User Guidelines for

Post Ethical Approval Submission

- Serious Adverse Event

National Medical Research Register v2.0

National Institutes of Health (NIH)

Version 1.0, May 2023

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Prerequisite For Submission

ID	Criteria
1.1	User has the access to NMRR Version 2.0 (nmrr.gov.my) via a stable internet connection
1.2	Prerequisite: ● Should logged in as Investigator or Clinical Research Associates (CRA) ● Should have completed the profile page ● Should have a submission submitted, registered successfully in NMRR (issued with a NMRR ID) with “Interventional” Research Type ● Submission has received Initial Ethical Approval from MREC (Approval granted via MREC Full Board)
1.3	User has a role assigned in an approved submission either as: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Serious Adverse Event Coordinator (SAE Coordinator) • Serious Adverse Event Corresponding Person (SAE CP) - based on site/s assignment

Information/ Documents Required

General Serious Adverse Event Study Information

1. Site Conducted – to select if multiple sites are assigned to a Serious Adverse Event Corresponding Person (SAE CP)
2. Subject ID
3. Reporting Investigator

Serious Adverse Event Detail Information

1. Subject's Information
    a. Gender
    b. Year of Birth
    c. Age (auto calculated)
    d. Weight
    e. Height

2. Serious Adverse Event Information
    a. Serious Adverse Event Information
    b. Common Terminology Criteria of Adverse Event by System
    c. Common Terminology Criteria of Adverse Event by Terminology
    d. Place of Occurrence
    e. Narrative of the SAE Occurrence
    f. Date of Onset
    g. Date of Awareness
    h. Date of SAE Resolution
    i. Criteria for Seriousness
        i. If Yes, Criteria of SAE (multi selection)
            a) Resulting In Death
                a. Is Autopsy done
                b. Date of death
                c. Cause of death
            b) Life-threatening
            c) Hospitalization or prolongation of hospitalization
                a. Date of Hospital Admission
                b. Date of Discharge
            d) Persistent or significant disability/incapacity
            e) Congenital anomaly/ birth defect
            f) Important medical event (protocol specify)
        ii. Is this SAE considered a Suspected Unexpected Serious Adverse Reaction (SUSAR)
    j. Criteria for Seriousness
    k. Action Taken with Regard to IP
    l. Subject Outcome

i. Recovered
    a) Date of recovery
ii. Recovered with sequelae
    a) Date of recovery
iii. On-going
iv. Died
    a) Improving
    b) Persisting
    c) Worsening
v. Unknown

3. Suspected Product Information
    a. Study Randomisation (auto populated)
    b. Study Masking/ Blinding
    c. List of Investigational Product / Process / Intervention
    d. IP's Association with SAE (In General)
    e. Suspected Product Information
        i. Product Name
        ii. Dosage
        iii. Frequency
        iv. Route
        v. Batch
        vi. Therapy Start Date
        vii. Therapy Stop Date
        viii. Recent Dose Date
        ix. Day To Onset
        x. Indication
        xi. Date most recent dose before SAE
        xii. Did the event abate after the dosage of the study therapy is reduced or stopped?
        xiii. Did the event reappear after reintroduction of the study therapy?
        xiv. Suspected relationship to study drug
    f. Emergency code broken
    g. In the investigator's opinion, are there other possible cause(s)

4. Concomitant Medication(s)
    a. Usage of Concomitant Medication
    b. If Yes, Listing of Concomitant Medication
        i. Drug name
        ii. Dosage
        iii. Frequency
        iv. Estimated Date Start
        v. Date Stop Medication
        vi. Indication
        vii. Suspected SAE Cause Relationship

5. Medical History / Concurent Comorbidity
    a. Known Medical History/Concurrent Comorbidity?
    b. If Yes, Listing of Medical History/Concurrent Comorbidity?
        i. Disease/ Syndrome Name
        ii. Estimated Date of Onset
        iii. Duration of comorbidity
        iv. Date of Resolution
        v. Suspected SAE Cause Relationship
        vi.
6. Protocol Related/ Study Procedure
    a. Any Significant Procedure Done (Not as investigational Product/ Procedure done to patient)
    b. If Yes, Please Explain
        i. Suspected SAE Cause Relationship

7. Other Etiology
    a. Other Etiology that Possibly Caused the Adverse Event
        i. Suspected SAE Cause Relationship

8. Relevant Laboratory Test(s) Listing
    a. Lab tests/ Procedures/ Investigation
    b. Result
    c. Date of Investigation
    d. Upload File

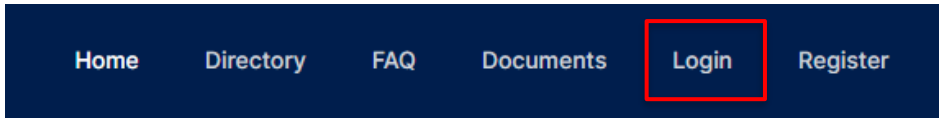
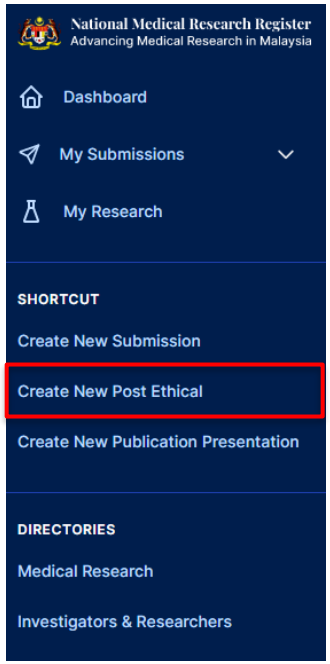
SAE SUPPORTING DOCUMENTS

1. Cover Letter to MREC
2. CIOMS Reporting Documents
3. Supporting Documents (user will be able to upload multiple documents in this part)

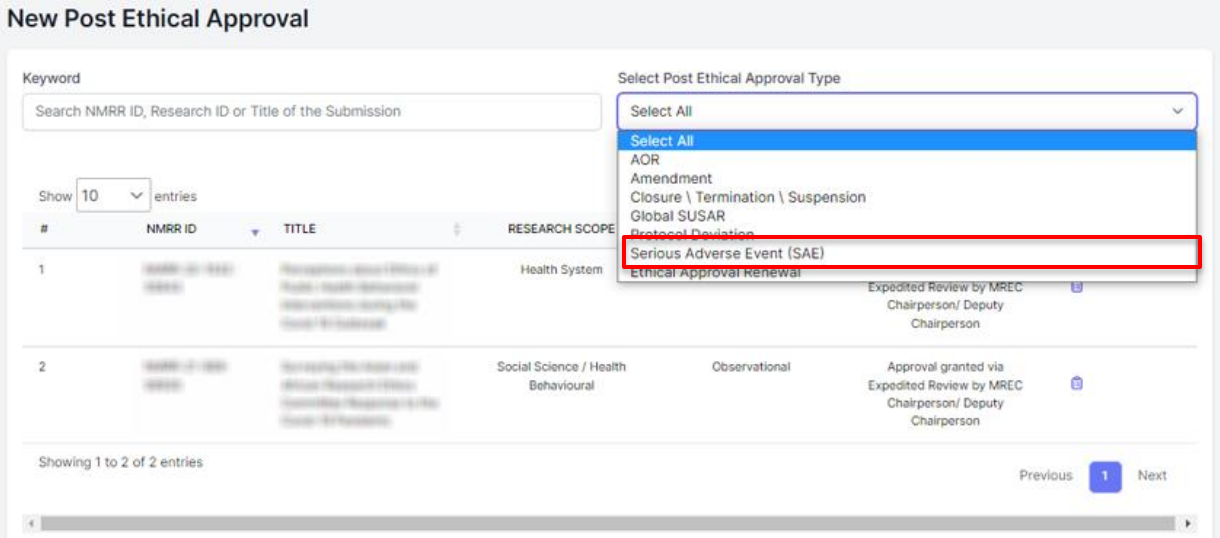
User Guidelines for Submission

1.0 - New Serious Adverse Event Submission

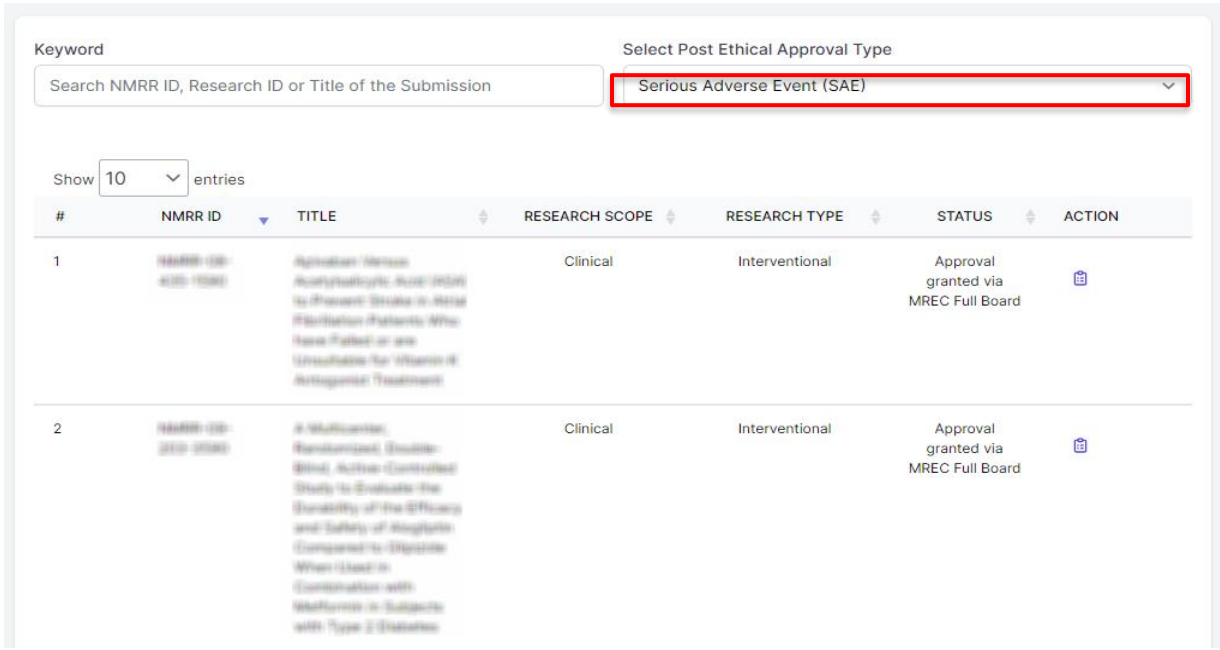
1.1 – Creating a new Serious Adverse Event Submission

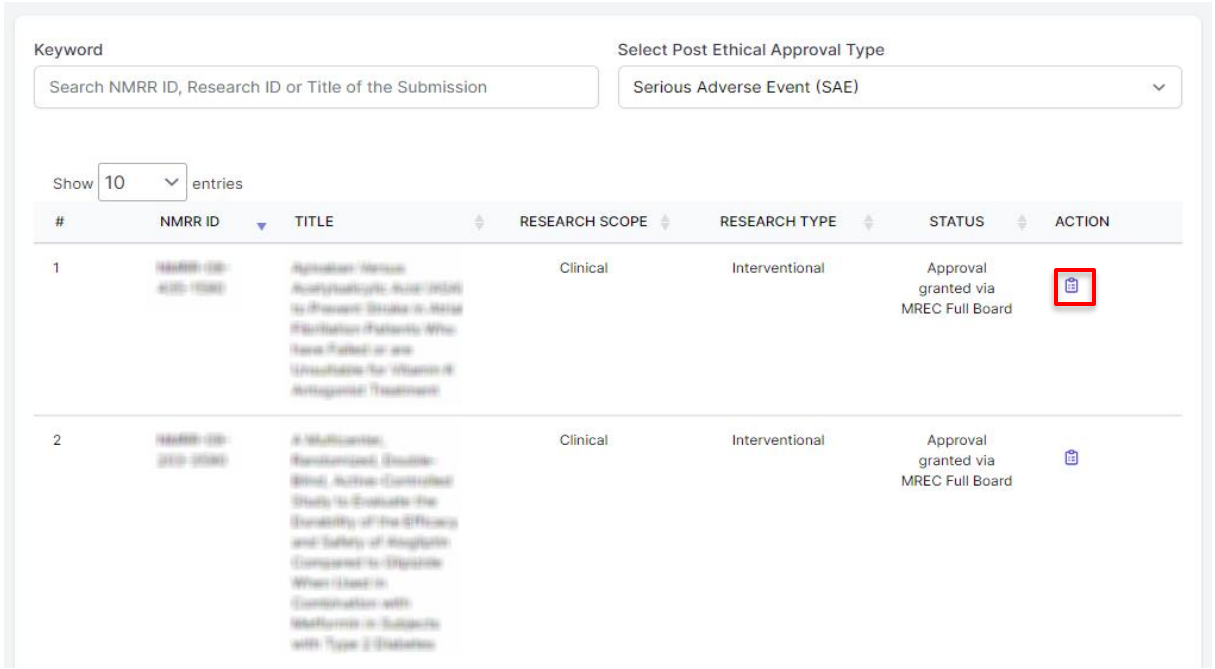
No	Step-by-step instructions	Remark
1.	Log in as Investigator or CRA in NMRR 	
2.	Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Post Ethical 	Shortcut access “Create New Post Ethical” is only available when user has a submission that has received an Initial Ethical Approval from MREC & user has been assigned with a role either as: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Serious Adverse Event Coordinator (SAE Coordinator) • Serious Adverse Event Corresponding Person (SAE CP)

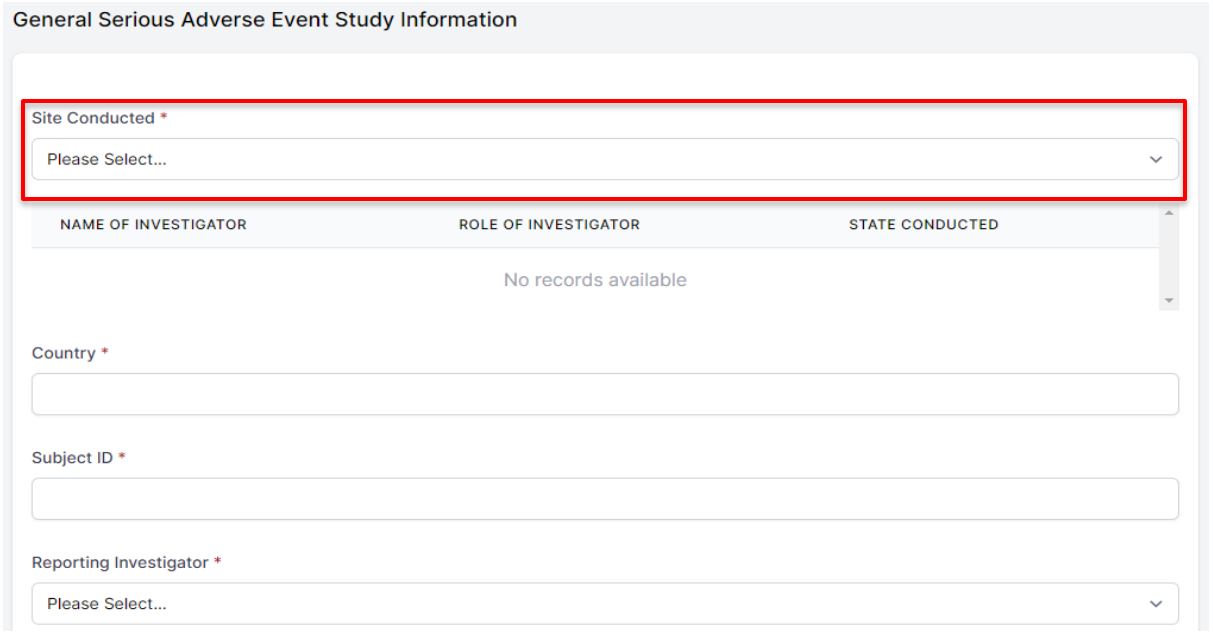
3. A list of all submission that has received MREC initial Ethical Approval will be shown on display. Go to “Select Post Ethical Approval Type” and choose “Serious Adverse Event”

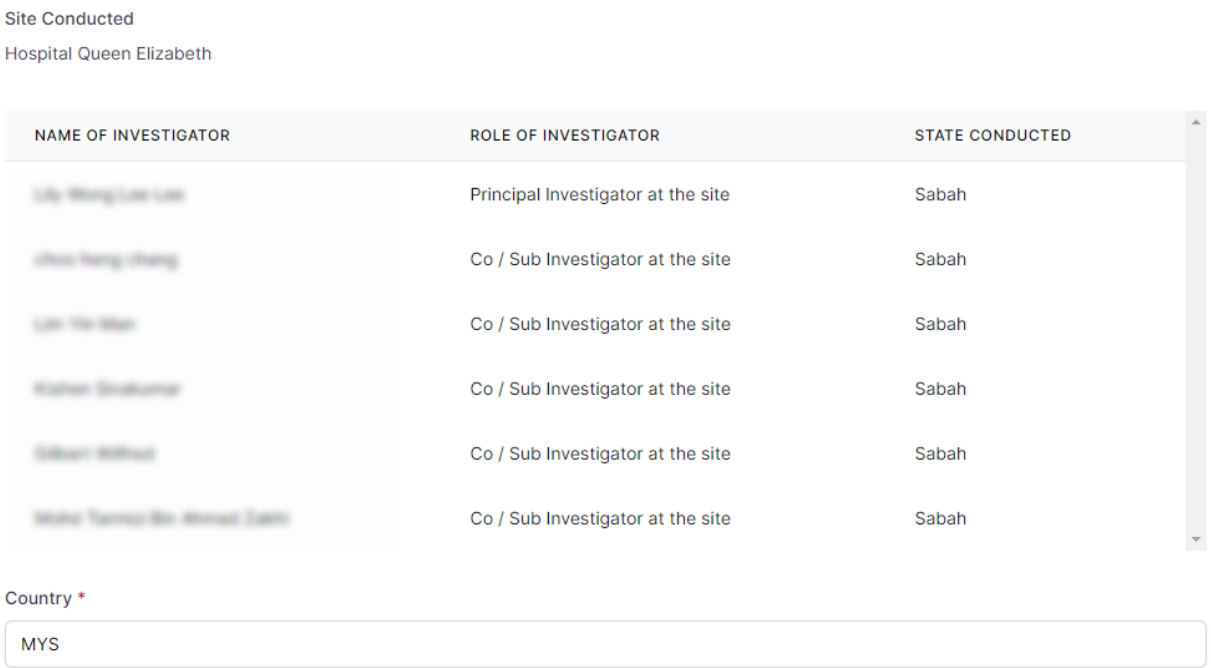


Once Serious Adverse Event (SAE) is selected, list of submission accessible for Serious Adverse Event Submission will be displayed

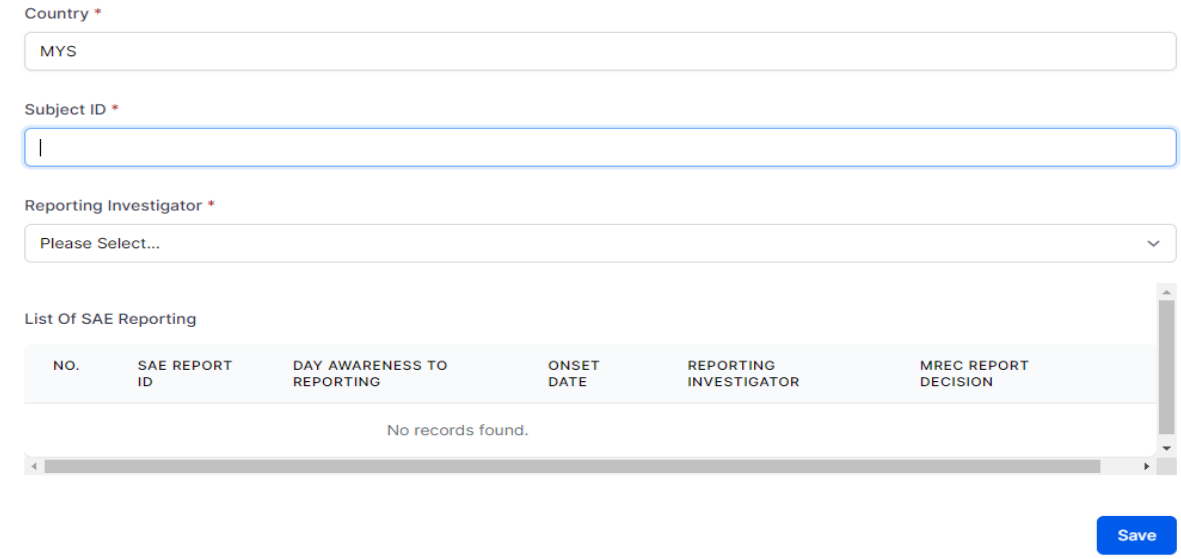


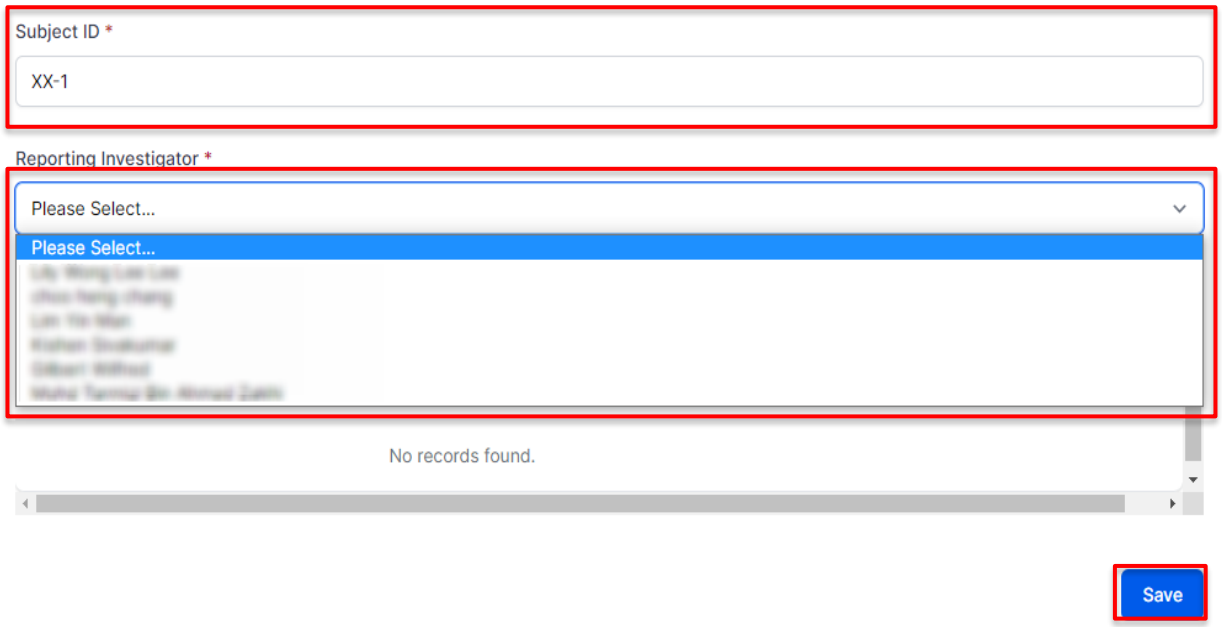
4.	Click on the icon to create a new Serious Adverse Event (SAE) Submission  	

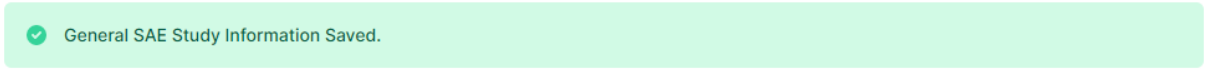
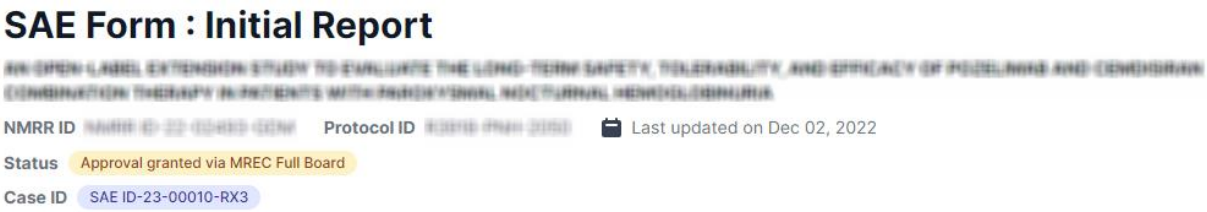
5.	A page will be displayed with the General information of the Submission is shown over the top part of the display page  	
6.	Scoll down the page to the “General Serious Adverse Event Study Information”. Select a site intended for the reporting.  	

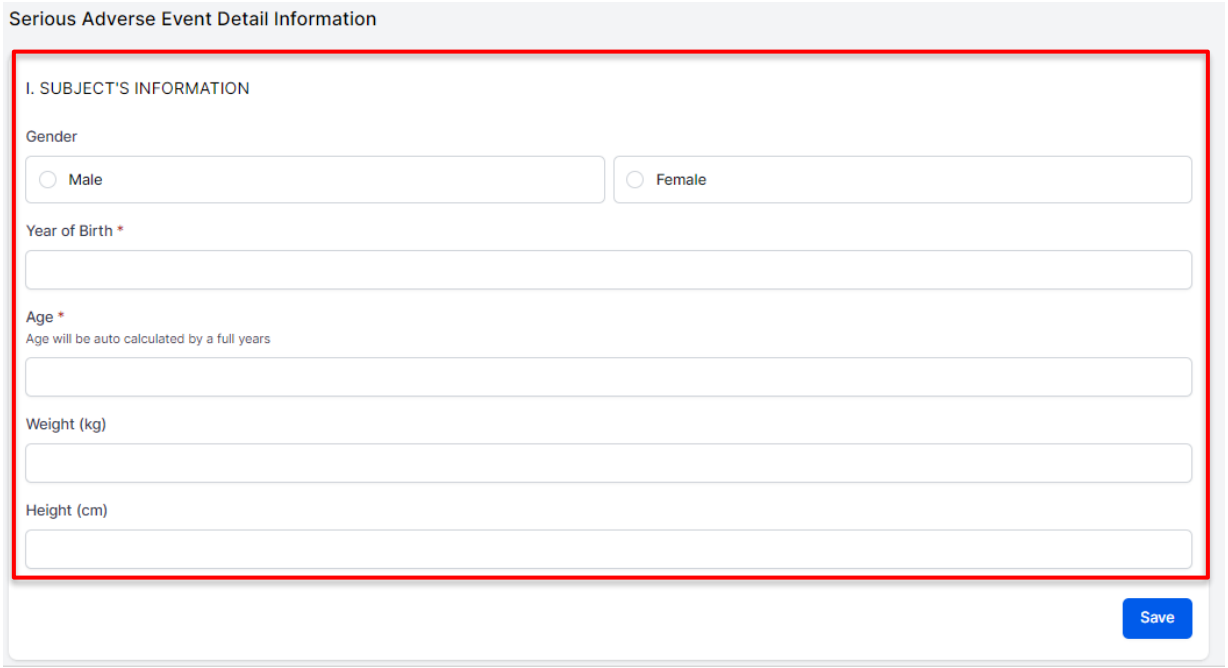
	In some submisison, site assigned has been auto selected and the list of investigator at site will be displayed  	**"Site Conducted"** will be auto-selected depending on the site assigned to user in the Serious Adverse Event Corresponding Person assignment during NMRR Registration Submission. **** Incase of a user is assigned with 2 or more sites, user is required to select the site intended for the reporting.**

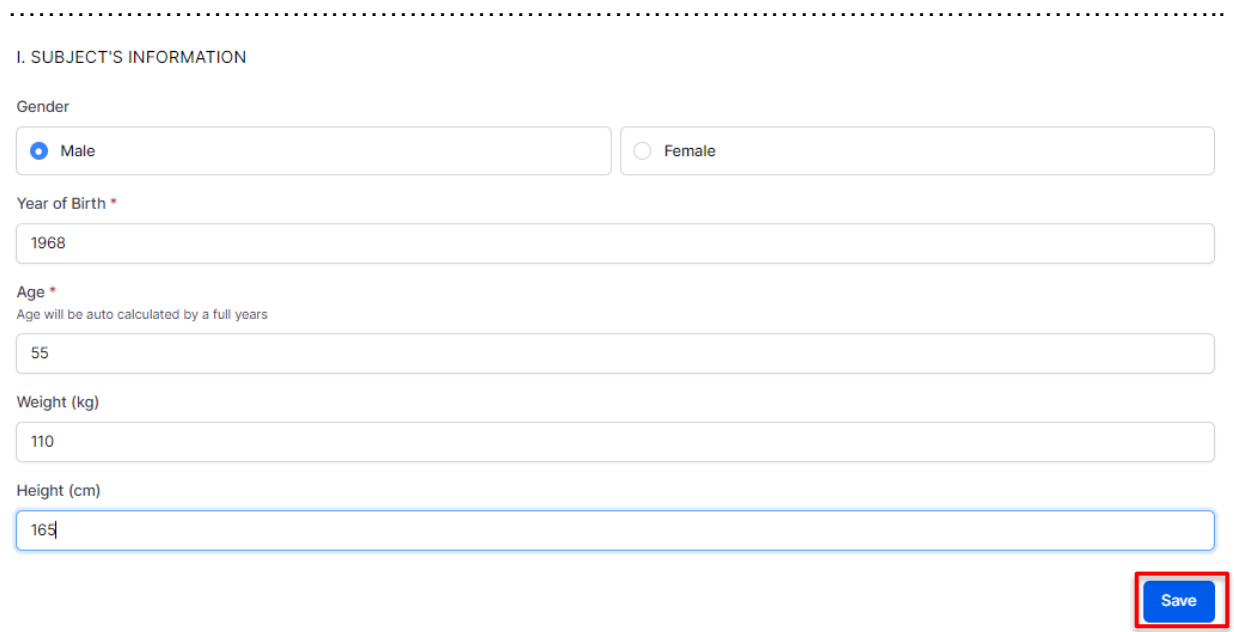
7. Insert the information on Subject ID and the “Reporting Investigator” . The selection of investigatoe is made by selecting a name from the list displayed. Click Save to save the information



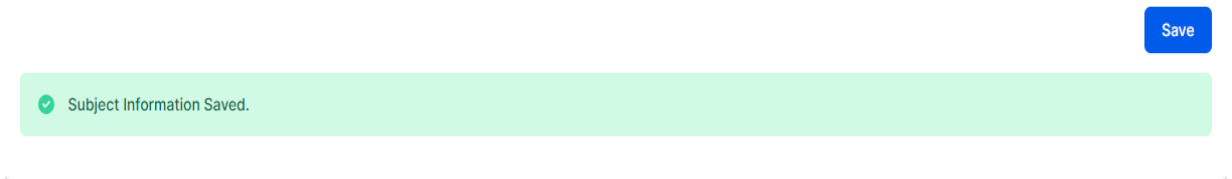


	A popup up will appear indicating the “General Serious Adverse Event (SAE) Information” has been succesfully saved  A Serious Adverse Event Post Ethical ID will be generated This information can be seen over the top part of the display page  	**Serious Adverse Event (SAE) Post Ethical ID”** will be the reference number for the Serious Adverse Event Submission from this point onwards. Once a Serious Adverse Event (SAE) Post Ethical ID is generated**, Serious Adverse Event Reporting Submission** has now been created successfully and is available to be accessed from “My Submission” menu. **Serious Adverse Event Post Ethical ID later in the submission** will also be referred to as **Serious Adverse Event Case (SAE Case ID)** **“Serious Adverse Event Status” or Case Status** refers to the **status of Serious Adverse Event Post Ethical ID** in general. “Case Open” means the reporting case is now open for submission. User may send SAE updates/follow up if needed/ required

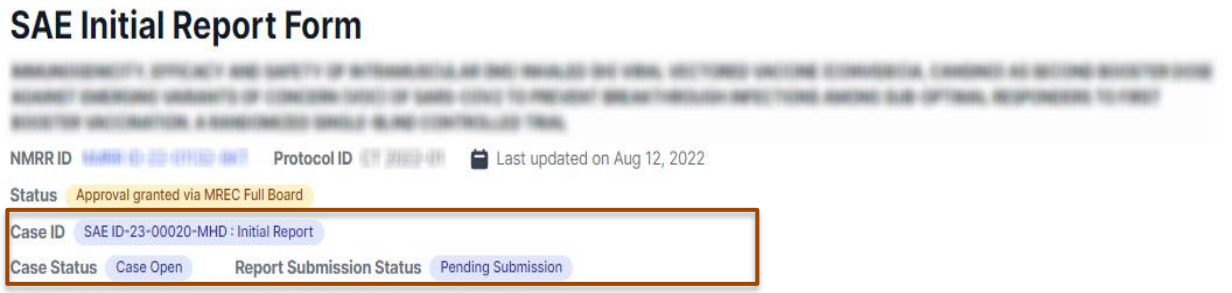
7.	Continue to scroll down on the page. User is then required to fill up the “Serious Adverse Event Details Information” on the “Subejct Information” subsection. Click Save to save the information . 	



A popup up will appear indicating the "Subject Information" has been succesfully saved.

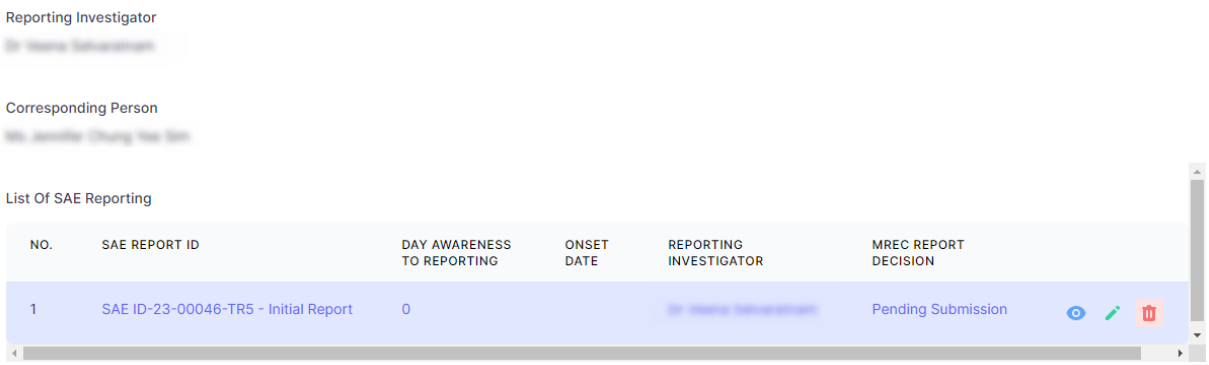
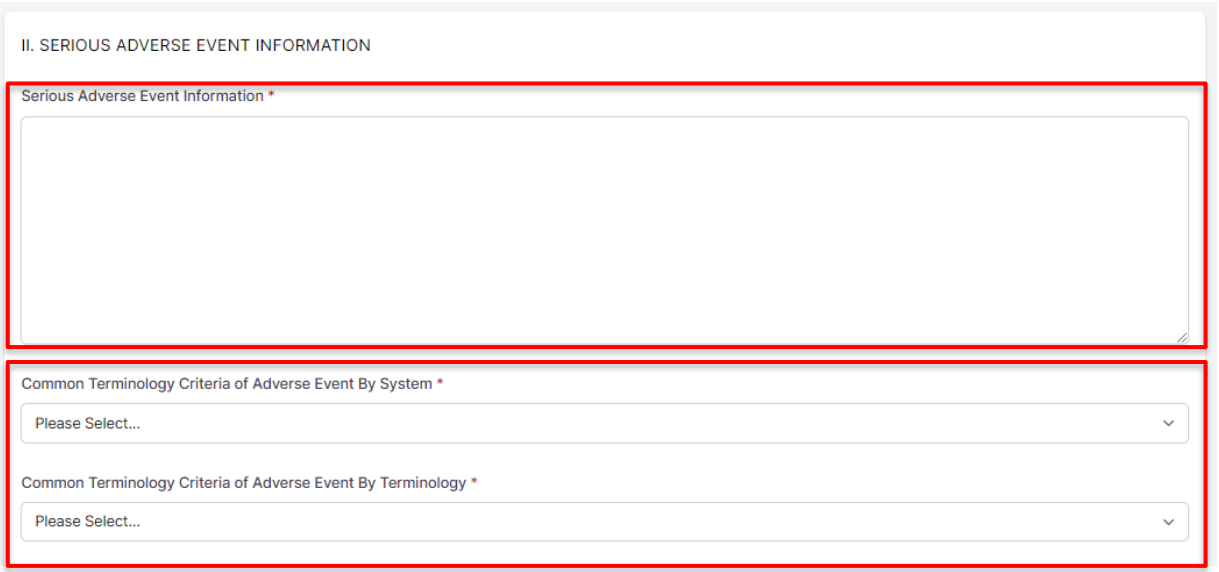


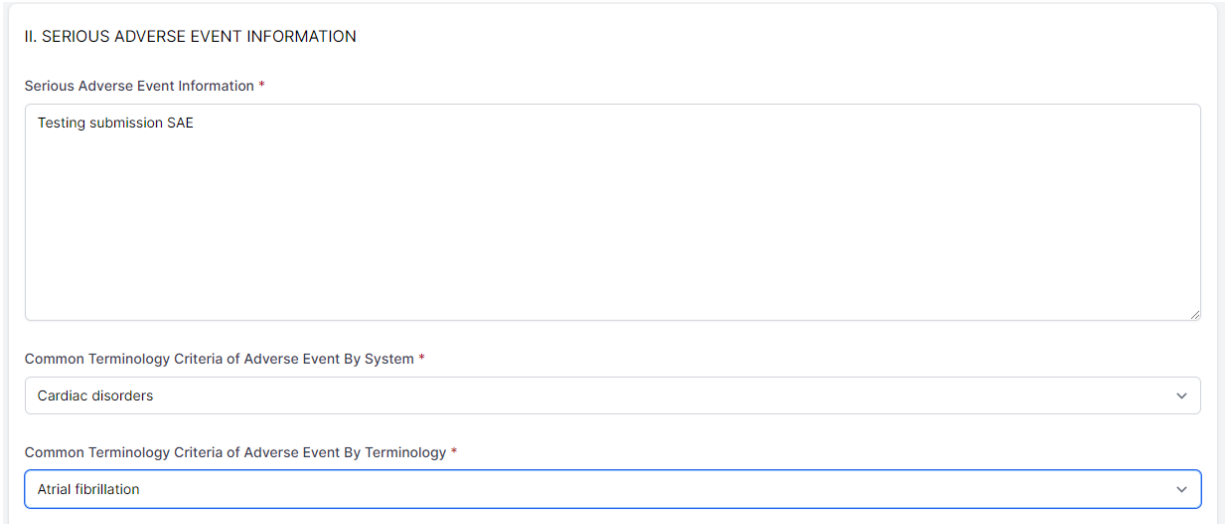
A change to Serious Adverse Event Post Ethical ID (SAE Post Ethical ID) will happen (ID is then assigned with a Report Type) and Report Submisison Status will be generated and displayed as "Pending Submisison". This information can be seen over the top part of the display page



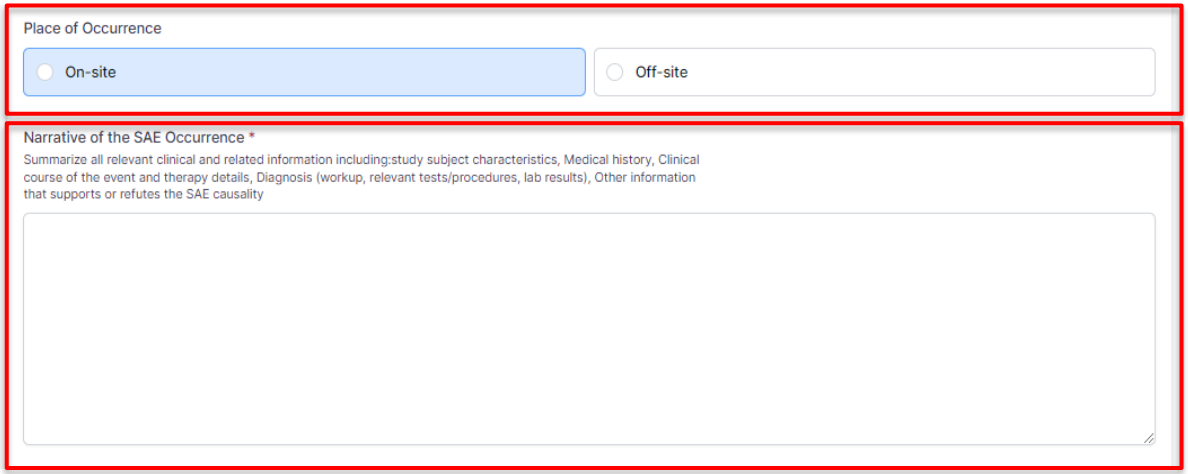
"Serious Adverse Event (SAE) Post Ethical ID/ Case ID – Report Type" will be the reference for the Serious Adverse Event Reporting Submission from this point onwards. **Case ID – Report Type later in the submission will also be referred to as Serious Adverse Event Report (SAE Report)**

"Report Submission Status" refers to the **current status of SAE Report** while **"Case Status"** refer to **status of Case ID or SAE Case** in general (can be either **Case Open or Case Closed or Case Reopen**)

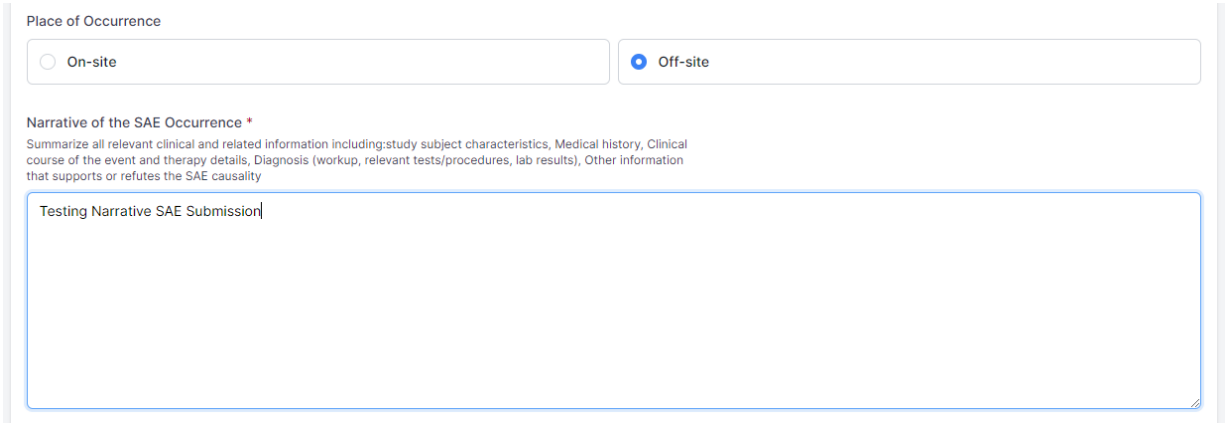
	User may also see the listring of SAE Reporting Generated in the General Serious Adverse Event Study Information section  Reporting Investigator Corresponding Person List Of SAE Reporting NO. / SAE REPORT ID / DAY AWARENESS TO REPORTING / ONSET DATE / REPORTING INVESTIGATOR / MREC REPORT DECISION 1 / SAE ID-23-00046-TR5 - Initial Report / 0 / Pending Submission	
8.	Scroll ddown to the Serious Adverse Event Information subsection and user is then required to insert the information on the Serious Adverse Event (SAE) , followed by selection of the Common Terminology Criteria of such event  II. SERIOUS ADVERSE EVENT INFORMATION Serious Adverse Event Information * Common Terminology Criteria of Adverse Event By System * Please Select... Common Terminology Criteria of Adverse Event By Terminology * Please Select... ……	**Common Terminology Criteria is based on the "Common Terminology Criteria of Adverse Event – CTCEA" - a set of criteria for used the standardized classification of adverse effects of drugs used in clinical trial/cancer therapy. Please refer to https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm#ctc_50 for more detail information on this criteria** **Serious Adverse Event Information** can be the same as CTCEA selection. A brief information or explanation can also be inserted to further explain on the event reported. **This should exclude the narrative and clinical presentation of subject.**



Next , insert the information on the place of SAE Occurrence and the narrative of the event



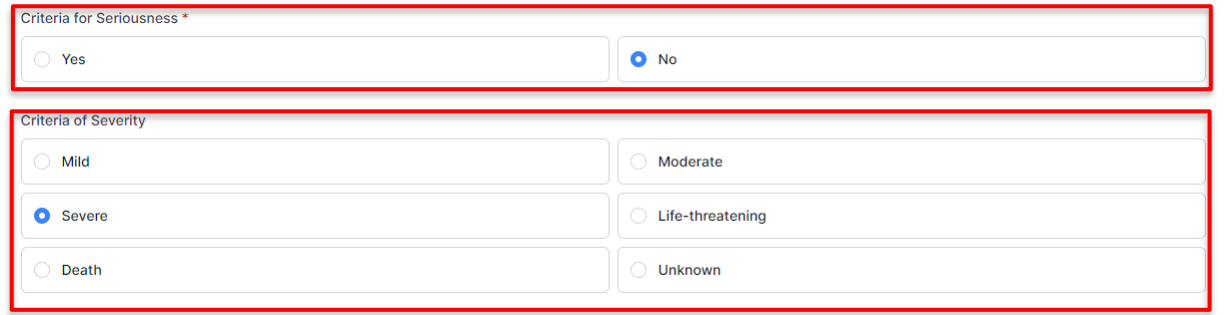
.....



Following that, user is required to insert information regarding the date of SAE event (date of event onset,awareness and its resolution)

.....

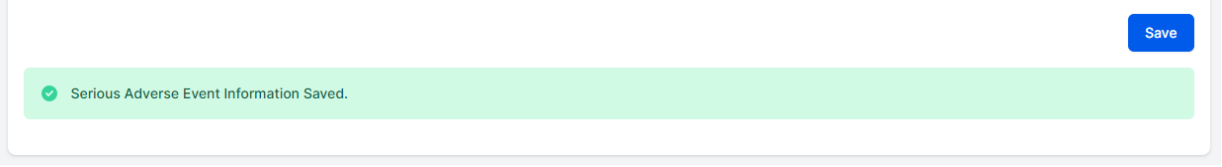
After that , insert the information on the Criteria of Seriousness followed by the Criteria of Severity

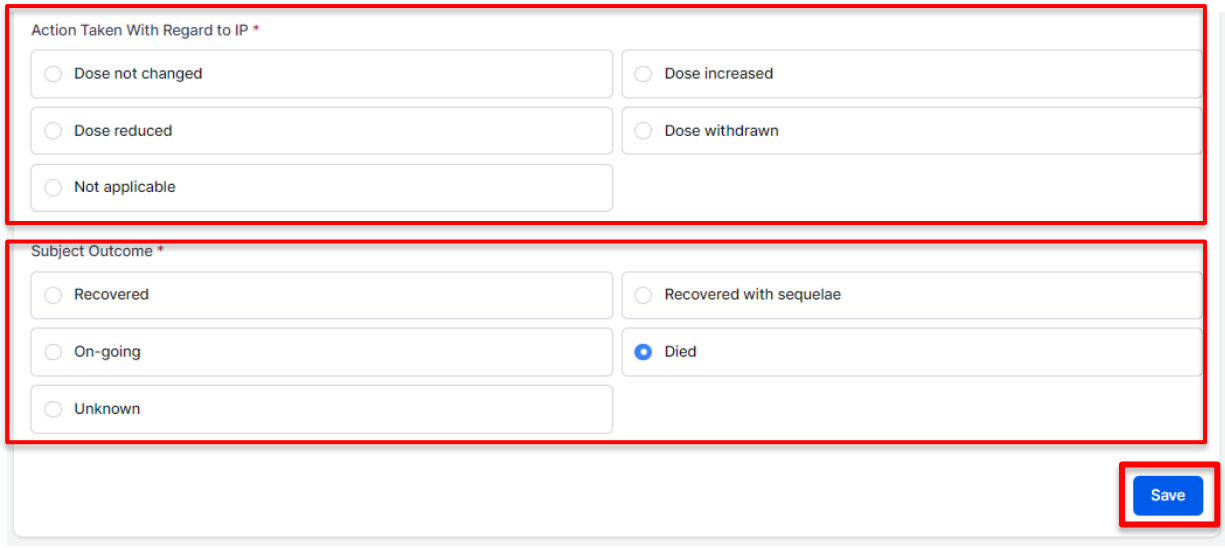


Days onsets is auto calculated showing the number of days since the onset to the awareness of the event

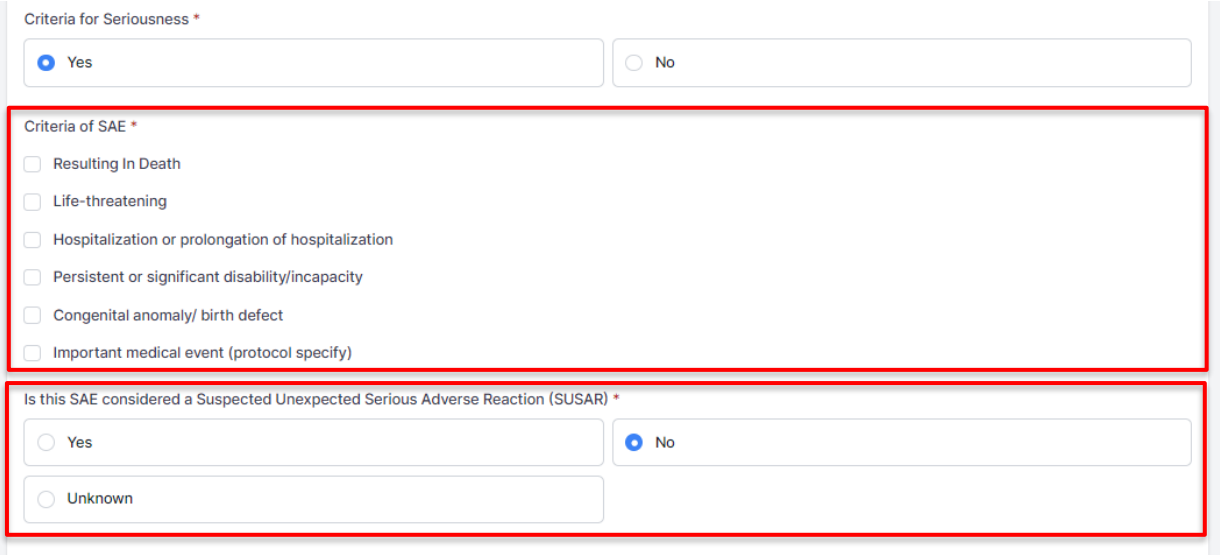
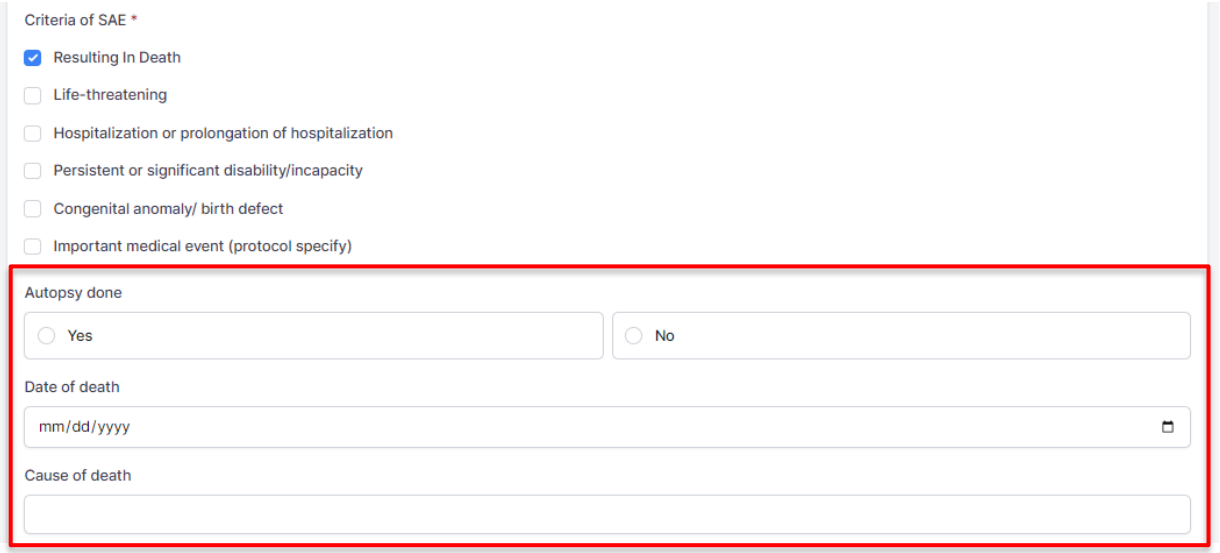
If Criteria of Seriousness selection is **"Yes"**, **refer to point no 9**

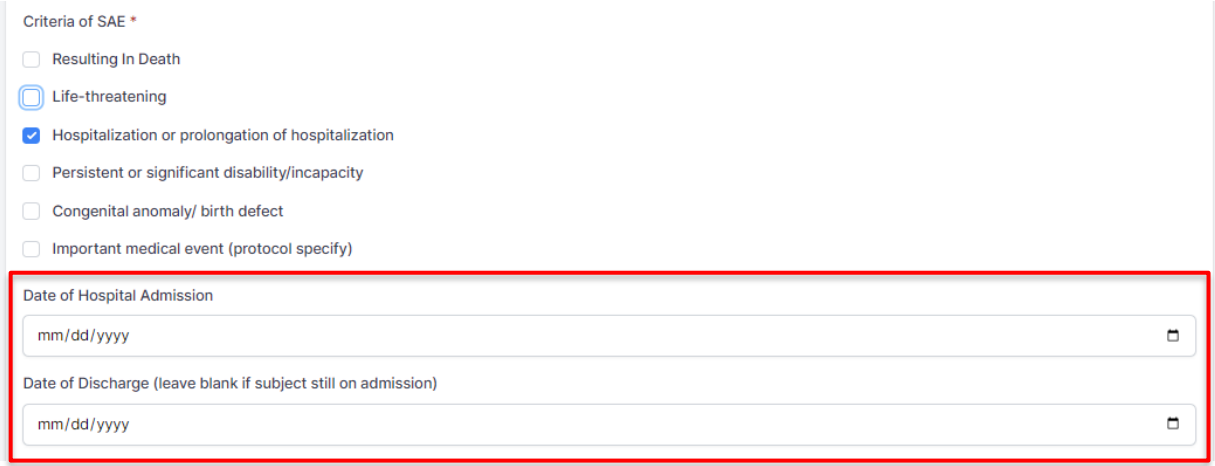
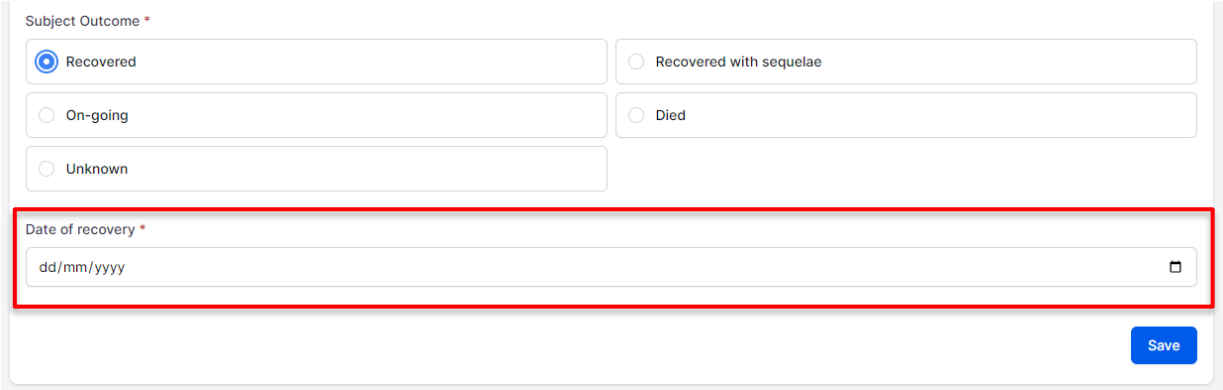
User is the required to insert information on the Action Taken with regard to IP and subject outcome. Click Save to save the information.
A popup up will appear indicating the “Serious Adverse Event Information” has been succesfully saved.

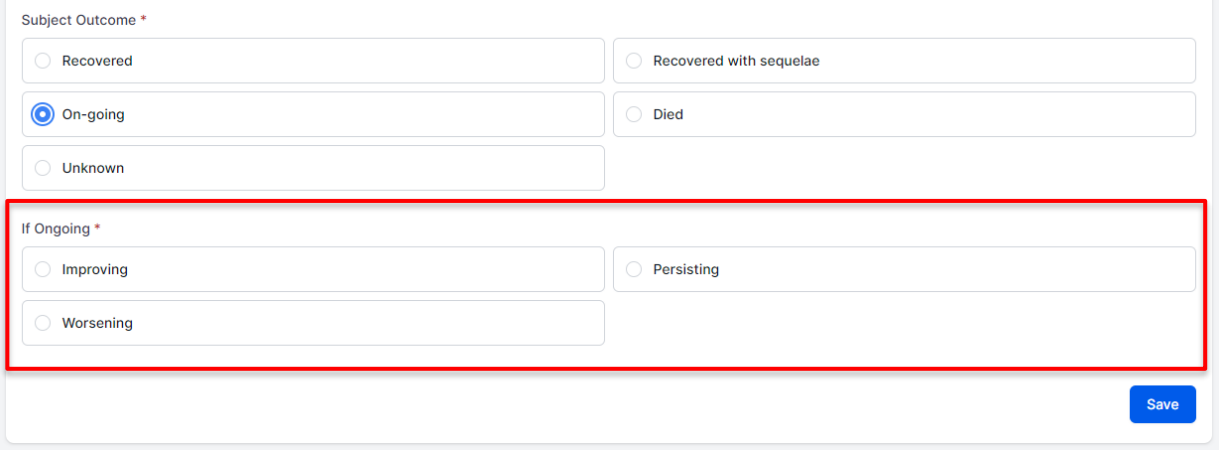
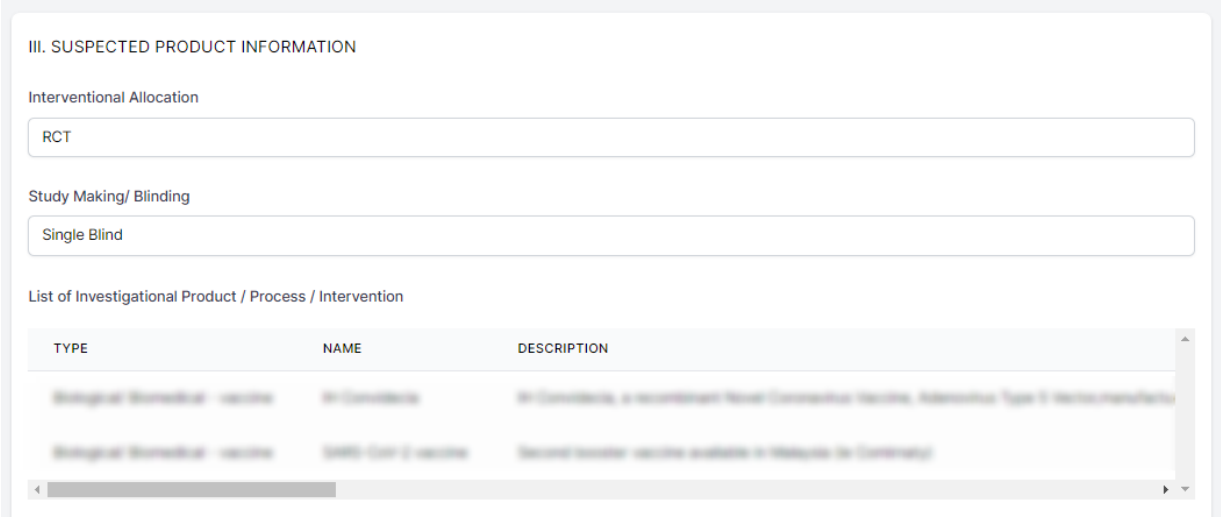




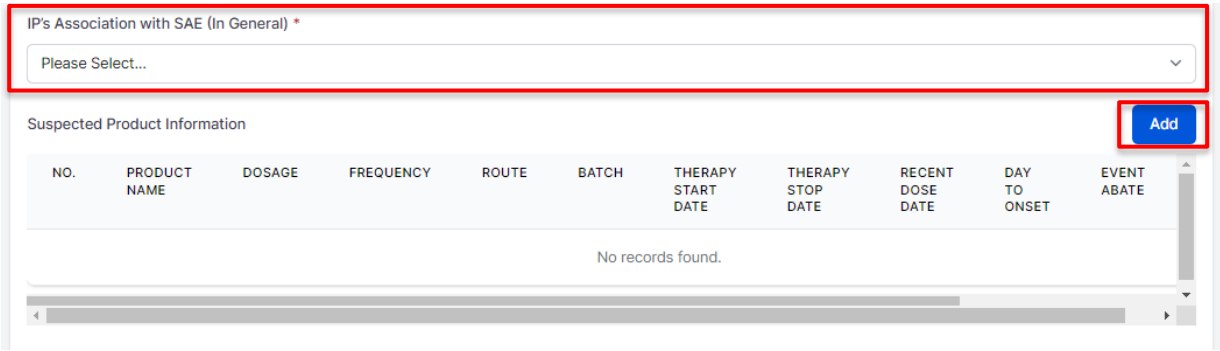
If Subject Outcome selection is **“Recovered”, “Recovered with sequalae”** or **“On-going”, refer to point no 10**

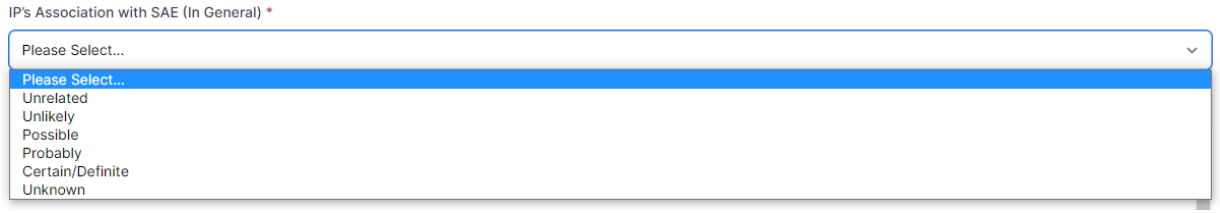
9.	If User choose “Yes” for Criteria of Seriousness selection , User is required to select criteria of SAE of the reported event as well to declare whether such SAE event is a Suspected Unexpected Serious Adverse Reaction (SUSAR)  …… If the selection of the criteria of SAE is “ Resulting in Death”, information regarding the date, cause of death and whether the autopsy is performed is required to be filled up.  	**More than 1 criteria of SAE can be selected from the list in one submission**

	…… If the selection of the criteria of SAE “Hospitalisation or Prolongation of Hospitalisation” , the information regarding Date of Admission and Date of Discharge is required to be filled up. 	
10.	If Subject Outcome selection is “Recovered” or “Recovered with sequalae” , user is required to insert the “Date of Recovery” of subejct  ……	

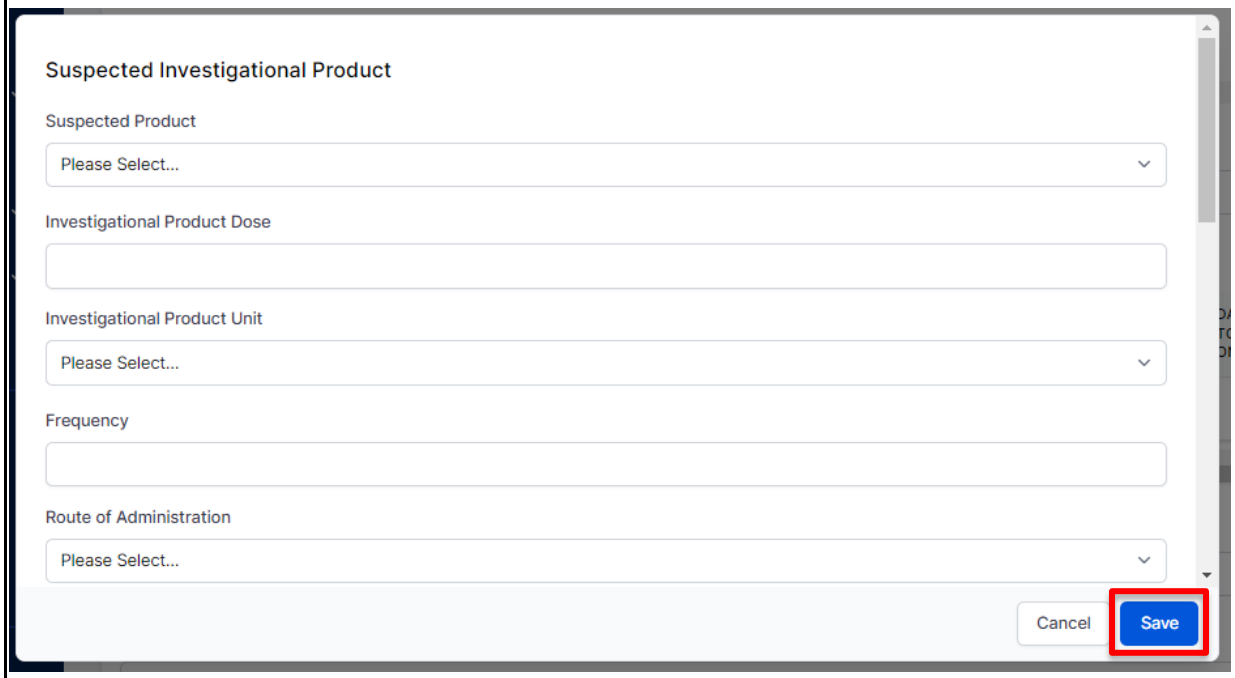
	If Subject Outcome selection is “Ongoing” , user is required to declare the on-going status of subejct 	
11.	Scroll down the page to the “Suspected Product Information” subsection ,the information regarding the Investigational Product (IP) based on the latest approval information will be displayed 	

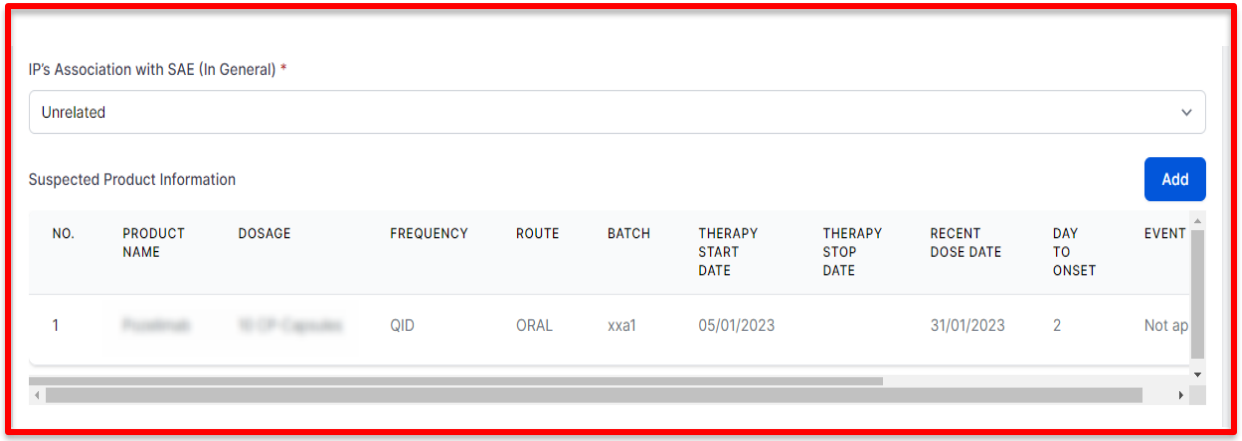
User is the required to declare the IP Association with SAE (in General) ,then followed by list out the suspected product by clicking the Add button.

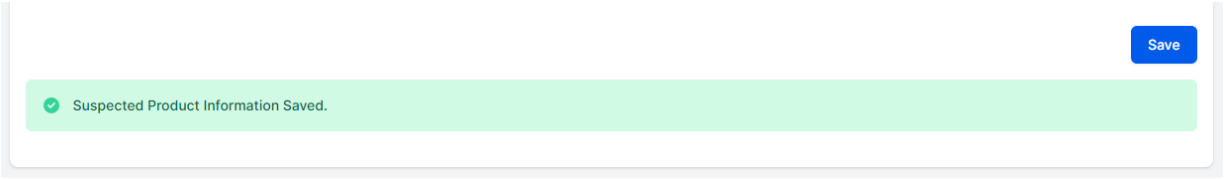
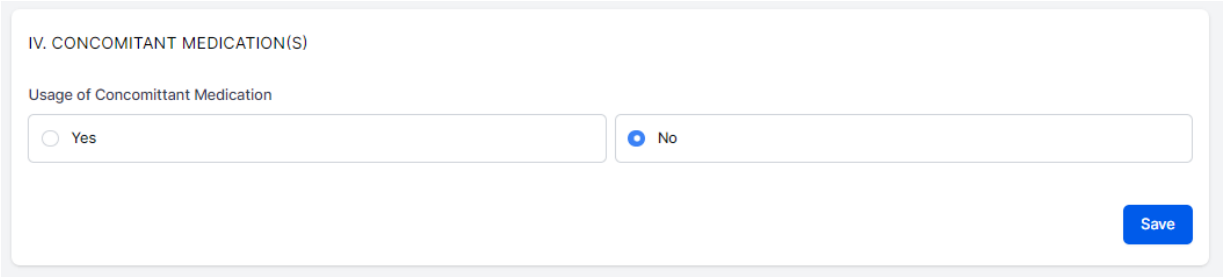


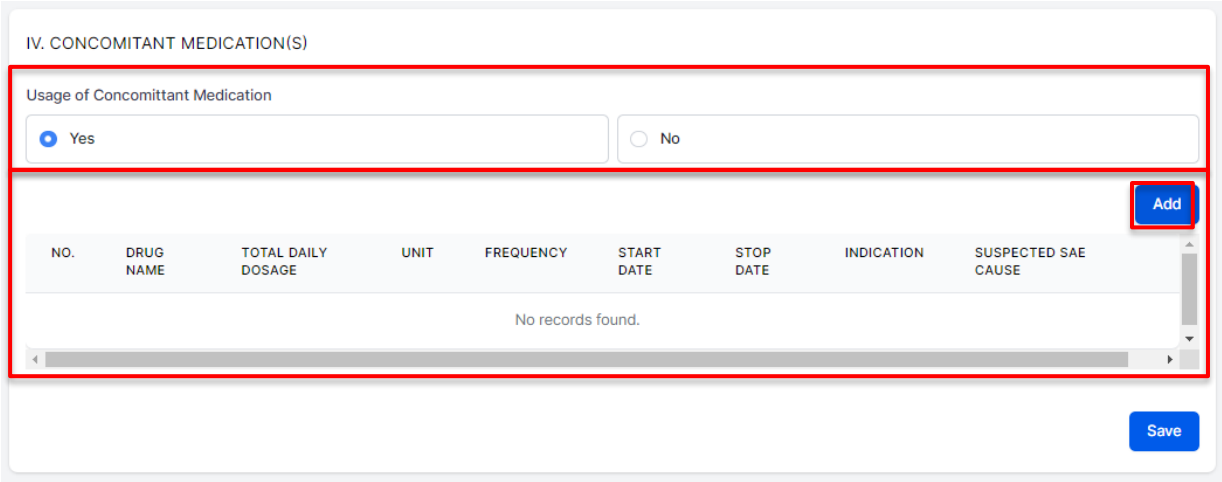


Insert the required information on the suspected product for the adverse event .Click Save to save the information. Information will be displayed in a table once it is saved. User may add multiple suspected IP.

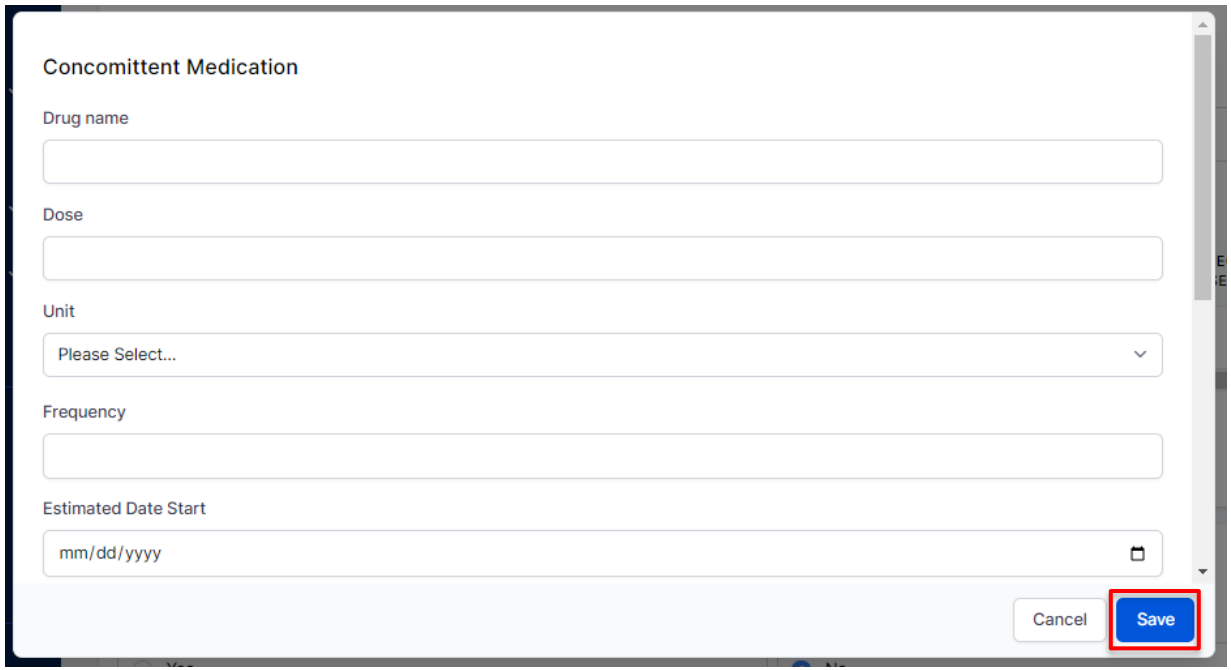


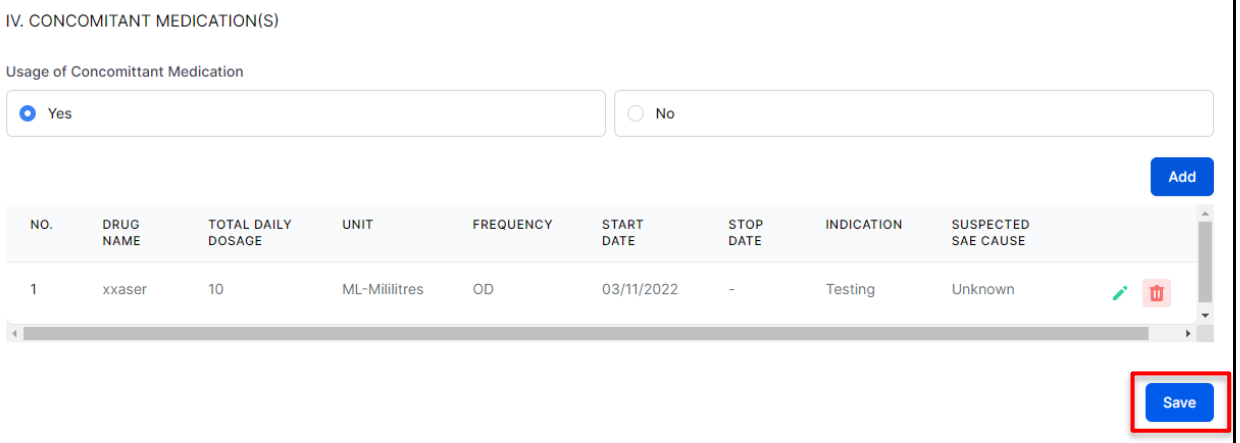
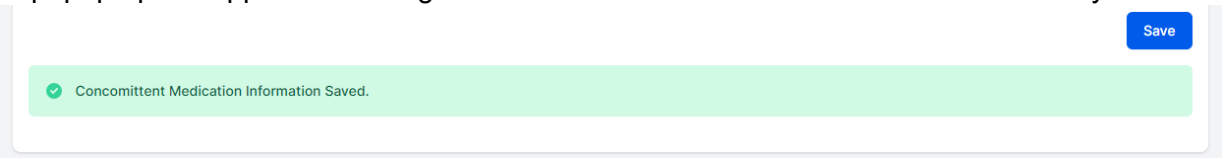
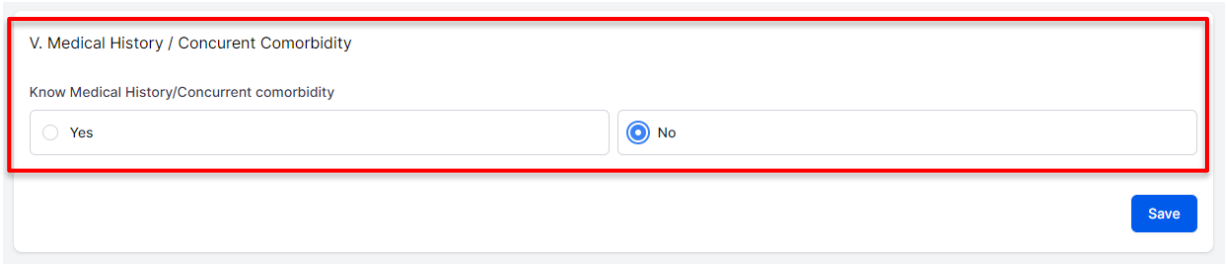


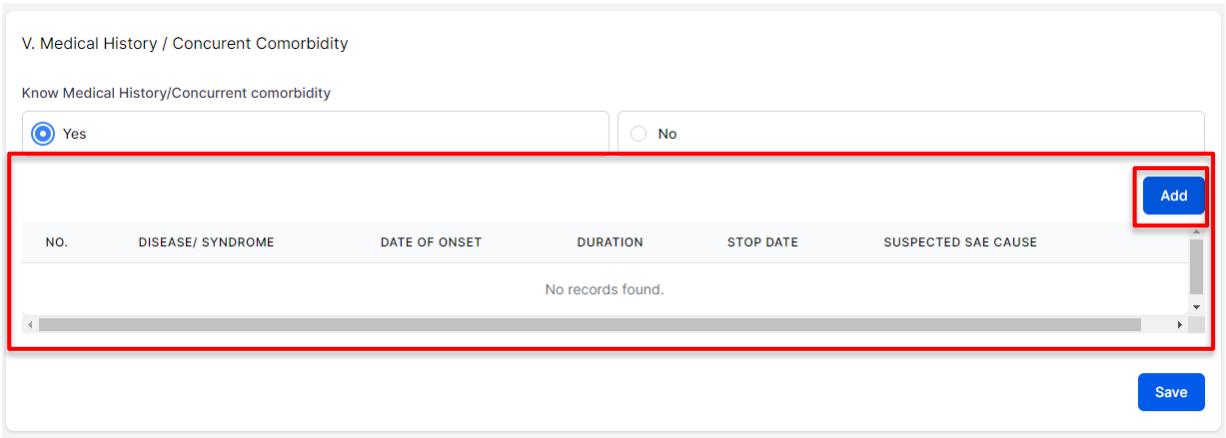
	Once the suspected product infoirmation has been inserted, user is required to declare whether the emergency code has been broken and whehter there are any other possible cause for the SAE. Click Save to save the information in the subsection.  A popup up will appear indicating the " Suspected Product Information" has been succesfully saved. 	
12.	Scroll down the page until the next subsection "Concomitant Medication". User is then required to insert information on the usage of any medication , followed by the list out the medication used that might or might not cause the SAE by clicking the Add button.  ……	



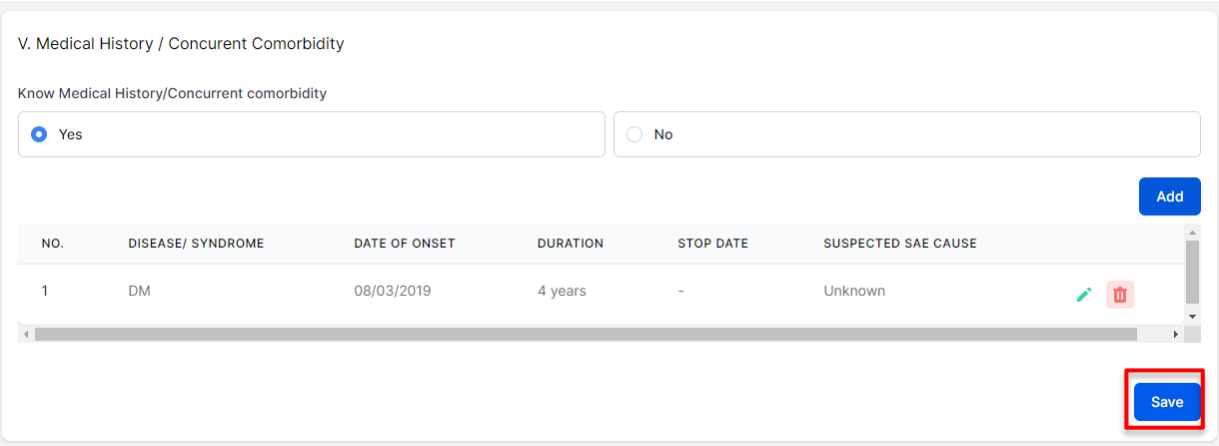
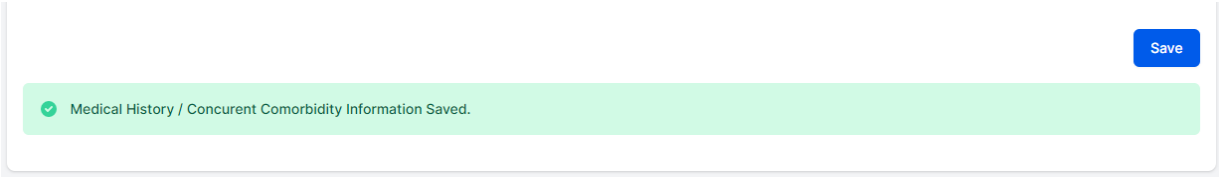
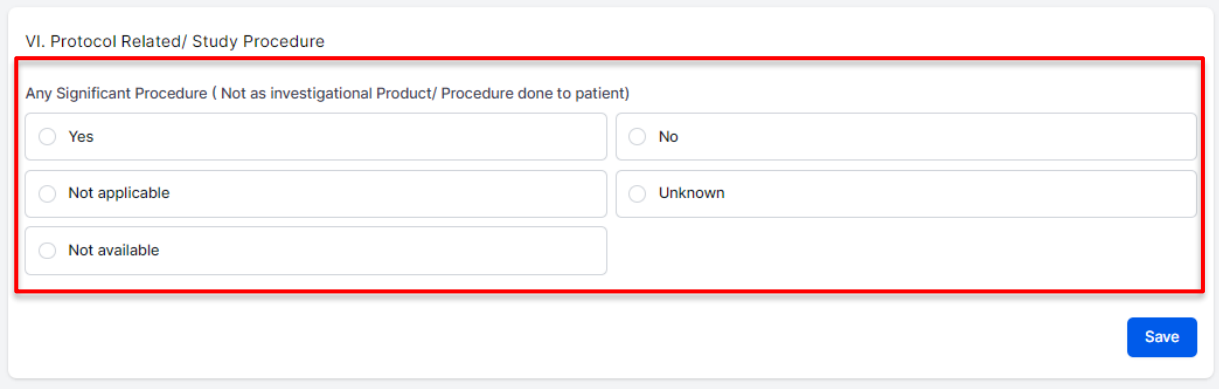
Insert the required information on the concomittent medication used.Click Save to save the information. Information will be displayed in a table once it is saved. User may add more than one medication.



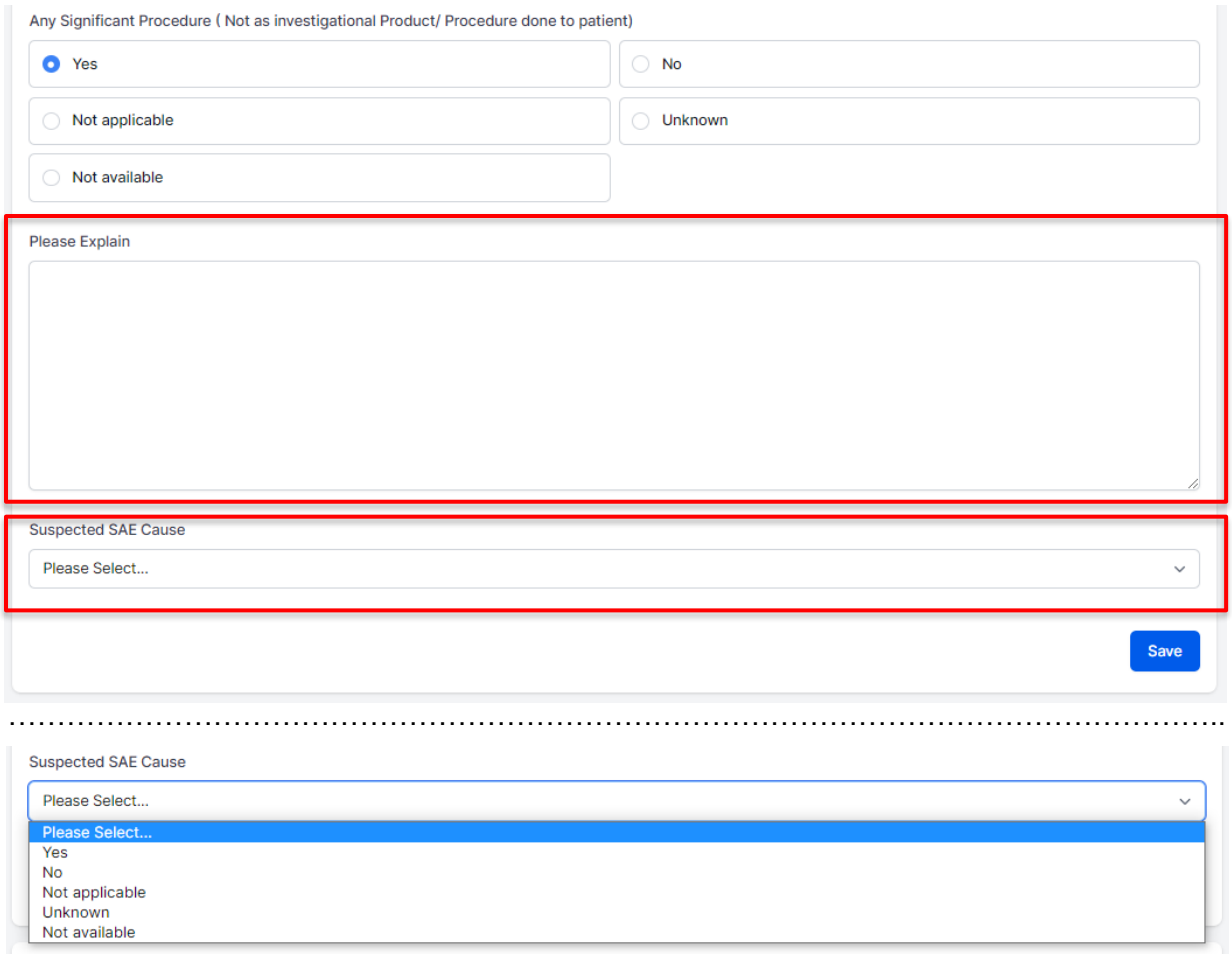
	Once all information has been added, click Save to save the information in the subsection.  A popup up will appear indicating the “Concomitant Medication” has been succesfully saved.  	
13.	Next scroll down the page until the next subsection “Medical History / Concurent Comorbidity”. User is required to insert information on the past medical history or any concurent morbidity suffered during the event , followed by the list of the morbidity that might or might not cause the SAE Information in the by clicking the Add button.  	



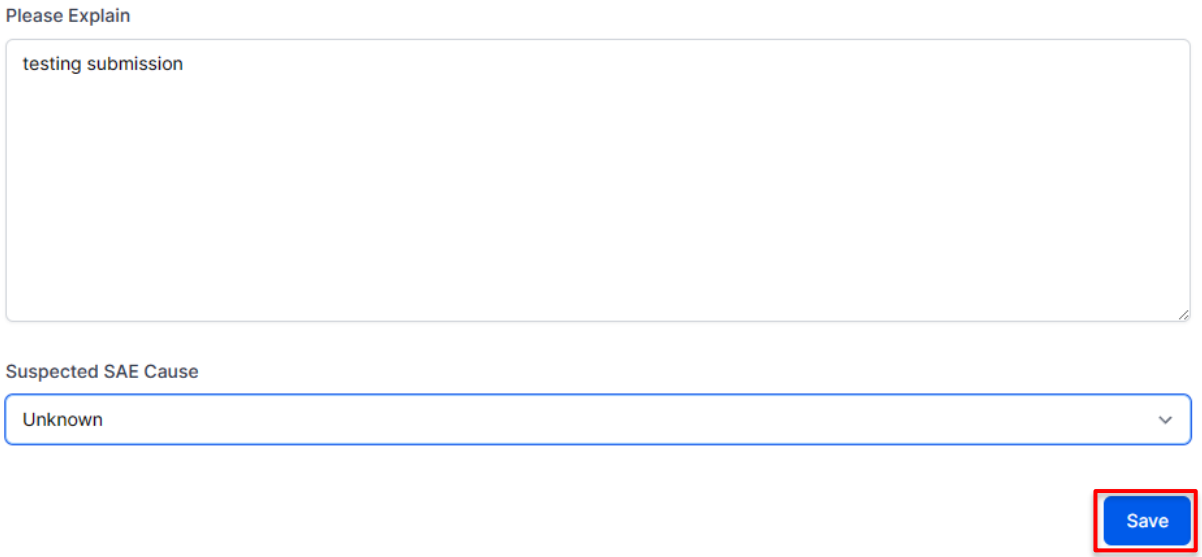
Insert the required information on the concomittent medication used.Click Save to save the information. Information will be displayed in a table once it is saved. User may add more than one medication.

	Once all information has been added, click Save to save the information in the subsection.  A popup up will appear indicating the “Medical History / Concurent Comorbidity” has been succesfully saved.  	
14.	Then , further scroll down to “Protocol Related/ Study Procedure” subsection. User is required to fill information whether is there any related procudure done according to the protocol that might cause the SAE  	

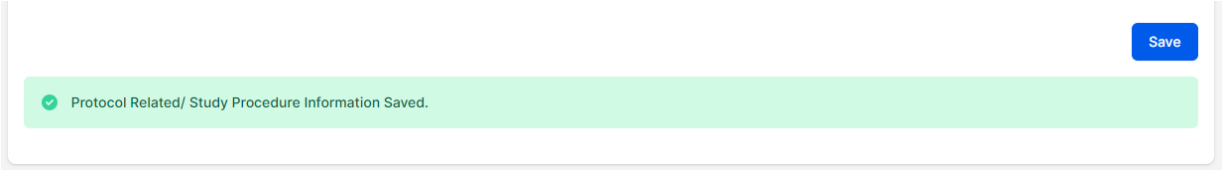
If “Yes” is the selection, user is required to insert the explanation and to declare the status whether the procedure has any relationship to the SAE that happened.



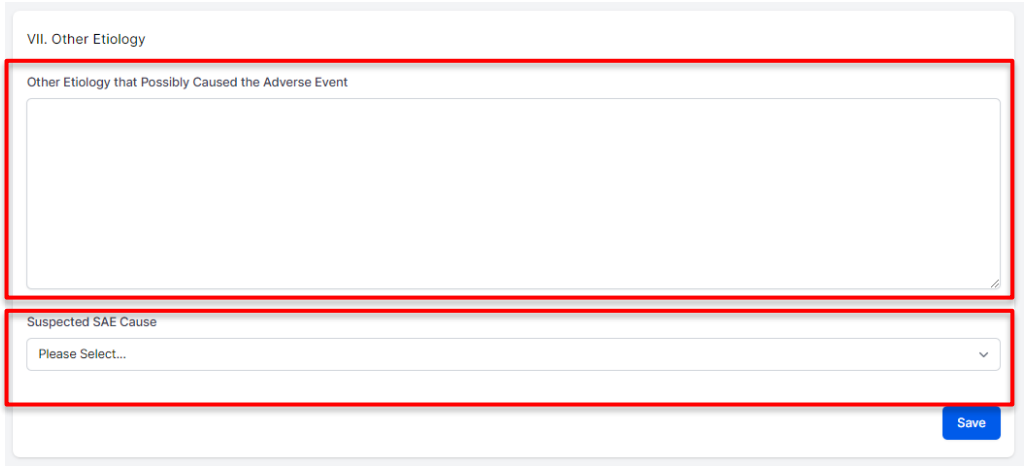
Once all information has been added, click Save to save the information in the subsection.

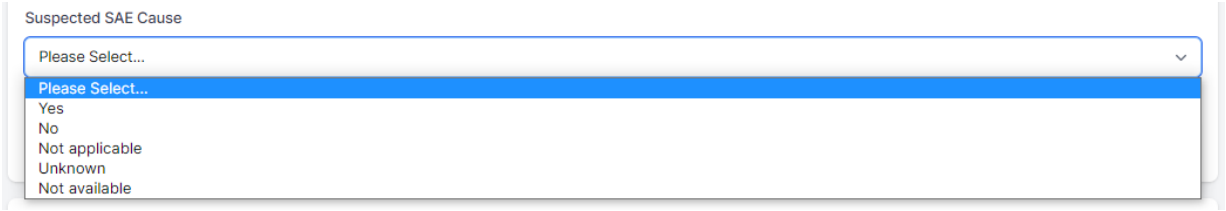


A popup up will appear indicating the “Protocol Related/ Study Procedure” has been succesfully saved.

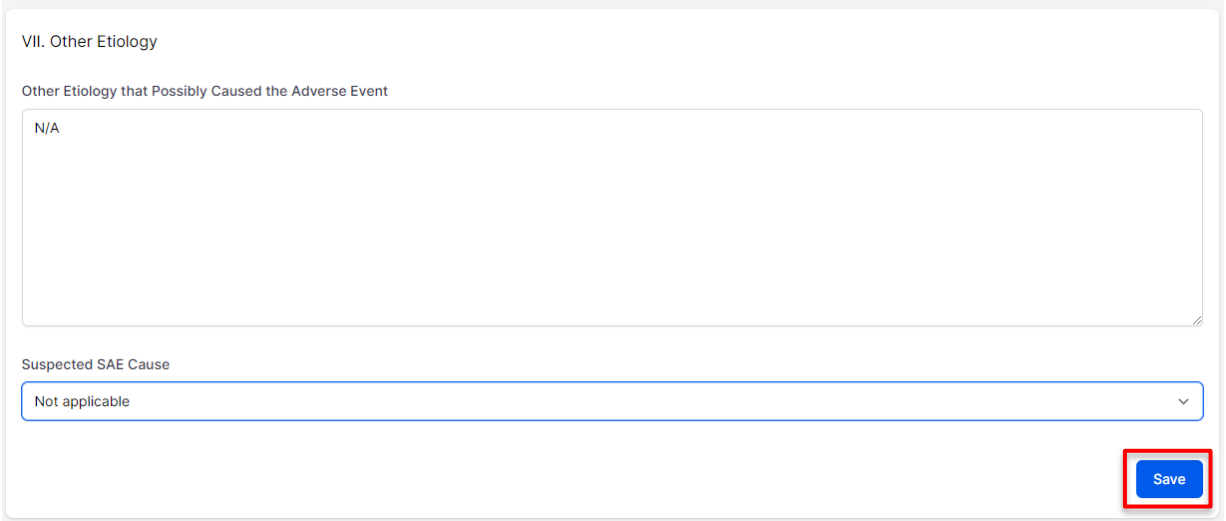


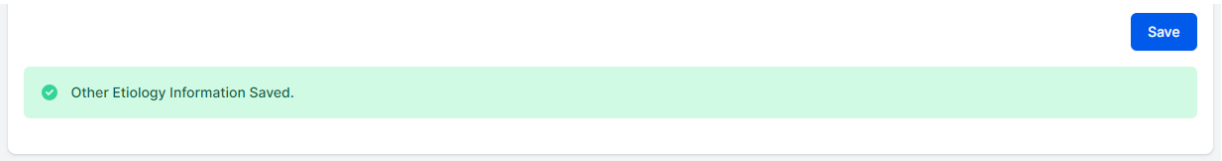
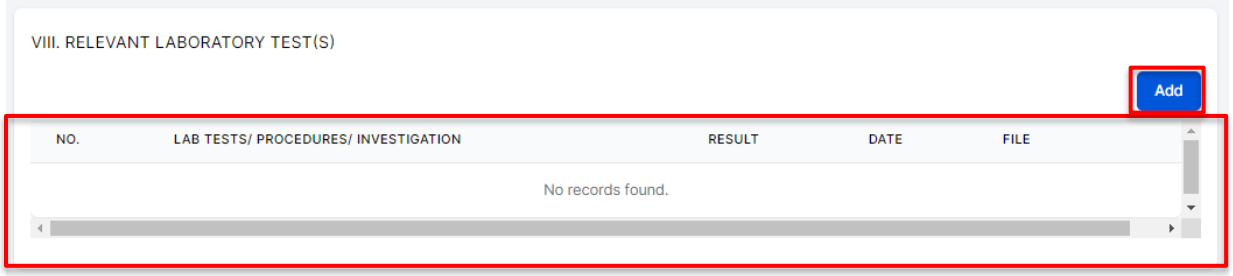
15. Further scroll down to “Other Etiology” subsection and user is then required to insert information whether is there any other etiology that migh cause the SAE.





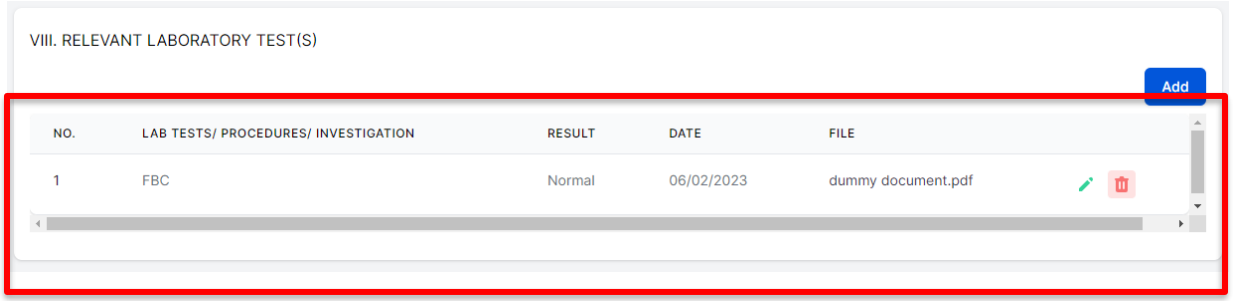
Once all information has been added, click Save to save the information in the subsection

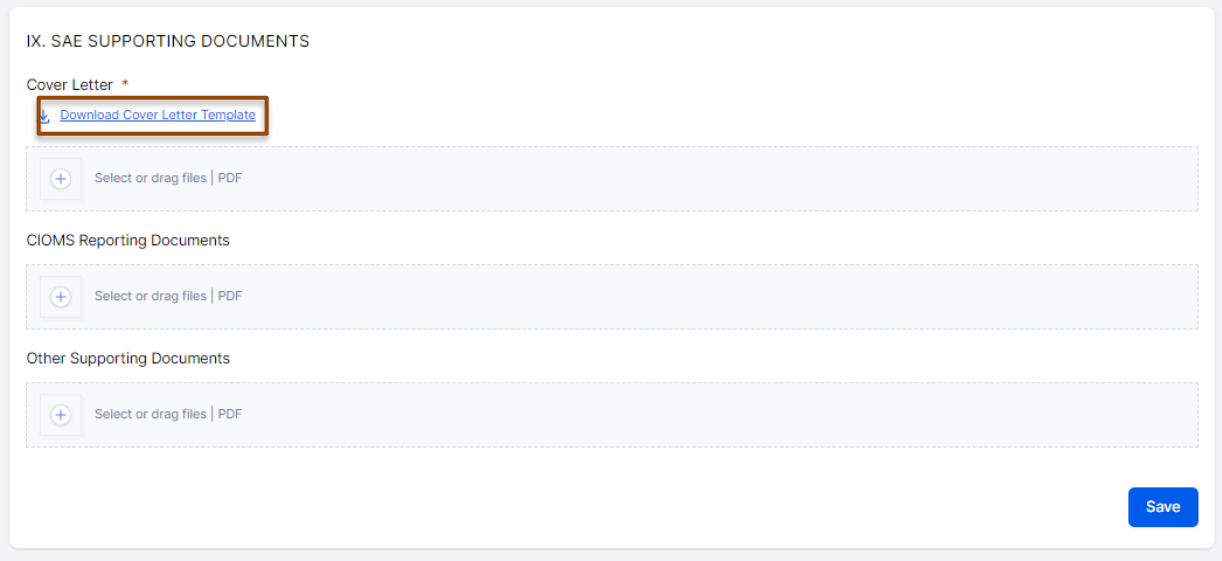
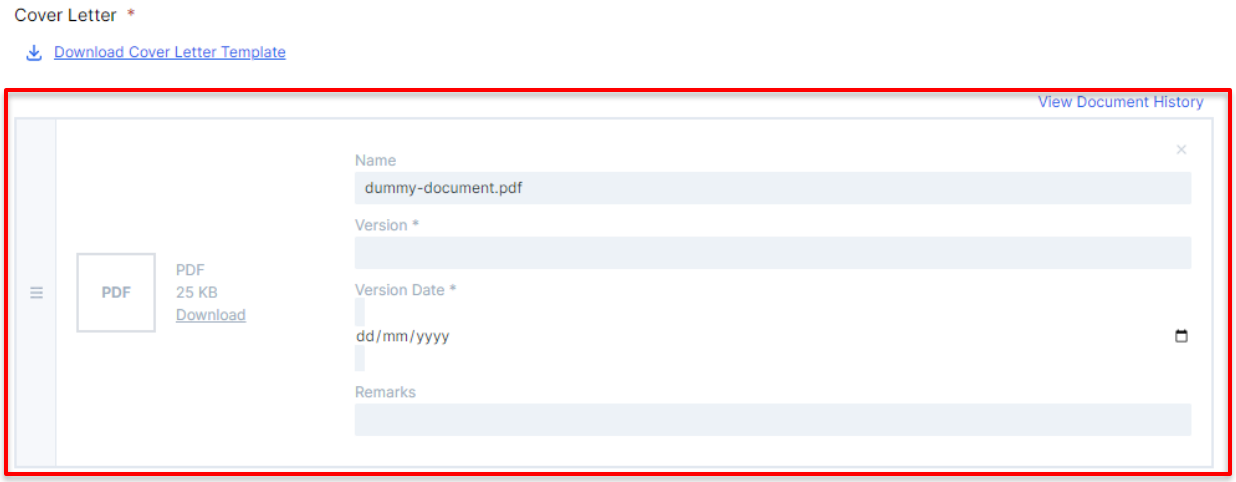


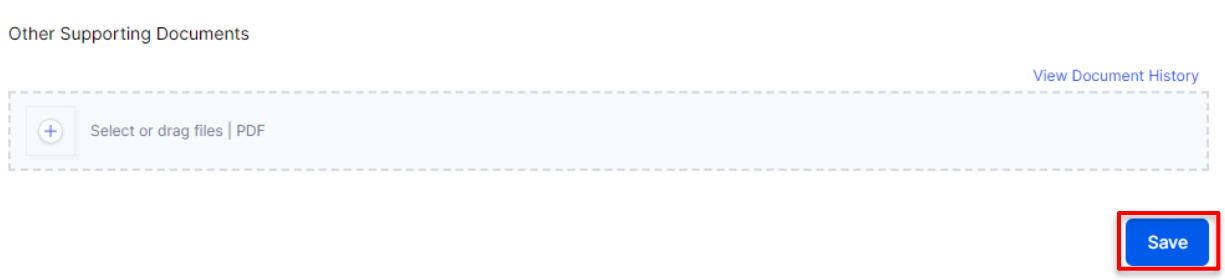
	A popup up will appear indicating the “Other Etiology ” has been succesfully saved.  	
16.	Next ,user may upload all relevant blood investigation during investigation od the SAE in the “Relevant Laboratory Test(s)” subsection.Click on the Add to add the listing of investigation.  …… Insert the relevant information related to the laboratory test. Click Save to save the information.  ……	Result or any relevant document related to the laboratory test can be uploaded by clicking on the + icon to acces the document file or by draging the document over the box available.

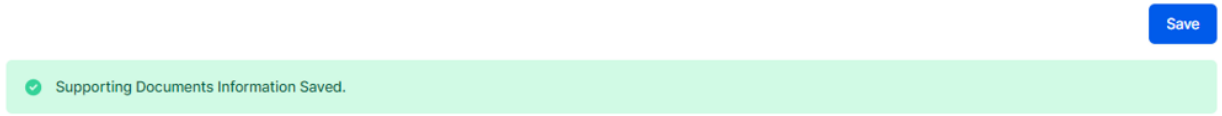
……

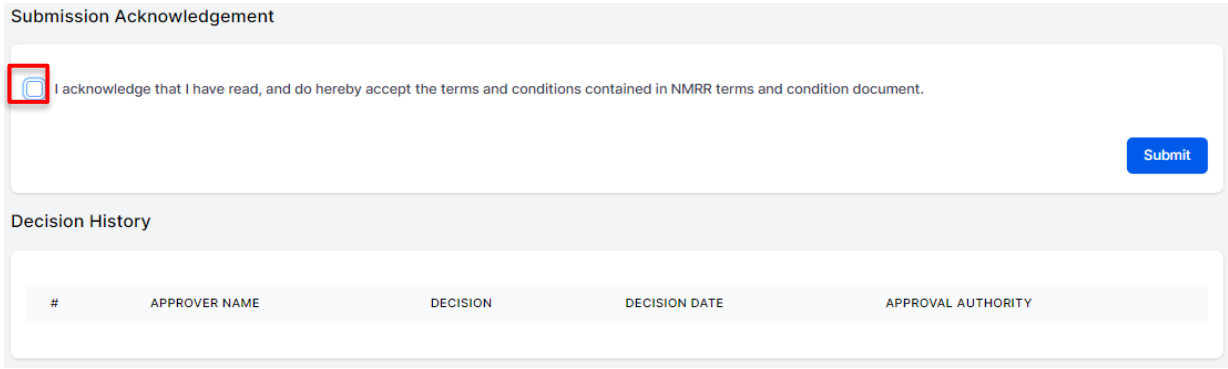
Once all information has been saved, a list of all investigation and laboratory test will be listed in a table

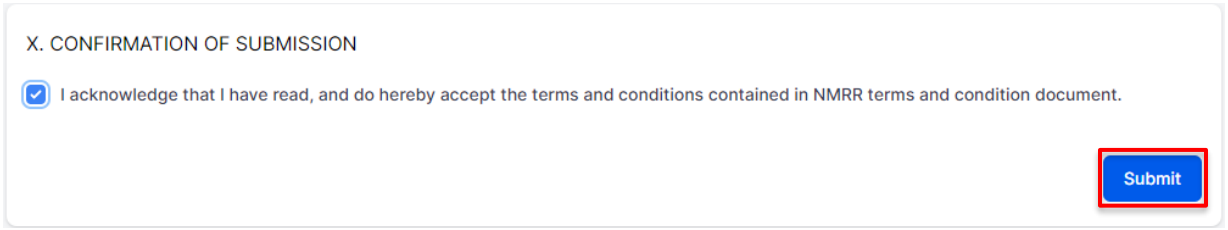


17.	Then ,continue to scroll down on the page. “Serious Adverse Event Supporting Documents” part will be availble for user to upload the relevent documents.  User can upload the “Cover Letter to MREC” , COIMS Reporting Document” and other “Supporting Document” by either click on the ⊕ icon to acces the document file or by draging the document over the box available.Once a document has been uploaded, user can insert the version & version date to the documents uploaded. File name can also be changed if needed. Once all documents have been uploaded, Click Save to complete and save the uploaded files.  	**“Serious Adverse Event Cover Letter to MREC Template”** can be downloaded for user to use as reference. **Only SAE format file is allowed to be uploaded in this section** **Please ensure the file name has the extension “.pdf” at the end of its name. Files without the extension “.pdf” may have the risk of not being able to be read later**

<table>
<tr>
<td></td>
<td>


A popup up will appear indicating the “Supporting Documents” has been succesfully saved


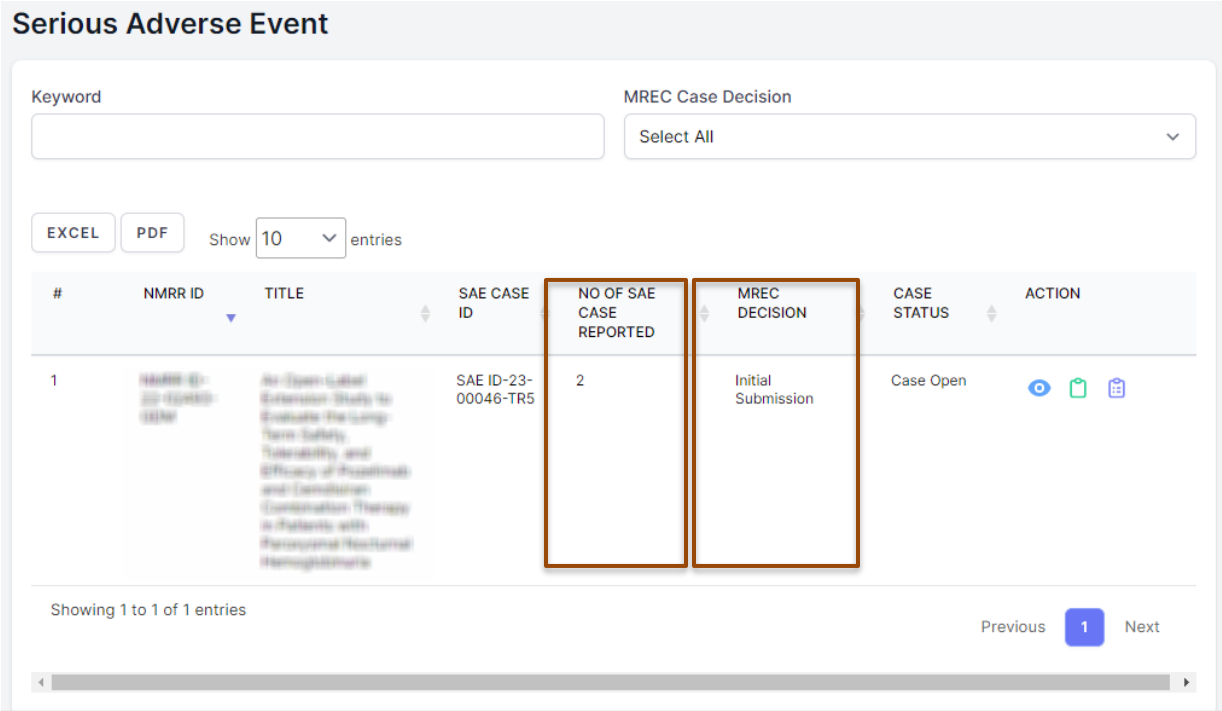
</td>
<td></td>
</tr>
<tr>
<td>18.</td>
<td>
Next, user needs to acknowledge the submisison made at the “Submisison Acknowledgement”. Tick on the box ☐ “I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.”


Once submission has been acknowledged, user can submit the entire Serious Adverse Event Reporting Submission by clicking the Submit button.


</td>
<td>**Please ensure all the information has been filled up and all the documents required has been uploaded and saved</td>
</tr>
</table>

In viewing data of Serious Adverse Event Reporting Submission, the General information of the Submission will be shown over the top part of the display page

Once a new Serious Adverse Even tReporting Submission has been successfully submitted, user will be brought to the Serious Adverse Event Case lisitng

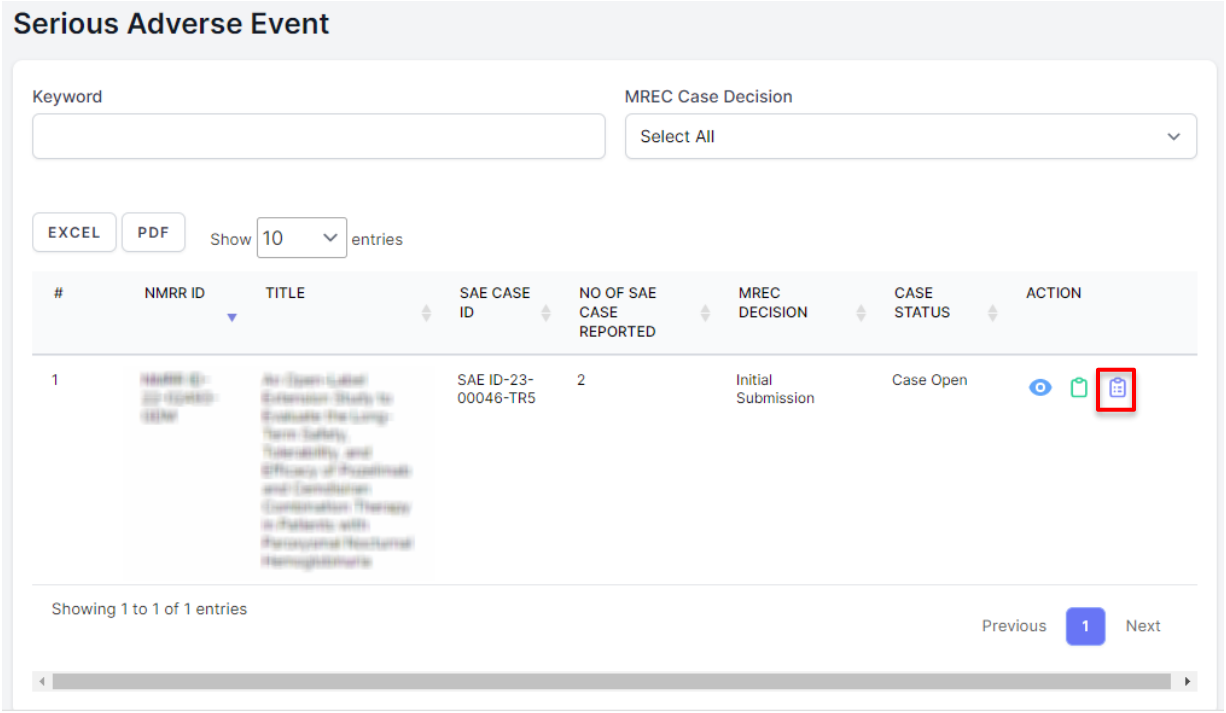


The status of new successful submission of a **SAE Report** will change from **"Pending Submission"** to **"Processing Submission by MREC Secretariat"**

In Serious Adverse Event Case listing, **No of Serious Adverse Event Case Reported** indicates the number of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report) that has been successfully created** by the Serious Adverse Event Corresponding Person (SAE CP) (e.g., **2** means there are one SAE Reports that have been created: **Serious Adverse Event Post Ethical ID – Initial Report & Serious Adverse Event Post Ethical ID – Follow up Report 1**

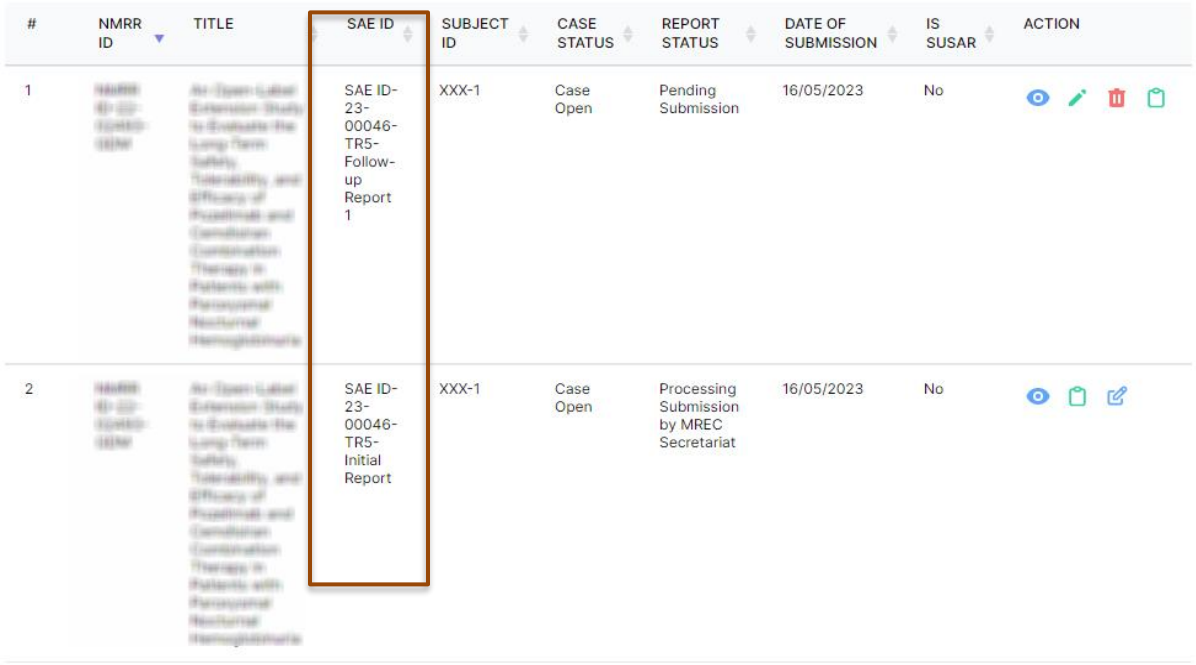
MREC Decision indicates **the latest decision assigned by MREC Secretariat** to either one of the SAE Report submitted to MREC for processing (latest).

To see the details listing of the Serious Adverse EventPost Ethical ID – Report Type (SAE Report) , click on SAE Report Listing icon.



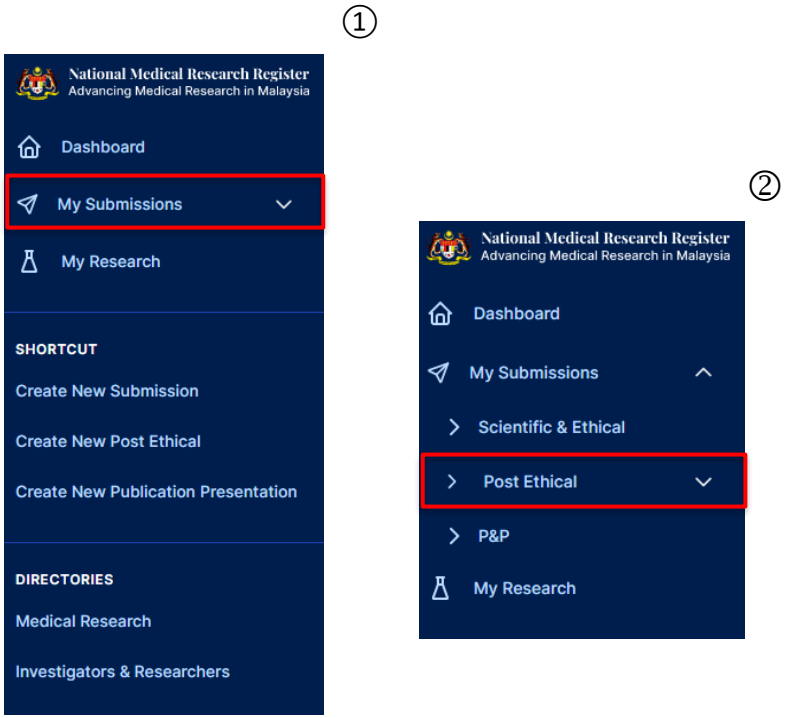
In Serious Adverse Event Case listing the following action icons are accessible to user:

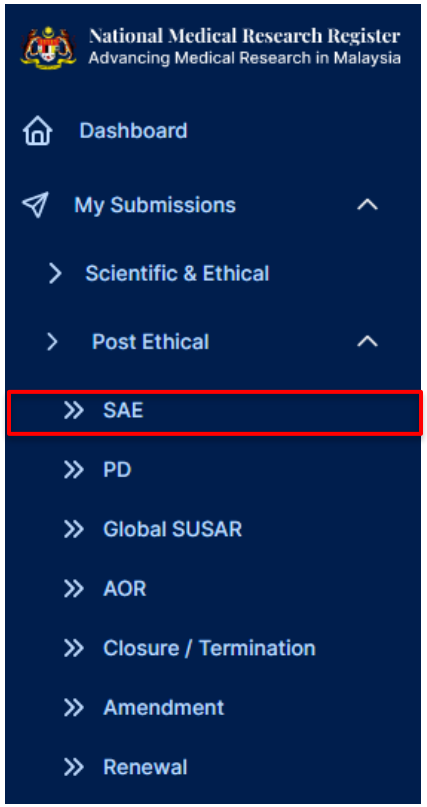
- Show icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID (SAE Case)**
- Initial Submission icon - to show the initial registration data of NMRR ID Submission
- SAE Report Listing icon - to view the detail listing of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**

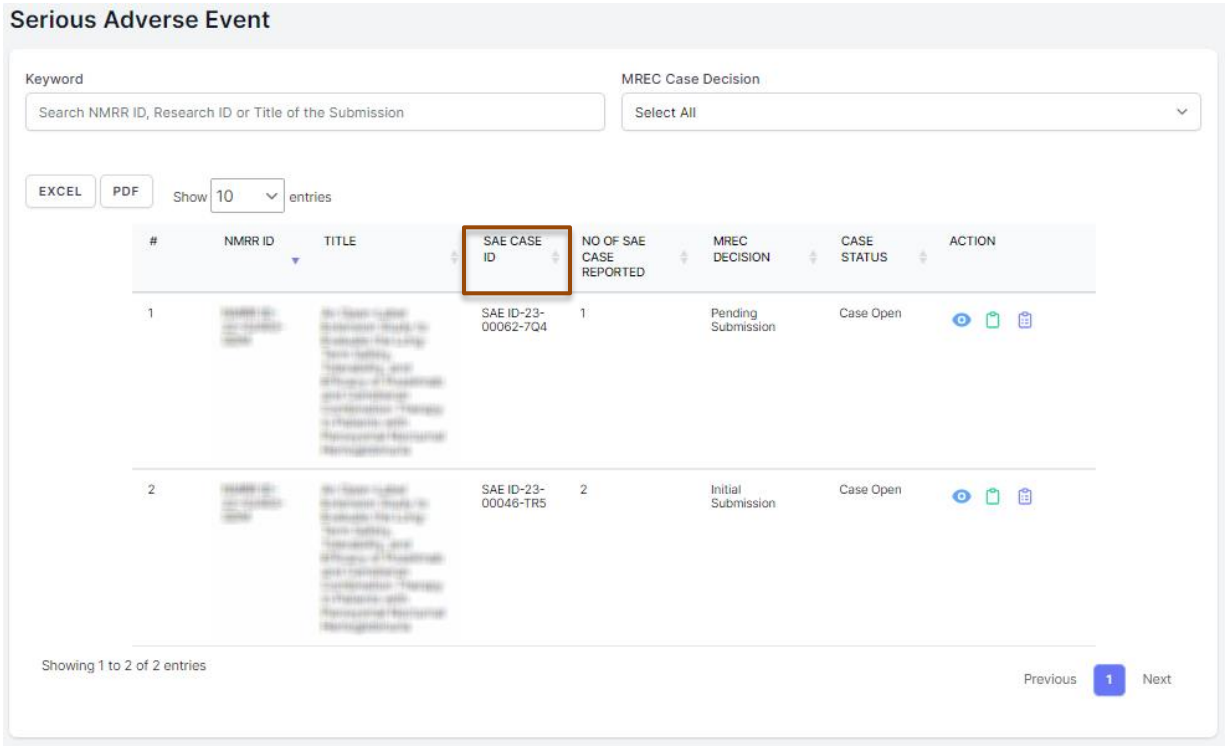
	Once clicked ,it will bring user to the Serious Adverse EventReport listing where the detail listing of the **"Serious Adverse Event Post Ethical ID – Report Type"** or **SAE Report** will be displayed together with the Current status of the submission.  	In Serious Adverse Event Report listing, the following action icons are accessible to user - Show icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)** - Initial Submission icon - to show the initial registration data of NMRR ID Submission - Follow up Report icon - to add/send a new follow up SAE Case (create a new SAE Report) - Edit icon - to edit SAE Reporting submission (icon available only for SAE Report Submission with status "Pending Submission") - Bin icon to SAE Reporting submission (icon available only in SAE Report Submission with status "Pending Submission')

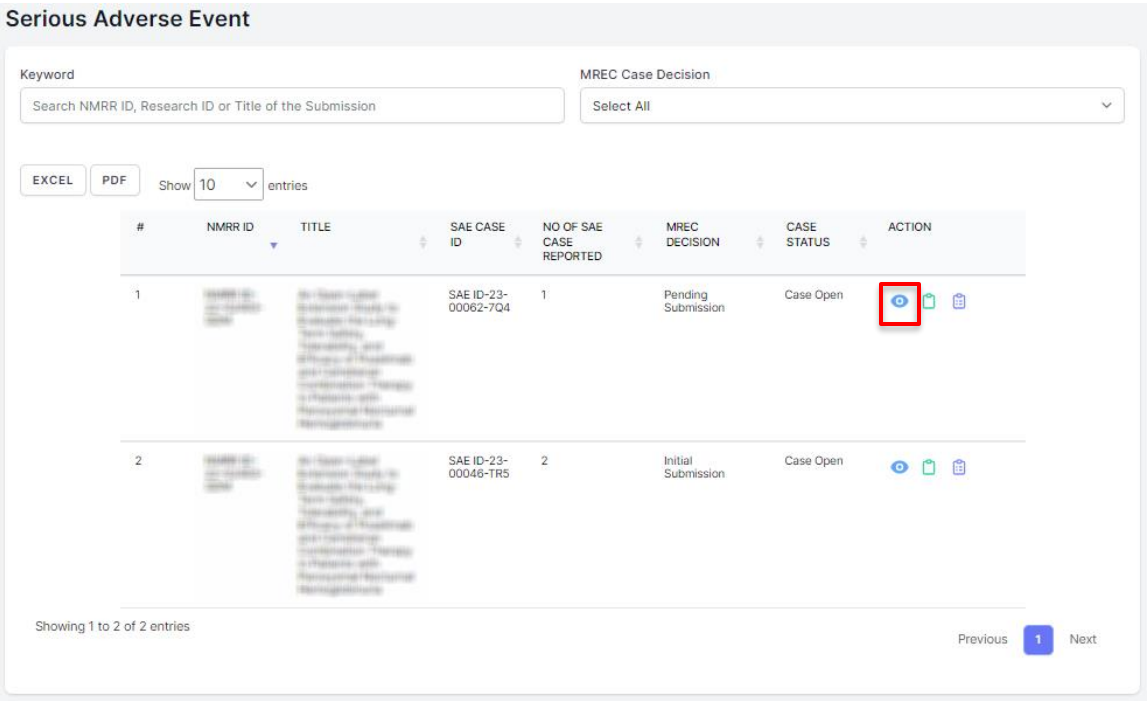
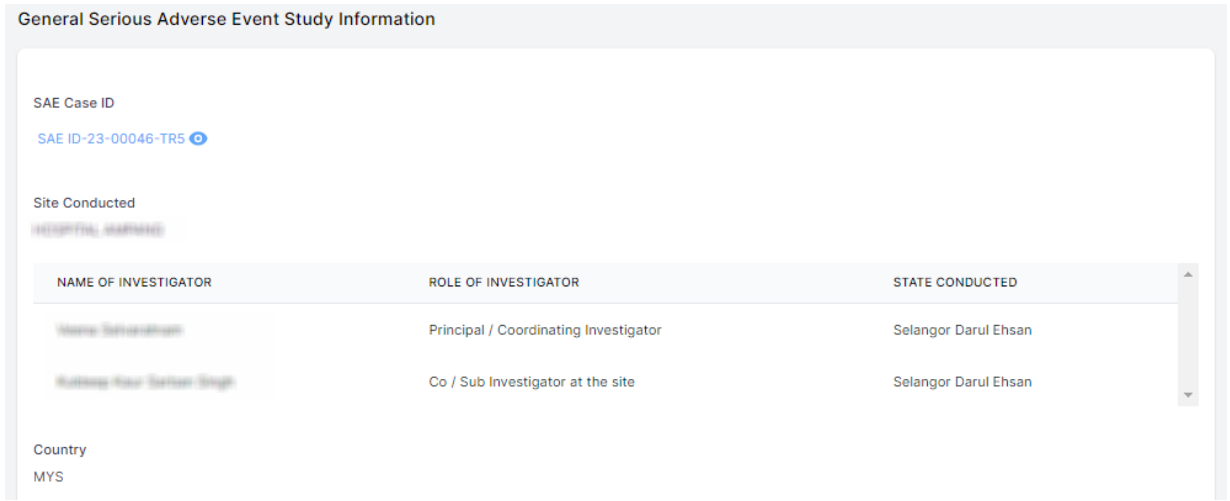
2.0 – Existing Serious Adverse Event Submission

2.1 – Viewing an existing Serious Adverse Event Submission (SAE Case & SAE Report)

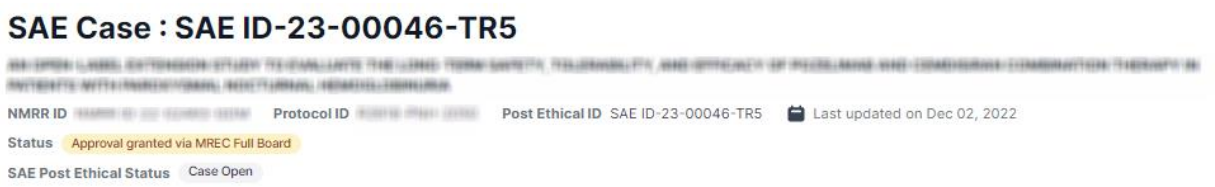
No	Step-by-step instructions	Remark
1.	Scroll over the main menu located on the side of displayed page, go to “My Submission.” Then Click on the “Post Ethical” 	

2.	Click on Serious Adverse Event to access the existing Serious Adverse Event Submission listing.  	

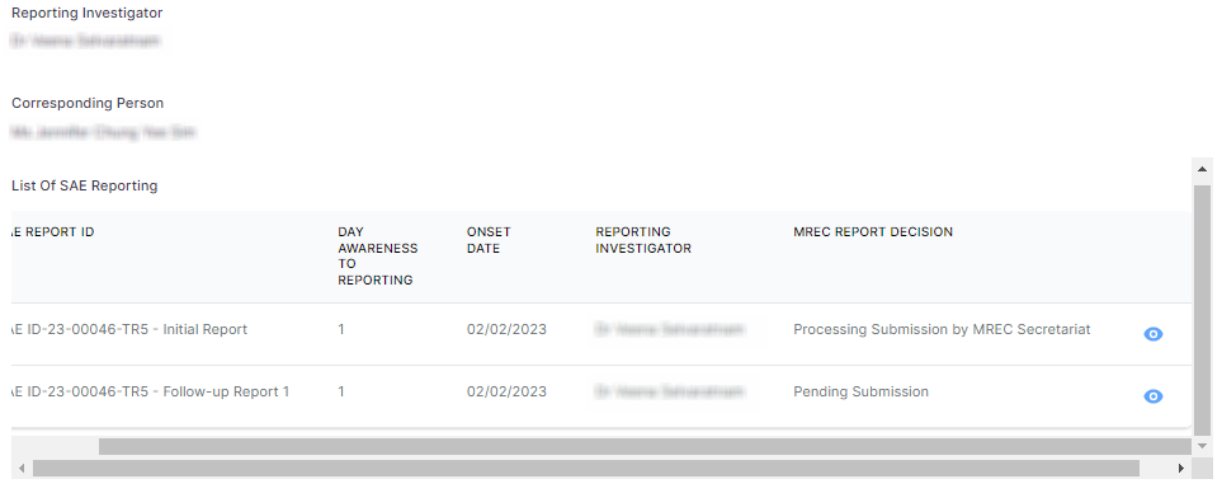
	A list of all existing Serious Adverse Event Post Ethical ID (Serious Adverse Event Case) submission will be displayed.  	Please note that one NMRR ID might have a multiple Serious Adverse Event Reporting Submission. Therefore, Serious Adverse Event Reporting Submission will be referred according to the **Serious Adverse Event Post Ethical ID** or **Serious Adverse Event Case ID** In Serious Adverse Event Case listing, the following action icons are accessible to user: - Show icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID (SAE Case)** - Initial Submission icon - to show the initial registration data of NMRR ID Submission - SAE Report Listing icon - to view the detail listing of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**

3.	To view a **Serious Adverse Event Case**, click on the icon at the intended **Serious Adverse Event Post Ethical ID (SAE Case)**  Once clicked, user will be able to view the data of General Serious Adverse Event Submission of the **Serious Adverse Event Post Ethical ID (SAE Case)**  	This can only be accessible by user that has been assigned with a role either as: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Serious Adverse Event Coordinator (SAE Coordinator) • Serious Adverse Event Corresponding Person (SAE CP)

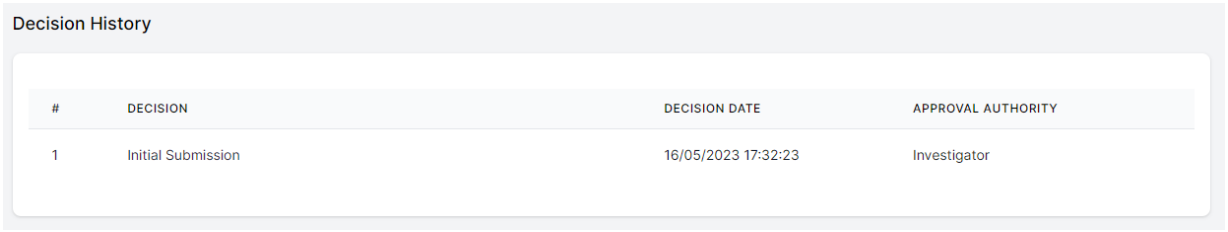
With the top of the display page show general information of the NMRR ID with SAE Case information



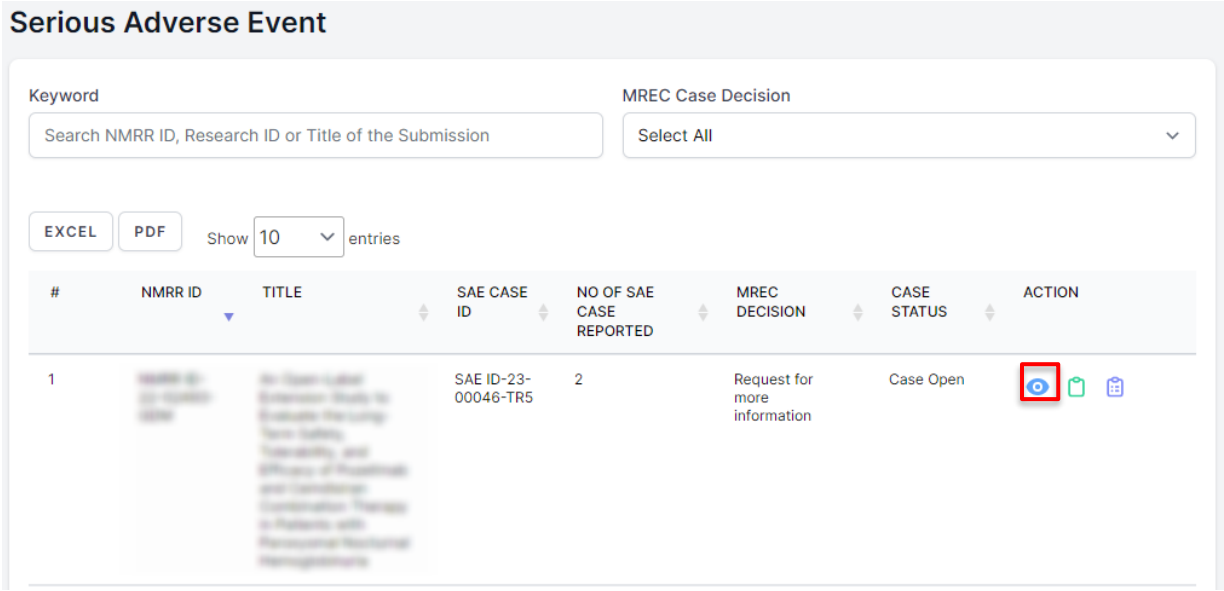
Following the general information, user will be able to see the list of Investigators assigned to the site involved & List of Serious Adverse Event Reporting



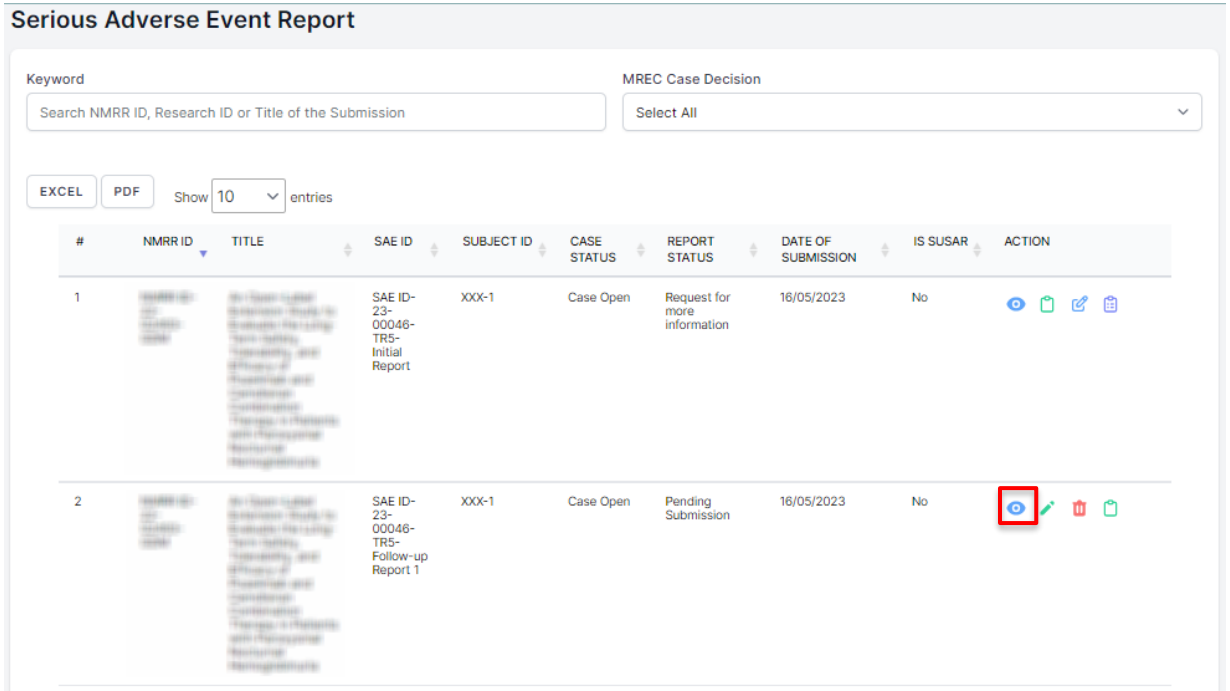
Other than that, user also will be able to see the Decision History of the SAE Case that has been submitted. The decision History is available at the bottom of the data submission page.



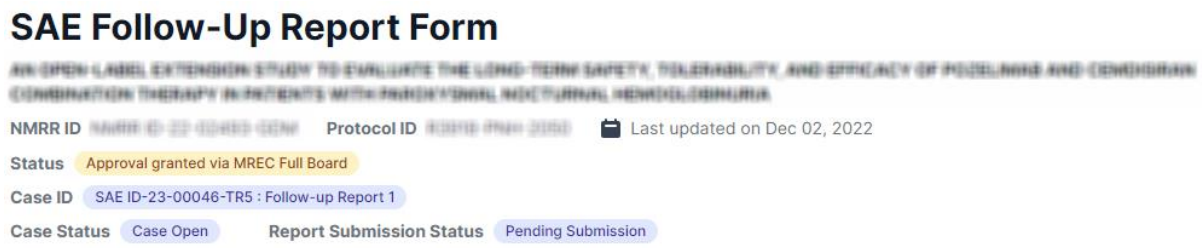
User may view the data of the **Serious Adverse Event Post Ethical ID - Report Type (SAE Report)** by clicking the icon inside the list of SAE Reporting available

4.	To view **SAE Case** data, other than the one mentioned previously, from the Serious Adverse Event Case lisitng page, click on the SAE Report listing icon.  	**SAE Case** versus **SAE Report?** 1. **SAE Case** is a reference term used referring to a particular group report. It contains **only Serious Adverse Event Post Ethical ID (e.g. ID 001)** **SAE Report** is the details report sequence of the Serious Adverse Event Post Ethical ID. It represented by the **report type at the end** of the **Serious Adverse Event Post Ethical ID** **(e.g. ID 001 – initial report,** **ID 001 – follow up report 1,** **ID 001 – follow up report 2,** **and so on….)** 2. **SAE Case listing** shows information as a group report which **latest MREC Decision made on either one of the submissions** is displayed **SAE Report listing** show information of **each sequence report as individual status of the current MREC Decision** 3. Comparing Data in between reports **only available in SAE Report** view icon

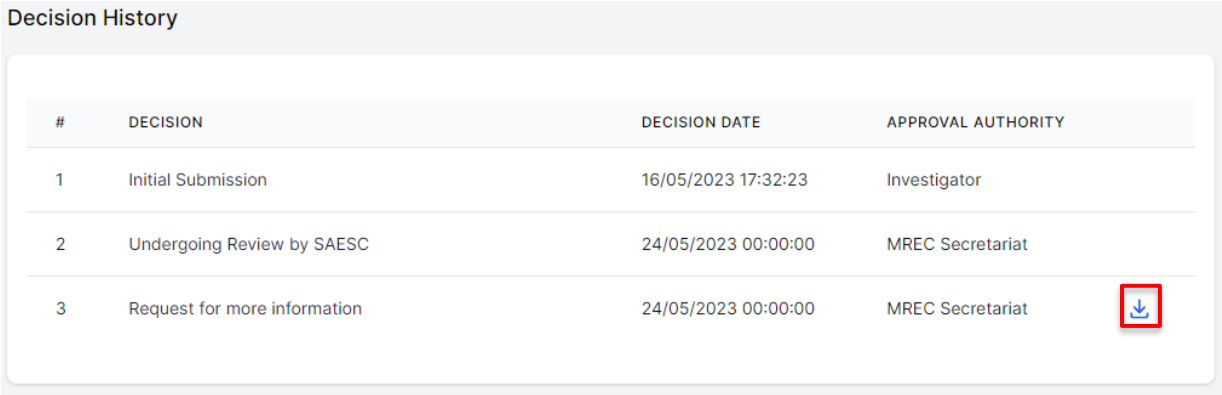
Serious Adverse Event Report listing will be then displayed. To view SAE Report, click on the icon of the intended **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**.



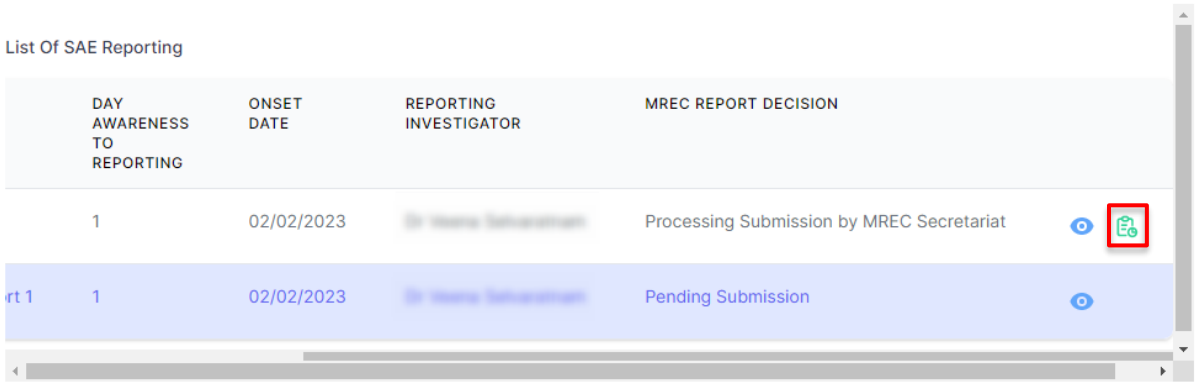
Display page will then show the general information of the Submisison with SAE. Report information **(Serious Adverse Event Report Type and Report Submission Status)** and user will be able to see the General Serious Adverse Submission (the same as in the SAE Case view).



In viewing the **SAE Report**, user is able to view the entire submisssion data. User also will be able to download attachment file if MREC Secretariat has uploaded any documents for user's attention or reference (if any) in the decision history. To download, click on the icon next to the approval authority list.

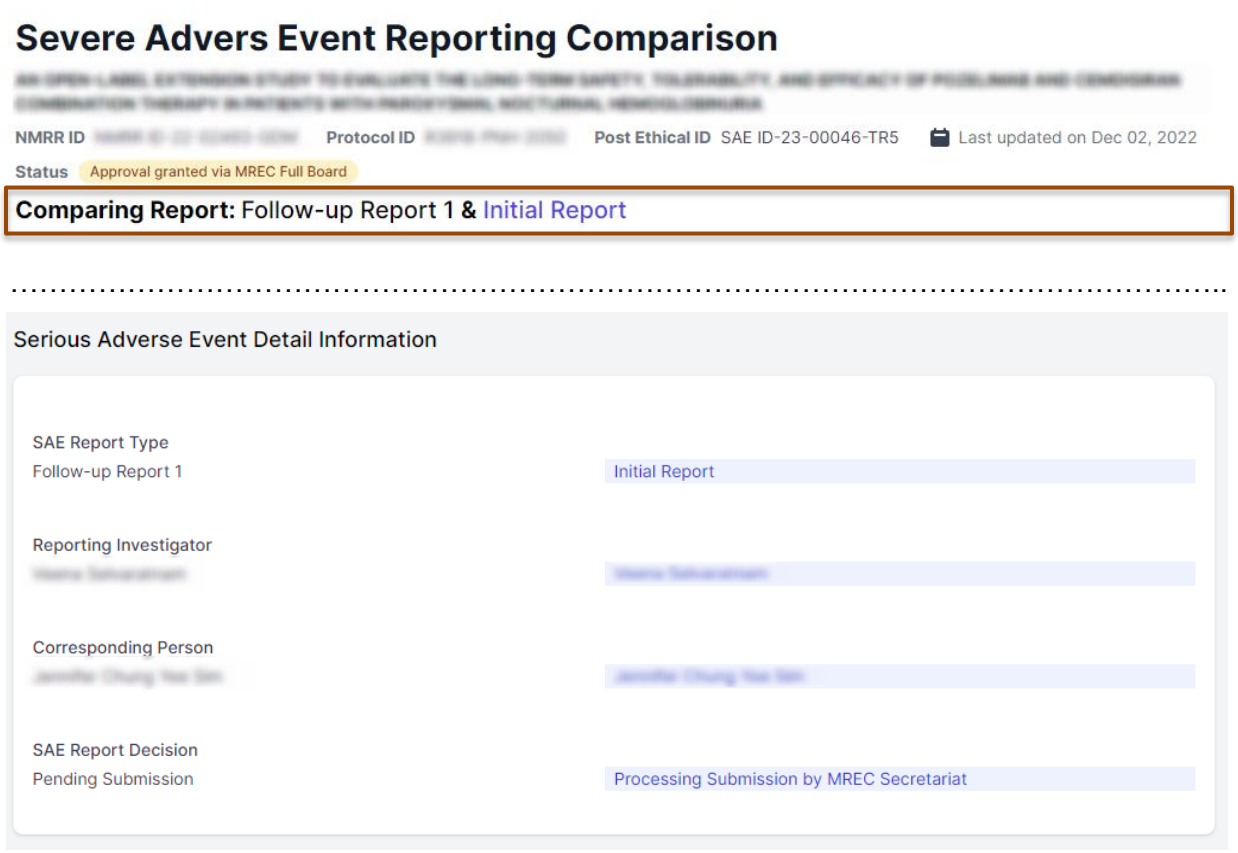


In SAE Report General Serious Adverse Event Reporting Submission, user will be able to compare in between different SAE Report submitted. To compare, click on the icon in the List of the Serious Adverse Event Reporting under the General Serious Adverse Event Reporting Information of the SAE Report



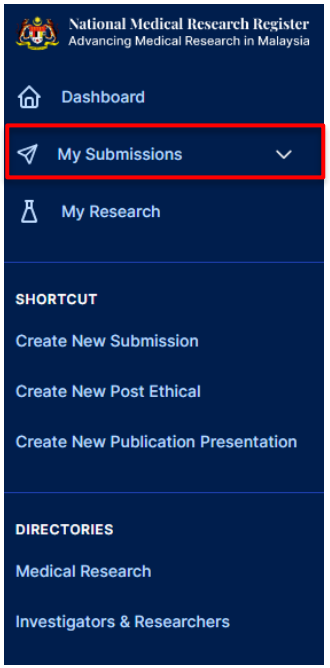
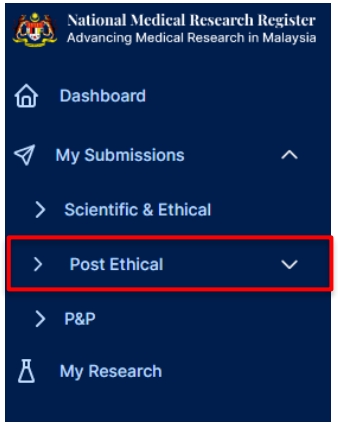
As reference, the blue colour highlight indicates that user is currently at the Follow up Report-1. By clicking icon on the initial report. – it will **compare in between these 2 SAE Reports**

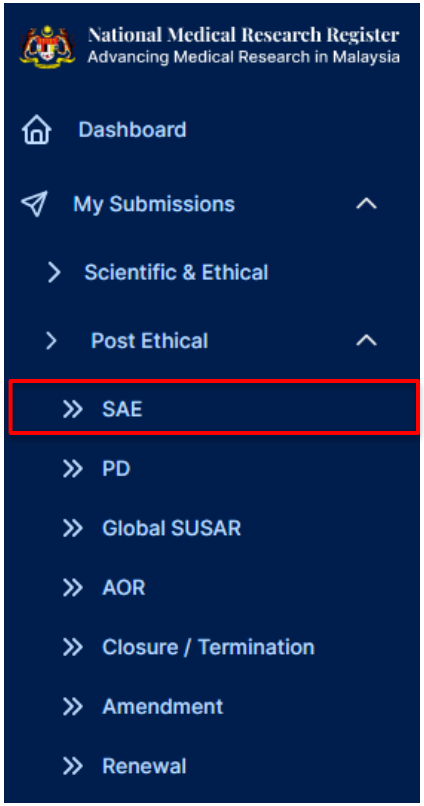
Once clicked, information between these two SAE Reports submissions will be displayed side by side



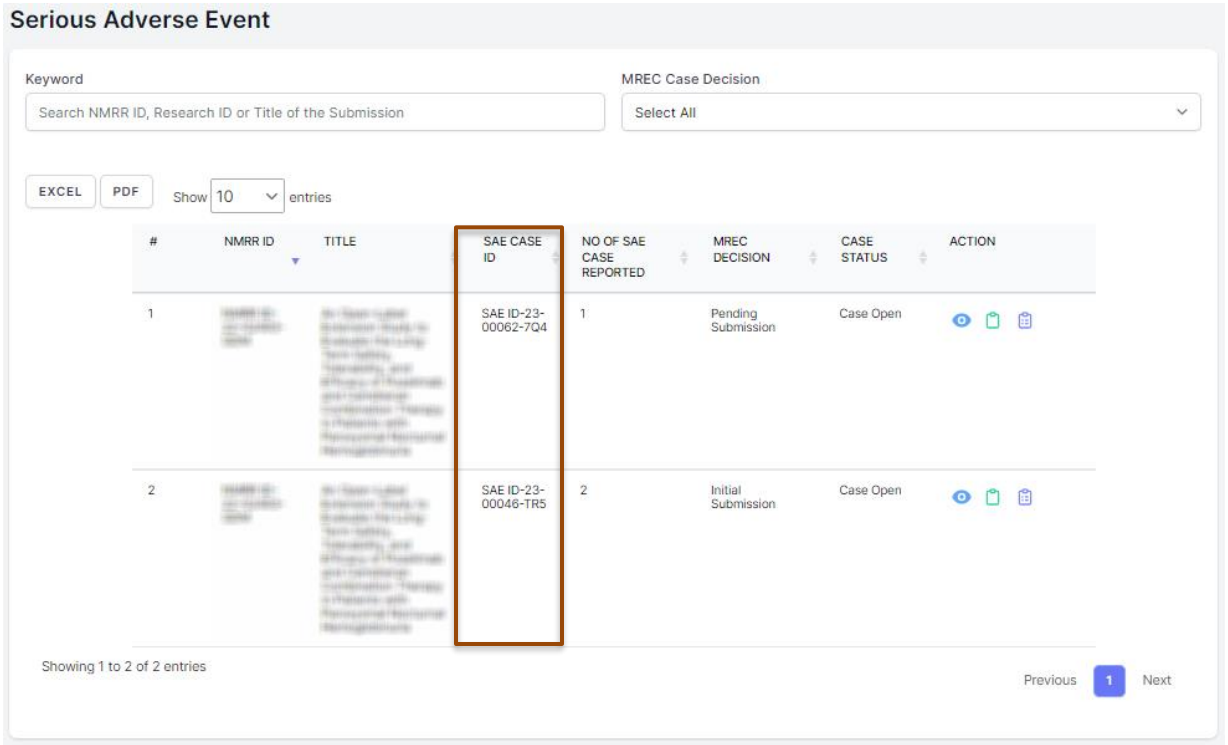
The blue-coloured information represents the set of data from the Initial Report as shown at the "Compare Report" header located at the top of the display page

2.2 – Submission of Follow up Serious Adverse Event Report (Subsequent SAE Report)

No	Step-by-step instructions	Remark
1.	In the case where user wants to submit a follow up report of **the Serious Adverse Event Post Ethical ID (SAE Case)**. Scroll over the main menu located on the side of display page, go to “My Submission”. Then Click on the “Post Ethical” ①  ②  	**Submission of Follow Up Serious Adverse Event Reporting can be done at any time following a complete submission of a Serious Adverse Event ID – Initial Report**. MREC may also request user/site for a Follow Up SAE Reporting Submission with decision status **“Request for More Information”** or **“Follow Up Submission Required”**

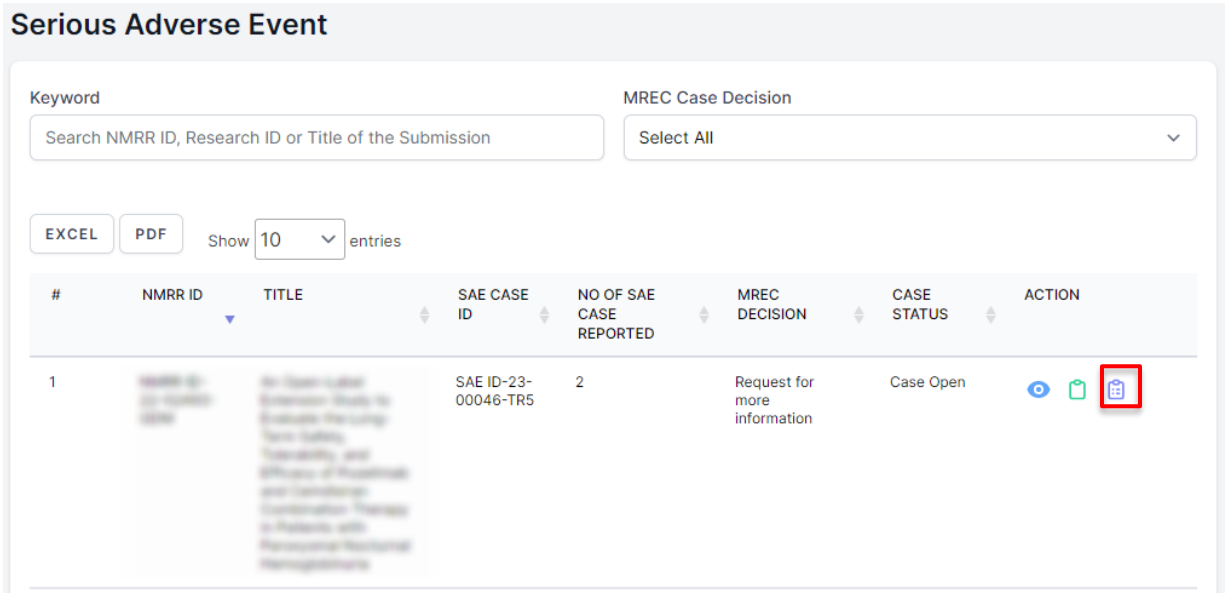
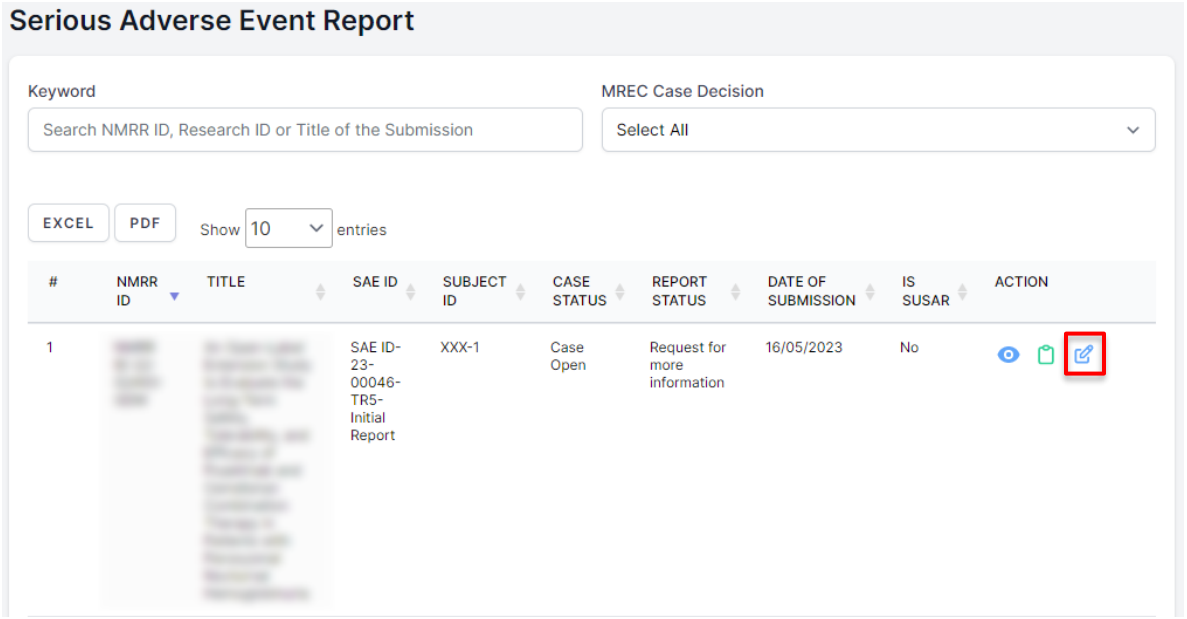
2.	Click on Serious Adverse Event to access the existing Serious Adverse Event Submission listing.  	Please note that one NMRR ID might have a multiple **Serious Adverse Event Reporting Submission**. Therefore, Serious Adverse Event Reporting Submission will be referred according to the **Serious Adverse Event Post Ethical ID** or **Serious Adverse Event Case ID**

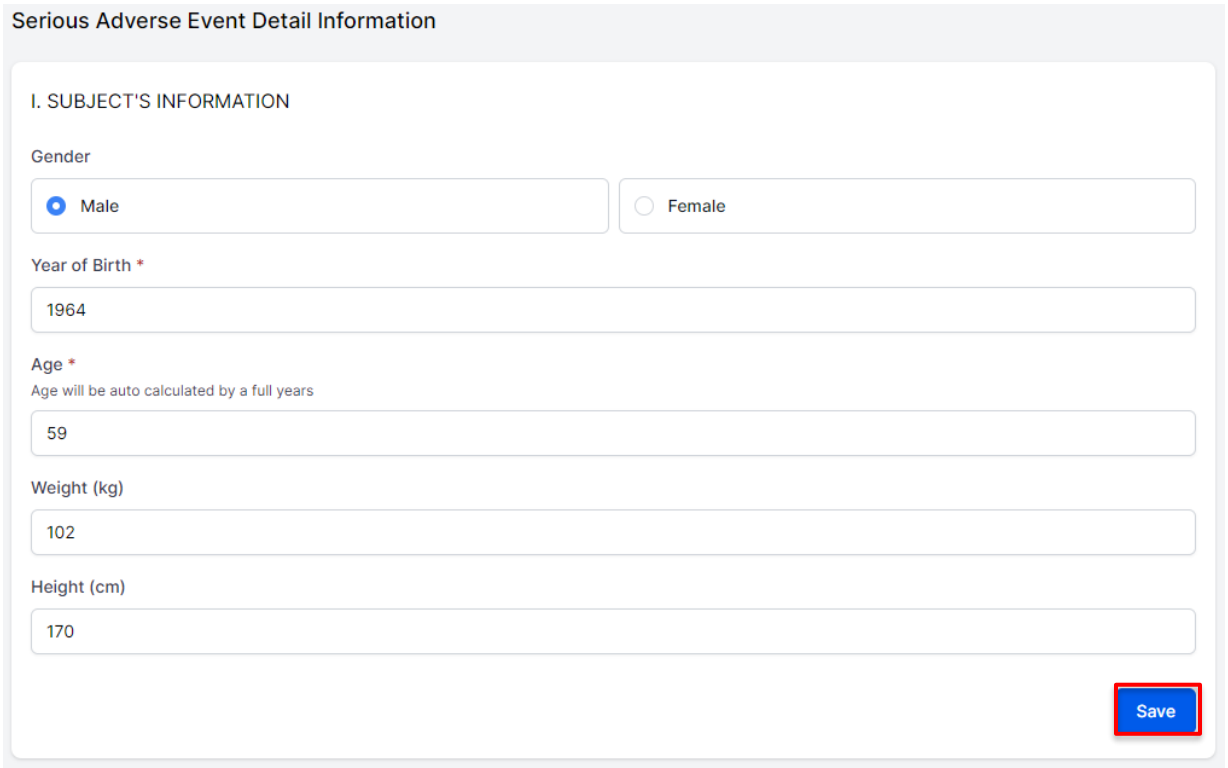
A list of all existing Serious Adverse Event Post Ethical ID (Serious Adverse Event Case) submission will be displayed.

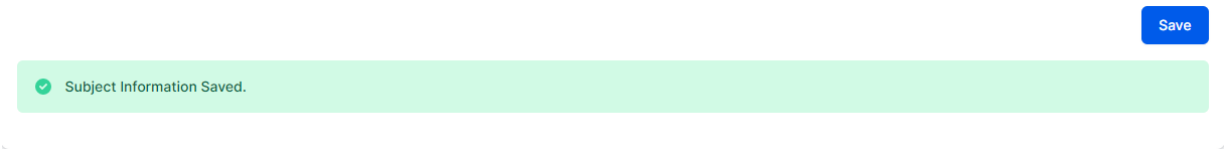
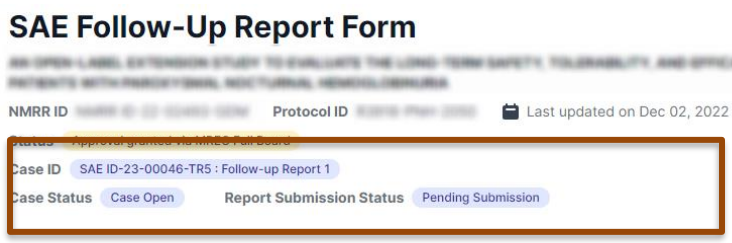
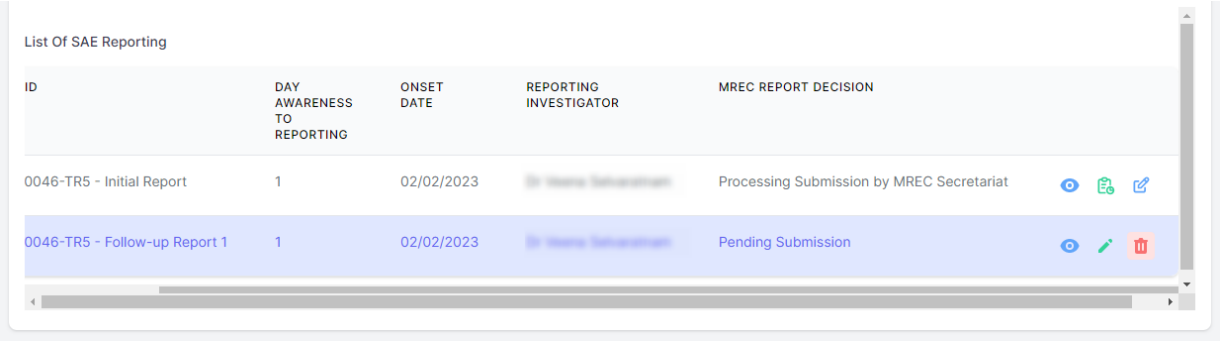


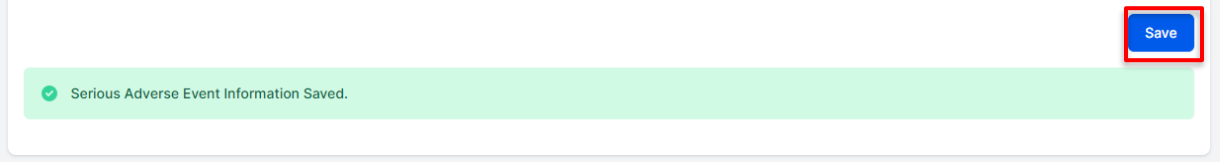
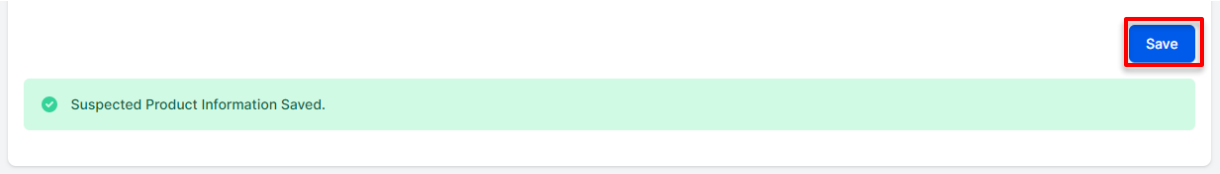
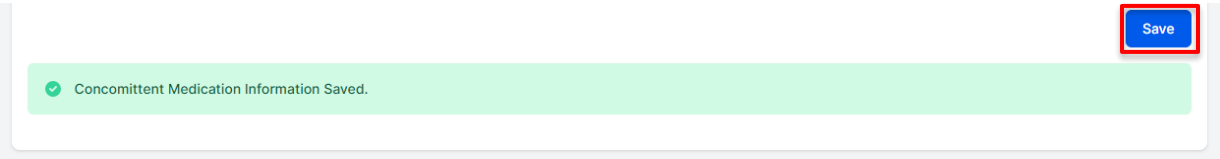
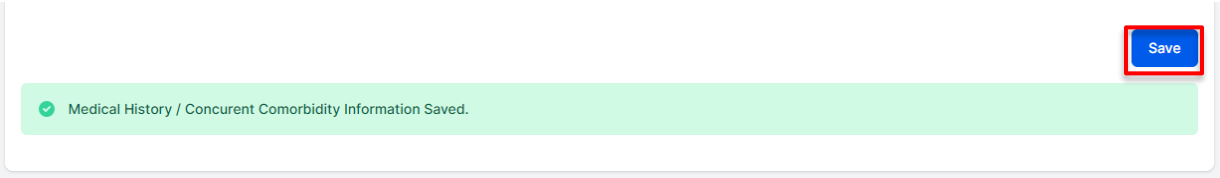
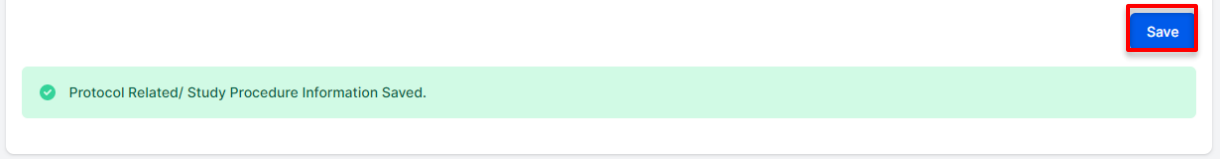
In Serious Adverse Event Case Listing, the following action icons are accessible to user:

- Show icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID (SAE Case)**
- Initial Submission icon - to show the initial registration data of NMRR ID Submission
- SAE Report Listing icon - to view the detail listing of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**

3.	Click on the icon at the intended **Serious Adverse Event Post Ethical ID (SAE Case)** which requires the follow up submission  Then, Serious Adverse Event Report List will be displayed. To create a follow up submission, click on the icon at the **intended SAE Report**  	This can only be accessible by user that has been assigned with a role either as: • Principal / Coordinating Investigator (PI) • Main Corresponding Person (Main CP) • Backup Corresponding Person (Backup CP) • Serious Adverse Event Coordinator (SAE Coordinator) • Serious Adverse Event Corresponding Person (SAE CP)

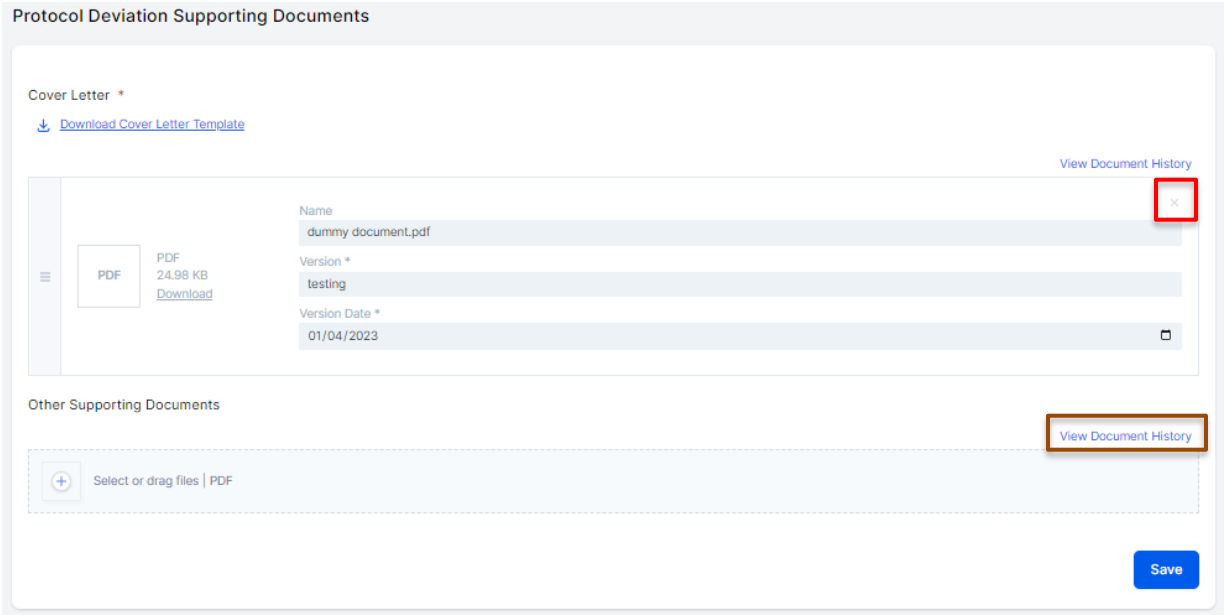
	General Serious Adverse Event Reporting Submission will be displayed with the List of Serious Adverse Event Reporting as depicted below with the latest SAE Report submission available is shown at the point of the follow up creation.  List Of SAE Reporting NO. / SAE REPORT ID / DAY AWARENESS TO REPORTING / ONSET DATE / REPORTING INVESTIGATOR / MREC REPORT DECISION 1 / SAE ID-23-00046-TR5 - Initial Report / 1 / 02/02/2023 / [redacted] / Processing Submission by MREC Secretariat	**It is advisable for user to always refer to the List of Serious Adverse Event Reporting in the "General Serious Adverse Event Reporting Information"**
4.	Insert relevant new information (if any) into the " Subject Information" under "Serious Adverse Event Detail Information" under and click save Save to save the information added (even without any changes happened in this subsection) .  Serious Adverse Event Detail Information I. SUBJECT'S INFORMATION Gender Male / Female Year of Birth * 1964 Age * Age will be auto calculated by a full years 59 Weight (kg) 102 Height (cm) 170 Save	

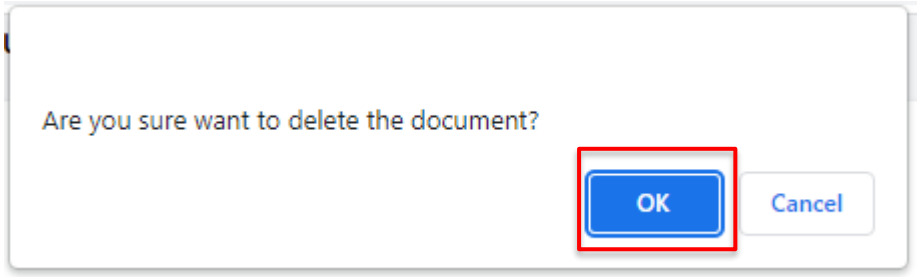
	A popup up will appear indicating the " Serious Adverse Event Detail Information – Subject Information" subsection has been succesfully saved 	
5.	Once Serious Adverse Event Detail Information - Subejct Information is saved, the **SAE Follow Up Report Form** has now been created successfully and its information will be displayed at the top of the display page together with the Report Submission Status  The List of Serious Adverse Event Reporting under the General Serious Adverse EventReporting information will have an additional listing added as follows : 	The status of a newly created **Follow Up SAE Report Submission** will be **"Pending Submisison"**

6.	User may then cotinue to update the information at other subsection as mention above in 1.0 (if any) .  .....  .....  .....  .....  To update and replace document in the “Serious Adverse Event Supporting Documents” - 1) Click on the  icon to select new updated document or drag the document over the old file – this will replace the old documents with the new one. Then click on the Save button to complete and save the new document.	

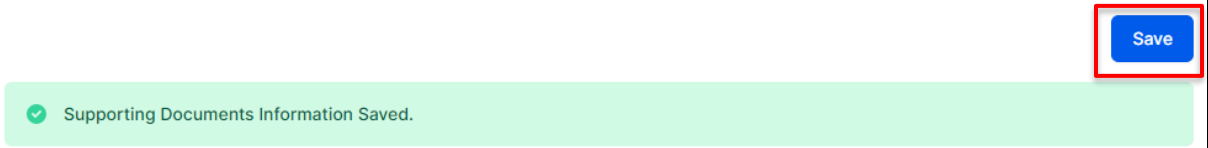
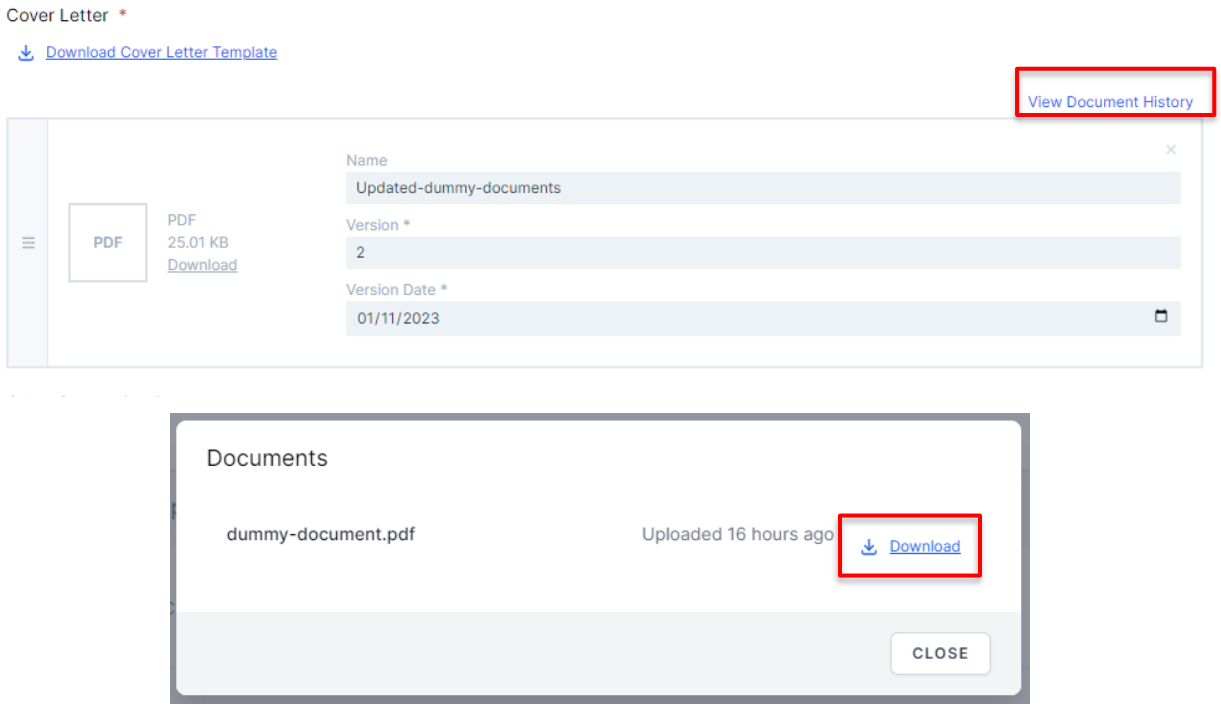
or

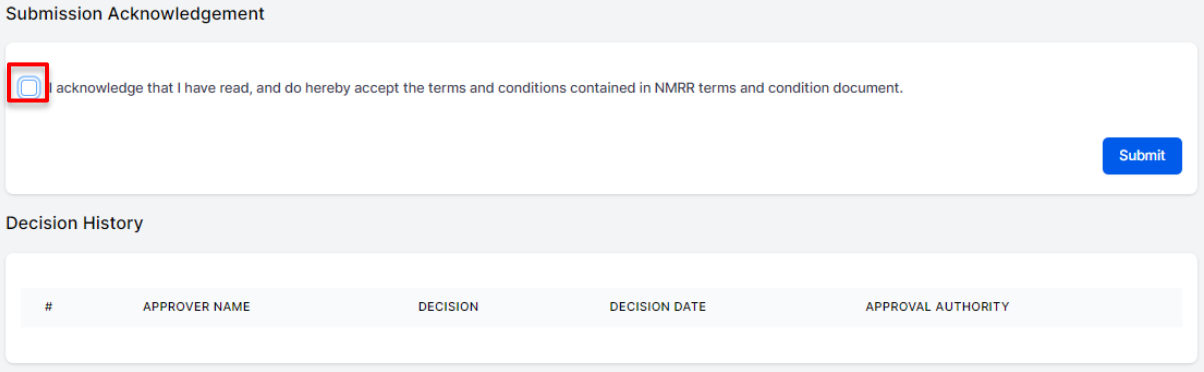
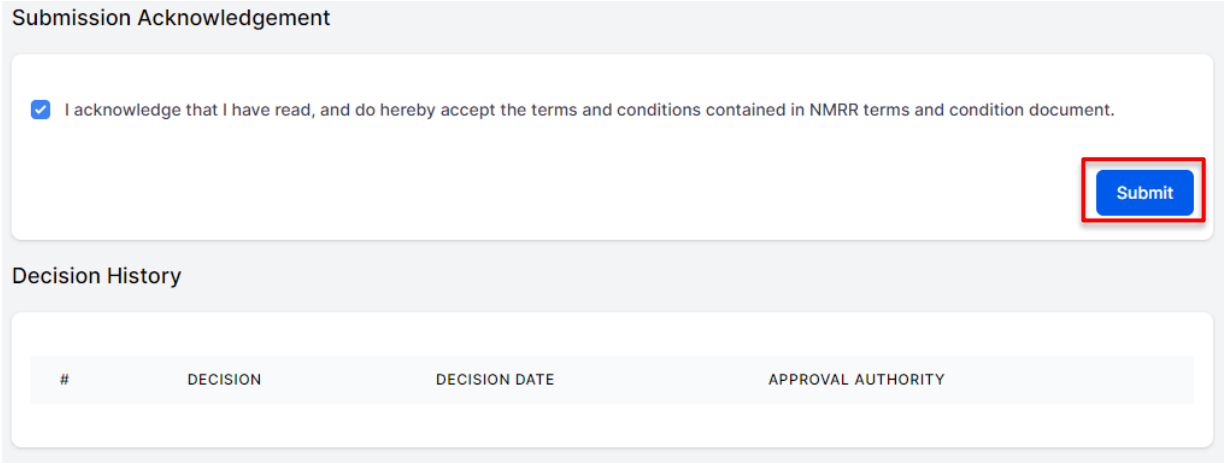
2) Click on the delete ‘x’ mark located at the right top corner of the document section. Select okay when popup appears asking user confirmation on the deletion of the document



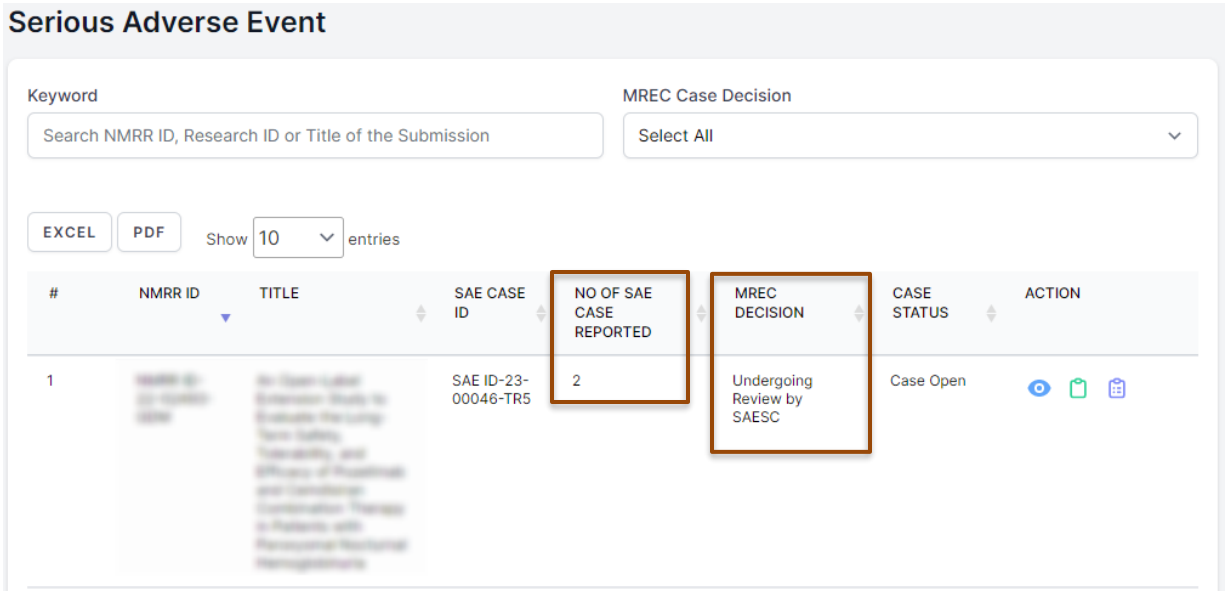


User may look back at the previous uploaded document in the **“View Document History”** located at the top right of each document section once documents section is saved.

	Then ,click on the ⊕ icon to acces the document file or drag the file over the box available. Once a document has been uploaded, user can update the version & version date to the document uploaded(if any) . File name can also be changed if needed. Once all documents have been uploaded, Click Save to complete the step and save the uplaoded documents. 	**Please ensure the file name has the extension ".pdf" at the end of its name. Files without the extension ".pdf" may have the risk of not being able to be read later**
6.	To view back the previously uploaded document, Click on the **"View Document History"** located at the top right of each document section. Document will be shown in chronological order. User also will be able to download the previously uploaded document (if needed) by clicking the Download icon next to the document title. 	

7.	Once all the required follow up information and documents have been uploaded, user is required to acknowledge the submisison made at “Submisison Acknowledgement” Tick on the box ☐ “I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.”  Once submission has been acknowledged, user can submit the Follow up Serious Adverse EventReporting Submission by clicking the Submit button.  	

Once a Follow Up Serious Adverse Event Submission has been successfully submitted, user will be broughtback to the Serious Adverse Event Case listing



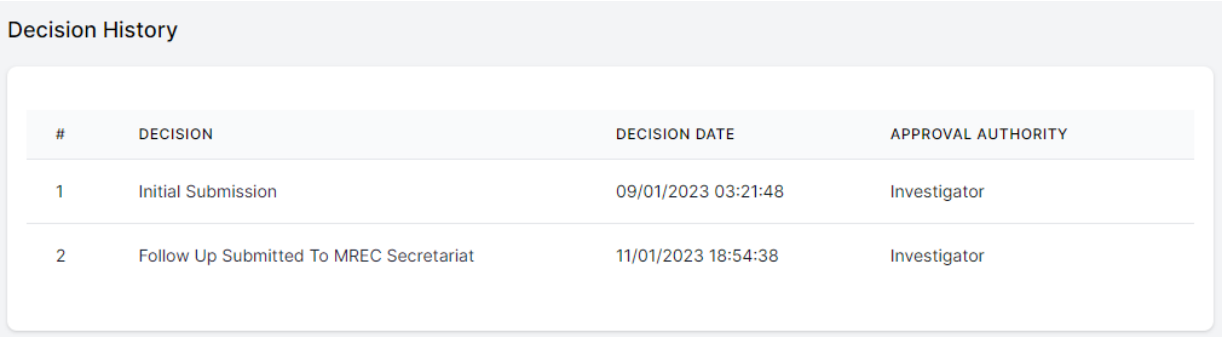
The status of a successful follow up submission of Serious Adverse Event Reporting will change from **"Pending Submission"** to either **"Undergoing Review by SAE SC"** or **"Follow up Submitted to MREC Secretariat"**

No of SAE Report Reported will also increase from the previous number of submissions

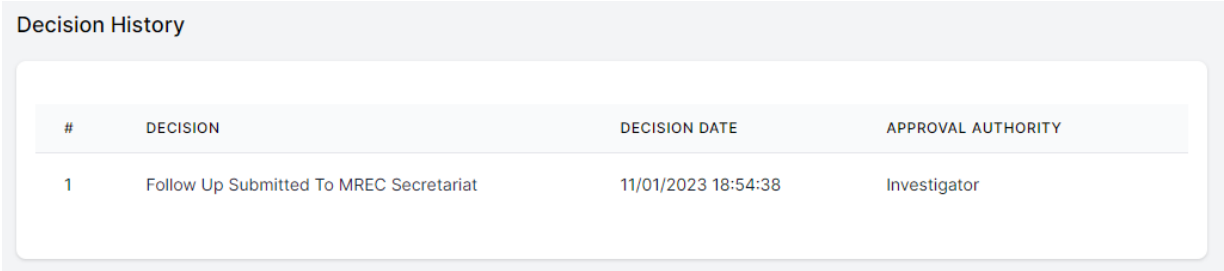
In Serious Adverse Event Case Listing, the following action icons are accessible to user:

- Show icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID (SAE Case)**
- Initial Submission icon - to show the initial registration data of NMRR ID Submission
- SAE Report Listing icon - to view the detail listing of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**

In viewing the Serious Adverse Event Case, user will be able to see the SAE Case Decision History as below:



While in viewing of the Serious Adverse Event Report for the follow-up , user will be able to just see the individual SAE Report

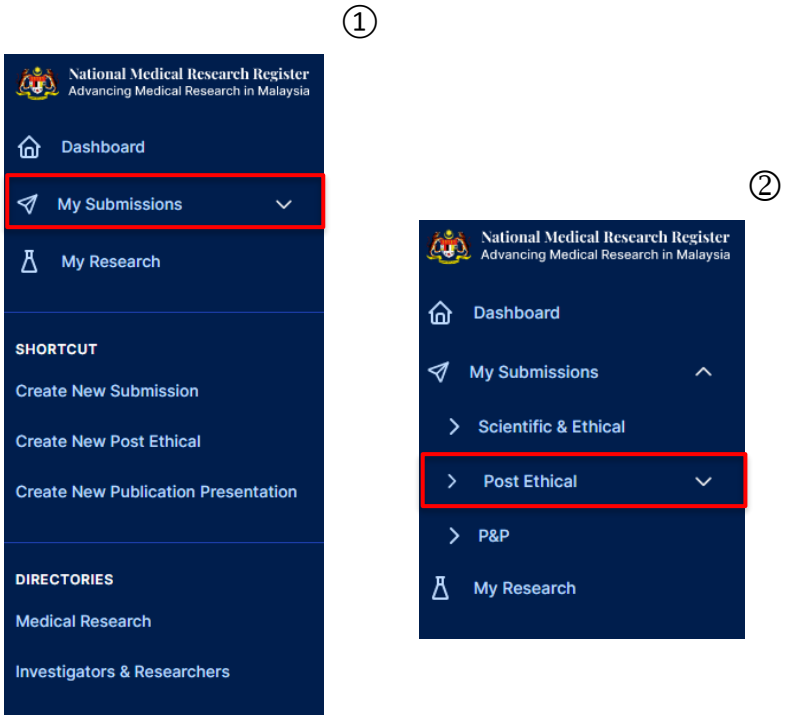


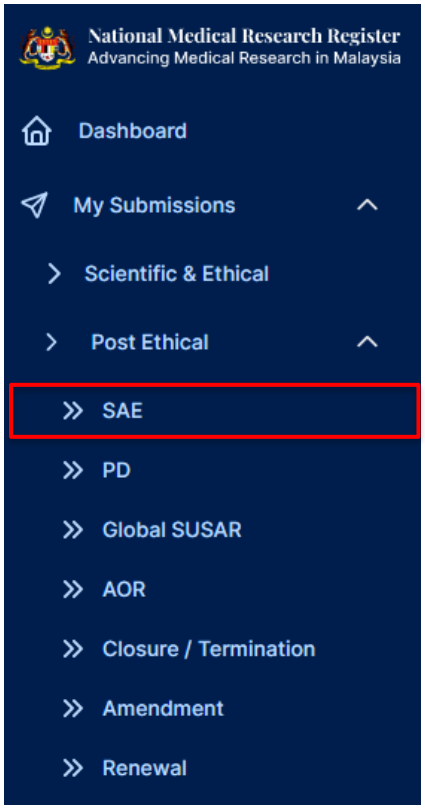
Decision history **SAE Case** versus **SAE Report**

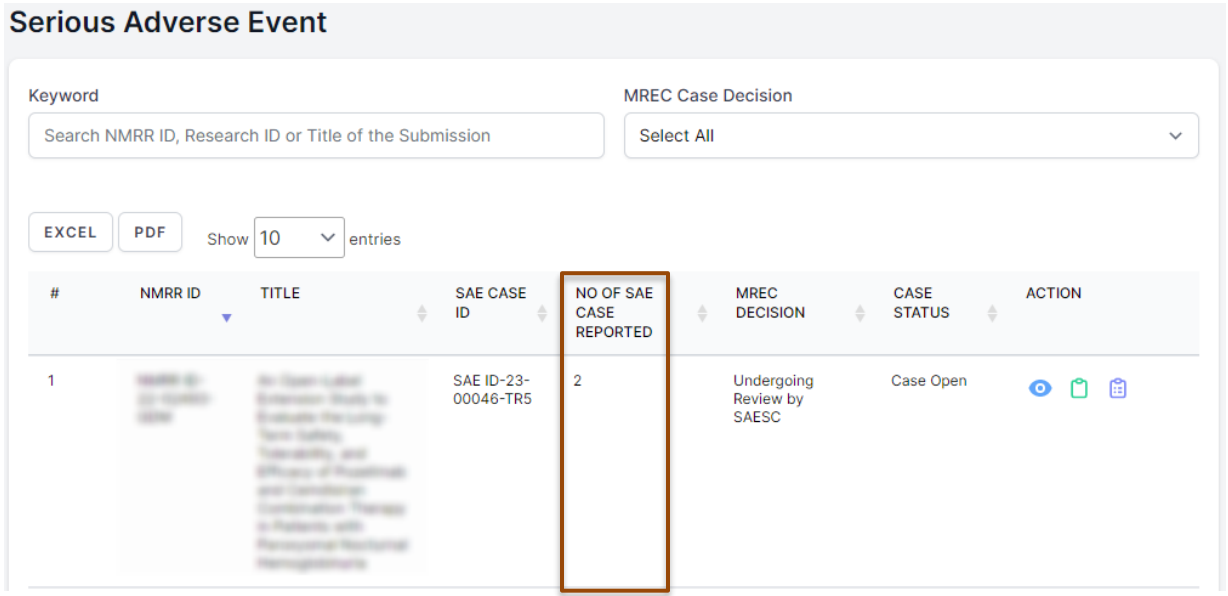
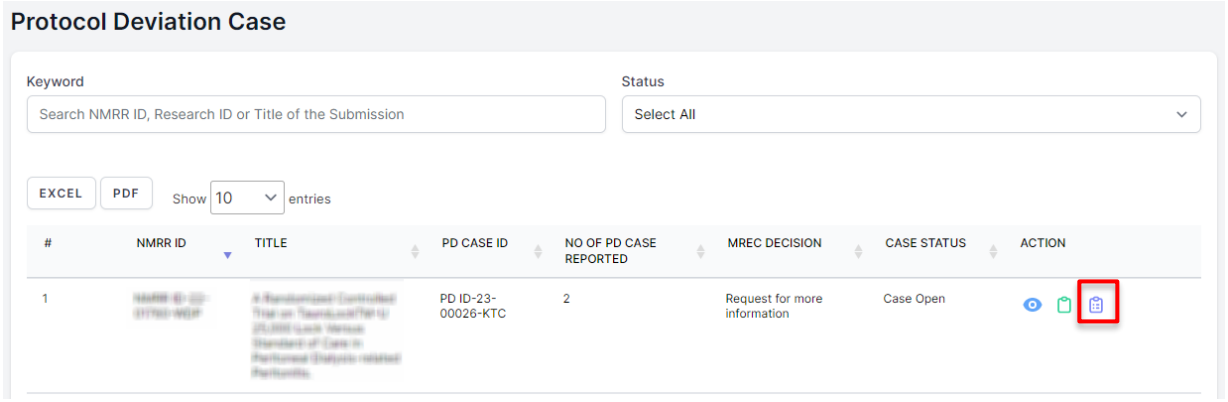
1. **SAE Case** shows only **history of submission of each SAE Reports** – (initial status of each SAE Reports under a same SAE Case ID)

   SAE Report shows **the history of processing decision status** of each individual SAE Reports

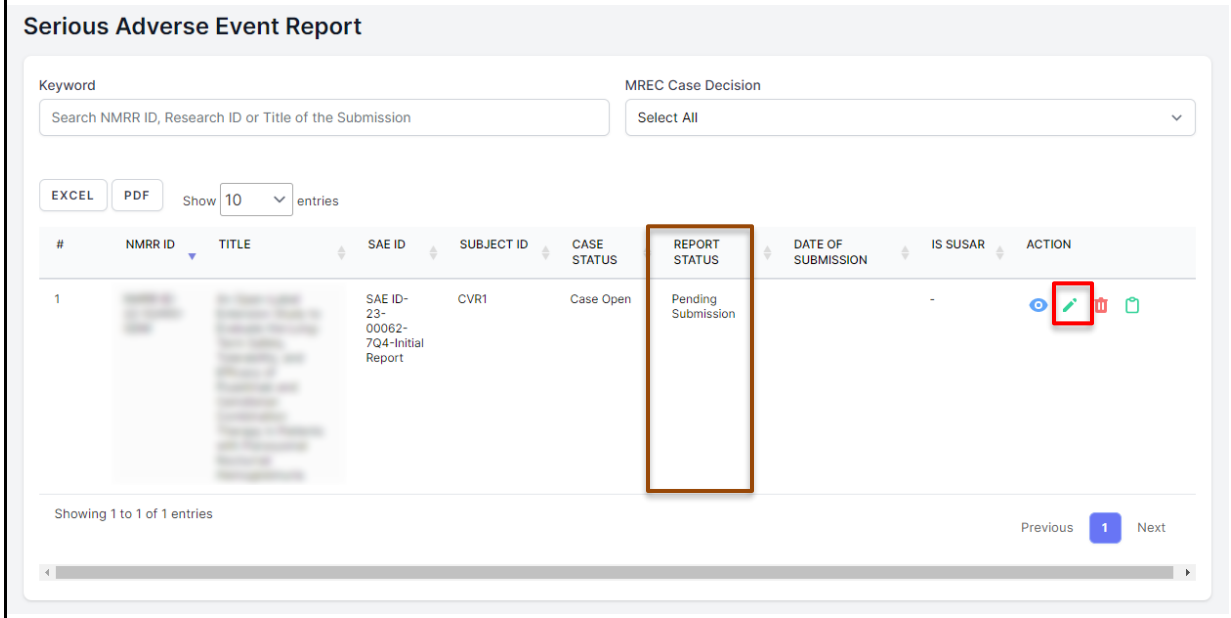
2.3 – Editing/ Deletion of Serious Adverse Event Submission with status “Pending Submission “

No	Step-by-step instructions	Remark
1.	In the case user have not managed to finish with submission and would like to come back to the existing Serious Adverse Event Submission to edit or delete the submission, scroll over the main menu located on the side of display page, go to “My Submission”. Then Click on the “Post Ethical” 	

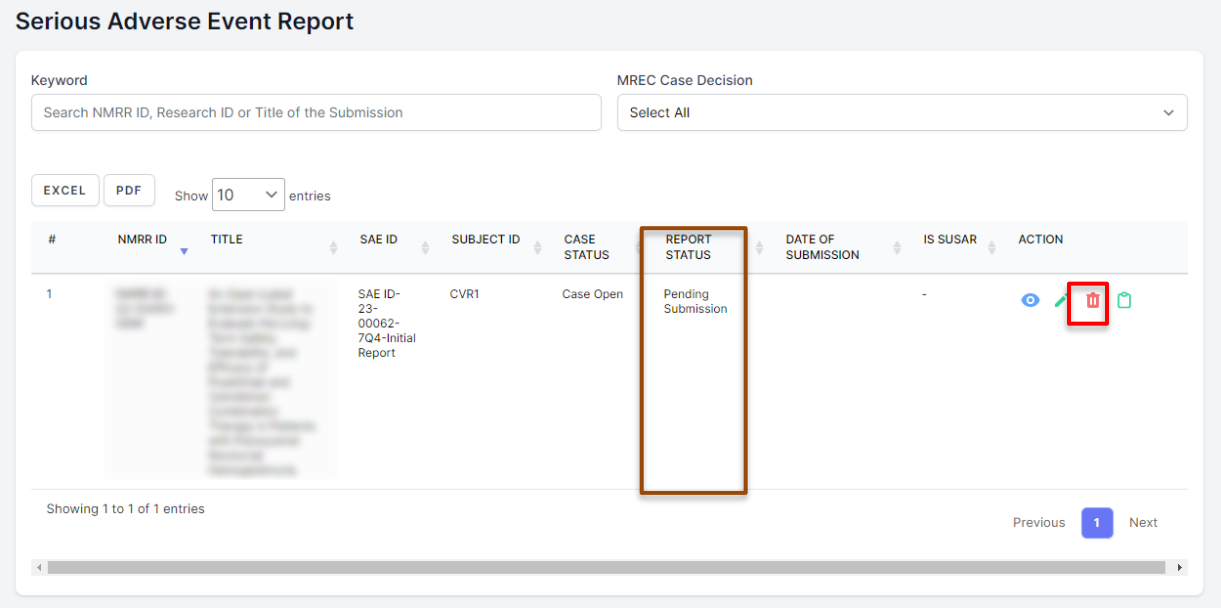
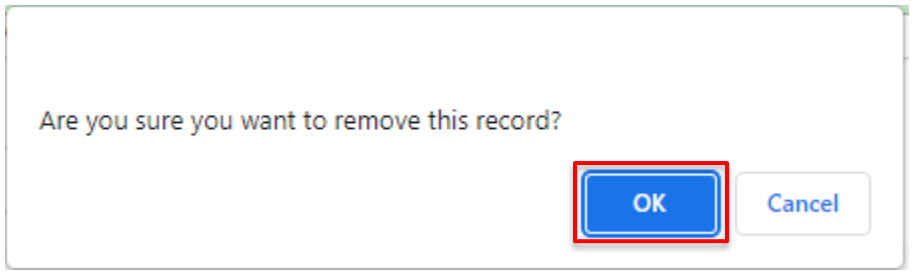
2.	Click on Serious Adverse Event to go to the listing on the existing Serious Adverse Event Submission. 	

	A list of all existing Serious Adverse Event Post Ethical ID (Serious Adverse Event Case) submission will be displayed. 	
3.	Click on the icon at the intended **Serious Adverse Event Post Ethical ID (SAE Case)** which requires the editing. 	

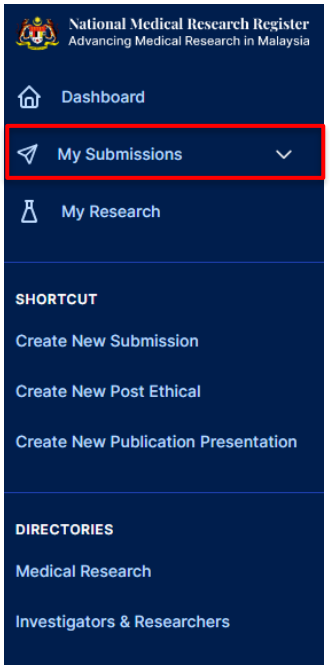
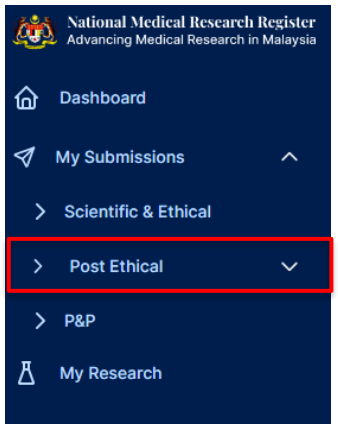
Then, Serious Adverse Event Report listing will be displayed. To edit a submission, click on the icon at the intended **SAE Report** and follow the step as mentioned above in **1.1 "Creating a new Serious Adverse Event Reporting Submission" or 2.2 – "Submission of Follow up Serious Adverse Event Reporting (Subsequent SAE Report)**

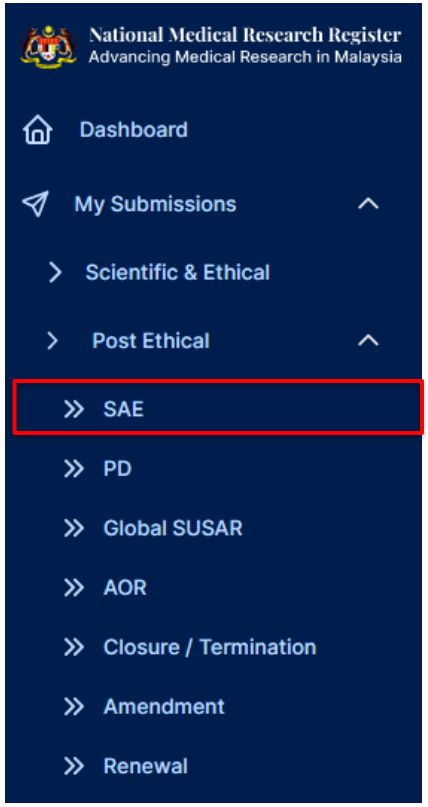


Editing of a submission is only available for a SAE Report with status **"Pending Submission"**

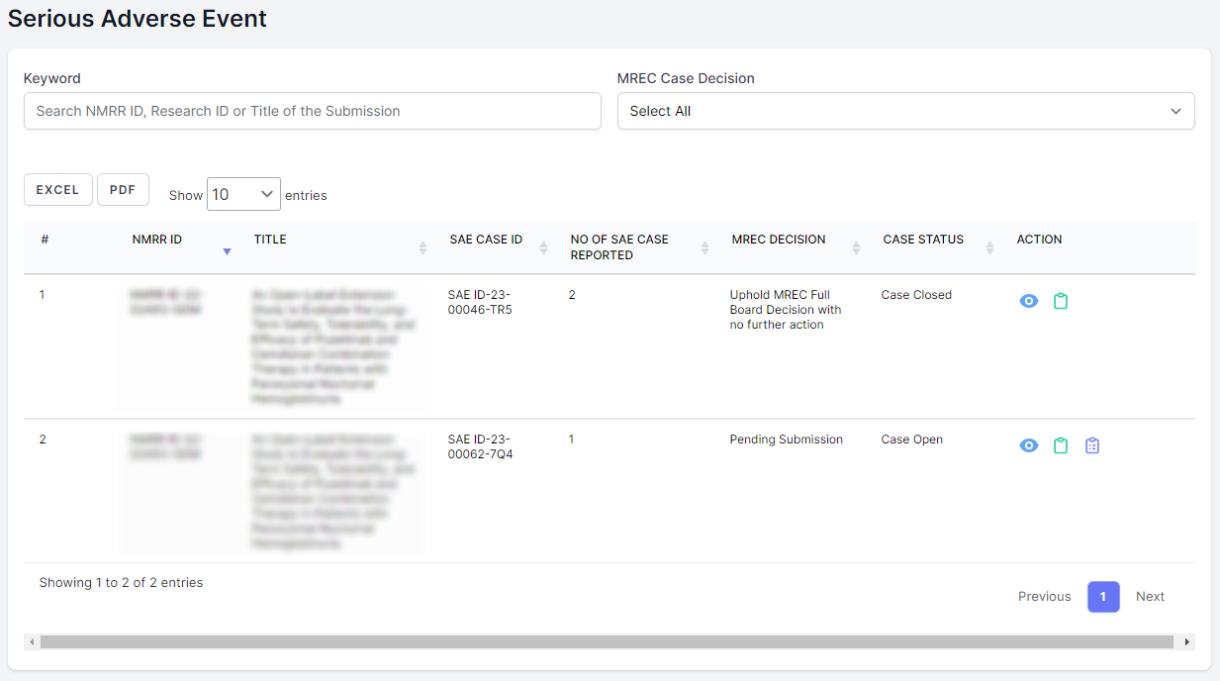
4	For Serious Adverse EventReporting Submisison deletion , click on the delete icon at the intended **SAE Report**  Click OK to confirm the deletion of the intended SAE Reporting Submission**.** Once it's clicked, the SAE Report will be deleted and removed from the Serious Adverse Event Report listing.  	Deletion of a submission is only available for a SAE Report with status **"Pending Submission"**

2.4 – Case Closed Serious Adverse Event Post Ethical ID (SAE Case)

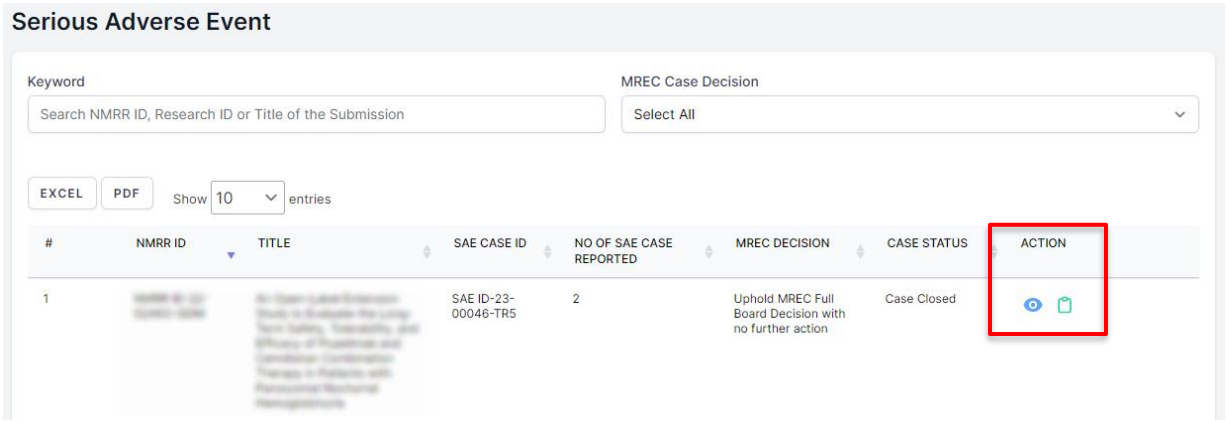
No	Step-by-step instructions	Remark
1.	In case where a **Serious Adverse Event Case** is no longer required to be updated or has completed the follow up and MREC Full Board is satisfied with the report provided, MREC Secretariat will close the **Serious Adverse Event Case** for filling and archiving. In order for to access the submission, scroll over the main menu located on the side of display page, go to “My Submission”. Then Click on the “Post Ethical” ①  ②  	

2.	Click on Serious Adverse Event to access the existing Serious Adverse Event Submission list. 	-

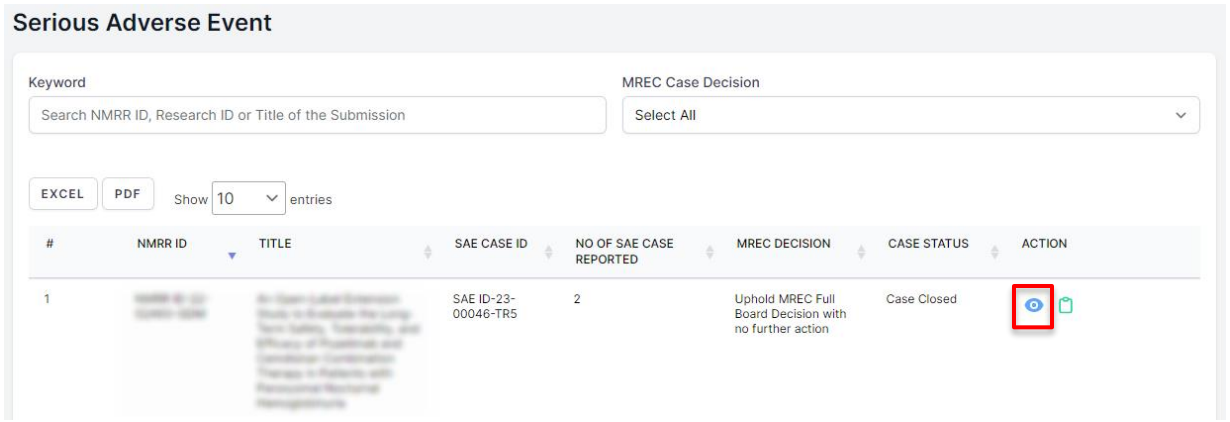
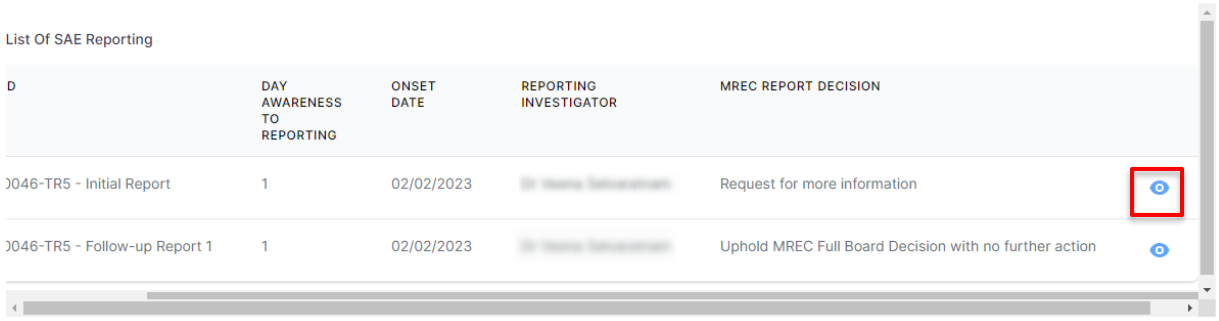
A list of all existing (Serious Adverse Even Case) submission will be displayed.



3. For a SAE Case that has been closed, the SAE report list icon **will not be available**



User will not be able to access the SAE Report list and follow up icon. To **reopen a SAE Case**, user is required to **contact MREC Secretariat** to make the request accordingly.

	However, user will still be able to access each of the SAE Report previously submitted by clicking on the icon at the closed SAE Case 	
4.	List of Serious Adverse Event Report is available under the General Serious Adverse Event Reporting Information. To view the SAE report details , click on the icon at the intended SAE Report. 	

-The End -

Prepared by: NMRR Secretariat

Checked & validated by: Dr Asyraf Syahmi Bin Mohd Noor (date: 10/05/2023)