
HESI Emerging Issues Session: *Strategic Enhancement of the HESI Scientific Portfolio*



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**Vice Chair, HESI Emerging
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HESI Annual Meeting
12 June 2013
Alexandria, VA

ILSI Health and
Environmental Sciences
Institute

Setting the Stage...

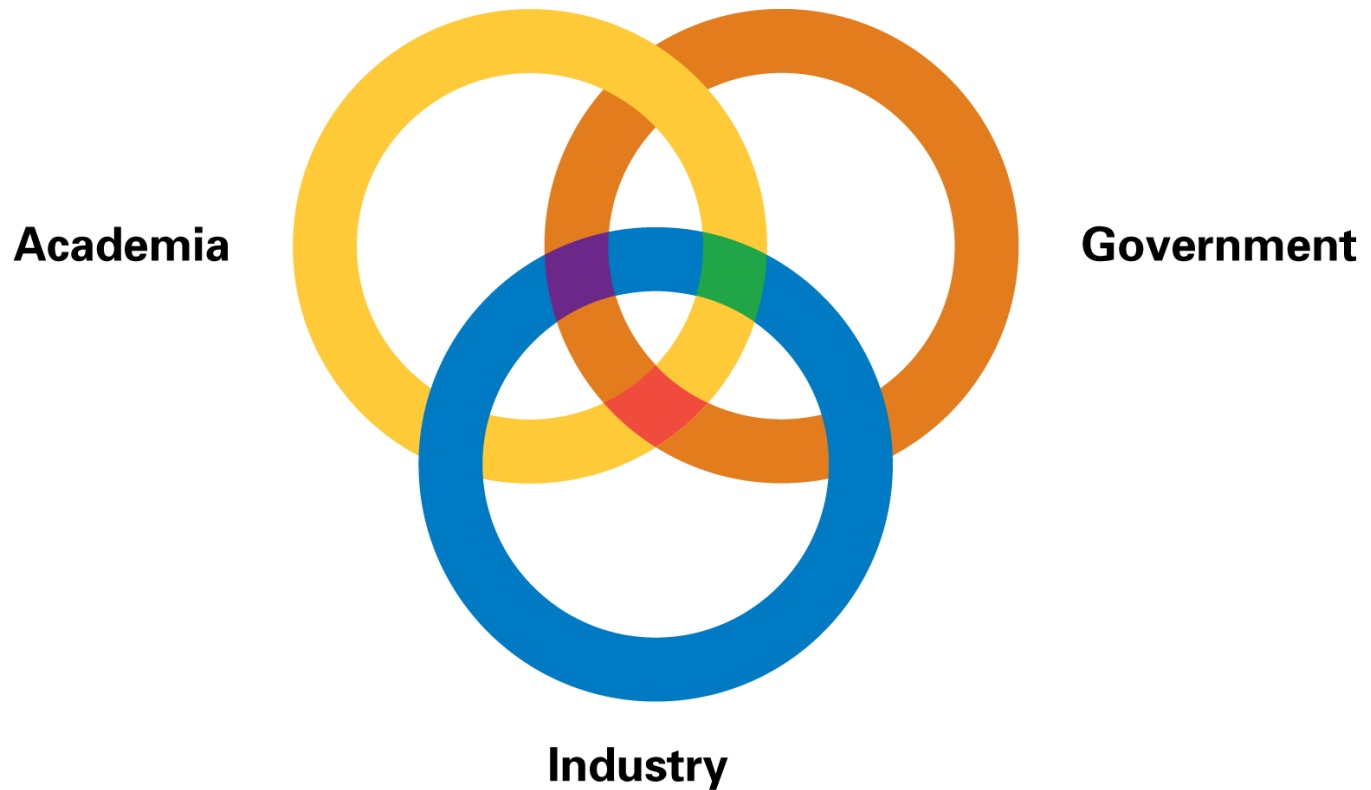
The remainder of this meeting is devoted to
***STRATEGIC ENHANCEMENT OF THE
HESI SCIENTIFIC PORTFOLIO.***

We need your full engagement!



A Unique Participant Base:

TRIPARTITE



Face-to-Face Discussion

How often are we together in the same room?

- ❖ HESI Board of Trustees
- ❖ HESI Emerging Issues Committee
- ❖ Official Representatives (HESI Assembly)
- ❖ Scientists from CPSC, Environment Canada, EPA, FDA, NIH, and many universities across the globe
- ❖ ILSI branch representatives



***A Diverse Mix of
Sectors, Disciplines, and Points of View***
Let's capitalize on this opportunity!



The Landscape of Opportunities

It's been *four years* since HESI developed the 2010-2020 Combined Challenges Map.

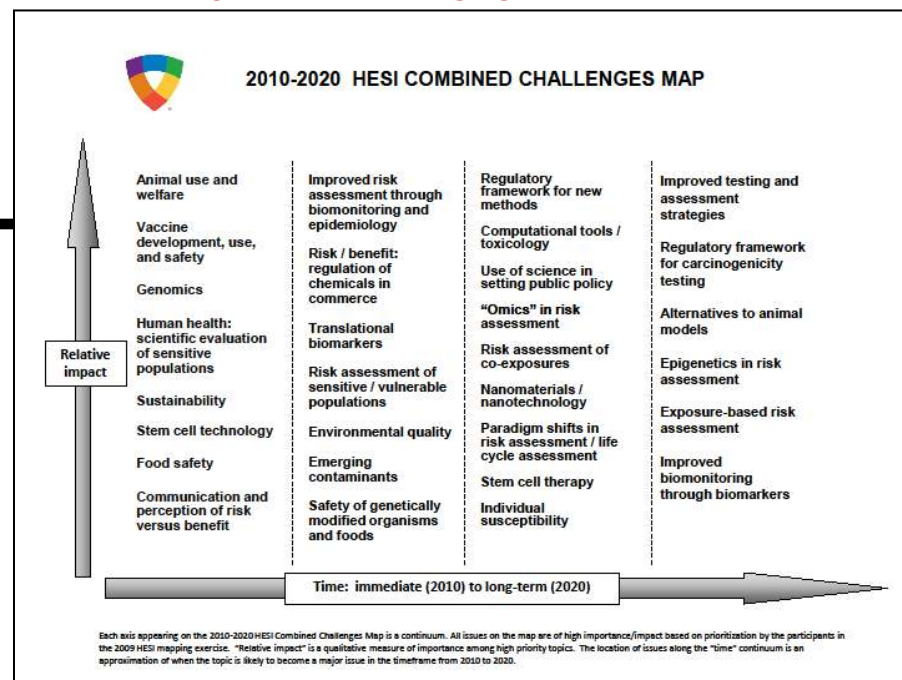
The Map isn't static... it's a *dynamic, ever-changing tool*. It needs to be refreshed periodically.

Let's use the Map to its full potential!

- ❖ to identify future challenges
- ❖ to guide new areas of investigation and research
- ❖ to consider and explore topics that are "out-of-the-box" for HESI

The HESI Board PSSC and the EIC have committed to a more deliberate and frequent evaluation of the Map.

In Program Book, Emerging Issues Session Tab





2013 HESI Scientific Portfolio

Technical Committees

- Animal alternatives in environmental risk assessment
- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Genetic toxicology
- Immunotoxicology
- Protein allergenicity
- Risk assessment for the 21st century (Risk 21)

Project Committees

- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation of chemicals
- Use of imaging for translational safety assessment
- Vaccines and adjuvants safety

Emerging Issues Subcommittees

- Evaluating causality in epidemiologic studies
- Frameworks for alternative chemical assessment and selection of safer, sustainable alternatives
- Translational biomarkers of neurotoxicity

Looking Around the Corner

**What are we
missing?**

**What are the
gaps in the HESI
Portfolio and Map?**

**What science is
critical for health
and environmental
risk and safety in
the 21st century?**



BREAKOUT GROUP INSTRUCTIONS

***Dr. Stephen J. Newsholme
(GlaxoSmithKline)
Chair, HESI Emerging Issues Committee***





Background

HESI distributed a Scientific Challenges and Priorities Survey this Spring.

Respondents identified **major scientific challenges/priorities that they or their institutions are currently facing or expect to face over the next few years.**

***A summary of survey results
can be found in the Program Book, Emerging Issues Session Tab.***



Selected Topics for Today's Breakout Groups

From the survey results, EIC Science Advisors selected six key topics:

- ❖ Alternatives to Animal Testing
- ❖ Exposure Science
- ❖ Epigenetics in Safety and Risk Assessment
- ❖ In Vitro to In Vivo Extrapolation
- ❖ Safety Assessment for New Therapeutic Modalities
- ❖ Personalized Medicine and Individual Susceptibility

These six topics are the focus of breakout group discussion (one topic for each group).



Questions for Group Discussion



Each Breakout Group is charged with exploring the following questions about their topic:

- ❖ What is important about the topic?
- ❖ Is it emerging, unresolved, or both?
- ❖ Does it have reasonable potential for resolution?
- ❖ Who is interested? (one or more sectors, government, industry, or academia?)
- ❖ Are other groups working on this topic?
- ❖ Could the topic fit within an existing HESI program?
- ❖ *What can HESI do?*



Resources



Consult the **Emerging Issues Session Tab** of the Program Book for:

- ❖ Summary of survey results
- ❖ HESI Scientific Portfolio
- ❖ Breakout Group descriptions
- ❖ Questions for discussion
- ❖ HESI Combined Challenges Map



HESI EMERGING ISSUES SESSION: *LOOKING AROUND THE CORNER*
2013 HESI Annual Meeting

Breakout Group Session

Wednesday, 12 June 2013, 2:15 pm – 3:45 pm

Hotel Monaco, Alexandria, VA

	<u>SECTOR</u>	<u>Group #1</u> Alternatives to Animal Testing	<u>Group #2</u> Exposure Science	<u>Group #3</u> Epigenetics in Safety and Risk Assessment	<u>Group #4</u> In Vitro to In Vivo Extrapolation	<u>Group #5</u> Safety Assessment for New Therapeutic Modalities	<u>Group #6</u> Personalized Medicine and Individual Susceptibility
EIC Science Advisors →	LEADER	Darlene Dixon (NIEHS)	Derek Muir (Environment Canada)	Dan Goldstein (Monsanto)	Ruth Roberts (AstraZeneca)	Jesse Goodman (US FDA)	José Manautou (University of Connecticut)
ORs and Trustees →	RAPPORTEUR	Craig Rowlands (Dow)	Don Marsh (Merck)	Mark Hurtt (Pfizer)	Tim Pastoor (Syngenta)	Mike Graziano (BMS)	David Brewster (Vertex)
	PARTICIPANTS (Board Trustees, EIC, and HESI staff) <i>All other meeting participants will self-select their breakout group of choice.</i>	Brian Berridge (GSK) Ann Blacker (Bayer CropScience) Alan Boobis (Imperial College London) Angelo Moretto (University of Milan) Michelle Embry (HESI)	Dennis Devlin (ExxonMobil) Serine Lau (University of Arizona) Hal Zenick (EPA) Jennifer Tanir (HESI) Brianna Farr (HESI)	Herman Autrup (University of Aarhus) Jay Goodman (Michigan State University) Charlene McQueen (EPA) Kathy Shelton (DuPont Haskell) Megan Harries (HESI)	Sam Cohen (University of Nebraska Medical Center) Jim Klaunig (Indiana University) Lois Lehman-McKeeman (BMS) Doug Wolf (EPA) Connie Chen (HESI)	Peggy Guzzie-Peck (Janssen; J&J) Ernie Harpur (University of Newcastle) Steve Newsholme (GSK) Raegan O'Lone (HESI)	Laurie Hanson (Pfizer) Toshi Ishikawa (RIKEN) Martin Philbert (University of Michigan) Flavio Zambrone (Brazilian Institute of Toxicology) Jennifer Pierson (HESI)

Floater: Cyril Pettit, Nancy Doerrer

**For those not assigned,
please SELF-SELECT your breakout group of choice.**

Roles: Leaders, Rapporteurs, Participants

LEADERS:

- ❖ Encourage discussion and broad participation.
- ❖ Focus discussion on your group's topic.
- ❖ If time remains, open discussion for other topics.
- ❖ Assist the Rapporteur with key points for plenary session.

RAPPORTEURS:

- ❖ Capture key points on the template.
- ❖ Give a 5-min oral summary at plenary – *high points!*
- ❖ Provide staff with final version of template by 8:30 am tomorrow.

PARTICIPANTS: ***BE ENGAGED!***



Results of Discussion

Results will be used tomorrow at a *joint meeting of the EIC and Board PSSC*.

- ❖ **Strategic enhancement of the HESI Scientific Portfolio**
- ❖ **Assessment of gaps in the HESI Combined Challenges Map**
- ❖ **Selection of possible theme(s) for Fall 2013 Emerging Issues Survey**



Logistics

2:15 pm: Breakout Group discussions
(90 mins)

3:45 pm: Break *(15 mins)*

**4:00 pm: Rapporteur reports
and open discussion** *(90 mins)*

5:30 pm: Adjourn



Majestic Suite
(5th Floor)



GROUP 4:
In Vitro / In Vivo Extrap.

Emerging Issues Session



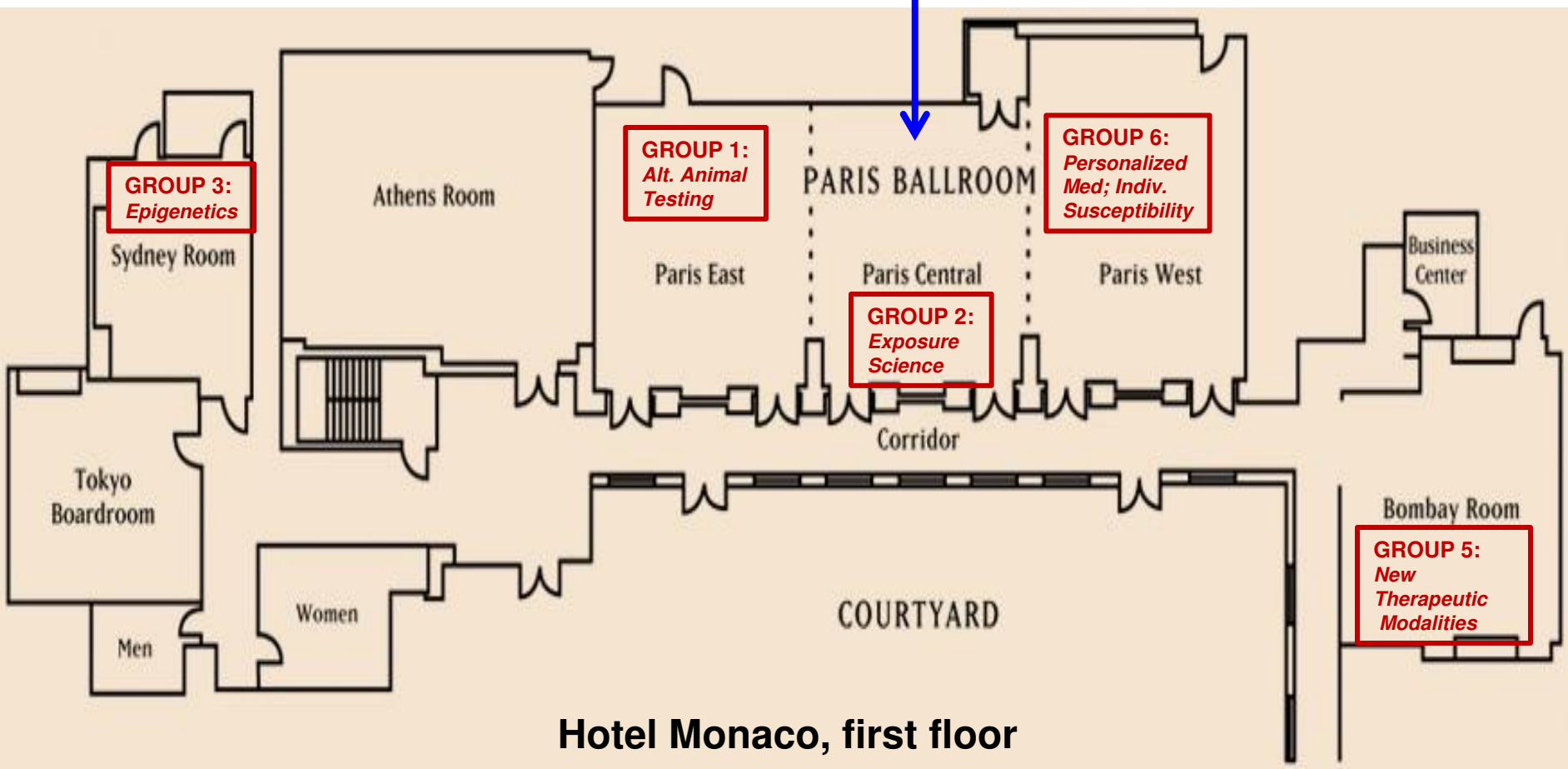
GROUP 3:
Epigenetics

GROUP 1:
Alt. Animal Testing

GROUP 6:
Personalized Med; Indiv. Susceptibility

GROUP 2:
Exposure Science

GROUP 5:
New Therapeutic Modalities



Hotel Monaco, first floor





***We'll see
you back
here at
4:00 pm!***

