



TRAINING SESSION:
ENHANCED PRISM E-SERVICES
AMENDMENT SUBMISSION

OUTLINE

1. Amendment Types
2. Amendment Application Process
3. References

AMENDMENT TYPES

1	Protocol and/or Patient Information Sheet & Informed Consent Form Amendments
1.1	<i>Protocol Amendment</i>
1.2	<i>Patient Information Sheet & Informed Consent Form (PIS/ICF) Amendment</i>
1.3	<i>Both Protocol & PIS/ICF Amendments</i>
2	Change of Principal Investigator /Addition of Trial Site
2.1	<i>Change of PI</i>
2.2	<i>Addition of Trial Site</i>
2.3	<i>Both Change of PI & Addition of Trial Site</i>
3	Add Sponsor (for Multi-Sponsor Investigator Initiated Trials)
4	Change of Manufacturer/CMC information
4.1	Change of Manufacturer
4.2	Change of CMC Information
4.3	Both Change of Manufacturer & CMC Information
5	Update of Investigator Brochure or New Safety Information
6	Change in Clinical Research Material Notification
7	Other Administrative/Trial Register information changes

The screenshot shows the HSA website with the following elements:

- Header:** Singapore Government logo with tagline "Integrity · Service · Excellence". Navigation links: ABOUT HSA | CAREERS | CONTACT INFO | FEEDBACK | SITEMAP | FAQS. Search bar with "Within HSA" dropdown.
- Secondary Navigation:** Health Products Regulation, Blood Services, Applied Sciences, **e-Services** (highlighted), Publications, News & Events.
- Hero Section:** "To be the leading innovative authority" and "Ensuring national health and safety".
- Content Tiles:**
 - Health Products Regulation:** Ensures health products are safe, of good quality and efficacious. Includes links for PRISM, MEDICS, and Bringing personal medication into Singapore.
 - Blood Services:** 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)

eServices>Health Products Regulation>PRISM>Clinical Trials>Amend Licence Section>CorpPass Login





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

CR0010 AUTHORISATION AND AUTHENTICATION MODULE > TERMS AND CONDITIONS

Terms and Conditions of Use

Updated as of 19/01/2005

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

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Select Protocol Number

PT0101 AMENDMENT APPLICATION FOR A CLINICAL TRIAL

Fields marked with an asterisk * are mandatory.

Introduction

Please select Protocol No: *

Select Protocol No → Retrieve application

AMENDMENT APPLICATION FORM

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

Section 0: Amendment Types (1 of 3)

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

Amendment Trial Information	
Title of Clinical Trial:	Randomized, double blind, placebo controlled of ABCDE for solid tumours (NEW TITLE 2)
Protocol Number:	ABCDE-1

Amendment Types	
Please select type of amendment:*	<input checked="" type="checkbox"/> 1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments <input checked="" type="checkbox"/> 2. Change of Principal Investigator /Addition of Trial Site <input checked="" type="checkbox"/> 3. Add Sponsor (for multi-sponsor investigator initiated trials) <input type="checkbox"/> 4. Change of Manufacturer / Chemistry, Manufacturing and Controls (CMC) information <input type="checkbox"/> 5. Update of Investigator Brochure or New Safety Information <input type="checkbox"/> 6. Change in Clinical Research Material Notification <input type="checkbox"/> 7. Other Administrative / Trial Register information changes
NEW	

Multiple amendment types could be selected

Amendment Summary for 1. Protocol & ICF Amendment	
0.1.1 Please select:*	<input type="radio"/> Protocol Amendment <input type="radio"/> Patient Information Sheet& Informed Consent Form (PIS/ICF) Amendment <input type="radio"/> Both Protocol & PIS/ICF Amendments
0.1.2 Rationale for Protocol Amendment:*	<input type="text"/>
0.1.3 Rationale for ICF Amendment:*	<input type="text"/>
0.1.4 IRB Approval:*	<input type="radio"/> Yes <input type="radio"/> Pending

Section 0: Amendment Types (2 of 3)

Amendment Summary for 2. If Change of PI/Add Site	
0.2.1 Please select:*	<input type="radio"/> Change of PI <input checked="" type="radio"/> Addition of Trial Site <input type="radio"/> Both Change of PI & Addition of Trial Site
0.2.2 Reason for Change of Principal Investigator:*	<div style="background-color: #cccccc; height: 40px; border: 1px solid #ccc;"></div> <div style="text-align: right; border-left: 1px solid #ccc; border-right: 1px solid #ccc;">^ v</div>
0.2.3 IRB Approval:*	<input type="radio"/> Yes <input checked="" type="radio"/> Pending

Amendment Summary for 4. If Change of manufacturer/CMC info	
0.4.1 Please select:*	<input type="radio"/> Change of Manufacturer <input type="radio"/> Change of CMC Information <input type="radio"/> Both Change of Manufacturer & CMC Information
0.4.2 Reason for Change of Manufacturer:*	<div style="background-color: #cccccc; height: 40px; border: 1px solid #ccc;"></div> <div style="text-align: right; border-left: 1px solid #ccc; border-right: 1px solid #ccc;">^ v</div>
0.4.3 Description for CMC Amendment:*	<div style="background-color: #cccccc; height: 40px; border: 1px solid #ccc;"></div> <div style="text-align: right; border-left: 1px solid #ccc; border-right: 1px solid #ccc;">^ v</div>

Section 0: Amendment Types (3 of 3)

Amendment Summary for 5. If IB update or new safety info

0.5.1 Is an updated Investigator Brochure being submitted:*

Yes NO

Amendment Summary for 6. If Change of Clinical Research Material (CRM) Notification Information

0.6.1 Reason for Change of Clinical Research Material (CRM) Notification Information:*

Amendment Summary for 7. If other Admin/CT Register changes

0.7.1 Summary of Changes:*

Amendment Summary: Supplementary info

0.8.1 Please provide supplementary information, if necessary:

UAT test

Next

Click “Next”, view CT application form (Section 1-12) and edit relevant section(s) accordingly.

Supporting Documents for Amendments

Type of amendments	Supporting documents
Amendment to Protocol	<ul style="list-style-type: none"> • Clinical Trial Protocol Amendment • Summary of Protocol Amendment • IRB Approval Letter [Mandatory for CTN]
Amendment to Informed Consent Form	<ul style="list-style-type: none"> • Revised Informed Consent Form • Track Change Version for Informed Consent Form • IRB Approval Letter [Mandatory for CTN]
Change of Principal Investigator	<ul style="list-style-type: none"> • Curriculum Vitae of Principal Investigator • Informed Consent Form, if revised • IRB Approval Letter [Mandatory for CTN]
Addition of Trial Site	<ul style="list-style-type: none"> • Curriculum Vitae of Principal Investigator • Informed Consent Form (for new trial site) • IRB Approval Letter [Mandatory for CTN]
Change of Manufacturer	<ul style="list-style-type: none"> • For change/ addition of a manufacturer not licensed/ certified by HSA, <ul style="list-style-type: none"> ○ Good Manufacturing Practice (GMP) certificate; or ○ Where the GMP certificate is not available, a declaration by the manufacturer of its compliance with cGMP, and the Certificate of Analysis of the product manufactured by the new manufacturer
Change of Chemistry, Manufacturing, Controls (CMC) Information [if CMC had been submitted in the initial clinical trial application]	<ul style="list-style-type: none"> • Supporting CMC information, where relevant

AMENDMENT APPLICATION PROCESS

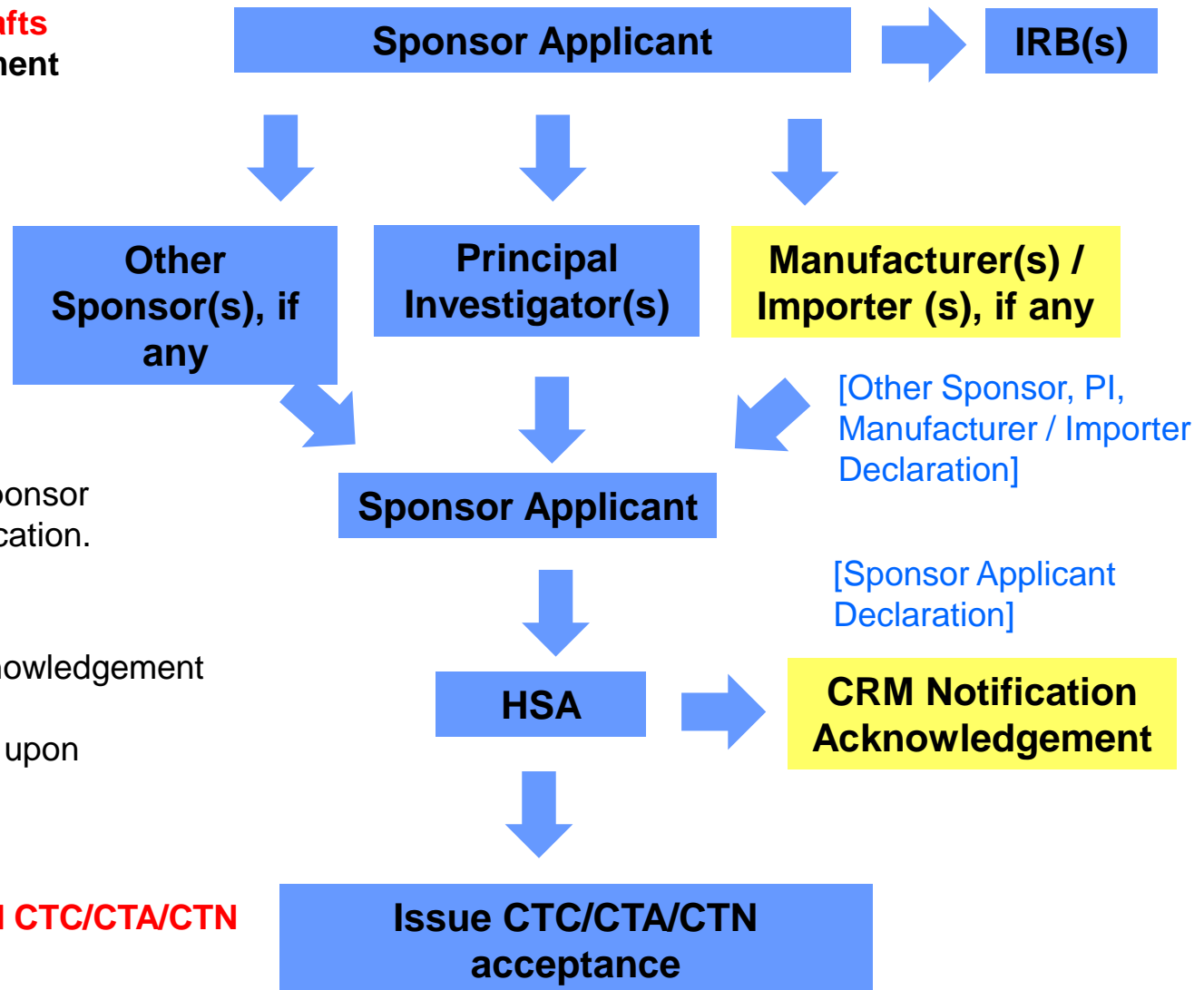
1. Sponsor applicant **drafts** CTC/CTA/CTN **amendment application**, sends for endorsement.

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 **amended CTC/CTA/CTN acceptance**.



Scenario 1: Addition of trial site(s)

Step 1: Amendment types: Select option 2)

Amendment Types	
Please select type of amendment:*	<input type="checkbox"/> 1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments <input checked="" type="checkbox"/> 2. Change of Principal Investigator /Addition of Trial Site <input type="checkbox"/> 3. Add Sponsor (for multi-sponsor investigator initiated trials) <input type="checkbox"/> 4. Change of Manufacturer / Chemistry, Manufacturing and Controls (CMC) information <input type="checkbox"/> 5. Update of Investigator Brochure or New Safety Information <input type="checkbox"/> 6. Change in Clinical Research Material Notification <input type="checkbox"/> 7. Other Administrative / Trial Register information changes

Step 2: Edit relevant amendment summary sections

Step 3: Edit relevant application form sections [For scenario 1, Section 2 (Trial Information, **Section 2.36**), Section 8 (Local Trial Sites, PI, IRB), Section 11 (Supporting Documents)]

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

NOTE:

To add a new trial site record in this Section, please go to Section 2.36 Number of Trial Site(s) in Singapore, to first update the number of trial sites. The number of trial sites indicated in Section 2.36 must match the number of trial site records in Section 8

Scenario 2: Adding participating site sponsor(s) [For multi-sponsor IITs]

Step 1: Amendment types: Select option 2) and 3)

Amendment Types	
Please select type of amendment:*	<input type="checkbox"/> 1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments <input checked="" type="checkbox"/> 2. Change of Principal Investigator /Addition of Trial Site <input checked="" type="checkbox"/> 3. Add Sponsor (for multi-sponsor investigator initiated trials) <input type="checkbox"/> 4. Change of Manufacturer / Chemistry, Manufacturing and Controls (CMC) information <input type="checkbox"/> 5. Update of Investigator Brochure or New Safety Information <input type="checkbox"/> 6. Change in Clinical Research Material Notification <input type="checkbox"/> 7. Other Administrative / Trial Register information changes

Step 2: Edit relevant amendment summary sections

Step 3: Edit relevant application form sections [For scenario 2, Section 2 (Trial Information), Section 8(Local Trial Sites, PI and IRB), Section 9 (Local Sponsors), Section 11 (Supporting documents, where relevant)]

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

Scenario 3: Change of study design by adding a new investigational arm

Step 1: Amendment types: Select option 1), 4) and 6) [if applicable]

Amendment Types	
Please select type of amendment:*	<input checked="" type="checkbox"/> 1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments <input type="checkbox"/> 2. Change of Principal Investigator /Addition of Trial Site <input type="checkbox"/> 3. Add Sponsor (for multi-sponsor investigator initiated trials) <input checked="" type="checkbox"/> 4. Change of Manufacturer / Chemistry, Manufacturing and Controls (CMC) information <input type="checkbox"/> 5. Update of Investigator Brochure or New Safety Information <input checked="" type="checkbox"/> 6. Change in Clinical Research Material Notification <input type="checkbox"/> 7. Other Administrative / Trial Register information changes

Step 2: Edit relevant amendment summary sections

Step 3: Edit relevant application form sections [For scenario 3, Section 2 (Trial Information), Section 3 and/or 4 (Investigational TP/ MP), Section 5 (Manufacturer Particulars), Section 10 (CRM-N, if applicable), Section 11 (Supporting documents, where relevant)]

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

CT AMENDMENT APPLICATION

Note:

- Concurrent drafts of the same study are not allowed.
- When there is a pending amendment application for approval, different but not the same amendment type could be drafted and submitted. [For e.g., a second protocol amendment application could not be submitted until the prior submitted protocol amendment application is approved.]

REFERENCES

- I. Health Products (Clinical Trials) Regulations
- II. Medicines (Clinical Trials) Regulations
- III. Guidance on regulatory requirements for new applications and subsequent submissions [GN-CTB-2-003A-001]
- IV. Guidance on determining whether an amendment to a clinical trial is a substantial amendment [GN-CTN-2-003B-001]

We welcome your queries!

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THANK YOU!