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**.

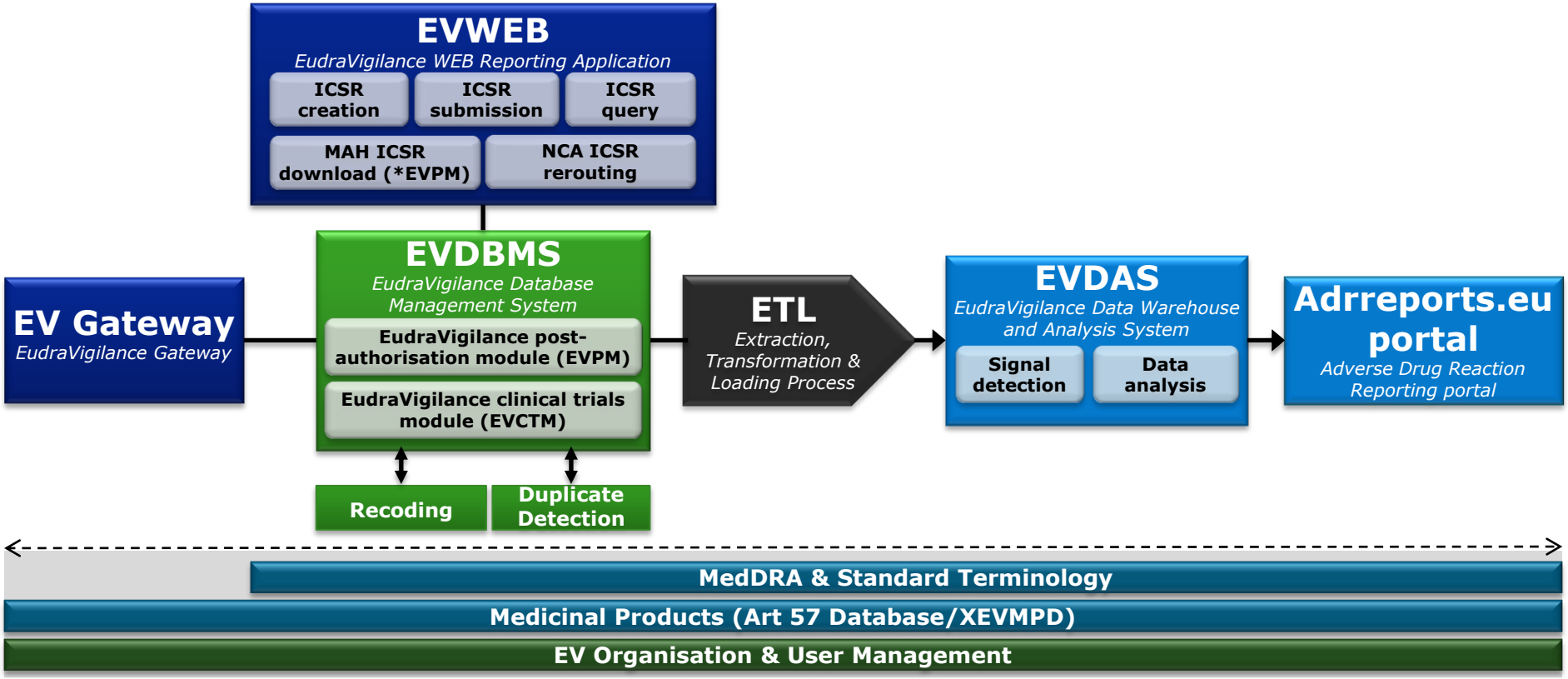
- The knowledge gained from this module will provide **the foundational basis for the subsequent training modules** that will focus more on specific technical components.

Introduction: Learning Objectives

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

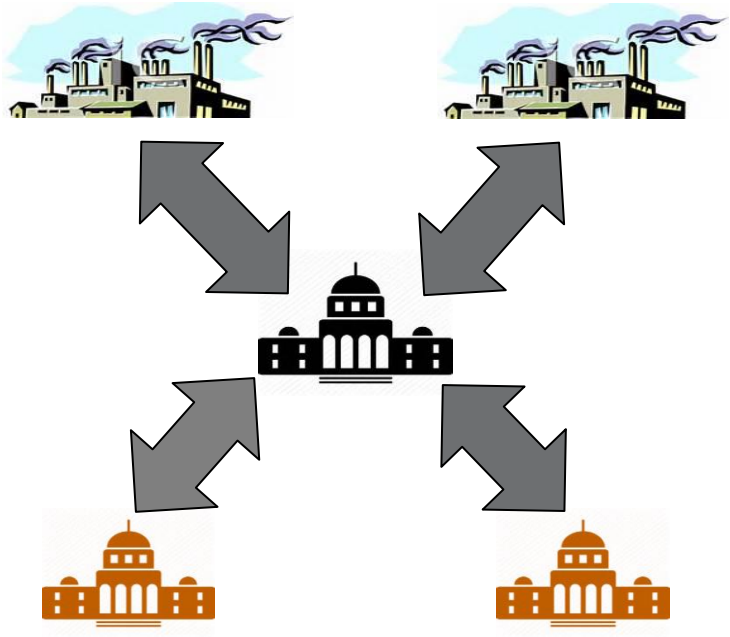
- Understand the key technical Components & Functionalities of the EudraVigilance system
- Recognise which of these Components & Functionalities are relevant from the perspective of an NCA, MAH, Sponsor of clinical trails

EudraVigilance System Components



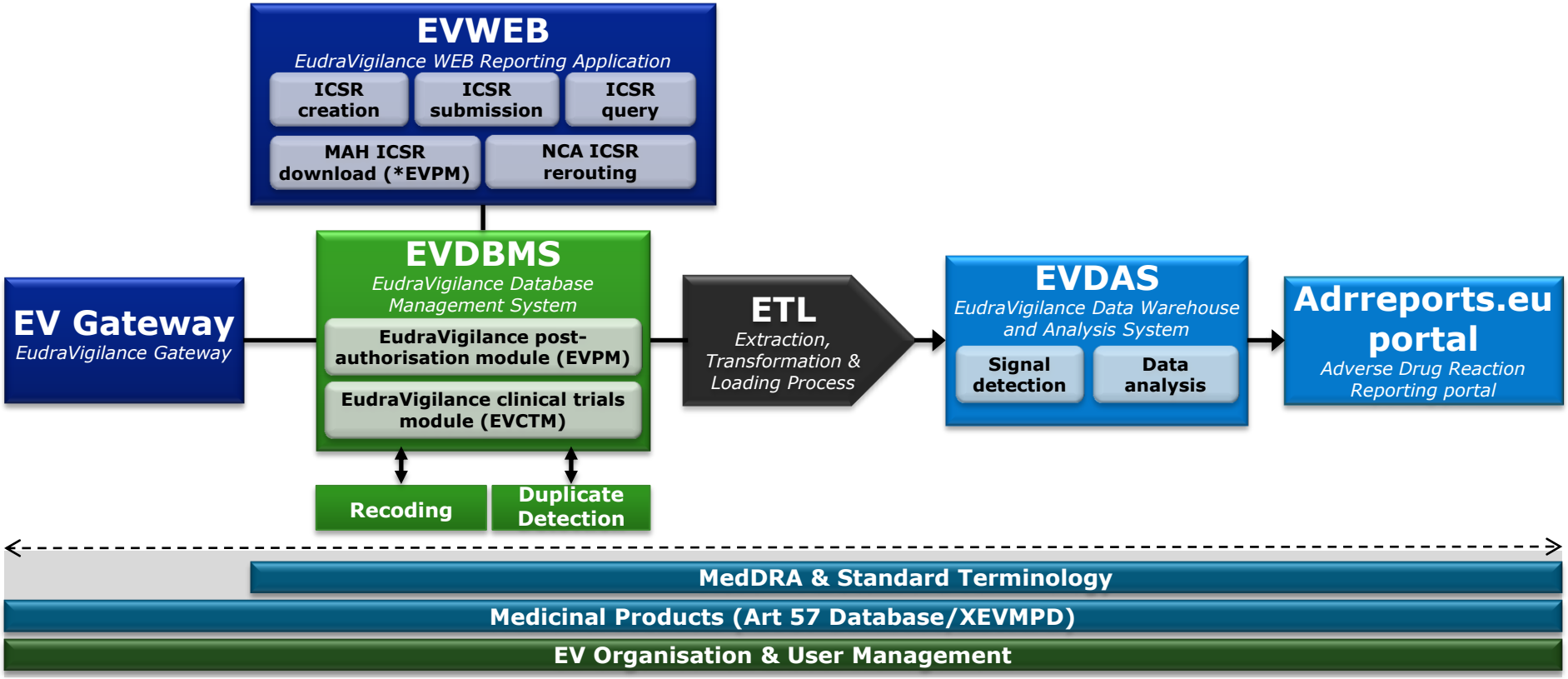
EudraVigilance Gateway

EV Gateway
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 System Components



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

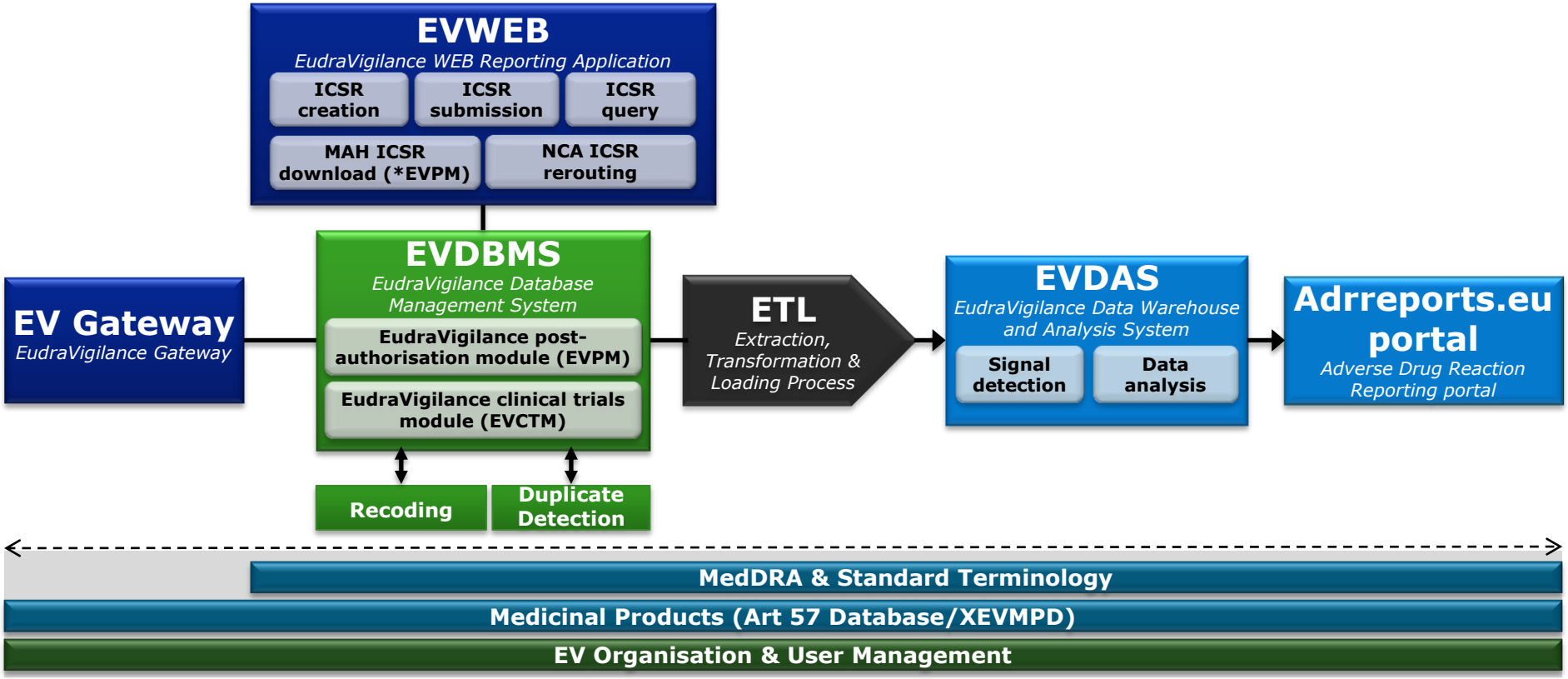
EudraVigilance Organisation and User Management

EV Organisation & User Management

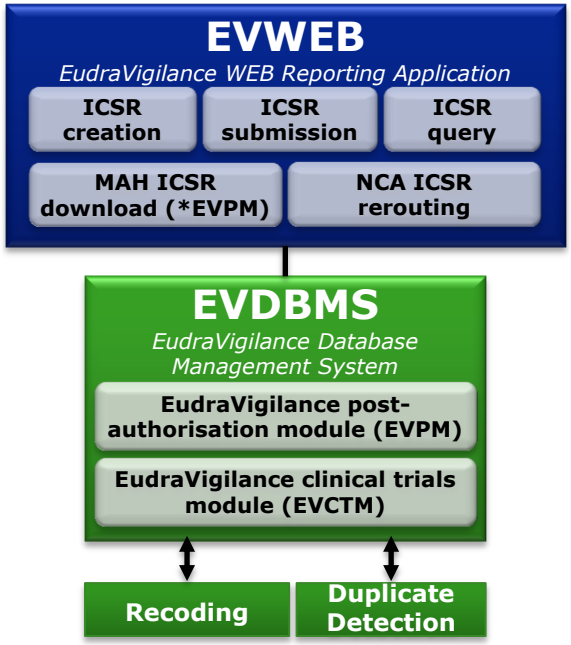
- Users will be able to access the different parts of the EudraVigilance system depending on the access rights assigned to them

- 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

EudraVigilance System Components

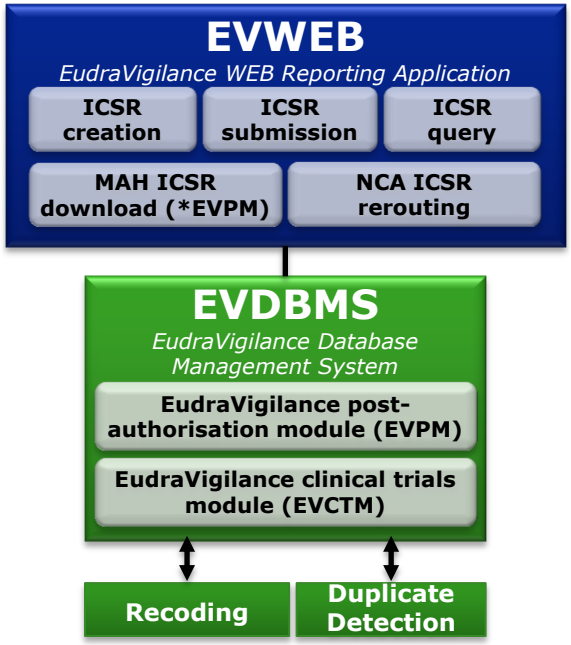


The EudraVigilance Database Management System



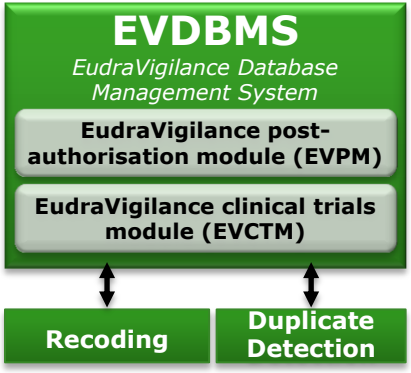
- The EudraVigilance Database Management System (EVDBMS) is the **core component** of the European pharmacovigilance database.
- It includes a **fully automated safety and message processing mechanism**, in accordance with ISO ICSR 27953-2:2011 and ICH E2B(R2) specifications
- It also includes **administrative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

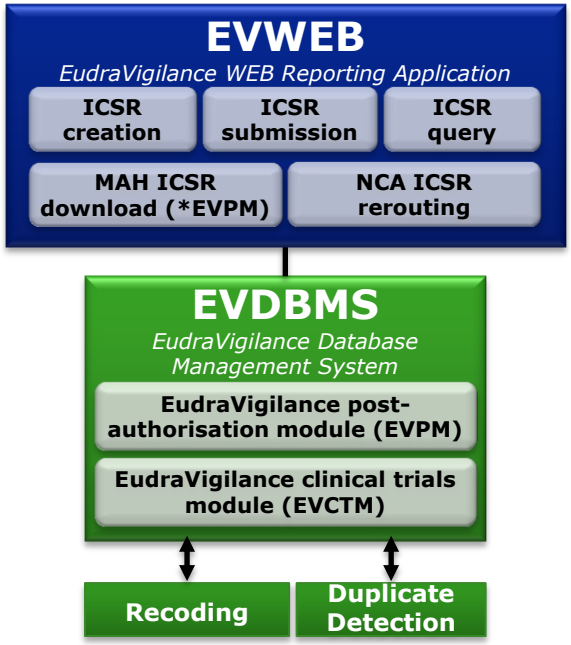


The EudraVigilance Database is divided into two parts:

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

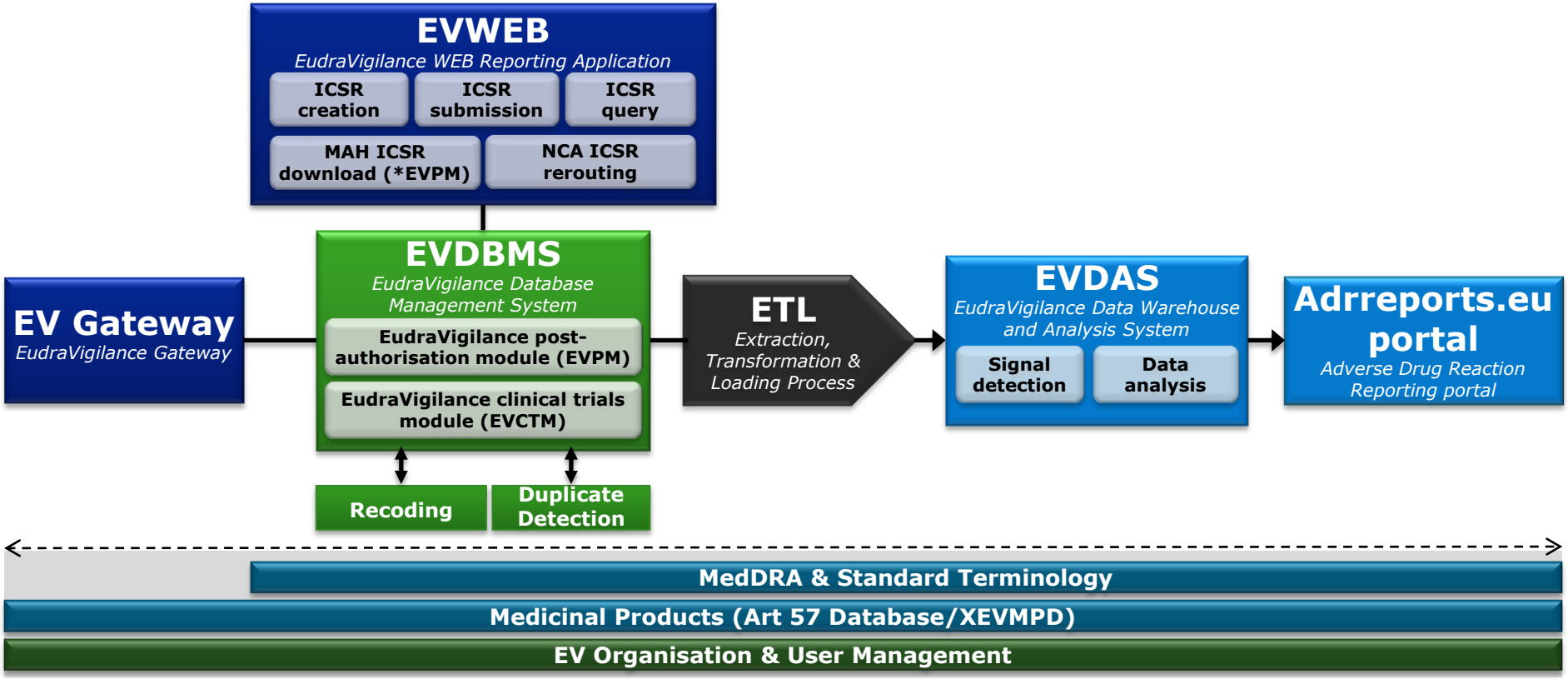
- The EudraVigilance Clinical Trial Module (EVCTM),
  - For ICSRs related to reports on suspected unexpected serious adverse reactions (SUSARs) that occur in the frame of interventional studies

The EudraVigilance Database Management System



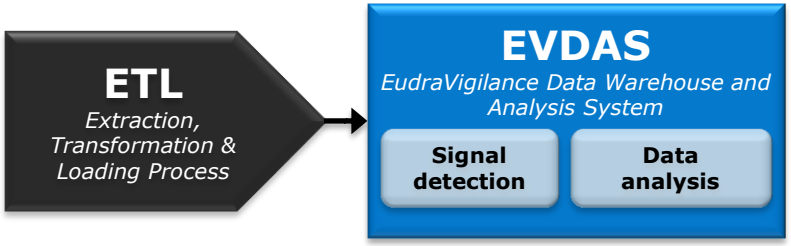
- The Re-routing component allows National Competent Authorities to choose which ICSRs should be re-routed to them following the implementation of simplified reporting
- The ICSR Download component allows Marketing Authorisation Holders to download ICSRs in accordance with the EudraVigilance Access policy
- 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 System Components



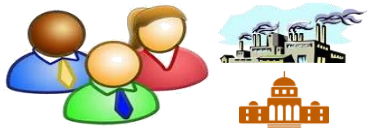
EudraVigilance Data Analysis System

- 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)



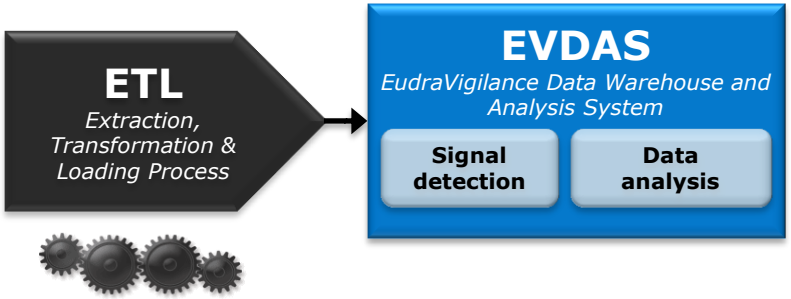
EudraVigilance Data Analysis System

ICSR Data

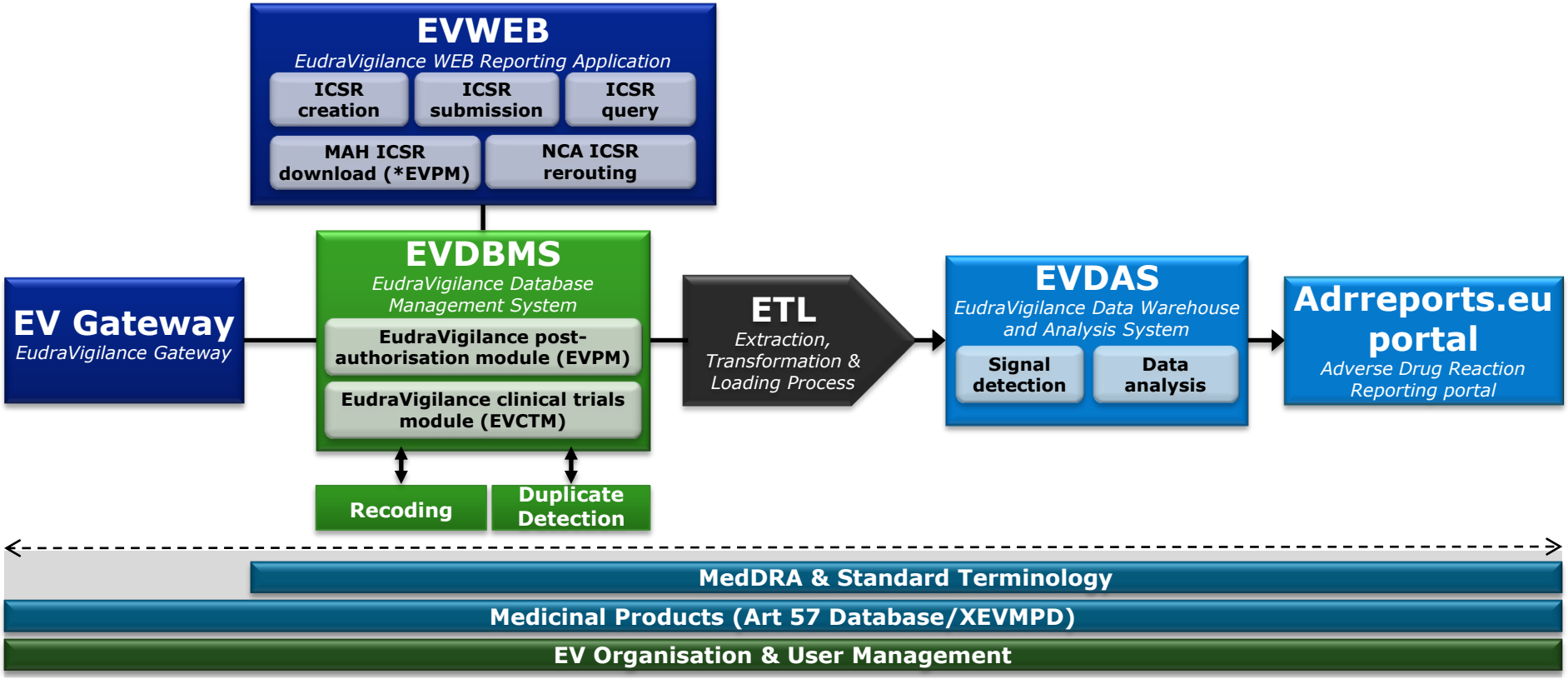


Organisations & Users

xEVMPD



EudraVigilance System Components

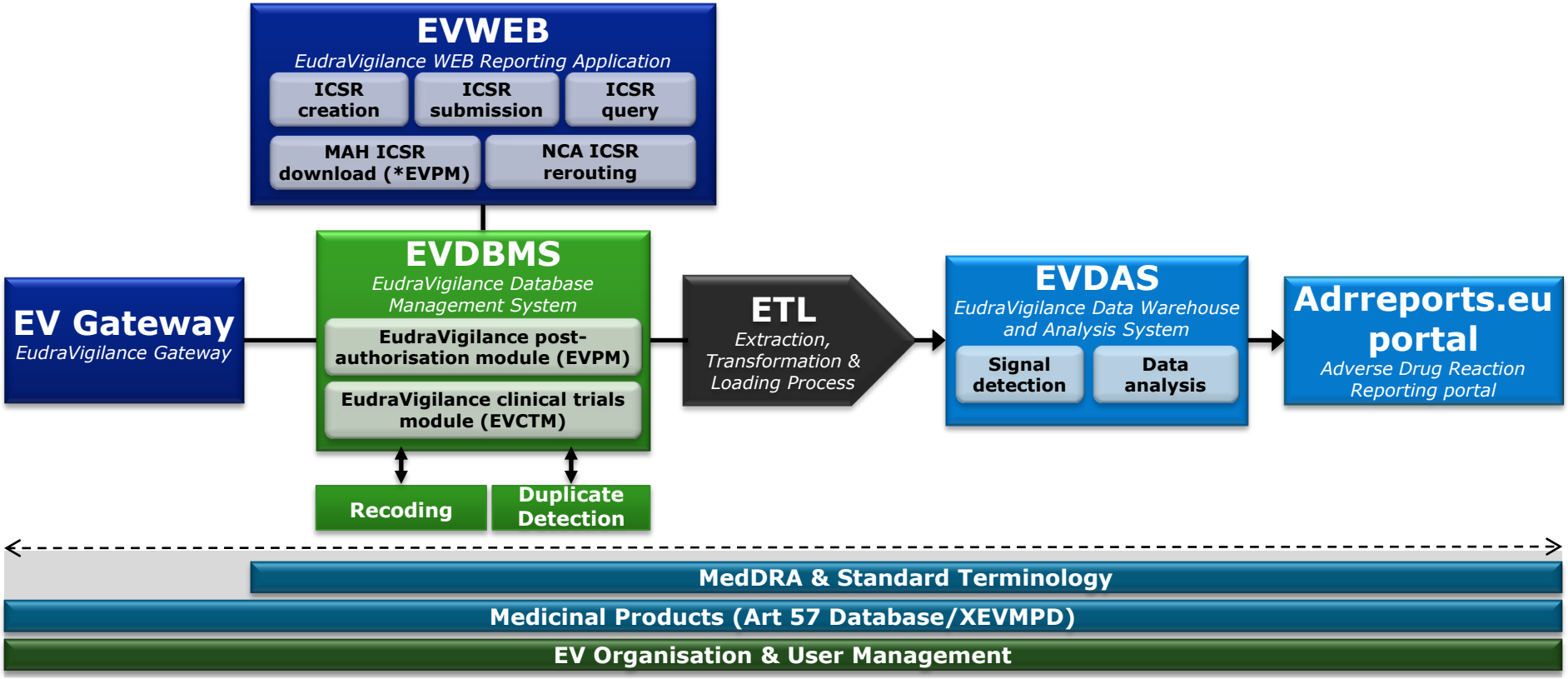


ADR Reports Portal (http://www.adrreports.eu/)

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.

EudraVigilance System Components



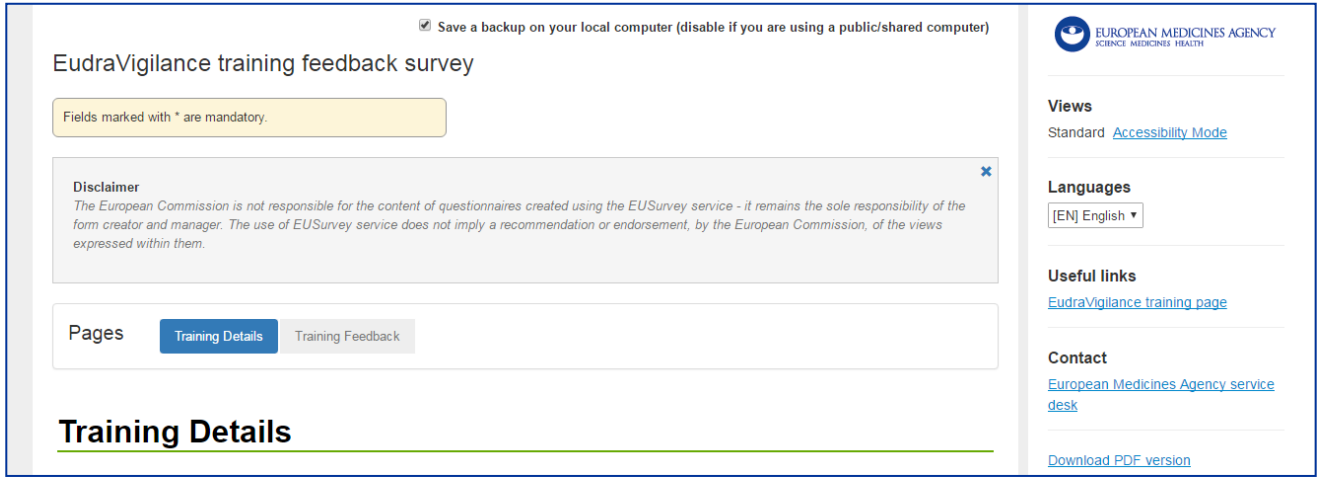
EudraVigilance System Components

- 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.



Thank you for your attention

Further information/ Contact information

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