



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) e-learning

Session 3: Database Architecture

Version 5.4





Roles of the XEVMPD in the EV System (1/2)

The roles of the XEVMPD in the EudraVigilance system are:

- to create a list of all medicinal products authorised in the EU/EEA including medicines authorised centrally via the European Medicines Agency and medicines authorised by regulatory authorities in EU Member States;
- to create a list of investigational medicinal products studied in clinical trials in the EU/EEA;
- to identify medicines accurately, especially medicines included in reports of suspected adverse reactions;
- allow for the coding of medicinal products and/or active substance(s) in Individual Case Safety Reports (ICSRs) transmitted to EudraVigilance;



Roles of the XEVMPD in the EV System (2/2)

- facilitate signal detection and data analysis in the EV Data Warehouse and Analysis System (EVDAS) by using coded medicinal product information;
- coordinate the regulation safety-monitoring and pharmacovigilance activities of medicines across the EU/EEA; and
- support the implementation of the EudraVigilance Access Policy.



XEVMPD

I. DATABASE ARCHITECTURE

II. PRODUCT REPORT DB

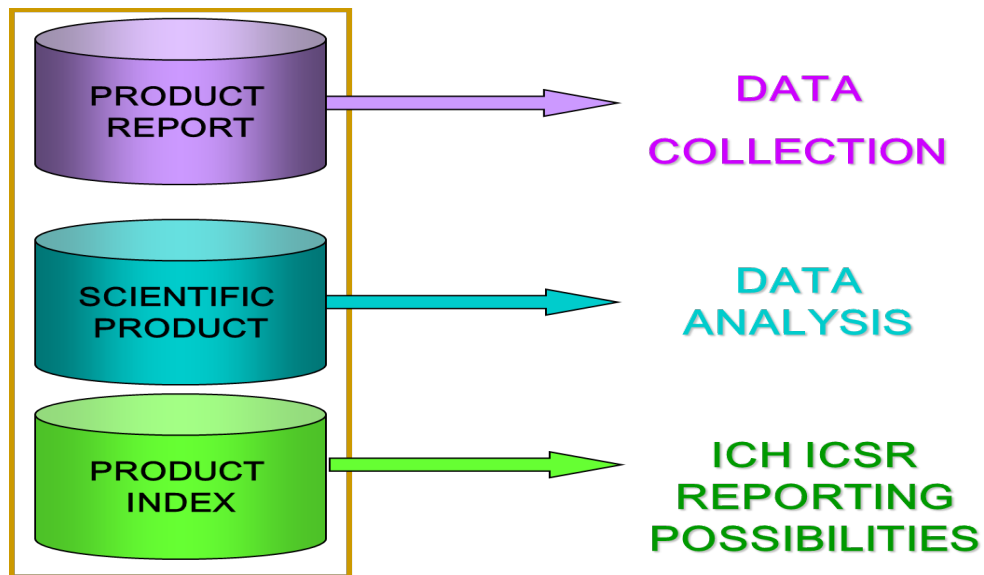
III. SCIENTIFIC DB

IV. PRODUCT INDEX

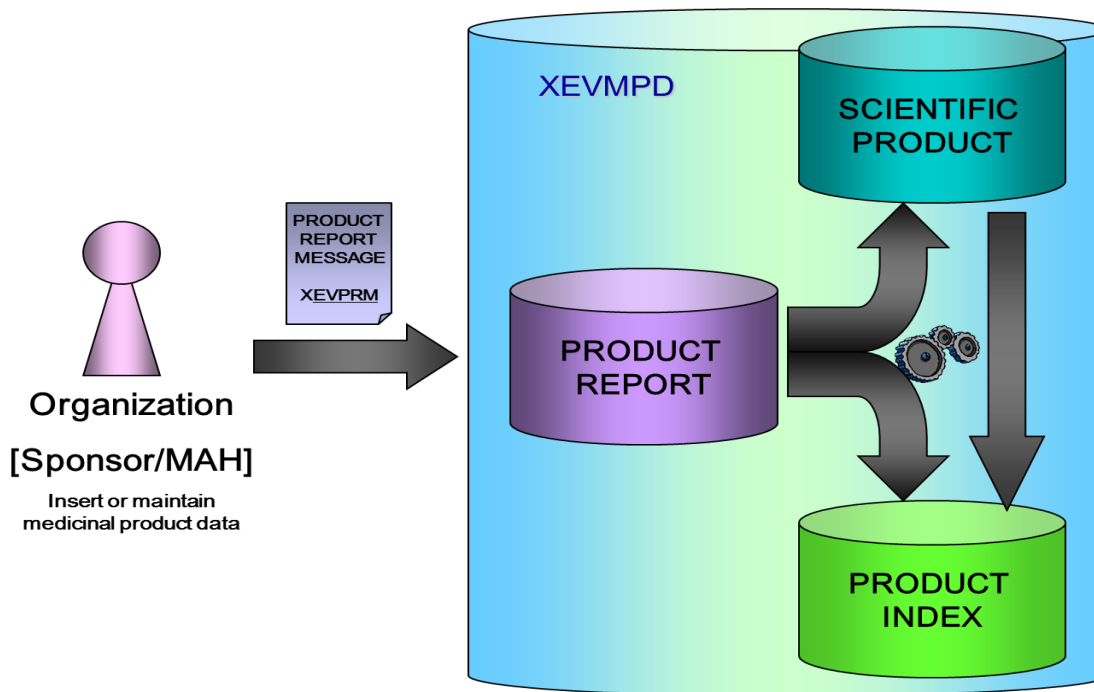
V. DATA COLLECTION



XEVMPD: Data architecture (1)

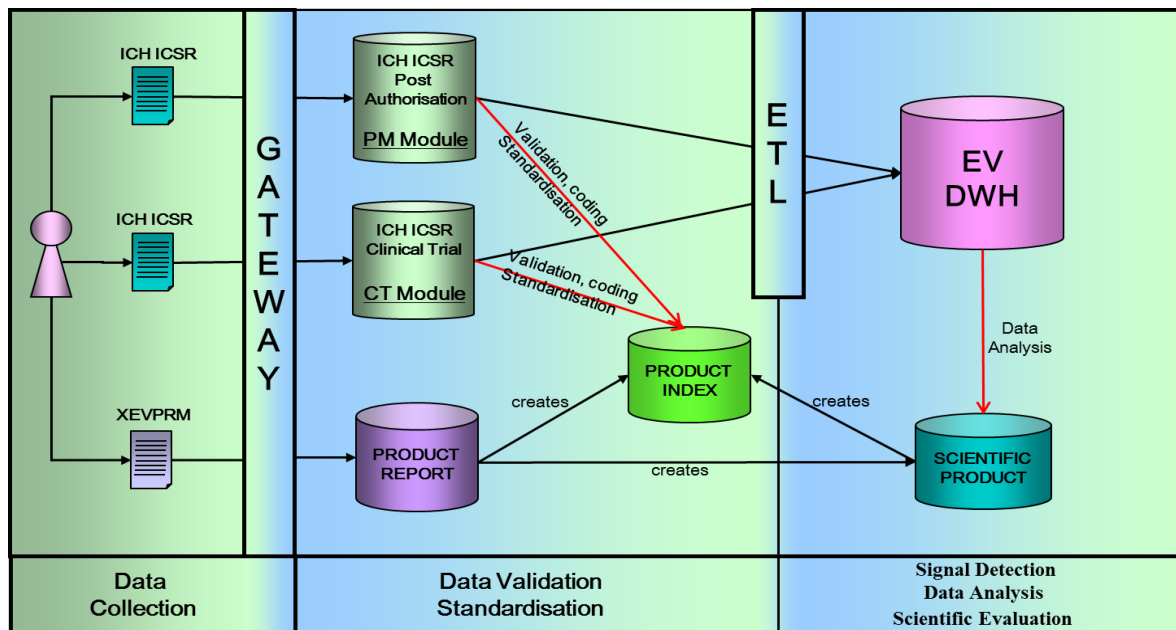


XEVMPD: Data architecture (2)



XEVMPD: Data architecture (3)

EudraVigilance System:





XEVMPD

I. DATABASE ARCHITECTURE

II. PRODUCT REPORT DATABASE

III. SCIENTIFIC DATABASE

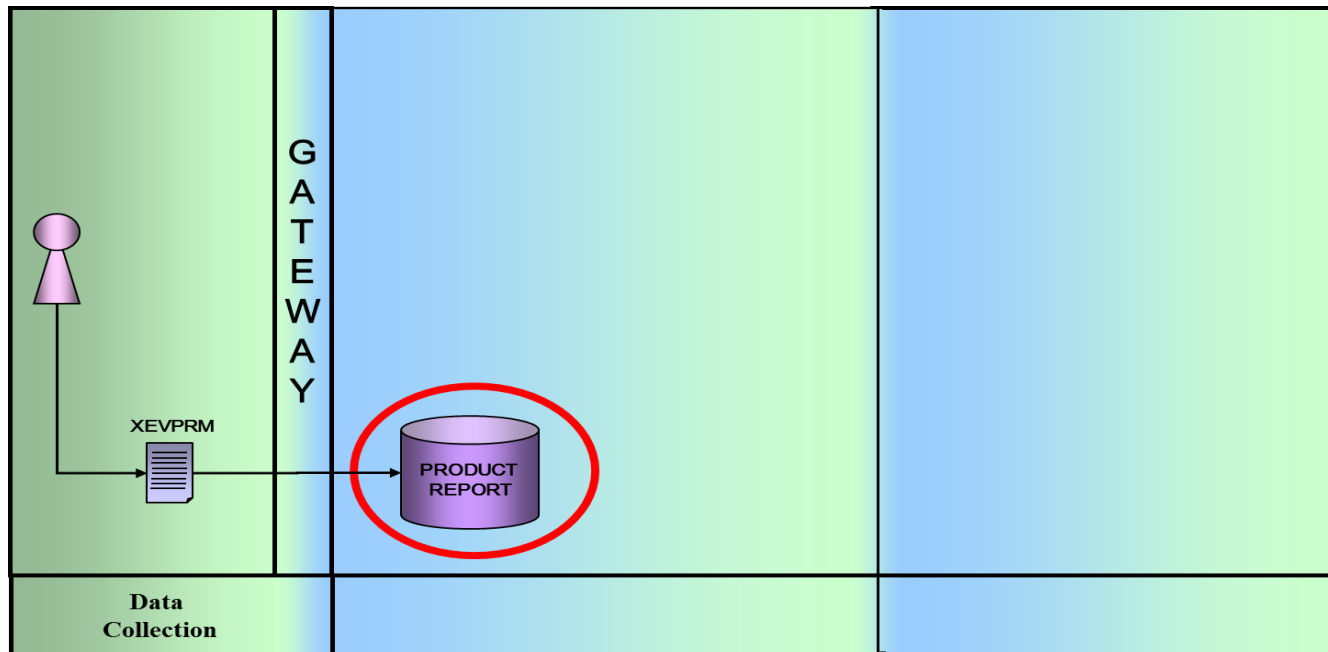
IV. PRODUCT INDEX

V. DATA COLLECTION



XEVMPD: Product report database (1/4)

EudraVigilance System





XEVMPD: Product report database (2/4)

The product report database collects:

- authorised medicinal products (AMPs);
- development medicinal products (DMPs);
- substances.



XEVMPD: Product report database (3/4)

Other look-up tables in the product report database that can be updated by MAHs and/or sponsors include:

- organisations (MAH/sponsor);
- pharmacovigilance system master file locations (PSMFLs);
- sources;
- terminology (proposed or development only; standard terminology is maintained by the European Medicines Agency (EMA) including:
 - pharmaceutical dose forms;
 - administration routes;
 - ATC codes.



XEVMPD: Product report database (4/4)

Other look-up tables in the product report database that are maintained by the EMA include:

- authorisation procedures;
- authorisation statuses;
- concentration types;
- medical devices;
- substance classes;
- units of measurement and presentation.

If a new term needs to be added on these look-up lists, a request needs to be submitted via the EMA Service Desk portal (<https://servicedesk.ema.europa.eu>)



XEVMPD

I. DATABASE ARCHITECTURE

II. PRODUCT REPORT DATABASE

III. SCIENTIFIC DATABASE

IV. PRODUCT INDEX

V. DATA COLLECTION



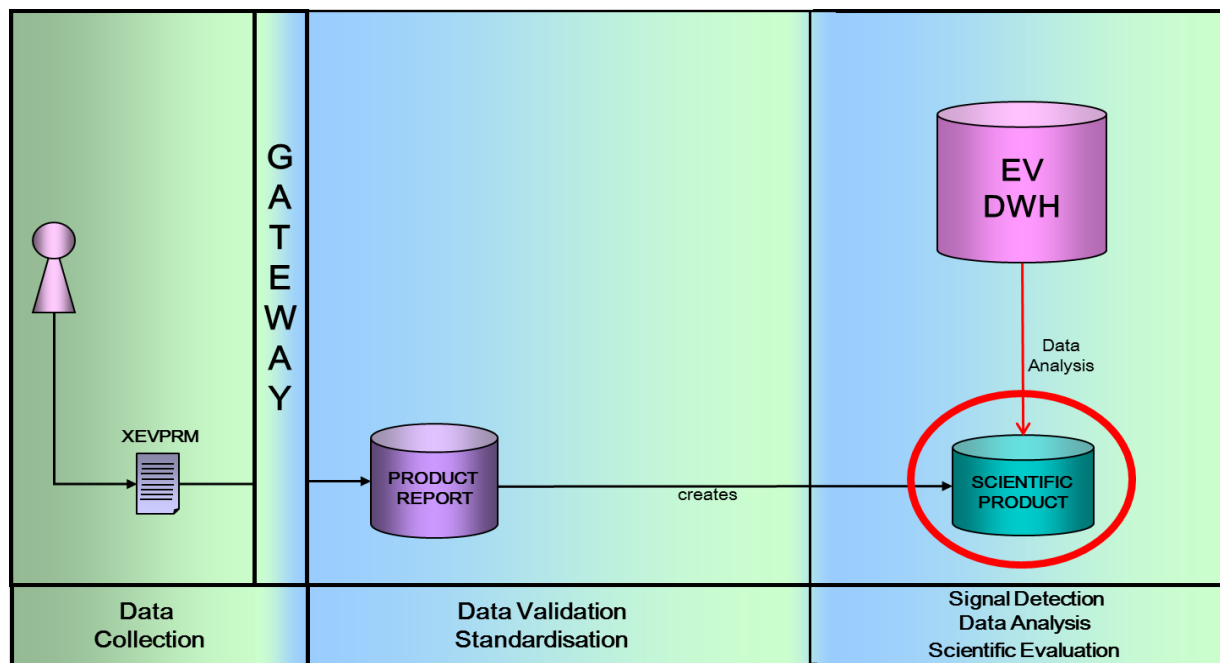
XEVMPD: Scientific product database (1/6)

The scientific product database:

- is designed to support data analysis using a scientific abstraction of the medicinal product information (AMPs and DMPs);
- implements a hierarchic structure that allows the classification and grouping of all medicinal products available in the XEVMPD on the basis of the active ingredient(s), the strength(s) and the pharmaceutical dose form(s);
- allows grouping of medicinal products solely on the basis of their composition, independently from trade names and specific marketing-authorisation holders or sponsors.

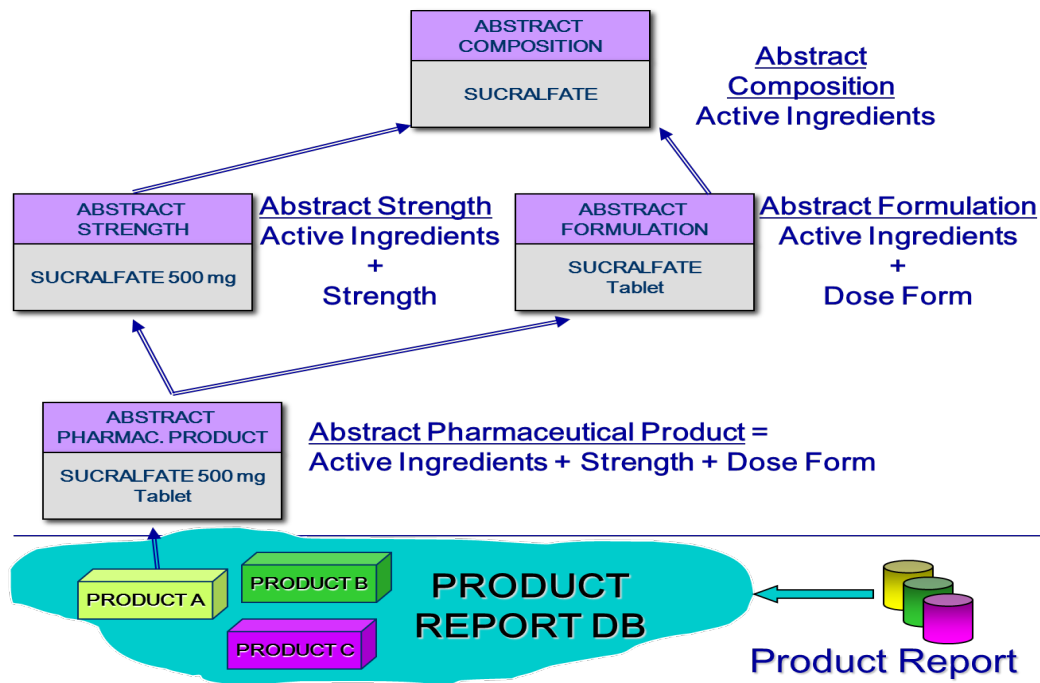
XEVMPD: Scientific product database (2/6)

EudraVigilance System:



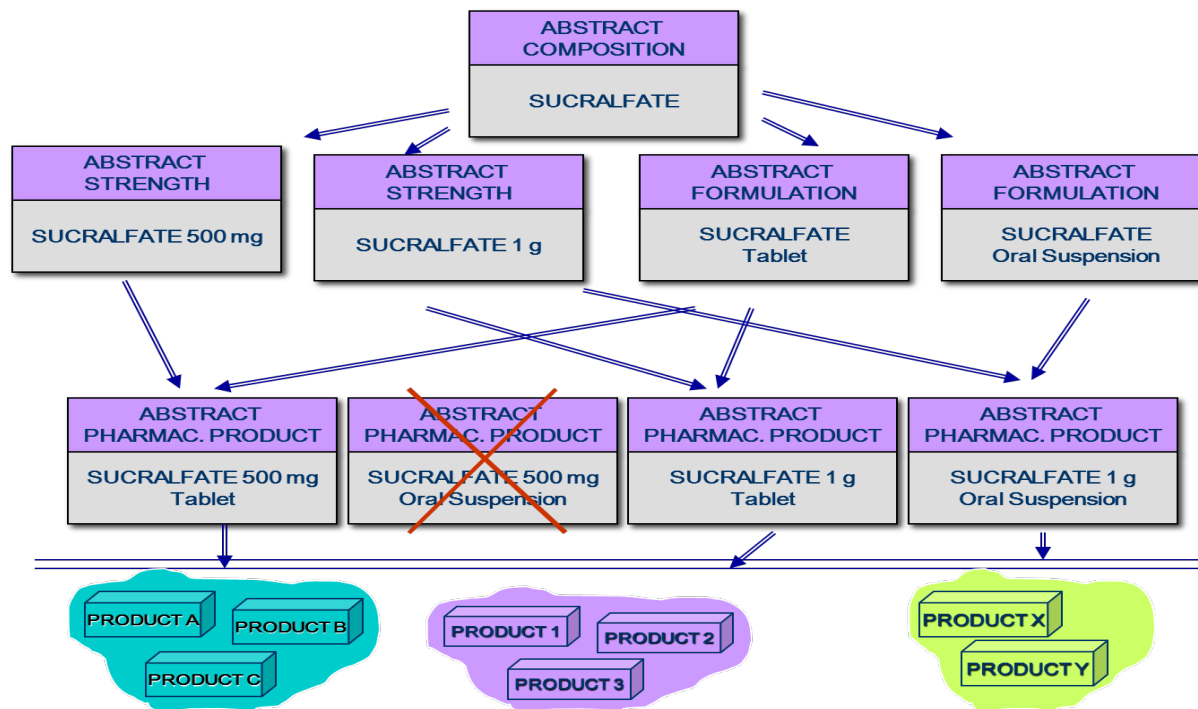


XEVMPD: Scientific product database (3/6)



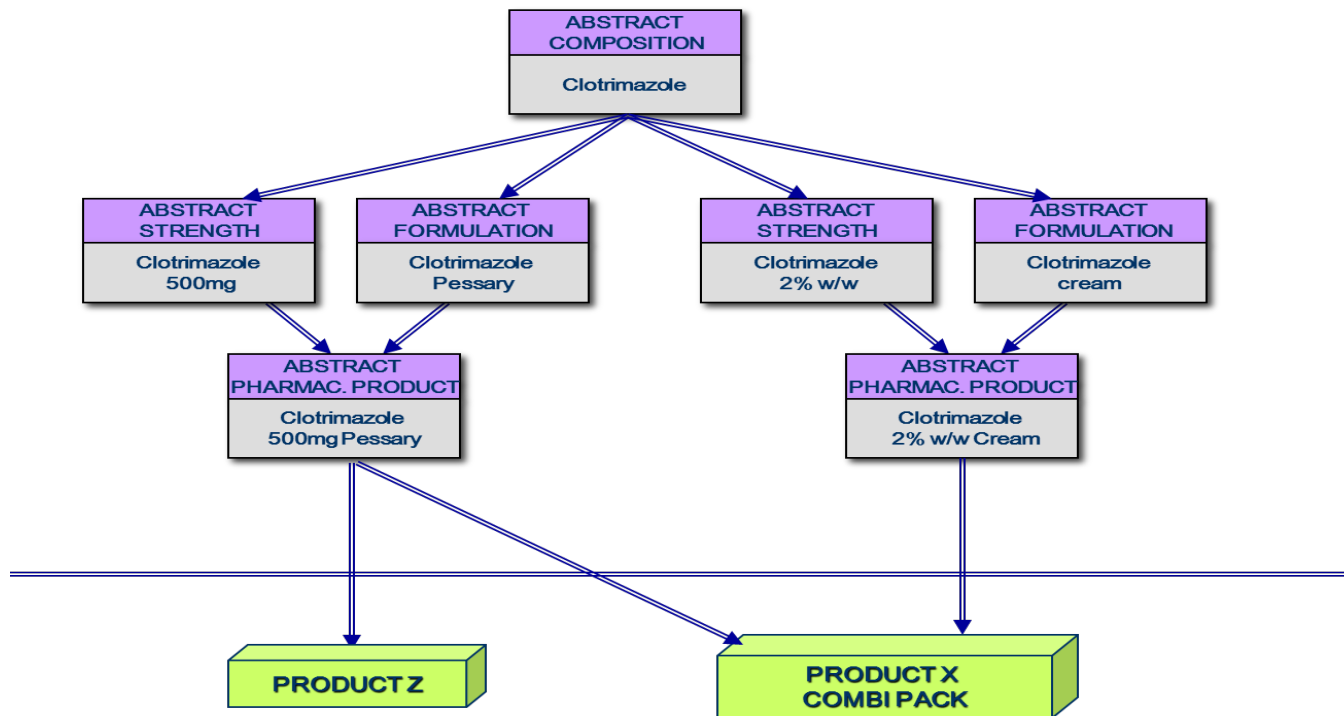


XEVMPD: Scientific product database (4/6)



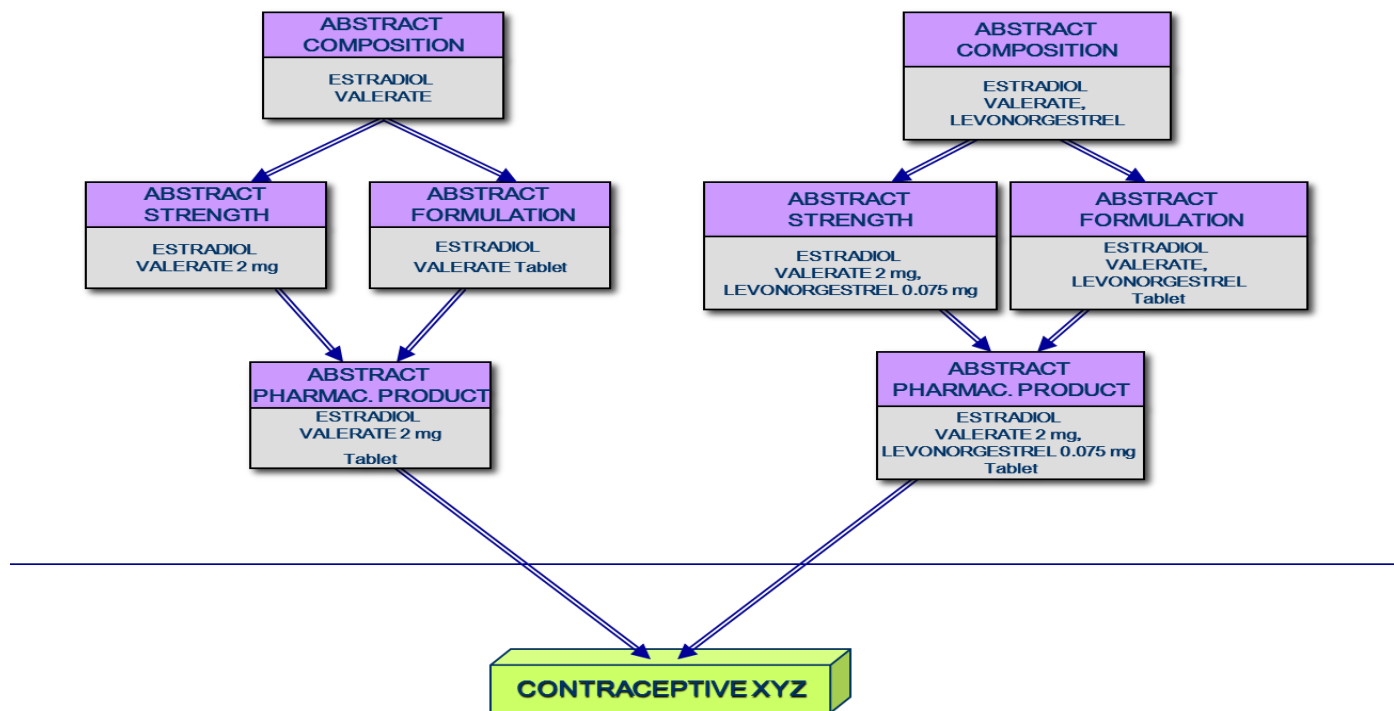


XEVMPD: Scientific product database (5/6)





XEVMPD: Scientific product database (6/6)





XEVMPD

I. DATABASE ARCHITECTURE

II. PRODUCT REPORT DB

III. SCIENTIFIC DB

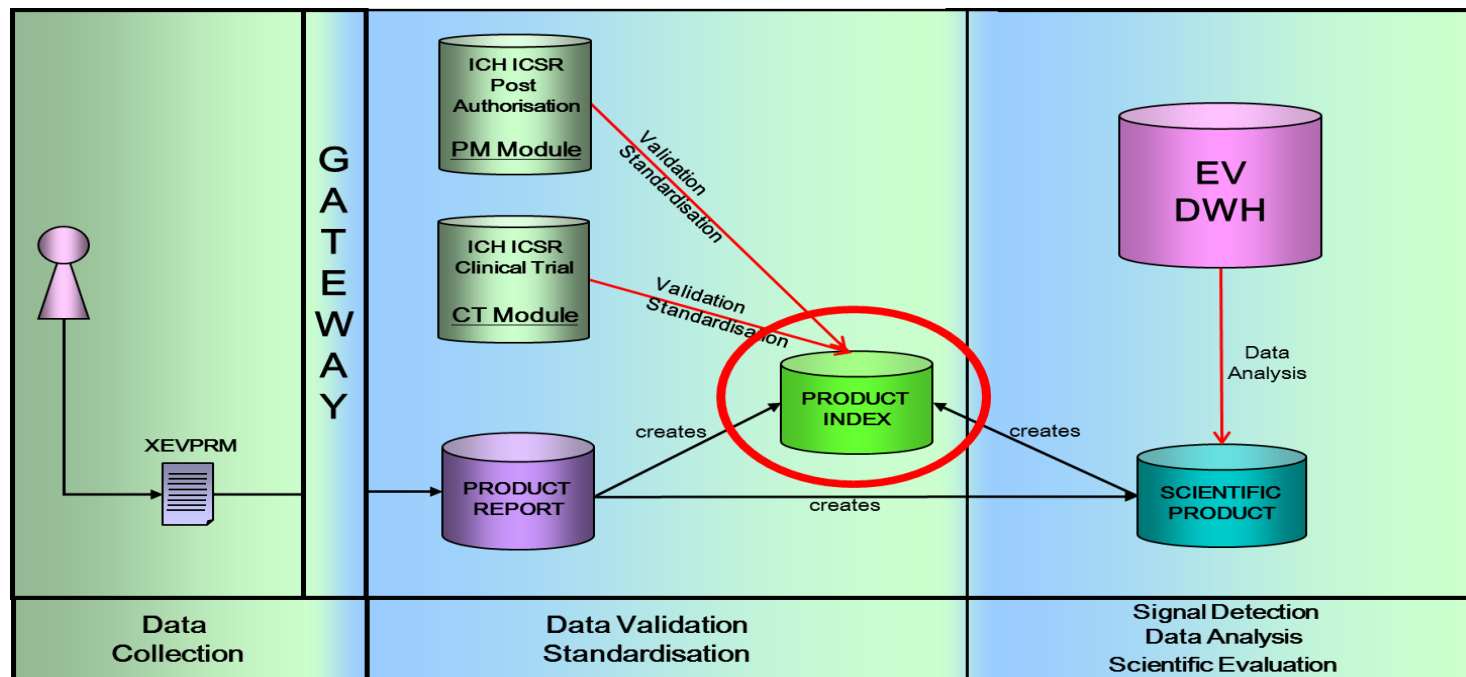
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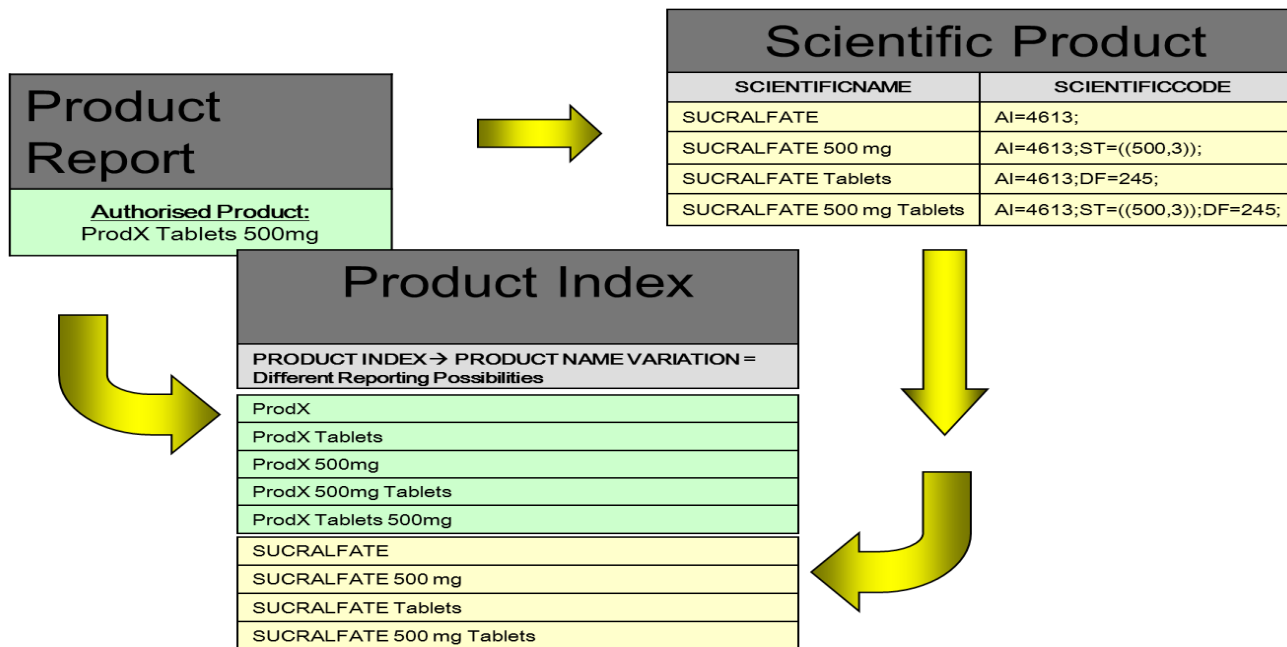
XEVMPD: Product index database (1/3)

EudraVigilance System:



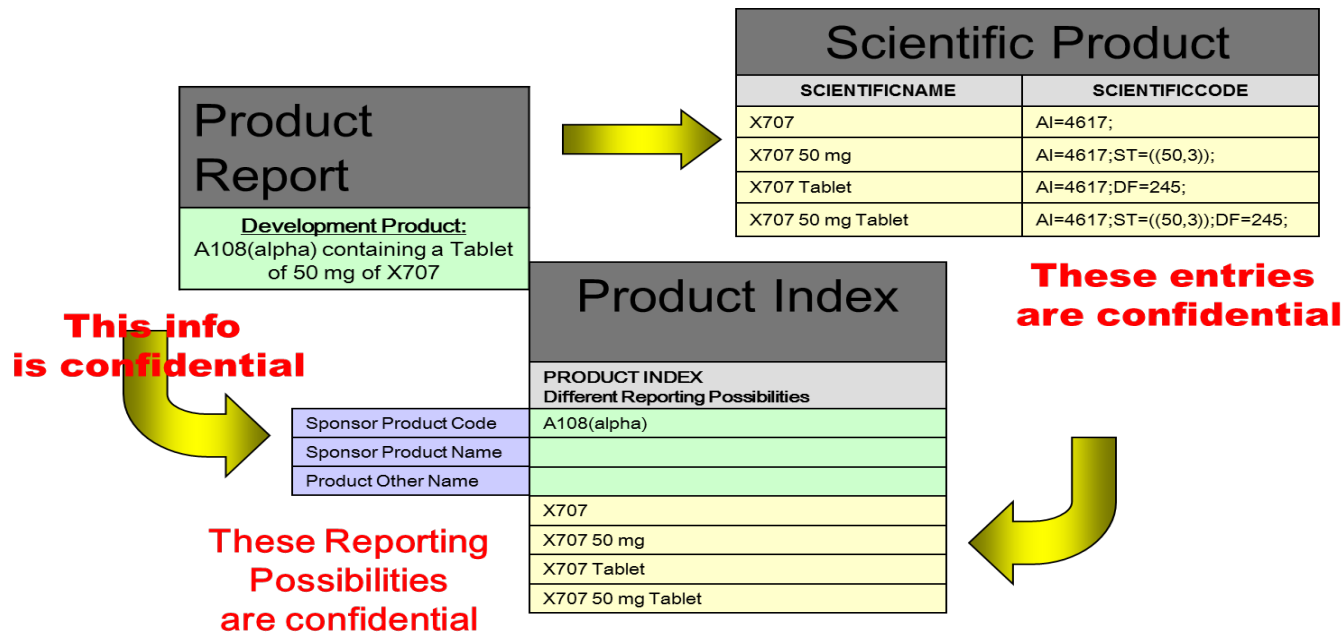


XEVMPD: Product index database (2/3)





XEVMPD: Product index database (3/3)





Product index and validation process (1/2)

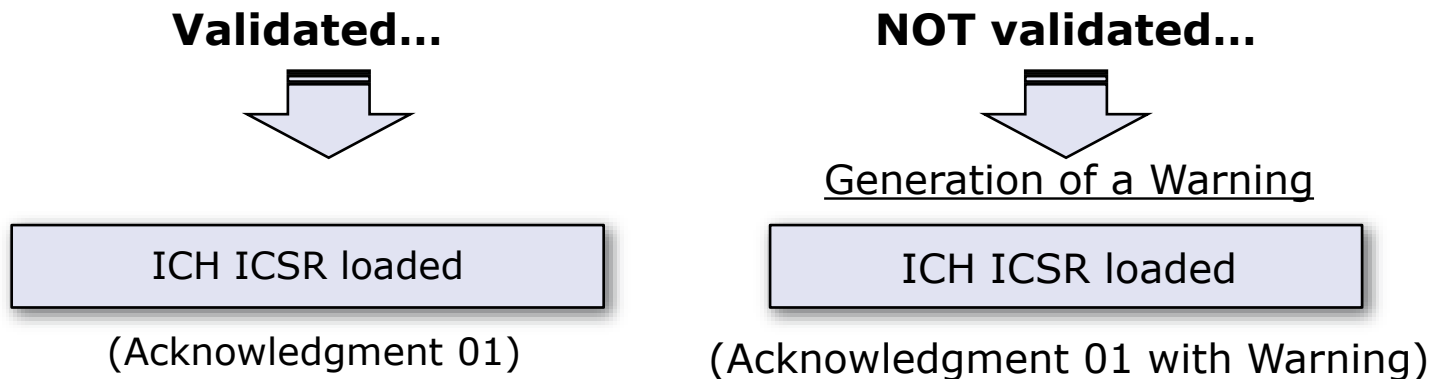
The product index is used as a reference for the validation of the product name in the following fields (*) of the ICH E2B(R2) ICSR:

- PATIENT PAST DRUG THERAPY SECTION;
 - B.1.8a / D.8.r.1 patient drug name
- PARENT PAST DRUG THERAPY SECTION;
 - B.1.10.8a / D.10.8.r.1 parent drug name DRUG SECTION;
 - B.4.k.2.1 / G.k.2.2 medicinal product name DRUG SECTION;
 - B.4.k.2.2 / G.k.2.3.r.1 active substance

(*) EudraVigilance Human - Processing of Safety Messages and Individual Case Safety Reports (ICSRs)

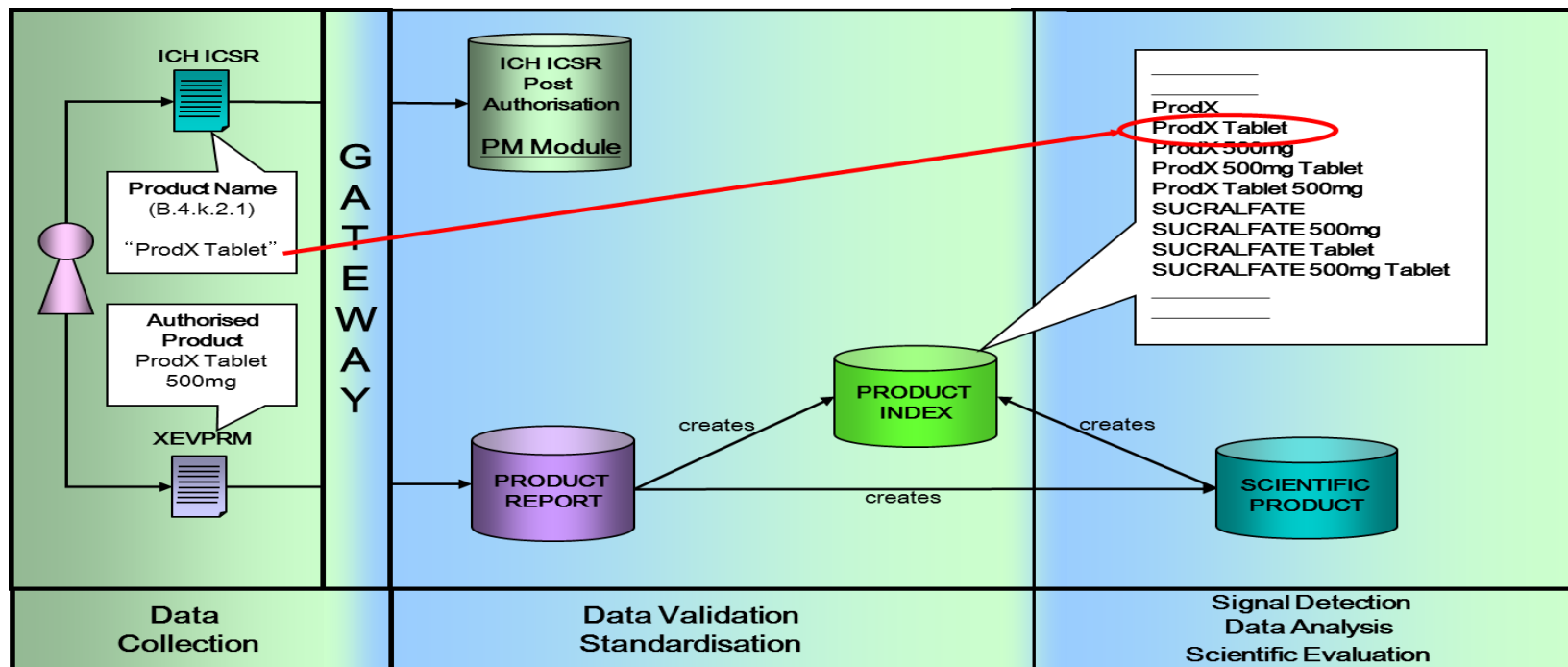
Product index and validation process (2/2)

If the information in the patient drug name (B.1.8a / D.8.r.1), parent drug name (B.1.10.8a / D.10.8.r.1) medicinal product name (B.4.k.2.1 / G.k.2.2) and active ingredient (B.4.k.2.2 / G.k.2.3.r.1) fields are:

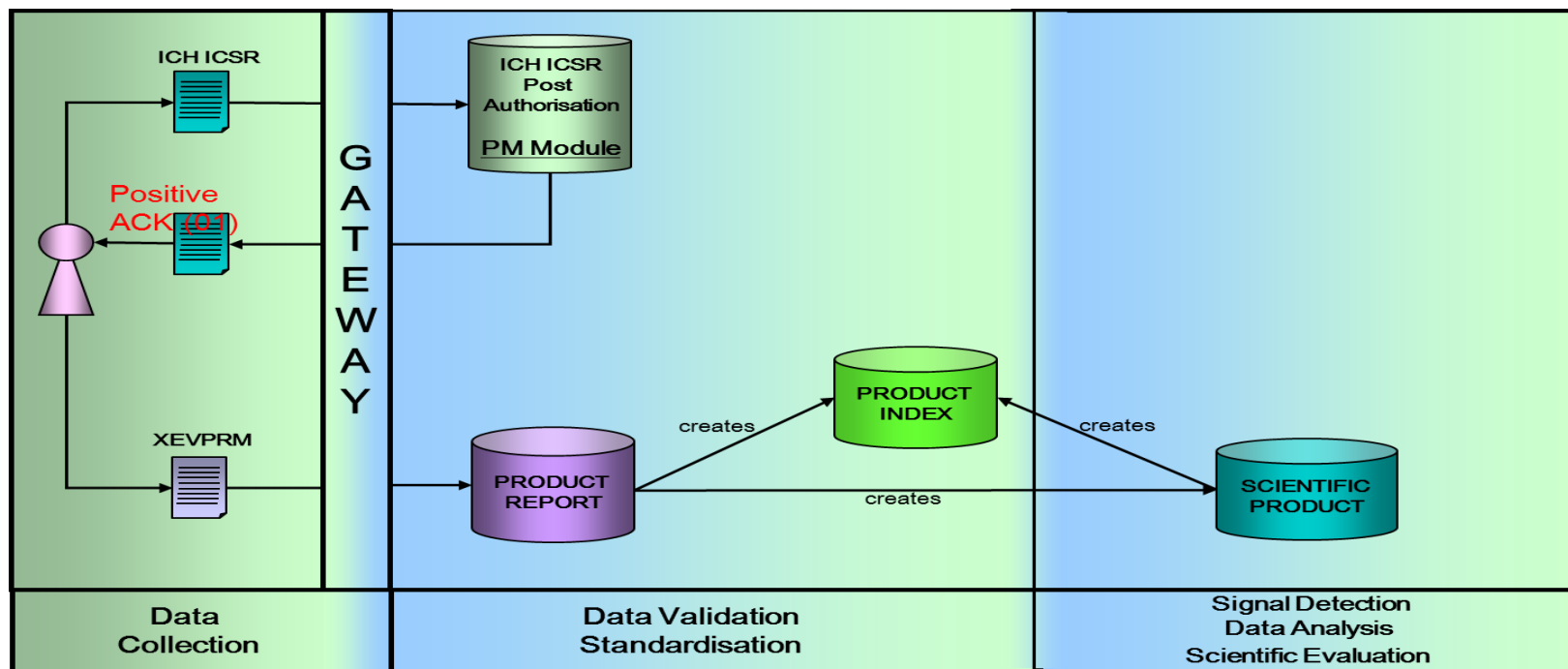




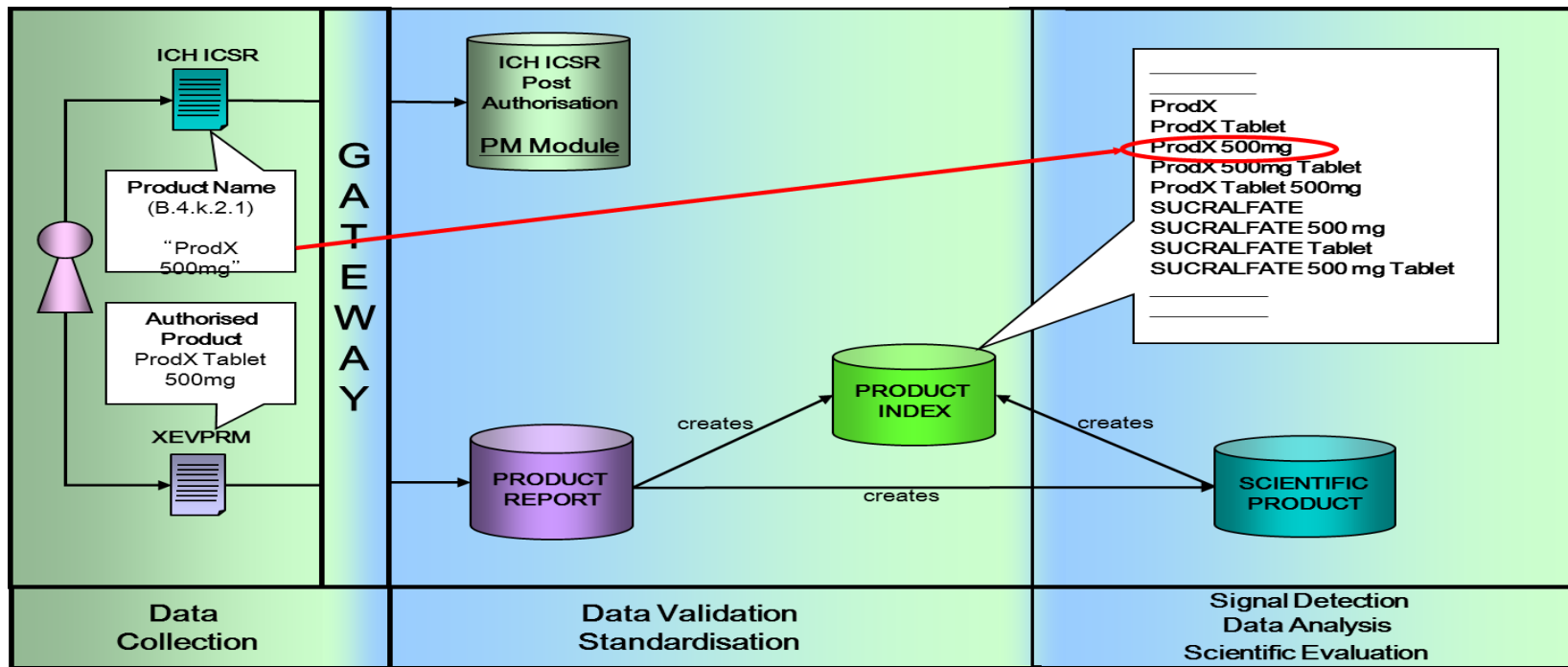
XEVMPD: Data architecture and validation (1)



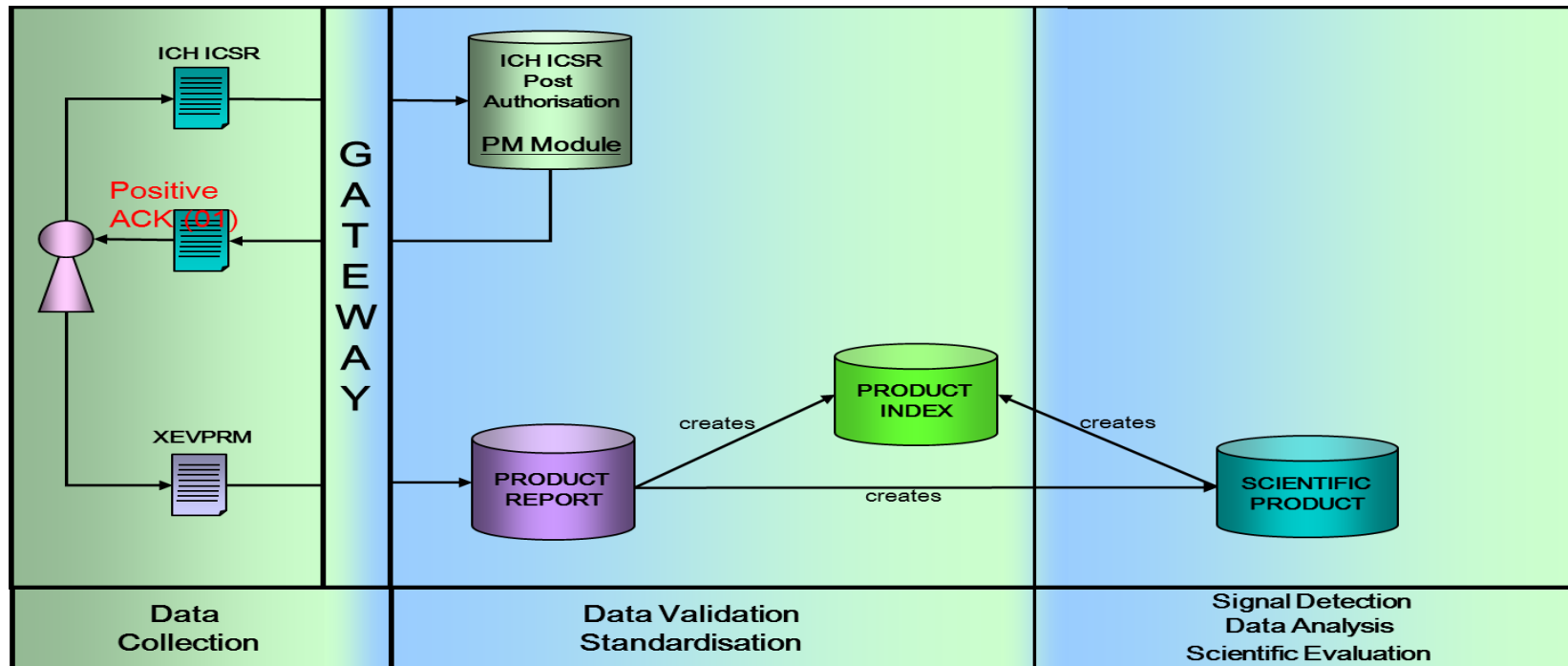
XEVMPD: Data architecture and validation (2)



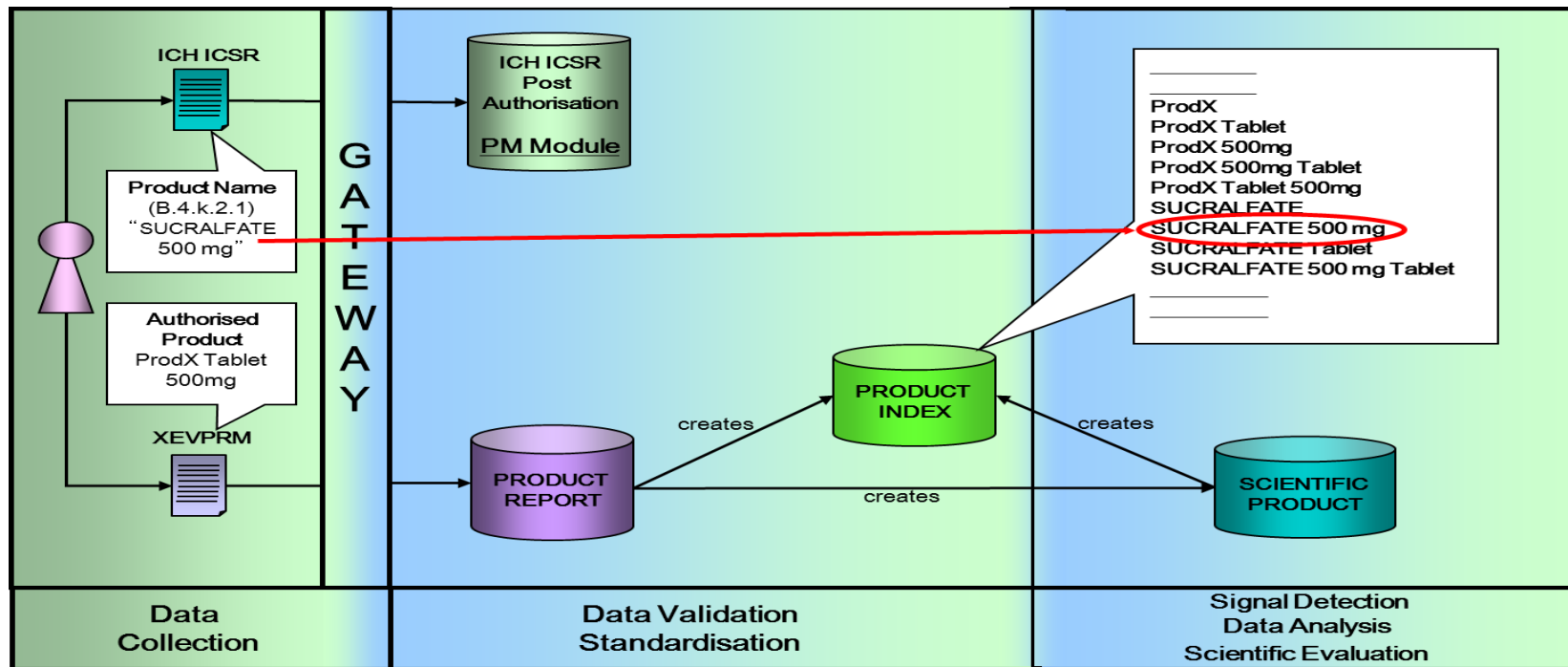
XEVMPD: Data architecture and validation (3)



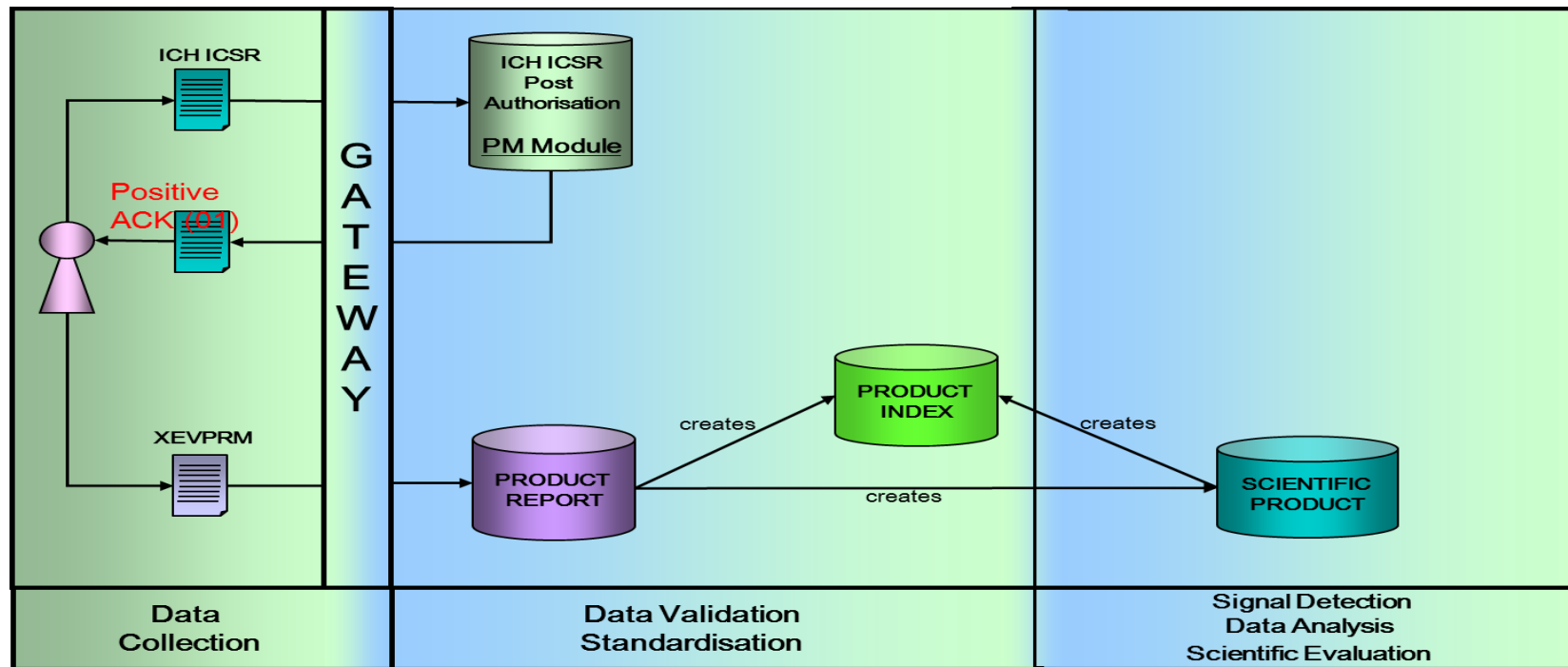
XEVMPD: Data architecture and validation (4)



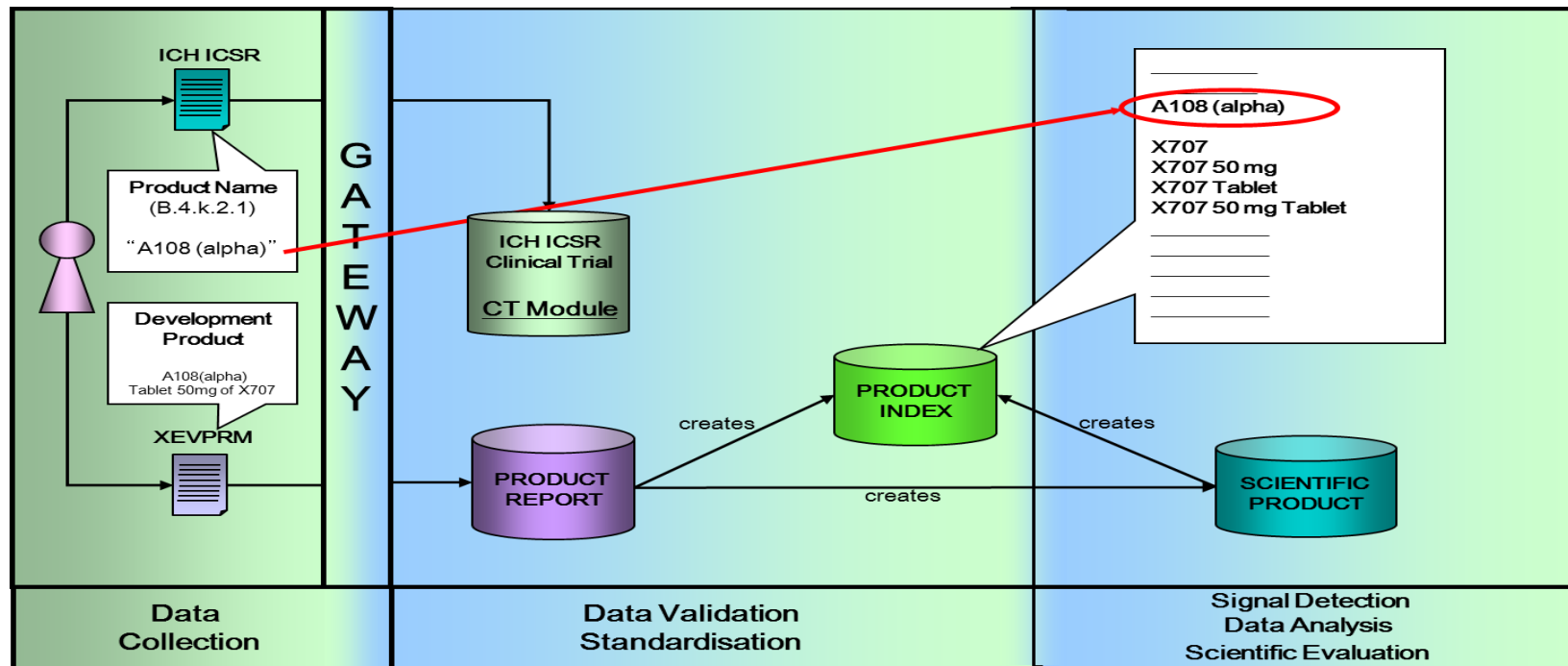
XEVMPD: Data architecture and validation (5)



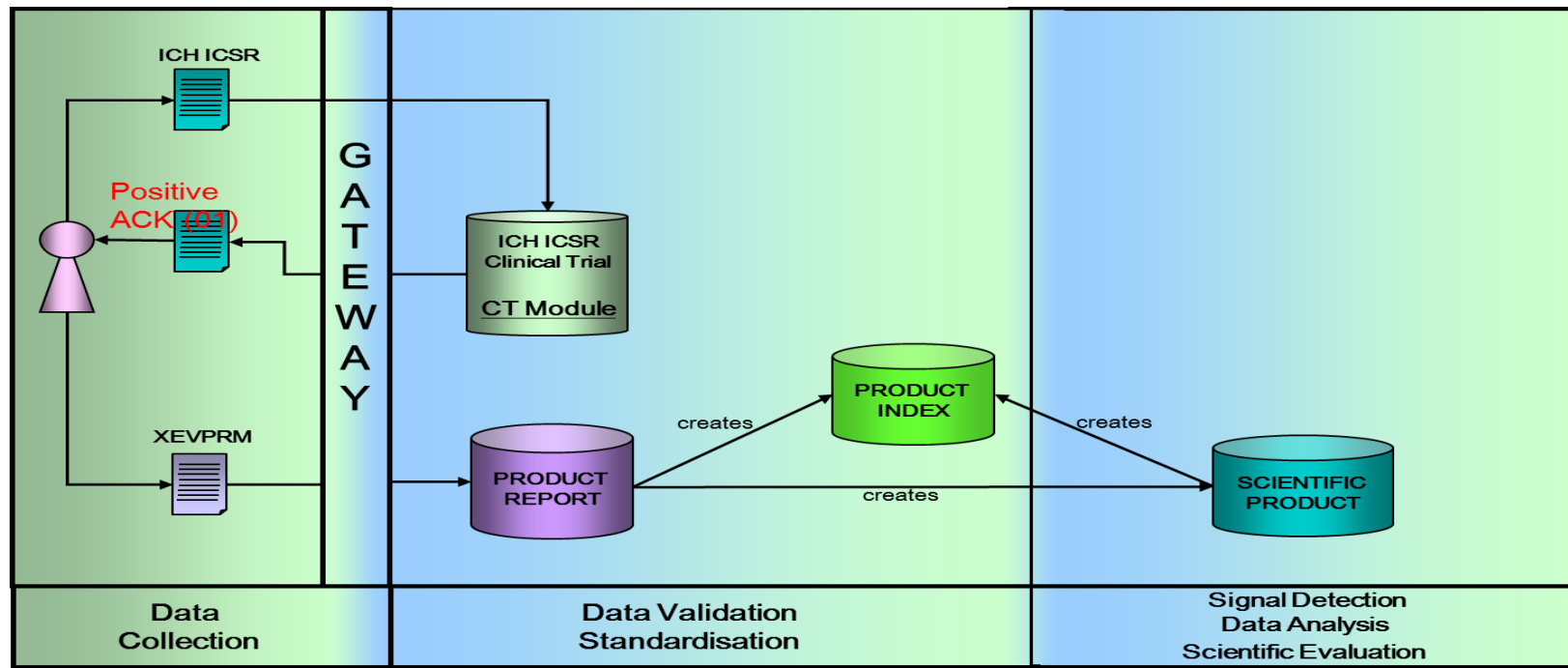
XEVMPD: Data architecture and validation (6)



XEVMPD: Data architecture and validation (7)

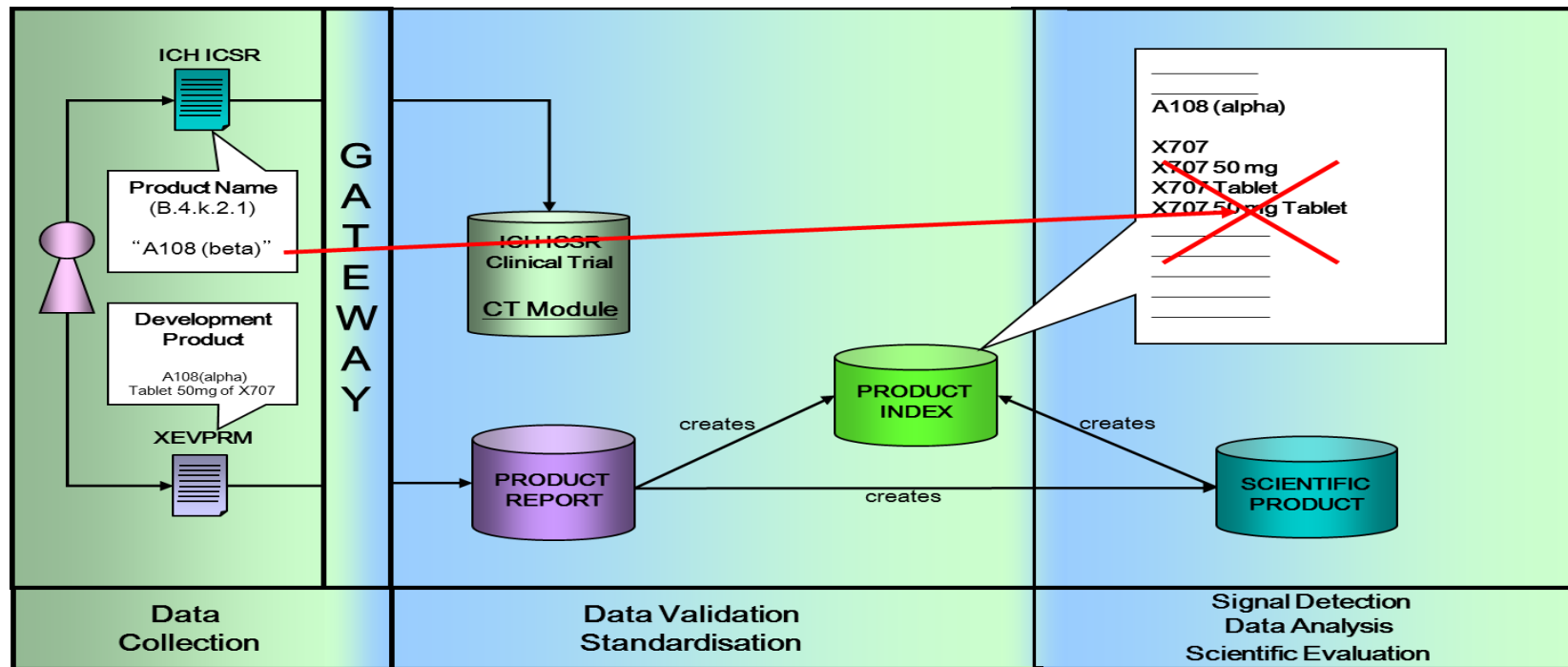


XEVMPD: Data architecture and validation (8)



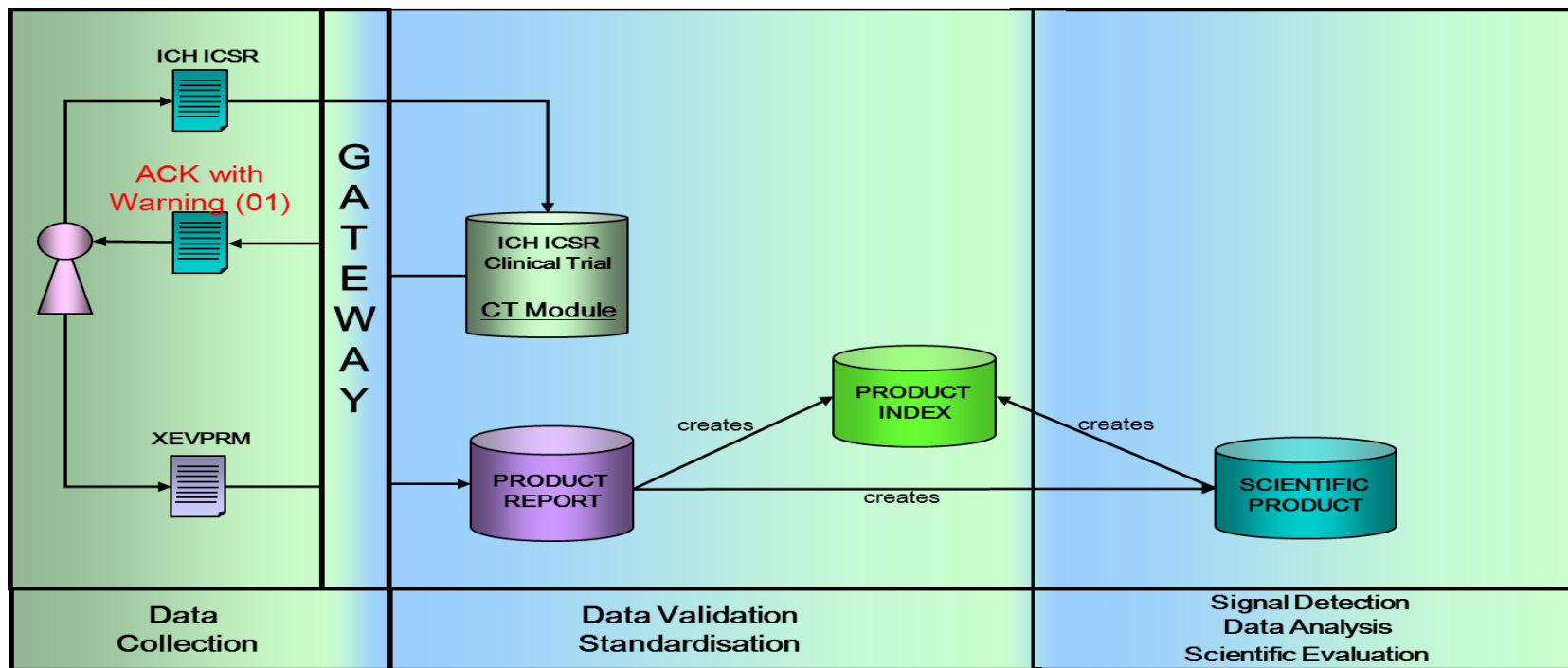


XEVMPD: Data architecture and validation (9)





XEVMPD: Data architecture and validation (10)





XEVMPD

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II. PRODUCT REPORT DB

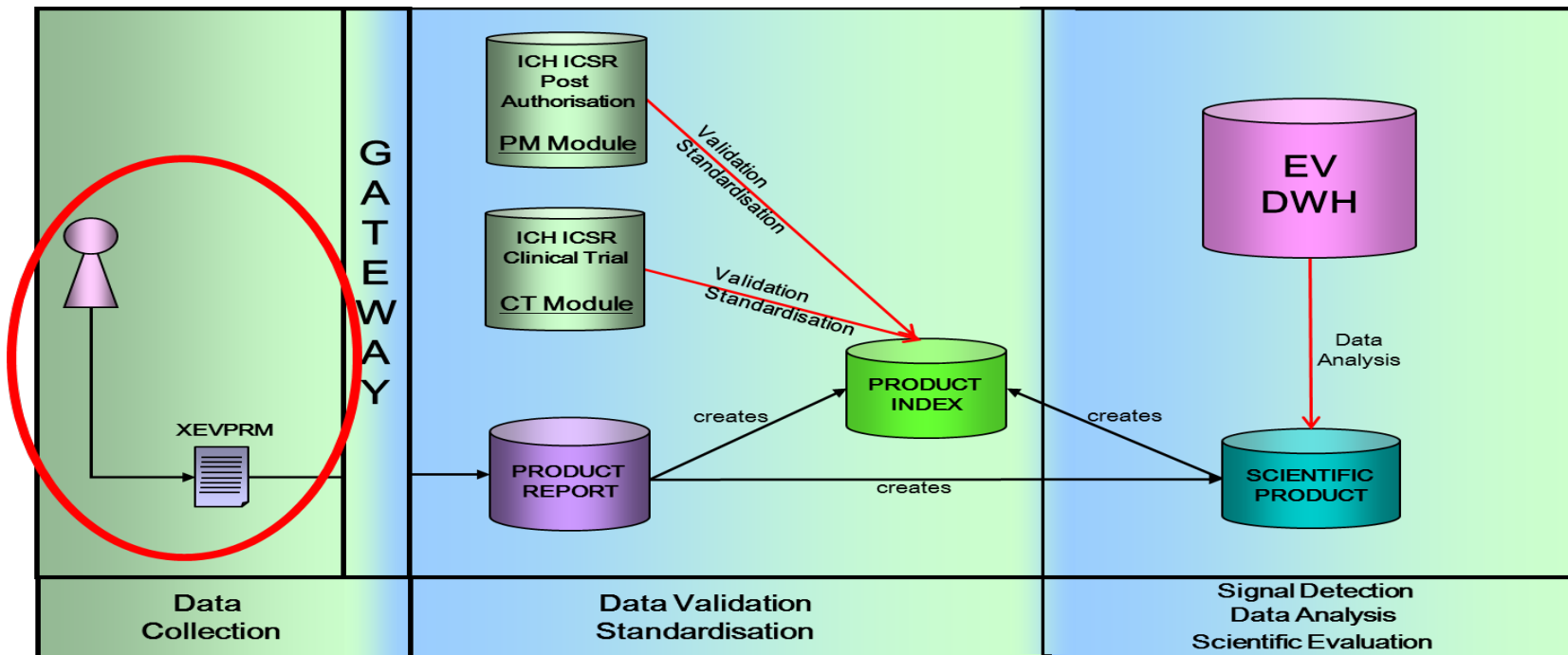
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XEVMPD: Data collection





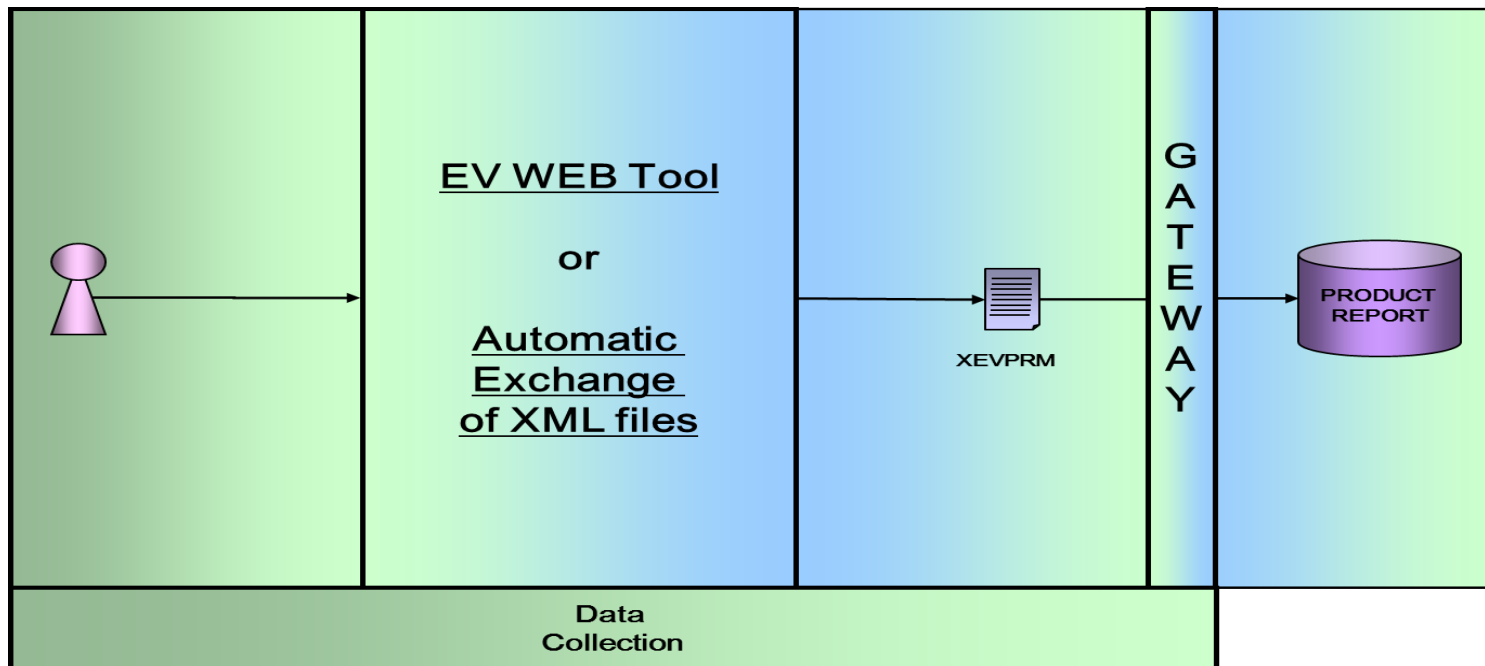
Data collection tools

- Insert and maintain information in the XEVMPD:
 - XEVMPD Data Entry Tool (EVWEB);
 - exchange of XML files: eXtended Eudravigilance Medicinal Product Reports (XEVPRMs).



XEVMPD: Data collection

Insert and maintain:



Data entry and maintenance

User rights:

The user can maintain Product Data			
	Via POST Function	Via Gateway	Via EVWeb Tool*
Gateway User	✓	✓	⊘
Web Trader User	✓	⊘	✓

* Except if they register a virtual affiliate as a WebTrader under the headquarter profile in EV



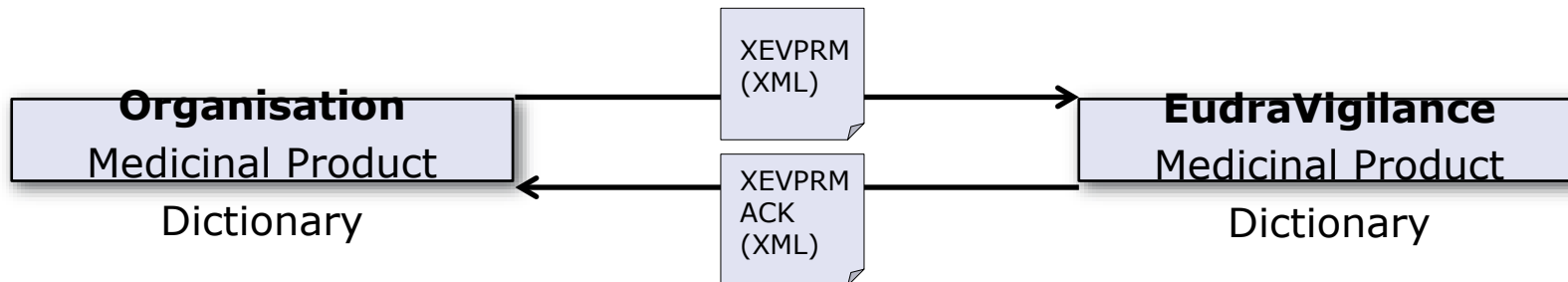
1. XEVMPD Data Entry Tool (EVWEB)

The XEVMPD data entry tool (EVWEB) application offers the possibility to:

- Manually create an XEVPRM and to send it to the XEVMPD
- Maintain the information already entered in the XEVMPD
- Access and query the XEVMPD

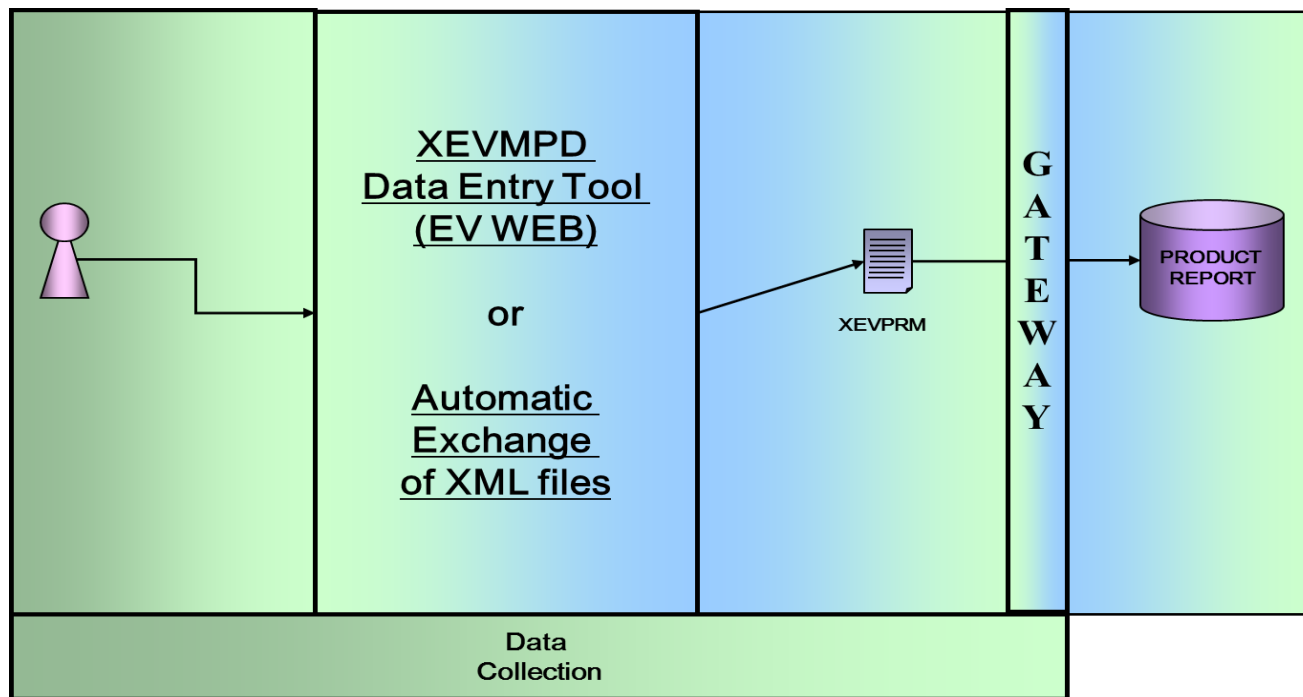
2. Exchange of XML files

- An organisation (MAH or sponsor) can exchange XML files with the XEVMPD to insert and maintain the information in the XEVMPD.
- The XML files are defined as eXtended EudraVigilance Product Report Messages (XEVPRMs).





XEVMPD: Data collection summary





XEVPRM Acknowledgement

- With all three tools, the user always sends an XEVPRM to the XEVMPD;
- The XEVPRM Acknowledgement is received as follows:

	The user receives the XEVPRM ack	
	Via Gateway*	In the EVWEB INBOX Folder
Gateway Trader User	✓	∅
WebTrader User	∅	✓

* Except if they register a virtual affiliate as a WebTrader under the headquarter profile in EV