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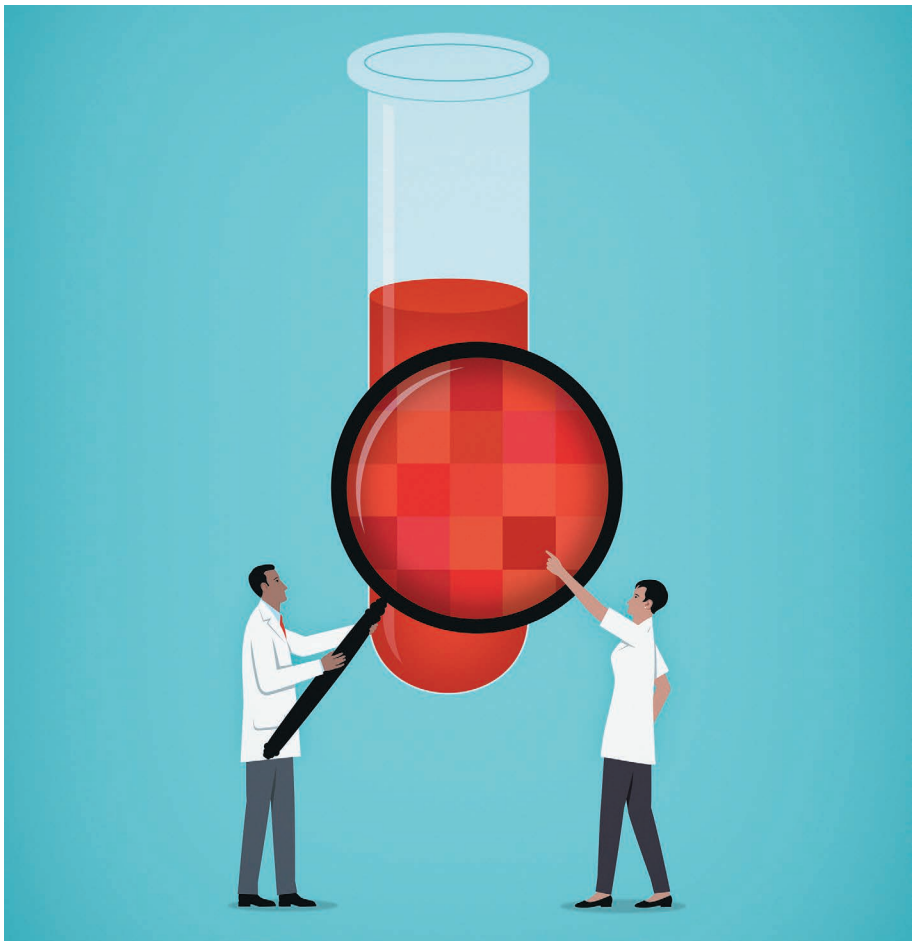

RESEARCH ENTERPRISE

The rise of outsourcing

Big pharma is downsizing, and contract research organizations are reaping the benefits.

BY ESTHER LANDHUIS

Alokta Chakrabarti manages drug-candidate identification and discovery for client pharmaceutical companies. As a project team leader at the contract research organization (CRO) ProQinase in Freiburg, Germany, she spends her days meeting clients, working at the bench, flying through data analysis — and chasing a lot of deadlines.

A few decades ago, drug makers did their own discovery work, along with every other element of getting a drug or medical device to the marketplace. But today, nearly anything that a pharmaceutical, biotechnology or medical-device business needs to do — from designing assays to planning and running clinical trials — can and may be outsourced to CROs.

These specialized companies fall into several categories. Preclinical CROs test drug or device candidates for client businesses before the compounds or devices undergo clinical or human testing. This might include helping a client to synthesize compounds, run biochemical assays or conduct animal studies. Clinical CROs focus on clinical-trial services, such as medical writing, data analysis, managing regulatory-affairs processes and other functions associated with getting new drugs or devices to market. A growing number of speciality CROs focus on a particular stage of clinical development, or offer services within a specific therapeutic niche.

The CRO industry is benefiting from recent downsizing trends in big pharma, as well as from a related proliferation of smaller drug makers, says Ken Getz, who studies research and development management practices at Tufts University in Boston, Massachusetts. The number of drugs entering clinical trials continues to rise, and companies that are slashing their workforce look to CROs to help them manage their portfolios. The need for outsourcing is even greater for smaller biopharmaceutical firms with lean headcounts and scant clinical experience, says Getz.

The global clinical CRO market topped US$23 billion in sales in 2014, and is predicted to exceed $35 billion in sales by 2020. More than one-third of all global drug-discovery research will be farmed out to CROs by 2021, predicts Kalorama Information, a market-research publisher in Rockville, Maryland, in its 2018 *Outsourcing in Drug Discovery* report (see go.nature.com/2jgjoqb).

As the CRO industry takes on larger and more-complex roles, the distinction between working in biopharma and at a CRO is blurring. Jobs in both areas are listed with life-sciences recruitment agencies and on job boards. Many people thought that few CROs could draw top researchers, says Josh Schultz, senior vice-president of Parexel, a full-service CRO headquartered near Boston, with a workforce of about 19,000 across more than 50 countries. Now, he says, those researchers are more evenly distributed. "CROs have become development partners in ways that we weren't before now," he says. "Client companies say, 'Can you take this compound from start to finish?'"

JOB BOOM

About 15 years ago, the top 5 CROs worldwide collectively employed around 30,000 people. Now, that group has nearly 100,000 ▶

employees, and a single CRO can have thousands of clinical trials in progress at any given time, estimates Schultz. According to the Association of Clinical Research Organizations (ACRO) in Washington DC, whose members run trials in 142 countries, more than half of CRO jobs are in the United States and Europe. India has 8% and the United Kingdom 7%, finds ACRO's 2015 member survey.

Researchers who have solid project-management and communication skills will be competitive for jobs at CROs — and could be even more strongly positioned if they have experience working with large data sets, say industry experts.

Chakrabarti joined ProQinase in 2016 after completing a postdoc in histone epigenetics at the University of Freiburg; before that, she had done undergraduate work in India and a cancer-biology PhD in the Netherlands. So it was a challenge to shift her mindset into a business-oriented, deadline-driven approach, she admits (see go.nature.com/2j0xipn). "You do your experiment, and if it does not work, you try another," she says of her PhD programme and postdoc. "There is no deadline."

Her CRO clients, however, often want results in one or two weeks. "You have to plan very wisely," Chakrabarti says. "If there's a problem, you have to troubleshoot. If you have too many projects, you end up with overlapping deadlines. It's a little stressful."

Many academic labs don't emphasize these kinds of project-management skills. "Particularly in PhD programmes, there's this culture saying you should learn how to do everything yourself," says Elizabeth Iorns, chief executive of Science Exchange in Palo Alto, California, a network of CROs, core labs and other scientific-service providers that runs experiments for a fee. But in industry, she says, you need to highlight and burnish specific skills and talents. "It's impossible to be trained in every technique," says Iorns.

Leaving academia requires a mental shift, Iorns says — less focus on creativity, invention and first-author papers, and more emphasis on discipline and quality control. Metrics for success also differ from those in an academic lab. "If your end goal is to bring a drug to market, you want to know as soon as possible that it's not going to work," she says. "Negative data are just as valuable as positive data."

CROs can offer excellent opportunities for those pursuing an undergraduate degree, say some, and they can provide a crash course in lab techniques and interpersonal skills. That was the case for Nikita Patel, who started a job at a local preclinical CRO after graduating from the University of San Diego in California. "CROs are often fast-paced, cut-throat environments that teach you a lot in a short time," Patel says. "Working there taught me to persevere and showed me the nitty-gritty nuances of doing science."

CROs can also be a good option for researchers who love science but hate benchwork. A few months into his master's degree in biology at Sonoma State University in California, Brian Wenzel realized that he wasn't suited for academia. "Lab work for me was really daunting," he says. "If you screw up halfway through, you could compromise two years' worth of data. It requires a certain kind of personality to be excited and tenacious enough to keep doing the same thing over and over with the precision needed for top-tier research."

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"CROs are often fast-paced, cut-throat environments that teach you a lot in a short time."

So after graduating, in 2008, Wenzel started as a customer-service representative at a contract manufacturing organization that specialized in protein research, and moved on to other CRO sales and business positions. Patel, too, pivoted to business development at her second CRO once her superiors saw that she could talk to people easily. She now works remotely from San Diego at Science Exchange, as a director of supplier relations.

A SHIFT IN FOCUS

Historically, CROs created positions that mirrored the services needed by the pharmaceutical sector. If a drug maker needed people to write journal manuscripts, for example, the CRO would supply medical writers — or project managers, or clinical-trial managers, or whatever a potential or existing client company might have required.

Now, however, large CROs are aiming to get ahead of the curve by providing data-management and data-analysis services, Getz says (see go.nature.com/2pnx2y5 and go.nature.com/2gg7sv9). Indeed, the landscape looks good for those who are skilled in these areas. CROs and biopharma plan to hire 25% more internal staff worldwide between now and 2020 for collecting, storing and making sense of the boatloads of data lurking in electronic health records (EHRs), social media and digital devices, according to a 2017 survey conducted by Tufts University's Center for the Study of Drug Development, where Getz is based.

Access to more-nuanced patient data is also enabling clinical-trial designs of greater complexity. As trial sponsors shift towards schemes that require different statistical and data-capture methods, researchers with those skills will be attractive to CROs, predicts Michael Winlo, chief executive of Linear Clinical Research, a mid-sized CRO in Nedlands, Western Australia, that specializes in early-stage clinical trials.

"Can you think about ways of accelerating a trial? If we drop from five to four patients, do we still get the statistical power we need?" Winlo says. "There's a lot of mental brainpower in trial design — in the statistics, in the writing, in making sense of the data."

Today, Parexel and other large CROs are hiring more data scientists — informaticians, epidemiologists and other people who can work with large data sets and extract insights from them. Candidates who can glean key information from insurance claims, EHRs and other real-world data will be in great demand, Schultz says. "Ten years ago, we had 2 people who could do this. Now we need maybe 100," he says. "It's become a skill set we actively seek."

Last year, Paraxel bought Anolinx, a small, speciality CRO in Salt Lake City, Utah. Normally, Schultz adds, the target CRO would have been too small to acquire, but its data scientists had exactly the skills that Parexel sought.

Another example of innovation in trial outsourcing is Science 37, a company in Los Angeles, California, that functions as both a research 'site' and CRO, says co-founder

Belinda Tan. The company conducts virtual clinical trials through a telemedicine platform that allows researchers to easily find participants, who are able to avoid a trip to the clinic and get instructions from study staff through video calls at home. The platform serves as a data repository for all Science 37's trials, and staff members have access to some, depending on their role. Tan says that, for her as a physician, the repository acts like a clinical-trial EHR for participants.

Trial participants use mobile apps on smartphones provided by Science 37 to get their daily task list — for example, to complete a questionnaire or wait for a nurse to visit. To make these virtual trials work, Science 37 seeks not only conventional CRO candidates who have experience with clinical data, but also marketing and media specialists, web engineers, product designers, graphic designers and others.

Salaries for CRO employees vary widely depending on the level of education and job responsibilities. Clinical-research associates, who typically do not have PhDs, earn $50,000–65,000 on average in the United States, and clinical-research managers and clinical-research directors, who might have a doctorate, can earn more than $100,000.

Because they work with multiple clients, CROs tend to offer job stability — if one project fails or ends suddenly, the company can shift flexibly to another project with a different sponsor. And because the work is fast-paced and varied, employees can often broaden their skill sets and climb the career ladder more quickly than they would working at a pharmaceutical company.

Chakrabarti concedes that she misses one element of academic research. "You can follow a drug there from birth to clinic," she says. Conversely, CRO scientists often work with many different drug candidates at varying stages of development. "You have confidentiality agreements with these client companies, so you don't know anything about the compound. You do the assay but you don't know what happens later," she says. "Even when a molecule leaves a powerful impression — like, 'this is the strongest inhibitor I've ever seen' — your interest in a particular project has to stop with a particular deadline. This is what I find sad."

At least once so far, however, a chance run-in has brought the process full circle for her. At a cancer-therapeutics conference in Philadelphia, Pennsylvania, last October, Chakrabarti saw one of her clients presenting data about a familiar compound. She asked him if it was one that she had screened. Indeed, it was, he said, and the compound was heading into clinical trials. ■

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COLUMN

Convert weaknesses into assets

Work out what you really enjoy doing, and pitch your skills accordingly, says **Lia Paola Zambetti**.

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"I'm afraid I won't renew your contract. I am giving you as much advance notice as I can so that you can find something else."

Hearing these words from my supervisor's mouth left me reeling. As a native of Italy, and as a postdoctoral researcher in a nation outside the European Union, I had a visa that depended on my having a work contract. Without a job, I would have to leave the country shortly after the end of my contract.

Furthermore, the words felt like a death knell for my research career. Surely no one would ever hire me for a second postdoc when this one had failed to yield any research papers. What would I do in a few months' time when my postdoc ended? I was literally dizzy — I needed a strategy to find another position, and fast.

That was a tough week, but I am now grateful for that shocking announcement: it gave me clarity and enough time to make a plan.

The deadline made me think hard about my next steps. Somehow, I was able to start spelling out to myself what I emphatically did not want to do any more. It doesn't sound like the most logical step ever — surely, planning what you actually want to do makes more sense — but it was spectacularly helpful in clarifying my thoughts. Soon, I came up with a two-pronged strategy: first, look only for a research project that perfectly matches my wishes and skills; second, explore non-academic options as a real possibility — for the first time.

Because it looked increasingly likely that my future career was going to be outside academic research, I set out to turn my weaknesses into strengths. All the points that my supervisors and potential employers had highlighted as faults for a researcher — a poor publication record; no specific research niche; a tendency to 'waste time' reading papers from very different fields; and indulging my passion for writing — I aimed to turn into strengths for non-lab-based jobs.

Because I couldn't count on papers to speak for my research, I decided to network more. I converted my lack of a speciality into a 'broad and diverse background' and an ability to speak knowledgeably to scientists from different fields. My keen interest in writing, seen by some as a time sink, nudged me towards jobs in editing and science writing — something I had considered only as a vague dream.

I was not sure whether a good occupational fit for me existed, but I still had a few months to find out, so I set up informational chats with nearly everyone I could think of. And, for the first time ever, I was always straightforward about what I was — and was not — looking for in my new role.

One serendipitous talk on a Saturday led to a meeting with the director of the institute where I was doing my postdoc, which in turn led to an informal chat with a senior representative from the institute's marketing and corporate communications unit. She had been tasked with forming a science-communication team on an institution-wide level, and wanted to recruit a scientist.

Three months and two interviews later, the representative became my boss, and I had found my perfect fit in a role that focused on science communication and editing and that was completely away from the bench. As it happened, I also received an offer for a postdoctoral research project that aligned perfectly with my skills and interests. I regretfully felt obliged to decline it.

In the end, although it took all the time I had, I got not one but two great offers. And both matched my skills and interests — all because I had been clear about what I no longer wanted and because I had turned my weaknesses into strengths. ■

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