New Application

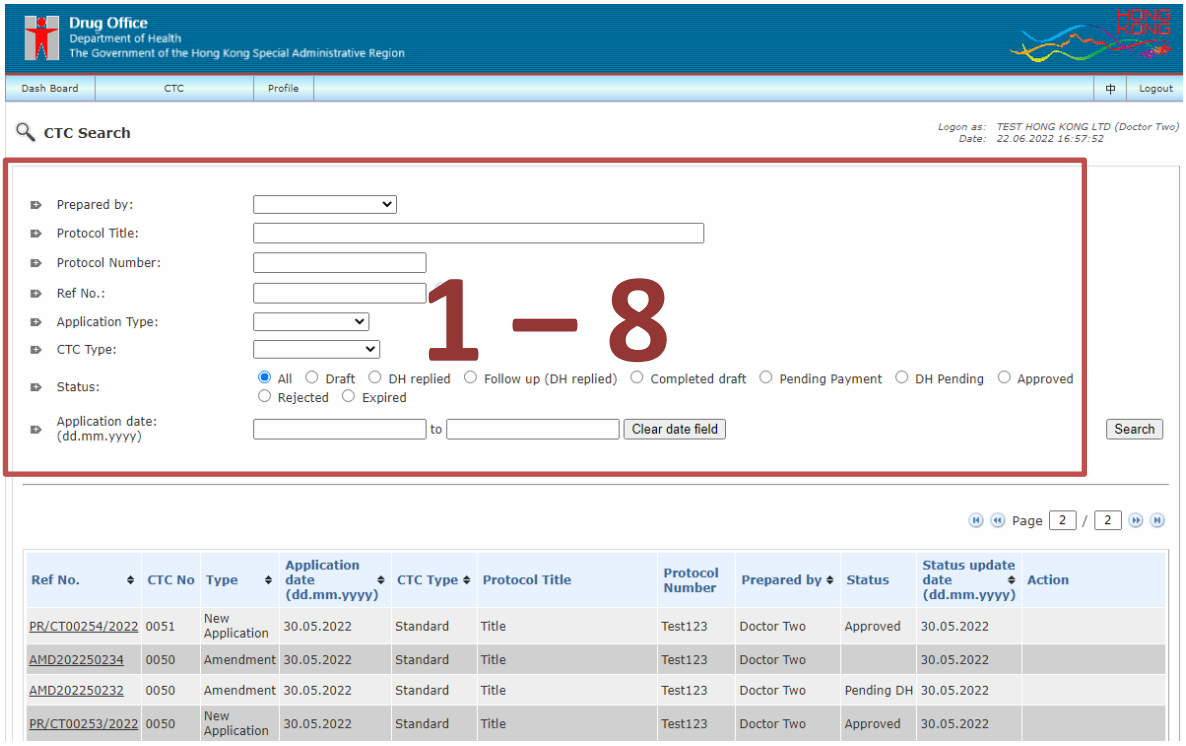
3. New Application

I. Certificate Application

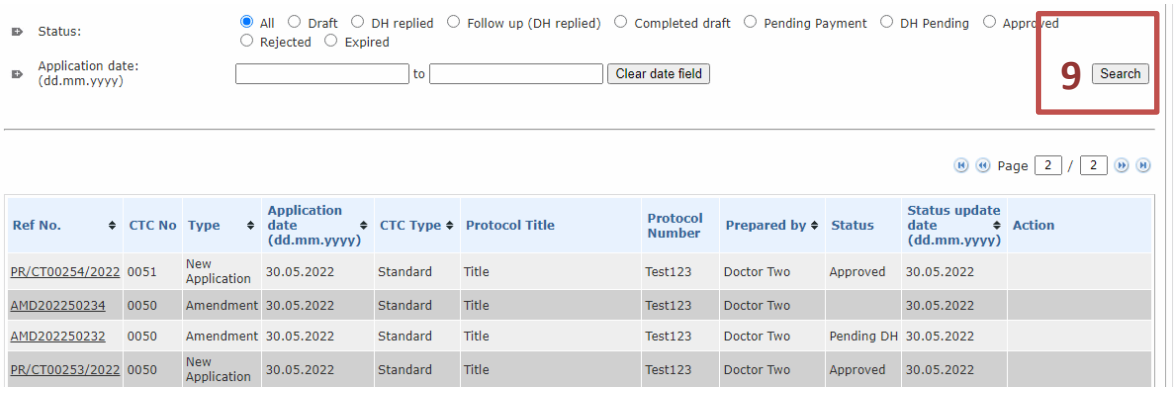
i. Certificate Search

In order to search specific record, user can select menu ”CTC” → “CTC Search” or redirect from Dash Board and then:

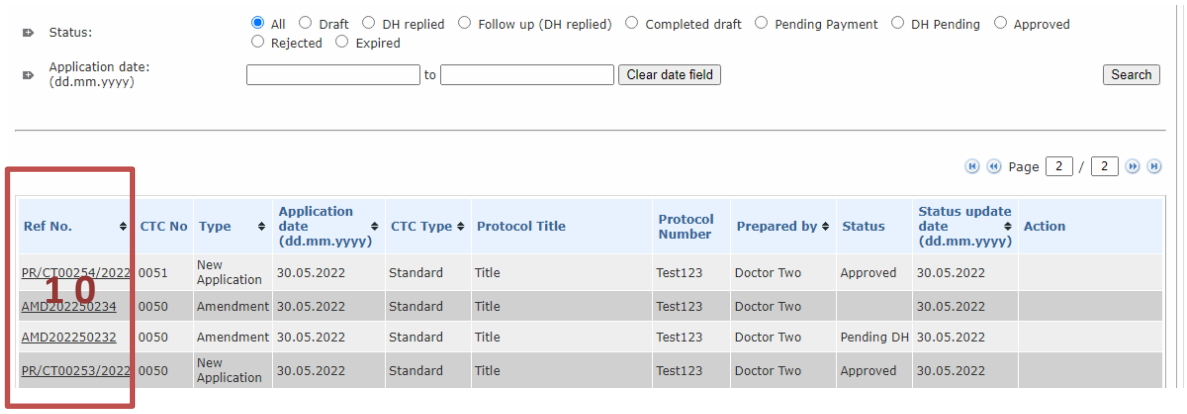
1. Select Prepared by and/or
2. Input Protocol Title and/or
3. Input Protocol Number and/or
4. Input Ref No. (support partial match) and/or
5. Select Application Type and/or
6. Select CTC Type and/or
7. Select Status and/or
8. Select Application date range



9. Click “Search” button, result will be displayed in the result table



10. Click link on related Ref No. to view / edit the certificate application

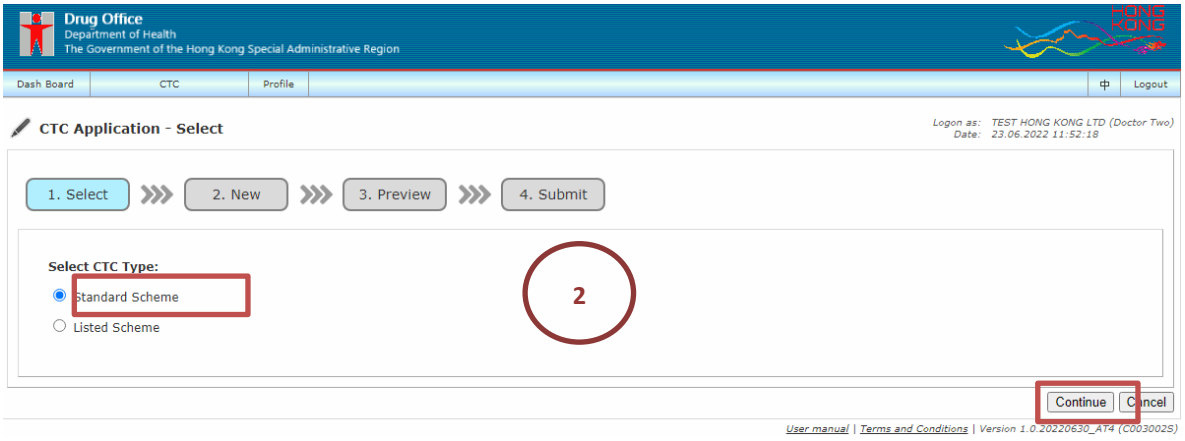


Ref No.	CTC No	Type	Application date (dd.mm.yyyy)	CTC Type	Protocol Title	Protocol Number	Prepared by	Status	Status update date (dd.mm.yyyy)	Action
PR/CT00254/2022	0051	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	
AMD202250234	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two		30.05.2022	
AMD202250232	0050	Amendment	30.05.2022	Standard	Title	Test123	Doctor Two	Pending DH	30.05.2022	
PR/CT00253/2022	0050	New Application	30.05.2022	Standard	Title	Test123	Doctor Two	Approved	30.05.2022	

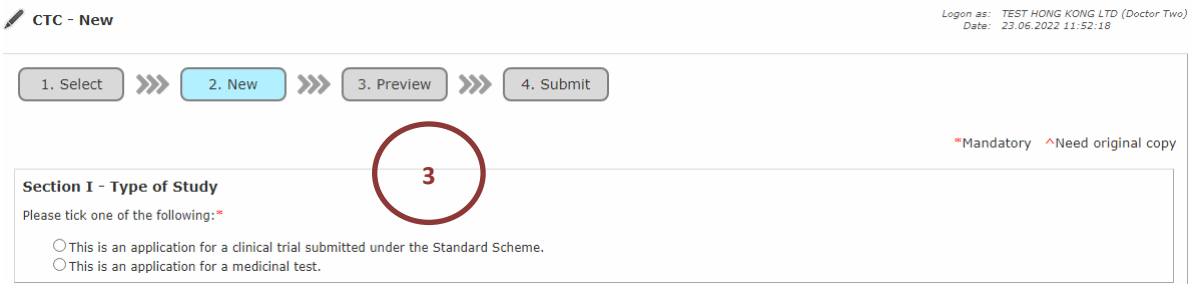
ii. Create, Preview and Submit New Application

A. Standard Scheme

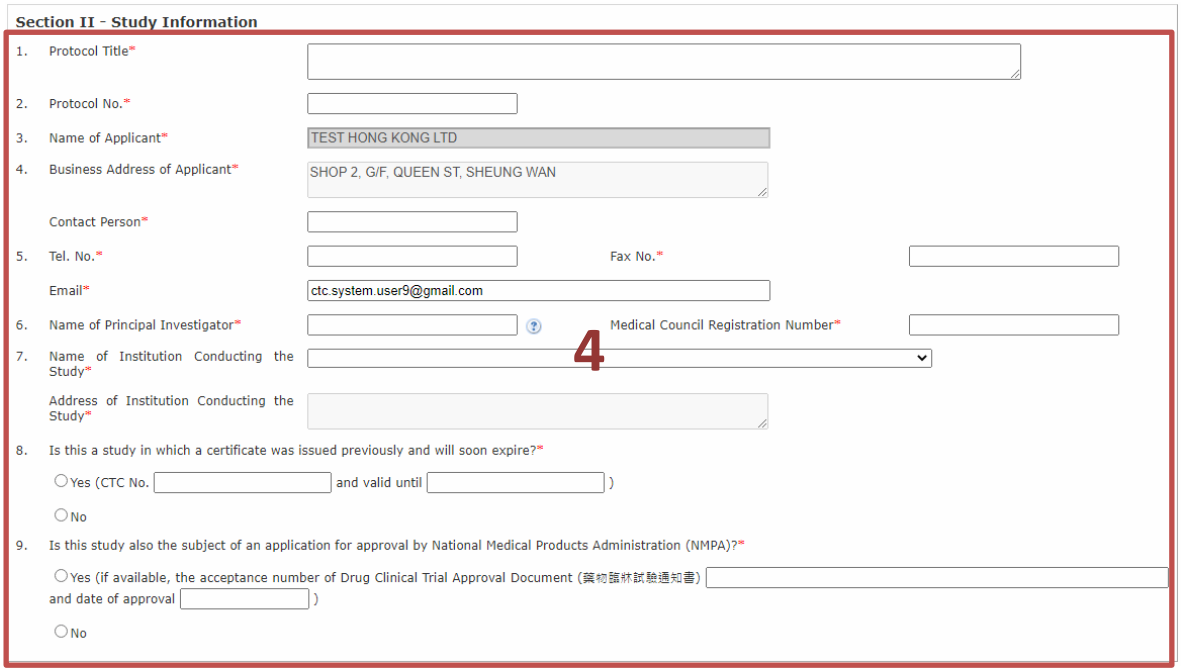
1. Go to menu "CTC" → "CTC Application"
2. Select "Standard Scheme" as the CTC Type and click "Continue"



3. Select the type of study in Section I of the application form



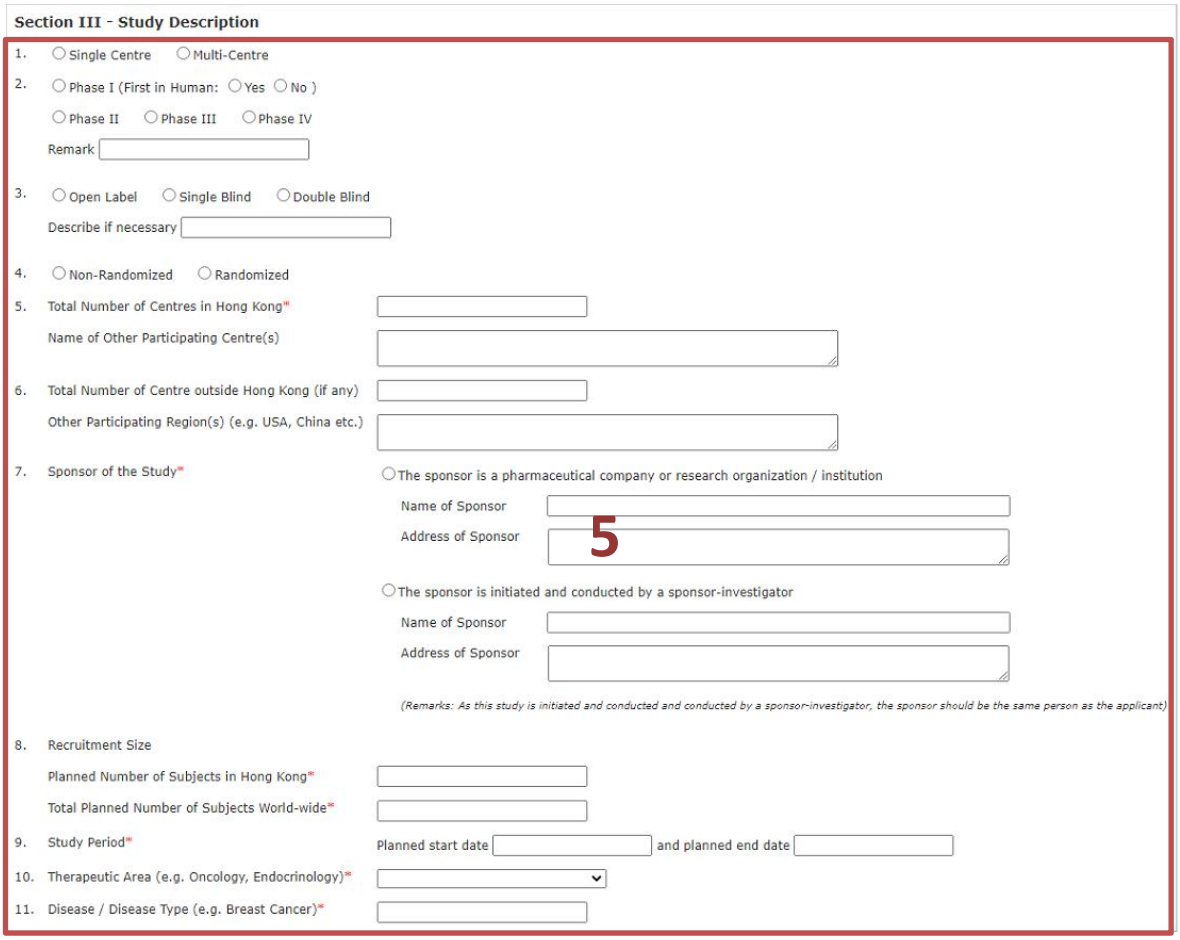
4. Fill-in Section II of the application form



Remarks:

- Name of Applicant and Business Address of Applicant will be filled-in automatically by the system and cannot be revised
- Address of Institution Conducting the Study will be filled-in automatically after selecting the Name of Institution Conducting the Study

5. Fill-in Section III of the application form

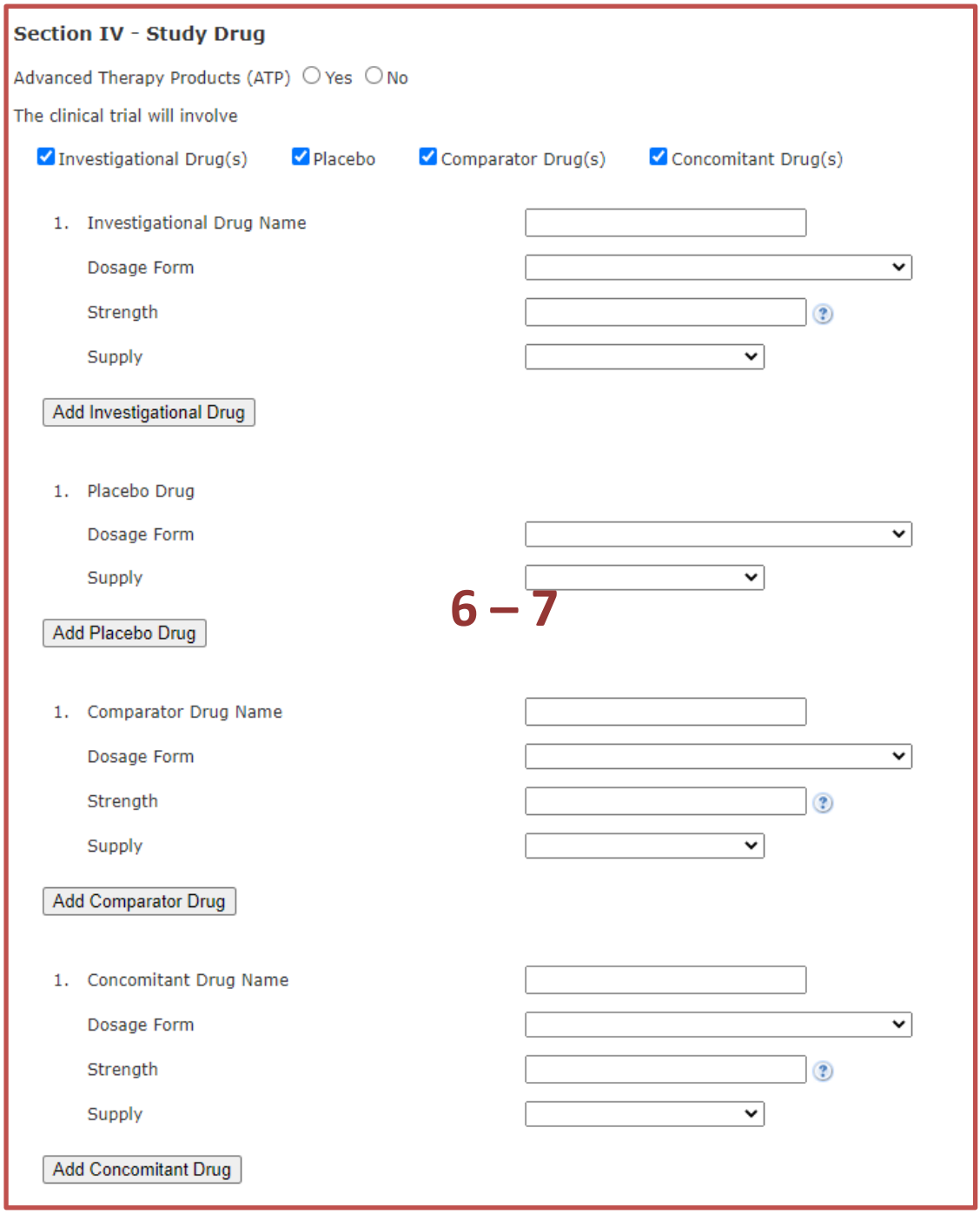


Section III - Study Description

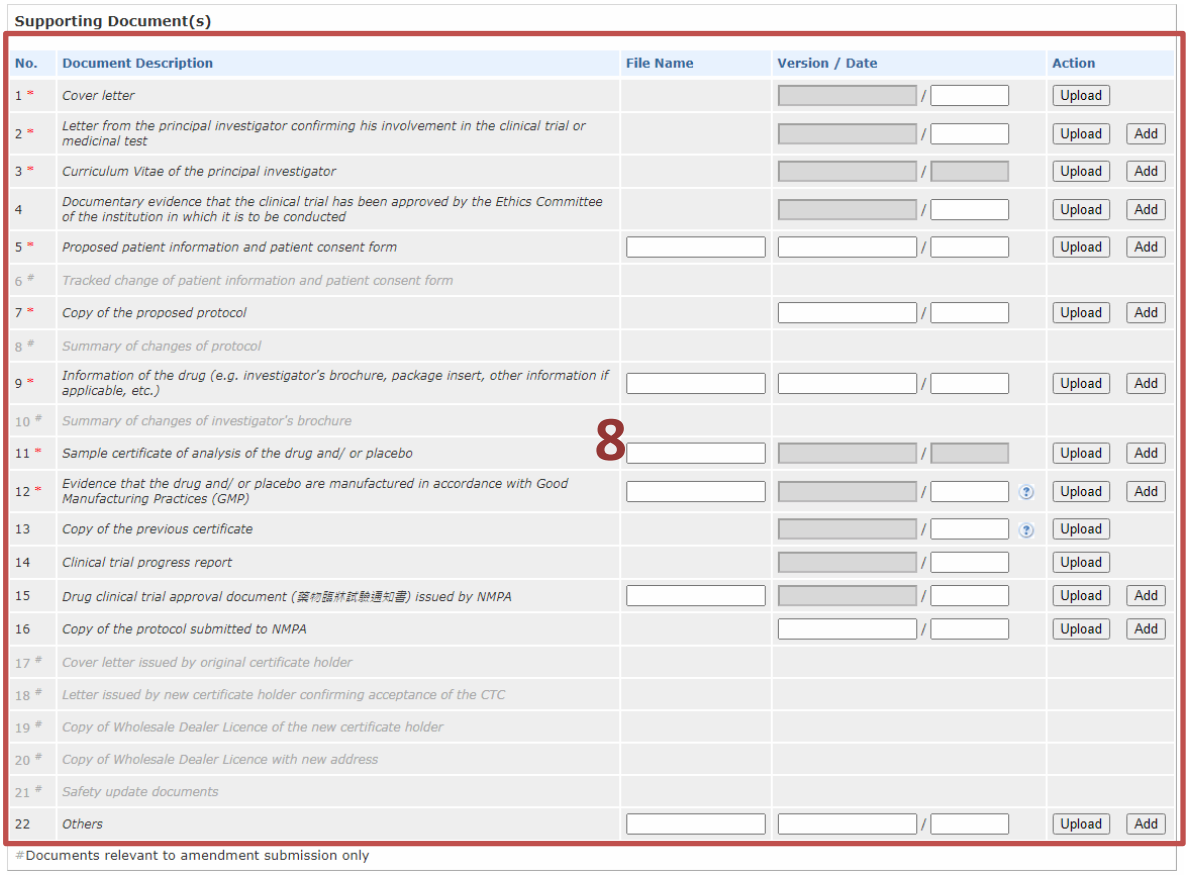
1. ○ Single Centre ○ Multi-Centre
2. ○ Phase I (First in Human: ○ Yes ○ No)
   ○ Phase II ○ Phase III ○ Phase IV
   Remark
3. ○ Open Label ○ Single Blind ○ Double Blind
   Describe if necessary
4. ○ Non-Randomized ○ Randomized
5. Total Number of Centres in Hong Kong*
   Name of Other Participating Centre(s)
6. Total Number of Centre outside Hong Kong (if any)
   Other Participating Region(s) (e.g. USA, China etc.)
7. Sponsor of the Study*
   ○ The sponsor is a pharmaceutical company or research organization / institution
   Name of Sponsor
   Address of Sponsor
   ○ The sponsor is initiated and conducted by a sponsor-investigator
   Name of Sponsor
   Address of Sponsor
   (Remarks: As this study is initiated and conducted and conducted by a sponsor-investigator, the sponsor should be the same person as the applicant)
8. Recruitment Size
   Planned Number of Subjects in Hong Kong*
   Total Planned Number of Subjects World-wide*
9. Study Period* Planned start date and planned end date
10. Therapeutic Area (e.g. Oncology, Endocrinology)*
11. Disease / Disease Type (e.g. Breast Cancer)*

6. Fill-in Section IV of the application form, select if Advanced Therapy Products (ATP) is/are involved in the study

7. Select applicable type of study drug(s) and fill-in the drug name, dosage form, strength and source of supply as applicable (Note: Please only provide name and address of final product manufacturer(s))



8. Upload related Supporting Document(s), fill-in File Name, Version and Date (Multiple upload is supported if needed)

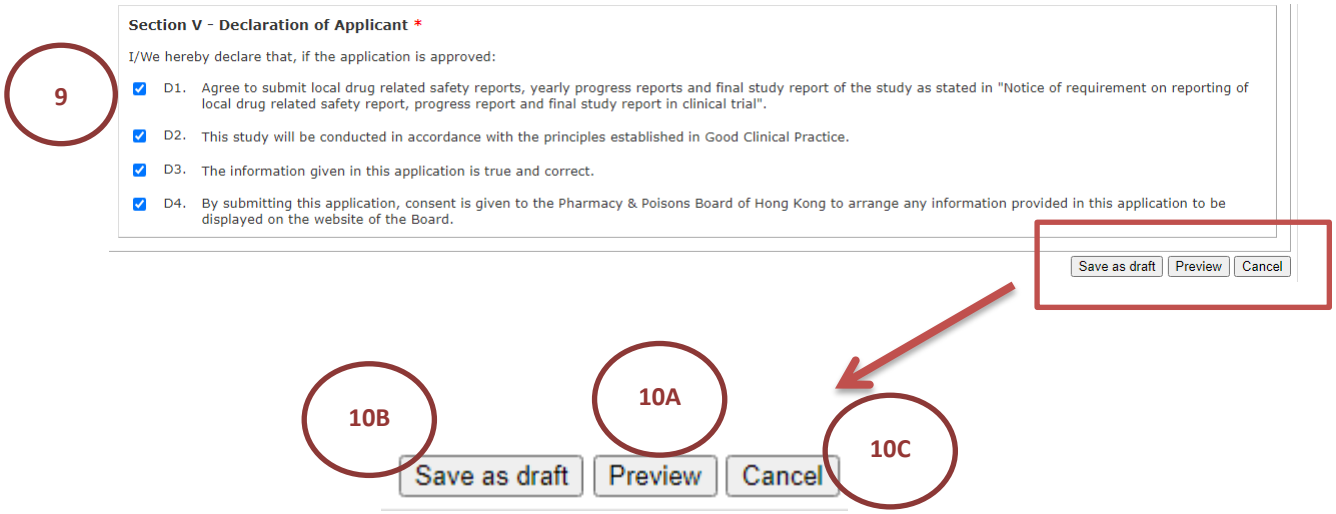


Supporting Document(s)

No.	Document Description	File Name	Version / Date	Action
1 *	*Cover letter*		/	Upload
2 *	*Letter from the principal investigator confirming his involvement in the clinical trial or medicinal test*		/	Upload Add
3 *	*Curriculum Vitae of the principal investigator*		/	Upload Add
4	*Documentary evidence that the clinical trial has been approved by the Ethics Committee of the institution in which it is to be conducted*		/	Upload Add
5 *	*Proposed patient information and patient consent form*		/	Upload Add
6 #	*Tracked change of patient information and patient consent form*			
7 *	*Copy of the proposed protocol*		/	Upload Add
8 #	*Summary of changes of protocol*			
9 *	*Information of the drug (e.g. investigator's brochure, package insert, other information if applicable, etc.)*		/	Upload Add
10 #	*Summary of changes of investigator's brochure*			
11 *	*Sample certificate of analysis of the drug and/ or placebo*		/	Upload Add
12 *	*Evidence that the drug and/ or placebo are manufactured in accordance with Good Manufacturing Practices (GMP)*		/	Upload Add
13	*Copy of the previous certificate*		/	Upload
14	*Clinical trial progress report*		/	Upload
15	*Drug clinical trial approval document (藥物臨床試驗通知書) issued by NMPA*		/	Upload Add
16	*Copy of the protocol submitted to NMPA*		/	Upload Add
17 #	*Cover letter issued by original certificate holder*			
18 #	*Letter issued by new certificate holder confirming acceptance of the CTC*			
19 #	*Copy of Wholesale Dealer Licence of the new certificate holder*			
20 #	*Copy of Wholesale Dealer Licence with new address*			
21 #	*Safety update documents*			
22	*Others*		/	Upload Add

#Documents relevant to amendment submission only

9. Put a tick in the declaration boxes

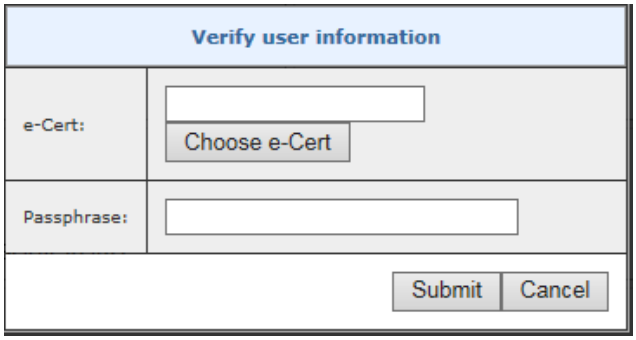


10. A) After all information is filled, user can click "Preview" button to view the filled details in the Preview page.

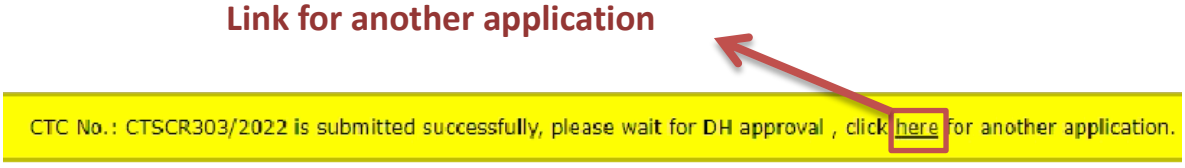
i) Click "Back" button to re-edit the form or

ii) Click "Submit" button to submit the new application to DHDO

- Click "Choose E-cert" button,
- Select the corresponding E-cert,
- Input the corresponding Passphrase of the login user account and
- Click "Submit" button to submit the new application to DHDO



- The successful message of the application will be shown.



B) Or click “Save as draft” button for future editing.

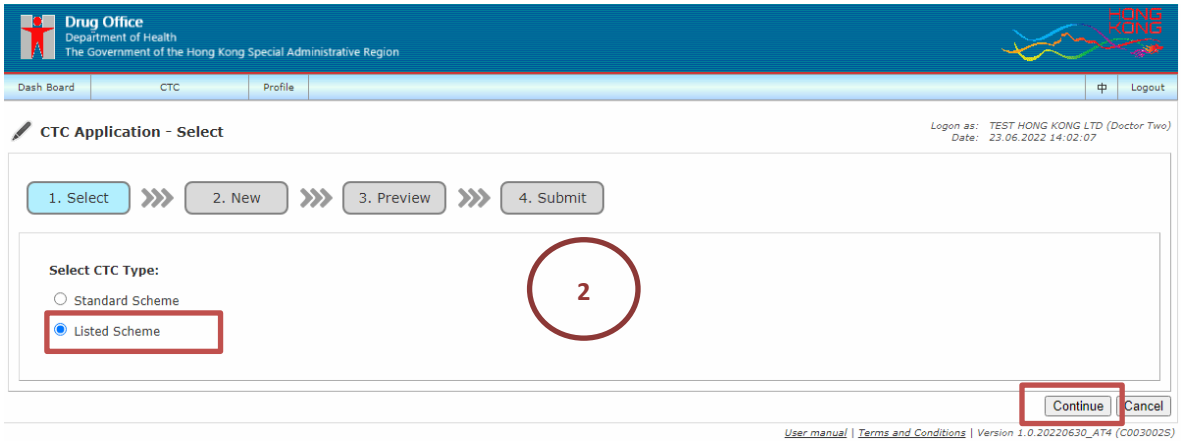
- The successful message will be shown.

Saved as draft. (Ref No.: TS03975)

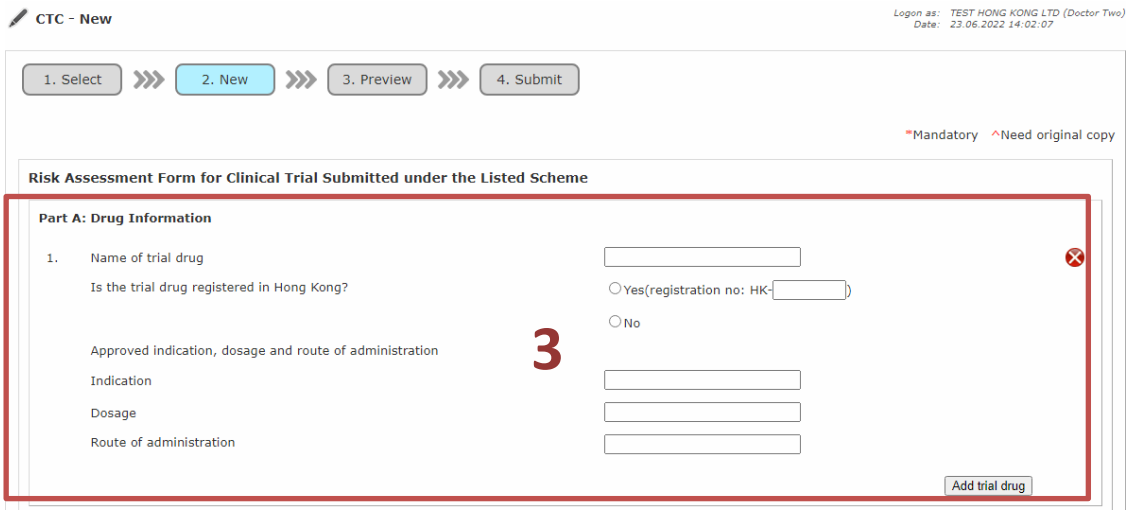
C) Or click “Cancel” button to leave the form and back to search page.

B. Listed Scheme

1. Go to menu “CTC” → “CTC Application”
2. Select “Listed Scheme” as the CTC Type and click “Continue”



3. Fill-in Part A of the Risk Assessment Form



Remarks: Applicant can add trial drug(s) if needed.

4. Fill-in Part B of the Risk Assessment Form

Part B: Trial Information

1. Protocol no.*

Protocol title*

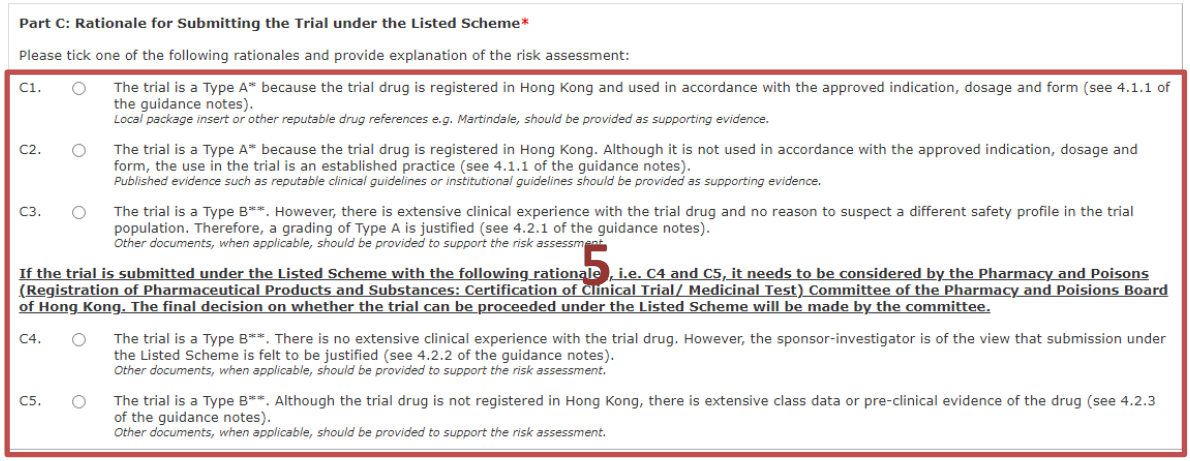
2. Is the trial initiated and conducted by a sponsor-investigator?*
   - ○ Yes
   - ○ No (the Listed Scheme is not applicable; please submit under the Standard Scheme)

3. Targeted disease or condition*

4. Trial regimen, including dosage and route of administration*

4

5. Select the Rationale for Submitting the Trial under the Listed Scheme



Part C: Rationale for Submitting the Trial under the Listed Scheme*

Please tick one of the following rationales and provide explanation of the risk assessment:

C1. ○ The trial is a Type A* because the trial drug is registered in Hong Kong and used in accordance with the approved indication, dosage and form (see 4.1.1 of the guidance notes).
Local package insert or other reputable drug references e.g. Martindale, should be provided as supporting evidence.

C2. ○ The trial is a Type A* because the trial drug is registered in Hong Kong. Although it is not used in accordance with the approved indication, dosage and form, the use in the trial is an established practice (see 4.1.1 of the guidance notes).
Published evidence such as reputable clinical guidelines or institutional guidelines should be provided as supporting evidence.

C3. ○ The trial is a Type B**. However, there is extensive clinical experience with the trial drug and no reason to suspect a different safety profile in the trial population. Therefore, a grading of Type A is justified (see 4.2.1 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

5

If the trial is submitted under the Listed Scheme with the following rationale, i.e. C4 and C5, it needs to be considered by the Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances: Certification of Clinical Trial/ Medicinal Test) Committee of the Pharmacy and Poisons Board of Hong Kong. The final decision on whether the trial can be proceeded under the Listed Scheme will be made by the committee.

C4. ○ The trial is a Type B**. There is no extensive clinical experience with the trial drug. However, the sponsor-investigator is of the view that submission under the Listed Scheme is felt to be justified (see 4.2.2 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

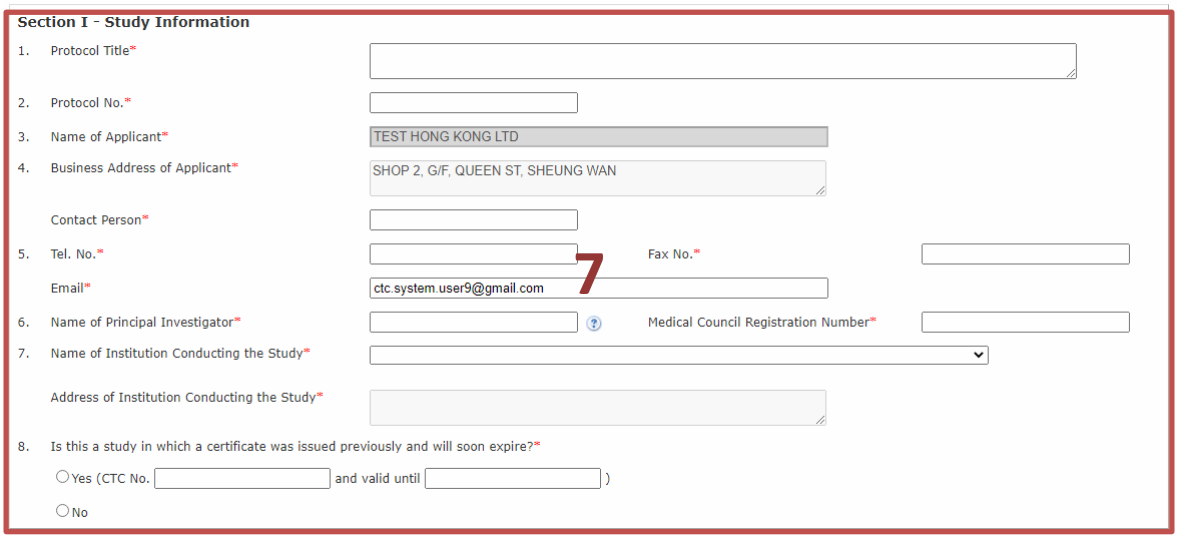
C5. ○ The trial is a Type B**. Although the trial drug is not registered in Hong Kong, there is extensive class data or pre-clinical evidence of the drug (see 4.2.3 of the guidance notes).
Other documents, when applicable, should be provided to support the risk assessment.

6. Fill-in Part D of the Risk Assessment Form

Part D: Explanation of the risk assessment*

6

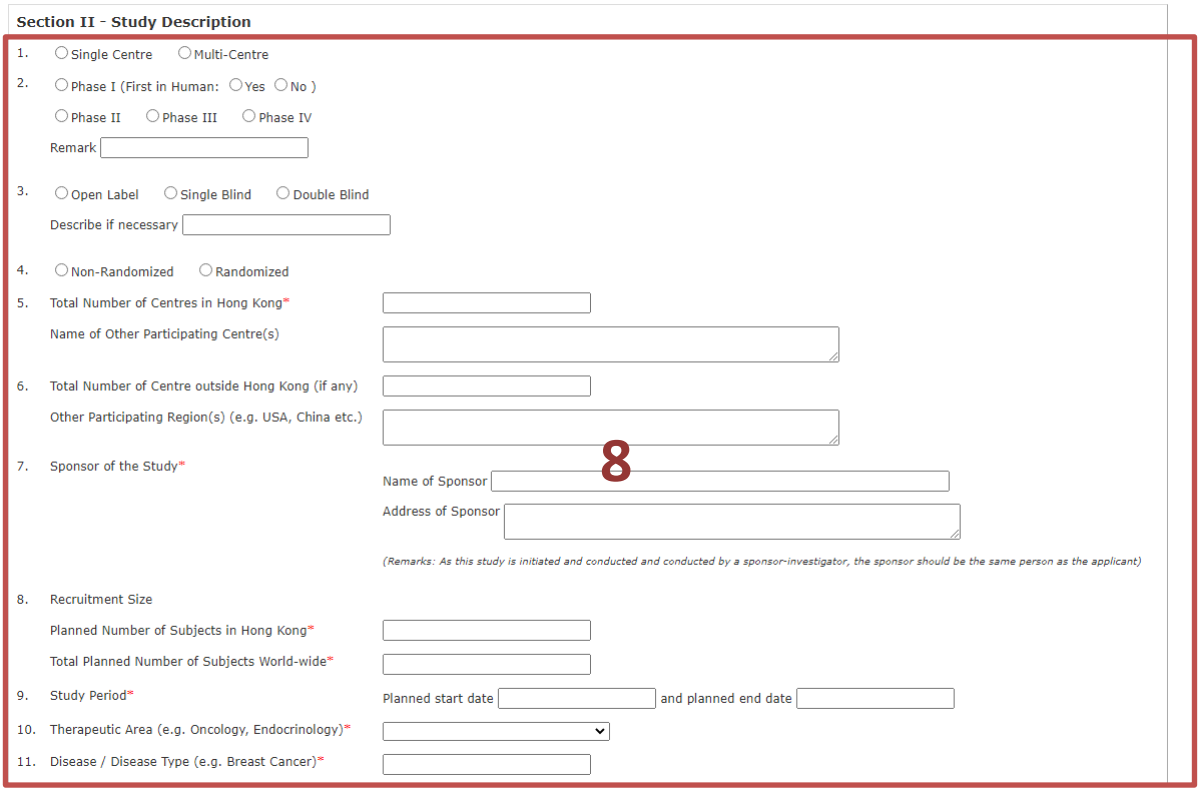
7. Fill-in Section I of the application form



Remarks:

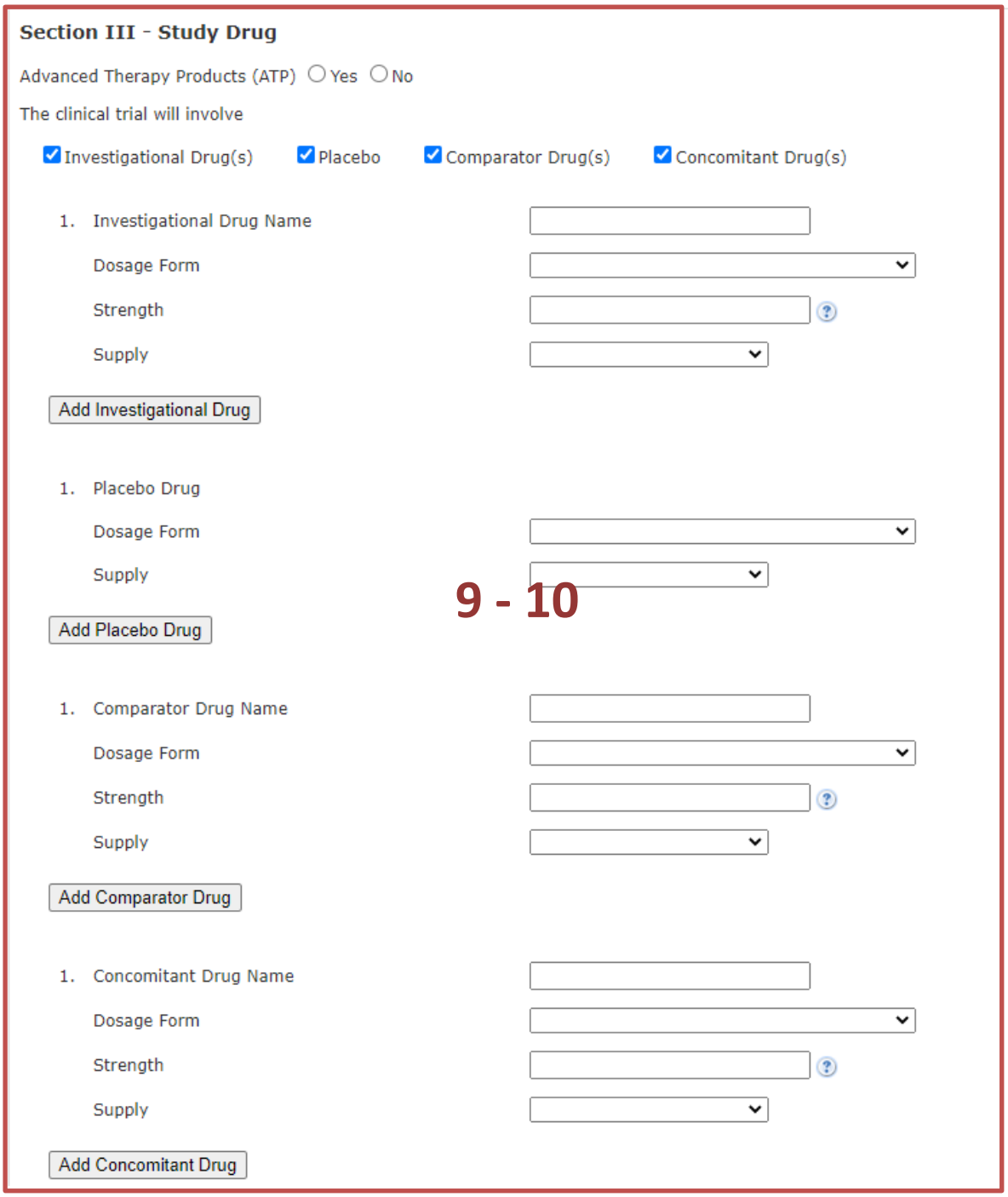
- Name of Applicant and Business Address of Applicant will be filled-in automatically by the system and cannot be revised
- Address of Institution Conducting the Study will be filled-in automatically after selecting the Name of Institution Conducting the Study

8. Fill-in Section II of the application form

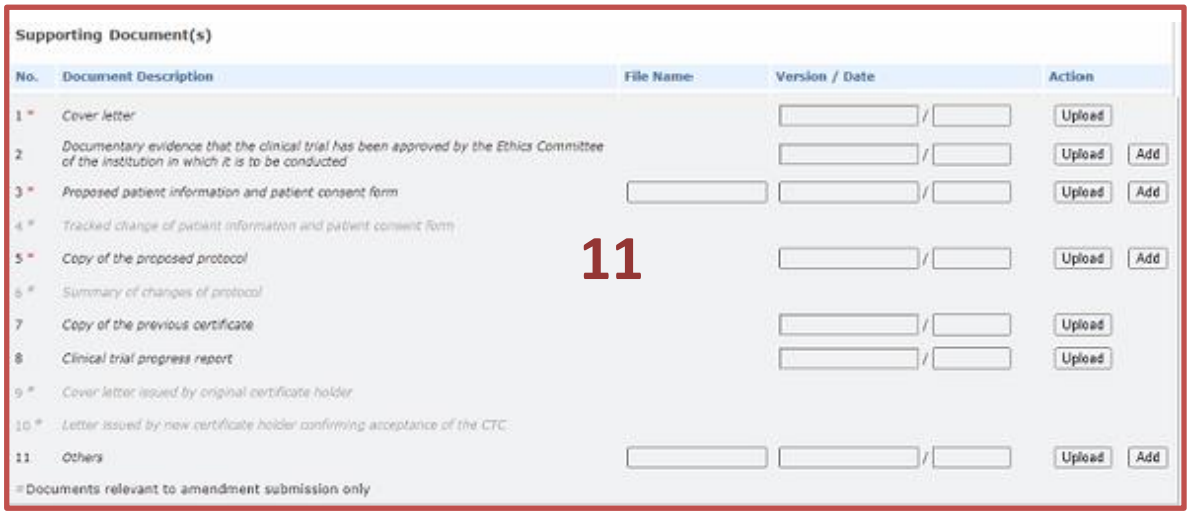


9. Fill-in Section III of the application form, select if Advanced Therapy Products (ATP) is/are involved in the study

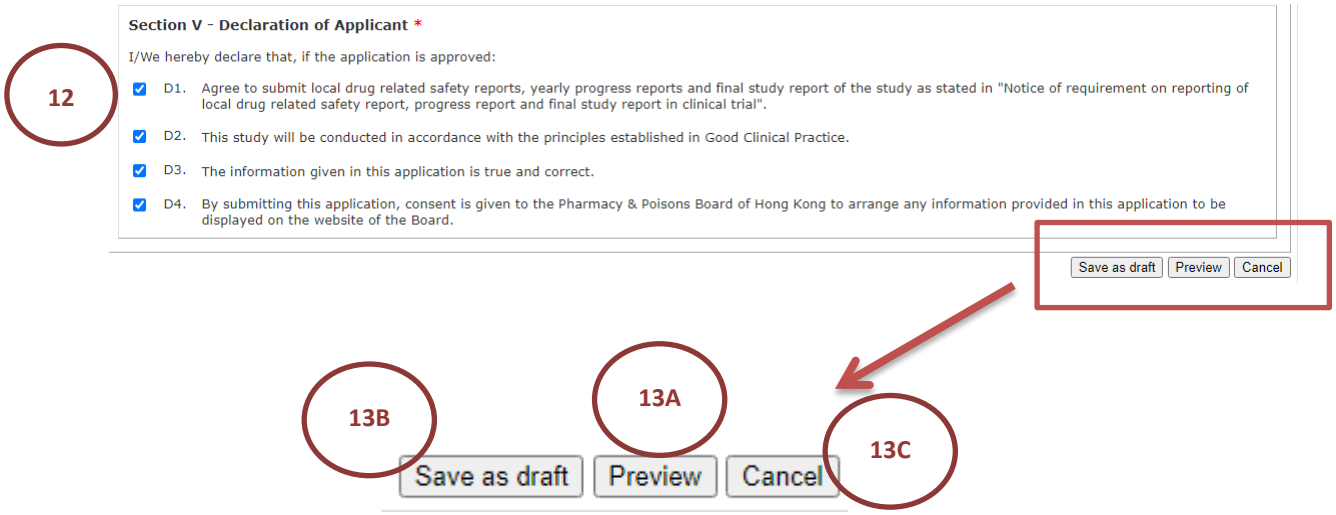
10. Select applicable type of study drug(s) and fill-in the drug name, dosage form, strength and source of supply as applicable (Note: Please only provide name and address of final product manufacturer(s))



11. Upload related Supporting Document(s), fill-in File Name, Version and Date (Multiple upload is supported if needed)



12. Put a tick in the declaration boxes



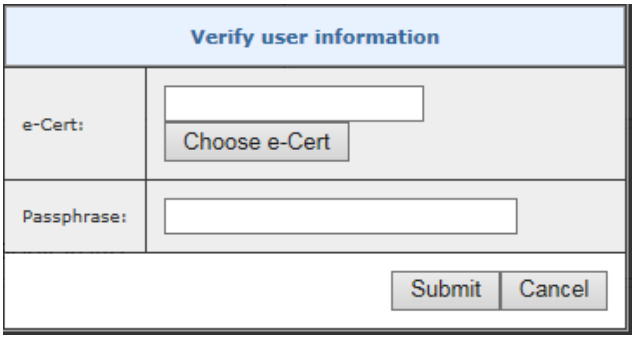
13. A) After all information is filled, user can click "Preview" button to view the filled details in the Preview page.

i) Click "Back" button to re-edit the form or

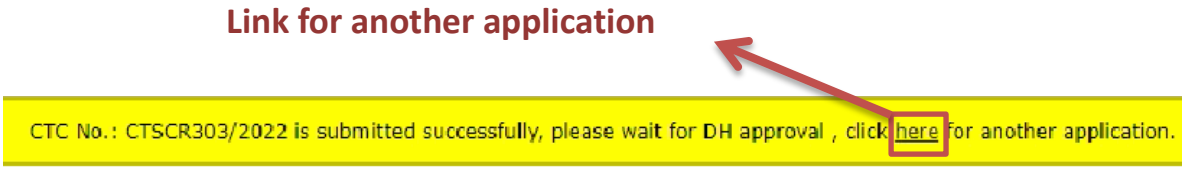
ii) Click "Submit" button to submit the new application to DHDO

- Click "Choose E-cert" button,
- Select the corresponding E-cert,
- Input the corresponding Passphrase of the login user account and

- Click “Submit” button to submit the new application to DHDO



- The successful message of the application will be shown.



B) Or click “Save as draft” button for future editing.

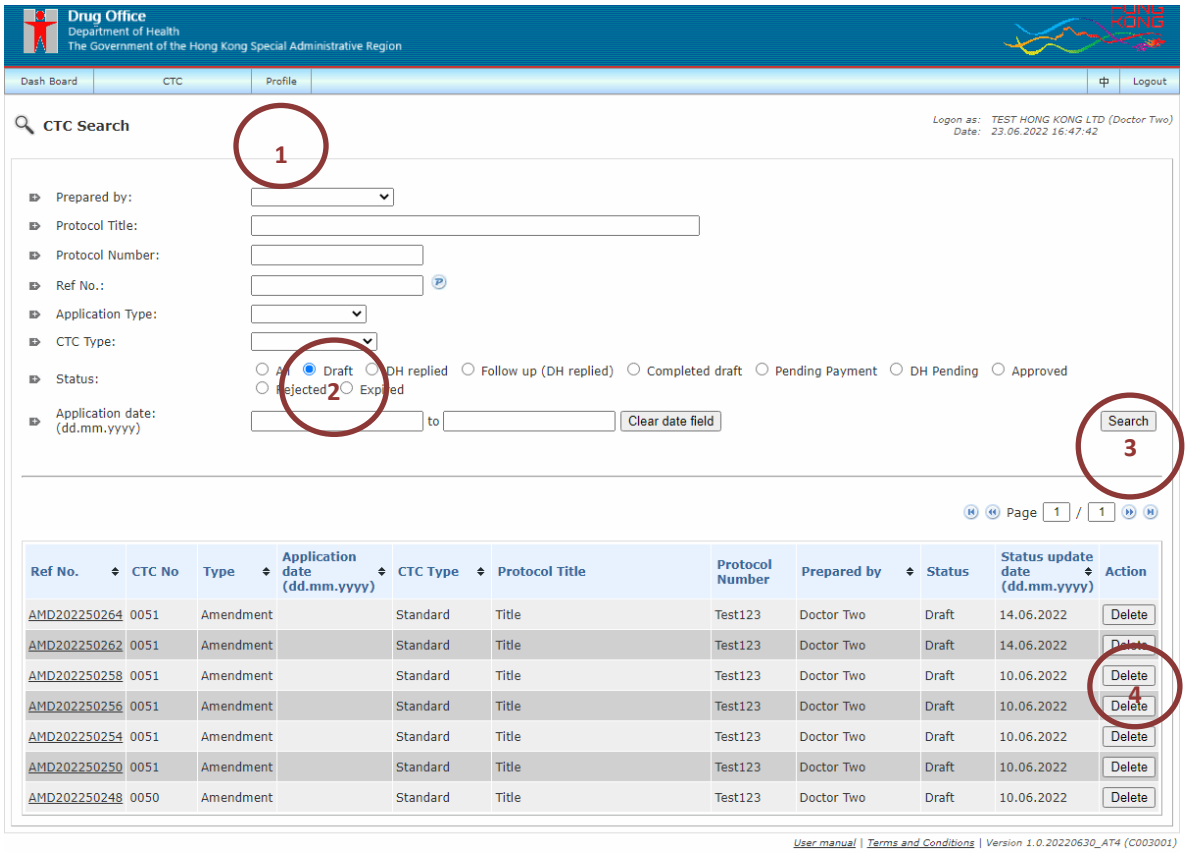
- The successful message will be shown.

C) Or click “Cancel” button to leave the form and back to search page.

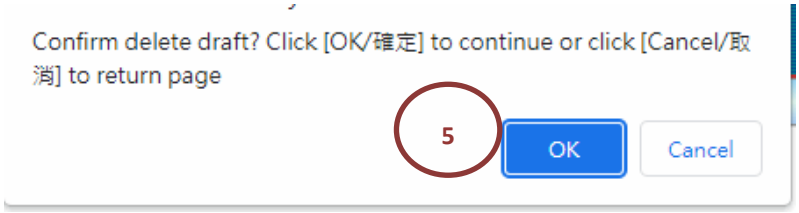
iii. Delete a Saved Draft

Only draft record can be deleted, the steps show as follows.

1. Select menu “CTC” → “CTC Search” or redirect from Dash Board
2. Select application with the status as “Draft”
3. Click “Search” button
4. Click “Delete” button on related record



5. Click “OK” button on the popup box



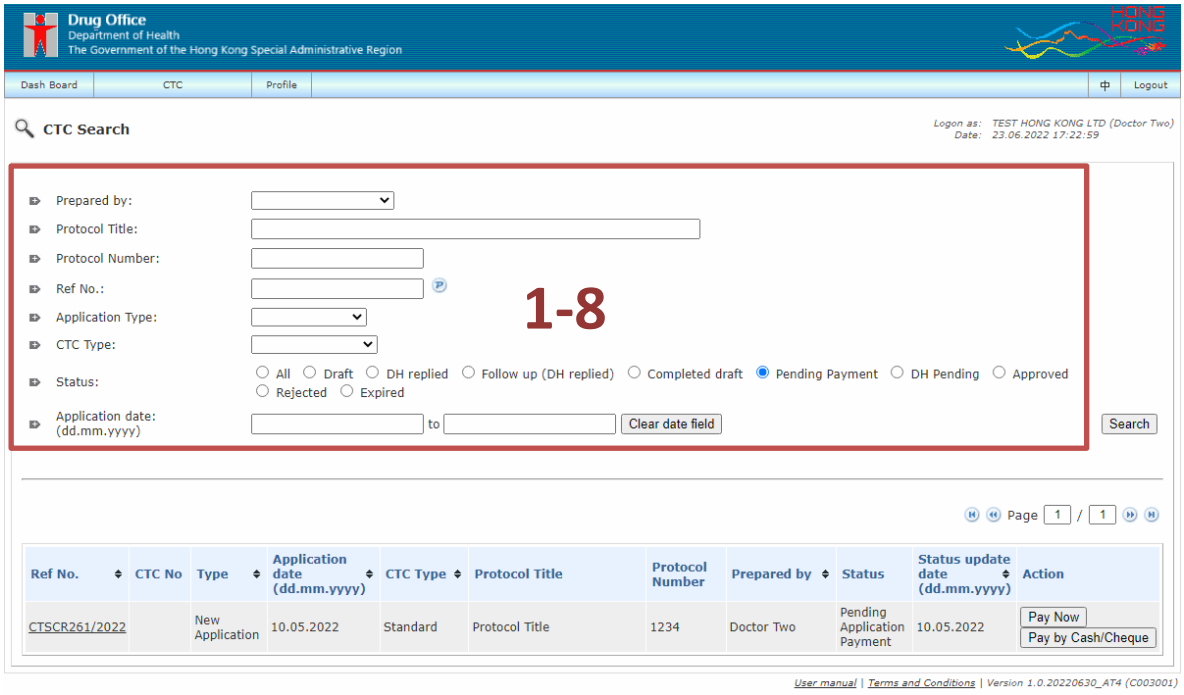
iv. Application Status

Status name	Status description
Draft	Applications are open for edit and delete.
DH replied	Applications are replied by DHDO, user need to follow DHDO officer's instruction before re-submit them.
Follow up (DH replied)	Follow up application are replied by DHDO.
Completed Draft	Applications are completed by normal users / supervisors and are ready to submit.
Pending Payment	Applications are pending for payment by applicant.
DH Pending	Applications are under screening or evaluation in DHDO.
Approved	Applications are approved by DHDO.
Rejected	Applications are rejected by DHDO.
Expired	CTCs are expired.

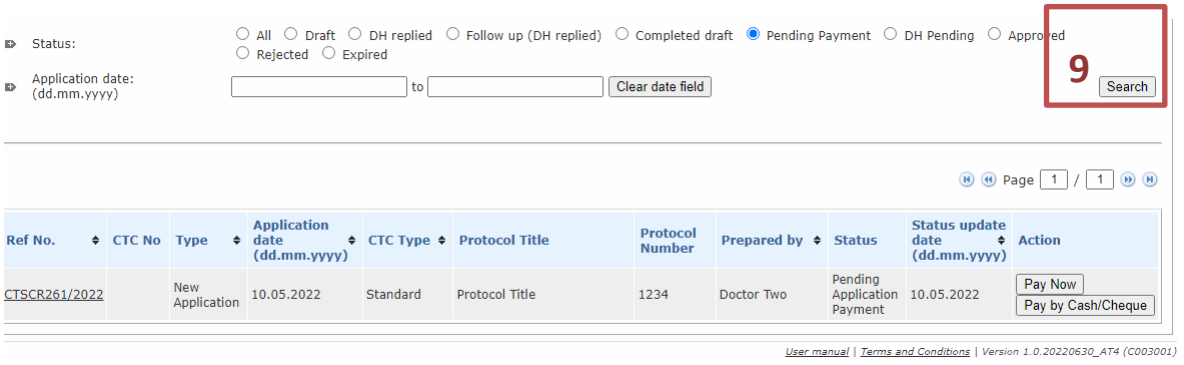
II. Payment

In order to complete payment, user can select menu “CTC” → “CTC Search” and search with following criteria:

1. Select Prepared by and/or
2. Input Protocol Title and/or
3. Input Protocol Number and/or
4. Input Ref No. (support partial match) and/or
5. Select Application Type and/or
6. Select CTC Type and
7. Select “Pending Payment” as Status and/or
8. Select Application date range



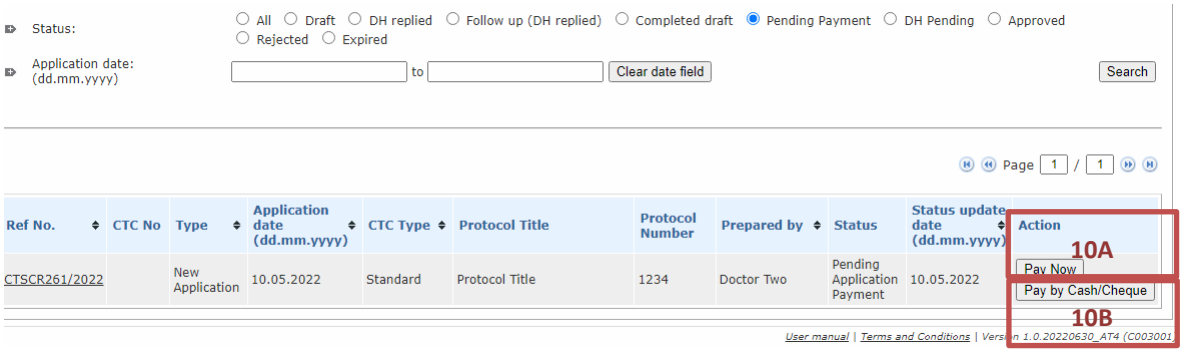
9. Click “Search” button, result will be displayed in the result table



10. Select pay method

A Click “Pay Now” button for making on-line payment or

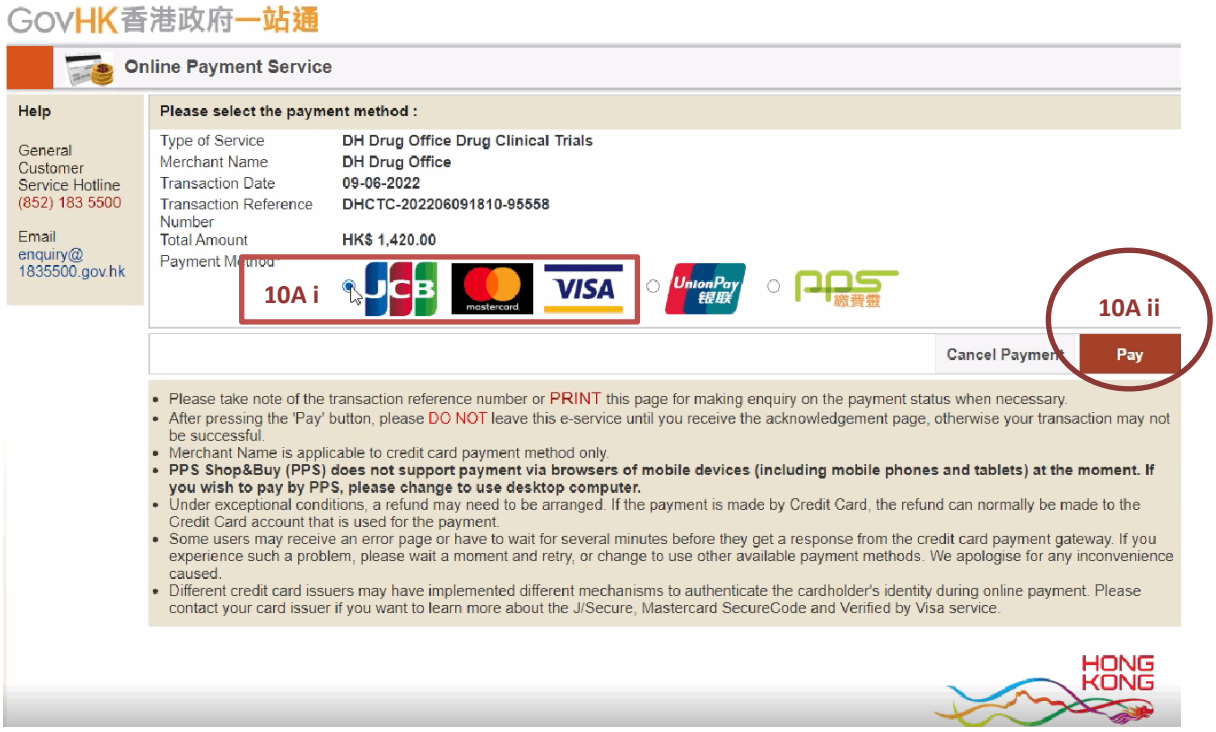
B Click “Pay by Cash/Cheque” button



10 A. On-line payment

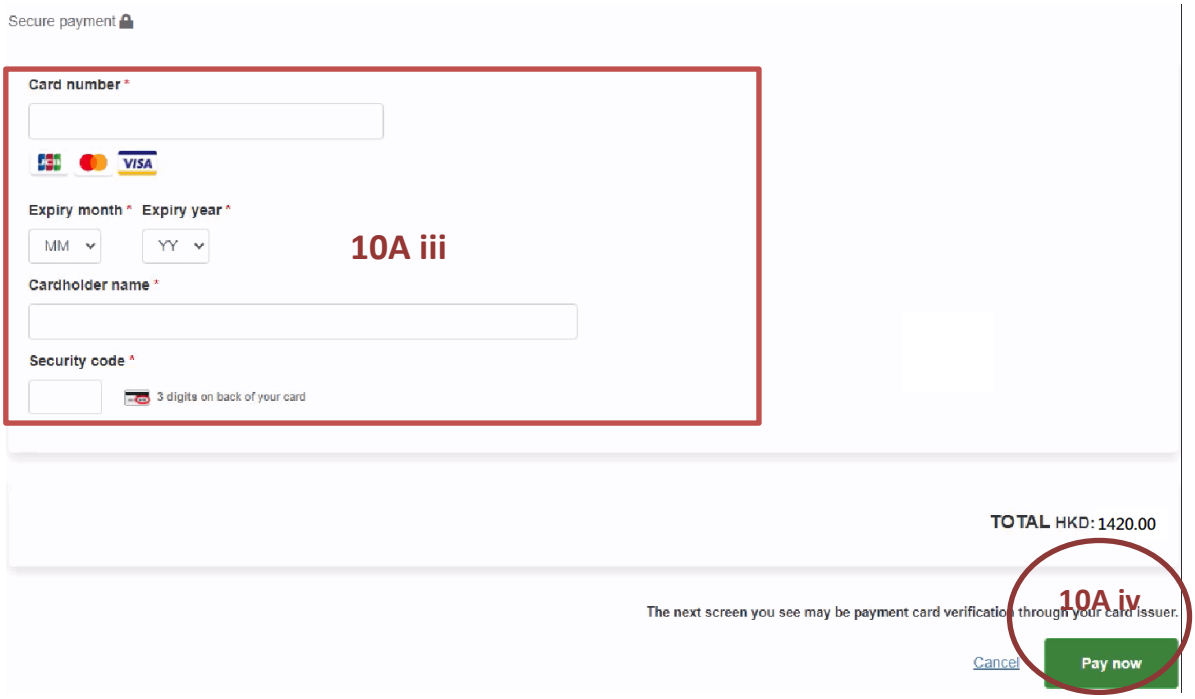
i. Select Payment Method and

ii. Click “Pay” button

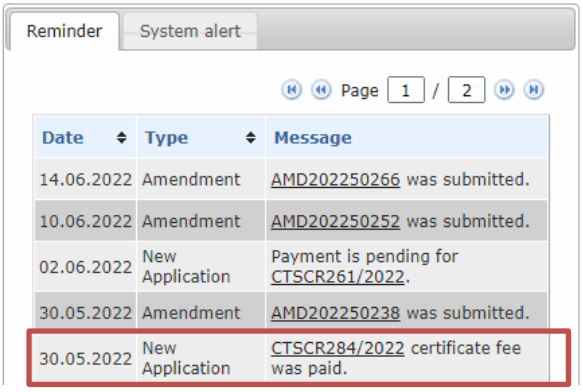


iii. Fill-in the details of the selected payment method

iv. Click “Pay now” button



v. Successful payment message will be shown



10 B. Pay by Cash/Cheque

i. Click “Pay by Cash/Cheque” button to download the payment notification

ii. The payment details are listed in the notification

PHARMACY AND POISONS ORDINANCE
(CHAPTER 138)

香港法例第138章藥劑業及毒藥條例

Ref.: CTSCR 288/2022
檔號

Date: 09 June 2022
日期

NOTIFICATION

通知書

This is to notify you to pay for the following application(s)/certificate(s):

現通知閣下繳交下列申請/註冊之費用：

		Number *數量*	Fee *費用*
Clinical Trial Application Fee	**10B ii**	1	1420
Clinical Trial Certificate Fee			
Amendment Certificate Fee			

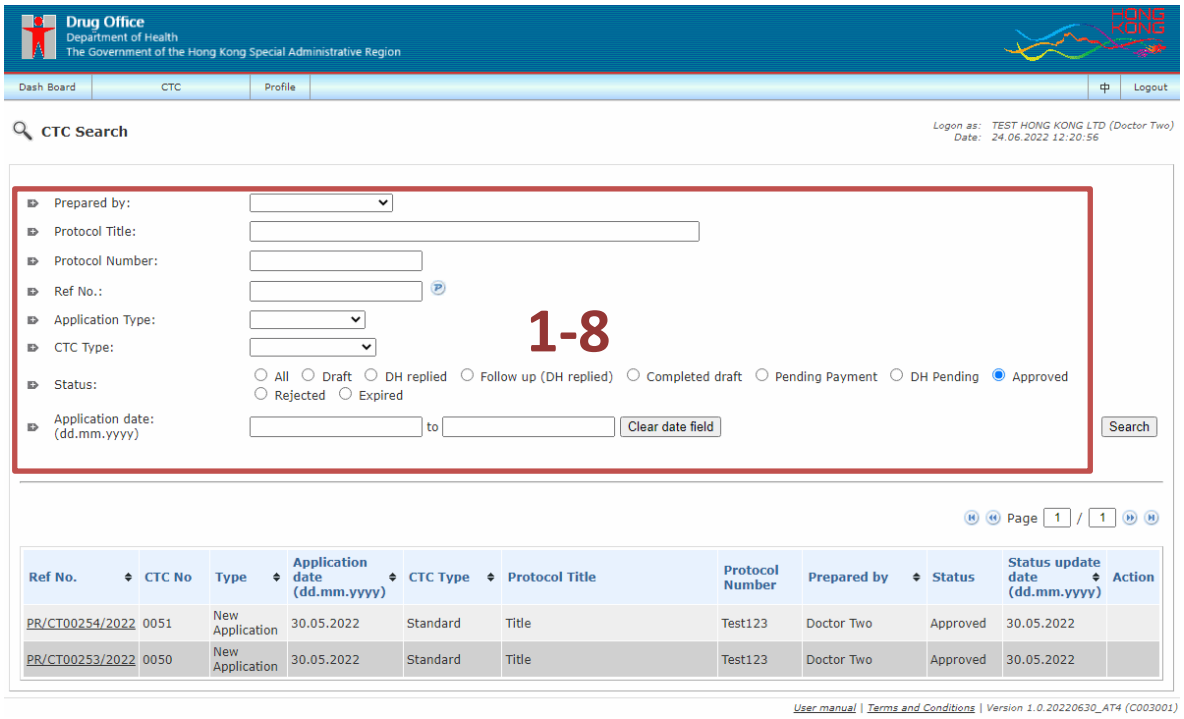
(W.K. NG)
For Chief Pharmacist
總藥劑師
（高級藥劑師代行）

iii. Bring along the notification to Drug office to complete the payment

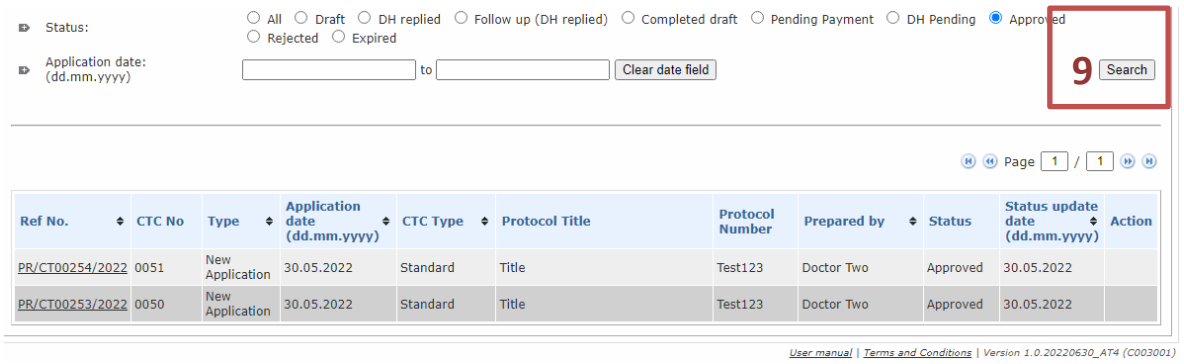
III. Certificate Download / Printing

In order to print the Approved Certificate(s), user can select menu "CTC" → "CTC Search" and search with following criteria:

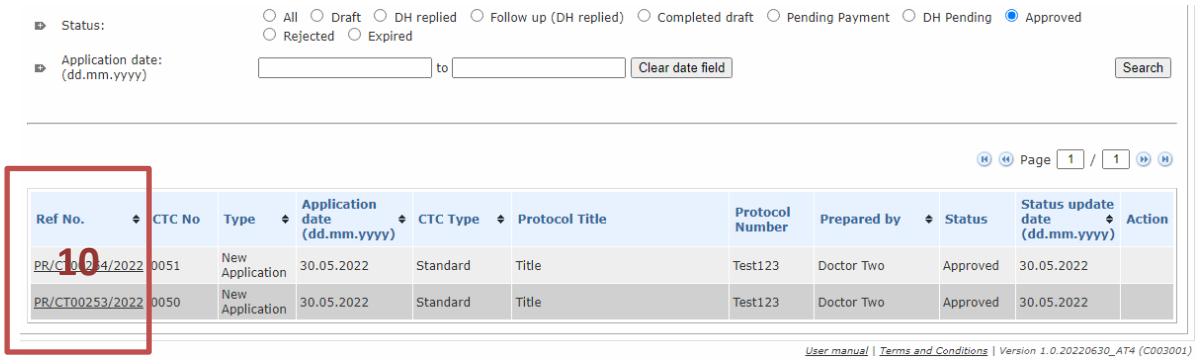
1. Select Prepared by and/or
2. Input Protocol Title and/or
3. Input Protocol Number and/or
4. Input Ref No. (support partial match) and/or
5. Select Application Type and/or
6. Select CTC Type and
7. Select "Approved" as Status and/or
8. Select Application date range



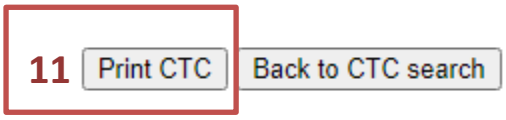
9. Click "Search" button, result will be displayed in the result table



10. Click link on related Ref No. to Download / Print the certificate



11. Click “Print CTC” button to Download / Print the certificate



Remarks: The “Print CTC” button would be disappeared after clicking once.