



## Five Corners

www.fivecorners.com.au

# Five Corners: Australian medical device CRO

Established in 1997 in Sydney, Australia, Five Corners is a privately owned clinical research organization (CRO) that provides contract services to manufacturers and distributors of medical technologies that wish to conduct clinical research in Australia and New Zealand. The focus on medical devices, including implantable devices, hybrid pharma/devices, neuromodulation devices, and energy-focused delivery systems, sets Five Corners apart from many other CROs in the region.

"We can provide comprehensive support for medical device manufacturers," said Deborah Bell, the company's managing director. "Essentially, we are their clinical and regulatory department on the ground here in Australia and New Zealand."

The company has worked in many therapeutic areas over the years and has gained strong experience in urology, orthopaedics, ophthalmology, cardiology and interventional radiology, and neuromodulation and neurostimulation. For example, Five Corners has partnered with several manufacturers of neuromodulation devices, managing clinical studies in the areas of pain, sleep apnea, and autoimmune diseases.

The clinically specialized team understands the obligations of a local sponsor acting on behalf of an

international medical device partner company. Five Corners provides all services necessary to conduct clinical trials in Australia and New Zealand, from first-in-human and early-phase feasibility studies through to pivotal studies and postmarketing studies. Importantly, clinical data collected from human studies in Australia and New Zealand can be used to support CE-mark submissions in the EU, as well as 510(k) and premarket approval (PMA) submissions in the United States, as both are listed as Tier 1 countries.

### Field clinical support

The highly skilled team at Five Corners also provide crucial field support. Clinical support at trial sites is particularly important where innovative technology is utilized in the operating room or where implanted devices require technical postoperative management.

Our staff are able to go into an operating theatre or interventional radiology laboratory to act on behalf of the manufacturer," said Bell. "They provide physician training and support, ensure the manufacturer's guidelines are followed, and report back to the client relating to any issues during the procedure or post-operative follow-up visits."

### Regulatory and reimbursement services

Another distinguishing feature of Five Corners is its ability to offer advice and assistance in navigating regulatory pathways to commercialization once a clinical trial is complete. The company's in-house specialists can develop regulatory strategies for the Asia Pacific region and Europe, as well as medical device reimbursement strategies for Australia.

All services are tailored according to the current development stage of a client's company, product, and study. "Five Corners is a relatively small organization, and that allows us to respond quickly to clients' needs and to be very flexible in meeting their requirements," said Bell.

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