



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# EV Reporting process for users: Introduction to EVWEB

---

**Training Module EV-M3b**



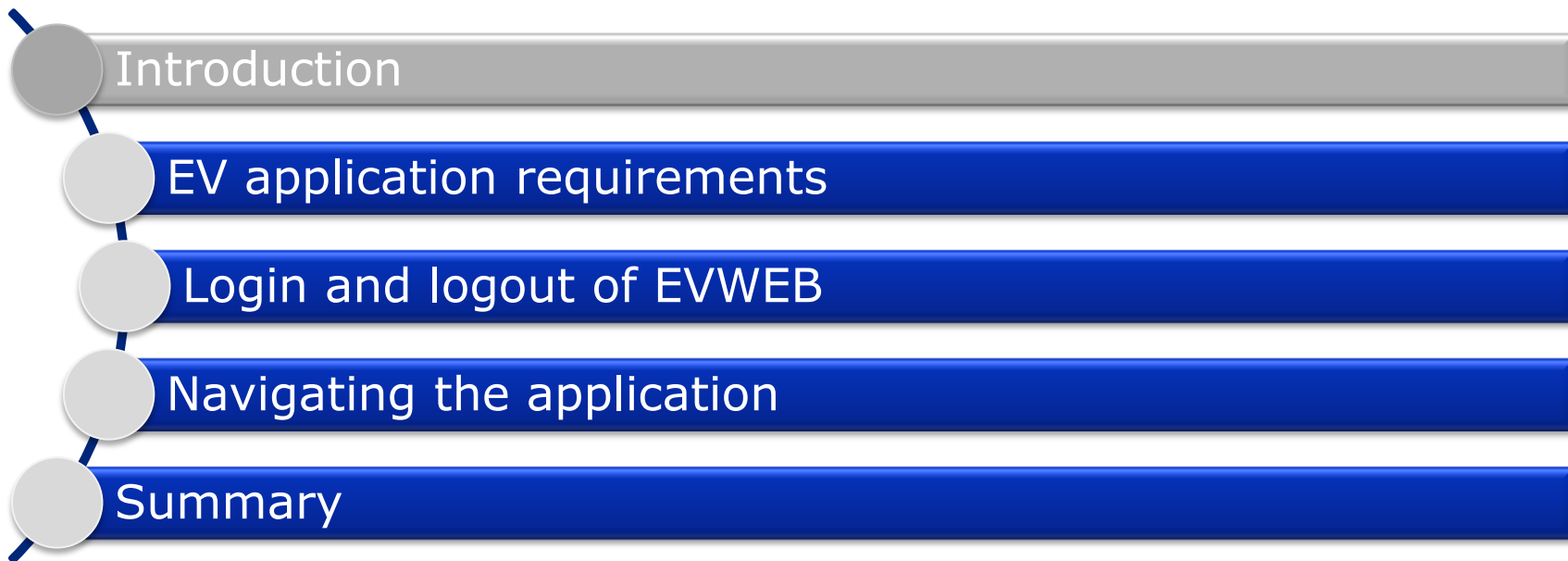


# Content Summary

- Introduction
- EV application requirements
- Login and logout of EVWEB
- Navigating the application
- Summary



# Content Summary



## Introduction: Target audience

- Target audience for this training module:
  - Users of EVWEB
    - National Competent Authorities (NCAs) in the European Economic Area (EEA)
    - Marketing authorisation holders (MAHs)
    - Sponsors of clinical trials (Sponsors)
    - Research institutions/Academia

## Introduction: Learning objectives

Following the completion of EV-M3b training module you should be able to understand:

- EVWEB application technical requirements
- Login and logout of EVWEB
- Navigate the sections of EVWEB



## EV application requirements

- XEVMPD
  - Requires Internet Explorer 11 and below
- EVWEB
  - Latest internet browsers IE 11, Firefox and Chrome



▶ [Home](#) ▶ [Human regulatory](#) ▶ [Pharmacovigilance](#) ▶ [EudraVigilance](#)

## EudraVigilance

[Email](#) [Print](#) [Help](#) [Share](#)

**EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised in the European Economic Area (EEA). The European Medicines Agency (EMA) operates the system on behalf of the European Union (EU) medicines regulatory network.**

EudraVigilance supports safe and effective use of medicines by facilitating:

- ▶ electronic exchange of individual case safety reports between EMA, national competent authorities, marketing authorisation holders and sponsors of clinical trials in the EEA;
- ▶ early detection and evaluation of possible safety signals;
- ▶ better product information for medicines authorised in the EEA.

This electronic reporting is obligatory for marketing authorisation holders and sponsors for clinical trials.

### Login for registered users



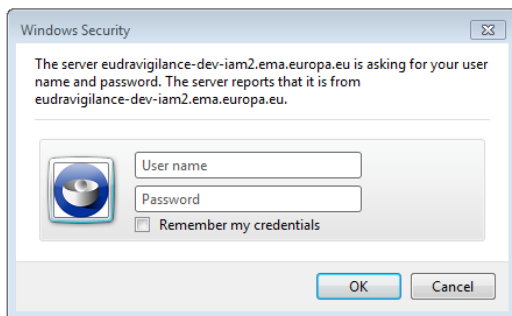
### Related content

▶ [Pharmacovigilance](#)

### Related EU legislation



# xEVMPD Login



*Log in with EMA unique credentials*

*select the organisation on behalf which actions need to be performed*





# EudraVigilance



Human Restricted



## EV Services

- ▼ EVWEB - ICSR
- ▼ art57/XEVMPD
- ▼ xEVMPD Export
- ▼ xEVMPD Bulk update
- ▼ EV Data Warehouse

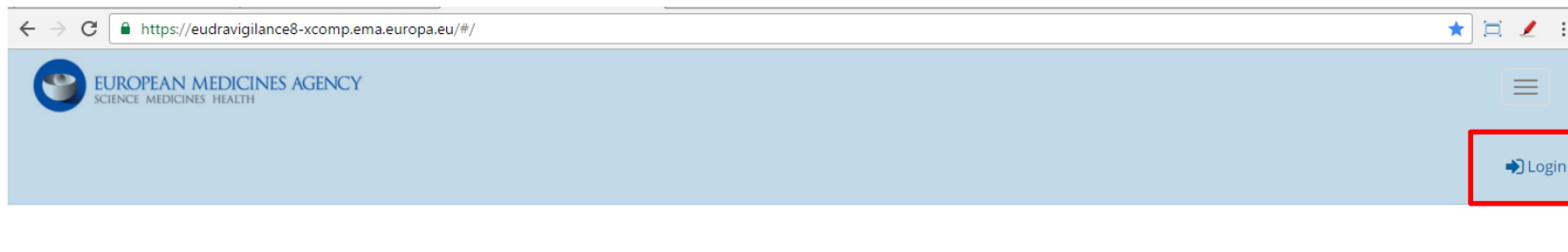


# xEVMPD





# EVWEB Login





## Display sections – Smaller computer screens

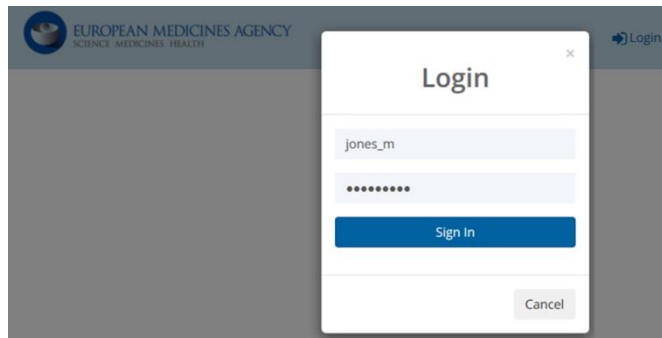




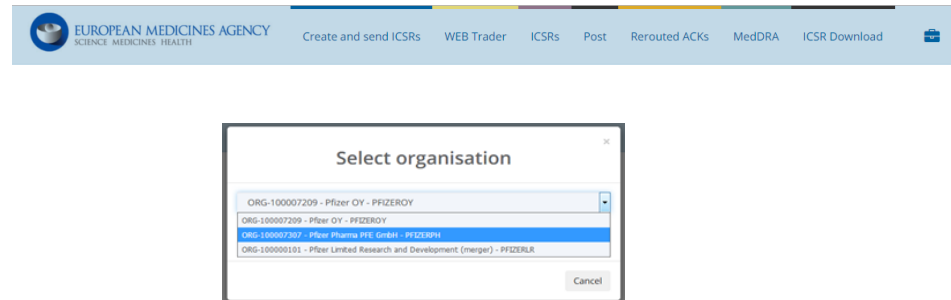
# Display sections – Smaller computer screens



# EVWEB Login



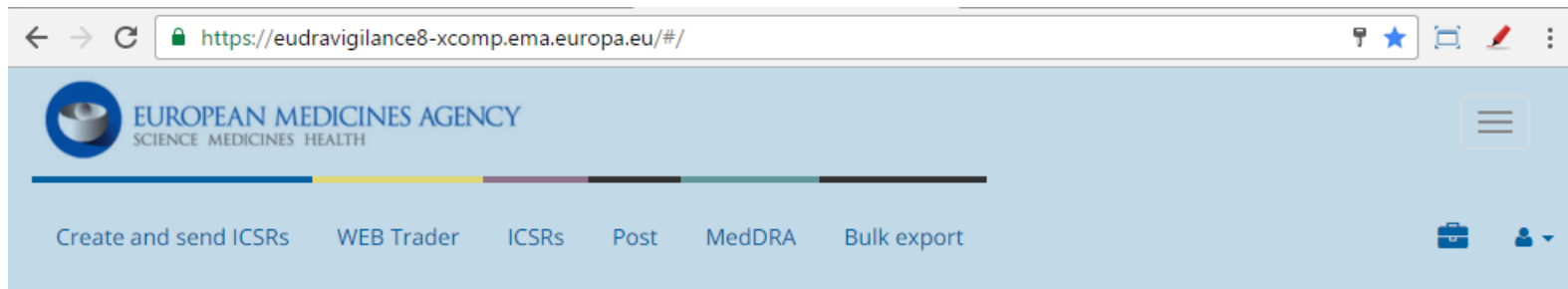
*Log in with EMA unique credentials*



*select the organisation on behalf which actions need to be performed*

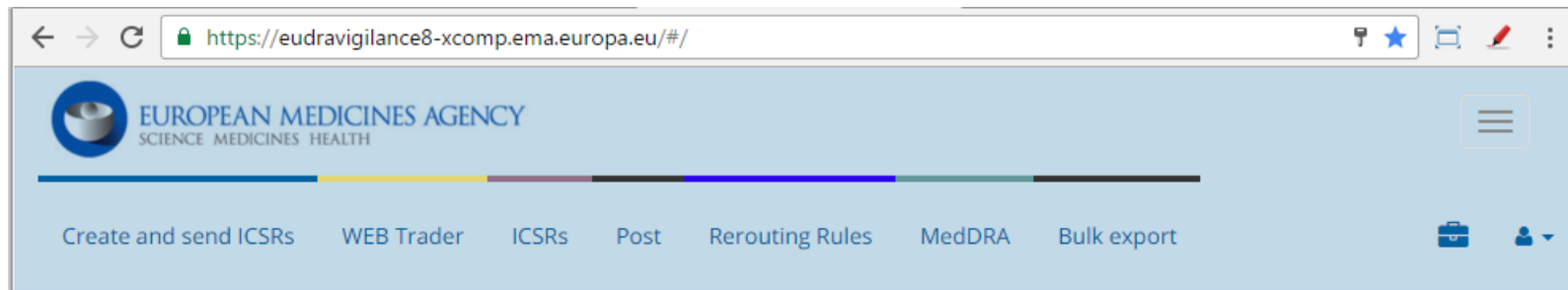


# MAH View



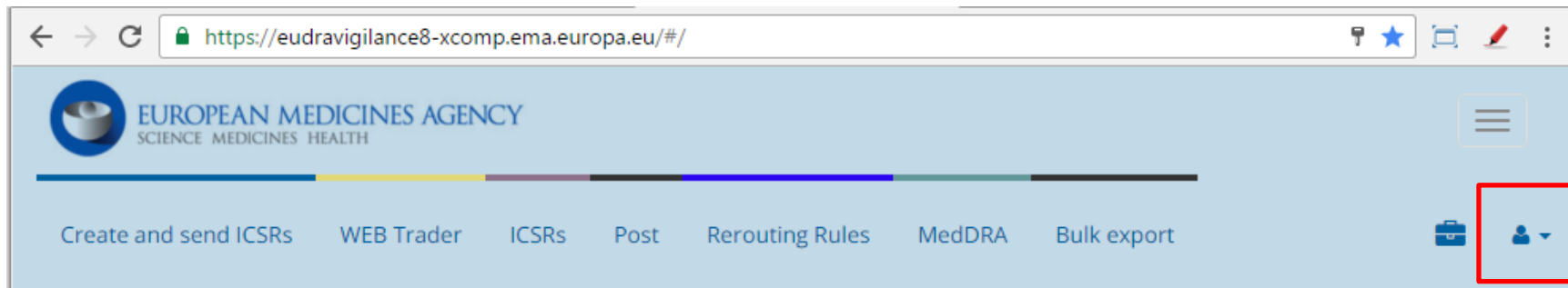


# NCA View

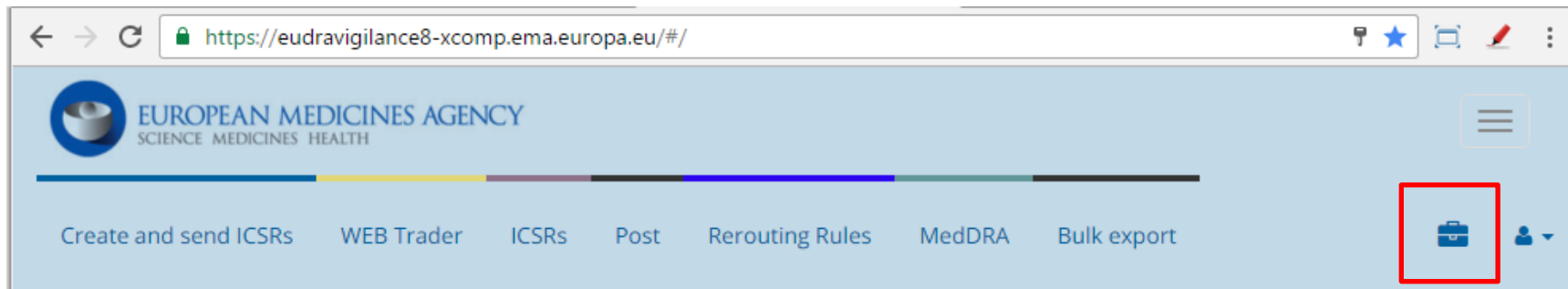




# User details and log out



# Work space



The screenshot shows a web browser window with the URL <https://eudravigilance8-xcomp.ema.europa.eu/#/>. The page header features the EMA logo and the text "EUROPEAN MEDICINES AGENCY" and "SCIENCE MEDICINES HEALTH". A horizontal navigation bar contains several menu items: "Create and send ICSRs", "WEB Trader", "ICSRs", "Post", "Rerouting Rules", "MedDRA", and "Bulk export". On the right side of this bar, there is a blue briefcase icon representing the "Work space", which is highlighted with a red square. Next to it is a user profile icon with a dropdown arrow.



# Work space



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH



Messages (0)

Reports (0)

Acknowledgements (0)



## Sections

Create and send ICSR (E2B(R3) format)

WebTrader – Inbox and Outbox

ICSRs

Post – EVPOST

Rerouting rules -NCA only

MedDRA

Bulk export for MAHs L2A/L2B access policy



Upload/import R2 and R3 files



# Summary

- EVWEB application technical requirements
- Login and logout of EVWEB
- Navigate the sections of EVWEB
- Use the basic functions of the application



# Feedback

- Please provide us with feedback on this E-learning module and any attendant guidance documents you have viewed by taking the EMA training survey.
- The survey is accessible via [this link](#).

Save a backup on your local computer (disable if you are using a public/shared computer)

## EudraVigilance training feedback survey

Fields marked with \* are mandatory.

**Disclaimer**

*The European Commission is not responsible for the content of questionnaires created using the EUSurvey service - it remains the sole responsibility of the form creator and manager. The use of EUSurvey service does not imply a recommendation or endorsement, by the European Commission, of the views expressed within them.*

Pages [Training Details](#) [Training Feedback](#)

### Training Details

EUROPEAN MEDICINES AGENCY  
SCIENCE. MEDICINES. HEALTH

**Views**  
Standard [Accessibility Mode](#)

**Languages**  
[EN] English ▾

**Useful links**  
[EudraVigilance training page](#)

**Contact**  
[European Medicines Agency service desk](#)

[Download PDF version](#)



Thank you for your attention

## Further information

---

### **European Medicines Agency**

30 Churchill Place • Canary Wharf • London E14 5EU •  
United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660  
5555

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

Follow us on  **@EMA\_News**

