Category: Clinical Trial Operations (Trial Start-up, Regulatory, Finance, Data Management, IITs) - Work in progress

Building Capacity and Operationalizing Hybrid and Fully Decentralized Clinical Trials in Community Oncology: a Thematic Analysis of Expert Roundtable Discussions

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1. Background

Despite growing interest in decentralized clinical trial (DCT) models, oncology programs—particularly in community settings—continue to face operational, regulatory, and workforce-related barriers to implementation. A 2024 multi-stakeholder summit convened by the Association of Cancer Care Centers (ACCC) Community Oncology Research Institute (ACORI) identified inconsistencies, misconceptions, and operational uncertainty surrounding DCT elements as priority challenges. In response, ACORI launched a structured roundtable series to identify real-world barriers and develop scalable, practice-informed solutions to support DCT implementation across diverse oncology settings.

2. Goals

This initiative aimed to:

1. Identify operational, regulatory, and workforce barriers to hybrid and fully decentralized oncology trials;
2. Synthesize cross-institutional lessons learned from academic and community sites; and
3. Inform the development of practical implementation tools, including a DCT Site Self-Assessment Tool and Playbook.

3. Solutions and Methods

ACORI partnered with the Decentralized Trials & Research Alliance (DTRA) to convene three expert roundtables (November 2025–March 2026) involving stakeholders from academic cancer centers, community oncology programs, industry sponsors, federal agencies, and advocacy organizations. Case study presenters shared real-world DCT protocols, highlighting operational barriers and mitigation strategies. Discussions were recorded and synthesized into thematic domains through qualitative analysis. Cross-institutional opportunities were identified to inform tool development.

4. Outcomes

Three primary thematic domains emerged:

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1. **Regulatory and Oversight Complexity:**

   Participants reported operational uncertainty in applying regulatory guidance across health systems, including ambiguity surrounding Form FDA 1572 responsibilities and oversight of local providers. Sites and sponsors emphasized the need for clearer, unified operational adoption strategies to balance expanded access with patient safety and data integrity.

2. **Operational Infrastructure and Workforce Readiness Gaps:**

   Key barriers included sample logistics, local laboratory integration, data workflows, and investigator comfort with decentralized elements. Participants emphasized the importance of piloting individual DCT components prior to broader implementation and maintaining active communication between treating oncologists and research teams.

3. **Patient-Centered Trial Design Opportunities:**

   Hybrid and fully decentralized supportive care trials were reported as feasible within integrated systems. Telehealth, remote monitoring, and virtual engagement models were described as reducing patient burden and supporting long-term follow-up. Participants noted potential improvements in participation and retention, while acknowledging the need for broader multi-site evaluation.

5. Lessons Learned and Future Directions

Successful DCT implementation requires broad adoption of consistent regulatory guidance, aligned site and sponsor operational readiness, intentional workforce development, and strong communication frameworks across clinical and research teams. Insights from this initiative are directly informing development of a DCT Site Self-Assessment Tool and implementation Playbook to support oncology programs in evaluating readiness and operationalizing decentralized elements. ACORI will also expand mentorship and peer-learning opportunities to facilitate scalable adoption of best practices across community and academic settings.