Health and Environmental Sciences Institute: the success of tripartite research initiatives

October 24, 2019
NCAC-SOT Symposium

Dr. Stan Parish
Senior Scientific Program Manager - HESI
Health and Environmental Sciences Institute (HESI)

- Non-profit scientific foundation based in Washington DC USA
- Operating Internationally
HESI: Creating Science for Safer, More Sustainable World
The HESI Model: Bridging Research to Application

IMPROVED SAFETY and INNOVATION FOR HUMAN and ENVIRONMENTAL HEALTH

Academic, Clinical, & Research Scientists & Organizations

Industry Research & Development

NGOs, Patient Advocacy Groups, & Foundations

HESI Scientific Staff

Government Research & Regulation
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<tr>
<td>Universities, Research Institutes, and Scientific Foundations</td>
<td>150</td>
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<td>Government Agencies &amp; Institutes</td>
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<td>Private Sector Companies with Scientific Staff</td>
<td>70</td>
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<td>Scientific Committees in Human &amp; Env Health</td>
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<td>Scientific Project Areas</td>
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More than 600 scientists around the globe participating in HESI work on ongoing basis throughout the year.
HESI PROCESS

Emerging or Evolving Safety Science Issue

Public-Private Team Convened to Define Researchable Question & Output Delivery

Joint Public-Private Resources to Develop & Conduct Science

Findings/Recommendations Made Public

Implementation and Follow-up

Professional scientific management

Impact

Member Input
How do we know the model works?
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:
- 20,000 total citations
- 3,600+ scientific journals citing HESI work
- 1,600+ citing organizations
- 75 citing countries

Impact Via Publication Uptake

Citations for HESI Publications by Year

Types of Organizational Affiliations for Lead Citing Authors
- Nonprofit
- Academic
- Private
- Gov

In a survey of 150 HESI participants, HESI’s scientific programs and publications have:

- Influenced their approach to safety or risk assessment decision-making; 70%
- Influenced their level of confidence in the use of particular technologies, markers, endpoints, or analysis approaches; 80%
Impacting Global Health Through Global Health Agencies

CIPA

OECD

ICH

Safety Guidelines

Impact via Science Adopted at the Global Level
Cisapride withdrawn because of cardiac side effects

Major reduction (elimination?) in unanticipated QT prolonging drugs to market

Impact via Improved Public Health

ICH S7b - 2005
Let's Look at Some Current Programs
Improve public health by reducing unanticipated cardiovascular-related adverse effects from drugs or chemicals

Early detection and prediction, improved understanding of cardiovascular toxicology and pathobiology
Can we improve public access to safe medicines by creating a NEW SYSTEM for evaluating potential cardiac risk??

Drug development pipeline

Development Candidates

MULTI CHANNEL ASSESSMENT

CIPA

Drug development pipeline

Building a New Paradigm for CV Arrhythmia Safety via CIPA

Comprehensive In Vitro Proarrhythmia Assay: Four Defined Technical Components

Drug Effects on Multiple Human Cardiac Currents

In Silico Reconstruction Human Ventricular Cellular Electrophysiology

In Vitro Effects Human Stem-Cell Derived Ventricular Myocytes

Clinical Evaluation Unanticipated EP Effects

New Data Driven Grading System to Assess Risk

Final Concept Paper

ICH S7B and E14 Q&A

Endorsed by the MC with support of the Assembly on 15 November 2018

Type of Harmonisation Action Proposed: Q&A to S7B and E14

Statement of the Problem:

ICH S7B 1 and ICH E14 2 were finalized in May 2005 and describe non-clinical and clinical risk assessment strategies to inform the potential risk for proarrhythmia of a test substance and contribute to the design of clinical investigations. Emergent data over the past several years demonstrate that different experimental results can arise for the same compound as a function of the study conditions used in preclinical assays. Guidance is needed regarding best practices for the design, conduct, analysis, and reporting of preclinical proarrhythmia data and data from clinical investigations. The EMA was asked by the European Medicines Agency (EMA) to provide guidance on proarrhythmia assessment. EMA is engaged in ongoing efforts in collaboration with the European Society of Cardiology (ESC) to develop best practices for proarrhythmia assessment. The ICH Steering Committee (ICH SC) is considering whether the current ICH guidance may be adapted to improve current proarrhythmia guidance or if a new ICH guidance may be needed.
Untreated animal (jacketed and telemetered animals and non-jacketed/telemetered animals).

Mini-pig, canine, cyno - N=100 per animal

Spontaneous arrhythmia in comparison with implanted and jacketed animals.

Subgroup focusing on LVP

Will inform how we assess variants.

Significant sample size and data source in this study is novel.
Exploring new models and test compounds

Improving Model Relevance to Co-Morbid Populations
New Project Areas

- Key ‘Failure Modes’ leading to drug attrition. Can we develop and use better in vitro mechanistic assays? ($1.5M Grant from USFDA)

- Bridging healthy animal studies with diseased/ co-morbid patient population
  - How do we enhance the translational relevance of nonclinical studies?
  - Are there alternative disease animal models or sensitized hiPSc-CMs that better represent disease pathology?
Genetic Toxicology

Committee Mission and Objectives

- Advance fields of genetic toxicology and human risk assessment
- Improve new and existing test guidelines, strategies, and interpretation of results
- Examine non-traditional modalities, including novel entities and technologies
8 ACTIVE WORKGROUPS OF GTTC

Integrate Risk Assessment & Decision Making
- Quantitative Analysis
- Clean Sheet/Next Generation Testing Strategy
- Mode of Action
- Error-Correcting Sequencing

Improve Test Guidelines & Strategies
- In Vivo Follow-up
- Germ Cells
- Pig-a Assay

Examine Non-Traditional Modalities
- Nanomaterials

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2019 GTTC PARTICIPATION

Industry Participation
- AbbVie
- Amgen*
- AstraZeneca
- BASF*
- Boehringer Ingelheim GmbH
- Bristol-Myers Squibb
- Celgene
- Charles River
- Corteva*
- Covance
- Denali Therapeutics*
- DowDuPont
- Gentronix
- Genetech
- Helix3, Inc.
- Hoffmann-La Roche Inc.
- Janssen Pharma
- Liton Laboratories
- L’Oreal
- Merck
- Merck KGaA
- Millipore Sigma
- Pfizer Inc.
- Procter & Gamble
- Sanofi
- Toxys

Government / Research Institution Participation
- European Chemicals Agency (ECHA, Finland)
- European Commission, Joint Research Centre
- European Centre for the Validation of Alternative Methods (ECVAM) - observer
- Federal Institute for Drugs and Medical Devices (BfArM, Germany)
- Health Canada
- National Institute for Public Health and the Environment (RIVM, NL)
- National Institute of Health Sciences (Japan)
- National Institutes of Environmental Health Sciences (NI-EHS)
- National Toxicology Program (NTP)
- U.S. Food and Drug Administration
- U.S. FDA National Center for Toxicological Research

Other Independent Scientific Advisors
- Marilyn Aardema
- David Kirkland
- Carol Bevers
- Martha Moore
- Kenny Crump
- Rita Schoney
- Kerry Dearfield
- George Douglass

Academic Participation
- Georgetown University
- Maastricht University
- Swansea University
- St. George’s University of London
- University of California, Riverside

(* New in 2019)
Genotoxicity Assessment of Nanomaterials: Recommendations on Best Practices, Assays, and Methods

Rosalie Elespuru,1,2 Stefan Pfuhler,1 Marilyn J. Aardema,1 Tao Chen,6 Shareen H. Doak,6 Ann Doherty,1 Christopher S. Farabaugh,10 Julia Kenny,11 Mugimane Manjanatha,6 Brinda Mahadevan,6 Martha M. Moore,6* Gladys Ouédraogo,11 Leon F. Stankowski Jr,11 and Jennifer Y. Tanir6,2

Analysis of negative historical control group data from the in vitro micronucleus assay using TK6 cells

David P. Lovell1, R. B. Mick, Fellows2, Francesco Marchetti1, Joan Christiansen1, Azeddine Elhajouji6, Kiyohiro Hashimoto1, Sawako Kasamoto3, Van Li1,4,5, Otsuki Masayasu1, Martha M. Moore1, Mark Schuler1, Robert Smith1, Leon F. Stankowski Jr1,11, Jin Tanaka6, Jennifer Y. Tanir6,11, Veronique Thybaud1,11, Freddy Van Goethem5,11, James Whitwell2,3

Environmental and Molecular Mutagenesis 58:264–283 (2017)


Kerry L. Doorfield1, Bhashkar Gallapudi2, Jeffrey C. Bermis3, R. Daniel Benz6, George R. Douglas1, Rosalie Elespuru5, George E. Johnson1, David J. Kirkland1, Matthew J. LeBaron1, Albert F. Li10, Francesco Marchetti1, Lynn H. Pettenger11, Emiel Rorije12, Jennifer Y. Tanir6, Veronique Thybaud1, Jan van Benthem1,5, Carole L. Yauk1, Errol Zeiger12, and Miriam Luiten12
Error Corrected Sequencing – A New HESI GTTC Workgroup

Error-Corrected Next Generation Sequencing as an alternative methodology for evaluating *in vivo* mutagenesis

- **Rationale:** EC-NGS can...
  - Detect ultra rare, new mutants following exposure to chemicals
  - Be applied to any gene, any tissue and any species, including humans
  - Be integrated into existing toxicology studies to reduce animal use
  - Measure mutants and mutation spectra for mechanistic information
  - Be used to detect chemical-induced mutagenesis for **hazard identification**
  - Detect oncogene mutations and clonal expansion to potentially improve the biological relevance for assessing cancer risk
Potential Error-Corrected Sequencing Opportunities

- **Nonclinical Biomarker of Cancer Risk - *i.e.* FDA/PhRMA NegCarc Program**
  - Use DS in 6 month rat toxicity studies as an enhanced biomarker of cancer risk
  - Goal is to replace 2 year rat cancer bioassays in many situations

- **Predictive Toxicology Applications - Add to early repeat dose tox studies**
  - Same endpoint to kill drugs early, work on alternatives or set safety margins

- **Follow-up to positive *in vitro* mutation or positive carcinogenicity data**
  - Replacement for TGR assays

- ***In Vitro* mutagenic biomarker and use for generating mutagenic spectra**

- **Evaluation of cells for biopharmaceutical cell banking or human gene editing**
Immuno-safety

Committee Mission and Objectives

- Advance immuno-safety science and scientific decision-making processes for guidelines and regulations for immune safety testing
- Educate stakeholders in safety sciences and promote the understanding and appropriate use of immune safety data
April 2020 - Madrid, Spain

Training Course Planned for JSIT Meeting

Kitasato University

September 2020
Cytokine Release Assessment

- Determine best practices for development of in vitro assays and nonclinical in vivo assessments of novel therapeutics for hazard identification of cytokine release syndrome in patients

- **Understanding Baseline**: Cross-institutional collation of in vivo cytokine data from control cynomolgus monkeys

- **Building Standards**: NIBSC Collaboration: Qualification of positive and negative control mAbs for CRA, mAbs to be available in NIBSC catalog in early 2020

Multi-Site Data Collection and Analysis to Improve Safety
Immunomodulators and Pregnancy Risk

- **Objectives**
  - Predicting risk of adverse pregnancy outcomes with immunomodulators.
  - Gather information from industry and academia on different approaches currently used to predict risk
  - To identify solutions in improving risk assessments

- **Activities**
  - Joint project with HESI DART
  - Manuscript in development

Workshop on February 11, 2020 at USFDA - acceptability criteria, immune system biomarkers, and best practices for pregnancy risk assessment
New Program – First in Human Dosing

Project Proposed by Dr. Mineo Matsumoto, Japan PMDA

To determine a safe and efficient FIH dosing approach across different types of immunomodulators.

- **Literature:** Review on FIH determination of immunomodulators in 2 groups (immunosuppressive, immunoenhancing)
  - Target, action, indication, MOA, preclinical model, assays/methods for FIH determination, FIH vs. therapeutic dose, etc

- **Data** - Collect internal data on immunomodulators and information used to determine a FIH dose

Summary

- Global, multi-partite structure allows for collaborative and impactful science to take place
- Public and private participation ensures balance and credibility
- Many project launch mechanisms to address evolving landscape
- HESI’s broad network allows for new opportunities to be addressed AND implemented to improve drug and patient safety
backups
Committee Mission and Objectives

- Develop consensus on the appropriate use of experimental data and produce developmental and reproductive toxicity data translatable to human health risk assessment
- Advance scientific knowledge in the areas of developmental toxicology, male fertility and toxicology, female fertility and toxicology, and neonatal and juvenile toxicology
2019 DART PARTICIPANT LIST

INDUSTRY
- AbbVie, Inc.
- Amgen, Inc.
- AstraZeneca AB
- Bayer
- Biogen Inc.
- Boehringer-Ingelheim GmbH
- Bristol-Myers Squibb Company
- Celgene Corporation
- Charles River Laboratories
- Corteva Agriscience/Dupont
- Covance, Inc.
- Eli Lilly and Company
- ExxonMobil Biomedical Sciences, Inc.
- Genentech
- GlaxoSmithKline
- Merck & Co. Inc.
- Pfizer, Inc.
- Procter & Gamble Company
- Sanofi
- Syngenta
- Takeda Pharmaceutical Company Limited
- Medcrosciences Evaluation Board (The Netherlands)
- National Agency of Medicine and Health Products Safety (ANSM, France)
- National Institute for Public Health and the Environment (RIVM, The Netherlands)
- National Institute for Quality and Organizational Development in Healthcare and Medicines (NIQODHM, Hungary)
- National Institute of Environmental Health Sciences
- National Toxicology Program
- National University of Singapore
- Paul Ehrlich Institute (Germany)
- US Environmental Protection Agency
- US Food and Drug Administration

ACADEMIC
- Erasmus University
- Georgetown University
- Ghent University
- Howard University
- McMaster University
- Radbound University, Nijmegen Medical Centre

CONSULTING/RESEARCH
- Aclario Pharmaceutical Developmental Group, Inc.
- ApConiX, Ltd.
- Critical Path Institute
- Exponent, Inc.
“The current analysis suggests that in general both species are equally sensitive on the basis of an overall EFDT LOAEL comparison, but selective EFDT toxicity in one species is not uncommon. .....the use of both species has a higher probability of detecting developmental toxicants than either one alone.”
Thyroid Hormone Assessment: Implications for Developmental and Reproductive Toxicology

Thursday, May 9 – Friday, May 10, 2019
Washington, DC

Co-Organized by:

- HESI DART Technical Committee
- European Teratology Society

• ~100 participants from US, Europe, Canada, Japan
• Pharma, Chemical, AgChem, Consumer Product
• Regulatory, Research, Industry
• Opportunities to leverage learnings, build central repositories.
• Summary recommendation manuscript in progress
Enhancing Drug Safety in Neonatal Population

SURVEY OF EXISTING MODELS
This workgroup’s goal is to identify relevant models of neonatal disease to explore therapeutic options and strategies.

- Workgroup members have designed and issued a survey for academic researchers, industry, regulatory in order to understand:
  - The breadth of available nonclinical models
  - Application of nonclinical models
  - Stage of clinical translation of the nonclinical model

The survey was sent to 100+ individual researchers contacted and HESI member companies. The survey was also advertised through a number of other scientific organizations and trade associations, including PhRMA/DruSafe, Teratology Society, Society of Toxicology, Critical Path Institute’s International Neonatal Consortium. Survey results will be compiled into a database that can be used as a resource for researchers in the field.

Team Leads: Vijay Unvaliya, Susan Laffan

NEONATE PHYSIOLOGY
This workgroup’s goal is to increase the understanding of comparative physiological development between neonatal and nonclinical animal species, focusing on the ontogeny of ADME related processes and underlying mechanisms for the following organ systems.

- Team Leads: Pieter Arnaert, Luc De Schaepeedrider

ESTABLISHING A RESEARCH FRAMEWORK
The workgroup’s goal is to frame the basic principles for evaluating existing and developing new animal models to address key therapeutic questions in neonates.

- The workgroup is reviewing the available nonclinical literature for six key neonatal therapeutics areas of highest priority and evaluating the models for:
  - Key clinical hallmarks
  - Species and model relevance
  - Model application

This will help to identify if there are common elements among the neonatal disease models or specific elements for each disease state. To date, few in vitro and in vivo models have been identified; however, gaps in animal models may lend itself to a broader integrated research program.

Team Leads: Sarah Camplon, Melissa Tassinari

STARTING DOSE IN NEONATES
This workgroup is building on the Clinical Pharmacology recommendations from Critical Path Institute’s International Neonatal Consortium by developing case studies to demonstrate key principles and additional considerations when determining doses for neonatal populations. Key considerations will include:

- ADME
- PK/PD modeling
- PBPK
- Trial design

Additionally, these case studies will highlight where nonclinical studies can inform the selection of starting doses in neonatal studies.

Team Leads: Suzie McCune

MODEL APPLICATION
A workshop is anticipated in late 2017 or early 2018, where the information, concepts and frameworks from the various workgroups will be integrated and communicated to the broader scientific and clinical community.

Team Co-Chairs: Karen Davis-Bruno, Luc De Schaepeedrider
Micro-CT used by some for embryos/fetuses in nonclinical EFD regulatory studies

- Micro-CT may reduce time/resources, improve automation/quantitation, facilitate peer review
- Do we know if it is better, worse, same as Alizarin Red? Should it be used for regulatory studies?

**Study Focus**

1. **Goal 1**: Evaluate whether skeletal developmental toxicity be detected by both micro-CT and alizarin red stain.
2. **Goal 2**: Evaluate variability, strengths, and weaknesses in each method.
3. **Goal 3**: Generate data that resembles "real world" variability in study design and implementation.

**New Project Area**
Classification of tumorigenic risk - Based on 6-month toxicology study, support via WOE

- **Cat 1**: highly likely to be tumorigenic in humans
  - 2 year carci study would not add value

- **Cat 2**: available data indicate human tumorigenic potential is uncertain
  - 2 year carci study warranted

- **Cat 3a**: highly likely to be tumorigenic in rats but not humans
  - 2 year carci study would not add value; transgenic mouse study will suffice

- **Cat 3b**: highly likely NOT to be tumorigenic in rats and humans
  - 2 year carci study would not add value, transgenic mouse study may be useful

Remains a challenge: Toxicogenomics may provide rationale to distinguish 3a from 3b

New Project Area - Seeking Participants
Building a New Approach to Refine Carcinogenicity Assessment in Drug Safety

Project Focus: Define rat liver transcriptomic biomarkers that identify established mechanisms of tumorigenesis

Why? Rat liver transcriptomic biomarkers of carcinogenicity can introduce a more comprehensive, integrated, and modernized approach to address mechanistic understanding of carcinogenicity of novel small molecule pharmaceuticals.

Proposed Markers: CAR, PXR, AhR, PPARα, ER, DNA damage, cytotoxicity

Analytical Methods: Analysis of transcriptomic biomarkers via open source machine learning methods. Affymetrix and RNA-Seq based training sets.

Implementation: Pursue regulatory qualification at FDA (EMA, PMDA)
Error-corrected (EC)-NGS Technology Comparison

- Measuring mutations *in vivo* is difficult
- Transgenic Rodent (TGR) Mutation assays measure Mutant Frequency (MF) in *one transgene in any tissue*
- Pig-a Mutation Assay measures MF in *one gene in one tissue*
- Next Generation Sequencing was revolutionary but has error rate of 1 in about 1000 bases sequenced
- Error-Corrected NGS drops error rate to 1 in $10^8$
- *This is below background MF of mammalian genomic DNA*
Translational Biomarkers of Neurotoxicity (NeuTox)

Committee Mission and Objectives

- Biomarkers for improving the prediction of neurotoxicity
- Correlate biomarkers of neurotoxicity with behavioral, imaging, and neuropathological endpoints
- Utilize multielectrode array (MEA) technology to characterize predictivity of seizurogenic activity
Accessible biomarkers of Neurotoxicity

A search for biomarkers of neurotoxicity:

- Trimethyltin as a prototypic neurotoxicant
- Identify biomarkers in bodily fluids and in tissue that are associated with the expression of neurotoxicity.

- Young adult, male, Sprague Dawley rats (12 weeks) were given a single 7 mg/kg intra-peritoneal injection of the known neurotoxicant Trimethyltin (TMT)
- Animals sacrificed at 2, 6, 10 and 14 days post treatment

Tissue Samples
- Brain
- Liver
- Kidney
- Spinal cord
- Satic nerve

Biological Fluids
- CSF
- Plasma
- Serum
- Urine

Proposed biomarkers: Fluid Based (plasma, serum, urine or CSF)

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<tr>
<th>Proposed biomarker</th>
<th>Damage/injury detection</th>
<th>Assay development</th>
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<tr>
<td>Glial fibrillary acidic protein (GFAP)</td>
<td>Biomarkers for all types of neural (neuronal and glial) damage</td>
<td>Sensitive and specific marker of axonopathy (indicative of CNS damage)</td>
</tr>
<tr>
<td>Microtubule Associated Protein (MAP-2)</td>
<td>Biomarker for dendritic injury</td>
<td>ELISA developed</td>
</tr>
<tr>
<td>Microtubule-associated protein tau (hyperphosphorylated and cleaved)</td>
<td>Biomarker of neurodegeneration/axonal injury</td>
<td>ELISA developed</td>
</tr>
<tr>
<td>Myelin basic Protein (MBP)</td>
<td>Biomarker of myelin disruption</td>
<td>Immunohistochemistry (not widely used)</td>
</tr>
<tr>
<td>Ubiquitin C terminal hydrolase (UCH-L1)</td>
<td>Biomarker of cell body injury</td>
<td>Immunohistochemistry (widely used)</td>
</tr>
<tr>
<td>Neurofilament (light chain and phospho-related heavy chain)</td>
<td>Biomarkers of axonal injury</td>
<td>ELISA developed</td>
</tr>
</tbody>
</table>

- Final study results by year end
- Additional study at NCTR FDA in design - cuprizone, rotenone, and acetaminophen (negative control)

Original Research

Changes in the metabolome and microRNA levels in biological fluids might represent biomarkers of neurotoxicity: A trimethyltin study


NCTR:
- Pre/Post TMT MRI
- Pre/Post TMT Behavior
- Neuropathy

Eli Lilly/Covance: miRNA analyses

CDC-NIOSH: GFAP ELISA

CDER/US FDA: Proteomics

Pfizer: Histopathology

Institute of Technology, Italy: Lipidomics

Work sites

US EPA: Biocrates Metabolome

HESI.
Can Micro-electrode Arrays (MEA) be used for seizurogenicity assessment?

**MEA SUBTEAM: Measuring Seizurogenicity**
- Cells (rat or iPSC) are plated and put into an MEA assay
- Raw voltage signals are processed to obtain extracellular action potentials from across the network via electrodes (number varies by platform type)

**Predictivity**
Understand and characterize whether seizurogenic activity can be predicted using MEA technology

**Biomarkers**
Determine if there are biomarkers that can be used to predict seizurogenic activity

**Standardization**
Standardize elements of the protocol and analysis techniques

**STATUS OF PILOT? SITES DATA ETC SUMMARY?**
MISSION:
To facilitate the translation of cell based therapies to the clinic by driving the development of tools, methods and knowledge required to evaluate *in-vivo* safety and fate of therapeutic cells.
Committee members and collaborators from > 25 organizations across EU, Japan and USA.

(CT-TRACS Multi-Sector Membership, as of August 2018)

**Regulatory bodies:**
- FDA
- Medicines Evaluation Board
- MHRA

**Universities/ Research Centers:**
- Kings College London
- Memorial Sloan Kettering Cancer Center
- Radboud University
- University of Liverpool

**Gov./Consortia/NGO:**
- CIRM
- CATAPULT
- eatris
- FIRM
- NIH
- National Institute for Public Health and the Environment
- Ministry of Health, Welfare and Sport
- PACT
- NGO Personalized Medicine and Healthcare

**Developers (Therapies and Tools), CROs:**
- astellas
- Athersys
- Boehringer Ingelheim
- Cellular Dynamics International
- Celsense
- charles river
- CTToxLAB
- COVANCE
- GE Healthcare
- Novartis
- Sumitomo Dainippon Pharma
- Taconic
- Takeda
CT-TRACS Work Groups

Point of Administration & Biodistribution

PoA: Localization, persistence, survival, proliferation.

Biodistribution: Types of effects, ability to detect, ability to assess fate and distribution.

Tumorigenicity

Need for prediction assays, consensus.

Collaboration w/ Japanese Consortium
FIRM-CoNCEPT & AMED MEASURE
Clinical Study Database

• Non-invasive cell tracking methods for safety

Design, Data, Interpretation

New Project Areas – Seeking Participants

Tracking and Safety of Cell Therapies

Tumorigenicity of Human Cell-Based Therapeutic Products

• No international standards to assess transformation potential

• iPS cells – in vitro testing for tumorigenicity potential

• Collaboration with MEASURE Japan

Study partners, participants
Patient Focused Programs

We all deserve to THRIVE!

40% of the population will be diagnosed with cancer in their lifetime.

THE NEED

The biomedical R&D has made tremendous strides in turning many cancers into survivable diseases. However, during treatment and in the years following treatment, many patients and survivors experience unwanted treatment-related effects that can adversely impact health outcomes and overall quality of life.

OUR MISSION

To improve outcomes for cancer patients and survivors by making quality of life an active research priority.

www.hesithrive.org

Patient Advocacy

Enhancing quality of life as a goal for anticancer therapeutics

The global biomedical community's successes in cancer therapy over the past 30 years and particularly in the last 5 years have made many cancers survivable diseases. The U.S. National Academy of Science's 2013 Quality Cancer Care report estimates 18 million survivors in the United States by 2018 and 1.5 million new cancer diagnoses per year. The increase in treatment options and survival progress for many cancer types brings into sharper focus the responsibility to also prioritize continued improvements in the quality of life throughout disease-directed treatment and the full continuum of care for both cancer patients and survivors.

In the weeks, years, and decades after treatment, many survivors experience a significantly higher incidence of certain and even life-threatening chronic conditions—often unintended.

The www.hesithrive.org/guidelines/

Biden Cancer

Accelerating progress in cancer prevention, detection, diagnosis, research and care through collaboration.

www.biden.org

Tweets

As one of over 50 new commitments that came out of the #BidenCancerSummit, @HESITHRIVE announced grants in an effort to catalyze research into cancer patient quality of life. The 2019 THRIVE grant award letters of intent are due November 30th. For more: hesithrive.org/guidelines/

NCICancerTrials

What is gene therapy? It's a type of experimental treatment in which foreign