

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 :



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1.0 INTRODUCTION

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

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

1.1 SYSTEM ACCESS

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

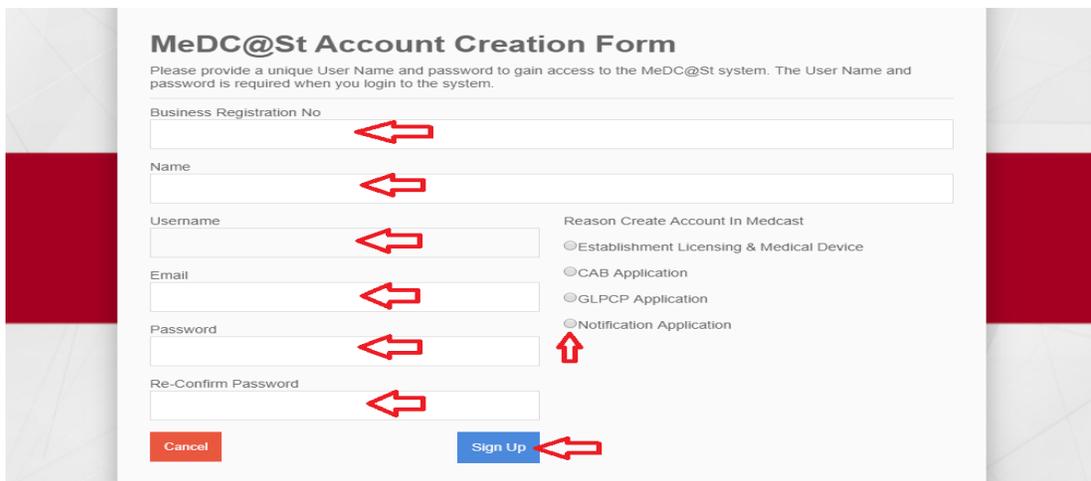
<https://medcast.mda.gov.my>

1.1.1 CREATE ACCOUNT

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

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

click  for new registration.



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

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

1.1.2 LOGIN

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

MeDC@St v2.0 MEDICAL DEVICE CENTRALISED ONLINE APPLICATION SYSTEM

Username
Enter username ←
Username cannot be blank.

Password
Enter password ←
Password cannot be blank.

Sign Up | Reset Password | FAQ | Helpdesk

Login ←

Pengumuman

ANNOUNCEMENT - ABOUT MeDC@St (2017-11-16) New!
MeDC@St is a web-bas..[Read More..](#)

SEMINAR WITH MEDICAL DEVICE INDUSTRY 2017 (2017-11-16) New!
Greetings from the A..[Read More..](#)

Optimal display using browser
with resolution of 1024 X 768 pixels

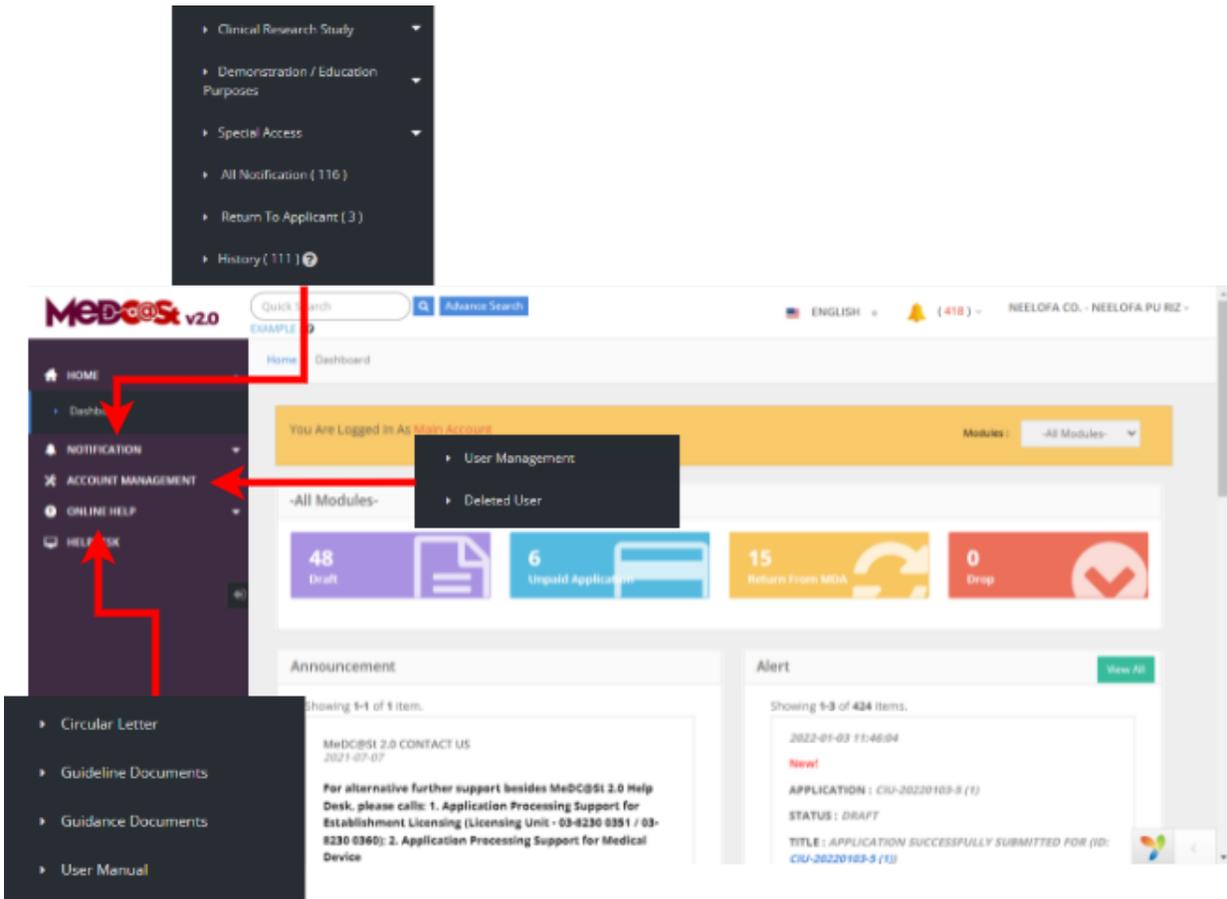
User has to log into the system using registered Username and its respective

Password. Click  to proceed.

2.0 FUNCTIONS

2.1 DASHBOARD

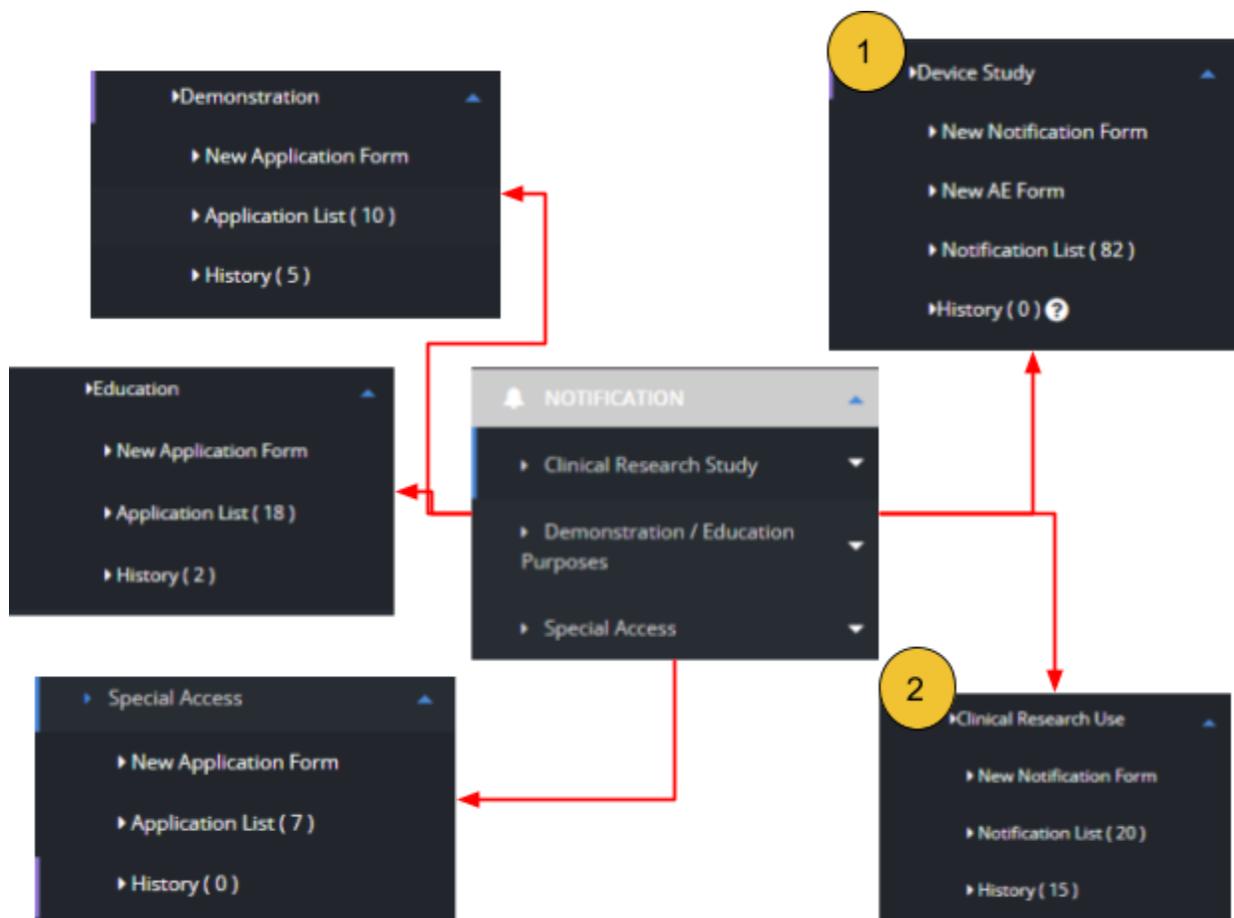
Below show the Dashboard page that will appear once Notification Module has logged into the system successfully.



2.2 MENU NOTIFICATION REGISTRATION

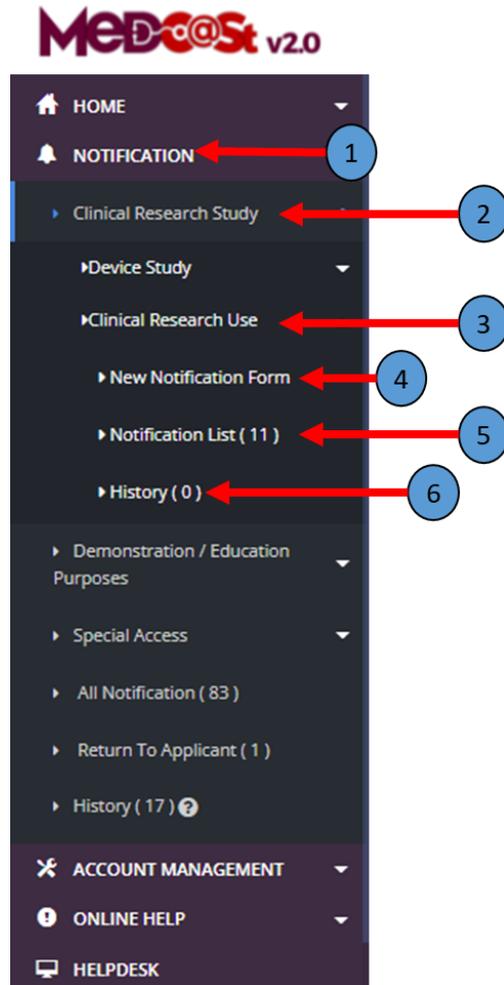
Menu Notification Registration has four type of notification which are *Clinical Research Study*, *Demonstration/Education Purposes* and *Special Access*. However, Clinical Investigational have three type which are *Investigational Use*, *Clinical Research Use* and *Notification of Change*. User should 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.

The screenshot shows the 'Clinical Research - Clinical Research Use (CRU-20220106-2)' application form. The form is divided into several sections:

- SECTION A: APPLICANT INFORMATION**
 - 1. Name Of Applicant *
 - 2. NRIC / Passport *
 - 3. Designation *
- SECTION B: ORGANISATION INFORMATION**
 - 4. Organisation Information
 - Organisation Name *
 - Address Of Organisation *

On the right side, there is a 'Notification Details' sidebar with the following sections:

- SECTION C: RESEARCH SITE INFORMATION
- SECTION D: MEDICAL DEVICE INFORMATION
- SECTION E: IMPORTATION ENTRY POINT
- SECTION F: MULTIPLE SHIPMENT
*This section is not applicable at this time. No information required
- SECTION G: ATTESTATION & IMPORTATION

At the bottom right, there is a green button labeled 'PREVIEW AND SUBMIT'.

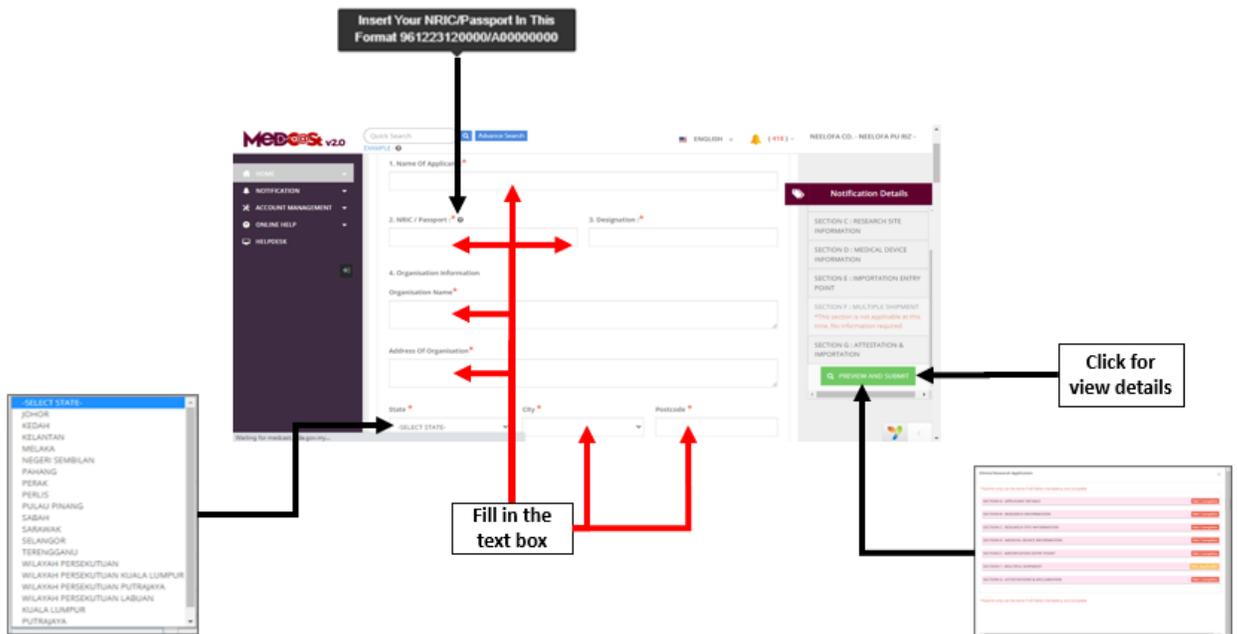
Callouts in the image indicate the following actions:

- Red arrows point to the 'Clinical Research - Clinical Research Use (CRU-20220106-2)' breadcrumb and the 'HOME' menu item.
- Black arrows point to the 'Hide Main Menu' and 'Hide Notification Details' buttons at the bottom.

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

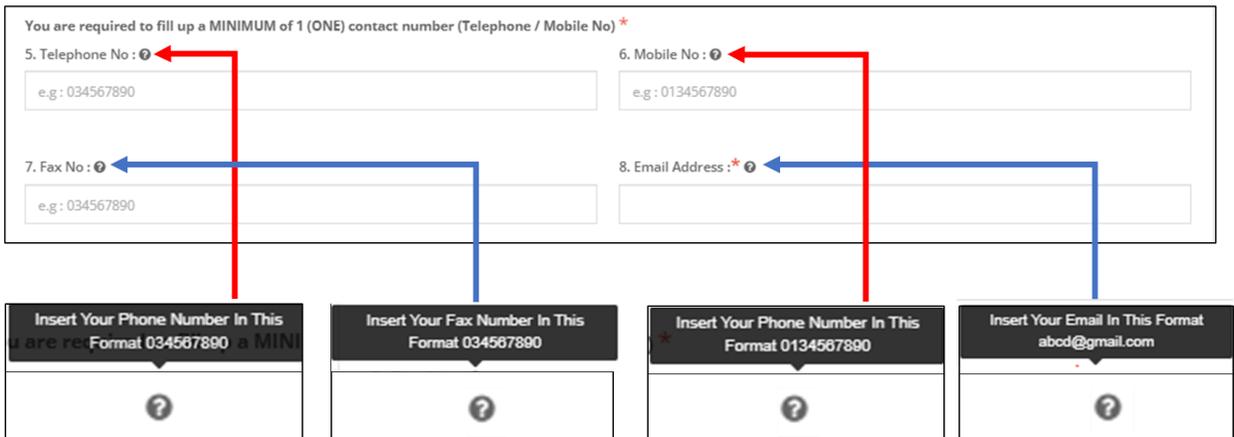


1. Name of Applicant
 The user should fill the name in the text box that provided.
2. NRIC /Passport
 The user must fill in the form according to the format displayed on the figure below. The user should click at  to appear the format.
3. Designation

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.

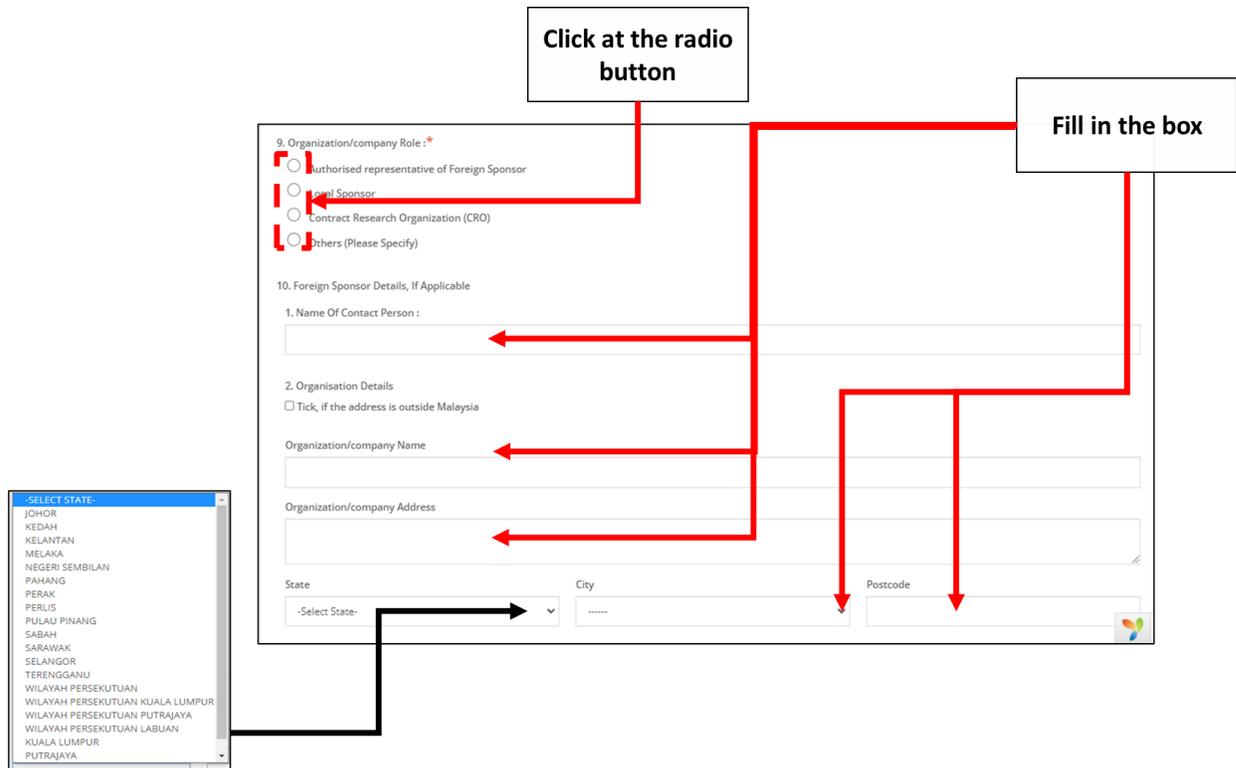
The user must fill the Mobile No in an integer. User can see the format which click at . If user fill in the form except number or more than eleven number, the message “Field must have NUMBERS between 3 - 11 numeric” will appear.

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

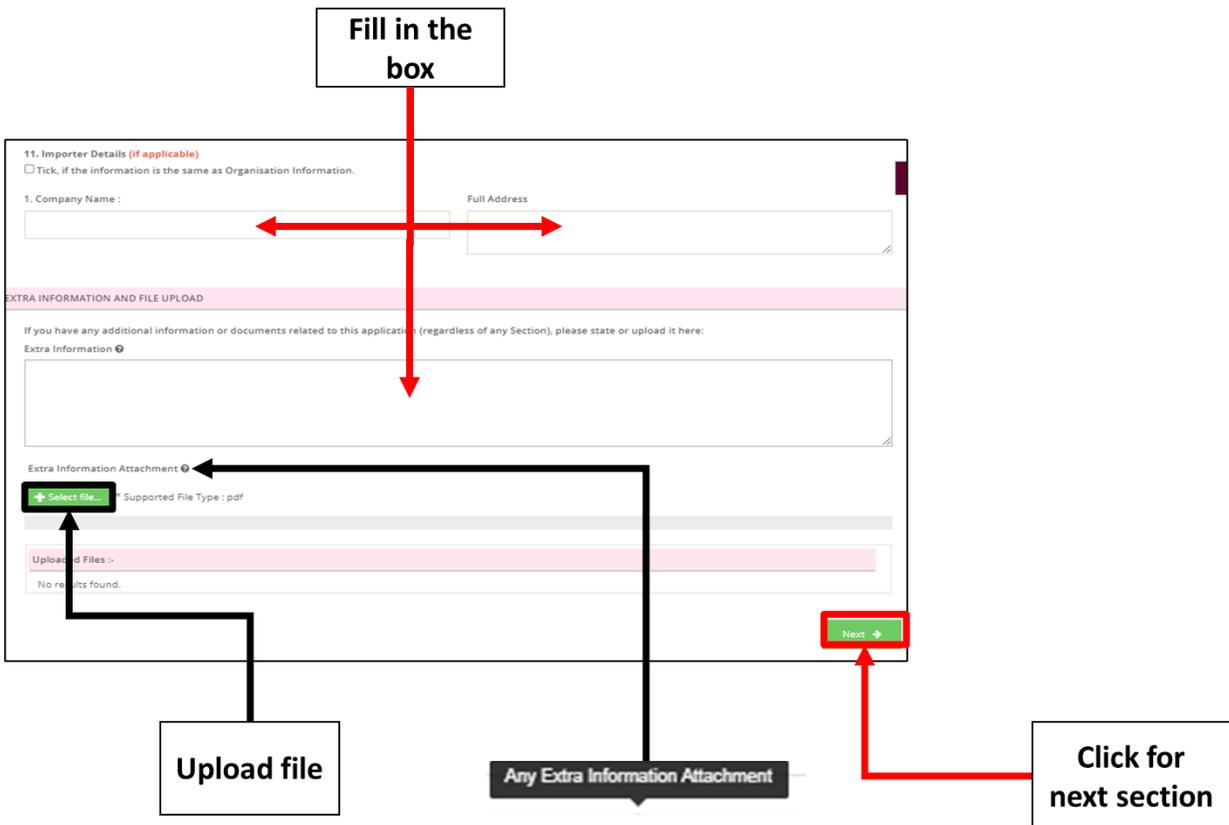
1. Name of Contact Person

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.”



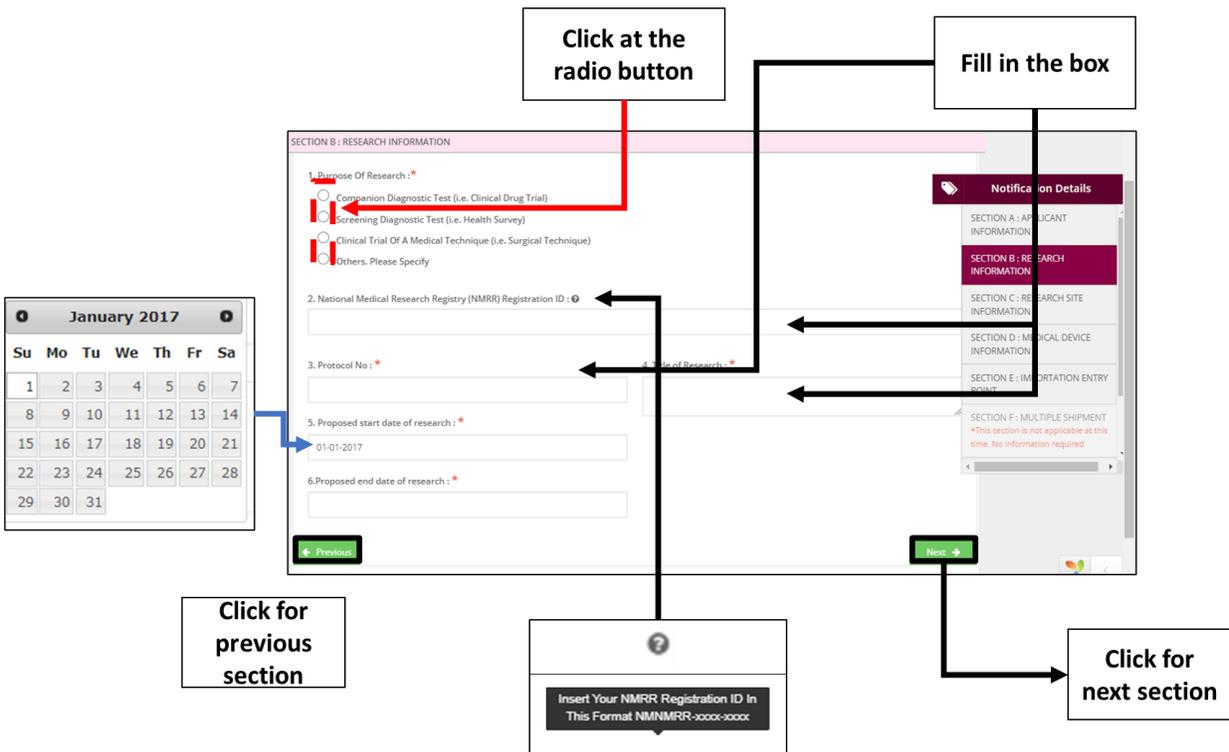
11. Importer Details (if applicable)

- 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  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 the purpose 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

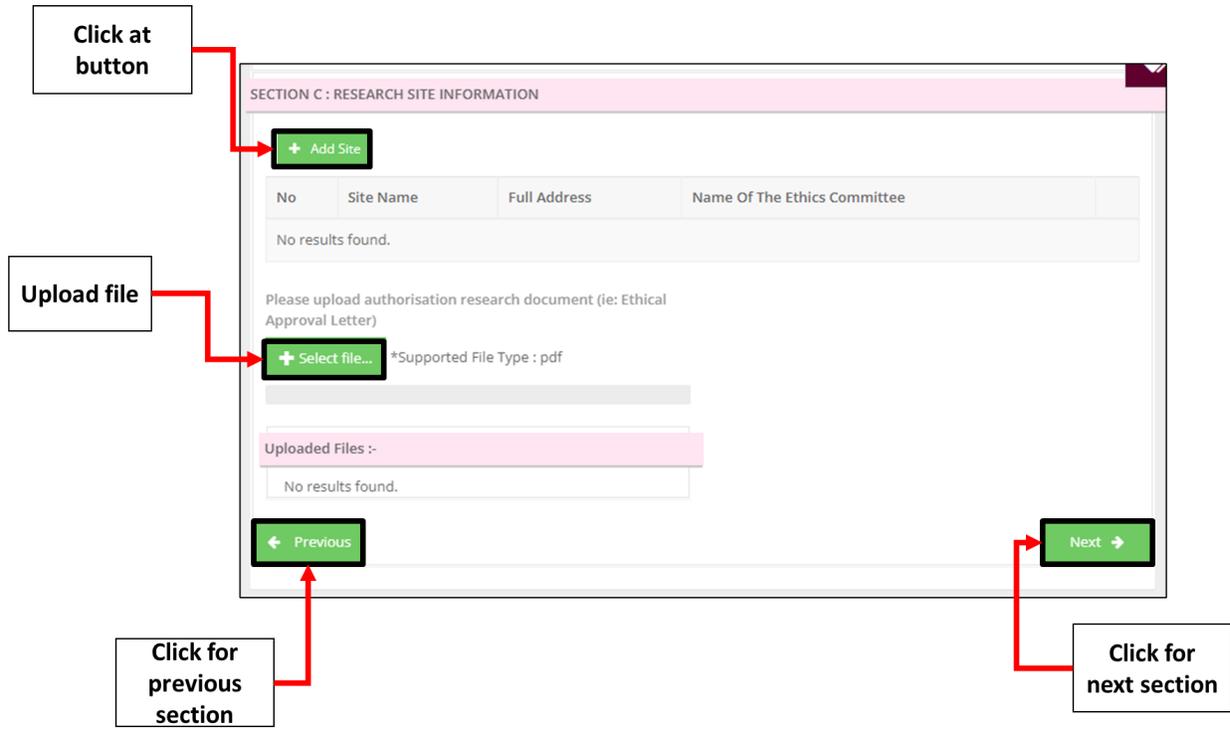


that shown in figure above. Then, user should click at button

next section.



Section C: Research Site Information



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.

The screenshot shows a web form titled "Add Trial Site" with a close button (X) in the top right corner. The form contains three text input fields:

- 1. Site Name*
- 2. Full Address*
- 4. Name Of The Ethics Committee : *

Below the form, there are two callout boxes with arrows pointing to the form elements:

- A red box labeled "Fill in the box" has a red line and three arrows pointing to the three text input fields.
- A black box labeled "Click for save" has a black arrow pointing to a green "Save" button located at the bottom right of the form.

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.

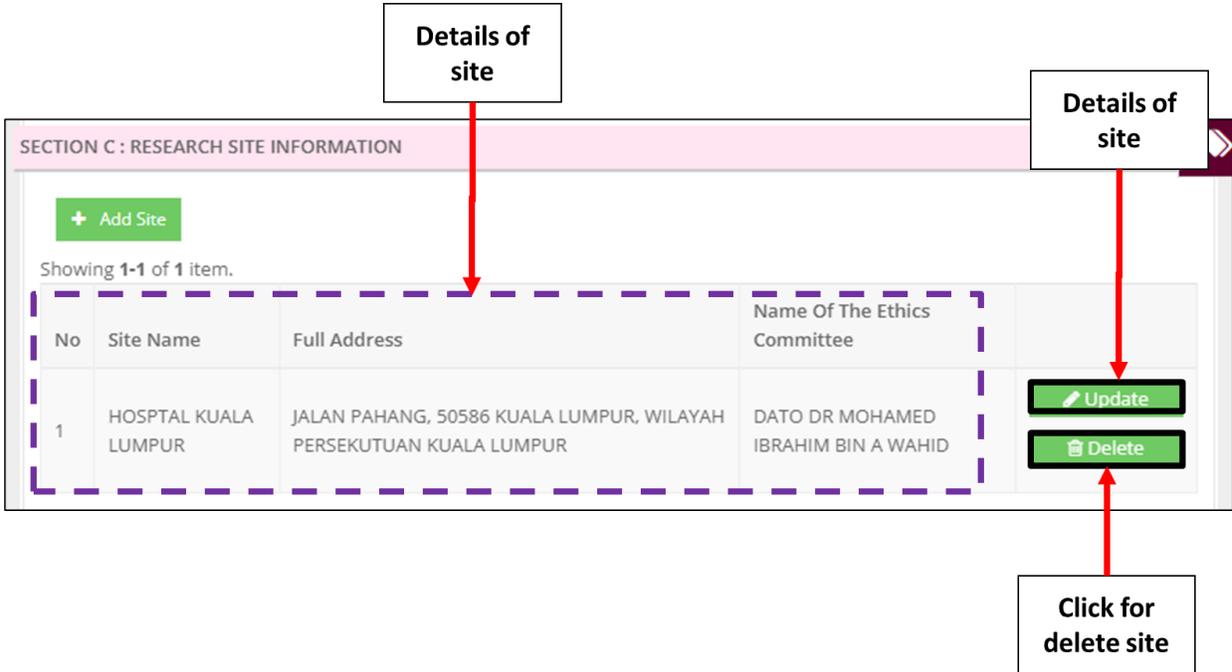
2. Full Address

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



SECTION C : RESEARCH SITE INFORMATION

[+ Add Site](#)

Showing 1-1 of 1 item.

No	Site Name	Full Address	Name Of The Ethics Committee	
1	HOSPITAL KUALA LUMPUR	JALAN PAHANG, 50586 KUALA LUMPUR, WILAYAH PERSEKUTUAN KUALA LUMPUR	DATO DR MOHAMED IBRAHIM BIN A WAHID	Update Delete

Details of site (points to table)

Details of site (points to table)

Click for delete site (points to Delete button)

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

The screenshot shows a web form titled "Add Trial Site" with a close button (X) in the top right corner. The form contains three input fields:

- 1. Site Name ***: A text box containing "HOSPITAL KUALA LUMPUR".
- 2. Full Address ***: A text box containing "JALAN PAHANG, 50586 KUALA LUMPUR, WILAYAH PERSEKUTUAN KUALA LUMPUR".
- 4. Name Of The Ethics Committee : ***: A text box containing "DATO DR MOHAMED IBRAHIM BIN A WAHID".

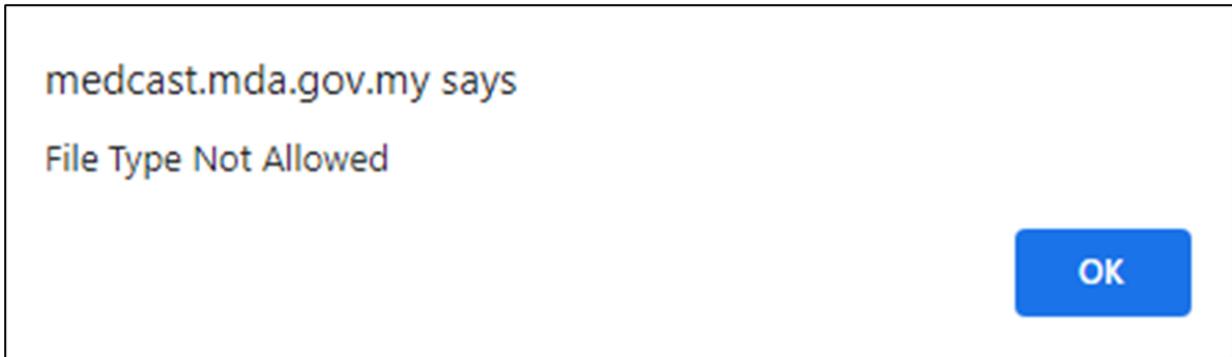
Below the form, there is a "Save" button. A red arrow points from a callout box labeled "Click for save" to the "Save" button.

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

The screenshot shows an alert dialog box titled "Delete Trial site?". The dialog has a close button (X) in the top right corner. At the bottom of the dialog, there are two buttons: "Cancel" and "OK".

- A red arrow points from a callout box labeled "Click for cancel deleted" to the "Cancel" button.
- A red arrow points from a callout box labeled "Click for proceed delete" to the "OK" button.

After the user completely fill the site details, the user must upload the authorisation research document (ie: Ethical Approval Letter) by clicking  button. The file must be in pdf. If the user upload file other than pdf, a pop-out message “File Type Not Allowed” appeared.



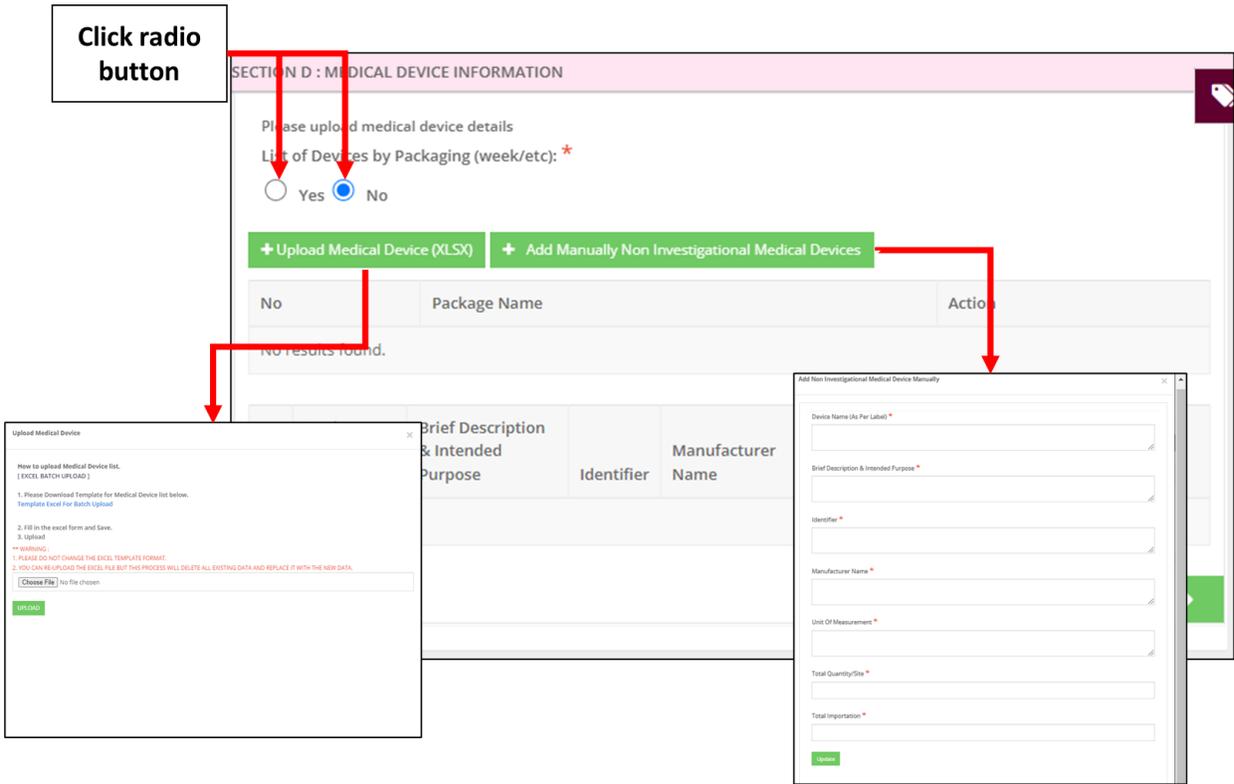
If user want back to previous section, user should click at button

← Previous

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

Next →

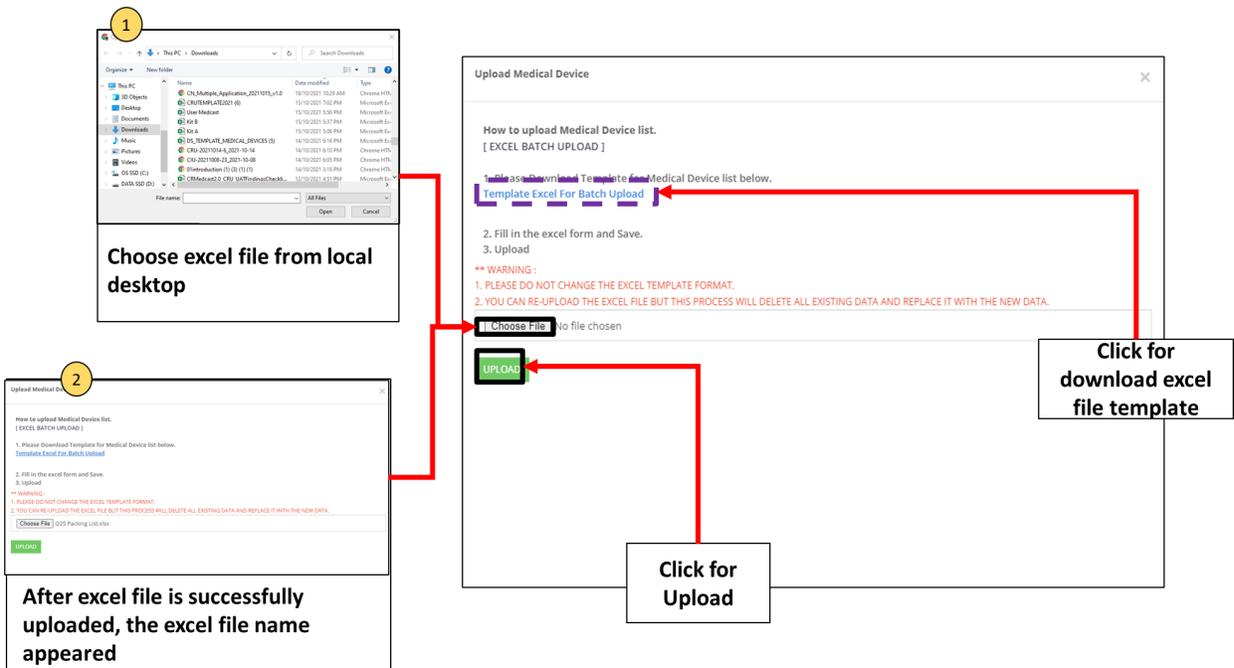
Section D: Medical Device Details



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

“Yes” or “No” . The user choose “No” Yes 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.



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.

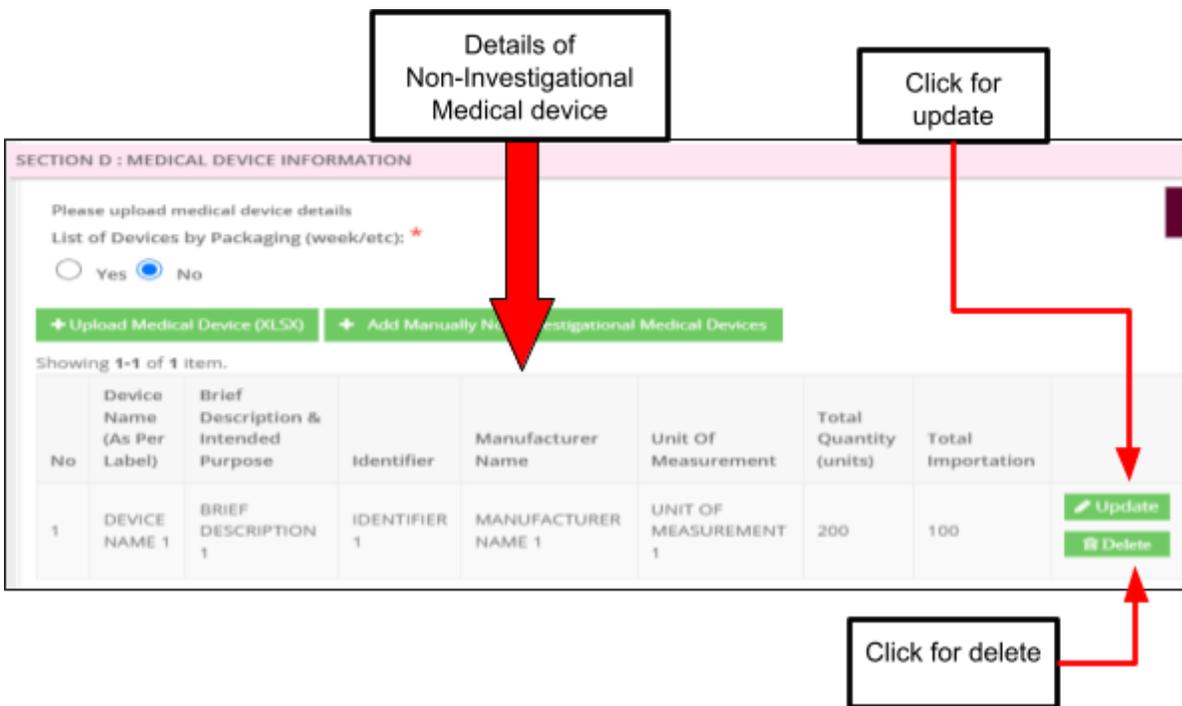
The screenshot shows a web form titled "Add Non Investigational Medical Device Manually". The form contains several text input fields, each with a red asterisk indicating a required field. The fields are: "Device Name (As Per Label)", "Brief Description & Intended Purpose", "Identifier", "Manufacturer Name", "Unit Of Measurement", "Total Quantity/Site", and "Total Importation". A red arrow points from a box labeled "Fill in the box" to the top of the form. Another red arrow points from a box labeled "Click for save" to a green "Update" button at the bottom left of the form.

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  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 →

Click for delete

Click for update

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

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

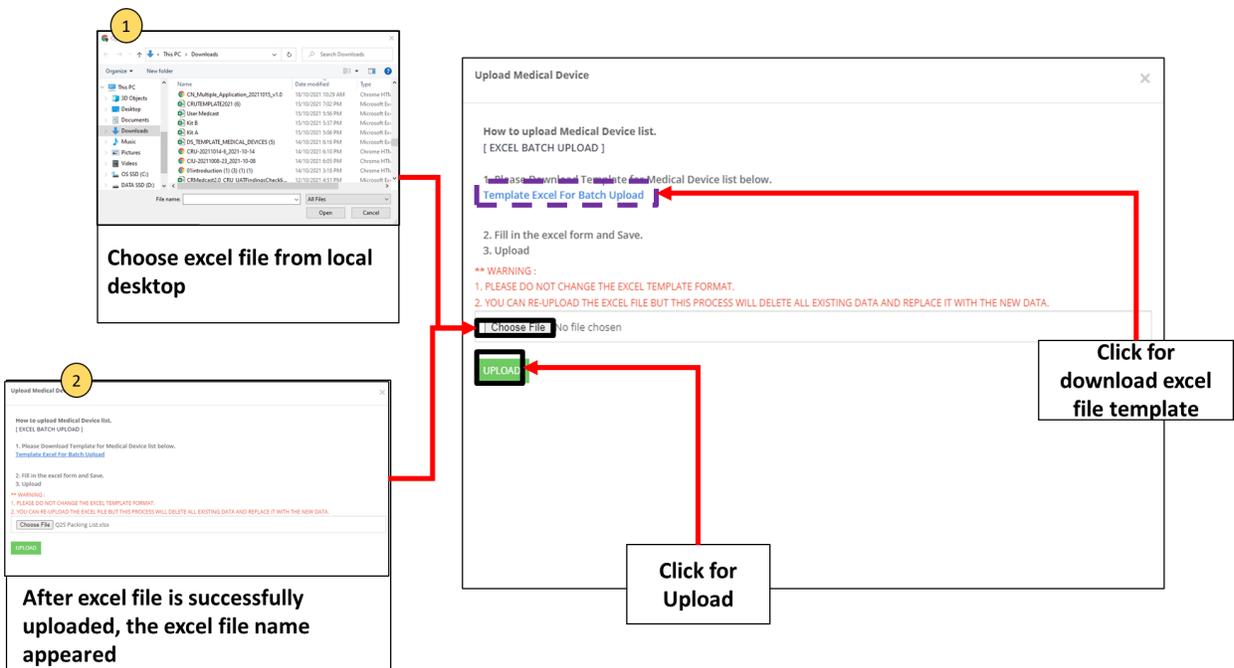
1

List of Devices by Packaging (week/etc) -> The user should click in radio button “Yes” or “No”. The user choose “Yes”   . Then, the user must fill the

“Package Name” and proceed to click the  button. The User can update and delete the package name.

2

The user should click at  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.



3

The user should click at  to fill the details of Non-Investigational Medical Device manually. The form will be displayed in figure below.

The screenshot shows a web form titled "Add Non Investigational Medical Device Manually". The form contains several text input fields, each with a red asterisk indicating a required field. The fields are: "Device Name (As Per Label)", "Brief Description & Intended Purpose", "Identifier", "Manufacturer Name", "Unit Of Measurement", "Total Quantity/Site", and "Total Importation". A red arrow points from a box labeled "Fill in the box" to the top of the form. Another red arrow points from a box labeled "Click for save" to a green "Update" button at the bottom left of the form.

Add Non Investigational Medical Device

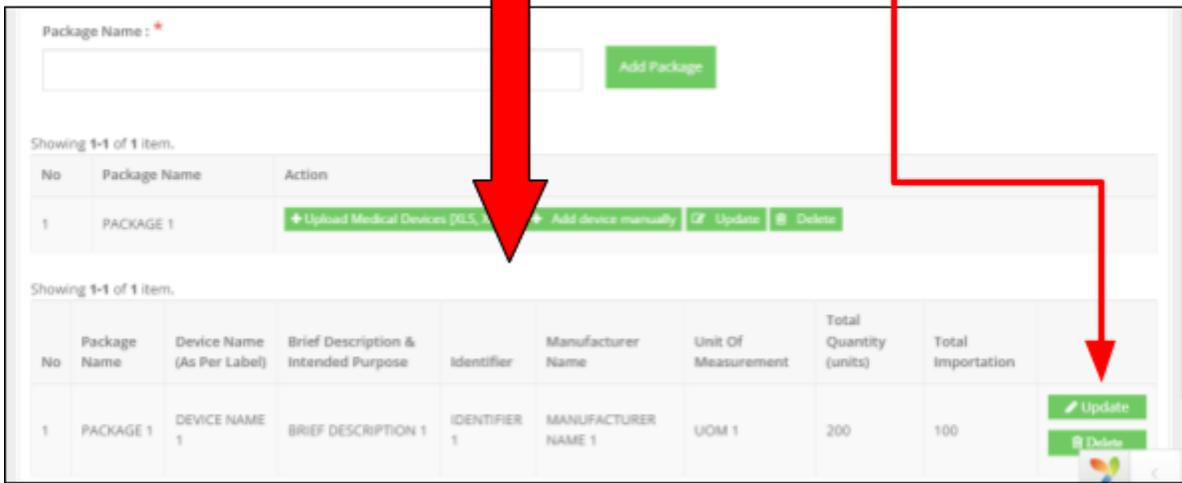
8. Device Name (As Per Label) -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name (As Per Label) cannot be blank." will appear.
9. Brief Description & Intended Purpose -> The user should fill in the textbox that provided. If the user don't fill 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  to save the details and the details will be displayed in table that shown in the figure below.

Details of Non-Investigational Medical device

Click for update



Click for delete

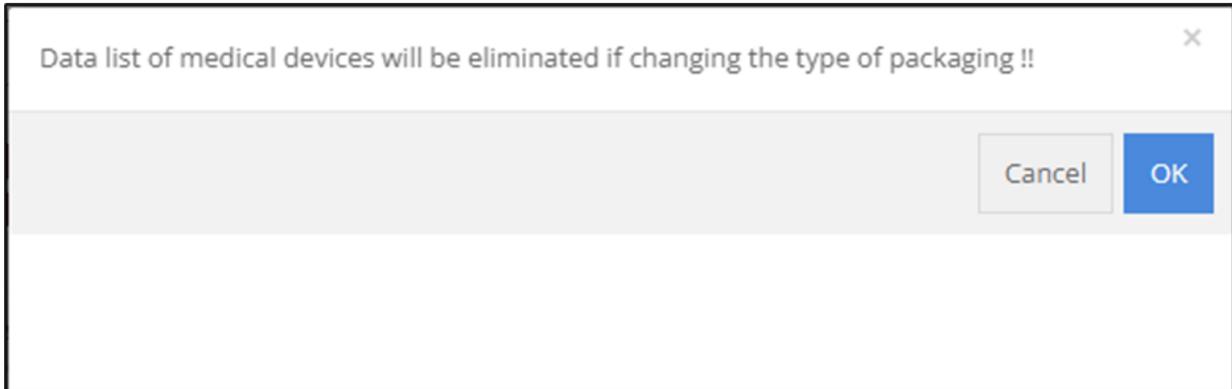
No	Package Name	Action	
1	PACKAGE 1	+ Upload Medical Devices (DLS, ...)	+ Add device manually Update Delete

No	Package Name	Device Name (As Per Label)	Brief Description & Intended Purpose	Identifier	Manufacturer Name	Unit Of Measurement	Total Quantity (units)	Total Importation	
1	PACKAGE 1	DEVICE NAME 1	BRIEF DESCRIPTION 1	IDENTIFIER 1	MANUFACTURER NAME 1	UOM 1	200	100	Update Delete

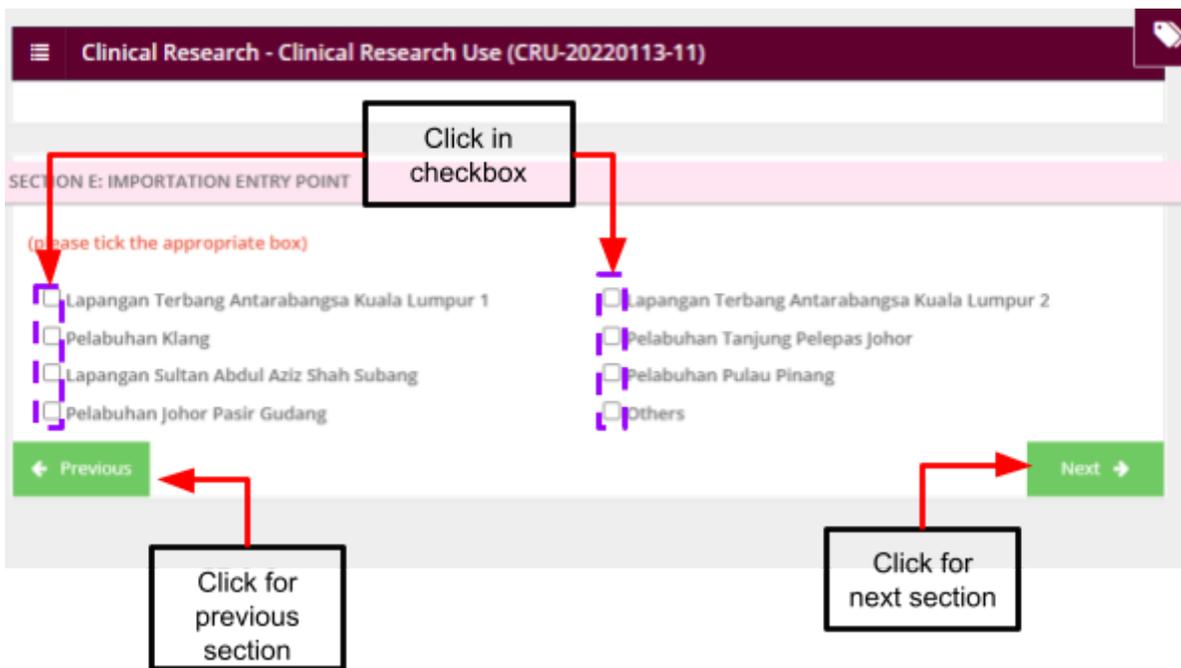
If user want back to previous section, user should click at button .

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

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

A green rectangular button with a white left-pointing arrow and the text "Previous".

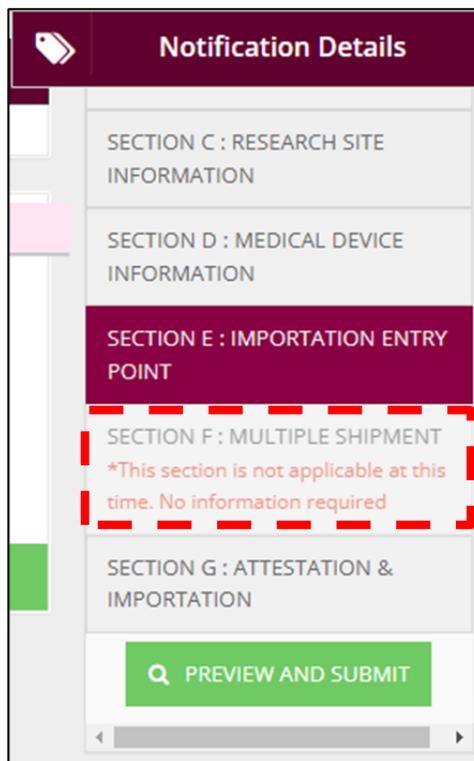
. that shown in figure above. Then, user should click at button

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

to the next section.

Section F: Multiple Shipment (Disabled)

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

A screenshot of a mobile application interface titled "Notification Details". The form contains several sections: SECTION C: RESEARCH SITE INFORMATION, SECTION D: MEDICAL DEVICE INFORMATION, SECTION E: IMPORTATION ENTRY POINT (highlighted in maroon), SECTION F: MULTIPLE SHIPMENT (highlighted with a red dashed border and containing the text "*This section is not applicable at this time. No information required"), and SECTION G: ATTESTATION & IMPORTATION. At the bottom of the form is a green button labeled "PREVIEW AND SUBMIT".

Section G: Attestations & Importation

The screenshot shows a form titled "SECTION G : ATTESTATION & IMPORTATION". The form contains a declaration: "I, the undersigned, on behalf of the company hereby attest and declare that :". Below this are seven numbered items (a-g) detailing the user's obligations regarding the importation and use of medical devices. At the bottom of the form, there is a checkbox labeled "I Have Read and Agree to The Above Terms and Conditions". To the left of the checkbox is a purple button with a left arrow and the text "Previous". To the right is a green button with a magnifying glass icon and the text "PREVIEW AND SUBMIT". Three callout boxes with arrows point to these elements: "Click for previous section" points to the "Previous" button, "Click in checkbox" points to the checkbox, and "Click for view and submit" points to the "PREVIEW AND SUBMIT" button.

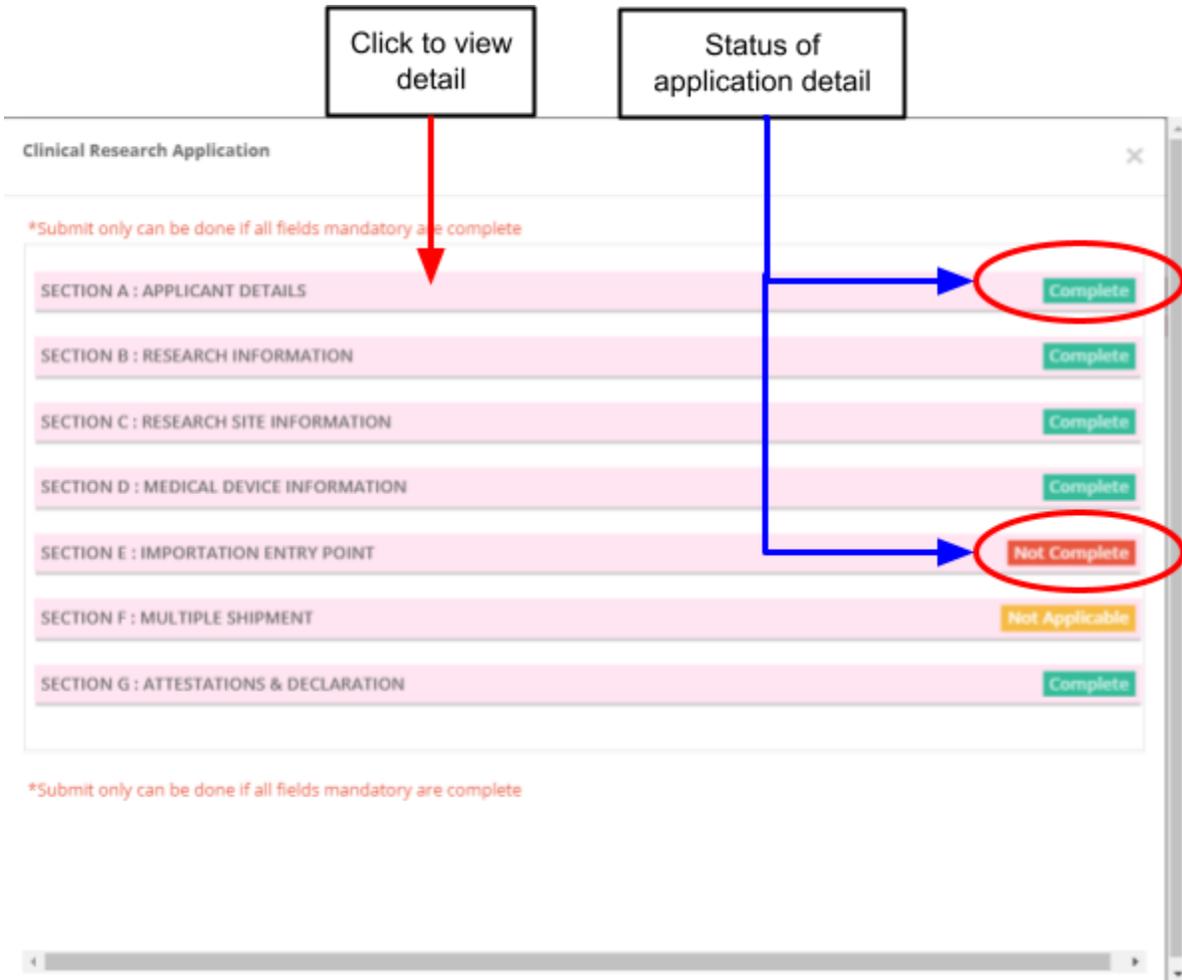
The user should click in checkbox that shown in figure above to agree of term and conditions.



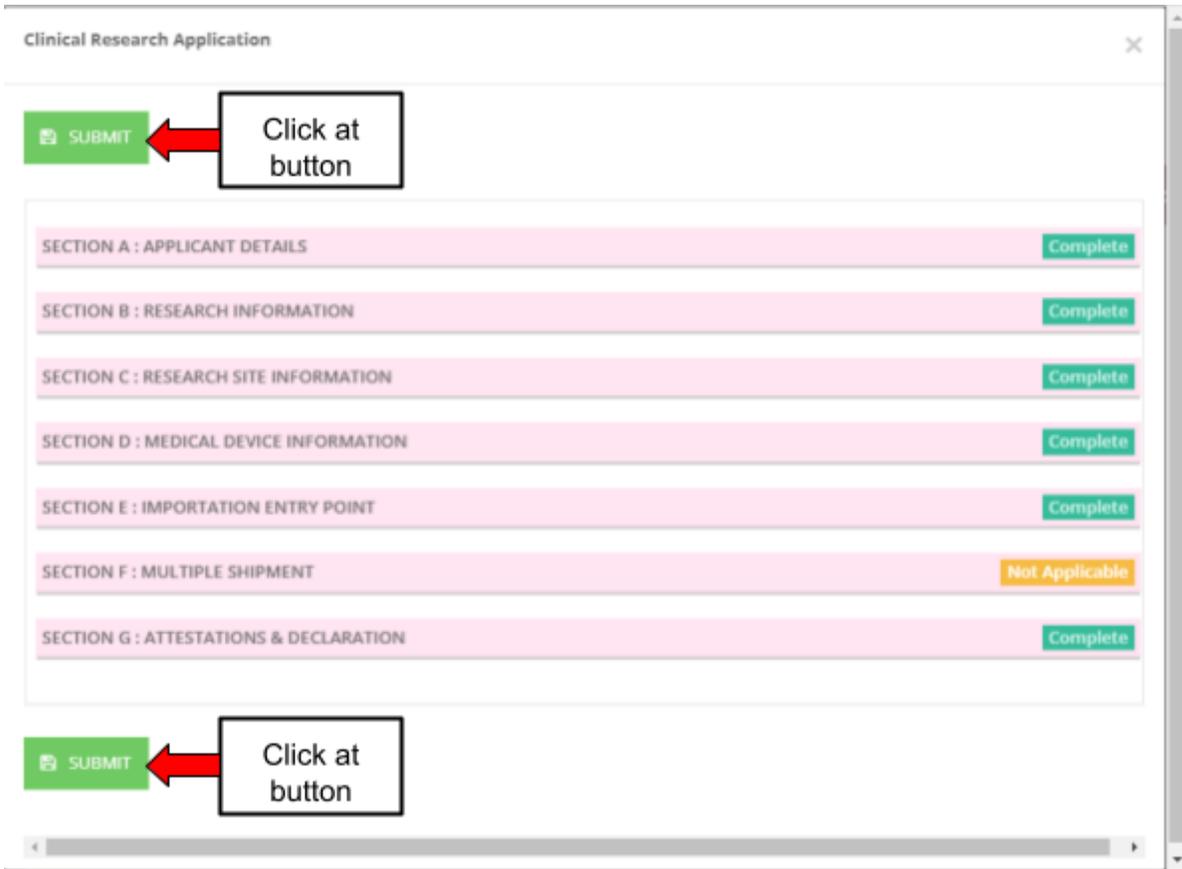
The user also can click at  to back the previous section and if user



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.



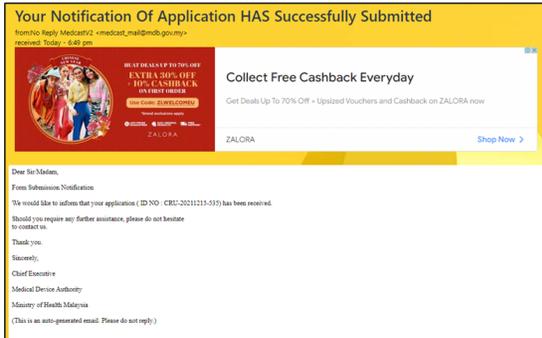
After user click button "Submit", the alert message will be displayed.



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

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.

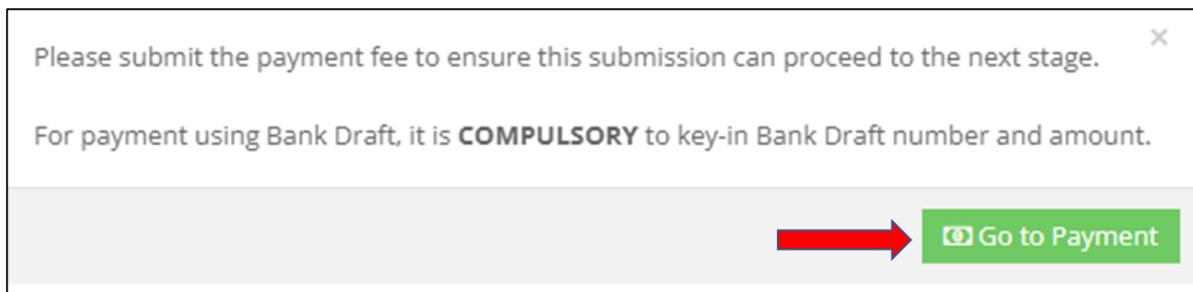
Submitted application email notice



Payment email notice

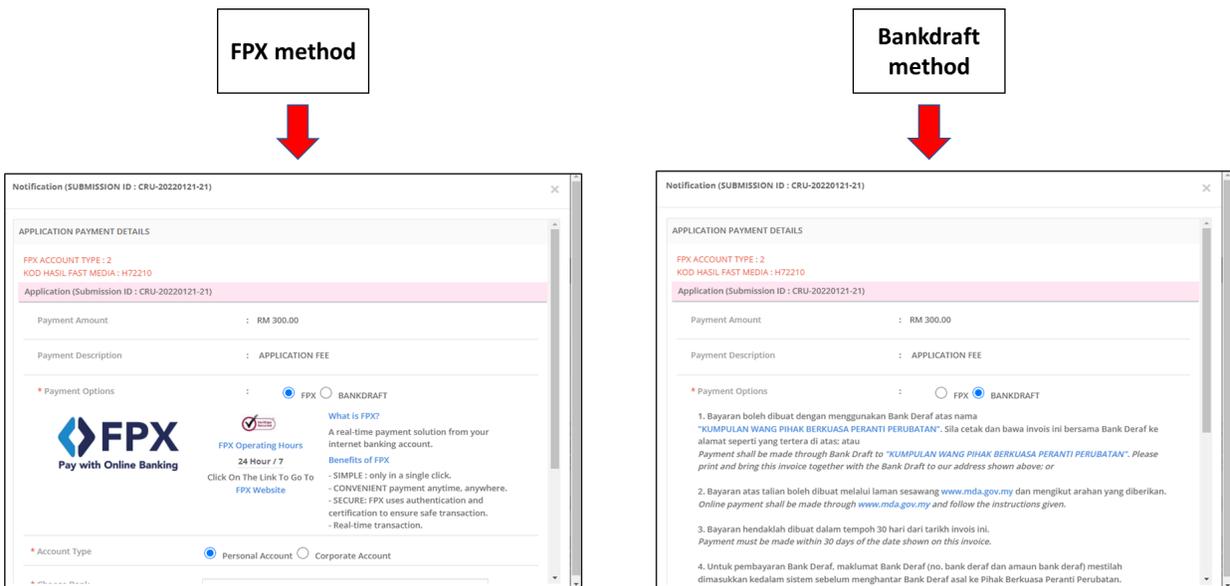


After the application is successfully submitted, a message “Please submit the payment fee to ensure this submission can proceed to the next stage. For payment using Bank Draft, it is **COMPULSORY** to key-in Bank Draft number and amount.” appeared.



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

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



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

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

1 Bulk Payment List

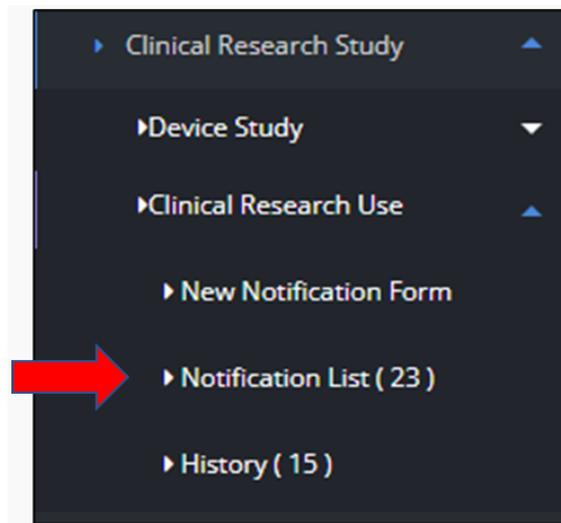
2 Status of the submitted application

3 Click button to make a payment

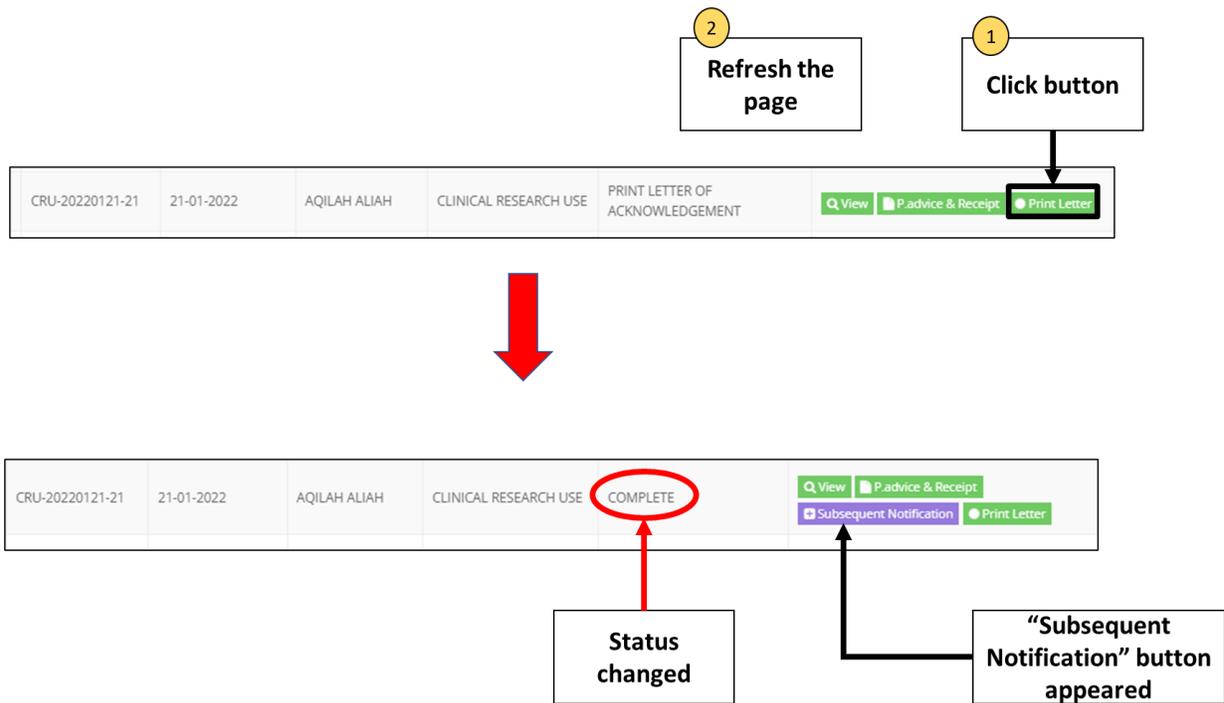
No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	CRU-20220121-21	21-01-2022	AQILAH ALIAH	CLINICAL RESEARCH USE	APPLICATION FEE (UNPAID)	View Payment Add To Bulk Payment Invoice & Receipt
2	CRU-20220120-16 (1)	20-01-2022	AQILAH ALIAH	SUBSEQUENT CLINICAL RESEARCH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

4 Payment method selection screen showing 'FPX method' and 'Bankdraft method' options.

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



When the status of the application is “PRINT LETTER OF ACKNOWLEDGEMENT”. To proceed to make a subsequent notification, The user must click  to generate the letter first. Then, refresh the page. Once the page is refreshed, the  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  button.

- The user can delete the application in the draft by clicking the  button.
- The user can print e-Letter if the application is approved by clicking the  button.
- The user can make a subsequent notification for completed application by clicking the  button.

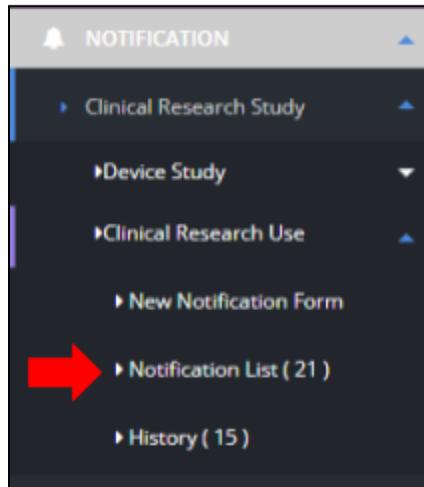
6

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'.

Notification							
Showing 1-15 of 15 items.							
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	 View  Application History
2	CRU-20211222-2 (5)	22-12-2021	SUBSEQUENT CLINICAL RESEARCH USE	COMPLETE	AQILAH ALIAH	ACTIVE	 View  Application History  Print Letter
3	CRU-20211222-4 (5)	22-12-2021	SUBSEQUENT CLINICAL RESEARCH USE	COMPLETE	AQILAH ALIAH	ACTIVE	 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..

Notification List

[Bulk Payment List](#)

Showing 1-20 of 21 items.

<input type="checkbox"/>	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
<input type="checkbox"/>	1	CRU-20220120-16	20-01-2022	AQILAH ALIAH	CLINICAL RESEARCH USE	COMPLETE	View P.advice & Receipt Subsequent Notification Print Letter
<input type="checkbox"/>	2	CRU-20211222-2	22-12-2021	AQILAH ALIAH	CLINICAL RESEARCH USE	APPLICATION FEE (BANK DRAFT SUBMITTED)	View P.advice & Receipt
<input type="checkbox"/>	3	CRU-20211222-2 (7)	22-12-2021	AQILAH ALIAH	SUBSEQUENT CLINICAL RESEARCH USE	COMPLETE	View Subsequent Notification Print Letter Notification History

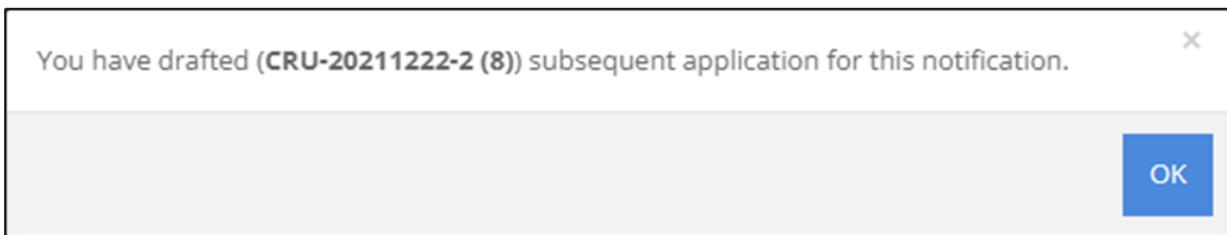
User click on [Subsequent Application](#) . Next step is click OK and the system will display *Subsequent Application* where the data has been copied from the previous application.

The screenshot displays the MeDC@St v2.0 interface. The main content area shows a notification details form for 'Clinical Research - Clinical Research Use (CRU-20220120-16 (1))'. The form is divided into sections:

- SECTION A: APPLICANT INFORMATION**
 - 1. Name Of Applicant :* (DR. SHARIFAH FARIDAH BINTI SYED OMAR)
 - 2. NRIC / Passport :* (990406107777)
 - 3. Designation :* (PRINCIPAL INVESTIGATOR)
 - 4. Organisation Information (Organisation Name: MEDICAL RESEARCH ETHICS COMMITTEE, UNIVERSITY MALAYA MEDICAL CENTRE)

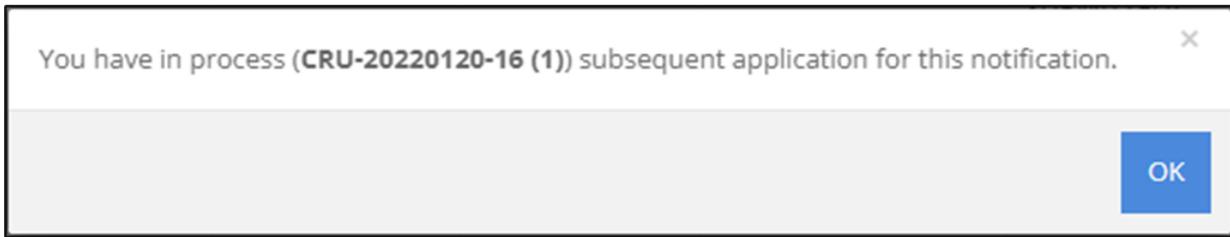
The right sidebar, titled 'Notification Details', lists sections A through F. Section F is marked as 'MULTIPLE SHIPMENT' and includes a note: '*This section is not applicable at this time. No information required'. The URL at the bottom is <https://medcast.mda.gov.my/staging/index.php/dashboard>.

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



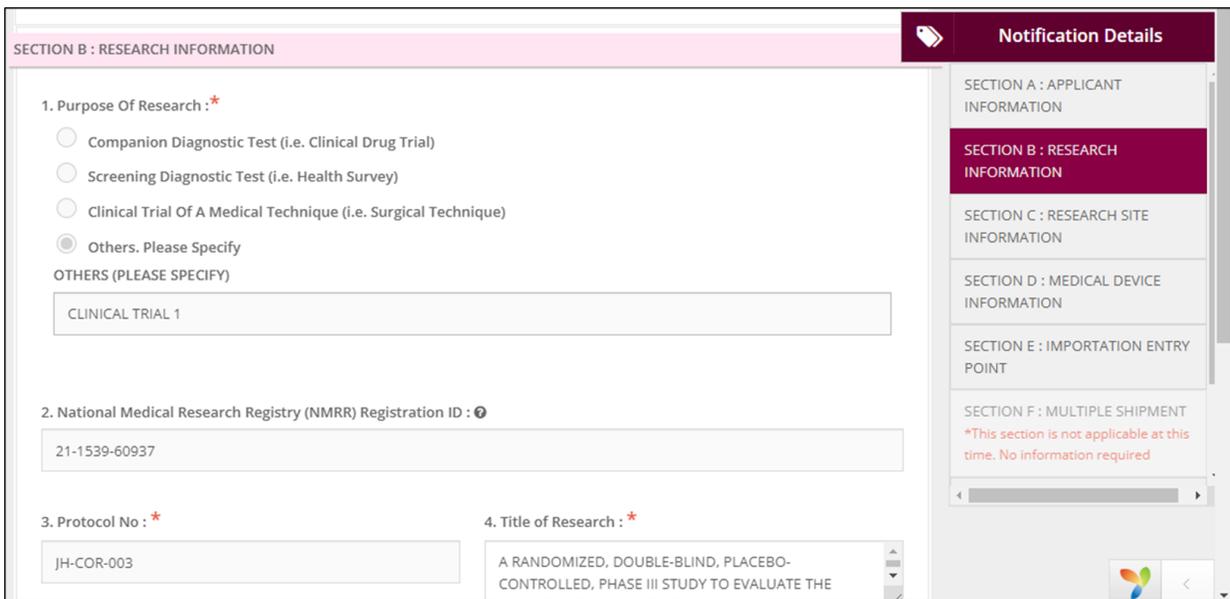
The user click “OK” to close the message.

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.

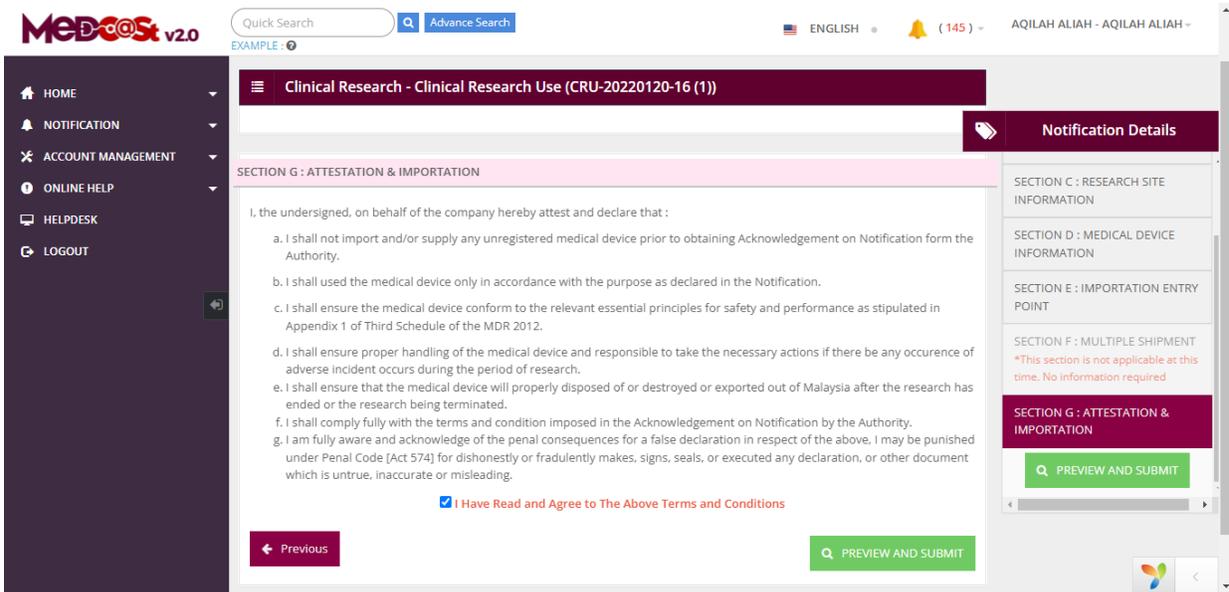


The user click "OK" to close the message.

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  .



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

Clinical Research Application
✕

SUBMIT

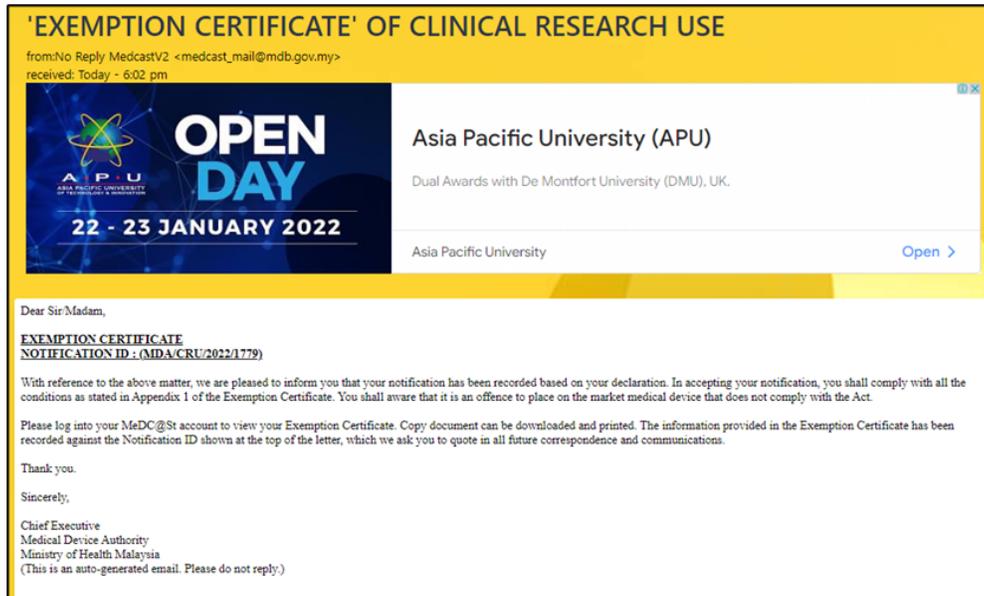
SECTION A : APPLICANT DETAILS	Complete
SECTION B : RESEARCH INFORMATION	Complete
SECTION C : RESEARCH SITE INFORMATION	Complete
SECTION D : MEDICAL DEVICE INFORMATION	Complete
SECTION E : IMPORTATION ENTRY POINT	Complete
SECTION F : MULTIPLE SHIPMENT	Not Applicable
SECTION G : ATTESTATIONS & DECLARATION	Complete

SUBMIT

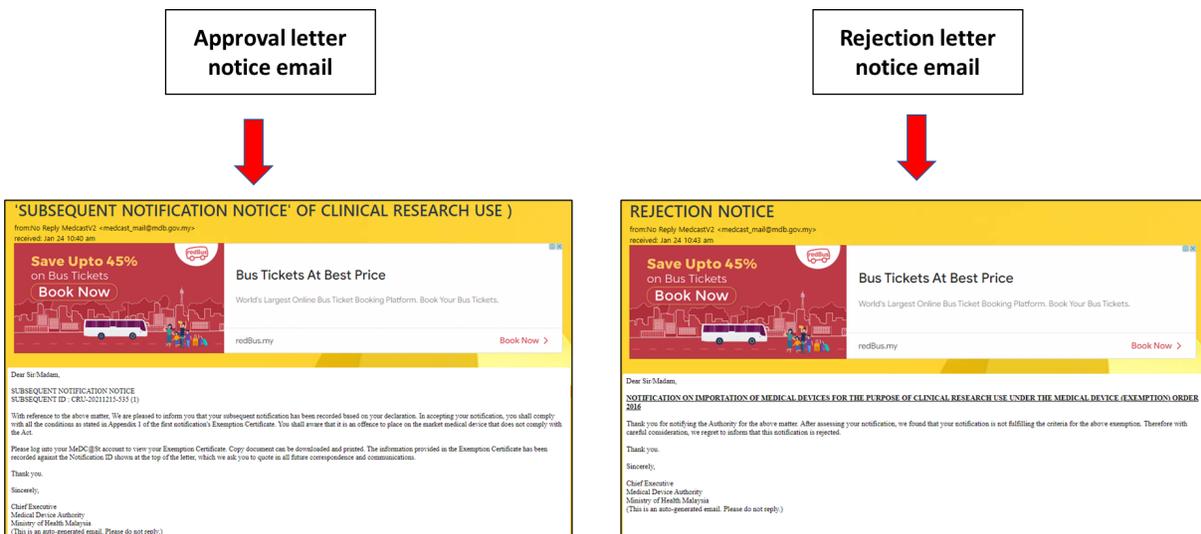
The status of application will be on evaluation stage.

Notification List							
<div style="display: flex; align-items: center;"> <div style="background-color: white; color: #28a745; padding: 2px 5px; border-radius: 3px; margin-right: 5px;"> Bulk Payment List </div> </div>							
Showing 1-20 of 22 items.							
<input type="checkbox"/>	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
<input type="checkbox"/>	1	CRU-20220120-16 (1)	20-01-2022	AQILAH ALIAH	SUBSEQUENT CLINICAL RESEARCH USE	EVALUATION	<div style="display: flex; gap: 5px;"> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> View </div> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> Notification History </div> </div>
<input type="checkbox"/>	2	CRU-20220120-16	20-01-2022	AQILAH ALIAH	CLINICAL RESEARCH USE	COMPLETE	<div style="display: flex; flex-direction: column; gap: 5px;"> <div style="display: flex; gap: 5px;"> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> View </div> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> P.advice & Receipt </div> </div> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> Subsequent Notification </div> <div style="background-color: #28a745; color: white; padding: 2px 5px; border-radius: 3px;"> Print Letter </div> </div>

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

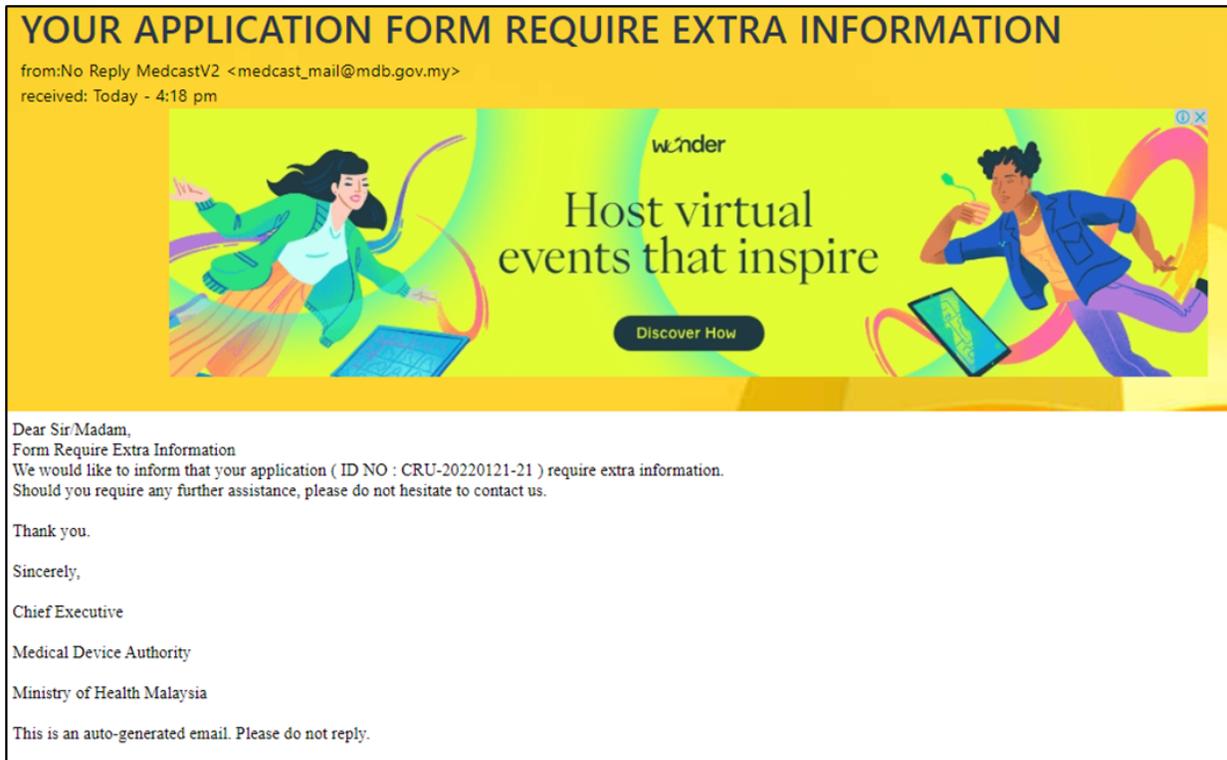


Then, after the application goes through all the stages, the user will get email notification once the application is approved or rejected. Figure below shows the “Approval” and “Rejection” notification email that received by the user.



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.

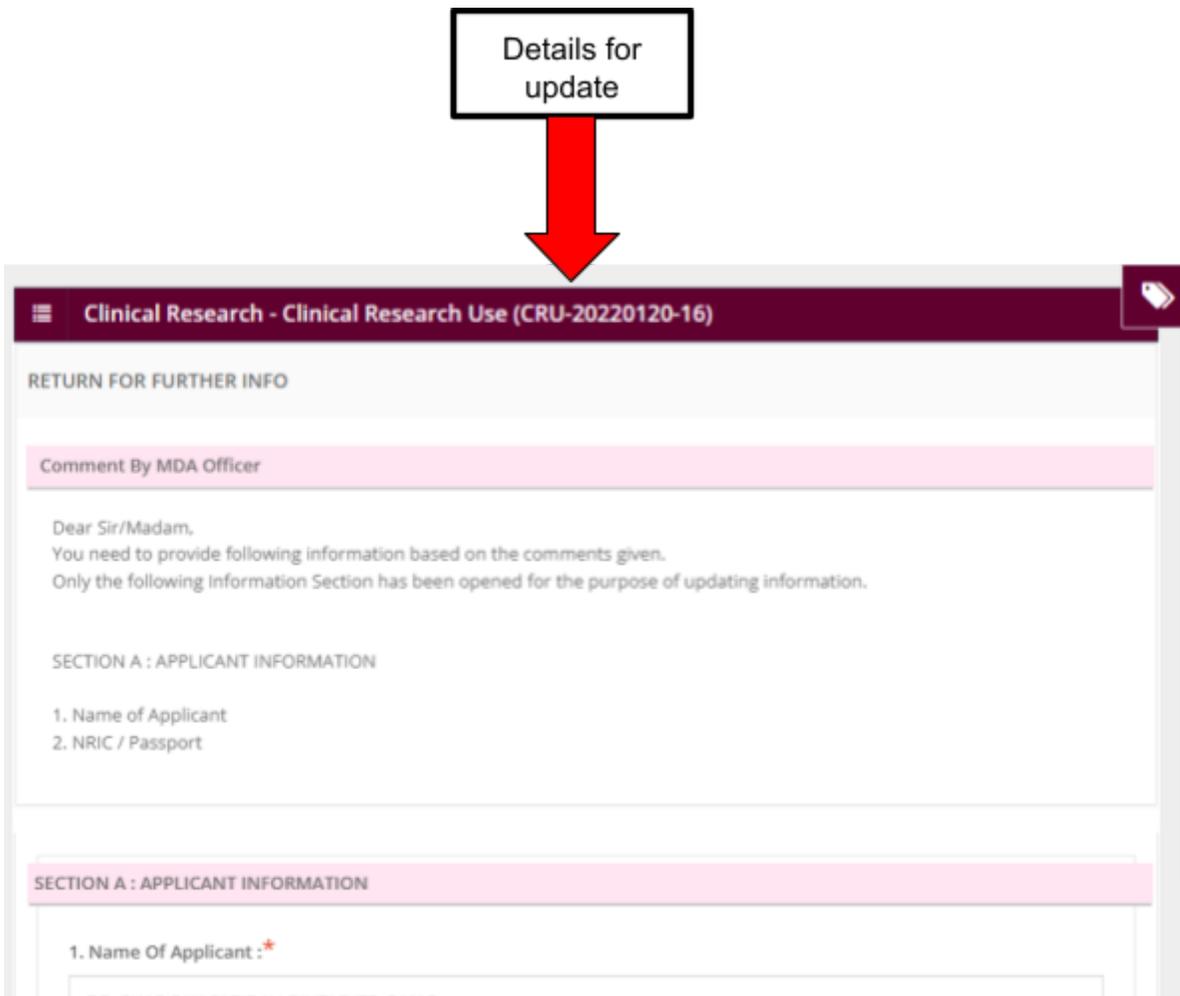
The figure below shows the application status that changed in front end user.

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

No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
1	CRU-20220120-16	20-01-2022	AQILAH ALIAH	CLINICAL RESEARCH USE	RETURN FROM MDA (REQUIRE CHANGES)	View, Update, Advice & Receipt
2	CRU-20211222-2	22-12-2021	AQILAH ALIAH	CLINICAL RESEARCH USE	APPLICATION FEE (BANK DRAFT SUBMITTED)	View, Advice & Receipt
3	CRU-20211222-2 (7)	22-12-2021	AQILAH ALIAH	SUBSEQUENT CLINICAL RESEARCH USE	COMPLETE	View, Subsequent Notification, Print Letter, Notification History

Annotations in the image include a box labeled 'Status changed' pointing to the 'RETURN FROM MDA (REQUIRE CHANGES)' status in the first row, and a box labeled 'Click for update' pointing to the 'Update' button in the action column of the same row.

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



The screenshot shows a notification titled "Clinical Research - Clinical Research Use (CRU-20220120-16)". The notification content is as follows:

RETURN FOR FURTHER INFO

Comment By MDA Officer

Dear Sir/Madam,
You need to provide following information based on the comments given.
Only the following information Section has been opened for the purpose of updating information.

SECTION A : APPLICANT INFORMATION

1. Name of Applicant
2. NRIC / Passport

SECTION A : APPLICANT INFORMATION

1. Name Of Applicant :*

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

SECTION A : APPLICANT INFORMATION

1. Name Of Applicant :*

DR. SHARIFAH FARIDAH BINTI SYED OMAR

2. NRIC / Passport :* ⓘ

990406107777

3. Designation :*

PRINCIPAL INVESTIGATOR

4. Organisation Information

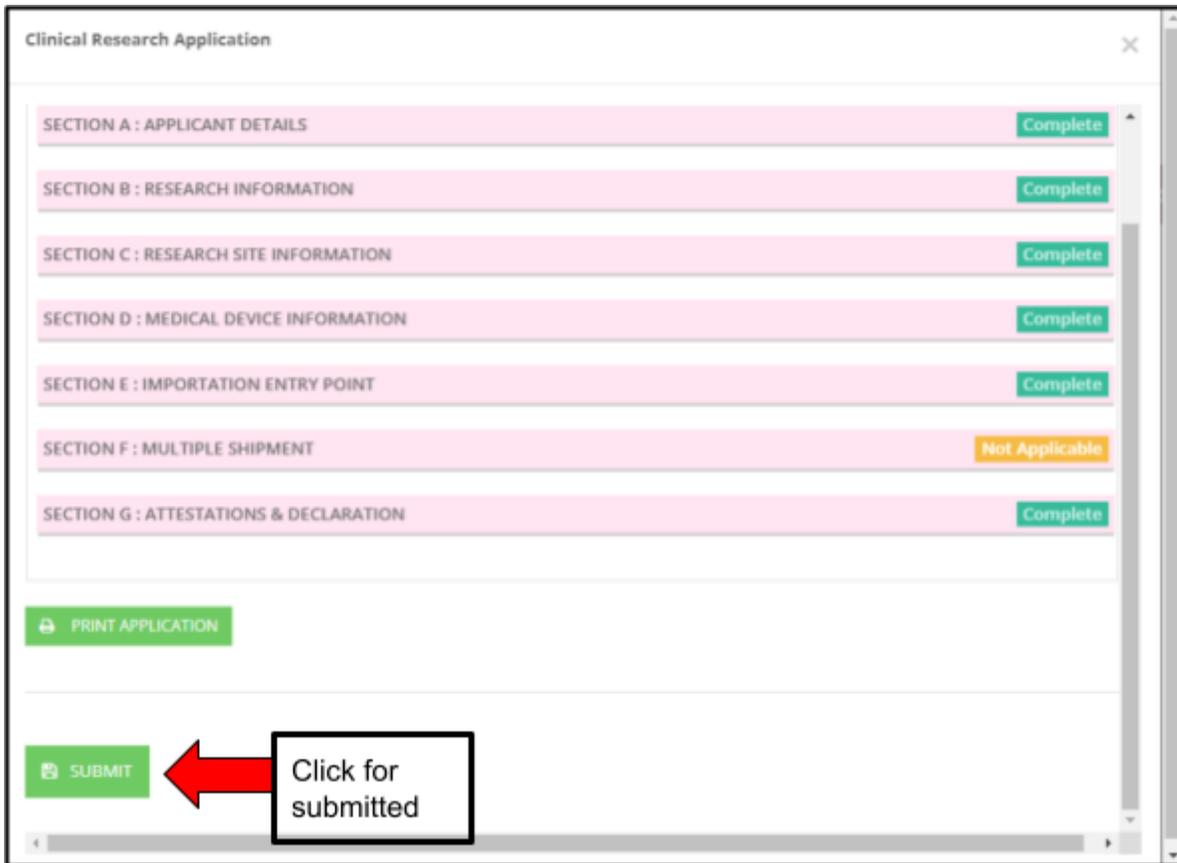
Organisation Name*

MEDICAL RESEARCH ETHICS COMMITTEE, UNIVERSITY MALAYA MEDICAL CENTRE

And then, click

 **PREVIEW AND SUBMIT**

to submit the application.



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



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