Strengthening Collaborations for Operating Pharmacovigilance in Europe (SCOPE)

15 September 2014

Paul Barrow

SCOPE context in EU

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Two years of operation

Establishment of:

- Pharmacovigilance Risk Assessment Committee
- Good Vigilance Practice modules
- Additional Monitoring

Member States need to operate pharmacovigilance to legislative requirements

EC recognise varying level of maturity in the system

From implementation to operation

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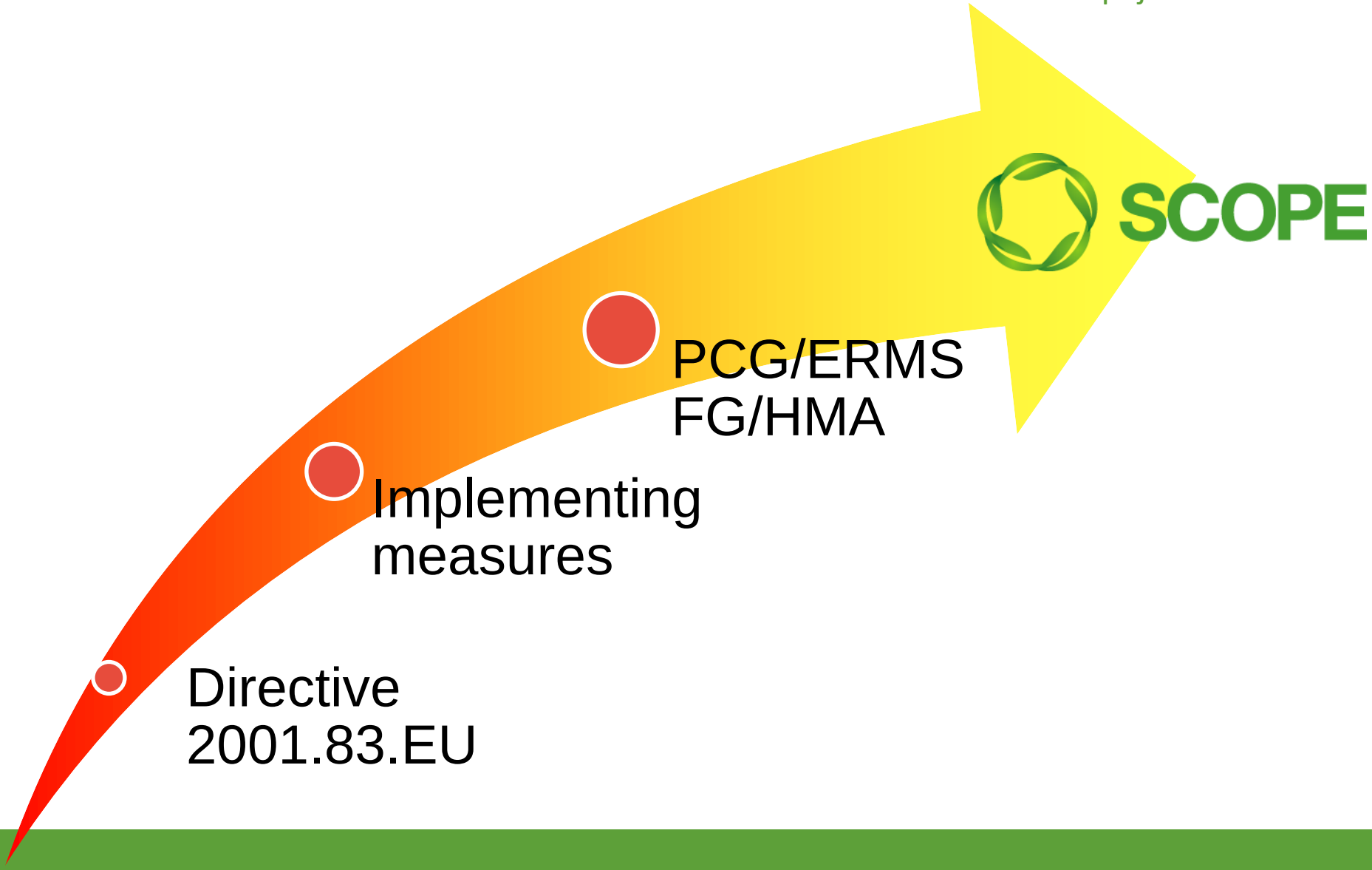

SCOPE Joint Action

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Share expertise and best practice

Deliver practical tools and guidance

Operate pharmacovigilance in Europe

By Member States

For Member States

With Member States

Delivery

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- Focus is on enabling and supporting capabilities of EU regulators
- Delivering tools for regulators
  - ‘best practice’ – i.e. recommendations/guidance based on successful systems/implementations
  - Training – such as for assessment
  - Practical tools – such as toolset for national promotion of reporting systems
- Deliverables may be relevant to other organisations/outside EU
- Deliver towards end of Joint Action i.e. in 2 years
- Complementary to existing EU system – supporting use of templates and procedures developed by Project teams/Project Co-ordination Group/ERMS FG/HMA

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Formal award decision adopted by Commission

SCOPE 36 month project launched in November 2013

Maximum level & largest possible contribution of 70% funding from Commission: *Consumers, Health and Food Executive Agency (CHAFEA)*

"Exceptional utility"

European Commission

SCOPE structure

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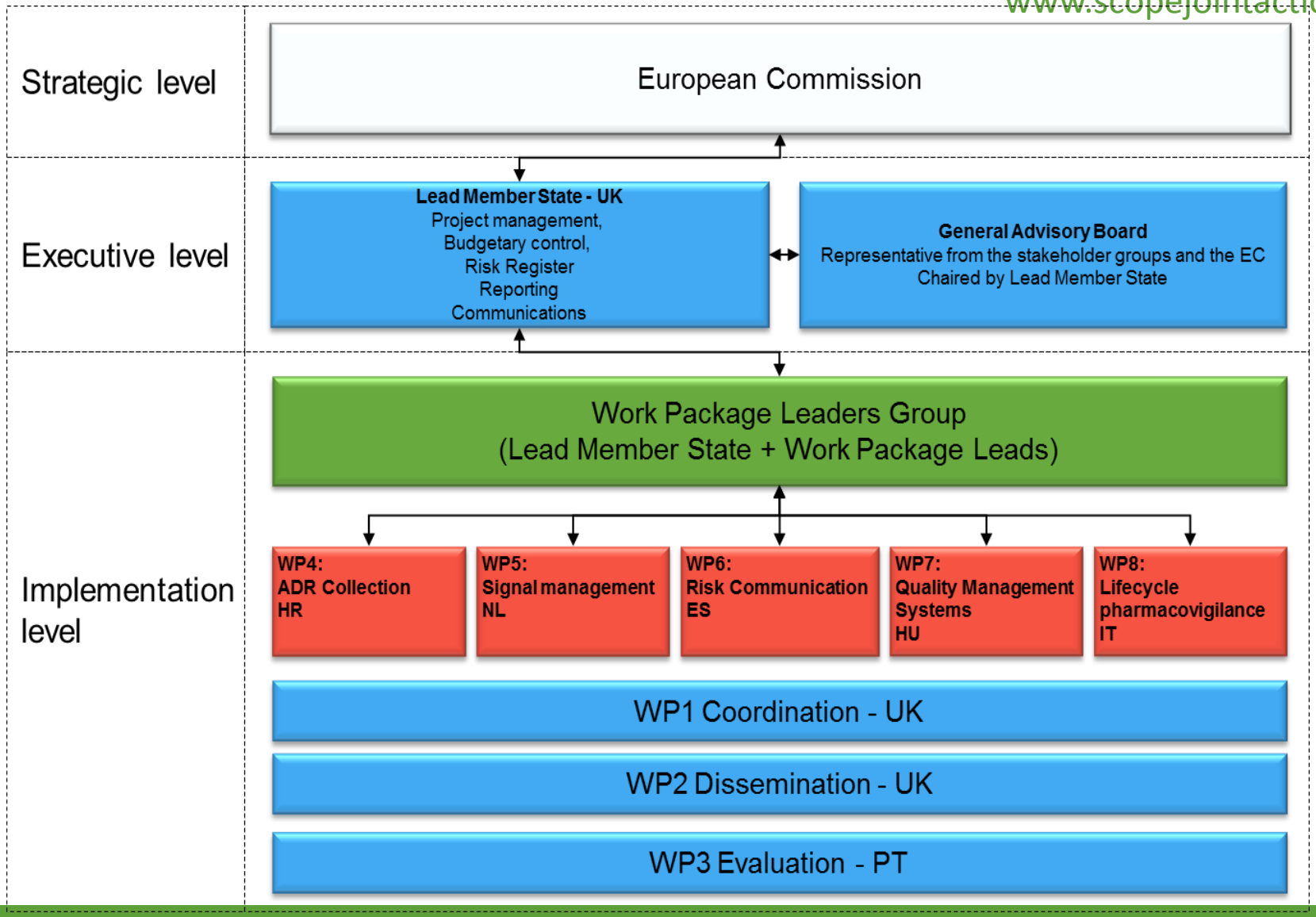

Industry stakeholder forum

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- Originally intention to include industry representative on SCOPE General Advisory Board
- Later considered to be preferable to have separate forum for industry
- Enables all industry stakeholders to participate
- Plans under way to organise
- Expected Q1 2015
- Invitations via EU trade associations

WP1 – Coordination

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Lead: **UK** MHRA Regulating Medicines and Medical Devices

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

- Delivery of project plan, manual
- Budget (time recording, expenses)
- Project Tools; Governance; reporting

Work Package Leaders/General Advisory Board AB meetings held

Project management/planning/finance systems

WP2 - Dissemination

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Lead: **UK** MHRA Regulating Medicines and Medical Devices

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

- Delivery of dissemination and communications plan, including **links with other projects**
- Stakeholder analysis & engagement
- Branding; Promotional activity work packages; Quarterly updates; stakeholder meetings; lay report

Website and promotional leaflet in place/updates

SCOPE Joint Action

The Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE) Joint Action aims to help medicines regulators operate pharmacovigilance systems to the EU legislative requirements. Regulators are collaborating to improve skills and capability in the network which will help safeguard public health in both national territories and the EU as a whole.

Find out more

Latest news: New SCOPE Website Launched

Read more

Work Packages

Work Package 1 – Governance

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

Work package 1 delivers the coordination and project management functions for SCOPE

Package details

Work Package 2 - Dissemination

Lead: Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom

This work package aims to effectively disseminate information about SCOPE and its deliverables

Package details

Work Package 3 – Evaluation

Lead: National Authority of Medicines and Health Products, I.P. (INFARMED), Portugal

This work package focusses on the evaluation of SCOPE to verify that the project is delivers what was planned to achieve the objectives

Package details

Work Package 4 – ADR collection

Lead: Agency for Medicinal Products and Medical Devices (HALMED), Croatia

This work package focuses on national adverse drug reaction reporting schemes, including patient reporting and efforts to improve awareness of national systems

Package details

SCOPE leaflet

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EU context/deliverables

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SCOPE Joint Action Deliverables

14/05/2014

ID	Project Team	Deliverable	Consultation	Target Date	Endorsement	Approval (PCG)	Agreement (ERMS-FG)	Adoption	Status/Comments	Inte
1.	SCOPE WP1	Three year work plan	SCOPE	March 2014	May 2014	WP leaders	General Advisory Board		Complete	N/A
2.	SCOPE WP1	First interim report to the CHAFEA about progress of SCOPE	SCOPE	Dec 2014		WP leaders	General Advisory Board			
3.	SCOPE WP1	Second interim report to the CHAFEA about progress of SCOPE	SCOPE	Oct 2015		WP leaders	General Advisory Board			
4.	SCOPE WP1	Final report to the CHAFEA about progress of SCOPE	SCOPE	Oct 2016		WP leaders	General Advisory Board			

WP3 - Evaluation

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Lead: **PT** infarmed Autoridade Nacional do Medicamento e Produtos de Saúde I.P.

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

- Establishment of baselines, success criteria, metrics
- Status reports; Audit reports;
- Audit report on training
- Ongoing Evaluation processes
- Final report & recommendations

Evaluation plan in place and collection of indicator data

SCOPE methods overview

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Audit

- Review current practice and experience of NCAs
  - Literature/Survey/Visits

Assess

- Collate and assess data
  - Examples of performing systems/practice, areas for clarification
  - Identify best practice features

Report

- Recommendations/ Good/Best practice
  - Anonymised examples/case studies

Train

- Develop training packages
- Deliver for NCA

WP4 – ADR collection

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HALMED
Agency for Medicinal Products and Medical Devices of Croatia

Lead: **HR**

Active Partners: **CZ, HU, IT, LT, NO, PT, UK**

- Audit of national reporting systems
- Delivering reports on operating best practice
- Toolset of materials for media campaigns
- Design of standard forms
- Review mobile reporting feasibility
- Case study of exemplar IT systems

WP4 – ADR collection

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Surveys complete and analysis to start

Types of questions included:

- Reporting forms & methods used
- Fields collected
- National promotion/marketing
- Integration with clinical IT systems

WP5 – Signal Management

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Lead: **NL**

Active Partners: **DK, ES, SE, UK**

Delivering best practice for:

- Signal detection
- Signal validation/prioritisation
- Signal assessment
- Reports of special interest

WP5 – Signal Management

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Surveys completed end August, analysis to start

Questions cover:

- Expert advice on signal management
- national system for tracking signals
- How signals are validated
- Structure of teams
- Data sources used
- Database/IT systems in place

WP6 – Risk Communications

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Lead: **ES**

Active Partners: **DK, HR, IE, IT, NL, NO, SE, UK,**

- Audit of national methods of communications
- Impact of risk communications
- Launch of communications toolbox with workshop
- Web portal best practice guide

Surveys just closed, developing plans for study on impact of risk communications

WP6 – Risk Communications

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Questions cover:

Risk communications team setup

Management of safety comms processes

Use of EU coordinated comms materials

What is provided on national web-portals

Who manages web-portals / expertise

Studies – impact of risk comms/DHPCs etc/case studies

WP7 – Quality Management Systems

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Lead: **HU**

Active Partners: **BG, ES, IT, PT, UK**

- Understanding national PV quality systems
- Understand how resources are managed
- Interfaces with pharmacovigilance inspections
- Establish Best Practice; SOPs

First round of informal visits to sample of NCAs complete

WP7 - Site visits

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Discussions covered:

- PV setup and organisation structure
- Interaction with PV inspectors
- Monitoring effectiveness
- Training and development
- Quality management
- Communications and websites
- Assessment
- Areas considered to work well

WP8 – Lifecycle PV

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Lead: **IT**

Active Partners: **ES, GR, IE, NL, NO, SE, UK**

- Data sources used other than spontaneous reports
- RMP, PSUR and referral assessments
- Assessment of PASS/PAES
- Training workshops and Best Practice framework
- Establish Competency levels across network

Surveys close end September

WP8 – Lifecycle PV

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Questions include:

RMP/PASS/PAES/PSUR assessment

Team/advisory structures

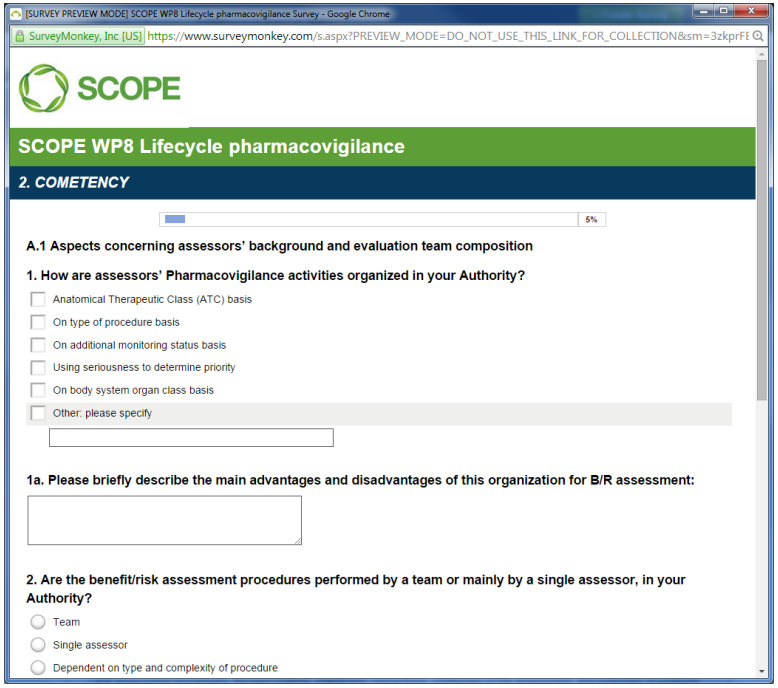
Key challenges

Training and staff competency

Management and prioritisation of work

Data sources used at assessment

Practical tools and methods used nationally



Summary

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- Enthusiasm and support from partners
- Wide collaboration across EU
- Significant thought and discussion on the topics

Keep up to date with progress on the website

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Thank you

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Keep up to date at

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