

AccrualNet™

Protocol Accrual Lifecycle Checklist and Guide



This document provides an easy-to-use, printable PDF guide to the AccrualNet™ Protocol Accrual Lifecycle. Our visual “wheel” design is meant to encourage you to think about accrual at every stage of a clinical trial—from developing a protocol through retaining participants and examining lessons learned. The Table of Contents can also be used as a handy checklist of important accrual issues.

To get even more out of this document, visit the AccrualNet™ website at accrualnet.cancer.gov. AccrualNet™ is NCI’s online resource for clinical trials professionals, providing a growing collection of resources, training materials, tools, and accrual best practices. There, you will find evidence-based peer-reviewed journal articles and practical tools from the field that will support your work at every stage of the Protocol Accrual Lifecycle.

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INTRODUCTION TO THE PROTOCOL ACCRUAL LIFECYCLE

Most clinical trials follow a sequence—from developing a protocol through recruiting participants to closing the trial and analyzing the results, as shown in the image to the right. We think of this as the protocol's life cycle. At every stage of the lifecycle, accrual matters.



AccrualNet™ can help by providing accrual strategies for you to consider at each stage, and carefully selected resources and tools for you to use. The following sections describe each stage and its accompanying strategies in more detail.

A. Developing a Trial

Successful clinical trial accrual begins at the protocol writing stage. The earlier in the trial's lifecycle that you plan for accrual, the more likely the trial is to recruit.

B. Selecting & Preparing to Open a Trial

“Should this clinical trial be opened at my site?” This is an important question and the answer isn't always “Yes!”

C. Recruiting and Communicating with Participants

The trial is open for enrollment. Now what? You should be finding, meeting, and establishing relationships with participants. But how?

D. Implementing the Trial

Managing recruitment and retention is a vital component of overall trial management. As recruitment, enrollment, and retention activities are underway, the trial team must keep communications and logistics running smoothly. A Recruitment and Retention Plan can help.

E. Evaluating Accrual and Reporting Lessons Learned

The closing of a trial is a time to take stock—to understand both what went well and what did not. Use the lessons learned to build the knowledge and capacity of your team and to strengthen future recruitment efforts.

A. DEVELOPING A TRIAL

Successful clinical trial accrual begins at the protocol writing stage. The earlier in the trial's lifecycle that you plan for accrual, the more likely the trial is to recruit enough participants to answer its scientific questions. Many clinical trials close without accruing a single participant.

Beyond the scientific merit of a proposed clinical trial, protocol developers should think carefully about how the field as well as potential participants might receive the trial.

In developing a protocol, consider competing trials, the availability of the study population, and ways to reduce the study burden on sites and participants.



Overview of Strategies

1. Consider national and local stakeholder enthusiasm for the trial

Take a realistic look at the state of the science on this topic. How much interest do you expect to find for your trial among your colleagues, institutional leadership, and researchers across the country?

2. Evaluate the trial for recruitment feasibility

In order for a trial to be “recruitable,” study sites must see enough potential participants who meet the eligibility criteria (e.g., who have a particular type and stage of cancer or relevant biomarker). Trials have failed because no one checked this.

3. Choose study sites carefully

In recruitment, a site’s past performance can predict future success. A strong recruitment history suggests that a site's staff is experienced with clinical research and that they know the patient population, how to reach them, and how to select trials that fit the site’s strengths.

4. Prepare trial-specific materials

People who feel familiar and comfortable with the concept of a clinical trial are more open to being part of one. Try to see your material as a participant would. Always keep trial-specific materials participant friendly, culturally appropriate and balanced when describing the costs, benefits, and goals of the trial.

1. Consider National and Local Stakeholder Enthusiasm for the Trial

Evaluate the level of scientific interest in the trial from the field and your institution

Does interest in the protocol vary if it is for a community or academic setting? Discuss your idea at your home institution and use what you learn from conferences, journals, and online communities to form an opinion about the level of scientific interest.

Evaluate the level of commitment from the field and your institution with an eye toward trial feasibility

Even when investigators are enthusiastic about the science behind a trial, you should look at other factors that may make them unable to commit—such as the lack of staff or funding, or even a participant population that differs too greatly from the needs of the trial.

Check for competing trials at your institution and nationally

What other relevant research is underway, either funded by a grant or sponsored by a pharmaceutical or biotechnology firm? Check within your institution and with other institutions to see what trials, open or planned, are related to the cancer type or study topic you are considering. Competing trials are especially problematic for research on rare types of cancer.

2. Evaluate the Trial for Recruitment Feasibility

Determine the availability of the study population at your institution and nationally

Review incidence and prevalence data nationally and in your institution's catchment area. Query your institution's data systems to determine the number of potentially eligible participants. Assess how proposed inclusion/exclusion criteria will affect recruitment. Overly restrictive eligibility criteria are a well-documented recruitment barrier. You may be able to identify criteria that can be broadened without sacrificing the outcome—such as allowing some co-morbid conditions or expanding an age requirement.

Assess and minimize the study burden on patients

View the trial through a participant's eyes. How “burdensome” is the research? Consider such questions as: “How much time away from home is required?”, “How many blood draws?”, and “What protocol costs are not covered by insurance?” Perhaps you can identify and eliminate some procedures that are not essential to the study outcome. AccrualNet™ encourages study sites to consider these questions when selecting and preparing to open a trial. So, potential sites will be thinking about participant burden, too.

Use feasibility studies to test recruitment strategies

A feasibility study compiles quantitative and qualitative data to illuminate issues that can affect recruitment. Such studies are of particular use for larger Phase III trials. They ask many of the same questions AccrualNet™ does—for example, questions about patient populations as well as the interest levels and capacity at potential study sites. Research teams use feasibility study findings to guide choices related to study design and site selection that aid the recruitment potential of the study.

3. Choose Study Sites Carefully

Evaluate the recruitment histories of potential sites

In some cases, sites are selected from a pool of potentials. This is especially true for earlier phase (phase I or II trials) clinical trials. In recruitment, a site's past performance can predict future success.

Determine the available resources of potential sites (e.g., staffing or facilities)

Ask about each site's capacity to recruit and carry out the trial. For example, you may need to discuss workspace, committed staffing, and lab and pharmacy needs. Ask the sites what study needs would cause difficulties at their site and determine if those can be overcome.

Look at the potential sites' competing trials

Ask prospective sites about existing trials that may compete with your trial for participants and resources, and how they propose to handle the situation.

Look at the sites' interest level in the trial—both scientific interest and their thoughts on feasibility

Meaningful research generates the enthusiasm and commitment among staff that helps recruitment. For example, are researchers at the site excited about the trial or are they considering opening the trial for other reasons?

4. Prepare Trial-Specific Materials

Prepare participant-friendly informed consent document

Try to see your material as a participant would. Avoid technical or legal jargon. Use active voice and personal pronouns. (Instead of “The patient may contact his or her physician at any time....,” say “You may call me any time....”). Use white space and diagrams, calendars, and simple outlines to make your document easier to read and understand.

Create trial-specific materials for participants

Items like brochures and fact sheets help participants understand the trial and talk about it with family and friends. Other materials like newsletters and buttons can be tangible tokens that show participants they are part of something meaningful. Always keep trial-specific materials participant friendly and balanced when describing the costs, benefits, and goals of the trial.

Ensure that materials are culturally appropriate

The racial and ethnic backgrounds of potential participants play an important role in the feelings, viewpoints, and communication needs they bring to their conversations with you about trials. For example, ethnically diverse populations may have issues related to trust, language barriers, and feelings about medical professionals that will impact their thinking about a trial.

B. SELECTING & PREPARING TO OPEN A TRIAL

“Should this clinical trial be opened at my site?” This is an important question and the answer isn't always "Yes!" By selecting trials you can recruit to, your site is far more likely to advance cancer research and avoid the costs of opening trials that will not accrue.

A clinical trial is more likely to succeed—and more likely to advance science—when the research team and the trial site are well-prepared to recruit and retain participants. Before your trial opens, set up smooth and successful accrual by writing a trial-specific recruitment and retention plan. Writing this plan enables you to carefully think through all the necessary activities related to accruing participants and keeping them involved.



Overview of Strategies

1. Evaluate your institution's clinical trial portfolio and participant population

Realistically assess your site's potential to recruit participants for the protocol. Does the trial fill a gap in your institution's existing portfolio? Or are other trials competing for the same participants? Think about the trial from the participant perspective—consider financial issues as well as study logistics.

2. Assess your institution's infrastructure and resources

Get feedback from key staff, evaluate the financial implications, and assess resource requirements before deciding whether to open a study. Does the protocol require specialized training of staff, testing of specimens, or new equipment? Ensure that your organization can meet the requirements or expand its capacity to perform the protocol.

3. Ensure stakeholder commitment

Scientific interest and clinical relevance are keys to generating investigator interest in a trial. A clinical 'champion' can help spread the word, generate support, and advocate for necessary resources. Listen to the opinions of the research team and front line staff—their commitment is essential to success.

4. Create a clinical trials friendly environment

Creating a 'culture of clinical trials' means that everyone—from staff to patients—knows that clinical trials are an essential part of your organization. It means that everyone in the organization, from receptionists, to billing clerks, from lab techs to managers, know their

role in the clinical trial process. It means that you talk about clinical trials to patients and you listen to their questions and address their concerns.

5. Plan internal processes to conduct the trial

Eliminate recruitment barriers by planning logistical processes and training staff. If it doesn't already exist, create a study start-up check list. Anticipate issues that are likely to come up and plan solutions early. Improve your protocol knowledge and hone your skills by role-playing the informed consent process with a colleague.

6. Write a comprehensive recruitment and retention plan

The importance of writing your plans cannot be overstated. Writing assures that you have done the thinking that will enable the trial to accrue enough participants. Written plans for recruitment and retention should give a brief background on the trial and spell out how you plan to identify potential participants. Include ways to communicate with referring physicians, community members, in-house staff, and participants. Address promotion and evaluation. Above all, tailor plans to your trial and your organization.

1. Evaluate Your Institution's Clinical Trial Portfolio and Participant Population

Confirm that the trial's scientific question is relevant and of interest to your institution

Talk with your colleagues and institutional leadership to gauge their interest. Think about whether the trial is important and salient to your organization's goals and the needs of its patient population.

Assess where the trial fits within your institution's portfolio of open trials and check for competing trials

Look at your organization's research as a whole- both basic scientific as well as clinical research. Evaluate whether the trial furthers your work in a relevant area. Also, look at all your institution's open trials and evaluate whether the proposed trial fills a gap or helps you offer patients a fuller spectrum of trials. Importantly, check for competing trials.

Verify that there are no conflicts of interest in this trial

Find out about any conflicts of interest early.

Ensure that the trial matches your patient population

Review your databases and what you know about your community. Determine whether your institution sees enough potentially eligible patients or can identify and reach sufficient numbers to meet recruiting goals in a timely way. Ask if your institution has succeeded in recruiting to similar studies in the past.

Assess the financial burden the trial will place on participants

Explore what expenses will be covered by the trial sponsor, private insurance or Medicare, and what the out-of-pocket costs will be to participants. Keep in mind that not all costs are medical (e.g., travel expenses and meals).

Determine the level of study burden on participants and their support systems

Ask your staff whether they think the burdens (e.g., blood draws, overnight stays, or unpleasant medical procedures) are within reason for your population.

2. Assess Your Institution's Infrastructure and Resources

Obtain feedback on the trial from key staff

Look at the protocol requirements through the eyes of staff who may be involved—from nurses, to research coordinators, to the pharmacy, to the lab. Share the protocol with investigators, the research team, and people from the other departments that will be involved. Ask questions to understand operational issues such as scheduling and resources.

Assess the financial burden of the trial on your institution

Spell out the costs (and benefits) of the proposed trial to your institution before opening the trial.

Assess the capacity of your institution to conduct the trial

List what the study will demand of your facility—for example, workspace, lab needs, pharmacy needs.

- Are new skills required?
- Does the protocol require new or complex internal processes or special equipment?
- Where do you see needs that may exceed capacity? What, if anything, can be done to improve or expand capacity in those cases?

Determine if you have adequate staffing levels

Be thoughtful about the staffing requirements for the new trial and how trial activities fit with current work.

3. Ensure Stakeholder Commitment

Ensure a clinical “champion”

“Champions” are clinicians who value a trial and lead the way by showing their support. The literature and experience show that trial champions have a clear and positive effect on recruitment. For example, a champion may help demonstrate the value of the trial to other clinicians, secure resources for the trial, or address recruitment and other difficulties in an ongoing way.

Ensure staff buy-in

Ask, consider, and respond to the opinions of the people who will make a trial happen. Demonstrate the trial’s relevance and meaning for research. Find ways to give ownership and allow for staff input early and throughout the trial.

Ensure buy-in from experts/specialists who are needed to implement the trial

Think broadly about all the people who make a trial work—beyond your core team. For example, inpatient or outpatient treatment nurses, laboratory staff, surgeons, radiologists, pharmacy staff, or the public relations team. As with your immediate team members, seek other experts’ and specialists’ opinions. Share your thoughts on the trial’s relevance and meaning with them as well.

Confirm buy-in at the institutional level

Each trial is part of a much bigger picture. Check that a trial you may adopt serves your institution well and that it is seen as doing so.

4. Create a Clinical Trials Friendly Environment

Integrate the importance of clinical trials into your institution's culture

Most people working in research agree that clinical trials are important. But, what does it mean to integrate such research into an institution's culture? It means that everyone- from front desk to executive staff- understands the basics of clinical trials and why they matter. Ideally, everyone would view trial-related work as central to their job—not an extra. This message should come from all corners of an institution—in what leaders say, in training offered to staff, and even in signage at your site. Why do it?

Making clinical trials central to your organization's culture: (1) shows potential participants that trials are routine, which can reduce anxiety, (2) helps staff understand how their contribution furthers progress against cancer, (3) increases enrollment in trials, and, (4) most importantly, helps advance the scientific knowledge.

Provide a comfortable physical environment for participants in trials

It may go without saying that the physical comfort of trial participants matters. But, over time even the most caring and intuitive among us can stop “seeing” the view through their eyes. Try walking through the arrival, greeting, waiting, treatment, and service areas at your institution. What do you see, hear, feel, and smell? Work with your institution to brighten rooms, reduce noise, install comfortable furniture, deal with heating or cooling, and add special touches. By seeing to their physical comfort you send participants a message that they are important to you and to the clinical trial.

Understand participants' perceptions of being part of a clinical trial

Many factors that facilitate clinical trial participation and many that create barriers are well-documented in the literature. Altruistic feelings and viewing participation in a trial as special and important are known to facilitate participation. Known barriers include fear of placebos, suspicion about research, worry about costs, or practical matters like transportation problems. Ethnically diverse populations may have specific issues related to trust and/or language barriers. The better you understand facilitators and barriers, the better you can anticipate questions and communicate with participants in helpful ways.

Establish an efficient work environment to effectively conduct clinical trials

Just as you carefully consider participants' needs you should not overlook staff needs. Review the work environment and find ways to help make daily tasks more efficient. For example, are staff members making several trips a day to a lab that could be rolled into a single trip? Are nurses trying to have sensitive telephone conversations with patients from a noisy location? Saving minutes eventually saves hours. Plus, reducing hassle quickly generates goodwill.

Discuss clinical trial options with every patient

This activity benefits you and your patients. First, presenting trial options to everyone helps ensure that all are treated equally. Second, the more potential participants who learn about

your trials, the more who may choose to enroll. And, most importantly, the more you talk about trials the more they become a normal and important part of your institution's work.

Ensure all staff members are trained in conducting clinical trials

This activity is part of integrating trials into your institution's culture. But, it is important enough to restate here. People with different roles will need different types and levels of training. By training everyone, you create a setting where staff members understand and value clinical research and know their own role in it. With training, you make it easy for staff to answer participants' and potential participants' questions (or, to direct them to the right place for answers). Keep in mind the story about the NASA janitor who was asked what he was doing at the Kennedy Space Center. His reply, "I am helping to put a man on the moon." (Source: <http://blogs.nasa.gov>)

Ensure staff is aware of your institution's available trials

Only when staff members know a particular trial exists can they take notice of potential participants. Staff should know enough about a trial to either present it effectively themselves or connect a potential participant with the right person to do so. Make it easy for staff to know about your trials. Institutions use varied approaches ranging from low-tech pocket cards and wall postings to electronic medical record systems.

5. Plan Internal Processes to Conduct the Trial

Complete a study start-up checklist

One quick and easy device to ensure that all staff, materials, and required tasks are covered is the study start-up checklist.

Plan trial logistics and scheduling

Seemingly minor barriers—like patient appointments booked after the local bus service stops running—can impact recruiting in a big way. While it is not possible to avoid every glitch, the more thought you give to logistical planning the less likely you are to encounter such problems.

Dedicate staff and budget to recruitment in the beginning

Doing this from the outset can help keep a trial out of accrual trouble. In many cases, resources are put toward recruitment efforts only when it becomes clear that a trial is not accruing well.

Identify "go-to" research staff for the trial

There is documented value in having one or two staff members designated as a "go-to" people for a trial—in other words, designated staff who can answer questions about the trial. With the "go-to" person or people widely known, all staff who encounter potential participants will know exactly whom to ask when eligibility and other questions come up. In short, a "go-to" staff member streamlines communication and problem-solving.

Provide trial-specific training to staff

When developing staff training programs, review basic information about the trial, including the informed consent document and answers to frequently asked questions. Make sure staff members know how to describe the trial and answer questions from the first discussion with a potential participant, through informed consent, and during the trial itself. Anyone in contact with participants on a trial should know exactly who the "go-to" person is to quickly address questions or concerns.

Pre-authorize insurance or develop alternate payment options for the trial

Financial costs are a key barrier to trial participation. If possible, work with insurance companies and get ideas and suggestions from your institution's specialists such as the billing office to help you plan ahead for how participant costs will be covered.

Implement information technology (IT) processes for the trial

Think about your IT needs for identifying potential participants, enrolling and tracking trial processes and results, and concluding the trial. Have you capitalized on IT systems or appropriate software to automate trial activities such as identifying and tracking eligible participants?

6. Write a Comprehensive Recruitment and Retention Plan

Integrate recruitment and retention plans with institutional activities

Make sure your recruiting activities take advantage of existing services your institution provides. Make sure that what you say about your trial is in synch with the overall messages coming from your institution.

Determine how to screen and identify potential participants

Set up a system to identify potential participants—ideally using your electronic medical record system. Make sure that whenever a potential participant is “found,” the right staff member is alerted (if not already involved) and knows exactly what to say.

Prepare site-specific trial promotional materials for potential participants

By tailoring general materials that describe clinical trials or a particular trial, and preparing other site-specific materials (such as facility maps), you convey professionalism and thoughtfulness to participants. Use site- and trial-specific materials that help people understand the trial and participation at your site.

Address diverse and underserved populations

Historically, racial and ethnic minorities have been underrepresented in cancer clinical trial research. One way to steer toward more inclusive trials is to specifically review recruitment plans and ask whether those plans reflect the community and reach populations that have been overlooked in the past. For example, do the medical practices you plan to reach all tend to have similar patients—or, have you accounted for diversity? Have you identified ways to reach people without Internet access and those whose primary language is not English?

Include plans for community outreach

Know the groups you are trying to reach. For outreach beyond your own walls, partner with organizations who are known and trusted in the community that can help you and potential participants understand one another and work together.

Include plans to work with referring physicians

Good working relationships with referring physicians matter to your institution and to clinical trial accrual. Key goals in working with referring physicians include: 1) Keeping them informed about your trial and its value so they can refer eligible patients, 2) Keeping them informed about how patients they have referred for the trial are doing, and 3) Making sure the physicians and their patients have good experiences working with you. Build specific ideas into your Promotion Plan to help establish good mechanisms and responsible habits for staying in touch with referring physicians.

Write a trial-specific Evaluation Plan

With an effective Evaluation Plan you will be ready to notice, understand, and respond to recruiting challenges. Writing such a plan allows you to think through how you will track accrual, understand barriers, and take corrective action. Many clinical trials fail because the research team waits too long to take action to correct low accrual. Your Evaluation Plan will highlight the tracking tools, procedures, and checkpoints that will keep your accrual on track.

Set milestones, metrics, goals, back-up plans

These topics will be spelled out in the Evaluation Plan. We highlight milestones, metrics, goals, and backup plans here because they are so important. In addition, learning a bit more about each of these key parts of evaluation can help you to plan this work more effectively.

Determine methods for tracking accrual progress

Your ability to track accrual progress depends on two factors—the tools you use and disciplined, responsible, and complete data entry by staff.

Set accrual performance thresholds (e.g., time from trial opening to first participant enrollment)

AccrualNet™'s evaluation section focuses heavily on getting your tools and your team situated to deliver complete and “actionable” accrual data in real time. By setting thresholds in advance, you preset triggers for action. In other words, you know when and how to respond if accrual is not going as planned.

C. RECRUITING AND COMMUNICATING WITH PARTICIPANTS

At this point the trial is open for enrollment. Now what? You should be finding, meeting, and establishing relationships with participants. But how? By following through on all the work and planning you did in the first three stages of the trial lifecycle, your earlier efforts will pay off.



At this stage, it is vital to continue to be thoughtful about participants, staff, and those in the community with access to participants such as physicians and partner organizations. Use good communication skills (like being participant-friendly) and habits (like keeping referring physicians in the loop).

Overview of Strategies

1. Engage intermediaries to aid accrual

Good planning and good relationships matter! Referring physicians, community leaders, members of community or advocacy organizations, and patient navigators can support your study. But in return, remember to share information, keep them informed, and listen to their feedback.

2. Identify potentially eligible participants

The main reason that people join clinical trials is because they were invited to do so by their physician. Jump start the process by reviewing patient records before clinic visits to identify potentially eligible patients. Implement a systematic process to identify potentially eligible participants and keep track of accrual performance. Reviewing reasons why people choose not to participate offers valuable insights.

3. Engage participants in the Informed Consent Process

Successful recruitment may depend on how you approach someone about participation. Informed consent is a process and every conversation with the patient is part of the process. Knowledge of the protocol is critical—so are good communication skills!

4. Consider participant financial issues

Coverage of clinical trials can be a major barrier to accrual, so it is important to understand the policies of insurers in your area concerning clinical research. A simple phone call might

help you understand insurer's viewpoints and constraints, and give you an opportunity to share your ideas, too

5. Maintain the morale and interest of staff, participants and their families

To advance science, clinical trials need participants to enroll, stay involved, and follow study guidelines. Yet, it can be easy to focus heavily on recruiting participants, sometimes to the detriment of retaining participants. Use a forward-looking approach and good two-way communication to foster the trusting relationships that support retention in the trial and adherence to the protocol.

6. Update participants regarding study related events and results

Good patient contact information is critically important if a study closes early or other unexpected events occur. Participants also appreciate hearing about study results when they are available.

1. Engage Intermediaries to Aid Accrual

Assure that plans to reach referring physicians are being executed

Check your Recruitment and Retention Plan and think about how well the ideas are being executed. How effectively is your team keeping referring physicians informed about your trial and its value? Letting them know about their patients' progress is essential to good working relationships. Good experiences today benefit today's and tomorrow's trials.

Assure community outreach plans are being executed

Ask how well the community outreach ideas defined in your Recruitment and Retention Plan are being executed. How effectively are you working with partner organizations? Pay particular attention to whether your outreach efforts reflect the community's diversity.

Generate advocate buy-in

Advocates who value your trial can be your greatest asset in reaching potential participants. Thus, it is important to share information and engage them early and often during the trial. Good relationships with advocates will benefit today's and tomorrow's trials.

Engage patient navigators

Patient navigators help patients negotiate the complex web of health care, which can be even more complex with trials. Their compassion and knowledge of the system can reduce fear and stress for patients. Their central goal is to find ways around barriers—which can greatly help patients and clinical research staff who are navigating the requirements for a trial.

2. Identify Potentially Eligible Participants

Query your institution's paper or electronic medical record system(s)

Your institution's information system is an obvious starting point for identifying potential clinical trial participants. If your medical records are electronic, then the process may be simpler. No matter which tools you use, it is important to know all the potentially eligible participants are being identified.

In other words, be alert to clues that a potential or existing participant may not be fully committed to the requirements of the trial. Your team's awareness of these indicators will enable them to avoid enrolling participants who, while eligible, are not a good match for other reasons, and to work more effectively with those on the trial who are having difficulty.

Follow up with potentially eligible but non-consented individuals

Keep track of individuals who are potentially eligible, but have not yet consented. Assure that they are undergoing work-up to confirm eligibility, and that any outstanding questions or concerns are addressed.

Identify and report on participant non-adherence indicators

In other words, be alert to clues that a potential participants may not be fully committed to trial requirements such as randomization. Your team's awareness of these indicators will enable them to avoid enrolling participants who, while eligible, are not a good match for other reasons.

3. Engage Participants in the Informed Consent Process

Use plain language

Researchers are used to talking about cancer and scientific studies every day. But, most people are not. In addition, the average adult in the U.S. reads between the 8th and 9th grade reading levels. Add to that the stresses of cancer and you can see how important it is to simplify and avoid jargon when presenting a clinical trial. If possible, rehearse what you will say so you can talk about the trial in a way that is confident, balanced, and easy to understand.

Use participant-friendly materials

Use active voice and personal pronouns (Instead of “The patient may contact his or her physician at any time....,” say “You may call me any time....”). Use white space, figures, diagrams, calendars, and simple outlines to make your document easier to read and understand. Leave wide margins and space so that participants or their friends and family can take lots of notes.

Present the trial in a culturally appropriate manner

The racial and ethnic backgrounds of potential participants play an important role in the feelings, viewpoints, and communication needs they bring to conversations with you about a trial. For example, ethnically diverse populations may have issues related to trust, differing cultural values, language barriers, and feelings about medical professionals that will impact their thinking about any trial you present. Take into account these perspectives and any culturally-rooted communication preferences as you present the trial.

Seek the help of translators when needed

There have been times when a participant and a clinical trial seemed a perfect fit, but language barriers made informed consent impossible so the participant could not even be given the option to join. Even after informed consent, participants whose primary language is not English will likely need the aid of a translator to get answers and refresh their understanding of the trial over time.

Emphasize the key role of the physician presenting the trial

The research is clear. The majority of participants enroll in trials because a physician asks them to join. Make sure key physicians are involved in talking with potential participants about the trial as early as possible.

Present the trial in a balanced manner—both pros and cons

It can be easy to overstate the pluses of a particular trial when talking with potential participants. The pressures of accrual or even a clinician’s heartfelt enthusiasm about the value of the trial itself can play a role. By preparing your materials and what to say about a trial, you can be sure to present it in a balanced way—so potential participants can make informed choices.

Provide continued support as people consider their decision to participate and continue on the trial

The informed consent document and the informed consent discussion are critical. Yet, they represent only the start of the consent process. People need time to make thoughtful decisions about joining a trial. As they consider this decision, provide access to any additional information or resources they may need. The two-way communication flow that helps participants feel comfortable and informed when originally joining the trial should continue throughout the study.

Manage communication of screening results and failures

It is important to remember that participants, and their primary care providers, require communication about both successes and failures. Consistently “close the loop” with potential participants—both those who are screened into and out of the trial. Doing so is common courtesy and, for those who are eligible, this step starts building your relationship. For those who are not eligible, thoughtful communication can help keep open the possibility of future trial participation.

Be aware of and monitor regulatory issues such as HIPAA regulations

Regulatory and IRB issues can be fluid, so it is important to keep on top of potential changes that may be occurring, both at your site and on a national level.

4. Consider Participant Financial Issues

Establish relationships with insurance companies to facilitate coverage

Coverage of clinical trials can be a major barrier to accrual, so it is important to understand the policies of insurers in your area concerning clinical research. A simple phone call might help you understand their viewpoints and constraints and give you an opportunity to share your ideas, too. Use the goals you share as a starting point for the relationship. If your institution's billing office has an insurance expert on staff, enlist his or her support to identify third-party payment options for your trials.

Track insurance coverage concerns for the trial

One goal in all clinical trial work is to limit the number of "surprises." Minimize insurance surprises by tracking past trial coverage and getting expert advice from your billing office. Tracking will enable you or your insurance specialists to speak knowledgeably with insurers about their past trial-related coverage decisions and to help make the case for future coverage.

Work with specialists to identify alternative financing if a potential participant has no insurance

The anticipated financial burden of a trial can easily become a deciding factor in whether or not a person enrolls. Therefore, it is helpful to have payment answers ready before questions arise. Find ways to include eligible participants who have inadequate or no insurance coverage in your trials. Specialists such as social workers can help identify local and national resources. Also, your institution or trial sponsor may have funds set aside for such needs.

5. Maintain the Morale and Interest of Staff, Participants and Their Families

Watch for early signs of non-adherence and provide support to meet needs

Certain early signs of non-adherence are documented in the literature. You may notice some that are particular to your trial as well. For example, indicators include losing interest and “forgetting” appointments or medications. Talk openly about the challenges together with the participant without pressure. Perhaps some of the issues can be easily resolved.

Keep in touch with participants on trials (e.g., through newsletters or reminders)

Find some great ideas on AccrualNet™ for helping participants see that they are part of something important, something bigger than any one person. See which among the many varied ways to keep in touch—from newsletters, to email, to small branded items—will work best for your participants.

Offer support groups, participant networking, lists of local and online support resources

Making it easy for participants to get the support they need is one way of maintaining morale. For example, some study coordinators set appointments so that particular groups of participants tend to be on-site at the same time—forming a cohort of sorts and social bonds develop, which motivate participants to keep their commitment to the trial. Ideas range from simply providing lists of resources to convening regular support groups.

Conduct satisfaction surveys with trial participants

Openly encouraging feedback (and listening and acting on it!) has two benefits. First, your genuine interest shows participants that you care about them and their experiences. Second, you learn what is helping recruitment and retention as well as what might not be helping. Remember, keeping surveys short is important for obtaining thoughtful feedback.

Acknowledge and celebrate successes while also supporting any staff who need help

Even with perfect planning, recruitment can be challenging. Help maintain the enthusiasm and clarity of staff members about the important role they play. Reward staff for following the recruitment and retention plan and for spotting surprises and eliminating barriers. Remember that they have other duties in addition to recruitment. Recognize their exemplary efforts in data management, audits, and more—especially important if accrual is lagging and morale is low.

Regularly update staff on trial accrual

Talking about accrual helps clinical trials and recruitment to be a part of the normal daily work. In addition, being open about how a trial is accruing will help you gain the insights of others in solving problems. It also helps keep team members and leadership from feeling unpleasantly surprised if accrual goes poorly.

Encourage staff to provide feedback about the trial

Being open to feedback is a key theme of AccrualNet™. Even with careful planning, new challenges will crop up. Empower staff to spot and solve problems and make it easy to give feedback about their trial-related experiences.

6. Update Participants Regarding Study Related Events and Results

Keep contact lists current and note the best way to communicate with individual participants (e.g., through email, newsletter, telephone call)

This activity is a basic step. Make sure you know how to reach your participants with trial information—especially if that information needs to reach them quickly. Ask whether they prefer email, telephone, or other forms of contact.

Monitor media regularly and have a plan in place to respond to trial-relevant media stories (to participants, to the media, and to stakeholders)

The Internet and the airwaves abound with advice, cautions, new scientific findings, and plenty of other information. Although you cannot monitor all of it, you can stay up-to-date on news (e.g., about a trial drug or procedure) and anticipate questions. You can also be ready in the event of a major new and relevant finding or story.

Have a plan for notifying participants/families, staff, and stakeholders if the trial is put on hold or closes unexpectedly

Prepare an explanation that is complete, clear and specific. Send it out to participants in a timely fashion. This will enable you to serve your participants in an ethically appropriate way, and can help engender positive feelings about the trial and your institution—feelings that can carry forth to future trials.

D.IMPLEMENTING THE TRIAL

Managing recruitment and retention is a vital component of overall trial management. As implementation activities are underway, the trial team must keep communications and logistics running smoothly. By using a written Recruitment and Retention Plan, the team will be well-prepared to manage recruitment, retention, promotion, and evaluation activities as well as quickly spot and respond to any major change or recruiting difficulty.



Overview of Strategies

1. Communicate regularly with stakeholders and referring providers

Provide specific opportunities to keep everyone up-to-date on accrual and to open the door to helpful input from the team. If accrual is not going well, talk about the difficulties and stay open to suggestions. Effective communication and establishing a rapport are key to keeping referring physicians, community partners, and others positively engaged in recruitment.

2. Monitor trial progress and accrual metrics

The Recruitment and Retention Plan and the Evaluation Plan are your tools for monitoring progress. Did you implement your strategies? What were the results? Is your rate of accrual as expected?

3. Implement alternative recruitment strategies when accrual milestones are not achieved

If accrual is lagging, first understand why. Then consider checking the literature for some new ideas and approaches. Be sure to re-assess at designated time frames.

1. Communicate Regularly with Stakeholders and Referring Providers

Conduct regular staff meetings to discuss trial accrual

At this point in the lifecycle of a clinical trial, your entire team is taking notice of what is working and what needs improvement. Provide specific opportunities to keep everyone up-to-date on accrual and to open the door to helpful input from the team. When you make clinical trials (and accrual to trials) part of the normal “conversation” among staff, recruitment can get much easier.

Regularly communicate the trial’s accrual status to key staff/stakeholders and seek feedback

Effective communication and establishing a rapport are key to keeping referring physicians, community partners, and others positively engaged in recruitment. Don’t just talk about accrual progress and adjustments within your own team; keep others at your institution as well as external stakeholders in the loop. Encourage their continued commitment and emphasize approaches that work. If accrual is not going well, talk about the difficulties and stay open to suggestions. It is almost always better to talk about recruitment difficulties when they are first detected and potentially easier to solve.

2. Monitor Trial Progress and Accrual Metrics

Monitor recruitment and retention plan activities and adjust when necessary

The Recruitment and Retention plan you wrote while Selecting and Preparing to Open the Trial was meant to be used. Look back at your plan. Is it being implemented as envisioned? What useful changes might be needed? Your willingness to judge existing efforts and your openness to making changes as needed is what matters most.

Monitor promotion activities and adjust when necessary

Are promotion activities going as intended? Are changes needed? Again, your openness to judging your own efforts and your willingness to adjust are key.

Monitor evaluation goals, objectives, and activities

Check your Evaluation Plan within your Recruitment and Retention Plan. Are you collecting the right information to know if you are meeting your goals in a timely manner? If not, what should be changed: the plan, the recruitment, or tracking activities?

Review trial accrual indicators against expected performance

This activity is a reminder to specifically check accrual performance as outlined in your Evaluation Plan and to use the data to make accrual performance judgments.

Regularly assess the trial's costs against its budget

In the spirit of aiming for “no surprises” (an AccrualNet™ theme), assess trial costs against your budget regularly. Discuss the assessment and thoughts on how the trial is performing and its value from a financial perspective.

Monitor screening data for diverse and underserved populations

Historically, racial and ethnic minorities have been underrepresented in clinical research. Take time to specifically review plans and ask whether they reflect the racial and ethnic makeup of the community and are reaching these populations. Check whether screening data matches the proportion of participants from diverse and underserved populations found in your community.

Monitor the impact of operations and logistics on trial accrual

You worked hard to remove logistical barriers as you prepared your Recruitment and Retention Plan. Check whether unforeseen operational or logistical issues have come up.

3. Implement Alternative Recruitment Strategies When Accrual Milestones Are Not Achieved

Use data to decide whether to make changes or close the trial

For better or worse, everything from the pressure of competition to the joy of discovery plays a role in clinical trial work. But, when it comes to deciding whether a trial is accruing well enough and remains feasible, data should play the central role. Be willing to ask the tough question, “Can this study be saved and at what cost?”

If changes are made, document expectations and monitor over a specific timeline

Your team may assess a trial with major accrual challenges and determine that it indeed remains feasible or is meaningful enough to keep active. If you make this choice, plan on how best to improve recruitment and set new goals and a specific timeline for meeting them. At the appointed time, reassess.

Determine if the state of the science has changed and accrual is unachievable

Most trials take place over a fairly long time period. During that time, your team should keep up with the relevant science. Perhaps new findings, treatments, or approaches mean that your trial cannot accrue as hoped.

E. EVALUATING ACCRUAL AND REPORTING LESSONS LEARNED

The closing of a trial is a time to take stock—to understand both what went well and what did not. Use the lessons learned to build the knowledge and capacity of your team and to strengthen future recruitment efforts.



Overview of Strategies

1. Analyze the trial's accrual data for lessons learned

Once a study is complete, it's tempting to quickly move on to the next trial. But it's worth investing some time to talk with your team, look at your data, and understand the experience—the good and the bad.

2. Report and share accrual experiences with others

This is the time to close the loop with the providers and organizations that supported accrual to your study. And think about the broader community of clinical trial professionals and consider sharing your experiences with them—perhaps here on AccrualNet™.

1. Analyze The Trial's Accrual Data for Lessons Learned

Review accrual data and discern lessons learned to improve future trials

The team will likely have a general sense of how recruitment went for the trial. You may even be able to think of a few things you know now that you wish you had known at the start of the trial. Use accrual data to confirm (or not) your impressions on recruitment. If your team faced accrual difficulties, use this stage for learning and improving. If your team was successful, pause and celebrate.

Determine the trial's value to your institution

In earlier stages (Developing a Trial or Selecting and Preparing to Open a Trial), you considered how this trial would fit into your institution's research portfolio. Take a moment to think about that. In what ways did the closed trial contribute to that portfolio? Given an opportunity, would you select such a trial again for your research portfolio? If so, what does that tell you about your site's strengths? If not, why not?

Analyze data from a terminated trial

This suggestion does not mean analyze the study data with respect to the research question; rather, it means analyze the data to see how realistic your accrual goals and actions for the trial were. Recruitment is often difficult and trials sometimes fail to accrue participants. We can learn from failures—perhaps even more than we can learn from success. So, analyze accrual-specific recruitment data from failed trials carefully—using your openness to learning as a way to avoid blame and to foster a deeper understanding. Hopefully, as the field learns and develops approaches, processes, and habits that support accrual, we will all have fewer “unaccrued” trials and more successes from which to draw lessons.

2. Report and Share Accrual Experiences with Others

Prepare and submit a summary of trial-specific accrual findings and lessons learned to key stakeholders

If you have been using the principles AccrualNet™ shares, you have kept stakeholders engaged throughout the trial. Even if you have not engaged them as much as you would have liked, take the opportunity now. This stage of a trial is the time to close the communication loop and share lessons learned. Doing so shows your thoughtfulness, accountability, and dedication to the trial. Prepare a simple summary of accrual findings that focuses on both strengths and areas to improve for next time.

Share your experiences on AccrualNet™

AccrualNet™ was created to give people just like you with trial recruitment responsibilities access to the literature, helpful tools, and each other. This trial has closed and you probably learned something that can help someone else, or asked a question that one of your peers is asking, too.

Document and submit your experiences and findings to journals and at professional meetings

Add your experience to the field in a more formal way. When you contribute findings to the literature or make presentations to professional colleagues, it helps the field develop as a whole.