Alveolar macrophage changes in response to inhaled drugs: Factors distinguishing adaptive from adverse effects.

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Each axis appearing on the 2010-2020 HESI Combined Challenges Map is a continuum. All issues on the map are of high importance/impact based on prioritization by the participants in the 2009 HESI mapping exercise. "Relative impact" is a qualitative measure of importance among high priority topics. The location of issues along the "time" continuum is an approximation of when the topic is likely to become a major issue in the timeframe from 2010 to 2020.
A number of Pharmaceutical and/or Chemical companies, Not-for-profit Organizations, Public Sector organizations, Contract Research Organizations and Professional Societies have expressed their interest in this proposal.
Lung macrophage EI project

- An emerging human health/safety-related issue
- Tripartite interest
  - industry, government, academia
- **Key need** is a neutral tripartite forum
  - Free from conflicts of interest
  - Credibility to all participants
  - Transparent exchange
- Focused and tangible objective
- Deliverable (publication) in short term (≤2 years)

Fit with HESI

- Clearly within scope
- Clearly within scope
- HESI is **uniquely placed** to offer this key opportunity
- HESI-preferred
- HESI-preferred

Conclusion: An ideal fit with HESI
Benefits of this proposal

• Better basis for risk assessments – agreed approach between Industry & Regulatory Agencies
• Increased confidence in dose escalation in clinical studies
• Increased likelihood of achieving clinically efficacious doses
• Improve likelihood of bringing much needed medicines to market
• Potential spin-off benefits for risk assessments for other particulates
Alveolar macrophage changes in response to inhaled drugs: Factors distinguishing adaptive from adverse effects.

Conclusions

• 3 pronged approach:
  – Expert working group
  – Symposium
  – Consensus document

• Emerging human health and safety-related issue

• HESI ideal fit for developing neutral tripartite consensus
Questions & Discussion