Taking the Mountain to Muhammad

Every time I consider offering a clinical trial to one of my patients, a swirl of concerns goes through my head. As you know, I provide care for patients with pancreatic cancer, who are often terrified about their future. To participate in a clinical trial—as if they don’t already have enough to worry about—they must deal with complicated consent forms and procedures, concerning side effects, and even the possibility of being selected for treatment with a placebo. Yikes! Then, if they do participate, they will probably need additional testing, imaging, and sample collection. That means they must make more trips—likely across one of our Bay Area bridges—face traffic gridlock, and pay exorbitant parking fees in the city each time. No wonder national clinical trial accrual rates are low!

So while at a recent FDA meeting, I was excited to sit in on a discussion of decentralized clinical trials—a mechanism designed to keep the patient at home as much as possible. Brilliant! Of course, I initially had no idea how that was possible, but the more I learned, the more I liked the concept.

Basically, it’s simple: mobile clinical teams, physician-led and part of the investigator team, perform home visits, make assessments, and collect biospecimens like skin biopsies, blood, and urine. In some settings, home infusions are even possible. Pair that with telehealth visits as needed, and add in patient-reported outcomes, and now we’re rolling!

This is already happening, and for some clinical conditions, such as skin conditions (even limited basal cell and squamous cell cancers), the initial evaluation and informed consent can occur at a patient’s home. For more complicated diseases and complex treatments, envision a hybrid approach in which a patient comes in occasionally for an infusion and imaging on schedule, but receives much of the remainder of care and undergoes certain research procedures like blood sampling at home.

Of course, there’s a cost for this, and it isn’t cheap. But if something like decentralized trials could double accrual and ensure compliance, it would be worth it for “big pharma.” For them, “time is money,” and completing trials quickly is important in drug development. This plan might also allow trials to be open in fewer sites, which is also a cost savings.

Personally, I think this is the way to go, and it’s great to know that the FDA is also on board. As for our patients, I think they’ll love it. And that’s what matters most.

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