

# **SCOPE Joint Action**

## **Progress in SCOPE**

**Stakeholder Event**  
**London, 21 September 2015**

Mick Foy, MHRA

# Progress in SCOPE

Today is Day 669.

This is equal to 1 year, 10 months, and 20 days.

13 months to go.....



# Progress in SCOPE



# Progress in SCOPE

**24**

face-to-face  
meetings

**80**

teleconferences

**764**

questions asked  
across all SCOPE  
surveys – 19K+  
answers

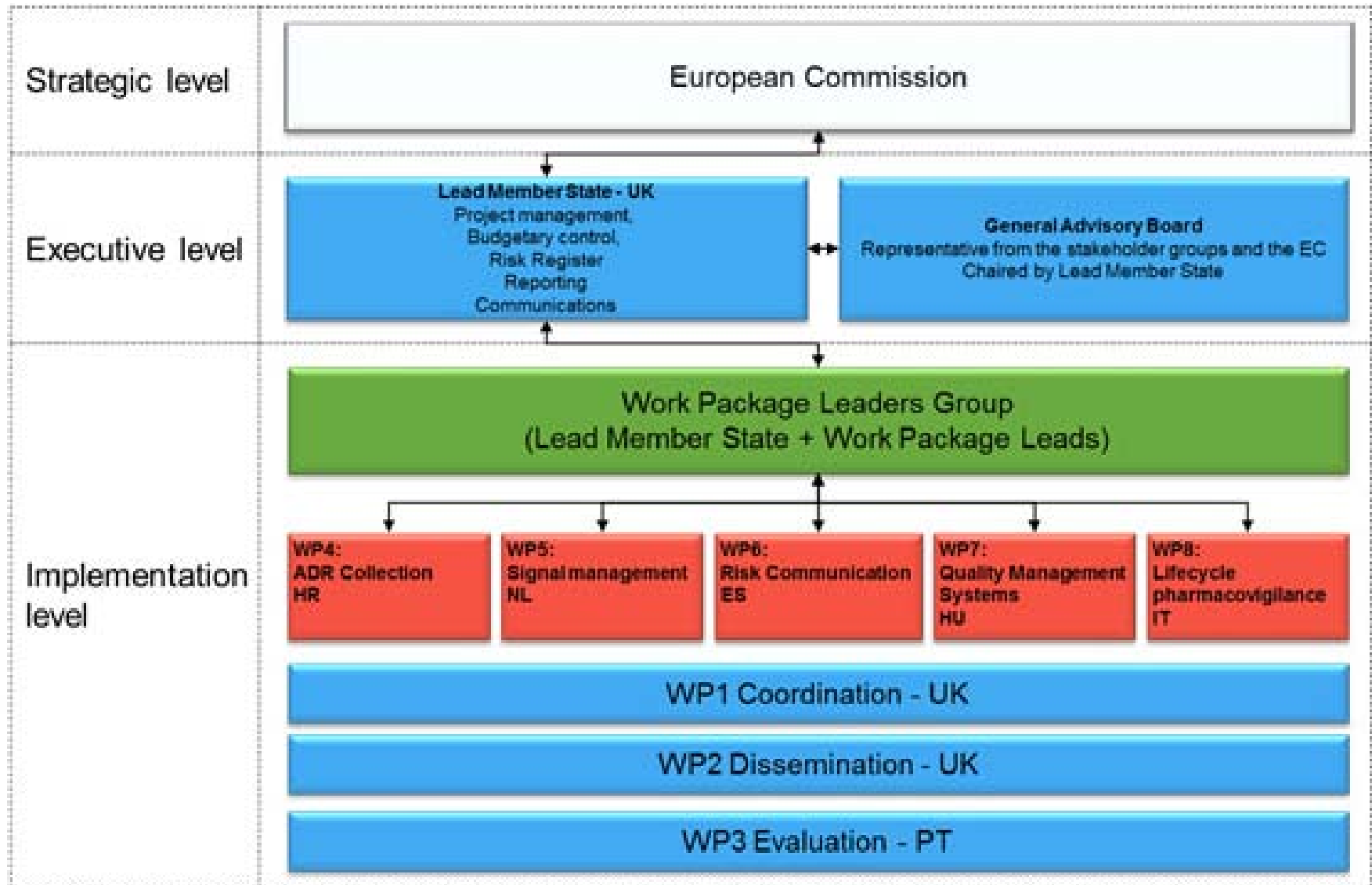
**4453** days  
of work logged by  
active partners and  
participants

# Progress in SCOPE: Milestones completed

- ✓ Start up meeting
- ✓ Overall Project Plan
- ✓ Governance and Management Structure
- ✓ Communications Plan
- ✓ Website and promotional brochure
- ✓ Evaluation Plan
- ✓ WP4, 5, 6, 7, 8 Surveys, Data Assessment, Draft Reports
- ✓ WP7 Site visits for 5 Member States
- ✓ Coordination meetings
- ✓ General Advisory Board meetings
- ✓ Work Packages face-to-face meetings
- ✓ Interim reporting to CHAFEA
- ✓ Technical report to CHAFEA



# Governance Structure



# Projects Teams: 3 to 8

- Huge effort from all involved
- Particular thanks to:
  - INFARMED
  - HALMED
  - MEB
  - AEMPS
  - OGYEI
  - AIFA

# WP1 - Coordination

**UK lead**

**Active Partners: ES, HR, HU, IT, NL, PT**





# Progress in SCOPE: Key Objective



**SCOPE**

[www.scopejointaction.eu](http://www.scopejointaction.eu)

**ON TARGET**

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**ON TIME**

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**ON BUDGET**

# Our aims

We have

- Establish project structure and organisation
- Produced effective project plan

We are

- Managing progress and quality
- Supporting partners to achieve success

To ensure

- SCOPE objectives are delivered



# Progress in SCOPE: Keeping on top of things



- Regular WP lead Teleconferences
- Routine reporting
- Keep it current, remain flexible
- Risk register
- Internal MHRA governance reviews

# SCOPE Risk Register

<b>Staff availability</b>	<b>Key SCOPE staff leave the project</b>	<b>Resources</b>	<b>Active</b>	<b>Medium</b>	<b>High</b>	<b>High</b>	<b>High</b>	<b>Medium</b>	<b>High</b>	<b>Medium</b>	<b>M 1-36</b>
<b>Problems with timesheets</b>	<b>The greatest risk here is with the timesheets having inaccurate data or not being completed.</b>	<b>Technical</b>	<b>Active</b>	<b>High</b>	<b>High</b>	<b>Low</b>	<b>Low</b>	<b>Medium</b>	<b>Low</b>	<b>Low</b>	<b>M 1-36</b>
<b>Resource no longer available in MS</b>	<b>Member States do not return data due to lack of time</b>	<b>Resources</b>	<b>Active</b>	<b>Medium</b>	<b>High</b>	<b>High</b>	<b>High</b>	<b>Medium</b>	<b>High</b>	<b>Medium</b>	<b>M 1-36</b>

## WP2 - Dissemination

**UK lead**

**Active Partners: ES, HR, HU, IT, NL, PT**

- Delivery of dissemination and communications plan
- Stakeholder analysis & engagement
- Branding, promotional activity for each work package, Quarterly updates

Public website and promotional brochure Month 6

2 Stakeholder meetings Months 23/36

Final Lay Report Month 36

# SCOPE website



- Website is a key WP2 dissemination deliverable
- For external and internal stakeholders
  - Publishing documents once completed
  - Providing news, updates from WPs
  - Information on events/training
- Integration to login for Internal Document Sharing

# SCOPE Website



The screenshot shows the SCOPE website interface. At the top, there is a green navigation bar with the SCOPE logo on the left and a menu on the right containing links for Aims, Partners, Work Packages, News, Glossary, Links, Contact, Downloads, and Calendar. Below the navigation bar, there are two main content areas. The left area is titled "News" and includes a sub-header "This page enables you to stories will be posted here" and a list of news articles. The right area is titled "Progress" and includes a sub-header "The SCOPE Joint Action was officially launched with a workshop in November 2013. Since then work on the project, within all of its eight work packages, has been progressing well. This page will provide an on-going update of progress, and will be regularly updated to keep all interested parties up to date with SCOPE." Below the "Progress" sub-header, there is a section for "Work Package 1 - Coordination" with a sub-section for "Current progress in Work Package" and "Upcoming work". At the bottom, there is a section for "Work Package 2 - Communication/Dissemination" with a sub-section for "Current progress in Work Package".



SCOPE Partner Login ShareFile High Contrast Vers

Aims Partners Work Packages News Glossary Links Contact Downloads Calendar

You are here: Home > Calendar



SCOPE Partner Login ShareFile High Contrast Vers

Aims Partners Work Packages News Glossary Links Contact Downloads Calendar

You are here: Home > News

You are here: Home > Work Packages > Progress

## News

This page enables you to stories will be posted here

Showing 1-10 of 13 news articl



**SCOPE Sta**  
04 August.  
The first St  
Society of I



**Work Pac**  
24 June 20  
The survey



**WP7 - Qua**  
27 January  
On Friday 1



**Work Pac**  
15 Septem  
A survey of

## Progress

The SCOPE Joint Action was officially launched with a workshop in November 2013. Since then work on the project, within all of its eight work packages, has been progressing well. This page will provide an on-going update of progress, and will be regularly updated to keep all interested parties up to date with SCOPE.

### Work Package 1 - Coordination

#### Current progress in Work Package

WP1 continues to deliver the coordination function for the SCOPE joint Action. The activities of WP1 include project management tasks including organising and facilitating the governance of SCOPE by the Work Package Leaders group and General Advisory Board, coordinating and arranging project governance meetings, and continuing monitoring of the finances. WP1 was not due to deliver any specific objectives were due during this period.

The WP1 team have been developing the first technical report (covering months 1-18) to CHAFEA. The report will summarise progress made by each Work Package including financial information, activities completed, challenges encountered and Work Package contribution to the overall project objectives.

WP1 organised two face-to-face meetings: Work Package Leaders on 22 January 2015 and the General Advisory Board on 23 January 2015. The participants discussed project progress and advised on various aspects including cross links with other initiatives and projects.

#### Upcoming work

The key activities over the next quarter will continue to be governance, coordination, and project management of SCOPE, including coordinating Work Package Leads group and General Advisory Board meetings.

The fourth face-to-face Work Package Leaders meeting will be hosted by INFARMED in Lisbon on 14 July 2015.

The third General Advisory Board meeting is scheduled to take place in London on 22 September 2015.

### Work Package 2 - Communication/Dissemination

#### Current progress in Work Package

Following development of the Communication Plan, efforts within WP2 have focussed on communications aspects of SCOPE. News items continue to be published on the website to give updates on WPs and progress. Alongside this updates and progress are often reported within existing meetings or forums of the well-established

# WP3 - Evaluation

## PT lead

Active Partners: **UK, WP leads (ES, HR, HU, IT, NL)**

- Establishment of baselines, success criteria and metrics
- Status reports; Audit reports; Audit report on training

Evaluation Plan

Month 1

Ongoing Evaluation processes

Months 1-36

Final report & recommendations

Month 36



# SCOPE General Advisory Board



**SCOPE**

[www.scopejointaction.eu](http://www.scopejointaction.eu)

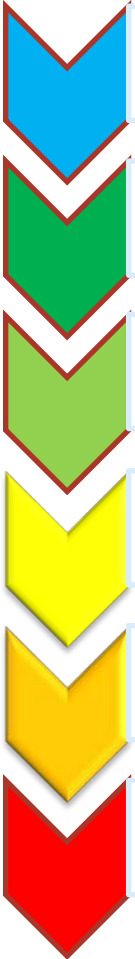
- June Raine (Chair) PRAC
- François Houyez EURORDIS
- Helen Lee EC
- Marie Lindquist UMC
- Hervé Le Louet ISOP
- Georgios Margetidis CHAFEA
- Luis Pinheiro EMA

# Staff effort



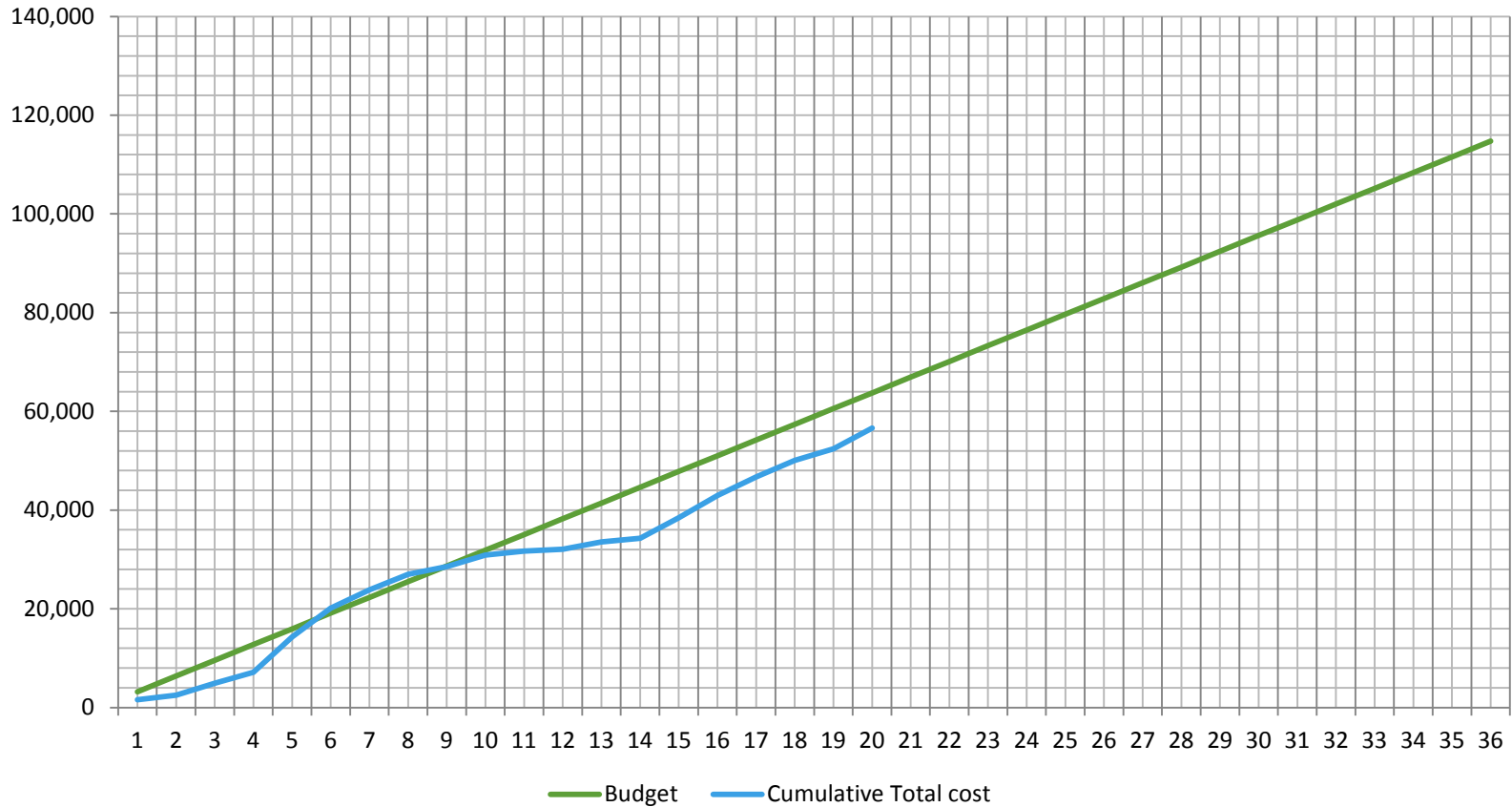
- Monthly return of time recorded as days
- Collation of timesheets – one submission per associate partner
- Spreadsheet template tabulates total for partner
- Approve from authorised signatory
- Email to [scope@mhra.gsi.gov.uk](mailto:scope@mhra.gsi.gov.uk)

# Process

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- Time recording/expenses
  - Collation of timesheets/expenses
  - Partner sign-off
  - Submit to MHRA
  - MHRA calculates contribution
  - Pre-financing

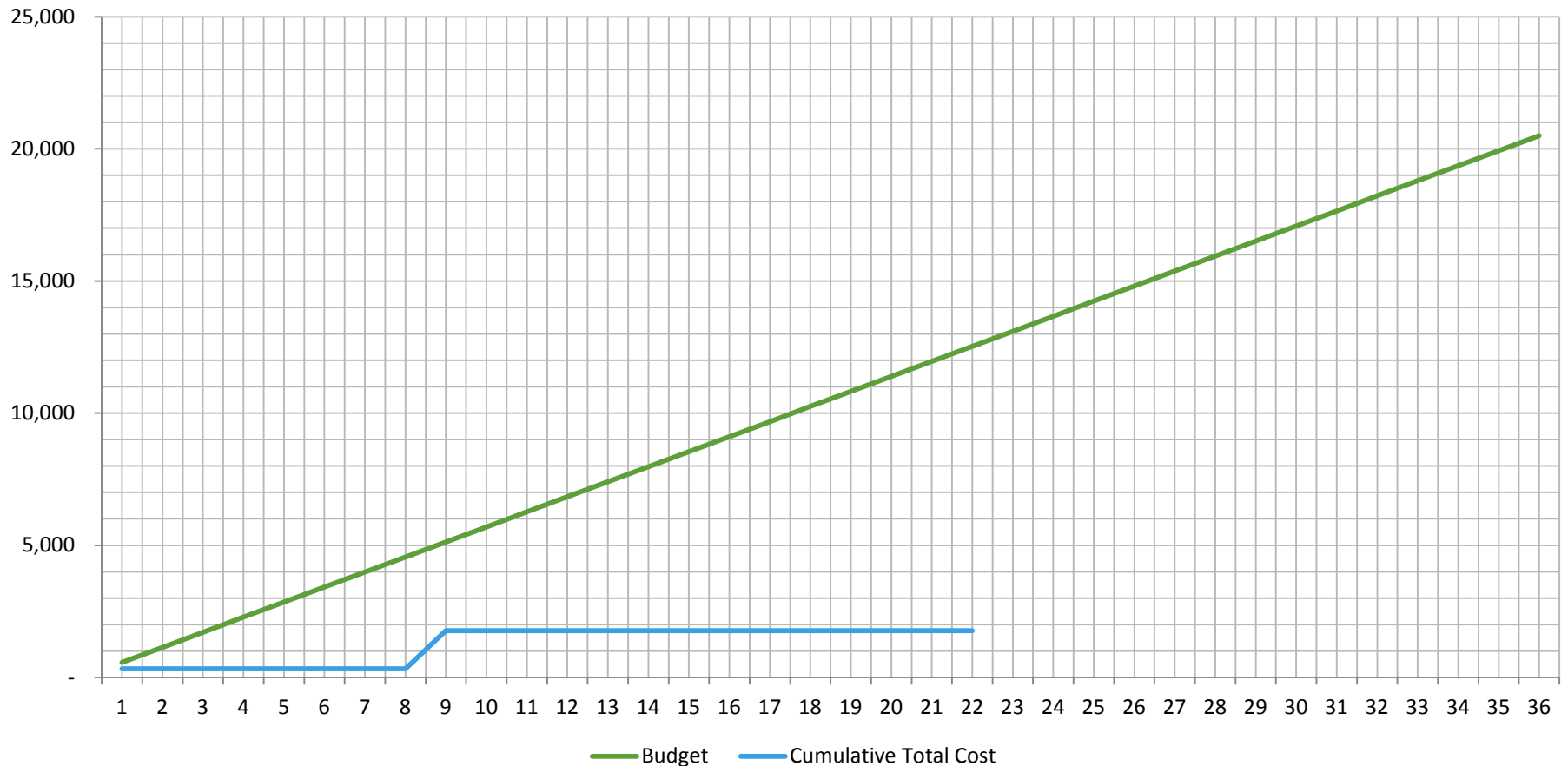
# Pre-financing: spending

## Costs incurred vs budget: Active Partner



# Pre-financing: spending

## Costs incurred vs budget: Non Active Partner



# Pre-financing: overall

- MHRA pre-finances Partners in six payments
- Last round of payments in August 2014
- Overall balance to date – below table

Financing from CHAFEA (€)	Payments to SCOPE Partners (€)		Subcontracting(€)	Balance in the bank (€)
	First	Second		
989,991.41	437,4061	438,059	65,049.65 <sup>3</sup>	49,476.35
	Total: 875,465			

- CHAFEA reviewing the M18 report, the next pre-financing payment in October 2015

# Reporting

- Interim and technical reports to CHAFEA
- European Medicines Agency
- Pharmacovigilance Implementation Group
- European Risk Management Facilitation Group
- Heads of Medicines Agencies
- Informal PRAC

# Interface with other activities

21	3	1.2.7	Project and Maintenance Group 2	Reflection paper: Strategy for supporting PRAC assessment with best evidence	N/A	Linked to PRAC Deliverables No.2.1.4, also linked to deliverable #ID 1.2.7 in the main checklist	PMG2 or direct PRAC	SCOPE WP8 topic 1 on Identification of available data sources outside of spontaneous reports aims to provide member states some guidance on evidence which may be used to support assessment, plus WP8 in general is about supporting assessor competency to improve EU wide assessment
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# Wider than SCOPE



# The Year Ahead

- All data collected and analysed
- Recommendations formed from the analysis
  - Best practice identified
  - Gaps identified
- Final outputs suggested by WP leads
- Guidance, toolkits, training, workshops etc.
- Delivery, delivery, delivery

# Thank you

Contact:

[scope@mhra.gsi.gov.uk](mailto:scope@mhra.gsi.gov.uk)