Stephen Whitehead

ABPI Chief Executive Officer

The benefits of adaptive licencing

Meets the needs of patients through enabling earlier access to medicines

Increasing efficiency of the drug development process

Bridges the funding gap for SMEs

Can provide better evidence of value and potential for cost savings in healthcare

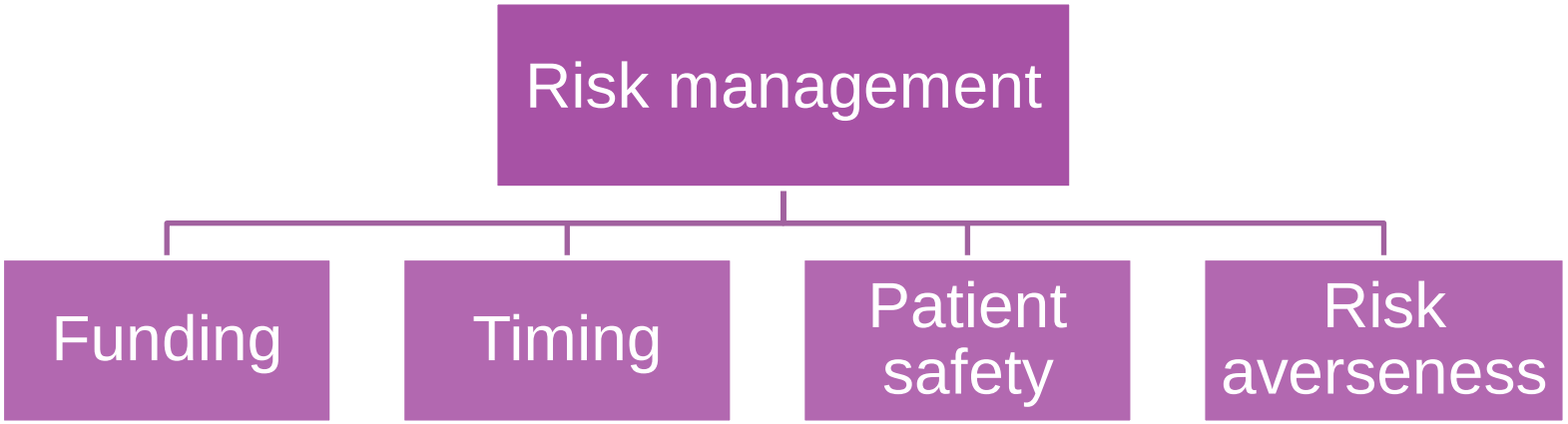
UK advantages through adaptive licencing

- ✓ The launch of the *Strategy for UK Life Sciences* in December 2011
- ✓ The UK has the MHRA – very progressive agency
- ✓ Having the European Medicines Agency based in London
- ✓ NICE – making joint advice from regulators and HTA attractive

MHRA
Regulating Medicines and Medical Devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Key challenges



Key challenges

Unclear Commissioning through evaluation

Regulatory/ operational

Affect of a Scientific Opinion on IP and data exclusivity

Exit strategy

Transparency around data

Questions on the use of Real World Evidence (RWE)

- **Where does value based assessment fit in the new system?**
  - How will this feed into pricing and reimbursement?
- **What type of RWE will regulators look for?**
- **Is the NHS fit for purpose?**
  - Are the systems in place to enable to collection of RWE required for the licensing process?
  - The Salford Lung Study – the benefits and hurdles

The patient is at the heart of the system

- ✓ Seeing pull through to patients
- ✓ Through patients we can drive the NHS to embrace innovation the regulators have already embraced
- ✓ Care.data and the use of data – we need to be trusted
- ✓ The patient voice – who is listening?
- ✓ If the patient is willing to take the risk – where does that leave the regulator and health service?

Thank you

abpi

Bringing medicines to *life*