

Translational Approaches to Training the Next Generation of Translational Scientists and Efforts to Promote Community Engagement to Reduce Health Disparities

CUNY Institute of Health Equity, (CIHE)
Inaugural Seminar Series

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Division of Clinical Innovation

National Center for Advancing Translational Sciences, NIH

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MORE TREATMENTS, MORE QUICKLY.

That's the goal
of translational
science.

95% of diseases have no treatments.

THOUSANDS
OF DISEASES



ONLY

HUNDREDS
OF TREATMENTS



TRANSLATIONAL SCIENCE IS IMPROVING THE PROCESS:



Learn more at:
ncats.nih.gov



Understanding what's
similar across diseases to
help develop multiple
treatments at a time



Developing models that
better predict a person's
reaction to a treatment



Enhancing the design and
conduct of clinical trials
so the results more
accurately reflect the
patient population

New treatments take far too long to develop:

require an average of
10-15 years



fail 95% of the time

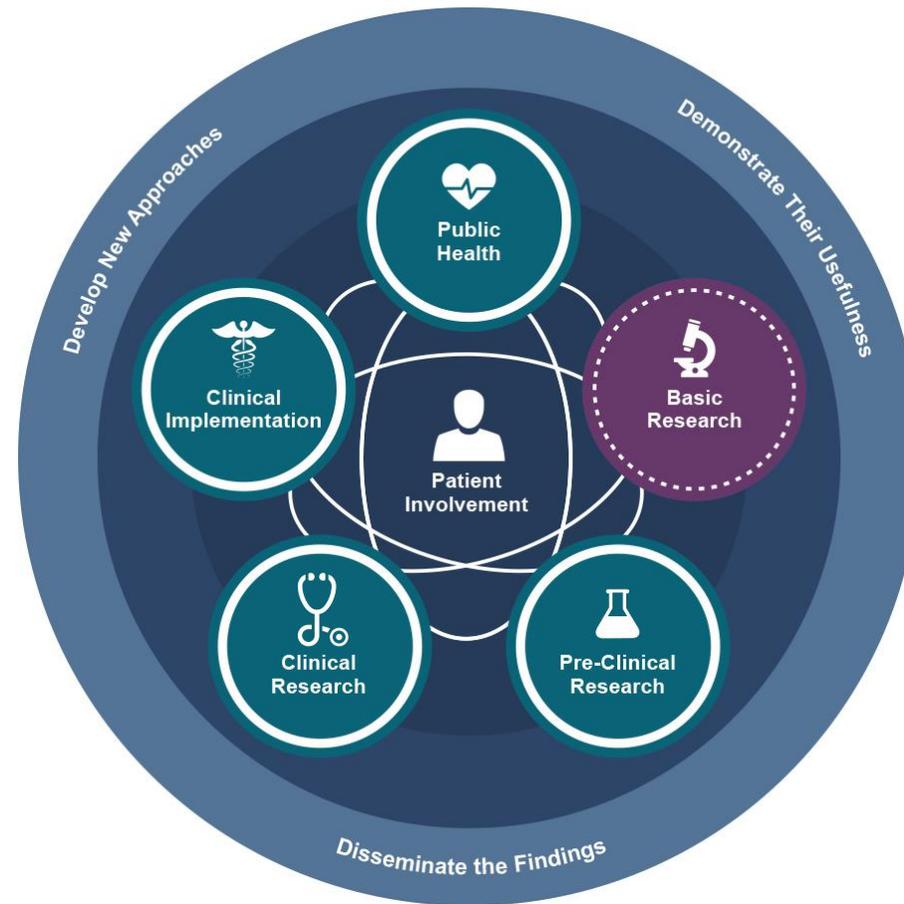


NIH NCATS: COLLABORATE. INNOVATE. ACCELERATE.



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The NCATS Translational Science Spectrum



NCATS Clinical and Translational Awards (CTSA) Program

Develops innovative solutions that will improve the efficiency, quality and impact of the process for turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public by:

- Collaboratively facilitating and accelerating translational projects locally/regionally/nationally
- Creating and providing domain-specific clinical and translational science research training combined with knowledge on how to cross translational hurdles*
- Supporting scientific and operational innovation to improve the efficiency and effectiveness of clinical and translational science research



CTSA Program Goals

- Train and cultivate the translational science workforce
- Engage patients and communities in every phase of the translational process
- Promote the integration of special and underserved populations in translational research across the human lifespan
- Innovate processes to increase the quality and efficiency of translational research, particularly of multisite trials
- Advance the use of cutting-edge informatics



What is Translational Science?

- Translational science (TS) describes the spectrum of research activity from preclinical investigations that elucidate the biological basis of health and disease to clinical and policy interventions that improve the health of individuals and populations.
- Training programs in TS aim to equip individuals with the knowledge, skills, and abilities (KSAs) that are needed to move discoveries along this translational spectrum.
- Concurrently, TS training also prepares individuals to glean insights from the bedside and community to inform discovery or basic science within their major research focus



CTSA Education and Training Accomplishments: Translational Science (TS) Competencies

- In 2011, the Clinical and Translational Science Awards (CTSA) Consortium provided direction for TS training programs by releasing the CTSA Core Competencies, a set of 97 KSAs grouped into 14 thematic areas (e.g., study design, research implementation, leadership, translational teamwork, community engagement, cultural diversity)
- Core competencies were developed for clinical and translational research, pediatric research and drug/medical devices
- https://clic-ctsa.org/sites/default/files/CTSA_Core_Competencies_final_2011.pdf

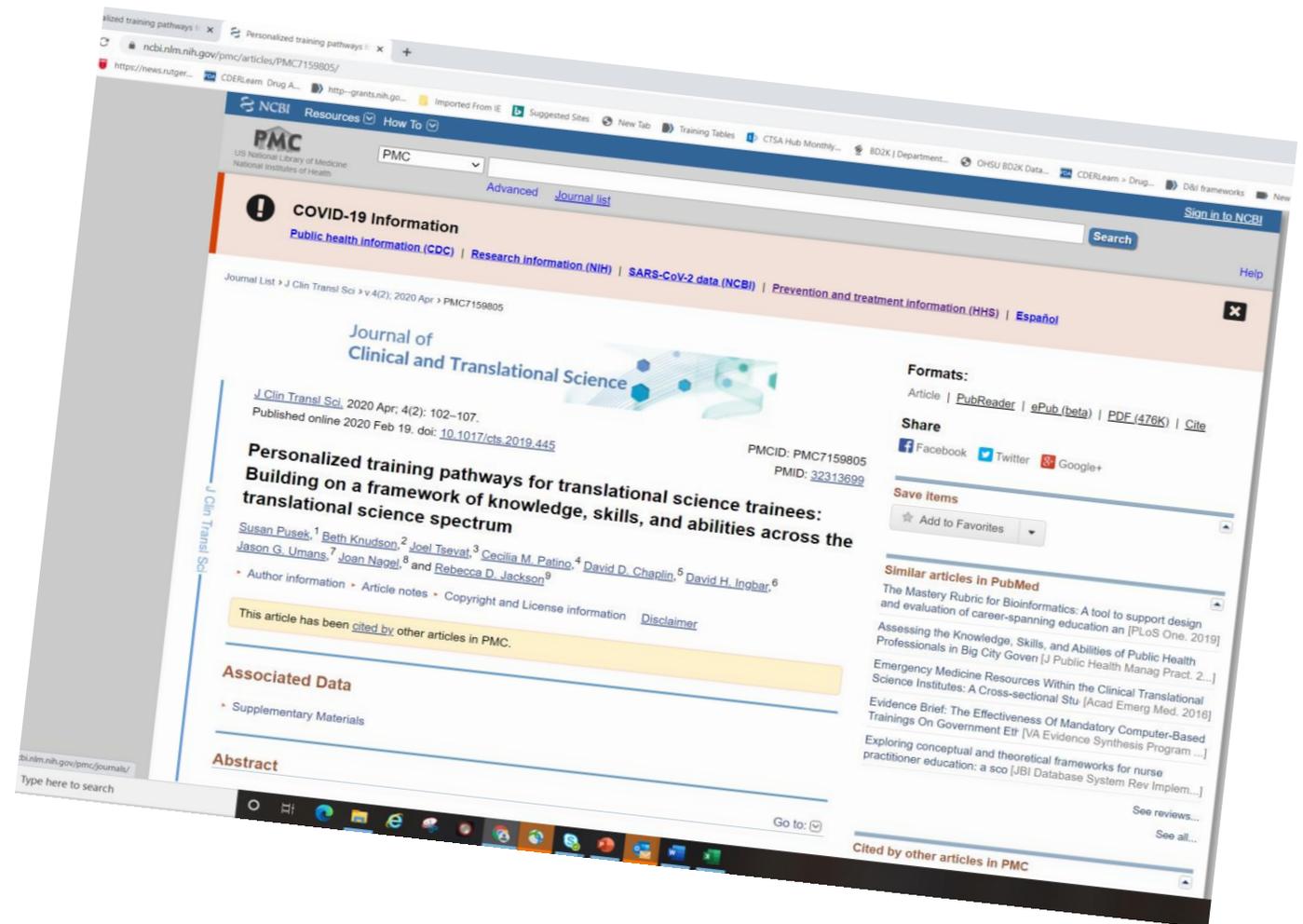


Personalized Training Pathways for Translational Science Trainees

To support more individualized education and training while ensuring some consistency of attainment of KSAs, CTSA Education Working Group adopted a conceptual model of training described as Personalized Pathways.

Applying this model, reassessed the individual KSAs recommended levels of mastery required depending on the desired career role or TS “phenotype”.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7159805/>



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Clinical/translational research phenotypes, or researcher types, defined by career goal

Phenotype name	Description of career goal
Preclinical Bench	To initiate the development of, and to provide supporting data for, the translation of scientific products toward use in a clinical setting
Clinical	To lead intervention and/or observational studies in the clinical setting
Community-Engaged	To perform research that involves a high level of collaboration between academic researchers and community partners
Dissemination/Implementation	To perform research to inform how to distribute, and to move efficacious health practices from clinical knowledge into routine, real-world use
Public Health/Big Data	To study factors and interventions that influence the health of populations that ultimately result in improved public health
Data Sciences/Analytics	To work with large datasets to answer questions of biomedical/public health/policy relevance (e.g., epidemiological, "big data")

Summary:

- First steps toward developing a framework to elucidate how the original 97 KSAs might be tailored to the individual career development goals of TS trainees to optimize efficiency and efficacy of TS training



Clinical Research Professionals are Integral to the Clinical and Translational Science Research Enterprise

The CTSA Program:

- **Support and train** members of translational and clinical research teams, experienced clinical research professionals such as research nurses or coordinators who can facilitate access to resources, can assist study-specific staff, and can provide oversight and help with quality control and assurance in human subjects research.
- **Retain** a limited cohort of experienced clinical research professionals to advise and support study-specific staff



Support for Clinical and Translational Scientists



Diversity and Re-Entry Supplements (hub grant)

Loan Repayment Program

NRSA Training Award Pre/Post/ST (TL1)

Institutional Career Development Award (KL2)

Small Grants Program for K Scholars (R03)

Key:

- Current Programs
- New Opportunity



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Supporting Diversity and Re-Entry

To address complex translational problems the translational science workforce must broadly representative across racial, ethnic, sex, gender, age, socioeconomic, geographic and disability status.

Fact Sheet

Research Supplements to Promote Diversity and Re-entry in the Clinical and Translational Science Workforce

NCATS' [Clinical and Translational Science Awards \(CTSA\) Program](#) supports a national network of medical research institutions—called hubs—that work together to improve the translational research process to get more treatments to more patients more quickly. The hubs collaborate locally and regionally to catalyze innovation in training, research tools and processes. The CTSA Program [diversity and re-entry research supplements](#) opportunities promote diversity in health-related research and re-entry into biomedical and behavioral research careers. The goal of these supplements is to build the clinical and translational research workforce that is prepared to improve the quality, safety, efficiency and speed of clinical and translational science research nationally.

What Do Diversity and Re-entry Supplements Offer?

- **Diversity supplements** provide opportunity (salary, fringe benefits, travel and limited supplies) to improve the diversity of the research workforce by recruiting and supporting students, postdoctorates and eligible investigators from diverse backgrounds, including those from groups that have been shown to be underrepresented in health-related research.
- **Re-entry supplements** provide opportunity (salary, fringe benefits, travel and limited supplies) to support individuals with high potential to re-enter an active research career after an interruption for family responsibilities or other qualifying circumstances.

ncats.nih.gov/diversity_factsheet



Aisha Langford, Ph.D., M.P.H., New York University School of Medicine, CTSA diversity supplement awardee



Juan Vasquez, M.D., Yale School of Medicine, CTSA diversity supplement awardee

Awardee Profiles



Jennifer Cunningham Erves, Ph.D., M.P.H., M.A.Ed., M.S., CHES
Assistant Professor of Research, Department of Internal Medicine, Meharry Medical College
Working to Reduce Cancer Disparities and Fulfilling Childhood Dreams

[Profile](#)



Anandi Krishnan, Ph.D.
Instructor, Department of Pathology, Stanford University
Discovering Science Yet Driven by the Heart

[Profile](#)



Aisha Langford, Ph.D., M.P.H.
Assistant Professor, Department of Population Health, New York University School of Medicine
Celebrating Wins Both Big and Small!

[Profile](#)



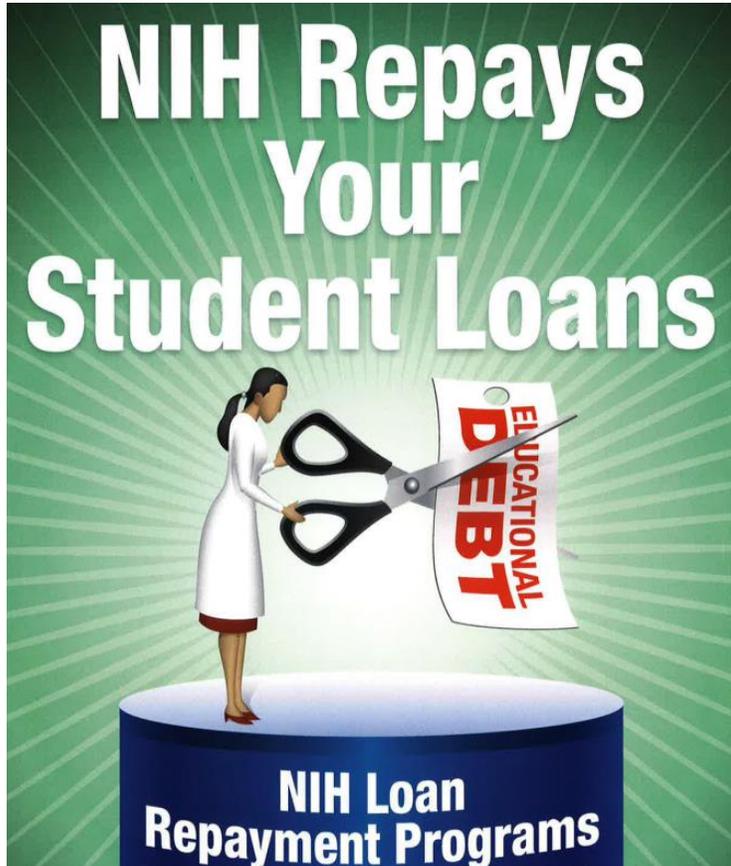
Juan Vasquez, M.D.
Assistant Professor, Department of Pediatrics (Hematology/Oncology), Yale School of Medicine
Harnessing the Immune System to Help Treat Cancer

[Profile](#)

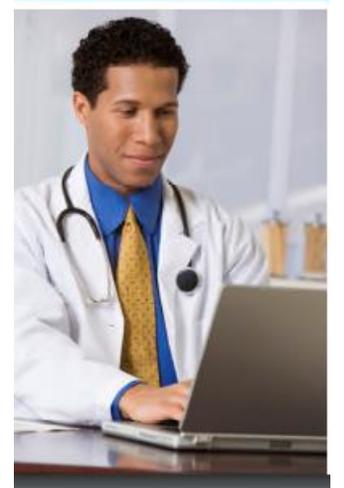


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NIH Loan Repayment Programs



- NIH Loan Repayment Programs (LRPs) are a set of programs established by Congress and designed to recruit and retain highly qualified health professionals into biomedical or biobehavioral research careers.
- NCATS CTSA Program supports:
 - Clinical Research LRP
 - Pediatric Research LRP
 - Health Disparities Research LRP



CTSA Program Institutional Career Development Program (KL2)

Preparing scholars for careers in clinical and translational science research

- Offers early-career postdoctoral scholars and junior investigators advanced training in clinical and translational science research aligned with the CTSA Program goals of advancing therapeutics (drugs, devices, and preventatives), clinical interventions, and behavioral modifications to improve health
- Offers protected time (75%), salary, research support, and multidisciplinary mentoring to support the transition to research independence
- Flexible learning models to engage scholars in team science, individual development plans, advanced research training, and career guidance to those committed to pursuing a career in clinical and translational science research

60 Programs (FY20):

- 332 scholars (postdoctoral scholars and junior faculty)



CTSA Program Institutional Training Program (TL1)

Preparing trainees to advance diagnostics, therapeutics, clinical interventions and behavioral modifications that improve health

- **Clinical and Translational Science Research:**

- Pre-clinical research, clinical research, clinical implementation, and public health research
- Entrepreneurship, regulatory science, team science and community engagement

- **Multi-disciplinary:**

- Engage multiple departments, schools and clinical research institutes to support a range of disciplines: medicine, dentistry, nursing, pharmacy, public health, epidemiology, biostatistics, bioinformatics, and bioengineering

- **Enhancement of the translational scientists' skill set**

- Optional experiential learning experiences (industry, community health settings, other hubs or research institutions, other)



47 Programs (FY20):

- 520 trainees: 181 postdoctoral fellows, 305 predoctoral fellows; 6/47 Programs with 34 short-term / summer trainee positions



The Fundamental Characteristics of a Translational Scientist

CHARACTERISTICS OF A TRANSLATIONAL SCIENTIST

Translation is the process of turning observations in the laboratory, clinic and community into interventions that improve the health of individuals and the public – from diagnostics and therapeutics to medical procedures and behavioral changes. The professionals involved in this process, either developing interventions or improving the process itself, are *TRANSLATIONAL SCIENTISTS*.

RIGOROUS RESEARCHER

Conducts research at the highest levels of rigor and transparency, possesses strong statistical analysis skills, and designs research projects to maximize reproducibility.

BOUNDARY CROSSER

Breaks down disciplinary silos and collaborates with others across research areas and professions to collectively advance the development of a medical intervention.

TEAM PLAYER

Practices a team science approach by leveraging the strengths and expertise and valuing the contributions of all players on the translational science team.

PROCESS INNOVATOR

Seeks to better understand the scientific and operational principles underlying the translational process, and innovates to overcome bottlenecks and accelerate that process.

DOMAIN EXPERT

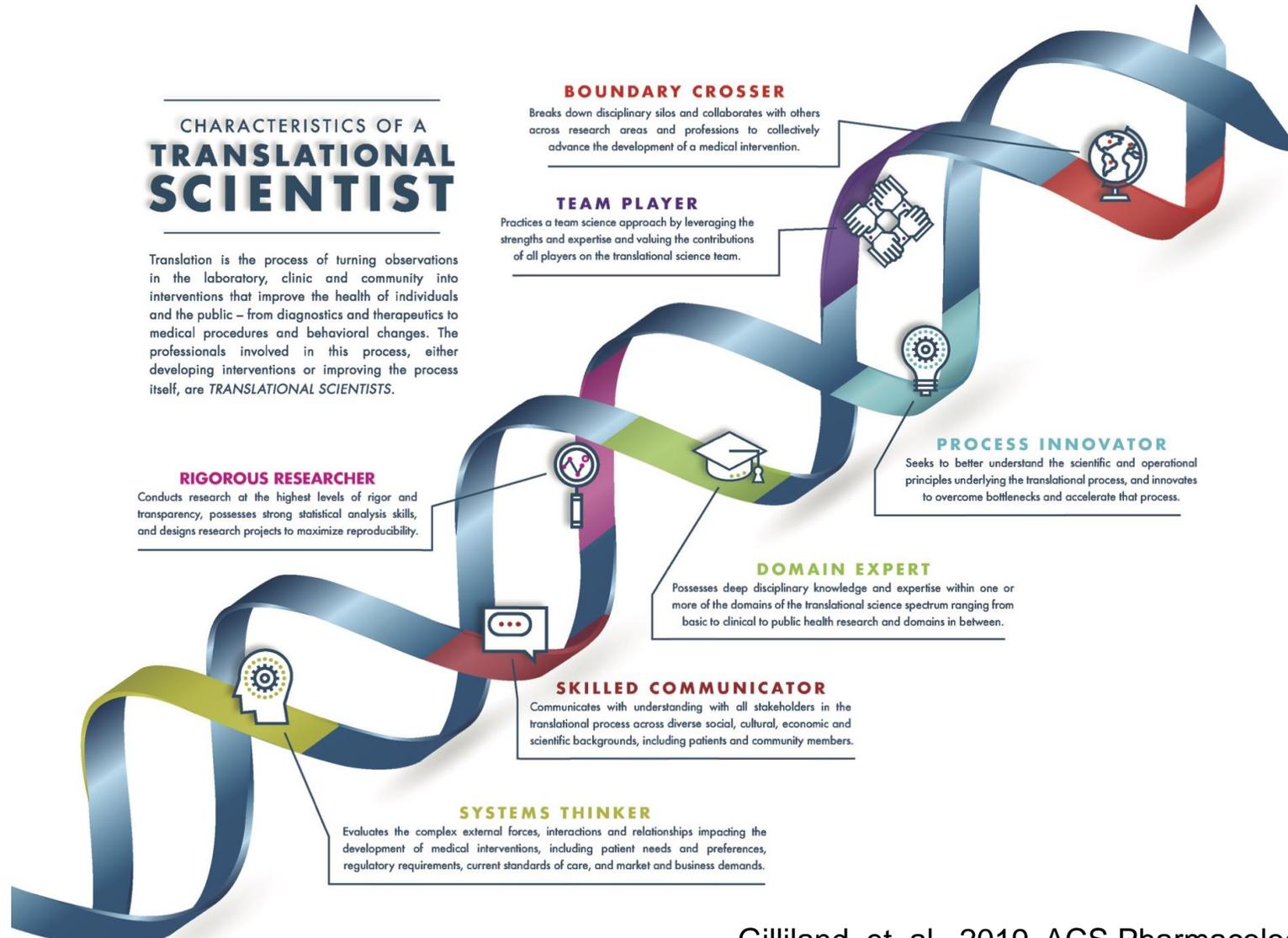
Possesses deep disciplinary knowledge and expertise within one or more of the domains of the translational science spectrum ranging from basic to clinical to public health research and domains in between.

SKILLED COMMUNICATOR

Communicates with understanding with all stakeholders in the translational process across diverse social, cultural, economic and scientific backgrounds, including patients and community members.

SYSTEMS THINKER

Evaluates the complex external forces, interactions and relationships impacting the development of medical interventions, including patient needs and preferences, regulatory requirements, current standards of care, and market and business demands.



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NCATS supported Educational Tool: Testing the Effectiveness of the Customized Career Development Platform (CCDP) - In progress

- NIH requires that all research trainees supported by NIH funds use Individualized Development Plans (IDPs) to guide their progress and productivity
- IDPs are important because they enable trainees to set goals and objectives, and to report milestones related to their research, training, and career progression
- Randomized control trial of online IDP (CCDP) vs. paper version (>300 participants so far)
- **Goal:** evaluate the effectiveness of the CCDP among programs that support NIH-funded clinical and translational science trainees across the US with the overall objective of sharing an evidence-based platform across NIH training programs and beyond

Innovative Career Planning:

- Goal-oriented, competency-driven, accessible
- Tracks progress and milestones
- Supports mentor-mentee relationships
- Ideal for variety of training programs



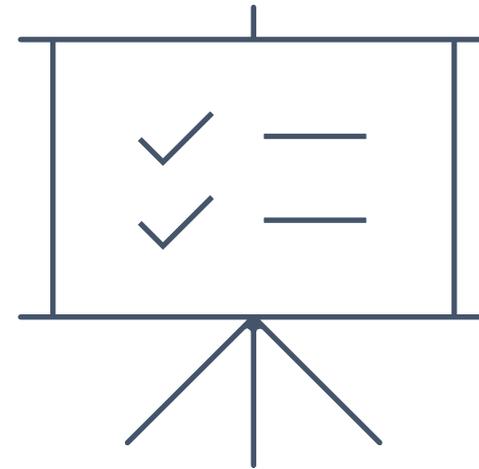
U Pittsburgh CTSI, Dr. Doris Rubio, PI, R21 TR003094



Approach

CCDP has an interactive Gantt Chart to:

1. Document goals
2. Track goals, milestones and achievements
3. Review progress with mentors



Gantt Chart

Trainees can view & edit goals, schedule meetings with their mentor, & add milestones!

The screenshot displays a user interface for a Gantt Chart. At the top, a dark blue navigation bar includes a profile picture, menu items for 'MY GOALS', 'MY MENTORS', 'MY COMPETENCIES', and 'ANNUAL REPORTS', along with a help icon and a gear icon. Below this is a gold-colored toolbar with 'Gantt View' (selected), 'List View', a person icon, a calendar icon, a date field showing '06/17/2020', and a calendar icon. The main area features a calendar grid for 'AUGUST 2020' with days 2 through 24. On the left, a sidebar lists goal categories: 'Grant Submissions' (with a dropdown arrow), 'Training' (with a dropdown arrow), and 'ADD A GOAL' (with a plus icon). Under 'Grant Submissions', the goal 'Submit an R21 in the fall cycle' is shown with a blue progress bar and a menu icon. Under 'Training', the goal 'Apply to Research Training Program' is shown with a blue progress bar and a menu icon. A context menu is open over the 'Submit an R21 in the fall cycle' goal, listing the following actions: 'Add a Milestone', 'Schedule a Meeting', 'Mark as Done', 'View Details', and 'Edit Goal'.

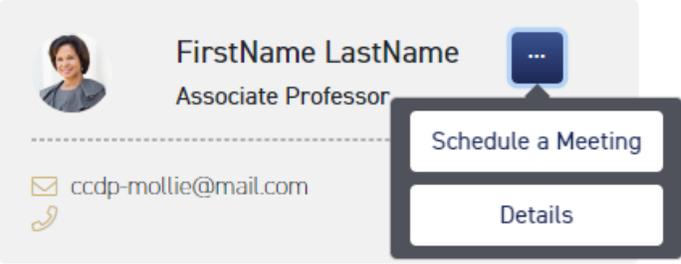
Trainees can Schedule Meetings with a Mentor

MY MENTORS

Search

Default

ADD A MENTOR


The profile card shows a mentor's name (FirstName LastName), title (Associate Professor), and email (ccdp-mollie@mail.com). A blue menu icon with three dots is positioned above the card. A dark grey tooltip box is open, containing two buttons: "Schedule a Meeting" and "Details".

Mentor will receive an email with the meeting details.

Schedule a Meeting ×

DATE

Month Day Year

Start Time End Time

Start time End time

LOCATION ⓘ

Street (or Zoom, Skype, Teams)

Apt, Suite, Office Number

City State Zip Code

GOAL

Select Goal

MENTOR(S)

Select all that apply (1 selected)

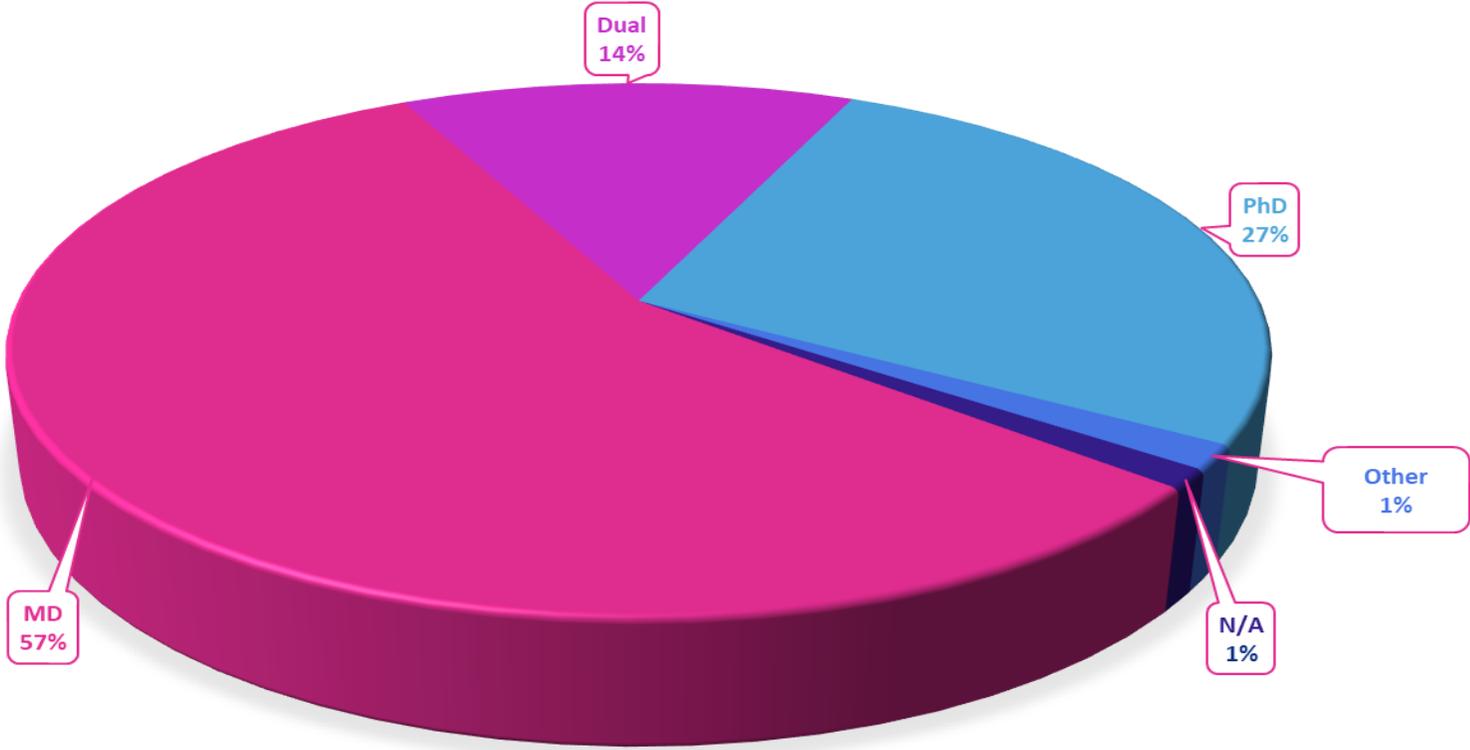
NOTES

SEND INVITATION

Mentors can see Trainees' Goals & Competencies



KL2 Scholar Degree Types (based on historical analysis of completed scholars 2006-2014)



Dual = MD-PhD



Subsequent Grants Awarded to CTSA KL2 Scholars (based on a historical analysis of completed scholars 2006-2014):

Key finding

Approximately 50% of KL2 scholars go on to get subsequent grants (all degrees) from NIH, CDC/FDA/AHRQ/VA

Degree	Total #	With any Subsequent Grant Award as PI	IC that awards the first subsequent grant mechanism
MD	539 (57%)	262 (49%)	HL – 19.5% DK – 14.1% HD – 9.9%
MD-PhDs	132 (14%)	67 (51%)	CA – 17.9% NS – 10.4% AI – 9.0%
PhDs	256 (27%)	132 (52%)	CA – 15.9% AG – 9.8% HL/MH – 8.3% (ea)
Other	14 (1%)	3 (21%)	DE – 100%
Not reporting	11 (1%)	N/A	
Total Number of Scholars	952	464 (49% of Total)	



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Where are they now?

Aisha Langford, Ph.D, M.P.H.



- Assistant Professor, Department of Population Health, New York University School of Medicine
 - 2016: CTSA Program Diversity Supplement (NCATS): study use of recruitment support tools
 - 2018: Career Development Award (NHLBI): Explore patient & clinician preferences for hypertension management
- Focus on health communication to improve individual decision making & reduce health disparities
- Co-Direct of the NYU CTSA Recruitment and Retention Core (RRC)
- Associate editor for two journals: Patient Education and Counseling and Clinical Trials



KL2 Scholar Highlight

Early language experiences contribute to later learning disparities

- Pediatric cochlear implants demonstrate variable results
- Lower socioeconomic children hear about thirty million fewer words by age four than their counterparts with a resulting lifelong impact
- Launched the Thirty Million Words Center for Early Learning & Public Health



“The key to intelligence is parents talking and interacting with their children, but just knowing that doesn’t mean parents know how to do that,”
“We have to help parents put that knowledge into play.”

Dana Suskind, M.D.

University of Chicago, Institute for Translational Medicine
CTSA Program Grant KL2 RR02500



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TL1 Trainee Highlight

Missed Opportunities to vaccinate young women against human papillomavirus (HPV)

- Two-thirds of young women aged 18-26 who were eligible to receive Human Papilloma Virus (HPV) vaccine have missed opportunities to receive the vaccine during an OB/GYN
- Missed opportunities included visits for contraception or STD screening



“These data are significant as they point to several key factors that could be prime targets for an intervention to improve rates of HPV immunization in this vulnerable population.”

– **Carlos R. Oliveira, MD**



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Congressional Appropriations

In the fiscal year 2019 appropriations, Congress recognized the role of the CTSA Program in leveraging statewide resources and capabilities to improve rural health outcomes and eliminate health disparities.

House of Representatives:

- *Rural Health Outcomes and Health Disparities.*—The Committee notes translational science and education is critical to developing new treatments and healthcare approaches that can be disseminated to underserved and special populations to improve health outcomes across the life span. The Committee continues and encourages NCATS, through its CTSA program, to enhance its commitment to the value of translational science and funding for universities to continue to innovate by leveraging statewide resources and capabilities to improve rural health outcomes and eliminate health disparities. The Committee requests an update on the actions within the **CTSA program to improve rural health outcomes and health disparities** in the fiscal year 2020 Congressional Justification. (pg. 70)

Senate:

- *Clinical and Translational Science Awards [CTSA] Program.*—The Committee encourages the NCATS to fund, through the existing CTSA Program hubs, expanded efforts to improve translational research that **address health disparities and the significant burden of conditions that disproportionately affect minority and special populations**. Accelerating translational research by making it more efficient and effective will reduce the burden of disease and promote health equity. Applying the CTSA model to address longstanding regional health disparities can provide innovative, multidisciplinary approaches to reducing the burden of disease among vulnerable populations. The Committee supports the goals of the NCATS program and believes the principles that serve as the foundation of NCATS; public-private partnerships, community outreach, faster access to clinical trials, have tremendous potential for addressing the long-standing diseases associated with health disparities. The Committee encourages NCATS to fund institutions with a history of serving health disparity populations. (pgs. 112-113)



Community Engagement is a Strategic Goal of the CTSA Program

- **Engage patients and communities in every phase of the translational process:**
 - Research in the structures, rationales, operations, purposes, outcomes, and metrics of engagement with stakeholders at each step of the translational process to elucidate principles and practices that make translation maximally efficient, focused, and relevant.
- **Community engagement activities help ensure that:**
 - communities and researchers have the capacity to participate as full partners;
 - communities are consulted for their research priorities;
 - all stakeholders are respected, valued and rewarded for their time and expertise;
 - more effective implementation and dissemination strategies are developed; and
 - there is increased public support for research, and ultimately improvements in the health and well-being of communities.



Collaboration & Engagement Enterprise Committee (CE EC)

- CE EC connects experts in community engagement, collaboration and team science.
- One of CE EC's main goals is to capitalize on successful local approaches for engaging community partners in research and to bring those approaches to a national level. Many CTSA Program hubs' community engagement programs have successfully built trusting relationships with underserved communities through inclusion in research design, clinical studies and the benefits of research.
- Goal: Stakeholders are engaged in collaborations to advance translation



Value of Community Engagement



Helping Basic Scientists Engage With Community Partners to Enrich and Accelerate Translational Research

Kost, Rhonda G.; Leinberger-Jabari, Andrea; Evering, Teresa H.

Academic Medicine. 92(3):374-379, March 2017.

2009-2014 CTSA / PBRN utilized navigators:

39 investigators pursued 44 preliminary projects

- 25 became 23 approved protocols and 2 substudies
 - 19 identified community partners
 - 9 named community partners as coinvestigators
 - 9 included T3-T4 aims
 - ✓ 7 secured external funding
 - 5 included a community partner as a coauthor



Community Engagement Contributes to Reducing COVID-19 Health Disparities



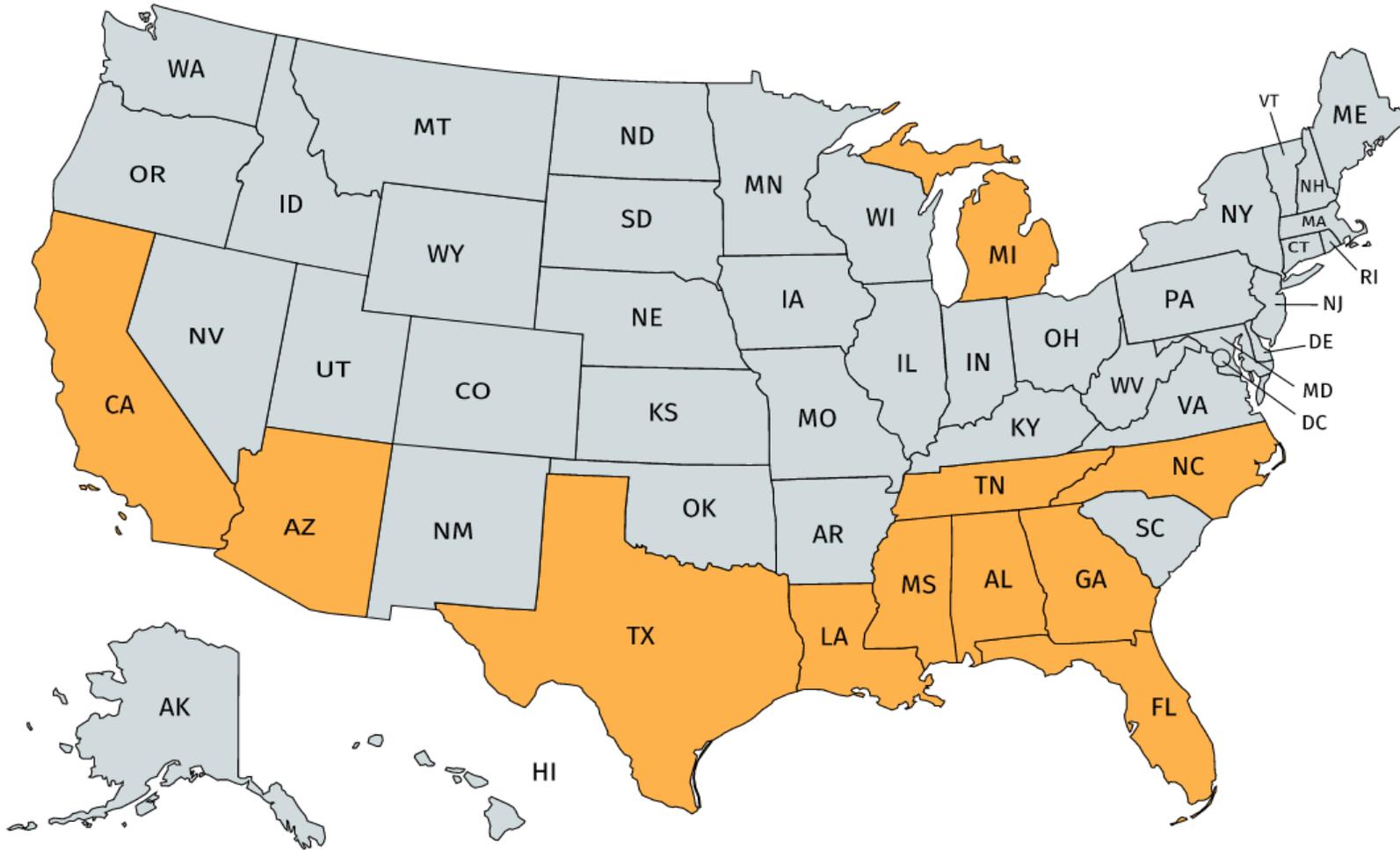
- **Community Engagement Alliance ([CEAL](#))**

- The NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities was stood up in July 2020 to lead outreach and engagement efforts in ethnic and racial minority communities disproportionately affected by the COVID-19 pandemic and in overall vaccine and therapeutic trials in the future.
- The CEAL research teams focuses on COVID-19 awareness and education research, especially among African Americans, Hispanics/Latinos, and American Indians —populations that account for over half of all reported cases in the United States.
- Ultimate goal: to provide trustworthy information through active community engagement with, investment in, and outreach to underserved communities, building long-lasting partnerships to improve diversity and inclusion in our scientific response to the COVID-19 pandemic
- Majority of sites have some connection to CTSA Program Hubs
- <https://covid19community.nih.gov/>



NIH-Funded Community Engagement Alliance (CEAL) Against COVID-19 Disparities

Vision: To become a trusted partner in community engagement efforts to improve inclusive participation in the scientific response to the COVID-19 pandemic and related disparities.



CEAL Awardee States

1. Alabama
2. Arizona
3. California
4. Florida
5. Georgia
6. Louisiana
7. Michigan
8. Mississippi
9. North Carolina
10. Tennessee
11. Texas



Identifying Treatments for COVID-19

ACTIV-1



Improving Outcomes of the Severely Ill

Convalescent plasma clinical trials



Understanding the Spread of the Virus

Sero-Survey



Understanding and Alleviating Barriers to COVID-19 Testing

RADx-UP



Raising Awareness and Educating About COVID-19

CEAL



CTSA Supported Community Engagement Tools

Trial Innovation Network

<https://ncats.nih.gov/ctsa/projects/community-engagement-at-CTSA-hubs-during-the-COVID-19-pandemic>



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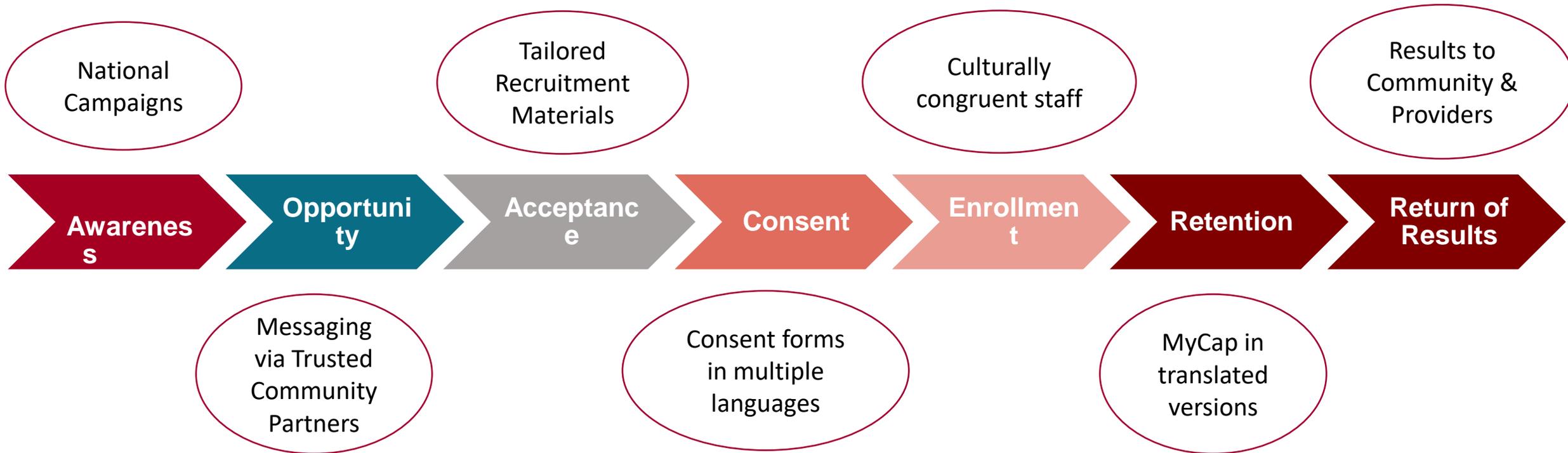
Vision and purpose

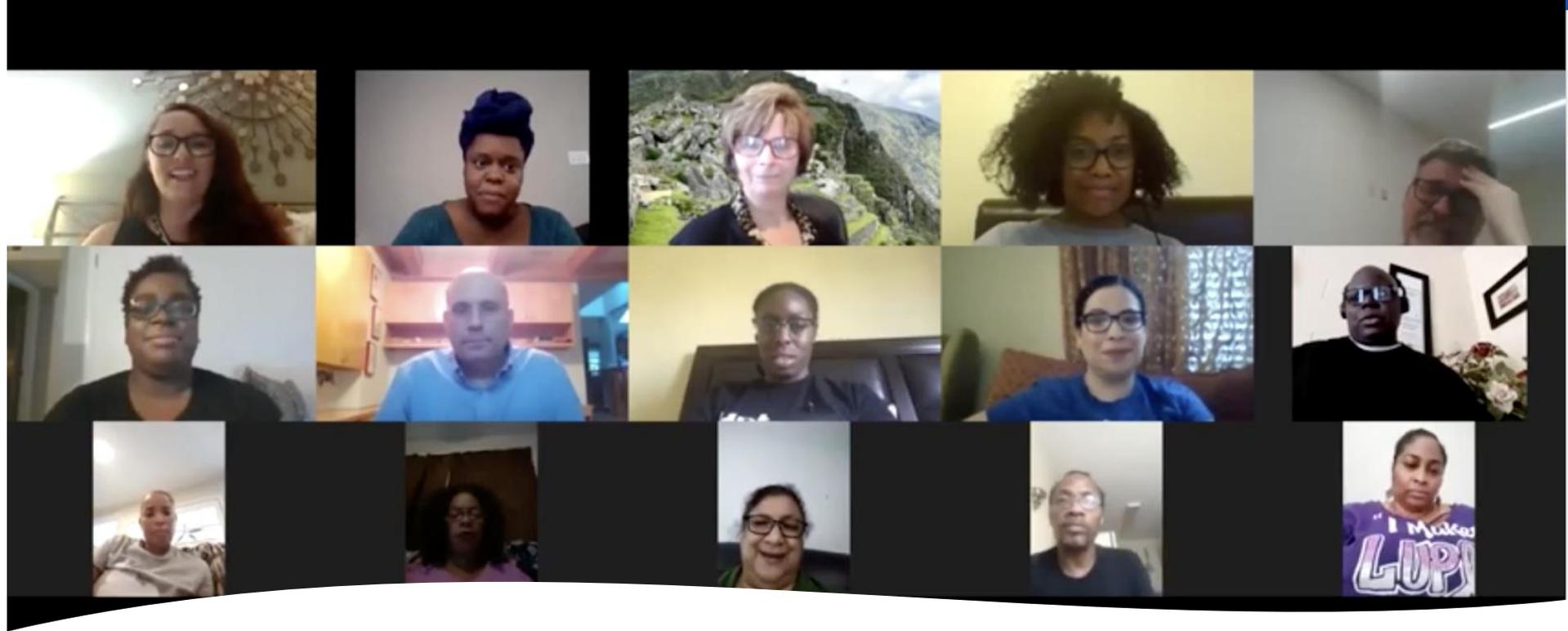
Goal is to positively impact human health by **improving participant enrollment and retention in multi-center clinical trials.**

Achieving this goal requires sophisticated **informatics-based recruitment tools** and **novel engagement approaches** to accelerate recruitment and retention.



Recruitment Continuum: Example COVID Vaccine Trials





Virtual Community Engagement Studio

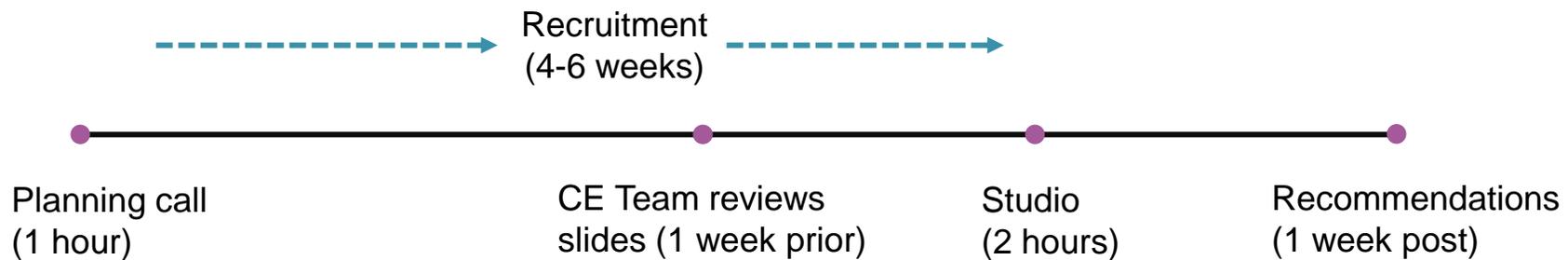
The Community Engagement Studio is a 1-time, 2-hour stakeholder consultative session with a researcher's population of interest:

- Conducted entirely via Zoom
- Allows inclusion of individuals from multiple sites/geographic location
- Increased flexibility for inclusion



The CE Studio Process

- Community Engagement Studio (CES) Team recruits and orients the Community Experts
- Prepares the research team to participate (reviewing slide set, coaching)
- Facilitates a focused discussion
- Drafts conversational summary and recommendations to inform the research project



Community Engagement Studios- guidance from CEs regarding clinical trial recruitment to date:

1. **Be aware of exclusion criteria** that limits participation.
2. **Remove systemic barriers** to participation (adding non-traditional times for study visits, transportation/stipends)
3. **Develop culturally tailored and translated** study materials being carefully not to pander.
4. **Partner** with respected community (national and local) organizations / contacts
5. **Train** study staff (e.g. cultural humility and bias) *Hire study staff **representative of community.**
6. **Disseminate** results in real time - full transparency to continue to establish and gain trust.

<https://victr.vumc.org/community-engagement-studio/>



ResearchMatch

¿En qué consiste ResearchMatch??

ResearchMatch es una plataforma útil en línea, gratis, segura y confidencial creada por instituciones académicas de todo el país que desean incluirlo en su misión de ayudar a que los estudios mejoren la salud en el futuro. ResearchMatch funciona al enviarle información por correo electrónico acerca de estudios que pueden ser adecuados para usted. [\[Preguntas frecuentes\]](#)

¿Por qué se necesita ResearchMatch?

Muchos estudios finalizan antes de tiempo porque no hay suficientes voluntarios para el estudio. Al mismo tiempo, las personas buscan estudios para participar, pero puede ser difícil encontrarlos. En consecuencia, las preguntas claves que pueden afectar la salud comunitaria quedan sin respuesta.

¿Es ResearchMatch para mí?

Cualquier persona que viva en los Estados Unidos, incluyendo Puerto Rico, puede unirse a ResearchMatch. Son bienvenidas personas de todas las edades y orígenes. Un padre de familia, tutor legal o guardián puede registrar a un menor de 18 años, o bien, registrar a un adulto que no pueda unirse por cuenta propia.

Son numerosos los estudios que necesitan voluntarios saludables así como aquellos que presentan todo tipo de condiciones médicas. ResearchMatch es una plataforma que pone en contacto a personas con los estudios de investigación que puedan resultar una combinación para ellos, por medio de una herramienta segura en línea para establecer coincidencias. Siempre tiene la opción de decidir qué estudios pueden interesarle. Si se une a ResearchMatch, no se le exige que participe en un estudio. ¡Usted siempre tiene la decisión!



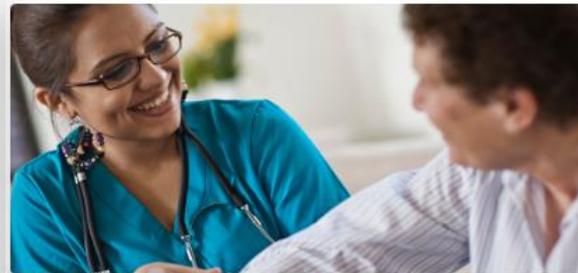
¿Cómo funciona ResearchMatch?



En este momento, dispone de:

voluntarios	investigadores	estudios	instituciones	publicaciones	mas estadísticas
146,308	8,599	774	176	454	

In English



¡Por medio de la investigación, usted se convierte en parte de la solución!

Los descubrimientos médicos no serían posibles sin voluntarios como **usted**.

¡Los investigadores necesitan su ayuda! La investigación sobre la salud cambia la vida de las personas a diario. Sin embargo, muchos estudios finalizan antes de tiempo porque no hay suficientes voluntarios. Nuestra plataforma le ayuda a encontrar el estudio de investigación que más se ajuste a sus necesidades. Los investigadores necesitan tanto personas saludables como personas que padezcan todo tipo de condiciones médicas. ¡Cualquier persona puede ser candidata para estas investigaciones!

Algunas partes de Researchmatch.org no se pudieron traducir al español en esta ocasión por razones técnicas. Pedimos disculpas por el inconveniente y agradecemos su paciencia.

Únase ahora mismo

- Supports recruitment of people that speak English or Spanish
- Matches Spanish recruitment messages with people selecting Spanish language
- Offers Volunteer support, education, and engagement in Spanish



eConsent



REDCap
REDCap features provide method to safely and securely consent COVID-19 patients



IRB Approval
eConsent is reviewed and approved for use



Contactless Consent
Participants consent to ORCHID via web link without direct study team contact



Part 11 & Regulatory Compliance
REDCap's mechanism for Part 11 compliance ensures eConsent documents are stored appropriately

eConsent has addressed the problems of:

- How to continue doing research studies during a pandemic?
- How to do studies with COVID-19+ participants and keep everyone safe, preserve PPE, and reach LARs, parents, translators, etc., when everyone is remote?

YouTube Channel for eConsent education videos:

https://www.youtube.com/playlist?list=PLiMIsWK5xzDsjG_slun3JTDJxlzVWOIR2

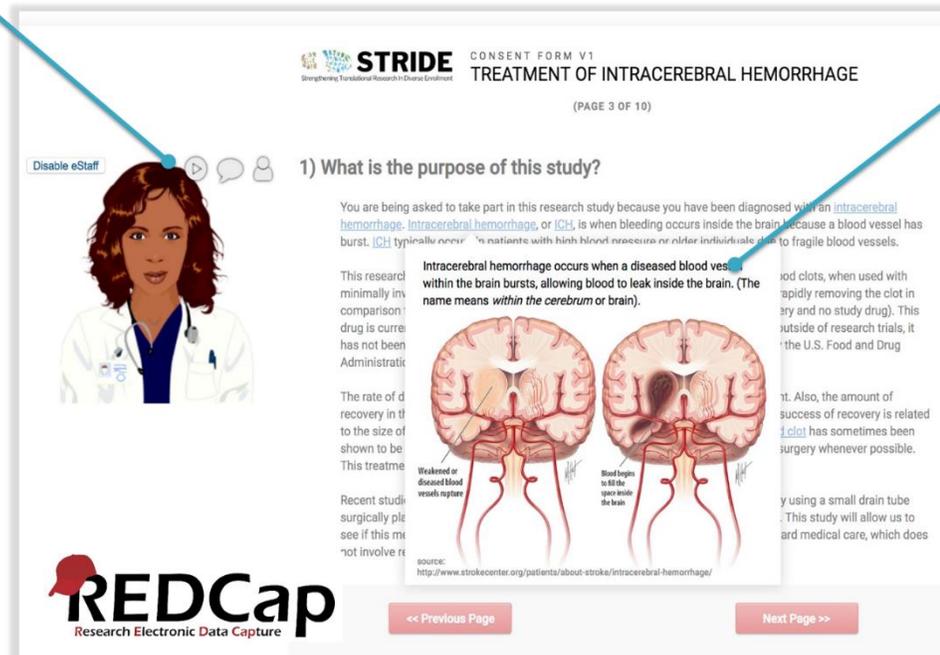
Redcap is a secure online database system designed to collect “capture”, store, organize and analyze data provided by patients in online questionnaires and data collection forms



Overview

Avatars

- Help guide through a consent document with voiceover instruction, clarification, or additional information.
- Customizable appearance/voice



STRIDE CONSENT FORM V1
TREATMENT OF INTRACEREBRAL HEMORRHAGE
(PAGE 3 OF 10)

1) What is the purpose of this study?

You are being asked to take part in this research study because you have been diagnosed with an [intracerebral hemorrhage](#), [intracerebral hemorrhage](#), or [ICH](#), is when bleeding occurs inside the brain because a blood vessel has burst. [ICH](#) typically occurs in patients with high blood pressure or older individuals who have fragile blood vessels.

Intracerebral hemorrhage occurs when a diseased blood vessel within the brain bursts, allowing blood to leak inside the brain. (The name means *within the cerebrum* or brain).

Weakens or dislodged blood vessel ruptures

Blood begins to fill the space inside the brain

source: <http://www.strokecenter.org/patients/about-stroke/intracerebral-hemorrhage/>

REDCap
Research Electronic Data Capture

<< Previous Page Next Page >>

Inline Descriptive Popup

- Customizable supplemental information(e.g., text definitions, images or video)
- Empowers research participants to decide how much and which information to view.



Multi-Lingual Module: allows research teams to more easily integrate different language versions of an instrument or eConsent.



METRICS



	Pre-pandemic (March 2020)	Post-pandemic (March 2021)
# of eConsent Projects REDCap Consortium-wide	3100	18,400
# of eConsent transactions REDCap Consortium-wide	140,000	1,215,000

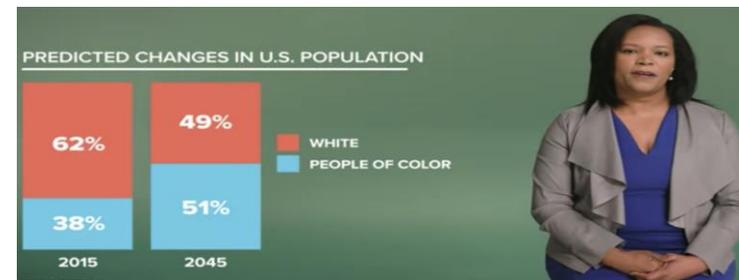
eConsent, Clinical Trials & a Pandemic





Enabling Minority Recruitment Skillsets

- **Identify** sites with capacity to recruit minorities
- **Support** research staff in minority recruitment
 - Massive training course in minority recruitment
 - 1663 learners, 250 completed 8 module course as of March 8th, 2021
 - Culturally tailored recruitment materials
- <https://www.coursera.org/learn/recruitment-minorities-clinical-trials>



RIC Covid consultations

RIC has participated in 24 consultations of COVID 19 proposals

- Examples of proposed interventions for COVID -19
 - Convalescent Plasma: provide antibodies from COVID patients
 - Immunomodulators: help decrease inflammatory pathways
 - Ramipril: Vasodilator, ACE 2 inhibitor (CHF, Hypertension)
 - Valproic Acid: Vasodilator, anti inflammatory , Ace 2 inhibitor (Seizures, Migraines)
 - Anakinra: Anti inflammatory, IL-1 inhibitor (Rheumatoid Arthritis)
 - Salmeterol: Inhibit viral replication, Beta antagonist, bronchodilator (Asthma, COPD)
 - Anticoagulants: Microvascular clotting associated with COVID
 - Vadadustat: Increases hypoxia-inducible factor (increased RBC production and oxygen delivery), mimics bodies response to altitude.



Launched February 2021!

The purpose of this toolkit is to share the community input we received, and the resources we have developed, that can help study teams conduct trials in a manner that is safe, trustworthy, and respectful of all participants.

Note that this toolkit is not comprehensive – only those areas in which the RIC has gained experience are shared here.

We encourage study teams to use this toolkit to fit their study-specific recruitment needs.

RIC COVID-19 RECRUITMENT + RETENTION TOOLKIT

Resources and community informed advice for
clinical trial recruitment during the pandemic

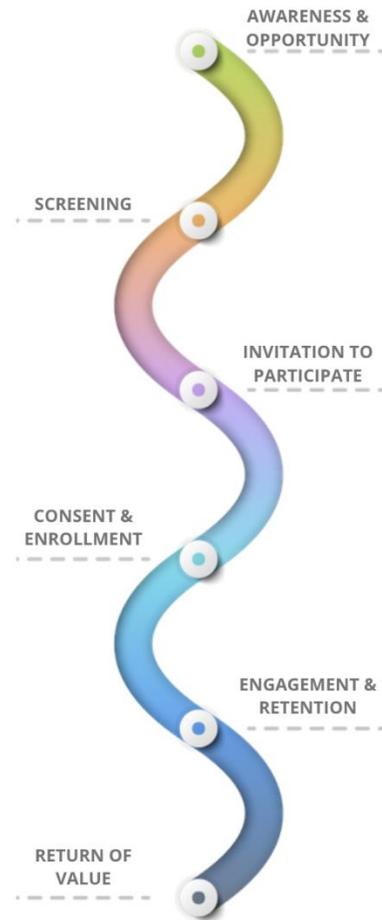


Download now from TIN Toolbox



NIH National Center
for Advancing
Translational Sciences

CONTINUUM OF CLINICAL TRIAL RECRUITMENT ACTIVITIES



Organized by the continuum of recruitment activities needed to complete a trial, we present the ideas, concepts, and materials that the RIC has successfully implemented to support recruitment and retention for COVID-19 trials, as well as for non-COVID trials taking place during the pandemic.



What's covered in the toolkit:

- ✓ Recruitment challenges during COVID-19
- ✓ Importance of Community Feedback
- ✓ Description of each recruitment continuum activity with related community expert feedback and RIC resources
- ✓ Best practices guides
- ✓ Strategies to increase inclusivity of disadvantaged populations in clinical research
- ✓ References



Toolkit Components

Advice and recommendations from a diverse group of patient and community stakeholders who participated in Community Engagement Studios conducted for multi-site COVID clinical trials.

RECRUITMENT + RETENTION COVID-19 TOOLKIT

06 AWARENESS & OPPORTUNITY

Awareness of available clinical trials is the first step in recruitment. The opportunity to enroll can be expanded by reducing or eliminating barriers that impede participation, and by designing materials, messaging, and recruitment strategies that are patient- and community-informed.

Lessons Learned

Problem: Fears regarding immigration status exposure – Potential participants are hesitant to join a study that might reveal their immigration status to enforcement agencies.

Solution: Apply for a Social Security Waiver to avoid having to report social security numbers when compensating participants for study participation. Remind participants that their information is confidential and will not be shared with outside agencies.

ADVICE FROM COMMUNITY EXPERTS

INCREASING AWARENESS AND OPPORTUNITY TO PARTICIPATE

General recommendations:

- Collaborate with local and state government and health agency leaders to highlight study launch in their own press announcements.
- Distribute recruitment materials to community and faith-based organizations, established coalitions, and other networks in order to reach traditionally underrepresented groups, including lower socioeconomic status (SES), BIPOC (Black, Indigenous, and People Of Color), and rural patients.

Healthcare Workers + Essential Workers:

- Utilize institutional leadership buy-in by pushing out promotional messaging at each individual clinical trial site.
- Partner with local group organizations (e.g., unions, childcare centers, restaurant industry, etc.) to expand study promotional reach.
- Consider recruiting participants via email and phone. Make sure you are available to answer questions and address concerns.

African American/Black Community Experts:

- Include primary care and specialist providers in the process to enroll chronic care patients to address patient concerns.
- Distribute information via testing sites, local clinics, and other community-based sites to reach highest potential patient population.
- Collaborate with BIPOC community to develop and co-brand materials and promote study via trusted thought leaders and established organizations that serve the community.
- Approach patients for enrollment upon hospital admission or early in the process to ensure ample time for decision-making.



Questions



To learn more about the RIC and the resources we offer, visit the [Trial Innovation Network website](https://www.trialinnovationnetwork.org), or contact us at info@trialinnovationnetwork.org

RIC COVID-19 RECRUITMENT + RETENTION TOOLKIT

Resources and community informed advice for clinical trial recruitment during the pandemic



Download now from TIN Toolbox



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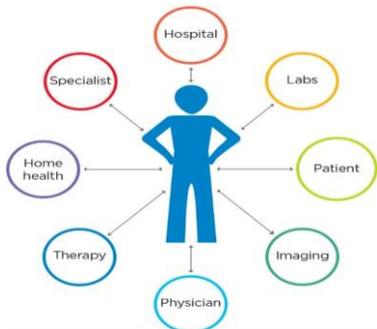
Collaborative Innovation Award Breast Cancer Disparities (U01TR002070)

**Tracy Battaglia, MD
MPH**

**Karen Freund, MD
MPH**

**Jennifer Haas, MD
MPH**

**Stephenie Lemon,
PhD**



**Patient Navigation
Guide and Support**



Registry Platform
RedCAP Patient Registry
Track Population Over Time



**Systematic screening to
address Social Barriers to
Care**

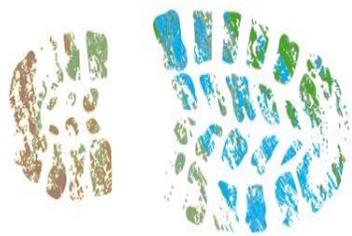
	Total n=182
Race	White 21%
	Black 53%
	Asian 13%
	Other Race 16%
Ethnicity	Hispanic 25%
	Non-Hispanic 75%
Preferred Language	English Speaking 95 (52%)
	Non-English Speaking 87 (48%)
Insurance Status	Private Insurance 53 (29%)
	Uninsured 1 (1%)
	Medicare 39 (21%)
	Medicaid 98 (54%)
	Other Insurance 25 (14%)

6 Clinical Sites



Driven by Community Partners





STRIDE

Strengthening Translational Research In Diverse Enrollment

GOAL: To improve recruitment of under-represented racial and ethnic minority group members in biomedical research by creating culturally and literacy relevant tools and interventions



University of
Massachusetts
Medical School

- **Simulation:** training research assistants to conduct **culturally appropriate** informed consent
- **Storytelling:** participant stories to **increase understanding** of the research process

VANDERBILT  UNIVERSITY
MEDICAL CENTER

- **eConsent** that integrates tools to increase **relevance and comprehension**
- **Community Engagement Studios** to provide feedback on intervention components.

UAB
SCHOOL OF
MEDICINE

- Intervention **pilot testing**
- **Integrating components** (storytelling, simulation, eConsent) **into existing protocols**



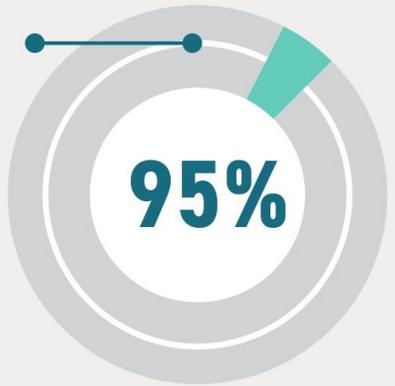
COLLABORATE

**MORE TREATMENTS,
MORE QUICKLY.**

That's the goal
of translational
science.

95% of diseases have no treatments.

THOUSANDS
OF DISEASES



ONLY

HUNDREDS
OF TREATMENTS



Translational Science is a Team Sport

“If you want to go fast, go alone. If you want to go far, go together” –
African Proverb



Acknowledgments

- NCATS DCI Colleagues
- Vanderbilt RIC team for sharing slides

