

Strengthening Collaboration for Operating Pharmacovigilance in Europe Joint Action

Maximising the potential of SCOPE

Flagship Event

23 November 2016, London

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SCOPE Deliverables

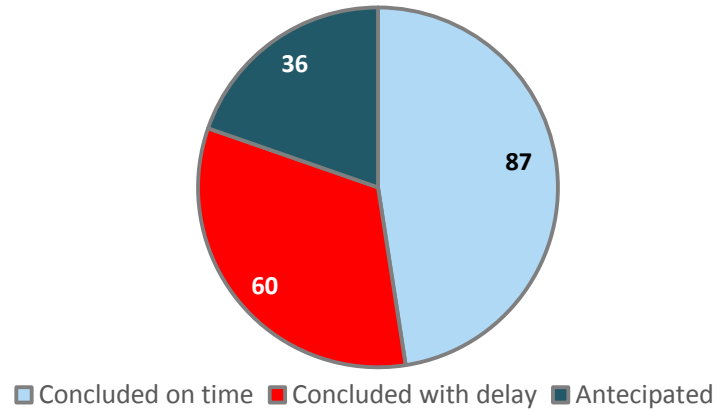
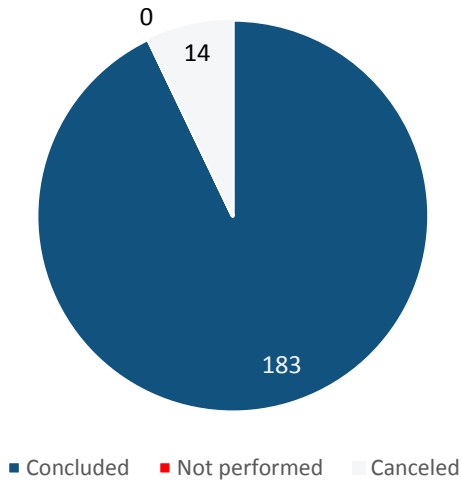


#	Title	Description	Confidentiality level	Month of delivery
1	Reports on project status: finances and operations	Interim reporting on project progress and results, including financial updates; first report M14	Public	26
2	Public project website	Public website to introduce the project and present key achievements in real time	Public	6
3	Project promotional brochure	Brochure to introduce the project to stakeholders	Public	6
4	Final lay project report	Report to summarise project, key achievements and learnings.	Public	36
5	Evaluation reports	Ongoing monitoring of progress every 6 months (M7, 13, 19, 25, 31); final report on lessons learnt (including training M33) and sustainability (M36)	Public	36
6	ADR Reporting media toolkit	Identifying effective MS activities to develop collective campaign toolkit – eg research and development may lead to: leaflets (translated); core materials for seminars; and campaigns for newspaper, internet, tv or radio	Public	23
7	Best practice guide on signal management	Evaluation of current working practice in MSs with respect to signal detection, validation and assessment in order to develop standard approach. Includes signal management for special situations such as medication error	Public	27
8	Risk communications toolkit	Communication strategies for MSs to target different audiences or risk-communication needs through a common, efficient, and effective approach (ie, what to communicate, when, how and to whom)	Public	34
9	Self assessment questionnaire on quality management systems	Checklist of performance indicators to enable MSs to continually self-assess their pharmacovigilance systems to help demonstrate capacity and operation of a quality system	Public	35
10	Training workshop to deliver competency framework	Helping skills transfer for optimum risk assessment throughout a product's lifecycle through a training workshop. A framework to characterise required assessment competencies will underpin the workshop content	Public	30

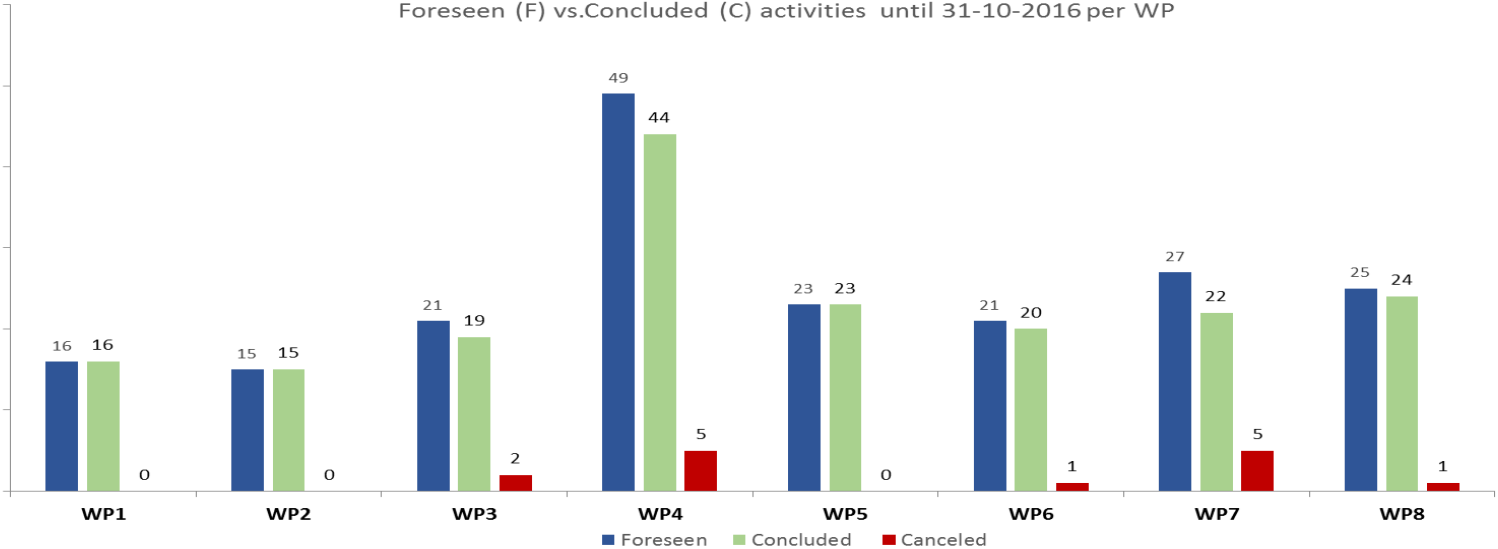
WP3: Activities until 31/10/2016



Activities Foreseen and Concluded until 31/10/2016



Foreseen (F) vs. Concluded (C) activities until 31-10-2016 per WP



SCOPE Trainings/Workshop



WP4+WP5+WP7	Pilot training	22-23/06	Budapest
WP5+WP7	Training	4-5/10	Budapest
WP4+WP7	Training	13-14/10	London
WP6	Workshop	16-17/06	Madrid
WP8	Pilot training	23-24/05	Lisbon
WP8	Training	20-21/09	Lisbon

SCOPE WP3 goals



Ensure:

- **Consistency of training**
- **Effectiveness**
- **Compliance with SCOPE's objectives**

Training deliverables:

- **Assess the programmes proposals**
- **Define consistent tools to evaluate the training's efficacy (e.g.: questionnaires...)**
- **Assess the information gathered in the questionnaires, including improvement suggestions**

SCOPE Questionnaires

e.g. https://docs.google.com/forms/d/1XJRO0_sUG8a2_J6cDYDgPKCCDnSrAUUX3vZLZ8oVa-A/viewform



Workshop Evaluation Questionnaire

Please complete the evaluation for the Scope's Workshop. Your feedback is valuable to us and is appreciated. We are committed to continual improvement and your suggestions will be considered for future sessions.

*Obrigatório



Work Package 6 – Risk Communication 16-17 June, Madrid

About You

Your name or organization are optional. The only mandatory question is your country.

Your Country *

Escolher

Name

Sua resposta

Your organization

Sua resposta

Materials used during the workshop

How would you rate the quality of: *

	Poor	Unsatisfactory	Satisfactory	Excellent
Presentations	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Case studies	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Electronic system (mQlicker)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Speakers - How would you rate the presentation skills and knowledge

In order to help you we have identified for each session Name/Country/Presentation.

Session 1 - ?????????????????? *

	Poor	Unsatisfactory	Satisfactory	Excellent
????????????????????	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
????????????????????	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
????????????????????	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
????????????????????	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Learning Objectives

The following issue was adequately presented *

	Strongly disagree	Disagree	Agree	Strongly agree
Awareness of the different National methods of communication	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Use of multiple channels/tools	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Applicability of combining multiple tools	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Elaboration of a safety communication, considering its specific target and the key messages	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Identification and usefulness of impact measuring tools	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Pilot trainings vs final trainings

- The feedback from participants was collected
- Improvement suggestions were made
- WP3/WPLeads worked together with WPLeads
- Improvement suggestions were implemented

and....



OVERALL SATISFATION POSITIVE

The majority of those who answered the questionnaires considered that the Scope's Final Trainings/workshop occurred in a way that was satisfactory or excellent and that it met their needs or expectations, was well-organized and encouraged the participants to express their opinions or ask questions

The documents provided were seen as clear and extremely useful for the daily work

WP3 Final evaluation report

Main considerations



- The project was extremely successful as it delivered the tools, guidance and training needed to support MSs in their PV activities.
- Nevertheless, we faced some difficulties throughout the project regardless of the majority being overcome and the impact on the main deliverables not being significant.
- Highlight the importance of the following aspects:
 - development of the SCOPE Sustainability Plan which provides an overview of approaches to **enhance the sustainability** of the SCOPE deliverables and training materials and maximise the benefits of the outputs from the SCOPE Joint Action;
 - most of the SCOPE's deliverables will outlast the duration of project such as **guidance, training** and other materials can remain up to date;
 - the **optimal partnerships** that allowed the strengthen of the projects quality;
 - the **several stakeholders close involvement** which provided valuable input arising from different sources;

WP3 Final evaluation report

Main recommendations



- **continue the fabulous work** which was developed throughout SCOPE delivering the tools, guidance and training needed to support MSs in their PV activities as well as ensuring the consistency in the PhV activities across the EU;
- there was an **extremely important step given** with this project and this work should be continuously improved through a robust sustainability plan as well as the consideration of the **development of a similar Joint action**.

Congratulations to everyone 😊

Project extension activities



- Build on ADR Awareness Campaign
- Pilot Exchange Programme and report
- Stakeholders engagement – an event and other opportunities
- Publications and promotional activities
- Other training opportunities
- Developing use of EU-NTC and PV Curriculum

EU exchange programme for PV Assessors



- Proof of concept - grounds for a sustainable exchange programme for European PV assessors
- Exchange of experience, knowledge and an on-the-job training framework
- Improvement of active contribution in the PV tasks foreseen in the legislation
- Launch between January - February 2017
- Findings will be fed to HMA to aid sustainability



Sustainability of SCOPE deliverables



- The strategic sustainability plan: maximising impact and continued accessibility of SCOPE deliverables
- Use extension period to maximise training opportunities
- SCOPE deliverables will be available in the EU Network Training Centre learning platform and included in Pharmacovigilance training curriculum
- Review and maintenance of the SCOPE training materials – to ensure the materials remain relevant and are used
- Publications

Obrigada!

(Thank You!)