ACP Entrepreneurship Spotlight

SiteBridge Research: Fostering Diversity in Clinical Trials
November 9, 2022

Presenters: Dr. Manesh Patel, MD and Chris Komelasky, MBA
Moderator: Dr. Cheryl Rucker Whitaker, MD, MPH, FACP

SITEBRIDGE RESEARCH

ACP® American College of Physicians
Leading Internal Medicine, Improving Lives

Today's Agenda

1. Share the SiteBridge entrepreneurial journey and inspire ACP physicians interested in becoming or working with entrepreneurs
2. Discuss how democratizing clinical research can impact your practice and improve diversity in clinical trials
3. Feedback / Q&A

Share the SiteBridge entrepreneurial journey and inspire ACP physicians interested in becoming or working with entrepreneurs

STARTUP TEAM FORMATION:
Mentors, Advisors, and Early Team Members are the foundation for success

SiteBridge Founding Team Members:

NEILE GRAYSON, PhD

Board Member;
Managing Director,
H2047

HEALTH 2047 SONUS Pharmaceuticals NEORx

MANESH PATEL, MD

Board Member / Co-founder
Chief of Cardiology Duke

DukeHealth
Duke Clinical Research Institute

CHRIS KOMELASKY, MBA

CEO / Co-Founder

PPD gsk ZS accenture

Why now?

Our SiteBridge team followed a standard entrepreneurial process to launch the business

In reality, that process has overlapping phases that take place in parallel

M1 M2 M3 M4 M5 M6 M7 M8 M9 M10 M11 M12 M13 M14 M15 M16 M17 M18 M19 M20 M21 M22 M23 M24 M25 M26 M27

Team Formation

Funding Decision

Launch

1st Hire

MVP

1st Site Contracted

1st Commercial Contract

Idea Generation

Collecting Resources

Opportunity Analysis

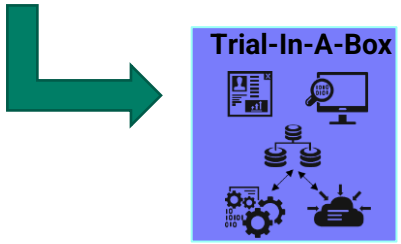
Forming Organization

Develop Planning

Growing Business

Forming Organization:

- Incorporation and registration
- Corporate services (legal, accounting, technology, HR, etc)
- Hiring plan and recruitment
- Refined strategy, mission/vision, and core values
- Capability roadmap and implementation plan



Discuss how democratizing clinical research can impact your practice and improve diversity in clinical trials

Common Themes and Industry Challenges are Driving Change in the Clinical Research Industry

Key Themes:

1. Health equity and the diversity in clinical trials
2. Real-world data (RWD) and Real-world evidence (RWE)
3. Staffing and Resource Challenges
4. Distributed and Decentralized Clinical Trials (DCT)

SiteBridge is directly addressing the first three and better enabling the fourth

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Health Equity Challenge:

Traditional Clinical Studies **do not** represent the U.S. population

Traditional Studies *		Actual U.S. Population
15% Black, Hispanic/Latinx, Indigenous	≠	33% Black, Hispanic/Latinx, Indigenous

*Source: Tufts CSDD Study – 2007-2017 Global Pivotal Studies (n=757)

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Diversity in Clinical Trials Continues to be in the Spotlight Across the Industry

FiercePharma

Bristol Myers Squibb takes on racial inequality with $300M ...

Improving clinical trial diversity is another key component in BMS' commitments. The goal is two-pronged: Through the nonprofit Bristol Myers

Fierce Pharma

J&J takes trial diversity push into communities with ...

The site not only addresses what clinical trials are and why a diverse population is needed to run them but also features a link so patients can find a trial...

Motley Fool

Moderna Slowed Enrollment in Its Phase 3 Coronavirus Vaccine Clinical Trial

Moderna Slowed Enrollment in Its Phase 3 Coronavirus Vaccine Clinical ... enrollment is its commitment to increase diversity in the clinical trial.

3 wee

WSJ Wall Street Journal

Covid-19 Vaccine Trials Have a Problem: Minority Groups Don't Trust Them

Photo: Joshua Rashaad McFadden for The Wall Street Journal. By. Jared S. Hopkins.

Aug 5, 2020

The New York Times

We Need to Recruit More Black Americans in Vaccine Trials

The paucity of diversity in these clinical trials creates problems on two fronts: treatment and trust. Unlock more free articles. Create an account or

Labiotech.eu

Plan launched to improve diversity of clinical trials

Medidata, a Dassault Systèmes company, has launched the intelligent trials diversity module. The new module will help sponsors and clinical...

23 hours ago

WFYI

Eli Lilly announces $500K to improve diversity in clinical trials

Eli Lilly announced Friday it will put $500,000 of seed money toward a new network focused on community public health research in Indiana...

Jun 15, 2022

TIME

We Must Use This Moment to Improve Diversity in Clinical Trials — And Not Just for Vaccines

ELSEVIER

Contemporary Clinical Trials

Volume 116, May 2022, 106740

Inclusion and diversity in clinical trials: Actionable steps to drive lasting change

Michelle D. Kelsey [a, b], Bray Patrick-Lake [c], Raolat Abdulai [d], Uli C. Broedl [e], Adam Brown [f], Elizabeth Cohn [g], Le H. Curtis [b, h], Chris Komelasky [i], Michael Mbagwu [j], George A. Mensah [k], Robert J. Mentz [a, b], Amesika Nyaku [l], Stephanie O. Omokaro [m], Judy Sewards [n], Kendal Whitlock [e], Xinzhi Zhang [o], Gerald S. Bloomfield [a, b]

The New England Journal of Medicine

New Federal Incentives for Diversity in Clinical Trials | NEJM

These diversity provisions, included as part of a broader reauthorization of user-fee funding of the Food and Drug Administration (FDA), would...

Regulatory Affairs Professionals Society

Experts call for federal incentives to promote clinical trial ...

... the diversity of populations enrolled in US clinical trials of new ... (FDA) – have not been sufficient to produce diversity in clinical...

In April ’22, the FDA Moved to Action with New Guidance for Diversity Plans to be Submitted for All Clinical Trial Programs

THE CALL AND EXPECTATIONS

Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials
Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHOfficeofEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Devices and Radiological Health (CDRH)
Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

Rationale to the new Guidance

- Ensuring people from diverse backgrounds join clinical trials is key to advancing health equity
- Participants in clinical trials should represent the patients that will use the medical products
- This is a concern because people of different ages, races, and ethnicities may react differently to certain medical products

FDA Commissioner Robert M. Califf, M.D.

*“The U.S. population has become increasingly diverse, and ensuring meaningful **representation of racial and ethnic minorities in clinical trials** for regulated medical products **is fundamental to public health.***

*Going forward, **achieving greater diversity will be a key focus throughout the FDA** to facilitate the development of better treatments and better ways to fight diseases that often disproportionately impact diverse communities.”*

This change validates the SiteBridge mission and path forward

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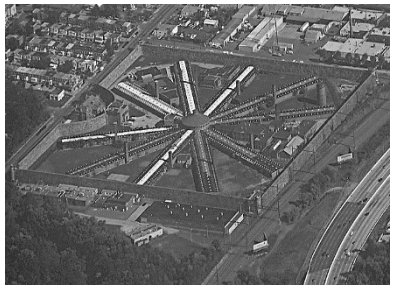
A history of racial and other medical atrocities on disadvantaged participants has led to mistrust in research but SiteBridge is changing the narrative and approach to do better

Tuskegee Syphilis Study 1932 -1972
600 "Bad Blood" patients
1943 – 1st patient treated with Penicillin
CDC approved to continue in 1969

Nuremburg Trials 1945
Nazi war crimes - human experimentation
without scientific merit or consent



Dr. Kligman – Holmesburg Prison 1951-1974
Dioxin (Agent Orange) and hallucinatory drugs
"All I saw before me were acres of skin… It was like a farmer seeing a fertile field for the first time."

These horrific examples have driven better patient protections, oversight and broader systematic change in the industry

Nuremburg Code & Belmont Report:

- Informed Consent
- Absence of Coercion
- Beneficence towards study participants
- Institutional Review Boards

SiteBridge is going further to build trust in minority and other diverse communities:

- Diversifying Leadership Team, Advisors and Board
- Engaging minority and mission-focused investors
- Focusing on health education and awareness in the community
- Providing clearly understood and culturally competent information
- Staying engaged with participants before, during and after trials are completed and sharing learnings with the community
- Finding ways to give back to the communities we serve

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Our Team and Advisors

KEVIN THOMAS, MD
Advisor / Cardiology Associate Professor of Medicine Duke DCRI

CHRIS KOMELASKY, MBA
CEO / Co-Founder

MANESH PATEL, MD
Board Member / Co-Founder
Chief of Cardiology - Duke

NEILE GRAYSON, PhD
Board Member /
Health2047 Managing Dir

NADINE BARRETT, PhD
Advisor / Duke CTSI, Head of the Center for Equity in Research

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NANCY SACCO, PhD
Head of Clinical Operations

MICKI LE
Snr Mgr, Clinical Research Coordinators

LUKE SNEDAKER
Snr Dir, Site Development Operations

MONAIR MCGREGOR, PhD
Lead Community Engagement Program Manager

Bill Elmore
Special Advisor to the Board

JOHANNE LABOY, PhD
Head of Community Engagement

Our Collective Experience & Background

More than 150 years of combined experience at your service

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GlaxoSmithKline

Stanford University

SiteBridge was founded in 2021 in collaboration with Health2047, the innovation and commercialization subsidiary of the American Medical Association (AMA), to transform healthcare at the system level.

SiteBridge is mission-aligned to transform clinical research

A Community-focused Integrated Research Organization (CIRO) that puts the trusted physician and patient relationship at the core

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Mission

To build bridges to reach further into the community and empower more physicians and patients to take part in clinical research

Vision

To ensure research participation reflects the diversity of the real world

Purpose

To enable access and improve health outcomes in the communities that can benefit the most

Reach Further. Empower More. Improve Health.

SiteBridge Research Core Values

We believe trust is earned

Integrity, respect, honesty, and transparency are non-negotiable. Authenticity of purpose is foundational. Mission driven to transform the clinical trial landscape. Our sustained commitment starts with doing the right thing at every turn and putting the trusted relationship of the physician-patient front-and-center.

We put community at the core

Communities connect us. We believe each of us is part of something greater, having a responsibility to support and give back to the communities around us. We want to find better ways to access, engage and sustain the communities we live and work in, creating hope for a better tomorrow.

We champion diversity

We celebrate the spirit of diversity and the different temperaments, talents and points of view it brings forward. Diversity is intentional in who we are, who we work with, who we aim to better support, and how we see the world at the intersection of different dimensions. Fundamentally, we believe diversity leads to better outcomes and improved health.

We have a relentless passion to deliver

Our team has a passion to have a meaningful impact through working together, focusing on collaboration, accountability, resiliency, and quality. We embrace the hard work needed to achieve our collective goals and go the extra mile in the pursuit of excellence. We have a service mentality that listens first and then acts. We know we do not have all the answers yet will find ways to win together with our strong partners and community champions.

We cultivate a continuous learning mindset

Change does not happen overnight. Our teams learn from the past, focus on today and look toward tomorrow. We embrace curiosity, challenge the status quo, foster change, and use innovative approaches and cutting-edge technology to disrupt with agility and purpose.

Next Generation CIRO

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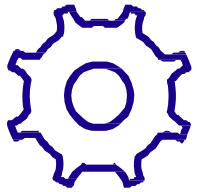
Placing the **trusted relationship between the physician and patient front and center**.

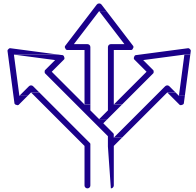
Developing authentic community engagement efforts that **build, maintain, and sustain ongoing dialog with all members of the community**

Building a national network of community-based practices to tackle challenges impacting the clinical research ecosystem – including **focus on key opinion leaders in the community, strengthening Sponsor relationships.**



Leveraging our 'Trial-In-a-Box' – a turn-key, best-in-class technology platform, optimized processes, and experienced support staff to minimize burden for the participants, physicians and study teams.

Delivering on-time and on-budget clinical research in communities historically vulnerable and hard to reach, **focusing on underrepresented and medically marginalized groups.**



Supporting decentralized and hybrid clinical trials giving **more options for patients to engage**.

SiteBridge supports the entire study process with focus on time, quality, and costs

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Site Readiness and Site Selection	Study Planning and Start-Up	Study Conduct	Study and Site Close-out
Proactive training and site development highlighting site and patient capabilities with centralized feasibility support decreases Sponsor or CRO Review by 2 - 4 months *Sponsors can spend up to 6 months working this aspect of pre-planning with CROs*	**Prework, including standardized budgets and contracts, patient recruitment planning, and other support by SBR decreases Time to SIV/Site Activation by 2 - 6 months** *Sponsors can spend up to 12 months to have all sites activated for Phase II and III clinical trials*	**Site support and oversight during Study Conduct ensures protocol adherence and mitigates risks brought forward through monitoring** *A plus for Sponsors relative to CRO monitoring plans*	**Site support for on-time completion of study, query resolution, regulatory documents review, drug accountability, and final invoices/payments decreases the time for study end activities by 50%** *A plus for Sponsors toward DBL/TLR and completion which impacts overall development plans*

Community Engagement

Community Engagement: WHAT WE DO & HOW WE DO IT

Build Trust

- *Establish meaningful connections*
- *Discuss pricing transparency and sustainable practices*
- *Assist with maintaining and sustaining relationships*

Develop Capacity

- *Conduct classes for the general public about clinical trials*
- *Teach community leaders to become clinical trial champions*
- *Hold seminars on Diversity, Equity and Inclusion for physicians/sites*
- *Enable network of peer navigators*

Engage Communities

- *Participate in local events & activities*
- *Bring community leaders to the table*
- *Collaborate with minority-owned and other local small businesses*
- *Work with faith-based organizations*
- *Facilitate community partnerships and collaboration*
- *Find opportunities to invest back in the community*

Disseminate Information

- *Interact and communicate with community leaders about clinical trials and health outcomes*
- *Disseminate clinical trials Information to stakeholders*
- *Provide culturally competent materials about therapeutic area*
- *Conduct open houses / lunch & learn sessions*

Expand Participant Voice

- *Participate in policy efforts aimed at reducing participation barriers (e.g., compensation, travel)*
- *Provide access to community for involvement in study design and recruitment planning*
- *Connect sponsors with patients and advocates that may provide feedback on participant –facing materials*
- *Facilitate the end-of-study, participant feedback process*

Support Investigators

- *Encourage minority physician participation in clinical trials*
- *Provide opportunities for physician engagement in the community*
- *Evaluate effectiveness of current community engagement efforts*
- *Assess SDOH*
- *Hold focus groups / interviews*
- *Conduct surveys*
- *Identify patient barriers*

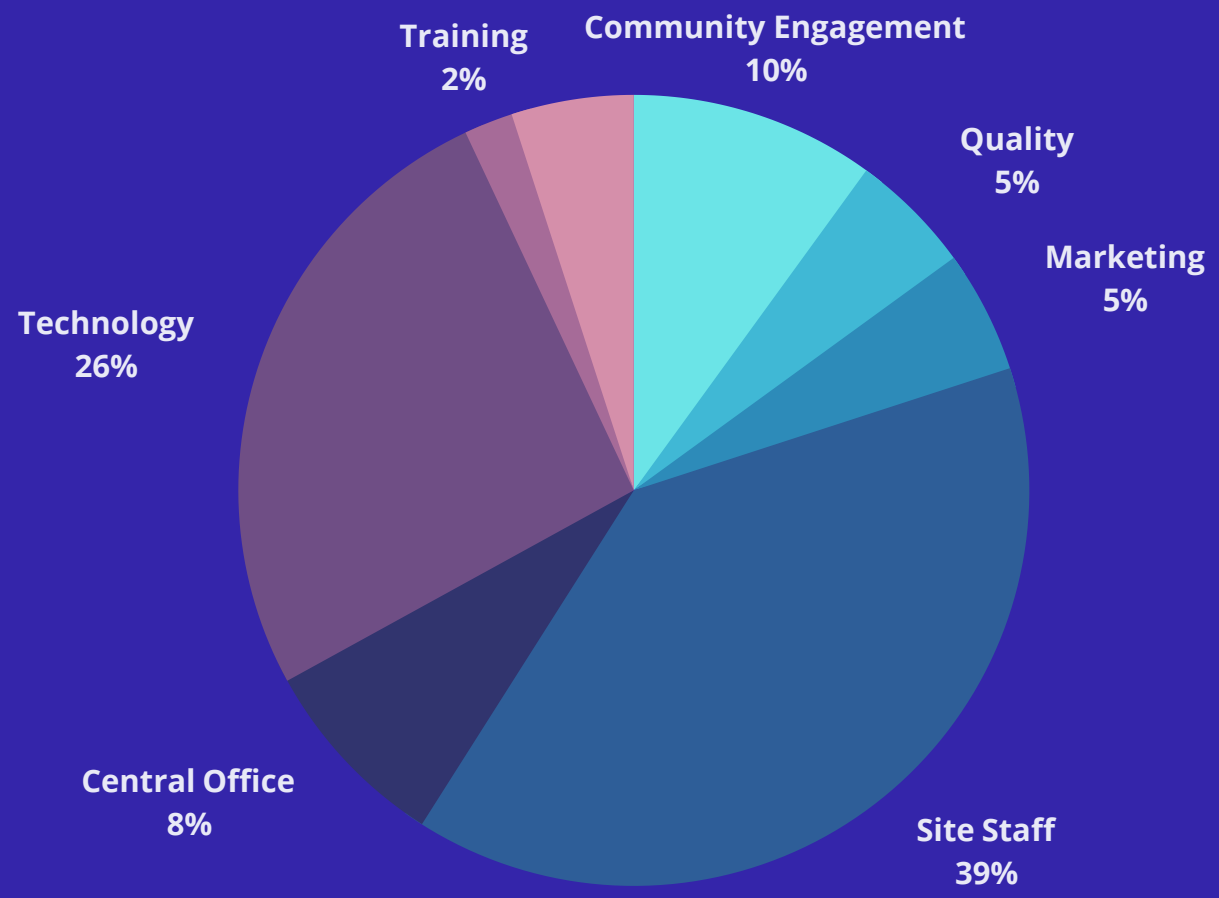
SiteBridge invests in the resources needed to scale research…

…So physicians can focus on what matters most:

- Clinical care
- Supporting and engaging with patients
- Continued education and innovation
- Advancing medical treatments
- Extending connectivity to new network of physicians
- Growing the practice

No upfront and fixed costs means
practice revenue is optimized

Example SiteBridge Year-1 Investment:



How SiteBridge Can Help Physicians

Saving time. Providing resources and staff. Adding a revenue stream.

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Time

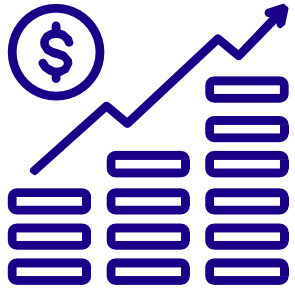
We offload the administrative burden in clinical studies from startup through study completion, including budgets and contracts, allowing existing practices to spend time focusing on the core – their patients.

Technology & Partners

Access to our technology platform and data partners that can increase quality, efficiency and reshape the way we think about real-world data related to current treatments and clinical trails

Staff

We provide training, experienced study coordinators, centralized start-up and quality oversight staff, and at home services for the convenience of your patients



Added Revenue Stream

Revenue from participants enrolled from your site could generate revenue of $50,000 or more for each study you conduct.

Community Engagement

Our community engagement efforts including health education/awareness, empower more of your patients to consider Clinical Research as a Care Option. We attract and retain more patients with additional visibility in the community

Getting Started with SiteBridge

Introduction to Site-Readiness can typically be achieved in < 90 days

1

SITEBRIDGE-PRACTICE INTRODUCTION

We are interested in physicians and practices who passionately desire to make research a part of their day and want to move forward.

2

ON-SITE ASSESSMENT

We'll meet to explain our approach and business model, compare it to your current resources and capabilities, and complete a research readiness assessment.

3

STUDY AND PATIENT MAPPING

We'll review potential studies and evaluate your patient database to match you with the right studies and progress contracting to join the SiteBridge network

4

SITE SETUP AND TRAINING

We'll meet to discuss logistics regarding communications, office space, staffing, standard processes, and training.

5

STUDY PLACEMENT

Working together, we'll match research opportunities with your clinic and support you through the selection process.

6

STUDY EXECUTION

Once awarded your first study we'll deploy all aspects of our Integrated Trial Engine to partner with you in enrolling and conducting a quality clinical trial.

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Feedback / Q & A

How to Contact Us

SITEBRIDGE RESEARCH

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