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Lucira Health's Unexpected Sprint To A First-Of-Its-Kind EUA From FDA: The Inside Story

The company wasn't aiming to be the first to get an emergency use authorization for an at-home molecular COVID-19 test – but it was

by Shawn M. Schmitt

Lucira Health executive VP Kelly Brezoczky explains in this *Medtech Insight* case study how the company shifted gears from making a test for influenza A and B to quickly developing one that detected SARS-CoV-2. The result was the company's COVID-19 All-In-One Test Kit, an at-home prescription molecular diagnostic test that was the first of its type to hit the market when the US FDA granted it emergency use authorization last November.

It was early 2020, and Lucira Health was busy working on an at-home test for detecting influenza A and B when the first reports of a novel coronavirus began trickling through the media.

"We were on the path to [US Food and Drug Administration] authorization in flu when the pandemic hit. And it didn't take long for everybody to realize that the pandemic was real, and it was global, and it was rapidly coming. So we challenged our technical teams to see if they could develop a COVID test," said Kelly Brezoczky, Lucira's executive VP for clinical, regulatory, commercialization and business development.

The result was the company's *COVID-19 All-In-One Test Kit*, an at-home prescription molecular diagnostic test for detecting SARS-CoV-2 that gives results within a half hour. "Very quickly our technical teams were able to transform the test from being a flu test into a COVID test," Brezoczky said.

It was a speedy seven months from test conception to FDA emergency use authorization (EUA),

during which time Lucira performed analytical testing, clinical studies, and more. "Our initial [pre-submission] happened the beginning of April [2020]," she said. "But we did not file for an EUA until October, *and we had an authorization in November*. It was about a four-week turnaround once we filed for an EUA, which is very fast."

She pointed to 21 October 2020 as the start of a whirlwind 24 hours for the firm as it readied its EUA application. On that day, Lucira officials attending a *virtual town hall* heard a plea from the FDA's Tim Stenzel for industry to make COVID-19 antigen and molecular tests for use at home or in a point-of-care (POC) setting like a doctor's office, a hospital, an urgent care center or an emergency room. (In fact, Stenzel – director of the agency's Office of In Vitro Diagnostics and Radiological Health [OIR] – had been making that request since at least early September, as we reported *here*.)

Stenzel "made a comment that the agency had not received any applications for those kinds of tests yet. And we were completely blown away, because we filed on October 22, which was the next day," Brezoczky said.

> ***"We were thrilled when we were first. You don't get to be first very often, so it was a really exciting moment." – Kelly Brezoczky***

When Lucira received its authorization a mere 26 days later on 17 November, it unwittingly became the first company to get an EUA for an at-home COVID-19 molecular test – a notable achievement the firm wasn't aiming for, but one in which it took pride.

"We actually were surprised. We thought there were others ahead of us, to be totally honest," Brezoczky told *Medtech Insight*. "We were thrilled when we were first. You don't get to be first very often, so it was a really exciting moment."

When the FDA announced Lucira's EUA, the agency's device center director, Jeff Shuren, *said* the authorization was "a significant step toward FDA's nationwide response to COVID-19. A test that can be fully administered entirely outside of a lab or health care setting has always been a major priority for the FDA to address the pandemic."

To use the All-In-One test, patients swirl a self-collected nasal swab in a vial that's then placed in a test unit. The unit shows the results on a light-up display within 30 minutes. The test can be used at home by people aged 14 and older; younger patients must have a sample collected by a

health care professional at a POC. The test's price is in the $50 to $60 range.

Lucira has two other EUA applications pending with the FDA: one for extending the All-In-One test's prescription EUA to include asymptomatic people, and another so the company can sell the test over the counter (OTC). Brezoczky anticipates a decision on those authorizations soon, and expects at some point to seek FDA clearance for the test to detect influenza A and B – which was, after all, the firm's original intent, pre-pandemic.

And she said that while Lucira's plan is to eventually have the All-In-One test approved by the FDA, "right now our current focus is on achieving these expanded authorizations and EUAs that we have under review. But clearly, it would be our intent to be able to have our tests available when the pandemic is over. And we'll work collaboratively with the agency at the appropriate time on those."

Ellume CEO Ponders Future Of Company's Rapid COVID-19 Antigen Test

By Ferdous Al-Faruque

07 Apr 2021
The developer of the at-home over-the-counter antigen test — the first of its kind to get an emergency use authorization from the FDA – received more than $200m from the government to manufacture in the US. So what's next for Ellume? In this *Medtech Insight* case study Q&A, the Australian company's CEO, Sean Parson, explains.

Read the full article here

[Editor's note: *The day after this story was published – on 9 April – the FDA granted emergency use authorization to Lucira Health for its CHECK-IT COVID-19 Test Kit, the OTC version of its All-In-One test.*]

Last October, the FDA's Shuren and Stenzel urged firms holding EUAs to begin thinking about whether they want their products on the market post-pandemic. If they do, then they shouldn't wait until the last moment of the public health emergency to gain agency approval, they said. (Also see "*Top CDRH Officials Tell EUA Holders: Don't Procrastinate In Getting Products FDA-Approved*" - Medtech Insight, 8 Oct, 2020.)

Jonathan Kahan, a partner with Hogan Lovells, said Lucira's lightning-fast authorization isn't a typical experience for most companies seeking an EUA. "I think that FDA did prioritize this test," Kahan, whose law firm worked with Lucira on the authorization process, said in an interview.

He went on: "One of the big issues right now in the EUA area for COVID testing is whether the test meets prioritization or not. There are other companies that are pushing for prioritized FDA review, and OIR is overwhelmed by its workload. So we were lucky compared to some of our other

clients and other companies, in that FDA saw immediately the value of [Lucira's test] and prioritized it."

And when the FDA sees a product as a priority, that can bring increased communications between developer and agency.

"That's neither good nor bad. It's just FDA managing workflow," Hogan Lovells partner Randy Prebula said. "When it's prioritized, the FDA can be extremely interactive, especially when they see the benefit of a product in the context of a pandemic – that it's lessening the pandemic's grip."

He stressed that the FDA's review of Lucira's test "was standard, the way the agency would review anything that it prioritizes. And what led us to be fast was primarily the quality of the data that we had."

Lucira, "in its original filing and in subsequent amendments, has a larger dataset than virtually any other EUA-authorized test that we're aware of. And that's because the company was very diligent in collecting data, and FDA was very clear in what they were looking for," Prebula said.

Brezoczky agreed. "To Randy's point – and I think this is very important – if you look at the clinical data that we've submitted to FDA at this juncture, we have a total sample of 132 positives, and a total population of over 400 individuals that have been enrolled in our studies," she said. "If you look at over-the-counter EUAs that have been authorized, for example, they have 37 and 38 positive samples, respectively.

Device Week, 9 April 2021 – A Look At The EUA Process For Lucira Health, Ellume COVID-19 Tests

By Ferdous Al-Faruque and Shawn M. Schmitt

09 Apr 2021

In this week's case study podcast we discuss first-of-their-kind US FDA emergency use authorizations for at-home COVID-19 diagnostics made by Lucira Health and Ellume.

Read the full article here

"So we have three-and-a-half times more clinical evidence on our product than other tests that have been authorized for OTC use," Brezoczky added. "It's been Lucira's explicit objective to exceed the FDA EUA template requirement with every single clinical study and usability study that we've conducted."

The FDA has published nine *templates* since the pandemic began to aid developers as they prepare molecular, diagnostic and serology tests for EUA submission.

"When you approach an authorization or clearance – whether it's an EUA, whether it's a 510(k), whether it's a PMA – if you bring clean, compelling data to the agency showing that you've done your work, I have found them to be always responsive and helpful," Brezoczky said. "If you can bring clean, compelling data, that's the recipe for success in moving products through the regulatory process. And I think in the case of Lucira, we truly set our objectives to do that."

Data From Community Studies, Usability Testing Key To EUA

Data in support of Lucira's November EUA was the output of a community testing study by the company of people who were exhibiting COVID-19 symptoms. It lasted roughly nine weeks.

"We took our product to people's homes, and people who had COVID came outside their home and performed our test, literally on the top of a recycling bin, or the hood of their car, or a bench they had in their yard," Brezoczky said. "Because of the way we did our clinical work, which was really in a real-world setting, we haven't really seen anything different in test performance since we got our product in the marketplace."

Lucira recently completed a second, larger community study – this time for asymptomatic people – that also lasted about nine weeks. Data from that effort was used to support the company's pending request with the FDA to extend its EUA for the All-In-One test so it can be used by people who aren't displaying symptoms of COVID-19.

"We're also in the process of completing an emergency room study with the *Cleveland Clinic* among symptomatic individuals that lasted several months," Brezoczky said. "So the Cleveland Clinic study is completing now, and that data has not yet been published or submitted to FDA. But our performance in the Cleveland Clinic study is similar to what we've seen in our community testing studies."

> ***"The FDA was exceedingly complimentary about how the usability had been established for the home-use environment." – Randy Prebula***

Data from usability work were also key – and Lucira was ahead of the curve.

"When we developed our instructions for use, we worked with over a thousand individuals to develop [the instructions] through an iterative process," Brezoczky said.

"So by the time we began our performance clinical work, and by the time we began our usability trial for FDA, at that juncture it was actually more of a verification study. Because we had worked with hundreds and hundreds and hundreds of users to optimize the ease of use of our product," she said.

And Lucira made sure it collected the type of usability data the agency would be looking for, attorney Prebula told *Medtech Insight*.

"Kelly and her team, on designing the usability testing, were actually ahead of FDA. They said, 'This is how we're going to do the testing, and this is why we're going to do it. This is what we're seeking to show. This is the preliminary data we have,'" he said.

"The FDA was exceedingly complimentary about how the usability had been established for the home-use environment," Prebula said. The agency "didn't say, 'Oh, you can only do this in a point-of-care laboratory,' or 'Oh, you only can only do this in this location.' Instead, the FDA said, 'If your data showed that this is appropriate, and it seems to be doing exactly that, we think this is achievable.' So it was a partnership with the agency."

Depending on the type of product, the FDA's EUA template for molecular and antigen tests used outside of a lab setting requires a hundred or fewer participants per usability test. "But we brought the agency data with nearly 400 people in our human usability tests," Lucira's Brezoczky said. "So, again, it's about bringing clean, compelling data to FDA that exceeds its objectives."

Has Pandemic Shifted FDA's Attitude Toward At-Home Diagnostics?

The FDA and industry have long sought to bring diagnostic testing closer to patients in the home setting, in a way that can be done rapidly and is reproducible.

But the agency "has been concerned that you really didn't have a good way of collecting data so you can get an appropriate sample in the home," Prebula said.

The ongoing pandemic may have upended the FDA's thinking around that.

Securing FDA Approval For Novel OPRA Prosthetic Wasn't A 'Slam Dunk.' Here's How Start-Up Integrum Made It Through The PMA Maze

By Shawn M. Schmitt

16 Feb 2021

In this case study, experts at the law firm Hogan Lovells and device maker Integrum AB tell *Medtech Insight* about some hurdles the Swedish start-up jumped when trying to win premarket approval from the US FDA for its Osseoanchored Prostheses for the Rehabilitation of Amputees (OPRA) Implant

System.

Read the full article here

"There are very few upsides associated with this pandemic. Let me be very clear with that: There are very, very few upsides coming out of the pandemic," Prebula said. "But one of the upsides we're aware of is that there's been an opportunity to evaluate some of FDA's underlying assumptions about how samples can be taken, who can take them, and how they can be tested."

When the pandemic started, "everybody wanted a nasopharyngeal swab. Everybody wanted it to come through a health care provider. And everybody wanted a health care provider to be able to walk across the hall to a laboratory so the test could be run. And that's just not conducive to testing hundreds of thousands – or millions – of people in a short period of time for an emerging disease," he said.

But Lucira "was able to tell FDA that with simpler sample types, [the All-In-One test] could compare favorably to the most difficult sample types taken in a home environment," Prebula said. "And in some cases, in a clinical, community study, when people are sitting in their driveway, running the test on top of their recycling bin."