Ninewells Hospital & Medical School

Central Mechanism for Industry Funded Studies

Tom MacDonald

ADRs / million adolescents

Placebo

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

Siegrist CA, Lewis EM, Eskola J, Evans SJ, Black SB.
Pediatr Infect Dis J 2007;26:979-84

Placebo

Looks a dangerous drug


Decision
Ahead
Proceed
Slowly

UNIVERSITY OF DUNDEE

MEMO

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

Mr Immortal Time Bias

Prof Sammy Suissa

Ethically Defensible Case for Use of Un-consented Data

Drug Safety Research

Effectiveness to supplement Benefit / risk assessment

For the Regulation of Medicines

Good Pharmacoepi Guidelines

International Society for Pharmacoepidemiology

Agenda | Registration | Sponsor/Exhibit Opportunities | Pre-Conference Courses | Poster/Presenter Guidelines | Travel/Hotel | Contact Us | ISPE Home

31st International Conference on Pharmacoepidemiology & Therapeutic Risk Management
August 22-26, 2015
Hynes Convention Center
Boston, MA USA

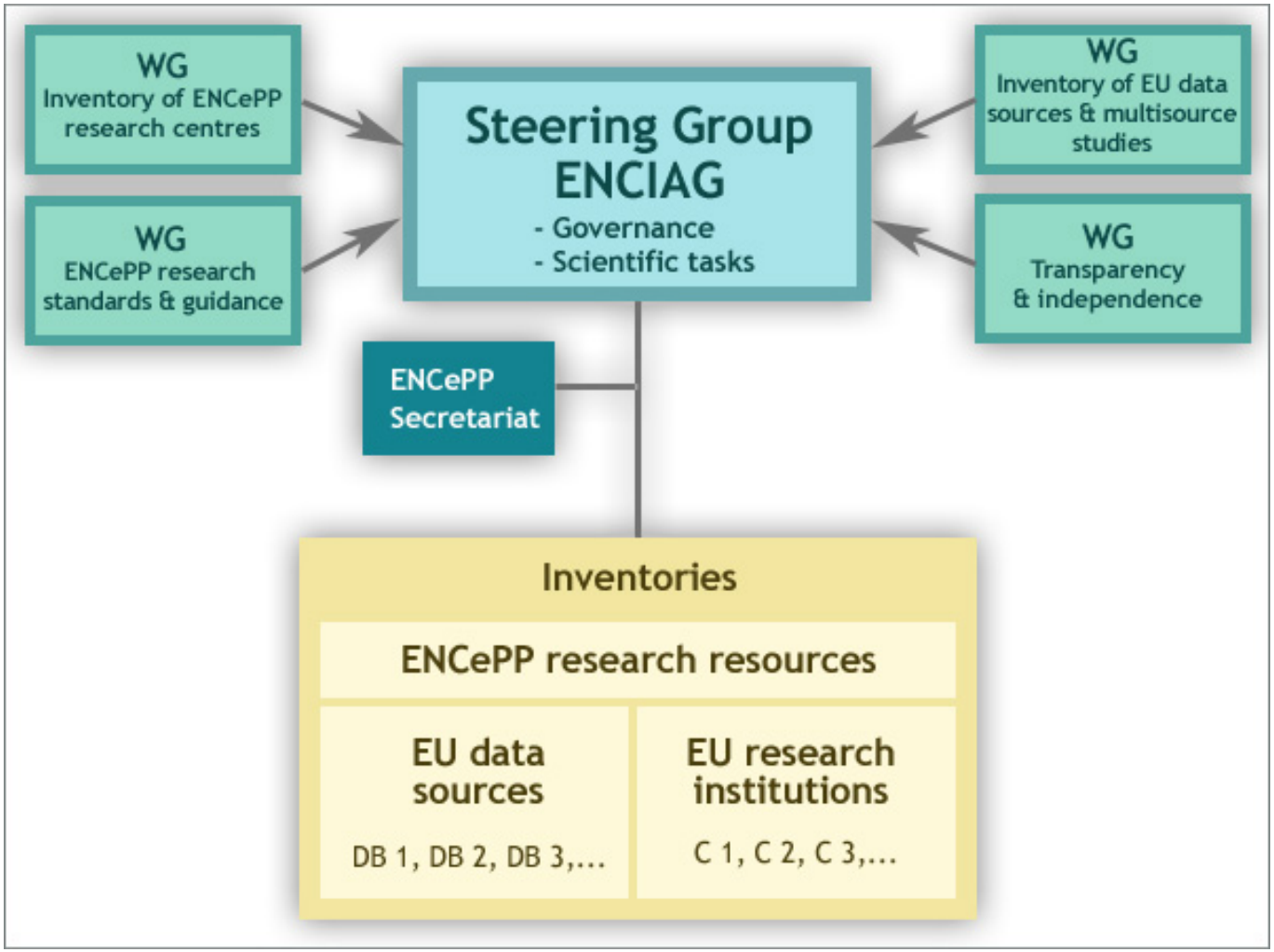
Jointly Sponsored By:

The International Society for Pharmacoepidemiology (ISPE)
Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine
Harvard Medical School and Brigham and Women's Hospital
Pharmacoepidemiology Program at the Harvard School of Public Health

ISPE INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY | DoPE BWH | HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH | BU Slone Epidemiology Center

Invitations have gone out to all current ISPE members to review abstracts submitted for presentation at ISPE's 31st International Conference on Pharmacoepidemiology and Therapeutic Risk Management (ICPE). If you did not receive an invitation please contact c4asupport@coetruman.com.

ENCePP Network



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 Lumpkin[1], H-G Eichler[2], A Breckenridge[3], MA Hamburg[1], T Lönngren[2,5] and K Woods[3,4]

"Regulatory Science remains underfunded and underappreciated by government, industry and academia"

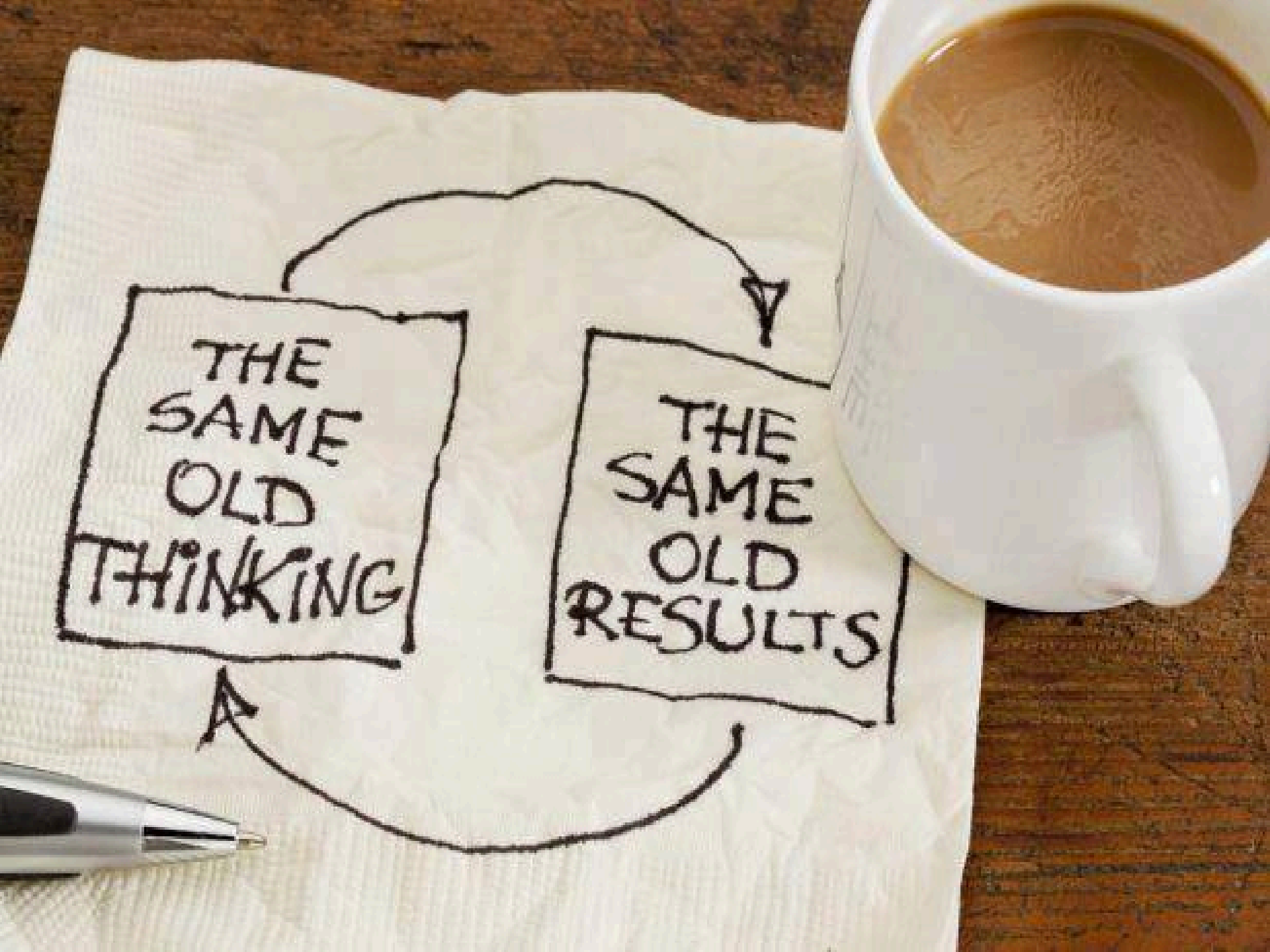
Clin Pharmacol Ther 2012;92:486-93.

FDA Safety and Innovation Act

(increase rigor and consistency in regulatory decisions)

Harness diverse data through information sciences to improve health outcomes

www.fda.gov/downloads/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FDASIA/UCM446236.pdf


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)

Pharma

€

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

€

wellcome trust

CALL FOR RESEARCH PROPOSALS

Recommended for funding

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

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Policy for handling conflicts of interest


Balancing Benefit & Risks

Yes, I believe there's a question?