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Competitors MDCI and CDSS form cross-continental CRO partnership

U.S.-based Medical Device Consultants (MDCI), which provides contract research and regulatory consulting services to the medical device industry, has formed a strategic partnership with a former competitor, U.K.-based contract research organization (CRO) Clinical Development & Support Services (CDSS).

The partnership will allow MDCI and CDSS to support medical device clinical trials in the United States and Europe while helping their clients meet both Food and Drug Administration (FDA) and European Union (EU) regulatory requirements. The MDCI-CDSS partnership is part of a growing trend toward mid-sized CROs taking advantage of opportunities to align with partners overseas as the outsourcing market has become more competitive in recent years. Strategic partnerships and alliances allow mid-sized CROs to expand their service offerings and infrastructure while maintaining a low-cost base.

"This happens fairly often where, for example, a small UK CRO partners with a CRO in Poland or India," said John Lewis, Vice President of Public Affairs for the Association of Clinical Research Organizations (ACRO). "It is also not uncommon for even a large CRO to partner with a small CRO that has specific geographic knowledge or a therapeutic niche."

CDSS Managing Director John Illingworth said by combining their skills and infrastructure, MDCI and CDSS can offer drug sponsors the global reach of working with a large, multinational CRO while preserving the advantages of working with a mid-size CRO.

"It was clear that our combined offering allowed us to preserve all the response and personalization benefits of working with a mid-size CRO whilst offering a seamless global reach," he said. "In a highly competitive market, success depends on enhancing both breadth and quality of offering."

Strategic partnerships also allow small or mid-sized CROs to distinguish themselves as leaders in their niche areas while still being sensitive to price.

"It is essential that small to mid-sized CROs highlight their strengths and areas of expertise," said William A. Morton, President of Massachusetts-based MDCI. "They must, however, also be able to support or guide clients throughout the development cycle. To do this in a cost-effective manner does require specific, complementary partnering."

The agreement calls for expanding services through mutual referrals, coordinated sales, marketing and presentation activities. Executives from both MDCI and CDSS believe the strategic partnership will give their companies a competitive edge.

MDCI's Morton said CDSS, which has a network of clinical research associates (CRAs) across Europe, will bring both the diversity of therapeutic experience and local regulatory knowledge to the relationship. "European medical device regulations are being upgraded, but many regulations still differ from country to country. By working with CDSS, overcoming these local hurdles is simplified," he said.

CDSS's Illingworth said the majority of medical device companies want to ensure that clinical trial pathways to market meet both EU and FDA requirements. "For non-U.S. companies, especially those with novel and innovative applications, the FDA pathway can often seem complex and difficult to navigate. MDCI has a deep understanding of FDA regulations, often beyond what is available in published guidance documents, and is also well-respected by the FDA. This, coupled with CDSS' expertise with regulations and clinical

trial approvals in the EU, affords us the perfect opportunity to allow our clients to maximize their return on research investment," he said.

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