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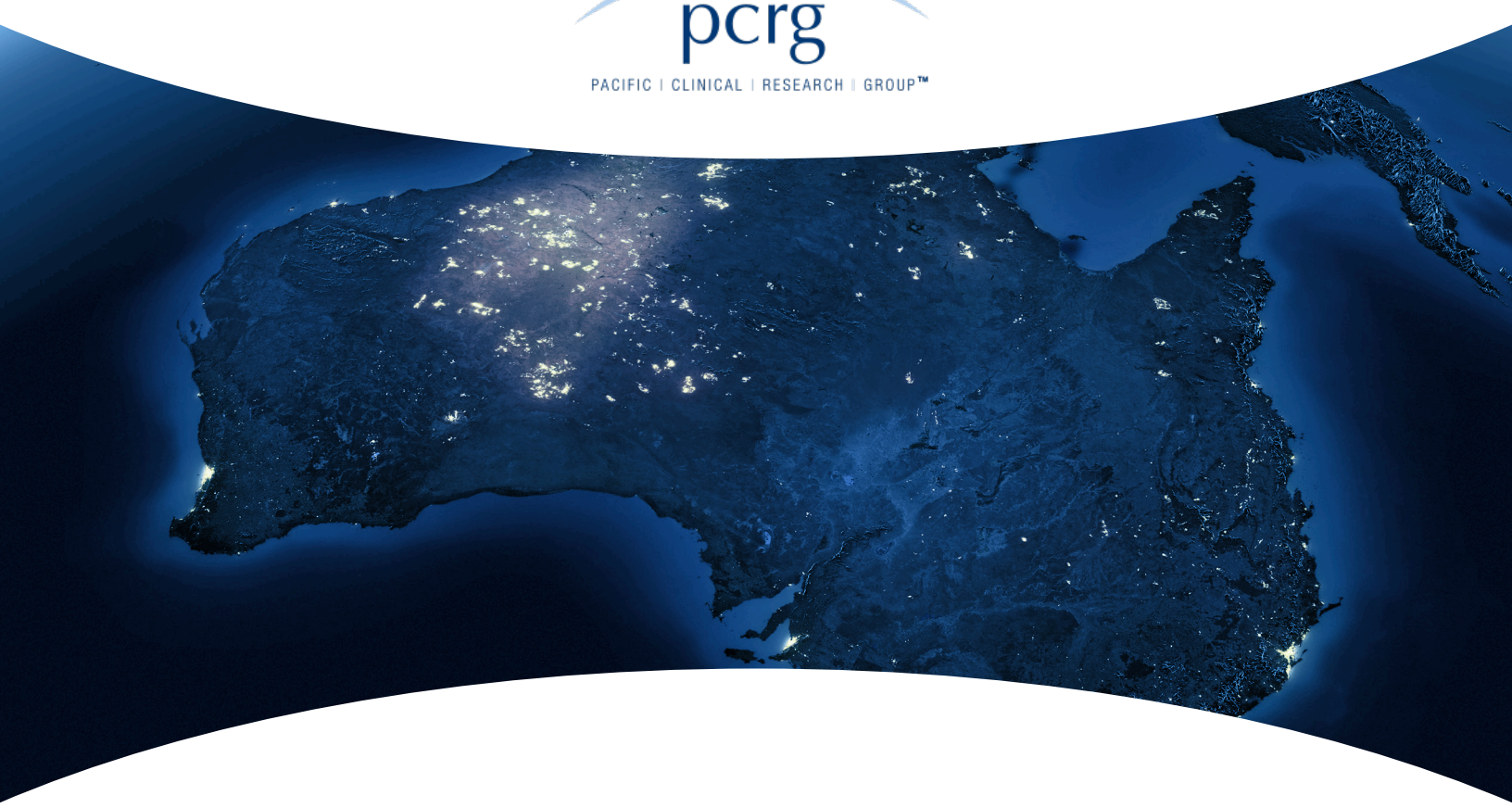

WHY AUSTRALIA?

Considering conducting a clinical trial abroad? Have you considered Australia? There are many hurdles seemingly stacked against Australia for study sites:

IT'S TOO FAR AWAY	IT'S TOO BIG	IT'S COMPLEX
Fully 19 hours from PST and 21 hours from EST	Actually broader than the United States with a total population of 26 million	The TGA imposes regulations governing aspects of trial deployment

Other parts of the world offer:

EASIER ACCESS	LOWER BARRIERS TO TRIAL DEPLOYMENT	QUICKER UPTAKE

However, if FDA approval and US Commercialization is your endgame, Tier 1 quality data from an FDA-recognized Center of Excellence is critical to your plan.

During an FDA-led session at the 2023 TCT Conference entitled Global Competition for Medical Device Innovation, the governing body stated that it seeks to leverage data obtained outside the US but needs proof that the processes and rigor match its own specifications to ensure the data presented is valid.

When considering data to support protocol approval, the FDA examines:

1. Site Selection Criteria
2. Site and Physician Expertise
3. Innovation
4. Centers of Excellence

For start-up companies in the medical device arena, cost-efficiencies are critical for survival – along with lab compatibilities. Lab oversight is a focal point for data quality validation.

During the panel (featuring the FDA, Boston Scientific, MedTronic, Europe, India), speakers stressed the critical importance of site selection in terms of regulatory review of the data obtained.

Moreover, they advised having a clear "Pathway to Commercialization" from inception, through approval and beyond. The body wants to see more Post Approval Studies and keep data streams going.

WHY AUSTRALIA?

COST EFFECTIVE
The exchange rate makes your money go farther here

TAX INCENTIVES
The Australian Government offers tax breaks for medical trials performed here

CENTER OF EXCELLENCE
Sites in Australia are considered Centers of Excellence by the FDA – delivering Tier 1 data; routinely taken for consideration

PROFESSIONAL STAFFING
Alongside highly skilled Australian physicians, medically-trained clinical field specialists support your trial on the ground in market.

COMMUNICATION
No language barrier

Sites in certain countries allow non-resident physician to perform procedures. This is not allowed in Australia, but:

1. **A World-Class animal Lab is at your disposal for training**
2. **Cadaver labs are also offered for demonstrations**
3. **Remote viewing for procedures is routine**
4. **Your team is allowed in the room during the procedure (as observers)**

Worth Considering:

Ideally your device will be used by physicians across the world, ultimately. Shouldn't you know how easy it is to train them on the device and procedure?

Some Questions & Answers by the Panel:

Q: Can the Early Feasibility Study program be extended to OUS sites?

A: Provided those sites meet the same criteria set for the US sites and they follow the exact same protocol.

Q: How to use OUS data/studies to support US market application-

A: FDA is willing to look at OUS high quality data so long as the standard of care matches and the data is proven

Data Quality is critical for site selection and to get to pivotal: it is THE deciding factor.

PCRG offers comprehensive trial deployment based on:

20+ years of Clinical Research Experience

Access to more than 30 clinical sites across Australia

20 full time, medically-trained employees

And led by a world-renown interventional cardiologist. **Let us help you.**

Contact us to learn more: jules.bligh@pcrg.com.au