


Strengthening Collaborations for Operating Pharmacovigilance in Europe Joint Action

SCOPE Activities Report

EMA stakeholder meeting,
21st September 2016



- Where has SCOPE come from?
Aims and objectives of the Joint Action
- Where are we now after 3 years of SCOPE?
Achievements and highlights to date
- Where next from here? Aspirations for
completing SCOPE and future sustainability

**Excellence in public health
protection**

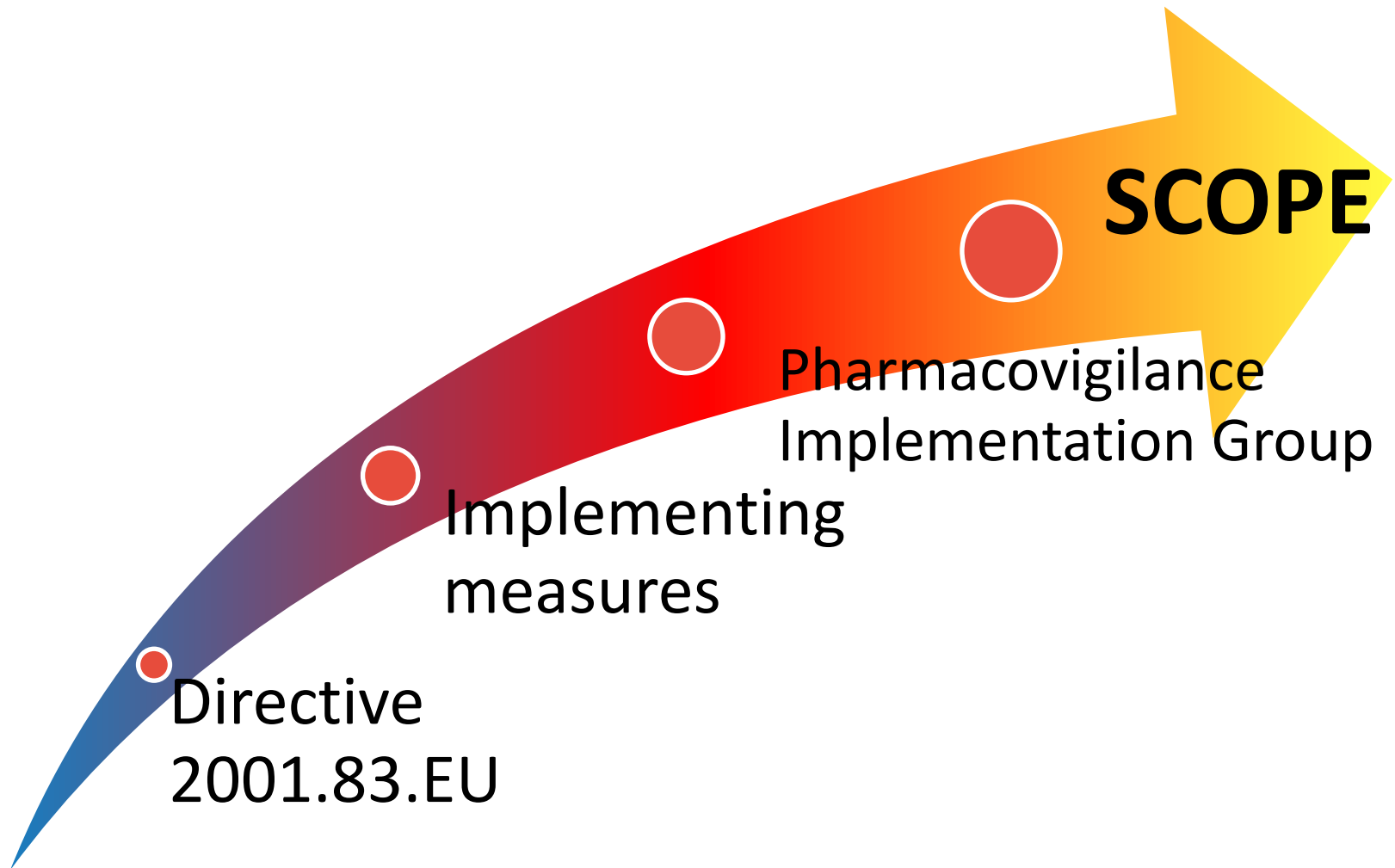


**PV legislative
framework**

**Science &
methodologies**

**PV capacity &
competency**

From implementation to operation



The beginning..



Formal award decision adopted by Commission –
project officially started 18 November 2013

Maximum level & largest possible contribution of
70% funding from Commission

“Exceptional utility”



SCOPE Joint Action



Share expertise and best practice

Deliver practical tools & guidance

Operate pharmacovigilance in EU

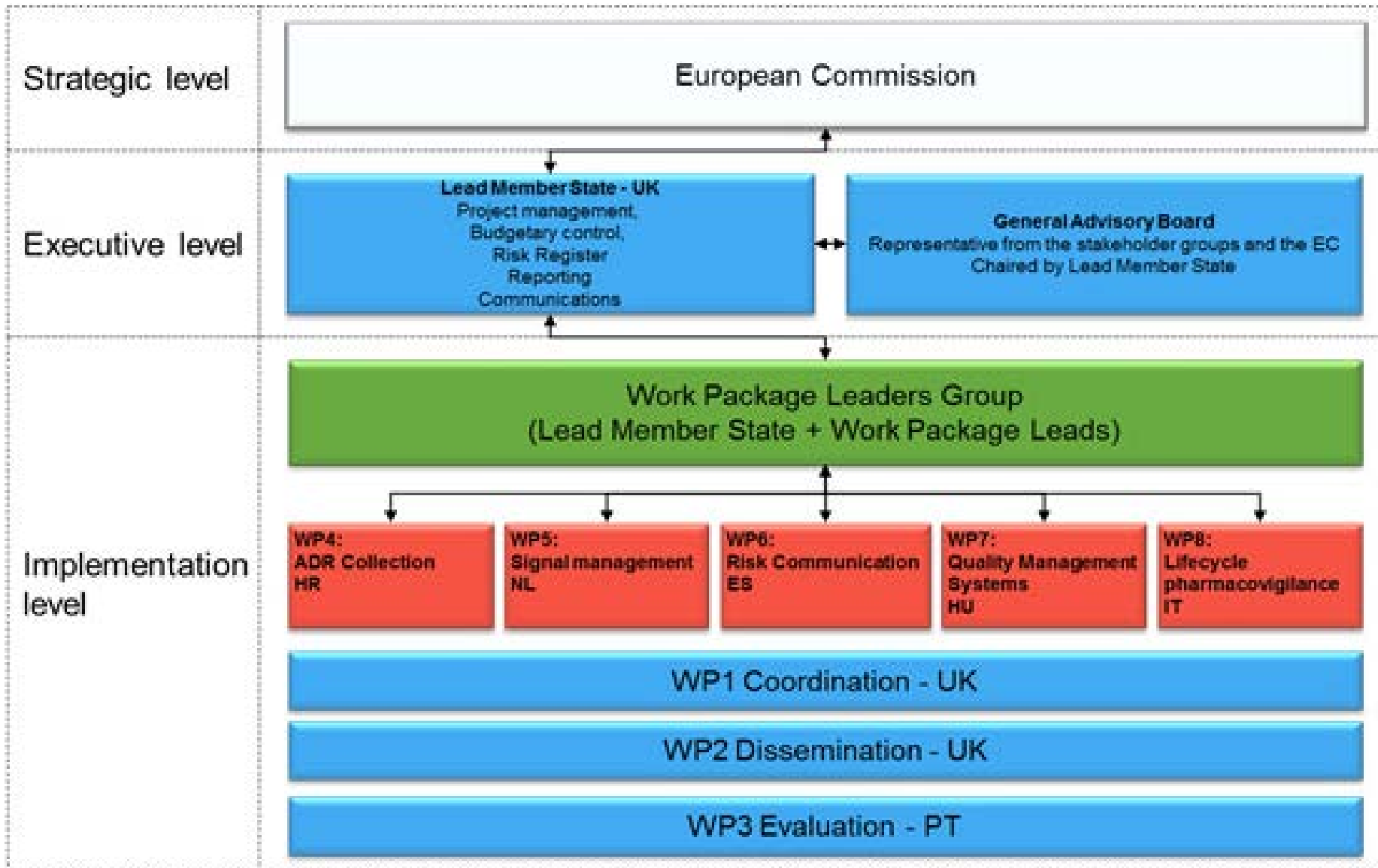
By Member States

For Member States

With Member States



Governance of SCOPE



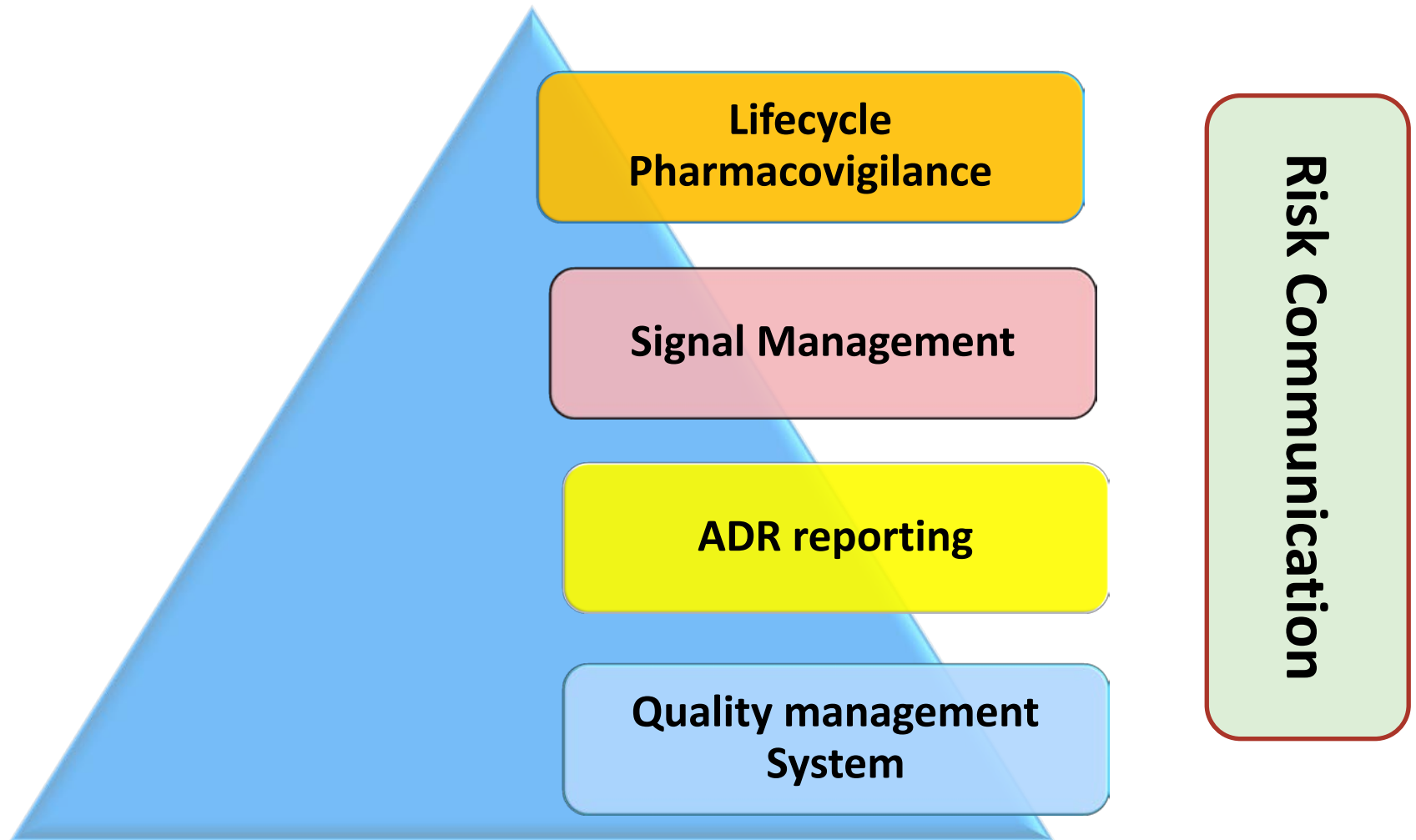
Providing strategic direction and advice to SCOPE



SCOPE “pyramid” of deliverables



SCOPE



SCOPE activities



>30
face-to-face
meetings

Pilot training for
WPs 4, 5, 7 & 8

>100
delegates at
Risk
Communicatio
n Workshop

5 GAB
meetings

764
questions asked
across all SCOPE
surveys – 19K+
answers

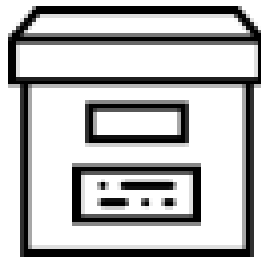
Monthly
teleconfe
rences

Thousands of days
of work logged by
active partners and
participants

Progress in SCOPE



- **ADR reporting-** WEB-FORM, learning materials, raising awareness tools
- **Signal Management** Best Practice Guide and e-learning module
- **Risk Communications** Practical guidance on strategy development, websites guide



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Risk Communication on Medicines Workshop



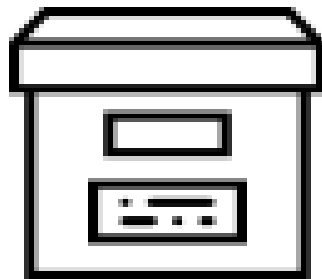
- Successful Workshop 16th- 17th June 2016, Madrid
- PV and communication experts, WHO, EMA, academia, patients, consumers, and healthcare professionals – 103 delegates
- Designed to share the results of surveys, and discuss how EU national agencies can improve their communication on the risk associated to medicines
- Videos and presentations from the workshop:
<http://www.scopejointaction.eu/events/wp6-workshop/>



SCOPE deliverables



- **Quality Management Systems** – A “toolkit” for further development of documents
- E-learning modules (resource management, interface of PV inspectors-assessors, introductory training on QMS)



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- **Lifecycle pharmacovigilance**

Recommendations from surveys, practical guides, and e-learning for PV Assessors

Additional Data Sources, Risk Management Plans, Post Authorization Safety Studies, Periodic Safety Update Report, Referrals

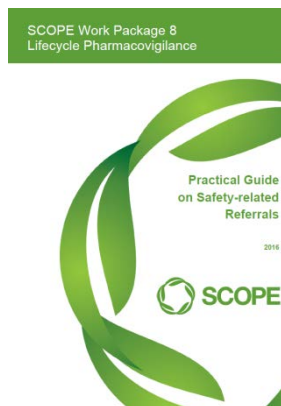
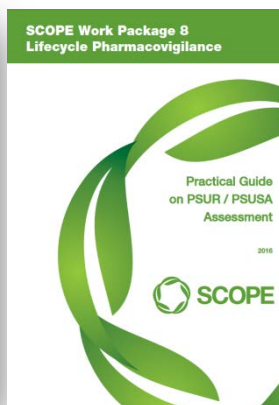


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What has SCOPE achieved?



- Tools produced to share practical advice on Benefit Risk processes and to improve skills
- Created for multitasking assessors
- Designed to be used in conjunction with other relevant guidance and templates



SCOPE WP8 TOPIC 4b

Safety Referrals

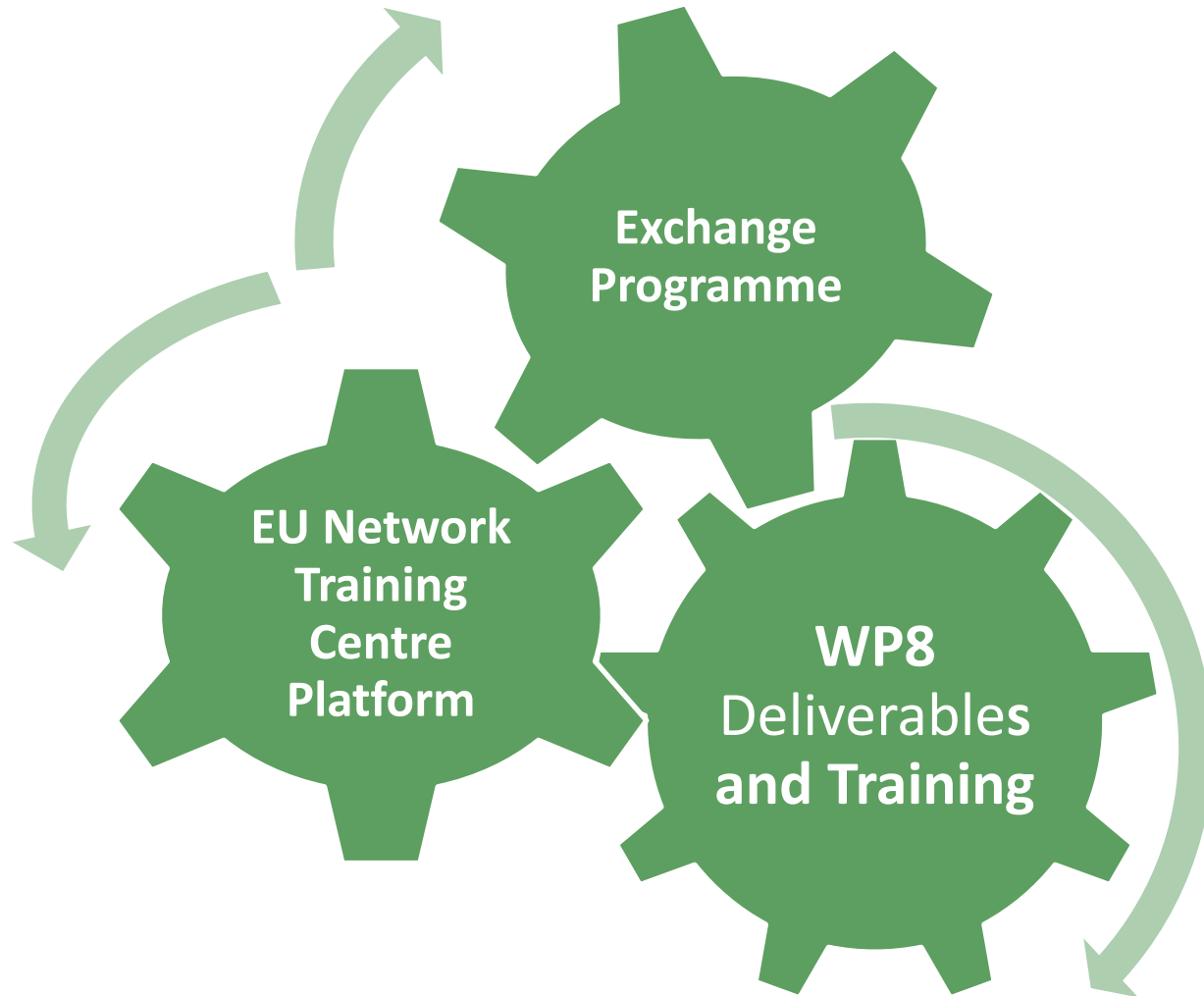


Storyboard Version 3.0

Version History

Version	Date	Notes	Author	Screen Count
0.1	12/06/2016	Initial draft	LH	47
0.2	20/06/2016	Internal review	BS	
0.3	04/08/2016	2 nd draft, client amendments included	CC	49
0.4	23/08/2016	Final to send	BS	52
0.5		Minor script changes		
0.6		Copyedited - final		

➤ DELIVERABLE 1 Topic 1 ADSs Recommendation doc (+ 4 annexes)
➤ DELIVERABLE 2 Topic 2 RMP Recommendations doc (+1 annex)
➤ DELIVERABLE 3 Topic 2 RMP Hints and Tips doc
➤ DELIVERABLE 4 Topic 3 PASS Recommendations doc
➤ DELIVERABLE 5 Topic 3 PASS Hints and Tips doc
➤ DELIVERABLE 6 Topic 4a PSUR/PSUSA Recommendations doc
➤ DELIVERABLE 7 Topic 4a PSUR/PSUSA Hints and Tips doc
➤ DELIVERABLE 8 Topic 4b Referrals Hints and Tips document
➤ DELIVERABLE 9 Topic 4b Referrals Top 10 tips document
➤ DELIVERABLE 10 Topic 5 Competency Recommendations doc +3
E-learning
➤ DELIVERABLE 1 Topic 4b REFERRALS e-learning package and assessment (to include 4b H&T and 4b top 10 tips)
➤ DELIVERABLE 2 Topic 2 RMP short e-learning based on H&T
➤ DELIVERABLE 3 Topic 3 PASS short e-learning based on H&T
➤ DELIVERABLE 4 Topic 4a PSUR/PSUSA short e-learning based on H&T



SCOPE deliverables will be available in **EU Network Training Centre** learning platform and included in the **Pharmacovigilance Training Curriculum**



Developing Pharmacovigilance Training Curriculum



SCOPE



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 August 2016

Pharmacovigilance Training Curriculum (PhVTC) Draft outline

Overview of general pharmacovigilance definitions and concepts

ADR Reporting

Signal
Management

PhV life cycle
management

Risk
Communication

Quality Management



Pharmacovigilance staff roles in each of the areas above

Pilot exchange programme for PV assessors



- Exchange of **experience** and **knowledge** and an **on-the-job training** framework
- **Areas of expertise** in PV assessment : RMPs, PASS, PSUR/PSUSA, referral procedures
- Improvement of **active contribution** in the PV tasks foreseen in the legislation
- **Norway, Portugal & Spain** supporting pilot exchange - working group looking at practicalities



- European Union–wide adverse drug reaction awareness week campaign
- Co-ordinated with Heads of Medicines Agencies Working Group of Communication Professionals
- Launch in November 2016



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SCOPE Flagship Event



- The aims of flagship event are to present SCOPE deliverables & achievements, and show how MSs can take advantage of SCOPE outputs to improve skills and capability in the EU network
- Attendees - pharmacovigilance staff from all NCAs, the General Advisory Board
- November 23rd, London



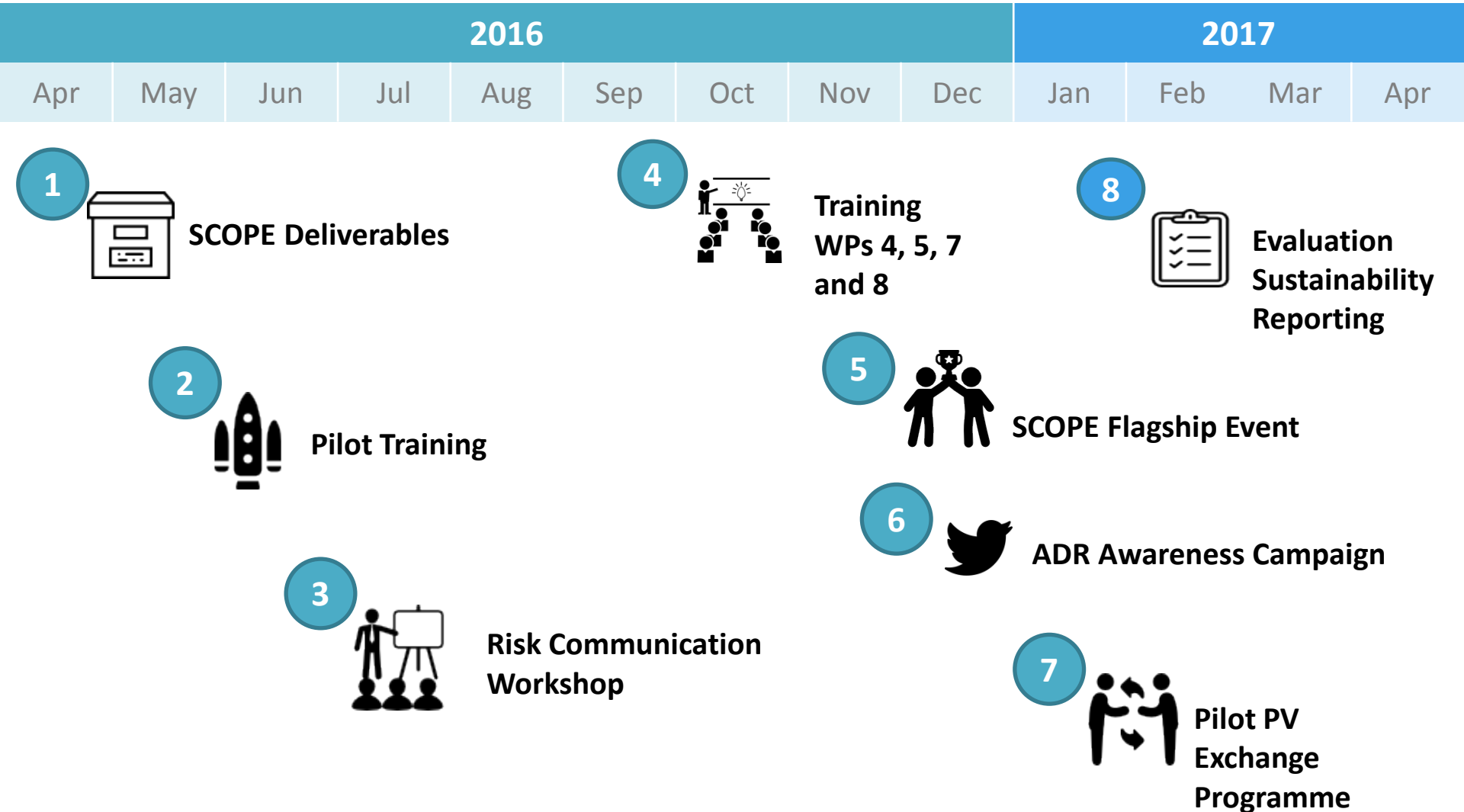
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Sustainability of SCOPE deliverables



- Strategic sustainability plan: maximising impact and continued accessibility of SCOPE deliverables
- SCOPE deliverables to be available in EU Network Training Centre learning platform and included in Pharmacovigilance training curriculum
- Review and maintenance of the SCOPE training materials – to ensure that the materials developed remain relevant and are used

SCOPE Timeline




Summary of SCOPE deliverables



- Guidance documents to support assessors - Best Practice and case studies and “toolkits”
- Training face to face and e-learning modules
- Pharmacovigilance Curriculum (in development)
- Exchange programme for PV assessors
- Platform for SCOPE materials via EU-NTC
- A co-ordinated ADR awareness campaign for MS
- Flagship launch event November 23rd

SCOPE Website





SCOPE Partner LoginShareFileHigh Contrast Version

AimsPartnersWork PackagesNewsGlossaryLinksContactDownloadsCalendar

SCOPE Joint Action

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators are collaborating to improve skills and capability in the network which will help safeguard public health in both national territories and the EU as a whole.

[Find out more](#)

Latest news: SCOPE Stakeholder Event 21 September 2015

[Read more](#)

Work Packages

Work Package 1 – Governance

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Work package 1 delivers the coordination and project management functions for SCOPE

[Package details](#)

Work Package 2 - Dissemination

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This work package aims to effectively disseminate information about SCOPE and its deliverables

[Package details](#)

Work Package 3 – Evaluation

Lead: National Authority of Medicines and Health Products, I.P. (INFARMED), Portugal

This work package focusses on the evaluation of SCOPE to verify that the project is delivering what was planned to achieve the objectives

[Package details](#)

Work Package 4 – ADR collection

Lead: Agency for Medicinal Products and Medical Devices (HALMED), Croatia

This work package focuses on national adverse drug reaction reporting schemes, including patient reporting and efforts to improve awareness of national systems

[Package details](#)

Thank you

Contact:

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Abstract graphic design featuring large, flowing, curved shapes in a vibrant green color against a white background. The shapes are organic and fluid, creating a sense of movement and depth. They appear to be layered, with some shapes in front of others, giving a three-dimensional effect. The overall composition is modern and minimalist.