

EudraVigilance – Electronic Exchange of Safety Data

Shalin Patel
Benefit Risk Management
Johnson and Johnson
Official EMEA EudraVigilance Trainer

EudraVigilance

- Key component in Supporting EMEA within its Committees in the supervision of medicinal products
- Facilitates evaluating and making information on adverse reactions to medical products available
- Data processing network for the rapid transmission of data between the competent community authorities

EudraVigilance Gateway

- One single electronic reporting point with the European Union
- One standard for all regulators, pharmaceutical industry and sponsors
 - XML format
 - Provides Non-repudiation through Message Disposition Notification (MDN)

EudraVigilance Gateway

- Technically considered a hub and all connections for Marketing Authorisation Holders, commercial and non-commercial sponsors and Competent authorities are known as spokes
- All Safety and Acknowledgement Messages are re-routed to the appropriate receiver specified in the message

EudraVigilance workflow



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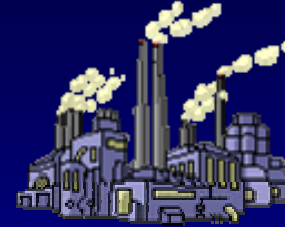
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EUDRAVIGILANCE GATEWAY



EUDRAVIGILANCE DBMS



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EudraVigilance User Types

- Gateway Users
- Web Traders
 - Post function users
 - EVWEB Users

Gateway users

- Can create XML ICSR's from their pharmacovigilance database
- Have an automated gateway software solution for exchanging ICSR's and acknowledgements with the EudraVigilance Gateway
- Have access to EVWEB but are unable to use send function

Web Trader function


- Is an integrated part of the EudraVigilance Gateway
- Allows organisations without an automated local gateway solution to send and receive safety and Acknowledgement Messages through the use of an internet browser
- Allows transmission of data to the EMEA as well as Competent Authorities and other registered organisations

WebTrader – Post function Users

- Can create XML ICSR's from their pharmacovigilance database
- No automated gateway software solution
- Can send XML ICSR's and acknowledgements using the Web Trader post function
- Able to receive ICSR's and Acknowledgements through Web Trader in the EVWEB tool

WebTrader – Post function Users

..:Choose the file to send:..

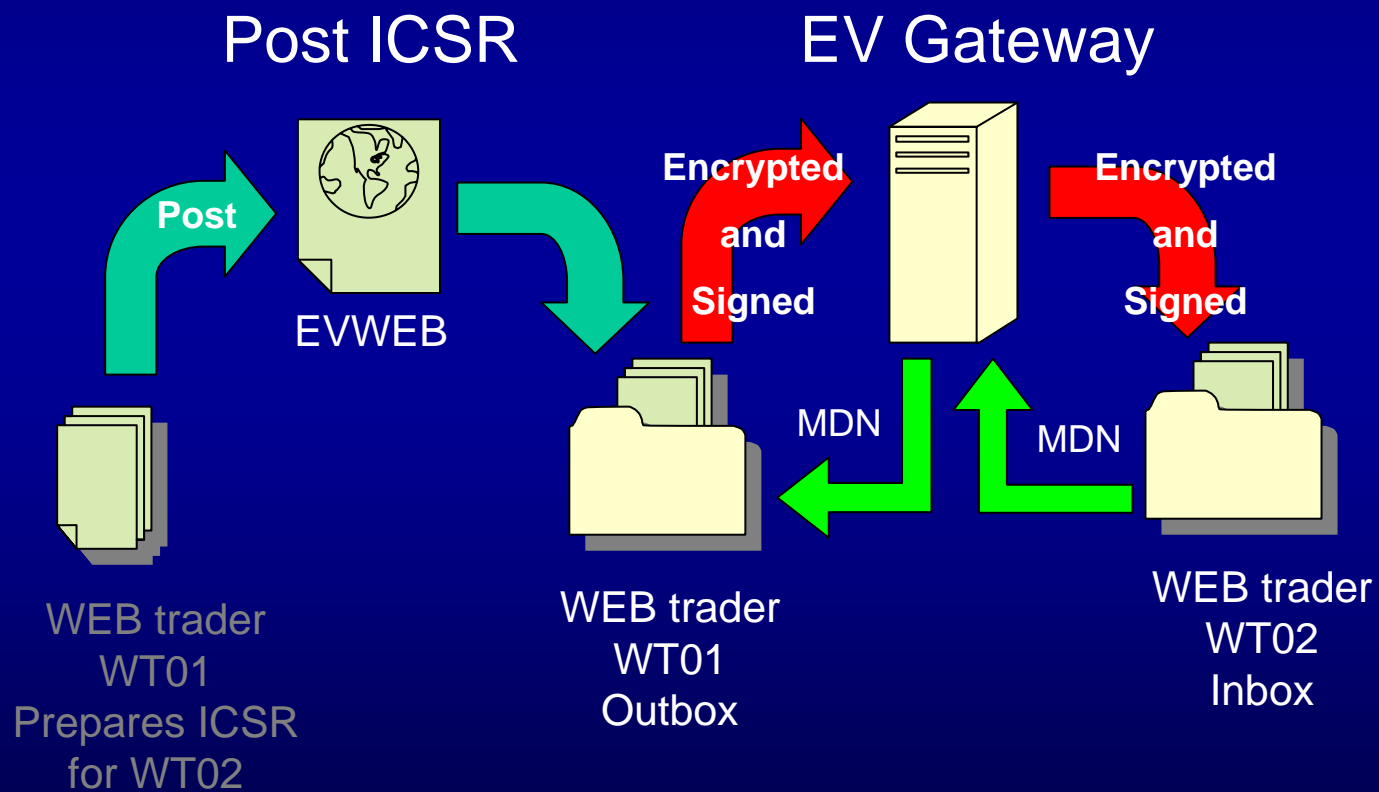


The screenshot shows a web form with a title bar that reads "..:Choose the file to send:..". Below the title bar is a large, faded image of a landscape with trees and a body of water. In the center of the form is a rounded rectangular container. Inside this container, there is a text input field on the left and a "Browse..." button on the right. Below the input field and button is a ">Send" button.

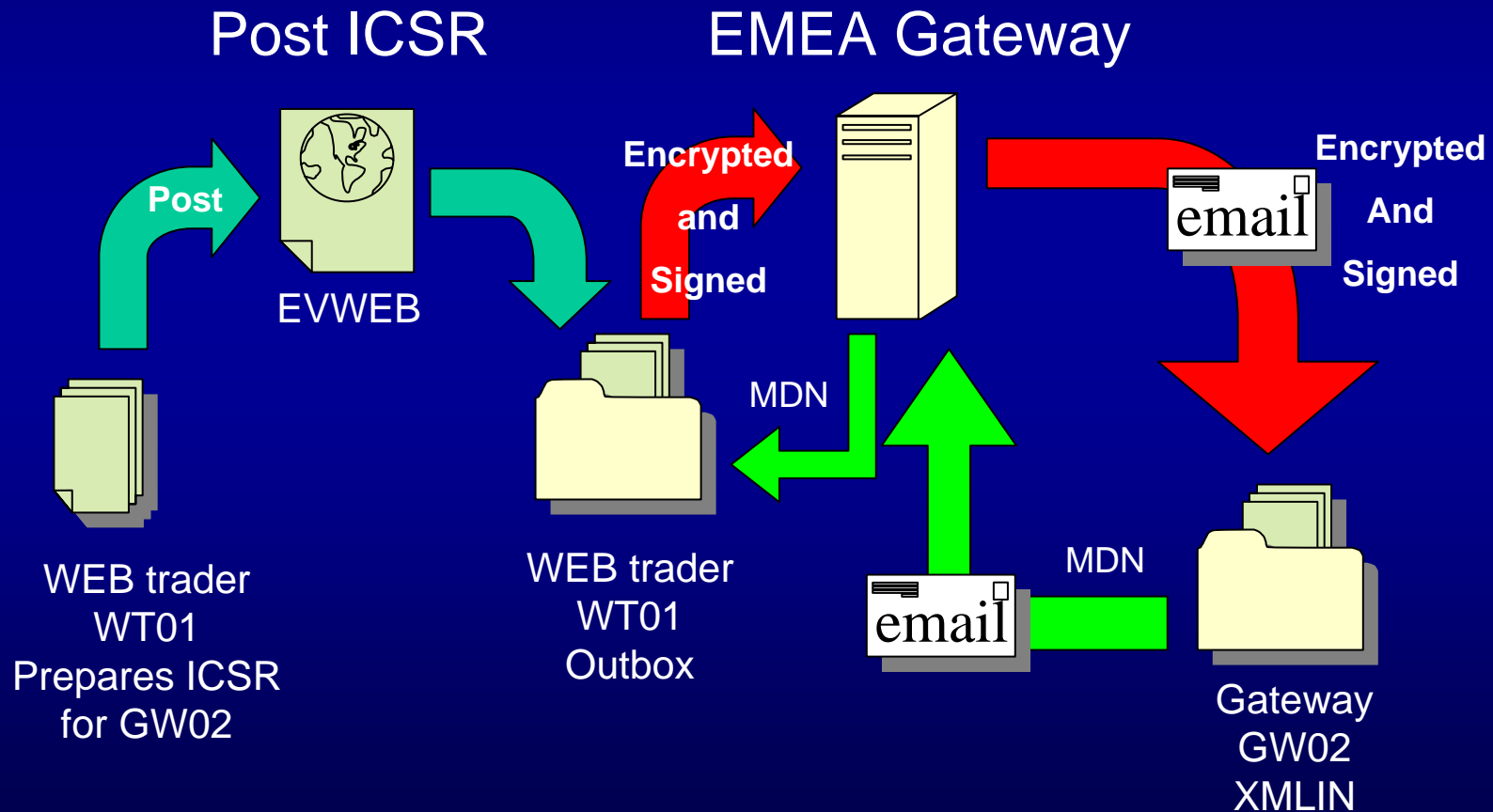
WebTrader – EVWEB Users

- Unable to create XML ICSR's from their pharmacovigilance database and don't have an automated gateway software solution
- Can send XML ICSR's and acknowledgements using the Web Trader post function
- Able to receive ICSR's and Acknowledgements through Web Trader in the EVWEB tool

WEB Trader to WEB Trader Communication



WEB Trader to Gateway Communication



Business partners in Electronic Data Interchange (EDI) community

- Pharmaceutical companies and the internal structure (affiliates) within the companies
- National competent authorities and regional pharmacovigilance centres
- Third party service providers or commercial and non-commercial sponsors

ICH ICSR (Safety) Message

- Document Type Definition (DTD)
- eXtensible Markup Language (XML)
- Message Header
- Message Body

ICH ICSR (Safety) Message

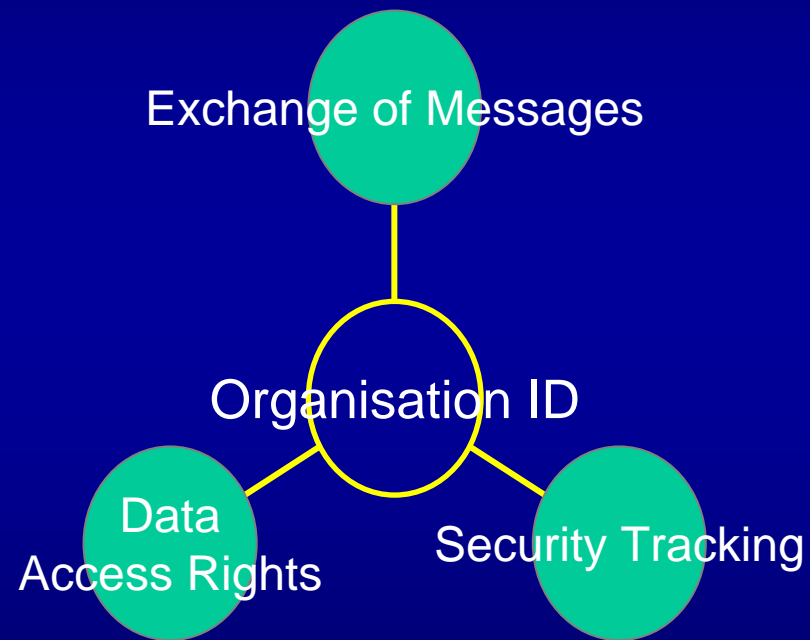
Safety
Message
(XML file)

DTD Reference

Sender Identifier

```
<?xml version="1.0"?>
<!DOCTYPE ichicsr SYSTEM "http://ers.emea.eu.int/dtd/icsr21.xml.dtd">
<ichicsr lang="en">
  <ichicsrmessageheader>
    <messagetype>ICHICSR</messagetype>
    <messageformatversion>0</messageformatversion>
    <messageformatrelease>V2</messageformatrelease>
    <messagenumb>M1024</messagenumb>
    <messagesenderidentifier>EMEA</messagesenderidentifier>
    <messagereceiveridentifier>EVHUMAN</messagereceiveridentifier>
    <messagedateformat>204</messagedateformat>
    <messagedate>20000808040841</messagedate>
  </ichicsrmessageheader>
  <safetyreport>
    <safetyreportversion>3</safetyreportversion>
    <safetyreportid>109073</safetyreportid>
    <transmissiondateformat>102</transmissiondateformat>
    <transmissiondate>20001024</transmissiondate>
  </safetyreport>
</ichicsr>
</xml>
```

Organisation Identifier



Exchange of Messages

- Identifying uniquely the sender and the receiver
- This info is specified in the Message Header
 - Message Sender Identifier (M.1.5)
 - Message Receiver Identifier (M.1.6)

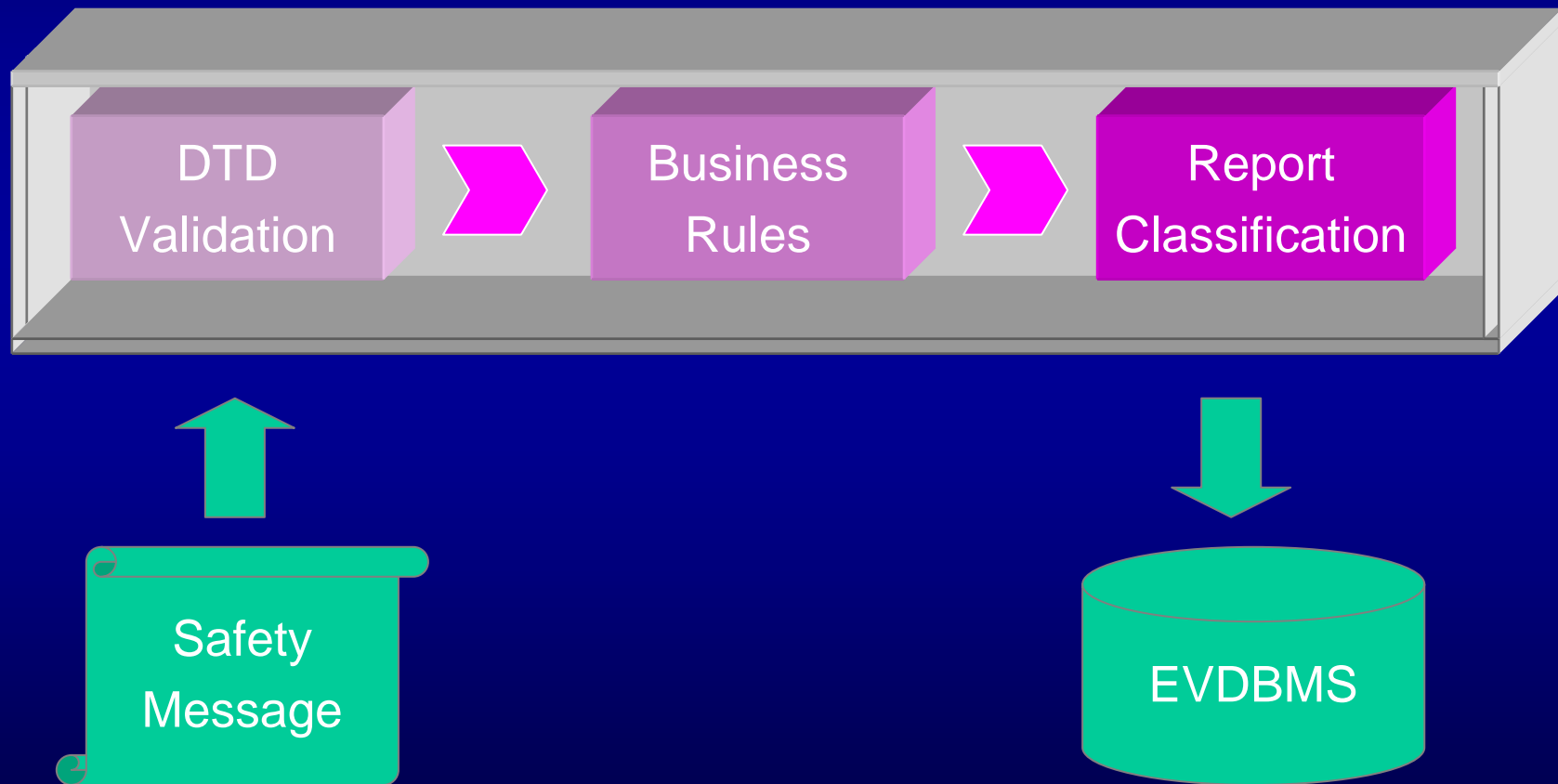
Security Tracking

- Each ICSR loaded in the EudraVigilance DBMS will always be marked with the Organisation ID of the organisation which sent the message

Data Access Rights

- Regulatory Authorities
- Marketing Authorisation Holder's
- Commercial and non-commercial sponsors

Safety Message processing by the EudraVigilance DBMS



DTD Validation

- Is it a correct XML document according to the general XML parsing rules
- Is it a correct safety message according to rules specified in the DTD

Business rules

- EMEA classification of what is needed in order to load a message
- Does it have the details to make a valid safety report

Automated Report classification

- Case reports
- Replaced reports
- Error reports

Acknowledgement

- Message Header section
- Acknowledgment section
 - Message acknowledgement
 - Report acknowledgement

Acknowledgement

- Safety Message validation
 - 03 Ack – e.g. parsing error with identifiable sender or no identifiable receiver
 - 02 Ack – at least one ICSR not loaded
 - 01 Ack – all ICSR(s) loaded

EudraVigilance Clinical Trial
Module (EVCTM)

Vs

EudraVigilance Post-authorisation
Module (EVPM)

EVCTM and EVPM Modules

- The EVCT module is a transactional database where adverse reaction reports arising from clinical studies are received
- The EVPM module is a transactional database where adverse reactions for authorised products are received
- Reporting rules have been clarified to avoid duplication of reporting

EudraVigilance Medicinal Product Dictionary (EVMMPD)

- EMEA Initiative
- Expanded to include Investigational Medical Products (IMP's)
- New ICH initiative

EudraVigilance Medicinal Product Dictionary (EVMMPD)

- Product Report Database
 - Data Collection
- Scientific Product Database
 - Data Analysis
- Product Index Database
 - Report Possibilities

The Future

- EudraVigilance Data Analysis Tool
- Access to EudraVigilance
- EudraVigilance Web Portal

EMEA EudraVigilance Training

- Compulsory for all Web Trader users
- Course Structure
- Attendance to date

EMEA EudraVigilance Training

- To attend the course
 - Registration at the DIA Website
 - <http://www.diahome.org>
- EudraVigilance Training Programme rolled out to many Member States
 - United States – Oct/Nov