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Role of Radiologists in Contract Research Organizations (CROs)

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A B S T R A C T

Clinical trials play a vital role in advancing technology and novel therapies in the healthcare world. However, the increasing scale of trials and the complexity of the regulatory approval process is often a barrier for those interested in conducting research. Contract research organizations (CROs) aim to address this problem by offering their infrastructure and expertise to bring a therapy from conception to approval without the need for in-house staff. Clinical trial imaging often plays an essential role in this process, creating a need for radiologists and a unique opportunity to provide irreplaceable value in their ability to interpret and analyze the imaging outcomes of therapies in question. This paper explores the concept of CROs, the crucial role played by radiologists in their operation, and the nature of the CRO – radiologist relationship.

The Growing Importance of Contract Research Organizations

As medicine has evolved over the course of the 21st century, the scale of clinical trial research aimed at developing novel pharmacotherapies and technologies continues to grow in scope. The global clinical trials market was estimated to be worth approximately USD $40-50 billion in 2021 and is expected to continue growing at a yearly rate of 5%-6% from 2021 to 2028.[1–4] To achieve this growth, physicians, and industry have often partnered with one another in order to bring a new therapy through the rigorous testing and approval process that is needed before it can benefit patients in day-to-day clinical practice. When carried out appropriately, these physician-industry relationships can benefit patients, the health care system, medical research, payers, providers, hospitals, and the medical industry.[5]

With the increasing scale of clinical studies and stringency of regulations, the logistical and financial barriers to conducting a proper trial can make it difficult for organizations to successfully carry out their research.[6,7] Because of this, some research institutions, government organizations (eg, NIH, EMA) and biopharmaceutical companies choose to outsource the heavy lifting of clinical trial management to Contract Research Organizations (CROs).[8,9] By offering clients their expertise in moving a new drug or device from conception to regulatory approval (eg, FDA, EMA), CROs can be an attractive option for those looking for additional help with the process, or those who would prefer to completely outsource and forgo the need for in-house staff.[10] Additionally, the separation between the sponsor and the CRO undertaking a clinical trial can provide health authorities a greater level of confidence that the results are blinded, independent, and unbiased.

While services that individual CROs offer can vary greatly, the most common include: product development and formulation, clinical trial management-preclinical through phase IV, central laboratory services for processing trial samples, data management services for preparation of an FDA New Drug Application (NDA) or an Abbreviated New Drug Application (ANDA), and various other complementary services.[7,11]

Due to the increasing demand for well-conducted research and the numerous barriers in place to doing so, the importance of CROs in today's world is substantial and likely to continue growing. The global CRO market size of around USD $44-60 billion in 2021 is expected to reach more than USD $80 billion in 2026 by most estimates.[12–15]

The Vital Role of Radiologists in CROs

When testing new interventions, there comes a need for parameters that can measure the magnitude of treatment response. While some conditions warrant the use of symptom reporting and lab values, many measures involving structure and anatomy such as tumor remission require the use of clinical trial imaging and a certified radiologist to report reliably.[16,17]

The importance of radiology in the research world is especially clear when observing the growth of clinical trial imaging. In sync with the increasing scale of clinical trials, today's global clinical trial imaging market of approximately USD $1 billion is expected to grow

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to nearly USD $2 billion by 2030 at an annual rate of around 8%.[18–21] CROs make up the bulk of this at ~46.4% of the market, followed by Biotech/Pharma Companies at ~20%.[19] With this projected growth comes an increasing demand for radiologists who are interested and capable of partnering with these organizations to fulfill their research needs.

In addition to working with traditional CROs and biopharmaceutical companies that operate along the entire range of services needed in the clinical trial spectrum, there are also some physicians who opt to utilize their skills in the more specialized setting of an imaging CRO. These CROs offer expertise specifically in imaging protocols, state-of-the-art image acquisition and analysis, data management and quality control related to imaging. By doing so, they provide value for clients who may lack the skilled staff, equipment, or experience required for their study, while ensuring the rules of the protocol and criteria are followed exactly.[22,23]

For radiologists invested in the research and development of innovative biopharmaceuticals and medical devices, or for those who seek to employ their talents in settings outside of clinical practice, education, or academic research, partnering with a CRO may be a rewarding alternative. By understanding more about the current operations of CROs, current and future radiologists interested in industry research can enter this world with an improved awareness of the nature of this commitment.

For radiologists interested in clinical trial imaging with CROs, the question of relevant expertise is a pertinent one to address. From the perspective of CROs, key qualifications that they look for in potential physician partners include standard board certification, expertise in advanced modalities (eg, CT, MRI, ultrasound, PET, nuclear medicine), and a relevant therapeutic subspecialty for the research topic in question.

While each therapeutic subspecialty typically only lends itself to 1 or 2 overlapping fields of research, certain disease areas contain greater volume or projected growth, creating more opportunities for research involvement. Disease indications with the greatest volume and projected growth of clinical trial imaging closely mirror that of the overall clinical trials market. Of note however, nonalcoholic steatohepatitis (NASH) research is the fastest growing field in clinical trial imaging at an expected 8.3% due to growing prevalence of the disease and strong demand for an effective treatment, which is lacking at the time of writing.[19] Other significant disease areas include cardiovascular and oncology, followed by neurology and musculoskeletal.

Aside from qualifications and skills, one of the most important qualities for a research radiologist is a willingness to undergo training and testing. As Richard Walovitch, MD, notes: “Contrary to what some people may believe, it isn’t the modalities that pose the biggest challenge to us. The biggest challenge centers on how to carry out trials to achieve reproducibility in reader performance, whether we are talking about a single radiologist and a single modality or a double-blind interpretation with adjudication using multiple modalities. It is critical for a study’s success to have a high level of agreement across readers and good consistency within assessments made by the same reader.”[24] To achieve consistency and reproducibility demanded of clinical trial imaging, the radiologist in question should be prepared for the dedicated training that is required to produce these results.

CRO Radiologist Perspectives

To better understand CROs from the viewpoint of a radiologist working in the clinical trials industry, we interviewed Dr J.C. and Dr C.S. to understand their experiences in the field thus far.

Dr C.S. began her career as a staff radiologist for Brigham and Women’s Hospital. Because of her department’s involvement with a CRO to provide radiology interpretations, she also read scans for clinical trials in addition to her clinical responsibilities. Eventually, her time spent reading clinical trials gradually replaced time in clinical practice, until she transitioned into full-time interpretation for CROs. Today, she continues to focus primarily on clinical trial reads while occasionally providing consulting advice on trial design.

Dr J.C. started her career in body and breast imaging, first in academic medicine, followed by private practice. She then accepted a clinical trial reading opportunity at a CRO that she learned about through a colleague from residency. Over the years, she recognized the importance of non-reading responsibilities in a CRO such as recruitment and training of new radiologists and process improvement within the company. Nowadays, she dedicates most of her time to various non-reader roles, with a strong focus on mentorship.

While there are some differences in the paths’ they took into CRO radiology and a key distinction in their roles and responsibilities, the perspectives they share on working as a CRO radiologist provide great insight into their world.

A Typical Path Into CRO Radiology

A Strong Background in Clinical Trial Reading is Required

Regardless of one’s journey into CRO radiology, all paths begin with experience in clinical trial reading. In addition to familiarizing oneself with the variety of response criteria that radiologists must adhere to for image interpretation, there are nuances regarding client preferences and needs that one must learn to adapt to over time.

As radiologists become familiarized with this process of standardization and adjustment for new clinical trials, they become adept at producing consistent results in different circumstances, which is necessary for CRO work. For anyone interested in this field as a potential career option, a strong background in clinical trial reading is crucial.

Even within oncology, trial criteria will change based on a variety of factors such as tumor type (solid vs hematologic malignancies), treatment (chemo vs immunotherapy), and trial sponsor. Not only does clinical trial experience show one’s familiarity with the work, but it also shows the adaptability and commitment to dedicated training that is necessary with every new trial.

- “Radiologists may participate in trials at the “site” (ie, not central) level if they work in a cancer center. It’s a good idea to keep a record of the types of trials you are involved with (eg, indication, phase, criteria) and the approximate number of reads done. This is a way to gain trial reading experience. ” - J.C. MD
- “The process required dedicated training to learn the rules of interpretation for each individual trial.” - C.S. MD

Word of Mouth is the Main Path Into CROs

Prospective hiring for radiologists tends to happen when CROs contact the radiologist, rather than vice-versa. Due to a strong supply of radiologists with interest in working with CROs, there has generally not been a need for CROs to openly advertise new positions when they need more readers. Thus far, they have had no trouble supplementing their staff with recommendations from their existing partners, and this practice is not expected to change within the next 10 years.

- “We can build our pool of excellent readers merely by word of mouth. We are well known and readers are happy to work with our organization. It’s an attractive opportunity so there is a lot of interest. ” - J.C. MD

Most CRO Radiologists are Contractors

CROs derive most their work from clinical trials that have clear start and end dates. Because the number of active projects and the number of reads needed at any one time can vary significantly, it is typically not

feasible for CROs to have salaried, full-time staff unless the organization can reliably predict their flow of work and the reader's capabilities. As a result, CROs will typically default to having contracted radiologists who moonlight or participate in trials part-time as needed. Among these radiologists are a variety of practicing, semiretired, or academic physicians, the balance of which varies between organizations.

- "Most of our readers are contractors, some of whom read full-time, and some who are part-time and have other career responsibilities. We also have some full-time radiologist employees, which helps us more fully meet the needs of the trials and sponsors. Regardless, I believe all of our readers share a passion for the work." - J.C. MD

Most Begin Part Time, Some Transition Into Full Time

Because CRO work is typically contract-based, the work typically lends itself to part-time arrangements with radiologists. Those who have enough concurrent projects to be working full-time have already established themselves as trustworthy readers and shown they are capable of juggling multiple clinical trials at once, while also being able to accommodate the varying workloads that come their way as project needs change.

- "I had a gradual transition from reading clinical trials 1 day per week to eventually doing it 4 days per week and then often up to 6 days per week while still in an academic clinical practice. I think many people would be interested in doing a little of this type of work to supplement revenue, but few people would like to do this as their full-time job." - C.S.

The Upsides of Working as a CRO Radiologist

A Variety of Pathologies

While clinical radiologists will typically see a set of similar cases on a regular basis, the experimental nature of clinical trials can present opportunities to interact with unique or rare orphan diseases that one would typically not encounter in everyday clinical practice.

- "As a central reader, one might see manifestations of these diseases that would never be seen as a community radiologist." - J.C.

The Freedom to set Your Own Schedule

Outside of the deadlines set for assigned reads, CRO radiologists are free to complete their work at whatever time of day suits them. However, this comes with the caveat that when multiple projects overlap, there can be unexpected spikes of workload.

- "The main upside for me is the job flexibility as far as work hours and working from home. No commuting time or cost and I can take time to do anything I need to do during the day, as I can catch up on the work in the evening or over the weekend. This is not as straight-forward as it seems, as you commit to individual trials and they may get very busy on short notice**.** If you want to be respected and get more work, you work hard to help the project team meet the sponsor expectation on timelines, but for the most part time is quite flexible. Vacation time does not need to be cleared through anybody; I just notify the project teams when I'll be away." - C.S.

Independent Work

- "I have full control over my work time with no reliance on others (residents, fellows, colleagues), and there's fewer interruptions (no clinical staff asking me to review cases read by colleagues). I have always been a very independent worker, so I perform very well when tasks are just assigned to me, and I can complete them on my own." - C.S.

The Downsides of Working as a CRO Radiologist

Less Patient Contact

The remote and blinded nature of clinical trial reading means that patient contact is lacking in CRO work. Thus, CRO work may not be suited for radiologists looking for those personal interactions.

- "The initial change from clinical practice was a big deal - as a mammographer I had a lot of patient contact and that was very gratifying, so I missed that at the beginning." - J.C.

Less Interaction With Physician Colleagues in Other Fields

- "I do occasionally miss the interaction with clinicians to hear about the symptoms or response the patients are undergoing, but not too much. One other thing that would be a downside for someone that enjoys academic or even private practice clinical work is that there is very little personal interaction with others. You need to be happy to just be by yourself and do your work. If you're someone who likes chatting with your colleagues or reviewing cases with others or teaching residents/fellows or interacting with clinical colleagues to get feedback about the patient whose images you're reading, this is probably not the job for you." - C.S.
- "The excitement of talking to a surgeon, saying you found a hot appendix, for example, is not something you're going to find here. People who thrive are those who don't need that type of clinical interaction." - J.C.

No PTO

- "One thing which is tough is that you only earn your pay when you are working. So, unlike a salaried position where vacation time and nights/weekends are 'off' time for the most part, any day, night, weekend that I don't read cases, I don't get paid. So, you need to find a work-life balance that suits your financial expectations." - C.S.

Variable Workload

Radiologists looking to take on CRO work as a full-time job often need dozens of trials on their plate at once to fill up their days. However, varying project workloads also means that there will be days with little work, and others where multiple deadlines will align for much busier days.

- "I think the main downside is that the workload can be variable. If you want to stay busy enough to have work every day, you need to accept many trials. For example, I'm probably on 50-60 trials at a time. Not all are busy or even active consistently, but you need to take that many so that 10-12 are busy at a time and it can fill your workdays. However, sometimes this means you will be really busy and have to work weeknights or weekends, when you may not want to. Alternatively, you can work less and sometimes have nothing to do after an hour or two a day. So, you need to be able to roll with the punches. It can be less consistent that a typical clinical job." - C.S.

FIG 1. The lifecycle of a project. (Color version of figure is available online.)

Fewer Opportunities for Academic Research

Due to the client-oriented nature of the clinical trial work that CROs undertake, it can be difficult to find arrangements where clients are willing and able to provide the data for purely academic research. When research is published however, it is typically in the form of a white paper from the CRO company.

- "If you are interested in writing academic manuscripts, there are probably some limited opportunities if you wanted to pursue them, but much less readily available than if you were in full clinical practice." - C.S.

The Types of Radiologists That Thrive in CRO Work

Unbothered by Repetitiveness

As many are aware, the role of a radiologist in clinical trials involves reading and quantifying the same disease state in a consistent way. Some full-time CRO radiologists will offset this repetitiveness by taking on trials in different disease states and intersperse their reads to provide some variety in their work. Regardless, being able to deal with this monotony is an essential quality for a successful CRO radiologist.

- "The most important skill is the ability to do repetitive tasks without becoming bored or disinterested. It can be mundane and tedious, but I rarely mind that type of thing. Some people would say it is too boring as the work is not particularly variable. For example, I might read 50 consecutive CT scans for the same disease-type. I usually try to mix in different studies when I have a lot to read for one trial. So maybe I read 10 subjects with CLL, but then will take a break by reading 10 subjects for a prostate trial." - C.S.

Committed to Their Role

While the majority of CRO Radiologists are part-time contractors who moonlight, clinical trial work still comes with a set of expectations. These include committing to a trial from beginning to end, which can sometimes take years, and showing commitment to completing reads in a timely and quality fashion. Only by showing these qualities can a new CRO Radiologist expect to be contacted for additional clinical trial contracts in the future.

- "A big difference between central reading vs community radiology is that you cannot just sit down at a workstation and start reading from the list of patients of that day. Once you start reading on a subject, You're committed to reading that subject for the life of the trial; which can last for years. Readers need to understand that it is expected for them to complete all reads on subjects they start; as well as meet any expedited turnaround times that the trial may require." - J.C.

Perspectives on CRO Radiology Over the Next 10 Years

Artificial Intelligence

- "Even if AI becomes more important, I think radiologists would still be involved. Either hybrid reading would occur, or radiologists would act as liaisons between sponsors and the results. There will always be a need for some service or consultation, but there may just be fewer jobs since reader jobs make up the majority of positions today." - J.C.

Increasing Competition, Lower Compensation

- "Likely because of finances, I have seen many, many radiology colleagues in academic and private practice pursuing opportunities as readers for CROs. This increases the pool of readers, likely driving down pay to radiologists as competition for work increases. I have also seen the start-up of tons of CROs, perhaps increasing competition to win bids from the pharmaceutical industry, which also drives down pay to CRO radiologists. The CRO that can do the job well for the lowest cost usually wins the bid." - C.S.

Duplicative Reimbursement of Clinical and Central Reads

- "Right now it seems that work is duplicative and costly (clinical reads and central reads, both being reimbursed by someone, either health insurance or pharmaceutical companies research costs), so perhaps there will be an evolution where site reads may conform to a standard that makes the CRO paradigm superfluous. However, I don't really see that being the case in the next 10 years as the CROs have the data package down to a science where it is easily digestible for regulatory agencies to grant approval for pharmaceuticals and that is why the sponsors are willing to pay large sums of money for the CROs to perform this service. It also allows consistency across many enrollment sites globally." - C.S.

The Lifecycle of a Project

Every clinical trial that a CRO takes on will usually go through a predictable pattern from start to finish. Here, we explore the typical timeline of a project (Fig 1).

1. Sales:

- The process begins when a sponsor/client provides a protocol for the CRO vendors they typically work with that delineates how the study will be run. The CROs each pitch their offerings to the sponsor, and the one that wins the project proceeds with pricing. Topics included in a pitch may include:
  - How the organization handles reading and what their reading system is like
  - Qualifications and introduction of their readers
  - How readers are monitored
  - Prior projects and experience
  - Unique offerings and lessons learned (pitfalls and limitations of indications)

2. Pricing

- Once the project has been sold to a CRO, they discuss the pricing of the project, which can vary significantly depending on certain requirements the sponsor has. Factors that may influence cost may include:
  - Standard run-of-the-mill trial criteria, which are typically the most affordable
  - Unique or newer reading criteria, which will typically cost more due to fewer radiologists being trained in the criteria, or new readers needing to be trained for the trial.
  - Specific training that requires a key opinion leader

3. Trial Startup

- Charter development: A document that explains the logistics of how the CRO will be operating, and what they can offer their sponsor that differentiates them from other CROs. Elements may include but are not limited to:
  - Number of readers, and reader services that will be offered
  - Reader monitoring and quality control - backup plans if reader needs to be substituted
  - Data management, what fields will be transferred
  - Data outputs and deliverables
  - Recommended trial design
- Project Team Onboarding: readers are chosen and trained; liaison, management, and non-reader personnel are finalized for the project
- Testing and debugging: the technology and processes needed for trial reading are developed and smoothed out
- Scans from the sponsor and data collection from reader outputs are coordinated, and images are quality checked for trial inclusion/exclusion criteria

1. Trial Maintenance

- Liaisons meet with and answer sponsor questions during the trial, such as audits regarding regulatory input or quality

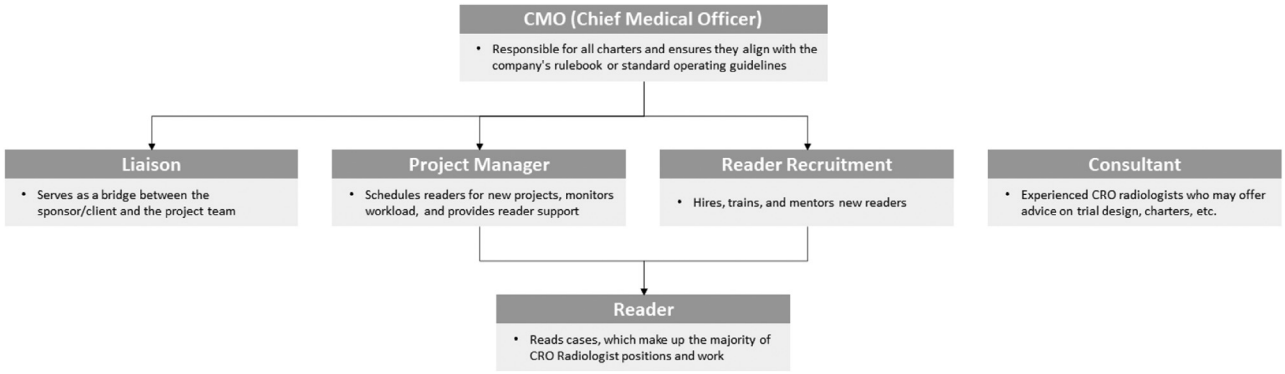

FIG 2. Roles in contract research organizations. (Color version of figure is available online.)

1. Final Transfer

- Primarily consists of non-read work, including data management, read management, edit checks, and project closeout.

The Roles a Radiologist May Play in a CRO

Clear explanation of roles can vary significantly between CROs. Some organizations will have clear titles and job descriptions, while others have their readers complete tasks as needed on an ad-hoc basis. Despite this variation, below we will explore the essential roles that are necessary for a CRO to function (Fig 2).

1. Reader: The bread and butter that makes up the majority of positions that radiologists fill
   - A day in the life: "I start my workday in the early morning and read any cases that I'm notified are ready for review. There are usually 50-100 cases a day on my ongoing list. Some have fast turnaround times and those are prioritized. I'm in constant e-mail communication about new cases to review and cases that have been completed. I read for 6 CROs, so I read on multiple platforms, some cloud server-based and others dedicated workstations, so I'm often moving around to different workstations reading multiple trials in a day. Volume of work can be variable depending on how many active trials one is reading for, but this can sometimes be 15-hour days and sometimes be 4-hour days. It can involve nights and weekends, but I think this could be controlled if one wanted to do less work." - C.S.
   - *Road to mastery:* "After reading on clinical trials and using the same criteria a few times, I felt like I was very good in that role. Perhaps 2 years into the process." - C.S.
2. Liaison: Serves as a bridge between the sponsor/client and the project team.
   - A Liaison's roles may include:
   - ☐ Prior to the trial launch - liaisons develop documents that are needed for the startup of a trial (eg, a charter, which is explored in next section)
   - ☐ During the trial:
   - Liaisons answer the sponsor's questions regarding data or trial design. While liaisons can also be non-radiologists, radiologists have become more necessary in this role as sponsor questions become more sophisticated and informed.
   - They also provide logistical support for project teams. Their questions may include: "Can we have a short turnaround? How many applications do we need? What kind of computer support do we need?"
3. *Project Manager:* Schedules readers for projects based on each radiologists' availability and expertise, provides day-to-day support, helps readers balance workload, and answers reader questions.
4. *Reader Recruitment:* Involves hiring, training, and mentoring new readers.

a. "I enjoy mentoring our readers and being available to answer questions. We are fortunate in my organization to have a strong team of employee radiologists who are available to help mentor and monitor new readers." – J.C.

1. *CMO:* Responsible for all charters and ensures they align with the company's rulebook or standard operating guidelines.

2. *Consultant:* Outside of the typical company structure, experienced CRO radiologists may offer advice on design of trials, charters, and a variety of other functions.
   - "Maybe six times a year, I will teleconference or help edit work as a consultant. I've reviewed trial charters for imaging and radiologist training requirements, consulted on application design, case report set-up, and image viewer functionality, and also given lectures on imaging criteria for clinical trials and reviewer monitoring for accuracy." - C.S.

Conclusion

Clinical trials play a vital role in advancing technology and care in the healthcare world and will only continue to grow in importance. CROs help to lessen the barrier to entry for a variety of organizations interested in conducting research, and radiologists provide irreplaceable value in their ability to analyze and interpret the imaging outcomes of the therapies in question.

Due to the COVID-19 pandemic, qualities that previously distinguished clinical imaging from CRO imaging such as norms around working from home and in-person collaboration have become less rigid. While this will likely reduce the friction of transitioning from 1 position to another, whether this results in the prospect of working with CROs becoming more desirable remains to be seen.

Regardless, by understanding the nature of existing relationships between CROs and radiologists, future radiologists with an interest in the development of novel devices and therapies may find a unique and rewarding niche within the world of clinical trial imaging and CROs.

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