Leveraging Community Engagement and Informatics-Based Tools to Increase Participant Recruitment and Retention

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NCATS
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Presentation Outline

• Overview of Operational Challenges in Clinical Trials

• Trial Innovation Network: Opportunity to Address Challenges in Clinical Trials

• Informatics-based tools and resources used to enhance engagement, recruitment, and retention

• Engagement, recruitment, and retention methods
NIH Clinical Trials: Operational Challenges

NIH Budget – FY 2015

$3.2 B
~10%

Clinical Trials

$27.1 B

NIH tackles clinical trial shortcomings
The NIH is developing new tools, and overhauling its clinical trial funding system, to improve the stewardship of NIH-funded clinical trials.

Additional Data Would Enhance the Stewardship of Clinical Trials across the Agency

United States Government Accountability Office
Report to Congressional Committees

Discoveries → Better Health

- Laboratory
- Clinic
- Community

Seamless hand-offs and streamlined multi-site collaborations

Impactful implementation and dissemination

Clinicians and patients can use data in a smarter way

Workforce is prepared to advance translation
NCATS’ Response: Opportunities to Address Operational Challenges

Trial Innovation Centers (TICs)

- Center for Innovative Trials in Children and Adults
  
  **Principal Investigators:** Daniel Benjamin, Jr., M.D., Ph.D. (Duke) / Gordon R. Bernard, M.D. (Vanderbilt)

- Utah Trial Innovation Center
  
  **Principal Investigator:** Mike J. Dean, M.D.

- Johns Hopkins -Tufts Trial Innovation Center
  
  **Principal Investigator:** Daniel Hanley, M.D. (Johns Hopkins)

Recruitment Innovation Center (RIC)

- Improving Clinical Trial Education, Recruitment and Enrollment at CTSA Hubs

  **Principal Investigators:** Paul A. Harris, Ph.D. / Consuelo H. Wilkins, M.D.
Trial Innovation Network: Mission

Mission: to **develop**, **demonstrate** effectiveness of, and **disseminate** scientific and operational innovations that dramatically increase the efficiency and effectiveness of clinical trials:

- Critical to bringing new interventions to patients and communities
- Critical to promoting clinical investigation as a career path
Trial Innovation Network: Goals

• Create a national platform for clinical trials and studies that focuses on Operational Innovation and Operational Excellence
  
  • *Operational Innovation* – implement and test new approaches to operationalize clinical trials
  • *Operational Excellence* – finish studies on time and within budget

• Serve as a resource for NIH, industry, and other partners
Trial Innovation Network

CTSA Institutions

TIN Liaison Teams

Trial Innovation Network

Trial Innovation Centers (TICs)

Recruitment Innovation Center (RIC)

Study Support: NIH ICs, Industry Foundations

Partners Participants/ Patients Providers Public
Unique characteristics of the Trial Innovation Network

- Imbeds a scientific hypothesis within the overall science of the individual trial or longitudinal study it supports.
- All TIN projects have operational, design or statistical hypotheses, such as testing methods to find, enroll and retain special populations or developing new, less-burdensome trial endpoints.
- Disease agnostic.
- Only supports multi-center trials at this time.
How the TIN innovates the design and execution of clinical trials/studies

**Trial Designs**
- Use novel study designs
- Have compelling scientific endpoints
- Limit trial complexity
- Have realistic budgets

**Data Driven Approaches**
- Use EHR-based cohort discovery and site selection tools
- Model recruitment to minimize amendments

**Recruitment Planning**
- Engage stakeholders in study design (via Community Engagement Studio)
  - Develop tailored messages and recruitment materials
  - Evaluate recruitment; modify strategies as needed

**Strategically Designed Protocols**

**Analitics**

**Execution**

**Innovation**

**Proactive Recruitment Planning**

**TIC and RIC Collaboration**
The Trial Innovation Network at 18 months

- **Feb 2017**: Launched Network.
- **2017**: Investigators prepared NIH applications for submission; Initial studies launched in network; Est. TIN Liaison Teams.
- **2017-2018**: Implemented harmonized system & refine processes as needed.
The TIN at 18 months: developed integrated website for proposal submission

https://trialinnovationnetwork.org/
The goal of the RIC is to improve participant enrollment and retention in multi-center clinical trials and studies. This includes enrolling and retaining diverse populations using customized strategies, and conducting studies on methods to enhance recruitment efficacy and efficiency.

Achieving this goal requires sophisticated informatics-based recruitment tools and novel engagement approaches to accelerate recruitment and retention.
Paul Harris, PhD and Consuelo H. Wilkins, MD, MSCI
Vanderbilt University Medical Center
RIC Vision and Purpose

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

Achieving this goal will require sophisticated **informatics-based recruitment tools** and **novel engagement approaches** to accelerate recruitment and retention.
Key principles

- Respecting CTSA autonomy and diversity
- A focus on minority and underserved populations
- Making the most of electronic health records
- Preserving a disease neutral approach
- Focus on cost efficiency
- Respecting and returning value to participants
- Build on best practice (avoid reinventing the wheel)
- Evidence based…. What works? (test bed)
- Finite resources – scalability / tools
- Home for recruitment experts (across + beyond CTSA)
What are the CTSAs’ recruitment and retention needs and priorities?

**Surveyed** all CTSAs in Sept 2016 (83% response rate)

**Purpose:** landscape review / gather insights on needs and priorities

**We have used the results to:**
- Prioritize our services
- Engage with recruitment specialists
- Build on best practices
- Provide practical & meaningful support

“**Tools**” rank high on the list of needs

- Tools to support social media
- Evaluation of recruitment and...
- Training in best practices
- Tools to support EHR use
- Resources for online presence...
- Tools to assess participant...
- Creating or revising...

[Bar chart showing the frequency of needs with categories: Extremely, Very, Moderately, Slightly, Not at all]
Meeting recruitment goals is hit & miss

How Often Meeting Goals

- Never
- Rarely
- Sometimes
- Often
- Always

Difficulty Meeting Goals

- Very Difficult
- Difficult
- Neutral
- Easy
- Very Easy

Recruitment

Retention
Challenging Recruitment Experiences

Specific challenges:

- Complicated trial with narrow eligibility criteria
- National trial with minority recruitment needs
- Undiagnosed condition (i.e., prediabetes, mild hypertension, depression)
- Web-based screening misses large population
- Engaging vulnerable population
- Logistical issues; need pre-trial identification

How can RIC support?

- Toolkits
- Best Practices
- Educational Webinars
- Better software
- Standardized approaches
- Evaluation
TRIAL INNOVATION NETWORK

OPERATIONAL INNOVATION, EXCELLENCE, AND COLLABORATION

The Trial Innovation Network continues to accept new proposals! Click the button below to get started.

Get Started now!

Welcome!
The Trial Innovation Network is a collaborative national network that focuses on operational innovation, excellence and collaboration and will leverage the expertise and resources of the CTSA Program.

http://www.trialinnovationnetwork.org
RIC service offerings

Starting with Tailored Consults:
- Recruitment Plan
- Feasibility Analysis
- Engagement Studios
- Recruitment Materials

And Generalized/Scalable Services:
- Webinar Series (Dissemination)
- Scalable/Generalizable Tools
RIC Consultations

Read, Review, Investigate Listen Recommend Act

The protocol

Proposals

CTSA Clinical & Translational Science Awards

TRIAL INNOVATION NETWORK
RIC Team Recommends Existing Tools & Service Offerings

Goal: Right methods for the right project at the right time
RIC Team Recommends Existing Tools & Service Offerings

Goal: Right methods for the right project at the right time

RIC Team Listens for Generalizable Problems

→ Opportunities
→ Innovation
→→ New Services
Community Engagement Studios

Consultative model of engagement

• Expert panel selected based on project
• All phases of research
• Experts are not research subjects
• Researcher prep prior to meeting
• Focus on 2-3 main questions
• 1.5-2 hour facilitated meeting
• Follow-up with detailed notes

CES Use Case: MoTrPAC-Dan Cooper, UC Irvine

- Convened CE studio with 10 Latinos/Hispanics in Irvine, CA
- Identified barriers (time, transportation, biopsy, cost, distrust)
- Identified facilitators (community partners, sharing data, altruism)
- Recommendations:
  - Culturally appropriate messaging
  - Enhance logistics of access
  - Cross-cultural communications
  - Return of value to the community
The TARGET Trial
Treatments Against RA and Effect on FDG PET-CT
NIH-U01-AR068043

DSMB October 2017
TARGET Study – Other Identified Challenges

Challenges:

• Recruitment relying primarily on referrals from primary care physicians – need early approach mechanism
• I&E is challenging and information to participants is complicated
• Lots of sites, many with competing studies
• Short time frame
TARGET Study Participant Brochure:
Before & After

Review, Recommendations, Feedback, Recommendations, CAB Presentation, Feedback ....
RIC National Community Advisory Board

Goal: Provide meaningful input to ensure that the RIC’s strategies reflect the needs, priorities and values of the broader community.

The Community Advisory Board (CAB) provides feedback and advice to RIC on:

- Overall approaches to effective recruitment, retention and participant engagement
- Methods, templates and standardized approaches to recruitment, retention, and participant engagement;
- Study-specific input regarding proposals for which the RIC is providing consultation and/or services
- Inform creation of recruitment, retention and participant engagement materials and messages
TARGET Study – Provider Study App

Clinician Study App

Customized menu

Site specific contact information

New Scales
Very
Well
+ Baked
In Evaluation Metrics
TARGET Study - Competing Site Review

Generated Using A RIC Public Facing Tool
ResearchMatch & Trials Today
A ‘matching’ tool helping volunteers connect with research studies

A national consortium

Free, complementary recruitment service

Safe, Secure (VU IRB Oversight)

Institution-neutral, Disease-neutral
Los descubrimientos médicos no serían posibles sin voluntarios como usted. La investigación sobre la salud cambia la vida de las personas a diario. Aun así, los investigadores necesitan su ayuda. 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!

Para iniciar, por favor haga clic en el botón “Siguiente” que aparece a continuación. Únase a ResearchMatch. Es gratis y solo toma unos pocos minutos. Usted puede participar o registrar a alguien más como padre o madre, su tutor legal o guardián (cuidador).
Prioritize public and community awareness of research opportunities and potential for return of value.

19,444 recruiting studies registered on ClinicalTrials.gov looking for volunteers
3,486 sponsors organizations looking for volunteers
2,416 medical conditions

To end disease tomorrow, begin with Trials Today.
Thousands of organizations across the country are looking for people like you to take part in research studies. Whether you are looking for treatment, or want to help out with research that will improve treatment, diagnosis, and prevention, there are studies that need you!

We know figuring out where to start can be the hardest part about finding research studies you might like to join. That’s why we’ve made it easier for you to find the information you need. We made a quick way to search the thousands of studies available on ClinicalTrials.gov. By answering a few short questions, we can help you find a list of studies that may interest you.
Promoting Trials

- Campaign messaging and creative concepts
  - Created and refined with marketing company
  - Included community/participant input
- Campaign launched **May 2017**
- Facebook, digital and print ads designed to increase awareness and use of the Trials Today tool.
- Targeted by:
  - Demographics (age, gender, location)
  - Health Condition
  - Availability of actively recruiting studies
  - Geographic location (near CTSA institutions)
Want to see what trials may be out there for you?

Thousands of institutions across the country are currently recruiting volunteers to participate in research studies. Whether you are looking for treatment or want to help contribute to research that will further the advancement of treatment, diagnosis, and prevention, there are studies out there who need YOU. We know that figuring out where to start can be one of the biggest obstacles a Volunteer faces when searching for study opportunities, that's why we’ve made it easier for YOU to find the information you need! We created a quick and simplified way to search the thousands of studies available on ClinicalTrials.gov. By answering a few short questions we can help you find a list of studies that may be of interest to you.

ClinicalTrials.gov is a database of federally and privately supported clinical trials conducted in the United States and around the world. This information should be used in conjunction with advice from health care professionals.
1. Which of these statements sounds most like your reason for searching for studies?

<table>
<thead>
<tr>
<th>I have/had a disease or condition and</th>
</tr>
</thead>
<tbody>
<tr>
<td>➔ have already tried the currently approved treatment options and they are not effective/are no longer effective for me.</td>
</tr>
<tr>
<td>➔ I am interested in finding studies that test new treatments.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I was recently diagnosed with a disease or condition and</th>
</tr>
</thead>
<tbody>
<tr>
<td>➔ I am looking for treatment options even those that are not yet approved.</td>
</tr>
<tr>
<td>➔ there are no available treatments at all.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>I am not seeking any treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>➔ but am interested in contributing to research that could help other people in the future by serving as a healthy volunteer.</td>
</tr>
<tr>
<td>➔ but am interested in studies that evaluate ways to diagnose diseases, preventative measures, or screening procedures.</td>
</tr>
</tbody>
</table>

🌟 I understand how clinical trials work and would like to fine-tune the search myself.
1. Which of these statements sounds most like your reason for searching for studies?

- I have/had a disease or condition and
  - have already tried the currently approved treatment options and they are not effective/are no longer effective for me.

2. Are you open to studies that are still in a very experimental stage?

- Yes

3. Provide additional information

All of these fields are optional, but providing more information will increase the relevance of your results.

- What is your gender?
- What is your age?
- What medical condition are you looking for?
- What is your ZIP Code?
1. Which of these statements sounds most like your reason for searching for studies?

- I have/had a disease or condition and
  - have already tried the currently approved treatment options and they are not effective/are no longer effective for me.

2. Are you open to studies that are still in a very experimental stage?

- Yes

3. Provide additional information

   All of these fields are optional, but providing more information will increase the relevance of your results.

   - What is your gender?
     - Male

   - What is your age?
     - 40

   - What medical condition are you looking for?
     - diabetes

   - What is your ZIP Code?
     - 37212

   - How far are you willing to travel?
     - 25 miles

[View Results]
Efficacy and Safety of Finerenone in Subjects With Type 2 Diabetes Mellitus and the Clinical Diagnosis... Beyer Diabetic Kidney Disease

The purpose of this study is to evaluate whether oral finerenone (study drug), in addition to standard daily therapy, is effective and safe in treating patients with type 2 diabetes mellitus and diabetic kidney disease, when compared to a placebo.

Effect of Chronic ACE and DPP4 Inhibition on Blood Pressure Vanderbilt University Type 2 Diabetes Mellitus Hypertension

In this study the investigators will test the hypothesis that dipeptidyl peptidase IV (DPP4) inhibition attenuates the antihypertensive effect of angiotensin-converting enzyme (ACE) inhibition but not angiotensin receptor blocker or calcium channel blockade. The Investigators...

Dapagliflozin Evaluation in Patients With Inadequately Controlled Type 1 Diabetes Bristol-Myers Squibb Type 1 Diabetes Mellitus

The purpose of this study is to determine if adding dapagliflozin to insulin is a safe and effective therapy to improve glycemic control in patients with type 1 diabetes.

A "Real World" Trial to Determine Efficacy and Health Outcomes of Toujeo (ACHIEVE CONTROL REAL LIFE STUDY... Sanofi Diabetes Mellitus, Type 2

Primary Objective: Demonstrate clinical benefit of Toujeo in achieving individualized HEDIS HbA1c targets (<8% if age 65 years or with defined comorbidities (as listed in Appendix G) or otherwise <7%) at 6 months without documented symptomatic (BG 70mg/dl) hypoglycemia at any...

A Clinical Proof-of-principle Trial in Adult Subjects With Newly Diagnosed Type 1 Diabetes Mellitus Investigating... Novo Nordisk A/S Diabetes Diabetes Mellitus, Type 1

This trial is conducted globally. The aim of this trial is to assess the clinical proof-of-principle of NNC0114-0006 and liraglutide on preservation of beta-cell function in adult subjects with newly diagnosed type 1 diabetes mellitus.

Tocilizumab (TCZ) in New-onset Type 1 Diabetes National Institute of Allergy and Infectious Diseases (NIAID) Type 1 Diabetes Mellitus New-onset Type 1 Diabetes Mellitus T1DM T1D

Type 1 diabetes mellitus (T1DM) is an autoimmune disease. Based on previous research, study doctors think that giving medicines to affect the immune system soon after diabetes is diagnosed may stop, delay or decrease the destruction of beta cells, resulting in better glucose...
A case study for integrating a research data collection system with Epic

RESEARCHERS

Customize the MyCap app interface to fit the specific needs for your research project using our web-based manager. Features:

- add project participants
- create studies/surveys using REDCap
- create active tasks
- schedule when and how often tasks should appear
- send secure messages to individual participants
- send announcements to all participants
- create information screens
- create a custom theme

Participant data is synchronized to your REDCap project. Available to Vanderbilt research teams now. Coming soon to other institutions running REDCap.

PARTICIPANTS

If you are participating in a research project that uses MyCap:
1. Install the app
2. Open the app and tap the Join Project button
3. Scan the QR code that your project coordinator provided

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TRIAL INNOVATION NETWORK
Collaboration Webinars

Includes:

- Collaboration Webinars
- Network Open Forums
- Network Meetings
- Archived slide sets and recordings
Enhancing Minority Recruitment
Faster Together

Clinical Trial Participants %

- **Cancer**
  - **WHITE**: 85.6%
  - **AFRICAN AMERICANS**: 9.2%
  - **HISPANIC**: 3.1%

- **HIV**
  - **WHITE**: 62%
  - **AFRICAN AMERICANS**: 23%
  - **HISPANIC**: 11%

- **Cardio**
  - **WHITE**: 92%
  - **AFRICAN AMERICANS**: 6%
  - **HISPANIC**: 1%

### Drug Response

<table>
<thead>
<tr>
<th>THERAPEUTIC AREA/INDICATION</th>
<th>INDICATION/DRUG CLASS</th>
<th>OBSERVATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular (Hypertension)</td>
<td>ACE Inhibitor (Lisinopril)</td>
<td>No response in African Americans, Whites respond well</td>
</tr>
<tr>
<td></td>
<td>ACE Inhibitor (Trandolapril)</td>
<td>2-4 times higher doses required in African Americans to achieve similar level of response to Whites</td>
</tr>
<tr>
<td></td>
<td>Beta-blockers (Propranolol, Nadolol)</td>
<td>Less effective in African Americans than Whites</td>
</tr>
<tr>
<td></td>
<td>Calcium Channel Blocker (Diltiazam)</td>
<td>More effective in African Americans than Whites</td>
</tr>
<tr>
<td>Cancer (Leukemia)</td>
<td>Cytotoxic agents (6-MP, Methotrexate etc.)</td>
<td>Better survival in Whites than in African Americans or Hispanics</td>
</tr>
<tr>
<td>Central Nervous System</td>
<td>Antipsychotic (Haloperidol)</td>
<td>Asians experienced higher extrapyramidal symptoms than Europeans, and accordingly required lower doses</td>
</tr>
</tbody>
</table>

**Source:** Am J Hypertens. 11 (6); Hypertension, 26 (1); JAMA, 258 (18); Am J Cardiol, 256 (18); J Clin Oncol, 18 (4); and Psychiatric Practice (The IDEAS Initiative - Applied Clinical Trials)

**Table 2:** Examples of drugs with different responses in minorities.
Faster Together: Enhancing Minority Recruitment
(RIC Supplement)

Test innovative approaches within trials:
• Culturally-tailored messaging
• Clinical trial recruitment plans created with minority communities
• Training on approaches to engaging minorities and marginalized communities in clinical trials.

Via a web-based portal, disseminate innovations in minority recruitment and engage underrepresented communities

http://i0.wp.com/panafricanalliance.com/wp-content/uploads/2011/05/RacialDifferences.jpg
Faster Together: Enhancing Minority Recruitment

A1. Culturally tailored messaging
A2. Training recruiters in engaging diverse populations
A3. Stakeholder co-designed recruitment plans
A4. Disseminate evidence-based innovative strategies to whole community: fastertogether.org

Embedded Trials

Build Evidence Base for Strategies Enhancing Diversity in Trials
RIC is looking for studies

We will embed 1 (or more) of the following:

a) Culturally tailored messaging
b) Recruitment plans to enhance recruitment of minorities
c) Training of recruiters

If you'd like to embed one of our strategies to enhance minority recruitment in your study, go to:

https://is.gd/FASTERGETOGETHER

Questions: victoria.villalta@meharry-vanderbilt.org
Contact us at info@trialinnovationnetwork.org