

USER MANUAL FRONT END USER

Medical Device Centralised Online Application System (MeDC@St 2.0)



MODUL UTAMA - DEVICE STUDY (FRONT-END
USER)

DISEDIAKAN OLEH :



MeDC@St v2.0

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1.0 INTRODUCTION

This manual is prepared for the purpose of operational functions of Medical Device Centralised Online Application System.

MeDC@St is a web-based Online Application System for Notification. It is a centralized system where only one account needs to be created by an applicant to apply for Notification Registration. This module that allows all Notification programme operations to run online and monitoring can be carried out in real time.

1.1 SYSTEM ACCESS

MeDC@st (Medical Device Centralised Online Application System) is developed using web-based method in which it utilizes the internet access via internet server. In order to access Medc@st, user has to key in the URL address onto the internet server as followed:

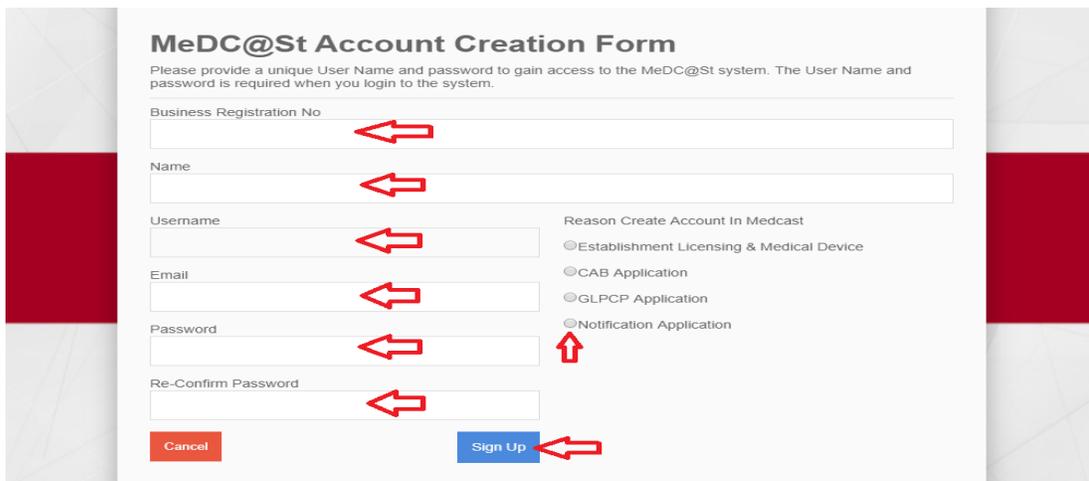
<https://medcast.mda.gov.my>

1.1.1 CREATE ACCOUNT

The screen below shows the expected webpage after the address has been key In.

For new user need to sign up a new account before login the account. User need to

click  for new registration.

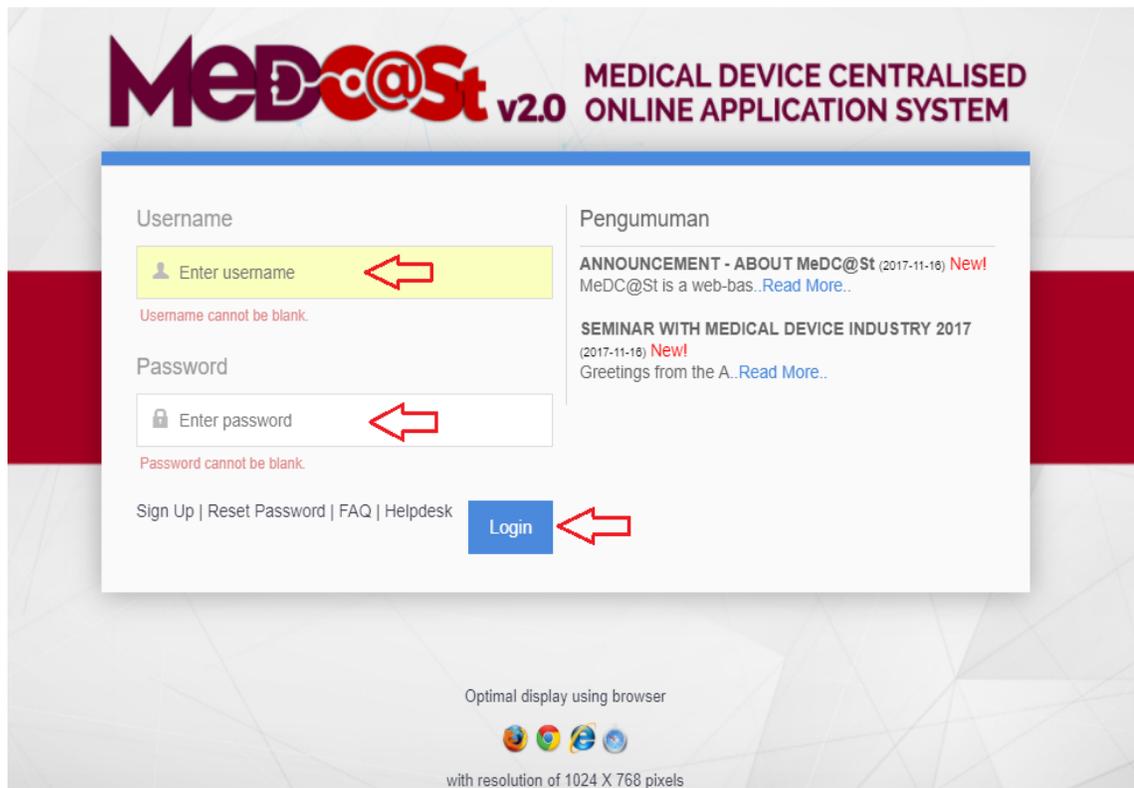


The image shows a screenshot of the 'MeDC@St Account Creation Form'. The form title is 'MeDC@St Account Creation Form'. Below the title, there is a instruction: 'Please provide a unique User Name and password to gain access to the MeDC@St system. The User Name and password is required when you login to the system.' The form contains several input fields: 'Business Registration No', 'Name', 'Username', 'Email', 'Password', and 'Re-Confirm Password'. To the right of the 'Password' field, there is a section titled 'Reason Create Account In Medcast' with three radio button options: 'Establishment Licensing & Medical Device', 'CAB Application', and 'GLPCP Application'. At the bottom of the form, there are two buttons: a red 'Cancel' button and a blue 'Sign Up' button. Red arrows point to each of the input fields and the 'Sign Up' button.

Complete the form and click  to sign up a new account. If you registration account have success, user need to check the email for confirmation.

1.1.2 LOGIN

The screen below shows the expected webpage after the address has been key In.



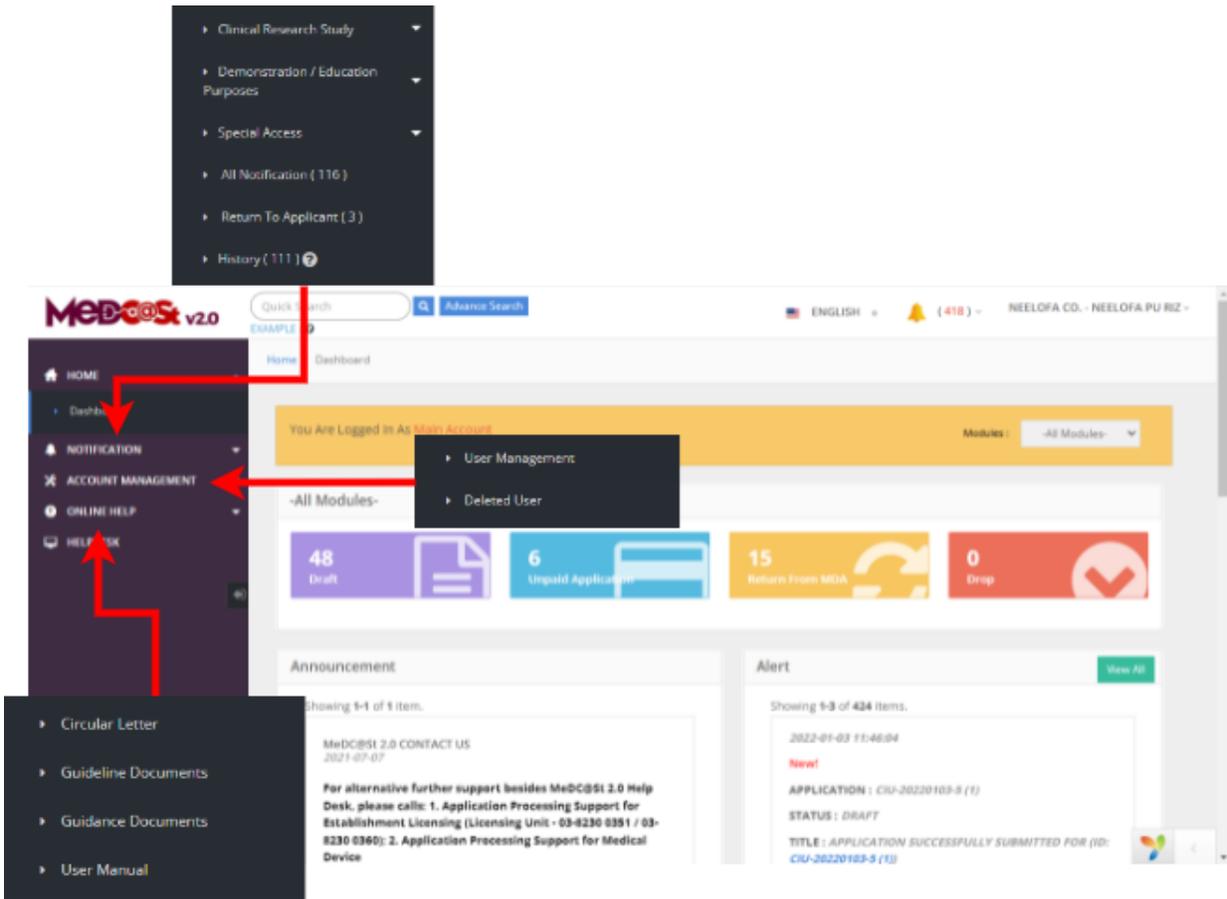
User has to log into the system using registered Username and its respective

Password. Click  to proceed.

2.0 FUNCTIONS

2.1 DASHBOARD

Below show the Dashboard page that will appear once Notification Module has logged into the system successfully.

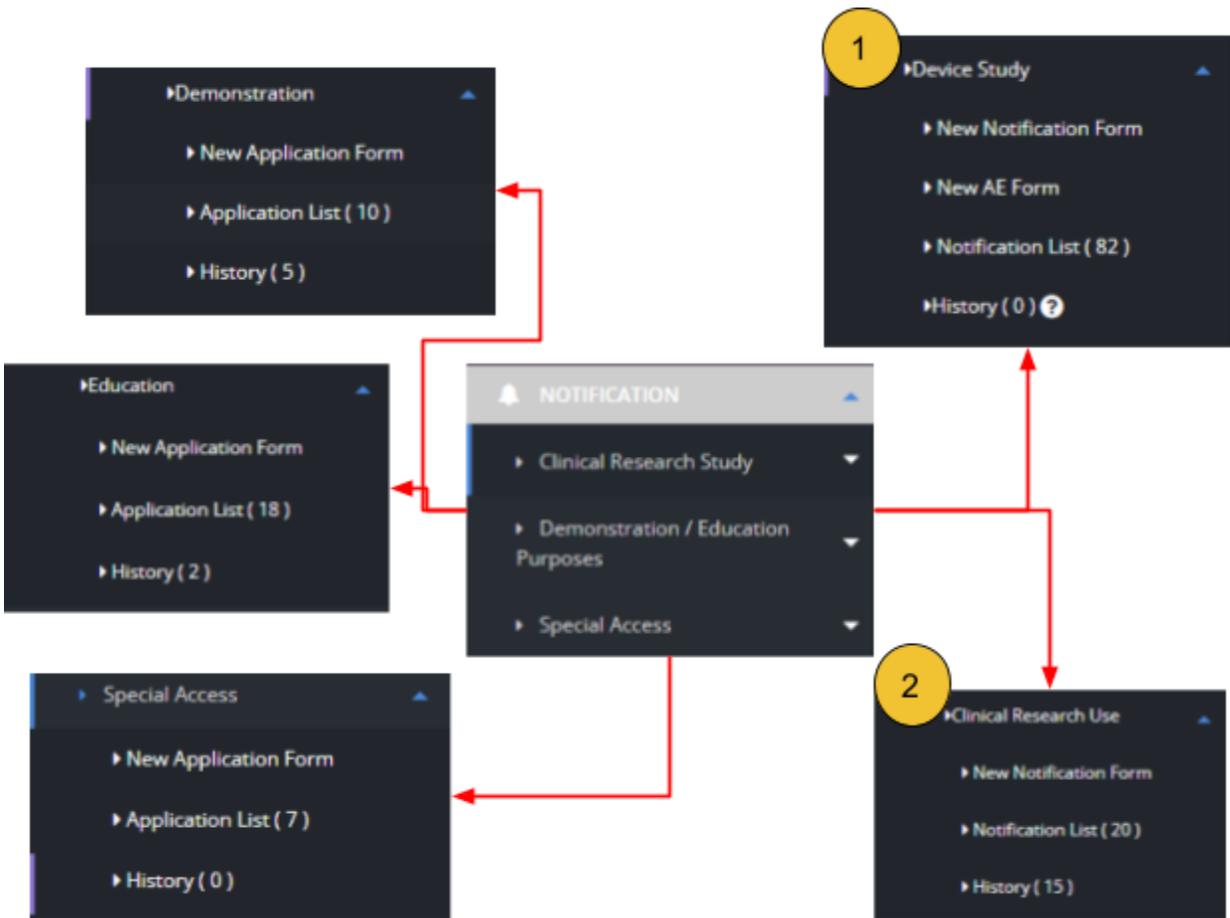


2.2 MENU NOTIFICATION REGISTRATION

Menu Notification Registration has four type of notification which are *Clinical Investigational*, *Custom Made*, *Demonstration/Education Purposes* and *Special Access*.

However, Clinical Investigational have three type which are *Investigational Use*, *Clinical Research Use* and *Notification of Change*. User should click on menu **NOTIFICATION** at left side menu for drop list sub menu Notification module.

2.2.1 NEW APPLICATION FORM

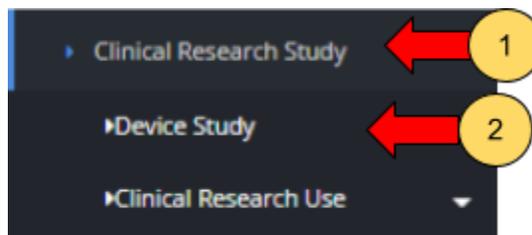


a) **CLINICAL RESEARCH STUDY**

First, user should click at sub menu **Clinical Research Study** to list down the three sub menu which are Device Study and Clinical Research Use.

DEVICE STUDY

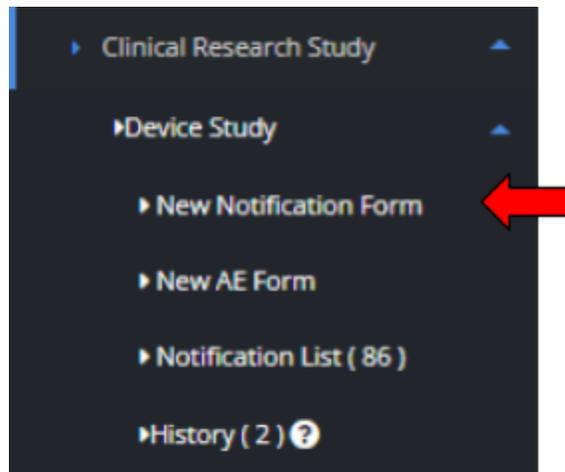
a) ***New Application***



1 - User should click at menu Clinical Research Study.

2 - User should click at sub menu Device Study.

After click at sub menu Device Study, the list down of sub menu will be displayed that shown in Figure below.



The user should click at sub menu **New Notification Form** to apply the registration form for Device Study Registration. The application form will be appear. The figure below shows the application form for applicant fill it. First, the user should choose the Device Study Notification Type by clicking the radio button. There are six type of notification which are :

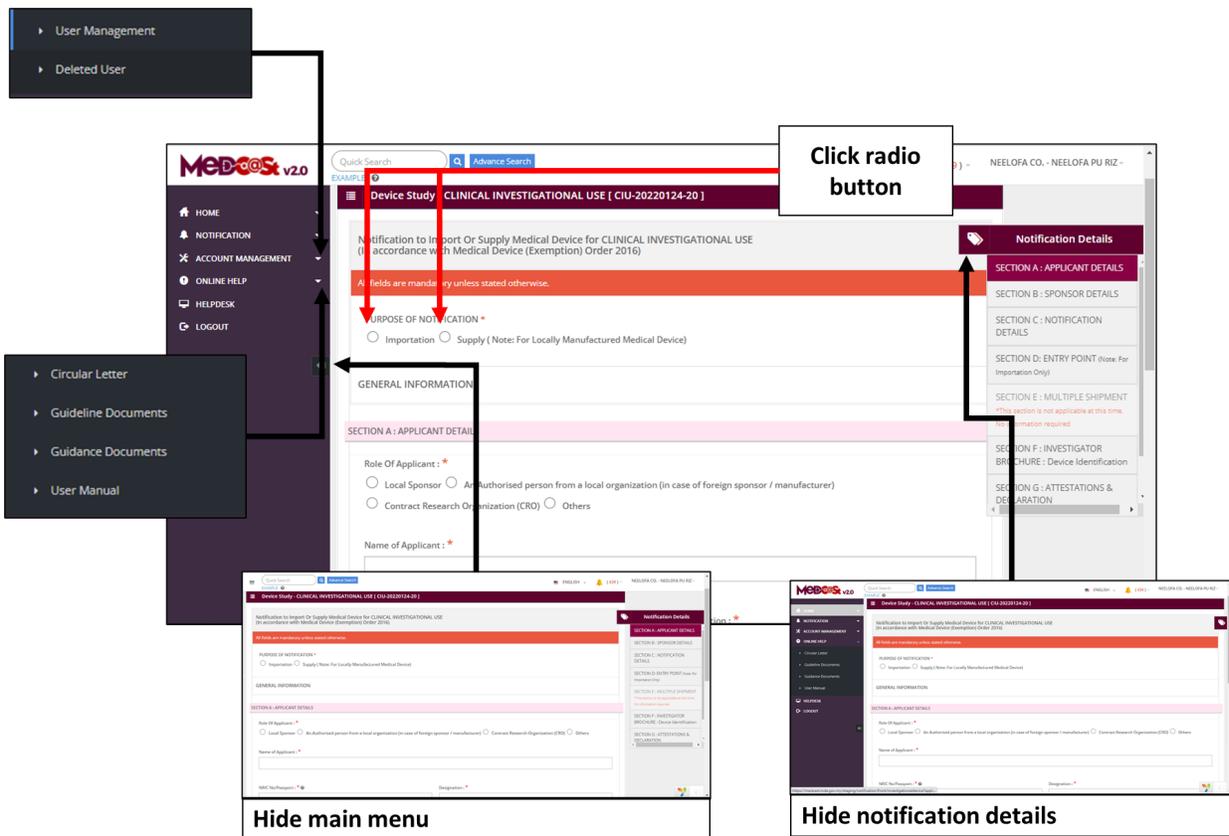
- **Clinical Investigational Use**
- **Performance Evaluation**
- **Clinical Use (GMD)**
- **Clinical Use (IVD)**
- **Feasibility Study (GMD)**
- **Feasibility Study (IVD)**

A screenshot of a web form titled 'Notification Of Unregistered Medical Devices For Study'. The form has a header with a hamburger menu icon and the title. Below the header is a red bar with the text 'Please Complete All Information Requested On This Form. (All Fields Are Mandatory Unless Stated Otherwise)'. The main content area is titled 'Device Study Notification Type' and contains a question: '1. Device Study Notification Type: *'. There are six radio button options: 'Clinical Investigational Use' (selected), 'Performance Evaluation', 'Clinical Use (GMD)', 'Clinical Use (IVD)', 'Feasibility Study (GMD)', and 'Feasibility Study (IVD)'. A green 'Next' button with a right arrow is located at the bottom right of the form.



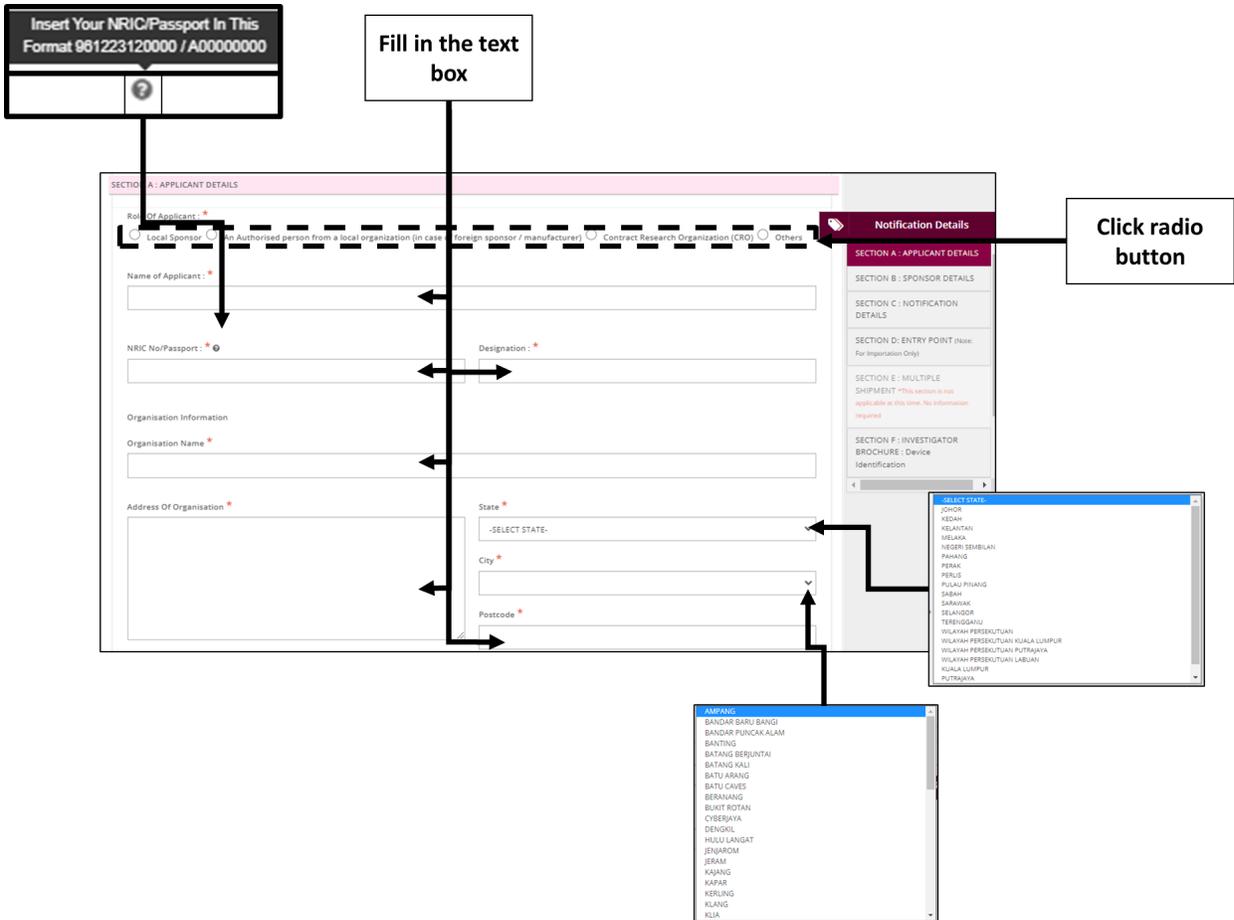
Then user click  button to fill all Clinical Investigational Use form. There have seven sections which are:

- SECTION A : Applicant Details
- SECTION B : Sponsor Details
- SECTION C : Notification Details
- SECTION D : Entry Point
- SECTION E : Multiple Shipment **(Disabled)**
- SECTION F : Investigator Brochure: Device Identification
- SECTION G : Attestations & Declaration



The user should choose the purpose of notification with click at radio button that shown in figure above.

Section A: Applicant Details



The symbol “*” means required field. The user must fill it.

- Role of Applicant:

- i) Local Sponsor,
- ii) An Authorised person from a local organization (in case of foreign sponsor / manufacturer),
- iii) Contract Research Organization (CRO),
- iv) Others -> if the user choose others, a text box appeared and the user need to fill the text box

If user choose local sponsor  **Local Sponsor** , user unable to fill the Section B. Except for **Feasibility Study (GMD) and GMD (IVD)**, the user able to fill the **Section B**

If user choose other than Local Sponsor, the form that user will fill which are all section.

- **Name of Applicant**

User should fill name in the textbox that provided.

- **NRIC No/Passport**

The user should click at  to see the format and fill the form based on the format that given that shown in the figure below. If user fill the textbox with character or number more than 12, the message “**Field can only contain number and word character and must between 5-12 numeric**” will be displayed.

- **Designation**

The user should fill in the textbox with designation of applicant that shown in figure above.

- **Organisation information**

i) Organisation name -> The user should fill name of organisation in the textbox that provided.

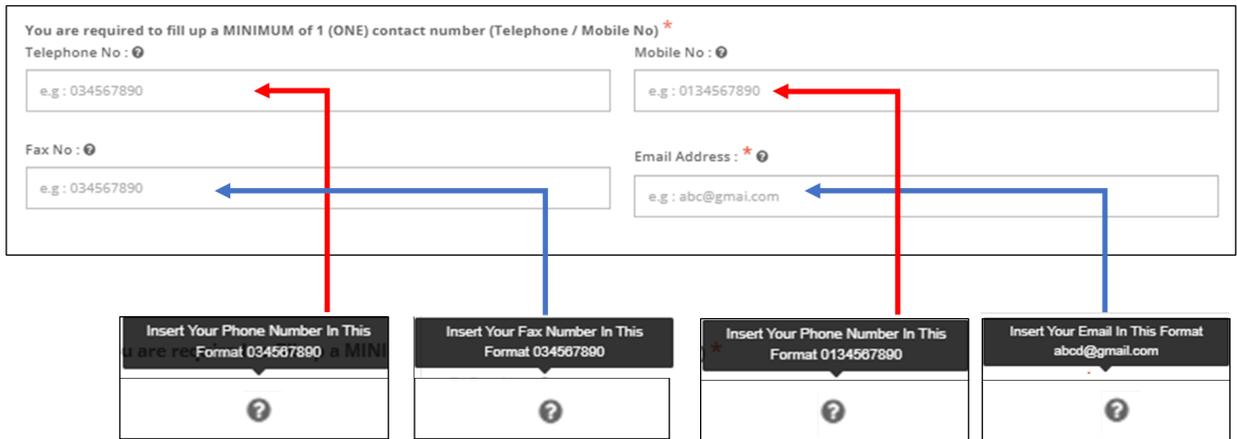
ii) Address of organisation ->The user should fill in the textbox with address of organisation.

iii) State -> User should click at textbox to drop down list and user should select the state that has shown in figure above.

iv) City -> If user select the state, automatically the city will appear in form and user should select specific city in drop down list. The user should select the

state before click city form to drop down list of city that shown in the figure below.

v) Postcode -> The field must contain exactly five numeric. If user fill the form with the alphabet or more than five number, the message “Field must contain exactly 5 numeric.”



- **Telephone No.**

The user must fill in the number only and click at to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message “Field must have NUMBERS between 3 - 11 numeric” will be displayed.

- **Mobile No.**

The user must fill in the number only and click at to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message “Field must have NUMBERS between 3 - 11 numeric” will be displayed.

- **Fax No.**

The user must fill in the number only and click at to see the format. User should follow the format that shown in the figure below. If user fills in the

form except number, the message “Field must have NUMBERS between 3 - 11 numeric” will be displayed.

- Email address

The user must fill the email based the format that shown in figure. User should click at  to see the format. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will appear is “ Email address is not valid.”

After user fill all form for section A, the user should click at button  to the next section. If the user is a **Local Sponsor**, the user goes to Section C and if the user is **other than Local Sponsor**, the user goes to Section B.

For Feasibility Study (GMD) and Feasibility Study (IVD), the user goes to Section

B even if the applicant is a Local Sponsor by clicking  .

Section B: Sponsor Details

The screenshot shows the 'SECTION B: SPONSOR DETAILS' form. The form includes the following fields and elements:

- Name of Contact Person ***: A text input field with an annotation 'Fill in the text box' pointing to it.
- Organisation Details**: A section containing:
 - Organisation Name ***: A text input field.
 - Address Of Organisation ***: A text input field.
 - State ***: A dropdown menu with '-SELECT STATE-' selected. An annotation 'Click radio button' points to the 'Non-Malaysia Address' radio button, which is also highlighted with a red dashed box.
 - City ***: A text input field that is populated with a city name based on the selected state.
 - Postcode ***: A text input field.
- Notification Details**: A sidebar on the right with a 'Notification Details' header and a list of sections: SECTION A: APPLICANT DETAILS, SECTION B: SPONSOR DETAILS (highlighted), SECTION C: NOTIFICATION DETAILS, SECTION D: ENTRY POINT (Note: For Importation Only), SECTION E: MULTIPLE SHIPMENT (Note: This section is not applicable at this time. No information required), SECTION F: INVESTIGATOR BROCHURE: Device Identification, and SECTION G: ATTESTATIONS & DECLARATION.

The symbol “*?” means required field. The user must fill it.

- **Name of contact Person**

The user should fill name in the textbox that provided in the figure below.

- **Organisation Details**

i) Organisation Name -> The user should fill name of organisation in the textbox that provided.

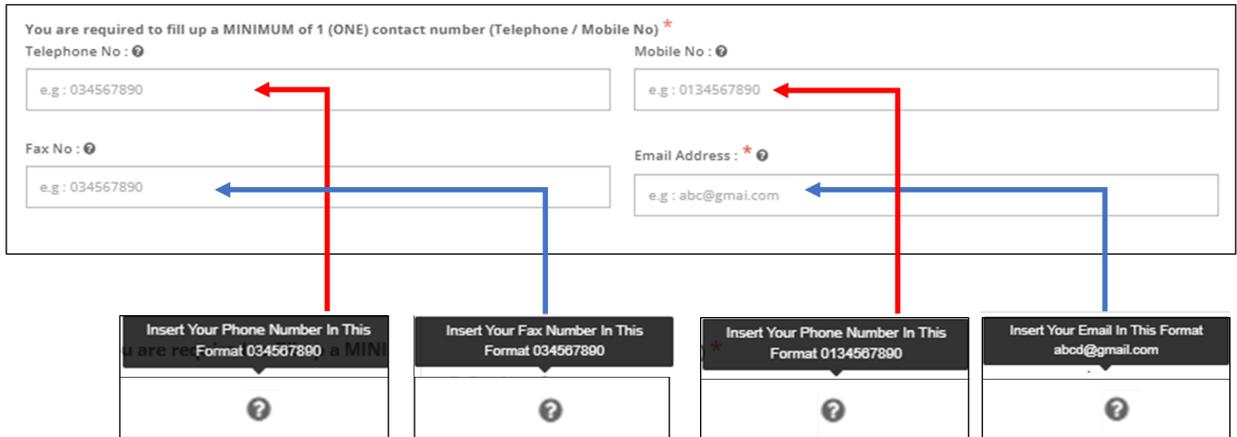
ii) Address of organisation -> The user should fill in the textbox with address of organisation.

iii) State -> User should click at textbox to drop down list and user should select the state that has shown in the figure below.

iv) City -> If user select the state, automatically the city will appear in form and user should select specific city in drop down list. The user should select the

state before click city form to drop down list of city that shown in the figure below.

v) Postcode -> The field must contain exactly five numeric. If user fill the form with the alphabet or more than five number, the message will appear "Organisation Postcode must be an integer."



- Telephone No.

The user must fill in the number only and click at ? to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field can only contain number and between 3 to 11 numeric." will be displayed.

- Mobile No.

The user must fill in the number only and click at ? to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field can only contain number and between 3 to 11 numeric." will be displayed.

- Fax No.

The user must fill in the number only and click at ? to see the format. User should follow the format that shown in the figure below. If user fills in the form

except number, the message “Field can only contain number and between 3 to 11 numeric.” will be displayed.

- **Email address**

The user must fill the email based the format that shown in figure. User should click at  to see the format. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will appear is “Sponsor email address is not valid.”

If user want back to previous section, user should click at button

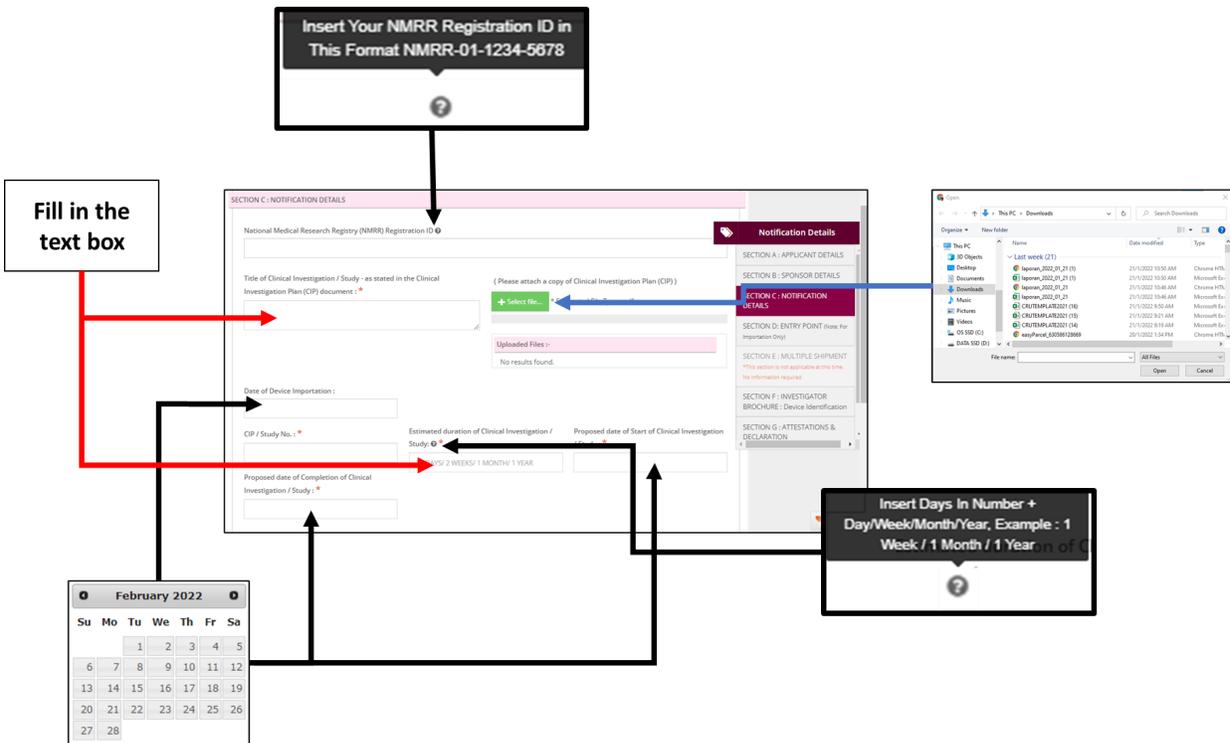


that shown in figure above. Then, user should click at button



to the next stage.

Section C: Application Details



The symbol “*” means required field. The user must fill it.

- National Medical Research Registry(NMRR) Registration ID

The user must fill in the textbox and click at  to see the format. User should follow the format that shown in figure above.

- Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document

The user must fill in the textbox field of title.

- Please attach a copy of Clinical Investigation Plan (CIP)

User must click at button  to upload file PDF only.

- Date of Device Importation

The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.

- **CIP / Study No.**

The user should fill in the textbox field that provided.

- **Estimated duration of Clinical Investigation / Study**

The user should fill in the textbox field with number and character and click at  to see the format. User should follow the format that shown in figure above.

- **Proposed date of Start of Clinical Investigation / Study**

The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.

- **Proposed date of Completion of Clinical Investigation / Study**

The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.

- **Clinical Investigation / Study Site**

Firstly, the user should click at  for fill the form of investigation site or study site that will be shown in the figure below.

The screenshot displays a web form titled "Clinical Investigational Plan". It features two main sections: "Investigator Site" and "Principal Investigator". Each section contains two text input fields. Red arrows point to the asterisk (*) next to each field label, indicating they are required. A callout box with the text "Click for move down" and a red arrow points to a vertical scrollbar on the right side of the form.

Investigator Site

Name of Clinical Investigation / Study Site *

Address of Clinical Investigation / Study Site *

Principal Investigator

Name of Principal Investigator *

Professional of Position Principal Investigator *

The symbol "*" means required field.

1. Investigator Site
 - a) Name of Clinical Investigation Site / Study Site -> The user should fill in the textbox that provided. If user don't fill the field, the message "Name of Investigation Site cannot be blank." will be displayed.
 - b) Address of Clinical Investigation Site / Study Site -> The user should fill in the textbox that provided. If user don't fill the field, the message "Address of Investigation Site cannot be blank." will be displayed.
2. Principal Investigator
 - a) Name of Principal Investigator -> The user should fill in the textbox that provided. If user don't fill the field, the message "Name of Principal Investigator cannot be blank." will be displayed.

- b) Professional of Position Principal Investigator -> The user should fill in the textbox that provided. If user don't fill the field, the message "Professional of Position Principal Investigator cannot be blank." will be displayed.
- c) Address of Principal Investigator -> The user should fill in the textbox that provided. If user don't fill the field, the message "Address of Principal Investigator cannot be blank." will be displayed.
- d) Contact Number of Principal Investigator -> The user should fill in the textbox that provided. If user don't fill the field, the message "Contact of Principal Investigator cannot be blank." will be displayed. The user must fill it with number only. If user fill it except number, the message "Field must have NUMBERS between 3 - 11 numeric" will be displayed.
- e) Email of Principal Investigator -> The user should fill in the textbox that provided. If user don't fill the field, the message "Email of Principal Investigator cannot be blank." will be displayed. The symbol "@" must have in email. Example: abc@gmail.com. If user fill the form incorrectly or not follow the format, the message will appear is "Email of Principal Investigator is not a valid email address." will be displayed.

After all the forms are complete filled, the user should click at  to save the details.

The screenshot shows a web form titled "Clinical Investigational Plan" with a close button (X) in the top right corner. The form contains four text input fields, each with a red arrow pointing to its right side:

- Professional of Position Principal Investigator *
- Address of Principal Investigator *
- Contact Number of Principal Investigator *
e.g : 0134567890
- Email of Principal Investigator *

At the bottom left, there is a green "Save" button with a floppy disk icon. A red arrow points from a box labeled "Click at button" to this button. At the bottom right, there is a vertical scrollbar. A red arrow points from a box labeled "Click for move up and down" to the scrollbar.

In addition, the details of the investigation site or study site will be displayed in the table shown in the figure below.

Details of the Clinical Investigation / Study Site

Clinical Investigation / Study Site

+ Add Clinical Investigation / Study Site *

Showing 1 of 1 item

No	Name & address of the Clinical Investigation / Study site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Committee	Approval Letter
1	<p>Name MAYA GONZALES</p> <p>Address VERITATIS MOLESTIAE</p>	<p>Name GRIFFIN WASHINGTON</p> <p>Position LABORUM PORRO ASSUM</p> <p>Address RECUSANDAE VEL ESSE</p> <p>Contact 393</p> <p>Email dxyx@mailinator.com</p>		(not set)	(not set)	

Click for update the Clinical Investigation / Study Site

↓

✎ Update

🗑 Delete

✎ Update List Coordinating Investigator

✎ Update EC/IRB

Click for delete the Clinical Investigation / Study Site

↖

If user wants to update the clinical investigation or study site, user should click on button “update” for change the details of site. The form investigation site will be displayed after clicking on button “update” that shown in the figure below.

Clinical Investigational Plan ✕

Investigator Site

Name of Clinical Investigation / Study Site *

Address of Clinical Investigation / Study Site *

Principal Investigator

Name of Principal Investigator *

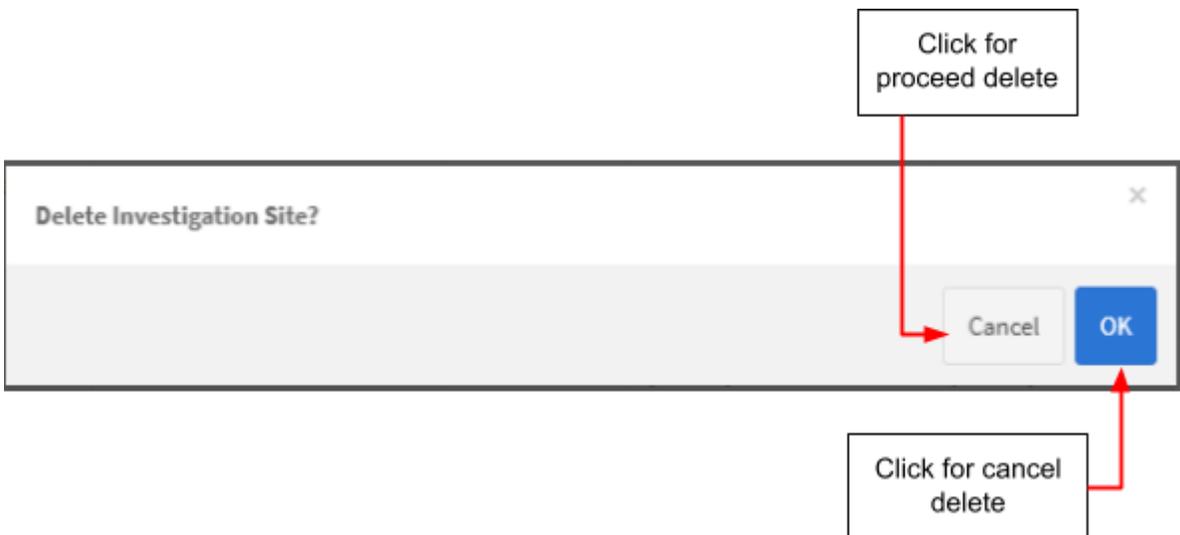
Professional of Position Principal Investigator *

Address of Principal Investigator *

Besides that, user can delete the investigation site with clicking at

 Delete

button. The alert message will be displayed after clicking the button that shown in the figure below.



The user should click "Cancel" for canceled the delete process or click "ok" for proceed delete the investigation site.

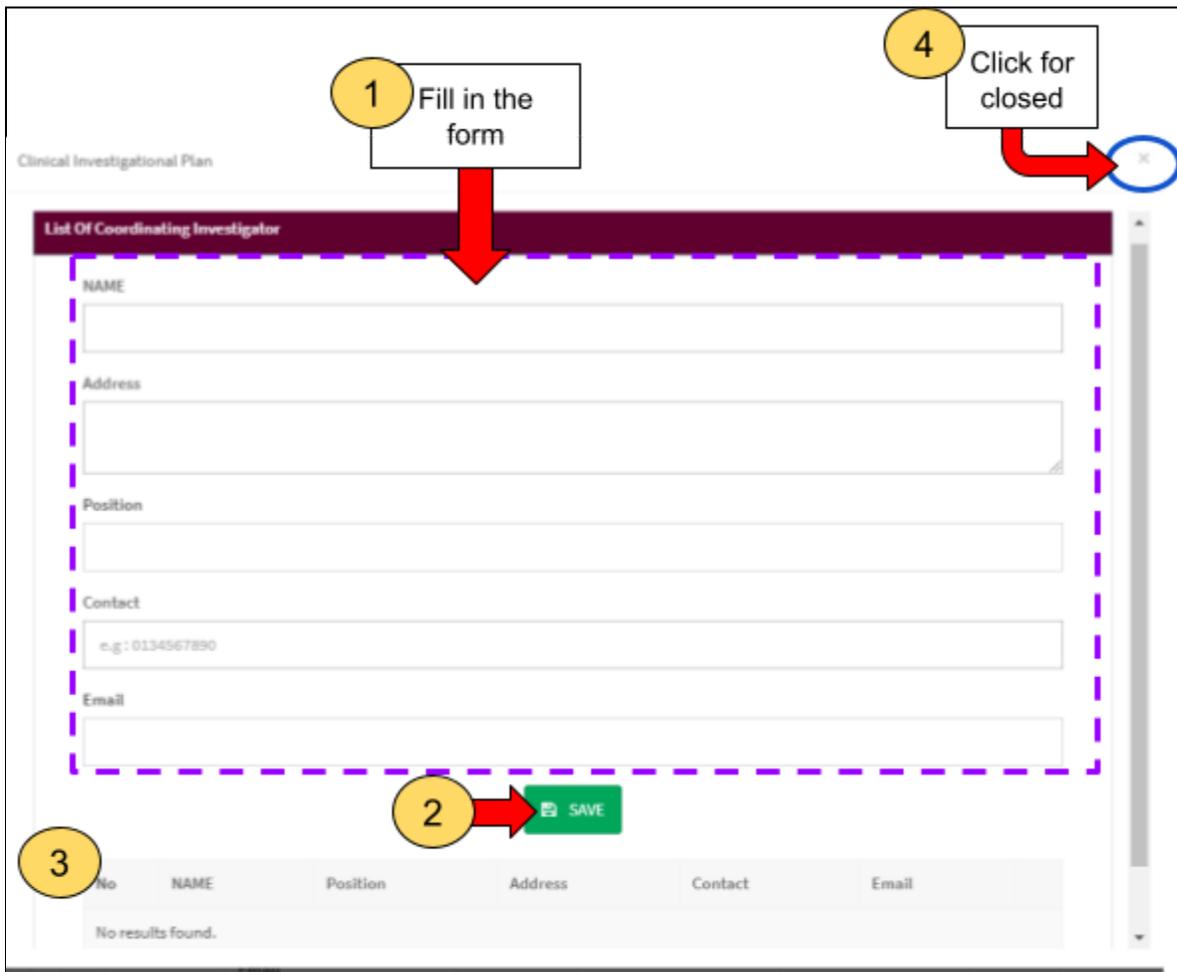
After that, user should click button  to update list coordinating investigator.

1

-> The user should fill in the details in the form provided. The details that user should fill in the form which are:

- Name -> The user should fill in the textbox that provided.
- Address -> The user should fill in the textbox that provided.
- Position -> The user should fill in the textbox that provided.
- Contact -> The user should fill in the textbox that provided. The user must fill it with number only. If user fill it more than 11 number, the message "Field must have NUMBERS between 3 - 11 numeric" will be displayed. Then, if user fills in the field with character, the message "Contact must be an integer." will be displayed.
- Email -> The user should fill in the textbox that provided. The user must fill it with number only. If user fill it more than 11 number, the message "Field must have NUMBERS between 3 - 11 numeric" will be displayed. Then, if user fills in the field with character, the message "Contact must be an integer." will be displayed.

The form of list coordinating investigator will be displayed that shown in the figure below.



2 -> The user should click at  to save details.

3 -> The details of coordinating investigator will be displayed in table after clicking button "save". Example details are:

Showing 1-1 of 1 item.

No	NAME	Position	Address	Contact	Email	
1	NURUL	AUDIT UNIT	NO.2B, BATU 2 JALAN KODIANG, 06100 KODIANG KEDAH.	0132732026	nazirah123@gmail.com	

Click for delete

The user can delete the details with clicking at  and alert message will be displayed. The alert message will be shown in the figure below.

Delete List Coordinating?

Cancel OK

Click for proceed delete

Click for cancel delete

4 -> The user should click to close the page.

The details of list coordinating investigator will be displayed in table.

1
Click for view details coordinating investigator

2

Click for close page

No	Name & address of the Clinical Investigation / Study site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Committee	Approval Letter	
1	Name MAYA GONZALES Address VERITATIS MOLESTIAE	Name GRIFFIN WASHINGTON Position LABORUM PORRO ASSUM Address RECUSANDAE VEL ESSE	1. IZZAH	(not set)	(not set)		Update Delete Investigator

Coordinating Investigator

Name : IZZAH
Position : DR.
Address : ALAMAT IZZAH
Contact : 0192873651
Email : izzah@getnada.com
Clinical Investigation / Study Site : MAYA GONZALES

After that, user should click button  to fill the details of EC/IRB. The form for EC/IRB will be displayed. The figure below shows the form for update EC/IRB.

The screenshot shows a web form titled "Clinical Investigational Plan". It contains two main sections. The first section is labeled "Ethics Committee (EC) / Institutional Review Board (IRB) *" and features a large empty text input field. A red arrow points from a box labeled "Fill in the textbox" to this field. The second section is labeled "Authorisation / Opinion Of Ethics Committee *" and contains three radio button options: "TO BE REQUESTED", "PENDING", and "AUTHORISATION ACCEPTED/FAVOURABLE OPINION". A dashed purple box highlights these radio buttons, with a red arrow pointing from a box labeled "Click at radio button" to the "AUTHORISATION ACCEPTED/FAVOURABLE OPINION" option. Below the radio buttons is a green "SAVE" button with a floppy disk icon. A red arrow points from a box labeled "Click at button" to the "SAVE" button.

Ethics committee(EC)/Institutional Review Board(IRB)

- The user should fill in the textbox that provided.

Authorisation/Opinion of Ethics Committee

- The user should choose whether "To be Requested" or "Pending" or "Authorisation Accepted/Favourable Opinion"



After that, user click at  to save details. The details will be displayed on table that shown in the figure below.

[+ Add Clinical Investigation / Study Site](#)

Showing 1-1 of 1 item.

No	Name & address of the Clinical Investigation / Study site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Opinion Of Ethics Committee	Approval Letter
1	Name MAYA GONZALES Address VERITATIS MOLESTIAE	Name GRIFFIN WASHINGTON Position LABORUM PORRO ASSUM Address RECUSANDAE VEL ESSE Contact 393 Email dyxy@mailinator.com	1. IZZAH	INSTITUTIONAL REVIEW BOARD 1	Pending	Update Delete Update List Coordinating Investigator Update EC/IRB

← Previous Next →

Click for previous section Click for next section

Then, If user want back to previous section, user should click at button

If user want back to previous section, user should click at button



Then, user should click at button

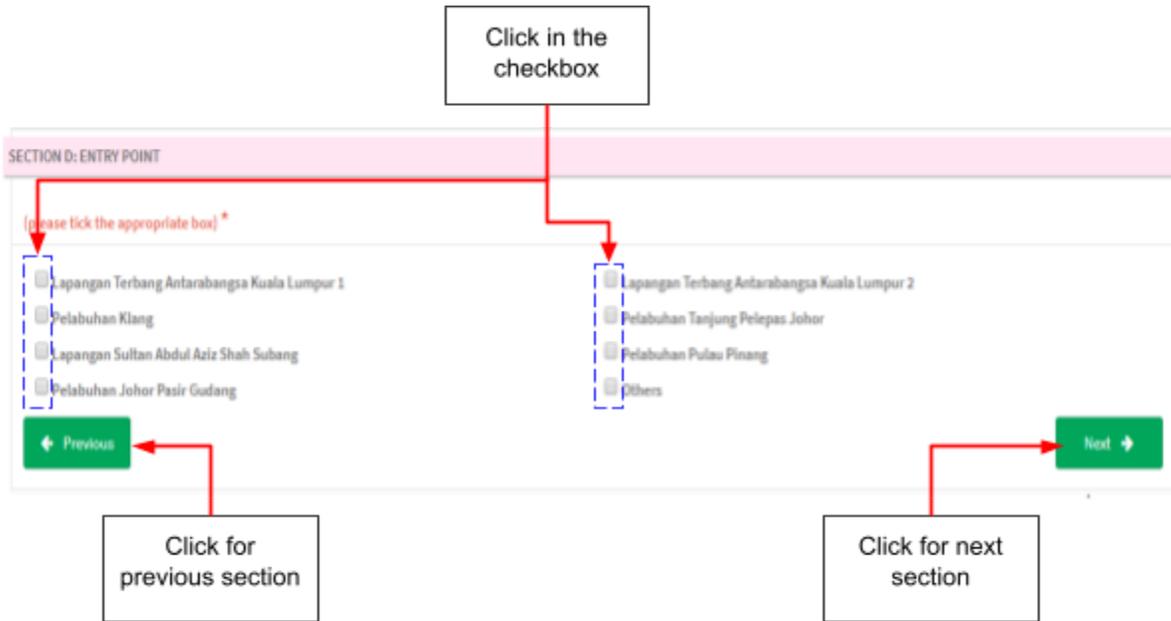


to the next stage.

Section D: Entry Point

The symbol “*” means required field.

The user should choose that type of entry that are provided.



The user must tick in checkbox that provided based the entry that user wanted. If user click at others, the textbox field will be displayed. The user should fill in textbox that provided.

Other (please specify)

If user want back to previous section, user should click at button



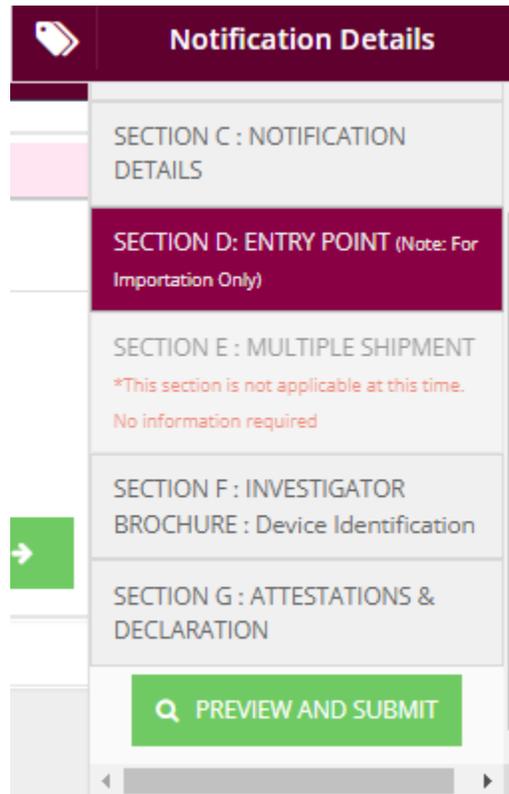
that shown in figure above. Then, user should click at button



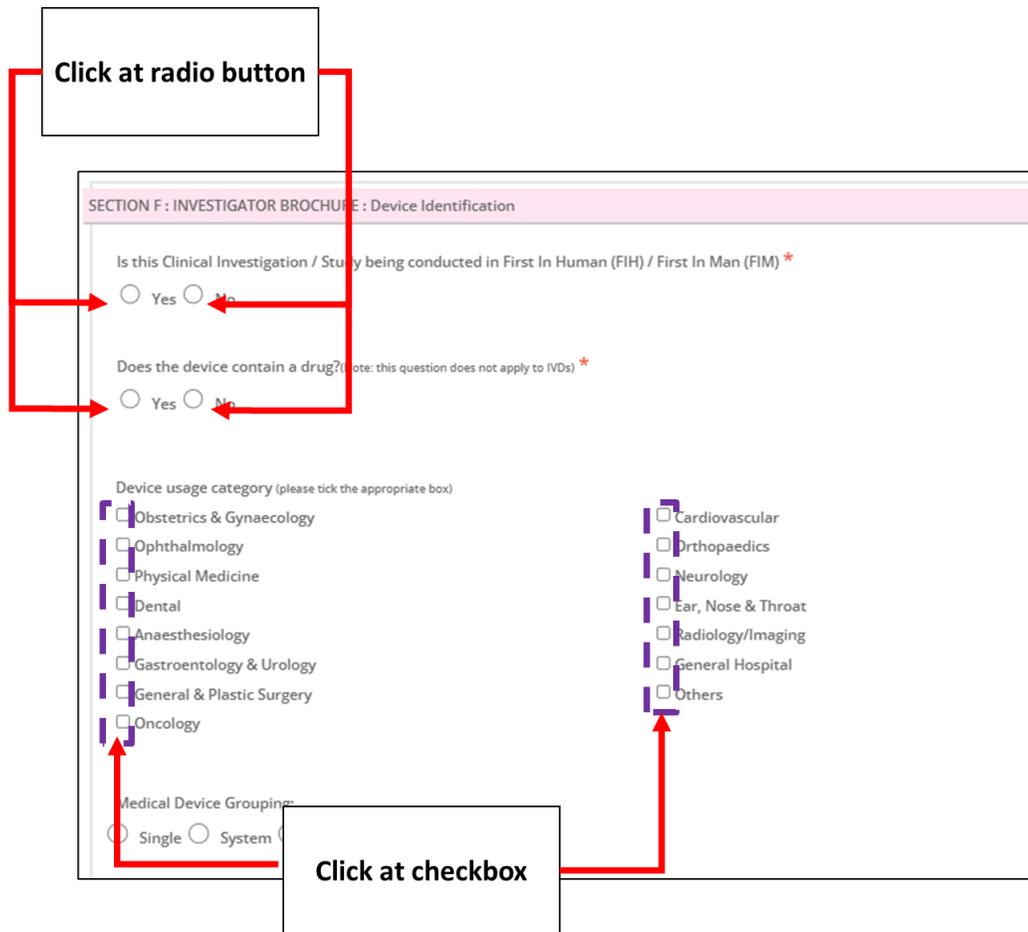
to the next stage.

Section E: Multiple Shipment (Disabled)

Section E: Multiple Shipment is disabled. The user unable to click Section F



Section F: Investigator Brochure: Device Identification



- **Is this Clinical Investigation / Study being conducted in First In Human (FIH) / First In Man (FIM)**

User should click at radio button whether “Yes” or “No” that shown in the figure below.

- **Does the device contain a drug?(Note: this question does not apply to IVDs)**

User should click at radio button whether “Yes” or “No” that shown in the figure below.

- **Device usage category (please tick the appropriate box)**

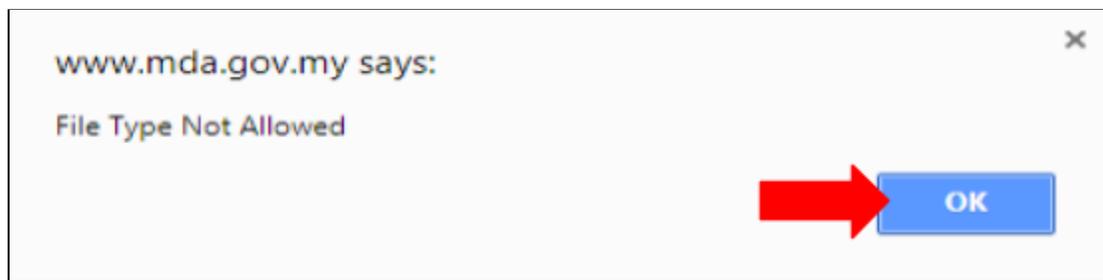
User should choose the category which is clicking in checkbox that provided.

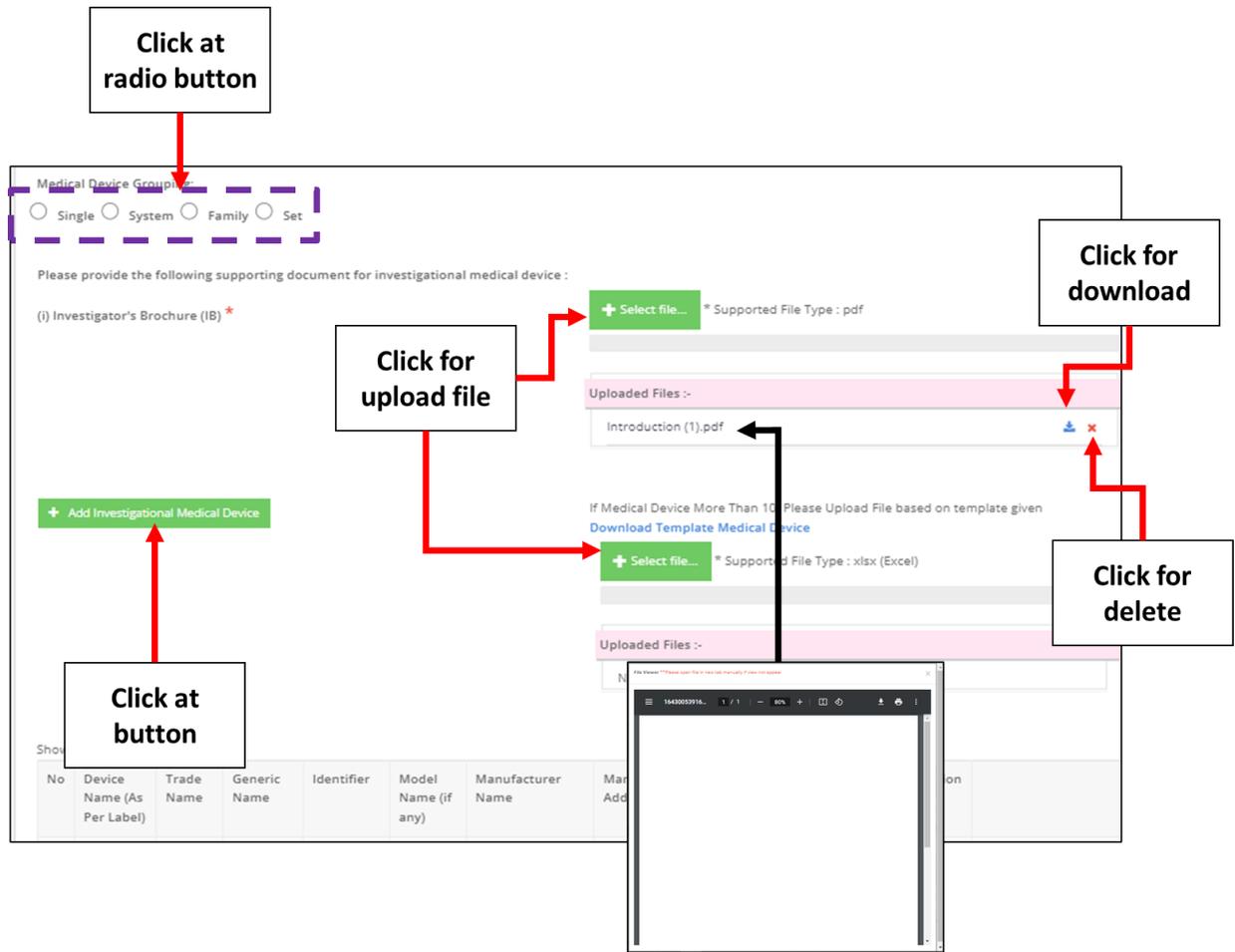
- **Medical Device Grouping**

The user should click on radio button that provided shown in figure above. The Medical Device Grouping has four types which are single, family, system and set. The user should choose the group of medical device.

- **Please provide the following supporting documents for investigational medical device**

User must click at button  to upload file PDF only. After upload file, User also can preview the file that uploaded which are user clicks the filename and file will appear. The user can download and delete the file with click at  for download and  for delete. If user upload file except PDF, the message will appear at the system which is "File Type Not Allowed". User should click "ok" to proceed in system.





After that, the user should click button **+ Add Investigational Medical Device** and the form for investigational medical device will be displayed. The figure below shows the form of investigational medical device.

The screenshot shows a web form titled "Investigational Medical Device" with a close button (X) in the top right corner. The form contains six text input fields, each with a red asterisk indicating a required field. The fields are: "Device Name (As Per Label)", "Trade Name", "Generic Name", "Identifier", "Model Name (if any)", and "Manufacturer Name". A vertical red line with arrows pointing to each field is accompanied by a box labeled "Fill in the textbox". A red arrow points from a box labeled "Click for move up and down" to the scrollbar on the right side of the form.

Add Investigational Medical Device

The symbol "*" means required field.

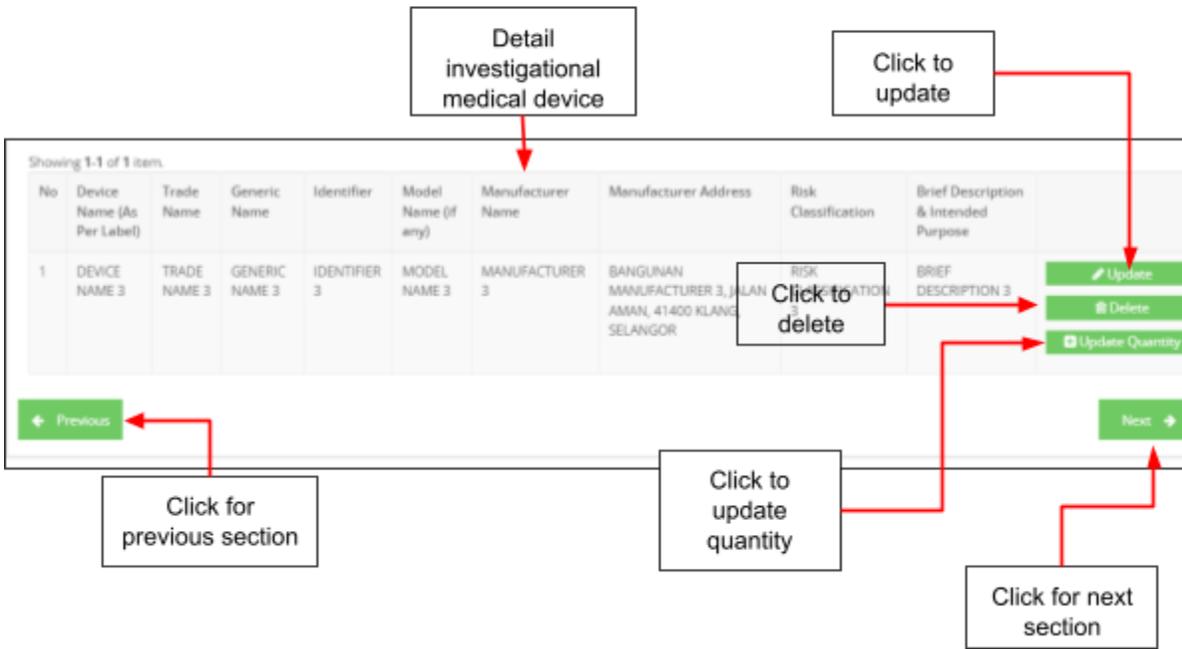
- Device Name (As Per Label) ->The user should fill the textbox that provided. If user don't fill the field, the message "Device Name (As Per Label) cannot be blank." will be displayed.
- Trade Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Trade Name cannot be blank." will be displayed.
- Generic Name -> The user should fill the textbox that provided.
- Identifier -> The user should fill the textbox that provided. If user don't fill the field, the message "Identifier cannot be blank." will be displayed. The user should

fill the textbox that provided. If user don't fill the field, the message "Trade Name cannot be blank." will be displayed.

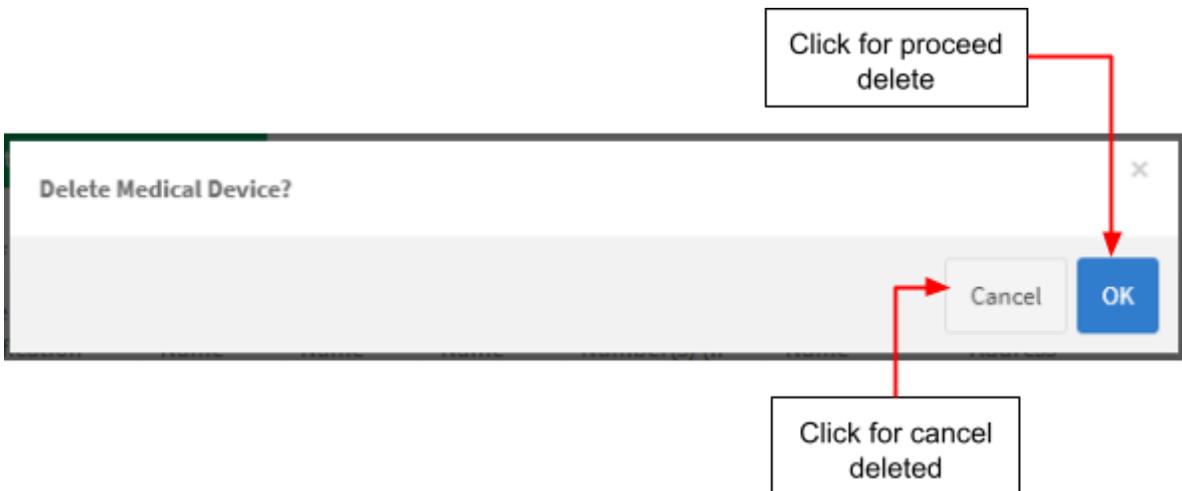
- Model Name (if any) -> The user should fill the textbox that provided..
- Manufacturer Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Manufacturer Name cannot be blank." will be displayed.
- Manufacturer Address -> The user should fill the textbox that provided. If user don't fill the field, the message "Manufacturer Address cannot be blank." will be displayed.
- Risk classification -> The user should fill the textbox that provided. If user don't fill the field, the message "Risk Classification cannot be blank." will be displayed.
- Brief Description & Intended Purpose -> The user should fill the textbox that provided. If user don't fill the field, the message "Brief Description & Intended Purpose cannot be blank." will be displayed.

The image shows a web browser window titled "Investigational Medical Device". The form contains several text input fields, each with a red asterisk indicating a required field. The fields are labeled: "Manufacturer Name", "Manufacturer Address", "Risk Classification", and "Brief Description & Intended Purpose". Below these fields is a green button labeled "Add Investigational Medical Devices". A red line with arrows points from a box labeled "Fill in the textbox" to each of the four text input fields. Another red line with an arrow points from a box labeled "Click at button" to the "Add Investigational Medical Devices" button.

The user should click at button **Add Investigational Medical Devices** to proceed and the details will be shown in the figure below.



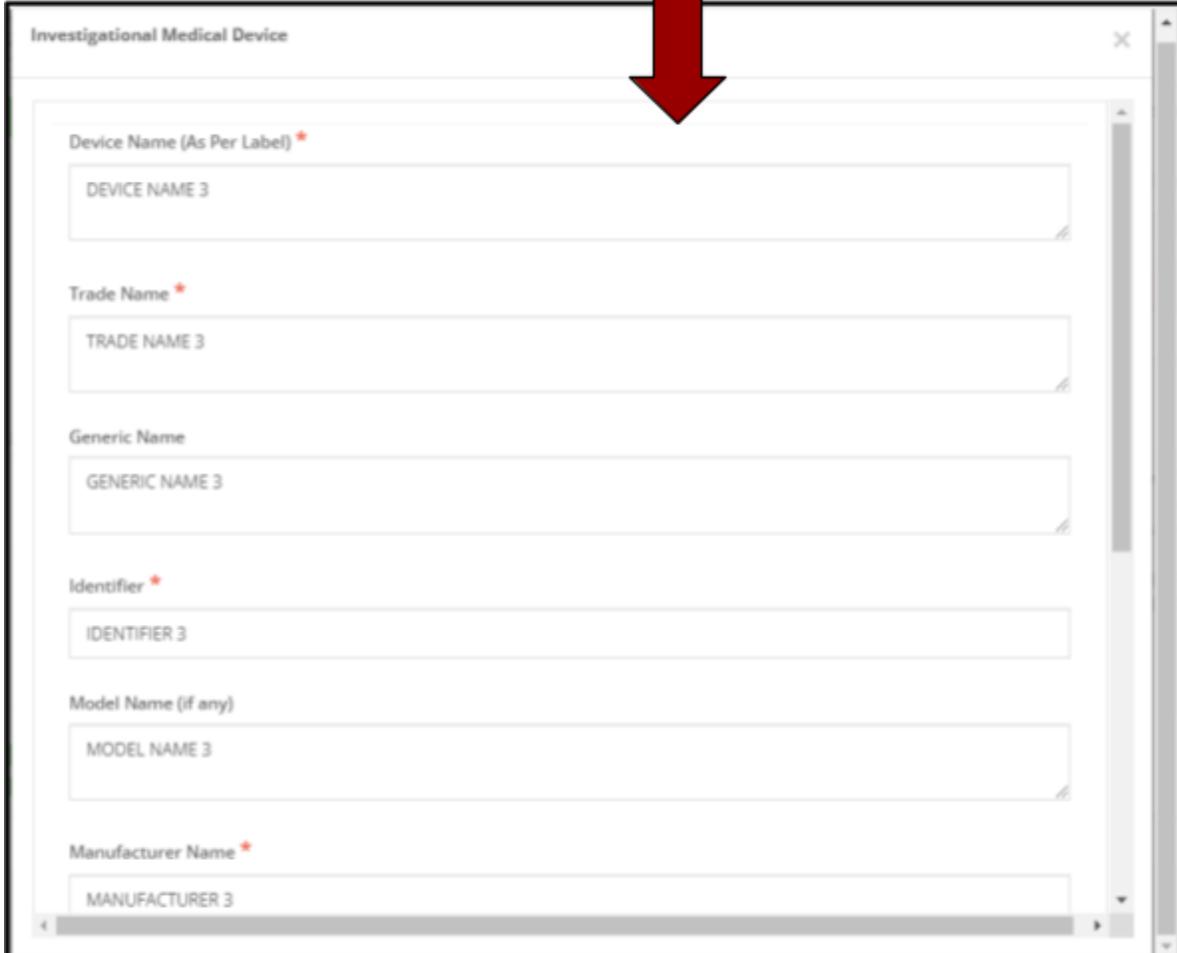
The details add investigational medical device will be displayed at table that shown in figure above. If user want to delete the investigational medical device, user should click at  and alert message "Delete Medical Device?" will be displayed that shown in the figure below.



The user should click at “OK” to proceed deleted and “Cancel” to cancel for deleted.

The user also can update the detail with clicking at  and form of investigational medical device will be displayed that shown in figure below.

Click in textbox fields to update



Investigational Medical Device

Device Name (As Per Label) *

DEVICE NAME 3

Trade Name *

TRADE NAME 3

Generic Name

GENERIC NAME 3

Identifier *

IDENTIFIER 3

Model Name (if any)

MODEL NAME 3

Manufacturer Name *

MANUFACTURER 3

After that, user click button  to save details and display again at table.

Showing 1-1 of 1 item.

No	Device Name (As Per Label)	Trade Name	Generic Name	Identifier	Model Name (if any)	Manufacturer Name	Manufacturer Address	Risk Classification	Brief Description & Intended Purpose	
1	DEVICE NAME 3	TRADE NAME 3	GENERIC NAME 3	IDENTIFIER 3	MODEL NAME 3	MANUFACTURER 3	BANGUNAN MANUFACTURER 3, JALAN AMAN, 41400 KLANG, SELANGOR	RISK CLASSIFICATION 3	BRIEF DESCRIPTION 3	<div style="text-align: right;">  Update  Delete  Update Quantity </div>

User also can add more than one investigational medical device with click again

button .

OR

If the medical device are more than 10, the user can download the excel template by clicking [Download Template Medical Device](#) and upload the excel file by clicking

.

The user can download and delete the file with click at  for download and  for delete.

Then, the user should click  to update quantity at each clinical investigational or study site.

The screenshot shows a web form titled "Investigational Medical Device". It contains several sections:

- Device Information:** Fields for Device Name (DEVICE NAME 1), Trade Name (TRADE NAME 1), and Generic Name (GENERIC NAME 1).
- Site Information:** Fields for Site Name (MAYA GONZALES) and Site Address (VERITATIS MOLESTIAE).
- Quantity:** A text input field containing the number "0".
- Action:** A green "Save" button.

Annotations include a box "Fill in the text box" with a red arrow pointing to the "Quantity" field, and a box "Click save" with a red arrow pointing to the "Save" button.

If user want back to previous section, user should click at button



that shown in figure above. Then, user should click at button



For **Clinical Use (GMD)** and **Clinical Use (IVD)**, the user need to fill the comparison

by clicking the  button. Figure below shows the form that user should fill.

**Fill in the
text box**



Comparison

Clinical Equivalent

Technical Equivalent

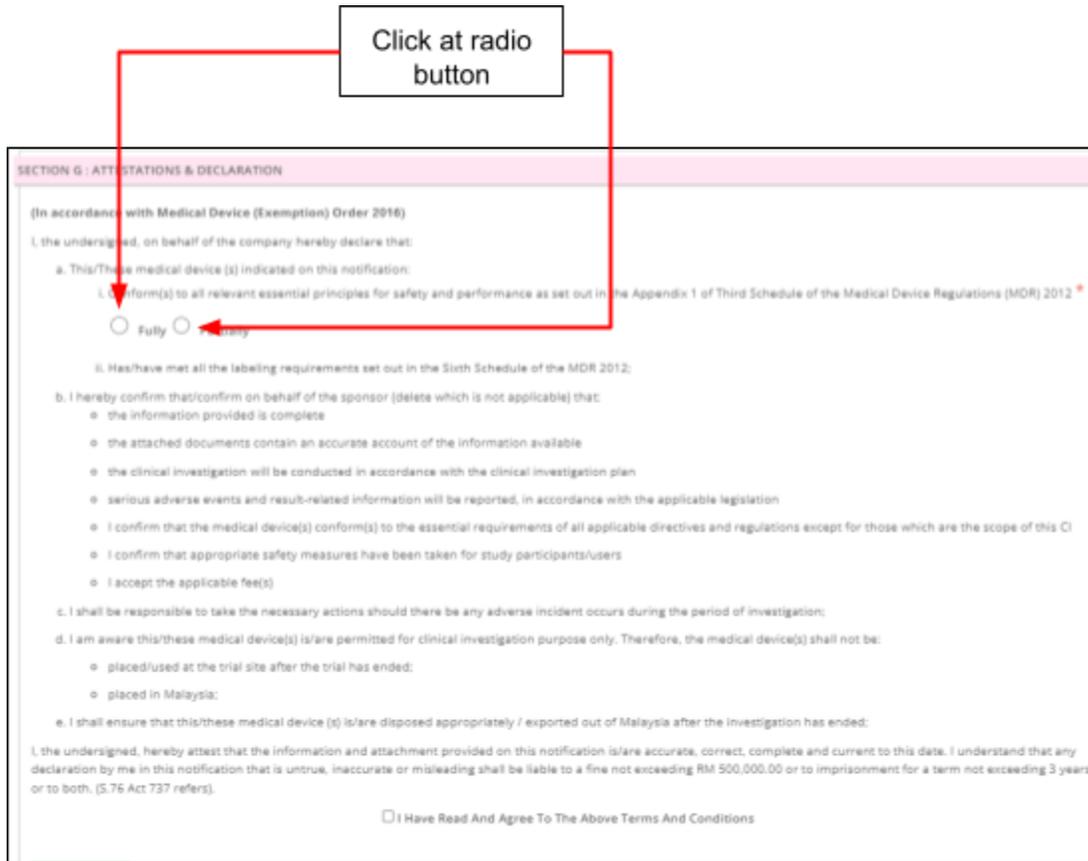
Biological Equivalent

Add Comparison

**Click
button**

Section G: Attestations & Declaration

The user should choose whether “Fully” or “Partially” in medical device application. The user should click on radio button that provided that shown in figure below.



The user must click on checkbox **I Have Read And Agree To The Above Terms And Conditions** that agree in terms and conditions that shown in the figure below.

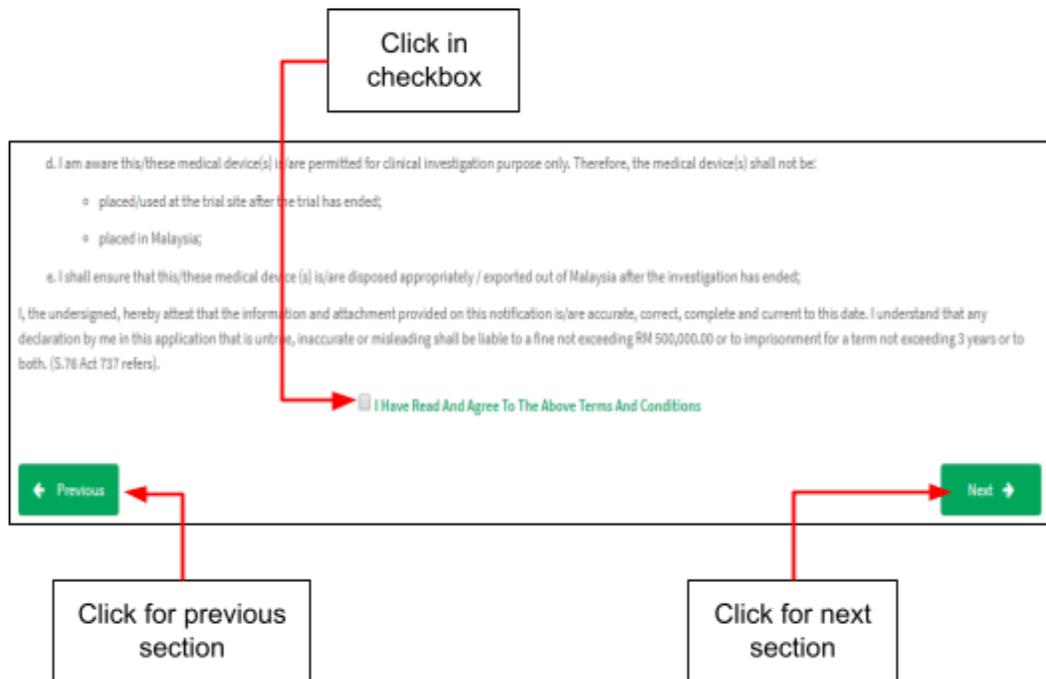
If user want back to previous section, user should click at button



that shown in the figure below. Then, user should click at



button to the next stage.



After all form in each section completed, the user should click at



to preview and submit the application form.

The page view will be shown after click button "PREVIEW AND SUBMIT". The figure below show the details of preview.

Investigational / Study Device Notification

*Submit only can be done if all fields mandatory are complete

Section	Status
SECTION A : APPLICANT INFORMATION	Complete
SECTION B : SPONSOR DETAILS	Complete
SECTION C : NOTIFICATION DETAILS	Complete
SECTION D : ENTRY POINT (Note: For Importation Only)	Complete
SECTION E : MULTIPLE SHIPMENT	Not Applicable
SECTION F : INVESTIGATOR BROCHURE	Complete
SECTION G : ATTESTATIONS & DECLARATION	Not Complete

*Submit only can be done if all fields mandatory are complete

If status **Not Complete**, the user should fill it again to change status **Complete** and the button “submit” will be displayed.

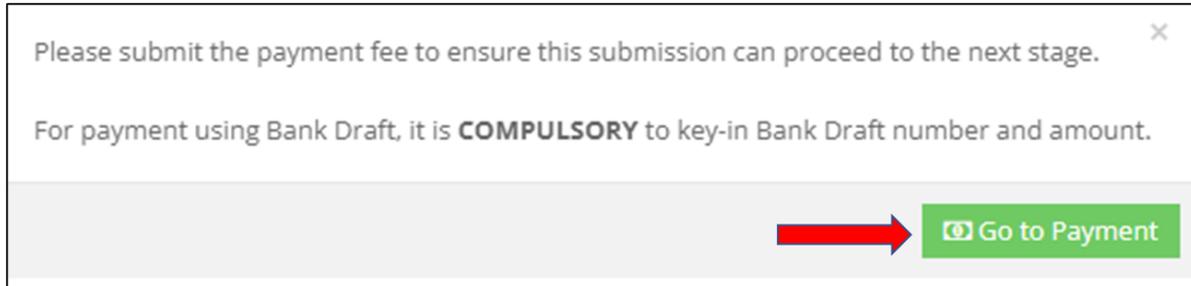
The screenshot shows a web form titled "Investigational / Study Device Notification". At the top left, there is a green "SUBMIT" button with a document icon, and a red arrow points to it from a box labeled "Click for submit". Below the form, there are seven sections, each with a "Complete" status indicator in a green box, except for "SECTION E : MULTIPLE SHIPMENT" which is "Not Applicable" in a yellow box. At the bottom left, there is another green "SUBMIT" button with a document icon, and a red arrow points to it from a box labeled "Click for submit".

After click "submit", message alert will be displayed to confirmation of submitted.

The screenshot shows a dialog box titled "Confirm Submit Application?". It has a close button (X) in the top right corner. At the bottom right, there are two buttons: "Cancel" and "OK". A red arrow points from a box labeled "Click to proceed" to the "OK" button. Another red arrow points from a box labeled "Click for cancel submitted" to the "Cancel" button.

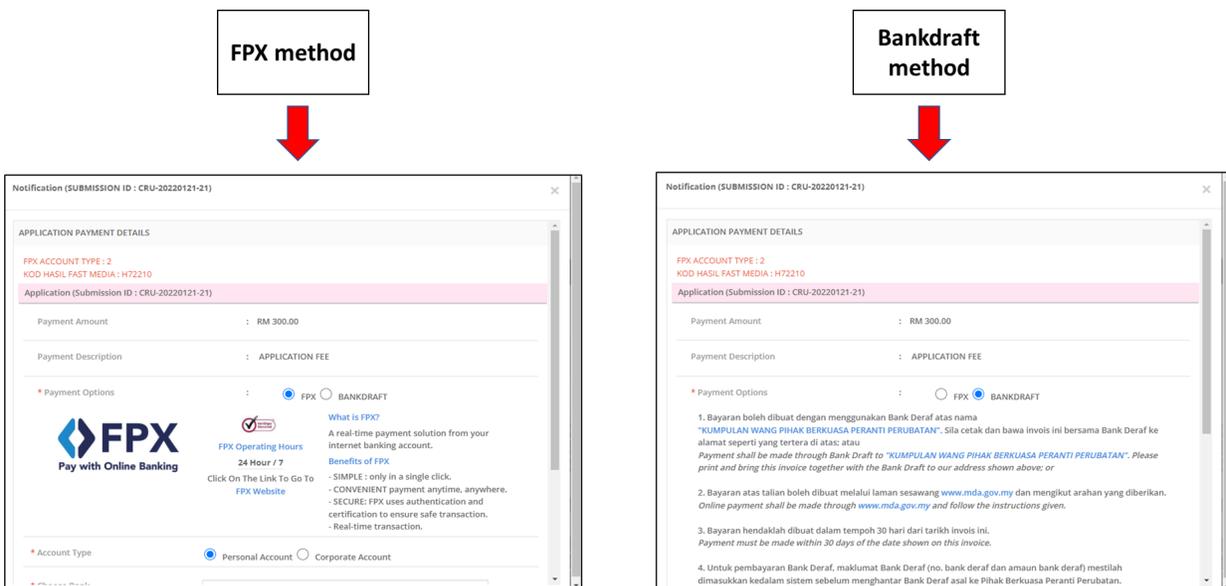
After the application is successfully submitted, a message "Please submit the payment fee to ensure this submission can proceed to the next stage. For payment

using Bank Draft, it is **COMPULSORY** to key-in Bank Draft number and amount.” appeared.



The user can click  button to make a payment or the user can click the  icon to make a payment later.

The Figure below shows the page once the user click . The user can pay using FPX method or Bankdraft method.



The Figure below shows the page if the user click the  icon to make a payment later.

1. The user at the notification list page.
2. Status of the submitted application -> **APPLICATION FEE (UNPAID)**
3. The user click **Payment** button or **Add To Bulk Payment** to make a payment.
4. The user can pay using FPX method or Bankdraft method.

The screenshot shows a 'Notification List' table with the following data:

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	CRU-20220121-21	21-01-2022	AQILAH ALIAH	CLINICAL RESEARCH USE	APPLICATION FEE (UNPAID)	Q View, Payment, Add To Bulk Payment, P Advice & Receipt
2	CRU-20220120-16 (1)	20-01-2022	AQILAH ALIAH	SUBSEQUENT CLINICAL RESEARCH USE	EVALUATION	Q View, Notification History

Annotations and flow diagrams:

- 1**: Points to the 'Notification List' header.
- 2**: Points to the 'APPLICATION FEE (UNPAID)' status in the table.
- 3**: Points to the 'Payment' and 'Add To Bulk Payment' buttons in the action column.
- 4**: Points to two payment method screens:
 - FPX method**: Shows the 'APPLICATION PAYMENT DETAILS' screen with the FPX logo and payment options.
 - Bankdraft method**: Shows the 'APPLICATION PAYMENT DETAILS' screen with instructions for bank draft payments.

The user received JKTPKPP meeting details email notification once their notification application is in JKTPKPP (EVALUATION) . Figure below shows the email notification that will be received by the front-end user. The user click [DOWNLOAD TEMPLATE](#) to download the presentation template.

[MDA] Presentation Schedule and Template for CIU-20220125-23
 from No Reply MedcastV2 <medcast_mail@medb.gov.my>
 received Jan 25 10:57 am



Buy Bus Tickets Online
 Easy Payment Method. No Additional Charge. Book Your Bus Tickets Now.
 redBus.my [Book Now >](#)

Dear Sir/Madam,
 For your information, your Presentation with MDA was scheduled as follows:
Submission ID: CIU-20220125-23
Presentation Date: 2022-01-26
Presentation Time: 10:30:00
Meeting Location:
 Dewan Seri Larkin, Medical Device Study CIU

Kindly prepare your Presentation based on template below:
[DOWNLOAD TEMPLATE](#)

If clicking above link does not download the file, please copy and paste below link in a new browser tab:
https://medcast.mda.gov.my/staging/files/template/notification_CIU_TEMPLATE_PRESENTATION.pdf

Thank you,
 Adrina MEDCAST

Click link



TCMDCE notes and presentation template for applicant: Device Study

Dear Sir/Madam,
 Thank you for your notification.
 We have received your notification and it will be forwarded for recommendation to the Technical Committee of Medical Device Clinical Evaluation (TCMDCE) Meeting.
 You are invited to present your study in the TCMDCE Meeting. Kindly be informed that the meeting will be held (physical) (online meeting) as in the notification sent to your email.

For online meeting	Please enter your Screen Name in the Zoom notification as (your name) - (Company's name). It is compulsory for all attendees to enter the online meeting room.
For physical meeting	Please be ready at the venue 15 minutes before your presentation scheduled time.

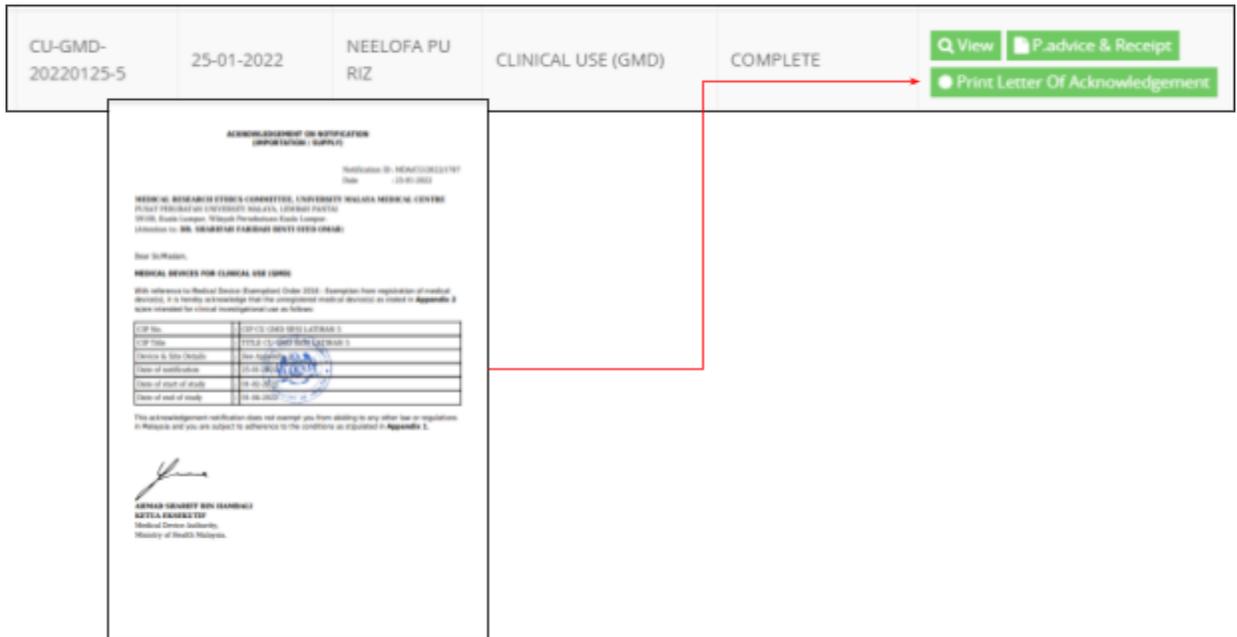
In order to present your study, you will need to prepare a presentation (30 minutes duration) in a PowerPoint document to explain the details of your study.
 Your presentation must contain P as follows as the following:

No.	Subtitles	Content
1.	Identification of the ID	<ul style="list-style-type: none"> Name of the Investigational Device Document reference number, if any Version / date of the ID Summary of the current history in the state of amendments, if appropriate It includes issue number and reference number, if any
2.	Sponsor/Manufacturer	<ul style="list-style-type: none"> Name Address
3.	Device Identification	<ul style="list-style-type: none"> Details identifying devices to be identified Trade name of device(s) Generic name of device(s) Model name or description/unique trade name or generic name of the investigational device(s) Model number(s) including revision number(s), if any (or reference from approved model number if applicable) Copy of document system and ID(s) (including version number and date of issue) including file, contributions and history (if available) A description of the device including a list of accessories, principles of operation and block or flow diagrams of major components, together with a label

After the status of the notification application is changed to “COMPLETE”, the user can print the Approval Letter by clicking the  button.

[Notification] -> [Clinical Research Study] -> [Device Study] -> [Notification List]

- **Approval Letter: New Notification**



The screenshot displays a notification record in a table with the following details:

CU-GMD-20220125-5	25-01-2022	NEELOFA PU RIZ	CLINICAL USE (GMD)	COMPLETE	View P.advice & Receipt Print Letter Of Acknowledgement
-------------------	------------	----------------	--------------------	----------	---

Below the table, the 'Print Letter Of Acknowledgement' button is highlighted with a red arrow. The letter itself is titled 'ACKNOWLEDGEMENT ON NOTIFICATION (IMPORTATION - SUPPLY)' and is dated 25-01-2022. It is issued by the Medical Research Ethics Committee, Universiti Malaya Medical Centre, and is addressed to NEELOFA PU RIZ. The letter includes a table with the following information:

CIP No.	CU-GMD-20220125-5
CIP Title	STUDI KLINIK TERBUKA TERHADAP 5
Device & Site Details	See Appendix 1 & 2
Date of notification	23-01-2022
Date of start of study	25-01-2022
Date of end of study	25-01-2022

The letter is signed by ARTITA HANISAH TAP, Medical Director, Ministry of Health Malaysia.

- **Approval Letter: Subsequent Notification**

CIU-20211230-79	30-12-2021	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	COMPLETE	View Print Advice & Receipt Print Letter Of Acknowledgement
-----------------	------------	----------------	------------------------------	----------	--

**ACKNOWLEDGEMENT ON NOTIFICATION
(IMPORTATION - SUPPLY)**

Notification ID: MED/CIU/2021/1899 (1)
Date: 30-12-2021

**MEDICAL RESEARCH ETHICS COMMITTEE, UNIVERSITY MALAYA MEDICAL CENTRE
UM ESKALA KAMPUS**
.....
Reference to: DR. HAZRATUN HAZRAN BINTI KHEE-CHENG

Dear Sir/Madam,

MEDICAL DEVICES FOR SUBSEQUENT CLINICAL INVESTIGATIONAL USE

With reference to Medical Device (Exemption) Order 2020 - Exemption from registration of medical devices, it is hereby acknowledge that the unregistered medical devices as stated in **Appendix 2** were intended for clinical investigational use as follows:

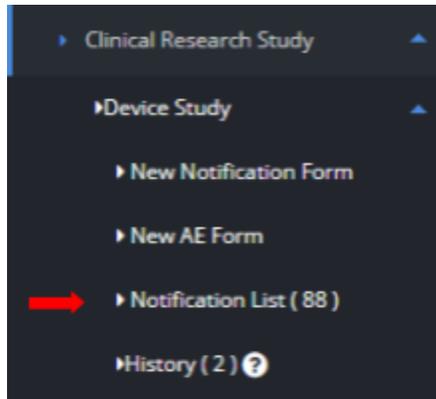
CIU No.	CIU 2021 79
CIU Title	TITIKU CIU 2021 79
Subsequent Notification Details	See Appendix 2
Date of notification	30-12-2021
Date of start of study	01-01-2022
Date of end of study	31-03-2022

This acknowledgement notification does not exempt you from abiding to any other law or regulations in Malaysia and you are subject to adherence to the conditions as stipulated in **Appendix 3**.

Computer-generated. No signature is required.

b) Subsequent application

User click on the Application List at Clinical Research Study -> Device Study -> Notification List



The system will display page of list application Investigational Use.

<input type="checkbox"/>	14	CIU-20211231-80 (1)	02-01-2022	NEELOFA PU RIZ	SUBSEQUENT CLINICAL INVESTIGATIONAL USE	COMPLETE	View Subsequent Notification Print Letter Of Acknowledgement Notification History
<input type="checkbox"/>	15	FS-GMD-20211231-13 (1)	02-01-2022	NEELOFA PU RIZ	SUBSEQUENT FEASIBILITY STUDY (GMD)	PRINT CERTIFICATE	View Print Letter Of Acknowledgement Notification History
<input type="checkbox"/>	16	FS-GMD-20211231-13	31-12-2021	NEELOFA PU RIZ	FEASIBILITY STUDY (GMD)	COMPLETE	View P.advice & Receipt Print Letter Of Acknowledgement
<input type="checkbox"/>	17	CIU-20211231-80	31-12-2021	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	COMPLETE	View P.advice & Receipt Print Letter Of Acknowledgement
<input type="checkbox"/>	18	CIU-20211230-79 (4)	30-12-2021	NEELOFA PU RIZ	SUBSEQUENT CLINICAL INVESTIGATIONAL USE	COMPLETE	View Subsequent Notification Print Letter Of Acknowledgement Notification History
<input type="checkbox"/>	19	CIU-20211230-79 (3)	30-12-2021	NEELOFA PU RIZ	SUBSEQUENT CLINICAL INVESTIGATIONAL USE	COMPLETE	View Notification History

User click on [Subsequent Application](#) . Next step is click OK and the system will display *Subsequent Application* where the data has been copied from the previous application.

The user is unable to make any changes in **Section A** and **Section B**. The user should go to **Section C** to make a subsequent. At Section C, the user must click at the “Please tick the appropriate box below:” checkbox. There are 10 types of subsequent that the user can tick at the checkboxes. Each checkbox will opened different field.

Below is the list of the checkboxes and their respectively opened field.

1

Add Device Quantity

- **Section C:** Date of Device Importation
- **Section D:** Entry Point
- **Section F:** Update button, Add quantity button

- **Section G**

2**Add Study Site and Device**

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Date of Device Importation, Add Clinical Clinical Investigation / Study Site button
- **Section D:** Entry Point
- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB), Add quantity button, Update button
- **Section G**

3**Additional Investigator**

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Add Clinical Clinical Investigation / Study Site button, Update button, Update List Coordinating Investigator button, Update EC/IRB button
- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB)
- **Section G**

4**Extension of Study Duration**

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Estimated duration of Clinical Investigation / Study, Proposed date of Completion of Clinical Investigation / Study , Add Clinical

Clinical Investigation / Study Site button

- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB)
- **Section G**

5

Change Study Site

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Add Clinical Clinical Investigation / Study Site button, Update button, Update List Coordinating Investigator button, Update EC/IRB button
- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB), Add quantity button, Update button
- **Section G**

6

Change EC/IRB

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Add Clinical Clinical Investigation / Study Site button, Update button, Update List Coordinating Investigator button, Update EC/IRB button
- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB),
- **Section G**

7

Change/Remove Principal / Co-Investigator

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan

(CIP) document, Add Clinical Clinical Investigation / Study Site button, Update button, Update List Coordinating Investigator button, Update EC/IRB button

- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB),
- **Section G**

8**Changes CIP / IB**

- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Add Clinical Clinical Investigation / Study Site button, Update button, Update List Coordinating Investigator button, Update EC/IRB button
- **Section F:** Investigator's Brochure, Changes Summary in Investigators Brochure (IB),
- **Section G**

9

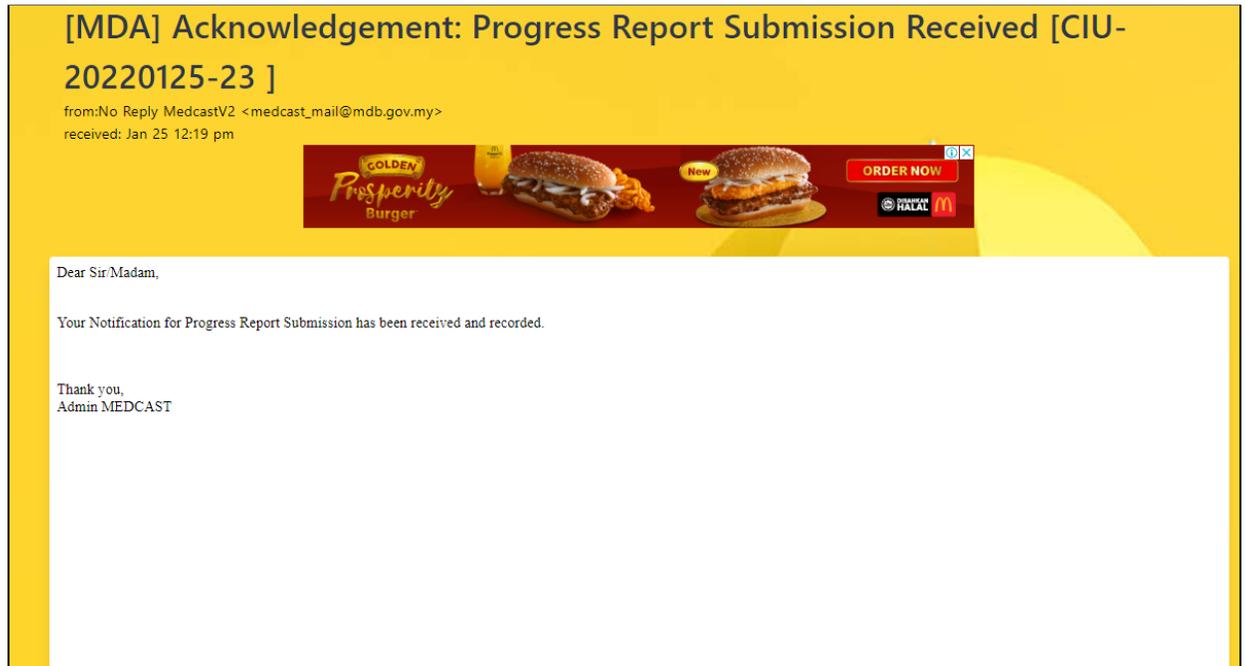
Submission of Progress Report

Update Progress Report

- **Section C:** Click **Update Progress Report** in Section C and fill the progress report form.

The image shows two screenshots from a web application. The left screenshot is titled "SECTION C: NOTIFICATION DETAILS" and contains several checkboxes for notification changes. The "Submission of Progress Report" checkbox is checked. Below the checkboxes are input fields for "Previous Submission ID" (containing "CIU-20211231-80 (1)") and "Previous submission date" (containing "02-01-2022"). At the bottom, there is a green button labeled "Update Progress Report". A black arrow points from this button to the right screenshot. The right screenshot shows a "Progress Report" form with fields for "Summary (in relation to investigational plans)", "No. of device shipped", "No. of subjects enrolled (indication / model)", "Summary of results", "Summary of Anticipated Adverse Effects", "Summary of Unanticipated Adverse Effects", and "Description of deviations (if any, since last progress report)". A red arrow points down to the form, and a text box above it says "Fill the study progress report form".

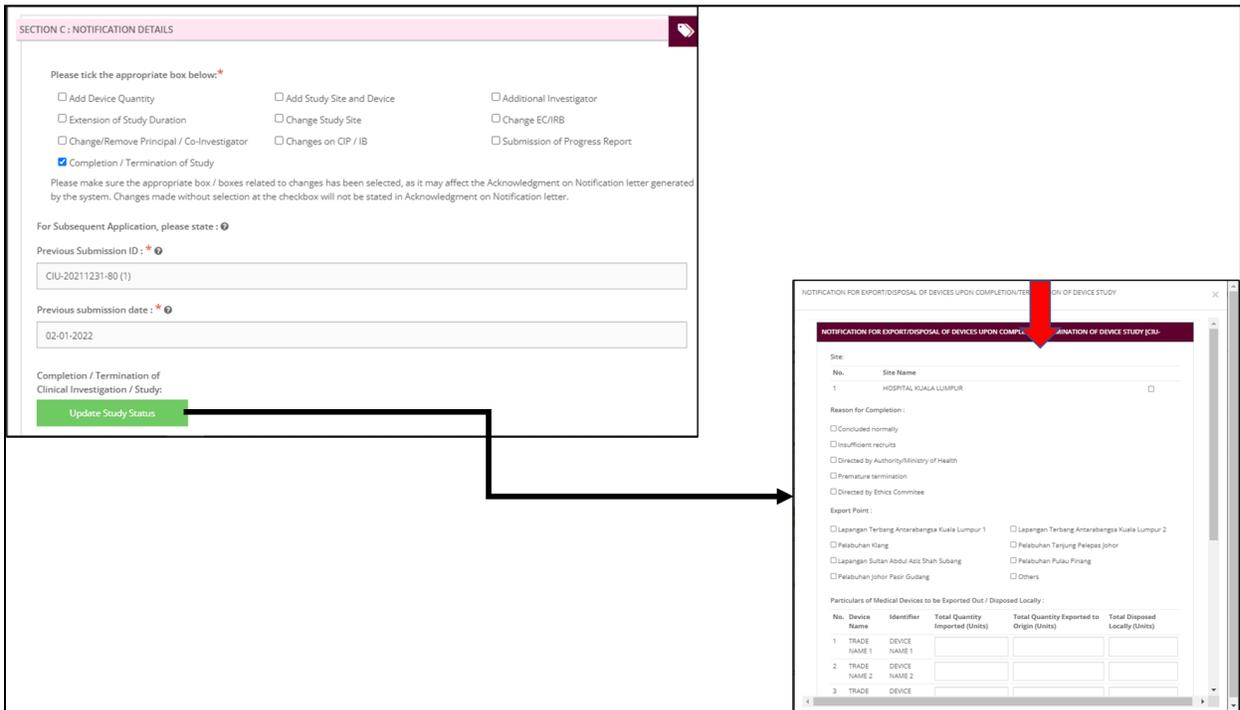
The user will get email notification after the completion of the progress report. Figure below shows the email notification that will be received by the front-end user.



- Section G

10 Completion / Termination of Study

- Section C: Click  in Section C and fill the study status form.



The image shows two screenshots from a web application. The left screenshot is titled 'SECTION C: NOTIFICATION DETAILS' and contains several sections:

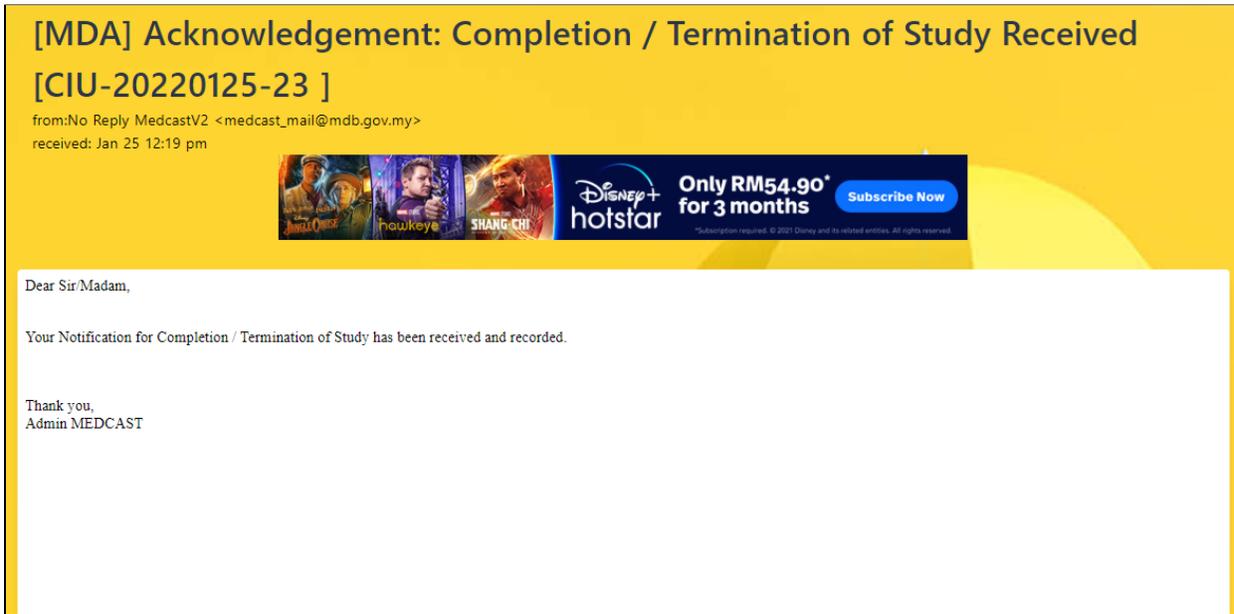
- Please tick the appropriate box below:** A grid of checkboxes for 'Add Device Quantity', 'Add Study Site and Device', 'Additional Investigator', 'Extension of Study Duration', 'Change Study Site', 'Change EC/IRB', 'Change/Remove Principal / Co-Investigator', 'Changes on CIP / IB', and 'Submission of Progress Report'. The 'Completion / Termination of Study' checkbox is checked.
- Please make sure the appropriate box / boxes related to changes has been selected, as it may affect the Acknowledgment on Notification letter generated by the system. Changes made without selection at the checkbox will not be stated in Acknowledgment on Notification letter.**
- For Subsequent Application, please state:** A section with 'Previous Submission ID' (value: CIU-20211231-80 (1)) and 'Previous submission date' (value: 02-01-2022).
- Completion / Termination of Clinical Investigation / Study:** A green button labeled 'Update Study Status'.

The right screenshot is titled 'NOTIFICATION FOR EXPORT/DISPOSAL OF DEVICES UPON COMPLETION/TERMINATION OF DEVICE STUDY'. It contains:

- Site:** A dropdown menu with '1 HOSPITAL KUALA LUMPUR' selected.
- Reason for Completion:** A list of checkboxes including 'Concluded normally', 'Insufficient recruits', 'Directed by Authority/Ministry of Health', 'Premature termination', and 'Directed by Ethics Committee'.
- Export Point:** A list of checkboxes for various locations like 'Lapangan Terbang Antarabangsa Kuala Lumpur 1', 'Lapangan Terbang Antarabangsa Kuala Lumpur 2', 'Pekabuan Klang', 'Pekabuan Tanjung Pelepas Johor', 'Lapangan Sultan Abdul Aziz Shah Subang', 'Pekabuan Kuala Pinang', 'Pekabuan Johor Pasir Gudang', and 'Others'.
- Particulars of Medical Devices to be Exported Out / Disposed Locally:** A table with columns: No., Device Name, Identifier, Total Quantity Imported (Units), Total Quantity Exported to Origin (Units), and Total Disposed Locally (Units). The table has three rows with placeholder text like 'TRADE NAME 1'.

Arrows indicate the flow from the 'Update Study Status' button in the first screenshot to the second screenshot.

The user will get email notification after the completion of the completion or termination of study. Figure below shows the email notification that will be received by the front-end user



- Section G

If the user wants to change the subsequent type, a “Unchecking this will reset the form, Continue?” a message appeared and all the information that the user fill automatically reset and the user need to fill again. Figure below shows the “Unchecking this will reset the form, Continue?” message. Then, user click “OK” to proceed or click “Cancel” to cancel and untick the checkbox.



If the user clicks “OK”, the page will be refreshed and the applicant goes back to **Section A** and the applicant needs to fill all the information that has been inserted before unticking the checkboxes since unticking the checkboxes will reset all the form.

The user complete the Subsequent Application form and click on button  to preview the information that user change.

Click on  to submit form.

The status of application will be on evaluation stage.

Showing 1-20 of 90 items.

<input type="checkbox"/>	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
<input type="checkbox"/>	1	CIU-20220124-21 (1)	25-01-2022	NEELOFA PURIZ	SUBSEQUENT CLINICAL INVESTIGATIONAL USE	EVALUATION	View Notification History

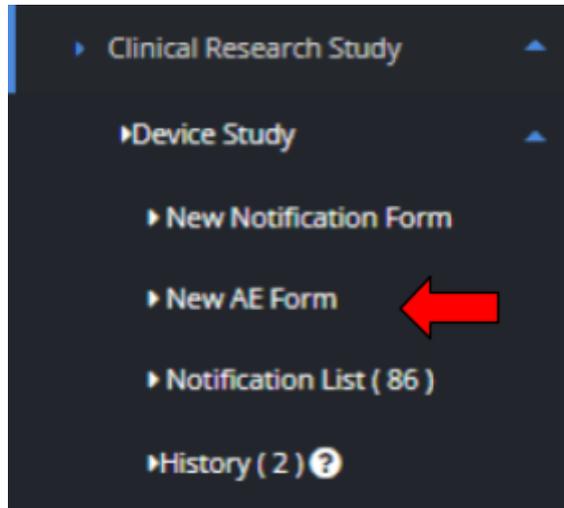
c) AE Form



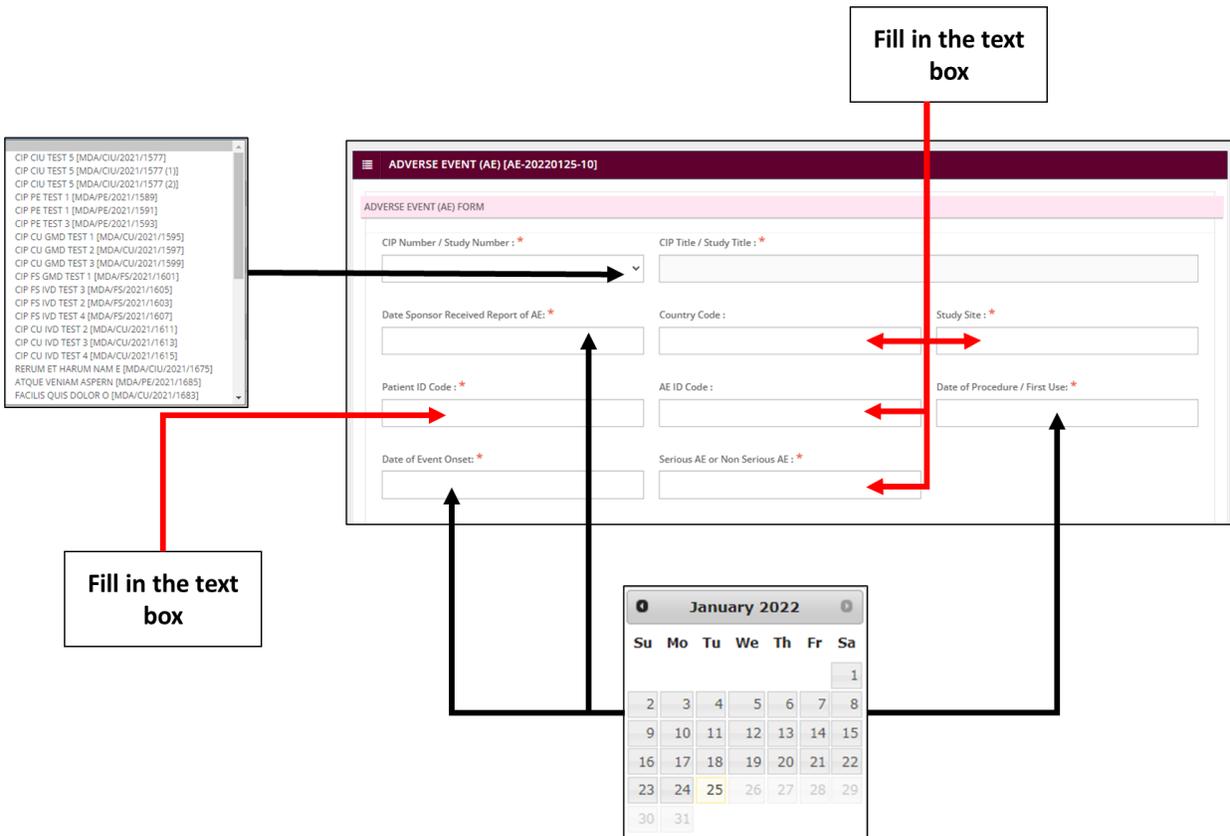
1 - User should click at menu Clinical Research Study.

2 - User should click at sub menu Device Study.

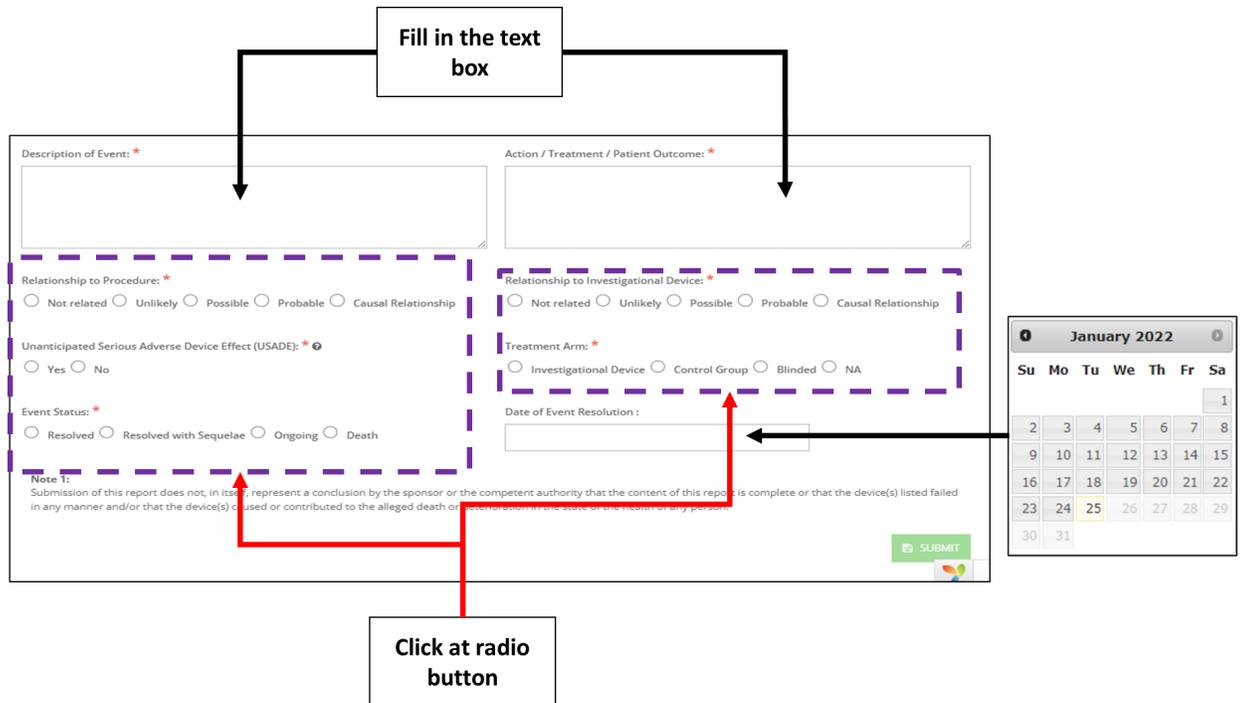
After click at sub menu Device Study, the list down of sub menu will be displayed that shown in Figure below.



The user should click at sub menu **New AE form**. The AE form will be appear. The figure below shows the AE form to applicant to fill it.



- **CIP Number / Study Number**
The user click at the dropdown list and choose the completed & approved Device Study application.
- **CIP Title / Study Title**
When the user choose at the CIP Number / Study Number dropdown list, CIP Title / Study Title appeared automatically,
- **Date Sponsor Received Report of AE**
The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above The user should fill in the textbox that provided.
- **Country Code**
The user should fill in the textbox that provided.
- **Study Site**
The user should fill in the textbox that provided.
- **Patient ID Code**
The user should fill in the textbox that provided.
- **AE ID Code**
The user should fill in the textbox that provided.
- **Date of Procedure / First Use**
The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.
- **Date of Event Onset**
The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.
- **Serious AE or Non Serious AE**
The user should fill in the textbox that provided.



- **Description of Event**
 The user should fill in the textbox that provided
- **Action / Treatment / Patient Outcome**
 The user should fill in the textbox that provided
- **Relationship to Procedure**
 Radio button -> Not related, Unlikely, Possible, Probable, Causal Relationship
- **Relationship to Investigational Device**
 Radio button -> Not related, Unlikely, Possible, Probable, Causal Relationship
- **Unanticipated Serious Adverse Device Effect (USADE)**
 Radio button -> Yes, No
- **Treatment Arm**
 Radio button -> Investigational Device, Control Group, Blinded, NA

- **Event Status**

Radio button -> Resolved, Resolved with Sequelae, Ongoing, Death

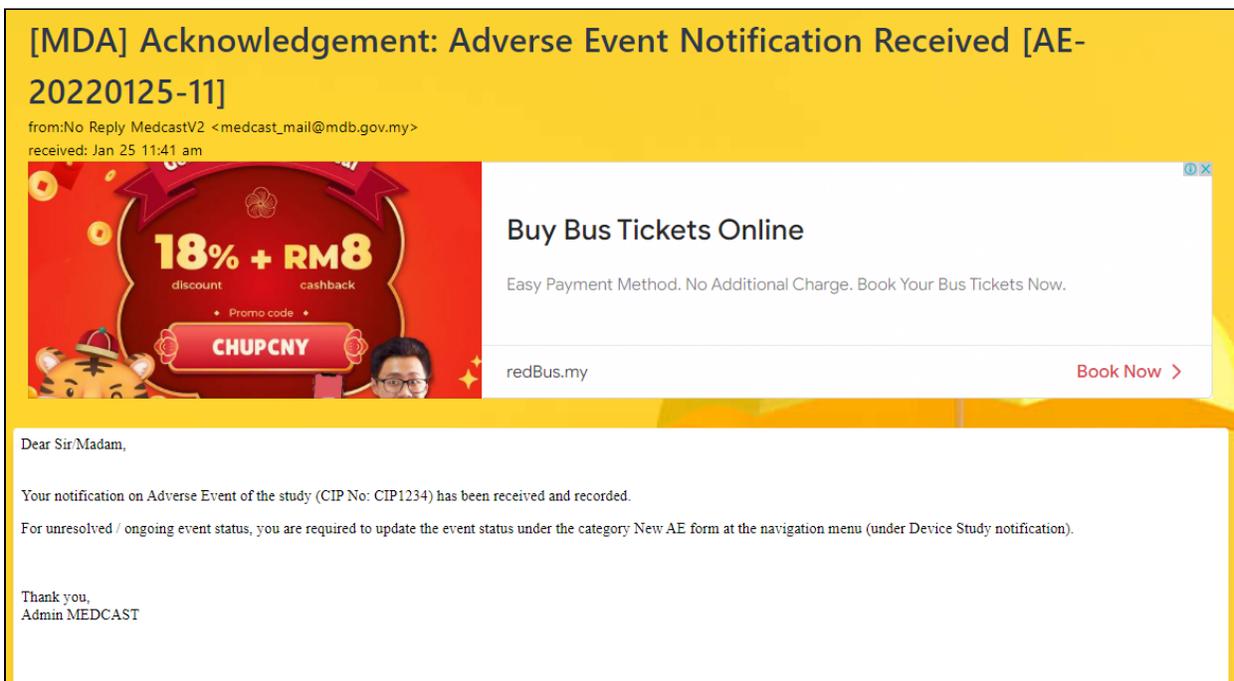
- **Date of Event Resolution**

The user should click at textbox field to display the calendar. The user should select a date in the calendar. The calendar was shown in figure above.



The user click  button once the user fill the mandatory field.

The user will get email notification after the completion of the AE form. Figure below shows the email notification that will be received by the front-end user



2.2.2 RETURN FOR FURTHER INFO

If back end user make the process “RETURN FOR FURTHER INFO” to front end user, the status of application will be changed and the Front End User should make the changed at application form that applied.

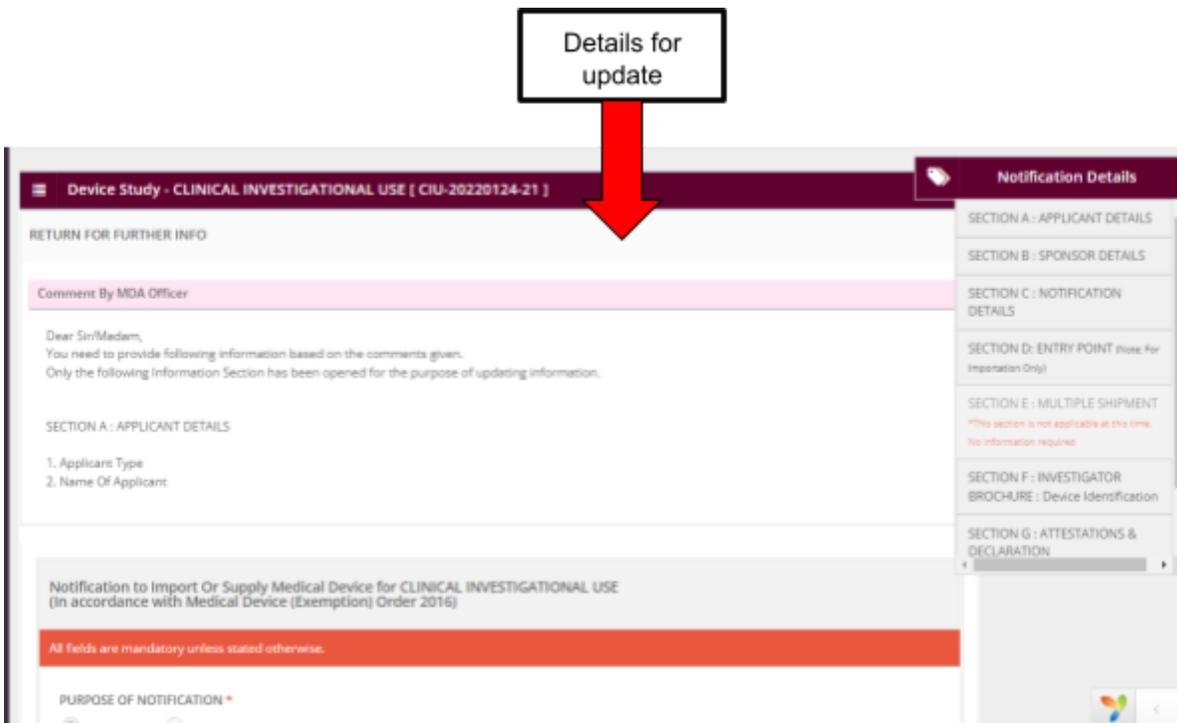
The figure below shows the application status that changed in front end user.

Status changed

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	CIU-20220124-21	24-01-2022	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	RETURN FROM MDA (REQUIRE CHANGES)	View Update Advice & Receipt
2	PE-20220120-6	20-01-2022	NEELOFA PU RIZ	PERFORMANCE EVALUATION	EVALUATION	View Advice & Receipt
3	CIU-20220117-18	17-01-2022	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	RETURN FROM MDA (REQUIRE CHANGES)	View Update Advice & Receipt
4	CIU-20220117-19	17-01-2022	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	RETURN FROM MDA (REQUIRE CHANGES)	View Update Advice & Receipt
5	PE-20220117-4	17-01-2022	NEELOFA PU RIZ	PERFORMANCE EVALUATION	RETURN FROM MDA (REQUIRE CHANGES)	View Update Advice & Receipt
6	PE-20220117-3	17-01-2022	NEELOFA PU RIZ	PERFORMANCE EVALUATION	RETURN FROM MDA (REQUIRE CHANGES)	View Update Advice & Receipt

Click for update

After that, user should click at  to update or make changes at application form. The details of information that user click “NO” at EVALUATION process will be



displayed that shown in the figure below.

Then, user should update the details of application information at the form. The user can edit at detail that changed only.

Details can be edited

The screenshot displays the 'SECTION A: APPLICANT DETAILS' form. The form includes the following fields and options:

- Role Of Applicant:** Radio buttons for 'Local Sponsor', 'An Authorised person from a local organization (in case of foreign sponsor / manufacturer)', 'Contract Research Organization (CRO)', and 'Others'. 'Contract Research Organization (CRO)' is selected.
- Name of Applicant:** Text input field containing 'CHRISTIAN SWEENEY'.
- NRIC No/Passport:** Text input field containing '2432543'.
- Designation:** Text input field containing 'IMPEDIT DESERUNT QU'.
- Organisation Information:**
 - Organisation Name:** Text input field containing 'MILLER WALTON LLC'.
 - Address Of Organisation:** Text input field containing 'IPSUM EX SED DELECT'.
 - State:** Dropdown menu showing 'WILAYAH PERSEKUTUAN KUALA LUMPUR'.
 - City:** Text input field (partially visible).

A red arrow points from the text 'Details can be edited' to the form. On the right side, there is a sidebar with a 'Notification Details' header and a list of sections: SECTION A: APPLICANT DETAILS, SECTION B: SPONSOR DETAILS, SECTION C: NOTIFICATION DETAILS, SECTION D: ENTRY POINT (Note: For Importation Only), SECTION E: MULTIPLE SHIPMENT (Note: This section is not applicable at this time. No information required), SECTION F: INVESTIGATOR BROCHURE: Device Identification, and SECTION G: ATTESTATIONS & DECLARATION.

And then, click  to submit the application.

Investigational / Study Device Notification

SUBMIT

SECTION A : APPLICANT INFORMATION Complete

SECTION B : SPONSOR DETAILS Complete

SECTION C : NOTIFICATION DETAILS Complete

SECTION D : ENTRY POINT (Note: For Importation Only) Complete

SECTION E : MULTIPLE SHIPMENT Not Applicable

SECTION F : INVESTIGATOR BROCHURE Complete

SECTION G : ATTESTATIONS & DECLARATION Complete

SUBMIT

PRINT NOTIFICATION

Click for submitted

The status will be changed to EVALUATION again that shown in figure below.

<input type="checkbox"/>	1	CIU-20220124-21	24-01-2022	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	EVALUATION	Q View	P Advice & Receipt
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The user should make the process EVALUATION at back end user.