



Health and Environmental Sciences Institute (HESI)

hesiglobal.org

Health and Environmental Sciences Institute (HESI)

- ▶ Non-profit scientific foundation based in Washington, DC, USA
- ▶ Operating internationally for 30+ years



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**



2020 Balance of Engagement & Resourcing

2020 Balance of Engagement

- ▶ 291 partner organizations
- ▶ ~71% public sector organizations
- ▶ ~29% private sector organizations

291 PARTNERS



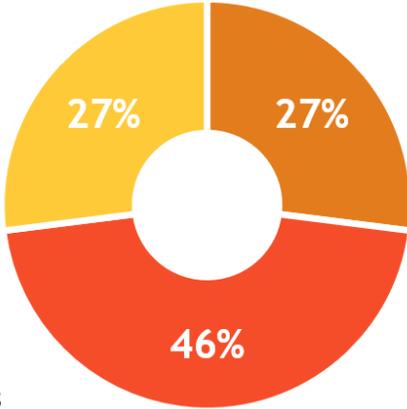
2020 Balance of Resourcing

- ▶ Grants will extent into 2021
- ▶ New grants submitted
- ▶ New grant opportunities pending

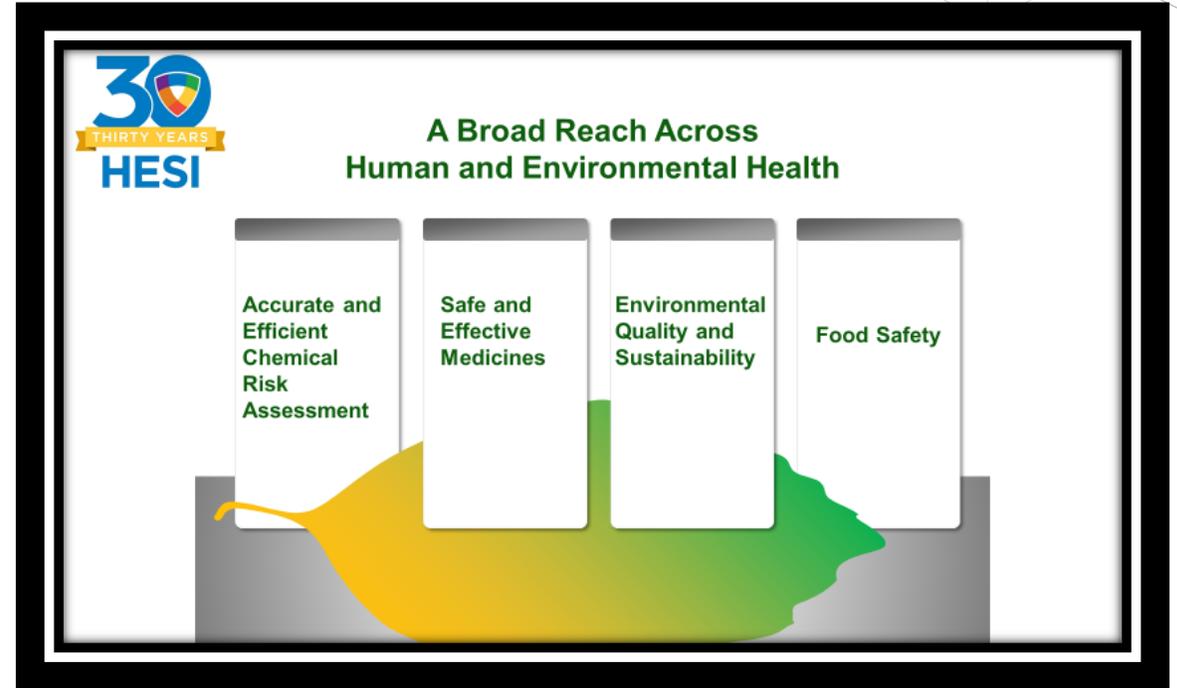
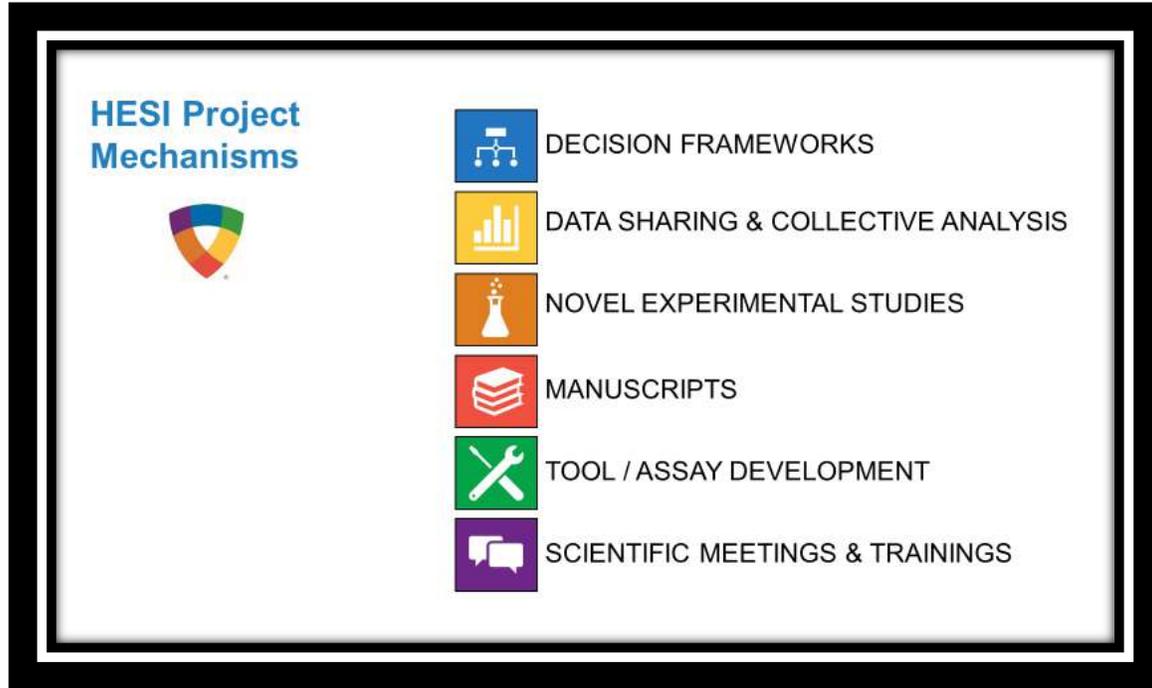


2020 FUNDING SOURCES

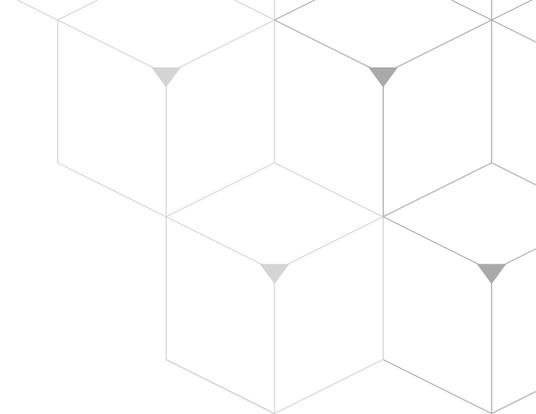
- Committee Dues
- Grants
- Corporate Sponsorships



HESI Scientific Focus Areas & Program Management



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*

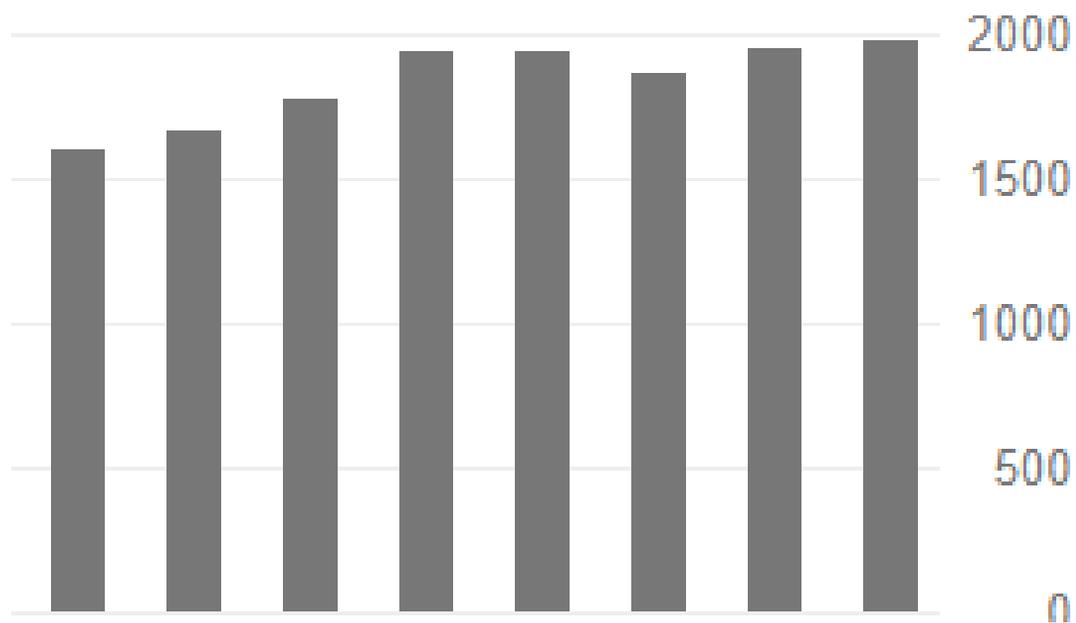


Development of scientists skilled in translational science

- ▶ *Through training and outreach*



	All	Since 2015
Citations	23431	11468
h-index	81	50
i10-index	284	224



HESI's Google Scholar Page

- ▶ <https://scholar.google.com/citations?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

Enhanced Efficiency & Accuracy in Safety Assessment

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



Increased Audiences for Collaborative Safety Science

- ▶ For the first time in our history:
 - In 2020 into 2021, HESI has simultaneous, active, programmatic participation & engagement from North America, South America, Europe, Asia, Oceania (Australia), and Africa



Facilitating New Science



- ▶ The adoption of new programs & projects allows HESI to address the most relevant emerging science & serve as a contemporary resource for our stakeholders
- ▶ The figure to the left illustrates our role in moving science from the idea stage to the implementation stage

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

EMBO Molecular Medicine | EMBOpress | JOURNALS | This Journal

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Latest Online
Articles published ahead of print

Correspondence | 27 May 2020 | OPEN ACCESS

'All In': a pragmatic framework for COVID-19 testing and action on a global scale

Syril D Pettit, Keith R Jerome, David Rouquié, Bernard Mari, Pascal Barbry, Yasunari Kanda, Mineo Matsumoto, Susan Hester, Leah Wehmas, Jason W Botten, Emily A Bruce

This paper proposes a novel 4Ps Framework (Prioritize, Propagate, Partition, and Provide) to guide multidisciplinary, scalable, resource-efficient, and achievable efforts towards enhanced SARS-CoV-2 testing capacity and improved public health decision-making in response to the COVID-19 pandemic.

ABSTRACT | FULL TEXT | PDF

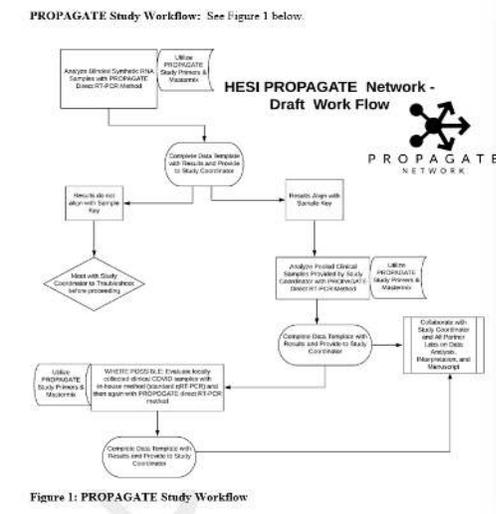
PROPAGATE Partner Organizations

- UW Medicine LABORATORY MEDICINE VIROLOGY
- The University of Vermont LARNER COLLEGE OF MEDICINE
- UNIVERSITÉ CÔTE D'AZUR
- UNIVERSITY OF THE WEST INDIES
- USP Universidade de São Paulo
- THE UNIVERSITY OF MALAWI
- UConn | SCHOOL OF PHARMACY
- UNIVERSITY OF MALAWI
- Facultad de Medicina Universidad del Ecuador
- HESI

Map showing global locations of partner organizations with red pins.

Legend:

- Nigeria
- Malawi
- Brazil (3 sites)
- Chile
- Trinidad
- USA (3 Sites)
- France



CHEMISTRY WORLD

NEWS RESEARCH OPINION FEATURES CULTURE CAREERS PODCASTS

NEWS

New Covid-19 test doesn't need reagents that are in short supply

BY REBECCA TRAGER | 12 OCTOBER 2020

A shortage of key chemicals needed for tests to diagnose

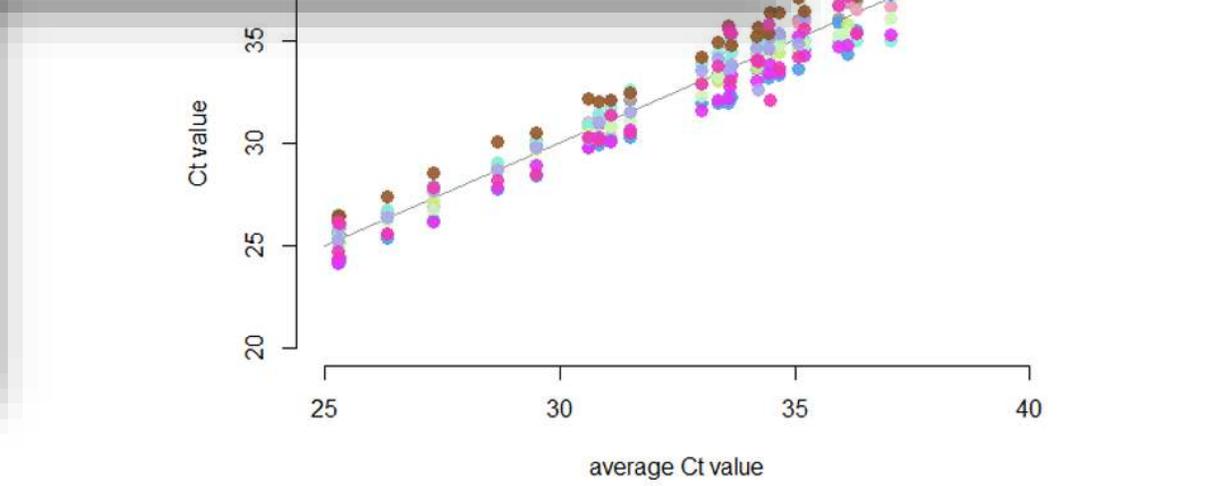
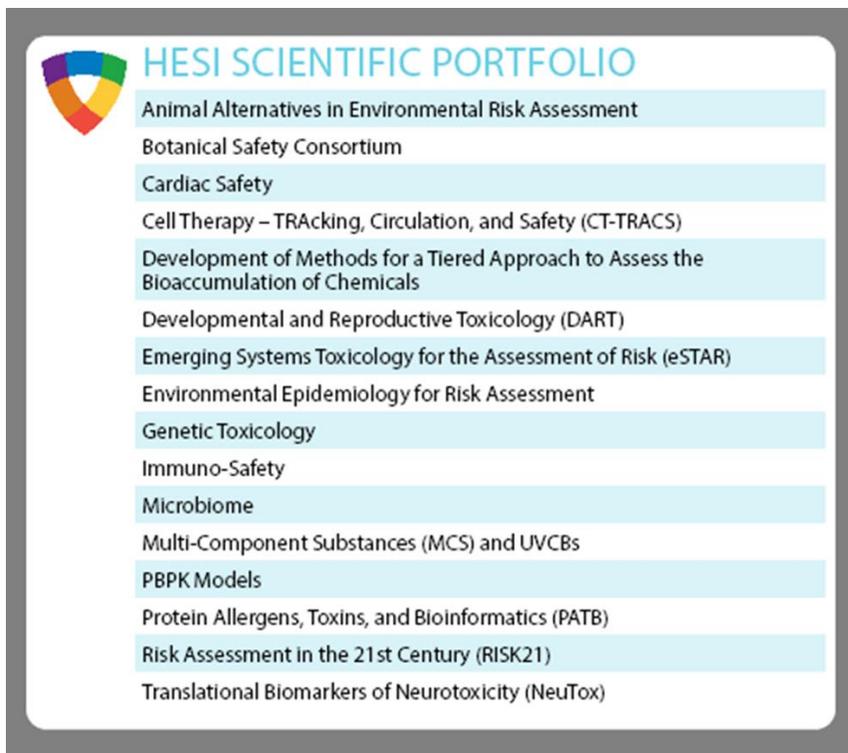


Figure 1. Ct values plotted against the sample-specific average Ct values from the 10 laboratories. The solid line indicates the line of equation $y = x$. Each color indicates one laboratory; a same color is used to identify a same laboratory in all plots of the report.

- ▶ Paper to press in next few weeks
- ▶ Method likely to be adopted by multiple test sites in Brazil & in use by Children's Hospital of Philadelphia
- ▶ Example of HESI innovation & public benefit

Joining HESI



HESI SCIENTIFIC PORTFOLIO

- Animal Alternatives in Environmental Risk Assessment
- Botanical Safety Consortium
- Cardiac Safety
- Cell Therapy – TRACKing, Circulation, and Safety (CT-TRACS)
- Development of Methods for a Tiered Approach to Assess 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
- Microbiome
- Multi-Component Substances (MCS) and UVCBs
- PBPK Models
- Protein Allergens, Toxins, and Bioinformatics (PATB)
- Risk Assessment in the 21st Century (RISK21)
- Translational Biomarkers of Neurotoxicity (NeuTox)

- ▶ Information on joining HESI is available here: hesiglobal.org/sponsorship-application
- ▶ 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.

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

- 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

Why Join HESI?

- ▶ Opportunity to collaborate with academic, regulatory, clinical, and other industry scientists working on issues that matter to your scientific portfolio
- ▶ Exposure to global best practices, evolving drug/development safety issues and discussions, etc.
- ▶ Opportunity to actively contribute to discussions and data generation/evaluation that impacts global safety assessment practices for drugs (HESI programs actively generate data and insights that inform ICH guidelines and have active participation from FDA, EMA, PMDA, and others)
- ▶ Opportunity to leverage resources by pooling data, expertise, funding, and lab facilities across partner organizations
- ▶ Opportunity to build scientific networks and professional development for your staff

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

- ▶ An overview of most recent efforts is available in [HESI's 2020 Annual Report](#)
- ▶ You may contact HESI's Executive Director – Cyril Pettit, DrPH (spettit@hesiglobal.org) – 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