Case Study:

Leveraging An Affective Trust Framework To Enhance Clinical Trial Diversity

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Affective Trust vs. Cognitive Trust

Emotion

Affective Trust is Based On:



Social Relations



Human Emotions



Personal Goodwill



Genuine Concern

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Intrinsic Virtue

Logic

Cognitive Trust is Based On:



Utility



Rationality



Competence



Knowledge



Evidence

- Meyer E. Building Trust Across Culture. Insead Knowledge. 2015. https://knowledge.insead.edu/blog/insead-blog/building-trust-across-cultures-3844.
- Leadership Skills: The 2 Types of Trust & Why You Need Both. Investors in People. https://www.investorsinpeople.com/knowledge/leadership-skills-trust.

Key Elements of an "Affective Trust Framework" for Clinical Trial Diversity

Trust-Enabling Technology Sustained Affective Inclusive **Community Engagement Study Design**

• Smith D and Pope C. Clinical Trial Diversity: An Affective Trust Framework for Engaging and Recruiting Communities of Color (Acclinate Webinar). 2022. https://www.acclinate.com/post/clinical-trial-diversity-an-affective-trust-framework-for-engaging-recruiting-communities-of-color.

Sustained Affective Community Engagement

A Comprehensive Strategy

- Involves community members, patients, caregivers, patient advocates, healthcare providers, etc
- Is implemented across all aspects of research, (including study design, clinical endpoint identification, recruitment, retention, and result dissemination)
- Leverages trusted messengers and local leaders reflective of cultural norms and community demographics (e.g., "Activation Points")



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Case Study

- In mid-2022, Acclinate partnered with a DCT-focused CRO to enhance African-American representation in an ongoing Phase 3 clinical trial
 - Therapeutic Area: Neurodegenerative Disease
 - Majority Minority City: Birmingham, AL
 - Contract Timeframe: 4 Months

Services leveraged:

- NOWINCLUDED community platform (in-person and digital) to access and engage communities of color, raise awareness of disease state/clinical research, and present study participation opportunity
- Existing and new "activation points" to serve as trusted connectors to large numbers of the targeted demographic
- **e-DICT**, our patent-pending analytics tool that uses AI and machine learning to identify community members most likely to participate clinical research

Based on previous 12-month results achieved by the CRO, Acclinate's 4-month goal was to increase interest and number of participants willing to participate (as measured by a pre-screener)

Prior Efforts By CRO (over 12 months)

Criteria	Total	Per Month
Screened Participants of Color	43	3.5

Acclinate's Goal (over 4 months)

Criteria	Total	Per Month
African-Americans Accessed	10000	2500
African-Americans Engaged	2000	500
African-Americans Pre-Screened for Trial	43	11

Community Engagement

Boots-on-the-Ground Engagement

Acclinate organized 6 in-person events with a 100+ people in attendance.

Acclinate's Community Engagement Specialists leveraged their network to connect with **50+ community members**.

Digital Engagement

Social media marketing efforts resulted in 17,109 impressions.

#NOWINCLUDED community email campaign, resulting in **532 engagements.**









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Participants ma

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Pre-Screener Completion Statistics

164 NOWINCLUDED community members completed the study-specific Pre-Screener

86 community members were deemed eligible for the trial

78 community members were deemed ineligible

Breakdown of Pre-screen source

146 through boots-on-the-ground and #NOWINCLUDED community efforts

18 through digital marketing efforts

Make a difference in clinical research
Help millions of people like you.

Yes, I'll help

press Enter -1

2+ Would you like to share more information? If so, provide your e-mail

name@example.con

Submit

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Post-Screen Follow-Up

After each completed pre-screener, Acclinate reached out to community members within **24 hours** to discuss the next steps.

Those that passed the pre-screener were informed that a CRO representative would reach out to them, while those who did not were provided additional disease state-related information and told they would be notified of future trials for which they may qualify.

39.2%

of those who completed a pre-screener answered a follow-up call from Acclinate and expressed interest in participating in the trial as opposed to 18.4% who answered 1-3 calls from the CRO's central call center.

Deliverable Metrics

17,109	African-Americans reached with disease-related messaging
718	African-Americans with an increased awareness of the disease-state
718	African-Americans with increased awareness of the specific study
157	African-Americans pre-screened online for the study
65	African-Americans willing to participate in the study*
80	African-Americans passing the the online pre-screener for the study

Discussion Point: Conversion of "pre-screened" participants to "enrolled":

- What's the benefit of a "warm hand-off" to the sponsor or trial site?
- What's the short-term vs long-term benefit of early, sustained community affective engagement?



