

ANALYSIS

First Genetic Trust banks on genes

Genes are money these days and, not before time, the depositors and borrowers of genetic information have their own commercial bank. The First Genetic Trust (Chicago, IL), formed in October, has put itself forward as “a third party intermediary among researchers, healthcare providers, and patients.” The idea of the First Genetic Trust, according to chair and CEO, Arthur Holden, is “to provide the operational infrastructure that enables the use of genetic information in a secure, private, and reliable way.” Also in October, First Genetic Trust announced that IBM (Armonk, NY) would be its partner in developing an information technology and data security infrastructure. The formation of the company has been welcomed by potential pharmaceutical clients such as Glaxo Wellcome (London) although bioethicists remain to be convinced that the lofty principles of First Genetic Trust can be maintained in practice.

The company is backed by venture capital from ARCH Venture Partners (Chicago, IL) and Venrock Associates (New York) but seems to have sprung—at least partly formed—from the loins of the SNP Consortium. The Consortium, which aims to complete its detailed human SNP map—one SNP (single nucleotide polymorphism) per 2–3 Kb—by the end of 2000, is a public–private partnership backed by the Wellcome Trust, eleven of the world’s largest pharmaceutical companies, IBM, and Motorola. “There is no formal connection between the SNP Consortium and First Genetic Trust,” says Holden who is chair of both groups. The informal connections extend to First Genetic’s other named officers: David Wang, the company’s executive vice president, was head of genomics and bioinformatics at Motorola and chair of the SNP Consortium’s scientific management committee, while Andrea Califano, chief technology officer, was director of IBM’s Computational Biology Centre and another member of the SNP Consortium’s scientific management committee.

Holden maintains that the connections are at a rather conceptual level: he says that discussions within the Consortium clarified certain key requirements needed to realize pharmacogenomic medicine and genetic epidemiology. The area of greatest concern, and a potential structural barrier to the development and exploitation of genomic information, was the need for security and sensitivity in the handling of individual genetic information. “Its all very well to have laws to stop abuse of genetic information,” says Holden, “but they just keep honest people honest.

What you really need is something that puts the individual in control. We can provide the information highway that will make this really work.”

In essence, First Genetic Trust will hold personal information accounts for those people who consent to be involved in genomic studies. These will comprise personal demographic data, health phenotype, and the genotypic information that has been determined with the various studies with which the person has been involved. As with a bank account, that information is owned by the individual, but it resides at First Genetic Trust. The data will be encrypted, but rather than “throwing away” the encryption keys as is usual practice for anonymized genetic studies, they will be retained.

This will allow First Genetic to institute what it calls “a structured dynamic consent process.” If its commercial clients—pharmaceutical companies and healthcare authorities, for instance—want to conduct follow-on studies, First Genetic will be able to identify the appropriate study group and, working through physicians, seek additional consent from individual participants. Arthur Holden sees this as a vast improvement over the current compromise solution in genomic studies where subjects know only that their data and samples will be used for research, but not precisely how. If researchers currently operated strictly within the confines of their Independent Review Board approvals, says Andrea Califano, only narrowly defined candidate gene studies could be conducted: associations derived through genomic screening would hardly be approvable. Importantly, First Genetic Trust does not intend to make genetic data “loans” to its clients. “The characterization and analysis of the DNA will be done by us,” says Holden, “firstly because of data security and secondly because we will have developed the most advanced genomic analysis algorithms.”

The association of First Genetic Trust management with large pharmaceutical companies through the SNP Consortium is likely to be a commercial advantage. Allen Roses, vice-president and worldwide director of Glaxo Wellcome’s Genetic Directorate, has already welcomed the initiative. “The mechanism they are proposing will satisfy the ultimate need for going back to the patient each time,” he says. “This will be a significant improvement on the methods adopted currently by certain small companies—of collecting people’s molecular and medical self-information and building business by, in effect, selling that information on

to pharmaceutical companies.” Glaxo Wellcome and First Genetic are actually already collaborating—in sponsoring an independent academic bioethics study lead by Alan Buchanan at the University of Arizona. This will report in the middle of next year on the ethical aspects of the kind of mechanisms for genomic studies that the two companies are pursuing.

The formation of secure genetic information brokerages such as First Genetic Trust was also welcomed in principle by Bartha Maria Knoppers, the chair of the Ethical, Legal, and Social Issues Committee of the Human Genome Project. Speaking in her capacity as professor of law at the University of Montreal, she said, “I like the idea of interactive partnership. I can see some very positive aspects. The idea of having a fiduciary company is a good suggestion. This is a recognition by the pharmaceutical companies that genetic research is not a ‘phase I, phase II, phase III’ scenario.” However, she had reservations about the operation of such bodies.

She was concerned about the way the information handling process might evolve. “My worry about on-line dynamic consent would be that it has the potential to eliminate the intermediary, the physician. Until genetic information becomes as ordinary as information on cholesterol levels and blood pressure, the responsible approach is to continue to go through the physician.” She was concerned, too, about the extent to which physicians can administer the necessary genetic counseling. There is no way of checking the “informed” bit of informed consent, she says. Knoppers also considered that the process would need continuing independent ethical oversight, not least to deal with the changeable circumstances of the real world. “People might, for instance, agree to participate in studies set up by an academic researcher or by a small company run by that researcher,” say Knoppers, “but would they be so keen if that company was taken over by a large multinational pharmaceutical concern?”

With the human genome sequence to be published early next year, and population genomics projects underway around the world, First Genetic Trust will have to act quickly if it is to have its secure system in place as the genetic data rolls in. Its goal is to have a pilot system in place and ready for testing by the end of 2001. Although discussions have not been finalized, Glaxo Wellcome may provide the medical and research end of the pilot.

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