



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

SPOR Communications and Change Management

Progress update for EUNDB & SPOR TF

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SPOR Change Team



The change management workstream is focusing on **two key areas**:

1. Communications and engagement

2. Training

Scope:

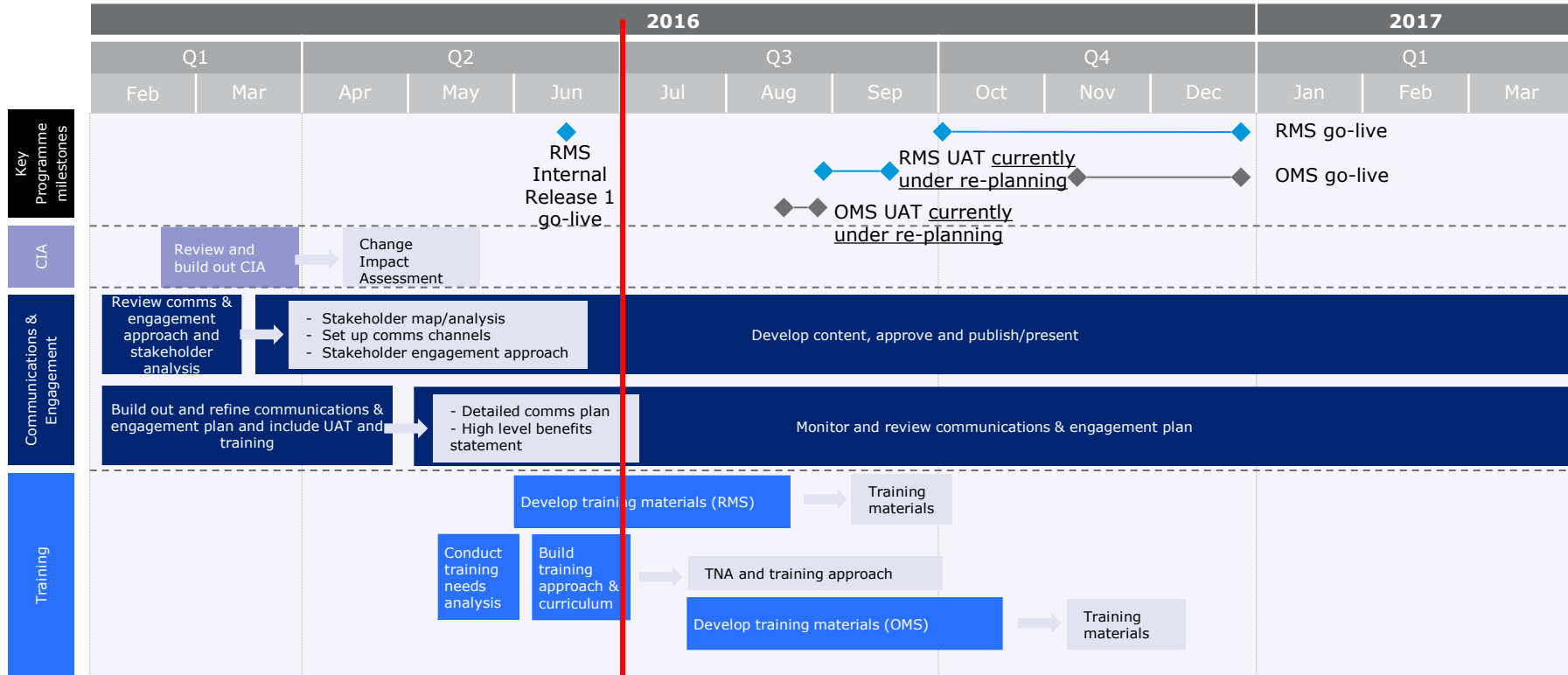
- External stakeholders: Industry, NCAs and public
- Internal EMA stakeholders

Other areas:

Change Impact Assessment (CIA). This was conducted as part of the Training Needs Analysis exercise to identify key impacts resulting from RMS and OMS projects

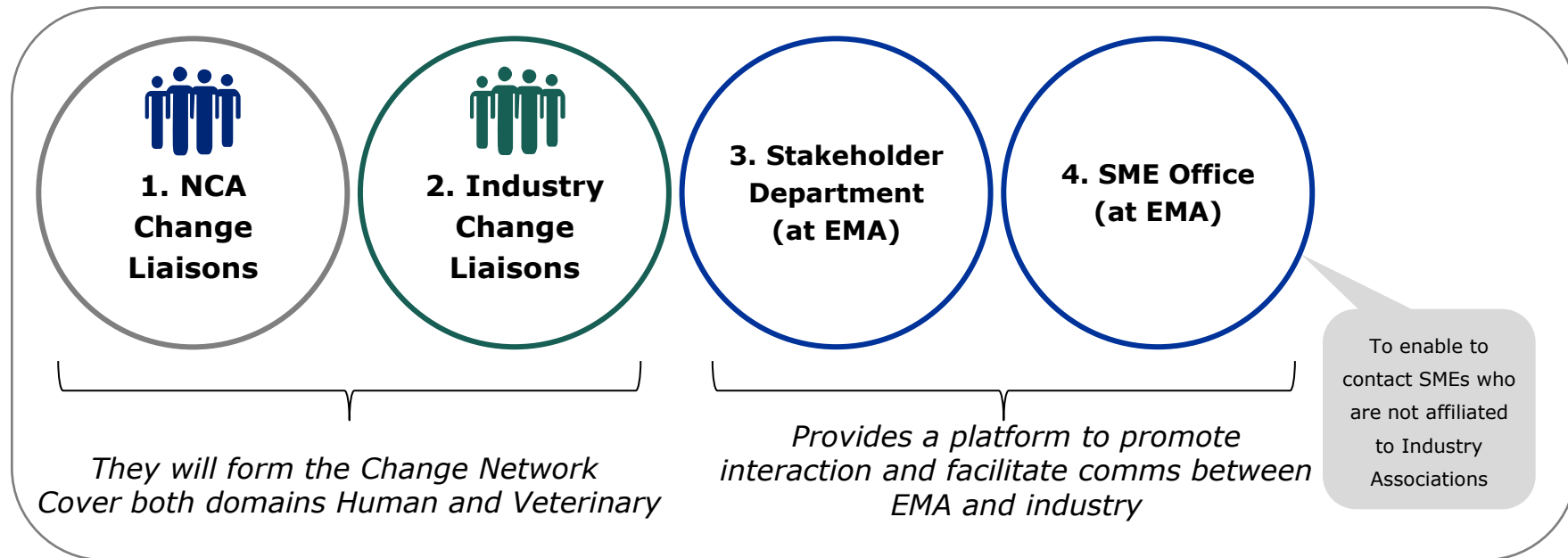
- **Benefits planning and review.** High level benefits identified so far. Dedicated resource is required to manage benefits planning and monitoring, so this activity is currently on hold

High level change management plan



Progress to date

We are using four mechanisms to cascade information to NCAs and to Industry and increase reach across the stakeholders



EMA provides centralised comms for Change Liaisons to cascade to the right people

NCA

- 37 NCA Change Liaisons were appointed in March 2016
- Engagement plan drafted and presented at the kick-off webinars 11 and 12 April. Follow up webinar 26 May.
- Key Actions from the webinars:
 - NCA Change Liaisons to start building their internal network (progress update to EUNDB, TF)
 - Help to complete SPOR implementation survey
- Face-to-face Change Liaison event planned for September

Comms cascaded and published on the EMA web site (and Telematics)



37 NCA
Change
Liaisons



NCAs

Comms cascaded to key stakeholders within NCAs and to national trade associations

Industry

- Industry Change Liaisons were appointed
- Engagement will begin in July (21st) through a 'kick-off' webinar to present the engagement plan
- 'Introduction to SPOR' webinar is being planned in late July for wider industry stakeholders

Comms will be cascaded and published on the EMA web site



EMA stakeholder department (established contacts at Industry Associations) + SME Office



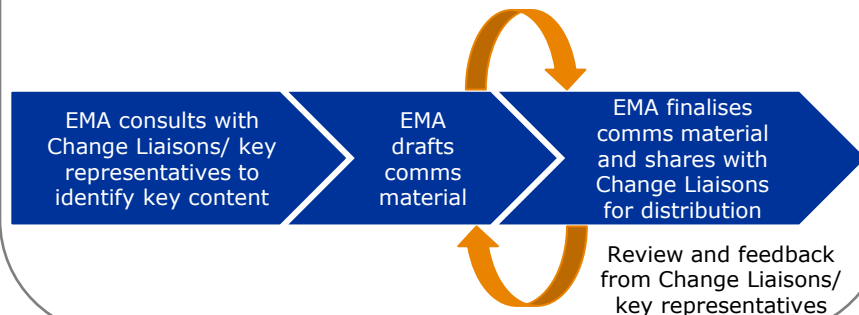
Industry Change Liaisons



The SPOR Change Team develops communications through consultation with and feedback from key internal and external stakeholders

Consultation with key stakeholders

- Consultation with Change Liaisons or other key representatives, when required, to identify key content and target audiences and to develop relevant communications materials
- Working with EMA Communications department to develop materials which adhere to EMA communications standards and to publish material on line



Feedback and collaboration

SPOR change team encourages Change Liaisons to :

- Open feedback and collaborative working to understand implementation progress and issues as they arise
- Sharing of knowledge, good practice and lessons learned



Webinars are hosted on various topics, opportunity to ask questions



Status reports via periodic SPOR implementation survey



Data Integration SPOR microsite has been included under [Telematics](#)



The **SPOR Change Liaisons mailbox** SPOR-Change-Liaisons@ema.europa.eu to channel questions and answers between SPOR and Change Liaisons



SPOR update emails give Change Liaisons an update on SPOR implementation activities and milestones

SPOR visual identity developed with a 'strapline' as well as icons and colours to denote each project: SMS, PMS, OMS and RMS

Name and Strapline

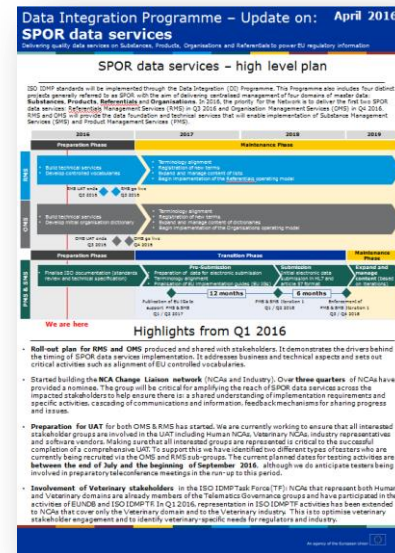
SPOR data services – Delivering quality data services on Substances, Products, Organisations and Referentials to power EU regulatory activities

Icons and Colours



Example of Visual Identity

SPOR update poster

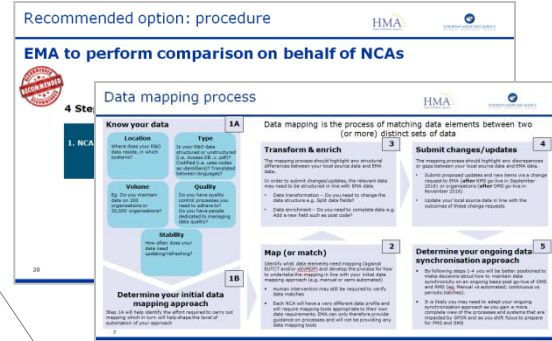


Key engagement milestones (March – June 2016)

April: NCA Change Liaisons kick-off webinars

March: R&O roll-out plan webinar to all IT Directors

June: R&O Data Mapping webinar

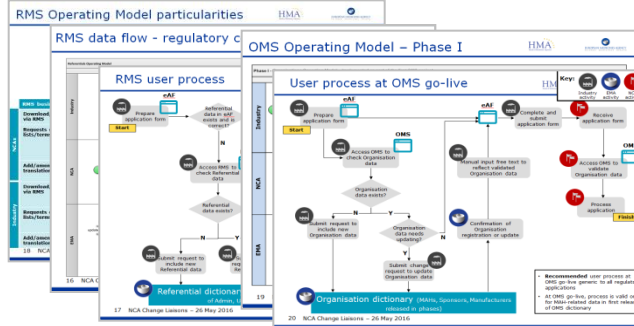
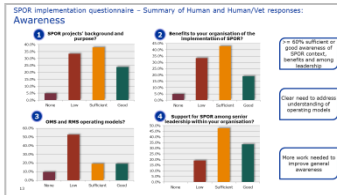


May: IT Directors, HMA meeting in Rotterdam

June: On boarding of Veterinary stakeholders prior to EUNDB / TF

May: NCA Change Liaisons follow-up webinar

Apr - May: SPOR implementation survey



We asked NCA Change Liaisons how they are enhancing the reach of SPOR within their organisations

MHRA (UK)

- **Business Analyst** to focus on various matters, including SPOR/IDMP and Telematics, and to actively participate in the Change Network
- **Established a Steering Group** for their Global Data Integration programme which includes within its remit both SPOR and Telematics work
- **Secured cross-Agency representation from senior managers** for the Steering Group, which provides excellent engagement across all operational units at the MHRA
- **Presented and gained MHRA Executive Team support for a programme proposal incorporating Telematics and SPOR** (and other programmes). MHRA is now mobilising resources and establishing programme governance

AIFA (Italy)

- **Held several internal meetings with the AIFA Head of Section** to share the SPOR programme roadmap, identify key processes impacted by SPOR and agree action plans for these impacts
- **Began a project to re-engineer AIFA IT architecture** to simplify the interoperability with EMA shared services (i.e., OMS, RMS, etc)

Norwegian Medicines Agency

- **Introduced the Change Liaison** for SPOR on the NoMA-intranet
- **Engaged the NCA IT Director and arranged an internal seminar** to introduce the internal NCA audience to SPOR
- **Planned preliminary work** on processes and systems impacted by SPOR
- **Established a small group of people to focus on data mapping**

State Agency of Medicines of the Republic of Latvia

- **Established two key groups:**
 1. A high level group focused on developing the internal strategy for SPOR, undertaking changes to internal processes (business and IT) as a result of SPOR and delegating tasks related to these
 2. Another group focused on data mapping and providing support to the high level group.
- **Established internal meetings** to identify what else is needed for SPOR

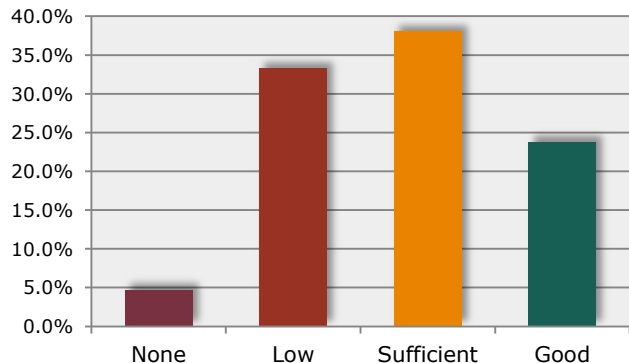
SPOR implementation questionnaire

Response Statistics

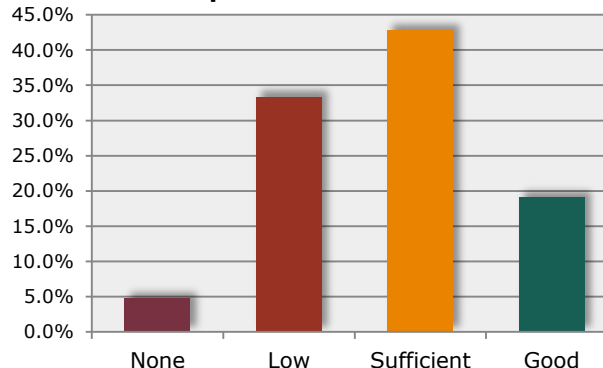
- **Questionnaires (H, H/V and V NCAs) circulated 26 April & 10 May 2016**
- To enable the Network to track progress of implementation of SPOR
- Analysis conducted in preparation for HMA Rotterdam meeting. Responses continued to come in after the deadlines, they were included prior to HMA until 23/24 May
- **Human NCAs and Human/Vet NCAs:** 21 out of 30 responses analysed; 9 discounted
- **Vet-only NCAs:** 4 out of 8 responses analysed; 4 discounted
- Responses have been discounted for two reasons: Responses are incomplete or the questionnaire has been answered by the wrong audience e.g. Vet-only responding to Human/Vet questionnaire

SPOR implementation questionnaire – Summary of Human and Human/Vet responses: Awareness

1 SPOR projects' background and purpose?



2 Benefits to your organisation of the implementation of SPOR?

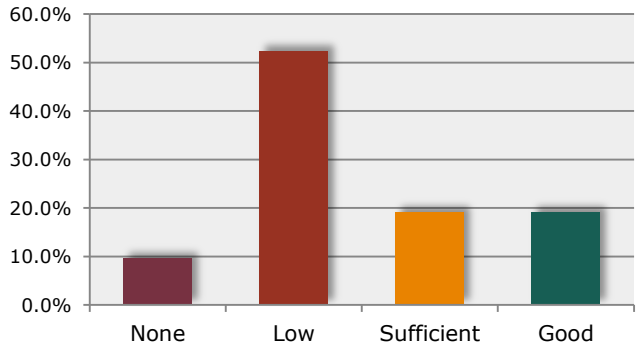


>= 60% sufficient or good awareness of SPOR context, benefits and among leadership

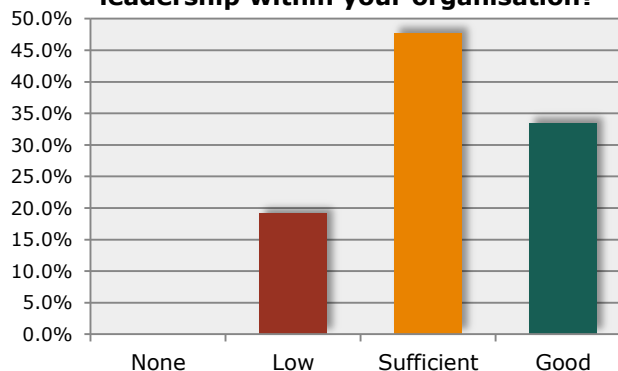
More work needed to improve general awareness

Clear need to address understanding of operating models

3 OMS and RMS operating models?

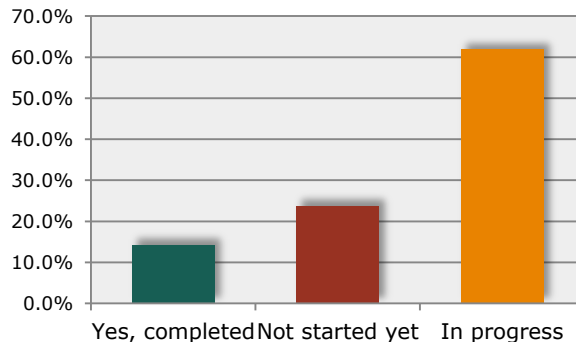


4 Support for SPOR among senior leadership within your organisation?



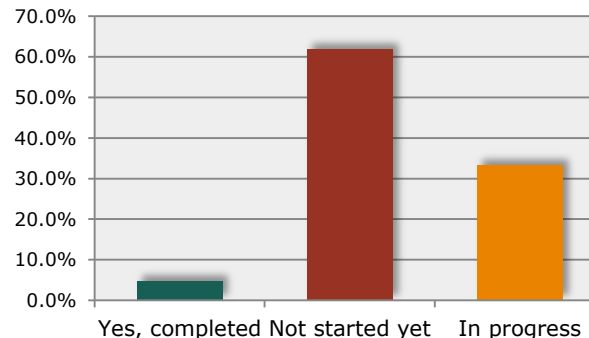
SPOR implementation questionnaire – Summary of Human & Human/Vet responses: Planning

5 Have you identified which systems SPOR data resides in and how these systems will need to be adapted?



Good progress in
identifying impacted
systems

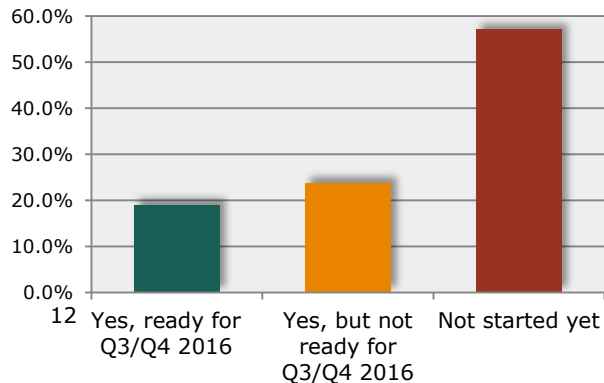
6 Have you identified which processes will be impacted and in what ways?



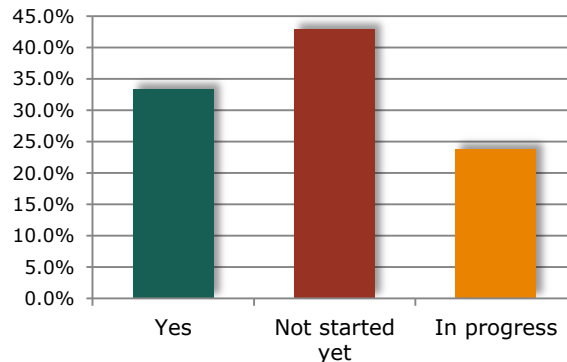
Poor progress
identifying impacted
processes

SPOR implementation questionnaire – Summary of Human & Human/Vet responses: Planning

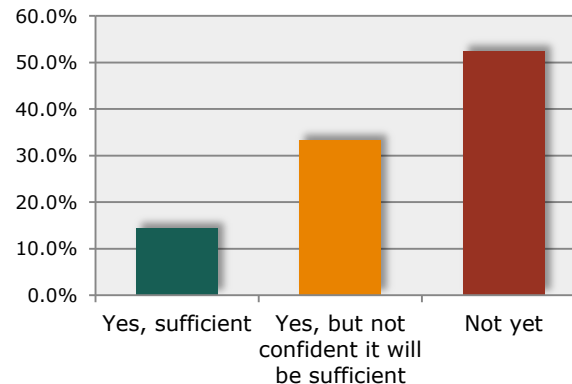
7 Do you have a SPOR implementation plan and will you be ready to use OMS and RMS in Q3/Q4 2016?



8 Have you identified resources to deliver your SPOR implementation plan?



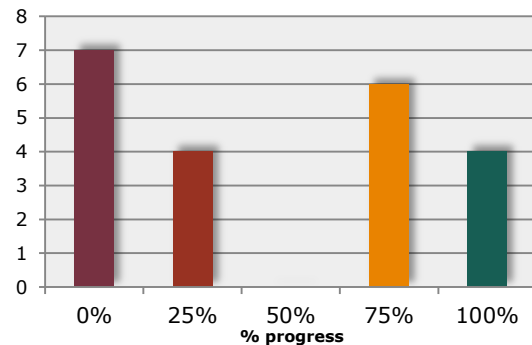
9 Have you allocated sufficient budget?



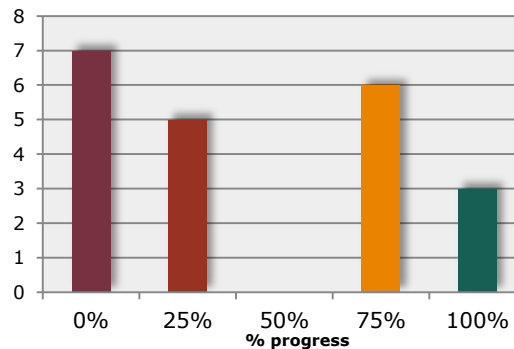
Some resource allocation but
insufficient progress in developing
plans and budget

10 RMS data mapping progress:

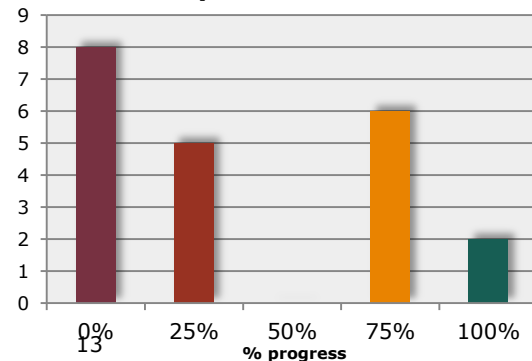
a) Routes of administration?



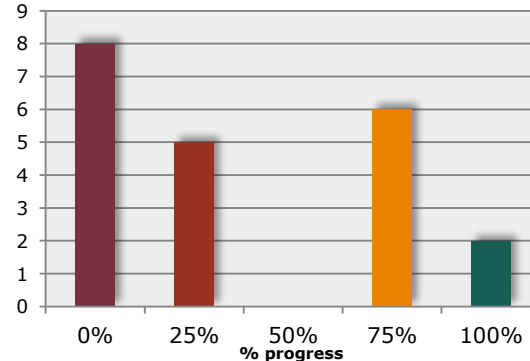
b) Dosage forms?



c) Containers?

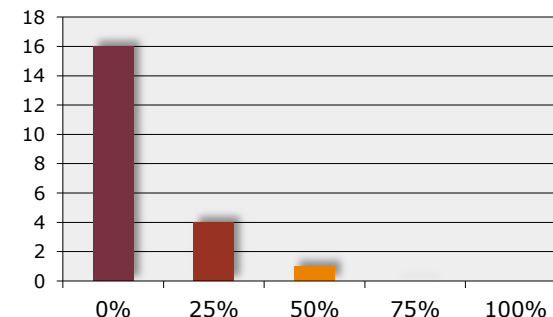


d) Units of measurement?



11 OMS data mapping progress:

a) Review product lists in xEVMPD to identify missing products and consequently missing MAHs

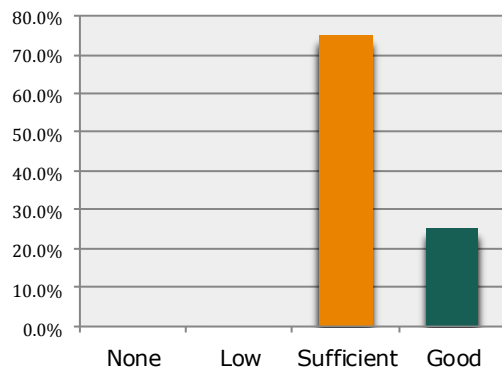


Broad range of degree of progress of RMS data mapping

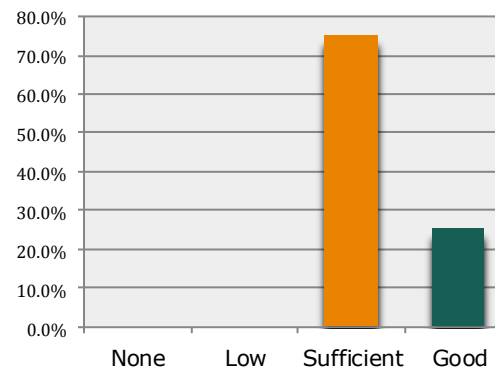
Notably poor progress in OMS mapping

SPOR implementation questionnaire – Summary of Vet only NCAs responses: Awareness

1 SPOR projects' background and purpose?



2 Benefits to your organisation of the implementation of SPOR?

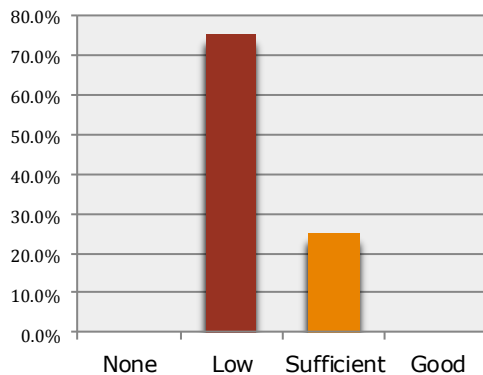


100% sufficient
or good
awareness of
SPOR context and
benefits

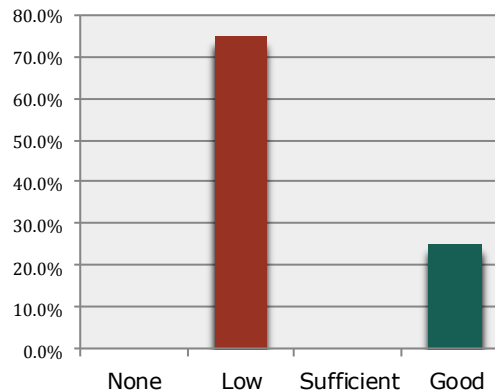
SPOR implementation questionnaire – Summary of Vet only NCAs responses: Awareness

3

OMS and RMS operating models?

**4**

Support for SPOR among senior leadership within your organisation?



Clear need to
improve
leadership
support for SPOR
(Vet)

Clear need to
address
understanding of
operating models

SPOR implementation questionnaire: Summary findings

Key

H/M

V

Human/Human and Veterinary Vet only

Issue

Response

H/M

OMS mapping: process not clear

Product data comparison approach process presented to NCAs and SPOR TF on 16 June via webinar

H/M

Systems & processes: Insufficient information on operating models

Webinar for NCA change liaisons held 26 May. Walk through the OMS & RMS operating models. More supporting information is being developed

H/M

Systems: Absence of finalised API specs

Draft RMS API specifications consulted & shared via Sub Groups. Consultation for OMS API ongoing. Final API expected to be released in July

H/M

Systems/data mapping: Need more practical guidance for how to undertake mapping (method, resources)

Data mapping guidance webinar held 16 June

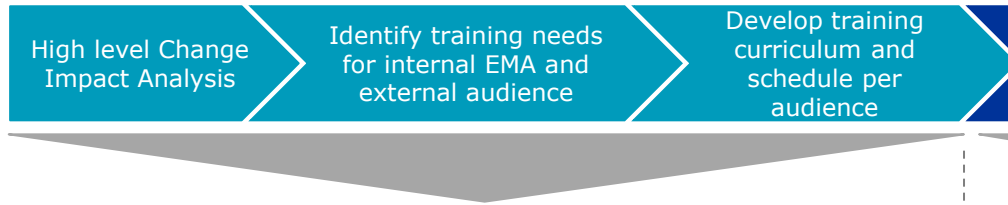
V

Awareness: Low senior leadership support for SPOR

Human and Human/Vet NCAs have participated in TF/EUNDB since 2015. Vet-only NCAs were recently invited to join the groups. They are engaged via their NCA Change Liaisons. Webinar to on-board Vet stakeholders prior to EUNDB / TF held 22 June

High level training approach - key updates

Progress so far



- 1. High level change impacts:** As part of the TNA, we identified the high level change impacts for RMS and OMS
- 2. Training Needs Analysis (TNA):** Working with the Project Managers for RMS and OMS we determined the training required for internal and external EMA stakeholders affected by the changes
- 3. Curriculum:** Using the TNA, we have developed a modular curriculum with a training schedule per stakeholder group

Next steps



- 1. Training development plan:** Draft a training plan to develop training materials (to include key content inputs, timelines, roles and responsibilities, review and sign off processes)
- 2. Training materials:** Begin developing training materials and **testing these with Change Liaisons** for completeness and message clarity
- 3. UAT lessons learned:** Update training materials with key lessons learned from UAT
- 4. Training delivery plan:** Plan for training delivery for each audience
- 5. Training delivery and evaluation:** Deliver and evaluate training effectiveness

High level training approach - key deliverables

Progress so far

Next steps

High level Change
Impact Analysis

Identify training needs
for internal EMA and
external audience

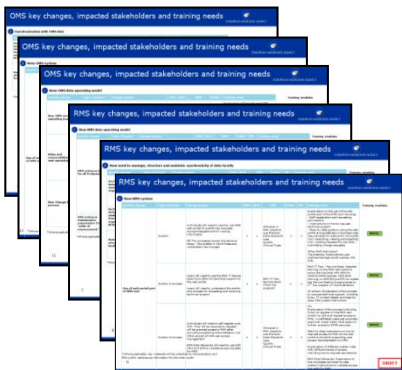
Develop training
curriculum and
schedule per
audience

Develop
training
materials

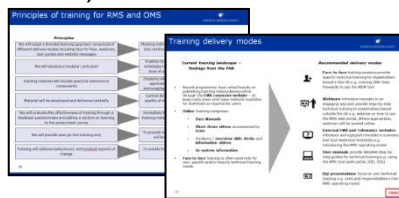
Deliver
training

Evaluate
effectiveness of
training

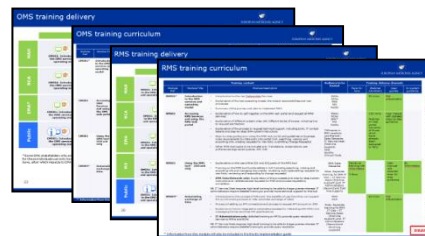
TNA document (including high level change impacts)



Training principles and modes of delivery



Training curriculum



Training development plan

*Training materials:
webinars, ppt,
guides, manuals etc.*

Training delivery plan

Training evaluation approach

Training evaluation results and plan to address any issues

Findings from the Training Needs Analysis

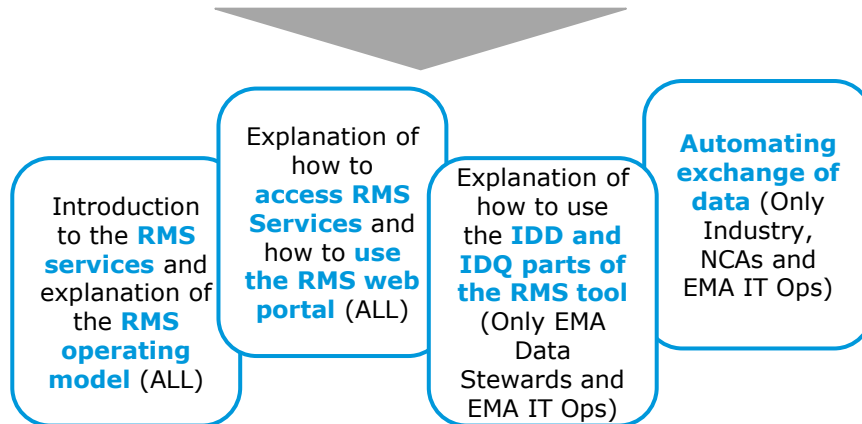
High level changes brought about by RMS and OMS have **common themes** which require us to deliver training to internal and external audiences for 'go-live' along **common topics**

RMS

1. New RMS data operating model
2. New RMS system
3. Synchronisation of local data with RMS data

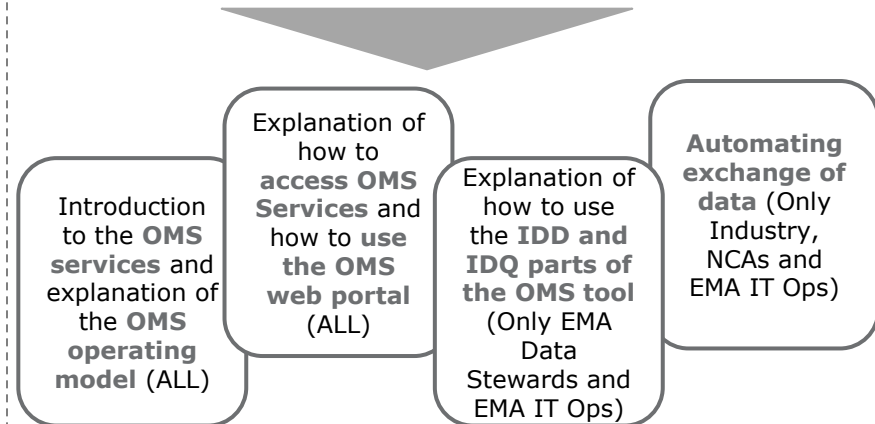
High level
changes

High level
training needs



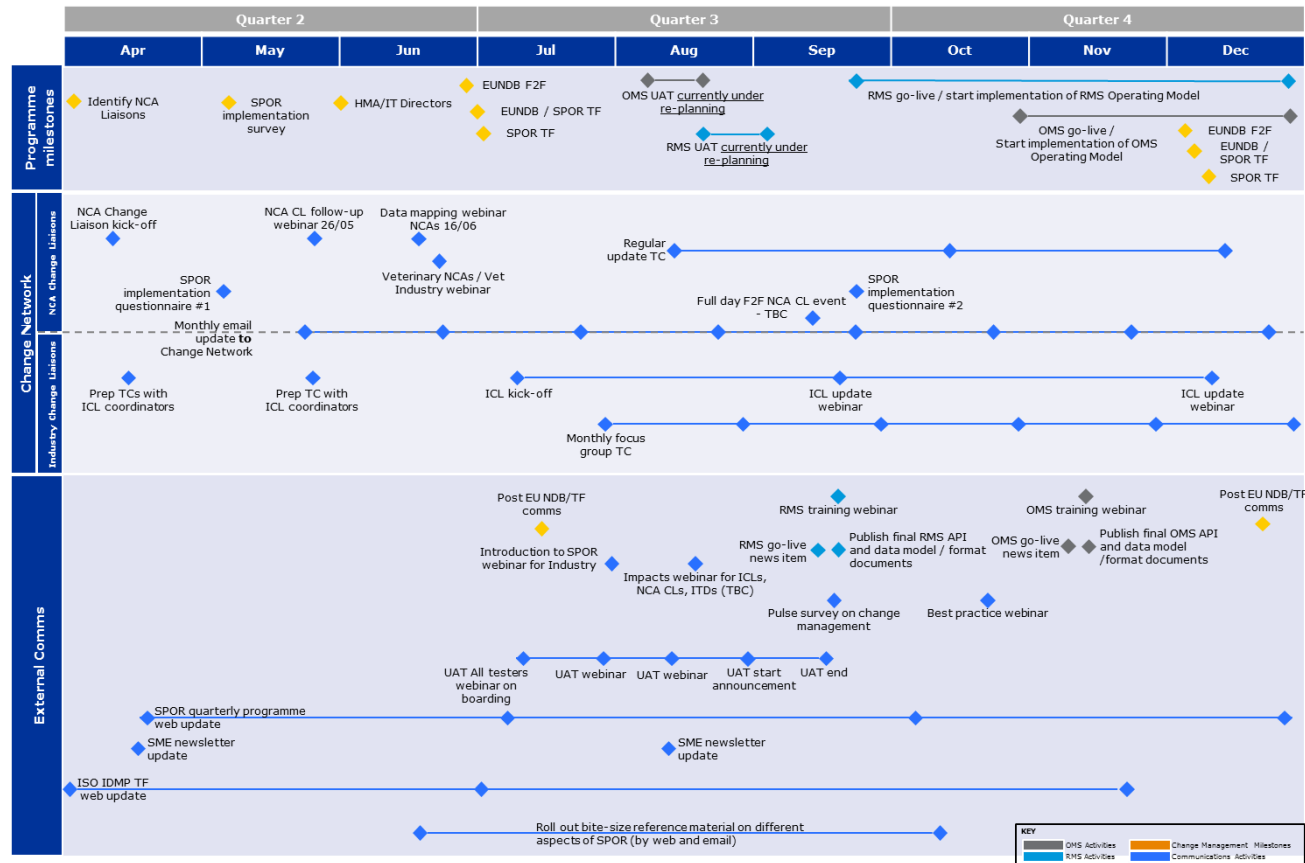
OMS

1. New OMS data operating model
2. New OMS system
3. Synchronisation of local data with OMS data



Annex

External Communications Plan 2016



Thank you!
