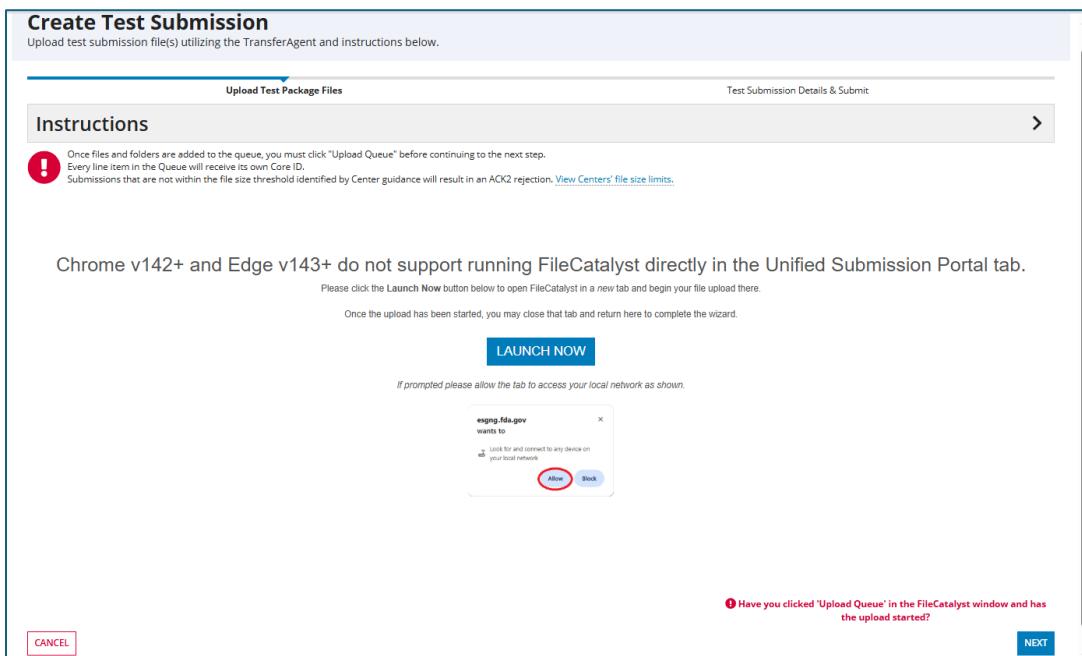


Submission Upload Workflow for Google Chrome version 142 (v142 or newer) and Microsoft Edge version 143 (v143 or newer) users

ESG NextGen Unified Submission Portal (USP) users utilizing Google Chrome v142 (or newer) or Microsoft Edge v143 (or newer) browsers will experience a modified workflow when uploading submissions. A new browser tab will open when FileCatalyst TransferAgent is launched. This document outlines the step-by-step process for this modified submission workflow.

Modified FileCatalyst TransferAgent Workflow

1. Log into the Unified Submission Portal (USP) and click on either the +NEW PRODUCTION SUBMISSION or Test Submission.
 - a. Agents/CROs/Consultants will need to select the company they are uploading on behalf of.
2. The Create Submission page will load and if your browser is Chrome v142 (or newer) or Edge v143 (or newer), instead of FileCatalyst TransferAgent loading within the USP, a message will show instructing to click 'LAUNCH NOW' to launch FileCatalyst TransferAgent.



3. Click 'LAUNCH NOW' to launch FileCatalyst TransferAgent.

Instructions

Once files and folders are added to the queue, you must click "Upload Queue" before continuing to the next step. Every line item in the Queue will receive its own Core ID. Submissions that are not within the file size threshold identified by Center guidance will result in an ACK2 rejection. [View Centers' file size limits.](#)

Chrome v142+ and Edge v143+ do not support running FileCatalyst directly in the Unified Submission Portal tab. Please click the Launch Now button below to open FileCatalyst in a new tab and begin your file upload there.

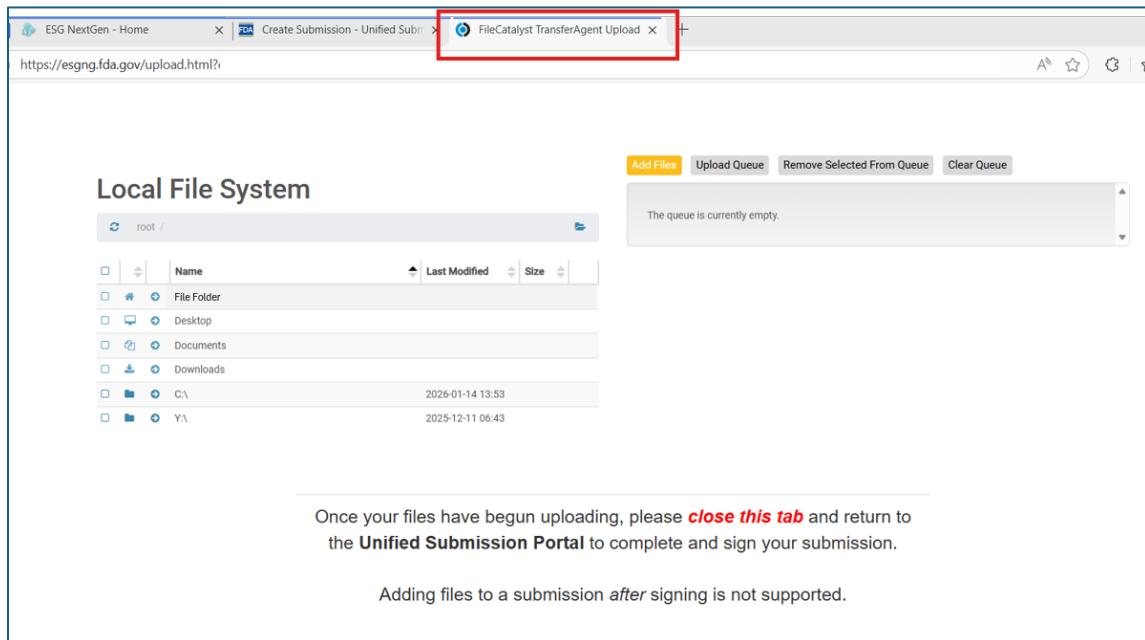
Once the upload has been started, you may close that tab and return here to complete the wizard.

LAUNCH NOW

If prompted please allow the tab to access your local network as shown.



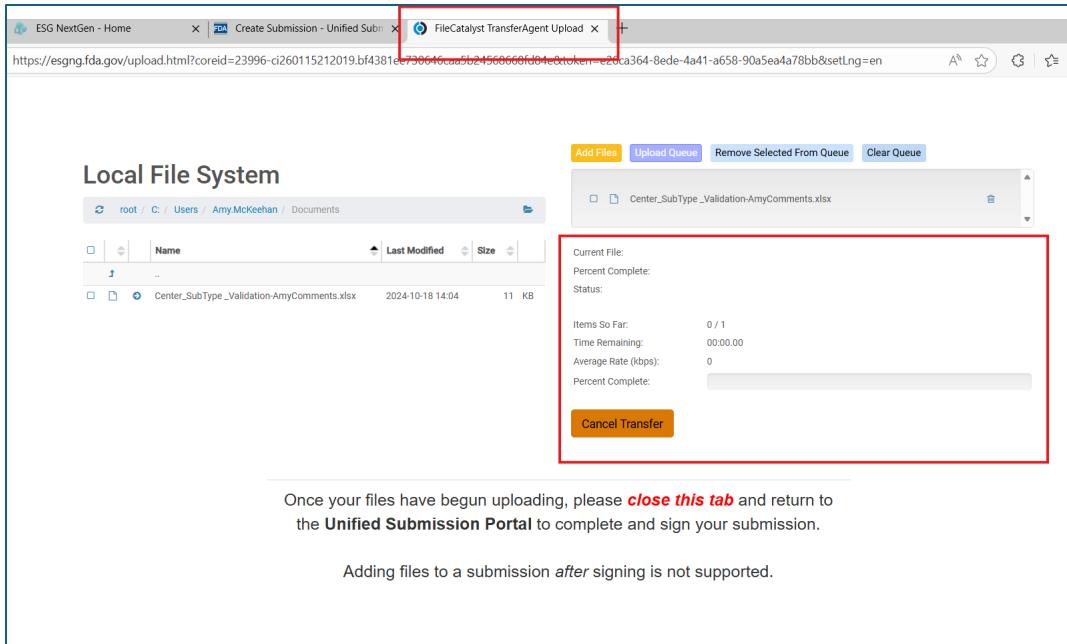
- FileCatalyst TransferAgent will open in a new browser tab.



Once your files have begun uploading, please **close this tab** and return to the **Unified Submission Portal** to complete and sign your submission.

Adding files to a submission *after* signing is not supported.

- Select the file(s) to upload and move them over to the queue and then click 'Upload Queue'.
- Once the upload shows in progress, close the FileCatalyst TransferAgent tab.
 - FileCatalyst TransferAgent will continue to upload the file(s) in the background as long as PC is on and connected to the internet.



Local File System

Add Files Upload Queue Remove Selected From Queue Clear Queue

root / C: / Users / Amy.McKeehan / Documents

Name Last Modified Size

Center_SubType_Validation-AmyComments.xlsx 2024-10-18 14:04 11 KB

Current File: **Percent Complete:**
Status:
Items So Far: 0 / 1
Time Remaining: 00:00:00
Average Rate (kbps): 0
Percent Complete:

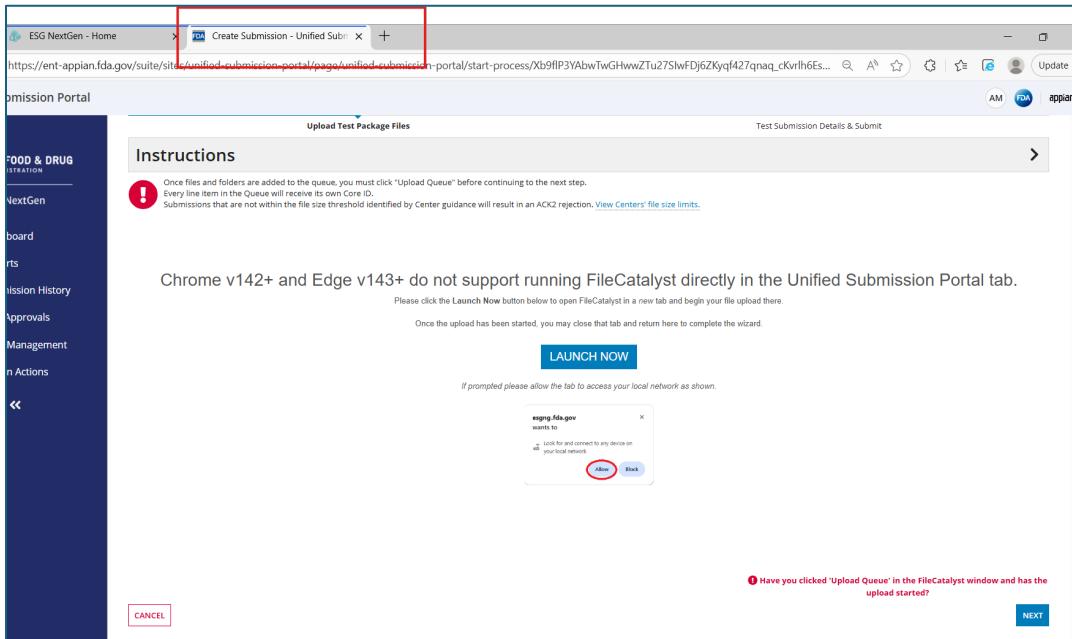
0%

Cancel Transfer

Once your files have begun uploading, please **close this tab** and return to the **Unified Submission Portal** to complete and sign your submission.

Adding files to a submission *after* signing is not supported.

7. Return to the USP tab.



ESG NextGen - Home Create Submission - Unified Sub... FileCatalyst TransferAgent Upload

https://esngng.fda.gov/upload.html?coreid=23996-c1260115212019.bf4381ee738646ca5b24560660fd04ec&token=e20ca364-8ede-4a41-a658-90a5ea4a78bb&setLng=en

AM FDA appian

Instructions

Once files and folders are added to the queue, you must click "Upload Queue" before continuing to the next step.
Every line item in the Queue will receive its own Core ID.
Submissions that are not within the file size threshold identified by Center guidance will result in an ACK2 rejection. [View Centers' file size limits.](#)

Chrome v142+ and Edge v143+ do not support running FileCatalyst directly in the Unified Submission Portal tab.
Please click the Launch Now button below to open FileCatalyst in a new tab and begin your file upload there.
Once the upload has been started, you may close that tab and return here to complete the wizard.

LAUNCH NOW

If prompted please allow the tab to access your local network as shown.

esngng.fda.gov
wants to
Allow Block

Have you clicked 'Upload Queue' in the FileCatalyst window and has the upload started?

NEXT

8. On the USP Upload Package Files tab, click 'Next'.

Upload Test Package Files Test Submission Details & Submit

Instructions

Once files and folders are added to the queue, you must click "Upload Queue" before continuing to the next step.
Every line item in the Queue will receive its own Core ID.
Submissions that are not within the file size threshold identified by Center guidance will result in an ACK2 rejection. [View Centers' file size limits.](#)

Chrome v142+ and Edge v143+ do not support running FileCatalyst directly in the Unified Submission Portal tab.
Please click the Launch Now button below to open FileCatalyst in a new tab and begin your file upload there.
Once the upload has been started, you may close that tab and return here to complete the wizard.

LAUNCH NOW

If prompted please allow the tab to access your local network as shown.



CANCEL **NEXT**

Have you clicked 'Upload Queue' in the FileCatalyst window and has the upload started?

9. On the 'Submission Details & Submit' tab, once all fields are completed, the submission signed, and reviewed, click 'Submit' to complete the process of uploading the submission.

Upload Test Package Files Test Submission Details & Submit

Receiving Center*
Center for Drug Evaluation and Research (CDER)

Submission Type ?*
ACA6004_Drug_Samples

Notes on Submission
This is a place where notes for the submissions can go. This information is not submitted to the center. Do not include any PII within the Notes on Submission.
159/200

e-Signature

After signing, package details cannot be altered.

Pursuant to Section 11.100 of Title 21 of the Code of Federal Regulations, this is to certify that I intend that all electronic signatures executed are legally binding and equivalent of traditional hand-written signatures.

I hereby certify that this submission is complete and ready to be reviewed by the FDA.

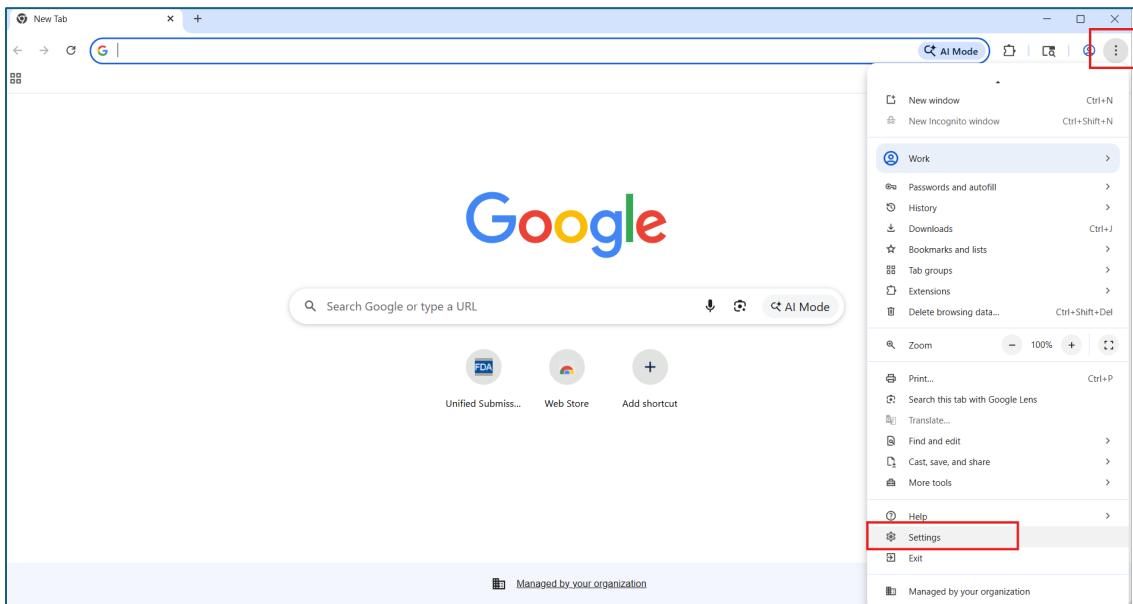


CANCEL **SUBMIT**

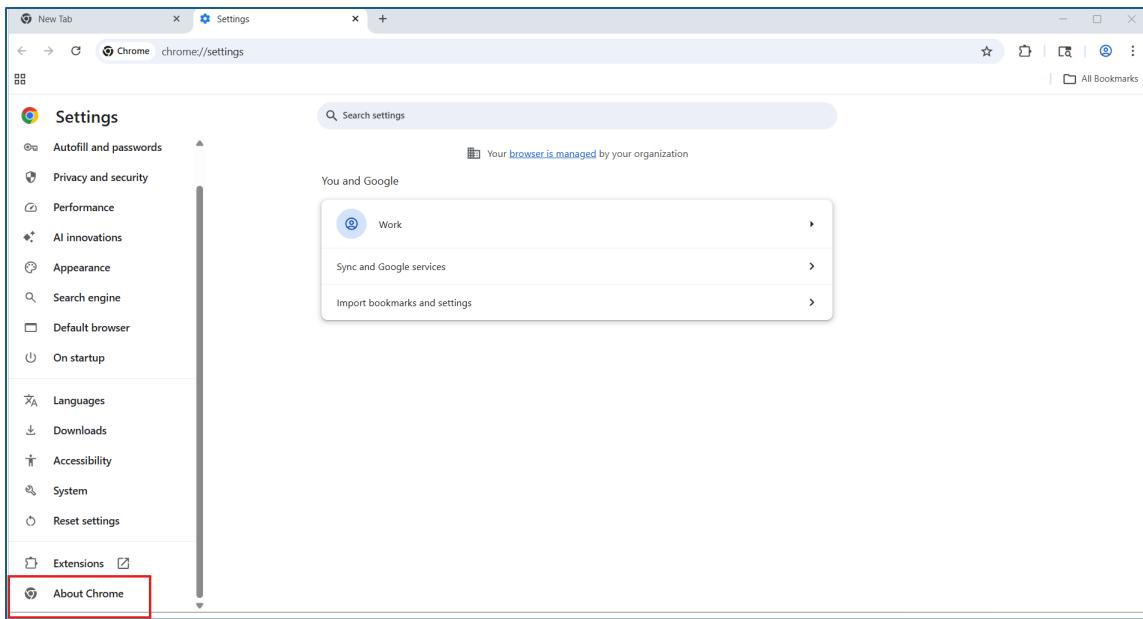
How to Determine the Version of Your Web Browser

Note: These steps apply to both Google Chrome and Microsoft Edge. The screenshots provided are of Google Chrome, for examples.

1. Open up your web browser (Google Chrome or Microsoft Edge)
2. In the upper right-hand corner, click on the three (3) vertical dots and select 'Settings' from the menu.



3. A new tab will open displaying Settings. Scroll down in the left navigation menu and select 'About Chrome' or 'About Microsoft Edge'



4. The web browser version will be within the main box on the About page.

