

Accrual Quality Improvement Program (AQuIP) Toolkit



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I. The Accrual Quality Improvement Program (AQuIP) Toolkit

Recruiting participants for cancer prevention trials can be a challenge. Although the pool of eligible individuals may be sizeable, prospective participants often have difficulty understanding the value of their involvement in cancer prevention trials in comparison to possible benefits of participating in treatment trials. Therefore, the primary goal of any outreach effort is to showcase the benefits of their participation and provide clear and concise information to address any concerns, constraints, and risks perceived.

The AQuIP Toolkit contains step-by-step guidance and helpful tips for creating high quality and professionally branded recruitment materials. It includes sample messages, media templates, an image library, and a list of references for obtaining additional information. Since many of the materials are already created, these can be easily customized for individual campaigns, thus allowing sites to successfully meet their enrollment targets while conserving staff resources.

Use this Toolkit in conjunction with the rules set by the communications/recruitment department of the site. As costs will vary between media channels, this Toolkit provides the knowledge necessary to discuss recruitment strategies within the limitations of the site's recruitment budget. Consult with the site's communications/recruitment department and website team on all inquiries regarding ad development, ad placement, and budget limitations.

The AQuIP Toolkit helps assist clinical sites working with the National Cancer Institute, Division of Cancer Prevention (NCI, DCP) to effectively recruit participants by providing trial teams with a detailed guide and turnkey resources.

The AQuIP Toolkit provides users with the necessary tools to successfully promote all types of organ studies needed to create cancer prevention trials awareness campaigns for a continuous and long-term approach to participant recruitment.

II. Using the AQuIP Toolkit

This AQuIP Toolkit has been customized to support study teams with the recruitment of participants for cancer prevention trials. The Toolkit presents the information in a logical sequence and explains how to do the activities required in planning and executing a participant recruitment campaign. In addition, it provides guidance and tips on important issues related to participant recruitment; templates and samples on specific recruiting materials; information on how to create and place advertisements; and how to obtain regulatory approval prior to launching the campaign.

The AQuIP Toolkit serves as a user-friendly tool to help site staff and other study personnel design, create, and manage an effective recruitment campaign in a timely way and using less resources.

1. Using Guidance and Tips to Develop Approach

The AQuIP Toolkit contains guidance and best practices that help users make strategically informed decisions necessary to implement a well thought out participant recruitment campaign.



Overcoming Clinical Trial Barriers

It is important to understand the barriers to recruitment so challenges can be overcome by highlighting general motivators that encourage individuals to participate in a clinical trial during a recruitment campaign.



Branding Clinical Trials

Helps to create a unique identifier of the trial so that it stands out among the myriad of advertising messages.



Reaching Different Target Audiences

Understanding the characteristics of the target audience and reviewing their potential response to different communication methodologies is a critical factor in planning a successful and diverse participant recruitment campaign.



Selecting Media Channels and Outreach Materials

Budgets are limited, so planning for the best combination of low cost and high impressions to reach potential participants is critical. To better facilitate users' understanding of how to optimize media selection, Templates and Samples are included with every suggested media channel.



Creating an Ad

Provides step-by-step guidance on 10 best practices to use when writing an ad. It also allows for rapid customization of samples provided — and with just a few changes, the ad is complete.

This AQuIP Toolkit can be used as an instructional tool to develop a brand new recruitment campaign and to improve or complement current recruitment efforts. This **AOuIP Toolkit** can be used in its entirety or on a mix and match basis.

2. Selecting the Appropriate Templates or Use Available Sample

AQuIP Toolkit users can use the pre-developed text, ready-to-edit templates, and an image library customized to generate interest in participants for cancer prevention trials. Each template is supplemented by a working sample. Feel free to customize the content (change text, images, graphics, and colors) or use it as it is and simply replace the text provided with relevant trial and contact information.

Templates provided in the Toolkit will help develop the following materials:

- Key Messages (Taglines, Positioning Statements, Call to Action Statements, and Supporting Facts/Statistics)
- Bi-Fold Brochure
- Print Ad
- Postcard
- Flyer
- Poster
- Social Media
- Email Recruitment Message
- Text Messaging
- Web Ad
- Radio Spot Script
- Video Spot Script
- PowerPoint Presentation to Potential Participants
- PowerPoint Presentations to Potential Referral Physicians
- Physician Referral Letter

3. Obtaining Approval of Recruitment Materials

Provides guidance on how to get recruitment materials approved for publication by and an Institutional Review Board (IRB) and NCI DCP.

4. Launch

III. Overcoming Clinical Trial Barriers

Understanding common barriers to clinical trial participation is critical to ensuring successful recruitment. This awareness allows for the creation of more focused and targeted strategies to overcome challenges while enhancing the ability of recruitment staff to efficiently communicate the trial purpose to prospective participants (e.g., provide informational sheets or brochures or organize informational lectures).

Some examples of participant-related challenges across studies and therapeutic areas include:

Misconception About Studies or Clinical Trials

Only 13% to 32% of the population are very confident that participants in clinical trials receive good medical care; clearly are told and understand the risks of participating; are well treated, and do not suffer more than they would from receiving standard care.

• Lack of Referral

According to an NCI research study, "32% of the American adults surveyed indicated they would be very willing to participate in a cancer clinical trial if asked to do so, and an additional 38% of adults are inclined to participate in a clinical trial if asked, but have some questions or reservations about participating."

Lack of Awareness

Potential participants may not know participation in clinical trials is an option for them or that a trial is enrolling in their geographical area. In addition, participants may not know what a clinical trial involves, as data from an NCI study¹ showed that only one-fourth of the population can describe a clinical trial.

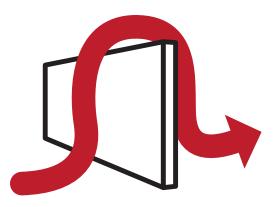
Fear or Mistrust

Fear of being treated like "guinea pigs" or receiving a placebo, and not having control over the treatment are common apprehensions of potential participants.

• Financial, Logistical, and Personal Objections

These impacts include costs and time away from work/home, lack of transportation, language and communication barriers, and concerns or confusion about what health insurance would cover.

Objections to participation in cancer prevention trials can be even greater as participants are often healthy volunteers who may feel they have little to gain from enrolling. This AQuIP Toolkit provides users with appealing recruitment strategies and materials to help overcome these barriers.



General Motivators

- Healthcare provider's recommendation
- Altruism/Will to advance science
- Access to leading specialist and cutting edge care
- Monetary
 incentives
- New treatment options

IV. Branding Clinical Trials

From a marketing perspective, branding is the process of creating a unique image in the mind of the target audience by using advertising campaigns with a consistent theme and message. Branding is useful to promote awareness of cancer prevention trials.

Effective branding:

- Helps build confidence in the advertised cancer prevention trials.
- Gives clinical trials an identity that helps potential participants recognize, remember, and better relate to trials.
- Creates a positive impact on how the trial is perceived by referring physicians, other investigators, and trial coordinators who can help with participant identification.
- Helps create a sense of belonging, fosters commitment, and triggers additional word-of-mouth communications by current cancer prevention participants.
- Helps differentiate between cancer prevention clinical trials at the clinical institution or competing sites.
- Builds lasting impressions of the clinical site through logo affiliation.

The branding process involves selecting a color scheme, font, imagery, logo, and developing key messages that are used consistently across media platforms, and other informational materials promoting awareness of cancer prevention trials. To accurately reflect diversity of cancer prevention trial participants, imagery can be modified slightly to appeal to different age groups, genders, and ethnicities, as needed.

Using a standard font or typeface is recommended so all sample templates included in this AQuIP Toolkit were developed using Arial font. To ensure consistency with a clinical organization's existing brand, the same or similar font shown in the organization's logo, company letterhead, or preset email signature block should be used.



The branding process involves selecting a color scheme, font, imagery, logo, and developing key messages that are used consistently across media platforms and other informational materials... **Examples of Well-Branded Materials and Non-Branded Materials**

Well-branded materials include:



change slightly between materials to target audiences with different For effective branding, the visual images should be identical or can

demographics.

Non-branded materials include:



- Organization's Logo
- Same Decorative Elements
 - X Different Color SchemeX Different ImageryX Different Messages

Different Messages

By using the same logo with varied color schemes, different imagery and taglines, these non-branded materials can make it less likely for prospective participants to remember the ad or receive the intended message.

V. Reaching Different Target Audiences

In most cases, cancer prevention trial participants are healthy volunteers who are identified as at risk of developing cancer. Eligible participants can represent many backgrounds with various characteristics and demographic profiles (e.g., age, gender, ethnicity). To successfully communicate to a broad and diversified audience, it is important to segment the population in homogeneous sub-groups and create tailored strategies that speak specifically to each group.

In this Toolkit, age, gender, and minority profiles provided were created for marketing purposes. These profiles represent the average characteristics of each population based on market research and studies (see page 12) and may not accurately capture singularities.

Profiles are grouped into the following categories:

• Age Group

Differences in age demographics can impact the way participants are best recruited; however, some recruitment tips may apply to multiple audiences.

• Pediatrics

The pediatric population is smaller and trial participation is dependent on guardian decision makers, specifically mothers. When protocols authorize enrollment of pediatric participants, use a mix of the preferred recruitment tips.

• Gender

Gender-based advertising can be used to effectively recruit participants to trials that target a population composed entirely of males or females.

Underrepresented Minority Groups

Recent studies showed less than 5 percent of non-white individuals participate in clinical trials.2 The preferred recruitment tips are designed to facilitate recruitment of several underrepresented minority groups including: African Americans, Asian Americans, Hispanic Americans, Native Americans, and the Lesbian, Gay, Bisexual, and Transgender, Queer or Questioning, and Others (LGBTQ+) community.





Age Group³: Generation Z





Key Values and Characteristics



Key Influencers



Key Media

Characteristics and Strategies^{4,5,6,7}

- Comfortable with dense and fast-paced information and entertainment.
- Prefer content designed for personal electronic devices over traditional media.
- Expect instant access to information and international news.
- Independent, entrepreneurial, and self-educating.
- Likely to donate, volunteer, and participate in local and global communities due to a heightened awareness of humanitarian challenges.
- Support tolerant and progressive social policies.
- Value digital privacy and the safe-guarding of personal digital information.
- Anticipated to become important influencers of future generations.

Targeted Recruitment Tips and Strategies

- Advertise on social media with direct, concise, and engaging recruitment content.
- Develop visually appealing infographics and videos for your recruitment campaign.
- Emphasize the clinical trial's potential to improve outcomes and/or treatments for the specific indication.
- Aim to capture and maintain a Generation Z participant's attention.
- Assert the importance of an individual's participation to the success of the trial.
- Highlight participant confidentiality and systems that protect participant identity throughout the recruitment process.
- Ensure online content is compatible with portable electronic devices.
- Target Generation Z as a method to establish participation in clinical trials as a norm for future generations.

Age Group³: Millennials

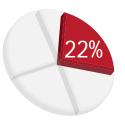


Characteristics and Strategies^{8,9,10}

- Accustomed to a technologically fluent society.
- Comfortable with social and web-based media.
- Hold a strong sense of independence and autonomy while also seeking social and peer acceptance.
- Discuss information and issues with online communities.
- Influenced by the opinions, reviews, and recommendations of others.
- Open-minded and goal-oriented.
- Expect instant gratification.

Targeted Recruitment Tips and Strategies

- Use online web-based recruitment efforts.
- Create a trial website where potential participants can connect to other trial-related media platforms and online forums.
- Provide an option for potential participants to ask questions and/or receive trial information via online chats and/or webinars.
- Broadcast trial information on social media platforms such as YouTube, Facebook, and Twitter.
- Advertise the trial through e-mail and digital radio (e.g., Pandora) rather than traditional AM/FM radio.
- Encourage existing participants to share their clinical trial experiences on social media and refer other potential participants.



1980-1995

Born

Percentage of Population



Key Values and Characteristics



Key Influencers



Age Group³: Generation X



Skeptical

Informal

Key Values and Characteristics

Information Driven





Characteristics and Strategies^{8,9,10}

- Consider multiple sources of information when making decisions.
- Skeptical of poorly sourced information.
- Expect flexibility.
- Prefer an informal communication style.
- Value peer opinions.

Targeted Recruitment Tips and Strategies

- Create a trial website with detailed information about the trial and links to external sources.
- Provide a toll-free phone number where potential participants can ask questions and receive a one-on-one communication source.
- Encourage referring physicians to provide and discuss trial information with participants.
- Advertise with Frequently Asked Questions (FAQ) sheets in doctors' offices and healthcare spaces.
- Create a video interview with the Principal Investigators (PIs) that can be posted online and e-mailed to referred participants.
- Offer educational lectures about the trial and/or medical indication.

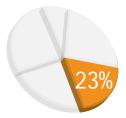


Key Influencers

Age Group³: Baby Boomer







Percentage of Population

Characteristics and Strategies^{8,9,10}

- Value family responsibilities.
- Accommodating towards parents and children.
- Will not make decisions based on online content alone.
- Consider technology as requiring a learning process.
- Favor open and direct communication via one-on-one interactions.
- Prioritize health and wellness in daily life.
- Value self-sufficiency.
- Seek personal gratification and public recognition.

Targeted Recruitment Tips and Strategies

- Appeal to family values and sense of responsibility in recruitment campaigns and while discussing the trial.
- Provide a toll-free phone number where potential participants can ask questions and receive a one-on-one communication source.
- Require multiple forms of content to make decisions, provide paper, brochure, or poster copies on any online or digital recruitment information.
- Advertise in lifestyle and wellness magazines.
- Create a "Thank You" webpage to recognize trial participants.
- Broadcast recruitment campaigns on the radio.
- Offer educational lectures about the trial and/or indication.



Age Group³: Silent Generation







Percentage of Population



Key Values and Characteristics



Key Influencers



Key Media

Characteristics and Strategies^{8,9,10}

- Value family time and social contact.
- Favor moral and ethical behaviors.
- Patriotic and willing to sacrifice for the common good.
- Avid readers.
- Prefer written and face-to-face communication.

Targeted Recruitment Tips and Strategies

- Encourage local physicians and pharmacists to discuss the trial when referring potential participants.
- Discuss the trial with a community spokesperson who can spread information regarding the study.
- Incorporate images of active seniors, seniors with families, and/or seniors with friends in recruitment campaigns.
- Use visuals that appeal to patriotism.
- Emphasize the importance of each participant, and the potential for improved outcomes and/or treatments for the specific indication.
- Advertise trials in newspapers.
- Send direct mail to provide trial information.

Pediatrics





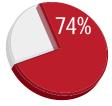
Characteristics and Strategies^{11,12}

- Includes infants, children, and adolescents up to 18 years old. .
- Recruitment involves targeting and reaching out to parents who are the primary decision-makers.
- Mothers play a crucial role in participation decisions for . their child.
- Women are the most active users on social media; moms follow more social networking sites and check Facebook more times per day than any other users.
- Moms are commuters and avid listeners of radio.
- 90% of moms own a cell phone that they consistently keep close by, and 80% report texting is their preferred method of communication.
- Parents usually rely on trusted physicians and advocacy groups for guidance.
- Concerns over risks are significantly higher when a child participates in research.
- Parents require detailed information about a trial before enrolling their child.

Targeted Recruitment Tips and Strategies

- Contact current patients and advertise within the clinical institution.
- Ask for physician referrals in the community.
- Target mothers by advertising on the radio, social media, and through text messaging.
- Create a video that provides details about the trial. .
- Organize and conduct educational lectures. •
- Use images of children in the trial materials.
- Enlist assistance of advocacy groups.
- Organize educational lectures.





Percentage of Population Percentage of Population Less Than 18 Years Old That Have Children



Key Values and Characteristics



Key Influencers



Key Media

Gender: Women





Key Values and Characteristics



Key Influencers



Key Media

Characteristics and Strategies^{13,14,15,16}

- Majority of decisions made by women are on behalf of others, especially their extended family members.
- Value relationships with others.
- Need interpersonal affiliations with other women, and look to them for their opinions.
- Want an opportunity to ask questions before making a decision.
- Studies show the impact of color on decision is significantly higher for females than for males.
- Act based on emotions.
- Most active users of social media.

Targeted Recruitment Tips and Strategies

- Use images portraying family members or groups of women.
- Consider preferences of women when designing the artwork. Colors are used in advertising to create a feeling of association between the target audience and the ad's message. Studies have shown that women prefer red to blue and yellow to orange.
- Use the image of a woman in the target age group in the materials.
- Trigger word of mouth communications by asking female participants to share their story. This appeals to women's need for affiliation and emotional connectivity.
- Emphasize how women can get answers to their questions about trials.
- Use social media to provide information.

Gender: Men

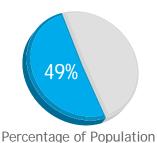


Characteristics and Strategies^{13,14,15,16}

- Respond to self-assertion, confidence, comradery, and achievement-oriented roles.
- Identify themselves as family-centric.
- Most decisions made are for themselves and these can be impulsive or pragmatic. For example, men may factor in the availability of parking and length of lines before making a purchase decision.
- Over 50% of U.S. men have not seen their physicians in the past year, and make half as many prevention-related doctor visits as women.

Targeted Recruitment Tips and Strategies

- Use images portraying men in social contexts in the materials, and use competition-related (e.g., sports) and family-centric themes emphasizing the central role of the man.
- Emphasize steps men can take today to join studies.
- Talk about pragmatic aspects of participation: free parking and flexible hours.
- Use an image of a man in the same target age group in the materials.





Key Values and Characteristics



Key Influencers



Minority Population: African Americans





Percentage of Population



Key Values and Characteristics



Key Influencers



Key Media

Characteristics and Strategies^{24,25,26,27,28}

- African Americans have long used prayer and religion to cope with and treat health concerns. Religion and religious institutions play an important role in providing both spiritual and psychological support in the community. African Americans believe in strong cultural connections.
- Studies of purchasing decisions have demonstrated that the community reacts positively to a product if sold or supported by an African American.
- Common health beliefs and practices include: belief in the well-being of the community, use of informal instead of professional help for health information, and fears and fatalism related to cancer.
- 52% of the community reads print magazines, which is 30% higher than the general population. More than 90% of the community listens to radio more than 12 hours each week.
- Mistrust due to previous unethical practices with this population is one of the most frequently cited barriers to African American participation in research.

Targeted Recruitment Tips and Strategies

- Conduct outreach through local religious institutions and community businesses
- Advertise on the radio and in magazines.
- Use African American fraternities and sororities on campus for education and recruitment.
- Use the image of an individual of the same target minority group in the materials.
- Assign someone of the same minority group as part of the recruitment team.

Minority Population: Asian Americans



Characteristics and Strategies^{19,20,21,22}

- Includes multi-national and multi-lingual individuals. Largest Asian groups in the U.S. are: Chinese, followed by Filipinos and Indians.
- In many Asian cultures, the goal of medicine is to restore Harmony — represented by the yin and yang in the Chinese culture — when it is unbalanced. Usually when Asian Americans feel well they do not see doctors.
- Often make decisions by group consensus, and the interest of the family as a whole is more important than the interest of the individual.
- Believe that uncertainty is inherent in life and have a fatalistic attitude toward sickness. Even though Asian American patients may be willing to listen to doctors and follow treatments, discussing fighting a disease may be perceived as a negative approach to healing.
- Asian Americans spend 18% less time than average reading magazines and 55% less time than average listening to the radio.
- Preferred media channels for this population include Internet and minority newspapers.

Targeted Recruitment Tips and Strategies

- Conduct research on the composition of the Asian American community surrounding the site (e.g., English literacy, nationalities, and languages spoken) and translate recruitment materials as needed.
- Advertise on the Internet and ethnic newspapers.
- Advertise in Asian American neighborhoods.
- Use the concept of Harmony in the messaging.
- Avoid using "fighting" themes in ads targeting this population.
- Organize face-to-face educational lectures to inform the community.
- Use the image of an individual of the same target minority group in the materials.
- Assign someone of the same minority group as part of the recruitment team.



Percentage of Population



Key Values and Characteristics



Key Influencers



Key Media

Minority Population: Hispanic Americans





Percentage of Population



Key Values and Characteristics



Key Influencers

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Key Media

Characteristics and Strategies^{13,14,15,16,17,18}

- Almost 70% of this population is proficient in English and speak Spanish at home.
- Median age of Hispanics in the U.S. is 29, which is 10 years younger than the national average.
- More than 75% of the population is religious, with 55% being Catholic and 22% Protestant.
- A majority feel it is important to be recognized as Hispanic through culturally relevant content.
- 40% of Hispanic Millennials are mobile-only internet users, and two-thirds of the population use social networks.
- Most received health information from doctors in the past year. Their secondary source for health information is TV, followed by friends and family, and print media including newspapers and magazines. Most not only obtained information from these media, but close to 80% of the population acted on this information.

Targeted Recruitment Tips and Strategies

- Conduct outreach through community representatives such as church leaders.
- Ask for physician referrals in the Hispanic community.
- Advertise on TV and in Hispanic print media.
- Engage the community on social networks.
- Create ads in both English and Spanish.
- Use the image of an individual of the same target minority group in the materials.
- Assign someone of the same minority group as part of recruitment team.

Minority Population: Native Americans





Percentage of Population

Characteristics and Strategies^{29,30,31,32,33}

- Most Native American families and communities reside in western states including Alaska, California, Oklahoma, and New Mexico.
- There are currently 573 Federally recognized tribes, each with their own culture, beliefs, and practices.
- Native Americans commonly experience a lower health status due to lack of insurance, poverty, and discrimination in the delivery of health services.
- About 78% of the population lives outside of Native areas. However, most counties with higher proportions of Native Americans were in close proximity to reservations, trust lands, or tribal areas
- In tribes and rural areas, many reservations lack highspeed Internet access and digital media
- Many Native Americans receive their education from neighboring colleges or libraries.
- The population as a whole has access to media including traditional and digital media outlets. However, while over 80% of the population report looking for information online and 90% read and send emails, a large majority of the population does not use social media.

Targeted Recruitment Tips and Strategies

- Organize face-to-face education lectures to inform the community.
- Advertise through digital media and email campaigns, but exclude social media.
- Incorporate symbolic imagery into ads.
- Use the image of an individual of the same minority group in the materials.
- Assign someone from the same minority group as part of the recruitment team.



Minority Population: LGBTQ+

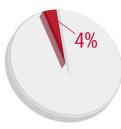


Health Acceptance

Key Values and

Characteristics

Brand Loyal



Percentage of Population



- This community includes people of all ages and minorities.
- It is estimated that 4.5% of adults in the U.S. identify as lesbian, gay, bisexual, and transgender. This represents approximately 11 million Americans.
- Members not only share the health concerns of the rest of the population, they also face a number of additional and important health risks, such as human immunodeficiency virus (HIV).
- The health care setting promotes stress, fear, and anxiety for LGBTQ+ patients.
- May feel more accepted by their LGBTQ+ community than by
- their family of origin or religious affiliation.
- Studies of purchasing decisions show gay and lesbian adults will select brands that have a reputation for being friendly to LGBTQ+ individuals.
- Preferred media in the community include LGBTQ+ websites and blogs, followed by mainstream TV including network and cable, and mainstream websites.

Targeted Recruitment Tips and Strategies

- Use images depicting same-sex couples and parents, and LGBTQ+ families.
- Use LGBTQ+-friendly symbols such as the rainbow flag, pink
- triangle, or Safe Zone sign in ads.
- Add non-discriminatory phrases to materials such as "LGBTQ+ participants welcome."
- Conduct outreach through LGBTQ+ advocacy groups in the community.
- Advertise on LGBTQ+ websites and publications.
- Train recruitment staff in using neutral and inclusive language and avoid sexual orientation assumptions.



Key Influencers

VI. Selecting Media Channels and Outreach Materials

Key Recruitment Materials

Initially, clinical sites should create a dedicated email address/ phone line and develop several key recruitment materials including:

- Trial flyer/brochure
- Scripts for reaching prospective participants
- Mailers targeting physicians and potential participants

Other materials can be developed to supplement these as needed based on the targeted groups.

After preparation and once required NCI DCP and IRB approvals are obtained, site staff can begin disseminating ads and announcements. Throughout the process of converting contacts into potential participants, it is important to adhere to the privacy policy of the clinical organization and the preferred methods of contact of potential participants.

Media Planning and Placement

Before starting media planning and placement activities, check on the staff and financial resources available within the site.

When considering the best marketing approach, it is helpful to understand some key marketing terms: Reach, Frequency, and Impressions.

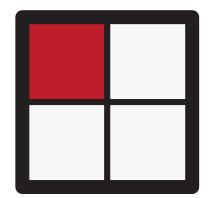
Reach

The total number of individuals exposed to an advertising message through a certain media over a given period of time.

Frequency The number of times an individual is exposed to an advertising message delivered through that media, or the number of times an ad is repeated through a specific medium, over a specific time period.

 Impressions (also called Views) The number of times the ad is displayed/loaded on a particular media = Reach x Frequency.

The media planning and placement guidelines in this Toolkit provide potential outreach options to use simultaneously or sequentially as part of a multi-step escalation plan that triggers additional ads based on accrual goals and actual results. These guidelines also indicate the potential for impression and cost range for each option, and provide tips to better communicate with specific audiences.



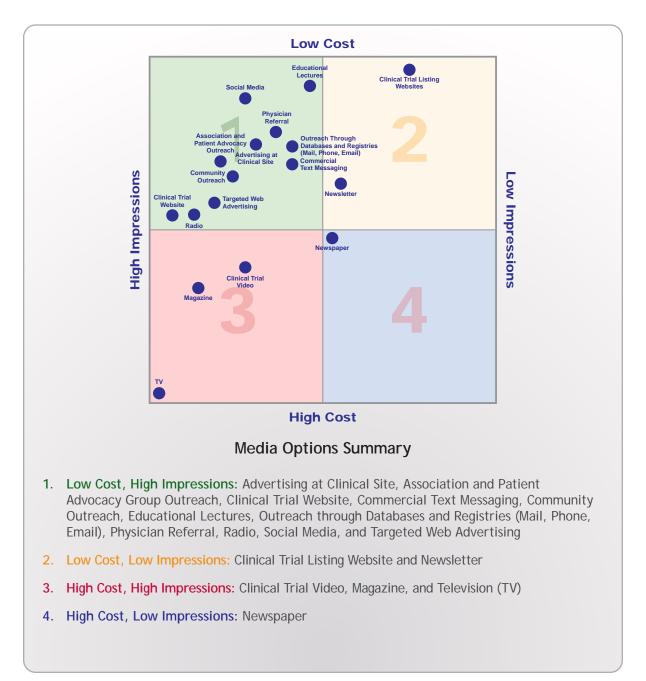


When deciding on your strategies and media mix, consider the:

- Audience's preferred media consumption.
- Available pool of potential participants as per the eligibility criteria.
- Protocol-specific requirements that can make recruitment more challenging (e.g., number of visits and types of procedures).
- Best media reach to target the intended audience.
- Time/effort required or available to implement different options.
- Budget. Media costs vary greatly.

Media Magic Quadrant

In media placement, the goal is to gain the greatest number of impressions per media platform at the lowest cost. The Media Magic Quadrant shows the potential cost versus number of impressions for each outreach type and divides the media in four main categories: (1) Low Cost, High Impressions; (2) Low Cost, Low Impressions; (3) High Cost, High Impressions; and (4) High Cost, Low Impressions. Further descriptions and details about each media platform (cost, reach, preferred target audience, advantages/disadvantages, and placement tips) are also provided in this Toolkit.



Low Cost, High Impressions Advertising at Clinical Site



1

Ads placed in these locations reach a target audience seeking medical information. Since visitors can take flyers or pamphlets home, there is a higher chance they will read or respond to the ad in the future. This media is especially effective on Boomers and the Silent Generation who tend to prefer written communications over digital media.

Action

• Strategically place brochures and flyers in the communal areas and waiting rooms at clinical sites, treatment facilities, doctor's offices, or hospitals.

Cost

Staff resources; printing

Reach

Clinical site patients and visitors

Preferred Target Audience

• All

Advantages

- Low cost to design.
- Can be produced in-house.
- May be placed in high traffic areas.
- Format provides opportunity to add details about a trial and how to enroll.
- Potential for direct interaction with site staff.
- Available to users without Internet access.

Disadvantages

- Effectiveness depends on the quality of media design.
- Competes with other ads at the site.



Low Cost, High Impressions Advertising at Clinical Site

Bi-Fold Brochure Template





Bi-Fold Brochure Sample

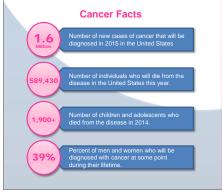


Certain types of cancer take years to develop and there is an opportunity to intervene early in the process. The best opportunity to slow, stop, or reverse cancer development is with cancer prevention clinical trials.

[Name of Clinical Site] is conducting cancer prevention clinical trials sponsored by the National Cancer Institute, (NCI), Division of Cancer Prevention (DCP) in the [City/Region] area.

What is a Clinical Trial?

A clinical trial is a research study that investigates the safety and efficacy of health-related interventions in humans. New treatments may include new drugs or new combinations of drugs, vaccines, devices, and new surgical procedures. ents



Benefits of Enrolling

- Delay or prevent your own disease.
- Gain access to new research treatments/procedures immediately.
- · Play an active role in your own health
- Receive regular and careful care from medical professionals and specialists.
- Contribute to cancer prevention research. Become part of the cancer prevention community and make a difference.

Our Study Team Clinical Trials are conducted by [Name of Principal Investigator] who has more than Iyears] of experience in [related expertise], as well as an experienced, competent, and caring team of nurses and professionals including a dedicated study coordinator.

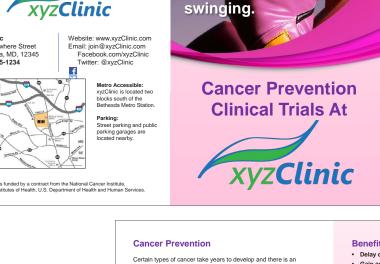


Our team provides trial participants with the highest standard of care.

Our Community At [Name of Clinical Site], we are a community of trial participants and medical professionals working together to prevent cancer.

We are looking forward to welcoming new participants elp make our mission a succ

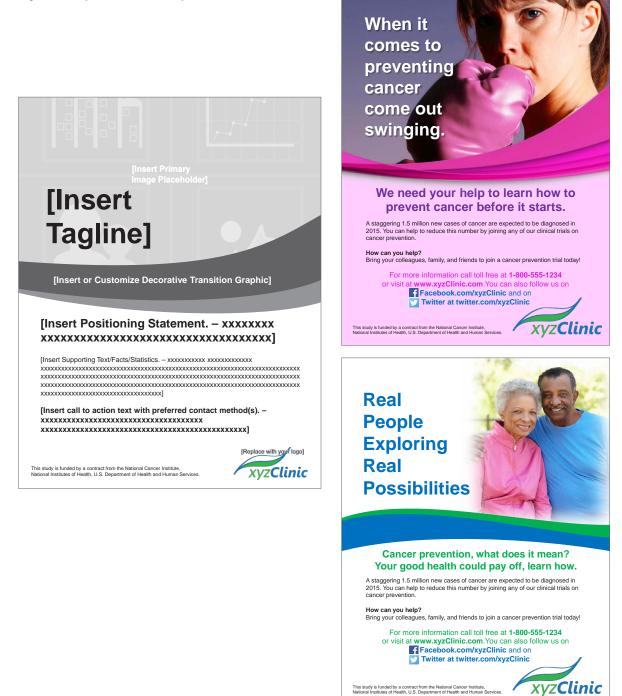






Low Cost, High Impressions Advertising at Clinical Site

Flyer Template and Samples



Low Cost, High Impressions Association and Patient Advocacy Group Outreach



1

Advertising in conjunction with advocacy groups creates strong partnerships and increases awareness of the trial brand. Collaboration can increase the audience reach and help target specific populations.

Action

• Contact relevant advocacy groups and patient/disease associations.

Cost

Staff resources

Reach

• Targeted association and advocacy group members

Preferred Target Audience

• All

Advantages

- Associations/advocacy groups can attract national attention to a trial.
- Increases branding and credibility of the trial.
- Expands reach of the ad.

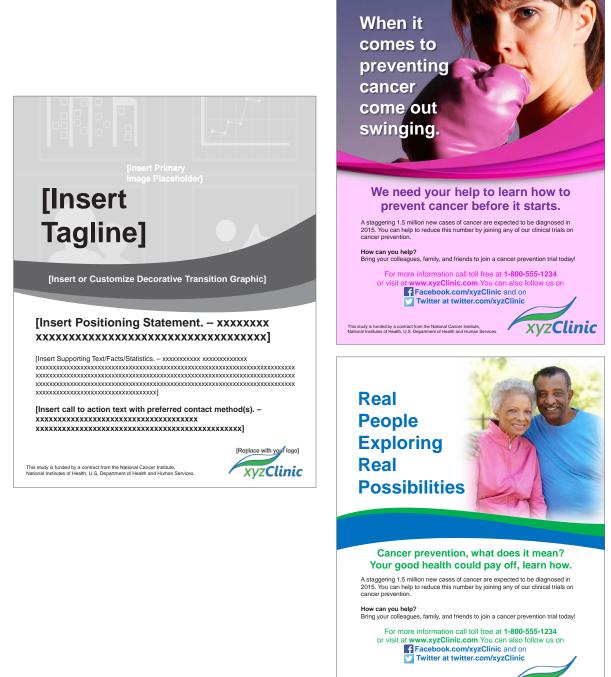
Disadvantages

- Competition to have listings advertised may necessitate having an established partnership with the associations/ advocacy groups.
- Resource intensive; contacting advocacy groups can be time-consuming.



Low Cost, High Impressions Association and Patient Advocacy Group Outreach

Flyer Template and Samples



xyzClinic

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services

Low Cost, High Impressions Clinical Trial Website



Developing a clinical trial website is essential because it is the main source prospective participants go to for trial information. It increases trial credibility and branding.



Check with the clinical site institution about website hosting and with university students for web development. Consider using free and easy-to-use website builder solutions such as <u>wix.com</u>, <u>weebly.com</u>, and <u>webs.com</u>.

Developing a Trial Website

Action

• Create a trial website with more details about the trial and a pre-screen questionnaire, and provide convenient ways to connect with the trial staff such as through a toll-free line, email, and/or chat.

Cost

• Staff resources; \$750+ (depending on the number of pages, mobile responsiveness, content creation, website maintenance, selected graphics, special programing needs, etc.)

Reach

• Individuals that are directed to the page through the other media mentioned in this section. The Internet is the public's top source for clinical research information.

Preferred Target Audience

Millennials, Gen X, and Boomers

Advantages

- Provides details about the trial and how to enroll.
- Allows for integration of a pre-screen questionnaire.
- Great potential for interaction.

Disadvantages

- Requires ongoing update and maintenance.
- Driving traffic to the website depends on the success of other marketing strategies.
- Internet access required to view information.
- Need to consider access using mobile devices.



Website Promotion and Search Engine Optimization (SEO)

For a website to be most effective, it is important that the intended audiences can easily find it when searching the Internet. For the trial website to appear among the first results on search engine pages and increase the number of visitors, staff can use either paid ranking (see the Targeted Web Advertising section) or organic ranking through SEO techniques which can be implemented at no cost.

When a search is performed:

- Keywords are run in the search engine's index which may return millions of possible results.
- Search engines use different algorithms composed of more than 200 page-level, website-level, and off-site signals to refine and rank the results.
- Most Internet users look at only half of the results on the first page and generally type a new query rather than clicking through to the second page of results, so the ranking of the trial website in search engines is crucial.

To better increase the position of the trial website in the ranking, it is important to consider and implement some of these basic strategies when building the site:

- Page Architecture: Every page should contain:
 - Unique topic
 - Unique title (displays in the search results)
 - Unique meta data description for the snippet (i.e., the short text preview Google displays for each web result)
 - Descriptive anchor text for every link

For a clinical trial website to appear among the first results on search engine pages and increase the number of visitors, staff can use either paid ranking (see the Targeted Web Advertising section) or organic ranking through SEO techniques which can be implemented at no cost.

Low Cost, High Impressions Clinical Trial Website

Important

Remember search engine algorithms constantly evolve, and search results may vary between different search engines and from one individual to the next.

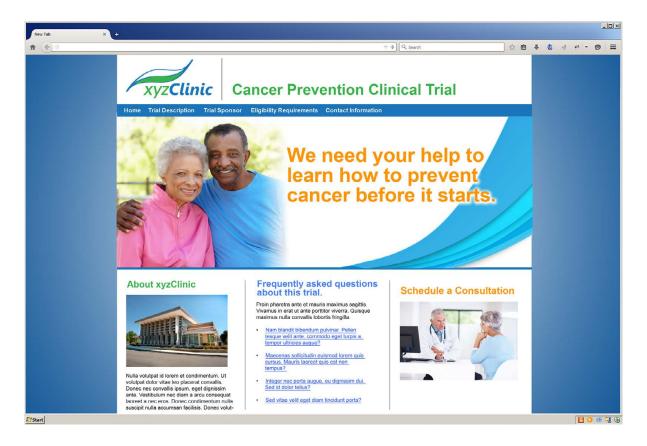
Also, because all pages will not rank well organically — particularly for newly created websites, those few inbound links, and websites with a lot of competition, consider complementing organic SEO techniques with web advertising. Keywords: Keywords should reflect common search terms. The best keywords are 2-3-words long and these should be appropriately placed throughout every aspect of the website: titles, content, URLs, meta data descriptions, and image names. The title tag (i.e., HTML element used to briefly describe the content of a webpage) and page header are the two most important areas to put keywords. It's also important to add synonyms of the primary keyword throughout the page. Search <u>www.google.com/trend</u> to learn about the latest keyword trends in the industry.

- **Content:** Occasionally emphasize useful terms on a page (bold, italics, underlined). Add "Alt Text" and captions to images. Updating the website regularly with fresh content is also crucial to build search engine reputation.
- Internal Links: Internal links should be present throughout website and anchor text should be descriptive. URLs should contain clear keywords. Add a site map (or navigation bar for small sites).
- External Links: Links from .edu domains are given extra weight by search engines. However, note that reciprocal links (links going to and from both pages) work less than unidirectional inbound links. Links to the website should also be distributed through social networking platforms.
- Mobile Friendliness: Websites should have a responsive design to rank well. A responsive design is one that adjusts the size and layout of the page based on the visitor's screen resolution.
- Website Submission: Submit the new website or newly updated pages to search engines to make sure they appear in search results. <u>See Google submission page for more</u> information.

It is important to remember search engine algorithms constantly evolve, and search results may vary from one individual to the next. Also, because all pages will not rank well organically particularly for newly created websites, those few inbound links, and websites with a lot of competition, consider complementing organic SEO techniques with web advertising.



Sample Clinical Trial Website Home Page



Low Cost, High Impressions Commercial Text Messaging



Text advertising allows contacting those who have signed up to receive trial messages and can reach the audience multiple times. Text messaging is fast, direct in its delivery, and very effective in reaching Millennials and Gen X. Text messaging recruitment may provide instant results.



If you don't have approvals from participants, ask them to enroll when they visit the practice and advertise in patient waiting rooms and administrative areas.

Action

Send commercial text messages to a registered list of participants telling them about the opportunity and where/ how to obtain more information. One limitation is that text messages cannot be sent, unless potential participants have explicitly given approval in writing to join this specific text message program. If a list of existing participants is obtained, and someone has opted in, then text messages can be sent.

Cost

• 3 cents/message; Plans: \$12/month - \$600/month

Reach

Individuals who opt in

Preferred Target Audience

• Millennials, Gen X

Advantages

- About 90% of text messages are read within 3 minutes⁴¹.
- Reach is immediate.
- Allows for two-way communication. Screening visits can be scheduled and eligibility questions answered by text.
- Less intrusive than phone calls.
- Allows for immediate follow-up with less staff.

Disadvantages

- Content must be short.
- Strictly regulated; individuals must provide explicit consent and permission must be documented.

Placement

- Variables including the number of contacts to be imported, texts to be sent, and keywords needed will impact the cost and should influence the selection of a Short Message Service (SMS) provider.
- Keywords (e.g., PREVENTION) will be used by-- recipients to opt-in. Only one keyword can be used per trial at a given time.
- Payments options include both pay-as-you-go and monthly plans. Examples of SMS providers include CallFire, TellMyCell, Moze, Text180, and Betwext. Contact these providers directly for specific pricing information based on the anticipated need.



Short Message Service (SMS) Message

To create a SMS/text message marketing campaign, we recommend the following steps:

- 1. Decide on who will distribute your messages (Staff members or Third Parties).
- 2. Set up a method to obtain consent and phone numbers.
- 3. Most marketing campaigns have the potential audience send a text message to a short code (i.e. "Text CANCER to 98-765 to receive messages").
- 4. Promote through various media (e.g., Internet, Flyers/Posters).
- 5. Keep messages simple. Must be limited to 160 characters.
- 6. Send confirmation text after users opt in.
- 7. Track results and continue marketing. Generally, text messages 2-4 times a month.

Text Message Content Rules and Requirements

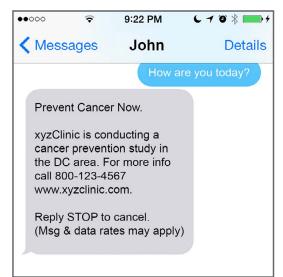
In addition to rules set by the FDA regarding marketing and advertising, all text marketing must adhere to the rules of the Federal Communications Commission (FCC) Telephone Consumer Protection Act 47 U.S.C. § 227 and the FTC CAN-SPAM act. Review all rules to ensure marketing campaigns are in agreement.

Some highlights are:

- Contacting audiences who have not signed an opt-in agreement is prohibited
- Text messages must contain:
 - The program's name and description
 - A link to terms and conditions or privacy policy
 - STOP instructions or the ability to opt out of receiving messages
 - Contact and support information
- Additional carrier costs disclosures (e.g., Msg and data rates may apply)

Template and Sample

Message from [Insert LAO/AO Name]: [Insert Tagline] [Insert Positioning Text] [Insert Call to Action with contact method(s)] Reply STOP to cancel. (Msg & data rates may apply)



Low Cost, High Impressions Community Outreach



Community outreach improves public perception of a clinical trial by building awareness. Community outreach is effective with all age groups and bypasses demographic restrictions as some populations may not have access to the Internet or other digital media outlets.

Action

 Advertise in local places (e.g., universities, pharmacies, local businesses such as gyms, grocery stores, coffee shops, and other businesses). Contact church and community leaders especially for special populations and brainstorm locations for advertising based on the specific cohort population.

Cost

Staff resources; printing

Reach

Community members and leaders

Preferred Target Audience

• All

Advantages

- More likely to lead to the recruitment of a diverse population sample.
- Helps raise awareness of trial information in the community.
- Buy-in from leaders boosts public perception and credibility of the trial.

Disadvantages

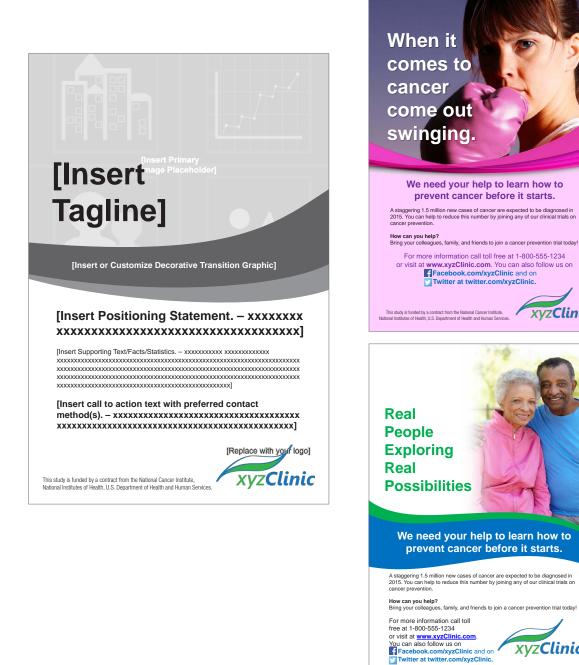
- Resource intensive; identifying and placing ads at strategic locations is time-consuming.
- Permission may be required to advertise in certain locations.

Placement

• Place ads (flyers, posters, or road signs) in strategic locations where they will be seen by a wide variety of community members. Grocery stores, coffee shops, and churches often have bulletin board advertising space for general use.



Large Poster Template and Samples



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Low Cost, High Impressions Educational Lectures



Conducting educational lectures is a great method to inform potential participants about all aspects of a clinical trial and resolve any misconceptions. This method is effective in reaching out to potential minority participants and Boomers who tend to be more involved in local community activities.

Action

 Organize educational lectures at the site and/or in the community universities and churches to educate community/participants and address questions and potential misconceptions. Send mail/email invitations to participants and disseminate social media and printed announcements (e.g., flyers).

Cost

Staff resources; announcements; transportation; other meeting costs

Reach

Local reach

Preferred Target Audience

• Boomers, Silent Generation

Advantages

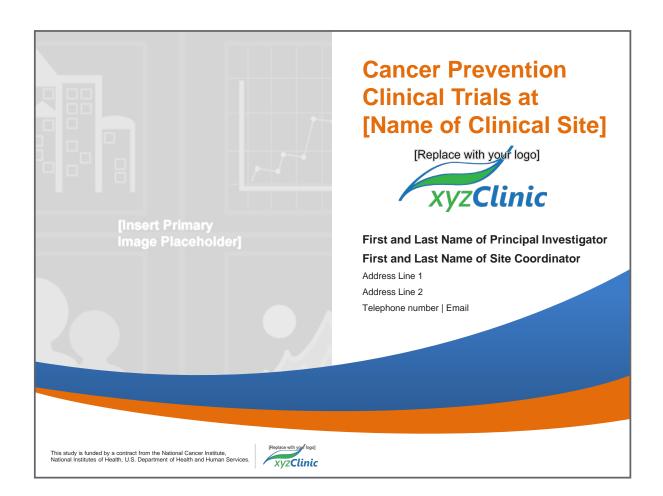
- Attracts people with an interest in participating in clinical trials.
- Encourages sense of community/belonging which is important in attracting clinical trial participants.
- Allows for Question and Answer discussions in a public forum.
- Fosters word-of-mouth communications.

Disadvantages

- Requires time to organize formal presentations.
- Requires meeting planning and equipment (projector, computer.)
- Must be scheduled and supported when people are available.



Participant PowerPoint Presentation Template/Sample





Our Cancer Prevention Community

We are [Name of Clinical Site], a community of trial participants and medical professionals working together to prevent cancer.

We are looking for new participants like you to help make our mission a success.

PREVENT CANCER NOW!

XVZClinic

Who We Are

a funded by a contract from the National Cancer Institute, titutes of Health, U.S. Department of Health and Human S

Our work researches new drugs and other interventions with the ability to block, reverse, or delay the progression of cancer.

We work alongside the Division of Cancer Prevention, National Cancer Institute, National Institutes of Health.







To conduct cancer research, raise cancer prevention awareness, and develop new cancer prevention methods.

Reasons to join a Cancer Prevention Clinical Trial

(Replace with your logo)

 Delay or prevent your own disease

Inded by a contract from the National Cancer Institute, itutes of Health, U.S. Department of Health and Human Se

- Play an active role in your own health
- Contribute to cancer prevention research
- Become part of the cancer prevention community and make a difference









Our Team	
[Insert picture of your site team]	
This study is funded by a contract from the National Cancer Institute, National Institutes of Heath, U.S. Department of Heath and Human Services.	8

Low Cost, High Impressions Outreach Through Databases and Registries (Mail, Phone, Email)





Search existing registries, pathology reports, and clinic and operating room schedules. Apply filters where possible to screen by key data such as gender, age, and medical condition to better target potential participants. Contact individuals by direct mail, email, and phone.

Direct Mail

Action

• Draft an invitation letter or create a postcard to reach out to potential participants. Consider including a flyer or a brochure with more information about the trial.

Cost

• Staff resources; printing; mailing

Reach

• Individuals identified through physician referral, existing database, and other referral methods.

Preferred Target Audience

Silent Generation, Boomers

Advantages

- Low cost
- Can often be produced in-house
- Ability to personalize the message
- Ability to provide details about the trial and how to enroll
- Effectiveness of response can be easily measured

Disadvantages

- Distribution is not immediate due to lead times for printing and mailing.
- Often considered junk mail.



Postcard Template and Samples



Low Cost, High Impressions Outreach Through Databases and Registries (Mail, Phone, Email)



1

Email

Action

• Create an email ad/invitation to send to identified contacts. Create and update a spreadsheet after each email campaign to keep track of the people who responded, individuals who requested to be removed from the list, and prospective participants to contact again.

Cost

Staff resources

Reach

• Individuals whose contact information is obtained through physician referral and existing database.

Preferred Target Audience

Millennials, Gen X, Boomers

Advantages

- Low cost medium.
- Instant delivery time.
- Easily shared with friends and family.
- Ability to provide details about the study and how to enroll.

Disadvantages

- The success of this medium depends on the quality of the mailing list.
- Emails may be filtered or rejected by email providers and never reach the recipient.
- No options for further geographic/demographic targeting.
- Appearance of graphics is unpredictable due to differences in email programs and computer screen displays.
- Often considered junk mail.



Email Template and Sample

Subject: [Insert [Organ Type] Cancer Prevention Clinical Trial] [Insert Tagline] [Insert Positioning Text, Trial Name, Eligibility Criteria] [Insert Call to Action with contact method(s)]

Sincerely, [Insert Name] [Insert LAO/AO Brand Identity] [Insert LAO/AO Contact Info] [Insert Social Media Icons (if applicable)]

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FILE MESSAGE McAfee E-mail Scan ADOBE PDF		
Tue 10/27/2015 9:52 PM Colon Cancer Prevention Trial		
Prevent Cancer Now		
	ancer prevention trial participants. xyzClinic is co by the National Cancer Institute (NCI), the Divisio	
	drugs, biologics, interventions, and vaccines, tha y block, reverse, or delay the progression of canc criteria.	
We looking for volunteers ages 35 to 50 years of will be conducted by John Smith (Principal Inv	old with no prior history of cancer to take part in a estigator) with the xyzClinic.	a colon cancer prevention trial. The trial
Please contact us at 1-800-123-4567 or visit us	at www.xyzClinic.com, www.facebook.com/xyzC	Clinic, and www.twitter.com/xyzClinic.
Join our cancer prevention trial toda	y!	
Sincerely, Jane Jones Nurse Researcher VyZClinic 1000 Washington Drive Washington DC, 20001 1-800-123-4567 (Ext. 890)		

Low Cost, High Impressions Outreach Through Databases and Registries (Mail, Phone, Email)



Phone outreach allows site staff to directly engage with the prospective participant. In addition, sites staff can display a warm and inviting attitude during conversations to create positive relationships with potential participants.

Phone

Action

 Call a list of prospective participants who agreed to be contacted about clinical trials to discuss the trial and methods to enroll. Remember that IRBs prohibit calling unknown potential participants. The trial should be introduced to participants by an individual who would normally have access to their contact information (e.g., personal physician, member of clinic or practice staff).

Cost

• Staff resources; cost of communications

Reach

• Individuals whose contact information is obtained through physician referral and existing databases.

Preferred Target Audience

Boomers, Silent Generation

Advantages

- Pushes the message to the target audience.
- Provides an interactive approach to recruitment.
- Allows for contacting numerous prospective participants in a short amount of time.
- Gives the opportunity to conduct screening or schedule an appointment right away.

Disadvantages

- Often requires multiple follow-up calls to reach the intended person.
- Often considered as an intrusive way to contact people.
- Permission to call should be given prior to contacting participants.
- Lacks visual impact and support.

Low Cost, High Impressions Physician Referral



Patients who receive trial information from physicians are more likely to trust the information they receive and enroll in a clinical trial. Physicians are also well positioned to reach diverse populations and older generations who visit clinicians regularly.

Action

• Contact physicians using the material templates provided in this AQuIP Toolkit (PowerPoint presentation, letter, brochure) to obtain referrals.

Cost

• Staff resources; printing; mailing

Reach

• Local specialists and primary care physicians and their patients.

Preferred Target Audience

• All

Advantages

- Participants trust physicians for clinical advice.
- Physicians can interact with potential participants and answer questions immediately.

Disadvantages

- Physicians may not be interested in promoting trials without incentives.
- Labor intensive; contacting physicians can be time-consuming.

Placement

- Use examples from this AQuIP Toolkit to develop effective communication pathways with physicians and clinical coordinators in the community. To disperse information about the trial, contact and work with:
 - Hospitals
 - Clinical organizations
 - Individual physicians

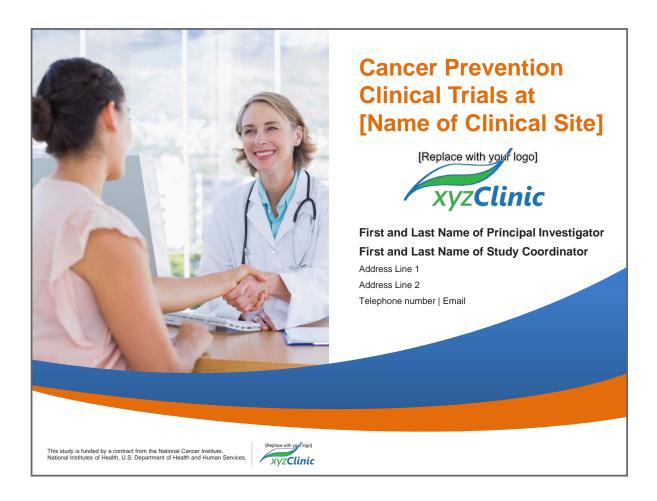


Physician Referral Letter Template





Physician PowerPoint Presentation Template/Sample







About Our Cancer Prevention Community

The [Cancer Prevention Group] at [Name of Clinical Site], includes a community of investigators and collaborators who conduct clinical research trials.

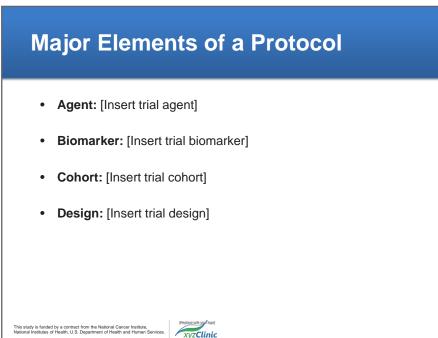
We are looking for physicians, just like you, to help us make our mission a success.

TOGETHER WE WILL MAKE A DIFFERENCE!













Reality of Clinical Trial Participation

Although,

- 87% of the public is willing to participate in a clinical trial, and
- 95% of volunteers would consider participating in another study.

Source: Center for Information and Study on Clinical Research Participation (CISCRP), (2013). Report on General Perceptions. 2013 Perceptions & Insights Study. Retrieved from: https://www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-General-Perceptions.pdf

Center for Information and Study on Clinical Research Participation (CISCRP), (2013). Report on Study Participant Experiences. 2013 Perceptions & Insights Study. Retrieved from: https://www.ciscrp.org/wp-content/uploads/2014/01/2013 CISCRP-Study-Study-Participant-Experiences.pdf

Reality of Clinical Trial Participation

Only

- **48%** of studies under-enroll participants.
- 11% of sites in a given trial fail to enroll a single participant.
- Trial timelines are frequently extended to nearly double their projected duration to meet target enrollment levels.

This results in treatments for <u>your patients</u> being: delayed, more expensive, or never released on the market.

Source: Tufts Center for the Study of Drug Development (2013, January/February). 8% of trials meet enrollment, but timelines slip, half of sites under-enroll. Impact Report, Volume 15, Number 1. Retrieved from: <u>http://csdd.tufts.edu/files/uploads/</u> jan-feb_2013 ir summary.pdf

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.



Importance of Your Involvement

xyzClinic

xyzClinic

- One of the main reasons for non-participation in clinical trials is a lack of awareness from potential participants that studies are even taking place.
- Primary and specialty care physicians are the top preferred choices for clinical trial information.
- Physician referral motivates participants to join clinical trials.

We need your support for the success of cancer prevention studies.



Our [cancer prevention group] is composed of participants with all levels of risk from healthy volunteers to late stage patients.

NCI DCP AQuIP Toolkit - Selecting Media Channels and Outreach Materials

Referring Physicians Benefits

Your support of clinical research may help:

- Further your mission as a physician.
- Learn more about clinical trial processes.
- Learn more about progress in cancer prevention.
- Increase your professional/name recognition.

Replace with your logo]

Increase your patient base through word-of-mouth discussions.

Benefits to Your Patients

Our participants:

is funded by a contract from the National Cancer Institute, stitutes of Health, U.S. Department of Health and Human Servi

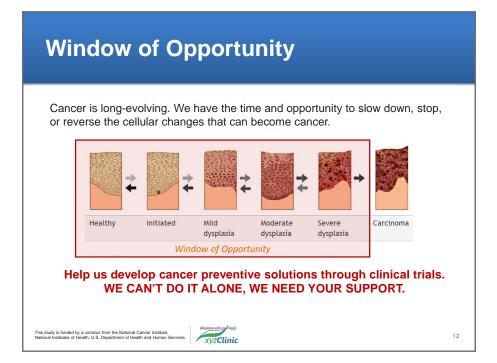
- Gain access to new research
 treatments/procedures immediately.
- Receive regular and careful care from medical professionals and specialists.
- Receive regular updates about the trial progress.
- May be compensated (depending on studies).
- Make a positive impact on other people's lives.
- Become part of a community that is actively involved in preventing cancer.
- Play an active role in their health.

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.



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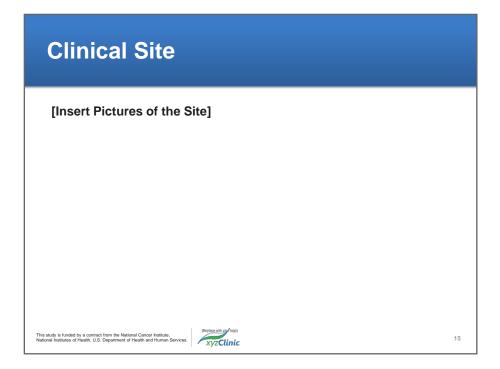






1 Low Cost, High Impressions Physician Referral

Clinical Site	
[Insert your clinical site experience conducting clinical trials]	
This study is funded by a sector from the Matteria Course both to process with sys ⁴ repol	
This study is funded by a contract from the National Cancer Institute. National institutes of Health, U.S. Department of Health and Human Services.	14





Dr. [Name], Principal Investigator	
[Resume of PI/BIO]	
This study is funded by a contract from the National Cancer institute, National Institutes of Health, U.S. Department of Health and Human Services.	16

Study Staff	
[Introduce:	
Study Coordinator	
Study Nurses	
Other Study Staff	
Include pictures if possible]	
This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.	17

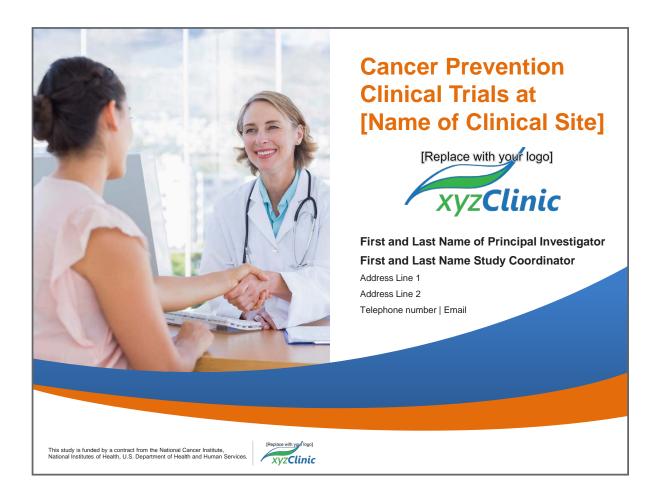




[Name of Clinical Site]	
Email: Phone: Facebook: Twitter: Website: Image: State of the sta	
This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.	19



Clinical Institution Physician PowerPoint Presentation Template/Sample





Low Cost, High Impressions Physician Referral



About Our Cancer Prevention Community

The [Cancer Prevention Group] at [Name of Clinical Site], includes a community of investigators and collaborators who conduct clinical research trials.

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.

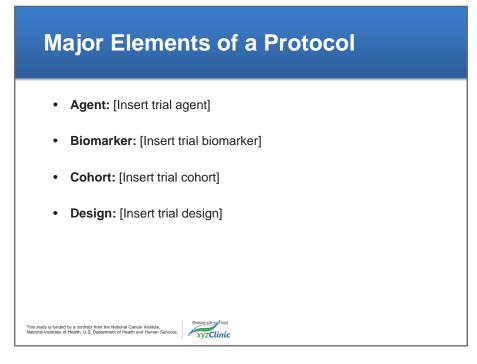
We need your support to make our mission a success and further our institutional research goals. Collaboration is key.

TOGETHER WE WILL MAKE A DIFFERENCE!













Reality of Clinical Trial Participation

Although,

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- 95% of volunteers would consider participating in another study.

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- 11% of sites in a given trial fail to enroll a single participant.
- Trial timelines are frequently extended to nearly double their projected duration to meet target enrollment levels.

Your participation contributes to our institution's success.

Source: Tufts Center for the Study of Drug Development (2013, January/February) 89% of trials meet enrollment, but timelines silp, half of sites under-enroll. Impact Report, Volume 15, Number 1. Retrieved from: <u>http://csdd.tufts.edu/files/uploads/</u> jan-feb 2013 ir summary.pdf

his study is funded by a contract from the National Cancer Institute, lational Institutes of Health, U.S. Department of Health and Human Services.



Importance of Your Involvement

xyzClinic

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- Primary and specialty care physicians are the top preferred choices for clinical trial information.
- Physician referral motivates participants to join clinical trials.

We need your support for the success of cancer prevention studies.

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Our [cancer prevention group] is composed of participants with all levels of risk from healthy volunteers to late stage patients.

Referring Physicians Benefits

Your support of clinical research may help:

- Advance the mission and reputation of our organization.
- Increase our ability to successfully compete with other universities and medical institutions.
- Further your mission as a physician.
- Increase your professional/name recognition within the institution.
- Increase your patient base through word-of-mouth discussions.
- Learn more about clinical trial processes.

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.

Benefits to Your Patients

Our participants:

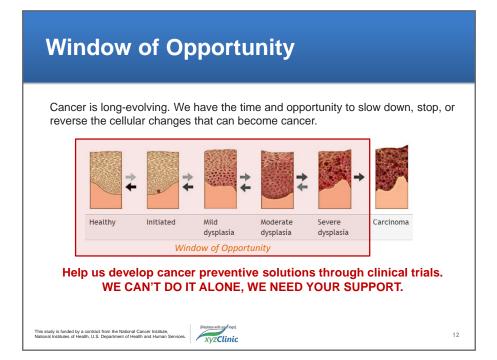
- Gain access to new research
 treatments/procedures immediately.
- Receive regular and careful care from medical professionals and specialists.
- Receive regular updates about the trial progress.
- Play an active role in their health.

This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.

- May be compensated (depending on studies).
- Make a positive impact on other people's lives.
- Become part of a community that is actively involved in preventing cancer.

10

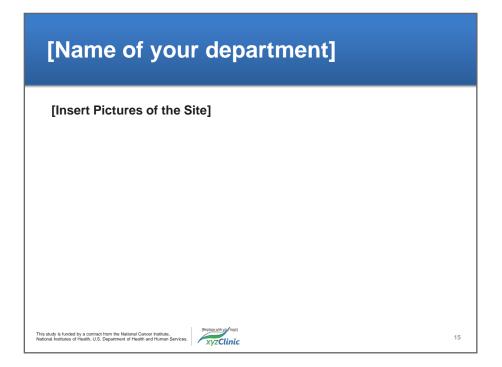






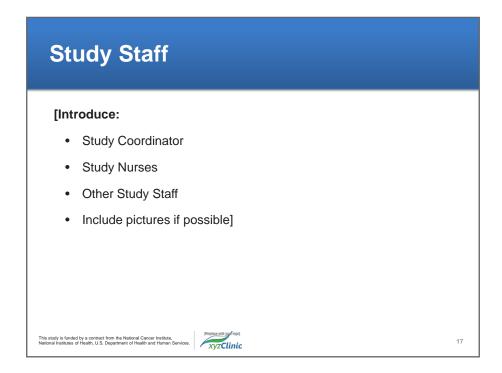


[Name of your department]			
[Insert your Department's experience conducting clinical trials]			
This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.	14		





Dr. [Name], Principal Investigator	
[Resume of PI/Biography]	
Protoce with type/topp	
This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services.	16







[Name of Clinical Site]			
Email: Phone: Facebook: Twitter: Website:	[Replace with your logo] XYZCLinic		
This study is funded by a contrast from the National Cancer Institute. National Institutes of Health, U.S. Department of Health and Human Services.	Clinic 19		

1 Low Cost, High Impressions Radio



Directly captures attention of target audience through morning and evening drive times through wide reach and frequency.

In addition, sites can create targeted radio ads for digital radio stations that are popular with Millennials.



In addition to distributing the message through traditional radio, consider using digital radio (e.g., Pandora) when targeting Millennials.



Action

• Create a radio spot using the radio script provided in this AQuIP Toolkit. Conduct research to identify potential stations, then request information on their primary audience and listeners or use Arbitron ratings to ensure the message is distributed to the correct target audience.

Cost

• From \$500 to \$8,000 for a spot airing 20 times in a week. Price varies greatly depending on the broadcast market and dayparts selected.

Reach

• Wide reach. Targeting possible based on selection of station, program, and time slot.

Preferred Target Audience

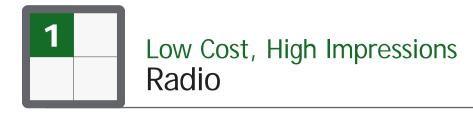
• Gen X, Boomers

Advantages

- Wide reach. People listen to the radio while commuting and at home and work.
- Rates can be negotiated.

Disadvantages

- Target audience may be spread over multiple stations.
- People usually perform other activities while listening to the radio.
- Does not allow for interaction and visuals.
- Radio relies on repetition. Ads may require multiple exposures to ensure message retention.



Placement

- Create a 30- or 60- second radio spot. Spots can be produced by the radio station or outside companies. For the spot to stand out consider using voice-over talent, sound effects, and music.
- Choose from two basic schedules: ROS (run of station) ads which are lower priced with a broad window of airtime, or Flights which guarantee broadcast at a specified time. In general, morning and evening rush hours are the most expensive. Stations can provide information about their most popular listening times.
- Negotiate to have the ad placed on the radio station's website, or ask them to distribute informational materials at local community or civic events.

Radio Script Template

The radio template is comprised of two sections: audio and notes. The audio section includes music/ sound effects, dialogue, and speakers. The notes section includes any extra instructions regarding the script. This template is for creating a 30-second ad.

Audio	Notes
Music: Background music	[Insert any extra instructions here.]
Speaker 1: Dialogue: [Insert Tagline], [Insert Positioning Text], and/or [Insert	
Facts].	
We are seeking [Insert Population Criteria], to participate in any of our [Insert Trial].	
[Insert Additional Promotional Information].	
[Insert Call to Action]! [Insert Phone] and visit [Insert Web Link].	

Some abbreviations for radio scripts can include:

- VO: Voice Over
- FX: Effect
- NAT SOUND: Natural Sound



Radio Script Sample

Audio	Notes		
Sound FX: Restaurant Noises (Plates, silverware, background conversations)	Scene occurs at restaurant. Actors represent the demographics of the target group reflected in the eligibility criteria.		
Man: Alright, love you. I'm heading over to the doctor's office.			
Woman: Oh, I didn't know you had an appointment? Everything okay?			
Man: Everything's fine. I'm just going over to look into that clinical trial I mentioned the other day.			
Woman: Oh, right. It's on cancer prevention?			
Man: Yeah. After my Dad's scare, I wanted to see what I can do to help. And from what I read, this trial is a great way.			
Woman: I have some time this afternoon, could I come with you?			
Man: Definitely! They're looking for all kinds of people.			
Narrator/VO: If you are interested in learning more about cancer prevention trials in your area, contact the xyzClinic at [phone, URL, etc.].			
Why wait? You can Make a Difference. Help Prevent Cancer Now.			

Abbreviations:

- VO: Voice Over
- FX: Effect





Especially successful with Gen Z, Millennials and Gen X individuals.

Social media platforms are great tools to create or enhance word-of-mouth communications and can also be used as a complement strategy to recruit other generations.



Action

Use social media to connect with communities such as groups of individuals with a predisposition to cancer (e.g., Previvors) and patient networks. Inform them about clinical trial opportunities and build cancer prevention awareness. Each media platform offers free advertising methods (e.g., creating a profile page, distributing posts on the page), or paid advertising (e.g., creating ads, promoting posts).

The AQuIP Toolkit provides details on using paid and unpaid advertising options for Facebook, Twitter, and LinkedIn. While the focus of each social media platform varies, the same audience often communicates and overlaps between social media platforms.

Cost

• Staff resources; an average of \$2 to \$5 per engagement (click, impression, follower, etc.)

Reach

- Unpaid promotion: page audience and their contacts.
- Paid promotion: wide reach of targeted social media users.

Preferred Target Audience

• Gen Z, Millennials, and Gen X

Advantages

- High usage, especially by Millennials and Gen X.
- Allows for interacting and building relationships with potential participants and the community including advocacy groups.
- Allows for real-time information sharing, stimulates word-ofmouth discussion, and offers a wide reach.
- Allows for better understanding of target audience through social listening.
- No cost for registration on most popular social media sites.

Disadvantages

- Unpaid targeting is limited due to the diversity and breadth of audience.
- Allow for limited content.
- Resource intensive; building awareness and generating traffic pages can be time-consuming and challenging.



Placement

- Create a social media page or account specific to the trial to allow posting short messages to the audience.
- Use complement posts with an image/graphic or an external link to add details and attract attention.
- Use free, online URL shortener services (see <u>www.bit.ly</u> or <u>www.goo.gl</u>) to stay within character limitations.

Budget and Objectives for Advertising on Social Media

- For paid advertising on social media, advertisers start by setting a daily budget. Users can select between a Cost Per Click (CPC) model where a flat fee is charged for each click on the ad or a Cost Per Impression (CPI) model where a flat fee is charged for each thousand views of the ad. Select from different campaign objectives (e.g., obtaining more followers, getting more traffic on the website, promoting a post, etc.), and filters to define the target audience. Social media filters include the following options to better target the intended group:
 - Location Country, state, or zip code.
 - Demographics Age, gender, and languages.
 - Interests Music, movies, sports, games, and shopping.
 - Behaviors Find participants based on the things they do (e.g., web search: history.)
 - **Connections** Reach the people who view the page and their connections.



Use hashtags

strategically to raise topics and create conversations.

Social Media Advertising Methods

Social media outreach is a fast and effective way to recruit participants and works well when combined with traditional advertising methods. Use social media to:

- Connect with online populations
- Engage discussions
- Raise cancer prevention awareness

Learn how to utilize both options to reach the target audience. Each site has a basic setup:

- Create a centralized profile with the organization/trial name, contact information, and trial information.
- Select audience demographics and advertising avenues, and methods for interacting with the audience.

Some social media platforms even include the ability to link services together. For example, Facebook can highlight tweets from a Twitter account on a Facebook page. Include links between various social media platforms in the biography section of each platform. In addition, data on how customers engage with trial ads can be accurate and easy to track.

Find an audience, create awareness, and engage the audience on one or more of these sites:



Facebook www.facebook.com

Twitter www.twitter.com

in

LinkedIn www.linkedin.com



Moderating Social Media Platforms

Proper guidance is needed to define appropriate use of social media by site staff. Please review the <u>HHS regulations at</u> <u>21 CFR Part 56 and 45 CFR Part 46, FDA Recruiting Study Subjects</u> <u>Information Sheet</u> and the <u>NIH Guidance Regarding Social Media</u> <u>Tools</u> for more information.

Each social media site has privacy settings to limit, hide, or stop user interaction. Review the steps on pages 85, 90, and 93 for each social media platform settings to fully moderate the page.

When posting to social media, IRB approval is required for any post or discussion which goes beyond these six topics:

- Trial title
- Purpose of the trial
- Protocol summary
- Basic eligibility criteria
- Trial site locations
- Contact information

When responding to a user post/comment beyond the six topics, it is suggested the conversation with the user is channeled off the social media page and continued by phone or email.

Use the following **template** in site comments to take a conversation off the social media site.

[Insert "Thank you for your comment" or Thank you for your concern"] Please contact us at 1-800-123-4567 or email us at mail@xyzclinic.com to speak with one of our representatives.





Facebook Advertising

Unpaid Advertising

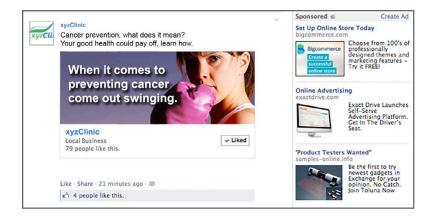
Advertising through Facebook begins by creating a Facebook business page for the trial. This page brands the trial, distributes trial information and drives traffic to a recruiting site. Creating a page involves creating a profile photo and a biography, and choosing search engine descriptions. Go to <u>https://www.facebook.com/</u> <u>business/</u> and follow the instructions on the "Create Page" link. Facebook offers six categories to brand a website, however, only one applies to clinical trials:

Causes or Communities

Once a page is set up, begin uploading posts and photos to the trial. Here is a recommended template and sample of information to include in both unpaid page posts and paid ads.

Facebook Template and Sample

[Insert Tagline] [Insert Positioning Text] [Insert Picture] and/or [Insert Video] [Insert Call to Action Text]





Paid Advertising

Once a page is set up, choose the ad campaign which best suits the trial. As more people like the page, the more extensive the reach becomes. Some Facebook ads are better for getting page likes and raising awareness, while others are preferable to drive traffic, or start conversations. Facebook offers nine paid advertising campaigns; use the following four:

- Clicks to Websites Get the audience to visit a website.
- Page Post Engagement Promoting page posts.
- Page Likes Get page likes to grow the audience and build a brand.
- Video Views Tell a story using a video in an ad.

Facebook ads can be formatted in three locations. Each location has different specifications for image sizes, characters for text, and placement on the website. The types of ads available are:

- Newsfeed Advertisements
- Facebook Mobile New Feed Advertisements
- Right Hand Column Advertisements

Following this choice, the trial must indicate the budget to use for advertising, and choose the audience based on:

- Location
- Age Interests
- Gender
- Languages
- Education Level
- Relationship Status
- Political Views
- Connections to other Facebook pages

Find more information about image sizes, recommended characters for text, and tips at <u>www.facebook.com/business/ads-guide.</u>

1

Moderating Facebook Pages

Facebook presents two filtering options which proactively block words and profanity, or moderates and block users/user comments once they have interacted with the Facebook page.

To proactively block words:

- 1. Click 'Settings' at the top of the page.
- 2. Click 'Page Moderation'.
- 3. Type the words to block, separated by commas. Add both the singular and plural forms of the word to be blocked.
- 4. Click 'Save Changes'.

To proactively filter profanity:

- 1. Click 'Settings' at the top of the page.
- 2. Click 'Profanity Filter'.
- 3. Select 'Medium' or 'Strong'.
- 4. Click 'Save Changes'.

To manage follower settings:

- 1. Go to 'Settings'.
- 2. Click 'Followers' in the left column.

From here:

- Click 'Follower Comments' to select who can comment on public posts.
- Click 'Follower Notifications' to select who should receive notifications when people start following and sharing the page and like or comment on public posts.



To block a user:

- 1. Click the 'Lock Icon' at the top right of any Facebook page.
- 2. Click 'How do I stop someone from bothering me?'
- 3. Enter the name or email address of the person to be blocked and click 'Block'.
- 4. When entering a name, select the specific person to be blocked from the list that appears.
- 5. After clicking on 'Settings' select 'Moderate'.

For more information visit www.facebook.com/help/.



Twitter Advertising

Unpaid Advertising

Advertising through Twitter begins by creating a Twitter account. This account brands the trial, distributes trial information and drives traffic to a recruiting site. Creating an account involves creating a profile photo, a header image, and biography, choosing a user name which will be the unique identifier of the trial, and adding a link to the trial recruitment website.

The biography should include:

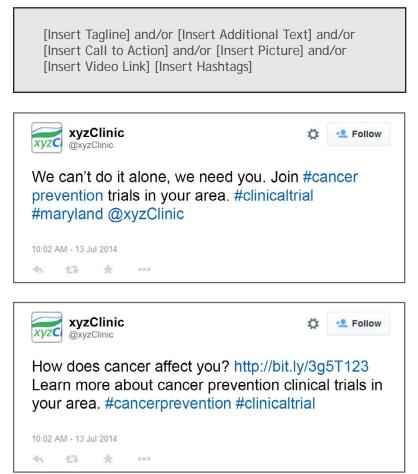
- Phone numbers
- Web links
- Email addresses
- Additional contact information

After creating a Twitter profile, begin tweeting information regarding the trial. Tweet regularly using various slogans and call to action tags to spread information regarding the trial. Tweet actively to raise awareness, retweet and converse with followers to keep the audience engaged, and use appropriate hashtags to increase reach.

All tweets must follow the same format and must be 140 characters or less. Tweets can also be sent out in a series to communicate more information, but be sure that each tweet can stand on its own. Use the following template to design tweets. Mix and match elements to create a clear message.



Twitter Template and Samples



Twitter allows the upload of specific lists (e.g., email list) to target with ads, target the followers of other pages, or target people who have a similar profile to the advertiser's follower base. In all cases, it is key to test the ad through short and low cost campaigns to identify the medium and strategies that are most efficient and cost-effective for the campaign.

Paid Advertising

Posted Tweets are only available to followers; however, the audience can be expanded by paying for tweets. First, decide what type of advertising campaign to run. To raise awareness, use the following campaigns:

- Followers Grow a Twitter community.
- Tweet Engagements Reach more people and drive conversation.
- Leads on Twitter Collect emails from audiences who express interest.
- Website Clicks and Conversations Drive traffic to the trial site.

More information about paid advertising is available at business.twitter.com/solutions/

Hashtag [#] Suggestions:

- Cancer
- Clinical Trial
- Prevention
- DCP
- NIH
- City or Region
- LAO or AO Name

More information on Twitter basics and advertising options is available at <u>www.business.twitter.com.</u>



Moderating Twitter Accounts

Public versus Protected Tweets

Twitter allows a tweet be public or protected. Accounts with protected tweets require manual approval of each and every person who may view tweets from that specific account. Public tweets are visible to anyone; protected tweets may only be visible to approved Twitter followers after manual approval. When tweets are protected, users must request permission to follow. In addition, users will not be able to retweet or quote protected tweets.

To protect tweets:

- 1. Go to 'Security' and 'Privacy Settings'.
- Scroll down to the 'Tweet privacy' section and check the box next to 'Protect my Tweets'.
- Click the blue 'Save' button at the bottom of the page. Enter the account password to confirm the change.

To block a user from commenting on a Tweet:

- From a Tweet, click the 'More Icon' (•••) at the bottom of the Tweet.
- 2. Click 'Block'.

To block a user from commenting on a profile:

- 1. Go to the profile page of the account to be blocked.
- 2. Click the 'Gear Icon' in their profile page.
- 3. Select 'Block' from the menu.
- 4. Click 'Block' to confirm.

For more information visit www.support.twitter.com.

Protect my Tweets

If selected, only those you approve will receive your Tweets. Your future Tweets will not be available publicly. Tweets posted previously may still be publicly visible in some places. Learn more.



LinkedIn

Unpaid Advertising

If a LinkedIn page for the site does not already exist, follow this link <u>www.business.LinkedIn.com</u> and create a profile. Use this page to develop an identity for the trial among the LinkedIn community.

Create an organizational profile and then posting information regarding the trial.

Paid Advertising

Go to LinkedIn Ads <u>www.LinkedIn.com/ads</u> and select 'Get started.' This presents the four step process to create a LinkedIn ad.

1. Fill out information to set up the advertising campaign.

There are six sections that need to be completed.

- Campaign Name Create a name for the campaign.
- Ad Language Select the language for the ad.
- Media Type Select either a basic ad or video ad.
- Ad Destination Link ad to either a LinkedIn profile page or an external URL. When driving traffic to the website, tag URLs to measure the engagement and quality of traffic.
- Ad Design Create a headline and a description.
- Ad Variations Create multiple variations of ads. For each ad, select either an external URL or a page on LinkedIn.



- 2. Target the audience by:
 - Job Title
 - Employer
 - Industry
 - Skills/Interests

LinkedIn advertising has the ability to turn on 'Lead Collection'. This feature allows users who engage with the ad to send contact info and give permission to be contacted.

3. Establish a budget for advertising.

LinkedIn offers two basic pricing models:

- Cost per click (CPC)
- Cost per 1,000 impressions (CPI)

Use the option that will have the greatest impact on driving audience traffic to the website.

4. Submit the ad by clicking on 'Launch Campaign'.

LinkedIn reviews almost all ads manually, so the campaign will not appear online until it goes through a quick review process.

Find out more information on LinkedIn basics and advertising at <u>www.LinkedIn.com/ads</u>.

LinkedIn Sample

xyzClinic	xyzClinic shared: Sponsored	Follow		
	A staggering 1.5 million new cases of cancer are expected to be diagnosed in 2015. You can help to reduce this number by joining any of our clinical trials on cancer prevention.			
	B	Cancer prevention, what does it mean? Your good health could pay off, learn how. xyzClinic.com - How can you help? Bring your colleagues, family, and friends to join a cancer prevention trial.		
	Like • Share			

Be sure to understand audience size. Impressions or metrics are different from other networks.

If it is determined the audience size is getting too small, use LinkedIn's suggested options to recommend audiences based on similar keywords in the ad. 1

Moderating LinkedIn Accounts

LinkedIn has the option to block users interactioin with the site and delete comments from the LinkedIn page.

To block a user on LinkedIn:

- 1. Navigate to the users profile and click the drop-down menu next to the button in the top section of the member's profile (this button may have different names depending on the account type).
- 2. Select 'Block' or 'Report' next to the users name and click 'Continue'.
- 3. Click 'Agree' to confirm it

To delete a comment:

- 1. Click the 'Discussion Title' to view the full discussion.
- 2. Click the 'Delete' link under the member's comment.

For more information visit <u>www.help.linkedin.com/app/home</u>.

Low Cost, High Impressions Targeted Web Advertising





Before committing to a medium and a strategy, test your ads in several short and low cost campaigns.

Action

• Disseminate messages through online advertising options such as search engine platforms and ad exchange and networks. Web advertisers can better target an audience by setting filters such as demographics, psychographics, and behavioral variables.

Cost

• A few cents to \$50/engagement (i.e., click and impression)

Reach

• Targeted audience: filtered by search term, demographics, interest, and location.

Preferred Target Audience

• Millennials, Gen X

Advantages

- Pay only for results (clicks or view).
- Immediate visibility, as ads are posted immediately.
- Real-time management of ads. Ads can be easily modified and immediately deleted depending on the results.
- Geo-targeting, the ability to select where ads are shown to better reach target audiences.
- Boost traffic to trial website and screener (if applicable).

Disadvantages

- Competition for specific keywords drives the cost of search term(s) up and lowers ad visibility.
- Risk of non-target abusers clicking on ad for the sole purpose of depleting your budget.
- Some search engine marketing tools limit the number of characters.

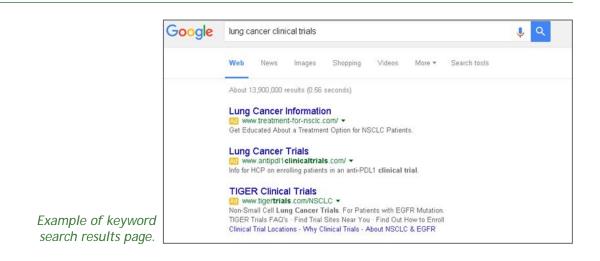
Placement

- Online advertising offers multiple platform options including:
 - Social media (see Social Media section)
 - Search engines
 - Ad display networks and exchanges



Low Cost, High Impressions Targeted Web Advertising

 Google AdWords, Bing Ads, and Yahoo Gemini are the most popular search engine advertising programs. These programs are used to ensure sponsored websites, webpages, and products appear at the top of search results when certain keywords are typed in the search bar.



• The placement process involves selecting keywords so the ads appear alongside search results relating to those terms and deciding on a maximum Cost-Per-Click (CPC). The maximum CPC is the maximum amount one is willing to pay for each click on the sponsored link. Keep in mind that competitive keywords require a higher maximum CPC.

Display Advertising

 Another advertising option is to place ads through a display ad network composed of a variety of website and blog partners (e.g., Google Display Network), or an ad exchange, a virtual marketplace where advertisers and publishers buy and sell advertising space (e.g., Rubicon Project). Networks usually charge a Cost-Per-Impression (CPI) fee, which is a flat fee for every thousand views of the ad.



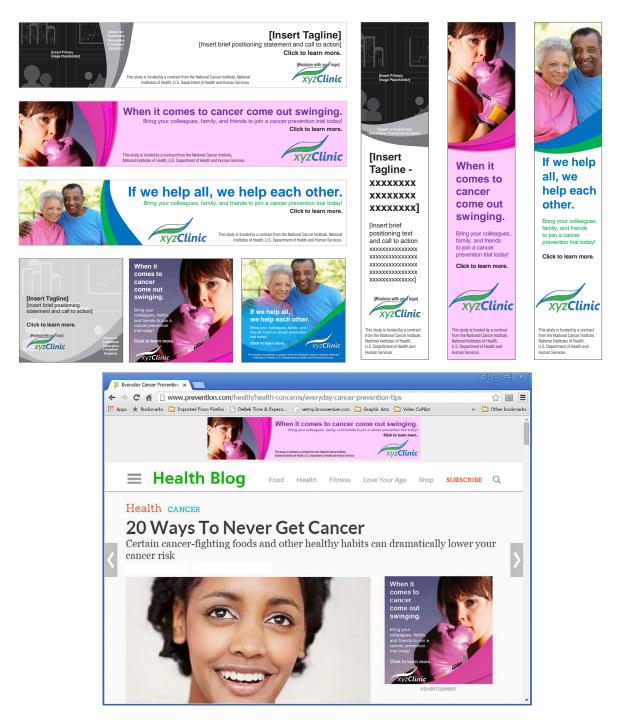
- Display advertising is used to create and place different types of ads including:
 - **Banner Ads:** Type of ads that use pictures, logos, videos, animations, and other types of graphics. Usually placed in the top, side, and bottom sections of webpages.
 - **Retargeting Ads:** Type of banner ads that involves attaching a cookie to users visiting the trial site. When the users visit other websites, the ad appears as a banner ad on these other sites.
 - Mobile Ads: Web ads that appear on smartphones, tablets, and other mobile devices.
- Samples of types of display advertising formats are provided as part of this Toolkit.
- Before committing to a medium and a strategy, the ads should be tested in several short and low cost campaigns.

Before placing any ad online, consider the Internet habits of the target population⁴⁰ as shown below. For example, over 80% of Millennials use social networks.

	Millennials (Born after 1980)	Gen X (Born 1965-1980)	Younger Boomers (Born 1955-1964)	Older Boomers (Born 1946-1954)	Silent Generation (Born 1928-1945)
Email					
Search					
Health Info					
Social Networks					
Watch Videos					
Get News					
Listen to Music					
Legend 20-2	29% 30-39%	40-49% 50-59	% <mark>60-69%</mark> 7	0-79% 80- 89%	90-100%



Web Ad Templates and Samples (Banner, Skyscraper, and Square)



Low Cost, Low Impressions Clinical Trial Listing Websites



Visitors to clinical trial listing sites are specifically seeking information about clinical trials.

In addition, posting information on clinical trials to these sites increases credibility and branding.

Action

• Add a listing at no cost on clinical trial listing databases and websites such as ResearchMatch, the Army of Women current research database, and other organ-specific registries.

Cost

Staff resources

Reach

Audience limited to site users

Preferred Target Audience

• Millennials, Gen X, Boomers

Advantages

- Low cost and low maintenance.
- Great source of individuals seeking clinical trial participation.
- Listings present trial information in a clear and understandable format to users.

Disadvantages

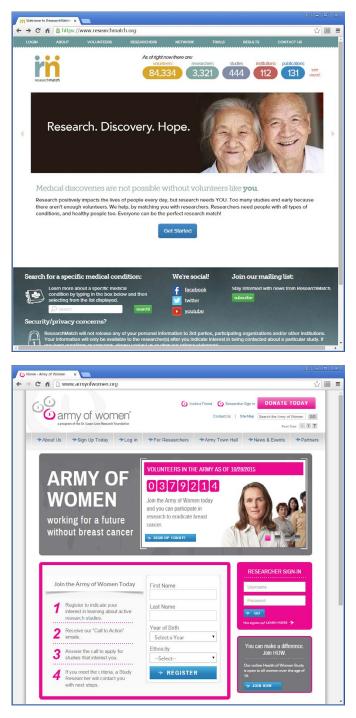
- Low visibility of listings.
- Narrow traffic to populations who already know about clinical trials.
- Direct competition with listings from other sites.

Placement

• Register the trial with various trial listing websites by creating an account on the clinical trial listing website and registering the trial; editing records during the trial, and submitting results to the trial website.



Examples of Some Clinical Trial Listing Websites



Low Cost, Low Impressions Newsletter



Action

 Publish information about studies through print and/or electronic newsletters. A newsletter is issued periodically to the members of a business, organization, or other support group. Contact patient associations and advocacy groups, local communities, doctors' offices, and clinical organizations regarding disseminating trial information through their newsletters.

Cost

• Staff resources to develop content. Publications with limited circulation or narrow distribution may be free or may charge a low flat fee. Newsletters with wider circulation may charge a \$25-\$250 fee per thousand subscribers for ads.

Reach

• Subscriber list of the publication

Preferred Target Audience

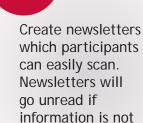
• All

Advantages

- Low cost with options available.
- Reach can be immediate.
- Benefit from the credibility and relationship the organization has established with its group.
- Ability to target certain geographic areas and specific groups.

Disadvantages

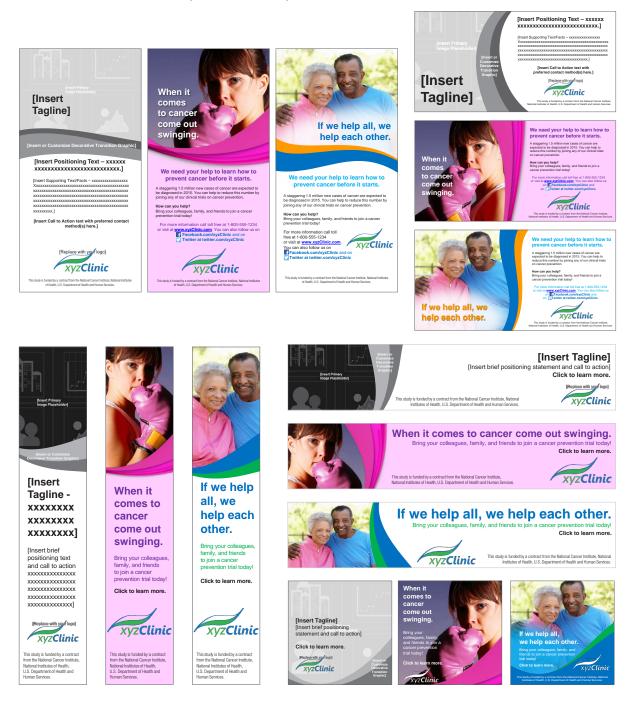
- Success of this medium depends on the quality of the subscriber list.
- Subscribers may not receive any e-newsletter as it may be filtered or rejected by the recipient's email provider.
- Content must be concise.
- Print newsletters have a short shelf life.



clearly presented.



Print Ad and Web Ad Template and Samples



High Cost, High Impressions Clinical Trial Video



Trial videos contain in-depth trial information to inform audiences about clinical trials and convince potential participants to enroll.

In addition, well produced trial videos tend to be circulated online. This is highly effective on younger generations like Millennials who prefer information in digital formats.

Action

 Create a YouTube video interview showcasing a Question and Answer session with the Principal Investigator or Study Coordinator. Distribute the video via email and social media.

Cost

• Staff resources; \$5,000 to \$10,000 production costs

Reach

• Database contacts, YouTube audience (mainly Millennials, Gen X, and younger Boomers), and general audience of other social media channels.

Preferred Target Audience

• Millennials, Gen X, Boomers

Advantages

- Builds trust in the trial, PI, and Study Coordinator.
- Provides in-depth information.
- Addresses the most common questions/concerns.
- Can be easily accessed, paused, replayed, and shared.

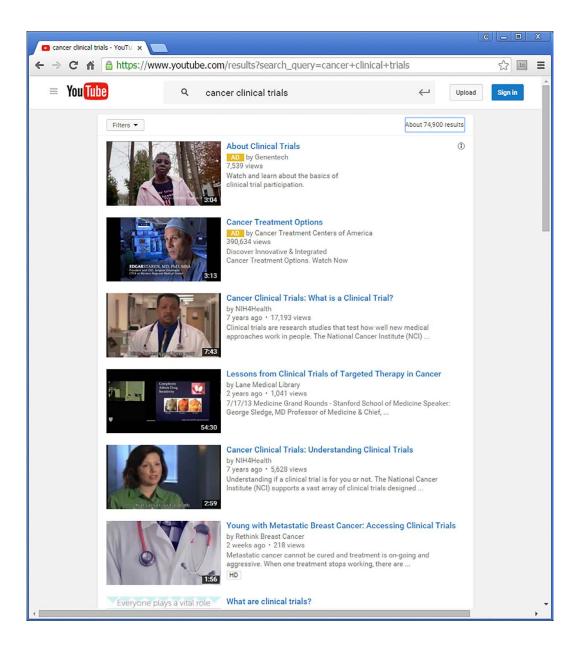
Disadvantages

- Requires script development, equipment, and editing software.
- Production cost and production quality can vary greatly.





Examples of YouTube Video Search Results



High Cost, High Impressions Magazine



Magazines have targeted audiences allowing sites to create focused ads. For example, an ad placement in Time magazine is designed to target Boomers and Gen X audiences. Requesting specific placement or increasing frequency will improve the impact of the ads and retention of the message.

For lower cost ad

placement, check with magazines for digital advertising options.

Action

• Place an ad in a regional or national magazine. Select a magazine based on the target audience. Examples of magazines that could fit the audience include health and lifestyles, gender-focused, or hobby and interest magazines (e.g., home, garden, pets, music).

Cost

• \$500 to \$20,000+ production and placement costs

Reach

• Readership of targeted audience

Preferred Target Audience

• Boomers, Silent Generation

Advantages

- Wide reach and ability to target a certain audience
- High print quality
- Long shelf life
- Flexibility in deciding the ad size and placement within the publication
- Pass-on and loyal readership (maximizes the chances of repeat exposure)

Disadvantages

- Ad space can be expensive and competitive.
- Cost impacts flexibility in terms of ad placement and format.
- Long lead times for publication. Magazines often require ads to be submitted weeks or months in advance.
- Limited geographic targeting.



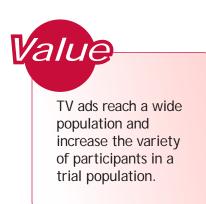
Placement

- Ads are sold as a full page or fraction of a page. The size of the ad influences pricing, but also drives the impact it will have on readers. Magazines generally have preferred rates for clients who commit to run ads multiple times. Another cost factor is the number of colors used in an artwork (e.g., four-color ads are more expensive than two-color ads). Preferred placement that will make an ad more visible include:
 - Inside the front or back covers
 - Close to the front of the magazine
 - Near the table of contents
 - Next to editorial content
- Preferred placements usually come at an extra cost and are subject to publication guidelines. To maximize exposure and credibility, it is recommended to run the same ad repeatedly over a short period of time and place the ad in a consistent position.

Print Ad Template and Samples



High Cost, High Impressions Television (TV)



Action

Create a TV ad using the sample script available in this AQuIP Toolkit. TV is the most expensive medium but also the platform that ensures the most coverage. Based on the target audience, select the TV category (cable, network, web, local) and associated station or related programs during which it should air.

Cost

 Staff resources; script development; production and placement costs for prime time 30-second TV spots range from \$5,000 to \$200,000.

Reach

• Wide reach. Targeting possible based on selection of channel, program, and time slot.

Preferred Target Audience

• Gen X, Boomers, Silent Generation; Millennials for Streaming TV

Advantages

- Reaches a wide audience on a national or regional level in a short period of time.
- Independent stations and cable offer opportunities to target local audiences.
- Ability to convey messages with audio and visually with images and motion.

Disadvantages

- High cost
- Preferred ad times are often sold out far in advance
- Limited length of ad exposure
- Labor intensive; requires equipment and software for production

Placement

 TV ads are usually between 15- and 60-seconds in length. Ads designed to air in local markets are much more affordable and production agencies are experienced in working with a variety of budgets. Broadcast the ad on national networks, local broadcast TV stations, or cable networks. Most cable networks sell local advertising on the paid cable networks at a lower rate (e.g., ESPN, CNN, Lifetime, and Discovery); however, consider that a smaller portion of the population has access to cable TV.



Steps include:

- Identifying the audience
- Selecting a station
- Producing the ad
- Selecting the time the ad will air and in relation to which program

Video Advertisement Script Template

The video template is comprised of three sections: video, audio, and notes. The video section labels the scene, length of time for the scene, and a description of the scene. The audio section includes music/sound effects, dialogue, and speakers. The notes section includes any extra instructions regarding the script. Use the abbreviations below the script template where applicable

Video	Audio	Notes
SCENE A (:00-1:00)	Music: [Insert Sounds]	[Insert any extra instructions here.]
Scene A Description	Dialogue: [Insert Tagline] and/or [Insert Fact].	
	Dialogue: We are seeking [Insert Popula- tion Criteria], to participate in any of our [Insert Trial].	
	Dialogue: [Insert Additional Promotional Information].	
	Dialogue: [Insert Call to Action]! [Insert Phone] or visit [Insert Web Link].	

Some abbreviations for video scripts can include:

- VO: Voice Over
- FX: Effect
- CG: Computer Graphic
- NAT SOUND: Natural Sound
- CU/MCU: Close -up/Medium Close-Up
- WS/MWS: Wide Shot/Medium Wide Shot



Video Advertisement Script Sample

Video	Audio	Notes
OPENING (:00-1:00) Scene opens at a restaurant with a couple and a waiter picking up the check.	Man: Alright, love you. I'm heading over to the doctor's office.	
ploking up the oncok.	Woman: Oh, I didn't know you had an appointment? Everything okay?	Woman displays a concerned look
Action: man gives copy of bi-fold pamphlet to woman	Man: Everything's fine. I'm just going over to look into that clinical trial I mentioned the other day.	
	Woman: Oh, right. It's on cancer prevention?	Woman displays look of relief
	Man: Yeah. After my Dad's scare, I wanted to see what I can do to help. And from what I read, this trial is a great way.	
Action: Man and woman stand up and leave the restaurant	Woman: I have some time this afternoon, could I come with you?	
	Man: Definitely! They're looking for all kinds of people.	Man is enthusiastic
Contact information shows on screen	Narrator/VO: If you are interested in learning more about cancer prevention trials in your area, contact the xyzClinic at 1-800-555-1234 or visit us online at xyzclinic.com.	Narrator (Female): Speaks in encouraging voice
	Why wait? You can Make a Difference. Help Prevent Cancer Now.	

High Cost, Low Impressions Newspaper



Δ

Newspaper ads have the flexibility of targeting local or national audiences. In addition, sites can advertise in digital newspapers to geo-target Millennials and Gen X, or in printed newspapers to engage Boomers and the Silent Generation.



This medium allows for good audience selectivity. It is especially efficient when recruiting individuals from the Silent Generation. Metro newspapers can also be an effective approach to recruiting other generations.



Action

• Place an ad in a local or regional newspaper. Some advantages of include geographic selectivity, reach, cost, timeliness, and audience interest. However, since newspaper ads have a short shelf life, to be effective, multiple rounds of advertising may be necessary.

Cost

• \$100 to \$20,000+

Reach

• Readership of targeted audience

Preferred Target Audience

Silent Generation

Advantages

- Wide reach and ability to target a certain geographic area.
- Flexibility in deciding the ad size and placement within the newspaper.

Disadvantages

- Ad space can be expensive and competitive.
- Cost impacts flexibility in terms of ad placement and format.
- Short shelf life, as newspapers are usually read once and then recycled.
- Declining readership and market penetration.
- Lower print quality than other print options.
- Limited targeting.

Placement

- Request section placements consistent with the target audience's profile, habits, and demographics. Preferred placement that will provide the ad with additional visibility include:
 - Bottom right-hand corner of the right-facing page so readers receive a long impression before flipping the page.
 - Next to an article instead of surrounded by other ads.
 - On the back page especially if paper is folded so that back page appears prominently when held by reader.



• Newspapers usually charge an extra fee for guaranteed or preferred placement, but these benefits may be provided at no cost to attract new advertisers or as added value for regular advertisers. To maximize exposure and credibility, it is recommended to run the same ad repeatedly over a short period of time and place the ad in a consistent position.

Print Ad Template and Samples



VII. Creating an Ad

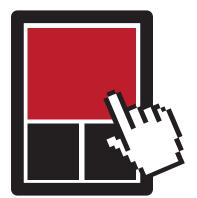
Clinical trials ads and informational materials need to be written in a convincing and appealing style while still ensuring compliance with regulations and facilitating IRB and NCI DCP approval.

Consider the following 10 best practices when writing messages and formatting materials:

1. Brand the trial.

Select a color scheme, a typeface, and an imagery to be used consistently across platforms and materials. Refer to the Trial Branding section of this Toolkit for more information.

- Create a key message. Follow the 1-1-1 rule: include at the minimum one tagline, one positioning statement, and one call to action in each material.
- 3. Use powerful action verbs throughout material to motivate participants such as fight, contribute, prevent, join, and unite. The tone of the content should be positive and aspirational.
- Use bold and different text sizes to guide the readers through the content.
 Do not bold or emphasize trial compensation.
- 5. Write in a participant-friendly style. Reword and simplify any technical and scientific language as possible.
- 6. Create a positive impact and avoid having too many visual cues by including only one large primary graphic per ad. This is in addition to the clinical organization's brand identity graphics. Visuals can be selected from the Image Library.
- 7. Do not overload ad information or potential participants may not read it through.
- 8. Include contact information (e.g., phone number, email, website, and social media information) or directions on how participants can learn more about the trial.
- 9. Include the logo of the research organization.
- 10. Follow the IRB and NCI OCPL writing rules.



Taglines and call to actions may change depending on the platform used to disseminate the materials. Posting on social media may require shorter messages.

Ready-to-use taglines are provided in the Key Messages for Use in Toolkit Layouts section (page 118). If creating a new tagline, keep it to a few words for maximum impact. For materials that allow for more details such as a brochure, also add some positioning facts and/or statistics.



AQuIP Toolkit Image Library Use and Licensing Requirements

If images are used from the AQuIP Toolkit Image Library the following text MUST appear on the finished piece to ensure proper licensing and copyrights are followed:

"This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services."



Templates contain guidelines on the recommended number of lines per ad format. Use bullet points for brevity when necessary (e.g., eligibility criteria).

Language Requirements

Advertising translation is not a word-for-word process. The meaning, feeling, and mood an ad is trying to convey can easily be sidetracked during the translation process. Expertise in languages and cultures is often needed to accurately translate intended messages. If translated materials are required:

- Check with the clinical institution about standard translation practices.
- Contact a linguist student or professional at the university.
- Contact the DCP Help Desk for additional assistance on how to develop translated documents.

Toolkit Templates

To maximize compatibility, templates are provided in Microsoft Office (Word or PowerPoint) format. When ready for publication, the finished piece can be saved or exported to a variety of other file formats (e.g., PDF, JPEG, PNG) for distribution. Consult with your media or vendor contact for more details.

Layout Formatting Tips:

- Content placeholders are marked in brackets []. Click into an element to edit text, images, or shapes.
- Pictures (images and graphics) can be placed by selecting 'Pictures' from the 'Insert' menu tab on the top ribbon. Using the Insert or replaced by right clicking on an image and selecting 'Change Picture'.
- The contour of shapes can be edited by right clicking on a shape and selecting 'Edit Points'.
- Use decorative images to provide additional visual interest and cover the edges of inserted photos, as needed.
- Align content within even balanced page margins.
- Don't put text or the key subject of images too close to the edge of the layout.
- Use fonts that are consistent with the organization's existing literature. Don't use more than one font for headlines and one font for body text.
- Balance the size with the amount of text on the layout, and periodically print or view the layout at actual size to get a sense of readability, and adjust and/or reduce the font size as needed.

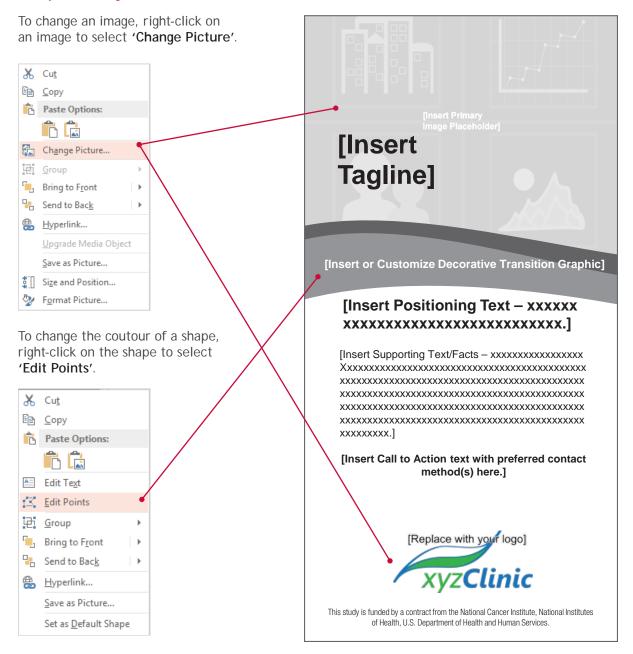
Image Library

Included in the Toolkit is an image library of DCP selected images available for download at <u>www.dcpquip.com</u>. If you use any of these images in your final piece the following text MUST appear on the finished piece to ensure proper licensing and copyrights are followed:

"This study is funded by a contract from the National Cancer Institute, National Institutes of Health, U.S. Department of Health and Human Services."

If this statement is not included, the LAO or AO using images from the image library is putting themselves at risk of violating licensing agreements which can result in fines and litigation.

Sample Ad Layout





Customize the key message to best suit the target audience.

The AQuIP Toolkit provides a wide variety of building blocks to creating great key messages.

Sites should customize the examples presented and create new key messages as needed to address the characteristics of the target audience.

All messages must adhere to the rules and guidelines set by the FDA and the IRB (See Obtaining Approval of Recruitment Materials on page 121).

Key Messages for Use in Toolkit Layouts

Key Message

The key message used in clinical trial advertising includes a tagline, a positioning statement, and a call to action statement. If the advertisement contains visuals, the key message should complement the visuals with correct language and vice versa. Use the provided list of taglines, positioning statements, and call to actions or develop new key messages for clinical trial advertising.

Taglines

Taglines capture the audience's interest and are the first point of engagement to attract attention. Choose appropriate positioning statements and call to action phrases based on which fit best.

If the clinical site chooses to develop a tagline not included in this list, we suggest generating taglines around a central approach or theme which will connect with the audience. For example, if the theme of the advertisement is emotion, the tagline should capture the audience's attention with a phrase designed to cause an emotional reaction. Sample themes include: emotions, altruism, community, and window of opportunity.

Theme: Emotions

- Is cancer targeting you?
- If we help all, we help each other
- Put your emotion into action
- How does cancer affect you?
- · Cancer prevention, what does it mean?
- Do it for your grandchildren
- Do it for your children
- Cancer. How can you help?
- Research is the start of a healthier life

Theme: Altruism

- Prevention saves lives
- You could be doing something
- Help your community
- Benefit your kids
- Help future generations
- Real people exploring real possibilities
- The journey to wellness begins with you
- Pave the road to wellness
- Express your love of life for future generations
- Your good health could pay off, learn how
- Sick of cancer, we need you
- Make a difference
- Join the fight
- Fight to prevent
- The more we know, the farther we'll go
- We can't do it alone, we need you

- Give the gift of hope
- Do you want to help? It can be easy!
- Stop cancer before it begins

Theme: Community

- Participate to prevent
- Cancer prevention works
- Good intentions lead to cancer prevention
- United we can succeed
- Come out fighting
- The average person makes a difference
- You can be a hero
- Let's work together
- Knock out cancer
- Knock out [Insert Organ] cancer
- Tell your friends

Theme: Window of Opportunity

- Life is a gift, don't let time pass you by
- Understand cancer risk factors
- Equip yourself with cancer prevention knowledge
- Screen out cancer
- Act now
- Time to participate

Positioning Statements

The positioning statement explains information regarding the Site and the purpose of the clinical trial. Combine the positioning statement with a supporting fact or statistic to link the positioning statement to the purpose of the trial and strengthen the overall key message.

- [Insert LAO/AO Name] is a research site exploring new methods of cancer prevention and we need you to participate.
- [Insert LAO/AO Name] is investigating new cancer prevention methods through a clinical trial. We are calling on you to join our community.
- [Insert LAO/AO Name] is calling on you to prevent cancer now.
- To those who want to be part of something bigger, join a cancer prevention trial at [Insert LAO/AO Name] today.
- [Insert LAO/AO Name] is conducting a cancer prevention trial in your area.
- [Insert LAO/AO Name] is conducting a cancer prevention trial in [Insert Location] and is in need of participants.
- We at [Insert LAO/AO Name] need you to participate in a cancer prevention clinical trial today.
- Find out more about [Insert Organ] cancer prevention with [Insert LAO/AO Name].

Call to Action Statements

The call to action statement directs the audience on how to become involved. Keep this phrase short and direct. The call to action statement is routinely placed at the end of the key message and close to any contact information. In this way, the audience understands how to obtain more information. Sample call to action statements include:

- Learn more about cancer prevention with [Insert LAO/AO Name]
- Join now
- Act now
- Sign up now
- Prevent cancer now
- Volunteer now
- Let's work together
- Enroll now
- Learn more about [Insert Organ] cancer prevention

Supporting Facts/Statistics^{42,43,44}

Supporting facts and statistics can be combined with the positioning statement to strengthen the message. Please note all statistics (provided below) are from 2015 and should be verified for relevancy before use.

- Risk factors for cancer include age, alcohol consumption, diet, hormones, obesity, radiation exposure, sunlight, and tobacco.
- In the U.S., the lifetime risk of developing cancer is higher in men (slightly less than 1 in 2) than for women (a little more than 1 in 3).
- 1,658,370 new cancer cases are expected to be diagnosed in 2015.
- In 2015, about 589,430 Americans are expected to die of cancer, or about 1,620 people per day.
- Cancer is the second most common cause of death in the U.S., exceeded only by heart disease, and accounts for nearly 1 of every 4 deaths.
- There are more than 100 types of cancers; any part of the body can be affected.
- Tobacco use is the single largest preventable cause of cancer in the world, causing 22% of cancer deaths.
- Anyone can develop cancer, however, the risk of getting it increases with age. Most cases occur in middle-aged adults or older. About 77% of all cancers are diagnosed in people age 55 or older.

- In 2007, there were an estimated 12 million new cancer cases and 7.6 million cancer deaths globally. By 2050, the global cancer burden is expected to grow to 27 million new cancer cases (an increase of 55.56%) and 17.5 million cancer deaths per year (an increase of 56.57) globally.
- Tobacco use increases the risk of cancers of the lung, mouth, larynx, pharynx, esophagus, stomach, colon/rectum, liver, pancreas, kidney, bladder, uterus/cervix, and ovary (mucinous), as well as myeloid leukemia.
- Thirty percent of all cancer deaths and about 80% of lung cancer deaths can be attributed to tobacco use.
- Each year, smoking results in an estimated 480,000 premature deaths, and about one-third of these premature deaths are due to cancer.
- Tobacco use killed 100 million people in the 20th century and will kill 1 billion people in the 21st century if current trends continue.
- Health and cancer disparities predominantly arise from inequities in work, wealth, education, housing, and overall standard of living, as well as social barriers to high-quality cancer prevention, early detection, and treatment services.
- Hispanics have the lowest rates of tobacco-related cancers, such as the lung and oral cavity, because of historically low smoking prevalence, but among the highest rates for cancers associated with infection, such as liver, stomach, and uterus/cervix.
- Asian and Pacific Islanders (APIs) have the lowest overall cancer incidence and mortality rates.
- Disparities in the cancer burden among racial and ethnic minorities largely reflect obstacles to receiving health care services related to cancer prevention, early detection, and high-quality treatment, with poverty as the overriding factor.
- ClinicalTrials.gov currently lists 195,352 trials with locations in all 50 states and in 190 countries.
- Clinical trials have increased every year; 195,352 total trials in 2015 compared to 5,635 in 2000.

VIII. Obtaining Approval of Recruitment Materials

To ensure human subject protection, any item used to recruit and directly contact participants for enrollment in clinical trials must be reviewed by the NCI DCP and an IRB. In addition to reviewing the content of the materials, the IRB and DCP also examine any associated graphics and visual effects. Materials should be submitted or reviewed in their final format.

Materials Requiring Review

To ensure human subject protection, submit materials designed to recruit participants to NCI DCP for review. In addition, FDA considers advertising to be part of the informed consent process and therefore requires IRB review to approve methods and all materials used in recruiting participants. Specific recruitment materials include emails, letters, flyers, posters, brochures, written and verbal scripts, informational sheets, videos, websites, media ads such as social media, newspapers, magazines, or radio ads.

Materials Not Requiring Review

Approval is not required in the following instances:

- Clinical listing (e.g., clinicaltrials.gov, National Cancer Institute's cancer trial listing PDQ, the AIDS Clinical Trial Information System ACTIS) that contains only basic information about the trial such as: title, purpose, protocol summary, eligibility criteria, trial sites, and contact information of the investigator.
- Materials sent to health care providers that are not distributed or seen by potential participants (e.g., "Dear Doctor" letters.)
- Public service announcements or news stories where the intent is not to recruit participants for an individual trial.

Suggested Elements to be Included

All materials need to contain some critical yet basic information that will attract potential participants, as well as general information that conveys the call to action and how to contact sites to get additional details on the trial.

- The word "research"
- Logo of the research institution
- Purpose of the project
- Contact information
- Eligibility criteria
- Time commitment
- · Location where the trial will take place
- IRB numbers

Elements to be Excluded

It is also required that ads developed:

- Are not unduly coercive.
- Are not misleading.
- Do not promise health benefits beyond what is outlined in the protocol.
- Do not imply the trial product/intervention is safe or effective.
- Do not claim the trial product/intervention is known to be equivalent or superior to any other drug, biologic, or device.
- Do not communicate the trial product/intervention was approved by regulatory authorities.
- Do not emphasize the compensation/payment to be given to participants. The payment amount may be included but it should not be bolded, enlarged, or emphasized in any way.
- Do not use the term "free" in reference to trial product/ intervention or procedures.
- Do not use the term "new treatment," "new medication," or "new drug" in reference to a drug or device without explaining the trial product/intervention is investigational.
- Do not use materials that include catchy words, like "exciting opportunity."

IX. Glossary

AQuIP Toolkit: The Accrual Quality Improvement Program Toolkit highlights general methodology to recruit participants into a clinical trial.

Audience: A group of potential participants who can be reached through trial advertising.

Baby Boomers (Boomers): A section of the population born during 1946 to 1964.

Branding: The process of creating a unique image in potential participants' minds for clinical research, mainly through advertising campaigns with a consistent theme.

Call to Action: The third section of the key message explaining how the audience should act upon seeing an advertisement.

Cost per click (CPC): An online ad price model where a flat fee is charged for each click on the ad.

Cost per impression (CPI): an online ad price model where a flat fee is charged for each thousand views of the ad.

Federal Communications Commission (FCC): An independent agency of the U.S. Government to regulate interstate communications by radio, television, wire, satellite, and cable.

Flights: A scheduling method for radio ads which guarantees broadcast at a specified time.

Food and Drug Administration (FDA): A federal agency of the U.S. Department of Health and Human Services responsible for protecting and promoting public health.

Frequency: Average number of times an individual is exposed to an advertising message delivered through that media, or the number of times an advertisement is repeated through a specific medium over a specific time period.

Generation Z (Gen Z): A subset of the population including individuals born after 1996.

Generation X (Gen X): A section of the population born during 1965 to 1980.

Tagline: The first section of the key message of an advertisement designed to gain an audience's attention.

Image Library: A collection of approved images to be used with clinical trial advertisements. The images can be located on <u>www.dcpaquip.com</u>.

Impressions: Number of times the advertisement is displayed/ loaded on a particular media (Media = Reach x Frequency). The greater the number of impressions, the more likely the audience is to react to the advertisement.

Institutional Review Board (IRB): A committee established to review and approve outreach/research methods involving human subjects. IRB's ensure all outreach methods are in accordance with Federal, institutional, and technical guidelines.

Key Message: Text used in participant recruitment advertising. The key message is composed of the tagline, positioning statement, supporting information, and call to action of the media.

Media Magic Quadrant: A comparative representation of potential cost/impression for different media and advertising methods. Use the media magic quadrant to select the proper avenue for advertising campaigns and estimate advertising budgets.

Millennials: A section of the population born during 1980 to the early 2000's.

National Cancer Institute (NCI): An U.S. Government Federal agency under the National Institutes of Health responsible for conducting research, training, and health information dissemination for activities related to the causes, prevention, diagnosis, and treatment of cancer.

National Institutes of Health (NIH): An U.S. Government Federal agency of the U.S. Department of Health and Human Services responsible for biomedical and health related research.

Positioning Statement: The second section of the key message expanding on the concept of the tagline and tying subject of the ad and the supporting text.

Reach: The total number of individuals exposed to an advertising message through a certain media over a period of time.

Recruitment Materials: Any outreach materials including but not limited to email, letters, flyers, posters, brochures, written and verbal scripts, informational sheets, and media ads such as social media, newspaper, radio, and video ads.

Run of Station: A scheduling method for radio ads which are lower priced with a broad window of air time.

Search Engine Optimization (SEO): The process of affecting the visibility of a website in a search engine's results.

Silent Generation: A section of the population born during 1928 to 1945.

Social Media: Social media is a group of Internet-based applications and websites that allow people to create, share or exchange information, ideas, and pictures/videos in virtual communities and networks.

Supporting Text: Additional information, statistics, and/or facts

included in an ad to motivate the reader to take action.

Tagline: The first section of the key message which is the first point of engagement to attract attention. Taglines should capture the audience's interest.

Targeting: A method of outreach designed to locate a specific audience of the general population.

Template: An example of a certain media/advertisement without key messages or images.

X. References

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