

Health and Environmental Sciences Institute

hesiglobal.org



) HESI

- Non-profit scientific foundation based in Washington, DC, USA
- Operating <u>internationally</u> for over 30 years

HESI: Science for a Safer, More Sustainable World

CONVENE. TRANSLATE. PROTECT.

FOR HUMAN AND ENVIRONMENTAL HEALTH



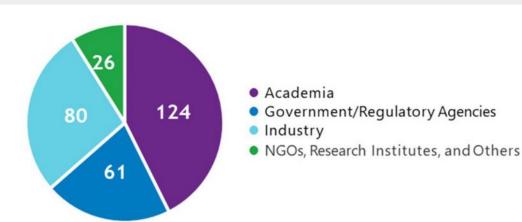


2020 Balance of Engagement & Resourcing

Engagement

291 partner organizations

- ~71% public sector organizations
- ~29% private sector organizations





Grants will extend into 2021

New grants submitted

New grant opportunities pending



SCIENTIFIC FOCUS AREAS



ACCURATE AND EFFICIENT CHEMICAL RISK ASSESSMENT



SAFE AND EFFECTIVE **MEDICINES**



ENVIRONMENTAL QUALITY AND SUSTAINABILITY

FOOD SAFETY

COMMITTEES

Animal Alternatives in Environmental Risk Assessment

Botanical Safety Consortium

Cardiac Safety

Cell Therapy – TRAcking, Circulation and Safety (CT-TRACS)

Collaboration on Ototoxicity Risk Assessment (CORA)

Development of Methods for a Tiered Approach to Assessment the Bioaccumulation of Chemicals

Developmental and Reproductive Toxicology (DART)

Emerging Systems Toxicology for the Assessment of Risk (eSTAR)

Environmental Epidemiology for Risk Assessment

Genetic Toxicology

Immuno-Safety

Multi-Component Substances (MCS) and UVCBs

PBPK Models

Protein Allergens, Toxins and Bioinformatics (PATB) and the **COMPARE** database

Risk Assessment in the 21st Century (RISK21)

Transforming the Evaluation of Agrochemicals (TEA)

Translational Biomarkers of Neurotoxicity (NeuTox)

PROJECT MECHANISMS



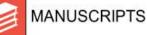
DECISION FRAMEWORKS



DATA SHARING & COLLECTIVE ANALYSIS



NOVEL EXPERIMENTAL STUDIES





TOOL / ASSAY DEVELOPMENT



SCIENTIFIC MEETINGS & TRAININGS



What Impacts Do HESI Programs Have?

ENHANCED EFFICIENCY & ACCURACY IN SAFETY ASSESSMENT

• By generating science that improves practices in drug development in companies, research labs, & in regulatory practice/policy

ENHANCED SOCIETAL KNOWLEDGE BASE OF BIOLOGICAL & ENVIRONMENTAL PROCESSES RELEVANT TO PROTECTING HUMAN & ECOLOGICAL HEALTH

• Through conducting & publishing novel laboratory studies on mechanisms of toxicity, biomarkers of effect, models of disease, etc.

CATALYSIS OF NEW SCIENCE

• By bringing together partners to synergize ongoing research, share resources, & develop efficient, innovative, & impactful study design & analysis

INCREASED AUDIENCES FOR COLLABORATIVE SAFETY SCIENCE

• By demonstrating the critical impact of bringing together academic, government, & industry scientists across different technical disciplines to improve public health

DEVELOPMENT OF SCIENTISTS SKILLED IN TRANSLATIONAL SCIENCE

• Through training & outreach

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HESI's Google Scholar Page

- https://scholar.google.com/citati ons?user=Vmk5S9YAAAAJ&hl=en
- H-index is the maximum value of H such that the given author has published H papers that have each been cited at least H times
- A good H-index score depends not only on a prolific output but also on a large number of citations by other authors
- Our H-index is considered high & represents a collective of HESI authors

	All	Since 2016
Citations	24871	10862
h-index	83	48
i10-index	304	232
		2100
t H H	ш	1575
		1050
HH		- 525
2014 2015 2016	2017 2018 2019	2020 2021 0

HESI's science is a key reference point for...

- ICH S1, S7, E14, S5, S2, S8, S11
- OECD (Genetox, PBPK, Bioaccumulation)
- Regulatory & research agency scientific strategy & resource evaluation
- US FDA
- PMDA (Japan) via active HESI involvement
- European Commission reports & discussions
- Brazilian risk assessment methods
- Canadian risk assessment methods
- And more!

Enhanced Efficiency & Accuracy in Safety Assessment



Increased Audiences for Collaborative Safety Science



In 2020 into 2021, HESI has simultaneous, active, programmatic participation & engagement from North America, South America, Europe, Asia, Oceana (Australia), & Africa



Why Join HESI?

Opportunity to BUILD SCIENTIFIC NETWORKS AND PROFESSIONAL DEVELOPMENT for your staff

Opportunity to LEVERAGE RESOURCES by pooling data, expertise, funding, and lab facilities across partner organizations

Opportunity to ACTIVELY CONTRIBUTE TO DISCUSSIONS AND DATA GENERATION/EVALUATION THAT IMPACTS GLOBAL SAFETY ASSESSMENT PRACTICES

EXPOSURE to global best practices, evolving drug/development safety issues and discussions, etc.

Opportunity to **COLLABORATE** with academic, regulatory, clinical, and other industry scientists working on issues that matter to your scientific portfolio



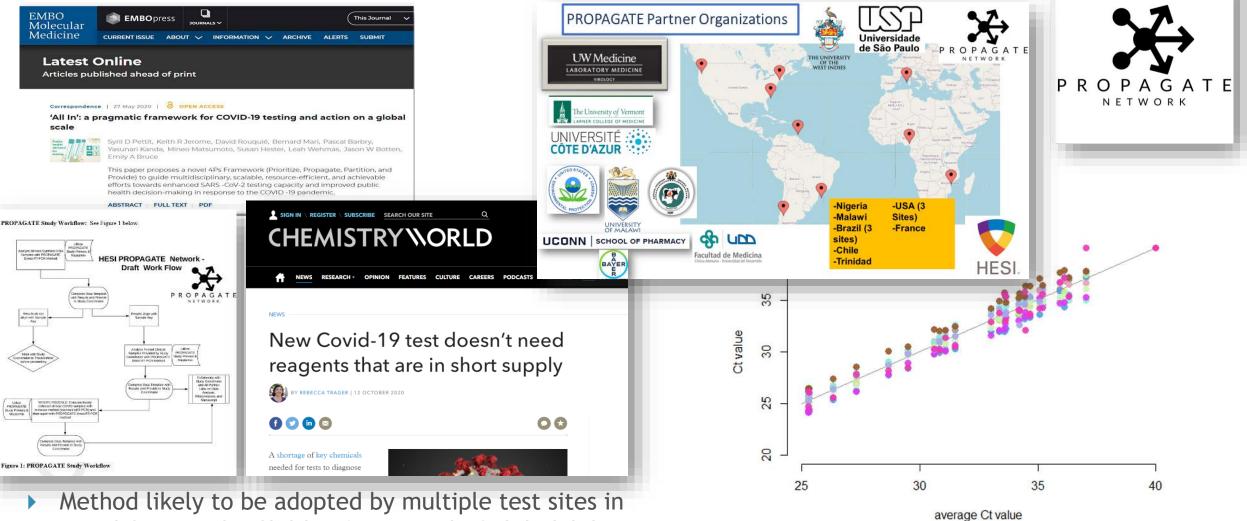


Facilitating New Science: Moving science from the idea stage to the implementation stage

The adoption of new programs & projects allows HESI to address the most relevant emerging science & serve as a contemporary resource for our stakeholders



PROPAGATE Network – A HESI Initiative to Advance Global Health Equity Through Efficient & Accurate Methods



- Brazil & in use by Children's Hospital of Philadelphia
- Example of HESI innovation & public benefit

Figure 1. Ct values plotted against the sample-specific average Ct values from the 10 laboratories. The solid line indicates the line of equation y = x. Each color indicates one laboratory; a same color is used to identify a same laboratory in all plots of the report.

Joining HESI

Sponsorship Fee Schedule in US Dollars

Worldwide Sales	Base Fee	
Less than \$5 Million dollars	\$800	
\$5 Million to \$49.99 Million	\$3,000	
\$50 million to \$499 million	\$5,400	
\$500 million to \$999 million	\$10,800	
\$1 billion to 1.99 billion	\$16,200 + (\$5,400 *billion over 1 billion)	
\$2 billion to 4.99 billion	\$21,600 + (\$1,800 * billion over 2 billion)	
\$5 billion to 9.99 billion	\$27,000 + (\$860 * billion over 5 billion)	
\$10 billion to 19.99 billion	\$31,300 + (\$290 * billion over 10 billion)	
\$20 billion to 29.99 billion	\$34,200 + (\$490 * billion over 20 billion)	
\$30 billion to 39.99 billion	\$39,100 + (\$490 * billion over 30 billion)	
\$40 billion to 99.999 billion	\$44,000 + (\$102 * billion over 40 billion)	
\$100 billion and above	\$50,100	

- Information on joining HESI is available here: <u>hesiglobal.org/sponsorship-</u> <u>application</u>
- Participation requires becoming a HESI sponsor and then selecting (and paying for) the scientific programs in which your organization would like to participate on an annual basis. Participation fees cover as many scientists as you would like to join for the same fee

Agricultural Chemical Safety Assessment (ACSA) 2.0 Committee - \$10,000 Animal Alternatives in Environmental Risk Assessment Committee - \$12,000 Application of Environmental Epidemiology in Risk Assessment and Decision-Making Committee - \$10,000 Bioaccumulation of Chemicals Committee - \$12,000 Cardiac Safety Committee - \$7,000 COMPARE Allergen Database - \$35,000 CT-TRACS Committee (Cell Therapy – TRAcking, Circulation, & Safety) - \$10,000 Development of a Tiered Approach for UVCB Ecological Risk Assessment Committee -\$12,000 Developmental and Reproductive Toxicology (DART) Committee - \$10,000 Emerging Systems Toxicology for Assessment of Risk (eSTAR) Committee- \$8,000 Genetic Toxicity Technical Committee - \$10,000 Immuno-Safety Technical Committee - \$9,000 PBPK Modeling Platforms Committee - \$10,000 Protein Allergens, Toxins, and Bioinformatics (PATB) Committee - \$25,000 Risk Assessment for the 21st Century (Risk 21) Committee - \$15,000 Translational Biomarkers of Neurotoxicity Committee - \$7,000 Select All

How Can I Learn More About HESI's Scientific Programs?

- An overview of recent efforts is available in HESI's 2020 Annual Report
- Contact HESI's Executive Director, Dr. Syril Pettit (<u>spettit@hesiglobal.org</u>), for more information
- Propose a webinar or in-person meeting to discuss HESI programs and opportunities for participation
- hesiglobal.org

Thank you for your interest! We look forward to speaking with you further.

