23andMe protects consumers' data

In October, consumer genetics testing company 23andMe released its first transparency report, which revealed that government agencies had

requested information on four customers. None of the requests were filled. According to the company's privacy officer, Kate Black, only two of the requests were valid, and the company was able to fight them on "procedural and substantive grounds." Whether all such requests can be denied is not clear. Bradley Malin, director of the Health Information Privacy Laboratory at Vanderbilt University in Nashville, says that requests must be specific. "They can't just say 'Do you have a DNA sequence that looks like this?', as it requires a search across the entire database, at which point, you're basically requesting information on the entire resource," he says. But, he points out, companies can decide whether or not to respond. "If they believe that the information they may have is going to solve something that is not going to have implications on the welfare of their consumers, they might respond to it," Malin says. From her perspective, 23andMe's Black says, "We don't see any public interest or positive outcome of transferring information, especially [given] the nature of DNA and our genetic database. I can't think of any scenarios under which we would comply."

Also in October, 23andMe resumed its personal genome testing offering, after the US Food and Drug Administration told the company it would not require pre-market review for a limited number of tests. This ruling was anticipated since February, when the Mountain View, California-based company gained approval to market a single test (*Nat. Biotech.* **33**, 435, 2015), Bloom syndrome carrier test, after providing extensive documentation. The agency had in November 2013 directed the company to stop selling its screening tests because of failure to obtain marketing clearance. With the recent go-ahead, the agency has enumerated a few requirements, among them that the customer must be given information on counseling services, and must be provided access to information on the validity of each variant, which can come from the peer-reviewed literature or professional society recommendations. 23andMe now offers 36 genetic carrier tests—many affecting small populations—including cystic fibrosis, sickle cell anemia and thalassemias, albeit at a slightly higher price than their previous genetic panel (\$199, previously \$99).

Laura DeFrancesco

If the approach is successful, the underlying technology could be applied to other genetic diseases. "That's all being done via cloud resources," Paten says.

IBM's Lee expects that the company's cloud computing will, in the short term, attract large partners such as universities, pharmaceutical firms and contract research organizations. Eventually it will appeal to startups and smaller medical device makers who wish to focus on developing their devices without having to develop their own computing infrastructure.

Jeff Cohen, co-founder and a vice president of Welltok, a Denver company offering health and diet advice, says his firm was attracted to IBM Watson Health Cloud for its ability to personalize recommendations to customers. Welltok draws on Watson's natural-language abilities to ease the interaction between human and supercomputer. Such sophisticated user-interaction is not possible for a firm Welltok's size to develop on its own, says Cohen.

For Teva, the decision to partner with IBM was clinched by Watson Health Cloud's advanced computing power for data analysis and interpretation. Another factor, according to a spokesperson from the Petach Tikva, Israel-based Teva, was IBM's "ecosystem of partners" that includes Medtronic, Apple and

the US pharmacy chain CVS. Sharing a platform and analytic tools not only facilitates working with one another's data but also may inspire new partnerships. Indeed, Microsoft launched an early-stage health accelerator in Herzliya, Israel, and IBM has followed with one in Haifa; both offer participants access to their cloud services. The platforms could provide a way to build relationships with the developers and business people at startups and other small companies who will shape healthcare's future. If Herzliya and Haifa prove the principle, the hosting firms can repeat the experiment in other tech hubs. To that end, IBM recently announced that it was opening more access to the programming interface of Watson, so that more outside developers could produce their own applications that use Watson's cloud computing services.

Even small outfits are producing big data—and need somewhere to store and analyze it. The big firms capable of building the cloud infrastructure for such work are betting on a big growth in demand for such services. "They're selling shovels," Paten says. "They see our data getting bigger much faster than Moore's Law and much, much faster than storage so they see us as a big market."

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"I lie in bed almost every night and ask myself that question. When I'm ninety, will I look back and be glad about what we have accomplished with this technology? Or will I wish I'd never discovered how it works?" University of California Berkeley's Jennifer Doudna expresses angst about her work on the CRISPR-Cas9 gene editing tool. (*The New Yorker*, 16 November 2015)

"Innovation might be great for the iPhone but it's not necessarily something I want to put in my mouth," said a friend of Ethan Brown, CEO of Beyond Meat. Beyond Meat markets protein products made without any animal protein. (*The New York Times*, 5 November 2015)

"It's impossible to have evidence-based medicine without the evidence," said Jennifer Miller, an ethicist at the New York University School of Medicine. Miller and colleagues analyzed the literature on drugs approved by the FDA in 2012 and found that only one-third of clinical trial results were

publicly reported, despite a 2007 FDA ruling requiring that late-stage trials be reported. (*The Washington Post*, 12 November 2015)

"CRISPR is far too important to become entangled in the same web of confusion that has made GMOs [genetically modified organisms] such a toxic issue. We ought to have learned something from those troubling and extended shouting matches; scientists, politicians, and everyone else needs to join in on this debate now." Michael Spector, writer for *The New Yorker*, warning CRISPR researchers not to repeat the "Monsanto problem." (*The New Yorker*, 12 November 2015)

"A former British environment minister complained last year that Europe was becoming a 'museum of world farming'," notes Mark Lynas, political director for Cornell's Alliance for Science in Ithaca, New York. Lynas calls the 17 EU countries that have banned the cultivation of genetically engineered crops the **"coalition of the ignorant."** (*The New York Times*, 24 October 2015)