

### Cardiovascular Clinical Studies (CCS) and Cardiovascular Core Laboratories (CCL) Boston, Mass.

An interview with Douglas Gregory, Ph.D., president and CEO

**Year founded:** 1996  
**Employees:** 30  
**PIs in database:** 600  
**Active projects:** 15  
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#### How and why was CCS founded?

The company was founded by Marvin Konstam M.D., who is chief scientific officer at CCS and also chief of cardiology at Tufts-New England Medical Center, and James Udelson M.D., who is chief medical officer at CCS and associate chief of cardiology at Tufts. They felt that there was a need for a new type of contract research organization [CRO]. Because what they know is cardiovascular, through clinical research and also through their work with FDA, they wanted to focus solely on cardiovascular studies. They also felt that there was an opportunity to combine the best of academic research organizations (AROs) with the best of commercial CROs. So they decided to create an entity that would be flexible and focused on the needs of the sponsor on the one hand, but reflect the AROs' commitment to high quality academic research on the other. CCS is highly competent with respect to providing sponsors with assistance in publication, data management, and other clinical trial services. CCS also offers sponsors support for protocol design, publications and presentations, pharmaco-economic analysis, and other academic services, if requested.

#### What else differentiates CCS from other CRO models?

One major differentiator is how we do site management, incorporating clinical expertise. Most CROs have a project management and CRA [clinical research associate] department and then they might have a medical affairs department. They work together, but they're different departments. CCS fuses them together. In our site management model, the CRA does not manage the site. The CRA is there to make sure that the integrity of the data is outstanding and that the protocol is being administered properly. We have full-time staff members, many of whom are cardiac nurses, who do site management. They are in contact with the sites at least weekly during study startup, helping the sites file regulatory documents and answering questions from the IRB [institutional review board]. Once the site is initiated, they call weekly to assist with patient enrollment. When site personnel can call and talk with a nurse, you bypass the problem of finding somebody in medical affairs to answer a site's question. So, a big differentiator is the cardiovascular clinical expertise of many of our clinical operations staff members. Our site managers

play a big role during study startup because we do a lot of very complex trials and there can be a lot of interaction with the IRB for some of these trials, particularly the invasive trials. If a study coordinator calls one of our site managers here, they're going to get a very fast response. That's a fundamental difference in the way we do site management. That melding of the clinical expertise with operational excellence is a core value for us, and it plays out on many levels.

#### What services differentiate CCS?


In addition to the traditional services offered by commercial CROs, such as clinical data management and monitoring, we provide specialized services that leverage our clinical experience in cardiovascular trials. We offer upfront consultation when that's part of a long-term relationship. We just did a five-year clinical development plan for a venture capital-funded, startup device company. Then we wrote the protocol for the first study. We also have a novel site selection process and an investigator database application which features a very rich database in terms of performance metrics and the types of studies the

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## Special Profile Reprint: Cardiovascular Contract Research Organization

sites have experience with. During site selection, we match the type of study with the capabilities of 600 investigative cardiovascular sites. We provide a clinical helpline, which is a complementary service to managing global medical monitoring and is a 24/7 line staffed by cardiac nurses to help sites with clinical issues in enrolling patients. We also provide a call center with clinical data collection, typically long-term data on major adverse cardiovascular events. Or it could be administration of quality-of-life questionnaires. We use our cardiac nurse staff call center for both.

In addition, we manage Global Clinical Events Committees (CEC). The CEC adjudicates cardiovascular outcomes for outcomes trials. The CEC is a very challenging committee to put together, but it is a critical one for an outcomes trial.

Many companies wait until later in the trial to do the planning for the CEC. We like to build that right into the startup of the trial. We've had trials for which 5,000 events needed to be adjudicated by 14 members of the committee from all over the world. We're doing a lot of CEC work right now. To do that, you have to have very experienced staff with cardiac expertise, who can prepare the dossiers for the members. We also have a core laboratory that we started about two years ago. We provide core laboratory services in the area of SPECT Myocardial Perfusion Imaging and cardiac echo. We provide the only hemodynamic core lab in the world, I believe. We've also done compliance studies for sponsors out of our core lab.

We offer a number of different pharmacoeconomic analyses, which are important for drug and device development companies, particularly when they're thinking down the road about reimbursement for their drug or device. We also provide certain analytical services in terms of clinical trial time-cost analysis. We have developed models for calculating cost-time tradeoffs in clinical trial design, and they're all driven from our experiential database of clinical trials. We

can help clients with cost-time tradeoffs and help them get financing if that is needed. It all comes down to our understanding of the protocol and what the company is trying to achieve with the drug. That's all grounded in our clinical academic expertise.

### What challenges do you face?

Although we provide a full range of cardiovascular services, we do not yet have a global footprint. Right now that is our biggest challenge. We are currently partnering with organizations that are similar to our own, in Europe, South America and Australia to help extend our reach, but that is a significant challenge for us and it is one that we are working on.

### How have cardiovascular studies changed since CCS was founded?

We do more trials of imaging agents of various kinds. And for phase IV, we'll provide either imaging or we'll do follow-up outcomes studies where we're using the call center or we're collecting long-term data on cardiac outcomes. In phase IV, we are seeing a number of follow-on trials from the phase III trials where we'll re-contact the patients and collect long-term cardiovascular event data on them or quality-of-life data. There's definitely a much greater emphasis on follow-on studies and phase IV studies and we're seeing pretty significant growth on that side of our business.

The other thing that has changed is, because of the clinical and pharmacoeconomic expertise that we're able to bring to bear on a project, we're seeing a great deal of interest from biotech companies, startup companies, drug and device single-compound companies. For those companies, we become their consultant for clinical development. We work on the protocol with them, go to the FDA with them and then

become their outsourced operations department as they move into phase I, II and III trials. Our fit is very good with biotech companies and drug and device development companies because we take a limited number of projects, so we're able to devote a lot of expertise to those companies. We work with big pharma, but they typically want only some of our services. We do a fair number of investigator-sponsored studies as well. That's an area that's seen a bit of growth too. Those are studies that are funded by big pharma, but they're not in the strategic plan, so they may outsource the complete trial administration. We provide all services for those types of studies. Then we do more narrowly focused studies for big and mid-size companies. We try to maintain a mix of business. But we're seeing a real growth in the biotech side.

### What are your plans for growth?

CCS's growth will be fueled to a large extent by the expansion of our service offering and the focus on linking those consultative services with our operational services through development of consultative products. We're going to see a lot of growth because we're working with companies at a very early stage. We want to participate in the full product life cycle with a company, so there will be natural growth from our existing clients. With the larger companies, we provide a more select service. They're usually looking for specific expertise in a particular cardiovascular area. With those companies it's finding the niche player that has a product where we can provide a clear advantage because of our experience and knowledge in that area. That's the challenge for growth—finding those opportunities and on the other hand letting companies that have such products know that we're available. We have a very selective approach to who we work with. We are also committed to creating a global footprint.