HESI Emergent Issues: Science session

HESI Annual Meeting
June 8, 2016
Arlington, VA

HESI EIC Chair, Dr. Jose Manautou, U Connecticut
Today’s session

What are ‘Emerging Issues’ and what is HESI’s role and process?

Some cool new science to get you thinking...

Update on the topic YOU voted to launch last year...

Two new projects for you to vote on!
Emerging Science Comes in Many Forms...
Issues and solutions are often disconnected....
**HESI Emerging Issues Process:**

A way to connect and get results

**Human Health and Environmental Challenges**

- Technical expertise, technology, resources
- Platforms for science design and communication
HESI Emerging Issues Process Provides:

- Management & Coordination
- Support for Problem Formulation
- Seed Funding
- Network of Experts

Human Health and Environmental Challenges

Technical expertise, technology, resources

Platforms for science design and communication
Why address emerging science via a (HESI) consortium?
HESI EIC works for issues that benefit from ability to...

- Cross-fertilize expertise and approaches across disciplines
- Reduce redundancy
- Partner and leverage resources
- Synergize effort to enhance potential for health impact
- Bring solvers together with those who need solutions!

*Meet shared challenges, with shared solutions*
The HESI Emerging Issues Process

- **Begin**: New project solicited via annual survey of global HESI
- **Jan-Feb**: HESI reviews proposals and picks top 2-4
- **June**: Top proposals presented at HESI Annual Meeting
- **Jun-Jul**: HESI vote on topics
- **Aug**: EIC reviews results and selects 1-2 topics
- **Oct-Dec**: New HESI Subcommittee
The HESI Emerging Issues Process

In addition to full proposals, EIC brings speakers to educate and challenge on new science areas.

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The rapidly changing and growing world of synthetic biology

Harnessing power of genetic circuitry

Synthetic biology pioneer explains advances that could address significant health problems

Will synthetic biology change the way we farm and eat?

Synthetic biology on a piece of paper: Brighter future for disease diagnostics?

If prevention and cure are the two arms of healthcare, diagnostics is the body that connects them.

Synthetic-biology firms shift focus

Switch to food and fragrances risks consumer rejection.
2015 HESI Emerging Issues ... You selected project on

Safety Assessment of Cell Therapies Status report

Presented by

—Dr. Bill Shingleton, Project Co-Chair
HESI Annual Meeting
June 8, 2016

HESI Emerging Issues 2016
Cell-Therapy: TRAcking, Circulation and Safety
CT-TRACS

Dr. Bill Shingleton, GE Healthcare, CT-TRACS Co-Chair.
Q4 2015
CT-TRACS
Selected as new EI sub-committee for 2016.

Dec. 2015
First sub-committee teleconference

Jan.2015
Leadership team established
New HESI Scientific Program Manager
~ 50 members

Q1 2016
Mission and goals definitions.

Q2-3 2016
Definition of 2 sub-groups and activities.

HESI AM 6/8/2016, EI Session: CT-TRACS
Leadership Team:

Dr. William (Bill) D. Shingleton
Technical Lead, GE Healthcare,
Amersham, United Kingdom.

Dr. Gregory Mullen
Sr. Lecturer in Imaging Biology,
King’s College London,
United Kingdom.

Mercedes Serabian
Chief, Pharmacology/Toxicology
Branch FDA/CBER/OCTGT/DCEPT,
Silver Spring MD, USA.
CT-TRACS Membership

CT-TRACS June 2016

- Biotech Industry: 50%
- Academia: 27%
- Govt: 23%

48 Participants
26 Organizations
Mission

To improve the safety of cell-based therapies for patients by enhancing our ability to reliably apply analytical methods, devices, and scientific knowledge to evaluate the distribution and fate of these cells in a patient.

CT-TRACS will 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.
Drug Development Pathway

Small Molecule

Large Molecule

Cell Therapy

Idea

Molecule synthesis

Pre-clinical

Manufacture

Clinical Trials

Safety, DMPK, ADME

Allogeneic?

Autologous?

Safety, DMPK, ADME

Safety, DMPK, ADME

Safety, DMPK, ADME

ILSI Health and Environmental Sciences Institute
Tools from Imaging to Support Cell Therapy

- Isolate and Enrich
  - Elutriation
  - DGM
  - Xuri
- Modify
  - Activation
  - Viral transduction
  - Transfection
- Expand
  - Media
  - Growth factors
  - Bioreactors
- Harvest
  - Centrifugation
  - TFF
  - Cytomate
  - KSep
- Formulate
  - Fill and Finish
  - Comparability
  - Safety
  - Identity
  - Purity
  - Potency
- Store & Distribute
  - Cold chain
  - Custody
  - RFID tracking
- Administer
  - Cell monitoring
  - In-vivo imaging

Regenerative medicine and stem cell clinical trials:
Tracers to potentially monitor cell therapy efficacy:

Cell Tracking

Heart disease

PD

AD

19F

PET

SPECT

MRI

Reporter
Gene
Imaging

Reporter
Probe

Vector

Gene
Product

18F

SPIO

IFP

F18-FDG

Tc-99m-HMPAO

In-111-Oxine

19F
1. Why cell fate and distribution are important?

2. What elements matter most?

3. Do we have the tools or approaches we need? What are we missing?

4. a) How to define a reliable and reproducible outcome?

4. b) How much precision/accuracy required for different decision-scenarios?

1. Characterize the role of cell fate and distribution in assessing the overall safety profile of cellular therapy products.

2. Identify which aspects of cell fate and distribution in safety assessment are most impactful to patient safety.

3. Match current technological or methodological approaches with key safety needs.

4. Establish the confidence required to allow the use of these approaches in decision-making.
Cell Fate & Distribution

What happens to cells differentiation?
How long do the cells persist?
Where do the cells go?

Tools, tests, and confidence

Biological Context for Patient Safety

Tools, tests, and confidence

Tools, tests, and confidence

Tools, tests, and confidence

What happens to cells re-differentiation?
Defining Workstreams

Biological Context for Patient Safety

**Sub-Group 1**

- **Point of administration safety effects**
  - Different routes, different cell types, other

- **Near-term/Acute Safety**
  - Types of effects, ability to detect, role of fate and distribution in acute safety

- **Tools, tests, and confidence**

**Sub-Group 2**

- **Not now**
  - Latent or delayed effects
  - Types of effects, ability to detect, role of distribution and fate in chronic safety

- **Tools, tests, and confidence**

**Sub-group 2**

- **Tumour-igenicity**
  - Prediction, assays, consensus

- **Tools, tests and confidence**
Two Sub-Groups being formed

1. Point of Administration & Acute Tracking
   - RIMLS
   - Takeda
   - AbbVie
   - Celsense
   - UK Catapult
   - Charles River
   - U. Liverpool, UKRMP
   - Covance Laboratories
   - Boehringer-Ingelheim

2. Tumorigenicity and Biodistribution
   - NGO
   - Takeda
   - U. Liverpool, UK
   - ACEA Biosciences
   - Medicines Evaluation Board, NL

HESI AM 6/8/2016, EI Session: CT-TRACS
 Tasks: Literature Review / Cases Studies

- Define the issues and the gaps
- Identify tools & technologies (TTs) currently available
  - Benefits and limitations of the methods
  - Use of detection methods that require modification of the clinical product in preclinical
- Determine feasibility/relevancy of the TTs to the goals
  - Specifications of the tool – reproducibility/precision, etc..
    - Sensitivity of methods vs. required sensitivity for valid results
    - Criteria for a valid result
  - What can be performed in animals?
    - Limitations from route of delivery
    - Lower limits of method detection capabilities versus dose
  - What can inform clinical?
  - What can inform MOA/efficacy?
  - What can be used clinically?
Japan FIRM-CoNCEPT for Tumorigenicity Evaluation

- Forum for Innovative Regenerative Medicine (FIRM), a Japanese industry association for RM, established a committee for non-clinical safety evaluation of pluripotent stem cell-derived product (FIRM-CoNCEPT) for tumorigenicity evaluation with the following mission:
  - To provide regulatory science-based globally acceptable consensus for safety evaluation policy in the R&D of pluripotent stem cell-derived products.
  - Especially, validated methods for tumorigenicity evaluation, which are in alignment with regulatory direction and international standards, will be developed through multi-institutional joint research.
- The committee started the activity since May, 2016 and will be continued for 4 years.
- The 1st step of the work focuses on landscape analysis for tumorigenicity, biodistribution and biocomparability.
- The 2nd step will be multi-institutional joint research to validate in vitro and in vivo tumorigenicity tests.
- The committee wishes to collaborate with HESI CT-TRACS to help develop rigorous science-based information required for cell therapies safety assessment and reach global consensus.
## FIRM-CoNCEPt Business Plan

### Step 1: Feasibility Assessment

<table>
<thead>
<tr>
<th>FY2015</th>
<th>FY2016</th>
<th>FY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec</td>
<td>Mar 29</td>
<td>End of August</td>
</tr>
</tbody>
</table>

**Preparation**

1. **Discussion**
   - w/ 4 Companies
   - w/ HESI CT-TraCS (Mar 30)
   - w/ Other Association

2. **Landscape analysis**
   - Biodistribution
   - Tumorigenicity
   - Comparability
   - Others
   - w/ HESI?

3. **Discussion on Regulatory Science**
   - WHY, WHAT, WHEN

**Step 2: Validation Consortium**

- Deliverables with HESI/JPMA
  - White paper, Manuscript w/ HESI?
  - Workshop (HESI, ARM, IABS, ISSCR, Japanese Soc Reg Sci etc.)

4. **Preliminary experiment** (HOW)
   - RM company
   - CRO
   - Academia etc...

**Exp Consortium 1** (in vitro ...)

**Exp Consortium 2** (in vivo ...)

**Exp Consortium 3** (in vitro ...)

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**Industry Framework will be organized by FIRM CoNCEPT**

© Forum for Innovative Regenerative Medicine

*presented in CT-TRACS f2f meeting on June 6, 2016@Arlington*
Deliverables and Outcomes

Plan for and execute a workshop

Develop a Publication

HESI AM 6/8/2016, EI Session: CT-TRACS
Thank you for your attention!
The HESI Emerging Issues Process - New proposals

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2016 EI PROPOSALS SUMMARY

<table>
<thead>
<tr>
<th>Submissions Received from:</th>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government-only</td>
<td>2 (10%)</td>
</tr>
<tr>
<td>Academic-only</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>Industry-only</td>
<td>3 (15%)</td>
</tr>
<tr>
<td>Consortium/Non-Profit</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>Multiple Sector</td>
<td>6 (30%)</td>
</tr>
</tbody>
</table>

How did they hear about HESI?

<table>
<thead>
<tr>
<th>Total (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HESI Outreach Email</td>
</tr>
<tr>
<td>HESI Partner Outreach</td>
</tr>
<tr>
<td>HESI Website</td>
</tr>
<tr>
<td>Word of Mouth</td>
</tr>
</tbody>
</table>

26 Total Countries!
Criteria for Identification and Prioritization of Emerging Issues

1. Has current public health significance.
2. Efforts will have measurable scientific impact.
3. Priority issue across sectors & stakeholders.
4. Not proprietary or product-specific.
5. Lengthy academic research proposals will not be considered.
6. Proposals should reflect applied science as opposed to basic discovery science.
7. Does not include lobbying or advocacy components.
8. Efforts are not be duplicative of other groups.
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Advisory Committee Input

Formal ‘votes’ from HESI multi-sector stakeholders around globe
Emerging Issues Committee Science Advisors

Suzanne C. Fitzpatrick, PhD, DABT, US Food and Drug Administration

George Gray, PhD, George Washington University

Ronald N. Hines, PhD, US Environmental Protection Agency

Toshihisa Ishikawa, PhD, NGO Personalized Medicine & Healthcare

James E. Klaunig, PhD, ATS, Indiana University

Terrence Monks, PhD, Wayne State University

Robert Tanguay, PhD, Oregon State University

Flavio A.D. Zambrone, MD, PhD, University of Taubaté / Planitox

Anthony Bahiniski, PhD, GlaxoSmithKline

Matthew S. Bogdanffy, PhD, DABT, ATS, Boehringer-Ingelheim

Jon C. Cook, PhD, DABT, Pfizer, Inc.

Mark Lampi, PhD, ExxonMobil

Monicah Otieno, PhD, Janssen Pharmaceuticals

Reza Rasoulpour, PhD, DowAgroSciences

Sue Yi, PhD, Syngenta Ltd.
Two Topics Presented today

1. Microbiome based biomarkers – Presented by Dr. Donna Mendrick, FDA NCTR and Dr. Tim Gant, Public Health England

1. Harnessing expanding exposure monitoring paradigms: a data interpretation tool for citizen scientists. Erica Jones, ExxonMobil and Charlene McQueen, EPA
After presentations
- turn in your voting forms
- vote later online

All welcome to provide input!
Microbiome: Biomarkers of Toxicity/Disease and Effect on Drugs and Environmental Chemicals

HESI Emerging Issues Proposal – June 2016
Presented by Dr Donna Mendrick, FDA NCTR
Working Group

- Matthew Bogdanffy (Boehringer Ingelheim)
- Carl Cerniglia (FDA/NCTR)
- Suzy Fitzpatrick (FDA/CFSAN)
- Steve Foley (FDA/NCTR)
- Tim Gant (Public Health England)
- Jose Manautou (University of Connecticut)
- Charlene McQueen (US EPA)
- Donna Mendrick (FDA/NCTR)
Overview

What is the microbiome??
The total number >10^{14}

10 times more than the total number of eukaryotic cells that compose a human individual

- Nose: 10^3 - 10^4
- Oral: 10^{10}
- Skin: 10^{10}
- GI tract: 10^{14}
- Urogenital: 10^{12}

http://whyfiles.org/2015/eight-ways-microbes-keep-you-healthy/
Human Microbiome

- Majority are bacterial, but also viruses and fungi - form complex communities called the human microbiota
- Gut microbiota largest and most complex, > 1,000 different intestinal microbes
<table>
<thead>
<tr>
<th>Drug</th>
<th>Use</th>
<th>Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetaminophen</td>
<td>Analgesic and antipyretic</td>
<td>Competitive metabolism with some gut bacteria. Can exaggerate clinical pharmacology and toxicity</td>
</tr>
<tr>
<td>Chloramphenicol</td>
<td>Antibiotic</td>
<td>Can cause bone marrow toxicity due to presence of coliforms that mediate its metabolism to toxic form</td>
</tr>
<tr>
<td>Digoxin</td>
<td>Cardiotonic</td>
<td>Microbiota can affect concentration of reduced digoxin metabolite leading to increased pharmacology and toxicology</td>
</tr>
<tr>
<td>Chemical</td>
<td>Use</td>
<td>Effect</td>
</tr>
<tr>
<td>---------------------------</td>
<td>---------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Diazinon</td>
<td>Organophosphate insecticide</td>
<td>Diazinon exposure perturbed gut microbiome in a sex-specific manner and may underlie observed neurotoxicity susceptibility in animals</td>
</tr>
<tr>
<td>Arsenic</td>
<td>Natural and industrial contaminant</td>
<td>IL-10 gene knockout changes the gut microbiome, which in turn substantially affects arsenic metabolism</td>
</tr>
<tr>
<td>Engineered Nanomaterials</td>
<td>Multiple</td>
<td>Impaired bacterial homeostasis of short chain fatty acids; decrease in intestinal coliform</td>
</tr>
</tbody>
</table>
Microbiome Interactions with Arsenic

IL-10 KO alters gut microbiome which then affects arsenic metabolism
Microbiome Research and its Applications are Expansive and Multidisciplinary

>13,000 new publications in last 3 years. Fewer than 2,000 total prior to 2010.

Applications for nutrition, drug safety, environmental health, precision medicine, etc.
This is a BROAD and DEEP research space. What is going on currently?

- Goals
  1. Support interdisciplinary research
  2. Develop platform technologies
  3. Expand the microbiome workforce
The goal of the IHMC is to work under a common set of principles and policies to study and understand the role of the human microbiome in the maintenance of health and causation of disease and to use that knowledge to improve the ability to prevent and treat disease.

The Consortium’s efforts are focused on generating a shared comprehensive data resource that will enable investigators to characterize the relationship between the composition of the human microbiome (or of parts of the human microbiome) and human health and disease.
Much Current Research is ....

Large scale cataloguing of the genomic sequence of the population of microbiota in the human gut and elsewhere in the human body
Relatively Little Focus on...

The metabolic products of these microbiota
- *these metabolites are the keys to signaling, predicting, and influencing disease states of the host organism*

The integration of metabolome, metagenome, and metatranscriptome data
- *to examine the relationship between the host and microbial dynamics to discover potential metabolite biomarkers*

The interdependence of the microbiome on drugs and environmental chemicals
What are Microbiome Metabolites?

- Host signaling pathways are greatly influenced by the microbiota
- Metabolites produced strictly by select microbiota members are mechanistic regulators of host cell functions
- GI tract microbiota is metabolize host indigestible dietary matter for maximum energy extraction

May serve as biomarkers of toxicity and disease
Microbiome Metabolites Implicated in...

- Influencing progression of cardiovascular disease (e.g., trimethylamine-N-oxide (TMAO) promotes atherosclerosis)
- Promoting (or suppressing) carcinogenic pathways (e.g., colorectal cancer)
- Directly influencing immunity, e.g., two microbiota-derived metabolites (short-chain fatty acids and tryptophan)
Microbiome Metabolites Implicated as Biomarkers of...

- Coronary heart disease (e.g., GLcNAc-6-P and mannitol)
- Autism spectrum disorder (e.g., short chain fatty acids and propionate)
- Biomarkers of reduced renal function (e.g., indoxyl sulfate)

The OSTP effort lists only one project that is looking at the metabolites as biomarkers: “develop a non-invasive test for ...accurate detection of colon polyps and colorectal cancer based on human microbiome biomarkers”
Can metabolites of microbiota reliably be used as predictive and translational signals of toxicity and disease?

In this context, what would we need to know about the interactions between the microbiome and drugs/environmental chemicals?
Build Multidisciplinary Input Forum to Address Key Questions

What data are available now or will be needed to support *in vivo* animal and *in vitro* models of microbiome metabolites as translational biomarkers of disease, toxicity, etc.?

What is known about microbiome & drug/chemical interdependence that will provide context to interpret these data?
Step 1:

Multi-sector Workshop on State of Science (Year 1-1.5)
Workshop on State of Science
Potential discussion questions…

✓ What biomarkers might serve for baseline variations?
✓ For key organ systems (e.g., liver, kidney, heart, lung) what do we know about which metabolites of microbiota are associated with toxicity or decreased functionality? What do we know about the systems biology at work?
✓ How do the microbiota metabolites contribute to disease and/or toxicity susceptibility?
✓ Are there any animal models available, or can they be created, to replicate these findings?
✓ What is the status of mathematical or *in silico* models that assess microbiome metabolism?
✓ What do we know about the interaction of the microbiome and drugs and chemicals?
✓ Where are there opportunities and gaps for further work?
Based on Feedback from Phase 1…

Phase II: Moving Knowledge to Application (Year 2-3)

1. Can we create or develop data to support confidence in *in vivo* and *in vitro* models of microbiome metabolites as biomarkers of disease and toxicity?

2. How can we learn more about the interaction of the GI microbiome and drugs/chemicals? How might this empower precision medicine?

3. Can, or should, the microbiome be considered in toxicity testing?
Anticipated Outputs

• Manuscripts on state of the science in safety assessment and recommendations for future research

• Web-based resource to link existing publications and models

• Identification of research and ‘assay validation’ needs

• Possible experimental programs as next steps
Why is this a good match for HESI?
HESI can bring...

- Program coordination and engagement across diverse technical disciplines
- Expertise in coordinated biomarker evaluation and application across species
- Organ-system toxicity expertise from existing HESI committees (immuno, cardiac, nephro, etc.)
- Potential support from other ILSI branches
Already strong multi-sector and multi-disciplinary interest in this at HESI

Opportunity to build!
Microbiome: Biomarkers of Toxicity/Disease and Effect on Drugs and Environmental Chemicals

Questions?

HESI Emerging Issues Proposal – June 2016

References (I)


Gao et al., 2016. Gender-specific effects of organophosphate diazinon on the gut microbiome and its metabolic functions. Environ Health Perspect; DOI:10.1289/EHP202
References (II)


References (III)


"The collection and analysis of data relating to the natural world by members of the general public, typically as part of a collaborative project with professional scientists."

Oxford British and World Dictionary
Levels of Citizen Science

http://www.openscientist.org/2013/01/the-levels-of-citizen-science.html
Christmas Day Bird Count

• Christmas Day Bird Count launched by US Audubon Society in 1900.
• Year One: 27 people participated
• Today: more than 50,000 participants
• Evaluate local bird populations
• Decrease can indicate environmental threats
The Great Backyard Bird Count

- Checklists Submitted: 162,052
- Total Species Observed: 5,689
- Total Individual Birds Counted: 18,637,974

Statistics last updated on March 2, 2016

http://gbbc.birdcount.org/
“Right now, you could look at almost any scientific discipline, and if you look deeply enough and carefully enough you’re going to see some aspects of citizen science happening.”
“Play Quantum Moves and contribute to cutting-edge physics research. Your task is to find clever ways of manipulating and moving atoms. By playing, you help physicists in the epic task of building a real quantum computer.”

https://www.scienceathome.org/games/quantum-moves/game

Schrödinger equation

Danish Science at Home
http://www.citizensciencecenter.com/
Examining the diversity of microbes on Earth and on the International Space Station

- Samples collected at youth sporting events by citizen scientists
- UC Davis grew microbes from these samples
- Selected samples were sent to the International Space Station
- Compared growth in zero gravity with growth on earth

Figure 1: Growth (OD600) over time of *Bacillus safensis* JPL-MERTA-8-2 in space (green) and on Earth (brown).
Values represent the mean of six wells, ± the standard deviation.

Foldit players:

- provided results that matched or outperformed computed solutions (Khatib F et al PNAS (USA) 108:18949, 2011)
- helped decipher the crystal structure of a AIDS causing monkey virus in 10 days (Khatib F et al Nat Struct Mol Biol 18: 1175, 2011)
- provided solutions to increase the potency of a synthetic enzyme used in synthetic chemistry (Eiben CB et al Nat Biotech, 30:190, 2012)

http://fold.it/portal/info/science
Project: Observatory of Garden Butterflies

https://www.mysciencework.com/omniscience/serve-society-through-citizen-science
A Role for HESI - Emerging Issues Proposal

Harnessing Expanding Exposure Monitoring Paradigms: A Data Interpretation Toolbox for Citizen Scientists

http://www.citizensciencecenter.com/what-is-citizen-science/
Harnessing Expanding Exposure Monitoring Paradigms: A Data Interpretation Toolbox for Citizen Scientists

E. N. Jones
HESI Emerging Issues Session
June 2016, Washington, D.C.
Expanding Exposure Monitoring Paradigm

New Technology = New Opportunity

• Potential to expand scientific understanding of exposure in previously unmeasured areas
New Technology = New Challenges

• Data quality and data interpretation challenges include:
  – Capture and understanding of spatial, temporal differences
  – Identifying new confounders, addressing in study design
  – Source attribution
  – Technology sensitivity, specificity, reproducibility
  – Generalization to non-assessed populations
  – Comparison to exposure reference values
“As part of your plan, identify the number of samples you will collect.”

“This document does not provide detailed guidance on health-based interpretation of sensor measurements.”

“This document does not provide detailed guidance on health-based interpretation of sensor measurements.”

“Make sure you are collecting data over the right spatial area for the right amount of time.”

“It’s important to minimise the opportunities for errors to occur and understand how data quality varies between samples or even participants.”

“Make sure you are collecting data over the right spatial area for the right amount of time.”

“This document does not provide detailed guidance on health-based interpretation of sensor measurements.”
How Can HESI Enhance Scientific Rigor?

• Develop educational resources to promote scientific literacy among non-professionals

Objective: improve the quality of citizen-based participatory science to enhance existing knowledge of the relationship between exposure and health
Anticipated Deliverables

Develop work product that educates non-professionals on one or more topics associated with data quality or data interpretation

**Potential Content**
- Collecting representative data
- Study designs to address spatial and temporal variability
- Minimizing bias
- Statistical significance and trend analysis
- Background/baseline exposure concepts
- Uncertainty
- Association or correlation versus causation
- Comparison to reference values

**Potential Formats**
- Web page
- Interactive PDF
- Curated Wikipage
- Podcast
- Youtube video

Potential synergies with other HESI projects (e.g. big data, Risk 21)
Propose Two Parallel Strategies

Content Strategy
- Engage collaborators
- Identify and prioritize needs
- Develop technical content

Communication Strategy
- Identify communication media
- Identify metrics of success
- Publish & promote technical content
Content Strategy

- **Engage**
  - Identify and engage collaborators/partners
  - Ideally including academic, government, industry, and citizen group representatives

- **Prioritize**
  - Host workshop
  - Identify and prioritize key needs, concepts
  - Select focus for pilot guidance package

- **Develop**
  - Develop technical content
Communication Strategy

Evaluate
- Evaluate and select media

Plan
- Develop plan
  - Identify internal or external resources needed
  - Identify metrics of success

Publish
- Convert technical information

Promote
- Engage collaborators and stakeholders to promote
Evaluate Success & Path Forward

• Metrics of success:
  – Metrics of distribution (e.g. resource downloads)
  – Acceptance and promotion by external partners

• Consider whether adding additional modules would be valuable
Proposal Timing

Year One:

• Identify and engage collaborators (ideally including academic, government, industry, and citizen group representatives)
• Host workshop to identify key survey design and data interpretation concepts relevant to citizen science projects
• Define focus areas for first guidance package
• Draft communication strategy and select communication media/delivery methods.
• Initiate development of technical guidance

Year Two:

• Progress and finalize technical guidance
• Finalize communication strategy
• Publish and actively promote guidance package
• Evaluate future guidance needs
Thank you - Questions?
1. HESI Strategy Map Alignment

2. Example Communication Formats
   – Interactive PDF
   – Layered Web Page
   – YouTube Video

3. Digital Communication Budget Scoping
Each axis appearing on the 2010-2020 HESI Combined Challenges Map is a continuum. All issues on the map are of high importance/impact based on prioritization by the participants in the 2009 HESI mapping exercise. “Relative impact” is a qualitative measure of importance among high priority topics. The location of issues along the “time” continuum is an approximation of when the topic is likely to become a major issue in the timeframe from 2010 to 2020.
Example Communication Formats: Interactive PDF

Example Communication Formats: Layered Web Page

- Webpage provides three layers of detail, targeting a range of audiences from lay people to professionals.

Example Communication Formats: Layered Web Page

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Example Communication Formats: Layered Web Page

- Webpage provides three layers of detail, targeting a range of audiences from lay people to professionals.
Example Communication Formats

YouTube Videos

• Visual/audio learning formats
## Digital Communications Budget Scoping

<table>
<thead>
<tr>
<th>Type</th>
<th>Key features</th>
<th>Best for</th>
<th>Benefits/Drawbacks</th>
<th>Access</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Native Apps</td>
<td>Animation, Audio / Video, Infographics, Gamification, Slideshows</td>
<td>Illustrating concepts/projects</td>
<td>Highly customizable, Large file size, Requires vendor</td>
<td>Apple, Android, Windows</td>
<td>Expensive ($100K+)</td>
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<tr>
<td>Adobe DPS</td>
<td>Audio / Video, Infographics, Pull-out tabs, Slideshows, Tap-to-reveal info</td>
<td>Enhancing static publications, presentations</td>
<td>In-house design maintenance, Quick, easy to update</td>
<td>Apple, Android, Windows</td>
<td>Reasonable ($30K+)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Learning tools, Sales enablement</td>
<td></td>
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</tr>
<tr>
<td>Mobile Web</td>
<td>Responsive web design, displays well on any screen</td>
<td>Basic information reference</td>
<td>Very accessible, always current, Internet access required</td>
<td>Any device</td>
<td>Reasonable (variable)</td>
</tr>
<tr>
<td>Interactive PDF</td>
<td>Clickable graphics</td>
<td>Displaying organized information</td>
<td>Great value, Limited functionality, Not ideal for mobile</td>
<td>Works on any PC</td>
<td>Inexpensive ($1K+)</td>
</tr>
<tr>
<td>Infographics</td>
<td>Static or animated</td>
<td>Communicating complex data visually</td>
<td>Can use in different platforms, Not ideal for mobile</td>
<td>Any platform</td>
<td>Cheap ($200+)</td>
</tr>
</tbody>
</table>
HESI Emerging Issues Process
Providing connections and solutions

Human Health and Environmental Challenges

Technical expertise, technology, resources

Platforms for science design and communication

Thank you for your attention

Questions?
A thank you to our outgoing Leadership
Dr. Jose Manautou
Chair of
Emerging Issues Committee
2015-2016
Thanks to Departing Trustees

Dennis J. Devlin, PhD - Trustee 2007 – 2016, Former HESI President

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Special Thanks
Outgoing HESI Chair
Herman Autrup
Chair of BoT
June 2014 - June 2016
Thank you for your support for HESI
See you next year

June 6-8, 2017

Dublin, Ireland (tentative)