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## E-PRO NICHE EXPANDS

### **Diary Alliance: ClinPhone & invivodata**

They were going to the same meetings. Seeing each other in the same airports. Bidding on the same projects. One thing lead to another. Then, just yesterday, **ClinPhone** and **invivodata** announced a global marketing alliance for electronic patient-reported outcomes.

It's the latest sign that the ePRO sector is getting hot. Evidently there are such abundant opportunities in the market that two presumed competitors can relax enough to work together, almost as two rival academic scientific groups would use different equipment to hunt down the same molecule.

Like many ePRO vendors, invivodata and ClinPhone hope to set themselves apart as reservoirs of scientific and regulatory expertise, touting mutual strength in guiding clients through the psychometric and regulatory validation of ePRO trials.

“By offering invivodata’s device-based ePRO options to our customers, we can expand our ability to meet their broader ePRO needs,” says Steve Kent, CEO of ClinPhone. “This partnership also means we are able to provide sponsors with additional balanced and science-based guidance in line with evolving regulatory considerations.”

#### **ePRO Allies**

There is a natural split between two types of projects that the two firms seek to apportion between themselves. ClinPhone has long articulated the virtues of telephone-based ePRO, building on its dominance of the phone-based interactive voice response (IVR) business.

And invivodata (in addition to having a separate consulting division) has built its franchise around ePRO solutions with handheld devices, mostly from Palm. “We’re going to say, ‘let’s unbiasedly direct you to the right modality based on science and regulatory considerations,’ ” notes Tom Henson, VP of marketing at invivodata.

“We’re really excited about the collaboration with ClinPhone,” adds Doug Engfer, founder, president and CEO of invivodata. He says the companies have similar visions for how to provide ePRO. “Our value systems are very similar. We come to the market from a similar place in terms of basing our work on valid, scientific foundations.”

## Choosing The Right Tool

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*—Doug Engfer, invivodata*

Sorting out which technology is appropriate for a particular trial should be cut and dried, the companies expect. They have developed rigorous criteria to evaluate a trial protocol and sort out whether an IVR implementation of ePRO—or a handheld diary—is appropriate. Says Engfer: “This eliminates a little bit of that turf war where people sell what they’ve got, as opposed to what’s right for the customer.”

He’s not sure what percentage of projects will have more ambiguous requirements that might be appropriate for both IVR and a handheld electronic device. But he thinks the ClinPhone-invivodata approach to guiding sponsors, not to mention a warm cultural fit with ClinPhone, will make such cases relatively easy to adjudicate.

Just how technology-agnostic is the ClinPhone-invivodata alliance? In select cases, Engfer says, an antique extrusion of pressed tree starch (popularly termed “paper”) might be appropriate for use at investigative sites. “We don’t think paper is valid in the field,” Engfer says. “It could be paper in the clinic.”

Oncology is a newly promising area for ePRO, he adds, with cancer patient experiences of pain and side effects having both regulatory and commercial import.

### Pipeline Help?

But there is also a broader change. “The biggest shift that we’ve identified is an increasing emphasis on what I think of as the nexus of the scientific and the regulatory,” Engfer says. For the first time, he reports, the firm is talking with some of the largest sponsors in the world about much broader, longterm usage of ePRO across many trials.

Indeed, Engfer notes that his firm is detecting new levels of appreciation for ePRO from some sponsors. They are exploring whether patient-recorded data could bolster a case for a product’s approval with regulators and help with a commercial market launch—thus easing the most urgent productivity and pipeline challenges in the industry. “[ePRO] can fit into the puzzle they’re trying to solve of getting stuff out of their pipeline faster, cheaper, better,”

Engfer says.

—MARK D. UEHLING