2014 CCTSI
Accomplishments and Challenges

January 15, 2014

Ronald J. Sokol, MD,
Director and PI
WELCOME TO COLORADO
January 15-16, 2015

University of Colorado
Anschutz Medical Campus
Dean Krugman to Step Down
School of Medicine

1/13/2014

Richard D. Krugman, MD, University of Colorado vice chancellor for health affairs and dean of the School of Medicine, announced in his Jan. 13 email to campus that he has asked the university’s leadership to begin the process of hiring his successor.

Krugman became dean of the University of Colorado School of Medicine on March 1, 1992, after serving as acting dean for 20 months. His is currently the longest-serving dean of a medical school in the United States.
Leadership Changes

• New Dean SOM: **John J. Reilly, Jr.** MD (Chair of Medicine, U of Pittsburgh)

• New Chancellor of UCD-AMC: **Don Elliman, Jr.**

• New CEO of UCHealth: **Elizabeth Concordia** (VP of UPMC)

• CEO of Children’s Hospital Colorado – stepped down Dec.
External Advisory Committee

• Rob Califf, MD  Vice Chancellor for Clinical Research, Director of Duke Translational Medicine Institute, Division of Cardiology, Duke SOM (CTSA PI)

• Rex Chisholm, PhD  Associate Vice President for Research, Northwestern University; Vice Dean Scientific Affairs and Graduate Education, NU Feinberg SOM

• Joe “Skip” Garcia, MD  Senior Vice President for Health Sciences, University of Arizona (Future CTSA PI)
External Advisory Committee

• **Larry W. Green, DrPH, MPH**  Professor of Epidemiology and Biostatistics, UCSF and UCSF Comprehensive Cancer Center

• **Doris Rubio, PhD**  Professor of Medicine, Biostatistics, Nursing and Clinical and Translational Sciences; Director of Data Center of Center for Research on Health Care; Co-Director of Institute for Clinical Research Education; Director Office of Evaluation, University of Pittsburgh
External Advisory Committee

• **James Heubi, MD** Associate Dean for Clinical and Translational Research, Co-Director Center for Clinical & Translational Sciences & Training, Associate Chair for CTR, Professor of Pediatrics, University of Cincinnati SOM, CCHMC (CTSA PI)

• **Steven Dubinett, MD** Associate Vice Chancellor for Research, UCLA; Sr. Assoc. Dean, David Geffen SOM; Director of Clinical and Translational Sciences Institute; Chief, Pulmonary and Critical Care, UCLA (CTSA PI)
NCATS Project Officer

• Mary Purucker, MD, PhD
Division of Clinical Innovation, NCATS, NIH
Internist, Pulmonary & Critical Care Medicine
This Year’s Format for EAC Meeting

• Overview, Accomplishments, Challenges, Responses to 2014 RFA
• Report from Each Pillar Program
• Key Core Presentations
• New Programs
• Dinner Presentation – Translational Informatics Program
• Closed EAC Session
• Feedback Session
2014 CCTSI Accomplishments and Challenges
History of UC Denver CTSA

• First CTSA Grant Award (2008-2013) $76.2 million
• 3rd “Class” of CTSA grantees
• Received 4 ARRA and 1 NICHD supplement in 2009 – $3.4 M
• Received $2.2 M unobligated balance in 2010
• Close out supplement in 2013 = $6.8 M
• Total NIH Funds for CCTSI 1.0 ~ $89 million
History of UC Denver CTSA

• “Renewal” (New) Grant application submitted on Jan. 8, 2013

• New budget formula: 3% NIH funding for 2012

• Included a 3.5% Sequestration Cut

• Total Award = $51,656,921 for 4 yr. and 7 mo.

• Now in year 2, which ends May 1, 2015
NIH Goals of 2013 CTSA Program

- Promote an **institutional environment** that enhances quality, safety, efficiency, and cost effectiveness of clinical and translational research for all conditions
- Provide **resources and services** to support and speed the planning and implementation of clinical and translational research across the entire range of research and communities
- Facilitate the **training and career development** of a robust translational research workforce
Vision CCTSI 2.0

- Vision of the CCTSI is to accelerate and catalyze the translation of innovative science into improved health and patient care
Mission

CCTSI 2.0

• Mission of the CCTSI is to further enrich and expand our integrated statewide academic home and research environment for clinical and translational science in order to enhance the quality, efficiency, safety and innovation of research and training across our institutions and communities.
Specific Aims of CCTSI 2.0

**Goal 1:** Further enrich and expand our integrated statewide academic home for clinical and translational sciences across the entire translational research spectrum

**Goal 2:** Institute new Clinical Research Management strategies to strengthen quality, safety, efficiency, cost-effectiveness and innovative team science throughout our research enterprise

**Goal 3:** Centralize and enhance the delivery of our resources, services and technologies to promote innovation and quality science
Specific Aims of CCTSI 2.0

Goal 4: Infuse key concepts of community engagement into the full spectrum of translational research

Goal 5: Increase the translational research workforce capacity through a broad curriculum of education and training opportunities
Re-Aligned Organizational Structure

- Major emphasis on Research Environment
- Quality, Efficiency, Effectiveness, & Safety
- Less emphasis on specific resources and cores, but on Resources and Services as a unit
- Strong emphasis on Pilot Grant Awards Program, Translational Informatics and Education Training and Career Development
- Breadth of T0.5 through T4
CCTSI 2013-18

- Education & Training
- Translational Informatics
- Translational Pilot Program
- CTR Resources & Services
- Enhanced Research Environment

Academic Home
Executive Vice Chancellor of UCD AMC

Vice Chancellor of Research

Vice Chancellor of Health Affairs

Evaluation & Tracking and QPIP

Director and PI CCTSI

Admin. Director

Administrative Core

CCTSI Advisory Council

External Advisory Committee

Executive Committee

Education Training

Research Environment

Resources & Services

Pilot Grant Program

Translational Informatics
CCTSI Associate Directors

• Wendy Kohrt, PhD
• Mark Geraci, MD
• Alison Lakin, RN, LLB, LLM, PhD
• Marc Moss, MD
• Michael Kahn, MD, PhD
• Janine Higgins, PhD–Operations Director
CCTSI Organizational Structure 2015

**Administrative Core**
- Sokol
- Lockie

**Tracking Assessment & Evaluation**
- Nearing

**Quality & Process Improvement**
- West

**Translational Pilot Program**
- Geraci
  - CO-Pilots
  - Community Engagement Pilots
  - CMH Pilots
  - Novel Methods

**Enhanced Research Environment**
- Lakin
  - Regulatory IRB
  - Contracting
  - Hospital Research Committees
  - Data Access & Security
  - Recruitment & Enrollment
  - Research Ethics
  - FDA, IND, IDE Support
  - TTO & Industry Relations

**CTR Resources & Services**
- Kohrt
  - Study Design and Analysis
    - BERD
    - Data Management
  - Study Implementation
    - CTRC Network – UCH, CHCO, Perinatal, NJH, CU-B

**Education, Training, Career Development**
- Moss
  - KL2
  - CLSC graduate program
  - TLI
  - Clinical Faculty Scholars
  - K to R
  - CO-Mentor
  - SUMMIT
  - LITEs

**Translational Informatics**
- Kahn
  - Database Development
  - Data Security
  - Data Sharing
  - Biomedical Informatics
  - Bioinformatics

**Technology & Lab Analyses**
- CTRC Core Laboratories
- (NeTT) Network of Translational Technologies

**Population-based Translational Research Programs**
- Community Engagement & Research
- Child and Maternal Health Research
- Practical Trials–Dissemination/Implementation
CCTSI Partners

• **Three Universities**

**UC Denver**
  – **Anschutz Medical Campus**: SOM, CON, SOP, SOD, CSPH, Graduate School
  – **Downtown Denver**: 7 colleges—Engineering, Arts & Sciences, Business, others

**CU Boulder**
  – 4 colleges

**Colorado State University** newest partner 2013
  – 8 colleges
CCTSI Partners

- **Six Affiliated Hospitals and Health Care Organizations**
  - University of Colorado Hospital - UC Health System (5 hospitals up front range)
  - Children’s Hospital Colorado
  - Denver Health
  - National Jewish Health
  - Denver Veterans Affairs Medical Center
  - Kaiser Permanente Colorado
Affiliated Institutions
University of Colorado Health System

- **2011-12** UCH formed joint non-profit system with Poudre Valley Health System (2 hospitals in Ft. Collins)

- **2012** UCH, CU SOM and Children’s were approved by Colorado Springs City Council to lease and operate Memorial Hospital (60 years)
  - New Branch SOM campus in CO Springs (2016)

- **2013** Ivinson Memorial Hospital, Laramie, WY

**UC Health**: 5 Hospital Front Range Health System

  - largest in the state, all on Epic EMR - huge potential for clinical research, outcomes and clinical trial expansion

  - NOT OWNED BY UNIVERSITY OF COLORADO
UC Denver and Partner Institutions

• CU Denver and CU Boulder are separate institutions

• Each Hospital partner is a separate, private, not-for-profit institution (except for the VA), none of which are owned by Univ. of Colorado (including Univ. of Colorado Hospital and UC Health System)

• Thus, *most important decisions are negotiations, collaborations and shared decisions*
### Table 2. Institutional Funds Supporting CCTSI

#### I. Infrastructure Support for CCSTI Cores or Programs*

<table>
<thead>
<tr>
<th>Source</th>
<th>Details of Support</th>
<th>Years</th>
<th>Funds</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dean, School of Medicine (Strategic Initiatives in Research Program)</td>
<td>Translational Technology support for IPS and Vector Construction Core, Microscopy Core, Genomics and Microarray Core</td>
<td>2009-2015</td>
<td>$2,006,229</td>
</tr>
<tr>
<td>Dean, School of Medicine</td>
<td>Baby Blanket Program</td>
<td>2010-2013</td>
<td>$149,625</td>
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<tr>
<td>Dean, School of Medicine</td>
<td>Bioinformatics Core Support</td>
<td>2012-2015</td>
<td>$565,599</td>
</tr>
<tr>
<td>Dean, SOM and Vice Chancellor of Research</td>
<td>PET/CT Scanner installation and Implementation (CTRIC)</td>
<td>2011-2013</td>
<td>$2,717,783</td>
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<tr>
<td>CU-Denver</td>
<td>Next Generation Gene Sequencing Equipment</td>
<td>2012</td>
<td>$1,485,000</td>
</tr>
<tr>
<td>CU School of Medicine</td>
<td>Biomedical Research Informatics Infrastructure</td>
<td>2012-2017</td>
<td>$5,000,000</td>
</tr>
<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>Infrastructure Supporting CCTSI</strong></td>
<td></td>
<td><strong>$11,924,236</strong></td>
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</tbody>
</table>

#### II. Ongoing Direct CCTSI Operations Support

<table>
<thead>
<tr>
<th>Institution</th>
<th>Yr-1</th>
<th>Yr-2</th>
<th>Yr-3</th>
<th>Yr-4</th>
<th>Yr-5</th>
<th>Total</th>
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</thead>
<tbody>
<tr>
<td>CU-D</td>
<td>$2,707,778</td>
<td>$2,424,818</td>
<td>$2,322,859</td>
<td>$2,302,538</td>
<td>$2,334,616</td>
<td><strong>$12,092,609</strong></td>
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<tr>
<td>SOM</td>
<td>$600,000</td>
<td>$600,000</td>
<td>$600,000</td>
<td>$600,000</td>
<td>$600,000</td>
<td><strong>$3,000,000</strong></td>
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<tr>
<td>VCR</td>
<td>$210,000</td>
<td>$210,000</td>
<td>$210,000</td>
<td>$210,000</td>
<td>$210,000</td>
<td><strong>$1,050,000</strong></td>
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<tr>
<td>CHCO</td>
<td>$1,200,000</td>
<td>$1,200,000</td>
<td>$1,200,000</td>
<td>$1,200,000</td>
<td>$1,200,000</td>
<td><strong>$6,000,000</strong></td>
</tr>
<tr>
<td>UCH</td>
<td>$645,588</td>
<td>$875,971</td>
<td>$1,096,461</td>
<td>$1,350,167</td>
<td>$1,906,813</td>
<td><strong>$5,875,000</strong></td>
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<tr>
<td>NJH</td>
<td>$467,950</td>
<td>$467,950</td>
<td>$467,950</td>
<td>$467,950</td>
<td>$467,950</td>
<td><strong>$2,339,750</strong></td>
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<tr>
<td>CSU</td>
<td>$193,331</td>
<td>$131,176</td>
<td>$134,025</td>
<td>$137,073</td>
<td>$140,224</td>
<td><strong>$735,829</strong></td>
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<tr>
<td>CU-B</td>
<td>$125,000</td>
<td>$125,000</td>
<td>$125,000</td>
<td>$125,000</td>
<td>$125,000</td>
<td><strong>$625,000</strong></td>
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<tr>
<td><strong>Sub-Total</strong></td>
<td><strong>$6,149,647</strong></td>
<td><strong>$6,034,915</strong></td>
<td><strong>$6,156,295</strong></td>
<td><strong>$6,392,728</strong></td>
<td><strong>$6,984,603</strong></td>
<td><strong>$31,718,188</strong></td>
</tr>
</tbody>
</table>

**Total Institutional Commitment** | **$43,642,424**

*Infrastructure funds are committed to support the CCTSI Allied Programs or CCTSI cores co-funded by other CU-D Centers or Schools. This infrastructure support is not specifically committed as cost-sharing to the CCTSI.*
CCTSI Community Partners

- 20 Community-Academic partnerships throughout the state, multiple PBRNs

  - **Populations:**
    - Native Americans, Latinos, African-Americans, rural populations, Nursing partnerships, Catholic churches, etc.

  - **PACT Focus Groups:**
    - San Luis Valley, Stapleton 2040, American Indian/Alaskan Native Programs, High Plains Research Network, Kaiser Patient/provider, LUCHAR
Value of CCTSI to UC Denver

Measured in several ways:

- Outcomes of our programs, resources and support services, pilot grants, education and training, etc. – ROI: individual reports
- Website utilization (redesigned 2014)
- COLORADO Profiles utilization
- UC Denver Grant support
PROFILES Utilization

Monthly Sessions & Pageviews

- Monthly Sessions
- Monthly Pageviews
- Linear (Monthly Sessions)
- Linear (Monthly Pageviews)

Number of Sessions & Pageviews

Month & Year

- Jul-12
- Aug-12
- Sep-12
- Oct-12
- Nov-12
- Dec-12
- Jan-13
- Feb-13
- Mar-13
- Apr-13
- May-13
- Jun-13
- Jul-13
- Aug-13
- Sep-13
- Oct-13
- Nov-13
- Dec-13
- Jan-14
- Feb-14
- Mar-14
- Apr-14
- May-14
- Jun-14
- Jul-14
- Aug-14
- Sep-14
- Oct-14
- Nov-14
- Dec-14
Total Grant Expenditures - UC Denver
Millions

![Bar chart showing total grants from 2005 to 2013. The expenditure increased from 2005 to 2013.](cctsi.ucdenver.edu)
Total Grant Expenditures - UC Denver
Millions

Total Grants

CCTSI

2005 2006 2007 2008 2009 2010 2011 2012 2013

Total Grants

CCTSI
Sources of Funding - UC Denver

- National Institutes of Health 46%
- Industry 14%
- Hospitals and Universities 8%
- Associations and Foundations 10%
- Non DHHS 7%
- Other DHHS 7%
- State/Local Government 7%
- International 1%
Total NIH Grant Expenditures - UCD
Millions

![Bar chart showing total NIH grants from 2005 to 2014.](chart.png)
Total NIH Grant Expenditures - UCD Millions
## Ranking of Research Funding

<table>
<thead>
<tr>
<th>University of Colorado</th>
<th>Year</th>
<th>Rank in NIH Funding (grants)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2004</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>2005</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>2006</td>
<td>24</td>
</tr>
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<td></td>
<td>2007</td>
<td>24</td>
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<tr>
<td></td>
<td>2008</td>
<td>24</td>
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<tr>
<td></td>
<td>2009</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>2010</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>2011</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>2012</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>2014</td>
<td>29</td>
</tr>
</tbody>
</table>
## 2013 Research Funding

<table>
<thead>
<tr>
<th>FY 2013</th>
<th>Total Award Expenditures</th>
</tr>
</thead>
<tbody>
<tr>
<td>• UC Denver G&amp;C</td>
<td>$489 million</td>
</tr>
<tr>
<td>NIH funding</td>
<td>189 million</td>
</tr>
<tr>
<td>• AMC Campus</td>
<td>391 million</td>
</tr>
<tr>
<td>• SOM</td>
<td>326 million</td>
</tr>
<tr>
<td>NIH funding</td>
<td>162.8 million (50%)</td>
</tr>
</tbody>
</table>
# 2014 Research Funding

## NIH Funding – FY 2014

<table>
<thead>
<tr>
<th>Department</th>
<th>Amount</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOM</td>
<td>$167,326,343</td>
<td>24</td>
</tr>
<tr>
<td>- Dept. of Medicine</td>
<td>48.3 million</td>
<td>22</td>
</tr>
<tr>
<td>- Dept. of Pediatrics</td>
<td>43.2 million</td>
<td>1</td>
</tr>
<tr>
<td>- Dept. of Psychiatry</td>
<td>12.1 million</td>
<td>21</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>$9,104,547</td>
<td>4</td>
</tr>
<tr>
<td>CSPH</td>
<td>$6,834,135</td>
<td>23</td>
</tr>
</tbody>
</table>
Distribution of NIH Funding

- SOM: $167,326,343
- Dept. of Medicine: $48.3 million
- Dept. of Pediatrics: $43.2 million
- Dept. of Psychiatry: $12.1 million
- Pharmacy: $9,104,547
- CSPH: $6,834,135

- National Institute of Diabetes and Digestive and Kidney Diseases/NIDDK, 17%
- National Heart, Lung, and Blood Institute/NHLBI, 14%
- National Cancer Institute/NCI, 13%
- National Institute of Neurological Disorders and Stroke/NIH/NINDS, 7%
- Other, 35%
Enter NCATS and CTSA 2013 RFA

• Despite this success in growing our research portfolio, funding and our national rankings…

• NCATS 2013 funding formula for our CTSA grant changed our funding model and so began our fiscal constraints

• Year 1 budget: $15.161 million

• Year 5 budget: New formula
NIH Calculation for Year 5 Budget

• Total NIH Grant Support (2011) for CCSTI
  $253,345,324 \times 3\% = 
  $7,600,359

+ $1,030,320     Addition of CSU
  8,630,879

Reduction of $6.5 \text{ million} \text{ for yr. 5 budget}

43\% \text{ Reduction}
Budget Strategies

1. Increase Efficiency
   New Quality and Process Improvement Program (QPIP)
   New Operations Director

2. Increase Institutional Support
   UCH, CHCO, SOM, CSU, Chancellor, Others

3. Program Income System
   Charge back for services
   Protect trainees and young investigators
   • MicroGrants & BERD Seeds

4. Philanthropy
CU Boulder  
Partner since 2008

• Flagship university for state of Colorado
• $450 Million grant support
• Strengths: aerospace science, physics, chemistry, molecular biology, integrative physiology, mathematics, psychology, Biofrontiers Institute (Tom Cech, PhD)
• CTRC unit, Proteomics Core, Chairs of two CCTSI committees, UCCC, investigators
Colorado State University
New Partner since 2013

- Top Veterinary Medicine College, Infectious Disease research program, UC Cancer Center, NORC, CSPH, Advanced animal imaging, GMP facilities for therapeutics and vaccine development, Comparative Pathology
- Many ongoing partnerships and collaborations
- Only 60 minutes by car to the North
- CU-CSU CCTSI Summit held July 2013, 2014, summer 2015
Spectrum of Translational Research

**CLINICAL TRANSLATIONAL RESEARCH SPECTRUM**

- **T0.5** Basic Scientific Discovery → Translation to Natural Animal Models
- **T1** Preclinical Insights → Translation to Humans
- **T2** Clinical Insights → Translation to Patients
- **T3** Implications for Practice → Translation to Practice
- **T4** Implications for Population Health → Translation to Population
- **Improved Global Health**

Diagram showing the progression from basic scientific discovery to improved global health through various stages of translational research.
CSU and CCTSI

• Clinical Trials in Natural Animal Models
  • Naturally occurring cancers and other diseases with similar biology – dogs, cats, etc.
  • Target identification, biomarker development, diagnostics, imaging and drug development, therapeutic trials (“One Medicine”)

• PK/PD/PG Core
• Joint Pilot grant projects – “T 0.5” translation
• GMP facility – BSL3
New Programs in Year 1-2

CCTSI Specific:

• Pragmatic Trials/Dissemination-Implementation Research Core
• Research Accelerator Studios (T1-T4)
• Community Consults (for T1-T2)
• Program Income System
  – MicroGrants
  – BERD Seeds
• CSU Cores
New Programs in Year 1-2

Campus Wide Initiatives:
- OnCore (CTMS)
- iLabs solutions (Core management system)
- Health Data Compass (EDW) and BIPM Program

National Initiatives
- PACT and PCORI Community Pipeline Grants
- Accrual in Clinical Trials (ACT)
- Good Clinical Practice Training (GCP)
- IRB Reliance
- Contracting Template Agreement
“Budget reduction requires a detailed evaluation of all programs, garnering of additional resources and offloading to other entities where it is possible without jeopardizing program quality”

- Increased resources obtained
- Process improvements underway
- Continued concerns about CTRCs (new FOA will make this even more challenging)
  - MicroGrants and BERD Seeds (voucher programs - ? Expand to more senior investigators
- Decisions about program sustainability- this year
“Need to develop informatics more quickly. Academic Division… seems meager”

- BIPIM and personalized medicine program have received over $55M support from partner institutions
- Recruitment for Division and Center Director underway
- Many other infrastructure pieces under development
- Compass (EDW) being implemented – Michael Kahn – Director

“Shortage of Biostatistical Collaborators… quality of current staff excellent … sheer numbers game”

- New Chair of Biostatistics and Informatics in CSPH (Center BIPIM)
  • Debashis Ghosh, PhD (Penn State Univ.)
- QPIP evaluation of BERD/CBC – proposal to SOM coming
Response to EAC Critique - January 2014

“Director of CCTSI – lack of institutional leadership position - CCTSI may be undervalued and deprives the CCTSI team of the opportunity to weigh in on major decisions

– Jan. 2015: Assistant Vice Chancellor for Clinical and Translational Sciences, UC Denver

“Retirement of Dean Richard Krugman…hope the new Dean will be as attentive to CCTSI”

– John J. Reilly, Jr., MD – Univ. of Pittsburgh, Chair of Dept. of Medicine, Pulmonologist, Clinical Investigator, involved in management of Pitt CTSA program
Strengths - Transition to New CTSA FOA Directives in 2018

• Multi-site trial/study facilitation – *faster and better*
  – cohort ID, recruitment, enrollment
  – contracting
  – IRB/hospital approvals
  – tracking, monitoring, intervening in trials
  – use of CTRCs

• Workforce Development
  – Our ETCD program is robust

• Pilot program - ? Changes needed
Our Challenges in Year 2-3

- Sustain vs. cut programs with shrinking budget
- Continue to attract investigators to CTRCs with charge backs for all services (except space – currently). Question? Continue to subsidize to lower charges
- Demonstrate value to justify increased institutional support
- New 2014 RFA – no rent, CRU staff, procedures, etc. (few exceptions) on CTSA budget
- Biostats and Informatics development and capacity
Questions or Comments