UCLA Translational Ecosystem

External Advisory Board

Michael Palazzolo, MD, PhD
June 2014
Overview of the UCLA Entrepreneurial Ecosystem
Goals of the Ecosystem

- Improve Patient Outcomes and Lower Healthcare Costs
- Support the Faculty
- Revenue Stream Makes Ecosystem Self-Sustaining
Goals of the CAI

- UC BRAID CAI
- One of three national centers
- $12 Million over 7 years
- 30 – 40 projects
  - In the areas of interest of NHLBI
    - Devices, Diagnostics, Digital Health, Therapeutics
- First projects launched in June
- Skills development program for the faculty
Plans to Integrate CTSI Partners with UCLA Ecosystem

- Four working group meetings
- Visits to Cedars and Harbor
- Several consulting sessions
Technological bottleneck - the mechanistic understanding of a disease
- Can use to validate therapeutic intervention points
- Primary occurrence - Universities

Value transition point - occurs at proof-of-concept in phase I/II clinical trials
- Primary occurrence - Biotech and Pharma

Historical Process:
Biotech Supplements Pharma’s Pipeline
Q: If Biotech shrinks and its ability to supplement Pharma’s pipeline is weakened... Can a university take advantage and recover value currently captured by VCs and Biotech?

YES, if it develops an ecosystem that develops products with qualities resembling those that emerge from Biotech

- IP has to move up to the value transition point
Multiple Roles

• Nurture innovation
  – Advance to value point with NIH funding
  – Instigate collaborations
  – Business Advice
• Identify opportunities
• Manage new ventures
• Business Development by Senior Business Executives

Investment philosophy

• Risk/reward
• Leverage non-dilutive funding
• Competitive edge
• Not a slush fund – focus is translation
What is a Platform?

- Attack most important **bottleneck** - the value chain
- **Integrated** and comprehensive in a manner that moves from discovery to valuable endpoint
- Provides **multiple shots on goal**, affords a variety of potential business strategies
- Provides multiple types of opportunities
  - example: therapeutics and companion biomarkers
- Opportunity for **the virtuous circle**
- **Singleton** - narrowly defined project with single shot on goal
Organizational Options

- **Traditional via OIP (UCLA Tech Transfer)**
  - Startups
  - License to existing company

- **Fund Internally to proof of concept**
  - Auction license to highest bidder
  - Build through non-dilutive funding

- **Faculty/UCLA companies in Renovated CHS space built by SBIR grants**
Skills Development

Translational Tools
- Target product profile
- Gantt charts
- Budgets
- Deal Database
  - Bill Boyle will describe

Consulting
- Deals
- How to generate increased value
- Translational databases
- Scientific and Business strategies
Examples of the Advantage of Leveraging CTSI, CAI, and Accelerator

• **Wireless Health Initiative**
  – A voucher program
  – Clinical testing laboratory
  – Accelerator business development

• **Monoclonal Antibody Core**

• **Systems Platform** to Integrate Patient Databases, Sample Bank, Clinical Trial Network, Genomics, Imaging
CTSI
Business Development Strategies

External Advisory Board

William J. Boyle, Ph.D.
Associate Professor
DGSOM Accelerator
What is Business Development?

- It is an essential component of growing and evolving organizations – even the University

- A customized mix of many things
  - Recognizing value
  - Capturing and increasing value
  - Making deals and partnering
  - Serendipity and opportunism
  - Timing
  - Leveraging your network

*Forbes*

Business development is the creation of long-term value for an organization from customers, markets, and relationships.
Three Case Studies

• **TORL** – Therapeutic antibodies and benchmarking

• **Wireless Health** – Partnering to generate funding for internal clinical development

• **Digital Dx** – Evaluating the market to develop an appropriate business model
• Translational Oncology Research Laboratory

• Leveraged discovery platform to identify a number of novel therapeutic mAb targets

• How do they generate value?
  – Answer: understanding the value of their “holdings” provides multiple opportunities and solutions

• Collaboration with UCLA Anderson School of Management
  – Bill Ouchi and EASTON ‘15 MBA students
# mAB Discovery Timeline and Costs

<table>
<thead>
<tr>
<th>Antibody Development Plan</th>
<th>Cost ($)</th>
<th>Time Frame (in Months)</th>
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<tbody>
<tr>
<td><strong>Milestone 1: mAb Synthesis and Profiling and Candidate Selection</strong></td>
<td>424,000</td>
<td>1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32 33 34 35</td>
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<tr>
<td>Hybridoma</td>
<td>25,000</td>
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<tr>
<td>Humanization</td>
<td>125,000</td>
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<tr>
<td>Optimization</td>
<td>275,000</td>
<td></td>
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<tr>
<td>mAbExpression for characterization</td>
<td>6,000</td>
<td></td>
</tr>
<tr>
<td>mAb product characterization</td>
<td>10,000</td>
<td></td>
</tr>
<tr>
<td>Pharmacokinetics</td>
<td>5,000</td>
<td></td>
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<tr>
<td><strong>Milestone 2: Clone Selection and Working Cell Bank Production</strong></td>
<td>396,000</td>
<td></td>
</tr>
<tr>
<td>Vector construction</td>
<td>26,000</td>
<td></td>
</tr>
<tr>
<td>Transfection and pool selection</td>
<td>100,000</td>
<td></td>
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<tr>
<td>Clone selection</td>
<td>270,000</td>
<td></td>
</tr>
<tr>
<td><strong>Milestone 3: Process Development Lock and Initiation of Master Cell Line</strong></td>
<td>1,487,000</td>
<td></td>
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<tr>
<td>Platform process and process lock</td>
<td>190,000</td>
<td></td>
</tr>
<tr>
<td>Master cell bank</td>
<td>222,000</td>
<td></td>
</tr>
<tr>
<td>Long lead pre purchase of chromatography resin (2000L)</td>
<td>600,000</td>
<td></td>
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<tr>
<td>GLP engineering run for pre Tox cyno dose ranging study</td>
<td>400,000</td>
<td></td>
</tr>
<tr>
<td>Pre Tox cyno dose ranging study</td>
<td>75,000</td>
<td></td>
</tr>
<tr>
<td><strong>Milestone 4: Preclinical Development and Manufacturing</strong></td>
<td>3,340,000</td>
<td></td>
</tr>
<tr>
<td>Analytical development and validation</td>
<td>132,000</td>
<td></td>
</tr>
<tr>
<td>Validation of analytical methods</td>
<td>160,000</td>
<td></td>
</tr>
<tr>
<td>Manufacturing of Tox and Clinical material under GMP conditions (2)</td>
<td>1,113,000</td>
<td></td>
</tr>
<tr>
<td>Manufacturing of drug product: One liquid fill lot under GMP conditions</td>
<td>86,000</td>
<td></td>
</tr>
<tr>
<td>Process validation (virus removal, development standard and product)</td>
<td>336,000</td>
<td></td>
</tr>
<tr>
<td>Bridging data for process lock GLP material</td>
<td>60,000</td>
<td></td>
</tr>
<tr>
<td>Stability testing cGMP material - drug substance and drug product ADME</td>
<td>96,000</td>
<td></td>
</tr>
<tr>
<td>Toxicology, Safety Pharmacology, Toxicokinetics, hERG, Genotox, Tiss</td>
<td>75,000</td>
<td></td>
</tr>
<tr>
<td>GMP single dose rat and cynomolgus pharmacokinetic and toxicity studies Pre-IND and IND</td>
<td>1,130,000</td>
<td></td>
</tr>
<tr>
<td>Animal Models and Biomarker Studies</td>
<td>425,000</td>
<td></td>
</tr>
<tr>
<td>Colorectal cancer models in mouse</td>
<td>150,000</td>
<td></td>
</tr>
<tr>
<td>Murine model of ulcerative colitis</td>
<td>150,000</td>
<td></td>
</tr>
<tr>
<td>Biomarker studies - human and murine samples</td>
<td>150,000</td>
<td></td>
</tr>
<tr>
<td><strong>Milestone 5: Clinical Development</strong></td>
<td>2,000,000</td>
<td></td>
</tr>
<tr>
<td>Single dose Phase Ia trial</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>Multiple dose Phase Ib trial</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>Consultants</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>Project management</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>CMC auditing and management</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>BioAssay and analytical development (particularly for the biomarker assays)</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>Toxicologist to review and sign off on Tox results</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td>Clinical regulatory</td>
<td>500,000</td>
<td></td>
</tr>
<tr>
<td><strong>Total Cost from discovery to end of phase 1</strong></td>
<td>8,572,000</td>
<td></td>
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</table>
Therapeutic Antibodies – Early Stage Exits

- Analyzed publicly available information on recent deals
- Accessed databases to look at recent deals
- Building a model for deal structures and exit structures

<table>
<thead>
<tr>
<th>Company</th>
<th>Target</th>
<th>Partner</th>
<th>Stage</th>
<th>Year</th>
<th>Upfront</th>
<th>Milestones (Royalty Net Sales)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aveo</td>
<td>RON</td>
<td>JNJ/Centocor</td>
<td>Preclinical</td>
<td>2011</td>
<td>$15 MM</td>
<td>$555 MM</td>
</tr>
<tr>
<td>Alder BioPharma</td>
<td>IL-6</td>
<td>BMS</td>
<td>Ph II</td>
<td>2009</td>
<td>$85 MM</td>
<td>$765 MM</td>
</tr>
<tr>
<td>Merrimack</td>
<td>HER3</td>
<td>Sanofi Aventis</td>
<td>Ph I</td>
<td>2009</td>
<td>$60 MM</td>
<td>$410 MM</td>
</tr>
<tr>
<td>Agensys</td>
<td>PsCA</td>
<td>Merck</td>
<td>Preclinical</td>
<td>2005</td>
<td>$17.5 MM</td>
<td>$200 MM</td>
</tr>
<tr>
<td>NovImmune</td>
<td>IFN/CD3</td>
<td>Serono</td>
<td>Preclinical</td>
<td>2005</td>
<td>$15 MM</td>
<td>$105 MM</td>
</tr>
<tr>
<td>Micromet</td>
<td>EpcAM</td>
<td>Serono</td>
<td>Ph 2</td>
<td>2004</td>
<td>$147 MM</td>
<td>ND</td>
</tr>
<tr>
<td>BioStratum</td>
<td>Laminin-5</td>
<td>Novo Nordisk</td>
<td>Preclinical</td>
<td>2004</td>
<td>$80 MM</td>
<td>ND</td>
</tr>
<tr>
<td>CytomX</td>
<td>EGFR and Platform</td>
<td>Pfizer</td>
<td>Preclinical</td>
<td>2014</td>
<td>$25 MM</td>
<td>$610 MM (tiered double digit)</td>
</tr>
<tr>
<td>Ablynx</td>
<td>IL-6</td>
<td>Abbvie</td>
<td>Ph 2a</td>
<td>2013</td>
<td>$175 MM</td>
<td>$675 MM (tiered double digit)</td>
</tr>
</tbody>
</table>
## Net Present Value of TORL Pipeline

<table>
<thead>
<tr>
<th>Stage</th>
<th>#</th>
<th>P (success)</th>
<th>P (at least 1 of 30 success)</th>
<th>($ in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Discovery</td>
<td>30</td>
<td>100%</td>
<td>Patent life</td>
<td>10 years</td>
</tr>
<tr>
<td>mAb Discovery</td>
<td>24</td>
<td>80%</td>
<td>Royalty rate</td>
<td>5%</td>
</tr>
<tr>
<td>Preclinical</td>
<td>18</td>
<td>75%</td>
<td>Pharma's discount rate</td>
<td>8%</td>
</tr>
<tr>
<td>IND-Enabling</td>
<td>14</td>
<td>80%</td>
<td>UCLA's discount rate</td>
<td>5%</td>
</tr>
<tr>
<td>Phase I</td>
<td>10</td>
<td>70%</td>
<td>Annual CF</td>
<td>500,000</td>
</tr>
<tr>
<td>Phase II</td>
<td>5</td>
<td>50%</td>
<td>DCF to Pharma</td>
<td>3,355,041</td>
</tr>
<tr>
<td>Phase III to Market</td>
<td>4</td>
<td>70%</td>
<td>DCF to UCLA</td>
<td>193,043</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Expected value (at least 1 of 30)</td>
<td>188,518</td>
</tr>
<tr>
<td>Through IND-Enabling</td>
<td></td>
<td>48%</td>
<td>Cost to UCLA?</td>
<td>600</td>
</tr>
<tr>
<td>Through Phase III to Market</td>
<td></td>
<td>11.76%</td>
<td>NPV</td>
<td>187,918</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>IRR</td>
<td>47%</td>
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</table>
TORL Program Exits

• **Preclinical**
  – Prior to cell line development and manufacturing
  – mABs tested for efficacy in predictive animal models
  – Select clinical candidate with manufacturability assessment and pre-Tox Cyno PK

• **IND ready**
  – IND enabling Tox and manufacturing of clinical supply

• **Proof of concept in the clinic (Phase 1b/2a)**
Digital Dx Test Development

Opportunity/Situation:
Clinical researchers at UCLA have developed a potential break-through diagnostic test for PD-1 in immunotherapy

- **Tumeh/Ribas Research**
  - Measuring PD-1 – PD-L1 interactions in tumors to predict patient response to PD-1 inhibitors
  - Validation using clinical samples obtained from ongoing studies in melanoma and NSCLC
  - Identification of responders and non-responders in the clinic
    - Patent Applications
    - Nature paper

- **Given the potential of PD-1 in oncology, there likely is significant value for UCLA**
  - Nascent opportunity to monetize the Dx test created at UCLA

- **Reached out to key industry opinion leaders for guidance on how to proceed**
## PD-1 Targeting – Market Opportunity

Approximately $15 B market in 2020 from Merck, BMS and Roche alone.

<table>
<thead>
<tr>
<th>Product</th>
<th>Company</th>
<th>Pharmacological Class</th>
<th>Annual Sales WW - (US $)</th>
<th>Technology Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>2013</td>
<td>2020</td>
</tr>
<tr>
<td>1</td>
<td>Humira</td>
<td>Anti-tumour necrosis factor alpha (TNFa) MAb</td>
<td>10,659</td>
<td>11,990</td>
</tr>
<tr>
<td>2</td>
<td>Avastin</td>
<td>Anti-VEGF MAb</td>
<td>6,751</td>
<td>6,572</td>
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<tr>
<td>3</td>
<td>Remicade</td>
<td>Anti-tumour necrosis factor alpha (TNFa) MAb</td>
<td>5,334</td>
<td>6,311</td>
</tr>
<tr>
<td>4</td>
<td>Nivolumab</td>
<td>Anti-programmed-death-1 (PD-1) MAb</td>
<td>-</td>
<td>5,979</td>
</tr>
<tr>
<td>5</td>
<td>Rituxan</td>
<td>Anti-CD20 MAb</td>
<td>7,503</td>
<td>5,607</td>
</tr>
<tr>
<td>6</td>
<td>Soliris</td>
<td>Anti-complement factor C5 MAb</td>
<td>1,551</td>
<td>5,119</td>
</tr>
<tr>
<td>7</td>
<td>Herceptin</td>
<td>Anti-HER2 (ErbB-2) MAb</td>
<td>6,562</td>
<td>5,082</td>
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<tr>
<td>8</td>
<td>MK-3475</td>
<td>Anti-programmed death-1 (PD-1) MAb</td>
<td>-</td>
<td>4,261</td>
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<tr>
<td>9</td>
<td>Perjeta</td>
<td>Anti-HER2 (ErbB-2) MAb</td>
<td>352</td>
<td>4,156</td>
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<tr>
<td>10</td>
<td>Staliara</td>
<td>Anti-interleukin-12 (IL-12) &amp; interleukin-23 (IL-23) MAb</td>
<td>1,504</td>
<td>3,539</td>
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<tr>
<td>11</td>
<td>RG7446</td>
<td>Anti-programmed cell death-1 ligand 1 (PD-L1) MAb</td>
<td>-</td>
<td>2,194</td>
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<tr>
<td>12</td>
<td>Simponi</td>
<td>Anti-tumour necrosis factor alpha (TNFa) MAb</td>
<td>932</td>
<td>2,607</td>
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<tr>
<td>13</td>
<td>Tysabrit</td>
<td>Anti-VLA-4 MAb</td>
<td>1,413</td>
<td>2,565</td>
</tr>
<tr>
<td>14</td>
<td>Yervoy</td>
<td>Anti-CD20 MAb</td>
<td>960</td>
<td>2,288</td>
</tr>
<tr>
<td>15</td>
<td>Gazyva</td>
<td>Anti-CD20 MAb</td>
<td>3</td>
<td>2,267</td>
</tr>
<tr>
<td>16</td>
<td>Lucentis</td>
<td>Anti-VEGF MAb</td>
<td>2,383</td>
<td>2,238</td>
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<tr>
<td>17</td>
<td>Xgeva</td>
<td>Anti-RANKL MAb</td>
<td>1,019</td>
<td>2,191</td>
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<tr>
<td>18</td>
<td>Adcrema</td>
<td>Anti-interleukin-6 (IL-6) MAb</td>
<td>907</td>
<td>2,128</td>
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<tr>
<td>19</td>
<td>Lucentis</td>
<td>Anti-VEGF MAb</td>
<td>1,823</td>
<td>1,793</td>
</tr>
<tr>
<td>20</td>
<td>Remicade</td>
<td>Anti-tumour necrosis factor alpha (TNFa) MAb</td>
<td>2,271</td>
<td>1,594</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td></td>
<td></td>
<td>9,354</td>
<td>36,656</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>61,282</td>
<td>117,836</td>
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</table>
Assessment by Key Opinion Leaders

• **Samarth Kulkarni** – McKinsey & Co. engagement leader in Personalized Medicine and Diagnostics

• **Terry Robins** – *former* Quest head of R&D; at three start-up companies acquired by Quest Diagnostics

Discussed the Dx concept and results and provided feedback on the business opportunity
Key Lessons Learned

• This is an important area and good opportunity for UCLA
  – Esoteric Dx Test; blackbox diagnostic that predicts patient response to therapeutic candidates in late-stage clinical development
  – Timing is critical

• A number of business models to bring such a diagnostic to the market.

• In vitro diagnostic market has seen slower growth in the last 3 years due to pricing and reimbursement pressures. Esoteric testing has been bright spot

• Esoteric tests continue to face challenges as they are introduced in the market, particularly on reimbursement and physician acceptance. A small fraction of new esoteric tests have reached sales of >$100M in the US
  – For esoteric tests launched through a services model, it has been difficult to maintain exclusivity, and competitive intensity is higher as other home brews are launched
Business Models

• NewCo spin out; need $5-10 MM investment to bring Dx to market
  – VC participation and dilution
  – 4-6 years to exit in the $100-150 MM range
  – Risk
  – Competition and need for follow-on products to de-risk investment

• Licensing to Dx provider
  – $100-200 K upfront with 8-10% royalty stream (~$10-15 MM/year)
  – Quest, LabCorp, Genomic Health, etc.

• Pharma/Payor services model
  – Non-exclusive license
  – Upfront payments larger but less upside on royalty stream
    • Merck, BMS, Roche/Genentech
  – FDA, CLIA

Current recommendation is to license to large Dx provider and push for largest upfront and royalty attachments – generate $10-15 MM revenue stream for UCLA and inventors over the lifetime of the product as is likely to exceed the risk –adjusted value of a NewCo in this area
Wireless Health Institute

Wearable motion sensors to continuously measure real-world physical activities

Bruce H. Dobkin

• Bill Kaiser and Bruce Dobkin have collaborated to develop leading-edge motion sensors to measure a multitude of physical activities relating to health and performance

• Seek to utilize their technology to impact decision making in the clinic

• Their technology has many applications in the consumer world that can be partnered to create funding opportunities

• Working with PepsiCo (Gatorade) to utilize WHI technology to measure athletic performance in a meaningful way that is not possible using their current methods
  – Provide funding to enable the building of teams at UCLA to support use of WHI technology in the clinic
Summary

• Each situation provides a different set of circumstances – customized business solutions

• Collaboration with Anderson School
  – Gaining key benchmarking insights
  – Training students about details of drug, diagnostic and device development in health care

• Leveraging networks to build key relationships
Center for Translational Technologies (CTT)

Y3 Progress Report

Christopher Denny, MD
Specific Aims & Strategic Goals

• **Aims**
  – Promote effective use of current cores
  – Develop new technologies into core services
  – Educate CTSI user base

• **Innovation**
  – Shift from direct core subsidy to support for user defined projects

• **Goals**
  – Give investigators what they need ASAP
  – Potentiate feedback loop between services/technologies and what investigators need
  – Incentivize investigators to engage in translational research
Response to EAB Year 2 Feedback

• The prior EAB recommendation for user dashboards has been thwarted by university accounting systems to date.
  – Development of Team Science System (TSS) to track voucher awardees

• For all CTSI resources and services: consider a shift from scheduled internal RFA’s for use of CTSI resources to continuous… This would require an ongoing continuous review process, which other CTSA’s have set up, and the ability to track obligations and actual expenditures in a timely and fine-grained fashion.
  – Preliminary strategy in place; depends on successful implementation of TSS

• The process for selecting new cores for development could be more transparent and systematic. You may also want to consider development of a process for the elimination of cores that are no longer widely used…
  – Creation of tools to evaluate cores by investigator demand and satisfaction
Scalable review process for applications

Supporting Software
- RFP - Application/Reviewer submissions (Oracle backed website)
- Voucher db - Rank order generation; Investigator/Core tracking (FileMaker)
- TSS - Voucher post award tracking (Oracle backed website)
Development of user dashboard – Team Science System (TSS)

CTSI
- Correspondence control
- Set awardee state
- Track awardee progress

TSS
- Award notification
- Access to IRB/IACUC amendment forms
- Award state: pending, active, completed

Core
- List of awardees
- Amount of committed service
- Awardee state

IRB/IACUC
Applications now include co-investigator option (postdocs, graduate students, project scientists)

<table>
<thead>
<tr>
<th></th>
<th># Applications</th>
<th># New Applicants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Westwood</td>
<td>106 (52 Co-PI)</td>
<td>52 (49%)</td>
</tr>
<tr>
<td>CSMC</td>
<td>55 (24 Co-PI)</td>
<td>15 (27%)</td>
</tr>
<tr>
<td>LA BioMed</td>
<td>11 (6 Co-PI)</td>
<td>4 (36%)</td>
</tr>
<tr>
<td>CDU</td>
<td>3 (1 Co-PI)</td>
<td>1 (33%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>175 (83 Co-PI)</strong></td>
<td><strong>72 (41%)</strong></td>
</tr>
</tbody>
</table>

Totals (2011 - present)

- Investigators - 665
- Applications - 906
- Reviews - 2539
## Vouchers Awarded – By Campus

<table>
<thead>
<tr>
<th></th>
<th>2011*</th>
<th>2012</th>
<th>2013</th>
<th>2014*</th>
<th>Total Award Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Westwood</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applications</td>
<td>-</td>
<td>304</td>
<td>168</td>
<td>106</td>
<td>$1,401,504</td>
</tr>
<tr>
<td>Awards</td>
<td>-</td>
<td>73</td>
<td>50</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td><strong>CSMC</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applications</td>
<td>74</td>
<td>50</td>
<td>58</td>
<td>55</td>
<td>$814,578</td>
</tr>
<tr>
<td>Awards</td>
<td>39</td>
<td>16</td>
<td>16</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td><strong>LA BioMed</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applications</td>
<td>16</td>
<td>18</td>
<td>22</td>
<td>11</td>
<td>$361,651</td>
</tr>
<tr>
<td>Awards</td>
<td>15</td>
<td>17</td>
<td>10</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td><strong>CDU</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Applications</td>
<td>-</td>
<td>14</td>
<td>7</td>
<td>3</td>
<td>$75,409</td>
</tr>
<tr>
<td>Awards</td>
<td>-</td>
<td>5</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

Total # of awards / awardees = 293 / 226  
Total amount awarded = $2,653,142

* Data represent 1 RFA cycle
## Tracking of Year 1 Voucher Awardees

<table>
<thead>
<tr>
<th>Subsequent Grant Funding</th>
<th>2013*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Federal NIH</td>
<td>$4,656,971</td>
</tr>
<tr>
<td>Federal non-NIH</td>
<td>$744,000</td>
</tr>
<tr>
<td>Non-Federal/Private</td>
<td>$250,000</td>
</tr>
<tr>
<td><strong>Total Return</strong></td>
<td><strong>$5,650,971</strong></td>
</tr>
<tr>
<td><strong>Total Vouchers Funded</strong></td>
<td><strong>$782,390</strong></td>
</tr>
<tr>
<td><strong>Return on Investment</strong></td>
<td><strong>6.2</strong></td>
</tr>
</tbody>
</table>

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer-reviewed Publications</td>
<td>122</td>
</tr>
<tr>
<td>Patent Applications</td>
<td>2</td>
</tr>
<tr>
<td>Licenses</td>
<td>1</td>
</tr>
<tr>
<td>Clinical Trials</td>
<td>1</td>
</tr>
</tbody>
</table>

* Scientific Productivity Survey conducted by UCLA CTSI-Evaluation
  - Cohort consisted of 2011 CSMC and LA BioMed awardees, and 2012 1st round UCLA and CDU awardees
  - Response rate: 79% (72/91 awardees)
  - Productivity reported from award date through the end of 2013
CTT Voucher Program Diversity at Westwood

**Awardees**

- 2/12: n = 38
- 9/12: n = 36
- 2/13: n = 34
- 9/13: n = 16
- 3/14: n = 27

**Applicants**

- Dental School - Clinical
- Other
- Physical Sciences
- Neuro-psychiatric Institute
- Engineering
- Nursing
- Life Sciences
- Dentistry
- DGSOM - Basic Sciences
- DGSOM - Clinical

3/2014
Core Recruitment & Retirement

- **Recruitment**
  - New technology ≠ New core
    - User demand must exist
    - Service has to be reproducible/robust
    - PI must be willing to act as director
  - Have taken opportunistic approach via RFA requests

- **Retirement**
  - Current system auto-regulatory
  - Increased role by Tech Officer to monitor core request/usage through vouchers

- **Role of Voucher database**
  - Monitor core demand
  - Identify requested services from ‘neo-cores’ via ‘other:’ requests
Evaluation of Cores

• Trend investigator demand on a core-by-core basis

• Investigator follow up
  – Correlate awardee publications with cores utilized
  – Rate your core(s)
Future Foci

• **Improved services to investigators**
  – Awardees
    • Streamline use of voucher funds via Team Science System (TSS)
    • Active follow up for impact assessments
  – Non-awardees
    • Provide in-depth feedback
      – Personalized notification with qualifying scores
      – Provide one-on-one consultation as needed
    • Personalized recruitment for future voucher RFAs

• **Improve monitoring core services**
  – Trend investigator demand
  – Improve curation of core information
    • CTT site
    • RFA selections
On-Time Voucher Program

• **Process**
  – Online Submission and Review unchanged
  – Pay line set based on previous voucher RFAs
  – Those that are not paid get rolled into next RFA cohort

• **Logistical Requirements**
  – TSS has to work
  – RFP software needs to be adapted to floating review process

• **Trial run in 2014**
  – Westwood only initially
  – One third of projected budget committed
Review of Program Area Goals

- Advance collaborative, translational research through broad-ranging funding mechanisms

- Develop novel clinical and translational technologies and methodologies

- Enable the next generation of faculty to establish careers in team-based clinical translational research
## Pilot Programs

<table>
<thead>
<tr>
<th>Pilots</th>
<th>Team Building</th>
<th>Proposal Development</th>
<th>Proof-of-Concept</th>
</tr>
</thead>
<tbody>
<tr>
<td>Junior Faculty Mentored Awards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Team Science Awards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inter-Institutional Awards</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Catalyst Grants</strong></td>
<td></td>
<td></td>
<td><strong>Business of Science Prototype Grants</strong></td>
</tr>
</tbody>
</table>

- Junior Faculty Mentored Awards
- Team Science Awards
- Inter-Institutional Awards
- Catalyst Grants
- Business of Science Prototype Grants
Challenges/Opportunities

• Be careful to harmonize your approach to assessing ROI with other CTSAs. Somewhere, you should document whether investigators note that follow-on external funding would not have been possible without your support, and ROI should only include funding thus identified.

➢ Faculty are being informed that they have to properly acknowledge the CTSI.
Challenges/Opportunities

• Are winners and losers being created in the current model of matching resources with co-funders of pilot studies? Perhaps this is an unavoidable consequence of leveraging your resources.

➢ The Team Science Award Program supports multidisciplinary team-based research with awards up to $200K. We require co-funding and collaboration.

_Importantly, Team Science awards must be made available to all faculty (regardless of department, campus site or institutional co-funder)._
Progress

• Awarded 280 pilot grants to date.

• Total of $5M in CTSI funds; $5.5 M leveraged institutional funds.

• Partnered with UCLA Centers and Institutes, both internal and external.
  - offered 20 Team Science Awards
  - $1.3M direct CTSI support and $1.6M in institutional matching support

• 58 Junior Faculty Mentored Awards.
Progress

- 68 Catalyst Awards totaling $1.1M. All catalyst awards were matched 1:1 or greater!

- Awarded $200,000 to the Rapid Response Team (RRT) to establish grant-preparation software, catalyze collaborations and develop its administrative infrastructure.

- $40,000 Prototype Award for the Business of Science program, awarded to Thoracic Surgery to support technology development of a Video-guided Chest Tube Insertion System (“VisiTube”)
  - supports technology development teams composed of UCLA faculty inventors and UCLA Anderson School of Management MBA students.

- **Reached $46 million** in new extramural funding resulting from Pilot investments.
CTSI and Leveraged Funds

Year 1 Pilots:
- CTSI Funds: $612,275
- Other Funds: $1,066,738

Year 2 Pilots:
- CTSI Funds: $2,191,647
- Other Funds: $1,463,943

Year 3 Pilots:
- CTSI Funds: $1,855,910
- Other Funds: $2,572,048
Progress - Return

- Return, > $46M
- CTSI, $5M
- Leveraged, $5.5M
<table>
<thead>
<tr>
<th>Team Science Awards: Partnering ORUs, Departments &amp; Other Institutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• AIDS Institute</td>
</tr>
<tr>
<td>• Cardiovascular</td>
</tr>
<tr>
<td>• Children’s Discovery and Innovation Institute</td>
</tr>
<tr>
<td>• Cousins Center</td>
</tr>
<tr>
<td>• Cedars-Sinai Department of Medicine</td>
</tr>
<tr>
<td>• Psychiatry &amp; Behavioral Science - CART</td>
</tr>
<tr>
<td>• Women’s Health Center</td>
</tr>
<tr>
<td>• RCMAR / CHIME</td>
</tr>
<tr>
<td>• University of Minnesota</td>
</tr>
<tr>
<td>• LA DHS</td>
</tr>
<tr>
<td>• School of Nursing - Patient Safety Institute</td>
</tr>
<tr>
<td>• School of Dentistry</td>
</tr>
<tr>
<td>• Brain Research Institute</td>
</tr>
<tr>
<td>• Center for Aging</td>
</tr>
<tr>
<td>• OVCR Transdisciplinary Seed Grant Program</td>
</tr>
<tr>
<td>• JCCC</td>
</tr>
<tr>
<td>• Business of Science Center</td>
</tr>
<tr>
<td>• Department of Mental Health</td>
</tr>
<tr>
<td>• USC</td>
</tr>
<tr>
<td>• Evolutionary Medicine</td>
</tr>
</tbody>
</table>
New Funding

Barbara Vickrey, MD, MPH

**CTSI Team Science Award:** Stroke/cardiovascular disease in underserved minority populations

**New Funding (U54 NS081764):** Systematic use of stroke averting interventions (SUSTAIN)

**Award Amount:** $11M

Yibin Wang, PhD

**CTSI Team Science Award:** Systems Genetics of Heart Failure: Paving the Road to Translation

**New Funding (R01 HL114437):** Systems Approach to Unraveling the Genetic Basis of Heart Failure

**Award Amount:** $4.8M

Ron Victor, MD

**CTSI Team Science Award:** Combatting Cardiovascular Disease in African American Men Through Blood-Pressure Testing in Los Angeles Barbershops

**New Funding (R01):** Barber-Pharmacist Coordination to Improve Blood Pressure Management in Black Men

**Award Amount:** $8M
Future Plans

• Continue to partner with ORUs, Departments and other Institutes to fund Team Science

• Partner with LA County to continue joint funding of pilot programs

• Partner with the University of California Center for Accelerated Innovation (CAI) and awardee departments to fund consultation awards

• Continue to leverage matching funds to expand the K program
Biostatistics Program

Y3 Progress Report

Robert M. Elashoff, PhD – Leader
Steven Piantadosi, MD, PhD – Leader
David Elashoff, PhD – Leader
Andre Rogatko, PhD – Leader
Program Organization

Biostatistics Program

Consultations
- Data analysis
- Study design
- Grant-preparation assistance
- Data management

Biostatistical Research
- Adaptive trial designs
- Novel statistical applications
- Novel randomizations
- Proteomic analysis

Biostatistical Education
- Workshops
- Trainings
- MS in Clinical Research
- Dept. of Pediatrics

Biostatisticians onsite at partner institutions
• Interaction with BIP on REDCap
• Name of the program
• Diagnostic Consults
• Evaluation
• Ascertaining needs and gaps
• Sustainable financial models
“Need informatics input into REDCap support to promote best practices for research database design that incorporates preferred ontologies and controlled vocabularies, to facilitate data sharing and meta-analysis.”

Response: We have initiated a collaborative working group with the BIP program to implement this recommendation.

- The biostatistics program assists investigators developing databases
- BIP will assist with larger infrastructure projects that can apply to all databases including preferred ontologies and controlled vocabularies, and data linkage between REDCap and xDR/CTRL etc.

Name of the program

“Consider renaming the from Biostatistics and Computational Biology Program”

- Response: Rename to “Biostatistics Program”? 
"Consider formally separating a statistical diagnostic consult (supported by the CTSI as a specific voucher type or offered for free) from the subsequent decision to assist with research design and data analysis. The output of the diagnostic consult would be a statistical support plan with a cost estimate that would in essence be a bid for the next steps, with the expectation that in some cases the costs would not be supported by the CTSI. Planning that involved writing a consultant into a grant could also be provided without charge."

**Response: This is fairly close to what we actually do.**

1. Initial consult to simultaneously develop scientific plan, estimate required effort and introduction to CTSI requirements
2. Grants with statistical co-investigator are free
3. Projects within the time/funding restrictions are free
4. Projects exceeding threshold need to identify additional funding
“Consider adding to your tracking system feedback from users on consultation quality and value.”

Response: Within TSS system evaluations are solicited. The first 48 surveys demonstrated a high degree of satisfaction with the quality and timeliness of service (90% of respondents reporting extremely or very satisfied on both metrics) and 95% responding that they are extremely likely (81%) or very likely (13%) to recommend the service.
“Try to define to the real need on campus, the gap, and then align your strategy to fill the most important gaps.”

Response: The program faculty include most of the collaborative biostatistician across the institutions.

- We provide the services that are most often requested: grant application assistance, data analysis, manuscript preparation, and data management strategies.
- In cases where existing infrastructure exists (example statistical computing consulting services through ATS) we do not duplicate it.
- The services that we do provide are those that are typically most difficult to find for junior investigators.
- Our increasing utilization (# of projects and # of investigators) suggest that there is great demand for the services that we currently provide.
“Consider more sustainable financial models.”

Response: We continue to pursue these models.

- making arrangements with divisions/departments to buy into the program
- including statistician as co-investigators on grant applications assisted
- requiring projects with large needs to find additional outside funding
Program Highlights

• **Development of Biostatistics consulting infrastructure across the institutions**
  – CTSI support catalyzed 7 new full time biostatistics collaborators in new model with centralized team based consulting infrastructure
  – Enabled widespread access to professional statistical collaboration, quicker turn around time, better expertise matching, career development of new staff statisticians

• **Cross-institutional biostatistics consulting and education**
  – Successful funding of three grants including community based Barbershop clinical trials with Dr. Victor at CSMC and Dr. Robert Elashoff at UCLA
  – Clinical research students from across institutions taking courses given by biostatistics program faculty from multiple institutions
Progress Aim 1: Consultation

Jan. 1–Oct. 31, 2013

• 899 Projects with 8442 consulting hours across four partner institutions
  – 4252 hours for data analysis
  – 1895 hours for study design
  – 1316 hours for designing analytic protocols and manuscript assistance
  – 842 hours for data management

• 461 unique investigators: equally split between trainees, assistant professors, and associate or full professors

• 50 co-authored manuscripts published during this period including 6 on novel statistical methodology

• High throughput molecular data analysis consulting service

• Implemented a drop-in consulting service with an average of 2 new consults each week. (over 100 new consults in the last year)

• Multiple cross-institutional consulting projects
Cumulative Biostatistics Consulting 2011-2014

- Number of Projects
- Number of Investigators
- Consulting Hours/10

Year:
- 2011 (6 months)
- 2012
- 2013
- 2014 (4 months)
Progress Aim 2: Grant Collaboration

• We provide grant application collaboration for investigators across the CTSA institutions
  – Study Design
  – Data Analysis plans
  – Sample Size Justifications

• Grant application collaboration has resulted in 30 grants funded with total direct/indirect costs of approximately $85 M
Progress Aim 3: Education

- Seminars on statistics in grant applications and statistical methods
- Participated in K and K-R workshops
- Master’s in Clinical Research Program (TPTS)
  - Biostatistics Program Faculty from Cedars/CDU/UCLA
  - Eleven courses given by program faculty
  - New courses in grant writing and microarray/next-gen sequencing analytic methods
  - Courses video-conferenced to all institutions and archived on Moodle
- Biostatistics program representative on CREST committee
- Assistance for developing K-awards
- Teaching quantitative methods in Long Beach Pipeline program
Appendix: Education

MSCR program Course List

- **BIOMATH 170A**: Introductory Biomathematics for Medical Investigators (Fall, 4 units, Year 1) available via videoconference
- **BIOMATH 258**: Introduction to Clinical Trials (Spring, 2 units, Year 1) available via videoconference
- **BIOMATH 259**: Controversies in Clinical Trials (Winter, 2 units, Year 1) available via videoconference
- **BIOMATH M261**: Responsible Conduct of Research Involving Humans (Fall, 2 units, Year 2) available via videoconference
- **BIOMATH M262**: Communication of Science - Grant Writing (Winter, 2 units, Year 2) available via videoconference
- **BIOMATH M263**: Clinical Pharmacology (Spring, 2 units, Year 2) available via videoconference
- **BIOMATH 265A**: Data Analysis Strategies I (Winter, 4 units, Year 1) available via videoconference
- **BIOMATH 266A**: Applied Regression Analysis in Medical Science (Winter, 4 units, Year 1) available via videoconference
- **BIOMATH 266B**: Advanced Biostatistics (Spring, 4 units, Year 1) available via videoconference
- **Methodology in Clinical Research** (3 quarter series)
- **BIOMATH M260A**: Methodology in Clinical Research 1: Clinical Trials (Fall, 4 units, Year 2) available via videoconference
- **BIOMATH M260B**: Methodology in Clinical Research 2: Longitudinal and Community Clinical Trials (Spring, 4 units, Year 2) available via videoconference
- **BIOMATH M260C**: Methodology in Clinical Research 3: Observational Studies (Fall, 4 units, Year 1) available via videoconference
- **BIOMATH 299**: Special Topics in Clinical Research: Microarrays, Proteomics and Next-Gen Sequence Analysis (Fall, 4 units, Year 1) available via videoconference
Clinical Translational Research Centers

Y3 Progress Report

Eric Kleerup, M.D.
CTRC Program Co-Leader
UCLA CTRC

Leslie Raffel, M.D.
CTSI Associate Director & CTRC Program Leader
Cedars-Sinai Medical Center CTRC

Isidro Salusky, M.D.
CTRC Program Co-Leader
UCLA CTRC

David Martins, M.D.
CTRC Program Leader
Charles Drew University CTRC

Christina Wang, M.D.
CTSI Associate Director & CTRC Program Leader
LA BioMed, Harbor UCLA Medical Center CTRC
Introduction

• Collaboration between four service sites
  – Charles Drew University (CDU)
  – Cedars-Sinai Medical Center (CSMC)
  – Los Angeles Biomedical Research Institute at Harbor-UCLA (LA BioMed)
  – UCLA Westwood Campus (UCLA)

• Goals
  – To broaden the scope and efficiency of clinical, translational and community research by implementing the CTRC without walls.
  – To promote collaborations across the CTSI partner institutions.
  – To recruit junior professionals into careers in translational clinical research.
“There is a major opportunity to engage the health system in expansion of CTRC-supported pilot studies to take advantage of resources available from all partner institutions and LA region, particularly for implementation science projects.”

- Implementation of CTRC seed grants at multiple sites
- LIFE Center
### Seed Grants

- **Spring 2013 UCLA RFP**
  - Submission (Mar 2013) 23 LOI, 11 Full
  - Award (Jul 2013) 6 (4 New PI)
  - Project completion (Dec 2014)

- **Fall 2013 UCLA RFP**
  - Submission (Nov 2013) 11 LOI, 8 Full
  - Award (Jan 2014) 4 (3 New PI)
  - Project completion (Jul 2015)

- **Spring 2014 RFP at multiple sites**
  - Submission (Apr 2014) 38 (10/0*/5/23) LOI 21 (8/0*/2/11) Full
  - Award (Jul 2014)
  - Project completion (Dec 2015)

The average subsidy beyond the usual CTRC support is $29,123/project (45% of total)

(CSMC/CDU/LA BioMed/UCLA)

* One applicant to UCLA is asking to use both CDU and UCLA resources.
Seed Grants: Funded Topics

• **New treatments**
  – Repositioning ivermectin for the treatment of alcohol use disorders.
  – Vitamin D3 versus 25-OH D3 supplementation on serum vitamin D metabolites, markers of mineral metabolism and immune function.

• **Biomarker development**
  – Development of a novel biomarker for liver fibrosis.

• **Disease pathophysiology**
  – Brain connectivity and structure, pain inhibition, and gut microbiota in pediatric irritable bowel syndrome (IBS).

• **Biospecimens for *ex vivo* studies**
  – Dose-response relationship of tenofovir with HIV-1 suppression in *ex vivo* model of tissue infectibility in adolescents.
Lifestyle Intervention and Food Education (LIFE) Center

• **Vision:** Health Promotion and Disease Prevention through collaborative academic-community partnership

• **Mission:** To promote health and prevent disease through research in a community-academic partnership focused on healthy cooking, eating, and lifestyle

• **Goals:**
  – To serve as a community resource for education on lifestyle and healthy cooking and eating.
  – To serve as a center for community-based recruitment into research.
  – To encourage healthy lifestyle changes to improve health and prevent disease.
  – To provide strategies to help the community develop better eating and activity habits.
  – To ensure information is culturally appropriate and meets community needs.
LIFE Center/Weingart YMCA
- 9900 S. Vermont Ave., Los Angeles, CA 90044
- 7000 members mostly racial ethnic minorities

Community Clinics (FQHC)
- South Central Family Health Center
- To Help Everyone Clinic
- UMMA Clinic
- Watts Health Center

Private Clinics
- Beth Medical Clinic
- Clinica Salvador del Mundo
- Community Healthcare Clinic
- Diop Family Medical
- Morningside Primary Care
- Nueva Esperanza Medical Clinic
- St. Anthony’s Medical Clinic
- Tri-City Medical Group

CTRCs
- CDU: David Martins, M.D.
- CSMC: Leslie Raffel, M.D.
- CSMC: Mindy Mamelak, R.D.
- LA BioMed: Rachelle Bross Ph.D.
- UCLA: Patrician Jardack, M.S., R.D.
Life Center Curriculum

Survey of Wiengart YMCA Participants

- Physical Activity to Overall Health
- Healthy Body Weight and Energy Balance
- Fruits and Vegetables
- Nutrition Facts on Food Labels
- Role of Diet in Disease Prevention
- Good vs. Bad Carbohydrates
- Meal Planning and Shopping on a Budget
- Healthy Fats and Unhealthy Fats
- How to Eat a Balanced Diet
- Aisle by Aisle Virtual Grocery Store Tour
- Popular Diets (e.g., Atkins, South Beach, Juice...

Priority Score

- 8
- 9
- 10

Curriculum

- Class 1: Orientation
- Class 2: Calorie Balance and Disease
- Class 3: Not all Fats and Carbs are Created Equal
- Class 4: Fruits and Vegetables
- Class 5: Physical Activity and Exercise
- Class 6: Nutrition Labels and Shopping on a Budget
Life Center

• **Current research projects**
  - Centrifugal medicine: optimizing access to care (PI: E Ipp, LA BioMed)
    - Diabetes eye (retinal) screening
    - Diabetes education and opportunities for life-style change to improve glucose (glycemic) control
  
• **Interested investigators**
  - Addressing Disparities in Obesity (PI: T Friedman, CDU)
  - Race and Rhythm Disorders (PI: S Chugh, CSMC)

• **Continuation/Evolution**
  - Repeat series 4 times per year
  - Offer at alternate times to attract younger, working participants
  - Addition of live cooking demonstrations by ethnically diverse chefs in training
  - Consider collaboration with Goldring Center for Culinary Medicine (Tulane CTSA)
  - Train community workers to continue program
• **Research target areas:**
  – Life style changes: low cost, low caloric diets
  – Low cost formula diets delivered by community health workers at YMCA

• **Diseases present in survey respondents**
  – Hypertension (54%)
  – Diabetes (38%)
  – Kidney disease (11%)
  – Cardiovascular disease (20%)
  – High cholesterol (48%)
  – Obesity (54%)
  – Food intolerance/allergies (9%)

• **Respondent demographics**
  – Black (African, Carribean, other) 64%
  – Hispanic 22%
“It would be nice to see more compelling metrics of success. Are you used because you provide subsidies, because you provide services not available elsewhere, or because you do things better? What large clinical research groups are NOT using your services and what is their rationale?”

• Performed a survey of recent users and non-users
• Plan to:
  – Provide services that accommodate needs
  – Address obstacles
  – Recruit new users
CTRC Services Survey

• Collaboration between CTRCs and Evaluation

• Goals
  – Understand the needs of users and non-users
  – Understand the barriers to use of the CTRCs
  – Identify new resources desired by investigators

• Online survey using REDCap

• Response: 21.7% (261/1205)
  – Recent users: 35.5% (124/349)
  – Non-Users: 16.0% (137/856)
CTRC User & Non-User Survey: Services & Settings Use in the Next 3 Years

Likely or Extremely Likely to Use Service (%)
Barriers to the Use of the CTRCs

Recent Users (106)

Non-Users (105)
Interest in Cross Institutional Use of CTRCs

“Will you use other CTRC sites in addition to your home institution CTRC? (select all that apply)”

<table>
<thead>
<tr>
<th>Interested in Going To: (Number of outside users interested)</th>
<th>Non-Users (N=56)</th>
<th>Recent Users (78)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CSMC (18)</td>
<td>LA Biomed (12)</td>
</tr>
<tr>
<td>Cedars Sinai (14)</td>
<td></td>
<td>0.0%</td>
</tr>
<tr>
<td>Charles Drew (13)</td>
<td>16.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>LA BioMed (17)</td>
<td>11.1%</td>
<td></td>
</tr>
<tr>
<td>UCLA Westwood (25)</td>
<td>33.3%</td>
<td>16.7%</td>
</tr>
<tr>
<td>UCLA Santa Monica (23)</td>
<td>5.6%</td>
<td>0.0%</td>
</tr>
</tbody>
</table>

CDU responses were too few to provide percentage responses
Census: Monthly Outpatient Visits

![Graph showing the monthly outpatient visits from January 2011 to July 2014. The graph includes data points for each month, with a trend line indicating the mean visits per month and control limits for 2011-2012. The mean visits for the current reporting period is shown as 845 per month, and the annual visits as 10,138.](image_url)
Other Achievements

• New infrastructure
  – Endoscopy
  – Neuromotor Recovery and Rehabilitation Center
  – Other technology

• Collaboration and standardization among four CTRCs
  – Common data set from protocol applications
  – Common services & resources description

• Operationalizing Clinical Research
  – LA BioMed: Industry trials partnering with Clinical Research Solutions
  – LA BioMed: Metabolic balance studies of phosphate in peritoneal dialysis
  – Phase I studies: Male contraceptives

• Education Initiatives
  – Long Beach Polytechnic program (high school)
  – Training in new techniques for nurses
  – GCP training for research support staff and coordinators
Plans for Coming Year

• **New infrastructure**
  – Based on cluster analysis of survey results
  – Formalize consulting for study design, DSMP, questionnaire development

• **Collaboration and standardization among CTRCs**
  – Process mapping of impediments to cross-institution barriers

• **Operationalizing clinical research**
  – Improve user friendliness
  – Targeted outreach to investigators and research teams
  – Collaboration with Biostatistics to deliver services

• **LIFE Center**

• **Seed grants**

• **Education initiatives**
  – Mentoring young investigators - identifying high risk points
  – Training for Research Nurse/Study Nurse/Coordinator training
Dealing with the financial realities of clinical research:

• Are there conflicting views about appropriate levels of user PI grant contribution to cost:
  – CTSA renewal grant reviewers?
  – NCATS?
  – Other NIH Institutes?

• Where should support come from for pilot data generation?

• What level of use of the CTRC for industry studies is optimal?
Regulatory Knowledge and Support, and Ethics

Y3 Progress Report

Stanley G. Korenman, MD
Leader
1. Harmonize regulatory mechanisms among the UCLA-CTSI partners
• Uniform tracking and evaluation (with baseline data) of time to decision for IRBs and contracts for all consortium partners.

• Scheme for expediting contracting would be a useful component of CTSI.

• Consider evaluating all steps in launching a new protocol (e.g., IRB approval, contract signature, etc.) so as to identify and correct sources of unnecessary delay.
• Tracking and evaluation from time to decision for both IRBs and contracts needs to be available uniformly from all consortium partners.
LABiomed utilizes WIRB extensively and in the recent 6 months had 17 studies approved by them.
IRB Approval Times

Mean Full Review IRB Approval Times at CTSI Partners

Mean Expedited Review IRB Approval Times at CTSI Partners

- Mean Turnaround time from 1st IRB Action to Approval
- Mean Turnaround Time from Submission to 1st IRB action
New IRB Reliances per Quarter

Protocols Processed via CTSI Reliance Review  
(1st Qtr 2012 to 1st Qtr 2014)

<table>
<thead>
<tr>
<th>Number of New Protocols</th>
<th>1st Qtr 2012</th>
<th>2nd Qtr 2012</th>
<th>3rd Qtr 2012</th>
<th>4th Qtr 2012</th>
<th>1st Qtr 2013</th>
<th>2nd Qtr 2013</th>
<th>3rd Qtr 2013</th>
<th>4th Qtr 2013</th>
<th>1st Qtr 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>5</td>
<td>4</td>
<td>7</td>
</tr>
</tbody>
</table>
• In addition to the new reliance reviews we are now managing renewals, of which there have been 12, to date.

• We have yet to figure out how to integrate the UCLA CTSI partnership into BRAID.
MOU with VA on Research

- This MOU constitutes a framework for research done jointly at the VA, the Non-profit grants management organizations and UCLA. Close to signature.

MOU among partners on use of animals in research.

- Completed, sent for signature.
Biobanking Consent Pilot Trial

- Purpose: to develop a system for consenting patients entering our health care system for the use of their discarded tissues and clinical data for unspecified research purposes.

- Supported by CTSI
Developed an ethical oversight process for two translational grant applications involving human deep brain stimulation
Future Plans

• Improve the metrics involved in IRB approval so that we can better address the delays.

• Achieve IRB integration for joint proposals with the VA.

• As part of BRAID facilitate the national IRB reliance program.
Clinical Research Infrastructure
Plan

External Advisory Board

Arash Naeim, MD PhD
Chief Medical Officer for Clinical Research
Assistant Vice Chancellor for Research
Associate Director, CTSI
Health Sciences Research with Human Subjects FY 2009 – 2013 >$1.6 Billion

- Medicine $1.1 B
- Public Health $152M
- NPI $319M
- Nursing $2M
- Dentistry $29M
- Broad Stem Cell $1.5M
- Life Sciences $22M

*Distribution by School*
How Many?

- 1450 human subjects active studies approved by IRB
- >980 studies registered in Epic
- What is in the difference in numbers?
- How many patients....How much clinical revenue....
Phase 1 Vision

PI PORTAL

Coverage Analysis

Contracting

WebIRB
- IRB and Safety Reviews
- CTMS Screening Question(s)
  - STUDY DATA/DOCS
  - REVIEW STATUSES
  - SAEs DEVIATIONS

PATS
- Contracts and Grants
  - FAUs

CTMS
- Study Management
- Coverage Analysis
- Patient Mgmt
- Adverse Events
- Research Reporting
  - ADT/MRN
  - STUDY RECORD BILLING GRID
  - PATIENT ASSOCIATION STATUSES

EPIC/CareConnect
- Scheduling
- Encountering
- Patient Timeline
- Order Sets
- Beacon Protocols
- Charge Queues/Billing
Parallel Review Processes Driven by a Core Form and Navigation

- Core Data View & Data Stream
  - For pre-existing studies derived from ORA Data

- Core Form
  - Navigate (Rules Based) & Pre-Populate

- EFM
- IRB
- Coverage Analysis
- Animal
- Biosafety
- CTSI
- Radiation
- Contracting
- Pharmacy
- CareConnect
- ISPRC
- IDE
- MTA
- OHIA

For pre-existing studies derived from ORA Data

CTMS

Biosafety

CTSI

Animal

IRB

Coverage Analysis

Parallel Review Processes Driven by a Core Form and Navigation
Parallel Review Processes Driven by a Core Data and Navigation

Core Data View & Data Stream

Navigate (Rules Based) & Pre-Populate

For pre-existing studies derived from ORA Data

IRB
Coverage Analysis
CTMS
CareConnect
Contracting
Coverage Analysis / Contracting
*Approved “research only” studies that undergo abbreviated review will be hard-coded in CareConnect to direct all study encounters to the research account at the published research rates.
Coverage Analysts transition to Calendar Building in OnCore

Streamlined Process

- Eliminates numerous rounds of correspondences (minimize PI/study team frustration)
- Eliminates Inconsistencies between calendar/budget
- Incorporation of required research coding and routine cost support
Total Review Time

50% of PIs/Study Teams expect 3-7 days for CA Review

- 3-4 days: 27%
- 5-7 days: 23%
- 10-14 days: 23%
- 30 days: 27%

Total Responses: 22

Industry Pass-Through Cost*

68% of PIs/Study Teams expect sponsors to pay less than $2,000 per CA Review

- <$2K: 68%
- $2K: 9%
- $3K: 9%
- $4-$5K: 14%

Total Responses: 22
Contracting - Numbers

Executed Contracts

- FY 12 / pre-coverage analysis: 310
- FY 13/coverage analysis: 250
- FY 14 partial year/coverage analysis: 300

Contracts
Contracting - Numbers

Executed Confidential Disclosure Agreement (CDA)

FY 12  FY 13  FY 14 - partial year

CDAs
Contracting – Improving Service

• Created easy to use interactive checklist for study team clients – with hyperlinks to forms

• Paperless Document Submission – As of May 1, 2014

• UC BRAID – Harmonization & Benchmarking
1. IRB Data (Common Fields)  Data Out
2. Review Status  Data Out
3. Award/FAU  Data Out
4. Serious Adverse Events*  Data In
5. Deviations*  Data In
6. Continuing Review Form*  Data In
7. Study Personnel  In Analysis

* Requires 2 parallel processes: field reconciliation as well as technical upload
CareConnect

- SmartSets for Complex Studies
- Appointment Search Review
- Research Charge Review

OnCore CTMS

Study Creation
- Study Creation
- Billing Grid
- Study Staff Management
- Patient Statuses
- Patient Timelines

Study Start-Up Management:
- Status Tracking
- Hand-offs & Notifications

Coverage Analysis
Budgeting

Sponsor Invoicing & A/R

Consent Management

SAE & Deviations Mgmt

Cross-Study Reporting

JCCC-Specific Features:
- ISPRC & DSMB
- TRIO Admin
- NCI Reporting
- Aggregate Accrual
- CTRP Reporting
Centralized Research Billing Office
Issues that can be optimized

• Designating Investigational Drug and Device CPTs/HCPCS
• Designation of research modifiers (V70.7, Q0, Q1) for qualifying studies
• Review of standard of care versus research at study, patient, and encounter level
• Working Charge Queues (Lack of Coverage Analysis, Mixed Visit)
• National Coverage Decisions
• Reconciliation and Analysis of pricing to research accounts
## PI Portal Clinical Research Dashboard

### Pre-study (not Active)

<table>
<thead>
<tr>
<th>Study 001</th>
<th>Attention</th>
<th>In Progress</th>
<th>Completed</th>
<th>N/A</th>
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<tr>
<td></td>
<td>3</td>
<td>5</td>
<td>1</td>
<td>3</td>
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<tr>
<td>Study 002</td>
<td>4</td>
<td>6</td>
<td>0</td>
<td>2</td>
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### Active / Completed Studies

<table>
<thead>
<tr>
<th>Study 003</th>
<th>Total Patients Enrolled</th>
<th>Sponsor Funds Received</th>
<th>Charges to Research Account</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>42</td>
<td>$250,000</td>
<td>$250,000</td>
</tr>
<tr>
<td>Study 004</td>
<td>125</td>
<td>$650,000</td>
<td>$400,000</td>
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</table>

### Quick Links

- CTMS
- webIRB
- CareConnect
- Compliance
- CTAO
Pre-Study Tracking Across Parallel Review Processes

ARASH NAEIM's Clinical Research Dashboard Study 001

### Needs Your Attention
- **IRB**: 4 DAYS
- **COVERAGE ANALYSIS**: 12 DAYS
- **CONTRACTING**: 12 DAYS

### Pending / Completed / NA
- **CTMS**: 4 DAYS
- **CARECONNECT**: 4 DAYS
- **OHIA**: 1/1/14
- **RADIATION**: 4 DAYS
- **INVESTIGATIONAL PHARMACY**: 4 DAYS
- **MTA**: 4 DAYS
- **IDE**: 4 DAYS
- **MTA**: 4 DAYS
- **ANIMAL**: 4 DAYS
- **ISPRC**: 4 DAYS
- **CTAO**: 4 DAYS

### Quick Links
- CTMS
- webIRB
- CareConnect
- Compliance
- CTAO
Pre-Study Tracking Across Parallel Review Processes

<table>
<thead>
<tr>
<th>Needs Your Attention</th>
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<tbody>
<tr>
<td>IRB</td>
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<td>COVERAGE ANALYSIS</td>
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<tr>
<td>CONTRACTING</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Pending / Completed / NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>CTMS</td>
</tr>
<tr>
<td>CARECONNECT</td>
</tr>
<tr>
<td>OHIA</td>
</tr>
<tr>
<td>RADIATION</td>
</tr>
<tr>
<td>INVESTIGATIONAL PHARMACY</td>
</tr>
<tr>
<td>MTA</td>
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<tr>
<td>ANIMAL</td>
</tr>
<tr>
<td>IDE</td>
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<td>ISPRC</td>
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</table>

<table>
<thead>
<tr>
<th>Quick Links</th>
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</thead>
<tbody>
<tr>
<td>CTMS</td>
</tr>
<tr>
<td>webIRB</td>
</tr>
<tr>
<td>CareConnect</td>
</tr>
<tr>
<td>Compliance</td>
</tr>
<tr>
<td>CTAO</td>
</tr>
</tbody>
</table>
### ARASH NAEIM's Clinical Research Dashboard Active Study 003

#### Study Data
- **Activation Date**: 01/01/2014
- **# of Sites**: 06
- **Total Patients Enrolled**: 42
- **UCLA Health System Patients Enrolled**: 32
- **External Patients Enrolled**: 10

#### Study Financials
- **Total Grant Award**: $1,500,000
- **Grant Funds Received**: 4 DAYS
- **Total Grant Award**: $1,500,000
- **Sponsor Contract**: $512,000
- **Sponsor Invoiced**: 4 DAYS
- **Sponsor Funds Received**: $250,000
- **Medicare Charges**: $250,000
- **Other Insurer Charges**: $150,000
- **Charges to Research Account**: $250,000

#### Quick Links
- CTMS
- webIRB
- CareConnect
- Compliance
- CTAO
Active Study Integrated Tracking

**Study Data**
- **Activation Date**: 01/01/2014
- **# of Sites**: 06
- **Total Patients Enrolled**: 42
- **UCLA Health System Patients Enrolled**: 32
- **External Patients Enrolled**: 10

**Study Financials**
- **Total Grant Award**: 4 DAYS
  - **Sponsor Contract**: $1,500,000
  - **Grant Funds Received**: $512,000
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  - **Other Insurer Charges**: $150,000
  - **Charges to Research Account**: $250,000

**Quick Links**
- CTMS
- webIRB
- CareConnect
- Compliance
- CTAO
Research Operations Advisory Group (ROAG)

- Study Team Members by Department
  - Research Coordinators
  - Fund Managers
- Key Operations Personnel
- Other Administrative Leadership (Compliance, etc.)

Clinical Research Governance Committee (CRGC)
Community Engagement & Research Program and Health Services Research (CERP/ HSR)

Arleen Brown, MD, PhD, Co-Leader
Keith Norris, MD, Co-Leader
Martin Shapiro, MD, PhD
Loretta Jones, MA
Daniel Castro, MD
Anish Mahajan, MD, MSPH
Ron Andersen, PhD

EAB Presentation
June 17, 2014
1. CERP Aims and Objectives
2. EAB Recommendations
3. Progress on Activities that Address CERP Aims and EAB Recommendations
4. Next Steps
5. Additional Detail in CERP Summary / Update
1. Promote and sustain bidirectional knowledge sharing between community and academia.

2. Strengthen academic and community infrastructure for sustainable partnered research.

3. Drive innovation in community engagement that accelerates the volume and impact of partnered research in diverse communities.

4. Build health services research (HSR) methods into partnerships to accelerate design, production, and wide adoption of evidence-based practice and behavior.
1. Opportunity to **partner with LA County programs** that could leverage resources for much greater impact.

2. Current metrics are mainly process, documenting infrastructure development and capacity building. What are the **outcome metrics**?

3. Increase focus on **evaluation of programs, and identify specific metrics for success of community-engaged research partnerships**, incorporating both quantitative and qualitative assessment methods.

4. Explore the role of CERP in the **dissemination and implementation of evidence-based interventions**; transferring knowledge from all forms of CTSA research to benefit community stakeholders and population health in a sustainable manner.
CERP Consultation Service
- Provide consultation to community partners / stakeholders on community engaged research methods and practice

Community-Partnered Projects
- Joint DHS/UCLA CTSI grants to fund projects to improve population health outcomes without increasing costs
- Healthy Aging Initiative – collaboration with LAC DHS, LAC DPH, and aging services organizations in LA County

Community Partnered Grant Writing Program
- Develop academic and community partner infrastructure for collaborating on corporate/foundation and NIH grants

Dissemination, Implementation, and Improvement Science Initiative
- Expand UCLA and regional capacity for and activities in DII
Goal: to help existing and new community partners and academic investigators incorporate community-based and health services research methods into their current and potential projects

- **Offer Training/Resources** in CBPR/CPPR, HSR, D & I, other methods
- **Connect** investigators and community partners
- **Advise** on study design, program implementation, and dissemination of results

<table>
<thead>
<tr>
<th></th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant or project-specific requests</td>
<td>18</td>
<td>52</td>
</tr>
<tr>
<td>Number of consults per month</td>
<td>1.5 per month</td>
<td>4.3 per month</td>
</tr>
</tbody>
</table>

**Next Steps:**
- Continue expansion of services based on feedback from consultations (e.g. need for assistance with cost analyses)
- Sustainability plan – where feasible, include CERP staff/faculty in proposals on projects
## Project Year CERP-Supported Awards

<table>
<thead>
<tr>
<th>Project Year</th>
<th>CERP-Supported Awards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1:</td>
<td>CTSI Community Engaged Research Awards ($350,000)</td>
</tr>
<tr>
<td>Year 2:</td>
<td>UCLA and University of Minnesota (UMN) Cross-Institutional Awards ($150,000)</td>
</tr>
<tr>
<td>Year 3:</td>
<td>UCLA CTSI-LAC Department of Health Services Collaboration Grants ($150,000)</td>
</tr>
<tr>
<td></td>
<td>UCLA and USC CTSI Healthy Aging Team Science Award ($200,000 - pending)</td>
</tr>
<tr>
<td>Overall:</td>
<td>$650,000 / Return on Investment: $44.2 M</td>
</tr>
</tbody>
</table>

### Process/Infrastructure Metrics:
CTSI Community-Partnered Projects
Community Partners in Care (CPIC)  
Demonstrating and Disseminating Outcomes

- Group-randomized trial of community engagement compared to technical assistance to improve depression services.
- Over 115 community and academic leaders from 30 organizations
- Enrolled 1246 adults with a positive PHQ-8 (>10); 981 completed surveys
- At 6-month follow up, the intervention was associated with
  - Higher **Mental Health-related Quality of Life**
  - Increased **physical activity**
  - Fewer risk factors for **homelessness**
  - Fewer behavioral health **hospitalizations** and specialty medication **visits**
  - More **primary care, faith-based, and park-based services** for depression
1994-Present: Collaborations between:
Healthy African American Families II (Jones), CDU (Norris), UCLA (Wells)

2003 - 2007: Witness for Wellness

2008 - 2012: CPIC

2012-2015: PCORI Award*, $2M

2014: $30M NIMH contract for depression treatment

Adoption underway by:
• LAC to treat depression
• VHA for homelessness

2011 - Present: CTSI Support
• CERP Pilot Project: CPIC Community-Partnered Cost Analysis
• CERP Pilot Project: B-RICH community intervention to reduce depressive symptoms
• Funding for Investigators (Chung, Jones, Lucas-Wright, Wells, Miranda J, Norris)
• FTE support for research staff
• Training of research staff in CBPR / CPPR methods by CERP community partners
• RRT support for PCORI and NIMH applications

2011-Present: Products and Outcomes
• Research and demonstration project funding (above)
• Publications (2 in press; 3 submitted)
• Training protocols for clinical research staff and for community members
• Evidence-based care for depression in safety net settings

*Long-Term Outcomes of Community Engagement to Address Depression Outcomes Disparities
Community Partners in Care (CPIC): Demonstrating Outcomes

1994-Present: Collaborations between: Healthy African American Families II (Jones), CDU (Norris), UCLA (Wells)

2003 - 2007: Witness for Wellness
2008 - 2012: CPIC
2012-2015: PCORI Award*, $2M

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2014: Adoption underway by:
- LAC for depression
- VHA for homelessness

*Long-Term Outcomes of Community Engagement to Address Depression Outcomes Disparities
2014 Team Science Award

Association for Clinical and Translational Science

Association for Clinical and Translational Science:
Community-Partnered Projects  
LA County Department of Health Services

**LAC-DHS RFA**
- Test approaches to allow DHS to improve and increase the delivery of high quality, patient-centered services without increasing costs
- Five awards of up to $30K each with Co-PIs at DHS & UCLA CTSI
- Population health impact + Translation + Dissemination

**Next Steps**
- Reissue in Year 4 with a focus on LAC DHS priority areas
- Evaluate dissemination / impact of the Year 3 projects
- Support for selected Year 3 awardees for papers, proposals, and/or extension of project
Healthy Aging RFA

- LAC DPH and DHS and community partnered projects to develop multidisciplinary approaches to healthy aging in LAC
- Will fund two projects at UCLA and two projects at USC
- Proposals submitted May 15
- External review is ongoing
- Awards announced end of June 2014

Joint UCLA-USC Activities

- Healthy Aging Scorecard
  - Develop metrics to assess healthy aging in LA County
- Healthy Aging Teambuilding Seminar
  - Presentations by S. Aguilar-Gaxiola (UC Davis), T. Hurd (UT San Antonio), W. Vega (USC), M. Shapiro (UCLA)
Objectives

1. To help the community-academic grant writing teams develop or revise an NIH or foundation proposal
2. To help teams demonstrate evidence of partnership in their proposals

Modules

- **Module 1:** Preparedness / Grant writing language
- **Module 2:** Collaborative community-academic grant writing
- **Module 3:** Corporate, community, and private foundations
- **Module 4:** NIH grant writing
## Community-Academic Grant Writing Participants

<table>
<thead>
<tr>
<th>Community Organization</th>
<th>Academic Partner</th>
<th>Proposal Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthy Improvements</td>
<td>UCLA - SOM</td>
<td>Project Life After: Cancer Survivorship</td>
</tr>
<tr>
<td>Brotherhood Crusade</td>
<td>UCLA - SOM</td>
<td>Mental Health Outcomes in Young Black Men</td>
</tr>
<tr>
<td>Centro Latino for Literacy</td>
<td>CDU /UCLA - SOM</td>
<td>Health Awareness &amp; Advocacy for Illiterate Spanish-speaking Parents</td>
</tr>
<tr>
<td>Crenshaw Education Partnership</td>
<td>Cal State University, Northridge (CSUN)</td>
<td>Academic Achievement, Leadership Development, and Mentorship for Young Men of Color</td>
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<tr>
<td>LAC DPH</td>
<td>UCLA - FSPH</td>
<td>Cultural &amp; Linguistic Competencies</td>
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<tr>
<td>Los Angeles Urban League</td>
<td>UCLA - SOM</td>
<td>Fuel Your Health Through Movement</td>
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<td>MLK-MACC (LAC DHS)</td>
<td>Harbor UCLA</td>
<td>Geriatric Care Transitions Collaborative</td>
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<tr>
<td>The Children's Clinic</td>
<td>UCLA - FSPH</td>
<td>Bright Beginnings Program</td>
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<td>Children's Nature Institute</td>
<td>UCLA - FSPH</td>
<td>Education by Nature (ExN)</td>
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<tr>
<td>UMMA Clinic</td>
<td>UCLA - SOM</td>
<td>Patient-Centered Community Action Board</td>
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</table>
Community-Academic Partnered Grant Writing
Six-Month Follow-up Funding for 10 Teams

<table>
<thead>
<tr>
<th>Partnered Proposals</th>
<th>N</th>
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<tbody>
<tr>
<td>Proposals funded / submitted</td>
<td>6 / 8</td>
</tr>
<tr>
<td>Planned submissions within the year</td>
<td>2</td>
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<table>
<thead>
<tr>
<th>Funded Project</th>
<th>Funder</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Everychild Bright Beginning Initiative (EBBI) (The Children’s Clinic/Inkelas)</td>
<td>Everychild Foundation</td>
<td>$1,000,000</td>
</tr>
<tr>
<td>Home Visitation Program (The Children’s Clinic)</td>
<td>First 5 LA (LA County)</td>
<td>$270,000</td>
</tr>
<tr>
<td>Enhancing Communities Award (The Children’s Clinic)</td>
<td>Direct Relief Foundation</td>
<td>$200,000</td>
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<tr>
<td>WalkABLE: Steps to a Better Quality of Life (LA County DPH/Wang)</td>
<td>LA County Quality and Productivity Commission</td>
<td>$200,000</td>
</tr>
<tr>
<td>Improving System-Wide Asthma Management Practices (LA County DPH)</td>
<td>LA County Quality and Productivity Commission</td>
<td>$150,000</td>
</tr>
<tr>
<td>Wellness Rx/Patient Navigator Program (UMMA Clinic/Bharmal)</td>
<td>UniHealth Foundation</td>
<td>$50,000</td>
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<tr>
<td><strong>Total:</strong></td>
<td></td>
<td><strong>$1.87M</strong></td>
</tr>
</tbody>
</table>
Community Partnered Grant Writing Program

- Evaluate impact on key metrics and share lessons learned
- Partnered Grant Writing Handbook
- Sustainability
  - Funding opportunities
  - Possible collaboration with LAC DPH
**Goals:**
Expand UCLA capacity and activity in dissemination, improvement, and implementation (D&I) research in order to:

1. Enhance societal impact of UCLA research to improve health care quality, health behaviors and outcomes in and beyond LA
2. Enhance UCLA competitiveness for funding in D & I
3. Contribution to national CTSA consortium

**Activities:**

- Education, Training, and Capacity Building
- Consultation and Technical Assistance
- Development of Tools and Resources
- Interface with other CTSI cores
Partnering Institutions:

- UCLA
- UCLA CTSI
- SC CTSI
- KAISER PERMANENTE®
- The California Endowment

Plenary Speakers:
- Ann Bonham, PhD, Chief Scientific Officer, Association of American Medical Colleges
- Jean Slutsky, PA, MSPH, Director for Communication and Dissemination Research Program, PCORI

Activities:
- Panel Discussions
- Brainstorming Sessions
- Poster Presentations
- Position papers – coordinating publication with the Clinical and Translational Science journal (University of Pennsylvania)
Dissemination & Implementation Research Initiative
Next Steps

• DII Position Paper Topics (plan to submit to Clinical and Translational Science (CTS) journal)
  – Local Barriers in DII Science In Los Angeles County
  – National and international barriers and solutions to expand DII Science
  – Inter-disciplinary strategies for DII Science
  – Improvement, Implementation and Dissemination Science in Public Health
  – Community-Academic Partnerships as a Framework to Develop DII Science
  – Research Priorities for DII Science
  – Accelerating DII Science in a CTSI

• Consultation and Technical Assistance
  – CERP Consultation Service – assistance on 10 proposals (2 funded to date)
  – Webinars – bimonthly starting June 4, 2014

• Education
  – Externships with DHS/DPH for Fielding School of Public Health students
  – Expanded coursework on DII – Masters and Doctoral students
Pictures from Southern California Regional Dissemination, Implementation and Improvement Science Symposium on March 4, 2014 at The California Endowment
Thank You!

Questions?
# CTSI Community-Partnered Projects

## Year 1: CTSI Community Engaged Research Awards ($XXX,XXX)

- Costs & Savings of Community **Depression** Screening & Treatment
- Increase Safety Net Clinic Use of **Patient-Reported Outcomes**
- Retaining Former Prisoners in **HIV** Care
- Infrastructure to **Increase Partnered Research** in WIC Programs
- **Enhancing Research in Communities of Color** with **Promotores**
- CBPR to **Enhance the Recruitment of Minority Elders**
- Technical Assistance and **Training for Health Disparities Research in East L.A**
- Behavioral Economics to Improve Safety Net **Hypertension** Control
- Collaborative to Reduce the Burden of **CHF & CVD in South LA**

## Year 2: UCLA and University of Minnesota (UMN) Cross-Institutional Awards ($150,000)

- Alzheimer’s Disease Coordinated Care for Hispanic and Latino Seniors
- HIE Use in Small- and Medium-Sized Primary Care Practices: Understanding & Eliminating the Disparity
- Correlation of Early Childhood Caries Risk and Obesity in Preschool Age Children Via Salivary Testing

## Year 3: UCLA CTSI-LAC Department of Health Services Collaboration Grants ($150,000)

- Implementation of a Primary Care-Based **Teleretinal Screening** Protocol for the LAC Safety Net
- Los Angeles County **Psychiatric Emergency Room Outcomes** Study
- **Asthma control, morbidity, quality of life (QOL), and health care expenditures** in asthmatic children during transition from acute care at Harbor-UCLA to community managed care organizations
- **Obesity Group Visits**: An innovative program to deliver obesity services at DHS facilities
- **Health Impact Assessment (HIA)** identifying **evidence-based programs to reduce school truancy**
Microfluidic Technology to Address Health Disparities in the Community Setting

“Oxidized Lipids & Inflammatory Markers as Stress Indicators”

Multi-Disciplinary Team
- Division of Nutrition
- Community
- UCLA Division of General Internal Medicine and Health Services
- School of Engineering & Applied Science
- Medicine/Cardiology
- Caltech Engineering

Clinical Trial
- CV prevention
  - Diet/Nutrition
  - Physical activities
  - Smoking
  - Hyperlipidemia
  - Blood pressure
  - Body mass
  - HbA1c

Community
- Screening events
- Community research sites
- Other

Basic Science
- Hemoglobin/haptoglobin/hemopexin
- HDL protective capacity
- Endothelial function
- Ox-Fatty acids
- Serum amyloid A
- Cholesterol efflux

Biomedical engineering
- Wireless/Hand-held monitors
- Functional assessment
  - Exercise Performance
  - Peripheral arterial tonometry (PAT)
  - NO determination

Lab-on-a-chip Microfluidics

*AHA application under review
Research Education, Training and Career Development

Y3 Progress Report

Carol M. Mangione, MD, MSPH, Program Leader
Mitchell D. Wong, MD, PhD, Program Co-leader
Program Goals

• Improve communication of science.

• Teach leadership to transform the health of communities.

• Improve cross-talk across the translational spectrum.

• Teach the skills needed to collaboratively accelerate drug development and the diffusion of new therapies.

• Improve the quality of translational science education and evaluation of the four CTSI institutions.
Institutional K12 scholars and faculty with individual translational science K awards are included in educational activities.

*CDU Saturday Science Academy
CDU/NIH STEP-UP
LA BioMed Summer Fellowship Program
Long Beach Polytechnic HS Biomedical Research Program
UCLA Brain Research Institute Outreach
UCLA Community School
UCLA Pre-Medical/Pre-Dental Enrichment Program
UCLA DOM Chief Residents’ Program
UCLA Dentistry’s Pipeline Program for Dentists-Scientists

**Institutional K12 scholars and faculty with individual translational science K awards are included in educational activities.
**Strengths**

- Great progress in improving support for K-level trainees.
- Nice progress in High School/College pipeline.
- Great job expanding TL1 training program.

**Weaknesses/Suggestions**

1. Evaluate success rates for K grants
2. Provide additional support beyond K workshops
3. Maintain diversity in the pipeline
4. Support trainees to diversify sources of funding
5. Evaluate success of entire spectrum of trainees at all the partnering institutions whether receiving CTSI support or not
1. Evaluate success rates for K grants

K Awards at UCLA, 2010-2013

- 2010
- 2011
- 2012
- 2013

Number of KL2 Scholars

Data compiled by Lourdes Guerrero and Lisa Chan
### 1. Evaluate success rates for K grants

Number of NEW K awards (or equivalent CDAs) that have been submitted by UCLA CTSI institutions and awarded.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total New Ks Submitted</th>
<th>Total Ks Awarded</th>
<th>Overall Success Rate (awarded/submitted)</th>
<th>National Success Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>49 (UCLA) 11 (Cedars) 2 (LA BioMed) 1 Unknown (CDU)</td>
<td>19 (UCLA) 3 (Cedars) 0 (LA BioMed) 0 (CDU)</td>
<td>38.8% (UCLA) 27.3% (Cedars) 0% (LA BioMed) 0% (CDU)</td>
<td>38.2%</td>
</tr>
<tr>
<td>2010</td>
<td>58 (UCLA) 8 (Cedars) 1 (LA BioMed) 1 Unknown (CDU)</td>
<td>22 (UCLA) 3 (Cedars) 1 (LA BioMed) 0 (CDU)</td>
<td>37.9% (UCLA) 37.5% (Cedars) 100% (LA BioMed) 0% (CDU)</td>
<td>35.5%</td>
</tr>
<tr>
<td>2011</td>
<td>63 (UCLA) 10 (Cedars) 1 (LA BioMed) 1 Unknown (CDU)</td>
<td>20 (UCLA) 3 (Cedars) 0 (LA BioMed) 0 (CDU)</td>
<td>31.7% (UCLA) 30.0% (Cedars) 0% (LA BioMed) 0% (CDU)</td>
<td>31.6%</td>
</tr>
<tr>
<td>2012</td>
<td>61 (UCLA) 8 (Cedars) 3 (LA BioMed) 3 Unknown (CDU)</td>
<td>14 (UCLA) 2 (Cedars) 0 (LA BioMed) 0 (CDU)</td>
<td>22.9% (UCLA) 25.0% (Cedars) 0% (LA BioMed) 0% (CDU)</td>
<td>31.6%</td>
</tr>
<tr>
<td>2013</td>
<td>51 (UCLA) 9 (Cedars) 3 (LA BioMed) 3 Unknown (CDU)</td>
<td>14 (UCLA) 2 (Cedars) 0 (LA BioMed) 0 (CDU)</td>
<td>27.5% (UCLA) 22.2% (Cedars) 0% (LA BioMed) 0% (CDU)</td>
<td>29.3%</td>
</tr>
</tbody>
</table>

Data compiled by Lourdes Guerrero and Lisa Chan
UCLA DGSOM/CTSI Mentors Advisory Committee

**Goal:** To increase the quality of mentorship and subsequently the number of NIH and VA career development grants submitted and awarded.

<table>
<thead>
<tr>
<th>Committee Membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>Judith Currier (Chair)</td>
</tr>
<tr>
<td>Sherin Devaskar (Pediatrics)</td>
</tr>
<tr>
<td>Carol Mangione (Medicine)</td>
</tr>
<tr>
<td>Mark Litwin (Urology)</td>
</tr>
<tr>
<td>Jonathan Hiatt (Vice Dean DGSOM)</td>
</tr>
<tr>
<td>Joe Hines (Surgery)</td>
</tr>
<tr>
<td>Mitchell Wong (Medicine)</td>
</tr>
<tr>
<td>Lynn Gordon (Associate Dean DGSOM)</td>
</tr>
<tr>
<td>Daniel Geschwind (Neurology)</td>
</tr>
<tr>
<td>Linda Baum (Pathology)</td>
</tr>
<tr>
<td>Steven Shoptaw (Family Medicine)</td>
</tr>
<tr>
<td>Becky Yano (VA)</td>
</tr>
<tr>
<td>Charalabos Pothoulakis (Medicine)</td>
</tr>
<tr>
<td>C. Noel Bairey Merz (Cedars-Cardiology)</td>
</tr>
<tr>
<td>Jose Escarce (Medicine)</td>
</tr>
<tr>
<td>Victor Chaban (CDU-Medicine)</td>
</tr>
<tr>
<td>Christopher Evans (Psychiatry)</td>
</tr>
</tbody>
</table>

Convened November 2013 and the committee has met 4 times in the last 6 months.
Advisory Committee Recommendations

- Increase the number of K/CDA Workshops.
  - Recruit more faculty to serve as reviewers.

- Develop a library of successful K, other career development, and diversity supplement awards.

- Organize a mentor training seminar series for faculty at all levels.

- Organize a “College of Mentors” that is similar to the main campus’ “Council of Advisors.”

- Offer stipends to mentors on K or other career development awards.
2. Provide additional support beyond K workshops

<table>
<thead>
<tr>
<th>Need</th>
<th>Response</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>More in-depth training</td>
<td>Grant &amp; Clinical Protocol Development Workshop</td>
<td>• Led by Steven Piantadosi (CSMC) &amp; Isidro Salusky (UCLA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2-week workshop first held July 2013</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 30 attendees</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Next workshop: July 14-25, 2014</td>
</tr>
<tr>
<td>Longitudinal mentoring</td>
<td>RCMAR/EXPORT CTSI Scientific Retreats</td>
<td>• 8-hour workshops</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Offered 3 times per year</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Support offered one on one between meetings</td>
</tr>
<tr>
<td>One-on-One Mentoring</td>
<td></td>
<td>• Extension of K workshop</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Start mid-late 2014</td>
</tr>
<tr>
<td>Extend beyond K trainees</td>
<td>K-to-R Transition Workshop</td>
<td>• First workshop December 12, 2013 at UCLA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 40 attendees</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Morning speakers: Carol Mangione (UCLA), David Elashoff (UCLA), Scott Filler (LA BioMed), Joan Tucker (RAND), and Vivek Shetty (UCLA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• In-person review of R grants</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• One on one support post meeting</td>
</tr>
<tr>
<td>Additional Funding</td>
<td>K Bridge Award</td>
<td>• Grant funding for those with scored, but unfunded K and R grants</td>
</tr>
<tr>
<td></td>
<td>K-to-R Bridge Award</td>
<td></td>
</tr>
</tbody>
</table>
CTSI K Award Workshops

- **Objective:** To help junior investigators to learn how to prepare successful K award applications.
- Next workshop scheduled for July 10, 2014 at UCLA.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th># of Attendees</th>
<th># of Draft Proposals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jul. 26, 2012</td>
<td>UCLA</td>
<td>58</td>
<td>14</td>
</tr>
<tr>
<td>Jul. 25, 2013</td>
<td>UCLA</td>
<td>55</td>
<td>16</td>
</tr>
<tr>
<td>Feb. 12, 2014</td>
<td>Cedars-Sinai</td>
<td>63</td>
<td>12</td>
</tr>
<tr>
<td>Jul. 10, 2014</td>
<td>UCLA</td>
<td>117 (registered)</td>
<td>11</td>
</tr>
</tbody>
</table>

*On average, 90% are new attendees at each workshop.*
“I understand the different components of a NIH K/CDA grant proposal.”

Pre-workshop

N/A = not applicable
1 = strongly agree
2 = agree
3 = neutral
4 = disagree
5 = strongly disagree

Post-workshop

N/A = not applicable
1 = strongly agree
2 = agree
3 = neutral
4 = disagree
5 = strongly disagree

Data compiled from July 2012 to February 2014 workshops.
• **Objective**: To help investigators to learn how to prepare successful R award applications.

• Next workshop is scheduled for November 13, 2014.

<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th># of Attendees</th>
<th># of Draft Proposals</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dec. 12, 2013</td>
<td>UCLA</td>
<td>38</td>
<td>7</td>
</tr>
</tbody>
</table>
“How confident are you with presenting your preliminary data from your K/CDA in an R grant application?”

Pre-workshop

1= very confident
2= somewhat confident
3= confident
4= somewhat unsure
5= unsure

Post-workshop

1= very confident
2= somewhat confident
3= confident
4= somewhat unsure
5= unsure

Data compiled from December 2013 workshop.
K & R Bridge Programs

Goal: Provide additional time to investigators to remain scientifically productive and strengthen their proposals for resubmission.

Eligibility: Submitted NIH grant applications, received competitive scores but not funded.

K Bridge
• Help junior faculty secure an NIH K award.
• 3 awardees in 2013
  • 1 NIH K started in Sept. 2013
  • 2 NIH Ks pending Notice of Award.

R Bridge
• Help new investigators make the critical transition to independent NIH R01 funding.
• 3 awardees in 2014.
3. Maintain diversity in the pipeline

- The K Workshop includes a brief discussion of diversity supplements by Dr. Mangione.

- CTSI/DGSOM to organize informational sessions about diversity supplements.

- Collect information from OCGA on new grants
  - Match eligible junior investigators/principal investigators
  - Support/encourage diversity supplements

- Organize library of successful diversity supplements.
NIH-wide Trends

SUPPLEMENTS TO INDIVIDUALS FROM UNDERREPRESENTED GROUPS OR DISADVANTAGED BACKGROUND

FISCAL YEARS 1990-2008

Number of Awards

Expenditures (millions)
<table>
<thead>
<tr>
<th>Program</th>
<th># of Trainees</th>
<th>% Female</th>
<th>% Male</th>
<th>% Minority</th>
</tr>
</thead>
<tbody>
<tr>
<td>KL2, K Bridge</td>
<td>17</td>
<td>59%</td>
<td>41%</td>
<td>12%</td>
</tr>
<tr>
<td>R Bridge</td>
<td>3</td>
<td>67%</td>
<td>33%</td>
<td>0%</td>
</tr>
<tr>
<td>TL1 Predoc</td>
<td>14</td>
<td>86%</td>
<td>14%</td>
<td>14%</td>
</tr>
<tr>
<td>TL1 Summer</td>
<td>40</td>
<td>68%</td>
<td>33%</td>
<td>45%</td>
</tr>
<tr>
<td>RCMAR/CHIME</td>
<td>10</td>
<td>90%</td>
<td>10%</td>
<td>100%</td>
</tr>
<tr>
<td>TPTPS Workshops</td>
<td>106 (current)</td>
<td>55%</td>
<td>45%</td>
<td>17%</td>
</tr>
<tr>
<td>TPTPS Certificate</td>
<td>40</td>
<td>65%</td>
<td>35%</td>
<td>13%</td>
</tr>
<tr>
<td>TPTPS MSCR</td>
<td>23</td>
<td>44%</td>
<td>57%</td>
<td>4%</td>
</tr>
<tr>
<td>TPTPS Pathway</td>
<td>86</td>
<td>43%</td>
<td>57%</td>
<td>11%</td>
</tr>
</tbody>
</table>
4. Support trainees to diversify sources of funding

- Panel discussions about non-federal support from non-profit and professional organizations, industry, and philanthropy.

- Topics: research priorities, funding mechanism, grant cycles, and application process.

- Frequency: Every 2-3 months

- Collaborate with the UCLA Office of the Vice Chancellor for Research Initiatives to expand the UCLA Research Escalator Workshops.

- Barriers: Identify additional resources to support the development and coordination of this panel series.
5. Evaluate success of entire spectrum of trainees at all the partnering institutions whether receiving CTSI support or not

**Metrics**
- Grant submissions
- Publications
- Successful promotion
- Successful acquisition of other extramural grant support.
- Survey data after participation in workshops, courses, and other training experiences

**Barriers**
- Heterogeneity across institutions
- Large number of trainees
- Access to adequate data
- Effort to compile new data and analyze
- Staffing
Rockefeller University
CTSA Graduate Tracking System (RU GTS)

- RU GTS is our current trainee tracking system and benchmark to national data.
- 22 CTSAs are using this system.
- Environmental scan for our renewal application to see if there is a need to switch systems.

<table>
<thead>
<tr>
<th>Program</th>
<th># of Trainees Surveyed</th>
<th>Response Rate&lt;sup&gt;1&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>KL2</td>
<td>6</td>
<td>83%</td>
</tr>
<tr>
<td>TL1 Predoc</td>
<td>9</td>
<td>89%</td>
</tr>
<tr>
<td>TL1 Summer</td>
<td>25</td>
<td>56%</td>
</tr>
<tr>
<td>TPTS Track 2</td>
<td>26</td>
<td>65%</td>
</tr>
<tr>
<td>TPTS Track 3</td>
<td>17</td>
<td>41%</td>
</tr>
<tr>
<td>TPTS Pathway</td>
<td>9</td>
<td>pending&lt;sup&gt;2&lt;/sup&gt;</td>
</tr>
<tr>
<td>RCMAR/CHIME</td>
<td>7</td>
<td>57%</td>
</tr>
</tbody>
</table>

<sup>1</sup> Response rate is based on the most recent survey released in Fall 2013.
<sup>2</sup> The first cohort received the first survey in May 2014.
CTSI Research Associates Program (RAP) Pilot

- Established at UC Irvine Medical Center.
- Aims to provide undergraduate students with the opportunity to gain exposure to hospital based medicine as well as clinical research in an academic medical center.
- Designed to build a stronger support infrastructure for the research initiatives of UCLA faculty physicians.
- Research associates are trained to develop and maintain a secure database, assist in the authorship of IRB protocols, aid in statistical analyses, and co-author abstracts, poster and papers.
- Students receive academic credit, professional development and mentorship, and a valuable experience.
- Student researchers contribute to the infrastructure needed to conduct clinical research.
- UCLA CTSI-RAP pilot launched in October 2013 in the MICU.
CTSI Research Associates Program (RAP) Pilot

• CTSI-RAP opportunity was announced to a pre-health interest student group at UCLA

• More than 40 applications received, with 16 received within 48 hours from high-level candidates

• A more widely advertised program would result in hundreds of applications.

• Interviews conducted

• 14 students accepted positions – primarily physiological science majors
Student Requirements:

• Completion of online modules in ethics, privacy, and human subjects research

• Care Connect Training

• GPA > or = 3.0 (Pre-Med major not required)

• An interest in a future in healthcare or research

• Ability to commit 9 hours a week starting January 2014 for at least six months. This includes two four-hour shifts at UCLA Ronald Reagan Medical Center or UCLA Santa Monica Hospital as well as one weekly group meeting
Formerly supported by the Howard Hughes Medical Institute and directed by Uptal Banerjee, PhD.

Students start as early as 1st year of college.

Every student does original research.

Students contribute to one large group project.

Top students may advance to the Minor in Biomedical Research.
STEM retention for URCFG students

95% (297/312) of STEM majors
96% (179/187) of women
100% (32/32) of URM students

National data – Hurtado et al. (2012) “Priming the Pump or the Sieve”
UCLA data – Office of Analysis and Information Management (communication from P. Barber)
Matriculation of URCFG students to advanced degree programs

- Total graduates as of 2013: 62% (n=197)
- After one gap year: 74% (n=147)
- After two gap years: 84% (n=99)

- PharmD: 2% (n=123)
- DMD: 3%
- MS: 6%
- PhD: 26%
- MD: 45%
- MD-PhD: 18%
Long Beach Polytechnic High School (LBPHS)
Biomedical Research Program

• Established at Cedars-Sinai and LA BioMed before the UCLA CTSI was funded.

• Expose high school science students to clinical research (experimental design, patient safety, ethics, etc.)

• Students are paired with an investigator mentor actively engaged in clinical protocol work and present a poster at the end of the program.

• CTSI-ED expanded the program to bring 5 high school students to UCLA Westwood and work with 2 KL2 Scholars (Shackelford & Walling) from December 2013 to February 2014.
Future Plans

• Continue the KL2 Scholars, TL1 Pre-doctoral Fellowship and Summer Health Disparities Programs
• Continue to offer the K and R Bridge awards.
• Expand the “K” and “K to R” Workshops.
• Fully launch CTSI RAP and expand to other clinical areas.
• Collaborate with URCFG to offer undergraduates training in basic sciences
• Refine Long Beach Polytechnic High School Program at UCLA Westwood
• Create workshops/seminars on:
  – How to communicate science to lay people and grow philanthropic support.
  – How to get research to products more rapidly.
• Continue the evaluation and feedback from all programs; this information is received by the CREST committee and real-time improvements are operationalized.
BIP Overview

• **Aim 1: Virtual Home**
  – Researcher Portal and Service Request system

• **Aim 2: Research Data Repositories**
  – Provision clinical data for research across institutions

• **Aim 3: Informatics Education**
  – Biomedical Informatics course

• **2013 EAB comment: Need an Organized Faculty Unit**
  – “The institution is without a graduate training program or organized faculty unit related to biomedical informatics. UCLA is behind the other UC campuses in its trajectory toward achieving critical mass of informatics faculty for advancing its missions.”
Aim 1: Virtual Home

- Redesigned Virtual Home website
  - Rebranded as CTSI Connections
  - Opportunities, News, Events, Service Catalog
Aim 1: Virtual Home

- Researcher Profiles
  - Bio, Titles, Education, Publications, Research interests
- Team Science Workflow System
  - Manages projects, service requests, tickets, tasks
    - Real-time tracking, automated evaluation and followup surveys
  - Since go-live (5/6/13), 754 requests → 871 tickets
    - 26% grant, 27% manuscript, 24% clinical study, 4% community
    - 12% of requests self-entered by investigators on the portal
Aim 2: Research Data Repository

- **UC-ReX**
  - Count patients meeting study criteria
  - Federates de-identified data from all 5 UC
- **I2b2/SHRINE software from Harvard**
Aim 2: Research Data Repository

- **UC-ReX Data**
  - Demographics
  - ICD-9 diagnoses and procedures
  - Top 100 lab tests
  - Medications (outpatient orders, inpatient admin)

<table>
<thead>
<tr>
<th>Site</th>
<th>DISTINCT PATIENTS</th>
<th>TOTAL DATA ELEMENTS</th>
<th>DEMOGRAPHICS</th>
<th>DIAGNOSES</th>
<th>PROCEDURES</th>
<th>LABS</th>
<th>VITAL STATUS</th>
<th>Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCSD</td>
<td>2,226,393</td>
<td>82,610,531</td>
<td>6,891,004</td>
<td>10,614,282</td>
<td>0</td>
<td>65,033,266</td>
<td>4,396</td>
<td></td>
</tr>
<tr>
<td>UCI</td>
<td>1,502,637</td>
<td>52,651,819</td>
<td>10,332,268</td>
<td>21,240,149</td>
<td>858,073</td>
<td>18,733,969</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCSF</td>
<td>1,898,967</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>70,649,908</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UCD</td>
<td>2,001,452</td>
<td>109,871,655</td>
<td>10,921,320</td>
<td>18,958,851</td>
<td>680,524</td>
<td>79,120,530</td>
<td>35,780</td>
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<td>UCLA</td>
<td>4,203,760</td>
<td>175,221,156</td>
<td>29,630,790</td>
<td>28,146,462</td>
<td>1,263,310</td>
<td>107,273,014</td>
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<td>Total</td>
<td><strong>11,833,209</strong></td>
<td><strong>82,690,869</strong></td>
<td><strong>2,957,971</strong></td>
<td><strong>340,810,687</strong></td>
<td><strong>8,864,770</strong></td>
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</tbody>
</table>
Aim 2: Research Data Repository

- **UC-ReX Usage**
  - 96 user accounts created to date
  - May-Sept. 2013 pilot group, October 2013 launch
Aim 2: Los Angeles Data Resource (LADR)

• **Vision**
  – Link patient data across many LA providers (including CTSI)
    → More complete data sets than any single institution

• **Pathway**
  – Step 1: Cohort discovery
    • SHRINE network, borrowing data standards from UC-ReX
  – Step 2: Link data sets
    • Initial test of Vanderbilt private record linkage software (Secure Open EMPI)
  – Step 3: Implementation Science Collaborative
    • Work with LA County on discovering best practices for health system transformation
Aim 2: Los Angeles Data Resource (LADR)

<table>
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<tr>
<th></th>
<th>Distinct Patients</th>
<th>Total Facts</th>
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<td>Cedars</td>
<td>2,424,482</td>
<td>19,468,005</td>
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<tr>
<td>UCLA</td>
<td>4,180,722</td>
<td>67,507,617</td>
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</table>
Aim 2: Other RDR-related Activities

• **Storefront for Research Access to UCLA Health Data**
  – Define data needs
  – Propose plans that will pass IRB and compliance review
  – Set up data mart or extract data file that researcher needs
  – Of 47 projects supported to date: 13 completed, 9 in-progress, 7 awaiting IRB approval, 4 awaiting compliance approval, 5 on hold

• **Support use of REDCap**
  – Installed at all 4 sites; preferred location for LADR output

<table>
<thead>
<tr>
<th></th>
<th>Drew</th>
<th>Harbor</th>
<th>UCLA</th>
<th>Total</th>
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<tbody>
<tr>
<td>Production</td>
<td>14</td>
<td>67</td>
<td>94</td>
<td>175</td>
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<tr>
<td>Development</td>
<td>19</td>
<td>58</td>
<td>190</td>
<td>267</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>33</td>
<td>125</td>
<td>284</td>
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</table>
Aim 3: Informatics Education

- Biomedical Informatics Module for the Training Program in Translational Science
  - 12 hours of instruction including hands-on tools exercises

- Training on CTSI-supported tools
  - UC-ReX, LADR

- DGSOM Biomedical Informatics Task Force
  - Recommendation to rename and expand Biomath Dept. to Dept. of Biomedical Informatics and Computational Medicine
    - Divisions: Clinical Informatics, Bioinformatics, Computational Modeling
  - Clinical informatics training program
Thank You
Overview

1) Review of Program Area Goals
2) Response to EAB Recommendations
3) Progress
   a) Areas most important to our renewal
   b) Infrastructure development
   c) Outcomes and CHR metrics summary
4) Future plans
IOM Recommendation #7 - Overall Vision - June, 2013

Because of the paucity of pediatric-specific research, health care providers caring for children often use their own personal experiences in clinical practice, rather than published evidence, as the basis for treatment decisions. *Thus, clinical and translational research is urgently needed in the area of child health.*

The **UCLA CTSI CHR Committee** embraces this important goal and so has forged initiatives to address the needs for advancing child health research.
Two concentrated efforts have been the establishment of the:

- **UC Biomedical Research Acceleration, Integration and Development (UC BRAID) Child Health Consortium** of five UC institutions (Los Angeles, Irvine, San Diego, Davis and San Francisco)

and the

- **UCLA Children’s Discovery and Innovation Institute** as a nexus of CHR at UCLA, CTSI partner institutions and the greater Los Angeles and wider UC system sites
2) Response to Y2 EAB Recommendations

- **Completed Child Health Research (CHR) Strategic Plan**
  Efforts encompass child health initiatives at UCLA, CTSI partner institutions, wider community collaborations, UC system and CTSA sites.

- **Determined CHR metrics and initiated tracking systems**
  Adopted EAB recommended metrics (*Pediatric Research* 2012) and launched initiative for rigorous tracking of CHR metrics.

- **Broadened CHR leadership to include UCLA Pediatrics Chair/Vice Chair**
  Also strengthened the CHR initiatives at a wider level with UC-BRAID Child Health initiative and other collaborative networks.
3) CHR Progress – UC BRAID

The IOM Recommendation led to the creation of UC BRAID Child Health:

A Consortium of UC Affiliated Departments of Pediatrics to Advance Multicenter Research Focused on Child Health

- August, 2013: Organized by Dan Cooper, M.D. (UCI), leaders of the Departments of Pediatrics from the 5 UC Medical Centers met
- Consensus was reached to create a UC BRAID-Child Health (CH)
- Translational research themes of interest for collaboration in child health were identified
- BRAID-CH Steering Committee was established (UCLA: Martin Martin)
- Christina Chambers, Ph.D. (UCSD) named as BRAID-CH leader
- Monthly meetings supported by UC BRAID
THEMES FOR UC-BRAID CHR COLLABORATION

• AUTISM (UCLA)

• BIOSENSORS (noninvasive sensing mechanisms)
  – Include Child Health within the BRAID Drug & Device Discovery & Development (D4) group

• RARE AND UNDIAGNOSED DISORDERS (UCLA)

• TELEHEALTH (UCLA)

• BIG DATA
  – potential to leverage NIH Big Data to Knowledge (BD2K) funding (U54)
  – potential to leverage UC-ReX (online Research Exchange aggregate database from 5 UC centers; 12 million de-identified patient records)
  – importance of creating mother-infant dyads for easy identification
• Autism Translational Research Summit
  Funded by UCOP; Scheduled for August 14 at UC Davis M.I.N.D. Institute

• Three trans-UC Applications submitted to the NIH Rare Disease Clinical Research Network (All three were scored; to date, one was funded by Council) [UCLA]

• One PCORI grant submitted [UCLA PI: Paul Chung, main site UCSF]

• BRAID-CH continues to endorse additional multisite proposals targeting CHR
• The UCLA CDI Institute was founded in 2013 to enhance the culture for innovation and groundbreaking, multidisciplinary and collaborative research, spanning from molecule to community, to ensure improved health for children.

Themes:
1) Brain, Behavior & Development
2) Infection, Inflammation & Immunity
3) Cancer and Regeneration
4) Nutrition, Metabolism & Growth

• Mission: To connect all research and training activities related to improving children's health and health care, spanning from discoveries in basic research laboratories, through translation to clinical care, and moving to community practice through collaborations and networks established locally, nationally and globally.
CHR Progress: CDI-CTSI Infrastructure Development

2012-2013

CDI-CTSI Steering Committee
- Established and biweekly plus ad hoc meetings held

CDI-CTSI Pre-Award Office
- Included establishment of CHR Clinical Trials Office

CDI-CTSI Pediatric Biostatistics Center
- Assists CHR investigators with studies

CDI-CTSI Telehealth Office
- Assists CHR investigators implement such studies
CHR Progress: CDI-CTSI Infrastructure Development

2014 - added key positions to increase child health research (CHR):

- **Scientific Officer, UCLA Children’s Discovery and Innovation Institute** to develop and direct research grant funding initiatives and resources to train and support child health scientist practitioners, build CHR team science partnerships and liaison with CTSI, UC BRAID-Child Health, and the wider research community (Candace Wilkinson).

- **Executive Director of Development for Children's Health at UCLA** to lead significant fundraising efforts for interdisciplinary research partnerships involving pediatrics among scientists and physicians across departments, divisions, and schools at UCLA (Melanie Burzynski).
CHR Progress: CDI Grant Funding

- **CDI Seed Grants** - $25K each, 4 awards 2014 (8 applications); starting with 2015 grant cycle (RFAs Fall 2014), will expand by partnering with UCLA Dean’s Office Seed Grants program

- **CDI-CTSI Child Health Team Science Grants** - $50-100K each, 5 awards 2014 (19 LOIs, 8 applications); involves co-investigators across CTSI

- **CDI Today’s and Tomorrow’s Children Fund Bridge Grants**
  3 awards 2013 (Total $62 to $100K) and pending Fall 2014 awards

- **CDI Harry Winston Fellowships** (similar to T32 grants), received 6 applications now under review ($1 million over 5 years, July 2014)

- **CDI Ray Scherr’s** Annual Loan Repayment Program for Pediatric fellows

- **CTSI Catalyst Award 2013** – cosponsored 1st Annual CDI-CTSI Symposium
  May 29, 2014 to enhance child health research collaborations (Brigitte Gomperts): 160 attendees, 27 scientific talks, 52 research posters
  (Shapiro Family Awards for Outstanding presentations)
<table>
<thead>
<tr>
<th><strong>CHR Progress: CDI Grant Highlights</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Research Grant Portfolio</strong></td>
</tr>
<tr>
<td>• $20 million awards annually (70% NIH)</td>
</tr>
<tr>
<td>• 125 active grants across pediatric specialties including nutrition, obesity, health services, autism; (IOM targets)</td>
</tr>
<tr>
<td><strong>CTRC Clinical Trials</strong></td>
</tr>
<tr>
<td>• 14 NIH</td>
</tr>
<tr>
<td>• 10 Industry</td>
</tr>
<tr>
<td>• 2 Seed Grants</td>
</tr>
<tr>
<td><strong>CTSI K Bridge Program</strong></td>
</tr>
<tr>
<td>• All Year 3 awardees were from Pediatrics</td>
</tr>
<tr>
<td>• Reflects our caliber in fostering career path</td>
</tr>
<tr>
<td>• Matched funds from CDI</td>
</tr>
<tr>
<td><strong>CHR-CDA K12 Program</strong></td>
</tr>
<tr>
<td>• Supports 4 awardees</td>
</tr>
<tr>
<td>• Each receives $5K vouchers to fund access to cores</td>
</tr>
<tr>
<td>• CDI Shapiro Fund</td>
</tr>
<tr>
<td>• All applying for K grants</td>
</tr>
</tbody>
</table>

Continued...
• **Child Health Services: PCORI grant** (PI: Coker) - Telehealth services for innovative model of community delivery of developmental, behavioral and mental health care for children of low-income families in San Fernando Valley

• **Unihealth grant** (PI: Slusser) – Telehealth model for innovative services targeting prevention of Childhood Obesity in their own communities

• **Unihealth grant** (PI: Evan) – Telehealth model for extending Palliative Care services to other facilities

• **CIRM grant** (PI: Kohn) – Targets Sickle Cell Disease in an LA consortium
# UCLA CDI Institute SEED GRANTS 2014

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Project Title</th>
<th>Research Theme</th>
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<tbody>
<tr>
<td>Kara Calkins, MD</td>
<td>Intravenous fish oil and pediatric intestinal failure associated liver disease</td>
<td>Nutrition, Metabolism and Growth</td>
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<tr>
<td>Clinical Asst. Professor</td>
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<tr>
<td>Subhadra Evans, PhD</td>
<td>Neural correlates of pediatric irritable bowel syndrome</td>
<td>Brain, Behavior and Development</td>
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<tr>
<td>Adjunct Asst. Professor</td>
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<tr>
<td>Kuk-Wha Lee, MD, PhD</td>
<td>Humanin as an inflammatory biomarker in Duchenne muscular dystrophy</td>
<td>Infection, Inflammation, and Immunity</td>
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<tr>
<td>Associate Professor</td>
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<tr>
<td>Joyce Matsumoto, MD</td>
<td>The ketogenic diet for neuroprotection after acute brain surgery in children</td>
<td>Brain, Behavior and Development</td>
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<td>Assistant Professor</td>
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### Children's Discovery and Innovation Institute CTSI-CDI Team Science Awards 2014

<table>
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<th>Principal Investigator</th>
<th>Project Title</th>
<th>CDI Research Theme</th>
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<tr>
<td>Joanna Jen, MD, PhD</td>
<td>Improving the diagnosis and treatment of enigmatic pediatric neurological disorders</td>
<td>Brain, Behavior and Development</td>
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<tr>
<td>Professor of Neurology, UCLA</td>
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<tr>
<td>Sheryl Kataoka, MD, MSHS</td>
<td>Redesigning depression detection and treatment for low-income minority adolescents in school health clinics</td>
<td>Brain, Behavior and Development</td>
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<td>Associate Professor of Child and Adolescent Psychiatry, UCLA</td>
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<tr>
<td>Donald Kohn, MD</td>
<td>Stem cell gene therapy for sickle cell disease</td>
<td>Cancer and Regeneration</td>
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<tr>
<td>Professor of Microbiology, Immunology and Molecular Genetics, &amp; Pediatrics, UCLA</td>
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<tr>
<td>Harley Kornblum, MD, PhD</td>
<td>Neural stem cells in autism pathophysiology</td>
<td>Brain, Behavior and Development</td>
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<td>Professor of Psychiatry, Pharmacology &amp; Pediatrics, UCLA</td>
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<tr>
<td>Biagio Saitta, PhD</td>
<td>Patient-derived induced pluripotent stem cells and mouse knock-in mutant as models to identify regulatory mechanisms of skeletal dysplasia disorders</td>
<td>Nutrition, Metabolism and Growth</td>
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<td>Research Scientist II, Cedars-Sinai Medical Center; Adjunct Associate Professor, Pediatrics, UCLA</td>
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<tr>
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<tr>
<td>Casillas</td>
<td>Childhood Cancer Survivor Study</td>
<td>NCI U54</td>
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<tr>
<td>Casillas</td>
<td>LIVESTRONG Center of Excellence Network – Survey of Young Adult Survivors</td>
<td>Nonprofit</td>
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<td>Casillas</td>
<td>Feasibility study for a collaborative Minority Serving Institution/NCI designated Cancer Center to establish collaborative partnerships</td>
<td>NCI P20</td>
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<td>Evans</td>
<td>Iyengar Yoga for Young Adults with Irritable Bowel Syndrome</td>
<td>NIH</td>
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<tr>
<td>Evans</td>
<td>Yoga for Young Adults with Irritable Bowel Syndrome [proposal submitted Feb.2014]</td>
<td>NIH</td>
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<td>Federman</td>
<td>A Pilot Study Evaluating the Use of the mTOR Inhibitor Sirolimus in Children and Young Adults with Desmoid - Type Fibromatosis [proposal submitted Feb.2014]</td>
<td>Maine Medical Center</td>
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<tr>
<td>Lotstein</td>
<td>Improving Palliative Care for Adolescents and Young Adults with Life-Limiting Illness [proposal submitted Mar.2014]</td>
<td>Foundation</td>
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</table>
Life Course Health Studies (LCHS) form the continuum throughout the life cycle linking health and disease factors across the lifespan:

- Maternal
- Infancy
- Childhood
- Adolescent
- Adult

Topics: Microbiome, Inflammation, Cognition, Exercise, Nutrition/Obesity

LCHS will be embedded within the core functions of the CTSI

Currently funded LCHS grants at UCLA (UCLA PI: Neal Halfon)

- MCHB: MCH Life Course Research Network (national agenda and handbook)
- MCHB: MCH Measurement Research Network (UCLA & CTSA site: Johns Hopkins)
- NICHD/Westat: National Children’s Study Health Measurement Network
- WKKF: Transforming early Childhood Community Systems (50 across USA)
- Kresge Foundation: Moving Health Care Upstream (community health centers)
Metrics Summary: Child Health Research at UCLA CTSI as Proportion of Total Activity

CTSA CHR national performance target range (CTSA EAB, June 2013)
4) CHR Future Plans

• Continue to build collaborative **CHR team science partnerships** at UCLA, CTSI partner sites, UC-BRAID and CTSA sites nationally (40/20)

• Increase **CHR leadership positions** at UCLA CTSI and collaborative networks

• Expand **Tracking of CHR metrics** across CTSI, UCLA and UC BRAID databases

• Expand **CHR grant funding and support resources at UCLA CDI** as research nexus for fostering translational child health research
CHR Future Plans

• Launch monthly **CDI Child Health Research Forum** to share scientific, logistic, and training initiatives to further stimulate CHR productivity and increase grant funding

• Continue **Annual CDI Institute Research Symposium**

• Expand and Optimize **CDI Website platform** as scientific and community outreach tool

  eg. add “Research Resources” and “Family & Community” pages to raise awareness of research process and study participation opportunities for families and to **increase community engagement**

  – per 2013 IOM recommendation #7 for child health research
4) CHR Future Plans – UC BRAID

• Support for new proposals (UC-wide)
• Exercise in children with congenital heart disease
• Biomarkers of long-term growth impairment in PICU survivors
• Addition of UC-affiliated children’s hospitals to UC-ReX
• Plans to convene another CHR consortium meeting
UCLA: CTSI-CHR Team Members

Martin Martin, M.D., M.P.P: UC BRAID-CH Representative

Paul Chung, M.D., M.S.: Community and Health Services Representative

Brigitte Gomperts, M.D.: CDI Symposium and Fellow Education

Isidro Salusky, M.D.: CTRC & Education Committee

Katrina Dipple, M.D., Ph.D.: Education Committee

Chris Denny, M.D.: Core Voucher Program

Neal Halfon, M.D.: Life Course Strategy

Isidro Salusky & Neal Halfon: UCLA Representation at CC-CHOC

Candace Wilkinson, Ph.D.: CDI Scientific Officer

Mattel Children’s Hospital UCLA Board Members