EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance project: Launch of the new system

12th industry stakeholder platform – 24 November 2017

Francois Domergue – EudraVigilance business project manager

Project milestones

- Independent audit report completed in February/April 2017
- Favourable PRAC recommendation in May 2017
- Confirmation and announcement by the EMA Management Board that full functionality of the new EudraVigilance database has been achieved on 22 May 2017
- Transition period for the launch of the new system: 8 November to 21 November 2017
- **Go-live of the new EV system: 22 November 2017**

EudraVigilance go-live activities

- Transition period for the launch of the new system:
  - 8 November to 21 November 2017
- Scheduled EudraVigilance downtime was communicated to all stakeholders.
- EudraVigilance go-live plan and technical note were published on 4 October.
- EMA project team completed the activities for the system installations and data migration according to plan.
- Key decision points were set-up during this process to
  - ensure control/checks;
  - decide to communicate to NCAs/MAHs in case of delays/issues.

EudraVigilance go-live

- As of 22 November the new EudraVigilance System is live

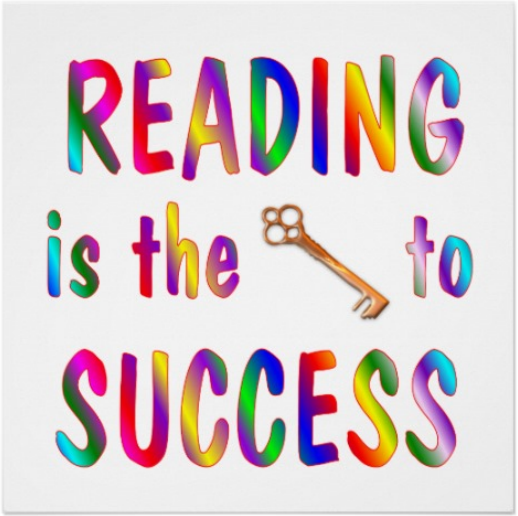
- It was a major undertaking
- It was a joint effort between all stakeholders
- There was/is excellent collaboration with NCA experts in Member States and pharmaceutical industry
- It is a really great team that delivered

Expected benefits

New feature	Benefit
• Enhanced signal-detection and data-analysis tools to support safety monitoring directly by Member States and marketing authorisation holders	• Better detection of new or changing safety issues, enabling rapid action to protect public health
• Improved quality and completeness of ICSR data	• Better searchability and more efficient data analysis
• Enhanced scalability of the EudraVigilance system	• Able to support an increased number of ICSRs due to the new requirement to report non-serious cases to EudraVigilance
• Simplified reporting of ICSRs to EudraVigilance and the rerouting of ICSRs to Member States	• Reduced duplication of efforts • Marketing authorisation holders no longer have to provide ICSRs to national competent authorities, they have to submit these to EudraVigilance only
• EMA will provide data to the World Health Organization (WHO) Uppsala Monitoring Centre directly from EudraVigilance	• Enhanced collaboration between EMA and WHO • Member States will no longer need to carry out this task

Stakeholder support and training (1/4)

- e-learning/technical documentation/revised change management plan/user guides/Q&A published on EMA website;
- Recent additions:
  - ADR website user guide – new
  - EVWEB release notes – new
  - XCOMP release notes (updated)
  - EudraVigilance EVWEB user manual (updated)
  - EVDAS user manual for MAHs – new
  - EVDAS release notes for MAHs – new



Stakeholder support and training (2/4)

- ICSR submission face-to-face training courses
  - To be continued in 2018, with increased frequency
- Monthly technical and pharmacovigilance related support webinars in support of MAHs
  - To be continued in 2018

Please consult the **“EudraVigilance training and support”** webpage

Stakeholder support and training (3/4)

EudraVigilance training: Face to face training

The new EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course

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Title	The new EudraVigilance System and the electronic reporting of ICSRs in the ISO/ICH E2B(R3) format: hands-on training course
Date	20/11/2017 - 22/11/2017
Location	European Medicines Agency, London, UK
Summary	The European Medicines Agency (EMA) will launch a new EudraVigilance system with enhanced functionalities for reporting and analysing suspected adverse reactions in November 2017. The system will make use of the individual case safety report (ICSR) standards developed by the International Organization for Standardization (ISO), in collaboration with the International Council for Harmonisation of Technical

Registration

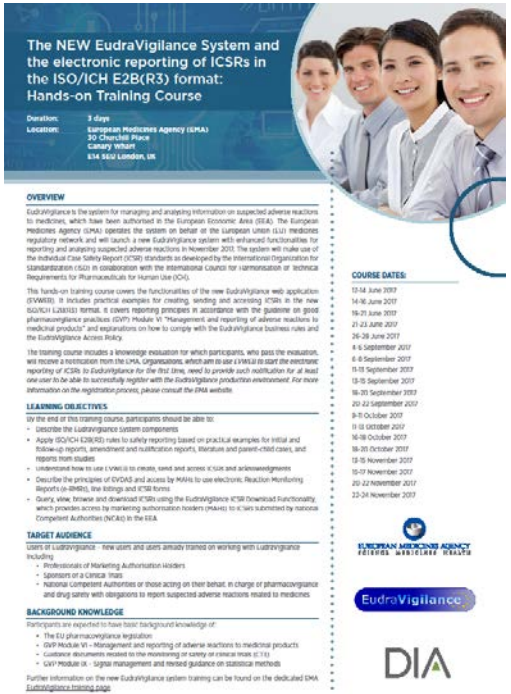
- Places limited

Related content

- EudraVigilance training

Contact point:

Malgorzata Durka-Grabowska
malgorzata.durka-grabowska@ema.europa.eu



Stakeholder support and training (4/4)

EudraVigilance Information Days

- 15 December 2017
- 16 March 2018
- 7 December 2018

Dec 2017 Info Day presents new EV and signal management activities & results from the IMI WEB-RADR project & social media analytics in phv

Stakeholder testing

EudraVigilance **test environment** (XCOMP) remains **available** to support:

- Interoperability testing
- Testing of transition to ICH E2B(R3) format
- Testing of major system changes

EudraVigilance post-go-live

- Increased monitoring of the system and support to users
- An additional EudraVigilance release (release 5) is planned for February 2018 to address potential bugs/issues identified after 22 Nov 2017; any downtime for release 5 is expected to be minimal and of similar nature to previous routine updates
- EudraVigilance operational plan is under development in consultation with the PhV Business Team and PRAC

Thank you for your attention

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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