EU Regulator’s perspective

- Back to basics
- Innovative ways of working

Back to basics

- Scientific advice to companies developing new medicines
- Robust scrutiny of and decision making on any new applications for new medicines
- Collection and assessment of all data relevant to the benefits and risks of medicines already authorised
- Place obligations on the marketing authorisation holders to conduct studies
- Enforce obligations on the marketing authorisation holders to submit any data that might impact on the benefit risk
- Work to optimise product information for HCPs and patients (including Patient Information Leaflets)
- Maintain and increase transparency regarding regulation e.g.
  - Clinical trails
  - Adverse reactions reported
  - Non-interventional studies

Innovative ways of working

- Workshop brings together key stakeholders
- Regulators foster capacity building through networking, information sharing, best practice, tackling obstacles
- Regulators endorse a PML research agenda
- Regulators support the dissemination of research agenda to funding bodies

Conclusion

- By identifying what we know and what we don’t know
- By ensuring the research agenda is disseminated
- We can impact PML improving the balance of risks and benefits for patients needing powerful medicines.