

21 October 2021 EMA/550318/2021 Information Management

Article 57 User Interface (UI) Installation Guide

Installation of Article 57 UI components and initial set up

This document provides detailed steps to follow to install Article 57 components on users' computers to support the use of the Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) data-entry tool user interface known as EVWEB.

Step 1: Check which version of Windows you are using on your computer by following Microsoft guidance <u>here</u>.

Step 2: If your windows version is W10 20H1 or later then download EudraVigilance.msi from here.

If your windows version is older than W10 20H1 then download EudraVigilance.msi from here .

Step 3: Run EudraVigilance.msi as Administrator and follow the installation wizard.

For a silent installation, the following command, as an example, can be used from the folder where you have downloaded the installer: "msiexec.exe /I EudraVigilance.msi /qb".

For a common installation, double click on EudraVigilance.msi and follow the installation wizard:



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 Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

 Address for visits and deliveries
 Refer to www.ema.europa.eu/how-to-find-us

 Send us a question
 Go to www.ema.europa.eu/contact

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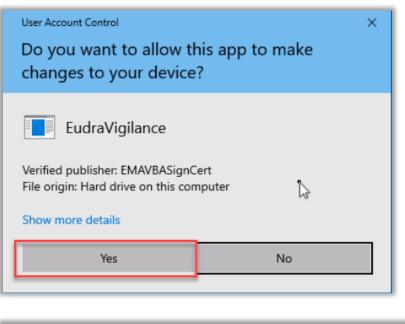


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Select the installation folder and confirm installation:

🔀 EudraVigilance	-		×
Select Installation Folder			-
The installer will install EudraVigilance to the following folder.			
To install in this folder, click "Next". To install to a different folder, enter it be	ow or	click "Bro	owse".
<u>F</u> older:			
C:\Program Files\Beyond\EudraVigilance\		Browse	
		<u>D</u> isk Cos	st
Install EudraVigilance for yourself, or for anyone who uses this computer:			
● Everyone			
⊖ Just <u>m</u> e			
< <u>B</u> ack Next>		Ca	ncel

😾 EudraVigilance	-		×
Confirm Installation			5
The installer is ready to install EudraVigilance on your computer.			
Click "Next" to start the installation.			
< <u>B</u> ack <u>N</u> ext >		Ca	ncel



😥 EudraVigilance	_		×
Installation Complete			5
EudraVigilance has been successfully installed.			
Click "Close" to exit.			
< <u>B</u> ack	<u>C</u> lose	Ca	ncel

You must now finalise the set up needed to access the required environment:

- EVWEB production: <u>https://eudravigilance.ema.europa.eu/x</u>
- XCOMP (test) environment: <u>https://evtest.ema.europa.eu/x</u>
- EVWEB training environment: <u>https://eudravigilance-training.ema.europa.eu/x/</u>

This will be done in *Internet Explorer or an Internet Browser which can emulate Internet Explorer* and will be further described in the next steps.

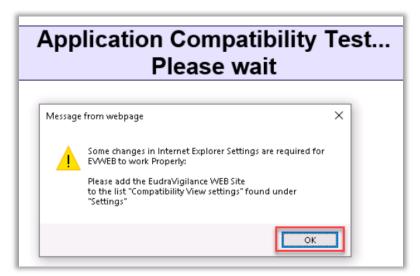
Step 4. Go to the required environment (our screenshot below shows the address of the production environment). Allow OCX file to be registered with the Internet Browser as follows below:

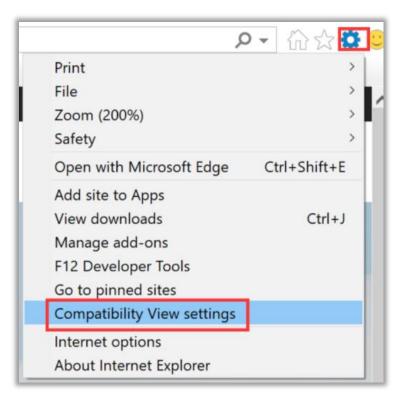
K 🧭 🗇 https://eudravigilance.ema.europa.eu/x/x.asp	τœ
Explorer mode. Most pages work better in Microsoft Edge.	
Application Compatibility Test Please wait	
Message from webpage × Next Some changes in Internet Explorer Settings are required for EVWEB to work Properly: Please add the EudraVigilance WEB Site to the list "Compatibility View settings" found under "Settings" OK	
This web page wants to run the following add-on: 'mscomctl.ozy' <u>from Microsoft</u> Corporation'. <u>What's the risk?</u> Microsoft Store	Allow 🔻 🗙

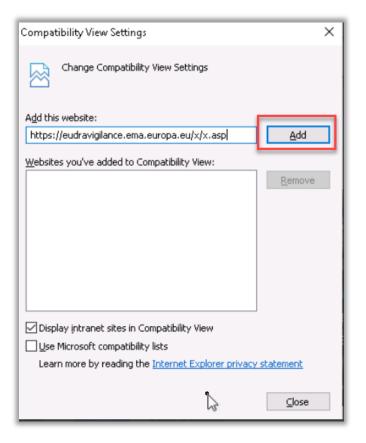
Step 5. Allow the Add-in:

C o https://eudravigilance.ema.europa.eu/x/x.asp	
Application Compatibility Test Please wait	
_	
This web page wants to run the following add-on: 'mscomctl.ocx' from 'Microsoft Corporation'. What's the risk?	Allow Allow for all websites

Step 6. Adjust the compatibility view in the Internet Browser; go to tools and then to Compatibility View Settings and follow the steps bellow:







Compatibility View Settings	×
Change Compatibility View Settings	
Add this website:	
Add	
Websites you've added to Compatibility View:	
Remov	e
Display intranet sites in Compatibility View	
□ Use Microsoft compatibility lists	
Learn more by reading the Internet Explorer privacy statement	
Glose	

Step 7. Adjust the pop-up blocker and allow Art57 UI to be whitelisted; once the pop-up warning is displayed, follow the instructions bellow:

Message	from webpage X
	Please disable any Popup Blocker for this Domain to allow EVWEB to work properly.
	The standard Internet Explorer Popup Blocker settings are located in Internet Options / Privacy
	Click OK to continue, and after having disabled the Popup Blocker refresh the page (F5) to retry.
	ОК
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nce - Restricted Area 🗴 🙋 EV6 WEB Interface - DHTML 🛛 🗙 🕂	
Attps://eudravigilance.ema.europa.eu/x/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 Attps://eudravigilance.ema.europa.eu/x.asp?XI=6 A	6 6
	Pop-ups blocked: ×
prer mode. Most pages work better in Microsoft Edge.	 <u>about:blank</u> <u>about:blank</u>
	Always allow pop-ups and redirects from https://eudravigilance.ema.europa.eu
Application Loadin	Continue blocking
Please wait	Manage Done
	لي ا

Once the Art57 website is whitelisted in the pop-up blocker, the website will finally load:

EudraVigilance - Restricted Area × E
← → C (https://eudravigilance.ema.europa.eu/x/x.asp?XI=6
Art57
You're in Internet Explorer mode. Most pages work better in Microsoft Edge.
Display Settings V (EVHUMANWT - Eudravigilance Web Trader) @ Hu
For the UK, as from 1.1.2021, EU Law applies only to the territory of Northern Ireland (NI) to the extent foreseen in the Protocol on Ireland/NI WEB Trader Products MedDRA
Reset App Reset Section Clear