EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA support to SCOPE sustainability

SCOPE Flagship event - Royal Society of Medicine, London

Presented by Georgy Genov on 23 November 2016
Head of Signal and Incident Management – European Medicines Agency

Congratulations!!!

How to ensure the sustainability of SCOPE

SCOPE deliverables will be:

- available in the EU Network Training Centre learning platform
- included in the Operation of Pharmacovigilance in the EU Training Curriculum

What is the EU Network Training Centre (EU NTC)?

The EU NTC is a joint HMA & EMA initiative,

with the mission to ensure the spread of good scientific and regulatory practice across the EU regulatory network,

by harmonising training standards and by offering high quality and relevant training opportunities to its members.

EU NTC curricula

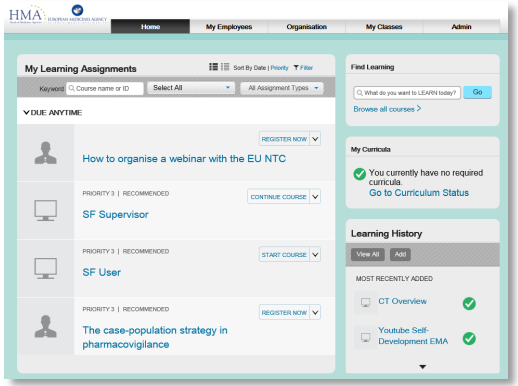
- The EU NTC has developed a pragmatic approach for the development of curricula in the different areas of expertise in the network.
- This approach is currently being rolled-out in 8 subject areas, one of which is pharmacovigilance.
- The first curricula are planned to be delivered by end 2016.
- The SCOPE training content can be promoted and indexed in the EU NTC training platform following sign off by PRAC.

A new milestone for the EU NTC and the network

EU NTC Interim platform

To fulfil its mission in a resource-effective and sustainable way, the EU NTC is launching a

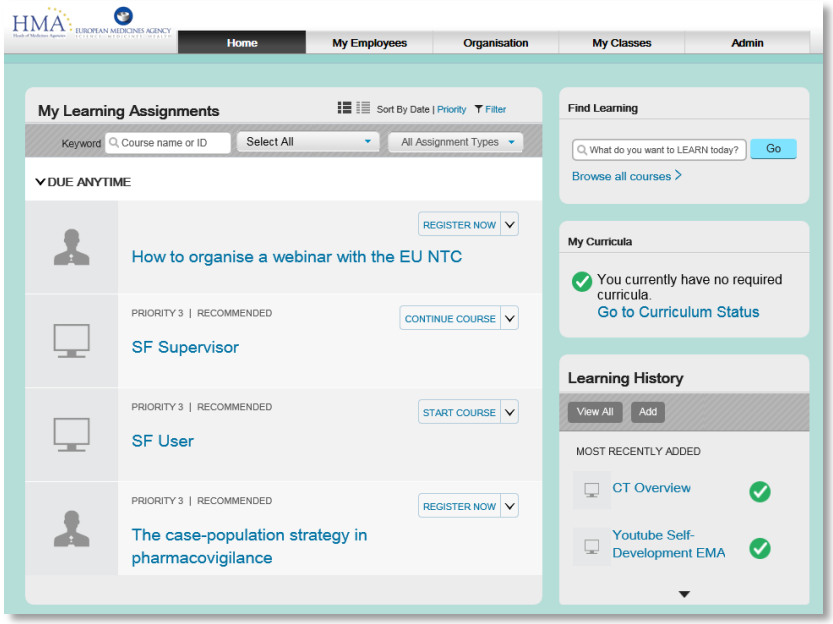
Learning Management System (LMS)



New EU NTC LMS

EU NTC learning management system (LMS)

- Centralised online training platform
- For NCA and EMA staff
- Giving access to relevant and qualitative scientific and regulatory training opportunities from across the network
- User-friendly and easy registration, tracking and feedback
- Learning paths for targeted professional development (curricula)



Screenshot of the landing page of the EU NTC learning management system (launched June 2016)

LMS is in its PILOT phase

- Pilot from 7 June 2016 until the end of the year
- 4000 licenses available for NCA staff during the pilot phase
- Interim platform - http://euntc.eudra.org/ - will be available during the transition period, until January 2017
- We need your feedback and remarks! networktraining@ema.europa.eu

Pharmacovigilance Training Curriculum
Where it comes from

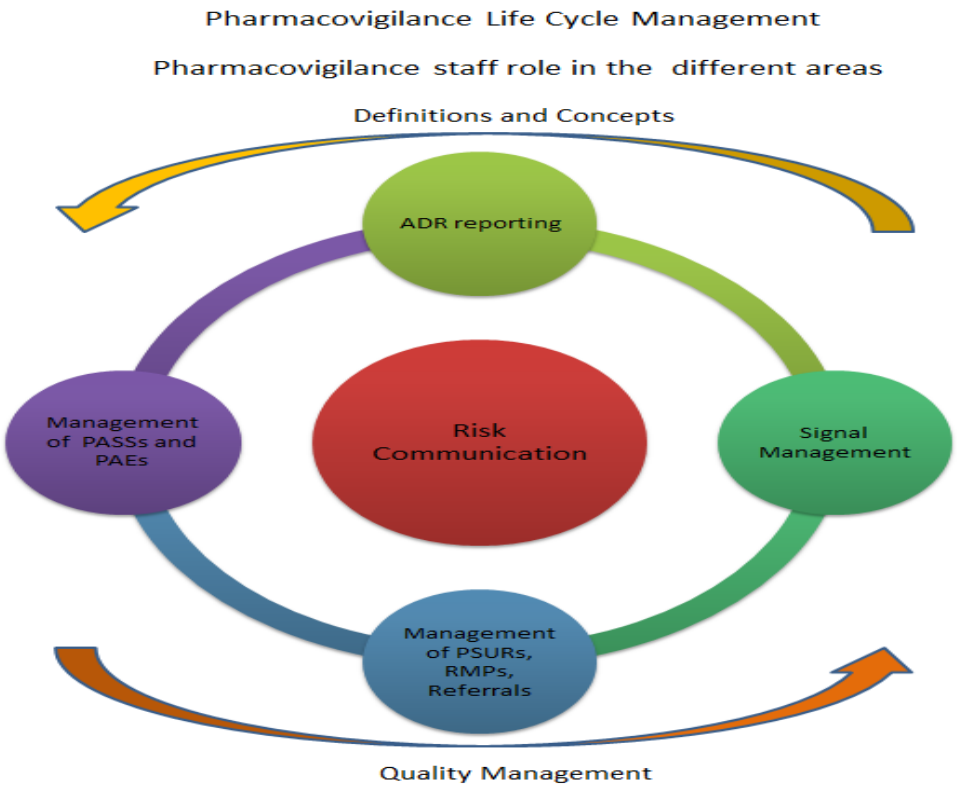
2016
- HMA approved development of operation of pharmacovigilance training curriculum

May July
- Drafting of the curriculum framework for the operation of pharmacovigilance (phv) by the EUNTC Curriculum Design resource and a sub-group of phv experts

Sept Oct
- Consultation of the Pharmacovigilance Business Team
- Consultation of the work package leads of the "Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE)" Joint Action (JA) programme

Oct
- Consolidation of comments and update of draft outline of the operation of pharmacovigilance training curriculum

Pharmacovigilance Training Curriculum Scope



Pharmacovigilance Training Curriculum Objectives

- Facilitate collaboration and thus a harmonised approach for teams working within and across the pharmacovigilance topic areas for the entire EU network;
- Assure consistency in the operation of pharmacovigilance business processes and the use of supporting IT systems across the EU network;
- Allow new staff to get effectively trained and inducted;
- Provide a platform for pharmacovigilance staff for knowledge share and exchange of best practices across the EU network.

Pharmacovigilance Training Curriculum
Target audiences

Primary target audience

- Pharmacovigilance staff in NCAs/EMA working in the different PhV topic areas
- Single roles covering the PhV topic areas vary by NCA across the network depending on the size and the operation of each organisation

Secondary target audience

- Inspectors who may wish to cover specific aspects of the curricula
- Regulatory affairs and other interested parties

Profiles of the target audience

Beginner profile	Competent profile	Advanced profile
• Typically early in their career with few experience • Contributes in his/her capacity as team member • Overall learning objective is to acquire/ requisite knowledge and understanding in one or more of the PhV topic areas	• Typically established with a number of years of experience • Is able to work independently and take a lead in one or more of the PhV topic areas • Overall learning objective is to have and maintain the required knowledge and understanding and also be able to apply these in practice in his/her role as a specialist in one or more of the PhV topic areas	• Meets all requirements of the competent profile • Overall learning objective is to further build expertise in one or more of the PhV topic areas • Is recognised for working in external groups and active in expert committees • Is able to coach and mentor other assessors

Emphasis that the profiles are not aimed to define specific competency levels!

Training needs across the three target groups are different to assist in developing appropriate training plans!

Governance

Governance of the Training Curriculum on the Operation of Pharmacovigilance in the EU

EU-POG	PRAC	EU PVOPS TC SG
• Approve training curriculum design document • Approve training priorities	• Give strategic direction on training needs and priorities for EU Network • Approve training curriculum design document	• Ownership of TC design document • Map existing training to EU PVPOP TC and identify gaps • Capture training needs from a variety of sources and propose training priorities • Plan and coordinate training implementation • Identify training leads and oversee content development • Oversee training deliverables and training feedback • Approve SOPs related to training • Report regularly to PRAC on the training activities

Details of the roles and responsibilities are still to be finalised

Pharmacovigilance Training Curriculum
Training content

- Training content will come from a variety of sources:
  - SCOPE Joint Action programme
  - other EU programmes (PRAC training for assessors, EV change management) or individual programmes run by NCAs which are open for the network
  - curated sources of content recommended by the Steering Group
- Draft template for identifying and recommending training priority areas developed
- Agreement by the SCOPE JA programme to transition the SCOPE training deliverables and to adapt and maintain these within the operation of pharmacovigilance curriculum framework (following closure of the programme)

Pharmacovigilance Training Curriculum
Next steps

Nov	• Operation of PhV training curriculum Steering Group reviewed updated draft based on comments received
Nov	• Pharmacovigilance Business Team to be informed about status of draft curriculum • Scope WP leads to be informed about status of draft curriculum
Dec Jan	• Consultation of PRAC/approval by PRAC
Feb 2017	• Approval by Pharmacovigilance Oversight Group

Next steps and future maintenance

- SCOPE team will need to provide an index of the material and format of the training which has been developed for the various topics.
- Critical piece of information: identify clearly the target audience for the SCOPE training (using the EU NTC guideline around the Beginner, Competent and Advanced profiles).
- Review and maintain the SCOPE training materials to ensure that the materials developed remain relevant and are used.
- SCOPE may decide to nominate for each topic a topic (co-)lead to contribute to the continuous development of the SCOPE training.

In conclusion…

- SCOPE has delivered really important contribution to capacity building
- Goes hand in hand with the finalisation of the implementation of the PV legislation
- Highly productive: apps for reporting, guidance, training, sharing of best practices..
- Solid building blocks for sustainability which has to be a priority
- EMA is fully committed to support

Thank you for your attention

Further information

Georgy Genov (georgy.genov@ema.europa.eu)

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**