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GLOBAL COMPETITION FOR MEDICAL DEVICE INNOVATION

Recently, PCRG attended TCT in San Francisco. The conference is still bouncing back from COVID, yet attendance was quite robust. Among the many sessions, one stood out for us (and should hold meaning for you).

The panel comprised eight participants from the FDA, Boston Scientific, Medtronic, Europe, India and others.

The main thrust of the discussion was **Evolving Clinical Trial Landscapes in the US and OUS**.

The panel was spoke frankly about the US EFS program and how enthusiasm for it among US sites has waned. This offers certain countries like Australia an extremely good opening. Why? Because the FDA plainly said that data from nations "whose standard of care meets our own and whose protocol procedures meet our rigor" is taken under consideration

The FDA want to leverage data from outside the US but only with proof about the data quality. This is where Australia comes in.

Our long-standing relationship with US regulators enables us to execute clinical research where the outcomes are on par with US-based sites at a fraction of the price.

The overall message is – keep doing what we're doing: execute with excellence; make our sponsors smarter about the process and endpoint definition.

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Advantages for early-stage clinical trial fielded in the US vs OUS

US- Centric	Outside the US (OUS)
EFS has proven very successful. FDA wishes it to continue and to grow. Sponsors prefer not to travel, incur logistics issues, etc.	Regulatory pathways often easier to secure approval – but that gap is closing (Europe becoming stricter).
But US enthusiasm around EFS has waned. Post pandemic, the amount of work feels 'too hard'; serious lack of resources at the site level; overwhelmed staff; patient access & screen failures temper enthusiasm. "The quality of a sponsor's idea idea can drive enthusiasm – third to market device; not exciting. Novel devices build excitement".	Europe will soon have its own version of EFS. For start-ups, cost-efficiencies are critical for survival – along with lab compatibilities.
FDA tries to leverage OUS data but needs assurances/proof that the processes/rigor match to ensure data supplied is valid, quality.	In the emerging paradigm, regulatory authorities will be in greater communication with MedTech companies.
The FDA is interested in rejuvenating EFS.	
Site Selection Criteria: Expertise; Innovation; Centers of Excellence – reach DEI populations using feeder sites and enrollment centers,	It is no longer clear that Europe will be first commercial place – this is different than before.
Growing need for all trials – US and OUS to 'speak the same language' in terms of end point definition. While regulatory standards differ OUS (which can present challenges), centralized design empowers all participants and especially patients.	Europe and OUS panelists echoed these points – especially around vocabulary.
EFS: "To do it right, it takes a lot."	

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SPONSORS/MEDTECH DEVELOPERS LOOK FOR A CONTINUED "PREDICTABLE REGULATORY PROCESS"

Q: Can the EFS 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.

"Come early" – FDA invites companies to share info "early & often" even pre-clinical data.

The Bottom Line

Australia enjoys something of a 'favored nation' status with the FDA (and other regulatory bodies). We are seen as home to Centers of Excellence with a superior regulatory environment for clinical research. To this end, we must elevate our profile among sponsors, sites and our community at large to maintain and grow our share of research trails.

Contact us to learn more. contact@pcrg.com.au