

Introduction

Bridging the Research Gap in Communities

Texas Southern University (TSU) is a prominent Historically Black College and University (HBCU) and a pillar to the Houston community stands unique among many institutions engaged in clinical research. TSU operates **without an affiliated hospital, clinic network, or pre-existing patient population**. This structural difference often limits research participation from diverse communities, exacerbating health inequities.

To overcome these limitations, TSU strategically established a **community-focused clinical research site**. Our primary goal is to enrich community members through education, expand research participation, and specifically meet the health needs of populations without access to clinical trials. This initiative aims to build a sustainable model for clinical research access within non-traditional settings.

Objective

The primary goal of this initiative was to establish a functional clinical research infrastructure to:

Educate: Improve research literacy and awareness within the community.

Recruit: Create sustainable pathways for research participation.

Expand Access: Increase participation opportunities specifically for individuals with unmet health needs.

Methods

Institutional Capacity Building

The development process was structured into four operational pillars designed to achieve site readiness.

Collaboration: Mentorship and Benchmarking

TSU partnered with UTMB to serve as a mentor site, focusing on knowledge transfer, alignment with industry standards, and operational benchmarking. Through structured guidance, the collaboration accelerated site development and ensured adherence to best practices, providing a strong foundation for ongoing research activities.

Workforce Development

Efforts to build a skilled research workforce included recruiting and training personnel with a focus on competency in Good Clinical Practice (GCP) and other research-specific certifications. Mentorship from experienced partners helped ensure consistent operational standards and facilitated the integration of new staff into the research environment efficiently.

Community Engagement

TSU prioritized engagement with local communities by establishing formal relationships with community members, stakeholders, and advisory board members. These partnerships created clear pathways for community participation in research, fostering trust and supporting inclusive recruitment for studies.

Infrastructure Development

The institution developed essential infrastructure to support research operations, including standard operating procedures (SOPs), regulatory processes, and data management systems. Additional initiatives included optimizing IRB workflows, streamlining contract and budget management, and deploying a clinical research registry to assess study feasibility and inform strategic planning.

Results

TSU successfully established a comprehensive clinical research infrastructure, laying the groundwork for participant recruitment, operational excellence, and community engagement. This sequential approach highlights the progression from internal capacity building to tangible outcomes in education, recruitment, and expanded access.

Team and Governance Structure

The initiative began by building a strong research team, with clearly defined roles to support study operations. Visuals include headshots of the TSU CCRTS team, illustrating leadership and staff responsibilities across clinical, administrative, and research functions. In parallel, a Community Advisory Board was established, providing guidance on study design, recruitment strategies, and community engagement. Headshots and organizational charts showcase the expertise and diversity of board members.

Workflow Development and Implementation

With the team in place, TSU developed and implemented **standardized workflows** to guide research operations from sponsor contact through patient enrollment. A **flowchart visual** highlights one of these processes. Others include regulatory review, IRB submission, staff training, and participant onboarding, ensuring efficiency, consistency, and adherence to research standards.

Registry Implementation and Participant Engagement

The TSU Clinical Research Patient Registry, launched in May 2025, served as the next step in operationalizing the workflow. Through registry enrollment, community members were educated about clinical research, creating hands-on opportunities to improve research literacy and awareness.

Results

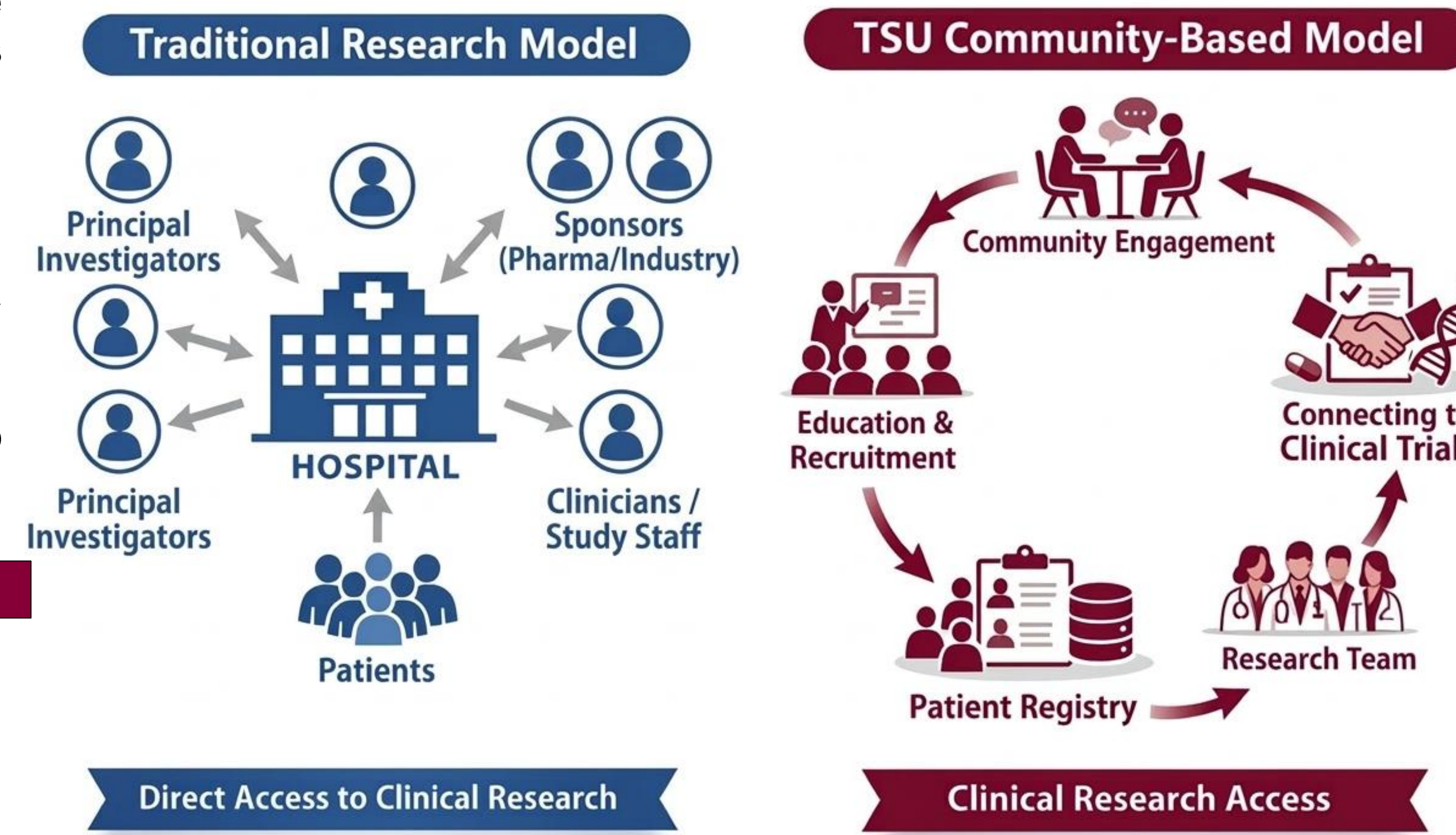


Figure 1: Comparison of clinical research access models. Left: **Traditional Model**, showing the hospital as the central hub for investigators, sponsors, and patients. Right: **TSU Community-Based Model**, highlighting a cyclical process of community engagement, patient registration, and collaborative research teams.



Figure 2: Illustration of the successful implementation of the TSU CCRTS team (headshots included) alongside the Community Advisory Board (headshots included).

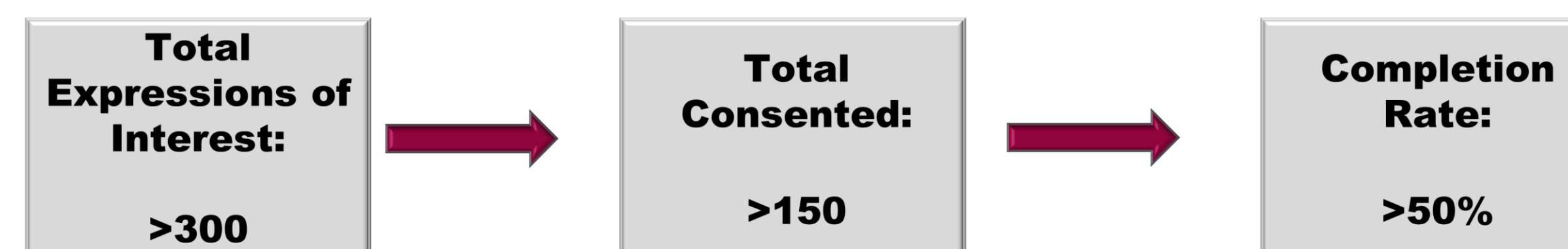


Figure 3: Diagram of the clinical research patient registry illustrating the progression from interested participants to enrolled individuals, with the study completion rate highlighted.

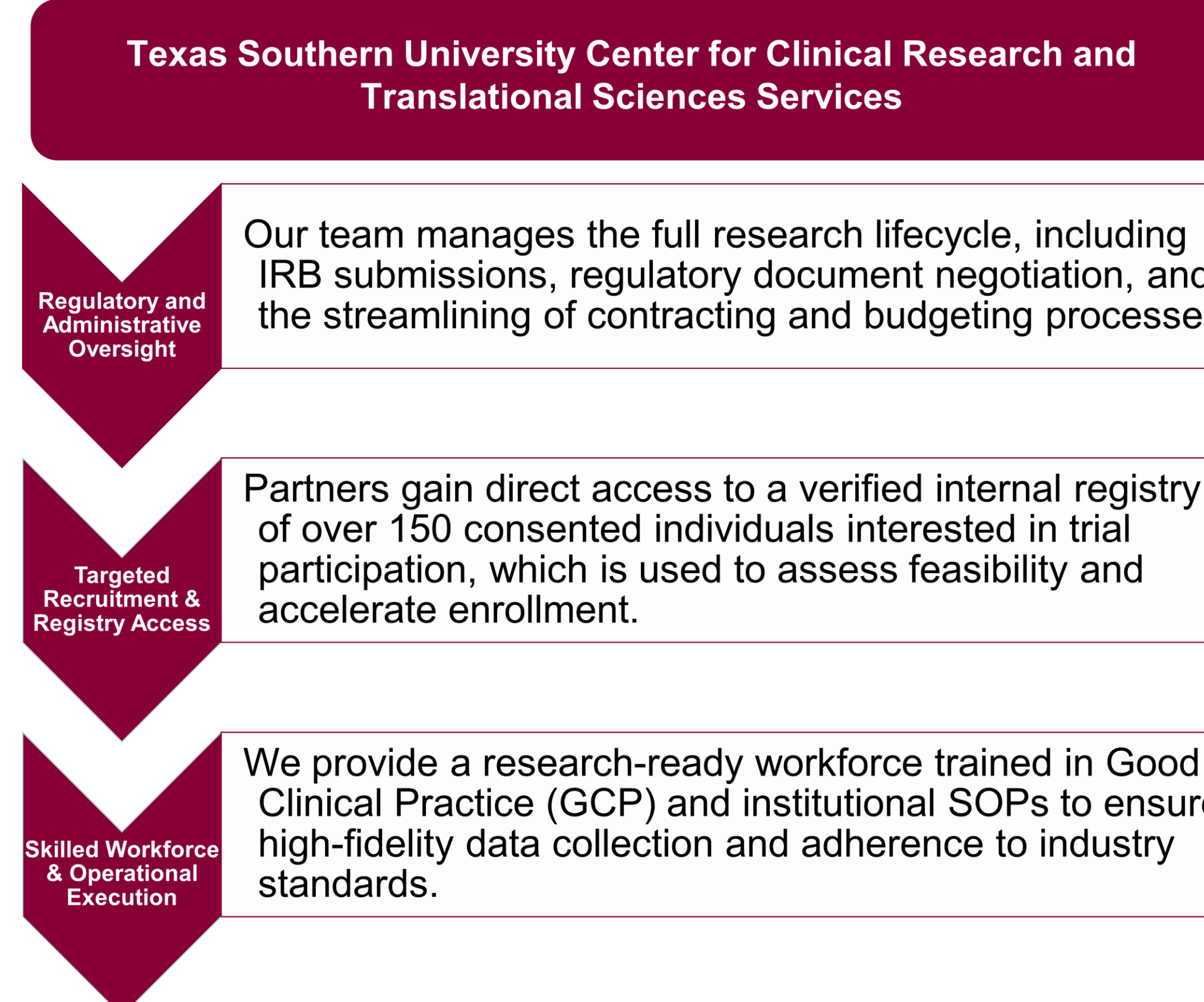


Figure 4: TSU Center for Clinical Research and Translational Sciences (CCRTS) provides a comprehensive service framework designed to support partners in navigating the complexities of community-based clinical trials.

Results Cont.

To date, the registry has received 300+ expressions of interest and 150+ full enrollments, demonstrating successful participant recruitment and engagement.

Next Steps: Expanding Access

Building on the registry and infrastructure, TSU is now preparing to initiate its first clinical trial partnership. This step will allow the site to expand access to research opportunities, particularly for individuals with unmet health needs, translating the capacity built into real-world impact.

Conclusion

The establishment of TSU's clinical research site demonstrates that building high-functioning research infrastructure within institutions lacking traditional medical hospital networks is not only feasible but essential for advancing clinical trial accessibility. This initiative confirms that success is predicated on two primary factors: the cultivation of deep-rooted community trust and the execution of strategic, cross-disciplinary partnerships that facilitate knowledge transfer and operational standardization.

By successfully navigating complex regulatory landscapes, contracting timelines, and institutional feasibility requirements, TSU has created a replicable framework. This model provides a clear, scalable blueprint for other non-traditional academic institutions seeking to increase clinical trial access, optimize research operations, and foster sustainable research capabilities within their own environments. Ultimately, this effort represents a shift toward more equitable and efficient research infrastructure, proving that institutional capacity can be effectively built through intentional design and collaborative expertise.

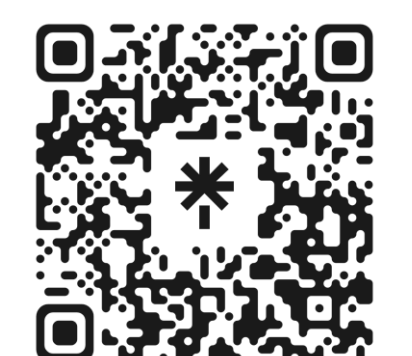
Future Direction

Moving forward, TSU aims to leverage its established clinical research infrastructure to secure and conduct a diverse portfolio of industry-sponsored clinical trials, with a primary focus on evaluating new therapeutic interventions. This expansion will involve deepening our existing partnerships—specifically our collaborative mentor-site relationship with UTMB—to enhance site capabilities and position the institution to serve as a pivotal site for cutting-edge pharmacological research. By successfully integrating these industry-sponsored studies, TSU intends to provide local populations with access to novel treatment options while further refining the operational efficiency and scalability of our replicable research model.

References

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