2025 SCRS Site Strategies for Inclusive Oncology Trials Survey

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Executive Summary

The 2025 SCRS Site Strategies for Inclusive Oncology Trials Survey aimed to assess the needs of oncology clinical research sites in fostering greater inclusivity and access within clinical trials. A total of 62 responses were collected, offering critical insights into the barriers, resource gaps, and opportunities for improving community outreach, patient engagement, and inclusivity in cancer research. Findings highlighted limited resources, challenges in patient recruitment, and the need for tailored sponsor support to foster equitable participation in oncology trials.

Introduction

Despite cancer being one of the leading causes of death in minority populations, underrepresentation in clinical trials remains a persistent issue. For example, African Americans, who make up 13% of the U.S. population and experience higher cancer mortality rates, typically account for only 5% of clinical trial participants (FDA, 2020). Similarly, Hispanic and Latino populations represent 18% of the U.S. population but comprise only about 1%-6% of oncology trial participants (Journal of Clinical Oncology, 2021).

Genetic and biological differences across racial and ethnic groups can affect how patients respond to cancer therapies. For example, tumor mutation prevalence and pharmacogenomics often vary between populations, influencing both treatment efficacy and side effects. Research shows that inclusive recruitment for clinical trials can help close gaps in health disparities.

By including typically underrepresented populations, trials can generate data that better guide treatment for underserved groups, ultimately improving cancer outcomes. A National Cancer Institute study emphasized that tailored interventions informed by representative trial data lead to improved screening, diagnosis, and survival rates in marginalized communities.

To address these critical gaps, SCRS conducted a comprehensive survey to evaluate the needs and current practices of oncology research sites. The objective was to identify resource limitations, recruitment barriers, and administrative challenges while providing actionable insights for sponsors, CROs, and sites to collaborate effectively in promoting inclusivity and equitable access to clinical trials.

These findings also highlight the administrative burden faced by sites due to inconsistent patient reimbursement practices and lengthy negotiations, emphasizing the need for streamlined budgeting processes to facilitate more equitable trial execution.

Survey Highlights and Analysis

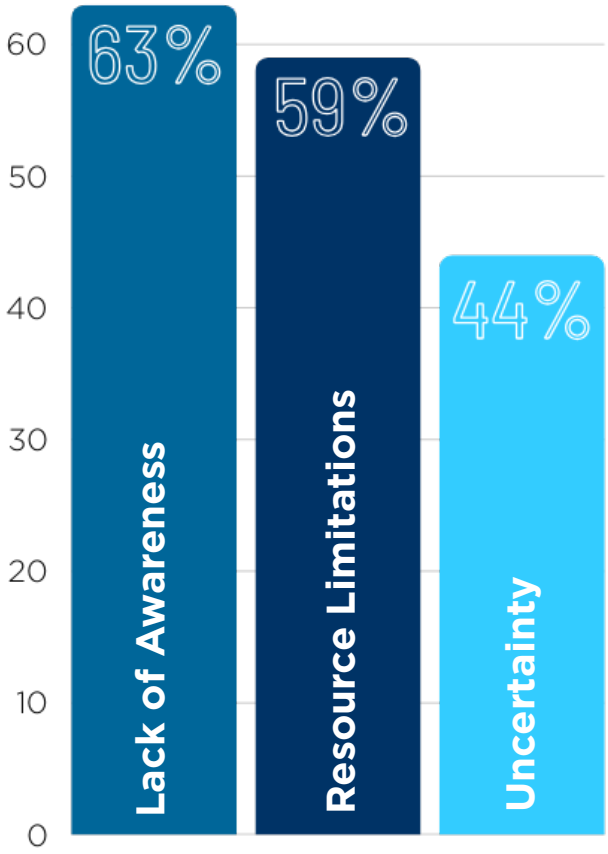
1. Site Demographics

- **Socio-Economic Locations:** Respondents represented diverse locations: 20% were from urban areas, 15% suburban, 25% rural, 20% remote, and 20% intercity. Sites in rural and remote areas face unique challenges in accessing broader patient populations, often requiring innovative strategies and additional resources to engage participants.
- **Regional Distribution:** Sites spanned various regions, including Northern-Central US (21%), Southern-Central US (16%), Western US (16%), South-Eastern US (11%), and international locations such as Asia (11%) and Western Europe (11%). Regional distribution impacts the cultural, linguistic, and socio-economic factors influencing trial participation.
- **Site Types:** A variety of site types participated, including hospitals (30%), freestanding/ independent sites (25%), and clinic-embedded sites (20%). Each site structure brings distinct strengths and challenges. For example, freestanding sites often require more external support to implement inclusive trial practices.
- **Catchment Areas:** The average patient reach varied, with 40% serving patients within 10-30 miles, 30% extending 31-50 miles, and the remainder reaching broader distances. Smaller catchment areas may limit access to diverse populations, while larger areas pose logistical challenges.
- **Trial Phases:** Most sites reported capability across multiple phases, with 65% conducting Phase 2 and 50% conducting Phase 3 trials. This range of expertise highlights opportunities for collaboration but also underscores the importance of considering inclusivity and representation across all trial phases to ensure broad participation.

2. Community Engagement

- **Engagement Practices:** Effective community engagement is critical as it establishes trust, raises awareness of clinical trials, and helps overcome historical skepticism. Common strategies included social media campaigns (44%), educational workshops (37%), and collaborations with local institutions such as community centers and faith-based organizations (41%). However, 56% of site respondents indicated insufficient resources to conduct these efforts, limiting their reach and effectiveness.

56% of site respondents indicated insufficient resources to conduct community engagement efforts



- **Barriers to Engagement:** The top three challenges identified were a lack of awareness about clinical trials (63%), resource limitations (59%), and uncertainty about how to engage underrepresented communities (44%). These barriers impede the ability of sites to connect with broader patient populations, thereby limiting opportunities to enhance enrollment and representation.

3. Patient Engagement and Inclusion

- **Recruitment Barriers:** Geographic constraints (35%), cultural or language differences (29%), and protocol complexities (18%) were among the most cited obstacles preventing inclusive patient participation. These challenges directly impact sites' ability to attract a representative patient population, which is essential for generalizing trial results to real-world populations.
- **Representative Communications:** Only 59% of sites reported using recruitment materials that reflect a range of patient demographics, highlighting the need for more representative communications. Materials that resonate with a broader audience can build trust and foster stronger connections with underrepresented communities, encouraging participation. The lack of such materials diminishes the perception of inclusivity, deterring potential participants from engaging in clinical trials.

ONLY **59%** *of sites reported using recruitment materials that reflect a range of patient demographics*

4. Financial and Logistical Challenges

- **Resource Gaps:** Most sites indicated critical resource and funding shortages, including patient transportation (65%), cultural competency training (48%), and translation services (39%). Without these resources, sites struggle to provide equitable access and support for participants, which can lead to low recruitment and retention rates.
- **Sponsor Subsidization:** While some sites received support through startup fees (32%) or grants (18%), preferences leaned heavily toward specific line-item funding for community engagement initiatives (59%). Clear and targeted funding mechanisms are crucial to ensure resources are appropriately allocated to address these needs and improve access.

59%

Preferences leaned heavily toward specific line-item funding for community engagement initiatives

- **Cost Justification:** Nearly half of sites reported they are frequently required to justify costs related to inclusive patient support, such as patient transportation, translation services, and recruitment actions. Conversely, some sites indicated these costs are included in initial budgets, suggesting variability in how sponsors address these needs. Sites without upfront inclusion face additional administrative burdens, slowing study execution and enrollment.

5. Insurance, Reimbursement, and Socio-Economic Impact

- **Insurance Limitations:** Coverage issues disproportionately affected uninsured or underinsured individuals, creating significant barriers to trial participation. 42% of respondents noted that insurance coverage impacts their ability to recruit patients from a broader range of patient demographics. This creates inequities in trial participation, potentially skewing trial representation and results.

42%

noted that insurance coverage impacts their ability to recruit patients

- **Patient Reimbursement:** Slightly more than half of sites believe patient reimbursement positively reinforces broader patient enrollment, with 48% of sites expressing concerns about its sufficiency. It has been further highlighted that a majority of sites feel they only sometimes have the ability to negotiate patient compensation with sponsors, leading to inconsistencies in participant support.

  When sites must negotiate reimbursement, it adds days or even weeks to the budget execution process. These findings emphasize the importance of setting reasonable and equitable patient compensation rates upfront in initial budgets to reduce negotiation timelines.

48%

express concern about sufficient patient reimbursement

- **Uncovered Costs:** Data showed significant gaps in reimbursement coverage, with frequent omissions for patient travel time, childcare, and lost wages. These gaps disproportionately impact participants from lower socio-economic backgrounds, limiting access and reducing the inclusivity of trials. Addressing these gaps is essential to ensure equitable participation across all patient populations.

6. Professional Services and Accessibility

- **Availability of Support Services:** Results revealed that many sites lack access to professional services such as disability accommodations, mobility assistance, and specialized equipment management. These gaps further hinder inclusivity, particularly for patients with physical or sensory disabilities. Only a small percentage of sites reported having these resources readily available.
- **Remote Visits:** It has been indicated that some sites conduct remote visits, which can alleviate geographical barriers and improve accessibility. However, this approach is underutilized and requires additional infrastructure and training to implement effectively.

Key Findings

1. **Resource Constraints:** The majority of sites (56%) lack adequate financial, logistical, and educational resources to implement initiatives to recruit underrepresented communities effectively.
2. **Recruitment Challenges:** 35% of respondents citing geography as a major obstacle, followed by protocol complexity and cultural barriers hindering patient participation in trials.
3. **Sponsor Collaboration Needs:** Sites expressed a need for better financial support, marketing tools, and logistical assistance from sponsors and CROs. Specific line-item funding for outreach initiatives was the most preferred method of support (59%).
4. **Impact of Representation:** Inclusive imagery and culturally sensitive materials were underutilized, with only 59% of respondents incorporating these practices.
5. **Administrative Burdens:** Cost justification and negotiation for patient reimbursement add significant delays to budget execution and study startup timelines.
6. **Demographic Insights:** Site location, type, and regional focus significantly impacted their ability to access and recruit patients from a variety of backgrounds.

Recommendations

1. **Enhance Sponsor Support:**
    - Provide targeted funding for community outreach efforts, with 59% of respondents preferring specific line-item funding.
    - Offer educational programs and resources tailored to address the lack of awareness cited by 63% of respondents.

2. **Simplify Protocol Designs:**
    - Address geographical (35%), cultural, and socio-economic barriers in trial eligibility criteria.
    - Consider adjustments to protocol complexity to reduce exclusion based on factors like language or behavioral conditions.

3. **Improve Representation:**
    - Develop recruitment materials featuring inclusive imagery and language, a practice currently underutilized by 41% of respondents.
    - Partner with local advocacy groups and culturally aligned organizations to foster trust and engagement.

4. **Streamline Patient Reimbursement:**
    - Include provisions for childcare, travel, and time-off compensation to alleviate participant burdens, addressing a concern raised by 63% of sites.
    - Set reasonable and equitable patient compensation rates in initial budgets to avoid delays and negotiation challenges.

5. **Expand Accessibility Resources:**
    - Increase availability of professional services such as disability accommodations and mobility assistance.
    - Invest in remote visit capabilities to reduce geographical barriers and improve trial accessibility.

By addressing these priorities, clinical research industry partners can collectively drive progress toward inclusive and equitable oncology clinical trials.

Conclusions

The survey results underscore the pressing need for oncology clinical research sites to receive enhanced support from sponsors and CROs. Addressing resource gaps, simplifying protocol designs, and fostering community trust are critical steps toward achieving equity in clinical trials. Setting fair and reasonable patient compensation rates in initial budgets can reduce administrative burdens and promote smoother study execution. Moreover, increasing community awareness and education about clinical trials can help dismantle barriers to participation and improve engagement.

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