

SCOPE Joint Action

Work Package 7

Stakeholder Event
London, 21 September 2015

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Work package 7



- Lead: HU



- Active members:

BG



ES



IT



PT



UK



Background



- **NCA's obligation to maintain a national pv system**
- **Pv systems need to be operated on the basis of a stable, yet flexible quality system (enable a robust and timely decision making and compliance with EU legislation)**
- **Legal basis: Dir 2010/84/EU; Regulation 1235/2010; EC implementing regulation 520/2012**
- **GVP Module 1**

WP 7 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 guidance (tool-kit) on how to improve quality management systems**
- 2. Training material for the use of the pv staff / new colleagues of NCAs on QMS including examples and good practices**

1. Tool-kit

It contains:

best operating **guides**; good **practices** to operate pv; **case studies** on quality planning, compliance and performance management, resource management, training development plans, etc

Sources of tool-kit

- Site visits (ES, NL, IE, CZ, LT + HR)
- Questionnaires
- Others (literature, experiences of other bodies, GVP)



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2. Training material (e-learning)

- **Increases knowledge of pv staff on quality management**
- **Applicable for introductory training of new colleagues in pv departments (but it takes also part of training package of all WPs of SCOPE at the end of the project)**
- **Provides a general knowledge on QMS (incl. resource mngt) with special focus on pv; and pv inspectors-assessors interfaces)**
- **A slide set with explanatory text (eligible for live presentation or for e-learning)**
- **Modular structure**
- **Provides examples for each area**

Already achieved...

- **20 January 2014 1st F2F meeting (introduction, presentation of topics, preparation for site visits)**
- **Monthly TCs**
- **May-June 2014 site visits (ES, NL, IE, CZ, LT + HR)**
- **20 October 2014 2nd F2F meeting (modified deliverables; drafting of surveys)**
- **Nov 2014 – May 2015 (pilot surveys, finalisation, analyses of responses, final reports)**
- **21-22 June 2015 3rd F2F meeting (presentation of results; finalisation of items for tool-kit and training)**

Next steps ...

- **23-24 November 2015 4th F2F meeting (discussion of draft tool-kit and training material)**
- **Feb-March 2016 site visit (CZ?, LT?)**
- **March 2016 5th F2F meeting (approval of final text of deliverables; preparation for training provided by SCOPE work packages)**
- **Sep-Oct 2016 common training for assessors and 6th F2F meeting**
- **Sep 2016 presentation of results of SCOPE joint action – closing meeting of project**



WP 7 team