



TRAINING SESSION:

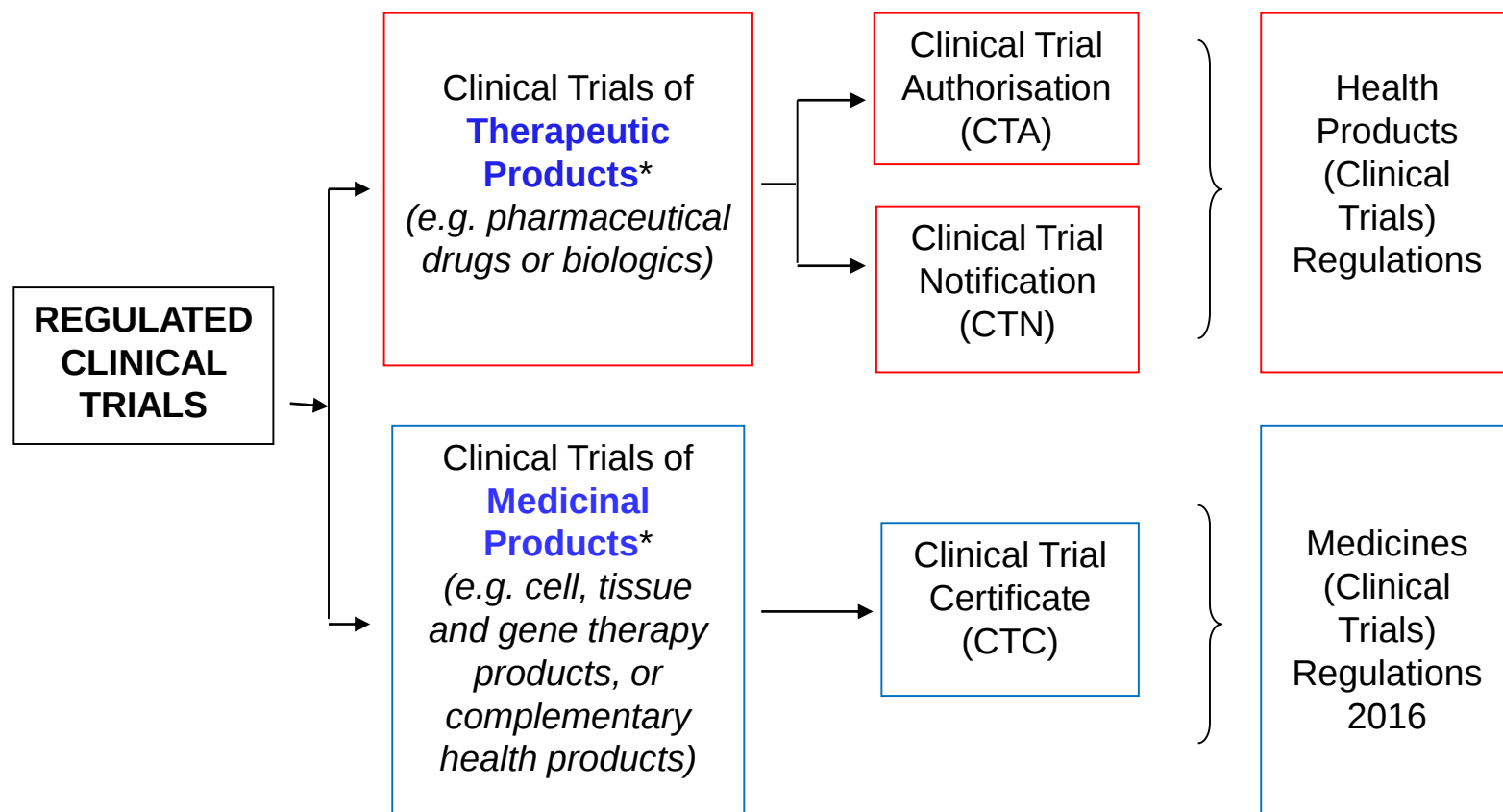
ENHANCED PRISM E-SERVICES

CTA/CTN/CTC APPLICATION SUBMISSION

OUTLINE

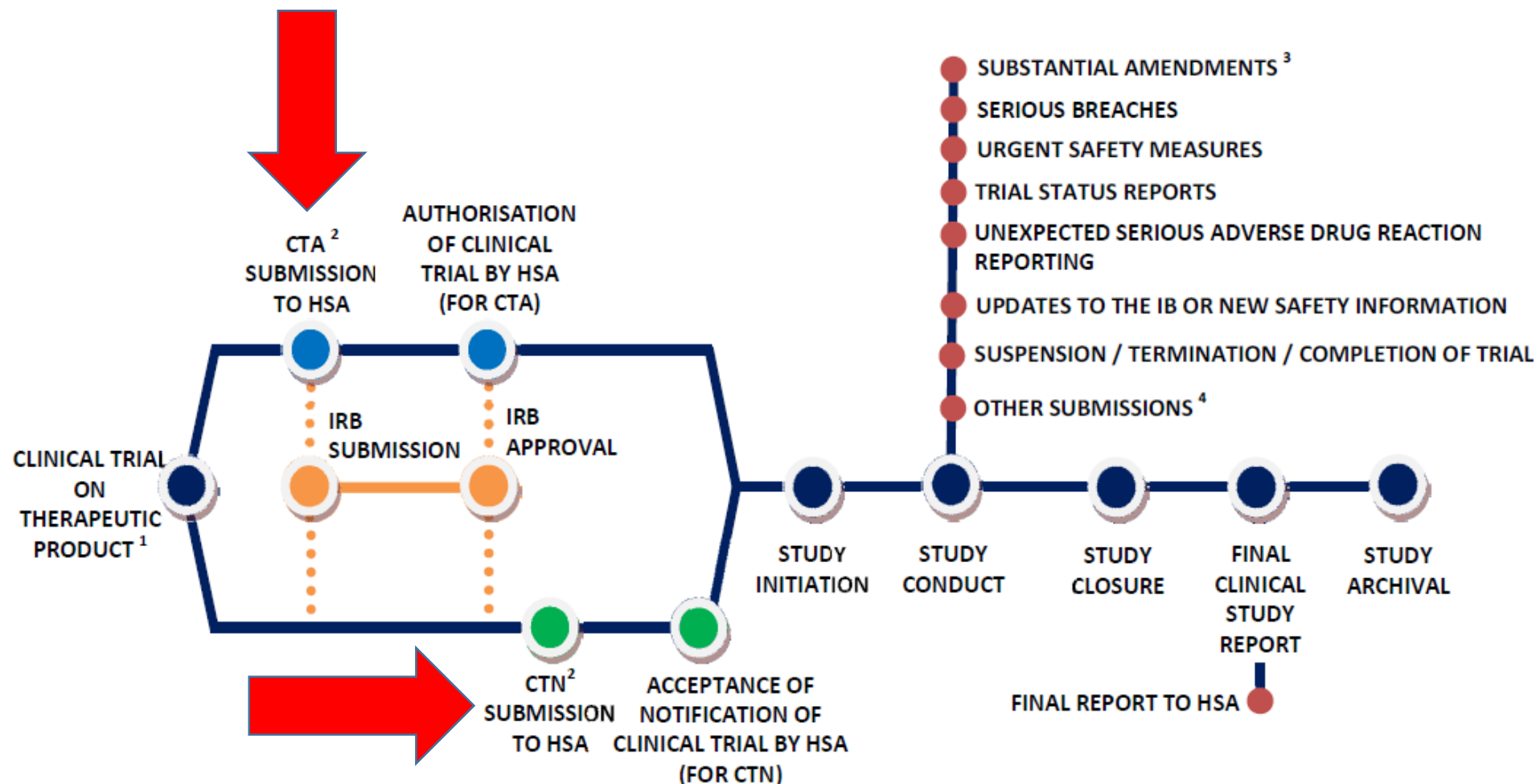
1. Overview of CT application types for PRISM submission
2. CT application process
3. Tips for a smooth submission
4. References

SCOPE OF TRIALS REGULATED UNDER CT REGULATIONS

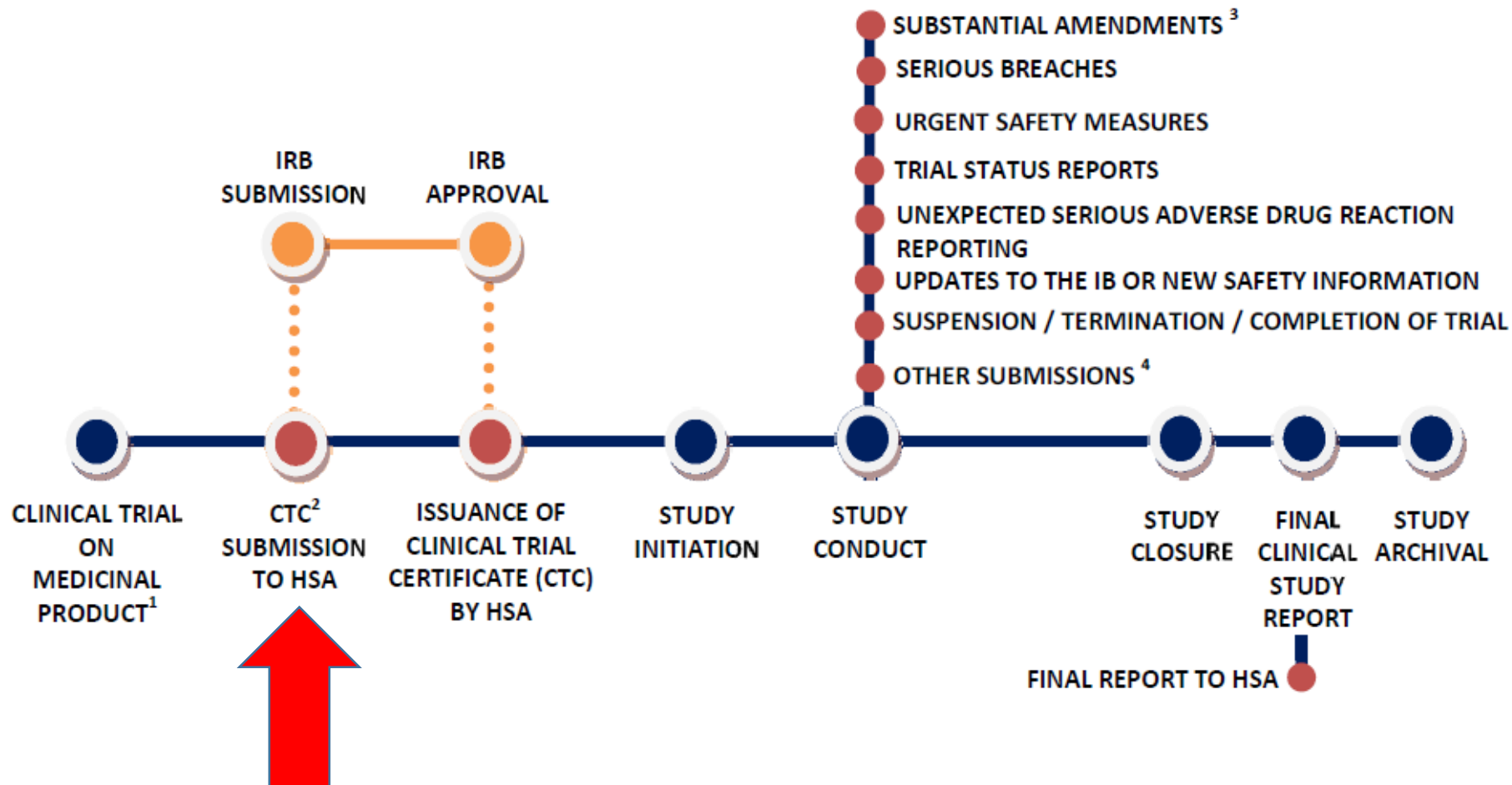


*Excluding observational trials

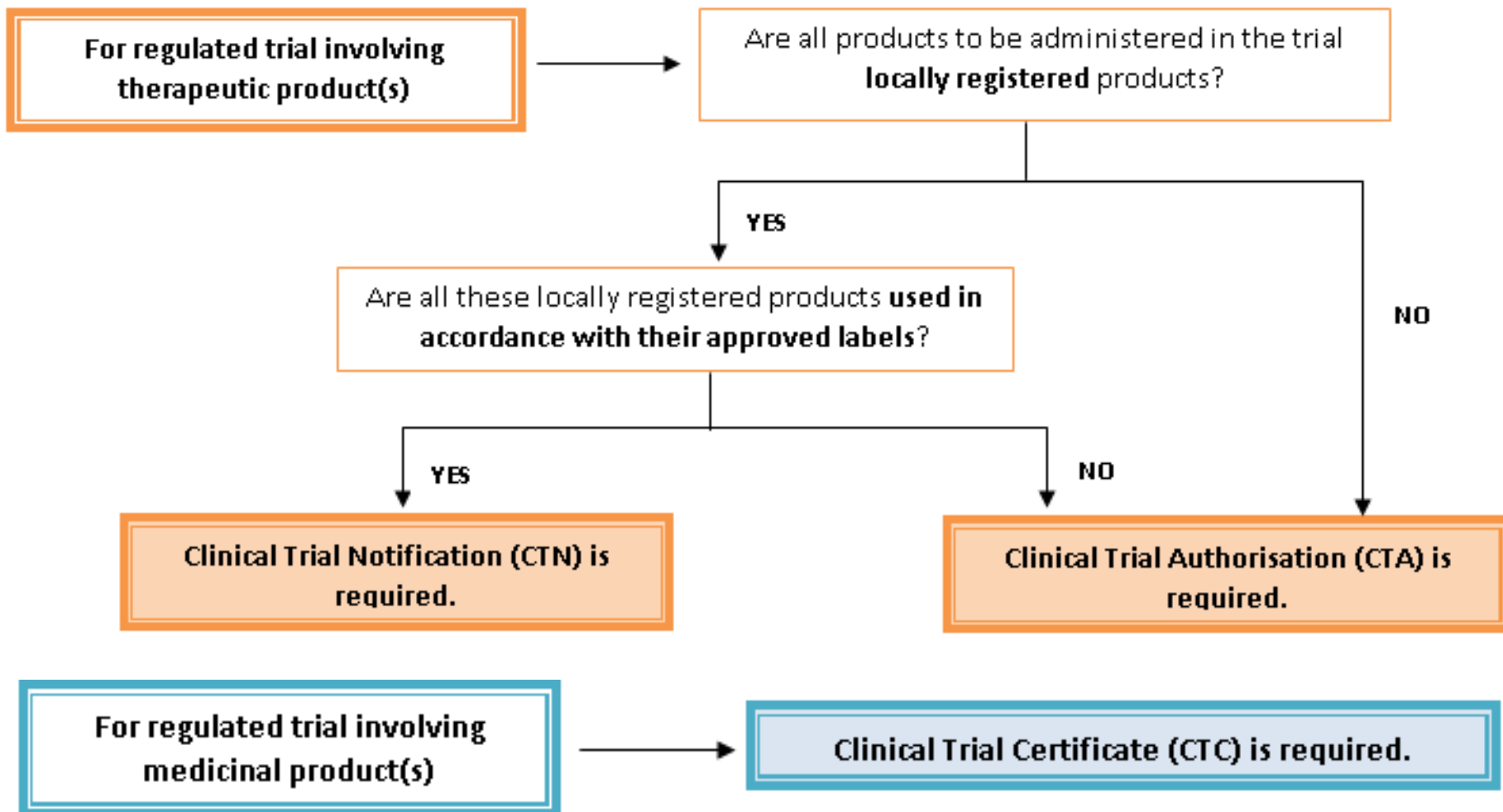
REGULATORY ROADMAP FOR TP TRIALS



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

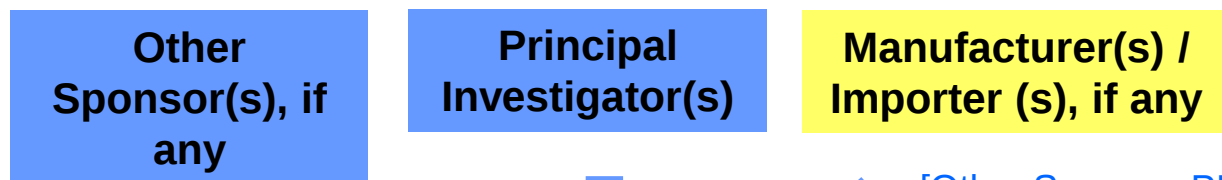
CTA/CTN/CTC with CRM notification: 30-45 minutes

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.

Sponsor Applicant

[Other Sponsor, PI, Manufacturer / Importer Declaration]

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

[Sponsor Applicant Declaration]



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

Issue CTC/CTA/CTN acceptance

Home | HSA | Health Sciences Authority

www.hsa.gov.sg/content/hsa/en.html

Apps ABPI Acts and regulations BBC - GCSE Bitesize S Biliary excretion Bioethics Advisory Co Cancer Cardiovascular CDC Centers for Disease C FDA Clinical Investigator T Clinical Practice Guide

HSA Health Sciences Authority

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Within HSA Search

Health Products Regulation Blood Services Applied Sciences **e-Services** Publications News & Events

To be the leading innovative authority

[Announcement] Important: The Blood Donor Carpark (HSA Carpark A) and HSA Bloodbank@HSA through the base

ing national health and safety

temporary carpark off 2nd Hospital Avenue and access details.

Health Products Regulation

Ensures health products are safe, of good quality and efficacious

> PRISM
> MEDICS
> Bringing personal medication into Singapore

Medicines | Medical Devices
Complementary Health Products
Tobacco Control | Clinical Trials

Blood Services

Provides forensic and analytical testing to support law enforcement and the courts

Provides a safe and sustainable national blood supply

Applied Sciences

Provides forensic and analytical testing to support law enforcement and the courts

Bloodbank@Westgate Tower is Now Open!

HSA Highlights

HSA Prosecutes Five for Unlicensed Sale of Shisha Tobacco
16 Sep 2016

Relocation of HSA'S Audit and Licensing Division to Helios@11 Biopolis Way
13 Sep 2016

HSA Alerts Public to Three Adulterated Products Purchased Overseas Which ...
1 Sep 2016

www.hsa.gov.sg/content/hsa/en/e-Services.html

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

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

Next

Fields marked with an asterisk * are mandatory.

Fields marked with ^ will be displayed in the Clinical Trial Register.

1. Application Type	
1.1 Please select application type: *	☒ Clinical Trial Authorisation (CTA) ☐ Clinical Trial Notification (CTN) ☐ Clinical Trial Certificate (CTC)

Next

Reset

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)

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

[Previous](#)
[Next](#)

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	NEW
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](#)

Section 2. TRIAL INFORMATION (2 of 10)

2.6 Phase of Clinical Trial: ^*

- ☐ Phase 0
- ☐ Phase 1 (First-In-Man ☐ Yes ☐ No)
- ☒ Phase 2
- ☐ Phase 3
- ☐ Phase 4
- ☐ Others

If others, please specify: ^

2.7 Type of Sponsorship: *

NEW

- ☐ Industry-initiated study
- ☒ Investigator-initiated study
 - ☐ Single sponsor
 - ☒ Multiple sponsor
 - Applicant is a
 - ☐ Lead sponsor

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	
2.14 Clinical Trial in Emergency Situation: *	
☐ Yes ☒ No	
2.15 Study Type: ^*	
☒ Interventional ☐ Non-Interventional	
2.16 Purpose of Trial: ^*	Treatment
If others, please describe: ^	
2.17 Primary Trial Objective(s): *	
PFS	

Section 2.16:

- 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: [^]

Section 2.21:

- Single-Blind, Double-Blind, Open Label, Others

Section 2.22

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

2.22 Intervention model: [^]^{*}

NEW

Parallel ▼

If others, please describe: [^]

Section 2. TRIAL INFORMATION (6 of 10)

NEW

2.23 Number of study arms/groups: *

2

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".

2.23.1 Study Arm/Group Type: ^*

☐ Experimental

☐ Control

☐ Others

If others, please describe: ^

2.23.2 Arm label (short name to identify arm, e.g. metformin, placebo, or lifestyle counselling): ^*

2.23.3 Brief description of study arm (for drugs, use generic name and include route of administration, dose and dosing regimen/administration schedule; for other interventions provide brief description of study arm): ^*

NOTE: Study arm description must be sufficiently detailed to distinguish between arms of a study

2.23.4 Duration of drug dosing/intervention: ^*

New Save

SN	Select All	Study Arm/Group Type	Arm Label	Brief Description	Duration
1	☐	Experimental	ABCDE	ABCDE	24 months
2	☐	Control	Placebo	Placebo	24 months

Remove

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
☒ 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)

Trial Sites	
2.34 Location of Trial Site(s): *	
☐ Only in Singapore ☐ Singapore / Asia Pacific ☒ Singapore / International	
2.35 List of Countries participating in the trial: ^	
available MICRONESIA MOLDOVA MONACO MONGOLIAN PEO RI MONTENEGRO MONTSERRAT MOROCCO MOZAMBIQUE MYANMAR NAMIBIA NAURU NEPAL	selected MEXICO
2.36 Number of Trial Site(s) in Singapore: * 1	
2.37 Planned Number of Trial Subjects in Singapore: ^* 6	
2.38 Total Planned Number of Trial Subjects per Protocol: ^* 200	
2.39 Overseas Sponsor: ^	
Testing	

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 v		
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 v		
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 Register. If there is no suitable choice, please leave it blank.	☐ 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? *	☐ Psychotropic Substance ☐ Controlled Drug ☐ Both ☐ No NEW
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.	

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

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".

3.8 Dosage Form: ^{^*}

3.9 Route of Administration: ^{^*}

3.10 Strength: ^{^*}

3.11 Category of Investigational Therapeutic 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

NEW

3.12 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

AFGHANISTAN
ALBANIA
ALGERIA
AMERICAN SAMOE
ANDORRA
ANGOLA
ANGUILLA
ANTIGUA AND BARE
ARGENTINA
ARMENIA
ARUBA
AUSTRALIA

>>
>
<
<<

selected

3.13 For Category III or IV products, provide the Product

Registration No: *

Note: Use [PRISM Information Search](#) to search for the relevant Product Registration No.

Click "Save" to add records

SN	☐ Select All	Dosage Form	Route of Administration	Strength	Category	Countries	Reg No.
1	☐	CAPSULE, COATED	ORAL	25mg	Category IIA		
Remove							

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

Product Owner			
3.14 Company Name: *	LION VIEW		
3.15 Address: *	☒ Local ☐ Overseas		
Postal Code: ^*	138667	Retrieve Address	
Block / House No.: ^*	11	Level - Unit:	# 23 - 23
Street Name: ^*	BIOPOLIS WAY		
Building Name:	HELIOS		
Country:	SINGAPORE		
3.16 Telephone number:	123233	3.17 Fax number:	123345

New **Save** Click "Save" to add records

SN	Select All	Active Ingredient
1	☐	ABCDE

Remove



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

4. Investigational Product (Cell- and Tissue-based Product)	
4.1 Investigational CTT Product:	No. 1 NEW
4.2 Active Ingredient / Generic Name / Any code designation: ^*	
4.2.1 Standardised Investigational Product Name: ^	☐ Not Applicable Select One
NOTE: Please select the appropriate Investigational Product Name to display in CT Register. If there is no suitable choice, please leave it blank.	
4.3 Brand/Trade Name, if any: ^	☒ Not Applicable Select One
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.	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 / differentiation / 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

AFGHANISTAN
ALBANIA
ALGERIA
AMERICAN SAMOE
ANDORRA
ANGOLA
ANGUILLA
ANTIGUA AND BARE
ARGENTINA
ARMENIA
ARUBA
AUSTRALIA

selected

>>
>
<
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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)

Product Owner			
4.18 Company Name: *			
4.19 Address: *			
☒ Local ☐ Overseas			
Postal Code: ^*		Retrieve Address	
Block / House No.: ^*		Level - Unit:	# -
Street Name: ^*			
Building Name:			
Country:	SINGAPORE		
4.20 Telephone number:		4.21 Fax number:	
New	Save	Click "Save" to add records	

Section 5. Manufacturer Particulars

5. Manufacturer Particulars

Note:

For Investigational Therapeutic Products / Medicinal Products that are registered in Singapore, manufacturer information is not required.

For Investigational Therapeutic Products / Medicinal Products that are not registered in Singapore, please include at least one manufacturer of Finished Product and one manufacturer of API/Drug Substance.

NEW

5.1 Investigational
Therapeutic Product /
Medicinal Product / Cell-
and Tissue-based
Product: *

ABCDE ▼

5.2 Manufacturer Name: *

TEST

5.3 Manufacturer Type: *

☒ Manufacturer of Finished Product

☐ Manufacturer of Active Pharmaceutical Ingredient (API)/Drug Substance

5.4 Address

5.4.1 Address Type: *

☒ Local

☐ Overseas

5.4.2 Postal Code: *

Retrieve Address

5.4.3 Block/House No.:

5.4.4 Level - Unit: #

5.4.5 Street name:

5.4.6 Building Name:

5.4.7 Country:

SINGAPORE

5.5 Telephone number:

5.6 Fax number:

New

Save

Click "Save" to add records

SN	Select All	Product Name	Manufacturer Name	Manufacturer Type
1	☐	ABCDE	Testing	FP manufacturer
2	☐	ABCDE	Testing	API manufacturer
Remove				

NEW

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: *	

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

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:	

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	
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			
<i>Note: Please indicate official contact details</i>			
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: *	sandy_chan@lionview.		
(please ensure that the email address is correct, otherwise you will NOT receive the system notifications)			
9.2.9 Alternative Email:			

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

9.3 Other 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".

NEW

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)

Other Sponsor Contact Details (To Be Filled By Endorser)

9.5.1 Salutation:

9.5.2 Name of Contact Person:

9.5.3 NRIC/FIN:

9.5.4 Designation:

9.5.5 Telephone number: 9.5.6 Fax number:

9.5.7 Mobile Number:

9.5.8 Primary Email:
(please ensure that the email address is correct, otherwise you will NOT receive the system notifications)

9.5.9 Alternative Email:

Click "Save" to add records

SN	☐ Select All	UEN	Company Name	Contact Person
1	☐	04325700C	CHEONG'S CLINIC	Mandy Chan

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

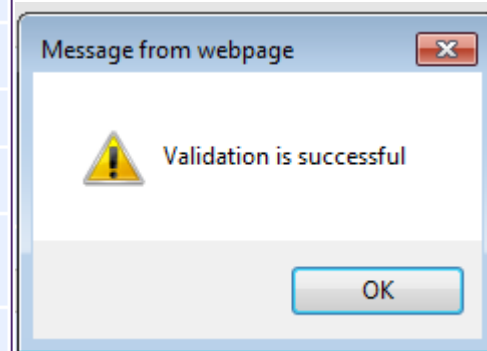
Section 11. Supporting Documents

	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 ☐	



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

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Section 12. Declaration and Confirmation (2 of 2)

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

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

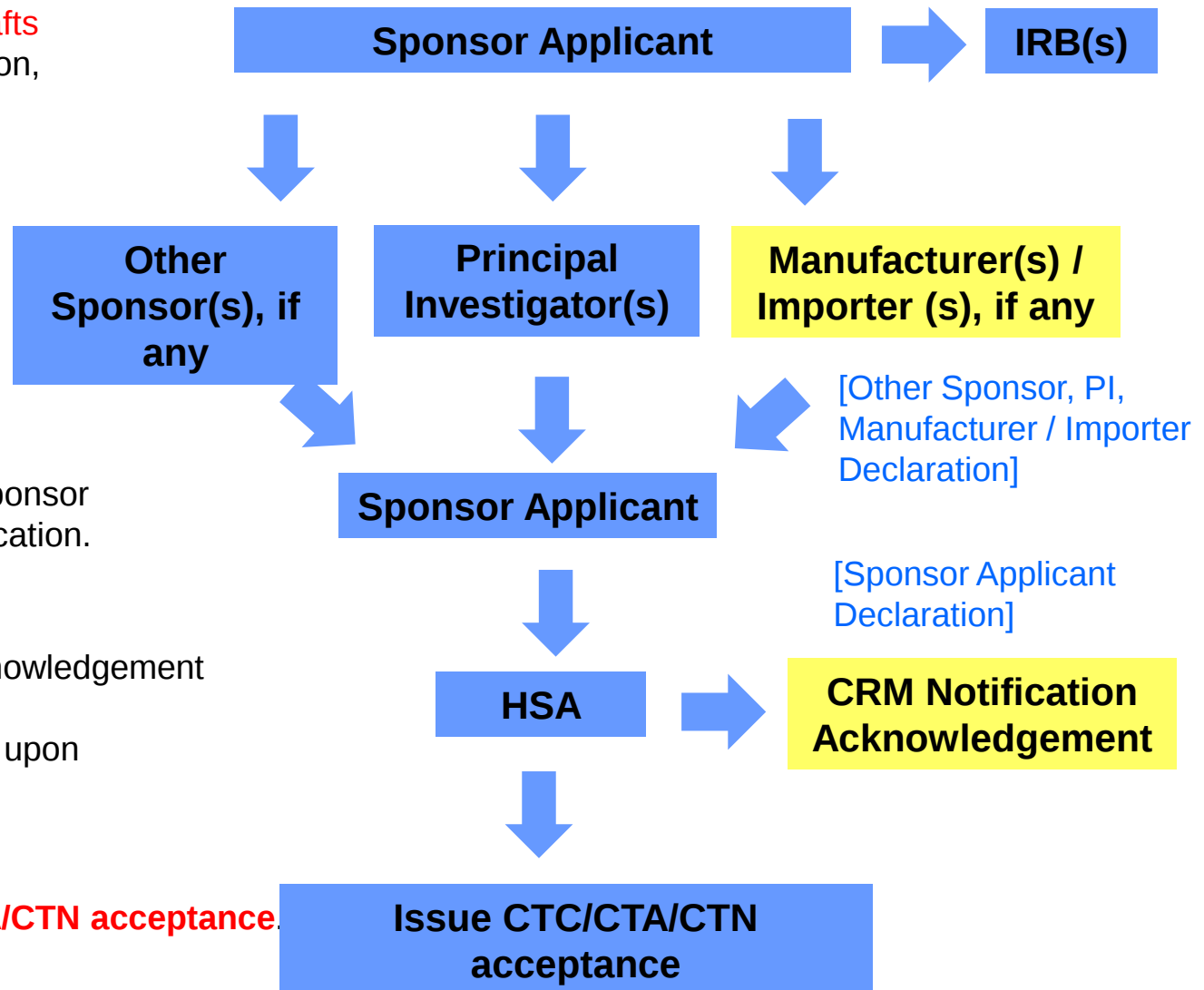
1. Sponsor applicant **drafts** CTC/CTA/CTN application, sends for endorsement.

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 Site 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 complete the submission 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 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 THIS IS A COMPUTER GENERATED LETTER, PLEASE DO NOT REPLY TO THIS EMAIL.	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:	Plprimaryemail@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 Contact Details (To Be Filled By Endorser)		
9.5.1 Salutation:	Mr	
9.5.2 Name of Contact Person:	XXXXXXX	
9.5.3 NRIC/FIN: *		
9.5.4 Designation: *		
9.5.5 Telephone number: *	66666666	9.5.6 Fax number:
9.5.7 Mobile Number:		
9.5.8 Primary Email: * (please ensure that the email address is correct, otherwise you will NOT receive the system notifications)		
9.5.9 Alternative Email:		

NRIC/FIN of Endorser will be auto-populated from his/her login



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.



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 retrieve 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

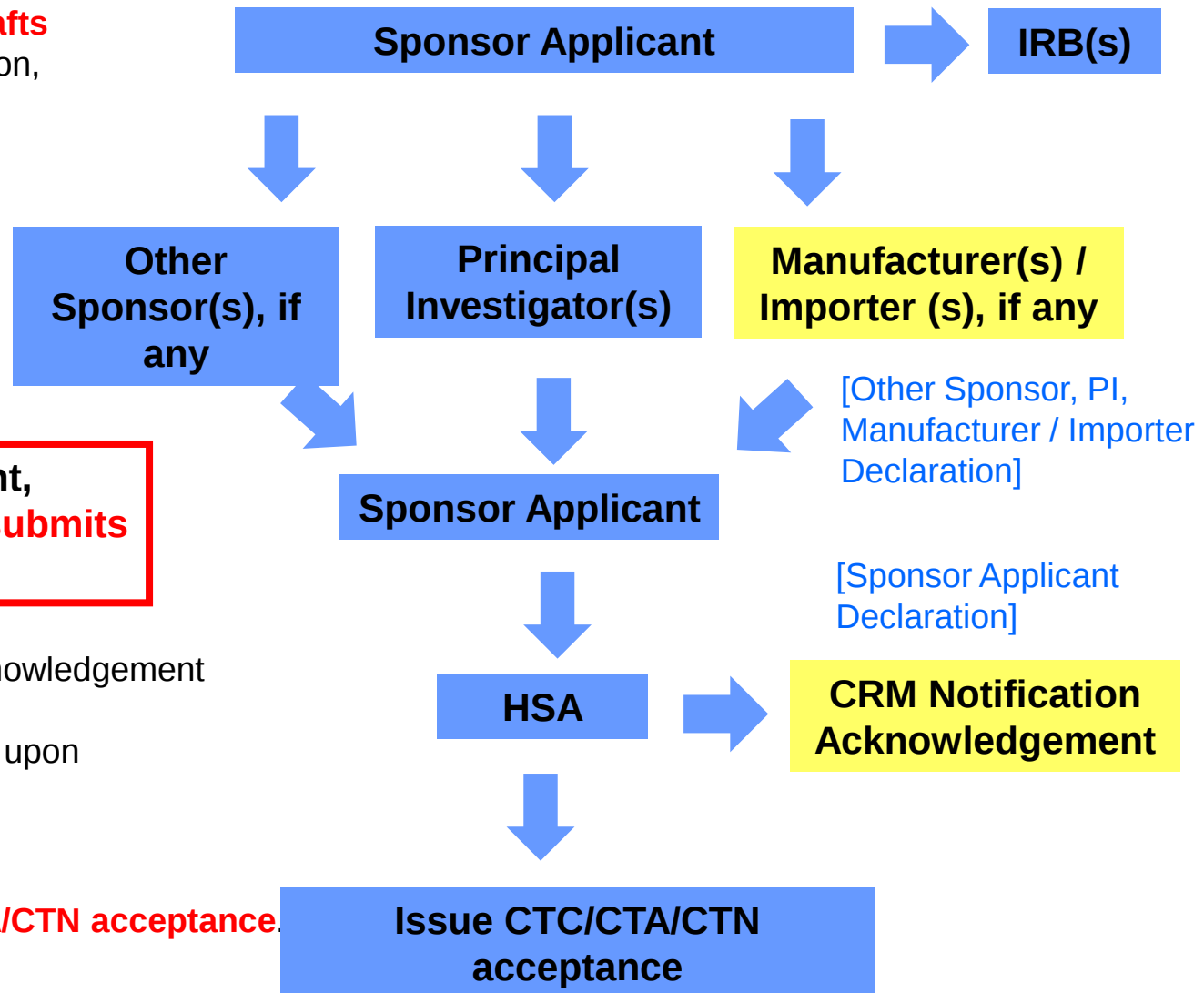
1. Sponsor applicant **drafts** CTC/CTA/CTN application, sends for endorsement.

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 Transaction

Application/Sub

Licence/Permit/
Type *

Enquiry Type *

Transaction No.

Licence/Permit/
No.

Product Name.

Last Update Date

Search

Reset

Please click here

Please do not

1 Matching Record(s)

New Application

S/No

Transa

No

1

Enquire Endorsement Status - Internet Explorer



To be the leading innovative authority protecting and advancing

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

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

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!