



Title: Connect to e-Submission trading community		
Applies to: EMEA Gateway Trading Partners		
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1. Changes since last revision

This document is a new WIN

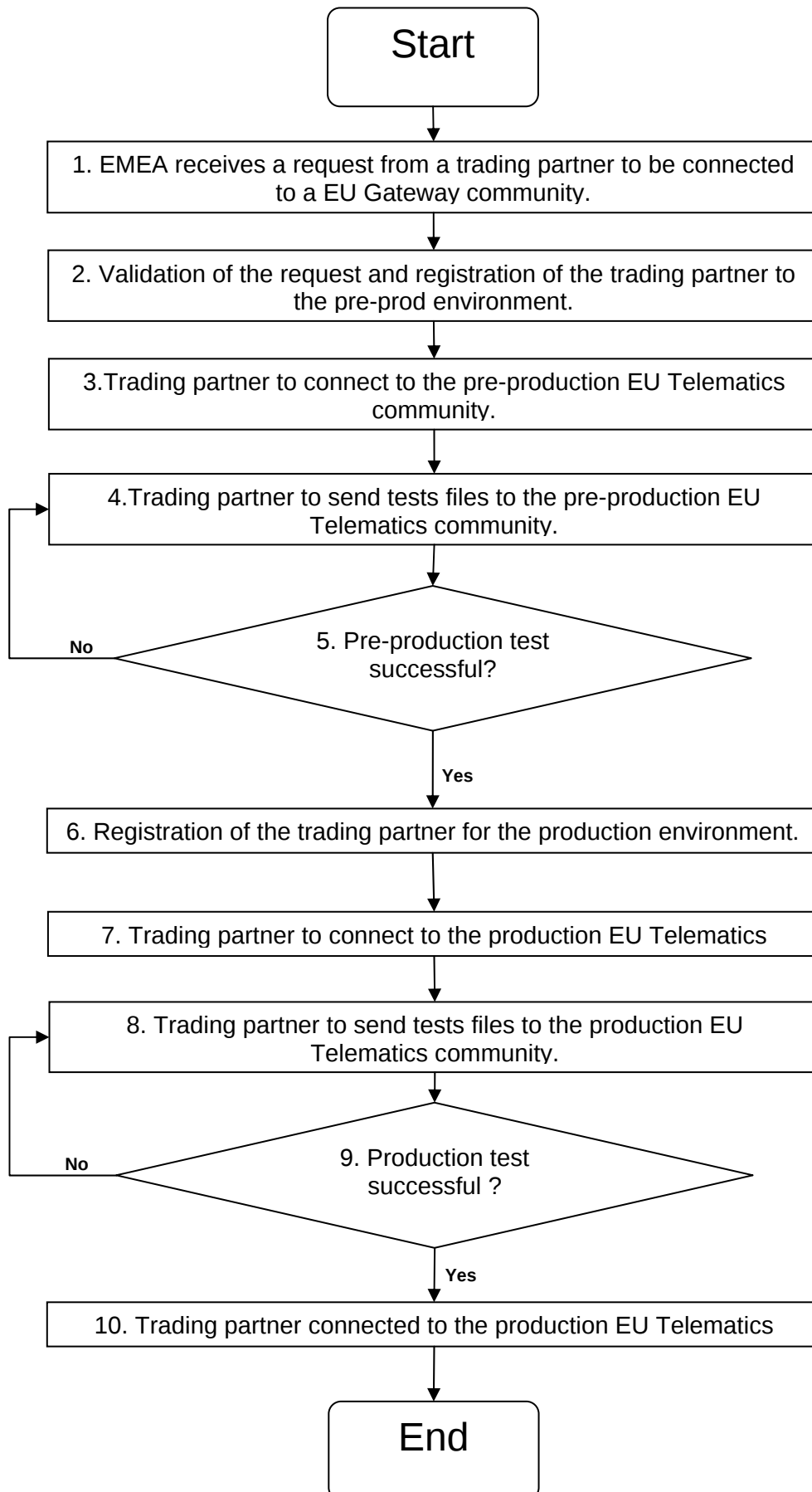
2. Records

This document is stored in EDMS, the EMEA Document Management System

3. Instructions

This document, WIN/IT/5030, is to be used in conjunction with SOP/IT/5019.
It implements, for e-Submission Traders Community, the generic procedure explained on SOP/IT/5019.

Please do follow the steps detailed within this document, WIN/IT/5030, to start submitting files to eSubmissions communities via the Gateway System.



Step	Action
1	The EMEA receives a request for a Trading partner to be connected to a EU Telematics Community via some communications channel (PM, helpdesk, other...)
2	The trading partner will register to connect to the pre-production environment.
3	The Trading partner will connect to the pre-production environment following a step-by-step manual.
4	Once connected to the pre-production environment, the trading partner will send test files as described in the associated WIN for the Eudra application.
5	Repeat test until succesful, as described in the associated WIN for the Eudra application.
6	The trading partner will register to connect to the production environment.
7	The Trading partner will connect to the production environment following a step-by-step manual.
8	Once connected to the production environment, the trading partner will send test files as described in the associated WIN for the Eudra application.
9	Repeat test until succesful, as described in the associated WIN for the Eudra application.
10	The Trading partner is considered connected to the Eudra production environment.

3.1 EMEA receives a request from a trading partner to be connected to an EU Gateway community.

3.2 Validation of the request and registration of the trading partner to the pre-prod environment

The registration form can be found at <http://www.emea.europa.eu/hsection/gateway/gateway.htm> under the eSubmissions documents section. The document is called "Registration Form.doc"

The trading partner fills in the form and contact the gateway support to get registered for the e-Submissions communities by contacting gatewaysupport@emea.europa.eu.

The Gateway Support team will contact back the trading partner once the process is completed.

3.3 Trading partner to connect to the pre-production EU Telematics community

a) Connect to the EMEA pre-production gateway where details can be found in the document called "Connecting to the EMEA Gateway eSubmissions communities" located under the eSubmissions documents section at <http://www.emea.europa.eu/hsection/gateway/gateway.htm>.

b) Please send the same information about your community to gatewaysupport@emea.europa.eu to enable connectivity to the pre-production gateway.

3.4 Trading partner to send tests files to the pre-production EU Telematics community.

The trading partner should perform the following test submission on Pre-production:

Send a Test eCTD submission (Module 1 to 5) clearly marking it as "TEST" in the file description (see file format under Q&A document for implementation of eSubmissions via the EMEA Gateway http://www.emea.europa.eu/htms/human/raquidelines/dossier_format.htm (under Electronic Submissions to EMEA)

E.g.

0012345678_ESUBPROD_GlaxoGroupLTD_Arixtra_HC0901_Fondapariux_MAA_5_TEST_
AnnexCommissions_01012009_0020.zip

3.5 Pre-production tests successful/unsuccessful

If the Pre-production test is successful, EMEA CIG (EMEA Central Information Group) will send an email back to the Submitting Organisation or IT Service organisation as specified on the Registration form in step 3.2 informing them of the successful test. Then continue with the next step.

In the case of an unsuccessful Pre-production test, the trading partner should perform it again until it is successfully completed.

3.6 Registration of the trading partner for the e-Submission Production environment

The registration form can be found at <http://www.emea.europa.eu/hsection/gateway/gateway.htm> under the eSubmissions documents section. The document is called "Registration Form.doc"

The trading partner fills in the form and contact the gateway support to get registered for the e-Submissions communities by contacting gatewaysupport@emea.europa.eu.

The Gateway Support team will contact back the trading partner once the process is completed.

3.7 Trading partner to connect to the Production e-Submission

a) Connect to the EMEA production gateway where details can be found in the document called "Connecting to the EMEA Gateway eSubmissions communities" located under the eSubmissions documents section at <http://www.emea.europa.eu/hsection/gateway/gateway.htm>.

b) Please send the same information about your community to gatewaysupport@emea.europa.eu to enable connectivity to the production gateway.

3.8 Once connected to the production environment, the trading partner will send test files as described in the associated WIN for the Eudra application

Step not applicable for e-Submission trading partners.

3.9 Repeat test until succesful, as described in the associated WIN for the Eudra application

Step not applicable for e-Submission trading partners.

3.10 The Trading partner is considered connected to the Eudra production environment

The trading partner is properly connected and can start sending files to the Production e-Submission community.