

SITC Crisis in Clinical Research Virtual Summit

Aug. 17, 2022



Problem Statement

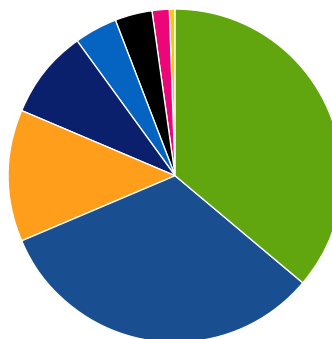
There is a national crisis slowing clinical research due to staffing shortages, administrative burden and current clinical trial business models. If the crisis is not rapidly addressed, the field of oncology faces a significant threat to patient treatment access and novel drug development that can affect the clinical landscape for years to come.

SITC's Call to Action and Summit Overview

Based on preliminary discussions with various stakeholders concerning the significance of the crisis, The Society for Immunotherapy of Cancer (SITC) hosted the **Crisis in Clinical Research Virtual Summit** on Wednesday, Aug. 17, from 10:00 a.m.–3:30 p.m. EDT. The summit was designed as a free, public event that featured expert panel discussions, invited speakers, and attendee question and answer periods. In all, the multi-stakeholder virtual summit convened over 600 attendees and 30 panelists demonstrating the critical need across the field for solutions pertaining to the crisis. Attendees included oncologists, administrators, the National Cancer Institute (NCI), the US Food and Drug Administration (FDA), pharmaceutical companies, contract research organizations (CRO) and other major oncology professional organizations.

Professional Roles of Attendees

*Attendees allowed to select multiple roles



Academic Research - 553
Industry - 498
Clinical Care - 194
Administration - 135
Scientist-in-Training/
Student - 60
Other - 57
Patient/ Patient Advocate/
Caregiver - 27
Investor - 5

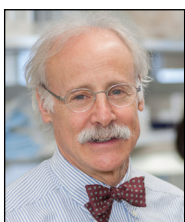
Summit Goals

The summit's primary objective was to define actionable solutions towards addressing the current staffing shortages, administrative issues and process inefficiencies facing oncology clinical trials, as well as consider alternative clinical trials administrative models to reduce the current burden.

Summit Organizers



Leisha Emens, MD, PhD
UPMC Hillman Cancer
Center



Marc Ernstoff, MD
National Cancer Institute



David Feltquate, MD, PhD
Palleon Pharma



Michael S. Gordon, MD
Honor Health



Kristen Hege, MD
Bristol Myers Squibb



David Hong, MD
MD Anderson Cancer
Center



Krystyna Kowalczyk
OncoBay



Mario Sznol, MD
Yale University



Stephanie Terzulli, PhD
Memorial Sloan
Kettering Cancer Center



Marc Theoret, MD
US Food and Drug
Administration

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Summit Takeaways

Summit attendees formalized possible solutions towards addressing the crisis and clinical research inefficiencies throughout the program. At the conclusion of the meeting, SITC was provided four key efforts that would create momentum in this arena:

Standardization and Centralization of Clinical Research Resources

- Develop consensus on structured data inputs
- Standardize clinical research contracting and budgeting language
- Adopt standard timelines across the field for implementation of EDC automations
- Implement consistent EMR builds and compatibilities
- Incorporate and accept centralized IRBs and SRCs

Cross-institutional Data Availability

- Collect clinical research accrual and activation data to drive future innovation
- Expand upon current data collection efforts
- Promote impartial and accepted data sharing culture across institutions and stakeholders

Maximizing Efficiency Across Clinical Research Operations

- Embrace automation
- Incorporate business-like operations within clinical research workstreams
- Perform work in parallel towards identifying potential efficiencies/inefficiencies
- Reduce silo's and streamline communications across stakeholders
- Develop processes that maximize personal and professional success for the available workforce

Diversification of Clinical Research Sites and Populations

- Expand access of clinical trials to underrepresented communities
- Increase patient education towards enhancing clinical trial acceptance
- Provide education to community centers towards becoming fully equipped clinical research sites

SITC's Next Steps

As a direct follow-up to this impactful summit, SITC is actively working with volunteers on formulating direct actions to address the four identified efforts. Immediately, published works are in development to provide awareness to the current crisis as well as to provide expanded insight concerning summit conclusions. Additionally, SITC has emphasized collaboration as a critical element of effective response to the crisis and is actively communicating with like-minded groups towards developing impactful solutions. Overall, SITC is committed to serving as a leader in addressing the crisis facing clinical research. Further information on how the attendees came to these recommendations can be found below in a detailed report of each talk and panel that occurred throughout the summit.