

SCOPE Joint Action

Work Package 5- Signal Management

Stakeholder Event

London, 21 September 2015

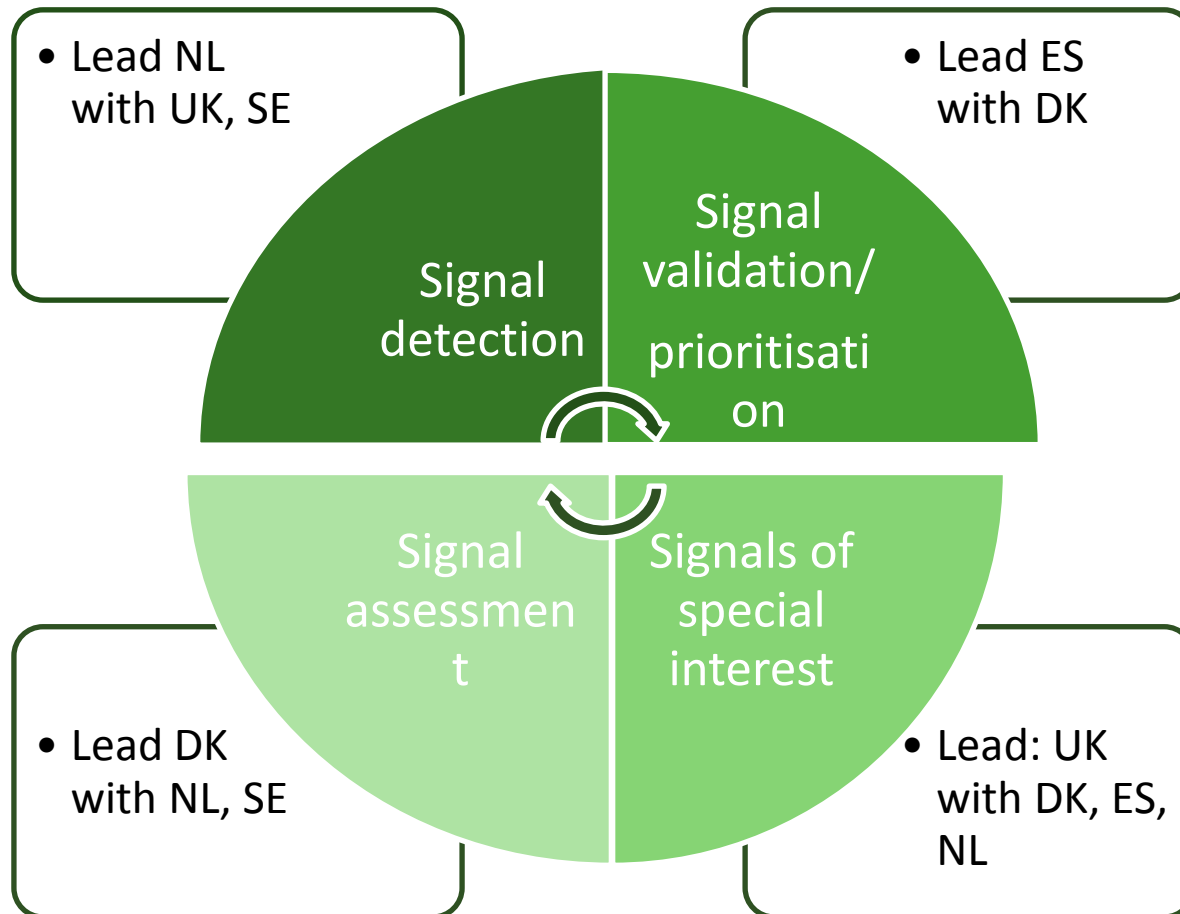


Objectives

Implementing shared understanding of best practice in signal management across the EU network

- **Create and deliver recommendations** for consistent and timely procedures for the timely **management of safety signals** across the EU network.
- Focus on the detection and management of **signals of special interest**.

WP5: Topics



WP 5 Survey



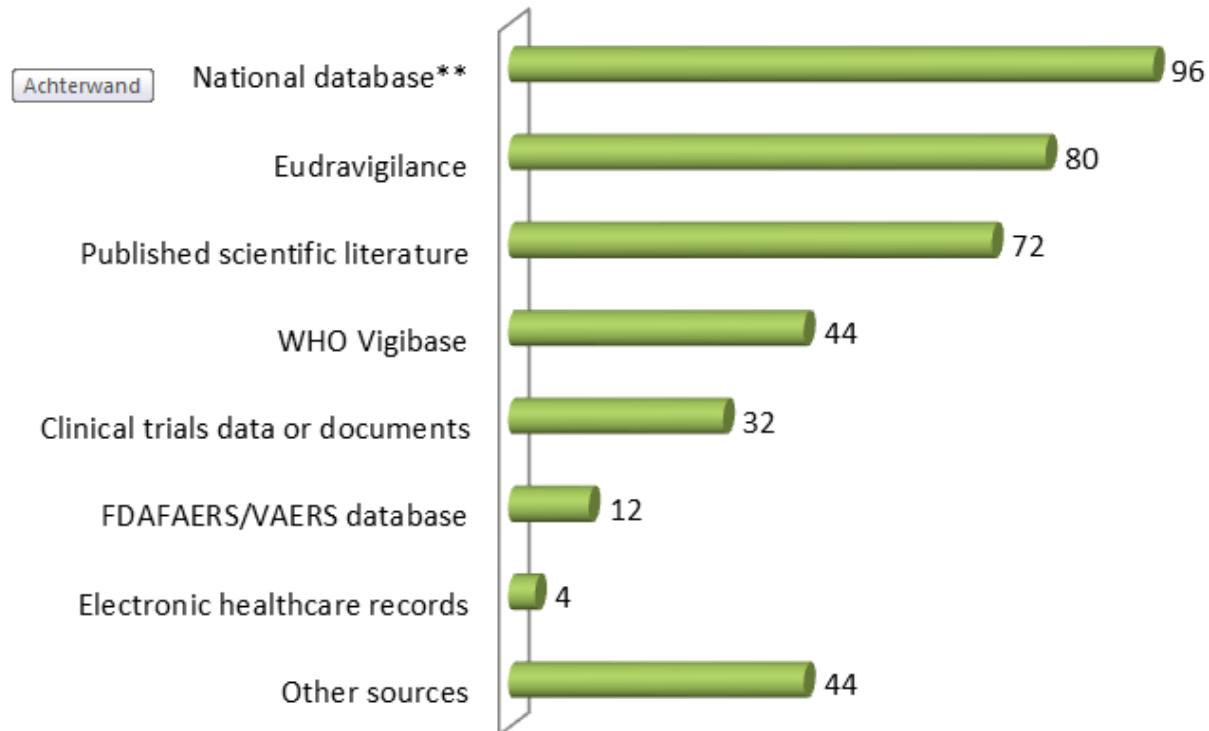
The survey was sent in July 2014 and completed in October 2014

- 60 questions
- 25 countries out of 31 answered (81% response rate)

Literature review

WP 5: Key survey findings

- All MS perform signal detection on national data, with methods fits for purpose



** Three countries screen national data by accessing EudraVigilance

WP 5: Key survey findings

- Listedness: manual process is resource intensive and can be improved. PV system would benefit from automated check
- (**PROTECT ADR database** is welcome and could be used as a base)
- Quality of data in spontaneous reports can be challenging with regards to signal detection

WP 5: Key survey findings



- GVP terminology could be improved especially with regards to validation, prioritisation and confirmation steps



22 June 2012
EMA/827661/2011

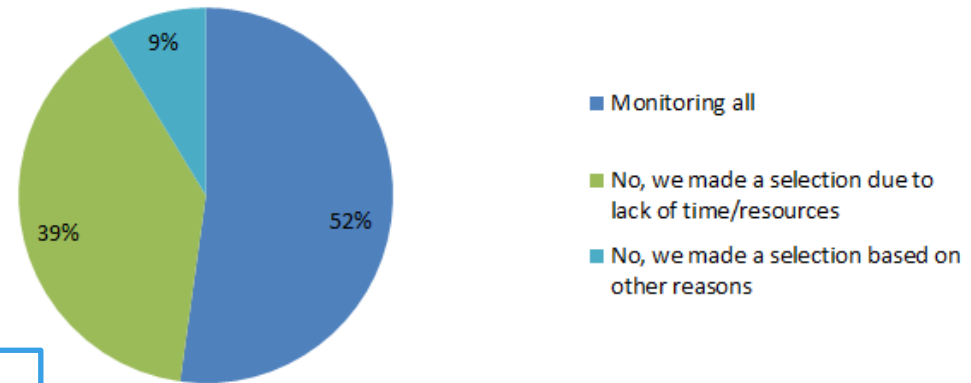
Guideline on good pharmacovigilance practices (GVP)
Module IX – Signal management

WP 5: Key survey findings



- e-RMR assessment- Explore further possibilities of more risk proportionate approach (in close cooperation with EMA and based on PROTECT findings)

Selection of the products to be monitored as Lead MS



Some MS have already implemented risk proportionate approaches and the lessons learned from the different options will be shared.

In the BPG we will try and present a consistent approach for monitoring of e-RMR

WP 5: Key survey findings

- Prioritisation step would benefit from more guidance and clear explanations
- Tracking -different systems used at MS level. Develop a consistent approach
 - Challenge:** Signals handled in other procedures are sometimes lost in tracking
- Sources of information necessary for validation and assessment step are sometimes challenging to access and retrieve

EPITT



- A need for an integrated signal management tool which would allow better communication of signals (at an early stage)

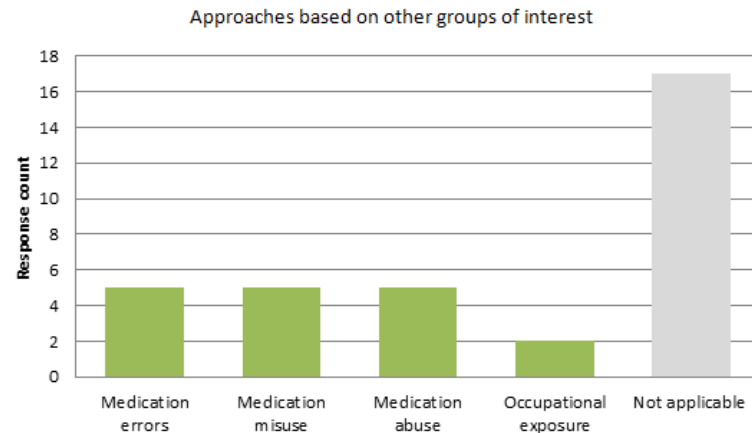
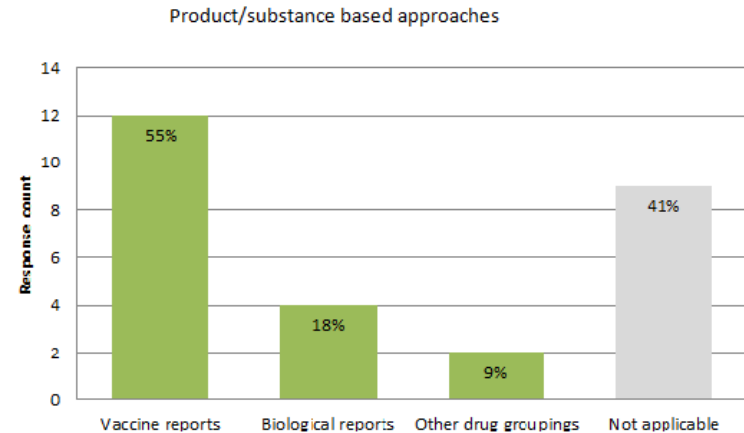
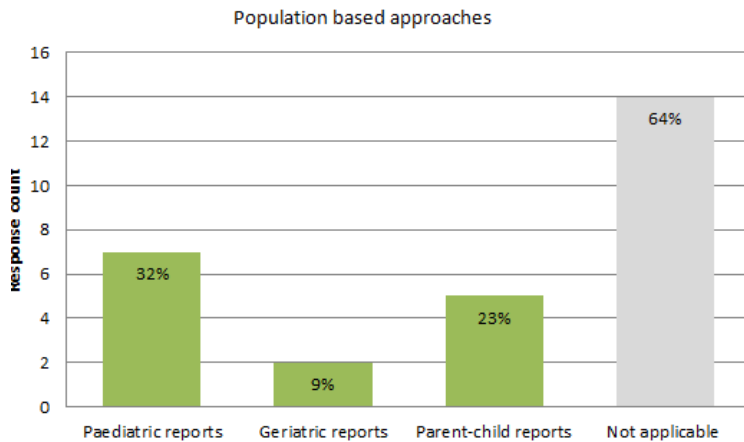
Identified as a desideratum from MS



Reactions of special interest



Limited strategies are available for managing reports of special interest.
Vaccines related reports receive most of the attention.



For reaction-based approaches, half of the 22 respondents indicated that their MS had additional strategies in place for designated medical events and/or important medical events

WP 5: Deliverables

Best practice Guidance -in development

Training



WP 5 Planned work

				2016									
Q4				Q1			Q2			Q3			
23	24	25	26	27	28	29	30	31	32	33	34	35	36
Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
	F2F			F2F			F2F						



Best Practice guidance



Training development and delivery

The team



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