




# RISK21 Risk Assessment Summit

February 18-19, 2020

Washington, DC

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HESI Executive Director





The purpose of information is not knowledge. It is being able to take the right action.



-Peter Drucker

# The HESI Model: Bridging Research to Application

**30**  
THIRTY YEARS  
**HESI**

*Science for a Safer,  
More Sustainable World*

IMPROVED

## SAFETY AND INNOVATION FOR HUMAN AND ENVIRONMENTAL HEALTH



Academic, Clinical,  
& Research Scientists  
& Organizations



Industry  
Research &  
Development



NGOs, Patient  
Advocacy Groups,  
& Foundations



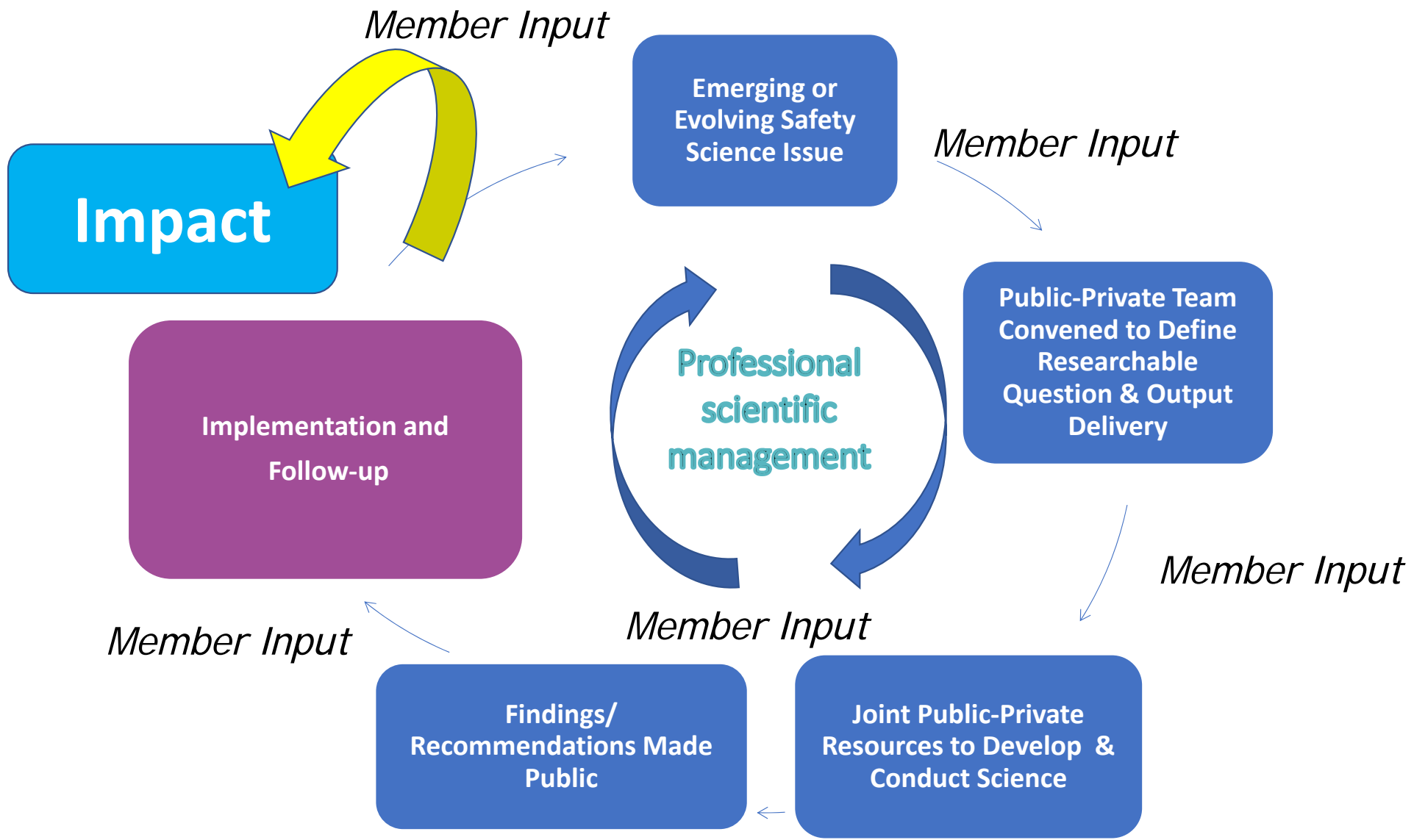
Government  
Research &  
Regulation





### HESI Participation & Support

- 65% Public Sector
- 35% Private Sector
- >250 Active Partner Organizations, >600 scientists
- Research Program Funding from Both Public & Private



## HESI Project Mechanisms



DECISION FRAMEWORKS



DATA SHARING & COLLECTIVE ANALYSIS



NOVEL EXPERIMENTAL STUDIES



MANUSCRIPTS



TOOL / ASSAY DEVELOPMENT

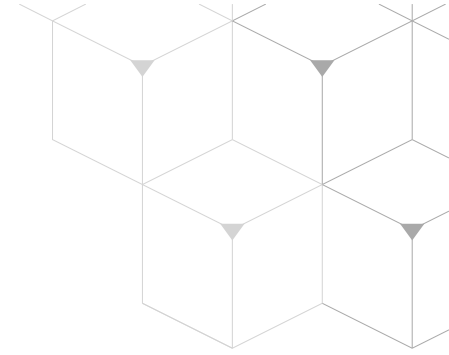


SCIENTIFIC MEETINGS & TRAININGS





## A Broad Reach Across Human and Environmental Health





## What impacts do HESI's Programs Have?

 Enhanced efficiency and accuracy in safety assessment

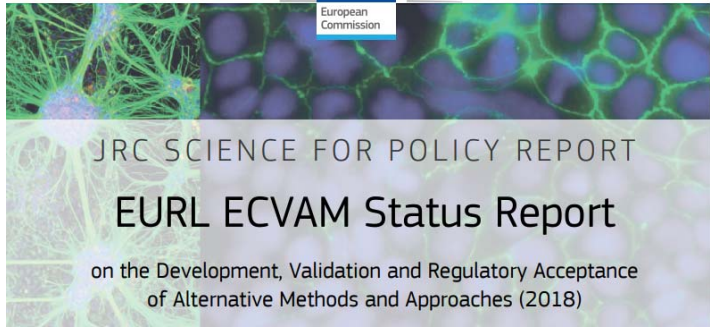
 Enhanced societal knowledge base of biological and environmental processes relevant to protect human and ecological health

 Catalysis of new science

 Increased audiences for collaborative safety science

 Development of scientists skilled in translational science





MOU 225-19-

Over 335 peer-reviewed publications from HESI scientific programs have been published over the last 30 years, with more than 100 publications in the last decade.

HESI citations by the numbers:



**MEMORANDUM OF UNDERSTANDING**  
 Among  
**The Food and Drug Administration (FDA)**  
 And  
**The National Institutes of Health**  
**National Institute of Environmental Health Sciences (NIEHS),**  
**Division of the National Toxicology Program (NTP)**  
 And  
**Health and Environmental Sciences Institute (HESI)**

MEMORANDUM OF UNDERSTANDING  
 BETWEEN  
 U.S. ENVIRONMENTAL PROTECTION AGENCY  
 AND  
 HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE

**I. PURPOSE**  
 Cardiovascular safety is a significant public health concern and challenge for those seeking to improve development and understanding of new drugs.

Environmental Protection Agency (EPA or the Agency) and the International Life Sciences Institute (ILSI) Health and Environmental Sciences Institute (HESI) (collectively, "Parties") are entering into this Memorandum of Understanding (MOU) to facilitate the exchange of scientific progress through the exchange of scientific capital to address the challenge of cardiovascular safety.

## CDER Biomarker Qualification Program



OECD Home About Countries Topics

OECD Home > Chemical safety and biosafety > Testing of chemicals > OECD Test Guidelines Programme

Testing of chemicals

### OECD Test Guidelines Programme

**Biomarker Qualification Program**

Qualified biomarkers can make drug development more efficient.

FDA





HESI.

# RISK ASSESSMENT SUMMIT

18-19 February 2020

Bringing together the  
'climbing community'

*(aka risk assessors who for whom this isn't a  
theoretical exercise!)*



Our Challenge: Use this opportunity to share hands-on experience to...

- Refine toolkits and techniques
- Identify new ways to 'climb'
- Improve our ability to use information to 'take the right action'