Strengthening Collaborations for Operating Pharmacovigilance in Europe Joint Action

11th Stakeholder forum on the pharmacovigilance legislation

21 September 2017, London

Louise Loughlin, MHRA

SCOPE overview - outline

- **Aims and objectives of the Joint Action**
- **SCOPE achievements and highlights**
- **SCOPE outreach and sustainability**

Strengthening Collaborations for Operating Pharmacovigilance in Europe

SCOPE Joint Action

To maximise effective implementation of EU Pharmacovigilance legislation

To enable coordinated pharmacovigilance operations in the EU Network making best use of work-sharing and resources

To help ensure a consistent approach across the Member States in identifying and managing risks relating to medicines…

SCOPE Joint Action

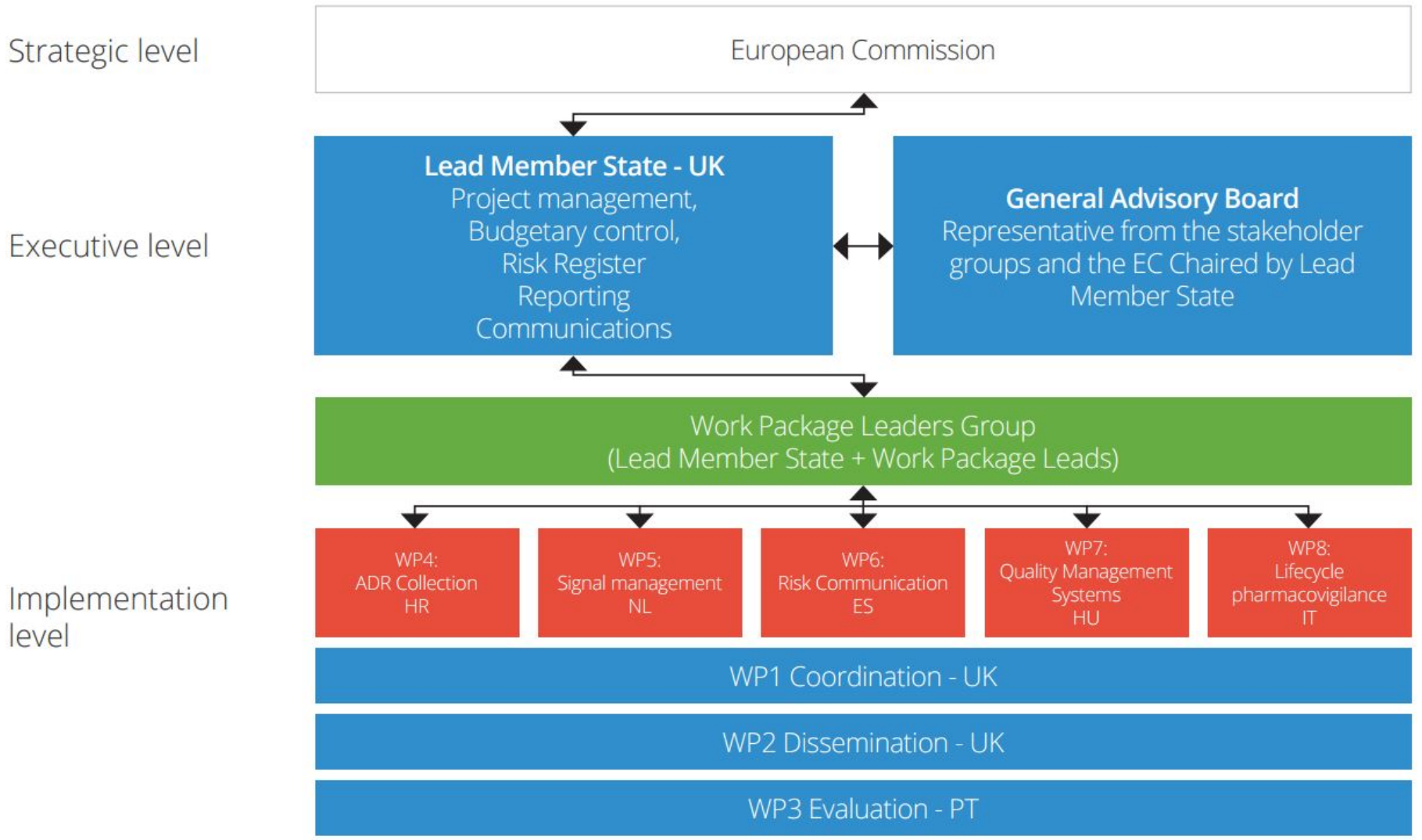
Collaboration of Member States
70% funding from European Commission
30% funding from NCAs

Share expertise and best practice

Deliver practical tools and guidance

Operate pharmacovigilance in Europe

Governance structure



SCOPE Timeline

SCOPE

SCOPE Launch Meeting

Reports and development of recommendations

Deliverables

Training Events Sept - Oct

Stakeholder Event and additional training/events

2013 2014 2015 2016 2017

Luxembourg,
EAHC H/SS AR/SC(2013)

Medicines and Healthcare products Regulatory Agency
Attn: Sir/Madam
151 Buckingham Palace Road
SW1W 9SZ London
UNITED KINGDOM

Registered letter sent by surface mail with advice of delivery and by email to: kent.woods@imhra.gsi.gov.uk & mick.foy@imhra.gsi.gov.uk

Subject: **Call for proposals 2013 - Second Programme of Community action in the field of Health (2008-2013)**

Ref.: **Your proposal Area no. 533446 - Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE)**

Dear Sir/Madam,

Thank you for taking part in the call for proposals referred to above and for submitting your proposal with the above reference.

I am pleased to inform you that the Commission has formally adopted the decision on the awarding of grants for proposals for 2013 under the second Health Programme (C(2013)7315 from 29 October 2013). Your proposal has been selected for funding.

March – July SCOPE Surveys

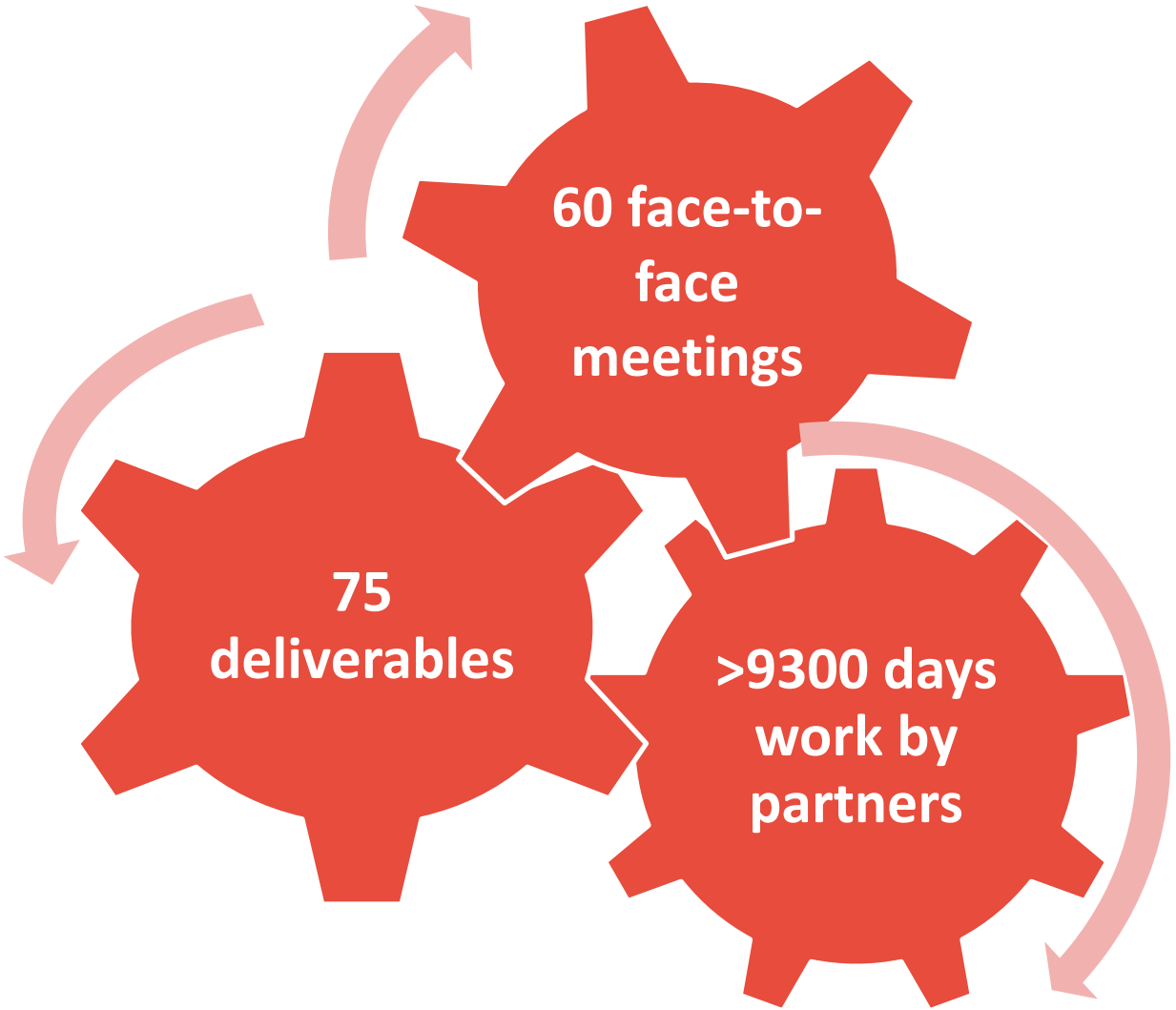
Pilot training May -June

Risk Communication Workshop 16-17 June

NCA Flagship Event Awareness Week

Pilot Exchange Programme

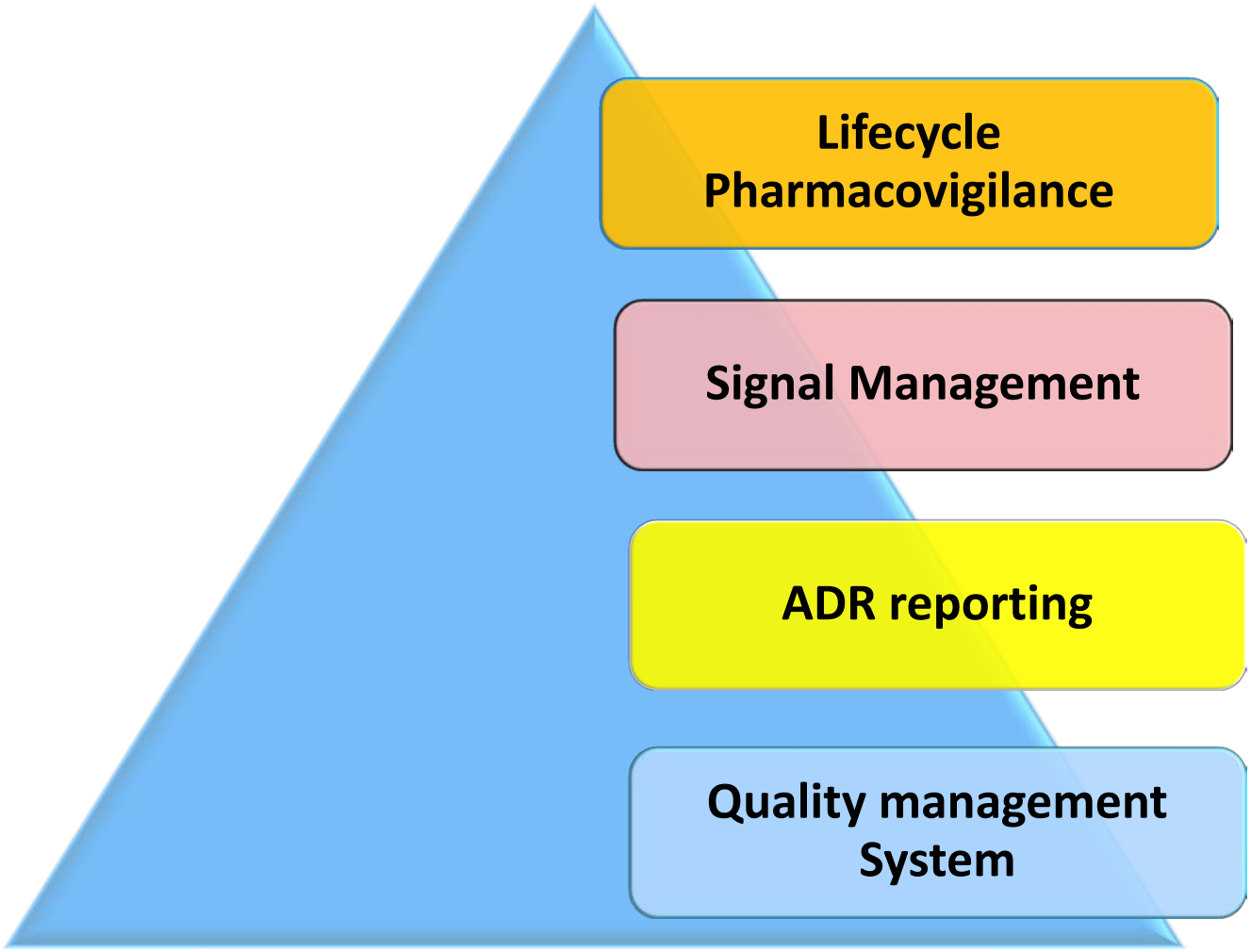
Work on SCOPE



SCOPE Outputs

- Survey Reports
- Pilot Training
- Guidance documents and recommendations
- E-learning modules
- ADR Web-form
- Publications
- Risk Communication Workshop
- Training WPs 4, 5, 7 and 8
- ADR Awareness Campaign
- SCOPE Flagship Event
- Stakeholder meetings
- Pilot PV Exchange Programme

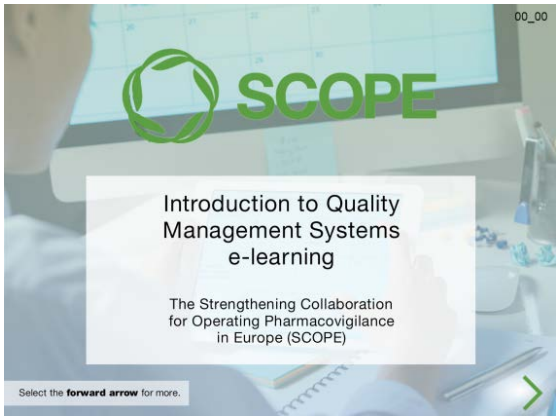
SCOPE “pyramid” of deliverables



Quality Management Systems

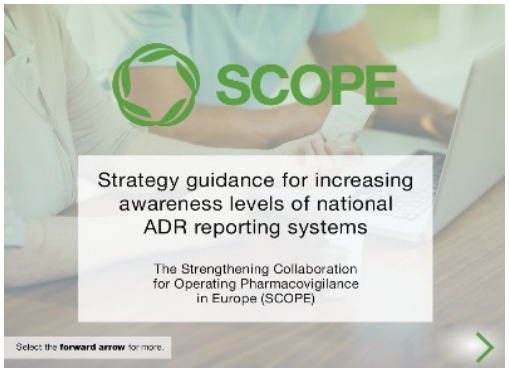
Deliverables:

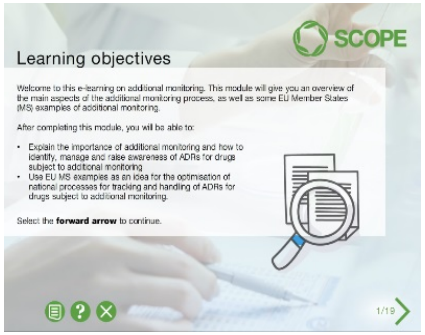
- Based on surveys, site visits and EU network experience
- Toolkit for further development of a QMS –documents, reports and **4 e-learning modules**
- WP7 training 4 October 2016 in Budapest
- Co-training with WP8 and WP4

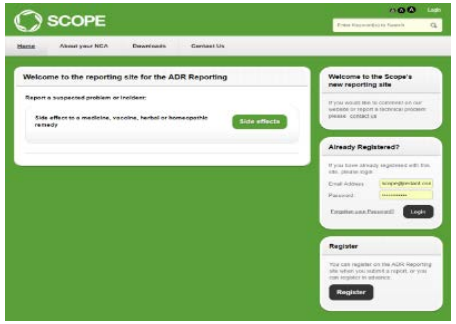


ADR Collection

- Surveys in European NCAs – information was gathered to understand national PV reporting systems
- Outputs: toolkit for raising awareness of ADR reporting systems, best practice guidelines, e-learning modules, a training course for NCAs, social media campaign, webform for ADR reporting





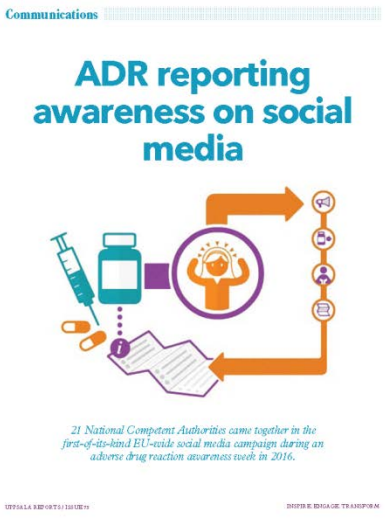


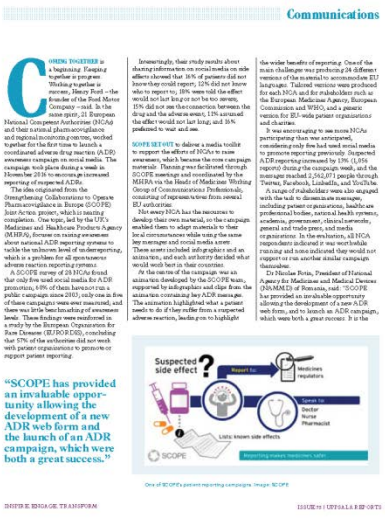
EU ADR social media campaign

- **21** NCAs
- **13%** increase in reporting (1,056 reports) in EU over campaign week
- **2,562,071** people were reached
- **337,781** people viewed the animation
- **22,584** likes, clicks, retweets and shares on Twitter, Facebook, LinkedIn and YouTube
- All participants indicated it was worthwhile running
- 88% would support another campaign

Uppsala Reports Issue 75 April 17

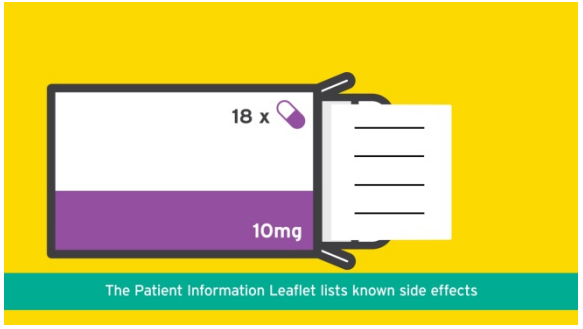
- Read about the ADR campaign in the April 2017 issue of WHO's UR

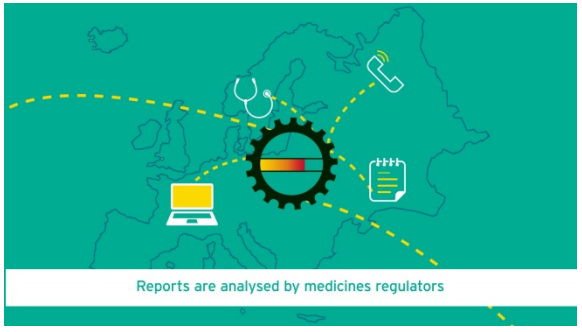


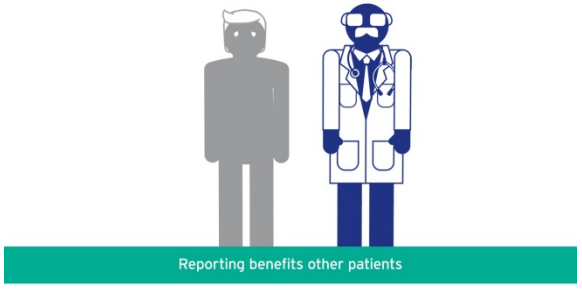


Key feature: animation

- Tailored and translated into 24 versions
- Simple but key messages for the ADR lifecycle which were broken down into small clips over the week supported by infographics







Example infographics

ADR Reporting Web Form

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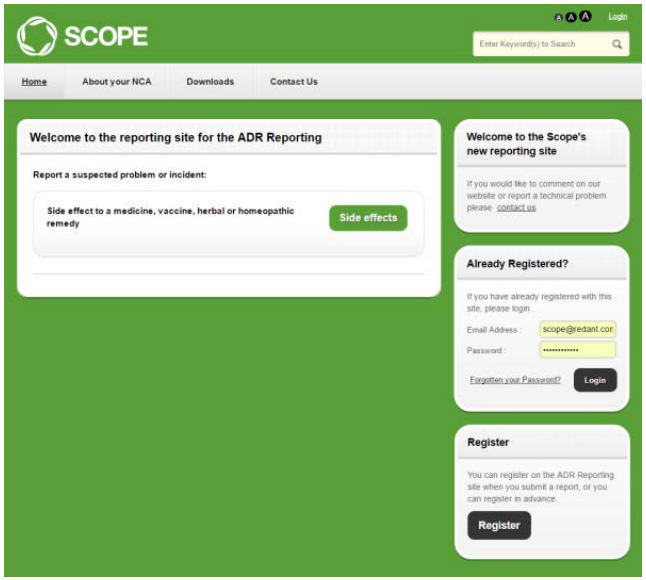
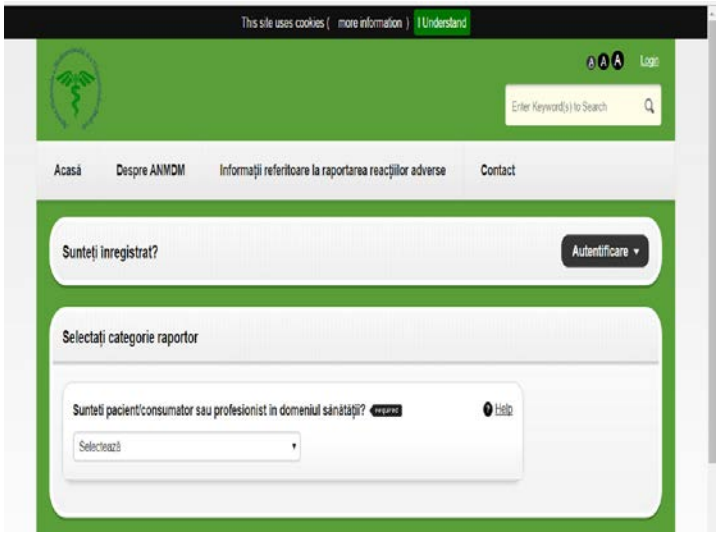
- Reporting from patients & healthcare professionals
- Transmits ICSRs direct to NCA database and EMA
- Can act as NCA database if required
- Adopted by Romania





ADR e-learning for HCPs

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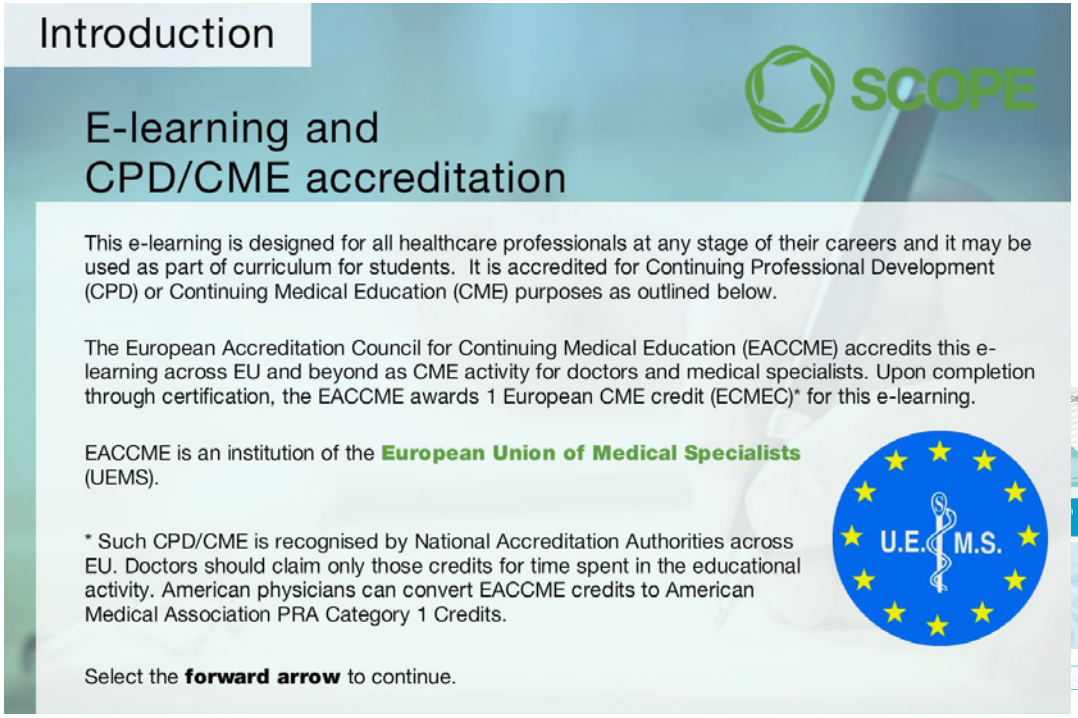
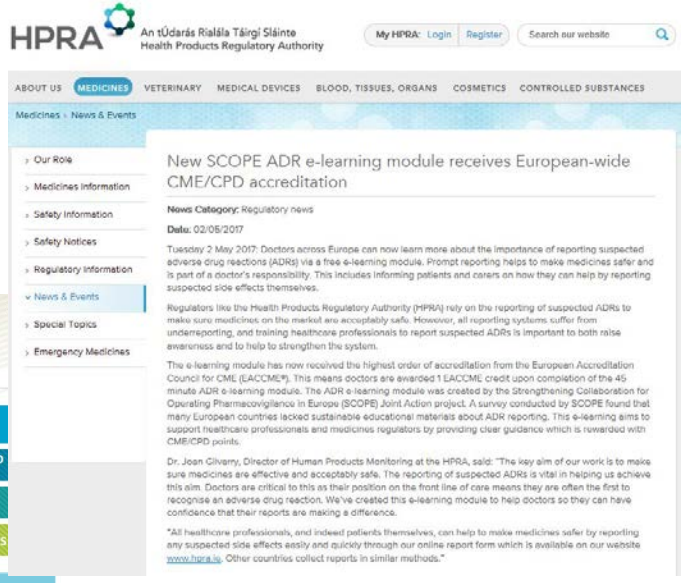
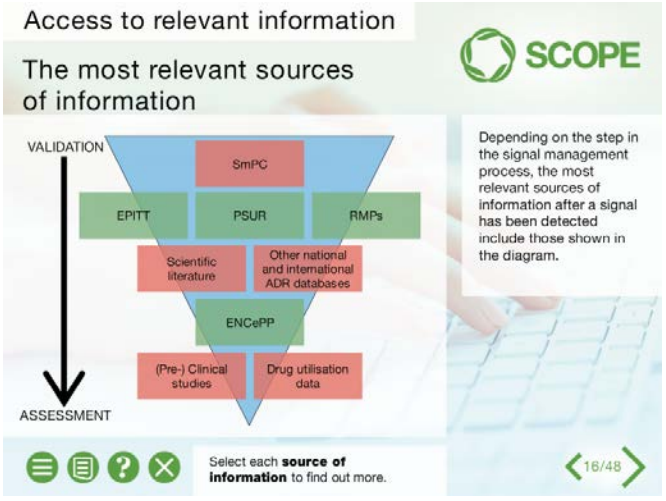


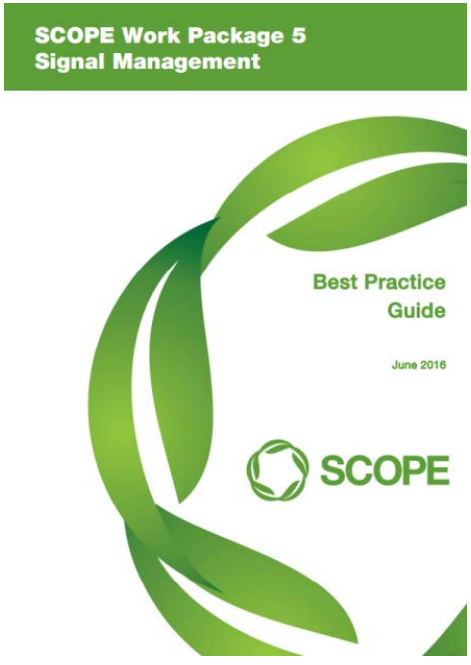


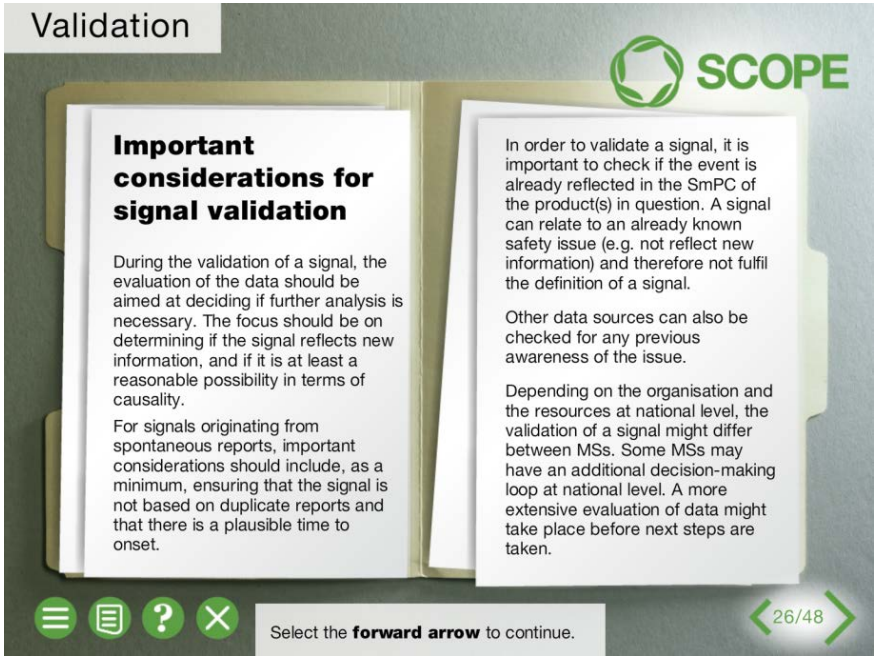
Signal management

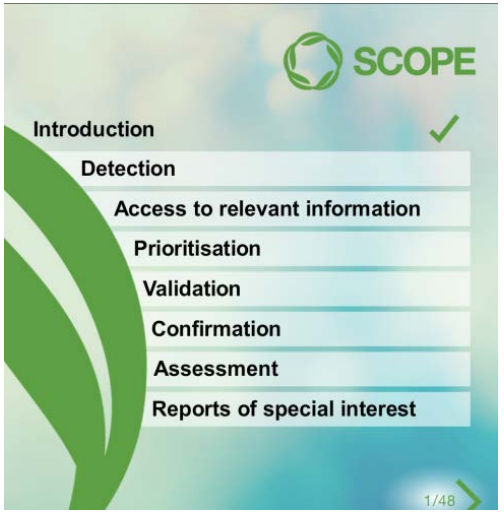
Deliverables:

- Comprehensive guide to all aspects of signal management
- Survey, e-learning module, literature review
- Training: 5 October 2016, Budapest, 24-25 April 2017





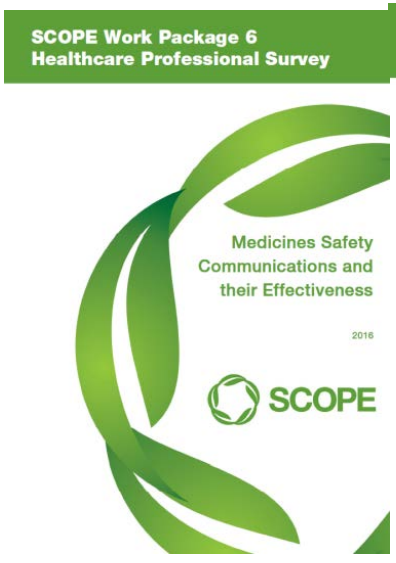




Risk Communication

Deliverables:

- Surveys Reports – NCAs and HCPs
- Web-portals Good Practice Guide, literature review
- Workshop 16-17 June 2016, Madrid, 103 delegates: PV and communication experts, WHO, EMA, academia, patients, consumers, and HCPs
- Videos and presentations from the workshops;



Publication on risk communications

Drug Saf
DOI 10.1007/s40264-017-0535-0

ORIGINAL RESEARCH ARTICLE

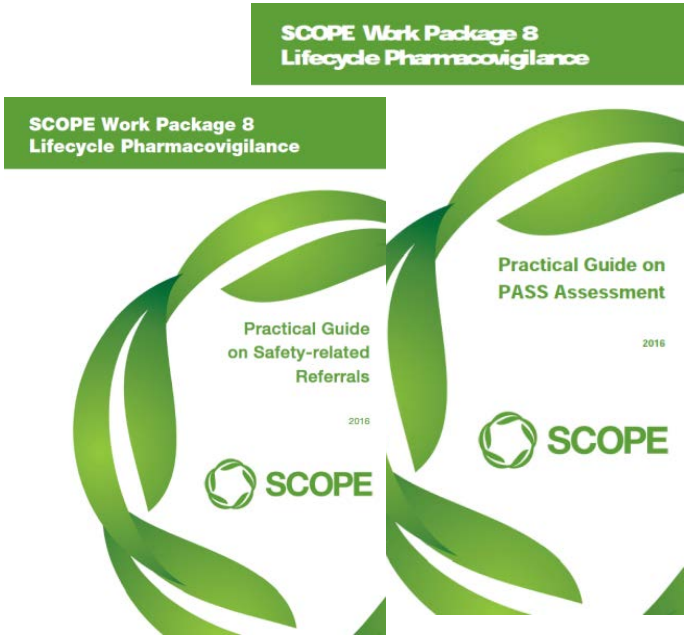
Communication on Safety of Medicines in Europe: Current Practices and General Practitioners' Awareness and Preferences

Sieta T. de Vries[1] · Maartje J. M. van der Sar[1,2] · Amelia Cupelli[3] · Ilaria Baldelli[3] · Anna Marie Coleman[4] · Dolores Montero[5] · Ivana Šipić[6] · Adriana Andrić[6] · Annika Wennberg[7] · Jane Ahlqvist-Rastad[7] · Petra Denig[1] · Peter G. M. Mol[1,2] · On behalf of SCOPE Work Package 6

Lifecycle Pharmacovigilance

Deliverables:

- Recommendations, practical guides
- 4 e-learning on Additional Data Sources, Risk Management Plans, Post Authorisation Safety Studies, Periodic Safety Update Report, Safety related referrals
- Training 20 - 21 September 2016



Pilot of EU programme for exchange of PV Assessors

- Grounds for a sustainable programme for European PV assessors
- Exchange of experience, knowledge and an on-the-job training
- Working group established: UK, PT, NO, ES
- Ran from Jan - Feb 2017; completed March 17
- Very positive comments: ‘excellent’ collaborative working



SCOPE training & stakeholder engagement

- Workshop on Risk Communication (June 16)
- 5 training sessions for NCAs (Sept-Oct 2016, Signal management repeat training April 17)
- SCOPE flagship event (Nov 16)
- SCOPE stakeholder event (March 17)
- Local stakeholder events in Croatia & Hungary (Mar- Apr 17)
- Further signal management training in the Netherlands (April 17)

Joint training opportunity

EURORDIS
RARE DISEASES EUROPE

EURORDIS-SCOPE PHARMACOVIGILANCE TRAINING

22nd March 2017, 8.30 to 13.30

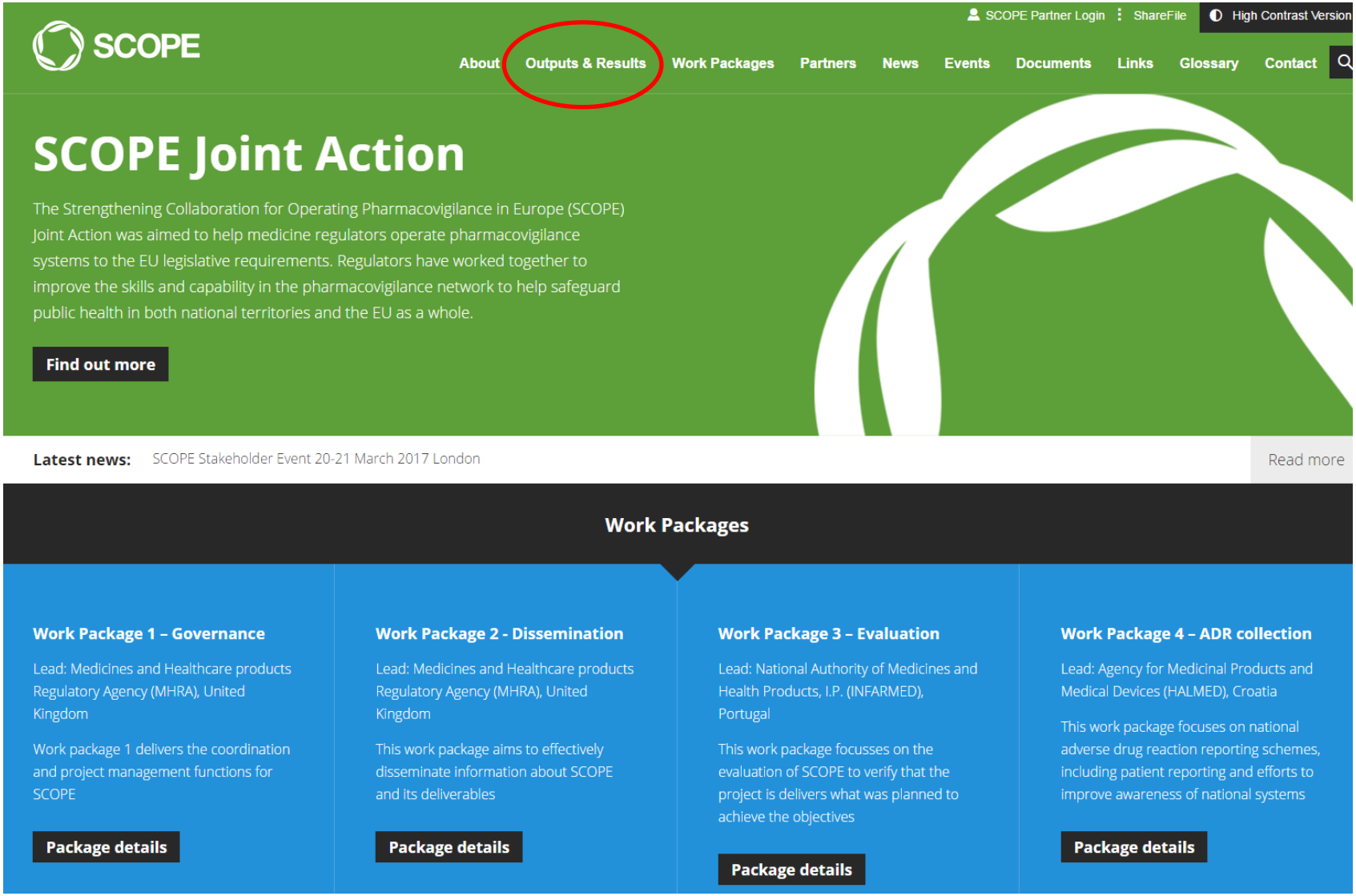
Holiday Inn London Regents Park, Carburton Street, W1W 5EE: Trinity room

François Houÿez

22nd March, London

EURORDIS.ORG

SCOPE Website
www.scopejointaction.eu



EU Network Training Centre

- SCOPE deliverables available in **EU Network Training Centre** learning platform
- **PV Training Curriculum** for NCAs

http://euntc.eudra.org/

SCOPE Further Outreach

- SCOPE publications & posters
- Presence at conferences & meetings – eg DIA, ISOP
- ?ISoP Pharmacovigilance training curriculum

- Materials available to use within your organisations

SCOPE Further Outreach

- Sharing SCOPE materials through the International Coalition of Medicines Regulatory Authorities

- Supporting launch of ADR app in Zambia and Burkina Faso (IMI WEB-RADR)

Working together

Thank you

Contact:

scope@mhra.gov.uk