A Collaborative Model for Translational and Regulatory Life Sciences Research, Training and Business Development Partnerships

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The Hamner Institutes at Research Triangle Park

Discovery Research

Capture & Translation

New/Safer Medicines & Diagnostics

Public Health Policy

Business & Economic Development
A Global Leader in Environmental Health and Safety Sciences Research and Training

The Hamner Institutes Campus is located on a 56 acre site in the center of Research Triangle Park and nearby to Duke University, the University of North Carolina at Chapel Hill, and North Carolina State University.

35 Years of Research in Small Molecule Safety

- Award Winning Scientific Staff
- 3000 Publications (including Science and Nature)
- **300 Postdoctoral Trainees**
- **100 Predoctoral Trainees**
- International Programs in Chemical Safety Assessment
- ToxCast 21 (US EPA)
- Toxicity Testing in the 21st Century (NRC/NAS)
CIIT/Hamner Postdoctoral Fellows
Career Paths

- Academia: 30%
- Chemical Industry: 27%
- Government: 9%
- Pharmaceutical Industry: 18%
- Other: 16%
Leveraging Chemical Safety Sciences

Protect Public Health  New and Safer Medicines

Chemical Industry  Chemical Safety Sciences  Drug Safety Sciences  Pharmaceutical Industry

Academe

Government
NIEHS – EPA – NIH – FDA
Hamner Institutes and Centers

- Institute for Chemical Safety Sciences
- Institute for Drug Safety Sciences
- Center for Genomic Biology and Bioinformatics
- Center for Human Health Assessment
- Center for Preclinical Safety and Efficacy
- Toxicology & Research Services
Transitioning Public Policy Decision Making from Hazard Identification to Predictive Health Outcomes

Response

Log Dose

NAS/NRC Report
Systems Integration to Accelerate Drug Development and Inform Public Policy

- Clinical Studies and Post-Marketing Surveillance
- Advanced Animal Models—"Humanized" Mice
- Advanced Multi-Dimensional Human Organ Systems
- High Throughput Readout and Capture
Quantitative Systems Computational Models of Pathways and Networks Predict Human Physiology
IDSS Awards and Partnerships

- $2.1 million awarded to date from pharmaceutical companies with $1.2 million pending
- Collaborative awards with Triangle Universities
  - NIH T32 Clinical Pharmacology Training Grant with Duke DCRI-DILIN (Danny Benjamin) and UNC School of Pharmacy (Kim Brouwer)
  - NIH/NIDDK ARRA grant with NCSU (David Threadgill)
  - Duke Center for Human Genome Variation (David Goldstein)
  - Gates Foundation with UNC School of Medicine (Richard Tidwell)
  - TB Hepatotoxicity Project with Shanghai CDC and UNC CTSA/TRACS Program
The 21st Century Drug Discovery & Development Paradigm

Pharma Companies – Decreasing Early R&D

Target Identification > Hit Identification > Lead Identification > Lead Optimization > Pre-Clin. Development

Phase 1: Single & repeat dose escalation HVTs
Phase 2: Dose Ranging in patients
Phase 3: patients
Pre-Reg.
Phase 3b/4

Bridging the Gap

Academic & other Non-Profit Organizations – Minimal Early Development Capability

Target Identification > Hit Identification > Lead Identification > Lead Optimization > Pre-Clin. Development

Phase 1: Single & repeat dose escalation HVTs
Phase 2: Dose Ranging in patients
Phase 3: patients
Pre-Reg.
Phase 3b/4
Technology Creation to Technology Commercialization
--An Iterative Continuum--

Technology Creation
- Basic Research

Translational Research

Technology Development

Technology Commercialization
- Accelerated Product Development
- Keeping Products “on the shelf”
- Informed Public Policy
Hamner Biosciences Accelerator

New Core Facilities
• Regulatory Compliant
• Education
• Training

Emerging Companies
• BioMedomics
• b3bio
• Chaperone
• Ascletis

Technology Development
• Research Partnerships
• Commercialization
• Global Partners

Strategic Alliances
• Academic
• Industry
• Government Agencies
Hamner/China Partnerships
Shanghai CDC-Hamner International Institute for Health and Safety Sciences

Official Signing Ceremony
October 26, 2009

Goal
Strengthen partnership in drug & environmental chemical safety

- New *in vivo* and *in vitro* safety assessment technologies
- Predictive computational models
- Environmental assessments
- Biomonitoring
- **Training and education programs**

1,000 Patient drug-resistant TB study launched in partnership with SCDC, The Hamner, and the University of North Carolina Chapel Hill