CWeekly
A CenterWatch Publication

Special Article Reprint • May 15, 2017

Movement for real-world evidence as PPD and Evidera launch new research unit

By Suz Redfearn

The CRO **PPD** and the evidence-based solutions company it acquired last year, **Evidera**, have just launched a new unit to focus on real-world research and market access.

The dedicated unit, which will retain the Evidera name, will pair PPD's medical affairs research operations (MARO) with the evidence-based solutions expertise of Evidera. Jon Williams, who has served as president and CEO of Evidera since it was founded 2013, will lead the new unit.

Said Williams, for decades CROs have done a great job of showing how drugs work in a controlled environment, but not so much how they work—or don't work—in a real world setting. Nowadays, however, such information is expected.

"Based on what we see in the marketplace from regulators, providers, patients and our clients, there is demand for evidence of how products work in the real world, with much greater detail about safety and efficacy," said Williams.

More information is needed on how, for example, specific drugs perform among various age groups, ethnicities and genders. Reactions of drugs to other remedies a patient might be ingesting are key as well. "What if, say, a person is taking aspirin?" said Williams. "Do we know how that will react with the drug we're looking at?"

Said William Sharbaugh, chief operating officer of PPD, in a release, "Through this new business unit, we will be able to help our clients seamlessly integrate and align regulatory and peri- and post-approval research efforts, improving their ability to meet the evidence demands of both regulators and payers."

"Based on what we see in the marketplace from regulators, providers, patients and our clients, there is demand for evidence of how products work in the real world, with much greater detail about safety and efficacy. ... The space is so dynamic and transforming so rapidly, using yesterday's solutions is inadequate."

—Jon Williams, president and CEO, Evidera

According to Evidera's Williams, the new unit has 450 dedicated staff that came from Evidera when it was acquired, many of whom are noted scientists, and since marrying with PPD last year, the new unit can offer the heft of a large CRO that has thousands of employees across the globe.

Williams, who calls real-world evidence a "mega trend, a seismic shift that's reshaping the healthcare industry," said the now popular movement is born of rapidly advancing technology, reams of data produced in medical settings, the willingness of organizations to tap into electronic medical records and increasing acceptance with regulators.

And those working in the space are having to move fast, said Williams.

"The space is so dynamic and transforming so rapidly, using yesterday's solutions is inadequate," he said.

Other CROs have made similar moves. Many CROs recently built up their own real-world research capabilities, then acquired small companies in the space. Due to the duplication, many scientists from the acquired companies fled. Williams rejects the notion that something similar happened with PPD and Evidera. PPD's offerings didn't overlap with Evidera's, and the noted scientists that gave Evidera its reputation are still very much on board.

Why not drop Evidera's name, which is what usually happens after an acquisition? According to Williams, that's not what clients wanted.

"We put together a working group, and we went out to clients and said, 'What is your unmet need? What aren't you getting from competitors?' " said Williams. "We heard, 'Evidera's name is stronger in the space than PPD's, so please keep it.' We heard, 'We're scared your scientists will scatter.' And we heard, 'Please tightly couple the science from Evidera with global operations from PPD.' So we took care of all those things."

Payers, in particular, are watching the real-world evidence space closely, and are beginning to require validation of a product's real world clinical value and cost-ef-

fectiveness to figure out optimal formulary placement.

Said Williams, "Healthcare costs are growing at an unsustainable rate. Payers have a finite set of resources to spread across a rapidly growing amount of spend. They need to know the relative and comparative effectiveness of drugs so they can make a more informed decision."

Williams believes this move toward real-world data has the potential to transform the clinical trials industry, making research exponentially cheaper to do while making the data exponentially more accurate and useful.

"Prospective studies now require tens of millions of dollars and years to do," he said. "I think with the convergence of data and technology, most of these will be able to be done in the cloud using medical data and claims data that are coupled together so we can prospectively examine how drugs are working. It will substantially reduce costs to drug developers and provide high-quality, valuable information to regulators and patients, and ultimately benefit patients.

"We want to be on the forefront of shaping what that future looks like," he added.

CWWeekly (ISSN 1528-5731). Volume 21, Issue 19.