USER MANUAL
FRONT END USER

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

MODUL UTAMA - NOTIFICATION

DISEDIAKAN OLEH :

LIST OF CONTENTS

1.0 INTRODUCTION **3**
1.1 SYSTEM ACCESS 3
1.1.1 CREATE ACCOUNT 4
1.1.2 LOGIN 5

2.0 FUNCTIONS **6**
2.1 DASHBOARD 6
2.2 MENU NOTIFICATION REGISTRATION 7
2.2.1 NEW APPLICATION FORM 8
a) CLINICAL INVESTIGATIONAL 8
I) INVESTIGATIONAL USE 9
New Application 9
Subsequent application 51
Change of Notification 54
II) CLINICAL RESEARCH USE 60
New Application 60
Subsequent application 90
Change of Notification 93
III) NOTIFICATION OF CHANGE 99
b) DEMONSTRATION/EDUCATION PURPOSE 119
New Application 119
Extension application 128
Post Handling 130
c) EDUCATION PURPOSE 133
2.2.2 RETURN FOR FURTHER INFO 142
2.2.3 RETURN TO EXTRA INFORMATION 145

1.0 INTRODUCTION

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

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

1.1 SYSTEM ACCESS

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

https://medcast.mda.gov.my

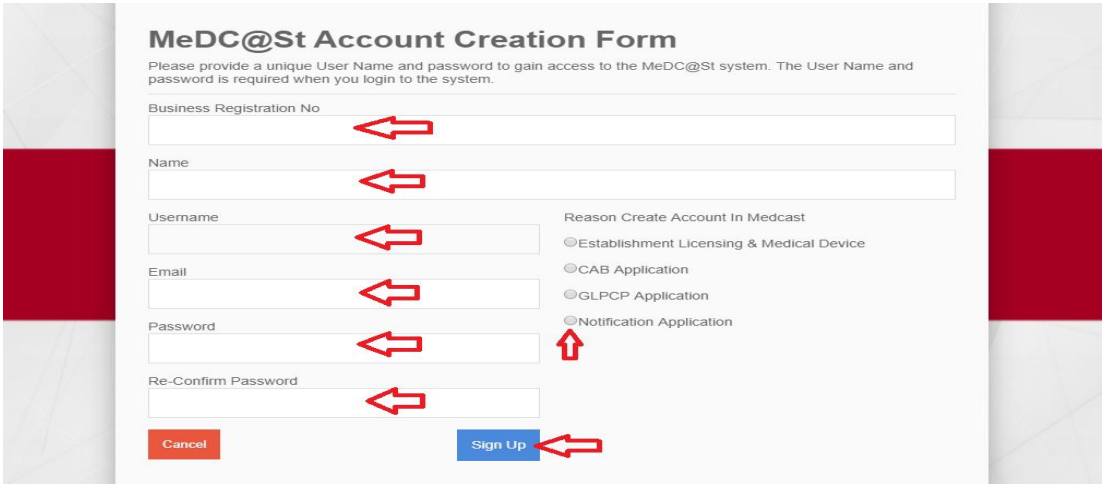
1.1.1 CREATE ACCOUNT

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

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

click

for new registration.

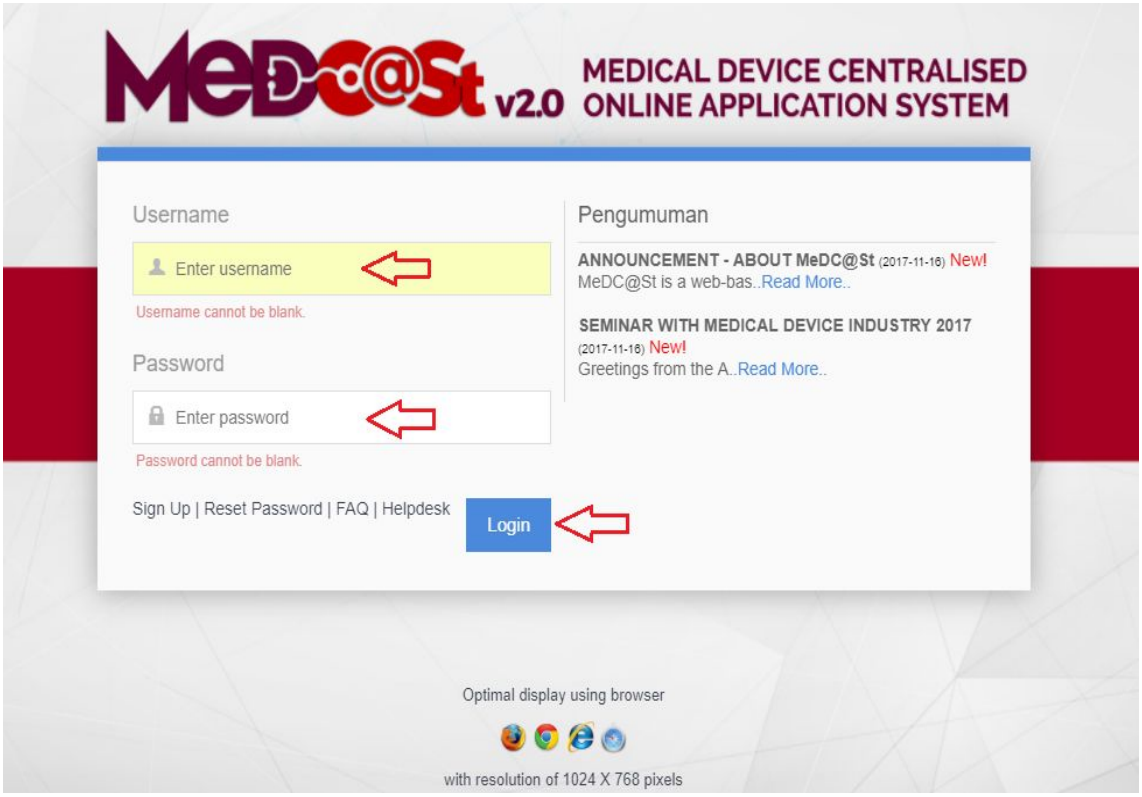


Complete the form and click

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

1.1.2 LOGIN

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

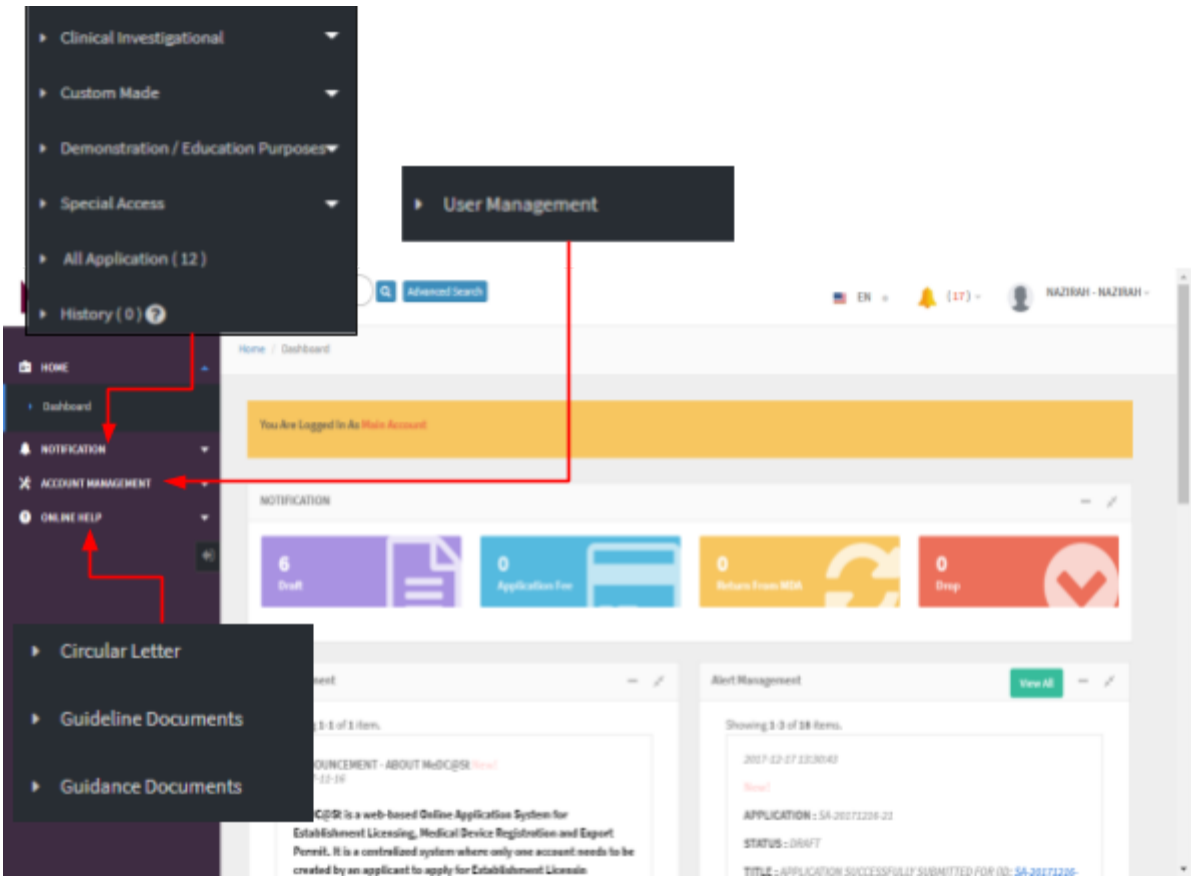


User has to log into the system using registered Username and its respective Password. Click to proceed.

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.

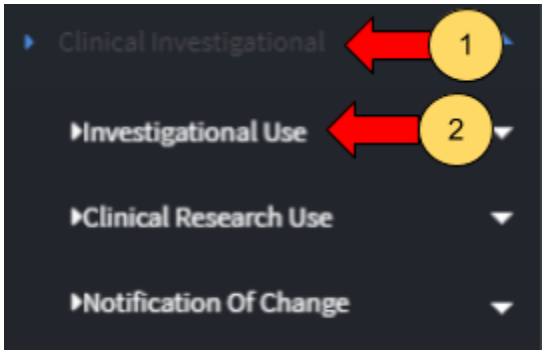
2.2.1 NEW APPLICATION FORM

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

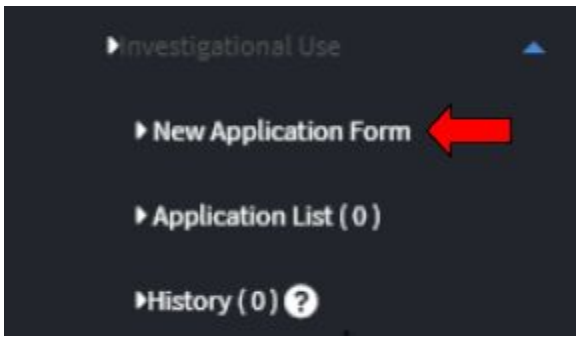
a) New Application



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

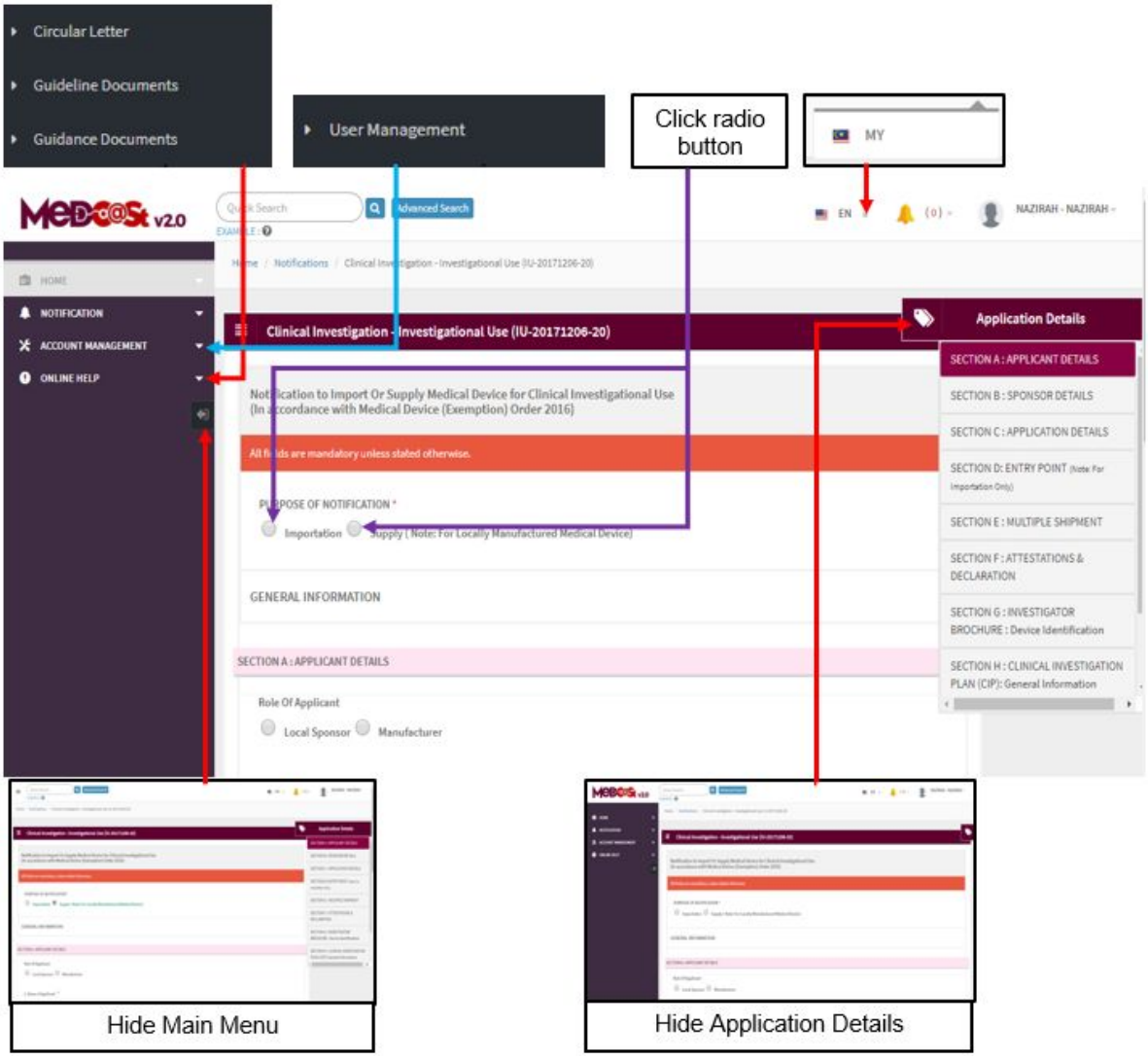
SECTION E : Multiple Shipment

SECTION F : Attestations & Declaration

SECTION G : Investigator Brochure

SECTION H : Clinical Investigation Plan(CIP)

SECTION I : Appendix A

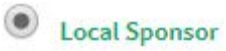


The user should choose the purpose of notification with click at radio button that shown in figure above.

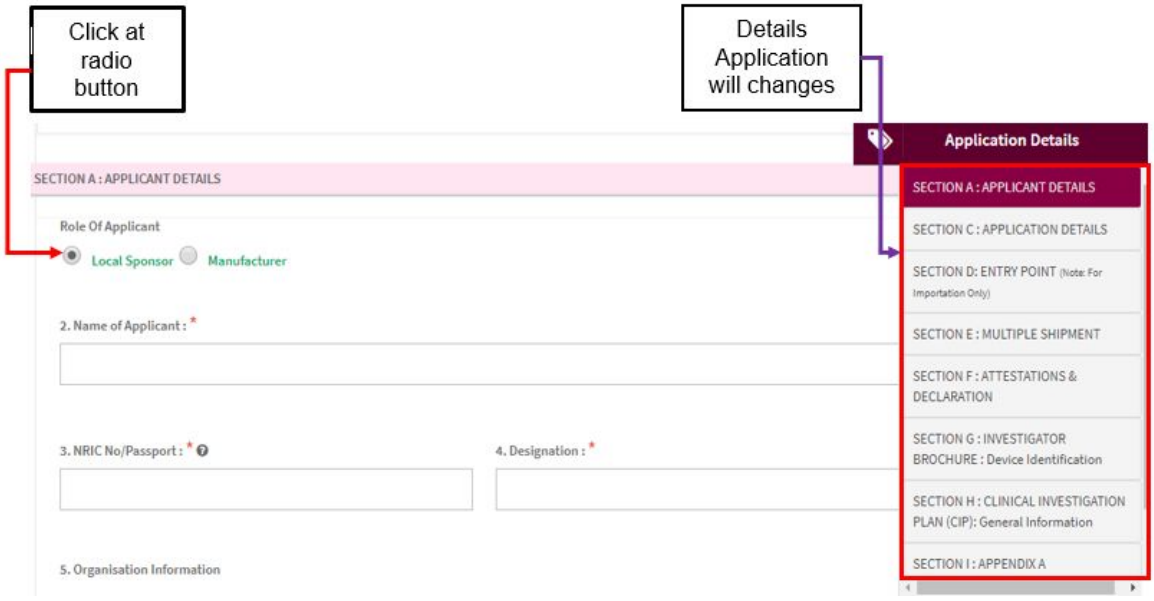
Section A: Applicant Details

The symbol "*" means required field. The user must fill it.

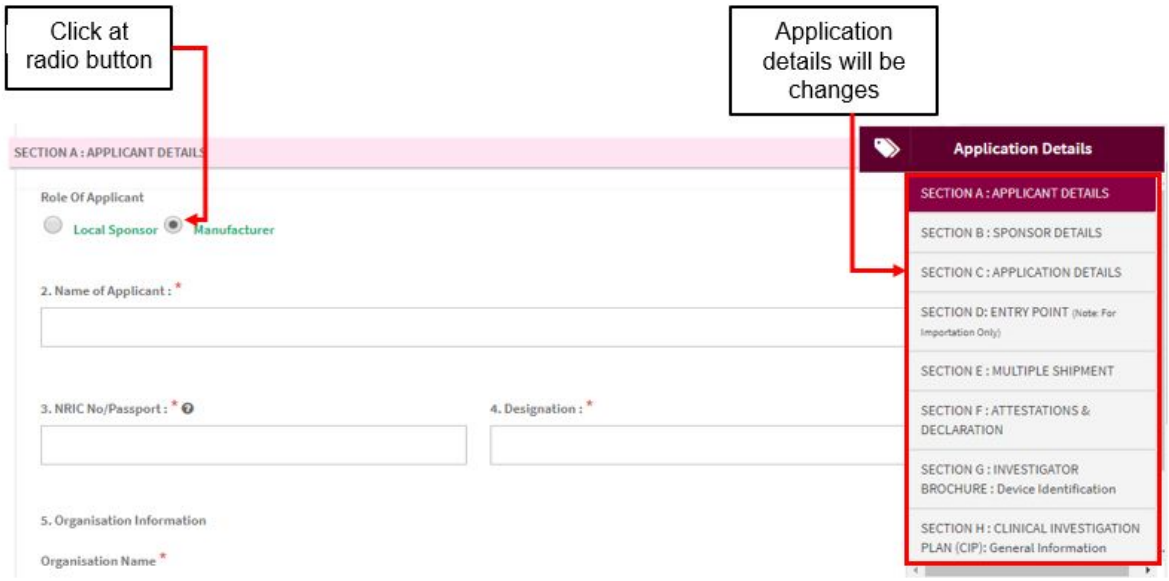
- Role of Applicant -> User should choose whether local sponsor or manufacturer.

  If user choose local sponsor 

, the form that user not to fill is section B.



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

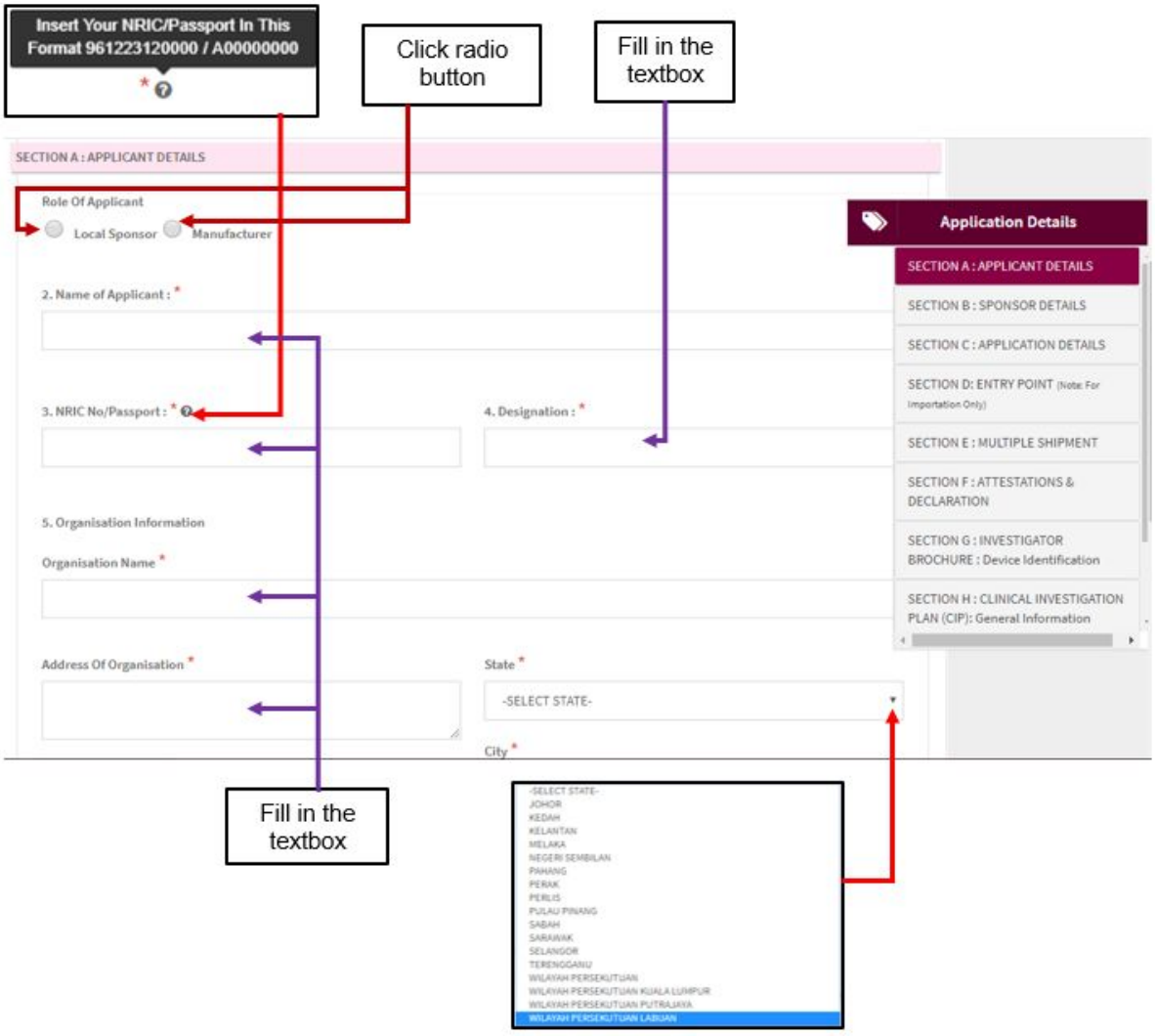


2. Name of Applicant

- 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.

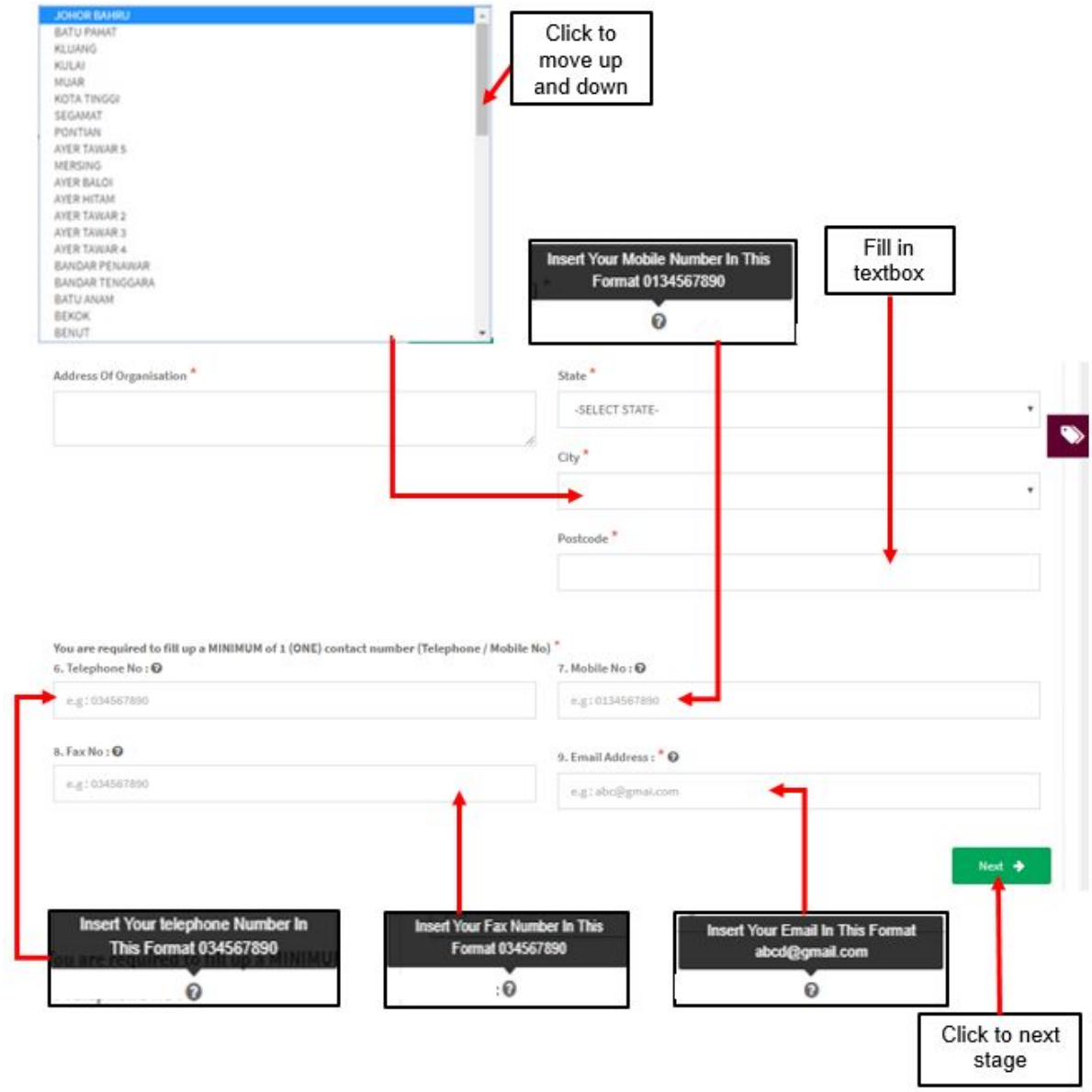
   The user must fill in the number only and click at to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field must have NUMBERS between 3 - 11 numeric" will be displayed.

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."



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

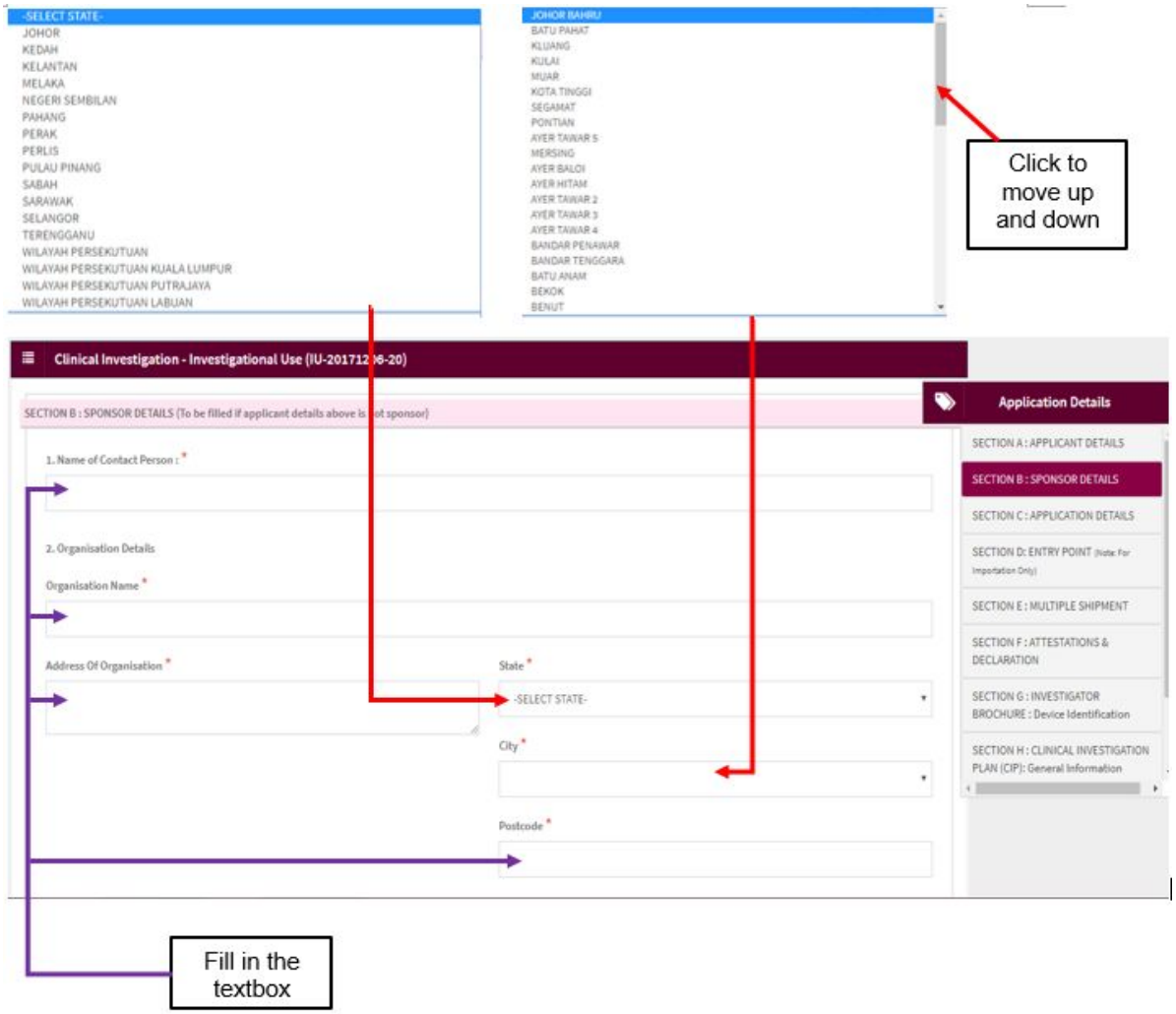
The symbol "*" means required field. The user must fill it.

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.

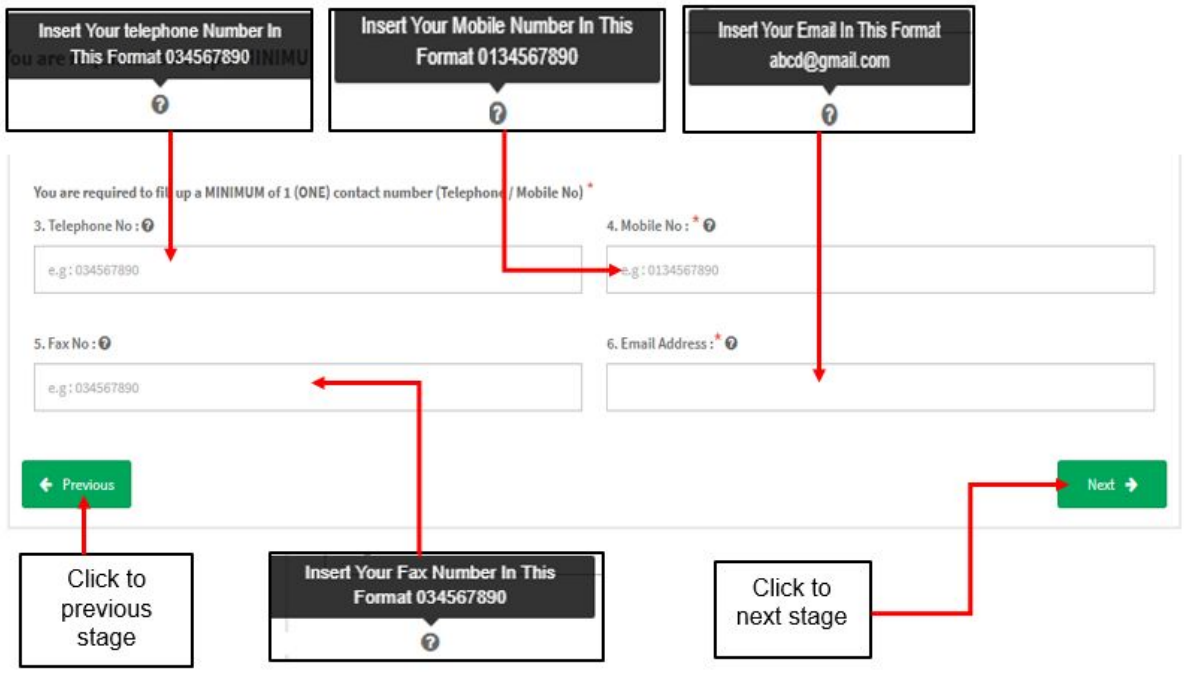
The user must fill in the number only and click at ? to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field can only contain number and between 3 to 11 numeric." will be displayed.

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.".



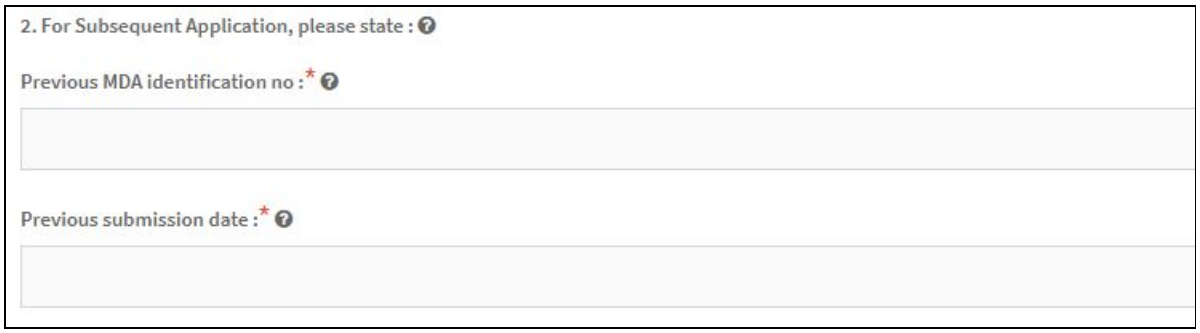
If user want back to previous section, user should click at button Previous. that shown in figure above. Then, user should click at button Next to the next stage.

Section C: Application Details

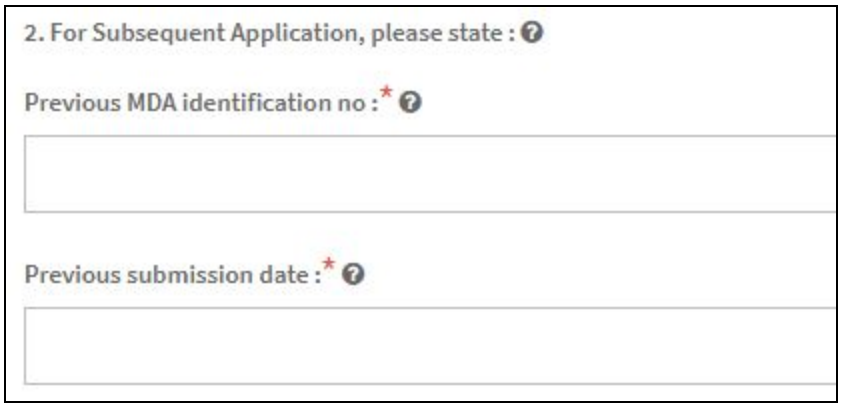
The symbol "*" means required field. The user must fill it.

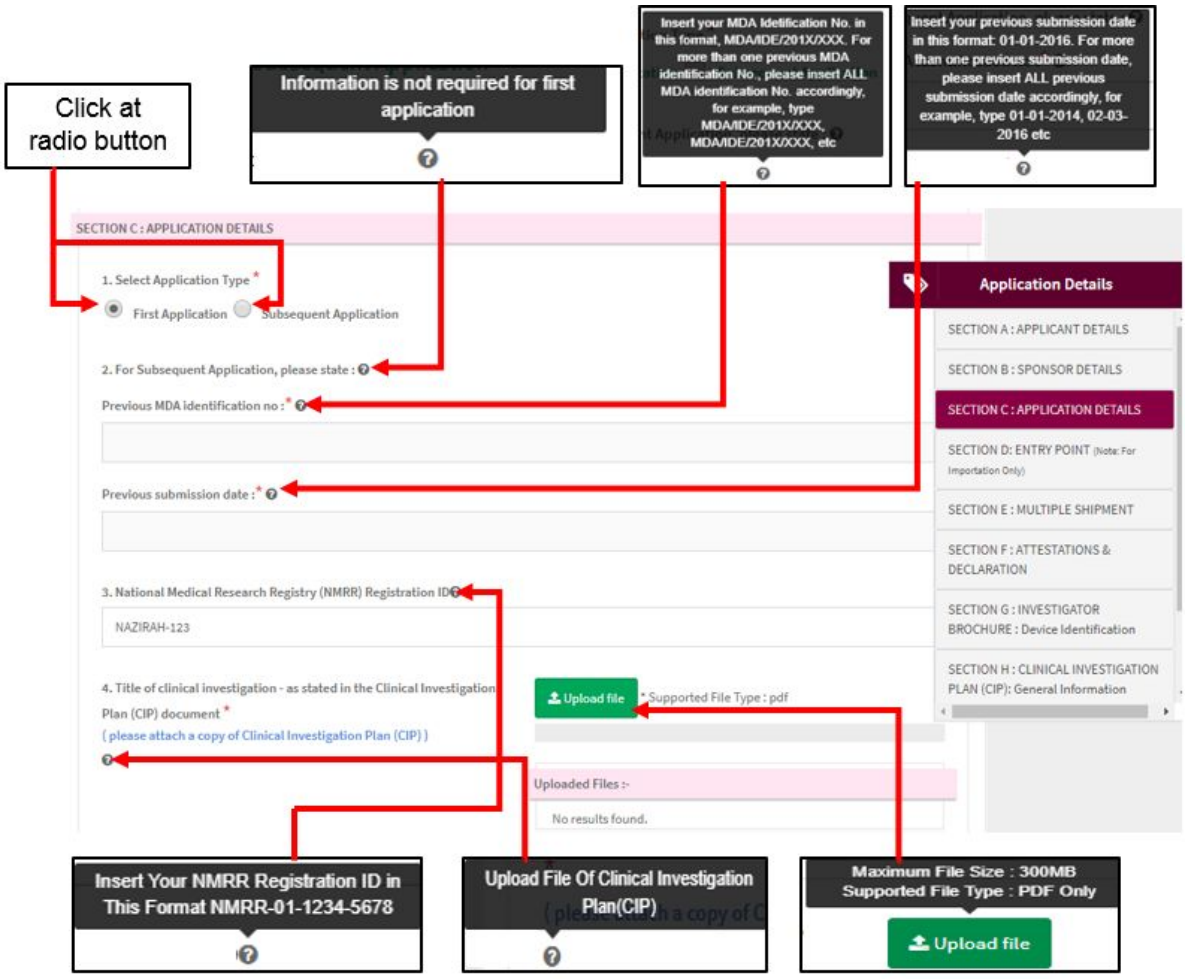
1. Select Application Type

- 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.



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 -> 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) Registration ID

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

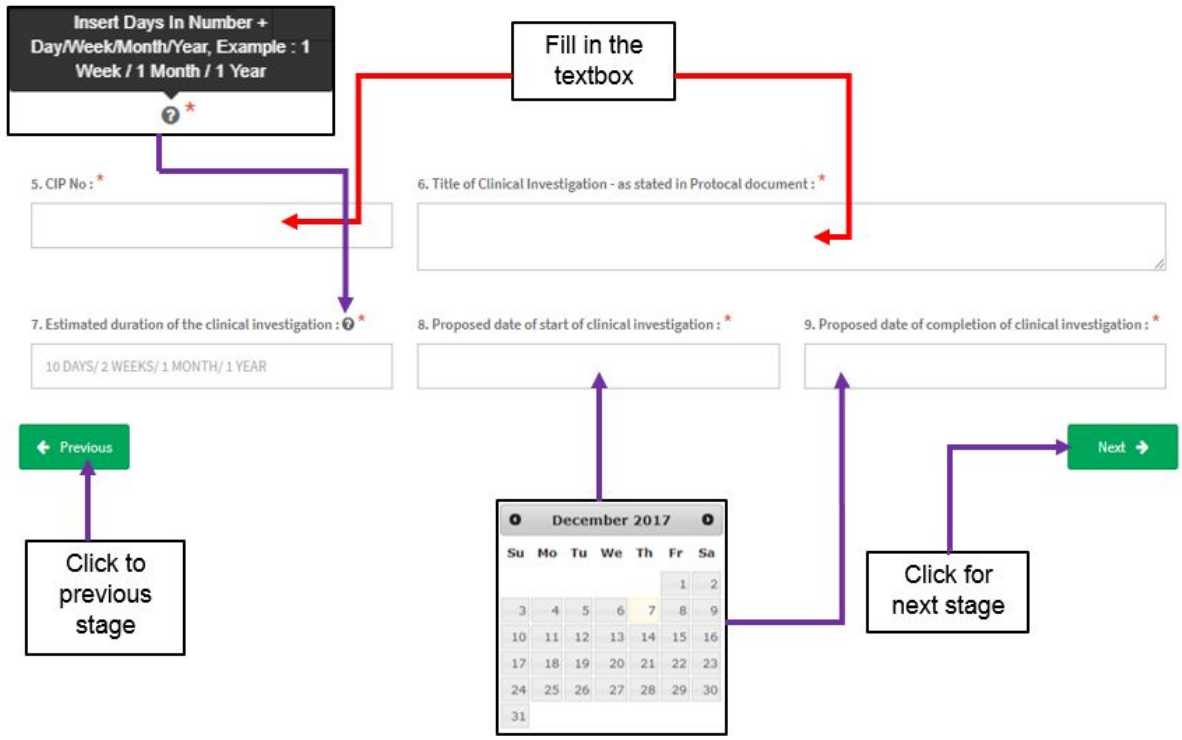
4. Title of clinical investigation- as stated in the Clinical Investigation Plan(CIP)

   User must click at button

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

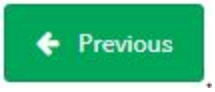
   The user should fill in the textbox field with number and character and click at to see the format. User should follow the format that shown in figure above.

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 

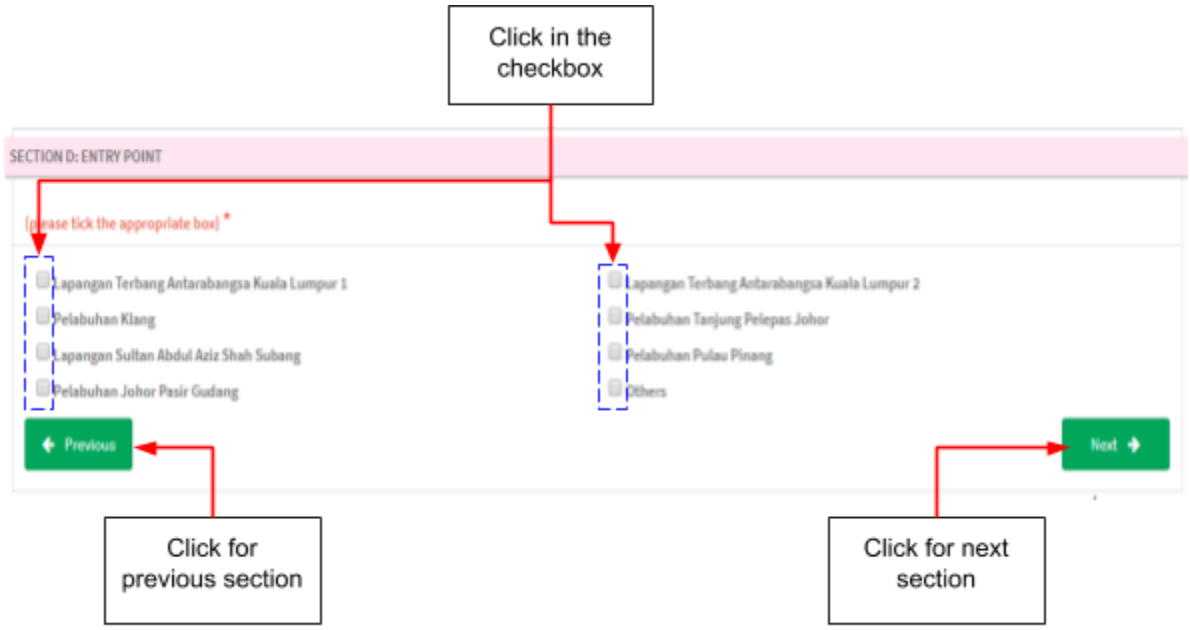
that shown in figure above. Then, user should click at button

to the next stage.

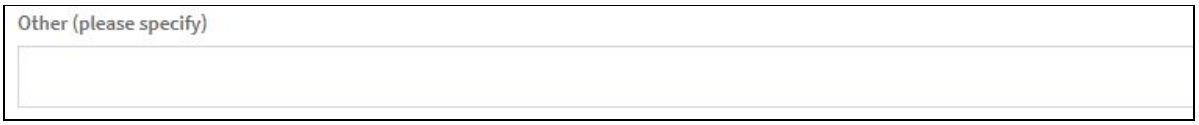
Section D: Entry Point

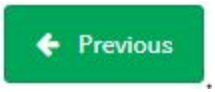
The symbol "*" means required field.

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.



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

.

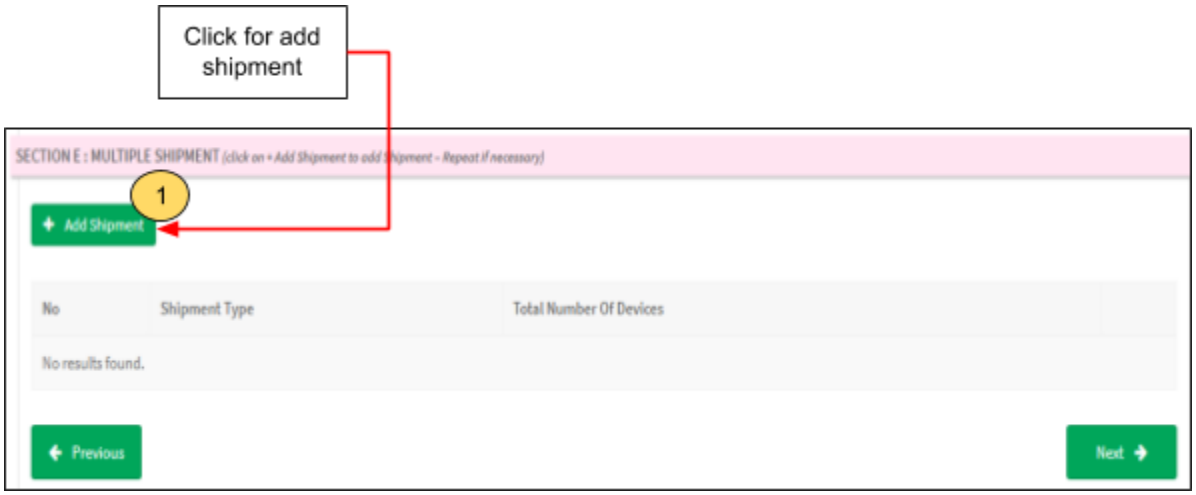
that shown in figure above. Then, user should click at button

to the next stage.

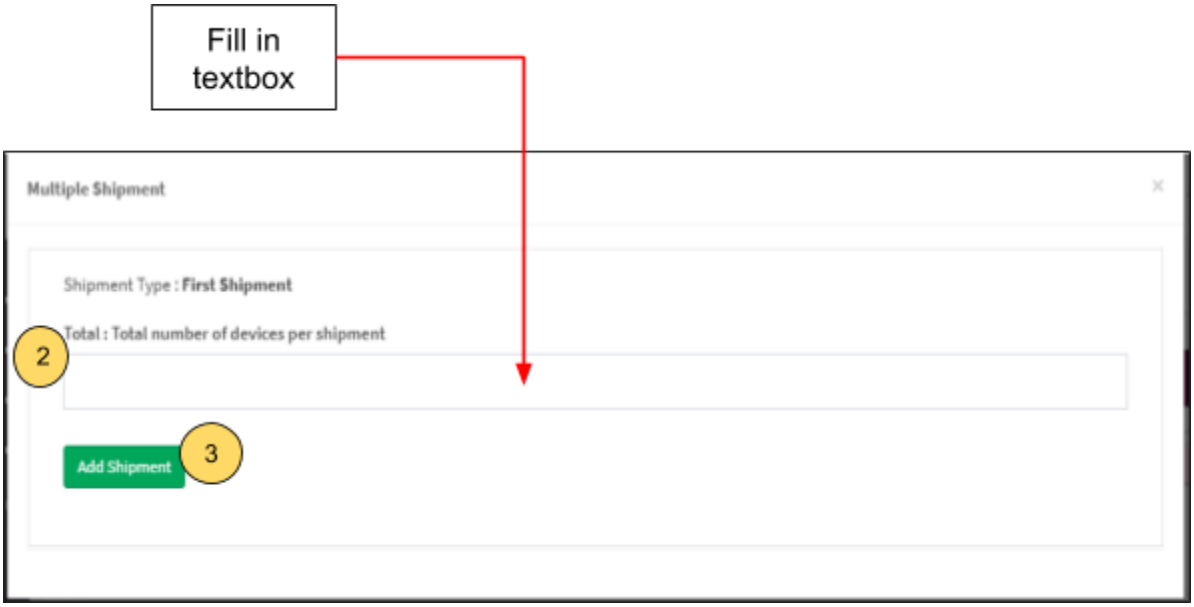
Section E: Multiple Shipment

1 The user should click at

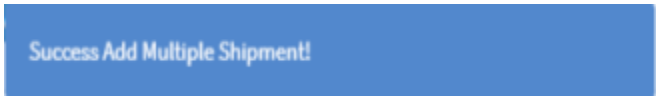
and the page form for shipment will be displayed.



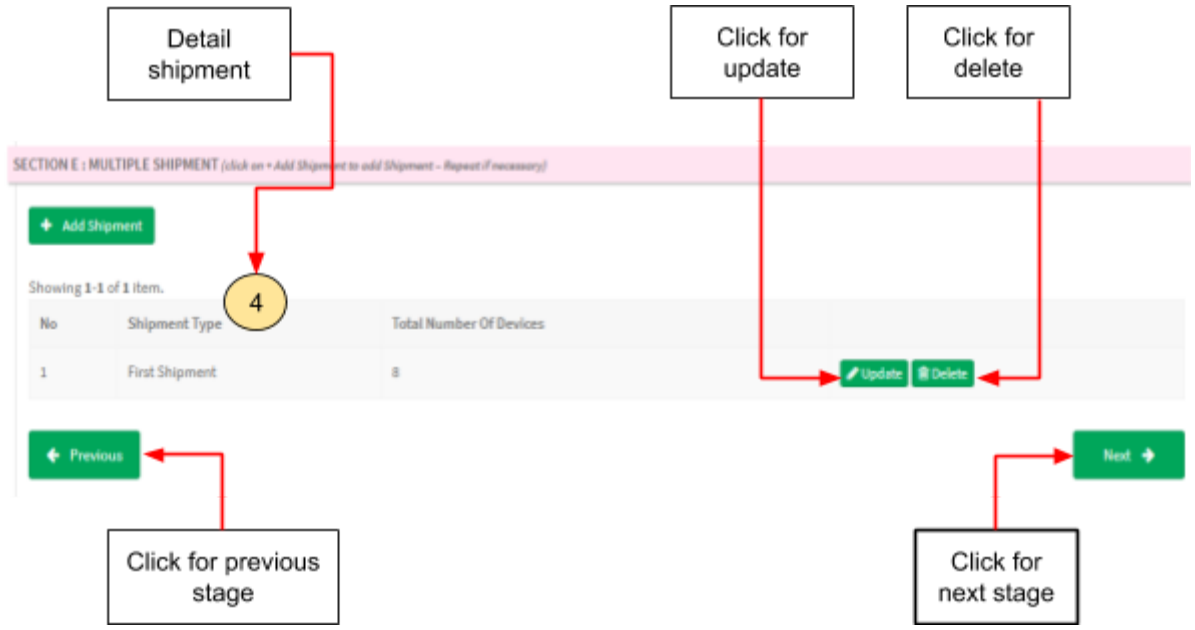
The form for shipment will be displayed after click on button that shown in figure above. The figure below show the form for add shipment.



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

3 -> The user should click at button “Add Shipment” and automatically the message  will be displayed.

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



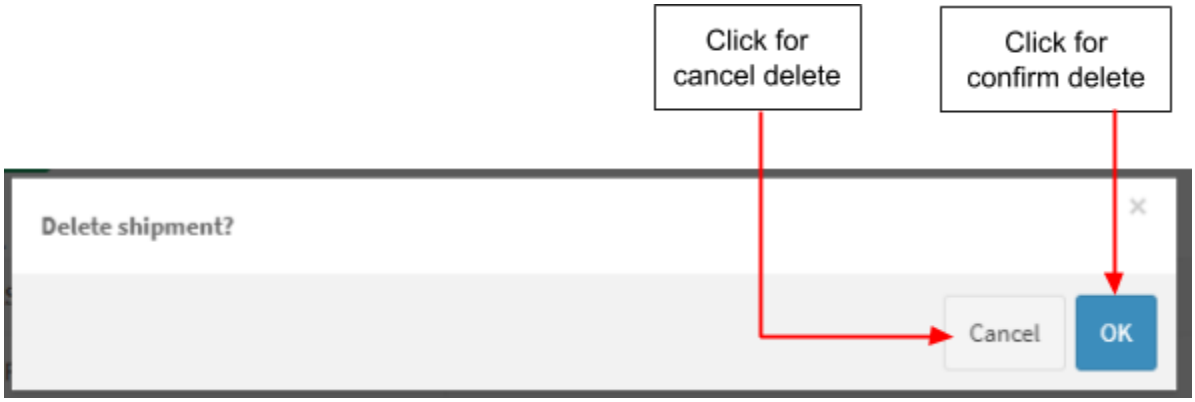
The user can update shipment with click at Update and the page update will be showed.

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

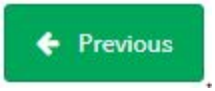
. The alert message “Delete shipment?” will be displayed that shown in the figure below.



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 

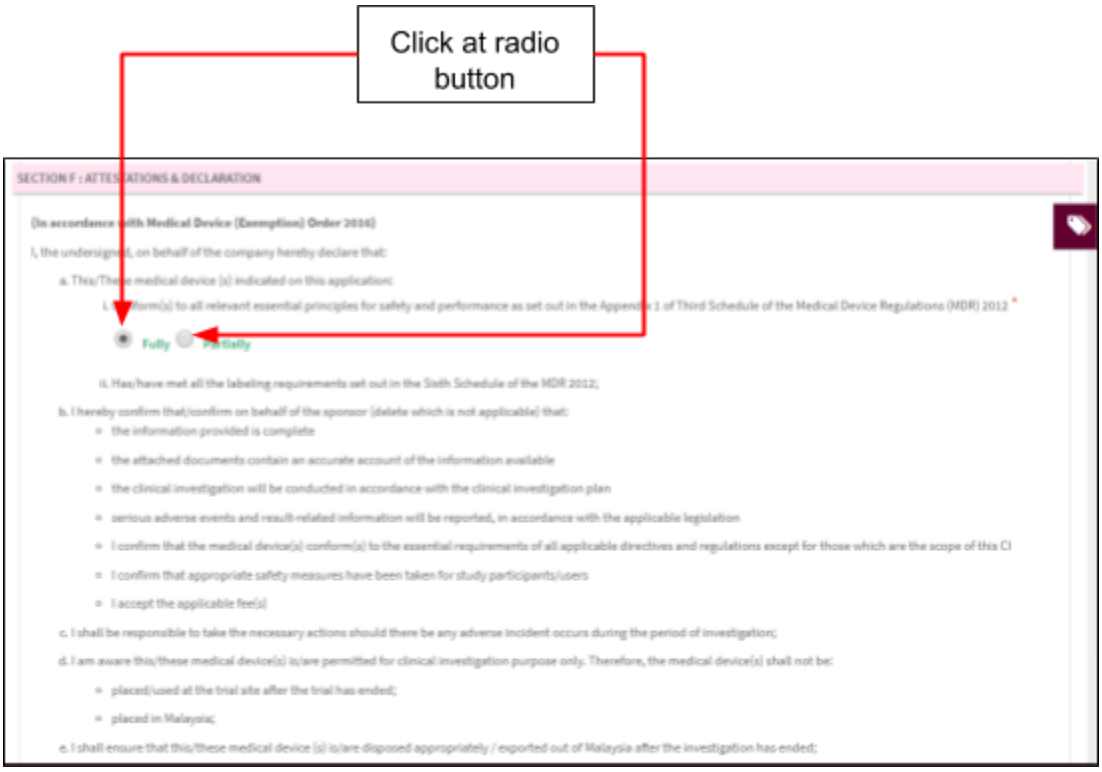
.

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

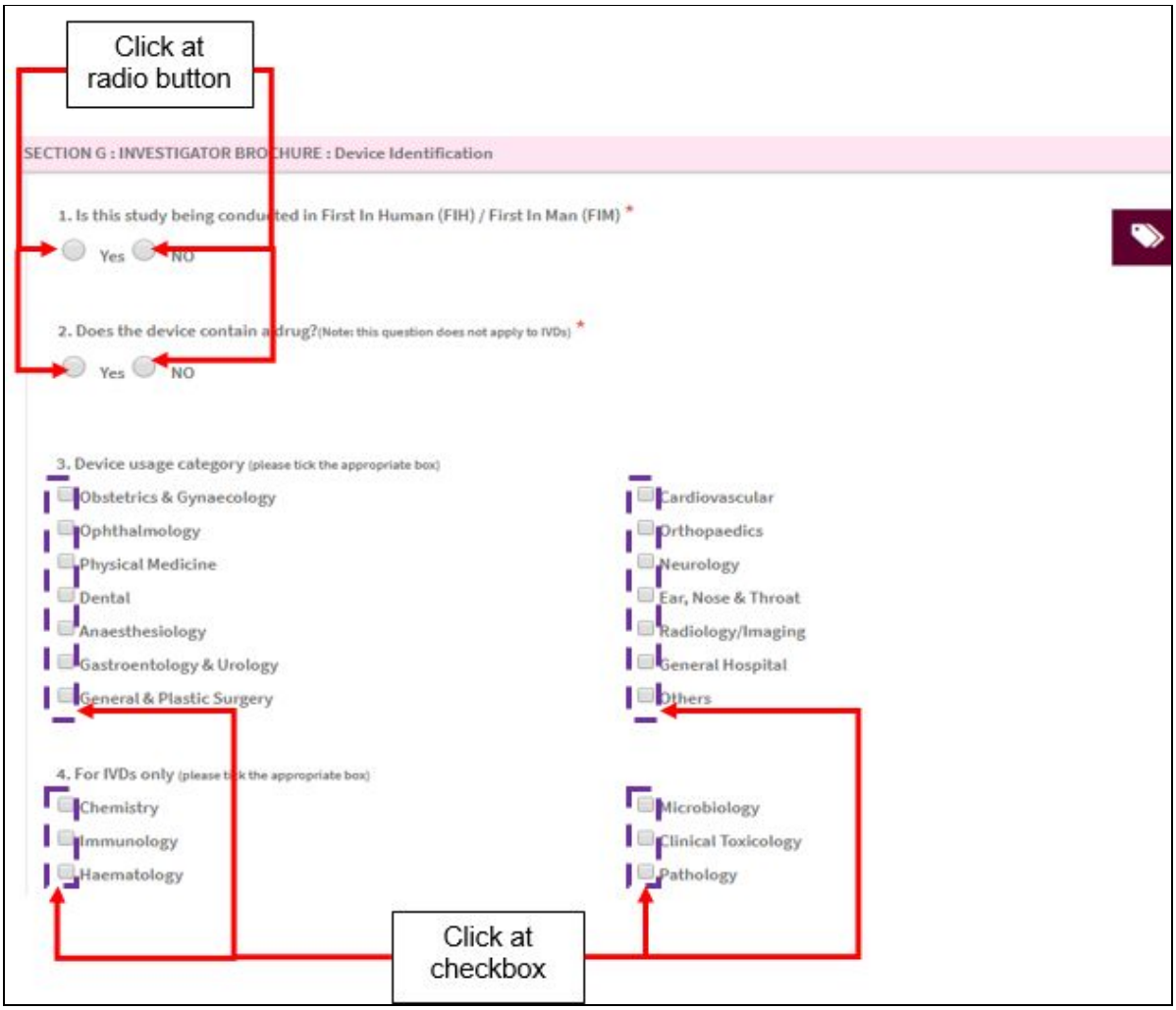
☑ I Have Read And Agree To The Above Terms And Conditions that agree in terms and conditions that shown in the figure below.

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

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

Section G: Investigator Brochure

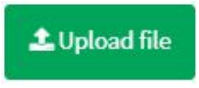
1. Is this study being conducted in First In Human (FIH)/First In Man(FIM)
   User should click at radio button whether “Yes” or “No” that shown in the figure below.
2. Does the device contain a drug?
   User should click at radio button whether “Yes” or “No” that shown in the figure below.
3. Device 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

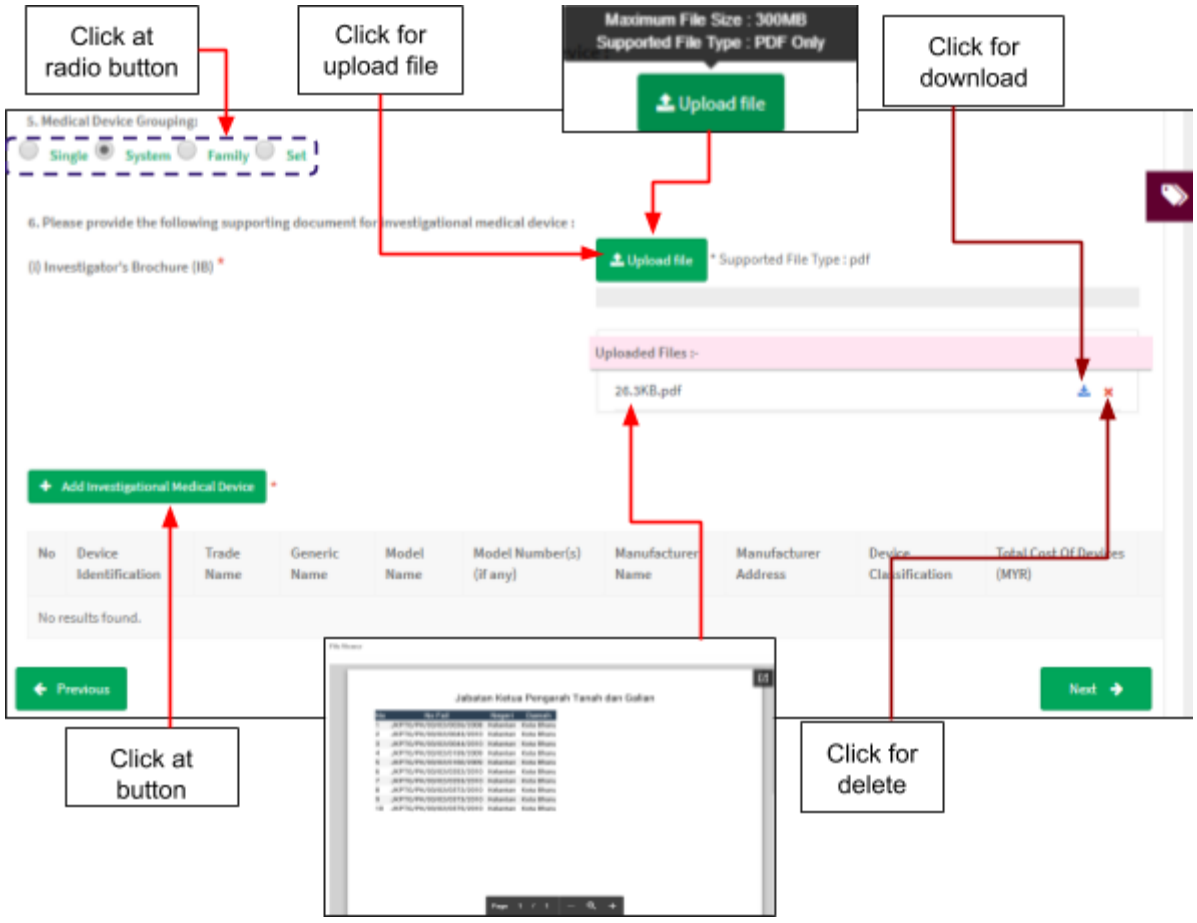
The user should click on radio button that provided shown in figure below. The Medical Device Grouping has four types which are single, family, system and set. The user should choose the group of medical device.

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

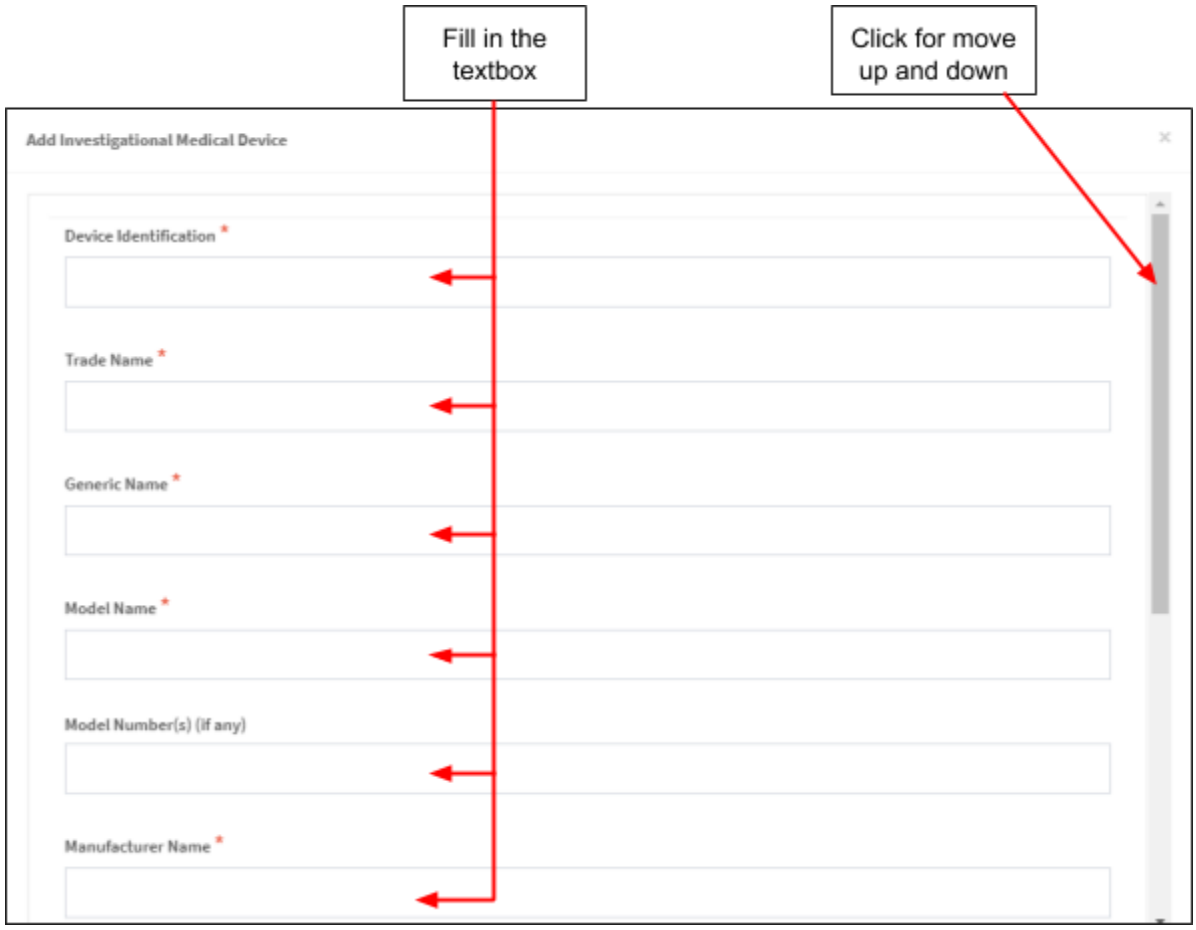
User must click at button 

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 + Add Investigational Medical Device and the form for investigational medical device will be displayed. The figure below shows the form of investigational medical device.

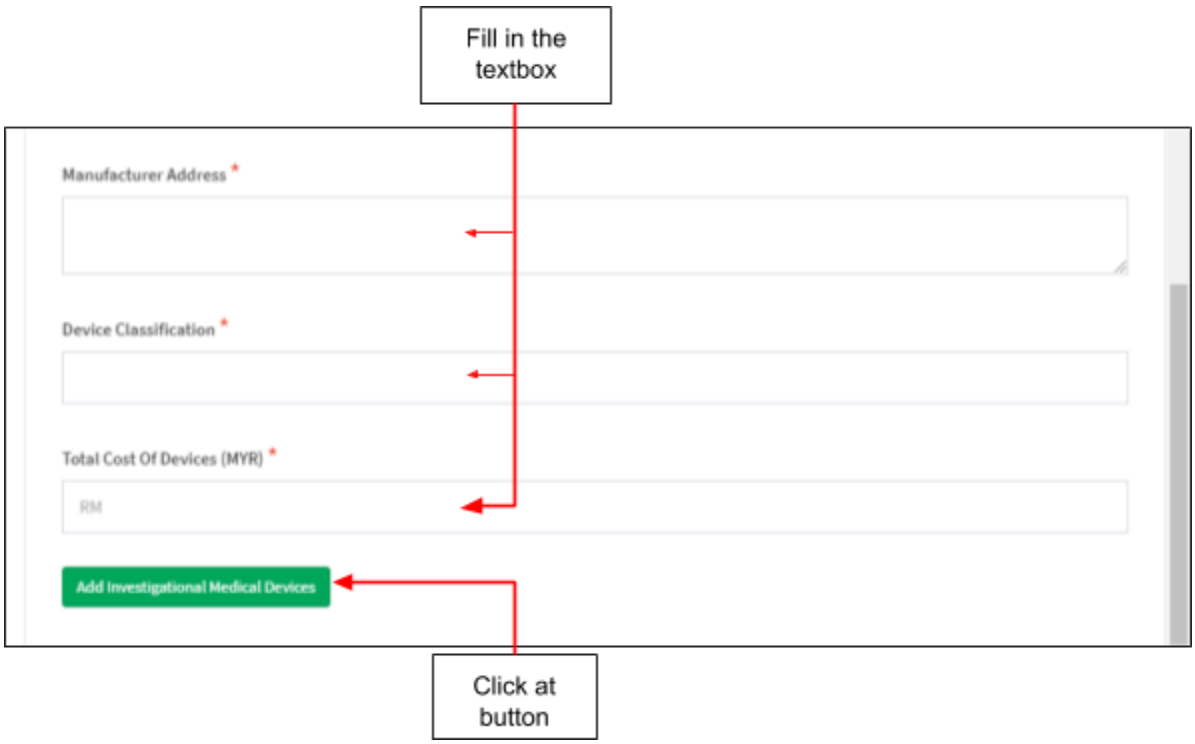


Add Investigational Medical Device

The symbol "*" means required field.

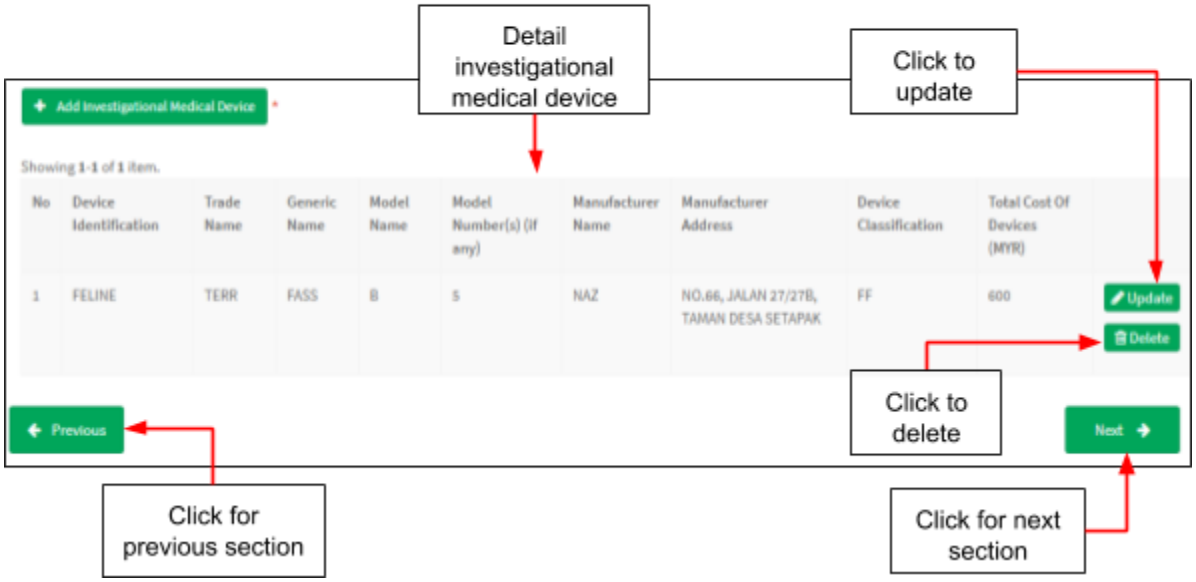
- Device Identification ->The user should fill the textbox that provided. If user don't fill the field, the message "Device Identification cannot be blank." will be displayed.
- Trade Name -> The user should fill the textbox that provided. If user don't fill the field, the message "Trade Name cannot 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.

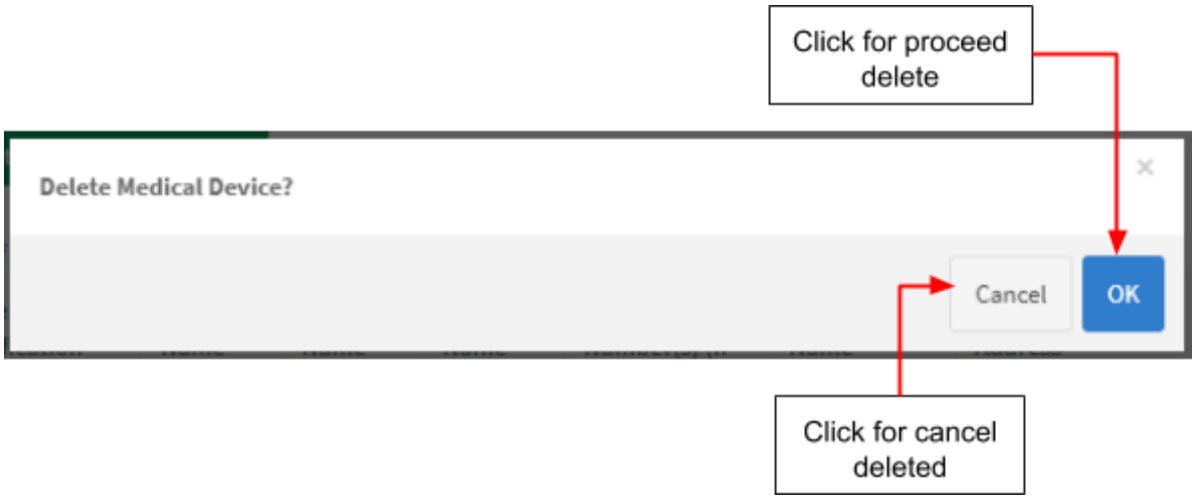


The user should click at button

to proceed and the details will be shown in the figure below.

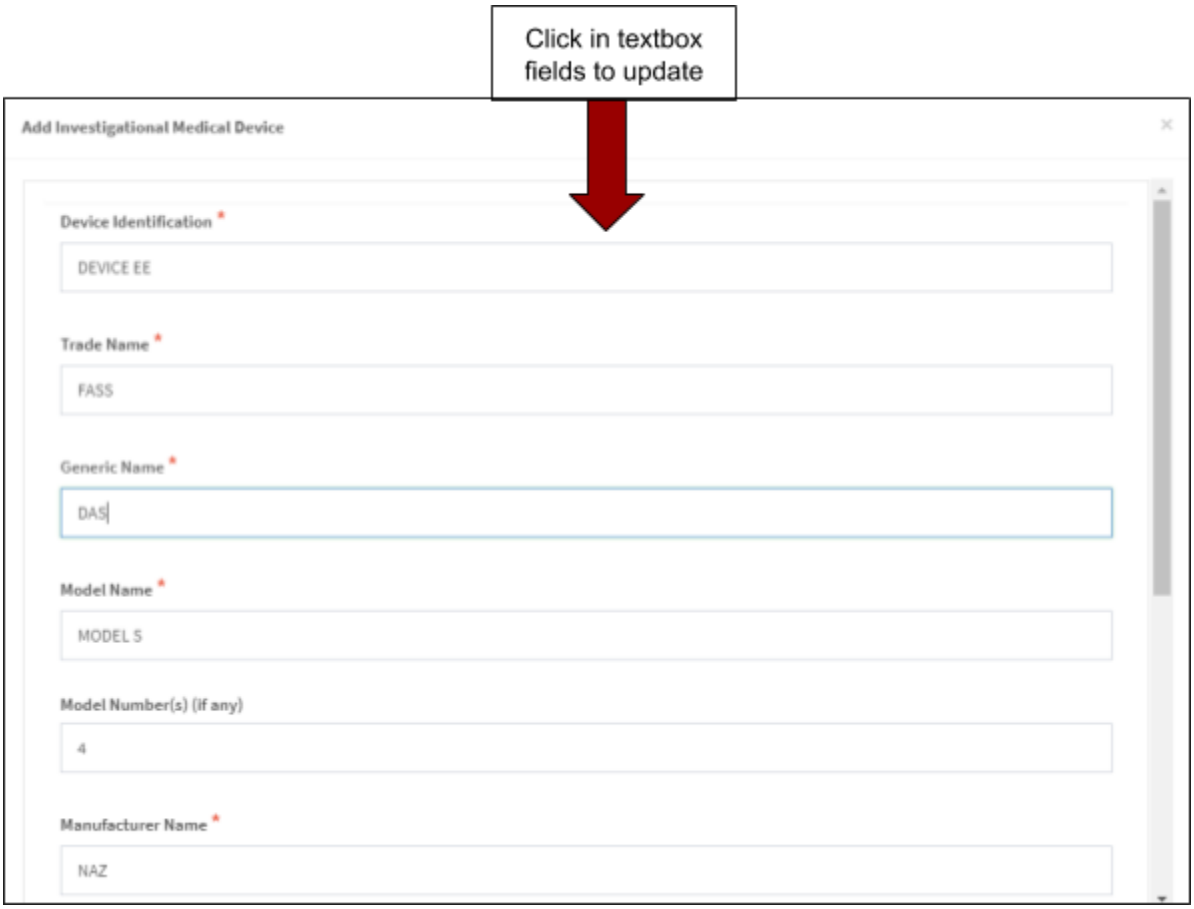


The details add investigational medical device will be displayed at table that shown in figure above. If user want to delete the investigational medical device, user should click at Delete and alert message "Delete Medical Device?" will be displayed that shown in the figure below.

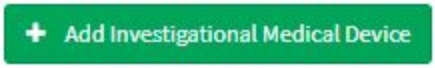


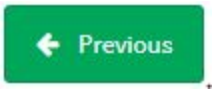
The user should click at "OK" to proceed deleted and "Cancel" to cancel for deleted.

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



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

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.

Clinical investigational plan

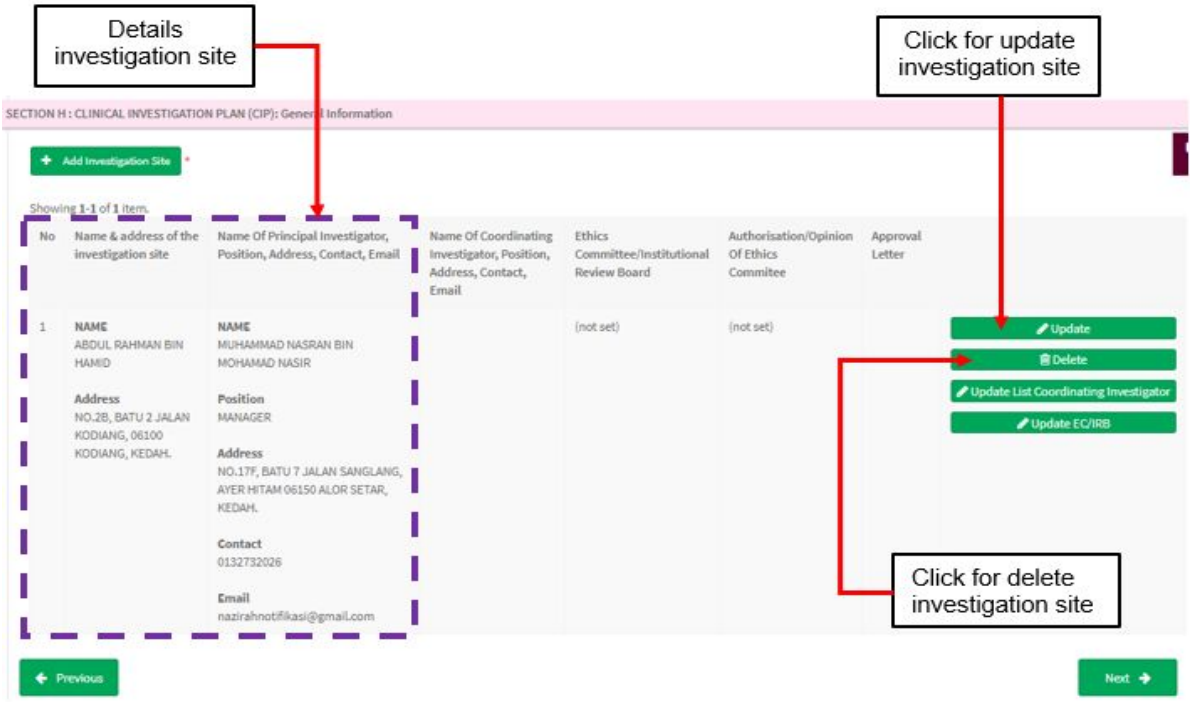
The symbol "*" means required field.

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.

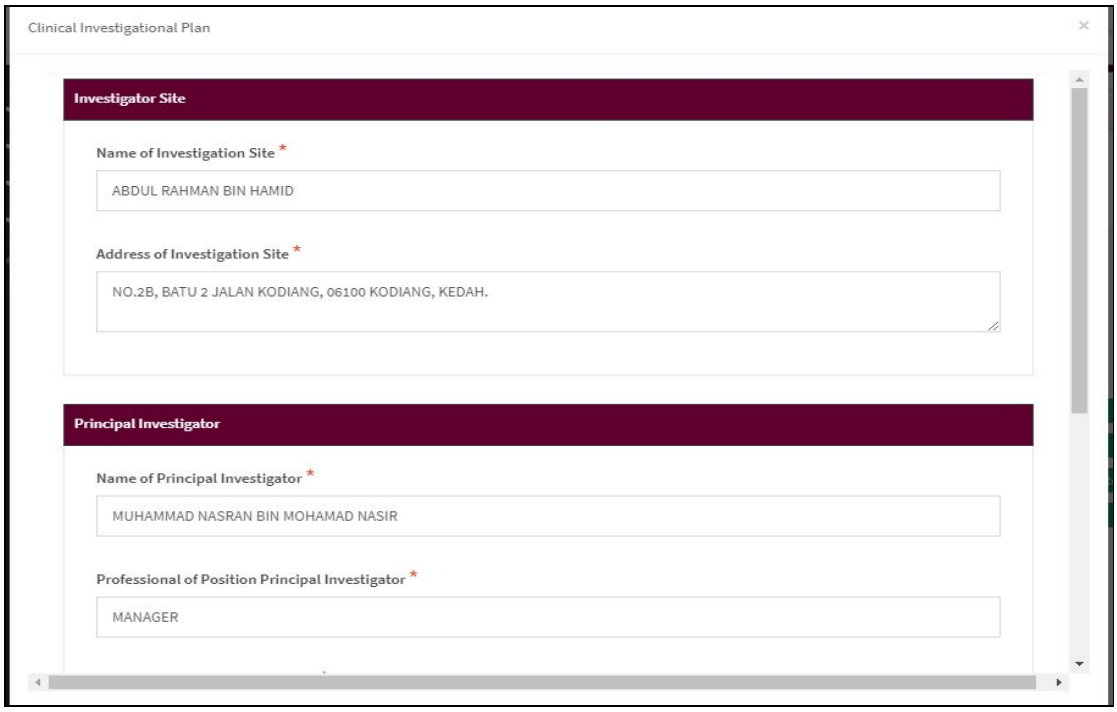
After all the forms are complete filled, the user should click at

to save the details.

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

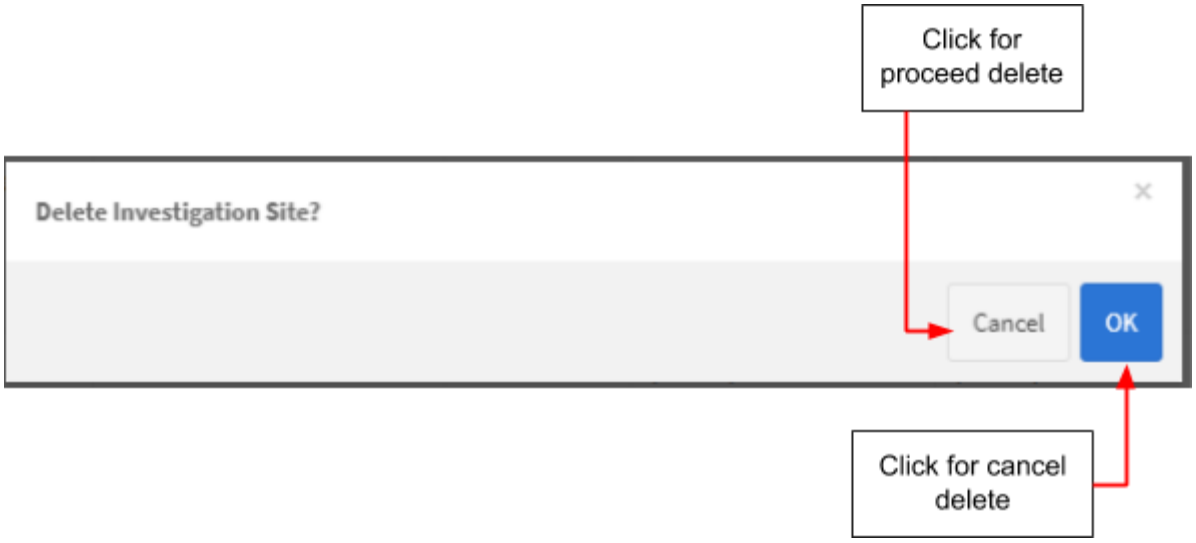


If user wants to update investigation site, user should click on button “update” for change the details of site. The form investigation site will be displayed after clicking on button “update” that shown in the figure below.



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

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



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

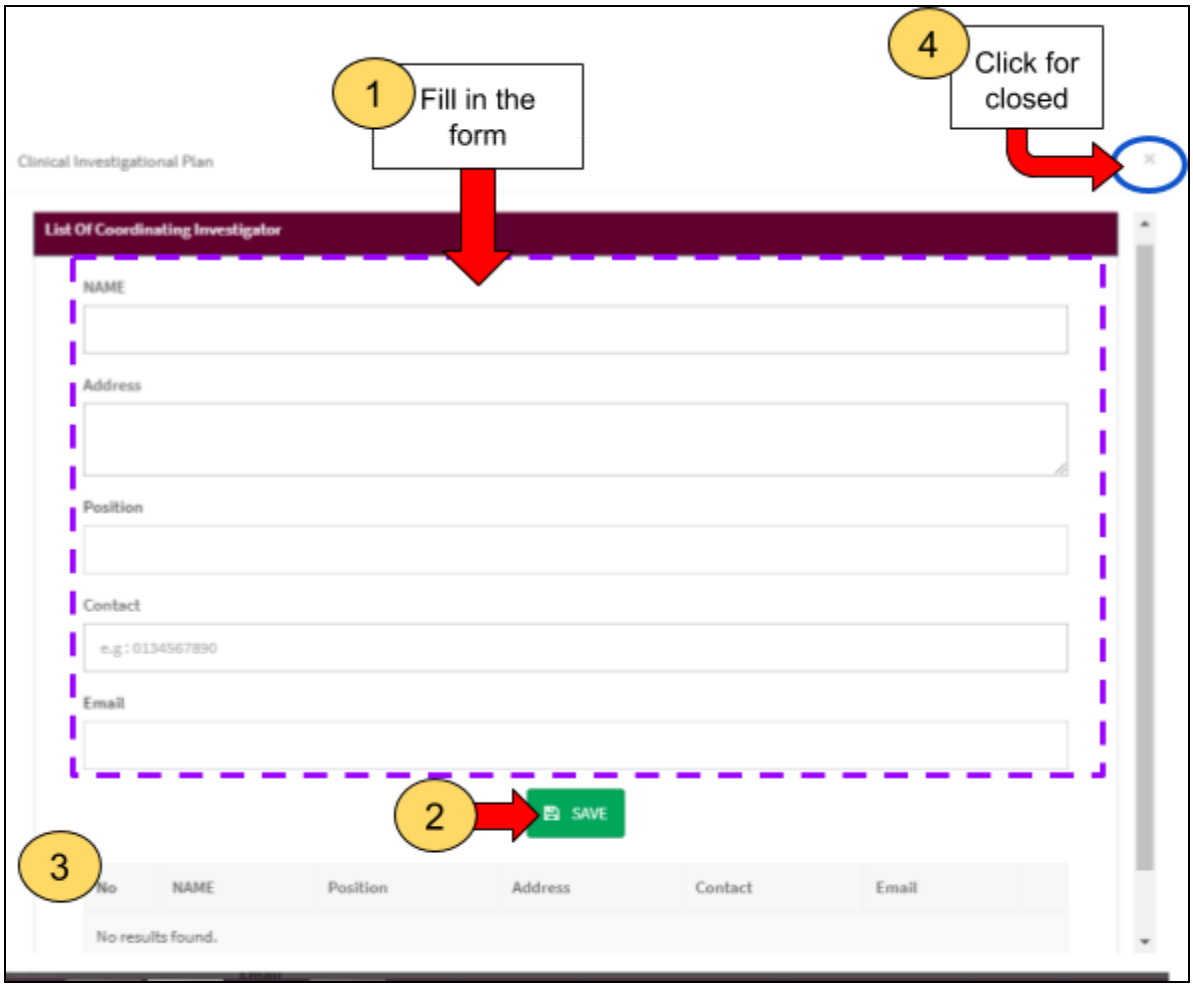
After that, user should click button

to update list coordinating investigator.

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

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

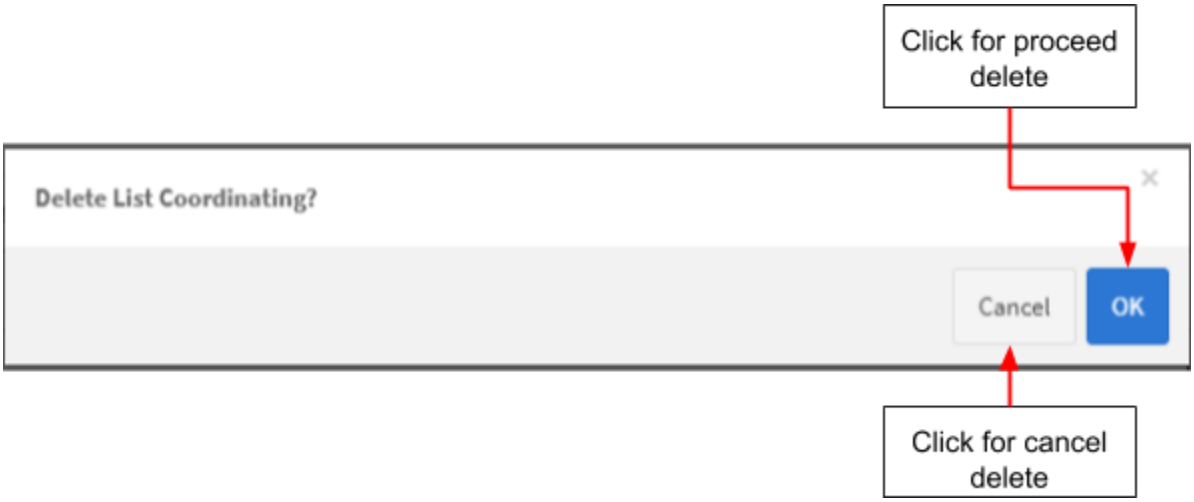
The form of list coordinating investigator will be displayed that shown in the figure below.



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

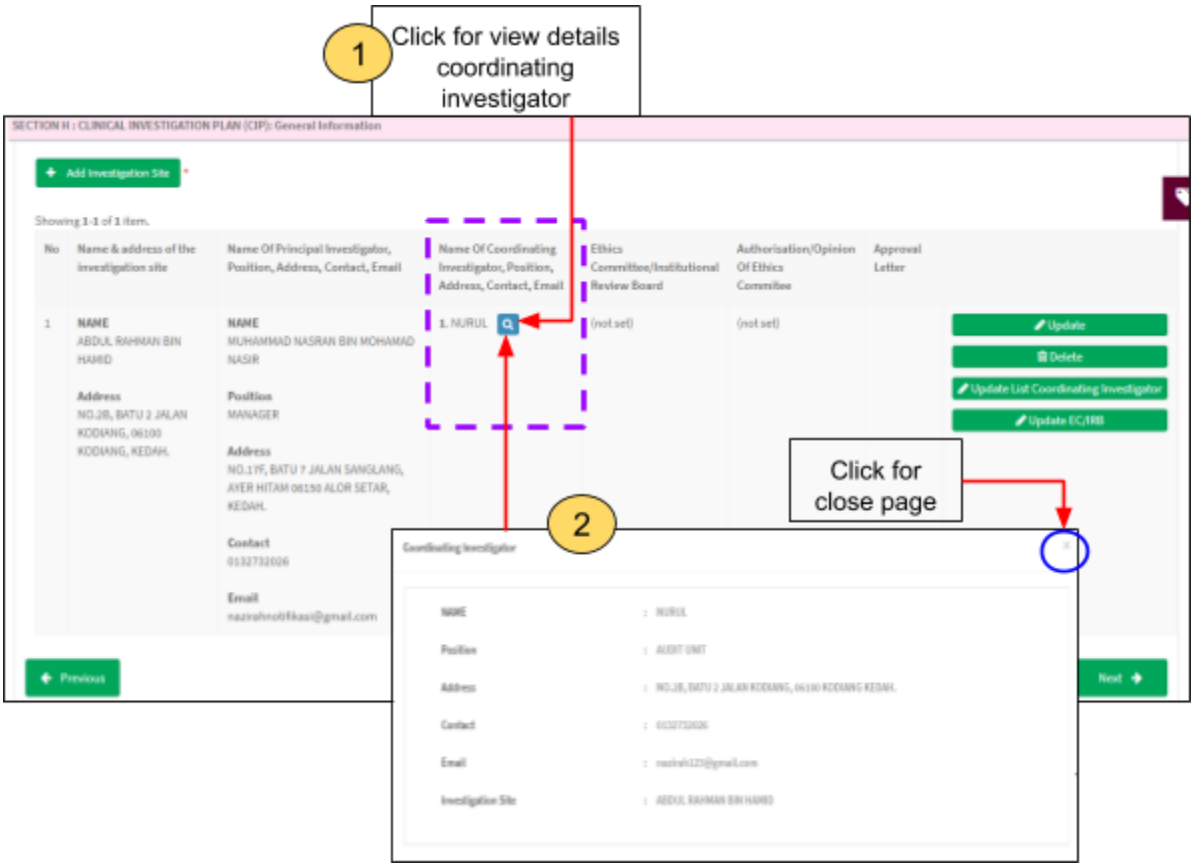
3 -> The details of coordinating investigator will be displayed in table after clicking button “save”. Example details are:

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



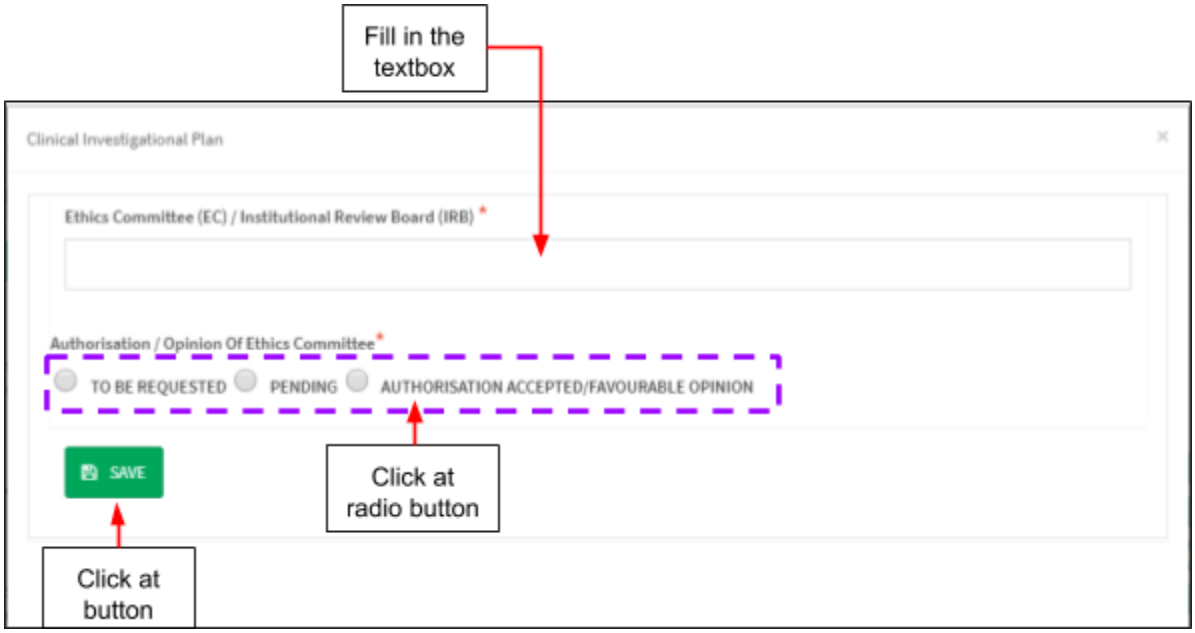
-> The user should click to close the page.

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



After that, user should click button

to fill the details of EC/IRB. The form for EC/IRB will be displayed. The figure below shows the form for update EC/IRB.



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

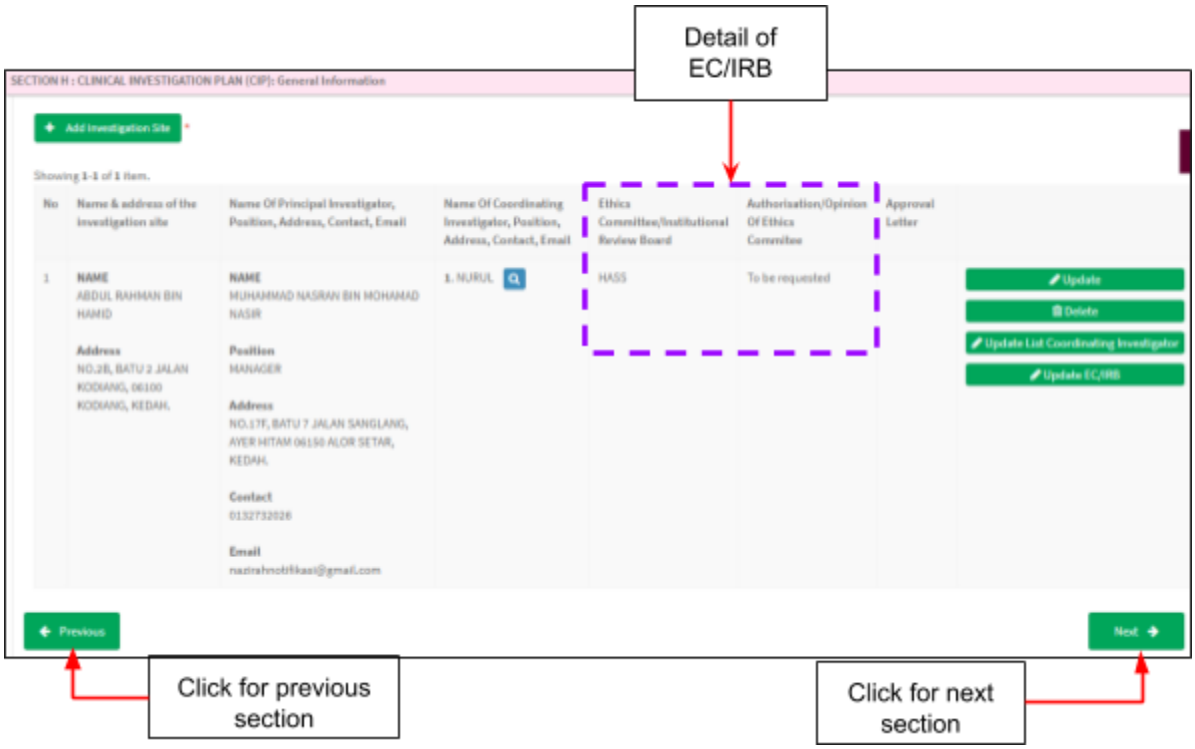
- The user should fill in the textbox that provided.

Authorisation/Opinion of Ethics Committee

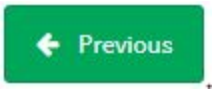
- The user should choose whether “To be Requested” or “Pending” or “Authorisation Accepted/Favourable Opinion”

After that, user click at

to save details. The details will be displayed on table that shown in the figure below.



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



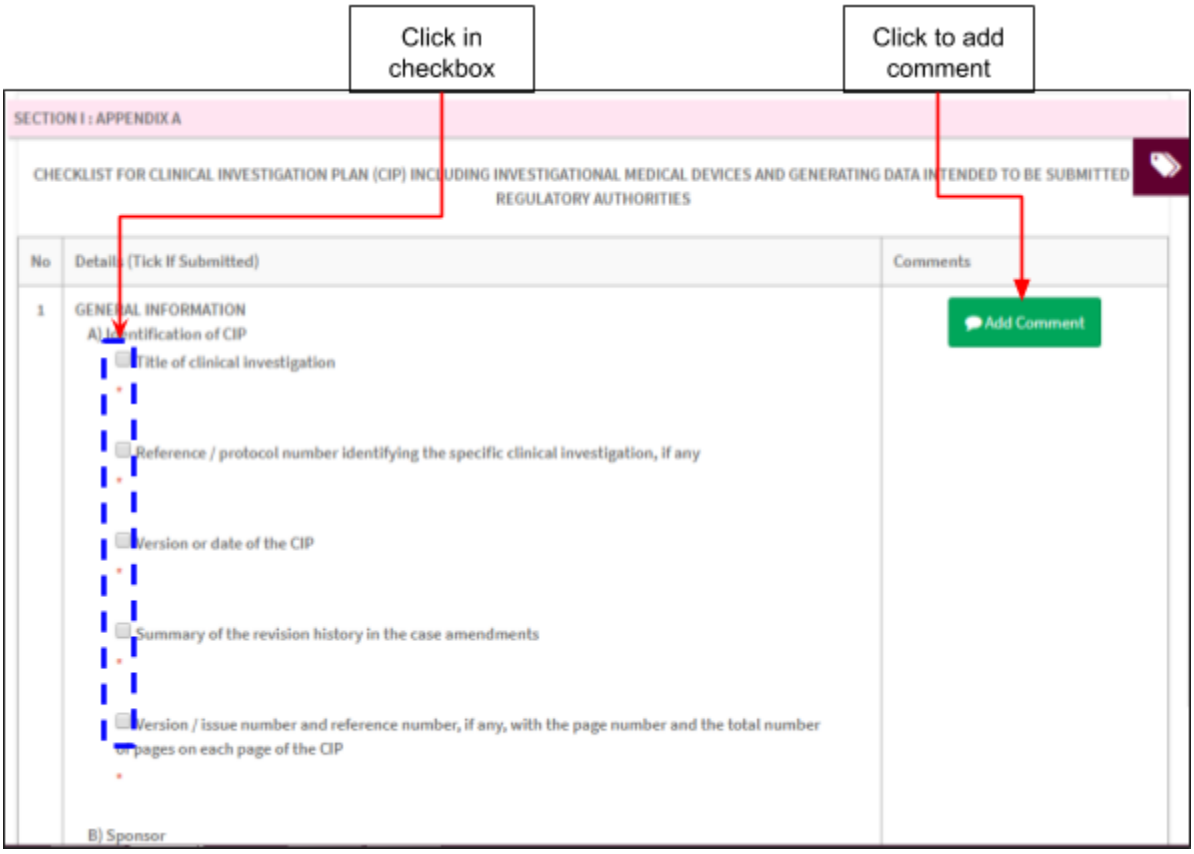
. that shown in figure above. Then, user should click at button

to the next section.

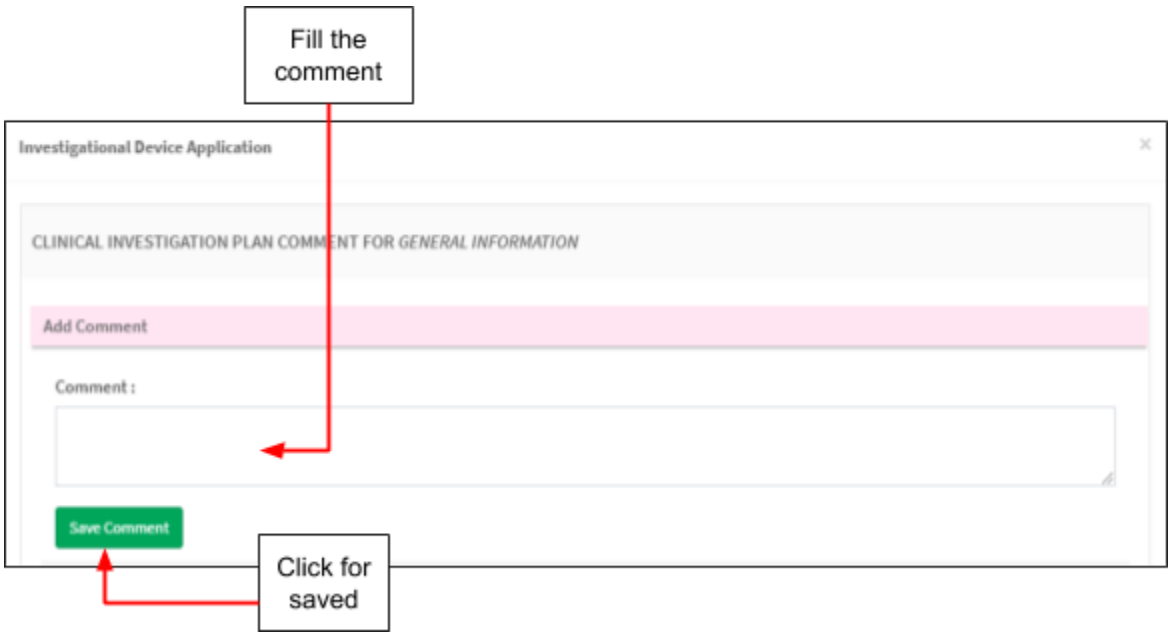
Section I: Appendix A

The user should tick on checkbox that provided in all details. The user also can add comment in each of details with clicking at

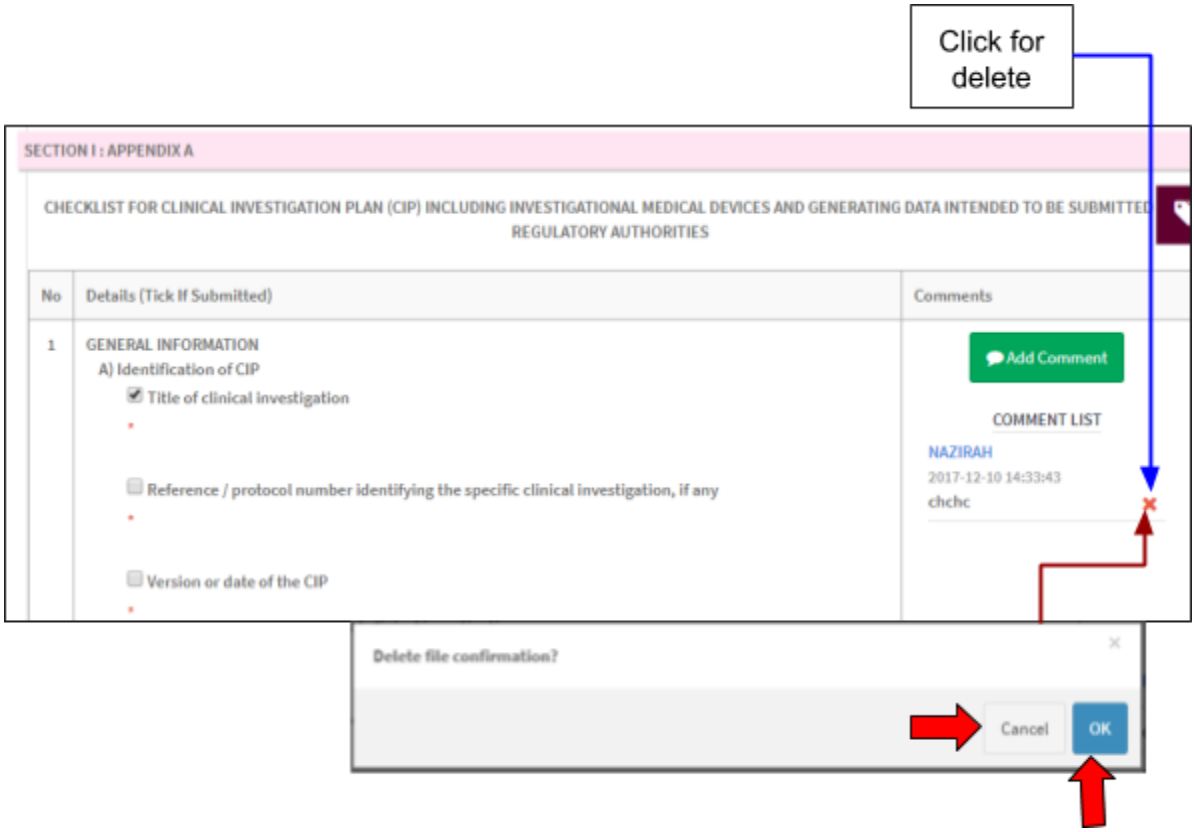
that shown in figure below.



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

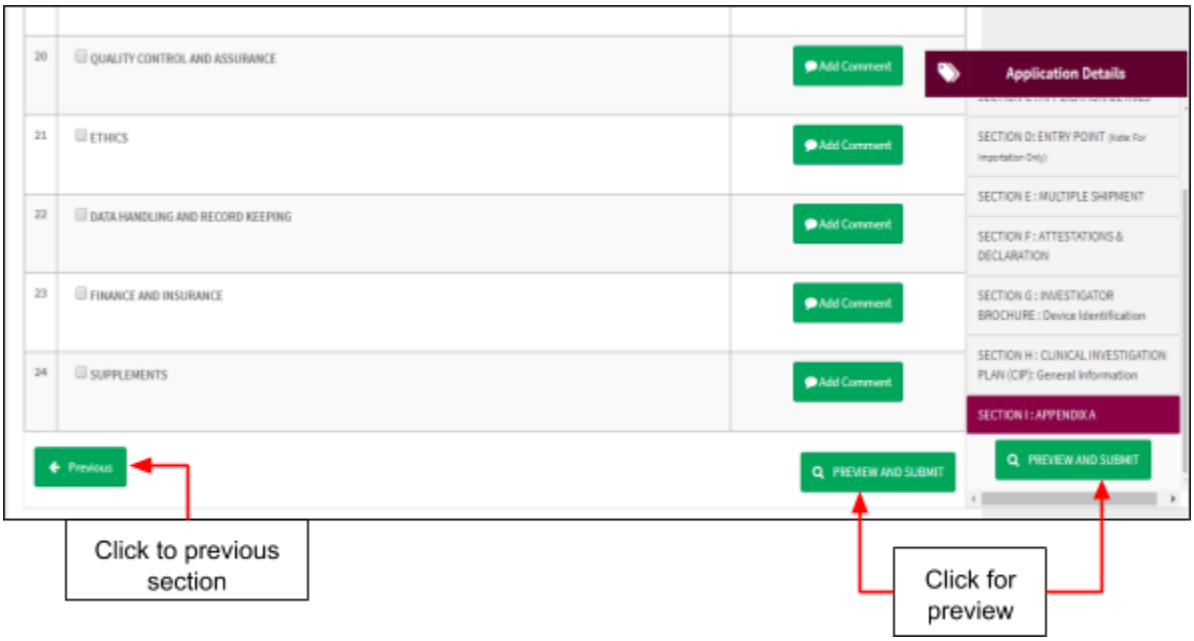


The user should fill the comment in form that shown in figure above. Then, click button Save Comment. The comments will be displayed on the table shown in the figure below.

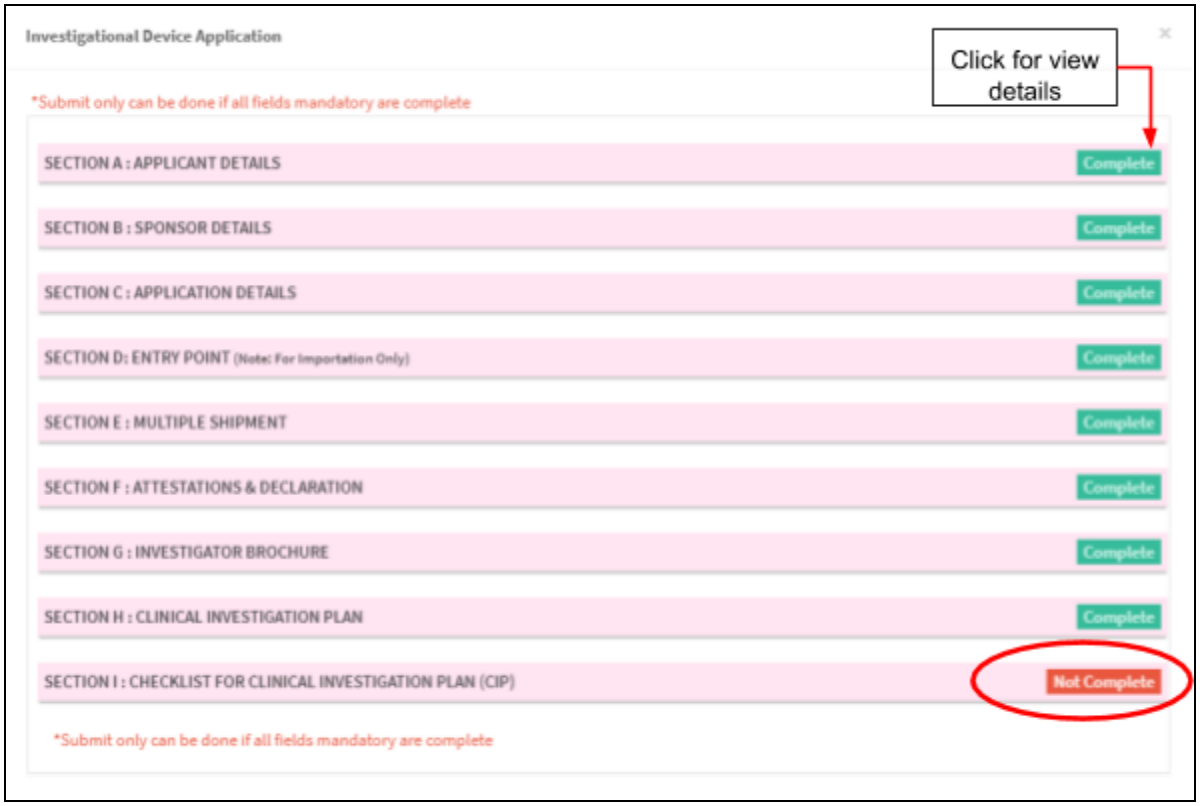


The user can delete the comment with click at ✖ and the message alert will be showed. The user should click “ok” to proceed deleted or “cancel” to delete canceled.

After all form in each section completed, the user should click at PREVIEW AND SUBMIT to preview and submit the application form.



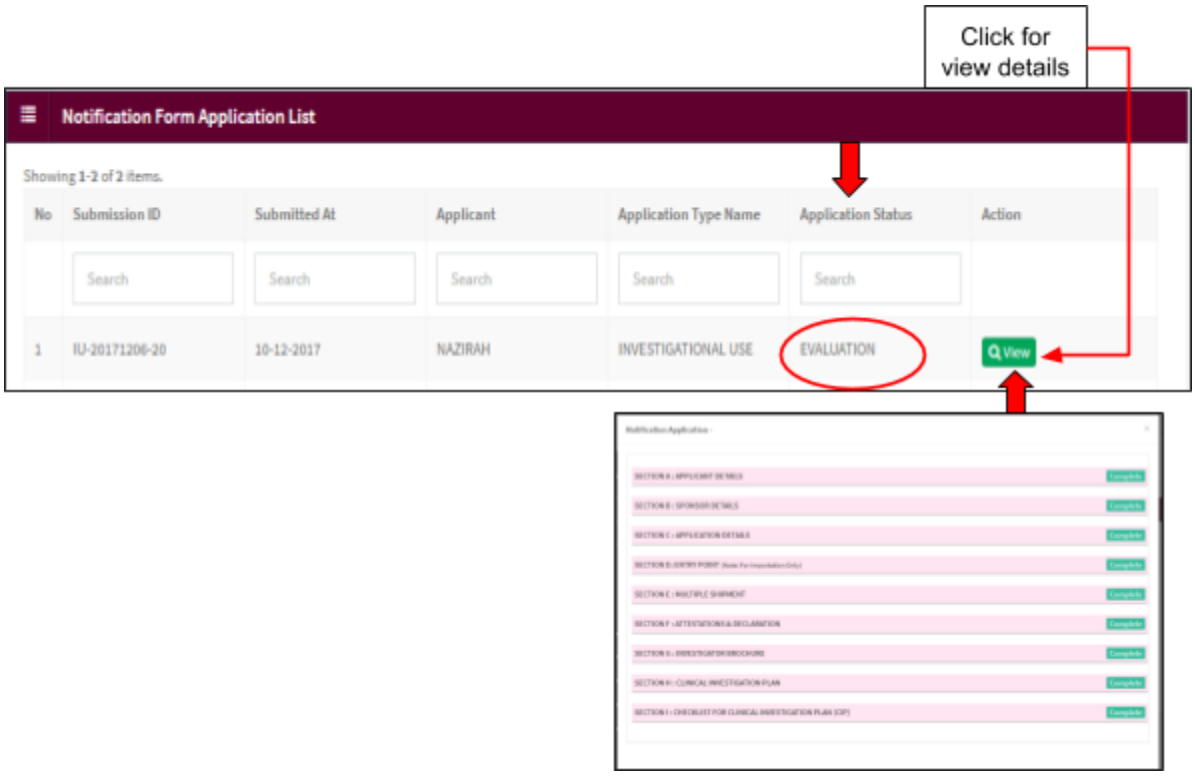
The page view will be shown after click button “PREVIEW AND SUBMIT”. The figure below show the details of preview.



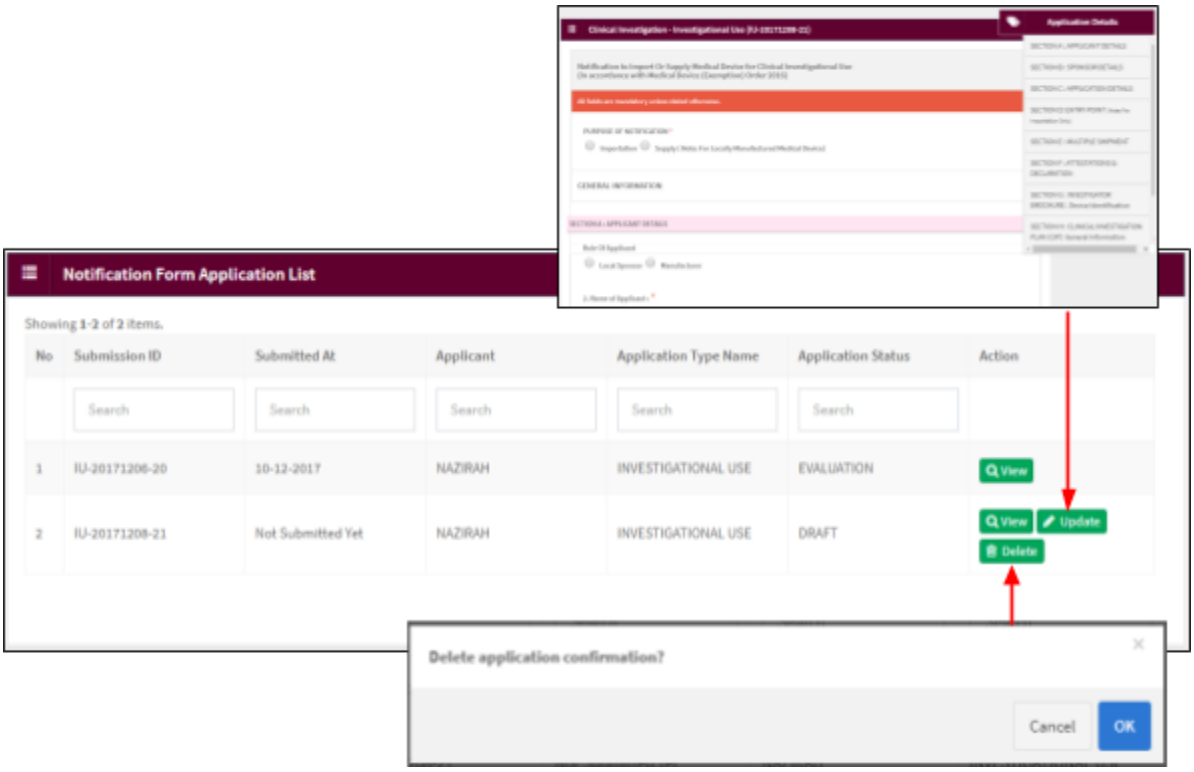
If status Not Complete , the user should fill it again to change status Complete and the button “submit” will be displayed.

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

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

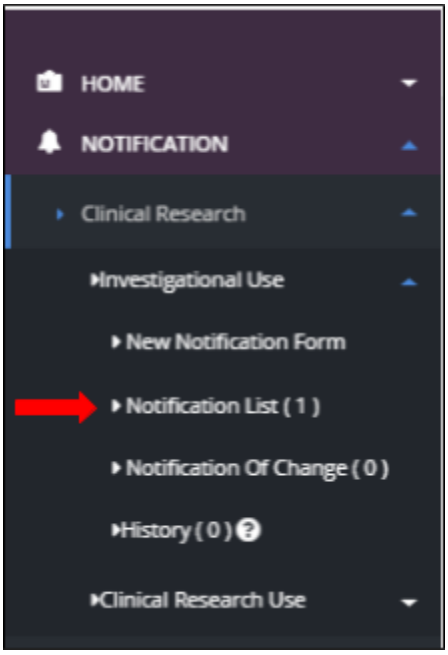


In addition, if application status “Draft” , the user can delete or update the application form.

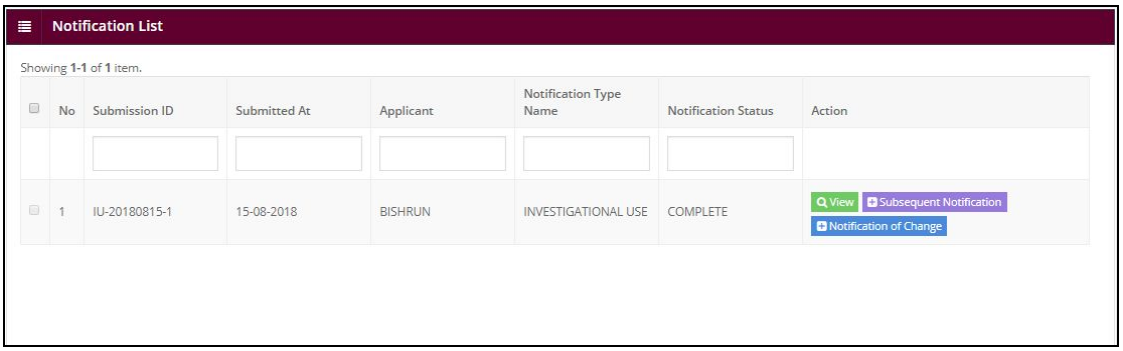


b) Subsequent application

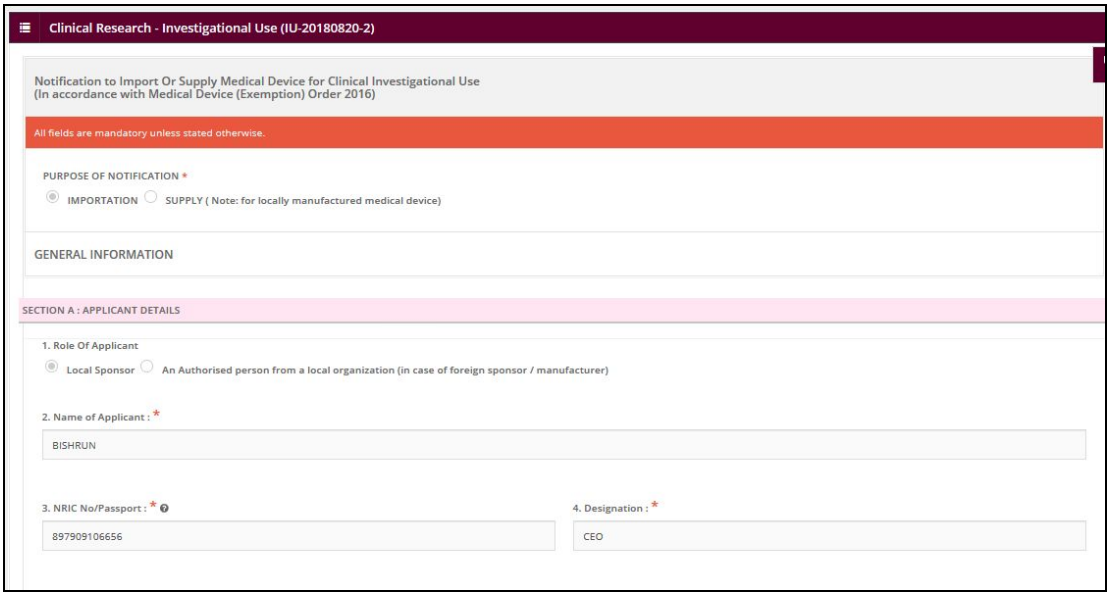
User click on the Application List at Clinical Investigation > Investigational Use.



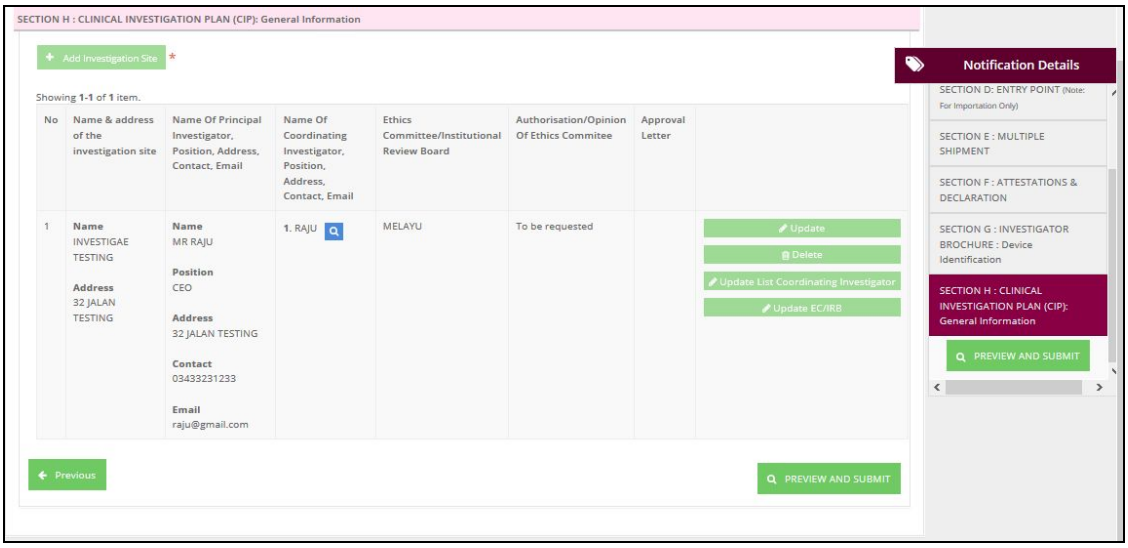
The system will display page of list application Investigational Use.



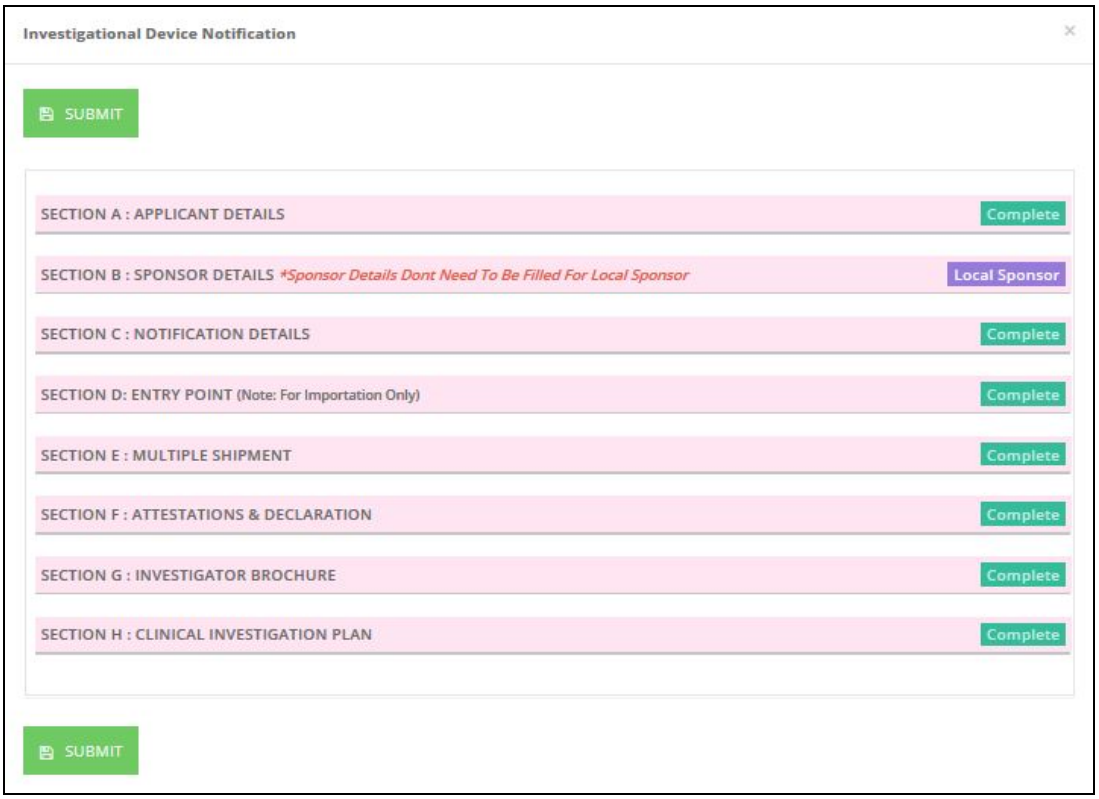
User click on Subsequent Application . Next step is click OK and the system will display *Subsequent Application* where the data has been copied from the previous application.



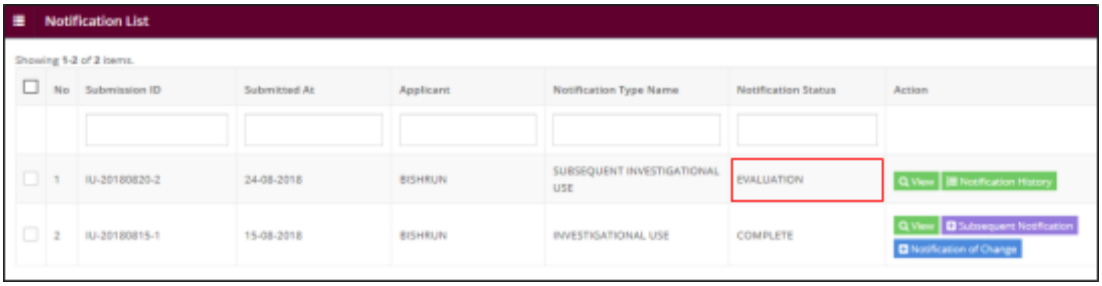
The user complete the Subsequent Application form. The user review all information in Section A, B C, D, E, F, G and H. Next step is the user click on button PREVIEW AND SUBMIT .



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

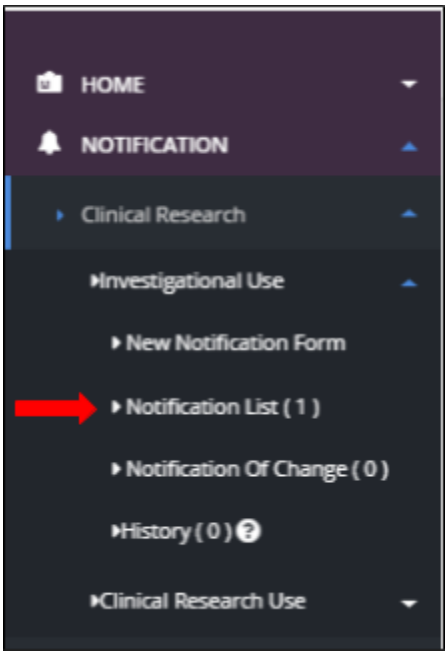


The status of application will be on evaluation stage.

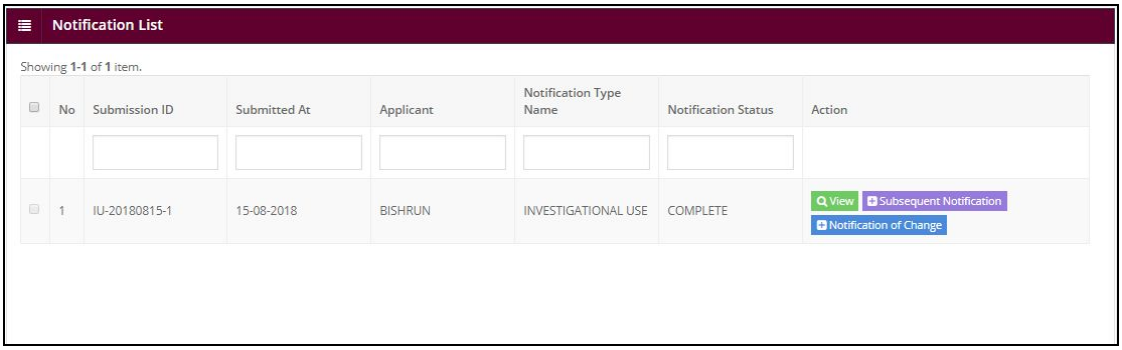


c) Change of Notification

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

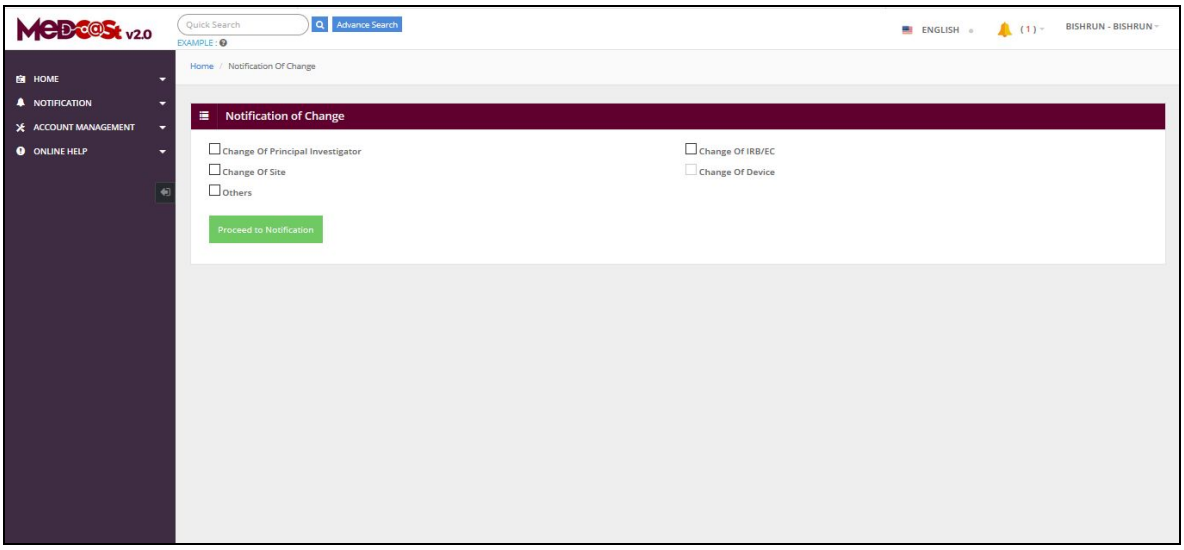


The system will display page of list application Investigational Use.

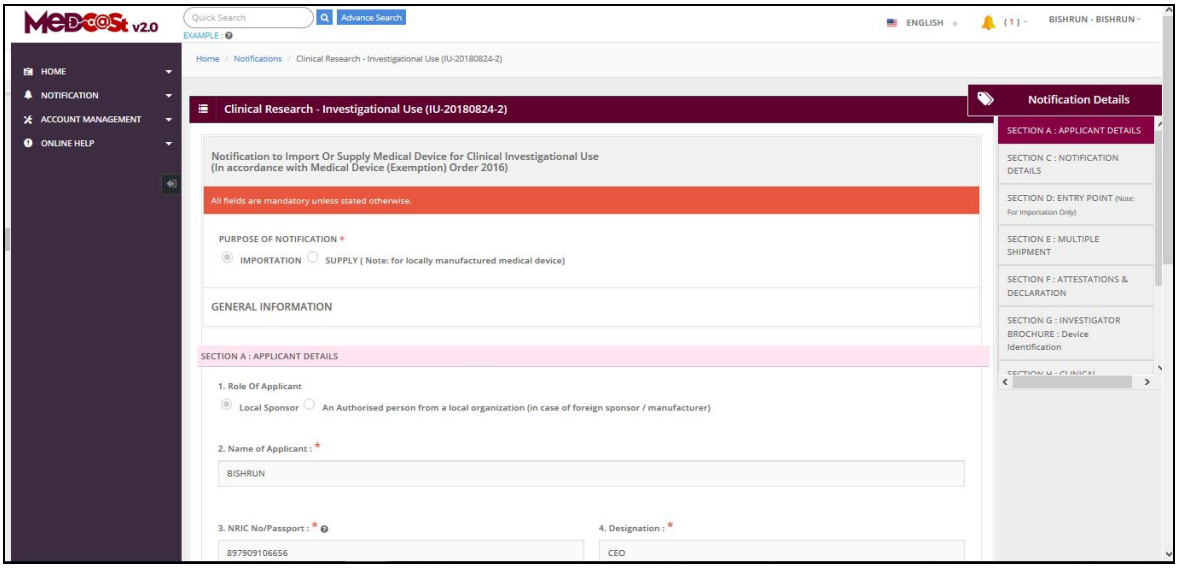


User click on

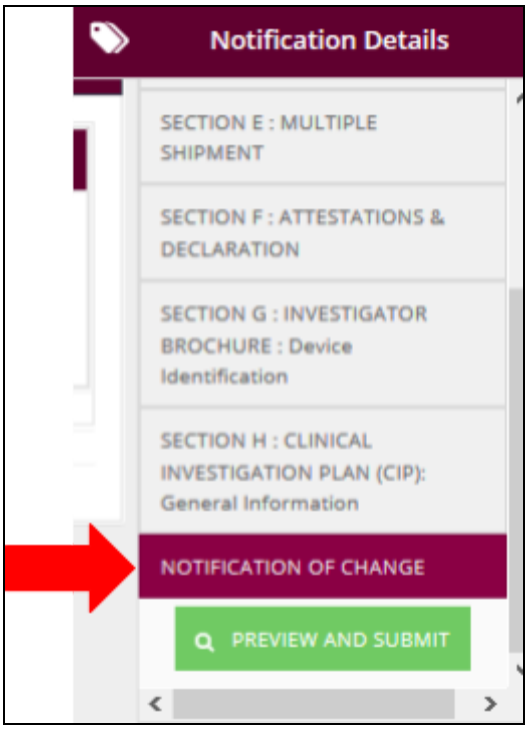
. Next step is click OK and the system will display *Notification of Change*.



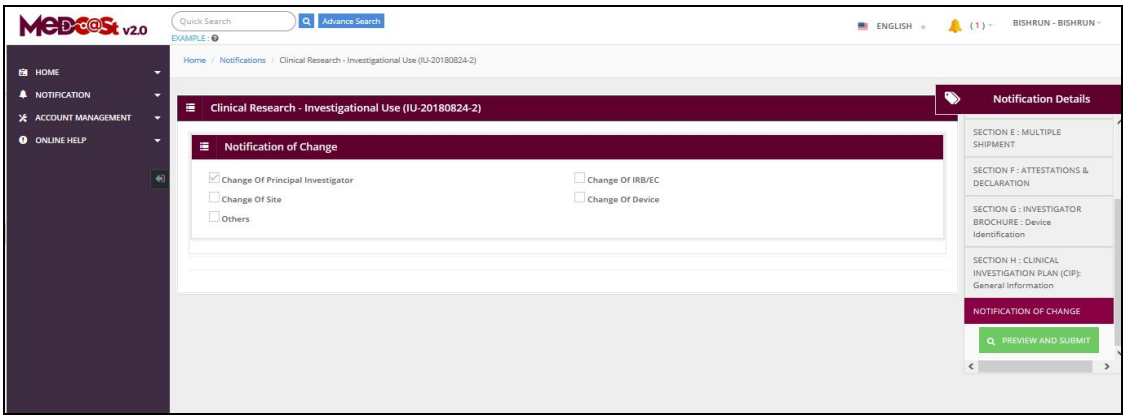
User choose type of change by click button Proceed to Application . The system will display Change Notification application form.



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

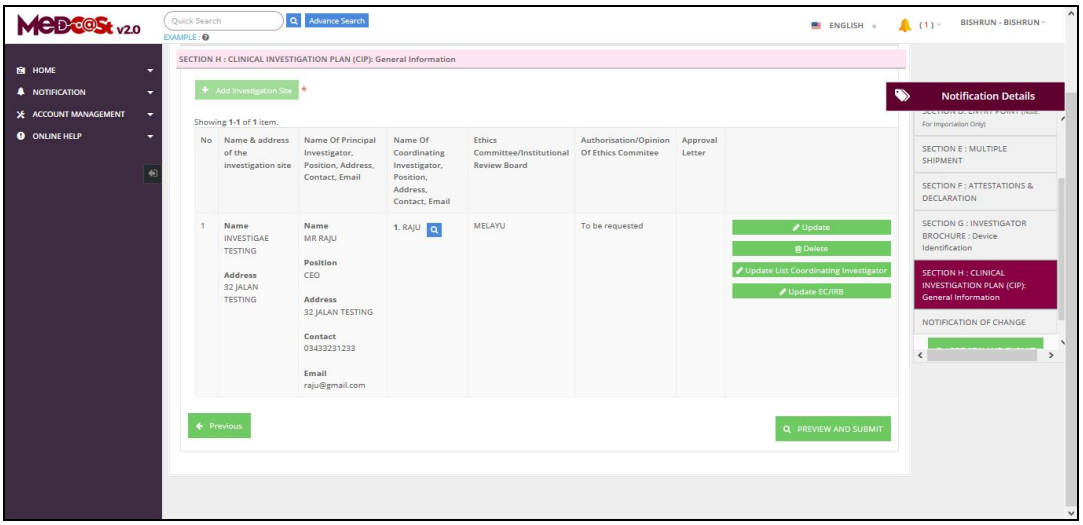


The list of changes that have been selected will be displayed.

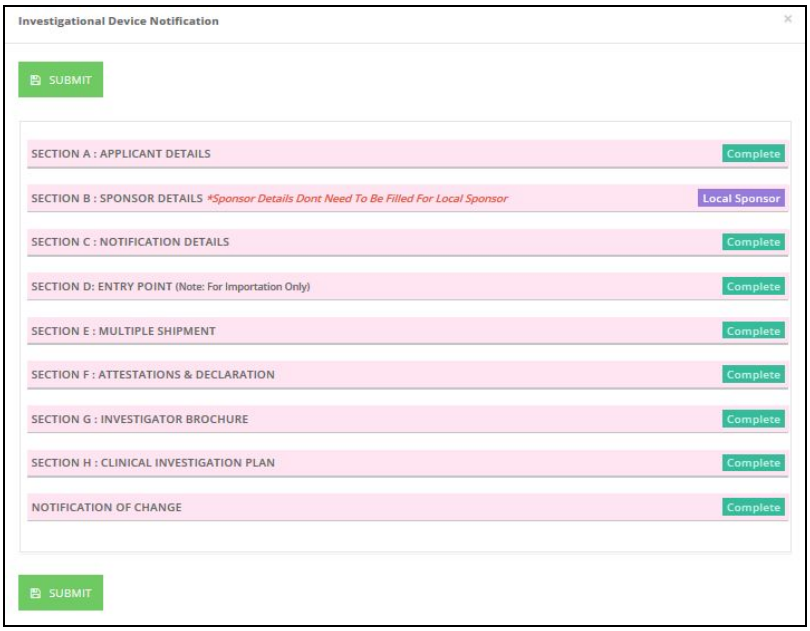


The applicant updates the information according to the type of change that has

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



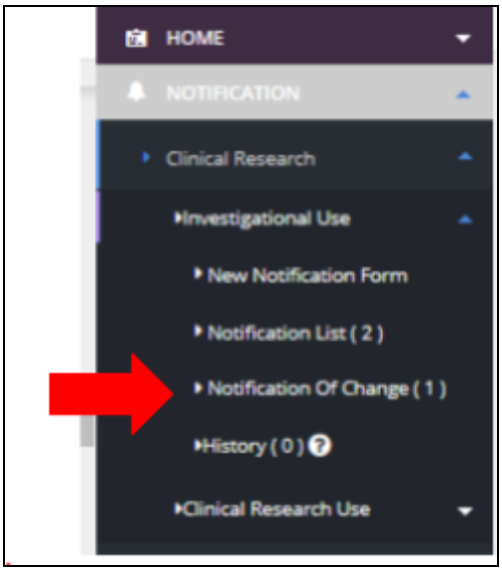
Next step is click on button to preview the information that user change.



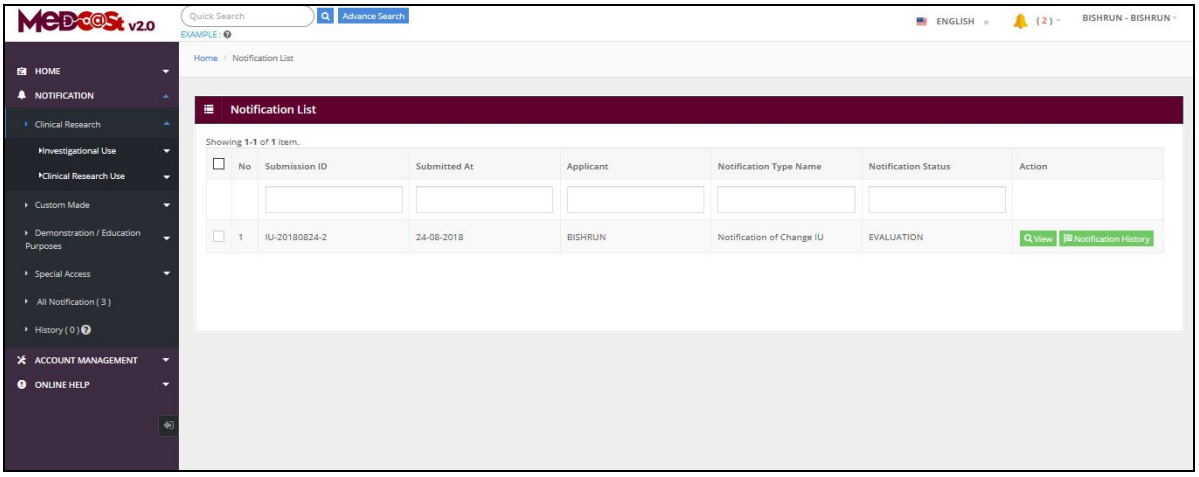
Click on

to submit form.

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

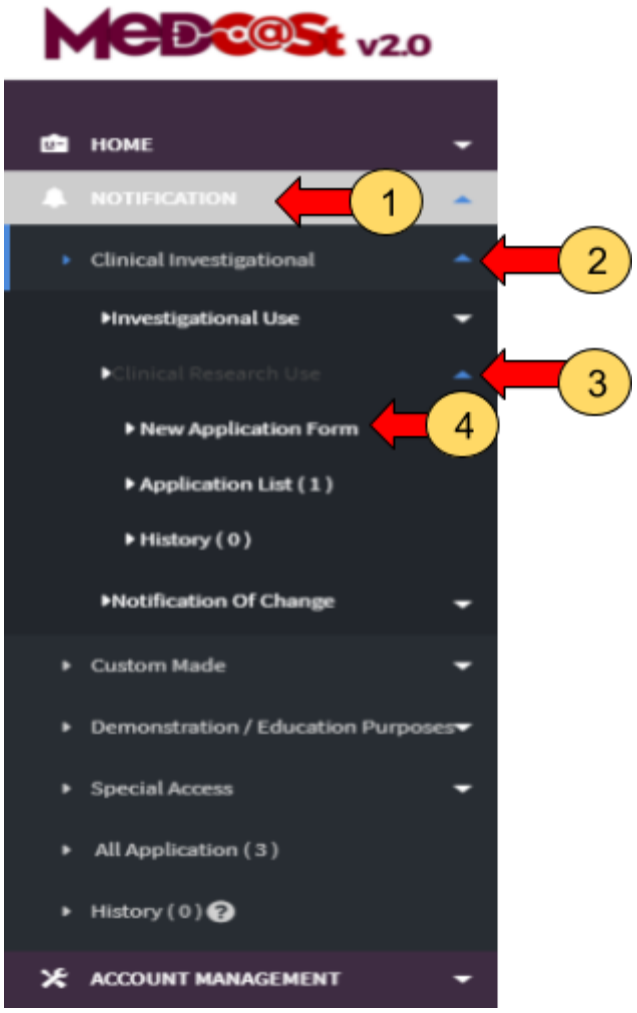


The system will display the list of Notification of Change.



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.

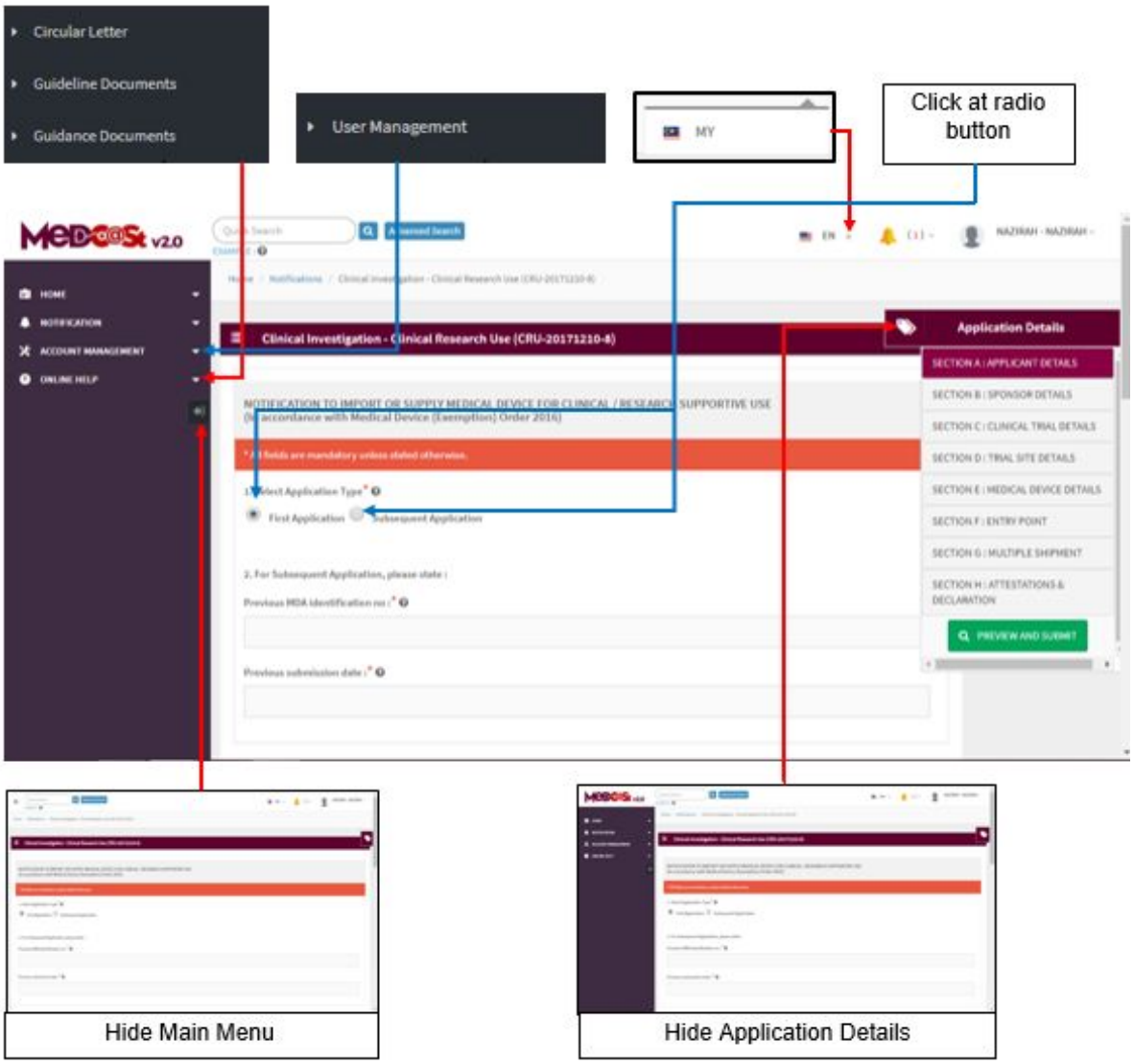
2 -> The user should click at menu module Clinical Investigational and list of sub module will be displayed which are Investigational Use, Clinical research use

and Notification of change.

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

-> The user should click at New Application Form.

The application form will appear.



The application details have eight sections which are:

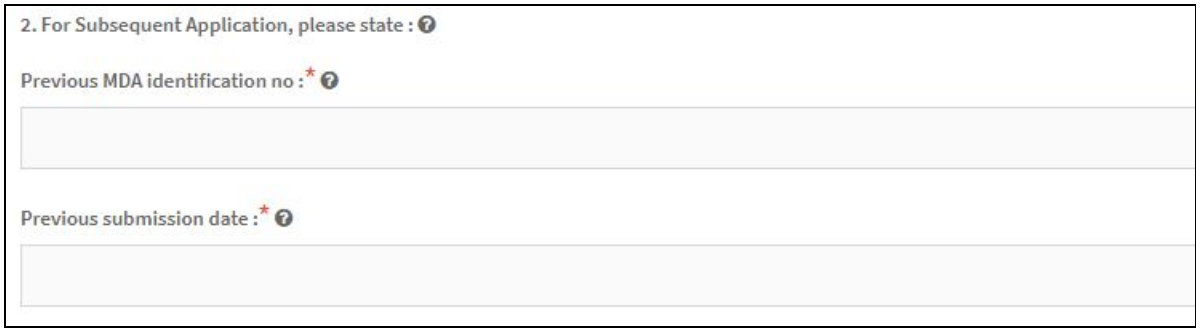
a) Section A: Application Details
b) Section B: Sponsor Details
c) Section C: Clinical Trial Details
d) Section D: Trial Site Details
e) Section E: Medical Device Details
f) Section F: Entry Point
g) Section G: Multiple Shipment
h) Section H: Attestations & Declaration

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

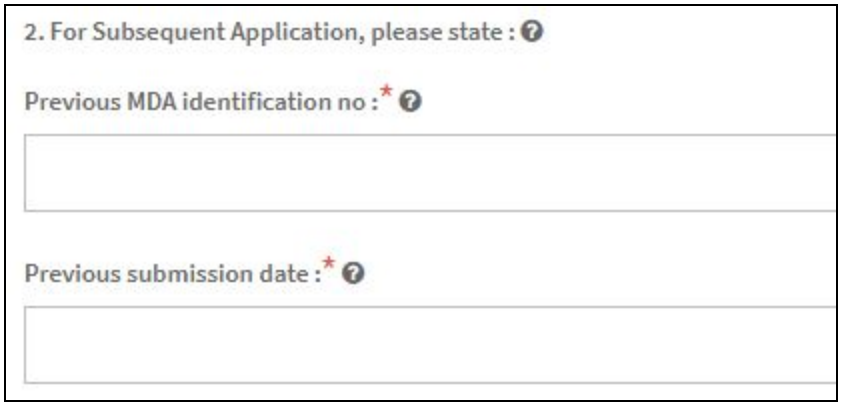
The symbol “*” means required field. The user must fill it.

1. Select Application Type

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



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



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.

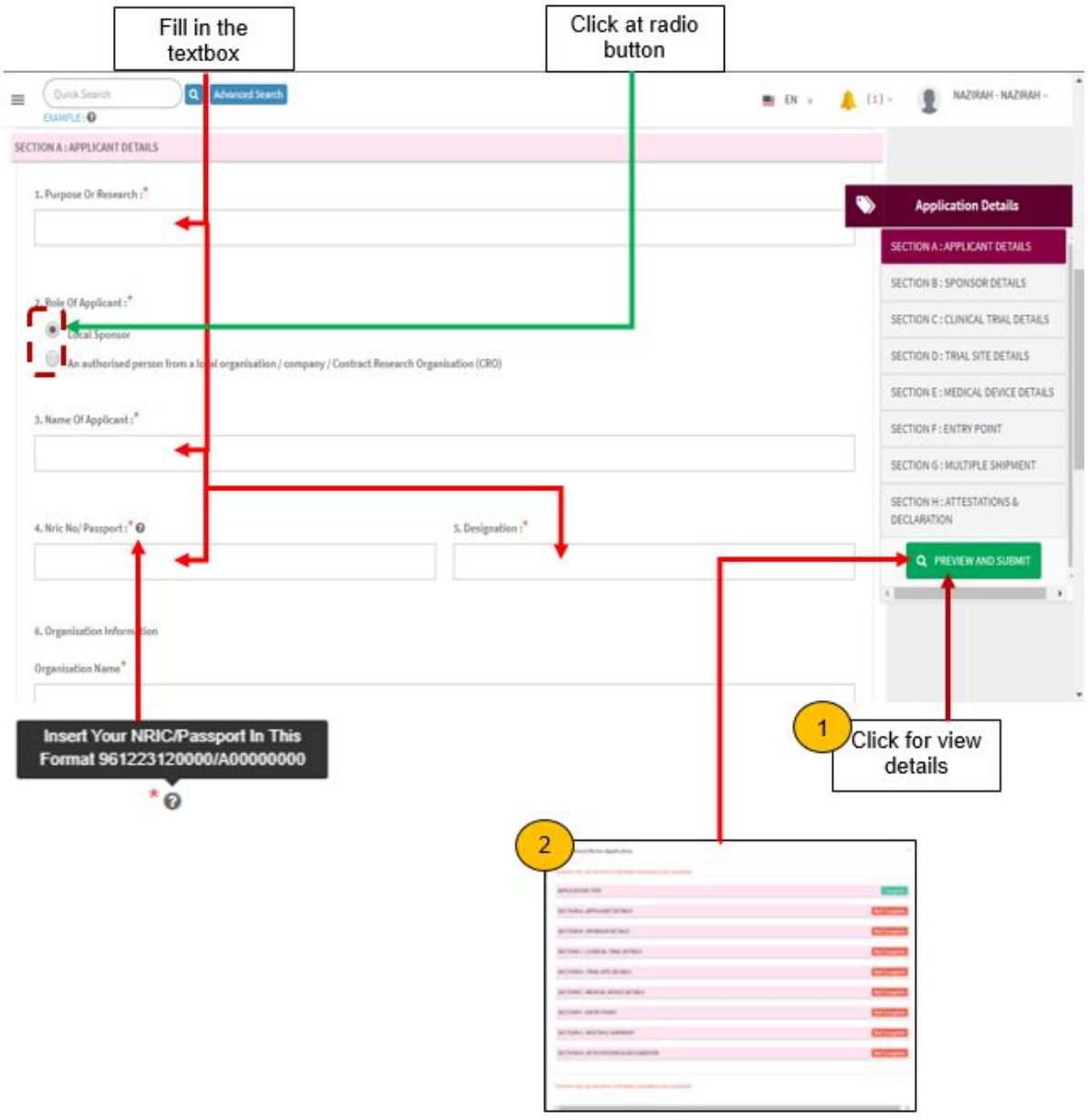
- An authorised person from a local organisation/company/contact research organisation(CRO).

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.

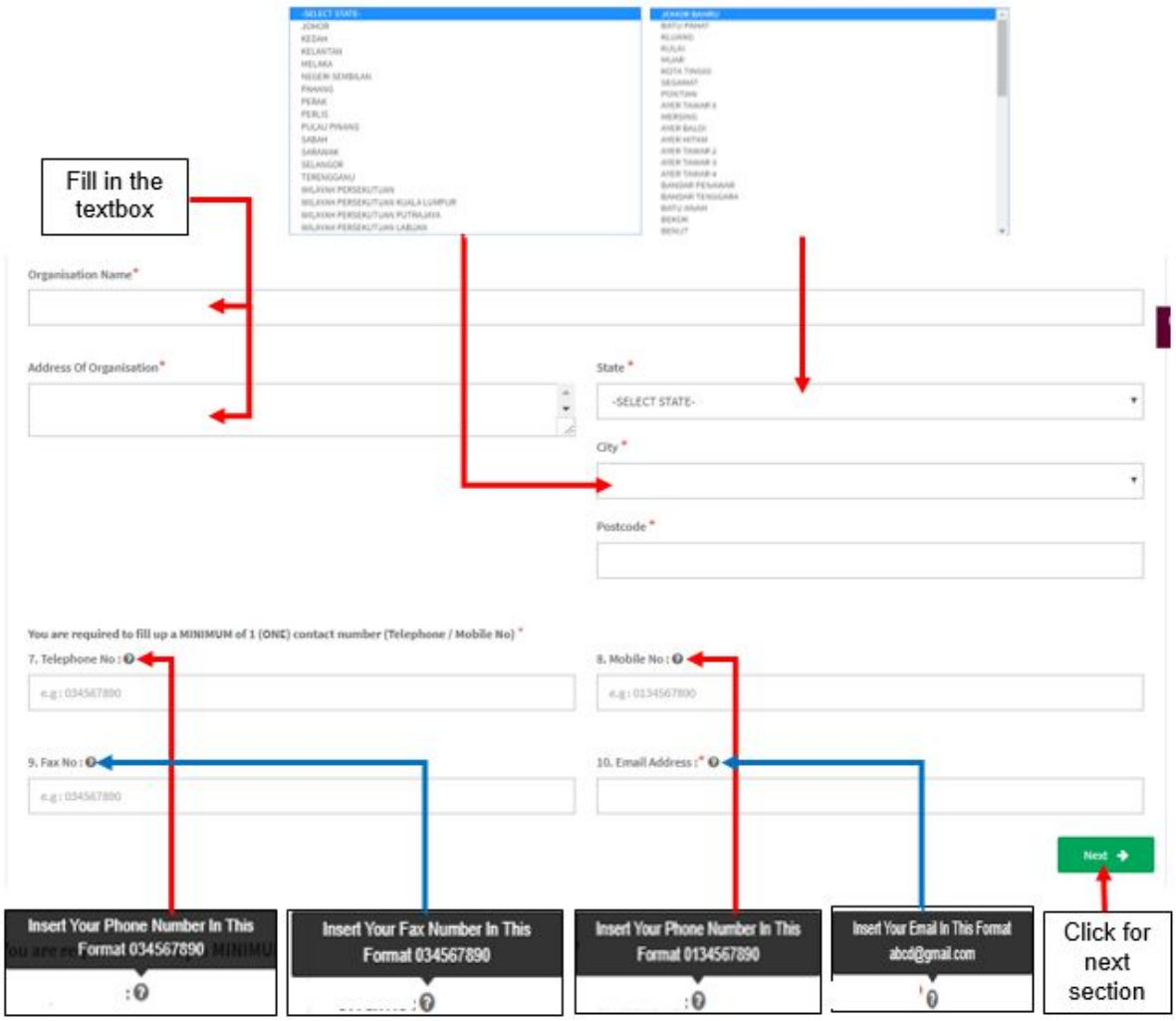


5. Designation

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.

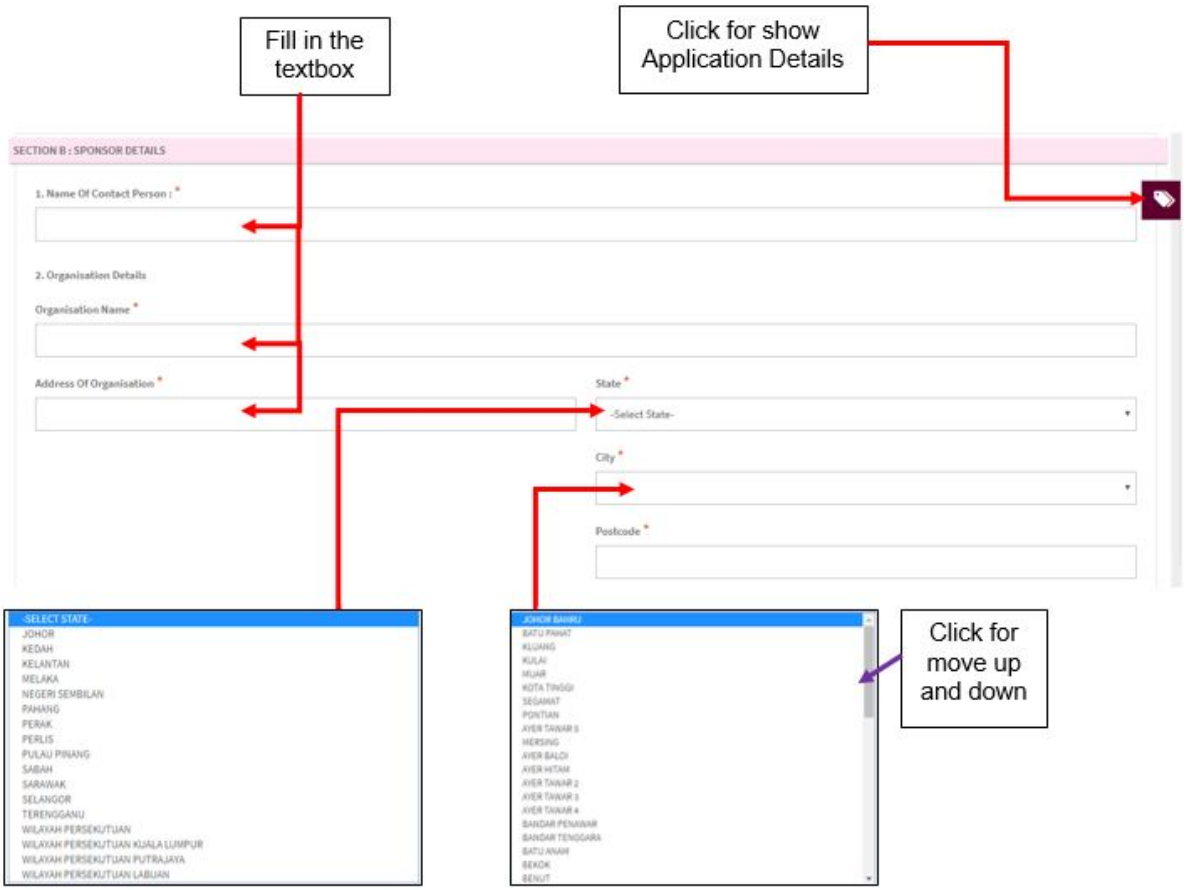
   The user must fill the Fax No in an integer. User can see the format which click at ? . If user fill in the form except number or more than eleven number, the message "Field must have NUMBERS between 3 - 11 numeric" will appear.

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.



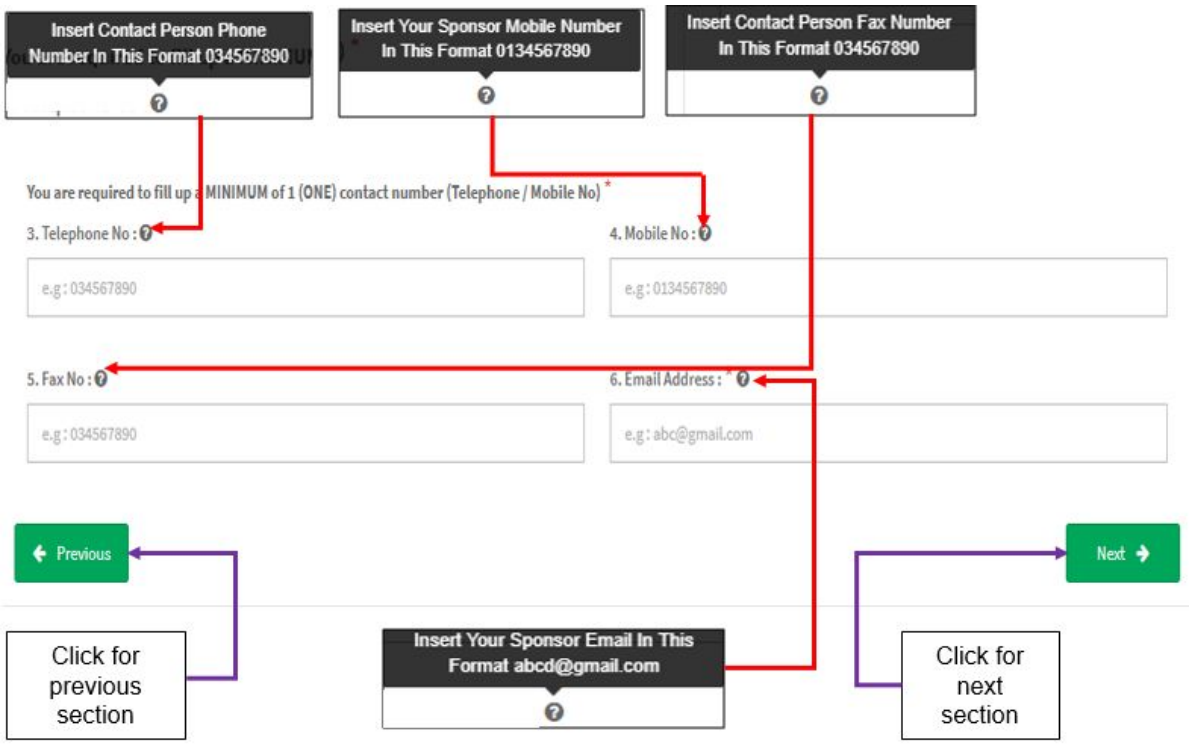
Section B: Sponsor Details

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.

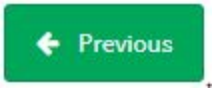
   The user must fill the Mobile No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message "Field can only contain number and between 3 to 11 numeric." will appear.

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 

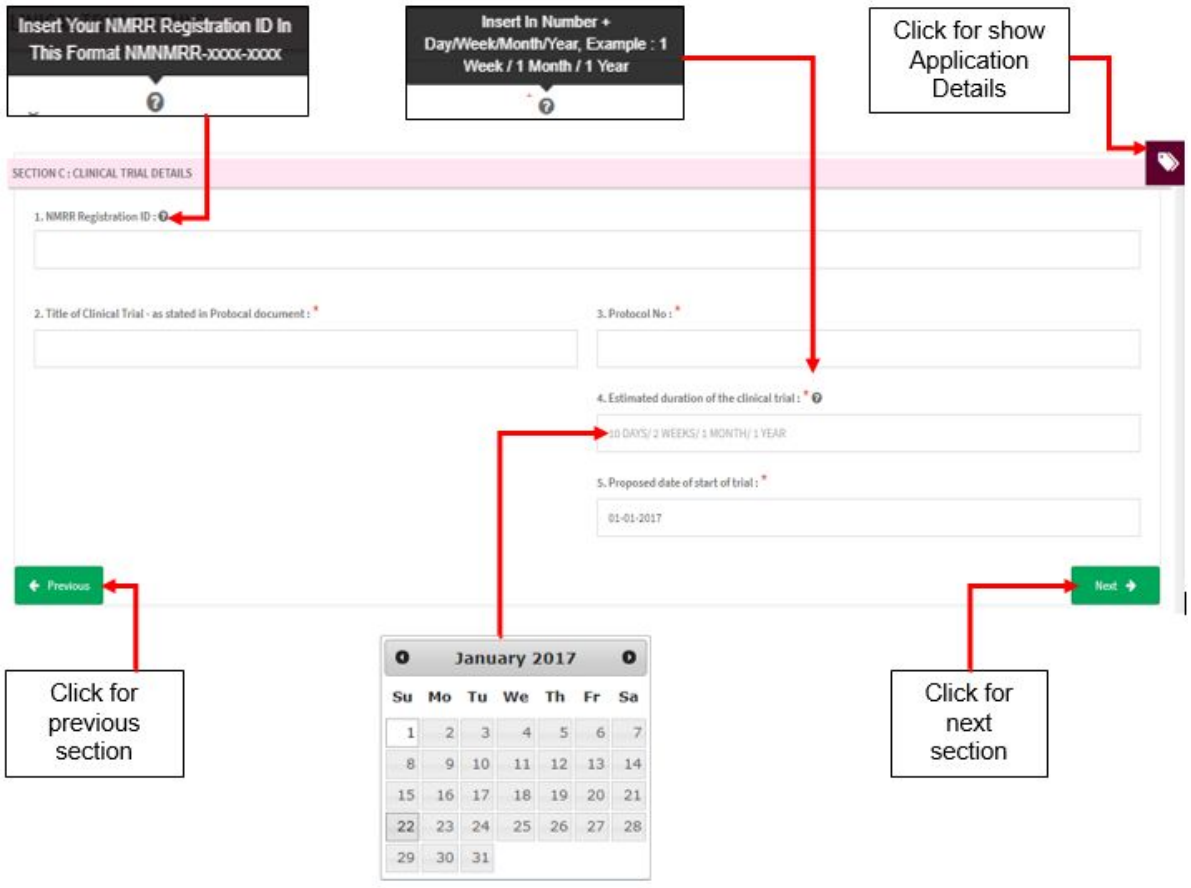
that shown in figure above. Then, user should click at button

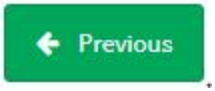
to the next section.

Section C: Clinical Trial Details

The symbol "*" mean required field. The user must fill it.

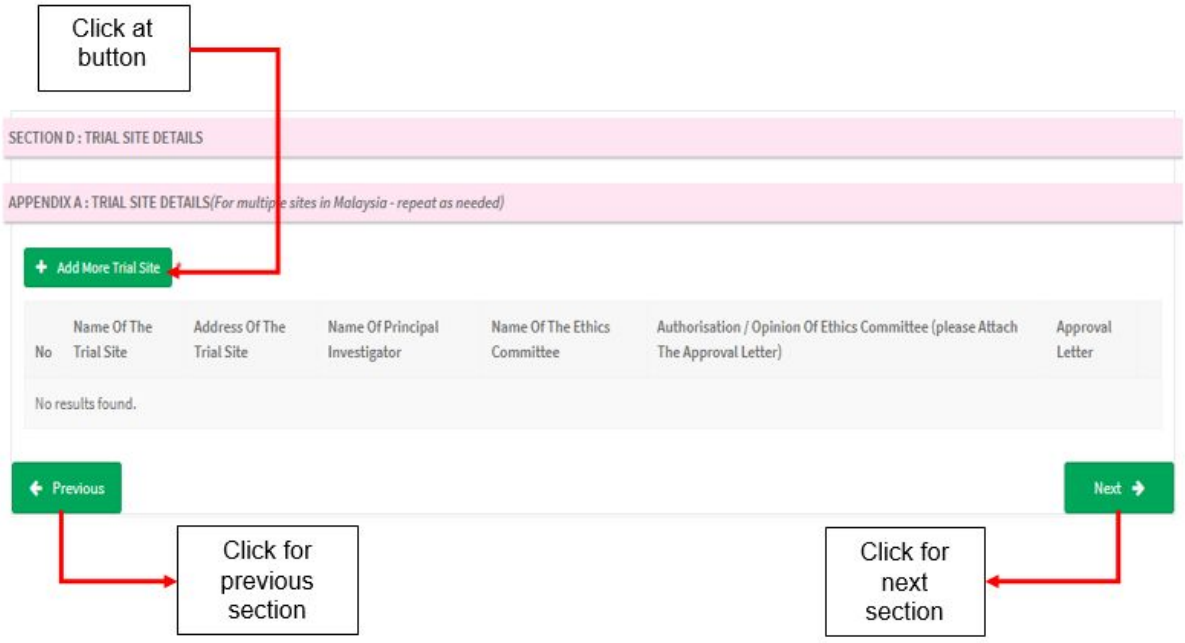
1. NMRR Registration ID
   The user must fill in the textbox the registration ID with follow the format that given in the figure below. User should click at to see the format.
2. Title of Clinical Trial- as stated in Protocol document
   The user must fill the title in the textbox that provided.
3. Protocol 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

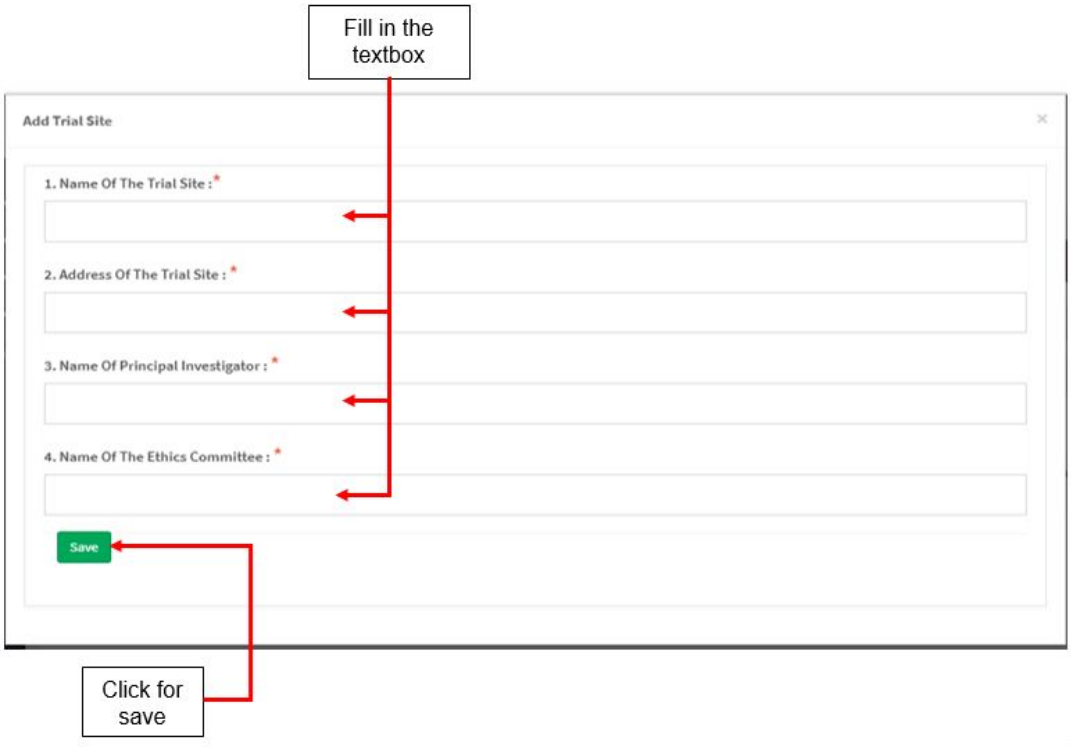
to the next section.



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.



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

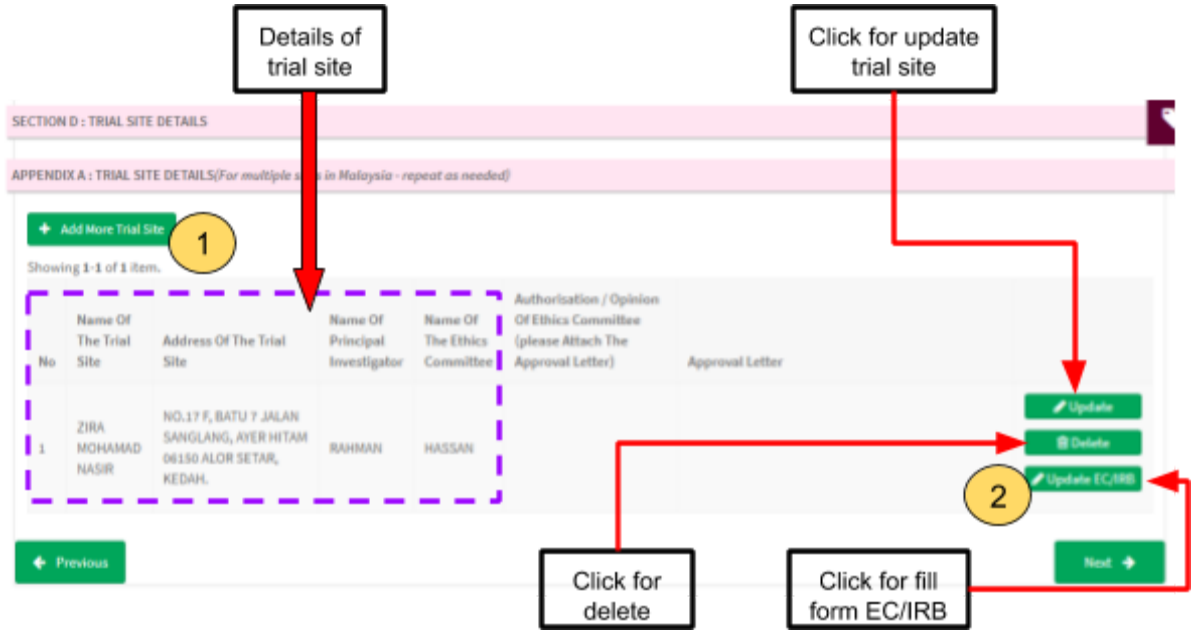
   The user should fill in the textbox that provided that shown in figure above. If the user don't fill the name, the message "Trail site Principal Investigator cannot be blank." will appear.

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

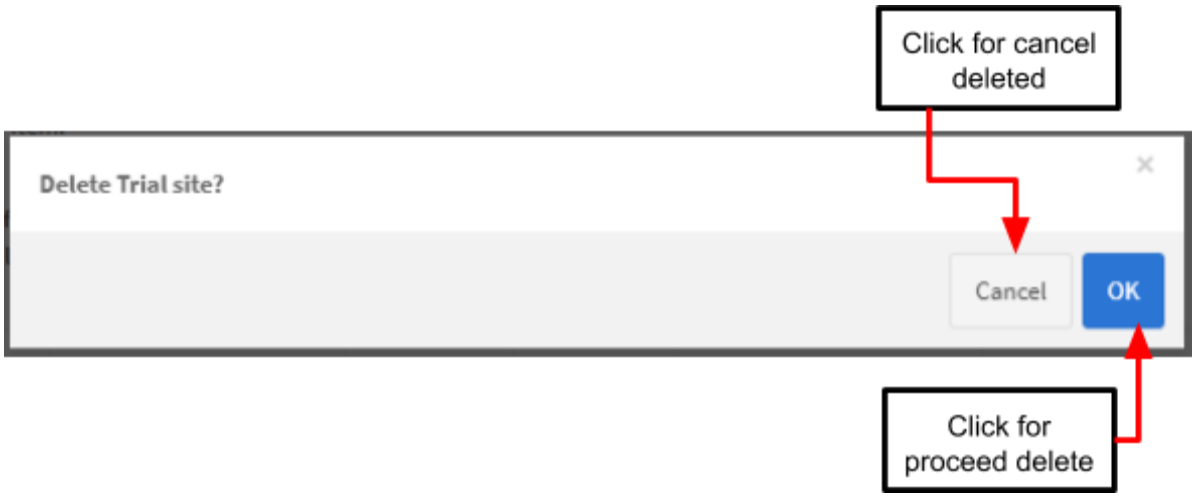
. The details of Trial Site will appear at table that shown in the figure below.



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.

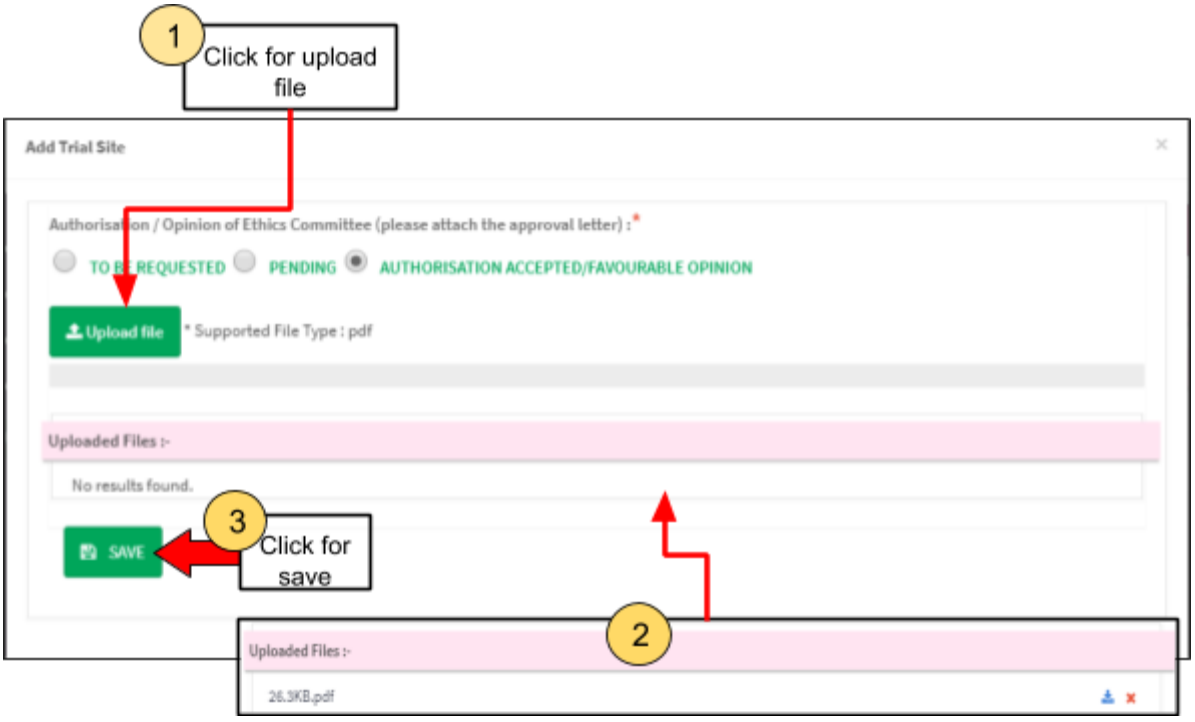


1 - the user should click on button “Add More Trial Site” to add trial site.

2 - the user should click at Update EC/IRB 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”.

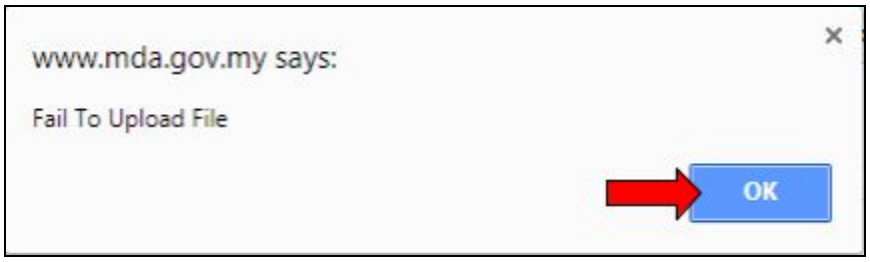
If user choose the button for upload file will be displayed.



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

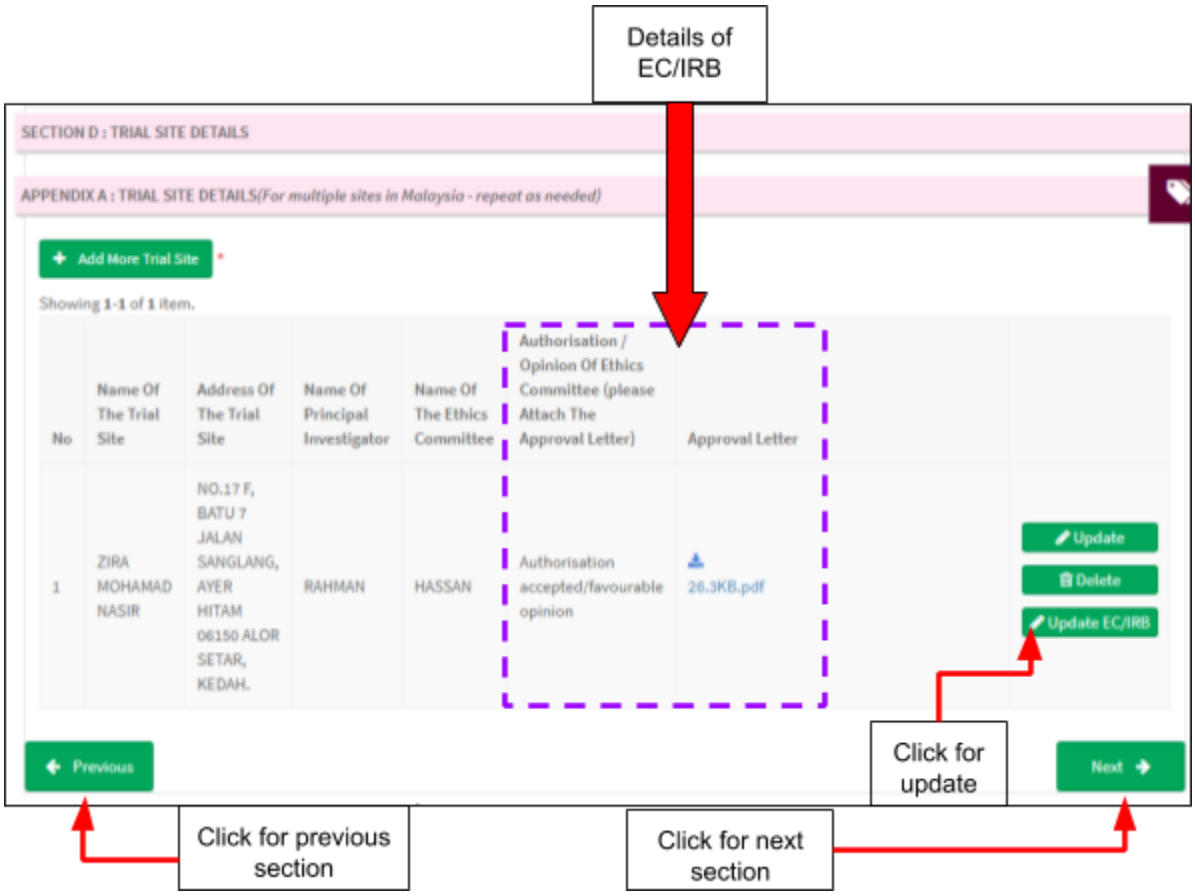
should click “ok” to proceed in system. .

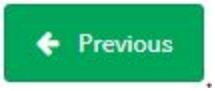
. The user can download the file with clicking at and delete the file with click at . If user upload the file more than 300MB, the alert message



will appear. The user should click “ok’ to proceed.

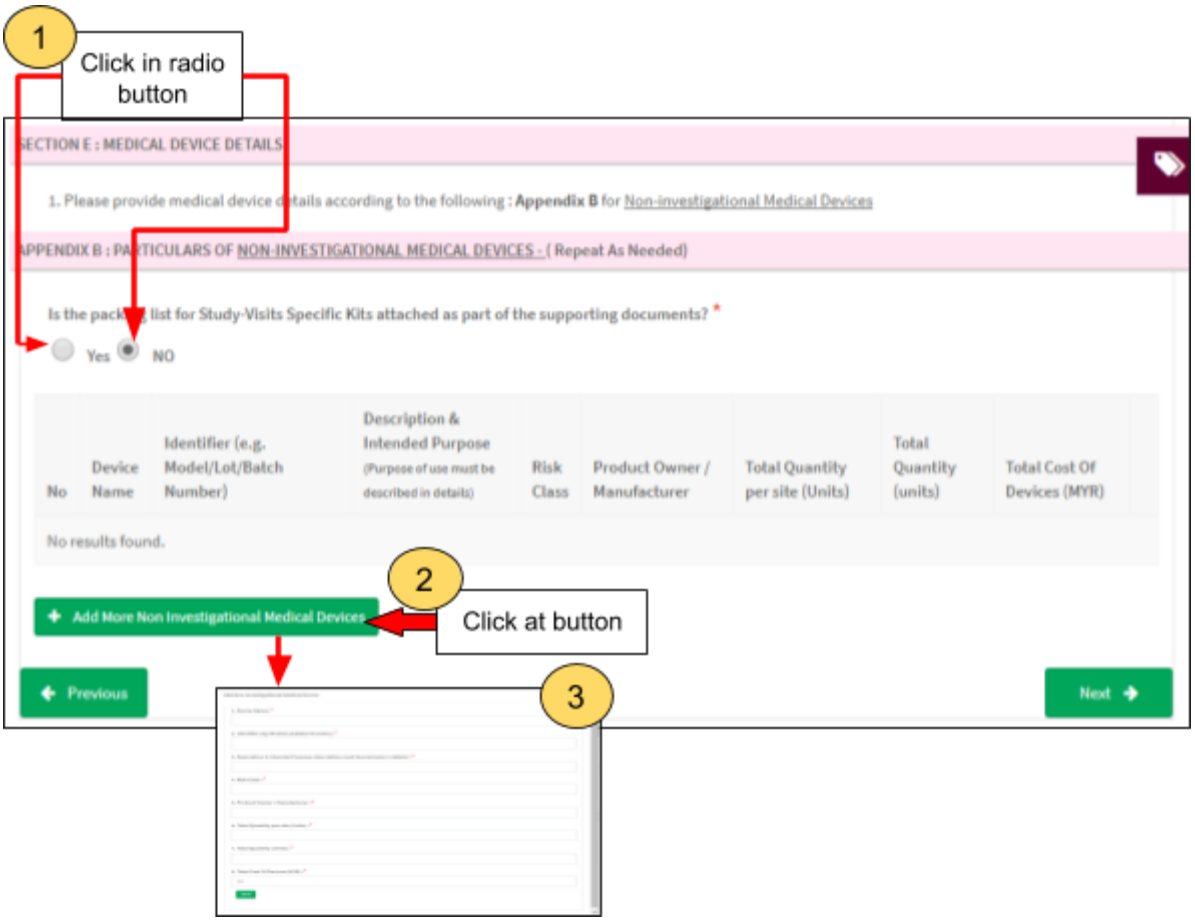
The details will automatically be displayed in the table shown in the figure below. The user can update again the detail with click button “Update EC/IRB”. The form for fill the EC/IRB will be displayed.



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

to fill the details of Non-Investigational Medical Device. The form will be displayed in figure below.

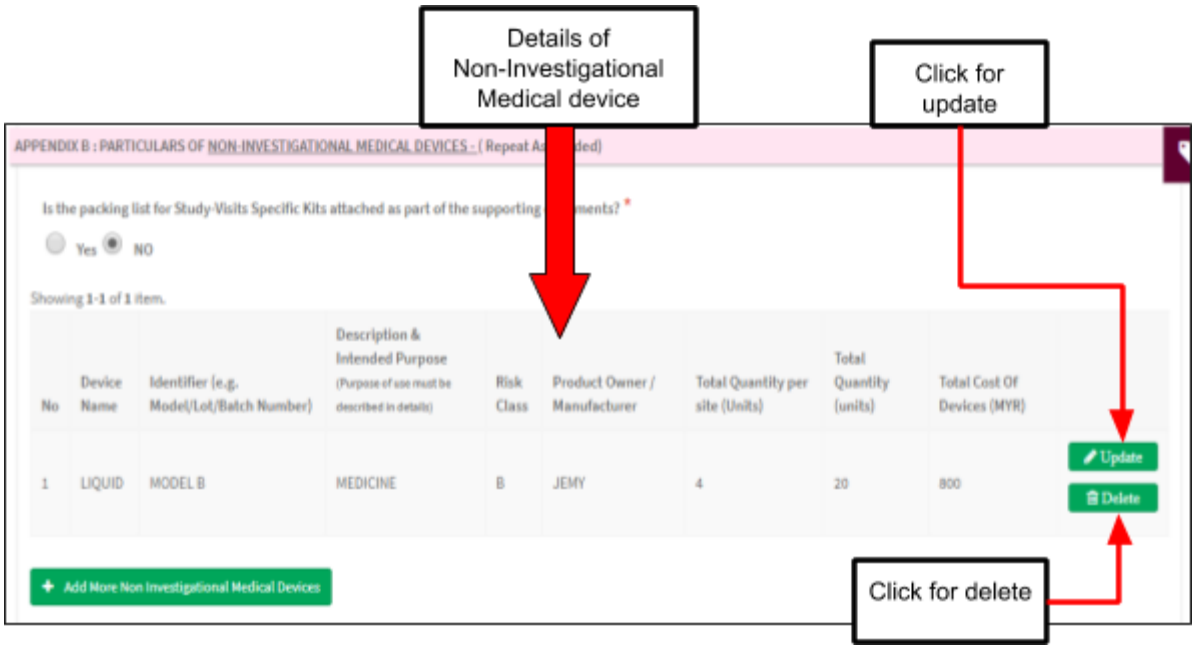
Add Non Investigational Medical Device

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.

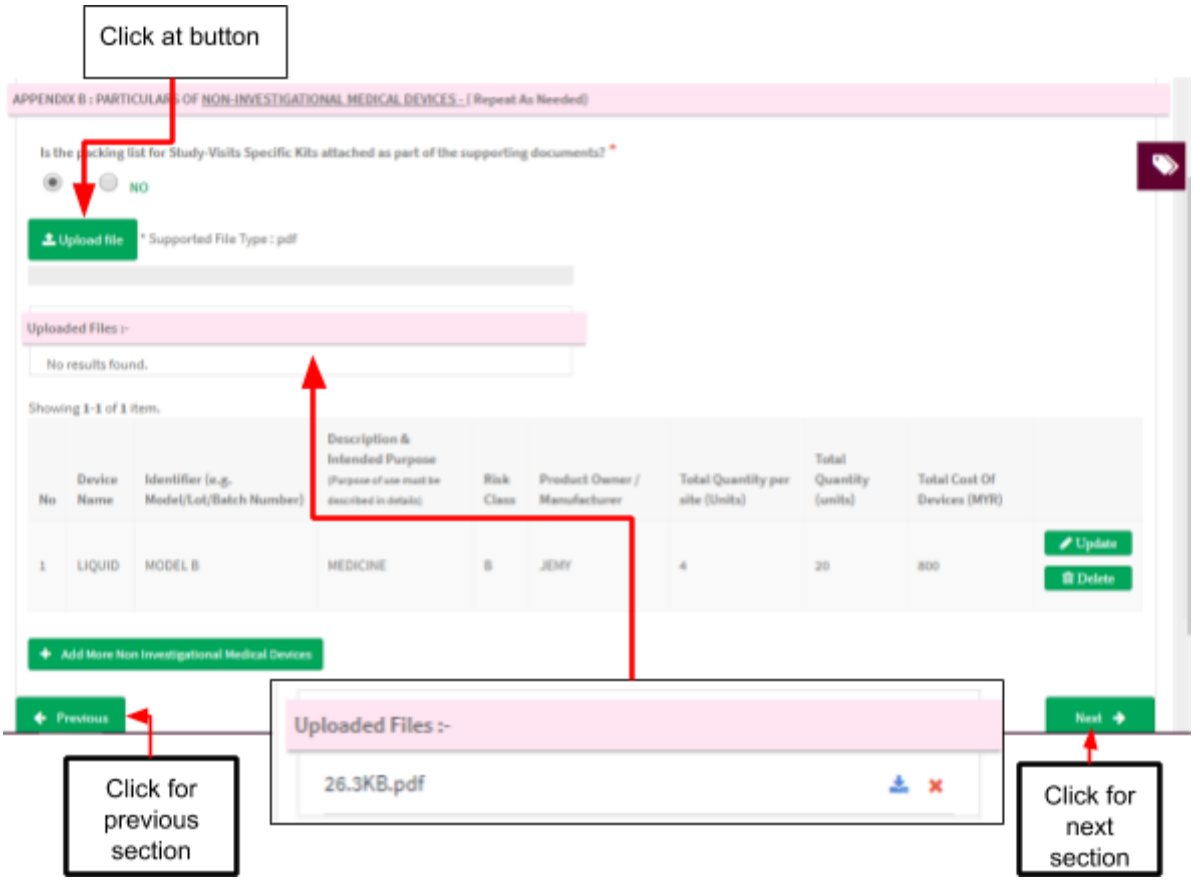
If user want to proceed delete, user should click at button “OK”. If user wants to cancel the deleted, user should click at button “Cancel”.

The user can add more Non-Investigational with click at

.

If the user choose the decision “yes”

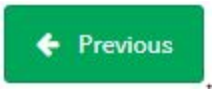
, the button upload file will be displayed.



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

The message that will display at button is

.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 

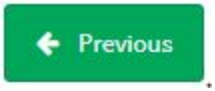
.

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

to the next section.

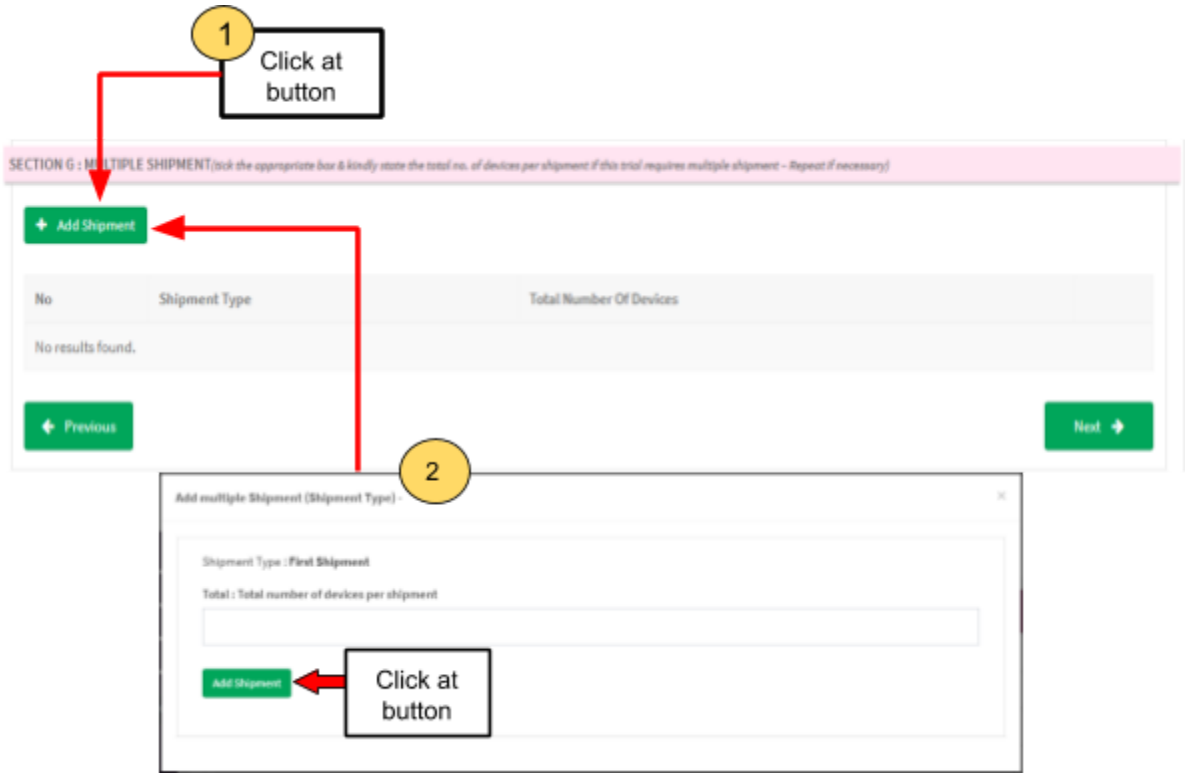
Section F: Entry Point

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.

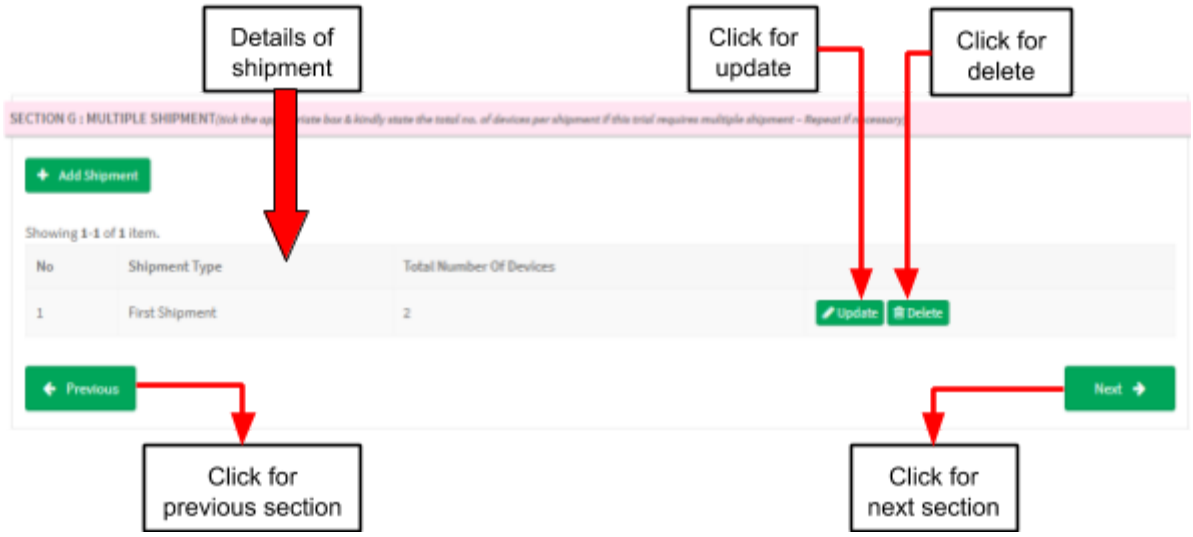


Section G: Multiple Shipment

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.

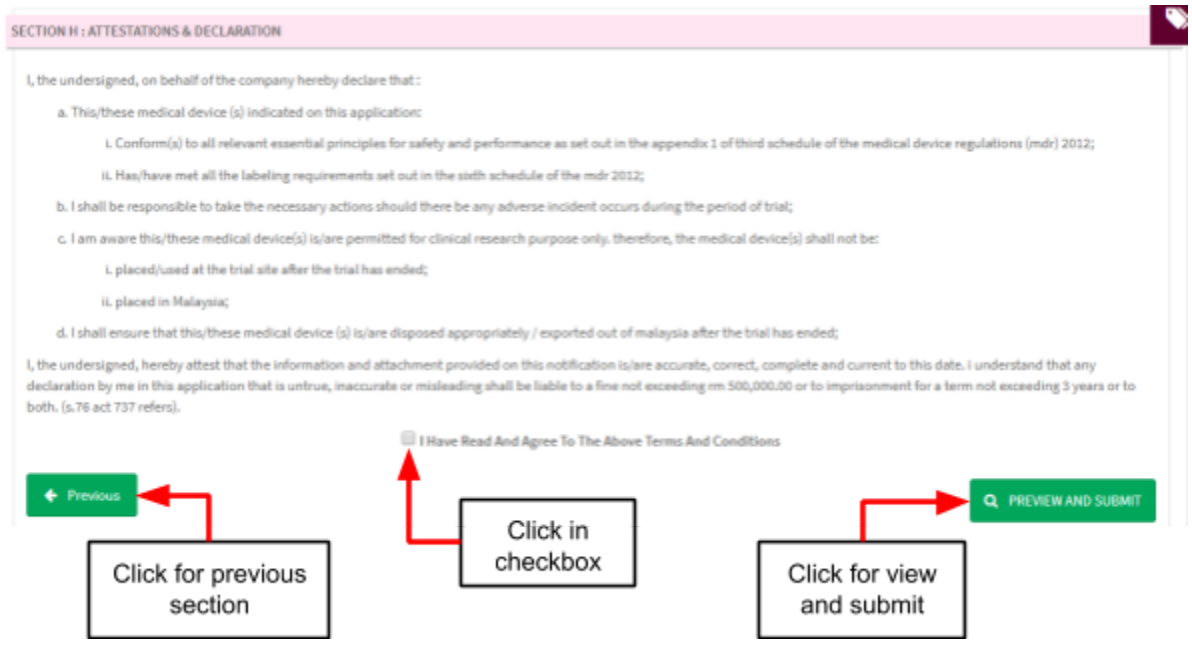
The details of shipment will be displayed in the table shown in the figure below.



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

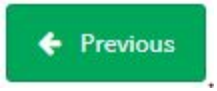
The user should click on button “OK” to proceed with the delete or click button “Cancel” to cancel deleted.

After that, If user want back to previous section, user should click on button Previous. that shown in figure above. Then, user should click at button Next to the next section.



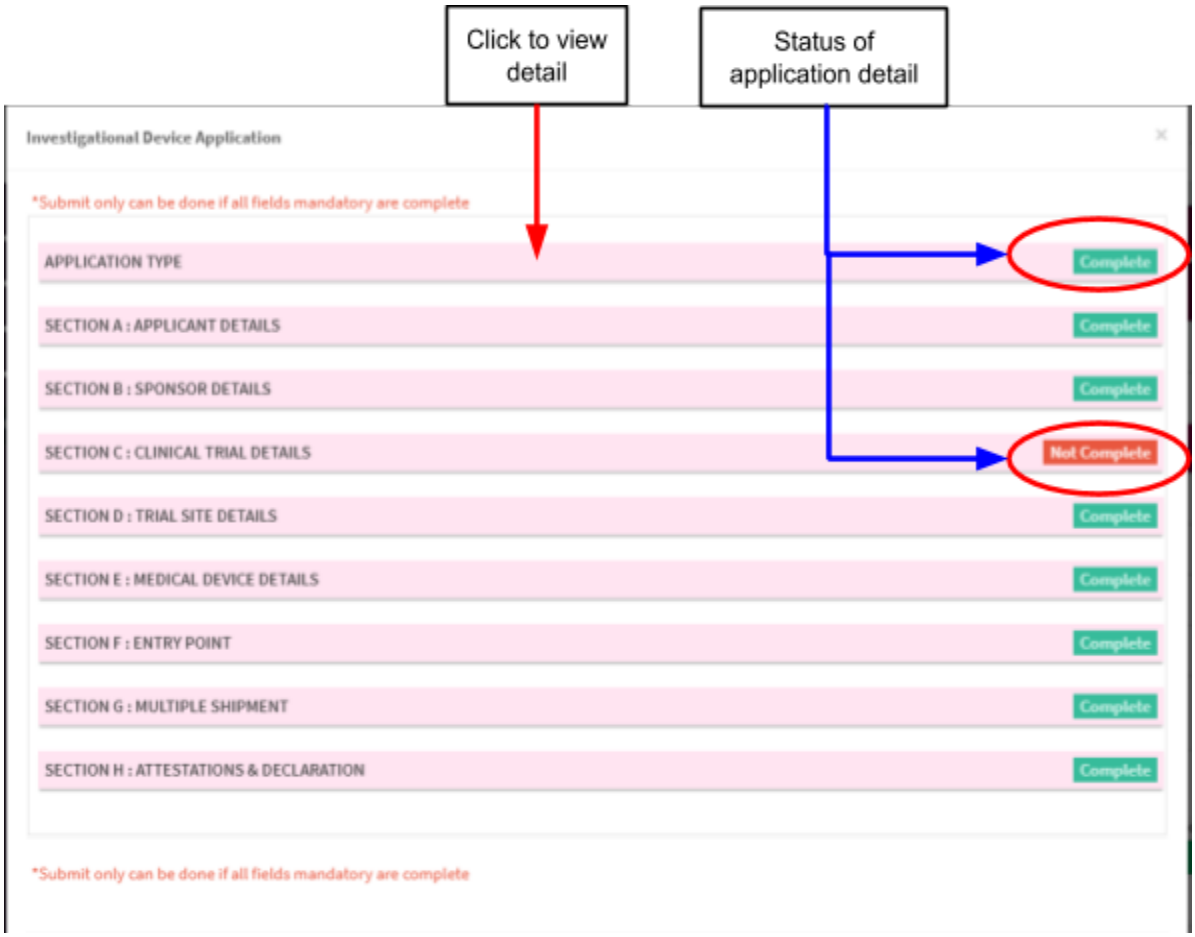
Section H: Attestations & Declaration

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

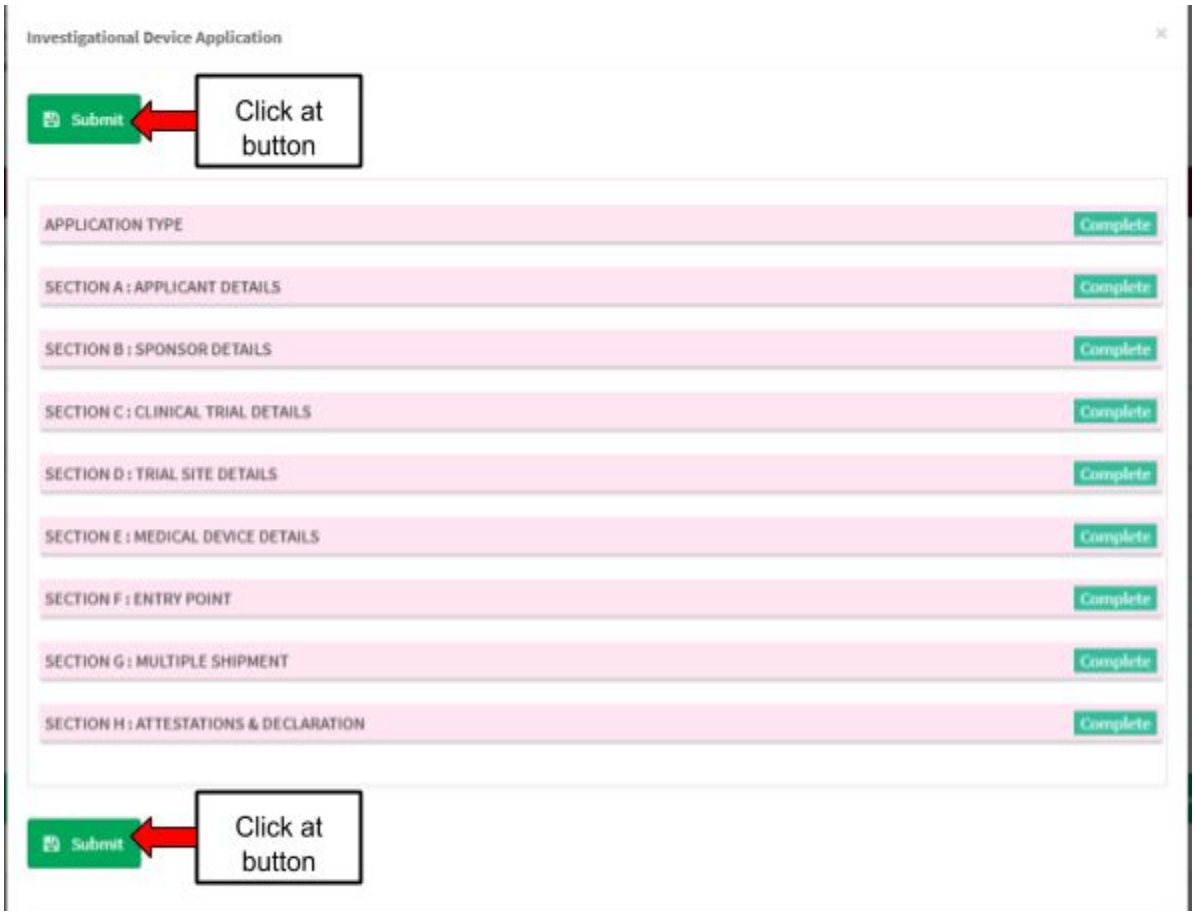
The user also can click at 

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

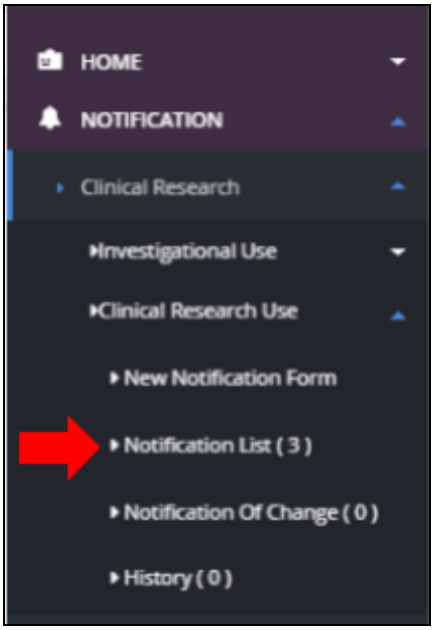


After user click button “Submit”, the alert message will be displayed.

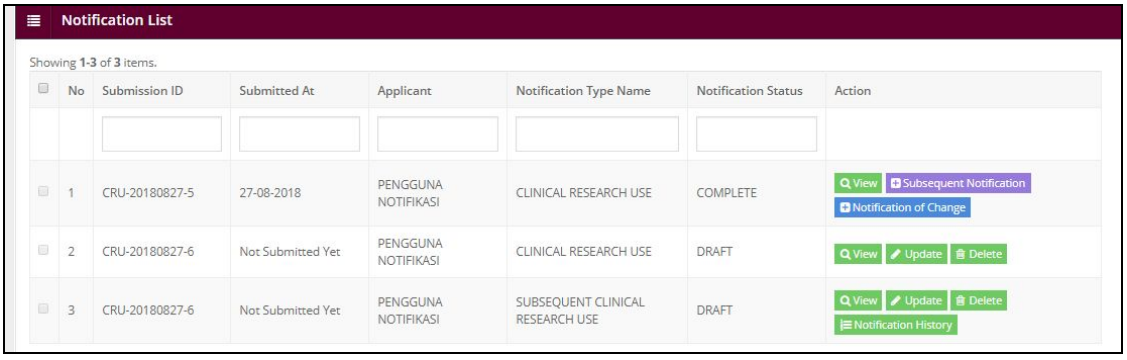
The user click “OK” to proceed to submit application and click “Cancel” to cancel the submitted application.

b) Subsequent application

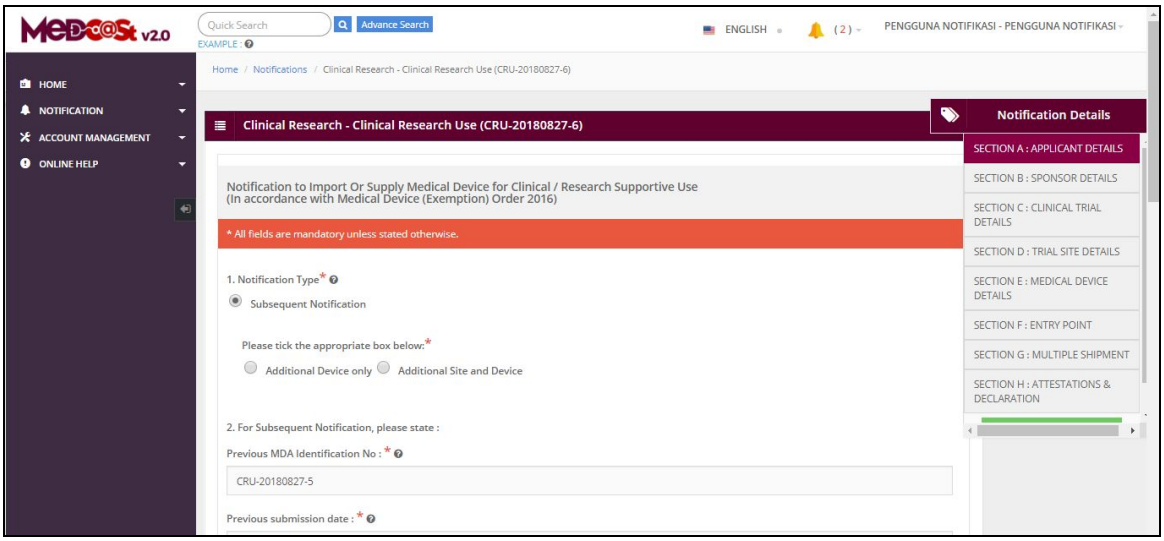
User click on the Application List at Clinical Investigation > Clinical Research Use.



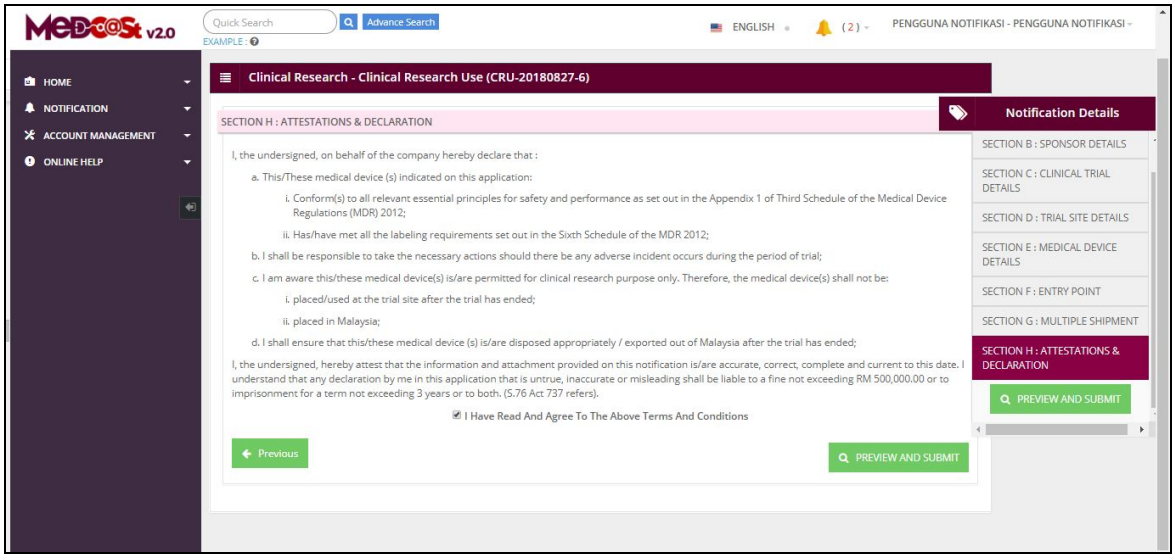
The system will display page of list application Investigational Use.



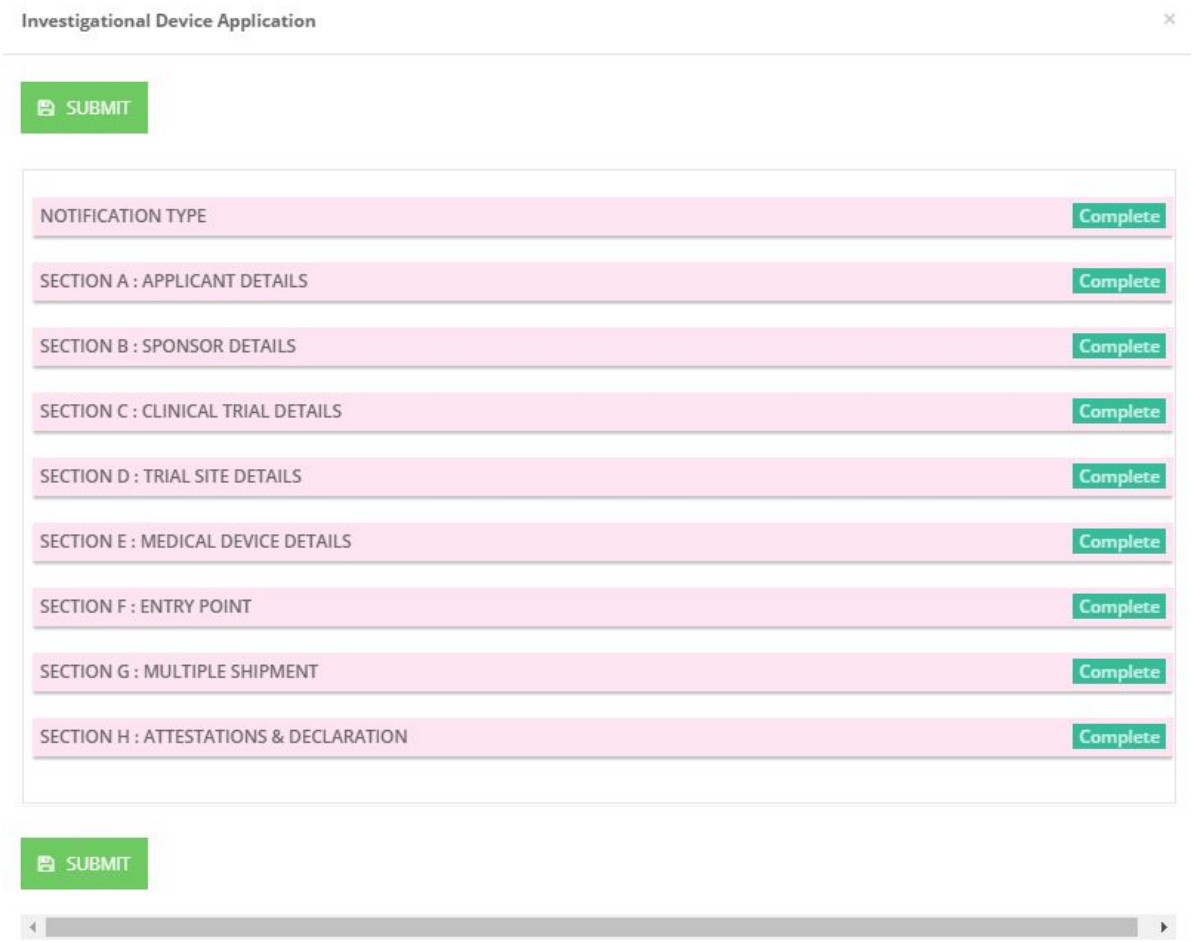
User click on Subsequent Application . Next step is click OK and the system will display *Subsequent Application* where the data has been copied from the previous application.



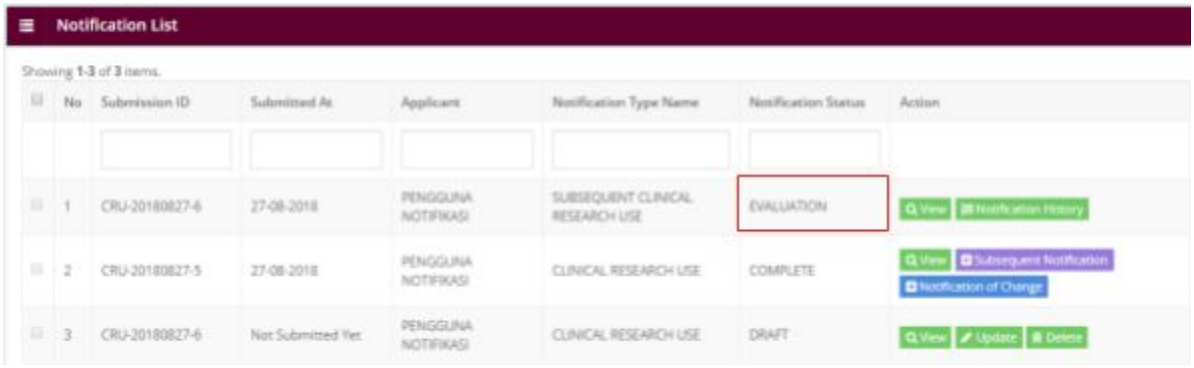
The user complete the Subsequent Application form. The user review all information in Section A, B C, D, E, F, G and H. Next step is the user click on button PREVIEW AND SUBMIT .



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

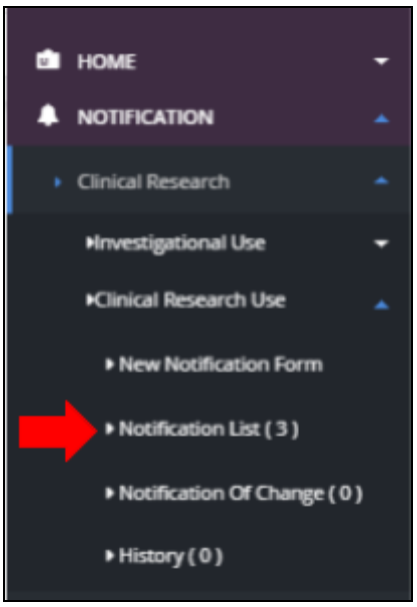


The status of application will be on evaluation stage.

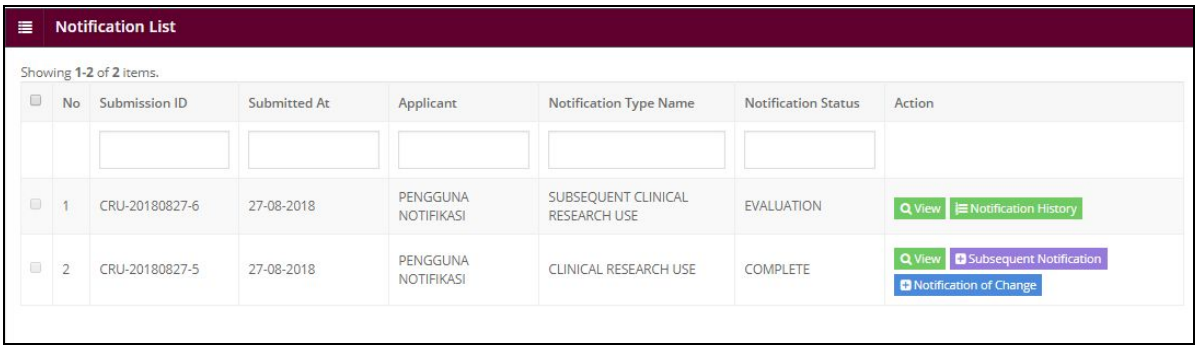


c) Change of Notification

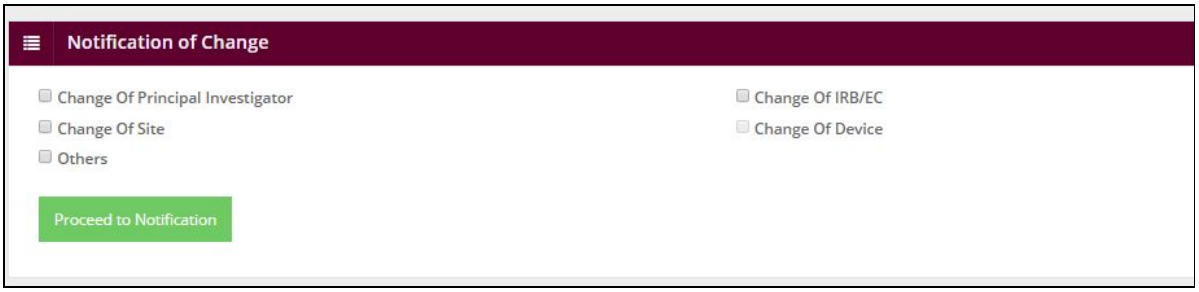
User click on the Application List at Clinical Investigation > Clinical Research Use.



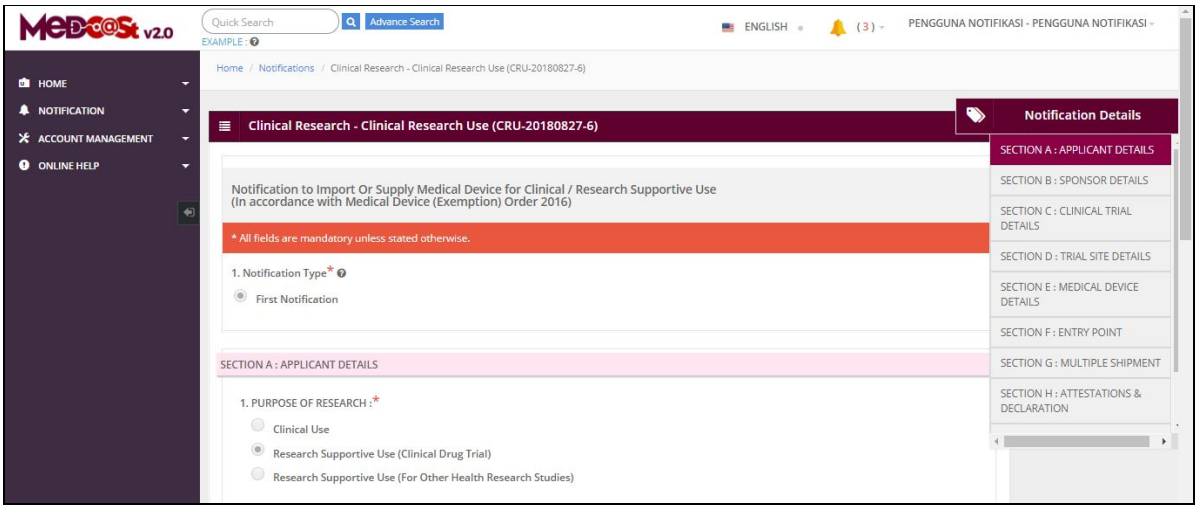
The system will display page of list application Investigational Use.



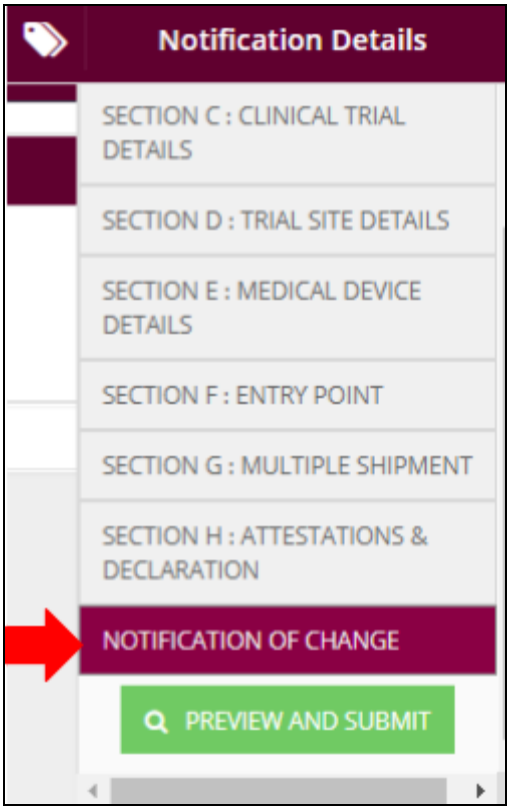
User click on Notification of Change . Next step is click OK and the system will display *Notification of Change*.



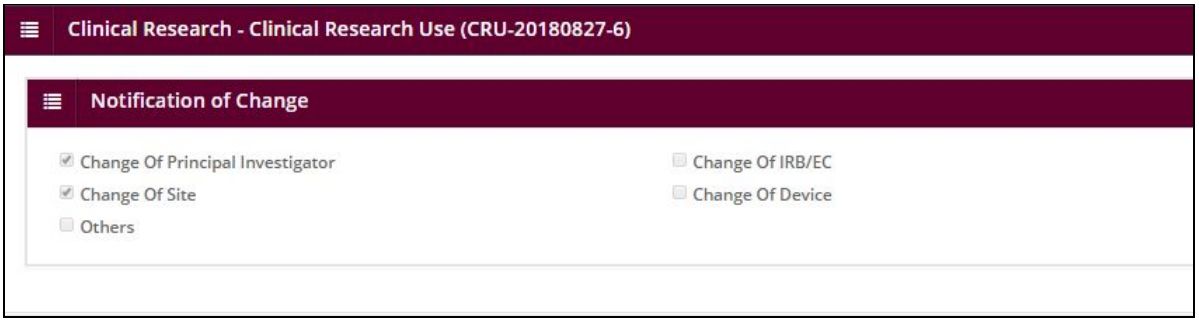
User choose type of change by click button Proceed to Application . The system will display Change Notification application form.



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

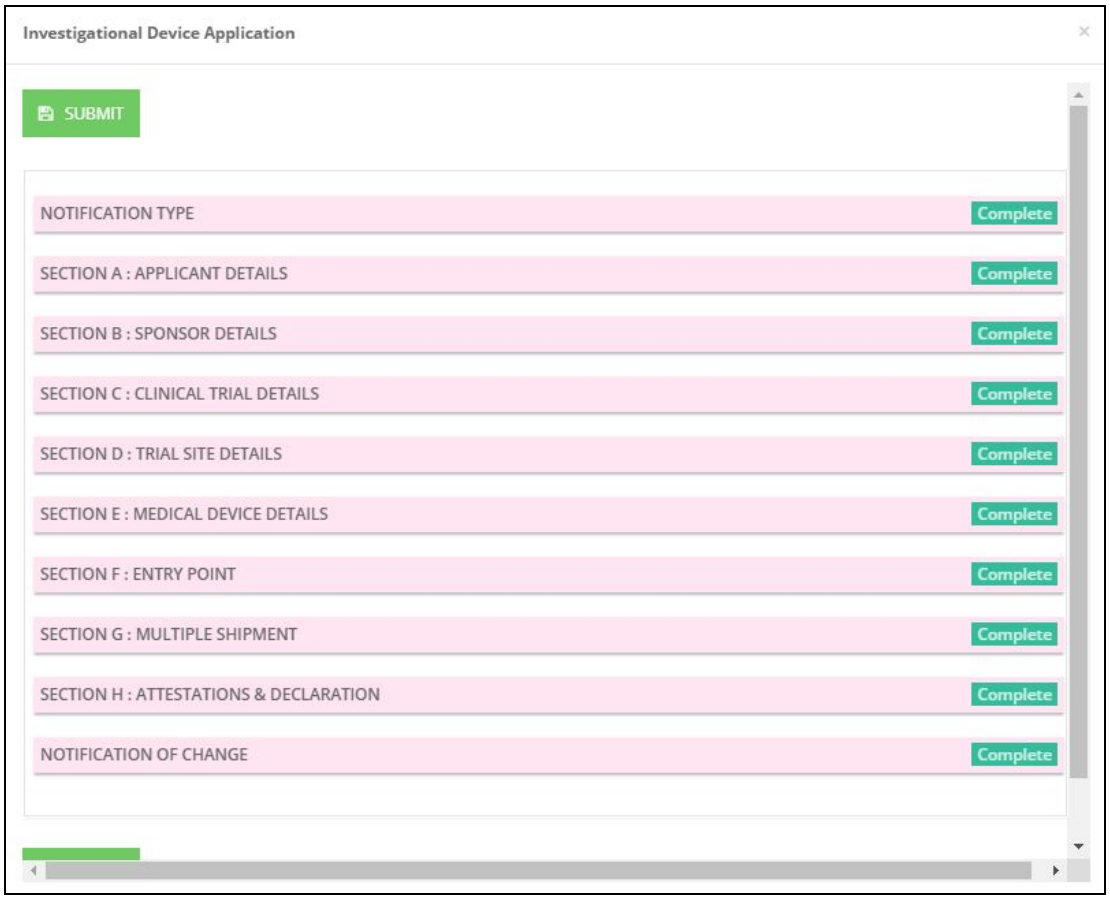


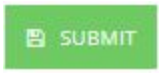
The list of changes that have been selected will be displayed.



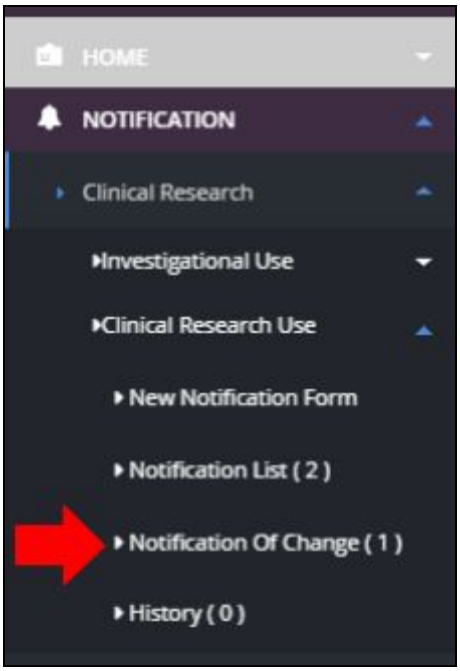
The applicant updates the information according to the type of change that has been selected. Only the field selected for making changes can be edited by the applicant.

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

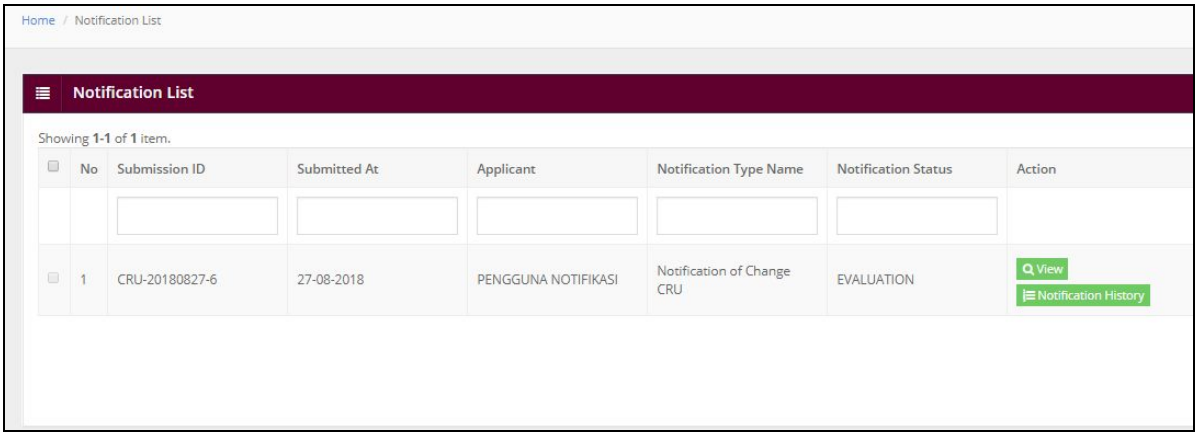


Click on  to submit form.

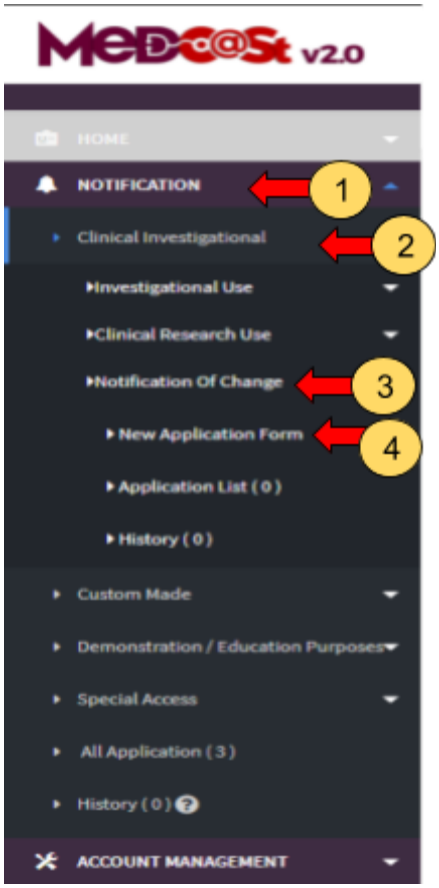
User click button Notification of Change under Clinical Investigation > Clinical Research Use.



The system will display list of Notification of Change.



III) NOTIFICATION OF CHANGE

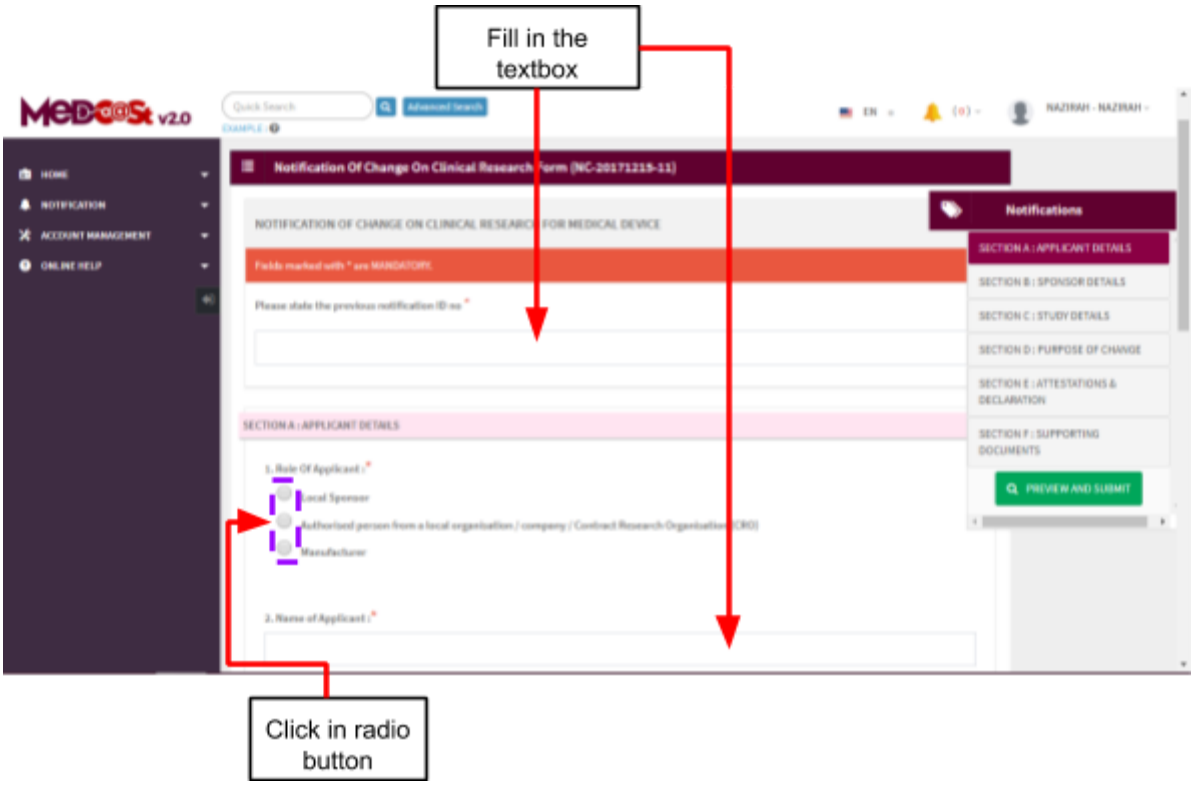


1 -> The user should click at main menu NOTIFICATION.

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.



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

Section A: Application Details

1. Role of Applicant

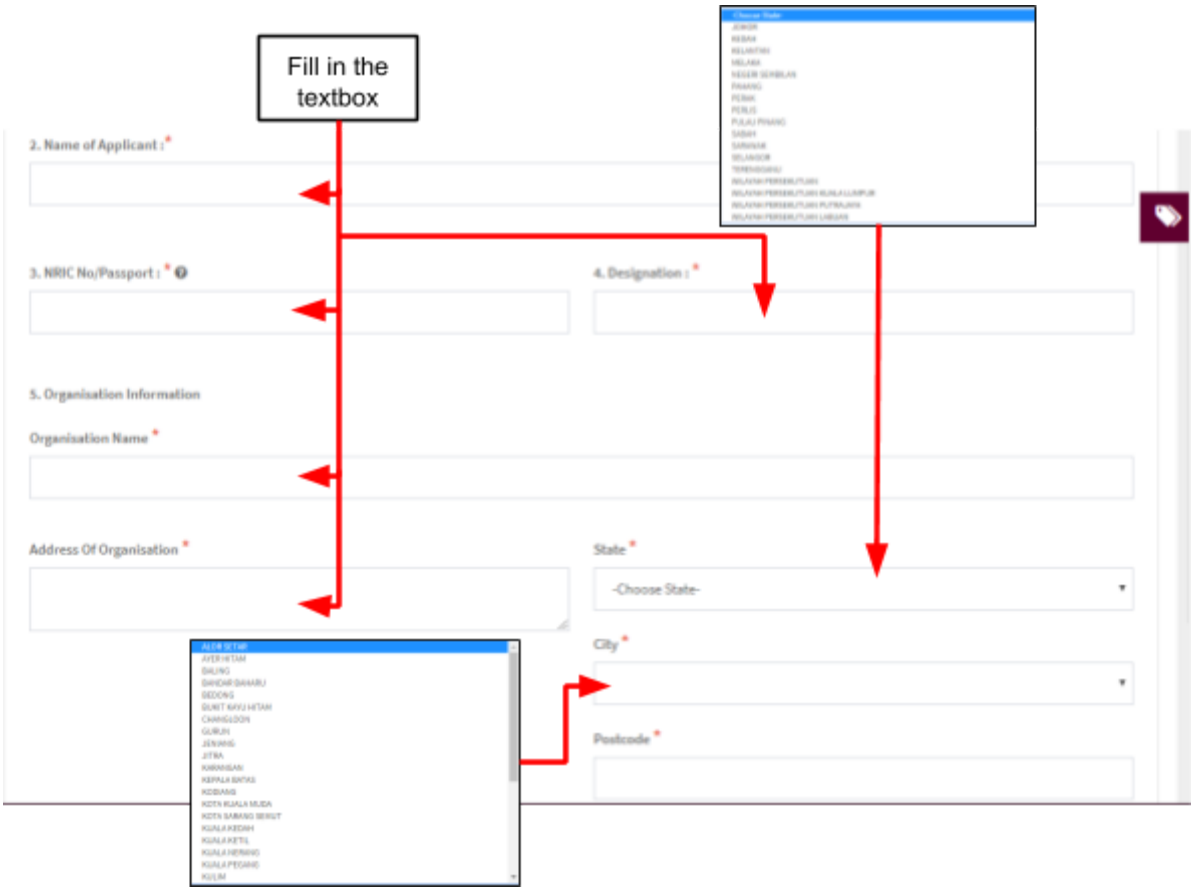
   The user should click at radio button that provided in the figure above. User should select the role of applicant which are Local sponsor, authorised person from a local organisation/company/contact research organisation(CRO) or manufacturer.

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.



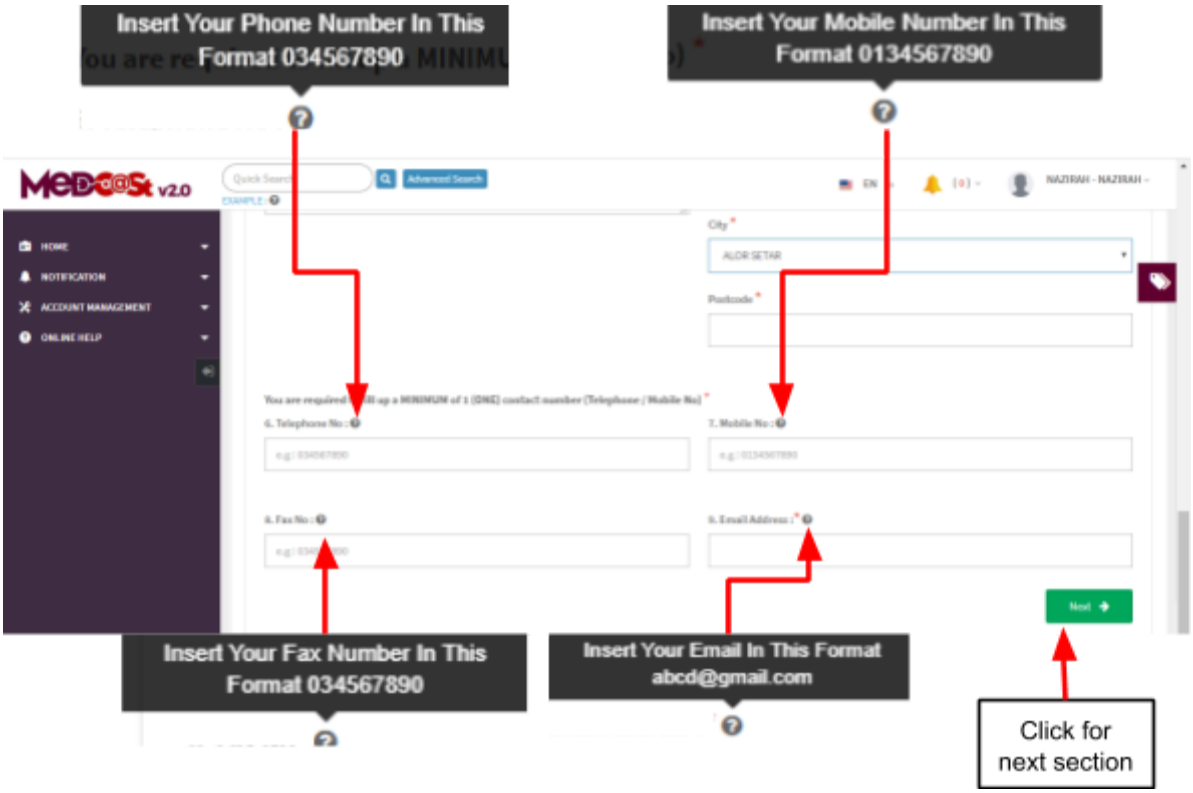
4. Designation

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 will appear "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.

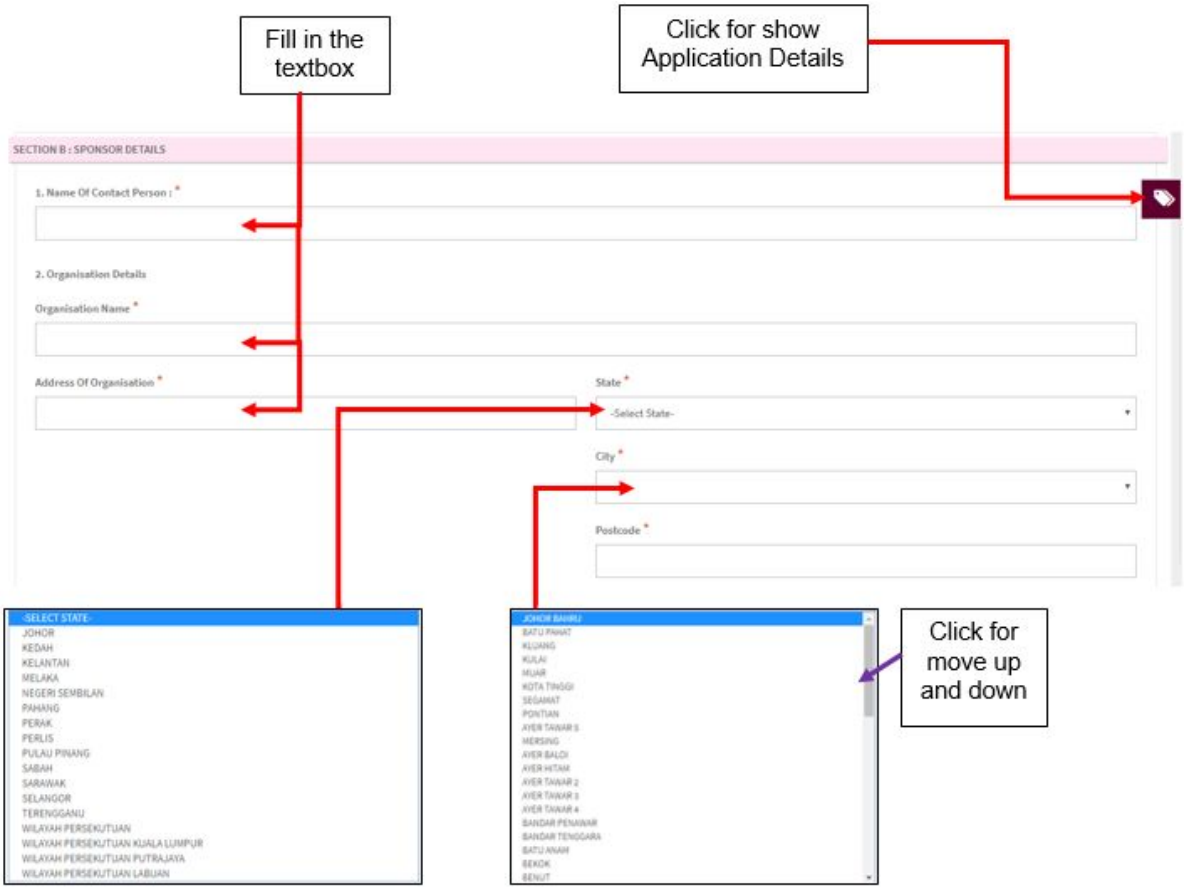
   The user must fill the Fax No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven

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 Next to the next section. The form for section B will be appeared.



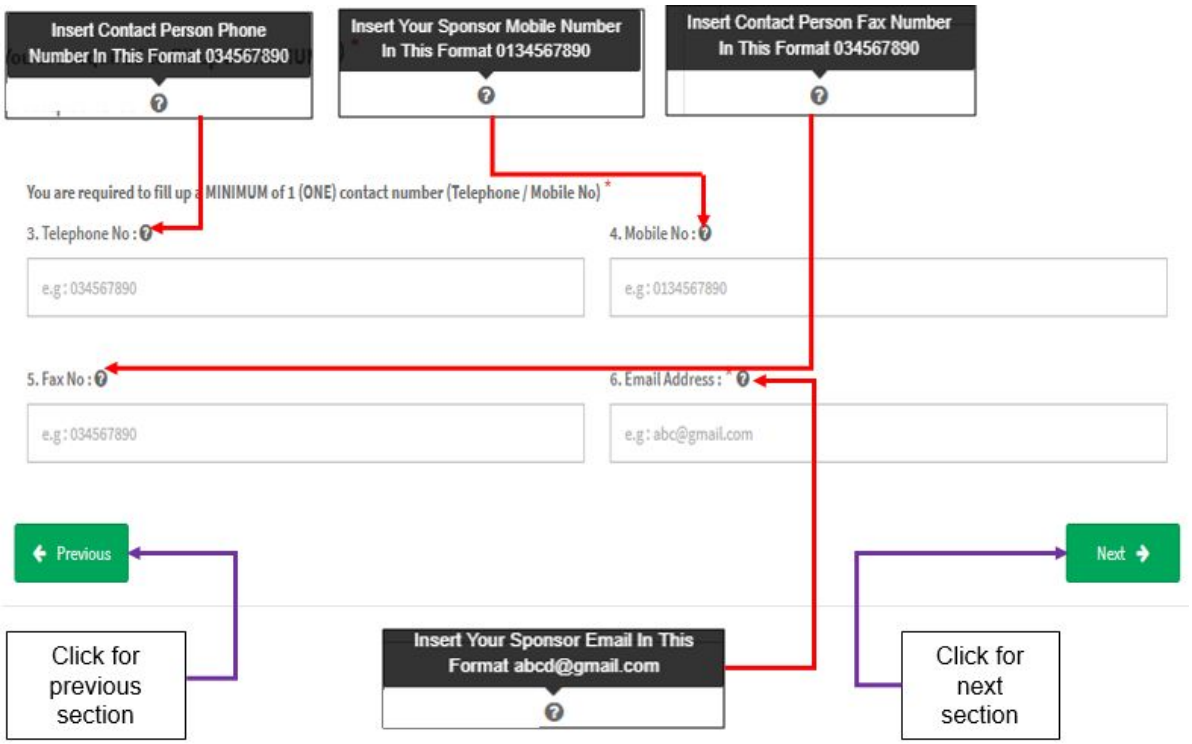
Section B: Sponsor Details

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.

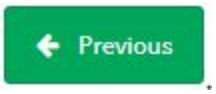
   The user must fill the Mobile No in an integer. User can see the format which click at . If user fills in the form except number or more than eleven number, the message "Field can only contain number and between 3 to 11 numeric." will appear.

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.

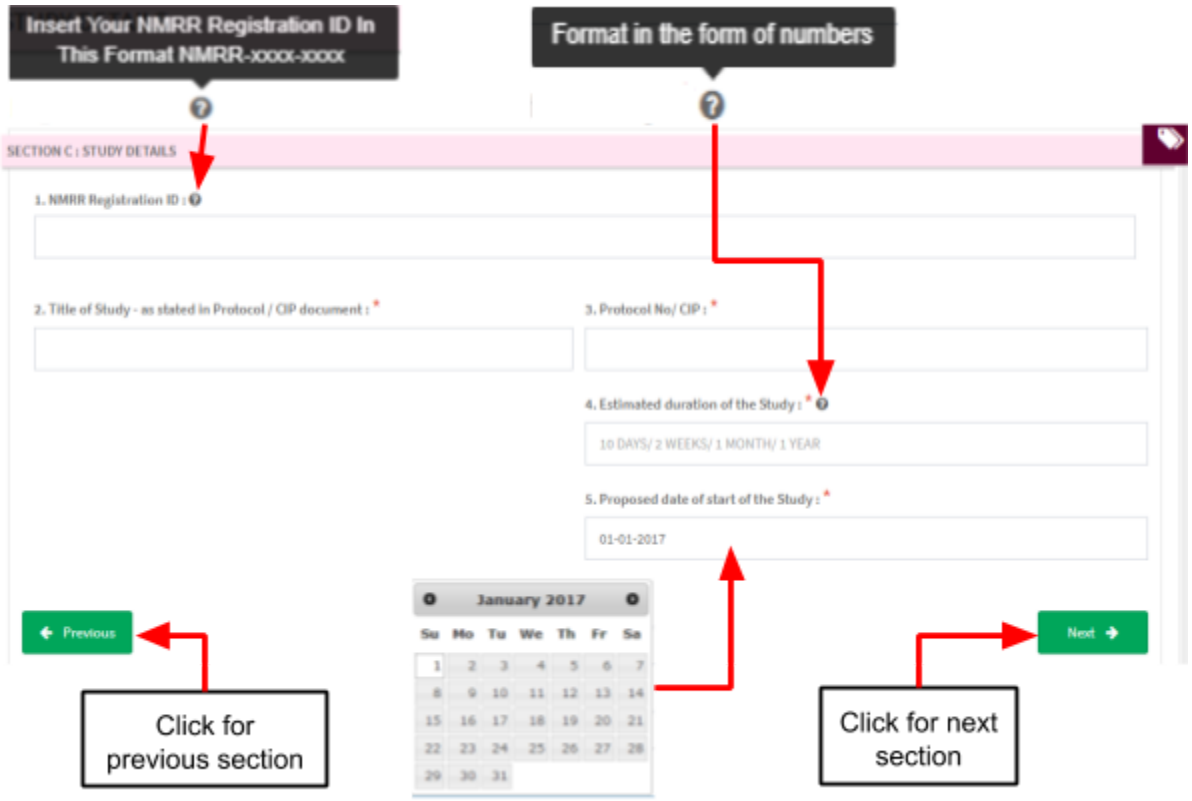
6. Email Address

   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

to the next section.



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.

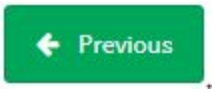
4. Estimated duration of the study

   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

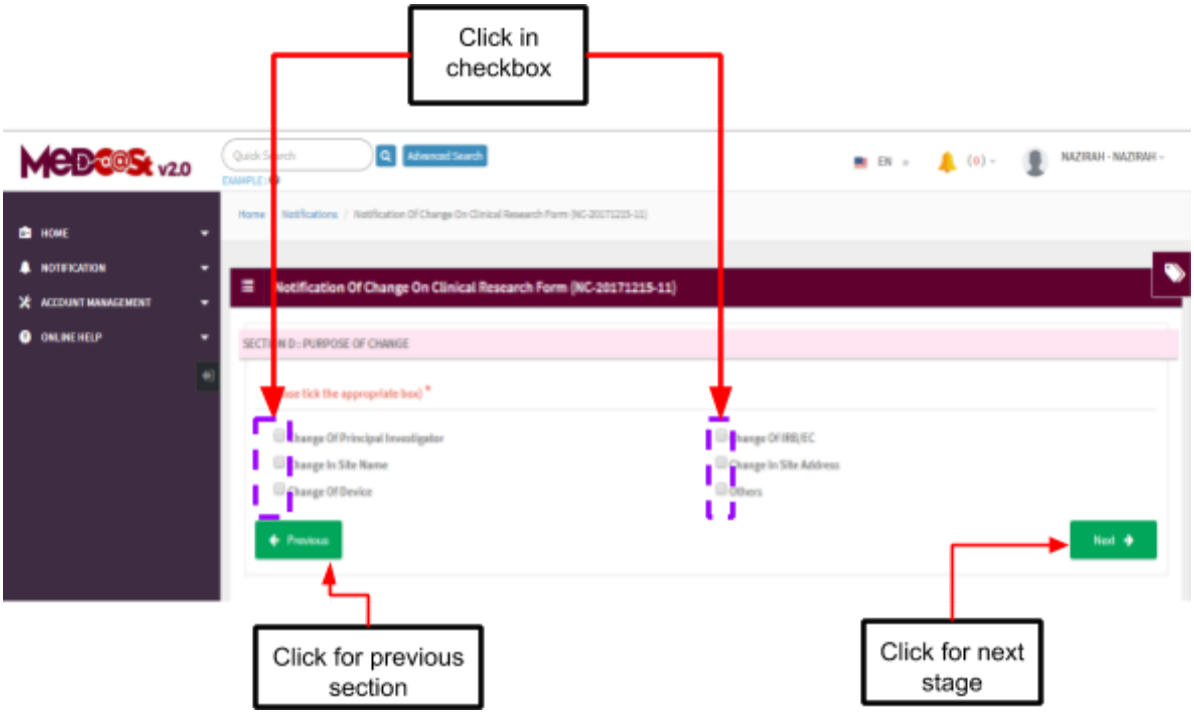
   The user should select a date in the calendar that provided. The user should click in textbox to appear the calendar.

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

.

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

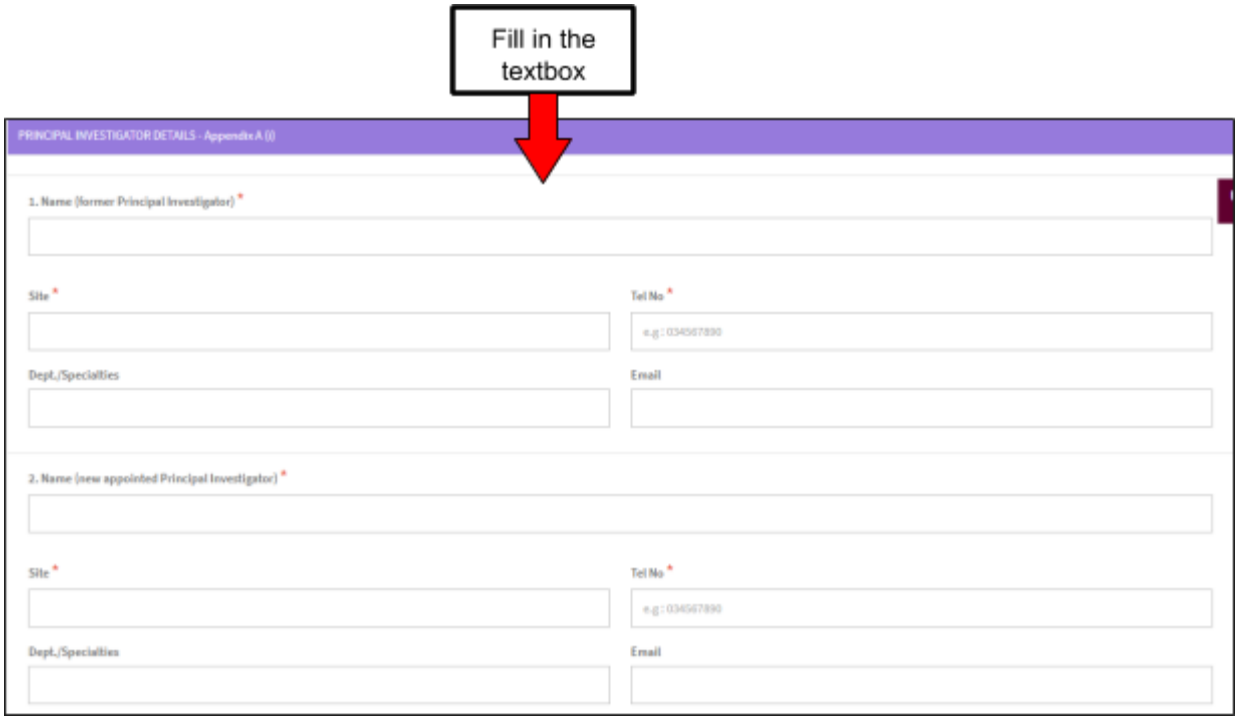
to the next section.



Section D: Purpose of Chance

The user should click in checkbox based the user wanted.

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



1. Name(former Principal Investigator)
   The user should fill in the textbox that provided.

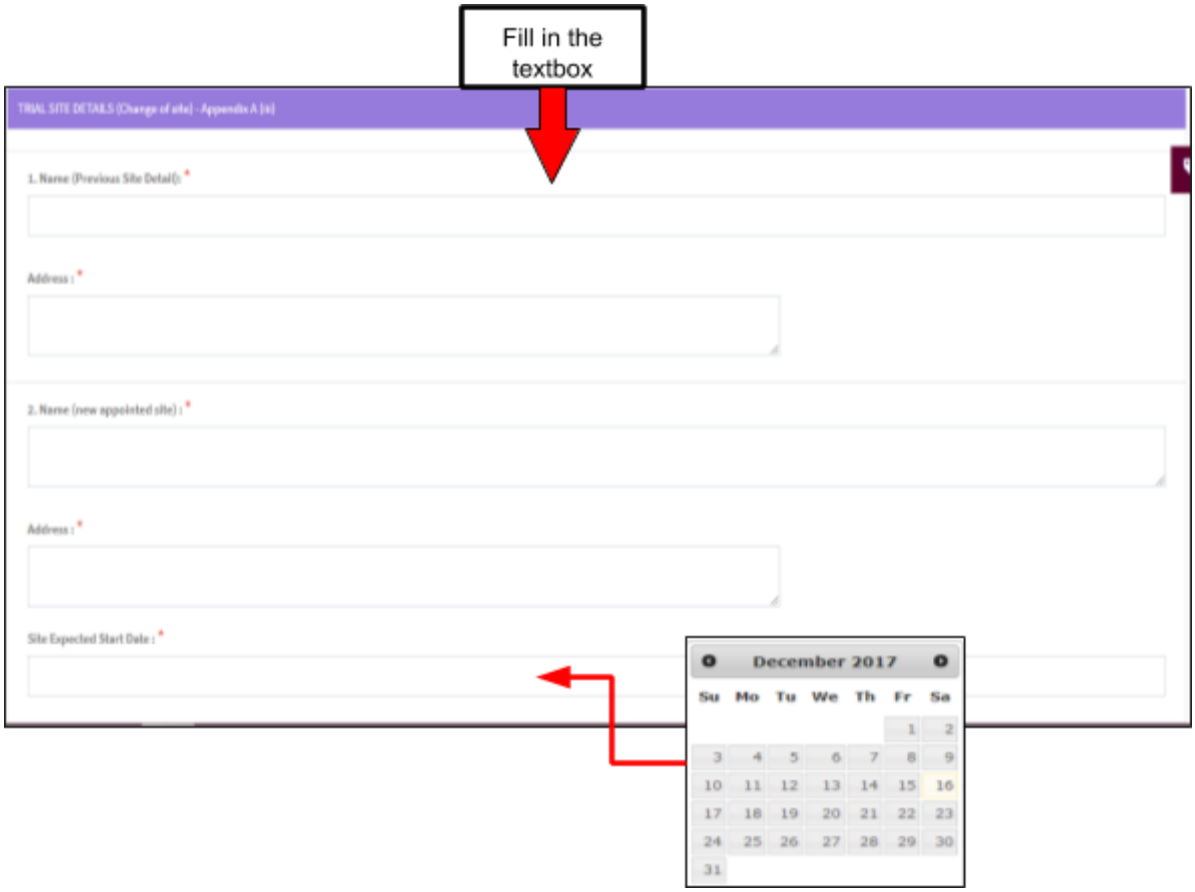
- Site -> The user should fill in the textbox that provided.
- Tel No.->The user should fill in the textbox that provided. If user fill it with character, the message "Telephone must be an integer." will be displayed. Besides that, if user fill it more than 11 number, the message "Field can only contain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

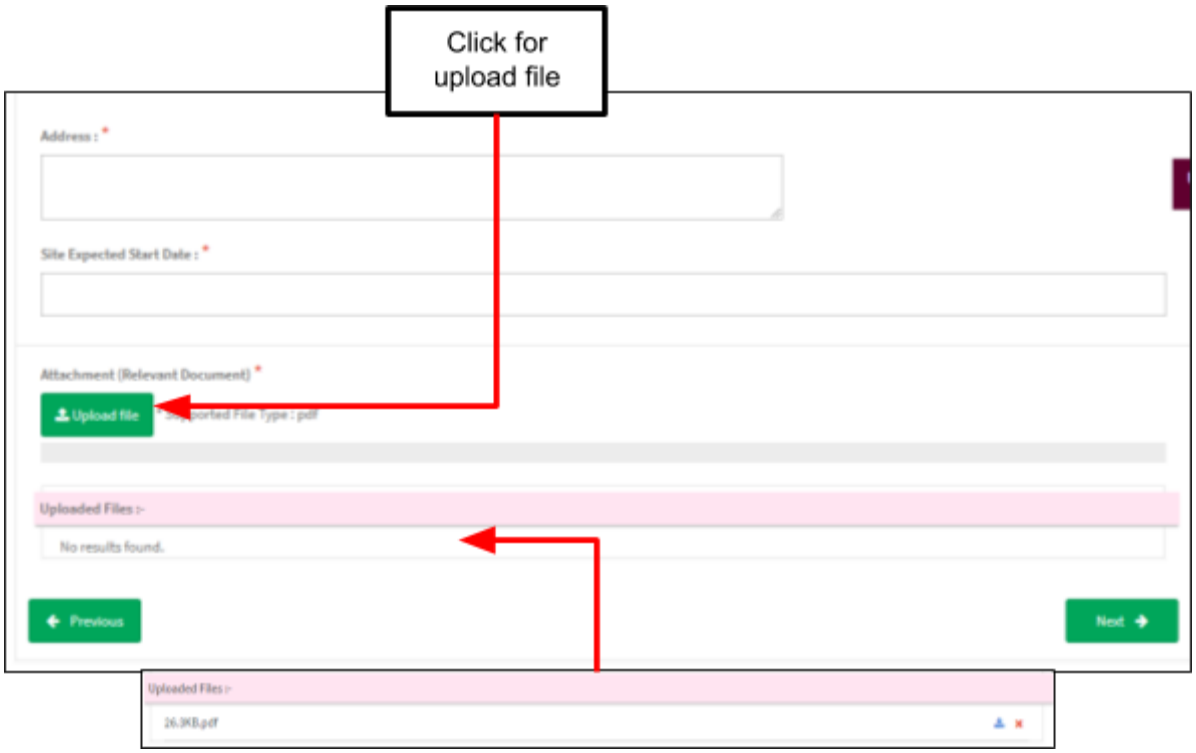
- Dept./Specialties-> The user should fill in the textbox that provided.
- Email -> The user should fill in the textbox that provided. If user fill it with not format email, the message "Email is not a valid email address.".

b) Change in site name-> The form for Trial Site Details will be displayed.

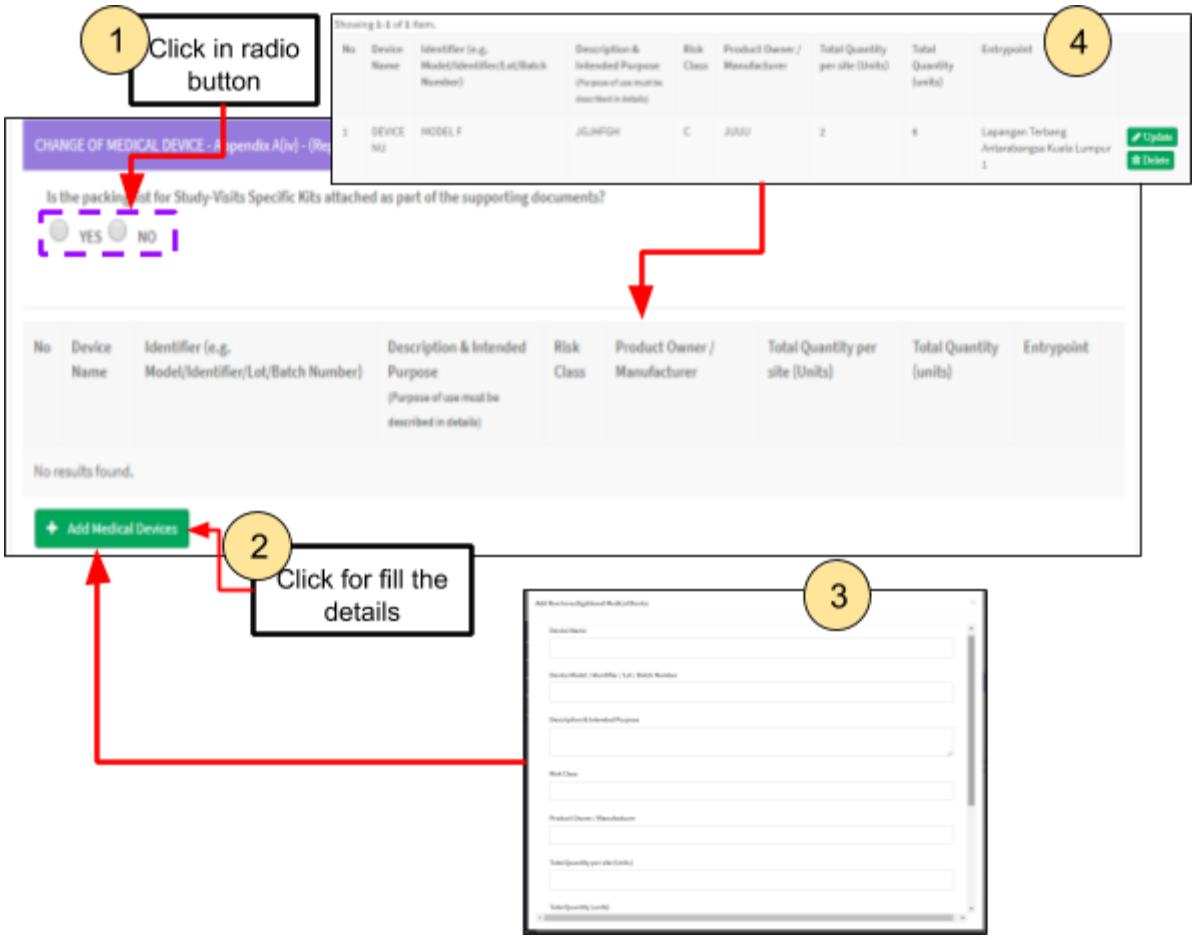


1. Name(Previous Site Detail)-> the user should fill in the textbox that provided.
   - Address -> The user should fill in the textbox that provided.
2. Name(new appointed site)

- 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.

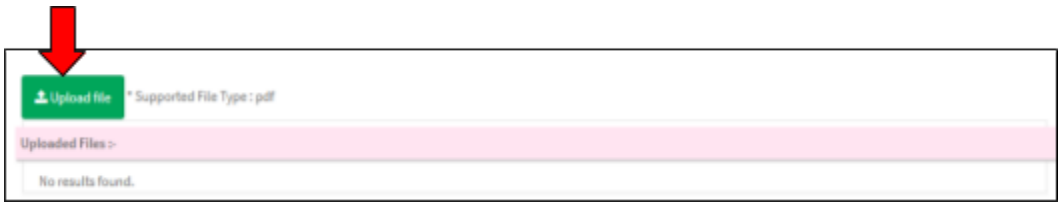

Click for upload file
Address :
Site Expected Start Date :
Attachment (Relevant Document)
Upload file
Uploaded Files :-
No results found.
Previous
Next
Uploaded Files :-
26.3KB.pdf

c) Change of Device



1 -> If the user choose the decision “yes”

, the button upload file will be displayed.



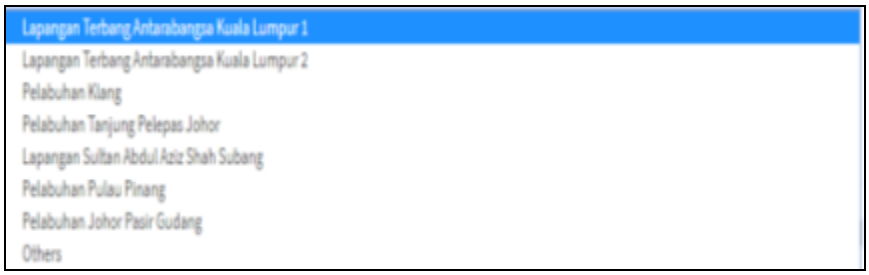
2 -> The user should click at

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

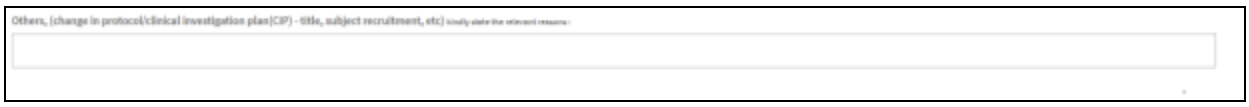
1. Name (former IRB/EC) -> The user should fill in the textbox that provided.

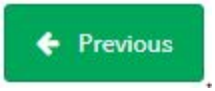
- Address -> the user should fill in the textbox that provided.

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.

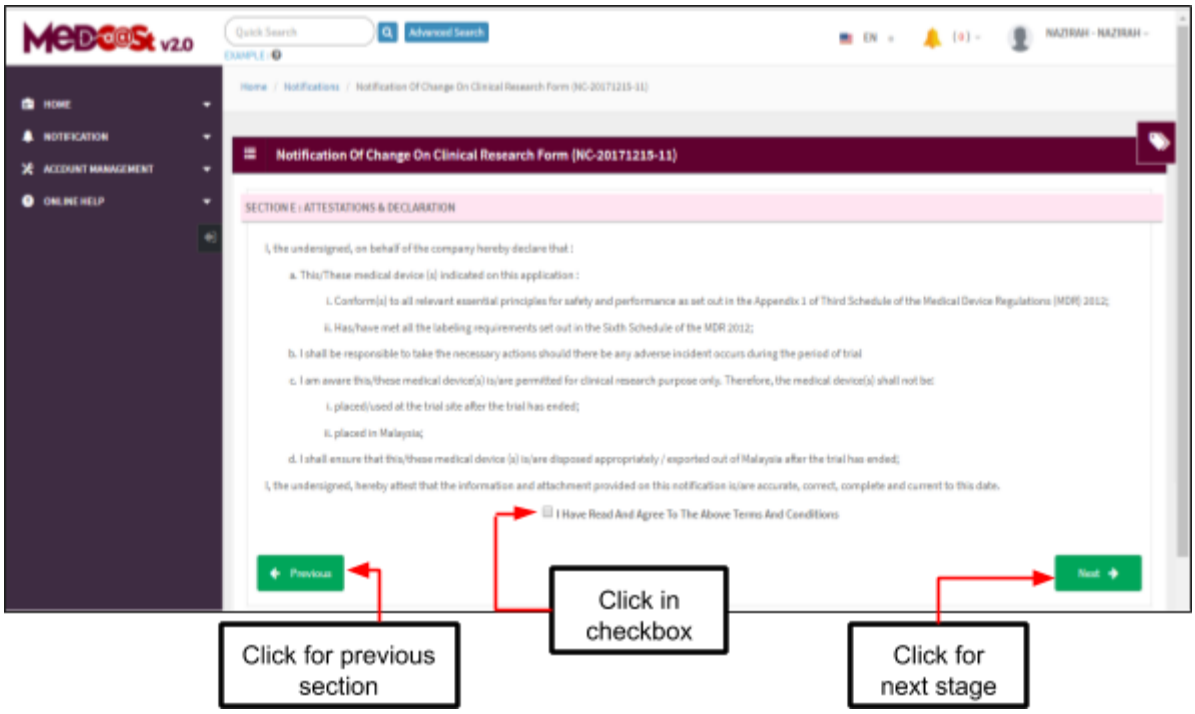


If user want back to previous section, user should click at button 

.

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

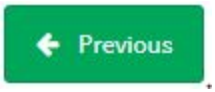
to the next section.



Section E: Attestations & Declaration

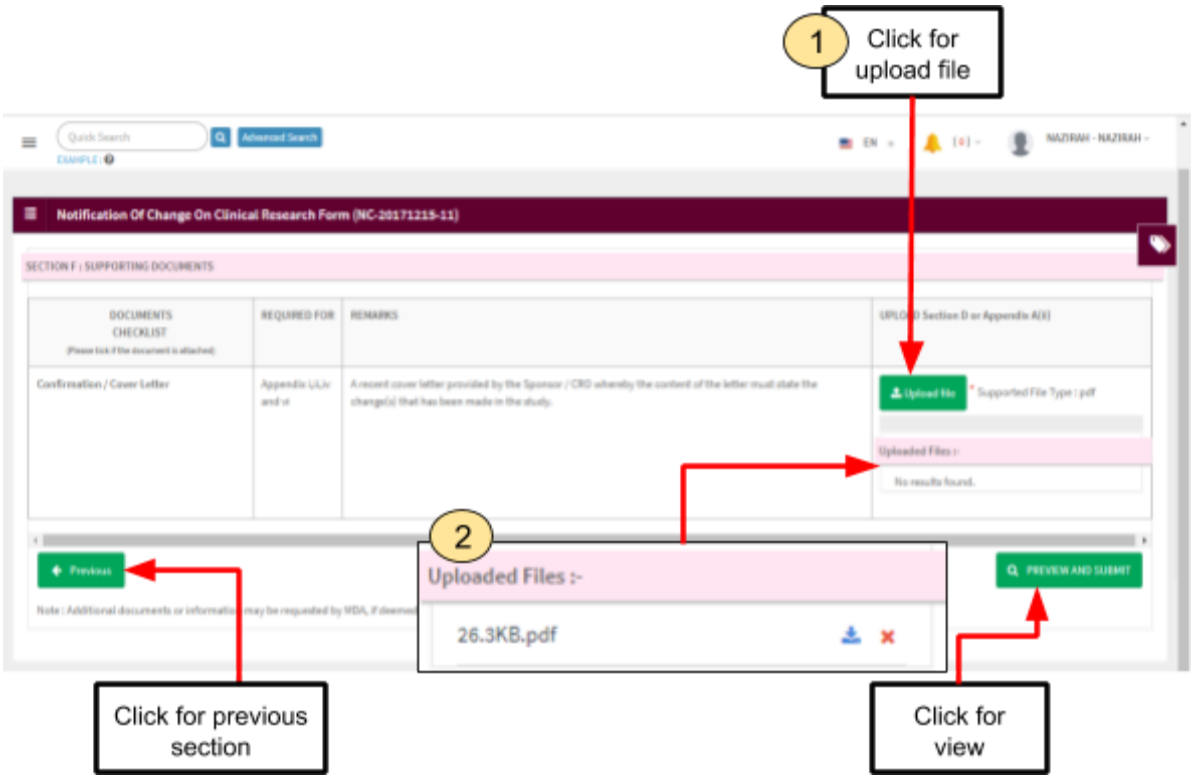
The user should click in the checkbox to agree the terms and conditions.

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

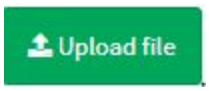


. that shown in figure above. Then, user should click at button

to the next section.



Section F: Supporting Documents

-> The user should click at 

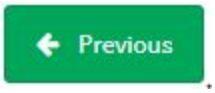
. to upload file. The file should PDF only and not more than 300MB. The user can see the message that display at

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 compete. 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.