USER MANUAL FRONT END USER

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

MODUL UTAMA - DEVICE STUDY (FRONT-END USER)

DISEDIAKAN OLEH :

LIST OF CONTENTS

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

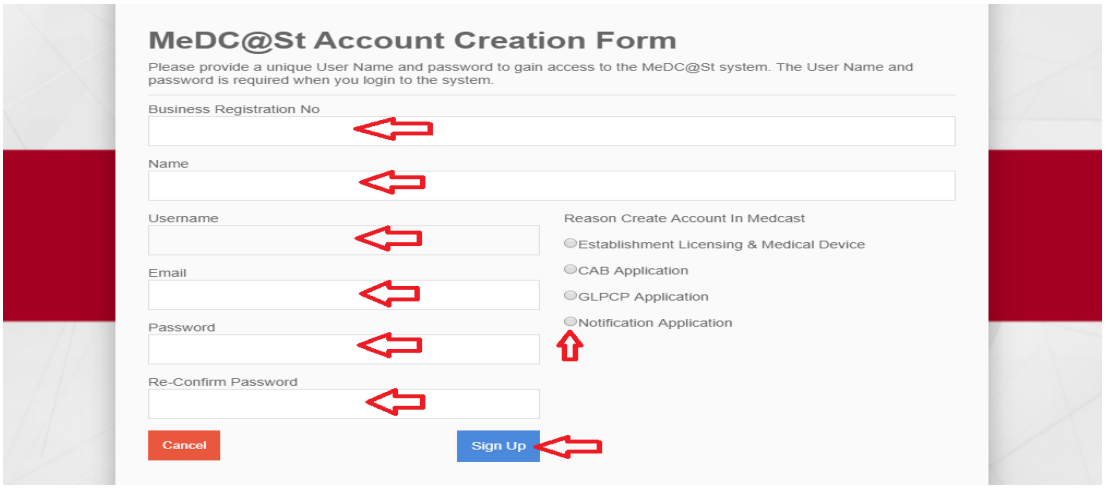
1.1.1 CREATE ACCOUNT

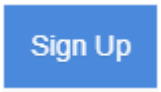
The screen below shows the expected webpage after the address has been key In.

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

click 

for new registration.

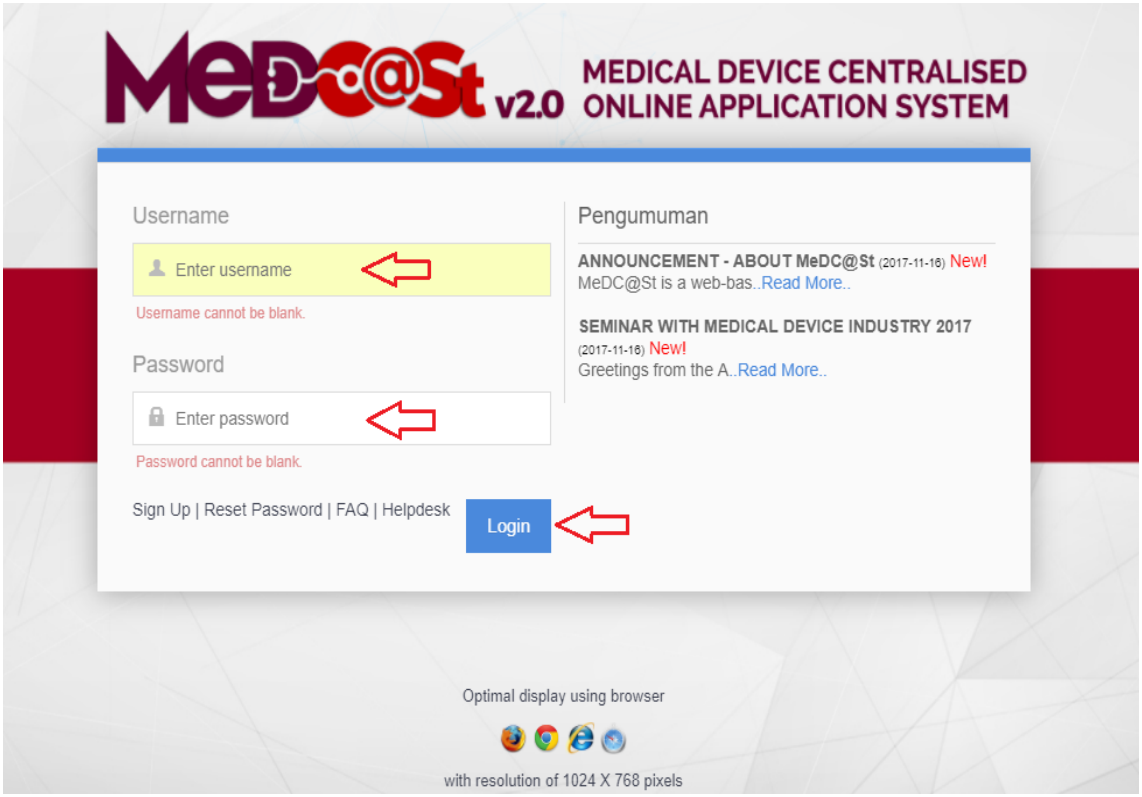


Complete the form and click 

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.

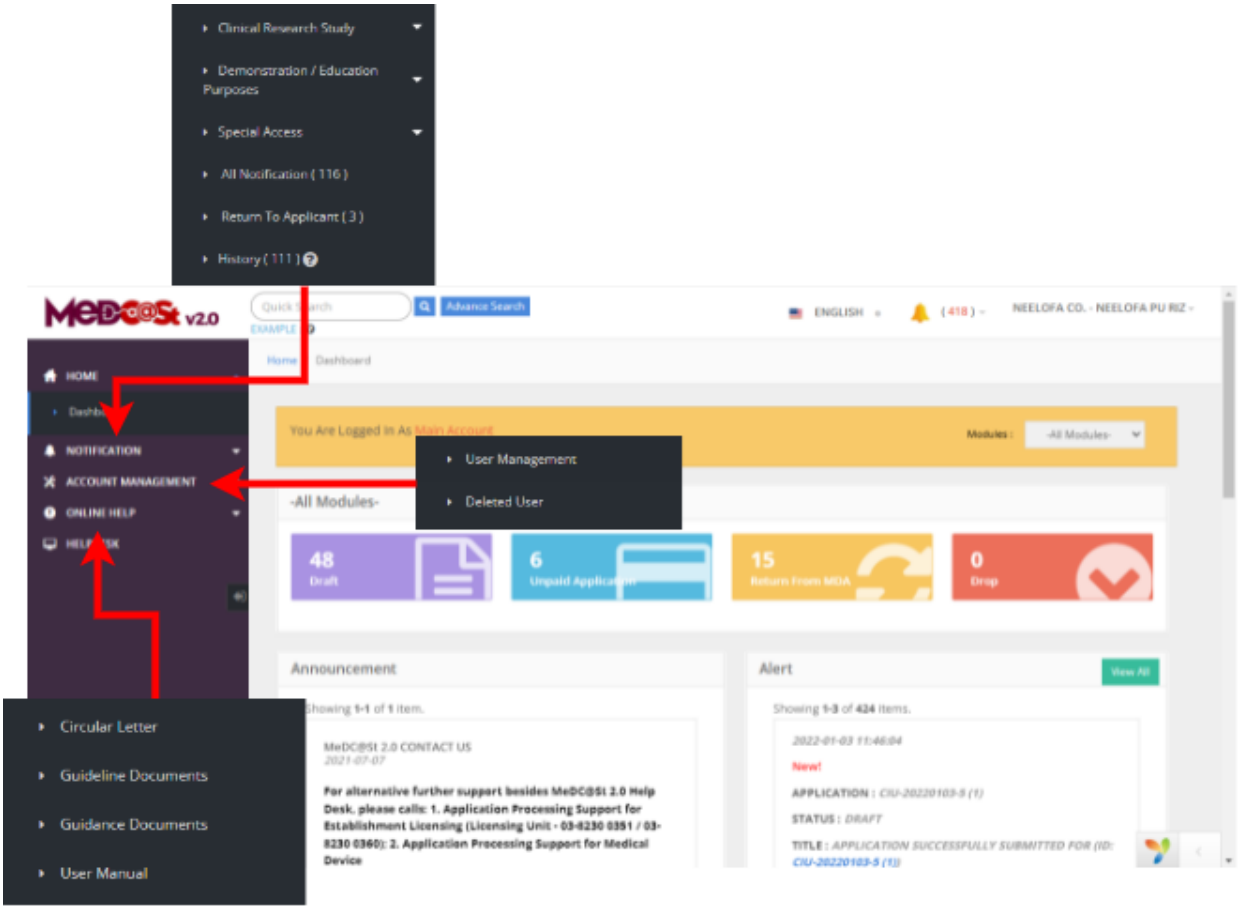


User has to log into the system using registered Username and its respective Password. Click Login to proceed.

2.0 FUNCTIONS

2.1 DASHBOARD

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

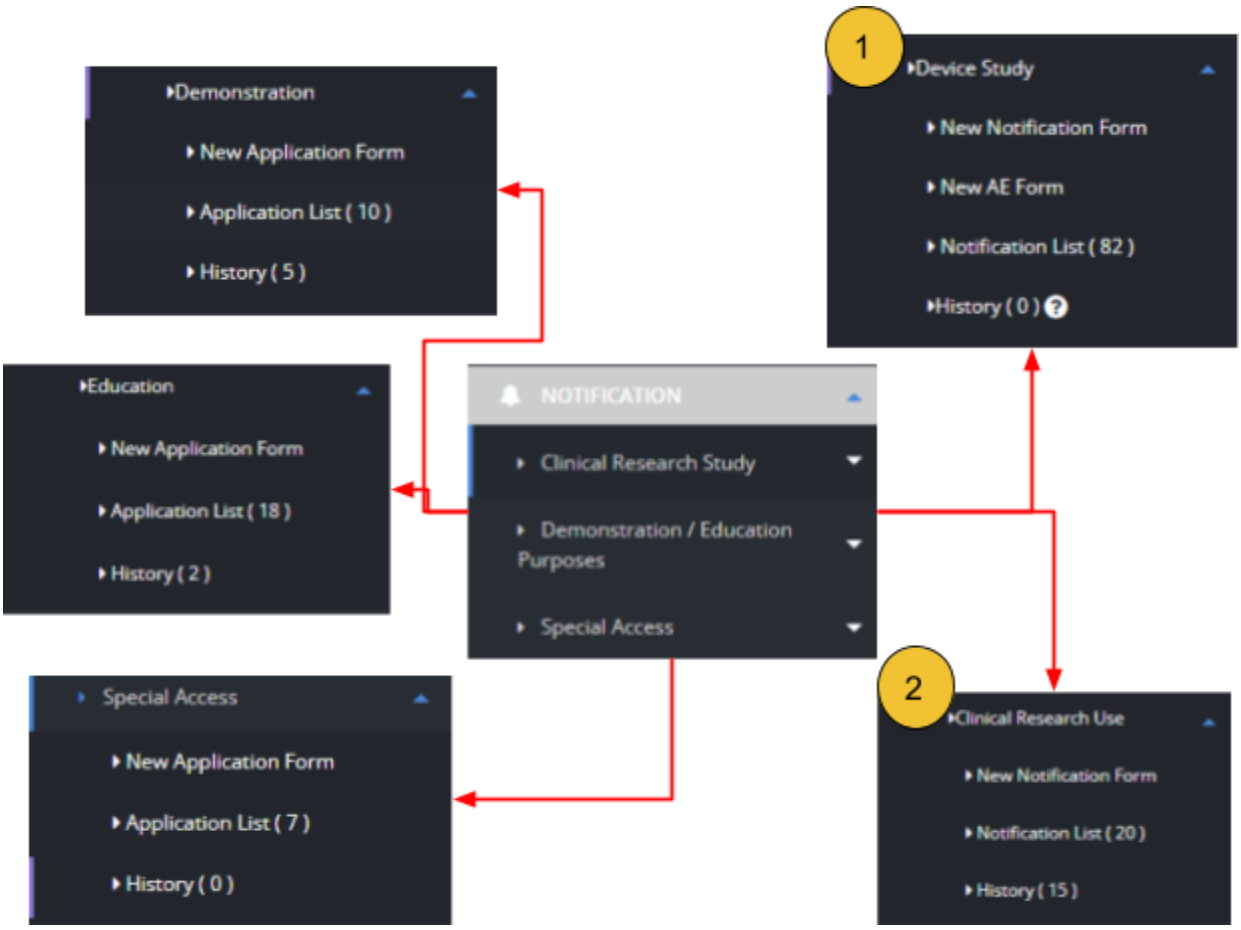


2.2 MENU NOTIFICATION REGISTRATION

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

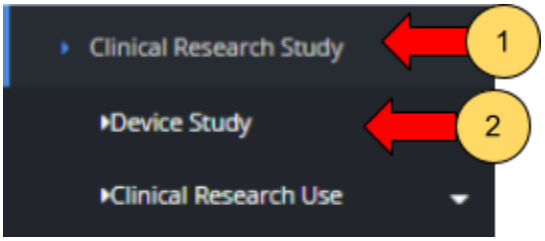


a) CLINICAL RESEARCH STUDY

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

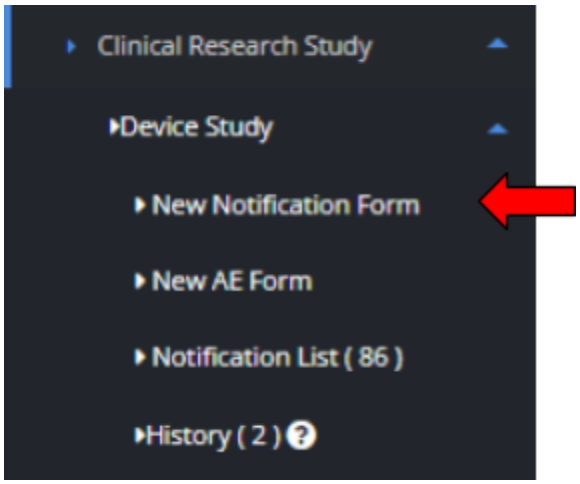
a) New Application



1 - User should click at menu Clinical Research Study.

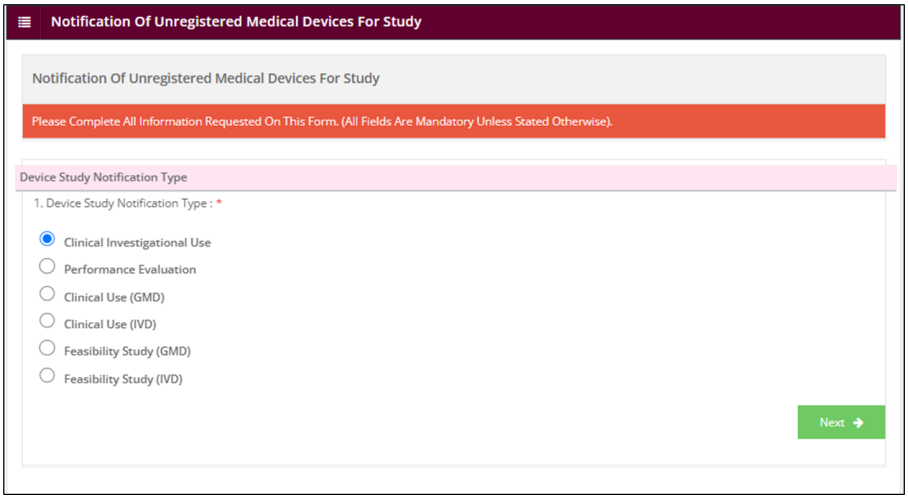
2 - User should click at sub menu Device Study.

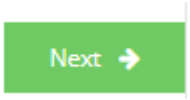
After click at sub menu Device Study, the list down of sub menu will be displayed that shown in Figure below.



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)**



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

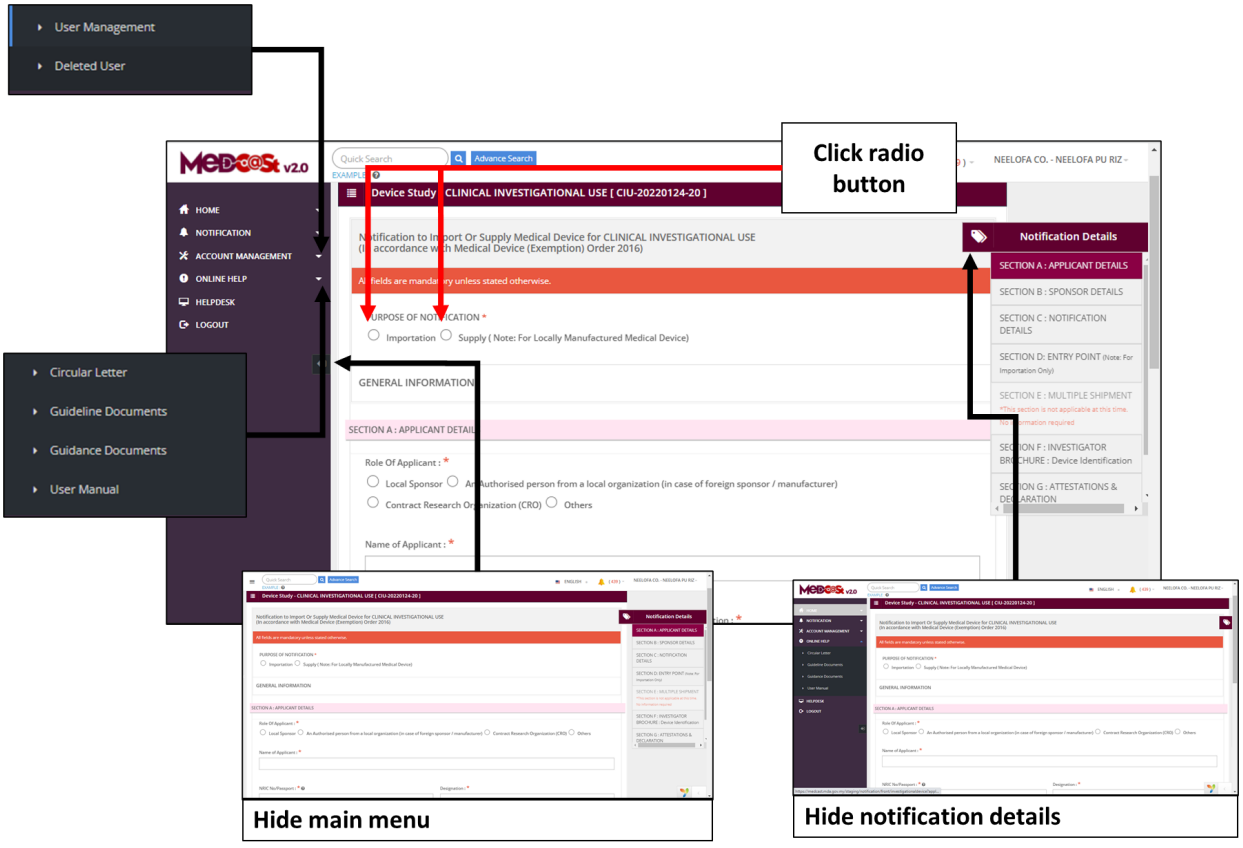
SECTION C : Notification Details

SECTION D : Entry Point

SECTION E : Multiple Shipment **(Disabled)**

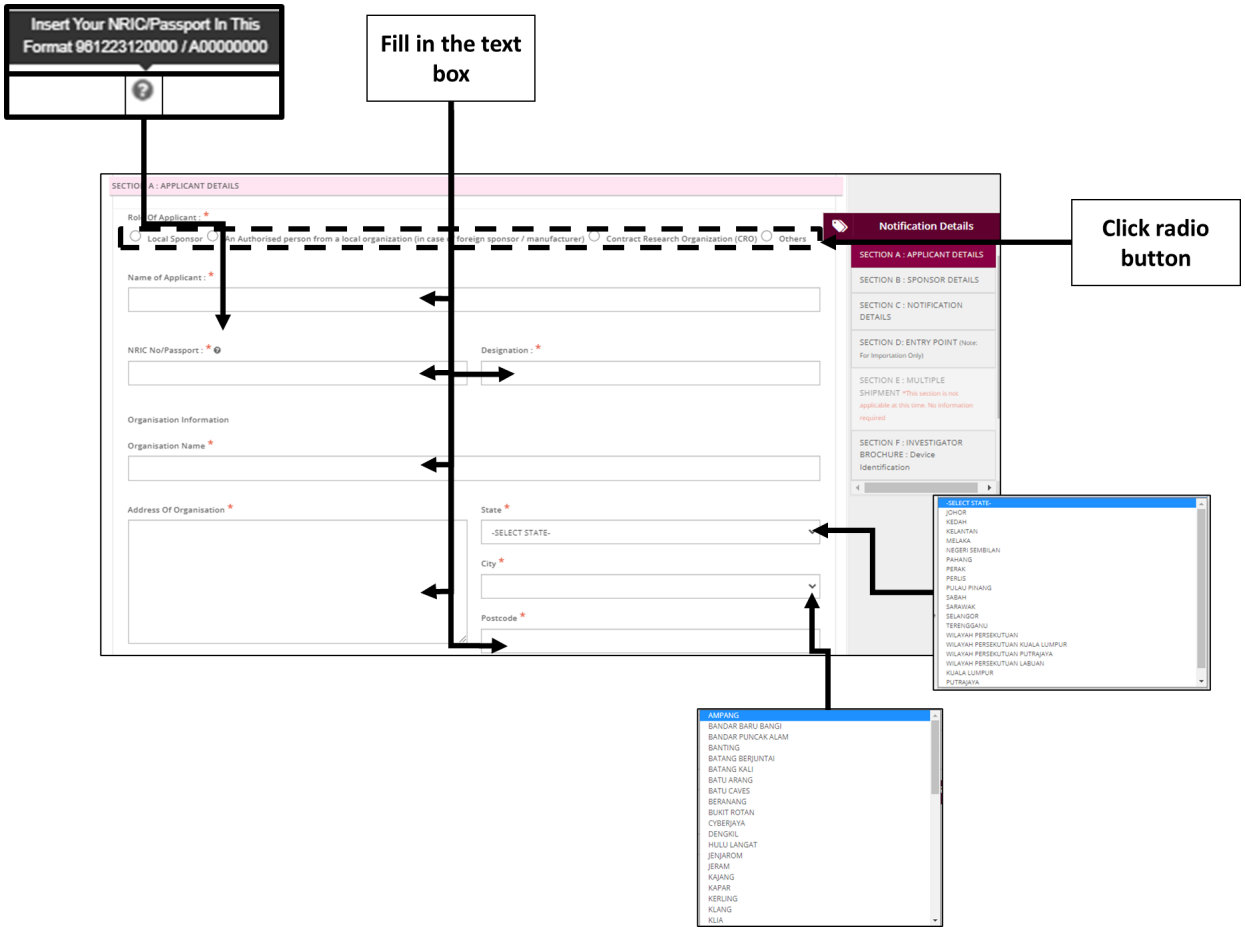
SECTION F : Investigator Brochure: Device Investigation

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.

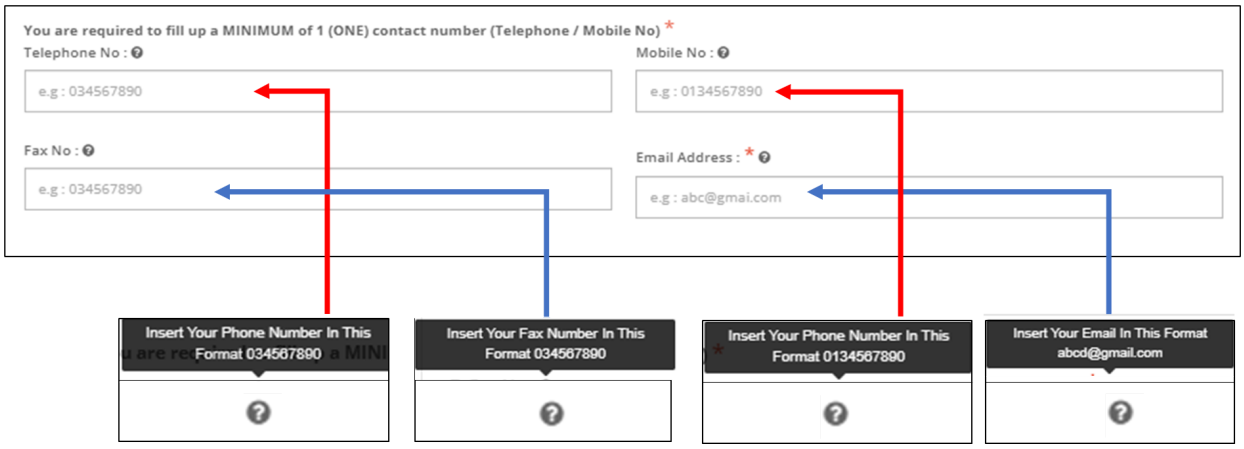
  ii) Address of organisation ->The user should fill in the textbox with address of organisation.

  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 will appear "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 

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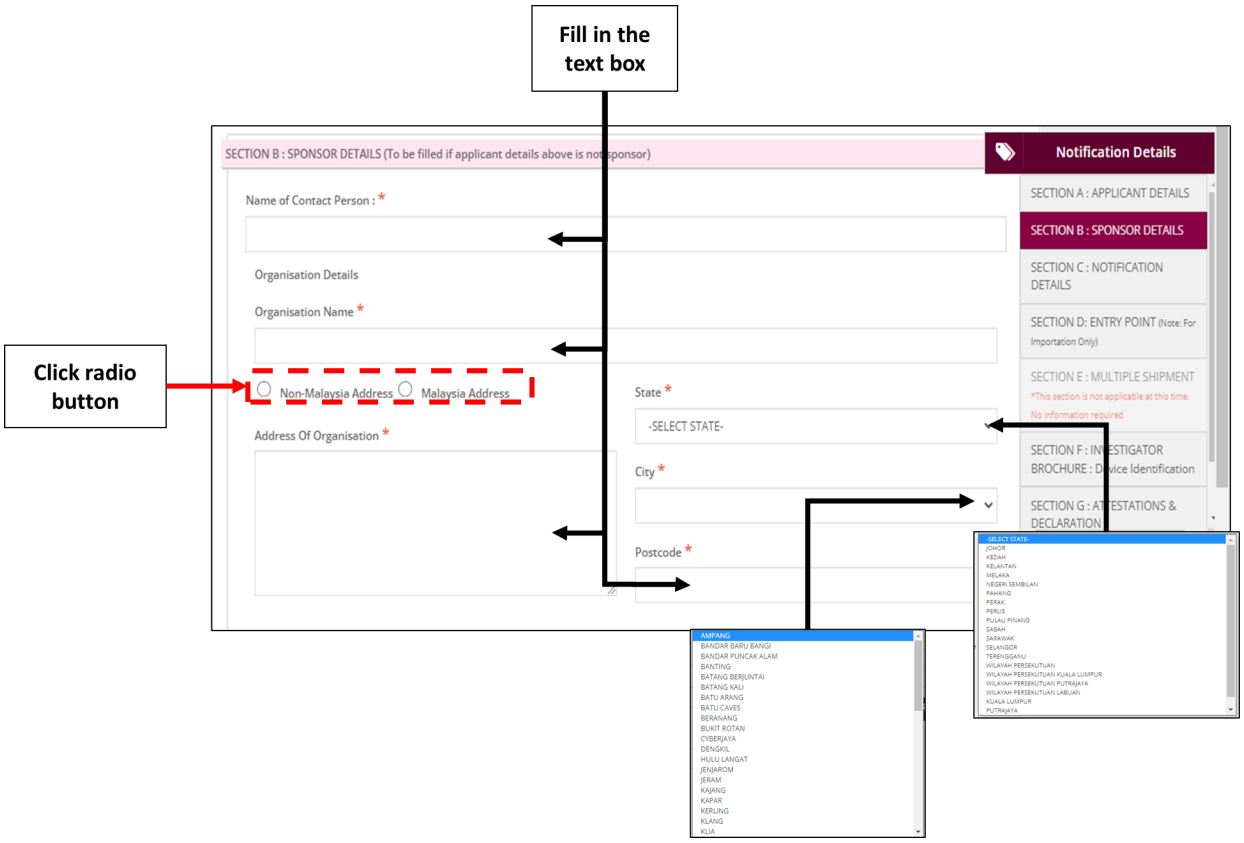
Section B: Sponsor Details



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.

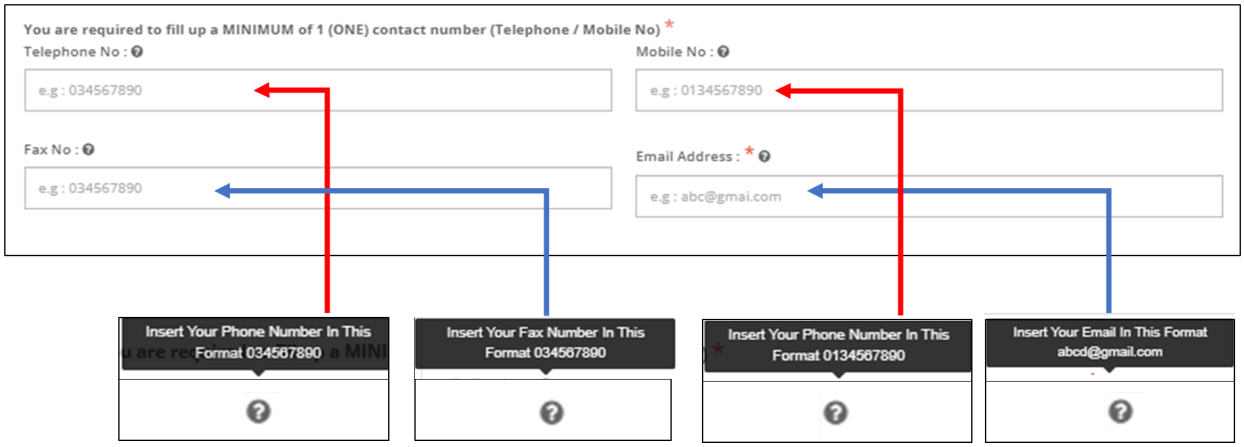
  ii) Address of organisation -> The user should fill in the textbox with address of organisation.

  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 

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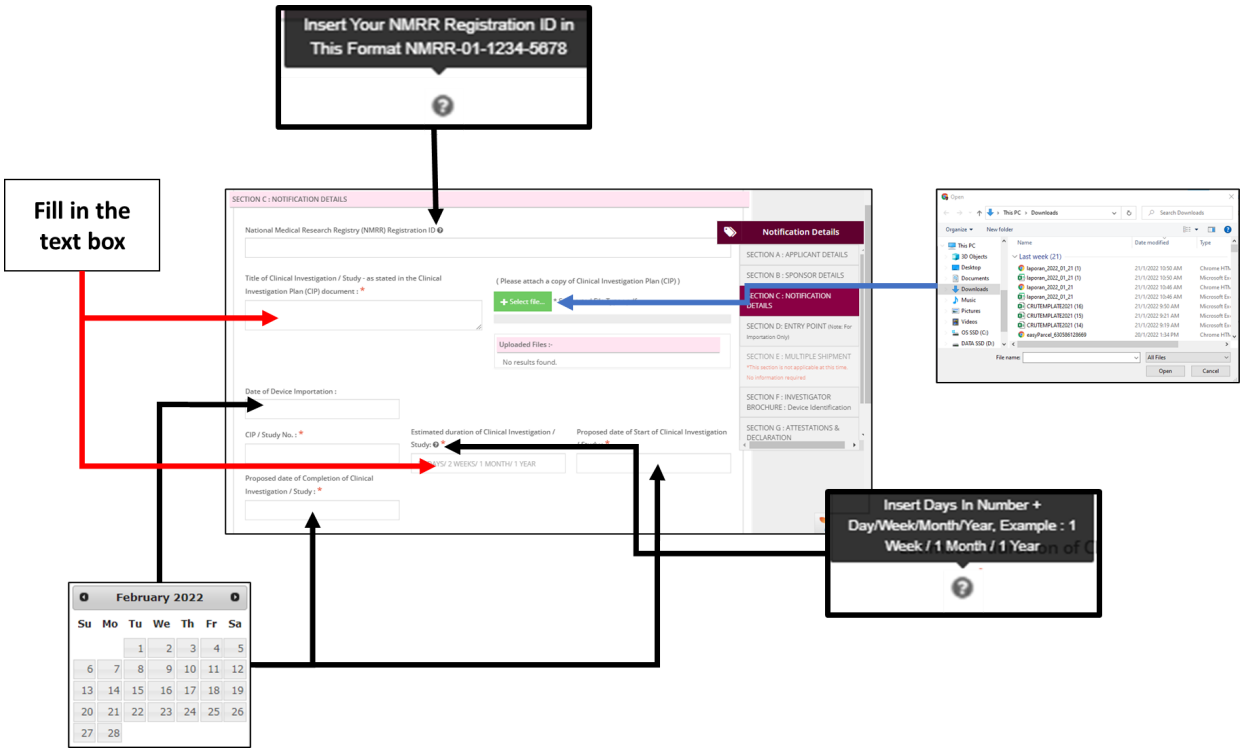
that shown in figure above. Then, user should click at button 

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 + Select file... 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 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.

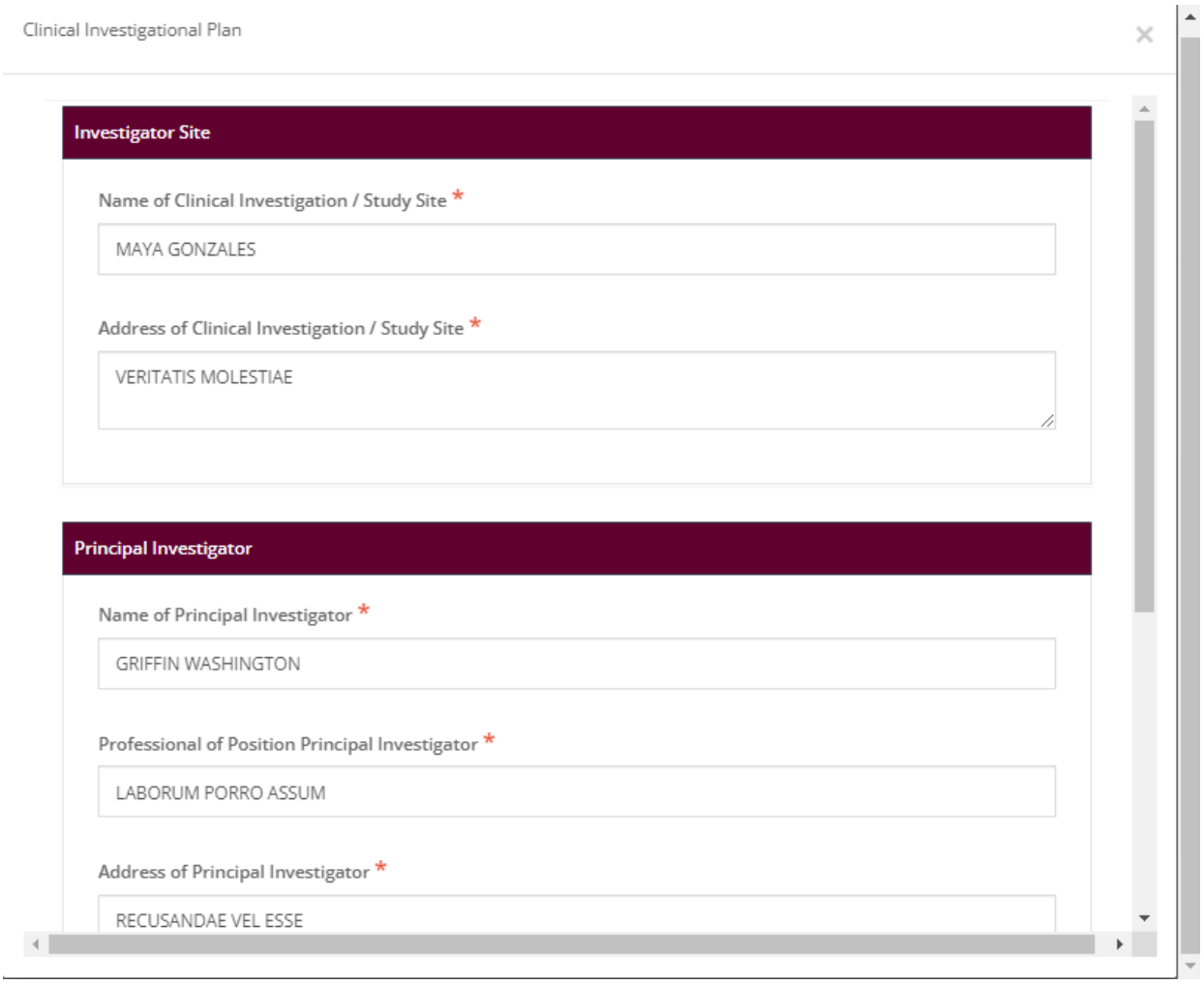
After all the forms are complete filled, the user should click at 

to save the details.


Clinical Investigational Plan
Professional of Position Principal Investigator *
Address of Principal Investigator *
Contact Number of Principal Investigator *
e.g : 0134567890
Email of Principal Investigator *
Save
Click at button
Click for move up and down

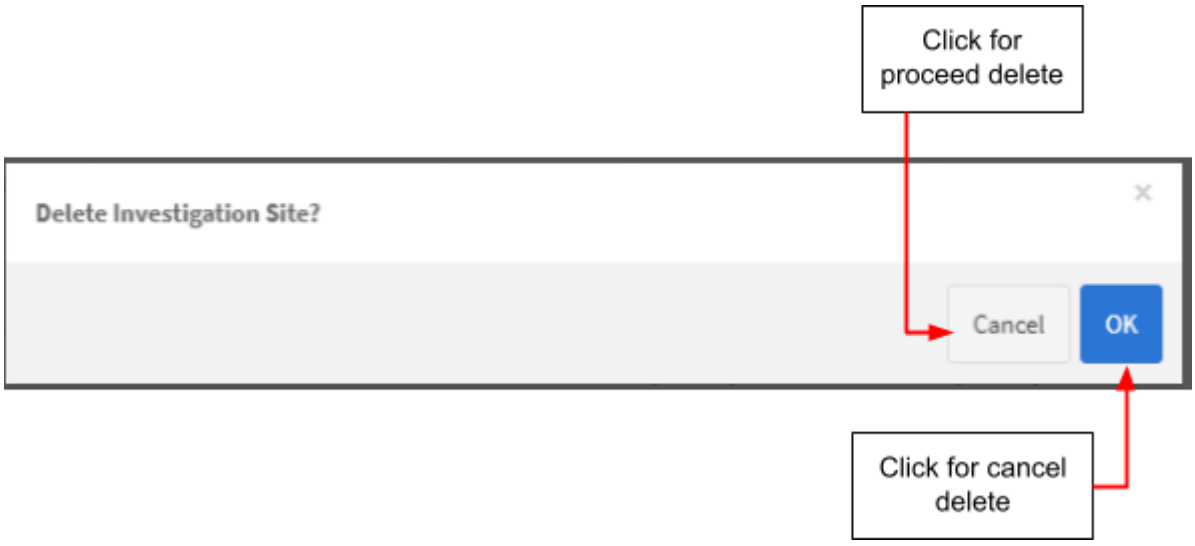
In addition, the details of the investigation site or study site will be displayed in the table shown in the figure below.

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.



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

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.

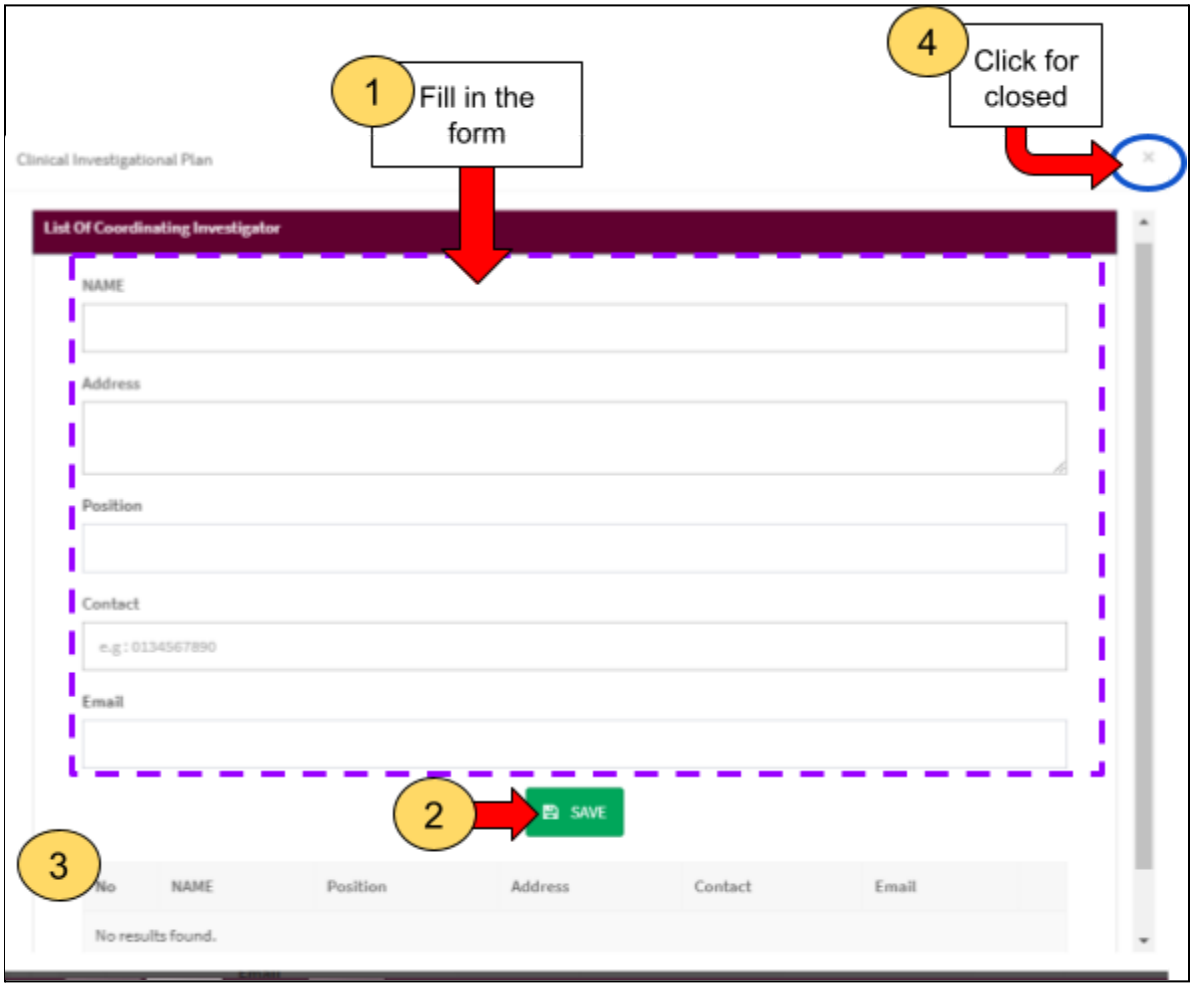
After that, user should click button 

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.

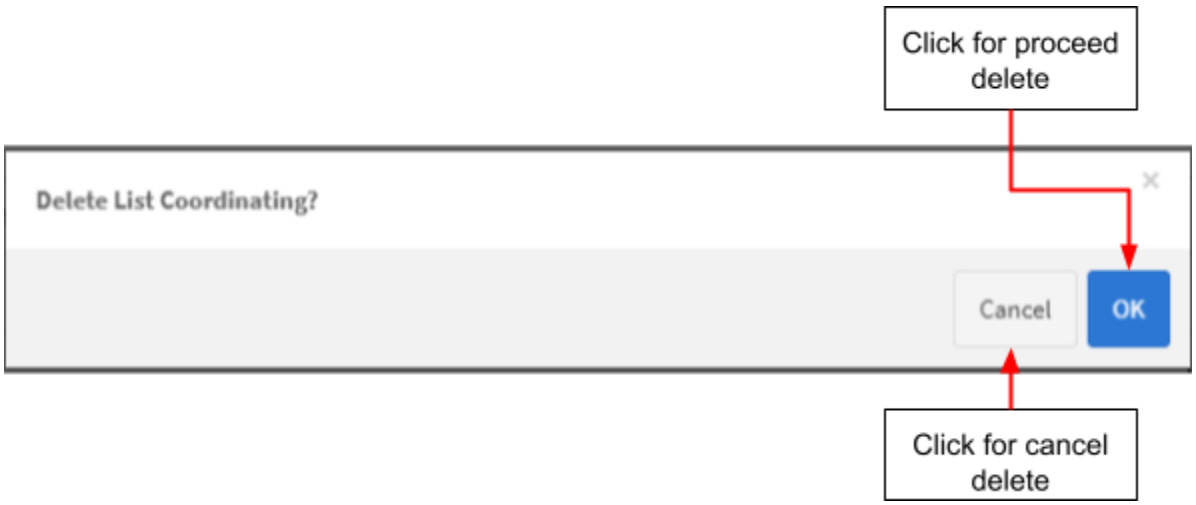
The form of list coordinating investigator will be displayed that shown in the figure below.



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

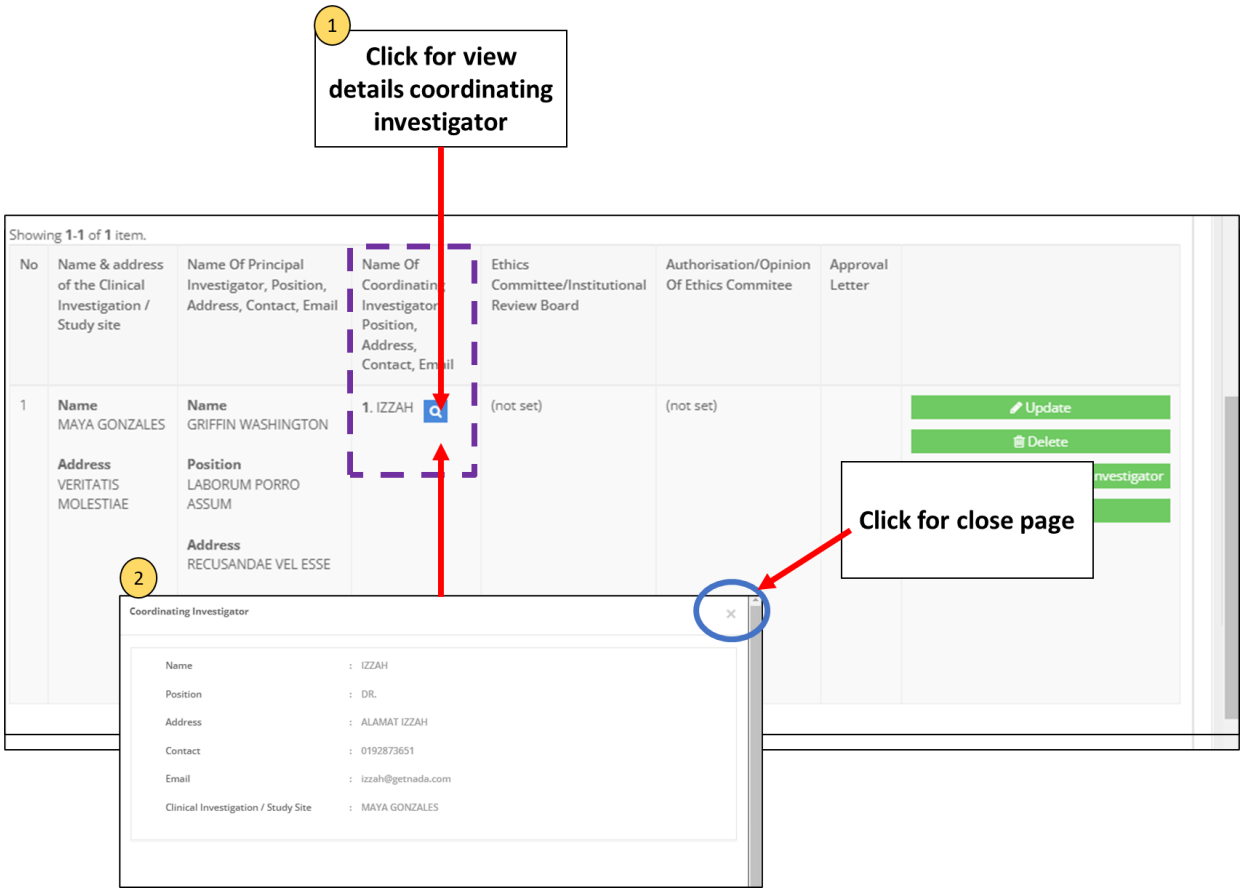
3 -> The details of coordinating investigator will be displayed in table after clicking button “save”. Example details are:

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.

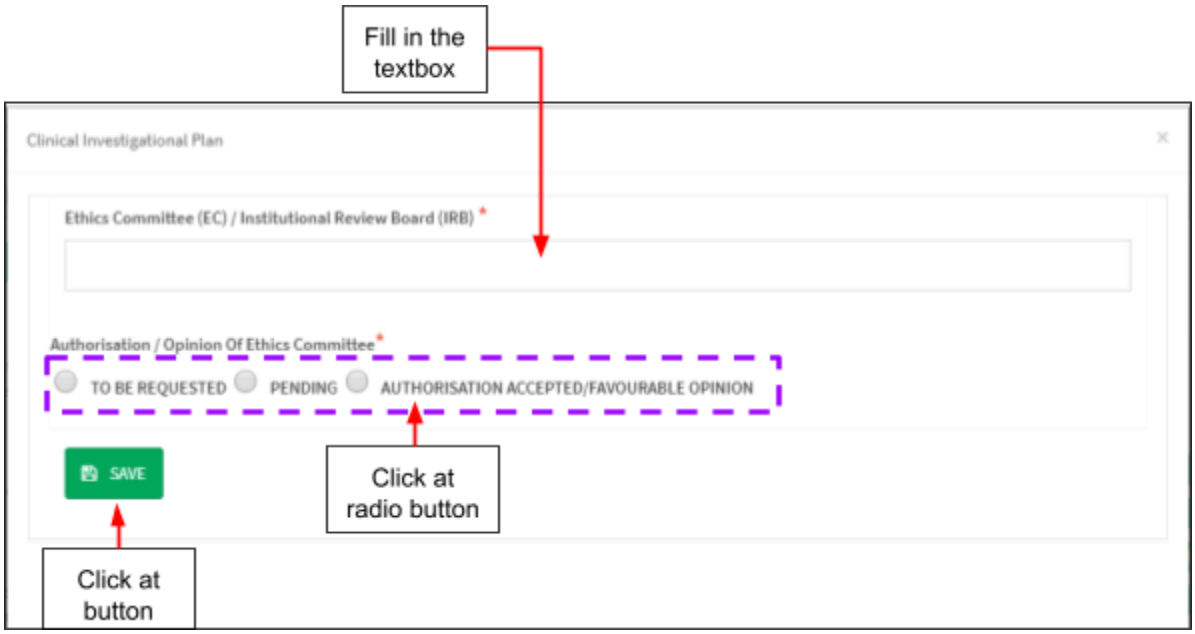


-> The user should click to close the page.

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



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.



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

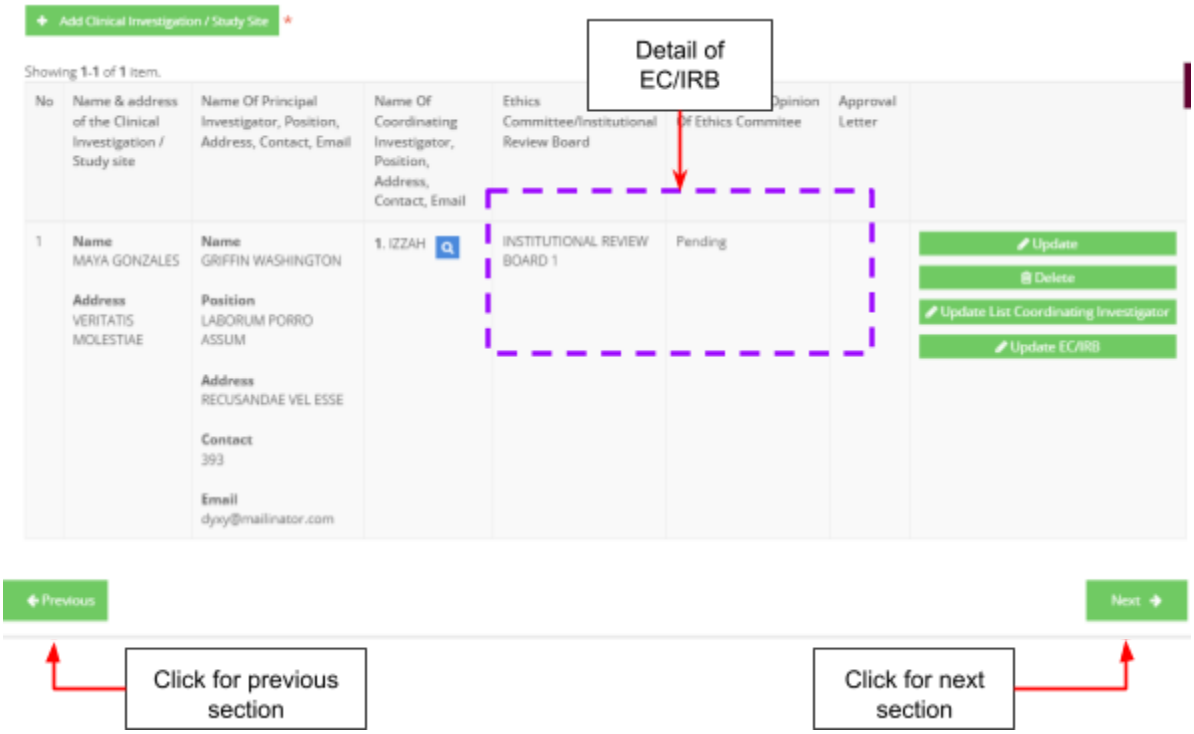
- The user should fill in the textbox that provided.

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.



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 

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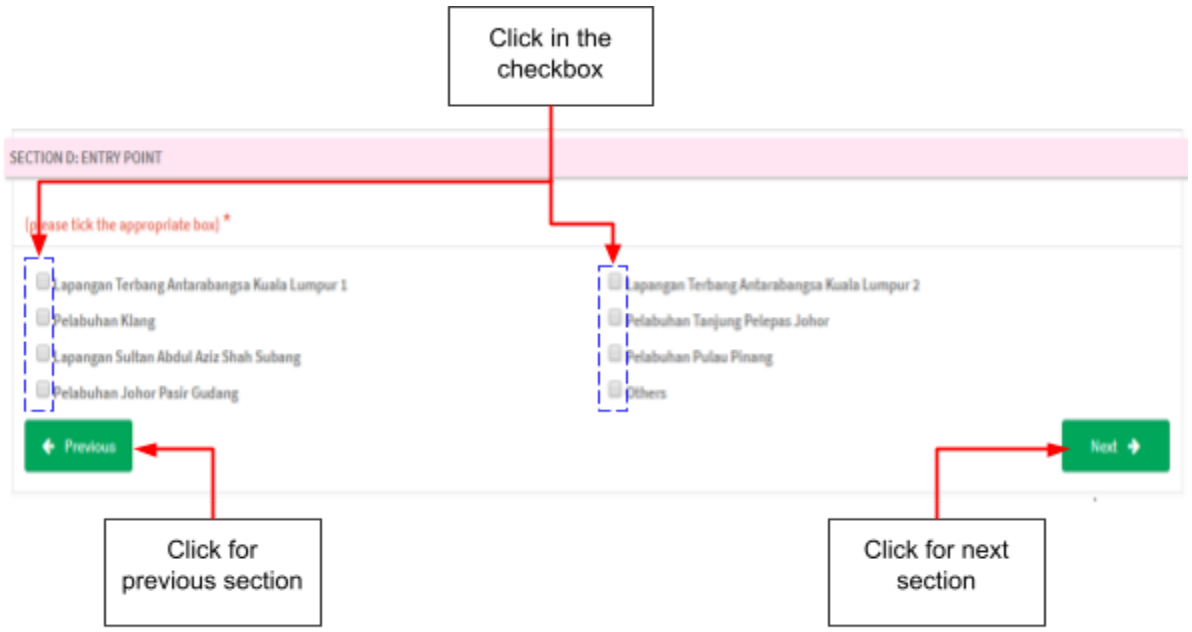
Then, user should click at button 

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.

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

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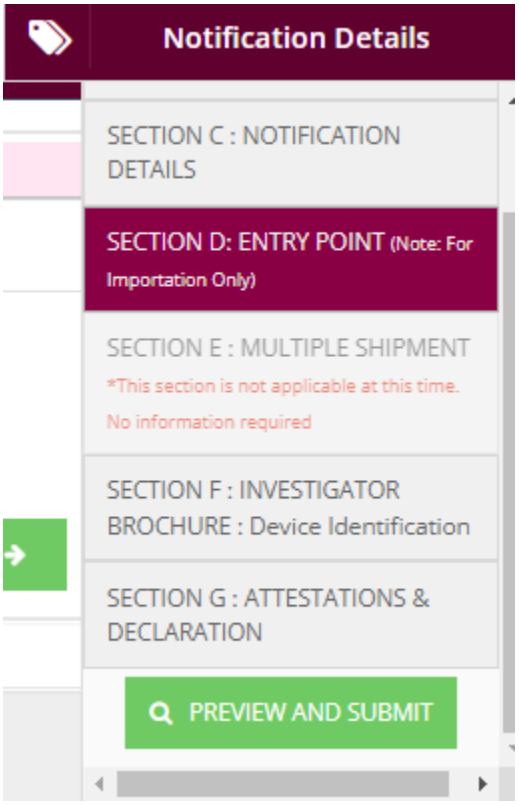
that shown in figure above. Then, user should click at button 

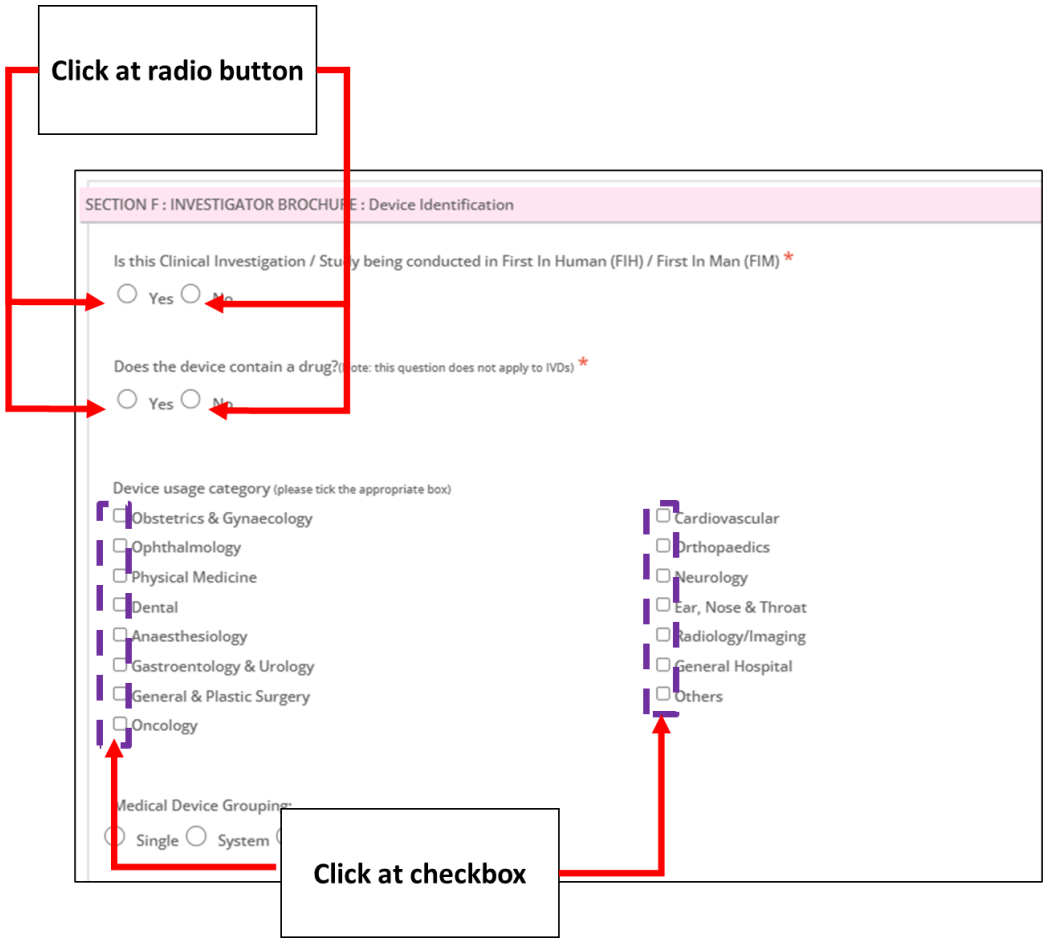
to the next stage.

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.

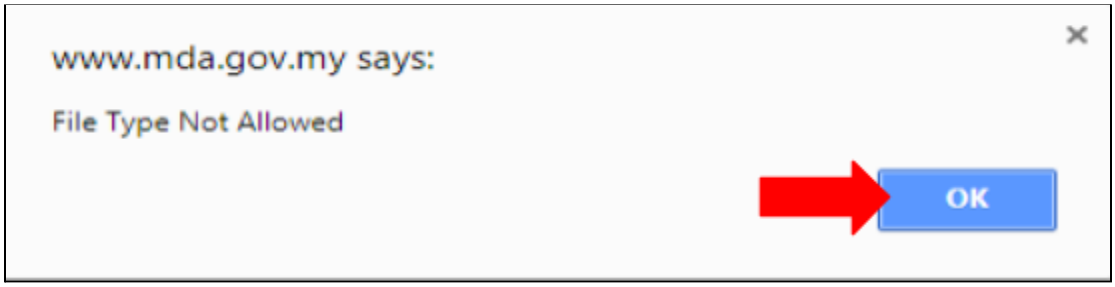
- **Medical Device Grouping**

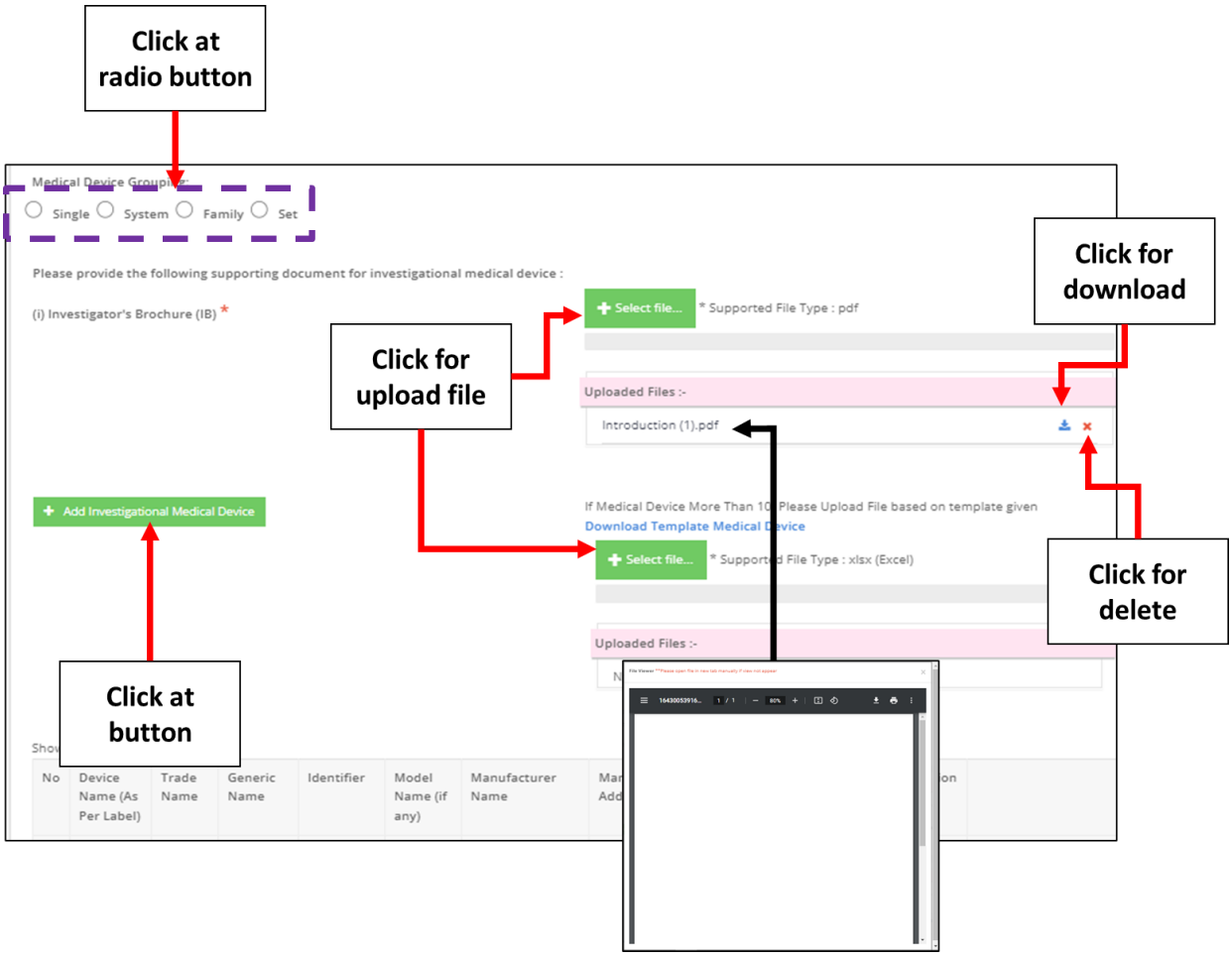
The user should click on radio button that provided shown in figure above. The Medical Device Grouping has four types which are single, family, system and set. The user should choose the group of medical device.

- **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  and the form for investigational medical device will be displayed. The figure below shows the form of investigational medical device.

Add Investigational Medical Device

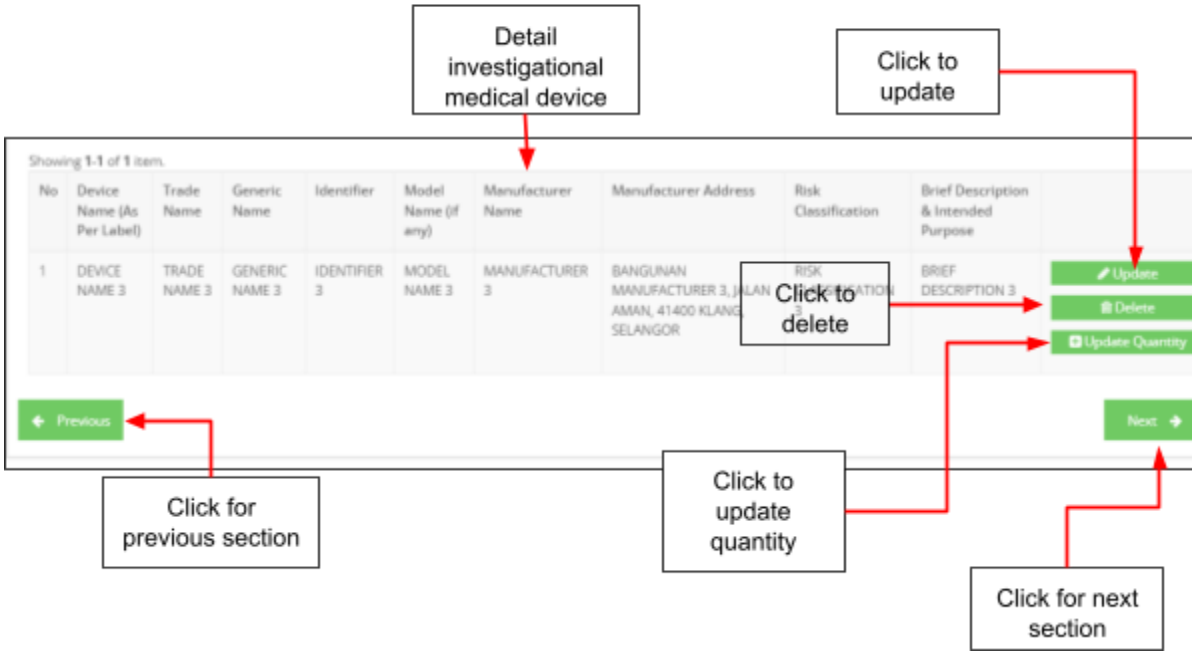
The symbol "*" means required field.

- 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

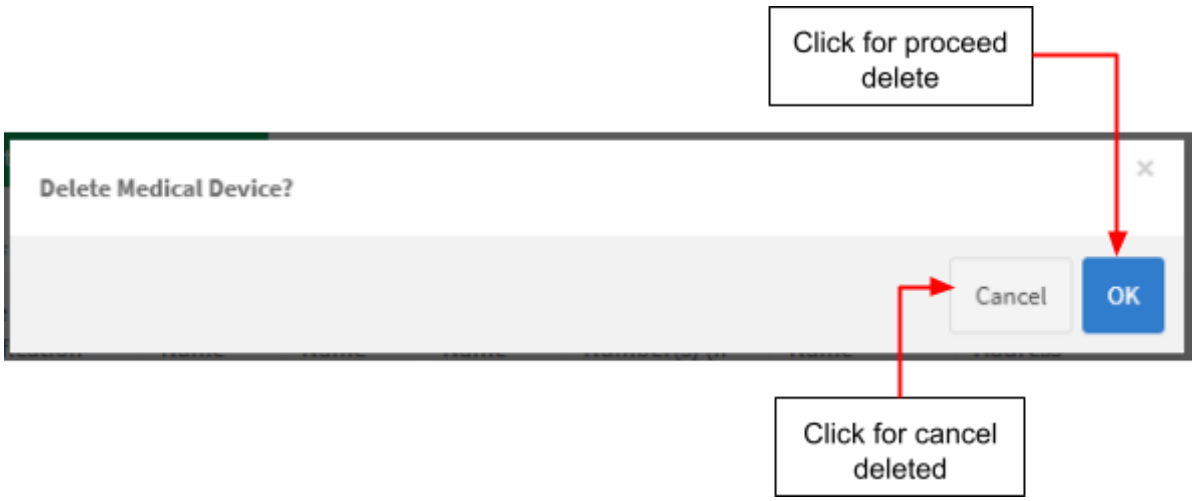
fill the textbox that provided. If user don't fill the field, the message "Trade Name cannot be blank." will be displayed.

- 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 user should click at button  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 Delete 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.

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	Update Delete Update Quantity

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

.

OR

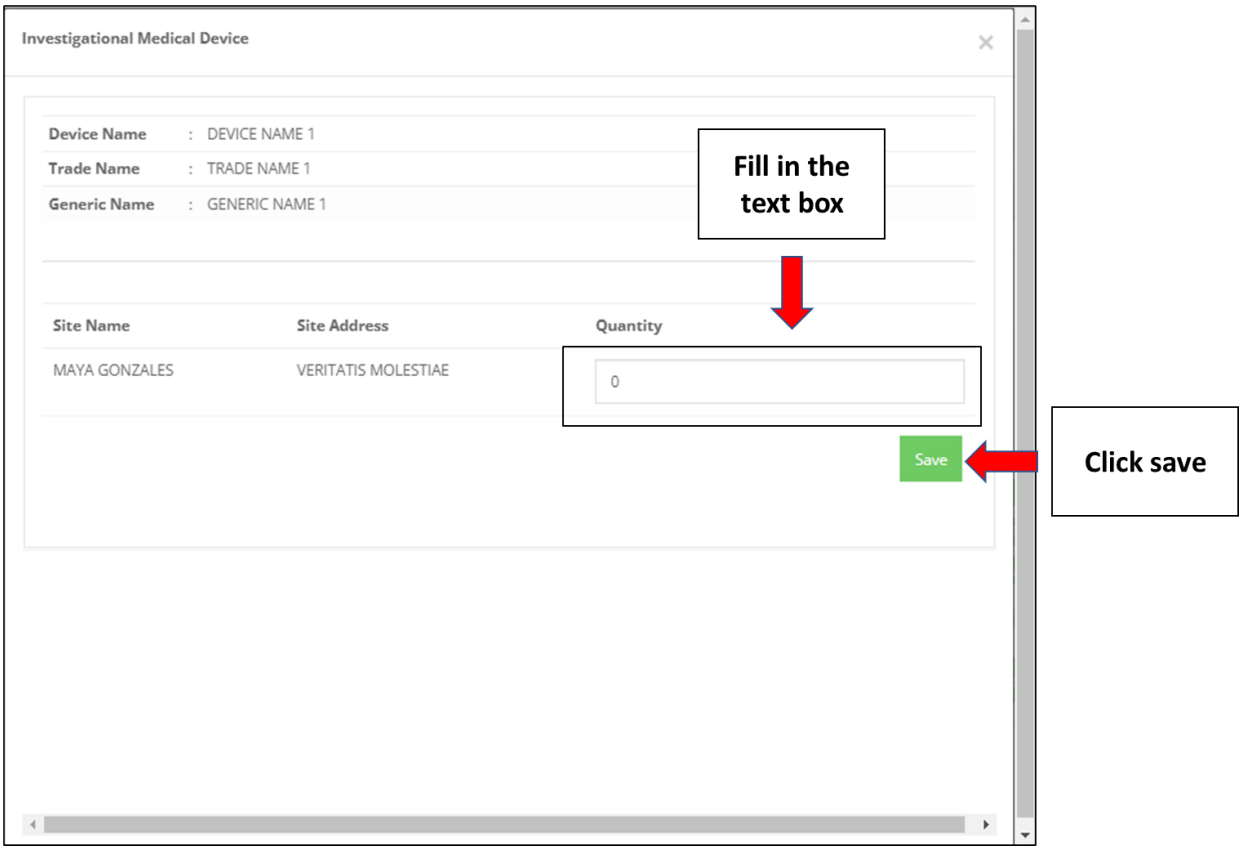
If the medical device are more than 10, the user can download the excel template by clicking 

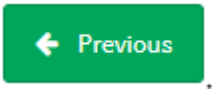
and upload the excel file by clicking 

. 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.



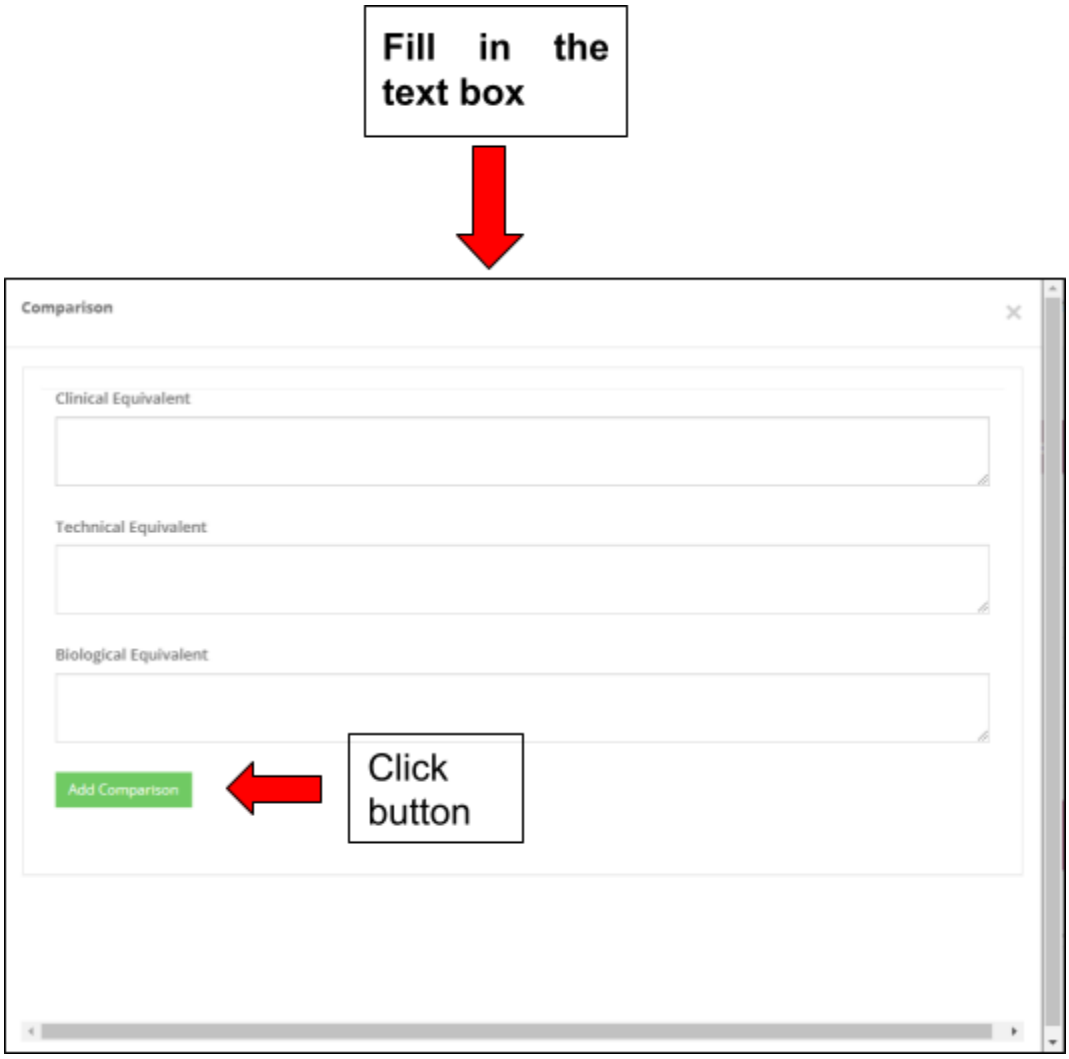
If user want back to previous section, user should click at button 

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

to the next section.

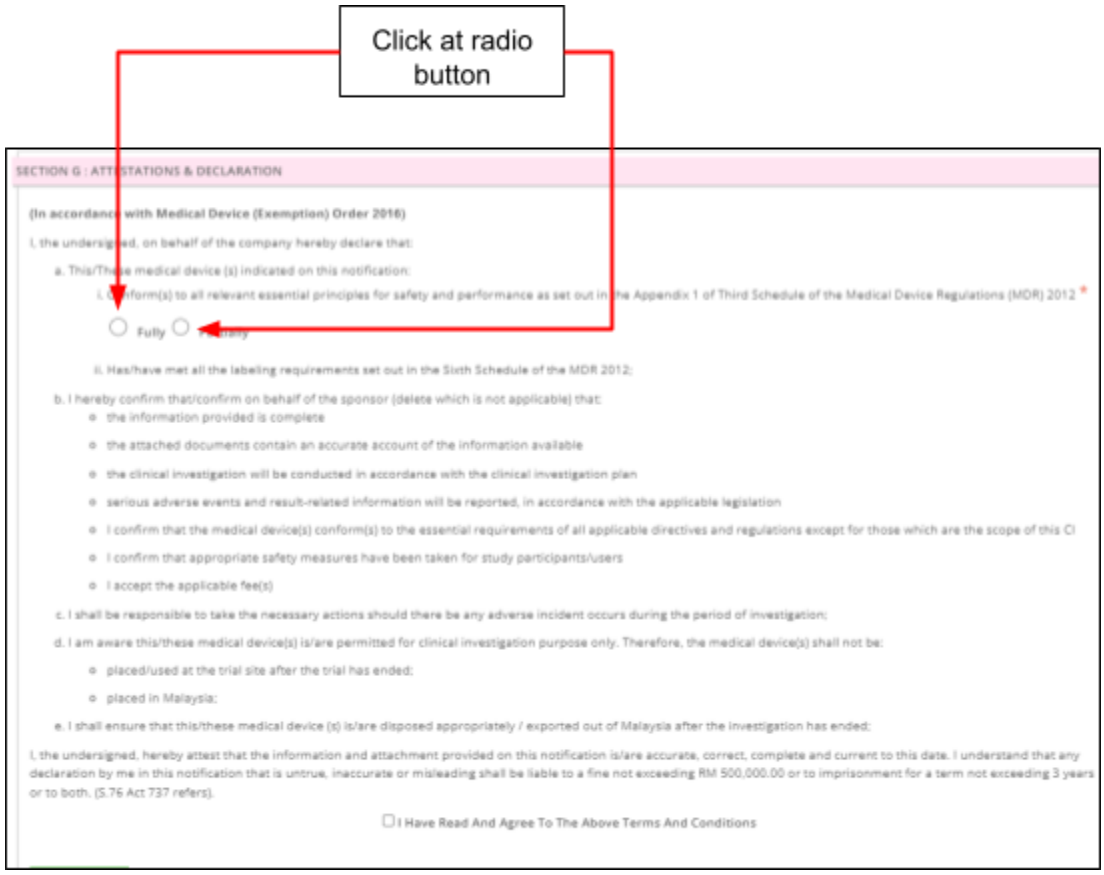
For **Clinical Use (GMD)** and **Clinical Use (IVD)**, the user need to fill the comparison by clicking the 

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

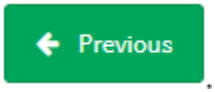

Fill in the text box
Comparison
Clinical Equivalent
Technical Equivalent
Biological Equivalent
Add Comparison
Click button

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.

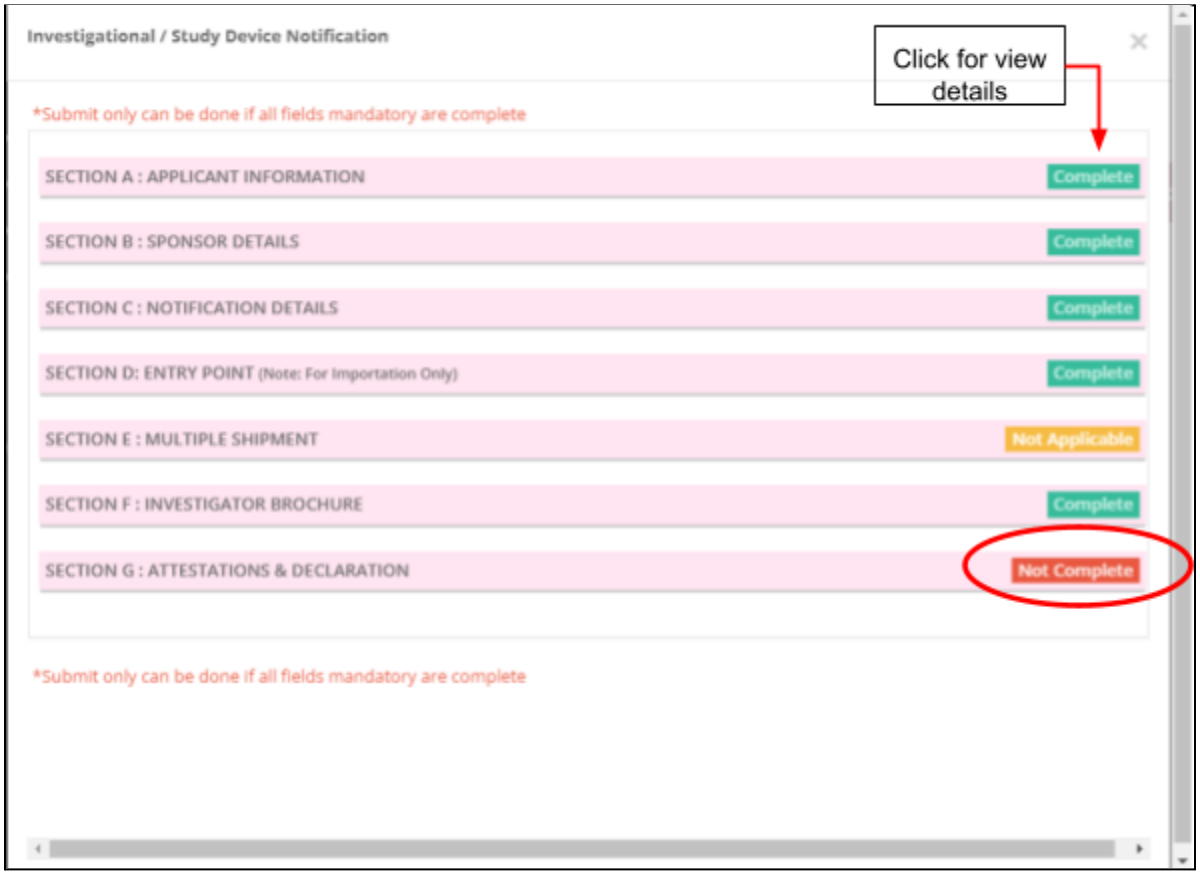


The user must click on checkbox  that agree in terms and conditions that shown in the figure below.

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.

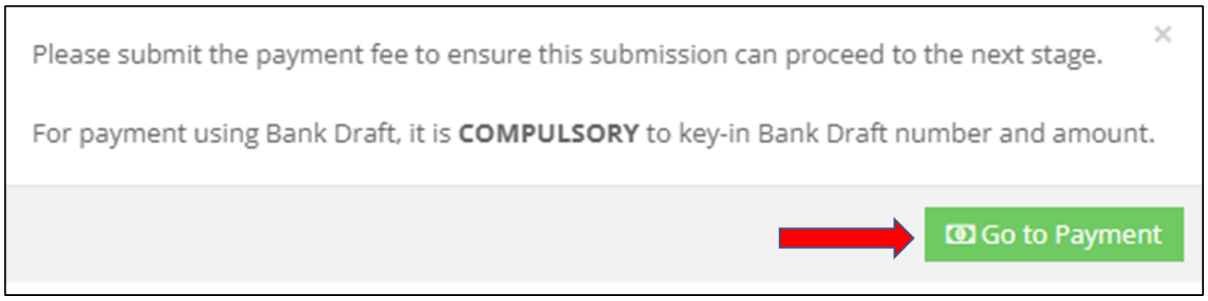


If status **Not Complete** , the user should fill it again to change status **Complete** and the button “submit” will be displayed.

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

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

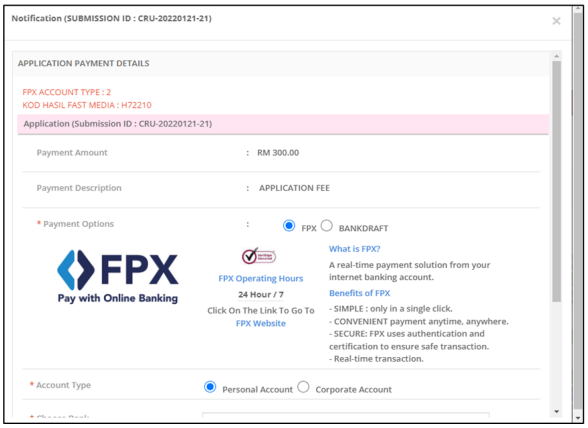
using Bank Draft, it is **COMPULSORY** to key-in Bank Draft number and amount." appeared.



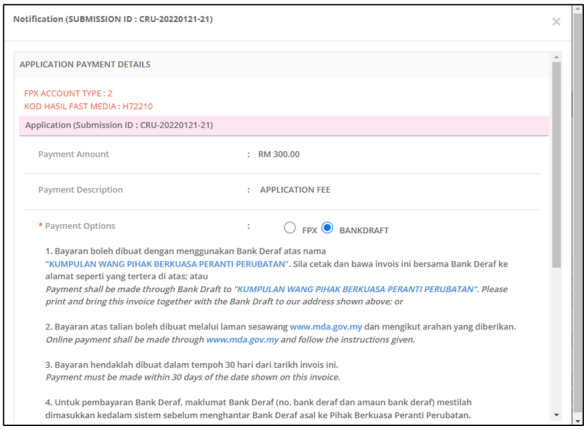
The user can click Go to Payment button to make a payment or the user can click the × icon to make a payment later.

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

FPX method

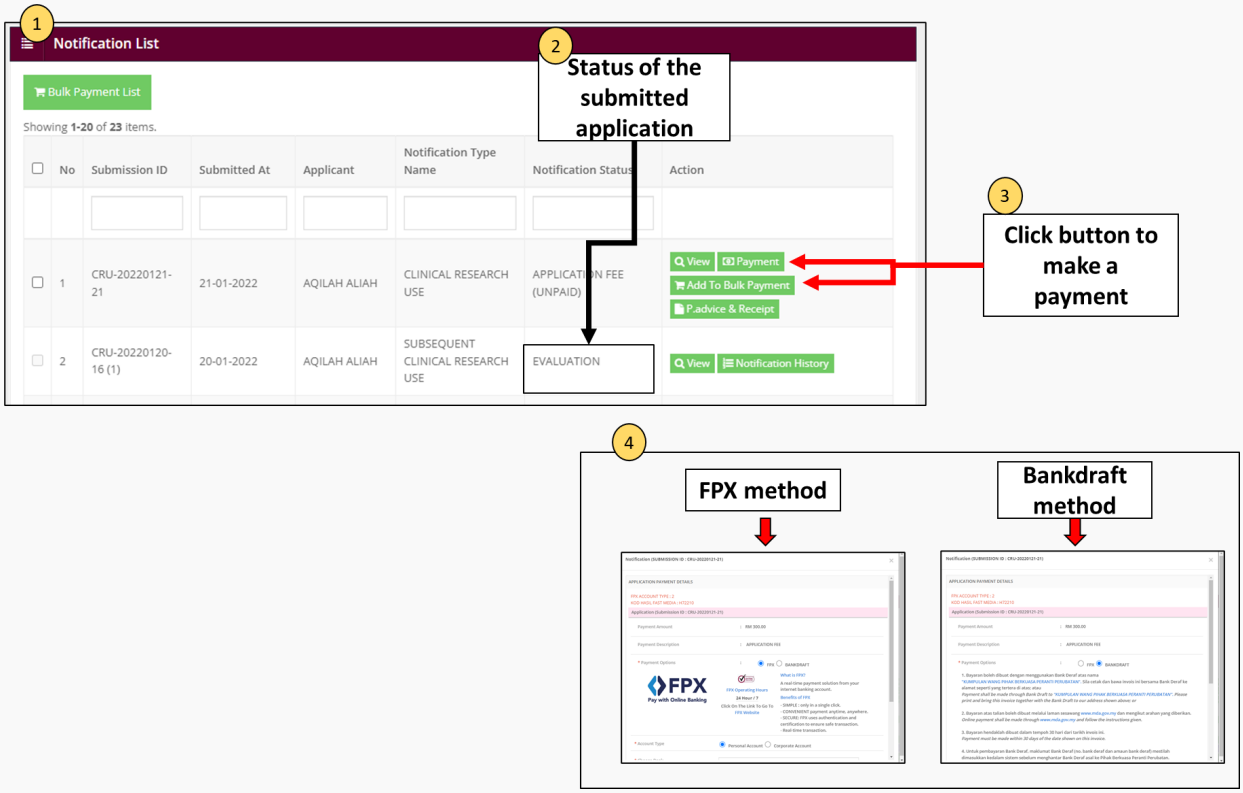


Bankdraft method

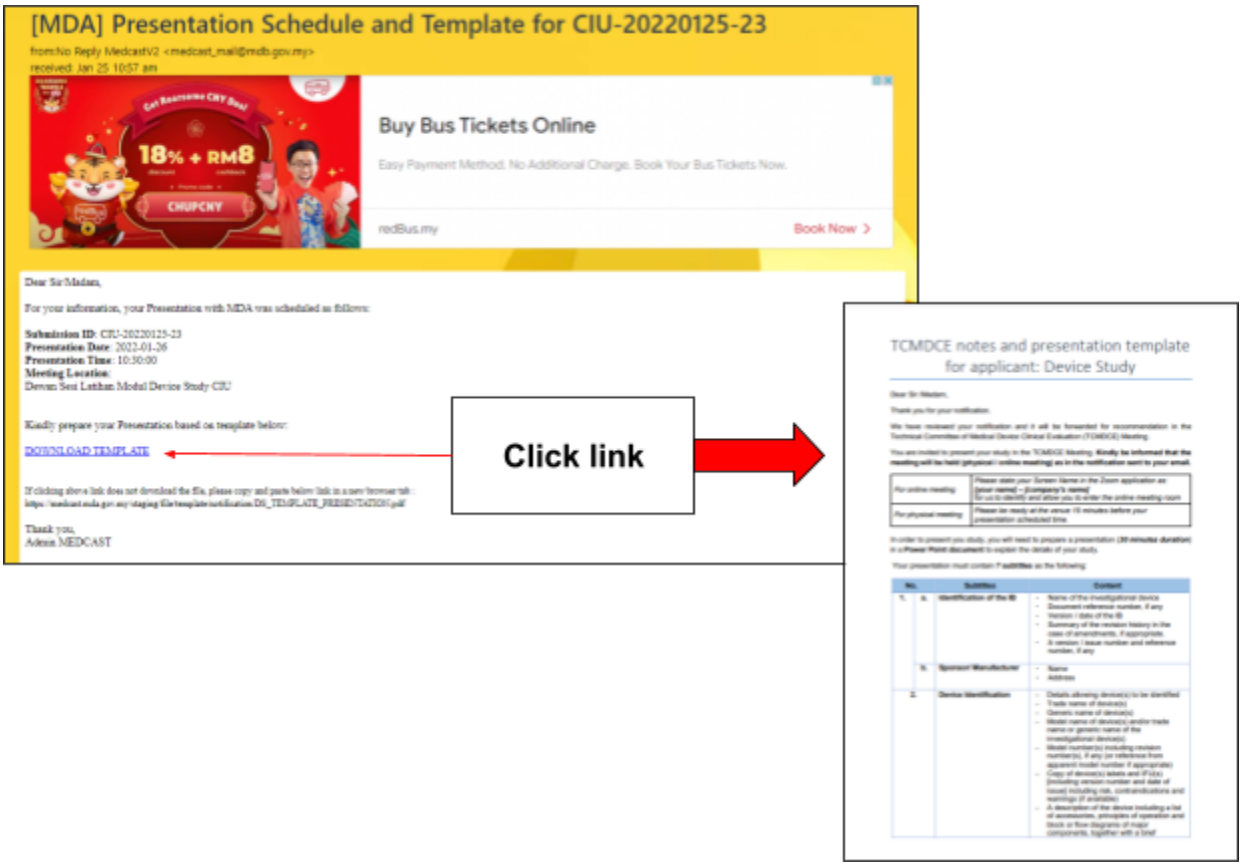


The Figure below shows the page if the user click the × icon to make a payment later.

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.



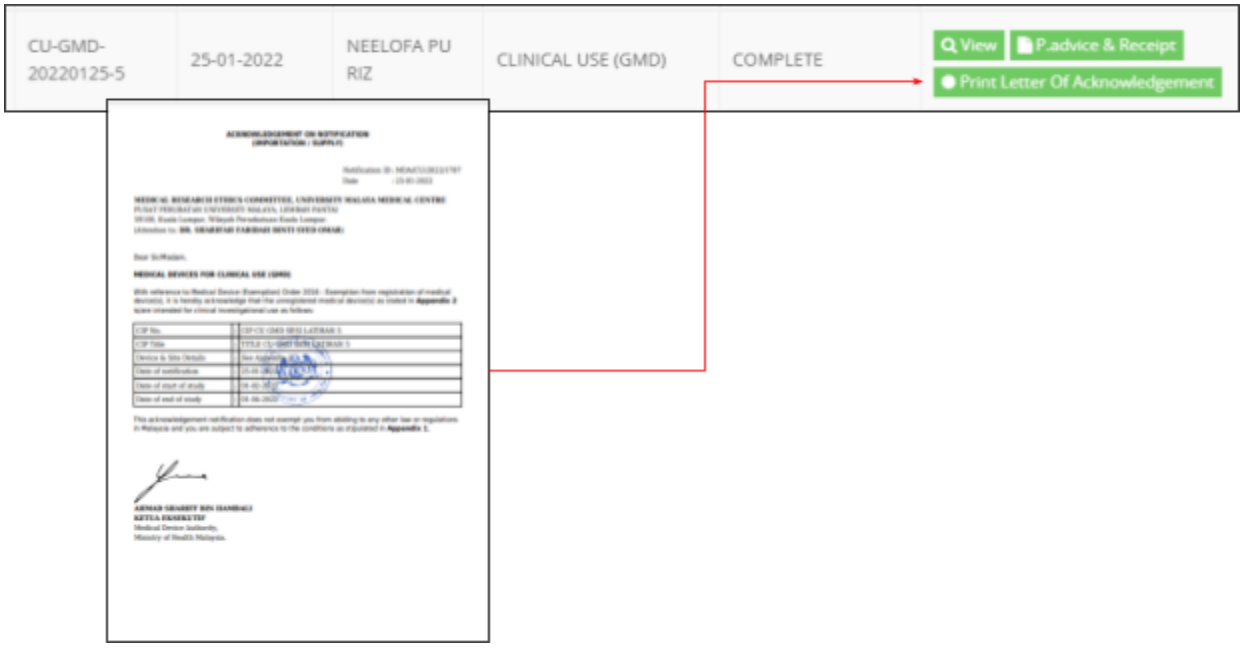
The user received JKTPKPP meeting details email notification once their notification application is in JKTPKPP (EVALUATION) . Figure below shows the email notification that will be received by the front-end user. The user click DOWNLOAD TEMPLATE to download the presentation template.


[MDA] Presentation Schedule and Template for CIU-20220125-23
Buy Bus Tickets Online
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:
Devan Seni Latihan Modul Device Study CIU
Kindly prepare your Presentation based on template below:
DOWNLOAD TEMPLATE
Thank you,
Admin MEDCAST
Click link
TCMDCE notes and presentation template for applicant: Device Study

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

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

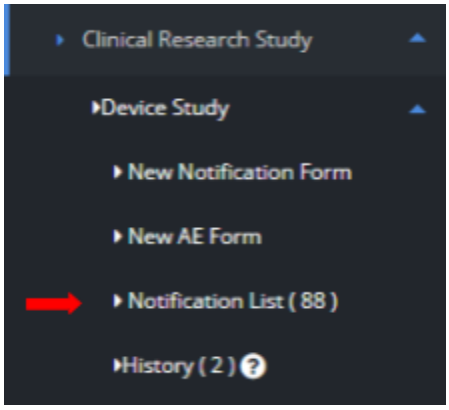
- **Approval Letter: New Notification**



- **Approval Letter: Subsequent Notification**

b) Subsequent application

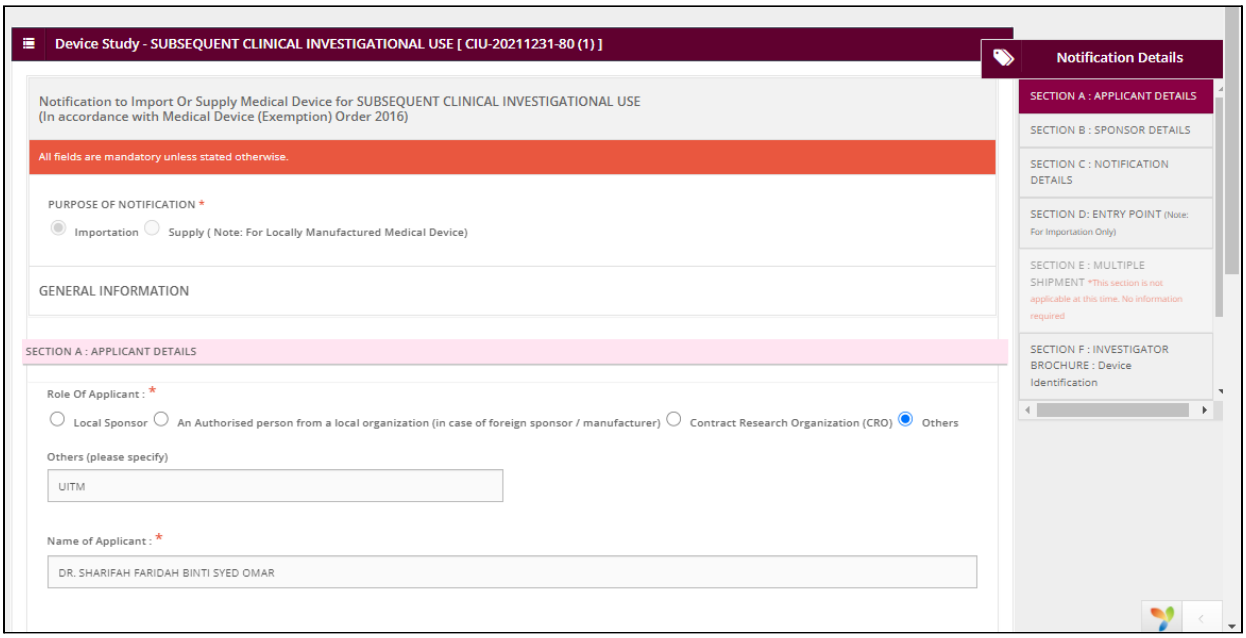
User click on the Application List at Clinical Research Study -> Device Study -> Notification List



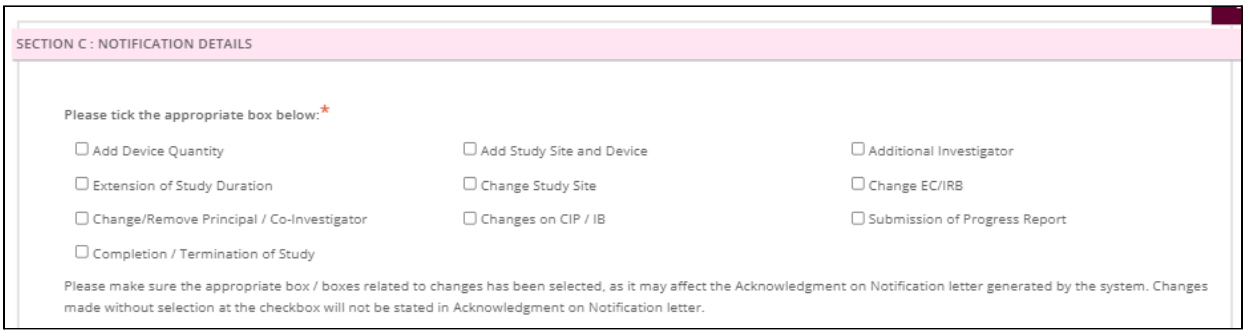
The system will display page of list application Investigational Use.

☐	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
☐	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
☐	16	FS-GMD-20211231-13	31-12-2021	NEELOFA PU RIZ	FEASIBILITY STUDY (GMD)	COMPLETE	View, P.advice & Receipt, Print Letter Of Acknowledgement
☐	17	CIU-20211231-80	31-12-2021	NEELOFA PU RIZ	CLINICAL INVESTIGATIONAL USE	COMPLETE	View, P.advice & Receipt, Print Letter Of Acknowledgement
☐	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
☐	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**

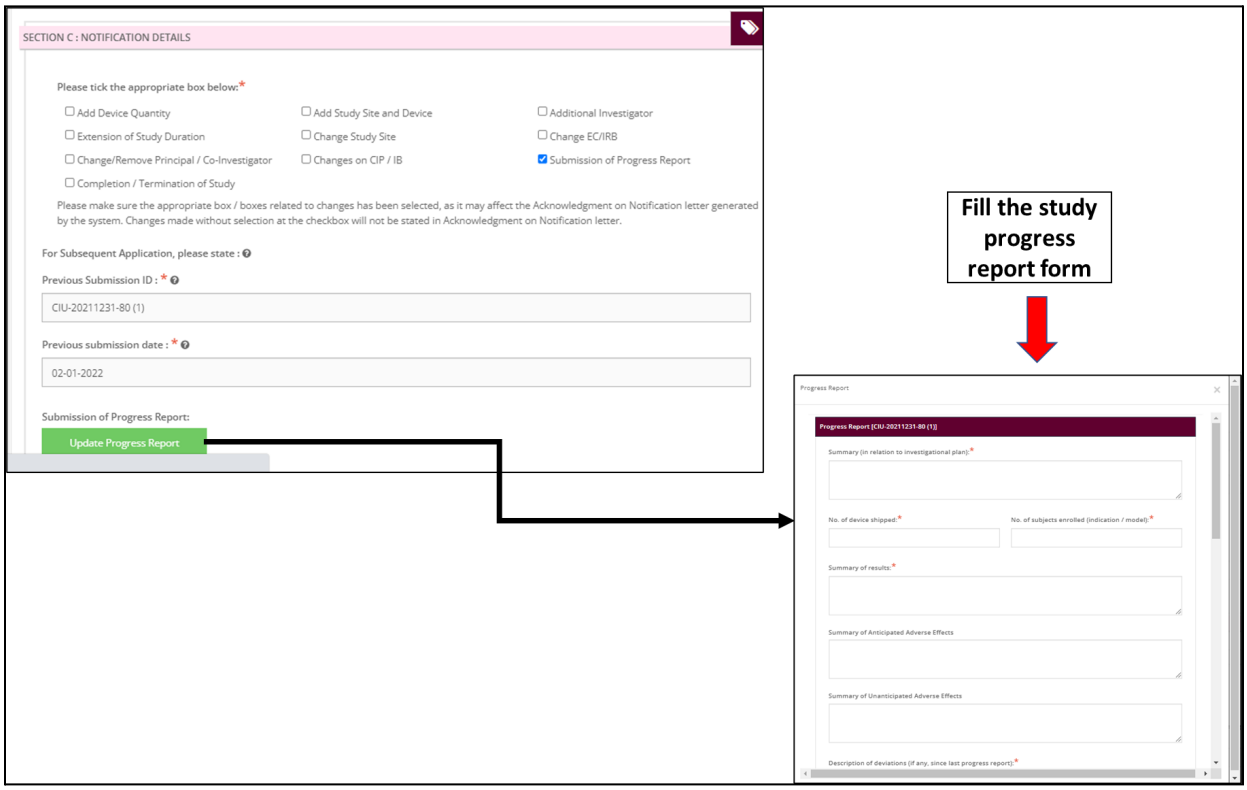
8

Changes CIP / IB

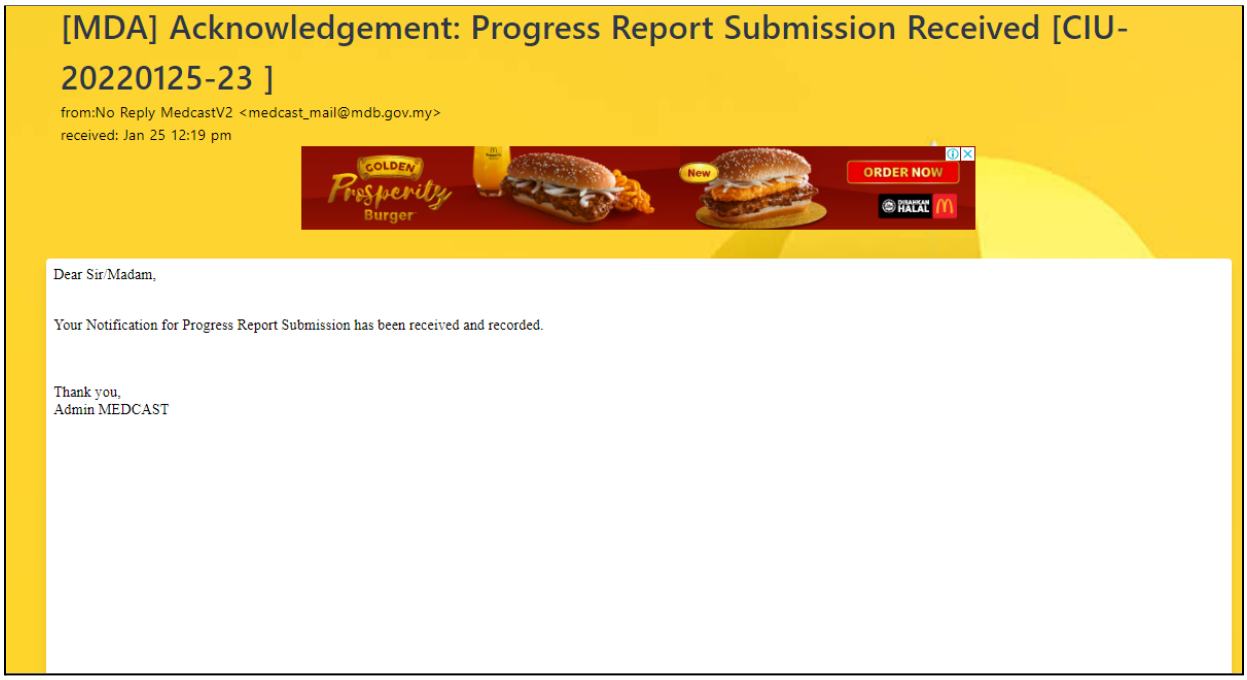
- **Section C:** Title of Clinical Investigation / Study - as stated in the Clinical Investigation Plan (CIP) document, Please attach a copy of Clinical Investigation Plan (CIP)), Changes Summary in Clinical Investigation Plan (CIP) document, Add Clinical Clinical Investigation / Study Site button, Update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

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



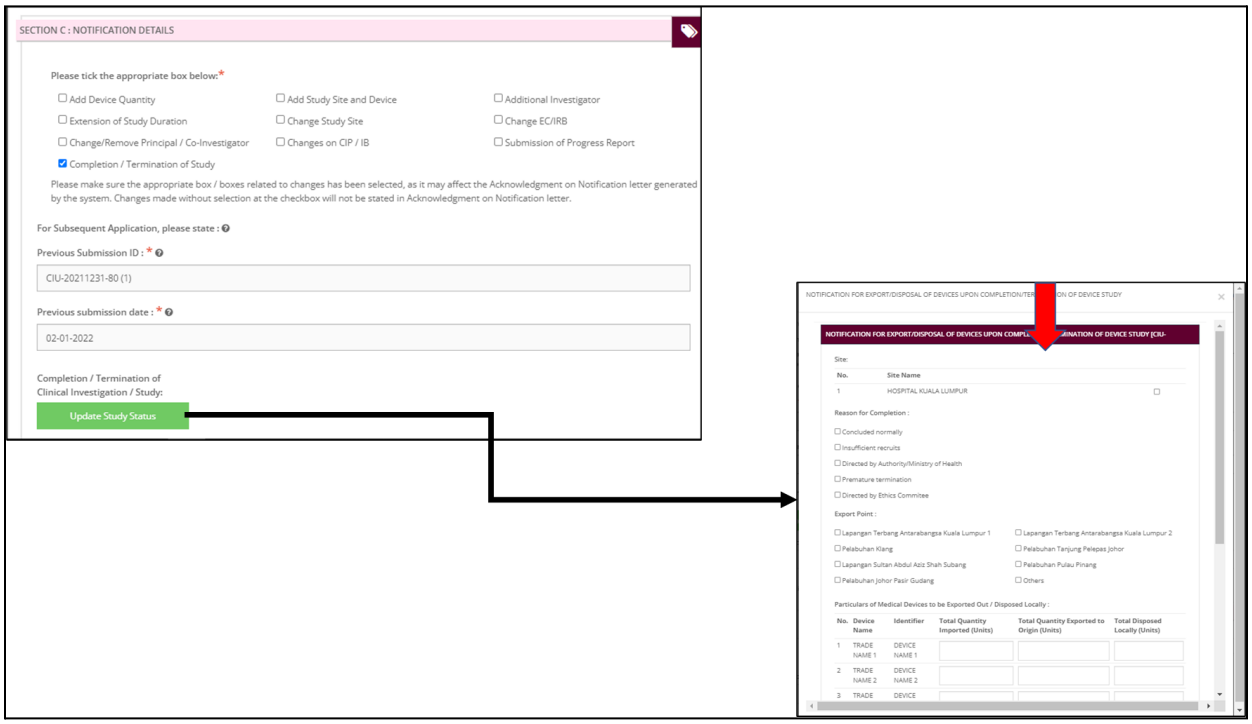
The user will get email notification after the completion of the progress report. Figure below shows the email notification that will be received by the front-end user.



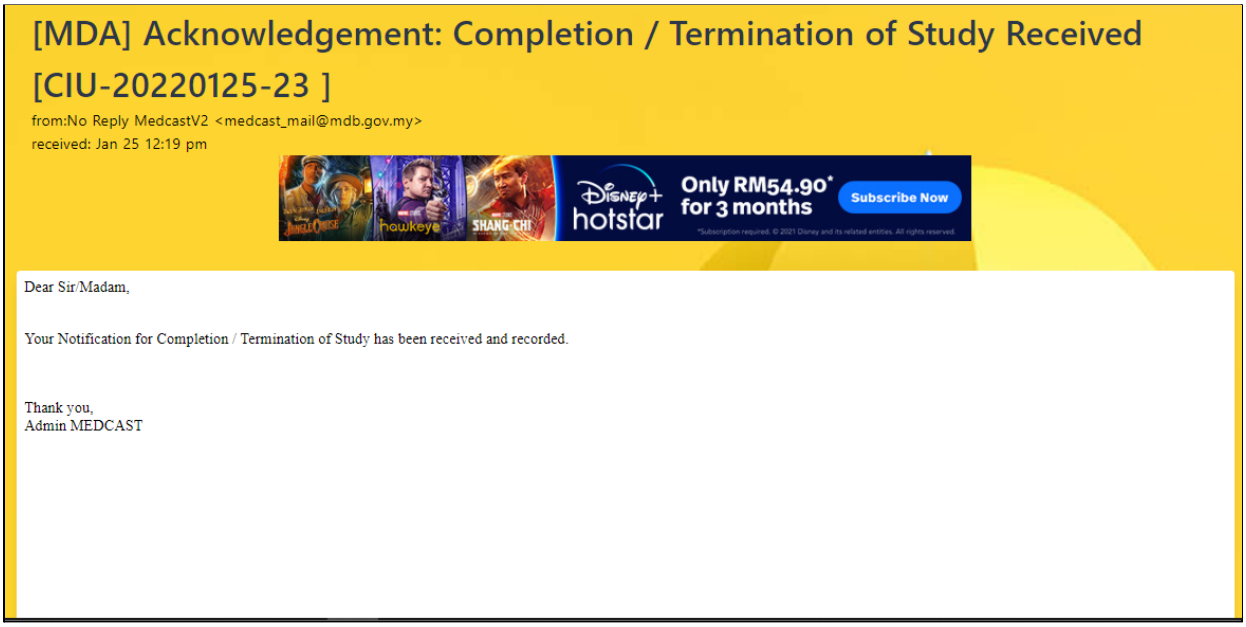
- **Section G**

10 Completion / Termination of Study

- Section C: Click **Update Study Status** in Section C and fill the study status form.

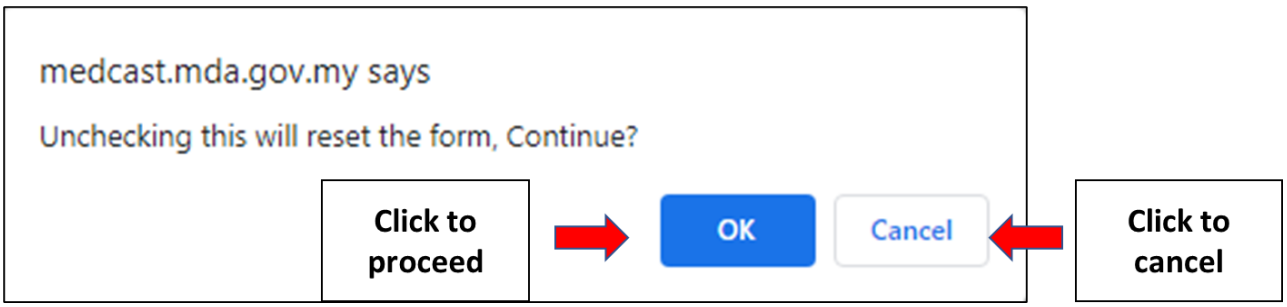


The user will get email notification after the completion of the completion or termination of study. Figure below shows the email notification that will be received by the front-end user



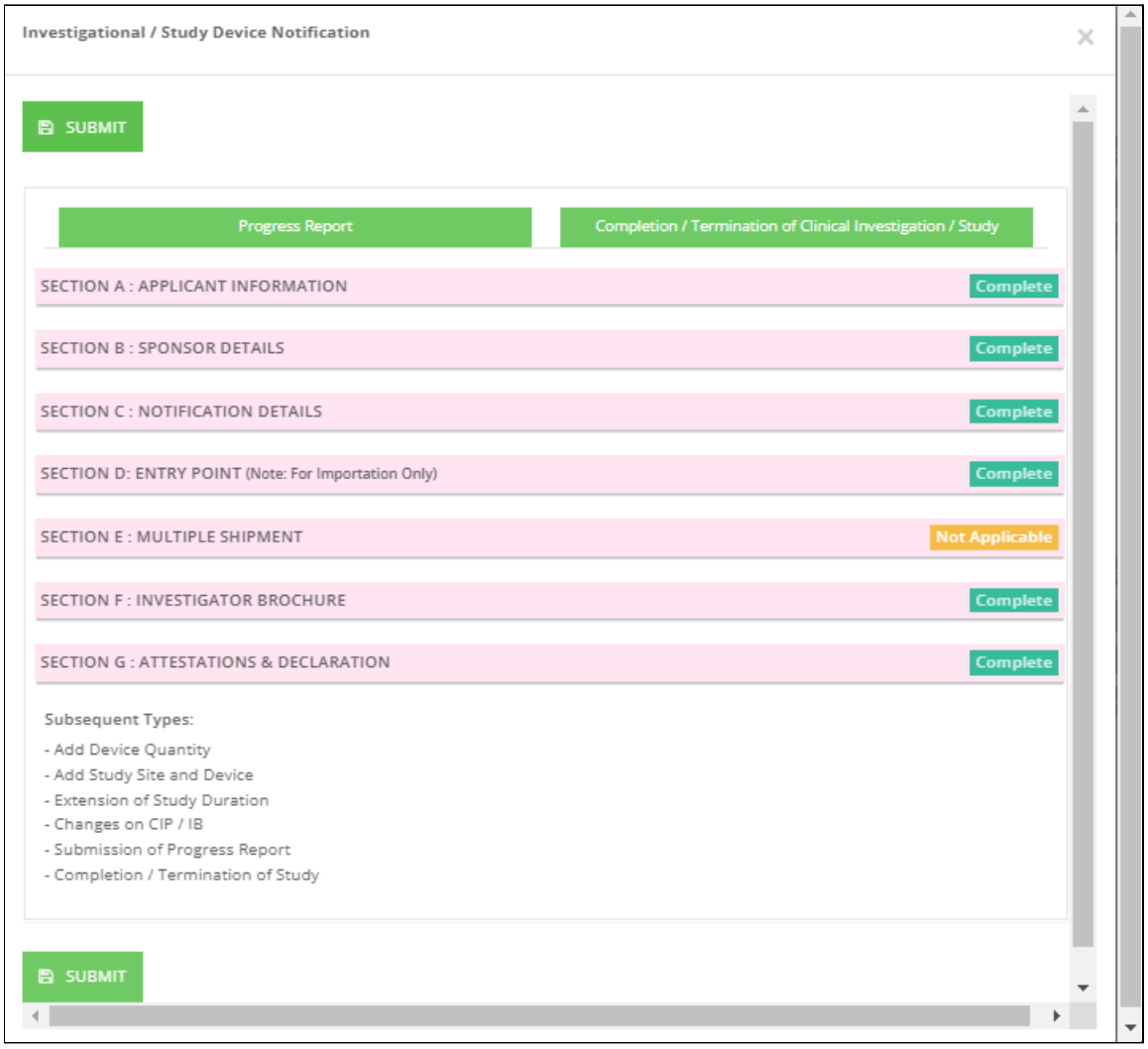
- **Section G**

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.

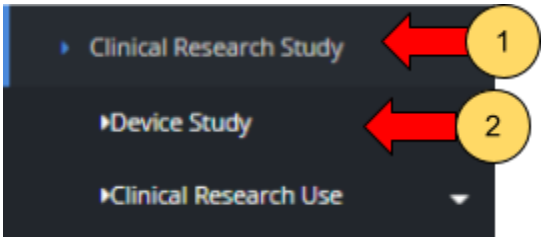
The user complete the Subsequent Application form and click on button PREVIEW AND SUBMIT to preview the information that user change.



Click on SUBMIT to submit form.

The status of application will be on evaluation stage.

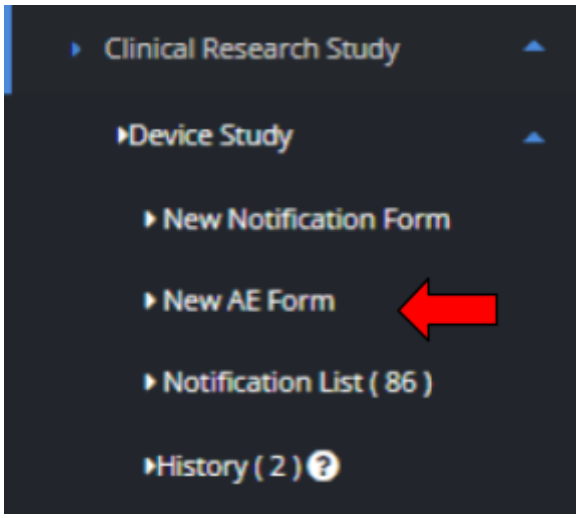
*c) **AE Form***



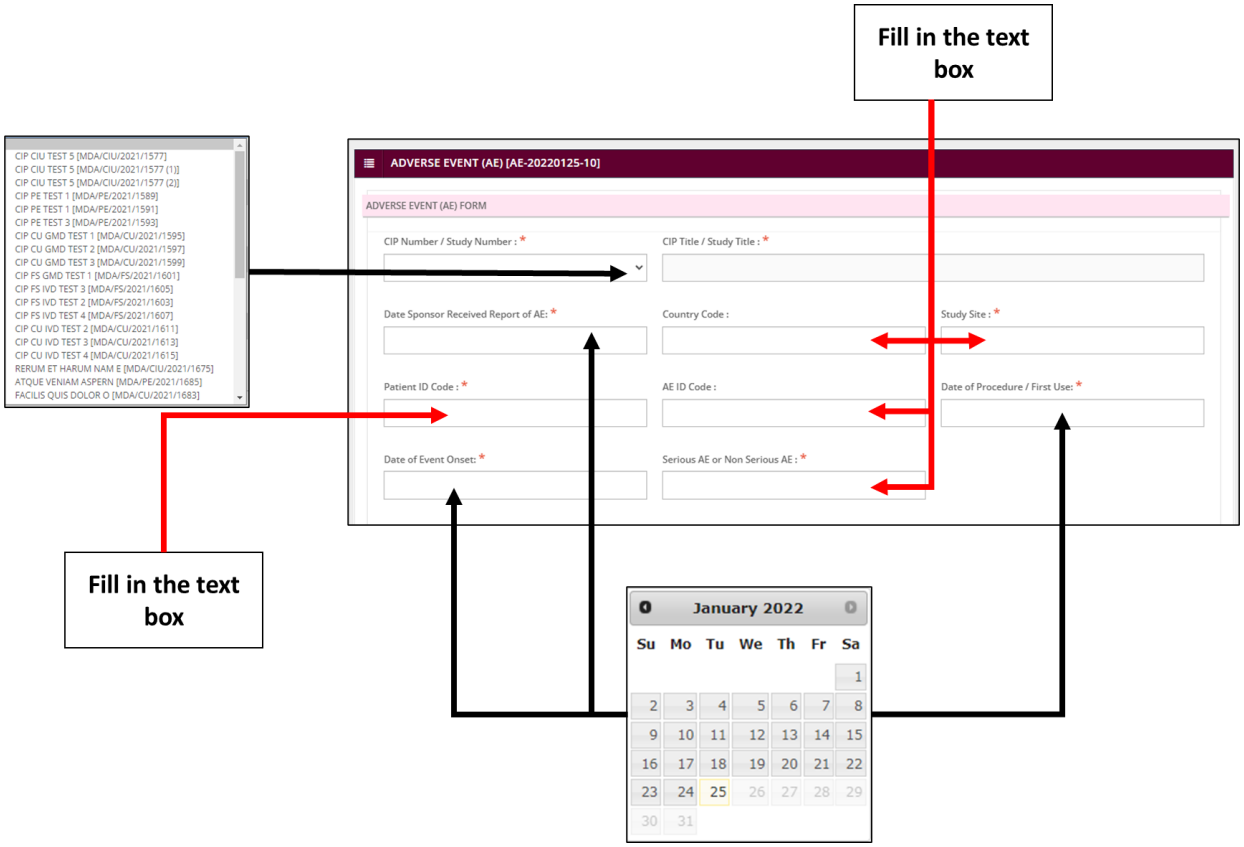
1 - User should click at menu Clinical Research Study.

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.

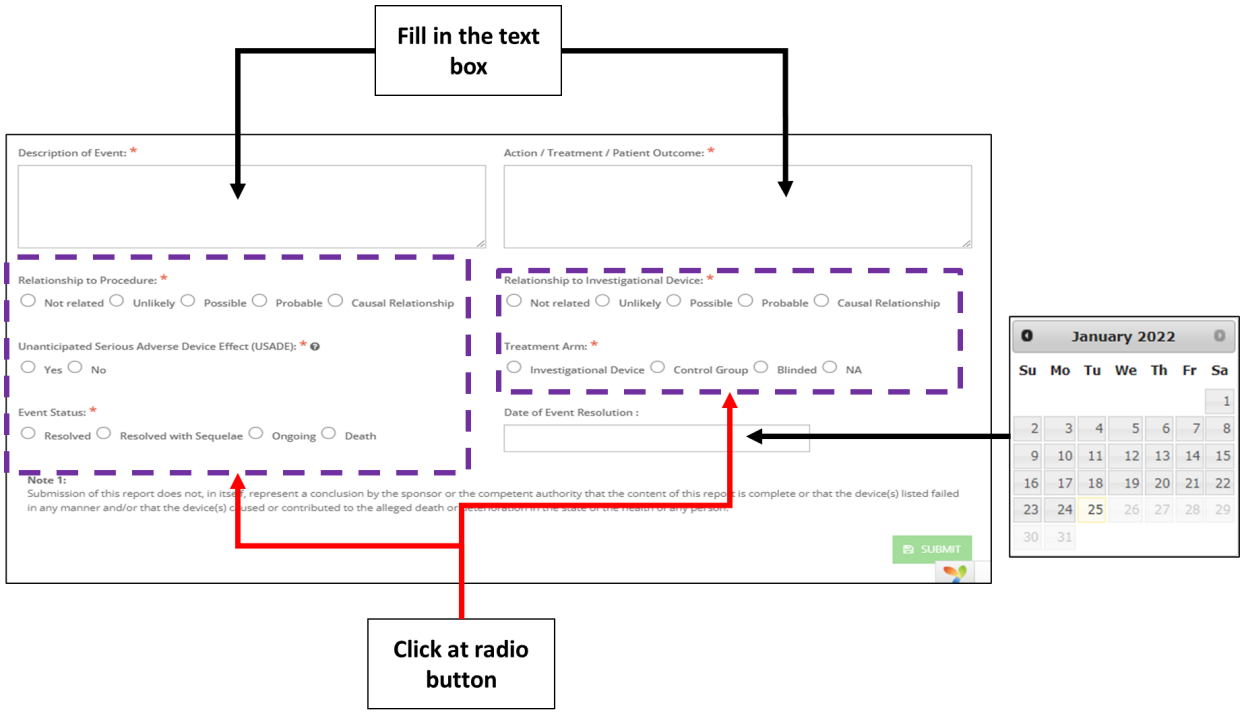
- **Patient ID Code**
  The user should fill in the textbox that provided.

- **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

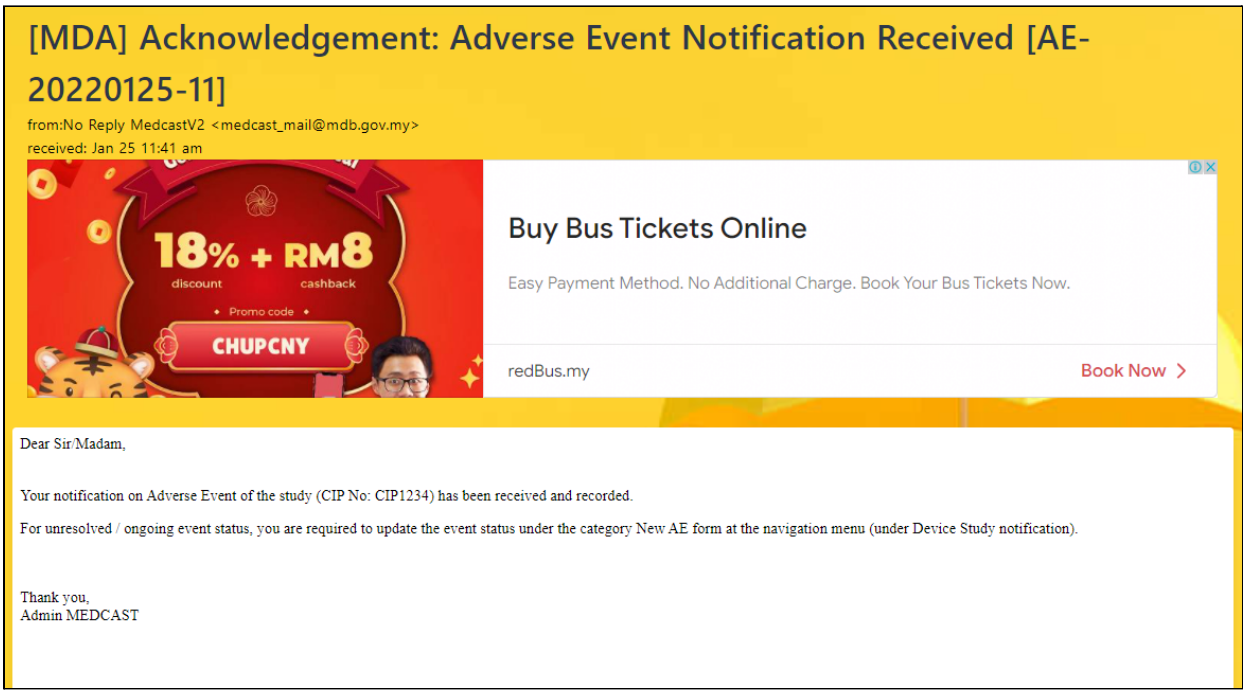
- **Date of Event Resolution**

  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.

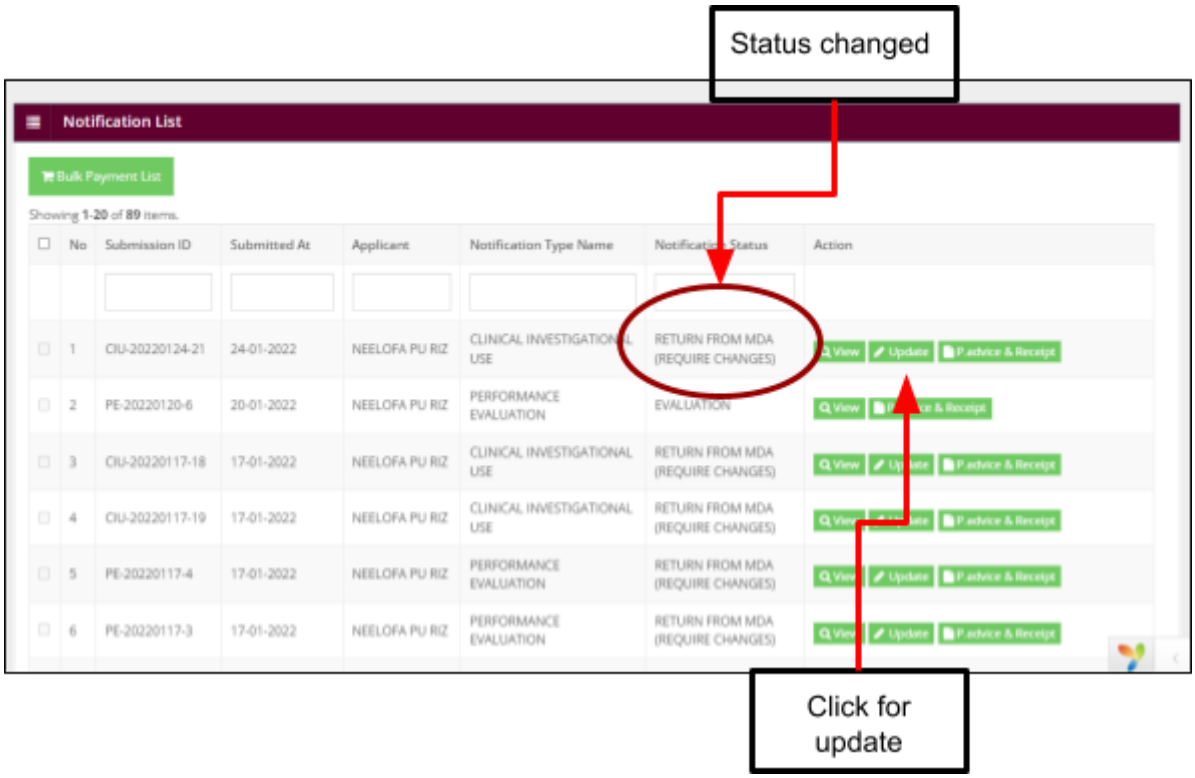
The user will get email notification after the completion of the AE form. Figure below shows the email notification that will be received by the front-end user



2.2.2 RETURN FOR FURTHER INFO

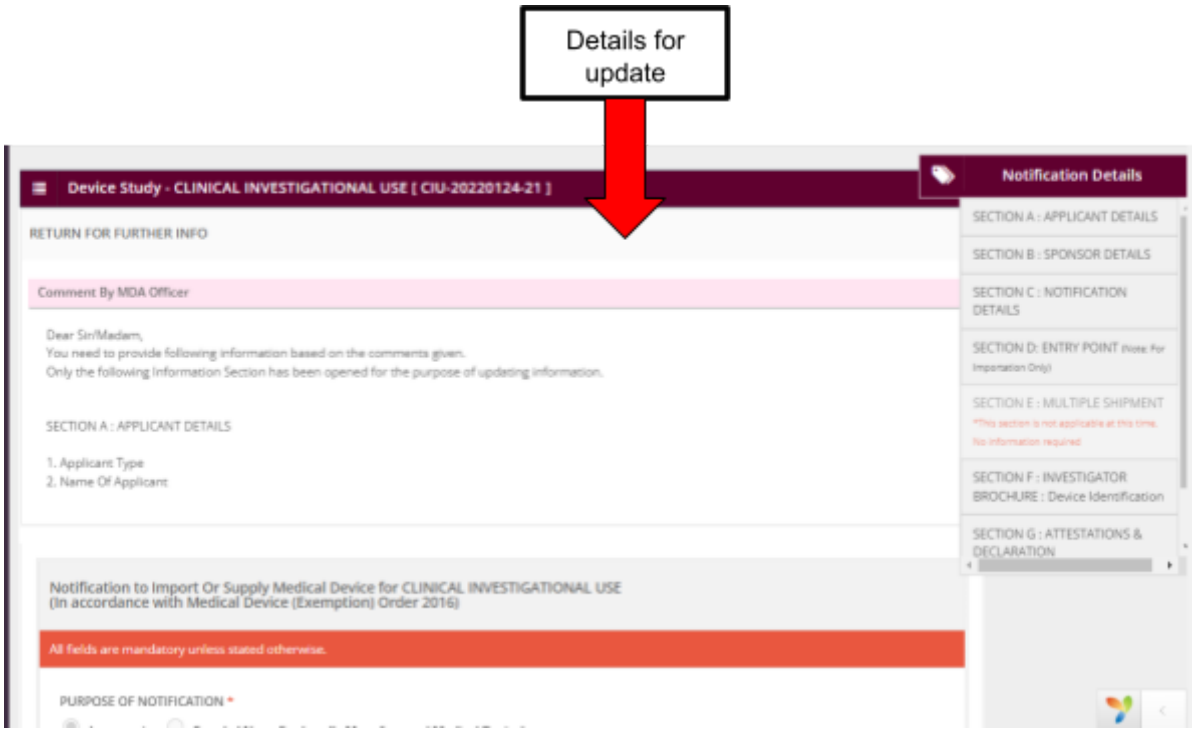
If back end user make the process “RETURN FOR FURTHER INFO” to front end user, the status of application will be changed and the Front End User should make the changed at application form that applied.

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


Status changed
Notification List
Bulk Payment List
Showing 1-20 of 89 items.
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)
2 PE-20220120-6 20-01-2022 NEELOFA PU RIZ PERFORMANCE EVALUATION EVALUATION
3 CIU-20220117-18 17-01-2022 NEELOFA PU RIZ CLINICAL INVESTIGATIONAL USE RETURN FROM MDA (REQUIRE CHANGES)
4 CIU-20220117-19 17-01-2022 NEELOFA PU RIZ CLINICAL INVESTIGATIONAL USE RETURN FROM MDA (REQUIRE CHANGES)
5 PE-20220117-4 17-01-2022 NEELOFA PU RIZ PERFORMANCE EVALUATION RETURN FROM MDA (REQUIRE CHANGES)
6 PE-20220117-3 17-01-2022 NEELOFA PU RIZ PERFORMANCE EVALUATION RETURN FROM MDA (REQUIRE CHANGES)
Click for update

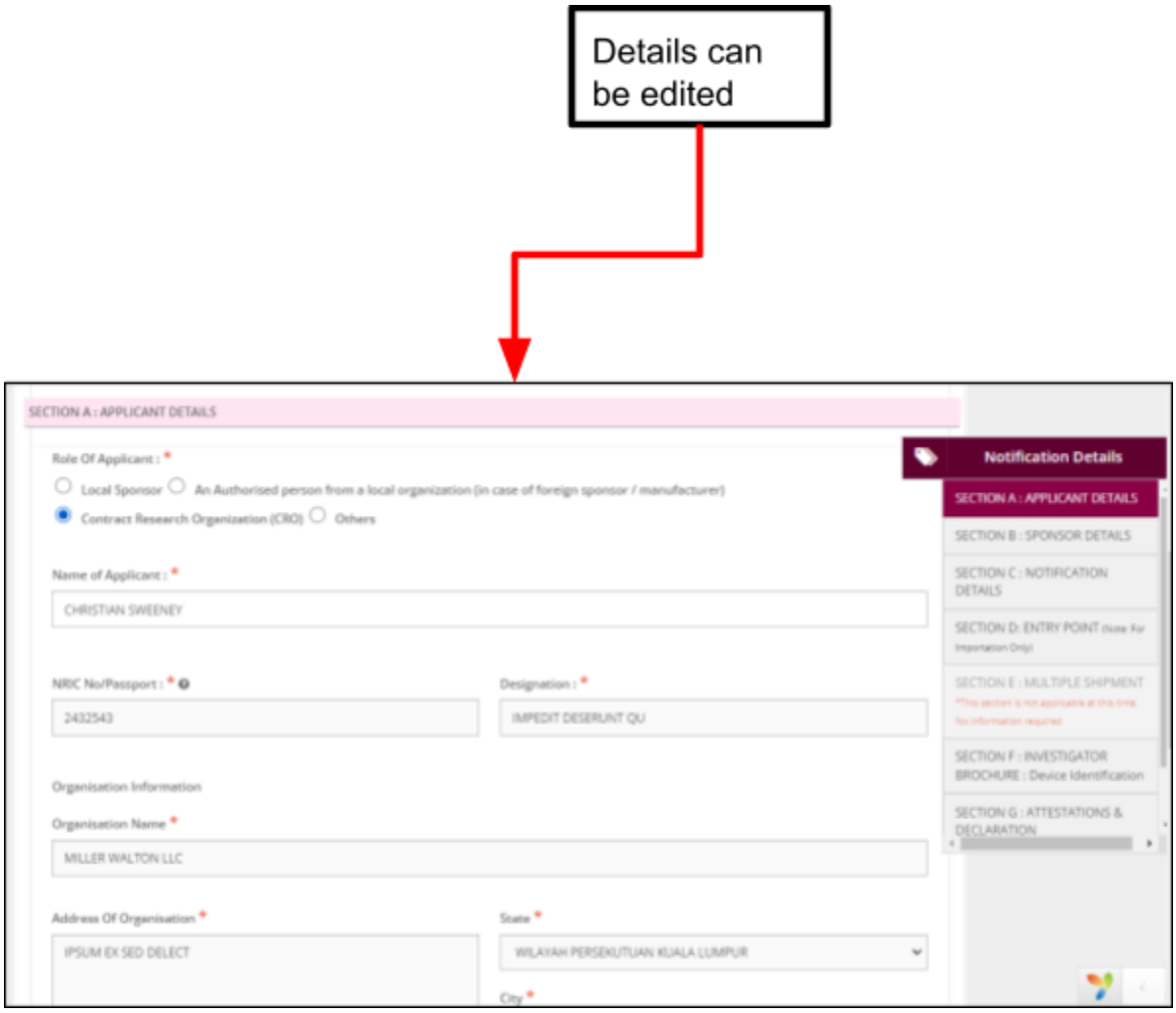
After that, user should click at 

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

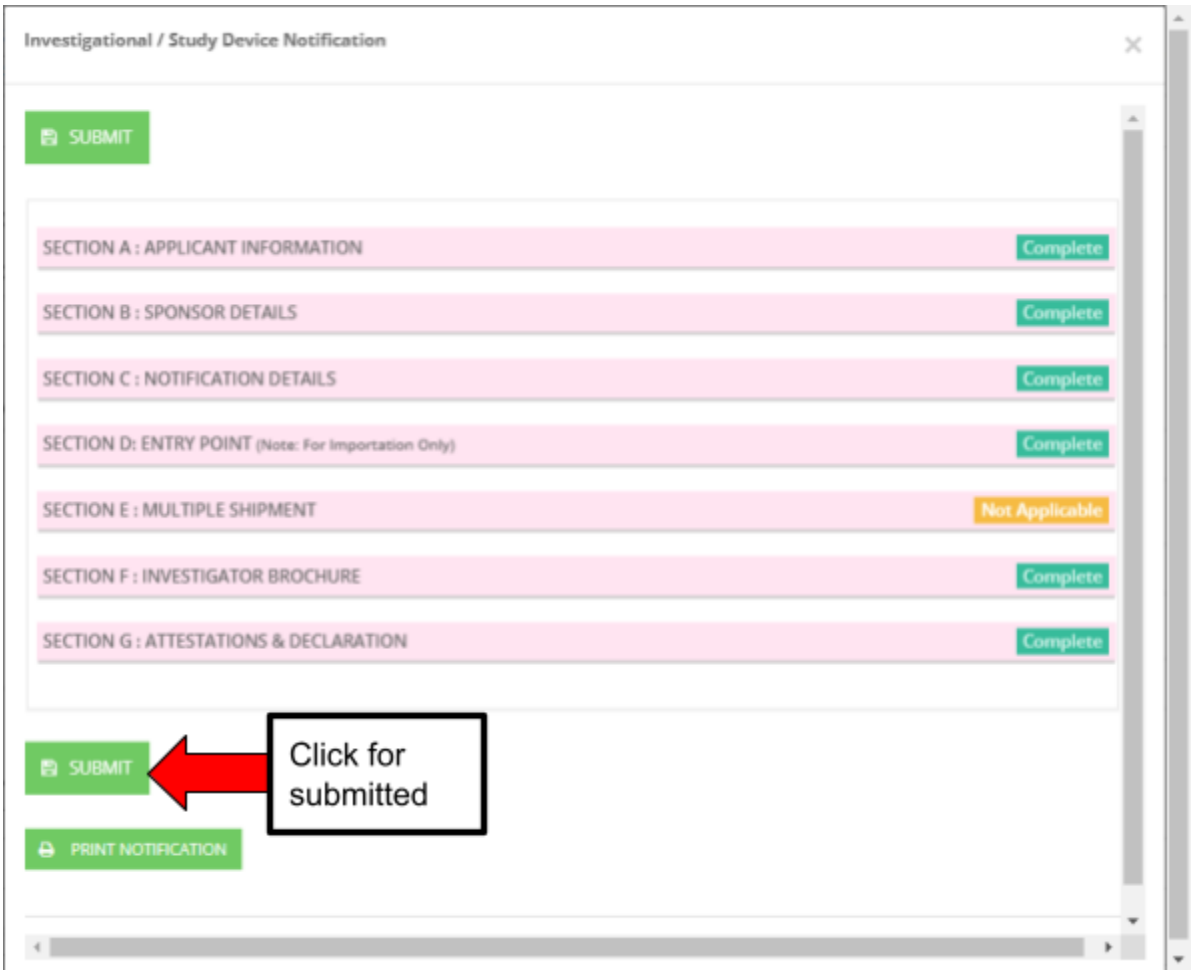


displayed that shown in the figure below.

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



And then, click PREVIEW AND SUBMIT to submit the application.



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

The user should make the process EVALUATION at back end user.