

Stakeholder Feedback

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SMEs & Vaccine Industry

- **SME and academic role in vaccine research is important and is growing**
- **Vaccine R&D is particularly demanding:**
 - Safety fundamental
 - Paediatric market greater than adult
 - High unmet needs only addressable from new technologies
 - “Personalisation” from insights into diversity
 - SMEs do not have time/funding buffers

What do SMEs need?

- **Do not expect Regulatory fundamentals to vary by type of application organisation**
- **So focus has to be on:**
 - **Reducing cost/time/risk, which are central, interlinked challenges to SMEs**
 - **Innovation inherently cannot follow an established pathway**
- **SME Office: benefit from workshops & newsletters**

Positive experience - highlights

SME workshops

- **CMC regulatory compliance for biopharmaceuticals and advanced therapies - April 2015**
- **Scientific and Regulatory Advice - May 2011**
- **Regulatory considerations in initiating clinical trials - May 2010**
- **Paediatric Medicines - October 2009**

Possible vaccine-specific initiatives

Regulatory requirements/scientific advice

- Age descending strategies
- Maternal vaccines
- Challenge studies
- Universal flu
- Non-infectious disease targets
- Cancer vaccines