

Diagnostics For All Set To Take The Field For Clinical Trials

NON-PROFIT BUSINESS MODELS

With more than \$10 million in funding from the Gates Foundation and other grant sources and a network of volunteer professionals to bolster its six-person staff, not-for-profit start-up **Diagnostics for All (DFA)** is set to begin a field trial in Kenya in March to evaluate its energy- and water-independent, postage stamp-sized diagnostic device to assess liver function in AIDS and tuberculosis patients. But the company, launched out of the **Harvard University** laboratory of George Whitesides, PhD, eschews the notion that it's a charitable endeavor. Rather, CEO Una Ryan, PhD, and Harvard have crafted a licensing deal and business model that anticipates leveraging its not-for-profit work in the developing world into a sustainable commercial First World business.

DFA is built around a Whitesides' technology for running clinical chemistries and immunoassays using a single-use disposable. The device is formed by printing layered patterns of microfluidics channels on water-repellent paper using wax. Each layer is stamped with a different pattern, basically creating a series of wells in which different reagents are deposited. The paper "wicks" a body fluid – blood, urine, sweat, or tears – so that the sample flows along the channels, where it is exposed to reagent, without the need for a pump or other energy source. Within minutes, the device provides an easily visible colorimetric readout. It's also possible to extend applications by incorporating LEDs, photodiodes, and ribbon batteries that are bendable and flexible onto the paper – to create a disposable glucometer, for example. Even the most sophisticated of these iterations should cost no more than pennies to produce, says Ryan. The technology could even be incorporated into threads, for use in wound dressings to indicate infection, or in panty liners and diapers to identify infectious agents.

Harvard set up DFA as a not-for-profit foundation and granted it an exclusive

worldwide license to develop and sell these paper diagnostics, waiving royalties on sales in the developing world. According to Isaac Kohlberg, Harvard's chief technology development officer and a DFA board member, the construct also anticipated a for-profit entity that would serve the developed world. "There will be royalties to us, and the profits from these sales will advance DFA's not-for-profit mission," he says. (This was Harvard's second attempt at transferring technology to a newly established not-for-profit: it had set up another foundation, Medicine in Need (MEND), also backed by a multi-million-dollar Gates Foundation grant, to transfer a drug delivery technology for tuberculosis. But that foundation "has not been as successful as we were hoping," says Kohlberg, the result of challenges in technology development.)

Admittedly, had Harvard been able to find backers for a start-up, it would have gone that conventional route. They didn't, but determined that in this case, a not-for-profit strategy could work, and hopefully segue into a more traditional start-up model.

Both MEND and DFA share the elements Ryan says are essential to make a not-for-profit model work: a cause and a platform that will attract grants. To address health issues in the developing world, the platform also had to be innovative and offer a low cost-of-goods. "I don't think these are things you can fix up with guaranteed prices," she says. Nor is the answer, at least for DFA, to provide technology that could not be used in developed countries as well. A diagnostic for the Third World "has to be as good or better," she says. That's because the developing world is an even more challenging proving ground. "If you can make something that falls within those very difficult guidelines of cost, ease of use, portability and safe disposability that make it good enough for the developing world, it seems to me you have a magnificent product for the developed world as well," Ryan says.

The not-for-profit structure also gives DFA financial flexibility it would not have

as a venture-backed start-up. "You leverage the value of both entities with grant money so that you have a more valuable for-profit as a result of the work you've done with those donations," says Ryan. "We are essentially taking cost off the table. There's no sunk money from investors that has to be returned at a multiple in a certain time. In most companies, you'd call that non-dilutive funding." Down the road, DFA could bring investors into the for-profit division.

For the DFA model to be sustainable, it will have to get its for-profit subsidiary, Paper Diagnostics, off the ground using traditional corporate dealmaking. Those arrangements may well include a data gathering IT collaboration component as well as distribution rights. By taking a picture of the readout display with a cell phone, the DFA device is telemedicine-compatible: using the phone's GPS, it'd be easy to collect data on date, time, and location of a test. "We are beginning to amass databases for global tracking of disease," says Ryan – monitoring how pandemics sweep across the world, looking for hot spots and watching how new therapies change disease as strains die off and old ones re-emerge. DFA is already working with "a major US telecom company," she says, to develop algorithms that will read multiplex tests and give instructions based on the results.

DFA is currently validating its liver function device by comparing it to the standard test done at Beth Israel Hospital and checking that an untrained observer gets the same results. Assuming the field trial plays out well, DFA will lock in the form factor. It's running the trial at Kenyatta Hospital, where the Gates-funded Partnership for Appropriate Technologies in Health is running a large AIDS trial, giving DFA a source of patients who need to be monitored to see if the drugs they are taking are damaging their livers.

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