Medicines & Healthcare products Regulatory Agency

Update on SCOPE - Strengthening Collaborations to Operate Pharmacovigilance in Europe



CPRD NIBSC MHRA

Background – Review Of The EU System

Fraunhofer Institute Systems and Innovation Research

Assessment of the European Community System of Pharmacovigilance

Final Report – Final version

25 January 2006

European Commission
Enterprise and Industry Directorate-General, Unit F2, Pharmaceuticals

Reference: Service Contract N°: FIF.20040739

Submitted by the

Fraunhofer Institute for Systems and Innovation Research, Karlsruhe, Germany

Pharmacovigilance Legislation

2012: EU Pharmacovigilance legislation

Directive 2010/84/EU (amending Dir 2001/83/EC)

Regulation (EU) No 1235/2010 (amending Reg (EC) No 1394/2007)

Extensive changes to the way PhV conducted

Supported by guidance: Good Vigilance Practice modules (replacing Vol. 9a)

In UK: transposed into: Human Medicines Regulation 2012 (consolidates most of Medicines Act 1968 & >200 statutory instruments)

GUIDANCE ON GOOD PHARMACOVIGILANCE PRACTICES (GVP)

MODULE I	Pharmacovigilance Systems and their Quality Systems
MODULE II	Pharmacovigilance System Master File
MODULE III	Pharmacovigilance Inspections
MODULE IV	Pharmacovigilance Audits
MODULE V	Risk Management Systems
MODULE VI	Management & Reporting of Adverse Drug Reactions
MODULE VII	Periodic Safety Update Reports
MODULE VIII	Post-Authorisation Safety Studies
MODULE IX	Signal Management
MODULE X	Additional Monitoring
MODULE XV	Safety Communications
MODULE XVI	Risk Minimisation Measures & Education Materials

SCOPE Context in EU

SCOPE
www.scopejointaction.eu

Progress to implement legislation

Establishment of:

- Pharmacovigilance Risk Assessment Committee
- Good Vigilance Practice modules
- Additional Monitoring

Member States now need to operate pharmacovigilance to legislative requirements

EC recognise varying level of maturity in the system

SCOPE Joint Action

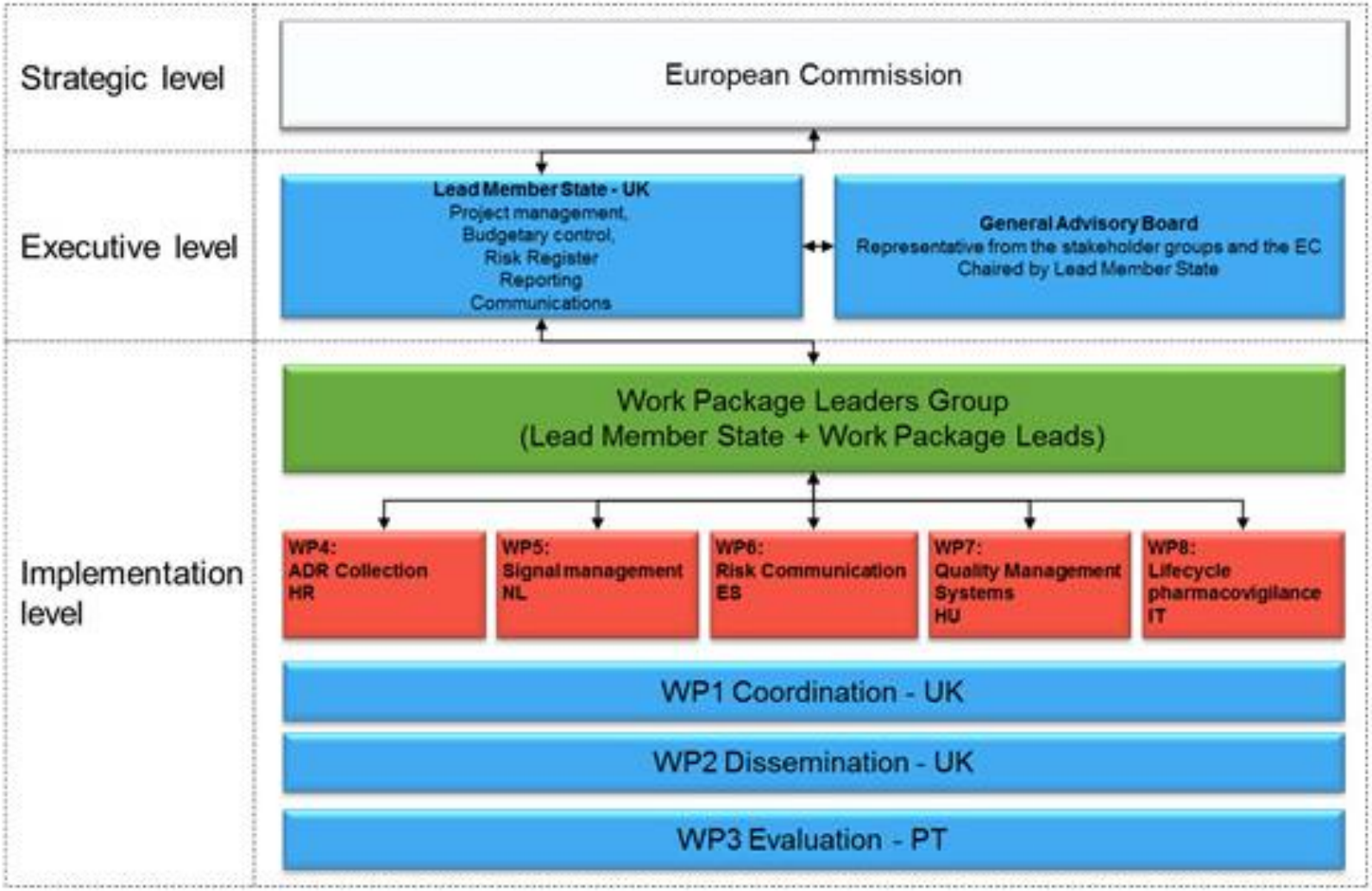
Formal award decision adopted by Commission

SCOPE 36 month project launched in November 2013

Maximum level & largest possible contribution of 70% funding from Commission: *Consumers, Health and Food Executive Agency (CHAFEA)*

"Exceptional utility"

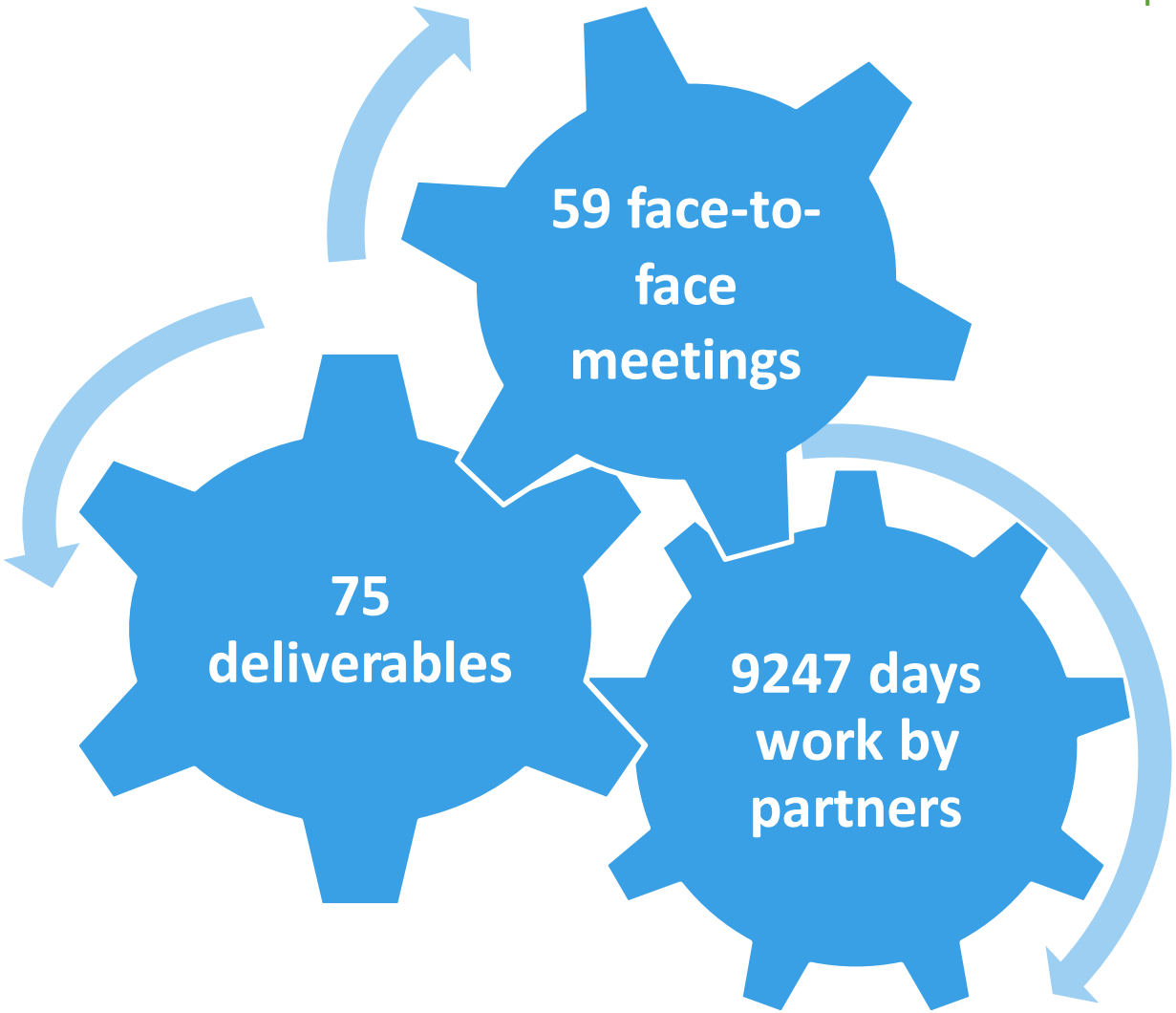
Governance Structure



Working together

Work on SCOPE

SCOPE
www.scopejointaction.eu



What SCOPE has delivered

- Survey findings/reports from each work package
- 34 “Best Practice” guidance documents
- 14 e-learning modules
- Web reporting form for free uptake
- Supported by
  - Interactive pdfs
  - Digital posters/infographics
  - Recordings of workshops and training
- Publications in scientific journals
- Training and stakeholder events

SCOPE Training Events

ADR Lifecycle

Signal Management

Quality Management Systems

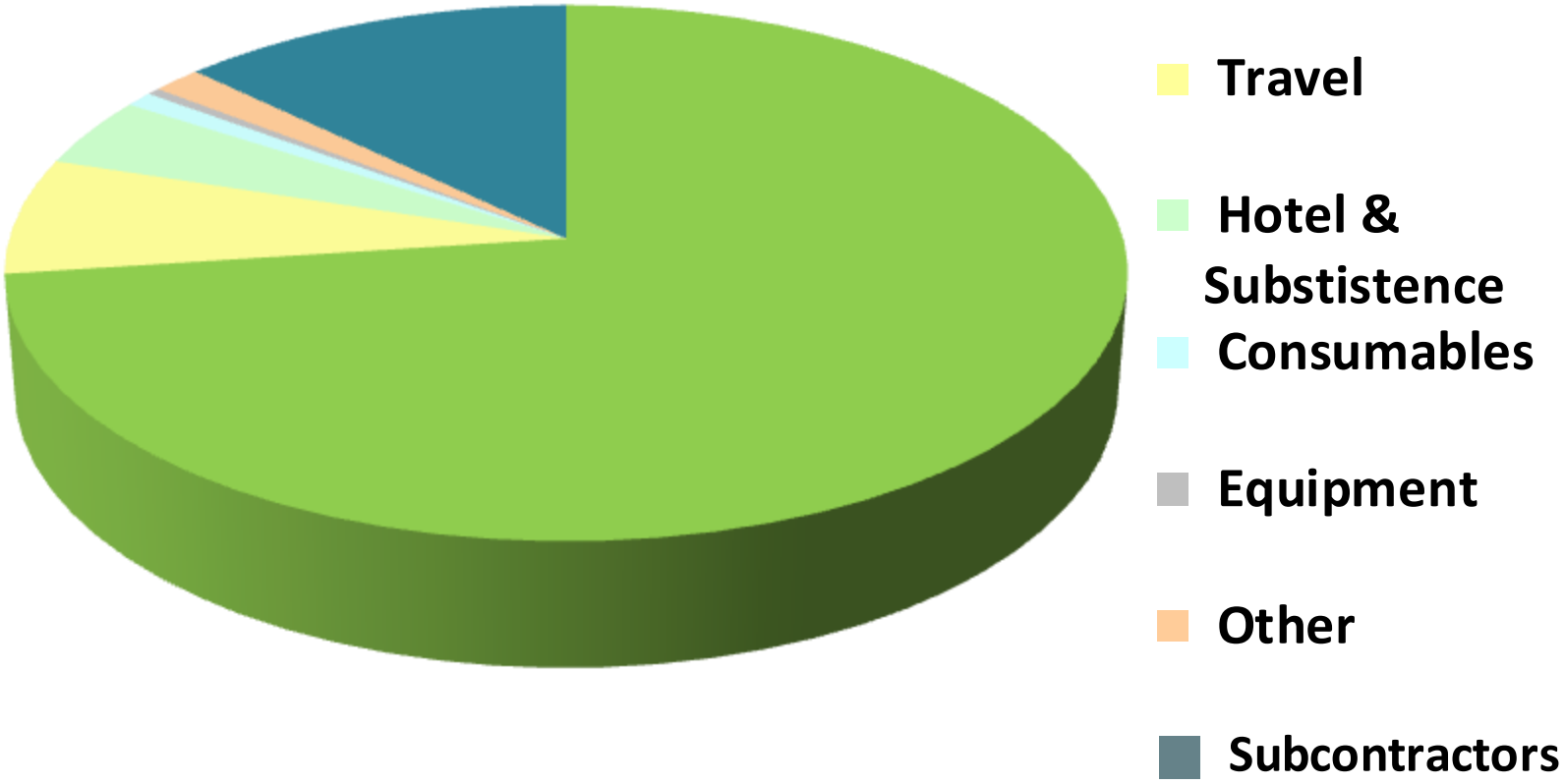
Lifecycle Pharmacovigilance

SCOPE Workshops

Risk Communication on Medicines

16-17 June 2016

Spend on SCOPE



WP4 – ADR collection

Deliverables:

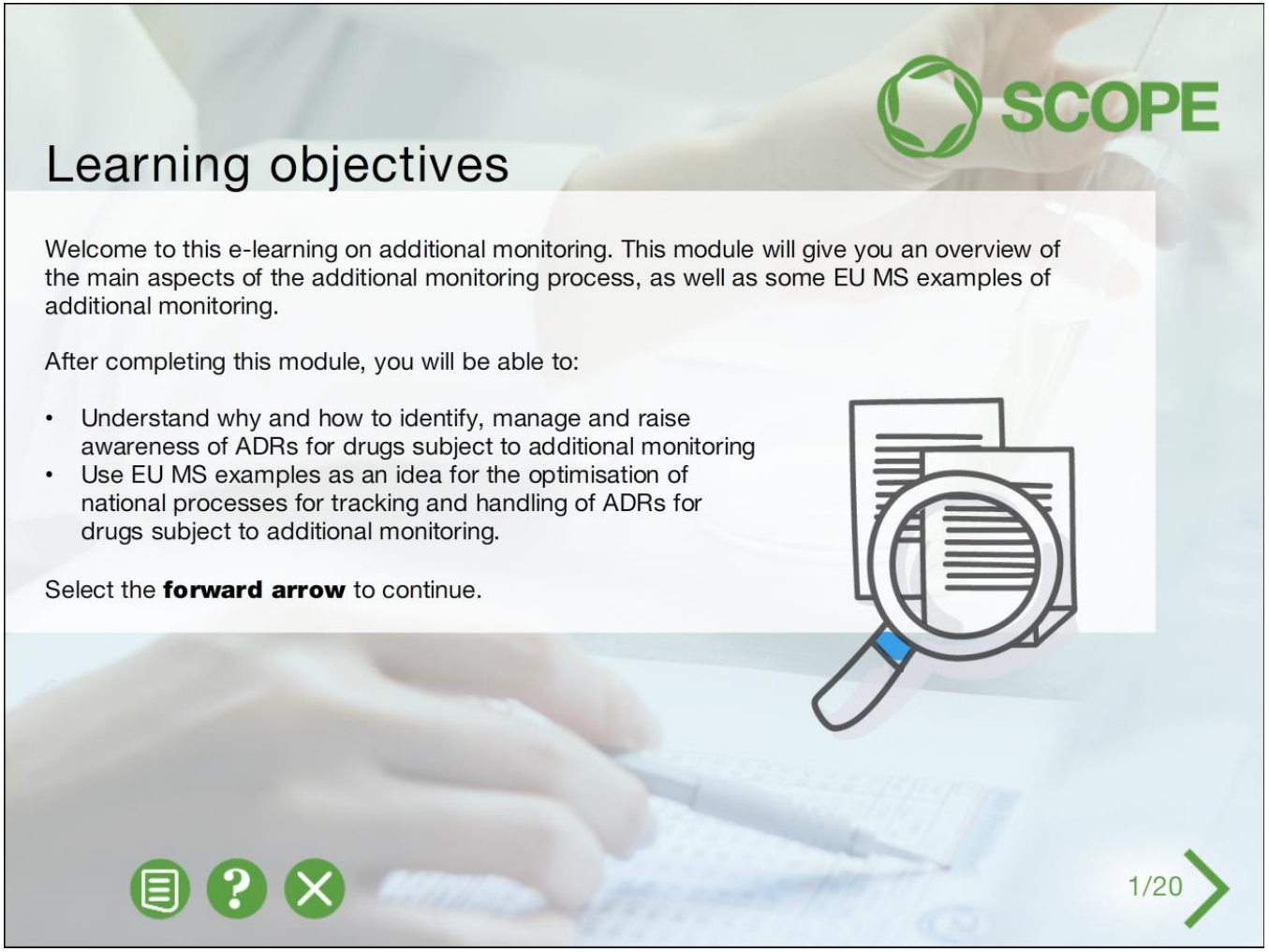
- Best Practice Guides:
  - Additional Monitoring
  - Duplicate detection
  - Approaches to comparing reports (HCP & Patient)
  - Medication errors
  - Collaboration with patient organisations
  - Feedback to patients
  - ADR IT systems (at differing levels of maturity)
  - Tools for measuring and improving quality of ADR reports

WP4 – ADR collection

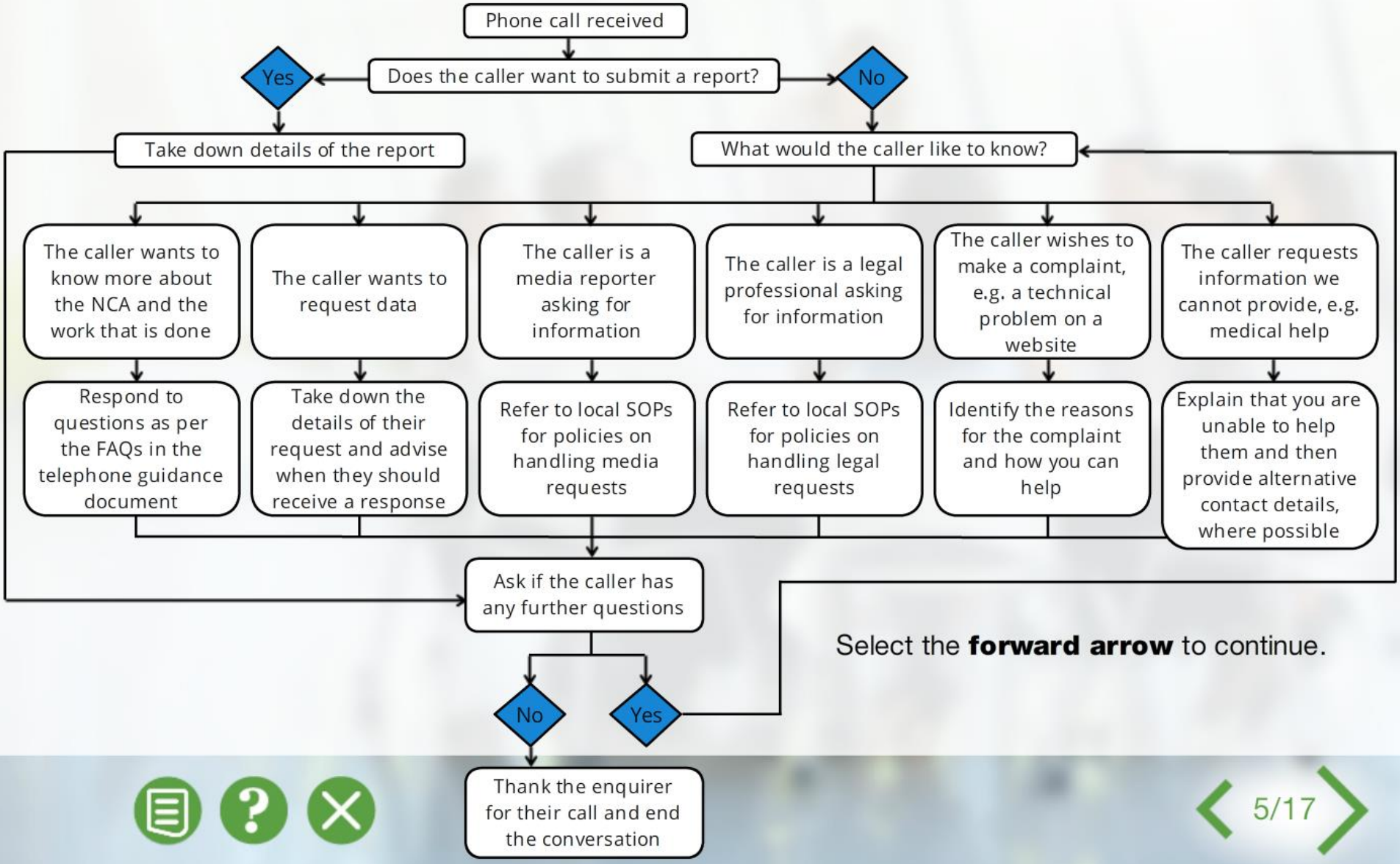
Deliverables:

- Online E-learning:
  - Additional Monitoring
  - Duplicate detection
  - CPD accredited e-learning for health professionals

E-learning module: Additional monitoring



Flowchart for responding to callers



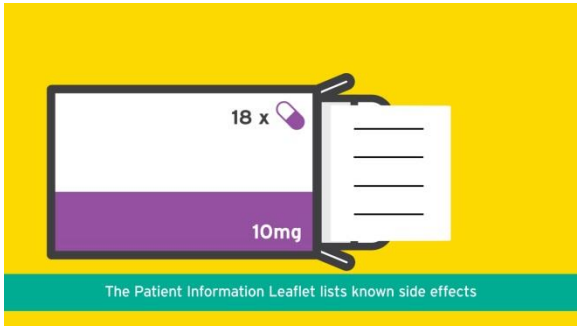
Select the **forward arrow** to continue.

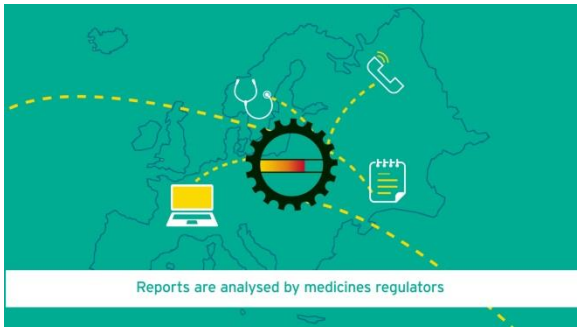
Raising awareness levels of national ADR systems in EU

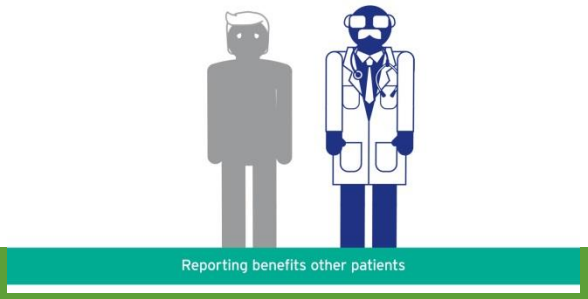
- SCOPE developed a media toolkit to raise awareness levels
- Social media campaign ADR week: 7-11 November 2016
- A first of its kind in Europe
  - Use of animations, polls, infographics, articles, press release etc
  - Twitter, LinkedIn, Facebook, websites
- **22 countries took part**
  - Support from Heads of Medicines Agency Working Group for Communications Professionals

Key feature: animation

- Tailored and translated into 22 versions
- Simple but key messages for the ADR lifecycle which were broken down into small clips over the week supported by infographics







Initial results & example animated infographics

- UK example :

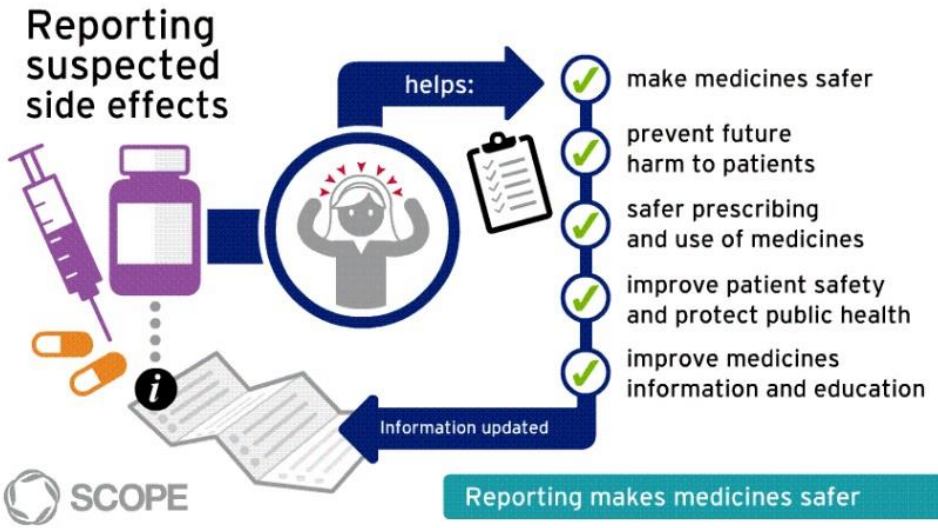
My Story

During our **SCOPE campaign** last week:

Each day more than **72,000 people** saw our key messages

Our animation has been seen more than **136,000 times**

Our infographics were **retweeted 650 times**



Medicines & Healthcare products Regulatory Agency

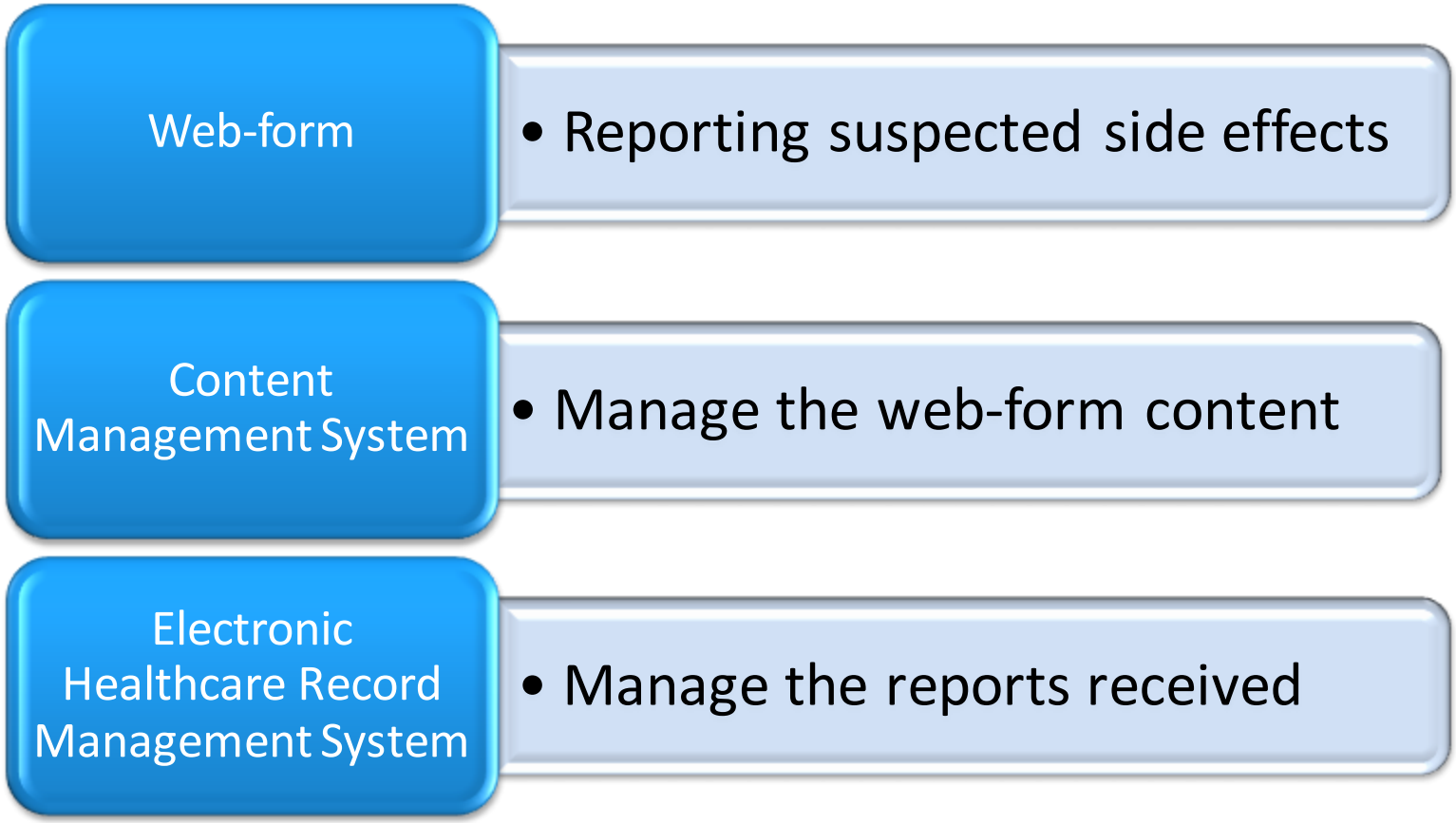
Yellow Card

You can report:

Suspected side effects from medicines
Adverse incidents with medical devices
Defective medicines
Counterfeit medicines
Side effects or safety concerns for e-cigarettes

Through our Yellow Card Scheme

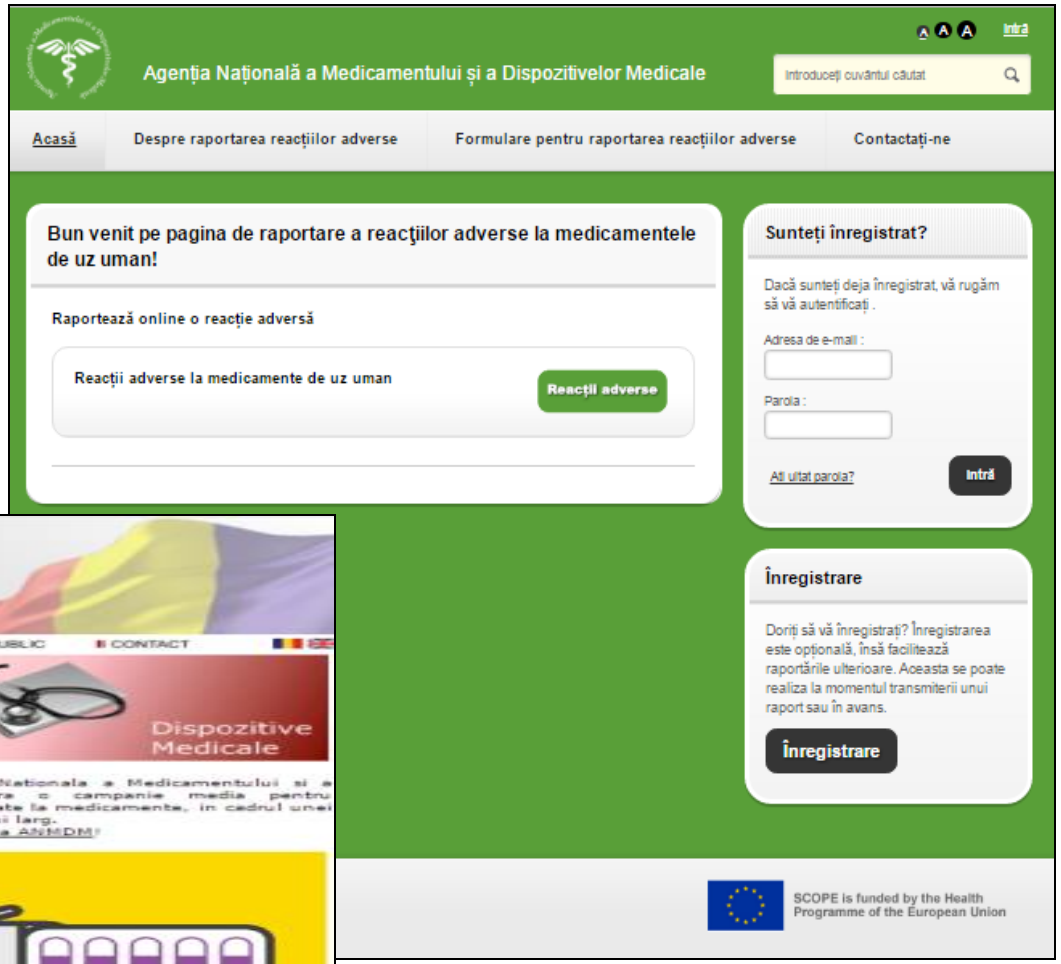
SCOPE WEBFORM



Detailed guidance document accompanies the web-form for local management after deployment

New ADR reporting site for Romania

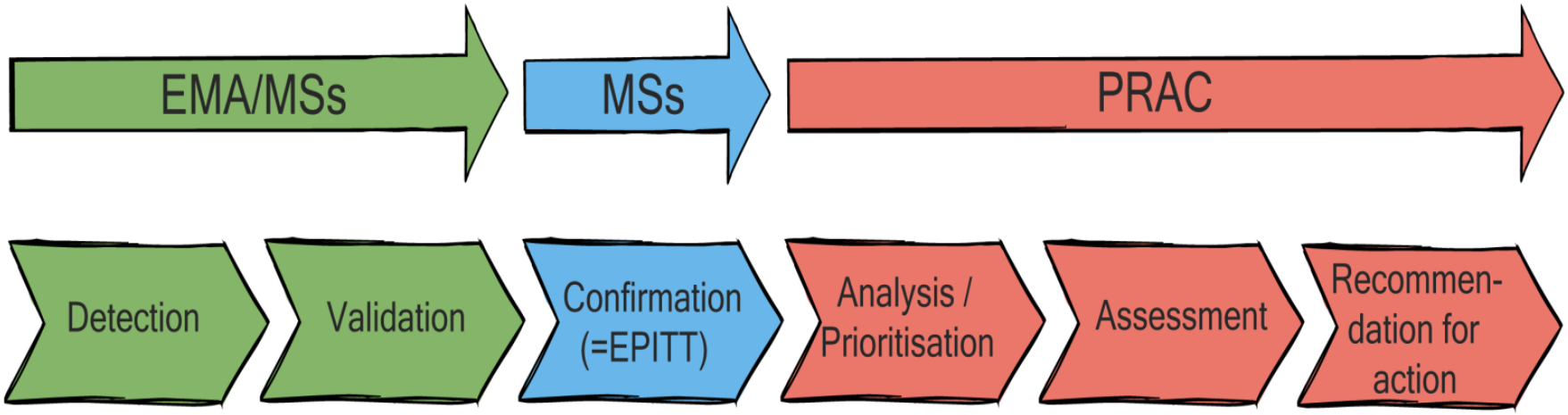
https://adr.anm.ro/



Work Package 5 – Signal Management

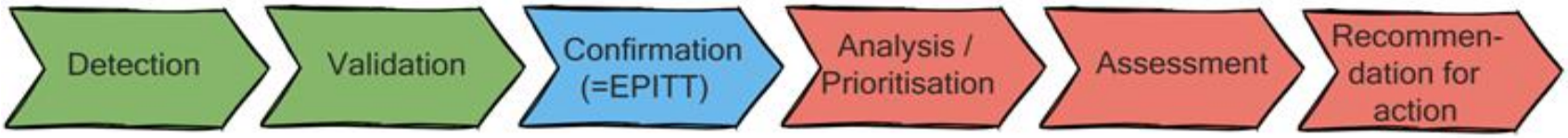
- WP 5 – Best practice in signal management within the network of National Competent Authorities (NCAs)
  - *Focus on the NCAs and the work at national level in SM*
  - *Make the best use of the currently available tools*
  - *Identify best practices in MSs*
  - *Focus on practical aspects and opportunities to improve at NCA level*

Signal Management
From Implementation to Operation



What we hope to have achieved

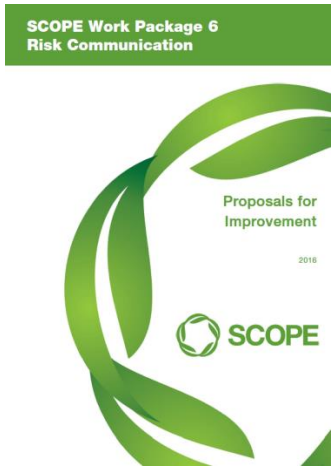
- More clarity on the concepts and the flow of the SM process in the EU
- Understand the concepts of **prioritisation, validation, confirmation, assessment** in the EU SM process
- Increase awareness regarding additional data sources and how to use them in signal management
- Gain some further insights in signal detection
- Awareness of existing supportive tools
- Awareness of possible approaches for reports of special interest to be used at national level
- Put into practice the knowledge acquired : real case scenarios workshop

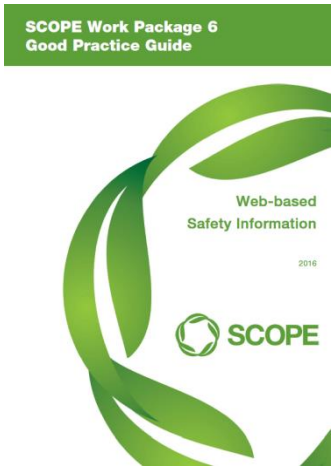


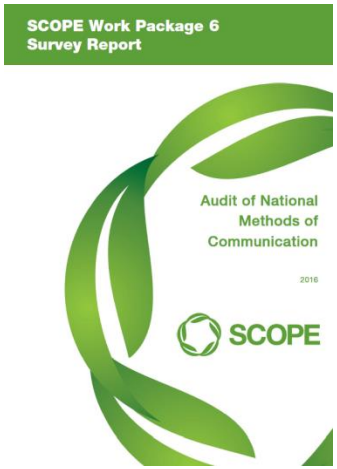
WP6 – Risk Communication

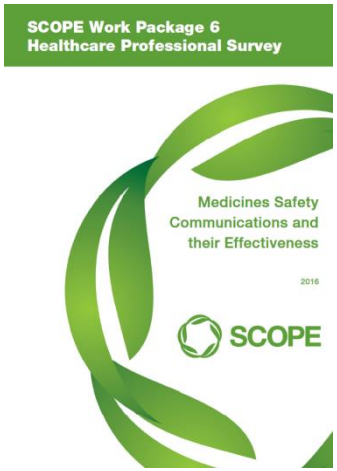
Deliverables:

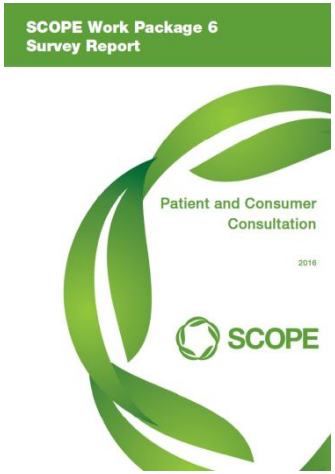
- Surveys Reports – NCAs and HCPs
- Web-portals Good Practice Guide
- Proposals for Improvement Document
- 3 publications in preparation











WP6 HCPs survey- Medicines Safety Communications and their effectiveness

3625 respondents

Aim: explore the attitudes, knowledge, preferences and behaviours of HCPs in Europe, regarding methods to communicate safety issues of medicines.

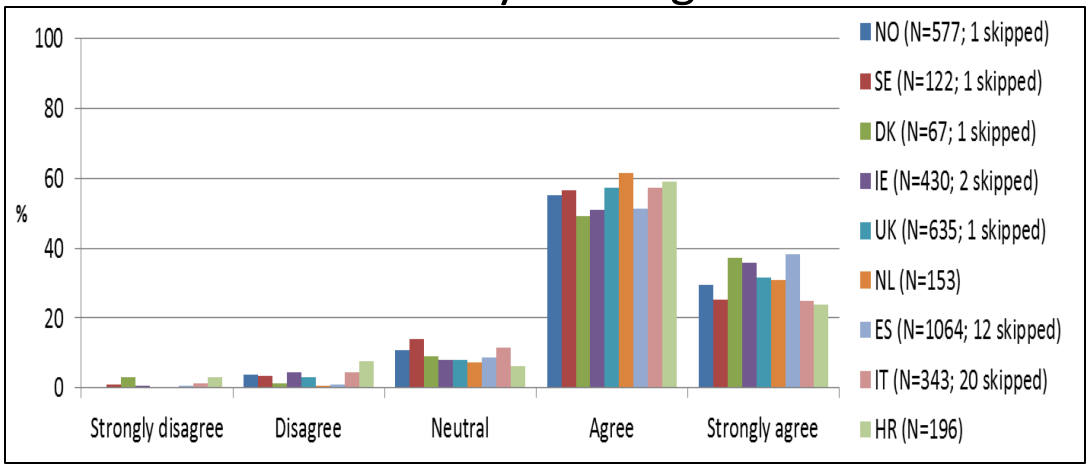
	N (%)
Female	2215 (61)
Primary employment setting	
Community-based	2570 (70)
Hospital-based	857 (24)
Other	244 (6)
Age	
<35 year	625 (17)
35 – 45 year	964 (27)
46 – 55 year	1071 (30)
>55 year	964 (27)
Accreditation	
<5 years	370 (10)
5 – 20 years	1394 (38)
>20 years	1859 (51)

Target population

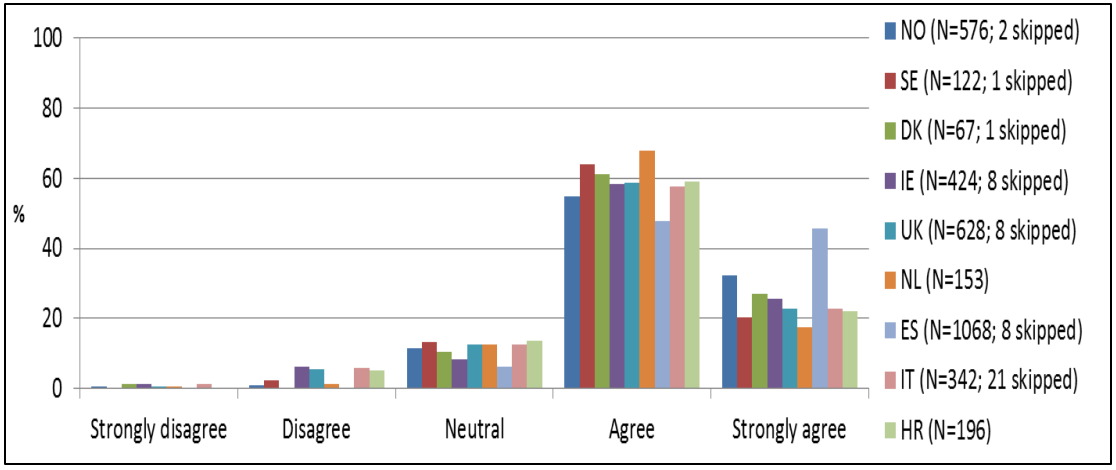
- General practitioners (GPs)
- Cardiologists
- Pharmacists (except ES, SE)
- *Other responders (HCPs active in clinical practice)*

Sender

- I only read the safety information if, I trust the sender of the safety message



- I only take action in response to a safety warning if, I trust the sender of the safety message



MOST POSITEVELY EVALUATED SENDERS
NCA
Professional bodies

MOST NEGATIVELY EVALUATED SENDERS
Lay press
Pharmaceutical companies

WP6 – Risk Communication workshop

- Hosted by AEMPS 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 WP6, 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/

Some recommendations

- Promote role of trusted sender (eg. NCA, professional body)
- Increase awareness of educational material, clear distinction from promotional materials
- GPs considered useful reminders of messages
- Format and alternative channels for distribution to be based on national preferences
- Integrate communication in electronic prescribing tools (point of care alerts)

WP7 (QMS) Objective and topics

Objective: enabling Member States to understand and develop their Quality Management System for pharmacovigilance

- Topic 1: to understand the functioning of national quality systems at various degrees of maturity across the EU
- Topic 2: resource management
- Topic 3: pharmacovigilance inspection

WP 7: Deliverables

1. Practical guidances (tool-kit) on how to improve quality management systems furthermore on interface of PV inspectors and assessors

2. 25-min e-learning course (Introduction of quality management systems)

3. Training(s)

Work Package 8: Lifecycle PV

SCOPE

Topic 1: Identification of available data sources outside spontaneous reports

Topic 2
NO lead
AC: ES, IE,IT, SE, PT,UK

Topic 3
SE lead
AC: ES,IE,IT,NO, PT,UK

Topic 4
IT lead
AC: ES,IE,NO,PT,SE,UK

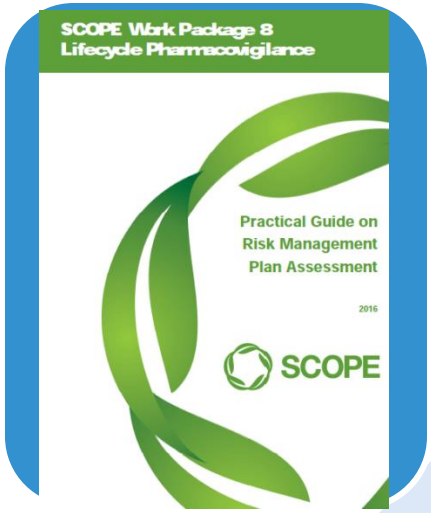
Risk Management Plan assessment

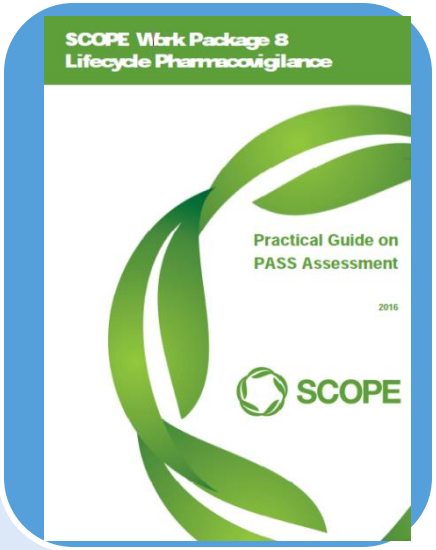
PASS assessment

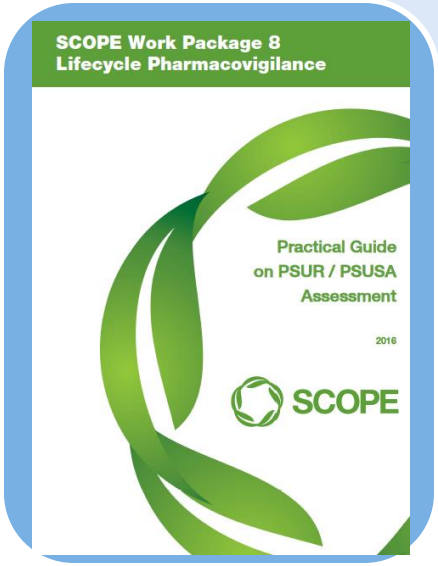
Benefit/risk assessment PSURs and Referrals

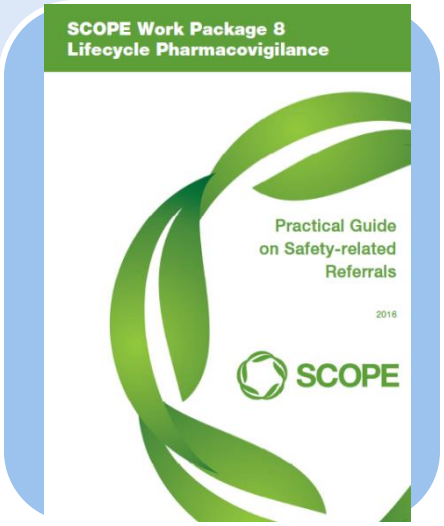
Topic 5: Competency

Deliverables- Practical guides

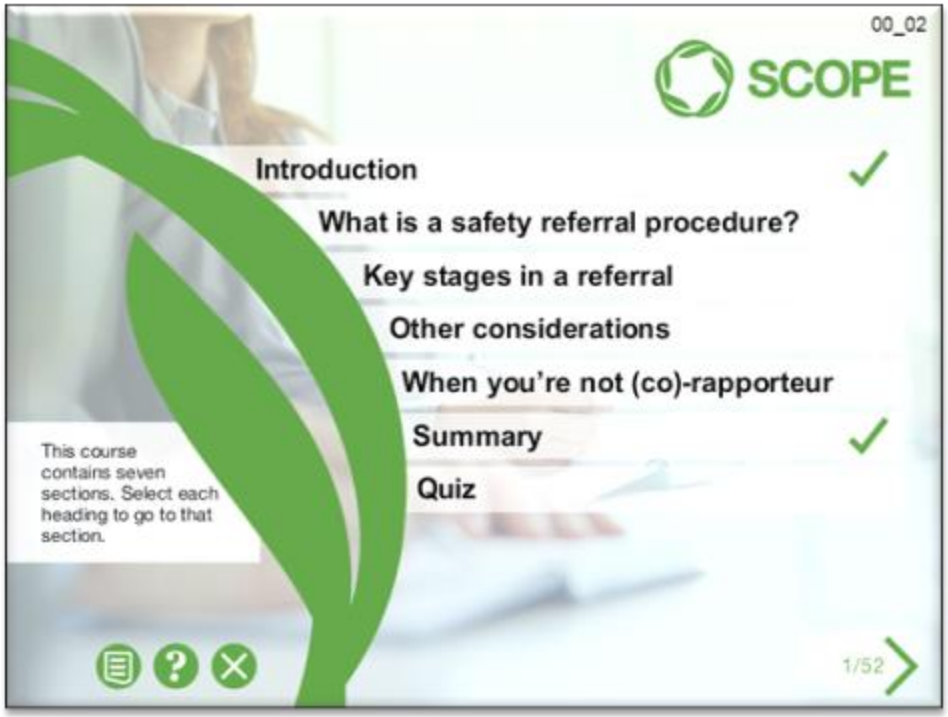


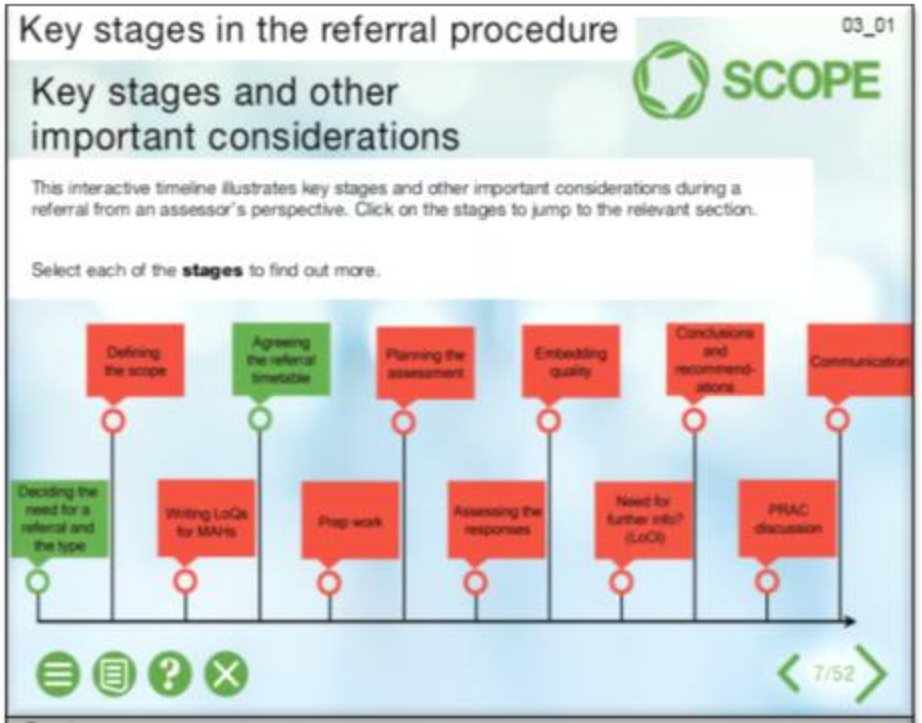


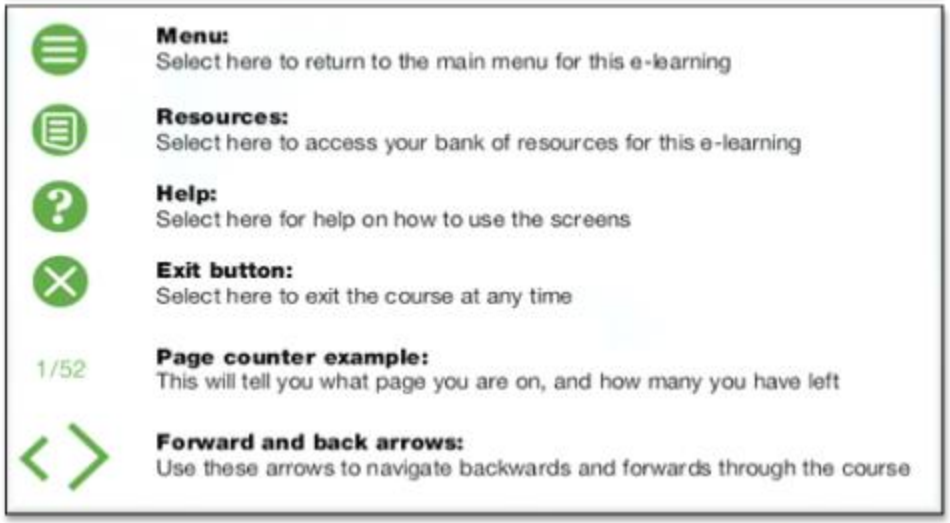


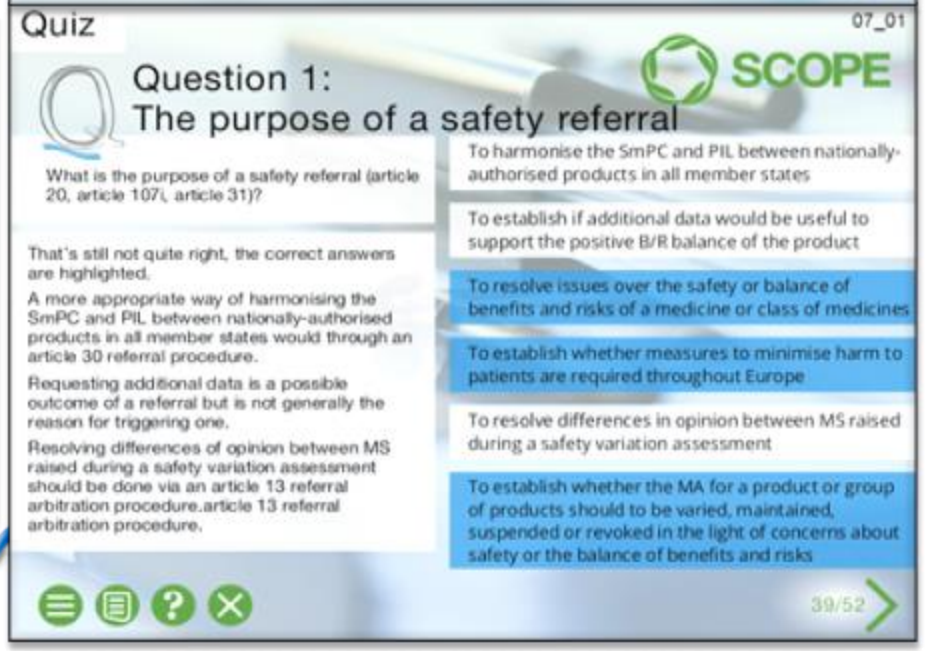


- **Key challenges and learnings from PRAC on handling PV procedures assessment**
- **Practical advice on some aspects**
- **"From assessors for assessors"**







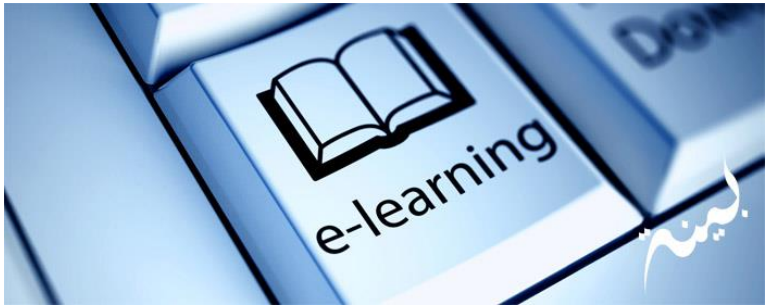


https://www.walkgroveonline.com/MHRA/WP8/wp8sr_gold_2/story.html

Deliverables: e-learning modules

- RMP
- PASS
- PSUR/PSUSA
- referral

…….to maximise training opportunities for PV assessors

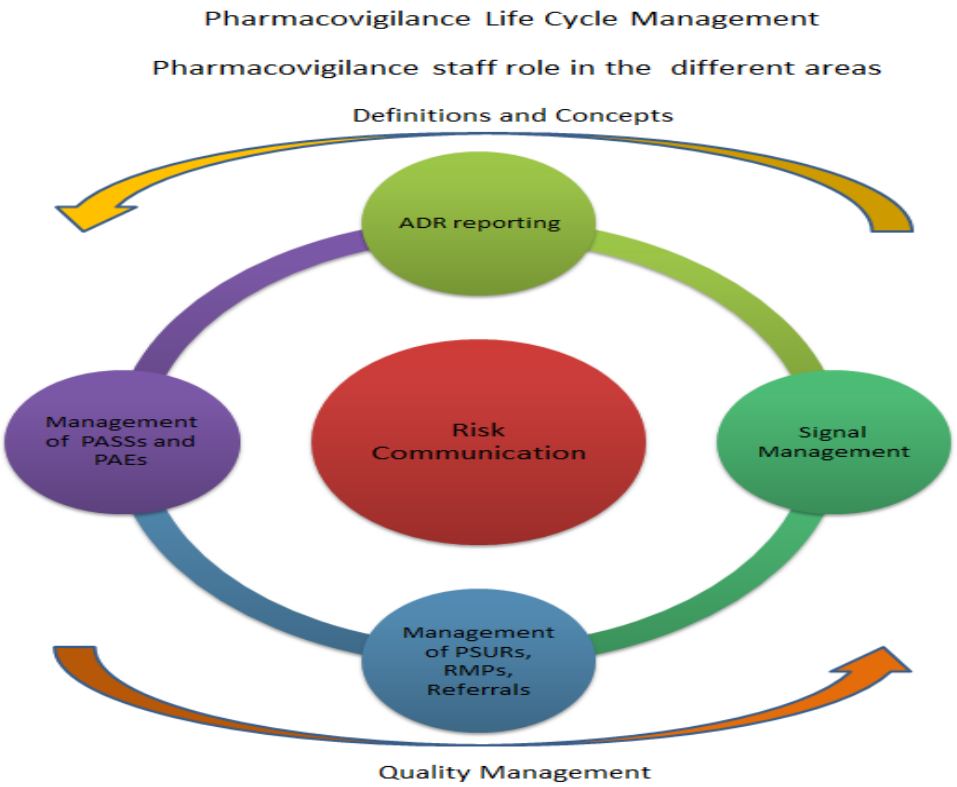


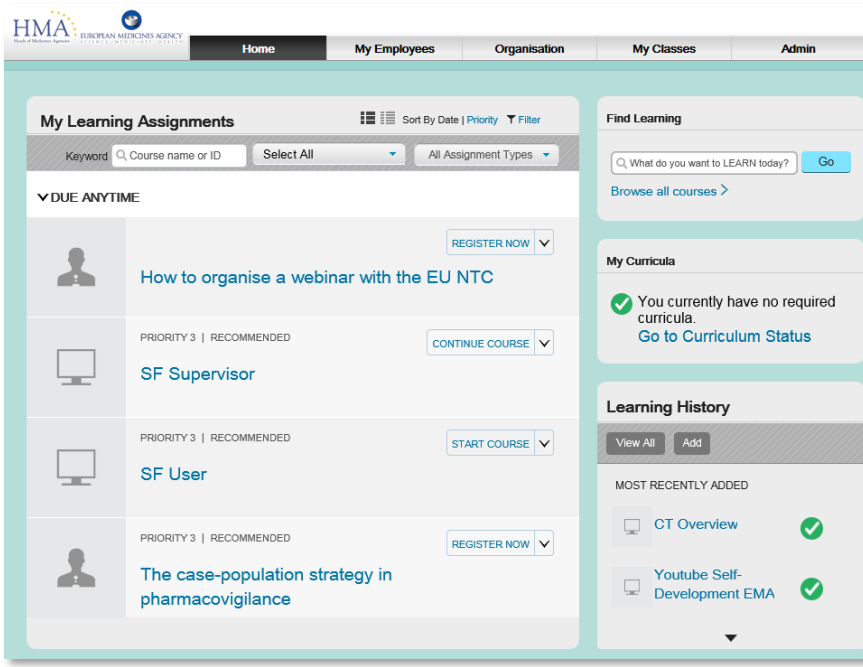
Pilot exchange programme

- Launch Nov ‘16 - Apr ’17
- Focus on WP8 areas: RMPs, PASS, PSURS, referral procedures
- Norway, Portugal & Spain supporting pilot exchange
- Working group looking at practicalities - UK, PT, NO, ES

Sustaining SCOPE Deliverables

Sustaining SCOPE Deliverables





Summary

- SCOPE has been an exemplar of collaboration across the EU network
- SCOPE has helped provide the learning and tools to improve national pharmacovigilance systems
- The transition of materials to support the PV curriculum via the EU NTC will ensure sustainability
- MHRA have been proud to lead on this important Joint Action

Ask