EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance Change Management Planning

Latest updates, new webpage and training support

8th Industry stakeholder platform meeting – 1st of July 2016

Introduction

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This session will:

- Provide an update on the **progress** of the EudraVigilance auditable requirements project.
- Inform participants of the release of the **revised EudraVigilance webpage**.
- Inform participants of the EudraVigilance training approach, and the release of the **first EudraVigilance training material**.

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EudraVigilance Auditable Requirements Project Update – Legal Context (1/2)

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Regulation (EC) 726/2004 requires the Agency to set up and maintain a PHV database and data processing network ('EudraVigilance (EV) database') in support of the following:

"**Auditable requirements"** as endorsed by the EMA Management Board in December 2013:

- **Simplified reporting of side effect reports for MAHs** with **re-routing to NCAs;**
- **Provision of reports to WHO** (respecting EU data protection legislation);
- **EV access for MAHs** to conduct product monitoring including signal detection (respecting EU data protection legislation);
- **Publication of data and search availability for healthcare professionals and the public for all medicines** authorised in the EU;
- **Compliance with international ICSR standards** (and compatibility with IDMP standards based on Article 57 data) by 1 July 2016 including backwards and forwards conversion tools for E2B(R2)/(R3) messages;
- **Conversion of legacy data (> 10 mill. ICSRs currently held in EV);**
- **System performance and scalability** based on increased number of users and volume of data;
- **Security** (authentication, authorisation and data transaction to limit the risks of unauthorised access).

- Before the move to centralised reporting and the new data structure for ICSRs, the new EudraVigilance system has to undergo an **independent audit** that will check that the required functionalities agreed with the Pharmacovigilance Risk Assessment Committee (PRAC) and the EMA Management Board in December 2013 have been implemented.
- The **audit report along with a PRAC recommendation** will be presented to the **EMA Management Board**, which will then announce if the EudraVigilance system has implemented the functionalities.
- **Six months after** the announcement of the EMA Management Board, the move to centralised reporting will take effect.

- The Audit will be performed by an **independent auditor**.
- The EV Audit company has been selected from the **main EMA framework contract for audits**.
- Volunteers from the Pharmacovigilance Risk Assessment Committee (PRAC) were consulted on this selection.
- The company has now been selected to perform the EV Audit.

EudraVigilance Auditable Requirements Project Update – Timeline update (1/3)

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- The EudraVigilance auditable requirement project has undergone re-planning with the effect of rescheduling the go-live from the third to the fourth quarter of 2017. This is due to:
  - The need to further strengthen the performance of the new EudraVigilance system prior to its go-live.
  - The need to optimise delivery on the projects within the EU Telematics Strategy and Implementation Roadmap 2015 – 2017, by balancing resource across the different projects.

- This rescheduling impacts key project milestones:
  - the EV stakeholder testing
  - the EV audit
  - the EMA Management Board decision
  - the month of the release of the enhanced EV system in 2017.

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The new timeline consists of:

1. Change of the **EV Stakeholder testing to November 2016**
2. Change of the **EV Audit to February 2017**
3. Change the **decision by EMA Management Board on simplified reporting** to **May 2017 via written procedure**

*Note: the key audit result will be presented to March 2017 EMA Management Board.

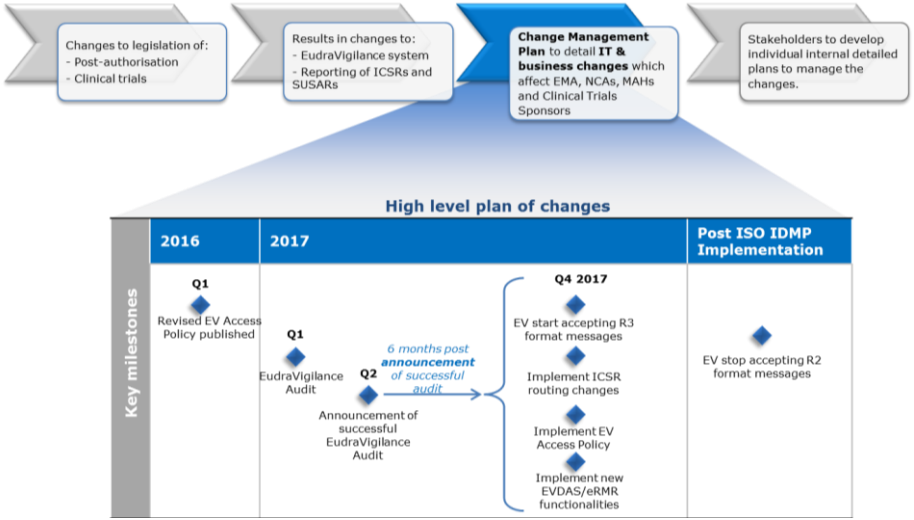
4. Change the **go-live date** delayed to **mid-November 2017**

The go-live to simplified reporting will therefore move by 4-months.

- Key audit milestones:

Steps	Timelines	Responsible party
Audit fieldwork	**06.02.2017 – 17.02.2017** (2 weeks)	**Auditor**
PRAC presentation of Audit results	**11.03.2017**	**PRAC**
EMA Management Board presentation of Audit result	**15.03.2017**	**EMA MB**
Auditor fieldwork to review previous audit findings	**13.04.2017 – 14.04.2017**	**Auditor**
Recommendation by PRAC on EudraVigilance	**02.05.2017**	**PRAC**
EMA Management Board confirmation of the Audit outcome	**16.05.2017 (Ad-hoc)**	**EMA MB**
Centralised reporting to EudraVigilance becomes mandatory and new EV/EVDAS system goes live	**Mid November 2017**	

- The **EudraVigilance stakeholder change management plan** provides stakeholders with information on the **technical changes** EMA is implementing in the EudraVigilance system as well as business processes changes required to work with the new system.



- Concerned National competent authorities, marketing-authorisation holders, and sponsors of clinical trials should use this document as a starting point to **develop their own internal implementation plans prior to the new system go-live**

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Revised EudraVigilance Webpage - Principles

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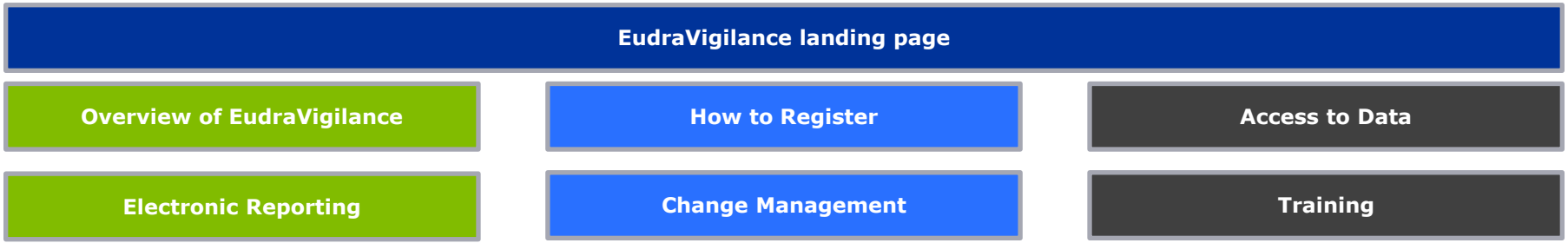
- On **16th June 2016,** revised EudraVigilance pages were launched onto the EMA corporate website, providing the following benefits:

  - Provision of **further details** relevant to Stakeholders regarding **upcoming changes in EudraVigilance**
  - **Streamlining** and **consolidation** of existing content.
  - Removal of legacy information.

- Existing public area of the EV website (http://eudravigilance.ema.europa.eu/human/index.asp) content will be **gradually decommissioned** in the coming months. Registered users will continue to be able to access the restricted area of the EV website as usual.



Revised EudraVigilance Webpage - Content

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EudraVigilance landing page

Provides a high level introduction to the EudraVigilance system, and details the content available on the revised EudraVigilance Webpage.

Overview of EudraVigilance

Provides an **overview of EudraVigilance system components** , system **functionality**, and processes supporting EudraVigilance.

How to Register

Provides an explanation of the **registration process** that stakeholders must undergo to use EudraVigilance for the electronic data interchange of pharmacovigilance information.

Access to Data

Provides an outline of the revised **EudraVigilance Access Policy**, including its objectives and **impact on affected stakeholder groups.**

Electronic Reporting

Provides an introduction to **electronic reporting requirements** and **supporting information** for stakeholders e.g. documentation for E2B(R3) implementation.

Change Management

Provides information regarding **upcoming changes** related to EudraVigilance enhancements e.g. change management plan, communication plan, stakeholder impact.

Training

Provides an **overview of the EudraVigilance training plan**, and details of **all existing and upcoming training materials.**

Revised EudraVigilance Webpage - Access

EMA website -> Human Regulatory -> Pharmacovigilance -> EudraVigilance

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Training – Introduction to Approach (1/2)

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- The European Medicines Agency has developed a **modular training course** to support stakeholders in **meeting their pharmacovigilance obligations** when using the enhanced EudraVigilance system.

- Training is organised by subject matter around **three areas**:

Pharmacovigilance Operations	Modules detailing the key changes in pharmacovigilance legislation, standards and guidelines and the impact of these on pharmacovigilance activities
EudraVigilance Operations	Modules describing the EudraVigilance and EVDAS functionalities and components, as well as the various data analysis, submission, visualisation and reporting options
IT Systems Operations	Modules providing instructions on the modifications required to prepare internal systems for the EudraVigilance system enhancements

Training – Introduction to Approach (2/2)

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Support through E-Learning
Training is predominately delivered through narrated information videos hosted on the EMA corporate website.

- Optional quizzes are provided for all E-learning modules to enhance user understanding.
- For new users, a mandatory competency assessment will have to be undertaken upon completion of the training courses

Support through guidance documentation
Detailed guidance documentation and user manuals will be produced to explain the functionality of each component of the EV system detailing step by step how the system should be used.

In addition, 'contextual help' information will be available online in the new EVWEB interface.

Support through face to face
Face to face training will have limited availability and will be mainly targeted at new users

Support through webinars
A series of webinars will be organised over the course of 2017 targeted at NCAs and MAHs. Participants will be reminded 4 days in advance to provide questions (this will help us to start the webinar session) and they will have the opportunity to ask questions during the webinars.

Training – Overview of release timelines

- Training materials will be provided to EudraVigilance stakeholders in **three publications** ahead of the Move to simplified reporting in Q4 2017:

- Stakeholders are advised to start training **well in advance of the new system being implemented** with regular refresher training ahead of the move to simplified reporting.

Training – Overview of release timelines

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- **The first EudraVigilance e-learning modules are now available via the EudraVigilance training page, comprising:**

PhV-M0 – Introduction to EMA's training offering

Provides an overview of all training offerings planned by EMA in the area of EudraVigilance, EVDAS, ADR reporting and signal detection providing learning paths for new and existing users

PhV-M1 – New EudraVigilance functionalities and the 2010 pharmacovigilance legislation

Provides an overview of the pharmacovigilance legislation which formed the basis for new or enhanced EudraVigilance functionalities.

PhV-M2a – Implementing ISO ICSR/ICH E2B(R3)

Outlines key principles of the ISO/ICH E2B (R3) ICSR standards and guidelines and the impact on the collection, reporting and processing of adverse reactions reports.

PhV-M3 – How to prepare for simplified adverse drug reaction reporting in the European Union

Provides an overview of the principles of the simplified adverse reaction reporting in the EU, how to prepare and the processes that should be discontinued.

PhV-M4 – Revised EudraVigilance access policy: impact on stakeholders

Provides an overview of the main characteristics of the revised EudraVigilance Access Policy: how stakeholders obtain access to EudraVigilance data in support of their pharmacovigilance obligations.

EV-M2 – Introduction to EV system components and system functionalities

Provides an overview of all training offerings planned by EMA in the area of EudraVigilance, EVDAS, ADR reporting and signal detection providing learning paths for new and existing users

Training – Evaluation

- **Optional self-assessment quizzes** have been produced to enable stakeholders to **enhance their content understanding**.

- Quizzes are provided for **each E-learning module within the first training release**, and can be accessed via the EudraVigilance training page.

- Stakeholders are invited to **provide feedback on released E-learning modules**. The survey link is available in all of the training materials, or can also be accessed via the EudraVigilance training page.

Thank you for your attention

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