Patient Recruitment

The Expanding Web of Clinical Trial Patient Recruitment

March 2014

ISR *reports*

Introduction

It is a poorly kept secret in the world of clinical trials that issues with patient recruitment and enrollment are the primary causes for missing clinical trial timelines. Most of us have seen the data. We know that for each day a company goes beyond the planned deadline for a clinical trial, that company could be losing as much as $600,000 in foregone sales of smaller products and as much as $8 million on blockbuster drugs. As necessity is the mother of invention, it comes as no surprise that sponsors and CROs are looking to any and all means by which to increase the rate of patient enrollment.

The costs associated with patient recruitment delays are not only high, but difficult to anticipate and control. Consistently updated regulations, newly developed media by which to attract patients and investigators, and selecting appropriate service providers for recruitment all play a role in patient recruitment dynamics. From the 30,000 foot view, ISR understands there are two primary ways clinical trial managers can find patients to fill their trials:

1. Pull: A patient can be pulled into clinical trials by way of their physician who happens to be a principal investigator for a clinical study. This method relies on the patient population of the physician/ site and the efforts of the investigator and their staff in identifying potential patients and enrolling them in the study. These types of recruitment efforts may be aided by in-practice recruiting tools (e.g. table tents, posters) and by paper or EMR chart reviews.

2. Push: A patient can also be pushed towards clinical trials. Using this method, patients are encouraged to find a particular investigator or site, typically one they may have little or no previous contact with. Pushing patients towards clinical trials may be done through media outlets such as television, social media, billboards, radio advertisements, email targeting, etc. In addition, outside services like patient networks and patient recruitment companies identify patients and attempt to push them towards clinical trials. Much of this white paper focuses on how these forces are used by clinical trial managers.

ISR has conducted primary and secondary research to uncover some of the fundamental trends in patient recruitment within the clinical trial space. ISR identified some of the industry leaders in patient recruitment and patient network services to get a sense of which providers drug developers use the most. Additionally, through primary research efforts, ISR gathered data that provide a high-level understanding of the patient recruitment outsourcing market – including both the current state of that market and future projections.
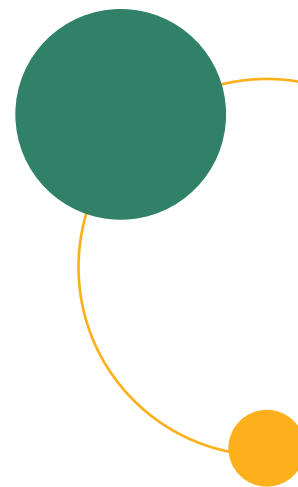
Overall, the use of standalone patient recruitment service companies and patient networks is relatively low, but their penetration is expected to increase. One thing that long-time watchers of the pharmaceutical industry will know is that sponsor companies often have a hard time changing. The industry is highly regulated and processes have been built around these regulations. Taking different approaches takes time to implement. If you think about the traditional product/ service adoption curve, some sponsors and CROs are early adopters and are

"experimenting" with these avenues for patient recruitment and some CROs are pushing hard with their own solutions.

AWARENESS ➤ ENROLLMENT

If standalone patient recruitment companies are going to have a significant impact on clinical trial recruitment, they will need to become experts at "pushing" patients towards clinical trials and converting awareness into enrollment. This will take time and pharma and CROs will want metrics to prove they are getting a solid return on their investment.

Primary data for this white paper were gathered from 102 survey respondents from mid to large pharma, biotech, and medical device companies who were asked a series of questions regarding their patient recruitment practices. The specifics of this primary research are detailed and further analyzed below.
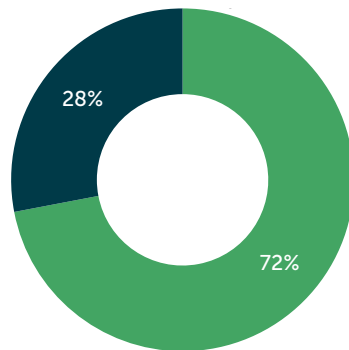
Where patients come from

These data suggest that currently 28% of patients in clinical trials are not active patients at the site. In other words, 72% of current trial participants are "pulled" into these trials and 28% are "pushed."

Respondents suggest that in two years' time there will be an increase in the proportion of patients that come from being "pushed" into clinical trials. Whether for need or desire, clinical trial managers and companies will have to invest in resources or find partners adept at enrolling clinical trial participants from outside of a site's realm of influence.

"Currently (and thinking 2 years into the future) what percent of the patients that enroll in your clinical trials do you believe are existing patients at an investigative site vs. those patients that are not existing patients and have to be persuaded to go to an investigative site? Please include hospital patients in the "already patients" segment below. Your best estimates are fine." (n=102)
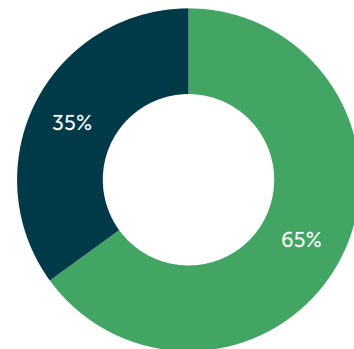
Current

■ Already patients at the site
■ Patients that are driven specifically to a site

2-year projection

■ Already patients at the site
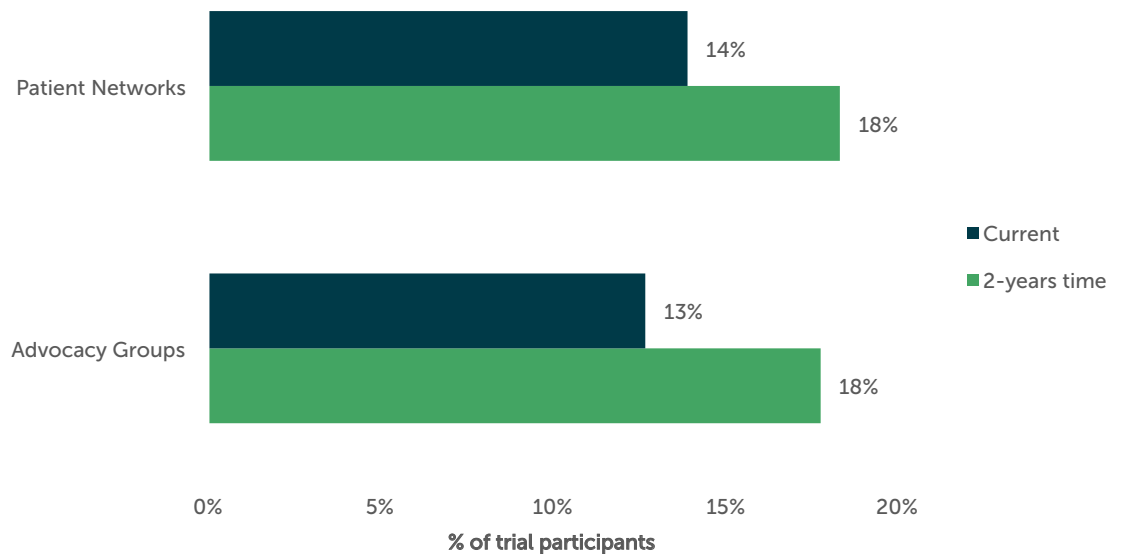■ Patients that are driven specifically to a site

Use of patient networks and advocacy groups

In previous research ISR discovered the potential power that patient networks (e.g. PatientsLikeMe) and advocacy groups (e.g. Multiple Sclerosis Society) can have when it comes to recruiting patients into clinical studies. Each type of organization has its own strengths, weaknesses, and policies when it comes to assisting the conduct of clinical trials.
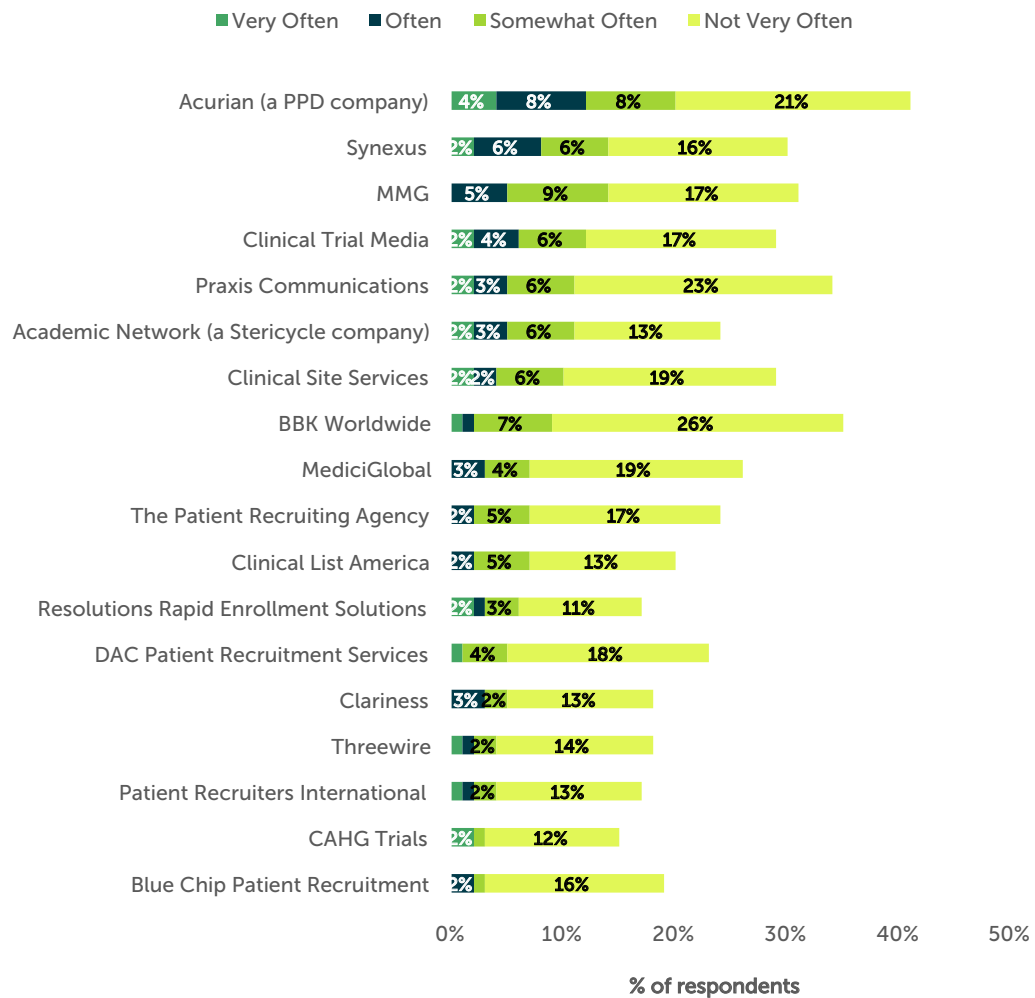
Currently, a minority of patients are recruited from these types of organizations. In two years' time, respondents suggest that trials will be garnering an increased proportion of patients from these types of organizations, which assumes the industry will develop stronger "push" strategies.

"Currently (and thinking 2 years in the future), what percent of the patients recruited into your clinical trials come from outside patient networks (e.g. PatientsLikeMe, Smart Patients, clinicalresearch.com) and from advocacy groups (cystic fibrosis foundation, Multiple Sclerosis Society, etc.)?" (n=102)

Patient recruitment company use

"How often does your company use the services of the following patient recruitment service providers?" (n=102)

■ Very Often ■ Often ■ Somewhat Often ■ Not Very Often

Company	Very Often	Often	Somewhat Often	Not Very Often
Acurian (a PPD company)	4%	8%	8%	21%
Synexus	2%	6%	6%	16%
MMG		5%	9%	17%
Clinical Trial Media	2%	4%	6%	17%
Praxis Communications	2%	3%	6%	23%
Academic Network (a Stericycle company)	2%	3%	6%	13%
Clinical Site Services	2%	2%	6%	19%
BBK Worldwide			7%	26%
MediciGlobal	3%		4%	19%
The Patient Recruiting Agency	2%		5%	17%
Clinical List America	2%		5%	13%
Resolutions Rapid Enrollment Solutions	2%	3%		11%
DAC Patient Recruitment Services			4%	18%
Clariness	3%	2%		13%
Threewire		2%		14%
Patient Recruiters International		2%		13%
CAHG Trials	2%			12%
Blue Chip Patient Recruitment	2%			16%

% of respondents

From these data, PPD's Acurian appears to be the industry leader for standalone patient recruit-ment services. One-fifth (20%) of respondents use Acurian as a patient recruitment provider at least "somewhat often" and an additional 21% of respondents have used them at some point. Overall, respondents report somewhat limited use of these providers, however the leading companies have been used by roughly 40% of respondents. Needless to say, this market is highly fragmented, which is typical for an industry in the early stages of development.
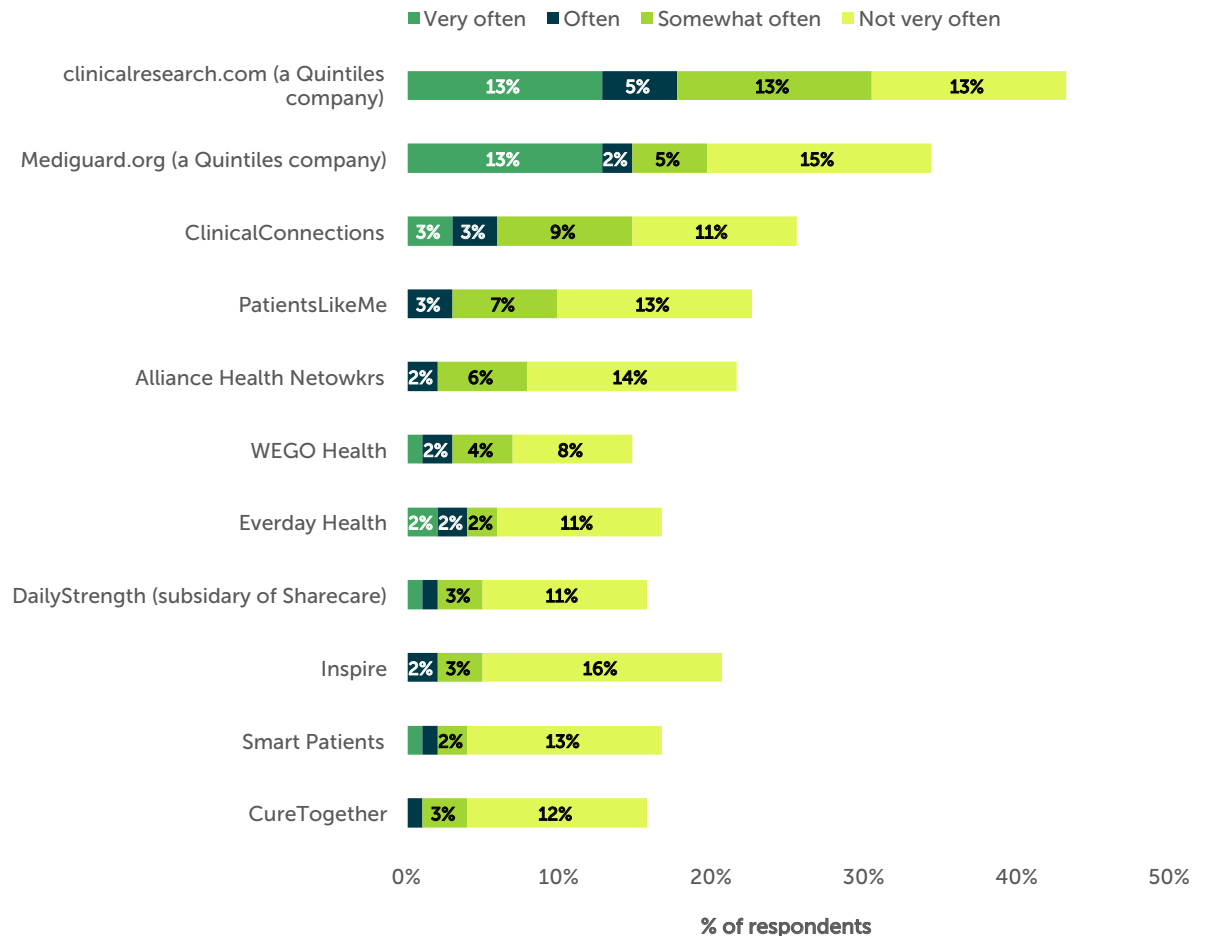
ISR also gave survey respondents an option of writing in service providers that were not listed as an option in our survey. Below is a list of the alternative patient recruitment providers:

- CCG
- Chandler Chico
- Dava Oncology (2 mentions)
- ePharmasolutions
- Galen Recruitment Services
- Hudson
- Innovative Trials (2 mentions)
- JLS
- Langland
- Local recruitment providers in respective countries
- Mediguard
- Moonlight Imaging
- Patient support networks
- PRA
- Quintiles (6 mentions)
- Therapeutic area patient support groups
- TMS Health
- X Factor

Patient network use

Similar to the patient recruitment service providers, ISR asked respondents about their usage of patient networks in patient recruitment efforts. Clinicalresearch.com, a patient network operated by Quintiles, is used the most frequently based on this survey with 31% of respondents indicating they use clinicalresearch.com at least "somewhat often." Mediguard.org, the second most frequently used patient network, was used at least "somewhat often" by 20% of respondents. Also similar to the patient recruitment service providers, the patient networks do not exhibit much variance in the usage besides the two primary providers (clinicalresearch.com and Mediguard.org). ClinicalConnections was the next most frequently used patient network, with 15% of respondents indicating they have used this network at least "somewhat often." Again, usage of these types of organizations is fairly uncommon, but growing.

"How often does your company use the services of the following patient networks to assist in patient recruitment?" (n=102)
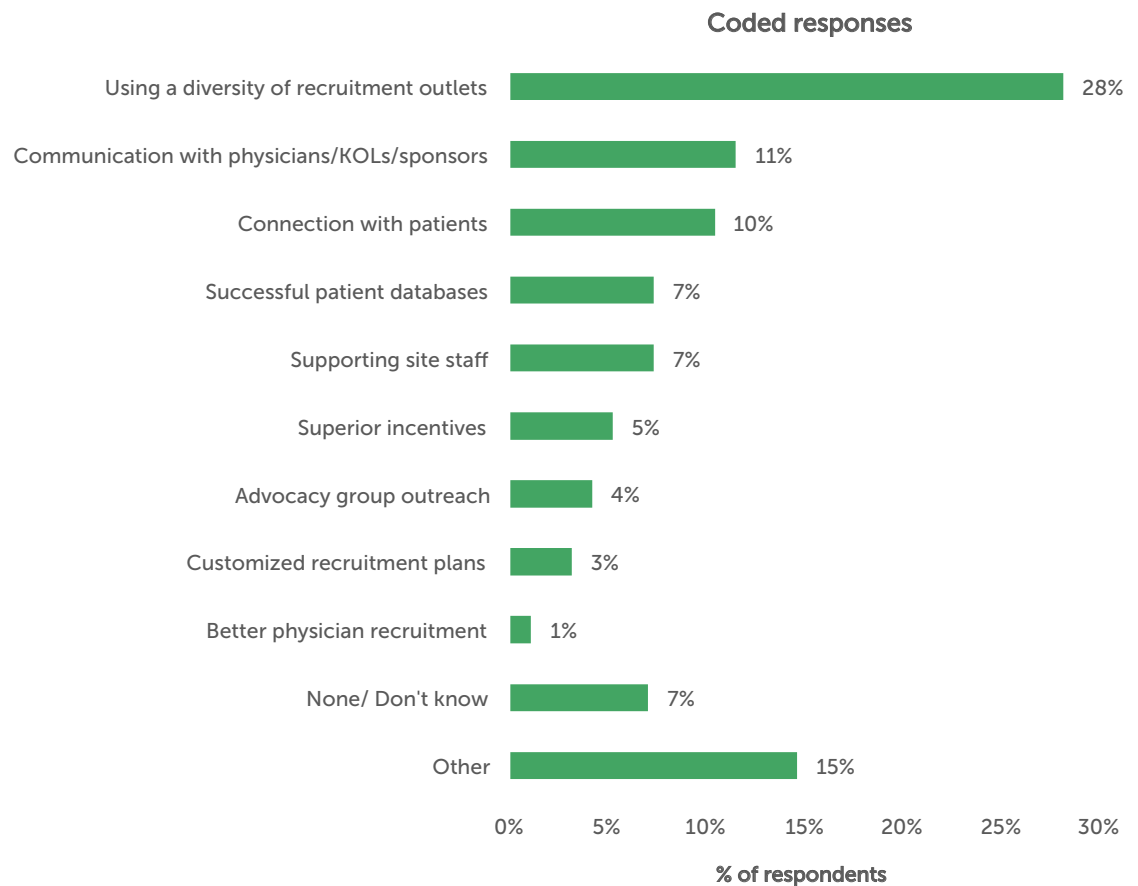
ISR provided respondents with an area to write in other patient networks they use. Several respondents stressed the point that they do their own patient recruitment.

- Clariness
- Climb
- Clinicaltrials.gov
- ClinLife
- Disease specific websites (2 mentions)
- Do own patient recruitment (3 mentions)
- NHS patient groups
- Oncology consortium
- Quintiles patient network
- Therapeutic specific groups
- Trial Reach

Best practices in patient recruitment

Of the best practices in patient recruitment listed by respondents, those relating to a diversity of recruitment outlets were most prevalent. For sponsors and CROs, this means it might be advantageous to develop a multifaceted approach to patient recruitment. For patient recruitment service providers, these same customers will be looking for you to develop and operationalize multiple avenues for enrolling patients.

"What are the best practices you are seeing in patient recruitment these days?" (n=102, open-ended question)

Coded responses

Category	% of respondents
Using a diversity of recruitment outlets	28%
Communication with physicians/KOLs/sponsors	11%
Connection with patients	10%
Successful patient databases	7%
Supporting site staff	7%
Superior incentives	5%
Advocacy group outreach	4%
Customized recruitment plans	3%
Better physician recruitment	1%
None/ Don't know	7%
Other	15%

% of respondents

Example verbatim responses:

"People who know how the patient thinks and what they want, integration of people suffering from the disease or touched by it in some way being involved in developing the recruitment strategies."

"Concentrating on supporting the site staff who have to convert the referrals via digital and other means. Simplicity is the new innovation."

"Sharing risk with sponsor (payment by result); Work with patient associations; Establish grass roots efforts in the community to increase awareness to clinical trials via a combined effort of pharma and non-profits, such as CISCRP."

"Directing sites on an individual basis to provide support as the site needs it. Site analysis that leads to an approach that fits for that site."

"Plan up-front, set money aside and don't wait to implement as a rescue effort."

"Getting studies set up at renowned sites who receive referrals from several feeder sites with a highly motivated investigational team."

"Referrals being provided to the sites by the recruitment companies. If our sites are using a patient recruitment company, they are much more likely to find a candidate through a referral than through educational material being displayed on site."

"Existing patient databases. We've noticed our advertising has become less effective more and more and that the sites themselves are recruiting patients, despite our social media efforts in advertising."

"Focus on diversity in clinical trials, we are building up an internal group to avoid use of vendors who deliver little for the cost of their services, use of technology to engage patients."

"Using patient insights to identify patient motivations and anticipate protocol challenges. Assessing site potential and leveraging site intelligence to customize strategies to the local level."

"Site / patient interaction is important to ensure the patient is comfortable with the medical care they will be provided over the course of the clinical trial. I find the higher level of site outreach (local health fairs, community events) I've seen recently to be an important tool in recruitment efforts. In general, I find that all efforts made directly by the site to bring in patients provide better quality research subjects. While recruitment companies can be very successful "getting a patient in the door," retention or that subject can be challenging."

Implications

The data gathered for this paper offer some interesting implications for a number of different players in the clinical trial process.

Pharma, biotech, and medical device companies

- Many of your colleagues are "experimenting" with standalone patient recruitment companies and advocacy groups. People responsible for patient recruitment activities are expecting a higher proportion of their patients to come from outside of an investigator's practice over the next two years. Putting formal plans in place that force the use of these external companies will allow your company to stay on top of current methodologies/ strategies as well as learning which activities have the best return on investment.
- Based on these data and from some of ISR's other work, there is definitely a framework that can be established for patient recruitment strategies based on the indication and target population of the compound. The more customized you can make a patient recruitment strategy, the better chance it has of success. Planning early never hurts. Ask your service providers for a proactive or triggered plan for patient recruitment before the trial gets started.

Patient recruitment companies, patient networks, etc.

- You are working in a highly fragmented industry with a lot of variability in terms of trial specifics and often you are working in a matrix fashion involving multiple stakeholders (e.g. sponsors, sites, CROs, patients, caregivers, technology providers). This highly complex environment necessitates the development of financial and operational metrics to ensure the value of your services can be easily discerned.
- Further, data from this whitepaper provide these companies an idea of what service offerings are preferred by potential clients – a diversity of recruitment outlets and valued communication with physicians, KOLs, and sponsors. Use this to help craft marketing messages that resonate with customers.

Contract Research Organizations

- CROs with patient recruitment services can use these data to understand the competitive landscape around patient networks and standalone patient recruitment service providers.
- CROs should have a stated corporate strategy for optimizing patient recruitment. This is often what separates a CRO from winning or losing projects. For example, Quintiles has decided to try to build/ own several components in the patient recruitment process, whereas PRA has decided to partner with leading companies based on the needs of the sponsor. Both strategies have merit and can be successful. Having a strategy is often half the battle.

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