How to send submissions via the Syncplicity Web Client

Guidance for applicants

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The eSubmission Gateway Syncplicity Web Client is an electronic submission channel that allows the applicants to submit documents supporting all types of applications to the Agency securely over the internet in any electronic format (structured or non-structured). The eSubmission Gateway Web Client users will benefit from an **automated confirmation of the technical validation feedback** (eCTD only) and an automated upload to the Agency's eCTD review system. The use of the eSubmission Gateway and the Web Client is **mandatory** for all human and veterinary submissions, including medical devices and paediatric submissions.

The various steps that need to be completed in the Syncplicity Web Client submission process are outlined below.

Please note that you will only be able to send submissions via the Syncplicity Web Client if you have successfully registered, received email confirmation with your login details and subsequently reset your password in Syncplicity.

VERY IMPORTANT:

1. Please **do not** use the 'Create Account' option. **If you need to register as a user**, please navigate to the **registration module** here: https://esubregistration.ema.europa.eu/registration/

2. The system allows you to create new folders and rename the existing 'archive', 'inbox' and 'outbox'. Please **DO NOT** rename or delete any of the folders. This will lead into malfunctioning of the system and you will not be able to send any submissions.

1. Registration (to new users only)

Review the published Registration Guide here

Complete the online registration form here

2. Reset of password

2.1. Reset your password using link from an email from Axway Syncplicity

If you have **previously registered** as an eSubmission Gateway Web Client user, you will have received an automated email from Axway Syncplicity (in July 2022) to prompt you to update your password to be able to access the new Web Client UI.

The email will look like the one below;
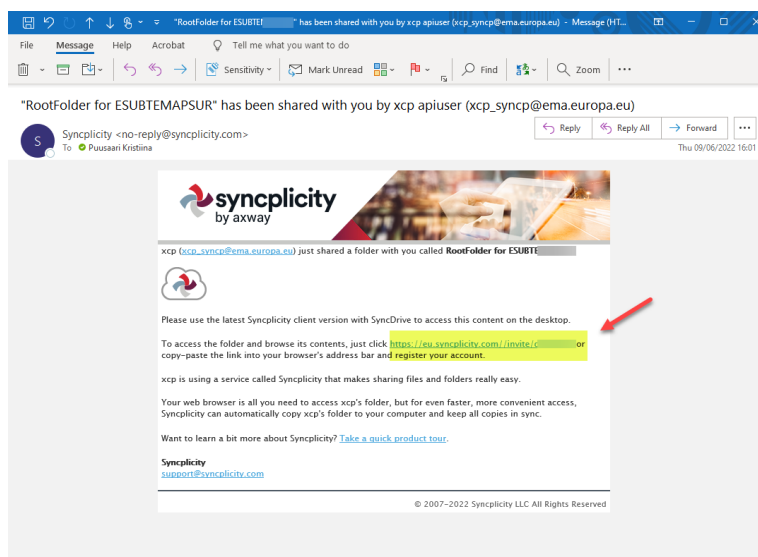
a) To reset your password, click to the link in the email. This will take you to a page that looks like this:

b) Enter the email address that you have **registered with** to use the eSubmission Gateway (the email address into which you received the notification email to). Please **do not** use any other email address. If the email address is no longer in use, please contact the [EMA Service Desk](#)

Create your password and click submit.

2.2. Reset your password without an email

Navigate to page: https://eu.syncplicity.com/ and click 'Reset Password'.

IMPORTANT NOTE: Please **do not** use the 'Create Account' option. If you need to **register** as a user, navigate to the registration module here: https://esubregistration.ema.europa.eu/registration/

d) When clicking 'Reset Password' you will be taken to this page:

e) This will take you to the same page as the link from the email where you can follow the password reset process.

3.   Accessing the Syncplicity Web Client

a) Please access the Web Client by clicking the link below for the EMA's Production environment:
https://eu.syncplicity.com/

b) If you have already reset your password/credentials during the UAT for XCOMP environment, the same credentials will now work for the production environment.

c) When you login using the 'login screen':

d) Please enter the email address and the password which you chose when you reset your password in the portal. This information can be found in the *bottom section* of the PDF attachment you received with the email confirming your registration for the Web Client.

Once you have logged in you will get to a screen as shown below. Please note that you **do not** need to install anything.

syncplicity
by axway

Activity Feed   Files   Shared Links   Install   Account

Windows • Outlook • Mac • Rights Management • iPhone and iPad • Android

Download Syncplicity

Supported Platforms   Latest Version Release Notes   Support Page

Also available for Mac, iPhone/iPad, Android
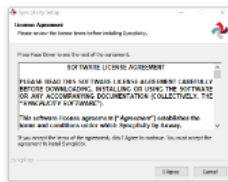
1. Install Syncplicity

Click on the download link above. Choose Save and double click the setup icon (or simply click Run) when the download completes. Setup will restart Windows Explorer during the installation in order to enable Syncplicity's icon overlays.
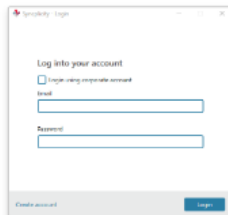
2. Log Into Your Account

Enter your account credentials to login to Syncplicity. If you are a corporate single sign-on user, enter your email address and select the "Login using corporate account" checkbox, otherwise for non-single sign-on accounts enter your email address and password.
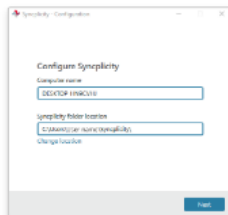
3. Register Your Computer

Your computer name and default Syncplicity folder location is entered automatically. However, you can change any of these values to enter a custom machine name and folder location. This step will link your computer to your Syncplicity account. Follow the installation steps.
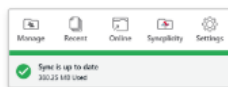
4. Let Syncplicity Run

Syncplicity will run in the background automatically, syncing all your files. This process will not slow down your machine. However, depending on the number of folders and size it might take several hours, even possibly days. To find out the status, simply click the Syncplicity icon using our new task bar panel.

d) Please navigate to option 'Files':

e) If you have access to both, XCOMP and Production, you will now see 2 'RootFolders' when you click to 'All Files'
f) Click the 'RootFolder for the routing ID, for example, in production this will be 'ESUBPYOURROUTINGID'

g) Please ensure you select the RootFolder for **your production routing ID** to send submissions to the EMA production environment. The submissions sent to the XCOMP are not considered received. You can recognise the production RootFolder from the letter 'P' in the middle of the Routing ID.

h) You will now be able to view your Web Client account. This is where you will send packages from **outbox**, you find the **archive** with your sent items and the **inbox** where you will receive acknowledgements and receipts for your submissions to the EMA.

Files

All Files ▸ **RootFolder for ESUB**

	Name ▲	Date modified	Type	Size
☐	👥 archive **Your sent items**	--	Editor	--
☐	👥 inbox **Receipts and Acknowledgements**		Editor	--
☐	👥 outbox **Send you submissions by adding the package in this folder**	--	Editor	--

4.   Sending Submissions

a) To send a submission to the EMA you will need to navigate to the "outbox" from the **RootFolder for your Production Routing ID**. Please ensure you select the correct routing ID for **Production**, you can recognise this from the letter P in the middle of the Routing ID e.g. ESUB**P**WONDERDRUGS

b) When you have navigated into the outbox, click the small 'cloud' icon to upload your submission package (zip package including the submission zip and the delivery file).
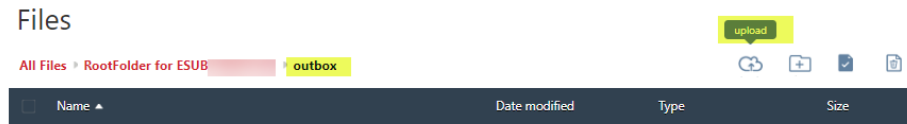
c) Select your package from your local drive by clicking 'Open'
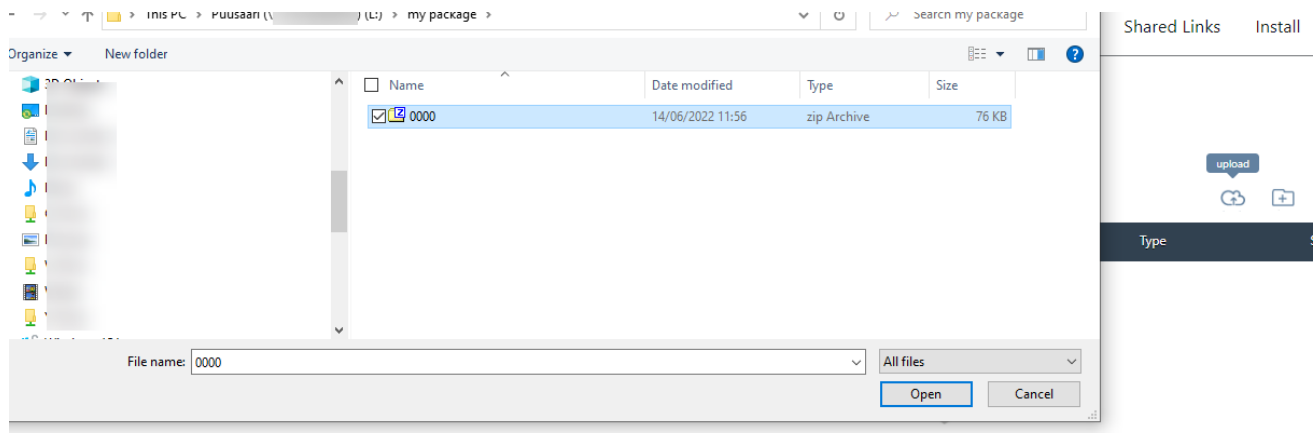
d) Selecting the package from your local drive will 'trigger' the sending. You will see a small 'Uploads' window as shown in the screenshot will appear while the upload (sending) is being automatically done.
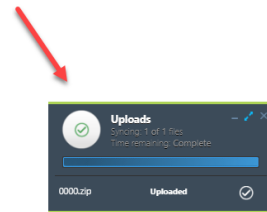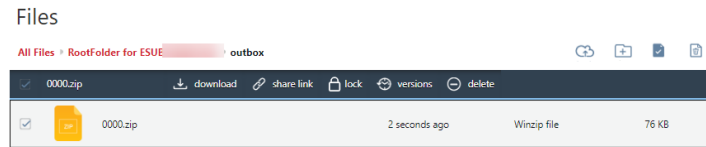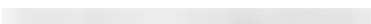

e) The system does **not** automatically refresh, but once the small 'Uploads' window has disappeared, the submission is sent. You can now either manually refresh the window and you can see that the outbox is again empty or you can navigate back to the RootFolder
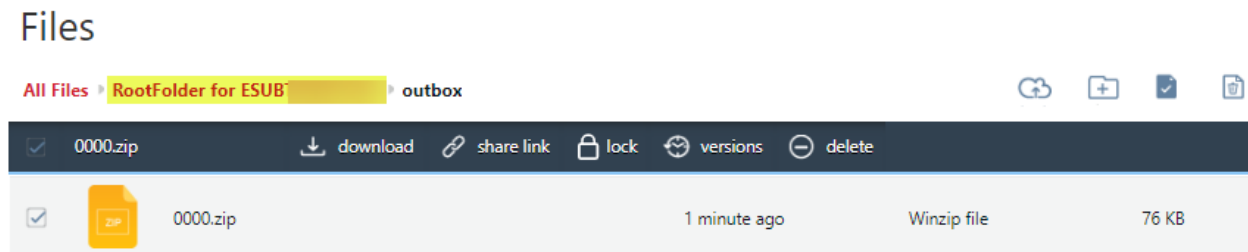
f) In the archive folder you can see the packages you have sent

g) In the 'inbox' you can find the MDN files (receipts) and the acknowledgements for your packages. It is possible to sort the view by clicking in the headers.

5. Viewing sent submissions

a) Once you have uploaded your submission package into the 'outbox' the submission is sent. The view doesn't autorefresh, but you can manually refresh the browser window or you can navigate back to the 'RootFolder' and into the 'archive' where you can see your sent submissions.

b) Please note that when navigating from one folder to another you need to click the folder icon, not the text

### 5.1. Viewing sent submission receipts and acknowledgements

a) To view receipts (MDN file) and acknowledgements select "Inbox" from the "RootFolder" below:

b) You will be able to see the receipt for the submission that was just sent. Please note that the order of files by default shows the oldest MDN on top and subsequently the oldest ACK (file) on top. You can sort this order by clicking the headers, for example to show the latest ACKs, please click 'Date modified' first and then 'Type':

Files

	Name	Date modified ▼	Type	Size
	FILE ci1655200949956.304235@uv2482_te.mdn	5 minutes ago	MDN file	1 KB
	FILE FAIL_ACK_pip_EMEA-123456_2022-06-10	4 days ago	file	1 KB
	FILE ci1654862372477.29292@uv2482_te.mdn	4 days ago	MDN file	1 KB
	FILE FAIL_ACK_UNKNOWN_SUBMISSION_TYPE	4 days ago	file	2 KB
	FILE ci1654846539916.2583@uv2482_te.mdn	4 days ago	MDN file	1 KB
	FILE FAIL_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
	FILE SUCCESS_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
	FILE FAIL_ACK_var-type2_WS_2274_0000	4 days ago	file	1 KB
	FILE ci1654802668937.4687@uv2483_te.mdn	5 days ago	MDN file	1 KB
	FILE ci1654801684437.3760@uv2483_te.mdn	5 days ago	MDN file	1 KB

All Files ▸ RootFolder for ESUB ▸ inbox

c) To read the MDN file from the inbox folder, select and download the file
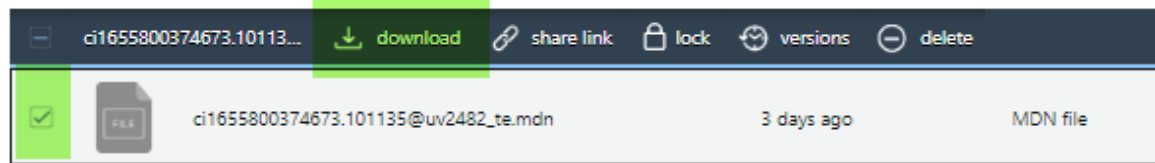
d) Once you have downloaded the MDN, you can open the file in a txt editor e.g. Notepad ++. The following screenshot shows an example of a test file where the users routing ID and the submission filename have been hidden.

c) When the submission has been successfully processed by the EMA's review system you will receive an acknowledgement in the Web Client inbox. You can download the ACK to see the details:

d) If your submission was processed unsuccessfully a failure acknowledment will be shown in the Web Client inbox as shown below:

6. Error codes

If your submission was unsuccessful, you will be able to find out the reason for this by viewing the error code inside the acknowledgement message. The error codes list is regularly updated and is available here: Error codes list

7. Important notes:

1. Please **do not** use the 'Create Account' option. **If you need to register as a user**, please navigate to the **registration module** here:
https://esubregistration.ema.europa.eu/registration/

2. The system allows you to create new folders and rename the existing 'archive', 'inbox' and 'outbox'. Please **DO NOT** rename or delete any of the folders. This will lead into malfunctioning of the system and you will not be able to send any submissions.

If you experience any issues during using the Web Client please contact:

EMA Service Desk