Interview with Marisa Petersen, Managing Director, George Clinical, Australia

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Would you begin by outlining the role & importance of George Clinical within the George Institute, highlighting recent milestones & achievements?

George Clinical is an important division of the Institute, contributing to its research goals in several ways: We provide operations teams to deliver clinical trials i.e. the (usually) randomized, interventional, prospective trials developed by researchers within the Institute in order to answer a scientific question that will contribute to the evidence around best practice in treatment. Clinical trials, especially interventional trials of new drugs, devices or even practices must be carried out in compliance with a range of regulatory and ethical laws and guidelines. Using an experienced team like George Clinical, that is dedicated to the conduct of trials, reduces the risk associated with these large and often complex studies. Furthermore the George Institute conducts clinical trials for commercial sponsors. These are often pre-registration (Phase II or III) studies which therefore are highly regulated and must be conducted to the highest international standards. These studies return a surplus to The Institute which underpins their broader portfolio of research. Moreover, George Clinical's work both with the Institute and for commercial customers focuses on large outcomes studies which provide "real world" evidence that impacts treatment guidelines and protocols worldwide. In the last 12 months we have completed enrolment on trials which have contributed 800 and 1500 subjects from the Asia Pacific region. George Clinical supports the Institute's process improvement and risk management initiatives through its experience and its

focus on conducting trials that demand the highest attention to regulatory requirements.

How challenging is it for George Clinical to differentiate itself from its competitors in an increasingly competitive landscape and as we see that the number of clinical trials conducted in Australia continues to drop? What is the key differentiating factor of George Clinical in the competitive landscape?

It is challenging to differentiate from competititors, however, George Clinical has significant points of differentiation: o Scientific Leadership – is our key point of differentiation. The opportunity for our internationally recognized experts in a range of therapeutic areas to contribute to the development plan, the design of the study and the clinically relevant outcomes provides tremendous benefit to commercial sponsors. Study designs with meet the clinical need in various countries, and designs that are intelligent and streamlined, whilst also meeting company expectations are the goal. The involvement of our academic leaders continues during the study – engaging the best investigators through their research networks, motivating them to remain engaged and to deliver on their commitment to the trial is a critical point of differentiation from other service providers. o A strong presence and extensive experience in the Asia Pacific region. Trials in Asia are on the increase, and will continue to increase given increasing experience in studies, government support for clinical research and of course the large population. o Leadership from Australia – a country with a strong reputation in quality delivery of clinical trials, and located in the Asia region. o Mid-sized – conducting studies in our region is our primary interest. We are large enough to deliver regional studies (operating in 10 countries with 150 staff) but not so large that the importance of any one trial, or of the regional needs are lost.

What is the pitch to American and European companies to go beyond capacity much closer to home? What is the biggest value added for Australia and George Clinical?

It is well known that the traditional markets of North America and Western Europe cannot meet the capacity requirements. In addition, it is important for companies to include various ethnicities in their studies to facilitate registration across the large and growing markets in China and India. Half the world’s population lives in Asia, and with growing expertise in clinical trials, and as well there is as an expanding middle class and market for new medicines. The growth of chronic disease and “western” diseases is greatest in Asia. This population needs to be part of trial plans. Australia (and George Clinical) is a natural leader for the region – a skilled workforce in clinical trials, and managers with 15 years and more of developing clinical trials opportunities in Asia. Location within the region is important not only because of timezones, but also cultural understanding.

Are there any internationally competitive examples you would like to showcase as case studies to demonstrate what George Clinical can do?

George Clinical specialises in conducting large outcomes studies globally (in collaboration with other AROs) and through our own teams in the Asia Pacific region. Two investigator led studies (led by researchers in The George Institute) recruited 11,000 patients globally in one case, and 2500 patients in Australia, New Zealand and Malaysia in the other. Three commercially sponsored studies each recruited above target, with between 800 and 1500 patients in the region (various countries). India, China and the Asian countries consistently reported more patients being enrolled per site, per month than countries in other regions. Dr. Shree Haran, European medical director at GSK and currently leading British CRO Transcrip Partner's expansion into Australia told us that in his vision the role of Australia in the clinical trial landscape of APAC can be similar to the one of UK in Europe: the UK cannot contribute in terms of volume in Phase 3 trials because of its size, but it is a great innovative base from which to lead the expansion and to participate in "high value" studies.

What position do you see for Australia in the Asian Century?

Australia has a reputation for delivering high quality clinical trials as a result of its experience, early development of GCP Guidelines (1991) and the quality of its investigators and sites. In addition, there is a pool of skilled clinical trial professionals, many of whom have been leading trial teams across Asia for up to 15 years. This experience together with our proximity to Asia has fostered a keen understanding of many of the cultural differences which must be considered when undertaking clinical trials in Asia. Together these characteristics place Australia in an excellent position to continue to lead expansion of clinical trial programmes in Asia. Some countries in Asia have gained terrific experience in the conduct of trials and are undertaking increasingly complex and earlier phase studies, however some countries are still emerging in this field. Australian expertise across the region will continue to be vital to growth of Asian clinical trials for some years to come. George Clinical is rapidly developing its footprint in Asia-Pacific.

Would you outline the internationalization strategy and tell us where the company stands today?

George Clinical will continue to strengthen its capabilities in Asia, including India, China and North and South Asia. We will continue to partner with other organisations, primarily academically led organisations in Europe and US for the foreseeable future.

Would you outline your vision for George Clinical in the coming three to five years?

Robust evidence is critical to effecting change in treatment options, so our vision is to continue to grow in our ability to deliver high quality clinical trials which are streamlined and intelligent in their design, efficient and effective in their delivery. Combining scientific excellence with operational expertise across a full range of clinical trial services will achieve this and ensure that we meet the needs of our customers in the therapeutics development industry.

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