Strengthening Collaborations for Operating Pharmacovigilance in Europe
Work Package 6 – Risk Communication

PCWP and HCPWP Joint Meeting Workshop on Benefit Risk Communication

London, 17th September 2014

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Contents

- **S**trengthening **C**ollaborations for **O**perating **P**harmacovigilance in **E**urope
- WP 6- Risk Communication
- Overall aims
- Participants
- Topics

Strengthening Collaborations for Operating Pharmacovigilance in Europe

SCOPE

- From 2013 to 2016
- Support operations of pharmacovigilance in Member States following requirements introduced by the European pharmacovigilance legislation (July 2012)
- Funded by the European Commission (CHAFEA) and with contributions of the involved Member States
- Gather information and expertise on how regulators in Member States run their responsibilities in the field of Pharmacovigilance

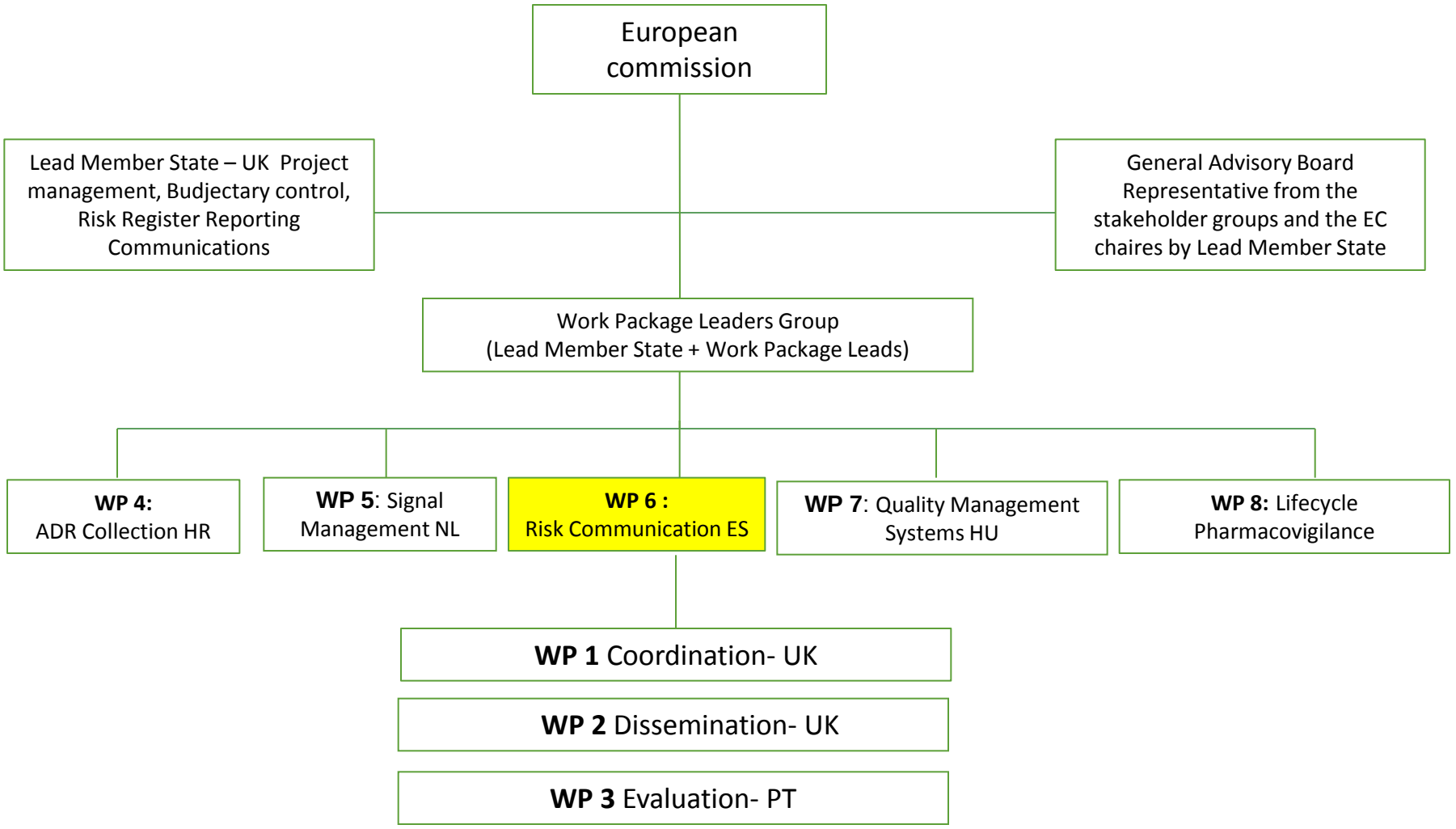
Overall aims of SCOPE

- Provide practical tools and guidance for NCAs to develop their pharmacovigilance obligations
- Develop and deliver guidance and training in key aspects of pharmacovigilance
- Benefit medicines safety monitoring and communications outputs
- Help to safeguard public health

Expected Outputs

- Improve reporting mechanisms for adverse drug reactions
- Implementation of shared understanding of best practice in signal management
- To identify the most appropriate practices in **Risk Communication** through the creation of a standardized toolkit
- To enable Member States to develop optimal quality management systems for pharmacovigilance.
- The development of a competency framework to support exemplary pharmacovigilance throughout the product lifecycle.
- **To create a platform for interaction amongst European NCAs to strengthen regulatory collaboration**.

SCOPE Management Structure



WP 6- Risk Communication

- Collect information on the risk communications practice in the EU network.
- Develop a series of recommendations in the form of a communications toolbox, so that MSs could select the most appropriate tools according to needs and expectations
- Develop a guide for the media on scientific risk communication.
- Particular focus on web portals

WP 6 Participants

- Croatia
- Denmark
- Ireland
- Italy
- The Netherlands
- Norway
- Spain (Leader)
- Sweden
- United Kingdom

WP 6-Risk Communication

Lead: ES

- Topic 1- National Competent Authorities methods for risk communication. Leader: SE
- Topic 2- Impact assessment on risk communication. Leader: IE
- Topic 3- Toolkit for improving practices. Leader: IT
- Topic 4- Web Portals. Leader: UK

Topic 1- Audit of national methods of communications

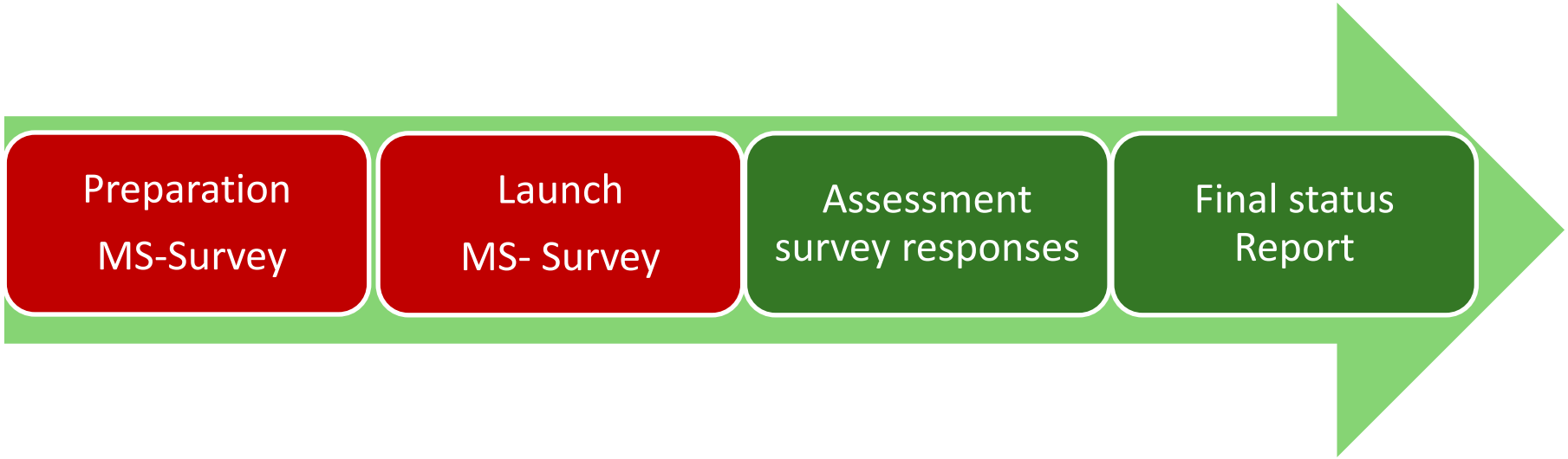
1. **MS- Survey :**

- communication channels and tools used
- frequency and timelines of communications
- engagement levels with stakeholders
- cascade systems and professional networks for dissemination of information
- Impact assessment
- What worked well? Problems? Ideas?

Topic 1- *Audit of national methods of communications*

Leader: SE Active participants: DK, IT, HR, NO, ES, NL, IE, UK

Workflow



Topic 2- *Impact assessment of risk communication*

Study protocol

- On knowledge, attitudes and preferences of target audiences towards different tools and channels for safety communication, relevance of communications and impact on their practices

Field study- in WP participating MS (DK, IE, IT, ES, HR, NO, SE, *UK, NL*)

Analysis of the study results

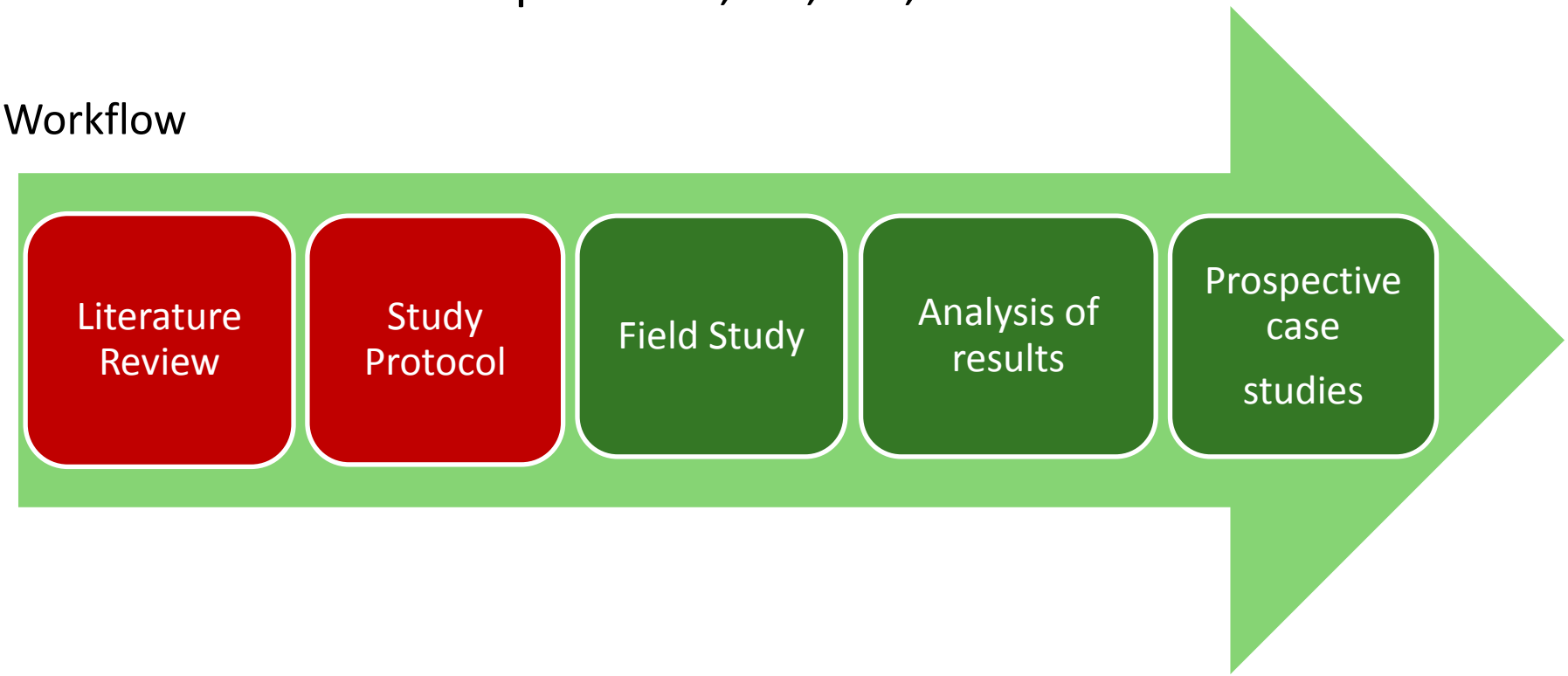
Prospective case studies

- To examine performance in practice of a number of communications for high profile drug safety issues from healthcare professional and, if feasible, patient perspective

Topic 2- *Impact Assessment of risk communication*

Lead: IE Active Participants: ES, NL, NO, SE

Workflow



Topic 3- *Toolkit for improving practices on risk communication*

Analysis of outputs from Topics 1 and 2:

- ways of communication, preferences from HCP, impact in clinical practice

Development of a toolkit

- What are the options that best worked and in which environment

Training session tailored to audiences

Workshop

- Involvement of interested parties (NCA, healtcare professionals, citizens, media)

Topic 3- *Best Practice*

Lead: IT Active Participants: DK, NL, SE, ES, IE, HR Additional experts involved

Workflow

Topic 4- *Web portals*

1. **Work from Outputs of other Topics in WP**
   - To scope needs and design of webportal

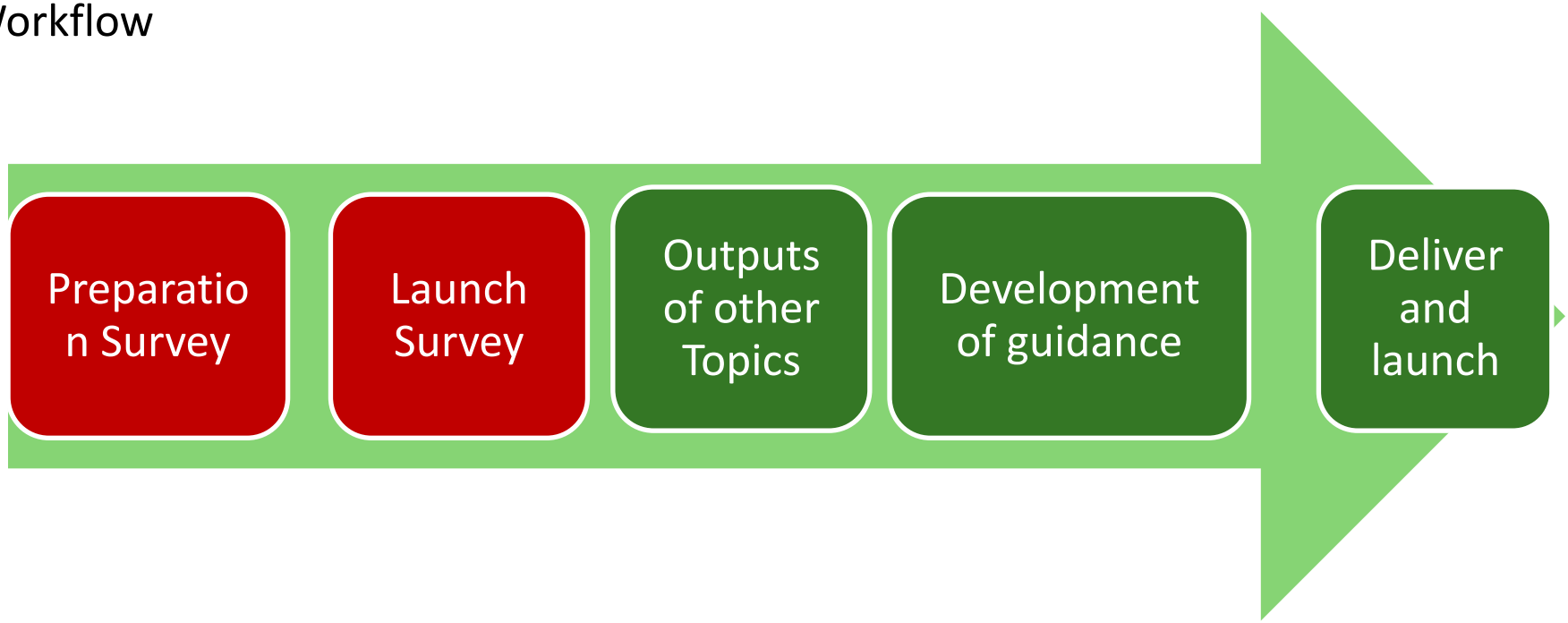
2. **Development of guidance**
   - For internal preparation of safety information for publication on web portal
   - For coordination of information presentation within the EU network

3. **Deliver and launch**

Topic 4- *Webportals*

Lead: UK Active participants: ES, NO, SE ICT Subcontractor needed

Workflow



Overall aims of WP 6

- To define best practice in Risk Communications through the creation of a standardised toolkit

- To create a forum for interaction amongst european National Competent Authorities to strengthen regulatory collaboration

For more information

- http://www.scopejointaction.eu

Thank you!

http://www.scopejointaction.eu