ADVANCING INCLUSIVE RESEARCH®
SITEALLIANCE

COMMUNITY OUTREACH TOOLKIT

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2. Getting Started
3. Available Resources
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1. Introduction.

This toolkit was developed by the AIR Site Alliance sites and Ophthalmology chapter to facilitate Community Outreach for sites who would like to explore or expand their clinical trial recruitment capabilities. Our aim was to develop a practical and easy to use resource that will give you all the information needed to begin this work at your site. This toolkit is organized by various sections and you can choose to review this in chronological order or jump ahead to a specific area of interest. Start early, start small and adjust based on your specific site and community. Our belief is by expanding outreach into our communities we can engage diverse participants and have them represented in our clinical trials. This will lead to better and more inclusive data and promote health equity for all patients. The time to act is now !!!

2. Getting Started

Communication and Marketing Needs

Effective communication and marketing are essential in establishing trust and engagement within the community. Lerch et al. (2024) highlight that trust in a patient-physician relationship is fostered by both patient-centered and physician-centered factors. Patient-centered factors include psychological aspects, health education, literacy levels, and social environment, while physician-centered aspects encompass competence, communication skills, genuine interest in patients, caring attitudes, provision of health education, and professionalism. Additionally, trust is significantly enhanced by a strong patient-physician alliance, sufficient time spent together, and shared decision-making. Institutional factors, payment methods, and supplementary healthcare services also play crucial roles. Understanding and integrating these elements into our communication and marketing strategies can improve trust and outcomes in our community outreach efforts.

- What are the communication, marketing, and information/data sharing needs of our organization and our target audience?
- Does our website require additional communication materials to better serve our community?

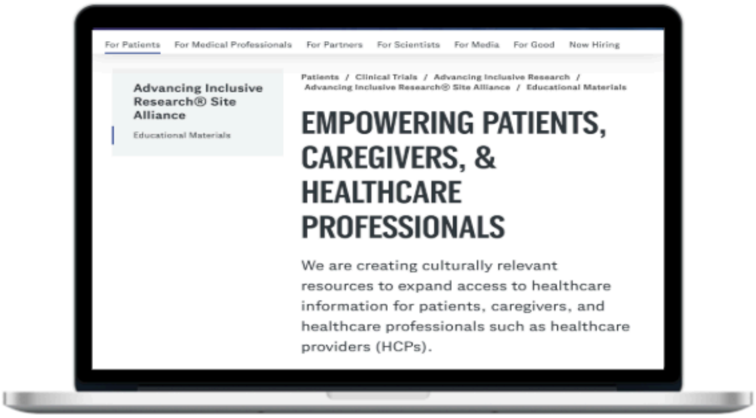
- Would an explainer video enhance our outreach process or facilitate data sharing with the general public?
- Who is our primary audience for these materials? Is it patients, caregivers, or healthcare professionals?
- How can we tailor our content to meet the needs and preferences of each audience segment?

3. Available Resources

At Genentech, we have developed various resources that can be leveraged by healthcare profesioonals (HCPs) and patients interested in learning more and advancing inclusive research.

These resources can also be found on our website at the following link:

https://www.gene.com/patients/clinical-trials/advancing-inclusive-research/air-site-alliance/educational-materials



EMPOWERING PATIENTS, CAREGIVERS, & HEALTHCARE PROFESSIONALS

We are creating culturally relevant resources to expand access to healthcare information for patients, caregivers, and healthcare professionals such as healthcare providers (HCPs).

The website is organized into 2 sections:

1. Patients & Caregivers

This section includes educational videos on the importance of testing, screening, and diverse representation in clinical trials. It also provides brochures that outline the foundations of clinical trials, aimed at patients who are curious about what a clinical trial entails and those considering whether participating in a trial is the right choice for them. Additionally, there are externally owned materials available designed for both study teams and patients, which cover a range of topics, including indication-specific and general clinical research information.

2. Clinical Research Sites & Healthcare Professionals

This section contains educational videos on why diverse representation matters in clinical trials, including our newly published video on advancing inclusive research in ophthalmology studies. These videos can also be used as shared-decision making tools (SDM) tools between healthcare professionals and patients. This section also includes a section on training resources such as the Advancing Inclusive Research Education Training Program.

Please leverage the resources listed here as you embark on your Community Outreach journey.

Keep in mind that this isn't a one-size-fits-all approach. Depending on your role or specific study needs, how you adapt these resources or how many you use may vary.

We recommend you revisit this website or bookmark it, as new resources and updates to existing ones (like this Community Outreach toolkit) will be included.

4. Community Outreach

Now that you are ready to get started, what community outreach activity would you like to explore further? There are many options a site can consider, here are some examples:

You can choose to try one of these approaches or multiple approaches at the same time. There is no right or wrong approach, just consider what may be prominent and common in your local community.

Some considerations and steps around Community Outreach include:

A. Having Informational Materials ready and on hand

1. Brochures and Flyers:
   Simplified, culturally tailored materials explaining the importance of clinical trials, eligibility criteria, benefits, and safety measures. Supplementing this with disease specific educational materials (and later study specific materials) can be very helpful.

   - Translated versions for non-English-speaking communities.
   - Use visuals representing diverse populations.
   - Ensuring electronic versions are posted on your website

FAQs:
Address common concerns, such as "What are clinical trials?" and "Will my participation affect my health privacy?"

Testimonial Videos:
Stories from diverse participants or community leaders sharing positive experiences with clinical trials.

*Leverage Section 3 Available Resources to select from available materials

2. Community Partner Engagement

- Key Stakeholder List:
  Identify local leaders, faith-based organizations, cultural groups, and nonprofits to engage with specific communities.

- Partnership Guide:
  Tips for collaborating with trusted community organizations, schools, and local businesses.

FOR CLINICAL RESEARCH SITES

Community Partnership Guide

Site Details:
Site Name:
Site Address:
Start Date:
Responsible Person(s):

Initial Steps

- **Feasibility:** Assess the feasibility by utilizing real-time data and EHR, including ICD-10 codes and claims, to understand population-specific needs and disease prevalence. This approach helps identify patient needs and provides granular insights for accurate study planning.
- **First Meeting:** Hold a project meeting with all parties before Institutional Review Board (IRB) submissions.
- **Proposal Review Phase:** Review proposals collectively, address questions about data collection, analysis, tool development, sampling, and broad scale submissions.
- **Regular Check-ins:** Establish a schedule for regular meetings to ensure a clear and frequent communication cadence.

Communication and Collaboration

- **Regular Check-Ins:** Maintain regular meetings to allign on shared objectives, review project progress, maintain connectivity, address concerns, and plan next steps.
- **Stakeholder Mapping:** Create a visual map of the central stakeholder perspectives (e.g., patients, caregivers, HCPs, patient advocates), influence, and potential impact on medical outcomes.

Data Collection and Analysis

- **Qualitative Measures:** Include qualitative components (e.g., process evaluation, case studies, focus groups) to capture comprehensive insights beyond quantitative data methodologies.
- **Joint Analysis:** Collaboratively analyze data with community and academic partners to ensure community input in interpreting results.
- **Impact Measurement:** Create a sustainable evaluation framework to measure impact based on populations served, patient outcomes, education, partnerships formed and community event attendees.

Key Evidence-Based Outcomes and Benefits of Community-Engaged Research (CEnR)

- **Research Benefits:** Gain entry into communities, learn about health needs and assets, and ensure the relevance of research questions, education, service, and programs.
- **Community Impact Benefits:** Access university resources, evidence-based practices, increased funding opportunities, and community-level social drivers of health data specific to health outcome factors.

Community Outreach Guide

FOR CLINICAL RESEARCH SITES

SITE INFORMATION:

Site Name ______________________________
Site Address ______________________ Responsible Person(s) ______________________
Start Date ______________________ ______________________

OUTREACH AT LOCAL EVENTS

1. Identify local events for partnerships

○ Schedule table sessions for health fairs, charitable run/walks
○ Leverage local businesses, restaurants, and pharmacies
○ Leverage existing relationships in the Community such as church leaders, community centers

2. Initiate discussions with local leaders

○ Provide referring doctors and networks with regular updates
○ Ensure there is a streamlined referral process
○ Encourage feedback and collaboration with local government officials and city council members

3. Prepare Materials for marketing

○ Seek IRB approval for marketing materials specific to studies
○ Consider funds and budget needed for internal approvals
○ Ask patients and employees for feedback on materials

4. Engage with patients in referring clinics

○ Coach staff on how to talk about research within your clinics
○ Design T-shirts to initiate intrigue “Ask me about research”
○ Design pins or posters in clinic to highlight research as an option

5. Build the collective mission at your site

○ Inspire research staff be local advocates
○ Encourage volunteer opportunities
○ Communicate the mission and highlight initiatives and goals

6. Share content and educate internally

○ Educate staff on importance of cultural humility
○ Share internally - weekly research enrollment randomizations and updates
○ Create a newsletter to highlight staff, achievements and post volunteer opportunities

7. Develop and execute a social network strategy

○ Consistently post for your local audience ** - partner with marketing team
○ Raise awareness for diseases with posts and community events
○ Adhere to company policies and standards

8. Distribute and engage

○ Staff maintain a positive, professional, and helpful nature
○ Track referrals and follow up
○ Place Ads in targeted areas, local restaurants, nail salons, and neighboring businesses

LIST COMMUNITY EVENTS AND OPPORTUNITES

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____
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SITE LEVEL MARKETING

○ Update website with enrolling studies
○ Share website link via online platforms
○ Prepare nonspecific study materials/handouts
○ Host open house events

PHYSICIAN INVOLVEMENT

○ Be the first to announce study to patient
○ Routinely network with referral base
○ Educate and lecture at focus/advocacy groups
○ Leverage existing relationships to advocate for your site

COMPLIANCE REMINDERS

*Be sure to only use IRB approved materials and brochures to handout to potential participants. General site brochures and the AIR study brochures that are nonspecific to studies are recommended for broader audiences.

**Consult with your administrators and marketing team to follow your site specific policies

- Event Planning Checklist:
    - Including steps for hosting health fairs, information sessions, or “Lunch & Learn” events in community centers, libraries, and churches.

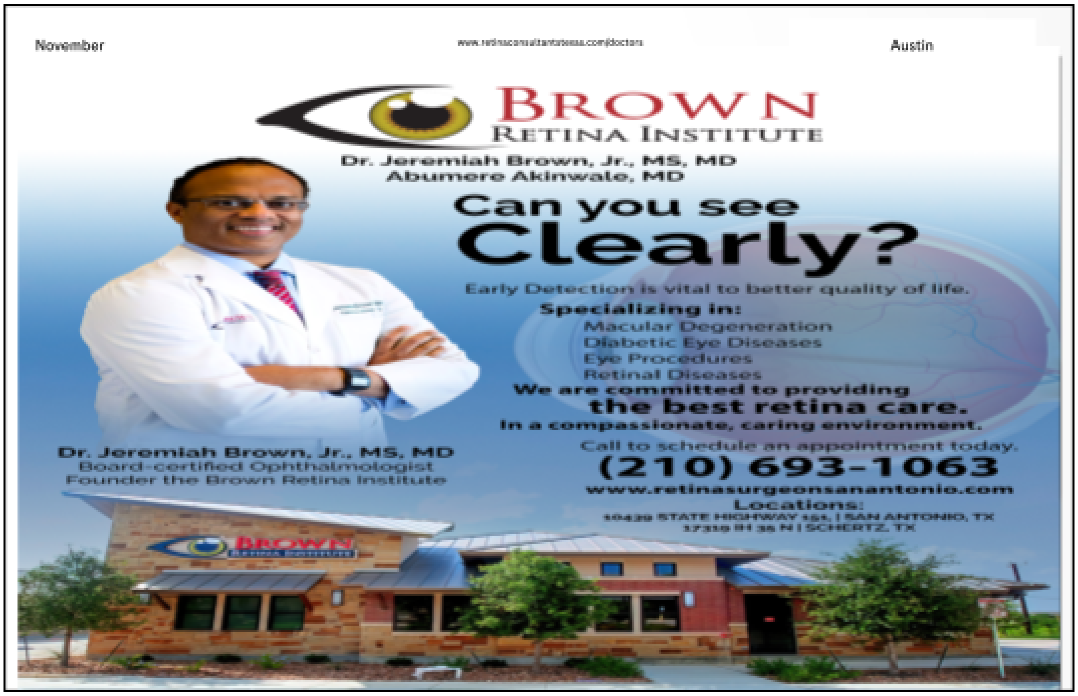
Please find an example that you can use here:

Please find the link here .

3. Accessible Communication Channels

- Social Media Toolkit:
    - Templates for posts and ads promoting trials, tailored to different platforms (e.g., Facebook, Instagram, LinkedIn).
    - Use hashtags and visuals that resonate with diverse groups.

Example in the Black Austin Magazine:



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- Community Radio/Podcast Scripts:

Ready-made scripts for local radio or podcasts to explain the significance of clinical trials and how to participate.

- Website Enhancements:
    - Multilingual information pages.
    - Easy navigation for signing up or learning more about trials.

4. Education and Training

- Inclusive Clinical Trial Administration Training:
  Provide modules for staff and outreach workers to understand patient inclusivity within the context of trial management.
  → **Leverage Section 3 Available Resources to locate available education for healthcare professionals (HCPs).**
- Participant Support Guide:
  Outline steps for addressing barriers, such as transportation, childcare, or fear of medical research.

- Clinical Trial 101 Workshops:
  Interactive workshops for community members to learn about trials and ask questions in a safe environment.

5. Tools for Feedback and Engagement

- Survey Templates:
    - Collect feedback from community members about their concerns and perceptions of clinical trials.
    - Include anonymous options for honest responses.
        - Community - Level Feedback Survey
            - Survey Template Link
        - Site - Level Feedback Survey
            - Survey Template Link
- Feedback Loops:
  Report back to communities about how their input has shaped trial design or outreach efforts.

- Incentive Plans:
  Provide stipends, gift cards, or meal vouchers for participation in focus groups or informational sessions, as appropriate. .

6. Logistics and Resources

- Resource Directory:
    - Include lists of transportation services, free clinics, and support groups for participants.

    - Childcare assistance programs or reimbursements.

Mobile Outreach Van: Case Study: Sight Forever® Mobile Eyecare Program

Sight Forever®, sponsored by Wagner Kapoor Institute (WKI), is a community-focused mobile eyecare initiative dedicated to improving eye health through accessible, on-site services. WKI, a leader in advanced eye care services, provides the clinical expertise and support that ensures high-quality care for every patient served.

Over the last few years, Sight Forever® has performed hundreds of screening eye exams in at-risk populations, particularly in rural areas and local nursing homes. In a recent outreach effort at a local health fair, the mobile unit provided over 90 free eye exams in a single day, identifying early signs of diabetic retinopathy in 20 patients who were unaware of their condition. By delivering exams and consultations directly within the community, Sight Forever® helps bridge critical gaps in healthcare access and empowers individuals to take control of their eye health.

Through strategic partnerships with local clinics and community organizations, Sight Forever® continues to expand its reach. The program not only raises awareness about preventable vision loss but also facilitates timely referrals for advanced care when needed. By prioritizing convenience and accessibility, Sight Forever® plays a vital role in preventing blindness and promoting long-term ocular health, particularly in underserved populations.

- Consent Form Samples:
    - Plain-language versions of trial consent forms.

7. Marketing and Outreach Materials

- Posters and Banners:
  Culturally inclusive visuals for community centers, health fairs, and local events.

- Email Templates:
  Pre-written messages for introducing trials to community leaders, potential participants, or local influencers.

Template 1: Partner Collaboration Invitation

Subject: Partner with Us: Free Eye Exams for Our Community

Dear [Partner's Name],

I hope this message finds you well. I’m reaching out on behalf of Sight Forever®, a mobile eyecare program sponsored by Wagner Kapoor Institute (WKI), a leading provider of advanced eye care services. We offer free eye exams, consultations, and treatments directly within the community to make eye health more accessible.

We’d love to collaborate with [Organization Name] to bring our services to your location and support better eye health in our shared community. Together, we can help individuals detect early signs of conditions like diabetic retinopathy and glaucoma—conditions that, when caught early, can often be managed to prevent vision loss. If you’re interested in partnering with us for a community event or learning more about our services, please let me know.

Thank you for your time and consideration.

Best regards,

[Your Name]

Template 2: Community Event Announcement

Subject: Free Eye Exams Coming to [Community Name]

Hi [Community Member/Partner],

We’re excited to announce that Sight Forever®, a mobile eyecare program sponsored by Wagner Kapoor Institute (WKI), will be providing free eye exams at [Location/Community Event] on [Date/Time]. WKI is a leading provider of advanced eye care services, and through this program, we aim to bring high-quality, accessible eye care directly into the community.

Our team of experts will offer comprehensive eye screenings, consultations, and information on how to maintain healthy vision. Eye health is crucial, especially for individuals with diabetes or those experiencing vision changes. Don’t miss this opportunity to take a proactive step toward better eye health.

Event Details:

📍 Location: [Address/Community Center]

📅 Date: [Date]

🕒 Time: [Time]

We look forward to seeing you there!

Best regards,

[Your Name]

- **Trial Recruitment Cards:**
  Insert pocket-sized cards with QR codes leading to sign-up forms or trial information.

8. Metrics and Measurement Tools

- Participation Tracking Tool:
  Dashboard for monitoring demographics and participation rates across different communities.

- Impact Reports:
  Templates for showcasing how outreach efforts are increasing inclusivity and participation.

- Community Feedback Google Forms:
  Quick ways to gauge how the toolkit and outreach are being received.

9. Digital Outreach Tools

- Webinars or Virtual Open Houses:
  Host live Q&A sessions about clinical trials, making it easier for remote communities to participate.

- SMS and Email Campaigns:
  Text message and email updates and reminders about trial opportunities.

- Interactive Chatbots:
  Provide instant responses to common questions about clinical trials in multiple languages.

10. Support and Advocacy

- Participant Advocate Role:
  Assign a team member to guide participants through the process, answering questions and addressing concerns.

- Post-Trial Support Plan:
  Ensure participants feel valued and informed about the trial results and next steps.

5. Assessing your work

Throughout your community outreach journey, be sure to check in and assess how things are progressing. You can ask yourself the following questions:

- How are our community outreach efforts going?

- What metrics are we achieving with respect to including more patients in clinical trials? (e.g., tracking usage counts of training programs, changes in staff cultural sensitivity perceptions)
- Do we feel we are successful when it comes to community outreach? Is this enhancing patient inclusion in our clinic?
- What did we learn from our experiences so far?
- Would we consider adjustments or changes to our strategies moving forward?
- Should we implement feedback surveys for patients to evaluate the usefulness and clarity of the videos in improving clinical trial understanding?
- How are we addressing our business longevity and continuity?

6. Continuing on the journey

Community Outreach is an ongoing activity and takes time and trust. Start small and do not get discouraged. Connect often and check in. Train others on the work that you are doing. Share your success and learnings. Review this toolkit to complete the necessary steps needed to engage with a broad community of patients. Enhancing inclusion at your clinic will allow you and your colleagues to present various clinical research options to all patients. This will have an important impact in our trials and ensure we have more inclusive data to promote health equity for all patients. If we all work together we can achieve significant results.