



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eSubmission Gateway web client

User Acceptance Testing (UAT) - Guidance

For companies testing the online registration and upload of submissions via the Gateway web client

The aim of the UAT is to verify that the eSubmission Gateway meets the requirements from the users' perspective. The objective of this phase is:

Test and confirm successful online registration, upload of submissions via the web client in the EMA test environment, receipt of acknowledgements

Companies who wish to participate in UAT must first complete the form at the end of this document and submit it via email to natasha.brown@ext.ema.europa.eu. Once the UAT participation request has been received and reviewed by the EMA, a confirmation email will be sent containing details of the next steps.

1.1. Compiling your UAT test dossiers

In order to participate in the UAT phase you will need to comply with the following requirements and complete the form on page 3 of this document:

- a. Companies must submit 10 eCTD sequences to the EMA. *In case of registered SME applicant: if you do not have 10 submission sequences we can still consider your participation in UAT.*
- b. It is recommended to use sequences from a previously submitted dossier which can be uploaded into the EMA test system. The content of the submissions will not be validated.
- c. The first submission has to be an initial submission to allow the creation of the test dossier.
- d. Subsequent submissions should vary and be of different types. We are expecting you to submit 6 correct / eCTD compliant submissions followed by 4 submissions with errors which do not comply with the eCTD specification or the naming convention.
- e. The names of products to be submitted must be provided on the form attached to this document in the specified filename convention.



1.2. UAT time requirement

UAT will take place between set dates which will be published as soon as possible. Unfortunately we are unable to accommodate individual requests to participate in UAT outside of the allocated timescale.

UAT Participation Request Form

Date of request:

Company Name:

UAT Contact Person:

Email address:

Details of dossiers to be submitted during UAT:

Please note that 4 of the 10 submissions must not be compliant with the current eCTD technical specification at the time of upload via the web client. The reason for this is to ensure that you are able to test both the negative and positive technical acknowledgements. In case of a registered SME applicant: if you do not have 10 submission sequences we will still consider your participation in UAT.

	Filename of submissions to be uploaded via EMA web client	Expected technical validation
Example	XYZ_ESUBVAL_Hxxxxxx_Wonderpill_initial-maa_0020.zip	Positive
1		Positive (compliant with current eCTD technical specification)
2		Positive
3		Positive
4		Positive
5		Positive
6		Positive
7		Negative (not compliant with current eCTD technical specification)
8		Negative
9		Negative
10		Negative

***Please ensure your submissions are uploaded in the order listed above.**