

Canada's Drug and Health Technology Agency

# Pharmaceutical Submissions SharePoint Site Set-Up Guide

## Background

Effective February 16, 2023, CADTH will be replacing its previous secure file submission portal, Collaborative Workspaces, with Microsoft SharePoint as a way for sponsors to securely exchange files with CADTH throughout CADTH pharmaceutical review programs. The Pharmaceutical Submissions SharePoint site will be used for all submissions that have not yet submitted an Advanced Notification Form as of February 16, 2023, and will be deployed to active projects on a rolling basis. This new system is a more user-friendly and reliable interface for sponsors and adds an increased level of security with Microsoft Authenticator multifactor authentication.

Sponsors must request access to the site a minimum of **10 business days before** the intended date of submitting the Pre-submission Meeting Request Form (or the Advanced Notification Form if not requesting a pre-submission meeting). In the event the sponsor has not requested or received access prior to their target date for providing advance notification of the pending application, please contact CADTH immediately (<u>support@cadth.ca</u>). CADTH will work with the sponsor to ensure that the application is not delayed due to the timeframe for setting up the platform to securely receive the required documents.

#### **Drugs Already Submitted to CADTH for Review**

CADTH will be reaching out via email to sponsors that have active projects in the pharmaceutical review programs to transition each project from Collaborative Workspaces to the new Pharmaceutical Submissions SharePoint site. Submissions that were received most recently will be transitioned to SharePoint first; other projects further through the review process will be transitioned on a rolling basis starting at the end of February.

To initiate the transition process, sponsors will receive an email from CADTH with a link to log in to the site to enable their access, followed by a link to the specific drug folder for their submission. Once sponsors receive the email from CADTH, they should follow the steps listed in the Steps for Setting up Pharmaceutical Submissions SharePoint Site Access section of this document, beginning at Step 2: Receive Link and Log In.

After the transition has been made to SharePoint for the project, all subsequent submissions related to the review should be sent via the Pharmaceutical Submissions SharePoint site, not Collaborative Workspaces.



#### **Sponsor Requirements for Set-Up**

Before proceeding with the set-up steps, please ensure the following:

- Each contact must have a smartphone capable of downloading the Microsoft Authenticator app from the App Store (iOS 13.0 or later for iPhone, OS Android 6.0 and later for Android).
  - It is recommended that the Microsoft Authenticator app is downloaded to your device before you
    proceed with set-up.
  - For further details on how to download and use Microsoft Authenticator, please refer to Microsoft Support.

### Steps for Setting up Pharmaceutical Submissions SharePoint Site Access

#### 1. Submit Form to CADTH

- 1.1. The sponsor must submit a <u>Pharmaceutical Submissions SharePoint Access Request Form</u> to <u>support@cadth.ca</u>.
  - This form must be sent a minimum of 10 business days before the intended date of submitting the Pre-submission Meeting Request Form (or the Advanced Notification Form if not requesting a pre-submission meeting).
  - This form contains primary and secondary email contacts, company name, brand and generic name (please omit brand name if confidential), and other relevant information.

#### 2. Receive Link and Log In

Please note that those who have previously received access to the Pharmaceutical Submissions SharePoint site for a past project should, after submitting the request form to <u>support@cadth.ca</u>, skip to Step 4: Log in to Project's Secure Area. If this is your first time submitting to CADTH using the Pharmaceutical Submissions SharePoint site, you should proceed with the following steps.

- 2.1. Each contact will receive an email from <u>invites@microsoft.com</u> indicating that a CADTH employee has "invited you to access applications within their organization." If an email is not received, please check your spam or junk folder.
- 2.2. Click the "Accept" or "Accept Invitation" link found at the bottom of the email (refer to Figure 1).



## Figure 1: Email Received With Invitation to Join the Pharmaceutical Submissions SharePoint Site

Alt text: The email received from CADTH inviting users to join the Pharmaceutical Submissions SharePoint site, indicating to accept the invitation by clicking the link at the bottom of the email.

Liam	Carson invited you to access applications within their organization	€, ∨ ≦, ∨
M	Microsoft Invitations on behalf of CADTH <invites@microsoft.com> To: You</invites@microsoft.com>	← ≪
	Please only act on this email if you trust the individual and organization represented below. In rare cases, individuals may receive fraudulent invitations from bad actors posing as legitimate companies. If you were not expecting this invitation, proceed with caution.	
	Sender: Liam Carson ( <u>Liam.Carson@cadth.ca</u> ) Organization: CADTH Domain: [cadth.ca]cadth.ca	
	This message was provided by the sender and is not from Microsoft Corporation.	
	LC Message from Liam Carson:	
	<ul> <li>CADTH is inviting you to join the Pharmacueticals Submissions SharePoint site. Please select "Accept" in this email to be added to the CADTH SharePoint site. Once you have successfully logged in, reply all to this email to notify the CADTH administrator that you have logged in. CADTH will then assign you to your designated project folder.</li> </ul>	
	If you accept this invitation, you'll be sent to <u>https://account.activedirectory.windowsazure.com/?</u> tenantid=c75f2c10-d20d-474c-8bef-d8112b6ced29&login hint=cadth.demo@outlook.com.	

- 2.3. You will be asked to accept a privacy statement.
  - Please note that this privacy statement refers solely to activity on the CADTH SharePoint site, not on any other apps or resources. CADTH and its employees will not have access to any of the your private information.
- 2.4. If you have a Microsoft account, you may be asked to log in with that account. If you do not have a Microsoft account, a verification code will be sent to your email. Copy this verification code into the window and click "Next." If you do not receive this verification code, please check your spam or junk folder.
- 2.5. Once you have logged in, you will reach the CADTH shared applications page. This indicates that your account has successfully been created.

Note that this page will be blank, and you will not have access to any applications from this page. You must notify the CADTH administrator that you have successfully logged in to receive access to your assigned SharePoint folder (refer to Figure 2).



#### Pharmaceutical Submissions SharePoint Site Set-Up

#### Figure 2: Microsoft Webpage User Reaches Upon Successful Login

Alt text: Web page indicating "There are no apps to show", which users will reach after successfully logged in showing that the page is blank.

		My Apps $\sim$	✓ Search apps	# ? C	
(i) Ar	improved app discovery	view is available! Try it now. You'll be able to return to the	current experience. Learn more	Try the preview $ imes$	
	Apps 🗸 🕀			$   \partial $ Edit $\equiv$ List view $\cdots$	
There are no apps to show. Hide this collection					

#### 3. Notify CADTH of Successful Login

- 3.1. To notify the CADTH administrator that you have successfully logged in, "Reply all" to the email that was received in Step 2.1 and include <a href="mailto:support@cadth.ca">support@cadth.ca</a> to ensure that both the CADTH contact and <a href="mailto:support@cadth.ca">support@cadth.ca</a> are included in the email.
- 3.2. When this email is received, CADTH will create the secure folder for your project.

#### 4. Log in to Project's Secure Area

- 4.1. Once your secure site has been created, each contact will receive a link through the email provided that a folder with the project number and drug name has been shared with you. If an email is not received, please check your spam or junk folder.
- 4.2. In the email received, click "Open," then "Microsoft Account," then "Log in with Microsoft Account."
- 4.3. If you have a Microsoft account, you may be asked to log in with that account. If you do not have a Microsoft account, a verification code will be sent to your email. Copy this verification code into the window and click "Next." If you do not receive this verification code, please check your spam or junk folder.

#### 5. Set up Microsoft Authenticator App

- 5.1. To log in to the sponsor's secure area, you will be required to use the Microsoft Authenticator app. If you have still not downloaded the Microsoft Authenticator app, you must do so now.
  - For detailed instructions for downloading and using the app, refer to the <u>Microsoft Support</u> <u>page</u>.
- 5.2. Once you have logged in to Microsoft on your computer, you will be notified with a "More information required" message on your desktop. Click "Next."
- 5.3. Microsoft will prompt you to set up Microsoft Authenticator.
- 5.4. Follow the directions provided on the screen. Ensure that Mobile app is selected in the "How should we contact you?" field. It is recommended to select "Receive notifications for verification" in the "How do you want to use the mobile app?" field. Click "Set up." Refer to Figure 3 for how the webpage should be completed.



#### Figure 3: Microsoft Web Page for Setting Up Microsoft Authenticator App

Alt text: Microsoft Webpage user must complete to set up Microsoft Authenticator app. Input fields are set to "Mobile App" and "Receive notifications for verification".

Microsoft	
Additional security verification	
Secure your account by adding phone verification to your password. View video to know how to secure your account	
Step 1: How should we contact you?	
Mobile app v	
- How do you want to use the mobile app?	
Receive notifications for verification	
O Use verification code	
To use these verification methods, you must set up the Microsoft Authenticator app.	
Set up Please configure the mobile app.	
	Next
	HEAT
©2022 Microsoft Legal   Privacy	

- 5.5. Open the Microsoft Authenticator app on your smartphone, select "Add account" from the "Customize and control" icon ("+" in the upper right corner), and then select "Work or school account."
- 5.6. Select "Scan a QR code" then use your smartphone to scan the QR code that SharePoint has created. Alternatively, you can select "Enter Code Manually" and enter the code that is displayed beneath the QR code (refer to Figure 4).



#### Pharmaceutical Submissions SharePoint Site Set-Up

#### Figure 4: How to Configure the Mobile App for SharePoint Site

Alt text: "Configure mobile app" webpage indicating to scan QR code located in middle of page and "Code" beneath the QR code.

Additional security verification		
Configure mobile app		now
Complete the following steps to configure your mobile app.		_
1. Install the Microsoft authenticator app for Windows Phone, Android or iOS.		_
2. In the app, add an account and choose "Work or school account".		
3. Scan the image below.		
If you are unable to scan the image, enter the following information in your app. Code: 912 909 705 Unt: https://mobileappcommunicator.auth.microsoft.com/activate/025232824/WUS		
If the app displays a six-digit code, choose "Next".		
	Next	cancel

- 5.7. Once your account has been added on your device, click "Next" on your computer until you reach Step 2.
- 5.8. At this point, Microsoft will send a notification to the Microsoft Authenticator app.
- 5.9. You must select "Approve" to the log in request in the app and you may need to enter your smartphone pin or password (depending on your smartphone's security settings).
- 5.10. Once the verification is successful, click "Next" on your desktop, wait for Microsoft to verify, then select "Done."

Note that for more information on setting up your work account with the Microsoft Authenticator app, you can visit the associated <u>Microsoft help page</u>.

#### 6. Access Site

- 6.1. Microsoft will automatically direct you to the project's secure folder that was shared with you.
- 6.2. Please bookmark this site for future logins.
- 6.3. Subsequent logins will require you to log in and approve the log in through Microsoft Authenticator (i.e., the process outlined in Step 7: Future Logins).



#### 7. Future Logins

- 7.1. To submit documents throughout the review, the sponsor will need to return to the link to the project folder (received via email in Step 4.1), if not bookmarked. If the link has been bookmarked, you can open the page from the bookmark.
- 7.2. Upon clicking the link or going to the bookmark, Microsoft users will be asked to log in with their Microsoft account. Non-Microsoft users will be asked to input their email and a verification code will be sent to that email. If you do not receive the verification code, please check your spam or junk folder.
- 7.3. After signing in, Microsoft will send a notification to your smartphone via Microsoft Authenticator to approve the request to sign in.
- 7.4. Open the notification on your device and select "Approve."
- 7.5. When you approve the request on your device, you will automatically be redirected to the SharePoint site on your desktop.



## How to Send and Receive Files With CADTH Throughout the Review

#### Sharing Files With CADTH Throughout the Review

Within each project folder are the subfolders "From CADTH" and "Sponsor Submissions." Files the sponsor is sending to CADTH should be uploaded into the "Sponsor Submissions" subfolder. Please note that sponsors are not permitted to edit or remove files once they are uploaded to this folder. If a file is uploaded in error, the sponsor should notify the project coordinator responsible for the project to remove the file.

When submitting multiple files, files must be zipped into a .zip file for uploading. Table 1 outlines the file limitations for uploading to the Pharmaceutical Submissions SharePoint site.

## Table 1: File limitations for Uploading to Pharmaceutical Submissions SharePoint Site

File type	.zip files are required.
	<ul> <li>Documents within the .zip file must be provided in PDF or Microsoft Word format, unless otherwise indicated in the requirement descriptions. These files must be unlocked, searchable, and printable, and users must be able to extract information or combine documents.</li> </ul>
	• If there are several .zip files, the number of files should be noted in the file name (e.g., 1of4). The root folder(s) should be clearly named with the brand or generic drug name.
Path length	<ul> <li>The entire decoded file path, including the file name, can't contain more than 400 characters.</li> </ul>
	<ul> <li>The limit applies to the combination of the folder path and file name after decoding.</li> </ul>
Invalid file name	• ~ " # % & * : < > ? / \ {   }
characters	• Leading and trailing spaces in file or folder names also aren't allowed.
Other notes	<ul> <li>SharePoint will not allow a file to be uploaded if a file with the same name already exists in that folder.</li> </ul>

Subfolders have been created within the "Sponsor Submissions" area for each submission type. When submitting files to CADTH, please add the files in the subfolder that best describes the type of files that the sponsor is submitting to CADTH. For example, please submit files for Advance Notification to the "Advance Notification" subfolder within the "1. Pre-submission Activities" subfolder.



#### **Receiving Files From CADTH**

Files that CADTH is sending to the sponsor will be found in the "From CADTH" subfolder. Sponsors are only permitted to download files from this folder, not to upload or edit them.

When a new file is available for download, CADTH will send a link to the documents via email. You can click the link in the email to open the documents. After clicking the link, you may be asked to log in to your account using your Microsoft account email and password (for Microsoft users) or by inputting your email and receiving a verification code (for non-Microsoft account users). Upon logging in, you will be prompted to approve the sign-in request using the Microsoft Authenticator app on your smartphone. Please refer to Step 7: Future Logins for further instruction on accessing the documents. After opening the link, you can download the files by selecting the file then clicking "Download."

### **Additional Support and Troubleshooting**

If you require assistance accessing the Pharmaceuticals Submissions SharePoint site, please contact <a href="mailto:support@cadth.ca">support@cadth.ca</a>.