

The UK Freelance Network

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Economic realities are changing the way companies do business. One significant change is the growing numbers of freelancers in the clinical trials arena.

The clinical research work force undergoes continual change in the ever-repositioning pharmaceutical industry. Mergers over the past decade have led to decreased numbers of permanent employees in sponsor companies and an increase in the freelance sector—and there are indications that the trend is gaining momentum.

The freelance workforce includes many highly experienced, self-motivated professionals, whose skills range from monitoring to senior project management. Freelancers also provide support services, such as data management, auditing, and regulatory affairs consulting.

During the past decade the number of freelance clinical research personnel in the UK and the rest of Europe has increased significantly. More than 270 freelance clinical research associates (CRAs) are currently registered in the UK and an increasing number are registering

in Eastern and Western Europe.

The escalation of layoffs in clinical research, and the resulting job insecurities, has had a significant effect on the growing numbers of clinical professionals who choose self-employment. Individuals now want to take control of balancing their personal and professional lives. For them, becoming freelance is a conscious act of will, a pathway to improving their quality of life, or a stance against the limitations of salaried employment. The motivation behind becoming a freelancer is “choice.” Parents may make the choice to control the amount and timing of work. For others, the incentives may be how much money they wish to earn, the opportunity to be their own boss, the freedom to choose a variety of work, and/or the chance to arrange flexible work hours to pursue a hobby or other interest.

Companies who contract with freelancers often do so because of their expe-

rience and flexibility. Typical freelancers offer their prospective clients more than seven years of clinical research experience. In addition, freelancers with a broad spectrum of knowledge and specialist skills in specific indications can adapt to new projects in a short time with minimal assistance.

Strategic use of freelancers

The responsibility of a project manager is to set up and run an effective project team. Recruiting appropriate members is an essential part of this process. In the current climate, however, most project managers have experienced external influences. Frozen headcounts or budget limitations, for example, can create negativity in a team. That, in turn, can make it difficult to perform a study effectively within its timelines.

Upon reviewing the study protocol, the project manager determines selection criteria for selecting study team members, taking into consideration such factors as the skills and expertise required and the study workload, location, timelines, and budget.

When hiring new permanent staff is not an economic option, project managers may wish to consider outsourcing. Contracting with freelancers can be particularly useful when the project manager needs local expertise for a pan-European trial or a multinational study to be conducted on more than one continent. Employing individuals with knowledge of local regulatory and ethics expectations can alleviate anxieties and agenda delays caused by conducting a trial in diverse cultures, with differing regulatory requirements, medical practices, and languages.

The introduction of new technologies has given hiring companies more flexibility to adapt and improve CRA staffing structures. Throughout Europe, companies that hire freelancers are decentralizing their management of CRAs. Although specific approaches differ widely by company, sponsors are turning to full time contract and freelance study monitors to assist in building stronger local relationships with investigator sites.

Over the past five years, however, their approach to freelance resourcing has changed—driven principally by the surge of small independent CROs. With limited resource budgets and profit margins to be considered, small CROs contract in freelance services as a temporary solution to cover working peaks and troughs. CRO study managers also cooperate and submit freelancers' curriculum vitae (CVs) when bidding for a project. As more clini-

cal trials become multinational, this working practice enables small CROs to tender for a variety of projects they would not have otherwise considered due to insufficient resources. In other words, American CROs can use freelance CRAs to monitor sites all over Europe.

Freelancers regard professionalism and a reputation for excellence as paramount to obtaining a steady flow of future work and repeat business.

Well-established, full-service contract research organizations (CROs) may seem the obvious choice. However, handing over full project responsibility may not be part of the sponsor's clinical agenda when it wishes to maintain control of the project. Consequently, many sponsors increasingly work with independent contractors (mainly monitors), whom they can control directly.

Project managers value direct communication with freelance clinical trial monitors. Also, individual commitment to and continuity for the study can be critical to maintaining a punctual and efficient project. Resource restrictions, personnel promotions, and internal employee rotation in sponsor companies can lead to a lack of continuity for project teams. Such factors can also affect CROs. Because freelancers are not ordinarily subjected to internal company politics, they are less likely to be distracted by in-house issues and more likely to be project-driven and committed to their assigned task.

A recent survey highlighted the idea that freelancers regard professionalism and a reputation for excellence as paramount to obtaining a steady flow of future work and repeat business.¹

Until recently, pharmaceutical and biotech companies outsourced only limited freelance services—to cover maternity and sick leave, or as extra temporary help to ensure project deadlines were met.

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A longer term solution can be freelance monitors for studies in which continuity is desired, but the budgets, resources, and workloads do not demand a full-time CRA. For example, a CRA may be required only one or two days a week to monitor a year-long study.

In some cases, a freelance project manager may be given full responsibility and a budget for running a clinical trial. This is often done by foreign pharmaceutical companies and CROs that do not have affiliates in the country where the trial is to be held, or when there is insufficient personnel or budget for the trial. A project manager who requires extra resources for a study may use the services of other freelancers.

Pharmaceutical companies and CROs have varying policies regarding the use of freelancers. Some companies are reluctant to use freelancers, and consequently contract via large outsource providers. Their main concern is liability, and not all freelance individuals hold professional indemnity insurance. Although study managers, auditors, and medical writers tend to be covered, only a small percent-

Choosing a freelancer

Companies, particularly non-European companies, may find it difficult to identify European freelancers and select suitable candidates. The majority of freelance work is obtained through colleague recommendation, referral, or an active freelance network. On receiving a freelancer's qualifications and experience, a sponsor generally interviews the candidate either by telephone or face-to-face. If the client is overseas, an in-depth telephone interview may be sufficient to establish whether the candidate has the relevant experience and knowledge and can provide the service required. A minimum of two references should be obtained, ideally from a former employer for whom the candidate worked in a relevant position.

Country-specific clinical associations may provide a directory or a Web link to freelancers' expertise and experience. Unfortunately, most European countries have yet to recognize the freelance work sector as a professional body.

Some CROs and employee recruiting agencies may occasionally place a freelancer for a fee. Other agencies specialize in freelance recruitment; they focus on finding and selecting suitable freelance candidates and verifying their expertise, experience, and suitability for various assignments. In these cases, a percentage of the contract value may be charged as a fee, or the involved parties may agree to another method of payment.

Although the freelancer is responsible for guarding against a conflict of interest when choosing contracts, the hiring manager should also consider potential conflicts when interviewing the candidate. Before any study documentation or study information is divulged, both the freelancer and the study sponsor should sign a confidentiality agreement.

Freelancer training

Clinical professionals, whether freelance or otherwise, are responsible for directing their own training and career progression. Most large companies have established

continuing professional development schemes that identify training needs and send employees to relevant training courses. Many also organize mentoring support. Freelancers, however, are likely to have limited budgets. Knowing what they need to know, and not having the budget to learn it can be frustrating. However, to offer services that meet professional clinical research standards, freelancers know they must keep updated on industry changes. They can achieve that in a number of ways.

The Institute of Clinical Research (ICR) in the UK instituted a continuing professional development (CPD) program in 2002. ICR defines CPD as “a structured approach to maintaining, improving, and broadening professional knowledge and personal qualities that enables practitioners to advance their professional development and fulfill their professional, technical, and ethical responsibilities throughout their working life.” Through the program, clinical research professionals can plan short-term learning to address both short- and long-term goals, enabling them to evaluate how to achieve their goals.

ICR plans that its program will evolve into one that allows individuals to accumulate credits for evidence of knowledge, competencies, and skills and that results in a formal qualification.

Courses offered. A number of societies and companies offer a range of courses covering clinical research topics, from project management and data management to pediatrics trials to advantaged monitoring skills. Unfortunately, many of those courses are relatively expensive for an individual who has no employer funding. This deters some freelancers from attending potentially useful courses, because they must not only pay for the course themselves but also potentially lose pay for the days they attend the course. Some course organizers give discounts to freelancers, but that may require pleading, begging, and negotiating. Some freelancers are lucky enough to have a contract with a company that considers training essential for all professionals working with them, direct or freelance, and will cover the course costs.

Publications. Other ways freelance individuals keep updated are through professional magazines and journals such as

Applied Clinical Trials, *The Monitor*, *CRFocus*, *GCP journal*, and other industry publications.

The Internet is another source of information. Web sites such as pharmacos.eudra.org and www.corec.org.uk provide updates on the ICH good clinical practice guideline, regulatory changes, and EU directive changes.

Freelancers who attend forums and seminars to learn industry news may also use these opportunities to network with freelance colleagues and potential clients. The purpose of the regional forums is to provide geographically accessible meeting places to train and update freelancers on relevant clinical research and pharmaceutical industry issues. ICR currently runs an annual Freelance Forum specifically for this purpose and several freelance regional meetings. Freelancers within the group or external specialists may present on these topics. The group enables individuals to seek trial-related

ing them to attend investigator meetings and making them feel part of a team. That involvement can also help to ensure that the individuals follow the company's procedures. By giving them instruction on the protocol, electronic data capture (if used), and monitoring reports at the start of the contract. This can prevent confusion and delays later on. Good communication is also essential.

Freelancers are cost-effective

Freelancers have been perceived as an expensive resource option, but as sponsors and CROs gain more experience with the freelance workforce, this attitude is gradually changing. Also to be considered, geographically spread freelancers can allow for project savings on the cost of travel, budgets, and time.

Direct costs. Most freelancers charge hourly, daily, or sometimes project-specific fixed rates. Whatever the method of invoicing, the contract should state what

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advice and provides knowledge and resource support.

It is important for a freelancer to collate a portfolio of evidence to demonstrate training updates, accentuating what has been learned and how it has been implemented in work settings. This evidence highlights a commitment to continued learning and, when presented to a potential client, may help win freelance contracts.

Although continued professional development is the individual freelancer's responsibility, sponsors or CROs who contract them should provide project-specific training. Giving all personnel relevant training allows them to work in a coordinated way with the sponsor company and its SOPs (standard operating procedures). It should not matter that members of the team may be located around the world.

It is advantageous to involve a freelancer from the start of the project—invit-

is included in the rate. A freelancer based in England with 7–10 years experience, for example, may charge £240–£300 (\$390–\$485) per day for basic monitoring, but rates are often open to negotiation. The freelance rate may include an office—complete with computer, email, phone, and fax—personal transport (a car) and insurance, national insurance (country-specific), personal pension, holiday pay, and training. It may not include the value-added tax (VAT), project-related phone charges, or other project-related expenses.

Hidden costs that need to be taken into account when considering freelance resourcing include the staff time required to locate, interview, and select the freelancers. The efficiency of this process varies and a number of other factors should be considered.

- Is there an established in-house database of freelancers?

- Can colleagues recommend individuals?
- Is using an agency to cut cost a practical option?
- Have standard contracts and confidentiality agreements already been created?

Once a sourcing system is in place, costs are reduced for future freelance contracts.

Daily rates for personnel contracted through CROs vary according to the negotiated agreement. Cars, training pensions, and the cost of insurance need to be taken into consideration if these are not included in the daily rate.

It is important to remember that freelance work is project-based, and that payment is for work performed. A sponsor may hire additional employees—monitors, for example—but if unforeseen delays occur, the company can find itself with too many resources, which can waste time and money. That situation is less likely to occur when a sponsor uses freelancers, because contracts are generally set after study start dates are confirmed. This advantage for the hiring companies can be detrimental to freelancers. “Total flexibility” means that until both parties sign the contract, the hiring company can delay commitment and avoid unnecessary risk. The hiring company should consult its finance department should when freelance contracts are signed, because invoices can increase the department’s workload.

Freelance teams

Changes in the clinical research environment have led to changes in resource requirements. Freelance teams have become the next resource business model. A freelance “virtual team” is not a fixed and permanent entity. “It usually comprises freelancers who possess complementary skills and expertise, working together within the same industry.”¹

In the UK, freelance teams evolved as colleagues worked together and collaborated in formal and informal networks. With the help of these networks, freelancers can attract and deliver projects, which an individual alone would be either unable or unlikely to contemplate or be awarded.

Teams can expand or contract depending on the nature and scale of the project. For each project, a team of freelancers

who possess the relevant expertise to meet a client’s needs can be assembled. Those teams can include members from several disciplines—project managers, CRAs, study co-coordinators, clinical trials administrators, data managers, or simply internationally located CRAs.

Though the individuals work within a unit they remain self-motivated as they keep their self-employed status and have the opportunity to work with like-minded freelancers in other geographical areas. Communication between clients and freelancers is direct and assured, because no third parties are involved.

Potential clients may have hesitated, thinking that the freelance work force lacks backup support. With an ever-growing freelance network and specialist freelance recruitment agencies, this is no longer the case. Contingency plans can be set up at the start of a project to ensure immediate resource cover in the event that unforeseen circumstances occur.

The skills needed to manage a freelance team are the same as those required for any company’s field-based division. As previously stated, it is important to ensure that each person involved in the study is included (if possible) at the beginning and made to feel a valued member of the team. Regular study updates, by telephone or email, can help prevent inaccuracies and ensure team competence. Monthly meetings can reinforce each person’s motivation and consolidate a group whose members normally work in isolation.

Time sheets are useful tools to trace the workload of team members and confirm that they are working at their potential. Time sheets can be used in conjunction with the invoices submitted by each individual.

Freelancers throughout Europe

Although this article focuses on freelancers in the UK, the rest of Europe has also seen a significant increase in the self-employed sector. Taxes, insurance, and employment regulations in each country help each person determine whether it is advantageous to become self-employed. Freelance opportunities have evolved in Germany, The Netherlands, France, Switzerland, and Belgium—and to a lesser extent in Spain and Italy.

With an increasing focus on establishing clinical trial programs in Central and

Eastern European countries, a growing number of freelancers are setting up to meet the demand there. They are doing so despite some difficulties with employment regulations.

The EU has proposed a “fixed term contract” directive (EU52002PC0149, europa.eu.int/eur-lex/en/com/reg/en_register_05202.html), which defines the general principle of nondiscrimination against temporary workers. The directive guarantees minimum rights for temporary workers by enabling them to gain access to permanent employment benefits, access to social services, and access to training. Whether this will have any effect on the freelance work force is still uncertain. Freelancers are not entitled to these rights as they are engaged on “a contract of services” not “contract of/for employment.”

Although this may seem at first glance to be detrimental to the individual freelancer, general opinion is that this is beneficial to both the freelance market and client companies. The “no hidden extras” contract with freelancers will be attractive to client companies. As a consequence it is anticipated that this will be a major drive toward further growth to freelance services.

References

1. The Freelance Survey (The Freelance Centre, Croft House, Clapton, Near Bath, Somerset, England BA3 4EB).

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