



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

June 2022  
EMA/737304/2012

## How to send submissions via the Syncplicity Web Client – XCOMP UAT

### Guidance for applicants

---

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands  
**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)  
**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

An agency of the European Union



## Table of Contents

<b>1. Reset of password .....</b>	<b>4</b>
1.1. reset your password using link from an email from Axway Syncplicity.....	4
<b>2. Accessing the Syncplicity Web Client.....</b>	<b>7</b>
<b>3. Sending Submissions.....</b>	<b>10</b>
<b>4. Viewing sent submissions .....</b>	<b>14</b>
4.1. Viewing sent submission receipts and acknowledgements .....	14
<b>5. Error codes .....</b>	<b>17</b>
<b>6. Important notes: .....</b>	<b>17</b>

The [eSubmission Gateway 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.

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

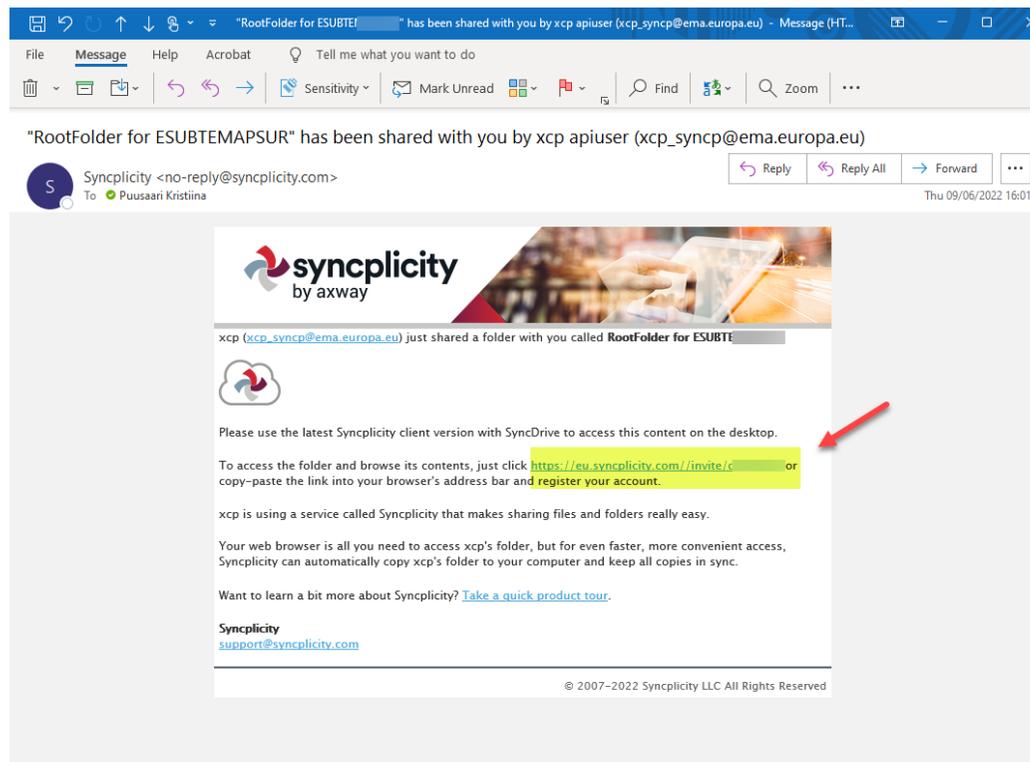
**Please note that you will only be able to send submissions via the Syncplicity Web Client if you have successfully registered, received email confirmation with your login details and subsequently reset your password in Syncplicity.**

# 1. Reset of password

## 1.1. 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 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:

syncplicity  
by axway

Login | Support

### Create an Account to View the Shared Folder

We just need a name and a real password for your account and you'll be on your way.

Email \*  
Kristina.Puusaari@ema.europa.eu

First Name \*  
[Input Field]

Last Name \*  
[Input Field]

Password \*  
[Input Field]

Confirm Password \*  
[Input Field]

PrivacyRegion:  
EU PrivacyRegion About PrivacyRegions

By checking this box, you are indicating you have read and agree to the Terms of Service.

Submit or Cancel

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.

c) Alternatively, navigate to page: <https://eu.syncplicity.com/> and click 'Reset Password'.

**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/>

https://my.syncplicity.com

syncplicity  
by axway

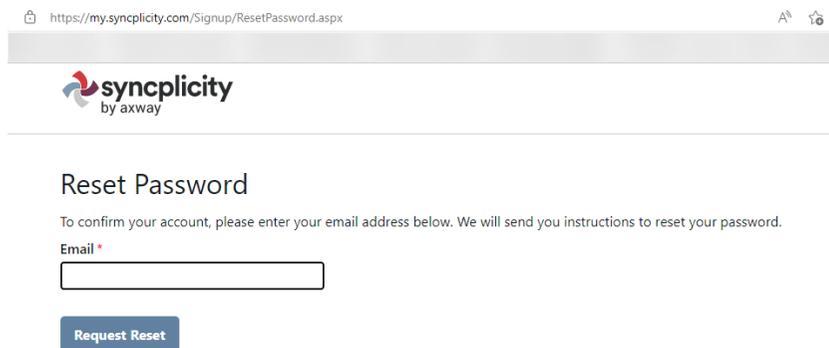
The easiest way to sync and share your files

Log in to Syncplicity

Email  
[Input Field] Next

Create Account  
Reset Password  
Where do I enter my password?

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



https://my.syncplicity.com/Signup/ResetPassword.aspx

**syncplicity**  
by axway

## Reset Password

To confirm your account, please enter your email address below. We will send you instructions to reset your password.

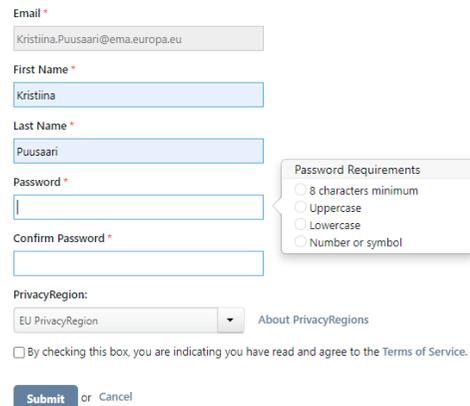
Email \*

Request Reset

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

## Create an Account to View the Shared Folder

We just need a name and a real password for your account and you'll be on your way.



Email \*

First Name \*

Last Name \*

Password \*

Confirm Password \*

PrivacyRegion:

EU PrivacyRegion [About PrivacyRegions](#)

By checking this box, you are indicating you have read and agree to the [Terms of Service](#).

Submit or Cancel

**Password Requirements**

- 8 characters minimum
- Uppercase
- Lowercase
- Number or symbol

## 2. 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) You will see the login screen:



---

The easiest way to sync and share your files

Log in to Syncplicity

Email

Password

Password required.

Log in

Create Account

Reset Password

Where do I enter my password?

c) 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.

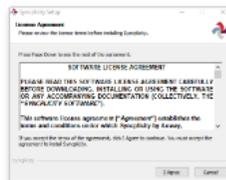
Once you have logged in you will get to a screen like this;

## Download Syncplicity

[Supported Platforms](#) [Latest Version Release Notes](#) [Support Page](#)

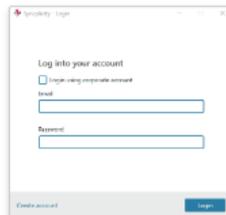
Also available for Mac, iPhone/iPad, Android

### 1. Install Syncplicity



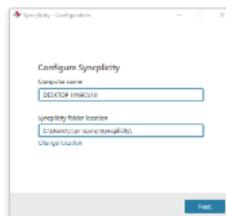
Click on the download link above. Choose Save and double click the setup icon (or simply click Run) when the download completes. Setup will restart Windows Explorer during the installation in order to enable Syncplicity's icon overlays.

### 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



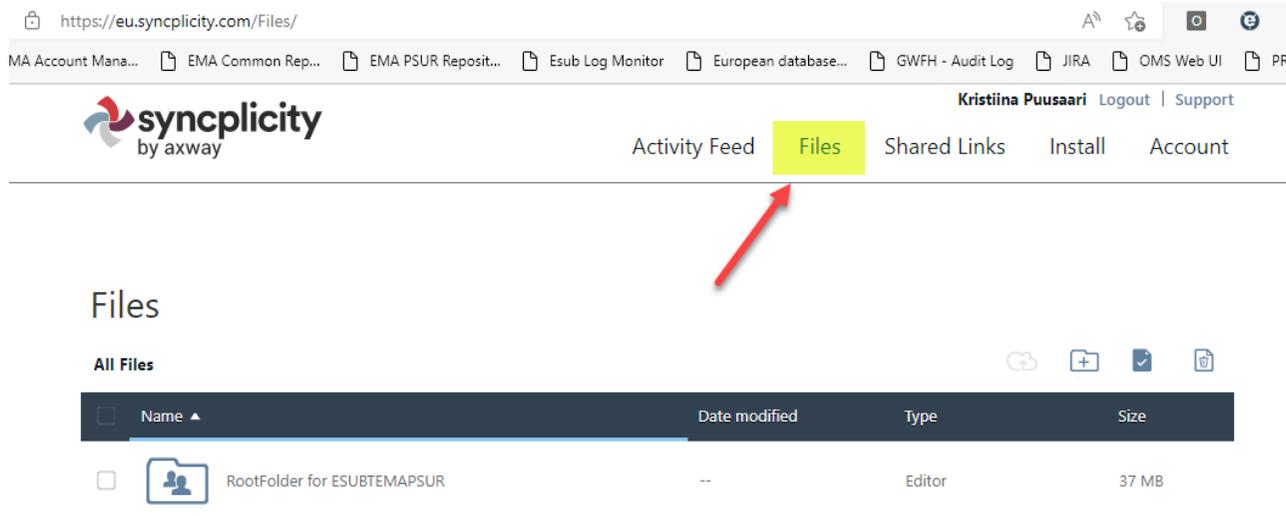
Your computer name and default Syncplicity folder location is entered automatically. However, you can change any of these values to enter a custom machine name and folder location. This step will link your computer to your Syncplicity account. Follow the installation steps.

### 4. Let Syncplicity Run

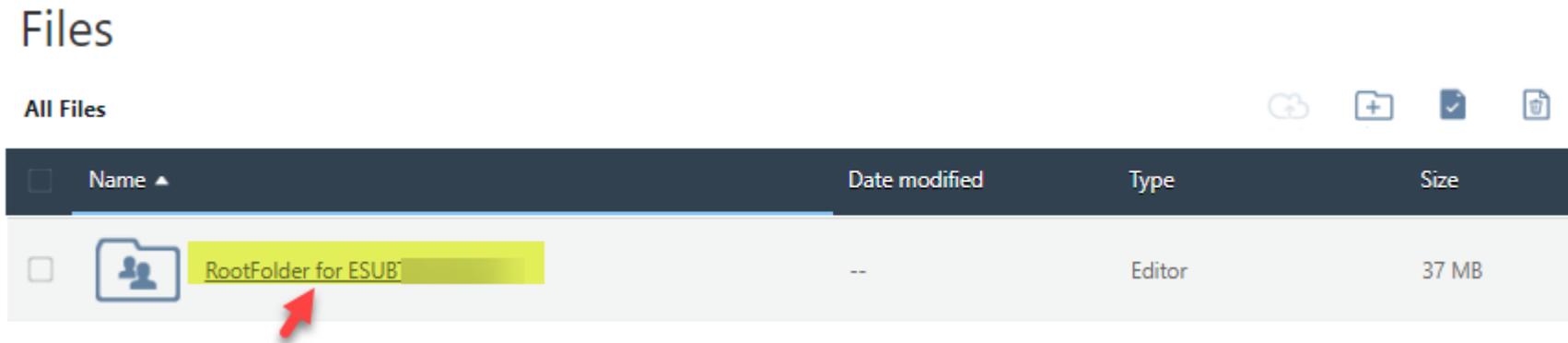


Syncplicity will run in the background automatically, syncing all your files. This process will not slow down your machine. However, depending on the number of folders and size it might take several hours, even possibly days. To find out the status, simply click the Syncplicity icon using our new task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

d) Please navigate to option 'Files':



e) Click the 'RootFolder for the routing ID, for example, in production this will be 'ESUBPYOURROUTINGID'



- f) 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



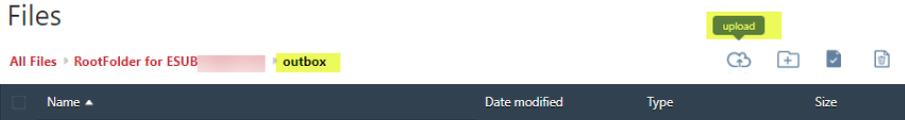
<input type="checkbox"/>	Name ▲	Date modified	Type	Size
<input type="checkbox"/>	 archive <b>Your sent items</b>	--	Editor	--
<input type="checkbox"/>	 inbox <b>Receipts and Acknowledgements</b>		Editor	--
<input type="checkbox"/>	 outbox <b>Send you submissions by adding the package in this folder</b>	--	Editor	--

### 3. 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. ESUBPWONDERDRUGS

**Note:** For the UAT on XCOMP this should be ESUBTYOURROUTINGID

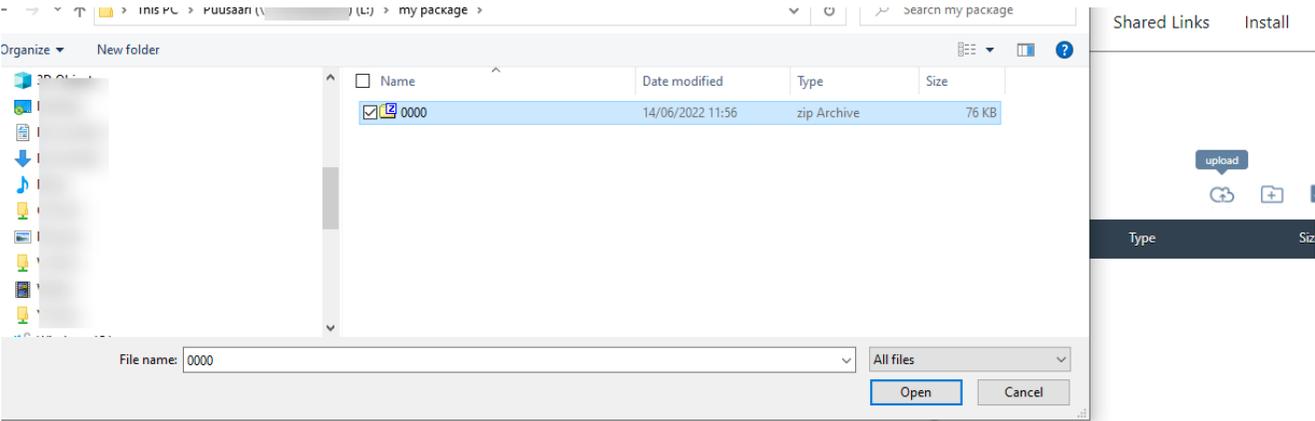
b) When you have navigated into the outbox, click the small 'cloud' icon to upload your submission package (zip package including the submission zip and the delivery file).



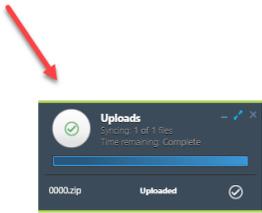
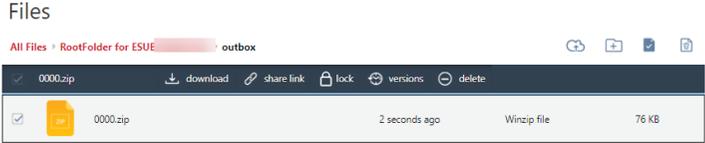
**This folder is empty**

You can add files with our [desktop application](#) or [web uploader](#).

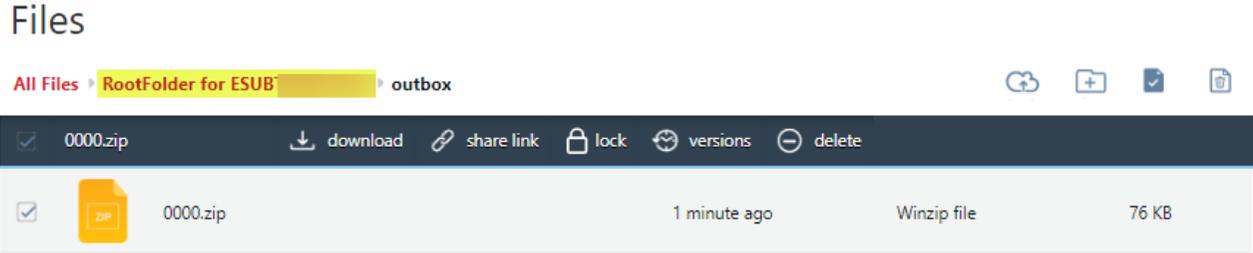
c) Select your package from your local drive by clicking 'Open'



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 doesn't 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

## Files

All Files > RootFolder for ESUB > archive

Name	Date modified	Type	Size
<input type="checkbox"/> 0000.zip	5 minutes ago	Winzip file	76 KB
<input type="checkbox"/> 0031.zip	5 days ago	Winzip file	31 MB
<input type="checkbox"/> [Word document icon]	4 days ago	Word document	477 KB
<input type="checkbox"/> delivery_1219714714.zip	4 days ago	Winzip file	2 MB

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.

## Files

All Files > RootFolder for ESUB > inbox

Name	Date modified	Type	Size
<input type="checkbox"/> ci1655200949956.304235@uv2482_te.mdn	5 minutes ago	MDN file	1 KB
<input type="checkbox"/> FAIL_ACK_pip_EMEA-123456_2022-06-10	4 days ago	file	1 KB
<input type="checkbox"/> ci1654862372477.29292@uv2482_te.mdn	4 days ago	MDN file	1 KB

## 4. 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.:

### Files

All Files > RootFolder for ESUB > archive



<input type="checkbox"/>	Name ▲	Date modified	Type	Size
<input type="checkbox"/>	 0000.zip	5 minutes ago	Winzip file	76 KB
<input type="checkbox"/>	 0031.zip	5 days ago	Winzip file	31 MB
<input type="checkbox"/>	 	4 days ago	Word document	477 KB
<input type="checkbox"/>	 delivery_1219714714.zip	4 days ago	Winzip file	2 MB

### 4.1. 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:

# Files

All Files > RootFolder for ESUB > inbox



<input type="checkbox"/>	Name	Date modified ▾	Type	Size
<input type="checkbox"/>	 ci1655200949956.304235@uv2482_te.mdn	5 minutes ago	MDN file	1 KB
<input type="checkbox"/>	 FAIL_ACK_pip_EMEA-123456_2022-06-10	4 days ago	file	1 KB
<input type="checkbox"/>	 ci1654862372477.29292@uv2482_te.mdn	4 days ago	MDN file	1 KB
<input type="checkbox"/>	 FAIL_ACK_UNKNOWN_SUBMISSION_TYPE	4 days ago	file	2 KB
<input type="checkbox"/>	 ci1654846539916.2583@uv2482_te.mdn	4 days ago	MDN file	1 KB
<input type="checkbox"/>	 FAIL_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
<input type="checkbox"/>	 SUCCESS_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
<input type="checkbox"/>	 FAIL_ACK_var-type2_WS_2274_0000	4 days ago	file	1 KB
<input type="checkbox"/>	 ci1654802668937.4687@uv2483_te.mdn	5 days ago	MDN file	1 KB
<input type="checkbox"/>	 ci1654801684437.3760@uv2483_te.mdn	5 days ago	MDN file	1 KB

- 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:

### Files

All Files ▶ RootFolder for ESUB [redacted] ▶ inbox



<input type="checkbox"/>	Name ▼	Date modified	Type	Size
<input type="checkbox"/>	 SUCCESS_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
<input type="checkbox"/>	 FAIL_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB

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

### Files

All Files ▶ RootFolder for ESUB [redacted] ▶ inbox



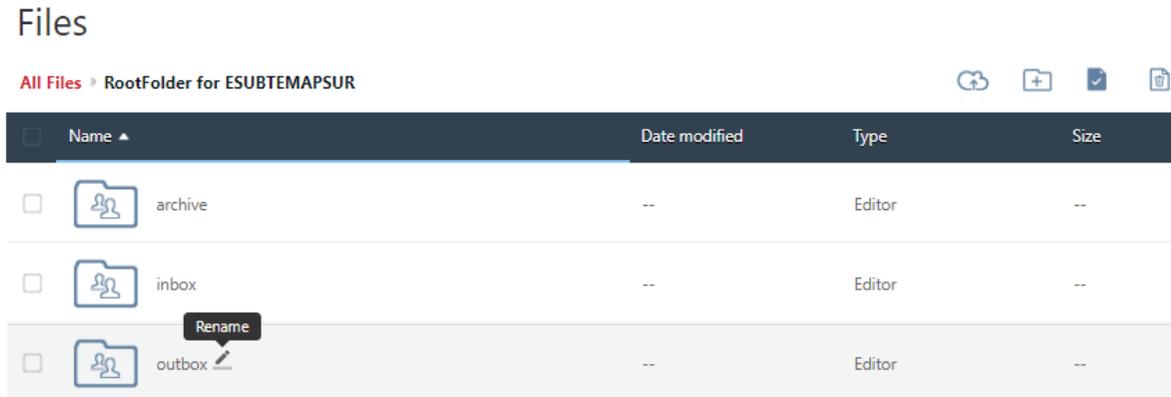
<input type="checkbox"/>	Name ▼	Date modified	Type	Size
<input type="checkbox"/>	 SUCCESS_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB
<input type="checkbox"/>	 FAIL_ACK_var-type2_WS_2274_0031	4 days ago	file	1 KB

## 5. 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](#)

## 6. Important notes:

The system allows you to create new folders and rename the existing 'archive', 'inbox' and 'outbox'. Please try to refrain from renaming the folders.



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

[EMA Service Desk portal](#)