About OMICS Group

OMICS Group is an amalgamation of Open Access Publications and worldwide international science conferences and events. Established in the year 2007 with the sole aim of making the information on Sciences and technology 'Open Access', OMICS Group publishes 500 online open access scholarly journals in all aspects of Science, Engineering, Management and Technology journals. OMICS Group has been instrumental in taking the knowledge on Science & technology to the doorsteps of ordinary men and women. Research Scholars, Students, Libraries, Educational Institutions, Research centers and the industry are main stakeholders that benefitted greatly from this knowledge dissemination. OMICS Group also organizes 500 International conferences annually across the globe, where knowledge transfer takes place through debates, round table discussions, poster presentations, workshops, symposia and exhibitions.

OMICS International Conferences

OMICS International is a pioneer and leading science event organizer, which publishes around 500 open access journals and conducts over 500 Medical, Clinical, Engineering, Life Sciences, Pharma scientific conferences all over the globe annually with the support of more than 1000 scientific associations and 30,000 editorial board members and 3.5 million followers to its credit.

OMICS Group has organized 500 conferences, workshops and national symposiums across the major cities including San Francisco, Las Vegas, San Antonio, Omaha, Orlando, Raleigh, Santa Clara, Chicago, Philadelphia, Baltimore, United Kingdom, Valencia, Dubai, Beijing, Hyderabad, Bengaluru and Mumbai.

Oviya MedSafe

Practising Safety

EUROPEAN PHARMACOVIGILANCE UNDER EUDRAVIGILANCE

Coimbatore, India

London, United Kingdom

EUROPEAN PHARMACOVIGILANCE UNDER EUDRAVIGILANCE

- Introduction
- Where it fits within the entire European framework
- Understanding the EudraVigilance system
- How it is implemented in the post-marketing approval of medicinal Drugs
- Challenges
- Questions

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Introduction

EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).

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Where it fits within the entire European framework

EudraVigilance (EV) – mandatory in EEA for post-marketing European-wide PV system for rapid dissemination of data of a safety nature for evaluation.

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Understanding the EudraVigilance system

EV is consistent with Electronic Data Interchange (EDI) principles and meets Electronic Standards for the Transfer of Regulatory Information (ICH E2B [E2B defines the data elements for transmission of **individual** case safety reports]).

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Understanding the EudraVigilance system

EV is a database for the EMA & NCAs – benefit/risk analysis (fully searchable), but only a portal for sponsors or MAHs (ie MAHs have access to their own data only).

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Understanding the EudraVigilance system

3 methods for updating EV

- E2B transfer
- EVWEB
- EVPOST

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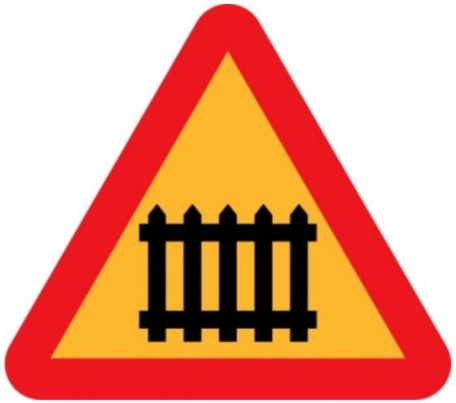
Understanding the EudraVigilance system

- E2B transfer – **automated** transfer of xml data via a Gateway (database to database - it's called the 'Gateway ' method)



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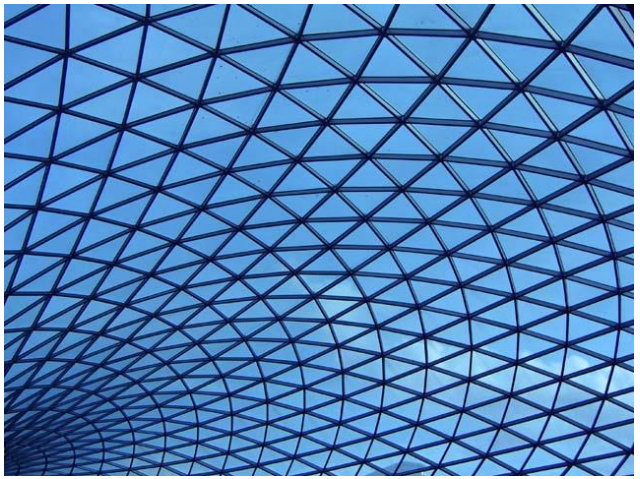
Understanding the EudraVigilance system

- EVWEB is a method of **manually** populating EV (it's called a 'Web trader' method)



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Understanding the EudraVigilance system

- EVWEB

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Understanding the EudraVigilance system

- EVPOST – which cannot transfer the data automatically via a Gateway (enter onto your database, then create the computer E2B xml, then the xml is given to EV)

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How it is implemented in post-marketing situations

i. Regulation (EU) No 1235/2010
(EC 726/2004 as amended)

ii. Directive 2010/84/EU
(2001/83/EC as amended)

iii. Good Pharmacovigilance Practice guidelines
(GVP module VI)

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How it is implemented in post-marketing situations

QPPV – specifically for MAHs & legislated (role is defined in GVP) because it covers PV

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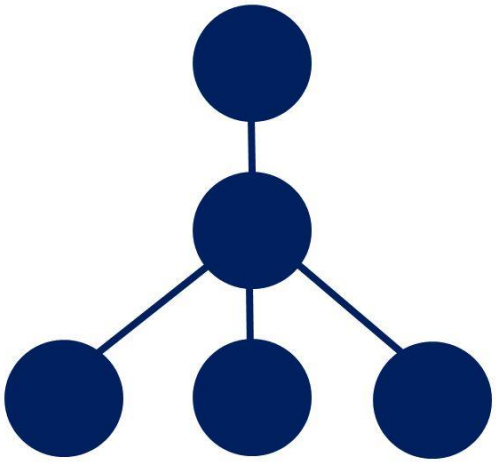
How it is implemented in post-marketing situations

The order [access rights]:

1. QPPV (super user)
2. ‘Trusted’ deputy
3. Standard users (DE only)



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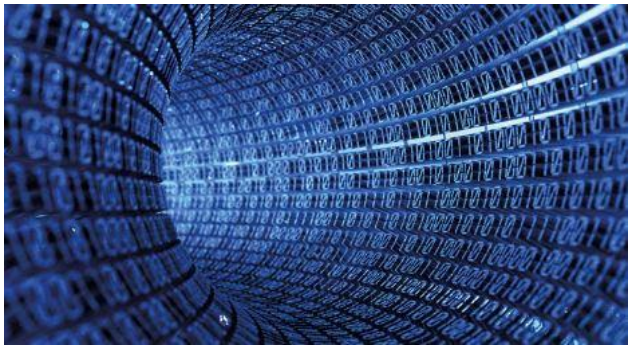
How it is implemented in post-marketing situations

Reason for rigorous registration procedure:

1. EMA want to be sure you've a valid reason for access
2. Security of proprietary data
3. Patient protection (individual anonymity)
4. Wider information protection (protecting against 'bandwagon' effect/media exaggeration)



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How it is implemented in post-marketing situations

Safety case complance timelines from: date case 1st received by MAH to date that acknowledgment message is returned.

Associated to EV, is XEVMPD ie the medical products dictionary for EV – Created Using SmPC

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Challenges

- Official User Training
- Registration
- Population of XEVMPD
- Resources (departmental organisation)
- Language (your safety DB v EV)
- Compliance Timelines (ICSRs)

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Thank You for your attention.

Questions?

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References

- http://ec.europa.eu/health/documents/eudralex/index_en.htm#
- https://eudravigilance.ema.europa.eu/human/docs/guid¯P¯Technical%20Documentation¯EMEA-H-20665-04-en-Final.pdf

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Let us meet again..

We welcome you all to our future conferences of OMICS International

5th International Conference & Exhibition on Pharmacovigilance & Clinical Trials

On

September 19 - 21, 2016 at Vienna, **Austria**

http://pharmacovigilance.pharmaceuticalconferences.com/