

Profusa and Partners Announce Initiation of Study to Measure Early Signs of Influenza Through Biosensor Technology

DARPA-Backed Study Leverages Profusa's Lumee® Oxygen Platform as Part of a Larger Effort to Speed Detection and Predict Disease Outbreaks



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EMERYVILLE, Calif., March 3, 2020 /PRNewswire/ -- Profusa, a digital health company that is pioneering the next generation of personalized medicine, today announced the initiation of a study that will use the Company's minimally invasive injectable biosensor technology, the Lumee® Oxygen Platform, as a platform to potentially assist in the early detection of influenza outbreaks. The study is part of a collaboration with RTI International, a nonprofit research institute developing algorithms for illness detection, and research centers including Duke University and Imperial College London.

The study, conducted at Imperial College London, will examine how sensors monitoring physiological status, including the Lumee Oxygen Platform which measures tissue oxygen levels, provide potential indicators of human response to infection or exposure to disease in

healthy volunteers. The goal of the study is to develop an early identification system to detect not only disease outbreaks, but biological attacks and pandemics up to three weeks earlier than current methods. The results of the study are anticipated to be available in 2021.

"This research marks an exciting step forward in the development of game-changing preventive care," said Ben Hwang, chairman and CEO of Profusa. "The Lumee Oxygen Platform can potentially function as a sort of canary in a coal mine for infectious disease, since subtle changes in oxygen at the tissue level may signal trouble and can help clinicians course correct quickly to avoid outbreaks."

Changes in oxygen levels and other physiological measures, such as heart rate, as a result of a respiratory infection may assist researchers in the study to develop algorithms that can detect early, pre-symptomatic flu activity more quickly than what is currently possible.

Despite the availability of antivirals and vaccines, influenza remains one of the greatest causes of illness and premature death worldwide. Seasonal influenza affects between 10% and 46% of the population each year, with mortality of up to approximately 12 deaths per 100,000 in developed countries.[1] During the 2009 H1N1 virus pandemic, many severe cases occurred in previously healthy young adults. With the entire worldwide population potentially at risk, the prevention and improved management of seasonal and pandemic influenza are of major importance.

"The potential significance of this new technology should not be underestimated, and Profusa is proud to be part of a joint effort funded by a DARPA, or Defense Advanced Research Projects Agency, award," said Sean Givens, head of government business for Profusa. "This is particularly exciting for Profusa as we look forward to leveraging learnings for future platform applications."

Profusa's Lumee Patch, a wireless reader that adheres to the skin and collects and reports tissue oxygen levels sensed by the Lumee Oxygen sensor to a mobile device for real-time data visualization, will be used in the clinical study.

The Lumee Patch and software being used in this study received approval as an investigational device from Medicines and Healthcare products Regulatory Agency (MHRA) in the UK to be used in conjunction with other devices. *The injectable Lumee Oxygen sensor and injector*

Lumee Pen being used in this study are CE Marked for use in the European Union and EEA.

The project is part of DARPA's SIGMA+ program in the Defense Sciences Office (DSO).

About Profusa

Based in Emeryville, Calif., Profusa is a digital health company led by visionary scientific founders, an experienced management team and a world-class board of directors who share the long-term goal of improving health and well-being for patients worldwide. With its long-lasting, injectable and affordable biosensors and its intelligent data platform, Profusa aims to provide people with a personalized biochemical signature rooted in data that clinicians trust and rely upon. These data may allow people to act as an active and educated participant alongside their care team and understand how their choices and decisions impact health and well-being, day-in and day-out.

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For more information, visit <https://profusa.com>.

About the Lumee[®] Oxygen Platform

Profusa's first clinical offering, the Lumee[®] Oxygen Platform, and the next-generation Wireless Lumee[®] Oxygen Platform, which are CE marked for use in the European Union, are indicated for use in patients with potential acute and/or chronic changes in tissue oxygen levels who may benefit from monitoring. The Lumee Oxygen sensor provides continuous and long-term monitoring of the oxygen in subcutaneous tissue. After a single injection, measurement thereafter is obtained non-invasively using an optical reader. In contrast to external pulse oximeters, which measure oxygen bound to the hemoglobin in larger blood vessels, the Lumee Oxygen Platform measures dissolved oxygen at the tissue level in the fluid that bathes cells.

About DARPA SIGMA +

The DARPA SIGMA+ program aims to expand SIGMA's advance capability to detect illicit radioactive and nuclear materials by developing new sensors and networks that would alert authorities to chemical, biological and explosives threats as well.

SIGMA+ calls for the development of highly sensitive detectors and advanced intelligence analytics to detect minute traces of various substances related to weapons of mass destruction (WMD) threats. SIGMA+ will use a common network infrastructure and mobile sensing strategy, a concept that was proven effective in the SIGMA program. The SIGMA+ chemical, biological, radiological, nuclear and high-yield explosive (CBRNE) detection network would be scalable to cover a major metropolitan city and its surrounding region.

Planned execution of SIGMA+ will occur in two phases. Phase 1 will focus on developing novel sensors for chemicals, explosives and biological agents while Phase 2 will focus on network development, analytics and integration.

Disclaimer

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¹ Monto, A. S. Epidemiology of influenza. *Vaccine* 26 Suppl 4, D45-48 (2008).

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