



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance Components & Functionality Introduction

Training Module EV-M2

This module outlines the EudraVigilance system components and system functionalities





Content Summary





Introduction: Target Audience

Target audience for this training module:

- National Competent Authorities in the European Economic Area (EEA)
- Marketing authorisation holders (MAHs)
- Commercial and non-commercial sponsors
of clinical trials (Sponsors)



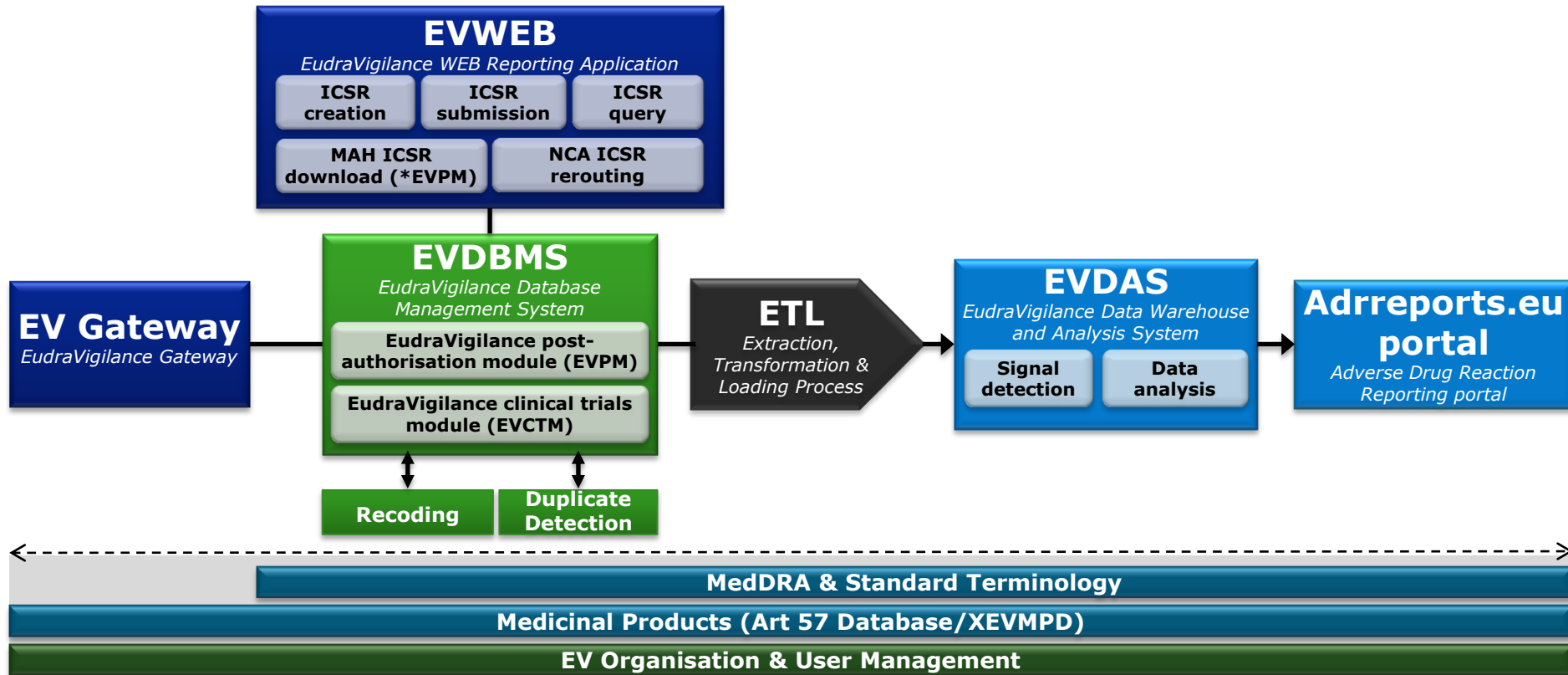
Introduction: Context

- The intention of this training module is to provide an **understanding of the technical components** that together provide all the functionalities of the system, from a users perspective.
- It will also provide an overview of how **all these components interact together**.
- The knowledge gained from this module will provide **the foundational basis for the subsequent training modules** that will focus more on specific technical components.

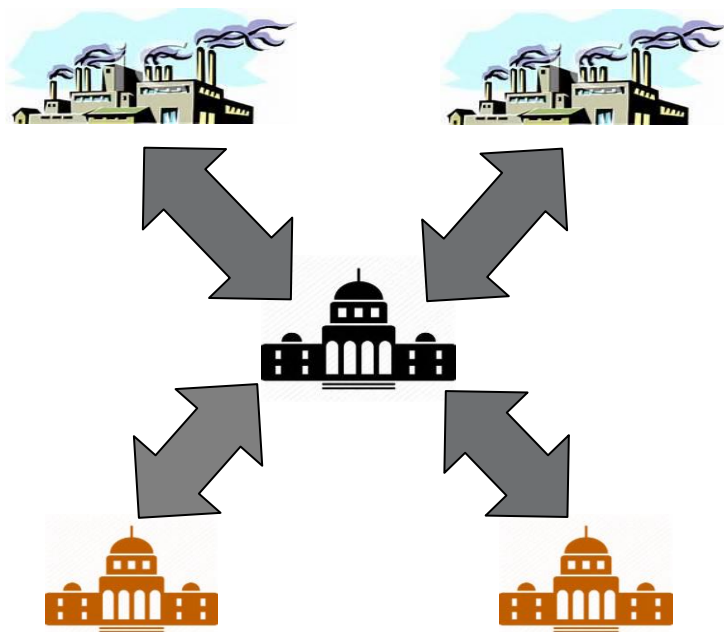
Introduction: Learning Objectives

At the end of module EV-M2 you should be able to:

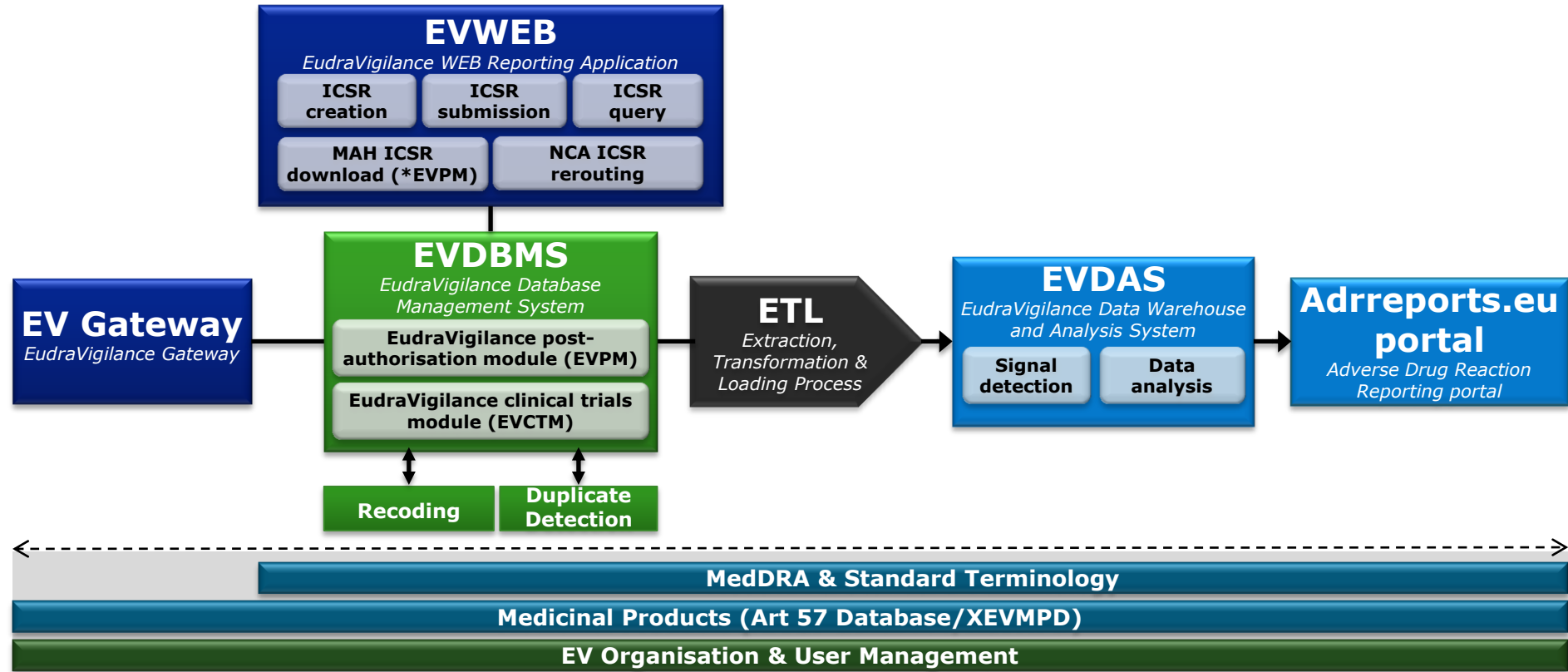
- Understand the key technical Components & Functionalities of the EudraVigilance system
- Recognise which of these Components & Functionalities are relevant from the perspective of an NCA, MAH, Sponsor of clinical trials



EudraVigilance Gateway



- Secures electronic submissions within the EEA
- Enables the exchange of ICH ICSRs & acknowledgment Messages
- Provides Non-Repudiation through Message Disposition Notification (MDN)



EudraVigilance Organisation and User Management



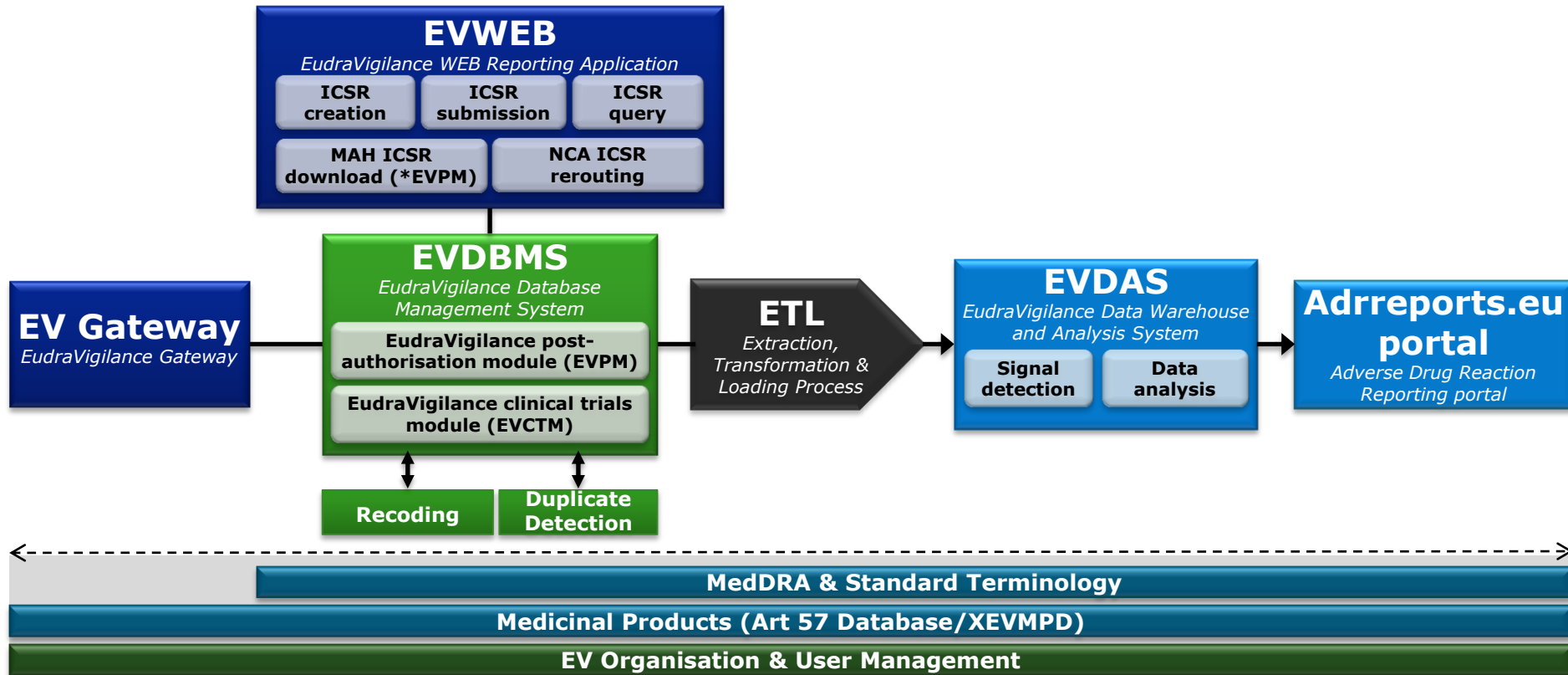
- Registration of EudraVigilance stakeholder organisations including their organisation's Identifier
- Organisation transmission mode
- Registration of Users within an organisation
- Assignment of user access rights

EudraVigilance Organisation and User Management

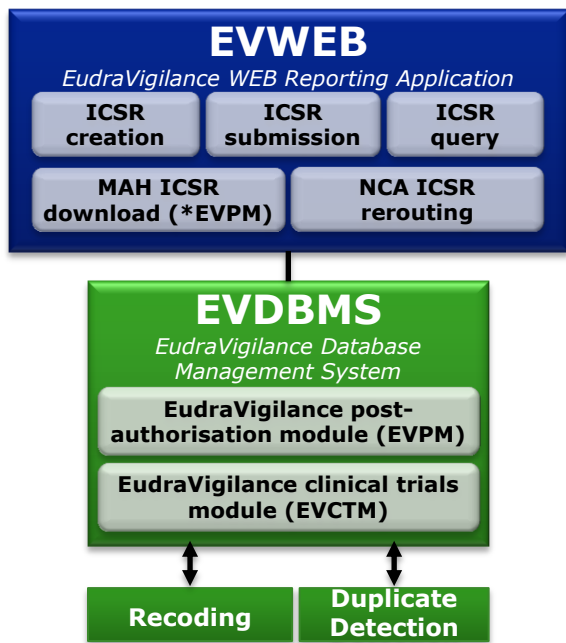
EV Organisation & User Management



- Users will be able to access the different parts of the EudraVigilance system depending on the access rights assigned to them
- At the time of registration of an organisation a user(s) within that organisation will be assigned the role of administrator which will enable them to:
 - Create new users
 - Remove existing users
 - Set access permissions for users

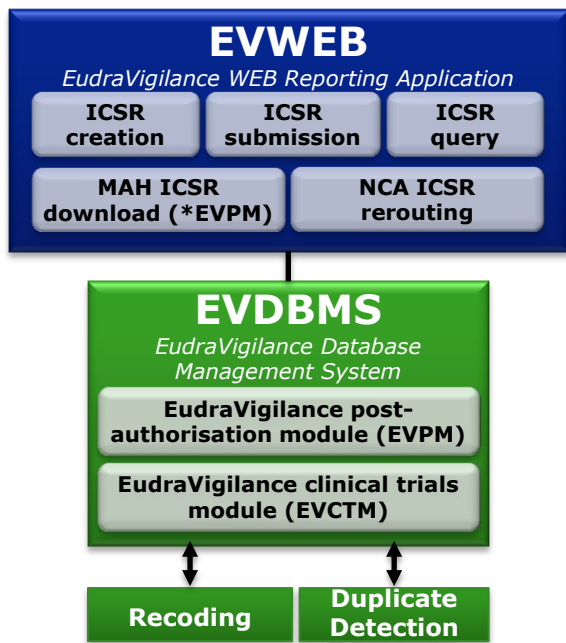


The EudraVigilance Database Management System



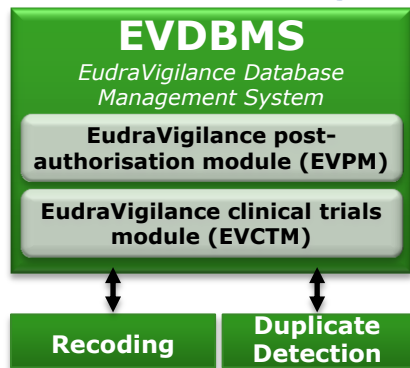
- The EudraVigilance Database Management System (EVDBMS) is the **core component** of the European pharmacovigilance database.
- It includes a **fully automated safety and message processing mechanism**, in accordance with ISO ICSR 27953-2:2011 and ICH E2B(R2) specifications
- It also includes **administrative systems** for managing the data held in the database
- Provides access to data in accordance with the EudraVigilance Access policy

EVWEB Application



- EVWEB is a web application that is specifically designed for **organisations that do not have a pharmacovigilance system for electronically reporting ICSRs** to the relevant regulatory authority.
- Using the Online EVWEB forms users **can create and send electronic ICSRs** in compliance with the required standards.
- **EVWEB enables the receiving** of safety and acknowledgement messages.
- The EVPOST function in EVWEB allows organisations to Post valid electronic ICSRs files created by their own pharmacovigilance system **without having a local gateway installed**.

The EudraVigilance Database



The EudraVigilance Database is divided into two parts:

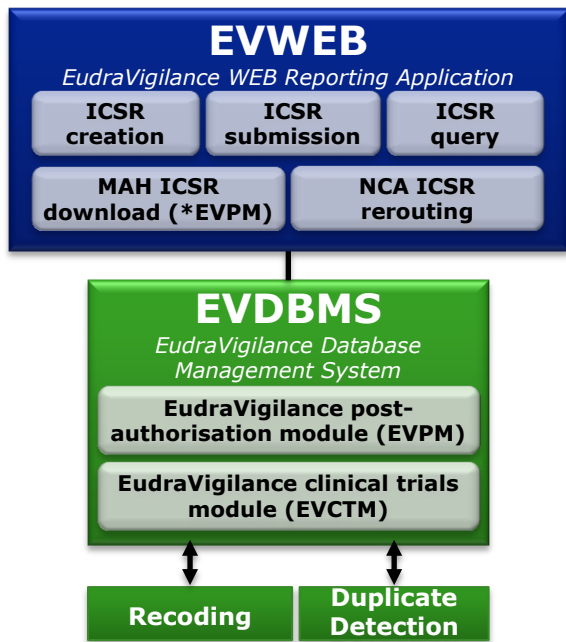


- The EudraVigilance Post-Authorisation Module (EVPM),
 - For ICSRs related to spontaneous reports and reports from non-interventional studies

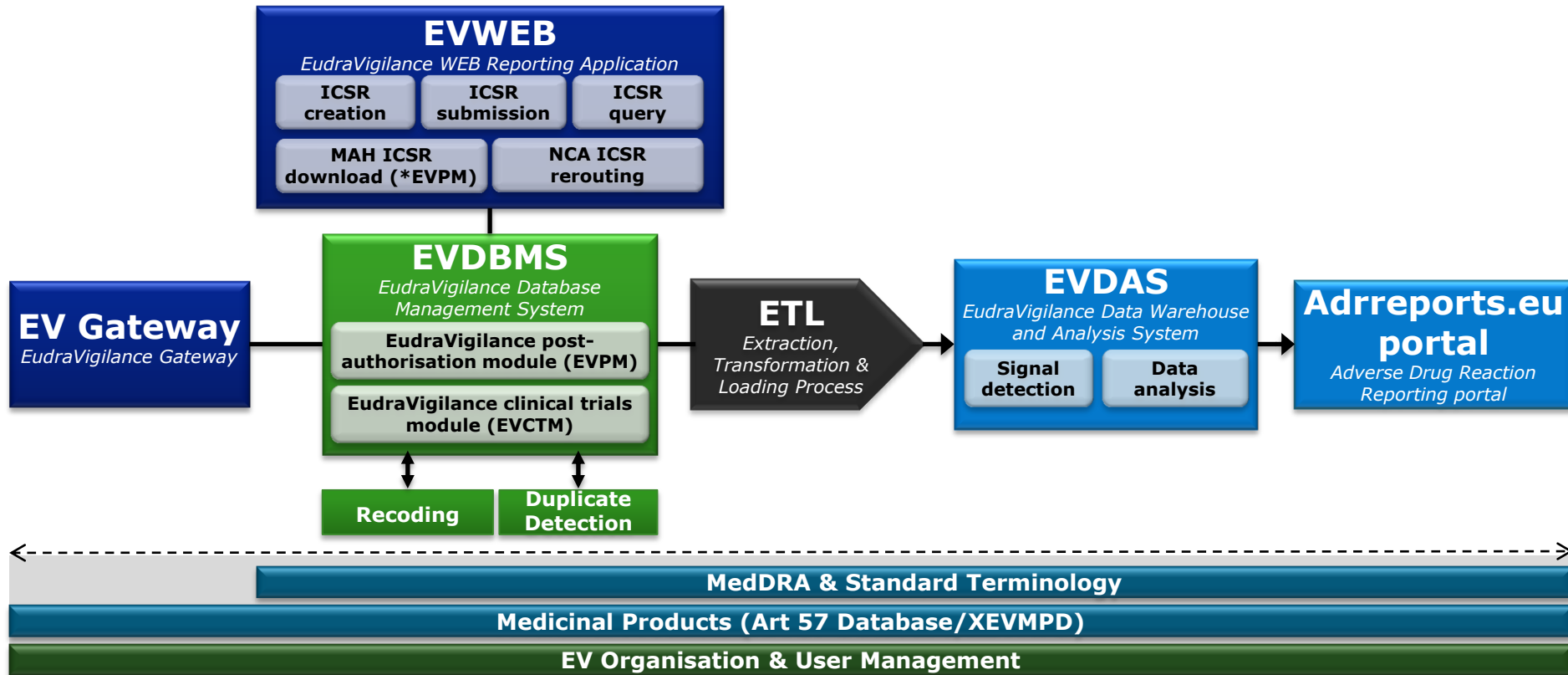


- The EudraVigilance Clinical Trial Module (EVCTM),
 - For ICSRs related to reports on suspected unexpected serious adverse reactions (SUSARs) that occur in the frame of interventional studies

The EudraVigilance Database Management System

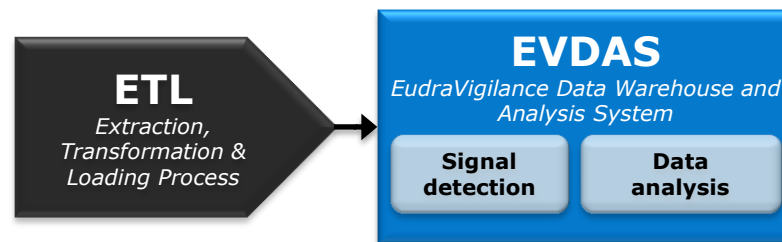


- The Re-routing component allows National Competent Authorities to choose which ICSRs should be re-routed to them following the implementation of simplified reporting
- The ICSR Download component allows Marketing Authorisation Holders to download ICSRs in accordance with the EudraVigilance Access policy
- The Duplication Detection component allows the EMA to manage duplicated ICSRs within EudraVigilance through the creation of master cases
- The Recoding component allows the EMA to recode verbatim drug and substance information reported in ICSRs against Art57 medicinal product information



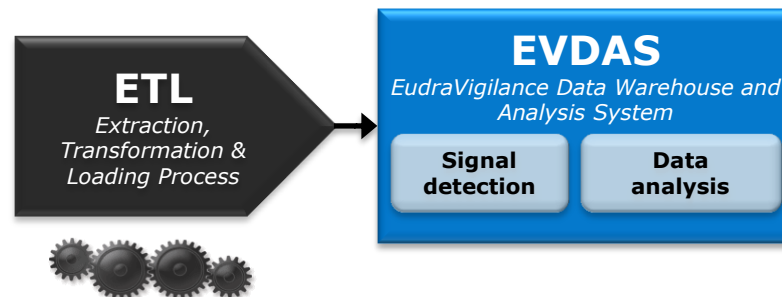
EudraVigilance Data Analysis System

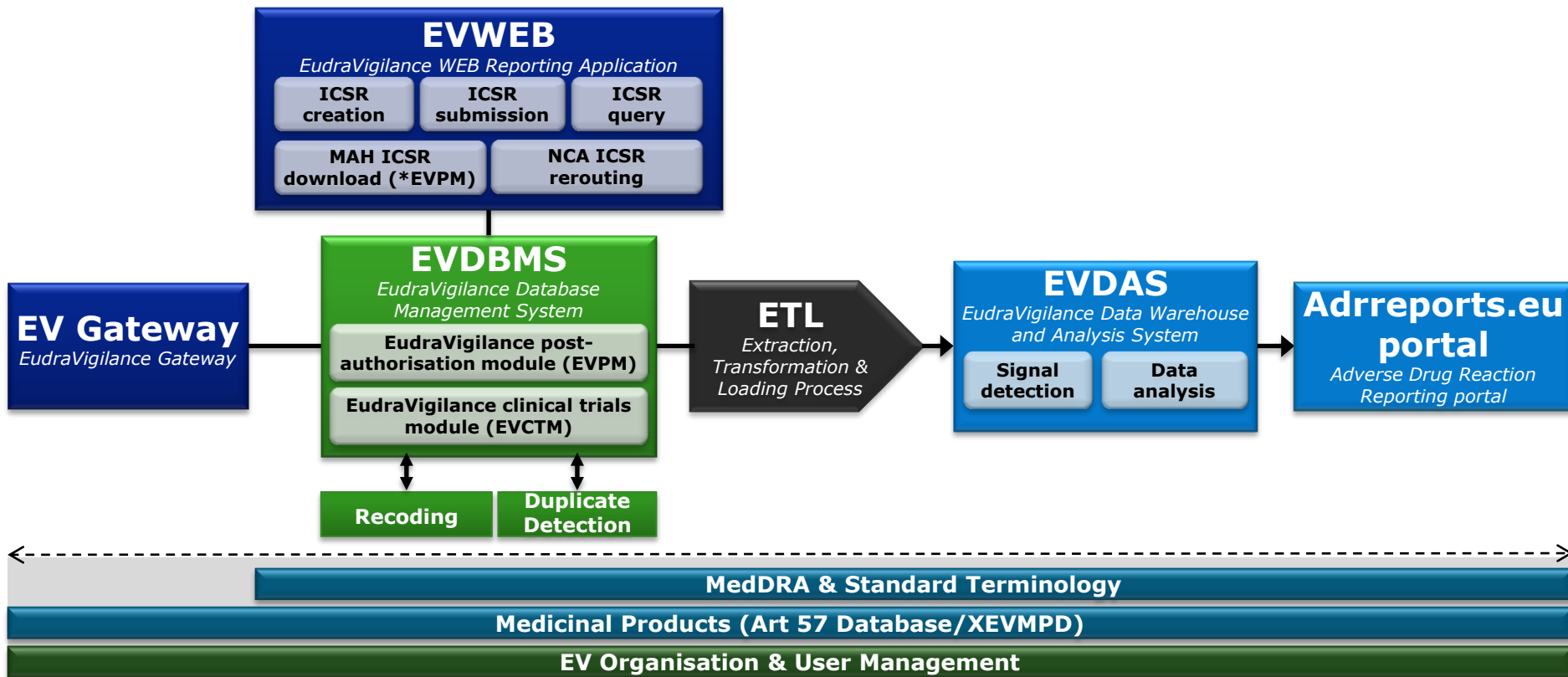
- The EudraVigilance Data Analysis System has been designed to allow users to analyse safety data collected in EudraVigilance
- It enables better-informed decisions about the safety profile of medicinal products
- It provides a range of analytical tools: from measuring reporting compliance for regulatory purposes, to pharmacovigilance analyses (such as signal detection tools)





EudraVigilance Data Analysis System





ADR Reports Portal (<http://www.adrreports.eu/>)



The screenshot shows the homepage of the ADR Reports Portal. At the top, there is a blue header with the European Union flag logo on the left, the text "European database of suspected adverse drug reaction reports" in the center, and links for "Contacts | FAQ | Glossary" and a language dropdown menu set to "English (en)" on the right. Below the header is a navigation bar with links: "Home", "About", "Understanding reports", "Search", and "Medicine safety". The main content area features a section titled "Online access to suspected side-effect reports" with a photograph of white pills on the left. To the right of the photo, text explains that users can view data on suspected side-effects for authorised medicines in the EEA, and details the access rules for centrally and non-centrally authorised medicines. Further right is a search box with a magnifying glass icon and the text "Search for a report" and "Search here for suspected adverse drug reaction reports".

European database of suspected adverse drug reaction reports

Contacts | FAQ | Glossary

English (en)

Home About Understanding reports Search Medicine safety

Online access to suspected side-effect reports



On this website you can view data on suspected side-effects also known as suspected adverse drug reactions for authorised medicines in the European Economic Area (EEA).

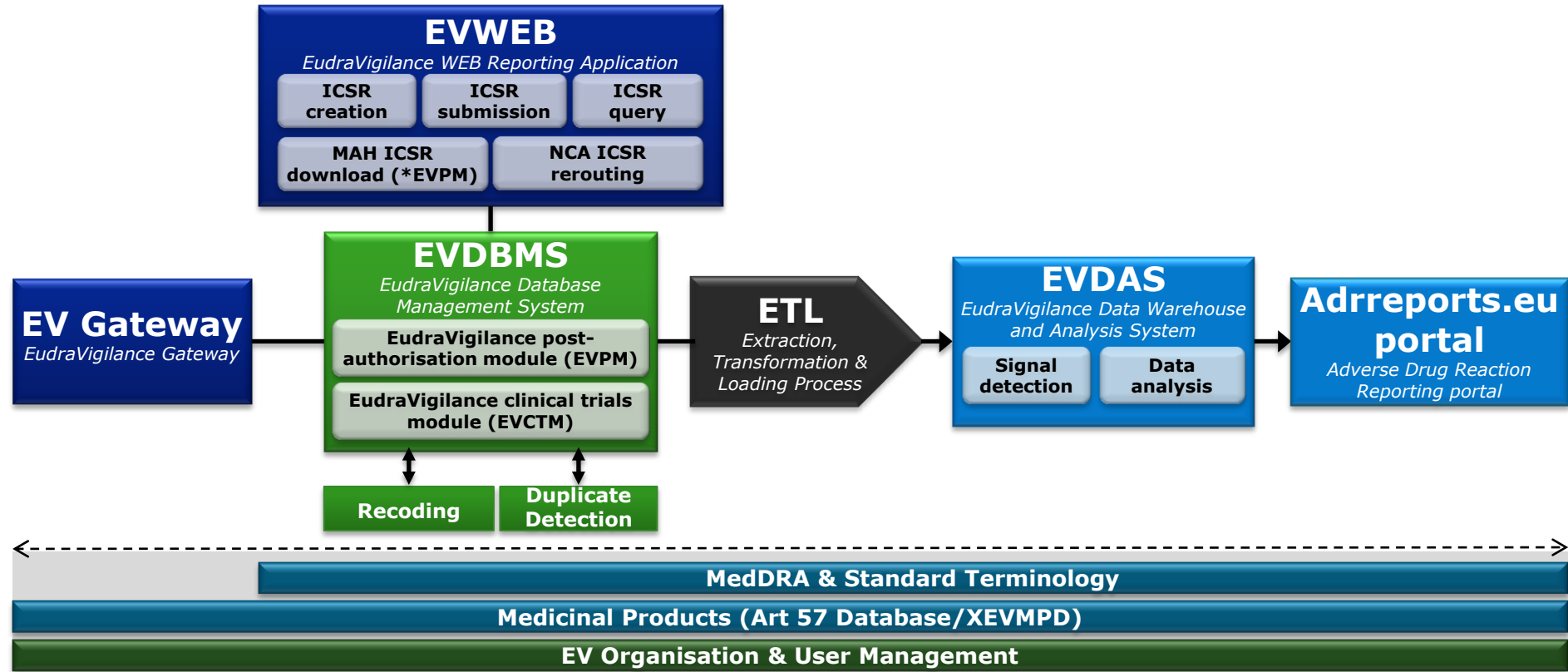
For centrally authorised medicines, access to reports is granted both by the name of the medicine or the name of the active substance. For non-centrally authorised medicines, access is granted based on the name of the active substance only.

Search for a report

Search here for suspected adverse drug reaction reports

Adrreports.eu
portal
*Adverse Drug Reaction
Reporting portal*

This website was launched by the European Medicines Agency in 2012 to provide public access to reports of suspected side effects inline with the EudraVigilance access policy.



- In this training module we have examined the Components & Functionality of the EudraVigilance system
 - Gateway
 - Organisation and User Management
 - Database Management System
 - EVWEB
 - ICSR Download
 - Data Analysis System
 - ADR Reports Portal



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.

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