SITC Corporate Member Roundtable on Diversity in Clinical Trial Enrollment Executive Summary

Held Saturday, November 12, 2022 in Boston, MA.

SITC 2022
NOVEMBER 8-12 BOSTON MASSACHUSETTS

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Society for Immunotherapy of Cancer

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About SITC

Society for Immunotherapy of Cancer

The Society for Immunotherapy of Cancer (SITC) is the world's leading member-driven organization specifically dedicated to professionals working in the field of cancer immunology and immunotherapy. Established in 1984, SITC is a 501(c)(3) not-for-profit medical professional society comprised of over 4,300 influential research scientists, physician scientists, clinicians, patients, patient advocates, government representatives and industry leaders dedicated to improving cancer patient outcomes by advancing the science and application of cancer immunotherapy.

Through emphasis on high-caliber scientific meetings; dedication to education and outreach activities; focus on initiatives of major importance in the field; and commitment to collaborations with like-minded domestic and international organizations, government and regulatory agencies, associations and patient advocacy groups, SITC brings together all aspects of the cancer immunology and immunotherapy community. SITC aims to make cancer immunotherapy a standard of care and the word "cure" a reality for cancer patients everywhere.

Mission Statement

It is the mission of the society to improve cancer patient outcomes by advancing the science, development and application of cancer immunology and immunotherapy through our core values of interaction/integration, innovation, translation and leadership in the field.

Core Values

- Interaction/Integration: Facilitate the exchange of information and education among basic and translational researchers, clinicians, young investigators, patients, societies and groups sharing the mission of SITC
- Innovation: Challenge the thinking and seek the best research in the development of cancer immunotherapy
- Translation: Facilitate the transfer of cancer immunology and immunotherapy research from the bench to the clinic and back
- Leadership: Define what is new and important and effectively communicate it to all relevant stakeholders

Roundtable Overview and Introduction

Opportunity Statement

The oncology community understands the need to ensure participants in clinical trials represent the broader patient community that will ultimately be treated using the therapies under investigation. The Food & Drug Administration (FDA) released draft guidance, Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials, which recommends that all sponsors submit a Race and Diversity Plan (RDP). Since the issuance of the draft guidance, many sponsors have worked diligently to draft RDPs; however, many uncertainties remain

Sponsors are:

- Unsure which methods are effective in increasing diversity in clinical trial enrollment
- How the FDA will monitor the effectiveness of the RDPs
- Whether the protocol will be reviewed poorly because of an ineffective RDP

SITC's Call to Action

In response to the desire from SITC Corporate Members for additional clarity and direction on effective RDPs, SITC leadership developed a one-day corporate roundtable that offered opportunities for sponsors to liaise directly with FDA leadership, understand how legislative action may influence future FDA guidance, and learn from a variety of critical perspectives, including contract research organizations (CROs), principal investigators, patients, patient advocates, and major cancer centers with diverse care models.

In all, the multi-stakeholder roundtable convened nearly 20 sponsors and 10 panelists who collectively explored opportunities for SITC to facilitate collaboration, consensus, and education that will ultimately support the critical need to increase diversity in clinical trial enrollment.

Roundtable Goals

The roundtable's primary objective was to finalize recommendations to the SITC Board of Directors on initiatives SITC might lead that positively impact diversity in clinical trial enrollment.

Roundtable Organizers

Leisha Emens, MD, PhD
Ankyra Therapeutics

Padmanee Sharma, MD, PhD
MD Anderson Cancer Center

John H. Stewart, IV, MD, MBA, FACS
LSU School of Medicine, New Orleans

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Roundtable Outcomes and Next Steps

Roundtable Takeaways

Roundtable attendees, through small group breakout sessions, suggested possible initiatives SITC could lead that would positively impact diversity in clinical trial enrollment.

Collaboration & Networking

- Hold a convening of sponsors that encourages an exchange of approaches to diversifying enrollment and publish a compilation of approaches for the broader community to access and utilize.
- Build a pilot program that focuses on a region or city and works to establish long-term relationships within the community (churches, barbershops, salons, and check-cashing stores), building trust that ultimately will lead to increased comfort from the community to participate in clinical trials.

Education & Research

- Build content on diversifying clinical trial enrollment into SITC clinician education (e.g. ACIs, certificate program, Winter School, etc.).
- Fund the translation of consent forms into various, diverse languages.
- Explore the epidemiology of various cancers to guide the community to develop RDPs that target the right type of diversity in a particular cancer clinical trial.
- Require SITC abstract submission to include clinical trial diversity data.

Consensus Building

- Work collaboratively with the FDA to outline best practices from submitted RDPs that were successful in diversifying clinical trial enrollment.
- Lobby to bring back COVID-era policies that allowed for cross-state telehealth.
- Develop an eligibility template for immunotherapy trials that is informed by real world data.
- Create universal forms for consent and order sets.
- Change the expectation for physician time spent educating patients on clinical trials to allow for more dedicated time with patients enrolling in clinical trials.

SITC's Next Steps

The results of the Roundtable will be shared with the SITC Board of Directors and SITC's Diversity, Equity, and Inclusion Taskforce. Both the Taskforce and the Board will utilize the recommendations from the Roundtable to set SITC DEI priorities for 2023 and beyond.

Most immediately, the Roundtable organizers recommend that SITC hold a virtual convening in 2023 that ensures the key functionalities within sponsor companies are present. The direct outcome of the 2023 convening will be a manuscript outlining SITC's recommendations for actions each stakeholder in the clinical trial ecosystem can take to positively impact diversity in clinical trial enrollment.

Presentations & Panel Discussions

Overview of FDA Guidance on Diversity in Clinical Trials and Project Equity

'Lola Fashoyin-Aje, MD, MPH - U.S. Food & Drug Administration (FDA)

Key Takeaways

- One of the goals of the FDA's draft guidance, Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials (Guidance), this is to ensure sponsors have a purposeful plan to enroll an adequate number of participants from underrepresented racial and ethnic populations in clinical trials of their products.
- The FDA would like the clinical trial population to reflect the population that has the disease being studied. Sponsors should endeavor to use the epidemiology of the disease to determine enrollment targets. The US census is not the appropriate benchmark.
- Using the epidemiology of a disease may mean that diversity also includes age or other demographics beyond race and ethnicity.
- If the sponsors do not meet the diversity goals pre-market, the FDA may request post-marketing studies.
- The current Guidance is draft, and FDA is reviewing many comments submitted in response to the initial draft. There is no definitive date for finalization of the Guidance. However, the final version will likely not be very different from the draft and the FDA is fully implementing the draft Guidance and expect sponsors to comply.
- Global populations can and should be utilized where appropriate to meet diversity goals. However, it is important that the patients enrolled globally represent ethnically diverse populations.
- While the FDA does not yet have data on which practices for diversifying enrollment are the most effective, Dr. Fashoyin-Aje focused on a few specific suggestions from her own observations:
  - Design trials around the patients, use real world data to inform the best trial design.
  - Forge new partnerships to reach clinical colleagues in the community setting, inviting and supporting them to be part of the research team. Put resources into the trial to support a successful partnership with the community hospitals/ physicians.
  - Allow CBC lab tests to be done anywhere, eliminating the need for patients to travel to get basic lab work.
  - Critically evaluate the amount and type of data required to be collected as part of the trial design.

Presentations & Panel Discussions

Overview of Legislative Action on Diversity in Clinical Trials

Erik Fatemi - Cornerstone Government Affairs

Key Takeaways
❖ There is broad bipartisan support for diversity in clinical trial enrollment.
❖ The Clinical Treatment Act was passed to specifically address diversity in clinical trial enrollment.
❖ There is a very good chance congress will pass additional legislation in 2022 that will build on the FDA policies currently in effect and include requirements for decentralization of clinical trials among other measures.
❖ In 2023, potential legislation includes applying diversity recruitment plan requirements to the National Institutes of Health and clarification of the safe harbor provisions.
❖ The National Cancer Institute (NCI) will also likely make diversity in clinical trials a priority in the coming year.
❖ SITC has a role in educating congress and the relative agencies in issues specific to diversity in immunotherapy trials and suggesting ways congress or the agencies might proactively address continued barriers.
❖ SITC could help address workforce development issues through its annual NCI appropriations language process.

Panel Discussions

Panel 1: Care Models that Work and What We Can Learn from Them

Elizabeth Fox, MD, MBA
St. Jude Children's Research Hospital

Augusto Ochoa, MD
Louisiana State University Health Sciences Center

Key Takeaways

- A critical element to expanding access to clinical trials and increasing diversity of patients is to expand the trials to the community setting. Both St. Jude and LSUHSC have successfully expanded excess into numerous satellite sites in the community setting.
- The complexity of enrollment criteria limits the eligibility of many patients. Real patients have co-morbidities, and the enrollment criteria should be simplified to better represent real patients.
- The volume of data collected in trials greatly limits the ability of patients to participate in trials that demand so much of their time and resources for lab testing. SITC and the broader oncology community could invest in analyzing what data is truly needed and how currently collected data is actually being used.

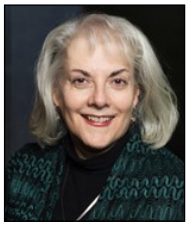
Panel Discussions

Panel 2: Articulating the Issues and Solutions

Padmanee Sharma, MD, PhD
MD Anderson Cancer Center

John H. Stewart, IV, MD, MBA, FACS
LSU School of Medicine, New Orleans

'Lola Fashoyin-Aje, MD, MPH
U.S. Food & Drug Administration (FDA)



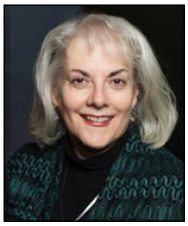
Deborah Collyar
Patient Advocates In Research (PAIR)

Key Takeaways

- The oncology community must shift to a precision design approach to clinical trial design that starts with the patient, not the trial or the endpoint.
- The community must be an engaged partner at every stage of planning and implementation of clinical trials. If the community is engaged and has a positive experience, a virtuous cycle will develop of support and collaboration.
- For patients to have a positive experience in clinical trials, the clinical care team must be trained to approach all patients with respect and explanations that make sense to them in the context of their lives.
- The oncology community must invest in the technology needed to expand access to clinical trials into the community setting.
- Patients want diversity in clinical trials and they want the demographics of the clinical trial enrollees to match that of the broader patient community for their cancer type.

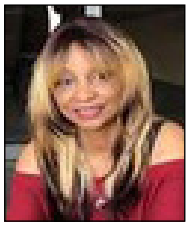
Panel Discussions

Panel 3: Patient Advocate Insights into Enrollment Experience



Deborah Collyar
Patient Advocates In Research (PAIR)

Cheryl McLaughlin
Coils to Locs



Sharon Rivera
Saving Pennies 4 a Cure

Key Takeaways
❖ A new model of clinical trial planning, development, and implementation is needed to truly become a patient-centric model. ❖ Four fundamental elements needed to shift the clinical trial model to be more inclusive are: - Buidling meaningful and intentional connections to communities - Investing in consistent, clear, multidirectional patient communication - Creating clinical trials that understand the needs of each community and developing trials in collaboration with the community - Offering counseling and coaching at every state of a patient's lifecycle and ensuring the counseling and coaching are sensitive and responsive to social determinants of health.

Panel Discussions

Panel 4: Contract Research Organization and Research Services Organization

Elizabeth George, MS
Labcorp Drug Development

Katie Cornish, PhD
WCG Patient Advocacy & Clinical Trial Diversity

Key Takeaways

- Sponsors should be clear from the outset that diversity recruitment goals matter, transparently and consistently sharing and monitoring those goals with internal study teams and sites.
- Sponsors must be strategic and intentional when developing RDPs, incorporating the strategies early into study design, planning, and budget.
- When developing the RDP, think about how the strategies will be implemented at the sites, making strategies pragmatic and actionable.
- Key to the success of an RDP is funding and sponsors need to build in the funding for the sites to fulfill the strategies identified in the RDP.
- A critical element of all RDPs must be education and long-term community relationship building.
- Not all sponsors have trained epidemiologists, and this can lead to unrealistic diversity enrollment goals. As an industry and in a pre-competitive way, SITC could help collate accurate epidemiological data to help set realistic goals for sponsors.
- Not all patient populations need the same education or outreach and strategies to engage each patient population should accommodate and be responsive to those differences.
- Educate physicians on how to talk about clinical trials to normalize participation in clinical trials.