ADRs / million adolescents

Placebo

- 30 get asthma within 24h
- 20 new diabetes within 1 week
- 100 hospitalized for autoimmune disease within 6 weeks

Placebo

Looks a dangerous drug
Decision Ahead
Proceed Slowly
cv ADRs
My Interest
Benefit: Risk Analysis
To Deliver Drug Safety / Benefit Research for Drug Regulation

We need to do things better and quicker and cheaper
Ill people take drugs
Ethically Defensible Case for Use of Un-consented Data

Drug Safety Research

Effectiveness to supplement Benefit / risk assessment

For the Regulation of Medicines
ENCePP Network

Steering Group ENCIAG
- Governance
- Scientific tasks

WG Inventory of ENCePP research centres

WG ENCePP research standards & guidance

ENCePP Secretariat

WG Inventory of EU data sources & multisource studies

WG Transparency & independence

Inventories
ENCePP research resources

EU data sources
DB 1, DB 2, DB 3,...

EU research institutions
C 1, C 2, C 3,...

http://www.encepp.eu/
“Investigators should develop and improve methods to help decision makers appraise the evidence”

Harveian oration at the Royal College of Physicians, London

www.rcplondon.ac.uk/pubs/brochure.aspx?e=262
Regulatory Science

Advancing the Science of Medicines Regulation: The Role of the 21st-Century Medicines Regulator

MM Lumpkin¹, H-G Eichler², A Breckenridge³, MA Hamburg¹, T Lönnberg²,5 and K Woods³,4

“Regulatory Science remains underfunded and underappreciated by government, industry and academia”

FDA Safety and Innovation Act
(increase rigor and consistency in regulatory decisions)

Harness diverse data through information sciences to improve health outcomes

THE SAME OLD THINKING ➔ THE SAME OLD RESULTS
Why are Academics not keen on Pharma Funding?

- Less (or no) kudos for industry studies
- Study design often 'fixed'
- Usually 'sponsored' by industry
- Institution keeps all the money
- Study question of limited interest
- Good publications 'difficult'
- Opportunity cost; less academic research
- Generates 'conflict of interest'
CONFLICT OF INTEREST IS A CRIME
Why I do ‘Industry Research’

- Industry studies: generate infrastructure
Academic 'Currency'

- Publications
- Peer review Grants
- Public Health
- Methodological expertise
- 'Opinion' leadership
- Reputation
Pharma ‘Currency’

• IP protection & exploitation
• Data on exposure & outcome
  - Emphasise good
  - Minimise bad
• ‘Control’ of the above
• Share price
Regulatory 'Currency'

- Excellent regulatory science to:
  - Generate robust data (and tools)
  - Underpin regulation
  - Manage benefit / risk throughout product lifecycle
- Promote public health
Raising the bar for Regulatory Science

- Utilise tried & trusted ‘peer review’ competitive grant award mechanisms
- Promote academic importance of regulatory science
- Stimulate innovation and excellence to create robust regulatory evidence
- Remove direct funding link between industry and academia
- Independent
HOW?
Suggested Voluntary System

• EMA decides on the data required to support regulation

• Industry offered the **option** to have regulatory requirement fulfilled by a voluntary scheme

• EMA partners with an ‘established’ scientific funding body (for example the Wellcome Trust)
Devil in Detail....

- Both EMA and Pharma agree to accept the recommended project(s) and costs
- Both live with the results
- Cost to include overheads
- Project ‘team’ to aid delivery
- Projects may deliver ‘added value’
- 10% to fund methodological research?
Advantages to Pharma

- ‘State of the art’ independent, peer-reviewed research that fulfils regulatory commitments
- Many academics interested
- Done at reasonable cost and time by opinion leader researchers
- Likely to be published in high impact journals
Advantages to EMA

- ‘State of the art’ independent, peer-reviewed research to support regulatory decision making
Advantages to Academics

• Regulatory science transformed into a ‘hot’ research topic in institutions
• Peer-reviewed grants, not Pharma
• Likely to be more publishable in high impact journals
• No conflicts of interest
Policy for handling conflicts of interest
Balancing Benefit & Risks
Yes, I believe there's a question?