ToolBox Genomics Launches Beta Test of Health Action Report for 23andMe Customers

Jan 24, 2017 | Elizabeth Newbern

Premium

NEW YORK (GenomeWeb) – ToolBox Genomics, a startup that provides customers with nutrition and lifestyle recommendations based on their genotyping profile, said earlier this month that it secured seed funding and plans to begin beta-testing its Health Action Report, which is initially only available to 23andMe customers.

The company also said that it is planning to complete a round of Series A funding in the second quarter during which it aims to raise between $1 million and $1.5 million.

Following this, ToolBox Genomics plans to develop its own genetic test and to take it through regulatory approval by the US Food and Drug Administration.

After completing beta-testing, the company plans to offer the Health Action Report to 23andMe customers for $49. The report, which is generated by the company's proprietary software, is based on an analysis of about 60 SNPs the firm has designated as “actionable” after reviewing more than 7,000 scientific publications. It provides customers with personalized lifestyle advice, such as nutrition, specific supplements, or types of exercise, that might be beneficial to them.

After watching the back and forth between 23andMe and the FDA several years ago, ToolBox worked to ensure that its own service offerings are fully compliant with current regulations. "The largest expense [to the company] has been to make sure that we are [FDA] compliant," ToolBox CEO Didier Perez said in an interview, adding that the company hired multiple consultants and lawyers to advise it on product development.

"What we do does not replace the healthcare professional," Perez said. Essentially, ToolBox’s advice isn't that different from that of a nutritionist, he added, but its Health Action Report takes an individual’s DNA into account.

Erika Gray, one of the company’s co-founders and its chief medical officer, worked with a team of company researchers to review approximately 7,000 PubMed scientific publications to identify the ones that reported links between genetic biomarkers and food, fitness, and lifestyle choices.

"All of our evidence comes from peer reviewed scientific journals," Perez said. "The types of studies range from genomewide associations to randomized controlled trials. We also use non-genetic research when necessary for health outcome recommendations. We prioritize higher quality, newer and larger research, and will use meta-analyses when a high quality single trial isn't available."

From that review, Gray and her team identified 60 SNP biomarkers with actionable health interventions. Based on this data, the ToolBox team created algorithms to analyze customer's 23andMe data for the 60 SNPs, then provide recommendations, which have been reviewed by a team of healthcare providers, nutritionists, geneticists, and fitness experts.

The company said that it determined whether a SNP was "actionable" in two ways. First, Gray's team designated a SNP as actionable when "a study includes an intervention and a genotype that combine for an effect." For example, if a study reported that individuals with SNP A lost more weight on a low fat diet than those without the SNP, it means that people with SNP A interested in weight loss are more likely to benefit from being on a low fat diet.

Second, the team determined that a SNP is actionable when "the SNP is associated with a health outcome that we have lifestyle or supplementation recommendations for." For example, a study shows that individuals with SNP B are more likely to have elevated LDL cholesterol. Then individuals with SNP B can be given specific supplements or lifestyle recommendations that have been shown to decrease LDL cholesterol or protect against its effects based on the literature.

Gray and her team also keep a close eye on the literature and plan to update the company's software as new papers connect genetic variants with specific health conditions. As these updates come down the pipe, ToolBox will offer an updated report to its customers, Perez said. "We will be offering a free [monthly] subscription [to customers] for the first year."

While the company says it has done its due diligence to ensure the safety of its services, there is skepticism regarding some of its claims.

"It doesn’t look like this service is aiming to influence major medical decisions. So that means there is less at stake and less regulatory interest," Joshua Sharfstein, associate dean for public health practice and training and professor in the department of health policy and management at John Hopkins University's Bloomberg School for Public Health, said in an email. "Nonetheless, in general, I’m skeptical of services that do not fully explain the science underlying their recommendations."

He explained that although ToolBox Genomics says that its service is based on scientific studies, this is not enough. "It’s important to be transparent about which studies [were used] and how specific conclusions are being drawn from them," he said.

Beta tester feedback

"The feedback [from beta testers] so far has been excellent," Perez said, adding that customers appear to be very satisfied with the results.

Cindy Abernathy, a beta tester for ToolBox's Health Action Report, said in an email that she had been waiting for some time for a company to provide this type of actionable health information.

"My report not only told me the proper names of each genetic marker," she said. "The report is written in an easy-to-understand format, especially for people who are not medically trained."

"I was really excited to have a broad picture with recommendations to work with," Conni Mainne, another beta tester for the report, said.

Both Abernathy and Mainne said that they received useful and even surprising information from their respective Health Action Reports. "One of the first things I noticed [in the report] is that my muscle composition works better with cardiovascular exercise than short, intense bursts," Mainne said.

"[One] surprise in my report was that I may be predisposed to having higher circulating homocysteine, which is an indicator of inflammation in the body," Abernathy said. "If the gene is triggered, I could look forward to hardened arteries, heart attacks, strokes, and dementia."

Once beta testing ends, the company plans to launch improved services more generally in mid-February, Perez said.

While the feedback has been largely positive, the company does plan to make some changes, for example a printable PDF version of the report.

Currently, Toolbox can only offer services to people who have received DNA test results from 23andMe. However, the company does have plans to launch its own DNA assay by the end of this year to make its services available to the general public, Perez said. The ToolBox assay would have a "much lower" price than 23andMe's health and ancestry service, which is currently available for $199 at its website.

At present, ToolBox does not plan to provide clinical education for healthcare providers, Perez said. But the company is developing a "pro" version of its data analysis service that physicians can use with their patients.

Abernathy and Mainne, the beta testers, said this type of report could be a valuable tool to physicians. "I believe that every doctor in the world should be testing the DNA of their patients, Abernathy said. “That way, they can see what DNA predispositions a person has and then treat them prophylactically, long before that gene has a chance to be triggered into disease.".

“Personally, I think it would be a great idea to make something like this a basic standard of care with every doctor," Mainne said.