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Title: The Research Equity and Diversity Initiative (READI): Changing the face of clinical research through community outreach and engagement

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Abstract

Current evidence underscores a need to transform how we do clinical research, shifting from academic-driven priorities to co-led community partnership focused programs, accessible and relevant career pathway programs that expand opportunities for career development, and design of trainings and practices to develop cultural competence among research teams. Failures of equitable research translation contribute to health disparities. Drivers of this failed translation include lack of diversity in both researchers and participants, lack of alignment between research institutions and the communities they serve, and lack of attention to structural sources of inequity and drivers of mistrust for science and research. The Duke University Research Equity and Diversity Initiative (READI) is a program designed to better align clinical research programs with community health priorities through community engagement. Organized around three specific aims, READI supported programs targeting increased workforce diversity, workforce training in community engagement and cultural competence, inclusive research engagement principles, and development of trustworthy partnerships

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Introduction

Failures of equitable research translation contribute to health disparities. Drivers of this failed translation include a lack of access to and diversity among research participants[1,2], a workforce that does not reflect the diverse communities it serves[3], mistrust in research stemming from historic injustices[4-6], and a lack of alignment of research priorities between academic research institutions and the communities they intend to serve[7,8]. Furthermore, the lack of engagement with the communities intended to benefit from clinical research limits the effectiveness of interventions and treatments[9,10], as does lack of attention to structural issues (uninsurance, social drivers of health, reimbursement policies, etc.) that affect translation[4]. These recognized and systemic problems negatively impact not only the quality of research data, but also the effectiveness and sustainability of implementation, and ultimately the overall health of these communities.

Reasons for lack of inclusion of underserved and historically marginalized populations in research are multifaceted[11-13]. These include well-known historic mistreatment of participants from underserved communities and vulnerable groups, resulting in well-justified mis- and distrust of research and the medical field more broadly[5,6,9]. A clinical research workforce that does not often reflect the communities from which they recruit further underscores the divide between the research establishment and the community[4,13,14]. Evaluation of the research landscape has indicated that improving inclusion in trial participation requires the diversification of the clinical research professional (CRP) workforce[2,14].

The long-standing[15-17] lack of purposeful inclusion of the community in the full research process results in research studies that do not reflect the pressing health needs of underserved and marginalized communities[18]. Meaningful community engagement must ensure that the community has a role in the decision-making process and that power and resources are shared bidirectionally with the community in ways that meet their needs, expectations, and goals[19]. Only through transparent and consistent engagement can we expect to see meaningful and sustainable change that translates to improved health and health equity for all communities.

In recent decades, numerous studies have focused on identifying and understanding the barriers and systemic conditions that perpetuate health disparities[4,10,20,21,22]. In a 2023 paper, Webb and Perez-Stable from The National Institute on Minority Health and Health Disparities described five key strategies for sustainably reducing health disparities: (1) increasing workforce diversity,

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equity, and inclusion, (2) ensuring inclusive research participation, (3) developing cultural competence and humility, (4) applying community-engaged research principles, and (5) going beyond "do no harm"[18]. To adequately address these issues, systematic solutions that ameliorate these facets must be implemented on local and national levels.

Here we describe the Duke University Research Equity and Diversity Initiative (READI), a community-partnered research initiative that aims to address health disparities through programs targeting increased workforce diversity, workforce training in community engagement and cultural competence, inclusive research engagement principles, and development of trustworthy partnerships.

Materials and Methods

READI was built upon existing partnerships within the Durham community that Duke investigators and academic partners (North Carolina Central University [NCCU] and Durham Technical Community College [Durham Tech]) have developed and sustained to enhance access to and engagement in research within the community. Expanding three existing collaborations with large community-based, multisectoral networks allowed READI to leverage trusted relationships to accelerate the program: 1) the AME Zion Health Equity Advocates & Liaisons (HEAL) Partnership, in which AME Zion churches in North Carolina serve as partners, co-learners, and advisers to Duke to ensure that clinical research participation accurately reflects the communities of North Carolina; 2) the Latinx Advocacy Team & Interdisciplinary Network for COVID-19 (LATIN-19), a multi-sector group focused on addressing health disparities within the Latine community as a result of the COVID-19 pandemic; and 3) the African American COVID Taskforce Plus (AACT+), a grass roots organization formed to encourage community conversations and share information through virtual town halls and social media dispelling myths regarding the COVID vaccination process.

READI proposed to develop programs that targeted the multifaceted issues in clinical research that contribute to health disparities through three specific aims, provided below. The aims were developed to achieve the overarching goals of READI, which included unifying schools, institutes, and centers across Duke University to ensure equity in access to clinical research for underserved populations and increase diversity in our research workforce and engaging our community in the development and implementation of programs, practices, and policies. The

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following aims will remove barriers to research participation, increase diverse participation in clinical research, build community trust, and reduce health disparities.

- Aim 1: Develop a sustainable and culturally relevant community-based outpatient clinical research site to increase awareness, access, and diverse participation in clinical research in Durham.
- Aim 2: Build upon new and existing community strengths, assets, and partnerships to build trust through bidirectional co-learning and community-based outreach and education with community experts.
- Aim 3: Develop, integrate, and evaluate diversity in a joint Duke University, NCCU, and Durham Tech led research workforce program.

To support these aims, READI created a multi-tiered and professionally diverse operational structure, including implementation and social scientists, medical faculty, operational and education leaders, nursing and public health professionals, project managers, communications specialists, and community partners, that ensured shared accountability, including dedicated working groups focused on each priority area and an evaluation team to develop metrics to measure impact (**Figure 1**).

To ensure that READI programming was informed by and represented community voices and priorities, a Community Advisory Committee (CAC) was created to provide critical community perspectives on all aspects of READI, from ideation to dissemination. Prior to the creation of the CAC, feedback from other research related community advisory groups was used to develop the goals and aims of READI, including the need for a community-placed clinical research site that was more accessible to the community than the existing research that largely occurs in clinical spaces. The CAC was engaged continuously to ensure programming, under the direction of the six working groups, was aligned with community health priorities, needs, and concerns, and to provide input to ensure the new clinical research site was more culturally appropriate than research spaces within existing clinical facilities and optimized to support community engagement events.

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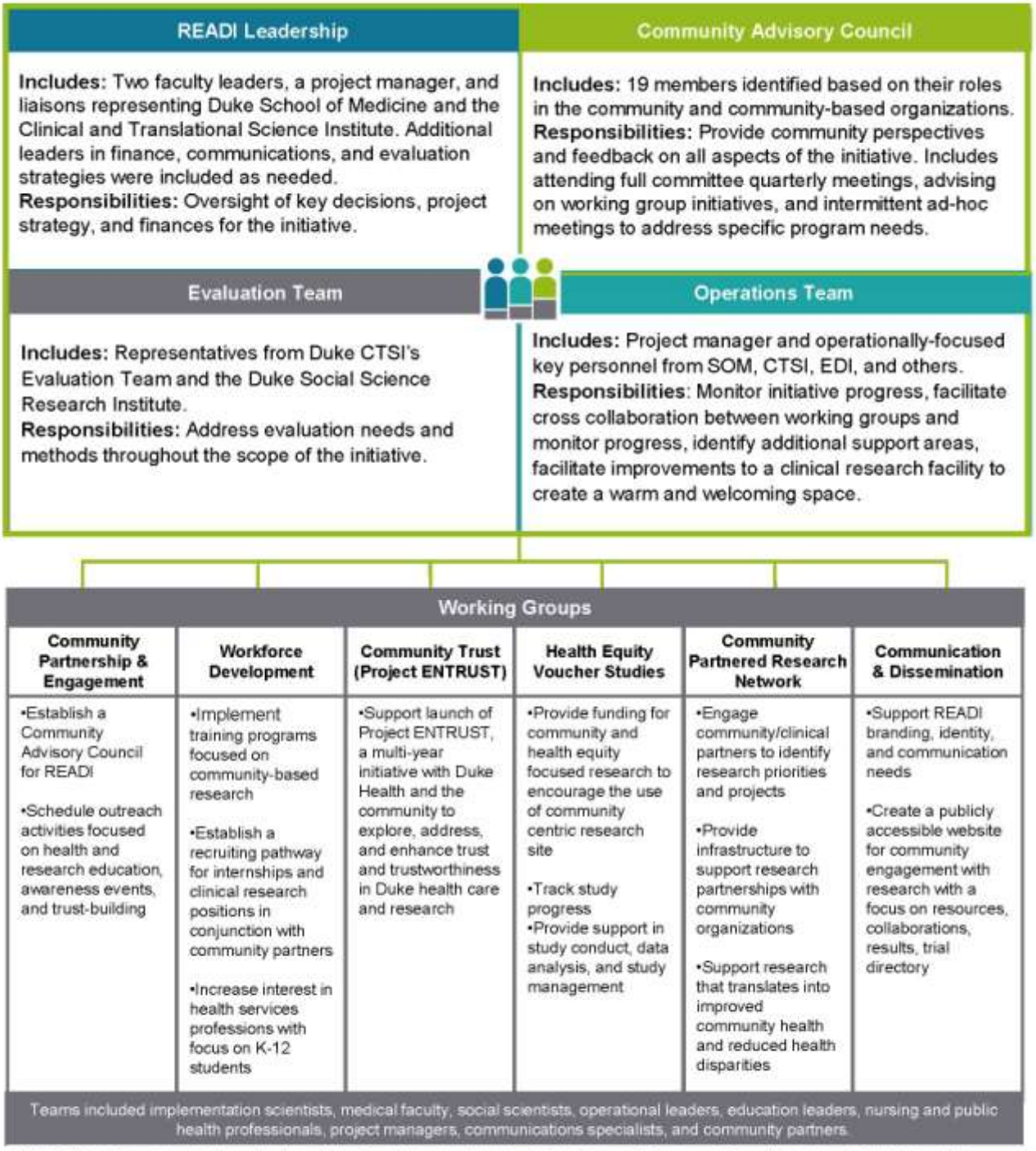
Figure 1: READI Organizational Structure



CTSI – Clinical Translational Science Institute; EDI – Equity Diversity Initiative; READI – Research Equity and Diversity Initiative; SOM – School of Medicine

To address the specific aims and goals of READI, the *5 W's of Racial Equity in Research Framework* set the foundation for integrating equity in research processes, environments, and among the research workforce[23]. Over time, and with CAC input, six working groups crystallized

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around the following themes: (1) community partnership and engagement, (2) workforce development, (3) community trust (Project ENTRUST) (4) health equity vouchers, (5) community partnered research network, and (6) communications (**Figure 1**).

Led by one faculty member and a project manager, working groups developed individual goals, created and implemented strategies to address issues within their focus area, and contributed to the initiatives of other working groups. To monitor progress and facilitate cross collaboration between the working groups, operational team members attended all working group meetings, and all working groups' leaders met monthly to discuss progress, activities, and future needs.

READI maintained a focus on evaluation across all stages of its development. At the grant proposal stage, an initial logic model (**Figure 2**) was developed for an early conceptual foundation. The 1-3 year indicators primarily address outputs, as the first three years had a strong focus on establishing READI processes; the >3 year indicators refer solely to outcomes intended to result from READI implementation. This logic model was further developed in the first year of the initiative to more directly specify activities and organizational structure as it developed, to more clearly outline and distinguish between intended outputs and outcomes, and to develop a more incremental view of intended outcomes (see **Supplemental Figure 1** for the revised logic model). Additionally, the evaluation team collaborated with READI working groups to develop evaluation questions for individual working groups and the overall initiative. To complete this, the evaluation team proposed sets of initial focal questions based on early-stage READI planning meetings, hosted structured discussion and provided asynchronous input mechanisms with individual working groups and the full team, and refined questions to reflect key identified needs. These questions served as key guideposts for all teams, helping to define areas of beneficial strategic inquiry.

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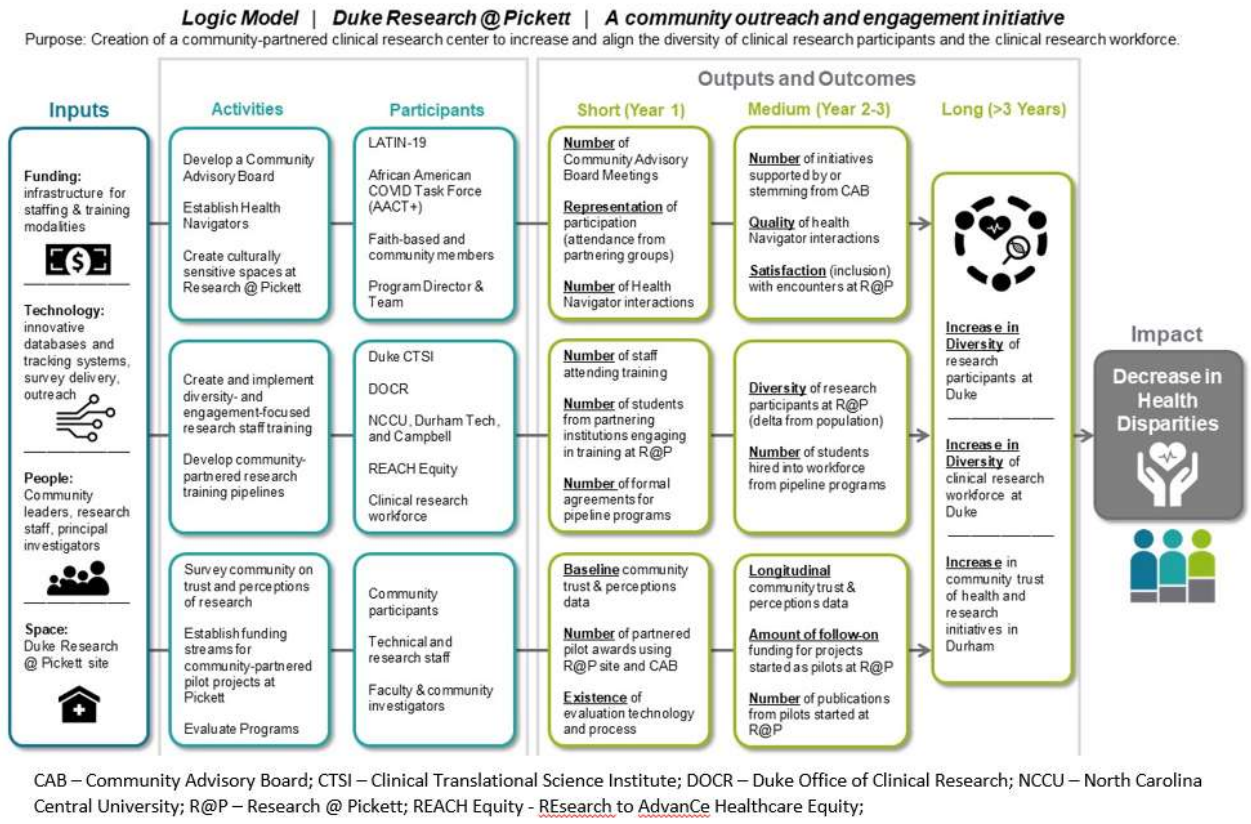
Figure 2: Initial READI Logic Model



CAB – Community Advisory Board; CTSI – Clinical Translational Science Institute; DOCR – Duke Office of Clinical Research; NCCU – North Carolina Central University; R@P – Research @ Pickett; REACH Equity - REsearch to AdvanCe Healthcare Equity;

In mid-term and later stages of READI, the evaluation included numerous specific empirical processes to examine process and outcomes. This included: investigating the implementation and effect of voucher-supported study teams through longitudinal semi-structured interviews, exploring the experience of study participants through a mixed-method survey and interview design, understanding the effect of workforce development outreach using surveys implemented across programs, and assessing the overarching facilitators and barriers to READI's success through a series focus groups implemented with working groups and the CAC. Evaluation processes were informed by translational science principles. For instance, evaluation infrastructure and processes were intentionally flexible to accommodate and reflect changes in program design and stages of development, informed by a focus on the principles of efficiency and rapid response. The close collaboration across READI working groups in evaluation design reflected tenets of cross-disciplinary team science.

Results

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Key process milestones and outputs, as outlined in **Figure 3**, indicate READI progress and focus. Here, we describe efforts for the three aims:

Aim 1: Develop a sustainable and culturally relevant community-based outpatient clinical research site to increase awareness, access, and diversity of participants in clinical research in Durham.

Based on feedback from multiple community advisory boards leading up to the READI program, the lack of a more accessible site for research was identified as a barrier to community members engaging in research at Duke. The Duke Research at Pickett (R@P) site was chosen based on the community-placed location, parking accessibility, and sufficient space to support research activities and community engagement activities simultaneously. R@P was subsequently renovated with guidance from the READI CAC. The fully furnished space, including murals from a community artist and the Durham School of the Arts Mural Club, community-focused photographs, a pollinator garden, and a Little Free Library, is now available for researchers and/or community organizations to reserve at no cost for events intended for general health education and to increase awareness of and engagement in clinical research. The transformation and evolution of the site after COVID is further described in Van Althuis L, et al, 2025[24].

Based on CAC input, READI's aim of developing a single culturally relevant community-based outpatient clinical research site was felt to be insufficient to fully support the breadth of

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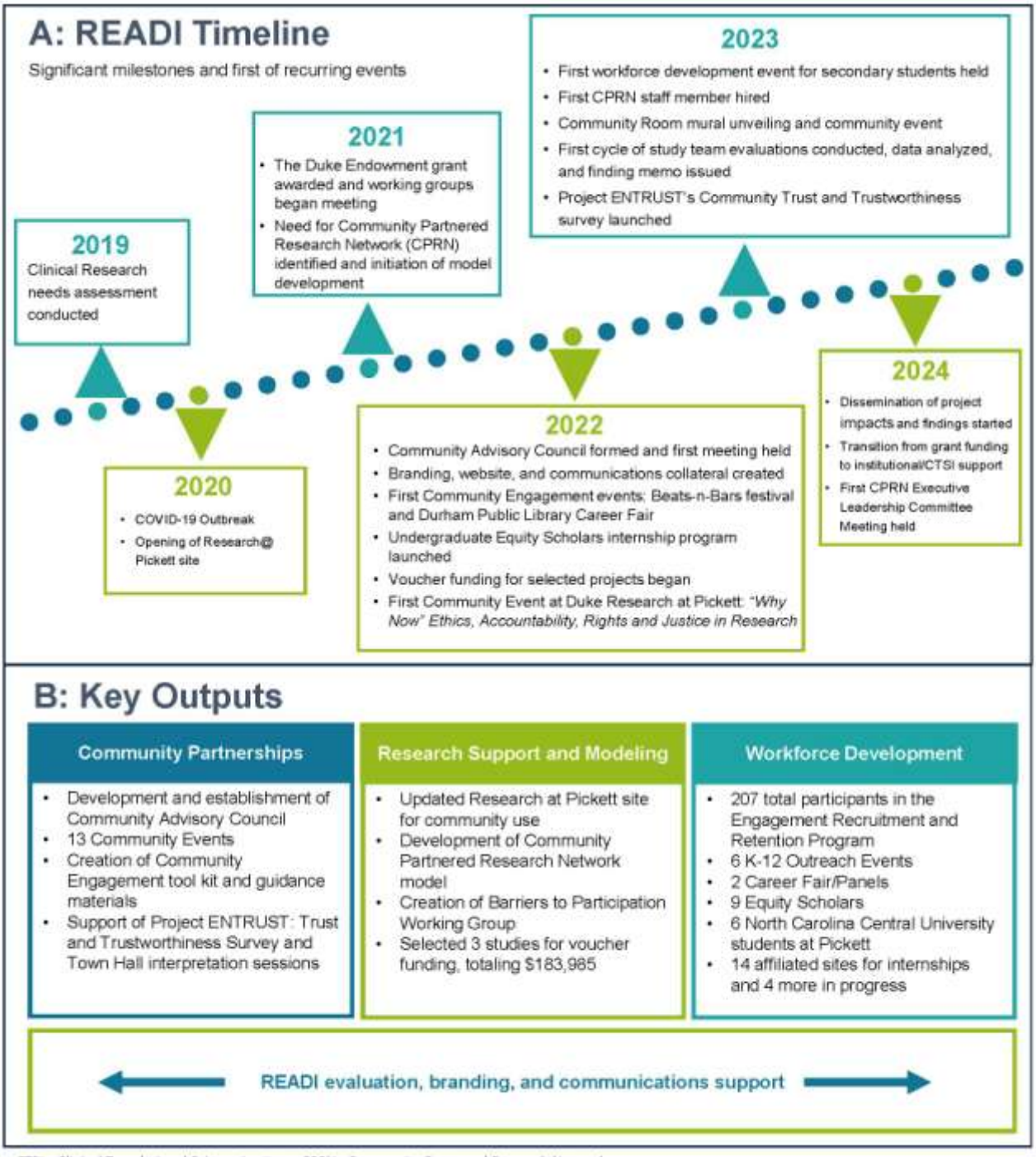
Figure 3: Timeline and Key Outputs for READI. A) READI implementation timeline; B) Key outputs achieved through READI



community-partnered research projects. While the CAC felt the R@P site was responsive to feedback on barriers to engaging in research at the primary Duke University Hospital and associated clinics, there was also a recommendation to address a need to decentralize research away from primary academic sites. After further discussion and review of existing successful

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decentralized community-engaged research programs, a Community Partnered Research Network (CPRN) was proposed. The CPRN was established with the goal to better facilitate the engagement of community-based clinics and organizations in the research process. While still in development, it aims to create sustainable processes and shared governance to support equal collaboration among academics, community members, and organizations. Factors and challenges identified in early CPRN development, such as limited bandwidth for partners, competing priorities, and the time needed for relationship-building, informed the intended future direction of the CPRN. CPRN activities will mirror those of a Clinical Research Organization providing important infrastructure to complement efforts of other existing programs/initiatives, and to add value, minimize redundancy, and improve navigation of resources for community organizations interested in engaging in their own research programming. Current CPRN partners represent diverse populations, including faith-based, LGBTQ, pediatric, and disability-focused organizations as well as public health offices and federally qualified health centers.

Aim 2: Build upon new and existing community strengths, assets, and partnerships to build trust through bidirectional co-learning and community-based outreach and education with community experts.

Outreach and Education

In collaboration with the CAC, the Community Partnership & Engagement working group organized and/or participated in 14 outreach events focused on health, research education, and awareness. Activities included: music festivals, blood drives, faith-based programs, and READI-organized, community-specific events held at the free-standing R@P site.

Voucher Program

An Engagement Voucher Program was developed to invest in community-partnered research projects aligned with community health priorities. Vouchers provided study teams with financial assistance to access staff support and/or to utilize space at the R@P facility. Through a request-for-proposals process, five studies were selected for their focus on increasing diverse participation in clinical research and promoting outreach activities that increase awareness, education, and participation in clinical research among underserved populations. These projects focused on health conditions disproportionately affecting Black/African American communities. Throughout the implementation of the voucher program, READI identified and addressed

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challenges related to integration of READI-supported core research team processes with pre-existing study operational plans.

Trust and Trustworthiness Survey

Project ENTRUST, a partnered program with READI, Duke Health, and the community, was created to assess trustworthiness and factors contributing to mistrust and lack of trust in health care and medical research at Duke Health. It uses a mixed-method collaborative approach to assess and enhance trustworthiness in health care and research at Duke. In the first wave of surveys, more than 6,000 respondents (composed of a mix of Duke patients and employees, community members, and community-based organizations) addressed questions to understand evidence of, and factors underlying, trust and trustworthiness or the lack thereof. The survey integrated existing measures of addressing trust, such as the Medical Mistrust Index[25] and the Research Engagement Survey Tool (REST)[26] with adaptations and augmentations informed by local institutional priorities and input from other university/health system researchers and community members to ensure clarity and comprehensibility[27]. Feedback from six town hall sessions, conducted in both English and Spanish, provided opportunities for attendees to participate in the interpretation of survey results. While this project is ongoing, early results have highlighted key areas within communication, transparency, and community engagement that are essential to building trustworthiness within our own institutions.

Aim 3: Develop, integrate, and evaluate diversity in a joint Duke University, NCCU, and Durham Tech led research workforce program.

To address lack of diversity in the clinical research workforce, READI's initial efforts focused on developing sustainable career pathways for students from the local community. Two internship opportunities developed in collaboration with Durham Tech and NCCU, both based at the R@P site. The NCCU Clinical Research Sciences Program internship (n=6) provided hands-on experience at R@P and other Duke research sties. The Durham Tech Clinical Research Equity Scholars Program internship (n=9) emphasized equity-based research training. A Professional Development Workshop series, offered through the Duke School of Medicine Clinical Research Internship Portal, was developed to provide tools and resources to prepare college students for entering the job market and/or workplace. Thirty-six students have completed the training. The Engagement Recruitment & Retention program, originally designed for Duke clinical research professionals, was expanded under READI and offered to students

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from Durham Tech and NCCU. To date, 202 individuals (including 19 students) have participated. Augmenting these programs, the READI team participated in several career fairs offered through the Durham Public Library, the Duke Bridging the Gap to Enhance Clinical Research program, NC Biotech's Contract Research Organization Collaborative, and NCCU to raise awareness of and increase interest in clinical research as a profession.

The READI CAC identified a need to begin clinical research career outreach at a younger age, reaching back to middle and high school students. In response, READI developed partnerships with a range of youth and community programs including the Duke Building Opportunities and Overtures in Science and Technology (BOOST) program, Duke Health Profession Recruitment and Exposure Program, West End Community Foundation, American Heart Association, and North Carolina Area Health Education Center. READI partnered on seven events introducing clinical research within the K–12 STEM landscape. Process evaluation highlighted challenges centered on the complexity of planning events (i.e., job fairs and youth-focused educational events) with multiple partners, helping to ensure ongoing learning.

Key Facilitators and Challenges to Implementation

Across these initiatives, numerous factors both facilitated and challenged implementation. Across working groups, key facilitators of success included: receiving and listening to community input; the diversity of thought informing READI initiatives beyond community input, including research personnel and faculty from varied disciplines and backgrounds; and intentionally integrating individuals and entities with existing READI-relevant knowledge and infrastructure from the start to provide a strong foundation. In the case of READI, a strong basis within the Clinical and Translational Science Institute, which already had READI-relevant knowledge and infrastructure, diversity among personnel involved, and strong community connections, provided a valuable organizational base. READI also experienced some challenges. Updating the R@P clinic improved access to clinical research in many ways, including free, surface lot parking, and comfortable and welcoming environments which community members helped to craft. However, a suburban site distanced from both urban and rural communities and without direct co-location with public transportation highlights remaining unmet needs.

Early Outcomes Achieved

In its first three years, READI placed a priority on developing mutually supporting and community-informed efforts poised to increase diversity in research participation, the research

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workforce, and trust in research. These processes take time to develop and implement; they require intention in design, including community input, and identification and navigation of challenges. The establishment of READI's numerous initiatives and programs, as described above, thus represents key accomplishments. Even at this early stage, we have indications of specific substantive intended outcomes emerging (as outlined in **Supplement** logic model). For instance, focus group data with community advisors provides evidence of READI efforts enabling community trust, aligning with community engagement principles[28], and identification of key facilitators, including clear and direct action based on community recommendations. Survey data addressing the Clinical Research Equity Scholars Program identified increased participant confidence in key learning areas, including identifying strategies to build trust with marginalized groups and incorporating equity into the clinical research process. We also identified unanticipated avenues toward intended outcomes. For example, evaluation of the voucher program found it provided key learning opportunities for early-career investigators.

Discussion

READI's successes and learnings offer insights that can inform program replication and extension. Among key learnings, READI has evidenced how systemic infrastructure change takes time and flexibility. Starting with a thoughtfully conceived framework and logic model, and including opportunities for input, evaluation, and intentional adaptation, enabled meaningful changes in how our academic institution and the community can work together to impact health and health disparities. Through initiatives developed by models like READI, Duke and collaborating partners are working to shift expectations in clinical research from "encouraging" to "expecting" diversity in participants and the workforce. As solutions are developed, new barriers and priorities are identified, starting a continuous cycle of identifying and engaging with partners to define needs and implement changes. This initiative shows that diverse solutions require flexible thinking informed by the lived experience of communities.

Several important considerations arose during the co-creation of the READI program. While the location of R@P is located within a multiracial, multi-ethnic, and multi-generational cluster of neighborhoods and more accessible to drivers than a hospital or clinic setting, it does not address barriers to access for people without access to a private vehicle. The previously available public bus stop at the location, that had been intended to allow for broad access across Durham communities, was discontinued by the county and the nearest active stop is 0.6 miles away

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without consistent sidewalk access. While all participants needing transportation accommodations have been provided transportation at no cost to them through ride-share and other shuttle services, additional initiatives are needed to create accessible research options for both urban and rural communities for whom R@P may not be feasible.

A cycle of continuous engagement is required to ensure that initiatives are progressing in a way that benefits all partners. This continuous and open process reinforces positive relationships between institutions and community partners and demonstrates values and practices that support trustworthiness. The initial READI program did not provide mechanisms to compensate community research partners outside of CAC membership. Resource sharing is an essential component of community partnered research and is an acknowledged weakness of the initial READI program. While READI was initially supported by a three-year grant, the timeline and scope of the work will require a much larger and longer investment. Implementing new programs and tracking resultant systemic changes cannot be measured in the short term. The goal of increasing diverse participation in research studies will take years to sustain and for us to achieve other goals of becoming trustworthy researchers, care providers, and partners in improving health equity. With such lofty goals, three years of directed, very intentional work is just the beginning. In that time, READI has demonstrated further understanding of perceptions of trust, created engagement opportunities and career pathways to increase diversity in both research participants and the workforce, and developed initiatives to better engage community organizations in setting research priorities. Our approach of iterative, collaborative development and evaluation of movement toward mutually developed goals offers a slow path to substantial change.

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Author Contributions

All authors contributed to the conception, design, and execution of the READI initiative, critically reviewed the manuscript, gave final approval for the manuscript and agree to accountability for the manuscript. PM, SQ, RS, JS analyzed data and interpreted results. ST prepared the figures, drafted the manuscript, and edited and approved the final manuscript. SF, LS, JS drafted the manuscript, and edited and approved the final manuscript. SN lead the conception, design and execution of READI, critically reviewed and edited the manuscript drafts and is accountable for all aspects of the work.

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Competing interests

The listed authors on this paper do not have any conflicts of interest to disclose.

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