

Strengthening Collaborations for Operating Pharmacovigilance in Europe Joint Action

Welcome and introduction

Stakeholder Event

London, 21 September 2015

Housekeeping



SCOPE

www.scopejointaction.eu



Agenda

Session 1 - Overview of Progress

Refreshments

11:30

Session 2 – Effective Systems for Managing ADRs and Signals

Panel Discussion

Lunch

13:10

Session 3 - Evaluating and Maximising Risk Benefit Assessment

Content of SCOPE deliverables

Session 4 – Questions and panel discussion: Agreeing the Outputs

Close

16:00

Tea and Coffee

Welcome

Formal award decision adopted by Commission –
project officially started 18 November 2013

Maximum level & largest possible contribution of
70% funding from Commission

“Exceptional utility”



SCOPE Context in EU



EMA led projects achieved enormous progress to implement legislation

- 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



Share expertise and best practice

Deliver practical tools and guidance

Operate pharmacovigilance in Europe

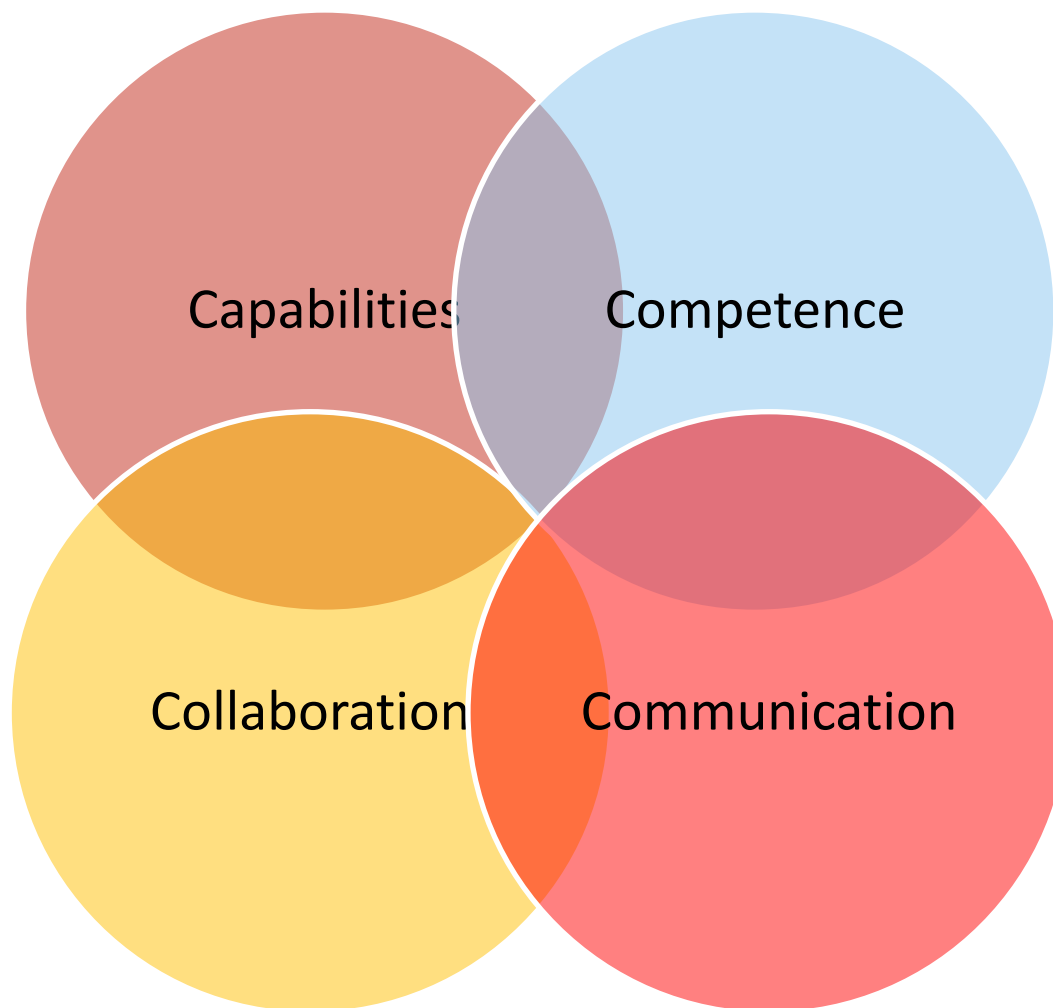
By Member States

For Member States

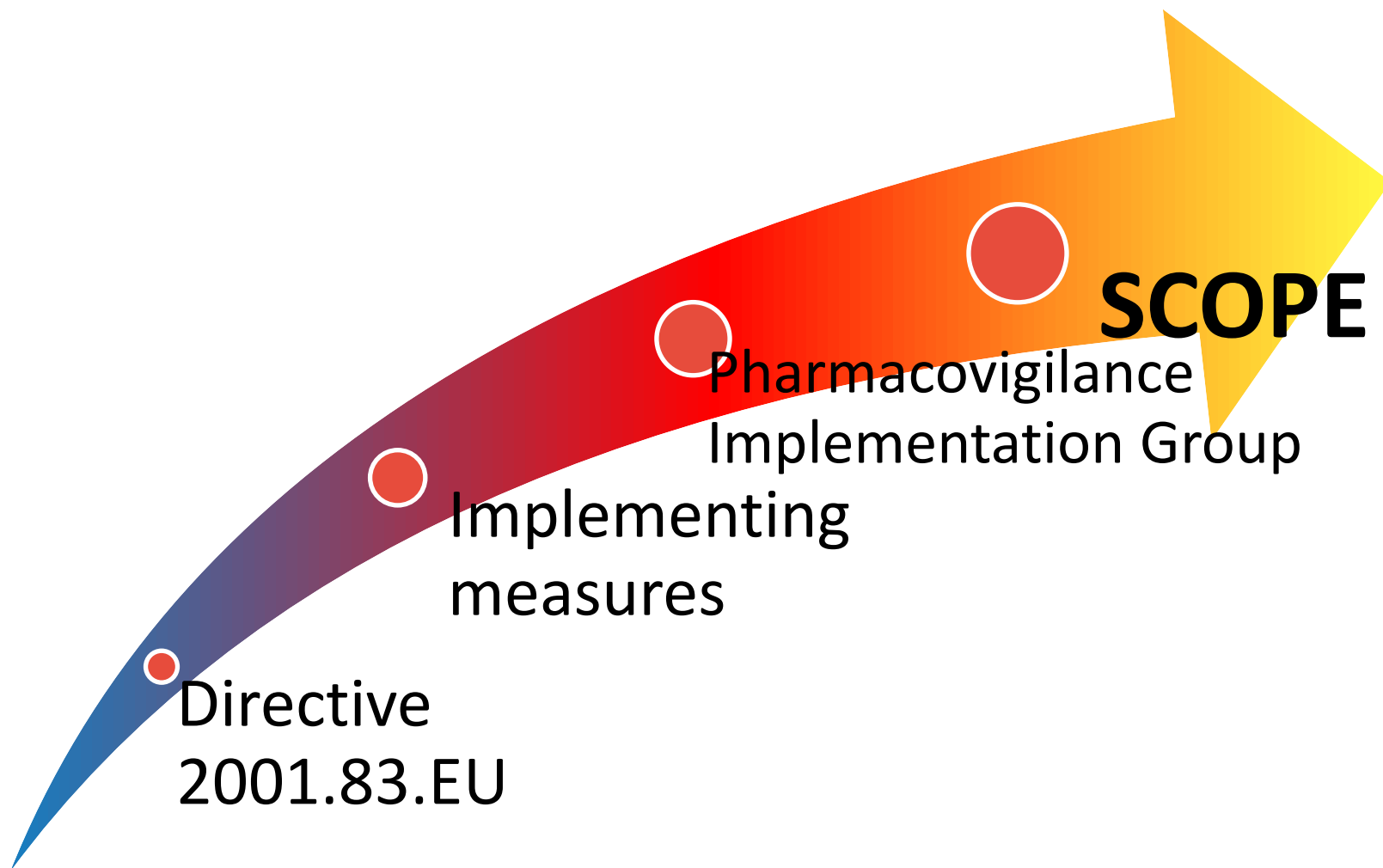
With Member States



Delivering public health benefits for Europe



From implementation to operation



Objectives for today

Share

- Update on progress
- Share information on findings

Test

- Will the SCOPE outputs help to make a difference for Pharmacovigilance in Europe

Enthuse

- To encourage partners to actively contribute

Format of the day

Three sessions

- Groups of presentations
- Update from SCOPE work packages
- External perspectives

Panel discussions

- Opportunity to discuss work packages
- Questions encouraged

Outputs and Deliverables

Remember....

By Member States

For Member States

With Member States

- So today is your opportunity to look forward to the deliverables
- Agree and comment on the outputs
- Prioritise what's most important

After today

- General Advisory Board will reflect on the discussions
- Report will be written and published
- Deliverables will be reviewed in light of comments received
- Project plan will be updated