HESI’s Role in Translational Science via CITE

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GlaxoSmithKline R&D
What is CITE?

- Inaugurated by a workshop in December, 2012, entitled ‘Towards New Science for Public Health
- Broad sector/discipline participation
- Consensus on value
- Explored mechanisms of collaboration, funding, and training

Combined Interdisciplinary and Translational Expertise
“Basic researchers, clinicians, regulators, industrial scientists, and entrepreneurs are all strongly invested in the ‘why’ and ‘what’ of translational science. But what about the ‘how’?

“...we must do more to enhance the “how” with relevant training, experience, and incentives.”
Creating Knowledge for a Healthier, Sustainable World

Since 1989, the Health and Environmental Sciences Institute (HESI) has engaged scientists from academia, government, industry, research institutes and NGOs to identify common health and environmental concerns and develop scientific knowledge leading to a healthier, more sustainable world.

**Shared Challenges, Shared Solutions**

HESI’s multi-sector, multidisciplinary stakeholders are passionate about working together to answer pressing scientific questions.
How does that manifest in our committees and working groups?

ILSI Health and Environmental Sciences Institute

<table>
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<tr>
<th>Working Group</th>
<th>Members</th>
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| Cardiac Stem Cells Working Group | Hugo Vargas, Amgen Inc.  
Kevin Dreher, EPA |
| Cardiac Biomarker Working Group | Eric Schultz, Lilly  
Marjory Brooks, Cornell U |
| Proarrhythmia Working Group | Jean-Pierre Valentin, AZ  
John Koerner, FDA |
| Integrative Strategies Working Group | Brian Berridge, GSK  
Dusty Sarazan, DSI |

- **Cardiac Safety Committee**
- **Working Groups**

- **Cardiac Stem Cells Working Group**
  - Initial workshop: March 18-19, 2013  
  - Manuscript in progress
  - Subteams in development
  - Data collection initiated

- **Cardiac Biomarker Working Group**
  - New Biomarkers Study Design
  - Platelet Subteam
  - Coagulation-Fibrinolysis Subteam
  - Endothelium Subteam
  - Proof of Concept Study Completed
  - Study model selection
    - Search initiated

- **Proarrhythmia Working Group**
  - Predicting QT Interval, Torsades de Pointes
  - Literature Search
    - Publication in progress
  - FDA Database
    - Publication in progress
  - Phase II Initiated: Assess discordant compounds

- **Integrative Strategies Working Group**
  - Preclinical - Clinical Concordance Contractility
  - Canine/Rodent Echo & Telemetry Studies
  - Review Paper in development

- **Committee Members**
  - Safety pharmacologists
  - Anatomic pathologists
  - Clinical pathologists
  - Toxicologists
  - Cell biologists
  - Physicians
Committees pushing the envelope-
Bridging disciplines in cardio-oncology

International Colloquium on Cardio-Oncology
Rome (Italy), March 12-14, 2014
Hotel Columbus - Via della Conciliazione, 33
Organized by DEPARTMENT OF DRUG SCIENCES AND CLINICAL PHARMACOLOGY UNIVERSITY CAMPUS BIO-MEDICO OF ROME
Promoted by FONDAZIONE INTERNAZIONALE MENARINI

The application for European accreditation has been granted 11 European CME credits (ECMEC) by the European Accreditation Council for Continuing Medical Education (EACCME)

Draft 28 May 2014 – Preshubmission, Do not cite
Opportunities to Meet Clinical Cardio-Oncology Needs with New Approaches to Nonclinical Safety Assessment
Berridge¹, B. R., Pettit, S² and Sarazan³, R. D.
Interesting Conversations

NASA Human Health Challenges

• Markers of health, disease and therapy
• In-flight bio-sample analysis
• Non-invasive imaging
• Drug delivery
• PK capabilities
• Drug stability
• Cell/tissue/animal models
• Sterilization systems

HESI-NASA Medicine StAbility Innovation Collaboration (MoSAIC) Project

Combining needs and expertise to solve earth and space based health-care challenges

Step 1: Brainstorming Meeting: Determine areas of potential mutual interest

- Focus on packaging & formulation
  - Packaging (Physical Methods – purging etc.)
  - Formulation (Liquid, Dry)
  - Reconstitution Process (Ease of use)
  - Delivery Techniques
  - Innovative Stabilization Techniques
  - Environmental Considerations
- Determine what health needs are unmet or underserved because of inadequate medicine stability;
- Determine what Drug Types can benefit from “enhanced” packaging/delivery techniques
  - Vaccines/Antibiotics/Antiseptics/Biologics?
- Determine if proposed Drug Types and potential packaging/formulation meet the earth and space needs for the partners

Defining the Point of Synergy & Impact

Step 2: If synergy and interest exists - form a collaborative project to address the options
Interesting Partnership Opportunities

GlaxoSmithKline (GSK) and McLaren Group announce innovative strategic partnership
Issued: Thursday 15 September 2011, London UK

GlaxoSmithKline (GSK) today announced that it has formed a long term strategic partnership with McLaren Group. The partnership, which will run initially until 2016, brings together two UK companies focused on innovation and high-tech research.

Not a HESI effort; used as an example
Potential for Re-inventing Approaches to Health and Therapeutics

3D Tissue printing

Miniaturization

Advanced Imaging

Biomonitoring

Novel testing platforms
Realizing the Potential

- Technology is not a limitation!
- Recognizing opportunity is not a limitation!
- Putting the two together is a challenge
- Requires intent, expertise and resource
- HESI uniquely positioned to facilitate