EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on the PSUR roadmap

Achieving a common understanding of the PSUR single assessment in Europe

Presented by Irene Rager
Head of Service E (PSUR/PASS); Procedure Management Department;
European Medicines Agency

Introduction

New Pharmacovigilance legislation

→

changes in PSUR submission requirements and content; strengthened coordination

→

Increased experience
Increased challenges

Concept of the PSUR, its assessment and role in the lifecycle of a medicinal product (critical appraisal)

Evidentiary standards in submissions and outcomes

Regulatory follow-up after procedure or for issues detected during assessment

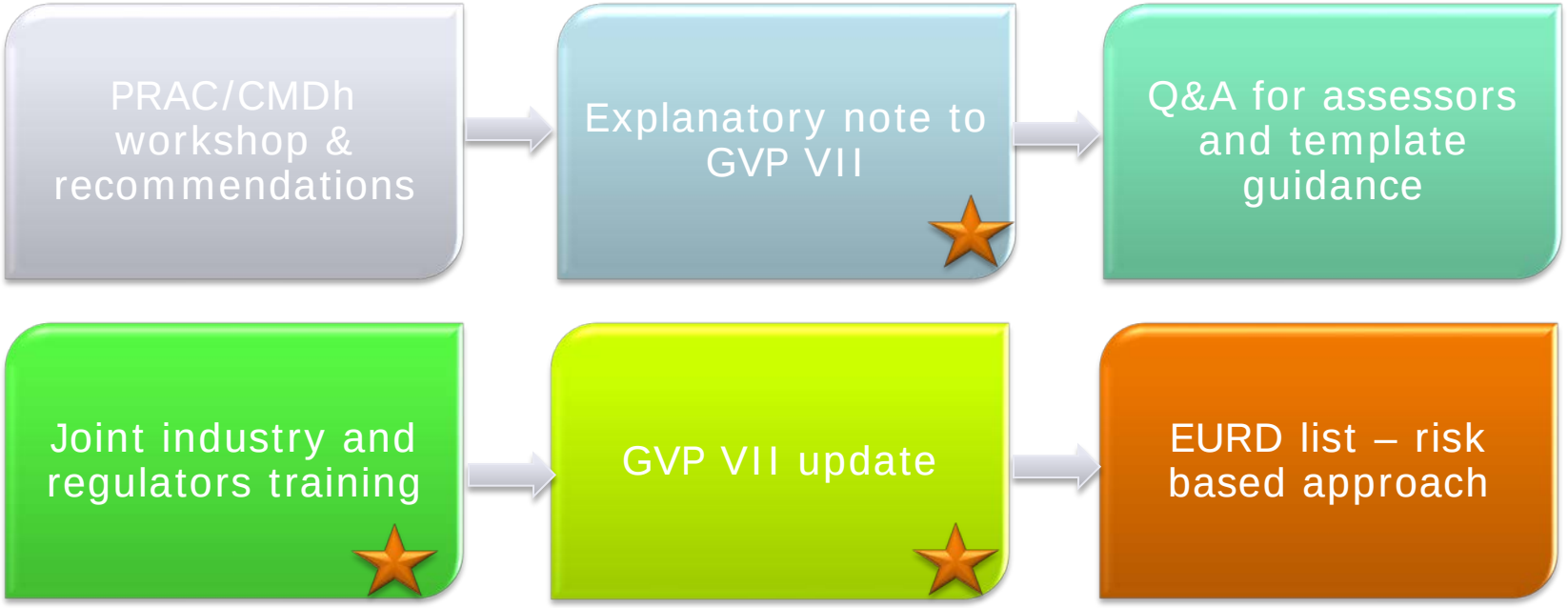
→ **PSUR Roadmap**

Update on the PSUR roadmap – where are we?

The Joint industry and EU regulatory network training is coming!

- When? → 22 Sep 2017
- Identifying key issues encountered by industry and regulators in the preparation of PSURS
- Sharing Best Practice (advice) on ways to address these key issues to achieve a common understanding:
  1. Signals/Close monitoring/Use of summary tabulations
  2. Product information/RSI/Safety specifications

PSUR Roadmap elements



Thank you for your attention

Further information

irene.rager@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**