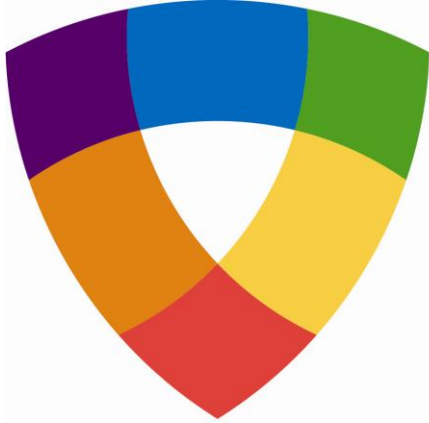

Building a Collaborative Team to Support Safety Science



**CSRC Annual Meeting
December 12 2013
Washington DC**

***Syril D Pettit
HESI Executive Director***

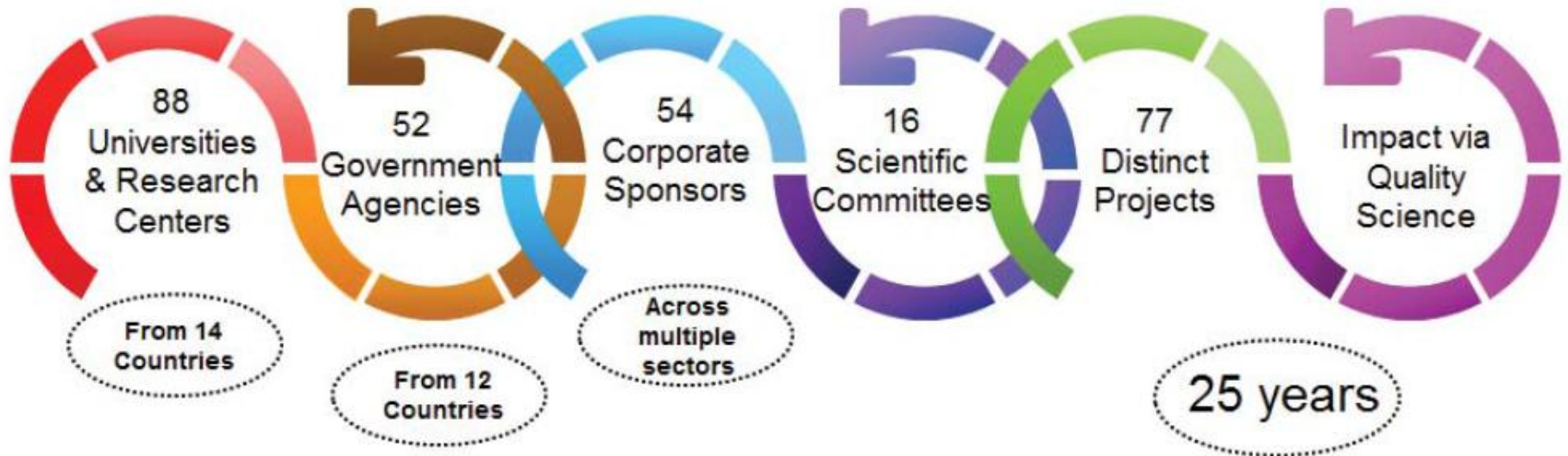
ILSI Health and
Environmental Sciences
Institute

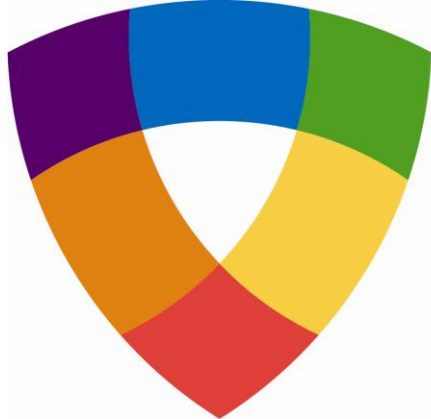


HESI:

Science for a Safer World

HESI[®]





HESI®

HESI: *Science for a Safer World*



HESI Technical
Committee

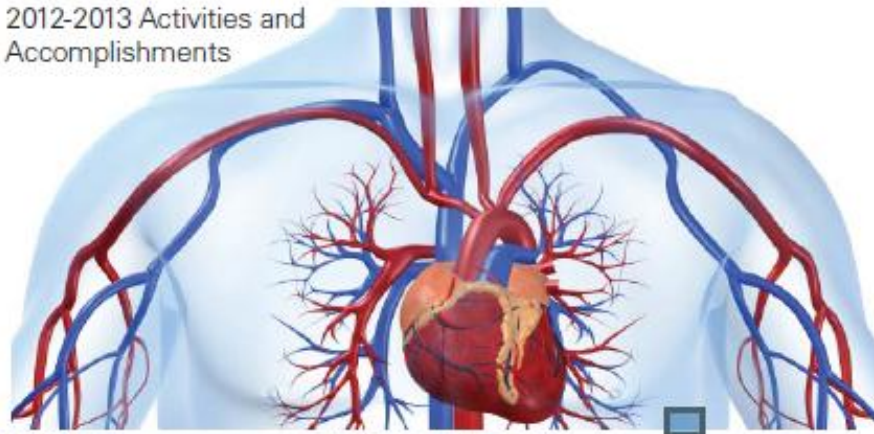
CARDIAC SAFETY

Committee leaders:
Dr. Brian Berridge
GlaxoSmithKline

Dr. Kevin Dreher
US Environmental
Protection Agency

HESI managers:
Syril D. Pettit, MEM
Jennifer B. Pierson, MPH

2012-2013 Activities and
Accomplishments



This scientific program is committed to:

Improving public health through modeling and early detection of adverse cardiovascular risks. The committee develops best practices for translation of *in vitro* and nonclinical cardiovascular data bridging technical disciplines; public, private, and government sectors; and nonclinical safety assessment communities.

Areas of scientific focus:

Key accomplishments:

- **Proarrhythmia.** The committee completed the first phase of the proarrhythmia project to assess concordance between nonclinical and clinical data (150 compounds) submitted to the FDA as NDAs and INDs. This is the only example of a joint public-private effort to analyze data from behind a regulatory agency firewall.
- **Contractility.** A series of multi-site experimental studies to evaluate the sensitivity and reproducibility of canine



CIPA Paradigm

Successful Integration

Existing

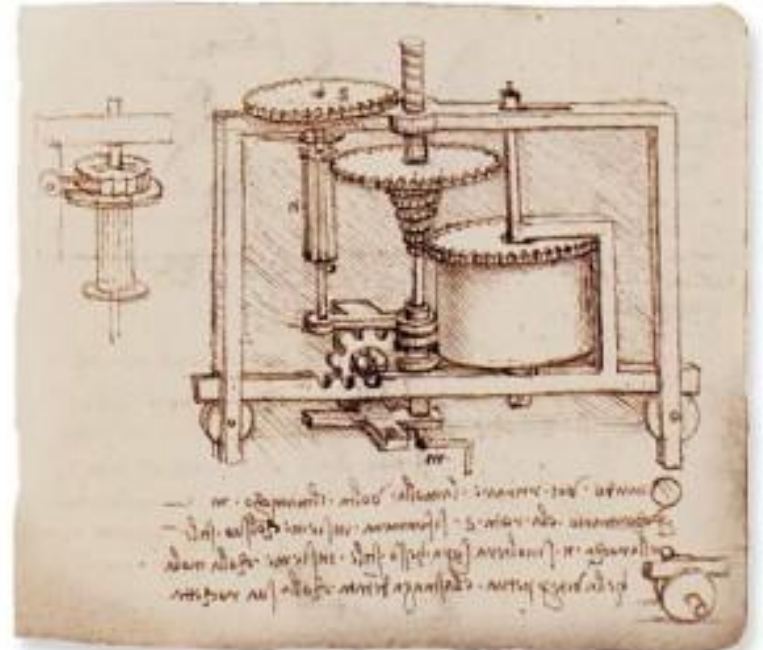
- Best Practice/Protocols
- Data
- Experience

New

- Consensus expert opinion
- Experimental data
- Technologies & models
- Protocols and Metrics
- Vetting & Validation

Across Communities of Practice

- Pharma industry
- Biotech/CROs
- Academe
- Clinical Medicine
- Regulatory
- Multi-disciplinary





Cardiac Safety Research Consortium



HESI



Health
Canada

Santé
Canada



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



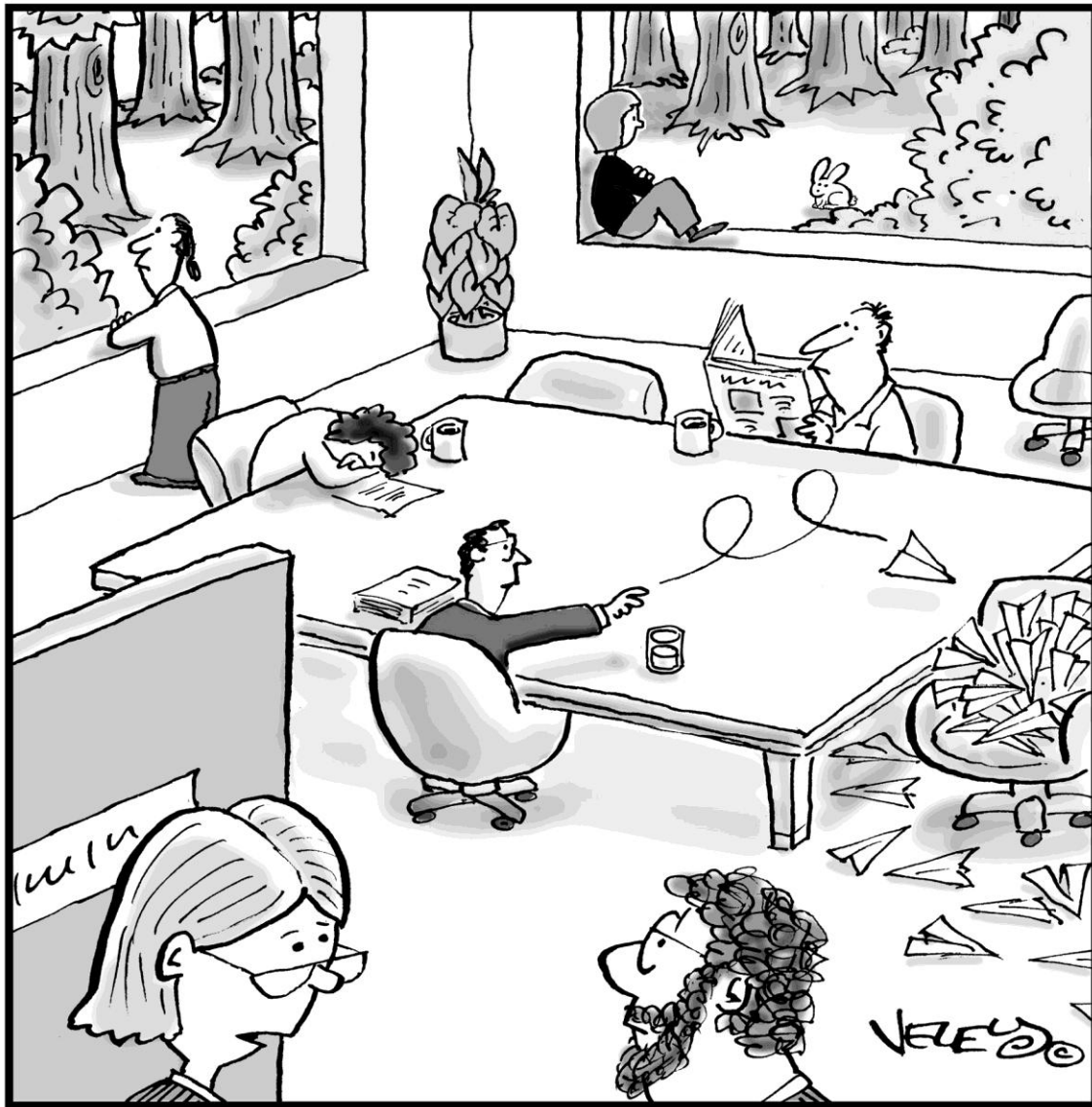
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Environmental Sciences
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Opportunity for Synergy, Resource & Labor Sharing, Innovative Thinking Across Disciplines

Or...



ILSI Health and
Environmental Sciences
Institute



“We like to bring together people from radically different fields and wait for the friction to produce heat, light and magic. Sometimes it takes a while.”

Turning the Crank...

- Work streams
 - In Silico, Ion Channel, Myocyte, Regulatory, Steering Team
- Topical area leads
- Coordination and cross-stream interaction



Work Stream Remits

- *In Silico* – model design, execution, feedback and vetting;
- *Ion Channel* – channel selection, protocol development, novel data generation to test model;
- *Stem Cell Myocyte* – protocols, platforms and validation.
- *Regulatory* – model design and validation compound selection, arrhythmia metrics, ECG assessment
- *Steering Team* – Coordination and integration



CIPA Steering Team

| Name | Organization | Representing | Work Stream Represented |
|----------------------|---------------|-------------------------------|--|
| Norman Stockbridge | FDA | US Regulators | All |
| Tom Colatsky | FDA | US Regulators | In Silico Work Stream |
| Gary Gintant | AbbVie | Pharm/Non-clinical community | All |
| Hugo Vargas | Amgen | Pharma/SPS | Ion Channel Work Stream |
| Derek Leishman | Lilly | Pharma/SPS | Ion Channel Work Stream |
| Jean-Pierre Valentin | AZ | Pharma/Non-clinical community | Ion Channel Work Stream, Regulatory Work Stream |
| Philip Sager | CSRC | Clinical Community | Regulatory Work Stream, Ion Channel Work Stream |
| Jiwen Zhang | GE Healthcare | Pharma/Stem Cell Community | Myocyte Work Stream |
| Krishna Prasad | EMA | Non-US Regulators | Regulatory Work Stream |
| Colette Strnadova | Health Canada | Non-US Regulators | Regulatory Work Stream |
| Natalia Trayanova | Johns Hopkins | Modeling Community | In Silico Work Stream |
| Sybil Pettit | HESI | HESI Cardiac Safety Committee | All |
| Jennifer Pierson | HESI | HESI Cardiac Safety Committee | All |



For more information

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