

# USER MANUAL FRONT END USER

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

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## MODUL UTAMA - NOTIFICATION

DISEDIAKAN OLEH :



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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:

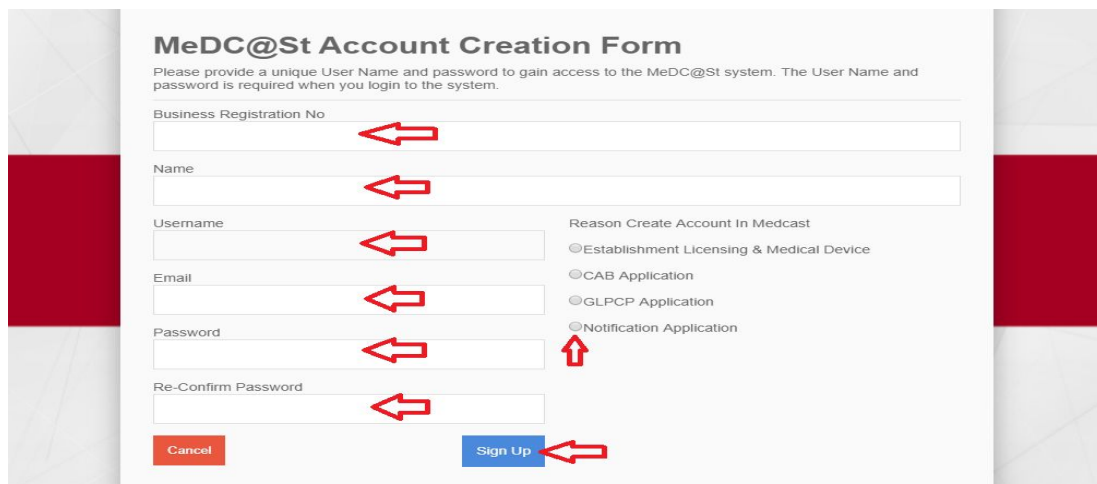
<https://medcast.mda.gov.my>

### 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.

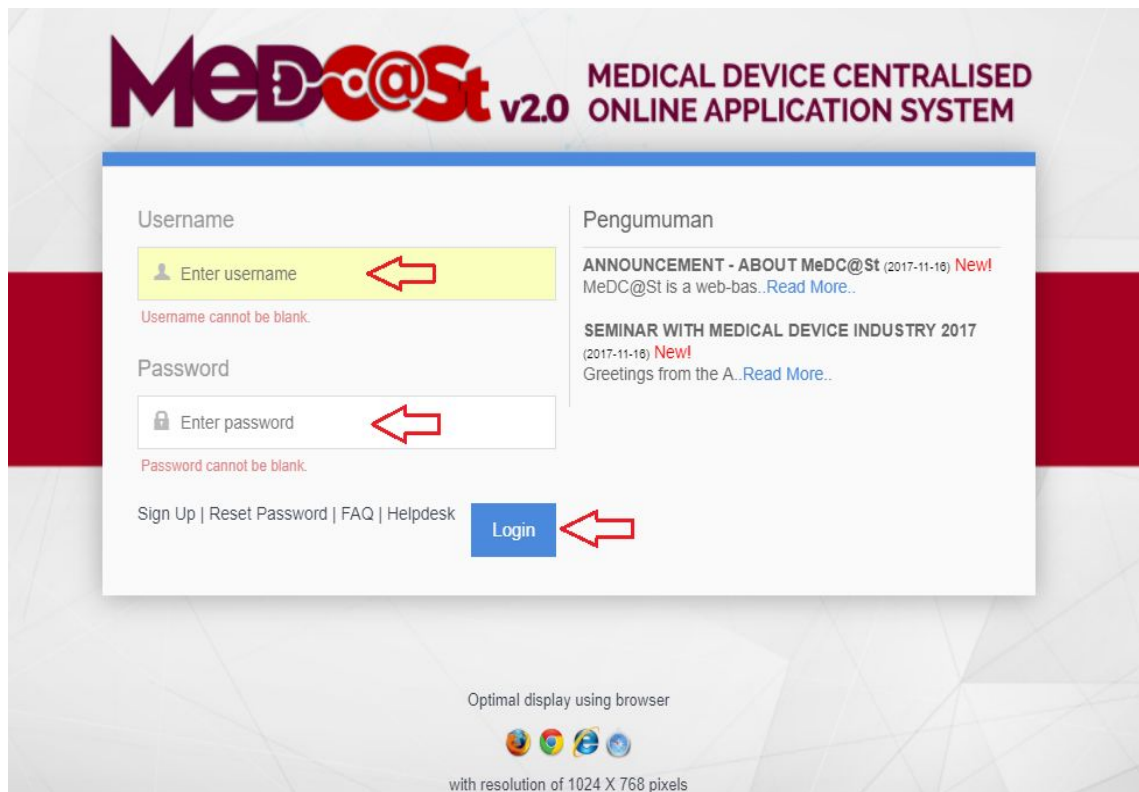


The image shows a screenshot of the 'MeDC@St Account Creation Form'. The form title is 'MeDC@St Account Creation Form'. Below the title, there is a sub-header: 'Please provide a unique User Name and password to gain access to the MeDC@St system. The User Name and password is required when you login to 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 'Notification 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.



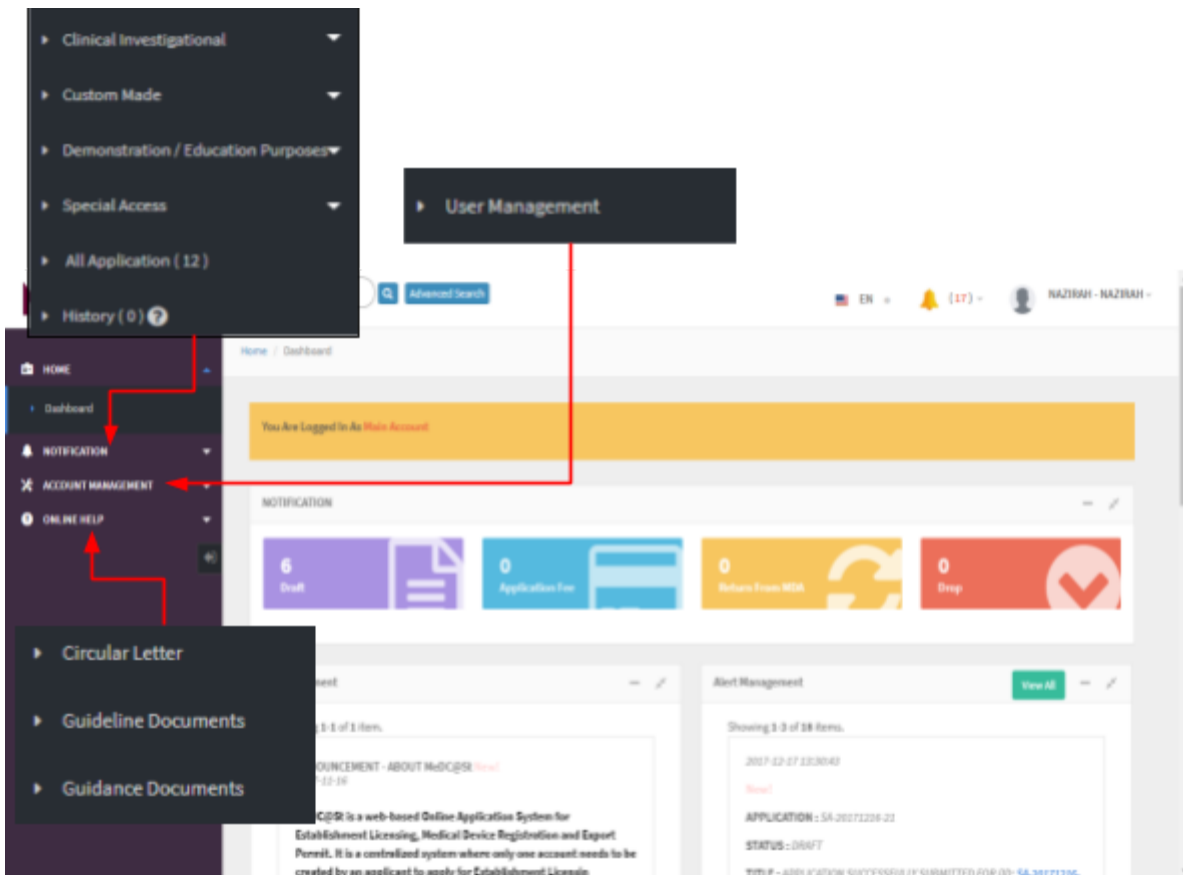
User has to log into the system using registered Username and its respective

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



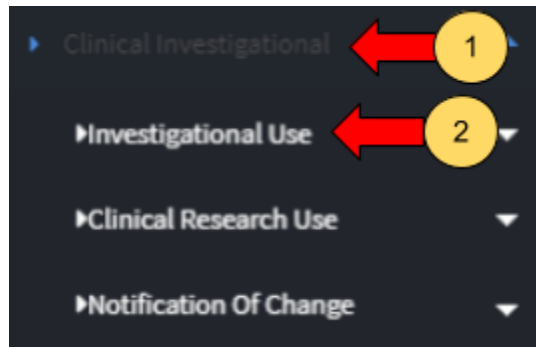
### a) CLINICAL INVESTIGATIONAL

First, user should click at sub menu **Clinical Investigational** to list down the three sub menu which are Investigational Use, Clinical Research Use, Notification of Change.



## I) INVESTIGATIONAL USE

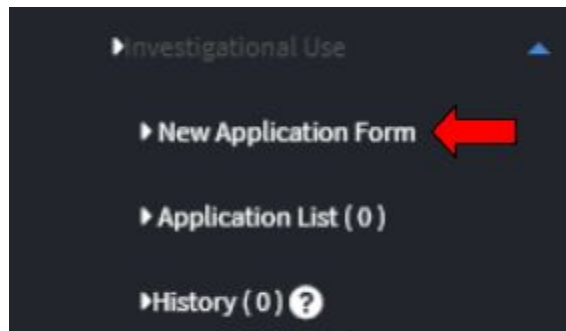
### a) *New Application*



1 - User should click at menu clinical investigational.

2 - User should click at sub menu investigational use.

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



The user should click at sub menu **New application form** to apply the registration form for Investigational Use Registration. The application form will be appear. The figure below shows the application form for applicant fill it. The user should fill all investigational use form. There have nine section which are:

SECTION A : Applicant Details

- SECTION B : Sponsor Details
- SECTION C : Application Details
- SECTION D : Entry Point
- SECTION E : Multiple Shipment
- SECTION F : Attestations & Declaration
- SECTION G : Investigator Brochure
- SECTION H : Clinical Investigation Plan(CIP)
- SECTION I : Appendix A

The screenshot displays the MeDC@St v2.0 application interface. At the top, there are navigation menus for 'Circular Letter', 'Guideline Documents', and 'Guidance Documents'. A 'User Management' menu is also visible. The main header includes a search bar, a language selector (EN, MY), and a user profile (NAZIRAH - NAZIRAH). The main content area is titled 'Clinical Investigation - Investigational Use (IU-20171206-20)' and contains a form for 'Notification to Import Or Supply Medical Device for Clinical Investigational Use (In accordance with Medical Device (Exemption) Order 2016)'. The form includes a 'PURPOSE OF NOTIFICATION \*' section with radio buttons for 'Importation' and 'Supply (Note: For Locally Manufactured Medical Device)'. A 'Click radio button' annotation points to the 'Supply' radio button. The right sidebar contains a table of contents for the application details, with sections A through H. Two inset screenshots at the bottom show the 'Hide Main Menu' and 'Hide Application Details' actions, with red arrows indicating the corresponding UI elements.

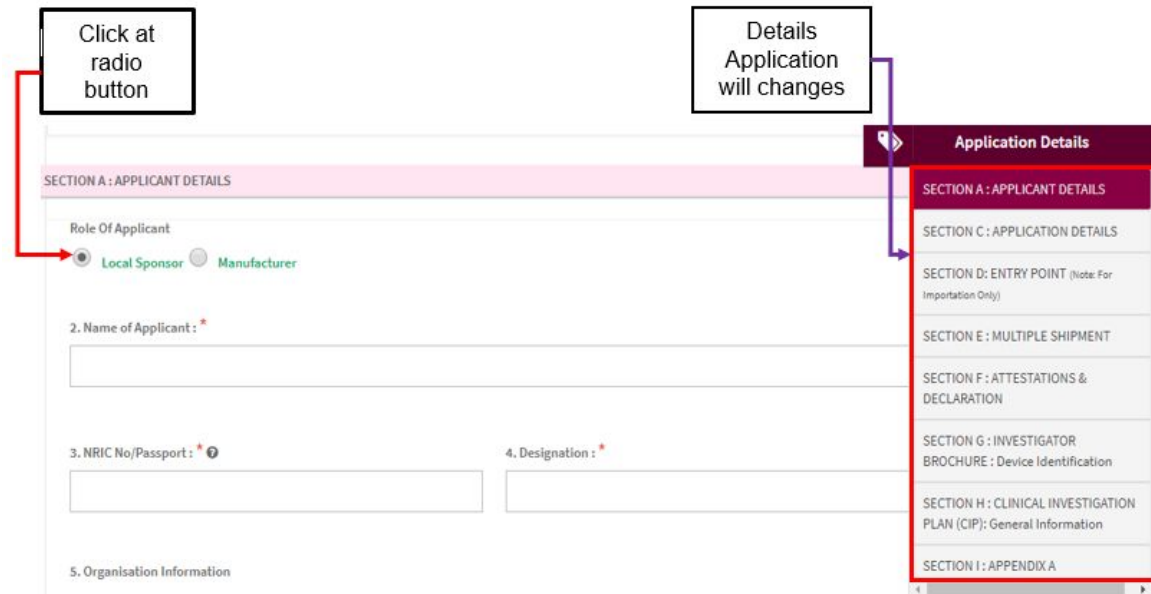
The user should choose the purpose of notification with click at radio button that shown in figure above.

**Section A: Applicant Details**

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

- Role of Applicant -> User should choose whether local sponsor or manufacturer.

If user choose local sponsor  **Local Sponsor** , the form that user not to fill is section B.




If user choose Manufacturer, the form that user will fill which are all section.

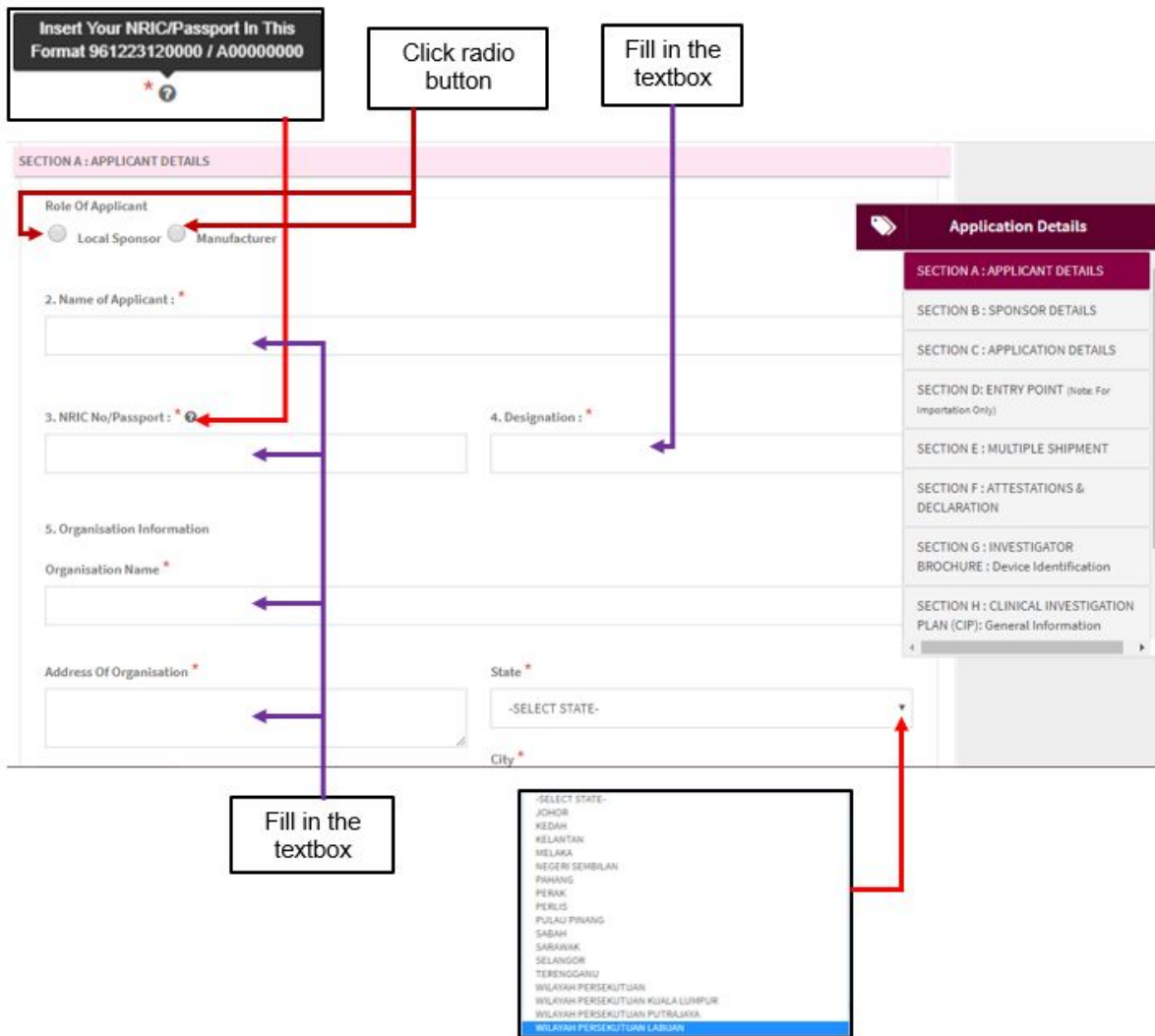
The screenshot shows the 'SECTION A: APPLICANT DETAILS' form. A callout box 'Click at radio button' points to the 'Manufacturer' radio button. Another callout box 'Application details will be changes' points to a sidebar menu titled 'Application Details' which lists sections from A to H. The form fields include: 'Role Of Applicant' (Local Sponsor, Manufacturer), '2. Name of Applicant: \*', '3. NRIC No/Passport: \*' with a help icon, '4. Designation: \*', and '5. Organisation Information' (Organisation Name \*).

## 2. Name of Applicant

- User should fill name in the textbox that provided.

## 3. 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.



4. Designation


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

5. Organisation information


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

- Address of organisation ->The user should fill in the textbox with address of organisation.
- State -> User should click at textbox to drop down list and user should select the state that has shown in figure above.
- 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.
- 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.”


#### 6. 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.


#### 7. 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.

#### 8. 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.


#### 9. 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.**”

The screenshot shows a registration form with the following fields and annotations:

- State:** A dropdown menu with a list of states (Johor Bahru, Batu Pahat, Kelang, Kulai, Muar, Kota Tinggi, Segamat, Pontian, Ayer Tawar 5, Mersing, Ayer Baloi, Ayer Hitam, Ayer Tawar 2, Ayer Tawar 3, Ayer Tawar 4, Bandar Penawar, Bandar Tenggara, Batu Anam, Bekok, Benut). An annotation "Click to move up and down" points to the dropdown arrow.
- Address Of Organisation:** A text input field.
- City:** A text input field.
- Postcode:** A text input field.
- 6. Telephone No:** A text input field with an example "e.g: 034567890". An annotation "Insert Your telephone Number In This Format 034567890" points to the field.
- 7. Mobile No:** A text input field with an example "e.g: 0134567890". An annotation "Insert Your Mobile Number In This Format 0134567890" points to the field.
- 8. Fax No:** A text input field with an example "e.g: 034567890". An annotation "Insert Your Fax Number In This Format 034567890" points to the field.
- 9. Email Address:** A text input field with an example "e.g: abc@gmail.com". An annotation "Insert Your Email In This Format abc@ gmail.com" points to the field.
- Next:** A green button with a right arrow. An annotation "Click to next stage" points to the button.

A green rectangular button with the text "Next" and a right-pointing arrow.

After user fill all form for section A, the user should click at button  to the next section which is Section B.

## Section B: Sponsor Details

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

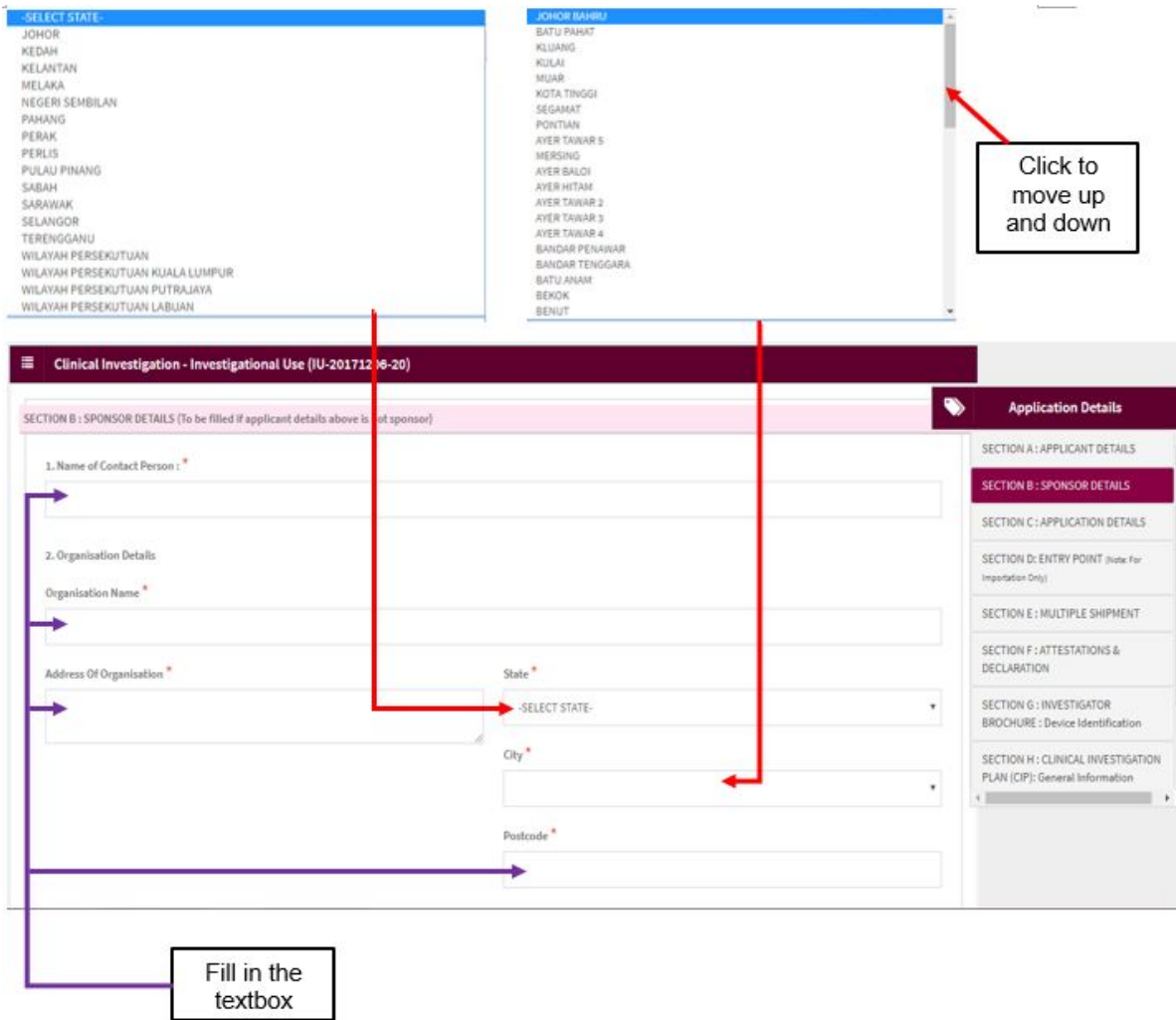
### 1. Name of contact Person

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


### 2. Organisation Details

- Organisation Name -> The user should fill name of organisation in the textbox that provided.
- Address of organisation -> The user should fill in the textbox with address of organisation.
- State -> User should click at textbox to drop down list and user should select the state that has shown in the figure below.
- 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.
- 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.”.







3. 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.


4. Mobile No.

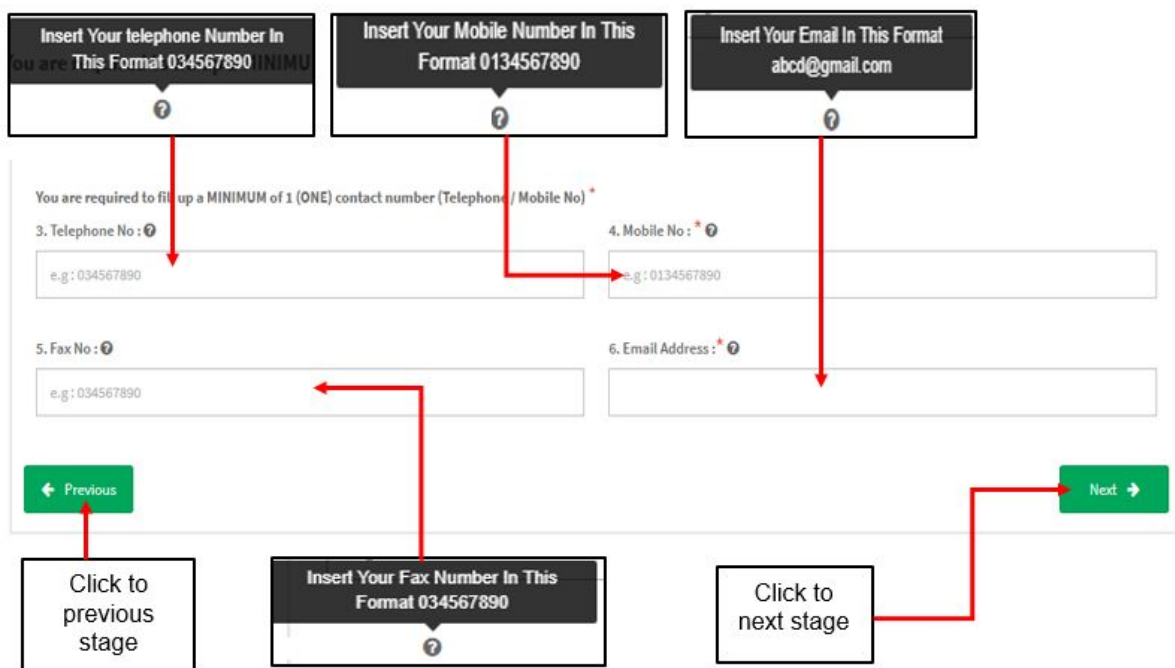
The user must fill in the number only and click at  to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message “Field can only contain number and between 3 to 11 numeric.” will be displayed.

5. 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.

6. 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.

1. Select Application Type


- User should choose the type of application whether “First Application” or “Subsequent Application”. If user click on radio button  **First Application** the field of number 2. will be disabled.


2. For Subsequent Application, please state : 


Previous MDA identification no : \* 

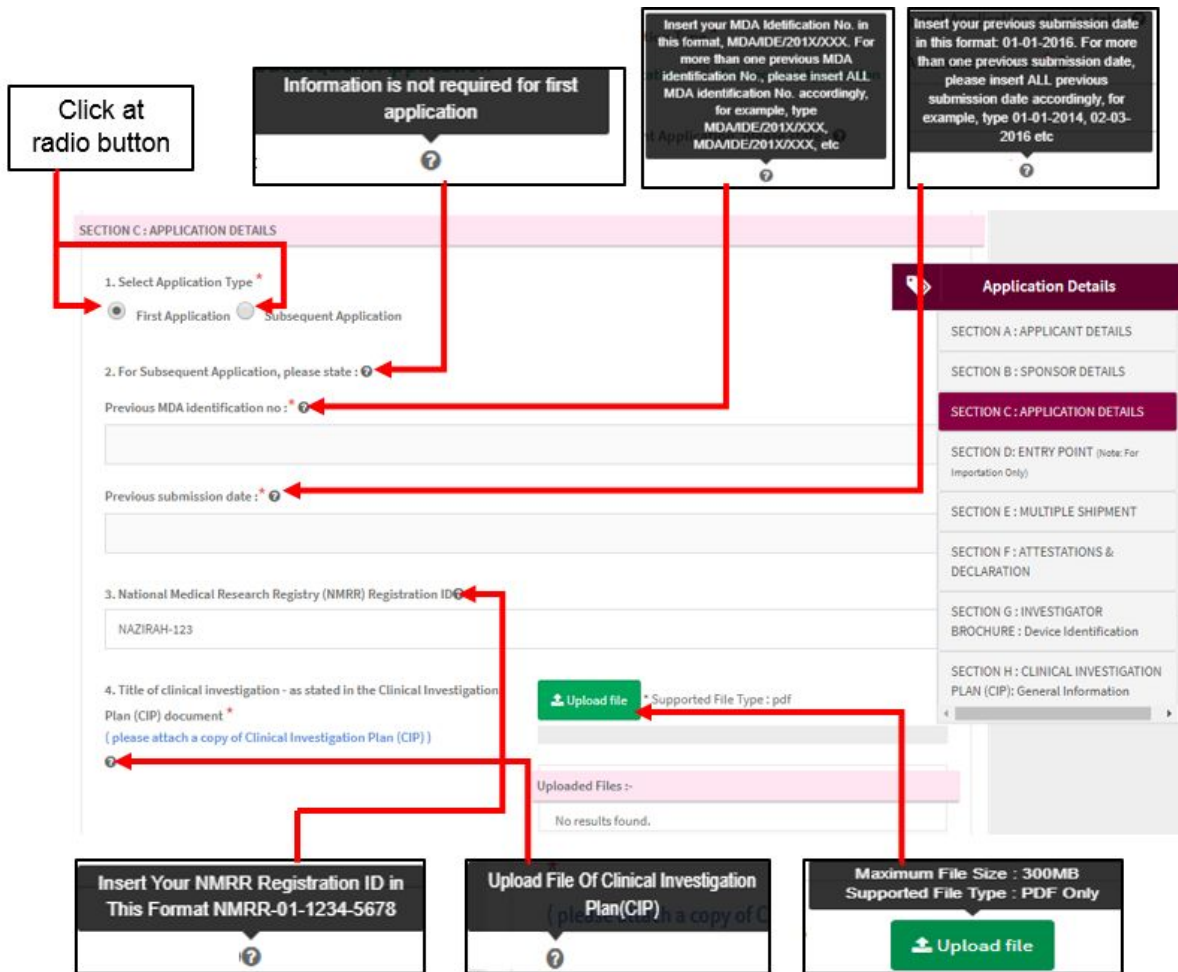
Previous submission date : \* 

If user click on radio button  **Subsequent Application** .the field of number 2 will be enabled.



2. For Subsequent Application, please state : 

Previous MDA identification no : \* 


Previous submission date : \* 



2. For Subsequent Application, please state:

- Previous MDA Identification no -> The user must fill in the textbox and click at  to see the format. User should follow the format that shown in figure above.
- Previous submission date -> The user must fill in the textbox and click at  to see the format. User should follow the format that shown in figure above. The user can insert more than one date in this field.

3. National Medical Research Registry(NMRR) Registratn 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.

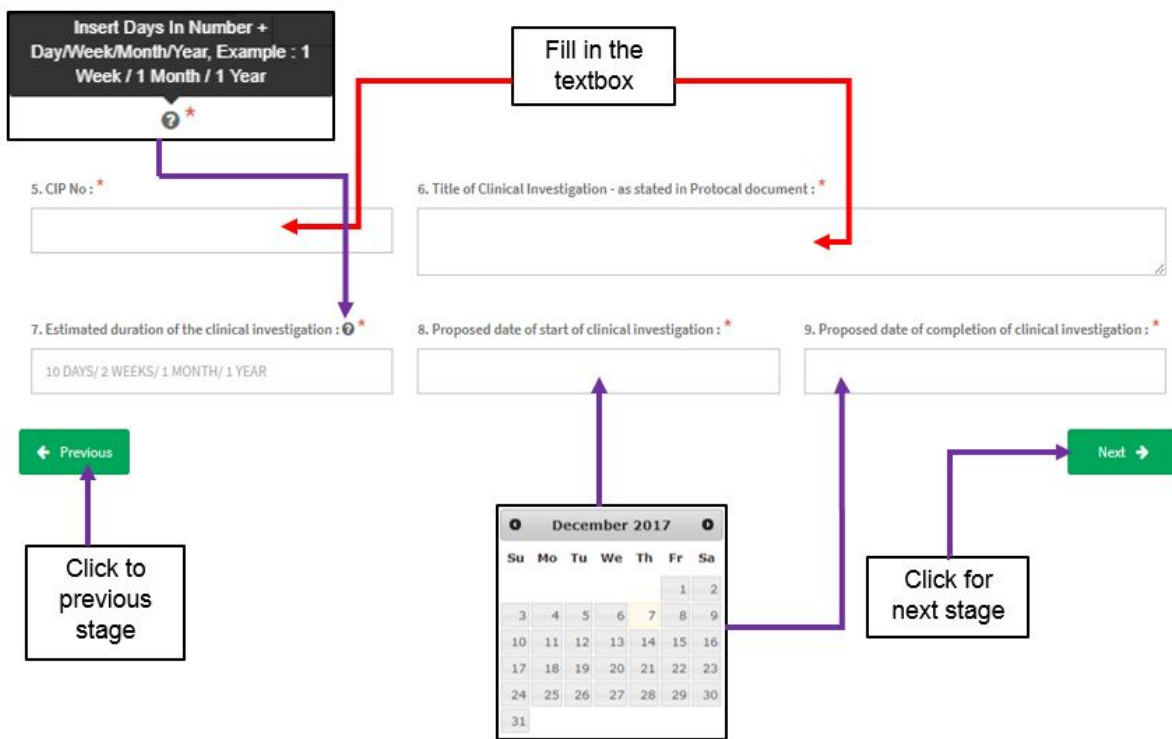
4. Title of clinical investigation- as stated in the Clinical Investigation Plan(CIP)



User must click at button **Upload file** untuk upload file PDF only and not more than 300MB for file size.

5. CIP no.


The user should fill in the textbox field that provided.



6. Title of Clinical Investigation- as stated in Protocol document

The user must fill in the textbox field of title.

7. Estimated duration of the clinical investigation

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.

8. Proposed date of start of clinical investigation

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.

### 9. Proposed date of completion of clinical investigation

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.

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



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

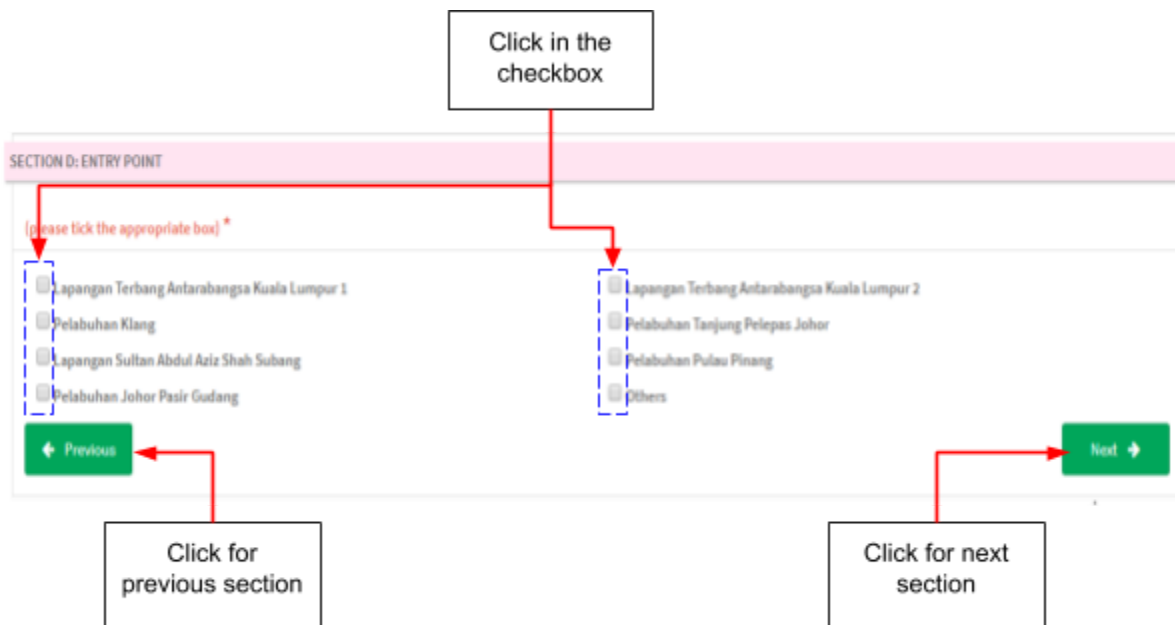


to the next stage.

### Section 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

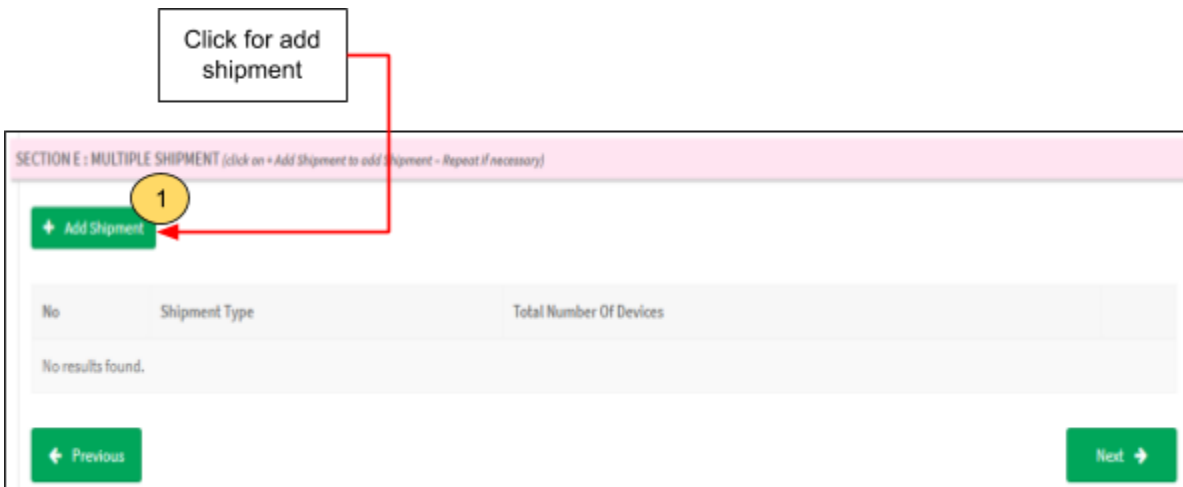


that shown in figure above. Then, user should click at button to the next stage.

### Section E: Multiple Shipment

1

The user should click at  and the page form for shipment will be displayed.



The form for shipment will be displayed after click on button that shown in figure above. The figure below show the form for add shipment.

The screenshot shows a web form titled "Multiple Shipment". Inside the form, there is a label "Shipment Type : First Shipment". Below it, a text input field is labeled "Total : Total number of devices per shipment". A red arrow points from a box labeled "Fill in textbox" to this input field. Below the input field is a green button labeled "Add Shipment".

Annotations in the image:

- A yellow circle with the number "2" is placed to the left of the text input field.
- A yellow circle with the number "3" is placed to the right of the "Add Shipment" button.

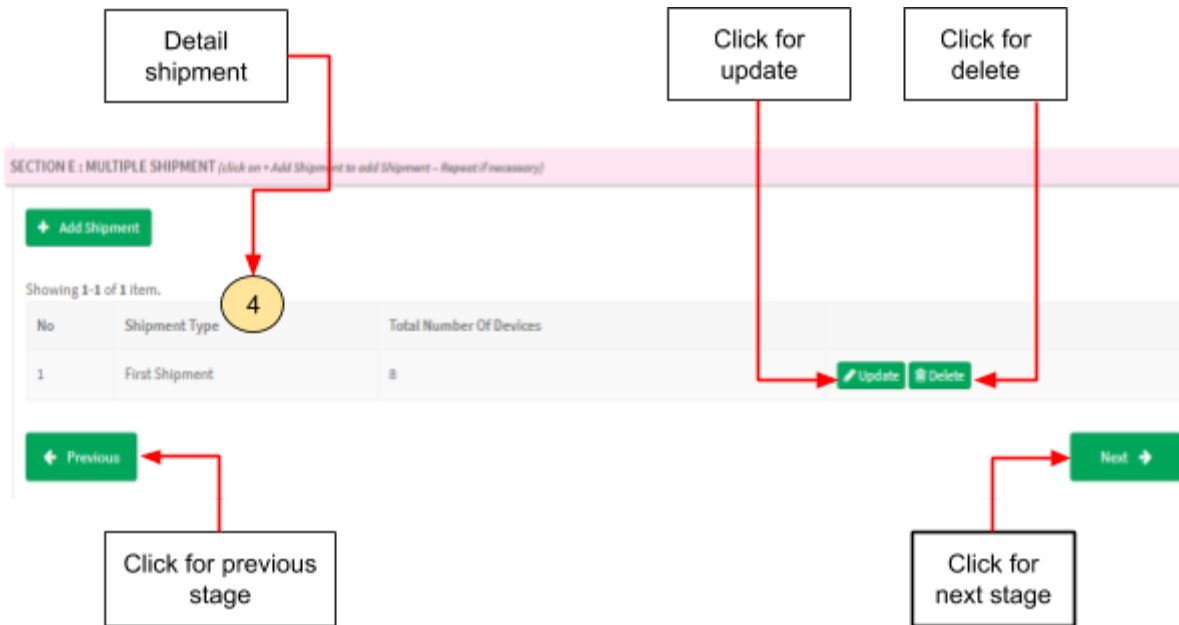
2 -> The user should fill the textbox with number of shipment.


3 -> The user should click at button "Add Shipment" and automatically the

message Success Add Multiple Shipment! will be displayed.

4 -> Detail of shipment will be displayed in the table that shown in figure below.






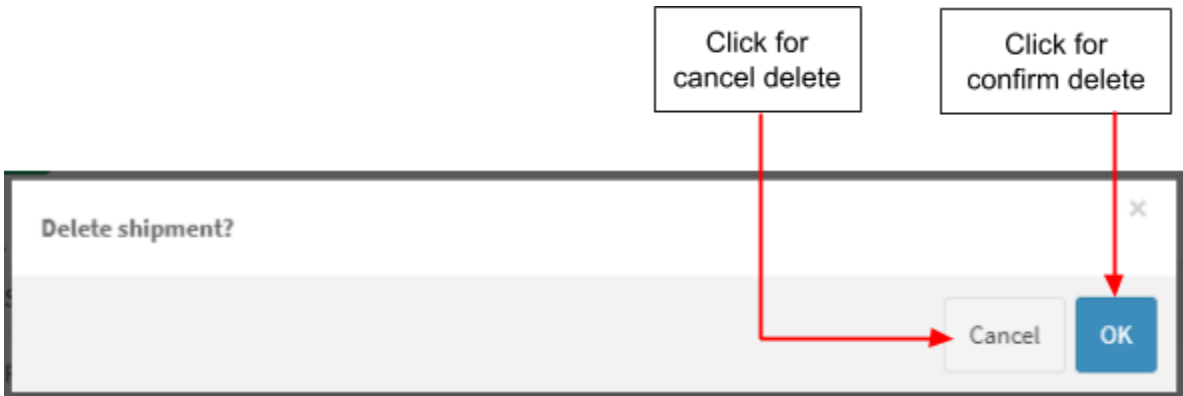
The user can update shipment with click at  and the page update will be showed.



1 -> The user can update or edit the total of shipment in the field.


2 -> The user should click button "Add shipment" to save updated.


If user want to delete the shipment, user should click at . The alert message “Delete shipment?” will be displayed that shown in the figure below.



The user can click at “cancel” to cancel the delete shipment or click “ok” to proceed delete.

If user click “ok”, the message  will be displayed.

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 F: 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

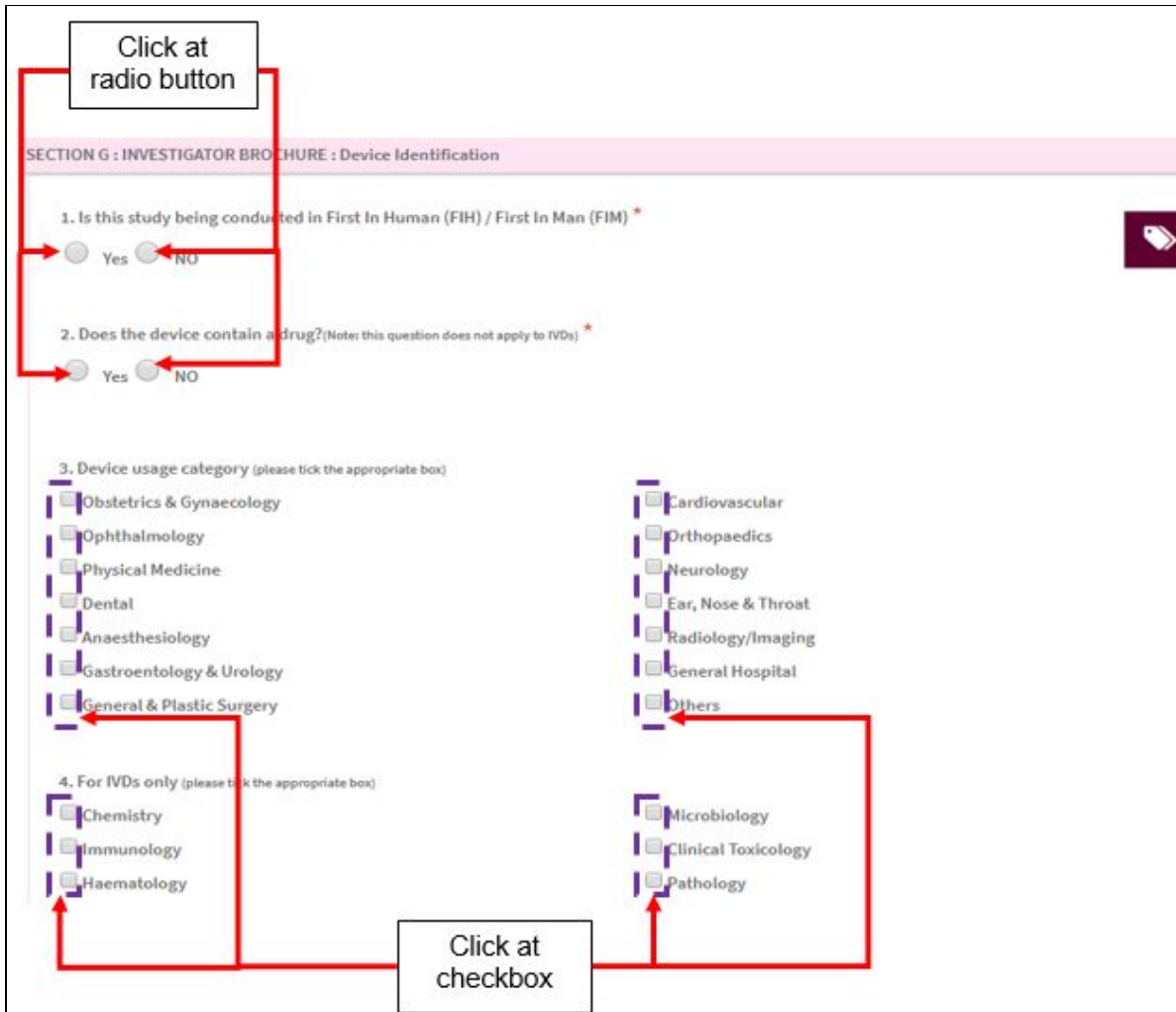


button to the next stage.



## Section G: Investigator Brochure

1. Is this 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.
2. Does the device contain a drug?  
User should click at radio button whether "Yes" or "No" that shown in the figure below.
3. Device usage category  
User should choose the category which is clicking in checkbox that provided.
4. For IVDs only  
User should choose the type which is clicking in checkbox that provided.




5. Medical Device Grouping



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

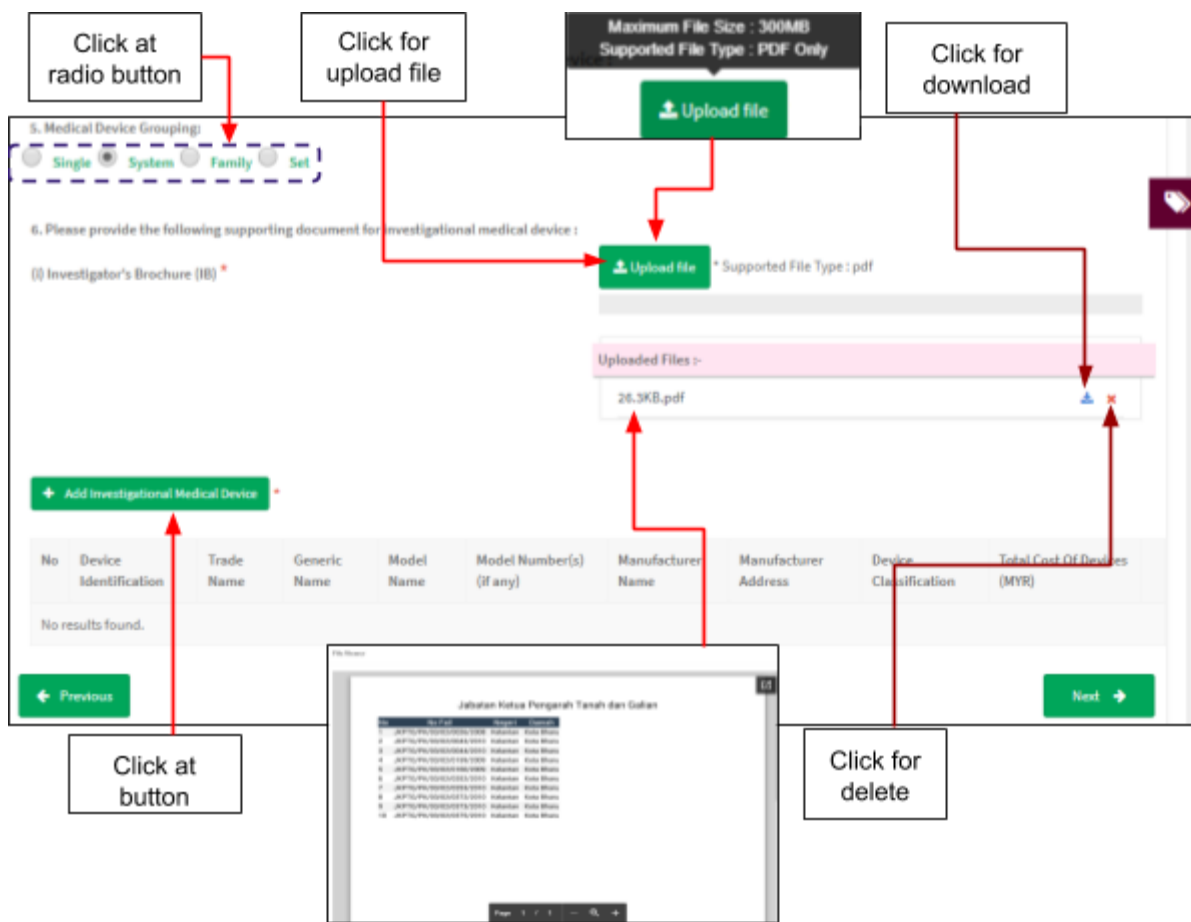
6. Please provide the following supporting documents for investigational medical device




User must click at button  untuk upload file PDF only and not more than 300MB for file size. After upload file, User also can preview the file that uploaded which are user clicks the filename and file will appear. Beside that, user

can download and print by clicking symbol  . 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.

The screenshot shows a web form titled "Add 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 it is a required field. The fields are: "Device Identification", "Trade Name", "Generic Name", "Model Name", "Model Number(s) (if any)", and "Manufacturer Name". A vertical red line with arrows pointing to each of these fields is accompanied by a callout box that says "Fill in the textbox". On the right side of the form, there is a vertical scrollbar. A red arrow points from a callout box that says "Click for move up and down" to the scrollbar.


### Add Investigational Medical Device

The symbol "\*" means required field.

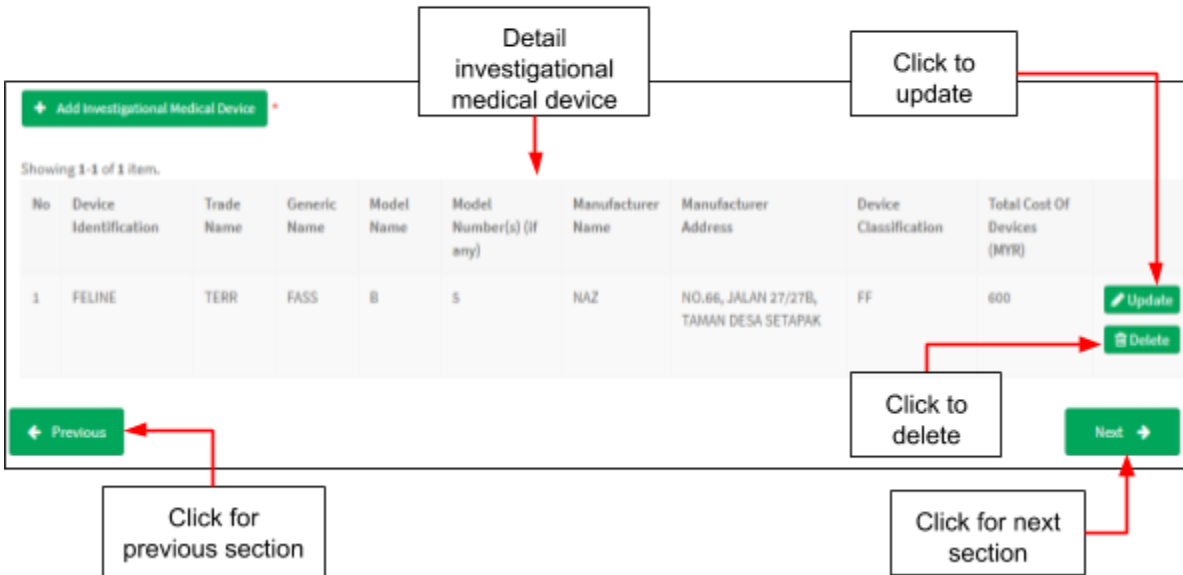
- Device Identification ->The user should fill the textbox that provided. If user don't fill the field, the message "Device Identification cannot be blank." will be displayed.
- Trade Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Trade Name cannot be blank." will be displayed.
- Generic Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Generic Name cannot be blank." will be displayed.
- Model Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Model Name cannot be blank." will be displayed.
- Model Number(s) -> The user should fill the textbox that provided. The number is not required field to fill it.

- 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.
- Device classification -> The user should fill the textbox that provided. If user don't fill the field, the message "Device Classification cannot be blank." will be displayed.
- Total cost of device -> The user should fill the textbox that provided. The user must fill the textbox with number only. If user fills it except number, the message "Total Cost Of Devices (MYR) must be a number." will be displayed. If user don't fill the field, the message "Total Cost Of Devices (MYR) cannot be blank." will be displayed.

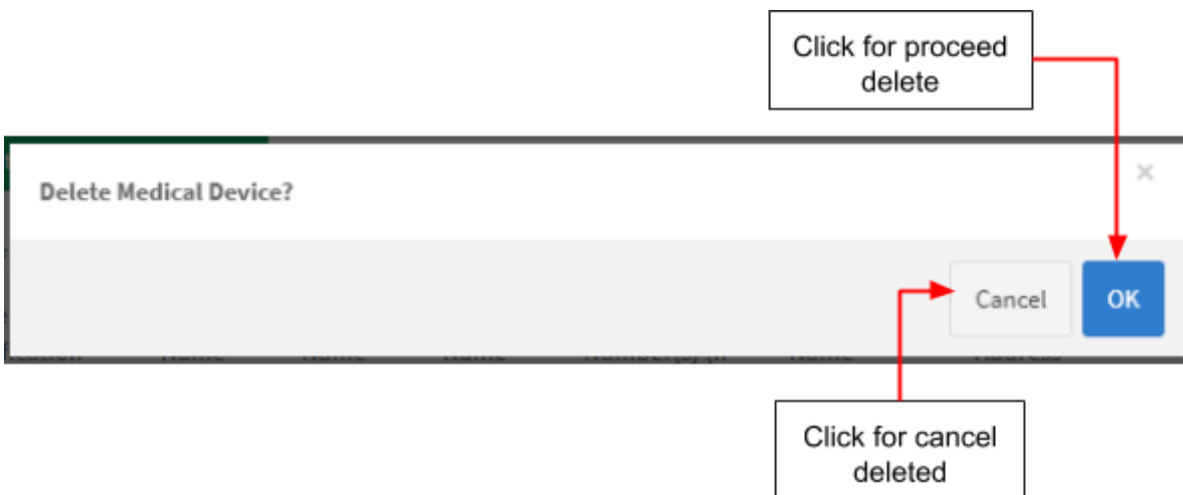
The diagram shows a form with three textboxes and a button. The textboxes are labeled "Manufacturer Address \*", "Device Classification \*", and "Total Cost Of Devices (MYR) \*". The button is labeled "Add Investigational Medical Devices". A red line with arrows points from a box labeled "Fill in the textbox" to each of the three textboxes. 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  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**

**Add Investigational Medical Device** ✕

**Device Identification \***

**Trade Name \***

**Generic Name \***


**Model Name \***


**Model Number(s) (if any)**

**Manufacturer Name \***

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

Showing 1-1 of 1 item.

| No | Device Identification | Trade Name | Generic Name | Model Name | Model Number(s) (if any) | Manufacturer Name | Manufacturer Address                    | Device Classification | Total Cost Of Devices (MYR) |   |
|----|-----------------------|------------|--------------|------------|--------------------------|-------------------|---|-----------------------|-----------------------------|---|
| 1  | DEVICE EE             | FASS       | DAS          | MODEL 5    | 4                        | NAZ               | NO.66, JALAN 27/27B, TAMAN DESA SETAPAK | G                     | 600                         | <div style="text-align: right;">  <br/>  </div> |

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



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.

### Section H: Clinical Investigation Plan(CIP)



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


The screenshot shows 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 each of these four input fields, indicating where the user should enter information. 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, suggesting that the form content can be scrolled down.

## Clinical investigational plan

The symbol “\*” means required field.

1. Investigator Site
  - a) Name of investigation 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 investigation 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

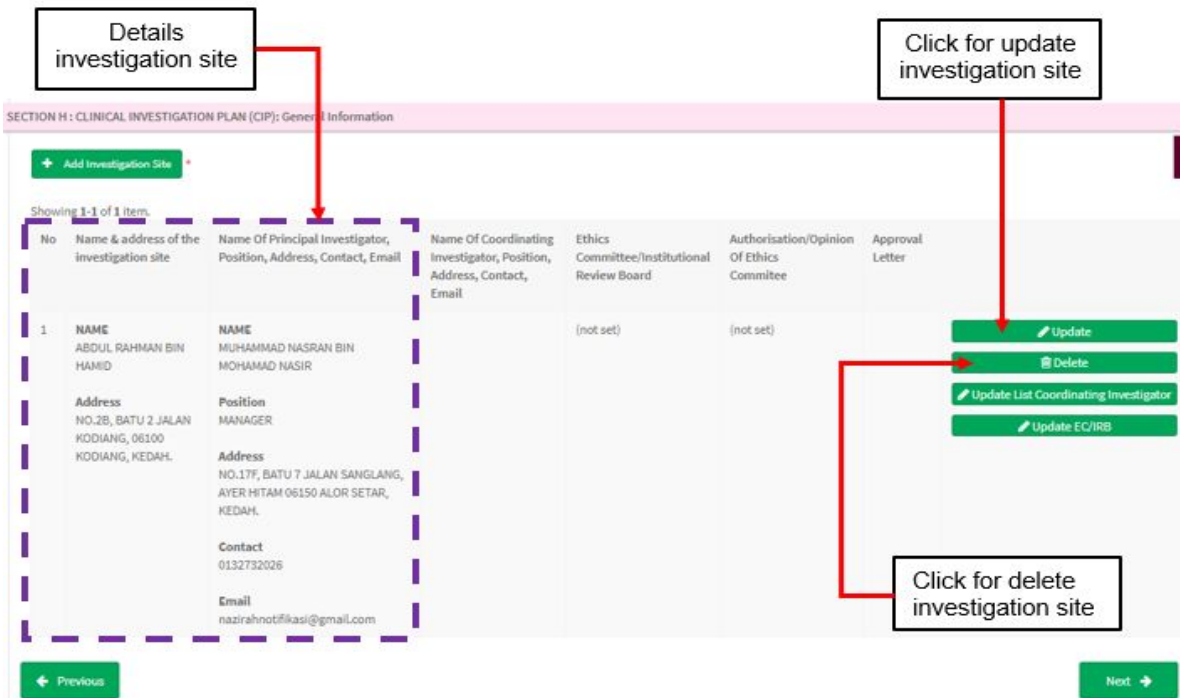
Email of Principal Investigator \*

Save

Click at button

Click for move up and down

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



If user wants to update investigation 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.

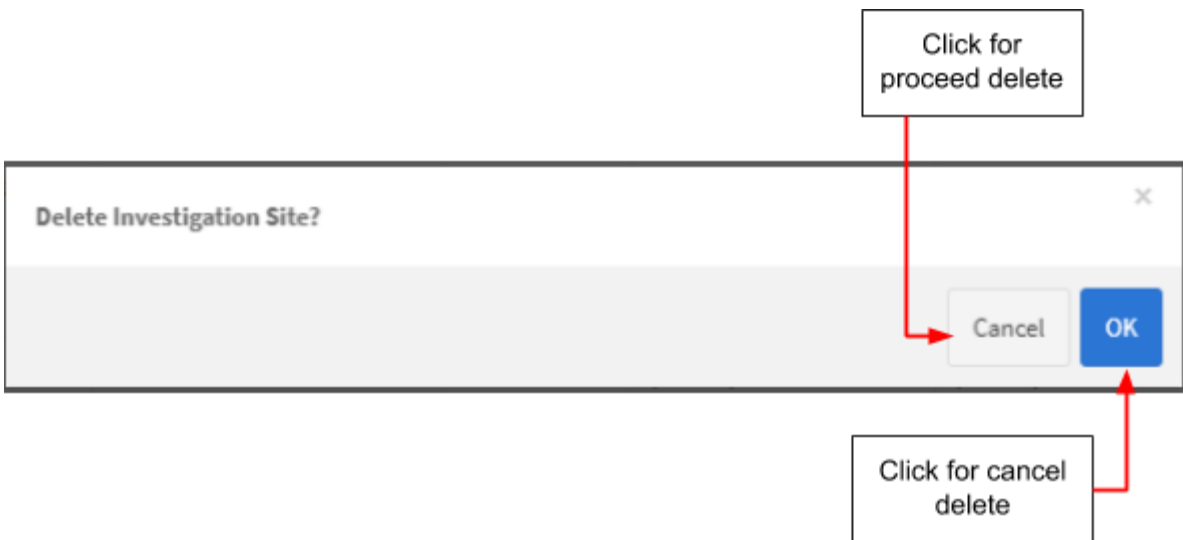
The screenshot shows a web form titled "Clinical Investigational Plan". It is divided into two main sections: "Investigator Site" and "Principal Investigator".

- Investigator Site:**
  - Name of Investigation Site \***: Input field containing "ABDUL RAHMAN BIN HAMID".
  - Address of Investigation Site \***: Input field containing "NO.2B, BATU 2 JALAN KODIANG, 06100 KODIANG, KEDAH."
- Principal Investigator:**
  - Name of Principal Investigator \***: Input field containing "MUHAMMAD NASRAN BIN MOHAMAD NASIR".
  - Professional of Position Principal Investigator \***: Input field containing "MANAGER".

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.



Clinical Investigational Plan

**List Of Coordinating Investigator**

NAME

Address

Position

Contact  
 e.g: 0134567890


Email

**2** → SAVE

**3**


| No                | NAME | Position | Address | Contact | Email |
|-------------------|------|----------|---------|---------|-------|
| No results found. |      |          |         |         |       |

**4** → Click for closed


**2** → The user should click at  to save details.

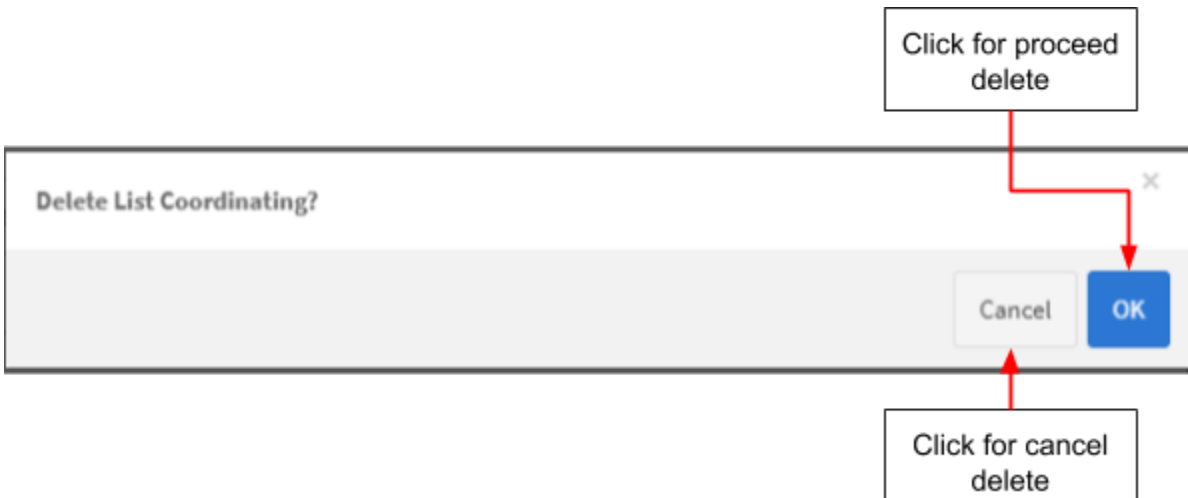
**3** → The details of coordinating investigator will be displayed in table after clicking button “save”. Example details are:

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 |  |

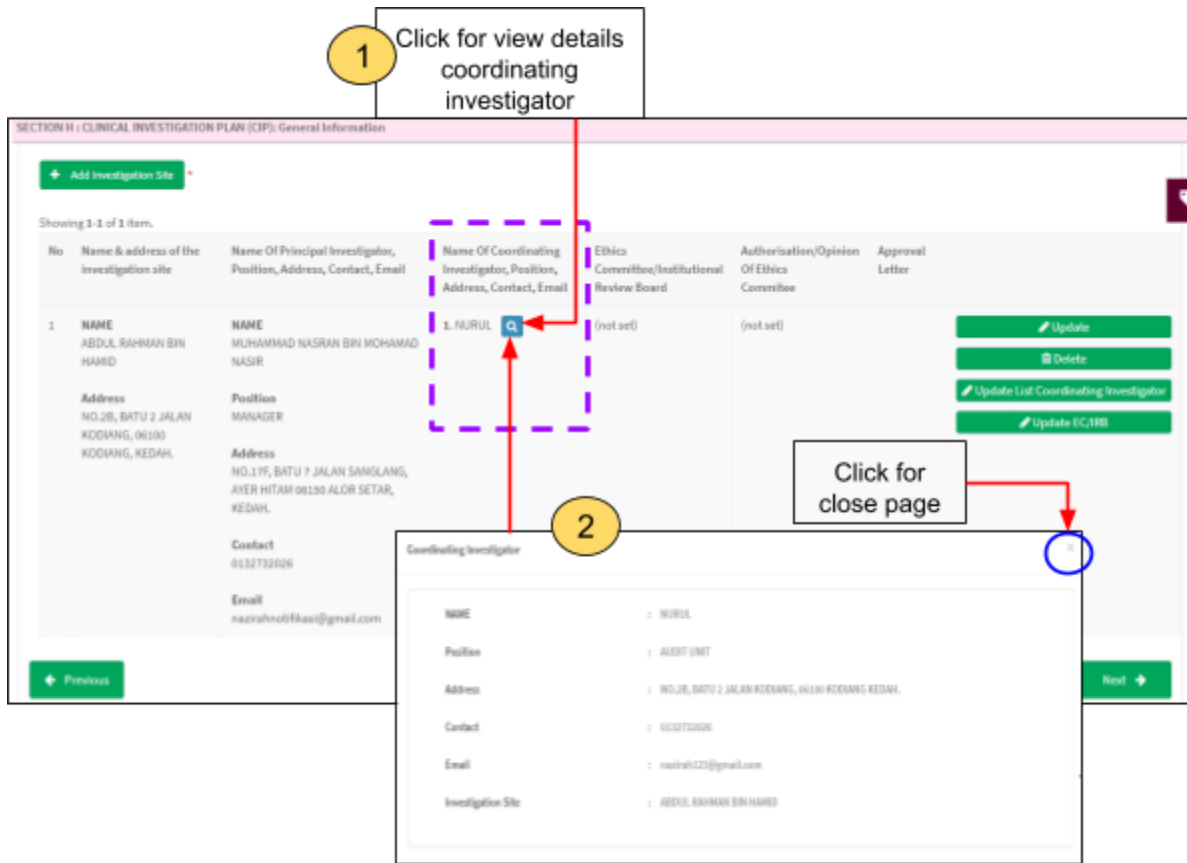
Click for delete


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.



**4** -> 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.

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 buttons: "TO BE REQUESTED", "PENDING", and "AUTHORISATION ACCEPTED/FAVOURABLE OPINION". A red arrow points from a box labeled "Click at radio button" to the "AUTHORISATION ACCEPTED/FAVOURABLE OPINION" radio button. 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)

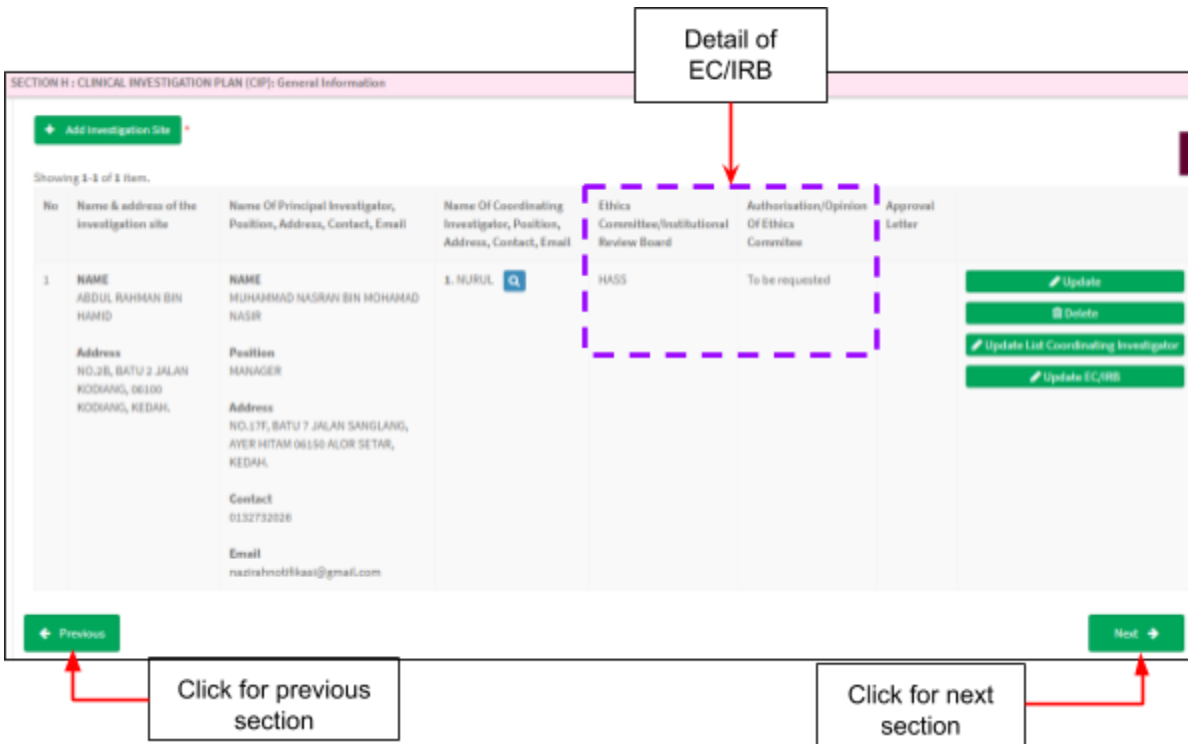
- The user should fill in the textbox that provided.

#### 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.



Then, 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.

### Section I: Appendix A

The user should tick on checkbox that provided in all details. The user also can add

comment in each of details with clicking at



that shown in figure below.

SECTION I : APPENDIX A

CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) INCLUDING INVESTIGATIONAL MEDICAL DEVICES AND GENERATING DATA INTENDED TO BE SUBMITTED REGULATORY AUTHORITIES

| No | Details (Tick If Submitted)  | Comments                    |
|----|--|-----------------------------|
| 1  | <b>GENERAL INFORMATION</b><br>A) Identification of CIP <ul style="list-style-type: none"><li><input type="checkbox"/> Title of clinical investigation</li><li><input type="checkbox"/> Reference / protocol number identifying the specific clinical investigation, if any</li><li><input type="checkbox"/> Version or date of the CIP</li><li><input type="checkbox"/> Summary of the revision history in the case amendments</li><li><input type="checkbox"/> Version / issue number and reference number, if any, with the page number and the total number of pages on each page of the CIP</li></ul> B) Sponsor | <a href="#">Add Comment</a> |

After click button “Add Comment”, the page comment will be displayed.

Investigational Device Application


CLINICAL INVESTIGATION PLAN COMMENT FOR GENERAL INFORMATION

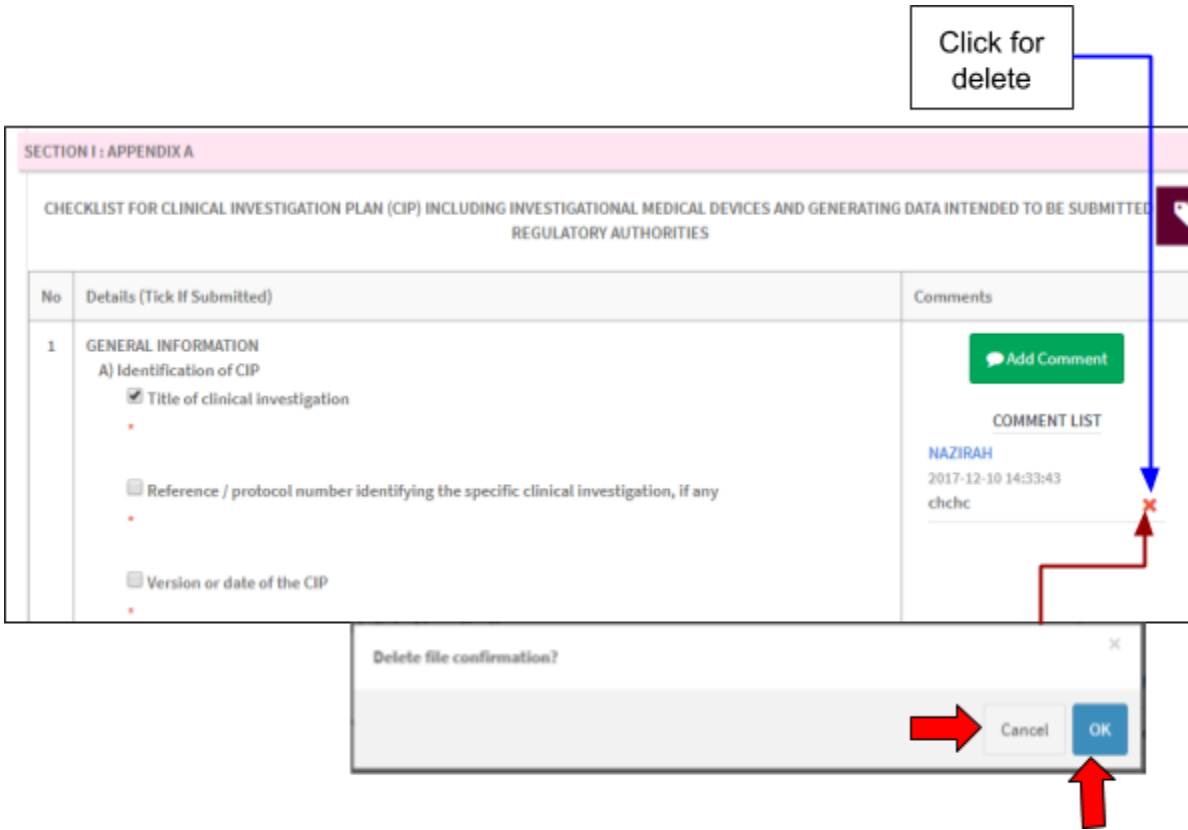
[Add Comment](#)


Comment :

[Save Comment](#)


The user should fill the comment in form that shown in figure above. Then, click

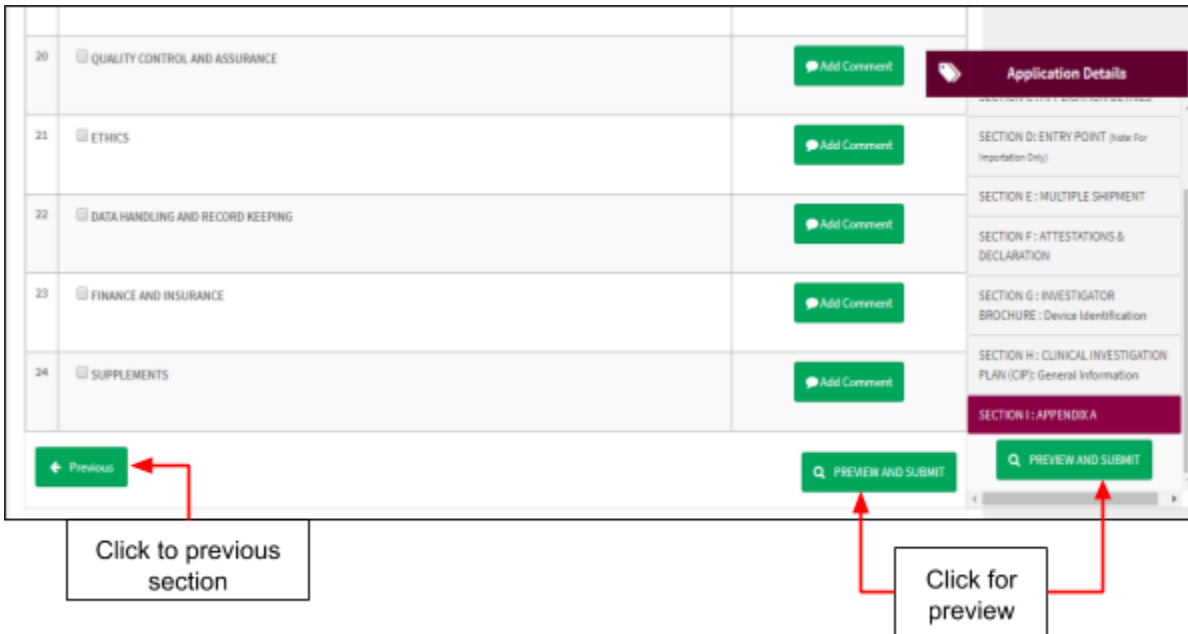
button . The comments will be displayed on the table shown in the figure below.



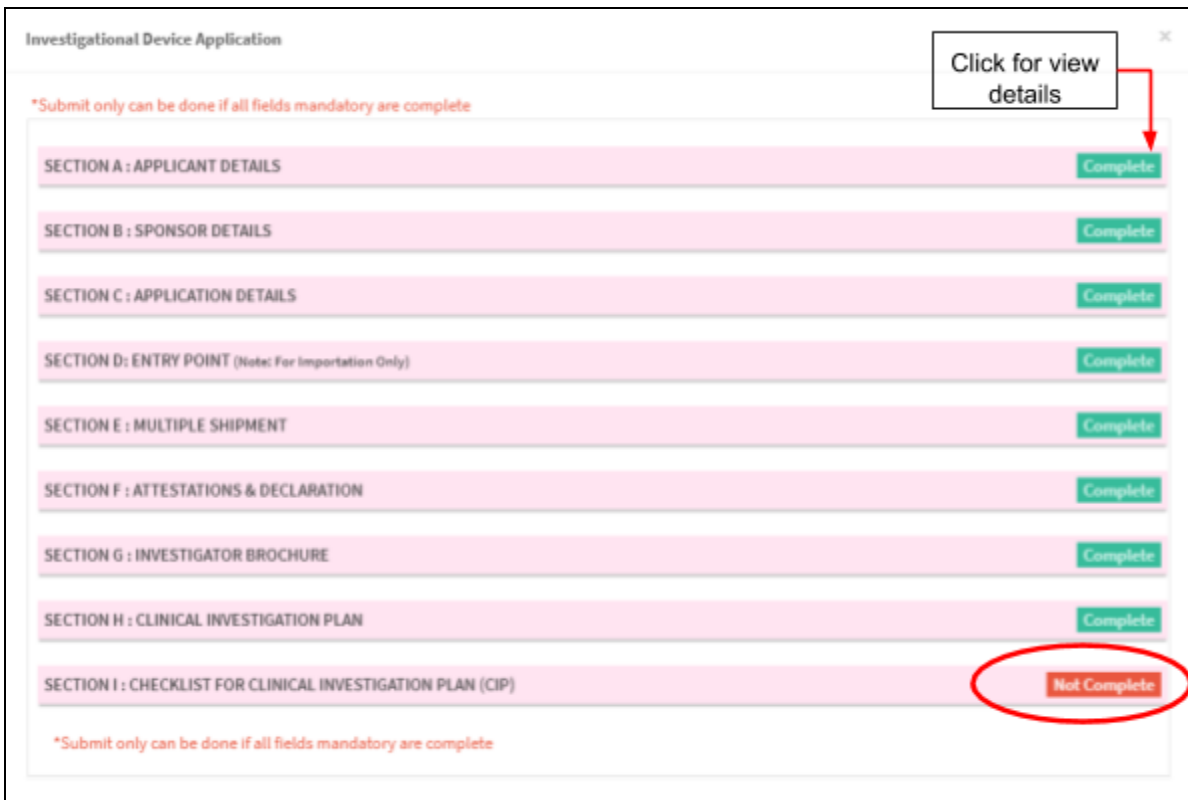
The user can delete the comment with click at  and the message alert will be showed. The user should click “ok” to proceed deleted or “cancel” to delete canceled.

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

 to preview and submit the application form.

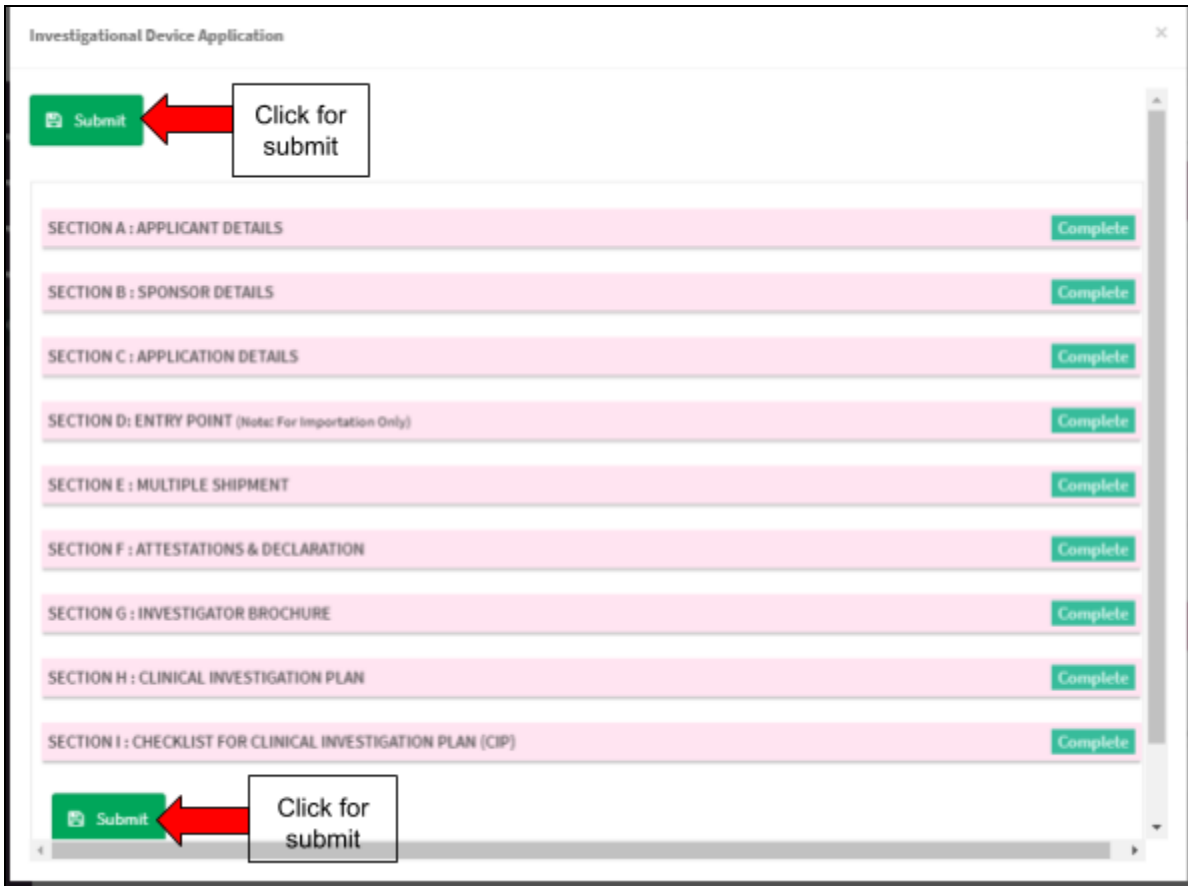


The page view will be shown after click button "PREVIEW AND SUBMIT". The figure below show the details of preview.





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.



If user click “ok” , the application status will be changed to “EVALUATION”.

Click for view details

| No | Submission ID  | Submitted At | Applicant | Application Type Name | Application Status | Action               |
|----|----------------|--------------|-----------|-----------------------|--------------------|----------------------|
| 1  | IU-20171206-20 | 10-12-2017   | NAZIRAH   | INVESTIGATIONAL USE   | EVALUATION         | <a href="#">View</a> |

Showing 1-2 of 2 items.

SECTION A - APPLICANT DETAILS [Complete](#)

SECTION B - SPONSOR DETAILS [Complete](#)

SECTION C - APPLICATION DETAILS [Complete](#)

SECTION D - DETAILED POINT (Only For Investigational Only) [Complete](#)

SECTION E - MULTIPLE SHIPMENT [Complete](#)

SECTION F - LETTERS/NOTES & DECLARATION [Complete](#)

SECTION G - INVESTIGATOR/PROXYING [Complete](#)

SECTION H - CLINICAL INVESTIGATION PLAN [Complete](#)

SECTION I - CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) [Complete](#)

In addition, if application status “Draft” , the user can delete or update the application form.

**Notification Form Application List**

Showing 1-2 of 2 items.

| No | Submission ID  | Submitted At      | Applicant | Application Type Name | Application Status | Action   |
|----|----------------|-------------------|-----------|-----------------------|--------------------|--|
| 1  | IU-20171206-20 | 10-12-2017        | NAZIRAH   | INVESTIGATIONAL USE   | EVALUATION         | <a href="#">View</a>   |
| 2  | IU-20171208-21 | Not Submitted Yet | NAZIRAH   | INVESTIGATIONAL USE   | DRAFT              | <a href="#">View</a> <a href="#">Update</a> <a href="#">Delete</a> |

**Delete application confirmation?**

Cancel [OK](#)

**b) Subsequent application**

User click on the Application List at Clinical Investigation > Investigational Use.

- HOME
- NOTIFICATION
- Clinical Research
  - Investigational Use
    - New Notification Form
    - Notification List ( 1 )**
    - Notification Of Change ( 0 )
    - History ( 0 )
  - Clinical Research Use

The system will display page of list application Investigational Use.

| Notification List        |    |               |              |           |                        |                     |   |
|--------------------------|----|---------------|--------------|-----------|------------------------|---------------------|---|
| Showing 1-1 of 1 item.   |    |               |              |           |                        |                     |   |
| <input type="checkbox"/> | No | Submission ID | Submitted At | Applicant | Notification Type Name | Notification Status | Action  |
| <input type="checkbox"/> | 1  | IU-20180815-1 | 15-08-2018   | BISHRUN   | INVESTIGATIONAL USE    | COMPLETE            | <a href="#">View</a> <a href="#">Subsequent Notification</a> <a href="#">Notification of Change</a> |

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.

**Clinical Research - Investigational Use (IU-20180820-2)**

Notification to Import Or Supply Medical Device for Clinical Investigational Use  
 (In accordance with Medical Device (Exemption) Order 2016)

All fields are mandatory unless stated otherwise.

**PURPOSE OF NOTIFICATION \***

IMPORTATION  SUPPLY ( Note: for locally manufactured medical device)

**GENERAL INFORMATION**

**SECTION A : APPLICANT DETAILS**

1. Role Of Applicant

Local Sponsor  An Authorised person from a local organization (in case of foreign sponsor / manufacturer)

2. Name of Applicant : \*

BISHRUN

3. NRIC No/Passport : \*

4. Designation : \*

The user complete the Subsequent Application form. The user review all information in Section A, B C, D, E, F, G and H. Next step is the user click on button [PREVIEW AND SUBMIT](#).

SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information

[+ Add Investigation Site \\*](#)

Showing 1-1 of 1 item.

| No | Name & address of the investigation 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  | <b>Name</b><br>INVESTIGAE TESTING<br><br><b>Address</b><br>32 JALAN TESTING | <b>Name</b><br>MR RAJU<br><br><b>Position</b><br>CEO<br><br><b>Address</b><br>32 JALAN TESTING<br><br><b>Contact</b><br>03433231233<br><br><b>Email</b><br>raju@gmail.com | 1. RAJU  | MELAYU                                      | To be requested                           | <a href="#">Update</a><br><a href="#">Delete</a><br><a href="#">Update List Coordinating Investigator</a><br><a href="#">Update EC/IRB</a> |

[← Previous](#) [PREVIEW AND SUBMIT](#)

**Notification Details**

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





SECTION E : MULTIPLE SHIPMENT

SECTION F : ATTESTATIONS & DECLARATION

SECTION G : INVESTIGATOR BROCHURE - Device Identification

**SECTION H - CLINICAL INVESTIGATION PLAN (CIP): General Information**

[PREVIEW AND SUBMIT](#)

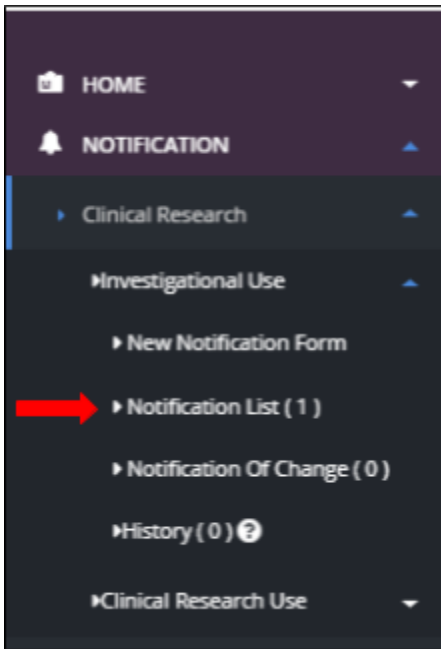
If all mandatory information has been filled out, button  and keyword  will display. If the information is not completed,  keyword will display and button  will not display until all information is filled.

The status of application will be on evaluation stage.

| No | Submission ID | Submitted At | Applicant | Notification Type Name         | Notification Status | Action  |
|----|---------------|--------------|-----------|--------------------------------|---------------------|---|
| 1  | IU-20180820-2 | 24-08-2018   | BISHRUN   | SUBSEQUENT INVESTIGATIONAL USE | EVALUATION          | View Notification History                           |
| 2  | IU-20180815-1 | 15-08-2018   | BISHRUN   | INVESTIGATIONAL USE            | COMPLETE            | View Subsequent Notification Notification of Change |

**c) Change of Notification**

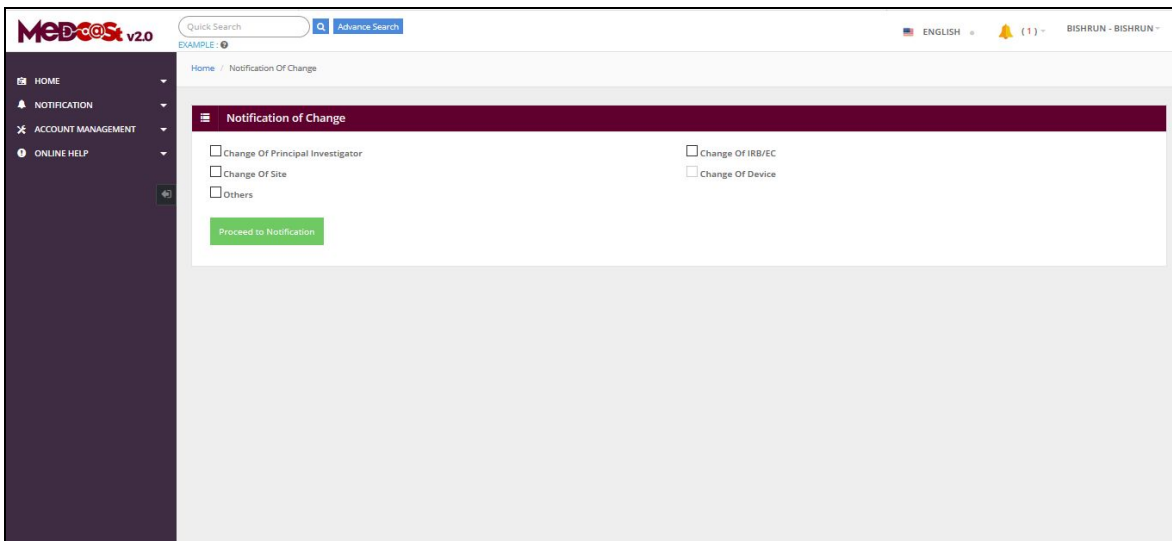
User click on the Application List at Clinical Investigation > Investigational Use.

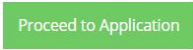


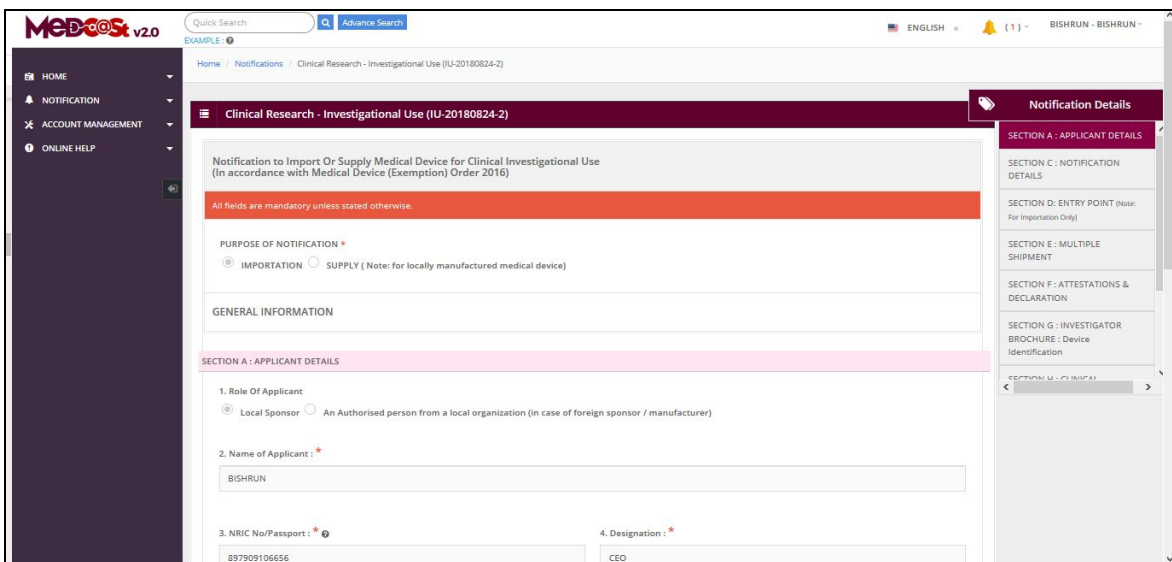
The system will display page of list application Investigational Use.

| Notification List      |               |              |           |                        |                     |                      |   |
|------------------------|---------------|--------------|-----------|------------------------|---------------------|----------------------|---|
| Showing 1-1 of 1 item. |               |              |           |                        |                     |                      |   |
| No                     | Submission ID | Submitted At | Applicant | Notification Type Name | Notification Status | Action               |   |
| 1                      | IU-20180815-1 | 15-08-2018   | BISHRUN   | INVESTIGATIONAL USE    | COMPLETE            | <a href="#">View</a> | <a href="#">Subsequent Notification</a><br><a href="#">Notification of Change</a> |

User click on [Notification of Change](#) . Next step is click OK and the system will display *Notification of Change*.

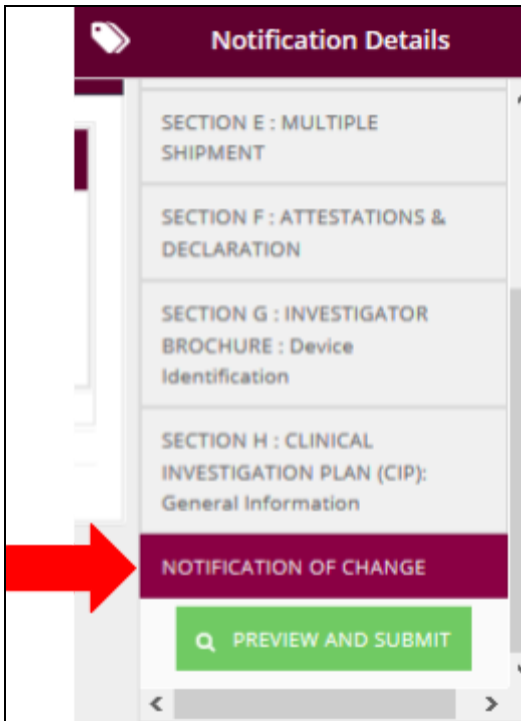


User choose type of change by click button  . The system will display Change Notification application form.

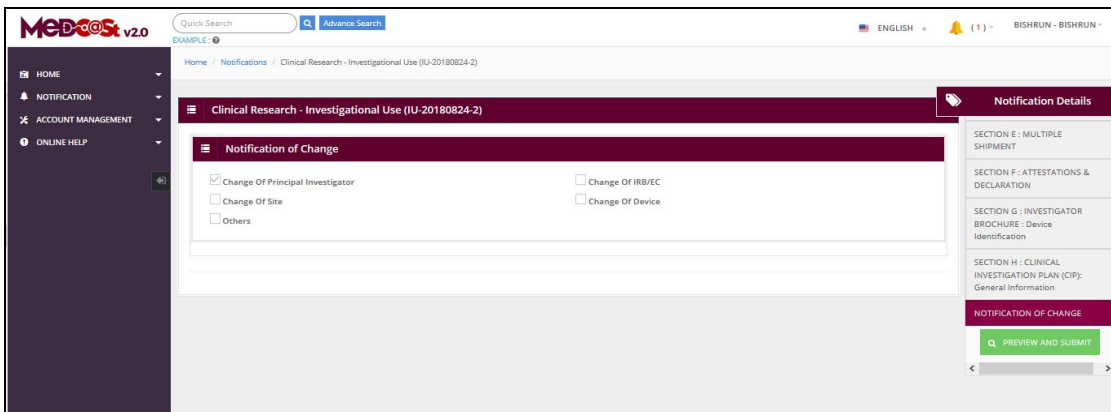


The user can revisits the changes that have been selected. User can click button Notification of Change on right side.



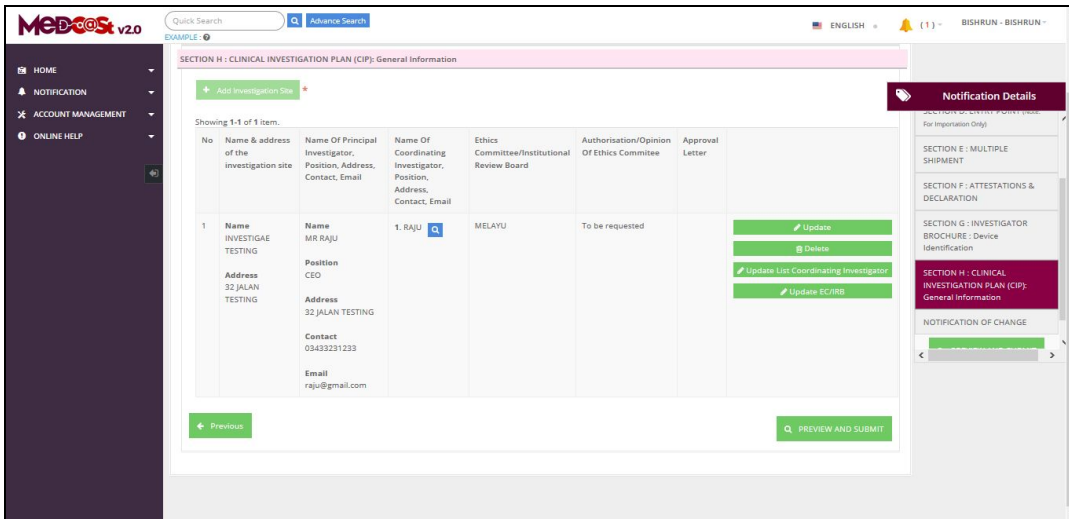


The list of changes that have been selected will be displayed.

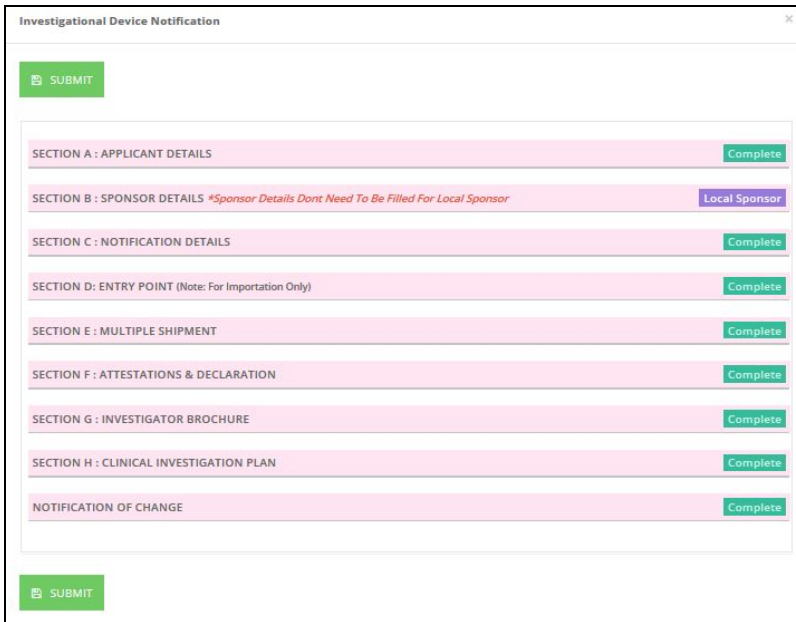


The applicant updates the information according to the type of change that has

been selected. Only the field selected for making changes can be edited by the applicant.

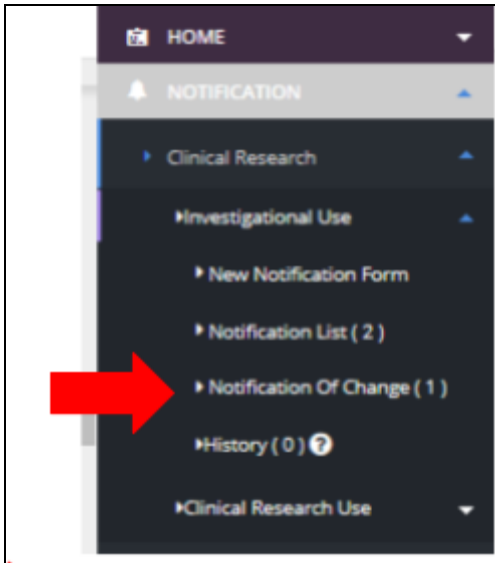


Next step is click on button  to preview the information that user change.

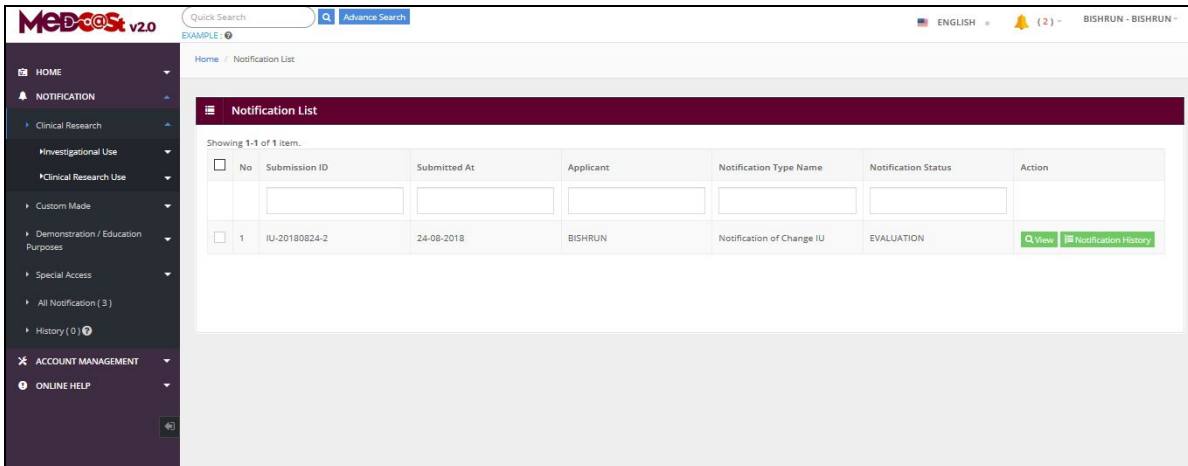


Click on  to submit form.

User click button Notification of Change under Clinical Investigation > Investigational Use.

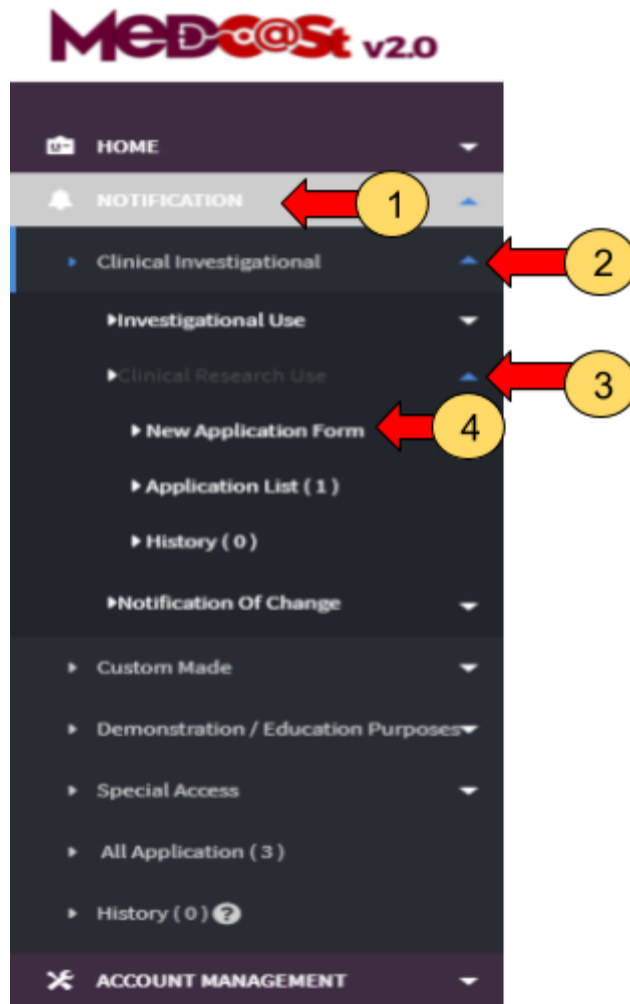


The system will display the list of Notification of Change.



## II) CLINICAL RESEARCH USE

### a) *New Application*



1 -> The user should click at menu NOTIFICATION and list of module will be displayed which are Clinical Investigational, Custom made, Demonstration/Education Purposes and Special Access.

2 -> The user should click at menu module Clinical Investigational and list of sub module will be displayed which are Investigational Use, Clinical research use

and Notification of change.

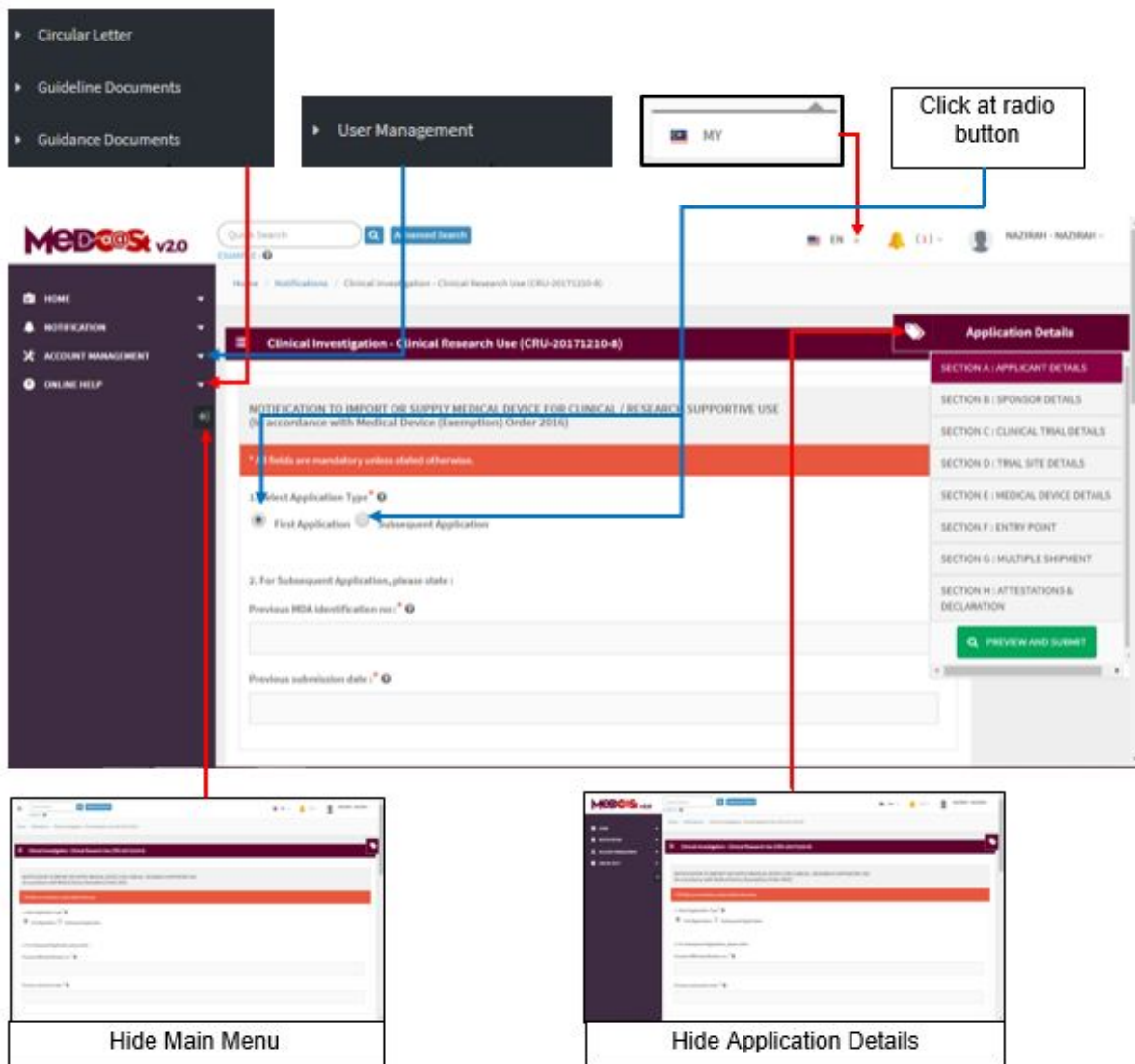
3

-> The user should click at sub module Clinical Research use and the New Application Form will be showed.

4

-> The user should click at New Application Form.

The application form will appear.



The application details have eight sections which are:

- a) Section A: Application Details
- b) Section B: Sponsor Details
- c) Section C: Clinical Trial Details
- d) Section D: Trial Site Details
- e) Section E: Medical Device Details
- f) Section F: Entry Point
- g) Section G: Multiple Shipment
- h) Section H: Attestations & Declaration

Firstly, the user should select application type whether “First Application” or “Subsequent Application”.

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

1. Select Application Type

- User should choose the type of application whether “First Application” or

“Subsequent Application”. If user click on radio button  **First Application** the field of number 2. will be disabled.

2. For Subsequent Application, please state : ?

Previous MDA identification no : \* ?

Previous submission date : \* ?

This screenshot shows a form section titled "2. For Subsequent Application, please state : ?". It contains two required fields: "Previous MDA identification no : \* ?" and "Previous submission date : \* ?". Both fields are currently disabled (greyed out) because the "First Application" radio button is selected.

If user click on radio button  **Subsequent Application** ,the field of number 2 will be enabled.

2. For Subsequent Application, please state : ?

Previous MDA identification no : \* ?

Previous submission date : \* ?

This screenshot shows the same form section as above, but now the "Subsequent Application" radio button is selected. Consequently, the two required fields, "Previous MDA identification no : \* ?" and "Previous submission date : \* ?", are now enabled and ready for input.


## Section A: Application Details

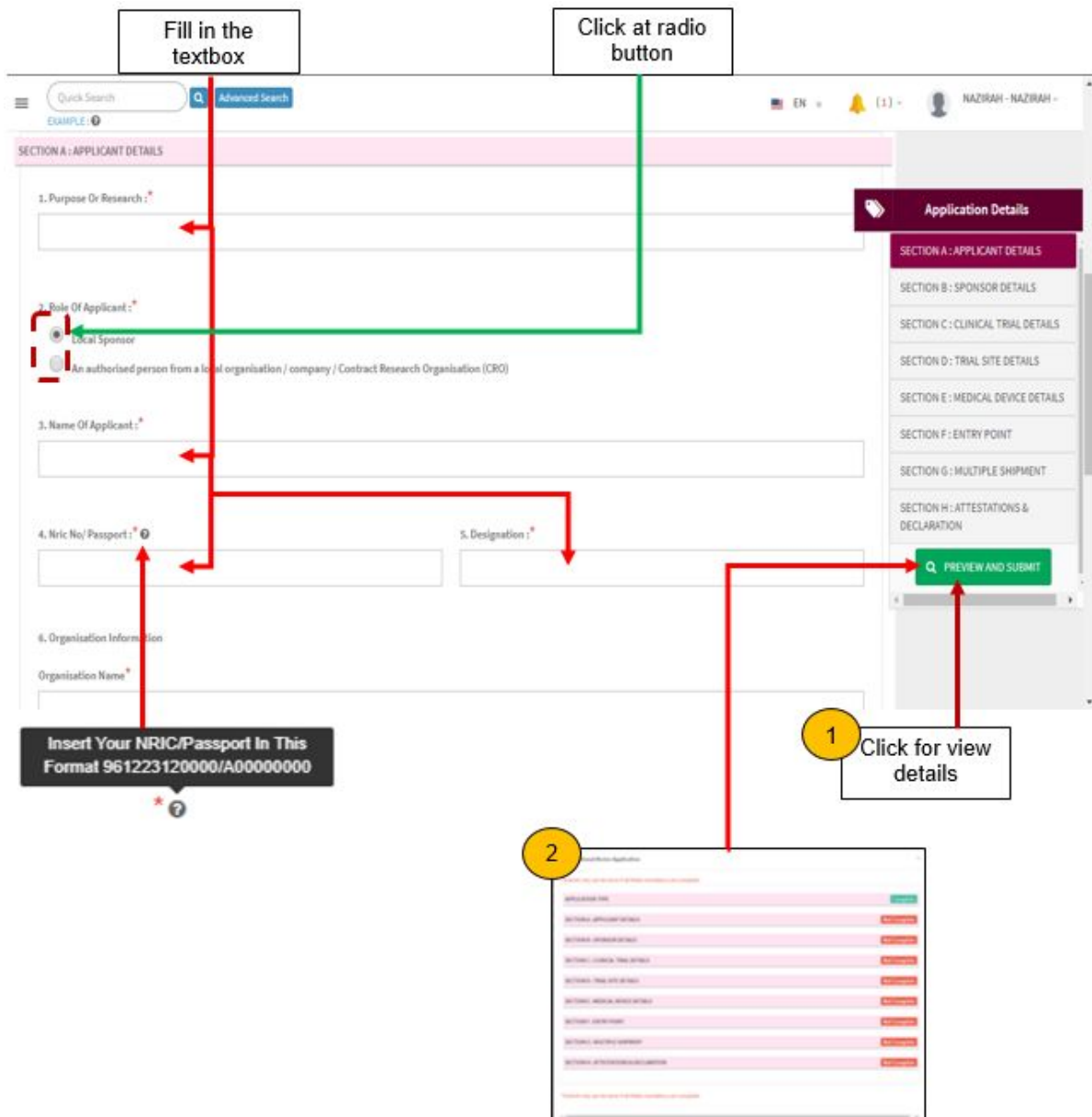
1. Purpose or Research

The user should fill the textbox that provided of purpose or research.

2. Role of applicant

- Local sponsor-> user should click at radio button that provided.

- An authorised person from a local organisation/company/contact research organisation(CRO).
- 3. Name of Applicant  
 The user should fill the name in the textbox that provided.
- 4. Nric No/Passport  
 The user must fill in the form according to the format displayed on the figure below. The user should click at  to appear the format.



- 5. Designation



The user should fill the designation in textbox that provided shown in figure above.

#### 6. Organisation information

- Organisation name -> The user should fill the name in the textbox that provided shown in the figure below.
- Address of organisation -> the user should fill in the textbox with address of organisation.
- State -> User should click in textbox to drop down list and user should select the state that has shown in the figure below.
- 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.
- 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.”


7. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at . The format will appear like shows in figure above. If user fills in the form except number or number more than eleven, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.


8. Mobile No.

The user must fill the Mobile No in an integer. User can see the format which click at . If user fill in the form except number or more than eleven number, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.

9. Fax No.

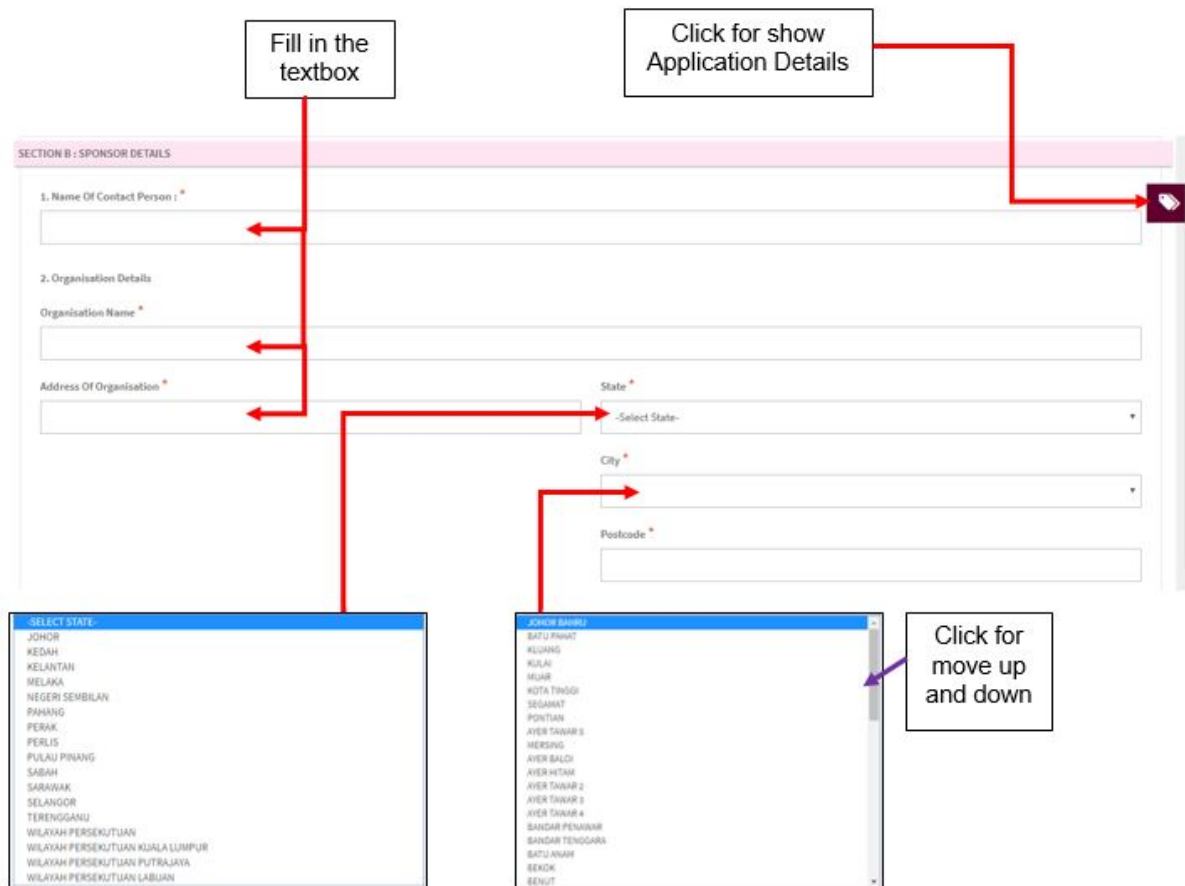
The user must fill the Fax No in an integer. User can see the format which click at . If user fill in the form except number or more than eleven number, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.

8. Email Address

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



After that, the user should click at button  to the next section. The form for section B will be appeared.



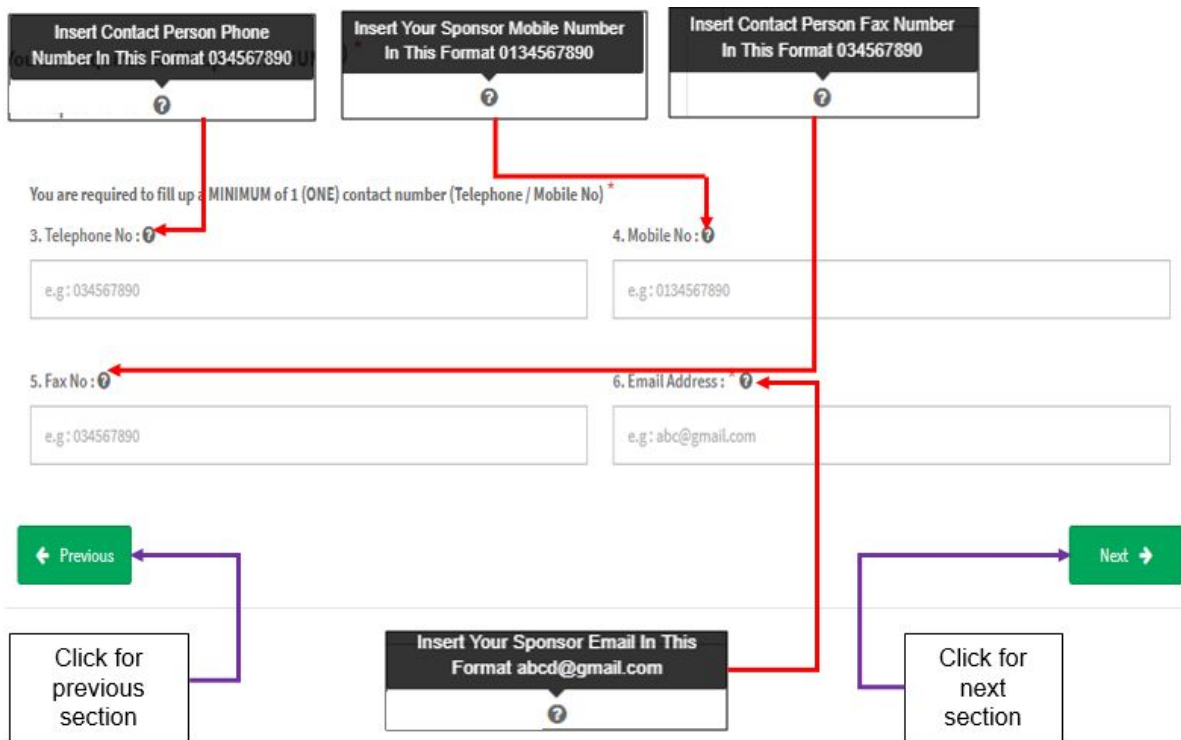
## Section B: Sponsor Details

### 1. Name of Contact Person

The user should fill the name in the textbox.

### 2. Organisation Details

- Organisation Name -> The user should fill the name in the textbox that provided shown in the figure below.
- Address of organisation -> The user should fill in the textbox with address of organisation.
- State -> User should click in textbox to drop down list and user should select the state that has shown in figure above.
- 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 figure above.
- Postcode -> The field must contain exactly five numeric. If user fill the form with the alphabet, the message will appear “**Organisation Postcode must be an integer.**”. If user fill in postcode more than five number, the message will appear “**Field must contain exactly 5 numeric.**”




3. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at . The format will appear like shown in figure above. If user fills in the form except number or number more than eleven, the message “Field can only contain number and between 3 to 11 numeric.” will appear.


4. Mobile No.

The user must fill the Mobile No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message “Field can only contain number and between 3 to 11 numeric.” will appear.

5. Fax No.

The user must fill the Fax No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message “Field can only contain number and between 3 to 11 numeric.” will appear.

## 6. Email Address

User must fill the email based the format. User should click at  to see the format. The format will be appeared. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will be appeared 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



## Section C: Clinical Trial Details

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

### 1. NMRR Registration ID

The user must fill in the textbox the registration ID with follow the format that given in the figure below. User should click at  to see the format.

### 2. Title of Clinical Trial- as stated in Protocol document


The user must fill the title in the textbox that provided.

### 3. Protocol No.

The user must fill the protocol number in the textbox that provided.

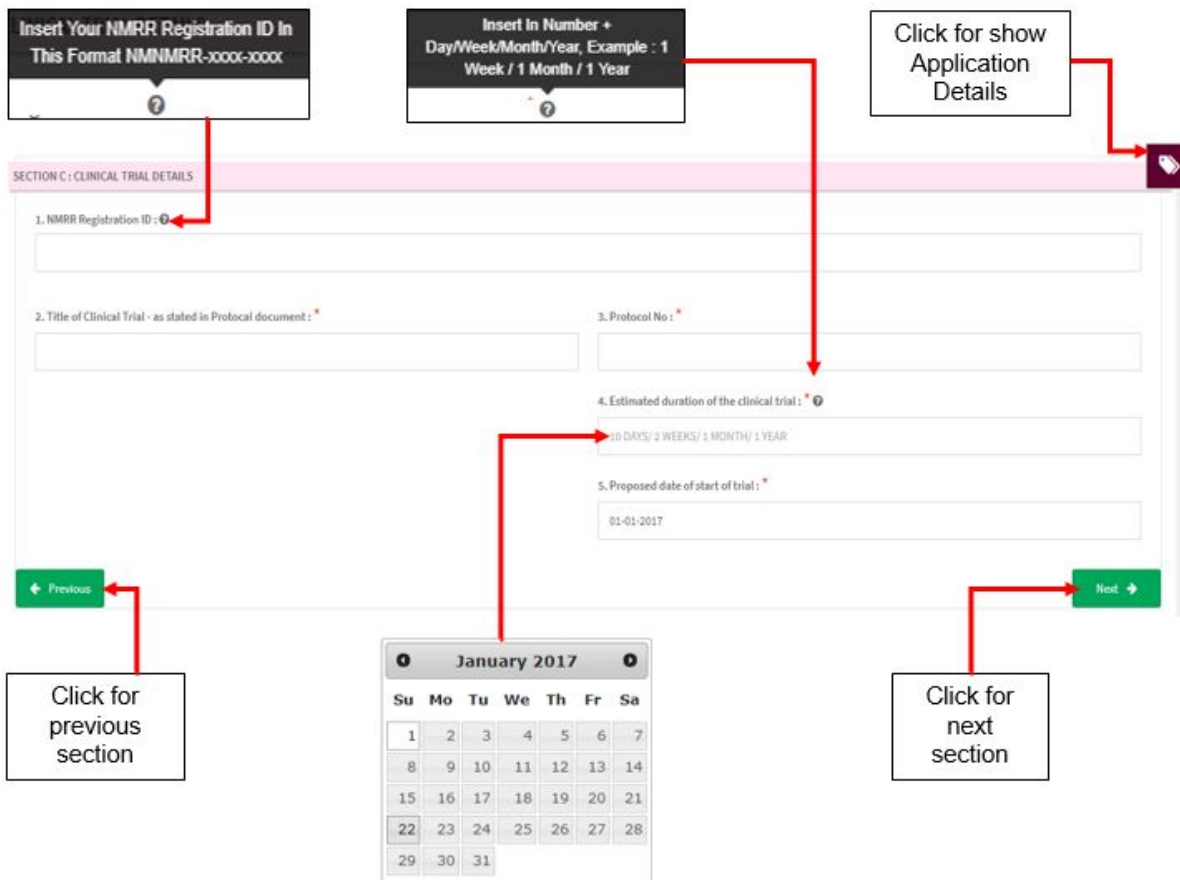
### 4. Estimated duration of the clinical trial

The user should fill in the textbox with follow the format duration that given.

User can see the format with click at  that shown in the figure below.

### 5. Proposed date of start of trial

The user should select a date in the calendar that provided. The user should click in textbox to appear the calendar.



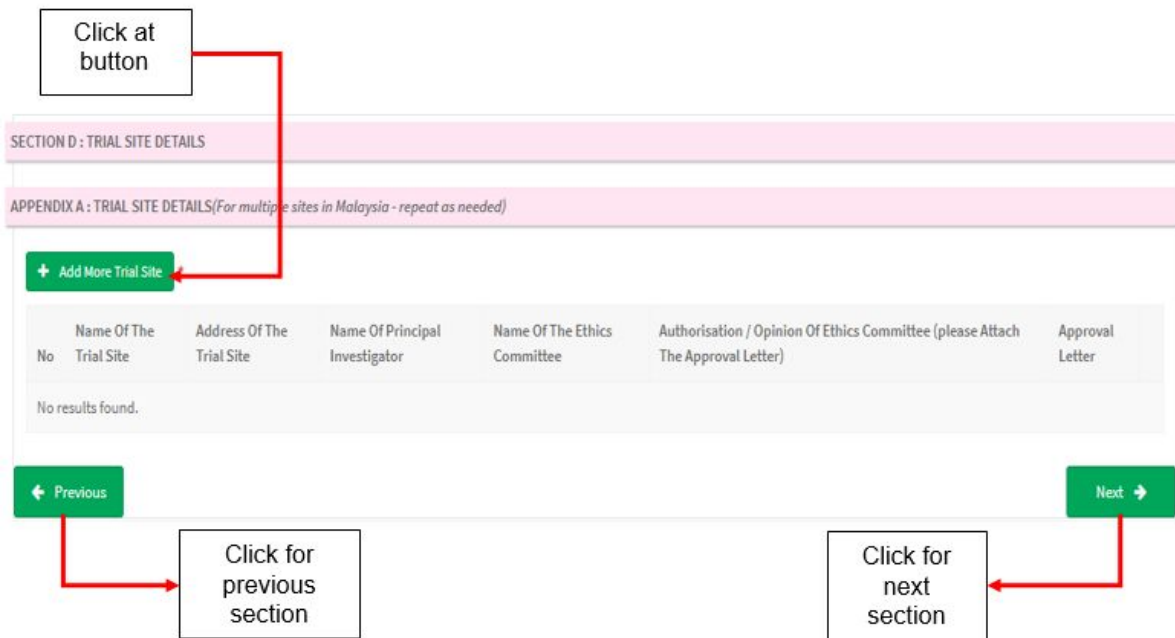
If user want back to previous section, user should click at button



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




to the next section.



**Section D: Trial Site Details**

Appendix A: Trial site details(for multiple sites in Malaysia-repeat as needed)

Firstly, the user should click at  to fill the form of trial site. The form will be displayed within click at button. The figure below shows the form of trial site.



The screenshot shows a web form titled "Add Trial Site" with a close button (X) in the top right corner. The form contains four required text input fields, each with a red asterisk: "1. Name Of The Trial Site : \*", "2. Address Of The Trial Site : \*", "3. Name Of Principal Investigator : \*", and "4. Name Of The Ethics Committee : \*". A green "Save" button is located at the bottom left of the form. A red box labeled "Fill in the textbox" has a vertical line with four arrows pointing to the four text input fields. Another red box labeled "Click for save" has an arrow pointing to the "Save" button.

### Add trial site

#### 1. Name of the trial site

The user should fill in the textbox that provided that shown in figure above. If the user don't fill the name, the message "Trail site Name cannot be blank." will appear.

#### 2. Address of the trial site


The user should fill in the textbox that provided that shown in figure above. If the user don't fill the address, the message "Trail site Address cannot be blank." will appear.

#### 3. Name of Principal Investigator

The user should fill in the textbox that provided that shown in figure above. If the user don't fill the name, the message "Trail site Principal Investigator cannot be blank." will appear.

#### 4. Name of The Ethics Committee


The user should fill in the textbox that provided that shown in figure above. If the user don't fill the name, the message "Trail site Name Committee cannot be blank." will appear.

After all the forms are completed, the user should click at . The details of Trial Site will appear at table that shown in the figure below.


The screenshot shows a table titled 'SECTION D : TRIAL SITE DETAILS' and 'APPENDIX A : TRIAL SITE DETAILS (For multiple sites in Malaysia - repeat as needed)'. The table contains one row of data. Annotations include:

- A red arrow labeled 'Details of trial site' points to the first row of the table.
- A red arrow labeled 'Click for update trial site' points to the 'Update' button in the action column.
- A red arrow labeled 'Click for delete' points to the 'Delete' button in the action column.
- A red arrow labeled 'Click for fill form EC/IRB' points to the 'Update EC/IRB' button in the action column.

| No | Name Of The Trial Site | Address Of The Trial Site   | Name Of Principal Investigator | Name Of The Ethics Committee | Authorisation / Opinion Of Ethics Committee (please Attach The Approval Letter) | Approval Letter |  |
|----|------------------------|---|--------------------------------|------------------------------|---|-----------------|--|
| 1  | ZIRA MOHAMAD NASIR     | NO.17 F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, KEDAH. | RAHMAN                         | HASSAN                       |   |                 | <input type="button" value="Update"/><br><input type="button" value="Delete"/><br><input type="button" value="Update EC/IRB"/> |

If user want to update trial site, user should click at  and the form will be displayed.

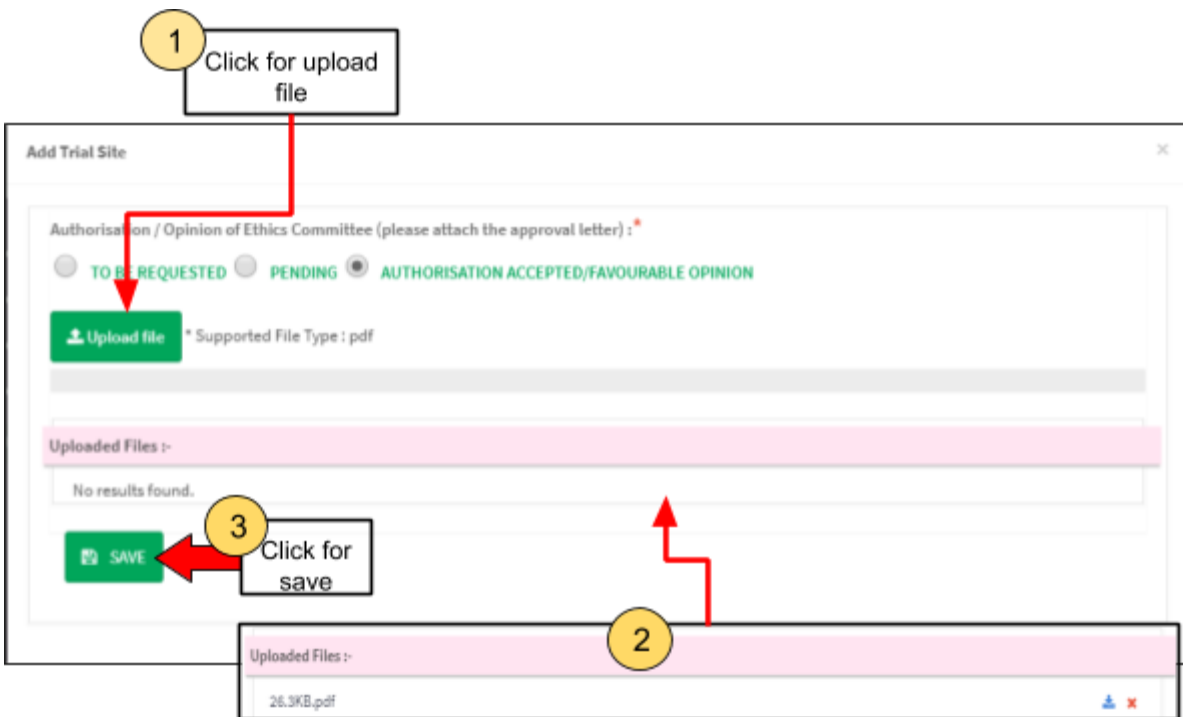
If user wants to delete trial site, user should click at button “delete” and the alert message will be displayed.

- 1 - the user should click on button “Add More Trial Site” to add trial site.
- 2 - the user should click at  to fill the form of Ethic Committee. The form will be displayed that shown in the figure below.



The user should choose the opinion whether “TO BE REQUESTED” or “PENDING” or “AUTHORISATION ACCEPTED/FAVOURABLE OPINION”.

If user choose  **AUTHORISATION ACCEPTED/FAVOURABLE OPINION** the button for upload file will be displayed.





User must click at button  untuk upload file PDF only and not more than 300MB for file size. If user upload file not in format PDF, the message will appear at the system which is “File Type Not Allowed”. User

should click “ok” to proceed in system. .



. The user can download

the file with clicking at  and delete the file with click at . If user upload the file more than 300MB, the alert message



will appear. The

user should click “ok’ to proceed.

The details will automatically be displayed in the table shown in the figure below. The user can update again the detail with click button “Update EC/IRB”. The form for fill the EC/IRB will be displayed.

**Details of EC/IRB**

**SECTION D : TRIAL SITE DETAILS**

**APPENDIX A : TRIAL SITE DETAILS(For multiple sites in Malaysia - repeat as needed)**

+ Add More Trial Site

Showing 1-1 of 1 item.

| No | Name Of The Trial Site | Address Of The Trial Site   | Name Of Principal Investigator | Name Of The Ethics Committee | Authorisation / Opinion Of Ethics Committee (please Attach The Approval Letter) | Approval Letter            |   |
|----|------------------------|---|--------------------------------|------------------------------|---|----------------------------|---|
| 1  | ZIRA MOHAMAD NASIR     | NO.17 F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, KEDAH. | RAHMAN                         | HASSAN                       | Authorisation accepted/favourable opinion                                       | <a href="#">26.3KB.pdf</a> | <div style="text-align: right;"> <span style="background-color: #28a745; color: white; padding: 2px 5px;">Update</span><br/> <span style="background-color: #28a745; color: white; padding: 2px 5px;">Delete</span><br/> <span style="background-color: #28a745; color: white; padding: 2px 5px;">Update EC/IRB</span> </div> |

← Previous
Click for update
Next →

Click for previous section

Click for next section

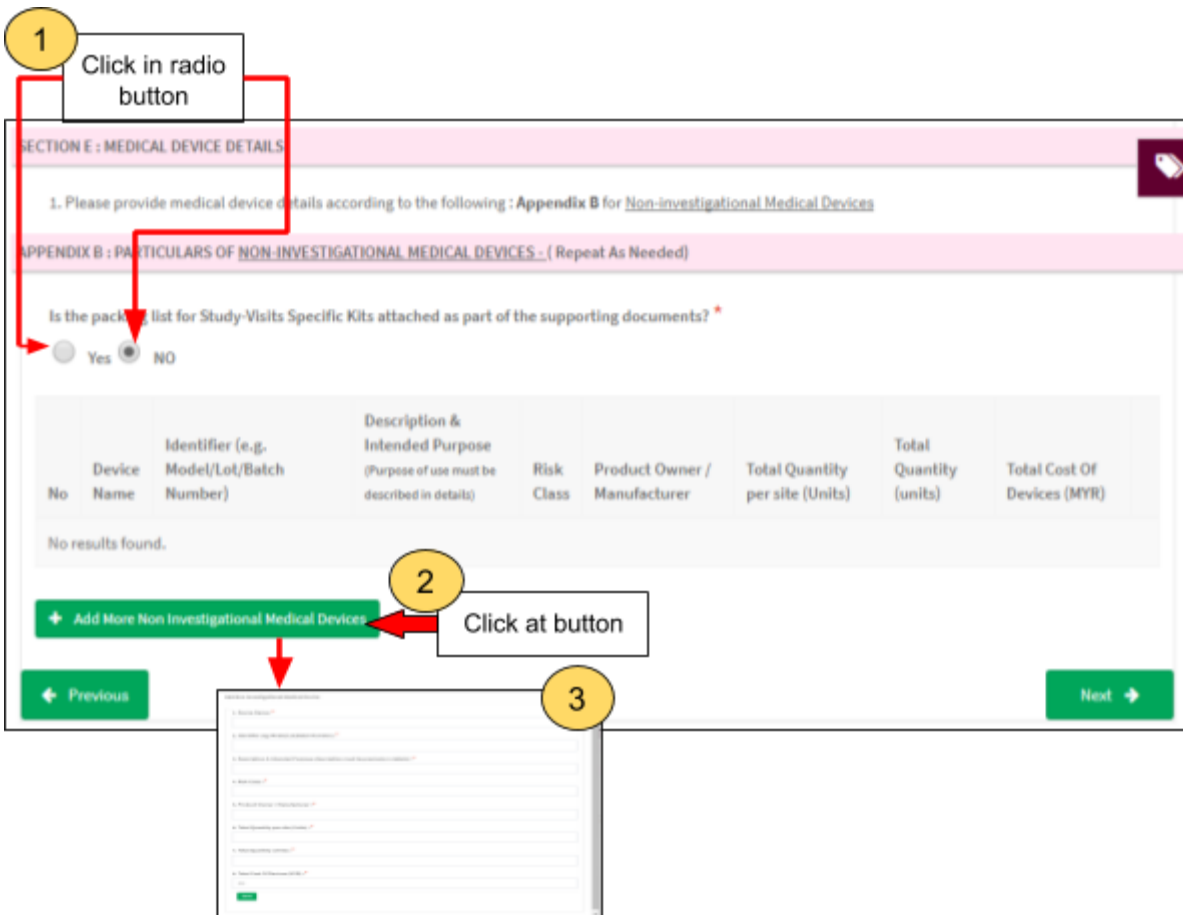
If user want back to previous section, user should click at button



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

to the next section.





**Section E: Medical Device Details**

Appendix B: Particulars of Non-Investigational Medical Devices

Is the packing list for Study-Visits Specific Kits attached as part of the supporting documents?

1 -> The user should click in radio button “Yes” or “No” . The user choose “No”



2 -> The user should click at [+ Add More Non Investigational Medical Devices](#) to fill the details of Non-Investigational Medical Device. The form will be displayed in figure below.


The screenshot shows a web form titled "Add Non Investigational Medical Device". The form contains eight numbered text input fields, each with a red asterisk indicating a required field. The fields are: 1. Device Name, 2. Identifier (eg: Model/Lot/Batch Number), 3. Description & Intended Purpose (description must be precisely in details), 4. Risk Class, 5. Product Owner / Manufacturer, 6. Total Quantity per site (Units), 7. Total Quantity (Units), and 8. Total Cost Of Devices (MYR). A green "Save" button is located at the bottom left of the form. A red arrow points from a box labeled "Fill in the textbox" to the first field. Another red arrow points from a box labeled "Click for save" to the "Save" button.

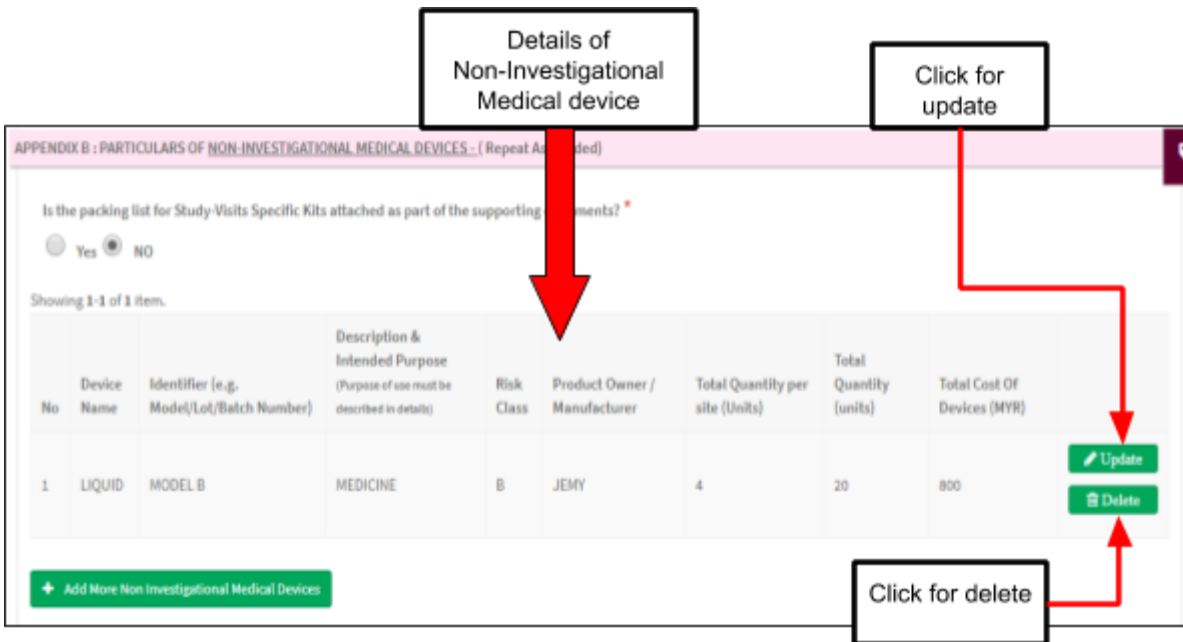
### Add Non Investigational Medical Device

1. Device Name -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name cannot be blank." will appear.
2. Identifier(eg: Model/Lot/Batch Number) -> The user should fill in the textbox that provided. If the user don't fill the identifier, the message "Device Model / Identifier / Lot / Batch Number cannot be blank." will appear.
3. Description & Intended Purpose(description must be precisely in details) -> The user should fill in the textbox that provided. If the user don't fill the description, the message "Description & Intended Purpose cannot be blank." will appear.
4. Risk Class -> The user should fill in the textbox that provided. If the user don't fill the risk, the message "Risk Class cannot be blank." will appear.



5. Product Owner/Manufacturer -> The user should fill in the textbox that provided. If the user don't fill the form, the message "Product Owner / Manufacturer cannot be blank." will appear.
6. Total Quantity per site(units)->the user should fill in the textbox that provided. If the user don't fill the name, the message "Total Quantity per site (Units) cannot be blank." will appear. The user should fill in the textbox with number only. If user fills in the textbox besides number, the message "Total Quantity per site (Units) must be an integer." will appear.
7. Total Quantity(Units)-> the user should fill in the textbox that provided. If the user don't fill the total, the message "Total Quantity (units) cannot be blank." will be appeared.The user should fill in the textbox with number only. If user fill in the textbox besides number, the message "Total Quantity (units) must be an integer." will appear.
8. Total Cost of Devices(MYR)->the user should fill in the textbox that provided. If the user don't fill the name, the message "Total Cost Of Devices (MYR) cannot be blank." will appear. The user should fill in the textbox with number only. If user fills in the textbox besides number, the message "Total Cost Of Devices (MYR) must be a number." will appear.

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



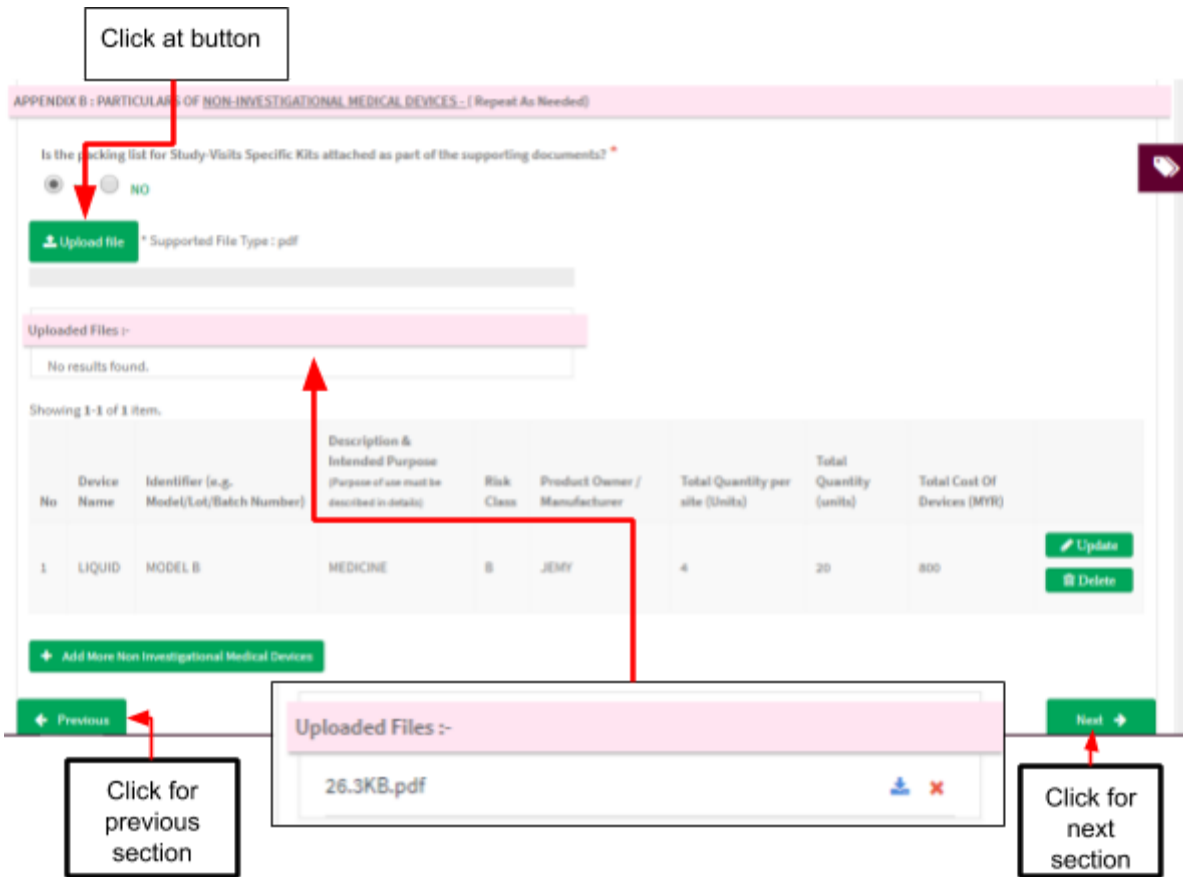
If user want to update details, the user should click at button “Update” that shown in figure above. The form will be displayed. Besides that, if user want to delete the details, user should click button “Delete” that shown in figure above. The alert message will be displayed.



If user want to proceed delete, user should click at button “OK”. If user wants to cancel the deleted, user should click at button “Cancel”. The user can add more Non-Investigational with click at






If the user choose the decision “yes”  Yes  NO , the button upload file will be displayed.




The file that will be uploaded with maximum size is 300MB and PDF format only.

**Maximum File Size : 300MB  
 Supported File Type : PDF Only**

The message that will display at button is **Maximum File Size : 300MB Supported File Type : PDF Only**. The user can download the file with clicking at  and delete the file with click at .

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.



**Section F: Entry Point**

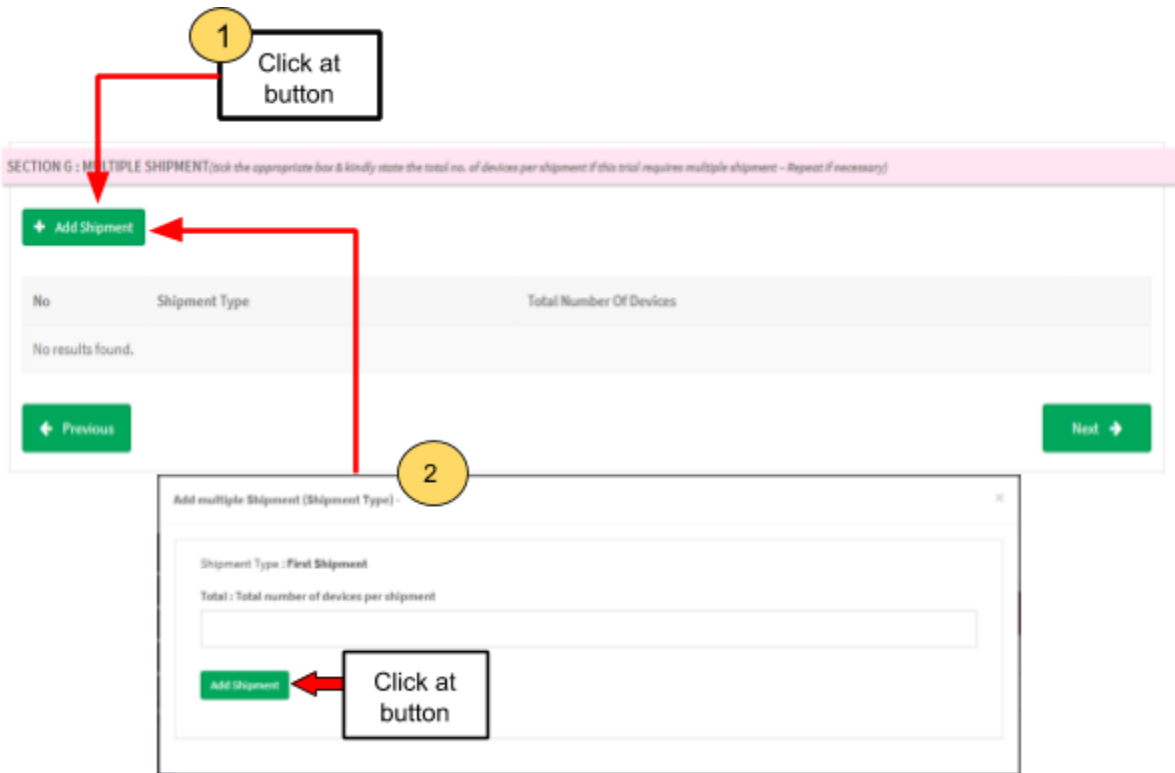
The user should click in checkbox based the place of entry point that user chosen. After that, If user want back to previous section, user should click on button



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



to the next section.

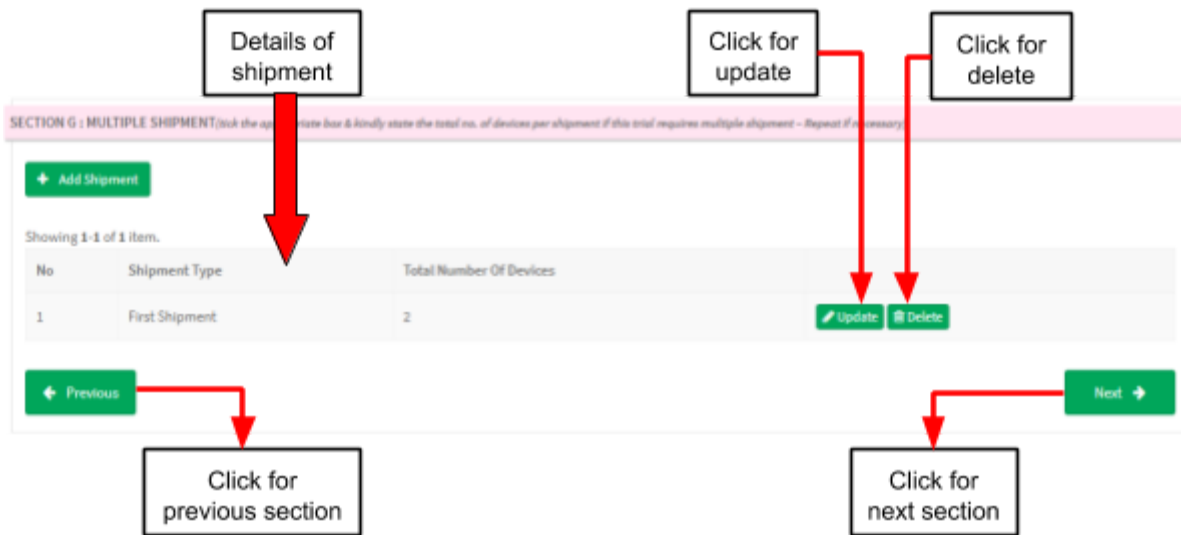


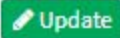
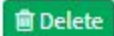
**Section G: Multiple Shipment**

1 -> The user should click button **+ Add Shipment** to fill the shipment.

2 -> The user should fill in the textbox the total of shipment and then click button “Add shipment” to save the shipment.

The details of shipment will be displayed in the table shown in the figure below.



The user can update the details with click at  and the form shipment will be displayed. Besides that, user can delete the shipment with click at  to delete the shipment. The alert message will be displayed that shown in figure below.



The user should click on button “OK” to proceed with the delete or click button “Cancel” to cancel deleted.

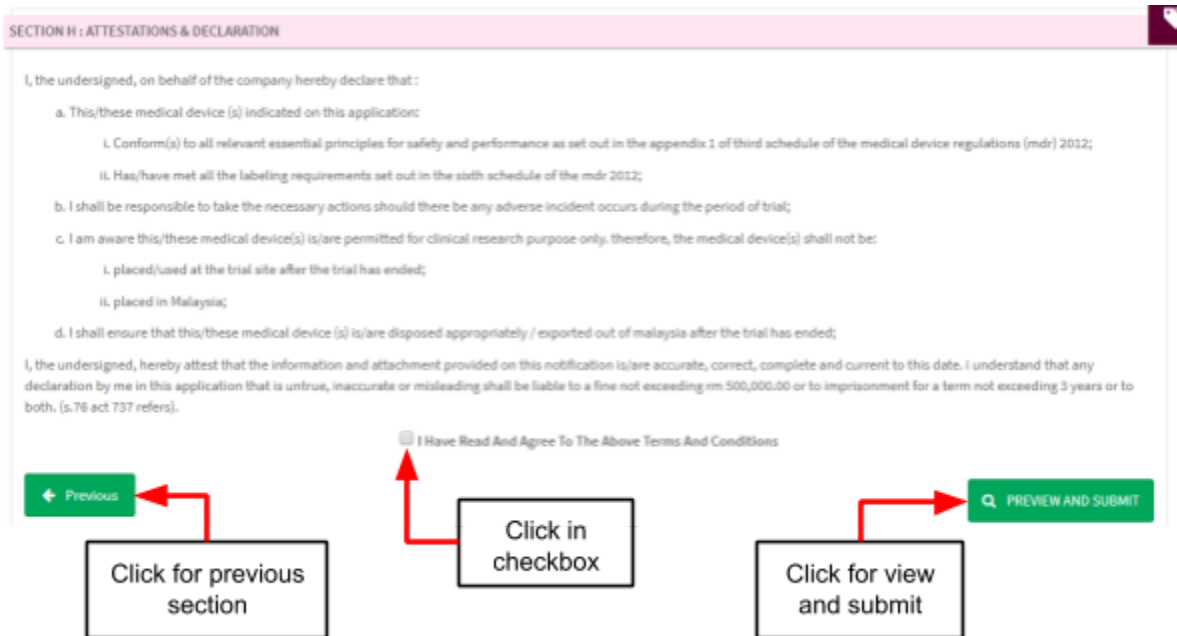
After that, If user want back to previous section, user should click on button



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




to the next section.



**Section H: Attestations & Declaration**

The user should click in checkbox that shown in figure above to agree of term and conditions.

The user also can click at  to back the previous section and if user

complete the form, user should click at  to preview details of application. The figure below shows the details of application with status "Complete" or Not Complete".

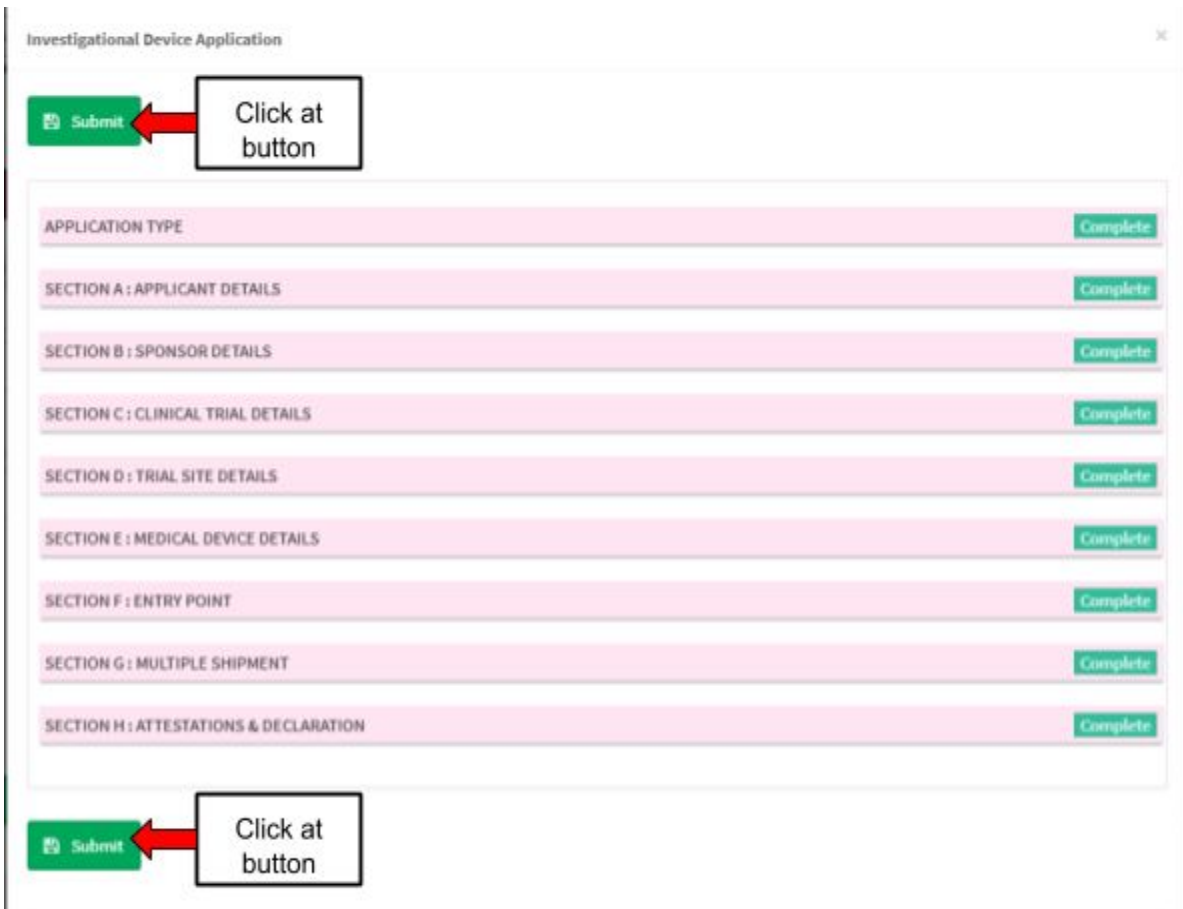
The screenshot shows a web form titled "Investigational Device Application" with a close button (X) in the top right corner. A red arrow points from a box labeled "Click to view detail" to the "APPLICATION TYPE" section. A blue arrow points from a box labeled "Status of application detail" to the status buttons of each section. The form contains the following sections and their status buttons:

| Section                                | Status       |
|--|--------------|
| APPLICATION TYPE                       | Complete     |
| SECTION A : APPLICANT DETAILS          | Complete     |
| SECTION B : SPONSOR DETAILS            | Complete     |
| SECTION C : CLINICAL TRIAL DETAILS     | Not Complete |
| SECTION D : TRIAL SITE DETAILS         | Complete     |
| SECTION E : MEDICAL DEVICE DETAILS     | Complete     |
| SECTION F : ENTRY POINT                | Complete     |
| SECTION G : MULTIPLE SHIPMENT          | Complete     |
| SECTION H : ATTESTATIONS & DECLARATION | Complete     |

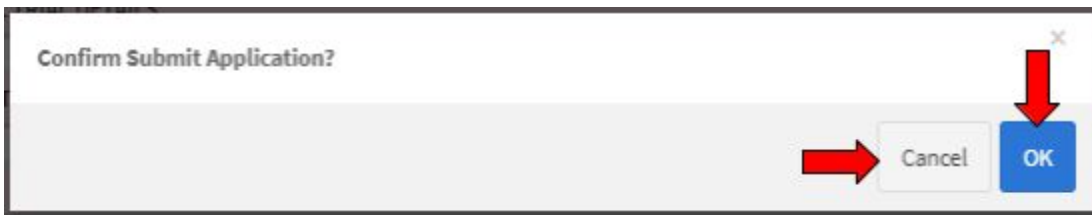
Red circles highlight the "Complete" button for "APPLICATION TYPE" and the "Not Complete" button for "SECTION C : CLINICAL TRIAL DETAILS". A red note at the top and bottom of the form reads: "\*Submit only can be done if all fields mandatory are complete".

The button "submit" will be displayed, if all the form status "complete".The user should complete all the form of application.





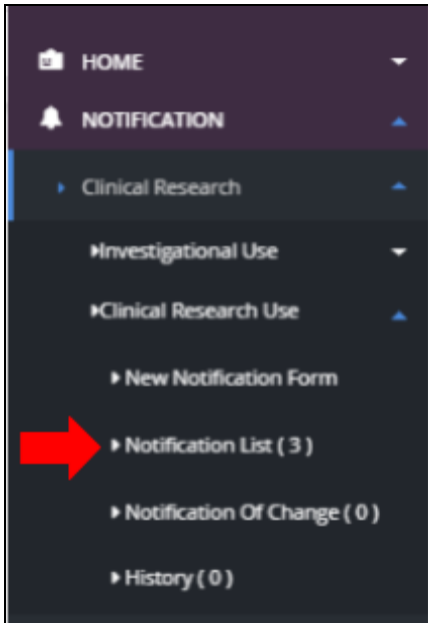
After user click button "Submit", the alert message will be displayed.



The user click "OK" to proceed to submit application and click "Cancel" to cancel the submitted application.

**b) Subsequent application**

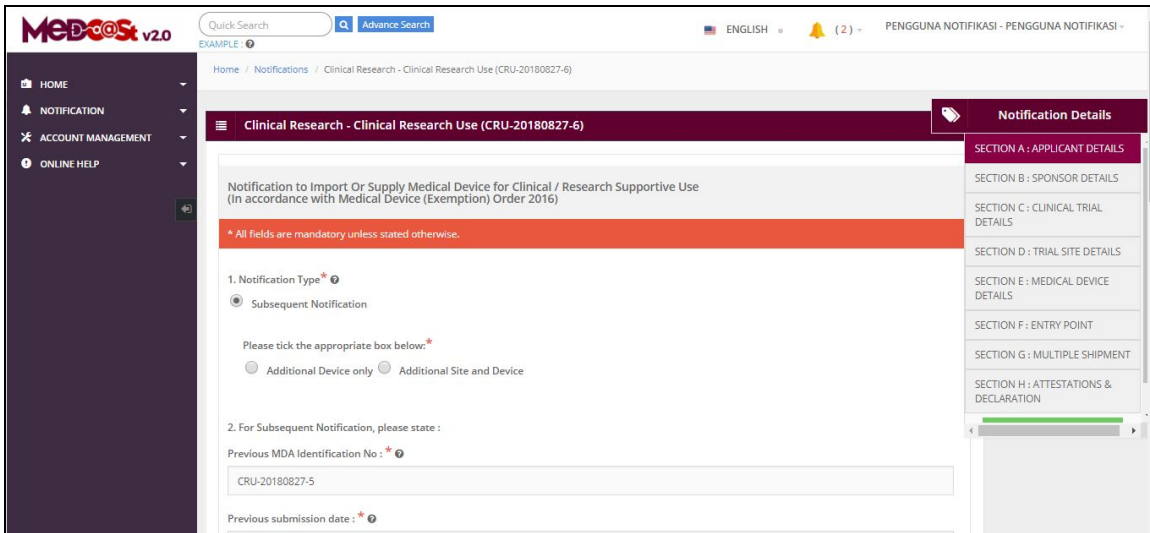
User click on the Application List at Clinical Investigation > Clinical Research Use.



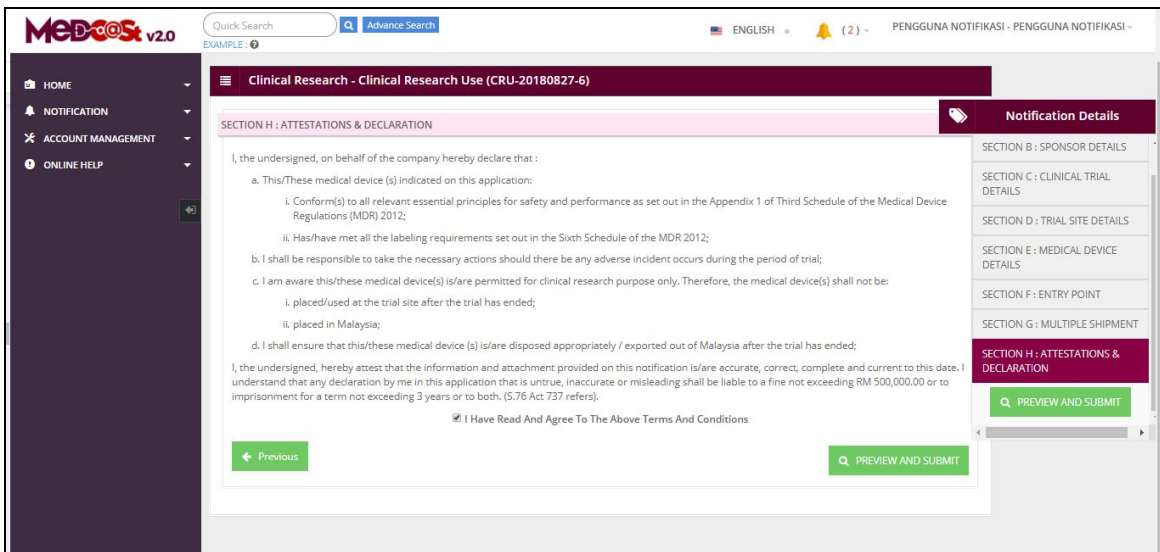
The system will display page of list application Investigational Use.


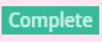


| Notification List       |                |                   |                     |                                  |                     |        |   |
|-------------------------|----------------|-------------------|---------------------|----------------------------------|---------------------|--------|---|
| Showing 1-3 of 3 items. |                |                   |                     |                                  |                     |        |   |
| No                      | Submission ID  | Submitted At      | Applicant           | Notification Type Name           | Notification Status | Action |   |
| 1                       | CRU-20180827-5 | 27-08-2018        | PENGGUNA NOTIFIKASI | CLINICAL RESEARCH USE            | COMPLETE            | View   | Subsequent Notification<br>Notification of Change |
| 2                       | CRU-20180827-6 | Not Submitted Yet | PENGGUNA NOTIFIKASI | CLINICAL RESEARCH USE            | DRAFT               | View   | Update Delete                                     |
| 3                       | CRU-20180827-6 | Not Submitted Yet | PENGGUNA NOTIFIKASI | SUBSEQUENT CLINICAL RESEARCH USE | DRAFT               | View   | Update Delete<br>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 complete the Subsequent Application form. The user review all information in Section A, B C, D, E, F, G and H. Next step is the user click on button [PREVIEW AND SUBMIT](#).













If all mandatory information has been filled out, button  and keyword  will display. If the the information is not completed,  keyword will display and button  will not display until all information is fill.

Investigational Device Application
×

---



|  |   |
|--|---|
| NOTIFICATION TYPE                      |    |
| SECTION A : APPLICANT DETAILS          |    |
| SECTION B : SPONSOR DETAILS            |    |
| SECTION C : CLINICAL TRIAL DETAILS     |    |
| SECTION D : TRIAL SITE DETAILS         |    |
| SECTION E : MEDICAL DEVICE DETAILS     |   |
| SECTION F : ENTRY POINT                |  |
| SECTION G : MULTIPLE SHIPMENT          |  |
| SECTION H : ATTESTATIONS & DECLARATION |  |

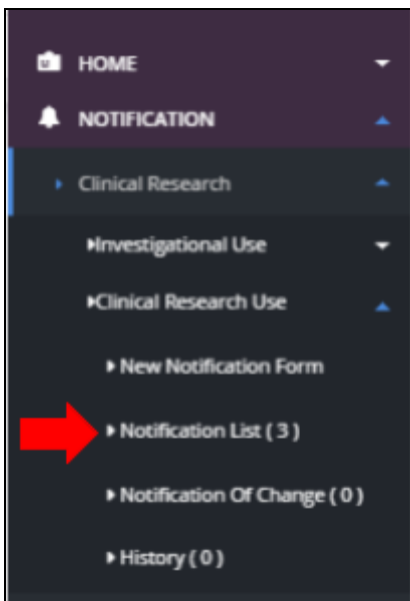


The status of application will be on evaluation stage.

| Notification List       |                |                   |                     |                                  |                     |                      |   |
|-------------------------|----------------|-------------------|---------------------|----------------------------------|---------------------|----------------------|---|
| Showing 1-3 of 3 items. |                |                   |                     |                                  |                     |                      |   |
| No                      | Submission ID  | Submitted At      | Applicant           | Notification Type Name           | Notification Status | Action               |   |
| 1                       | CRU-20180827-6 | 27-08-2018        | PENGGUNA NOTIFIKASI | SUBSEQUENT CLINICAL RESEARCH USE | EVALUATION          | <a href="#">View</a> | <a href="#">Notification History</a>  |
| 2                       | CRU-20180827-5 | 27-08-2018        | PENGGUNA NOTIFIKASI | CLINICAL RESEARCH USE            | COMPLETE            | <a href="#">View</a> | <a href="#">Subsequent Notification</a><br><a href="#">Notification of Change</a> |
| 3                       | CRU-20180827-6 | Not Submitted Yet | PENGGUNA NOTIFIKASI | CLINICAL RESEARCH USE            | DRAFT               | <a href="#">View</a> | <a href="#">Update</a> <a href="#">Delete</a>                                     |

**c) Change of Notification**

User click on the Application List at Clinical Investigation > Clinical Research Use.



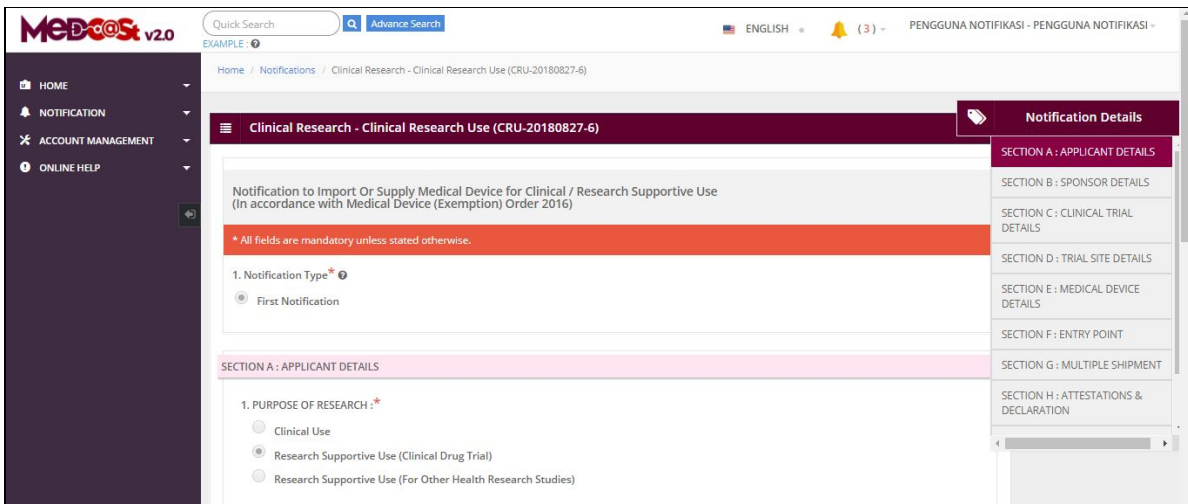
The system will display page of list application Investigational Use.

| Notification List        |    |                |              |                     |                                  |                     |  |
|--------------------------|----|----------------|--------------|---------------------|----------------------------------|---------------------|--|
| Showing 1-2 of 2 items.  |    |                |              |                     |                                  |                     |  |
| <input type="checkbox"/> | No | Submission ID  | Submitted At | Applicant           | Notification Type Name           | Notification Status | Action   |
| <input type="checkbox"/> | 1  | CRU-20180827-6 | 27-08-2018   | PENGGUNA NOTIFIKASI | SUBSEQUENT CLINICAL RESEARCH USE | EVALUATION          | <a href="#">View</a> <a href="#">Notification History</a>  |
| <input type="checkbox"/> | 2  | CRU-20180827-5 | 27-08-2018   | PENGGUNA NOTIFIKASI | CLINICAL RESEARCH USE            | COMPLETE            | <a href="#">View</a> <a href="#">Subsequent Notification</a><br><a href="#">Notification of Change</a> |

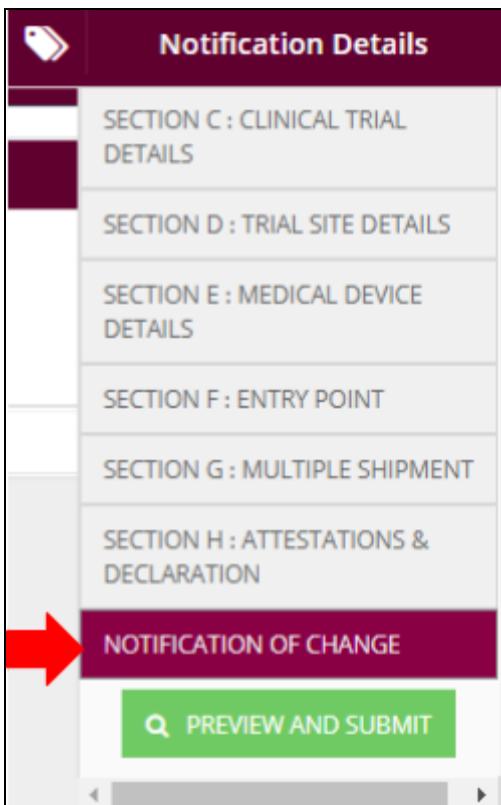
User click on [Notification of Change](#). Next step is click OK and the system will display *Notification of Change*.

| Notification of Change                                    |   |
|---|---|
| <input type="checkbox"/> Change Of Principal Investigator | <input type="checkbox"/> Change Of IRB/EC |
| <input type="checkbox"/> Change Of Site                   | <input type="checkbox"/> Change Of Device |
| <input type="checkbox"/> Others                           |   |
| <a href="#">Proceed to Notification</a>                   |   |

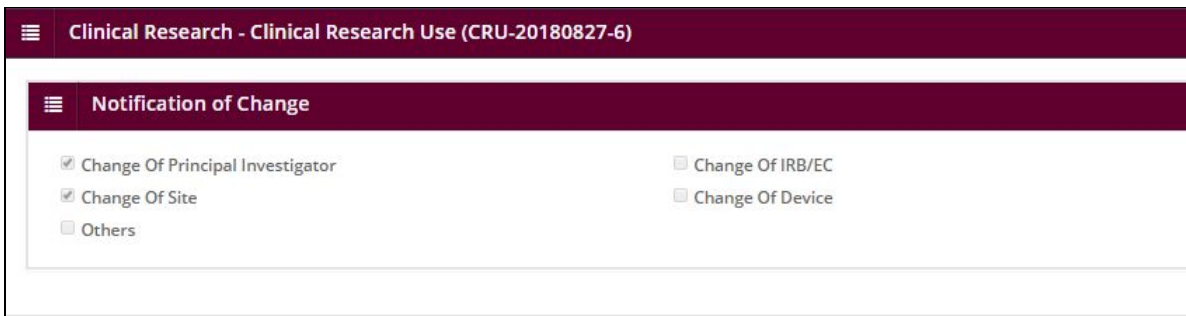
User choose type of change by click button [Proceed to Application](#). The system will display Change Notification application form.



The user can revisits the changes that have been selected. User can click button Notification of Change on right side.



The list of changes that have been selected will be displayed.

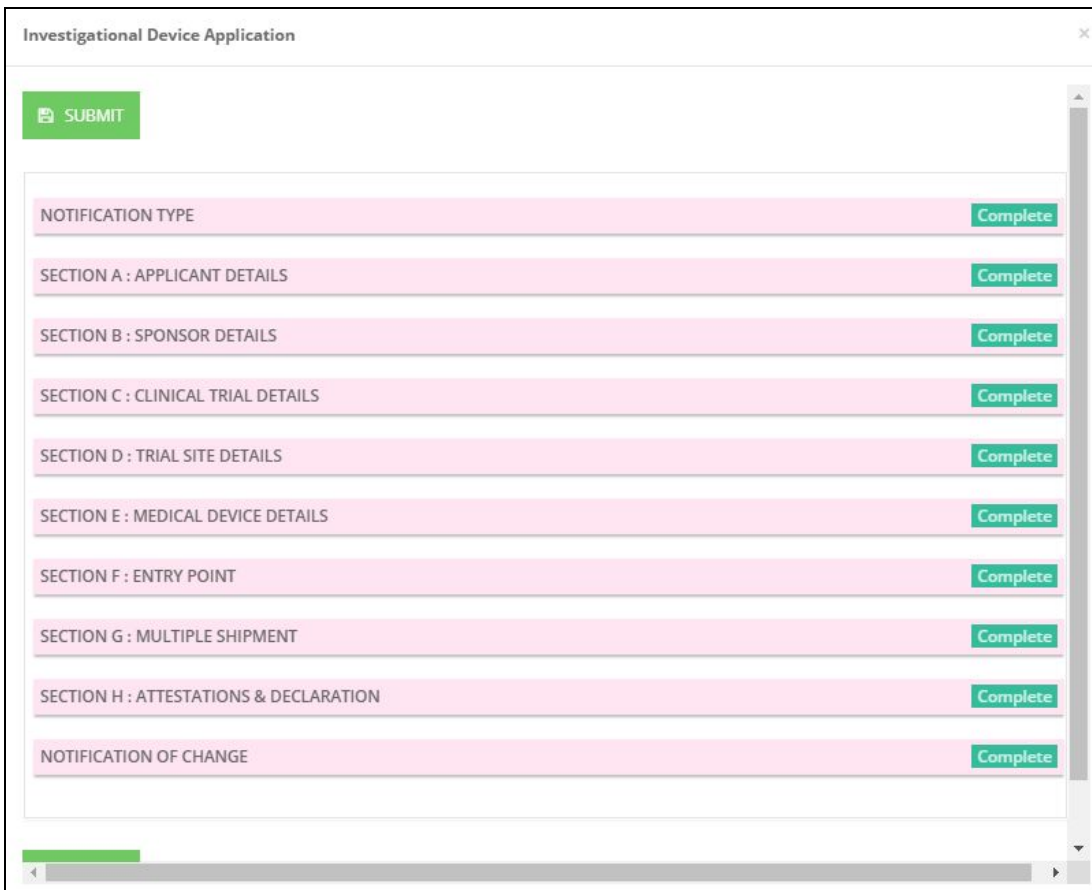


The screenshot shows a web interface for 'Clinical Research - Clinical Research Use (CRU-20180827-6)'. Under the 'Notification of Change' section, there are five checkboxes: 'Change Of Principal Investigator', 'Change Of Site', 'Others', 'Change Of IRB/EC', and 'Change Of Device'. The first three are checked, and the last two are unchecked.

The applicant updates the information according to the type of change that has been selected. Only the field selected for making changes can be edited by the applicant.

Next step is click on button  to preview the information that user change.

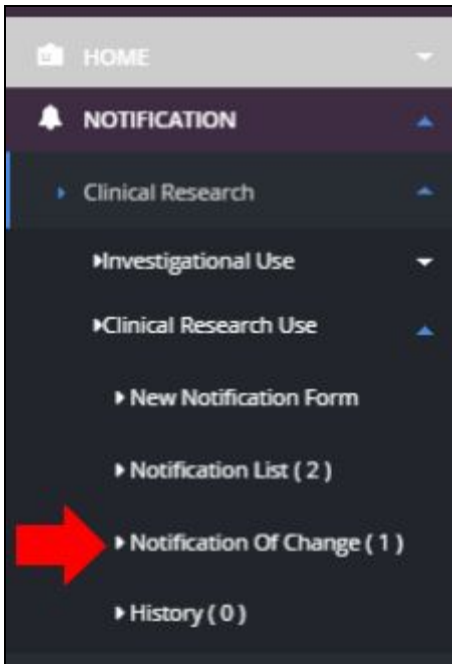




The screenshot displays a web application window titled "Investigational Device Application". At the top left, there is a green button with a document icon and the text "SUBMIT". Below this, a progress bar consists of ten horizontal bars, each representing a section of the application. Each bar is light pink and has a green "Complete" button on its right side. The sections are: NOTIFICATION TYPE, SECTION A : APPLICANT DETAILS, SECTION B : SPONSOR DETAILS, SECTION C : CLINICAL TRIAL DETAILS, SECTION D : TRIAL SITE DETAILS, SECTION E : MEDICAL DEVICE DETAILS, SECTION F : ENTRY POINT, SECTION G : MULTIPLE SHIPMENT, SECTION H : ATTESTATIONS & DECLARATION, and NOTIFICATION OF CHANGE. A vertical scrollbar is on the right, and a horizontal scrollbar is at the bottom.

Click on  to submit form.

User click button Notification of Change under Clinical Investigation > Clinical Research Use.

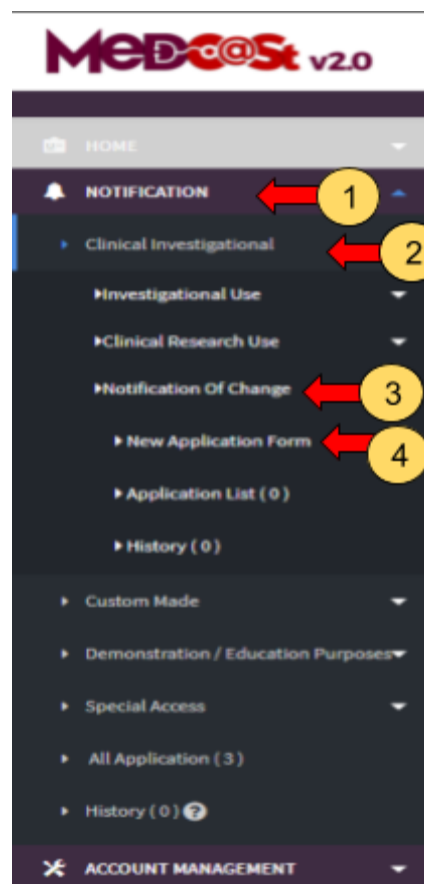


The system will display list of Notification of Change.

Home / Notification List

| Notification List        |    |                |              |                     |                            |                     |  |
|--------------------------|----|----------------|--------------|---------------------|----------------------------|---------------------|--|
| Showing 1-1 of 1 item.   |    |                |              |                     |                            |                     |  |
| <input type="checkbox"/> | No | Submission ID  | Submitted At | Applicant           | Notification Type Name     | Notification Status | Action   |
| <input type="checkbox"/> | 1  | CRU-20180827-6 | 27-08-2018   | PENGGUNA NOTIFIKASI | Notification of Change CRU | EVALUATION          | <a href="#">View</a><br><a href="#">Notification History</a> |

### III) NOTIFICATION OF CHANGE



1

-> The user should click at main menu NOTIFICATION.

2

-> The user should click at menu Clinical Investigational.

3

-> The user should click at sub menu Notification Of Change.

4

-> The user should click at New Application Form and the application form will be showed.

Fill in the textbox

Click in radio button

Firstly, the user should fill the previous notification ID in the textbox that provided.

### Section A: Application Details


#### 1. Role of Applicant

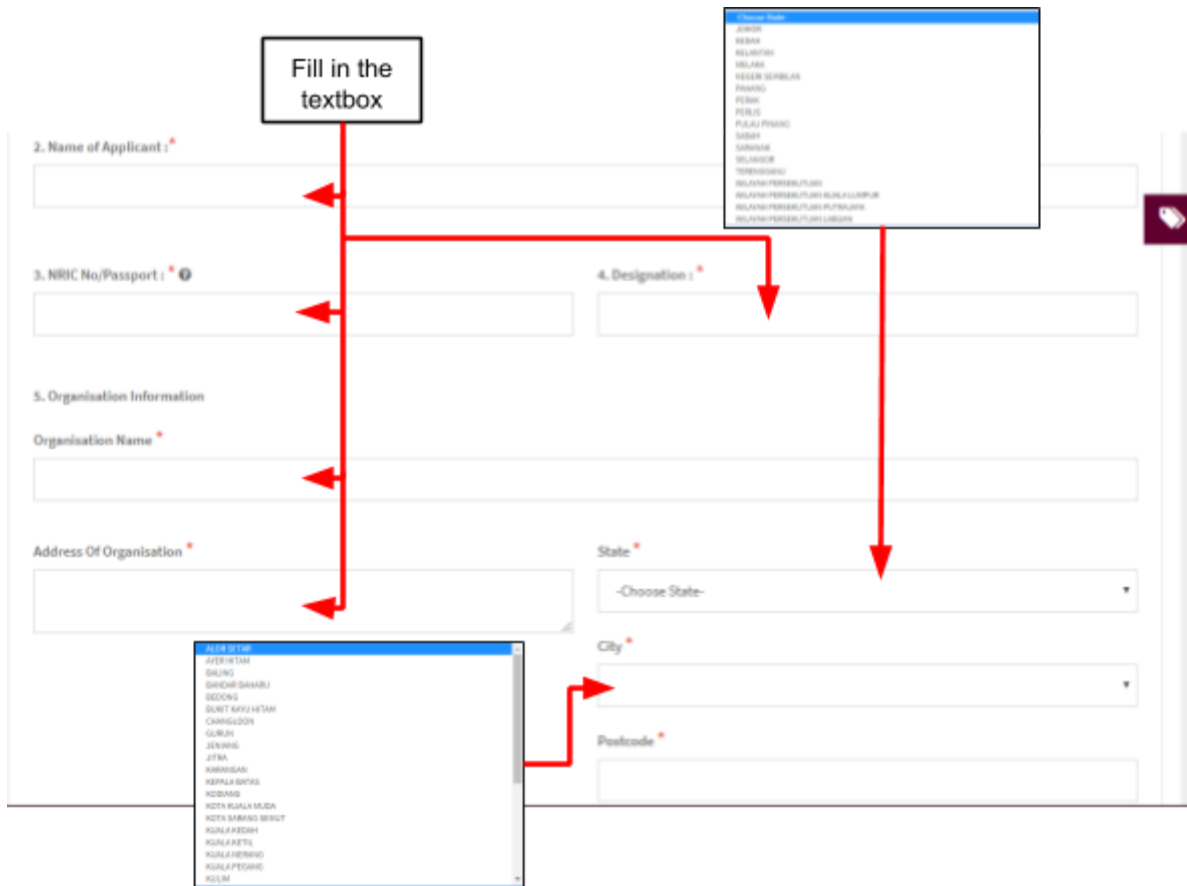
The user should click at radio button that provided in the figure above. User should select the role of applicant which are Local sponsor, authorised person from a local organisation/company/contact research organisation(CRO) or manufacturer.

#### 2. Name of applicant

The user should fill in the textbox that provided.

#### 3. Nric No/Passport

The user must fill in the form according to the format displayed on the figure below. The user should click at  to appear the format.



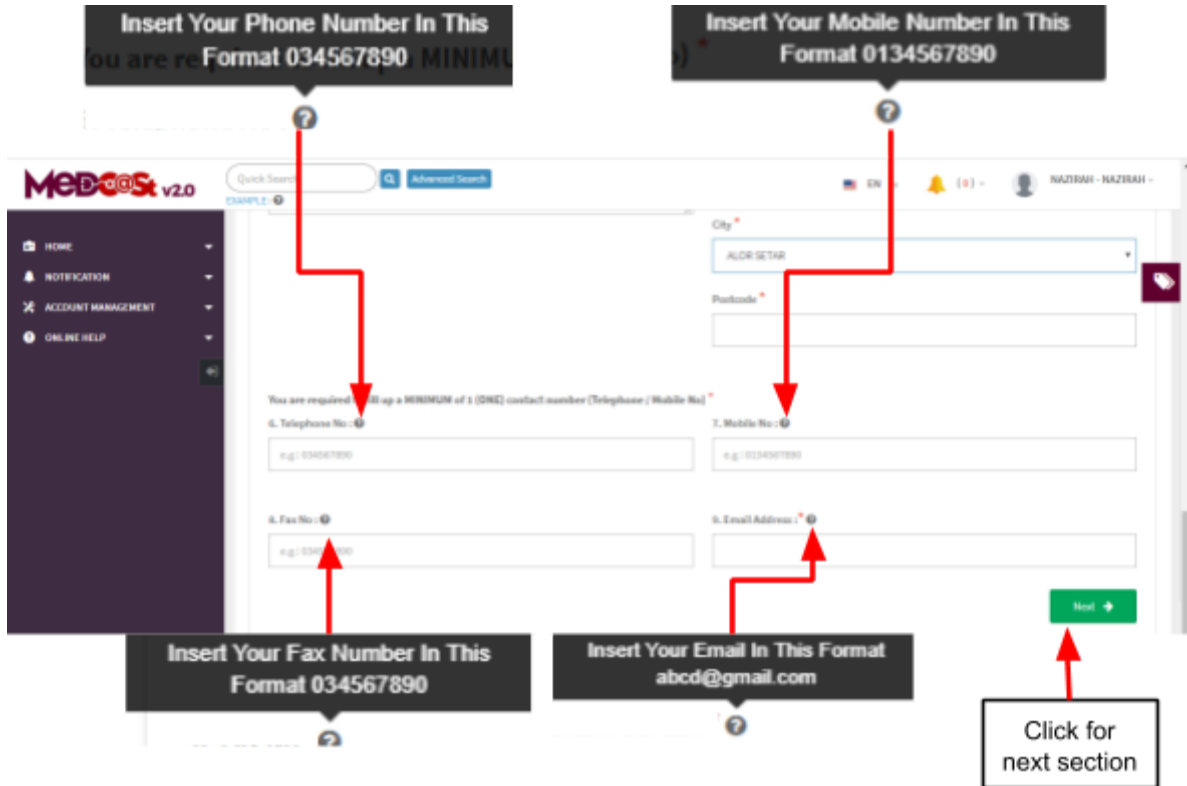
4. Designation

The user should fill the designation in textbox that provided shown in figure above.

5. Organisation information

- Organisation name -> The user should fill the name in the textbox that provided shown in figure above.
- Address of organisation -> the user should fill in the textbox with address of organisation.
- State -> User should click in textbox to drop down list and user should select the state that has shown in figure above.
- 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 figure above.

- 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.”



6. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at . The format will appear like shown in figure above. If user fill in the form except number or number more than eleven, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.

7. Mobile No.


The user must fill the Mobile No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message “Field must have NUMBERS between 3 - 11 numeric” will appear

8. Fax No.


The user must fill the Fax No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven

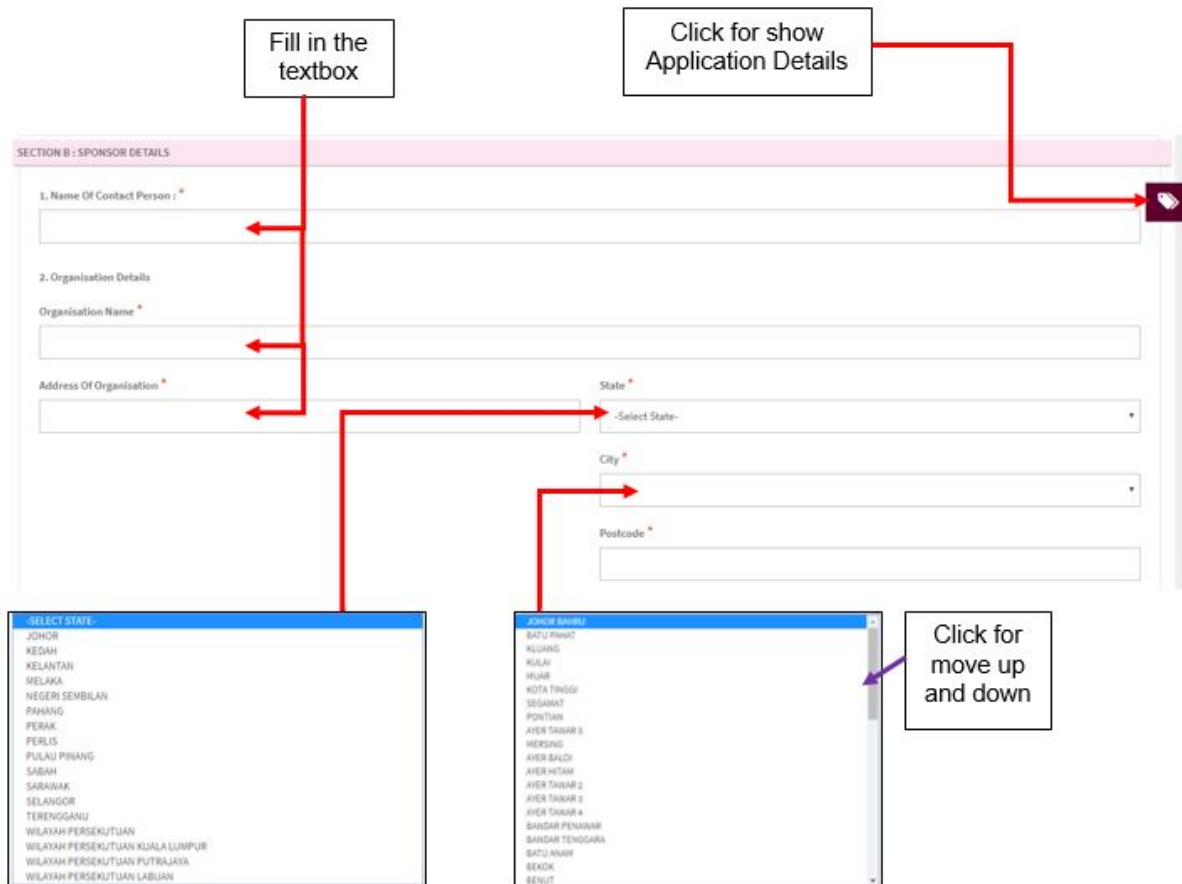
number, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.

9. Email Address

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



- After that, the user should click at button  to the next section. The form for section B will be appeared.



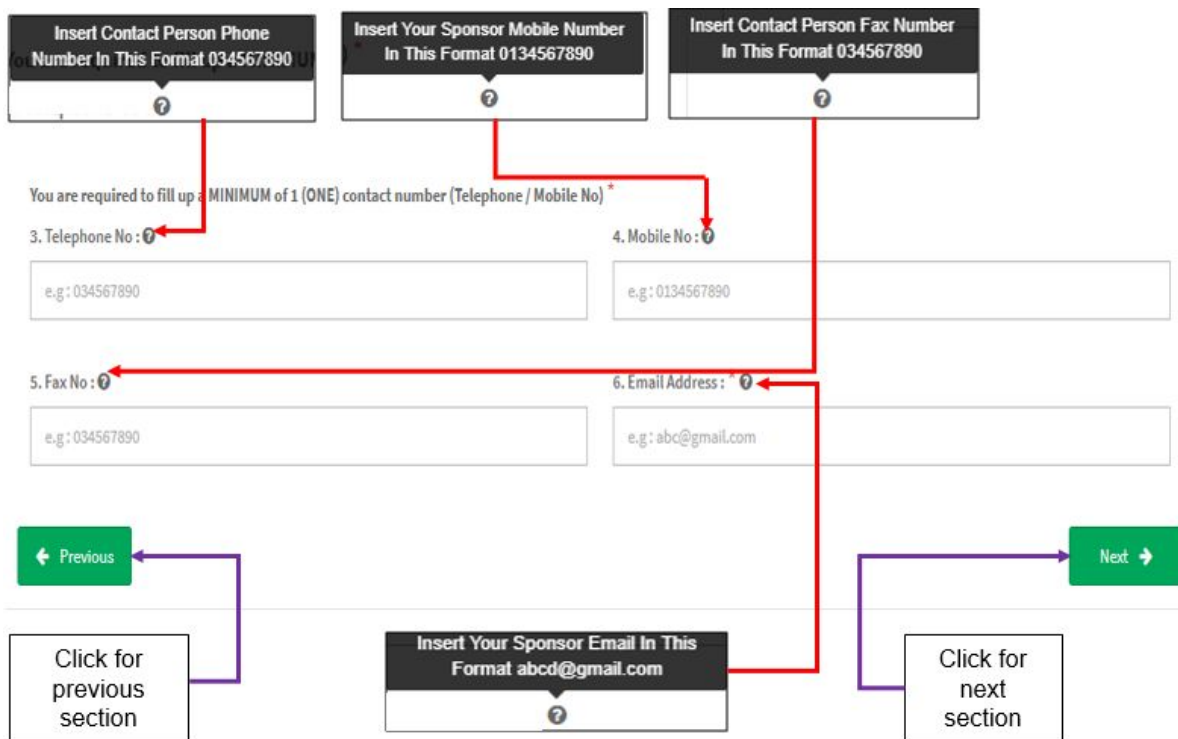
**Section B: Sponsor Details**

1. Name of Contact Person

The user should fill the name in the textbox.


2. Organisation Details

- Organisation Name -> The user should fill the name in the textbox that provided shown in the figure below.
- Address of organisation -> the user should fill in the textbox with address of organisation.
- State -> User should click in textbox to drop down list and user should select the state that has shown in figure above.
- 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 figure above.
- Postcode -> The field must contain exactly five numeric. If user fill the form with the alphabet, the message will appear "Organisation Postcode must be an integer." If user fill in postcode more than five number, the message will appear "Field must contain exactly 5 numeric."




3. Telephone No




The user must fill the Telephone No in an integer and user can see the format with click at . The format will appear like shown in figure above. If user fills in the form except number or number more than eleven, the message “Field can only contain number and between 3 to 11 numeric.” will appear.


#### 4. Mobile No.

The user must fill the Mobile No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message “Field can only contain number and between 3 to 11 numeric.” will appear.

#### 5. Fax No.

The user must fill the Fax No in an integer. User can see the format which click at . If user fill in the form except number or more than eleven number, the message “Field can only contain number and between 3 to 11 numeric.” will appear.

#### 6. Email Address

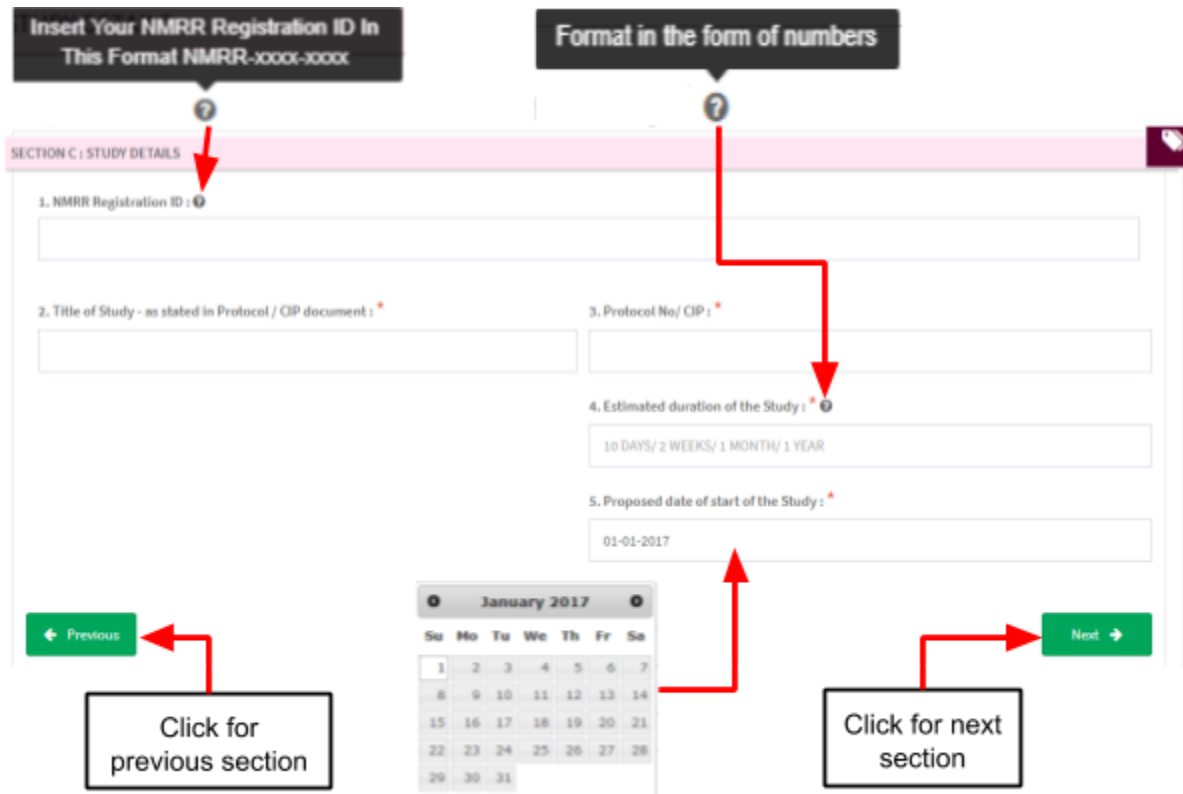
User must fill the email based the format. User should click at  to see the format. The format will be appeared. The symbol “@” must have in email. If user fill the form incorrectly or not follow the format, the message will be appeared is “Sponsor email address is not valid.”.

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



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





**Section C: Study Details**

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

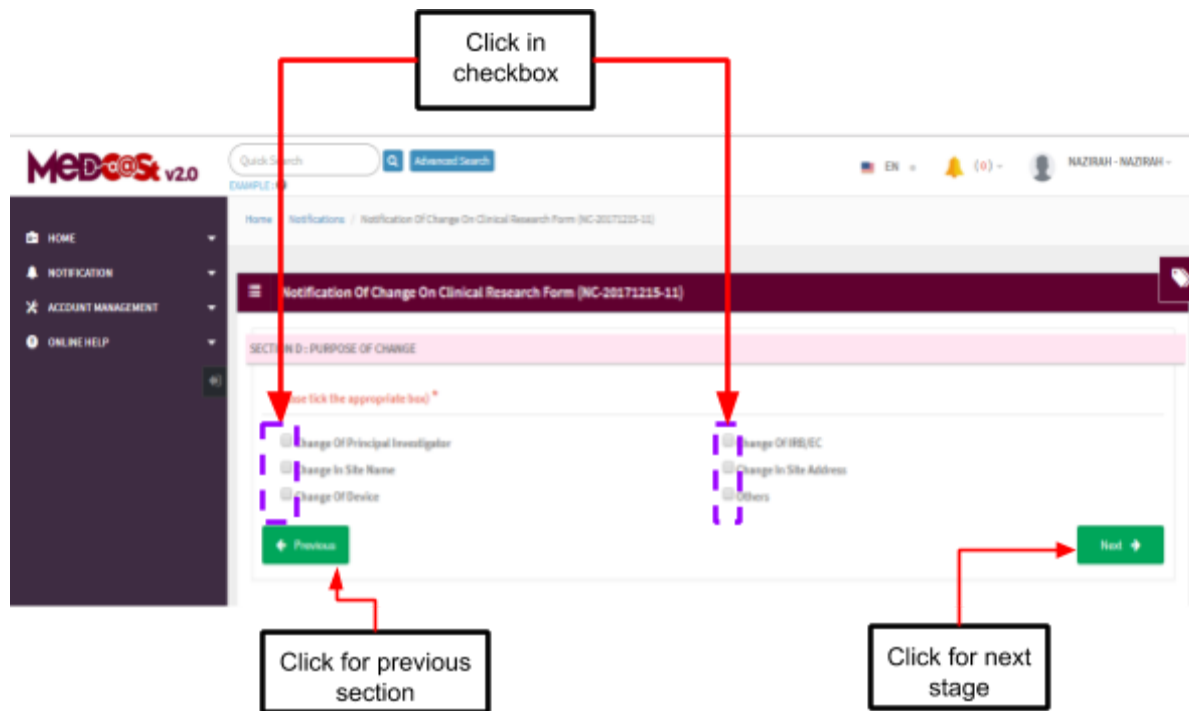
1. NMRR Registration ID  
 The user must fill in the textbox the registration ID with follow the format that given in the figure below. User should click at ? to see the format.
2. Title of Study- as stated in Protocol/CIP document  
 The user must fill the title in the textbox that provided.
3. Protocol No/CIP.  
 The user must fill the protocol number in the textbox that provided.
4. Estimated duration of the study  
 The user should fill in the textbox with follow the format duration that given. User can see the format with click at ? that shown in figure above.
5. Proposed date of start of the study  
 The user should select a date in the calendar that provided. The user should click in textbox to appear the calendar.



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.



**Section D: Purpose of Change**

The user should click in checkbox based the user wanted.

- a) Change of Principal Investigator-> The form for Principal Investigator Details will be displayed.

**Fill in the  
textbox**

PRINCIPAL INVESTIGATOR DETAILS - Appendix A (i)

1. Name (former Principal Investigator) \*

Site \*

Tel No. \*

Dept./Specialties

Email

2. Name (new appointed Principal Investigator) \*

Site \*

Tel No. \*

Dept./Specialties

Email

1. Name(former Principal Investigator)

The user should fill in the textbox that provided.

- Site -> The user should fill in the textbox that provided.
- Tel No.->The user should fill in the textbox that provided. If user fill it with character, the message “Telephone must be an integer.” will be displayed. Besides that, if user fill it more than 11 number, the message “Field can only contain number and between 3 to 11 numeric.” will be displayed.
- Dept./Specialties-> The user should fill in the textbox that provided.
- Email -> The user should fill in the textbox that provided. If user fill it with not format email, the message “Email is not a valid email address.”.

2. Name(new appointed Principal Investigator)

The user should fill in the textbox that provided.

- Site -> The user should fill in the textbox that provided.
- Tel No.->The user should fill in the textbox that provided. If user fill it with character, the message “Telephone must be an integer.” will be displayed. Besides that, if user fill it more than 11 number, the message “Field can only contain number and between 3 to 11 numeric.” will be displayed.

- Dept./Specialties-> The user should fill in the textbox that provided.
  - Email -> The user should fill in the textbox that provided. If user fill it with not format email, the message “Email is not a valid email address.”.
- b) Change in site name-> The form for Trial Site Details will be displayed.

TRIAL SITE DETAILS (Change of site) - Appendix A (ii)

1. Name (Previous Site Detail) \*

Address \*

2. Name (new appointed site) \*

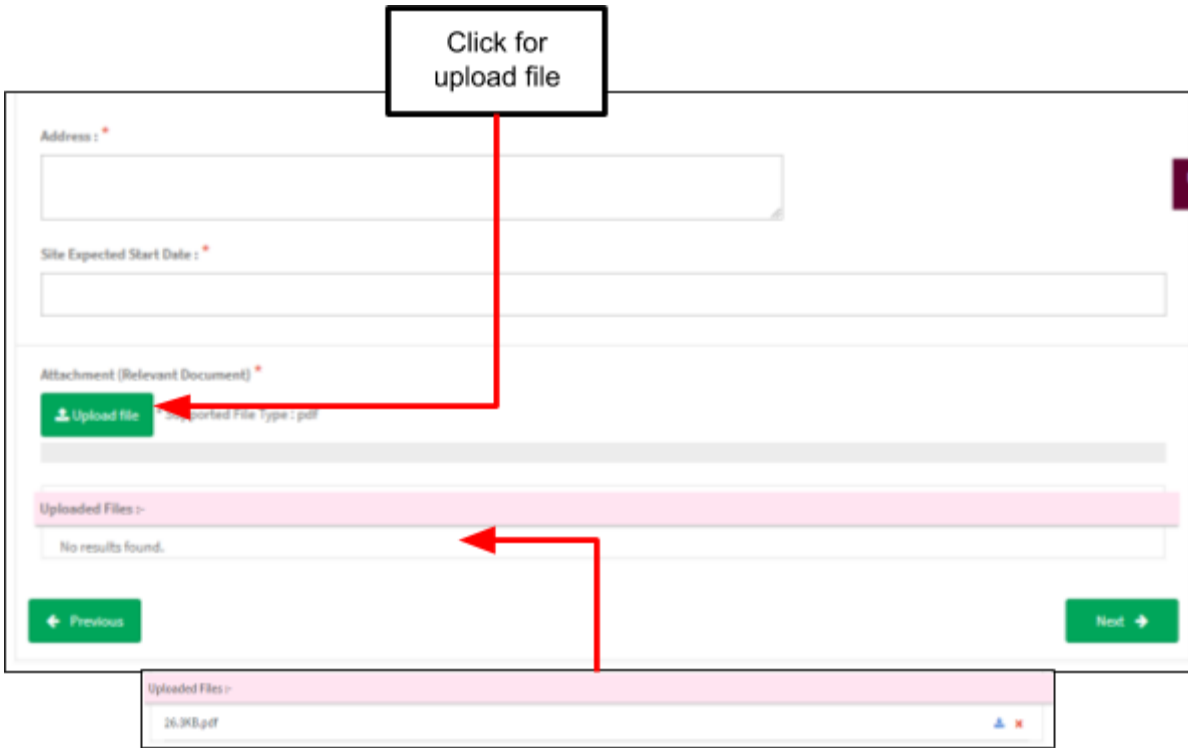
Address \*

Site Expected Start Date \*

December 2017

| Su | Mo | Tu | We | Th | Fr | Sa  |
|----|----|----|----|----|----|-----|
|    |    |    |    |    |    | 1 2 |
| 3  | 4  | 5  | 6  | 7  | 8  | 9   |
| 10 | 11 | 12 | 13 | 14 | 15 | 16  |
| 17 | 18 | 19 | 20 | 21 | 22 | 23  |
| 24 | 25 | 26 | 27 | 28 | 29 | 30  |
| 31 |    |    |    |    |    |     |

1. Name(Previous Site Detail)-> the user should fill in the textbox that provided.
  - Address -> The user should fill in the textbox that provided.
2. Name(new appointed site)
  - Address -> The user should fill in the textbox that provided.
  - Site Expected Start Date-> The user should click in textbox to display the calendar and user should select the date.
  - Attachment -> The user should upload the file with click on button “Upload file” that shown in the figure below.



c) Change of Device

1 Click in radio button

2 Click for fill the details

3

4

| No | Device Name | Identifier (e.g. Model/Identifier/Lot/Batch Number) | Description & Intended Purpose (Purpose of use must be described in detail) | Risk Class | Product Owner / Manufacturer | Total Quantity per site (Units) | Total Quantity (units) | Entrypoint                                   |
|----|-------------|---|---|------------|------------------------------|---------------------------------|------------------------|--|
| 1  | DEVICE NU   | MODEL F   | JLJNFGH   | C          | JURU                         | 2                               | 4                      | Lapangan Terbang Antarabangsa Kuala Lumpur 1 |

Is the packaging list for Study-Visits Specific Kits attached as part of the supporting documents?

YES NO

+ Add Medical Devices

Add New Medical Device

Device Name

Device Model Identifier (Lot, Batch Number)

Description & Intended Purpose

Risk Class

Product Owner / Manufacturer

Total Quantity per site (Units)

Total Quantity (units)

Update Delete

1 -> If the user choose the decision "yes"  Yes  NO , the button upload file will be displayed.

Upload file Supported File Type : pdf

Uploaded Files -

No results found.

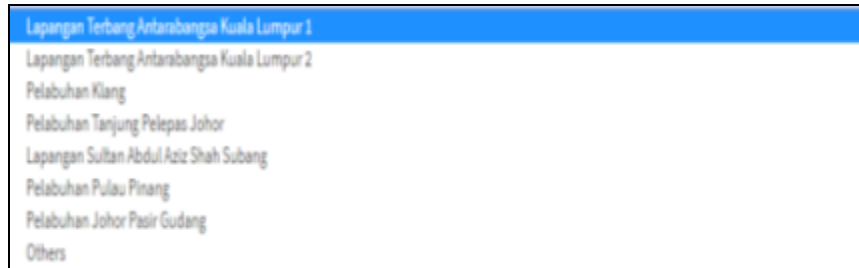
2 -> The user should click at **+ Add Medical Devices** to fill the form of medical device.

3 -> The user should fill the form which are:

1. Device Name -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name cannot be blank." will appear.
2. Device model/identifier/lot/batch number-> The user should fill in the textbox that provided. If the user don't fill the identifier, the message "Device Model / Identifier / Lot / Batch Number cannot be blank." will appear.
3. Description & Intended Purpose-> The user should fill in the textbox that provided. If the user don't fill the description, the message "Description & Intended Purpose cannot be blank." will appear.
4. Risk Class -> The user should fill in the textbox that provided. If the user don't fill the risk, the message "Risk Class cannot be blank." will appear.
5. Product Owner/Manufacturer -> The user should fill in the textbox that provided. If the user don't fill the form, the message "Product Owner / Manufacturer cannot be blank." will appear.
6. Total Quantity per site(units)->The user should fill in the textbox that provided. If the user don't fill the name, the message "Total Quantity per site (Units) cannot be blank." will appear. The user should fill in the textbox with number only. If user fills in the textbox besides number, the message "Total Quantity per site (Units) must be an integer." will appear.
7. Total Quantity(Units)-> The user should fill in the textbox that provided. If the user don't fill the total, the message "Total Quantity (units) cannot be blank." will be appeared.The user should fill in the textbox with number only. If user fill in the textbox besides number, the message "Total Quantity (units) must be an integer." will appear.
8. Total Cost of Devices(MYR)->The user should fill in the textbox that provided. If the user don't fill the name, the message "Total Cost Of Devices (MYR) cannot be blank." will appear. The user should fill in the textbox with number only. If user fills in the textbox besides number, the message "Total Cost Of Devices (MYR) must be a number." will appear.



9. Entrypoint -> the user should select the place of entry that shown in figure below.



After that, user should click at  to save the details and the details will be displayed in table.

**4** -> The details of medical device will be displayed.

d) Change of IRB/EC

1. Name (former IRB/EC) -> The user should fill in the textbox that provided.
- Address -> the user should fill in the textbox that provided.

2. Name (new appointed IRB/EC)-> The user should fill in the textbox that provided.

- Address-> The user should fill in the textbox that provided.
- Approval letter-> the user should upload file with click on button that shown in figure above.

e) Others -> the user should fill in the textbox that provided.

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.

### Section E: Attestations & Declaration

The user should click in the checkbox to agree the terms and conditions.

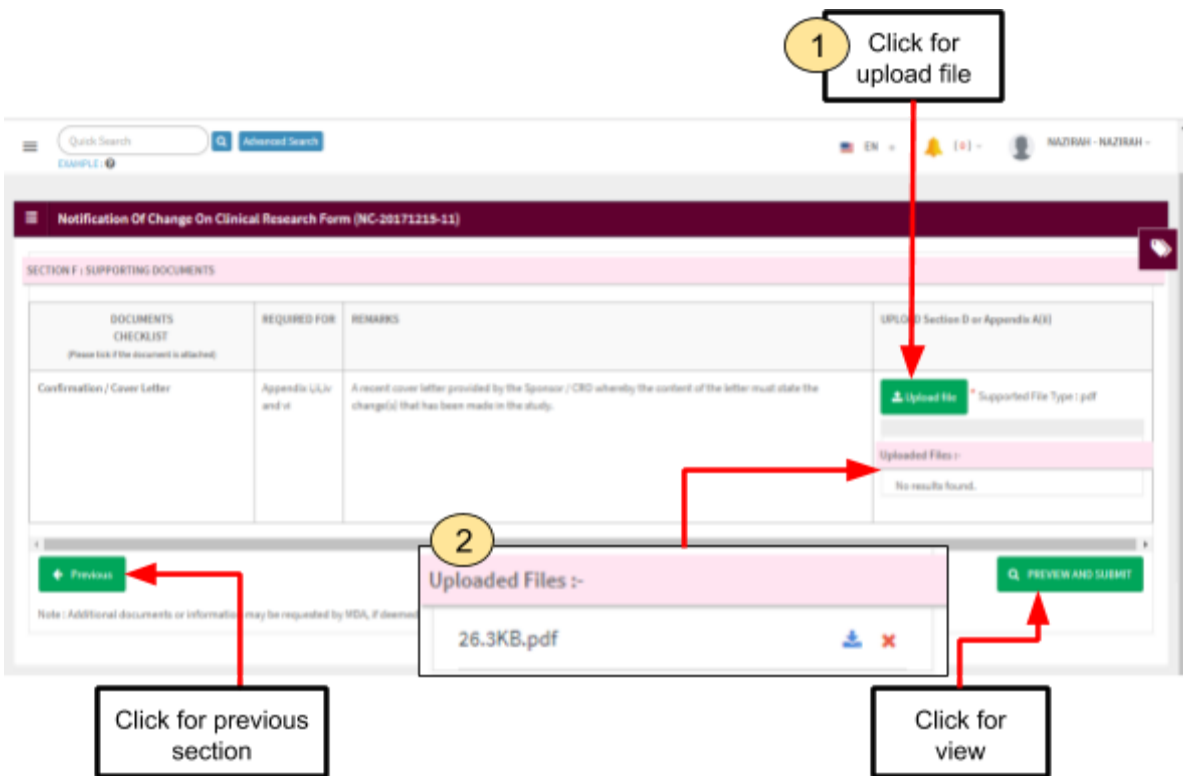
After that, If user want back to previous section, user should click on button



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




to the next section.



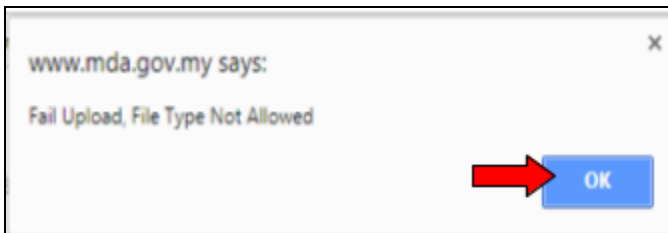
### Section F: Supporting Documents





-> The user should click at  to upload file. The file should PDF only and not more than 300MB. The user can see the message that display at

Maximum File Size : 300MB  
Supported File Type : PDF Only

button . If user upload file in others format, the alert message will be displayed that shown in the figure below.



The user should click button "OK".

-> The file that uploaded will be displayed. The user can download the file with clicking at  and delete the file with click at . User can view file with click at file name that uploaded. The file will be displayed.



If user want back to previous section, user should click at button that shown in figure above. After all the form of application are completed, the user

should click at .The details of application will be displayed.

The user should click at to submit the application. The alert message will be displayed.

The user should click “Cancel” to cancel the submitted application and click “OK” to proceed with submission of the application.

**b) DEMONSTRATION/EDUCATION PURPOSE**

***1)New Application***

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.

Next, it will show like below and user have to click “Demonstration” then “New Application Form” to create new application.

The user should click at sub menu **New application form** to apply the registration form for **Demonstration Purpose**. The application form will appear. The figure below shows the application form for applicant fill it. The user should fill all demonstration form. There are three sections which are:

SECTION A : General information

SECTION B : Medical Device Information

SECTION C : Attestation and declaration

### **Section A: General information**

Figure below are shown the layout for Section A : GENERAL INFORMATION. User have to fill all the form and that symbol “\*” means required field. The user must fill it.

For total date is already show like “ ”.



This is form for Details of Applicant, user have to fill all the form properly like shown below.

After user fill all the form with properly, they have to click “ ” button to next section like shown below.

## **Section B: Medical Device Information**

After clicks “ ” button at section A, it will display section B like shown below.

After user click “ ” and fill all the form, it will be shown like below.

For , users have to add first like shown below.

After the user fill all form, users have to click “ ” button to the last section.

## **Section C: Attestation And Declaration**

After clicking “PREVIEW AND SUBMIT” button, it will display all the section are already complete fill out or not complete like shown below.

User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below.

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

If user click “ok” , the application status will be changed to “EVALUATION”. It will automatically jump to all application page like shown below.

## **2) *Extension application***

Extension application for demonstration can be registered from new application demonstration that have been completely registered. To register for extension demonstration, user can click button .



After user click button “Ok”, form extension as below will be displayed. User only have permission to update their previous application data at section A (Event Details) and Section B (Site Details).

After all the forms are completed, the user must click button “PREVIEW AND SUBMIT” to view and click button “Submit” to submit the application. The alert message will be displayed and user should click “OK” to proceed and “Cancel” to cancel the submitted.

If user click “OK”, the status at application will be changed to EVALUATION.

### **3) Post Handling**

Post Handling can be registered after application in status complete. To register for post handling, user can click button “

”.





**c) EDUCATION PURPOSE**

Firstly, user should click **Demonstration / Education Purpose** at sub menu to create new registration like shown below.

Next, it will show like below and user have to click “Education” then “New Application Form” to create new application.

The user should click at sub menu **New application form** to apply the registration form for **Education Purpose**. The application form will appear. The figure below

shows the application form for applicant fill it. The user should fill all education form. There are three sections which are:

SECTION A : General information

SECTION B : Medical Device Information

SECTION C : Attestation and declaration

### **Section A: General information**

Figure below are shown the layout for Section A : EDUCATION / TRAINING CENTRE DETAILS. User have to fill all the form and that symbol "✖" means required field.

This is form for Details of Applicant, user have to fill all the form properly like shown below.

After user fill all the form with properly, they have to click “ ” button to next section like shown below.

## **Section B: Medical Device Information**

After clicking “ ” button at section A, it will display section B like shown below.

After user click “ ” and fill all the form, it will be shown like below.



For users have to add first like shown below.

After the user fill all form, users have to click “ ” button to the last section.

## **Section C: Attestation And Declaration**

After clicking “PREVIEW AND SUBMIT” button, it will display all the section are already complete fill out or not complete like shown below.

User cannot submit the application yet because, users have to complete that application first before submitting it. User can submit their application after all applications are complete like shown below.

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

If user click “ok” , the application status will be changed to “EVALUATION”. It will automatically jump to all application page like shown below.

### **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.

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  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.

### **2.2.3 RETURN TO EXTRA INFORMATION**

If back end user make the process “RETURN TO EXTRA INFORMATION” to front end user, the status of application will be changed and the Front End User should add the information at application form.

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

After that, user should click at \_\_\_\_\_ to update or add information in the application form. The section of extra information will be displayed.

Then, user should add information at the form. The user can upload the file that shown in the figure below.

After click on button “include upload file” , the will be displayed and user should upload file.

If user not want to upload file, the user should click at “Hide Upload File”. After that, user should click “save remark” to save the information only. If user upload file, the file will automatically be displayed the details that shown in the figure below.

And then, click  to submit the application.

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

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