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PEER REVIEWED

Being an Independent Contractor: Seeking Success in the Workforce

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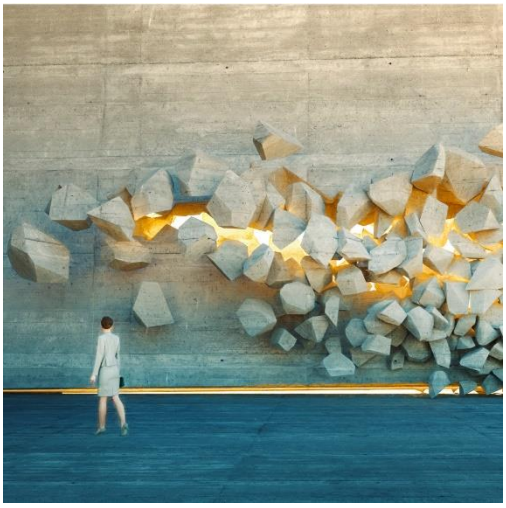

The model has changed. Millions of people have exited full-time positions to work as independent contractors (ICs) in hundreds of industries. Experts say it is better for the economy. Do I care? Or what if I really need to know whether it is best for me, but it's too soon to know? This article provides 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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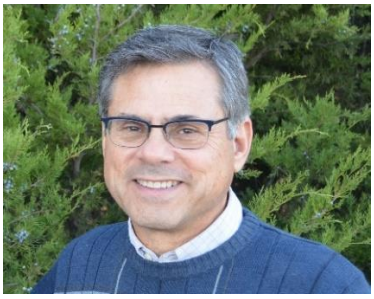

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SITES & SPONSORS

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 Europoean 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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ACRP HOME STUDY
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Overlooked No More

Article #1: **Being an Independent Contractor: Seeking Success in the Workforce**

LEARNING OBJECTIVE
After reading this article, the participant should be able to describe the current state of and factors tied to the independent contractor workforce in the clinical research enterprise, summarize multiple strategies for attracting business, and outline advantages and disadvantages of being a solo worker.

DISCLOSURES
Jerry M. Stein, PhD, ACRP-CP, ACRP-MDP, FACRP; Suheila Abdul-Karrim, CCRT, CCRA, ACRP-MDP, FACRP; Ernest Allen: *Nothing to disclose*

1. Which two sectors of independent contractors likely to include clinical researchers were found to be among the largest in the U.S. government study cited by the authors?
a. The finance and insurance sector and the educational services sector.
b. The information sector and the manufacturing sector.
c. The professional, scientific, technical sector and the healthcare and social assistance sector.
d. The transportation and warehousing sector and the management of companies sector.

2. The transfer of research and development risk to independent clinical contractors and small companies is cited as resulting in which of the following shifts in the job market?
a. Former principal investigators now working as chief medical officers or clinical operations executives.
b. Former study site managers now working for sponsors or for patient advocacy organizations.
c. Former institutional review board (IRB) leaders at academic medical centers now working for centralized IRBs or regulatory authorities.
d. Former employees of sponsors now working for contract research organizations (CROs) or as independent contractors.

3. What is the primary source of income for most independent contractors in clinical research?
a. Academic medical centers
b. Sponsors of clinical trials
c. Health maintenance organizations
d. Institutional review boards

4. What kind of work schedule can an independent contractor expect on most clinical research projects?
a. One in which a mandatory number of hours is not set for each day.
b. One in which every work week will be set at more than 50 hours.
c. One in which several weeks at a time will require no billable hours.
d. One in which projects for multiple sponsors must be completed each week.

[Test continues on next page…]

5. What happens when a sponsor approaches an independent contractor with a project?

a. The sponsor is legally obligated to contract with the lowest independent bidder for the work.
b. The independent contractor must say "yes" to sponsors with which they have worked before.
c. The sponsor can demand the independent contractor refuse work with any of its competitors.
d. The independent contractor is free to say "yes" or "no" to the work for any reason.

6. What kind of compensation terms can an independent contractor expect from a sponsor?

a. A lower hourly rate of pay than full-time employees but greater benefits.
b. Hourly rates of pay and benefits on par with those for full-time employees.
c. A higher hourly rate of pay than full-time employees but lesser benefits.
d. Hourly rates of pay and benefits that exceed those for full-time employees.

7. Independent contractors in the U.S. are responsible for paying for which of the following themselves?

a. All travel expenses and research documentation.
b. Tax payments and medical insurance coverage.
c. Criminal history checks and employment verification.
d. Non-disclosure agreements with all sponsor employers.

8. Which of the following kinds of common insurance might a sponsor require an independent contractor to have?

a. Professional liability, workman's compensation
b. Health, accidental death and dismemberment
c. Long-term disability, property and casualty
d. Homeowners/renters, travel, education

9. Which of the following levels of experience or qualifications are most sponsors looking for in independent contractors?

a. Graduate school training and medical licensure.
b. Four-year college degree and relevant certification.
c. Must have been employed by a site, sponsor, and CRO.
d. Three to five years of work with established companies.

10. The authors recommend which of the following as an independent contractor's best path to employment?

a. File their resumes/CVs with as many recruiters and job sites as possible.
b. Rely on a single company as their source of project contracts.
c. Leveraging their network of business and personal contacts.
d. Look for work outside the U.S., as contractors are in short supply there.

[Test continues on next page…]

Article #2: **Real-World Late-Phase Trials: How They're Helping Sponsors Bridge the Gap from Drug Efficacy to Effectiveness**

LEARNING OBJECTIVE
After reading this article, the participant should be able to describe the purpose and execution of real-world late-phase trials, differentiate the roles of real-world data and real-world evidence in clinical research, and provide examples of interventional and non-interventional forms of these trials.

DISCLOSURE
Lucia Zaccardi: *Nothing to disclose*

11. Sponsors are cited as using real-world evidence (RWE) in support of which of the following purposes?
a. Ethics committee approvals
b. Regulatory filings
c. Protocol amendments
d. Site trainings

12. RWE is derived from analysis of which of the following?
a. Regulatory filings
b. Adverse events reports
c. Real-world data
d. Protocol amendments

13. Which of the following is cited as a key objective of real-world late-phase (RWLP) trials?
a. Ensure safety and effectiveness of marketed drugs in broader patient population.
b. Correct any inaccurate information associated with a drug's marketing claims.
c. Collect data for potential legal actions to be taken against competing products.
d. Confirm that the dosing recommendations for different age groups are accurate.

14. The author cites which of the following as encouraging the use of RWLP trials?
a. Study coordinators
b. Patient advocacy organizations
c. Institutional review boards
d. Regulatory authorities

15. Which of the following is a difference between an interventional and non-interventional RWLP?
a. Non-interventional studies are only conducted in pre-marketing conditions.
b. Interventional studies are usually requested by regulatory agencies.
c. Non-interventional studies are parts of compassionate use programs.
d. Interventional studies make use of registries and natural history studies.

[Test continues on next page…]

16. The author suggests which type of trial format to bring non-interventional RWLP studies to patients in the real world?

a. Observational
b. Double-blind
c. Decentralized
d. Basket

17. Which of the following are noted as being involved in potential applications for RWE?

a. Patient recruitment campaigns and clinical study agreements
b. Determinations of the relative efficiencies and costs of competing study sites
c. Pilot tests of new regulatory guidances and principal investigator training
d. Value-based contracts and comparative effectiveness research

18. Among others, RWE can help which of the following persons make better decisions regarding study designs and clinical endpoints?

a. Regulators and monitors
b. Patients and physicians
c. Patient recruiters and compliance officers
d. Ethics committees and data managers

19. When should planning for real-world studies begin?

a. During Phase I
b. During interim safety evaluations
c. During Phase III
d. During post-approval reviews

20. What expected trend in RWLP activity in the U.S. is noted by the author?

a. Low levels for the foreseeable future.
b. More trials in the next few years, followed by a leveling off.
c. A rapid increase in the next five years.
d. A shift to trials conducted mainly for pain management and weight control.