

User Guidelines for
Post Ethical Approval Submission
- Serious Adverse Event

National Medical Research Register v2.0

National Institutes of Health (NIH)

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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: <ul style="list-style-type: none">● 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: <ul style="list-style-type: none">● 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
 - ii. 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 / Concurrent 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

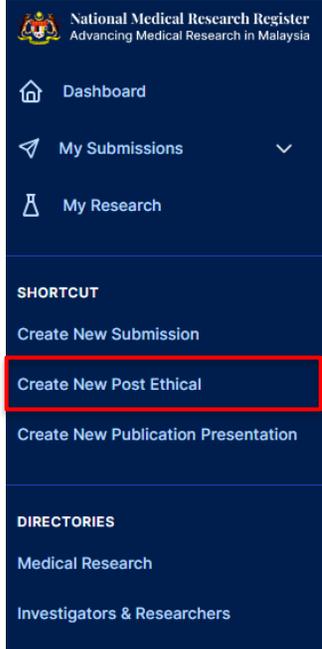
SAE SUPPORTING DOCUMENTS

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.	<p>Log in as Investigator or CRA in NMRR</p> 	
2.	<p>Scroll over the main menu located on the side of the display page, go to shortcut, and select Create New Post Ethical</p> 	<p>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:</p> <ul style="list-style-type: none"> • 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”

New Post Ethical Approval

Keyword: Search NMRR ID, Research ID or Title of the Submission

Show 10 entries

Select Post Ethical Approval Type:

- Select All
- Select All
- AOR
- Amendment
- Closure \ Termination \ Suspension
- Global SUSAR
- Protocol Deviation
- Serious Adverse Event (SAE)
- Ethical Approval Renewal

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR ID: 4444-4444	Research on the Effect of Public Health Interventions on Health Inequality	Health System		Expedited Review by MREC Chairperson/ Deputy Chairperson	
2	NMRR ID: 4444-4444	Research on the Effect of Public Health Interventions on Health Inequality	Social Science / Health Behavioural	Observational	Approval granted via Expedited Review by MREC Chairperson/ Deputy Chairperson	

Showing 1 to 2 of 2 entries

Previous 1 Next

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

Keyword: Search NMRR ID, Research ID or Title of the Submission

Select Post Ethical Approval Type: Serious Adverse Event (SAE)

Show 10 entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR ID: 4444-4444	Approval to Screen Antipsychotics Used in the Treatment of Schizophrenia in the UK	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR ID: 4444-4444	A Multicentre, Randomised, Double-Blind, Active-Controlled Study to Evaluate the Efficacy and Safety of Meprobamate Compared to Placebo When Used in Combination with Meprobamate in Subjects with Type 2 Diabetes	Clinical	Interventional	Approval granted via MREC Full Board	

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

Keyword Select Post Ethical Approval Type

Serious Adverse Event (SAE) 

Show entries

#	NMRR ID	TITLE	RESEARCH SCOPE	RESEARCH TYPE	STATUS	ACTION
1	NMRR (20-432-1000)	Approval versus Acetylsalicylic Acid (ASA) to Prevent Stroke in Atrial Fibrillation Patients Who Have Failed or are Unavailable for Vitamin K Antagonist Treatment	Clinical	Interventional	Approval granted via MREC Full Board	
2	NMRR (20-212-1000)	A Multicenter, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Durability of the Efficacy and Safety of Angiotensin Compared to Digoxin When Used in Combination with Metformin in Subjects with Type 2 Diabetes	Clinical	Interventional	Approval granted via MREC Full Board	

5. A page will be displayed with the General information of the Submission is shown over the top part of the display page

SAE Case Form

AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGOLIZED AND GENETICALLY MODIFIED COMBINATION THERAPY IN PATIENTS WITH PERIODONTAL INFECTIONS

NMRR ID: NMRR-22-00453-02M Protocol ID: E0310-PMW-2022 Last updated on Dec 02, 2022

Status: Approval granted via MREC Full Board

6. Scroll down the page to the “General Serious Adverse Event Study Information”. Select a site intended for the reporting.

General Serious Adverse Event Study Information

Site Conducted *

Please Select...

NAME OF INVESTIGATOR

ROLE OF INVESTIGATOR

STATE CONDUCTED

No records available

Country *

Subject ID *

Reporting Investigator *

Please Select...

In some submission, site assigned has been auto selected and the list of investigator at site will be displayed

Site Conducted

Hospital Queen Elizabeth

NAME OF INVESTIGATOR	ROLE OF INVESTIGATOR	STATE CONDUCTED
Lily Hong-Lan Lee	Principal Investigator at the site	Sabah
Chen Hong-Hong	Co / Sub Investigator at the site	Sabah
Lim Ho-Min	Co / Sub Investigator at the site	Sabah
Kohari Sookhuma	Co / Sub Investigator at the site	Sabah
Gilbert Wilfred	Co / Sub Investigator at the site	Sabah
Wong Tze-Ho (Dr. Howard Goh)	Co / Sub Investigator at the site	Sabah

Country *

MYS

“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.

**** In case 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 investigator is made by selecting a name from the list displayed. Click **Save** to save the information

Country *

MYS

Subject ID *

|

Reporting Investigator *

Please Select...

List Of SAE Reporting

NO.	SAE REPORT ID	DAY AWARENESS TO REPORTING	ONSET DATE	REPORTING INVESTIGATOR	MREC REPORT DECISION
No records found.					

Save

Subject ID *

XX-1

Reporting Investigator *

Please Select...

Please Select...

- Lim Hong Lim
- Lim Hong Lim
- Lim Ho Min

No records found.

Save

A popup up will appear indicating the “General Serious Adverse Event (SAE) Information” has been successfully saved

✔ General SAE Study Information Saved.

A Serious Adverse Event Post Ethical ID will be generated This information can be seen over the top part of the display page

SAE Form : Initial Report

AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF POZILONE AND CENOSORBIN COMBINATION THERAPY IN PATIENTS WITH PREVIOUSLY METASTASIZING HEMATOLOGICAL MALIGNANCIES

NMRR ID [NMRR ID-23-00010-RX3](#) Protocol ID [R3316 \(PAIN 2022\)](#) Last updated on Dec 02, 2022

Status [Approval granted via MREC Full Board](#)

Case ID [SAE ID-23-00010-RX3](#)

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  to save the information .

Serious Adverse Event Detail Information

I. SUBJECT'S INFORMATION

Gender

Male

Female

Year of Birth *

Age *

Age will be auto calculated by a full years

Weight (kg)

Height (cm)



I. SUBJECT'S INFORMATION

Gender

Male

Female

Year of Birth *

1968

Age *

Age will be auto calculated by a full years

55

Weight (kg)

110

Height (cm)

165

Save

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

Save

✔ Subject Information 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 Submission Status will be generated and displayed as "Pending Submission". This information can be seen over the top part of the display page

SAE Initial Report Form

REGISTRATION, EFFICACY AND SAFETY OF INVESTIGATIONAL DRUGS (IND) AND/OR MEDICAL DEVICES (MD) AND/OR COMBINATION PRODUCTS, CONDUCTED AS SETTING RESEARCHERS
RESEARCHERS SHOULD BE AWARE OF THE IMPORTANCE OF REPORTING ALL SUSPECTED ADVERSE EVENTS (SAEs) TO THE IRB/IEC AND/OR FDA, INCLUDING ALL SUSPECTED
ADVERSE EVENTS (SAEs) THAT ARE NOT REPORTED TO THE IRB/IEC AND/OR FDA, INCLUDING ALL SUSPECTED ADVERSE EVENTS (SAEs) THAT ARE NOT REPORTED TO THE IRB/IEC AND/OR FDA,

NMRR ID [NMR-23-00020-MHD](#) Protocol ID [ET 2122-01](#) Last updated on Aug 12, 2022

Status Approval granted via MREC Full Board

Case ID [SAE ID-23-00020-MHD : Initial Report](#)

Case Status Case Open Report Submission Status Pending Submission

“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 listing of SAE Reporting Generated in the General Serious Adverse Event Study Information section

Reporting Investigator

Dr. Maria Subramanian

Corresponding Person

Ms. Jennifer Chung, MD, PhD

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		Dr. Maria Subramanian	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/protocoldeveloment/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.

II. SERIOUS ADVERSE EVENT INFORMATION

Serious Adverse Event Information *

Testing submission SAE

Common Terminology Criteria of Adverse Event By System *

Cardiac disorders

Common Terminology Criteria of Adverse Event By Terminology *

Atrial fibrillation

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

Place of Occurrence

On-site

Off-site

Narrative of the SAE Occurrence *

Summarize all relevant clinical and related information including: study subject characteristics, Medical history, Clinical course of the event and therapy details, Diagnosis (workup, relevant tests/procedures, lab results), Other information that supports or refutes the SAE causality

Place of Occurrence

On-site

Off-site

Narrative of the SAE Occurrence *

Summarize all relevant clinical and related information including: study subject characteristics, Medical history, Clinical course of the event and therapy details, Diagnosis (workup, relevant tests/procedures, lab results), Other information that supports or refutes the SAE causality

Testing Narrative SAE Submission

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

Date of Onset *

Date of Onset *

02/02/2023

Date Awareness (Days onset : 1) *

03/02/2023

Date of SAE Resolution (Leave blank if still on ongoing)

dd/mm/yyyy

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

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

Criteria for Seriousness *

Yes

No

Criteria of Severity

Mild

Moderate

Severe

Life-threatening

Death

Unknown

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.

Save

✔ Serious Adverse Event Information Saved.

Action Taken With Regard to IP *

<input type="radio"/> Dose not changed	<input type="radio"/> Dose increased
<input type="radio"/> Dose reduced	<input type="radio"/> Dose withdrawn
<input type="radio"/> Not applicable	

Subject Outcome *

<input type="radio"/> Recovered	<input type="radio"/> Recovered with sequelae
<input type="radio"/> On-going	<input checked="" type="radio"/> Died
<input type="radio"/> Unknown	

Save

If Subject Outcome selection is **“Recovered”**, **“Recovered with sequelae”** 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)

More than 1 criteria of SAE can be selected from the list in one submission

Criteria for Seriousness *

Yes No

Criteria of SAE *

- Resulting In Death
- Life-threatening
- Hospitalization or prolongation of hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/ birth defect
- Important medical event (protocol specify)

Is this SAE considered a Suspected Unexpected Serious Adverse Reaction (SUSAR) *

Yes No Unknown

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.

Criteria of SAE *

- Resulting In Death
- Life-threatening
- Hospitalization or prolongation of hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/ birth defect
- Important medical event (protocol specify)

Autopsy done

Yes No

Date of death

mm/dd/yyyy

Cause of death

.....

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.

Criteria of SAE *

- Resulting In Death
- Life-threatening
- Hospitalization or prolongation of hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/ birth defect
- Important medical event (protocol specify)

Date of Hospital Admission

mm/dd/yyyy



Date of Discharge (leave blank if subject still on admission)

mm/dd/yyyy



10. If Subject Outcome selection is “Recovered” or “Recovered with sequelae” , user is required to insert the “Date of Recovery” of subejct

Subject Outcome *

Recovered

Recovered with sequelae

On-going

Died

Unknown

Date of recovery *

dd/mm/yyyy



Save

If Subject Outcome selection is “Ongoing” , user is required to declare the on-going status of subejct

Subject Outcome *

Recovered

On-going

Unknown

Recovered with sequelae

Died

If Ongoing *

Improving

Worsening

Persisting

Save

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

III. SUSPECTED PRODUCT INFORMATION

Interventional Allocation

RCT

Study Making/ Blinding

Single Blind

List of Investigational Product / Process / Intervention

TYPE	NAME	DESCRIPTION
Biological/Biomedical - vaccine	IP-123456789	IP-123456789, a recombinant Novel Coronavirus Vaccine, Adjuvanted Type 1 Vaccine/Manufacture
Biological/Biomedical - vaccine	IP-987654321	Second vaccine vaccine available in 10/20/2020 (in Continues)

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.

IP's Association with SAE (In General) *

Please Select...

Suspected Product Information **Add**

NO.	PRODUCT NAME	DOSAGE	FREQUENCY	ROUTE	BATCH	THERAPY START DATE	THERAPY STOP DATE	RECENT DOSE DATE	DAY TO ONSET	EVENT ABATE
No records found.										

IP's Association with SAE (In General) *

Please Select...

- Please Select...
- Unrelated
- Unlikely
- Possible
- Probably
- Certain/Definite
- Unknown

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.

Suspected Investigational Product

Suspected Product
Please Select...

Investigational Product Dose

Investigational Product Unit
Please Select...

Frequency

Route of Administration
Please Select...

[Cancel](#) [Save](#)

IP's Association with SAE (In General) *

Unrelated

Suspected Product Information [Add](#)

NO.	PRODUCT NAME	DOSAGE	FREQUENCY	ROUTE	BATCH	THERAPY START DATE	THERAPY STOP DATE	RECENT DOSE DATE	DAY TO ONSET	EVENT
1	Foodmate	1000 Capsules	QID	ORAL	xxa1	05/01/2023		31/01/2023	2	Not ap

Once the suspected product information has been inserted, user is required to declare whether the emergency code has been broken and whether there are any other possible cause for the SAE. Click **Save** to save the information in the subsection.

The screenshot shows a form with two dropdown menus and a Save button. The first dropdown menu is labeled "Emergency code broken" and has a "Please Select..." option. The second dropdown menu is labeled "In the investigator's opinion, are there other possible cause(s):" and also has a "Please Select..." option. A blue "Save" button is located at the bottom right of the form.

A popup will appear indicating the " Suspected Product Information" has been successfully saved.

The screenshot shows a success message popup with a green background and a white checkmark icon. The text reads "Suspected Product Information Saved." A blue "Save" button is located at the top right of the popup.

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.

The screenshot shows a form titled "IV. CONCOMITANT MEDICATION(S)". Under the heading "Usage of Concomittant Medication", there are two radio button options: "Yes" and "No". The "No" option is selected. A blue "Save" button is located at the bottom right of the form.

IV. CONCOMITANT MEDICATION(S)

Usage of Concomittant Medication

Yes

No

Add

NO.	DRUG NAME	TOTAL DAILY DOSAGE	UNIT	FREQUENCY	START DATE	STOP DATE	INDICATION	SUSPECTED SAE CAUSE
-----	-----------	--------------------	------	-----------	------------	-----------	------------	---------------------

No records found.

Save

Insert the required information on the concomittant 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.

Concomittant Medication

Drug name

Dose

Unit

Please Select...



Frequency

Estimated Date Start

mm/dd/yyyy



Cancel

Save

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

IV. CONCOMITANT MEDICATION(S)

Usage of Concomittant Medication

Yes No

Add

NO.	DRUG NAME	TOTAL DAILY DOSAGE	UNIT	FREQUENCY	START DATE	STOP DATE	INDICATION	SUSPECTED SAE CAUSE	
1	xxaser	10	ML-Millilitres	OD	03/11/2022	-	Testing	Unknown	 

Save

A popup up will appear indicating the “Concomitant Medication” has been succesfully saved.

Save

✔ Concomittant Medication Information Saved.

13. Next scroll down the page until the next subsection “Medical History / Concurrent Comorbidity”. User is required to insert information on the past medical history or any concurrent 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.

V. Medical History / Concurrent Comorbidity

Know Medical History/Concurrent comorbidity

Yes No

Save

V. Medical History / Concurrent Comorbidity

Know Medical History/Concurrent comorbidity

Yes No

Add

NO.	DISEASE/ SYNDROME	DATE OF ONSET	DURATION	STOP DATE	SUSPECTED SAE CAUSE
No records found.					

Save

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.

Co-Morbidities

Disease/ Syndrome

Estimated Date of Onset

dd/mm/yyyy

Duration of comorbidity

Date of Resolve (leave blank if comorbidity is still on ongoing)

dd/mm/yyyy

Suspected SAE Cause

Please Select...

Cancel **Save**

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

V. Medical History / Concurrent Comorbidity

Know Medical History/Concurrent comorbidity

Yes No



NO.	DISEASE/ SYNDROME	DATE OF ONSET	DURATION	STOP DATE	SUSPECTED SAE CAUSE	
1	DM	08/03/2019	4 years	-	Unknown	 



A popup up will appear indicating the “Medical History / Concurrent Comorbidity” has been successfully saved.





14. Then , further scroll down to “Protocol Related/ Study Procedure” subsection. User is required to fill information whether is there any related procedure done according to the protocol that might cause the SAE

VI. Protocol Related/ Study Procedure

Any Significant Procedure (Not as investigational Product/ Procedure done to patient)

Yes No

Not applicable Unknown

Not available



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.

Any Significant Procedure (Not as investigational Product/ Procedure done to patient)

Yes No

Not applicable Unknown

Not available

Please Explain

Text area for explanation.

Suspected SAE Cause

Please Select...

Save

Suspected SAE Cause

Please Select...
Please Select...
Yes
No
Not applicable
Unknown
Not available

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

Please Explain

testing submission

Suspected SAE Cause

Unknown



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



 Protocol Related/ Study Procedure Information 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.

VII. Other Etiology

Other Etiology that Possibly Caused the Adverse Event

Suspected SAE Cause

Please Select...

Save

Suspected SAE Cause

Please Select...

Please Select...

Yes

No

Not applicable

Unknown

Not available

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

VII. Other Etiology

Other Etiology that Possibly Caused the Adverse Event

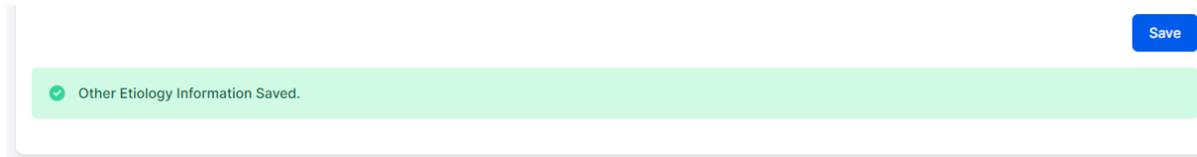
N/A

Suspected SAE Cause

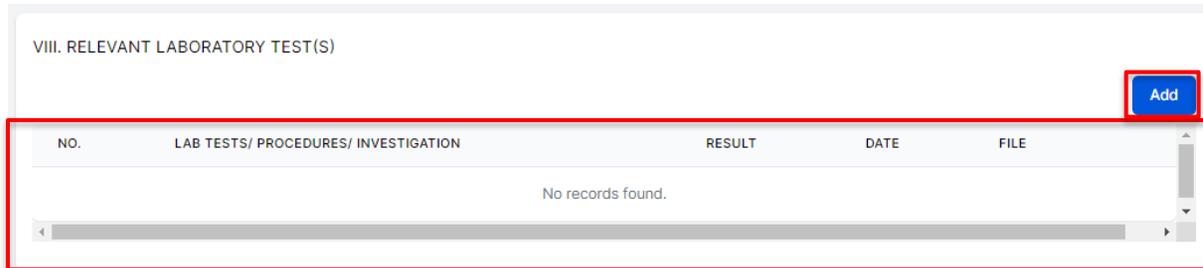
Not applicable

Save

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.

A screenshot of the "Laboratory Test" form. It contains several input fields: "Lab tests/ Procedures/ Investigation", "Result" (with a note: "(Overall laboratory result if normal can be mentioned in general e.g. 'Normal/ 'Within acceptable range' / 'NAD' , incase of any abnormal finding or abnormality to the investigation - to mentioned the abnormality or finding)"), and "Date" (with a placeholder "mm/dd/yyyy" and a calendar icon). At the bottom, there is an "Upload" section with a red border, containing a plus icon and the text "Select or drag a file | PDF". At the very bottom of the form are "Cancel" and "Save" buttons.

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 dragging the document over the box available.

Laboratory Test

Lab tests/ Procedures/ Investigation

FBC

Result

(Overall laboratory result if normal can be mentioned in general e.g. 'Normal' 'Within acceptable range' / 'NAD' , incase of any abnormal finding or abnormality to the investigation - to mentioned the abnormality or finding)

Normal

Date

06/02/2023

Upload

PDF dummy-document.pdf
137.35 KB
[Remove](#)

Cancel

Save

[Download Cover Letter Template](#)

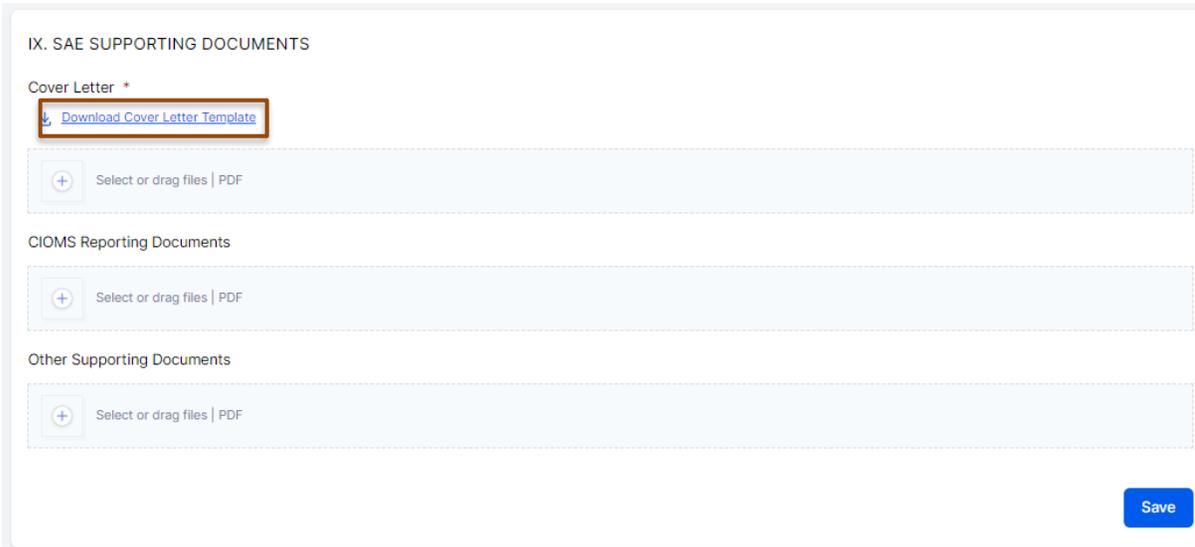
Once all information has been saved, a list of all investigation and laboratory test will be listed in a table

VIII. RELEVANT LABORATORY TEST(S)

Add

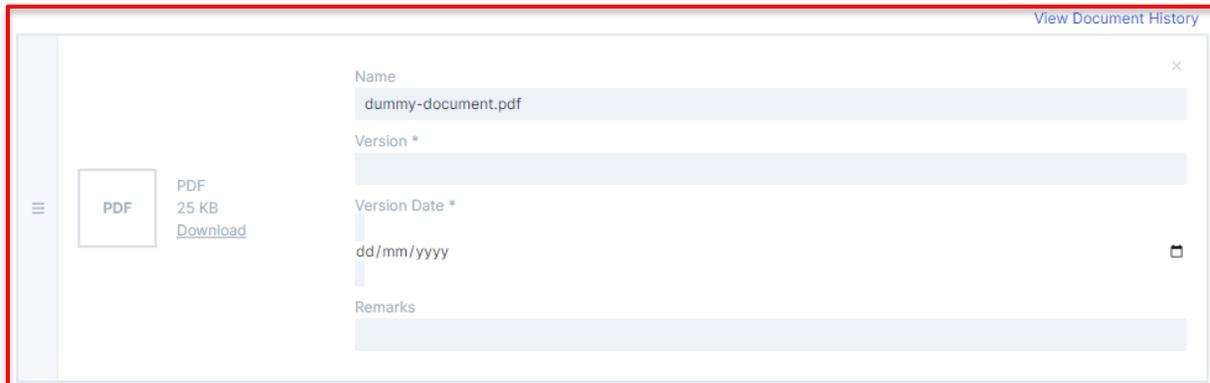
NO.	LAB TESTS/ PROCEDURES/ INVESTIGATION	RESULT	DATE	FILE	
1	FBC	Normal	06/02/2023	dummy document.pdf	 

17. Then ,continue to scroll down on the page. “Serious Adverse Event Supporting Documents” part will be available 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 dragging 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.

Cover Letter *
[Download Cover Letter Template](#)



“**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

Other Supporting Documents

[View Document History](#)

+ Select or drag files | PDF

Save

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

Save

✔ Supporting Documents Information Saved.

18. 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.”

Submission Acknowledgement

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.
 Submit

Decision History

#	APPROVER NAME	DECISION	DECISION DATE	APPROVAL AUTHORITY

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

X. CONFIRMATION OF SUBMISSION

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

****Please ensure all the information has been filled up and all the documents required has been uploaded and saved**

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

SAE Initial Report Form

AN OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF POZELIMAB AND CEMDISIRAN COMBINATION THERAPY IN PATIENTS WITH PAROXYSMAL NOCTURNAL HEMOGLOBINURIA

NMRR ID NMRR ID-22-02493-GDM Protocol ID R3918-PNH-2050 Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

Case ID SAE ID-23-00046-TR5 : Initial Report

Case Status Case Open Report Submission Status Processing Submission by MREC Secretariat

Once a new Serious Adverse Event Reporting Submission has been successfully submitted, user will be brought to the Serious Adverse Event Case listing

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1	NMRR ID-22-02493-GDM	An Open-Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of Pozelimab and Cemdisiran Combination Therapy in Patients with Paroxysmal Nocturnal Hemoglobinuria	SAE ID-23-00046-TR5	2	Initial Submission	Case Open	

Showing 1 to 1 of 1 entries

Previous 1 Next

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 Event Post Ethical ID – Report Type (SAE Report) , click on SAE Report Listing  icon.

Serious Adverse Event

Keyword

MREC Case Decision

Select All



EXCEL

PDF

Show

10



entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1	NMRR ID- 22-02463-0356	An Open Label Extension Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of Placebo and Combination Therapy in Patients with Pericardial Myxomatous Hemorrhage	SAE ID-23-00046-TR5	2	Initial Submission	Case Open	  

Showing 1 to 1 of 1 entries

Previous **1** Next



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.

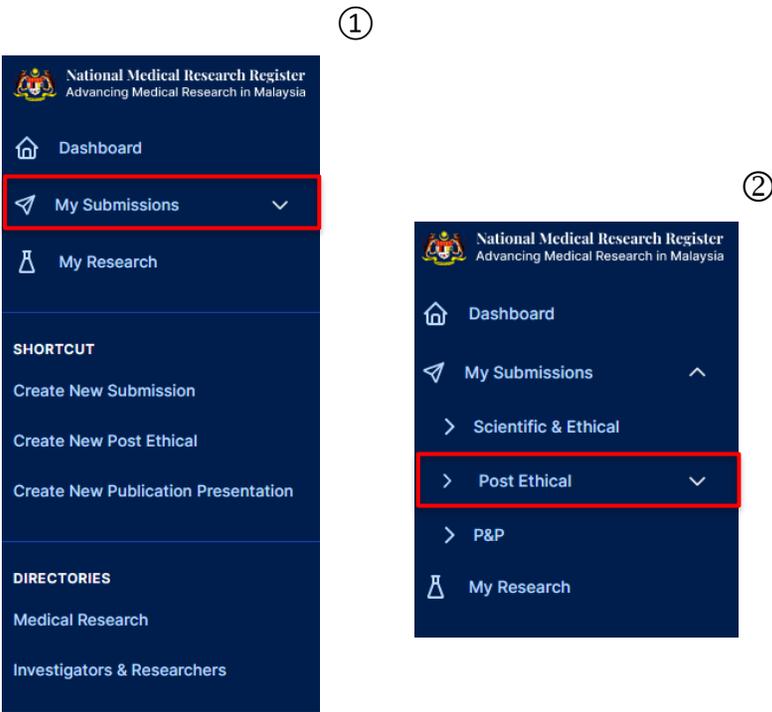
#	NMRR ID	TITLE	SAE ID	SUBJECT ID	CASE STATUS	REPORT STATUS	DATE OF SUBMISSION	IS SUSAR	ACTION
1	NMRR ID-23-00046-TR5-0001	An Open Label Extension Study to Evaluate the Long Term Safety, Tolerability and Efficacy of Fostemsavir and Combination Combination Therapy in Patients with Periphera Peripheral Hemoglobinuria	SAE ID-23-00046-TR5-Follow-up Report 1	XXX-1	Case Open	Pending Submission	16/05/2023	No	   
2	NMRR ID-23-00046-TR5-0001	An Open Label Extension Study to Evaluate the Long Term Safety, Tolerability and Efficacy of Fostemsavir and Combination Combination Therapy in Patients with Periphera Peripheral Hemoglobinuria	SAE ID-23-00046-TR5-Initial Report	XXX-1	Case Open	Processing Submission by MREC Secretariat	16/05/2023	No	  

In Serious Adverse Event Report listing, the following action icons are accessible to user

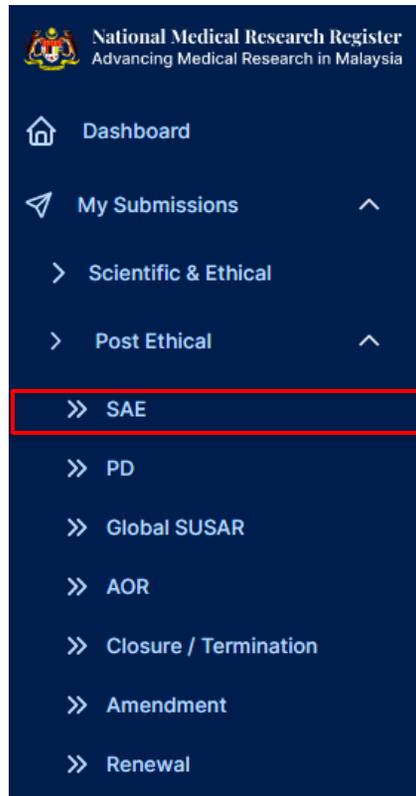
- Show  icon - to view of the General Serious Adverse Event Submission of **Serious Adverse Event Post Ethical ID – Report Type (SAE Report)**
- Initial Submission  icon - to show the initial registration data of NMRR ID Submission
- Follow up Report  icon - to add/send a new follow up SAE Case (create 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.	<p data-bbox="205 370 1346 435">Scroll over the main menu located on the side of displayed page, go to “My Submission.” Then Click on the “Post Ethical”</p> <div data-bbox="210 470 982 1182"><p>The image shows two screenshots of the National Medical Research Register dashboard. The first screenshot, labeled with a circled '1', shows the main menu with 'My Submissions' highlighted by a red box. The second screenshot, labeled with a circled '2', shows the 'My Submissions' dropdown menu with 'Post Ethical' highlighted by a red box. The dashboard header includes the logo and text 'National Medical Research Register Advancing Medical Research in Malaysia'. The main menu includes 'Dashboard', 'My Submissions', and 'My Research'. The 'SHORTCUT' section includes 'Create New Submission', 'Create New Post Ethical', and 'Create New Publication Presentation'. The 'DIRECTORIES' section includes 'Medical Research' and 'Investigators & Researchers'.</p></div>	

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.

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00062-7Q4	1	Pending Submission	Case Open	  
2			SAE ID-23-00046-TR5	2	Initial Submission	Case Open	  

Showing 1 to 2 of 2 entries

Previous **1** Next

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)**

Serious Adverse Event

Keyword: MREC Case Decision:

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1	[REDACTED]	[REDACTED]	SAE ID-23-00062-7Q4	1	Pending Submission	Case Open	  
2	[REDACTED]	[REDACTED]	SAE ID-23-00046-TR5	2	Initial Submission	Case Open	  

Showing 1 to 2 of 2 entries

Previous **1** Next

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)**

General Serious Adverse Event Study Information

SAE Case ID
SAE ID-23-00046-TR5 

Site Conducted
[REDACTED]

NAME OF INVESTIGATOR	ROLE OF INVESTIGATOR	STATE CONDUCTED
[REDACTED]	Principal / Coordinating Investigator	Selangor Darul Ehsan
[REDACTED]	Co / Sub Investigator at the site	Selangor Darul Ehsan

Country
MYS

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

SAE Case : SAE ID-23-00046-TR5

THE OPEN LABEL EXPANSION STUDY TO EVALUATE THE LONG TERM SAFETY, TOLERABILITY, AND EFFICACY OF PROCRABINE AND COMBINATION THERAPY IN PATIENTS WITH METASTASIZING, RECURRENT, HER2-POSITIVE BREAST CANCER

NMRR ID [SAE ID-23-00046-TR5](#) Protocol ID [PROCRAB-2301](#) Post Ethical ID [SAE ID-23-00046-TR5](#) Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

SAE Post Ethical Status Case Open

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

Reporting Investigator

[Dr. Heena Sahasrabudhe](#)

Corresponding Person

[Ms. Jennifer Chung New Site](#)

List Of SAE Reporting

SAE REPORT ID	DAY AWARENESS TO REPORTING	ONSET DATE	REPORTING INVESTIGATOR	MREC REPORT DECISION	
SAE ID-23-00046-TR5 - Initial Report	1	02/02/2023	Dr. Heena Sahasrabudhe	Processing Submission by MREC Secretariat	
SAE ID-23-00046-TR5 - Follow-up Report 1	1	02/02/2023	Dr. Heena Sahasrabudhe	Pending Submission	

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

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.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	16/05/2023 17:32:23	Investigator

4. To view **SAE Case** data, other than the one mentioned previously, from the Serious Adverse Event Case listing page, click on the SAE Report listing  icon.

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Request for more information	Case Open	  

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)**.

Serious Adverse Event Report

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE ID	SUBJECT ID	CASE STATUS	REPORT STATUS	DATE OF SUBMISSION	IS SUSAR	ACTION
1			SAE ID-23-00046-TR5-Initial Report	XXX-1	Case Open	Request for more information	16/05/2023	No	   
2			SAE ID-23-00046-TR5-Follow-up Report 1	XXX-1	Case Open	Pending Submission	16/05/2023	No	   

Display page will then show the general information of the Submission 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).

SAE Follow-Up Report Form

AN OPEN LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF FOSOPHENE AND CENOSARIN COMBINATION THERAPY IN PATIENTS WITH PAINFUL NEUTRAL NEUTROPHILIC GRANULOCYTOCLASIS

NMRR ID [NMRR ID-23-00046-GEN](#) Protocol ID [R3310-PMH-3105](#)  Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

Case ID SAE ID-23-00046-TR5 : Follow-up Report 1

Case Status Case Open Report Submission Status Pending Submission

In viewing the **SAE Report**, user is able to view the entire submission 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.

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	16/05/2023 17:32:23	Investigator
2	Undergoing Review by SAESC	24/05/2023 00:00:00	MREC Secretariat
3	Request for more information	24/05/2023 00:00:00	MREC Secretariat 

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

List Of SAE Reporting

DAY AWARENESS TO REPORTING	ONSET DATE	REPORTING INVESTIGATOR	MREC REPORT DECISION
1	02/02/2023	Dr. Henna Sankaranarayanan	Processing Submission by MREC Secretariat 
Report 1	1	02/02/2023	Dr. Henna Sankaranarayanan Pending Submission 

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

Severe Advers Event Reporting Comparison

AN OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF PEGOLADOLAN AND COMBINATION COMBINATION THERAPY IN PATIENTS WITH PERIPHERAL NEUROPATHY/NEURALGIA

NMRR ID [NMRR 23-00046-0001](#) Protocol ID [R0123-Phase 2/001](#) Post Ethical ID [SAE ID-23-00046-TR5](#)  Last updated on Dec 02, 2022

Status Approval granted via MREC Full Board

Comparing Report: [Follow-up Report 1](#) & [Initial Report](#)

Serious Adverse Event Detail Information

SAE Report Type

Follow-up Report 1

[Initial Report](#)

Reporting Investigator

[Name Information](#)

[Name Information](#)

Corresponding Person

[Jennifer Chung, MD, PhD](#)

[Jennifer Chung, MD, PhD](#)

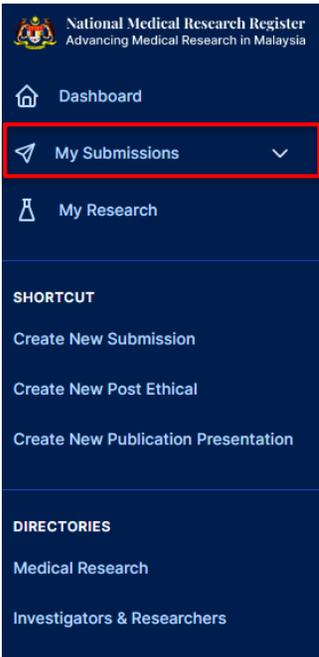
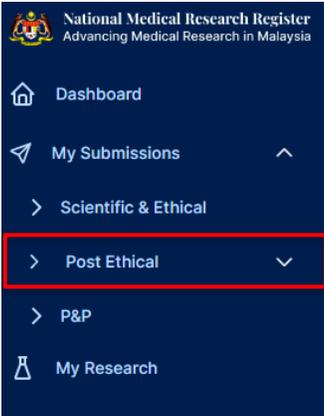
SAE Report Decision

Pending Submission

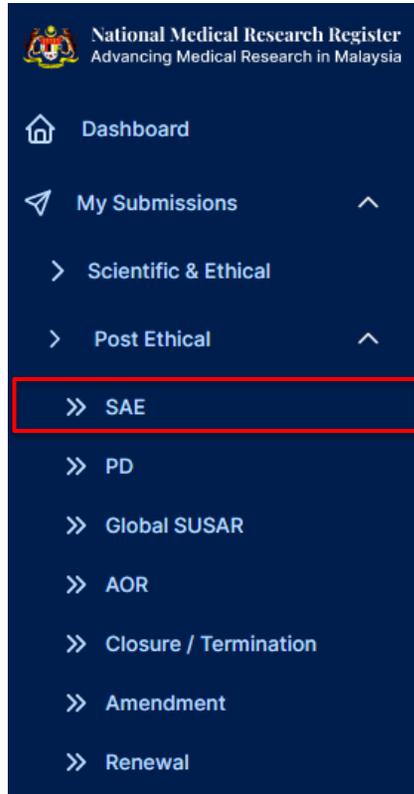
[Processing Submission by MREC Secretariat](#)

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.	<p>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”</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>①</p>  </div> <div style="text-align: center;"> <p>②</p>  </div> </div>	<p>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.</p> <p>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”</p>

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.

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00062-7Q4	1	Pending Submission	Case Open	  
2			SAE ID-23-00046-TR5	2	Initial Submission	Case Open	  

Showing 1 to 2 of 2 entries

Previous **1** Next

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

Serious Adverse Event

Keyword MREC Case Decision

Show entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Request for more information	Case Open	  

Then, Serious Adverse Event Report List will be displayed. To create a follow up submission, click on the  icon at the **intended SAE Report**

Serious Adverse Event Report

Keyword MREC Case Decision

Show entries

#	NMRR ID	TITLE	SAE ID	SUBJECT ID	CASE STATUS	REPORT STATUS	DATE OF SUBMISSION	IS SUSAR	ACTION
1			SAE ID-23-00046-TR5-Initial Report	XXX-1	Case Open	Request for more information	16/05/2023	No	  

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	Dr. [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  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



A popup up will appear indicating the “ Serious Adverse Event Detail Information – Subject Information” subsection has been successfully saved

Save

✔ Subject Information 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

SAE Follow-Up Report Form

AN OPEN-LABEL, EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY, TOLERABILITY, AND EFFICACY OF PROLIXIMA AND COMBINATION THERAPY IN PATIENTS WITH METASTASIS, METASTASIS, METASTASIS

NMRR ID **0046-TR5-00046-TR5** Protocol ID **0046-TR5-00046-TR5** Last updated on Dec 02, 2022

Case ID **SAE ID-23-00046-TR5 : Follow-up Report 1**

Case Status **Case Open** Report Submission Status **Pending Submission**

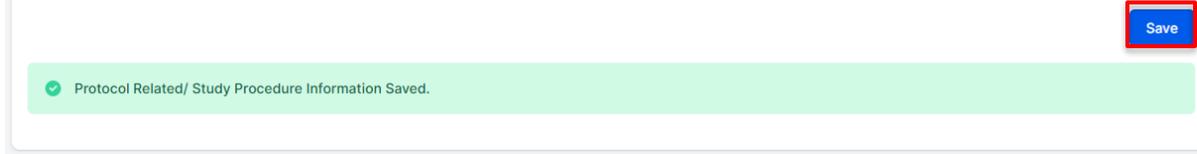
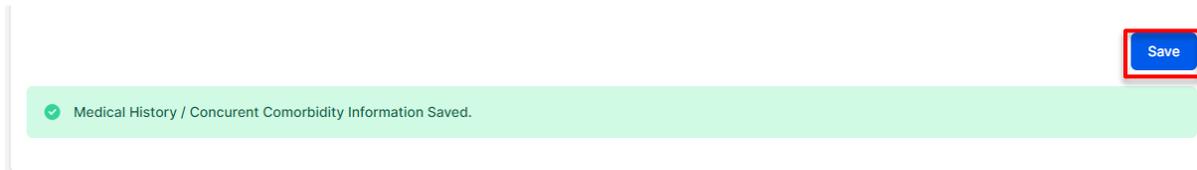
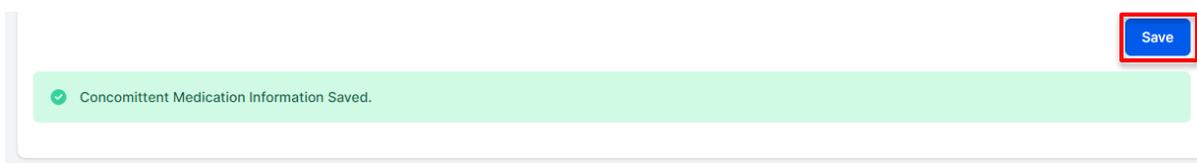
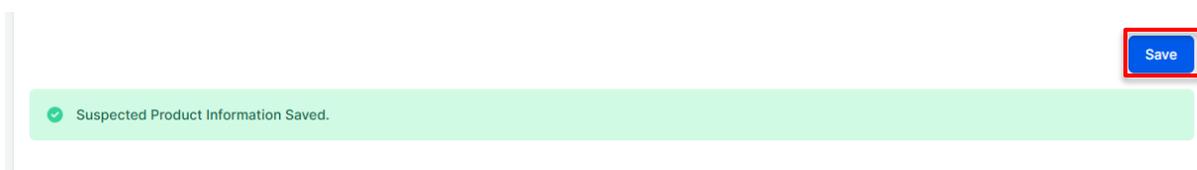
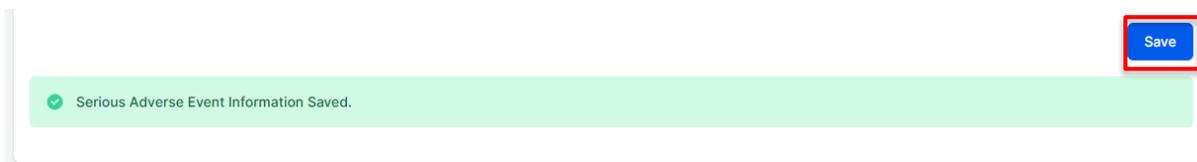
The List of Serious Adverse Event Reporting under the General Serious Adverse EventReporting information will have an additional listing added as follows :

List Of SAE Reporting

ID	DAY AWARENESS TO REPORTING	ONSET DATE	REPORTING INVESTIGATOR	MREC REPORT DECISION	
0046-TR5 - Initial Report	1	02/02/2023	Dr. Henna Srinivasan	Processing Submission by MREC Secretariat	👁️ 📄 📝
0046-TR5 - Follow-up Report 1	1	02/02/2023	Dr. Henna Srinivasan	Pending Submission	👁️ ✏️ 🗑️

The status of a newly created **Follow Up SAE Report Submission** will be **“Pending Submisison”**

6. User may then continue to update the information at other subsection as mentioned 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  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

Protocol Deviation Supporting Documents

Cover Letter *

[Download Cover Letter Template](#)

[View Document History](#)

Name
dummy document.pdf
Version *
testing
Version Date *
01/04/2023

Other Supporting Documents

[View Document History](#)

Select or drag files | PDF

Save

Are you sure want to delete the document?

OK Cancel

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  to complete the step and save the uplaoded documents.



 Supporting Documents Information Saved.

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.

Cover Letter *

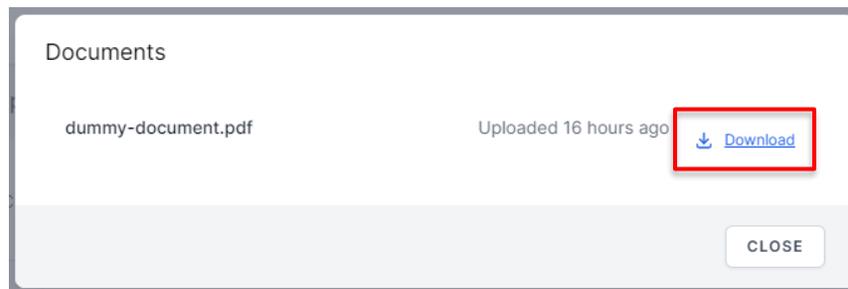
 [Download Cover Letter Template](#)





Document details panel showing:

- Name: Updated-dummy-documents
- Version: 2
- Version Date: 01/11/2023
- File type: PDF
- Size: 25.01 KB
- Download link



Documents modal showing:

- dummy-document.pdf
- Uploaded 16 hours ago
-  [Download](#)
- CLOSE button

7. Once all the required follow up information and documents have been uploaded, user is required to acknowledge the submission made at "Submission 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."

Submission Acknowledgement

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

Decision History

#	APPROVER NAME	DECISION	DECISION DATE	APPROVAL AUTHORITY
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Once submission has been acknowledged, user can submit the Follow up Serious Adverse Event Reporting Submission by clicking the button.

Submission Acknowledgement

I acknowledge that I have read, and do hereby accept the terms and conditions contained in NMRR terms and condition document.

Submit

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
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Once a Follow Up Serious Adverse Event Submission has been successfully submitted, user will be brought back to the Serious Adverse Event Case listing

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Undergoing Review by SAESC	Case Open	  

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:

Decision History

#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Initial Submission	09/01/2023 03:21:48	Investigator
2	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator

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

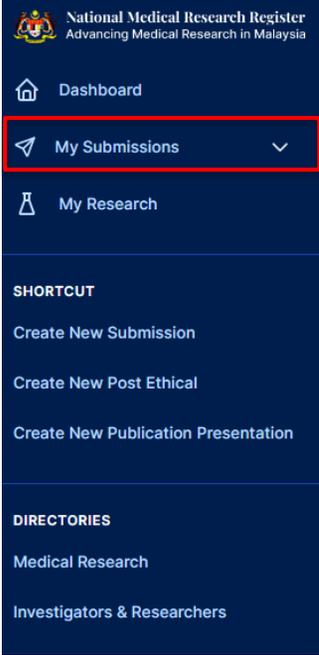
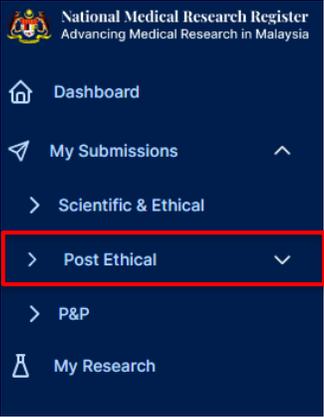
#	DECISION	DECISION DATE	APPROVAL AUTHORITY
1	Follow Up Submitted To MREC Secretariat	11/01/2023 18:54:38	Investigator

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

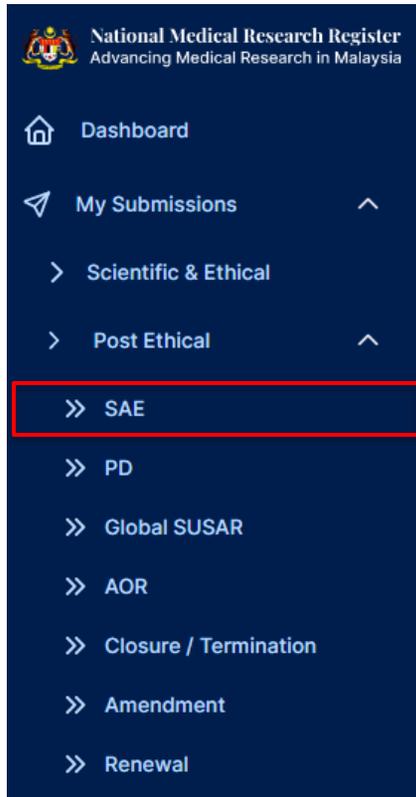
1. **SAE Case** shows only **history of submission of each SAE Reports** – (initial status of each SAE Reports under a same SAE Case ID)

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.	<p>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”</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>①</p>  </div> <div style="text-align: center;"> <p>②</p>  </div> </div>	

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.

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Undergoing Review by SAESC	Case Open	  

3. Click on the  icon at the intended **Serious Adverse Event Post Ethical ID (SAE Case)** which requires the editing.

Protocol Deviation Case

Keyword Status

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	PD CASE ID	NO OF PD CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			PD ID-23-00026-KTC	2	Request for more information	Case Open	  

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)”

Serious Adverse Event Report

Keyword MREC Case Decision

Show entries

#	NMRR ID	TITLE	SAE ID	SUBJECT ID	CASE STATUS	REPORT STATUS	DATE OF SUBMISSION	IS SUSAR	ACTION
1			SAE ID-23-00062-7Q4-Initial Report	CVR1	Case Open	Pending Submission		-	  

Showing 1 to 1 of 1 entries Previous Next

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

4

For Serious Adverse Event Reporting Submission deletion, click on the delete  icon at the intended **SAE Report**

Serious Adverse Event Report

Keyword: MREC Case Decision:

Show entries

#	NMRR ID	TITLE	SAE ID	SUBJECT ID	CASE STATUS	REPORT STATUS	DATE OF SUBMISSION	IS SUSAR	ACTION
1			SAE ID-23-00062-7Q4-Initial Report	CVR1	Case Open	Pending Submission		-	  

Showing 1 to 1 of 1 entries

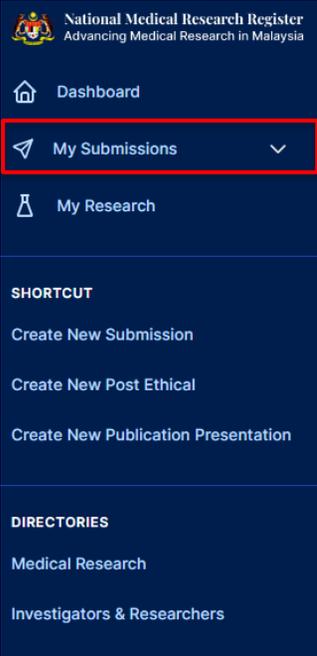
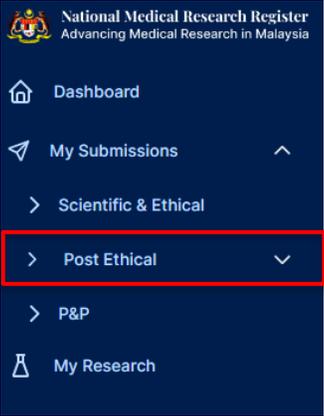
Previous Next

Deletion of a submission is only available for a SAE Report with status **“Pending Submission”**

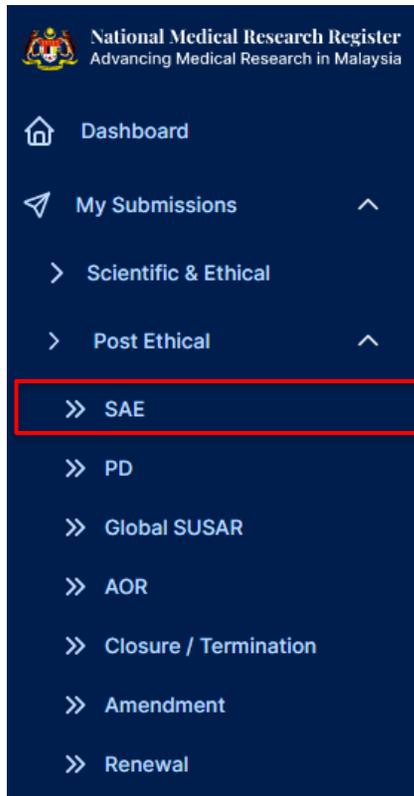
Click to confirm the deletion of the intended SAE Reporting Submission. Once it's clicked, the SAE Report will be deleted and removed from the Serious Adverse Event Report listing.

Are you sure you want to remove this record?

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

No	Step-by-step instructions	Remark
1.	<p>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”</p> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;"> <p>①</p>  </div> <div style="text-align: center;"> <p>②</p>  </div> </div>	

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.

Serious Adverse Event

Keyword MREC Case Decision

Show entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Uphold MREC Full Board Decision with no further action	Case Closed	 
2			SAE ID-23-00062-7Q4	1	Pending Submission	Case Open	  

Showing 1 to 2 of 2 entries

Previous Next

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

Serious Adverse Event

Keyword MREC Case Decision

Show entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Uphold MREC Full Board Decision with no further action	Case Closed	 

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

Serious Adverse Event

Keyword MREC Case Decision

EXCEL PDF Show 10 entries

#	NMRR ID	TITLE	SAE CASE ID	NO OF SAE CASE REPORTED	MREC DECISION	CASE STATUS	ACTION
1			SAE ID-23-00046-TR5	2	Uphold MREC Full Board Decision with no further action	Case Closed	 

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.

List Of SAE Reporting

D	DAY AWARENESS TO REPORTING	ONSET DATE	REPORTING INVESTIGATOR	MREC REPORT DECISION	
J046-TR5 - Initial Report	1	02/02/2023	Dr. Asyraf Syahmi Bin Mohd Noor	Request for more information	
J046-TR5 - Follow-up Report 1	1	02/02/2023	Dr. Asyraf Syahmi Bin Mohd Noor	Uphold MREC Full Board Decision with no further action	

-The End -

Prepared by: NMRR Secretariat

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