USER MANUAL FRONT END USER

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

MODUL UTAMA - NOTIFICATION

DISEDIAKAN OLEH:



Medical Device Authority, Ministry of Health Malaysia

.

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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:

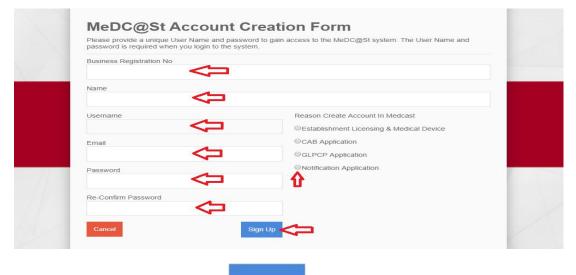
https://medcast.mda.gov.my

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 Sign Up for new registration.



Sign Up

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.

Username	Pengumuman
L Enter username	ANNOUNCEMENT - ABOUT MeDC@St (2017-11-16) New! MeDC@St is a web-basRead More
Usemame cannot be blank. Password	SEMINAR WITH MEDICAL DEVICE INDUSTRY 2017 (2017-11-16) New! Greetings from the ARead More
Enter password	1
Password cannot be blank.	
Sign Up Reset Password FAQ Helpde	esk Login

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

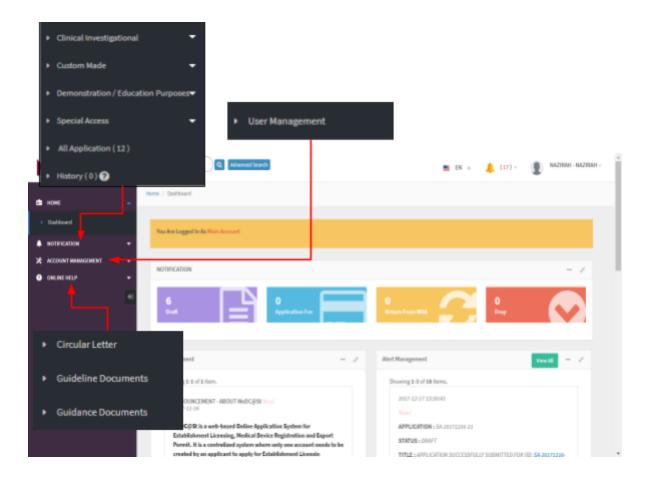
Password. Click

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.

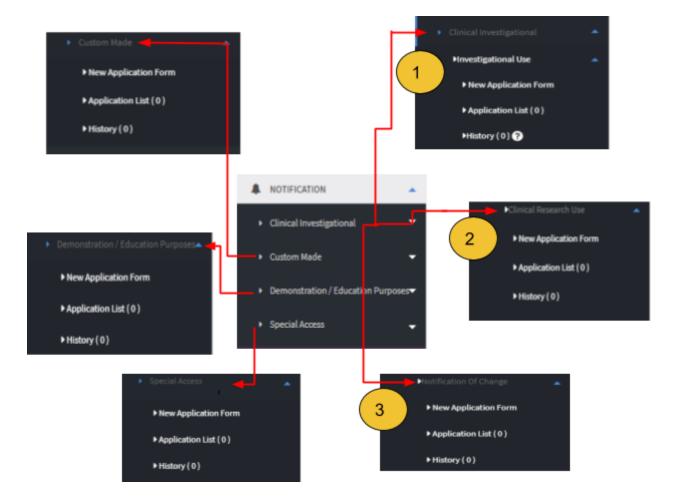


2.2 MENU NOTIFICATION REGISTRATION

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

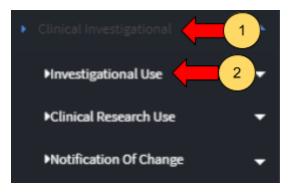


a) CLINICAL INVESTIGATIONAL

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

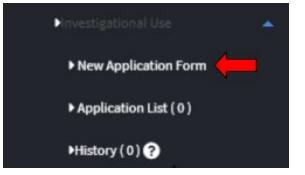
a) New Application



- User should click at menu clinical investigational.

- 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

Guideline Documents	
Click radio	MY
WCDCOCS: v2.0 Quick Search Quick Search It dearced Search Image: Note Search DAME E: 0 Note (v2.00) Note (v2.00) Image: Note (v2.00) M Inter-CATION Image: Note (v2.00) Image: Note (v2.00) Image: Note (v2.00)	(0) - RAZIRAH - NAZIRAH -
ACCOUNT MANAGEMENT Clinical Investigation - Investigational Use (IU-20171206-20) Not lication to Import Or Supply Medical Device for Clinical Investigational Use (In a condance with Medical Device (Exemption) Order 2016) Alth ids are mandalmy unless stated otherwise. PulsPOSE OF NOTIFICATION * Importation Supply (Note: For Locally Manufactured Medical Device) GENERAL INFORMATION	Application Octalls SECTION A : APPLICANT DETAILS SECTION B : SPONSOR DETAILS SECTION C : APPLICATION DETAILS SECTION C : APPLICATION DETAILS SECTION C : MULTIPLE SHIPMENT SECTION F : MULTIPLE SHIPMENT SECTION S : MULTIPLE SHIPMENT
SECTION A : APPELICANT DETAILS Role Of Applicant Cocal Sponsor Manufacturer	SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information
Image: Section of the section of th	etails.

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.



Click at radio button		Details Application will changes	
			Application Details
SECTION A : APPLICANT DETAILS			SECTION A : APPLICANT DETAILS
Role Of Applicant			SECTION C: APPLICATION DETAILS
→ ● Local Sponsor [©] Manufacturer			SECTION D: ENTRY POINT (Note: For Importation Only)
2. Name of Applicant : *			SECTION E : MULTIPLE SHIPMENT
			SECTION F: ATTESTATIONS & DECLARATION
3. NRIC No/Passport : * 😡	4. Designation : *		SECTION G : INVESTIGATOR BROCHURE : Device Identification
			SECTION H : CLINICAL INVESTIGATIO PLAN (CIP): General Information
5. Organisation Information			SECTION 1: APPENDIX A

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

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alaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

Click at radio button		Application details will be changes	
SECTION A : APPLICANT DETAILS			Application Details
Role Of Applicant			SECTION A : APPLICANT DETAILS
Local Sponsor Manufacturer			SECTION B : SPONSOR DETAILS
		L	SECTION C : APPLICATION DETAILS
2. Name of Applicant : *			SECTION D: ENTRY POINT (Note: For Importation Only)
			SECTION E : MULTIPLE SHIPMENT
3. NRIC No/Passport : * 😧	4. Designation : *		SECTION F : ATTESTATIONS & DECLARATION
<u> </u>			SECTION G : INVESTIGATOR BROCHURE : Device Identification
5. Organisation Information Organisation Name *			SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information

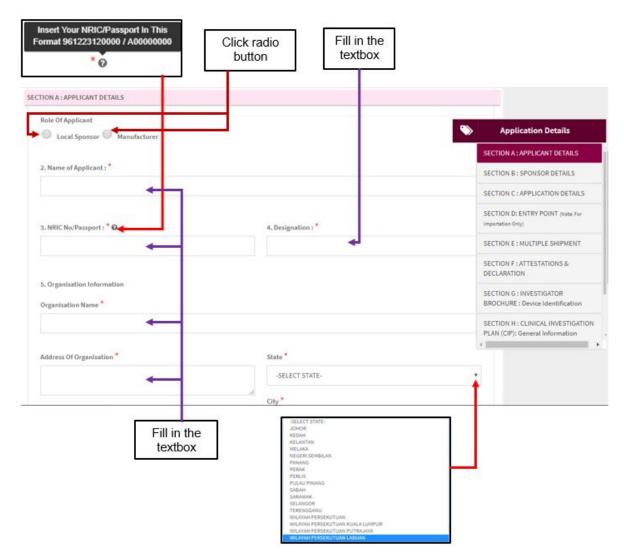
2. Name of Applicant

- User should fill name in the textbox that provided.
- 3. NRIC No/Passport
 - The user should click at ² 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.

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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 ¹ 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.

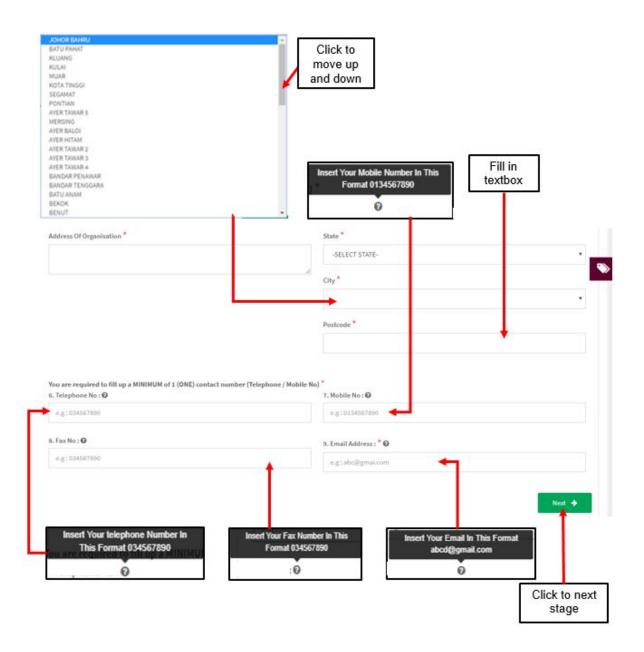
The user must fill in the number only and click at ¹ to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field must have NUMBERS between 3 - 11 numeric" will be displayed.

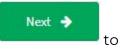
8. Fax No.

The user must fill in the number only and click at ¹ 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 ⁽²⁾ 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 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.".

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LECT STATE-	JOHOR MAHRU	A	
40R	BATU PAHAT		
лан	KLUANG		
ANTAN	KULAI		
LAKA	MUAR		
SERI SEMBILAN	KOTA TINGGI	R.	1
IANG	SEGAMAT		
BAK.	PONTIAN		
RLIS	AYER TAWAR 5 MERSING		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
LAU PINANG	AYER BALOI		Click to
IAH	AYER HITAM		
AWAK	AVER TAWAR 2		move up
ANGOR	AYER TAWAR 3		and down
RENGGANU	AYER TAWAR 4		and down
AYAH PERSEKUTUAN	BANDAR PENAWAR		
AYAH PERSEKUTUAN KUALA LUMPUR	BANDAR TENGGARA		
AYAH PERSEKUTUAN PUTRALAYA	BATU ANAM		
	BEKOK		
AYAH PERSEKUTUAN LABUAN	BENUT	· · · · ·	
Clinical Investigation - Investigational Use (IU-201	712 16-20)		
TION B : SPONSOR DETAILS (To be filled if applicant details abov		•	Application Details
	a and a second t		SECTION A : APPLICANT DETAILS
1. Name of Contact Person :*			SECTION B: SPONSOR DETAILS
	-		SECTION C: APPLICATION DETAILS
2. Organisation Details			
z. organisation betails			SECTION D: ENTRY POINT (Note: For
Organisation Name*			Importation Only)
Urganisacion name	-		SECTION E : MULTIPLE SHIPMENT
Address Of Organisation *	State*		SECTION F : ATTESTATIONS & DECLARATION
needed of organization			SECTION G : INVESTIGATOR
	-SELECT STATE-	A	BROCHURE : Device Identification
	City *		SECTION H : CLINICAL INVESTIGAT
			PLAN (CIP): General Information
		• •	+ EAN (CIP): General Information
	Postcode *		
Fill in the			

3. Telephone No.

The user must fill in the number only and click at ²⁰ 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.

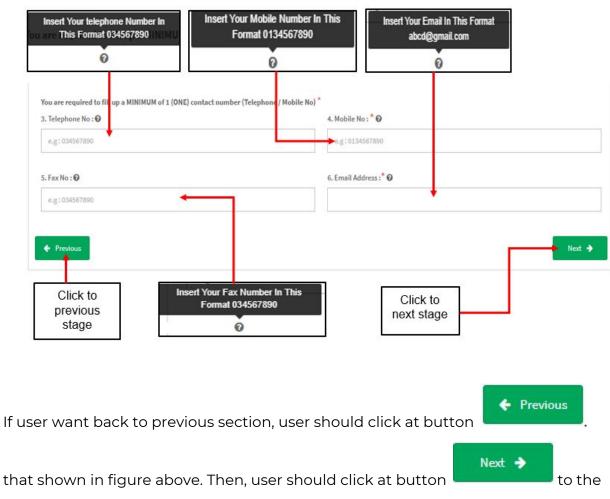
The user must fill in the number only and click at ¹ to see the format. User should follow the format that shown in the figure below. If user fills in the form except number, the message "Field can only contain number and between 3 to 11 numeric." will be displayed.

5. Fax No.

The user must fill in the number only and click at ¹⁰ 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 ⁽²⁾ 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.".



next stage.

2

Subsequent Application. the field of number 2 will

Section C: Application Details

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

- 1. Select Application Type
- User should choose the type of application whether "First Application" or

"Subsequent Application". If user click on radio button 🄍 First Application the	
field of number 2. will be disabled.	

2. For Subsequent Application, please state : 🕜	
Previous MDA identification no :* 🕜	
Previous submission date :* 🕜	

If user click on radio button be enabled.

2. For Subsequent Application, please state : 🕖	
Previous MDA identification no :* 0	
Previous submission date :* 0	

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Click at	Information is not requ application	1931년 1931년 1937년 1931년 - 11월 11일 - 11일	Insert your MDA Idelification this format, MDA/NDE/201XD more than one previous identification No., please ins MDA Identification No. acco for example, type MDA/DE/201XXXX	OCX. For in th MDA than rent ALL rdingly, su	It your previous submission date is format: 01-01-2016. For more n one previous submission date, please insert ALL previous abmission date accordingly, for ample, type 01-01-2014, 02-03-
adio button	0		MDA/IDE/201X/XXX, e	łc	2016 etc
			, v		
SECTION C : APPLICATION I	DETAILS				
1. Select Application T	ype*			٩>	Application Details
 First Application 	Subsequent Application				SECTION A : APPLICANT DETAILS
2. For Subsequent App	lication, please state : Ø				SECTION B : SPONSOR DETAILS
Previous MDA identific	ation no :* 🐼				SECTION C: APPLICATION DETAILS
					SECTION D: ENTRY POINT (Note: For Importation Only)
Previous submission d	ate :* 0			1.1	SECTION E : MULTIPLE SHIPMENT
					SECTION F : ATTESTATIONS & DECLARATION
3. National Medical Re NAZIRAH-123	search Registry (NMRR) Registration ID				SECTION G : INVESTIGATOR BROCHURE : Device Identification
	tigation - as stated in the Clinical Investiga	tion 🕹 Upload file	Supported File Type : pdf		SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information
Plan (CIP) document * (please attach a copy	of Clinical Investigation Plan (CIP))				•
0		Uploaded Files :-			
		No results fou			
		and the second second			Fil. Ci
	R Registration ID in MRR-01-1234-5678	Upload File Of Clin Plan(C			File Size : 300MB File Type : PDF Only
This Format N		I picose to	h a copy of C	1	Upload file
5	0	0			

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 $^{\it O}$ 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)



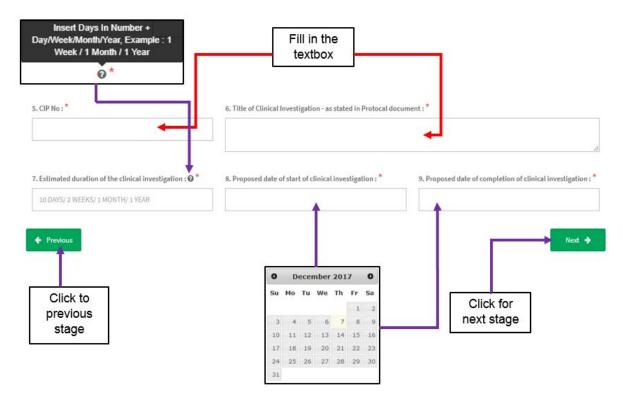
untuk upload file PDF only and not more

User must click at button

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 *o* 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.

Previous

to the

Next 🔶

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.

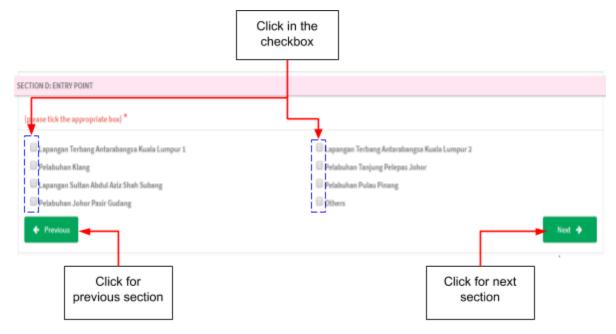
If user want back to previous section, user should click at button

that shown in figure above. Then, user should click at button 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. Medical Device Authority, Ministry of Health Malaysia Medical Device Centralised Online Application System (MeDC@St 2.0)

Other (please specify)		
If user want back to previous section, user should click at butto	rev	ious
that shown in figure above. Then, user should click at button	Next 🔶	to the

Section E: Multiple Shipment

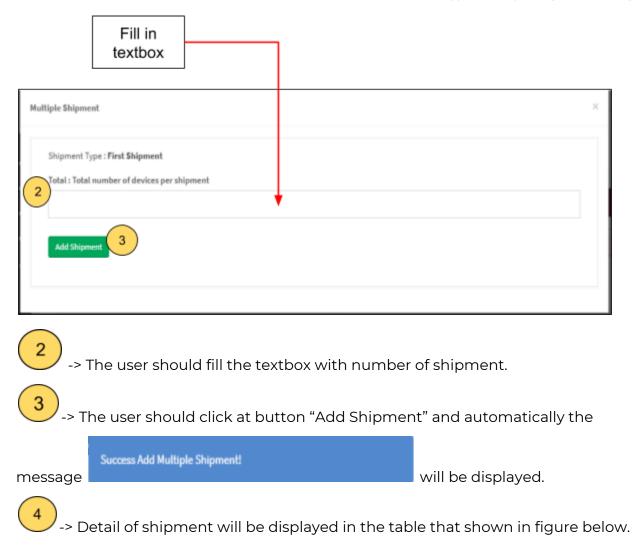
٦

Г

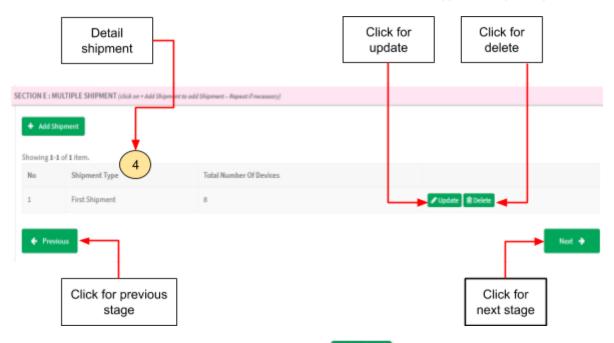
1 The user should click at	+ Add Shipment	and the page form for shipment will be
displayed.		

	Click for add shipment		
SECTION E : MUL	TIPLE SHIPMENT (click on + Add Shipment to an	Npment – Repeat if necessary)	
No No results fo	Shipment Type	Total Number Of Devices	
Previou			Next 🔶

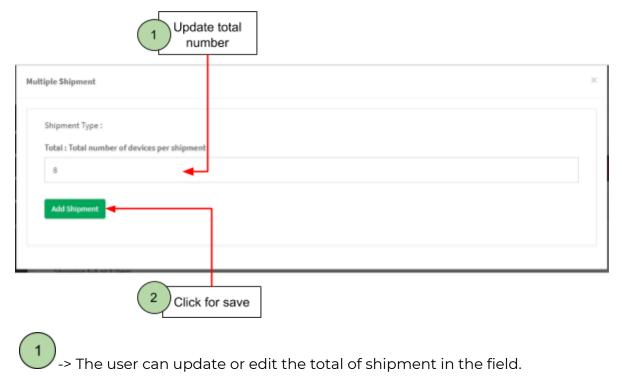
The form for shipment will be displayed after click on button that shown in figure above. The figure below show the form for add shipment.



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

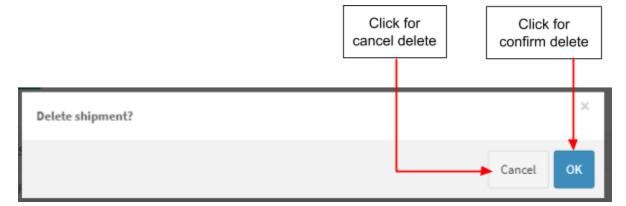


-> The user should click button "Add shipment" to save updated.

2

If user want to delete the shipment, user should click at

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	e message		/ed.
If user want back to previous s	ection, user should click at but	ton	bus
that shown in figure above. Th	en, user should click at button	Next 🔸	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. Medical Device Authority, Ministry of Health Malaysia

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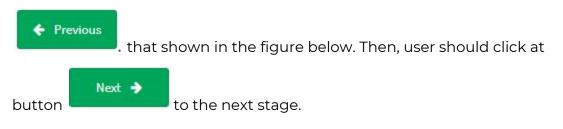


The user must click on checkbox

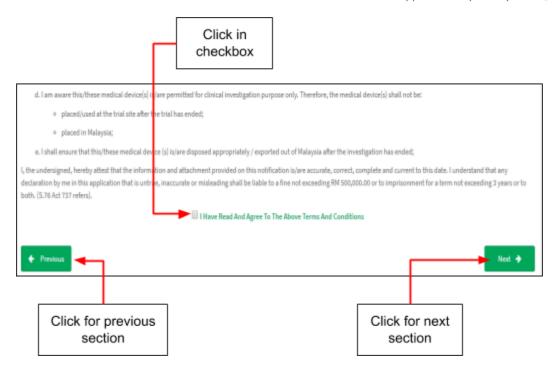
✓ I Have Read And Agree To The Above Terms And Conditions that agree in terms and

conditions that shown in the figure below.

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



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Section G: Investigator Brochure

- 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.

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.

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Click at radio button			
CTION G : INVESTIGATOR BROCHURE : D	evice Identification		
1. Is this study being conducted in Fin	st In Human (FIH) / First In Man	(FIM) *	
Yes Ves			
2. Does the device contain a drug?(Not			
-	e: this question does not apply to IVDs)		
Yes NO			
2 D. (
3. Device usage category (please tick the	(ppropriate box)		
Obstetrics & Gynaecology		Cardiovascular	
Ophthalmology		Prthopaedics	
Physical Medicine		Neurology	
Dental		Ear, Nose & Throat	
Anaesthesiology		 Radiology/Imaging General Hospital 	
		General Hospital	
Gastroentology & Urology		1 ml	
Gastroentology & Urology		Dthers	
General & Plastic Surgery		1 ml	
	box)	1 ml	
General & Plastic Surgery	bas)	1 ml	
4. For IVDs only (please to k the appropriate	bax)	Dthers	
4. For IVDs only (please tick the appropriate Chemistry	box)	Microbiology	
4. For IVDs only (please to k the appropriate Chemistry Immunology	Click at	Microbiology	

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

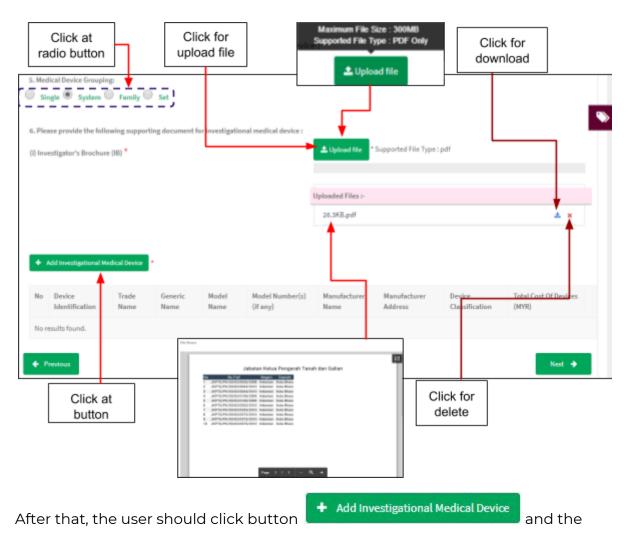
can download and print by clicking symbol



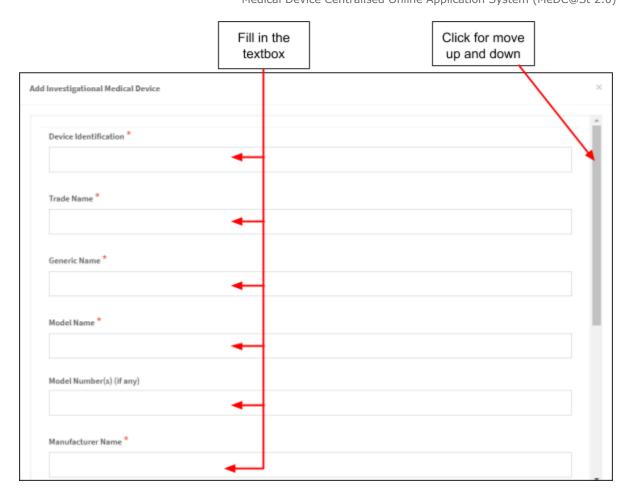
. The user can download and

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.





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.

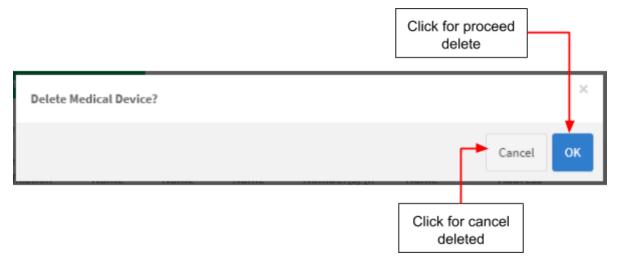
	Fill in the textbox	
Manufacturer Address *		
	•	
Device Classification *		
Total Cost Of Devices (MYR) *		
RM	_	
Add Investigational Medical Devices		
	Click at button	
e user should click at	Add Investigational	Medical Devices

details will be shown in the figure below.

	Add Investigational M	edical Device	ŀ	[Deta investiga medical o	tional		Click to update		
No	Device Identification	Trade Name	Generic Name	Model Name	Model Number(s) (if any)	Manufacturer Name	Manufacturer Address	Device Classification	Total Cost Of Devices (MYR)	
1	FELINE	TERR	FASS	В	5	NAZ	NO.66, JALAN 27/278, TAMAN DESA SETAPAK	FF	600	₽ Upd
Þ P	revious 🗲	-						Click to delete		Next 🔸
		Click for ous sec							for next	

The details add investigational medical device will be displayed at table that shown in figure above. If user want to delete the investigational medical device, user

should click at and alert message "Delete Medical Device?" will be displayed that shown in the figure below.



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

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

	Click in textbox fields to update	
Investigational Medical Device		
Device Identification *		
DEVICE EE		
Trade Name *		
FASS		
Generic Name *		
Model Name *		
MODEL S		
Model Number(s) (if any)		
4		
Manufacturer Name *		
NAZ		

After that, user click button

Add Investigational Medical Devices

to save details and display

again at table.

No	Device Identification	Trade Name	Generic Name	Model Name	Model Number(s) (if any)	Manufacturer Name	Manufacturer Address	Device Classification	Total Cost Of Devices (MYR)	
1	DEVICE EE	FASS	DAS	MODEL S	4	NAZ	NO.66, JALAN 27/27B, TAMAN DESA SETAPAK	G	600	✓ Update Image: Control of the second se

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

+ Add Investigational Medical Device

If user want back to previous section, user should click at butt	on	🔶 Pre	vious
that shown in figure above. Then, user should click at button	N	ext 🔶	to the
next section.			

Section H: Clinical Investigation Plan(CIP)

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

ical Investigational Plan	Click for move down	
Investigator Site		
Name of Investigation Site *		
Address of Investigation Site *		
		
		8
Principal Investigator		
Name of Principal Investigator *		
Professional of Position Principal Investigator*		

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	🖹 Save	to save
the details.		

2

Professional of Position Principal Investigator *	
Address of Principal Investigator *	
	le de
Contact Number of Principal Investigator *	
Email of Principal Investigator *	
Email of Principal Investigator *	
Email of Principal Investigator *	Click for move

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

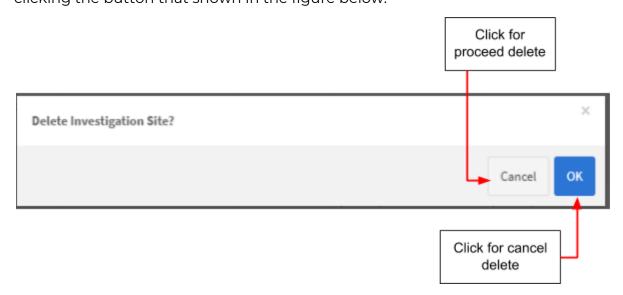
		N PLAN (CIP): Gener Linformation				L	
	Add Investigation Site						
No	Name & address of the investigation site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Commitee	Approval Letter	
1	NAME ABDUL RAHMAN BIN HANID Address NO.28, BATU 2 JALAN KODIANG, 68300 KODIANG, KEDAH.	NAME MUHAMMAD NASRAN BIN MOHAMAD NASIR Position MANAGER Address NO.17F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, KEDAH. Contact 0132732026 Email naireinatfilikasi@gmail.com		(not set)	(not set)	Click	Update Delete Update List Coordinating Inve ✓Update EC/IR8 for delete tigation site

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.

vestigator Site		
Name of Investigatio	n Site *	
ABDUL RAHMAN BI	N HAMID	
Address of Investigat	ion Site *	
NO.2B, BATU 2 JAL	N KODIANG, 06100 KODIANG, KEDAH.	
		11
incipal Investigator		
Name of Principal In	restigator *	
MUHAMMAD NASR	N BIN MOHAMAD NASIR	
Destantional of Desit	on Principal Investigator *	
Professional of Posit		

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 *Vpdate List Coordinating Investigator* to update list coordinating investigator.

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

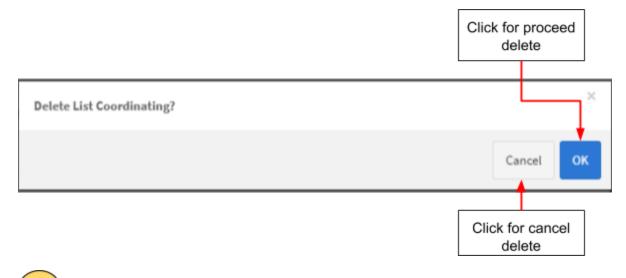
- Name -> The user should fill in the textbox that provided.
- Address -> The user should fill in the textbox that provided.
- Position -> The user should fill in the textbox that provided.
- Contact -> The user should fill in the textbox that provided. The user must fill it with number only. If user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

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

Clinical Investigational Plan		in the form		4	Click for closed
List Of Coordinating Investigator					
Address					
Position					
Contact e.g: 0134567890					
Email					
3	2	Save			
No NAME No results found.	Position	Address	Contact	Email	
2 -> The user sł	nould click a	🖺 SAVE	to save deta	ails.	
3 -> The details			gator will be	displayed	in table after
clicking button "sav	e". Example	e details are:			Click for

nowi	ng 1-1 of 1 it	tem.			
No	NAME	Position	Address	Contact	Email
1	NURUL	AUDIT UNIT	NO.2B, BATU 2 JALAN KODIANG, 06100 KODIANG KEDAH.	0132732026	nazirah123@gmail.com

The user can delete the details with clicking at ¹ and alert message will be displayed. The alert message will be shown in the figure below.



4 -> The user should click to close the page.

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

ION H	: CUNICAL INVESTIGATION	PLAN (CIP): General Information	coordinating investigator				
	Add Investigation Site *						
No	Name & address of the investigation site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Committee	Approval Letter	
1	NAME ABDUL RAHMAN BIN HAMD	NAME MUHAMMAD NASRAN BIN MOHAMAD NASIR	1. NURUL	(not set)	(not set)		✔ Update
	Address NO.28, BATU 2 JALAN KODUANG, 66109 KODUANG, KEDAH.	Position MANAGER Address NO.17F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, KEDAH. Contact 01327326026	dealing localizator	2		ck for e page	*Update List Coordinating Investige # Update EC/188
		Email nazirahnol/fikasi@gmail.com	NRE	: NURLL			
€ P	revious		Pasilion	: AUDITUMT : NO.36, BATU 2.3	ALAN KEDIANG, 06110 KEDIANG	KEDAH.	Nest 🌩
			Cantact	: 0032732026			
			Email	: natinh123@gm	allcom		
			Investigation Sile	: AEDUL RAHMAN	EIN HANED		

After that, user should click button

Update EC/IRB

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.

	Fill in the textbox	
Clinical Investigational Plan		×
Ethics Committee (EC) /	Institutional Review Board (IRB) *	
Authorisation / Opinion Of TO BE REQUESTED	Ethics Committee*	
SAVE	Click at radio button	
Click at button		

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

- The user should fill in the textbox that provided.

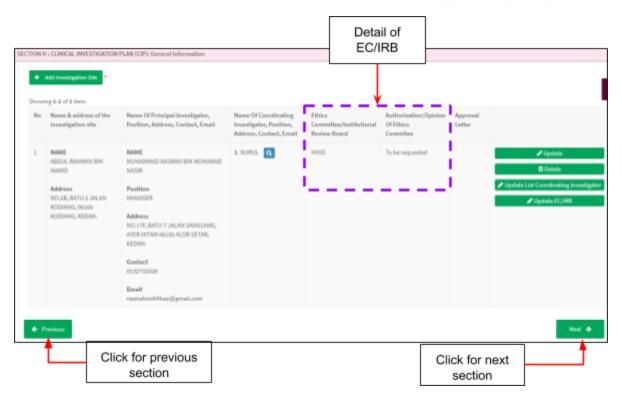
Authorisation/Opinion of Ethics Committee

 The user should choose whether "To be Requested" or "Pending" or "Authorisation Accepted/Favourable Opinion"

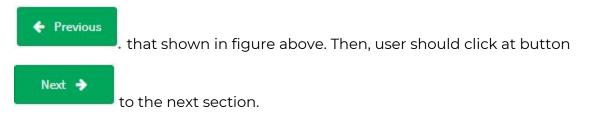
B SAVE

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

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)



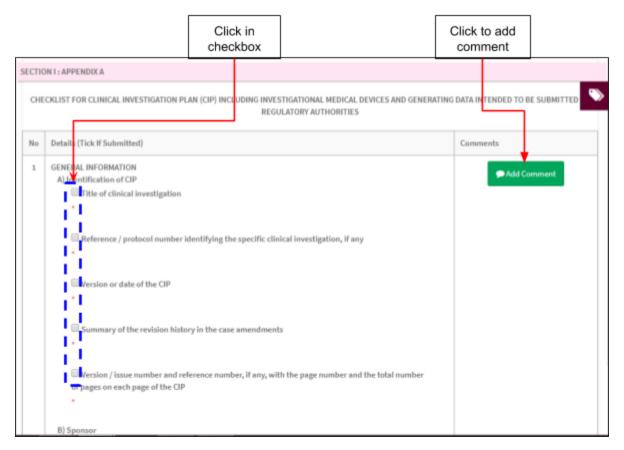
Then, If user want back to previous section, user should click at button



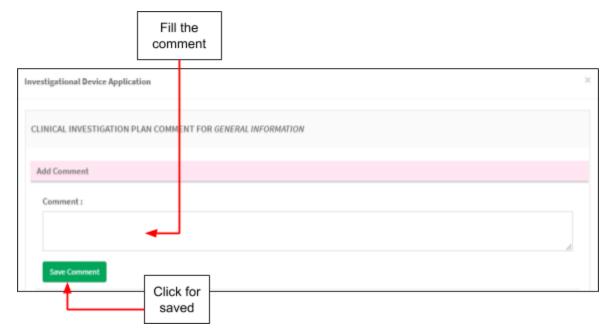
Section I: Appendix A

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.

			Click for delete
SECTIO	ON I : APPENDIX A		
CHE	CKLIST FOR CLINICAL INVESTIGATION F	LAN (CIP) INCLUDING INVESTIGATIONAL MEDICAL DEVICES AND GENERATING REGULATORY AUTHORITIES	G DATA INTENDED TO BE SUBMITTED
No	Details (Tick If Submitted)		Comments
1	GENERAL INFORMATION A) Identification of CIP Title of clinical investigation Reference / protocol number Version or date of the CIP	identifying the specific clinical investigation, if any	Add Comment COMMENT LIST NAZIRAH 2017-12-10 14:33:43 chchc
		Delete file confirmation?	Cancel OK

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

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



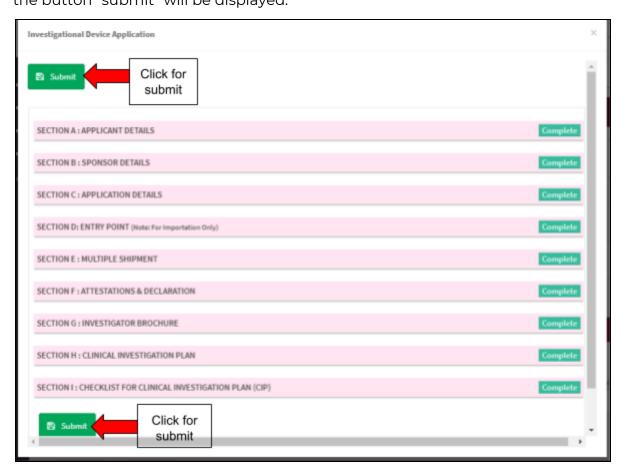
to preview and submit the application form.

20	QUALITY CONTROL AND ASSUBANCE	Add Comment Application Details
21	ETHICS	Add Comment SECTION D: ENTRY POINT (Nate: For Importation Only)
		SECTION E: MULTIPLE SHIPMENT
22	DATA HANDLING AND RECORD KEEPING	Add Comment SECTION F : ATTESTATIONS & DECLARATION
23	FINANCE AND INSURANCE	SECTION 6 : INVESTIGATOR BROCHURE : Device Identification
24	SUPPLEMENTS	SECTION H : CLINICAL INVESTIGATION Add Comment PLAN (CIP): General Information
		SECTION 1: APPENDIXA
¢	Peedous	Q PREVIEW AND SUBMIT
	Click to previous section	Click for preview

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

SECTION A : APPLICANT DETAILS Complete SECTION B : SPONSOR DETAILS Complete SECTION C : APPLICATION DETAILS Complete SECTION D : ENTRY POINT (Hote: For Importation Only) Complete SECTION D : ENTRY POINT (Hote: For Importation Only) Complete SECTION D : ENTRY POINT (Hote: For Importation Only) Complete SECTION D : ENTRY POINT (Hote: For Importation Only) Complete SECTION E : MULTIPLE SHIPMENT Complete SECTION F : ATTESTATIONS & DECLARATION Complete SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Net Complete *Submit only can be done if all fields mandatory are complete *Submit only can be done if all fields mandatory are complete	Investigational Device Application "Submit only can be done if all fields mandatory are complete	Click for view details
SECTION C : APPLICATION DETAILS Complete SECTION D: ENTRY POINT (Note: For Importation Only) Complete SECTION E : MULTIPLE SHIPMENT Complete SECTION F : ATTESTATIONS & DECLARATION Complete SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION A : APPLICANT DETAILS	Complete
SECTION D: ENTRY POINT (Note: For Importation Only) Complete SECTION E : MULTIPLE SHIPMENT Complete SECTION F : ATTESTATIONS & DECLARATION Complete SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION B : SPONSOR DETAILS	Complete
SECTION E : MULTIPLE SHIPMENT Complete SECTION F : ATTESTATIONS & DECLARATION Complete SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION C : APPLICATION DETAILS	Complete
SECTION F : ATTESTATIONS & DECLARATION Complete SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION D: ENTRY POINT (Note: For Importation Only)	Complete
SECTION G : INVESTIGATOR BROCHURE Complete SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION E : MULTIPLE SHIPMENT	Complete
SECTION H : CLINICAL INVESTIGATION PLAN Complete SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP) Not Complete	SECTION F : ATTESTATIONS & DECLARATION	Complete
SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP)	SECTION G : INVESTIGATOR BROCHURE	Complete
	SECTION H : CLINICAL INVESTIGATION PLAN	Complete
*Submit only can be done if all fields mandatory are complete	SECTION I : CHECKLIST FOR CLINICAL INVESTIGATION PLAN (CIP)	Not Complete
	*Submit only can be done if all fields mandatory are complete	

lf status	Not Complete	, the user should fill it again to change status	Complete	and
the butto	on "submit" v	/ill be displaved.		



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



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

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

						Click for view details	
	Notification Form A	pplication List					
owin	ng 1-2 of 2 items.						
lo	Submission ID	Submitted At	Applicant	Application Type Name	Application Status	Action	
	Search	Search	Search	Search	Search		
	IU-20171206-20	10-12-2017	NAZIRAH	INVESTIGATIONAL USE	EVALUATION	Q View	
				Natification Application -			
				SECTION A UNIVERSITY OF MICH			(market)
				SECTION 8 - SPONSOR-SCINE,5			Complete
				SECTION C - MPERATION DETAILS			Emplete
				SECTION D. ARTIST FORM (Auto Factoryania)	e Gelgi		trophts
				SECTION E : MILLION E SHEMOLE			Conglete
				BETTORY APTERTORES DECLARING			Canglele
				SECTION 6 - INVESTIGATION DROKOLAURE			Complete
				SECTION HIL CLINICAL INVESTIGATION PLAN			Conglete
				RECTION 1 - CHECKLIFT FOR CLINICAL INVEST			Complete

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

User Manual Front End User - Notification

Medical Device Authority, Ministry of Health Malaysia

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

						18C1014_4#059/181903
				Hatillication in Import Or Tappiy Wedleal Device for Clinic (In accordance with Wedleal Device (Deception) Order 20	d Investigational Dae 19	SCIONE SPENDROCKS BCIDIC APPLOTENCEME
				All failth art transferiory orders statistical afformation		1007010 0170 P007 Autor
				PAPER IF STRUCTURE		Sector Cost
				C Importation C Supply Chills For Locally Merubational	Hedical Deviced	IETO/F ATELNISHES
				CEMERAL INFORMATION		SCLANTER BUTCHS MEDIATOR
				INCOME APPLICATIONS		BCDUE Intellectuation
				Role 31 Applicant		PLM IOP: Screek Information
	Notification Form A	polication List		O Lostqueer O Restator		
				2. Hanne of Replaced s		
mi	ng 1-2 of 2 items.					
0	Submission ID	Submitted At	Applicant	Application Type Name	Application Status	Action
	Search	Search	Search	Search	Search	
	IU-20171206-20	10-12-2017	NAZIRAH	INVESTIGATIONAL USE	EVALUATION	Q, View
	IU-20171208-21	Not Submitted Yet	NAZIRAH	INVESTIGATIONAL USE	DRAFT	Q View 🖍 Update
						1
			Delete application	n confirmation?		×

b) Subsequent application

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

ы н	OME	•
🐥 N	OTIFICATION	•
• c	linical Research	•
,	Investigational Use	•
	New Notification Form	
\rightarrow	 Notification List (1) 	
	 Notification Of Change (0) 	
	History (0)	
,	Clinical Research Use	•

The system will display page of list application Investigational Use.

Showing 1-1 of 1 item.							
	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
	1	IU-20180815-1	15-08-2018	BISHRUN	INVESTIGATIONAL USE	COMPLETE	Q View Subsequent Notification Notification of Change

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

Clinical Research - Investigational Use (IU-20180820-2)		
Notification to Import Or Supply Medical Device for Clinical In (In accordance with Medical Device (Exemption) Order 2016)	vestigational Use	
All fields are mandatory unless stated otherwise.		
PURPOSE OF NOTIFICATION *		
IMPORTATION O SUPPLY (Note: for locally manufactured med	dical device)	
GENERAL INFORMATION		
CTION A : APPLICANT DETAILS		
1. Role Of Applicant		
Local Sponsor	on (in case of foreign sponsor / manufacturer)	
2. Name of Applicant : *		
2. Name of Applicant : BISHRUN		
3. NRIC No/Passport : * 🔞	4. Designation : *	

The user complete the Subsequent Application form. The user review all information in

Section A, B C, D, E, F, G and H. Next step is the user click on button

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

howir	ng 1-1 of 1 item.							SECTION D: ENTRY POINT (Not For Importation Only)
No	Name & address of the investigation site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Commitee	Approval Letter		SECTION E : MULTIPLE SHIPMENT SECTION F : ATTESTATIONS & DECLARATION
1	Name INVESTIGAE TESTING Address 32 JALAN TESTING	Name MR RAJU Position CEO Address 32 JALAN TESTING Contact 03433231233 Email raju@gmail.com	1. RĄJU 🔍	MELAYU	To be requested		Update Delete Update List Coordinating Investigator Update EC/IR8	SECTION G : INVESTIGATOR BROCHURE : Device Identification SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information Q PREVIEW AND SUBMIT

If all mandatory information has been filled	out, button 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.

nvestigational Device Notification	3
SUBMIT	
SECTION A : APPLICANT DETAILS	Complete
SECTION B : SPONSOR DETAILS *Sponsor Details Dont Need To Be Filled For Local Sponsor	Local Sponsor
SECTION C : NOTIFICATION DETAILS	Complete
SECTION D: ENTRY POINT (Note: For Importation Only)	Complete
SECTION E : MULTIPLE SHIPMENT	Complete
SECTION F : ATTESTATIONS & DECLARATION	Complete
SECTION G : INVESTIGATOR BROCHURE	Complete
SECTION H : CLINICAL INVESTIGATION PLAN	Complete
SUBMIT	

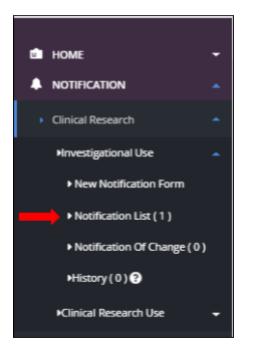
The status of application will be on evaluation stage.

•	Notif	ication List						
Showi	howing 1-2 of 2 items.							
	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action	
	1	IU-20180820-2	24-08-2018	BISHRUN	SUBSEQUENT INVESTIGATIONAL USE	EVALUATION	Q, View III Notification Hatory	
	2	IU-20180815-1	15-08-2018	BISHRUN	INVESTIGATIONAL USE	COMPLETE	View Distrequent Notification Notification of Change	

c) Change of Notification

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

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)



The system will display page of list application Investigational Use.

Noti	fication List							
Showing 1-1 of 1 item.								
No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action		
1	IU-20180815-1	15-08-2018	BISHRUN	INVESTIGATIONAL USE	COMPLETE	Q View Subsequent Notification		
						- Hodinghou ou change		
	ving 1-'	No Submission ID	No Submission ID Submitted At	No Submission ID Submitted At Applicant	No Submission ID Submitted At Applicant Notification Type Name	No Submission ID Submitted At Applicant Notification Type Name Notification Status		

Notification of Change.

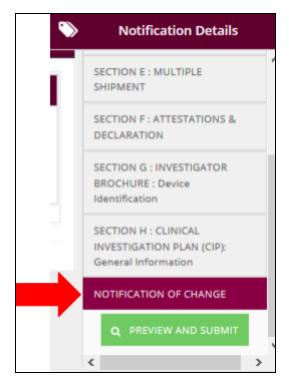
MCDCOSt v2.0	Quick Search Q Advance Search	🔳 ENGLISH = 🙏 (1) - BISHRUN - BISHRUN -
раноме •	Home / Notification Of Change	
NOTIFICATION	Notification of Change	
ONUNE HELP		Change Of IRB/EC

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

MCDC@St v2.0	Quick Search Q Advance Search		🔳 ENGLISH 💿 🙏 (1) - BISHRUN - BISHRUN -
ба номе	Home / Notifications / Clinical Research - Investigational Use (IU-20180824-	2)	
	Clinical Research - Investigational Use (IU-20180824	2)	Notification Details
ACCOUNT MANAGEMENT			SECTION A : APPLICANT DETAILS
ONLINE HELP	Notification to Import Or Supply Medical Device for Clinic (In accordance with Medical Device (Exemption) Order 20	al Investigational Use 16)	SECTION C : NOTIFICATION DETAILS
	All fields are mandatory unless stated otherwise.		SECTION D: ENTRY POINT (Note: For Importation Only)
	PURPOSE OF NOTIFICATION * IMPORTATION O SUPPLY (Note: for locally manufacturee)	medical device)	SECTION E : MULTIPLE SHIPMENT
			SECTION F : ATTESTATIONS & DECLARATION
	GENERAL INFORMATION		SECTION G : INVESTIGATOR BROCHURE : Device
	SECTION A : APPLICANT DETAILS		Identification
	1. Role Of Applicant	ization (in case of foreign sponsor / manufacturer)	
	2. Name of Applicant : *		
	BISHRUN		
	3. NRIC No/Passport : * 😡	4. Designation : *	
	897909106656	CEO	

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

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)



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

MCDCOSt v2.0	Quick Search Q Advance Search		💻 ENGLISH 🔹 🙏 (1) - BISHRUN - BISHRUN -
ей номе -	Home / Notifications / Clinical Research - Investigational Use (IU-20180824-	2)	
NOTIFICATION	Clinical Research - Investigational Use (IU-20180824	-2)	Notification Details
ONLINE HELP	Notification of Change		SECTION E: MULTIPLE SHIPMENT
43	Change Of Principal Investigator	Change Of IRB/EC	SECTION F: ATTESTATIONS & DECLARATION
	Change Of Site	Change Of Device	SECTION G : INVESTIGATOR BROCHURE : Device Identification
			SECTION H : CLINICAL INVESTIGATION PLAN (CIP): General Information

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.

			Advance Search	eneral Information				ENGLISH 6	(1) - BISHRUN - BISHRUN -
NOTIFICATION	-	Add Investigation Site	*						Notification Details
ONLINE HELP	Sho	wing 1-1 of 1 item. Name & address of the investigation site	Name Of Principal Investigator, Position, Address, Contact, Email	Name Of Coordinating Investigator, Position, Address, Contact, Email	Ethics Committee/Institutional Review Board	Authorisation/Opinion Of Ethics Commitee	Approval Letter		For Importation Only) SECTION E : MULTIPLE SHIPMENT SECTION F : ATTESTATIONS & DECLARATION
	1	Name INVESTIGAE TESTING Address 32 JALAN TESTING	Name MR RAJU Position CEO Address 32 JALAN TESTING Contact 03433231233 Email Email	1. RAJU Q	MELAYU	To be requested		Vipdase Boleta Deleta Updase Lan Coordinating Investigator Updase €C/IRB	SECTION G: INVESTIGATOR BIOCUME: Device Identification SECTION H: CLINICAL INVESTIGATION EVAL (CIP: General Information NOTIFICATION OF CHANGE
		Previous						Q PREVIEW AND SUBMIT	

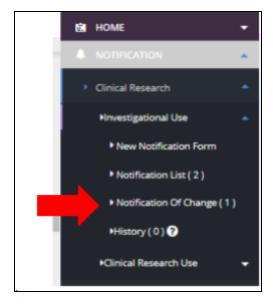
Next step is click on button **Q** PREVIEW AND SUBMIT to preview the information that user change.

B SUBMIT	
SECTION A : APPLICANT DETAILS	Complet
SECTION B : SPONSOR DETAILS *Sponsor Details Dont Need To Be Filled For Local Sponsor	Local Sponse
SECTION C : NOTIFICATION DETAILS	Comple
SECTION D: ENTRY POINT (Note: For Importation Only)	Comple
SECTION E : MULTIPLE SHIPMENT	Comple
SECTION F : ATTESTATIONS & DECLARATION	Comple
SECTION G : INVESTIGATOR BROCHURE	Comple
SECTION H : CLINICAL INVESTIGATION PLAN	Comple
NOTIFICATION OF CHANGE	Comple

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)



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

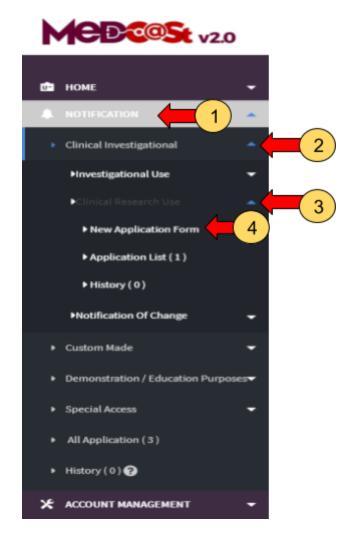


The system will display the list of Notification of Change.

MCDCOSt v2.0	, (Quick Sea		Q Advan	ce Search			ENGLISH	BISHRUN - BISHRUN -
B HOME	-	Home /		ation List					
	-								
Clinical Research	-		Notif	ication List					
Movestigational Use	-			of 1 item.					
Clinical Research Use	-		No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
Custom Made	-								
 Demonstration / Education Purposes 	-		1	IU-20180824-2	24-08-2018	BISHRUN	Notification of Change IU	EVALUATION	Q View III Notification History
 Special Access 	-								
 All Notification (3) 									
History (0)									
X ACCOUNT MANAGEMENT	-								
ONLINE HELP	-								
	1								
	40								

II) CLINICAL RESEARCH USE

a) New Application



1 -> The user should click at menu NOTIFICATION and list of module will be displayed which are Clinical Investigational, Custom made,

Demonstration/Education Purposes and Special Access.

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

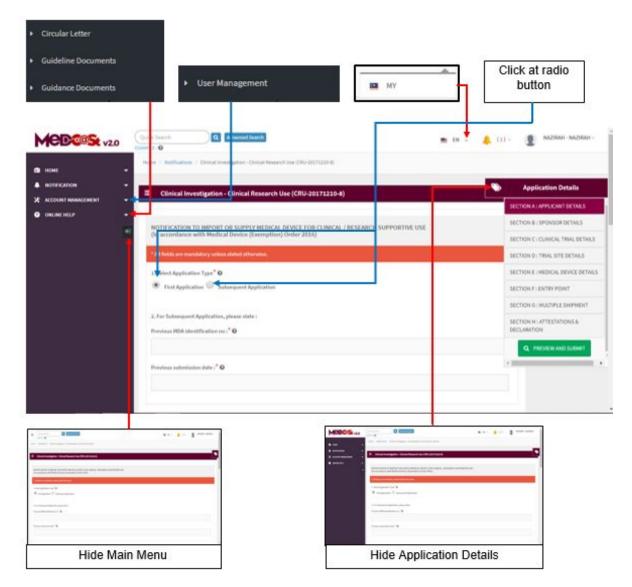
and Notification of change.

3 -> The user should click at sub module Clinical Research use and the New

Application Form will be showed.

-> 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

Subsequent Application .the field of number 2 will

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

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

- 1. Select Application Type
- User should choose the type of application whether "First Application" or

"Subsequent Application". If user click on radio button ⁽⁾ First Application the field of number 2. will be disabled.

2. For Subsequent Application, please state : 🔞		
Previous MDA identification no :* 🛛		
**		
Previous submission date :* 🛛		

If user click on radio button be enabled.

2. For Subsequent Application, please state : 📀	
Previous MDA identification no :* 🕜	
Previous submission date :* 0	
Sta water en uppendier i ne dater in de land dat en de de de de de la seconde com	

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.

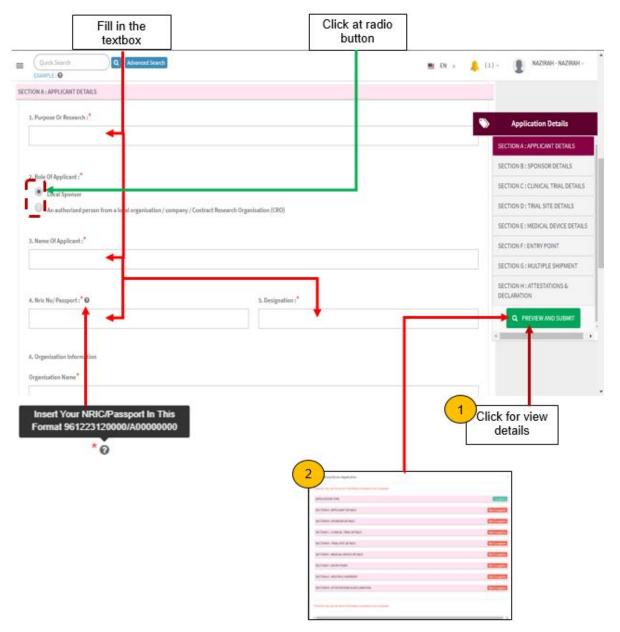
- An authorised person from a local organisation/company/contact research organisation(CRO).
- 3. Name of Applicant

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 60 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."

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Medical Device Authority, Ministry of Health Malaysia

	ARECENTE:	Categoria Mandel
	JCHOR KEISAN	RUTU FAINT HEURIN
	KELANTAH	8,5,4
	MELAKA	MUM .
	NEOLIN SEMIDLAN	ACTS TOVING SECURIC
	Provincia.	PUN TANK
	PERAK PERJE	ANTER TRANARIA
	PUCAL PNING	AND IN BRIDE
	SABAH	Artist unitst
	SHRANNA	A TRANSITION OF A TRANSITICA A TRAN
	SELANDOR	AUG P TANALA 3 AUG TANALA 4
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	INTLANDA PERSENCITURE ROAL & LOMPUR	RANGON TENDERANA . Ratio adulta
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		94 - 950G - 946
ganisation Name*		
paratation mame		
-		
1.000		
		222
dress Of Organisation*		State *
		-SELECT STATE-
-		-SELECT STATE-
	b	£
		City*
		→
		Postcode *
		FORCON
ware required to fill up a MINIMUM	of 1 (ONE) contact number (Telephone / Mobile No) *	
Telephone No : 0		8. Mobile No : 🛈 🚽
and the second		
e.g: 034587800		e.g: 0154567890
N-BA MARKARA BARK		- THE CONSTRUCTION
Fax No : O		10. Email Address 1" O
e.g: 034567800		
		1.2
		Nest 🚽
		Nezt -
sert Your Phone Number In TI	his Insert Your Fax Number In This	Insert Your Phone Number In This Insert Your Email In This Format Click
Format 034567890		
Format 034367650	Format 034567890	Format 0134567890 abcd@gmail.com next
		TICX.
:0		le sectio
		0 secur

7. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at ¹ . 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 ⁽²⁾. 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.

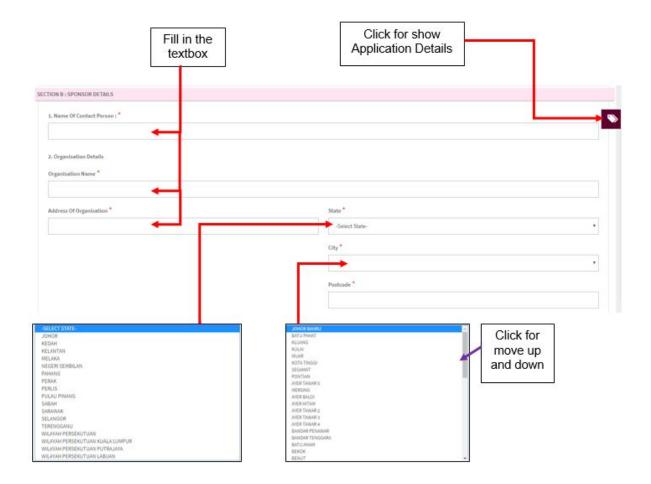
The user must fill the Fax No in an integer. User can see the format which click at

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 ¹ 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."

Insert Contact Person Phone Number In This Format 034567890	Insert Your Sponsor Mobile Number In This Format 0134567890	Insert Contact Person Fax Number In This Format 034567890
. 0	0	0
You are required to fill up a MINIMUM of 1 (ON		
3. Telephone No : 0		oile No : 😧
5. Fax No : 0	6. Ema	ail Address : " 🖸 🗲
e.g:034567890	e.g:	: abc@gmail.com
♦ Previous		Next 🔶
Click for	Insert Your Sponsor Email In	Click for
previous section	Format abcd@gmail.com	next section

3. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at ¹ . 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 ⁽²⁾. 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.

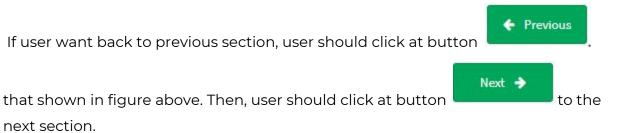
5. Fax No.

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 ¹⁰ 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.".



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 ⁶⁰ 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.

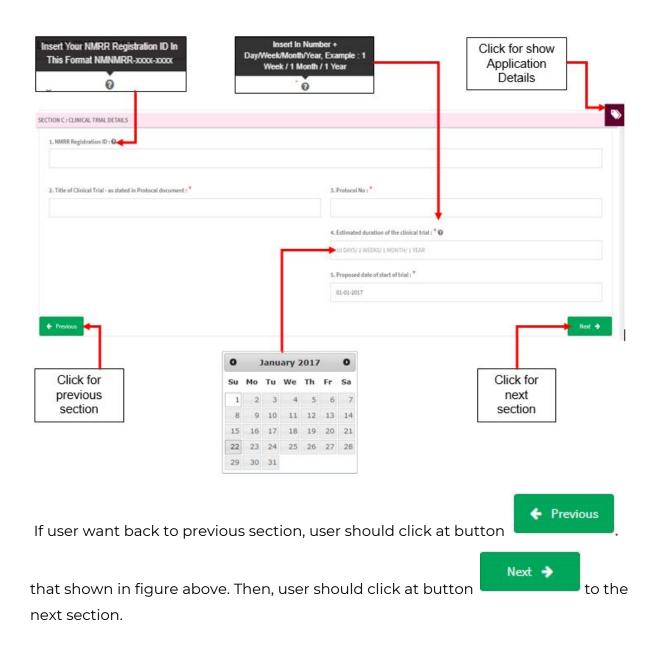
4. Estimated duration of the clinical trial

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

User can see the format with click at $^{\textcircled{0}}$ 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.



N D : TRIAL SITE DE	FAILS				
DIX A : TRIAL SITE D	TAILS(For multiple site	es in Malaysia - repeat as n	eeded)		
Add More Trial Site					
Name Of The Trial Site	Address Of The Trial Site	Name Of Principal Investigator	Name Of The Ethics Committee	Authorisation / Opinion Of Ethics Committee (please Attach The Approval Letter)	Approval Letter
results found.					
results found. Previous					Next

Section D: Trial Site Details

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

Firstly, the user should click at

+ Add More Trial 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.

	textbox	
ld Trial Site		
1. Name Of The Trial Site :*	-	
2. Address Of The Trial Site : *		
3. Name Of Principal Investigator : *		
4. Name Of The Ethics Committee : *		
Save		
Click for		

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

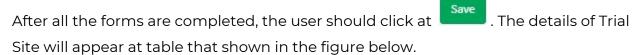
The user should fill in the textbox that provided that shown in figure above. If the user don't fill the address, the message "Trail site Address cannot be blank." will appear.

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.



		Detai trial					Click for trial	· ·	_
TION	D : TRIAL SITE	DETAILS							<u> </u>
PENDI	X.A : TRIAL SIT	E DETAILS(For multiple s	ı in Malaysia - re	peat as needed	9				
	idd More Trial S	(1)					l		
No	Name Of The Trial Site	n. Address Of The Trial Site	Name Of Principal Investigator	Name Of The Ethics Committee	Authorisation / Opinion Of Ethics Committee (please Attach The Approval Letter)	Approval Letter			1
1	ZIRA MOHAMAD NASIR	NO.17 F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, KEDAH.	RAHMAN	HASSAN	Г			2	♥ Update B Delete ♥ Update EC/18B
€ P	revious				Click for delete]	Click fo form EC	r fill	Nest 🌢
	er war isplay		e trial s	ite, use	er should cli	ck at	🖋 Upda	te ar	nd the form v

dd Trial Site	2
1. Name Of The Trial Site :*	
ZIRA MOHAMAD NASIR	
2. Address Of The Trial Site :	
NO.17 F, BATU 7 JALAN SANGLANG, AYER HITAM 06150 ALOR SETAR, REDAH.	
3. Name Of Principal Investigator : *	
RAHMAN	
4. Name Of The Ethics Committee : *	
HASSAN	
Click for	
save	

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

	С	ick for cancel deleted	
Delete Trial site?			×
		Cancel	ок
	рі	Click for roceed delete	ŀ

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.

Click at radio button	
Add Trial Site	×
A provisation / Opinion of thics Committee (please attach the approval letter) :* TO BE REQUESTED PENDING AUTHORISATION ACCEPTED/FAVOURABLE OPINION	
Click for save	

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

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

×
≜ ×

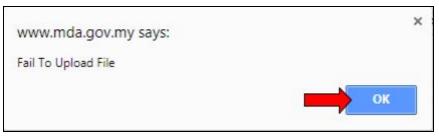
🍰 Upload file

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. .

www.mda.gov.my says:	×	
File Type Not Allowed		
	ок	
		l. 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

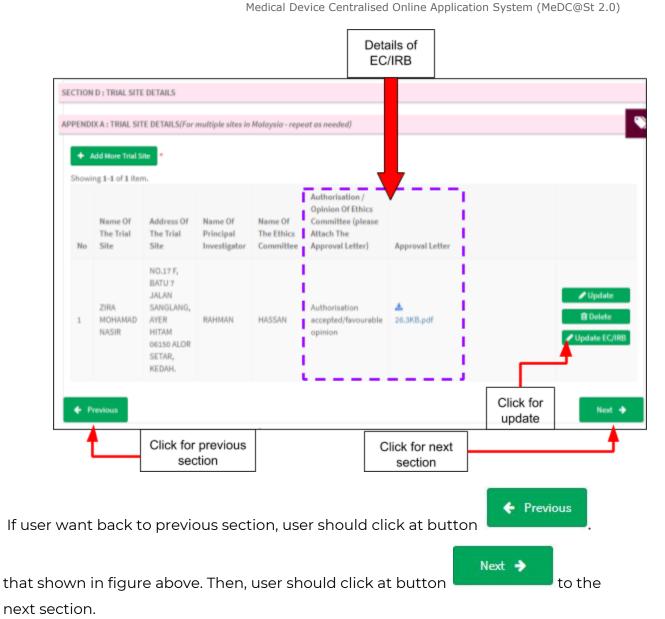


will appear. The

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. Medical Device Authority, Ministry of Health Malaysia

User Manual Front End User - Notification



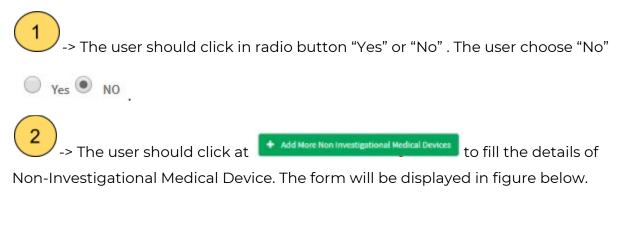
UNIJAYA RESOURCES SDN BHD

1		n radio iton						
ION	E : MEDIC	AL DEVICE DETAILS						
L PI	ease provi	de medical device d a tails a	ccording to the following :	Appendit	B for Non-investigati	ional Medical Devices		
NDI	X B : PAKI	ICULARS OF NON-INVESTI	GATIONAL MEDICAL DEVIC	<u>.ES- (</u> Rep	eat As Needed)			
s th	e pack	list for Study-Visits Specif	ic Kits attached as part of	the suppo	orting documents? *			
	· .	NO			-			
		NO						
		Identifier (e.g.	Description & Intended Purpose				Total	
No	Device Name	Model/Lot/Batch Number)	(Purpose of use must be described in details)	Risk Class	Product Owner / Manufacturer	Total Quantity per site (Units)	Quantity (units)	Total Cost Of Devices (MYR)
	Harrise	Humber/	deachibea in deanay	Class	Plantanaccurrer	per site (onica)	(unital)	bences (HTR)
	esults foun	d.	\frown					
	esults foun	d.	2					
Nore		d. on Investigational Medical De		at bu	tton			
Nore				at bu	tton			
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No re	Add More No	on Investigational Medical De						Next 🌢
No re	Add More No	on Investigational Medical De						Next 🏓
No re	Add More No	on Investigational Medical De					_	Next 🌢

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?



Medical Device Authority, Ministry of Health Malaysia

id Non Investigational Medical Device	•	
2. Identifier (eg: Model/Lot/Batch Number) :*		
3. Description & Intended Purpose (description mu	st be precisely in details) :*	
4. Risk Class :*		
5. Product Owner / Manufacturer :*		
6. Total Quantity per site (Units) :*		
7. Total Quantity (Units) :*		
8. Total Cost Of Devices (MYR) :*		
RM Click for		

Add Non Investigational Medical Device

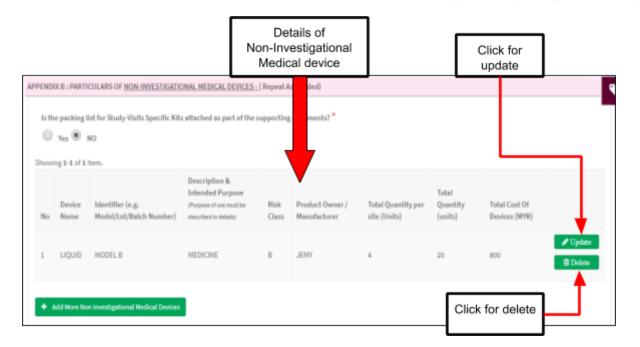
- 1. Device Name -> The user should fill in the textbox that provided. If the user don't fill the name, the message "Device Name cannot be blank." will appear.
- Identifier(eg: Model/Lot/Batch Number) -> The user should fill in the textbox that provided. If the user don't fill the identifier, the message "Device Model / Identifier / Lot / Batch Number cannot be blank." will appear.
- 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.
- 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.

- 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.

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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.

Delete Non Medical Device?	×
	Cancel OK

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

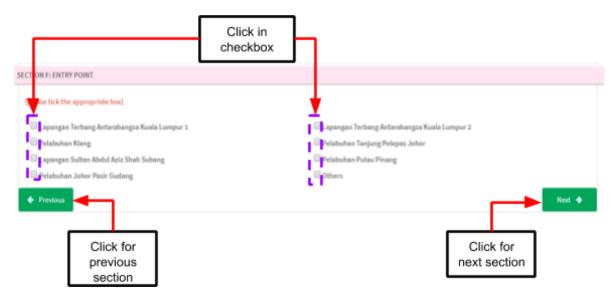
+ Add More Non Investigational Medical Devices

If the user choose the decision "yes" ^(*) ^(*) ^(*) , the button upload file will be displayed.

۰ د	pload file		s attached as part of the	sabbound	and an				
	fed Files :-								
	results fou								
No	Device Name	ldentifier (e.g. Model/Lot/Batch Number)	Description & Intended Purpose (Purpose of use must be described in details)	Risk Class	Product Owner / Manufacturer	Total Quantity per site (Units)	Total Quantity (units)	Total Cost Of Devices (MYR)	
1	LIQUID	MODEL B	MEDICINE	•	YMIL	4	20	800	✔ Update II Delete
• •	ldd More No	n Investigational Medical Devices							
									Next 🌩

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

Maximum File Size : 3 Supported File Type : F The message that will display at button is	
download the file with clicking at 📥 and delete the file wit	h click at ื.
If user want back to previous section, user should click at b	eutton
that shown in figure above. Then, user should click at butto	n Next 🗲 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

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

SECTION G : MILITIPL		indly state the total no. of devices per objament if this trial requires multiple objament – Repeat if necessary)	
No No results found.	Shipment Type	Total Number Of Devices	
Previous	Add multiple Shipment (Shipme Shipment Type : First Shipen Total : Total number of devic	ent	Next

Section G: Multiple 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.

SECTION G : 1	Details of shipment	state the total on. of devices per shapment if this trial requires	Click for update Click for delete	
+ Add S Showing 1	Jupment -1 of 1 item.			
No	Shipment Type	Total Number Of Devices	
1	First Shipment	2	🖊 Update 🗎 Delete	
🔶 Prev	Click for previous section		Click for next section	

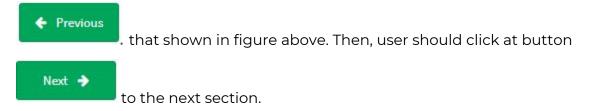
The user can update the details with click at **Update** and the form shipment will

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

Delete shipment?	×
	Cancel

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



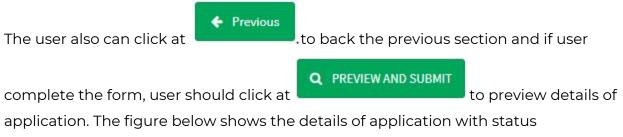
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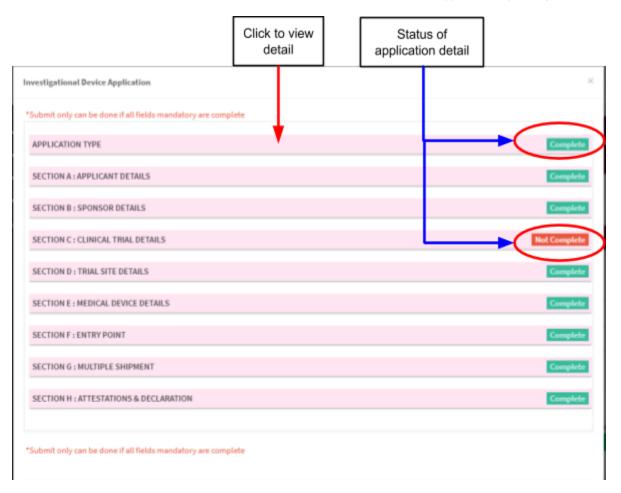
SECTION H : ATTESTATIONS & DECLARATION	
I, the undersigned, on behalf of the company hereby declare that :	
a. This/these medical device (s) indicated on this application:	
L Conform(s) to all relevant essential principles for safety and performance as set out in the appendix 1 of third	schedule of the medical device regulations (mdr) 2012;
ii. Has/have met all the labeling requirements set out in the sixth schedule of the mdr 2012;	
b. I shall be responsible to take the necessary actions should there be any adverse incident occurs during the period of	trial;
c. I am aware this/these medical device(s) is/are permitted for clinical research purpose only. therefore, the medical de	vice[s] shall not be:
L placed/used at the trial site after the trial has ended;	
ii. placed in Malaysia;	
d. I shall ensure that this/these medical device (s) is/are disposed appropriately / exported out of malaysia after the tria	I has ended;
I, the undersigned, hereby attest that the information and attachment provided on this notification is/are accurate, correct, declaration by me in this application that is untrue, inaccurate or misleading shall be liable to a fine not exceeding rm 500,00 both. (s.76 act 737 refers).	
Previous Click for previous section	Click for view and submit

Section H: Attestations & Declaration

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



"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.

Click at button	
IPPLICATION TYPE	Complet
ECTION A : APPLICANT DETAILS	Complet
ECTION B : SPONSOR DETAILS	Complet
ECTION C : CLINICAL TRIAL DETAILS	Complet
ECTION D : TRIAL SITE DETAILS	Complet
ECTION E : MEDICAL DEVICE DETAILS	Complet
ECTION F : ENTRY POINT	Complet
ECTION G : MULTIPLE SHIPMENT	Complet
ECTION H : ATTESTATIONS & DECLARATION	Complet

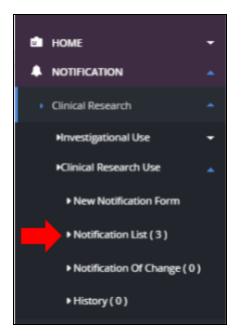
After user click button "Submit", the alert message will be displayed.

Confirm Submit Application?	×
	Cancel OK

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.

101	owing 1-3 of 3 items.							
9	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action	
	1	CRU-20180827-5	27-08-2018	PENGGUNA NOTIFIKASI	CLINICAL RESEARCH USE	COMPLETE	Q View Subsequent Notification	
	2	CRU-20180827-6	Not Submitted Yet	PENGGUNA NOTIFIKASI	CLINICAL RESEARCH USE	DRAFT	Q View 🖋 Update 🛢 Delete	
	3	CRU-20180827-6	Not Submitted Yet	PENGGUNA NOTIFIKASI	SUBSEQUENT CLINICAL RESEARCH USE	DRAFT	Q View VUpdate 🖻 Delete	

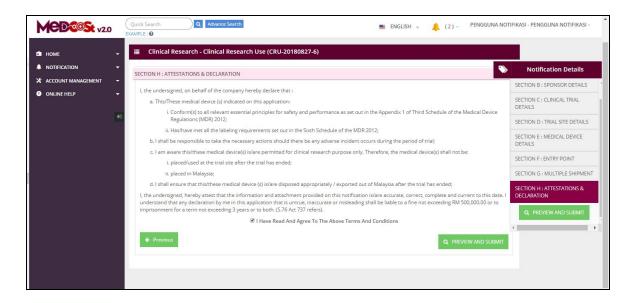
User click on Subsequent Application . Next step is click OK and the system will display *Subsequent Application* where the data has been copied from the previous application.

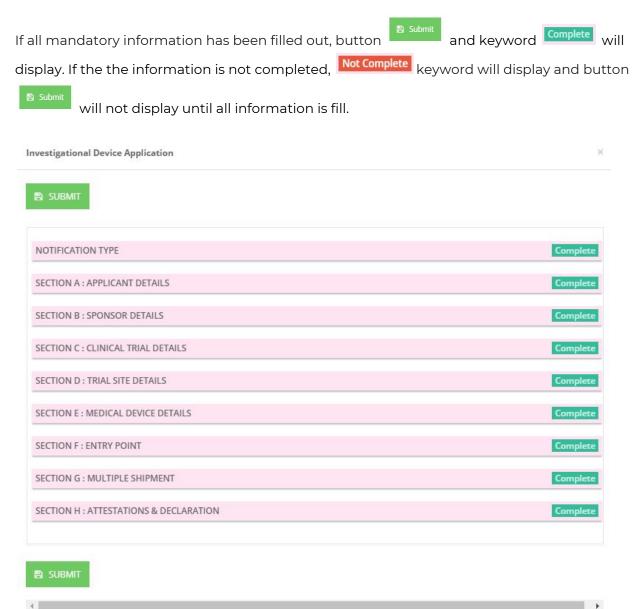
Medical Device Authority, Ministry of Health Malaysia

	Home / Notifications / Clinical Research - Clinical Research Use (CRU-20180827-6)	
HOME NOTIFICATION ACCOUNT MANAGEMENT	E Clinical Research - Clinical Research Use (CRU-20180827-6)	Notification Details
	•	SECTION A : APPLICANT DETAILS
UNLINE HELP		SECTION B : SPONSOR DETAILS
	Notification to Import Or Supply Medical Device for Clinical / Research Supportive Use (In accordance with Medical Device (Exemption) Order 2016)	SECTION C : CLINICAL TRIAL DETAILS
	* All fields are mandatory unless stated otherwise.	SECTION D : TRIAL SITE DETAILS
	1. Notification Type* O Subsequent Notification	SECTION E : MEDICAL DEVICE DETAILS
	Please tick the appropriate box below:* Additional Device only Additional Site and Device	SECTION F : ENTRY POINT SECTION G : MULTIPLE SHIPMEN SECTION H : ATTESTATIONS & DECLARATION
	2. For Subsequent Notification, please state :	4
	Previous MDA Identification No : * @	
	CRU-20180827-5	

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



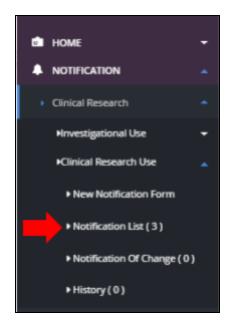


The status of application will be on evaluation stage.

haw	ing \$-3	3 of 3 isems.					
8	No	Submission ID	Submitted At	Applicant	Notification Type Name	NetiFication Status	Action
	1	CRU-20180827-6	27-08-2018	PENGGUNA NOTIFIKASI	SUBSEQUENT CLINICAL. RESEARCH USE	EVALUATION	Q Vew all North atom History
	2	CRU-20180827-5	27-08-2018	PENGGUNA NOTIFIKASI	CLINICAL RESEARCH USE	COMPLETE	Q Vere Subsequent Notification
	3	CRU-20180827-6	Not Submitted Vet	PENIGGUNA NOTIFIKASI	CUNICAL RESEARCH USE	DRAFT	Q.Vew / Update @ Delete

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.

DWC	ing 1-3	2 of 2 items.					
	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
	1	CRU-20180827-6	27-08-2018	PENGGUNA NOTIFIKASI	SUBSEQUENT CLINICAL RESEARCH USE	EVALUATION	Q View ENtification History
	2	CRU-20180827-5	27-08-2018	PENGGUNA NOTIFIKASI	CLINICAL RESEARCH USE	COMPLETE	Q View Subsequent Notification

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

Notification of Change	
Change Of Principal Investigator	Change Of IRB/EC
Change Of Site	Change Of Device
Others	
Proceed to Notification	

User choose type of change by click button Change Notification application form.



. The system will display

lalaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

Medical Device Authority, Ministry of Health Malaysia

MCDCOSt v2.	Quick Search Q Advance Search EXAMPLE: • (3) - PENGGUNA	NOTIFIKASI - PENGGUNA NOTIFIKASI -
	Home / Notifications / Clinical Research - Clinical Research Use (CRU-20180827-6)	Notification Details
X ACCOUNT MANAGEMENT	Elinical Research - Clinical Research Use (CRU-20180827-6) ✓	SECTION A : APPLICANT DETAILS
	Notification to Import Or Supply Medical Device for Clinical / Research Supportive Use (In accordance with Medical Device (Exemption) Order 2016)	SECTION B : SPONSOR DETAILS SECTION C : CLINICAL TRIAL DETAILS
	* All fields are mandatory unless stated otherwise. 1. Notification Type [®] ● First Notification	SECTION D : TRIAL SITE DETAILS SECTION E : MEDICAL DEVICE DETAILS
	SECTION A : APPLICANT DETAILS	SECTION F : ENTRY POINT SECTION G : MULTIPLE SHIPMENT
	1. PURPOSE OF RESEARCH :* Clinical Use Clinical Use Research Supportive Use (Clinical Drug Trial) Research Supportive Use (For Other Health Research Studies)	SECTION H : ATTESTATIONS & DECLARATION

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

\sim	Notification Details
	SECTION C : CLINICAL TRIAL DETAILS
	SECTION D : TRIAL SITE DETAILS
	SECTION E : MEDICAL DEVICE DETAILS
	SECTION F : ENTRY POINT
	SECTION G : MULTIPLE SHIPMENT
	SECTION H : ATTESTATIONS & DECLARATION
	NOTIFICATION OF CHANGE
	Q PREVIEW AND SUBMIT
	4

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

Notification of Change		
Change Of Principal Investigator	Change Of IRB/EC	
Change Of Site	Change Of Device	

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

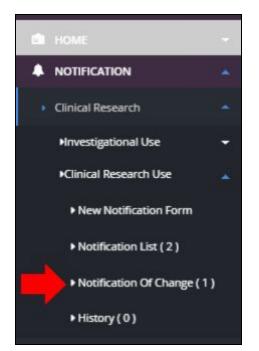
to preview the information that

user change.

nvestigational Device Application	
SUBMIT	
NOTIFICATION TYPE	Complete
SECTION A : APPLICANT DETAILS	Complete
SECTION B : SPONSOR DETAILS	Complete
SECTION C : CLINICAL TRIAL DETAILS	Complete
SECTION D : TRIAL SITE DETAILS	Complete
SECTION E : MEDICAL DEVICE DETAILS	Complete
SECTION F : ENTRY POINT	Complete
SECTION G : MULTIPLE SHIPMENT	Complete
SECTION H : ATTESTATIONS & DECLARATION	Complete
NOTIFICATION OF CHANGE	Complete
	•



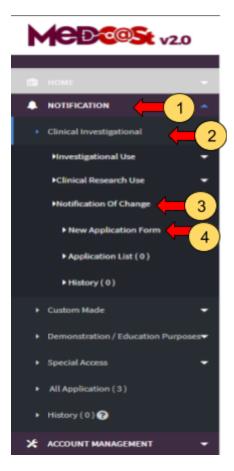
User click button Notification of Change under Clinical Investigation > Clinical Research Use.



The system will display list of Notification of Change.

low	ing 1-1	l of 1 item.					
	No	Submission ID	Submitted At	Applicant	Notification Type Name	Notification Status	Action
	1	CRU-20180827-6	27-08-2018	PENGGUNA NOTIFIKASI	Notification of Change	EVALUATION	Q View
		CRU-20180627-0	27-00-2010	PENGOUNA NO IPINASI	CRU	EVALUATION	j ≡ Notification History

III) NOTIFICATION OF CHANGE



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

 ${\it \bigcirc}$ -> The user should click at menu Clinical Investigational.

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

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

3

	Gash Sourch C Meaner Mean	🌲 (0) - 📳 NAZIBAH - NAZIBAH -
HONE HONE NOTIFICATION ACCOUNT MANAGEMENT ONLINE DELP	Notification Of Change On Clinical Research Serm (NC-20171215-11) NOTIFICATION OF CHANGE ON CLINICAL RESEARCO Folde marked with Service Address of the Clinical Research Packet marked with Service Address of the Clinical Research Packet marked with Service Address of the Clinical Research	Notifications SECTION A LAMPLICANT DETAILS DECTION B SPONSOR DETAILS
	SECTION AT APPLICANT DETAILS	SECTION C : STUDY DETAILS SECTION D : PURPOSE OF CHAVIDE SECTION E : ATTESTATIONS & DECLARATION SECTION F : SUPPORTING
	 Itale Of Applicant :* Cocal Spensor Authorized person from a local organization / company / Contract Research Organization (CRO) Manufacturer Name of Applicant :* Name of Applicant :* 	DOCLIMENTS Q PREVIEW AND SLIDMIT
	Click in radio button	

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

Section A: Application Details

1. Role of Applicant

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

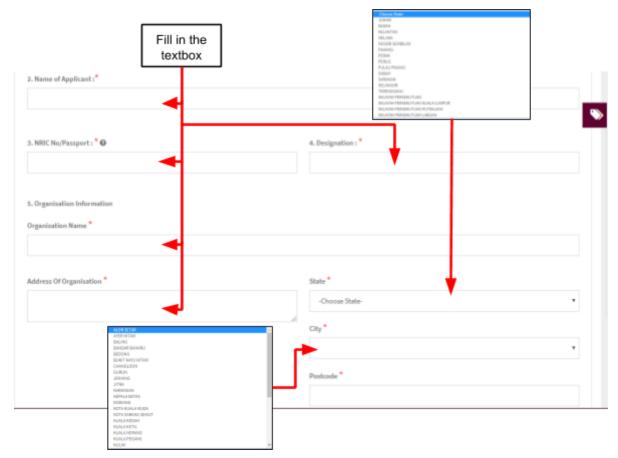
2. Name of applicant

The user should fill in the textbox that provided.

3. Nric No/Passport

The user must fill in the form according to the format displayed on the figure

below. The user should click at 60 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."

Insert Your Phone Number In This ou are re Format 034567890. MINIMU	Insert Your Mobile Number In This Format 0134567890
ø	Õ
	🖿 EN - 🌲 (0) - 🧝 NAZIBAH - NAZIBAH -
HOME HOME HOTEKCATION ACCEDUNT MANAGEMENT ONLINE HELP ON Yous are required. If up a HENINUM of 1 (DNE) confactor G. Telephone No :Q cg : ESECTED	Gly* ALDR SETAR Puttoode*
Insert Your Fax Number In This Format 034567890	Insert Your Email In This Format abcd@gmail.com Click for next section

6. Telephone No

The user must fill the Telephone No in an integer and user can see the format

with click at ². 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 ²² . 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

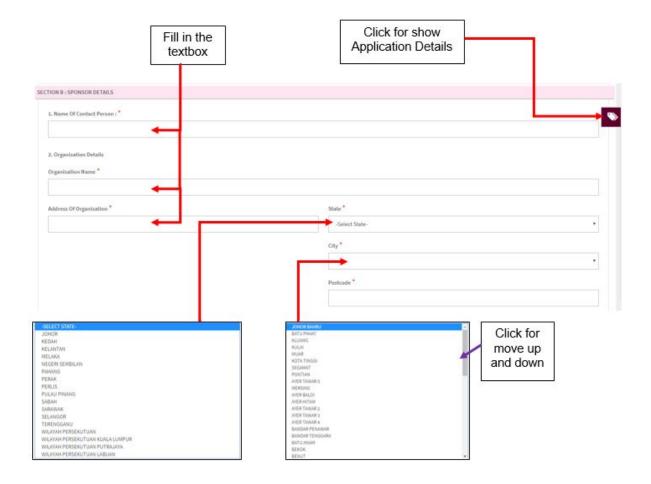
click at 🙆 . If user fills in the form except number or more than eleven

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 ¹⁰ 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
 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."

Insert Contact Person Phone Number In This Format 034567890	Insert Your Sponsor Mobile Number In This Format 0134567890	Insert Contact Person Fax Number In This Format 034567890
. 0	0	0
You are required to fill up a MINIMUM of 1 (Ol 3. Telephone No : O	NE) contact number (Telephone / Mobile No) * 4. Mob	ile No : 🖸
e.g: 034567890		1134567890
e.g:034567890		abc@gmail.com
+ Previous		Next 🔶
Click for previous	Insert Your Sponsor Email In Format abcd@gmail.con	

3. Telephone No

The user must fill the Telephone No in an integer and user can see the format with click at ¹ 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 ⁽²⁾. 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.

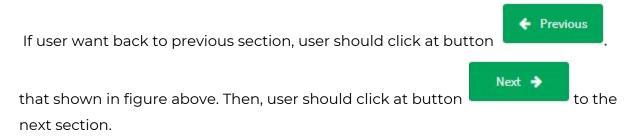
5. Fax No.

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 ¹ 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.".



User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)

Medical Device Authority, Ministry of Health Malaysia

Insert Your NMRR Registration ID In This Format NMRR-x000x-x000x					Fo	rma	at in	the form of numbers
CTION C I STUDY DETAILS								
1. NMRR Registration ID : 🖗								
2. Title of Study - as stated in Protocol / CIP document : *						3. Pre	otocol	No/CIP:*
						4. Est	timate	ed duration of the Study : *
								2 WEEKS/1 MONTH/1 YEAR d date of start of the Study : *
						01-	-01-20	17
	0	1	lanu	ary 3	2017	,	0	
Previous	5u	2 0	Tu 3 10	4	5 12	6 13	5a	
Click for previous section	15		17	18	19	20	21	Click for 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 60 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 $^{\textcircled{0}}$ 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.

lf user want b	back to previous section, user sho	uld click at button
that shown ir next section.	n figure above. Then, user should a	click at button
	Click in checkbox	EN = (0) - (0) - NAZIRAH - NAZIRAH -
Home Home Hotekation Account management Online help	Home NetRations / NetReation Of Change On Clinical Research Form (NC-20171215-11) Notification Of Change On Clinical Research Form (NC-20171215-11) SECT N.D.: PURPOSE OF CHANGE	
	See tick the appropriate back * Duarge Of Principal Investigator Duarge of Principal Investigator Duarge of Device Duarge of Device	Change Of IRE,EC Change In Site Address Others Not
	Click for previous section	Click for next stage

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.

	Fill in the textbox]
PRINCIPAL INVESTIGATOR DETAILS - Appendix A ()		
1. Name (former Principal Investigator) *		
Site *		Tel No * e.g: 034067/890
Dept,/Specialties		Email
2. Name (new appointed Principal Investigator) *		
Sile*		Tel No *
Dept./Specialties		e.g: 034567890 Email

1. Name(former Principal Investigator)

The user should fill in the textbox that provided.

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

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

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

	Fill in the textbox							
RAL SITE DETAILS (Change of aile) - Appendix A (#)								
Name (Previous Sile Detail): *								
iddress : *								
				d.				
. Name (new appointed site) : "								
2. Name (new appointed site) : *								
Name (new appointed site) (*								
). Name (new appointed site) : " Iddress : "								
lddress 1 *								
		0	D	ecen	nber	201	7	0
bdress : *	•				nber We		Fr	Sa
dress : *		Su	Мо	Tu	We	Th	Fr 1	Sa 2
tress 1 *		Su 3	Mo	Tu 5	We 0	Th 7	Fr 1 8	Sa 2 9
dress : *	-	Su 3 10	Mo 4 11	TU 5 12	We 6 13	Th 7 14	Fr 1 8 15	Se 2 9 16
bdress : *		Su 3 10 17	Mo 4 11 18	Tu 5 12 19	We 0	Th 7 14 21	Fr 1 8 15 22	Sa 2 9 16 23

- 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.

Medical Device Authority, Ministry of Health Malaysia

IalaysiaUser Manual Front End User - NotificationMedical Device Centralised Online Application System (MeDC@St 2.0)

	Click for upload file	
Address : *		-
Site Expected Start Date : *		
Attachment (Relevant Document) *		
▲ Upload file Sectoried File Type: pdf		
Uploaded Files :-		
No results found.		
Previous		Next 🔶
Uploaded Files		
26.3KB.p.07		A *

c) Change of Device

		Thursday I	-L of 1 fam.									
	Click in radio button	No D	exice Identifier (ing, differ(Lal(Balch	Description Intended P Purpos et an Inscription (supere a multile		roduct Owner / fanufacturer	Total Quartity per site (Units)	Total Quantity (units)	Entrypoint 4	
CHANGE OF M	EDICAL DEVICE - A spendix A(iv) - (Re	1 0	EVICE MODELF		JEMPON		c J	000	2	•	Lapangan Terbang Antarabangsa Kuala Lumpur 1	♥ Update @ Delete
Is the packie		attached	as part of the si	upporting doo	cuments?	Ł						
No Device Name	ldentifier (e.g. Model/Identifier/Lot/Batch Nu	mber)	Description & Purpose (Purpose of use m described in detail	uat be		roduct Ow anufactur		Total Q site (U	kantīty per nīts)	Total Qua (units)	ntity Entrypoint	
No results four	ıd.											
+ Add Hedi	(2)_											
Î		k for detai	fill the ils	~~~	Restored Ballon	(forks		(3)-		-	
				'	Serie Hans Serie Hold, Hold No. 1				\smile		i	
					Deciption & Interded Prop	prov						
L				-	RokCase							
					Westani Daver, Wanakaka	-						
					Taka Quantily per alle (Sala	-						
					Telerijeer Ng (eerbj							
1												
<u> </u>	If the user cho	oose	e the d	ecisio	on "ye	s"	Yes	NO NO	, the k	outto	n upload 1	file w
e displ	ayed.											
± Upload file	* Supported File Type : pdf											
Uploaded Files :-	adda an an Abrida.											
No results four	ıd.											
2>	The user shou	ld c	lick at	+ Add Ne	idical Devices	to	fill 1	the fo	orm of	med	ical device	9.
3>	The user shou	ıld f	ill the	form	whick	n 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.
- 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.
- 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.
- 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.

Lapangan Terbang Antarabangsa Kuala Lumpur 1	
Lapangan Terbang Antarabangsa Kuala Lumpur 2	
Pelabuhan Klang	
Pelabuhan Tanjung Pelepas Johor	
Lapangan Sultan Abdul Aziz Shah Subang	
Pelabuhan Pulau Pinang	
Pelabuhan Johor Pasir Gudang	
Others	



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

-> The details of medical device will be displayed.

d) Change of IRB/EC

	Fill in the textbox		
INSTITUTIONAL REVEW BOARD / ETHIC COMMITTEE DETAILS - Appendix A.(II) (IRB/EC)			
Name (former INB/EC):*	•		
Address : *			
		à	
Name (new appointed SR)(CC); *			
Address : *			
		ŝ	
Approval Letter :*			
No results found.			

- 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.

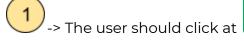
utnen, jonenge in prosocia, cansar inve	stigation plan(CP) - title, subject recruitment, etc) usaly date the elocati resonance.
f user want b	ack to previous section, user should click at button
hat shown in next section.	figure above. Then, user should click at button to the
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OWCHEINED	SECTIONE E: ATTESTATIONS & DECLARATION I, the undersigned, on behalf of the company hereby declare that :
	L, the undersigned, hereby attent that the informations and attachement provided as this notifications is/here accurrent, complete and current to this date.

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

♦ Previous	hat shown	in figure above. T	Then, user sho	ould click at but	ton
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Section F: Supporting Documents

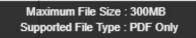


🛓 Upload file

to upload file. The file should PDF

only and not more than 300MB. The user can see the message that display at

Medical Device Authority, Ministry of Health Malaysia User Manual Front End User - Notification Medical Device Centralised Online Application System (MeDC@St 2.0)



. If user upload file in others format, the alert

message will be displayed that shown in the figure below.

www.mda.gov.my says: Fail Upload, File Type Not Allowed	×
	ок

The user should click button "OK".

button

-> 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 will be displayed.

to submit the application. The alert message

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 " below. " and fill all the form, it will be shown like

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.