Welcome to the Duke CTSA Virtual Town Hall
September 27, 2016

Please note that you have been muted upon entry to this WebEx. Click the microphone by your name in the participant list to unmute as needed. This presentation is being recorded.
Today’s Topic:
“Creating Research-Ready Communities and Community-Ready Researchers”

Presenters

**Ebony Boulware:**  Brief introduction to CTSI, CTSA, and C4

**Bray Patrick-Lake:**  Director, Stakeholder Engagement, Duke CTSA

**Nadine Barrett, Jennifer Gierisch, and Lisa B. Davis:**
Center for Community Collaborations and Connections (C4)

**Q&A**
A brief introduction to a world of Cs:

CTSI  (Clinical & Translational Science Institute)

CTSA  (Clinical & Translational Science Award from NIH)

C4    (Community Collaborations and Connections Core)
Accelerating the translation of scientific discoveries into health benefits for patients and communities

- Officially launched on August 17, 2016
- Part of the School of Medicine, but working with programs and people across Duke and the community
- Academic home for the Clinical and Translational Science Award, a $47M grant from the NIH through NCATS (National Center for Acceleration of Translational Science)
CTSI Network of Communities

- Navigation and Team Science
- Translation Acceleration and Pilot programs
- Translational Sciences Integration
- Learning Health System
- Precision Health
- Data Sciences and Research Informatics
- Clinical Research Networks and Engagement
- Methods and Data Support
- Community Engagement and Population Health Research
- Translational Training and Workforce Development
- Stakeholder Engagement

Duke CTSI
On to the presenters:

Bray Patrick-Lake
Director, Stakeholder Engagement, Duke CTSA

Nadine Barrett, Jennifer Gierisch, and Lisa B. Davis:
Community Collaborations and Connections Core (C4)
Duke CTSA Town Hall on Engagement
Bray Patrick-Lake, MFS
September 27, 2016
Engagement with Patients Finally Recognized as Crucial to Research and Regulatory Success

- NIH
- PCORI
- Patient-focused drug development
- Patient-preference risk-benefit
- 21st Century Cures
- Precision Medicine Initiative
- Value and reimbursement
- Push for national center to advance the science of patient input (SPI)

“...There is the whole trend of patient-driven outcomes like the PCORI initiative. Now every NIH-sponsored study wants to see advocates on the steering committee at the time of the conceptual design... And for any of us who want Federal funding, when NIH says ‘jump!’ we jump!”

CTTI PGCT Academic 2014
Interview Respondent
Through active, continuous engagement patients/caregivers demonstrate value by helping to develop more effective, efficient research with a greater chance of success through:

- Better questions and study design
- Efficient recruitment and improved retention
- Fewer protocol amendments
- Procedures that are better-suited to the patient
- Clinical endpoints that are well-grounded in the natural history of the disease
- Potential benefits that are most important to the patient
- Deeper, more swift uptake of findings
- Advocating for reimbursement
Shift from Transactional to in the Fabric

Old engagement model
- Advisory boards; 1 rep on boards or committees
- Grant review rather than research development

New engagement model
- Participant/patient engagement in foundation of research and health system programs so true co-learning can occur
- Young investigators trained in engagement
- Frictionless research invitation and participation
- Team science with stakeholders at every touchpoint of study
  - Protocol, endpoint, PRO design in partnership with stakeholders
  - Feasibility assessment, trial simulation, recruitment planning and development of study communications
  - Engaged end to end: conduct, oversight and dissemination
- Data is shared and shared value is imperative
1. Participation is open to interested individuals
2. Representing the rich diversity of America is essential
3. Participants are partners in all phases of the cohort program
4. Participants have access to study information and data about themselves
5. Data can be accessed broadly for research purposes
6. Adherence to the PMI privacy principles and forthcoming security framework
7. PMI is a catalyst for progressive research programs and policies
PG Engagement Across the Research & Development Continuum

- From Bench to Bedside and Back

- Input re interest of research question to patient community
- Providing data on unmet need & therapeutic burden
- Fundraising and direct funding for research to identify target molecules
- Facilitating collaboration with NIH
- Characterizing the disease & relevant mechanisms of action

- Fundraising & direct funding for research, trial operations support
- Assistance in selecting & recruiting optimum clinical sites
- Clinical infrastructure support
- Helping educate/motivate patient community & recruit for trials
- Providing patient feedback on participant experience
- Serving on Data & Safety Monitoring Board
- Input for any trial adaptations or modifications
- Accompanying sponsor to milestone meetings, e.g., after phase 2 &3

- Serving on post-market surveillance initiatives
- Helping return study results to participants
- Co-presenting results
- Publications/communications re results
- Feedback on how patient community views results
- Natural history database & registry support
- Working with payers re reimbursement

Pre-Discovery

Pre-Clinical

Phase 1/2/3

FDA review & approval

PAS/Outcomes

- Fundraising and direct funding for research
- Providing translational tools (assays, cell & animal models, bio-samples, biomarkers, etc.)
- Helping define study's eligibility criteria
- Natural history database & patient registry support
- Input on meaningful clinical endpoints
- Assistance re informed consent form
- Working with FDA re benefit-risk and draft guidance
- Accompanying sponsor to Pre-IND FDA mtg to advocate for study

- Providing public testimony at the FDA Advisory Committee & other FDA hearings
- Preparing submission for newborn screening when appropriate

- Natural history database & registry support
- Working with payers re reimbursement

Duke Clinical & Translational Science Institute

Closing thoughts

• Us and Them separations are dead. It is a time of We and sharing in research. **We are all one team** – patients, providers, researchers and health systems – with a common goal of improving lives; it is a time of **power and information sharing and partnership** to achieve this.

• Opportunities for co-learning and improving the quality and efficiency of research and care have never been greater. **Start breaking down siloes and do your part in building a national movement for research.**
Thank you!

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COMMUNITY CONNECTIONS & COLLABORATIONS CORE

NADINE J. BARRETT, PHD, MA, MS; DIRECTOR
JENNIFER M. GIERISCH, PHD, MPH; ASSOCIATE DIRECTOR
VISION AND GOALS

VISION: To be a national leader in facilitating equitable, authentic, and robust community engaged research for community and population health improvement

GOALS:
• Build research-ready communities and community-ready researchers.
• Facilitate meaningful and equitable community-research partnerships
• Foster transparent, bidirectional communication between community stakeholders and academic investigators
WHERE WE FIT WITHIN DUKE

Clinical and Translational Sciences Institute (CTSI)

Center for Community and Population Health Improvement (CCPHI)

Community Connections and Collaborations Core

Community Advisory Council (CAC)

Community Connections & Collaborations Core
COMMUNITY ENGAGED RESEARCH

• Working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people

• CTSA definition of “community”: stakeholders connected to clinical and translational research

• Includes community members, disease advocacy groups, community-based organizations, health care providers, and many others
INTEGRATED PROGRAMS AND SERVICES

Enhancing Capacity Across the Translational Spectrum T1 -T4

Consultation and Matchmaking Services
PCARes
Sparks Program
Clearinghouse
Enrichment Tours
T4 Pilot Funding Program

Integrated and Tailored Internal and External Communication and Outreach Plans

- Enhanced Capacity to Effectively Conduct Community Engaged Research
- Impactful and Equitable Community Partnerships and Research Programs

Community and Population Health Improvement
CONSULTATION AND MATCHMAKING SERVICES

• Builds capacity for community-based organizations and researchers to equitably engage in research through our matchmaking process

• Includes intensive consultation, assessment, and resource matching to organizations to enhance equitable research partnerships
CLIENT CONSULTATIONS

Reproductive health for women with rare disorders

Autism

Substance Abuse

Palliative Care

Transgender Youth

Implantable cardiac devices

Epilepsy
PATIENT AND COMMUNITY ADVISORS IN RESEARCH

• Offers multi-level trainings that support authentic, robust, and equitable engagement

• Engages patients and the broader community in every aspect of the research enterprise

• Values patient and community expertise

• Trains participants to engage in multiple roles including community advisory council members to co-investigators
AME ZION & DUKEHEALTH PARTNERSHIP

• Obtained buy-in from NC AME Zion leadership

• Hosted AME Zion partnership-building opportunities

• Submitted U01 with Yale University and AME Zion collaborators

• Teamed up with Hood Theological Seminary to host research trainings
SPARKS PROGRAM

• Creates innovation incubators that “Spark” ideas for community-engaged research projects

• Provides platform for the cross-pollination of ideas

• Brings together researchers, community groups, patients, and other stakeholders who work on the same health issue but from different approaches
SPARKS PROGRAM

• Reached 14 researchers and community partners at the inaugural Obesity Sparks

• Discussed paradigm-shifting ideas for lasting change in the obesity epidemic

• Focused on special populations and health disparities
**ADDITIONAL SERVICES**

- Developing guided **community and research enrichment tours** that promote transparency and trust between community members, community organizations, and academic researchers.

- Building an **electronic clearinghouse of resources** that provides trainings, videos, and other evidence-based resources to build capacity for research teams and communities to equitably engage in partnered research.

- Offering **T4 pilot funding program** with two levels of support:
  - **Level 1:** Stimulates new community engaged partnerships that resulted from the consultation and matchmaking service.
  - **Level 2:** Supports established community-research partnerships to provide pilot funding for research proposals.
ENGAGEMENT IN ACTION: COMMUNITY TOWN HALL

• Goal: Develop comprehensive 5-year roadmap to broaden involvement, reach, and understanding of patient and community engagement

• Funding: PCORI Eugene Washington Engagement Award

• Progress to date:
  • Hosted town hall on June 17
  • Engaged 88 patients, community members, researchers, and health care partners
  • Started conversation on how to jointly establish health and research priorities that matter to community and academic research stakeholders
ACTIVITIES ON THE HORIZON

• Community Advisory Council
• PCOR Outcomes that Matter Community Workshops
• Sparks Underrepresented Minority Faculty Mentorship
• AME Zion and DukeHealth Research Partnership Training at Hood Theological Seminary in Salisbury, NC
• Community and Research Enrichment Tours
• T4 Pilot Funding Program
GET INVOLVED. . .

Want to **bolster your grant application** to make it more competitive?

Want to **generate collaborative and innovative research opportunities** with diverse community and academic stakeholders?

Can we **add you as a partner** in the advancing collaboration across the research translational spectrum?

Need help knowing **creative ways to disseminate your research findings**?
WE WANT TO HEAR FROM YOU

- Visit our website: http://www.c4partners.org/

- Take **STAKEHOLDER INTEREST SURVEY** and tell us about your skills, needs, and capacity

- Complete survey by **September 30. . . chance for $50 gift card!!!**
CONTACT US

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Questions?

Don’t forget to unmute yourself!
Upcoming Deadlines

• October 1
  Applications open for KL2 Awards

• October 21
  Submission deadline for Duke/UNC CTSA Consortium Collaborative Translational Research (T1/T2) Pilot Grant ($50,000)

• November 2
  Submission deadline for CTSI Translational Accelerator Funding ($150,000)

• November 18
  Submission deadline for KL2 Applications
Thank you for participating

A recording of this presentation will be posted on

www.ctsi.duke.edu