

Frequently Asked Questions on Electronic Clinical Trial System (e-CTS)

Account Registration and System Access	
Q.1	How to become a user of e-CTS?
A.1	<p>Applicants are required to obtain e-Cert from the Hongkong Post. Afterwards, complete the e-CTS Account Registration Form and submit to Drug Office by email or by post with required supporting documents.</p> <p>For details, please refer to the “Guidance Notes on New Account Registration for e-CTS” available on following website: https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Guidance_Notes_on_application_for_new_user_account_of_e-CTS.pdf?v=1k2y33p</p> <p>The “e-Cert (Personal) application form” can be downloaded from the following website: https://www.ecert.gov.hk/product/ecert/apply/img/e-Cert_(P)_N.pdf</p> <p>The “e-Cert (Organisational) application form” can be downloaded from the following website: https://www.ecert.gov.hk/product/ecert/apply/img/e-Cert_(O_E_S)_N.pdf</p>
Q.2	What are the system requirements for using e-CTS?
A.2	<p>System requirements are as follows:</p> <ul style="list-style-type: none"> a. Web browser: Google Chrome, Microsoft Edge and Mozilla Firefox (Internet Explorer is <u>not</u> supported); b. Web browser settings: Accept cookies and JavaScript; c. Java Runtime Environment (JRE) 1.6.x or above; d. Adobe Flash Player 13 or above.
Q.3	With ONE Hongkong Post e-Cert, can ONE company apply for multiple accounts for submission of applications via e-CTS?
A.3	<p><u>EACH</u> Hongkong Post e-Cert can only apply for <u>ONE</u> primary account (supervisor role) in e-CTS for submission of applications. Upon successful account registration, primary account can create secondary accounts (normal user role) for other staff members to prepare and draft applications if needed.</p>
Q.4	How many accounts can one company create?
A.4	<p>One company can hold a maximum of 20 accounts.</p>

New Applications, Amendments and Subsequent Submissions via e-CTS	
Q.5	For what kind of submissions should applicants submit via e-CTS?
A.5	<p>Starting from 30 June 2022, <u>ALL</u> new applications for Certificate for Clinical Trial/Medicinal Test (the certificate) should be submitted via e-CTS. Manual application is no longer accepted.</p> <p>For clinical trial/medicinal test that <u>the certificate was issued via e-CTS</u>, applicants should also submit relevant amendments and subsequent submissions via e-CTS.</p>
Q.6	Will e-CTS capture information of certificates that were issued via manual application? How to handle amendments and subsequent submissions for this kind of on-going clinical trial/medicinal test?
A.6	<p>Information of historical/existing certificates that were issued via manual application will NOT be transferred to e-CTS.</p> <p>For on-going clinical trial/medicinal test that <u>the certificate was issued via manual application</u>, certificate holders should submit relevant amendments and subsequent submissions manually.</p>
Q.7	How to submit renewal application for certificates that were issued via manual application?
A.7	<p>In order to avoid interruption of the ongoing clinical trial/medicinal test, applicants are advised to submit a new application not later than 4 months before the expiry of the current certificate. If such application is submitted on/after 30 June 2022, the submission should be made via e-CTS.</p>
Q.8	Is there any change in application procedure when submission is done via e-CTS?
A.8	<p>In general, the application procedure and required documents remain unchanged. For details, applicants may refer to the “Guidance Notes on the Application for Certificate for Clinical Trial/Medicinal Test” on the following website:</p> <p>https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Guidance_Notes_en_Version.pdf?v=c211c4c</p>
Q.9	Is it acceptable to supplement the Ethics Committee approval document at a later date after submitting the application?
A.9	<p>For new applications for the certificate, applicants may supplement the Ethics Committee approval document at a later date via e-CTS. However, this option does NOT apply to amendment or subsequent submissions.</p>

Q.10	How to submit local drug-related safety reports for clinical trials?
A.10	<p>The holder of the certificate may refer to the “Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial” on the following website:</p> <p>https://www.drugoffice.gov.hk/eps/do/en/doc/guidelines_forms/Reporting_Requirement_en_Version.pdf?v=xg7ga51</p>
Q.11	Will acknowledgement of receipt be issued via e-CTS?
A.11	After submitting a new application, amendment or subsequent submission on e-CTS, the acknowledgement of receipt will be available for applicants to download/print.
Q.12	What is the file size limit of e-CTS?
A.12	The file size limit for each file is 10MB.

The Certificate for Clinical Trial/Medicinal Test issued via e-CTS	
Q.13	How to confirm the validity of the certificate issued via e-CTS?
A.13	<p>The certificate issued via e-CTS is an electronically signed PDF document. When opening a valid certificate with Adobe Acrobat Reader, a “Signature panel” ribbon will appear on the top of the document to show the validity of the signature(s) on the certificate. [Please ensure Hongkong Post e-Cert CA 2 – 17 is added as Trusted Certificates of Adobe Acrobat Reader following the instructions under Part 5 of e-CTS User Guide.]</p> <p>It is important to note that the electronically signed PDF document is the ORIGINAL of the certificate.</p>
Q.14	If the certificate issued via e-CTS is lost, how to obtain a new copy?
A.14	<p>The certificate issued via e-CTS will be available for download ONE time only after approval of the application. Therefore, please ensure the certificate is successfully downloaded and saved before closing the PDF document.</p> <p>If a new copy is requested, the certificate holder should contact the Drug Evaluation and Pharmacovigilance Division of the Drug Office and apply for a certified true copy. Payment of HKD\$220 will apply on such request.</p>
Q.15	How to handle amendments that will change the particulars on the certificate?
A.15	For <u>certificate that was issued via e-CTS</u> , the certificate holder should submit the application for certificate amendment together with the required supporting documents on e-CTS. When the amendment on the particulars are approved and upon payment of

HKD\$155, a NEW certificate will be available for download/print via e-CTS.

[On the other hand, there is no change on the current practice for certificate that was issued via manual application, the original certificate together with the required supporting documents should be submitted to Drug Evaluation and Pharmacovigilance Division of the Drug Office. A notification for payment of HKD\$155 and collection will be sent to the certificate holder to collect the amended certificate.]