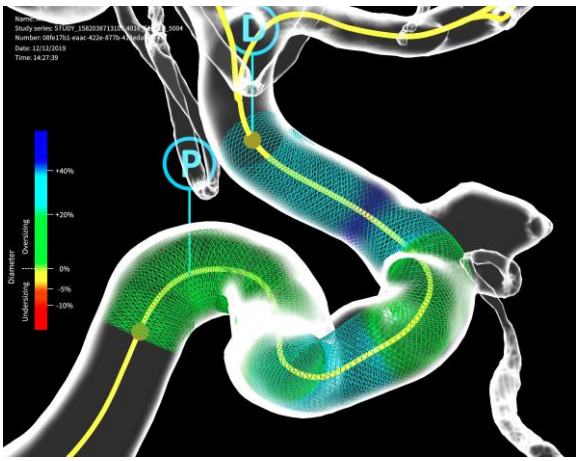
Evidence Generation Case Study: Oxford Heartbeat

Overview

Oxford Heartbeat's medical device software PreSize® Neurovascular enables clinicians to accurately test and predict the behaviour of stents in patients' cerebral blood vessels prior to surgery, all within a safe virtual environment. This helps clinicians to make surgical decisions with greater confidence. More crucially, it significantly reduces the risk behind stenting procedures, and diminishes the propensity for device-related surgical complications, vastly improving patient outcomes.



Oxford Heartbeat was founded by Katerina Spranger, a fellow of the Royal Academy of Engineering. She holds a PhD in Biomedical Engineering and has a background in commercial and non-commercial Artificial Intelligence (AI) research. Katerina is supported by a team of biomedical engineers, software developers and other staff members with an array of expertise on the non-technical aspects of medical technology. PreSize® Neurovascular is the result of co-innovation between the Oxford Heartbeat team, interventional neuroradiologists boasting ample experience with brain stenting, and a patient advisory board.

Oxford Heartbeat was successful in being selected for Cohort 4 of the DigitalHealth.London Accelerator in 2019-20. Its baseline knowledge of research and evaluation methods was high, given the academic backgrounds of its founder and staff. It conducted a retrospective validation of its software by comparing the predicted stent location with the actual location of stents in patients following surgery. The study results demonstrated that PreSize® had an excellent degree of accuracy and led to Oxford Heartbeat applying for NIHR funding for a prospective clinical trial of their software in a clinical setting. Cognisant of the highly competitive nature of this additional funding, the DigitalHealth.London Accelerator provided an abundance of useful counsel and opportunities for Oxford Heartbeat to hone its funding strategy.

Protocol Development and Brokerage of Key Relationships

While applying for funding, Oxford Heartbeat had received feedback from the NIHR that the initial trial protocol was very ambitious for the first real-world testing of PreSize® Neurovascular, and could be simplified. Oxford Heartbeat was referred to

Prof Paul Wallace and the DigitalHealth.London Generator by their DigitalHealth.London Accelerator NHS Navigator for guidance. In an initial meeting, Paul Wallace suggested that it would be advantageous for Oxford Heartbeat's trial to include more sites and Clinical Trials Units (CTU), and to have some of the primary and secondary outcomes revised.

The Generator had previously engaged with the NIHR Research Design Service (RDS) in South London and knew that they were keen to support SMEs to develop research protocols for large grants. A series of meetings were subsequently arranged between Oxford Heartbeat, the Generator and RDS to design a new protocol and prepare application for a grant and an introduction to one of the CTUs was facilitated. The combined assistance offered by the Generator and RDS was immensely helpful in enabling Oxford Heartbeat to act on the best advice of the NIHR.

Interview Practice and Successful Grant Application

When the NHSX AI award was announced, Oxford Heartbeat was ready with its revised and improved protocol and applied. Its written application was reviewed, and the company was invited by NHSX to attend an interview. They were given a list of the 10 interviewers that would be on the panel – it included clinicians, academics and IT professionals with expertise in AI. Interviews were taking place during the COVID-19 lockdown and so the interview would take place virtually via Zoom. Given the novelty of the interview conditions and the importance of the grant for Oxford Heartbeat's business and product development, their NHS Navigator offered to arrange a mock interview.

The NHS Navigator tapped into the full DigitalHealth.London network and coordinated a highly relevant and expert mock interview panel made up of digital health tech leaders from London's AHSNs, the NIHR, academics, as well as representatives from the Accelerator and the Generator DigitalHealth.London programmes. Interviewers prepared questions based on the grant application guidance, which helped Oxford Heartbeat to practice their answers and manage their expectations regarding typical questions. The mock interview also offered the opportunity for Oxford Heartbeat to immerse themselves in the setting of a Zoom interview with a large number of interviewers, and to establish good practices appropriate for the platform. After the mock interview, detailed feedback was offered from each interviewer. This brokering of key relationships and expert inputs came at a critical juncture in Oxford Heartbeat's evidence generation journey.

Outcomes

Oxford Heartbeat was successful at interview and was awarded the NHSX AI grant – an impressive achievement, considering the fierce competition involving over 530

applications from other digital health companies. The award also places Oxford Heartbeat at the forefront of the UK Government's pioneering push to bring digital transformation to the NHS. Preparations to initiate pilots in five NHS trusts across England (three in London) and implementing the new protocol that they designed with the help of the Generator and the RDS began immediately.

"The DigitalHealth.London Accelerator introduced us to an invaluable network of experts, who gave us guidance in understanding the NHS and how it works. The Accelerator also assisted us in setting up a clinical pilot to test our product, which is something we have never done before.

"The advice we received on protocol design and the mock interview were pivotal moments in our year on the Accelerator and key to our successful NHSX AI grant application. The efforts of the Accelerator have been immensely helpful because ultimately, we want our product to make complex surgeries safer, and reduce the burden on the NHS."

Katerina Spranger, founder of Oxford Heartbeat, DigitalHealth.London Accelerator 2019-20