TRAINING SESSION:

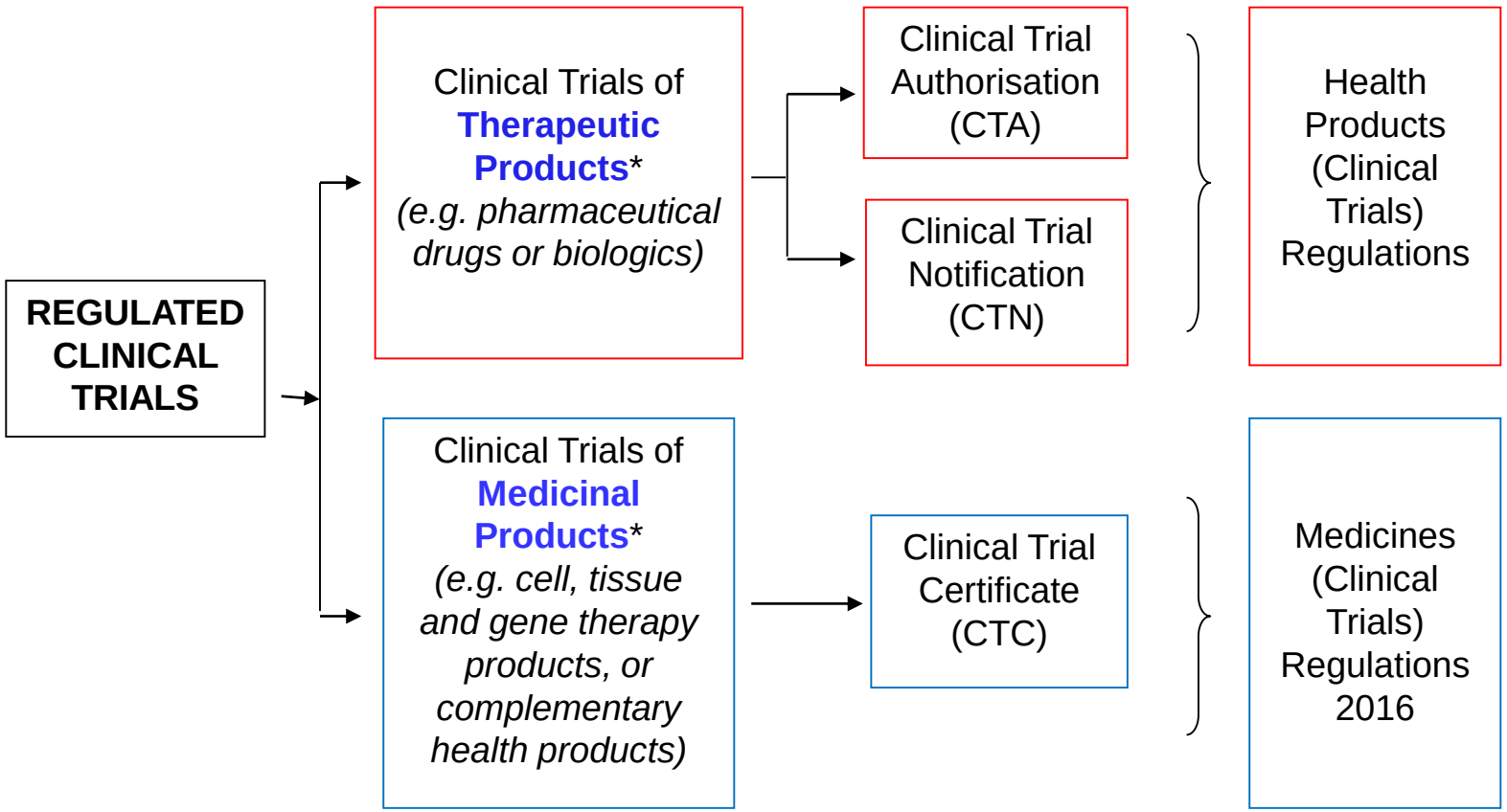
ENHANCED PRISM E-SERVICES

CTA/CTN/CTC APPLICATION SUBMISSION

OUTLINE

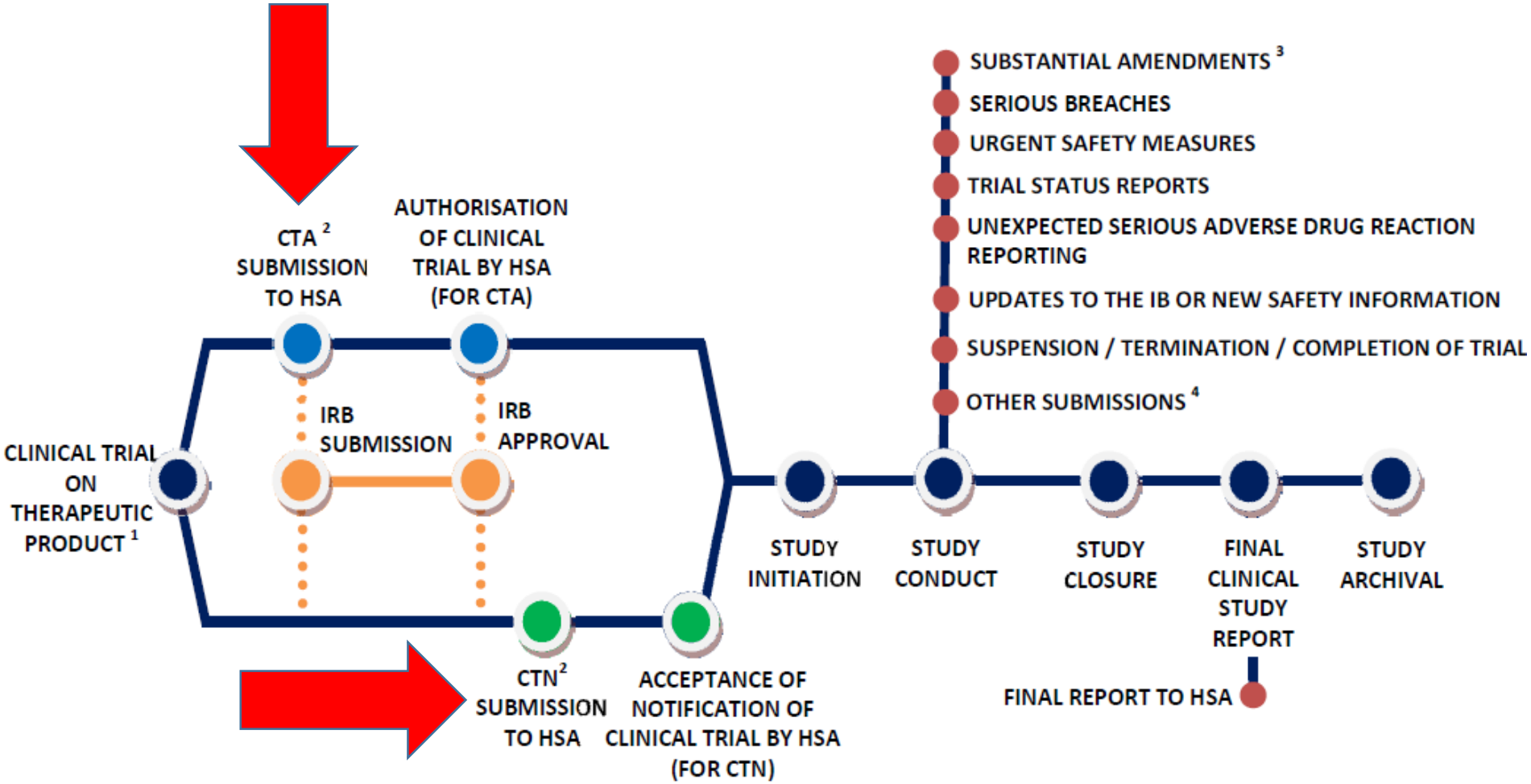
1. Overview of CT application types for PRISM submission
2. CT application process
3. Tips for a smooth submission
4. References

SCOPE OF TRIALS REGULATED UNDER CT REGULATIONS



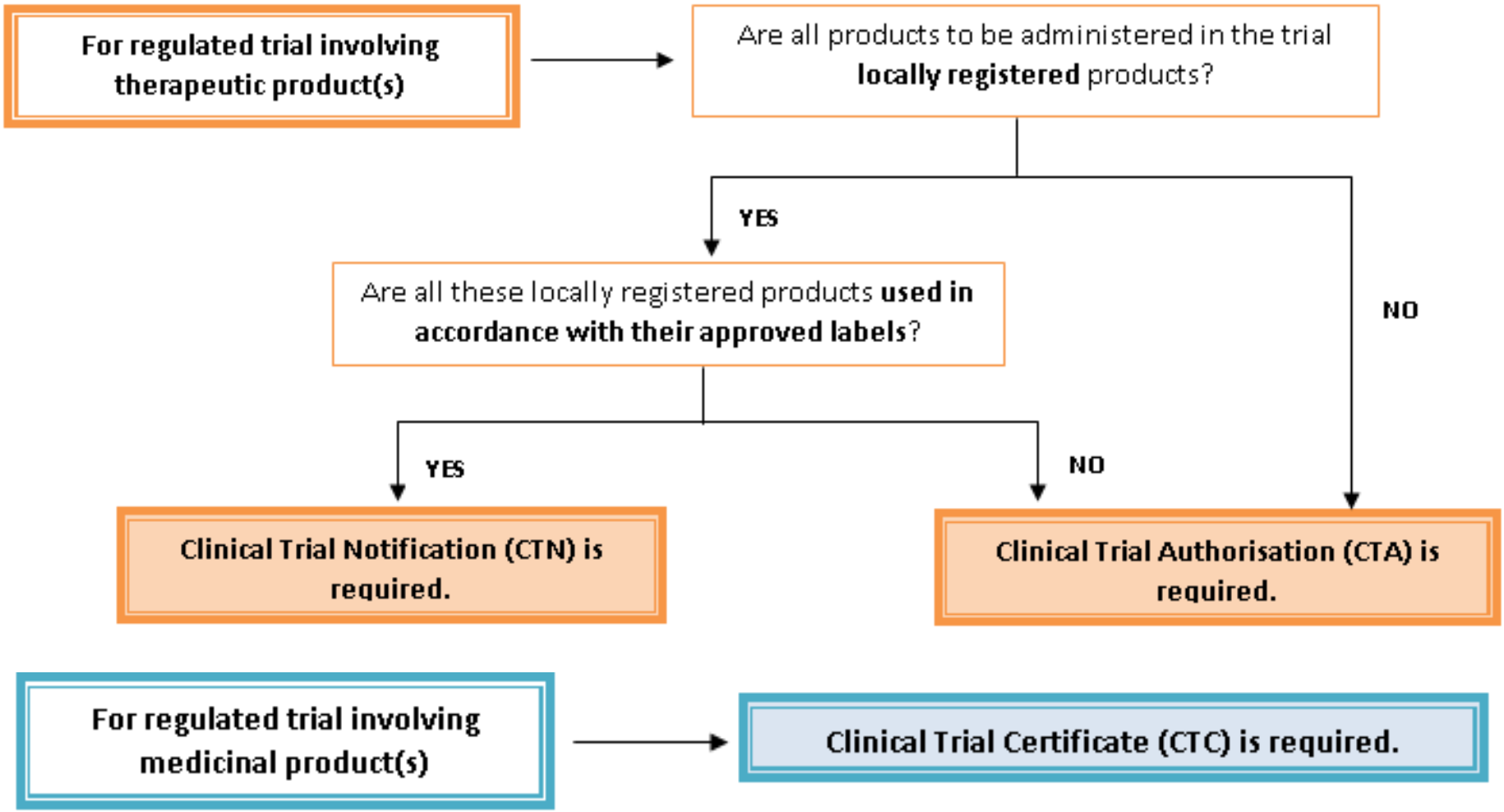
*Excluding observational trials

REGULATORY ROADMAP FOR TP TRIALS



REGULATORY ROADMAP FOR MP TRIALS

DETERMINATION OF SUBMISSION ROUTES



CT APPLICATION FORM

- The new application form is longer to include new data set in CT Register.

Current Data Set in CT Register (PRISM)

- Protocol Title/ No.
- Phase
- Therapeutic Area
- Intervention [Name of Study Drug]
- Sponsor
- Trial Site
- Principal Investigator
- Trial Status

NEW Data Set in CT Register

TABLE 1. Minimum data set that should be recorded for clinical trial registration, according to the World Health Organization, 2005

- Primary register trial number
- Trial registration date
- Secondary IDs
- Source(s) of monetary or material support
- Primary sponsor
- Secondary sponsor(s)
- Contact for public queries
- Contact for scientific queries
- Public title (of the study)
- Scientific title
- Countries of recruitment
- Health condition or problems studied
- Intervention(s)
- Key inclusion and exclusion criteria
- Study type
- Date of the first enrollment (anticipated or actual date of the enrollment of the first study participant)
- Target sample size
- Recruitment status
- Primary outcome(s)
- Key secondary outcomes

CT APPLICATION FORM

1	Application Type
2	Trial Information ← **NEW Data Set in CT Register**
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

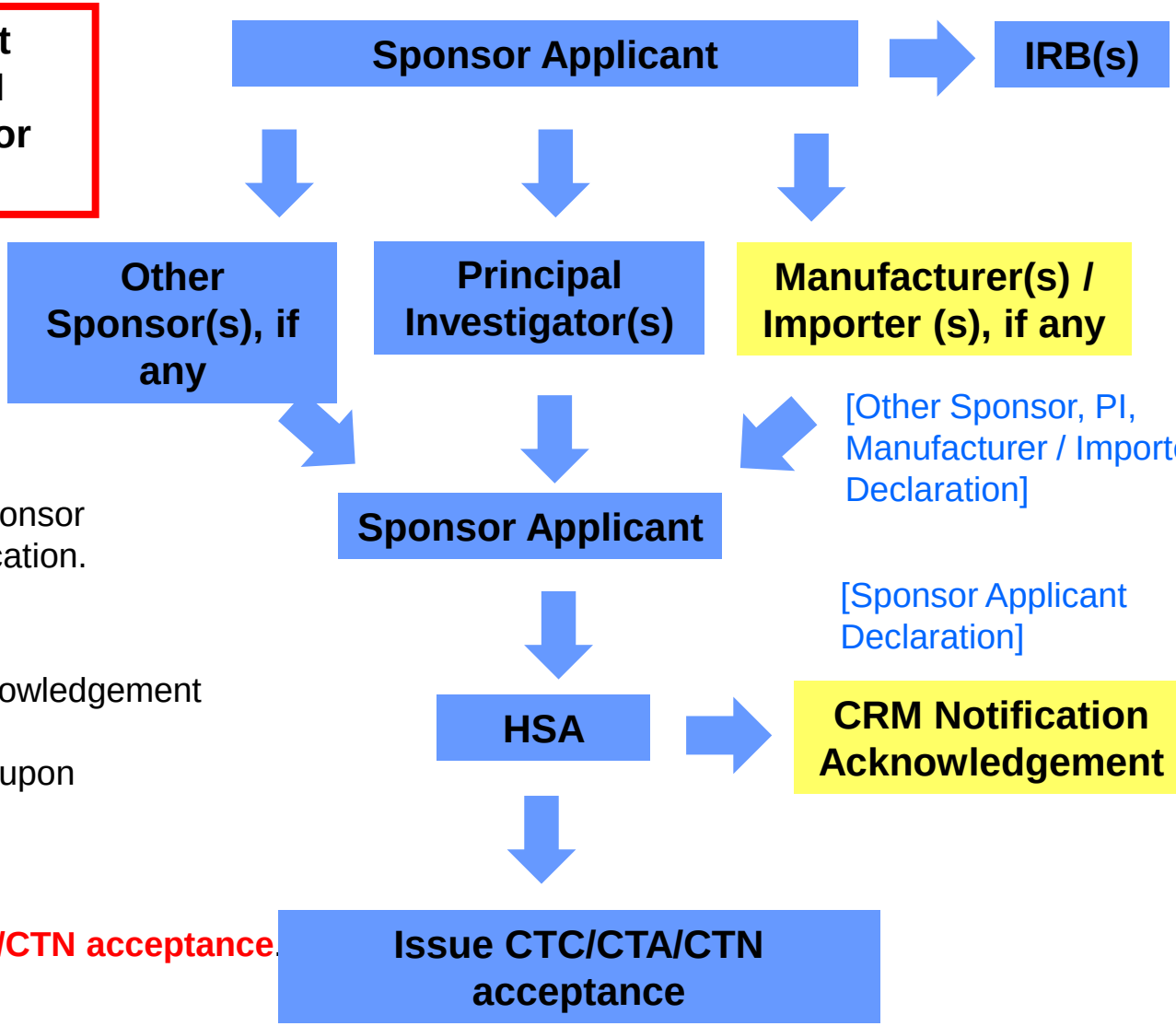
ESTIMATED TIME FOR DRAFTING ONLINE CT APPLICATION

CTA/CTN/CTC: 20-40 minutes

CTA/CTN/CTC with CRM notification: 30-45 minutes

CT APPLICATION PROCESS

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

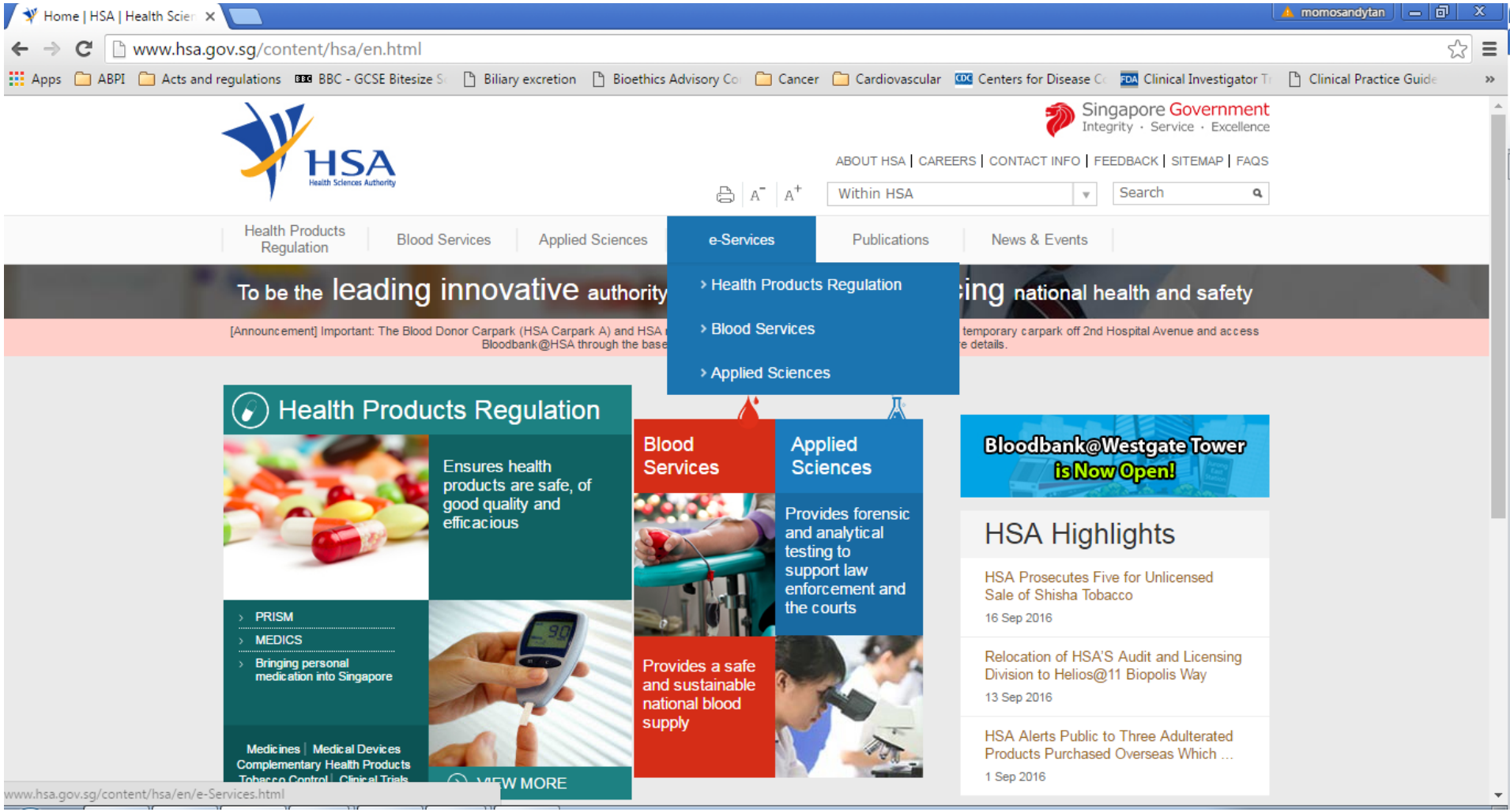


2. Draft application **endorsed** by relevant parties.

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**.



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

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CR0010 AUTHORISATION AND AUTHENTICATION MODULE > TERMS AND CONDITIONS

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Updated as of 19/01/2005

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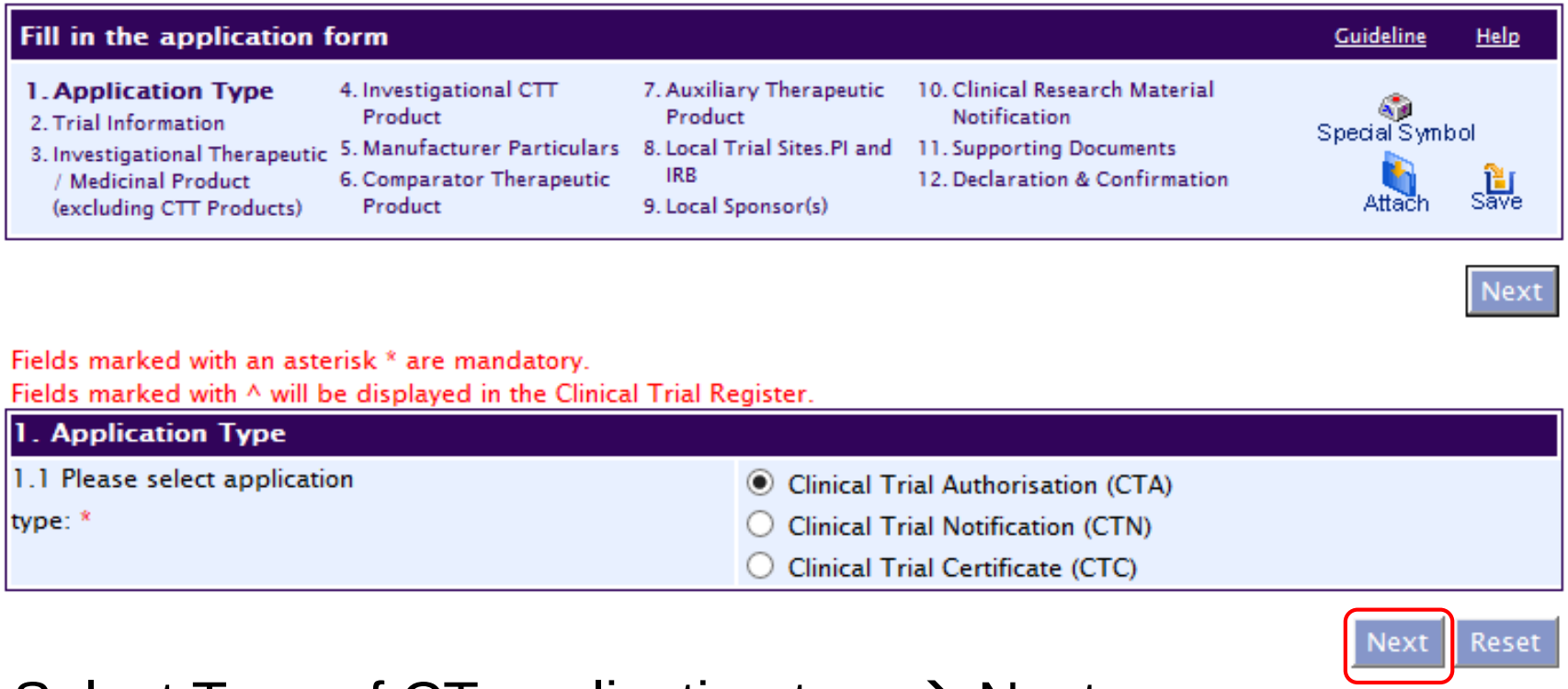
Section 1. APPLICATION TYPE



Select Type of CT application type→ Next

Note:

1) It is recommended for applicants to fill in the application form details in a systematic serial manner as the later sections could reference information in the earlier sections.

Section 2. TRIAL INFORMATION (1 of 10)

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

2. Trial Information

2.1 Title of Clinical Trial (as stated in Protocol document): ^*

Testing

2.2 Brief Title of Clinical Trial for the Public (in easily understood, non-technical language): ^*

Testing

2.3 Protocol Number: ^*	Testing
2.4 Protocol Acronym, if any: ^	Testing

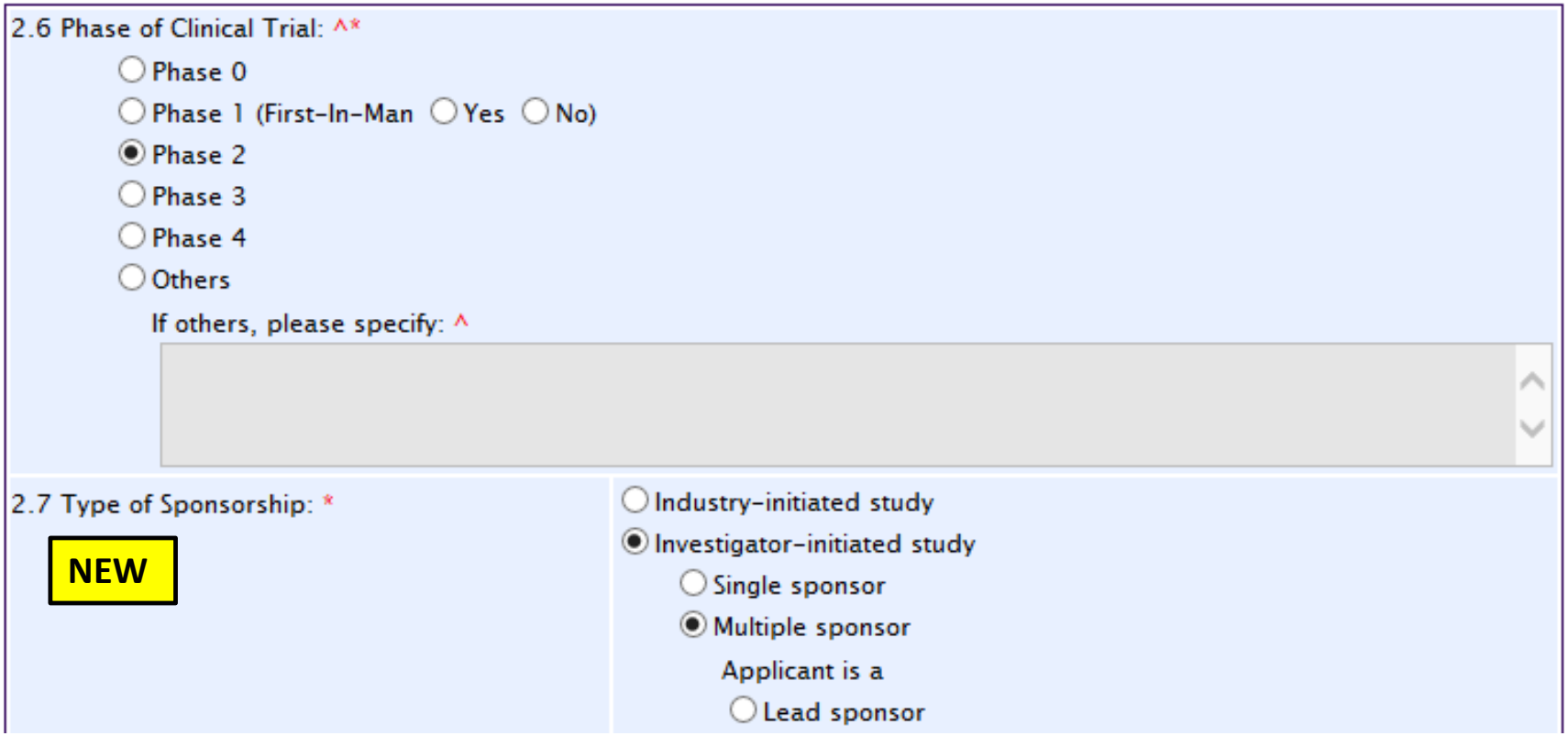
NOTE: The following is a multiple record sub section.
1) To add New record, enter details and click "Save".
2) To clear information in the sub-section, click "New".
3) To remove a record after it has been saved, check the checkbox beside the record and click "Remove".

2.5 Secondary ID(s), if any: ^*	☑ Not Applicable
2.5.1 ID Type (e.g. ClinicalTrials.gov Identifier, EudraCT Number, name of organization that issued ID, etc): ^*	
2.5.2 ID: ^*	

New Save

NEW

Section 2. TRIAL INFORMATION (2 of 10)



Note: For investigator initiated trials (IIT) involving multiple sponsors where each site acts as a sponsor for their site, one of the sponsors should be designated as the **Lead Sponsor**. The Lead Sponsor shall be the primary contact person for HSA. Please refer to HSA Guidance on Multi-Sponsor IIT(s).

Section 2. TRIAL INFORMATION (3 of 10)

2.8 Source of Monetary or Material Support for the clinical trial (e.g. name of funding company, agency, organisation etc): ^*

NEW

2.9 Therapeutic Area: ^* Select One

If others, please describe: ^

2.10 Health Condition(s) Studied: ^*

NEW

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 saved, check the checkbox beside the record and click "Remove".

2.11 List the PRISM application number(s) of any previous application(s) for trials involving the same investigational product(s): *

☐ Not Applicable

New Save Click “Save” to add records

Section 2. TRIAL INFORMATION (4 of 10)

Trial Summary

2.12 Involves: *
- ○ Healthy Volunteers
- ◉ Patients
- ○ Both Healthy Volunteers and Patients

2.13 Involves subjects who (please select where applicable): *
- ☑ Are Unconscious
- ☐ Are < 21 Years of Age
- ☐ Lack Mental Capacity
- ☐ Are Pregnant
- ☐ Are Nursing
- ☐ Not Applicable

NEW

2.14 Clinical Trial in Emergency Situation: *
- ○ Yes
- ◉ No

NEW

2.15 Study Type: ^*
- ◉ Interventional
- ○ Non-Interventional

2.16 Purpose of Trial: ^* Treatment

If others, please describe: ^

2.17 Primary Trial Objective(s): *

PFS

NEW

Section 2.16: NEW
- Treatment
- Prevention
- Diagnostic
- Supportive Care
- Screening
- Health Service Research
- Basic Science
- Others

Section 2. TRIAL INFORMATION (5 of 10)

2.18 Primary Outcome Measure(s) (please include outcome measure and timepoint of interest, e.g. all-cause mortality at 1 year, cognition as measured by ADAS-Cog at week 24, dose-limiting toxicities, maximum tolerated dose, recommended phase 2 dose, etc): ^*

PFS **NEW**

2.19 Key Secondary Outcome Measure(s) (please include name of outcome, method of measurement and time point(s) of interest): ^*

OS **NEW**

2.20 Allocation: ^*

- (•) Randomised
- ( ) Non-randomised

2.21 Blinding: ^* Double-Blind

If others, please describe: ^

2.22 Intervention model: **NEW** Parallel ^*

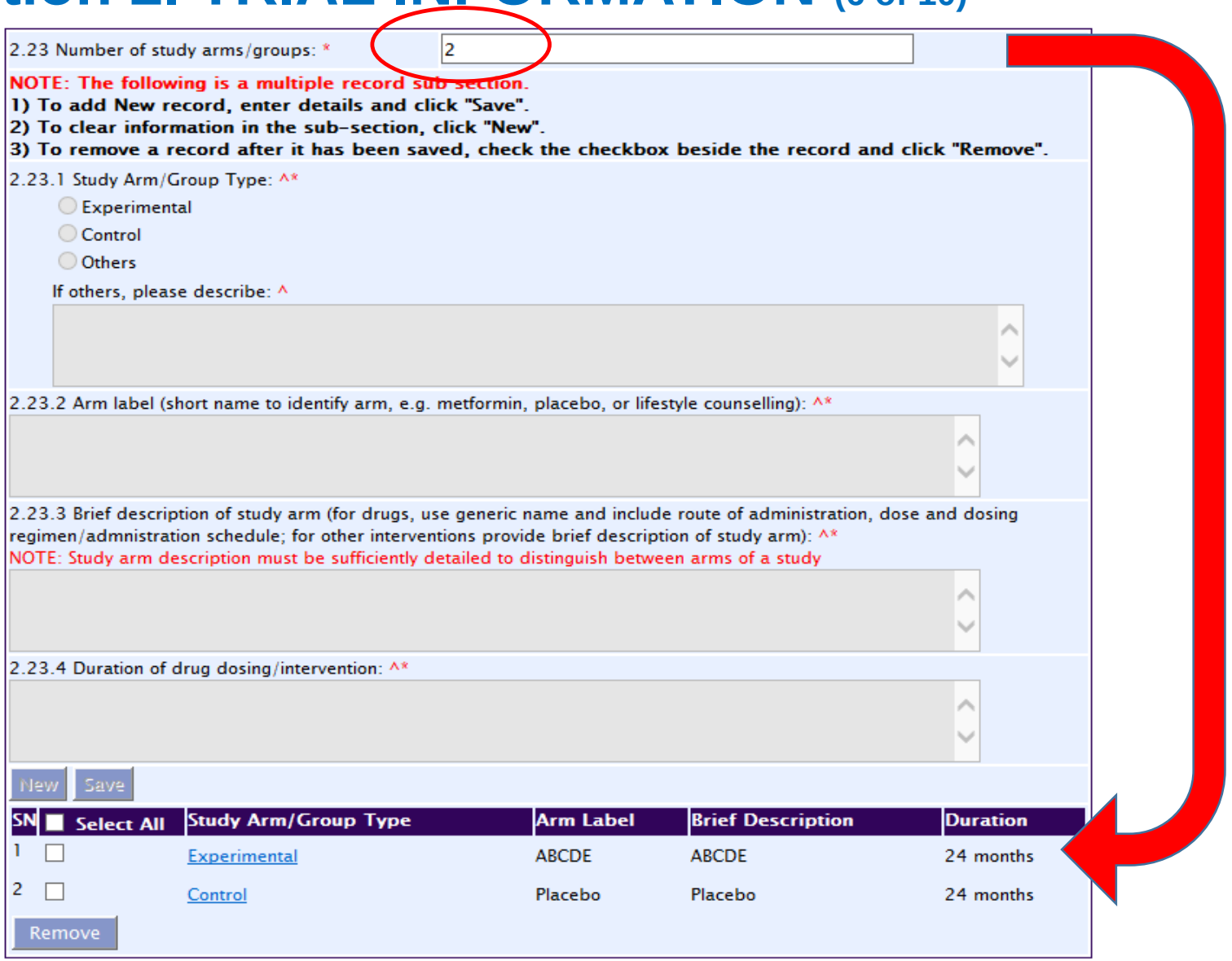
If others, please describe: ^

Section 2.21:
- Single-Blind, Double-Blind, Open Label, Others

Section 2.22
- Single arm, Parallel, Cross Over, Factorial, Others

Section 2. TRIAL INFORMATION (6 of 10)

NEW



Note: Section 2.23- The number of study arms entered must correspond to the number of study arms described.

Section 2. TRIAL INFORMATION (7 of 10)

2.24 Involves the use of (please select where applicable): *

- [ ] Comparator Therapeutic Product
- [ ] Auxiliary Therapeutic Product
- [x] Placebo
- [ ] Not Applicable

2.25 Number of Therapeutic / Medicinal Product (excluding CTT Products) to be Investigated: * 1

2.26 Number of Cell- and Tissue-based Therapeutic (CTT) Product to be Investigated: * 0

2.27 Number of Comparator Therapeutic Product used: *

2.28 Number of Auxiliary Therapeutic Product used: *

Section 2.24-2.28: Correspond to later Sections

2.29 Key Inclusion and Exclusion Criteria: ^*

Test

NEW

2.30 Describe the design of the trial if necessary to supplement the information provided above:

Test

2.31 Please provide the benefit-risk assessment for the clinical trial: *

Test

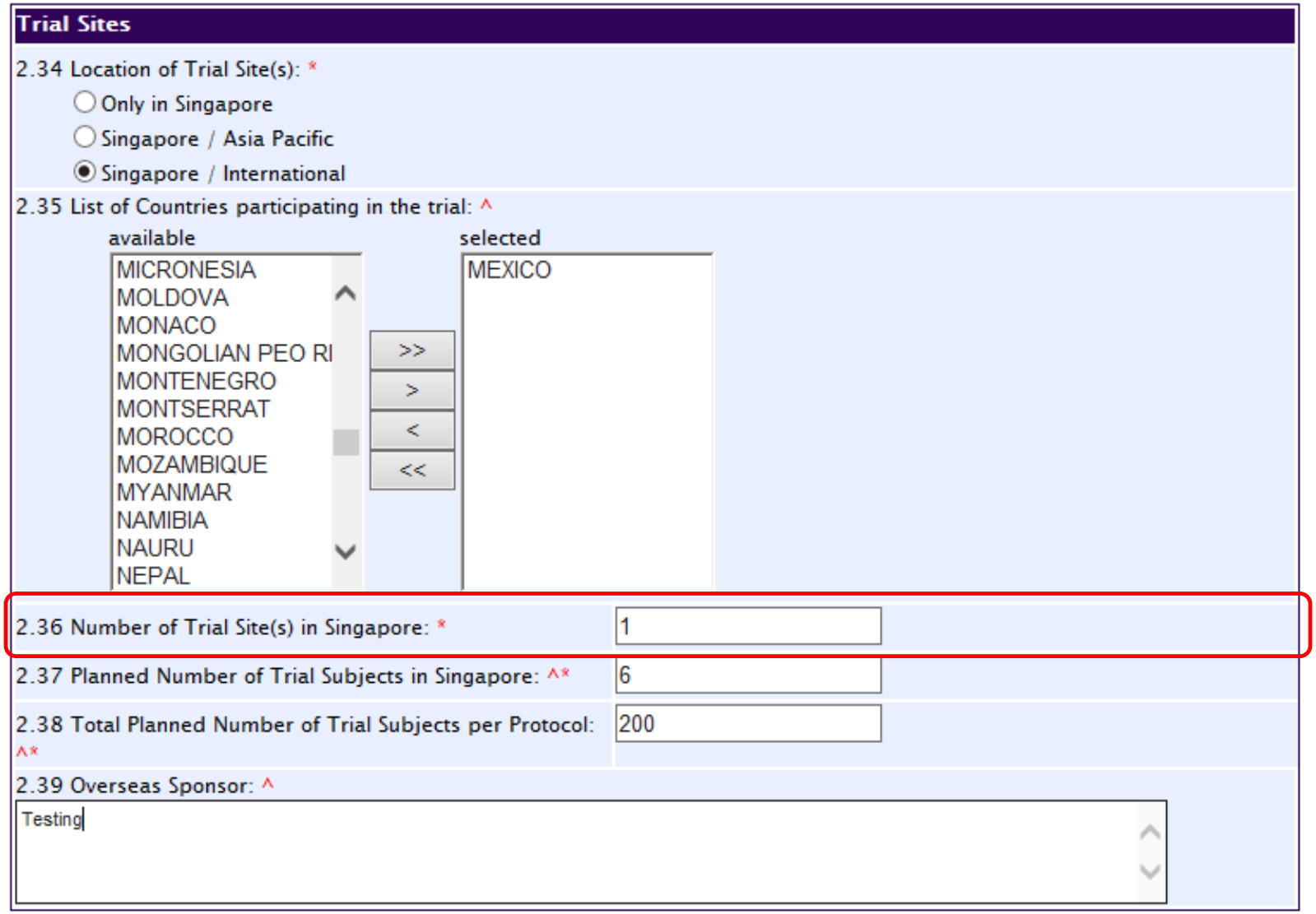
2.32 Is there a Data Safety Monitoring Committee for this study? *

- ( ) Yes
- (•) No

2.33 Website URL link to the study record in ClinicalTrials.gov, if applicable: ^

Note: If this clinical trial is already registered in ClinicalTrials.gov, please insert the URL link by copying and pasting the website address of the study specific record into this field. If this clinical trial is not yet registered in ClinicalTrials.gov, this information can be provided later via an administrative amendment to update this field.

Section 2. TRIAL INFORMATION (8 of 10)



Note:

1) Section 2.36- The number of trial sites must correspond to Section 8 [Local Trial Sites, PI and IRB].

Section 2. TRIAL INFORMATION (9 of 10)

Regulatory Status of Study	
2.40 Is this a US IND/IDE study? *	(•) Yes ( ) No
2.41 Is this a EUDRACT study? *	( ) Yes (•) No
2.42 Is there a negative opinion (including clinical hold) for this study elsewhere by a Regulatory Agency or Ethics Committee? *	( ) Yes (•) No
If yes, please provide reasons for negative opinion: *	

Duration of Study	
2.43 Planned Study Start Date: ^*	23/03/2016
2.44 Planned Study Start Date in Singapore: ^*	23/04/2016
2.45 Planned Study End Date: ^*	23/03/2018

Section 2. TRIAL INFORMATION (10 of 10)

Contacts for Public and Scientific Queries

Contact for Public Queries NEW

2.46 Salutation: ^	Ms
2.47 Name: ^*	Sandy Chan
2.48 Company/Organisation/Institution: *	LION VIEW
2.49 Email: ^*	sandy_chan@lionview.sg
2.50 Telephone number: ^*	12323434
2.51 Fax number:	
2.52 Address: *	Local
Postal Code: ^*	138667 Retrieve Address
Block / House No.: ^*	11 Level – Unit: # 23 – 23
Street Name: ^*	BIOPOLIS WAY
Building Name:	HELIOS
Country:	SINGAPORE

Contact for Scientific Queries NEW

2.53 Salutation: ^	Dr
2.54 Name: ^*	David Jones
2.55 Affiliation/Designation (e.g. principal investigator, medical director employed by the sponsor): ^*	PI
2.56 Company/Organisation/Institution: *	LION VIEW
2.57 Email: ^*	davidjones@lionview.sg
2.58 Telephone number: ^*	123123
2.59 Fax number:	
2.60 Address: *	Local
Postal Code: ^*	138667 Retrieve Address
Block / House No.: ^*	11 Level – Unit: # 23 – 23
Street Name: ^*	BIOPOLIS WAY
Building Name:	HELIOS
Country:	SINGAPORE

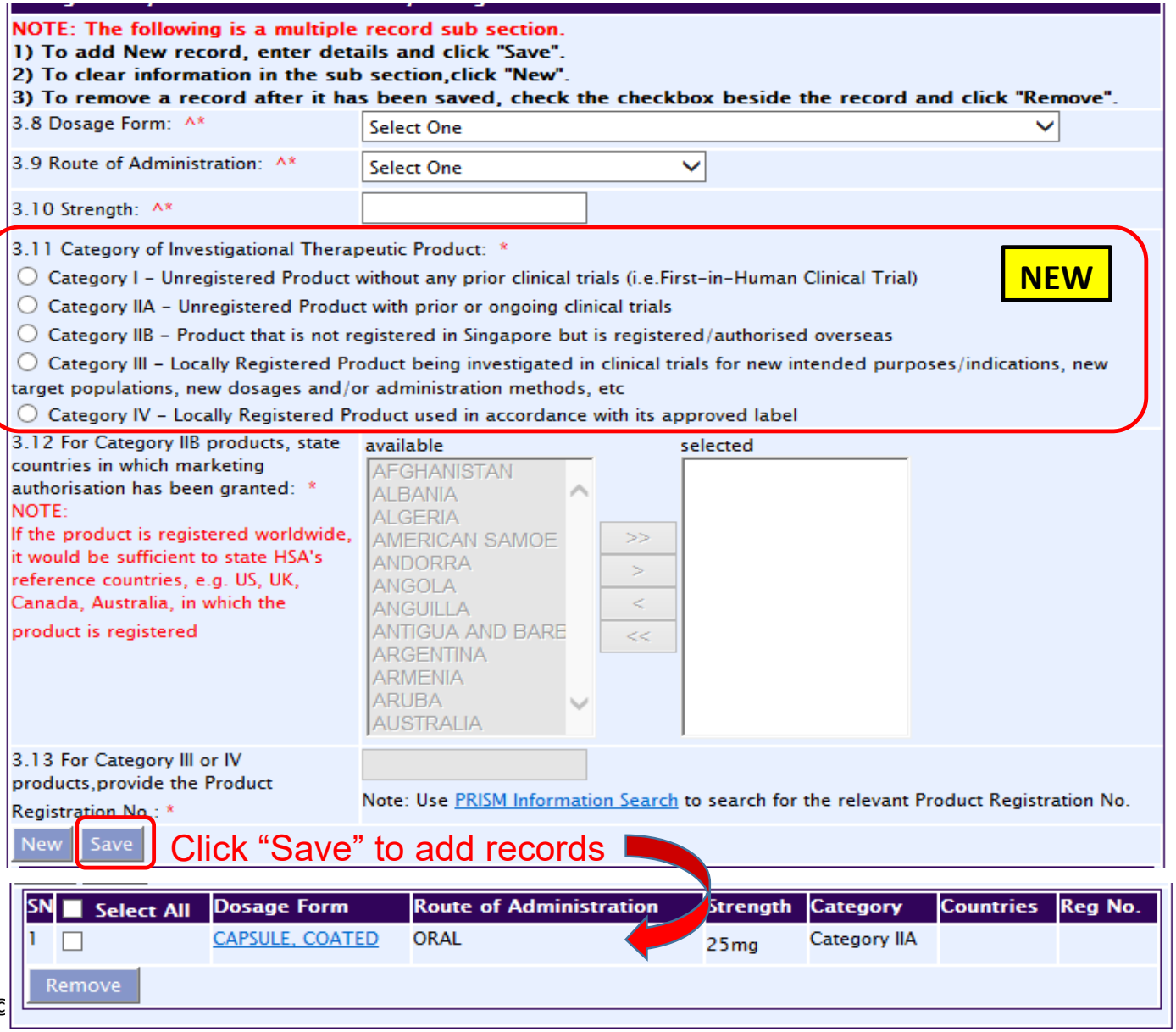
Section 3. Investigational TP / MP (excluding Cell and Tissue Therapy) (1 of 4)

3. Investigational Therapeutic / Medicinal Product (excluding CTT Products)	
3.1 Investigational Therapeutic / Medicinal Product:	No. 1
3.2 Active Ingredient / Generic Name / Any code designation (please use the active ingredient/generic name stated in the Investigator Brochure): ^*	
3.2.1 Standardised Investigational Product Name: ^ NOTE: Please select the appropriate Investigational Product Name to display in CT Register. This should correspond to the International Non-Proprietary Name, where applicable. If there is no suitable choice, please leave it blank.	☐ Not Applicable Select One
3.3 Other Product Identifier(s), if any: ^	☐ Not Applicable
3.4 Brand/Trade Name, if any: ^ NOTE: Please select the appropriate Brand/Trade Name to display in CT	☐ Not Applicable Select One Please specify, if "Others"

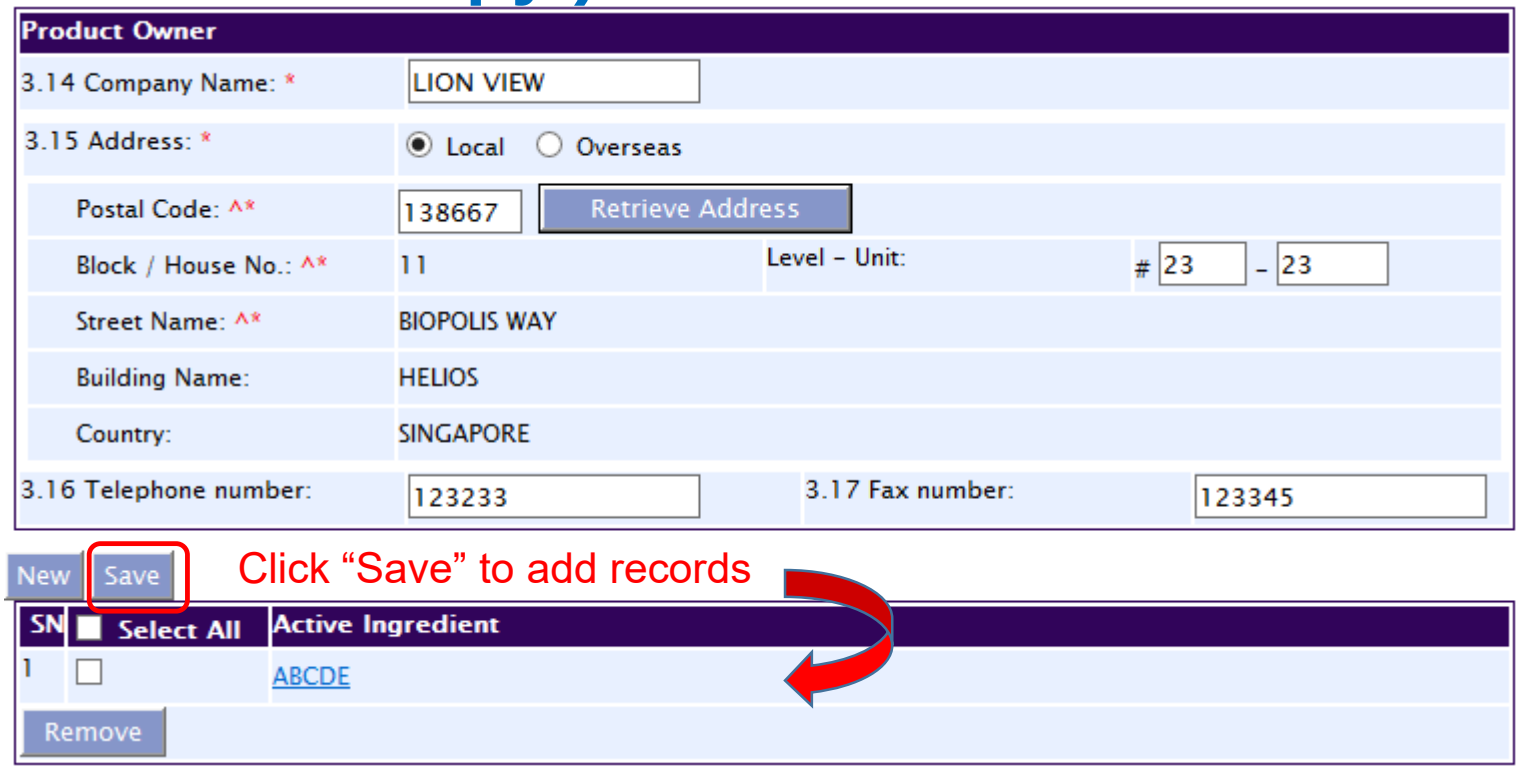
Section 3. Investigational TP / MP (excluding Cell and Tissue Therapy) (2 of 4)

3.5 Pharmacological Class: *	
3.6 Is there any re-packaging and/or re-labelling done for the investigational product at local trial sites? *	○ Yes ○ No **NEW**
3.7 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 **NEW**

Section 3. Investigational TP / MP (excluding Cell and Tissue Therapy) (3 of 4)



Section 3. Investigational TP / MP (excluding Cell and Tissue Therapy) (4 of 4)



Section 4. Investigational Product (Cell and Tissue Therapy product) (1 of 5)

4. Investigational Product (Cell- and Tissue-based Product)

NEW

4.1 Investigational CTT Product:	No. 1
4.2 Active Ingredient / Generic Name / Any code designation: ^*	
4.2.1 Standardised Investigational Product Name: ^ NOTE: Please select the appropriate Investigational Product Name to display in CT Register. If there is no suitable choice, please leave it blank.	☐ Not Applicable Select One
4.3 Brand/Trade Name, if any: ^ NOTE: Please select the appropriate Brand/Trade Name to display in CT Register. If there is no relevant choice, please select "Others" and provide Brand Name or leave it blank.	☑ Not Applicable Select One Please specify, if "Others"
4.4 Pharmacological Class: *	
4.5 Product Description:	

Section 4. Investigational Product (Cell and Tissue Therapy product) (2 of 5)

4.6 Origin of Cells/Tissue: *	○ Autologous ○ Allogeneic ○ Xenogeneic
Please describe, if necessary:	☑ Not Applicable
4.7 Cell/Tissue Type: *	○ Stem cells ○ Differentiated cells
4.7.1 If stem cells, please select: *	☐ Embryonic ☐ Adult ☐ Others
If others, please describe: *	
4.7.2 If differentiated cells, please describe type of cells (e.g. Keratinocytes, fibroblasts, chondrocytes etc): *	
4.8 Please describe degree of cell/tissue processing/manipulation (e.g. In vitro / ex vivo expansion / activation / differntiation / genetic manipulation / cryo-conservation, etc): *	☐ Not Applicable

Section 4. Investigational Product (Cell and Tissue Therapy product) (3 of 5)

4.9 Proposed Use: *	○ Homologous (i.e. cell/tissue is used for a function consistent with its original function) ○ Non-homologous (i.e. cell/tissue is used for a function different from its original function)
Please describe, if necessary:	☑ Not Applicable
4.10 Combined with Drug/Biologic/Device? *	○ No ○ Yes ☐ Drug ☐ Biologic ☐ Device
Please describe, if necessary:	☑ Not Applicable
4.11 Primary Intended Action: *	○ Achieved by physiological, pharmacological, immunological, or metabolic means ○ Not achieved by physiological, pharmacological, immunological, or metabolic means
4.12 Regulatory Classification in the US (for product manufactured in US):	☐ Not Applicable ○ '351 products' i.e. Human Cells, Tissues, Cellular or Tissue-based Products (HCT/Ps) regulated under Section 351 of the US Public Health Service (PHS) Act and/or Federal Food, Drug and Cosmetic Act ○ '361 products' i.e. Human Cells, Tissues, Cellular or Tissue-based Products (HCT/Ps) regulated solely under Section 361 of the US Public Health Service (PHS) Act
4.13 Regulatory Classification in the EU (for product manufactured in EU):	☐ Not Applicable ○ Advanced Therapy Therapeutic Product ○ Others (please specify)
4.13.1 If advanced therapy therapeutic product, please select:	○ Somatic Cell Therapy Product ○ Tissue Engineered Product

Section 4. Investigational Product (Cell and Tissue Therapy product) (4 of 5)

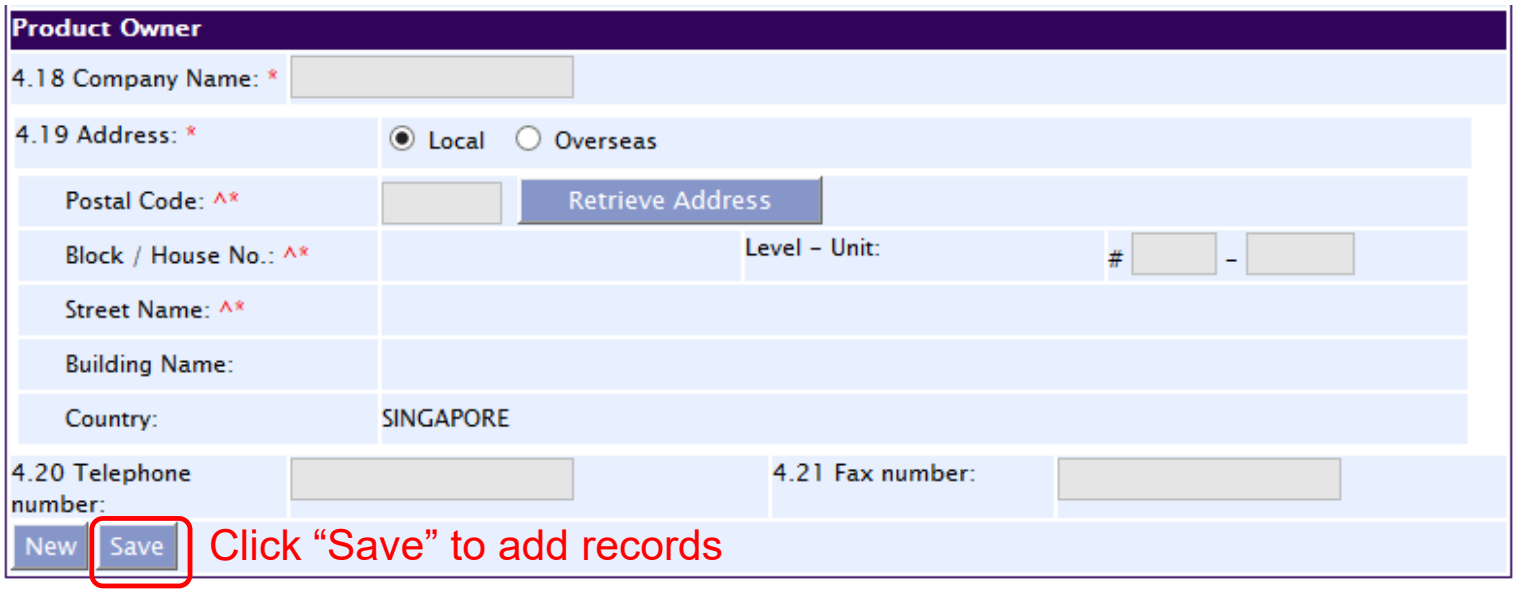
4.13.2 If others, please specify:	
4.14 Route of Administration: *	Select One

4.15 Category of Investigational CTT Product: *

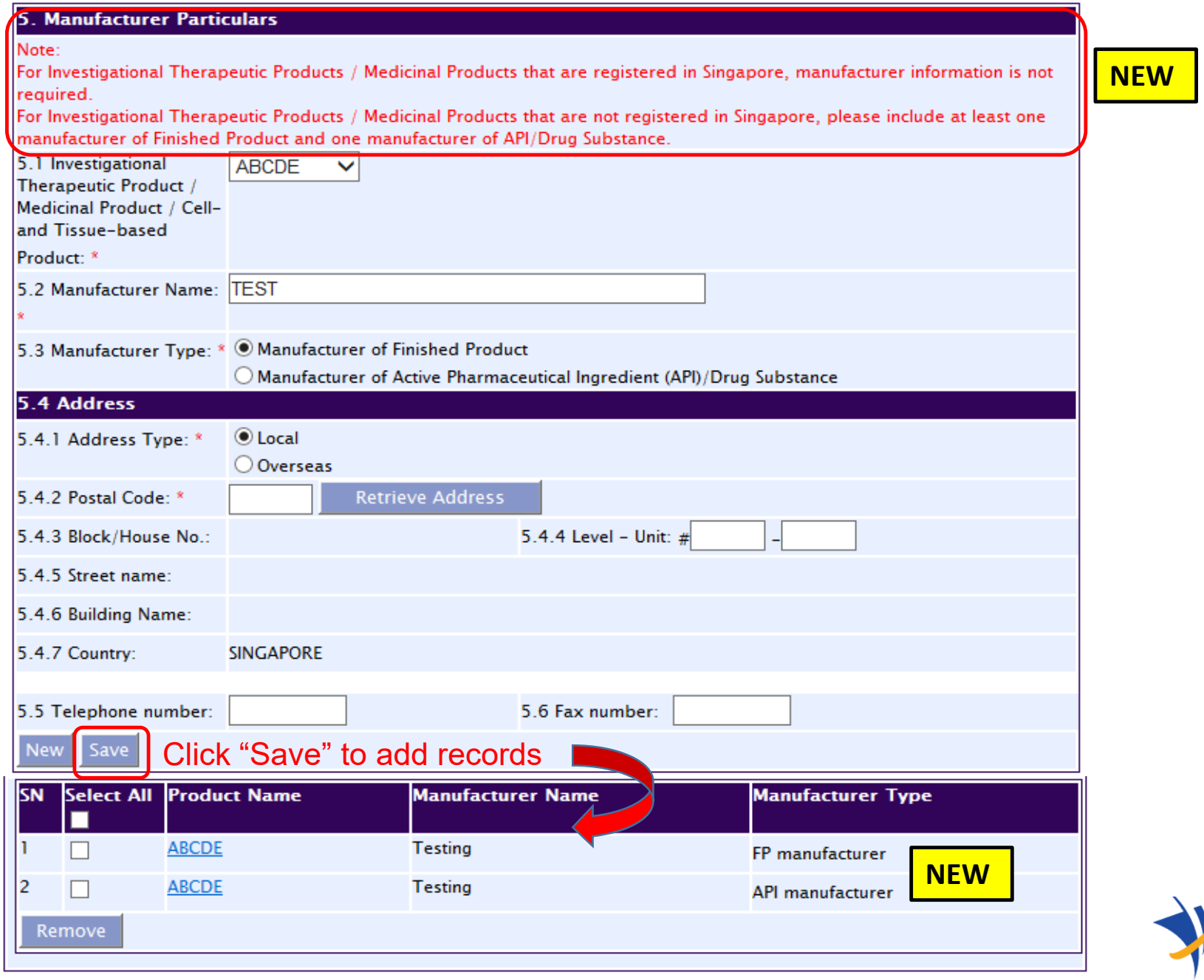
- Category I – Unregistered Product without any prior clinical trials (i.e. First-in-Human Clinical Trial)
- Category IIA – Unregistered Product with prior or ongoing clinical trials
- Category IIB – Product that is not registered in Singapore but is registered/authorised overseas
- Category III – Locally Registered Product being investigated in clinical trials for new intended purposes/indications, new target populations, new dosages and/or administration methods, etc
- Category IV – Locally Registered Product used in accordance with its approved label

4.16 For Category IIB products, state countries in which marketing authorisation has been granted: * NOTE: If the product is registered worldwide, it would be sufficient to state HSA's reference countries, e.g. US, UK, Canada, Australia, in which the product is registered	available	>> > < <<	selected
	AFGHANISTAN ALBANIA ALGERIA AMERICAN SAMOE ANDORRA ANGOLA ANGUILLA ANTIGUA AND BARE ARGENTINA ARMENIA ARUBA AUSTRALIA		
4.17 For Category III or IV products,provide the Product Registration No.:		Note: Use PRISM Information Search to search for the relevant Product Registration No.	

Section 4. Investigational Product (Cell and Tissue Therapy product) (5 of 5)



Section 5. Manufacturer Particulars



Section 6. Comparator Therapeutic Product
Section 7. Auxiliary Therapeutic Product

Section 6. Comparator TP	Section 7. Auxiliary TP	Fields
6.1.1	7.1.1	Comparator/Auxiliary TP
6.1.2	7.1.2	Brand/Trade Name, if any
6.1.3	7.1.3	Pharmacological Class
6.2.1	7.2.1	Dosage Form
6.2.2	7.2.2	Route of Administration
6.2.3	7.2.3	Strength
6.2.4	7.2.4	Category of Investigational TP
6.2.5	7.2.5	Marketing Authorisation Status in other countries
6.2.6	7.2.6	Product Registration Number (if applicable)

Section 8. Local Trial Sites, PI and IRB (1 of 2)

8. Local Trial Sites, PI and IRB

8.1 Trial Site No.:	No. 1
8.2 Name of Trial Site: ^*	Select One
8.2.1 If others, please specify: ^	
8.3 Planned No. of Trial Subjects: *	

Principal Investigator Details

8.4 Salutation:	Select One
8.5 Name of Principal Investigator: ^*	
8.6 NRIC / FIN of PI: *	
8.7 Designation: *	
8.8 Qualified Area(s) of Specialty: *	Select One
If others, please specify:	
8.9 Name of Place of Practice: *	Select One
If others, please specify:	
8.10 Department:	

8.11 Trial Site Address

8.11.1 Address Type:	Local		
8.11.2 Postal Code: *	Retrieve Address		
8.11.3 Block/House NO.:		8.11.4 Level – Unit:	# –
8.11.5 Street name:			
8.11.6 Building Name:			
8.11.7 Country:	SINGAPORE		
8.12 Telephone number: *		8.13 Fax number: *	

Please ensure that the email address is correct, otherwise the relevant parties will NOT receive the endorsement notification.

8.14 Primary Email: *	
8.15 Alternative Email:	

The PI will receive endorsement email via the primary email address.

Section 8. Local Trial Sites, PI and IRB (2 of 2)

Study Coordinator Details

8.16 Salutation:	Select One		
8.17 Name of Study Coordinator:			
8.18 Telephone number:		8.19 Fax number:	
8.20 Email:			

Satellite Site(s) Details

NEW

8.21 Is there any satellite site(s) for this trial site? * (Yes / No)

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".

8.22 Name of Satellite Site: * Select One

If others, please specify:

8.23 Trial activities to be carried out: *

8.24 Satellite Site Address

8.24.1 Address Type:	Local		
8.24.2 Postal Code: *	Retrieve Address		
8.24.3 Block/House NO.:		8.24.4 Level – Unit:	# –
8.24.5 Street name:			
8.24.6 Building Name:			
8.24.7 Country:	SINGAPORE		
8.25 Telephone number: *		8.26 Fax number: *	

New | Save

Click “Save” to add records

Section 9. Local Sponsor (s) (1 of 3)

9. Local Sponsor(s)			
9.1.1 UEN *	38245900L		
9.1.2 Company Name ^*	LION VIEW MINIMART		
9.1.3 Company Address			
9.1.3.1 Address Type: *	Local		
9.1.3.2 Postal Code: *	380056		
9.1.3.3 Block / House No: *	56	9.1.3.4 Level - Unit: *	# -
9.1.3.5 Street Name: *	SIMS DRIVE		
9.1.3.6 Building Name: *			
9.1.3.7 Country: *	SINGAPORE		
9.1.3.8 Telephone number: *	22222223	9.1.3.9 Fax number: *	12312
Sponsor Contact Person			
Note: Please indicate official contact details			
9.2.1 Salutation:	Ms		
9.2.2 Name of Contact Person: *	Sandy Chan		
9.2.3 NRIC/FIN: *	T5000178J	Please note that this field is auto-populated with the NRIC / FIN information of the most recent SingPass login user.	
9.2.4 Designation: *	Manager		
9.2.5 Telephone number: *	123123	9.2.6 Fax number: *	1231231
9.2.7 Mobile Number:			
9.2.8 Primary Email: * (please ensure that the email address is correct,otherwise you will NOT receive the system notifications)	sandy_chan@lionview.		
9.2.9 Alternative Email:			

Section 9. Local Sponsor (s) (2 of 3)

9.3 Other Sponsor(s)

NEW

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".

NOTE:
Companies listed under this section must have a CRIS Account in PRISM
The company contact person must be authorised to endorse on behalf of the company.

9.3.1 Company Name: ^*	Select One		
9.3.2 UEN: *			
9.3.3 Address Type: *	Local		
9.3.4 Postal Code: *			
9.3.5 Block / House No: *		9.3.6 Level – Unit: *	# –
9.3.7 Street Name: *			
9.3.8 Building Name: *			
9.3.9 Country: *	SINGAPORE		
9.3.10 Telephone number: *		9.3.11 Fax number: *	

Other Sponsor Contact Person

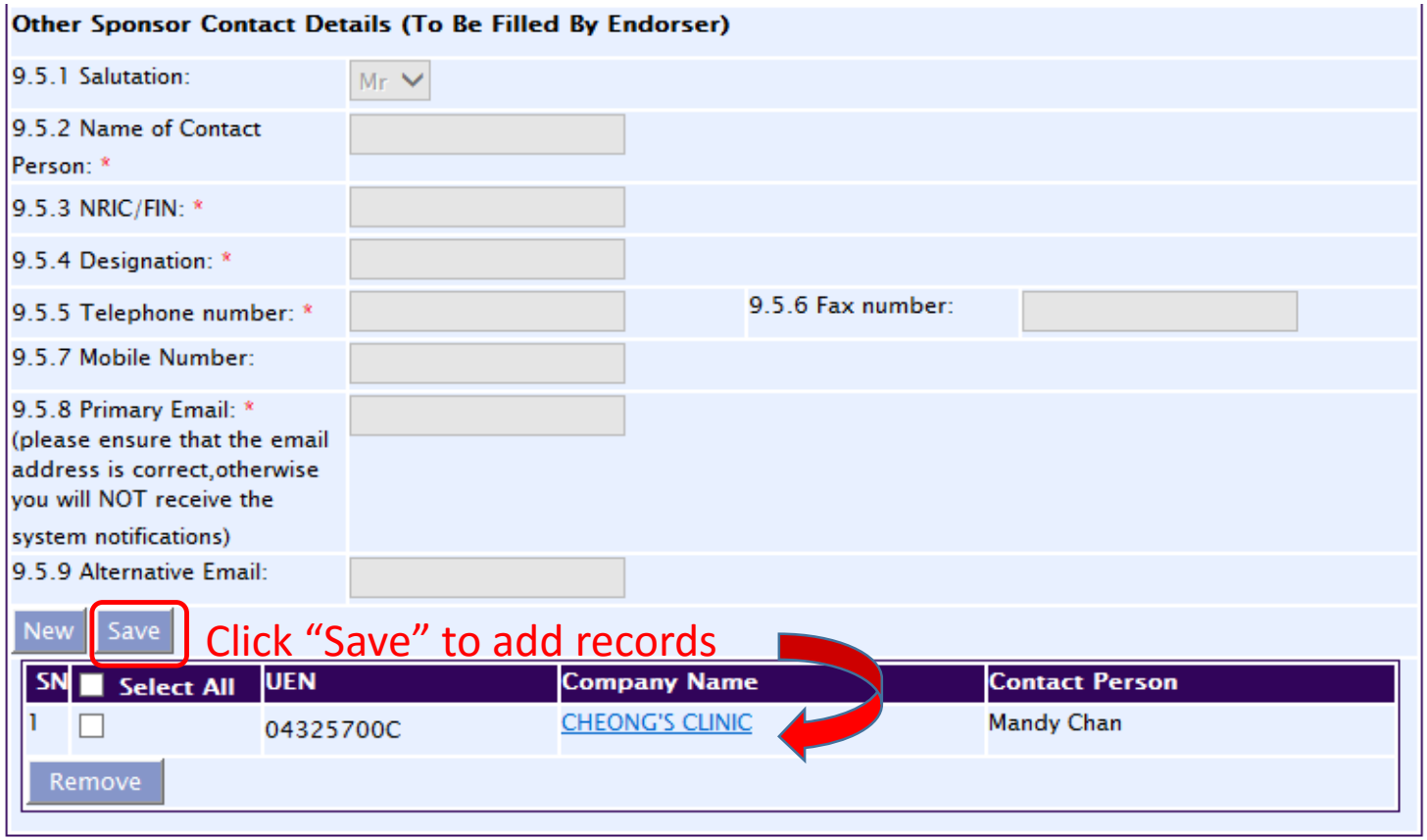
Please note that only persons who are authorised by the company (e.g. given submitter role for new clinical trial applications for the company's account) can endorse the application on behalf of the company

9.4.1 Name of Contact Person: *	
9.4.2 Primary Email: * (please ensure that the email address is correct, otherwise the relevant party will NOT receive the endorsement email):	

Other Sponsor(s) Contact Person will receive endorsement email via the primary email address

Note: For multi-sponsors clinical trial indicated in Section 2, particulars of Other Sponsor(s) are required in Section 9.3.

Section 9. Local Sponsor (s) (3 of 3)



Note: Section 9.5.1-9.5.9 will be editable from the endorsement form.

Section 11. Supporting Documents

	Clinical Trial Certificate (CTC)	Clinical Trial Authorisation (CTA)	Clinical Trial Notification (CTN)
Submission Dossier	• Protocol • Informed Consent Form • Investigator's Brochure • Principal Investigator's CV • GMP Certificate • COA • CMC documents, if requested		• Protocol • Informed Consent Form • Approved Product Label • IRB approval letter

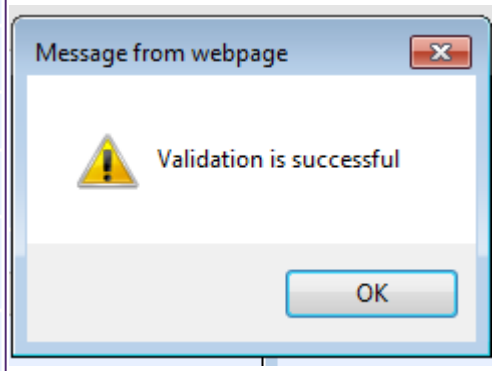
Section 12. Declaration and Confirmation (1 of 2)

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 confirm that the information submitted in this application is true and accurate.
2.	I shall abide by the Medicines Act, the Medicines (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial.
3.	I agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register.
4.	I shall inform the Health Sciences Authority of any substantial changes to the information submitted in the application.
5.	I shall submit status reports of the clinical trial every 6 months and when there is a change to the status of the clinical trial to the Health Sciences Authority.
6.	I undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect of any loss, injury or death of any person whomsoever arising out of or in connection with the clinical trial.
7.	As a lead sponsor, I shall evaluate on an on-going basis the safety of the investigational therapeutic product(s) being tested or used in the trial.
8.	As a lead sponsor, I shall promptly notify all participating site sponsors and principal investigators of any information which suggests that the safety of subjects of the trial could be adversely affected (including any unexpected serious adverse drug reactions), and any findings which could impact the conduct of the trial.
9.	As a lead sponsor, I shall ensure that all unexpected serious adverse drug reactions and serious breaches of the trial protocol, the principles of Good Clinical Practice, or the Medicines (Clinical Trials) Regulations are reported to the Health Sciences Authority in accordance with applicable regulatory requirements.
10.	As a lead sponsor, I shall be responsible for all trial-related regulatory submissions and notifications to the Health Sciences Authority.
11.	I, on behalf of my company, confirm that the information in Section 10 (relating to CRM imported or supplied by local manufacturer for this trial) of this application is true and accurate.
12.	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.
13.	I, on behalf of my company, shall not supply the CRM stated in Section 10 of this application except for the purpose of this clinical trial.

Accept ○ Decline ○

Previous | Validate | Notify | Submit | Reset



Note: Upon clicking “Notify”, endorsement emails, will be sent to PI(s), Other Sponsor (s), CRM importers [if applicable].

Section 12. Declaration and Confirmation (2 of 2)

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

Your notification has been sent successfully.

Back to HSA Home Page

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

1. Application Type

1.1 Application type: *	Clinical Trial Authorisation (CTA)

2. Trial Information

2.1 Title of Clinical Trial (as stated in Protocol document): ^*	ABCDE for NSCLC

CTA/CTN/CTC APPLICATION PROCESS

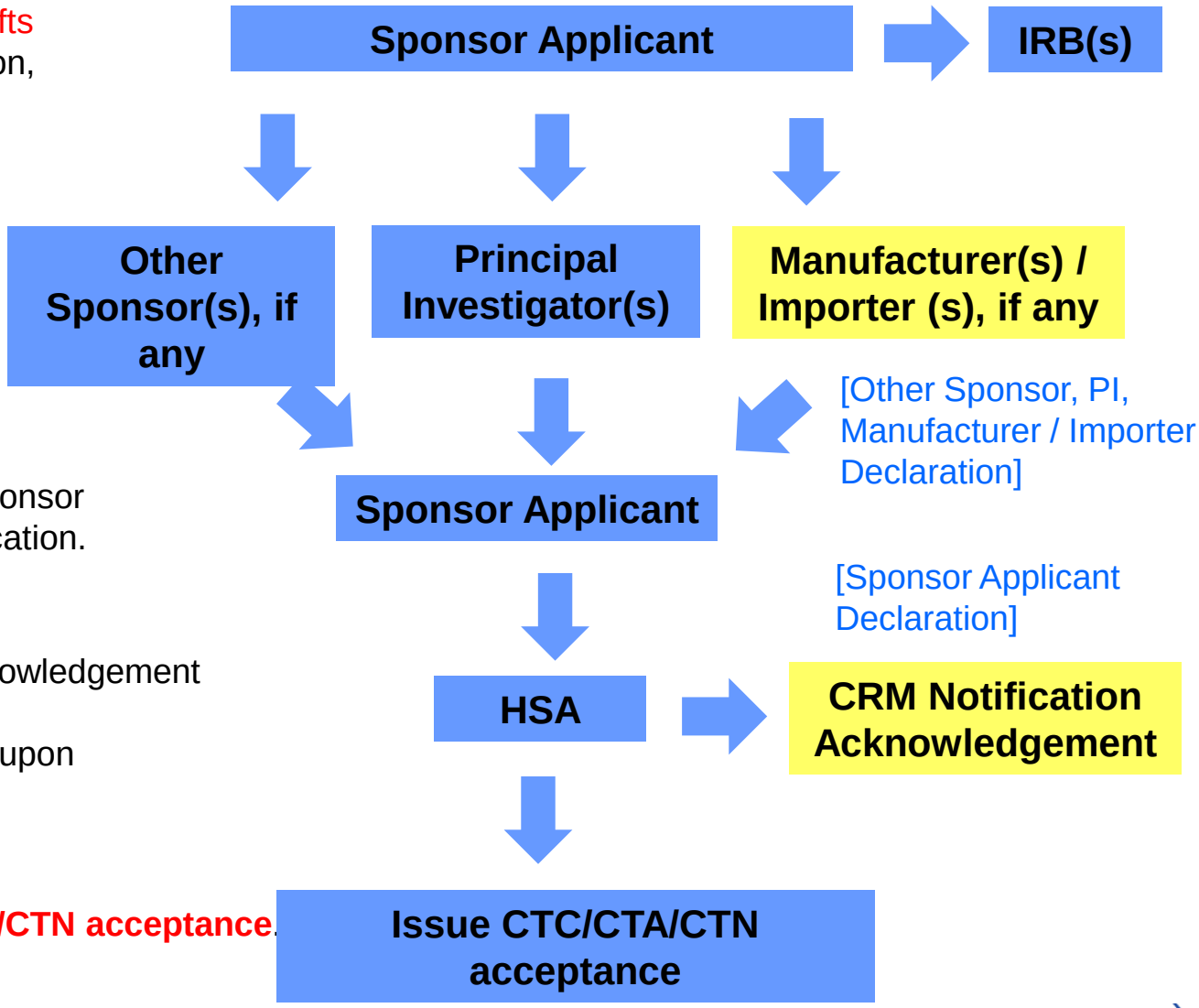
1. Sponsor applicant drafts CTC/CTA/CTN application, sends for endorsement.

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**.



Endorsement Email(s)

11 Oct 2016

Transaction No: T1602018K

Protocol Title:
ABCDE for NSCLC

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

To Principal Investigator,

This e-mail is to notify you to endorse
the above clinical trial.

The sponsor will only be able to comple
including you.

You may access this draft submission fo

https://www-uat.hsa.gov.sg:443/osc/port

(Recommended to copy the entire link ab
webpage)

Please contact the Sponsor if there are
Name of Contact Person: Sandy Chan
Email Address: sandy_chan@lionview.sg

For other enquiries, please contact the
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, PL

11 Oct 2016

Transaction No: T1602018K

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

To Sponsor,

This e-mail is to notify you to endorse an online submission drafted by the Lead Sponsor, LION VIEW MINIMART (Lead Sponsor), for the above clinical trial.

The Lead 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=26

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

Please contact the Lead Sponsor if there are any inaccuracies or inconsistencies in the draft submission form:
Name of Contact Person: Sandy Chan
Email Address: sandy_chan@lionview.sg

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

Note: Endorsement emails (copied sponsor applicant), will be sent to the PI(s), Other Sponsor(s) and CRM Importer(s) [if applicable].

PI Endorsement (1 of 2)

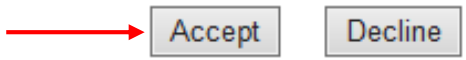
- PI logs in using Corppass to retrieve and view drafted application form; and edit particulars of Principal Investigator [Section 8.4-8.10].

Principal Investigator Details			
8.4 Salutation:	Dr		
8.5 Name of Principal Investigator: ^*	Name of PI		
8.6 NRIC / FIN of PI: *			
8.7 Designation: *	Consultant		
8.8 Qualified Area(s) of Specialty: *	Neurology		
If others, please specify:			
8.9 Name of Place of Practice: *	National Cancer Centre		
If others, please specify:			
8.10 Department:	Haematology-Oncology		
8.11 Trial Site Address			
8.11.1 Address Type: *	Local		
8.11.2 Postal Code: *	138667		
8.11.3 Block/House NO.:	11	8.11.4 Level - Unit:	#-
8.11.5 Street name:	BIOPOLIS WAY		
8.11.6 Building Name:	HELIOS		
8.11.7 Country:	SINGAPORE		
8.12 Telephone number: *	1232434	8.13 Fax number: *	123123
8.14 Primary Email:	PIprimaryemail@cgh.sg		
8.15 Alternative Email:			

NRIC/FIN of PI will be auto-populated from his/her login; and would be masked from the applicant subsequently.

PI Endorsement (2 of 2)

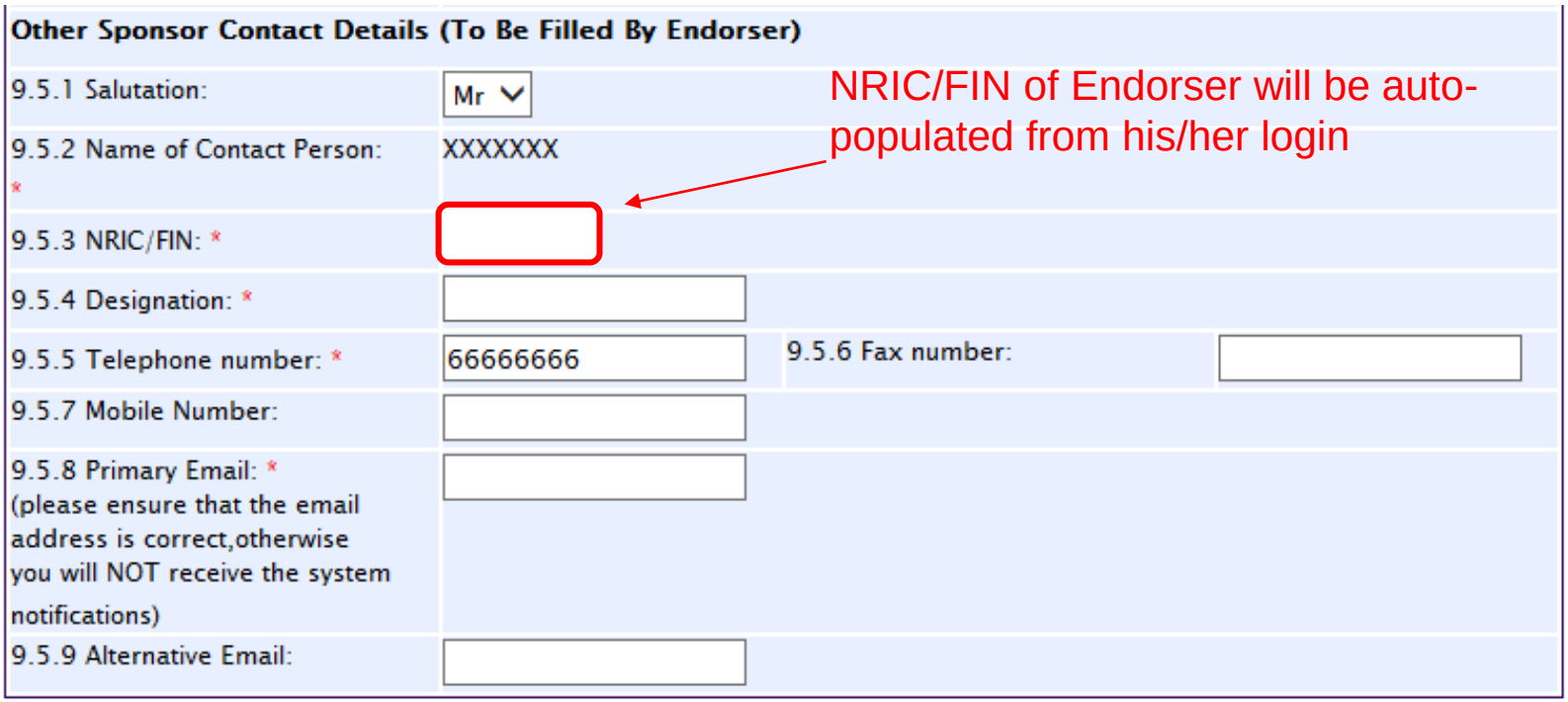
Declaration	
1.	I shall abide by the Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial.
2.	I shall not initiate this trial until the Health Sciences Authority has granted a clinical trial authorisation for the clinical trial.
3.	I shall not initiate this trial until the relevant Institutional Review Board has granted approval for the clinical trial.



Acknowledgement
Your endorsement decision for this application has been successfully submitted. Please note that the transaction number is T1602018K

Other Sponsor(s) Endorsement (1 of 2)

- Other Sponsor Endorser logs in using Corppass to retrieve and view drafted application form; and edit particulars of Other Sponsor Contact Details (Endorser)[Section 9.5.1-9.5.9]



Other Sponsor(s) Endorsement (2 of 2)

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 Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial.
3.	I, on behalf of my company agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register.
4.	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 of any person whomsoever arising out of or in connection with the clinical trial.
5.	As a participating site sponsor, I, on behalf of my company, shall immediately report to the lead sponsor any serious adverse event which occurs in a subject during the clinical trial conducted at the participating site, except those specified in the protocol as not requiring immediate reporting, and furnish to the lead sponsor a detailed written report on the event as soon as possible thereafter.
6.	As a participating site sponsor, I, on behalf of my company, shall promptly report to the lead sponsor any information which suggests that the safety of any subject of the trial could be adversely affected and any findings which could impact the conduct of the trial.
7.	As a participating site sponsor, I, on behalf of my company, shall provide all relevant information to the lead sponsor that is necessary for the lead sponsor to perform trial-related regulatory submissions and notifications to the Health Sciences Authority.

Accept Decline

Acknowledgement
Your endorsement decision for this application has been successfully submitted. Please note that the transaction number is T1602018K

Endorsement(s) Complete

- Once endorsement(s) from relevant parties are completed, the sponsor/lead sponsor will receive an email notification to proceed with submission

11 Oct 2016

Transaction No: T1601987K

Protocol Title:
ABCDE for NSCLC

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

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

Local Manufacturer (s) or Importer (s) of Clinical Research Material:
DHL
GSK

To Sponsor,

This e-mail is to notify you that all relevant parties have reviewed and endorsed this draft submission.

You may proceed with the submission to HSA.

To retreive this draft submission:
1. Please visit our website: www.hsa.gov.sg/content/hsa/en/Health_Products_Regulation/PRISM_e-services/Clinical_Trials.html.
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

CTA/CTN/CTC APPLICATION PROCESS

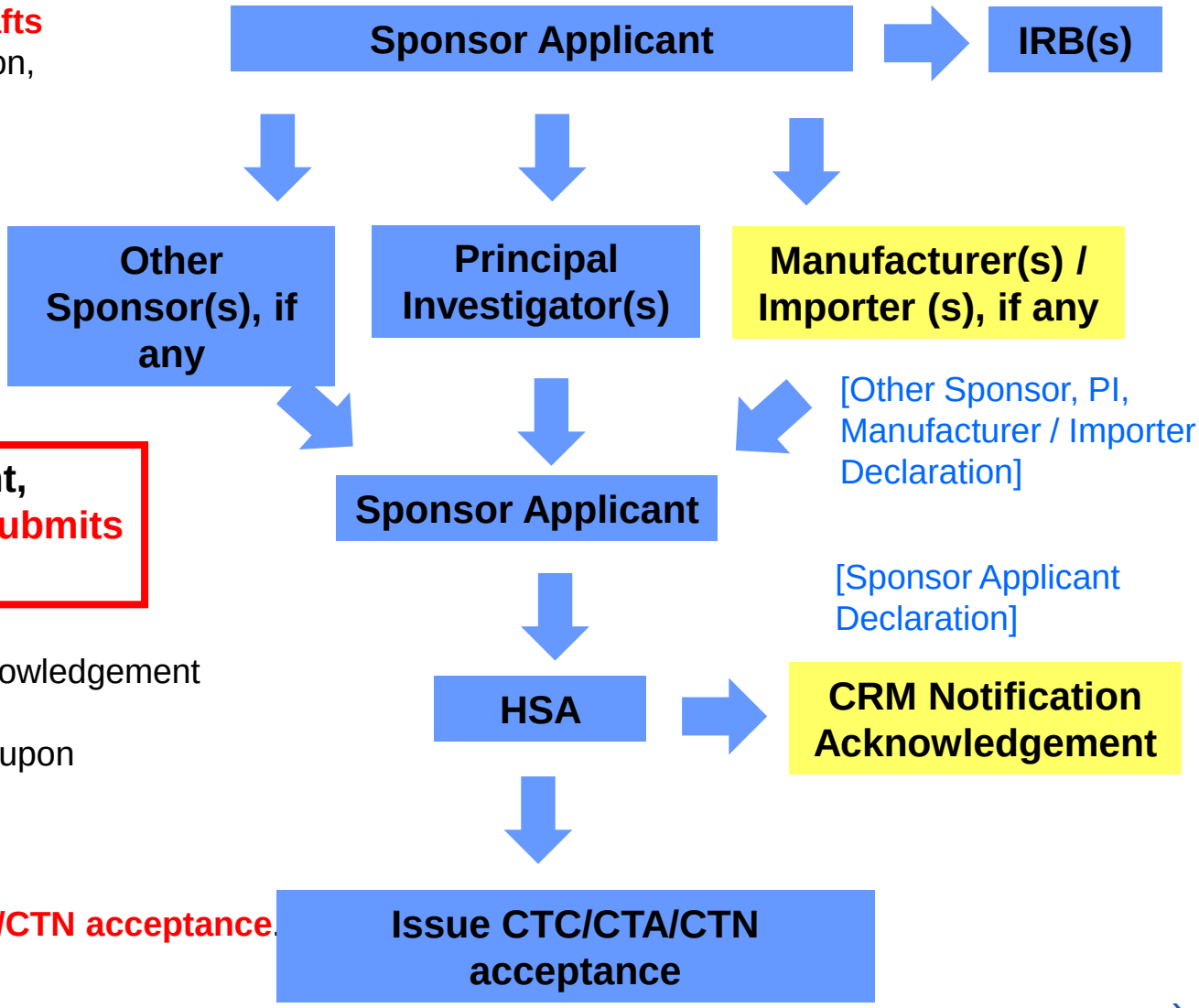
1. Sponsor applicant **drafts** CTC/CTA/CTN application, sends for endorsement.

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**.



Check Endorsement via TRACK@PRISM

PZ0951 TRACK@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.

General Search

Enter Transac

Application/Sub

Licence/Permit/ Type *

Enquiry Type *

Transaction No.

Licence/Permit/ No.

Product Name.

Last Update Dat

Search Re

Please click here

Please do not a

1 Matching Record(t] | [Last]

New Applicat

S/No	Transa No			Date		Status	
1	T1601987K	NA	Draft	10/10/2016	Copy to Draft	Check endorsement	Delete Draft

Enquire Endorsement Status - Internet Explorer

HSA Health Sciences Authority

To be the leading innovative authority protecting and advanc

Enquiry on application Endorsement

Transaction No : T1601987K

Endorser Type	Notify Date	Name	Status*	Endorse Date
CRM Type	10/10/2016	Sandy Chan	Y	10/10/2016
CRM Type	10/10/2016	Sandy Chan	Y	10/10/2016
Other Sponsor	10/10/2016	Mandy Chan	Y	10/10/2016
PI	10/10/2016	David Bowie	Y	11/10/2016

Close

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

Submission Declaration

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 Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial.
3.	I, on behalf of my company agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register.
4.	I, on behalf of my company, shall inform the Health Sciences Authority of any substantial changes to the information submitted in the application.
5.	I, on behalf of my company, shall submit status reports of the clinical trial every 6 months and when there is a change to the status of the clinical trial to the Health Sciences Authority.
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 of any person whomsoever arising out of or in connection with the clinical trial.
7.	As a lead sponsor, I, on behalf of my company, shall evaluate on an on-going basis the safety of the investigational therapeutic product(s) being tested or used in the trial.
8.	As a lead sponsor, I, on behalf of my company, shall promptly notify all participating site sponsors and principal investigators of any information which suggests that the safety of subjects of the trial could be adversely affected (including any unexpected serious adverse drug reactions), and any findings which could impact the conduct of the trial.
9.	As a lead sponsor, I, on behalf of my company, shall ensure that all unexpected serious adverse drug reactions and serious breaches of the trial protocol, the principles of Good Clinical Practice, or the Health Products (Clinical Trials) Regulations are reported to the Health Sciences Authority in accordance with applicable regulatory requirements.
10.	As a lead sponsor, I, on behalf of my company, shall be responsible for all trial-related regulatory submissions and notifications to the Health Sciences Authority.

Accept ○ Decline ○

Lead Sponsor Declaration for multi-sponsor IIT(s)

Validate | Submit | Reset

Submission Complete

Acknowledgement

Your application has been successfully submitted.

Please note that your application number is 1601186R

Show Printer-Friendly version

ESTIMATED TIME FOR DRAFTING ONLINE CT APPLICATION

CTA/CTN/CTC: 20-40 minutes

CTA/CTN/CTC with CRM notification: 30-45 minutes

TIPS FOR A SMOOTH ONLINE SUBMISSION

Before drafting CT application…

1. Determine application type before drafting [Refer CTA/CTN/CTC Determination Guidance Nov 2016]

2. Determine the number of site(s), PI(s), Other Sponsor(s)

3. Prepare trial information [Study Design, No. of Investigational TP/MP, comparator TP/MP, auxiliary TP/MP, Investigational CTT(s), manufacturer details etc.]

4. Prepare CRM importer(s) information, if applicable

5. Prepare supporting documents [Protocol, ICF(s), Product label/IB, CoA, GMP etc.]

REFERENCES

I. Health Products (Clinical Trials) Regulations

II. Medicines (Clinical Trials) Regulations

III. Guidance on determination of whether a clinical trial requires a CTA, CTN or CTC [GN-CTB-2-001A-001]

IV. Guidance on regulatory requirements for new applications and subsequent submissions [GN-CTB-2-003A-001]

We welcome your queries!

HSA_CT@hsa.gov.sg

THANK YOU!