Delaware Health Sciences Alliance
5th Annual Research Symposium
Transitions Toward Clinical Translational Research
Conference Welcome

Patrick Harker
President
University of Delaware
Robert Laskowski
President & CEO
Christiana Care Health System
Paul Kempinski
Chief Operating Officer
Nemours A. I. duPont Hospital for Children
Alfred I. duPont Hospital for Children Expansion Project
Richard Gozon
Interim President
Thomas Jefferson University
The DHSA: Impact and Promise

Kathleen Matt
Executive Director, DHSA
Dean, College of Health Sciences, UD
Connections

Networks

2009 – 2013
- Special Topic Conference (3)
- Spring Research Symposia (5)
- Education Workshops (2)
- Global Health Symposia (2)
- Education Grants (5)
- Research Grants (9)

- More than 70 participants on Coordinating Council & task force
- Direct participation in conferences/workshops: @1,850
  - Research @ 650
  - Topical @ 1,200

Over 1,100 international site visits from India, China, Germany, Egypt and Spain.
DHSA: Impact and Promise
THE IOWA CLINICAL & TRANSLATIONAL MODEL - ICTS

Raymond J Hohl, MD PhD
Holden Family Chair
Professor of Internal Medicine and Pharmacology,
Division of Hematology, Oncology and Blood & Marrow Transplantation
Associate Chair, Technology Transfer, Department of Internal Medicine
Associate Director, Clinical and Translational Research, Holden Comprehensive Cancer Center
Director, Holden Family Program of Experimental Therapeutics, Holden Comprehensive Cancer Center
Co-Director, Drug Discovery & Development Core, Institute for Clinical & Translational Science (ICTS)
http://www.healthcare.uiowa.edu/Labs/Hohl/Default.html

May 10, 2013
Disclosure

DR. HOHL IS A FOUNDER AND OFFICE HOLDER IN TERPENOID THERAPEUTICS INC WHICH WAS ESTABLISHED IN 2005
NIH CTSA funding initiative established in 2006
First NIH awards funded in 2006
University of Iowa ICTS established in 2006 by the Iowa Board of Regents
Iowa funded in 2nd round in 2007 in a group of ~12 other institutions (Case Western, Emory University – partnering with Morehouse School of Medicine, and Georgia Institute of Technology, Johns Hopkins University, University of Chicago, University of Michigan, University of Texas Southwestern Medical Center at Dallas, University of Washington, University of Wisconsin-Madison, Vanderbilt University – partnering with Meharry Medical College, Washington University, and Weill Cornell Medical College – partnering with Hunter College)
Renewal 2011 – not funded
Submission in 2013
Approximately 60 medical research institutions in 30 states (including the District of Columbia) are active members of the CTSA Consortium.
MISSION STATEMENT: “To nurture the translation of advances in the biomedical and clinical sciences into novel therapies and diagnostic techniques and into more effective healthcare delivery and health policy.”

- Support clinical and translational research studies
- Assist investigators to prepare research grants and IRB applications
- Support education & training needs of junior investigators & staff
- Seek partnerships to more effectively leverage existing strengths and resources to develop new initiatives in translational science
- Bring people & programs together in new ways to improve translational science and to lead to innovative discoveries to improve health
Gary Rosenthal, MD
Professor of Internal Medicine
Director, Division of General Internal Medicine
Director K30 Iowa Scholars in Clinical Investigation (2003-07)
Director, University of Iowa Institute for Clinical and Translational Science
Director, Center for Research in the Implementation of Innovative Strategies in Practice, Iowa City VA Medical Center
TRAINING PROGRAMS

- NON-DEGREE
- DEGREE
- CERTIFICATE
NON-DEGREE PROGRAMS

- KL2 PROGRAM
- MEDICAL SCIENTIST TRAINING PROGRAM
- PHYSICIAN SCIENTIST TRAINING PATHWAY
- TL1 PROGRAM
• **MS CLINICAL INVESTIGATION**
  ○ This is a 2-year, 30 student hour graduate program

• **MS TRANSLATIONAL BIOMEDICINE**
  ○ Requires coursework and research equivalent to 54 semester hours of graduate credit. Each student's plan of study for the three-year program is based on his or her chosen discipline

• **PhD TRANSLATIONAL BIOMEDICINE**
  ○ Requires a minimum of 72 semester hours of graduate credit
CERTIFICATE IN TRANSLATIONAL AND CLINICAL INVESTIGATION

The ICTS and the Department of Epidemiology offer the Certificate in Translational and Clinical Investigation. This certificate program requires a minimum of 19 s.h. of graduate credit and may be completed in one year. It is designed for clinicians who seek advanced training in clinical methodology and applied patient-oriented research skills. Completion of the certificate is noted on the student's transcript.
ACADEMIC CAREER DEVELOPMENT

- BENCH TO BEDSIDE SERIES
- COMPETENCY BASED CORE COURSES
- COURSE IN SCIENTIFIC LEADERSHIP
- ETHICS IN CLINICAL RESEARCH
- HEALTH SCIENCES RESEARCH WEEK
- IRB TRAINING
- MOCK STUDY SECTIONS
- SEMINAR IN CLINICAL AND TRANSLATIONAL SCIENCE
- SEMINAR IN COMPARATIVE EFFECTIVENESS RESEARCH
- SURVIVAL SKILLS FOR CLINICAL INVESTIGATORS
- VIRTUAL UNIVERSITY
This seminar pairs a basic scientist and a clinical scientist to demonstrate the bench and bedside aspects of translational research. The one-hour, monthly seminar includes two brief presentations with discussion. The informal atmosphere allows presenters to share personal success stories and challenges, and encourages dynamic interactions between junior and senior researchers.
The two-day Course in Scientific Leadership enhances junior investigators' skills in scientific leadership, team building, participant networking, and research program management. It was offered in 2012 and will be held biannually thereafter.

The 2011 course, based on a course initially implemented at the University of Pittsburgh, was facilitated by Brian Fitch, PhD, a nationally recognized management consultant. It attracted 33 investigators (18 PhD, 7 MD, 3 MD/PhD, 2 DDS, 1 PharmD, and 2 pre-doctoral) from six colleges (Medicine, Public Health, Pharmacy, Dentistry, Liberal Arts and Sciences, and Nursing) and covered the following topics:

- leadership
- communication
- conflict management
- delegation
- coaching and facilitative leadership of teams
Recognizing the complex regulatory environment and the need for investigators to be fluent in the principles of ethics, the ICTS introduced this new course. Taught by senior faculty from the Program in Biomedical Ethics and Medical Humanities, Program Director Lauris Kaldjian, MD, PhD, and Christian Simon, PhD, Associate Professor of Internal Medicine, course topics include

- informed consent
- minimizing patient risk
- the role of the IRB
- ethical issues in genetic testing
- conflict of interest
- data ownership
- principles of authorship
- availability of data collected through federally funded research

Course content is delivered using case studies, such as the Tuskegee experiment, as well as actual and fictional scenarios to highlight more contemporary dilemmas. In lieu of a final exam and to enhance the relevance of the material, scholars develop a report on the ethical principles and issues germane to their research project (e.g., informed consent, patient recruitment, confidentiality, privacy, conflicts of interest), including citing basic ethical principles, key prior regulatory statutes, and the extant literature.
MENTORING

- COUNCIL OF T32 TRAINING PROGRAMS
- ICTS MENTORS
- MENTOR TRAINING PROGRAM
- TOPICAL RESEARCH SYMPOSIA
The Council of T32 Directors was introduced to better support the needs of the T32 program. The council meets quarterly and includes the directors and administrators of the 30 NIH-funded T32 programs at the University of Iowa.

The five primary goals of the Council are to:
- identify and disseminate best practices across T32 programs for recruiting high caliber pre- and post-doctoral candidates from under-represented groups
- provide consultation on preparing new and renewal applications
- promote interdisciplinary collaborations among trainees from different T32 programs
- develop common curricula in mentoring, scientific writing, grant preparation, networking, human subjects training, and conflict of interest
- develop automated protocols for collecting data on trainees and mentors
OVERALL GOALS

- Provide University of Iowa investigators with resources to translate understanding of disease biology into discovery of novel therapeutics.
  **DISEASE AGNOSTIC**
- Promote the usage of essential clinical manufacturing services within the ICTS and CTSA network.
- Provide University of Iowa investigators with project management expertise necessary for rapid and effective advancement of drug discovery and development projects.
- Connect University of Iowa investigators with internal/external expertise necessary to effectively promote commercialization of therapeutic entities.
- **CHANGING CULTURE**
LEADERSHIP TEAM

- **Michael Henry**: Industry experience; Assoc. Prof Molecular Physiology & Biophysics
- **Raymond Hohl**: Startup experience; Professor, Internal Medicine
- **Patrick Schlievert**: Startup experience; Chair, Microbiology
- **Mani Subramanian**: Director, UI Center for Bio-catalysis & Bioprocessing; Prof, Chemical Engineering
- **Mickey Wells**: Director, UI Pharmaceuticals; Assoc Prof Pharm. Sci. & Exp. Therapeutics
- **Meng Wu**: Director, UI High-Throughput Screening Facility

INTERNAL ADVISORY BOARD

- **Mark Anderson**: Chair, Internal Medicine
- **Charles Brenner**: Chair, Biochemistry
- **Kevin Campbell**: Chair, Molecular Physiology & Biophysics
- **James Potash**: Chair, Psychiatry
- **Curt Sigmund**: Chair, Pharmacology
- **Joseph Zabner**: Associate Director for T1 Translational Science, and Director, PILOT Grant Program

EXTERNAL ADVISORY BOARD

- **Andy Dahlem**, Vice President and Chief Operating Officer, Lilly Research Laboratories
- **Howard Dittrich**, Chief Medical officer, Sorbent Therapeutics, ChanRx, and Ocera
- **Hal Ebetino**, Precision Rx LLC, Pharmaceutical R&D Consulting
- **Scott Weir**, Director, Institute for Advancing Medical Innovation, KUMC
SERVICES

• HIGH THROUGHPUT SCREENING FACILITY
  • http://pharmacy.uiowa.edu/high-throughput-screening-facility

• cGMP FACILITIES
  • Center for Biocatalysis and Bioprocessing
    http://www.uiowa.edu/~biocat/about.html
  • UI Pharmaceuticals http://uip.pharmacy.uiowa.edu/
    ▪ Pursuing ways to make this service more accessible to academic investigators on a cost basis.
    ▪ Will assist in grant development.

• PROJECT MANAGEMENT AND SUPPORT
STANFORD ‘SPARK’ PROGRAM

- http://sparkmed.stanford.edu/
- Directed by Drs. Daria Mochly-Rosen and Kevin Grimes
- Brings together senior Stanford scientists and individuals from Bay-area biotechnology and venture capital firms, to provide ongoing advice to selected drug-development projects over 1–2 years
- Eligible projects must have associated invention disclosures or patents and a high potential for licensure
- SPARK has remarkable success (greater than 50%) in moving projects to licensure and/or early-phase trials
- ICTS will fund two UI participants. Each will receive $50,000 in support from the ICTS for further work, and will participate in 6–8 on-site SPARK meetings. Fall 2013-Spring 2014
- Identify elements of SPARK that could be implemented at the UI
PRODUCT INVESTMENT STRATEGY – DIFFERING DEVELOPMENT PATHS

- **NOVEL DRUGS**

  - Biology
  - Drug Discovery
  - Animal Efficacy
  - Clinical Proof of Concept
  - Drug Development
  - Registration and Launch

  - CBI
  - IAMi
  - Commercial Partner

  - $250,000

- **RE-PURPOSED DRUGS**

  - Biology
  - Drug Discovery
  - Animal Efficacy
  - Clinical Proof of Concept
  - Drug Development
  - Registration and Launch

  - IAMi
  - External Partners
  - Commercial Partner

  - $250,000
  - $2,000,000
University of Iowa Pharmaceuticals (UIP) and the Clinical Materials Service Unit (CMSU) at the University of Rochester Medical Center formed a strategic partnership in 2008 and have been providing clinical-trial drug supply and distribution services to researchers ever since.

UIP provides front-end supply-chain services (manufacturing and analytical testing), while CMSU provides back-end services (supply-chain management, secondary packaging and labeling, distribution, returns, and destruction).

University of Iowa and University of Rochester were awarded a seven-year grant in 2011 by the NINDS to support trials conducted through the NeuroNext network.
HIGH LEVEL SUPPORT (DEAN)

- Work with faculty to gauge interest in start-up companies
  - DEOs for candidate faculty names
  - VPR related to mechanisms
  - Next steps ..
    - Recruit faculty for start-up meeting
    - Recruit faculty from Business Administration
HOLDEN COMPREHENSIVE CANCER CENTER (HCCC)

COLLABORATIONS
1999 - The Holden Comprehensive Cancer Center (HCCC) at the University of Iowa established with an NIH Core Grant award

2000 NIH conferred “Comprehensive” status. Renamed “Holden Comprehensive Cancer Center”

2000 NCI conferred “NCI Designated Cancer Center” status

2002 HCCU receives its 1st SPORE (Specialized Program of Research Excellence) grant from the NCI for Lymphoma Research

2005 NCI renews HCCC as an NCI designated Cancer Center

2007 Renewal of $11.9M SPORE grant for Lymphoma Research

2010 NCI renews HCCC as an NCI designated Cancer Center
1. Challenges in external funding environment
   • Need to optimally leverage institutional resources and reduce duplicative efforts across research programs → but maintain center mission and focus

2. CTSAs and CCS share institutional roles to provide infrastructures to enable innovative investigation
   • Conducting clinical trials (e.g. space, coordinators)
   • Regulatory assistance with IRB and IND applications
   • Consultation and/or support personnel in biostatistics, study design, bioinformatics, and other areas
   • Support for bio and tissue repositories
3. CTSAs and CCs share institutional responsibilities in driving improvements in research efficiency
   • Enhancing clinical trial recruitment and retention
   • Developing novel approaches for data collection
   • Promoting adoption of innovative research designs (e.g. adaptive designs) and use of central IRBs and master contracts
   • Streamlining and improving approval processes for IRB submissions and contracts

4. CTSAs and CCs support the full T1-T4 spectrum of translational research
   • Bench-to-bedside
   • Clinical trials
   • Dissemination and implementation of evidence-based practice
   • Policy
5. CTSAs and CCs share similarities in perspective, operations, and organization
   - Engage investigators from multiple departments or colleges and from diverse scientific and methodological disciplines
   - Have strategic institutional value beyond NIH funding
   - Typically receive significant institutional investments
   - Engage investigators from multiple departments or colleges and from diverse scientific and methodological disciplines

6. CTSAs and CCs share roles in catalyzing national research priorities
   - Drug discovery, development, and repurposing
   - Comparative effectiveness research
MINI RETREAT “Summit on Drug Discovery, Development & Commercialization: Building a Research Roadmap for the University of Iowa” - May 25, 2012

- Hosting visiting Faculty with expertise in drug development and re-purposing
- Contributed to development of High Throughput Screening Core
- University of Iowa Pharmaceuticals
- Center for Biocatalysis & Bioprocessing
- Drug Discovery in Cancer
- Research in Drug Discovery in the College of Pharmacy
- Programs & Resources to support Drug Development at the UI Research Foundation
CLINICAL RESEARCH

- Discussing establishing satellite clinical research unit in Cancer Center Infusion area
- Sharing best practices related to recruitment of subjects for clinical trials
- Jointly coordinate a series of process improvement events in collaboration with V-P Research and Sponsored Programs Office related to clinical research infrastructure
- ICTS and CC programs in population-based research and CER led by Elizabeth Chrischilles
  - Greater synergies in developing novel methodologies (e.g. web-based personnel health records)
  - Dual support for developing community-based research networks for conducting prevention research in cancer and other areas and to serve as recruitment sites for clinical trials
  - Larger pool of resources to support development of new research proposals → joint sponsorship and development of several proposals for recent PCORI RFAs
Growing use of telehealth, web-based, and mobile technologies to deliver healthcare and monitor patients, presents new opportunities for research

- Joint ICTS and CC leadership of University of Iowa task force to develop recommendations for building e-health research programs and for capitalizing on new research funding opportunities
- Recent funding from CMS Healthcare Innovation Challenge initiative for ICTS proposal to improve transitional care for University of Iowa patients being discharged to rural communities → focus on cancer, CV, and psychiatry patients using telehealth technologies
BIO-SPECIMENS

1. Collaborated on development of a single IRB approval for subjects willing to provide de-identified bio-specimens (discard blood and tissue)
2. Established joint task force to select best informatics systems for bio-specimens
   - Identifying consented subjects in HER
   - Tracking available samples
   - Linking samples to de-identified or identified clinical or molecular information
From data compiled by the University of Iowa Research Foundation on January 25, 2013

- 288 Invention Disclosures received – 174 are active
- 243 US Filed Patent Applications – 104 are active
- 72 Filed PCT Patent Applications – 24 are active
- 1 Filed Copyright Application – 1 is active
- 75 Foreign Filed Patent Applications – 58 are active
- 120 US Issued Patents – 111 are active
- 217 Foreign Issued Patents – 149 are active
## CLINICAL TRIALS ACTIVITY AND THERAPEUTIC AGENTS

### CLINICAL TRIALS ACTIVITY

<table>
<thead>
<tr>
<th>Description</th>
<th>#</th>
<th>%</th>
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<tbody>
<tr>
<td>Total number of CLINICAL TRIALS</td>
<td>468</td>
<td>100%</td>
</tr>
<tr>
<td>• Total number of Clinical Trials from the Department of Internal Medicine</td>
<td>222</td>
<td>47%</td>
</tr>
<tr>
<td>• Total number of Clinical Trials from the Holden Comprehensive Cancer Center</td>
<td>26</td>
<td>5%</td>
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</tbody>
</table>

### UNIQUE THERAPEUTIC AGENTS

<table>
<thead>
<tr>
<th>Description</th>
<th>#</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of UNIQUE THERAPEUTIC AGENTS</td>
<td>157</td>
<td>100%</td>
</tr>
<tr>
<td>• Total number of unique Therapeutic Agents from the Department of Internal Medicine</td>
<td>148</td>
<td>94%</td>
</tr>
<tr>
<td>• Total number of unique Therapeutic Agents from the Holden Comprehensive Cancer Center</td>
<td>91</td>
<td>58%</td>
</tr>
</tbody>
</table>
Thank you
The Delaware INBRE: A Catalyst for Biomedical Research

Karl Steiner
Sr. Associate Provost for Research Development
Professor, Electrical & Computer Engineering
University of Delaware
A Catalyst for Biomedical Research

Karl V. Steiner
Principal Investigator, Delaware INBRE
5th Annual DSHA Symposium
UD – Clayton Hall, May 10, 2013
IDEA Background

NIH-NCRR IDEA – INBRE, COBRE, CTR
• IDEA – Institutional Development Awards
• INBRE – IDEA Network of Biomedical Research Excellence
• COBRE – Center of Biomedical Research Excellence
• CTR – Infrastructure for Clinical and Translational Research

INBRE (24 in the Nation)
• Delaware INBRE - Partnership between UD, DSU, Wesley, Delaware Tech, Christiana Care and Nemours,
• Delaware Funding since 2001: $45 M

COBRE (90+ in the Nation)
• Five COBREs in Delaware
  • 3 at UD and 1 each at Nemours and DSU
  • Delaware funding since 2000: $100 M

CTR (up to 5 in the Nation)
• 2 Awarded in WV and LA
Delaware INBRE History

**BRIN (Years 1 – 3)**
- Sept 2001 – June 2004
- Network and Infrastructure Development
- Budget: $8.3M

**INBRE-1 (Years 4 – 8)**
- July 2004 – April 2009
- Biomedical Focus Areas: Cancer, Cardiovascular, Biomedical Imaging, Animal Modeling, Infectious Diseases, Biochemistry, Nursing Research
- Budget: $16.7M

**INBRE-2 (Years 9 – 13)**
- May 2009 – February 2014
- Biomedical Focus Areas: Cancer, Cardiovascular, Neurosciences
- Budget: $17.4M plus $2M in ARRA Supplements
- **Plus $5M in State of Delaware Supplementary Support**
IDeA Network across the State

- Close collaboration among the Delaware IDeA programs leverages resources

Five COBREs currently active in Delaware

- Membrane Protein Production & Characterization
  - PI: Abraham Lenhoff, UD*

- Women in Science and Engineering on Osteoarthritis
  - PI: Thomas Buchanan, UD*

- Molecular Design of Advanced Biomaterials
  - PI: Thomas Beebe, UD

- Center for Pediatric Research
  - PI: Thomas Shaffer, Nemours*

- Delaware Center for Neuroscience Research
  - PI: Melissa Harrington, Nemours*

* Members of Delaware INBRE Research/Mentoring Committees
Delaware INBRE – Overall Goal

A sustainable biomedical research capability in Delaware

- Independent and inter-dependent faculty/investigators
  - Grants, Publications, Students, Recognition

- Centers of Expertise (Core Instrumentation Centers)
  - Leverage Expertise and Equipment

- Establishment and growth of the biomedical network
  - Joint Proposals & Publications

- Full Integration of Primarily Undergraduate Institutions

Institutionalizing INBRE Initiatives across the Partner Institutions
INBRE Research Program

INBRE Research Committee
Steven J. Stanhope – Chair

Research Themes
- Cancer
  Developmental Research Projects
  Nicholas Petrelli – Christiana
- Cardiovascular Health
  Developmental Research Projects
  David Edwards – UD
- Neurosciences
  Developmental Research Projects
  Melissa Harrington – DSU

Partnerships & Centers
- Center for Translational Cancer Research
- Delaware Cardiovascular Research Center
- Delaware Neurosciences Consortium
- Cancer Tissue Procurement Center
- Christiana Clinical Outcomes Center
- Delaware Center for Neuroscience Research

Support Cores
- Bioinformatics Core
- Centralized Research Instrumentation Core
INBRE Pilot Research Grants

- 143 Pilot Grant Applications in 5 Competitions since 2004
- 62 Pilot Grants selected and awarded (34 at UD)
  - Scientific focus on Cancer, Cardiovascular, Neurosciences
  - 2009/11 Cohort – 16 Pilot Grants (incl. ARRA Supplements)
  - 2012/14 Cohort – 11 Pilot Grants

![INBRE Institutional Success Ratio](chart.png)
Pilot Grants – Outcomes

• INBRE Investments in Pilot Grants since 2004 – $10 Million

• External Grants secured by Pilot Grantees as PI/Co-PI to Date:
  – 75 Awards – valued at over $27 Million
  – Including three NIH R01 awards and one COBRE award
  – Plus two NIH R01 proposals with very high Priority Scores

• In addition, INBRE has supported a diverse group of 305 undergraduate students from across the State to conduct biomedical research.
INBRE-3 Pilot Project Workshops

- Recent Workshops on INBRE-3 Pilot Grant Mechanism
  - UD, DSU, CCHS & Nemours
- Almost 60 Faculty attended the four workshops
- Overview of INBRE-3 Program and Pilot Grant Mechanism to create awareness and encourage early development of proposal ideas and teams.
INBRE-3 Pilot Grants Process

• New Call for Pilot Project Proposals to be issued in August 2013
  – Focus on Cancer, Cardiovascular, Neurosciences
  – **Up to 2 Years of Funding, up to $80k/year in Direct Costs**
  – Submission of Proposals – Due in October 2013
  – Confirmation of Awards – March 1, 2014
  – Start Date for Research Proposals: **September 1, 2014**

• Eligibility
  – *Early-Stage* investigators and *New Investigators* with full-time career or career-conditional appointments

• Additional Review Criteria
  – Career Development Plan
  – Mentoring Plan
NECC Initiative

Northeast Cyberinfrastructure Consortium (NECC)

• Launched in 2006
• Support secured to date – $16.7 M
  – $8.4 Million from NIH–NCRR; $8.3M from NSF–EPSCoR
• Cyber-connectivity across New England States
• Broadband Upgrades at DE Institutions
• Delaware Contribution
  – Sequencing, Distributed Data Center
  – Annotation Workshops
• INBRE Scientific Focus
  – Little Skate Genome
• EPSCoR Scientific Focus
  – Metagenomes of Algal Blooms
**Bioinformatics Network of Delaware (BiND)**

- Integrate bioinformatics and biostatistics resources across INBRE partner institutions to strengthen the Delaware cyberinfrastructure and collaborative research and training
- Steering Committee: Representatives from all DE INBRE Partners

<table>
<thead>
<tr>
<th>Member</th>
<th>Title</th>
<th>Organization</th>
</tr>
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<tbody>
<tr>
<td>Edward Ewen</td>
<td>Director, Clinical Informatics</td>
<td>Christiana Care Health System</td>
</tr>
<tr>
<td>William Weintraub</td>
<td>Director, Center for Outcomes Research (CCOR)</td>
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<tr>
<td>Lori Maramante</td>
<td>Instructor, Science/Medical Laboratory Technology</td>
<td>Delaware Technical &amp; Community College</td>
</tr>
<tr>
<td>Barbara Wiggins</td>
<td>Chair, Department of Science and Laboratory Technology</td>
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<tr>
<td>Tomasz Smolinski</td>
<td>Associate Professor, Computer and Information Sciences</td>
<td>Delaware State University</td>
</tr>
<tr>
<td>Hacene Boukari</td>
<td>Associate Professor, Physics and Pre-Engineering</td>
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<tr>
<td>Tim Bunnell</td>
<td>Director, Nemours Bioinformatics Core Facility</td>
<td>Nemours/Alfred I. duPont Hospital for Children</td>
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<tr>
<td>Andy Kolb</td>
<td>Director, Blood and Bone Marrow Transplantation</td>
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<tr>
<td>Malcolm D’Souza</td>
<td>Professor, Chemistry</td>
<td>Wesley College</td>
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<tr>
<td>Derald Wentzien</td>
<td>Professor, Mathematics</td>
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<tr>
<td>Masaru Teramoto</td>
<td>Assistant Professor, Kinesiology</td>
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<tr>
<td>Cathy Wu</td>
<td>Director, Center for Bioinformatics &amp; Computational Biology (CBCB)</td>
<td>University of Delaware</td>
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<tr>
<td>Shawn Polson</td>
<td>Bioinformatics Core Coordinator, CBCB</td>
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<tr>
<td>Katie Lakofsky</td>
<td>Education and Outreach Coordinator, CBCB</td>
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Core Facilities and Shared Resources Network

Welcome to our searchable Core Facilities and Shared Resources Network at the University of Delaware hosted at the Delaware Biotechnology Institute. This website was created to compile and facilitate the location of specific equipment and services at the University of Delaware as well as other local academic and partner institutions.

We welcome new resources, so if you have equipment/services to share, please feel free to complete the “Add New Facility” automated web form to be include in our database. If your core does not fit any of the existing categories or institutions, please contact Jeff Caplan (jcaplan@udel.edu) or Kirk Czynmek (kirk@udel.edu) with your specific request.

To begin, simply click on “Summaries” or “Equipment”, enter a search term and click “FIND”.

Alternatively, you may browse by choosing “Categories” or “Institutions” and select a facility/resource from available drop-down menus.

www.corefacilities.dbi.udel.edu
Supporting Translational Research in Delaware (STRiDE):

- Obtained institutional Commitment at Christiana Care
  - Thomas Bauer, Angela DiSabatino
- Obtained institutional Commitment at Nemours
  - Vicky Funanage, Robert Akins and Terry Pedicone
- Provided recruitment support to 3 Investigators in DE-INBRE Community
  - William Farquhar, David Edwards, Christopher Knight
- Monitored the progress of eight clinical and translational research projects in the INBRE network; three of which involve collaboration between INBRE Institutions
- Created a toolbox of forms and agreements for executing inter-institutional clinical/translational research
NERIC Conference

• 5th Biennial Northeast Regional IDeA Conference
  – IDeA Programs from Northeast Region
    • New Hampshire, Maine, Rhode Island, Vermont and Delaware
  – www.inbre.udel.edu/IDeAMeeting/index.html
  – University of Delaware, August 14–16, 2013
  – 20 Scientific Sessions and Workshops
  – Welcome Reception at Winterthur

• Organization Committee
  – Delaware INBRE and COBRE Leadership
  – Northeast INBRE PIs
  – NIH-NIGMS IDeA Program Directors
Today, IDeA programs represent about 1/3 of Delaware’s total NIH funding.
Delaware has outperformed the Nation and the IDeA Community in NIH Funding secured over the past 20 years.
A Growing Biomedical Research Capability

Number of active NIH Awards to Delaware Institutions has increased three-fold over 15 years.
Publications per $1 Million in Academic Research (2009)

- 2.97 articles per $1 Million in Academic R&D Nationally
- 4.64 articles per $1 Million in Academic R&D in Delaware (Ranked 1st)

- Delaware INBRE – 239 publications for $50 Million in Support (NIH & State)
  - 4.78 articles/$1 Million
The DHSA Landscape

Delaware INBRE

Delaware COBREs
UD (3), DSU and Nemours

Delaware Health Sciences Alliance

Delaware Valley Institute for Clinical and Translational Science

$200 Million in External Funding

CMMI Awards
Christiana Care and Nemours

IDeA
Institutional Development Award

STRiDE
Supporting Translational Research in Delaware

DE–CTR
Promoting Clinical and Translational Research
Delaware IDeAs Magazine

- Issued in January, 2013
  - 1000 copies distributed to NIH, Federal and State Officials, IDeA program leaders across the Nation

- Interactive, online issue available at www.expeditions.udel.edu/chs/inbre/

- Highlights the catalytic impact of the NIH–IDeA programs across Delaware
Delaware-Clinical and Translational Research (DE-CTR) Program

William Weintraub

John A. Ammon Chair and Chief of Cardiology Department
Director of the Christiana Care Center for Outcomes Research
Christiana Care Health System
Delaware-Clinical and Translational Research (DE-CTR) Program

PI: Stuart Binder-Macleod, PT, PhD
DHSA Symposium
May 10, 2013
Overview

- Institutional Development Award Program (IDeA) Infrastructure for Clinical and Translational Research
- NIH Budget $20M for 5 years
- Original Program Announcement – June 10, 2011
- 5 total awards anticipated:
  - 2 in 2011, 2 in 2012, 1 in 2013
- Must include at least one partnering state
The **General Objectives** of the IDeA-CTR Program are:

- To support the development of infrastructure and human resources required to conduct clinical and translational research in IDeA-eligible states.
- To enhance the ability of IDeA institutions and investigators to develop competitive clinical and translational research programs.
- To foster and sustain collaboration and coordination of clinical and translational activities within and across IDeA institutions/organizations.
DE-CTR Partner Institutions

Delaware-Clinical and Translational Research (DE-CTR) Program

Christiana Care

University of Delaware

Nemours

Medical University of South Carolina
The **overall Specific Aims** of the DE-CTR are to:

- develop the infrastructure to facilitate the growth and development of clinical and translational research within the States of Delaware and South Carolina;
- facilitate the recruitment, training, and professional development of clinicians, scientists, and engineers that will synergistically develop outstanding clinical and translational research programs; and
- develop model community engagement outreach programs that promote health and wellness to a diverse population of Delawareans.
Executive Team

- **Stuart Binder-Macleod (UD) – PI**
- Karl Steiner (UD): Program Coordination
- William Weintraub (CCHS): Co-PI
- Julia Barthold (Nemours): Co-PI
- Tom Buchanan (UD): Co-PI
- Steven Kautz (MUSC): Co-PI
DE-CTR Components

• Administrative Core – Binder-Macleod and Steiner

• 5 Key Component Activities (KCAs)
  o Clinical and Translational Pilot Grants Program
  o Clinical Research Mentoring, Education & Career Development Core
  o Clinical Research Design, Epidemiology, and Biostatistics Core
  o Clinical Research Expansion and Support Program
  o Community Engagement and Outreach (CEO) Program

• Evaluation Core
The specific goals of the Administrative Core are to:

1) **Create an effective administrative infrastructure** that ensures sound fiscal management and compliance with all federal, state and local regulations;

2) **Promote synergistic relationships and effective collaborations** across the DE-CTR components and within each of the participating institutions in a cost-effective and time-efficient manner;

3) **Promote open and ongoing communication across all components** and participating institutions through regular meetings of the DE-CTR leaders and the development of a user-friendly website that serves the needs of each of the components;

4) **Monitor the progress of each component** and take appropriate steps to ensure the overall success of the DE-CTR; and

5) **Work effectively with the NIGMS program staff** to ensure that the DE-CTR program successfully achieves the overall IDeA-CTR goals.
The Specific Aims of the \textit{DE-CTR Clinical and Translational Pilot Grants Program} are as follows:

1) To \textbf{promote interdisciplinary research}, we will establish a means to \textbf{fund small grants for clinical and translational pilot projects}. These grants will require multi-institutional partnerships across the DE-CTR institutions and/or with the IDeA state collaborators at MUSC.

2) To \textbf{promote high-impact areas of research and interdisciplinary collaboration}, we will establish a mechanism to \textbf{fund proposals for small conferences and symposia} on special interest topics, and we will provide pilot project funding in those areas.

3) To \textbf{strengthen the quality of our biomedical researchers}, we will work with the MED-Core (KCA 3.2) to \textbf{establish a mentoring program to train, support and encourage junior faculty participating in the pilot project program}. To promote a sense of community among these junior clinical and translational researchers, we will establish forums for interaction for those receiving pilot project funding.
The Specific Aims of the DE-CTR MED-Core Program are as follows:

1) Drawing on the experience of the CTSA team at MUSC, the MED-Core will develop and implement a multilevel, cross-institutional mentoring program in Delaware, with opportunities for cross-state mentoring of MUSC faculty. The MED-Core will support faculty development and programmatic expansion and provide mechanisms to promote mentoring excellence at all four sites.

2) We will combine, streamline, organize and develop the educational infrastructure needed to provide comprehensive training in clinical and translational research to a multidisciplinary group of investigators. We will leverage existing resources and expertise to develop coordinated education and training programs in areas of mutual need and to broaden the scope of training opportunities available to investigators in both states.
The Specific Aims of the DEAC are:

1) Develop a multidisciplinary, integrated center that provides epidemiological, biostatistical, research design and bioinformatics expertise to clinical and translational investigators of the member institutions.

2) Establish a forum for epidemiologists, biostatisticians and investigators to develop, validate and disseminate innovative design and analytical methodologies.

3) Expand and develop biomedical informatics capabilities to promote improved data and project management, strengthen infrastructure and coordination for innovative clinical and translational research, and extend our culture of collaboration and scientific community outreach.
The **Specific Aim** of the *DE-CTR Clinical Research Support and Expansion Program* is to recruit transformational, clinical and translational faculty candidates who demonstrate:

1) Ability to contribute towards transformation and positive change, within and across institutions,

2) Ability to advance clinical translational strategic initiatives within and across institutions,

3) Capacity to enhance interdisciplinary clinical translational research, and

4) Established excellence in research and scholarship.
The Specific Aims of the DE-CTR Community Engagement and Outreach (CEO) are as follows:

1) Establish a new infrastructure that actively involves the community in setting clinical and translational research priorities.

2) Develop new community-institution partnerships in clinical and translational science.

3) Identify, educate and prepare community leaders, healthcare providers and institutional trainees, researchers and scholars in the principles and practices of community-engaged and community-based participatory research.
The DE-CTR Web Site

www.de-ctr.org
The Delaware Valley CTSI

Scott Waldman
Chair, Department of Pharmacology & Experimental Therapeutics
Thomas Jefferson University
Clinical and Translational Science Award (CTSA)

- NIH program initiated 2005
- Objective
  - Create organizational home for components essential to advancing laboratory-based discoveries into clinical practice e.g.,
    - Patient-Based Research
    - Educational Programs
    - Novel Clinical and Translational Methodologies
    - Omic Technologies
    - Informatics
    - Community Engagement
- 60 academic centers funded @ >$20M each
- Annual competition for new centers
Clinical and Translational Science Award (CTSA)

- **Partnership with the Delaware Health Sciences Alliance (DHSA) members**
  - Jefferson
  - University of Delaware
  - Christiana Health System
  - AI DuPont-Nemours

- **Formed the Delaware Valley Clinical and Translational Science Institute**
  - Seamless integration of clinical and translational research leveraging the state of Delaware as a living laboratory
Clinical and Translational Science Award (CTSA)

- **Application History**
  - First application 2010 (score 50/90)
  - Revised application 2011 (score 33/90)

- **NIH re-organization**
  - Eliminated home institute for CTSA Program
    - *National Center for Research Resources (NCRR)*
  - Established a new home
    - *National Center for Advancing Translational Sciences (NCATS)*
  - CTSA applications placed on hold for 2012

- **RFA re-issued and competition restarted January 2013**

- **Assembling an application for a new center for the January 2014 submission deadline**
Cluster: Significance, Approach, Governance
Waldman (TJU)

Cluster: Staffing, Institutional Commitment, Collaboration, Data Sharing Dissemination
Waldman (TJU)

Evaluation
S. Martin
L. Cooksy (UD)

Cluster: Biomedical Informatics
J. London (TJU), C. Wu (UD)

Cluster: Translational Technologies & Resources; Novel Clinical & Translational Methodologies; Pilot & Collaborative Studies

Transl. Tech. & Resources
K Lee (UD)
R. Davidson (TJU)

Novel Clinical & Trans. Meth.
V. Funanage (Nem)
S. Waldman (TJU)

Pilot & Collab. Studies
K. Steiner (UD), A. Rajasekaran (Nem)

Cluster: Participant & Clinical Research; Ethics; Regulatory Knowledge & Support

Partic.& Clin. Int.
D. Whellan (TJU)
J. Ross (Nem)

Reg. Knowledge & Support & Ethics
B. Little (CCHS)
B. Smith (TJU)

Cluster: Clinical Research Design & Biostatistics; Community Engagement & Research

Res. Design, Epi, Biostatistics
P. Kolm (CCHS)
T. Hyslop (TJU)

Comm. Engage. & Research
R. Myers (TJU), M. Rosenthal (CCHS)

Cluster: Res. Education, Training & Career Development
S. Binder-McLeod (UD), D. Usher (UD), C. Arenson (TJU)
Special Emphasis

What do we bring to the table?

- Unique Consortium Features (what makes us special)
  - Community Engaged Research
  - DHIN and DE as a Living Laboratory
  - Rehab and Bioengineering
  - Women and Children’s Health
  - Global Health
  - Large National Pediatric Organization
  - State-Level Participation
Special Emphasis

- Special RFA Components
  - Clinical Pharmacology Unit
  - Biological and Clinical Informatics
  - Practical Trials in Healthcare Setting
  - Resources for Early Stage Translation
  - Multisite/International Collaborations
  - Expertise in Global Health
  - Innovative Community Engaged Research
Strategic Considerations

- Compelling Need
- Inventory of Marquee Programs
- Compelling Plan for Development
- Innovation Improving Efficiency and Efficacy
- Unique Asset Contribution Nationally
- Real Time Evaluation for Continuous Process Improvement
- Innovative Education & Training
- How to Create a Single Integrated Home for CTS across the Delaware Valley
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Next Steps

- Identify
  - Participating Institutions
  - Institutional PIs
  - Thematic Groups
    - Team Members and Leaders
  - Programmatic Assets-Inventory
- Identify Administrative Team
- Establish **Timeline**-Submission Early January 2014
- Establish Meeting/Writing Schedule
  - Working Groups
  - Leadership Team
- Draft Proposal
- Budget Development
- Collect Letters of Support
- Collect Biosketches
Delaware Health Sciences Alliance
5th Annual Research Symposium
Transitions Toward Clinical Translational Research