



Leuko is developing the world's first portable, non-invasive white blood cell monitoring device to screen for severe neutropenia. In May 2020 MeHI awarded \$60,000 to Leuko to work with the MIT Center for Clinical and Translational Research (CCTR) to test and validate their solution. The grant enabled Leuko to test their PointCheck™ device with untrained operators in a simulated home environment, helping to prepare them for a clinical trial and FDA certification. We spoke with Ganimete Lamaj, Leuko's Human Factors Engineer, to learn more.

- **What is the health issue you are addressing?**

For cancer patients, one of the most serious side effects of cytotoxic chemotherapy and targeted cancer therapy is neutropenia—a decrease in neutrophils, the most common type of white blood cell and the most important cell needed to prevent bacterial infection. Every year, approximately 140,000 cancer patients will endure at least one episode of febrile neutropenia (FN), a life-threatening bacterial infection that typically requires immediate admission to the emergency department, hospitalization, and treatment. Unfortunately, current neutropenia-monitoring options rely on venipunctures in the clinical setting or finger-prick blood samples at the point of care. These technologies either require laboratory infrastructure or cannot be accurately operated by minimally trained users.



PointCheck™ Technology

- **What is PointCheck™ and what makes your solution unique to the market?**

PointCheck™ is the first noninvasive device designed to screen for severe neutropenia in a home setting with minimal training. By imaging the blood flowing through the capillaries in the finger, PointCheck™ enables real-time, remote monitoring of white blood cell levels based on optical imaging and without a blood draw. This allows for frequent monitoring without intervention from a healthcare professional, reducing costs and improving patients' quality of life (no transportation to healthcare facilities, no wait-time). If severe neutropenia is detected early and monitored routinely, severe infections can be avoided through treatment.

- **Briefly, can you describe the project you did with MIT CCTR?**

At MIT CCTR, we were able to conduct a performance and usability evaluation of PointCheck™ with healthy volunteers in a simulated home environment. We had the pleasure of working directly with Catherine E. Ricciardi, Director Clinical and Research Operations, and Tatiana Urman, the Clinical Research Nurse and Research Coordinator to design and conduct this study. We recruited healthy volunteers around MIT's campus to participate in the study, which involved observing how they interacted with the device as an untrained, first-time user, as well as a blood draw as a gold standard comparison. The data collected in this study was used to inform the design of the device to improve usability and overall functionality.

- **What outcomes were you anticipating when you began this project?**

When we began this project, our anticipated outcomes included finding that most of the minimally-trained users would be able to operate PointCheck™ without errors, with a majority of users having a favorable perception of usability, as assessed by a standardized System Usability Survey (SUS).

By the end of the project, we exceeded these outcomes, finding that 96% of users learned how to use PointCheck™ very quickly, 93.4% felt very confident using the device, and the average SUS score was 86.1 points, placing PointCheck™ on the top 10% of systems by usability. These findings were published in a [high impact peer reviewed publication](#) (JMIR).

- **How did this project help accelerate the growth of your company? How have you applied what you learned?**

This was our first chance to gather formal usability data from first-time users of PointCheck™, and we were able to gain valuable insight into how to improve our product to one that could eventually be used by real patients in the home environment. The participant feedback we received informed many of the design changes made to our user interface in addition to technical improvements that enhanced performance. We now have a fully functional device to be tested in a pivotal trial which will support the regulatory approval of the device.

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- **What was the value of conducting this pilot in Massachusetts as opposed to somewhere else?**

By conducting this pilot in Massachusetts, we can benefit from collaborating with world-leading institutions, such as the MIT Clinical Research Center, to develop our product. We also benefit by receiving input from users and key opinion leaders from some of the most important cancer centers in the country, including the Massachusetts General Hospital Cancer Center, Boston Medical Center, Boston Children’s Hospital and Dana-Farber. We also benefited from the support we received from Massachusetts Life Sciences Center, MassBio and MassVentures.

- **Where is PointCheck™ going next?**

Now that we have completed our usability studies, the team is collaborating with leading cancer centers, such as Boston Medical Center and MD Anderson Cancer Center, to conduct our pivotal clinical trial for FDA approval. To learn more about Leuko, visit leuko.com.

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