Benchmark

CASE STUDY

Accelerating Prototype to Production in the Fight Against COVID-19

The Customer

U.K. MedTech innovator DnaNudge has developed the world's first device that uses a combination of a person's DNA and lifestyle to "nudge" them towards healthier choices while they shop for groceries.

When the pandemic hit, DnaNudge realized its DNA testing system could be used to identify patients with COVID-19 rapidly. The company approached Benchmark to help manufacture its NudgeBox, a tabletop consumer-grade 'lab-in-box' that combines advancements in biochemistry, microfluidics, electronic circuits, and electronic miniaturization to analyze DNA in just over an hour.

The lab-free testing system requires a swab sample (nasal for COVID-19, buccal cheek for nutrition), which is then placed in a cartridge and inserted into and read by the NudgeBox. The cartridge extracts RNA from the sample for analysis and reverse transcribes to DNA, meaning the device can detect human DNA and viral RNA to eliminate false negatives. The test can also analyze several COVID-19 genes, Type A flu, Type B flu, and Respiratory Syncytial Virus.

The Challenge

The U.K. government placed a substantial order with DnaNudge: €161 million for 5.8 million tests and 5,000 devices to provide all British hospitals with the COVID-19 rapid testing device. The sheer volume of the order provided a significant challenge for the company. DnaNudge not only needed to fill this order quickly, but it also needed the resources and expertise to increase the production quickly.

DnaNudge needed to find and work with a highly skilled partner to source and develop talent and provide the infrastructure and technology to manufacture the devices in volume. The company assessed the state of

current testing facilities and technology and looked for a solutions partner capable of accomplishing the following:

- Quickly industrialize and certify the device
- Manufacture the product at scale – 4000% ramp-up in only six months
- Reinforce the supply chain to secure component supply and increase reliability.

The Solution

DnaNudge chose Benchmark to meet these challenges because of its expertise in the medical technologies industry and its design for excellence and manufacturing capabilities at its European Design Center of Innovation in The Netherlands. Leveraging DnaNudge's innovative design, Benchmark applied its in-house manufacturing and design expertise together to conduct a design for excellence (DFX) process in three key areas to industrialize the NudgeBox.

Design for manufacturability included reviewing five critical considerations of the product's ability to be manufactured: process, design, material, environmental, and compliance. A qualified and lean single-piece flow manufacturing line was realized in a short time. Various tactics were used to accomplish this, including paperless work instructions at stations, component traceability control, and operator multi-level training. **Design for test** included a documented strategy considering 20 critical test considerations. **Design for component** combined capability considerations with supply chain availability and reliability to successfully manage the complete product lifecycle of the NudgeBox device.

Benchmark's ability to manufacture the product while working hand-in-hand with the customer's engineering team to identify and solve technical, complex challenges together during ramp-up stood out as a critical differentiator.

Benchmark's supply chain architects looked at a wide variety of factors to select the most efficient and cost-effective supply chain vendors and logistic providers, resulting in a 50% cost reduction of the product. With an optimized supply chain to lower product costs and ramped up production, DnaNudge was able to get the product in the hands of healthcare professionals as quickly as possible.

The Result

Together, Benchmark and DnaNudge brought 'COVID Nudge' to market on time and at the volume necessary to meet the U.K. government and healthcare industry's need for rapid testing systems. In March 2020, DnaNudge started the process of validating the device and testing its efficacy. Against very sophisticated double-nested PCR machines, DNANudge's new technology achieved 94% sensitivity.

"By combining our expertise in DNA testing with Benchmark's world-class design and production capabilities, and its ability to deliver complex medical technology manufacturing at scale, we can meet the huge global demand for this [COVID testing] technology." Chris Toumazou, CEO and co-founder, DnaNudge.

Because of Benchmark's ability to rapidly and cost-effectively develop the device in response to the crisis, DnaNudge managed to build a processing capacity of more than 1M test per month to serve its customers, including the United Kingdom's National Health Service (NHS).

Benchmark's more than 40-year history has positioned the company as the leading solution partner for the most complex engineering and manufacturing challenges in medical device development.

To learn more about Benchmark's capabilities and services in medical device development, please visit www.bench.com/medical-technologies.

Improving the Bottom Line of the Community.

To hire the right talent to help meet the ongoing demand, Benchmark & DnaNudge worked with Almelo's mayor Arjen Gerritsen on a sustainable, long-term plan to develop highly skilled technical professionals.

The partners explored how the two companies could serve as a training institute in cooperation with the Regional Education Centre (ROC) of Twente in Almelo to build a strong pipeline of talent. The still-active partnership equips students in vocational education, offers them apprenticeships at high-tech companies, and fosters lasting connections through employment.

In the Almelo region of The Netherlands, secondary vocational education is the backbone of the economy. Benchmark and DnaNudge benefit from the technical education of the ROC and establish a natural pipeline for specific, highly-skilled professionals needed to manufacture the COVID-19 test devices.

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