

# ESM Portal

## Compliance Software for Electronic Submission of Information on Medicines

**Centrally manage XEVMPD data and associated submissions in an XML repository  
Intuitive application interface provides easy data and submission management**



### Top Features

- Web Application
- Global Access
- Enterprise Reporting
- Enterprise Audit Trail
- Full Compliance
- Risk Mitigation
- System Integration

### Function

ESM Portal supports the European Medicines Agency's (EMA) article 57 initiative regarding electronic submission of information on medicines (ESM) by marketing-authorization holders. The application is a web-based solution with a central repository that allows global pharmaceutical companies to manage the life-cycle associated ESM submissions.

### Central Repository

Updates to associated data will be automatically propagated to all mapped products, allowing for the most up-to-date information to be included with each subsequent submission.

### Transformation

The ESM Portal application has been developed to make the transition from XEVMPD to IDMP easy. Application data is stored in the central data repository and then published to the required standard. For the short term, the application will publish using the XEVMPD standard, and in 2016 the application logic will be updated to publish the required data to IDMP format.

### Integration

For site installed ESM Portal instances, Intagras can integrate with existing systems to pull data. Integration allows divisions of your organization to maintain data based on business division and role. ESM Portal brings data together at the time of publication to ensure the most up-to-date data is utilized.

### Audit Trail

All modifications will be captured by user name and date. Additionally, ESM Portal captures content values before and after an update. This feature will provide the basis for ESM Portal's audit trail functionality.

### Multiple Delivery Models

ESM Portal can be hosted internally by your organization or companies can subscribe to the hosted Software-as-a-Service (SaaS) application. The SaaS model provides immediate global access with no software to purchase or install.

### Dashboard

ESM Portal provides robust statistics dashboard that details how many submissions an organization has created by: date, type, product and more.



# Features

## Submission Management

- Generation
- Life-cycle management
- Full compliance
- Integrated AS2 Gateway

## Organization Data

- Associated EV Codes
- Organization Type
- Local Number
- Sender ID
- More...

## Source Data

- Associated EV Codes
- Source Name
- Local Name
- More...

## Substance management

- Associated EV Codes
- Substance Name
- Translation(s)
- Alias / Synonym(s)
- International Codes
- Previous Codes
- More....

## Product Data

- Associated EV Codes
- Product Name
- Short Name
- Authorization Information
- Marketing Authorization Holder
- EV Registration System QPPV Code
- PV System Master File Code
- More...

## E-Mail

- Alerts for submission response
- Alerts for submission errors

## County Configuration

- Product mapping
- E-Mail notification

## Administration

- User management
- E-Mail notification management
- Role based access and security
- Country based access
- Product management

## Reports

- Dashboard