





EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EudraVigilance auditable requirement project: ADRreports.eu portal update

Patients and Consumers Working Party – 30th November 2016



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- ADR project context and status
 - Introduction to the ADRreports.eu portal
 - Portal enhancements and Use Cases
 - Next Steps

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ADR project context and status

Introduction to the ADRreports.eu portal

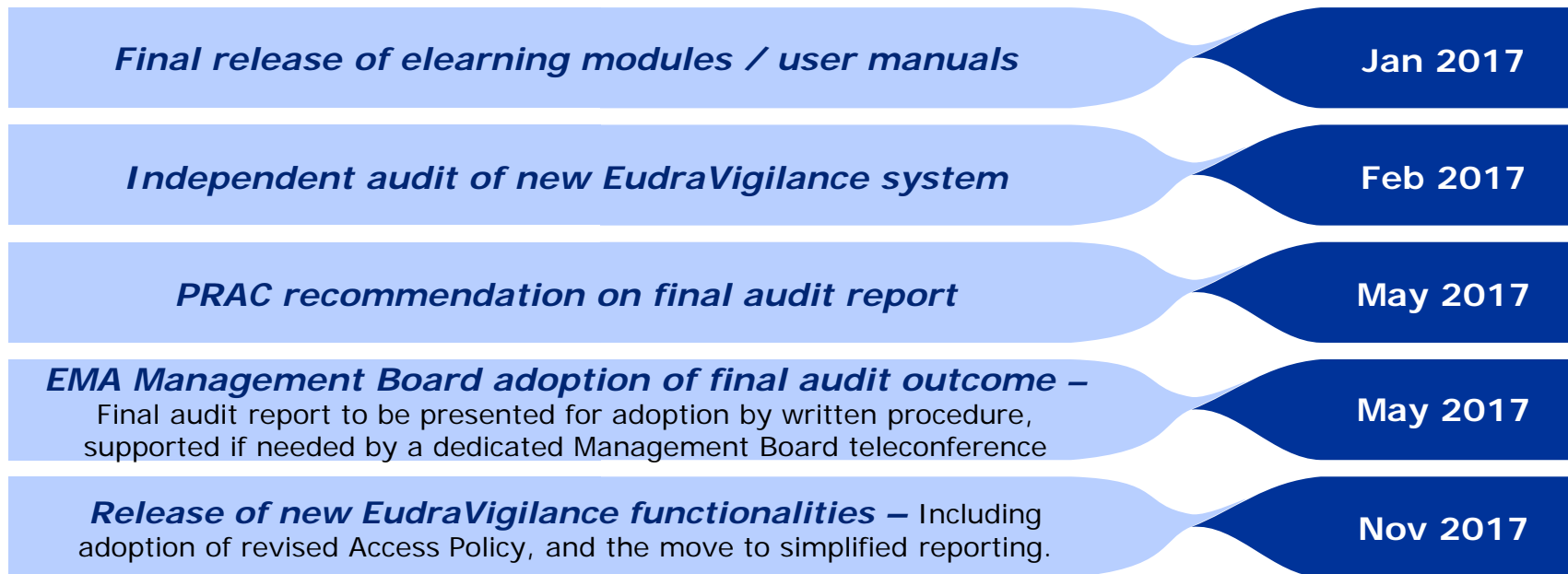
Portal enhancements and Use Cases

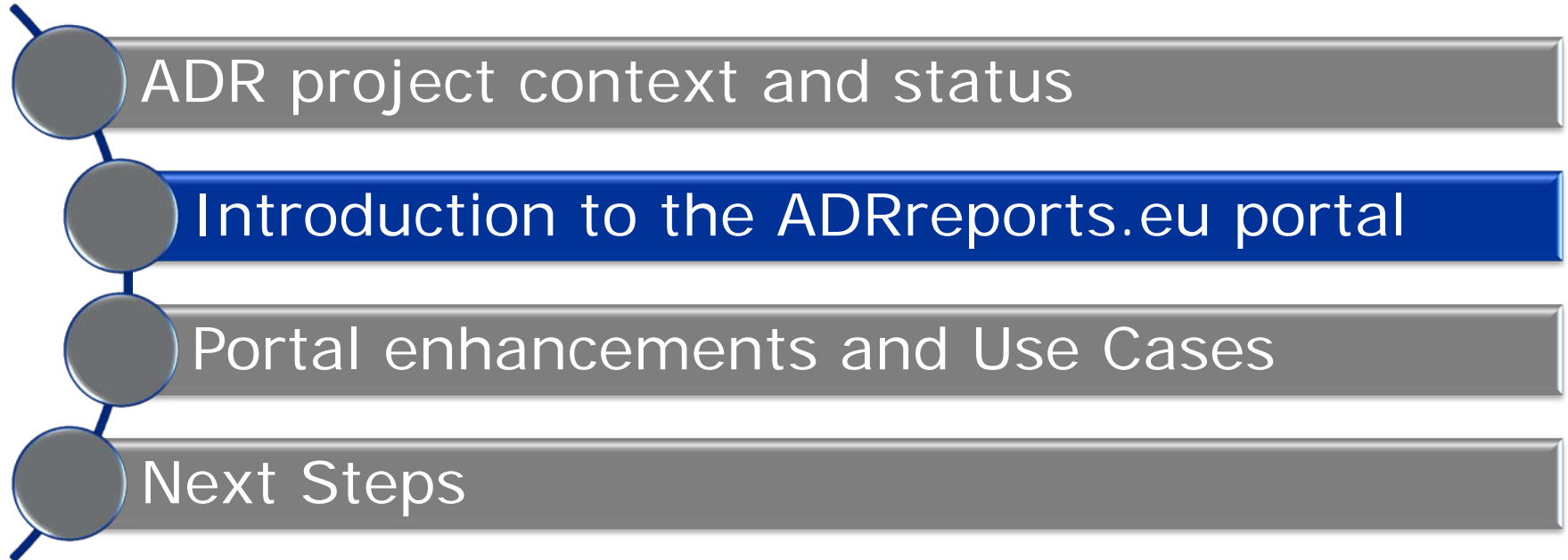
Next Steps

In December 2013, the EMA Management Board endorsed the “**EudraVigilance Auditable requirements**” :

- **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**
- **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)

- The '**EudraVigilance Auditable Requirements Project**' was set-up to **deliver the new EV system**.
- Before the move to simplified reporting, the new EudraVigilance system has to undergo an **independent audit** against the functionalities agreed with the EMA Management Board in December 2013.
- To further strengthen system performance ahead of its launch, in June 2016, the **EMA Management Board approved an updated schedule**:





- The European Medicines Agency (EMA) plays a **key role in the safety monitoring of medicines in the European Union (EU)** - this is known as pharmacovigilance. The Agency's main role in this area is to **support the coordination of the European pharmacovigilance system** and to provide **advice on the safe and effective use of medicines**.

- As part of this responsibility, the Agency is responsible for the **development, maintenance and co-ordination of [EudraVigilance](#)**, a system for reporting suspected cases of adverse reactions to a medicine.

- **Data from EudraVigilance are published in the [European database of suspected adverse drug reaction reports](#). (ADRreports.eu portal).**
 - Since May 2012, this portal allows users to view the total number of individual suspected side effect reports (also known as Individual Case Safety Reports, or ICSRs) submitted to EudraVigilance for each centrally authorised medicine. Users can view these reports by age group, sex, type of suspected side effect and outcome.
 - Since October 2014, reports for common drug substances used in nationally authorised medicines are available.

Information on suspected side effects **should not be interpreted** as meaning that the medicine or the active substance causes the observed effect or is **unsafe to use**.

How to report a side-effect

Normally carried out by healthcare professionals. Patients can report adverse reactions through their national competent authorities

The information on the portal relates to **suspected side effects**, i.e. medical events that have been observed following the use of a medicine, but which are **not necessarily related to or caused by the medicine**.

Search for a report

Search here for suspected adverse drug reaction reports

A browsing tab will appear allowing you to select data for a specific product or substance

The European Medicines Agency publishes this data so that its stakeholders, including the general public, can access information that European regulatory authorities use to review the safety of a medicine or active substance. **Transparency** is a key guiding principle of the Agency.

How can I use the portal?



View suspected ADR reports for products (brand names)

View suspected ADR reports for substances (scientific name)

View suspected ADR reports by age, sex, geography

Patients (or patient's behalf)



Healthcare Professionals



Drug safety experts



There are a number of ways in which the ADRreports.eu portal could be used

View number of cases by reaction or reaction group

View suspected ADR reports over time

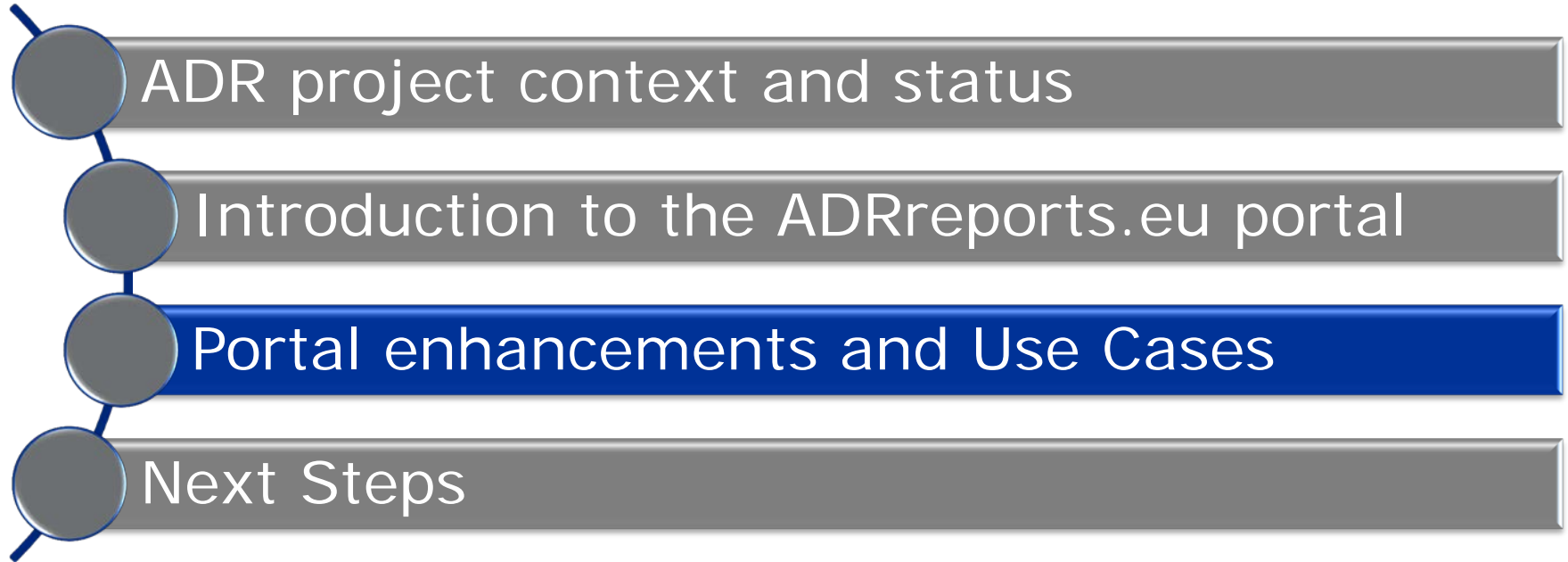
Compare data for different products & substances

Download reports using the line listing tab

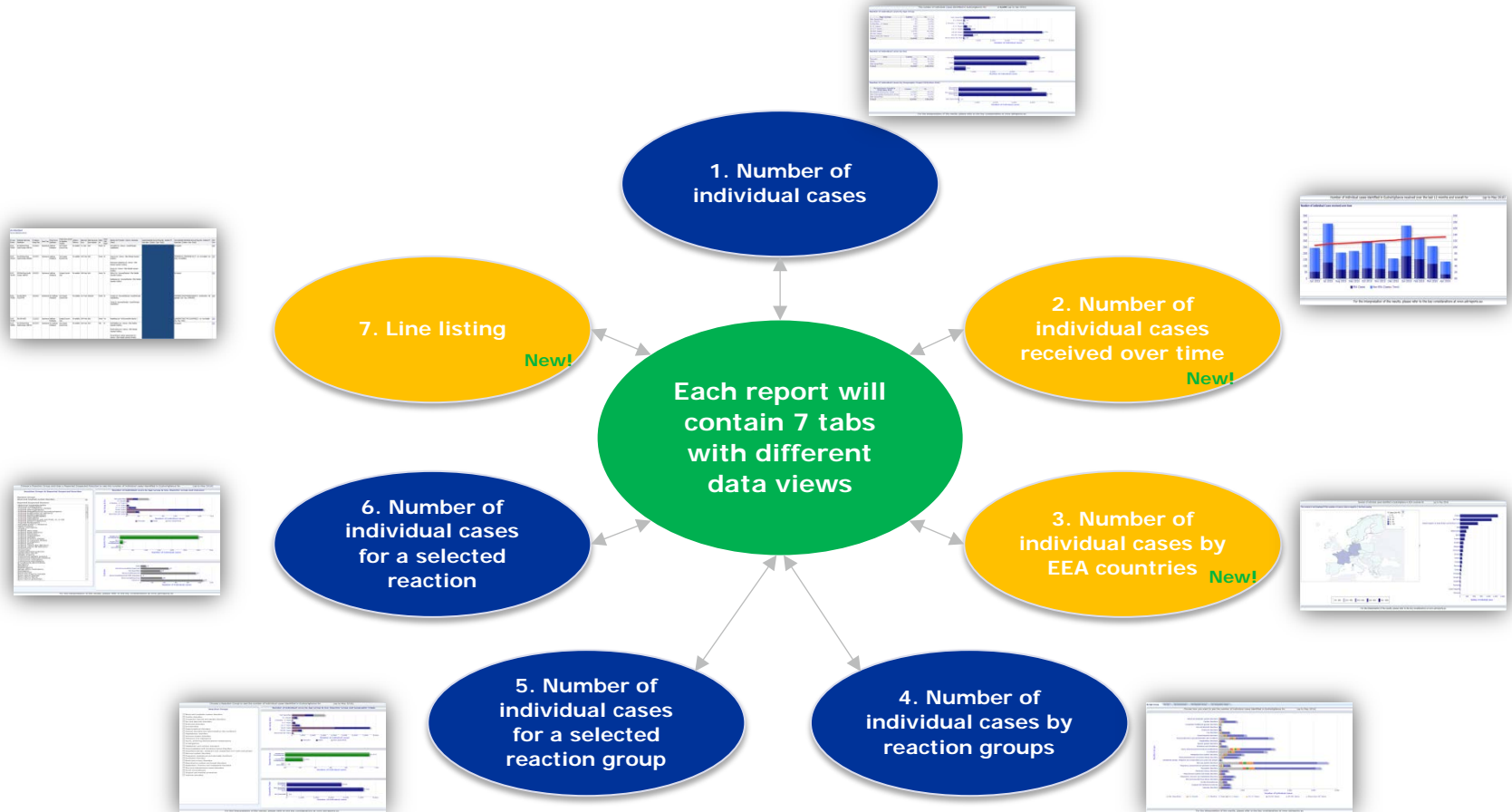


The following information can be accessed through the [ADRreports.eu](https://adrreports.eu) portal web reports:

- Aggregated data outputs based on predefined queries
- **Individual Case Safety Report (ICSR) line listings** (based on core ICSR data elements)
- **ICSR forms** (for individual case review)

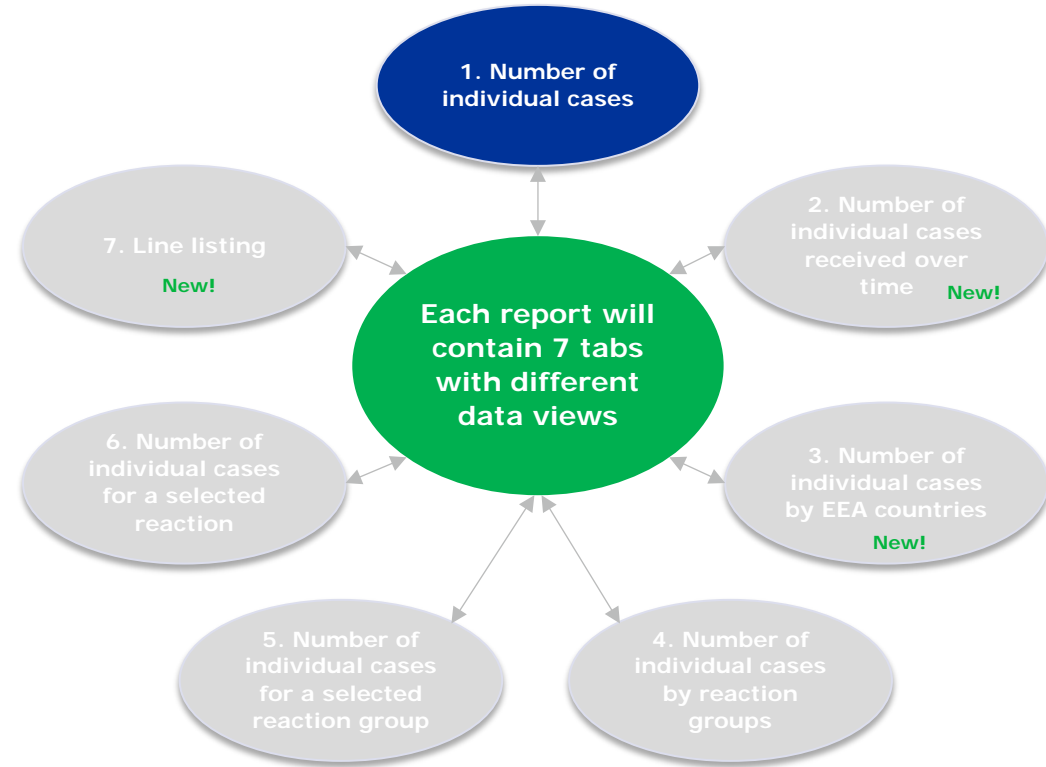


- As of November 2017, the ADRreports.eu portal contains **3 additional tabs** providing **enhanced functionality** relative to the current implementation.
- **These enhancements will allow the general public to:**
 - ✓ View the number of cases received over time
 - ✓ View the number of cases received in a particular geography
 - ✓ Download data using various criteria (age, sex, time, geography) in an excel file for further analysis



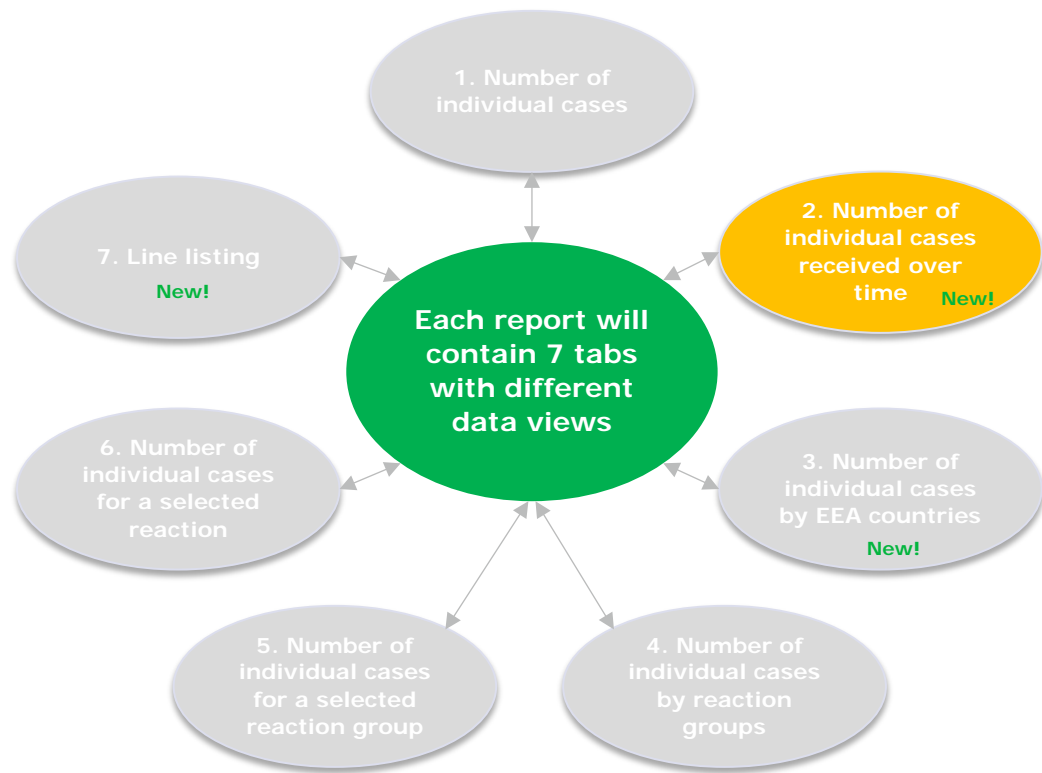
Number of individual cases

- Displays the running total of individual cases split age group, sex, and geographic origin.
- Running total of cases identified in EudraVigilance up to the end of the previous month is displayed.



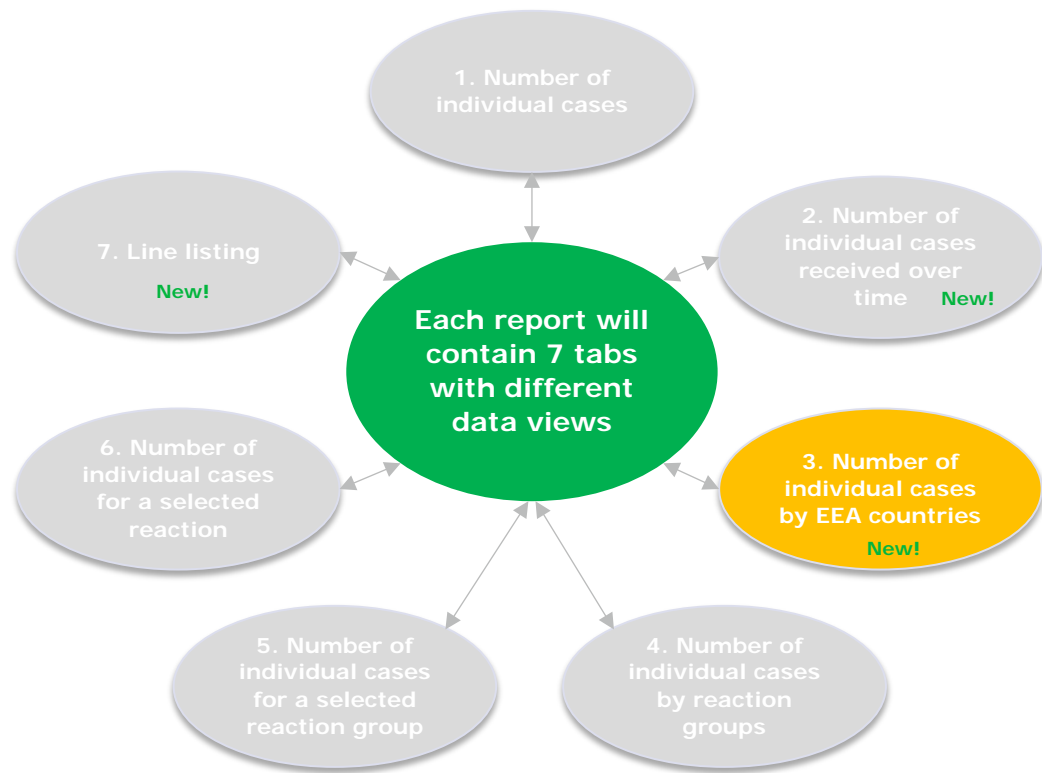
Number of individual cases received over time

- Displays the number of individual cases received over the last 12 months split by geographic origin (cases that arose in EEA countries vs those that occurred outside the EEA).
- **A new addition to the ADRreports.eu portal that will be implemented in 2017.**



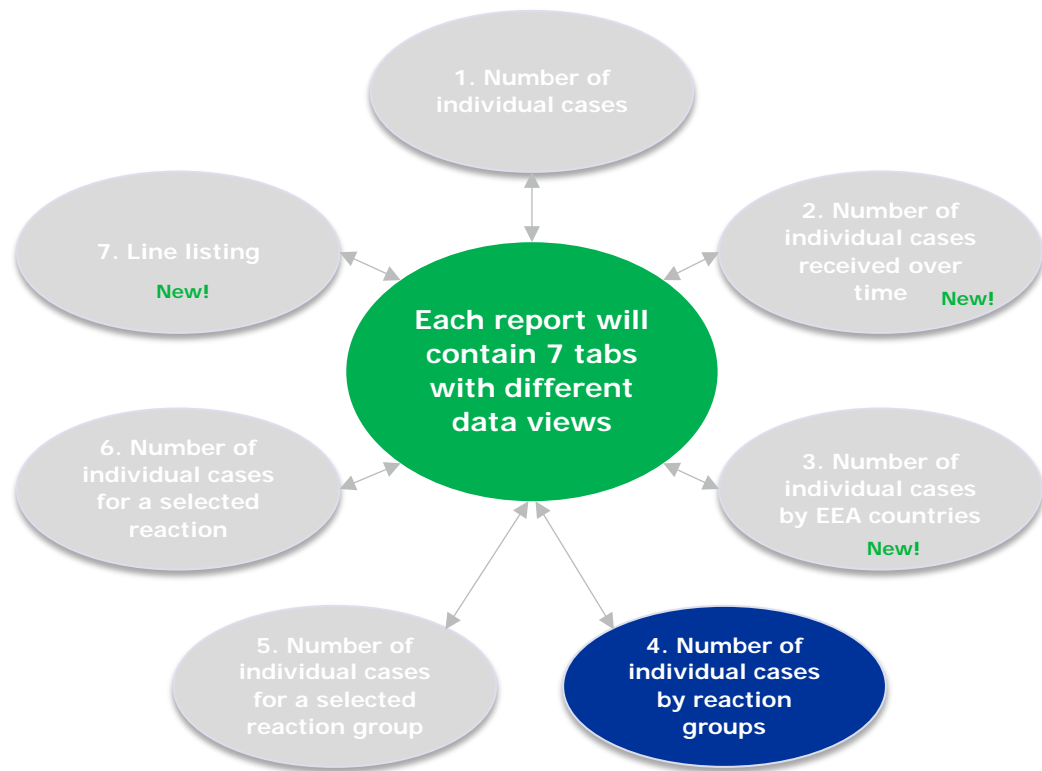
Number of individual cases by EEA countries

- Displays the number of individual cases in each European Economic Area country for the selected medicinal product.
- **A new addition to the ADRreports.eu portal that will be implemented in 2017.**



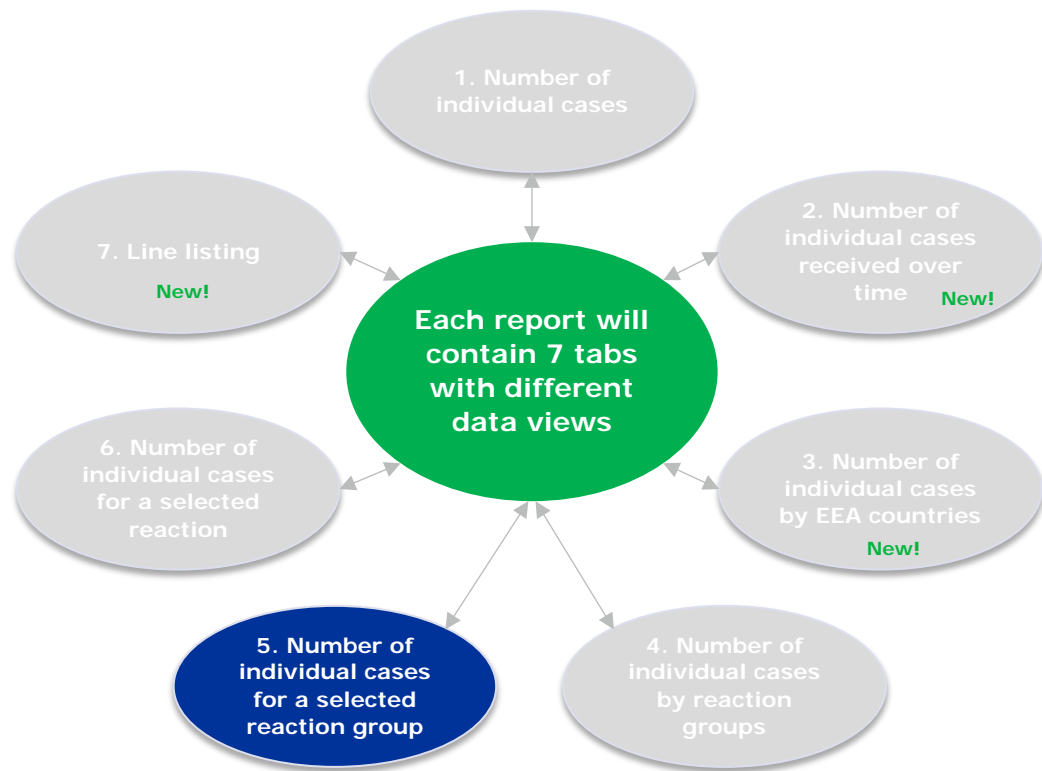
Number of individual cases by reaction groups

- Displays a graph that visualises the number of individual cases per MedDRA reaction group
- Results can be split by one other variable (age group / sex / seriousness / reporter group / geographic origin).



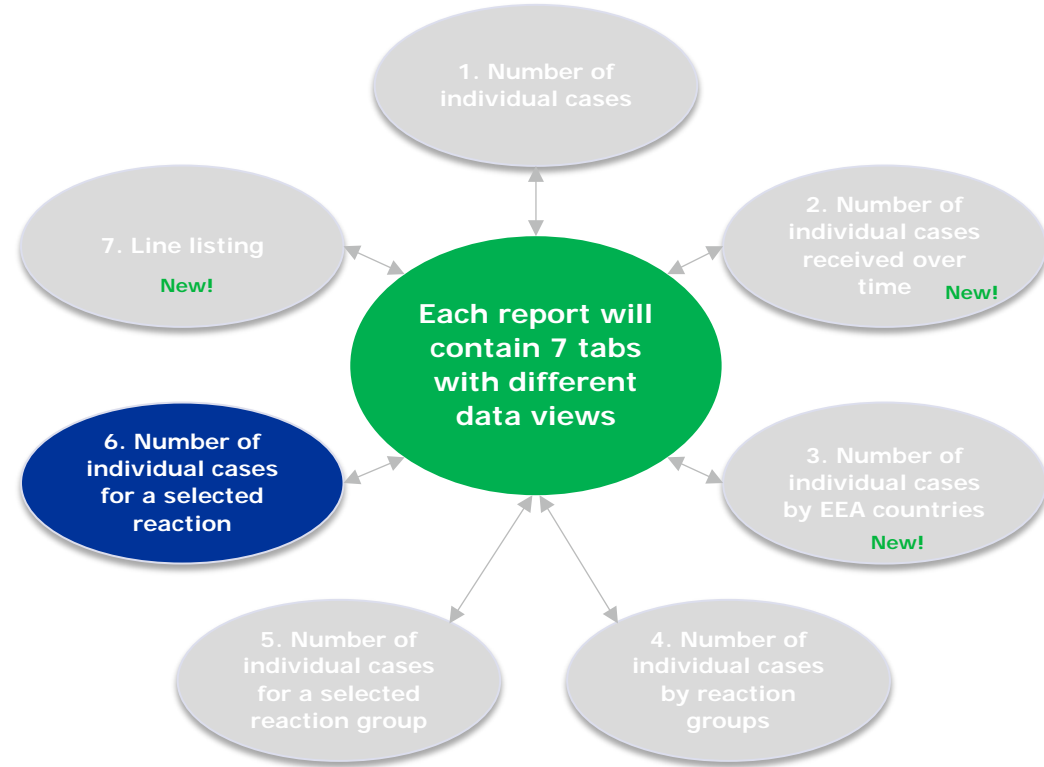
Number of individual cases for a selected reaction group

- Displays individual case data split by age group and sex, reporter group, and geographic origin for a reaction group specified by the user.



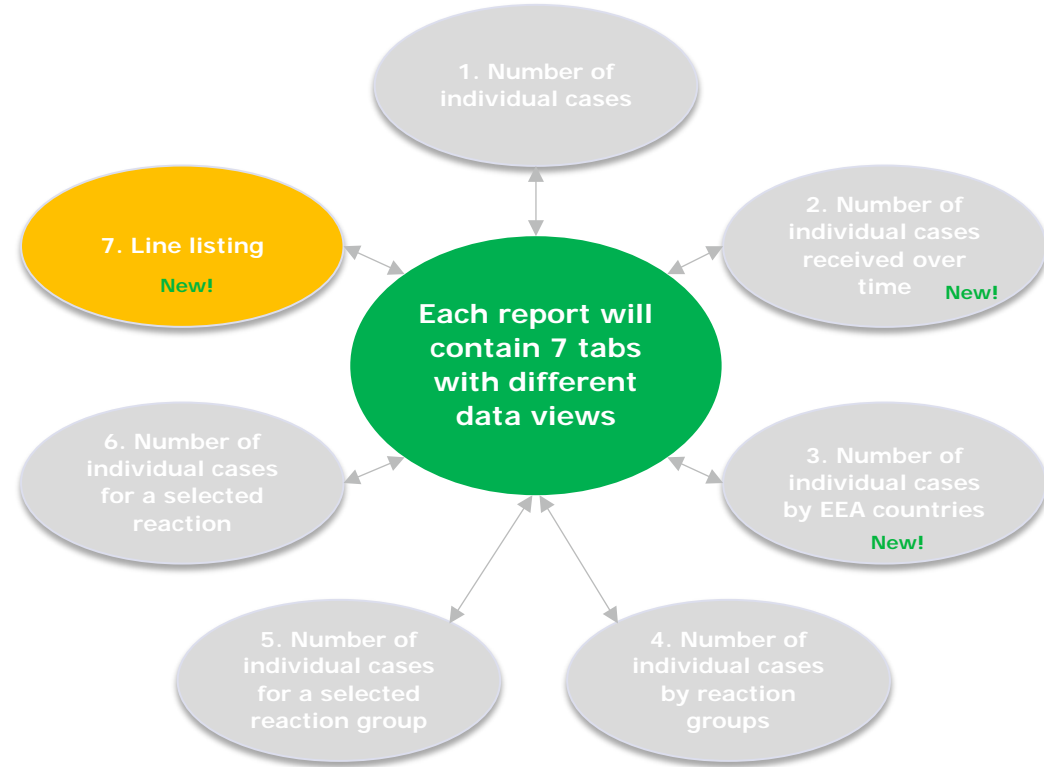
Number of individual cases for a selected reaction

- Similar to tab 5 – but allows data to be filtered to the level of an individual reaction type within a MedDRA reaction group.
- Relevant data is visualised in three graphs, split by age group and sex, reporter group, and outcome.

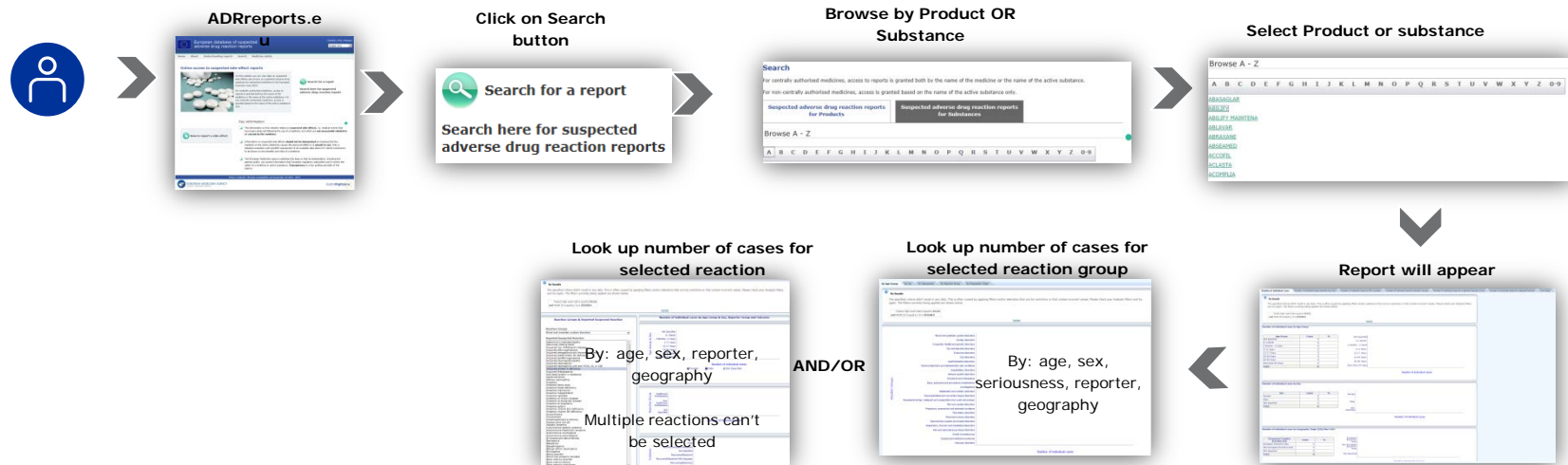


Line Listing

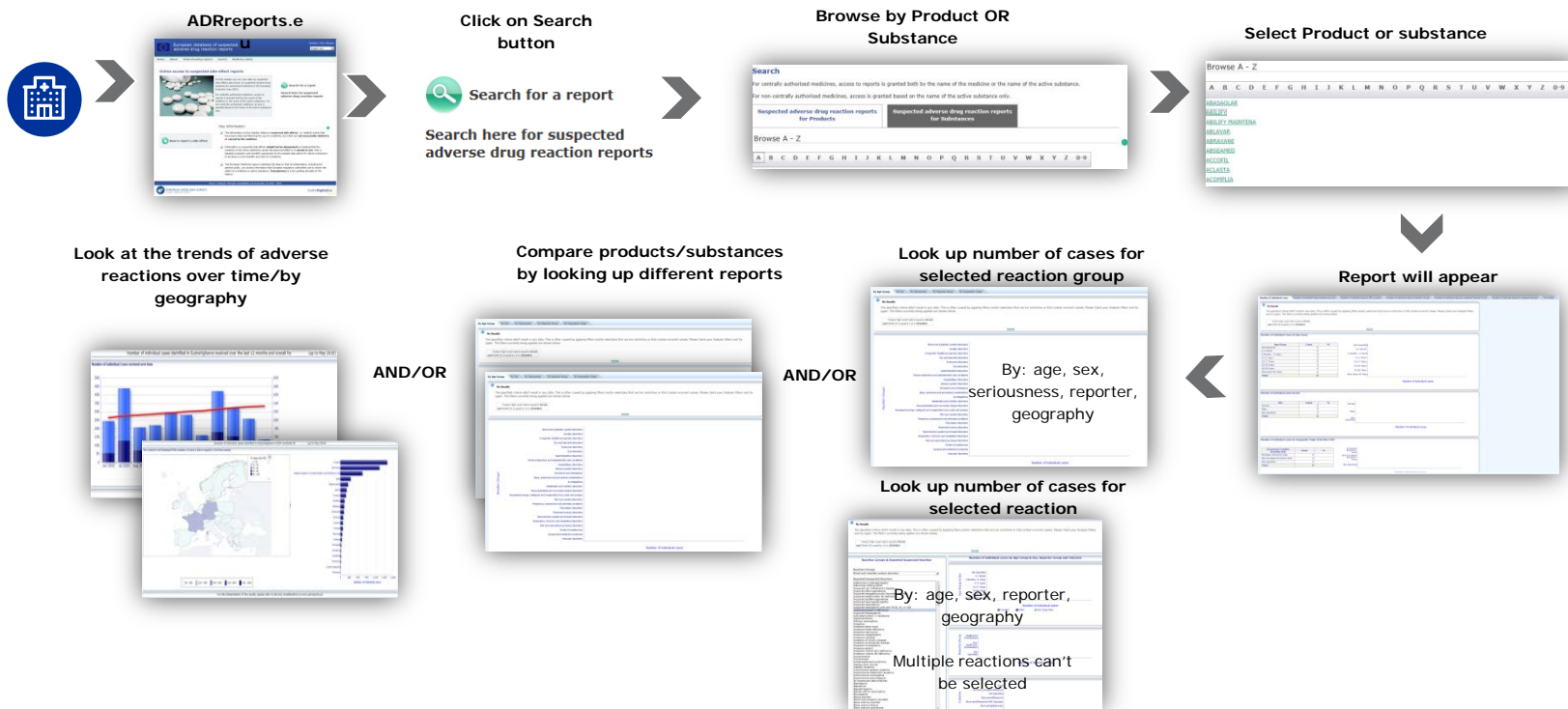
- Allows users to access a data table of all cases that match the criteria specified by the user.
- Individual cases can be downloaded as an ICSR form.
- **A new addition to the ADRreports.eu portal that will be implemented in 2017.**



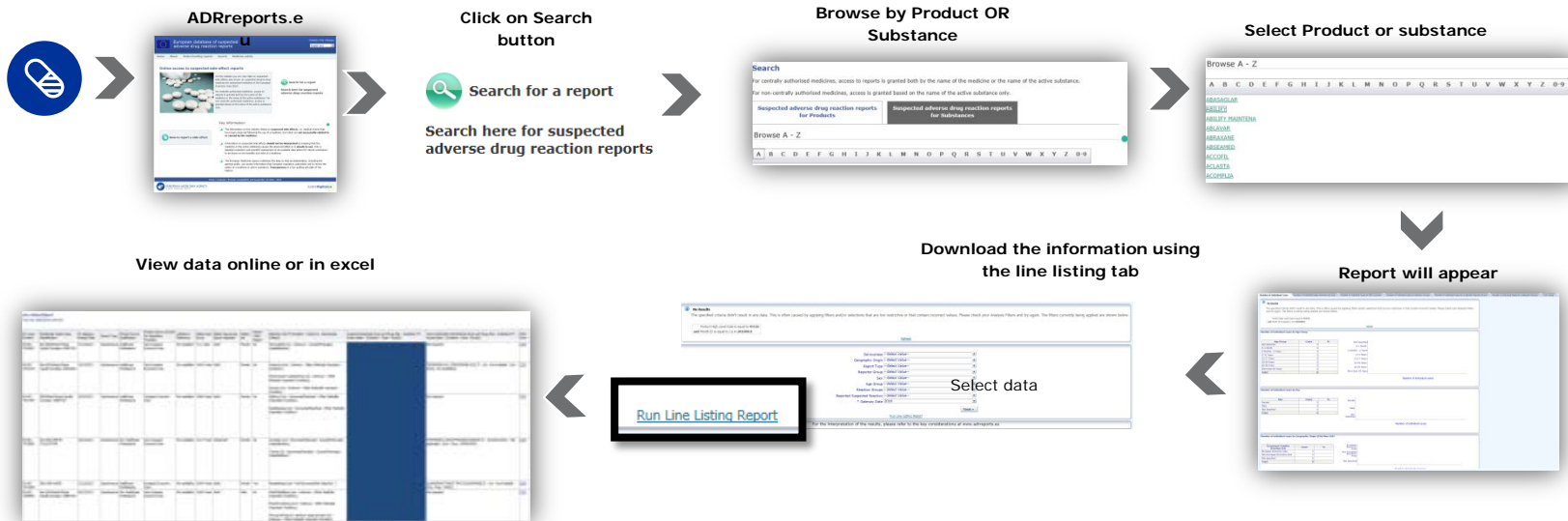
Example of using the ADRreports.eu portal to look up adverse reaction for particular reaction groups

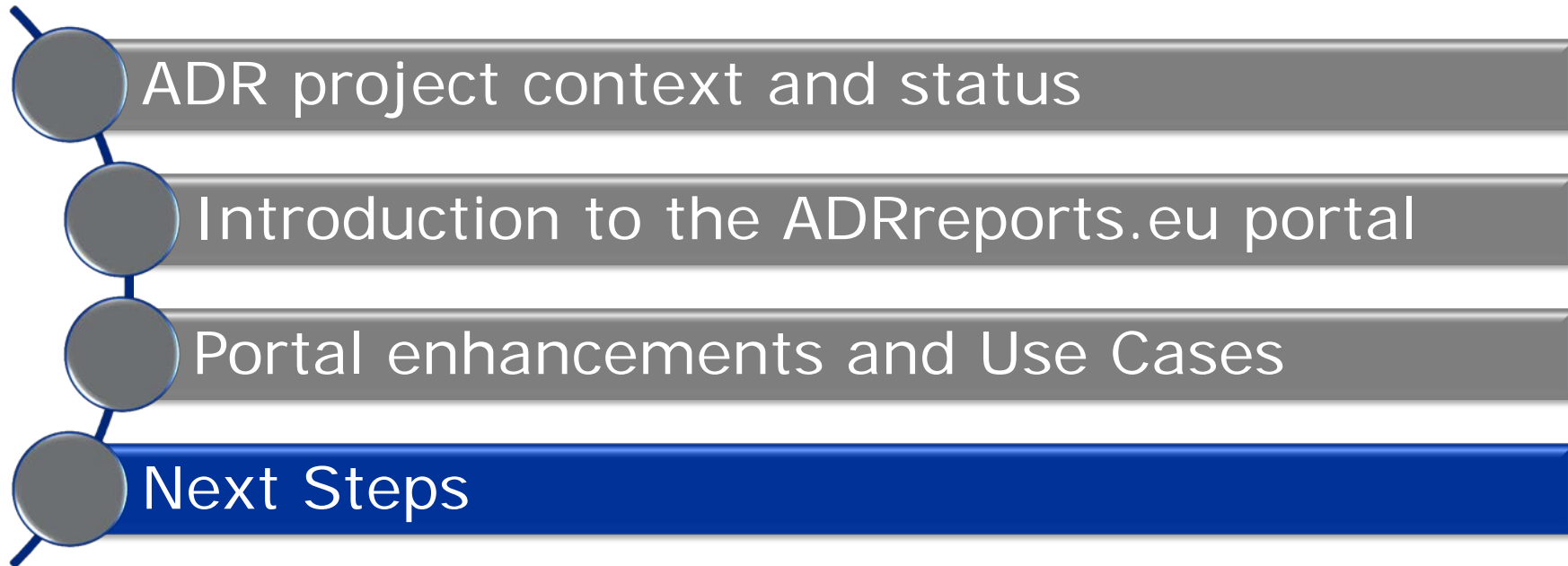


Example of using the ADRreports.eu portal for comparison purposes



Example of using the ADRreports.eu portal to perform detailed analysis







- Implemented comments received from consultation of PCWP members on elearning.
- Look out for training module EV-M6 – “ADRreports.eu portal” before the end of the year via the [EudraVigilance training page](#).
- Enhanced functionalities will be released in November 2017
- Use the [existing adrreports.eu portal](#) for any suspected adverse reaction data queries.



Thank you for your attention

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