TRAINING SESSION:

ENHANCED PRISM E-SERVICES

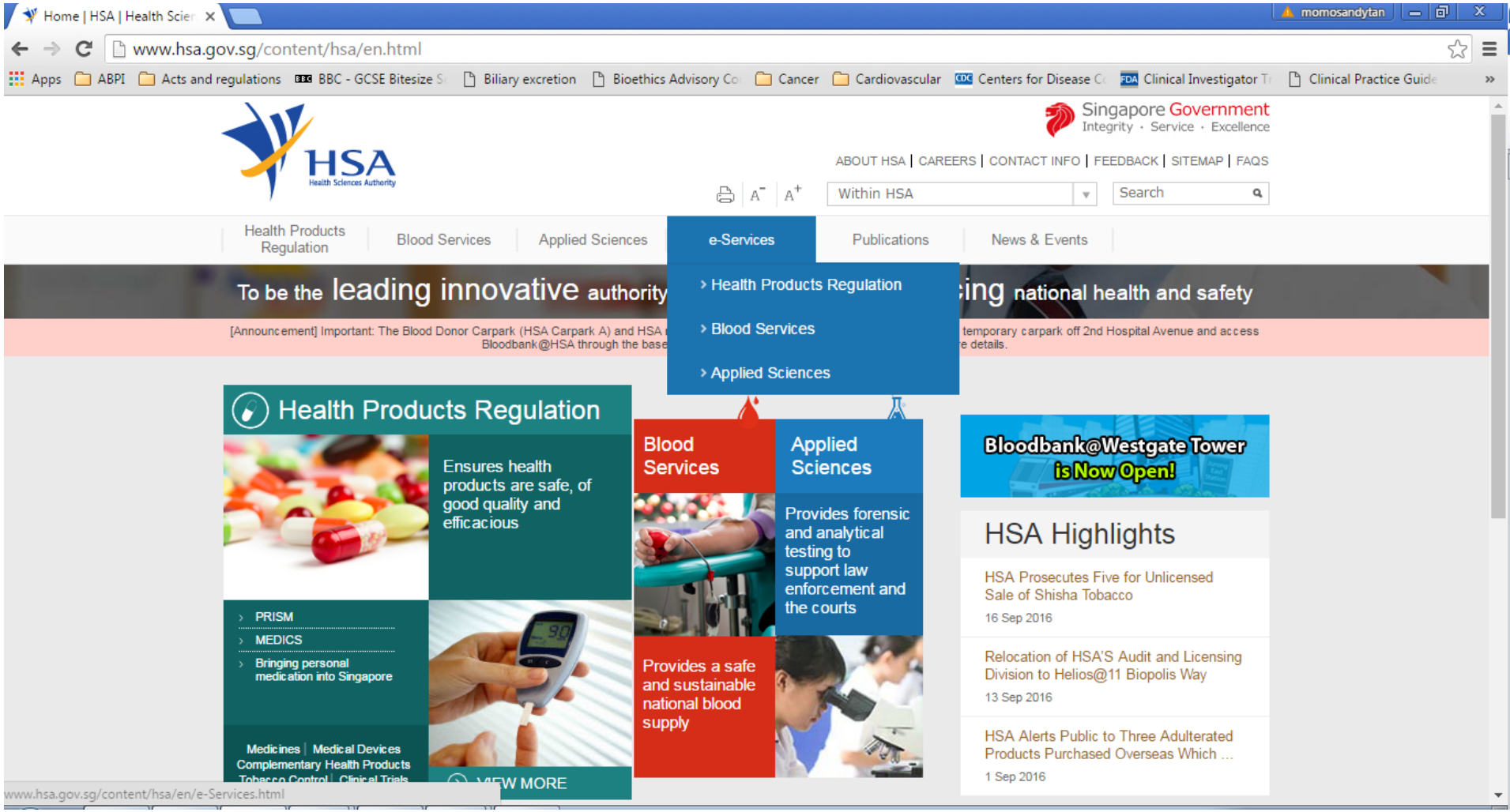
AMENDMENT SUBMISSION

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	*Protocol Amendment*
1.2	*Patient Information Sheet& Informed Consent Form (PIS/ICF) Amendment*
1.3	*Both Protocol & PIS/ICF Amendments*
2	**Change of Principal Investigator /Addition of Trial Site**
2.1	*Change of PI*
2.2	*Addition of Trial Site*
2.3	*Both Change of PI & Addition of Trial Site*
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**



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

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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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Select Protocol Number

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
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

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:*

NEW

- [x] 1. Protocol and/or Patient Information Sheet & Informed Consent Form Amendments
- [x] 2. Change of Principal Investigator /Addition of Trial Site
- [x] 3. Add Sponsor (for multi-sponsor investigator initiated trials)
- [ ] 4. Change of Manufacturer / Chemistry, Manufacturing and Controls (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

Multiple amendment types could be selected

Amendment Summary for 1. Protocol & ICF Amendment

0.1.1 Please select:*	○ Protocol Amendment ○ Patient Information Sheet& Informed Consent Form (PIS/ICF) Amendment ○ Both Protocol & PIS/ICF Amendments
0.1.2 Rationale for Protocol Amendment:*	
0.1.3 Rationale for ICF Amendment:*	
0.1.4 IRB Approval:*	○ Yes ○ Pending

Section 0: Amendment Types (2 of 3)

Amendment Summary for 2. If Change of PI/Add Site	
0.2.1 Please select:*	○ Change of PI ◉ Addition of Trial Site ○ Both Change of PI & Addition of Trial Site
0.2.2 Reason for Change of Principal Investigator:*	
0.2.3 IRB Approval:*	○ Yes ◉ Pending

Amendment Summary for 4. If Change of manufacturer/CMC info	
0.4.1 Please select:*	○ Change of Manufacturer ○ Change of CMC Information ○ Both Change of Manufacturer & CMC Information
0.4.2 Reason for Change of Manufacturer:*	
0.4.3 Description for CMC Amendment:*	

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	• Clinical Trial Protocol Amendment • Summary of Protocol Amendment • IRB Approval Letter [Mandatory for CTN]
Amendment to Informed Consent Form	• Revised Informed Consent Form • Track Change Version for Informed Consent Form • IRB Approval Letter [Mandatory for CTN]
Change of Principal Investigator	• Curriculum Vitae of Principal Investigator • Informed Consent Form, if revised • IRB Approval Letter [Mandatory for CTN]
Addition of Trial Site	• Curriculum Vitae of Principal Investigator • Informed Consent Form (for new trial site) • IRB Approval Letter [Mandatory for CTN]
Change of Manufacturer	• For change/ addition of a manufacturer not licensed/ certified by HSA, ○ 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]	• Supporting CMC information, where relevant

AMENDMENT APPLICATION PROCESS

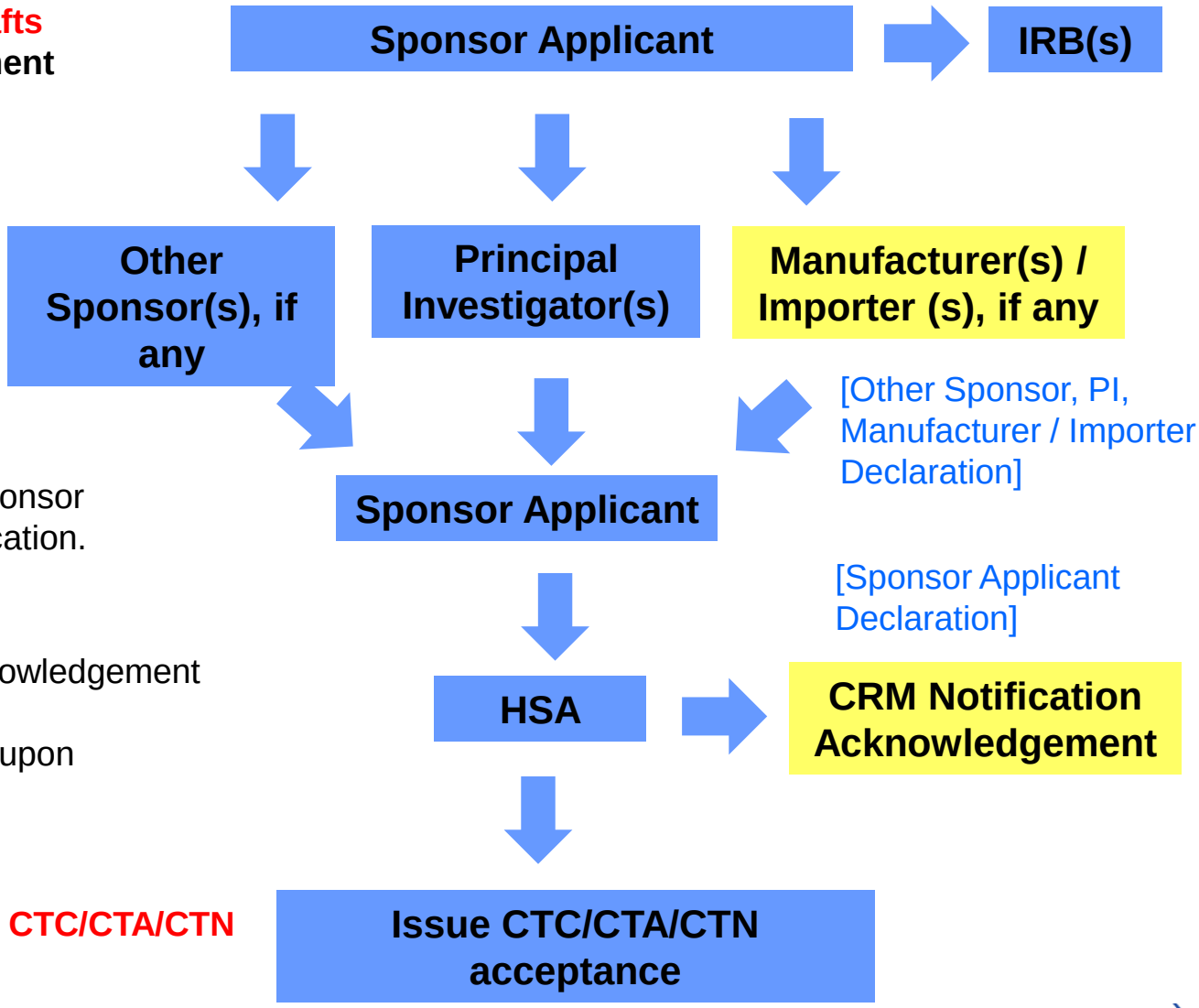
1. Sponsor applicant **drafts** CTC/CTA/CTN **amendment application**, sends for endorsement.

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

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

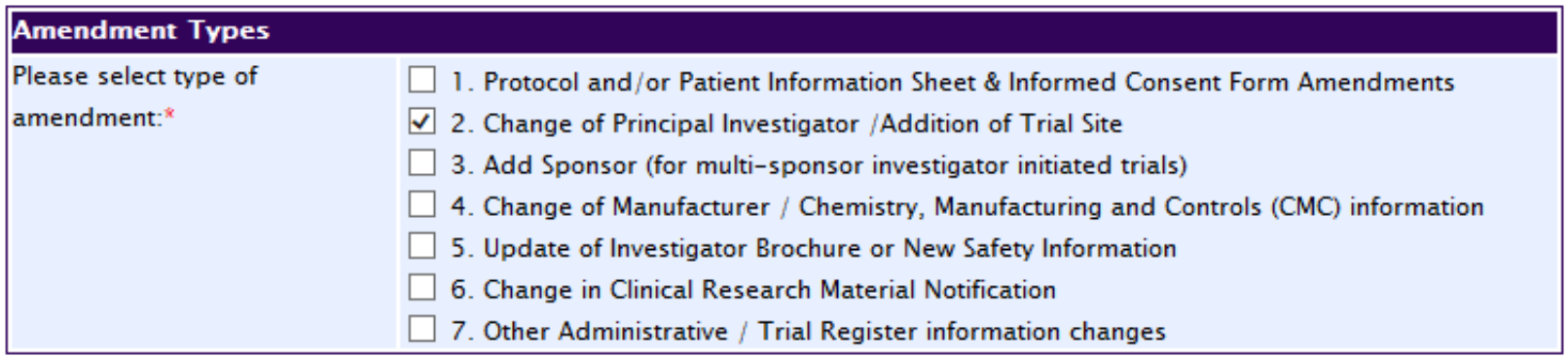
4. CRM notification acknowledgement sent to manufacturer(s)/ importer(s) and sponsor upon application submission.

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



Scenario 1: Addition of trial site(s)

Step 1: Amendment types: Select option 2)



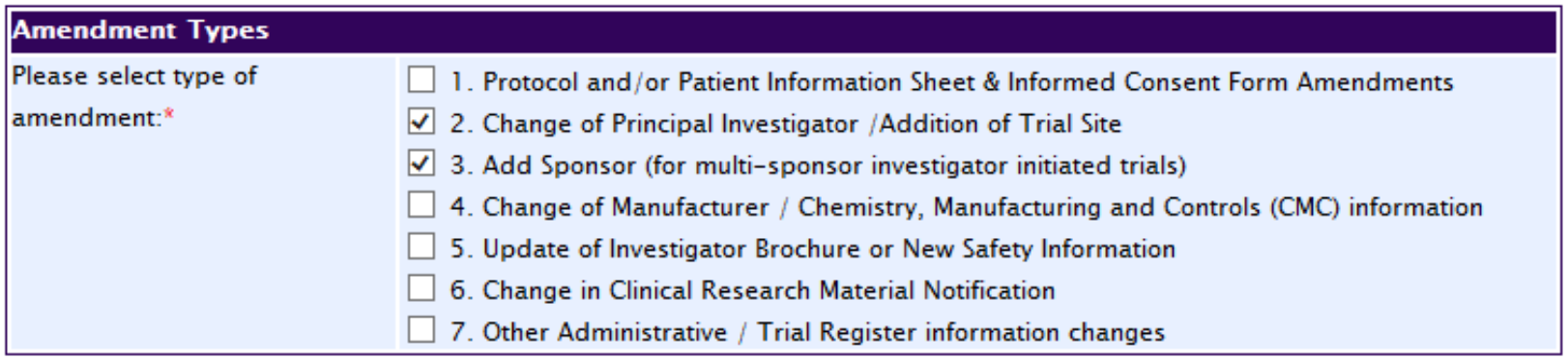
Step 2: Edit relevant amendment summary sections

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)]

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)

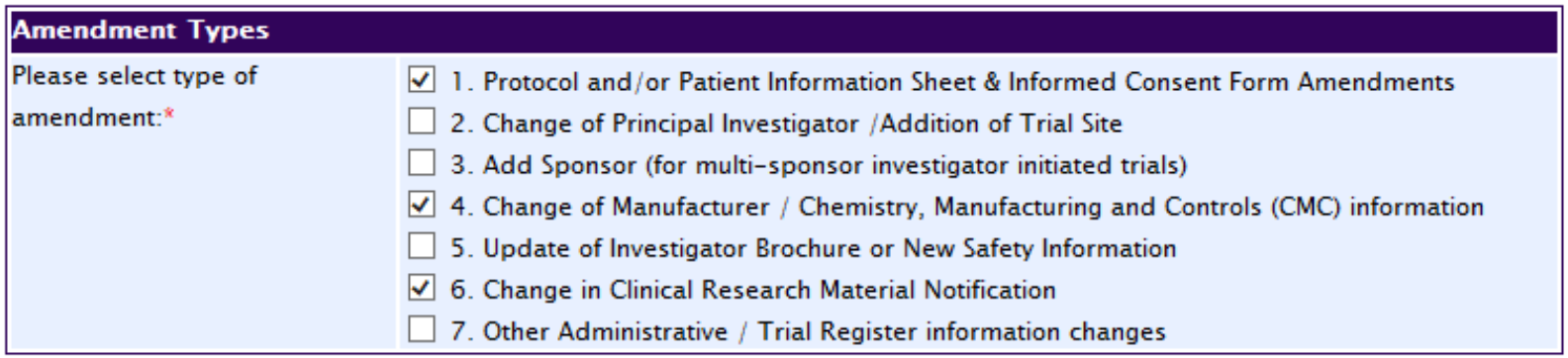


Step 2: Edit relevant amendment summary sections

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)]

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

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



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)]

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!

HSA_CT@hsa.gov.sg

THANK YOU!