Enhancing Inclusivity in Oncology Clinical Trials: Key Strategies from the ACORI Community Oncology-Inclusive Clinical Trial Design Summit

Authors: Kimberly Demirhan[1], Latha Shivakumar[1], Shaalan Beg[2], Al B. Benson III[3], Lora Black[4], Michelle Lacy[5], Jane E. Myles[6], Sumanta Pal[7], Lawrence Wagman[7], Nicole A Colwell[1], Molly Kisiel[1], and Elana Plotkin[1]

Institutions: [1]Association of Cancer Care Centers, Rockville, MD; [2]National Cancer Institute, Bethesda, MD; [3]Robert H. Lurie Comprehensive Cancer Center, Chicago, IL; [4]Sanford Health, Sioux Falls, SD; [5]Metro Minnesota Community Oncology Research Consortium, Minneapolis, MN; [6]Decentralized Trials and Research Alliance, Pacifica, CA; [7]City of Hope, Duarte, CA

WHAT IS ACORI?

ACORI
ACCC COMMUNITY ONCOLOGY RESEARCH INSTITUTE

Approximately 85% of all patients with cancer are diagnosed and treated in community settings. Despite this, only 3% of patients receiving care in the community are enrolled in clinical trials. Inadequate time, infrastructure, resources, incentives, and reimbursement all contribute to this sparse participation rate.

To address this disparity, the Association of Cancer Care Centers (ACCC) Community Oncology Research Institute (ACORI) was launched in 2021. ACORI's mission is to establish clinical trials as a standard of care for all patients, regardless of where they are treated, by helping community oncology programs access the tools, knowledge-sharing, effective practices, and peer mentorships that can increase their ability to offer clinical trials.

PRIMARY DOMAINS:

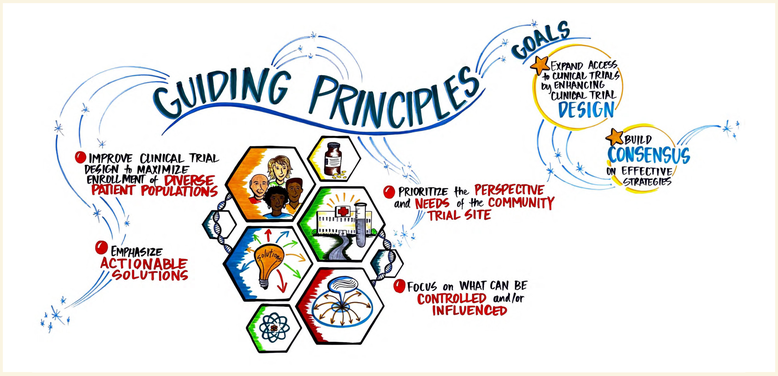
- EQUITY
- CAPACITY BUILDING
- RESEARCH DIFFUSION

SUMMIT BACKGROUND AND METHODS

ACCC hosted the ACORI Community Oncology Inclusive Clinical Trial Design Summit on October 29–30, 2024 to convene multidisciplinary stakeholders to address barriers to participation in community clinical trials by underrepresented groups.

- 24 Cancer Center Providers
- 17 Partner Organizations
- 17 Industry Members
- 2 Tech Company Representatives
- Members from FDA Oncology Center of Excellence, NCORP, and the National Cancer Institute

The summit focused on identifying actionable solutions to expand access to clinical trials by optimizing clinical trial design, employing innovative operational delivery of trial opportunities, and building consensus for effective strategies around engagement, recruitment, and retention of participants and communities.



Session topics were selected based on recommendations from the advisory committee, focusing on key areas for meaningful discussion among attendees. Each session followed a structured format, beginning with didactic or case-based presentations, followed by small group discussions and concluding with idea generation to drive actionable insights.

SUMMIT TOPICS

Artificial Intelligence (AI) in Trial Design → Inclusion/ Exclusion Criteria → Decentralizing Clinical Trials → APPs in Clinical Research → Trial Design for Diverse Populations → Industry Case Studies

PRIORITY AREAS AND TACTICS

Several key themes emerged from the discussion characterizing actionable strategies to promote clinical trial inclusivity:

Strengthen the clinical trial workforce

- Hold consensus-building events to raise awareness.
- Advocate for institutional support to expand advanced practice provider (APP) roles in clinical research.
- Standardize training programs and networking for APPs in research.
- Address clinical research coordinator shortage through flexible qualifications and education.
- Employ clinical trial navigators to reduce time burden.
- Support training programs for a representative trial workforce.

Engage with communities outside of clinical trial interactions

- Build relationships with communities prior to diagnosis.
- Involve a mixed group of community stakeholders early and often in the design process.
- Address systemic barriers through long-term institutional action plans, non-traditional recruitment efforts, and incorporating social drivers of health (SDOH) and peer support into trial frameworks.
- Focus on accountability through standardized measures and benchmarking.
- Address unconscious biases through education.

Leverage AI and digital tools for clinical trial efficiency

- Demonstrate the value of AI in clinical research by measuring impact on trial enrollment and outcomes.
- Advocate for transparency in the use of AI and technology to expand clinical research.
- Use AI tools for matching patients with trials, centralizing lab operations, and protocol adjustments for matching individual patients.

Optimize trial design to reflect real-world patient populations

- Promote pragmatic clinical trials.
- Consistently reassess and redesign eligibility criteria to minimize restrictiveness.
- Simplify trial protocols and assessments to increase adherence.
- Engage community providers early in the design process.

Expand research access through decentralized clinical trials (DCTs)

- Refine regulatory and oversight standards with flexible standards for principal investigator (PI) oversight and delegation of authority (DOA).
- Inform stakeholders of benefits of DCTs through data, return on investment (ROI), and case study sharing.
- Develop education resources for operational guidance and implementation of DCT trials.
- Provide a framework for partnering with community health resources to deliver DCT elements.

CONCLUSION

Patient-centered trial design and accessible research opportunities are essential for improving cancer care. Addressing systemic barriers and adopting innovative approaches can expand trial participation and improve the generalizability of clinical research. Through ACORI, ACCC will continue to foster collaboration among stakeholders. This remains critical to ensuring sustainable progress in community oncology research.

ACKNOWLEDGMENTS

Thank you to the 76 attendees of the ACORI Summit who contributed their thoughts and voices to the priority area discussions.

This project was made possible with support from AstraZeneca, Eli Lilly and Company, Gilead Sciences, and Sanofi.

AUTHOR CONTACT INFORMATION

Kimberly Demirhan, MBA, BSN, RN
Assistant Director, Education Programs
Association of Cancer Care Centers (ACCC)
kdemirhan@accc-cancer.org

Learn more about the ACORI Community Oncology-Inclusive Clinical Trial Design Summit by scanning the quick response (QR) code or by visiting **accc-cancer.org/ACORI**.