Debra Lerner
Marisha E. Palm
Thomas W. Concannon *Editors*

Broadly Engaged Team Science in Clinical and Translational Research

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Editors
Debra Lerner
Tufts Medical Center
Boston, MA, USA

Marisha E. Palm
Tufts Medical Center
Boston, MA, USA

Thomas W. Concannon
RAND Corporation
Boston, MA, USA

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About the Book

Despite the large national investment in health science, and the vast and growing body of peer-reviewed research findings it has produced, a compelling body of evidence suggests that research too often has been slow, inefficient, and fallen short of desired impacts on health. Many are asking how research might be changed to be more innovative, less wasteful, and more responsive to unmet health needs. One emerging response within clinical and translational science, the motivation for this book, is to advance an approach that attempts to close the gap between research scientists and key stakeholders; the individuals and groups responsible for or affected by health-related decisions. Broadly engaged team science promises to support this aim by transforming the gold standard, multidisciplinary team science to include key stakeholders in activities across the research spectrum. These new roles and responsibilities range from generating research questions to implementing research projects, to aiding in the translation of discoveries from the laboratory to the community. A transition to broadly engaged team science reflects the idea that inclusivity and a diversity of perspectives are necessary to achieving progress in addressing complex health issues while representing a new benchmark for ethical research practice. This book is one of the first collections of papers describing how clinical and translational science researchers are defining and implementing new research practices and some of the successes and challenges involved. It represents the collective efforts of the Tufts Clinical and Translational Science Institute (CTSI) and its partner organizations. Tufts CTSI is supported by a grant from the National Center for Advancing Translational Science, within the National Institutes of Health. This book represents an initial and critical step toward organizing knowledge of broadly engaged team science and advancing the development of evidence-based practices. It includes examples of multidisciplinary, broadly engaged team science projects, the perspectives of academic leaders about the changes needed to encourage scientists to conduct broadly engaged team science, and a separate resource directory. Written in an accessible style, this book is intended to highlight the breadth of broadly engaged team science within the Tufts CTSI community, motivate researchers and stakeholders to build inclusive teams, bring rigor to often informal stakeholder engagement research practices, and encourage both practicing scientists and stakeholders to think more broadly about the development of scientific knowledge.

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Chapter 1
Broadly Engaged Team Science at Tufts Clinical and Translational Science Institute

Alice M. Rushforth and Harry P. Selker

Abstract Tufts Clinical and Translational Science Institute (CTSI), from its start as a Clinical and Translational Science Award (CTSA) Program hub in 2008, has focused on practicing and promoting both multi-disciplinary team science and community-engaged research. This approach reflects the civic life and service focus of Tufts University and Tufts CTSI's inclusion of all schools across Tufts and multiple other academic and community organizations. It also reflects Tufts' strengths in community-based, health services, policy, and multidisciplinary team-based research. However, we found that implementing team science and community-engaged research as two distinct independent approaches failed to take advantage of potential synergies and left gaps in the translational continuum. To promote the synergies in these two approaches and to bridge gaps in optimal translation, we proposed a framework that merges these approaches and goes beyond involving stakeholders as advisors, to an approach that includes stakeholders as full team members, which we call "broadly engaged team science." This book reflects our journey in building and supporting broadly engaged team science by documenting current perspectives and practices and reflecting our continuing challenges to innovate and to foster widespread implementation.

Keywords Broadly engaged team science. · Science communication strategies. · Translational research.

Despite dramatic advances in biomedical science, translation into clinical care and impact on public health took far too long in the face of enormous need. Therefore, in 2006, the National Institutes of Health (NIH) launched the Clinical and Translational Science Award (CTSA) Program to move biomedical science discoveries more quickly and efficiently into practice and achieve real-world

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A. M. Rushforth (✉)
Tufts Clinical and Translational Research Institute, Tufts Medical Center, Boston, MA, USA
e-mail: arushforth@tuftsmedicalcenter.org

H.P. Selker
Tufts Clinical and Translational Science Institute, Tufts University; Institute for Clinical Research and Health Policy Studies, Tufts Medical Center, Boston, MA, USA

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benefits. Over the past 15 years, translational science has evolved significantly, with increased research funding, specialized journals and societies, and organizations across the world dedicated to this growing scientific discipline. To sharpen its focus on this work, in 2011, NIH established the National Center for Advancing Translational Sciences (NCATS), which took over the CTSA Program, "to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster" [1]. Now, as the largest single program at NIH, over 60 CTSA hubs at academic health centers and universities provide research expertise, resources, services, education, training, and career development to investigators, all directed at accelerating translation into impact on health.

To fulfill the promise of having impact on health, the discipline of translational science was intended to be disruptive and to transform research practices with new and different approaches to research, education, and training. When introducing the CTSA Program, then NIH Director Elias Zerhouni identified "translational roadblocks" that needed to be surmounted in moving from the laboratory bench to the patient's bedside, and from demonstration at the bedside into clinical practice [2]. Soon, it was also noted that there were barriers further along the translational chain, to widespread and equitably distributed medical care, and to wide public benefit and policy. Focus on these translational roadblocks has been uppermost for CTSAs, including self-assessment in this mission and willingness to disrupt old approaches and to try new practices.

In carrying out this translational mission, CTSA hubs practice and promote both multi-disciplinary team science and community-engaged research, including a broad array of groups, organizations, and diverse individuals. Recognizing that academic institutions' structures and processes are legacies of infrastructure, policies, and practices built to support single-*discipline research,* in the 2014 CTSA Funding Opportunity Announcement (FOA), NIH tasked CTSAs with engaging their home institutions to update promotion and tenure policies to recognize and incentivize team science for all members of a translational team. At the same time, it was appreciated that, historically, community-engaged research has not been integrated into the path of research that starts at the bench and the research bedside. To address this, in the 2014 CTSA FOA, NIH also challenged CTSAs to take an experimental, data-driven approach to identify best practices for community engagement in all stages of research across the translational spectrum. This included addressing this need even in the early translational phases, which had not been common. Furthermore, based on the 2013 Institute of Medicine Recommendations Report on the CTSA Program, NIH also tasked CTSAs with embedding community engagement in "leadership, implementation, research, and communication strategies across all levels of the CTSA program" [3, 4].

Tufts Clinical and Translational Science Institute (CTSI), from its start as a CTSA hub in 2008, has focused on translation into impact on broadly practiced health care and health in the community. This approach reflects the civic life and service focus of Tufts University, Tufts Medical Center's pioneering role in advancing the science of patient-reported outcomes and health-related quality of life, and Tufts CTSI's inclusion of all schools across Tufts and multiple other academic and community organizations. It also reflects Tufts' strengths in community-based, health services, policy, and multidisciplinary team-based research.

In its early years, Tufts CTSI developed frameworks to identify stakeholders and guide engagement strategies, some described in later chapters of this book. We led development of the widely used 7Ps taxonomy for stakeholder engagement in research and the Six Stages of Comparative Effectiveness Research framework in 2012, and a systematic review of stakeholder engagement activities in Comparative Effectiveness Research in 2014 [5, 6]. To increase the research readiness of our communities, we collaborated with other Boston-area CTSAs and community organizations to publish a capacity-building primer for community engagement, *Building Your Capacity: Advancing Research through Community Engagement Curriculum Guide* [7, 8]. We also developed a new concept for partnered research, community-engaged pedagogy [9], provided innovative education and training to community members in a nationally recognized Community Fellows program, and sponsored efforts to build a coalition of community-based organizations in Boston's Chinatown, adjacent to the Tufts Health Sciences campus, through our Addressing Disparities in Asian Populations through Translational Research (ADAPT) initiative. ADAPT promotes sustained engagement to address historical tensions and mistrust in communities around research and investigators, with the long-term goal of shared action to address health concerns of greatest concern to the community [10, 11].

However, we found that implementing team science and community-engaged research as two distinct independent approaches failed to take advantage of potential synergies and left gaps in the translational continuum. To promote the synergies in these two approaches and to bridge gaps in optimal translation, we proposed a framework that merges these approaches and goes beyond involving stakeholders as advisors, to an approach that includes stakeholders as full team members, which we call "broadly engaged team science." To take full advantage of the potential contributions of diverse perspectives and experiences, broadly engaged team science holds that clinical and translational science must shift from using stakeholders as consultants, to *full membership of all stakeholders in the research team* [12].

This book reflects our journey in building and supporting broadly engaged team science by documenting current perspectives and practices and reflecting our continuing challenges to innovate and to foster widespread implementation. Broadly engaged team science is aligned with Tufts CTSI's vision and culture. Our identity as "The Extrovert CTSI" includes engaging a large number of diverse partners at the organizational and individual levels. We also include focusing on our collective impact by building multi-partner, multi-disciplinary, multi-stakeholder collaborations. However, putting theory into practice is challenging and we, like others, face acknowledged systemic roadblocks in an academic research culture deeply seated in single-disciplinary traditions.

Research has most relevance and impact when it addresses issues of importance to patients, communities, clinicians, caregivers, and others who make medical and health decisions. Additionally, to be optimally disseminated, which ultimately determines its impact, research must engage the healthcare system, industry, and policymakers. Incorporating these perspectives requires meaningful connections, collaboration, and full team membership of key stakeholders. Broadly engaged team science emphasizes that all relevant perspectives must be actively involved in posing research questions, defining meaningful outcomes, conducting research, interpreting findings, and disseminating results. This requires including the technical knowledge, skills, and the lived experience of diverse stakeholders. It also requires leadership that is committed to broad active inclusion in the joint work. As a research paradigm, this enhances study design and protocol development, the use of culturally sensitive study enrollment approaches, and the ultimate adoption of research results into practice. In turn, this provides the public with a greater return on its investment in research and promotes public engagement and trust in science. It also promotes development of an engaged, diverse research workforce.

We see this as being a natural progression. Historically, team science and community-engaged research developed as distinct research fields. However, both are grounded in similar foundational principles and values that we believe merge well into a larger unified approach as broadly engaged team science. Both fields are built on trust, respect, a shared vision among members of the research team, power-sharing and equity, melding of cultures, and flexibility and adaptability in pursuing goals. All varieties of both approaches involve purposeful team building, managing conflict, clear and timely communication, and setting clear expectations for roles, responsibilities, and acknowledgment. A byproduct of the distinct evolution of the team science and community-engaged research fields is that in each tradition different terms have often been used to describe similar activities. We hope this commonality will be evident throughout this book, even though we have not attempted to harmonize terms and concepts across approaches; rather we have honored the contexts and voices of contributing authors.

As we continue to try to put the concept of broadly engaged team science into authentic practice, and to promulgate broadly engaged team science practices across diverse departments, schools, and organizations, we are continually evolving our roadmap to a future where teams work seamlessly across fields, organizations, communities, and individuals. We examine our organizational structure and culture, the initiatives we support, and the services, education, and training we provide, all through the lens of broadly engaged team science. As we look to the future, there are many examples to draw inspiration from and areas in which we plan to develop further:

- The first and third sections of the book explore how broad engagement can transform research and improve treatments for patients. These demonstrate some of the ways in which the vision of broadly engaged team science is being realized at the organizational level and the team level. We are witnessing a transformation in the structure and culture of science leveraging new relationships and collaborative processes to improve impact on public health.
- In the second and fourth sections of the book, authors describe the principles and practices necessary for broadly engaged team science. At Tufts, we want to

incorporate diverse stakeholders into CTSI governance, strategic management, and program planning. We are looking to do this by expanding our existing Stakeholder Expert Panel, which is comprised of representatives from diverse groups and citizens, to implement broadly engaged team science throughout all aspects of Tufts CTSI. As you will read, the goal is for diverse stakeholders to be an integral part of research management infrastructure as well as part of the research team.

- We, like many others, also recognize the need to find better ways to compensate and recognize stakeholders for the critical role they play on research teams. This includes, for faculty, adopting promotion and tenure criteria that acknowledge, reward, and incentivize broadly engaged team science. It also necessitates providing financial compensation to community stakeholders for the roles they perform on research teams.
- It is well-recognized that funding agencies and scientific journals have a role to play in promoting broadly engaged team science. While less in the purview of CTSAs and academic institutions, to the extent that we can in our advocacy and leadership roles, we will support needed changes in these key parts of the research enterprise to support broadly engaged team science to take hold at scale.
- We are developing and implementing new approaches to help investigators working at the earliest translational stages to identify and include relevant stakeholders in their research teams. Recognizing that different research projects will need to include stakeholders engaged in different activities and roles, a one-size fits all approach to broadly engaged team science does not work. Here a fit-for-purpose approach needs to be developed and deployed for each research team. In addition, frameworks and more general practical guidance and real-world examples on how to implement broadly engaged team science in basic and pre-clinical research are needed.
- We believe that broadly engaged team science should improve diversity, equity, and inclusion in research and thereby improve its impact on all of society. We recently completed an organizational anti-racism action plan that includes working with investigators to identify and involve relevant stakeholders in their work through a diversity, equity, and inclusion lens. We also will examine all Tufts CTSI programming, resources, services, training, and educational offerings to ensure the metrics for involvement of *diverse* stakeholders include race, ethnicity, socio-economic, and other considerations relevant to the social determinants of health.
- Throughout this book, authors stress the importance of developing, deploying, and providing training on science communication strategies that acknowledge community perspectives, find common ground, and engender a common purpose. The erosion of public faith in science jeopardizes clinical and translational research. To improve public understanding of the purposes and value of clinical research and to build and maintain trust among diverse participants, we are hosting dialogues on important scientific issues in communities with the goal of breaking down stereotypes, inspiring curiosity, building empathy, and enabling participants to link their health and well-being to their personal and civic

decision-making. We are also providing science communication training and education to researchers to enhance their ability to work in diverse, multi-discipline, multi-stakeholder research teams and to create a respectful team environment where all members can contribute as equals.

- Although broadly engaged research seeks to include diverse stakeholders as members of the research team, there are still challenges to its implementation. In addition to public mistrust in science and research that may limit engagement, for large sectors of society, public involvement in research may not be viewed as a civic or social responsibility. Also, it may not be perceived as linked to their own health and well-being or that of their community. Thus, we wonder if broadly engaged team science might be fostered by understanding cultural influences and applying practices that encourage and promote community volunteerism and civic engagement. How might we best expand knowledge and capacity for all members of society to be active agents in clinical and translational research? With clear examples of the impact of social movements on research, such as Act Up on AIDS research, promoting broadly engaged team science as civic engagement may help to increase public involvement in research and the impact of translational research on public health.

In summary, Tufts CTSI seeks to facilitate translational science across the full spectrum of translational biomedical and related research to achieve impact on health. We realize that this requires a broad commitment in our research and educational programs, organizational structures, and internal and external communications. Success will require engagement of institutional leaders and stakeholders and a comprehensive approach and plan. It also requires a focus on including all relevant disciplines and stakeholders. A major public undertaking that fails to include all relevant disciplines and partners, and only includes those in a single silo, would be incomplete and would reflect a limited and flawed vision. Why should we not have the same breadth of inclusion of disciplines, resources, perspectives, and capabilities in our academic enterprises that ultimately aim for real-world impact? We recognize that in academic institutions, there are challenges to these approaches, including, but not limited to, academic appointments, access to resources, financial accountability, and internal and external communications. Major efforts by institutional and university leadership are needed to become the cross-cutting academic and community-based enterprise that Tufts CTSI seeks to become, and we believe this will be worth the effort. Now, several years into this path, we believe that broadly engaged team science is an important approach for this work.

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Part I

Transforming Research with Broad Engagement

Chapter 2
The Transformative Power of Broadly Engaged Team Science: A Mother's Quest to Understand PXE

Sharon F. Terry

Abstract I came to the world of medical research not as a career choice, but as a response to an unexpected challenge, and my journey has been anything but typical. This chapter chronicles my quest to understand the disease pseudoxanthoma elasticum (PXE). I explain how adopting an open and collaborative approach led to not only the formation of PXE International, but also the establishment of the first clinical registry and biospecimen repository designed and managed by a lay advocacy disease organization and the discovery and patent of the gene associated with PXE. Today, PXE International's research collaborations have expanded worldwide as a natural history study, a biomarker study, and early trials in pyrophosphate (PPi) and other potential therapies commence. In addition, my recent work with the Genetic Alliance has led the way in putting people—individuals, families, and communities—at the center of health research and services. We have contributed our leadership to help in the passage of the Genetic Information Nondiscrimination Act, the formation of the All of Us program, the establishment of the International Rare Disease Research Consortium, and many other international and national endeavors.

Keywords PXE international · pseudoxanthoma elasticum (PXE) · Patient Centered Outcomes Research Institute · PCORnet · Genetic Alliance

I came to the world of medical research not as a career choice, but as a response to an unexpected challenge, and my journey has been anything but typical. Once a college chaplain with a master's in theology, I never imagined that I would create the first clinical registry and biospecimen repository designed and managed by a lay advocacy disease organization or be the first and only lay person to discover and patent a gene discovery.

The journey began when, after a diagnostic odyssey, my two children were diagnosed with a rare genetic condition a few days before Christmas in 1994. They were

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S. F. Terry (✉)
Genetic Alliance, Damascus, MD, USA
e-mail: sterry@geneticalliance.org

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5 and 7 years old at the time. For several years, I had been in search of an answer as to why my daughter had a “rash” on her neck. The quest for their diagnosis came after my father and brother had both died terrible deaths that could have been handled better medically. Neither were consulted before undergoing major surgeries that would not prolong their lives. Two weeks before he died, my father had a colostomy for colon cancer with metastases to his liver and lungs. He felt shame about this and would have gladly forgone the surgery had he been given a clear picture of his extremely poor prognosis. My brother’s doctors told him of a wonderful future that would be made possible by stereotactic radiosurgery for his glioblastoma multiforme. As we cajoled him to get out of bed and stop being lazy about his recovery, he was actually dying. A kind nurse told me that if he was her brother, she would cease treatment and prepare for his death, for his sake and for ours. His young wife, with their 10-month-old daughter, was not ready to hear that after being sold a different bill of goods. We rushed to get him what he needed to die.

I do not fault the teams of physicians in either case. I quickly discovered that we were not partners in the process of managing my loved ones’ health; instead, we were expected to be the docile recipients of someone else’s decisions. After the fact, it was clear to me that I should not accept any decision without evidence and discussion, and that I would have to be an advocate should anyone in my family face another medical dilemma. As a result, I did not accept that there was nothing wrong with my kids and doggedly pursued a diagnosis. And then, upon hearing the diagnosis of pseudoxanthoma elasticum (PXE), I went into overdrive to secure a position on the team that would determine what was or wasn’t to be done.

The Formation of PXE International

Researching a disease was not easy in 1994, when the internet was rudimentary, and few people had access to online information. I had a master’s in theology, with little background in any sort of science, let alone biology. To start, I copied and read hundreds of articles, most of which were case studies from medical journals. Though my understanding of methods, analysis, results, and thousands of complex and unfamiliar terms was sorely lacking, it seemed clear that these studies were not good representations of the PXE’s characteristics or progression. Another enormous red flag to me were requests a day apart, from two different research groups, to take my children’s blood to search for the disease’s genetic marker. When I asked these two teams of scientists to share the samples, and not take blood from the kids twice, they scoffed at the idea and said they were in competition—a race to find the gene. As a parent, naïve to the process of scientific discovery, I was appalled.

All of this led my husband and me to establish PXE International. It appeared to us that the incentives of the research groups were not aligned with the individuals and families suffering from PXE. Fortunately, creating a nonprofit was not difficult in 1995, and there were many other support groups dedicated to helping people with diseases. A law firm in the Boston area, where we lived, incorporated the foundation and filed the 501 (c) (3) application for us, pro bono. Organizations like Genetic Alliance, an umbrella group that helped with starting and sustaining support groups, taught us the basics [1].

Collaborating with Patients Leads to the First Biospecimen Repository and Disease Registry Established by a Patient Advocacy Organization

The board of PXE International felt strongly that it was not enough to support people with the condition; they also wanted us to drive the research. Shortly after we had PXE International up and running, we began to search for other people with the condition. We quickly learned that most of those affected were adults in their 40s and 50s, often suffering with skin signs and vision loss, the major morbidities of the disease. I connected with many of these individuals by mailing pamphlets to ophthalmologists and dermatologists, and with their collaboration, PXE International became the first patient advocacy organization to establish a biospecimen repository.

We invited the affected individuals we located to donate blood to the PXE International BioBank. We also mailed an extensive 900-question survey to them, collecting information about their experience of living with PXE. We coded the responses to the paper survey and entered the data into a low cost, off-the-shelf software program, establishing the first disease registry with what is now called Patient Reported Outcomes (PROs). We also collected thousands of medical records—all paper, since this was before electronic health records existed—and blinded and scanned them to create a repository of information. Thus, we created our own real world evidence basis well before it was fashionable or encouraged. We did this in part to challenge a large cadre of researchers who felt that PROs would be useless information filled with bias from the person's lived experience. Once we had gathered PROs from 600 people, we analyzed information from 10 percent of them to determine how much concordance or discordance we saw compared to their medical record. We saw a great deal of concordance, and we also saw a good deal of misinformation in the medical records. We knew in 1996 that having both PROs and health records was critical if we were to understand the characteristics and progression of this condition.

Research Sparks Additional Collaborations, New Understanding, and Discovery of the PXE Gene

This information we gathered helped us discover several previously unknown aspects of PXE that I believe would not have been found without PROs. For example, women with PXE consistently reported that they were asked to have biopsies with every mammogram. Microcalcifications seen on the images had to be sampled to rule out cancer. As a result of these reports from women in our registry, we undertook a double-blind study, in which we examined the mammograms of 51 women with PXE and compared them to 109 controls. The mammograms of affected women all showed microcalcifications and none had cancer. Based on these results, we offered a new guideline to women and their clinicians: women with PXE have microcalcifications in the breast as a result of PXE, not as an indicator of a cancerous pathology [2]. We pursued a similar concern for men, precipitated by a urologist discovering testicular microlithiasis in a boy affected by PXE. This time we had to recruit participants, since imaging of the testes is not routine, and the discovery was analogous: men affected by PXE have testicular microlithiasis [3]. In both cases, the discoveries and resulting guidelines allayed a great deal of anxiety, unnecessary biopsies, and misinformation.

Early in our sojourn, we borrowed bench space at Harvard, and learned from post-docs late at night how to extract DNA, perform gel electrophoresis, score gels, and enter data in a spreadsheet. We shared our samples with our newly formed PXE International Research Consortium, with the requirement that they share with one another. In annual research meetings, we shared methods and results, and worked toward discovering the gene. In 1999, together with a number of research teams, we discovered that mutations in ABCC6, a membrane transport protein, were responsible for the autosomal recessive condition pseudoxanthoma elasticum (PXE). Along with a number of labs, we published the discovery, and then applied for a patent on the gene [4, 5]. We wanted to control the gene patent so that that we could freely share access to the gene and the variants found in it, rather than have a university technology transfer office gatekeep that access and/or create a proprietary database. PXE International licensed the gene for $100 in perpetuity to any labs that requested access. In turn, we required that the testing labs share all of the variants they found with PXE International. This prevented a proprietary database of mutations from being built since we published them online in the Leiden Open Variation Database (LOVD). These have since been transferred to ClinVar, where we verify and curate all of the variants we and others have found.

Expanding PXE International’s Research Collaborations

Once we discovered the gene, we engaged a company looking to validate its technology to help us sequence the gene in hundreds of individuals around the world. We placed their instruments in Philadelphia, Honolulu, South Africa, and Belgium. I traveled, often with my kids whom I was homeschooling, to each of these areas, meeting with people affected by PXE in the regions around these labs and providing education, support, and asking for biological samples and PRO in exchange. PXE International brought these data together and explored whether there was a phenotype-genotype correlation, and though we did not discover one, we laid the groundwork for understanding the genetic basis of the disease. This, and extensive funding of labs in Budapest, Amsterdam, Modena, Cape Town, Hawaii, and eventually the founding of the PXE International Center of Excellence in Research and Clinical Care at Jefferson Medical College in Philadelphia, led to the discovery that ABCC6 facilitates the cellular efflux of ATP, which is rapidly converted into pyrophosphate (PPi), a major calcification inhibitor. This discovery has opened the door to many more research projects, closer to the translation end of biomedical research. In the past several years, PXE International's research collaborations have expanded to include several companies as a natural history study, a biomarker study, and early trials in PPi and other potential therapies commence.

Shortly after establishing the first biobank and registry run by a patient advocacy organization, with help from experts on human research ethics, biological specimen storage, and data science from the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and Genetic Alliance, many other patient advocacy organization founders and leaders came to ask me to help them establish biobanks and registries for their health conditions. With my children's permission, in 1996, I began to work with these other groups, and by 1998 joined the board of directors of Genetic Alliance, becoming President in 2002, and CEO in 2004. At Genetic Alliance, we expanded the methods, resources, and tools PXE International had developed so that all organizations could use them. We formally established the Genetic Alliance Registry and BioBank in 2003. We articulated the importance of collaboration among all stakeholders, including patients, clinicians, researchers, and policy makers. We established guidelines, principles, and trainings [6–9]. We enlisted ethicists, anthropologists, theologians, sociologists, and Barack Obama's campaign leaders to help us understand the importance of culture and the barriers between the stakeholders. We began to understand that cultural humility, whether about systemic racism, or the competitive culture of academic science, was critical to our having an impact in our quest to have people recognized as part of the team. Immense support from leaders at the Health Resources Services Administration (HRSA) allowed us to explore and add to the science of engagement [10–12].

Genetic Alliance has led the way in putting people—individuals, families, and communities—at the center of health research and services. We have contributed our leadership to help in the passage of the Genetic Information Nondiscrimination Act passed, the formation of the All of Us program, the establishment of the International Rare Disease Research Consortium, and many other international and national endeavors [13]. We influenced the inclusion of people-centered concepts and ideas such as those codified in the law through which the Food and Drug Administration gets it authority to oversee drug development: patient-focused drug development and real-world evidence [14]. We aren't satisfied with having a place at the table; we want to collaborate with others to decide where the table will be, who will be invited to it, what and how the meal will be served. People-centered, team science cannot be just given lip-service; there must be meaningful and dynamic actions.

Two recent projects of Genetic Alliance exemplify our deepening understand of what it means to be collaborative, to lead teams, and play well. The first is our involvement in PCORnet, the clinical research network of the Patient Centered