5 Factors to Consider when CHOOSING A CRO for your CARDIOVASCULAR CLINICAL TRIAL

Introduction

Clinical trials conducted in the Cardiovascular (CV) arena are challenging, first and foremost, due to the variety of underlying disease states and conditions that affect a majority of potential trial participants. In addition to participants coming into the study with multiple co-morbidities, CV studies themselves can be quite complex. From the selection of meaningful endpoints and measurement techniques, to complex randomization schemes, the differences between CV trials from other trial types become obvious. Layer these initial complexities with protocol designs that may incorporate a control group, retrospective and prospective elements, long-term follow-up, or imaging requirements to support the safety and efficacy of new technology, and a sponsor can easily see the scope of the study becoming much more difficult to manage. These difficulties can result in opportunities for inconsistency, inferior quality and non-compliance by sites struggling with a very complex protocol.

This is why choosing the right Contract Research Organization (CRO) for your CV clinical trial is imperative. The company you choose to work with over the next several years needs to have a strong therapeutic background, as well as a strong regulatory foundation. A powerful knowledge of CV trials is a must along with the know-how to manage the complexities of your trial. Finally, the right company will have the ability to understand you and your specific clinical trial needs. **Here, we expand on five factors you should consider when choosing a CRO for your CV clinical trial.**

1 Choose a company with a strong regulatory foundation and robust therapeutic background.

Regulation-focused compliance should be at the foundation of your CRO partner. Being aware of the requirements the Food and Drug Administration (FDA) has put in place to ensure high quality clinical research data and protection of human subjects is critical in a CRO partner. While that sounds obvious, it unfortunately is the exception, not the rule, as evidenced by the number of warning letters issued year after year. By working in a regulatory framework, non-compliances can be identified readily, and corrective actions can be put in place to secure compliance. Clinical trials, by nature, are complex. You don't have unlimited time for a CRO to get comfortable. You will want to find a company that, with minimal ramp up, can hit the ground running due to its background and knowledge. To be successful in any clinical trial, a company should be well-versed in the disease process, as well as the regulatory framework within which researchers developing these novel treatments must work. This happens over time by covering such therapeutic areas as thoracic and abdominal aortic aneurysms, peripheral vascular disease, coronary artery disease, heart failure, ischemic cardiomyopathy, and arrhythmias, among others.

Look for a company that has experience in a vast majority of these therapeutic trials:

- Abdominal aortic, aortoiliac, or iliac aneurysms
- Thoracic aneurysms
- Coronary disease
- Renal artery disease
- Superficial femoral artery disease
- Heart failure
- Ischemic cardiomyopathy
- Aortic dissection
- Fibrillation (both atrial and ventricular)

This expansive experience is important in order to develop the creative problem-solving and critical thinking skills needed to navigate adversities the client or sponsor will face.

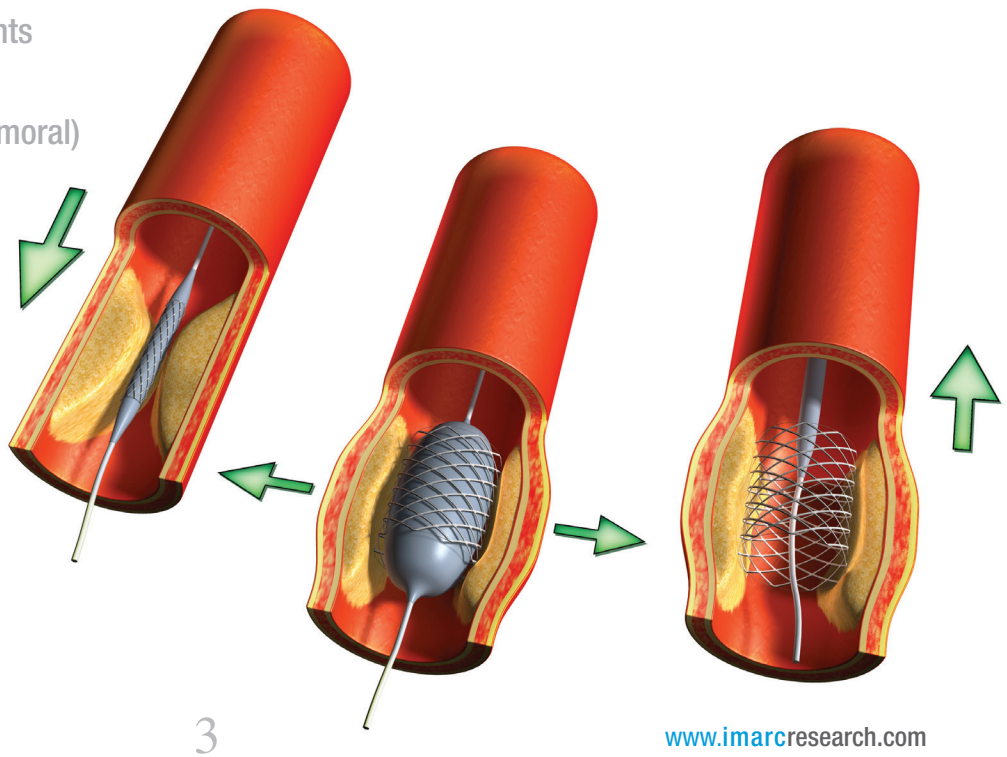
2 Choose a company where employees have a powerful knowledge of CV trials.

Your trial deserves a higher level of expertise than can come from a company that participates in CV trials every now and then, or a company that does the majority of its work on pharmaceutical trials; it deserves a company that has a proven track record of managing the complexities of CV trials every day. Consistency requires a depth of knowledge and experience that comes with companies that work with both large medical device manufacturers running multi-national studies to single center investigator-initiated IDEs.

If possible, take a look at the professional background of employees. Ideally, many of those who will be working on your trial will have a CV background. You may be able to find nurses who have 15 to 20 years of CV experience. This helps individuals to understand the therapeutic area and the scrutiny the FDA puts on cardiovascular device manufacturers. It also creates an understanding of the typical hospital charts that will be presented during the trial and many of the challenges that will arise.

If applicable, look for a company with a medical device focus, which includes knowledge of 21 CFR 812 regulations, a core competency. **A company that has previously worked with many of the sites in the CV arena and knows the thought leaders in the field, as well as their research coordinators can have real benefits, too.** Finally, ensure the company you choose understands the technology, the clinical setting it is used in, and its application. Preferably, a company will have vast experience in various CV technologies, including implantable devices, imaging studies, and IVD studies focused on the various stages of CV disease. **Look for a company that has experience with at least a majority of these CV trials:**

- Endovascular grafts
- Balloon-expandable stents
- Drug-eluting stents (coronary, iliac, renal, femoral)
- Vena cava filter
- Defibrillators
- IVDs for diagnosing MI
- IVUS imaging



CV trials are five, sometimes 10, years long. They often involve lifesaving, significant risk devices, and there are regulations that need to be followed, including 21 CFR 11, 50, 54, 56, and 812. Consequently, a lot of long-term data is collected, which can be challenging. Due to the long length of time, subjects may not return for follow-up visits, sites may have staff turnover or inconsistencies within their study teams, and the energy level of a trial may wane as the trial progresses, among other challenges. Adapting to the cycles within a long trial may require a company to rapidly identify the problem and set its problem solving engine into motion, perhaps conducting additional training, supporting a new research coordinator, visiting the sites more often to reduce the possibility of complacency, or any other number of interventions. **The bottom line?** Find a company that understands what sponsors need in order to run a successful clinical trial from beginning to end.

3 Choose a company that has the capacity to monitor your trial.

Your trial is unique. You can't just rely on anyone to monitor your trial, and the size of some research companies is certainly worrisome. **Choose a company that is big enough to accommodate your work, yet small enough to remain flexible.** In the end, you want a company that can handle the complexities of your trial and make logical suggestions for optimizing protocol implementation. Look for that "all hands on deck" mentality, so you know your trial will be handled professionally, regardless of what situations present themselves.

So how will you know a CRO has the capacity to work on your trial? To ensure the company has the expertise and ability to successfully manage your trial, you will want to make sure the company has worked with both large global corporations and small start-up organizations. Monitors should be able to integrate seamlessly into your existing study team, follow your procedures or their own, depending on your preference, and go above and beyond to exceed your expectations.

4 Choose a company that puts patients first.

Regardless of the type of trial, the primary mission of any CRO should be to protect human subjects. During CV trials, protocols may be more challenging, and the data may be more complicated. In fact, there is a lot of scrutiny when it comes to CV device trials.

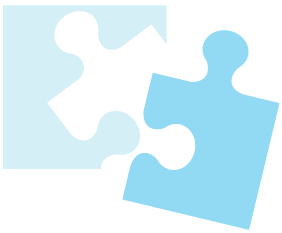
Investigational CV devices provide opportunities for treatment that may not have existed for certain patient populations, but despite that, participation in clinical trials is voluntary, and patients need to be given adequate time to make autonomous, informed decisions based on an accurate description of the risks and benefits of participating in the clinical trial. In addition, as new information becomes available that may impact that subject's willingness to continue his or her participation, patients need to be informed. **You will want to work with a company that understands the requirements, puts human subject protection at the forefront, and will work with the sites to ensure there is no compromising in this regard.**

5 Choose a company that understands you and your trial.

During your trial, the last thing you want is a company that will come in and apply a heavy-handed approach. Instead, you want a company that will take the time to listen to what is needed – both at the sponsor and the site level, and then work to build a rapport with the various study team members that will bring great value to the study team. Approaching sites with a teamwork-oriented attitude rather than a hierarchical punitive attitude will facilitate a positive study experience that serves to protect that important relationship between the sponsor and the sites. **Your CRO should help you build upon and maintain the relationships you have worked so hard to develop.** If your monitors are out in the field interacting with investigators on your behalf, you want to know they will not do anything to damage that relationship. Find a company that understands this important relationship and is committed to representing your company well.

How does IMARC compare?

IMARC Research, Inc, based in Cleveland, Ohio, was built upon a regulation-focused compliance foundation and has an expansive resume, which touts several therapeutic verticals, including CV. The company possesses a unique depth of knowledge and experience in the CV realm. Started by a nurse whose background includes coronary, medical, and surgical intensive care units and with a depth of nursing experience on the monitoring team, the level of expertise provided by IMARC during CV clinical trials will meet your approval.



Across the board, IMARC focuses on quality over quantity and strives to get it right the first time.

During a recent trial for a drug-eluting stent, IMARC:

- ✔ Monitored 40+ sites in the US
- ✔ Provided enrollment support
- ✔ Audited each site/followed up on audit findings
- ✔ Provided training and guidance to Japanese monitors
- ✔ Audited 4 Japanese sites and sponsor
- ✔ Monitored 3 sites in Canada for registry
- ✔ Audited European sponsor for registry sites/oversight
- ✔ Provided AE and device audits for sponsor
- ✔ Audit Prepped for 5 sites receiving audit
- ✔ Established presence with the sponsor for FDA inspection

The company was happy to report no findings GLOBALLY. **If you are interested in experiencing success like this, consider IMARC as your go-to CRO for CV clinical trials.**

Conclusion:

When choosing a CRO, rely on one that sets the bar high for itself and its employees. Each person is responsible for ensuring the company delivers the highest quality and best possible product to clients and, ultimately, to patients.

For more information on how you can help prepare your CV trials for success, please contact John Lehmann at 440.801.1540 or via e-mail at **jlehmann@imarcresearch.com.**

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