

Clinical Researcher

The Authority in Ethical, Responsible Clinical Research

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**Overlooked No More: Leveraging Lesser-Known Roles, Designs, and Tactics for
Success in the Clinical Research Enterprise**

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Clinical Researcher

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EXECUTIVE DIRECTOR'S MESSAGE

Passion, Potential, and Patience

Susan P. Landis



I am almost 60 days in as the Executive Director of ACRP. It's been an exciting whirlwind of information and insights. I want to give an enormous shout-out to the ACRP staff for being flexible, understanding, and supportive as I continue to onboard. I also want to acknowledge the encouragement of our board members, fellows, and chapters, and acknowledge the input they have shared that inevitably will be embedded in the blueprint for the Association's future.

Three themes have consistently emerged. First, the *passion* of our volunteers is palpable. Every ACRP member I have spoken with conveys a deep commitment to the organization and a desire to participate fully in its success. Thank you.

That enthusiasm is matched by a deep belief in the Association's *potential*. As our Board Chair Erika Stevens writes in her message for this issue, innovation in clinical research has the potential to change fundamentally how we study and improve human health. We have—you have—the opportunity to innovate—to transform how clinical research is imagined and implemented. The potential is unlimited.

Finally, *patience*. As one volunteer said recently, "Let's take a breath and determine where we go next." Asking "what's next" is where I'm focused, albeit impatiently! I feel a real sense of urgency to harness the passion and potential of ACRP for our clinical research professionals and for the benefit of the participants and patients we serve. Yet, I know that taking the time to identify both the possibilities and improvements needed will result in a more cohesive, more fruitful future for ACRP.

Thanks to all for your support. I share your excitement and enthusiasm for the future.

Susan P. Landis (susan.landis@acrpnet.org) is Executive Director of ACRP.

CHAIR'S MESSAGE

Innovation in Clinical Research

Erika Stevens, MA



How can innovation support the clinical research workforce?

The topic of innovation may not typically resonate within said workforce, but leveraging this framework could be the key to sustainability in the overall clinical research enterprise.

Innovation focuses on larger scale transformation initiatives that are cross-functional and tied to specified outcomes. In the field of clinical research, which is driven by data, constrained by time, and compelled to regulatory compliance, new initiatives could bring vast improvement.

Some examples of transformation in the clinical research workforce include remote data review, risk-based monitoring, and electronic data capture. These innovations redistributed the workforce, enabled real-time information, and improved the quality of data—all of which contribute to accelerating workforce performance to bring therapies to market and ultimately improve health.

The first step in the innovation continuum is to assess the current issue or problem. For example, the clinical research workforce quickly needed to pivot and respond to the global pandemic. The next phase of innovation is to bring forth a solution or multiple solutions. The activity of identifying the improvement should leverage current tools, methods, and technologies to reframe the approach.

The new idea(s) should bring value and efficiency (cost, time, resources). The unique or “out of the box” solution improves quality and provides a benefit. The result is a positive shift in the business outcome, which requires a cross-functional review of the various business workstreams.

I wish you all the best jusqu’*a la* prochaine fois (until the next time),

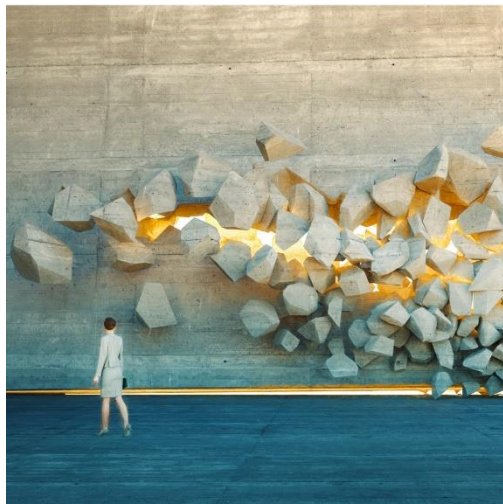
A handwritten signature in black ink, appearing to read 'Erika'.

Erika Stevens, MA, is the 2021 Chair of the Association Board of Trustees for ACRP.

PEER REVIEWED

Being an Independent Contractor: Seeking Success in the Workforce

Jerry M. Stein, PhD, ACRP-CP, ACRP-MDP, FACRP; Suheila Abdul-Karrim, CCRT, CCRA, ACRP-MDP, FACRP; Ernest Allen



The model has changed. Millions of people have exited full-time positions to work as independent contractors (ICs) in hundreds of industries. Experts say it is better for the economy. Do I care? Or what if I really need to know whether it is best for me, but it's too soon to know? This article provides guidance on career choices, essential business practices, and tools for ICs involved with clinical research to help you survive while working under this competitive model.

Who Are Independent Contractors?

For the purposes of this article, independent clinical research contractors include any clinical monitor, clinical project manager, statistician, medical monitor, data manager, and medical writer hired for a specific project or time period and not dedicated on a long-term basis to one employer.

If you fit into any of these job titles and if your relationship to your employer matches this situation, congratulations! You have joined a growing segment of freelance professionals. In addition, you are now a small business owner with one employee: you. You are responsible for everything; there are no more support services down the hall or a phone call away. This includes the business development (finding clients), legal (contract negotiations), payroll and benefits (taxes, 401(k)), information technology (equipment, help desk), purchasing (office supplies, toner cartridges), and insurance (liability) departments. It is all you.

While the change from employee to contractor is often an individual decision, there have been significant changes across the entire workforce. A U.S. government study estimated 22% of workers received income as ICs, with the largest growth during the 2001 to 2016 period occurring among individuals identified as primary earners.^{1} Thus, this is not just a “side-hustle” phenomenon among secondary earners. The same report found that the largest number of ICs (both men and women) were in the “professional, scientific, technical” sector followed by the “healthcare and social assistance” sector—two categories that likely include clinical monitors, study coordinators, and other clinical researchers. However, specific statistics regarding the number of clinical research ICs could not be found.

Forty years ago, most large sponsors employed everyone necessary to discover, test, manufacture, market, and support new drugs and medical devices. This A-to-Z approach required a long-term commitment to lots of employees and entailed significant financial risk to the companies.

Prominently beginning in the 1990s, the industry experienced downsizing that was triggered by economic downturns, mergers, and new corporate strategies.^{2-4} Today, a large portion of research and development risk has been transferred to independent clinical contractors and small companies. In various forms, employees who traditionally worked for sponsors are now either employed by contract research organizations (CROs)—some embedded at large sponsors—or hired as contractors directly from a marketplace filled with ICs.

The required workforce expands and contracts using individuals who serve on-demand in response to additions or losses of contracts, projects, or changes in scope. Many companies only hire contractors when there is a high probability that the company will be paid or will successfully develop a new product.

In some cases, hiring an IC with unique expertise or skills is essential for project success. In other instances, hiring the IC only occurs when internal resources are limited and it would be risky to hire full-time, “permanent” employees. It is not too dissimilar to situations in which sponsors employ investigational study sites on an as-needed basis. However, while income from

clinical studies is typically a side business for most sites outside academic medical centers, working for a sponsor is the primary source of income for most ICs.

What Are the Benefits of Being an Independent Contractor?

There are significant financial and non-tangible benefits to being a clinical IC (see Figure 1) and many of these features have been previously reported.^{5–7} Foremost is control of your schedule. While contracts and teams can significantly vary, it is often the case that a strict 9-to-5, mandatory schedule is not an expectation of most contract assignments. Although 50- or 60-hour work weeks are not uncommon, these high-pressure periods are often transitory, predictable, and may be voluntary.

Figure 1: Advantages of Being an Independent Contractor

- Flexibility
- Getting to choose projects
- Not getting caught up in company/office “politics”
- Working from your own office where YOU control the environment
- A wider range of experiences in different phases of clinical trials, with different therapeutic areas and at different companies

The contractor has the benefit of focus, flexibility, and choice. Being a contractor liberates you from many meetings that are not specific to your immediate job responsibilities and allows more time to focus on your assigned project. For parents with young kids, the work-life balance can be much better: drop the kids off at school, work six hours, pick up the kids, attend after-school activities, put the kids to sleep, and work some more when the house is quiet. For those with elderly family members, work can be planned around their treatments and schedules.

Contractors working across time zones can plan personal chores around team meeting schedules. Planning a two-week, international vacation? While there are no paid vacations, you can adapt by working longer hours in advance, delegating key responsibilities to other team members while you are unavailable, and/or refusing to take on an assignment that creates a conflict. The key to success is maintaining good communication with the company that hired you and the entire team. Almost every obstacle has a work-around.

There are also significant emotional benefits when you are not dependent on one supervisor or employer. You may realize a significant increase in self-esteem. You will likely develop significant pride in being a self-sufficient, independent business owner. Finally, you get to say “no, thank you” much more often. Perhaps anticipated, project-related air travel is too extensive. Perhaps you expect database lock pressures will be too much, the protocol too boring, or the therapeutic area beyond your comfort zone. Perhaps a better opportunity is on the horizon. Saying “yes” or “no” is your choice.

Finally, the existence of a significant number of clinical ICs has a particular benefit in the age of COVID-19 and in anticipation of future epidemics. While many employers faced challenges moving their employees from central offices to home settings, the ICs were already working from home offices and were ready to go,{8} which was a win-win for both contractors and sponsors.

Money Matters: Income

Improved compensation has been cited as one of the reasons individuals aspire to change from traditional employment to contracting.{6} The authors of the current article caution that this is not a guarantee—especially for newcomers.

The first step is a smart negotiation strategy, including knowing your marketplace value. How much are companies currently paying someone with your set of skills and experience? Can you justify a higher rate of pay by promising better responsiveness, efficiency, or skills?

When negotiating your compensation terms, remember that the company does not have to provide benefits frequently paid to so-called permanent employees (e.g., health insurance, disability, paid time off, and retirement). Traditional, full-time employee salaries are often 60% to 80% of total compensation budgets. Thus, a contractor’s higher hourly rate of pay is somewhat misleading.

Of course, in a competitive marketplace, you may decide to sell your services for significantly less than your peers in order to more easily land a contract. However, you may regret the

decision with every hour you add to your timesheet, and your perceived value to this employer will be forever diminished.

Developing a network of peers has an impact on your compensation and job satisfaction. Networking—in person or electronically—is not simply a social function. Information about customary compensation, as well as common job expectations, is often only available through word-of-mouth sources. This will require an investment of your time. Professional meetings and other educational opportunities are also excellent forums for learning your value.

What About Taxes and Insurance?

Although a contractor's income is generally higher compared to that of a full-time employee, you must be prepared to pay expenses and for financial surprises to pop up. The category of anticipated expenses includes insurance (general liability), income taxes (U.S.), value-added taxes (in some international markets), office supplies, travel considerations, professional dues, and training events.

Taxes vary from country-to-country and state-to-state. We will concentrate on the U.S. tax situation for simplicity, recognizing that the vast majority of our readers reside in the U.S. If you are paid as an IC, the company that hired you will typically not withhold federal, state, or local taxes. These tax payments are your responsibility, and some must be paid quarterly to avoid penalties. This requires planning and discipline.

Contractors must also pay for their own medical insurance and consider their options for paying for dental and vision care services. Planning for a comfortable retirement requires lots of time and, often, some short-term sacrifices. Finally, not all companies pay promptly; receiving a check 30 or 60 days after submission of an invoice is not unusual.

Most major companies require clinical ICs to have professional liability insurance, and some require workman's compensation insurance. Premiums will vary with your role and responsibilities. For example, medical writers frequently document actions that have occurred already and are outside their control. Therefore, liability insurance (e.g., errors and omission insurance) for medical writers should be relatively inexpensive.

In contrast, if you are making decisions that directly impact the health of patient volunteers, higher premiums may be required. Although the chances of being sued are very small, securing these type of insurance policies is a common requirement based on our experience. Companies often require a minimum dollar level of insurance, and you must decide on your tolerance for risk. If you are successful and, hopefully, your net worth has increased, your risk tolerance may change. You may have more to lose if sued and might be considered a larger target for a lawsuit.

Individuals with higher net worth should consider umbrella liability insurance to economically protect their assets. The highest risk to your income stream might be your health. Health insurance might pay your medical bills, but will not feed your checkbook. A disability insurance policy will provide a portion of your lost income when you are unable to work under certain conditions.

Finally, setting up a limited liability company (LLC) or the equivalent will help separate your personal finances from your business activities. The Internal Revenue Service and your accountant will thank you.

What is Considered a Business Expense?

Deducting legitimate business expenses from your gross business income is allowed and is essential for your business to survive. The list of business expenses is extensive and includes, but is not limited to travel (air, automobile mileage, lodging, out-of-town meals), home office (toner, paper, office supplies, telephone, internet), professional dues, payments to sub-contractors, insurance, and continuing education. Maintaining certification through ACRP or other professional organizations is also an expense. Deduct it!

Itemizing business expenses also requires tools and discipline. Keep a log (hard or electronic copy) on everything you spend related to the business. Be sure to document a date and business reason for all expenditures. You should open a business checking account and obtain a credit card to use exclusively for business expenses.

While you might want to hire a bookkeeper and/or an accountant, Quickbooks and TurboTax are simpler to use when compared to reading standard operating procedures or regulatory

documents. Of course, the authors of this article are not accountants or tax experts. Please consult with your Certified Public Accountant or the government tax office concerning all tax issues.

What Are Helpful Business Development Strategies?

If you are new to clinical research, your chances of finding a well-paying contract situation will be limited. Competition abounds and sponsors are looking for maturity, education, and experience in hopes of minimizing risk to their projects. While there are no firm, industry-wide education or experience requirements, professional certification expectations, or government-mandated qualifications, most sponsors are looking for individuals with three to five years of experience working for established companies.

Certifications (e.g., the ACRP-Certified Professional [ACRP-CP]) and academic/clinical training achievements (e.g., earning an RN, PA, MD, or PhD) offer advantages but are not guarantees of being taken seriously as an IC. Exceptions might include unique educational backgrounds, experiences, and therapeutic area expertise.

Someday, when you have a proven track record, clients will reach out to you spontaneously through word-of-mouth and there will be lots of repeat business. Someday, you will be able to say “no” when approached to accept a job with a rate of pay lower than you expected or a project with unrealistic timelines. You might be able to pick your next employer/client from among several who are hoping to work with you at the same time (see Figures 2 and 3). However today, especially if you are just starting out, it is more likely that you will say “yes” to some unfavorable job offers. Building your experience and reputation is your short-term goal. Be careful not to over-commit, and only take on what you know you can manage and deliver on-time in a quality manner.

Figure 2: Picking Your Employer/Client

Big clients will probably:

- Know what they want, and your voice may not be heard
- Be less flexible on all matters (contracts, processes, time)
- Have a larger team

- Have established standard operating procedures and processes in place
- Have more stringent continuing education requirements
- Pay more slowly

Small clients will probably:

- Let you influence their decisions to a greater extent
- Have more flexibility on all matters
- Have a smaller team
- Have no or fewer standard operating procedures or processes
- Have fewer continuing education requirements
- Pay more quickly

Figure 3: Key Questions to Ask About a Proposed Clinical Project

- Where is the client located? Does the client speak your language?
 - This may impact communication and travel expectations.
- Who will be your contact point with the client?
 - A team? An individual?
- When are periodic meetings and written reports required?
 - Good communication and knowing expectations are essential.
- How soon after an invoice is received is payment processed?
- What is the turnaround time for reimbursement of expenses?

Where Do You Look for Jobs?

Our experience indicates that submitting your resume to most large staffing services will *not* lead to a job. It will be tempting to respond to every advertisement for a monitor, study coordinator, or other position. Unfortunately, each recruiter receives hundreds of resumes or CVs, and the odds are against you.

It is highly likely that your responses to too many job postings will simply consume your time, elevate your hopes, and lead to frustration. Occasionally, you will get a positive response—a phone call from the agency, human resources department, or hiring manager—but not very often. This is a classical intermittent, positive-reinforcement regimen that is strongly addictive, similar to putting coins in slot machines. Do not do it!

There are superior strategies for finding jobs that are much more productive and less frustrating (see Figure 4). By far, the best path to employment involves your network: business colleagues, ex-supervisors, principal investigators, site personnel, friends, and family. Personal referrals significantly influence the decisions of hiring managers and cultivating them is a highly recommended practice. Attend meetings, contact individuals employed in positions similar to what you are seeking, and get out there to “press the flesh” in person or virtually.

Figure 4: Business Tools, Tips, and Strategies

- Don't put all your eggs in one basket. Have two or more clients (just in case!)
- Be flexible—clients like someone who is willing to adapt or accommodate.
- Be disciplined—especially when working from a home office.
- Identify services you will need, including to:
 - Develop a webpage
 - Develop one or more CVs
 - Plan your office supply needs
 - Build a network, both in person and through social media (LinkedIn, Facebook, Twitter)
- Always look ahead to the next job
 - Friends, friends, friends (essential)
 - Professional recruiters and job post sites (worthless?)
 - References

What Are the Disadvantages of Being an Independent Contractor?

Being a clinical IC has several disadvantages (see Figure 5). First, to be fair, there are many excellent employers who treat their dedicated employees very well: providing long-term employment, excellent benefits, flexible workhours, team spirit, training, and career growth. If you are working in this type of situation, do not leave the nest without lots of planning and good reasons—the grass is not always greener in the next situation.

Figure 5: Disadvantages of Being an Independent Contractor

- You are not a “company man or woman”—you may not participate in company successes. You are the outsider.
- No bonuses, annual compensation increases, health benefits, profit sharing, etc.
- Once a contract ends, there is no guarantee of continued employment—you will have to find a new contract.

- If working for start-up company, there are risks of company funding issues, bankruptcy, lack of payment.
- Late or delayed payment is common.

Some individuals thrive in the IC marketplace while others fail financially or emotionally. You might not want to be a small business owner with record-keeping responsibilities or the occasional 50- or 60-hour week, mentioned earlier, that comes without overtime or a thank you. A contractor may experience significant gaps in employment and periods when income is insufficient. A contractor is likely to find both good companies and bad ones.

Finally, even if you are working as a clinical IC for a company with a great reputation, it is likely that you will still be considered an outsider and not part of the core clinical research team. You will likely be excluded from training opportunities outside the immediate scope of work related to your assigned project. You might never know the results of a study that consumed your time for months or the outcome of a registration submission. The emotional aspects of employment are often very important.

Conclusions

There are significant advantages and disadvantages to being a clinical IC. Individuals are encouraged to consider each of the factors presented in this article, speak to experienced contractors about their careers, and plan carefully. Improved long-term compensation, flexible schedules, and strengthened self-esteem are among the many benefits that might make this a good career choice for you.

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SPECIAL FEATURE

Reducing Barriers to Participation in Clinical Trials for Rare Diseases

Scott Gray



In the United States, a rare disease is defined as an illness affecting fewer than 200,000 people. Similar definitions apply across the globe, with some variations in the incidence rate. Ultra-rare diseases are even less common, and impact just one in every 50,000 individuals.

There are approximately 7,000 known rare and ultra-rare diseases, and 6% of the world's total population suffers from one. However, less than [10% of rare diseases](#) currently have an available treatment approved by the

U.S. Food and Drug Administration (FDA). Thus, it is imperative to move new drugs and therapies through the lengthy channels of development with maximum efficiency. Yet the very nature of rare diseases complicates clinical trial participation.

The process of bringing novel drugs and therapies to market for rare and ultra-rare diseases is extremely challenging for a variety of reasons. Patients with such diseases frequently have cognitive or physical impairments that place limitations on their mobility, which in turn can restrict their clinical trial participation.

The smaller patient population also translates into greater challenges for pharmaceutical companies to identify and recruit potential trial participants. Often, patients with a rare indication live in rural areas without access to healthcare and must travel long distances to clinical research sites in order to participate. The complexities of managing travel logistics create emotional and financial burdens for the patients, who are already under physical and emotional stress. Many cannot contemplate participating in a trial because of these additional challenges.

The FDA is actively investing resources to “to catalyze product development for rare diseases,” and the majority of its programs are centered around [patient advocacy and education](#) to encourage clinical trial participation. Similarly, patient logistics companies can help drive trial participant recruitment and retention. Patients and caregivers say they feel comforted and empowered when they are connected to a logistics coordinator who has demonstrated they have their best interests at heart.

Logistical Considerations in International Clinical Trials

Ethnic populations suffering from rare and ultra-rare diseases are often concentrated in remote areas of the world. Rare and ultra-rare disease trials frequently require international travel for patients due to the smaller concentrations of them being dispersed across the globe.

Clinical study managers often do not have the knowledge or expertise to anticipate the additional assistance involved in arranging the complex international and cross-border logistics required of many rare disease trials. How will the study team manage communications between their home government and the patient’s government? Does travel require a visa, passport, or international travel insurance? What travel and lodging accommodations unique to a patient must be considered?

It is absolutely crucial to tailor specific solutions which anticipate the needs of a patient while meeting the requirements of the clinical trial. Considerations include:

Communication—Patients often require a translator or interpreter when participating in an international clinical trial. Providing these services ensures full understanding of the overall proceedings of the study, for both the patient and/or caregiver and any other travel companions who will be involved. Conversations with the physicians and site staff

should be in the native language of the patient, beginning at recruitment and continuing through consent, and throughout the duration of the clinical trial. Patients who feel at ease with a translator or interpreter who understands their language and cultural expectations are much more likely to enroll in a clinical trial and stay enrolled until the end.

Transportation—Rare and ultra-rare diseases often present a host of accessibility and mobility challenges for patients. Patients are often very ill or have diseases that are debilitating and impact cognition and/or mobility. For patients with those challenges, a customized travel plan must be created. Visas, passports, and other documents also need to be managed on an individual basis. Country regulations must be researched, and compliance is mandatory for the validity of the trial and the protection of the patient.

Accommodation—In some instances, accommodations may only mean an overnight hotel stay. In others, it is a long-term relocation for the duration of the study. Often in the case of rare diseases, the entire family travels with the patient, relocating for extended periods of time. Thorough knowledge of the protocol requirements, combined with a deep understanding of the patient's unique needs and family structure, allows for proactive planning, ongoing support, and repatriation.

International travel is not always straightforward, and challenges often vary between different regions and countries. Patient logistics coordinators should be familiar in the specific requirements of the geographic locations of the patients assigned to them and have a true understanding of the unique nuances of the cultures they support. Working with an expert saves clinical trial participants crucial time and money by making it easier to manage the ins and outs of visas, passports, and medical requirements like vaccinations.

International Patient Management During the Pandemic

During the COVID-19 pandemic, trial participants still needed to receive potentially life-saving therapies, but strict sanitation measures and limitations on in-person visits created roadblocks in the established norms for their study participation. Many were forced to adjust or, in some cases, totally replace their travel itineraries.

Patient logistics management companies had to constantly monitor and react nimbly to the rapidly changing travel restrictions during the pandemic. Having local patient coordinators close to the patients themselves enabled rapid response despite frequent regional regulation changes. Patient coordinators worked around-the-clock in many instances to ensure alternative

transportation methods were available, as many flights were cancelled. They ensured accommodations matching accessibility needs for the participant would be sanitary and available for quarantine and beyond, and dietary needs could be met daily, in spite of restaurant closures and reduced capacity at food markets.

With the impact of COVID-19 and its variants continuing well into 2021, unexpected hurdles for participants in rare and ultra-rare disease trials will continue to arise and require creativity in planning international logistics. For clinical study teams lacking the resources and experience necessary to enable compliant and secure travel for patients in particular countries, partnering with an experienced patient support services team is often the only way to ensure participant retention and a trial completion that is both on time and on budget.

Why a Logistics Management Vendor Makes a Difference

To date, the FDA has approved drugs and biologics for more than 800 rare disease indications. In 2019, the agency approved 22 novel drugs and biologics with orphan drug designation. Even in the wake of pandemic, we have continued to see significant progress in treating rare diseases and ongoing interest in developing rare disease treatments, despite their unique challenges. This is partially due to initiatives like the [Orphan Drug Act](#) and the FDA's [Orphan Products Clinical Trials Grants Program](#), which create incentives to offset the costs of developing drugs in this space and increase their potential return on investments.

Going forward, the [Orphan Drug Technology Modernization](#) effort is expected to streamline the orphan drug designation request process by moving from a paper-based process to a cloud-based submission portal. Given the complex nature of these studies, as more clinical trials for rare and ultra-rare diseases are planned, support services for facilitating patient logistics will become more sought after. Partnering with a company that specializes in patient logistics can help streamline a clinical trial from its earliest stages.

Conclusion

Research teams who appreciate the unique needs of rare disease patients and invest in a white-glove approach on behalf of trial participants can reduce barriers to participation. For clinical study teams and site staff, this means easier patient recruitment at the beginning of a study and fewer dropouts through the duration of the trial—with the added bonus of having more time to dedicate to the trial itself. For pharmaceutical sponsors, efficient recruitment and higher retention improves trial performance, which ultimately culminates in getting treatments to market sooner.

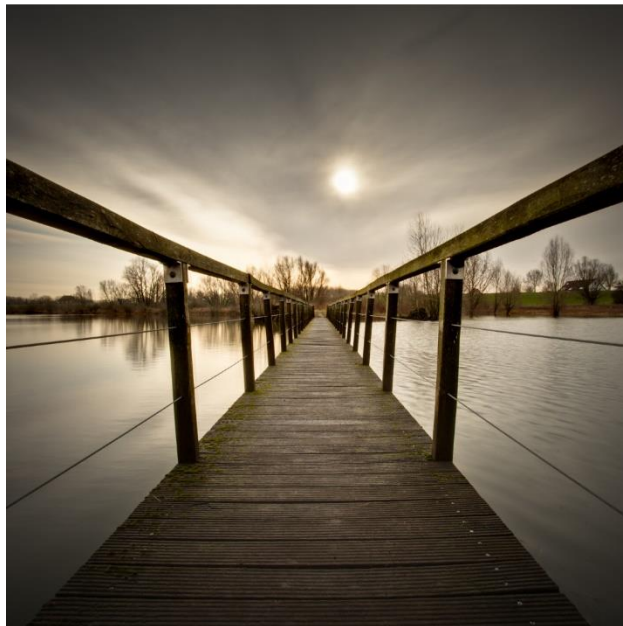


Scott Gray is co-founder and CEO of [Clincierge](#), a provider of logistics management services for clinical trials.

SITES & SPONSORS

Real-World Late-Phase Trials: How They're Helping Sponsors Bridge the Gap from Drug Efficacy to Effectiveness

Lucia Zaccardi



In a multilateral paradigm shift, sponsors, payers, regulators, physicians, and patients are increasingly recognizing the value of real-world late-phase (RWLP) trials. The increasing use of real-world data (RWD) and real-world evidence (RWE) to support clinical development has been informed by recent regulatory guidance and accelerated by the global COVID-19 pandemic. Stakeholders across the spectrum are demanding evidence of the benefits of treatment interventions. According to “The State of the

Biopharmaceutical Industry 2021,” a survey by GlobalData, RWE ranks fourth among the top trends in the industry.^{1} Verified Market Research estimates that the global RWE market will reach \$1.9 billion by 2026.^{2}

Data from RWLP studies are invaluable in bridging the gap from drug efficacy to effectiveness and from development to commercialization. As pricing and market access pressures mount and the cost of drug development rises, the use of RWE in research and development has become a strategic focus for sponsors and regulators alike. Increasingly, RWE is being used to support regulatory filings and augment traditional randomized controlled trials.

Understanding the Need for Real-World Data and Evidence

Drugs are typically approved on the basis of pivotal Phase III trials involving strict inclusion criteria and clinical endpoints that have been agreed upon between the sponsor and the relevant regulatory agency(ies). Regulatory approval is not synonymous with market adoption and reimbursement. Sponsors are increasingly tasked with demonstrating that a drug is meaningful to patients, prescribers, and payers.

RWD—unstructured data relating to patient health status and/or healthcare delivery that are routinely collected from a variety of sources, including wearables, disease registries, and electronic medical records—form a critical bridge from clinical effectiveness to commercial viability. RWE is the clinical evidence about the usage and potential benefits and risks of a medical product derived from the analysis of RWD. It provides:

- The evidence physicians need to prescribe a drug with confidence.
- The information patients need to adhere to a drug.
- The value story payers need to authorize and pay for a drug.

RWLP trials seek to collect data in less-controlled, more real-world settings. One of the key objectives of these trials is to ensure that once a drug is on the market, it is safe and effective for a broader patient population within the approved indication. RWLP trials may be designed to collect additional efficacy data or to perform surveillance. Given that these trials are often of long duration, they may be costly. As regulators increasingly require RWLP trials, sponsors are seeking ways to conduct these studies in a more efficient, cost-effective manner. This can be accomplished by using integrative technologies and decentralized trial strategies that break down traditional evidence-generation silos.

Regulatory authorities are encouraging the use of RWLP trials and are becoming more supportive of using RWD and RWE in both the pre-approval and post-marketing phases of development. Both the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) have released guidance on the use of RWD in pre-market decision-making. In 2019, the FDA released draft guidance on the use of RWE in regulatory submissions.^{3} An EMA reflection paper, “Regulatory Science to 2025,” promotes the use of high-quality RWD in decision making as one of the EMA’s key strategic goals.^{4}

Defining the Scope of RWLP Studies

RWLP studies can be categorized broadly as interventional and non-interventional studies.

Interventional studies are generally requested by regulatory agencies to generate supporting data for full market authorization. These studies involve an investigational product (IP) or conditionally approved drug.

Non-interventional studies, which may or may not be conducted with a marketed drug, are used to build or broaden the value story. If a marketed drug is used, it is purchased from the pharmacy or taken during a physician consultation, not supplied by the sponsor. Non-interventional studies generate RWD to support commercial viability.

Table 1: Types of Real-World and Late-Phase Studies

| Interventional Studies | Non-Interventional Studies |
|---|--|
| Late Phase IV studies | Registries |
| Expanded access or compassionate use programs | Natural history studies |
| Extended access programs or open-label extensions | Post-authorization safety and efficacy studies |
| Competitive marketing claims studies | Medical chart review studies |
| Pragmatic trials under standard of care | Health economics and outcomes research |

The regulatory framework for non-interventional studies differs from traditional studies. In the U.S., non-interventional studies do not need to follow Good Clinical Practice guidelines, and data formatting guidelines typically do not apply. In the European Union, these studies need to conform to country regulations, and while submission to ethics committees is required, submission to competent authorities is not.

What non-interventional studies have in common with studies in earlier phases is the need to deliver high-quality data but at reduced site cycle time. That said, conducting real-world and late-phase studies is quite different from conducting clinical trials to support regulatory approval. As such, sponsors need to think differently about the process, costing, and strategies.

Implementing a decentralized trial strategy—whether it is a completely virtual trial or a hybrid, decentralized study—and applying remote monitoring enables sponsors to bring these trials to patients in the real world.

Value of Real-World Evidence Outside the Clinical Trial

Outside the controlled clinical trial environment, patients may interact differently with the therapy under investigation. Potential applications for RWE include:

- Supporting regulatory submissions and/or label expansion
- Performing comparative effectiveness research
- Augmenting study design by using RWD as a synthetic control arm
- Understanding subpopulations and heterogeneity of treatment responses
- Informing the design of value-based contracts

The ability to build evidence during and after a clinical trial—whether through natural history studies, patient registries, RWLP data, or health economics and outcomes research, enables sponsors to show differentiated outcomes. This is essential for demonstrating value and ensuring that the product is accessible and affordable to the patients who need it most.

RWE can aid in regulatory decision-making, spur faster approvals, and reduce the need for further studies by providing supporting data that cannot be found elsewhere. Importantly, RWE can be used to inform decisions about which study designs and clinical endpoints are most meaningful for patients, caregivers, physicians, and payers. It can also shed light on the existing patient population size and demographics, which, in turn, helps sponsors better define inclusion and exclusion criteria and reduce trial failure rates through improved protocol design and site selection strategy. Still, while RWLP trials are a practical data source to support pre- and post-approval research, they do not replace proof-of-concept or pivotal studies.

Key Considerations for RWLP Trials

There is no one-size-fits-all approach to designing and conducting RWLP trials, but there are some key considerations to keep in mind. Planning for real-world studies should begin as early as Phase I. Well-designed real-world studies can shorten timelines, lower costs, optimize the impact of research investments, and, most importantly, get therapies to patients more quickly.

When developing the protocol, even if there is no IP, sponsors should be mindful of the need to keep the study procedures as closely aligned to the standard of care as possible. If a late-phase trial includes any procedures that are not performed in routine clinical practice, it will fall under the interventional regulatory framework, even if it is designed as an observational study. If biomarkers are used in a therapeutic area where the treatment pathway is well defined, they may not be reimbursed by the healthcare system if they are not considered to be standard of care.

Managing the protocol so it is simple for both the patient and the site increases the likelihood of success. Leveraging secondary data that already exist in the healthcare ecosystem can reduce the number of data entry points required on the case report form, limiting duplicative efforts and allowing investigators to focus on capturing new information. These secondary data may come from electronic health records, administrative claims, or other real-world sources.

The ultimate goal of RWLP trials is to decrease patient and site burden and costs while increasing value and participation.

Trends in RWLP Trials

Over the next five years, we expect a rapid increase in RWLP trials in the U.S., particularly in the therapeutic areas of oncology, central nervous system diseases, and cardiology. The Asia-Pacific market will be the fastest-growing one for RWD. As sponsors adopt decentralized strategies for RWLP studies, we will see increased cost efficiency in commercialization and improved access.

For many sponsors, lack of research-grade data is an obstacle to using RWE in research and development, emphasizing the need for strategic partnerships. According to Deloitte's 2020 RWE benchmarking study, more than 80% of companies surveyed are developing partnerships to access new sources of RWD.^{5} Companies are also investing in data and analytics platforms that provide more meaningful access to RWD and internal capabilities that enable them to design, conduct, and analyze RWE studies.

Conclusion

Market approval is just the beginning. We are entering a new era of healthcare where demonstration of value through RWD will increasingly determine market access. Sponsors, regulatory authorities, physicians, patients, and payers want to know how a product performs in the real world.

RWLP studies can answer critical questions about the long-term effects of a drug or its impact on different types of patients excluded from the clinical trials used to support market approval. Working with a contract research organization experienced in these post-marketing trials leads to optimal, cost-effective management of RWLP studies and more substantial regulatory submission packages. By accessing, analyzing, and interpreting the right data in late-phase studies, sponsors can fill the knowledge gap between clinical trials and clinical practice, bringing revolutionary therapies to the patients who can benefit from them.

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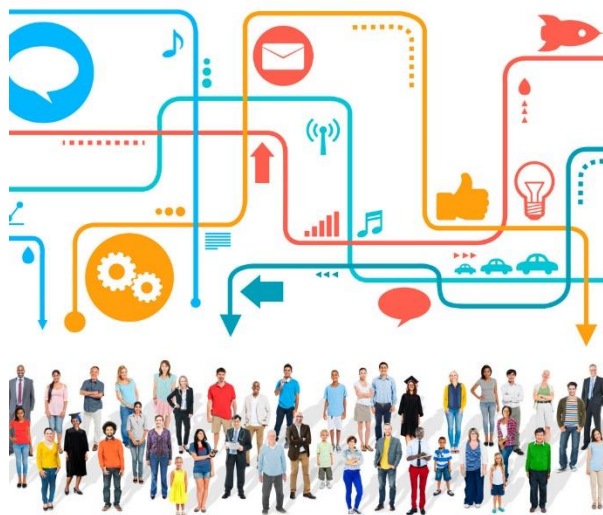


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RECRUITMENT & RETENTION

Leveraging Data to Improve Patient Recruitment Pain Points

Jason Bhan, MD



At every level, data silos remain commonplace throughout healthcare. { 1 } These silos represent unconnected repositories of segmented information that not only complicate communications across organizations and health facilities, but can also slow or prevent the successful recruitment process for crucial clinical trials. Identifying the gaps and bringing these data together are critical to overcoming isolated silos and improving clinical trial outcomes.

Clinical research is often an expensive and time-consuming undertaking. When a company develops a new drug, the average cost is estimated at \$2.6 billion. { 2 } Even at that price, only a small fraction of drugs under development eventually gain regulatory approval. A significant portion of the company's tab comes from conducting clinical trials, especially if a contract research organization (CRO) involved in the process is forced to restart recruitment efforts due to an initial lack of patient retention.

Further, the phenomenon of participants dropping out of clinical trials isn't rare; typically, 30% of patients withdraw from a study before its completion. { 3 } It typically costs organizations \$6,533 to recruit one patient to a clinical study, and recruiting a new patient if one withdraws costs \$19,533. { 4 } Harnessing the power of real-world patient data can help sponsors and CROs minimize delays, increase participant retention, rein in costs, and increase operational efficiencies.

The recruitment phase of a clinical trial is probably the most important differentiator among CROs, which are continuously seeking more sophisticated and accurate methods to identify patients. Leveraging data and analysis technologies provides that insight. Technology analytics can help process and survey data to make it easier to recruit and retain the right patients for the right trial, ensuring lower costs and faster results.

The Importance and Challenge of Data Access

In addition to the costly process, the average clinical trial generates up to 3 million datapoints{5} that typically remain siloed and inaccessible. Clinical trials aren't alone in this; there are more than 6,000 hospitals in the U.S.{6} and each implements its own, specific data record management system. Within these databases, fields are labeled differently and extracting the data isn't easy. This is true of any electronic health record (EHR), whether in a hospital system, laboratory, radiology department, or medical office.

A survey conducted by the U.S. Office of the National Coordinator for Health Information Technology{7} found that nearly 70% of hospitals reported integrating patient data into their EHRs, but only one in 10 facilities used exclusively electronic methods to send or receive secure electronic health messages to and from outside organizations. Enabling global data flows and greater interoperability would liberate information across healthcare systems. The right data analysis technology enables CROs to leverage real-world patient data, which translates to improved quality performance, advanced care for patients, and more accurate participant recruitment for clinical trials.

The COVID-19 pandemic has demonstrated at scale the inadequacies within EHR systems in the U.S.{8} The inharmonious electronic records left Americans vulnerable as teams worked to target outbreaks, chronicle patient recoveries, and identify which treatments were widely successful. Pulling COVID-19 patient data from EHRs in hospitals across the U.S. proved a technical nightmare,{9} largely due to the various EHR software being unable to retrieve and integrate information with competing software designs.

Realizing the pandemic called for a more centralized data system, the National Institutes of Health created the National COVID Cohort Collaborative, which extracted siloed data to answer

key questions and track successful treatments. It houses 6.3 million de-identified patient records from 56 institutions and counting. Experts believe it is one of the most promising tools for studying the disease now and in the future.{10}

To make clinical research and recruitment as effective as possible and develop the most widely successful treatments, CROs need to abandon the inflexible, non-interoperable, siloed data approach of the past and gain consistent access to real-world data.

Breaking Down the Silos Ensures Greater Success

Powerful analytics tools can mine millions of EHRs, claims data, and other resources to home in on specific patient groups faster than other methods. These Health Insurance Portability and Accountability Act–compliant solutions allow CROs to break down the data silos and easily integrate with systems to help ease clinical trial burdens. Clinical investigators can then find patients that meet their trial criteria more easily, which speeds up the timeline and increases the odds of recruitment success.

Once the organization resolves the challenge surrounding data access, it can begin to review patient data while patient recruitment is organized into two key parts: 1) the criteria for the target patient; 2) locations where key patients can be recruited.

Determining inclusion and exclusion criteria for clinical participants is a key practice when designing high-quality research trial protocols.{11} To determine the inclusion criteria for the trial, investigators will narrow down the key features of the target population needed to conduct the trial.

Typical inclusion criteria include diagnosis, demographic, clinical, and geographic characteristics. In contrast, exclusion criteria are the characteristics of potential participants that could interfere with the success of the study. The most common exclusion criteria that disqualify otherwise eligible patients include traits that could make them highly likely to be lost to follow-up, miss scheduled trial appointments, or have comorbidities that could increase their risk for adverse effects. During this process, it's crucial to make sure the inclusion and exclusion criteria give the team a more accurate funnel from the start.

Inclusion and exclusion criteria impact the team's recruitment funnel and it's important to have an understanding of them up front. Many times, teams are collecting these data blind and cannot incorporate insight from real-world patient information. Without being able to broadly sort through population data, research teams end up making the funnel too narrow from the start, thereby limiting recruitment options. Gaining access to laboratory or healthcare data that are more readily accessible can be a game changer and open doors to larger recruitment opportunities.

Once the necessary criteria have been selected, teams must begin considering how they'll find the patients. This may present as a highly complicated problem, especially without access to broadscale, real-world data. However, once CROs have access to de-identified patient information, the recruitment team can begin locating areas with qualifying patients. Investigators may not be able to identify patients down to the individual level, but can identify doctors who have high concentrations of the appropriate patients.

To gain the most impact from the accessible data, investigators can connect with the identified doctors to enroll their facility as a clinical trial site or patient recruiting center. This approach allows doctors to directly connect with their own patients and recommend the trial to those who are the best fit.

Impact of Real-World Data on Clinical Trials

The use and application of real-world data and advanced analytics is increasingly important to inform clinical trial work. Enhanced analytical models inform faster decisions around trial execution, which saves time and money. By breaking down the siloed real-world data using powerful analytics tools, clinical trial coordinators can gain access to the crucial data necessary to develop the strongest roster of clinical participants.

A clinical trial's recruitment phase plays the largest role in determining if the study will succeed. CROs continue to seek sophisticated methods for leveraging data. Analysis technology and real-world patient data provides clinical trial investigators with more transparent access to the team's recruitment funnel. They still may not be able to review data down to the individual level, but the teams can highlight geographical areas and healthcare facilities with qualifying patients.

By gaining this insight, CRO teams can establish connections with the doctors, hospitals, and patients who most need access to the trials. In this way, clinical trial coordinators can better ensure the retention of their patient participants and develop better results for the healthcare community and world.

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PRESCRIPTIONS FOR BUSINESS

A Bird’s-Eye View of Health Inequities in Clinical Trials: Observations, Lessons Learned, and the “Flight Path” Forward

Elizabeth Marshall, MD, MBA



Sometimes life seems to bring you full circle. Lately, I find myself having conversations about utilizing data to obtain insights with just as many people in the pharmaceutical industry—where I began my career path—as I do with those in healthcare. COVID 19 and its impact on the world population has taught us many hard lessons, but the one positive is *inequity awareness*.

Inequity awareness is an unfortunate theme that I have tried to both question and bring mindfulness to over much of my adult life. I am a physician, a researcher, a veteran, and a patient. I have provided insight and awareness around situations of health disparities for well over a decade. I have also tried to assist where I can.

I am happy to report that, now that this awareness has been brought into clear view, people seem to be much more receptive to learning about social determinants of health (SDoH). More importantly, this awareness has now prompted actions...or at least plans for future actions.

Bird's-Eye View—Circling from Above

The odds of success for a Phase III clinical trial are [3 out of 5](#). Surely, those aren't very good odds for such an expensive venture. The [length of the Phase III trial](#) also needs to be considered, because a lot can happen to those 300 to 3,000 research participants during the one to four years it takes to complete a trial. This is one reason that real-world evidence is imperative, and why we must take into consideration the SDoH information that is available in unstructured data.

Recent discussions I've had with folks in the pharmaceutical sector have certainly conjured many memories of the days when I was a researcher, including my observation that overall health is mainly influenced by factors outside the clinical setting. Capturing SDoH information as part of the clinical trial process can help patients, people, and the industry be more successful. Because so much can happen to influence the results beyond trial visits, clinical researchers can no longer accept business as usual.

Observations: Assessing the Need for a New Approach

Beware—and be vigilant of—unintentional bias

Bias may not be obvious, but it is there. Research cohorts are biased, not intentionally, but by the very nature of a study. Most participation requires hours of “free” time. Think about how many full-time working people that you know. Now—how many of them have been a participant in a clinical trial? Not many, I'm almost certain...especially if they need to sacrifice vacation time to do so.

With an [unemployment rate](#) regularly under 10% (thankfully so), not many people have the ability to participate with their work/family schedules. How does this biased collection of research cohorts represent the population? It doesn't. Another unfortunate truth: there are those participants that partake in clinical trials as their *career*.

Social determinants of health are abundant

If you have ever had the misfortune of either suffering from or observing someone that is desperate for relief of an ailment, you aren't alone. From my experience, those suffering are first

in line for a new chance for relief. Pain and suffering affect so many aspects of one's life. Many of the participants I recall had one or many SDoHs—they lived alone, lacked social support, had transportation issues, etc. Even if the participants didn't enter the trial with said stressors, that doesn't mean one or more didn't subsequently develop.

I know plenty of people with an ailment who struggled maintaining a job or lost their social support over time. We know many clinical trials fail because participants drop out. By utilizing proper communication channels and understanding underlying issues, many missed appointments can either be avoided or addressed (e.g., rescheduled or replaced by a virtual visit). For example, addressing potential transportation problems with protocol changes may ameliorate problems with dropped participation.

Lessons Learned: Resetting Our Compass with NLP

The use of [natural language processing](#) (NLP) to capture SDoH and other relevant data from visit reports provides an important means for identifying vital unstructured information that can be utilized in informed ways. We can say for certain that understanding SDoH can make an impact and improve clinical trial recruitment and results. Here are a few areas based on my own experience and important tidbits from colleagues:

- Collect and address clinical trial recruitment inequities so that the trial cohort is characteristic of the wider population.
- Determine how to translate observed environmental inequities into clinical research. (e.g., a higher rate of disease for those living in a particular environment, such as *Vibrio vulnificus* outbreaks after Hurricane Katrina).
- Integrate and assess factors of health inequality within analyses, models, and initiatives.
- Assess clinical trial outcomes with a more granular approach. For example, consider whether the drug itself failed or if there were extenuating circumstances that contributed to lack of efficacy.

The “Flight Path” Forward

Birds migrate because of their awareness that new resources are needed. We too should learn from such wisdom. It’s time to migrate away from our conventional thinking that we have more control than we *actually* have. In the end, neither clinical settings nor clinical trials have as much to do with our health portfolio as we may think. Our traditional approach to clinical care and clinical trials requires a new trajectory. We must embrace new resources and seek new understandings—and fly swiftly toward a path that is more beneficial for all.



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COVID-19 Lessons Learned: A New Approach to Clinical Trial Design

Jonathan Andrus



The immediate need to control SARS-CoV-2 and the ongoing need to treat diseases such as malaria, tuberculosis, and pneumonia highlight the critical nature of research and development of new anti-infectives and vaccines. Speed is an advantage here, as ready availability of effective vaccines and therapies has a direct impact on the magnitude of epidemics and pandemics.

We can learn from the experiences of COVID-19 vaccine developers and clinical trial sponsors who continued or completed studies during the pandemic as we devise practical solutions for future development. Most of these lessons involve the use of eSource technology that allows clinical trial sponsors to develop therapies more efficiently, at a lower cost, with less burden on patients and sites.

Implementing technologies such as videoconferencing, mobile technology, and remote patient monitoring (pulse oximeters, blood glucose monitors) allows patients to participate from anywhere. **Real-time** access to direct data capture (DDC), electronic patient-reported outcomes (ePRO), and electronic clinical outcomes assessments (eCOA) provides study teams with immediate insights and interim analysis reporting.

Not all commonly used technology improves clinical trial efficiency. Many sponsors utilize electronic data capture (EDC) systems to collect clinical data. With EDC, clinicians typically record vitals, outcome assessments, and other patient data on paper. As an additional step in the process, data are later transcribed into the EDC system and saved in an electronic case report form (eCRF). After this step, data in the eCRF are verified against the paper form—a process

called source data verification (SDV). With SDV complete, clinicians can access data and manage queries.

During the pandemic, many sponsors moved to a decentralized approach out of necessity, recognizing that a paper-based process does not integrate with advanced digital technology. A more immediate approach using DDC, ePRO, eCOA, and similar electronic forms, which we collectively call eSource DDC, eliminates the paper-form step and nearly all SDV.

Using eSource DDC, timelines shorten by months—in some cases, time to database lock is reduced from months to 48 hours. When time, budget, and patient access are high priorities, advanced digital technology that integrates seamlessly with remote technology and eliminates paper-based processes is an asset for clinical trial deployment.

Be Ready to Switch Gears

eSource DDC platforms are designed to handle the complex workflows that are part of decentralized trials. They're also designed to scale as needed when protocols change or an outbreak occurs.

If a public health emergency strikes mid-program, for example, that program must pivot quickly. A recent neurology study enrolled nearly 2,000 patients across more than 250 sites for Phase II and Phase III clinical trials. By the time the studies started, the SARS-CoV-2 virus had spread around the world. Participants did not want to visit research sites for fear of contracting COVID-19.

To keep patients enrolled, the sponsor rapidly transitioned from paper-based assessments to eCOA and ePRO and adopted a bring your own device (BYOD) strategy. It built and deployed 10 different collection forms for home use as quickly as possible. By reducing the amount of user acceptability testing and proactively reaching out to questionnaire license holders, the sponsor completed the build and was in production within 10 days.

All participants completed assessments from home and attended virtual clinic visits. If they didn't have access to a mobile device, the sponsor provided one.

As a result of its ability to shift to a new approach quickly, the sponsor retained participants who would have otherwise dropped out of the study, and because of the 10-day build, the study stayed on track. This positive outcome happened because of the flexibility gained by using eCOA, BYOD, and eSource DDC.

Design the Study for the Patients

Remote technology not only allows sponsors to recruit more patients—an advantage for large, late-phase studies—it allows them to use both structured and unstructured data in a meaningful way.

For example, a leading pharmaceutical company moved from EDC to eSource DDC for a SARS-CoV-2 prophylactic Phase III trial. The study aimed to evaluate post-exposure prophylaxis and preemptive treatment in 1,000 participants, all of whom were age 60 or more and lived in long-term care facilities. These high-risk patients could no longer travel to sites, nor could they risk contracting or transmitting the virus.

To keep the study running, the sponsor hired traveling coordinators and nurses to remotely collect data. Clinicians captured vitals, handwritten notes, and photos of drug dispensation records directly into the electronic record using eSource DDC. Unlike EDC systems, most eSource DDC platforms accept both structured and unstructured data.

Because of the rapidly evolving COVID-19 situation, clinicians needed to respond quickly if a patient's health status changed or if health departments updated mandates. Real-time data made this happen. Edit checks allowed for on- or offline, in-form, and cross-form/cross-visit alerts and calculations (derivations, scoring, etc.). All edit checks were performed during the patient visit and all were critical to patients' health.

By shifting to a decentralized model, participants could fully participate in the trial without leaving their communities. As a result, the sponsor not only kept its clinical trial on track, but it also completed study startup in 10 weeks—significantly quicker than would have been possible using traditional methods.

Integrating digital technology such as eSource into anti-infective clinical trials enables faster study startup and access to a wider range of data. By capturing and validating data directly into the electronic record at the point of care, sponsors can address abnormally high and low values with the participant present. Addressing anomalies early helps prevent data queries later, leading to a more efficient clinical trial overall.

Advancing Antiviral Drug Development

To continue to advance clinical research, we must learn from our victories as well as our mistakes. We can model new victories from the success of COVID-19 vaccine developers, which used all available resources and the latest technology to develop vaccines in a tenth of the standard time.

We're moving in the right direction. The recently formed [Decentralized Trials & Research Alliance](#) (DTRA) is dedicated to accelerating adoption of patient-focused decentralized trials and research. One of the priorities for the organization and its more than 100 members is to identify and remove barriers to decentralized research implementation.

In March 2020, a group of more than 20 life sciences companies formed the [COVID R&D Alliance](#) to further coronavirus drug development. The [Rapidly Emerging Antiviral Drug Development Initiative](#) (READDI) brings together worldwide industry leaders to develop antivirals.

Remote monitoring, eSource DDC, and related solutions such as telemedicine and remote patient monitoring are pivotal in enabling these organizations and other pharma and biopharma companies to develop vaccines and therapies with efficiency and speed unheard of in the pre-

pandemic era. These tools also encourage research participation by putting the patient at the center of the clinical trial experience, a crucial consideration in the race to control infectious diseases.

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OVER THE TRANSOM

Finding Participants Where They Are

Gary W. Cramer



Although he later denied ever being so pithy, bank robber Willie Sutton, who in a 40-year career of being dastardly stole some \$2 million, once supposedly replied to a reporter’s line of questioning about why he robbed banks by saying “because that’s where the money is.”

Things are less straightforward for clinical researchers. One simply doesn’t walk into “the place where the potential participants are” and start signing folks up for clinical trials. The challenges abound: Where are the people with the condition under study? How many of them are willing to join the study? How many from that group match up with the inclusion criteria? How many still remaining will comply with the protocol and stay engaged in the study through to its conclusion?

Taking a “first things first” approach, this column initially offers up portions of communications from stakeholders outside the confines of ACRP (no endorsements implied) about the never-ending quest just to find those blessed would-be participants and get the ball rolling. We’ll also delve a bit into the follow-on efforts necessary to retain participants and then keep them satisfied after their “work” is done by sharing study results. As you’ll see, much of the attitude being invested in recruitment these days honors the spirit of “we’ll meet you where you are” as much as “you only get what you give.”

Virtual Trial of COVID-19 Rapid Detection Test Starts with Drive-Through Consent

Curebase and InBios International Inc. in July [announced](#) that InBios successfully utilized Curebase's virtual site solution to power clinical studies for its SCoV-2 Ag *Detect*TM Rapid Test, which was granted Emergency Use Authorization by the U.S. Food and Drug Administration on May 6. For this study, Curebase converted drive-through COVID-19 testing centers in southern California into clinical research sites with its decentralized clinical trial software platform and virtual site support model.

Study participants were able to be screened and offer consent in real time from the safety of their vehicles while they were waiting for a COVID-19 test. By accessing a specific study website on their own phones, candidates could answer screening questions and consent to participate in the InBios study all in the time it took to wait in line at the drive-up clinic. The process required no physical interaction with patients and enabled hundreds of people to be screened in a few weeks.

Companies Collaborate to Speed Studies to Rare Disease Patients

uMotif and Xperiome in July [announced](#) a collaboration focusing on what they call a new approach to patient recruitment for rare disease studies. The partnership aims to bring value to both life science companies conducting clinical trials and the patients participating in them through outreach to a community of "motivated, research-ready patients" using a recruitment platform designed to drive retention.

The partnership will leverage Xperiome's knowledge bank for the lived experience of rare disease to build an understanding of hard-to-reach populations and combine these insights with a specialized matching engine to connect potential participants to clinical and real-world study opportunities. Once enrolled, uMotif's patient-engagement app will capture participants' electronic patient-reported outcome, eDiary, and symptom data in real time throughout the duration of a clinical study.

According to the partners, the effort "is designed with patients in mind, to help sponsors and research professionals capture the best quality data in a way that suits study participants" and recognizes that, in orphan drug studies, "populations are hard to reach and participation in research can add significant burdens for patients and their families."

Mobile Communications Approach Confronts One of the Biggest Problems in Trials

ScienceMedia in July [announced](#) that its SMi Trial mobile communication technology aims at keeping clinical trial stakeholders “in the loop” with educational support throughout the research lifecycle. Noting that “the complex communication between doctors, nurses, pharmacists, and patients all around the world makes closing the loop difficult,” the company goes on to indicate that its approach addresses a concern of the European Medical Writers Association—namely that, “for studies of long duration, educational and engagement efforts should ideally be continued throughout the study to support retention of participants.”

Depending on the needs of the participant population and the study specifics, the company says this may take the form of a comprehensive, multichannel participant support and communications program, or may be a simple, automated text messaging service that sends motivational, informational, or reminder messages at set points in time. In any event, “an educational program throughout the life of a clinical trial is paramount,” a company executive stresses, adding that you “don’t just build the education so that it can be consumed, [you] ensure that it’s being consumed by every single participant throughout the trial and tailored to their learning needs.”

Happy Birthday! Here’s Your Report Card

As noted in a recent [ACRP Blog](#) entry, the *All of Us* Research Program from the National Institutes of Health (NIH) is celebrating its third birthday this month and touting recent successes in recruiting participants for the program, including more than 24,000 volunteers from the Southeast region with a high percentage of them being minorities who are under-represented in medical research. By asking 1 million or more volunteers across the nation to share different types of health and lifestyle information, the initiative aims to speed up health research breakthroughs to improve health outcomes and deliver precision and personalized medicine to patients.

Not mentioned in the blog, but highlighted in [a press release](#) from the University of Miami Miller School of Medicine, were details about how participants are being kept engaged in the long-term program. According to Jacob L. McCauley, PhD, director of the Hussman Institute’s

Center for Genome Technology at the school, “We are really excited that participants have started receiving some of their genetic results from the biosamples that they have donated. The initial results will provide insights into the participants’ genetic ancestry and traits, with additional health-related results coming at a later phase. This is one of the first opportunities to return value to our participant partners in this groundbreaking research program.”



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