Pharmacovigilance system impact – EU regulatory network collaboration and initiatives
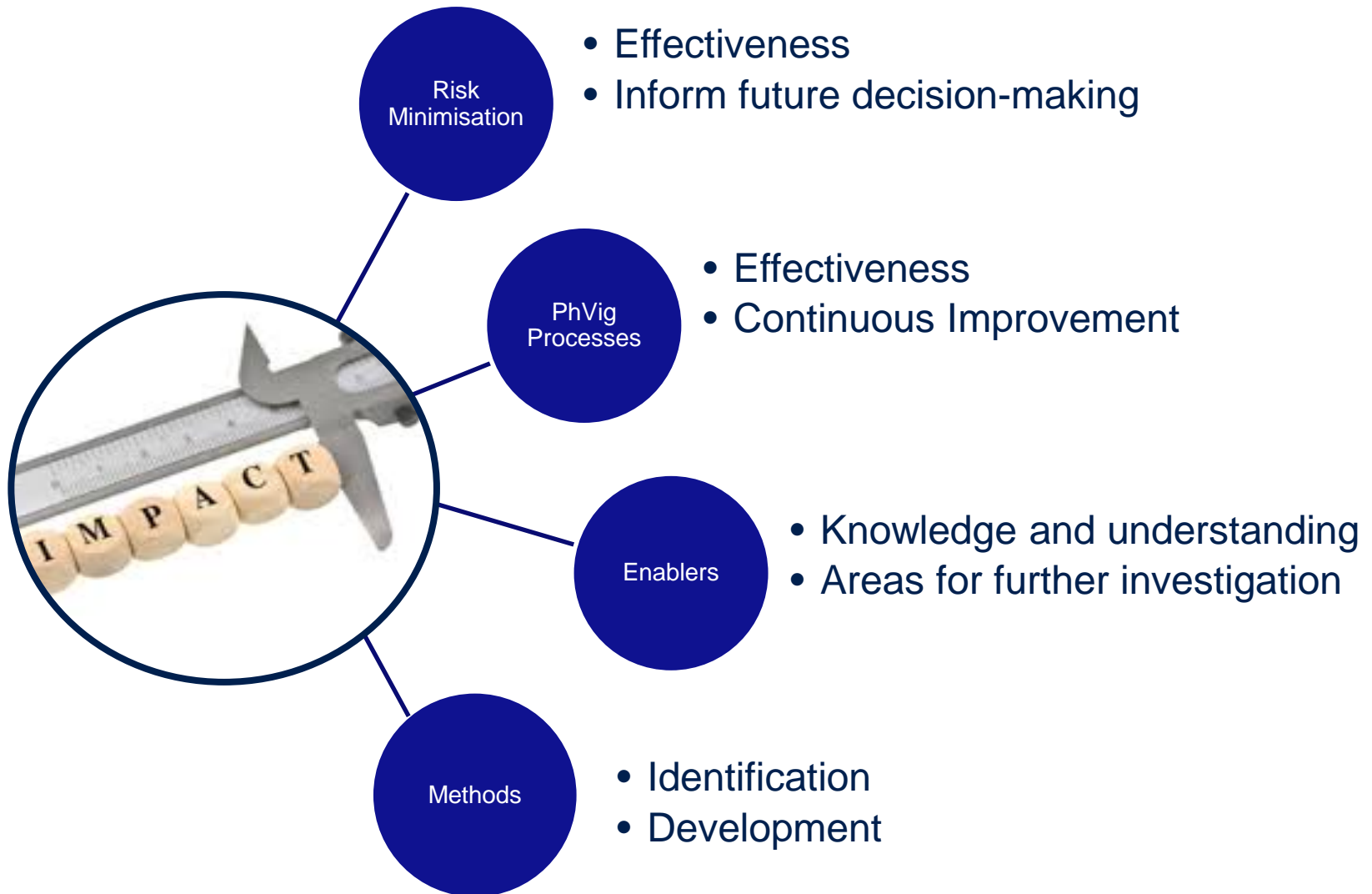
Julie Williams

PRAC Impact Strategy

Risk Minimisation
- Effectiveness
- Inform future decision-making

PhVig Processes
- Effectiveness
- Continuous Improvement

Enablers
- Knowledge and understanding
- Areas for further investigation

Methods
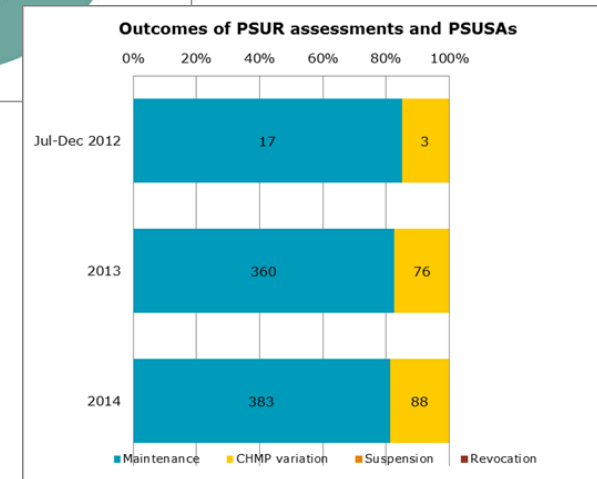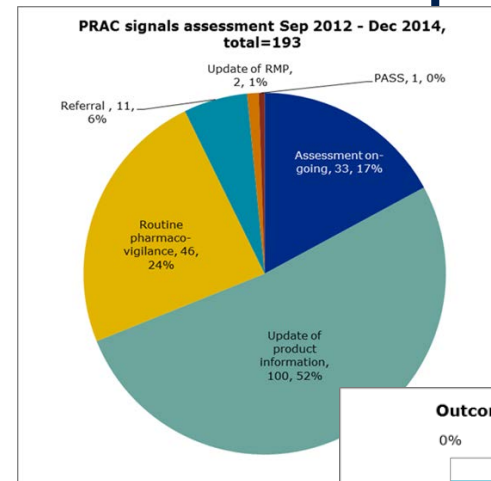- Identification
- Development
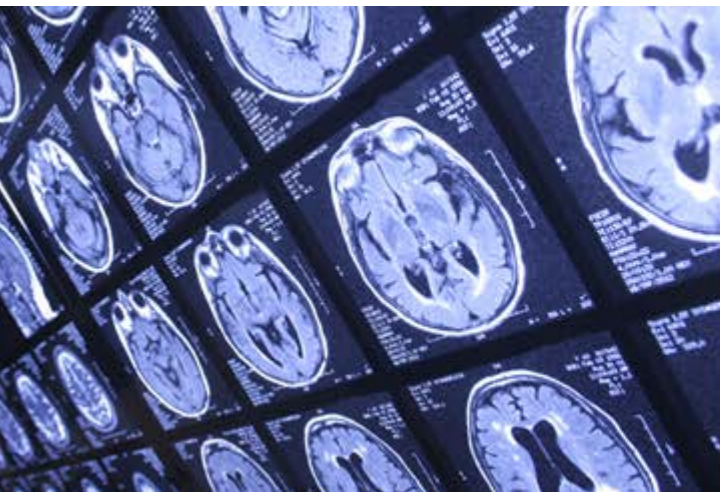
Delivery through collaboration

European Commission report:

- Risk Management Plans evaluated:
  - 1,282 CAPs (PRAC)
  - ~20,000 NAPs (MS level)

- 193 signals (52% led to PI updates)

- 927 PSUR (18% led to variation to MA)

- 31 Safety Referral procedures:
  - 26 Variation of MA
  - 4* Suspension of MA
  - 4* Revocation of MA

- Imposed PASS: 38 (PRAC), 17 (MS level)

- 149 Public safety communications

* Action taken for at least one concerned product

EUROPEAN COMMISSION

Brussels, 8.8.2016
COM(2016) 498 final

REPORT FROM THE COMMISSION

Pharmacovigilance related activities of Member States and the European Medicines Agency concerning medicinal products for human use (2012 – 2014)

{SWD(2016) 284 final}

PRAC signals assessment Sep 2012 – Dec 2014, total=193

- Update of RMP, 2, 1%
- PASS, 1, 0%
- Referral, 11, 6%
- Assessment on-going, 33, 17%
- Routine pharmaco-vigilance, 46, 24%
- Update of product information, 100, 52%

Outcomes of PSUR assessments and PSUSAs

	Maintenance	CHMP variation
Jul-Dec 2012	17	3
2013	360	76
2014	383	88

Maintenance · CHMP variation · Suspension · Revocation

3

Effectiveness of Risk Minimisation

Initiatives at national level

Driver tends to be national

Results not consistently shared

Ad hoc collaborative work:
        DUS codeine

Article 31 Referral - codeine

- Collaborative, coordinated research within regulatory network
- Electronic healthcare records to measure the impact of RMMs

Codeine

- Evaluate effectiveness of RMMs after codeine referral
- Work under agreed common approach with shared objectives (BIFAP, CPRD and IMS Disease Analyser (FR and DE)
- Initial analyses completed and results being prepared
- Proposal to have a joint report (co-ordinated by EMA)
- Lessons learnt

Article 31 referral - CHCs

EMA commissioned study to:

- Trends in first ever user prescribing (Jan 2016 to February 2016)

- Systematic tendencies to switch

- Changes in utilisation - patient clinical characteristics and demographic risk factors for VTE

- Changes in the two time periods in the population attributable risk of VTE in association with CHC intake

Key considerations for initiating impact studies
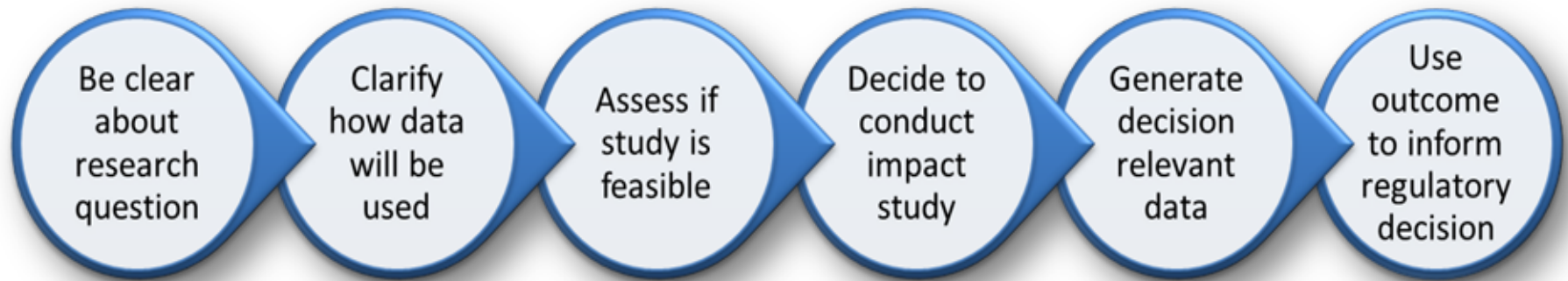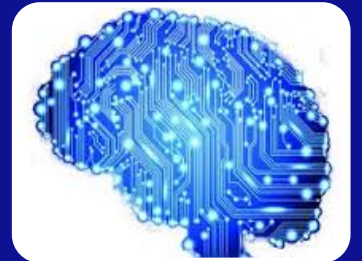
Prioritisation criteria

Public Health Importance

- Nature and severity of the risk
- Magnitude of the risk (relative and absolute)
- Level of Public Concern

Impact on Clinical Practice

- Extent of regulatory intervention
- Should it impact on clinical and/or patient behaviour
- Should it change the use of the product(s)

Decision Relevant Data

- Amenable to study
- Suitable data sources and methodologies available
- Fill gaps in knowledge

PRAC agenda items for prioritisation

Criteria to be applied to safety topics in the following areas:

- **Urgent EU referral procedures**
- **Other EU referral procedures**
- **Signals assessment and prioritisation**

Focus is on those where PRAC recommends **changes to Product Information and/or RMP** including:

- New contraindication(s),
- New warning(s),
- Restriction of the indication or
- Additional risk minimisation measures

To be reviewed after the pilot

- **Pilot duration:** 6 months starting with PRAC Plenary Dec'16
- **Pilot results** and revision of criteria as necessary: Q2/2017

Network Collaboration – moving forward

Continuous improvement of processes to maximise delivery

Collaborative targeted studies of key regulatory actions
- Generate data beyond that from MAHs
- Key considerations and criteria to inform identification
- PRAC selection + prioritisation

Timely decision relevant information