



HESI Annual Meeting

May 12, 2010

Welcome!!!!

Business Meeting of the
HESI Assembly of Members

Dr. Marc Bonnefoi
President of HESI



2009 HESI Assembly of Members

- Abbott Laboratories
- Actelion Pharmaceuticals
- Allergan
- Amgen Inc.
- Astellas Pharma, Inc.
- AstraZeneca AB
- BASF Corporation
- Bayer Cropscience / Bayer AG
- Biogen Idec MA, Inc.
- Boehringer Ingelheim GmbH
- Bristol-Myers Squibb Co.
- Charles River Laboratories
- The Coca-Cola Corporation
- Covance
- Daiichi-Sankyo Co., Ltd.
- Dow Chemical Co. / Dow Agro.
- Dow Corning
- E.I. du Pont de Nemours & Co.
- Eisai Co., Ltd
- Eli Lilly and Company
- Experimental Pathology Labs
- ExxonMobil Biomed. Sciences
- F. Hoffman-La Roche Inc.



2009 HESI Assembly of Members

- GlaxoSmithKline
- Institut de Recherches Int. SERVIER
- Johnson & Johnson Pharma.
- L'Oreal Corporation
- Merck & Co., Inc.
- Mitsubishi Tanabe Pharma Corp.
- Monsanto Company
- Novartis Pharmaceuticals Corp.
- Pfizer Inc.
- The Procter and Gamble Co.
- Purdue Pharma LP
- Rohm and Haas Company
- sanofi-aventis
- Schering-Plough Research Inst.
- Shell Chemicals, Ltd.
- Sumitomo Chemical
- Syngenta, Ltd.
- Takeda Pharmaceuticals Co., Ltd.
- Valent U.S.A. Corporation



2009 HESI Assembly of Members

- ❖ We had **42 members** in the HESI Assembly in 2009.
- ❖ We thank all of our members for their continued support of HESI.
- ❖ Special thanks to . . .
 - ❖ . . . **Chevron** (currently not a HESI member) for a special contribution to HESI.



HESI Staff in 2009

❖ **Nancy G. Doerrer, MS**

Associate Director, Scientific
Program Stewardship

❖ **Michelle R. Embry, Ph.D.**

Senior Scientific Program
Manager

❖ **Regina G. Graham**

Executive Assistant

❖ **Michael Holsapple, Ph.D.,
Fellow, ATS**

Executive Director

❖ **James Kim, Ph.D., DABT**

Scientific Program Manager

❖ **Eric L. Moore**

Administrative Assistant

❖ **Cynthia J. Nobles**

Senior Executive Assistant

❖ **Raegan O'Lone, Ph.D.**

Scientific Program Manager

❖ **Syril D. Pettit, MEM**

Associate Director, Scientific
Outreach



Approval of the Minutes

(in the AOM packet)

HESI Assembly of Members Meeting January 19, 2009

In the AOM packet, you will also find:

- ❖ ILSI Anti-trust Statement
- ❖ ILSI Code of Ethics
- ❖ List of Attendees to AOM Meeting
- ❖ 2010 HESI Scientific Portfolio
- ❖ Information about Board Nominees



HESI in 2009: Some highlights . . .

- Extensive portfolio of technical committees, project committees and subcommittees.
- Excellent productivity – 14 publications, 13 workshops, and 41 presentations in 2009; see Mike's presentation later today
- Modification of the management of new projects in order to strengthen the relevance of HESI's portfolio for its partners
 - Emerging Issue Subcommittees financial support the second year of these projects only if matched by members.
 - Resource at Initiation process, a new way of initiating projects around topics that generate sufficient interest for resources to be made available immediately.



HESI in 2009: Some highlights . . .

➤ Mapping exercise

- Repeated the exercise of 2004 seeking input from a large and diverse group of scientists that represent multiple sectors including government, academia and industry, each of whom excitedly volunteered time to identify issues that are, or are likely to become, highly relevant for the future landscape of HESI constituents.
- Conducted a mapping session in Japan before hand.
- Outcome written up and submitted for publication in Critical Reviews of Toxicology.



HESI in 2009: Some highlights . . .

- **Decision for HESI to hold its 2010 annual meeting separately from ILSI in spring 2010 in the continental US**
- **Financial considerations**
 - **Efforts to make the organization even leaner**
 - **Revision of due structure with the goal of ensuring long-term sustainability**
 - **These changes provided an opportunity for HESI leadership to communicate by phone with almost all member representatives and hear their feedback.**
- **Modification of the by-laws in order to reach new member categories such as Contract Research Organizations**
- **Looking for opportunities to collaborate with other ILSI entities, e.g. Risk Assessment for the 21st Century (RISK₂₁)**



HESI in 2009: ... and a conclusion.

➤ Twenty years of partnering ... and a bright future!

As issues in safety assessment and environmental sciences become increasingly complex and the resources available to address them become more limited, partnering within HESI provides a unique way forward.

The HESI “tripartite” approach represents one of the richest examples of scientific partnering in existence today.



HESI Nominations Report - 2009

(in the AOM packet)

HESI Board of Trustees
(election by AOM)

**HESI Emerging Issues Steering
Committee** *(election by AOM)*



But first . . .

*With special thanks to our trustees
whose terms are completed
at the close of this Ann. Meeting:*

- **Dr. Jim Klaunig**, I.U. School of Medicine.
- **Dr. James MacDonald**, Chrysalis Pharma



Renominated to the HESI Board

- **Prof. Alan Boobis**, Imperial College of London.
- **Dr. Neil Carmichael**, Bayer CropScience.
- **Dr. Henry Chin**, The Coca Cola Company.
- **Dr. Samuel Cohen**, Univ. Nebraska Med. Center.
- **Dr. Dennis Devlin**, ExxonMobil Biomed. Sci.
- **Dr. Ruth Lightfoot-Dunn**, Amgen, Inc.
- **Dr. James Stevens**, Eli Lilly & Company.
- **Dr. Jan Willem van der Laan**, RIVM.
- **Dr. Kendall Wallace**, University of Minnesota.



New nominees to the HESI Board

- **Dr. Scott Belanger**, The Procter & Gamble Company (*1-year term*).
- **Dr. Peggy Guzzie-Peck**, Johnson & Johnson Pharmaceutical (*3-year term*).
- **Dr. Timothy Pastoor**, Syngenta CropScience (*1-year term*).
- **Dr. Lewis Smith**, Medical Research Council (*3-year term*).



Election of new HESI Trustees

HESI Board of Trustees (election by AOM)

**We have a quorum of the AOM –
we need a motion, a second and
a vote.**

Nominated to the EISC

Members-at-Large:

- **Dr. George Pugh**, The Coca Cola Company.
- **Dr. James Stevens**, Eli Lilly & Co. (*one-year term*)
- **Dr. Mark Tirmenstein**, Bristol-Myers Squibb.

Scientific Advisors:

- **Prof. Ian Kimber**, University of Manchester.
- **Dr. James Klaunig**, I.U. School of Medicine.
- **Dr. Derek Muir**, Environment Canada.



HESI Nominations Report

HESI Emerging Issues Steering Committee (election by AOM)

**We have a quorum of the AOM –
we need a motion, a second and
a vote.**



HESI Nominations Report

For Informational Purposes

HESI Board Officers

(election by the HESI Board on 5/12/10)

HESI Executive Committee

(election by the HESI Board on 5/12/10)

HESI representatives to the ILSI Board

(elected by the ILSI Board on 1/23/10)



Nominees for HESI Board Officers

HESI Leadership Succession Plan:

- Elect new Vice President (an industry member in odd yrs) or Vice Chair (a public member in even yrs).
- Elect new Treasurer and Secretary, as needed.
- All officers elected to two-year terms.



Nominees for HESI Board Officers

Chair (roles and responsibilities):

- Ensures that Board and ExCom provide sound programmatic and fiscal policy and oversight.
- Ensures smooth operation of Board and ExCom – presides at all meetings of Board and ExCom.
- Assists President, where appropriate, in HESI member development and fund raising activities.

Vice Chair (roles and responsibilities):

- As with Chair, an elected public trustee.
- Assists Chair.
- Co-chairs HESI PSSC with Vice-President.



Nominees for HESI Board Officers

Secretary (roles and responsibilities):

- Automatically becomes Chair of HESI Communication and Outreach Committee.
- Ensures that notices and minutes are issued in a complete and timely fashion.

Treasurer (roles and responsibilities):

- Automatically becomes Chair of HESI Finance Committee.
- Ensures that funds are collected and deposited or invested.
- Ensures that disbursements are made as ordered.



Nominees for HESI Board Officers

- ✓ **'10 CHAIR:** Dr. Kendall Wallace.
- ✓ **'10 VICE CHAIR:** Dr. Ron Hines.
- ✓ **'10 SECRETARY:** Dr. Jan Willem van der Laan.
- ✓ **'10 TREASURER:** Dr. Norb Kaminski.



Nominees for '10 HESI Exec. Comm.

- ✓ **Dr. Marc Bonnefoi**, President.
- ✓ **Dr. Dennis Devlin**, Vice President.
- ✓ **Dr. Kendall Wallace**, Chair.
- ✓ **Dr. Ron Hines**, Vice Chair.
- ✓ **Dr. Jan Willem van der Laan**, Secretary.
- ✓ **Dr. Norbert Kaminski**, Treasurer.
- ✓ **Prof. Alan Boobis**, Past-Chair.
- ✓ **Dr. Henry Chin**, Member-at-Large.
- ✓ **Dr. Jay Goodman**, Member-at-Large.
- ✓ **Dr. Laurie Hanson**, Member-at-Large.
- ✓ **Dr. Peter Moldeus**, Member-at-Large.
- ✓ **Dr. Lewis Smith**, Member-at-Large.



HESI Representatives on ILSI BOT

New Nominees:

- ✓ **Dr. Henry Chin**, Term expires after 2013 A.M.
- ✓ **Dr. Samuel Cohen**, Term expires after 2013 A.M.

Current Representatives:

- ✓ **Dr. Marc Bonnefoi**, Term expires after 2011 A.M.
- ✓ **Dr. Alan Boobis**, Term expires after 2012 A.M.
- ✓ **Dr. Jay Goodman**, Term expires after 2011 A.M.
- ✓ **Dr. Lewis Smith**, Term expires after 2012 A.M.



HESI 2010 Budget

**Approved via HESI Board
Teleconference on
Friday, December 11, 2009**

**Dr. Jack Dean
HESI Treasurer**



HESI Financial Report

General Operating Budget

	2009 Budget	2009 Projections	2010 Proposed
Revenue	\$1,346,000	\$1,340,611	\$1,416,714
Expenses	\$1,479,222	\$1,513,252	\$1,241,246
Net Income / (Loss)	(\$133,222)	(\$172,641)	\$137,968*
Net Assets	(\$72,567)	(\$111,987)	\$25,981

** 2010 Proposed Budget Net Income includes an intra-company transfer expense of \$37,500.*



HESI Financial Report

Assessing Committees

	2009 Budget	2009 Projections	2010 Proposed
Revenue	\$1,379,305	\$1,535,623	\$1,827,117
Expenses	\$2,249,287	\$1,984,641	\$2,386,153
Net Income / (Loss) *	(\$834,982)	(\$465,403)	(\$521,536)
Net Assets	\$477,018	\$846,596	\$325,060

** Net Income / (Loss) includes intra-company transfers. Net losses may result when committees expend prior year net asset reserves. Committees have been encouraged to do so.*

HESI Financial Report

*HESI Reserve Fund **

	2008 Actual	2009 Projections	2010 Budgeted
Net Income / (Loss)	(\$271,110)	\$77,304	\$16,740
Net Assets	\$861,962	\$939,266	\$956,006

** Includes both the Reserve Fund & the 'Sunsetted' Committee Fund*



HESI Financial Report

HESI's Net Assets =
General Operating Budget
+ Assessing Committees
+ HESI Reserves

2008 Year End	2009 Projections	2010 Proposed
\$2,234,616	\$1,673,876	\$1,307,048



2010 Annual Meeting Overview

Dr. Marc Bonnefoi
HESI President



2010 HESI Scientific Program

- ❖ **Scientific Session** – Wednesday, 1:30-5:30:
"New Strategies and Approaches for Assessing Genetic Toxicity and its Role in Human Risk Assessment."
- ❖ **Emerging Issues Session** – Thursday, 8:30-12:00: Hear about current EI subcommittees and new HESI EI topics!!
- ❖ **Scientific Session** – Thursday, 1:30-5:00:
"State-of-the-Science within HESI." Hear about Cardiac Safety, Risk 21 and Translational Imaging.



Upcoming HESI Annual Meetings

❖ **June 6 – 10, 2011** – Crowne Plaza
Old Town Alexandria. **Alexandria,
VA.**

❖ **2012 Annual Meeting** – Location
and Dates. **To be determined ***.

* We need your input!!!!



Impacts of HESI Scientific Portfolio

Dr. Marc Bonnefoi
HESI President

Dr. Michael Holsapple
HESI Executive Director



HESI Scientific Portfolio

Introduction to the Portfolio

Dr. Marc Bonnefoi

HESI President

Highlights of the Portfolio

Dr. Michael Holsapple

HESI Executive Director



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Special Activities

- Methodology for intermittent / short-term exposure to carcinogens (MISTEC)
- Risk Assessment in the 21st Century (Risk 21)

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation
- Relevance and follow-up of positive results from *in vitro* genotoxicity (IVGT) testing
- Use of Imaging in Preclinical Safety Assessment

Emerging Issues Subcommittees

- Distinguishing adverse from adaptive, non-functional and pharmacological changes in toxicology studies



Historical Highlights of Portfolio

- ❖ For many years, most activities were represented by their own posters (ILSI AM).
- ❖ This approach was replaced by a series of individual presentations for all activities(8-10 minutes) at the HESI AOM meeting or HESI EI session.
- ❖ Several years ago, we decided to focus one of our scientific sessions on the 'State-of-the-Science' within HESI for more in-depth presentations (30-45 minutes) of a few activities.

How to Judge Impact of Portfolio?

- ❖ One measure of 'impact' can be illustrated by the PSSC review process, which emphasizes both output and outcome of committees.
- ❖ Other measures of impacts are HESI-sponsored workshops, and other HESI presentations.
- ❖ Obvious measures of impact are HESI publications in peer-reviewed journals. We have recently begun a citations analysis to further assess the 'impacts' of our papers.

PSSC Review of Project Committees

COMMITTEE	FOUNDING YEAR	FIRST REVIEW DATE (re-charter period)	SECOND REVIEW DATE (re-charter period)
Animal Alternative Needs in Environmental Risk Assessment Project Committee	2007	Fall, 2010	Fall, 2012
Biological Significance of DNA Adducts Project Committee	2003	July, 2008 (2-yr re-charter)	Fall, 2010
Biomarkers of Nephrotoxicity Project Committee	2008	March, 2010 (2-yr re-charter)	Spring, 2012
Development of Methods for a Tiered Approach to Assess the Bioaccumulation of Chemicals Project Committee	2005	January, 2009 (2-yr re-charter)	Spring, 2011
Relevance and Follow-up of Positive Results in In Vitro Genetic Toxicology Testing Project Committee	2005	April, 2010 (2-yr re-charter)	Spring, 2012
Use of Imaging in Preclinical Safety Assessment	2010	Spring, 2011	Spring, 2013

PSSC Review of Technical Committees

COMMITTEE	FOUNDING YEAR	FIRST REVIEW DATE (re-charter period)	SECOND REVIEW DATE (re-charter period)
Application of Genomics to Mechanism-based Risk Assessment Technical Committee	1999	January, 2007 (2-yr re-charter)	January, 2009 (3-yr re-charter)
Cardiac Safety Technical Committee	2008	July, 2009 (3-yr re-charter)	Fall, 2012
Developmental and Reproductive Toxicology Technical Committee (DART)	1996	January, 2007 (2-yr re-charter)	January, 2009 (3-yr re-charter)
Immunotoxicology Technical Committee (ITC)	1992	January, 2007 (2-yr re-charter)	July, 2009 (3-yr re-charter)
Integration of Biomonitoring Exposure Data into the Risk Assessment Process Technical Committee	2002	January, 2008 (3-yr re-charter)	Spring, 2011
Mixtures – risk assessment	2010	July, 2008 (as RAM) (3-yr re-charter)	Fall, 2011
Protein Allergenicity Technical Committee (PATC)	1997	July, 2007 (2-yr re-charter)	March, 2010 (3-yr re-charter)

HESI Outreach 2009

(Workshops)

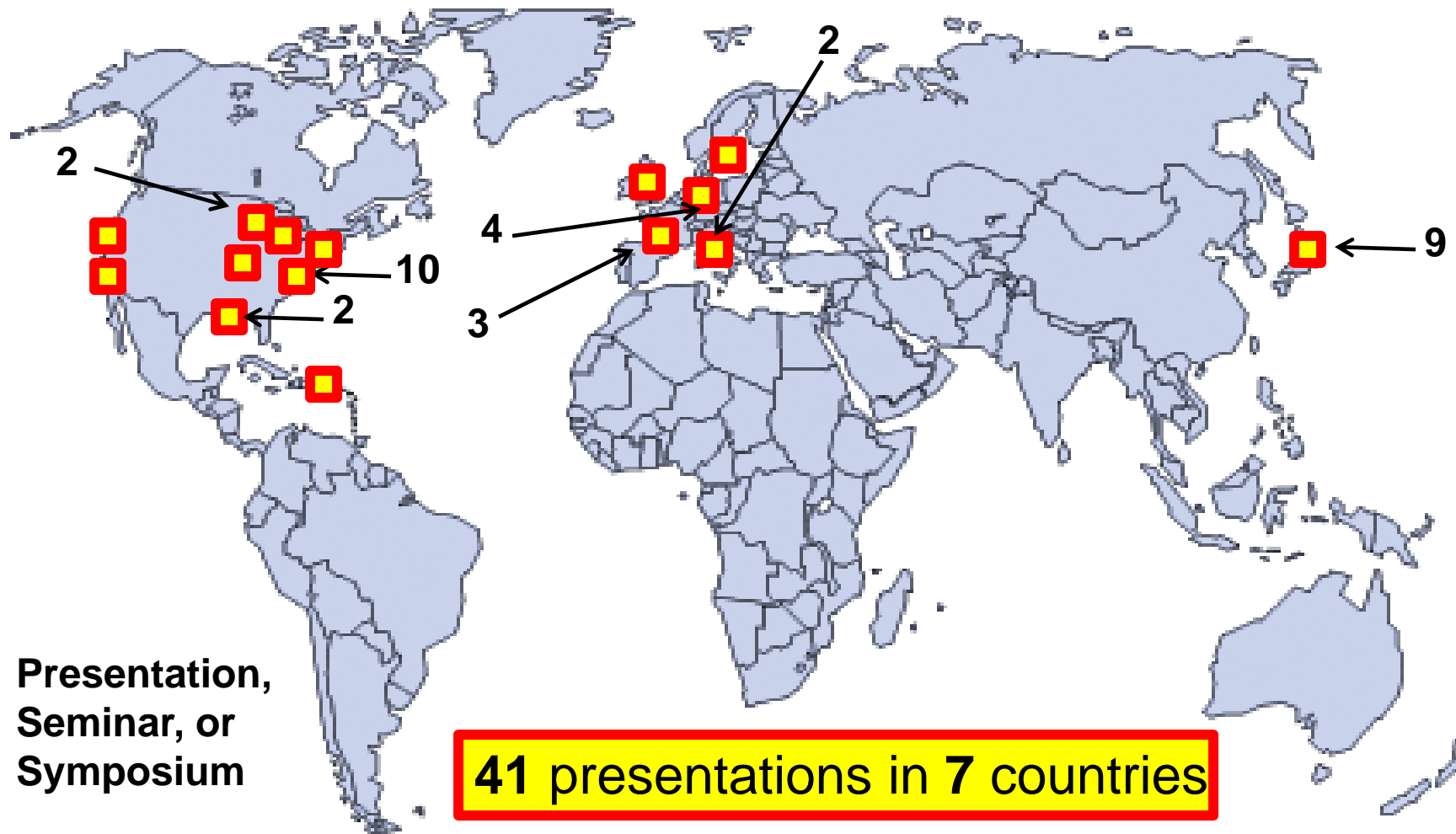


2009 HESI Workshops (=committee sponsored or HESI wide meeting– not in context of a larger meeting/not a workshop ‘session’)

Workshop	Committee	Date	Location
DART New Directions Workshop	DART	April 29-30	Washington DC
Current Practice in Structural and Functional Assessment of Cardiovascular Toxicity: Issues and Opportunities	Cardiac Safety Technical Committee	June 2-4	Washington, DC
Maternal Toxicity and its Impact on Study Design and Data Interpretation	DART	September 9	Arles, France
Alternative Assays Workshop II	DART	September 10	Arles, France
Genomics in Cancer Risk Assessment	Genomics	August 27-28	Venice, Italy
HESI Workshop on the State of the Science of Epigenetics	Epigenetics	October 28-30	RTP, NC
Using Mode-of-Action Information to Improve Regulatory Decision Making	HESI/ILSI RF/ECETOC – Mode of Action	November 2-3	London, UK
HESI Workshop on Evaluating Biological Variation in Non-Transgenic Crops	PATC	November 16-17	Paris, France
HESI Workshop on Lab – Field Bioaccumulation	Bioaccumulation /SETAC/US EPA	November 18-19	New Orleans, LA
Translational Imaging in Preclinical Safety Assessment and Environmental Hazard Identification	Imaging in Safety Assessment	December 1-2	Washington, DC
HESI Workshop to Develop a Framework for Estimating Potential Human Cancer Risk from Intermittent and/or Short-Term Exposures	MISTEC	December 1-3	Washington, DC
Japanese Scientific Mapping	HESI	January 28-29	Hamamatsu, Japan
U.S. Scientific Mapping	HESI	July 28-29	Reston, VA

HESI Outreach 2009

(Presentations, seminars, symposia)



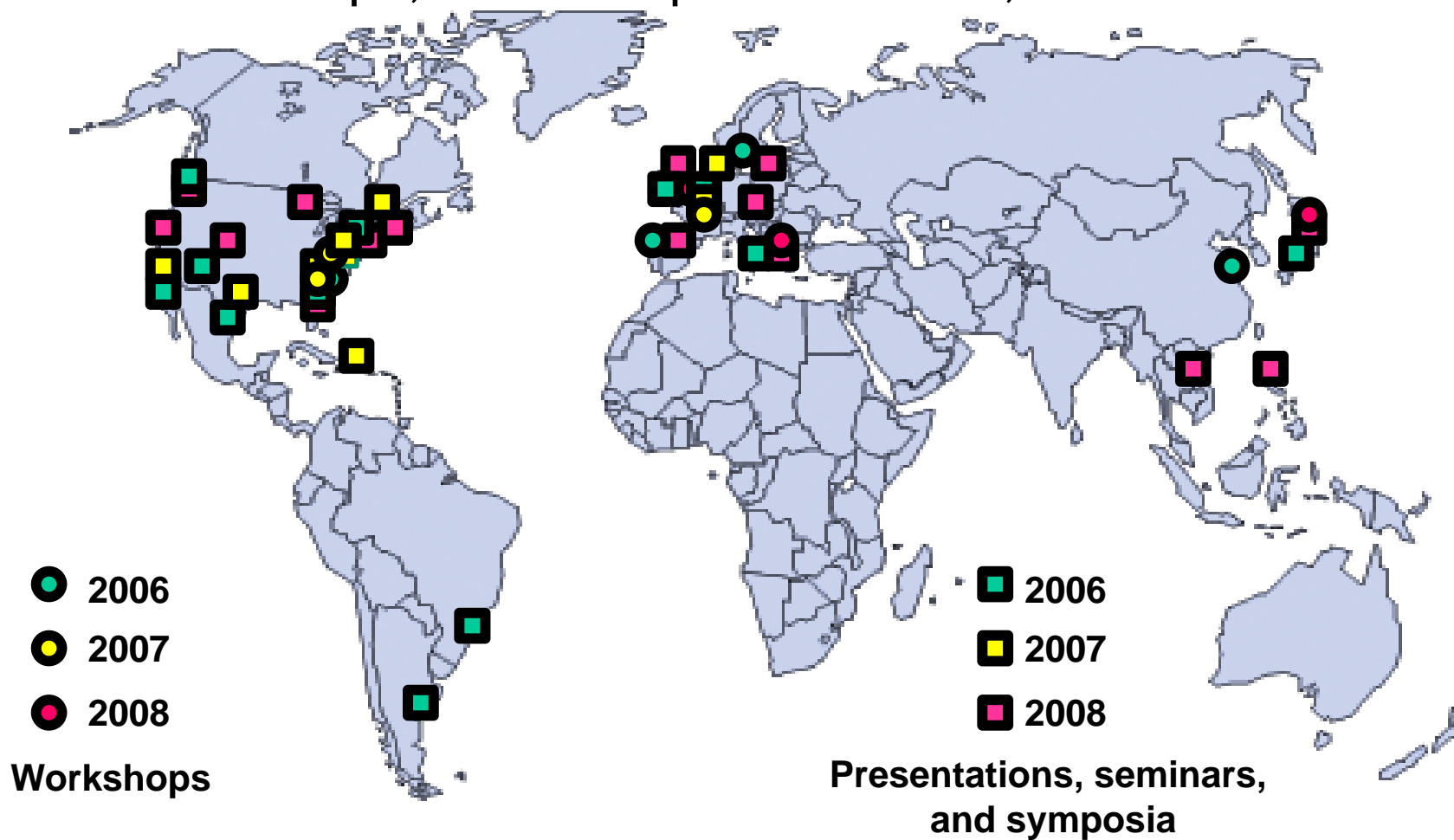
HESI Presentations in 2009

- **20 in USA** (4-Washington DC area, 6-Baltimore, MD {DC & Baltimore combined on current map}, 1-Ann Arbor, MI, 1-San Francisco, CA, 1-Palm Springs, CA, 1-San Juan, PR, 1-St. Louis, MO, 2-Minneapolis, MN, 2-New Orleans, LA, 1-Boston, MA).
- **9 in Japan** (1-Hamamatsu, 1-Morioka, 3-Tokyo, 1-Chiba, 1-Tsukuba, 2-Osaka)
- **1 in Sweden** (Goteborg)
- **1 in United Kingdom** (Warwick)
- **4 in Germany** (3-Dresden, 1-Munich)
- **2 in Italy** (1-Rome, 1-Florence)
- **3 in France** (Strasbourg)
- **1 LiveMeeting** (*not currently captured on map*)

HESI Outreach 2006 - 2008

(Workshops, Presentations, Symposia)

20 workshops, over 100 presentations, 18 countries



HESI Peer-reviewed Publications

- ❖ 14 publications in 2009 reflecting output from 8 committees.
- ❖ Citations Analysis:
 - 73 publications from '04 -> '08; 797 citations.
 - 13 publications from '06; 212 citations.
 - Citations from authors in 23 countries.
 - Sectors of citing authors: INDUSTRY -> 22%; GOVERNMENT -> 35%; & ACADEMIA -> 43%.



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Special Activities

- Methodology for intermittent / short-term exposure to carcinogens (MISTEC)
- Risk Assessment in the 21st Century (Risk 21)

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation
- Relevance and follow-up of positive results from *in vitro* genotoxicity (IVGT) testing
- Use of Imaging in Preclinical Safety Assessment

Emerging Issues Subcommittees

- Distinguishing adverse from adaptive, non-functional and pharmacological changes in toxicology studies



2010 HESI Scientific Program

H E S I

❖ **Scientific Session – Wednesday, 1:30-5:30:**

"New Strategies and Approaches for Assessing Genetic Toxicity and its Role in Human Risk Assessment."



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Special Activities

- Methodology for intermittent / short-term exposure to carcinogens (MISTEC)
- Risk Assessment in the 21st Century (Risk 21)

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation
- Relevance and follow-up of positive results from *in vitro* genotoxicity (IVGT) testing
- Use of Imaging in Preclinical Safety Assessment

Emerging Issues Subcommittees

- Distinguishing adverse from adaptive, non-functional and pharmacological changes in toxicology studies



2010 HESI Scientific Program

H E S I

❖ Scientific Session – Wednesday, 1:30-5:30:

"New Strategies and Approaches for Assessing Genetic Toxicity and its Role in Human Risk Assessment."

❖ Emerging Issues Session – Thursday, 8:30-12:00: Hear about current EI subcommittees and new HESI EI topics!!



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Special Activities

- Methodology for intermittent / short-term exposure to carcinogens (MISTEC)
- Risk Assessment in the 21st Century (Risk 21)

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation
- Relevance and follow-up of positive results from *in vitro* genotoxicity (IVGT) testing
- Use of Imaging in Preclinical Safety Assessment

Emerging Issues Subcommittees

- Distinguishing adverse from adaptive, non-functional and pharmacological changes in toxicology studies



2010 HESI Scientific Program

H E S I

❖ Scientific Session – Wednesday, 1:30-5:30:

"New Strategies and Approaches for Assessing Genetic Toxicity and its Role in Human Risk Assessment."

❖ Emerging Issues Session – Thursday, 8:30-12:00: Hear about current EI subcommittees and new HESI EI topics!!

❖ Scientific Session – Thursday, 1:30-5:00: *"State-of-the-Science within HESI."* Hear about Cardiac Safety, Risk 21 and Translational Imaging.



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Cardiac safety
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Special Activities

- Methodology for intermittent / short-term exposure to carcinogens (MISTEC)
- Risk Assessment in the 21st Century (Risk 21)

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation
- Relevance and follow-up of positive results from *in vitro* genotoxicity (IVGT) testing
- Use of Imaging in Preclinical Safety Assessment

Emerging Issues Subcommittees

- Distinguishing adverse from adaptive, non-functional and pharmacological changes in toxicology studies



H E S I®

2010 HESI Scientific Portfolio

Technical Committees

- Application of genomics to mechanism-based risk assessment
- Developmental and reproductive toxicology (DART)
- Immunotoxicology
- Integration of biomonitoring exposure data into the risk assessment process
- Protein allergenicity
- Mixtures – Risk Assessment

Project Committees

- Animal alternative needs in environmental risk assessment
- Biological significance of DNA adducts
- Biomarkers of nephrotoxicity
- Development of methods for a tiered approach to assess bioaccumulation

Special Activities

Emerging Issues Subcommittees

What about remaining committees?

- ❖ All components of portfolio are described in detail in our Annual Report (*elements of an 'activity report'*). Read the Annual Report.
- ❖ Most components of portfolio are described in 'Fact Sheets' available on our website. Visit the website.
- ❖ Members of HESI staff are invaluable resources regarding components of portfolio. Contact the staff.

Closing Remarks

- ❖ We value your input.
- ❖ Any questions?
- ❖ Any comments?
- ❖ Any concerns?



Highlights of HESI Outreach

Outreach in Japan
Ms. Ayako Takei

Outreach in Europe
Ms. Cyril Pettit & Dr. Michelle Embry

Plenary Lecture

Introduction of 'keynote speaker'

Dr. Marc Bonnefoi



Keynote Address

**“Where Science Stops
and Policy Begins.”**

Dean John Graham
Indiana University School of Public
and Environmental Affairs



‘Special Presentation’

Dr. Marc Bonnefoi