

SCOPE Joint Action

Work Package 7

Stakeholder Event
London, 21 September 2015
Julia Pallos

Work package 7

SCOPE

• Lead: HU



Active members:



Background



- NCAs 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)

2. Training material (e-learning) SCOPE www.scopejointaction.eu

- 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 inspectorsassessors interfaces)
- A slide set with explanatory text (eligible for live presentation or for e-learning)
- Modular structure
- Provides examples for each area



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preparation of draft training material (slides with explanatory texts)																							
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training program implementation (incl WP7 section)		_																					

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

