

Map Measure Mobilize Recruitment Plans to Ensure Diversity

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Duke Clinical Research Institute

FROM THOUGHT LEADERSHIP
TO CLINICAL PRACTICE

Outline



- FDA Guidance and Action Plan



- Diversity Infrastructure for Clinical Research
- Map Mobilize Measure



- DCRI's Approach
 - Patient, Site, and Community Engagement
 - Case Study

ACTIV-6



- Q & A





DCRI Diversity and Therapeutic Goals



OUR MISSION:

To develop, share and implement knowledge that **improves health around the world** through innovative clinical research.



Cardiovascular



Respiratory
Medicine



Neurosciences
Medicine



Infectious
Diseases



Population
Health



Nephrology



Gastroenterology



Pediatrics



Musculoskeletal and
Surgical Sciences



Digital
Health



Research Opportunities

- **Health disparities research:**

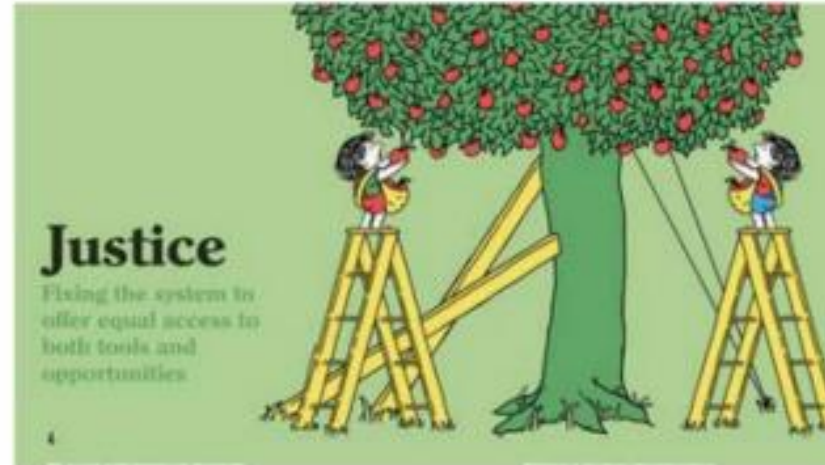
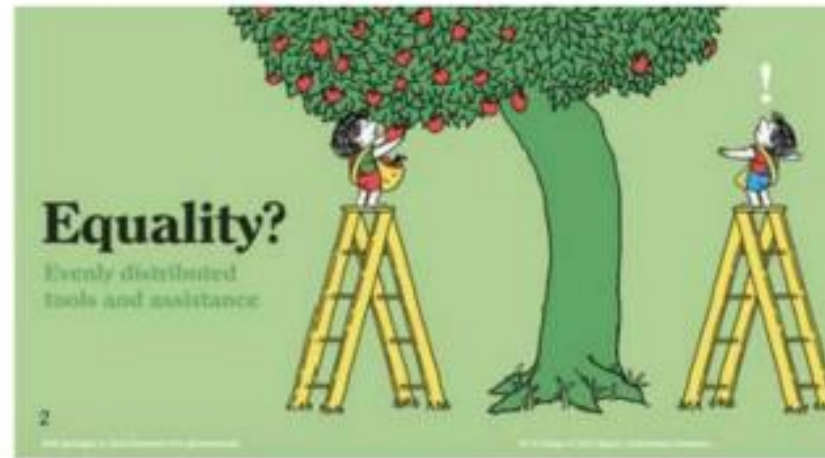
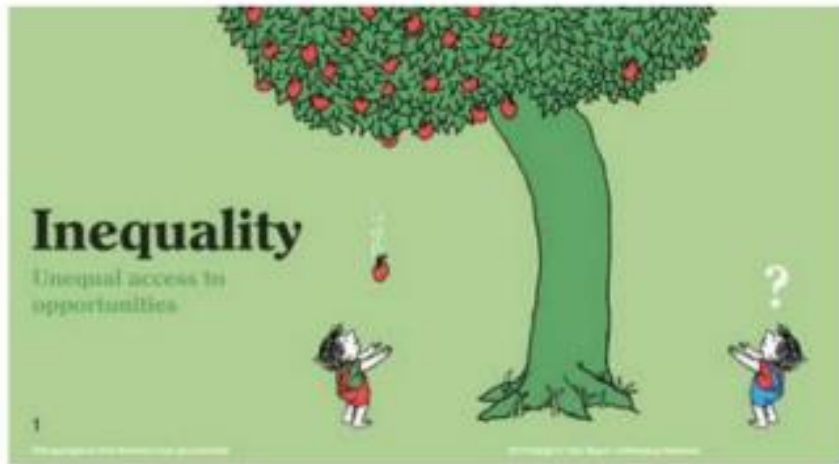
- Investigates a health difference that adversely affects individuals who have experienced greater obstacles to health due to their race, ethnicity, socioeconomic status (SES)

- **Health equity research:**

- Projects that develop and *evaluate evidence-based solutions* to health differences that are driven largely by social, economic, and environment factors



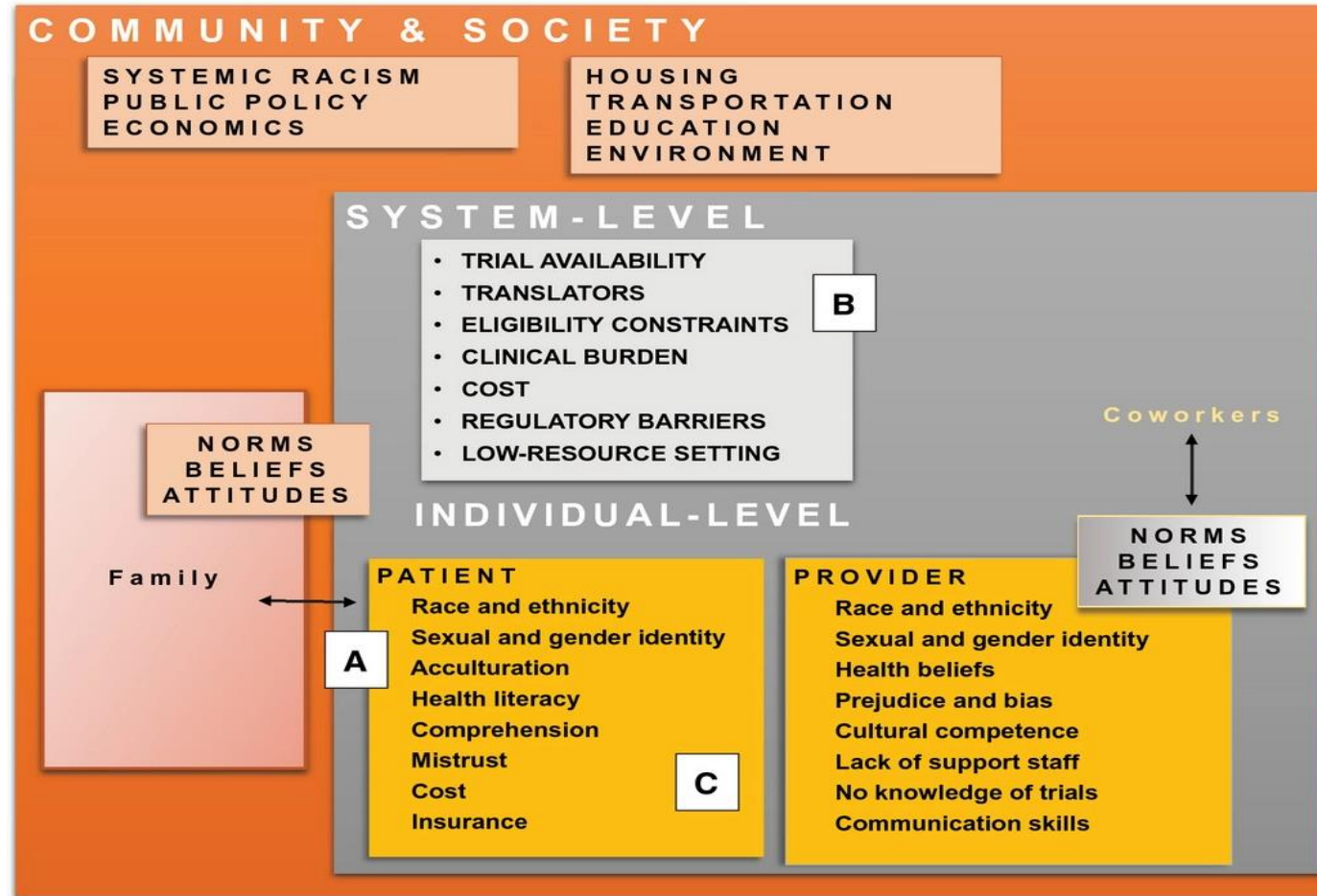
Equity, Diversity and Inclusion



<https://onlinepublichealth.gwu.edu/resources/equity-vs-equality/>



Barriers to Health Equity and Participation in Research



DCRI's Health Equity strategy to improve clinical research opportunities



Create diversity & inclusion targets for every new proposal



Establish future benchmarks for success & a system to track representation



Evaluate recently published DCRI trials for URM representation



Include equity discussions and targets in site selections/partnerships



Develop operational tools & templates that support HER aims



Identify expert partners to help advance URM/URE recruitment



Measure and test innovative strategies as secondary aims via pragmatic methods



Build evidence generation into our multi-site nationwide studies



Better understand patient and community concerns/engagement





FDA Guidance

- **Long History of Efforts to Improve Clinical Research Diversity**
- **Most Recent FDA's Diversity Plan Guidance (April 2022)**
 - *“FDA advises sponsors to seek diversity in clinical trial enrollment beyond populations defined by race and ethnicity, including other underrepresented populations defined by demographics such as sex, gender identity, age, socioeconomic status, disability, pregnancy status, lactation status, and co-morbidity.”*
 - Establishing a baseline, *“FDA encourages sponsors to leverage various data sources (e.g., published literature and real-world data) to set enrollment goals.”*
- **Clinical Trial Diversity Under section 3601 of Food and Drug Omnibus Reform Act (FDORA) (Jan 2023)**
 - **Requires sponsors of device and any phase 3 or other pivotal drug study to submit diversity action plans by the time they submit the study protocol.**
 - Focuses on demographic information such as age, sex, geographic location, socioeconomic status in addition to race and ethnicity.
 - Requirement will apply to clinical trials that commence enrollment **180 days** after FDA finalizes guidance, which is expected by the **end of 2023**.





FDA Diversity Action Plans / Next Steps

1. Sponsor's goals for clinical study enrollment, disaggregated by age group, sex, and racial and ethnic characteristics
2. Rationale for these enrollment goals, including information about the disease or condition and its prevalence or incidence among various demographics
3. How the sponsor intends to meet such goals, including demographic-specific outreach and enrollment strategies, inclusion and exclusion practices, and diversity training for study personnel.

➤ *Its these FDA Diversity Action Plan elements along with the motivations and supporting processes that we are focused on developing for ongoing clinical research, knowing success will take dedicated training, effort, time, and investment.*



Cost and Time



Impact Not
Immediately
Measurable



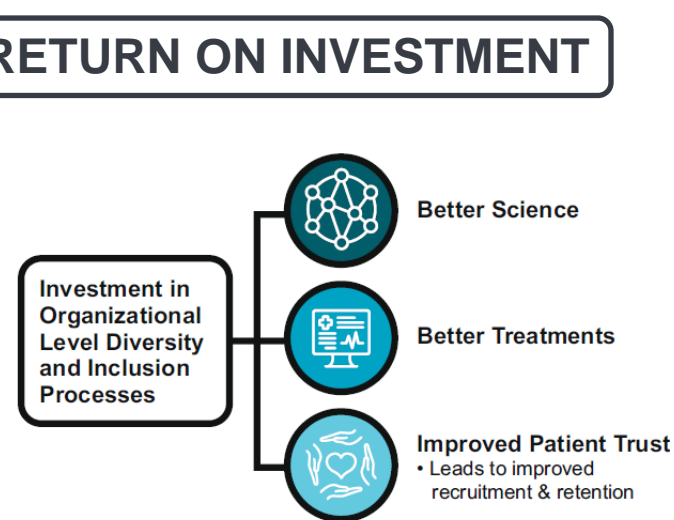
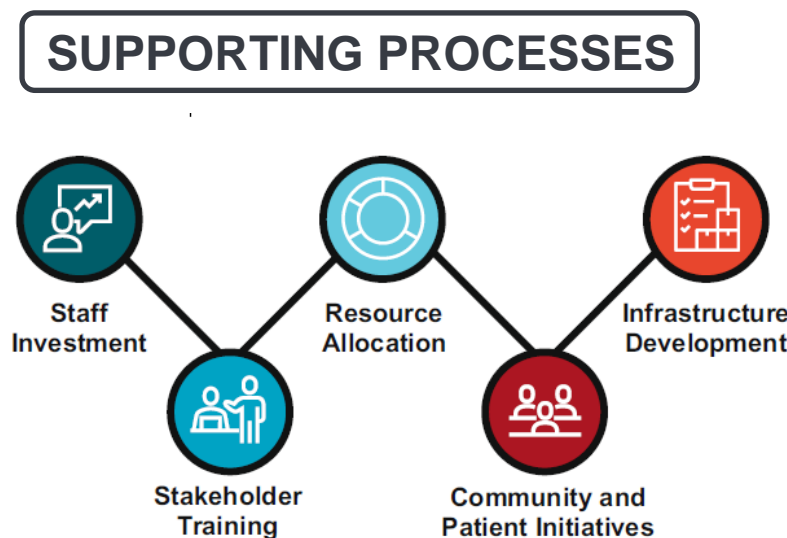
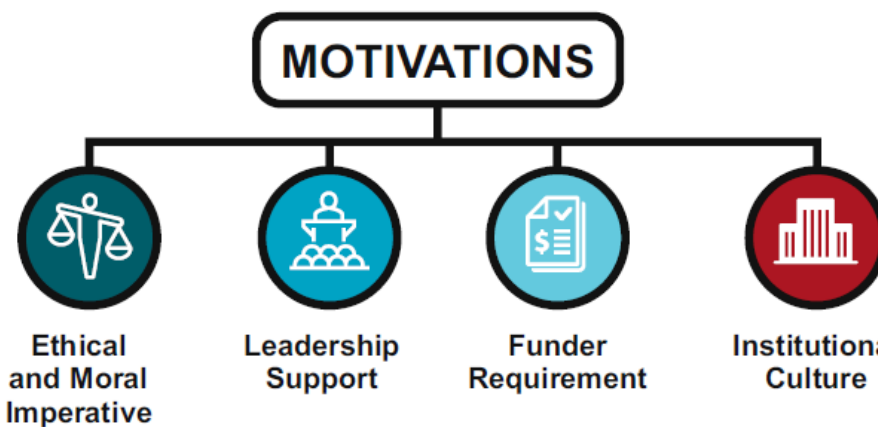
Employee
Unfamiliarity with
Diversity & Inclusion
Processes





Recent Learning & Guiding Principles

- Clinical Trials Transformation Initiative (CTTI) is a public-private partnership between Duke University and FDA where we continue to learn and recognize the importance of diversity and inclusion practices at the organizational level for us and our partners
- Motivations and supporting processes for organizational-level diversity and inclusion practices are key to creating sustainable change and return on investment





Challenges & Solutions

Challenge	Solution
Cost & Time	Develop Sustainable and Trusted Relationships for Real Change
Impact Not Immediately Measurable	Early Identification, Monitoring, and Optimization of Key Performance Metrics
Research Staff Unfamiliar with Diversity & Inclusion Processes	Providing Education and Tools Across Research Staff and Partners



Cost and Time



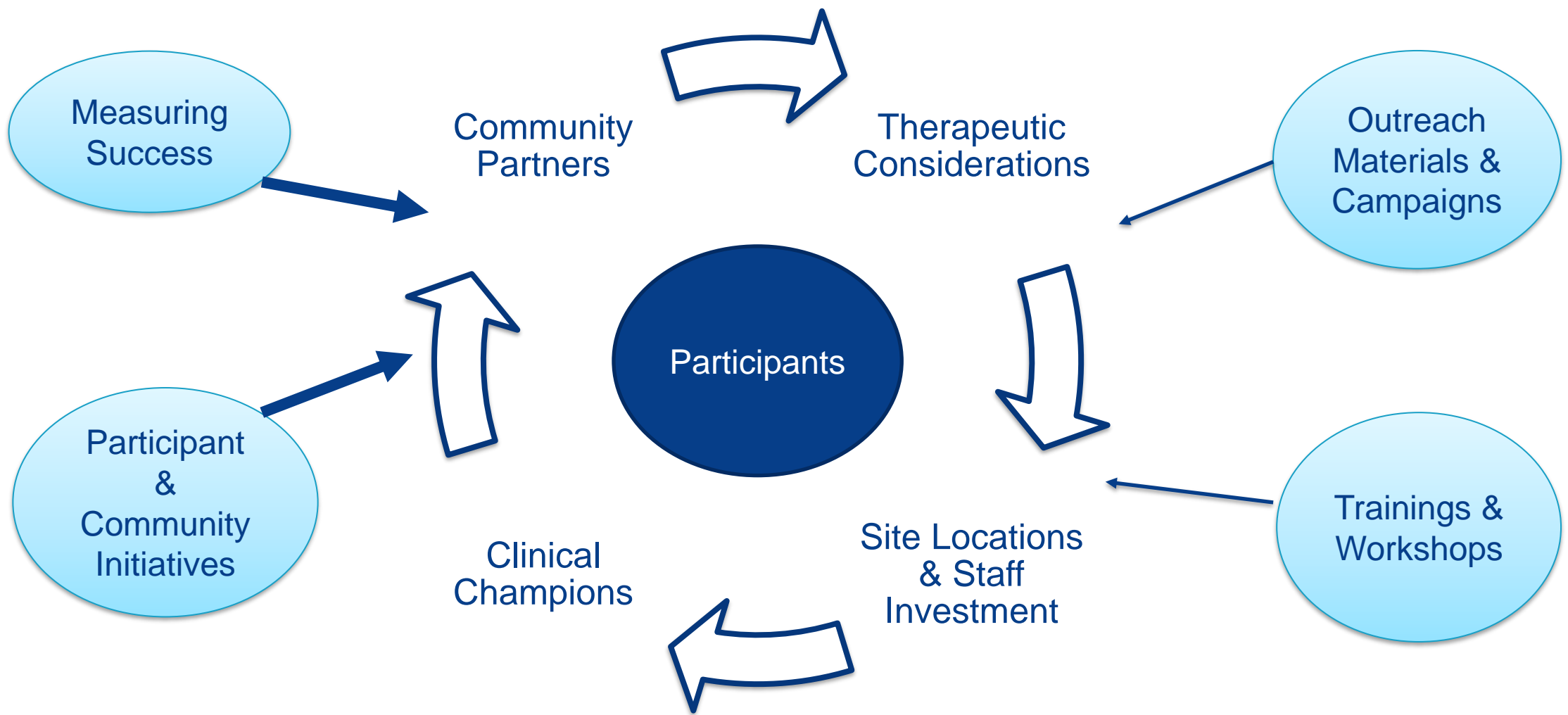
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Building a Diversity Infrastructure





Patient Outreach and Engagement starts with Study Goals/Plan

Set Diversity Goals

XX% of under represented populations including...

- Race/Ethnicity
- AGE
- LGBTQIA+
- Disabilities/Co-morbidities
- ZIP code

Why these populations?

- Overall disease burden or reflective of population?
- Equity Questions?
- Build trust in results?
- Lived experience?

Plan for Recruitment & Engagement of Diverse Sites/Participants

- Previous partnerships with advocacy orgs?
- Site PIs & Staff Reflective of Population?

- New partnerships?
- Site partnership plans?

Tailor Outreach

“Why participate” messages segmented by key participant audiences

Best communication and engagement channels segmented by key participant audiences

- Therapeutic and Clinical Knowledge –
- Targeted Sites/Participants
- Create Access To Research/Community



Then We Build and Support Site-Based Recruitment Tools that are intentional, meaningful, and measurable



Map

- Embed goals in the protocol & site recruitment plans
- Share goals with sites and community partners
- Match sites with community partners



Mobilize

- Create meaningful messages and materials
- Identify channels, tactics, & strategies
- Lead workshops that focus on recruitment challenges, successes, & lessons learned



Measure

- Identify key performance indicators (KPIs)
- Monitor and optimize strategies and tactics in real time based on KPIs
- Share results and build upon lessons learned





Our DCRI Approach to Reaching Diverse Communities



Hispanic

Unique Considerations

- Have not been asked to take part in research
- Possible language barrier
- Family and community oriented

Messaging

- Culturally intuitive Spanish translations
- Strong themes of family/community in copy & imagery

Platforms/Strategies

- Print, website, radio, digital & social media ads
- Community outreach

Black

Unique Considerations

- Hesitant to take part in research due to historic events
- Reside in urban areas more than rural areas
- Consume more media than other groups

Messaging

- Representation in imagery is key
- Strong themes of family/community in copy

Platforms/Strategies

- Print, website, radio, digital & social media ads
- Community outreach

Rural

Unique Considerations

- Barriers to internet access
- More time driving than other groups

Messaging

- Opportunities to take part from home for decentralized studies
- Access to care as part of the research study

Platforms/Strategies

- Print, website, radio, digital & social media ads
- Community outreach
- Radio is one of the most important tactics for this audience





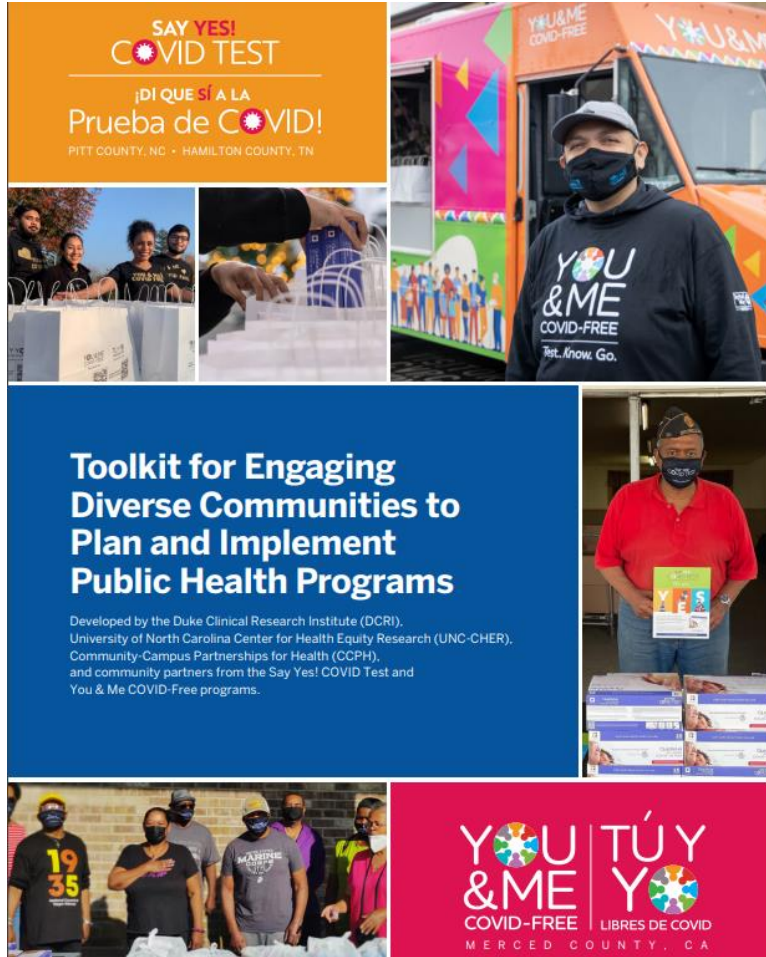
Leverage and Grow Community Partnerships

- National government supported agencies such as Community Engagement Alliance Consultative Resource (CEACR) & Community Engagement Alliance (CEAL) Against COVID-19
- National and local non-profit organizations
- National and local professional organizations such as Hispanic Nurses Association and ¡Salud America
- National and local faith-based organizations
- National and local patient advocacy groups
- Local health departments





Providing Site Recruitment and Retention Tools to Educate and Engage



- Shared enrollment & diversity goals
- Importance of diversity and inclusion
- Barriers to participation with suggested solutions
- Key messages
- Engaging with community partners
- Inclusive language guide
- Materials, tools, templates, kits, materials
- Outreach methods – paid digital & social media campaigns, radio





And a Participant Research Operations (PRO)- Call Center to Further Support Efforts

Overview



- Leader in de-centralized trials (first touch to consent/enroll to close out/thank you)
- Experts in participant research data collection (Medications, hospitalizations, quality of life, MACE, patient education)
- Large and small volume study capabilities

3 Types of Projects

- ✓ Traditional [*Site enrolls and stays involved*] (e.g. Ischemia and IPF/ILD)
- ✓ Hybrid [*Sites enroll and PRO completes/ rescue follow-up*] (e.g. TRANSFORM-Heart Failure)
- ✓ Direct to Participant [*Pt self enrolls/PRO enrolls and follow-up/rescue*] (e.g. ACTIV 6, HERO)

Study Benefits



- Ensure quality data to achieve study endpoints
- Reduce site burden for participant engagement
- Regulatory expertise w/ FDA validation of practices

Unique Capabilities



- Vigorous Interviewer Training for every study – ties to Diversity/Community
- Staffed 7 days/week, >70 team members, 16 hours/day and covers all U.S. time zones; Offers Spanish language
- Use a wide range of sponsor databases and EDC systems (CareEvo, Clintrak, eSOCDAT, IBM Clinical, InForm, IPO, Medidata, OC4, Outcomes Model, Qualtrics, RAVE, RedCap, Redcap cloud, Science 37, SignalPath, Verily, Vital Health)



ACTIV-6 Case Study: Demographic Diversity

Participant Demographic	Overall Number Randomized	Percentage of Total Randomized	% of US Population from United States Census Quick Facts	% of US COVID Cases from CDC COVID Data Tracker
Female	4,063	61%	51%	53.8%
Male	2,585	39%	49%	46.2%
Age 30-64	5,795	87%		49.3%
Age 65+	859	13%	17%	13.2%
White	4,933	74.6%	76%	53.7%
Asian	334	5%	6.1%	4.4%
Black/African American	504	7.6%	13%	12.4%
Hispanic/Latino	1,526	22.9%	16.5%	24.3%



Thank You!

