



CLINICAL TRIALS

PATIENT RECRUITING AND RETENTION

TIPS FOR SUCCESS

Introduction by Noel Chandler
Illustrations by Brenda Brown



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Introduction

Regardless of the specifics, the most recently published statistics show that patient recruitment and retention issues are a challenging, persistent problem in clinical trials. From many of these reports, it is almost certain that the problem will only continue to grow as the years go on. Patients and caregivers are increasingly busy with their lives outside of clinical trials. As consumers in the modern world, all have an augmented amount of information, access to devices, and higher expectations of the immediacy of customer service. With this access to instant information, the care, approach, and ongoing management of how volunteers are treated, communicated with, and the mediums used for that communication is not only important, it is ever-changing.

This book was put together with the goal of taking the advice and experience from professionals in a variety of areas within clinical research and compiling them for anyone in patient recruiting and retention. We're confident that you'll find at least a handful of useful tips to add to your patient recruiting and retention toolbox in the 68 we provide.

As the landscape of media, technology, and communications change, our plan is to publish one of these books a year. Our goal is to provide a consistent and thorough platform through which clinical trial personnel can receive tips to adapt clinical trials with changing culture. We welcome any thoughts or feedback you have about how to improve this book in the future. If you or someone you know would make a great contributor in future editions, please feel free to get in touch with us.

Thank you for reading, and thank you for your work making medical treatments safe, effective, and accessible to all.

*Noel Chandler,
CEO, Mosio, Inc.*

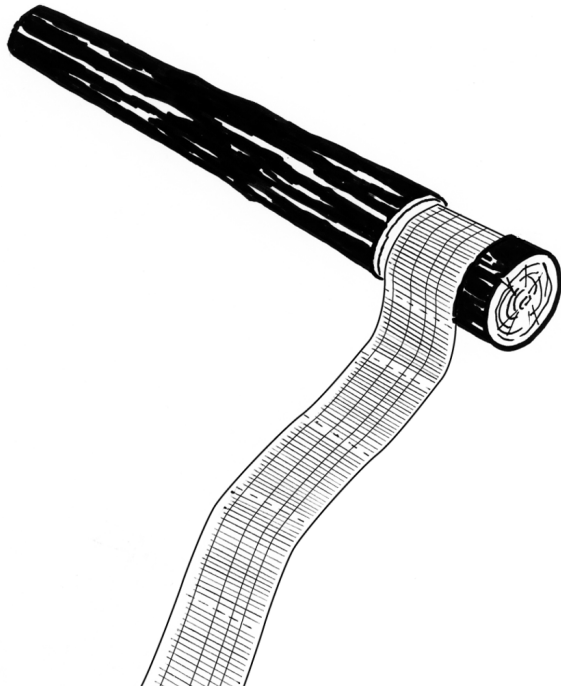
Recruit. Retain. Report.

<http://mosio.com/research>

info@mosio.com

877.667.4699





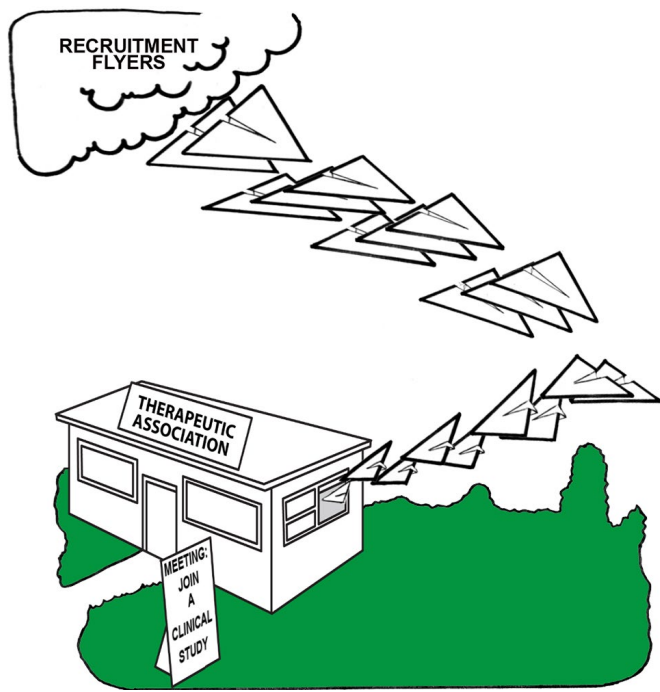
1. Keep a pre-screening log

A pre-screening log is helpful to expediting study enrollment and gauging study interest. The log does not have to be shared with the Sponsor and can be used for studies in accordance with applicable privacy laws and guidelines for protected health information.

2. Consider utilizing Sponsor-provided recruitment materials

By utilizing the Sponsor materials, you reduce the timelines for incorporation and implementation into your already-active recruitment plan.



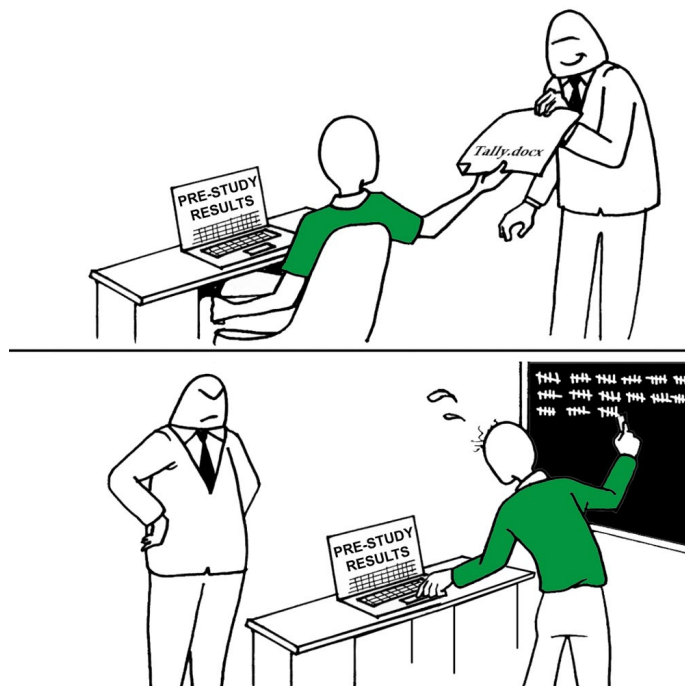


3. Don't forget that local therapeutic associations can be “diamonds in the rough” in regard to recruitment

Partner with your local chapters to hold informational meetings, place flyers in their offices, or send study details to their mailing lists.

4. Effective feasibility is key

A review of your clinical database should be completed *prior to* agreeing to participate in the trial, *but after the pre-study visit!* This will allow you to truly assess if you have the patient population to be successful in enrolling the trial.





5. Use your network

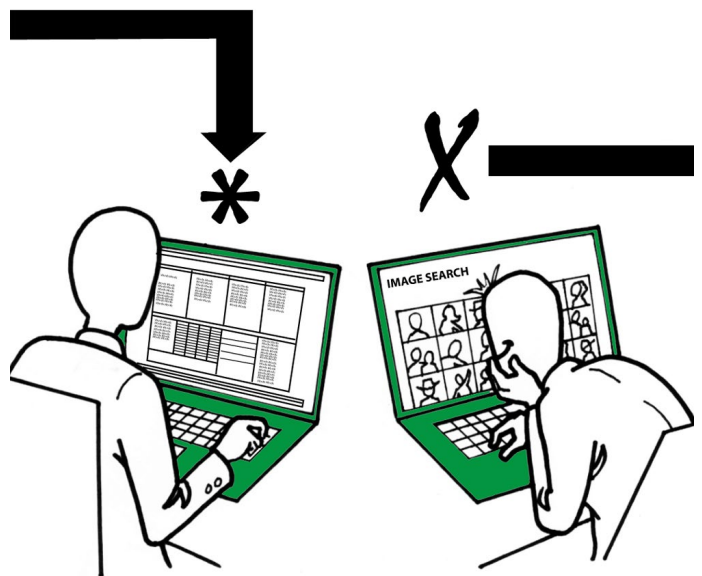
Staff training and updates are essential to continued study recruitment. Make use of physician referral networks and meetings to discuss any new recruitment ideas from sites and advertise your studies via casual conversation.

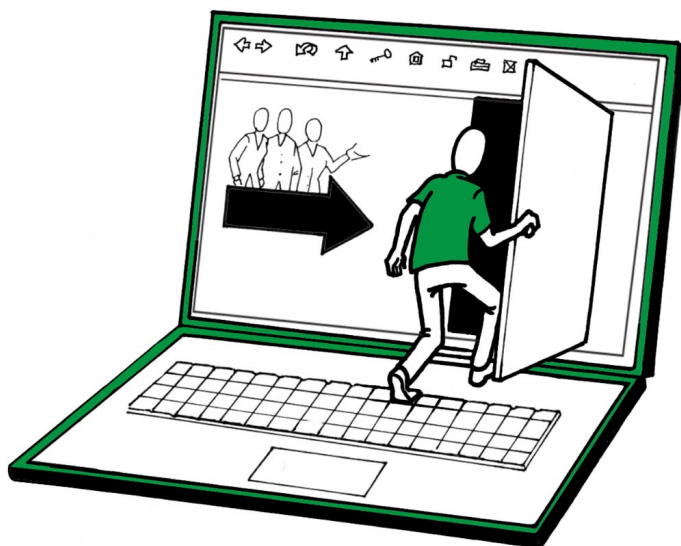
Tips by Bio-Optronics

Submitted by Kyle Ricketts and Sergio Armani
bio-optronics.com

6. Use the right information to get the right patients

Use the searchable patient database in your Clinical Trial Management System (CTMS) to filter out ideal patients based on specific criteria, and create lists of perfect trial patients you can easily call and email.



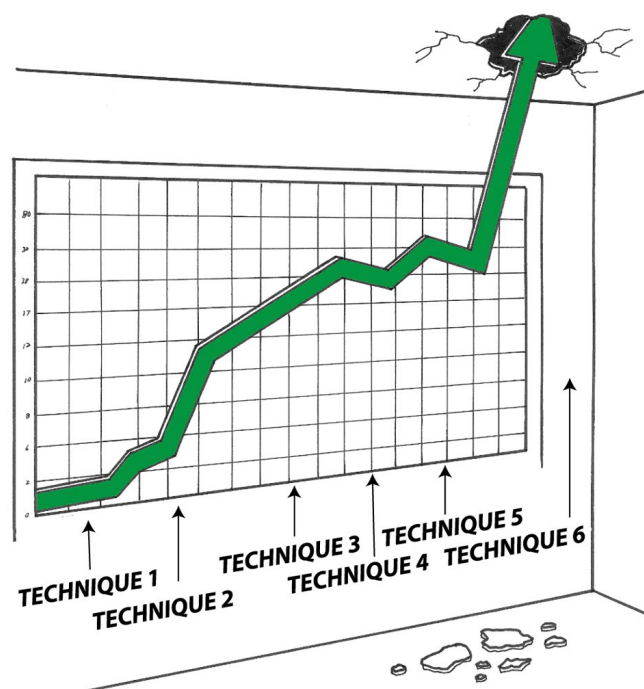


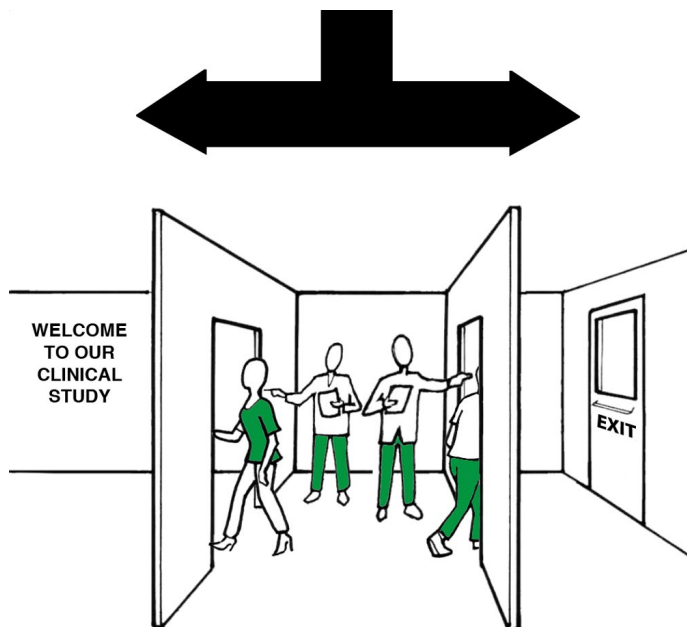
7. Let your patients come to you

Allow individuals to see the types of studies you have open by making them available on your website through your CTMS and let readers request information.

8. Practice what works for your organization

Use your CTMS to track recruitment campaign effectiveness as well as Return on Investment.



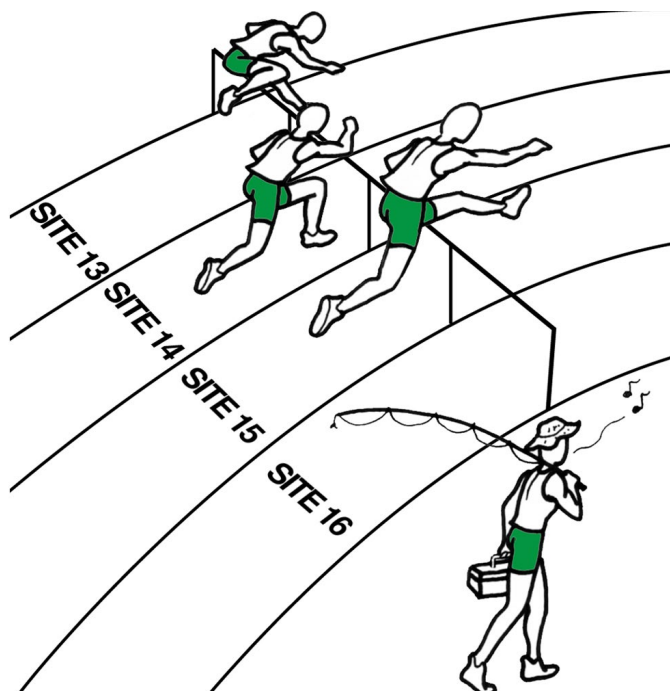


9. Let site staff know the patient population you need before recruitment begins

Set up prescreening requirements so that sites know exactly what types of individuals are needed for a specific study.

10. Easily set and track recruitment goals

Define specific recruitment goals for each study and each site, and then allow your CTMS to alert you when sites are falling off track.





11. Assign recruitment milestones for your sites

Establish milestones for your recruitment and know where your sites are throughout every step of the recruiting process.

Tips by ClinEdge

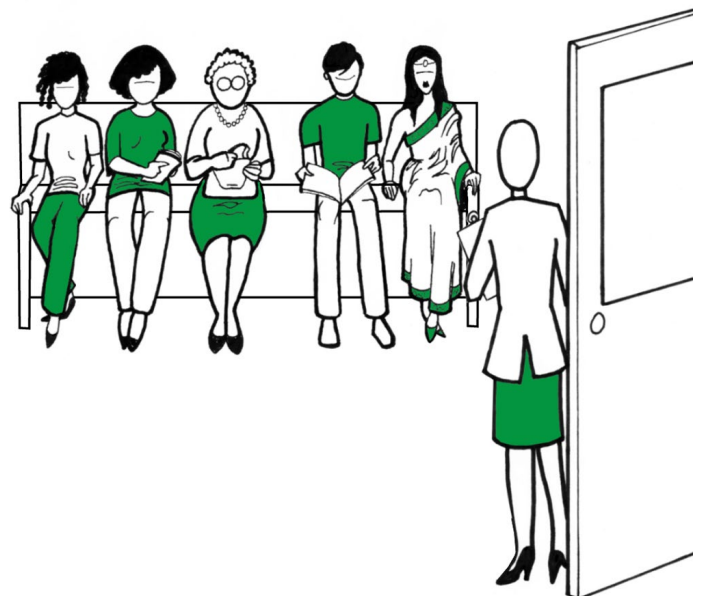
Submitted by Erin Phares

clin-edge.com

12. Be culture-conscious

When working with patients of different ethnic backgrounds, be sure to recognize and accommodate cultural differences. In some cultures, health decisions are made by an entire family. In others, the head of the household may be the decision-maker for all family members. Being respectful of cultural norms and adapting your relationship in recognition of these norms can help overcome language and cultural barriers and ensure that your patients feel comfortable.

SUBJECTS AND DECISION-MAKER(S)





15. Know where to go

Meet potential patients on their turf. Connect with local clinics, support groups, and health organizations. Identifying and building relationships with referral sources is a cost-effective tactic for growing your patient database and recruiting for specific studies. Having a strong referral network is especially important for studies that are not well-supported through traditional advertising campaigns.

16. Provide a service

Understanding your patients' needs can also translate into offering services to meet those needs. Offer free health screenings: free memory screenings, free blood pressure screenings, and other such measures that allow site staff to interact directly with potential patients while meeting a community need. As a bonus, site staff can also use this opportunity to identify patients who may potentially fit into an ongoing study.





17. All social media are not created equal

Using social media platforms and blogs can be fiscally feasible ways to engage with potential patients. These efforts are most effective when tailored based upon your target audience. Know where your audience is and what they want to hear. Start a conversation with health polls, questions, and tips. Be sure to seek Sponsor and IRB approval for postings that discuss study details. Establishing a trusting relationship online is often the first step to building a positive patient-caregiver relationship.

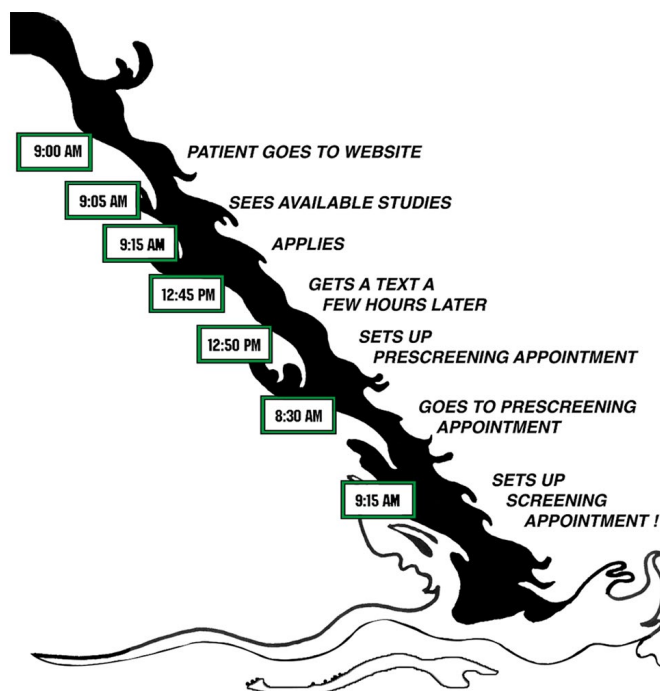
Tips by Clinical Trials of Texas, Inc. (CTT)

Submitted by Dale Korth

SAresearch.com

18. Use CTMS to create a fluid recruitment process

One of the best practices, from the perspective of a standalone research site, is the importance of having a robust CTMS system to work in conjunction with your website. Having a well-optimized website is obvious, because if people can't find your site, then they can't apply to your studies. Having subjects apply from an advertisement or your website and be placed directly into a study roster is incredibly important. Recruiters are able to reach out to new applicants immediately



so that their research interest can be captured at its optimal peak, or at least within 24 hours of application. Another suggestion is to manage subject statuses in real time so that the coordinators are able to schedule a screening within minutes of a recruiter qualifying a subject. This creates a very fluid process.



19. Use free resources

Another practice is to utilize all possible free resources, especially social media. Craigslist and various online classifieds are other successful, free mediums for research. Local support groups, free press releases, and just a flyer on your website are also great ways to get the word out for free.

Tips by DAC Patient Recruitment Services

Submitted by Melynda Geurts
dacprs.com

20. Patient recruitment and retention should be part of protocol design

Protocol design is typically developed through scientific eyes only. Operationally, this can pose a challenge. Recent metrics support that \$1 million is spent on each study protocol amendment. Millions of potential dollars can be saved if Sponsors engage operational team members during the protocol design stage. Suggested members may include clinical trial managers, study managers, patient recruitment specialists, and selected study coordinators.





21. Follow through on all commitments

A key de-motivating factor for sites is for a Sponsor not to follow through on their commitments. Re-engaging a de-motivated site is a significant investment of time and money. Maintaining open lines of communication and doing what you say you are going to do make a lasting impression. This is also an important principle for all supporting vendors to follow.

22. Let study coordinators have a forum to be heard independently of the investigators

Invest the time to convene study coordinators through a face-to-face training or webinar. These trainings allow the coordinators' voices to be heard and are an excellent way for Sponsors to "give" back to the sites participating in their studies through certified training programs. Look for providers that can offer continuing education units (CEUs).





BUDGET

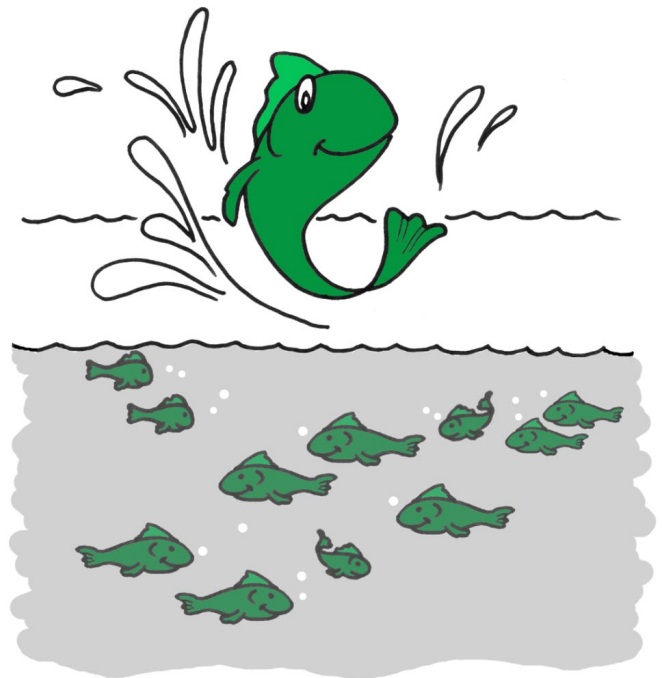
23. Budget for recruitment and retention up front whether you use it or not

Not earmarking budget that may be needed to support future recruitment or retention needs can cause enrollment delays.

Developing a proactive contingency plan can offset potential costs associated with the implementation of a rescue program. Partner with a vendor that is flexible in their service and budget approach (i.e. tiered services).

24. Make your trial stand out in a crowd

According to data recently reported by clinicaltrials.gov, Tufts, and ISR Reports Data, there is a 233% increase in patients required per New Drug Application (NDA). This means that your trial is a small fish in a very large sea. Now more than ever, Sponsors must make their trials stand out in the crowd. Creatively branding your trial is an excellent way to give trials “life.” This branding is important within the sea of all trials, but is most important among study sites. Remember, you aren’t just competing for study participants. You are competing for experienced research sites!

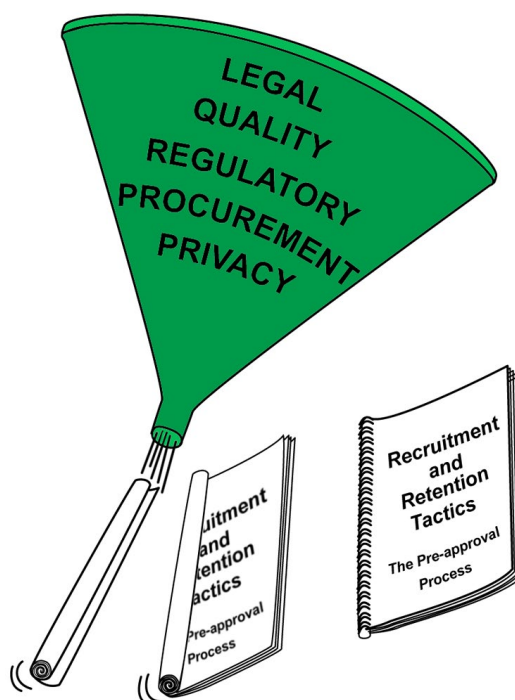


25. Pre-approve patient recruitment / retention tactics

To be more efficient and reduce timelines, it has been helpful to develop a standard process to “pre-approve” selected recruitment tactics that are commonly used across all therapeutic areas. An example would be advertising a study in a scientific journal. Usually a key member of your recruitment department will form a small committee of the key decision makers from the departments that are involved in the approval process. Those decision-makers include: project management, regulatory, legal, quality, compliance, privacy, and procurement.

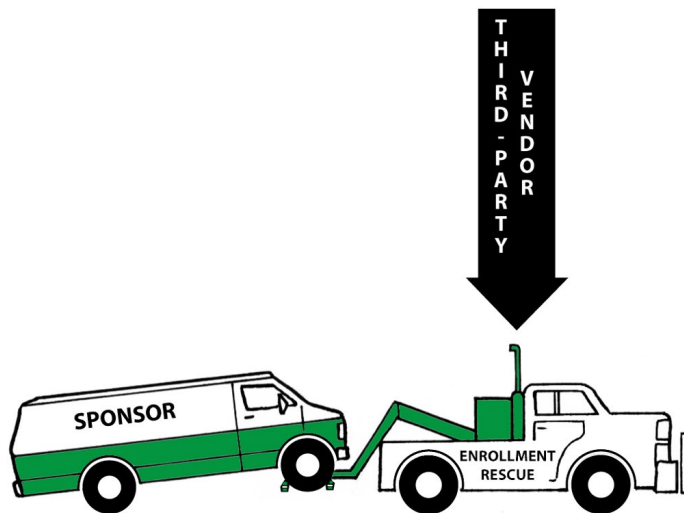
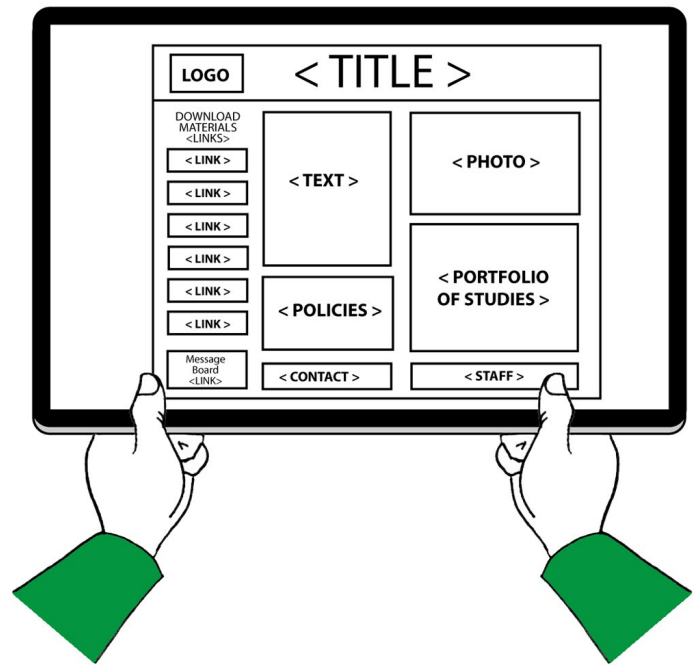
A simple spreadsheet can be created for each tactic, in which each representative can weigh in to answer these key questions:

- Confirm what our company (sponsor, CRO, etc.) is approved to do.
- What is needed for the approval? (review, signatures, etc.)
- What do we know is “not allowed” per company policy, regulation, SOP, etc.?
- What are the expectations?
- What are the risks? (usually comes from legal)
- Possible contingencies to mitigate the risk.
- Clearly designate who has the final decision-making responsibilities to sign off and approval.



26. Create generic recruitment and retention templates

Create a website that hosts “generic” templates with recruitment and retention materials (e.g. patient reminder cards, brochures) that are accessible to the clinical teams. They can then customize the materials for each unique trial. This can also be used for “branding” a portfolio of trials at the program level. If you do not have in-house capabilities to do this, find a vendor that can do the development work.



27. Sponsors: Create a strategic plan by conducting a capability assessment for each third party recruitment / retention vendor

To save time and reduce costs, it is extremely helpful to develop a tactical recruitment and retention vendor strategy. A simple spreadsheet can be created to capture the key capabilities for all existing and potential third-party vendors and consultants.

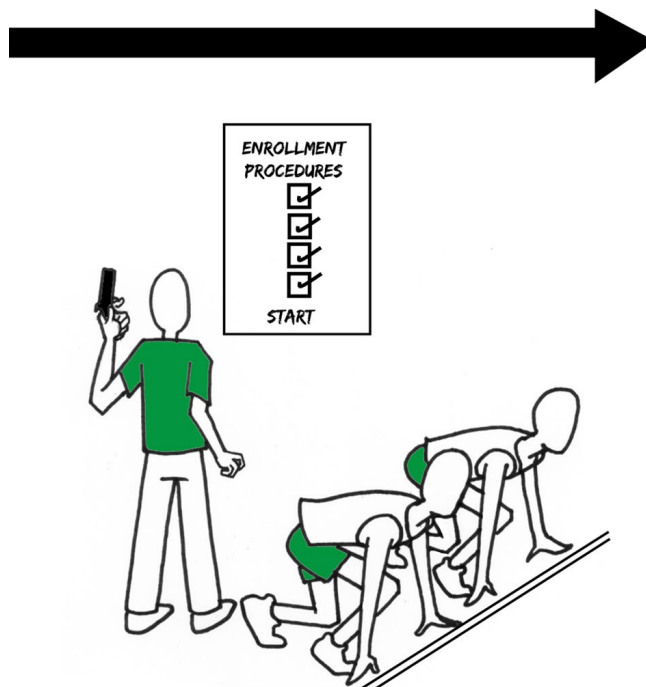
Data might include:

- Countries and relevant experience (number of trials, etc.)
- Have an office or use a subcontractor in that country?
- Therapeutic area specialties
- In-house or subcontracted services?
- Niche markets

Ultimately the goal is to have the ability to quickly assess recruitment options for that trial and provide quality recommendations to the clinical teams.

28. Develop study start-up recruitment procedures

The most successful enrolling sites are proactive with their efforts, leaving nothing to chance. You should be ready to hit the ground running once your site is initiated. Develop a list of enrollment procedures that you can apply to nearly every trial and other procedures that you can employ with Sponsor funding. Know what you're going to do before the study starts (i.e. charting EMR queries, using IRB-approved outbound communication, resourcing via Internet, etc.)



29. Create a clinical research section on your site's website

Your site's website is how you can best put a human face to your recruitment efforts. Successful sites have an easily identifiable section of their website devoted to clinical research. You can easily list therapeutic specialties and study specifics (with IRB approval) for your site, and can use Sponsor recruitment efforts to link back to your site. Pictures and staff biographies help humanize your website and provide the visitor with a deeper connection to your team. Your IT department should make your site mobile device accessible.

30. Develop study start-up recruitment procedures

There is an ever-expanding list of cost-free Internet resources, both local and national, that you can utilize to help grow your web presence and recruitment efforts.

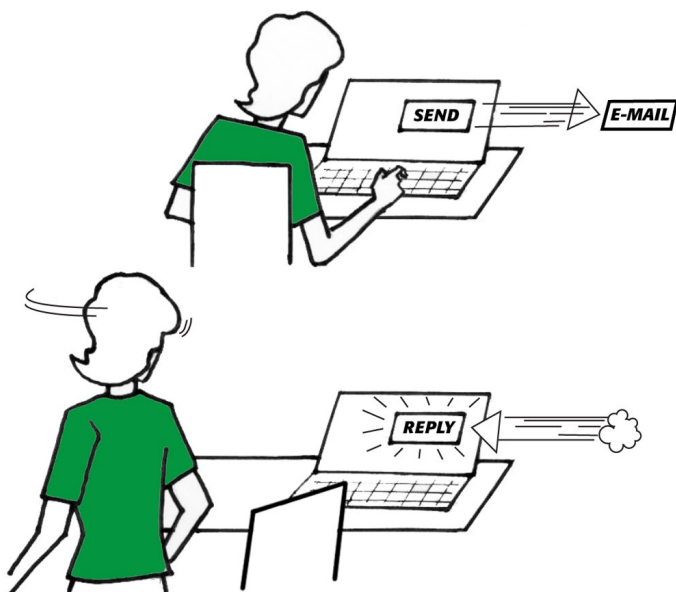
From Craigslist to Facebook, Twitter, YouTube and others, you can energize your online recruitment performance by interconnecting all of your efforts. Use Facebook and Twitter links on your study website and in any online advertising, and put a link to your website on Craigslist and other online classifieds. Make sure you're

NOT advertising in a help wanted section, but in one that applies to the clinical trial. Ads generally don't work exceptionally well as stand-alone efforts. Use circular marketing (meaning that the different tactics should work well together to engage and educate those who are interested in learning more) to capture the attention of website visitors.



31. React to inquiries quickly

When you receive an interest inquiry via email, study website question, or phone call, respond immediately. When someone contacts you, they are at the highest level of interest. The more quickly you respond, the more likely you are to connect when interest is piqued.



32. Follow up and follow through

After someone contacts you, be sure to follow up with them. By sending study information or an invitation letter as follow up, you set up a successful situation for your phone call by giving an additional reason for making the call. This two-step process is vastly more rewarding than cold calling. If you send a study information letter, be ready to place a follow-up call within a week's time. If you leave a message for someone, be ready to call again within three days. Evenings and weekends are the best time for phone contact.



Tips by inVentiv Clinical Trial Recruitment Solutions

Submitted by Jim Kremidas

inventivhealth.com



33. In a changing environment, rely on facts, not experience

- Don't rely on your personal experiences... things change.
- Get facts to support your strategy, not opinions.

34. Never assume that investigator sites will find all their study patients from their practices

- The demand for patients is growing exponentially.
- The number of investigators is growing linearly.
- You know what they say about “assuming!” (Don’t do it!)



35. Get actual patient perspectives before building a recruitment plan

- Take the time to hear patients out.
- It’s hard to “walk a mile in their shoes”; have a professional help you.
- Take time to understand feelings and emotional drivers of patients.

**36. Avoid this recruitment strategy:
“When in trouble, when in doubt,
run in circles, scream and shout!”**

- Planning drives success; take the time to do it well.
- Don’t wait until you have a problem to execute your plan; be proactive.

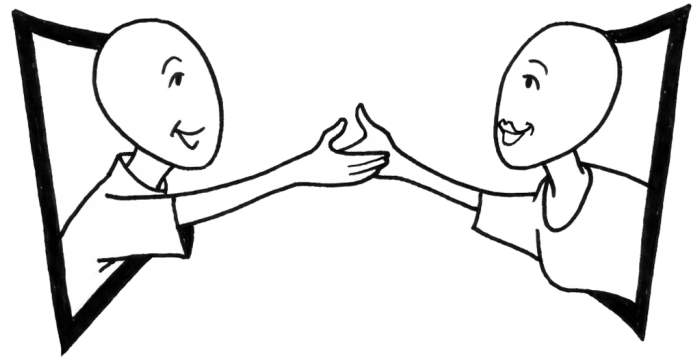


**37. It’s not all about the media
you choose; the message is just as
important**

- Remember to develop a message that engages your target patient.
- Don’t just say, “Do you have (insert disease here)?” You have to appeal to people as humans... not subjects.

38. Keep friends in social media

For clinical research organizations to maintain friends in social media, they should create messaging that does more than just share study subject criteria. They must educate, entertain and inspire.



39. Have a personality in social media

Create a social media persona for your organization. It should be like that cool, smart, funny friend.

40. Teach your audience

Educate: teach your audience something. Make the connection to your work subtle and occasionally direct.



41. Have fun!

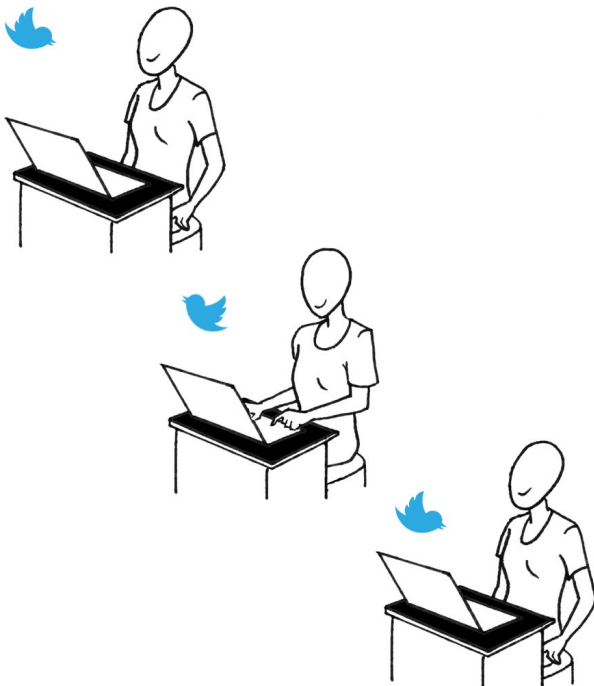
Entertain: It's okay to have fun. Clinical research subjects do like to laugh.



42. Inspire your audience

Inspire: appeal to the best that humanity has to offer. Help your audience feel good about themselves and what clinical research has to offer.

*To participate in a clinical study
is how you—as one person—
can contribute to many people
who are in need of healing now,
and for generations to come.
You will make a difference!*

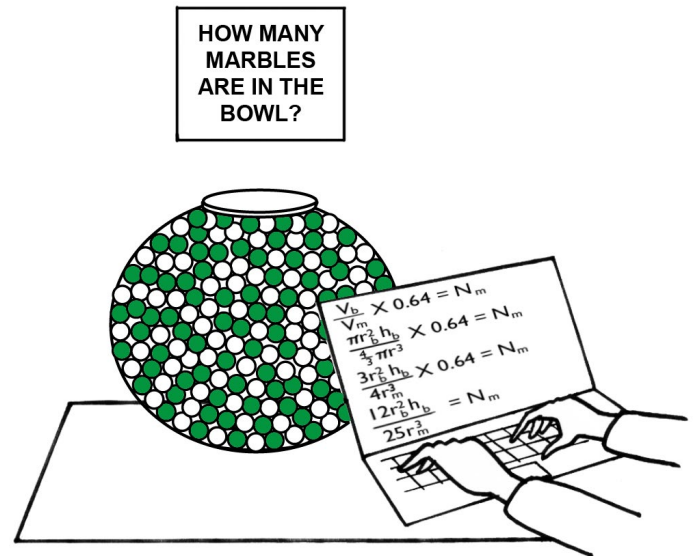


43. Connect using social media

Use social media to make a connection with your audience. If you build that relationship, you will increase the likelihood that when the person is at the critical moment when they consider participating in your trial, they may be more inclined to say yes.

44. Predict, don't guess!

Are you using software to analyze big data and find patterns and trends in your trials? Software can move the needle from failure to success. Sponsors are fortunate to have a wealth of data at their fingertips; Sponsors that make the best use of this data will succeed where others do not.



45. The most important person at your site: recruitment specialist

The crucial position for every site is the person responsible for getting in touch with patients who have shown an interest in being a part of your study. This person is a critical hire, and should be vetted to have the following characteristics:

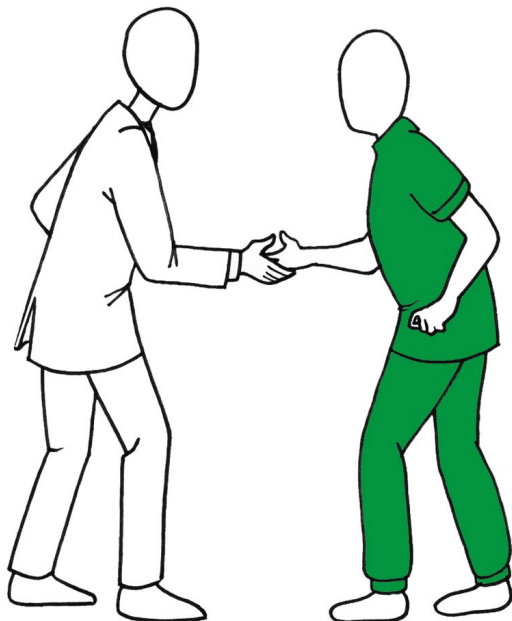
- Great communicator that is easy and pleasant to talk to, and will make your patients feel like they are being listened to and appreciated.
- Dedicated and organized. Look to hire someone that has a proven track record of organization and management skills. They should be able to handle multiple trials and patients at one time, but still remain friendly and approachable to patients during phone calls.

46. Double-down on Internet recruitment

No other medium allows for as much transparency and insight into future success patterns as the Internet. From a Return on Investment perspective, knowing your randomization / screening / failure rates across all channels—and knowing this in real time—is ultra powerful. This allows you to throttle up strategies that are succeeding and course-correct if something isn't working before your trial ends.



Thank you !

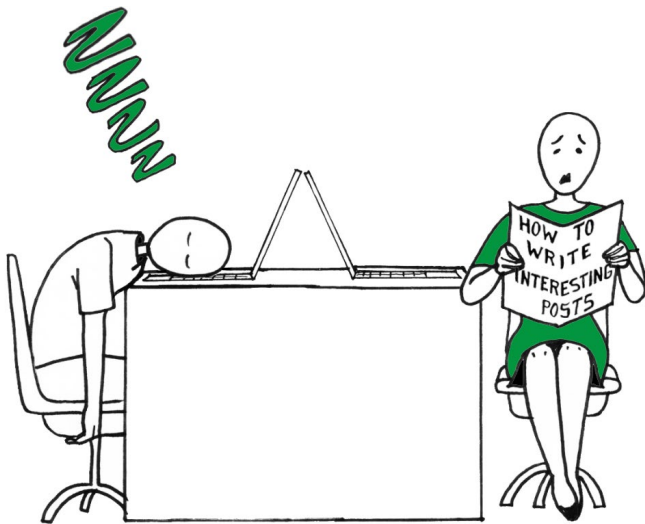
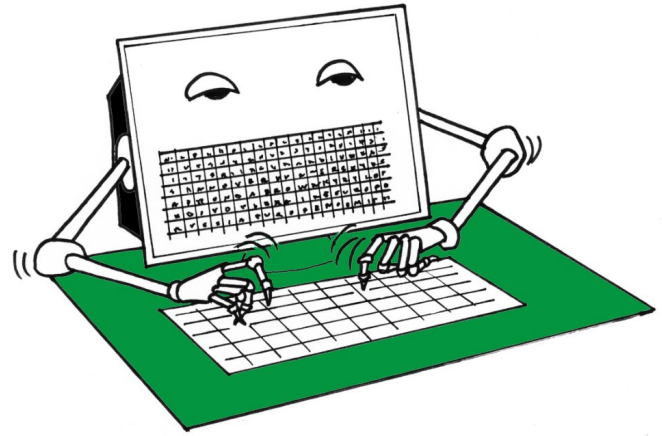


47. Patient appreciation is key

An overlooked factor to running a successful trial is to make sure your patients know they are appreciated. Without them, there would be no advancements in medicine! Establish personal, not just clinical, one-on-one contact with each of your patients.

48. Automate any process you can

Update your systems to automate processes that might take your staff away from doing more important things (like talking to your patients!). Use cloud-based software to manage all aspects of your site and seamlessly share with your entire staff.



49. Social media is only as good as the person updating it

Ask yourself: if you were a patient, would you be interested in receiving this email, newsletter, Facebook post, etc.? If the answer is no, then make it better. Think of something more valuable to offer patients in the way of information, prevention, or education.

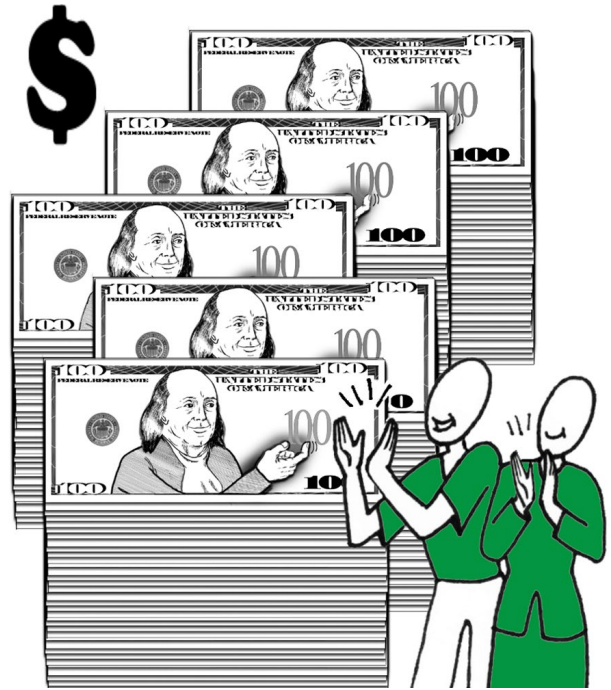
50. Sponsors: stay “top of mind” with your sites

Qualified clinical trial investigators have various trials and responsibilities competing for their attention. As a Sponsor, what can you do to delight your site? A clinical trial site will recruit for your trial first if you provide tools and resources to save them time and energy. Provide thoughtful items (source documents, inclusion/exclusion reminder cards, pocket protocols, IRB-approved advertising materials, etc.) that can be used when screening subjects or starting up a trial to motivate and assist the site staff to recruit for your trial. Stay in touch regularly to remind the site personnel of the study objectives and encourage ongoing recruitment.



51. Money will motivate

Clinical trial site payments from Sponsors should not be coercive, but they should be fair and reasonable to reimburse for actual costs of recruitment and conduct. Don't nickle and dime when negotiating clinical site contracts; arguing over nominal amounts for individual fees and other small items can strain your relationship with the site. Ill will bred through budget negotiations can have a negative impact on recruitment. Even worse, if the margins aren't good enough for the investigative site, they will be less likely to prioritize recruitment for your trial. Ask the site for guaranteed enrollment and request refundable start-up fees to confirm the recruitment goals.

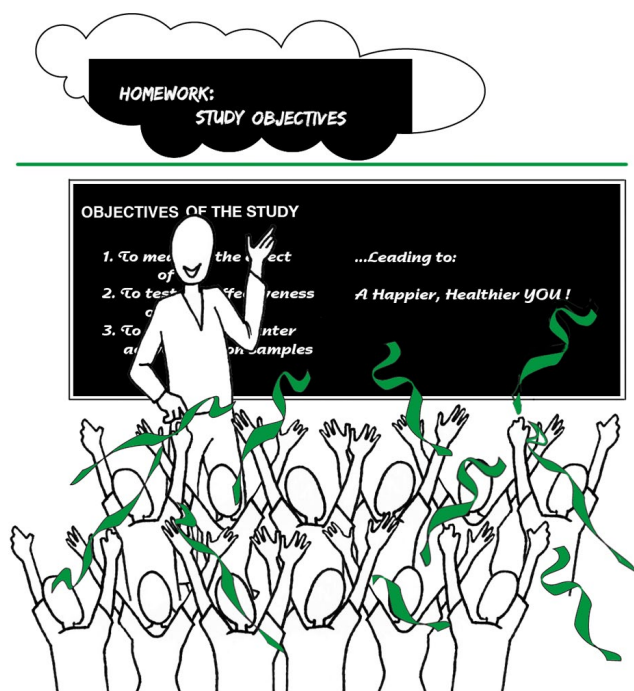
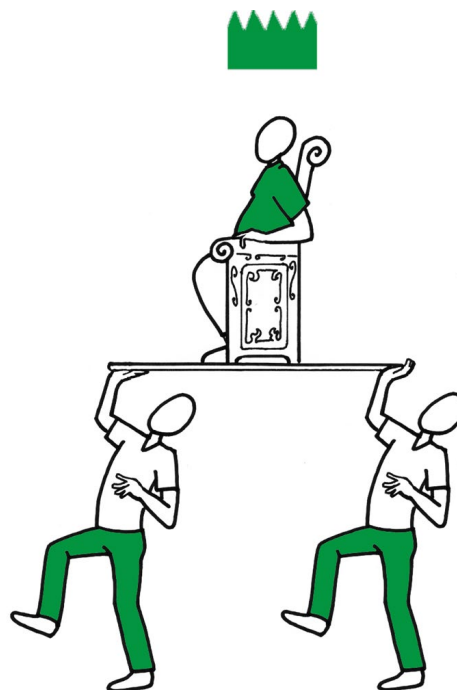


52. Recruitment starts before the screening visit

Outreach to potential study subjects can begin before the screening visit by sharing IRB-approved advertisements, letters to other clinicians, and the Informed Consent Form earlier to your patients and their families. Subjects can arrive at the screening visit having given the trial more consideration and also having prepared questions. As they will be more informed about the trial objectives and requirements, the subjects that receive trial information prior to the visit will also be more likely to consent.

53. Quality subjects versus a large quantity of subjects

Clinical trial sites must closely observe the inclusion and exclusion criteria for a trial. Then, sites must only include subjects who will adhere to all study requirements and complete all planned assessments. One patient included in the analysis set is more valuable than a handful of patients who are excluded due to non-compliance. Focus on recruiting only quality subjects that are appropriate for the trial.



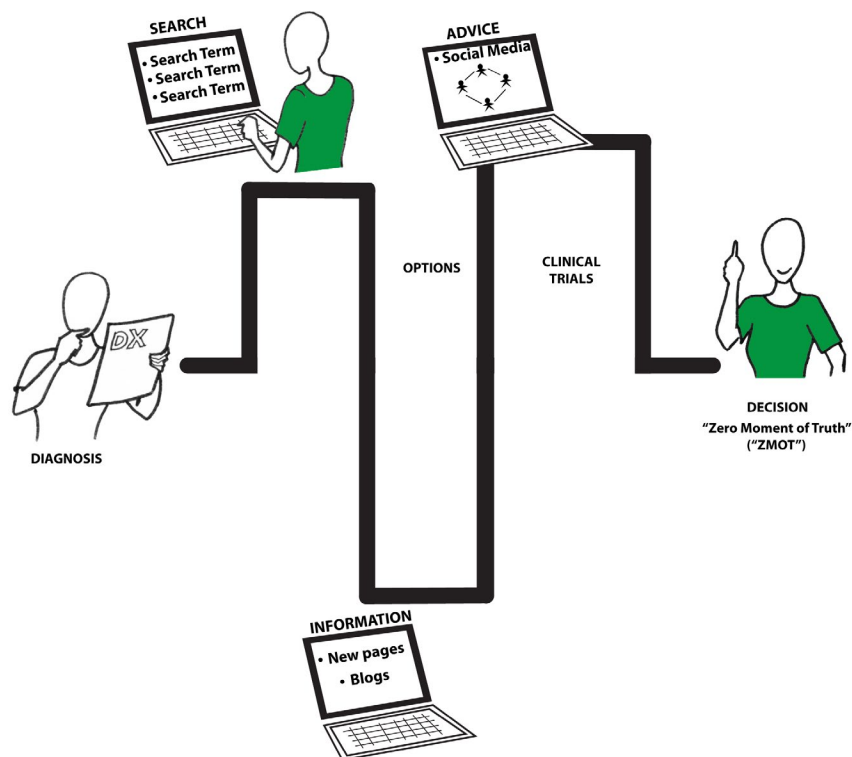
54. Know (and be able to explain) the trial objectives

Whether you engage with your patients through advertising, your database, social media, or routine visits, you must impress upon them the goals of the study early and often. As investigative site personnel, participate only in trials that you are excited about. If the science is good and you believe that the research is important, then you will more easily be able to explain to your patients why you are asking them to join the study. If you share your enthusiasm and understanding of a study with prospective participants, you will recruit more subjects in a clinical trial.

55. Make your website work for you

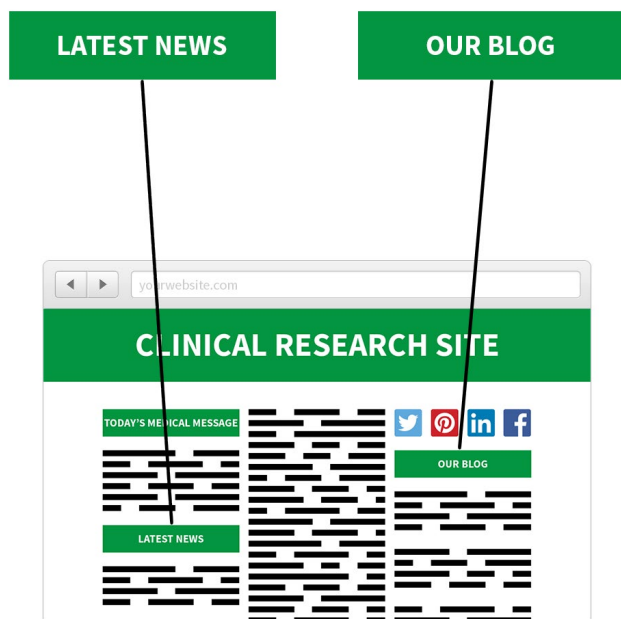
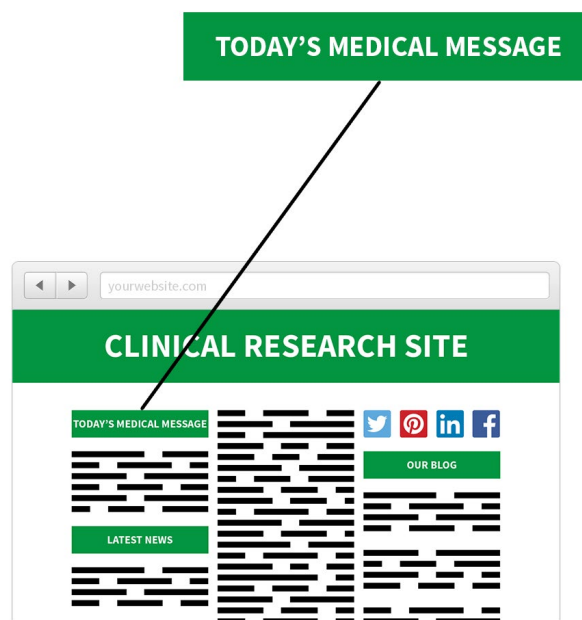
If you are thinking about purchasing a new product or service, would you conduct research online to find out your options, read reviews, and pick the one that is right for you? Many people usually do, and it's a growing trend among most consumers. Google market researchers have coined this the "Zero Moment of Truth (ZMOT)," or when a person decides that he or she needs to solve a problem and begins to research options that eventually lead to a purchase. Recognizing this new model, many companies have begun to engage potential buyers online.

So what does selling a product or service have to do with recruiting patients? Well, quite a bit, actually. Potential research participants are very similar to potential buyers. For example, if a patient has a health condition, he or she may turn to the Internet to find out about options. It's at this time, the "Zero Moment of Truth," that a site and its trials must be visible online so that research participants can find trials that are a good fit for them. How do you get started engaging potential research participants online? Here are a few steps that will help your site.



55.1. Update your website

It's important to provide clear direction for your website visitors. If it's a potential patient, is it easy for them to find information about the trials that are open? The information should be well organized on your website to facilitate this. Also, the language that is used should be friendly and invite visitors to learn more.



55.2. Add a blog and/or news page

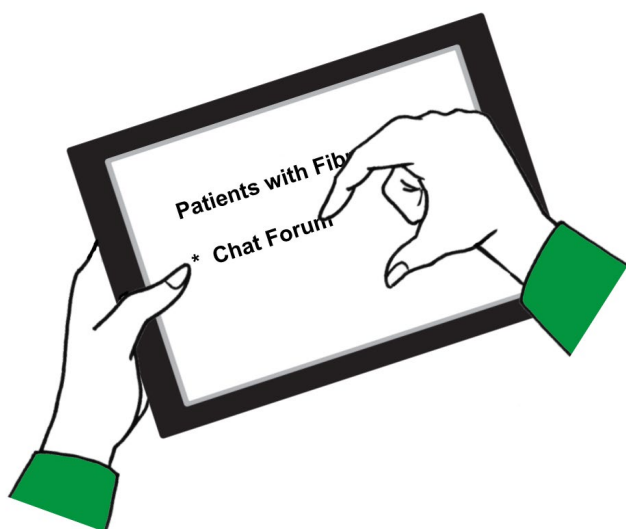
This can help with search engine optimization, which means that patients will be more likely to find you based on the terms they search for online.

55.3. Set up social media accounts

Even if you don't have a plan for messaging through the accounts, it's a good idea to secure the name of your site online (before someone else does). It's also advised to create a master document with the logins and passwords for the accounts to reference when needed.



56. Completely understand your patients



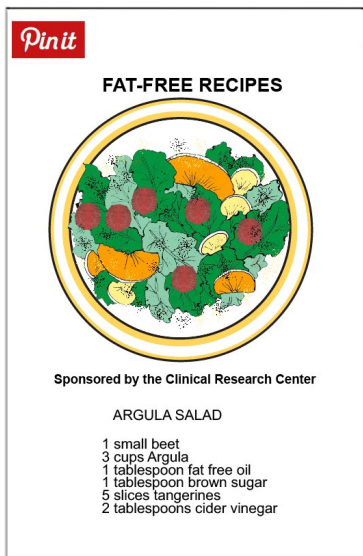
56.1. The right place

Where are your patients spending their time online? Perhaps they're on social sites such as Facebook and LinkedIn (which every site should be active on). But also consider what their interests are. Are they spending time in specialized chat forums, perhaps speaking with others about their condition? Also, consider how they are accessing this information. Are they active on smartphones and tablets? Ensuring your content—both text and graphics—is easily readable on these smaller-screened devices may be something to consider.

56.2. The right time

Timing is important in the ZMOT process, as it is crucial that you stay in front of your ideal patient population. Consider the frequency in which you engage in online activities. It is also important to note that repetition can play a big role in the decision-making process. How often is your target demographic seeing your content? Be consistent and offer value.

Sun	Mon	Tues	Wed	Thurs	Fri	Sat
	1 <i>Blog post</i> <i>website</i>	2 <i>Blog post</i> <i>website</i>	3 <i>Pinterest article</i>	4 <i>Blog post</i> <i>website</i>	5	6 <i>Blog post</i> <i>website</i>
	7 <i>Facebook, Twitter</i>	8	9	10 <i>Facebook, Twitter</i>	11	12 <i>Facebook, Twitter</i>
13 <i>Blog post</i> <i>website</i>	14 <i>Facebook, Twitter</i>	15 <i>Blog post</i> <i>website</i>	16 <i>Blog post</i> <i>website</i>	17 <i>Pinterest article</i>	18 <i>Pinterest article</i>	19 <i>Blog post</i> <i>website</i>
20 <i>Facebook, Twitter</i>	21	22	23	24 <i>Facebook, Twitter</i>	25	26
27 <i>Blog post</i> <i>website</i>	28 <i>Facebook, Twitter</i>	29 <i>Blog post</i> <i>website</i>	30 <i>Blog post</i> <i>website</i>	31 <i>Pinterest article</i>	1 <i>Pinterest article</i>	2 <i>Blog post</i> <i>website</i>
3	4 <i>email from list</i>	5	6	7	8	9
10 <i>Blog post</i> <i>website</i>	11 <i>Blog post</i> <i>website</i>	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30
31	1	2	3	4	5	6



56.3. The right content

What does your potential patient want to see? What are they searching for? Are they a diabetic who is looking for new sugar-free recipes? Are they moms who are looking for tips to help with their child's eczema? Providing the type of content that appeals to your target audience will improve your credibility and increase the chance that members of your audience will reach out to you to learn more about a study for which you are enrolling.

Tips by Quintiles Early Clinical Development

Submitted by Benjamin Sieve

StudyForChange.com

57. Customer Service is what will separate you from your competitors

Volunteers want to be comfortable while participating in a trial at your facility. If they are treated with respect and care, it will increase their chances of participating in research again.



58. Connect to your patients through social media channels such as Facebook

Provide your patients with interesting content, such as articles, info-graphics, facts, and tips, rather than just advertisements. This will likely allow them to be more receptive to your brand when you do use an advertisement.



59. Education is king

At every opportunity, allow patients to ask questions. Educating the public on what you do is important not only to helping people understand the study, but also to helping people to understand the drug development process and where they fit in.

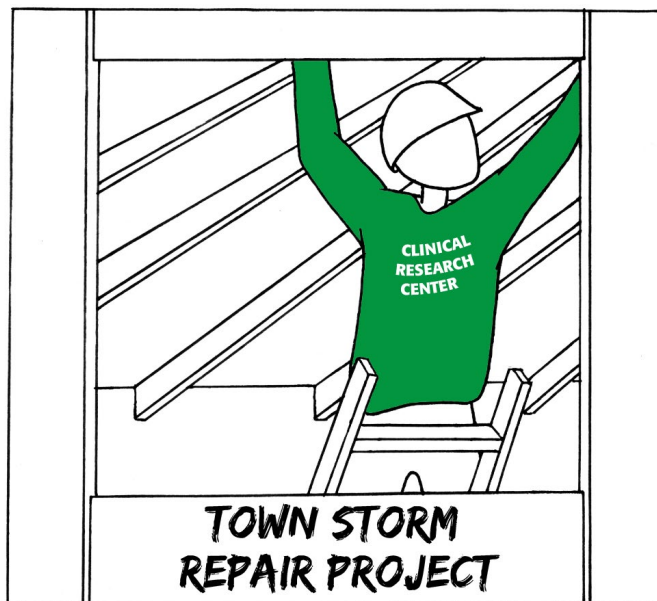


60. Personal referrals can be the greatest source of advertising

Treating patients with respect, one of the basic principles of Good Clinical Practice, and providing education about the benefits of clinical research will often lead to your patients providing a positive referral to others. These personal referrals will hold much more weight than a radio or TV ad ever could.

61. Get involved with the community

The more patients that see your company supporting causes, the more likely they are to come by and talk. Getting involved with the community will also increase your visibility and credibility with local businesses, which could lead to fruitful partnerships.



63. Take time to thank your volunteers

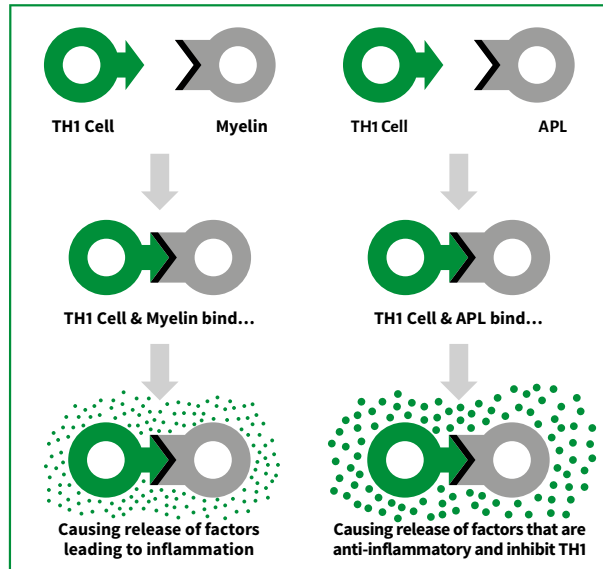
Volunteers are extremely valuable. Participants volunteering their time for a study are potentially helping millions of lives across the globe. Remind them that they are deeply appreciated.

62. Create a consistent brand image

Unify your brand image across all mediums. Use similar messages, colors, logos, etc. This will increase your brand recognition and make the market much more comfortable with your company.



Subject Information Sheet: The MS APL Study



The APL Concept:

Lorem ipsum dolor sit amet, consectetur adipiscing elit. Nullam placerat enim sodales convallis placerat. Vestibulum congue facilisis elit at consequat. Fusce placerat, enim bibendum lobortis accumsan, justo tellus tempus lacus, at commodo purus est in leo. Cras auctor ligula in nisl semper dictum. Cras in lacinia odio. Fusce molestie dolor non congue facilisis. Maecenas nec molestie nisl. Praesent vel accumsan ligula, ac dapibus orci. Mauris sit amet dolor sed magna hendrerit aliquet nec quis urna. Nulla vulputate dignissim felis vel dapibus. Nam congue ligula nec ligula malesuada, at consectetur urna rhoncus.

64. Simplify and explain

Provide an easy graphic that helps explain the clinical study in lay terms to the study subject. The Informed Consent Form is usually too long for a subject to truly absorb all of the information. Depicted is a sample Subject Information Brochure that the Sponsor can provide to assist with this task. This tool requires IRB review and approval.

65. Set expectations

The study coordinator should review the potential study visit dates with the patient early in the enrollment process so that the expectations and the amount of time required are well understood before enrolling in the study. This can be the time to look ahead at potential timing around vacations, holidays and other life events.



**Protocol XXXXX
Patient Time and Events Scheduling Tool**

Patient: _____ / _____
Number Initials

Date Consented: _____

Group (check one):

- ☐ Group 1
☐ Group 2

Qualification Screening Visit	Cycle 1 and Cycle 2 Visits	Assessment 1 Visit (10 weeks after Cycle 1 completed)	Cycle 3 and Cycle 4 Visits	Assessment 2 Visit (26 weeks after Cycle 1 completed)
Enter Dates Scheduled	Cycle 1: Cycle 2:		Cycle 3: Cycle 4:	
Sign Informed Consent	Stop Drug 1 prior to hos- pital admis- sion		Stop Drug 1 prior to hos- pital admis- sion	
Assess ability to carry on daily activities (ECOG PS)	ECOG PS	ECOG PS	ECOG PS	ECOG PS
Date of Birth, gender, height, weight, race and ethnicity	Physical Exam	Physical Exam	Physical Exam	Physical Exam
Study staff review Medical Records to en- sure meets all study requirements (Inclu- sion/Exclusion) including cardiac rhythm	Report Events since last visit	Report Events since last visit	Report Events since last visit	Report Events since last visit
Leftover Tumor Biopsy Tissue, or request new biopsy				Continue Drug 1
Collect information about the medica- tions you are currently taking	Drug 2 dosing		Drug 2 dosing	
	Daily Assess- ment of cardi- ac rhythm		Daily Assess- ment of cardi- ac rhythm	
Group 1: Begin Drug 1 Group 2: Continue Drug 1	Start Drug 1 after dis- charge	Continue Drug 1	Start Drug 1 after dis- charge	Continue Drug 1
		Tumor Re- sponse As- sessment		Tumor Re- sponse Assessment

66. Review study milestones

The study coordinator should review the tasks for each visit with the patient. Depicted is a sample Patient Scheduling tool that the Sponsor can provide to assist with this task. Actual scheduled visit dates can be entered at the top of each visit description. This form requires IRB review and approval.

67. Utilize Sponsor-provided recruitment materials

The Sponsor can provide prepared recruitment materials and get central IRB approval in advance of the study startup. The various patient recruitment approaches can then be presented at the Investigator Meeting. Sites can modify these as appropriate and potentially get expedited IRB approval.





68. Create marketing relationships

Primary investigators and study coordinators can reach out to the marketing departments at their hospitals. One example site has a marketing coordinator who always pays close attention to the site investigators and emphasizes having a great relationship with the local TV stations. She asked to attend the Site Initiation Visit, which gave her a solid background to successfully pitch a story about the study treatment to a local TV station.

Banks Group, LLC

Tips submitted by Avie Banks

Banks Group, LLC is a certified clinical research company with over thirteen years of clinical research experience in site, vendor, personnel, and data management. Banks Group is a Licensed Training Provider through the American Red Cross, with instructors providing training and skill certification in Adult and Pediatric First Aid/CPR/AED. Banks Group is able to support you in whatever your clinical research short or long-term needs are, including clinical study operations management, site support, and staff training.

banksgroupllc.net

Bio-Optronics

Tips submitted by Kyle Ricketts and Sergio Armani

Tips were provided by Sergio Armani, Director of Global Business Development, and Kyle Ricketts, Marketing Specialist, of Bio-Optronics, the makers of Clinical Conductor Site and Enterprise CTMS Applications. Clinical Conductor Enterprise CTMS is the leading enterprise-level clinical trial management system, giving organizations the ability to revolutionize their clinical and business operations by centralizing information from multiple research locations into one application. Clinical Conductor Site CTMS, the market-leading, site-specific trial management solution, is used in over 1,600 organizations around the world.

bio-optronics.com | bio-optronics.com/Blog.aspx | twitter.com/BioOptronics

ClinEdge

Tips submitted by Erin Phares

ClinEdge is a full-service business development and marketing company. ClinEdge strives to increase the productivity, innovation and revenue of their clients through personalized services and a profound understanding of the clinical research industry. ClinEdge's business development team represents a network of experienced, highly-qualified research sites. Using the ClinEdge network accelerates the site selection process and ultimately amplifies the success of clinical trials. ClinEdge's marketing and engagement team offers a range of traditional/interactive marketing and patient recruitment services. Their evocative

marketing techniques are designed to increase patient engagement while enabling site staff to remain focused on what matters most: excellence in research and patient care.

clin-edge.com

Clinical Trials of Texas, Inc. (CTT)

Tips submitted by Dale Korth

Clinical Trials of Texas, Inc. (CTT) is a standalone research site based in San Antonio that has been conducting Phase I-IV studies since 2001. Operating in a wide variety of therapeutic areas such as diabetes, psychiatry, vaccine, women's health, dermatology, device, cardiovascular and many more, CTT has established itself as a nationwide leader of clinical research sites. With a dedicated QA/QC, regulatory and recruitment department, CTT is recognized as a site capable of rapid enrollment, fast startup and all while still meeting the highest quality standards.

SAresearch.com

DAC Patient Recruitment Services

Tips submitted by Melynda Geurts

Melynda Geurts, Vice President of Operations at DAC Patient Recruitment Services, is a 20- year industry veteran with expertise that spans protocol planning, recruitment and retention, global regulations, emerging markets, and more. A respected presenter, trainer, writer, and mentor, she has been instrumental in DAC's rise from a niche SMO to a global recruitment and retention leader. DAC is part of the Imperial Family of Companies—a clinical research support organization with 60 years' combined experience in 40+ therapeutic areas and 100 countries.

dacprs.com

Donna Karsnick

Tips submitted by Donna Karsnick

Donna Karsnick is currently a consultant working with clients in the pharmaceutical industry. Prior to that, she was the Director of Global Recruitment and Retention at Eli Lilly and Company. In this leadership role, she was responsible for providing accurate patient enrollment predictions, tailored recruitment and retention strategies and value-based Return on Investment. Responsibilities spanned all therapeutic areas for Phase

IB-IV global trials. Prior to this role, she was an Advisor, Clinical Project Management for the Psychiatry team, responsible for the clinical development programs for several high-priority Neuroscience molecules. She is an advocate for process improvement and has held leadership roles on many Six Sigma projects. She has expertise working with alliance partners and has widespread international experience including Eastern Europe, Japan, and China. Educated in eastern Pennsylvania, she received her Bachelor of Science in Nursing degree from Messiah College.

[linkedin.com/in/donnakarsnick](https://www.linkedin.com/in/donnakarsnick)

Integrated Clinical Trial Services, LLC

Tips submitted by Gregg Sweet

Gregg Sweet, MBA, ICTS VP Strategy & Development, joined ICTS as one of its founding partners after having successfully operated his own firm since 1995, Clinical Communications Group, a patient recruitment company. He is responsible for the development of ICTS products and client strategy, working with Sponsors to develop and implement integrated tactics to increase the efficiency of clinical trial investigator meetings, patient recruitment, enrollment conversion, retention and post-marketing programs. Gregg has successfully planned and executed hundreds of patient recruitment programs including international, full-scale centralized recruitment involving over 20,000 subjects. He works closely with Sponsors to identify processes that can decrease cost and increase operational efficiency by providing a flexible, zero-base planning method focused on the specific requirements of the protocol.

[icts.us](https://www.icts.us)

inVentiv Clinical Trial Recruitment Solutions

Tips submitted by Jim Kremidas

Jim Kremidas has over 26 years of experience in the healthcare industry, including positions in the lab, sales, marketing, strategic sourcing and clinical operations. He has particular expertise in the field of clinical trial enrollment and is an internationally renowned thought leader on topics related to the design, implementation, and tracking of successful clinical trial enrollment campaigns. He has extensive experience in supplier management, negotiations, marketing management and clinical trial recruitment.

inVentiv Clinical Trial Recruitment Solutions (iCTRS) is part of inVentiv Health, Inc. Led by a team of industry experts, iCTRS enables trial Sponsors to effectively assess study feasibility,

accelerate recruitment and reduce study timelines by engaging patients, caregivers and study sites. iCTRS's communications strategies for recruitment, retention and engagement are informed by patient and physician insights that are deployed through a flexible suite of tactics ranging from more traditional methods to innovative digital and mobile technologies and social networking.

inventivhealth.com

KMED Marketing

Tips submitted by Kevin Ketels

Kevin Ketels is the CEO of KMED Marketing, which specializes in serving the healthcare and clinical research industries. In addition to 16 years of marketing experience, he also carved out six years of managing multiple clinical research sites, giving him broad industry perspective. Kevin is also an Adjunct Professor of Marketing in the School of Business Administration at Wayne State University.

kmedmarketing.com

launchcure

Tips submitted by Christina Gilmartin

LaunchCure is powerful patient recruitment software that uses prediction, not guesswork, to recruit patients. LaunchCure delivers the highest standard of qualified, randomized patients for clinical trials. By leveraging powerful behavioral targeting algorithms, LaunchCure recruits the right patients at the right time for the right studies.

launchcure.com

Nadia Bracken

Tips submitted by Nadia Bracken

Nadia Bracken, Clinical Program Manager based in San Francisco, has eight years of Phase I-IV clinical operations experience in a variety of therapeutic areas for trials in the US, Canada, South America, and Europe. Ms. Bracken has expertise as a Clinical Research Associate and Clinical Data Manager for pharmaceutical companies and CROs. Ms. Bracken is the author of the "ClinOps Toolkit" and "The Lead CRA" blogs.

[linkedin.com/in/nadiabracken](https://www.linkedin.com/in/nadiabracken)

PatientWise

Tips submitted by Annie Garvey

Annie Garvey has an extensive history of applying commonsense marketing and recruitment tactics for clinical trial patient recruitment. She has a keen focus on optimizing available advertising dollars allotted to sites to ensure measurable and scalable results. Ms. Garvey is a strong proponent of mixing traditional and online tactics to generate strong subject referrals. She graduated from DePaul University and resides in Madison, Wisconsin.

PatientWise Creative is a full-service patient recruiting and marketing agency for clinical trials. Whether you are looking for healthy volunteers, or have a hard-to-recruit patient population, PatientWise is there to optimize your recruitment effort. PatientWise is committed to a common sense approach to both central and local campaigns.

patientwise.com | twitter.com/PatientWise | facebook.com/patientwisecreative

Quintiles Early Clinical Development

Tips submitted by Benjamin Sieve

Quintiles Early Clinical Development specializes in Phase One clinical research. Their state-of-the-art facility in Overland Park, Kansas was built in 2007 and houses up to 150 volunteers at one time, making it one of the newest and largest Phase One clinics in the world. Quintiles Early Clinical Development strives to continue their goal of bringing people and knowledge together for a healthier world.

StudyForChange.com

Regulus Therapeutics

Tips submitted by Jacqui Blem

Jacqui Blem has been working in clinical research at small biotechs, CROs and large pharma companies for over 15 years. Currently the Director of Clinical Operations at Regulus Therapeutics, she has a breadth of experience managing development of compounds from Phase I through IV, as well as development of In Vitro Diagnostics and medical devices. Jacqui has worked across multiple therapeutic areas including CNS, endocrinology, Cardiovascular, Women's Health, and Oncology.

regulusrx.com