TRAINING SESSION:

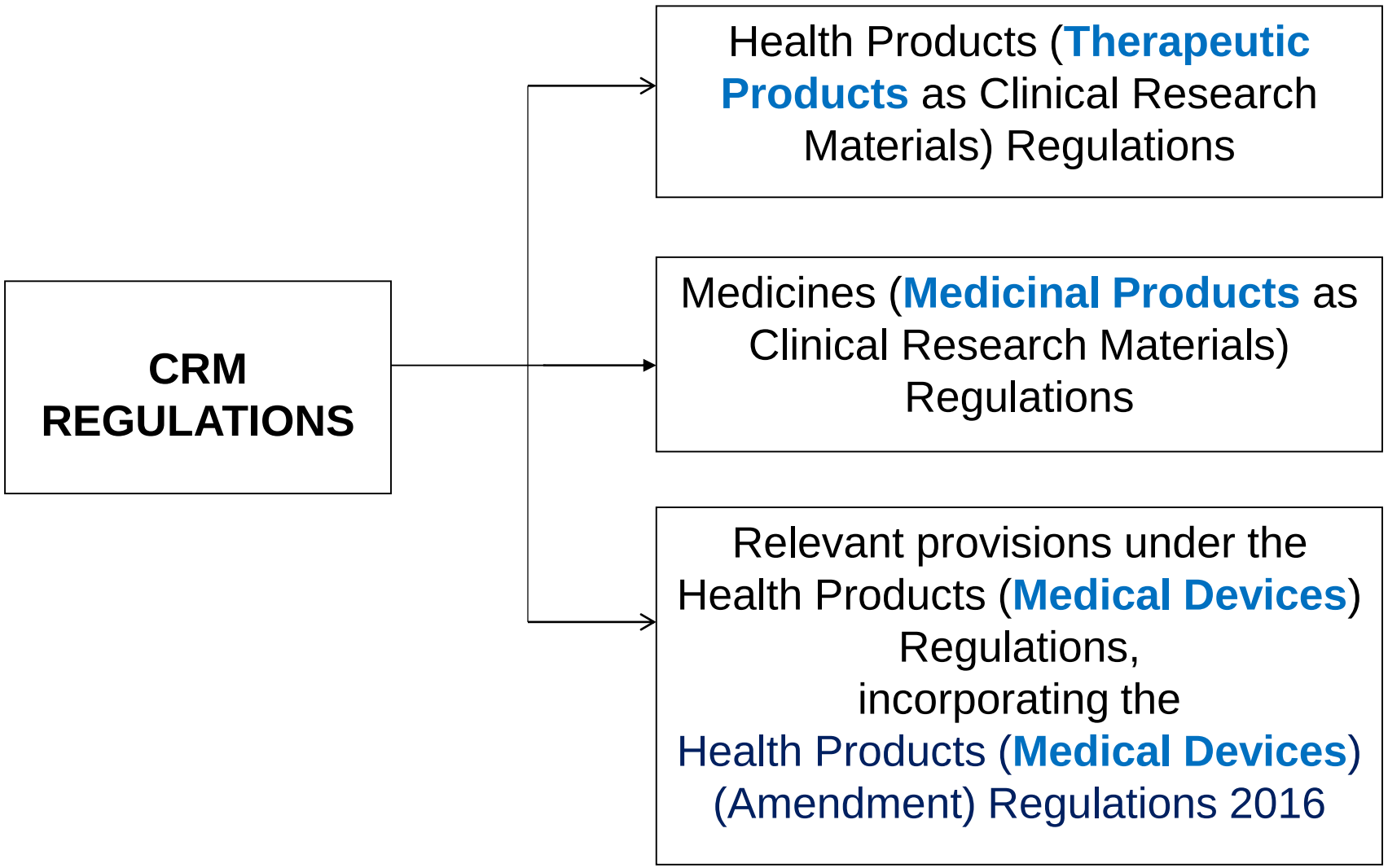
ENHANCED PRISM E-SERVICES

CRM NOTIFICATION SUBMISSION

OUTLINE

1. Overview of CRM Notification Requirements
2. CRM Notification for Clinical Research Not Regulated by HSA
3. Amendment of CRM Notification (clinical research not regulated by HSA)
4. Extension of CRM Notification (clinical research not regulated by HSA)
5. CRM Notification for Regulated Clinical Trials (New and Amendment)

CRM REGULATIONS



CLINICAL RESEARCH MATERIALS (CRM)

Clinical Research Materials (CRM)

- Registered or unregistered therapeutic product (TP)
- Licensed or unlicensed medicinal product (MP)
- Placebo
- Medical Device (MD)

Manufactured, imported or supplied for the purpose of being used in any **clinical research** in accordance with a research protocol

Regulated Clinical Trials
Clinical Trials requiring a CTA/CTN/CTC

Clinical Research not regulated by HSA

- Observational clinical trials of TP and MP;
- Clinical research for which TP or MP is not the subject of investigation
- Medical device clinical trials; or
- Food and nutrition studies involving the use of MD

CRM NOTIFICATION

~ Facilitates access to CRM

Activity	Licence	CRM Notification
Manufacture of CRM	Manufacturer's Licence Not required	**CRM Notification** required prior to supply of CRM by local manufacturer
Import of CRM	Importer's Licence Not required	**CRM Notification** required prior to import of CRM
Wholesale of CRM	Wholesaler's Licence Not required	-
Supply of CRM	Product Registration Not required	-

CRM NOTIFICATION

Regulated clinical trials vs. other clinical research

	Clinical research not regulated by HSA	Regulated clinical trial
Drafter of CRM notification form	Importer or local manufacturer	Sponsor (on behalf of importer or local manufacturer)
Notification Form (PRISM)	CRM Notification form	Part of CTA/CTN/CTC application form
Endorsement Workflow	Importer/Local manufacturer –> Sponsor	Sponsor -> Importer/Local Manufacturer (endorsement)
Submitter	Importer or local manufacturer	Sponsor (on behalf of importer or local manufacturer)
Acknowledgment notification	Importer, local manufacturer, sponsor	Importer, local manufacturer, sponsor
Validity period of notification	1 year from the date of notification	Duration of the clinical trial

OUTLINE

1. Overview of CRM Notification Requirements
2. **CRM Notification for Clinical Research Not Regulated by HSA**
3. Amendment of CRM Notification (non-regulated clinical research)
4. Extension of CRM Notification (non-regulated clinical research)
5. CRM Notification for Regulated Clinical Trials (New and Amendment)

CRM NOTIFICATION

For Clinical Research Not Regulated by HSA

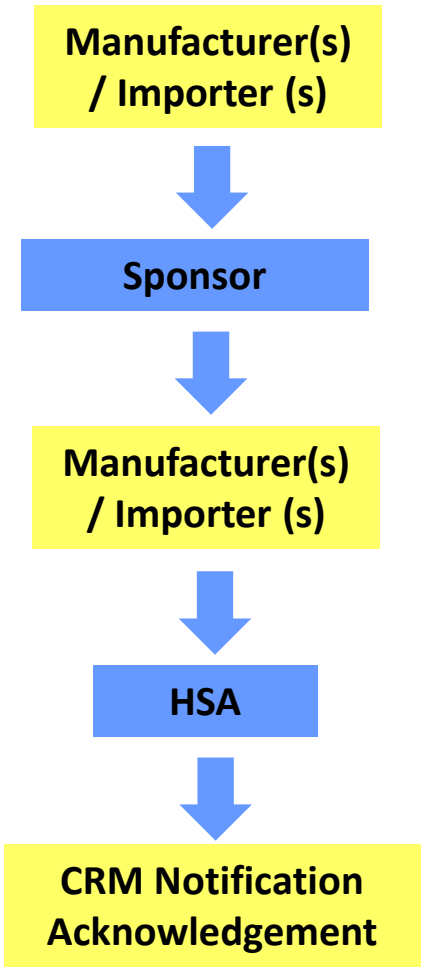
A. Import / Supply by Local Manufacturer of CRM for Clinical Research Not Regulated by HSA

1. Manufacturer/Importer applicant **drafts** CRM notification, sends for endorsement.

2. Draft notification **endorsed** by sponsor.

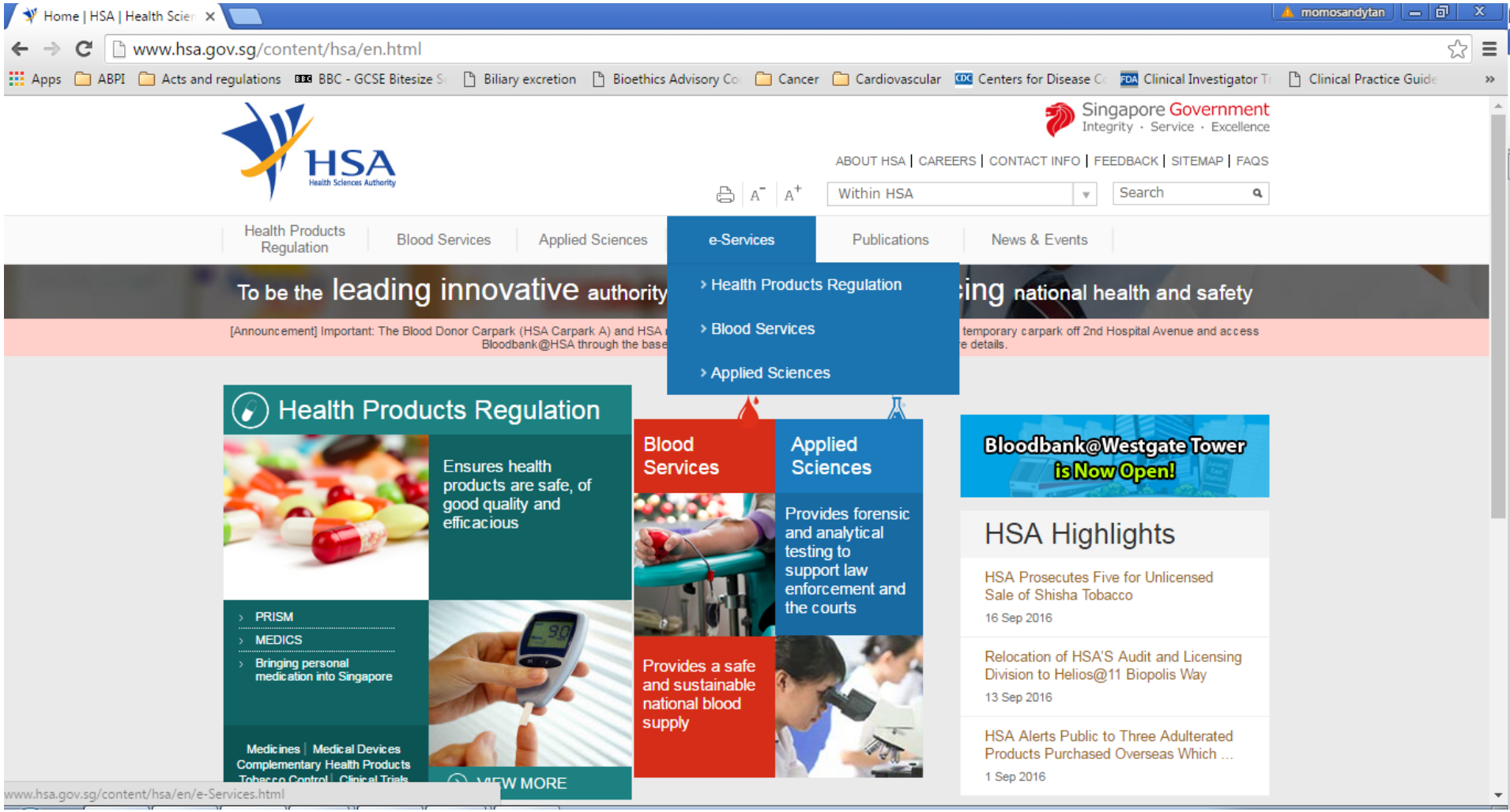
3. After endorsement, manufacturer/importer applicant **submits** notification

4. **CRM notification acknowledgement** sent to manufacturer(s)/ importer(s) and sponsor



CRM NOTIFICATION FORM

	Application Type (New or Amendment)
1	Introduction Particulars of Importer/Local Manufacturer
2	Particulars of Clinical Research
3	Particulars of Clinical Research Material (CRM) 3.1 Medicinal / Therapeutic Product 3.2 Medical Device for Investigational Purpose 3.3 Medical Device for Non-Investigational Purpose
4	Supporting Documents
5	Declaration & Confirmation



eServices>Health Products Regulation>PRISM>Clinical Trials>CorpPass login>Submit>Select Company

To be the leading innovative authority protecting and advancing national health and safety

CR0010 AUTHORISATION AND AUTHENTICATION MODULE > TERMS AND CONDITIONS

Terms and Conditions of Use

Updated as of 19/01/2005

By accessing this website and these electronic services, you shall be deemed to accept unconditionally and without any amendments the following terms:-

1. You are responsible for all usage/access authenticated by your SingPass and/or HSA PIN (where applicable).

2. The information/materials/contents contained in the HSA website are protected by copyright, trademark and other forms of proprietary rights. All rights, title and interest in the same are owned by, licensed to or controlled by HSA.

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Last updated on 01 July 2014

APPLICATION TYPE

PT0101 CLINICAL RESEARCH MATERIAL NOTIFICATION

Application Type

NOTE: Please complete this notification only if therapeutic products / medical devices / medicinal products are to be imported, or supplied by a local manufacturer, for the purposes of an IRB-approved clinical research.

This is a *

- ○ New notification
- ○ Amendment of an existing notification — Select CRM No. – Protocol No.

Next Reset

Section 1. INTRODUCTION

PT0101 CLINICAL RESEARCH MATERIAL NOTIFICATION

Fill in the application form Guideline Help

1. **Particulars of Importer / Local Manufacturer**
2. Particulars of Clinical Research
3. Particulars of Clinical Research Materials (CRM)
4. Supporting Documents
5. Declaration & Confirmation

Special Symbol | Attach | Save

Next

Fields marked with an asterisk * are mandatory.

1. Introduction

1.1 Please select *	○ Importer of CRM ○ Supply of CRM by Local Manufacturer
1.2 Please select the type of CRM to be imported or supplied *	☐ Therapeutic Product ☐ Medical Device ☐ Medicinal Product (e.g. Cell- and Tissue-based Product, Complementary Health Products)

Section 1. PARTICULARS OF IMPORTER/LOCAL MANUFACTURER

Particulars of Importer / Local Manufacturer			
1.3 UEN: *	196400192M		
1.4 Company Name: *	PFIZER PTE LTD		
1.5 Address			
1.5.1 Address Type:	Local		
1.5.2 Postal Code: *	189721		
1.5.3 Block / House No:	152	1.5.4 Level – Unit: *	# – 00
1.5.5 Street Name:	BEACH RD		
1.5.6 Building Name:	GATEWAY EAST		
1.5.7 Country:	SINGAPORE		
1.6 Contact Particulars			
1.6.1 Salutation	Select One		
1.6.2 Company Representative *			
1.6.3 NRIC / FIN	T5000178J	Please note that this field is auto-populated with the NRIC / FIN information of the most recent SingPass login user.	
1.6.4 Designation *			
1.6.5 Tel *		1.6.6 Fax	
1.6.7 Handphone			
1.6.8 Email *			
1.6.9 Preferred Contact Mode *	○ Email ○ Fax ○ Sms (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)		

Only NRIC of applicant with submitter rights will be auto-populated from login. NRIC will be masked subsequently e.g. SXXXXXX1G

Next Reset

Section 2. PARTICULARS OF CLINICAL RESEARCH

2. Particulars of Clinical Research	
2.1.1 CRM is intended for *	○ Single study ○ Multiple studies with single sponsor (e.g. re-usable heavy medical equipment) ○ Multiple studies with multiple sponsors (e.g. lab kit components imported in bulk)
2.1.2 For CRM intended for multiple studies with multiple sponsors, has any of the sponsors been identified? *	○ Yes ○ No
If the research sponsor(s) for the study(ies) has not yet been identified, please ensure that the research sponsor(s), once identified subsequently, is made aware of their legal obligations under the Health Products (Therapeutic Products as Clinical Research Material) Regulations, the Health Products (Medical Devices) Regulations, or the Medicines (Medicinal Products as Clinical Research Material) Regulations, as applicable.	

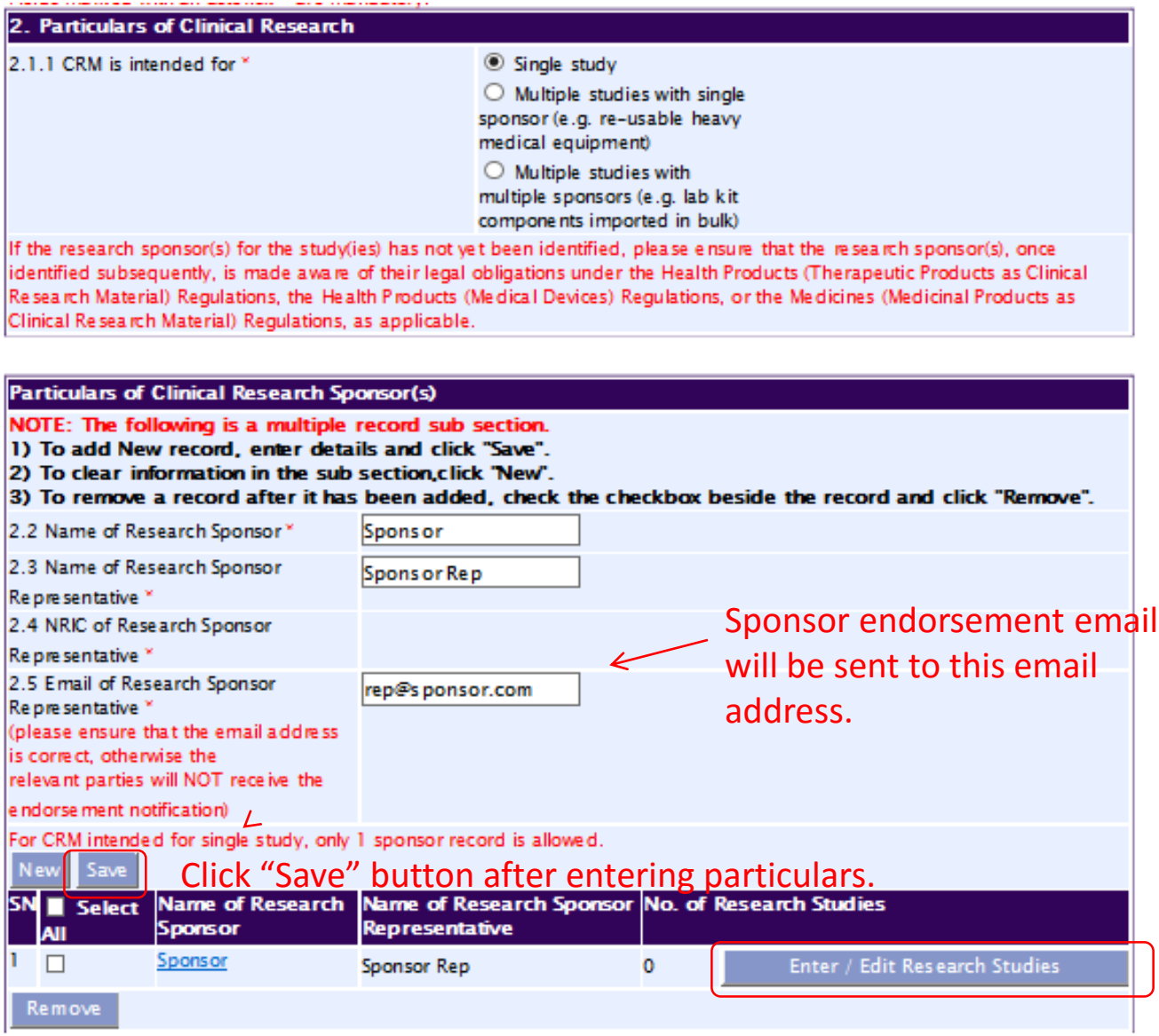
Note:

(A) 2.1.1 = Single Sponsor
- Particulars of sponsor and research study mandatory

(B) 2.1.1 = Multiple Studies with Single Sponsor
- Particulars of sponsor mandatory, particulars of research studies non-mandatory

(C) 2.11 = Multiple Studies with Multiple Sponsors
- Particulars of sponsor (mandatory only if identified), particulars of research studies non-mandatory

Section 2. PARTICULARS OF CLINICAL RESEARCH



2. Particulars of Clinical Research

2.1.1 CRM is intended for *

- (•) Single study
- ( ) Multiple studies with single sponsor (e.g. re-usable heavy medical equipment)
- ( ) Multiple studies with multiple sponsors (e.g. lab kit components imported in bulk)

If the research sponsor(s) for the study(ies) has not yet been identified, please ensure that the research sponsor(s), once identified subsequently, is made aware of their legal obligations under the Health Products (Therapeutic Products as Clinical Research Material) Regulations, the Health Products (Medical Devices) Regulations, or the Medicines (Medicinal Products as Clinical Research Material) Regulations, as applicable.

Particulars of Clinical Research Sponsor(s)

NOTE: The following is a multiple record sub section.
1) To add New record, enter details and click "Save".
2) To clear information in the sub section,click "New".
3) To remove a record after it has been added, check the checkbox beside the record and click "Remove".

2.2 Name of Research Sponsor *	Sponsor
2.3 Name of Research Sponsor Representative *	Sponsor Rep
2.4 NRIC of Research Sponsor Representative *	
2.5 Email of Research Sponsor Representative * (please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification)	rep@sponsor.com

Sponsor endorsement email will be sent to this email address.

For CRM intended for single study, only 1 sponsor record is allowed.

New | Save

Click “Save” button after entering particulars.

SN	Select All	Name of Research Sponsor	Name of Research Sponsor Representative	No. of Research Studies	
1	☐	Sponsor	Sponsor Rep	0	Enter / Edit Research Studies

Remove

Previous | Next | Reset

Particulars of Clinical Research Sponsor(s)

2.2 Name of Research Sponsor *	Sponsor
2.3 Name of Research Sponsor Representative *	Sponsor Rep
2.4 NRIC of Research Sponsor Representative *	
2.5 Email of Research Sponsor Representative * (please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification)	rep@sponsor.com

Particulars of Clinical Research

1) To add New record, enter details and click "Save".
2) To clear information in the sub section,click "New".
3) To remove a record after it has been added, check the checkbox beside the record and click "Remove".

2.6 Title of Clinical Research *	Research Title
2.7 Research reference or protocol number *	Research Ref No

New Save

Particulars of Clinical Research Site

NOTE: The following is a multiple record sub section.
1) To add New record, enter details and click "Save".
2) To clear information in the sub section,click "New".
3) To remove a record after it has been added, check the checkbox beside the record and click "Remove".

2.8 Principal Investigator *	Ash Chua
2.9 Research Site *	National Cancer Centre
If Others, please specify	

New Save

SN	Select All	Name of PI	Name of Research Site
1	☐	Ash Chua	National Cancer Centre

Remove

SN	Select All	Title of Clinical Research
1	☐	Research Title

SN	Name of PI	Name of Research Site
1	Ash Chua	National Cancer Centre

Remove

Previous

Section 3. PARTICULARS OF CLINICAL RESEARCH MATERIALS (CRM)

3.1 Medicinal / Therapeutic Product

Particulars of Clinical Research Materials (CRM)

NOTE: The following is a multiple record sub section.
1) To add New record, enter details and click "Save".
2) To clear information in the sub section,click "New".
3) To remove a record after it has been added, check the checkbox beside the record and click "Remove".

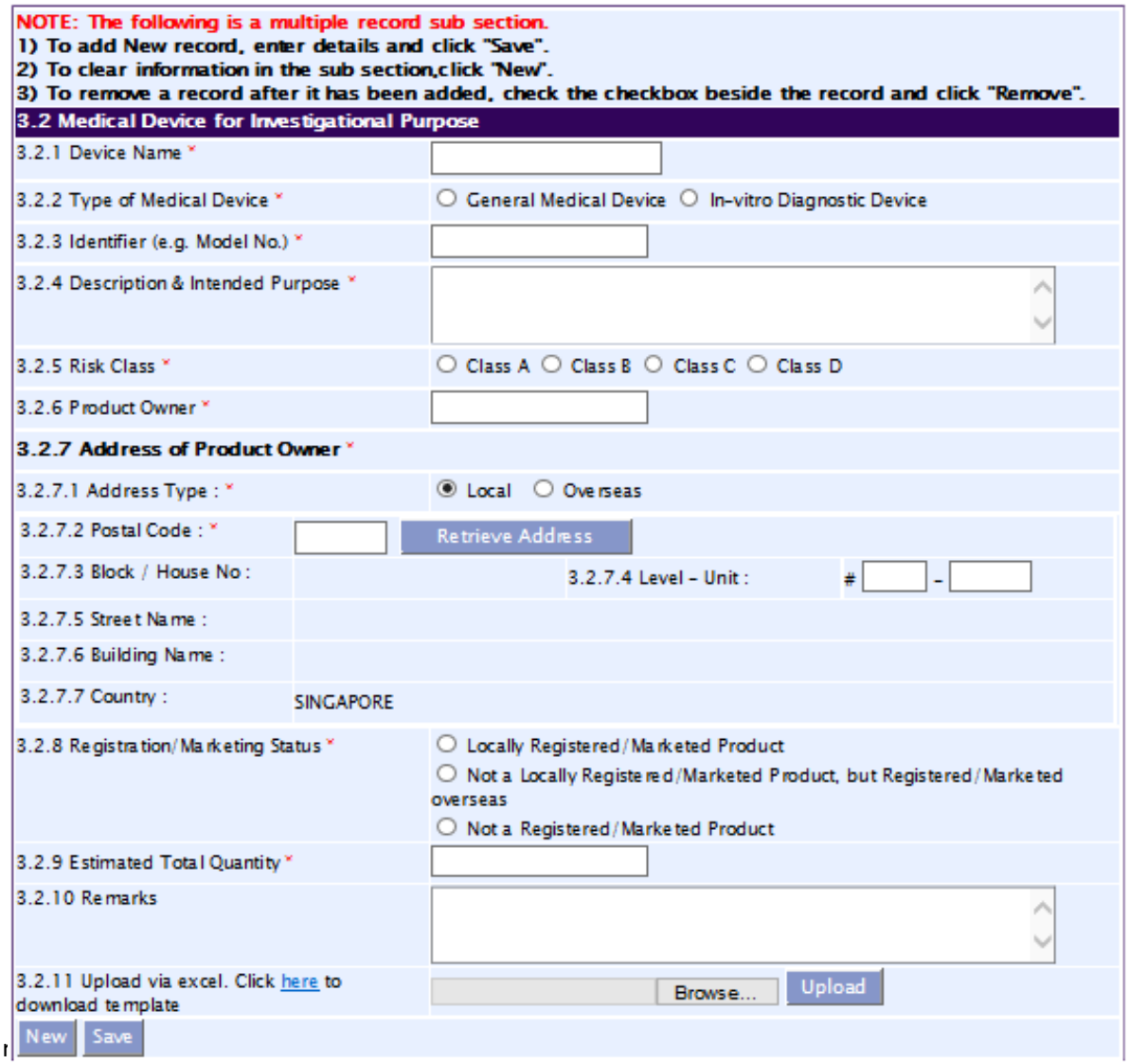
3.1 Medicinal / Therapeutic Product

3.1.1 Active Ingredient / Generic Name / Any code designation * (please use the active ingredient / generic name stated in the Product Label or investigator Brochure)	
3.1.2 Brand/Trade Name, if any:	
3.1.3 Does this product contain a psychotropic substance or a controlled drug? * Please note that a separate approval is required for the import of each consignment of therapeutic/medicinal product containing a psychotropic substance or a controlled drug. Please refer to [hyperlink to the relevant e-services] for more information on the requirements and application process.	○ Psychotropic Substance ○ Controlled Drug ○ Both ○ No
3.1.4 Dosage Form *	Select One
3.1.5 Route of Administration *	Select One
3.1.6 Strength *	
3.1.7 Registration/Marketing Status *	○ Locally Registered/Marketed Product ○ Not a Locally Registered/Marketed Product, but Registered/Marketed overseas ○ Not a Registered/Marketed Product
3.1.8 Estimated Total Quantity *	
3.1.9 Remarks	

New Save

Section 3. PARTICULARS OF CLINICAL RESEARCH MATERIALS (CRM)

3.2 Medical Device for Investigational Purpose



NOTE: The following is a multiple record sub section.
1) To add New record, enter details and click "Save".
2) To clear information in the sub section,click "New".
3) To remove a record after it has been added, check the checkbox beside the record and click "Remove".

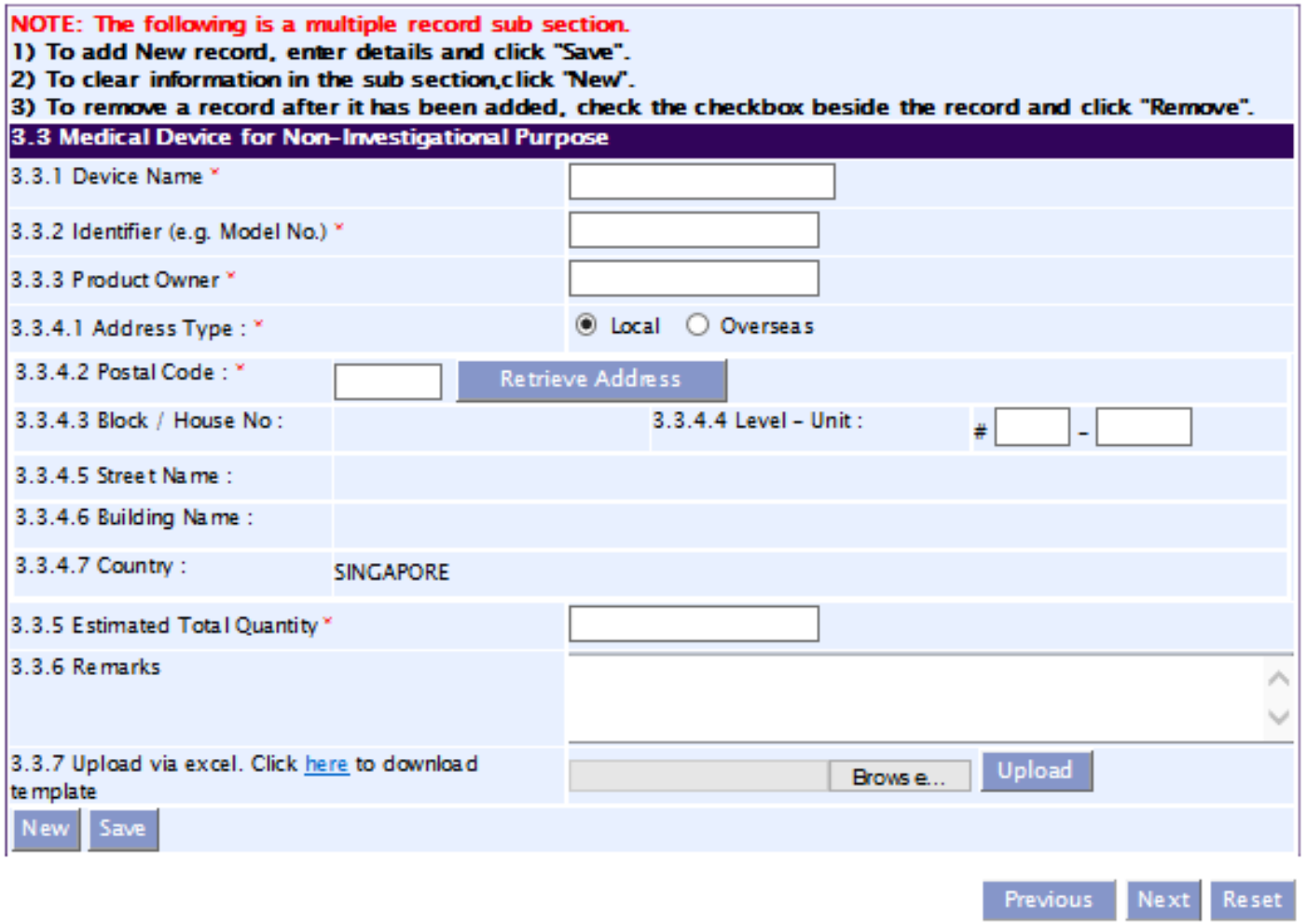
3.2 Medical Device for Investigational Purpose

3.2.1 Device Name *	
3.2.2 Type of Medical Device *	○ General Medical Device ○ In-vitro Diagnostic Device
3.2.3 Identifier (e.g. Model No.) *	
3.2.4 Description & Intended Purpose *	
3.2.5 Risk Class *	○ Class A ○ Class B ○ Class C ○ Class D
3.2.6 Product Owner *	
3.2.7 Address of Product Owner *	
3.2.7.1 Address Type : *	◉ Local ○ Overseas
3.2.7.2 Postal Code : *	Retrieve Address
3.2.7.3 Block / House No :	3.2.7.4 Level - Unit : # -
3.2.7.5 Street Name :	
3.2.7.6 Building Name :	
3.2.7.7 Country :	SINGAPORE
3.2.8 Registration/Marketing Status *	○ Locally Registered/Marketed Product ○ Not a Locally Registered/Marketed Product, but Registered/Marketed overseas ○ Not a Registered/Marketed Product
3.2.9 Estimated Total Quantity *	
3.2.10 Remarks	
3.2.11 Upload via excel. Click here to download template	Browse... Upload

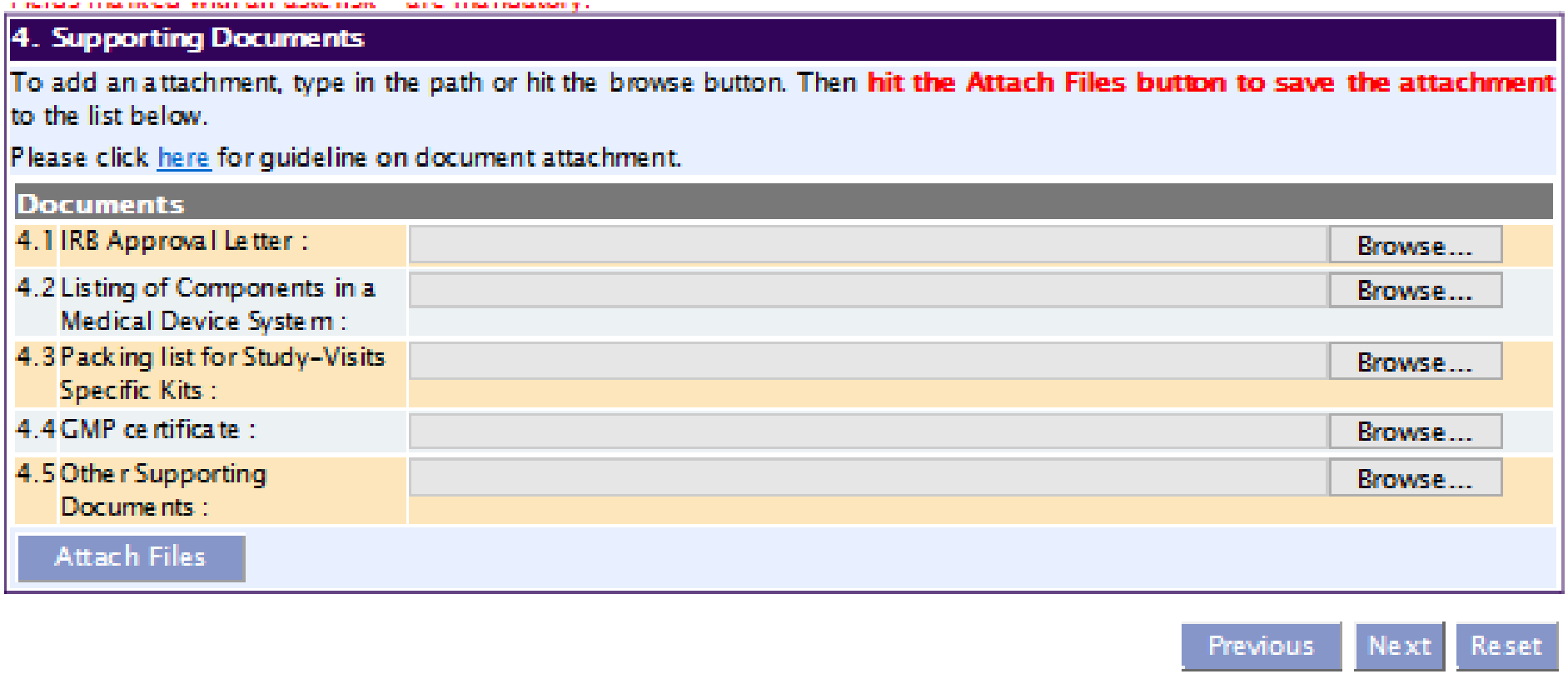
New Save

Section 3. PARTICULARS OF CLINICAL RESEARCH MATERIALS (CRM)

3.2 Medical Device for Non-Investigational Purpose



Section 4. Supporting Documents



4. Supporting Documents

To add an attachment, type in the path or hit the browse button. Then **hit the Attach Files button to save the attachment** to the list below.

Please click here for guideline on document attachment.

Documents		
4.1	IRB Approval Letter :	Browse...
4.2	Listing of Components in a Medical Device System :	Browse...
4.3	Packing list for Study-Visits Specific Kits :	Browse...
4.4	GMP certificate :	Browse...
4.5	Other Supporting Documents :	Browse...

Attach Files

Previous Next Reset

Section 5. Declaration and Confirmation

All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.

Declaration	
1.	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
2.	I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Therapeutic Products as Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) (Amendment) Regulations, where applicable.
3.	I, on behalf of my company, shall not supply the CRM stated in section 3 of the notification other than for the purpose of a clinical research approved by an Institutional Review Board.
4.	I, on behalf of my company, acknowledge that the CRM notification is valid for one year from date of notification, and shall ensure that the CRM stated in section 3 are disposed of appropriately / exported out of Singapore within 6 months of the completion/termination of the clinical research.
5.	I, on behalf of my company, acknowledge that the acknowledgement of this notification is not an endorsement of the safety, efficacy and quality of the products, which you are dealing in.

Accept ○ Decline ○

For Sponsor Endorsement

Previous | Validate | Notify | Submit | Reset

Logon ID: T5000178J Client Name: PFIZER PTE LTD Transaction No: T1602009K

Logout

PT0101 CLINICAL RESEARCH MATERIAL NOTIFICATION

Fill in the application form — Guideline | Help

1. Particulars of Importer / Local Manufacturer
2. Particulars of Clinical Research
3. Particulars of Clinical Research Materials (CRM)
4. Supporting Documents
5. **Declaration & Confirmation**

Special Symbol | Attach | Save

Your notification has been sent successfully.

Back to HSA Home Page

Sponsor Endorsement

- Email to Sponsor(s), copied to CRM importer/manufacturer applicant

10 Oct 2016

Transaction No: T1602009K

Clinical Research Material Importer
PFIZER PTE LTD

Clinical Research Material Notification for Product(s) to be Imported :

Medical Device(s) for Investigational Purpose:
1. MD , MD01 - 1000

for use in the following clinical research study:

Title of Clinical Research:
Title

Principal Investigator(s) and Research Site(s):
Ash Chua ,National Cancer Centre

Sponsor(s):
Sponsor Name

To Sponsor,

This e-mail is to notify you to endorse an online Clinical Research Material Notification drafted by the
Importer of Clinical Research Material for the above clinical research study.

The CRM applicant will only be able to complete the submission to HSA upon endorsement by all relevant parties, including you.

You may access this draft submission for review and endorsement by using the following link:

https://www-uat.hsa.gov.sg:443/osc/portal/jsp/AA/process.jsp?eService=31&TX_NO=UkcxczZZYkdTdnFxV2V4MjVxUWJnUT09&CRM_ID=c2grQjdlQmJ0TS95Z2RENnQ4alUydz09

(Recommended to copy the entire link above and paste it directly to the browser's address bar to access the webpage)

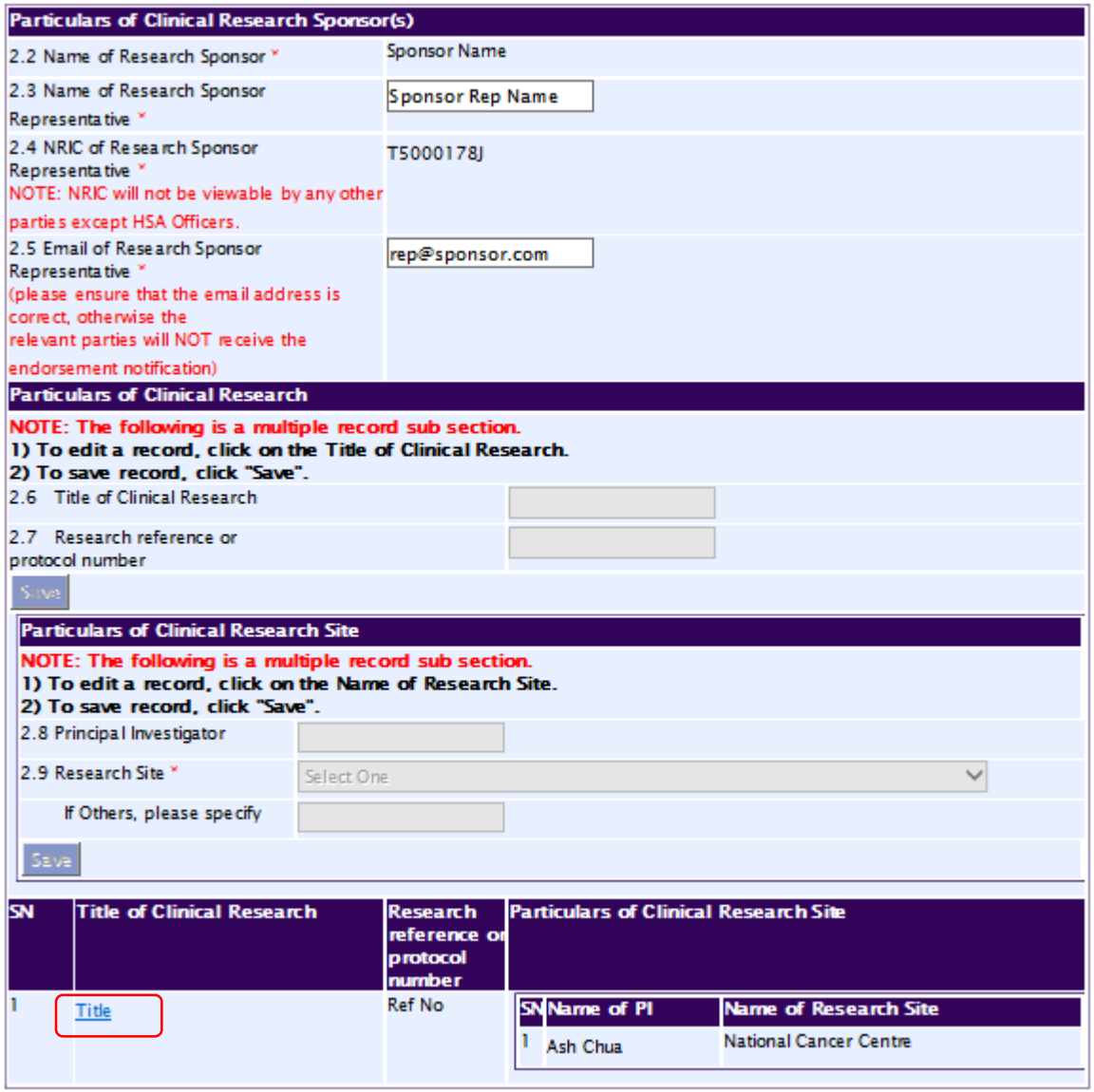
For other enquiries, please contact the Clinical Trials Branch at
Tel No. 6866-3446, Fax No. 6478-9034
Email Address: hsa_ct@hsa.gov.sg

PRE-MARKETING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

THIS IS A COMPUTER GENERATED LETTER, PLEASE DO NOT REPLY TO THIS EMAIL

Sponsor Endorsement Form

- Sponsor logs in using CorpPass, can view entire form and edit particulars of clinical research



Particulars of Clinical Research Sponsor(s)

2.2 Name of Research Sponsor *	Sponsor Name
2.3 Name of Research Sponsor Representative *	Sponsor Rep Name
2.4 NRIC of Research Sponsor Representative * NOTE: NRIC will not be viewable by any other parties except HSA Officers.	T5000178J
2.5 Email of Research Sponsor Representative * (please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification)	rep@sponsor.com

Particulars of Clinical Research

NOTE: The following is a multiple record sub section.
1) To edit a record, click on the Title of Clinical Research.
2) To save record, click "Save".

2.6 Title of Clinical Research	
2.7 Research reference or protocol number	

Save

Particulars of Clinical Research Site

NOTE: The following is a multiple record sub section.
1) To edit a record, click on the Name of Research Site.
2) To save record, click "Save".

2.8 Principal Investigator	
2.9 Research Site *	Select One
If Others, please specify	

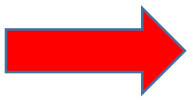
Save

SN	Title of Clinical Research	Research reference or protocol number	Particulars of Clinical Research Site
1	Title	Ref No	SN: 1 — Name of PI: Ash Chua — Name of Research Site: National Cancer Centre

Sponsor Endorsement Form

- Sponsor Declaration

Declaration	
1.	I, on behalf of my company, confirm that the information in Section 2 (relating to the clinical research) of this application is true and accurate.
2.	I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Therapeutic Products as Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) (Amendment) Regulations, where applicable.
3.	I, on behalf of my company, shall ensure that the CRM stated in the notification is not used other than for the purpose of a clinical research that has been approved by an Institutional Review Board.
4.	I, on behalf of my company, shall ensure that any unused CRM stated in section 3 of the notification are disposed appropriately / exported out of Singapore within 6 months of the completion / termination of the clinical research, unless otherwise allowed by the Authority.
5.	I, on behalf of my company, undertake to keep proper records of the receipt, supply and/or disposal or export of the CRM, where applicable, in accordance with prescribed requirements.
6.	I, on behalf of my company, undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect of any loss, injury or death or any person whomsoever arising out of or in connection with the use of the CRM stated in section 3 of the notification.



Accept Decline

Acknowledgement
Your endorsement decision for this application has been successfully submitted. Please note that the transaction number is T1602009K

When Sponsor endorsement completed

- Email to CRM importer/manufacturer applicant

10 Oct 2016

Transaction No: T1602009K

Clinical Research Material Importer
PFIZER PTE LTD

Clinical Research Material Notification for Product(s) to be Imported :

Medical Device(s) for Investigational Purpose:
1. MD , MD01 - 1000

for use in the following clinical research study(ies):

Title of Clinical Research:
Title

Principal Investigator(s) and Research Site(s):
Ash Chua, National Cancer Centre

Sponsor(s):
Sponsor Name

To CRM Applicant,

This e-mail is to notify you that the sponsor(s) has reviewed and endorsed this draft CRM Notification.

You may proceed to submit it to HSA.

2. Select "My Draft Applications" from Track@prism and login.
3. Retrieve your application. The "Application Type" is New Application, and the "Enquiry Type" is Draft. Enter the Transaction No stated above.
4. Once you have retrieved your draft application , please proceed to submit it.
5. Please print the acknowledgement receipt on the display screen.

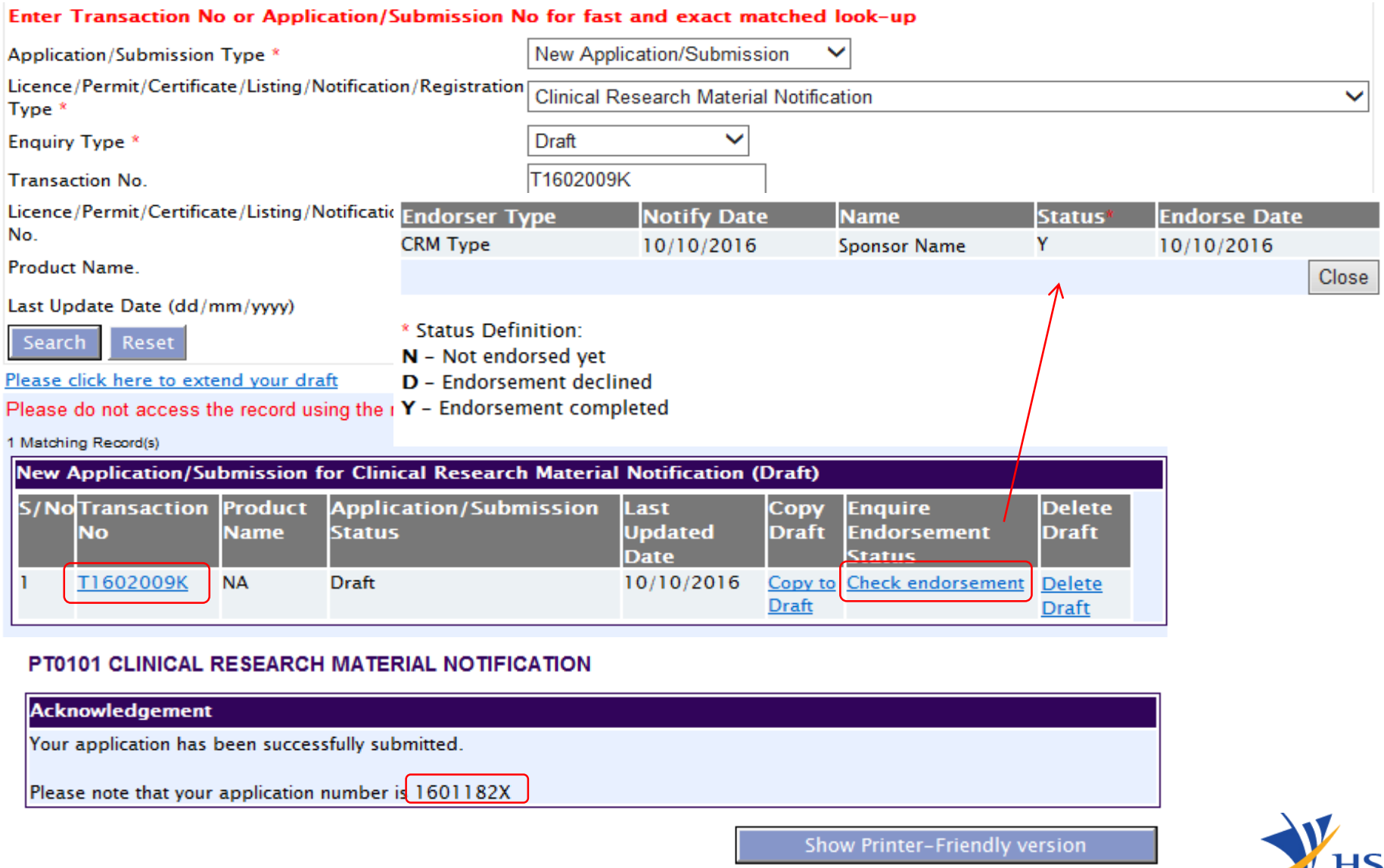
For other enquiries, please contact the Clinical Trials Branch at
Tel No. 6866-3446, Fax No. 6478-9034
Email Address: hsa_ct@hsa.gov.sg

PRE-MARKETING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

THIS IS A COMPUTER GENERATED LETTER, PLEASE DO NOT REPLY TO THIS EMAIL

Application Submission after Sponsor Endorsement

- Retrieve application from Track@PRISM



CRM-N Acknowledgement

- To CRM Importer/Manufacturer, copied to Sponsor

10 Oct 2016

Dear Ms Paris,

Application No: 1601182X
CRM Notification No: CRM1600118
Expiry Date: 09 Oct 2017

← 1 year validity period

Clinical Research Material Importer
PFIZER PTE LTD

Clinical Research Material Notification for Product(s) to be Imported :

Medical Device(s) for Investigational Purpose:
1. MD , MD01 - 1000

for use in the following clinical research study(ies):

Title of Clinical Research:
Title

Principal Investigator(s) and Research Site(s):
Ash Chua, National Cancer Centre

Sponsor(s):
Sponsor Name

The above Clinical Research Material Notification submitted by PFIZER PTE LTD has been received.

To retrieve the online Clinical Research Material Notification:
1 Please visit our website:
www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/Clinical_Trials.html
2 Select "My Approved Licences" from Enquire@prism.
3 Select the following:
"Licence type" - Clinical Trial - Clinical Research Material Notification
"Status" - Active
4. Enter the CRM Notification no CRM1600118 under licence no.

PRE-MARKETING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

This is a computer generated letter, no signature is required.

CRM-N Retrieval from Enquire@PRISM

PZO901 ENQUIRE@PRISM

Important Notes:
For HSA CRIS registered companies, user has to be authorised with the appropriate access rights via CRIS management module to access the required eservices.

Search Criteria

Licence/Permit/Certificate/Listing/ Notification/Registration Type * : Clinical Research Material Notification

Status * : Active

Licence/Permit/Certificate/Listing/ Notification/Registration No : CRM1600118

Product Name :

Start Date (dd/mm/yyyy) : To

Expiry Date (dd/mm/yyyy) : To

Search | Reset

Please do not access the record using the new window via right mouse click.

1 Matching Record(s)

Page 1 Of 1 [First] | [Previous] | [Next] | [Last]

Active Clinical Research Material Notification

S/No	HSA Appl No	CRM No	Date of Notification/Approval	Valid Until / Date of Expiry	CTC/CTA/CTN No	Research Reference / Protocol No
1	1601182X	CRM1600118	10/10/2016	09/10/2017		

CRM-N Retrieval from Enquire@PRISM

1. Clinical Research Material Notification	
Notification Number	CRM1600118
Notification Date	10/10/2016
Valid Until	09/10/2017

2 Particulars of Importer/Manufacturer			
2.1 Unique Entity No.(UEN)	196400192M		
2.2 Company Name	PFIZER PTE LTD		
2.3 Address			
2.3.1 Address Type:	Local		
2.3.2 Postal Code: *	189721		
2.3.3 Block / House No:	152	2.3.4 Level - Unit: *	# - 00
2.3.5 Street Name:	BEACH RD		
2.3.6 Building Name:	GATEWAY EAST		
2.3.7 Country:	SINGAPORE		
2.4 Company Representative	Paris		
2.5 Designation:	RP		
2.6 Tel.No. :	12341	2.7 Fax.No. :	
2.8 Email:	paris@pfizer.co		

3. Particulars of Clinical Trial/Research	
3.1 Name of Trial/Research Sponsor:	Sponsor Name
Particulars of Clinical Research (1)	
3.2 Title of Clinical Trial/Research:	Title
3.3 Protocol/Research Reference Number:	Ref No

3.4 List of Principal Investigator(s) & Clinical Trial/Research Site(s)

Principal Investigator(s)	Clinical Trial / Research Site
Ash Chua	National Cancer Centre

4 Particulars of Clinical Research Material (CRM)

4.2 Medical Device for Investigational Purpose

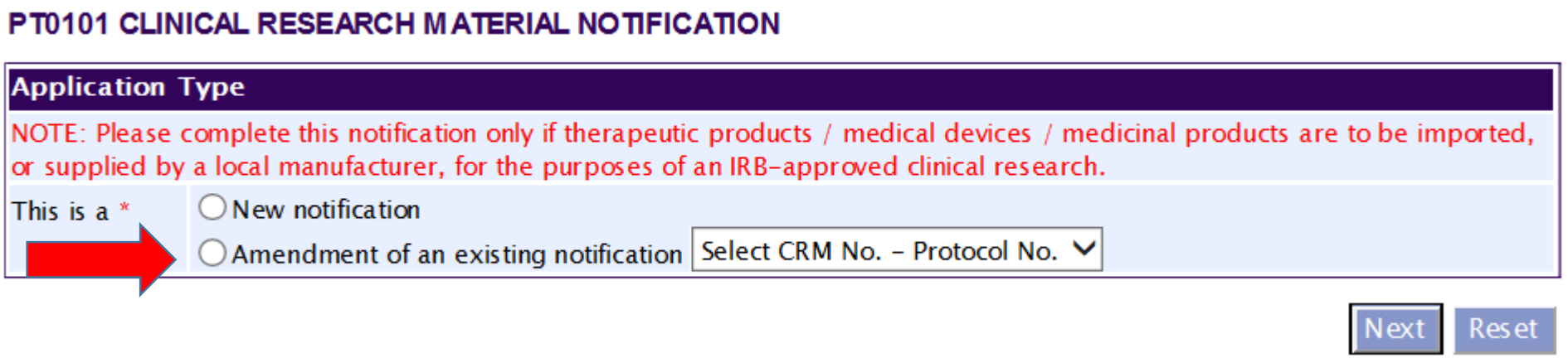
No.	Device Name	Type of Medical Device	Identifier	Estimated Total Quantity	Remarks
1	MD	General Medical Device	MD01	1000	

5. The CRM Notification for company, stated in Section 2, to import the clinical research material, stated in Section 4, for the purposes of the clinical trial/research, stated in Section 3, has been received.

OUTLINE

1. Overview of CRM Notification Requirements
2. CRM Notification for Clinical Research Not Regulated by HSA
3. **Amendment of CRM Notification (non-regulated clinical research)**
4. Extension of CRM Notification (non-regulated clinical research)
5. CRM Notification for Regulated Clinical Trials (New and Amendment)

AMENDMENT OF CRM-N (NON-REGULATED RESEARCH)



Note:

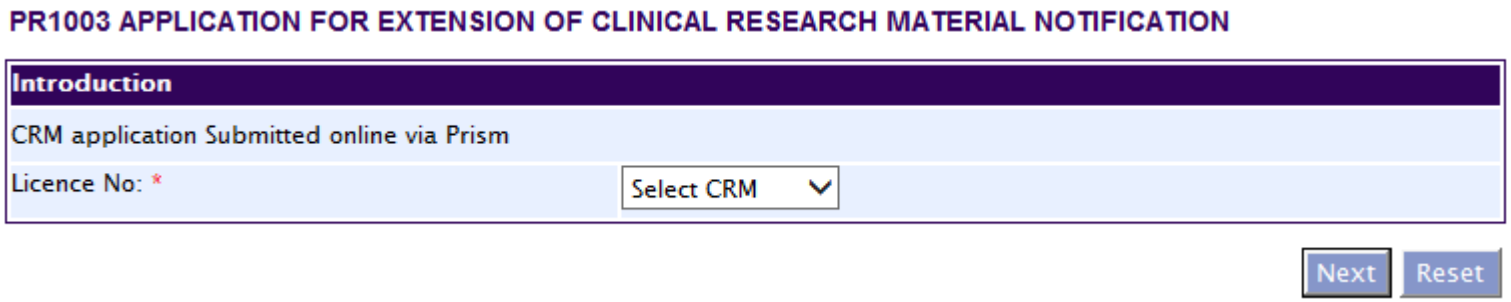
1. Can amend particulars of CRM and/or add new CRM sponsor, but cannot remove existing sponsors and CRM.
2. CRM Sponsor endorsement process will only be triggered when new CRM Sponsor is added.
3. CRM Sponsor endorsement not required for any other amendments to CRM-N.

OUTLINE

1. Overview of CRM Notification Requirements
2. CRM Notification for Clinical Research Not Regulated by HSA
3. Amendment of CRM Notification (non-regulated clinical research)
4. **Extension of CRM Notification (non-regulated clinical research)**
5. CRM Notification for Regulated Clinical Trials (New and Amendment)

EXTENSION OF CRM-N (NON-REGULATED RESEARCH)

	Introduction (Select CRM-N to Extend)
1	Particulars of CRM-N
2	Applicant Particulars
3	Reason for extension of CRM-N
4	Supporting Documents
5	Confirmation



Section 1. PARTICULARS OF CRM-N

1. Introduction	
1.1 Please select *	Importer of CRM
1.2 Please select the type of CRM to be imported or supplied *	Medical Device

Particulars of Importer / Local Manufacturer			
1.3 UEN: *	196400192M		
1.4 Company Name:	PFIZER PTE LTD		
1.5 Address			
1.5.1 Address Type:	Local		
1.5.2 Postal Code: *	189721		
1.5.3 Block / House No:	152	1.5.4 Level - Unit: *	# - 00
1.5.5 Street Name:	BEACH RD		
1.5.6 Building Name:	GATEWAY EAST		
1.5.7 Country:	SINGAPORE		
1.6 Contact Particulars			
1.6.1 Salutation	Ms		
1.6.2 Company Representative *	Paris		
1.6.3 NRIC / FIN	T5000178J		
1.6.4 Designation *	RP		
1.6.5 Tel *	12341	1.6.6 Fax *	
1.6.7 Handphone		1.6.8 Email *	paris@pfizer.co
1.6.9 Preferred Contact Mode	Email (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)		

2. Particulars of Clinical Research	
2.1.1 CRM is intended for *	Single study

Particulars of Clinical Research Sponsor(s)	
2.2 Name of Research Sponsor *	Sponsor Name
2.3 Name of Research Sponsor Representative *	Sponsor Rep Name
2.4 NRIC of Research Sponsor Representative *	T5XXXXXXX
2.5 Email of Research Sponsor Representative *	rep@sponsor.com

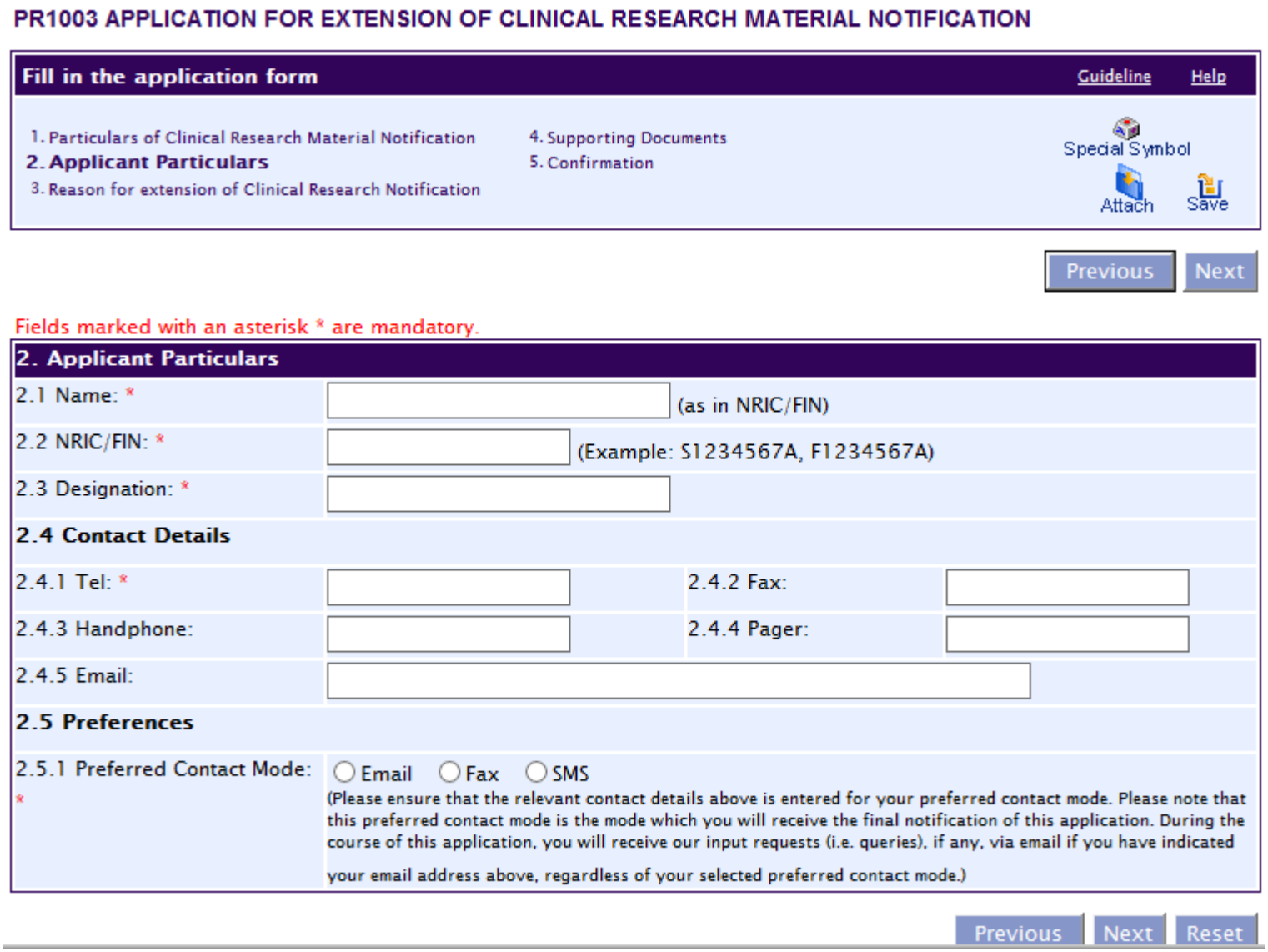
Particulars of Clinical Research 1	
2.6 Title of Clinical Research	Title
2.7 Research reference or protocol number	Ref No

Particulars of Clinical Research Site 1	
2.8 Principal Investigator	Ash Chua
2.9 Research Site	National Cancer Centre

3.2 Medical Device for Investigational Purpose			
3.2.1 Device Name *			MD
3.2.2 Type of Medical Device *			General Medical Device
3.2.3 Identifier (e.g. Model No.) *			MD01
3.2.4 Description & Intended Purpose *			MD
3.2.5 Risk Class *			Class B
3.2.6 Product Owner *			Owner
3.2.7 Address of Product Owner			
3.2.7.1 Address Type:			Local
3.2.7.2 Postal Code: *	138667		
3.2.7.3 Block / House No:	11	3.2.7.4 Level - Unit: *	# -
3.2.7.5 Street Name:	BIOPOLIS WAY		
3.2.7.6 Building Name:	HELIOS		
3.2.7.7 Country:	SINGAPORE		
3.2.8 Registration/Marketing Status *			Not a Registered / Marketed Product
3.2.9 Estimated Total Quantity *			1000
3.2.10 Remarks			

Next Reset

Section 2. APPLICANT PARTICULARS



PR1003 APPLICATION FOR EXTENSION OF CLINICAL RESEARCH MATERIAL NOTIFICATION

Fill in the application form Guideline Help

1. Particulars of Clinical Research Material Notification
2. **Applicant Particulars**
3. Reason for extension of Clinical Research Notification
4. Supporting Documents
5. Confirmation

Special Symbol | Attach | Save

Previous Next

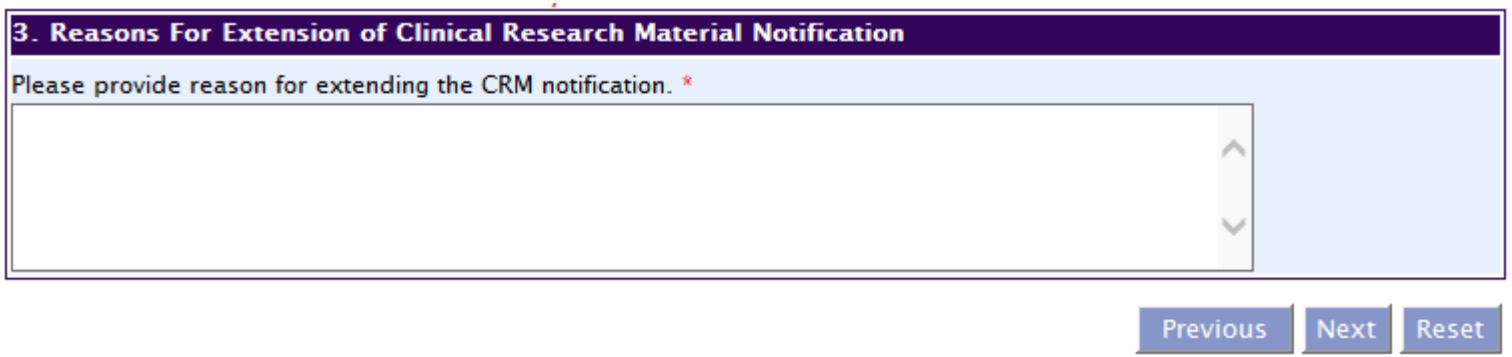
Fields marked with an asterisk * are mandatory.

2. Applicant Particulars

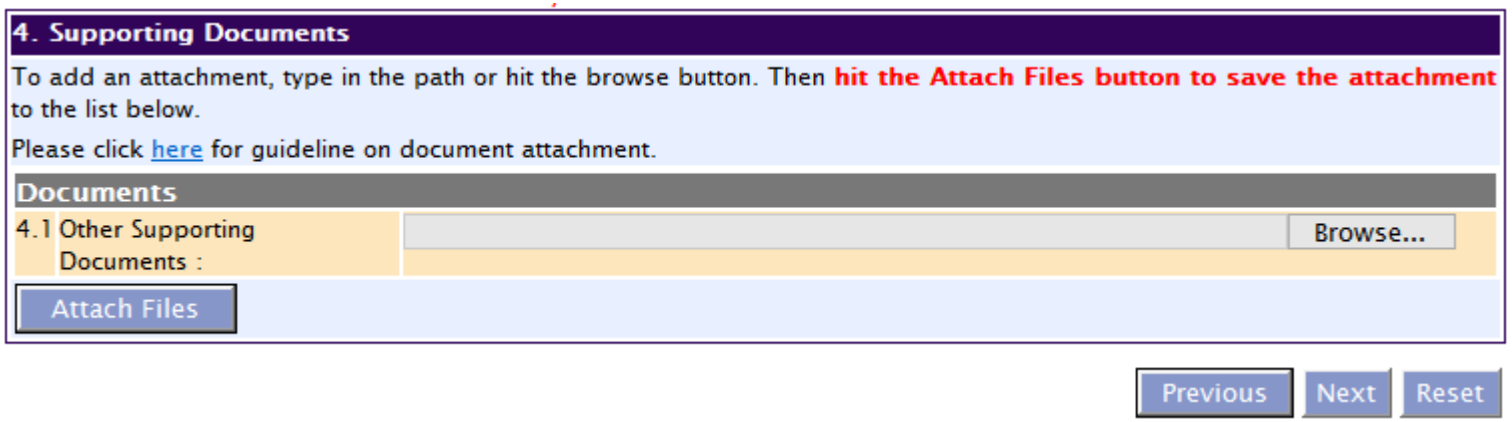
2.1 Name: *	(as in NRIC/FIN)		
2.2 NRIC/FIN: *	(Example: S1234567A, F1234567A)		
2.3 Designation: *			
2.4 Contact Details			
2.4.1 Tel: *		2.4.2 Fax:	
2.4.3 Handphone:		2.4.4 Pager:	
2.4.5 Email:			
2.5 Preferences			
2.5.1 Preferred Contact Mode: *	○ Email ○ Fax ○ SMS (Please ensure that the relevant contact details above is entered for your preferred contact mode. Please note that this preferred contact mode is the mode which you will receive the final notification of this application. During the course of this application, you will receive our input requests (i.e. queries), if any, via email if you have indicated your email address above, regardless of your selected preferred contact mode.)		

Previous Next Reset

Section 3. REASONS FOR CRM-N EXTENSION

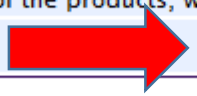


Section 4. SUPPORTING DOCUMENTS

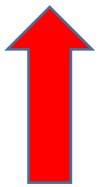


Section 5. CONFIRMATION

Declaration	
1.	I, on behalf of my company, confirm that the information submitted in this application is true and accurate.
2.	I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Therapeutic Products as Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) (Amendment) Regulations, where applicable.
3.	I, on behalf of my company, shall not supply the CRM stated in the notification other than for the purpose of a clinical research approved by an Institutional Review Board.
4.	I, on behalf of my company, acknowledge that the CRM notification is valid for one year from date of this extension notification, and shall ensure that the CRM stated in the notification are disposed of appropriately / exported out of Singapore within 6 months of the completion/termination of the clinical research.
5.	I, on behalf of my company, acknowledge that the acknowledgement of this notification is not an endorsement of the safety, efficacy and quality of the products, which I am dealing in.
	Accept ○ Decline ○



Previous | Validate | Submit | Reset



OUTLINE

1. Overview of CRM Notification Requirements
2. CRM Notification for Clinical Research Not Regulated by HSA
3. Amendment of CRM Notification (non-regulated clinical research)
4. Extension of CRM Notification (non-regulated clinical research)
5. **CRM Notification for Regulated Clinical Trials (New and Amendment)**

CRM NOTIFICATION

For Regulated Clinical Trials *(i.e. requiring CTA / CTN / CTC)*

B. Import / Supply by Local Manufacturer of CRM for Regulated Clinical Trial

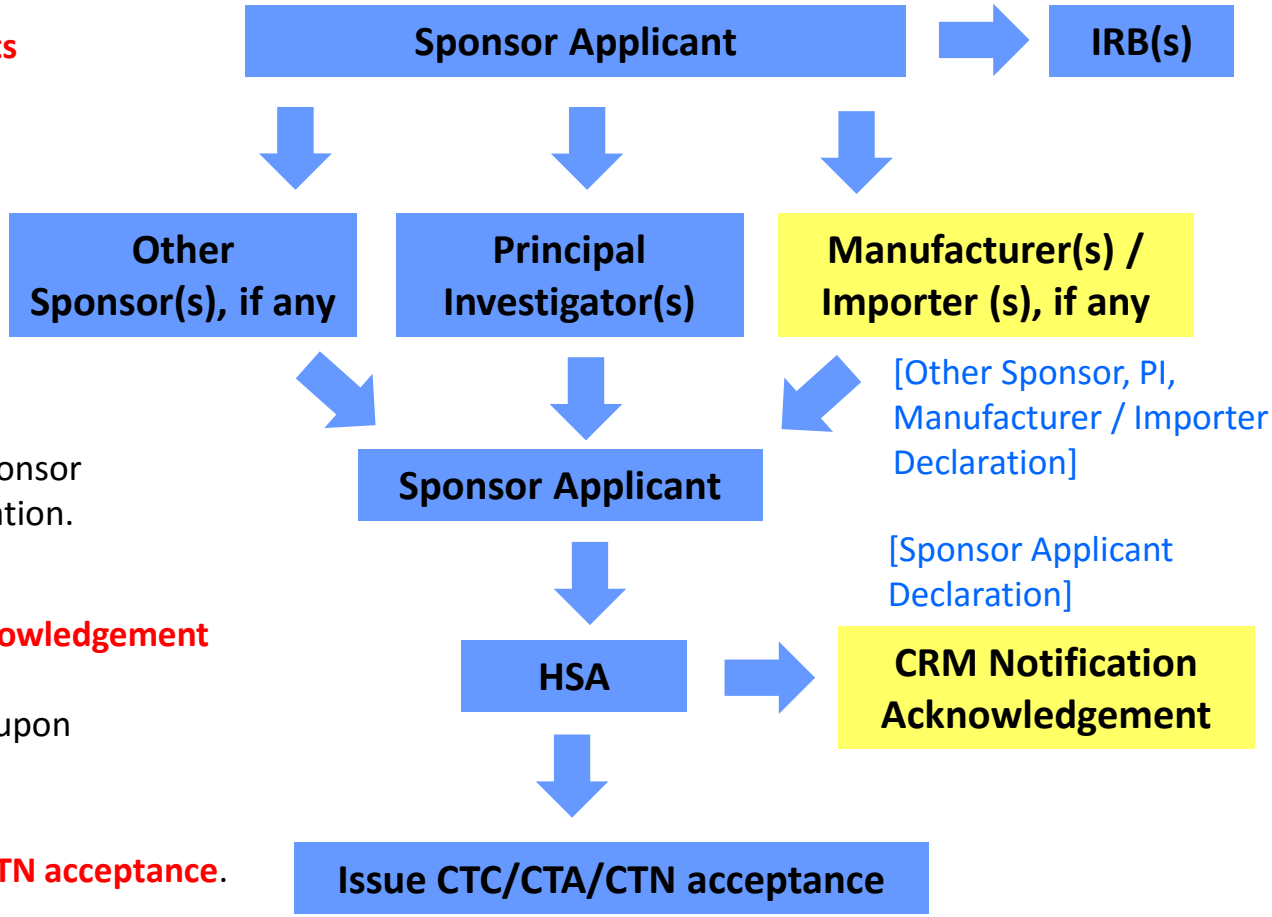
1. Sponsor applicant **drafts** CTC/CTA/CTN application, sends for endorsement.

2. Draft application **endorsed** by relevant parties.

3. After endorsement, sponsor applicant **submits** application.

4. **CRM notification acknowledgement** sent to manufacturer(s)/ importer(s) and sponsor upon application submission.

5. HSA issues **CTC/CTA/CTN acceptance**.



CTA/CTN/CTC APPLICATION FORM

1	Application Type
2	Trial Information
3	Investigational Therapeutic/Medicinal Product (excluding CTT products)
4	Investigational CTT product
5	Manufacturer Particulars
6	Comparator Therapeutic Product
7	Auxiliary Therapeutic Product
8	Local Trial Sites, PI and IRB
9	Local Sponsor (s)
10	**Clinical Research Material Notification**
11	Supporting Documents
12	Declaration & Confirmation

Section 10. CRM NOTIFICATION

PT0101 APPLICATION FOR A CLINICAL TRIAL AUTHORISATION

Fill in the application form Guideline Help

1. Application Type
2. Trial Information
3. Investigational Therapeutic / Medicinal Product (excluding CTT Products)
4. Investigational CTT Product
5. Manufacturer Particulars
6. Comparator Therapeutic Product
7. Auxiliary Therapeutic Product
8. Local Trial Sites.PI and IRB
9. Local Sponsor(s)
10. Clinical Research Material Notification
11. Supporting Documents
12. Declaration & Confirmation

Special Symbol Attach Save

Previous Next

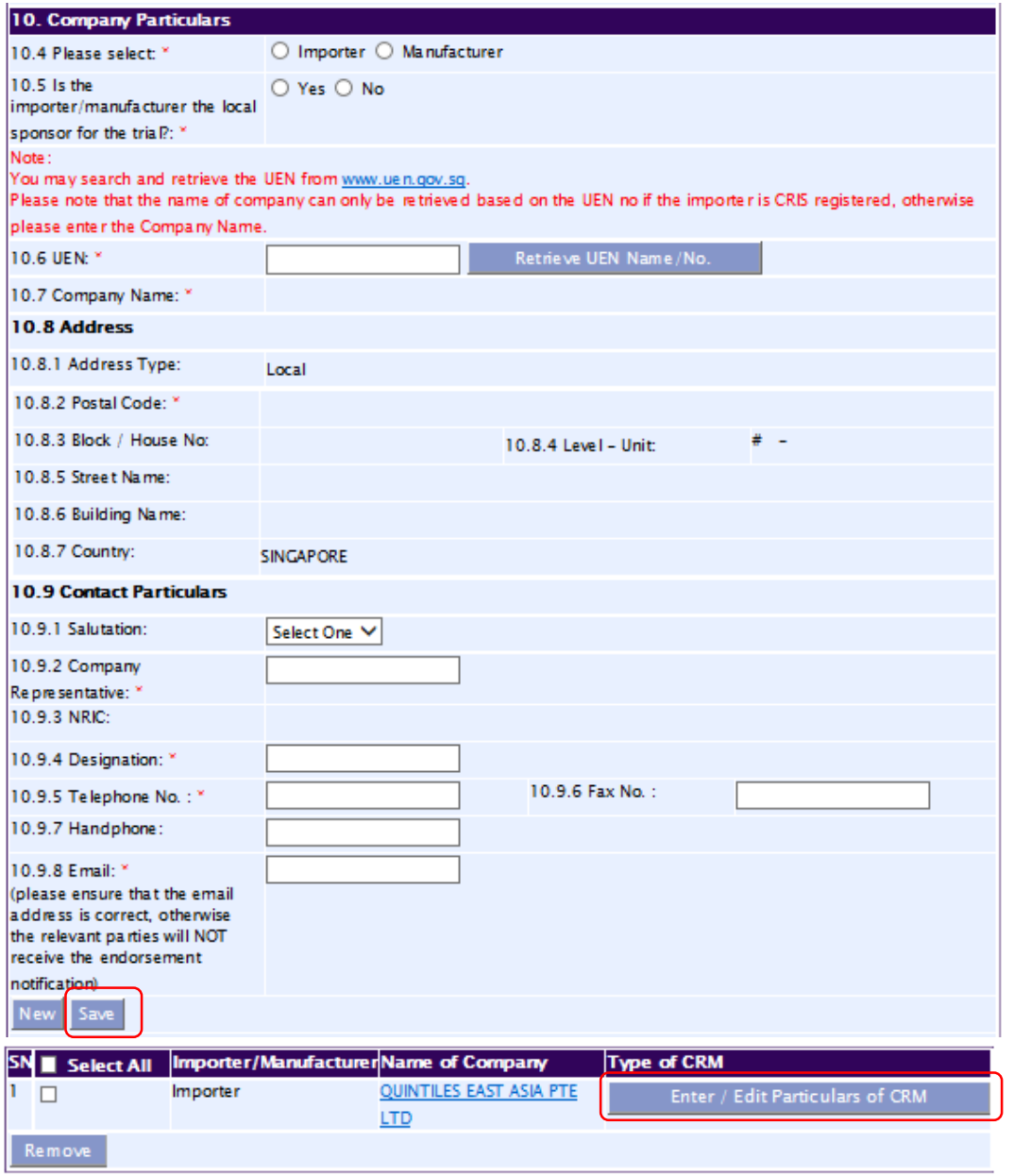
Fields marked with an asterisk * are mandatory.
Fields marked with ^ will be displayed in the Clinical Trial Register

NOTE:
Please complete this section only if the import of the therapeutic products / medical devices / medicinal products, or the supply of therapeutic products / medical devices / medicinal products by a local manufacturer is required for this trial.

10. Clinical Research Material Notification

10.1 Is import of the therapeutic products / medical devices / medicinal products, or the supply of therapeutic products / medical devices / medicinal products by a local manufacturer required for this trial? *	(●) Yes ( ) No
10.2 Please select all that applies: *	☐ Import of CRM ☐ Supply of CRM by Local Manufacturer
10.3 Please select the type of CRM to be imported or supplied: *	☐ Therapeutic Product ☐ Medical Device ☐ Medicinal Product (e.g. Cell- and Tissue-based Product, Complementary Health Products)

Section 10. COMPANY PARTICULARS



10. Company Particulars

10.4 Please select: *	○ Importer ○ Manufacturer
10.5 Is the importer/manufacturer the local sponsor for the trial?: *	○ Yes ○ No

Note:
You may search and retrieve the UEN from www.uen.gov.sg.
Please note that the name of company can only be retrieved based on the UEN no if the importer is CRIS registered, otherwise please enter the Company Name.

10.6 UEN: *		Retrieve UEN Name/No.	
10.7 Company Name: *			
10.8 Address			
10.8.1 Address Type:	Local		
10.8.2 Postal Code: *			
10.8.3 Block / House No:		10.8.4 Level - Unit:	# -
10.8.5 Street Name:			
10.8.6 Building Name:			
10.8.7 Country:	SINGAPORE		
10.9 Contact Particulars			
10.9.1 Salutation:	Select One		
10.9.2 Company Representative: *			
10.9.3 NRIC:			
10.9.4 Designation: *			
10.9.5 Telephone No. : *		10.9.6 Fax No. :	
10.9.7 Handphone:			
10.9.8 Email: * (please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification)			

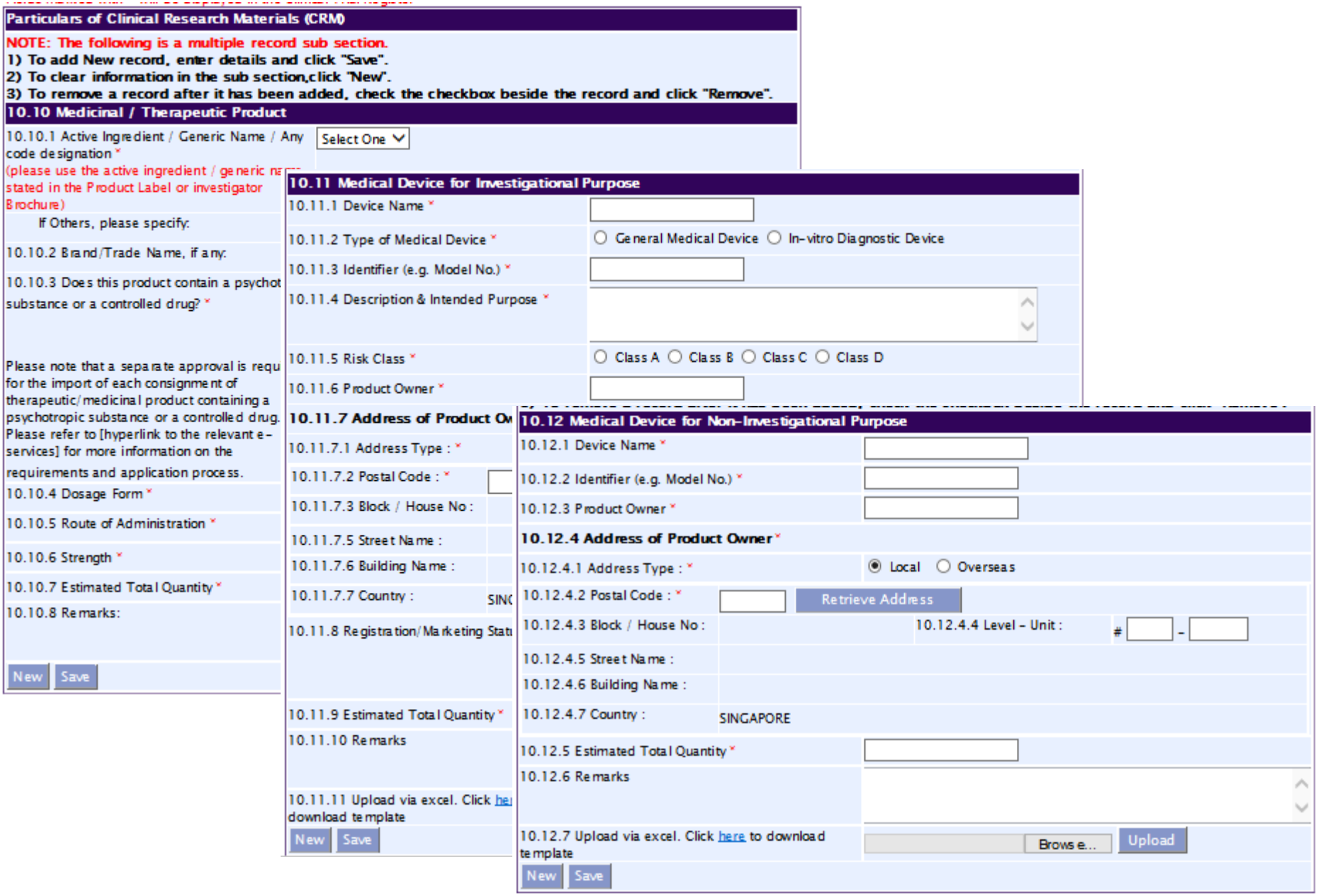
New Save

SN	Select All	Importer/Manufacturer	Name of Company	Type of CRM
1	☐	Importer	QUINTILES EAST ASIA PTE LTD	Enter / Edit Particulars of CRM

Remove

Previous Next Reset

Section 10. PARTICULARS OF CRM



CTM Importer/Manufacturer Endorsement

- Email to CRM importer/manufacturer contact, copied to Sponsor applicant

10 Oct 2016

Transaction No: T1602000K

Protocol Title:
ABCDE for NSCLC

Principal Investigator(s) and Trial Site(s):
Ms David Bowie, National Cancer Centre

Sponsor(s):
LION VIEW MINIMART (Lead Sponsor)
CHEONG'S CLINIC

Clinical Research Material Importer
DHL

Clinical Research Material Notification for Product(s) to be Imported :

Medical Device(s) for Investigational Purpose:
1. Respirator , 12345X - 2

To Importer of Clinical Research Material,

This e-mail is to notify you to endorse the Clinical Research Material Notification to be made as part of an online submission drafted by the Sponsor, LION VIEW MINIMART (Lead Sponsor), for the above clinical trial.

The sponsor will only be able to complete the submission to HSA upon endorsement by all relevant parties, including you.

You may access this draft submission for review and endorsement by using the following link:

https://www-uat.hsa.gov.sg:443/osc/portal/jsp/AA/process.jsp?eService=29&TX_NO=T3N5enA5c1J6WFdxV2V4MjVxUWJnUT09&CRM_ID=emRwQ2pDdWMycXJSaVozUDN1UmsxZz09

(Recommended to copy the entire link above and paste it directly to the browser's address bar to access the webpage)

Email Address: hsa_ct@hsa.gov.sg

PRE-MARKETING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

THIS IS A COMPUTER GENERATED LETTER, PLEASE DO NOT REPLY TO THIS EMAIL

CRM Importer / Manufacturer Endorsement Form

- CRM Importer / Manufacturer Rep logs in using CorpPass, can view CRM-N related fields and edit CRM importer/manufacturer contact details.

1. Trial Information

1.1 Title of Clinical Trial (as stated in Protocol document): *^	An investigator--initiated, multi-national, open-label, randomised trial to demonstrate the non-inferiority of Drug ABC to the standard XYZ drug for the treatment of chronic hepatitis B infection.
1.2 Protocol Number: *^	HEP1234

2. Local Trial Site and PI

SN	Name of Principal Investigator:	Name of Trial Site:
1	Jones	Singapore General Hospital

3. Clinical Research Material Notification

3.1 Please select: *	Importer		
3.2 Company Name: *	DHL		
3.3 Address			
3.3.1 Address Type: *	Local		
3.3.2 Postal Code: *	138667		
3.3.3 Block / House No:	11	3.3.4 Level - Unit: *	# -
3.3.5 Street Name:	BIOPOLIS WAY		
3.3.6 Building Name:	HELIOS		
3.3.7 Country:	SINGAPORE		
3.4 Contact Particulars			
3.4.1 Salutation:	Ms		
3.4.2 Company Representative: *	Di		
3.4.3 NRIC:	T5000178J NOTE: NRIC will not be disclosed to any other parties except for HSA officers.		
3.4.4 Designation: *	RP		
3.4.5 Telephone No. : *	1234214	3.4.6 Fax No. :	
3.4.7 Handphone:			
3.4.8 Email: *	Di@dhl.com		

NRIC will be auto-populated from log in, and subsequently masked.

Particulars of Clinical Research Materials (CRM)

3.6 Medical Device for Investigational Purpose

3.6.1 Device Name *	Respirator
3.6.2 Type of Medical Device *	General Medical Device
3.6.3 Identifier (e.g. Model No.) *	12345X
3.6.4 Description & Intended Purpose *	Respirator
3.6.5 Risk Class *	Class C
3.6.6 Product Owner *	LION VIEW
3.6.7 Address of Product Owner	
3.6.7.1 Address Type:	Local
3.6.7.2 Postal Code: *	138667
3.6.7.3 Block / House No:	11
3.6.7.4 Level - Unit: *	# -
3.6.7.5 Street Name:	BIOPOLIS WAY
3.6.7.6 Building Name:	HELIOS
3.6.7.7 Country:	SINGAPORE
3.6.8 Registration/Marketing Status *	Not a Locally Registered/Marketed Product, but Registered/Marketed overseas
3.6.9 Estimated Total Quantity *	2
3.6.10 Remarks	

SN	Device Name	Type of Medical Device	Identifier	Risk Class	Estimated Total Quantity	Remarks
1	Respirator	General Medical Device	12345X	Class C	2	

4. Sponsor(s)

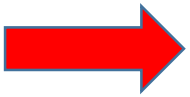
4.1 Local Sponsor

4.1.1 Company Name *^	LION VIEW MINIMART
4.1.2 Salutation:	Ms
4.1.3 Name of Contact Person: *	Sandy Chan
4.1.4 Email *	sandy_chan@lionview.sg

4.1 Other Sponsor(s)

SN	Company Name	Contact Person	Email
1	CHEONG'S CLINIC	Mandy Chan	

Declaration	
1.	I, on behalf of my company, confirm that the information in Section 3 (relating to CRM imported or supplied by local manufacturer for this trial) of this application is true and accurate.
2.	I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Therapeutic Products as Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) (Amendment) Regulations, where applicable.
3.	I, on behalf of my company, shall not supply the CRM stated in Section 3 of this application except for the purpose of this clinical trial.



Accept Decline

Acknowledgement

Your endorsement decision for this application has been successfully submitted.

Please note that the transaction number is T1602000K

Application Submission after Endorsement complete

- Retrieve application from Track@PRISM

Enter Transaction No or Application/Submission No for fast and exact matched look-up

Application/Submission Type * : New Application/Submission

Licence/Permit/Certificate/Listing/Notification/Registration Type * : Clinical Trial - Authorisation

Enquiry Type * : Draft

Transaction No. : T1602000K

Licence/Permit/Certificate/Listing/Notification No. :

Product Name. :

Last Update Date (dd/mm/yyyy) :

Search | Reset

Please click here to extend your draft

Please do not access the record using the

1 Matching Record(s)

Endorser Type	Notify Date	Name	Status*	Endorse Date
CRM Type	10/10/2016	Sponsor Name	Y	10/10/2016

Close

* Status Definition:
N – Not endorsed yet
D – Endorsement declined
Y – Endorsement completed

New Application/Submission for Clinical Trial – Authorisation (Draft)

S/No	Transaction No	Product Name	Application/Submission Status	Last Updated Date	Copy Draft	Enquire Endorsement Status	Delete Draft
1	T1602000K	NA	Draft	10/10/2016	Copy to Draft	Check endorsement	Delete Draft

PL0106 APPLICATION FOR A CLINICAL TRIAL AUTHORISATION

Acknowledgement

Your application has been successfully submitted.

Please note that your application number is 1601050U

Show Printer-Friendly version

CRM-N Acknowledgement

- To CRM Importer/Manufacturer, copied to Sponsor

Dear Ms Ques,

Application No: 1601050U
CRM Notification No: CRM1600091
Expiry Date: Until Trial Completion (i.e. Last Patient Last Visit)

Clinical Research Material Importer
Quintiles

Clinical Research Material Notification for Product(s) to be Imported :

Medical Device(s) for Investigational Purpose:
1. lab kits , labkitA - 1000

for use in the following clinical trial:

Protocol Title:
Brief Trial Title

Principal Investigator(s) and Trial Site(s):
Dr Jane, KK WOMEN'S AND CHILDREN'S HOSPITAL

Sponsor(s):
DIETHELM SINGAPORE PTE LTD (Lead Sponsor)
GLAXOSMITHKLINE PTE LTD

The above Clinical Research Material Notification, made as part of the APPLICATION FOR CLINICAL TRIAL AUTHORISATION has been received.

For enquiries, please contact the Clinical Trials Branch at
Tel No. 6866-3446, Fax No. 6478-9034
Email Address: hsa_ct@hsa.gov.sg

PRE-MARKETING DIVISION
HEALTH PRODUCTS REGULATION GROUP
HEALTH SCIENCES AUTHORITY

This is a computer generated letter, no signature is required.

CRM NOTIFICATION FOR REGULATED TRIALS

Note:

- If CTA/CTN/CTC application subsequently not approved/accepted, associated CRM Notification will automatically expire.
- Notification will be sent to CRM importer/manufacturer (copied sponsor applicant) on expired status of CRM Notification.
- Amendment of CRM Notification is via CTA/CTN/CTC amendment application.
- CRM importer/manufacturer endorsement will be triggered for all changes to CRM Notification relevant to that particular CRM importer/manufacturer.

We welcome your queries!

HSA_CT@hsa.gov.sg

THANK YOU!