genomeweb

InformedDNA, WCG Aim to Fill Growing Need for Genetics Expertise in Clinical Trial Management

Jun 27, 2018 | Molika Ashford

NEW YORK (GenomeWeb) – InformedDNA and WIRB-Copernicus Group (WCG) announced this week that they have teamed up to create what they call a "Center for Genetics and Precision Medicine in Clinical Trials," offering consulting and management services for precision medicine drug development.

The companies said that their pairing reflects the steady growth of the use of genetics in clinical trials — due both to increases in the development of genetically targeted drugs for rare diseases and to a growing recognition that genetic signatures can define subsets of responders or non-responders to a variety of therapies.

"Our pipelines have really changed and we all sense it," Ken Getz, a professor at Tufts University's center for the study of drug development, said in a roundtable discussion on the new partnership at the Drug Information Association's Global Annual Meeting in Boston on Tuesday.

"With the mapping of the human genome, we thought overnight we would have treatments that would target a specific patient with a specific genetic profile, [and it turned out that it's] taken a long time for that to really influence our pipeline. We're really there now," he said.

"Today, about half of all drugs are collecting biomarker or genetic data, and in oncology its over 80 percent … [and] companies view this as one of the most critical areas for increasing investment," he added.

According to Travis Quigley, senior director of clinical development at BlueBird Therapeutics, this reflects growing recognition among drug makers that while developing precision medicines involves new challenges, it also offers both immense promise from a patient perspective and potentially also an economic or strategic benefit.

"I frame it in a glass half full kind of way," he said during the roundtable. "You're increasing the complexity, but you're also increasing the probability of success, of really transforming some patients lives. … [Especially] in this world of value-based medicine that we're all kind of headed towards, being able to provide that two-year benefit versus a three-month benefit" has real value, he added.

The structure of the new partnership between WCG and InformedDNA essentially takes InformedDNA's genetics know-how and inserts it into the overall consulting services that WCG already offers to customers — providing more of a one-stop stop, which the companies hope will help support trials that don't just integrate genomics, but do so in rational, efficient, and innovative ways.

Jill Johnston, president of site activation at WCG's Clinical Services division, said during the roundtable this week that as WCG has been negotiating this on its own so far, it has become clear that the prospect of precision medicine is much more complex than simply adding a genetic test.

"We're finding that a lot of organizations are simply deciding just to add a genetic test to a protocol, no different than any other laboratory test, but there's really a lot more thinking that has to be done," she said.

"As we're getting more and more genetic testing that's either needing to be done before patients are coming into a trial … or that [must] be thought about before the study even starts … we really need to think … about how the patient is being prepped for that type of genetic testing, what will the outcomes be? How are they progressing through the study?"

In an interview this week, Karmen Trzupek, director of ocular and rare disease genetics services at InformedDNA, described the company's role in the partnership as an extension of what it has already been doing over the last few years as part of genetic testing initiatives sponsored by particular foundations or pharma companies looking to identify patients with rare genetic subtypes.

According to Getz, genetics introduces a "tremendous amount of [new] operating complexity and scientific complexity into clinical trial design and management.

"We are collecting a lot more data now than ever before," he added. "Historically, in a Phase III study, we collect about a million data points of information for a chronic disease. With a study where we're now conducting genetic tests, and we're gathering genetic information, we could be looking at 3 to 5 million data points per single protocol."

This translates into challenges across the board, he said: for the investigators who are actually conducting the research, "for the clinical teams who interpreting the data, for [data management], and of course even [in] the burden that we place on the patient and the professional that interfaces with that patient."

In an interview, Johnston and Trzupek said that InformedDNA's expertise is going to be incorporated into the services that the new center offers in a variety of ways, including informing trial design strategies. But some of the most important work will be in offering a genetic counselling backbone as trials are conducted.

"A big part of our partnership and collaboration is exactly around supporting patients and their families. When you're talking about genetic testing … sometimes these tests are being run on huge panels, and you get back these very complex results," said Trzupek

Outside of its new partnership with WCG, InformedDNA has already had experience contracting with drug makers to offer counselling, sometimes in the context of sponsored free-testing programs, in which it has had to grapple with some of these complexities. One example is Alnylam Therapeutics, which InformedDNA has joined in programs for amyloidosis and for porphyria.

"In the case of the TTR amyloidosis, this is a progressive, adult-onset neurodegenerative disease for which there is no existing therapy. Some of the family members are asking to be tested, but now you're talking about a disease where currently the average age of death is five years after diagnosis. Without a clear therapy in mind, do you want to do predictive testing?" Trzupek asked during the roundtable this week.

InformedDNA's involvement enabled the pharma company to "confidently be able to say, 'we can reach out to patients and families, knowing somebody is there to really talk with them about the potential implications of this," she added.

In the case of porphyria, the rarity of the disorder and the fact that symptoms overlap with many other conditions, has posed different challenges. "The symptoms can be quite general, and patients sometimes self-diagnose, so you have lots of patients that are

interested and think they might qualify for this study, [but it] turns out they don't have porphyria."

In this case, genetic counselling is crucial to manage that funnel — identifying patients who are the most eligible for genetic testing in the first place, and then providing the right kind of support to individuals who test both positive and negative.

Regarding negative test results, Truzpek said that counselling can provide a way to help maintain contact with patients who might be ineligible for a current trial but could be candidates for something else that comes up in the future.

Another "classic example," she said, would be the need for counselling in areas like BRCA1 and BRCA2 in breast cancer, where "one of the most important components … is ensuring that women who have a negative genetic test don't erroneously think that they're no longer at risk for breast cancer," Trzupek said.

According to Johnston, certain types of oncology trials that WCG services might fall outside of the purview of the new partnership with InformedDNA, even if they do incorporate genetics. These would be protocols where biomarker analyses are being done retrospectively on banked samples.

But, she added that based on the company's experience over the last year especially, it's clear that there is huge growth in efforts that involve the return of results to patients and their doctors, which, especially when germline samples are sequenced alongside tumor DNA, opens up a need for more extensive patient and family counselling.

BlueBird's Quigley noted during the roundtable discussion that clinical knowledge and capability doesn't necessarily mirror the growing use of broad genomic testing in oncology or other trials. "Providers really don't even want to know the results because they don't have the resources to successfully manage their patients' expectations and family expectations … so, it's often a challenge from the sponsor side."

The services InformedDNA and WCG propose to offer "could really help bridge that gap between what sponsors are doing, what academic and other centers are doing from a testing perspective, to make sure patients have those resources to be able to get the information that they need," he added.