# USER MANUAL FRONT END USER

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

## MODUL UTAMA - CLINICAL RESEARCH USE (FRONT-END USER)

**DISEDIAKAN OLEH :**

## LIST OF CONTENTS

## 1.0    INTRODUCTION

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

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

## 1.1    SYSTEM ACCESS

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

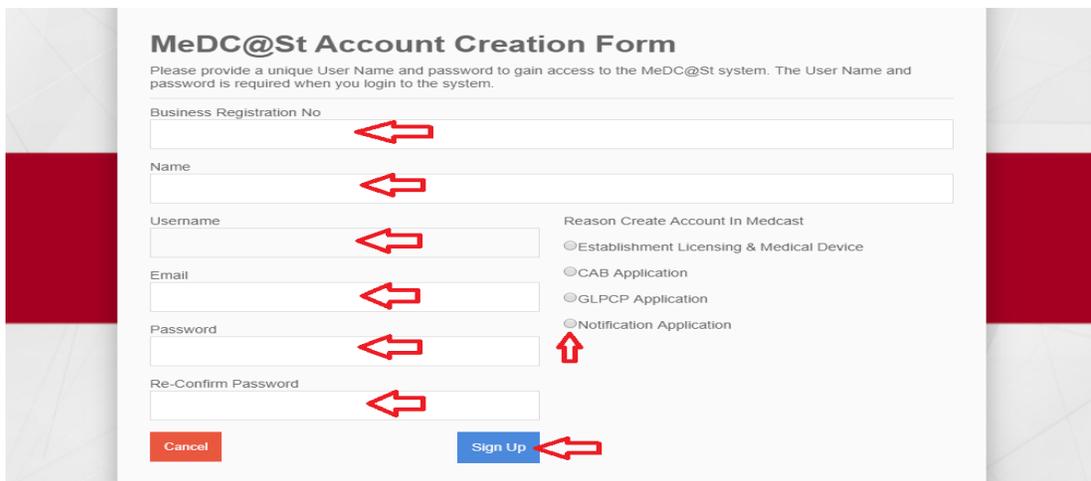https://medcast.mda.gov.my

### 1.1.1    CREATE ACCOUNT

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

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

click Sign Up for new registration.



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

### 1.1.2    LOGIN

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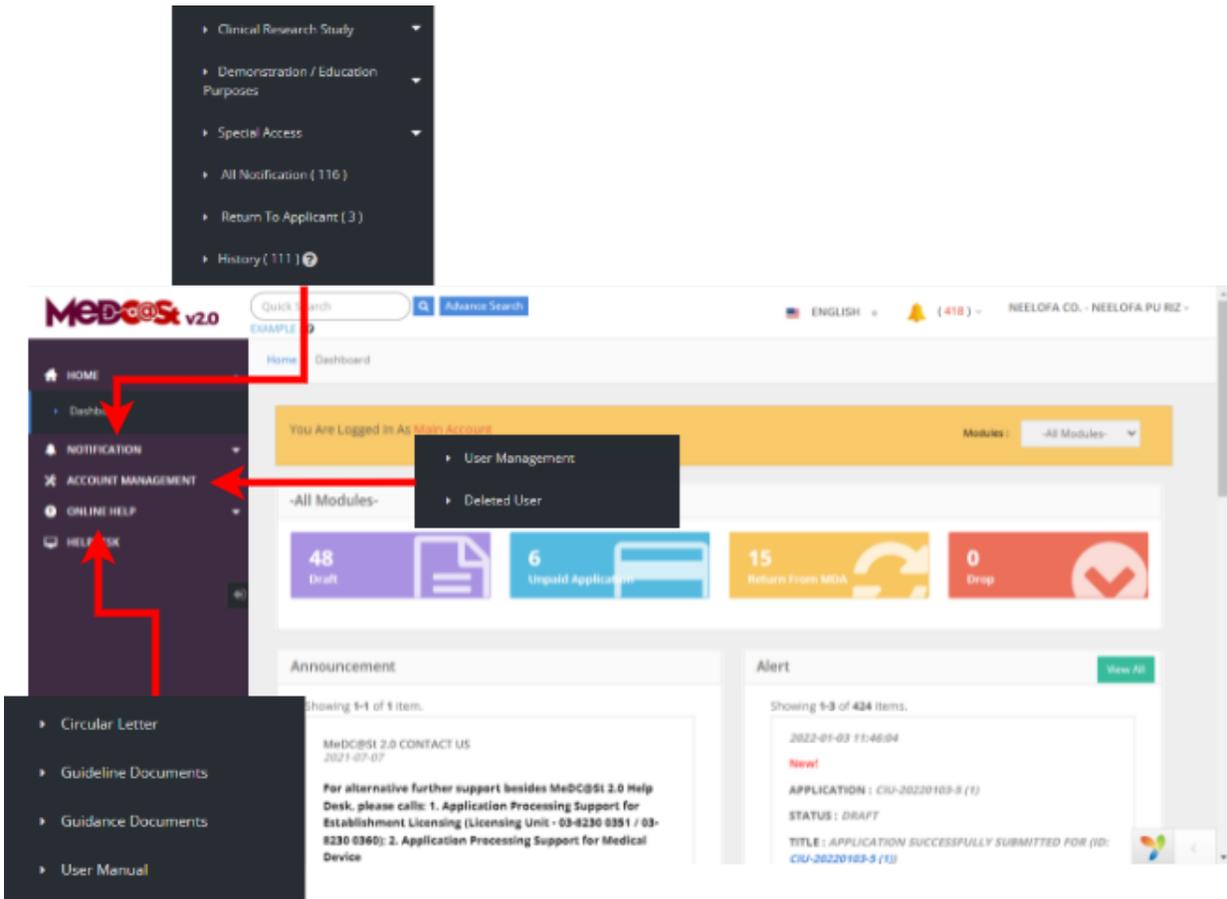


User has to log into the system using registered Username and its respective Password.  Click [Login] to proceed.

## 2.0    FUNCTIONS

### 2.1    DASHBOARD

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

## 2.2    MENU NOTIFICATION REGISTRATION

Menu Notification Registration has four type of notification which are *Clinical Research Study, 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
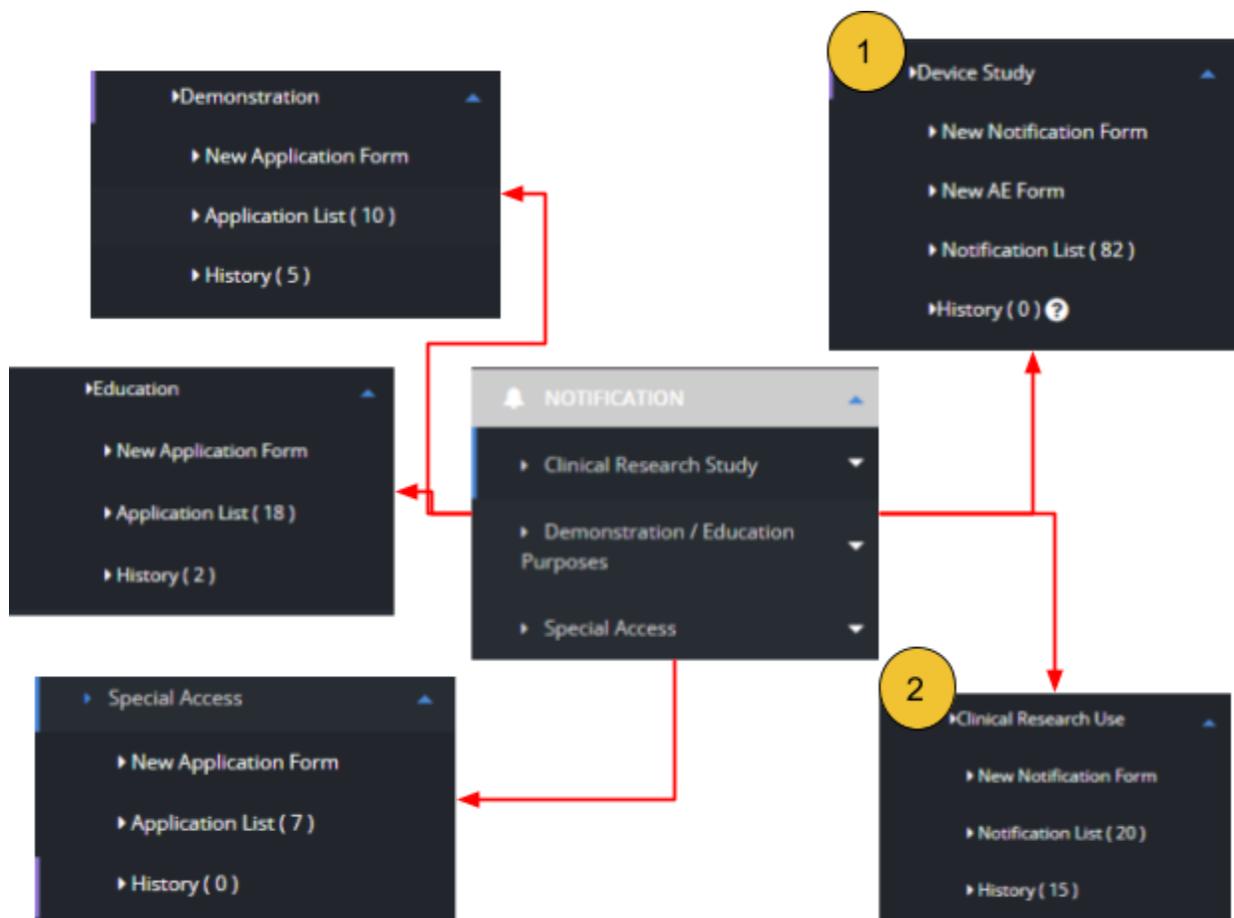
## CLINICAL RESEARCH USE

### *a)     New Application*



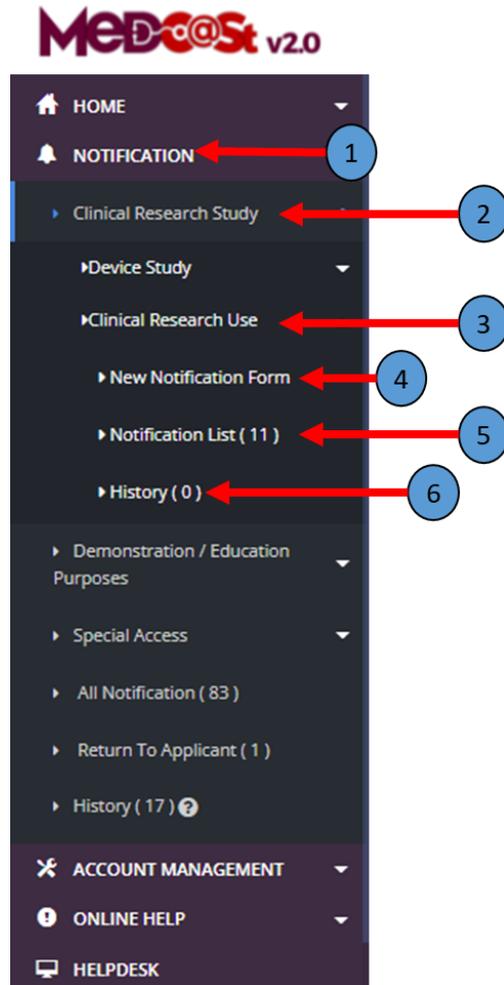①-> The user should click at menu NOTIFICATION and list of module will be displayed which are Clinical Research Study,  Demonstration/Education Purposes and Special Access.

②-> The user should click at menu module Clinical Research Study and list of sub module will be displayed which are Device Study and Clinical Research Use.

**3** -> The user should click at sub module Clinical Research Use and the New Application Form will be shown.

**4** -> The user should click at New Application Form to make a new Clinical Research Use application..

The application form will appear.



| Hide Main Menu | Hide Notification Details |

The application details have eight sections which are:

a) Section A: Applicant Information
b) Section B: Research Information
c) Section C: Research Site Information
d) Section D: Medical Device Information
e) Section E: Importation Entry Point
f) Section F: Multiple Shipment **(Disabled)**
g) Section G: Attestations & Declaration

**Section A: Applicant Details**
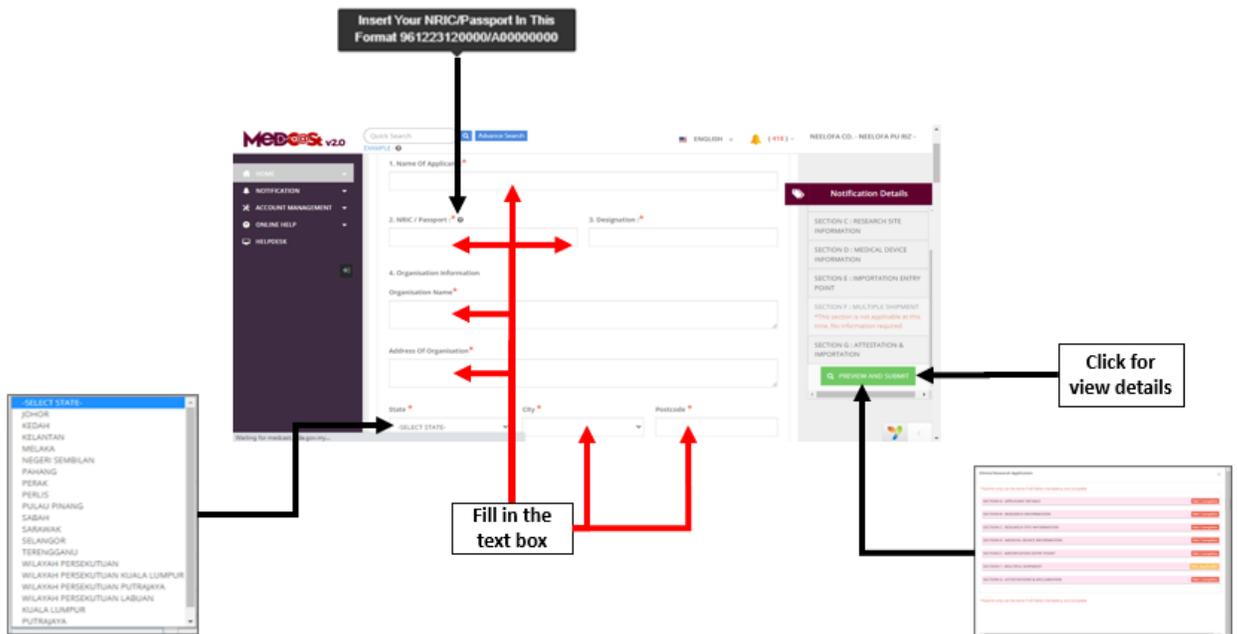


1. Name of Applicant

   The user should fill the name in the text box that provided.

2. NRIC /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.

3. Designation

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

4. 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."
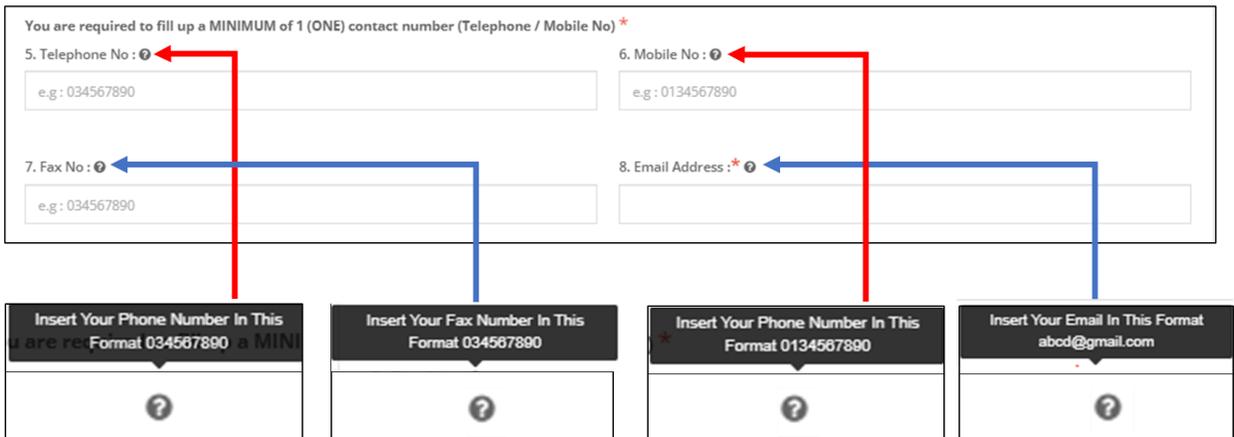


5. Telephone No

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.

6. 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.

7. 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.".
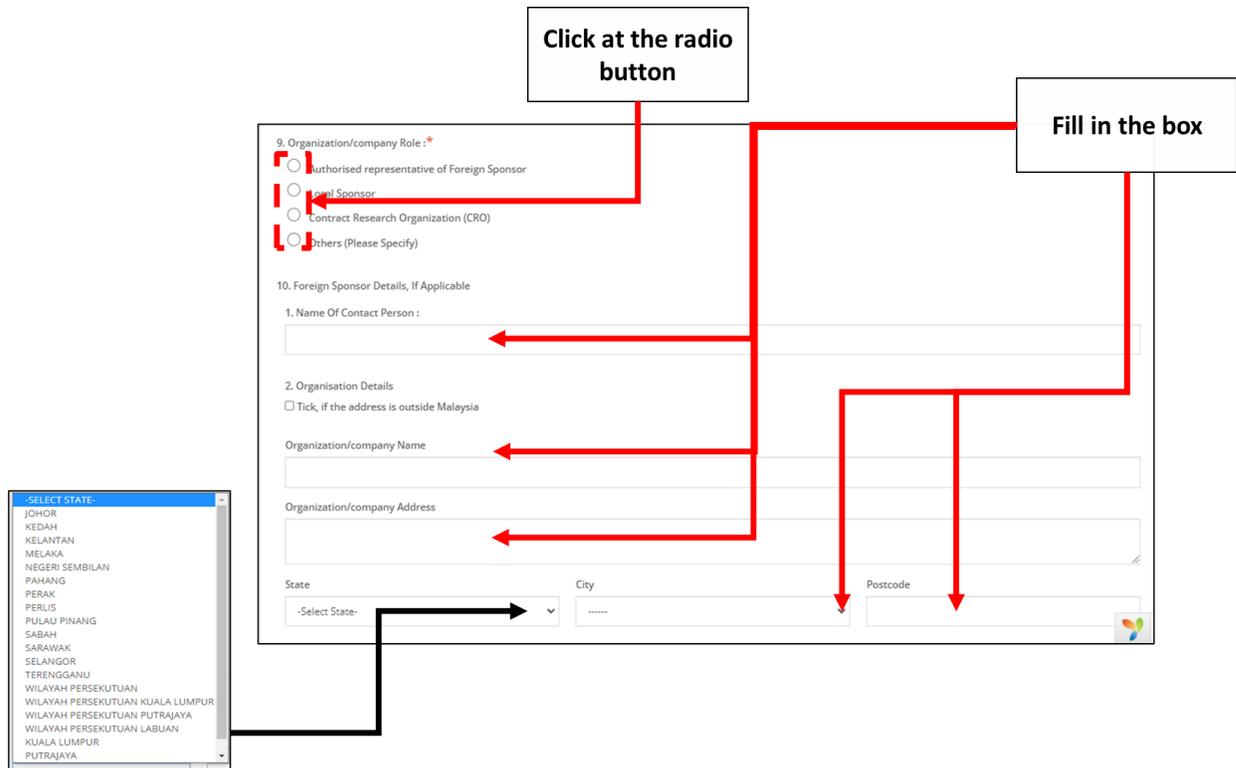
9. Organization/company Role

   - Authorised representative of Foreign Sponsor -> user should click at radio button that provided.

   - Local sponsor

   - Contract Research Organization (CRO)

   - Others (Please Specify) -> Once user click this radio button, the user must specify the role in the text field

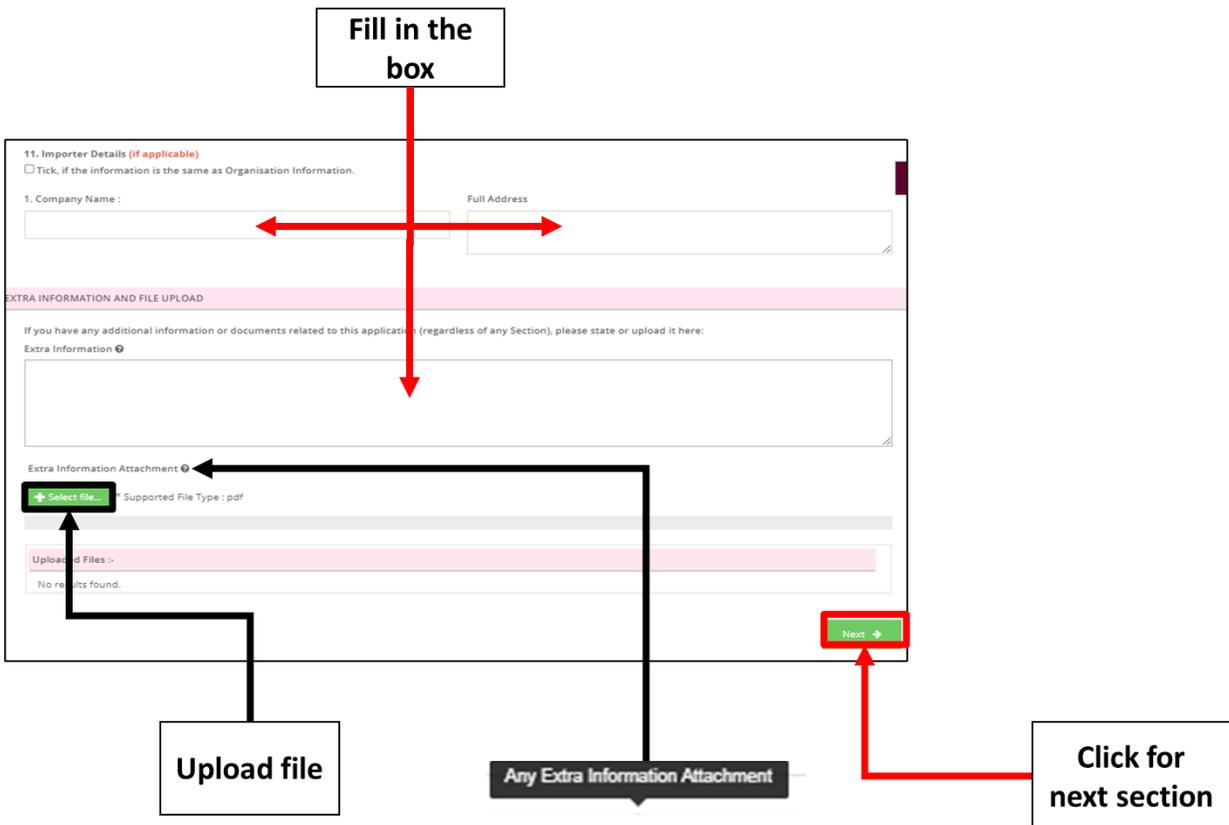10. Foreign Sponsor Details, If Applicable

   1. Name of Contact Person

      The user should fill the name in the textbox.

   2. Organisation Details

   -

   - Click at the "Tick, if the address is outside Malaysia" if the address is outside from Malaysia.

- 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."
-

**Fill in the box**

**11. Importer Details (if applicable)**
☐ Tick, if the information is the same as Organisation Information.

1. Company Name :                                    Full Address

EXTRA INFORMATION AND FILE UPLOAD

If you have any additional information or documents related to this application (regardless of any Section), please state or upload it here:
Extra Information ❷

Extra Information Attachment ❷

➕ Select file...    * Supported File Type : pdf

Uploaded Files :-
No results found.

Next ➔

**Upload file**

Any Extra Information Attachment

**Click for next section**

11. Importer Details (if applicable)

- Click at the "Tick, if the address is outside Malaysia" if the address is outside from Malaysia.
- Company Name -> The user should fill the name in the textbox that provided shown in the figure below.
- Full Address -> The user should fill in the textbox with address of organisation.

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

**Section B: Research Information**
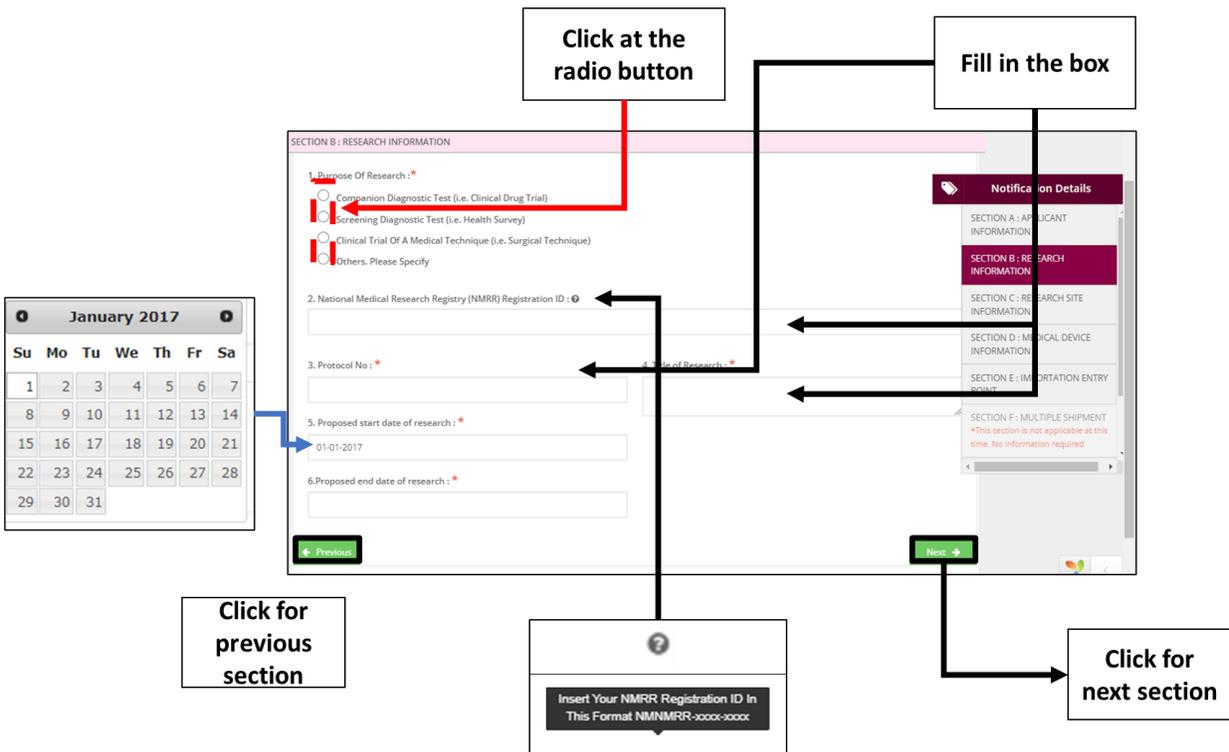


The symbol "**\***" mean required field. The user must fill it.

1. Purpose for Research

- Companion Diagnostic Test (i.e. Clinical Drug Trial)
- Screening Diagnostic Test (i.e. Health Survey)
- Clinical Trial Of A Medical Technique (i.e. Surgical Technique))
- Others. Please Specify -> Once user click this radio button, the user must specify thepurpose in the text field.

2. National Medical Research Registry (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.

3. Protocol No.

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

4. Title of Research

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

5. Proposed start date of research

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

6. Proposed end date of research :

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

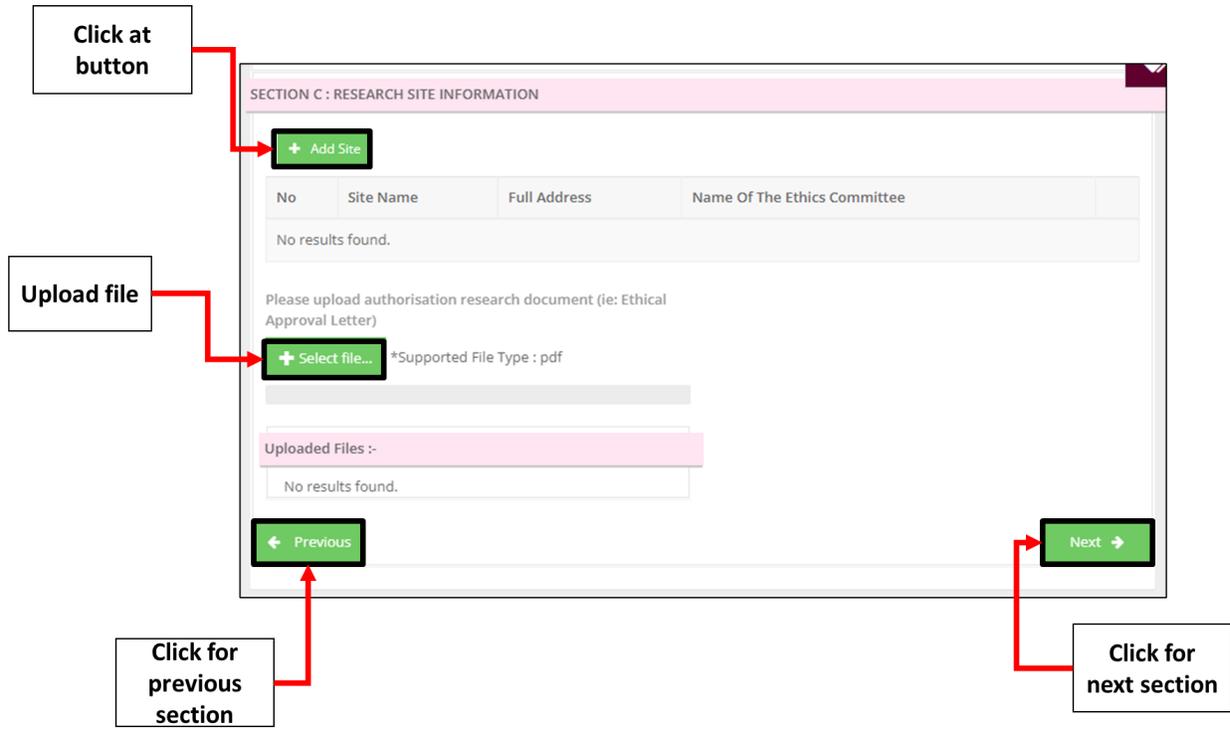If user want back to previous section, user should click at button **← Previous**.

that shown in figure above. Then, user should click at button **Next →** to the next section.

## Section C: Research Site Information

**Click at button**

SECTION C : RESEARCH SITE INFORMATION

+ Add Site

| No | Site Name | Full Address | Name Of The Ethics Committee | |
|----|-----------|--------------|------------------------------|---|
| No results found. | | | | |

Please upload authorisation research document (ie: Ethical Approval Letter)

**Upload file**

+ Select file...     *Supported File Type : pdf

Uploaded Files :-

No results found.

← Previous

Next →

**Click for previous section**

**Click for next section**

Firstly, the user should click at  + Add Site  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. Site Name*

2. Full Address *

4. Name Of The Ethics Committee : *

Save

**Fill in the box**

**Click for save**

## Add trial site

1.  Site Name

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

2.  Full Address

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

3.  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 "Trailsite Name Committee cannot be blank." will appear.

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



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

**Add Trial Site**                                                            ✕

1. Site Name*

HOSPTAL KUALA LUMPUR

2. Full Address *

JALAN PAHANG,
50586 KUALA LUMPUR,
WILAYAH PERSEKUTUAN KUALA LUMPUR

4. Name Of The Ethics Committee : *

DATO DR MOHAMED IBRAHIM BIN A WAHID

**Click for save** → Save

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

Click for cancel deleted

**Delete Trial site?**                                                     ✕

Cancel     OK

Click for proceed delete

After the user completely fill the site details, the user must upload the  authorisation

research document (ie: Ethical Approval Letter) by clicking **+ Select file...** button.
The file must be in pdf. If the user upload file other than pdf, a pop-out message
"File Type Not Allowed" appeared.

medcast.mda.gov.my says

File Type Not Allowed

OK

 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 section.

## Section D: Medical Device Details

**Click radio button**



**1** List of Devices by Packaging (week/etc) -> The user should click in radio button "Yes" or "No" . The user choose "No"

**2** The user should click at **+ Upload Medical Device (XLSX)** to fill the details of Non-Investigational Medical Devices in excel. The steps to upload the Non-Investigational Medical Devices in excel form displayed in figure below.

**1**

**Choose excel file from local desktop**

**2**

**After excel file is successfully uploaded, the excel file name appeared**

**Upload Medical Device**      ✕

**How to upload Medical Device list.**
[ EXCEL BATCH UPLOAD ]

1. Please Download Template for Medical Device list below.
Template Excel For Batch Upload

2. Fill in the excel form and Save.
3. Upload

** WARNING :
1. PLEASE DO NOT CHANGE THE EXCEL TEMPLATE FORMAT.
2. YOU CAN RE-UPLOAD THE EXCEL FILE BUT THIS PROCESS WILL DELETE ALL EXISTING DATA AND REPLACE IT WITH THE NEW DATA.

Choose File   No file chosen

UPLOAD

**Click for download excel file template**

**Click for Upload**

**3** The user should click at [ **+ Add Manually Non Investigational Medical Devices** ] to fill the details of Non-Investigational Medical Device manually. The form will be displayed in figure below.

**Add Non Investigational Medical Device**

1. Device Name (As Per Label) -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name (As Per Label) cannot be blank." will appear.

2. Brief Description & Intended Purpose -> The user should fill in the textbox that provided. If the user don't fill the description, the message "Brief Description & Intended Purpose cannot be blank." will appear.

3. Identifier -> The user should fill in the textbox that provided. If the user don't fill the identifier, the message "Model Name cannot be blank." will appear.

4. Manufacturer Name -> The user should fill in the textbox that provided. If the user don't fill the form, the message "Manufacturer Name cannot be blank." will appear.

5. Unit of Measurement ->the user should fill in the textbox that provided.

6. Total Quantity/Site -> 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.

7. Total Importation->the user should fill in the textbox that provided.

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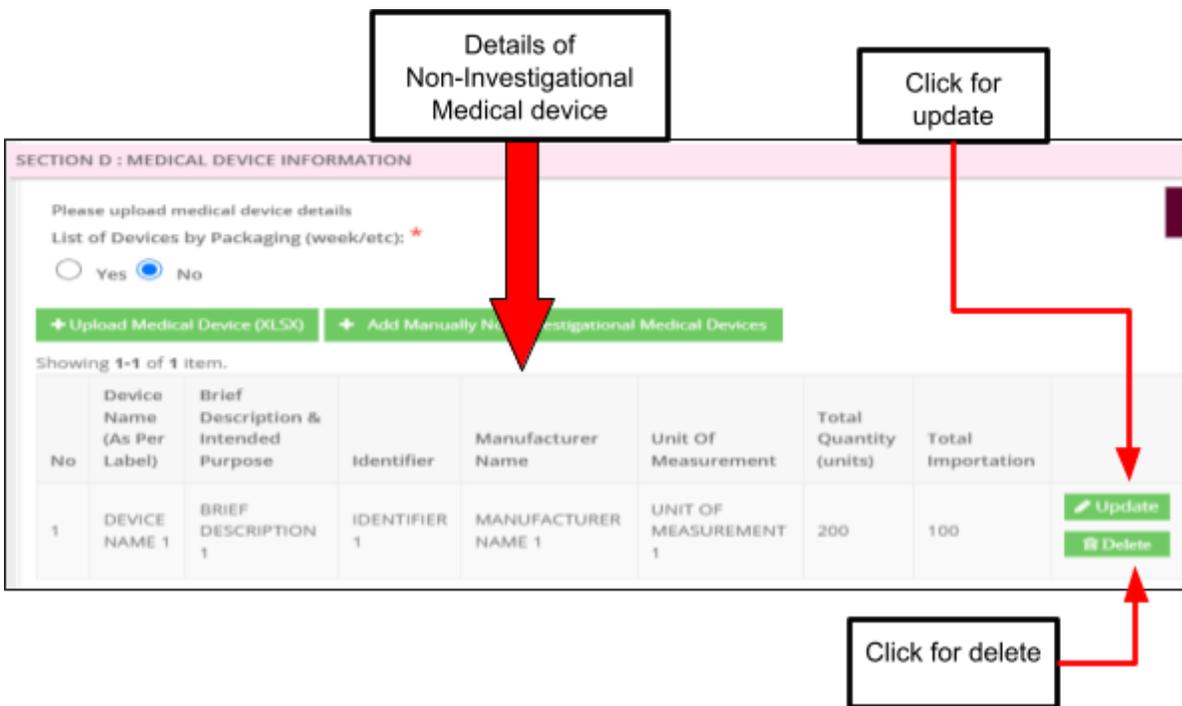


If user want to update details, the user should click at button "Update" that shown in figure above. The form will be displayed. Besides that, if user want to delete the details, user should click button "Delete" that shown in figure above. The alert message will be displayed.

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".

**Click radio button**

**Fill in the box**

**Click button**

SECTION D : MEDICAL DEVICE INFORMATION

Please upload medical device details
List of Devices by Packaging (week/etc): *

◉ Yes ○ No

Package Name : *

[                                                ] Add Package

| No | Package Name | Action |
|----|--------------|--------|
| No results found. | | |

| No | Device Name (As Per Label) | Brief Description & Intended Purpose | Identifier | Manufacturer Name | Unit Of Measurement | Total Quantity (units) | Total Importation |
|----|----|----|----|----|----|----|----|
| No results found. | | | | | | | |

← Previous          Next →

SECTION D : MEDICAL DEVICE INFORMATION

Please upload medical device details
List of Devices by Packaging (week/etc): *

◉ Yes ○ No

Package Name : *

[                                                ] Add Package

Showing 1-1 of 1 item.

| No | Package Name | Action |
|----|--------------|--------|
| 1 | PACKAGE 1 | + Upload Medical Devices [XLS, XLSX]  + Add device manually  ☑ Update  🗑 Delete |

**Click for delete**

| No | Device Name (As Per Label) | Brief Description & Intended Purpose | Identifier | Manufacturer Name | Unit Of Measurement | Total Quantity | Total Importation |
|----|----|----|----|----|----|----|----|
| No results found. | | | | | | | |

**Click for update**

**1** List of Devices by Packaging (week/etc) -> The user should click in radio button

"Yes" or "No" . The user choose "Yes" ⚫ Yes ◯ NO . Then, the user must fill the

"Package Name" and proceed to click the **Add Package** button. The User can

update and delete the package name.

**2** The user should click at **+ Upload Medical Device (XLSX)** to fill the details of

Non-Investigational Medical Devices in excel. The steps to upload the

Non-Investigational Medical Devices in excel form displayed in figure below.



**Choose excel file from local desktop**

**After excel file is successfully uploaded, the excel file name appeared**

**Click for download excel file template**

**Click for Upload**

**3** The user should click at **+ Add Manually Non Investigational Medical Devices** to fill the

details of Non-Investigational Medical Device manually. The form will be displayed in

figure below.

**Add Non Investigational Medical Device**

8. Device Name (As Per Label) -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name (As Per Label) cannot be blank." will appear.

9. Brief Description & Intended Purpose -> The user should fill in the textbox that provided. If the user don't fill the description, the message "Brief Description & Intended Purpose cannot be blank." will appear.

10. Identifier -> The user should fill in the textbox that provided. If the user don't fill the identifier, the message "Model Name cannot be blank." will appear.

11. Manufacturer Name -> The user should fill in the textbox that provided. If the user don't fill the form, the message "Manufacturer Name cannot be blank." will appear.

12. Unit of Measurement ->the user should fill in the textbox that provided.

13. Total Quantity/Site -> 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.

14. Total Importation->the user should fill in the textbox that provided.

After that, user should click at <span style="background:green;color:white;">☑ Update</span> to save the details and the details will be displayed in table that shown in the figure below.



If user want back to previous section, user should click at button <span style="background:green;color:white;">← Previous</span>.

that shown in figure above. Then, user should click at button <span style="background:green;color:white;">Next →</span> to the next section.

Below shows a pop-out message "Data list of medical devices will be eliminated if changing the type of packaging !!" when the user want to change the "Yes" or 'No radio button.
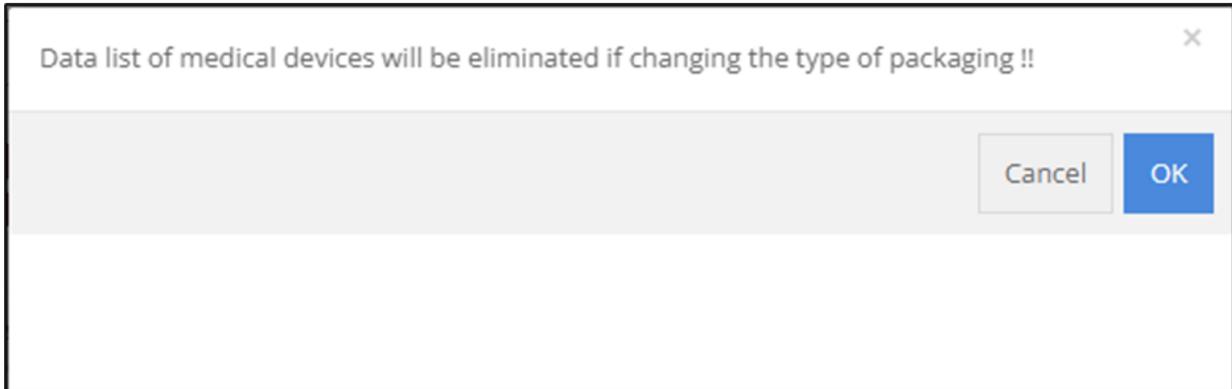


**Section E: Entry Point**
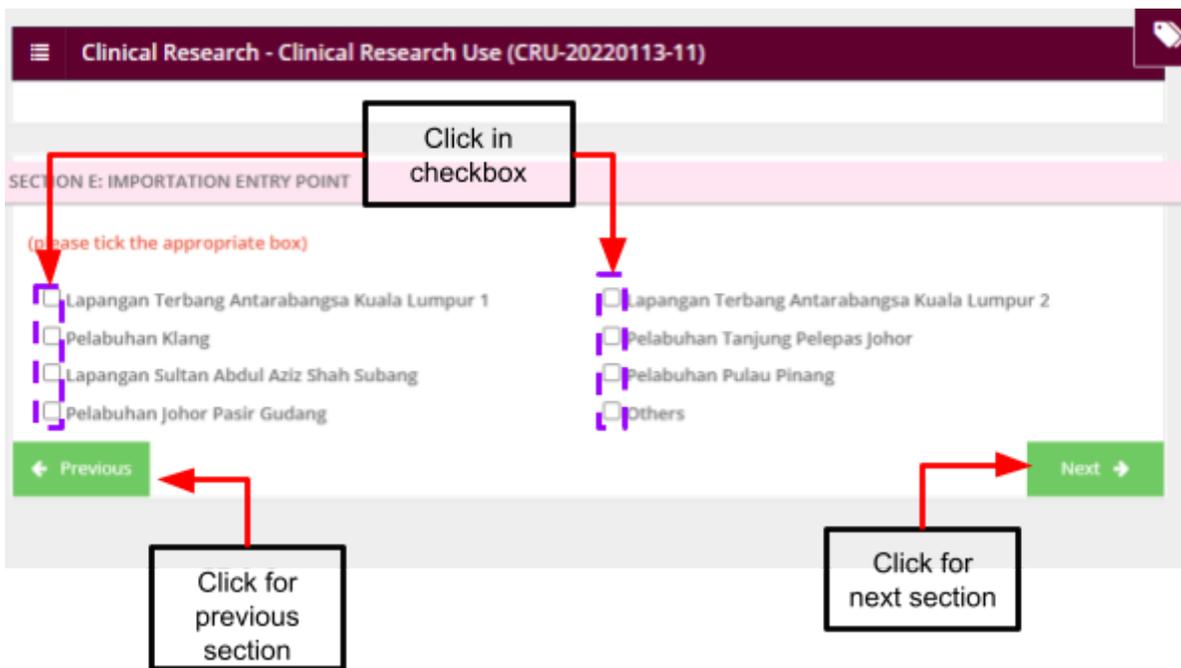


The user should click in checkbox based the place of entry point that user chosen. After that, If user want back to previous section, user should click on button

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

 to the next section.

**Section F: Multiple Shipment (Disabled)**

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

## Section G: Attestations & Importation



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

The user also can click at **← Previous** .to back the previous section and if user

complete the form, user should click at **Q PREVIEW AND SUBMIT** to preview details of

application. The figure below shows the details of application with status

"Complete" or Not Complete".
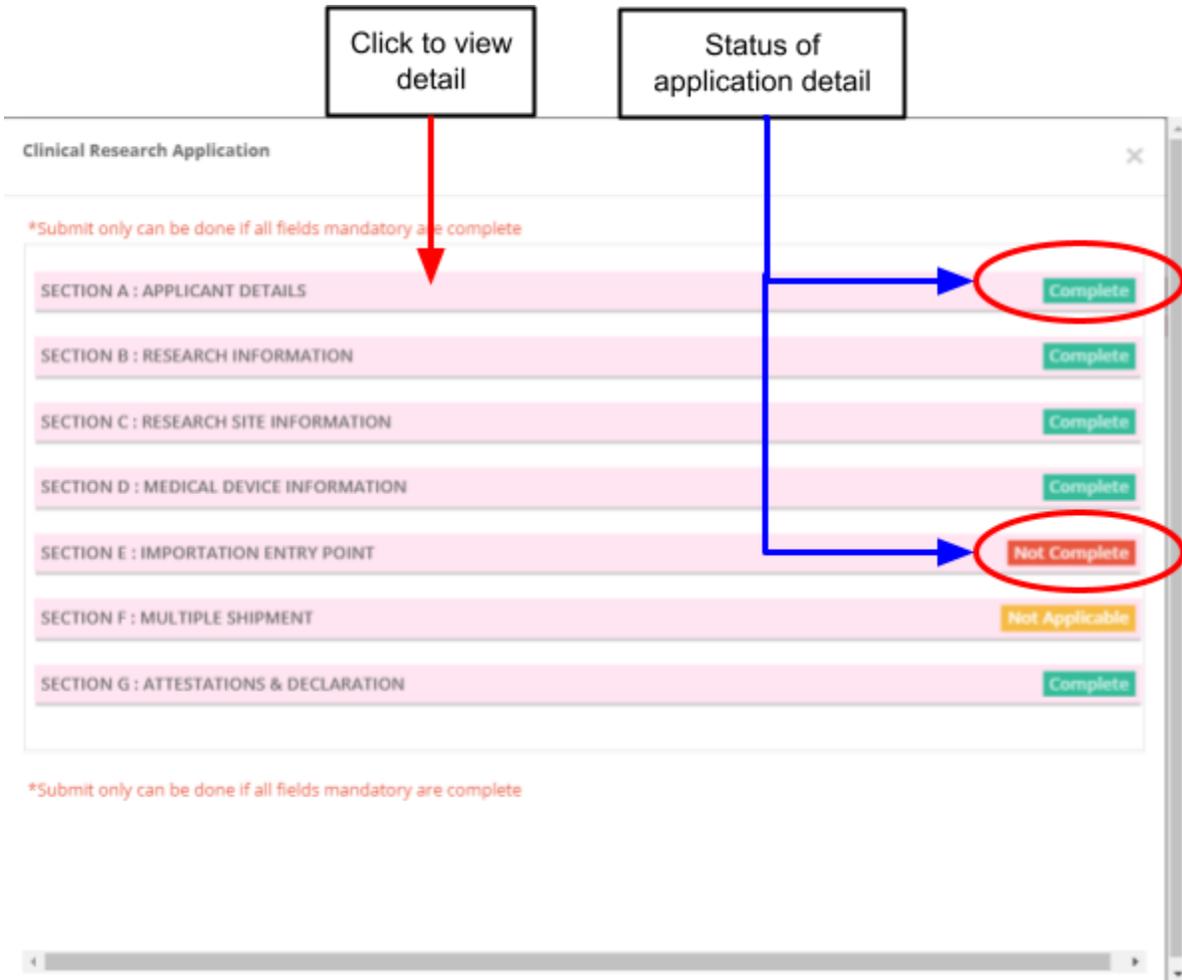


The button "submit" will be displayed, if all the form status "complete".The user

should complete all the form of application.
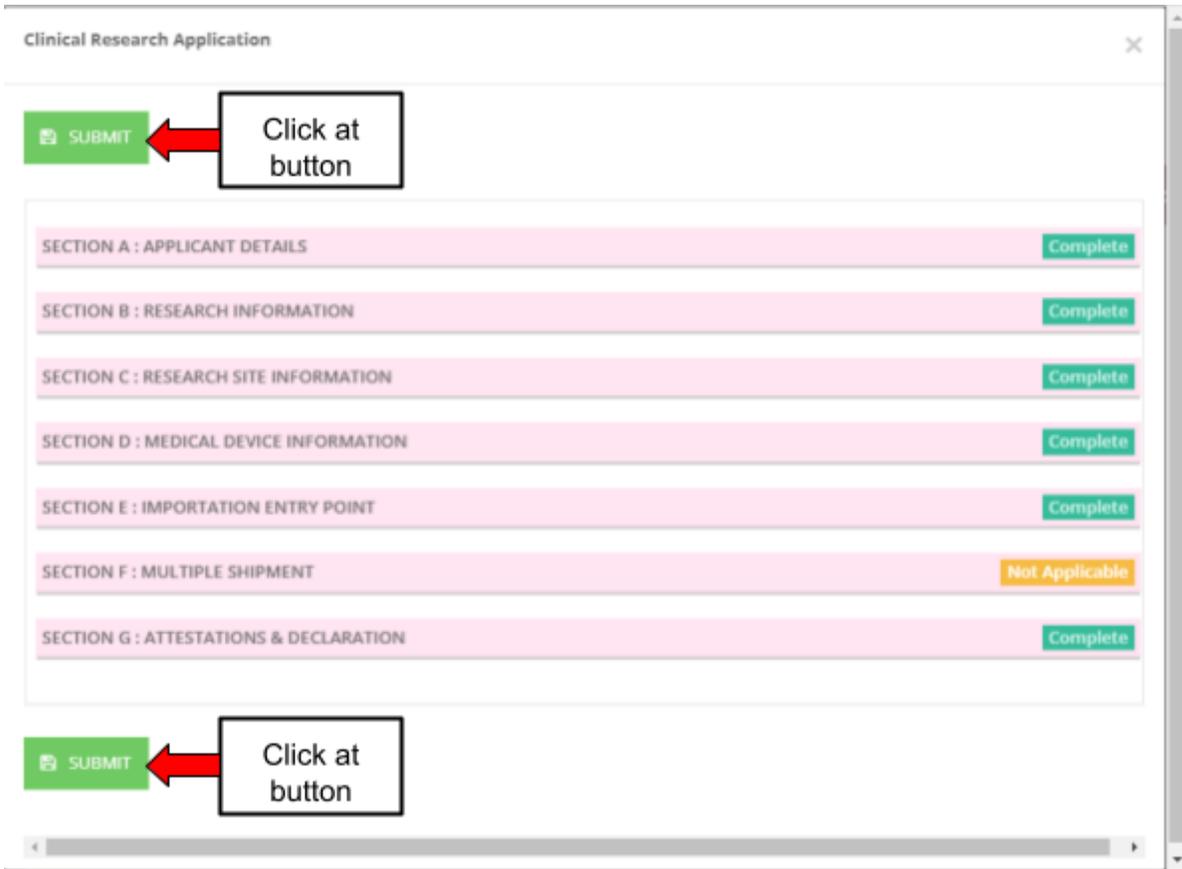
After user click button "Submit", the alert message will be displayed.



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

Once the user click "OK" button, the user will get the two notification emails which are the submitted application notice and the payment notice. Figure belows the email that received by the user.

Submitted application email notice
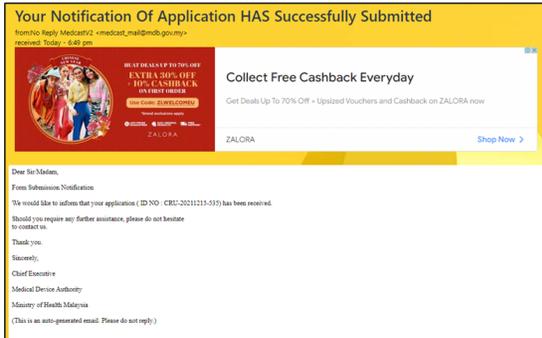
Payment email notice

After the application is successfully submitted, a message "Please submit the payment fee to ensure this submission can proceed to the next stage. For payment using Bank Draft, it is **COMPULSORY** to key-in Bank Draft number and amount." appeared.
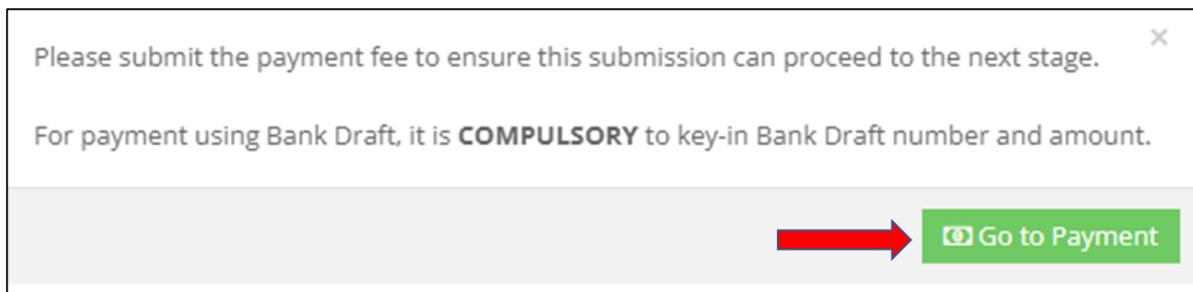


The user can click ⬛ Go to Payment button to make a payment or the user can click the ✕ icon to make a payment later.

The Figure below shows the page once the user click ⬛ Go to Payment . The user can pay using FPX method or Bankdraft method.
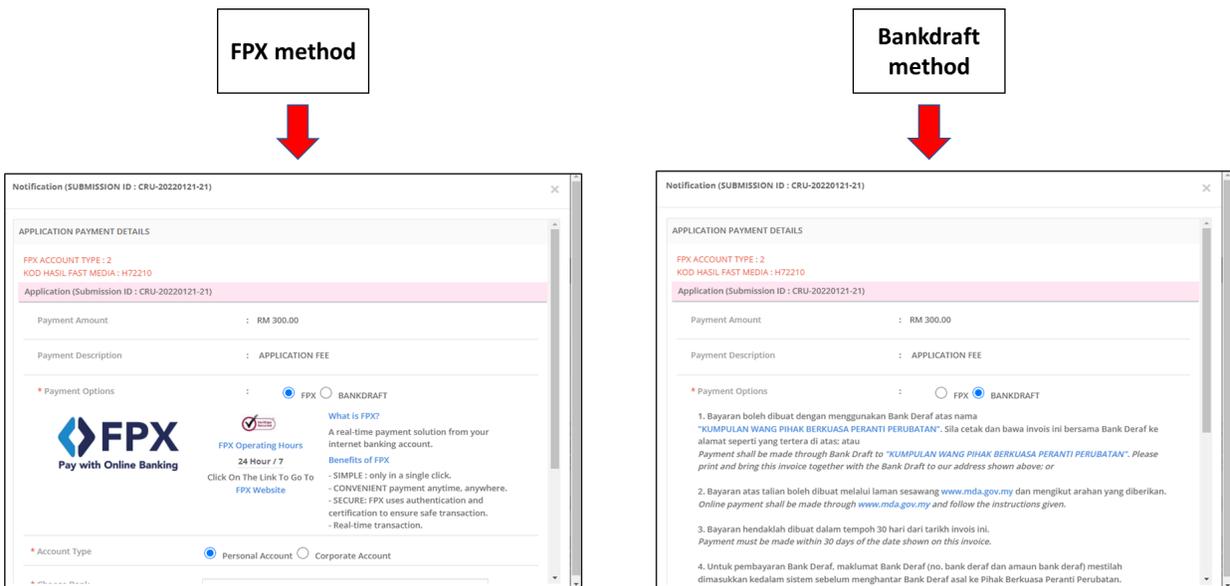
The Figure below shows the page if the user click the ✕ icon to make a payment later.

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

The user also can view and print the submitted application by go to [Notification List] then,

**1** Click **Q View** button, and the preview of the application appeared.

**2** Click **🖶 PRINT APPLICATION** button to print the submitted application.



**Click button to print the application**

Then, after the application goes through all the stages, the user will get email notification once the application is approved or rejected. Figure below shows the "Approval" and "Rejection" notification email that received by the user.

When the status of the application is "PRINT LETTER OF ACKNOWLEDGEMENT". To proceed to make a subsequent notification, The user must click **Print Letter** to generate the letter first. Then, refresh the page. Once the page is refreshed, the **Subsequent Notification** appeared and the status of the application is changed to "COMPLETE".
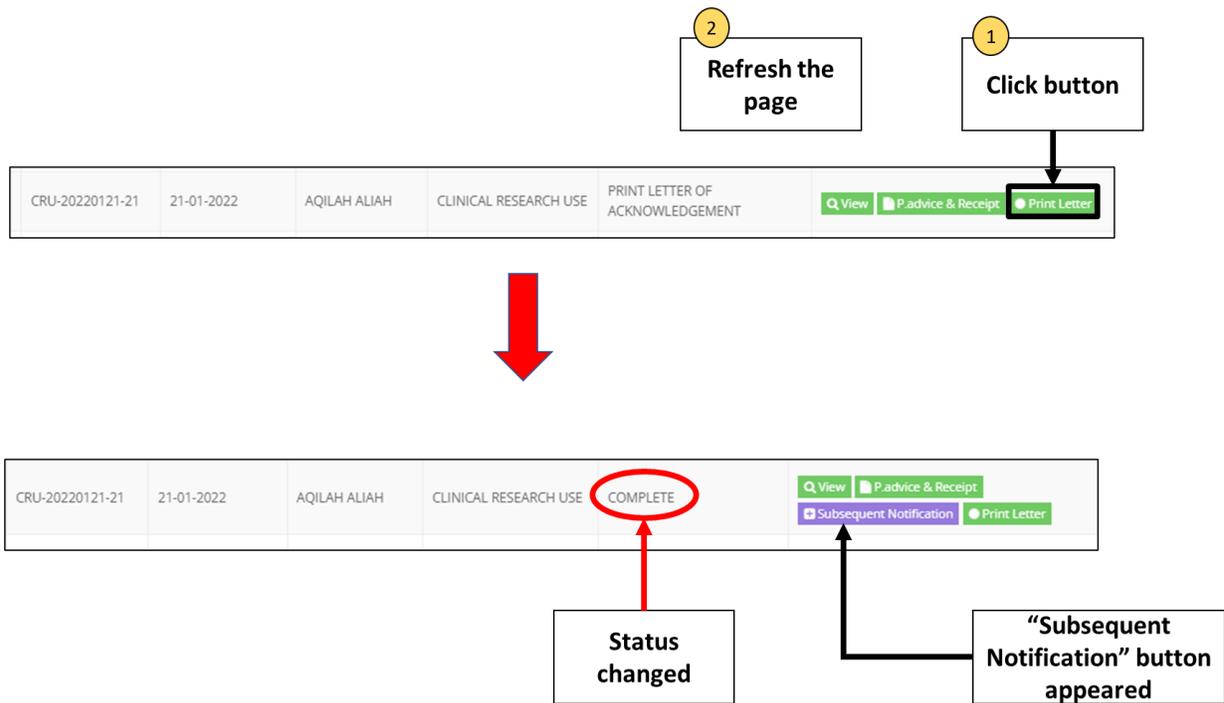


5  The user click at Notification List to view all the ACTIVE applications. applications. Several actions that can be made in the Notification List such as

- The user can update the application in the draft by clicking the **Update** button.

- The user can delete the application in the draft by clicking the 🗑 **Delete** button.

- The user can print e-Letter if the application is approved by clicking the ✱ **Print Letter** button.

- The user can make a subsequent notification for completed application by clicking the ➕ **Subsequent Notification** button.

**6** The user click at History to view all the Inactive 'COMPLETE' and rejected applications for both First Application and Subsequent. Activeness for rejected application is marked as 'ARCHIVED'.



| No | Submission ID | Submitted At | Application Type Name | Application Status Name | Created By | Activeness | Action |
|---|---|---|---|---|---|---|---|
| | | | | | | | |
| 1 | CRU-20211222-2 (6) | 22-12-2021 | SUBSEQUENT CLINICAL RESEARCH USE | REJECT | AQILAH ALIAH | ARCHIVED | Q View  ≣ Application History |
| 2 | CRU-20211222-2 (5) | 22-12-2021 | SUBSEQUENT CLINICAL RESEARCH USE | COMPLETE | AQILAH ALIAH | ACTIVE | Q View  ≣ Application History  ● Print Letter |
| 3 | CRU-20211222-4 (5) | 22-12-2021 | SUBSEQUENT CLINICAL RESEARCH USE | COMPLETE | AQILAH ALIAH | ACTIVE | Q View  ≣ Application History  ● Print Letter |

### b)   Subsequent application

User click on the Application List at Clinical Investigation > Clinical Research Use.
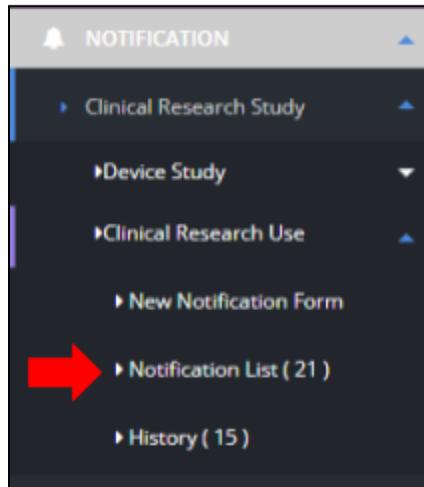
The system will display page of list application of Clinical Research Use..



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

If the subsequent application is in draft and the user click the **Subsequent Notification** button again, a "You have drafted (**No. Submission ID**) subsequent application for this notification." message appeared.



The user click "OK" to close the message.

Also, if the subsequent application is in process, if the applicant click the subsequent button, a "You have in process (**No. Submission ID**) subsequent application for this notification."message appeared.
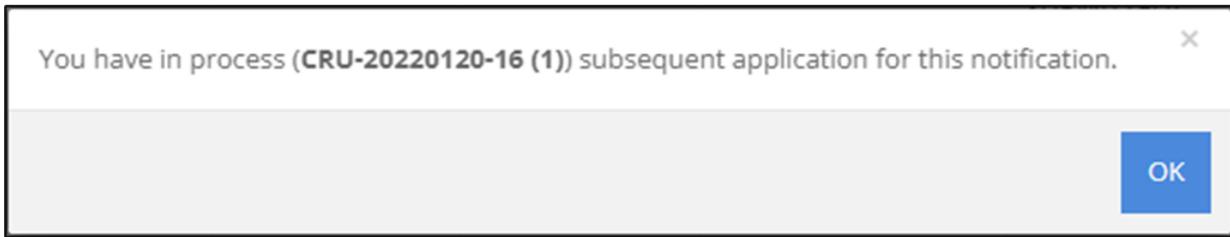
The user click "OK" to close the message.

Then, the user complete the Subsequent Application form. The user can make any changes in Section A, B, C, D, E and G. But in Section B, there a 3 fields are are which are **"Purpose Of Research", "National Medical Research Registry (NMRR) Registration ID"** and **"Protocol No"**. Therefore, the user are unable to make any changes to that 3 fields.
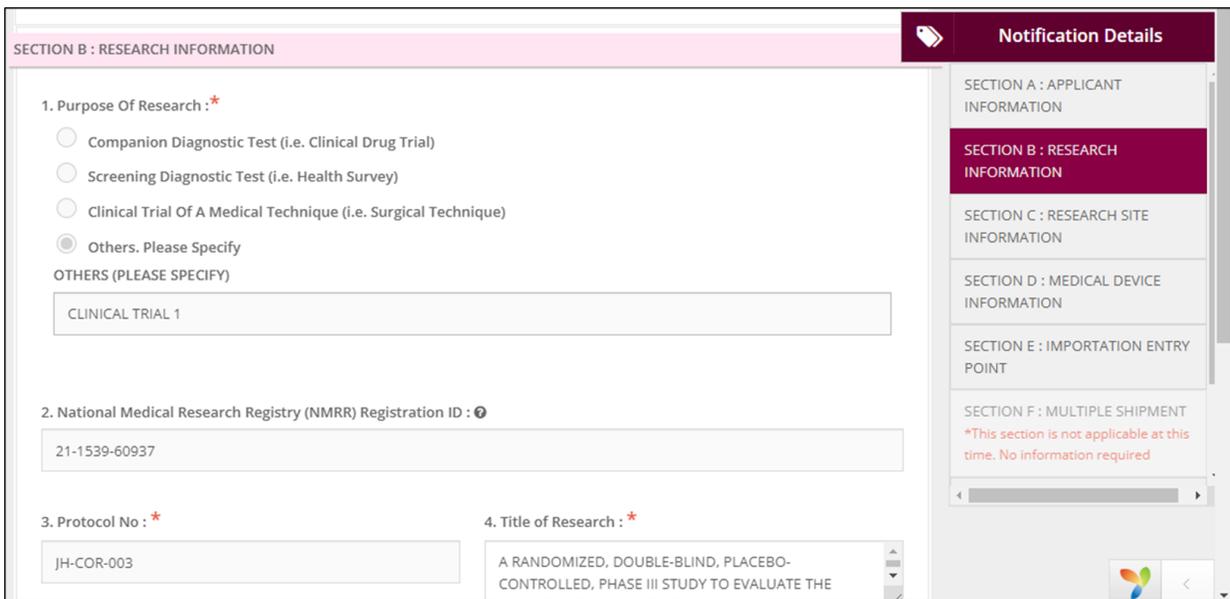


Next, the user review all information in Section A, B C, D, E and G and the user click on button **PREVIEW AND SUBMIT** .
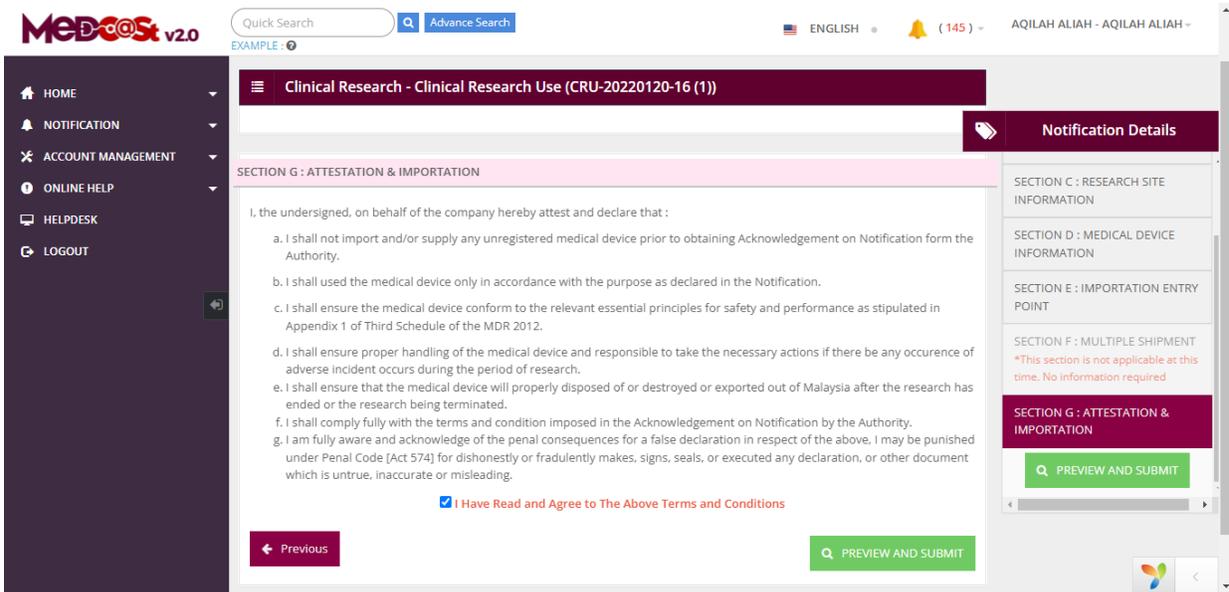
If all mandatory information has been filled out, button [Submit] and keyword [Complete] will display. If the the information is not completed, [Not Complete] keyword will display and button [Submit] will not display until all information is fill.

The status of application will be on evaluation stage.

And the user will get the submitted subsequent application notice emails. Figure belows the email that received by the user.
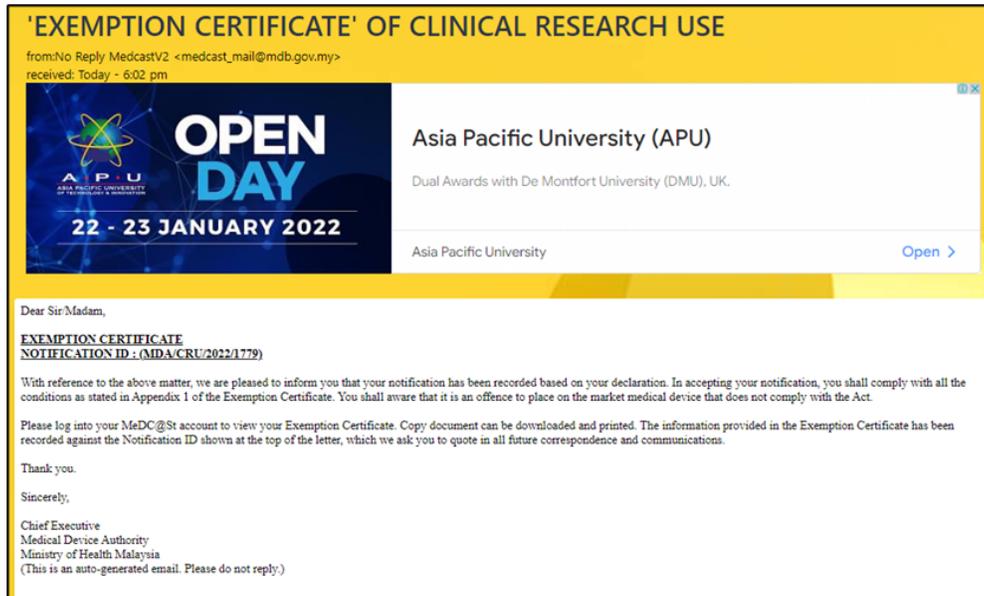


Then, after the application goes through all the stages, the user will get email notification once the application is approved or rejected. Figure below shows the "Approval" and "Rejection" notification email that received by the user.
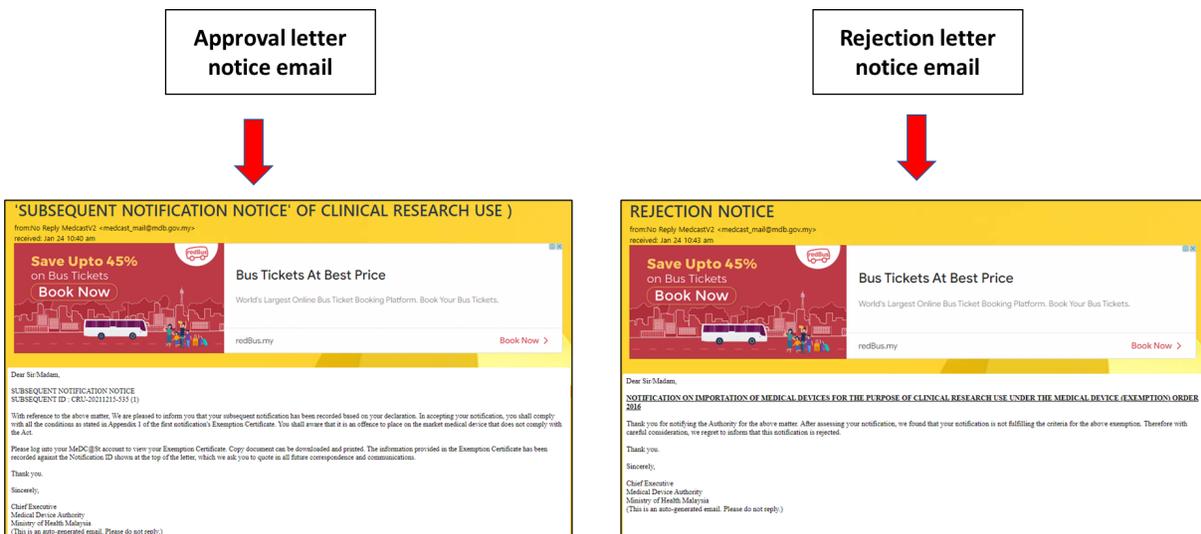
### 2.2.2 RETURN FOR CHANGES

If back end user make the process "RETURN FOR CHANGES" to front end user, the user will get the "RETURN FOR CHANGES" notification email. The Figure belows shows the "RETURN FOR CHANGES" notification email that received by the user.
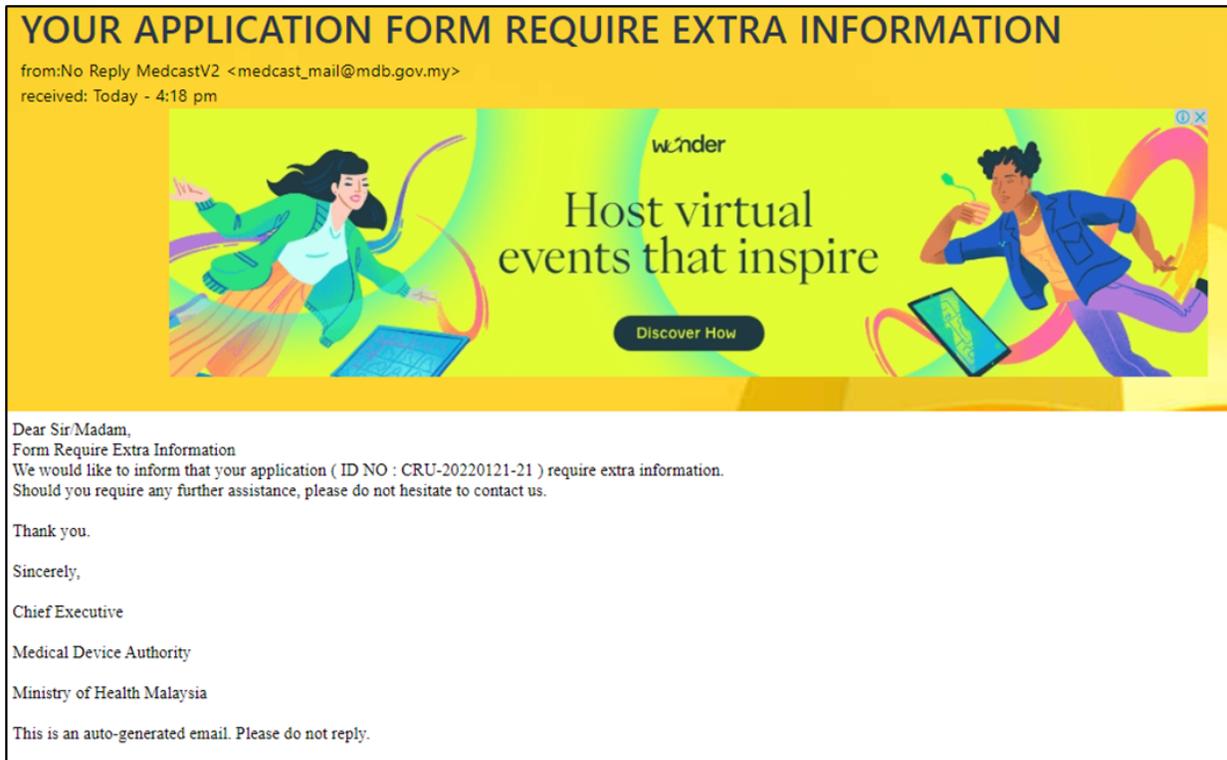


Also, the status of application will be changed and the Front End User should make the changed at application form that applied.
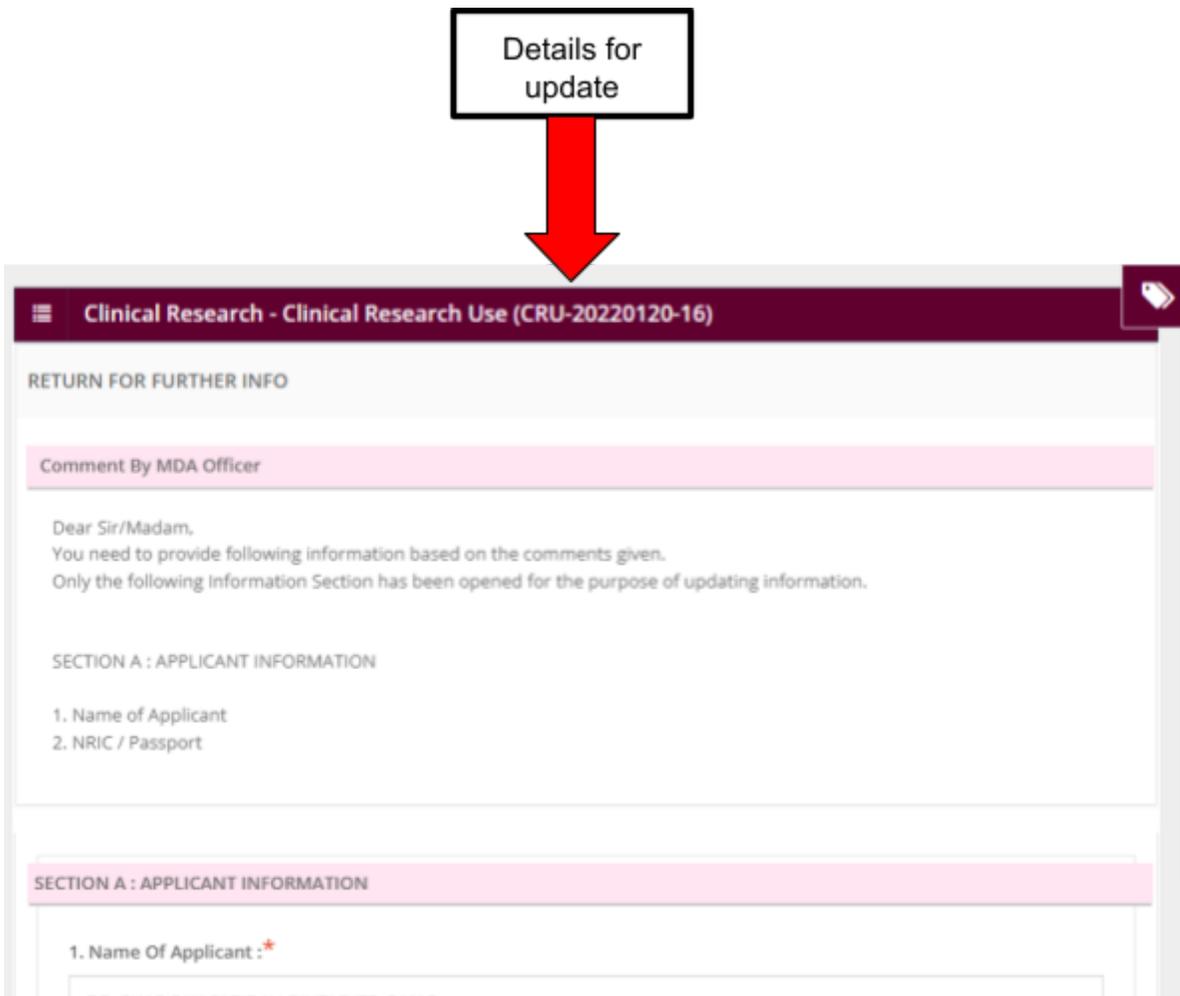
The figure below shows the application status that changed in front end user.

After that, user should click at **✎ Update** 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.

SECTION A : APPLICANT INFORMATION

1. Name of Applicant
2. NRIC / Passport

Details can be edited

SECTION A : APPLICANT INFORMATION

1. Name Of Applicant :*

DR. SHARIFAH FARIDAH BINTI SYED OMAR

2. NRIC / Passport :* ❓                3. Designation :*

990406107777                            PRINCIPAL INVESTIGATOR
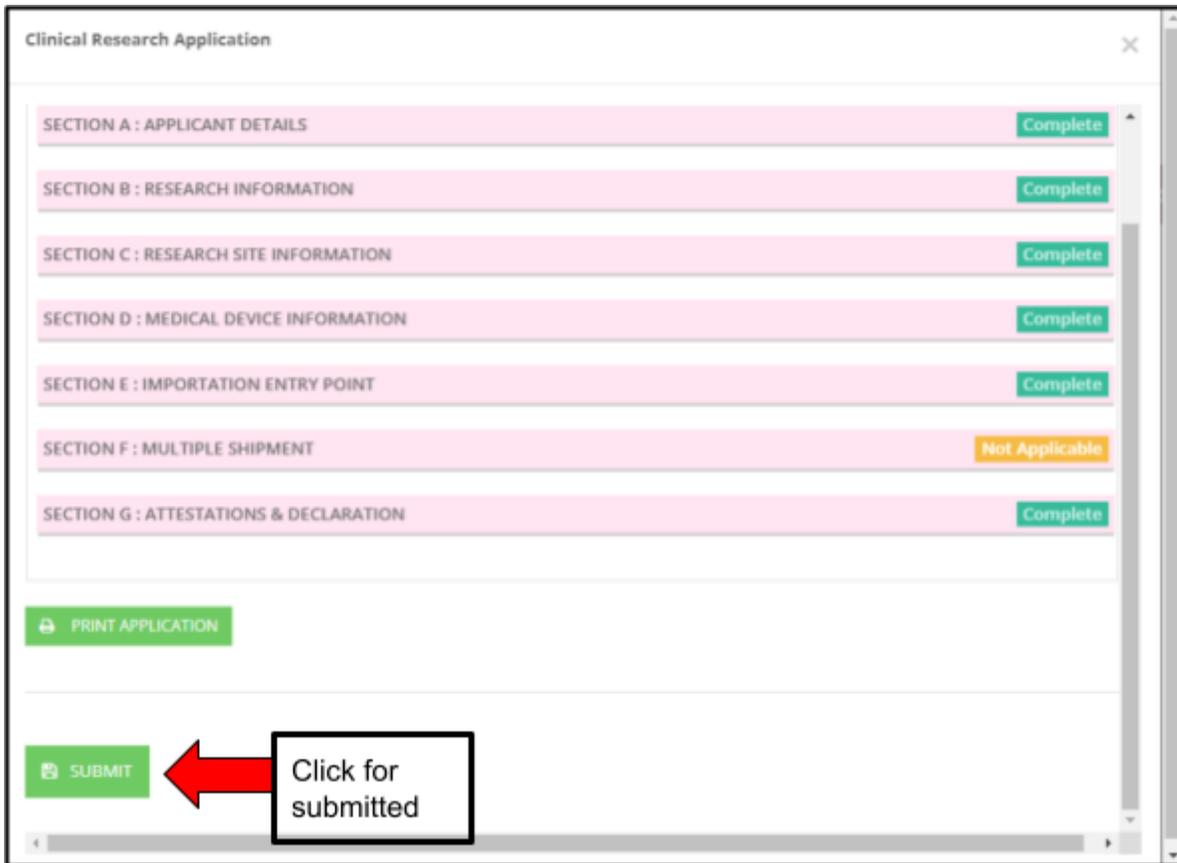
4. Organisation Information

Organisation Name*

MEDICAL RESEARCH ETHICS COMMITTEE, UNIVERSITY MALAYA MEDICAL CENTRE

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

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



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