

Insider Insights:

Novella Clinical

CWWeekly's semi-monthly company profile feature, *Insider Insights*, interviews executives of companies and organizations in the clinical trials space. Writer Ronald Rosenberg sat down with W. Richard Staub III, president and CEO of Novella Clinical.

Q The FDA is embroiled in evaluating proposals for overhauling the 510(k) regulatory process, which raises concerns about getting approvals for low-risk devices and the threat of expanding clinical research requirements. What was your experience in 2011 regarding regulatory changes for medical devices?

A We have definitely seen the impact of regulatory changes on our medical device clients and it presents itself in three different ways. The first are the clinical studies, and how new regulations are focused more on efficacy and safety endpoints. Device trials are starting to look a lot more like pharmaceutical trials in terms of the overall rigor. The volume of data required for any given device trial is going up dramatically.

The second piece is an increase in device trials. Some products may already have approval, but insurance companies like Blue Cross, Cigna and others are now requiring more clinical data to support reimbursement. So even though products are technically approved through old 510(k) regulations, many insurance companies

are still treating these devices as investigational products until there is enough clinical data. We've seen a tremendous uptick in the post-marketing data requirements for registry type programs. The types of data they need is much more safety and efficacy oriented. Certainly there are significant impacts in terms of the size of the trials sponsors are running plus how robust the protocols are.

From where we sit, sponsor/client companies are taking a lot of time to try to understand exactly what the FDA wants. What typically used to be a two-to-three-month selling cycle from request for proposals to decision on award is now extended to five and six months.

The third way is a real push for device companies to go to Europe first. The regulatory environment over there is more friendly. Sponsors are able to get their CE mark (marketing approval) much faster than in the U.S., so they can generate a revenue stream and use it to fund the larger development programs they now have to run in the U.S.

Q With 50% of investigative sites in oncology unable to meet their recruitment targets, finding cancer volunteers for clinical trials in the U.S. remains a major problem, prompting a bigger push for volunteers overseas along with a new pharmacogenetic approach to target prospective volunteers. What is your company's approach to these problems?

Novella Clinical

Headquarters: Durham, N.C.

Year founded: 1998 as PharmaLink; 2009 renamed Novella Clinical

Description: A full-service CRO supporting oncology, medical device and biopharmaceutical companies with early phase through post-marketing approval. Its medical device and diagnostic business unit has preferred vendor status with two top medical device companies; its oncology unit provides a global footprint and infrastructure to support cancer trials. The biopharma unit focuses on cardiovascular and gastrointestinal diseases, CNS, endocrinology, urology and infectious disease. In 2008, the acquisition of Matrix Clinical, a British CRO and staffing company, led to the company name change to Novella Clinical.

Officers: W. Richard Staub III, President and CEO
Charles Lambert, Chief Financial Officer
Frank Santoro, M.D., Chief Medical Officer
Rob King, Chief Operating Officer

Offices: Durham and Wilmington, N.C.; Boulder, Colo.; Columbus, Ohio; Stevenage, England

Employees: 800 including 243 in North Carolina (45 added in 2011)

Clinical trials: Currently running 60 to 75 medical device and oncology trials

Customers: 50 to 55 clients in medical devices, biotechnology and large pharmaceuticals

Website: www.novellaclinical.com

A Oncology is one of our key business areas. Currently we are conducting oncology trials in over 23 countries, and that global spread is critical for us in terms of delivering for our clients.

Like everybody else, we are challenged every day as it relates to patient recruitment, knowing that fewer than 5% of cancer patients participate in clinical trials. Yet the number of trials in oncology has increased dramatically as new compounds come into the pipeline. So we address this issue on a number of different fronts.

First, we work very closely with our biotech and major pharma sponsor companies. Early on in the initial planning of the trial design—we've run over 230 oncology studies—there



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is a lot of expertise we can bring to the table from the start both in setting up the trial and in the protocol design.

Second, once we have a tight design, we do a lot of work around feasibility in picking the right sites, whether in the U.S. or abroad. It is driven by a good understanding of the disease prevalence, the standard of care in any given country or region and the regulatory environment. Some places may have great patient populations but may take 12 months to get regulatory approval. Certainly, we need to understand the historic performance of the sites as well. We do a great job putting that information together to get a thorough understanding of what the enrollment rate is going to be and find the best place to achieve that.

As a company, Novella has over 270 employees dedicated to oncology development. That resource is located primarily in the U.S. and Western, Central and Eastern Europe. So we have a solid handle on what it takes to do research on sites in those regions. For the rest of the world, we have proven partnerships with other CROs that buy into our oncology business unit model and the depth of experience in clinical trials.

The majority of studies started in the last year have pharmacogenetic targeting as part of how they qualify and enroll patients. The issue is both positive and challenging with regard to enrollment. Obviously, it is important in terms of understanding the science and which patients are going to be potentially high responders to that therapy. However, it does further cull down patient populations, as you end up with a subset of a subset of oncology patients. The good news for our sponsors is that they can run smaller trials with this targeted approach. We think the outcomes are obviously going to be better.

Q Increasingly large pharmaceutical companies are pursuing strategic

partnerships with a handful of major CROs—a strategy that initially has led to some financial problems and efficiency concerns for CROs. How do you see this approach affecting mid-sized CROs like Novella, which provide comparable services but without the deep pockets?



“Novella is a little bit unique in this mid-tier CRO space. We are not a “generalist” CRO. A number of large pharma companies are deviating from their preferred provider relationships within the oncology franchise.”

W. Richard Staub III, President and CEO

A Novella is a little bit unique in this mid-tier CRO space. Our business model is very focused in a couple of areas. We are not a “generalist” CRO. Our depth is in medical devices, oncology and working with biotechs. Our only exposure on the large pharma side is working with their oncology divisions, in which they think about oncology differently than the rest of their business.

We have seen a number of large pharma companies deviating from their preferred provider relationships within the oncology franchise. With Novella, they get what they need in terms of therapeutic expertise, and that’s why we’ve been very successful in oncology with large pharma and biotech.

Q Under your leadership as CEO for the past seven years, Novella’s revenue has grown ten-fold with the heftiest increases during the last three years, in part from acquisitions. Looking to expand to China as well as to India and Russia, what areas of growth and new opportunities are you seeking to differentiate Novella from the competition?

A Our differentiation is that we will provide more depth of experience in medical devices and oncology and continue to build out those business units. One place we expanded and made some strategic investments in 2011 is in our enhanced Clinical Oversight Group

Services. Both oncology and medical device companies are heavy users of end-point adjudication committees, safety monitoring boards, etc. There is a specialized service in overseeing those oversight boards, and we developed a dedicated group within the organization to provide that service.

In addition, we are certainly looking to expand our geographic footprint where it is relevant for medical device, oncology and other therapeutic areas. We are looking to expand our presence into India/Pacific Rim, and we have M&A targets for that area.

We also expect to formalize an exclusive partnership in China which will provide us with greater access. Again, anywhere we can add services and/or talent around oncology and medical device we will make investments this year and in the coming years.

Q While CROs have become more strategic in the clinical design process, how will U.S. employment of CRAs and their role change in the coming years?

A This topic is something we think about. There will always be a demand for clinical research in the U.S. I don’t think that will change. But when we think about where the growth of clinical trials will occur, and the needs for CRAs and clinical research staff, it is certainly in the emerging markets, whether Eastern Europe, Russia, India, Latin America or elsewhere.

This is still a great industry to be in in the U.S. but it is an even better industry outside the U.S.

Also interesting is how the FDA has changed some of the guidance around clinical monitoring at the site and whether or not 100% source document verification will continue to be the standard. So I think with the use of EDC and eClinical technologies, we will see CRAs doing their jobs differently going forward. There will be more remote data review and targeted site activities. Novella’s eClinical foundation will serve us well. 