairman/Member Secretary (with reasoning, Justification & criteria under Rule 41 of New Drugs and Clinical Trials Rules).

Relatedness* ✖
Please choose an option

Remarks:* ✖
Remarks is required and cannot be empty

Figure 40: SAE Reporting (Part 2)

Once EC has filled all required details, there is an option to “save as draft” for future modification and status will change as shown in figure below:

List of Serious Adverse Events Reported by Site Investigator

30D Reporting 24Hr Reporting

Search:

BE or CT NOC No. ↓	Application File No. ↓	CTRI Registration No. ↓	SAE Terminology ↓	SAE Type ↓	Sponsor's created Subject Id ↓	Status ↓	Processing Status ↓	Action ↓
+ BE/18/002491	CT/SAE-ND-64/2020-277(30Days)	TESTINGDEEPSHIKHA	sdasd	Other than Death	patient 01	SAE 30th Day Report Saved as Draft	NA	

Figure 41: List of SAEs reported by EC

After saving the form, EC will have option to modify the form

List of Serious Adverse Events Reported by Site Investigator

30D Reporting 24Hr Reporting

Search:

BE or CT NOC No. ↓	Application File No. ↓	CTRI Registration No. ↓	SAE Terminology ↓	SAE Type ↓	Sponsor's created Subject Id ↓	Status ↓	Processing Status ↓	Action ↓
+ BE/18/002491	CT/SAE-ND-64/2020-277(30Days)	TESTINGDEEPSHIKHA	sdasd	Other than Death	patient 01	SAE 30th Day Report Saved as Draft	NA	<div style="border: 1px solid red; padding: 5px;"> Delete Form View/Modify/Submit SAE Form View SAE Report(24 Hour) Preview View SAE Report(14th Day) Preview </div>

Figure 42: Options to modify the form

After final submission of 30th Day SAE report by EC, a unique file number will be generated for future reference as shown in Figure below:

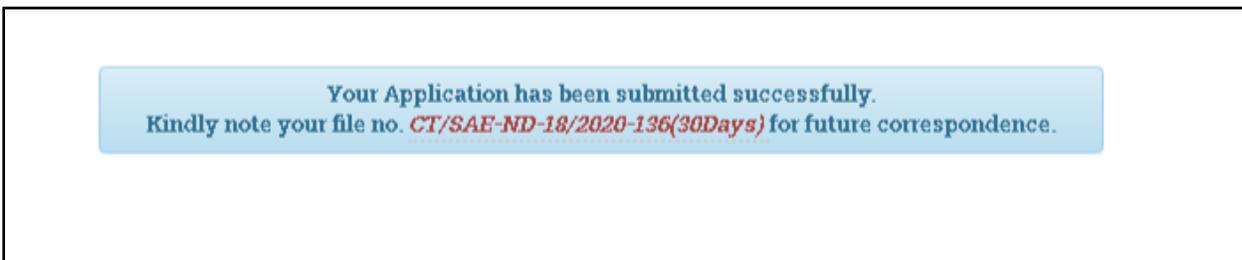


Figure 43: File number for 30th Day report by EC

After successful submission, status will change as shown in Figure below:

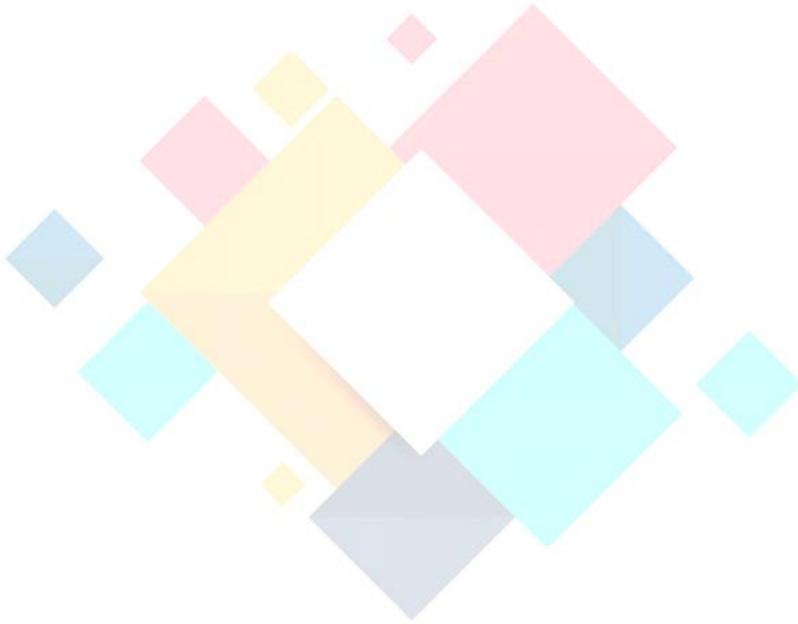
List of Serious Adverse Events Reported by Site Investigator

30D Reporting
24Hr Reporting

Search:

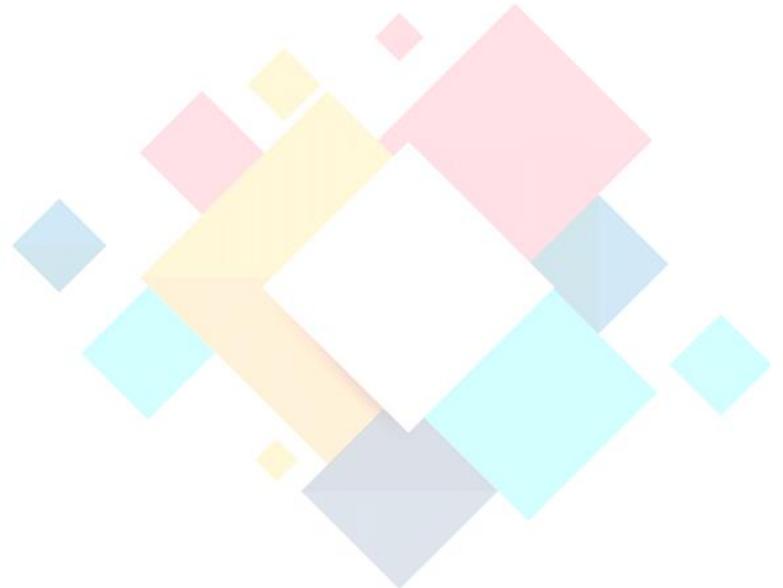
BE or CT NOC No. ⌵	Application File No. ⌵	CTRI Registration No. ⌵	SAE Terminology ⌵	SAE Type ⌵	Sponsor's created Subject Id ⌵	Status ⌵	Processing Status ⌵	Action ⌵
+ BE/18/002491	CT/SAE-ND-41/2020-193(30Days)	TESTINGDEEPSHIKHA	Test SAE	Other than Death	T patient 1	SAE 30th Day Report Submitted by EC	Inprocess	⌵

Figure 44: Successful form submission



Chapter- 3

SAE Reporting For Offline CT (Applicable for CT-NOC's issued offline and not through SUGAM online application system)



To Report SAE Firstly Sponsor has to map the offline CT Application with Investigator

Click on “*Offline CT Investigator Mapping*” tab under “*Clinical Trials*” in Menu as shown in figure below:

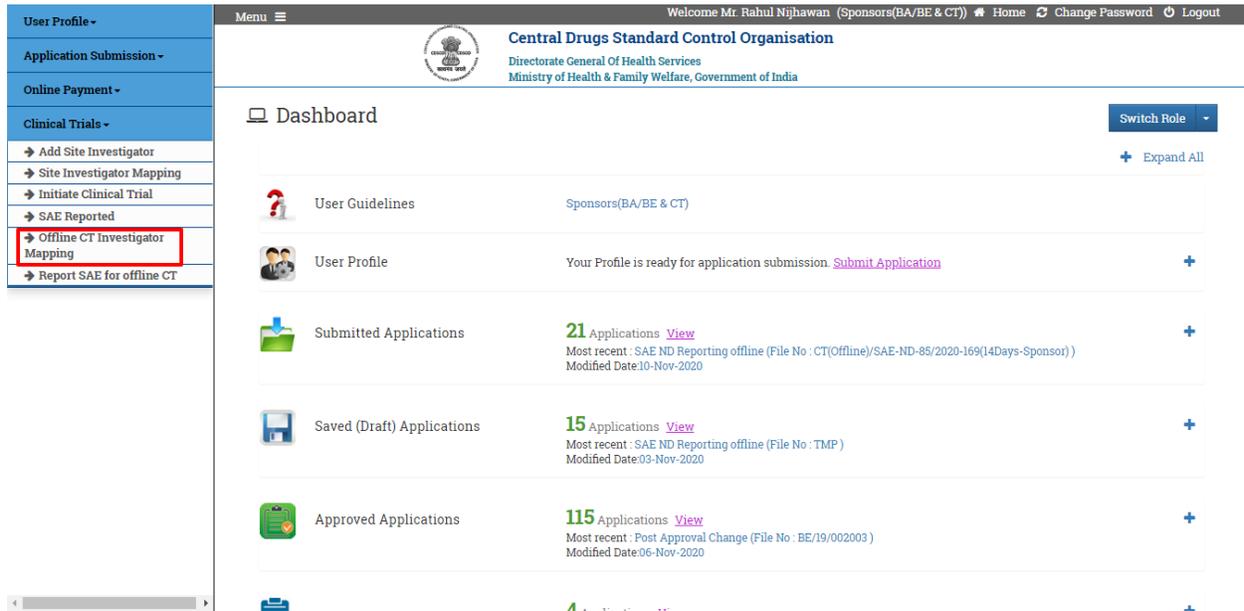


Figure 445: Sponsor Dashboard

After clicking on the “*Offline CT Investigator Mapping*” tab , mapping page will be shown to map the offline CT with Investigator as shown in figure below:

Menu ☰
Welcome Mr. Rahul Nijhawan (Sponsors(BA/BE & CT))
Home ↻ Change Password ↻ Logout



Central Drugs Standard Control Organisation
 Directorate General Of Health Services
 Ministry of Health & Family Welfare, Government of India

Offline CT Investigator Mapping

*** All fields are mandatory**

BE / CT Application: *

Select Investigator: *

[Save](#)

Details:

Search:

Sr.No. ⚙	BE/CT Application No. ⚙	Investigator Id ⚙
1	BE/CT-Off-0011	dimpysingh1994@gmail.com
2	BE/CT-OFF-0022	TMPSNAIK@CIPLA.COM
3	BE/CT-OFF-0023	DIMPYSINGHI994@GMAIL.COM
4	BE-CT0123	DIMPYSINGHI994@GMAIL.COM
5	BE/CT-Offline-2233	DIMPYSINGHI994@GMAIL.COM
6	BE-CT-Off-0011222	DIMPYSINGHI994@GMAIL.COM
7	ABC12345	INVESTIGATOR@GMAIL.COM
8	CNT0148ARA4007	INVESTIGATOR@GMAIL.COM
9	CNT0148ARA4007	INVESTIGATOR@GMAIL.COM
10	CNT0148ARA4007	INVESTIGATOR@GMAIL.COM


Designed, Developed and Maintained by C-DAC.

Figure 46: Offline CT Investigator Mapping Page

To report serious adverse events (SAE) for Offline CT , there are three types of forms same as SAE reporting for online CT:

- SAE Reporting (24-hour Report by PI)
- SAE Reporting (14th Day Due Analysis Report by PI and Sponsor)
- SAE Reporting (30th Day Report by Ethics Committee)

Investigator has to click on “Report Offline CT SAE” to report SAE for offline CT.

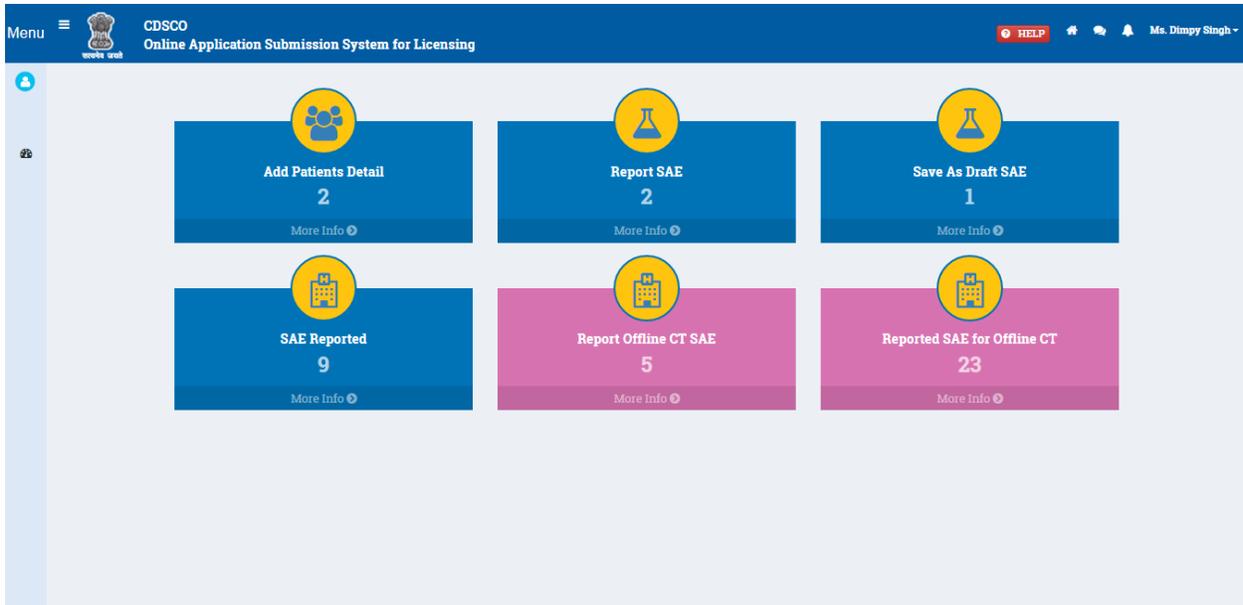


Figure 47: Investigator Dashboard

3.1 SAE Reporting (24 Hours)

Investigator will fill the *SAE Reporting* form with the following details:

- **BE/CT Application Number**
- **SAE Report Type**
- **Site No**
- **Protocol No**
- **Investigator Name**
- **Subject No**

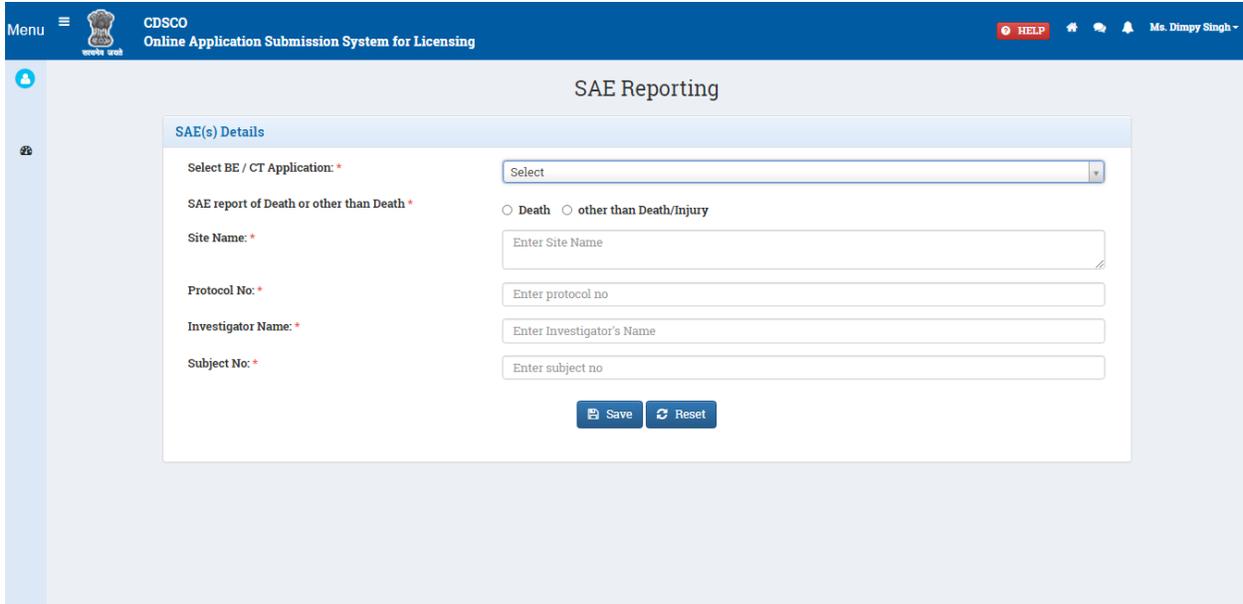


Figure 48: SAE Reporting Form

Investigator can see the preview of the form after save as shown in below figure:

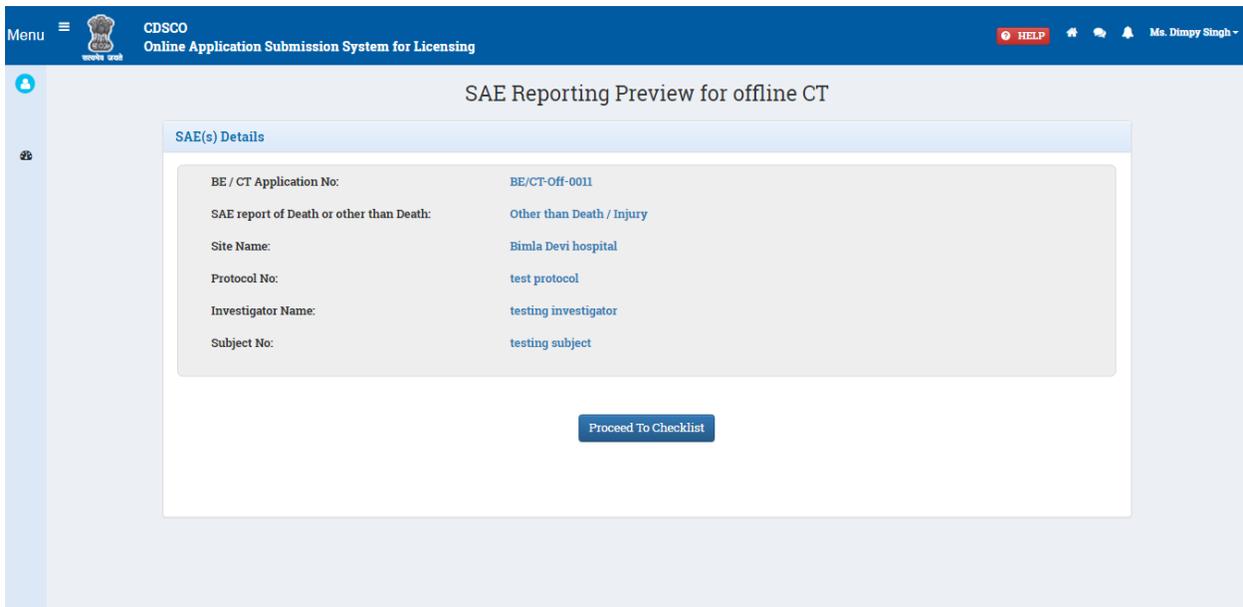


Figure 49: SAE Reporting Preview

Investigator has to fill Checklist For 24H reporting after clicking on “Proceed To Checklist” shown in below figure:

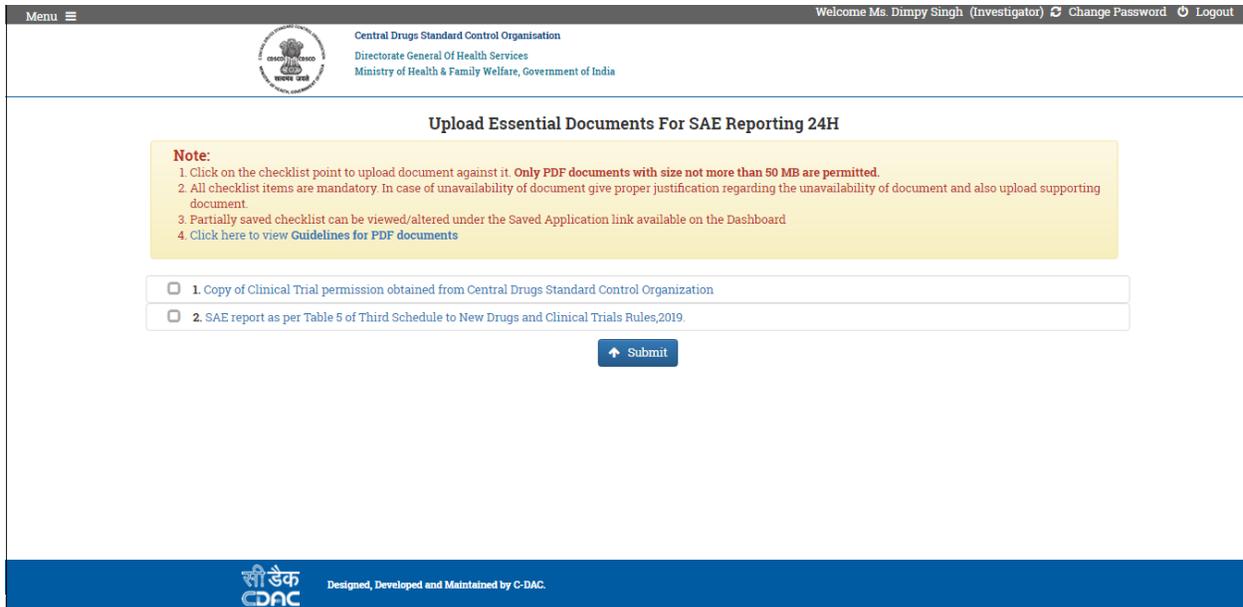


Figure 50: Checklist page for 24H SAE Reporting

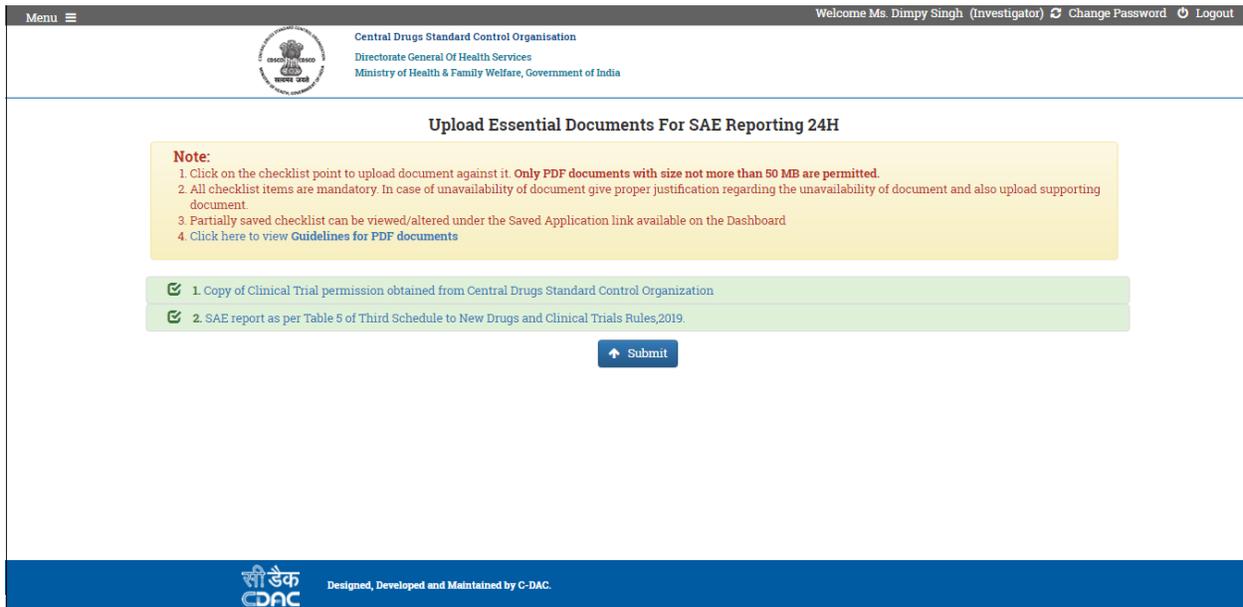


Figure 51: Checklist page for 24H SAE Reporting

After filling all the checklist items investigator has to click on “Submit” button for the final submission of the SAE Reporting .

After final submission of 24H SAE report by Investigator, a unique file number will be generated for future reference as shown in Figure below:



Figure 52: Successful form submission

After 24H SAE reporting , the 24H application is shown on Sponsor as well as to EC to fill 14D SAE reporting and 30D SAE Reporting respectively.

3.2 SAE Reporting (14th Day due Analysis Report)

After 24-hour SAE report is submitted, investigator may proceed to fill the 14Day Due Analysis Report.

List of Serious Adverse Events Reported by Site Investigator

BE or CT NOC No. ↓	Application File No. ↓	Site Name ↓	SAE Type ↓	Sponsor's created Subject Id ↓	Status ↓	Processing Status ↓	Action ↓
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-212(24Hours)	Bimla devi hospital	Other than Death	tesing subject	SAE 24 Hour Report Submitted by Investigator	Inprocess	<ul style="list-style-type: none"> View Preview View Checklist 14th day Due Analysis Reporting

Figure 53: SAE Reporting List

After clicking on “14th Day Due Analysis reporting” action, Investigator can see the preview of the form.

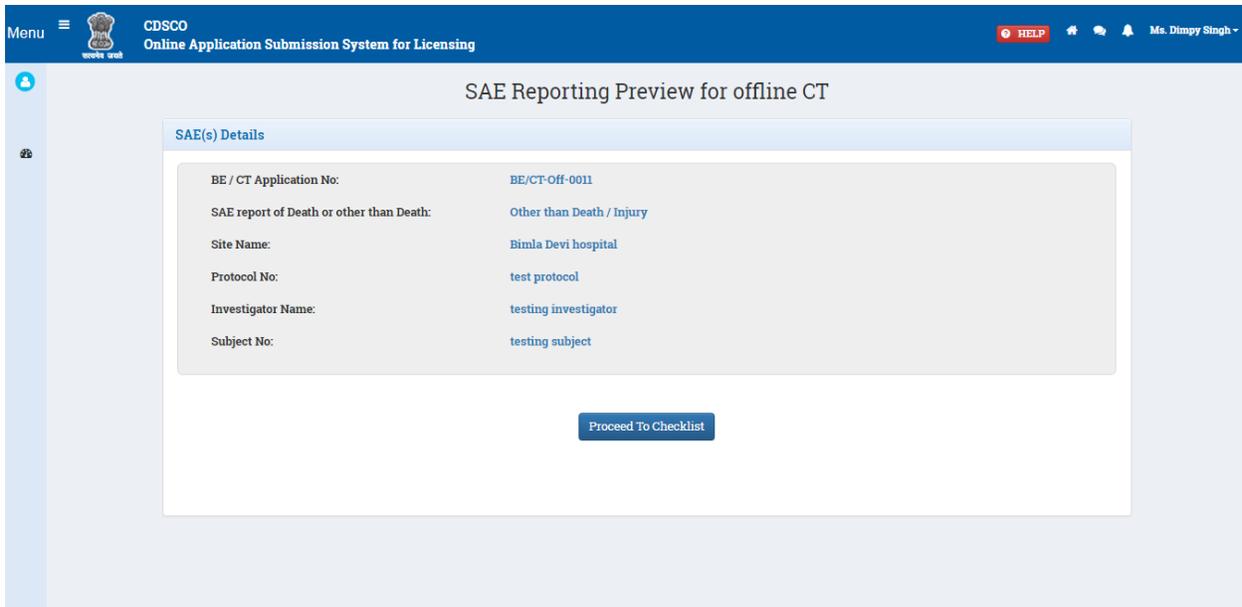


Figure 54: SAE Reporting Form Preview

Investigator has to fill Checklist For 14th Day reporting after clicking on “Proceed To Checklist” shown in below figure:



Figure 55: Checklist page for 14D SAE reporting

After filling all the checklist items investigator has to click on “Submit” button for the final submission of the SAE Reporting .
 After final submission of 14th Day SAE report by Investigator, a unique file number will be generated for future reference as shown in Figure below:



Figure 56: Successful form submission

3.3 SAE Reporting (14th Day Report by Sponsor)

After 14-day report submitted by Investigator, the file will be displayed on Sponsor’s dashboard as shown in Figure below:

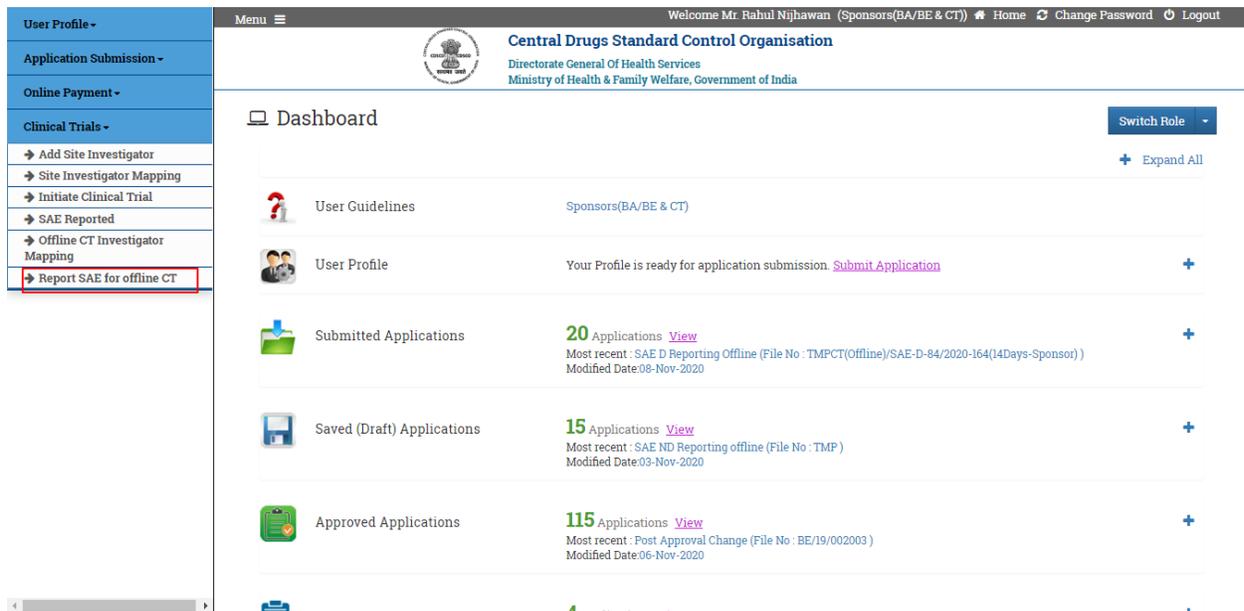


Figure 57: Sponsor Dashboard

List of Serious Adverse Events Reported by Site Investigator

Search:

BE or CT NOC No. ▾	Application File No. ▾	Site Name ▾	SAE Type ▾	Sponsor's created Subject Id ▾	Status ▾	Processing Status ▾	Action ▾
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-212(24Hours)	Bimla devi hospital	Other than Death	tesing subject	SAE 24 Hour Report Submitted by Investigator	Inprocess	<ul style="list-style-type: none"> View Preview View Checklist 14th day Due Analysis Reporting
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-213(14Days)	Bimla devi hospital	Other than Death	tesing subject	SAE 14		

Figure 58: SAE Reporting List

After clicking on “14th Day Due Analysis reporting” action, Investigator can see the preview of the form.

Menu CDSCO Online Application Submission System for Licensing HELP Ms. Dimpy Singh

SAE Reporting Preview for offline CT

SAE(s) Details

BE / CT Application No:	BE/CT-OFF-0011
SAE report of Death or other than Death:	Other than Death / Injury
Site Name:	Bimla Devi hospital
Protocol No:	test protocol
Investigator Name:	testing investigator
Subject No:	testing subject

[Proceed To Checklist](#)

Figure 59: SAE Reporting Preview

Sponsor has to fill Checklist For 14th Day reporting after clicking on “Proceed To Checklist” shown in below figure:

Upload Essential Documents For SAE Reporting 14D

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. [Click here to view Guidelines for PDF documents](#)

<input type="checkbox"/> 1. Due analysis report on causality assessment with reasoning for Relatedness/Un-Relatedness
<input type="checkbox"/> 2. Complete copy of duly filled and signed CRF/e-CRF
<input type="checkbox"/> 3. Investigator Brochure

 Submit

Figure 60: Checklist Page for 14D SAE Reporting by Sponsor

After filling all the checklist items Sponsor has to click on “Submit” button for the final submission of the SAE Reporting .

After final submission of 14th Day SAE report by Sponsor, a unique file number will be generated for future reference as shown in Figure below:



Figure 61: Successful form submission

3.4 SAE Reporting (30th Day Report)

After 14th day SAE report is submitted by investigator and sponsor, the ethics committee may proceed to fill its 30th day SAE Report.

Step 1 - First map ethics committee form shown as figure: -

The dashboard shows the following navigation menu items under Clinical Trials:

- Ethics Committee Mapping
- SAE Reported
- Report SAE for offline CT
- Map Offline CT (highlighted)

The dashboard content includes:

- User Guidelines: Ethics Committee Registration Guidelines
- User Profile: Your Profile is ready for application submission. [Submit Application](#)
- Submitted Applications: 12 Applications [View](#). Most recent: SAE ND Reporting offline (File No : CT(Offline)/SAE-ND-85/2020-170(30Days)) Modified Date:10-Nov-2020
- Saved (Draft) Applications: 12 Applications [View](#). Most recent : SAE ND Reporting offline (File No : TMP) Modified Date:08-Nov-2020
- Approved Applications: 2 Applications [View](#). Most recent : SAE ND Reporting offline (File No : BE/CT-Offline-2233) Modified Date:26-Oct-2020
- Rejected Applications: 0 Applications [View](#)

Figure 62: EC Dashboard

Step 2 - After mapping the form, EC go to SAE Reported option as shown figure below:

The form is titled "Offline CT Investigator Mapping" and includes a dropdown menu to "Select BE / CT Application:" and a "Save" button. Below is a table of application details:

Sr.No.	BE/CT Application No.
1	BE/CT-Off-0011
2	BE/CT-OFF-0022
3	BE/CT-OFF-0023
4	BE-CT0123
5	BE/CT-Offline-2233
6	BE-CT-Off-0011222
7	ABC12345
8	CNT0148ARA4007
9	CNT0148ARA4007

Figure 63: Offline CT Investigator Mapping

Step 3 - EC can see the preview of submitted 24th and 14th day reports and fill the 30th days form: -

List of Serious Adverse Events Reported by Site Investigator

Search:

BE or CT NOC No. ↕	Application File No. ↕	Site Name ↕	SAE Type ↕	Sponsor's created Subject Id ↕	Status ↕	Processing Status ↕	Action ↕
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-213(14Days)	Bimla devi hospital	Other than Death	tesing subject	SAE 14 Day Report Submitted by Investigator	Inprocess	⌵
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-212(24Hours)	Bimla devi hospital	Other than Death	tesing subject	SAE 24 Hour Report Submitted by Investigator	Inprocess	⌵
+ CNT0148ARA4007	CT(Offline)/SAE-ND-99/2021-214(14Days-Sponsor)	Bimla devi hospital	Other than Death	tesing subject	SAE 14 Day Report Submitted by Sponsor		<ul style="list-style-type: none"> View Preview View Checklist 30th day SAE Reporting

Figure 64: SAE Reporting List

Step 4 –30days form will open in new window and it looks as below: -

SAE Reporting Preview for offline CT

SAE(s) Details

BE / CT Application No:	BE/CT-Off-0011
SAE report of Death or other than Death:	Other than Death / Injury
Site Name:	Bimla Devi hospital
Protocol No:	test protocol
Investigator Name:	testing investigator
Subject No:	testing subject

[Proceed To Checklist](#)

Figure 646: SAE Reporting Preview

EC has to fill Checklist For 30th Day reporting after clicking on “Proceed To Checklist” shown in below figure:

Upload Essential Documents For SAE Reporting 30D

Note:

1. Click on the checklist point to upload document against it. **Only PDF documents with size not more than 50 MB are permitted.**
2. All checklist items are mandatory. In case of unavailability of document give proper justification regarding the unavailability of document and also upload supporting document.
3. Partially saved checklist can be viewed/alterd under the Saved Application link available on the Dashboard
4. Click here to view [Guidelines for PDF documents](#)

1. Due analysis report on causality assessment as per Rule 41 of New Drugs and Clinical Trials Rules with reasoning for Relatedness/Un-Relatedness

Submit

Figure 66: Checklist Page for 30D SAE Reporting by EC

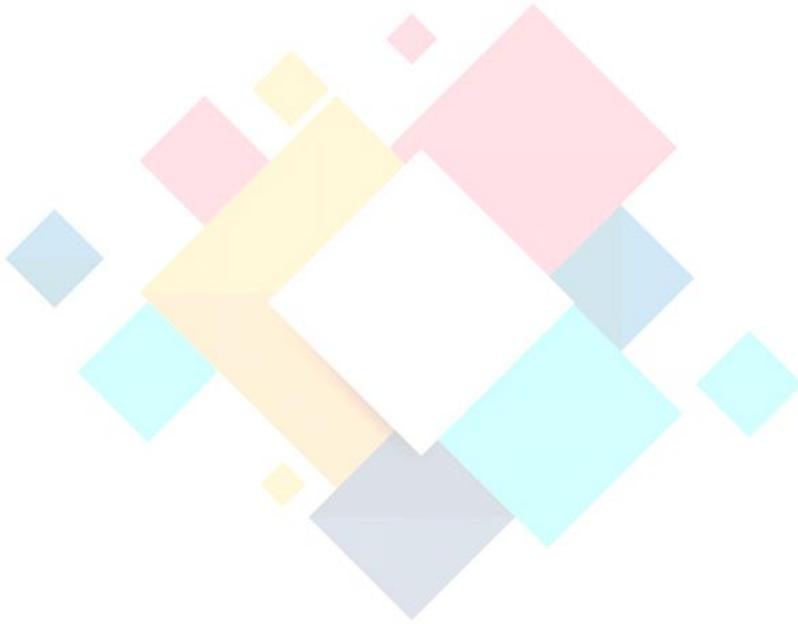
After filling all the checklist items EC has to click on “Submit” button for the final submission of the SAE Reporting .

After final submission of 30th Day SAE report by Sponsor, a unique file number will be generated for future reference as shown in Figure below:

Your Application has been submitted successfully.
Kindly note your file no. *CT(Offline)/SAE-ND-85/2020-170(30Days)* for future correspondence.

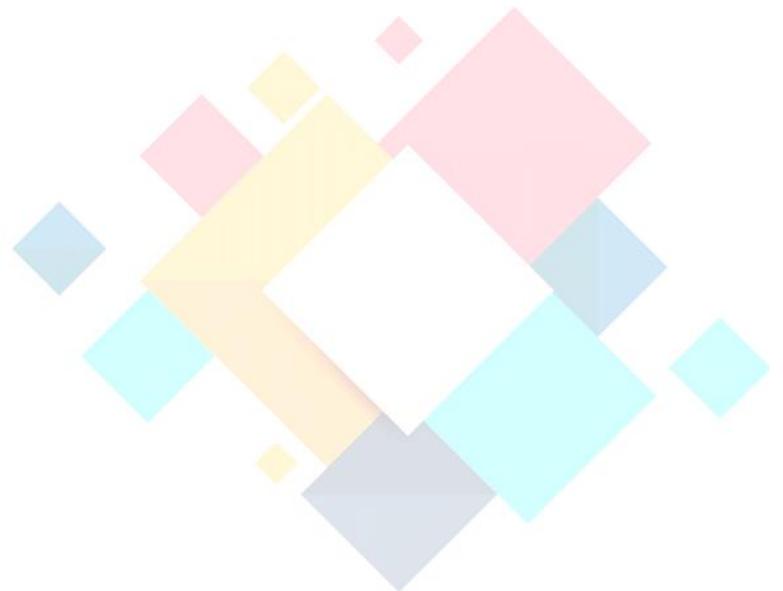
Close

Figure 67: Successful form submission



Chapter- 4

E-Vartalaap



To communicate with official, Applicant can use e-vartalaap facility.

Step 1: Click on chat icon which is just after the file number as shown in figure below:

List of Serious Adverse Events Reported by Site Investigator

30D Reporting
24Hr Reporting

Search:

BE or CT NOC No. ⌵	Application File No. ⌵	CTRI Registration No. ⌵	SAE Terminology ⌵	SAE Type ⌵	Sponsor's created Subject Id ⌵	Status ⌵	Processing Status ⌵	Action ⌵
+ BE-EXPORT/20/001166	CT/SAE-ND-9/2020	CTRI001166	fever	Other than Death	Patient sub 2	SAE 30th Day Report Submitted by EC	Inprocess	
+ BE-EXPORT/20/001166	CT/SAE-ND-4/2020-15(30Days)	CTRI001166	fever	Other than Death	Patient sub 2	SAE 30th Day Report Submitted by EC	Inprocess	
+ BE-EXPORT/20/001166	CT/SAE-ND-10/2020-29(30Days)	CTRI001166	test sae term	Other than Death	Patient sub 3	SAE 30th Day Report Submitted by EC	Inprocess	
+ BE-EXPORT/20/001234	CT/SAE-D-11/2020-33(30Days)	CTRI001234	sae death	Death	Patient sub 2L	SAE 30th Day Report Submitted by EC	Inprocess	

Figure 68: Chat icon in SAE Reporting List

After clicking on chat icon, a communication box has open for entering the remarks. Applicant can enter their remarks and uploaded the supported document(if any) as shown in below:

Menu
CDSO Online Application Submission System
HELP
Mr. Investigator Singh

Communications with Officials

Remarks:

Upload Document: (Single PDF < 10 MB) Download(WrittenConfirmation (21).pdf) Remove

Send
Cancel

BE or CT NOC No. ⌵	Application File No. ⌵	SAE Terminology ⌵	SAE Type ⌵	Sponsor's created Subject Id ⌵	Status ⌵	Processing Status ⌵	Action ⌵
+ BE-EXPORT/19/002135	CT/SAE-ND-8/2020-28(24Hours)				SAE 24 Hour Report Submitted by Investigator	Inprocess	
+ BE-EXPORT/19/002135	CT/SAE-ND-80/2020-276(24Hours)	COPD EXACERBATION	Other than Death	12345.0	SAE 24 Hour Report Submitted by Investigator	Inprocess	
+ BE-EXPORT/19/002135	CT/SAE-ND-82/2020-278(24Hours)	Test SAE	Other than Death	XYZ1	SAE 24 Hour Report Submitted by Investigator	Inprocess	
+ BE-EXPORT/19/002135	CT/SAE-ND-82/2020-279(14Days)	Test SAE	Other than Death	XYZ1	SAE 14 Day Report Submitted by Investigator	Inprocess	
+ BE-EXPORT/19/002135	CT/SAE-ND-85/2020-283(24Hours)	Test SAE123	Other than Death	XYZ1	SAE 24 Hour Report Submitted by Investigator	Inprocess	

Figure 69: Communication Model

After sending the message to the official, Applicant can view their previous communication on clicking on same chat icon as shown in figure below.

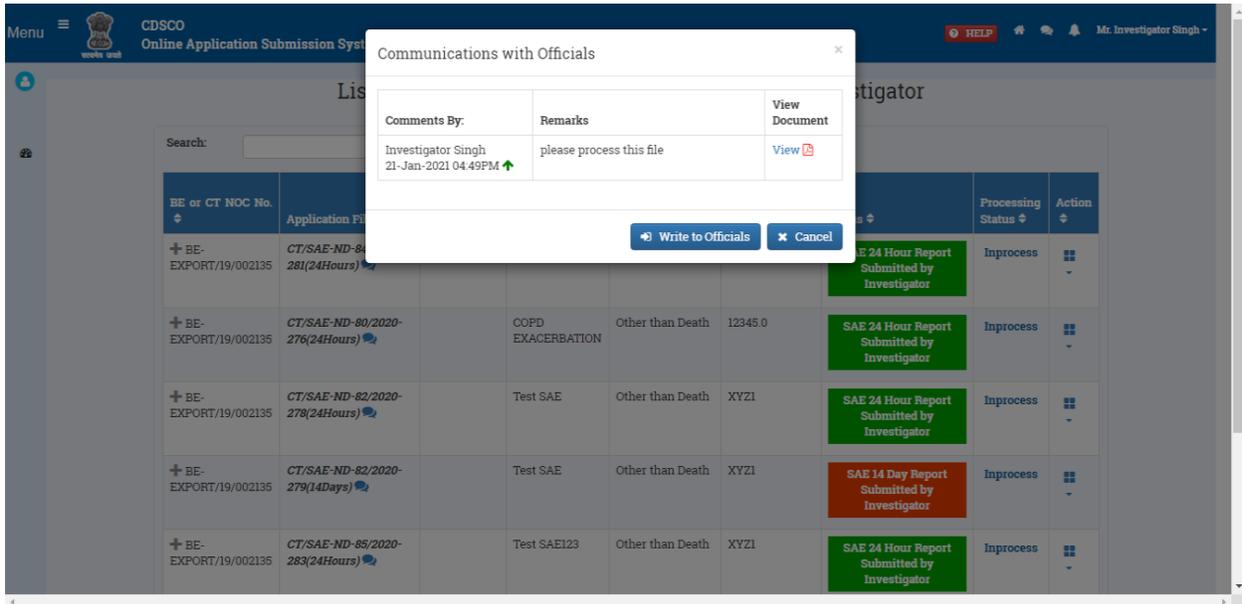


Figure 70: Previous Communication view

If Applicant can again communicate with official after clicking on the “Write to Officials” button as shown below:

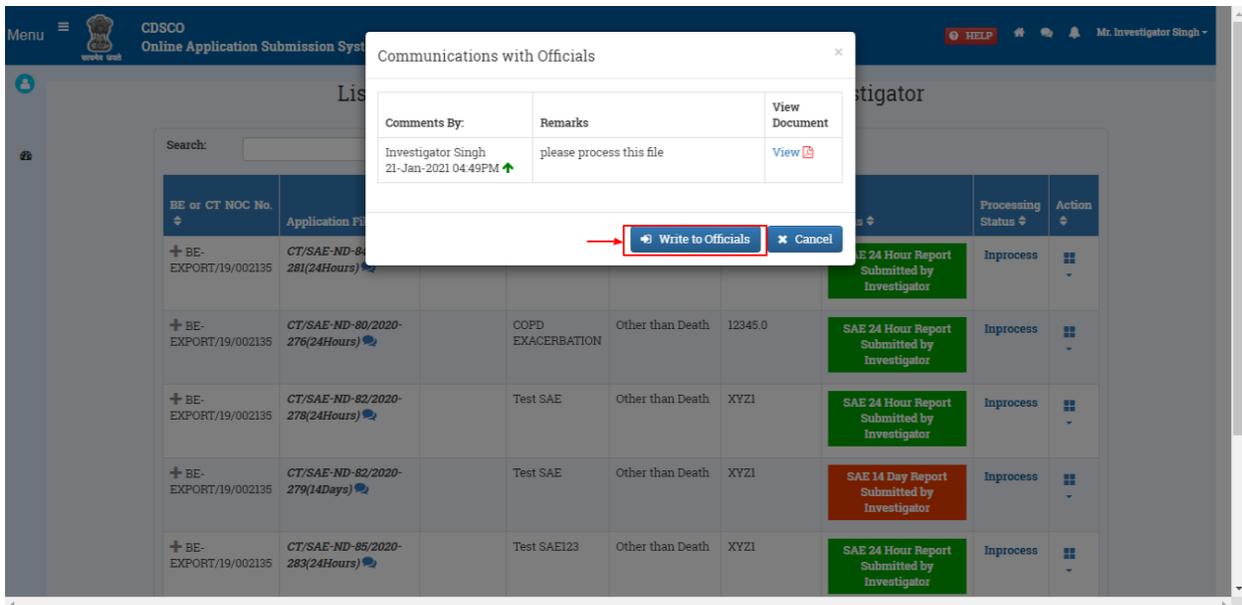


Figure 71: Communication Model with previous chat

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