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Addressing Rural Participant Underrepresentation in U.S. Clinical Trials Through Transportation Support, Telehealth Access, and Community Health Worker Engagement

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ABSTRACT

Representative clinical trials are essential for producing evidence applicable to diverse populations and supporting equitable access to investigational care. Rural communities in the United States face participation challenges associated with geographic isolation, limited research infrastructure, transportation costs, unreliable connectivity, and competing employment or caregiving responsibilities. This proposed narrative review examines how transportation support, telehealth access, and community health worker engagement can address these interconnected barriers. The review will synthesize U.S. evidence on travel assistance, mileage reimbursement, coordinated transportation, remote screening, electronic consent, selected virtual visits, and community health worker navigation. Particular attention will be given to broadband availability, digital literacy, disability access, confidentiality, clinical suitability, and coordination between research centers and local healthcare providers. Evidence from different diseases and trial settings will be distinguished to avoid assuming uniform effectiveness. An integrated framework will connect practical assistance with trusted communication and flexible trial delivery. Evaluation priorities will include invitation opportunities, enrollment, retention, participant burden, comprehension, and implementation costs. The review aims to inform contextually appropriate recruitment strategies that improve rural research access while preserving patient safety, voluntary decision-making, and institutional accountability.

Keywords: Rural populations; Clinical trial participation; Transportation support; Telehealth access; Community health workers; Research equity.

1. INTRODUCTION

1.1 Clinical trials, representative evidence, and equitable opportunity

Clinical trials evaluate the efficacy and safety of interventions, identify adverse events, and generate evidence that informs clinical practice. Their usefulness depends partly on whether participants reflect the populations expected to receive the intervention. Inclusive eligibility criteria and enrollment practices can improve the applicability of findings across differences in geography, socioeconomic circumstances, comorbidity, and access to healthcare [1].

Rural participation therefore concerns both evidence quality and equitable opportunity. When research pathways overlook patients outside major centers, investigators may obtain less information about how interventions function under differing care circumstances. Equitable recruitment should provide opportunities for assessment and informed consideration, without suggesting that trial participation guarantees therapeutic benefit [2].

Investigational interventions may offer uncertain benefits and carry unknown risks. Patients must understand the research purpose, alternatives, and voluntary nature of participation [3]. Addressing rural exclusion consequently requires accessible opportunities and informed choice, rather than treating increased enrollment as the sole objective.

1.2 Rural populations and the participation challenge

This review focuses on rural communities in the United States. Rurality includes remote settlements, agricultural regions, small towns, and rural areas within metropolitan counties. The Census Bureau defines rural territory as territory outside urban areas [3], while other federal classifications use different criteria [4]. These distinctions matter because geographic definitions influence which populations are identified and compared.

Participation challenges include distance from research centers, limited local trial infrastructure, transportation demands, unreliable connectivity, and

competing employment or caregiving responsibilities. Research involving rural older cancer survivors identified transportation difficulties and inadequate information about trials among reported barriers [5]. Community research also highlights the importance of communication and locally relevant engagement [6].

However, evidence of barriers does not independently establish the magnitude of underrepresentation. Participation estimates require a defined disease population, trial setting, observation period, rural classification, and comparison denominator. Findings from communities should not be generalized to all rural residents. Rural populations differ in resources, healthcare relationships, clinical needs, and preferences, making individualized assessment essential to designing appropriate recruitment and participation support.

1.3 Review objective, scope, and central proposition

This narrative review examines transportation support, telehealth access, and community health worker engagement as complementary strategies for adult U.S. interventional clinical trials across disease areas. It prioritizes directly relevant rural evidence and identifies findings transferred from oncology or other specialized settings. Transportation assistance addresses necessary travel; telehealth enables selected activities outside traditional trial sites [7]; community health workers may support locally informed communication and navigation, provided roles and clinical integration are clearly defined [8].

The central proposition is that practical assistance, flexible delivery, and trusted navigation must operate together within accountable research systems. Institutions remain responsible for consistent assessment, resources, safety, and responsiveness to participant concerns. The following section explains how evidence is identified and interpreted, distinguishing documented outcomes from proposed mechanisms and recommendations requiring further evaluation in rural settings.

2. NARRATIVE REVIEW APPROACH

2.1 Review questions and conceptual boundaries

Three questions guide this review: which barriers limit rural patients' opportunities to participate in U.S. clinical trials; how transportation, telehealth, and community health worker strategies address those barriers; and which implementation conditions and outcomes should determine evaluation. Oncology evidence informs barrier identification [5], while community research contributes engagement perspectives [6]. Recruitment identifies and invites potential participants; consent establishes informed agreement; enrollment records trial entry; retention concerns continued participation. Telehealth represents selected remote activities within flexible delivery, not replacement of every clinical procedure [7]. Community health worker roles require defined boundaries and coordination with clinical teams responsible for participant care [8].

2.2 Literature identification and selection

Evidence identification used targeted web searches on 11 October 2026 to retrieve PubMed records, full texts, publisher articles, and federal guidance. PubMed and PubMed Central were retrieval sources; direct database searches were not performed. Queries addressed rural clinical trial participation, transportation barriers, community recruitment, rural definitions, telehealth, digital access, community health workers, and navigation.

Sources were selected for relevance to adult U.S. trials, rural participation barriers, intervention mechanisms, or implementation requirements. Priority was given to rural studies and authoritative guidance. Selection considered geographic definitions, population characteristics, disease setting, and whether findings concerned evaluated interventions or proposed strategies.

Evidence from nonrural populations and international settings will be identified as indirect rather than assumed transferable. The review uses a narrative approach requiring explicit objectives, transparent search descriptions, and qualified reasoning [9]. No exhaustive coverage, independent duplicate screening, or systematic review designation is claimed. Search limitations remain material to interpretation throughout the manuscript.

2.3 Evidence interpretation and review limitations

Findings will be organized by barrier, intervention mechanism, disease area, setting, and outcome. Measured enrollment and retention will be distinguished from reported willingness, feasibility, satisfaction, and anticipated benefits; survey evidence cannot independently establish participation effects [10]. Interpretation will consider differing rural definitions, comparison groups, study designs, and combined intervention packages. Complex intervention guidance supports examining context and mechanisms before attributing outcomes to components [11]. Implementation assessment will consider organizational capacity and workflow fit [12]. Targeted retrieval limits completeness, while heterogeneous evidence constrains causal conclusions. This framework guides the following examination of where rural patients encounter exclusion across the participation pathway.

3. MULTILEVEL BARRIERS TO RURAL TRIAL PARTICIPATION

3.1 Geographic access and uneven research infrastructure

Rural exclusion from clinical trials begins before recruitment materials reach prospective participants. Distance from research centers is one constraint; the absence of suitable studies within local care networks is another. Investigator research identifies communication and organizational difficulties in reaching rural communities [13]. These conditions can restrict whether patients encounter research opportunities at all.

Geographic isolation and institutional invisibility therefore require different responses. Patients aware of a trial may struggle to reach its site, whereas others receive routine care without trial consideration. Research involving rural older cancer survivors identified inadequate information from physicians alongside transportation difficulties [5]. Enrollment records alone cannot distinguish these preceding losses.

Effective referral networks require accessible trial information, designated contacts, and coordination between local clinicians and specialist investigators. Screening should form part of an organized workflow rather than depend entirely on individual awareness. Implementation frameworks emphasize organizational capacity and compatibility with existing processes [12]. Specialist shortages and limited research staffing must consequently inform planning. Assessing geographic reach alongside referral practices provides a clearer account of exclusion than attributing low participation to rural residence or presumed reluctance alone.

3.2 Transportation, financial, and scheduling burdens

Travel requirements convert geographic distance into recurring financial and practical demands. Fuel, parking, lodging, unreliable vehicles, missed employment, and caregiving obligations can accumulate across repeated visits. National research documents transportation barriers to healthcare, although these findings do not independently quantify their effect on trial enrollment [14].

The burden depends on both visit intensity and clinical condition. Weekly assessments impose different demands from occasional follow-up. Fatigue, pain, impaired mobility, or treatment effects may make driving difficult or inappropriate. Sedation and certain procedures may require a companion, creating additional scheduling and employment pressures.

Financial feasibility also depends on payment timing. Reimbursement cannot remove an upfront barrier when patients lack funds to undertake the journey. Recommendations for clinical trial access emphasize transparent costs and practical assistance [15]. An evaluated travel and lodging intervention reduced related financial concerns but did not eliminate broader hardship [16]. These findings support targeted assistance rather than assumptions of uniform benefit.

Rural households differ in income, vehicle access, paid leave, and support networks. Travel assessment should therefore establish individual circumstances, including companion needs, accommodation, reimbursement timing, and contingency arrangements.

3.3 Digital access and communication barriers

Telehealth changes the location of participation without necessarily removing access barriers. Reliable broadband, mobile coverage, suitable devices, accessible interfaces, and digital confidence determine whether remote activities are usable. Guidance on digital research technologies emphasizes participant suitability, training, and support [17]. Connectivity must also permit stable communication, while home circumstances must allow privacy.

Research communication introduces a challenge. Unfamiliar terminology and limited opportunities for discussion can undermine understanding even when technology functions. Community research supports locally relevant engagement rather than standardized assumptions about patient preferences [6]. Rural residence does not establish low literacy, distrust, or inability to use digital services.

Consequently, mandatory digital participation may exclude some patients while reducing travel for others. Equity recommendations caution against assuming universal access or benefit [18]. Telephone, paper, and in-person alternatives should remain available where appropriate. Teach-back helps staff identify unclear explanations and address misunderstanding [19]. Technical completion, comprehension, and voluntary agreement are distinct outcomes. Accessible platforms must therefore be accompanied by responsive communication and clinical coordination, with unresolved questions addressed before participation proceeds.

3.4 Interacting barriers across the participation pathway

Rural participation barriers operate cumulatively rather than independently. Internet access cannot replace transport for required procedures, and travel assistance cannot compensate for an absent referral. Research among rural people who use drugs identifies participation influences spanning individual circumstances, staff relationships, and trial characteristics [20].

Single interventions may therefore improve one stage while leaving another inaccessible. Reported willingness to use decentralized tools cannot establish actual enrollment or retention [10]. Evaluation must examine how intervention components interact within local systems and clinical settings

[11].

Figure 1 maps these stages and barrier domains. Its implication is coordinated support across the pathway. The next section examines transportation assistance, focusing on physical access requirements that persist after trial information and referral opportunities become available locally.

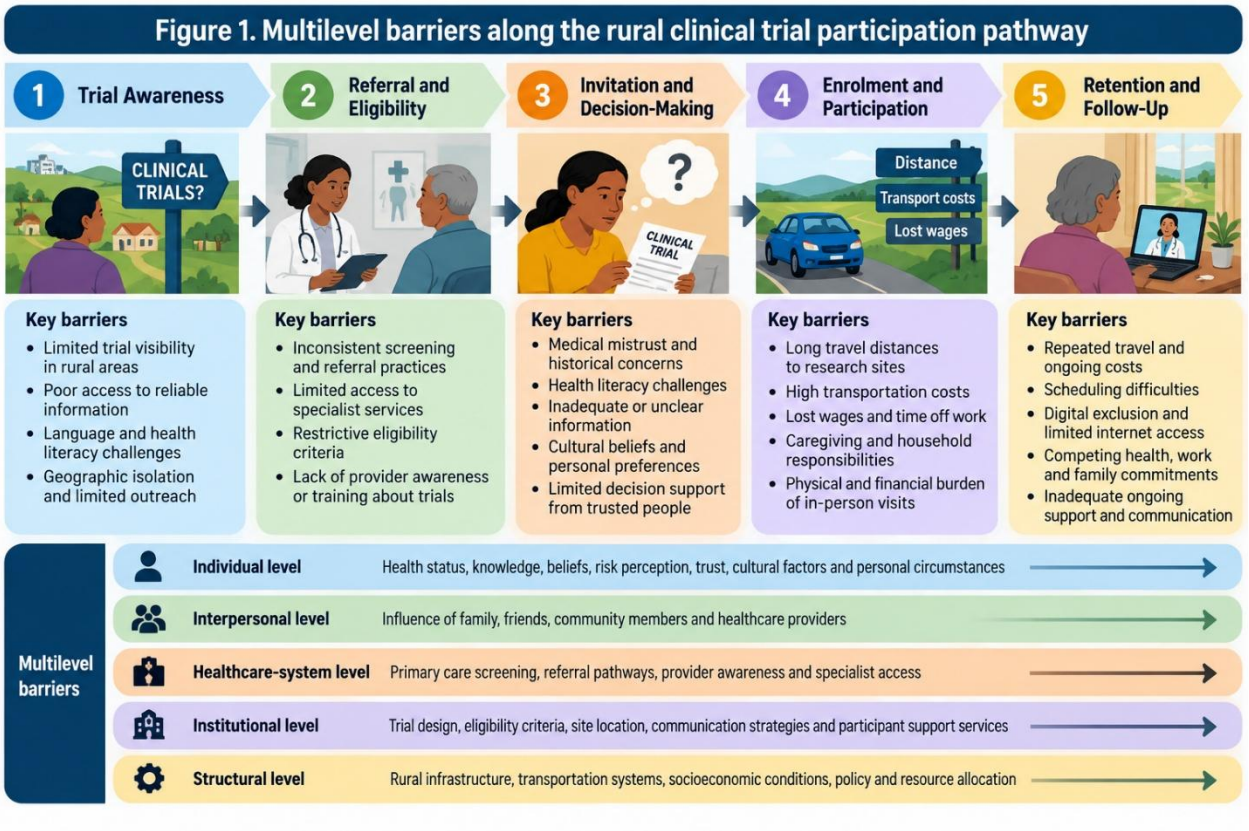


Figure 1. Multilevel barriers along the rural clinical trial participation pathway

4. TRANSPORTATION SUPPORT AND PARTICIPATION FEASIBILITY

4.1 Identifying travel needs and selecting assistance

Transportation support should begin with an assessment of what each participant must undertake to reach the trial site. Distance, visit frequency, mobility, vehicle access, companion requirements, and overnight accommodation determine whether a proposed arrangement is usable [18]. Assistance should match these conditions rather than offer every patient the same reimbursement mechanism.

Mileage reimbursement may suit participants with reliable vehicles and sufficient funds, whereas prepaid transport can address cash constraints. Coordinated rides may help patients unable to drive, while lodging assistance can reduce repeated long journeys. Local organizations may contribute transport links, but availability, accessibility, and reliability require confirmation.

Evidence from a cancer care equity program associated travel and lodging assistance with increased accrual, although the observational design limits causal interpretation [21]. For rural implementation, payment timing remains critical: reimbursement after travel cannot enable a journey that patients cannot initially afford. Assessment should therefore establish financial timing alongside geographic and clinical requirements.

4.2 Coordinating visits and reducing avoidable travel

Reducing transportation burden also requires examining whether every journey is necessary. Trial teams can consider clustering assessments, aligning research visits with clinical appointments, and offering scheduling flexibility. Local services may accommodate selected procedures when qualifications, protocol requirements, and oversight permit. Research integrating telehealth with local chemotherapy illustrates potential reductions in travel demands within a specific oncology setting [22].

Consolidation must preserve required assessment intervals and avoid exhausting patients through excessively long visits. Investigational treatment,

specialized procedures, and safety monitoring may still require designated facilities. Coordination should therefore involve investigators, treating clinicians, transport providers, and participants before arrangements are confirmed [18].

A shared schedule should identify visit purpose, location, expected duration, companion needs, and contingency contacts. Changes require timely notification to prevent unnecessary expenditure or missed assessments. Travel reduction and remote delivery should remain complementary strategies, with digital suitability assessed rather than presumed [17]. Coordination reduces duplication without transferring responsibility to patients.

4.3 Funding, transparency, and ethical safeguards

Funding arrangements should explain covered expenses, reimbursement limits, payment timing, documentation, and cancellation procedures [23]. Participants need a named contact for cost questions and a process for resolving delayed payments. Policies should specify whether assistance extends to screening visits when patients prove ineligible or choose not to enroll.

Expense reimbursement must be distinguished from payment for participation. FDA guidance indicates that reimbursement for travel and associated costs does not itself raise undue influence concerns [23]. Nevertheless, assistance should never be presented as evidence of treatment benefit or as creating an obligation to participate. Consent must preserve informed consideration and voluntary choice [24].

Support criteria should be transparent and applied consistently, while accommodating different levels of need. Programs should budget for screening, necessary companions, and unavoidable cancellations. Assistance should remove participation barriers without making continued access conditional on completing the entire trial [23].

4.4 Evaluating transportation support and remaining barriers

Evaluation should measure completed visits, missed appointments, travel time, participant expenditure, retention, and reported experience. Implementation outcomes, including acceptability and feasibility, should be distinguished from clinical or enrollment outcomes [25]. Reduced travel concerns alone cannot establish improved recruitment [21].

Residual barriers require assessment. Transport assistance cannot resolve missing referrals, unsuitable eligibility criteria, or inaccessible digital requirements; equity recommendations emphasize examining these interacting conditions [18]. Table 1 maps complementary responses across the three approaches. Transportation support makes necessary journeys more feasible, while telehealth can reduce selected journeys [22]. The next section examines when remote delivery is clinically appropriate, accessible, and coordinated with local care, rather than assuming that convenience guarantees equitable participation.

Table 1. Barrier-to-strategy mapping across the three access approaches

Barrier	Transportation response	Telehealth response	Community health worker response	Remaining institutional requirement
Long distances and repeated journeys	Coordinate rides, mileage assistance, and lodging	Replace suitable visits with remote assessments	Help coordinate appointments and identify travel needs	Determine which activities require specialist facilities
Inability to pay travel costs upfront	Provide prepaid arrangements or timely advances	Reduce some travel-related expenditure	Identify financial constraints and explain assistance	Fund support and publish payment procedures
Limited mobility or companion requirements	Arrange accessible transport and necessary companion support	Offer appropriate remote contact	Identify accessibility needs and communicate them to staff	Ensure clinical suitability and safe travel arrangements
Work and caregiving conflicts	Coordinate transport around agreed schedules	Offer suitable remote appointments	Help identify scheduling constraints	Provide flexibility within protocol requirements
Unreliable connectivity or limited devices	Enable attendance when remote access is unsuitable	Offer technical support and appropriate alternatives	Assist with access and escalate technical difficulties	Provide accessible options without mandatory digital participation

Barrier	Transportation response	Telehealth response	Community health worker response	Remaining institutional requirement
Missing referrals or limited trial awareness	Facilitate travel after referral; cannot create referral opportunities	Support preliminary contact with trial teams	Connect patients and local clinicians with research staff	Maintain consistent assessment and referral procedures
Unclear information or unresolved concerns	Explain travel arrangements and remaining costs	Provide opportunities for remote questions	Support plain-language discussion and navigation	Preserve informed choice and escalate clinical questions

5. TELEHEALTH ACCESS AND FLEXIBLE TRIAL DELIVERY

5.1 Remote contact, preliminary screening, and consent

Remote contact can widen the recruitment pathway through telephone conversations, video consultations, and preliminary screening. These approaches can establish whether a study may be relevant without requiring a journey. However, remote screening identifies potential suitability; final eligibility requires protocol-specific assessment by qualified clinical personnel.

Electronic consent should provide information, opportunities for questions, and documentation that participants can retain. A digital signature does not demonstrate comprehension or voluntary agreement; consent remains a process of informed consideration [24]. Identity verification, confidentiality, and information transfer must therefore accompany electronic procedures.

Communication methods should accommodate language, sensory, cognitive, and accessibility needs. Teach-back can identify unclear explanations by asking participants to describe information in their own words [19]. Staff should clarify outstanding examinations, records, or laboratory results before implying eligibility. Equity recommendations support offering alternatives when digital access is limited [18]. Remote recruitment must expand options without creating technological pathways or replacing necessary clinical judgment.

5.2 Hybrid trial activities and local clinical coordination

Hybrid delivery combines remote activities with necessary visits. Symptom discussions, follow-up consultations, electronic patient-reported outcomes, and local laboratory services may reduce travel. Research integrating telehealth with local chemotherapy illustrates possible burden reductions in one oncology context, without establishing universal suitability across diseases or interventions [22].

Location decisions must follow treatment complexity, protocol requirements, staff competence, and available emergency support. Investigational infusions, invasive procedures, specialized imaging, or examinations requiring immediate specialist interpretation may need designated facilities. Remote data technologies also require assessment of their suitability and reliability for the intended measurement [17].

Central and local teams should specify who reviews laboratory results, responds to abnormal findings, records adverse events, and contacts participants. Escalation plans must identify response times and emergency pathways. Shared records and communication can reduce duplication, but accountability cannot depend on participants relaying information between services.

Practical coordination should also consider whether local delivery introduces unfamiliar costs or responsibilities. Participants need clear explanations of arrangements and covered expenses [23]. Flexibility remains valuable only when monitoring and continuity are preserved.

5.3 Digital inclusion and participant support

Digital inclusion requires resources that make remote participation workable. Loaned devices, connectivity assistance, accessible platforms, technical training, and troubleshooting can address different access constraints. Technology guidance emphasizes usability and participant support rather than assuming that device ownership establishes readiness [17]. Programs should assess both access and opportunities for private communication.

Telephone and in-person alternatives should remain available where clinically appropriate. Preferences and capabilities can change as symptoms, fatigue, disability, or treatment intensity increase. Equity recommendations therefore support responsive arrangements instead of a fixed assumption that remote delivery suits every participant [18]. Assistance should avoid requiring caregivers to provide technical support without agreement or adequate preparation.

Connectivity also leaves other burdens intact. Employment losses, caregiving demands, and costs associated with remaining visits may persist. Evidence from transportation support programs shows why practical assistance remains relevant alongside flexible delivery [21]. Information about

remaining expenses should be transparent [23]. Navigation, coordinated scheduling, and transport support should complement digital services, ensuring that reduced travel does not conceal new financial, administrative, or household workload demands.

5.4 Evidence of benefit, limitations, and safeguards

Convenience, satisfaction, and expressed willingness indicate acceptability, not necessarily equitable enrollment or sustained retention. Implementation evaluation should distinguish these outcomes from observed participation effects [25]. Programs need subgroup comparisons, defined observation periods, and reasons for discontinuation.

Safeguards must address privacy, missing data, technical failures, and tasks transferred to participants or caregivers [18]. Remote measurements require suitable systems and procedures for identifying unreliable information [17]. In-person assessment remains necessary when clinical examination, urgent evaluation, or protocol requirements cannot be met remotely.

Flexible delivery expands options, but options require guidance and practical coordination. The next section examines how community health workers can help rural participants navigate these arrangements within their local circumstances.

6. COMMUNITY HEALTH WORKER ENGAGEMENT

6.1 Local relationships, role definition, and partner selection

Community health workers can connect research teams with patients, local organizations, and healthcare services through established relationships and knowledge of community circumstances. CDC describes their role in linking communities with needed services and addressing barriers to care [26]. Applying this role to trial recruitment requires explicit responsibilities rather than assuming that trusted relationships automatically produce enrollment.

Selection should consider community connections, communication skills, relevant experience, and participant preferences. Workers should not be treated as interchangeable representatives of all rural residents. Their navigation and educational functions must remain distinct from investigators' clinical decisions and the responsibilities of personnel authorized to obtain consent.

Early involvement allows workers to identify impractical outreach methods, appointment arrangements, and support procedures. Partnership guidance emphasizes ongoing engagement, compensation, and meaningful participation in decisions [27]. Programs should establish supervision, escalation routes, and fair remuneration based on work performed rather than recruitment totals. These arrangements recognize community expertise while maintaining accountability for clinical assessment, research oversight, and informed consent.

6.2 Trial communication and voluntary decision support

Trial communication should explain scientific purpose, alternatives, potential harms, uncertainty, costs, privacy, and withdrawal rights in language participants can understand. Community health workers can reinforce information and identify questions requiring clarification, but should not promise eligibility, enrollment, or therapeutic benefit. Consent remains the responsibility of authorized personnel and must preserve informed, voluntary consideration [24].

Research literacy involves understanding how trials differ from routine care, including randomization and protocol requirements. Teach-back and repeated questions should support clarification rather than signal resistance. Training resources for community health workers support accessible education and connection with healthcare teams, although trial-specific instruction remains necessary [29].

Workers should disclose research affiliations and distinguish institutional responsibilities from personal relationships. Familiarity must not become pressure to participate. The Belmont Report warns against influence that compromises autonomous choice [28]. Patients should be able to decline without losing care or community support. Communication quality therefore depends on understanding, respect, and freedom to decide, rather than agreement with the recruitment objective.

6.3 Navigation, referral tracking, and practical coordination

Navigation translates information into practical access. Community health workers may help coordinate appointments, submit transport requests, identify digital support needs, and communicate concerns to research staff. These functions extend their bridging role but require trial-specific procedures and supervision [26]. Workers should facilitate access without independently interpreting eligibility criteria or managing clinical risk.

Referral tracking should record agreed contact, clinical assessment, invitation, and decisions. Unanswered questions need recipients, response expectations, and escalation routes. Participants should not be expected to carry messages between disconnected services or resolve failures themselves.

Optional feedback from patients who decline or withdraw can reveal burdens overlooked by enrollment statistics. Requests must remain voluntary and protect confidentiality [24]. Recurring problems, such as delayed reimbursements or inaccessible scheduling, should trigger procedural review rather than repeated instructions for patients to adapt. Implementation evaluation distinguishes acceptability, feasibility, and other delivery outcomes from clinical outcomes [25].

Figure 2 shows a navigation pathway. Its feedback route directs unresolved concerns toward responsible teams and program improvement while preserving patient choice throughout recruitment and participation.

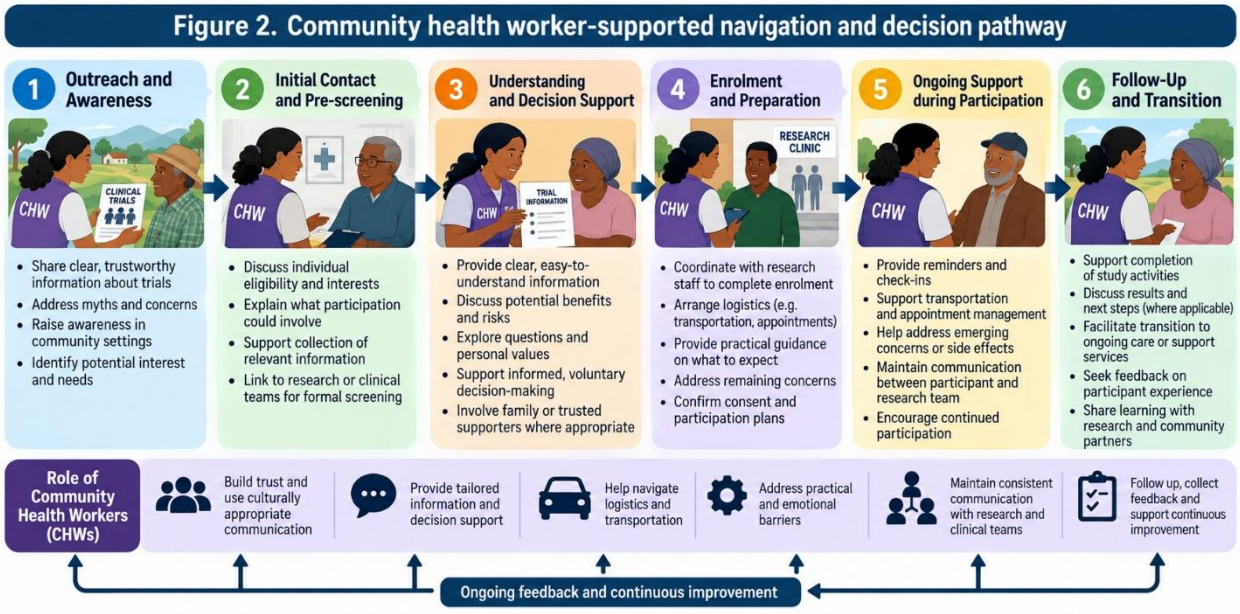


Figure 2. Community health worker-supported navigation and decision pathway

7. INTEGRATED IMPLEMENTATION AND EVALUATION FRAMEWORK

7.1 Coordinating the three approaches

The proposed model coordinates functions within one program. Research institutions provide funding, trial information, screening, and clinical oversight. Community health workers support communication and navigation; transportation services facilitate required journeys; telehealth enables activities suitable for remote delivery. Training and role definition remain essential when community workers connect participants with clinical teams [29].

Responsibilities should be assigned before recruitment begins. A program lead oversees resources and coordination; clinical investigators determine eligibility and safety requirements; referral coordinators track assessment and invitations; designated staff manage transport, technology, and privacy. Community partners and participants need clear routes for questions and feedback.

Funding should cover coordination, worker compensation, participant assistance, and evaluation rather than isolated outreach campaigns. Sustainability research identifies stable financing and strategic planning as important to maintaining community health worker services [30]. Voluntary choice must remain protected throughout implementation, including decisions to decline participation [28].

Figure 3 presents an operational framework, not a validated causal model. Its feedback loop links experience and pathway data to procedural improvement. Evaluation should examine reach, adoption, implementation, and maintenance alongside participation outcomes [31]. Coordinated responsibilities make access an institutional commitment rather than a task delegated to patients.

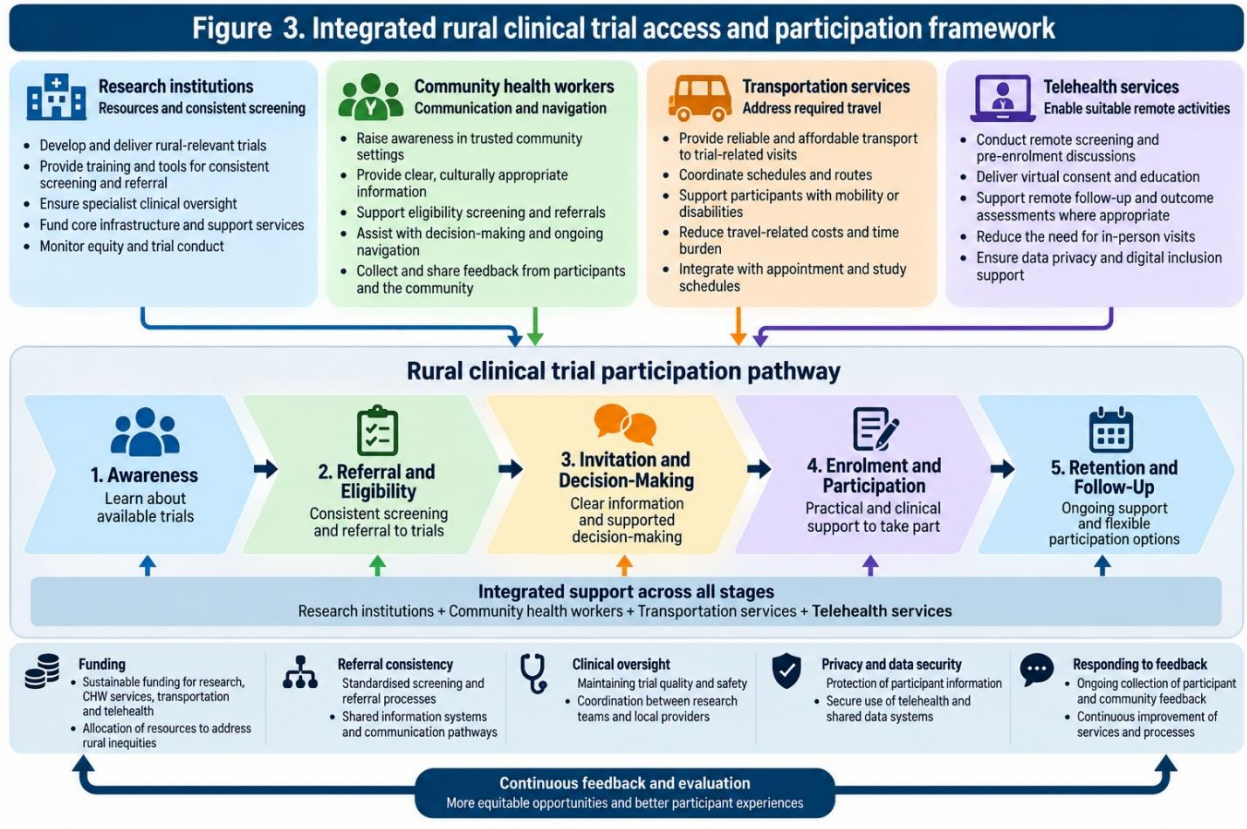


Figure 3. Integrated rural clinical trial access and participation framework

The framework proposes coordinated responsibilities and feedback. Arrows indicate operational relationships rather than established causal effects. Informed choice includes declining or deferring par**ticipation.**

7.2 Measuring opportunities, outcomes, and participant experience

Evaluation should follow patients through assessment, potential eligibility, confirmed eligibility, invitation, consent, enrollment, and retention. Each measure requires a defined denominator, observation period, and unit of analysis. Invitation coverage, for example, should use confirmed eligible patients as its denominator; enrollment should be reported among invited patients and consenting patients separately. Incomplete assessments and missing records must remain visible.

Rurality should be classified consistently, with the chosen definition and geographic level stated. Federal classifications differ, making similar rural samples potentially noncomparable [33]. Analyses should examine distance, connectivity, age, disability, disease area, and socioeconomic characteristics where data permit. Equity reporting guidance supports explicit attention to population characteristics and contextual disadvantage [32].

Participant experience adds information that enrollment cannot provide. Measures should address comprehension, perceived respect, travel burden, digital difficulties, and optional reasons for declining or withdrawing. Small subgroup estimates require uncertainty reporting and confidentiality safeguards. Research evaluating equity reporting identifies gaps that can obscure interpretation of participation patterns [34].

Table 2 specifies indicators and responsibilities. Recruitment totals cannot establish equitable access when unassessed patients, missed invitations, and burdens remain unrecorded. Evaluation must connect observed outcomes with preceding opportunities, using comparable cohorts and handling of missingness and differing clinical circumstances across study settings.

Table 2. Implementation and evaluation indicators

Pathway stage	Indicator	Denominator or measurement method	Data source	Interpretation	Responsible team
Assessment	Screening coverage	Patients assessed ÷ predefined screening population during a	Clinic roster and screening log	Identifies patients not considered for trial	Local clinical team and referral coordinator

Pathway stage	Indicator	Denominator or measurement method	Data source	Interpretation	Responsible team
		specified period		participation	
Potential eligibility	Preliminary suitability	Potentially eligible patients ÷ patients assessed	Screening records	Describes screening yield; does not confirm eligibility	Research coordinator
Confirmed eligibility	Eligibility confirmation	Confirmed eligible patients ÷ potentially eligible patients completing assessment; report incomplete assessments separately	Clinical records and protocol checklist	Identifies exclusions and losses during assessment	Investigator and clinical team
Invitation	Invitation coverage	Eligible patients invited ÷ confirmed eligible patients	Invitation and referral logs	Detects missed opportunities to offer participation	Recruitment lead
Consent	Agreement after invitation	Patients consenting ÷ patients invited	Consent records	Describes decisions after invitation; requires separate assessment of understanding and voluntariness	Authorized consent personnel
Enrollment	Enrollment conversion	Enrolled patients ÷ invited patients; also enrolled ÷ consenting patients	Enrollment database	Distinguishes recruitment outcomes from losses after consent	Trial coordinator
Retention	Continued participation	Participants meeting a predefined retention criterion at a specified time ÷ corresponding enrollment cohort	Follow-up and discontinuation records	Distinguishes withdrawal, loss to follow-up, death, clinical discontinuation, and planned completion	Follow-up team
Participant experience	Understanding, respect, and burden	Defined questionnaires, comprehension checks, and optional interviews; report response rates	Participant feedback	Identifies experiences concealed by enrollment totals	Evaluation team and community partners
Support delivery	Assistance received and unresolved needs	Requests fulfilled ÷ requests received; time to resolution; participant expenditure	Transport, navigation, and technical support logs	Assesses practical accessibility and service responsiveness	Support coordinators
Program sustainability	Resources and continued delivery	Staffing, expenditure, service continuity, and feedback actions completed	Budgets, workforce records, and decision logs	Assesses feasibility and maintenance	Institutional management and program lead

7.3 Implementation priorities, research gaps, and review limitations

Implementation should proceed through local assessment, partnership development, referral redesign, appropriate support, pilot delivery, and evaluation. Early pilots should examine workflow reliability, participant experience, and resource requirements before expansion. Evidence on telehealth implementation shows the importance of assessing contextual conditions rather than assuming that technical availability ensures successful delivery [35].

Research priorities include comparative effectiveness, sustained retention, costs, remote rural settings, and variation across diseases. Programs should test whether combinations improve equitable opportunities rather than simply increase total enrollment. Reach and maintenance require assessment after initial adoption [31].

Causal interpretation remains challenging. Trial availability, staffing, eligibility changes, and concurrent support programs may influence outcomes independently of the proposed intervention. Transportation, telehealth, and navigation delivered together also make individual effects difficult to isolate. Comparative designs and process evaluation can examine mechanisms, while economic assessment clarifies staffing and infrastructure demands.

This review uses targeted retrieval rather than comprehensive database searching. Selection limitations, indirect evidence, inconsistent rural definitions, and heterogeneous interventions constrain generalizability. Guidance-supported safeguards and documented findings should therefore be distinguished from proposed strategies requiring further evaluation. The framework offers an implementation rationale, not proof of effectiveness. Its practical contribution is to connect opportunity, informed choice, and feasible participation within accountable systems, which the conclusion brings together without overstating the available evidence.

8. CONCLUSION

8.1 Synthesis of the central argument

Rural participation in U.S. clinical trials depends on encountering a suitable study, receiving a fair invitation, understanding available choices, and managing participation requirements. Transportation support addresses necessary journeys and associated costs. Telehealth can reduce selected travel demands when remote activities are clinically appropriate. Community health workers connect information with locally informed navigation and practical support.

These approaches address different but interconnected conditions. Their effectiveness depends on coordination rather than isolated delivery. Institutions remain responsible for consistent screening, adequate resources, clinical oversight, privacy, and responses to participant concerns. Accountability therefore requires examining where opportunities are lost and correcting avoidable barriers. Patients must remain free to decline or withdraw without pressure while retaining appropriate care and benefits to which they are entitled.

8.2 Implications for clinical research practice

Research organizations should establish sustained local partnerships, consistent referral opportunities, credible decision support, and practical assistance tailored to individual needs. Transportation and telehealth arrangements should reflect clinical requirements, household circumstances, and participant preferences, supported by trained community health workers.

Evaluation should follow opportunities from assessment through retention and examine comprehension, respect, travel burden, and digital difficulties. Success means more equitable opportunities and better participant experiences, demonstrated through transparent evaluation rather than higher recruitment totals alone or assumptions about intervention effectiveness.

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