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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TABLE OF CONTENTS

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 abilityto conductnormal life functions
5) Congenital anomaly/birth defect
6) Important Medical Event (IME) that may not result in death, be life threatening, orrequire hospitalization may be considered a serious adverse drug experience when,based upon medicaljudgment, it may jeopardize the patient or subject and mayrequire medical or surgical intervention to prevent one of the outcomes listed in thisdefinition.

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 1.1criteria 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 LicensingAuthority (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 andEthics 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.

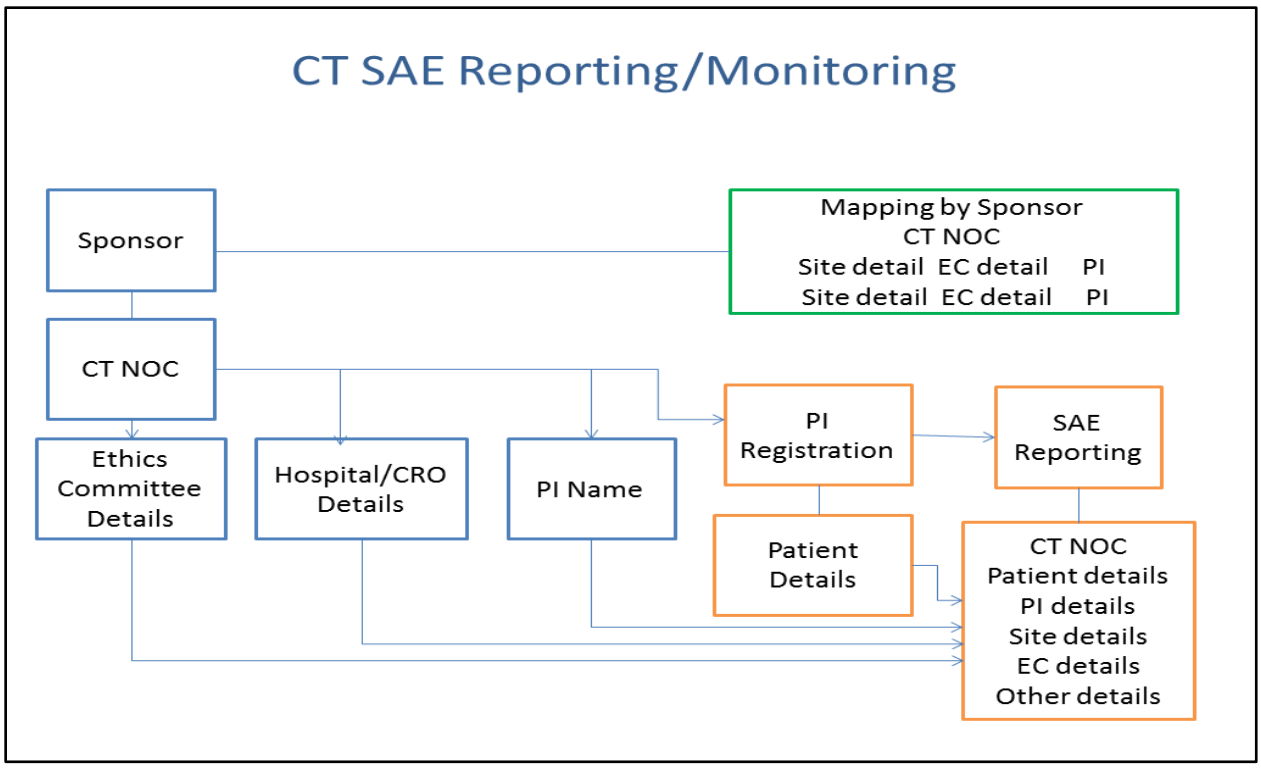

Figure 1: CT SAE Reporting/Monitoring

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 initiatetrial 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 SUGAMportal and then click on CLINICAL TRIALS tab under MENU from their dashboard.

<u>Step 1:</u> 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.

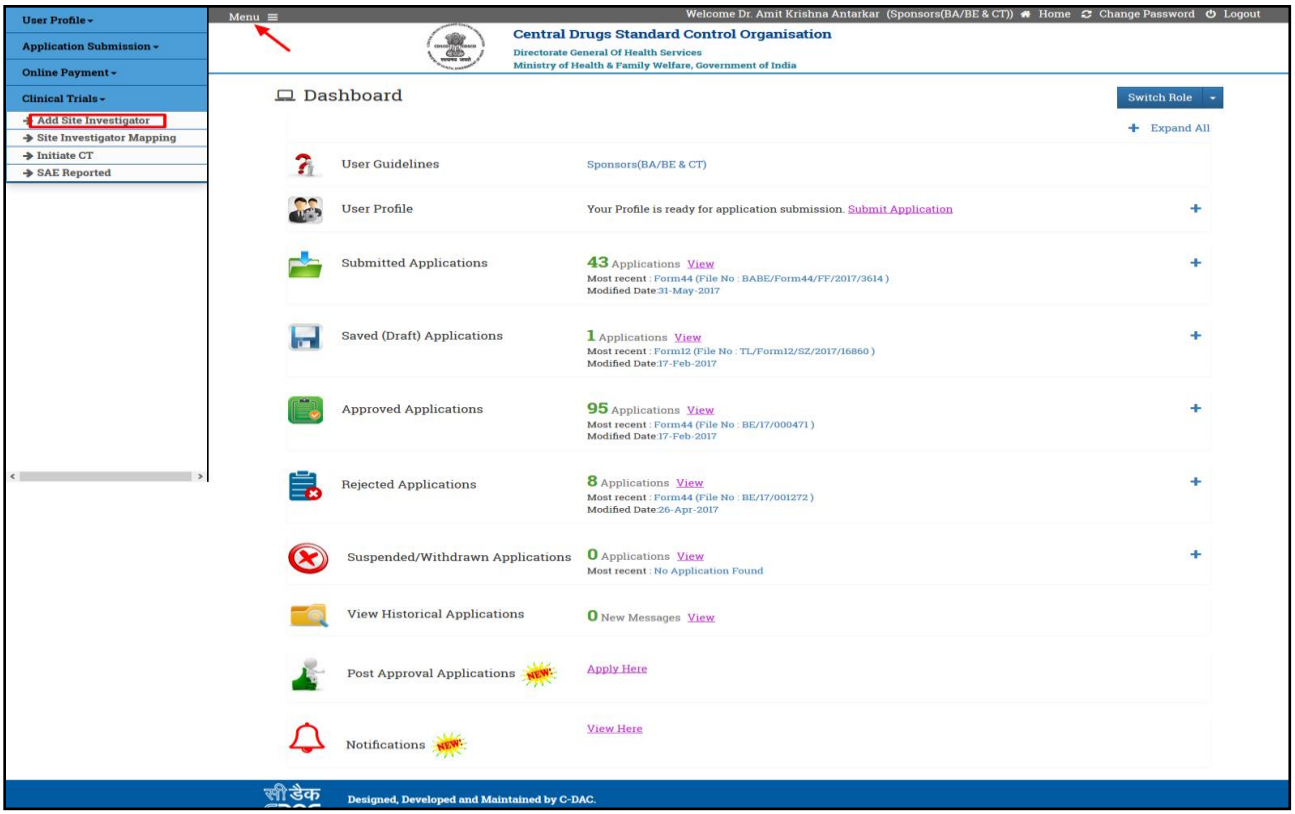

Figure 2: Sponsor Dashboard

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.

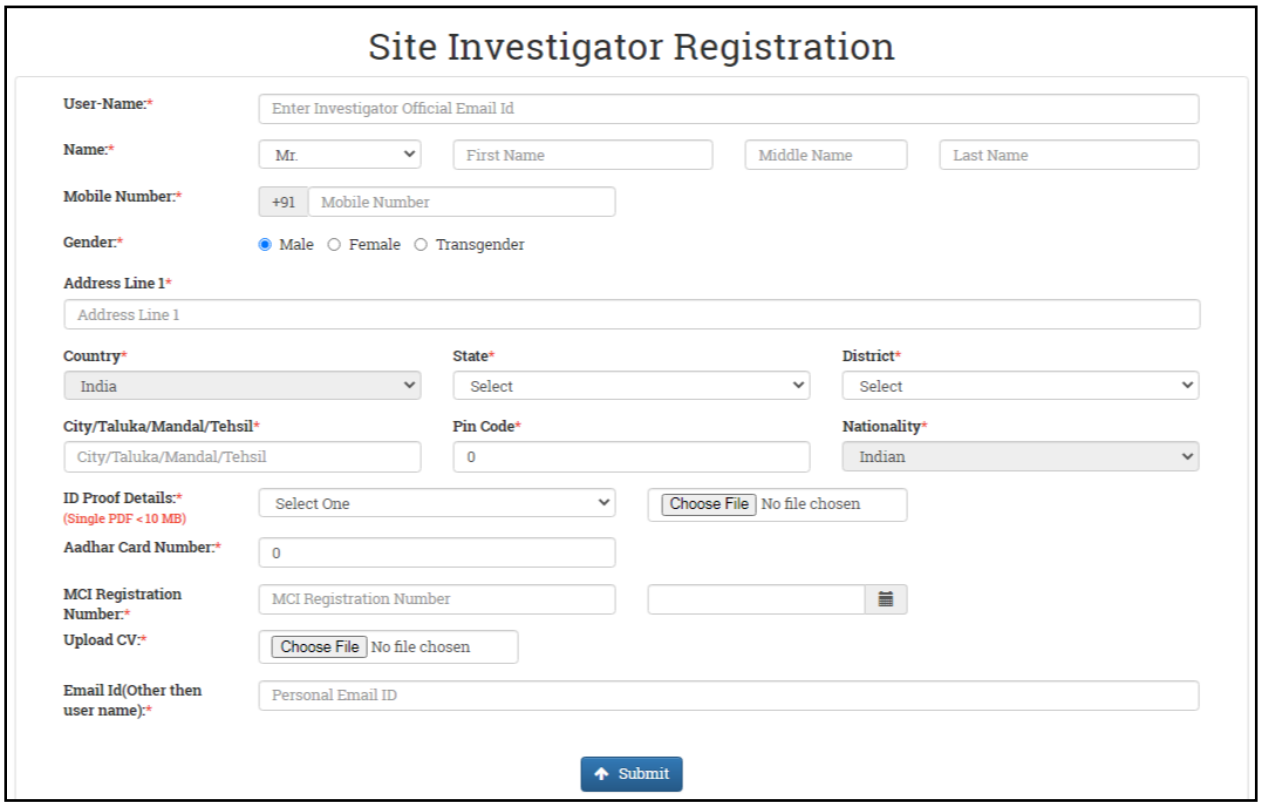

Figure 3: Site Investigator Registration

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 figurebelow:

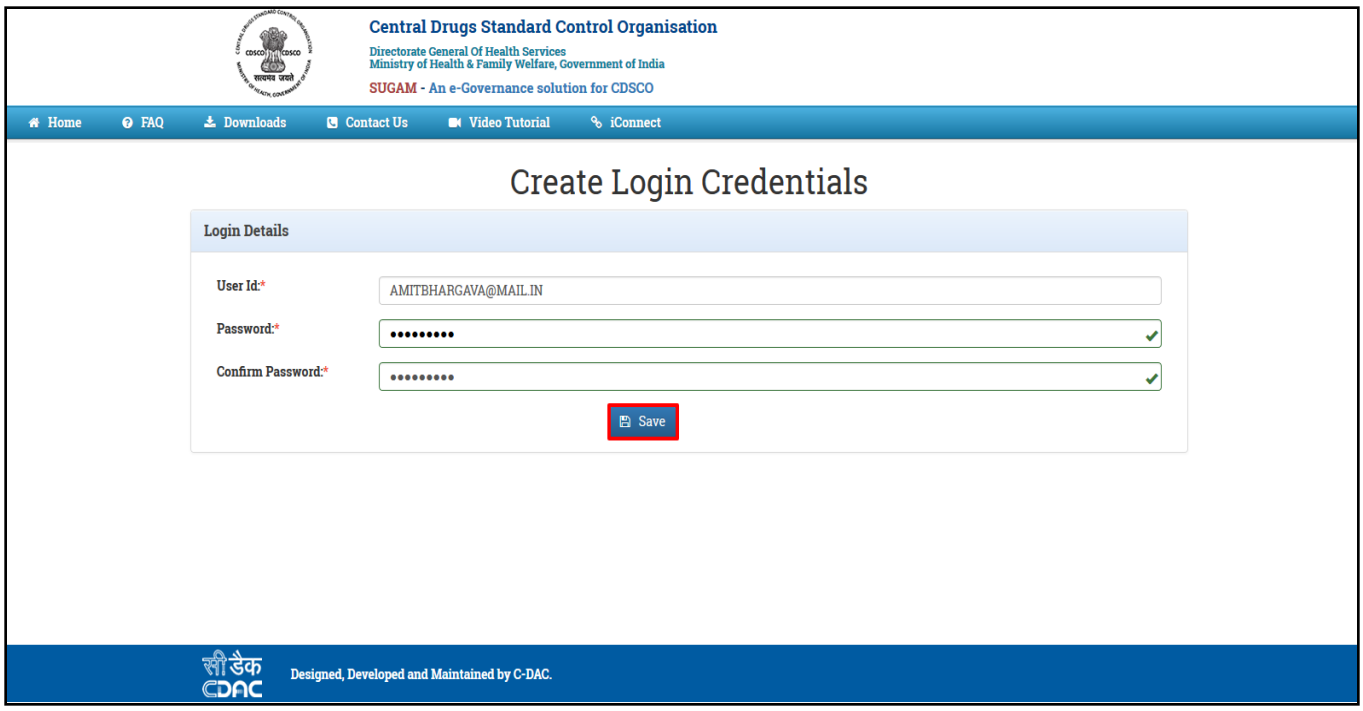

Figure 4: Login Credential Window

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 figurebelow:

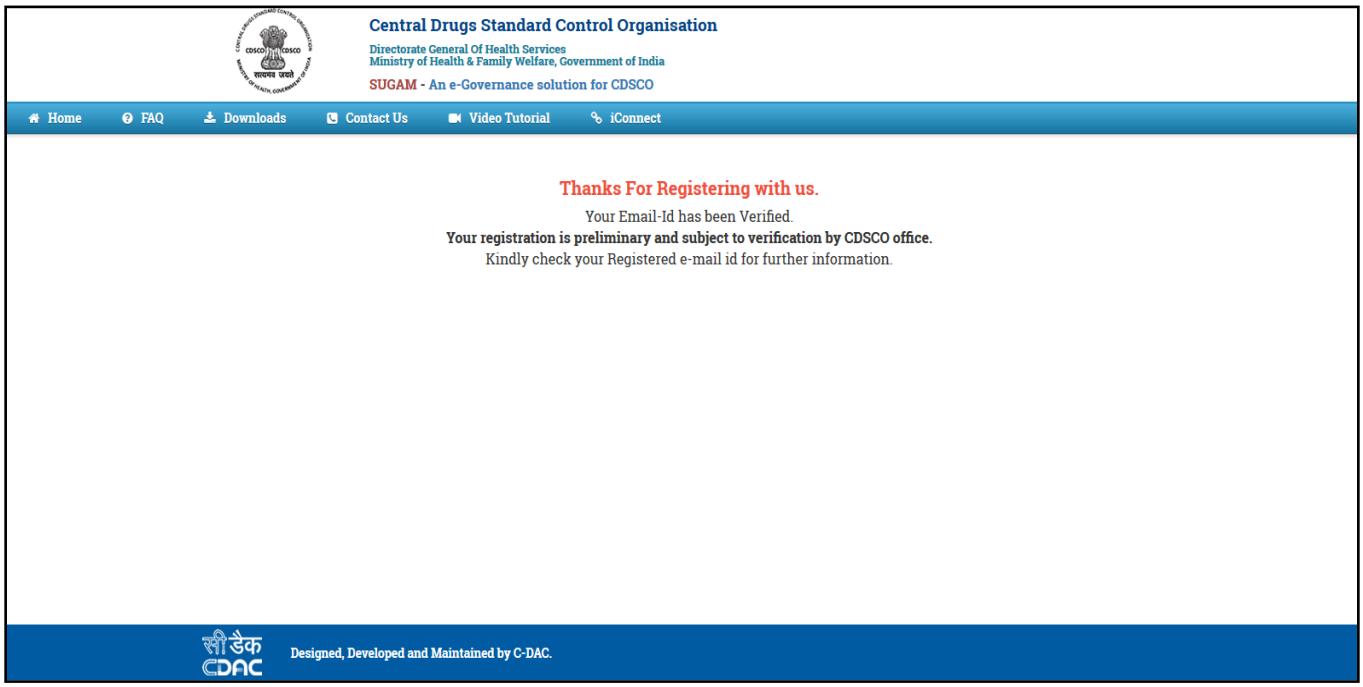

Figure 5: Successful Registration Pop-up

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.

<u>Step 2:</u> 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:

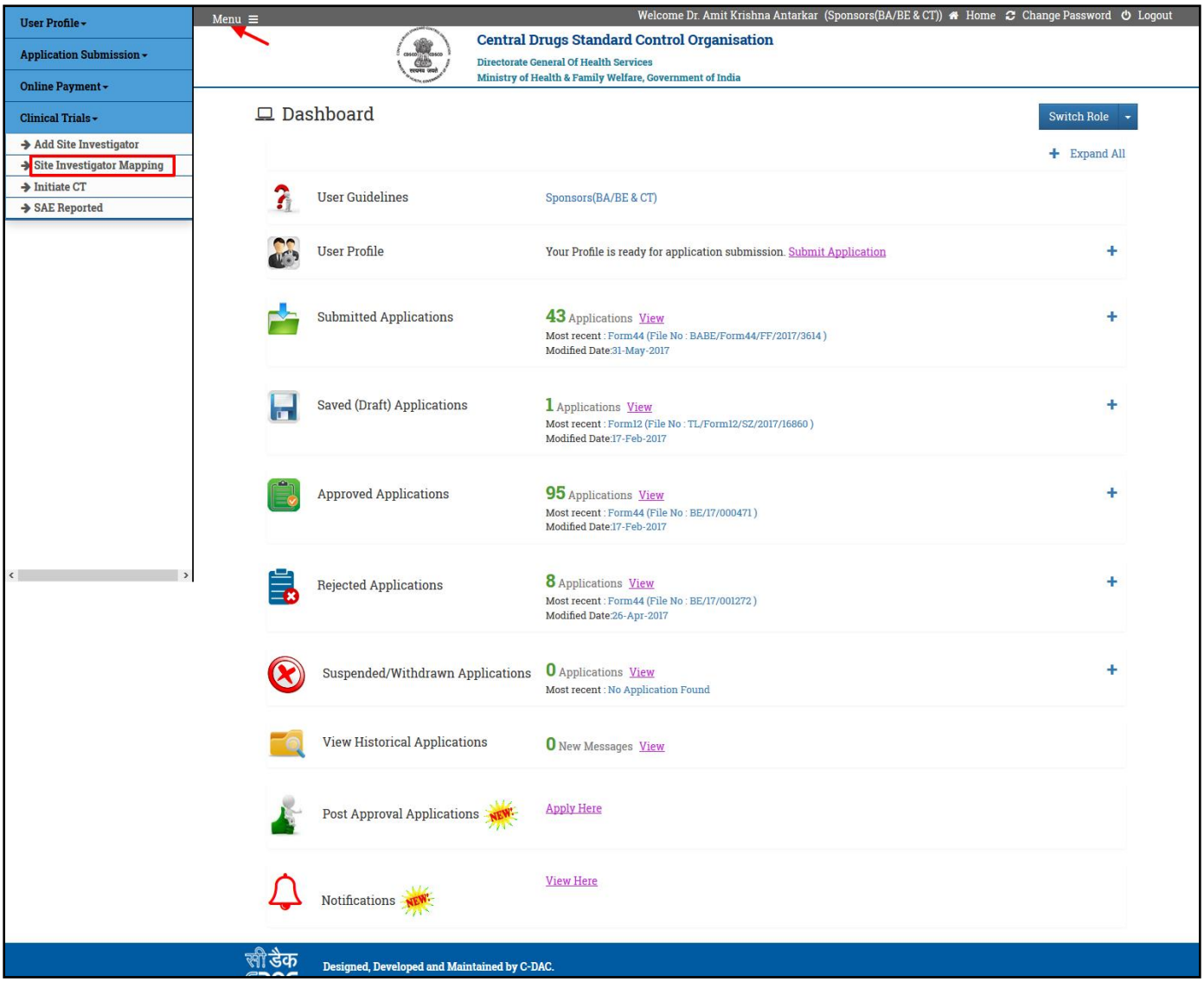

Figure 6: Sponsor Dashboard

After that a new window will open as shown in figurebelow. 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.

Figure 7: Application Investigator Mapping Form

<u>Step 3:</u> 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:

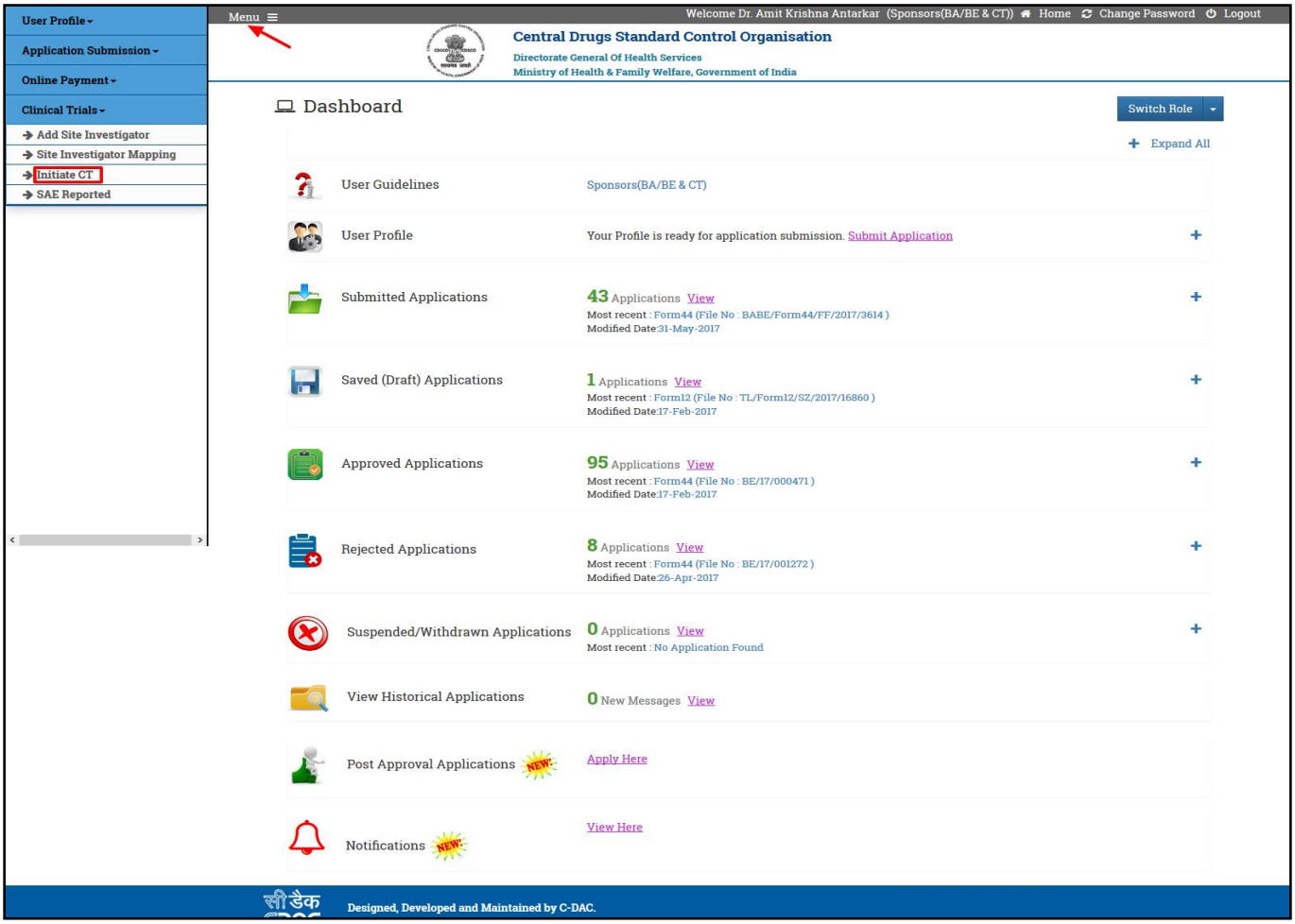

Figure 8: Sponsor Dashboard

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

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:

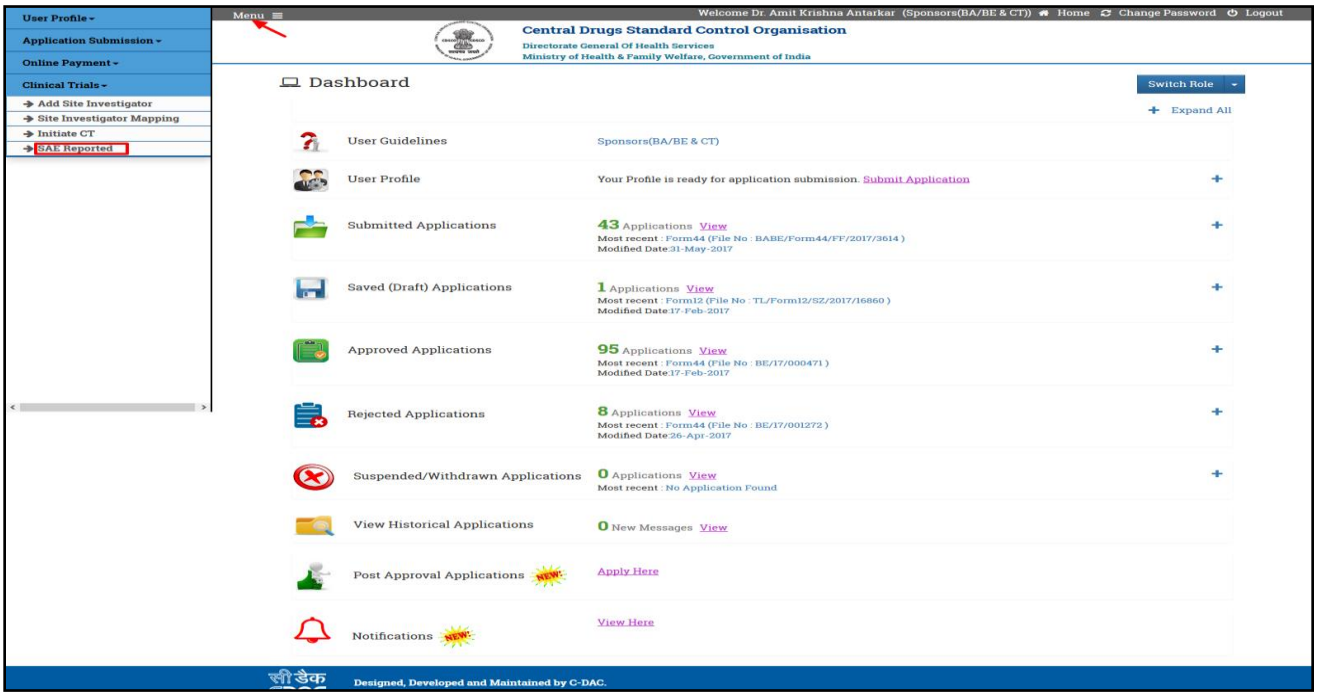

Figure 10: Sponsor Dashboard

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).

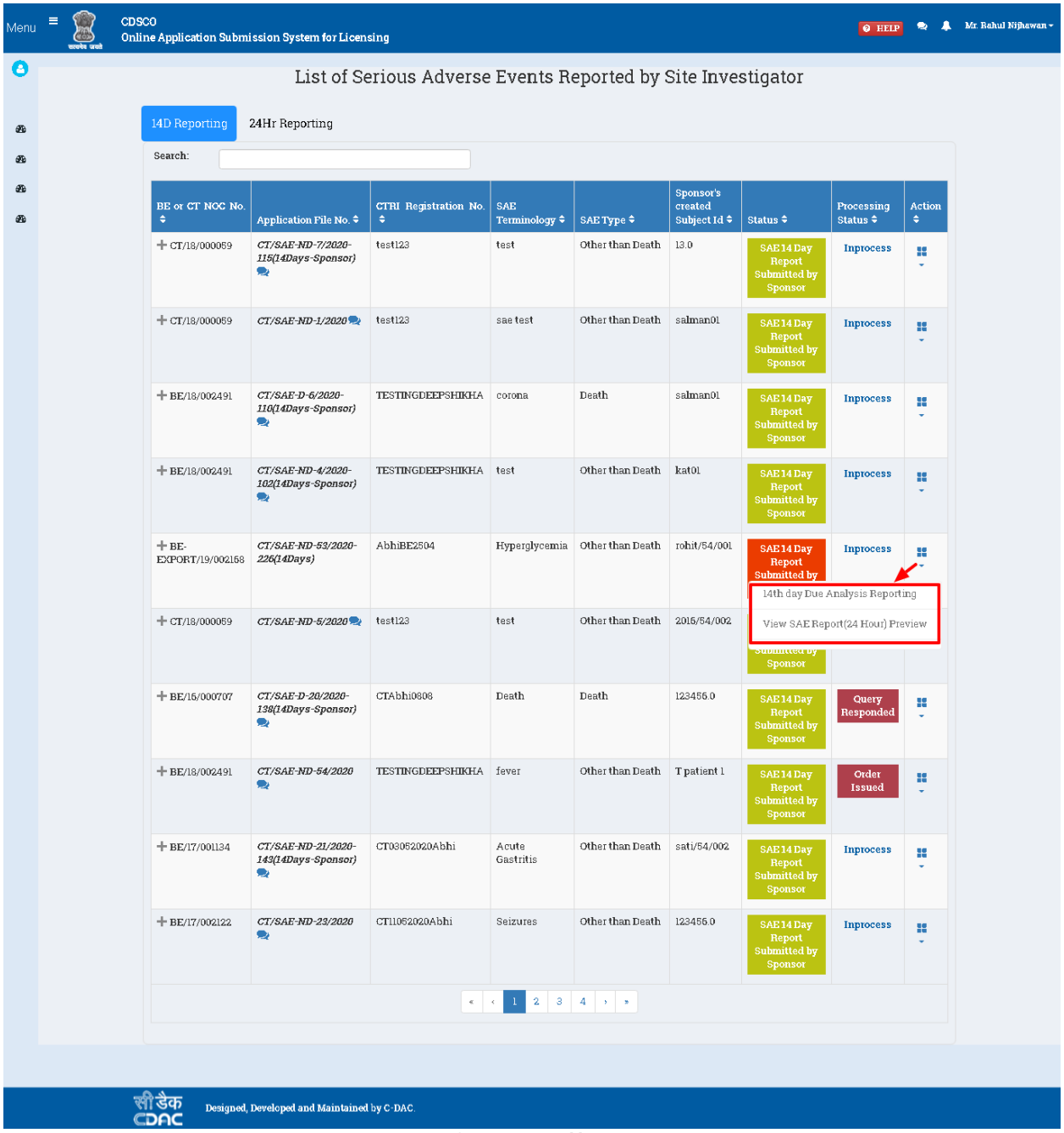

Figure 11: List of SAEs reported by Site Investigator

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 Registartion No. provided by CDSCO:	ECR/40/Indt/GJ/2013/RR-19
Address:	Nirmal Ashram Deepmala Pagarani Public School ,Shyampur P.O. 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 XRTM (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 XRTM (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fed conditions.
Protocol No.:	C1B00315

SAE(s) Details

Expectedness of SAE ○ Expected ○ Unexpected

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

SAE(s) Terminology * SAE(s) Terminology

Brief description of the SAE * Brief description of the SAE including medical management given an outcome

Start Date of SAE(s) DD/MM/YYYY

SAE Stop or Ongoing?* Select

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

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

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

Save As Draft | Close

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:

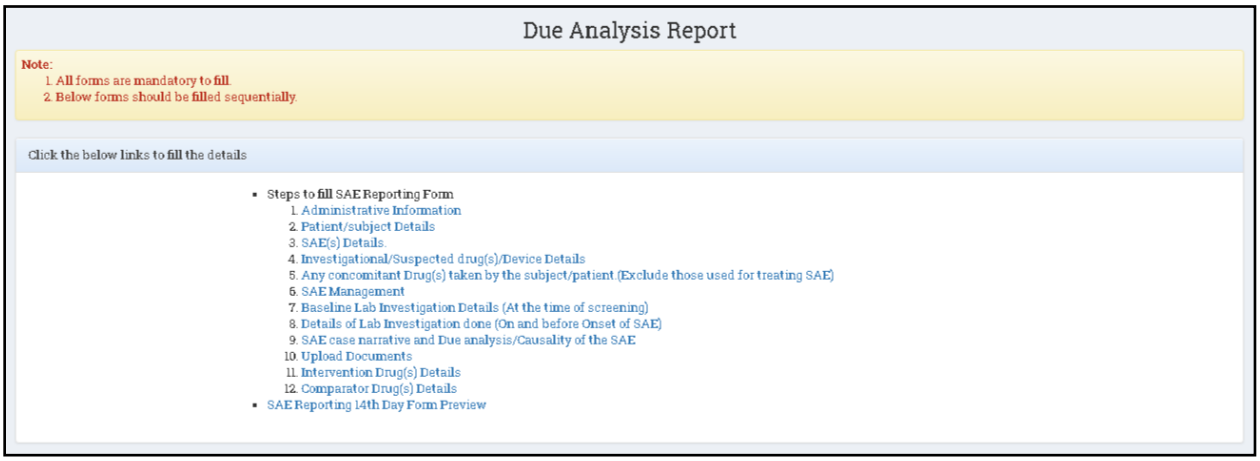

Figure 14: 14 days Due Analysis Report Form List

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 Registartion No. provided by CDSCO:	ECR/40/Indt/GJ/2013/RR-19
Address:	Nirmal Ashram Deepmala Pagarani Public School ,Shyampur P.O. 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 XRTM (Oxcarbazepine) Extended-Release Tablets 600mg in healthy adult human subjects under fasting conditions.
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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)

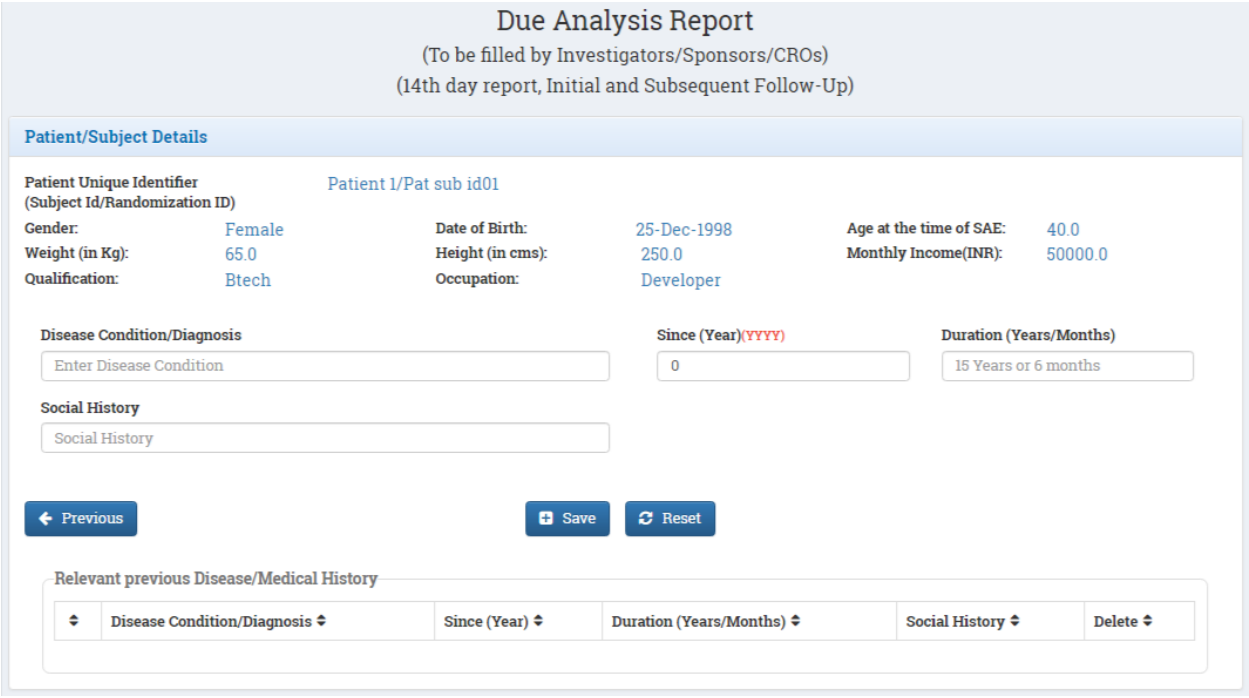

Figure 16: 14th day Due Analysis Report (Patient/Subject Details)

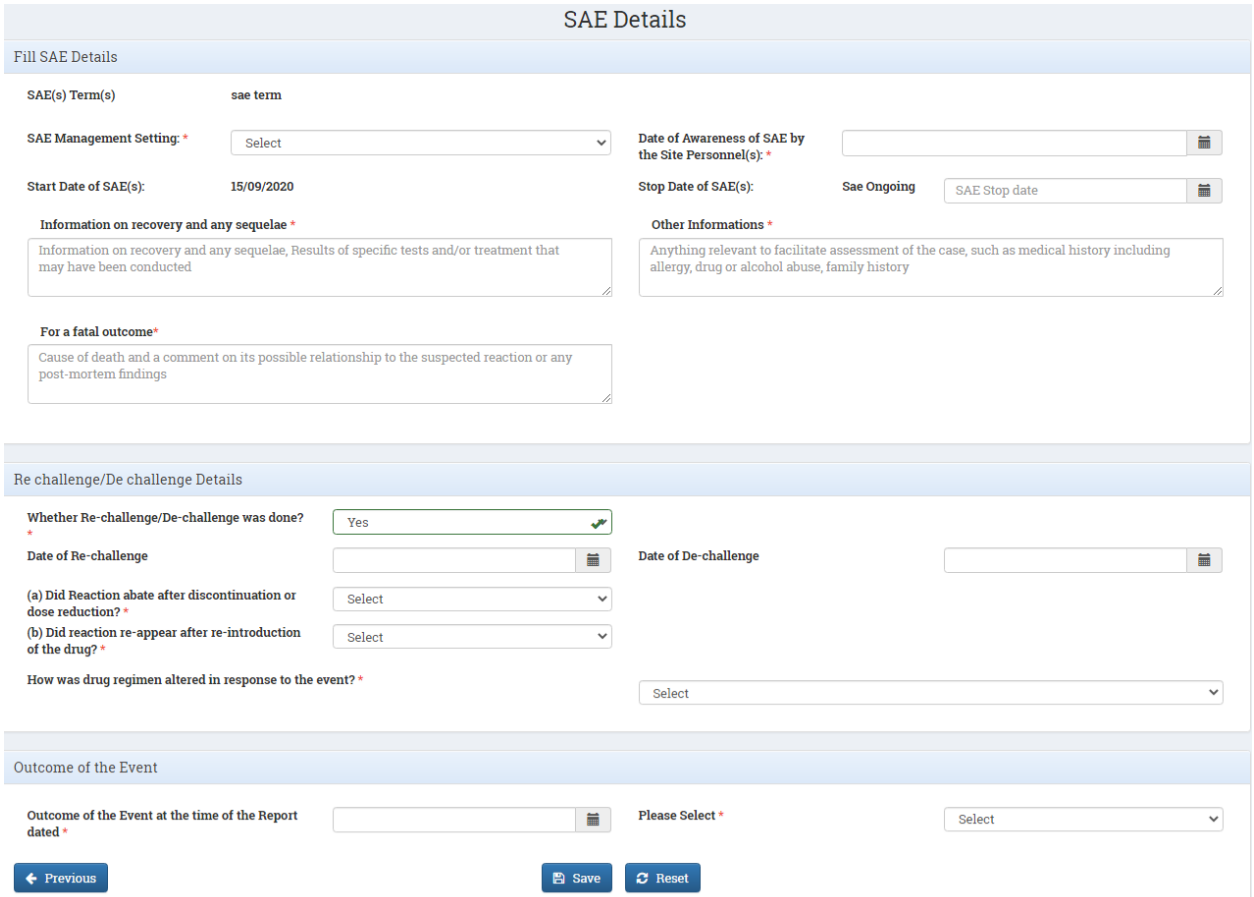

Figure 17: 14th day Due Analysis Report (SAE Details)

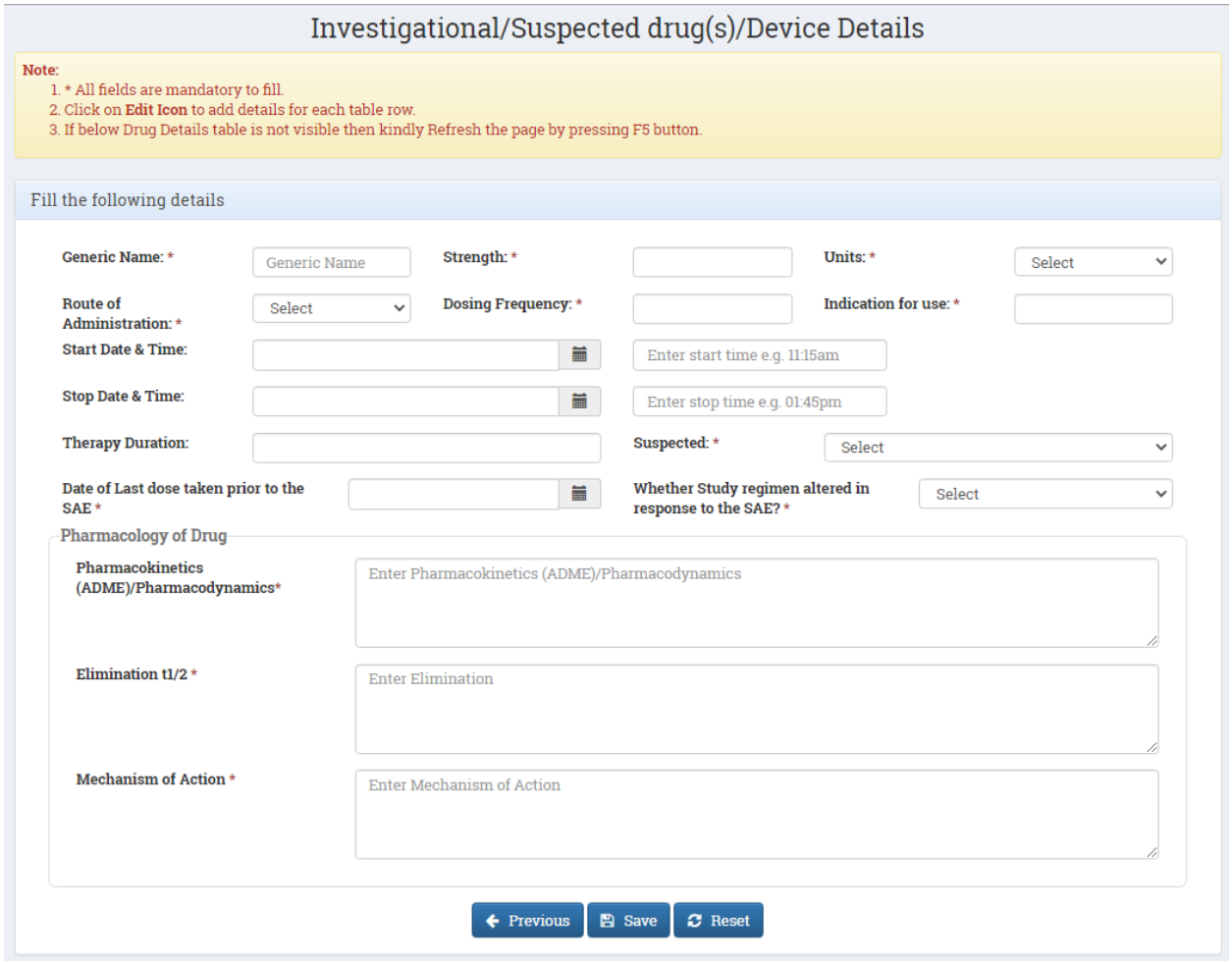

Figure 18: 14th day Due Analysis Report (Investigational/Suspected drugs/Device details)

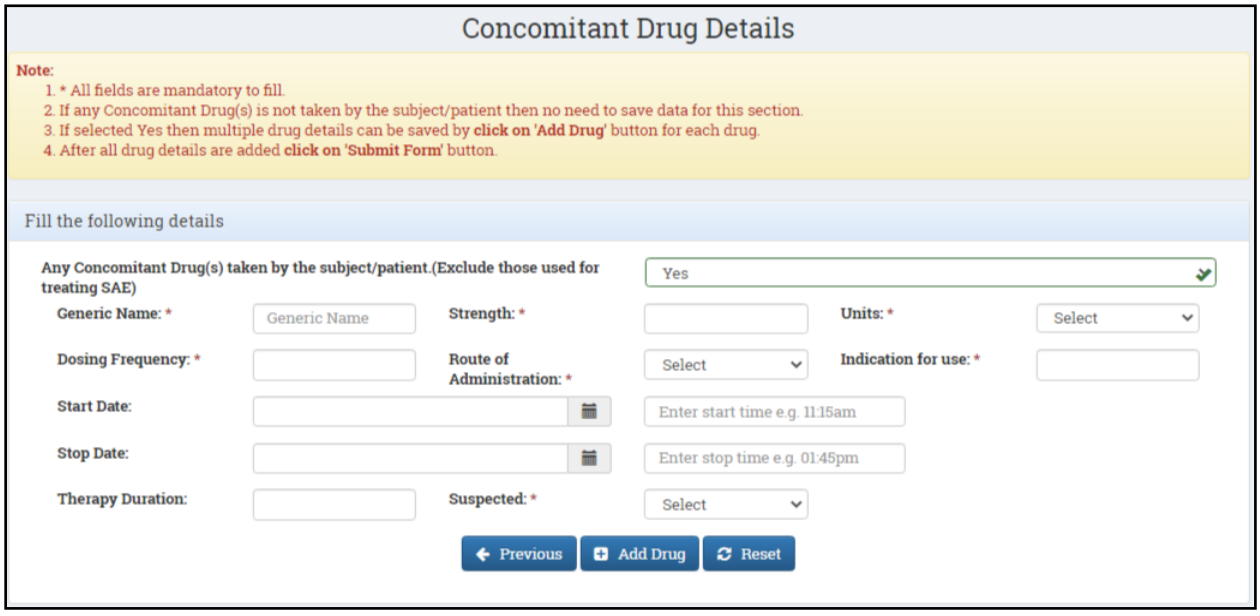

Figure 19: 14th day Due Analysis Report (Concomitant Drug Details)

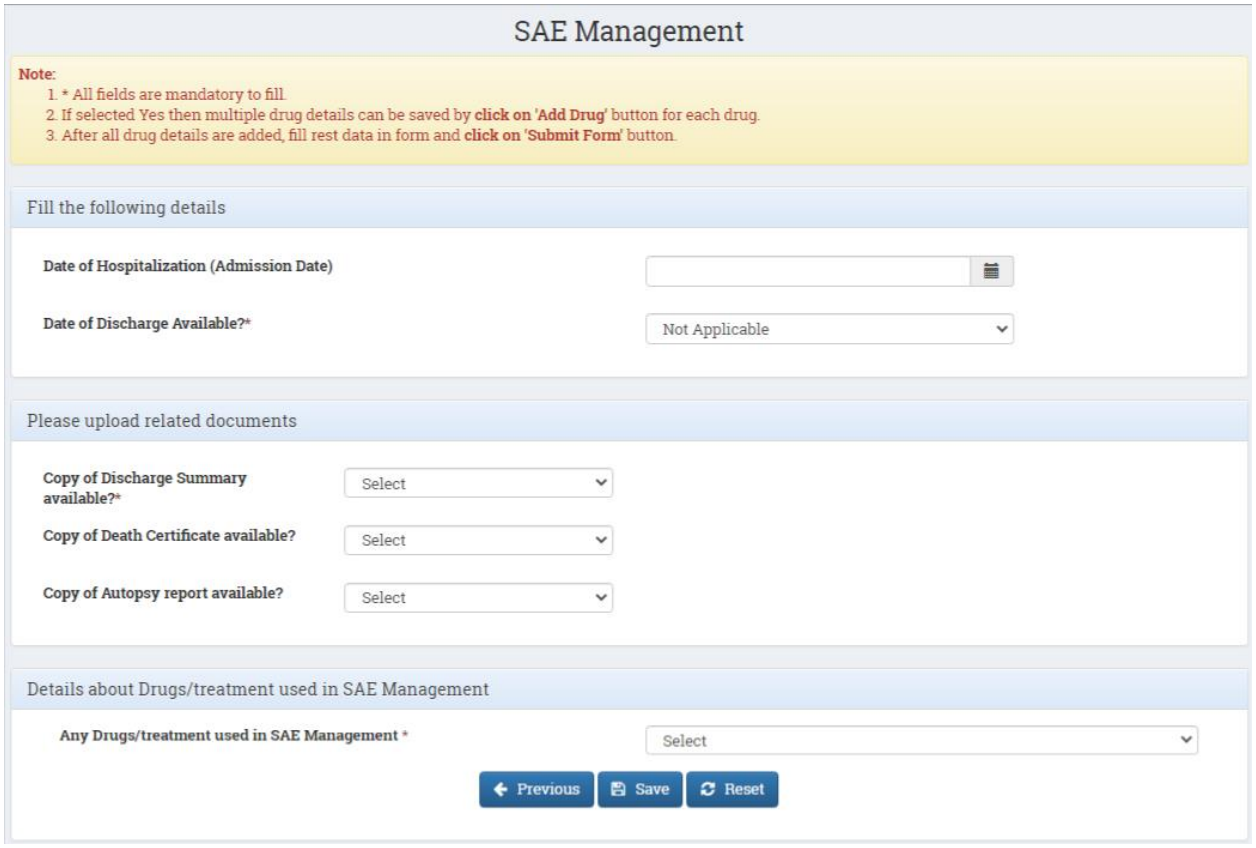

Figure 20: 14th day Due Analysis Report (SAE Management)

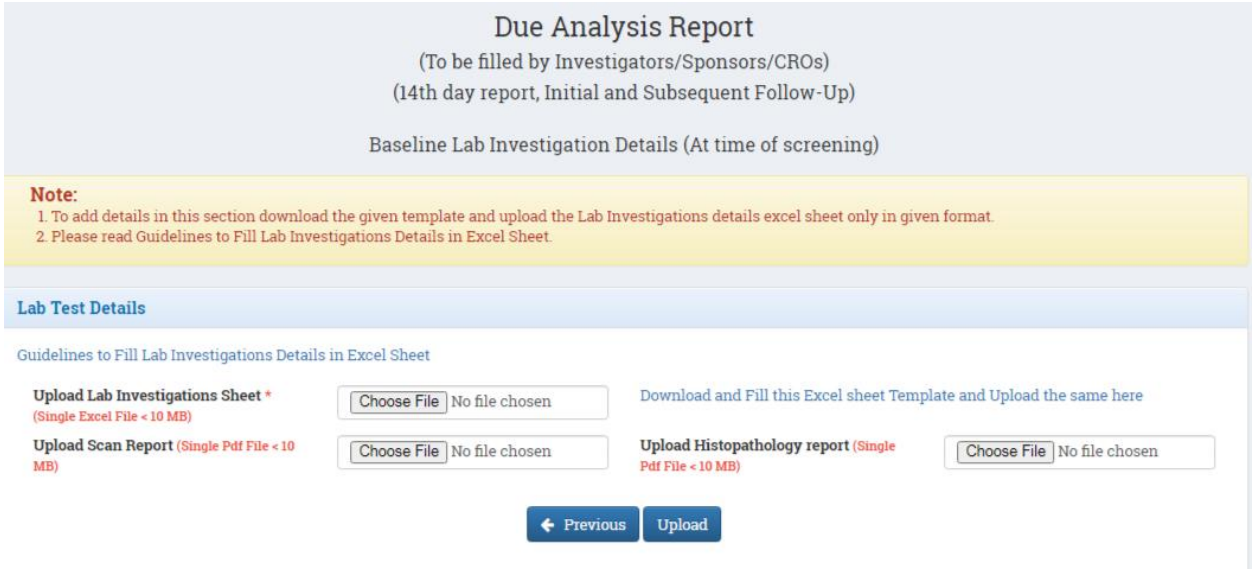

Figure 21: 14th day Due Analysis Report (Baseline Lab Investigation Details)

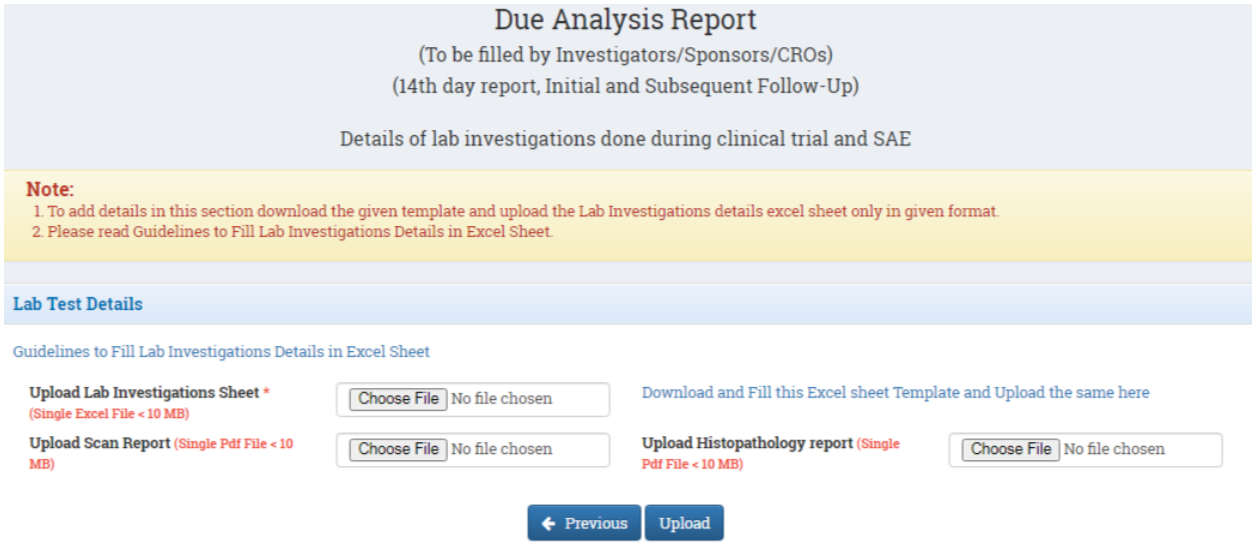

Figure 22: 14th day Due Analysis Report (Lab Investigation done during clinical trial)

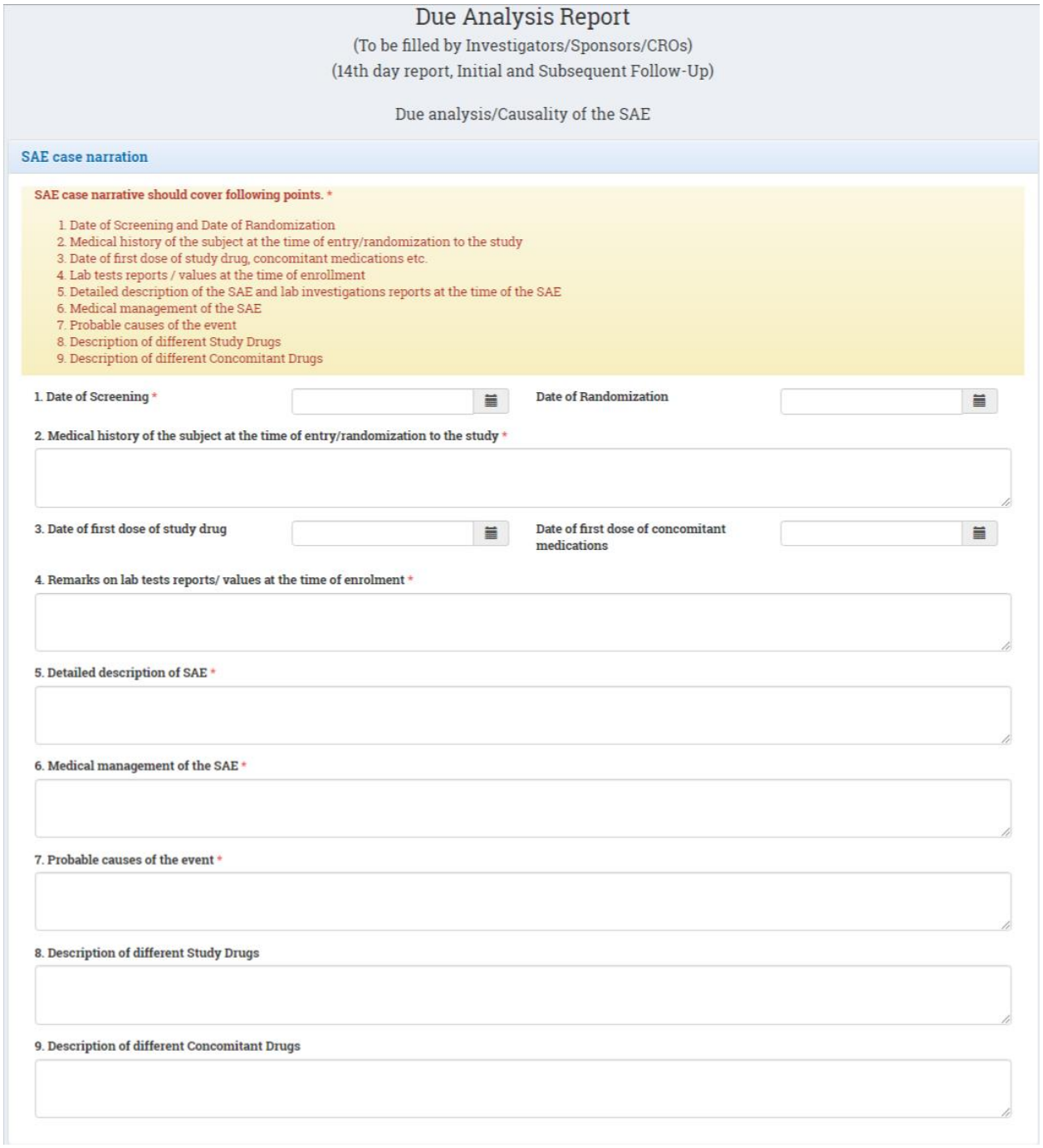

Figure 23: 14th day Due Analysis Report (Due Analysis/Causality of the SAE (Part 1))

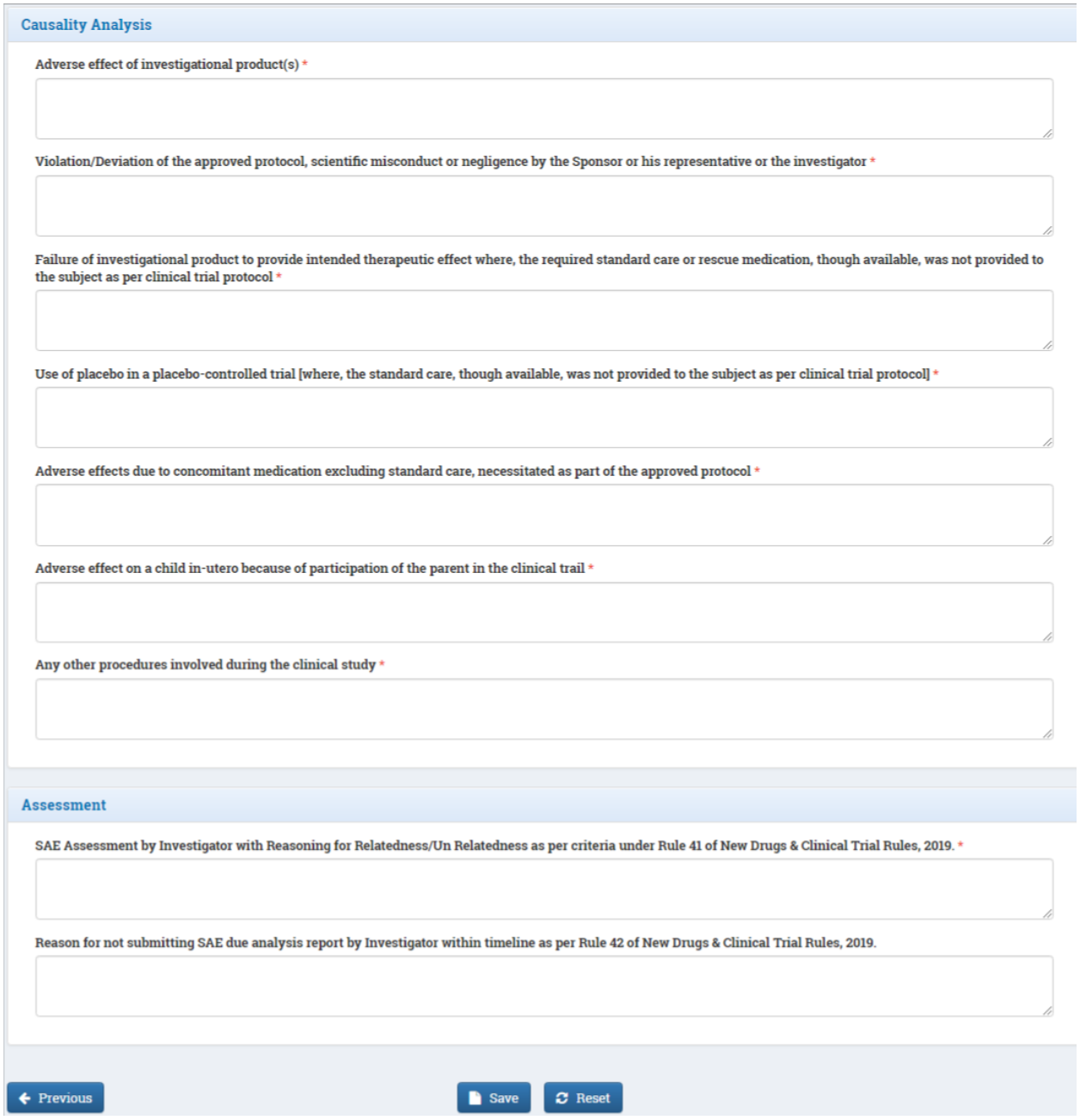

Figure 24: 14th day Due Analysis Report (Due Analysis/Causality of the SAE (Part 2))

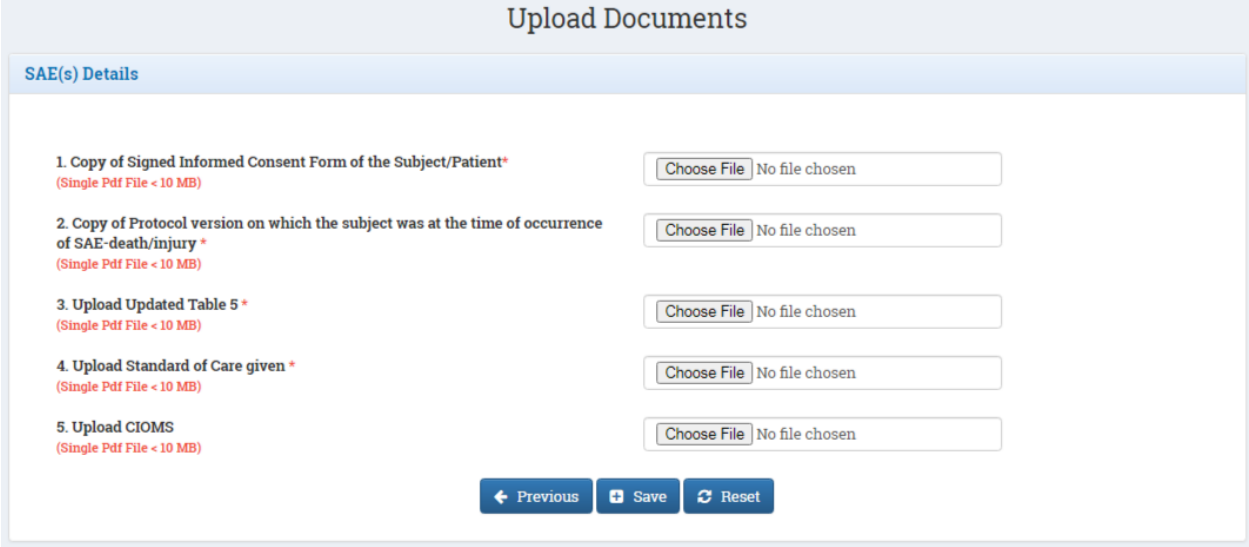

Figure 25: 14th day Due Analysis Report (Upload Document)

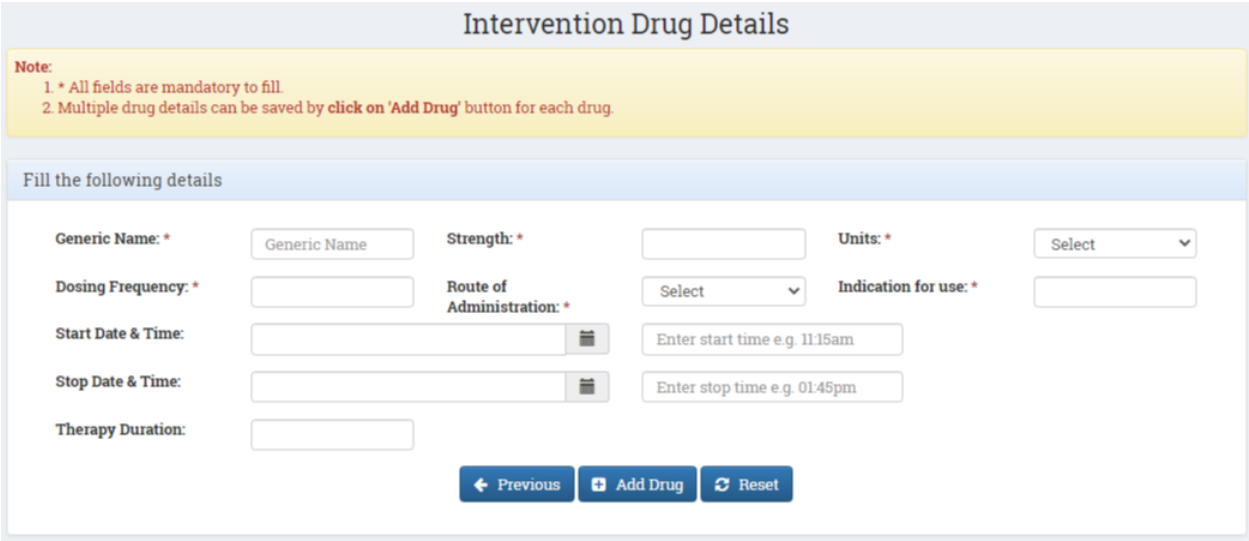

Figure 26: 14th day Due Analysis Report (Intervention Drug Detail)

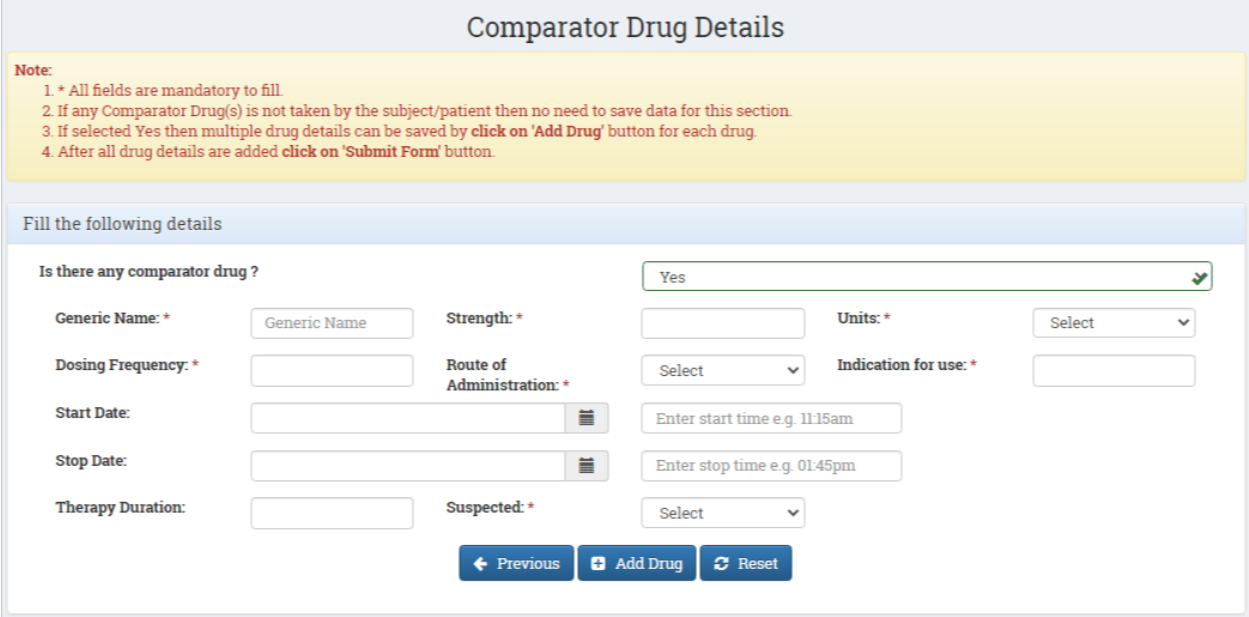

Figure 27: 14th day Due Analysis Report (Comparator Drug Detail)

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:

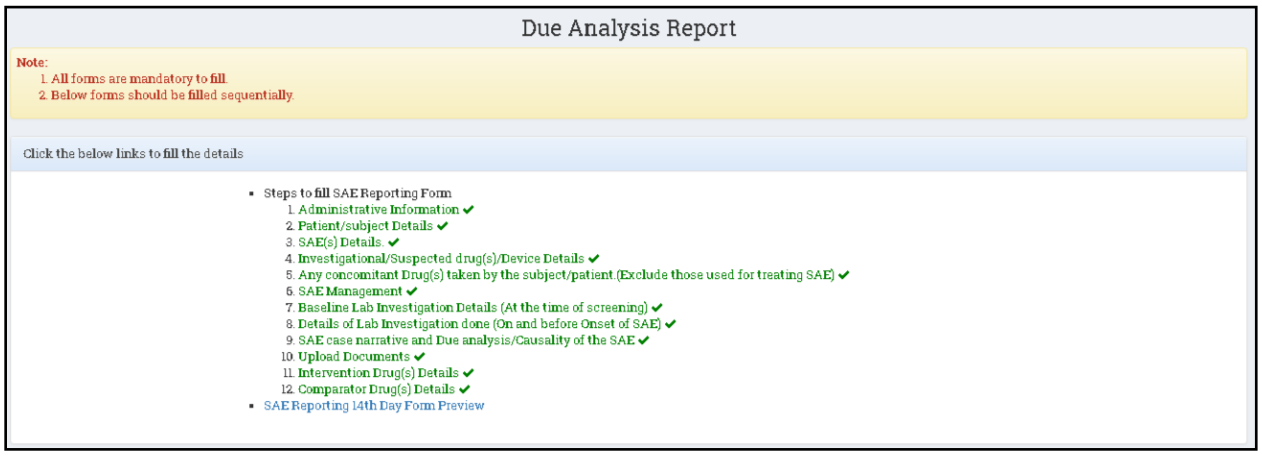

Figure 28: Filled Form List of 14D Report by PI

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

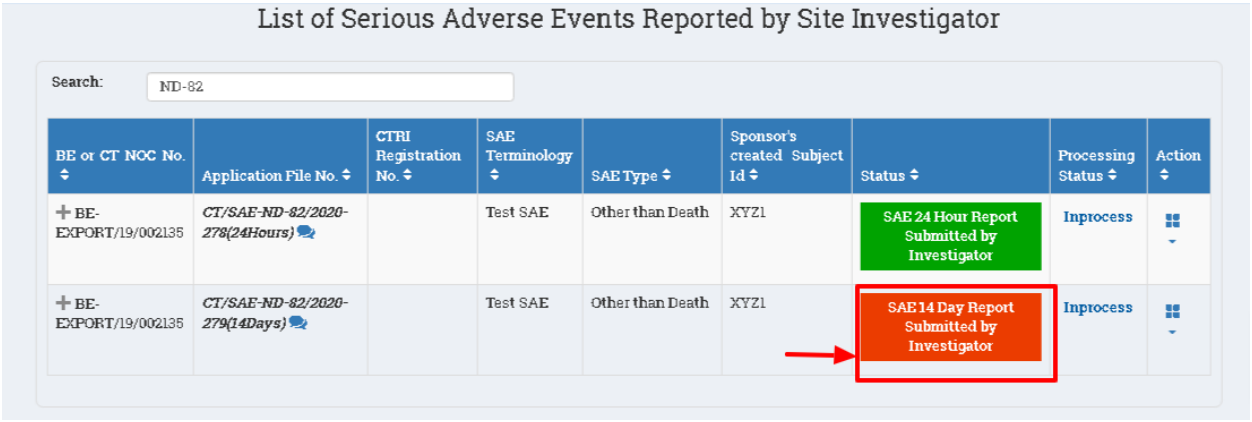

Figure 30: List of SAEs reported by Site Investigator

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:

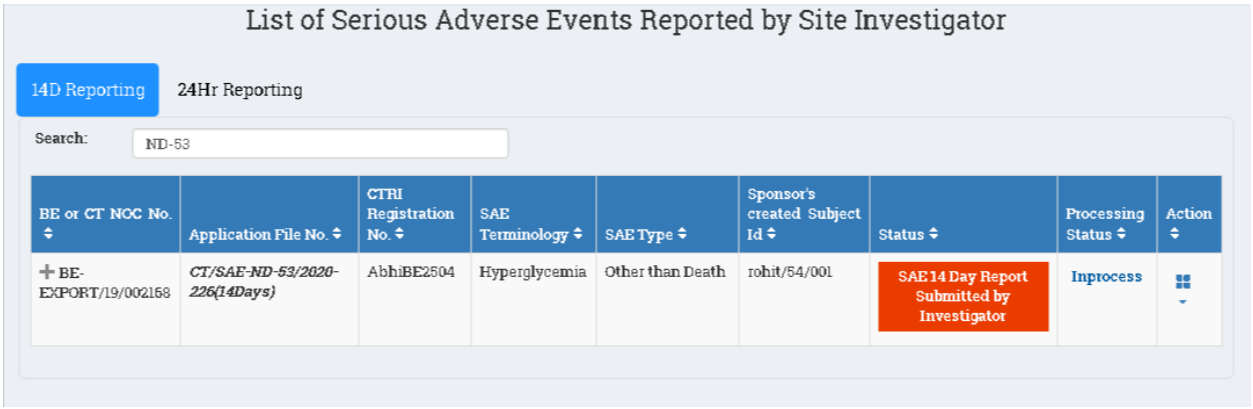

Figure 31: List of SAEs reported by Site Investigator at Sponsor

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

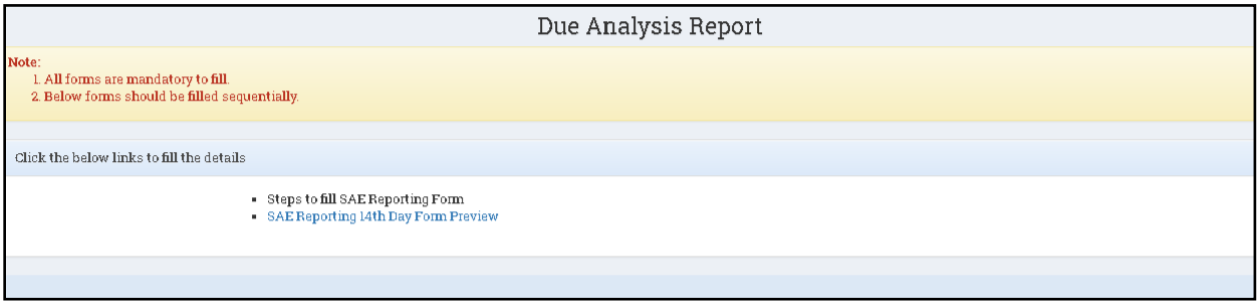

Figure 32: List of SAEs forms by Sponsor

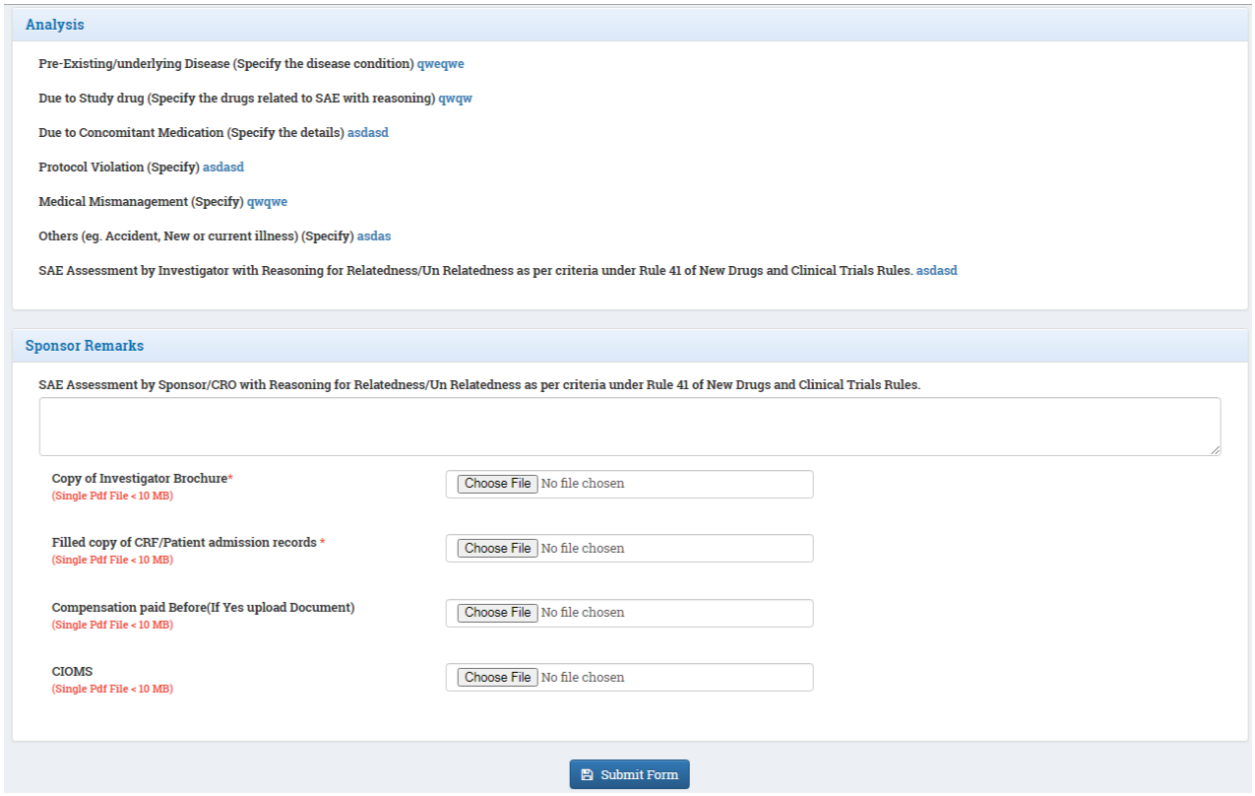

Figure 33: SAE 14 days Due Analysis Report Form by Sponsor

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 andthis file will be visible to Ethicscommittee to submit its 30 Day report as shown in Figure.

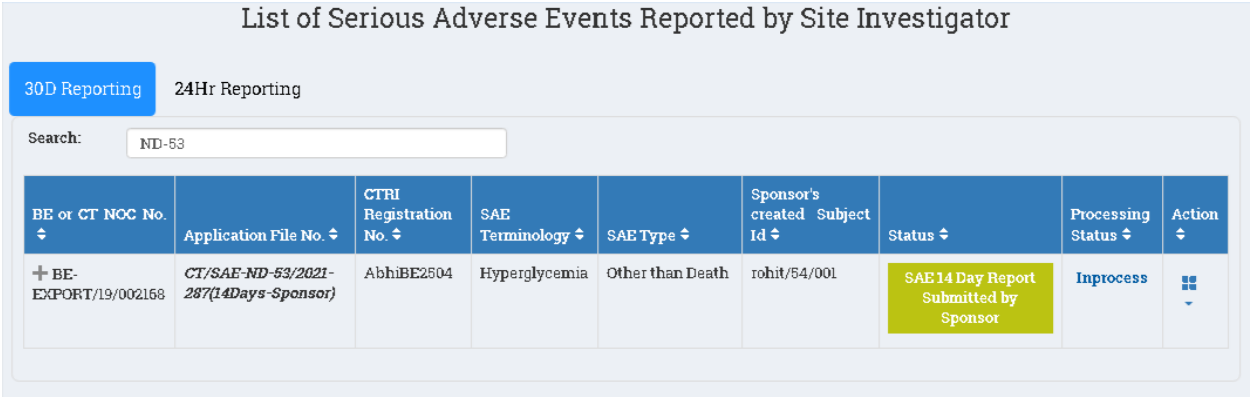

Figure 35: List of SAEs reported by Sponsor at EC

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: -

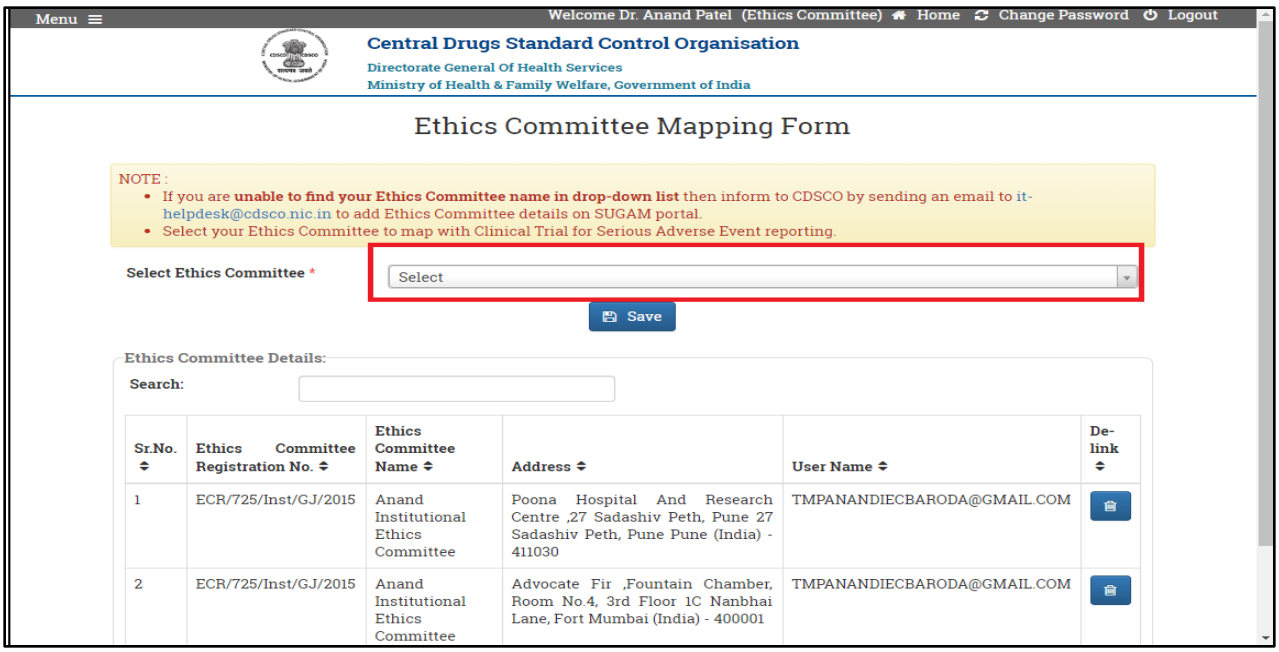

Figure 36: Ethics Committee Mapping Form

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

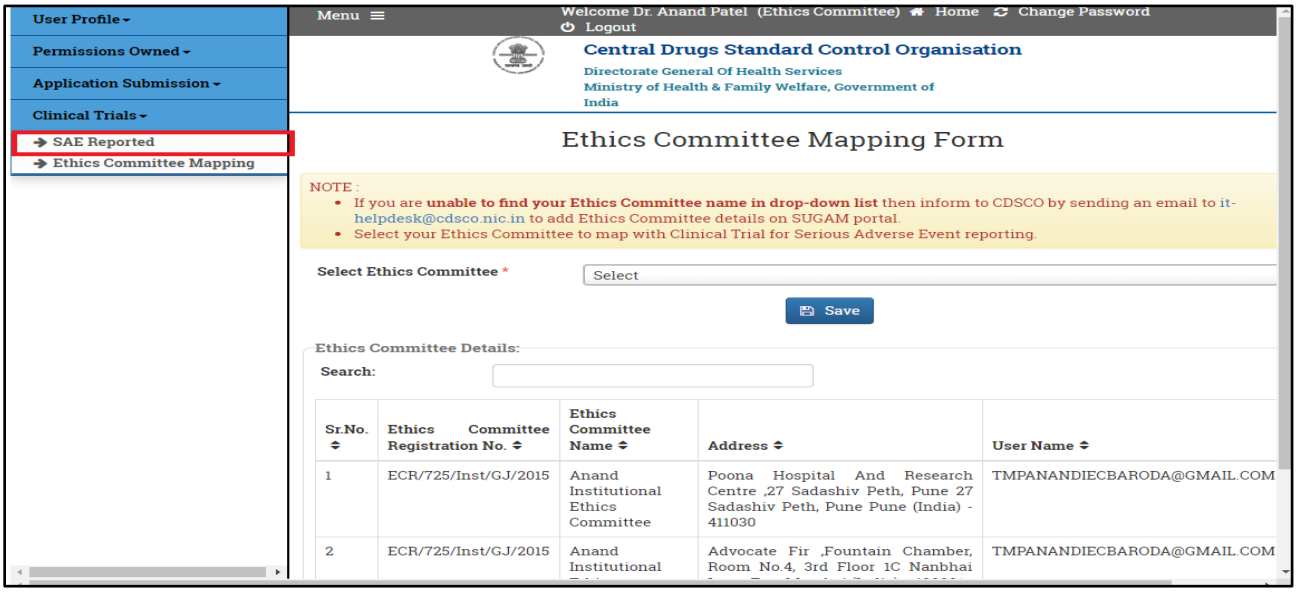

Figure 37: SAE Reported option in the dashboard

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

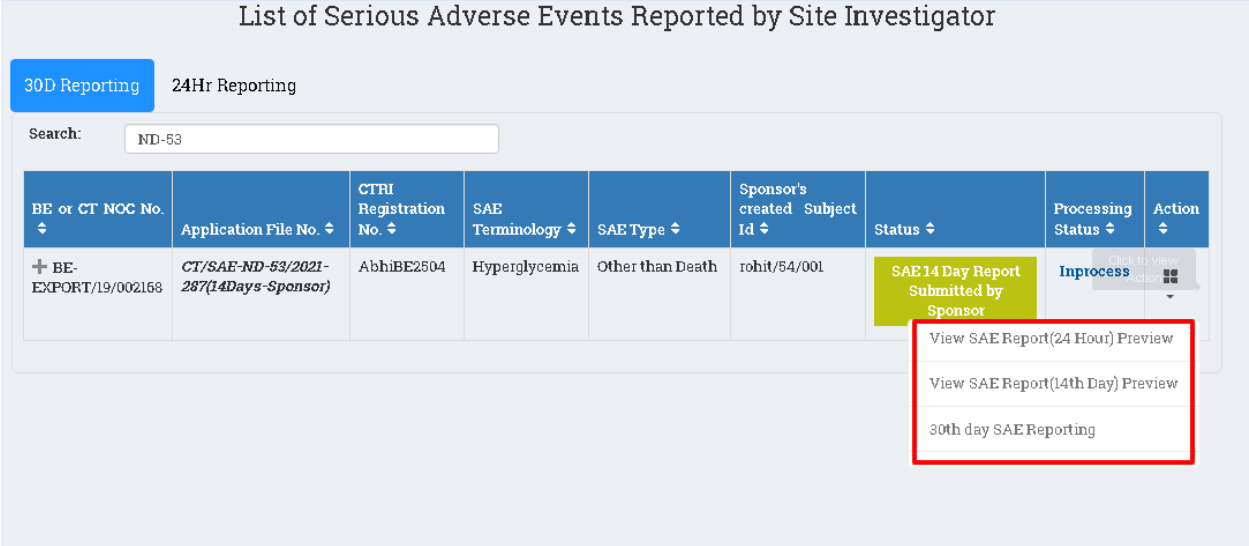

Figure 38: List of SAEs reported by Site Investigator at EC

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

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

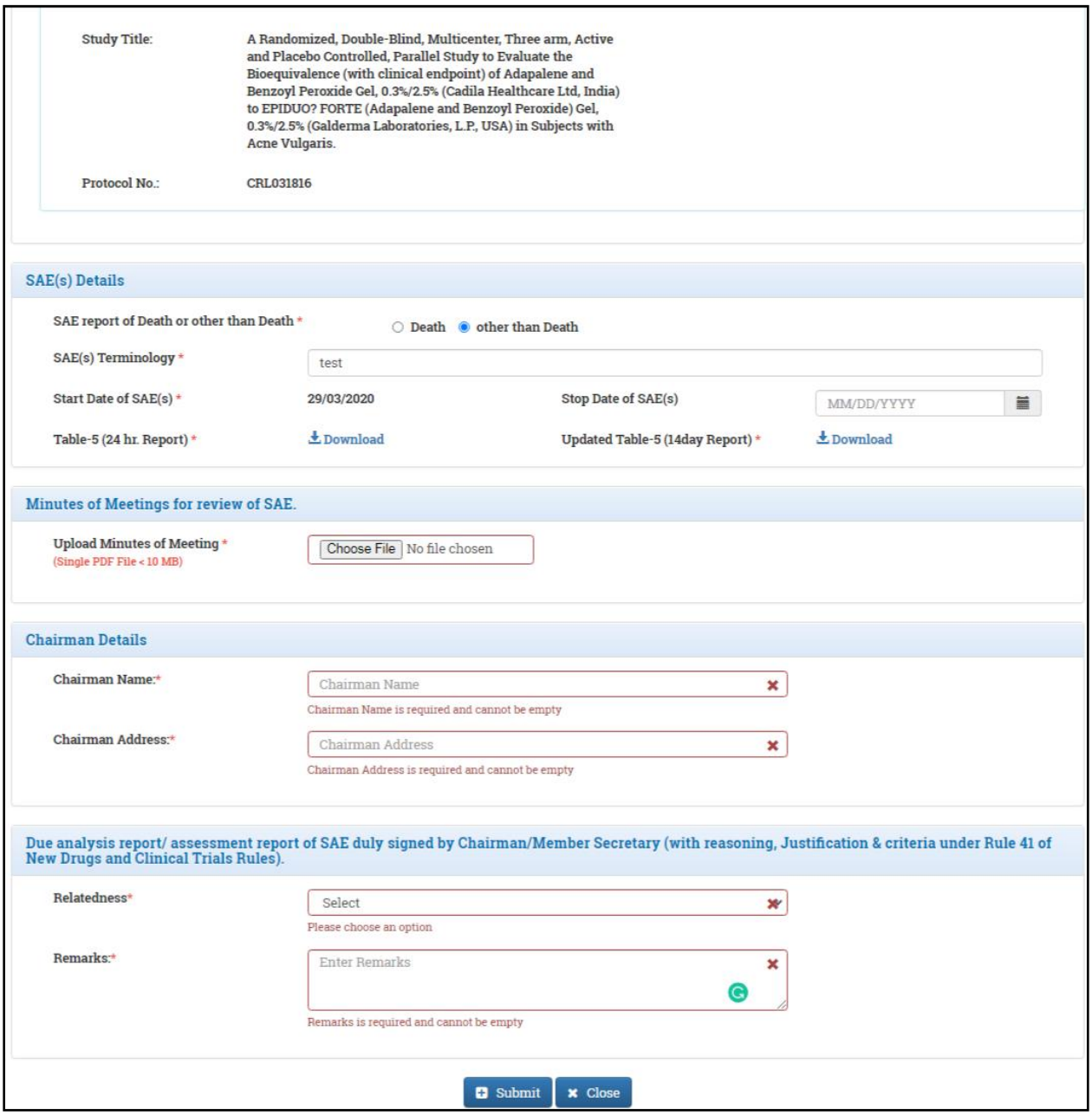

Figure 40: SAE Reporting (Part 2)

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 figurebelow:

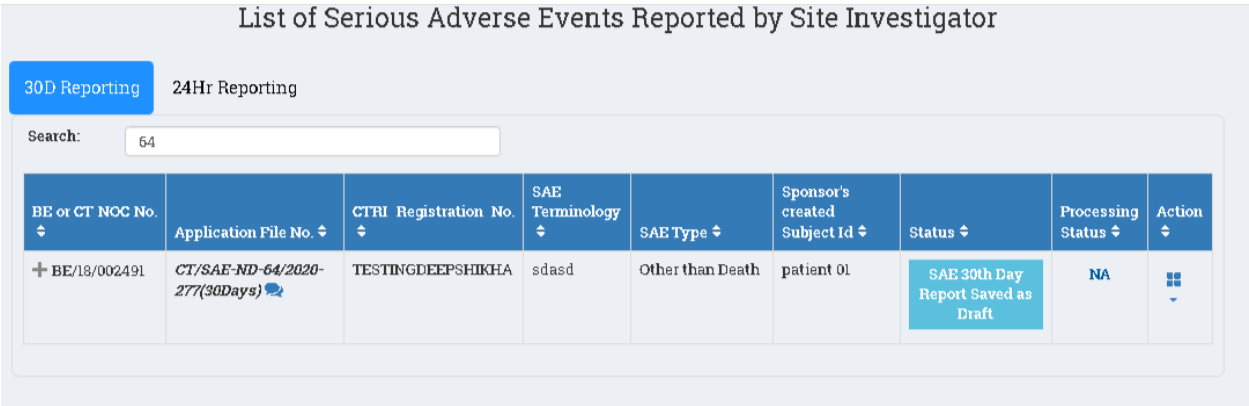

Figure 41: List of SAEs reported by EC

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

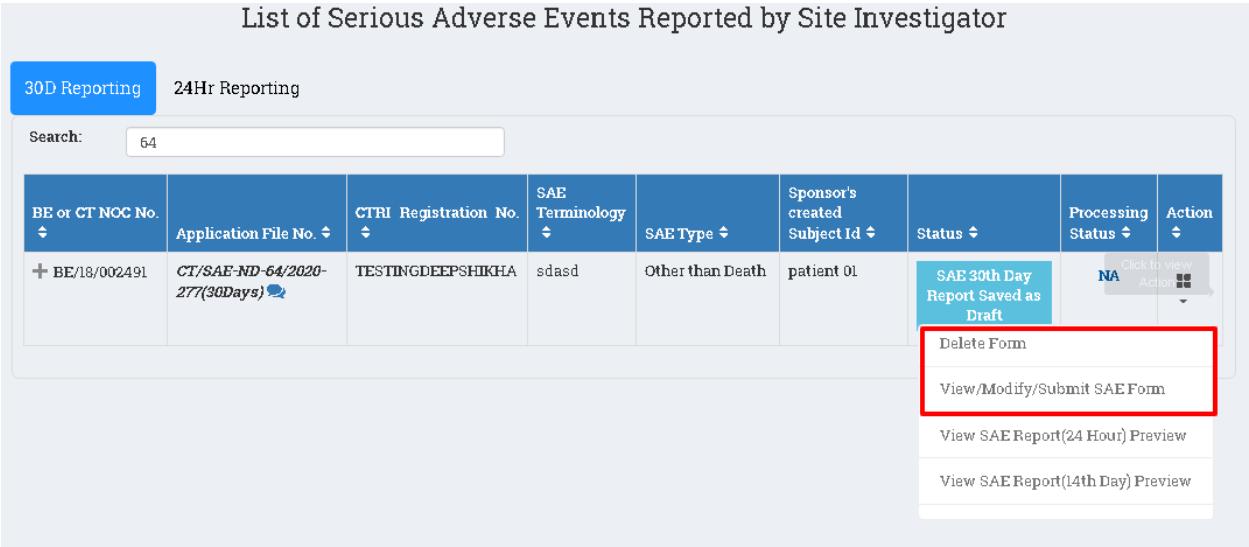

Figure 42: Options to modify the form

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:

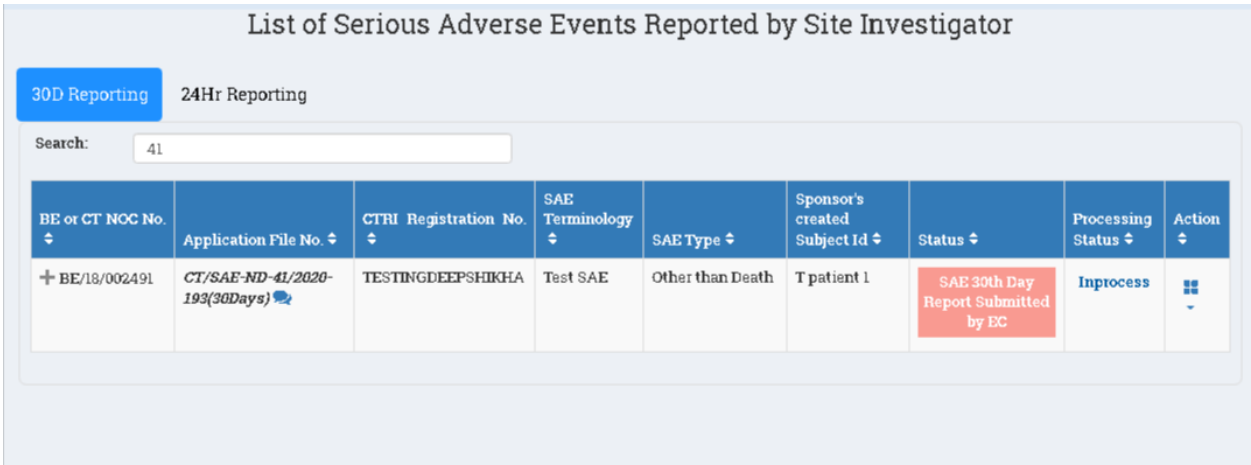

Figure 44: Successful form submission

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:

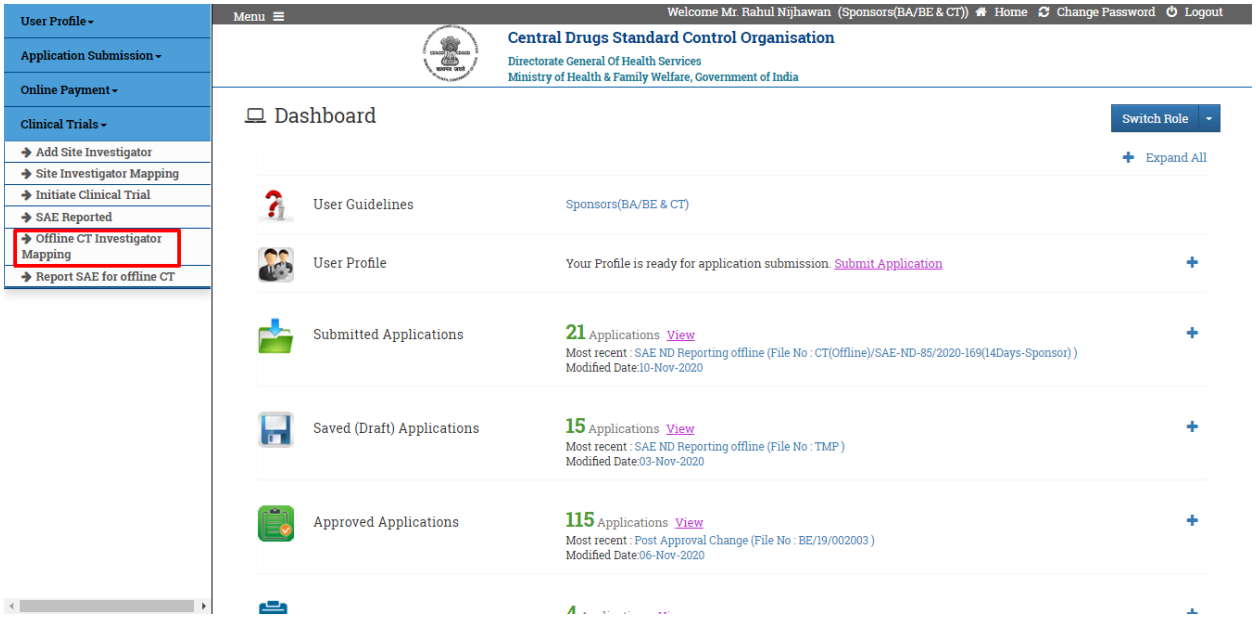

Figure 445: Sponsor Dashboard

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:

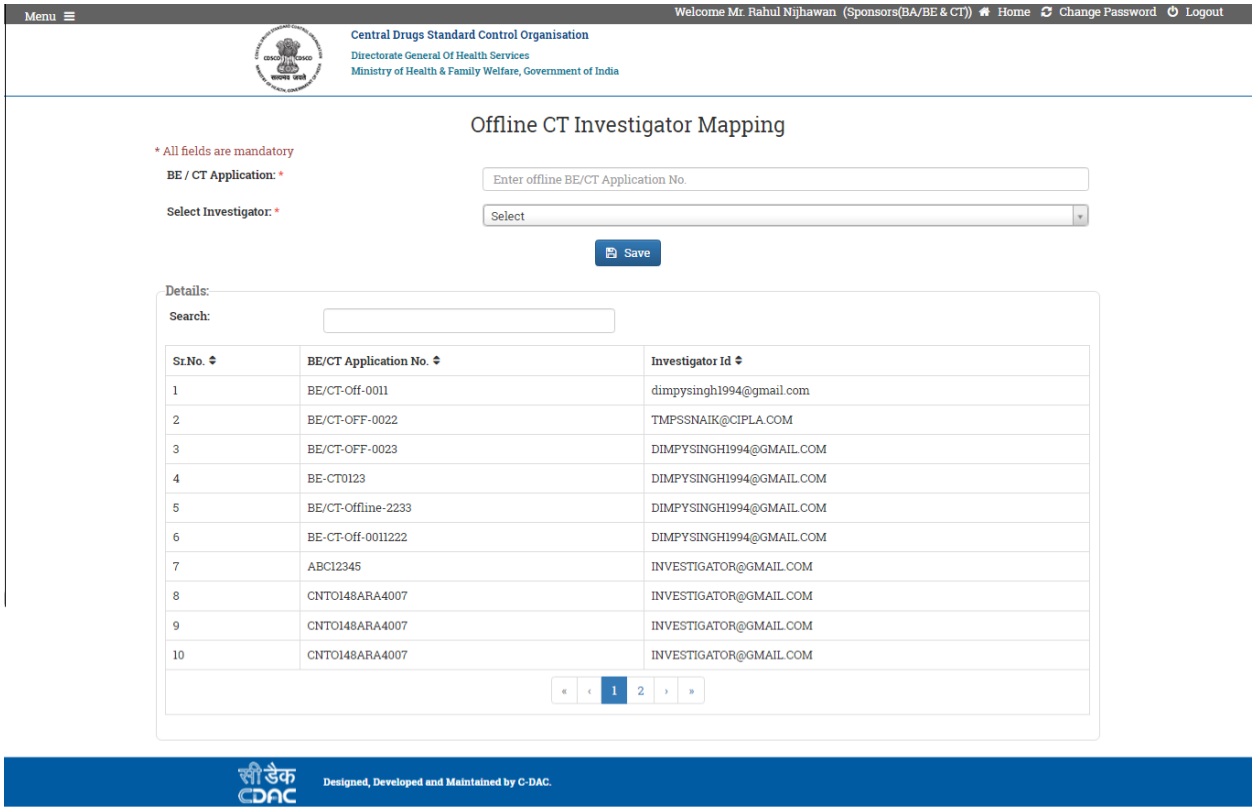

Figure 46: Offline CT Investigator Mapping Page

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.

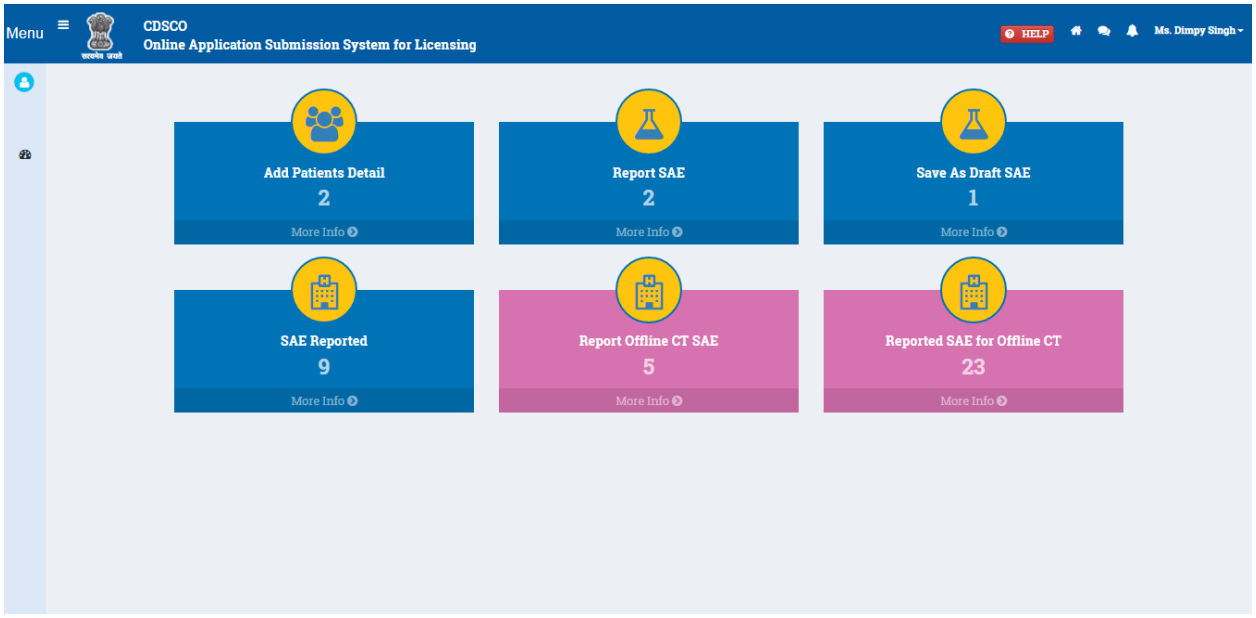

Figure 47: Investigator Dashboard

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**

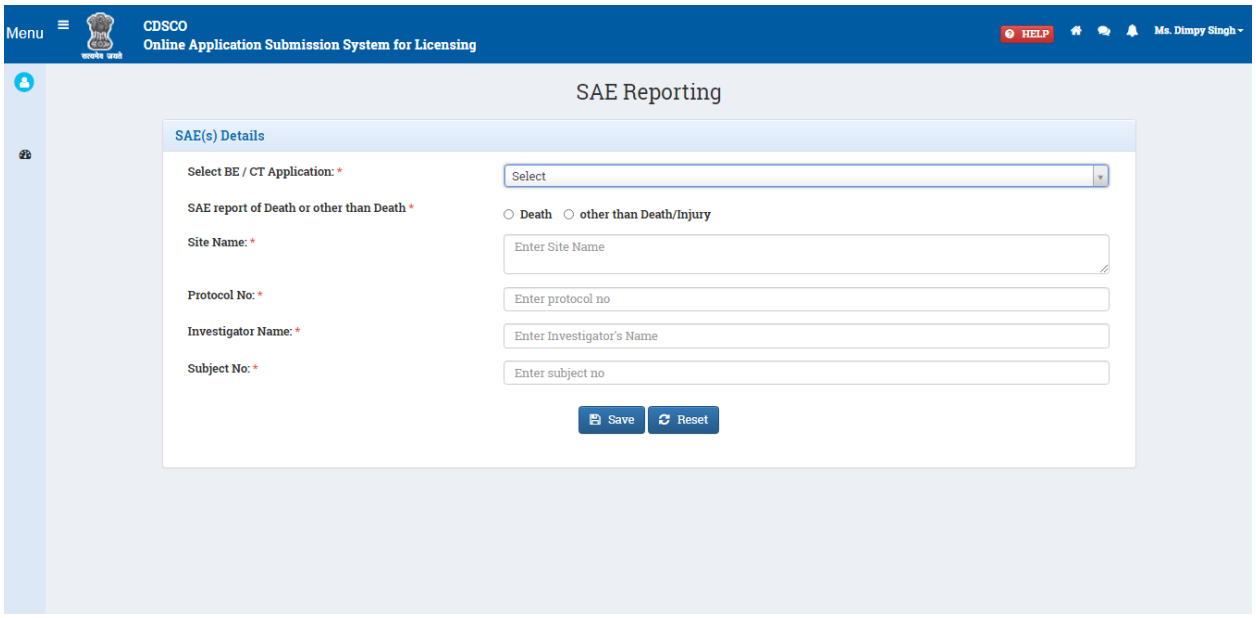

Figure 48: SAE Reporting Form

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

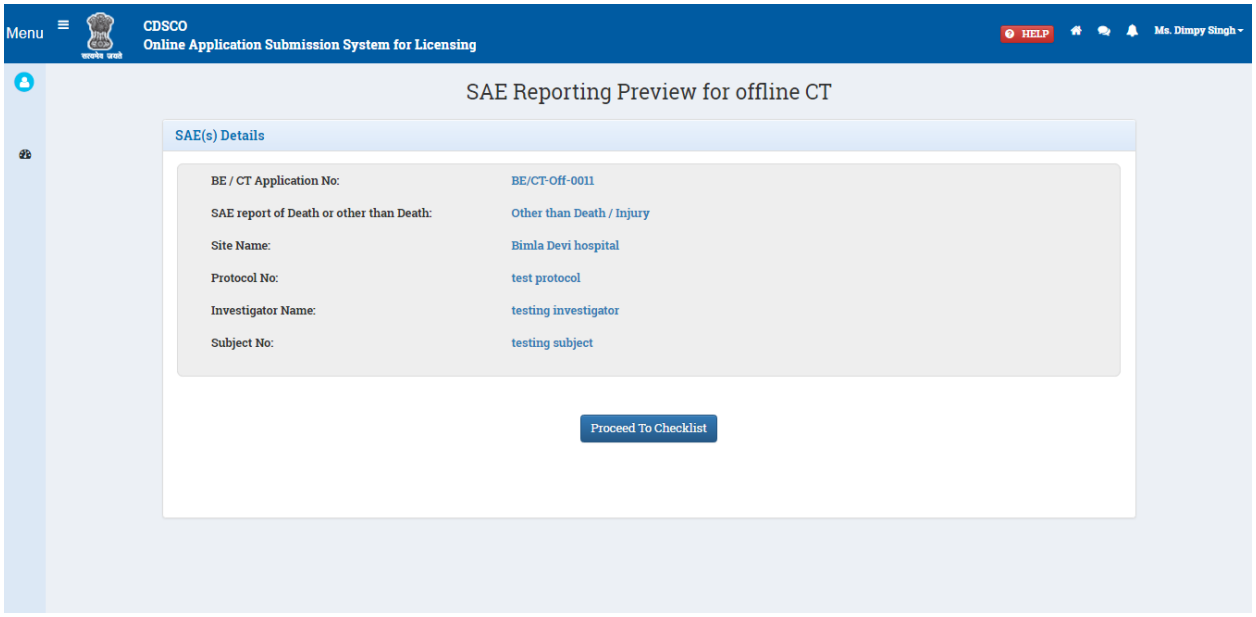

Figure 49: SAE Reporting Preview

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

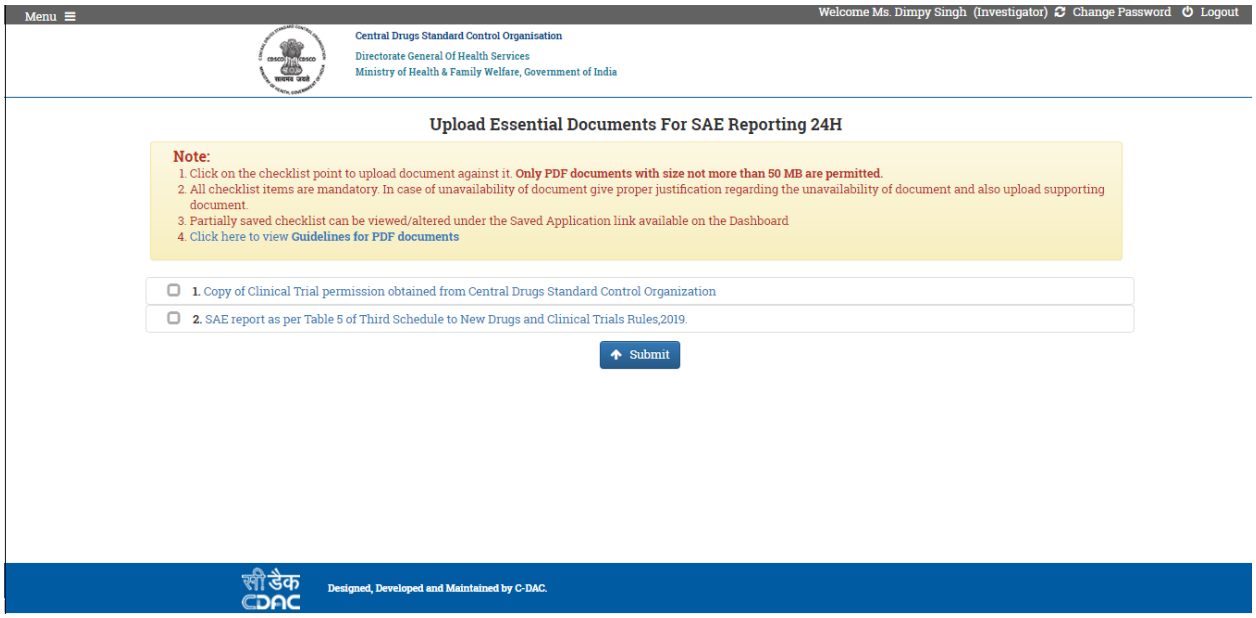

Figure 50: Checklist page for 24H SAE Reporting

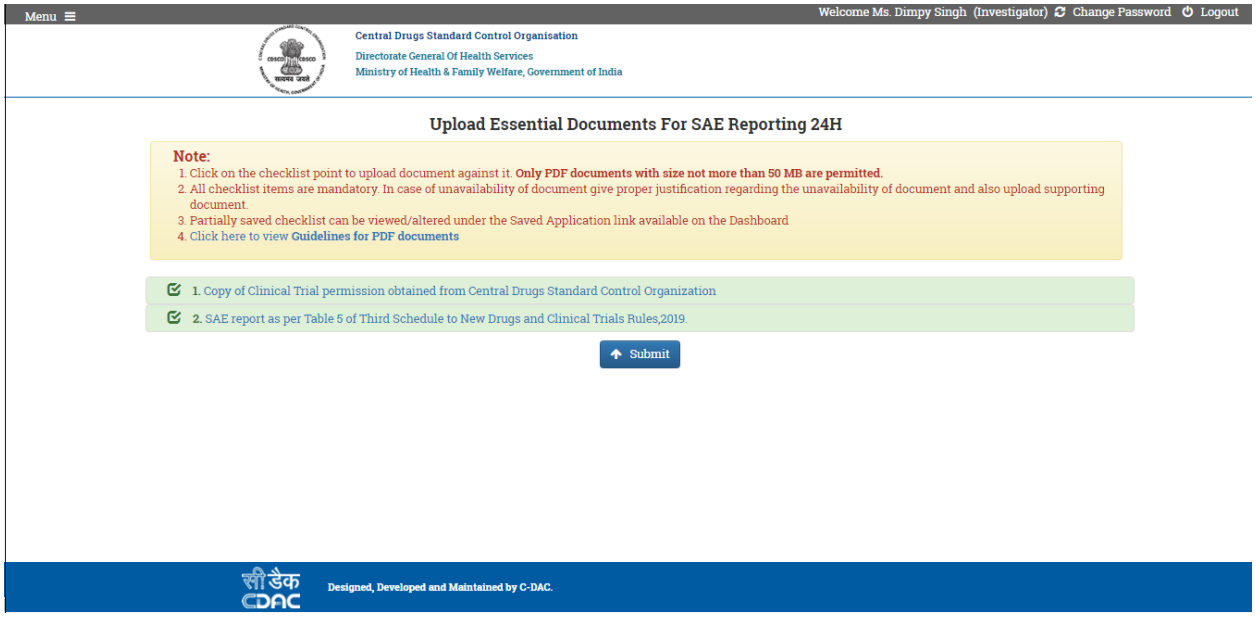

Figure 51: Checklist page for 24H SAE Reporting

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.

Figure 53: SAE Reporting List

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

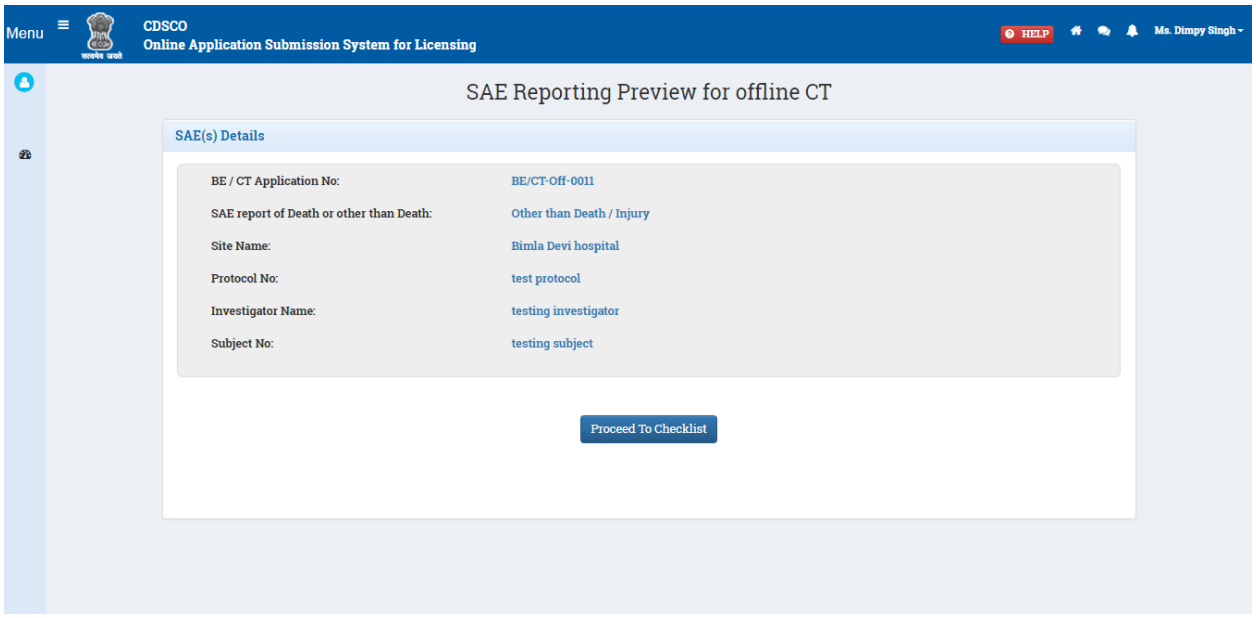

Figure 54: SAE Reporting Form Preview

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

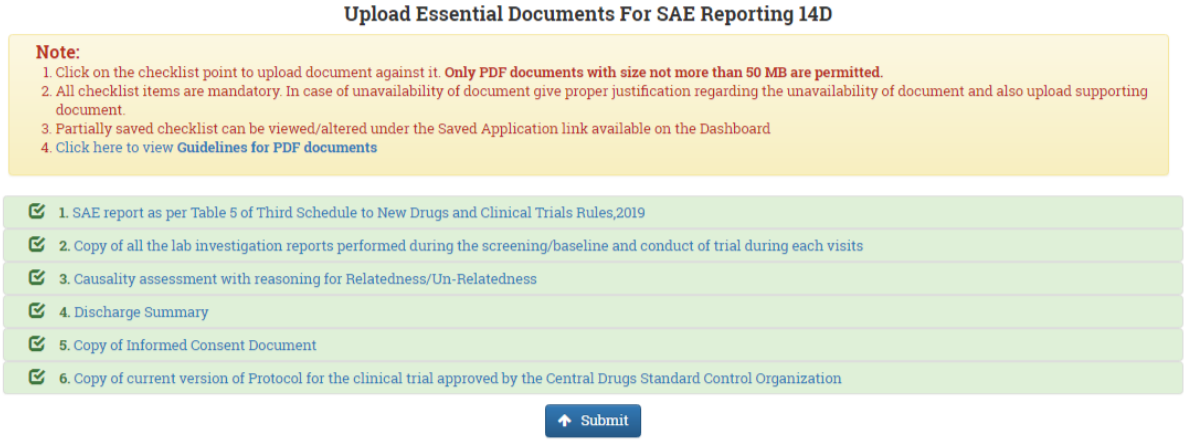

Figure 55: Checklist page for 14D SAE reporting

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:

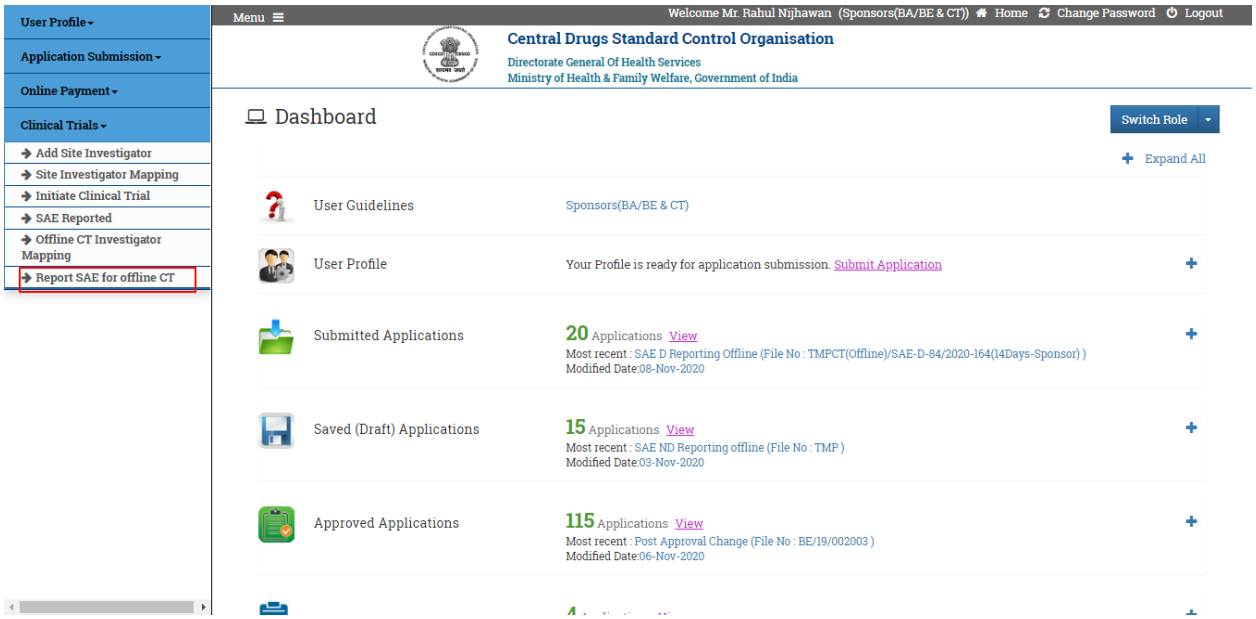

Figure 57: Sponsor Dashboard

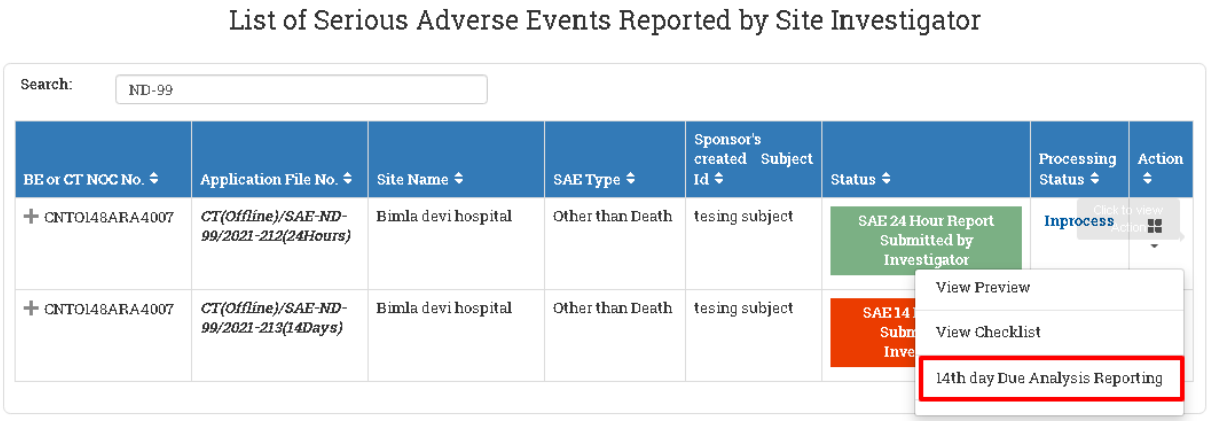

Figure 58: SAE Reporting List

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

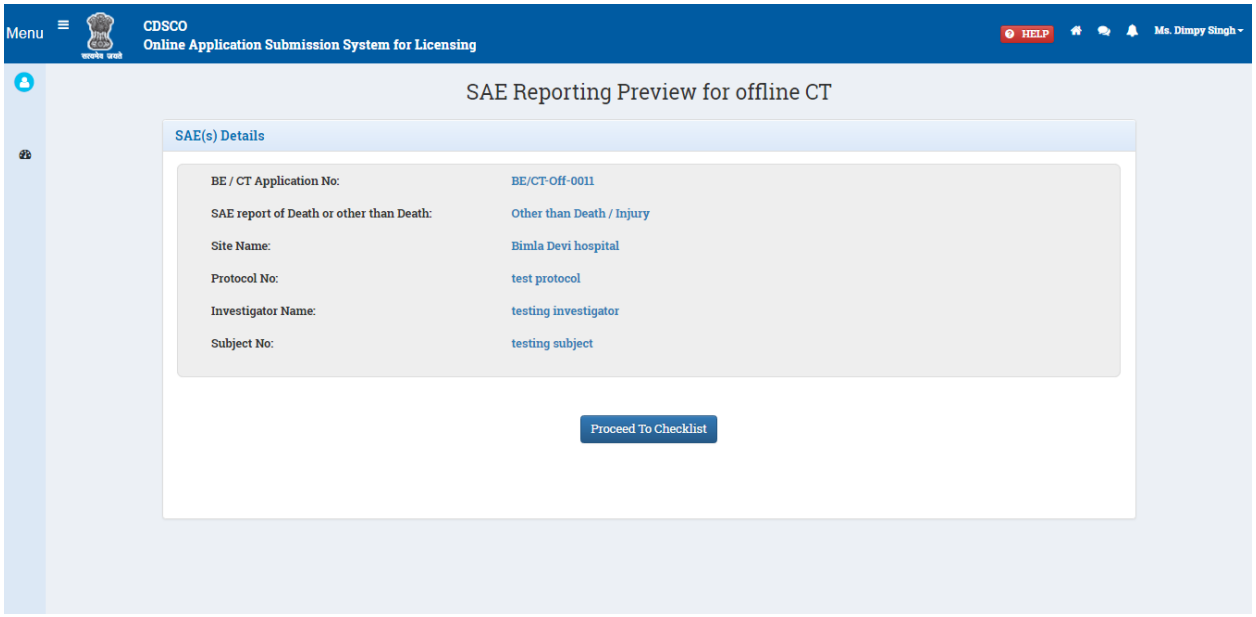

Figure 59: SAE Reporting Preview

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

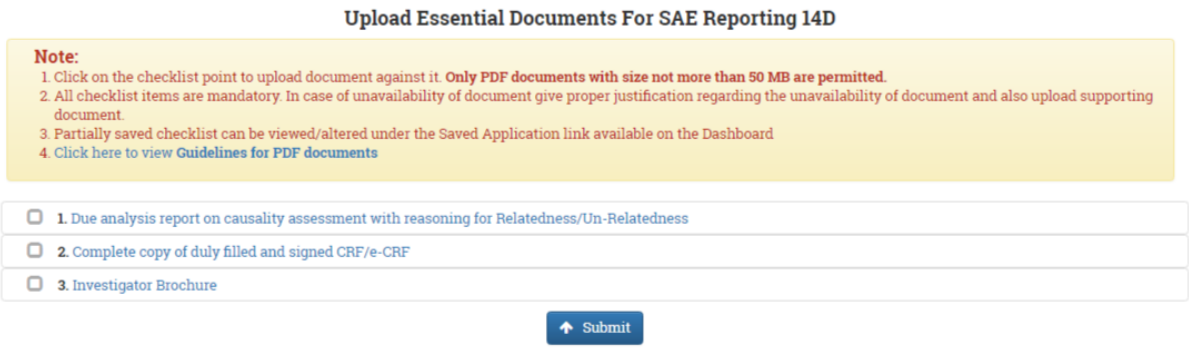

Figure 60: Checklist Page for 14D SAE Reporting by Sponsor

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: -

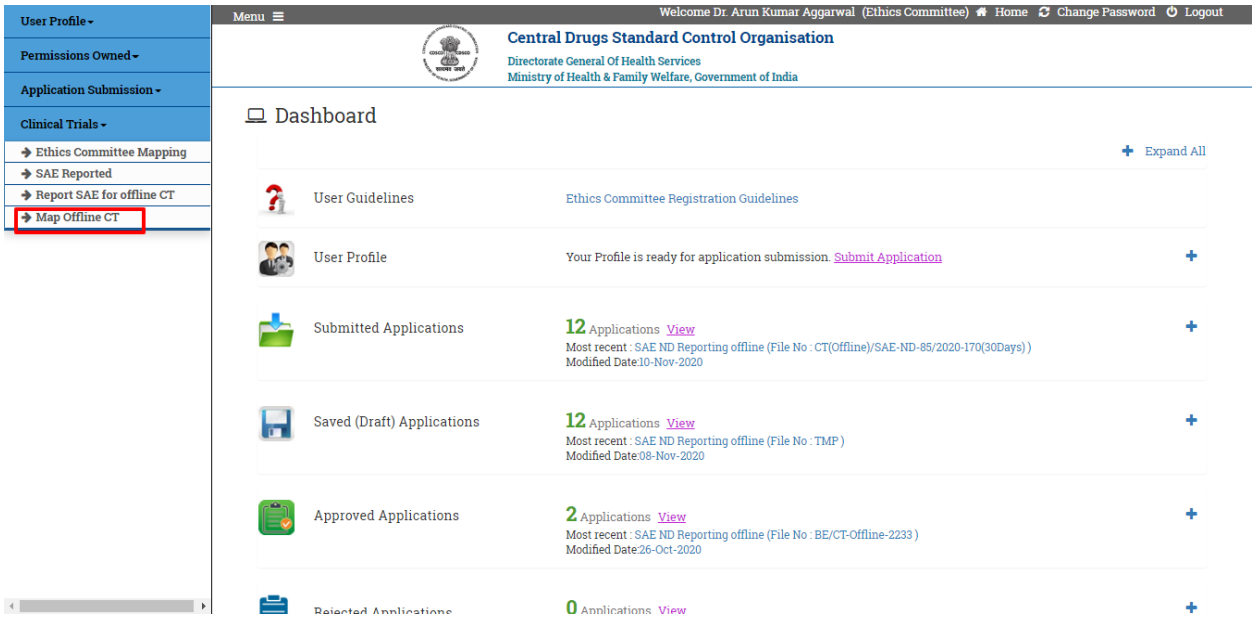

Figure 62: EC Dashboard

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

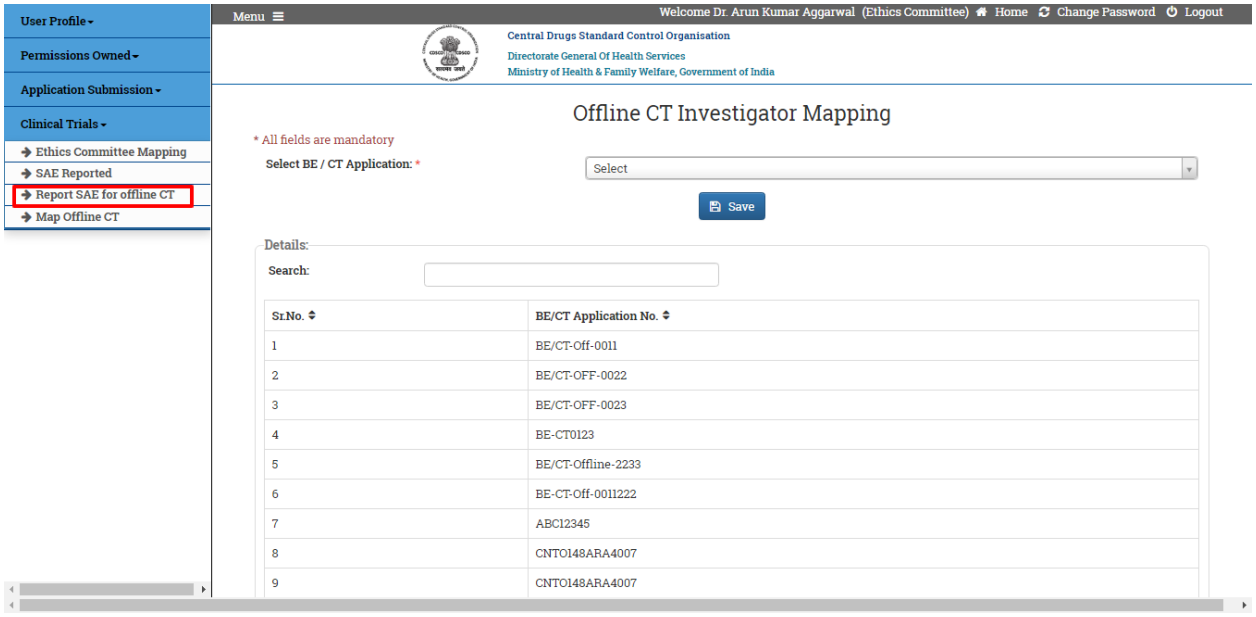

Figure 63: Offline CT Investigator Mapping

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

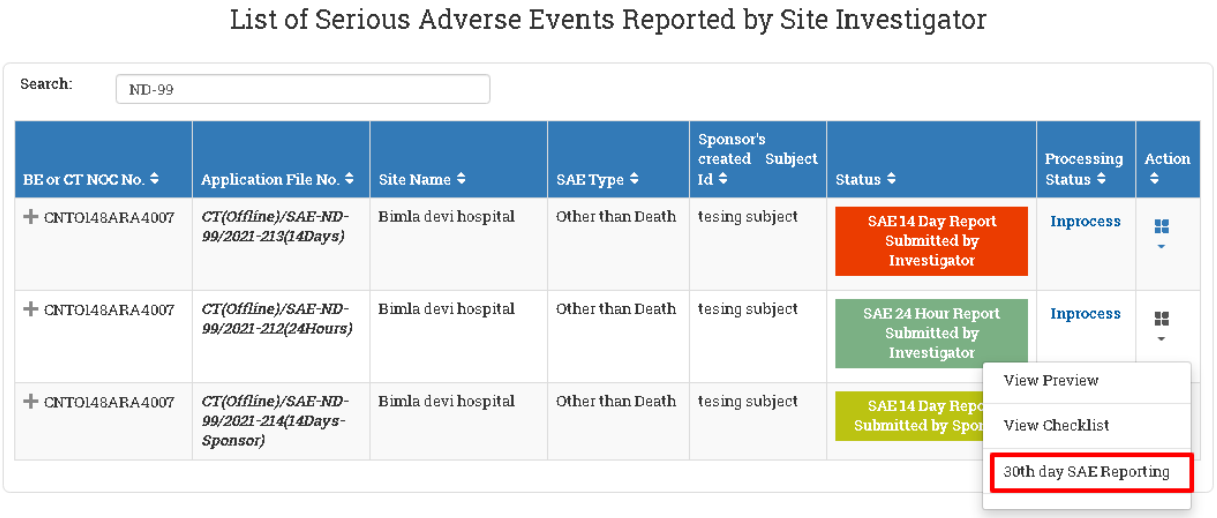

Figure 64: SAE Reporting List

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

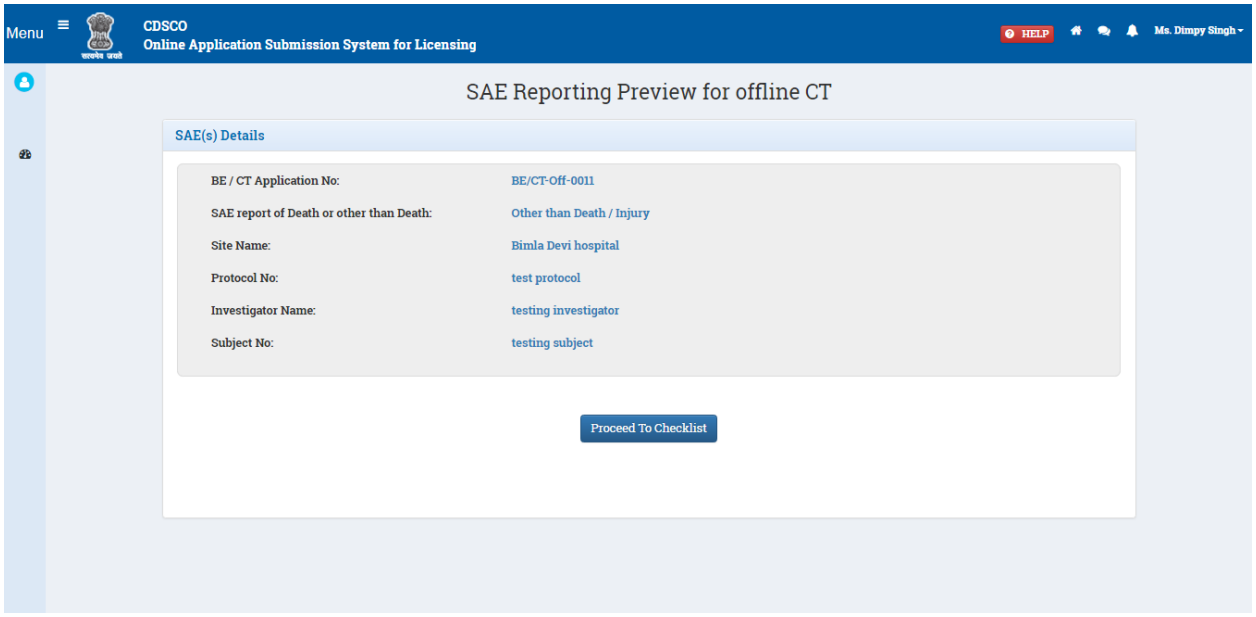

Figure 646: SAE Reporting Preview

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

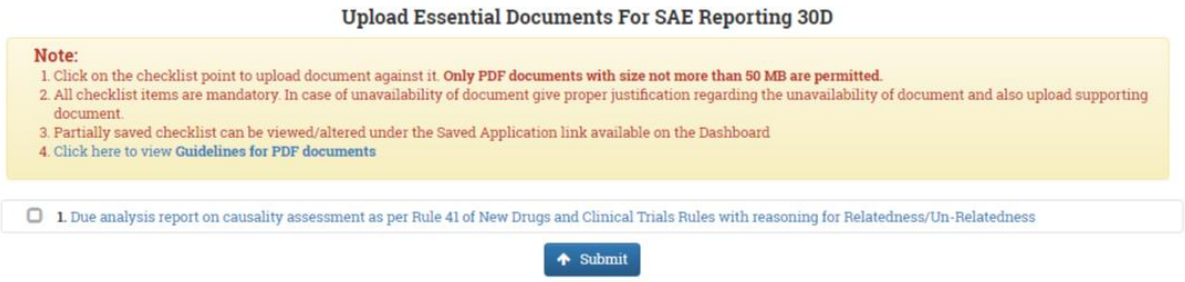

Figure 66: Checklist Page for 30D SAE Reporting by EC

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:

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:

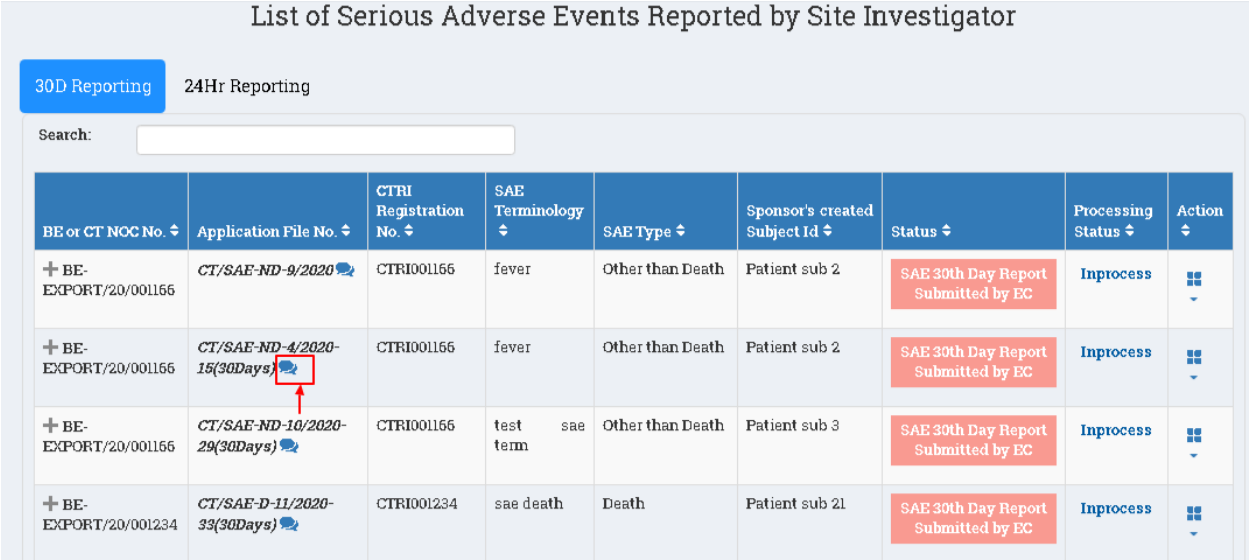

Figure 68: Chat icon in SAE Reporting List

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:

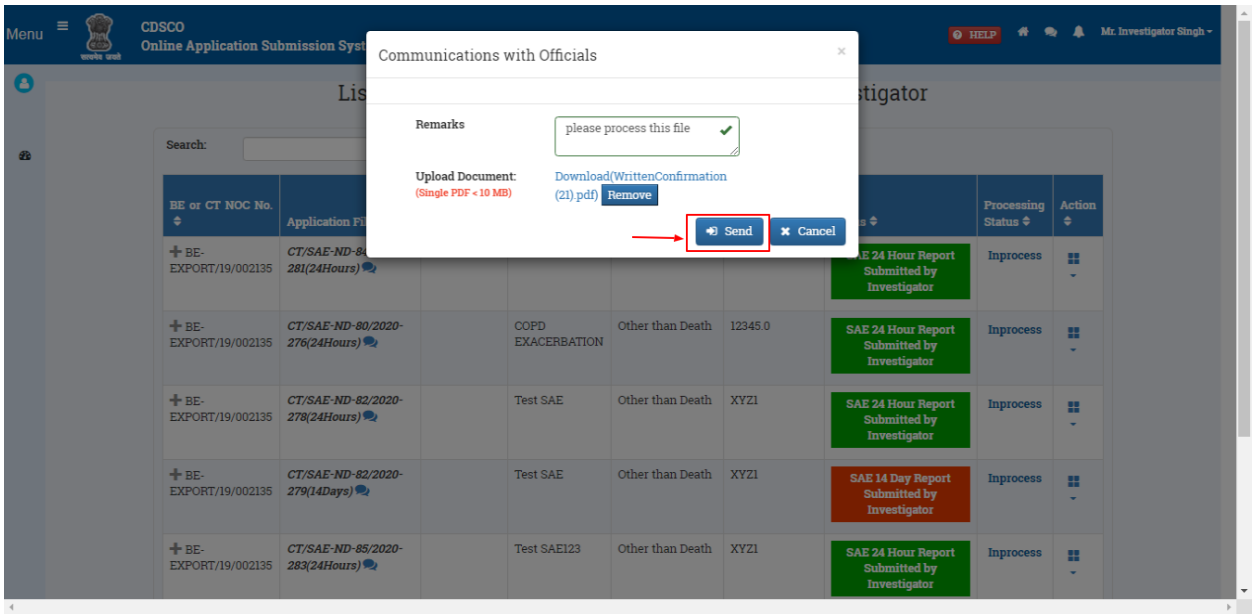

Figure 69: Communication Model

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

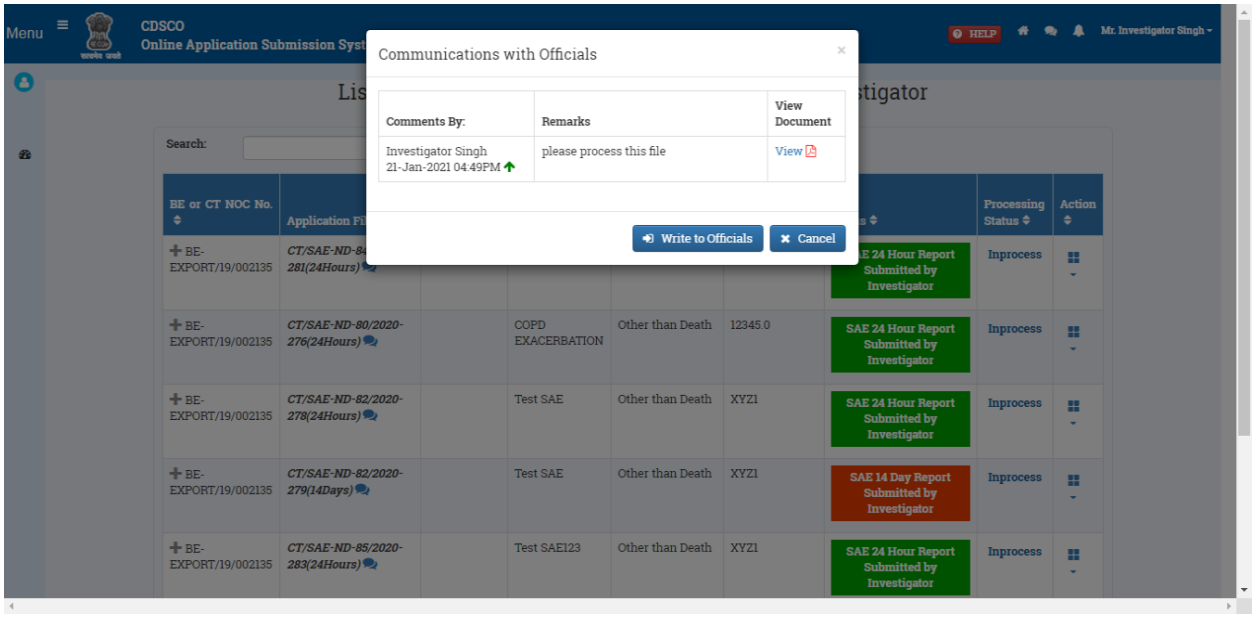

Figure 70: Previous Communication view

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

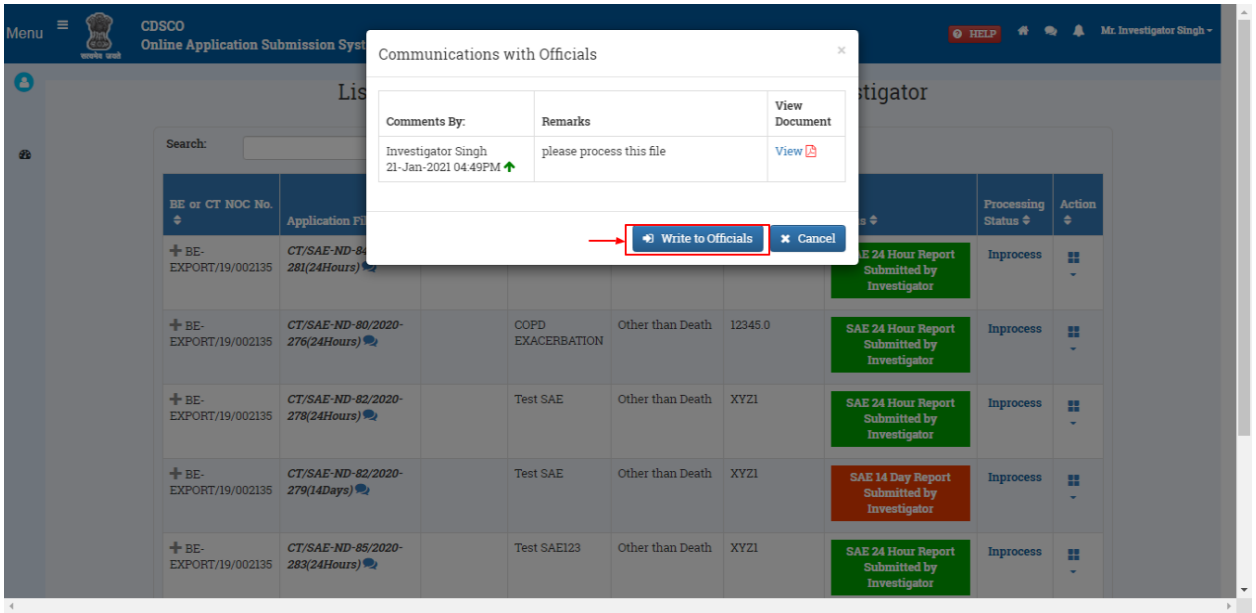

Figure 71: Communication Model with previous chat

LIST OF FIGURES