

XaTek Inc.

Category:

Best Startup

Company Name:

XaTek Inc.

Turnover and/or Funding:

Series-A of \$9,100,000 in 2018

Series- B of \$6,000,000 in 2023

Sub-Category:

Medical Technology / Digital Health

Corporate history (creation, key milestones, main funding,...)Information on Condition / Disease and need for solution / product (prevalence, existing treatments / solutions):

Xatek was founded by a team of physicians, engineers and entrepreneurs with a proven track record of dozens of innovative discoveries with successful commercial launches. The core technology was first developed at Case Western Reserve University (Cleveland, OH) and then licensed to the company in 2017. The technology known as ClotChip is a handheld point-of-care device that can measure the hemostatic profile of virtually any patient population.

The company first received Breakthrough Device designation from the FDA for its application in monitoring patients on DOAC therapies. ClotChip is awaiting a decision on Breakthrough Device designation for use in non-factor therapy monitoring for hemophilia patients and expects regulatory clearance in 2026. ClotChip was inducted into the National Museum of Health and Medicine located in Silver Spring, Maryland in 2024 and was recognized by the museum as one of the key innovations of this decade.

XaTek has raised \$15,000,000 in private investment through a series-A of \$9M in 2018 and a series-B of \$6M in 2023. The company also received \$2,000,000 in funding (2020) from the Department of Defense for development of a ruggedized version of ClotChip for use in transport helicopters and as a clinical tool of assessment in Trauma Induced Coagulopathy (TIC), a deadly sequela that evolves in multi-system trauma.

Bleeding risk is an important clinical metric across every specialty of medicine. However, there are many clinical scenarios where there is no diagnostic technology currently available. For example, tens of millions of patients throughout the United States alone, require anticoagulation therapies that are frequently referred to as “blood thinners”. These pharmaceutical interventions reduce the risk of excessive clotting which can lead to the formation of emboli leading to strokes patients with cardiovascular disease and in orthopedic surgical patients. The most popular drug therapies are called Direct Oral Anti-Coagulants (DOACs). Approximately 5,000,000 people take DOACs in the US; however, 200,000 seek emergency care for spontaneous bleeding annually- an increase of 30% during the last decade. Despite an improved safety profile, there remains a 4% risk of major bleeding events, that include death. There was no known diagnostic test able to quantify bleeding risk in the DOAC patient prior to the invention of ClotChip.

ClotChip also serves urgent unmet needs in hemophilia patients. Although considered a rare genetic disease with approximately 35,000 patients in the US and 800,000 globally, the hemophilia patient is missing a crucial protein that allows the body to stop bleeding once it occurs. Typically, this missing protein is known as either factor VIII or IX. Factor replacement therapy makes hemophilia one of the costliest diseases in the United States today, with per patient annual expenses as much as \$1,000,000 annually. Hemophilia patients are obligated to have a lifetime of expensive weekly injections. The newest class of drug therapy for hemophilia patients is referred to as non-factor therapy. These are synthetic drug compounds that mimic patients’ genetically absent protein. Prior to ClotChip invention, there was no known diagnostic test to quantify excessive bleeding risk in hemophilia patients.

History of the development of the solution/product (Intellectual Property, preclinical and clinical datas, development collaborations):

The underlying core technology was first developed at Case Western Reserve University, a renowned institution in science, engineering and medicine. The technology is based on a fully electric technique known as dielectric spectroscopy. ClotChip represents a completely novel approach to characterizing the very complex physiological process of coagulation. Historically most diagnostic assays available to analyze bleeding employ labile reagents or complicated moving parts and are confined to a central laboratory or are not sensitive to the global hemostatic process – rendering them ineffective in a wide variety of urgent unmet clinical needs. To the contrary, the ClotChip invention deploys a fully electric novel technique to characterize the global hemostatic process without the use of labile reagents or moving parts. The ClotChip system is delivered in a compact handheld embodiment that employs a single use disposable sensor that functions on a single finger stick drop of blood. Importantly,

ClotChip delivers actionable clinical data at the point-of-care delivery within minutes. ClotChip provides data driven decisions when and where they're needed most, at the bedside, as opposed to less sensitive or less specific laboratory tests that can take several hours to produce data in a laboratory that is remotely situated on a hospital campus.

The ClotChip technology has strong intellectual property protection with a total portfolio of seven issued international patents: five issued utility patents protecting the use of dielectric spectroscopy for evaluating coagulation of whole blood and two issued patents protecting the ClotChip handheld device and disposable sensor design and usage in evaluating the coagulation status of a patient.

The ClotChip has accumulated both preclinical and clinical data in a variety of patient scenarios where the assessment of bleeding risk is essential to making life saving clinical decisions, including trauma ($CV < 5\%$), hemophilia ($r > 0.95$), DOAC therapy ($p < 0.001$; $auc = 0.92$) and pre-surgical patient screening ($p < 0.002$; $auc = 0.88$). This data has been presented in front of clinical, scientific and industry peers at a variety of forums, including the American Society of Hematology (ASH), The International Society of Thrombosis and Hemostasis (ISTH), and the European Hematology Association (EHA).

XaTek has collaborated in sponsored research with numerous global pharmaceutical companies, across a variety of clinical scenarios. ClotChip has shown utility in monitoring not only DOAC therapy and patient compliance but has also demonstrated usefulness during DOAC reversal (Portola Pharmaceuticals) in situations of life-threatening spontaneous bleeds. Additionally, ClotChip has demonstrated the ability to monitor the newest generation of therapy for hemophilia patients, known as non-factor treatment compounds (Novo Nordisk). These mimetic compounds are not a traditional recombinant factor replacement and therefore there is currently no assay to monitor their use in treatment of hemophilia patients. However, ClotChip has the resolution and precision to monitor these mimetic compounds in a dose-response assessment.

XaTek has an ongoing collaborative contract with the US Navy to commercialize ClotChip as a ruggedized field deployable device for use in extreme field settings such as in patient transport helicopters and mobile surgical hospitals. XaTek was provided with \$2,000,000 in funding from the Department of Defense to support this collaboration.

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition:

The ClotChip system defines innovation from all respects: clinical, scientific and

engineering. Through the diligence of ethnographic research and the discipline of scientific rigor, XaTek developed ClotChip as a disruptive technology that would forever change how we assess the complexities of the coagulation process and determine bleeding risk for any patient or clinical condition. Innovating a diagnostic approach is not a simple task, especially when it involves a physiologic process as complex as the coagulation process – arguably the most complex process in the human body. The design requirements for ClotChip included that it be sensitive to the entire hemostatic process, which includes aspects of both protein-based clotting factors, as well as cellular components of the clotting process, such as platelets. There does exist a variety of assays focused on single components of coagulation, but none that can assess the global process in any patient condition such as ClotChip. The depth of complexity throughout the hemostatic process means that different medical conditions may be susceptible to different defects in the body or be influenced by different pharmaceutical interventions, therefore a true global assessment of bleeding risk must include an assessment of the coagulation process in its entirety.

There are large laboratory-based devices that require expensive labile reagents to operate or contain moving sub-components that are susceptible to vibration and technique and cannot be deployed to the bedside. Therefore, it was equally important to develop the capabilities of monitoring the entire hemostatic process in a portable, handheld device that would allow urgent assessment of the at-risk bleeding patient directly at the point-of-service – at the bedside. It is the versatility of use case environment that attracted the attention of the US Navy to collaborate with XaTek on a ruggedized version of ClotChip.

Lastly, it was critical for the design to allow for patient assessment with only a small amount of whole blood required to be analyzed. When dealing with the at-risk bleeding patient, you want to limit the amount of blood required for testing. The ClotChip system was designed to operate on a single drop of finger stick blood. The proprietary smart sensor maintains the blood sample at human body temperature or 37 degrees Celsius throughout the test. This provides an accurate physiological assessment of coagulation, which can otherwise be impacted by extreme temperature fluctuations.

The ClotChip system has proven utility for the future of clinical medicine but also has shown significant value as a research tool in collaboration with global pharmaceutical companies. It has the capability to shape the future of medicine and improve the human condition. Through improved assessment of safety and efficacy of existing therapies, as well as a clinical tool of assessment in drug development. The ClotChip not only can impact rare conditions like hemophilia or trauma induced coagulopathies seen in war or our nation's highways but can be effective in saving lives and improving outcomes for tens of millions of patients on anti-coagulant therapies ("blood thinners") or for pre-surgical screening to detect at-risk patients before surgery.

Please provide appropriate references (PubMed, Abstract, Website):

Website: www.clotchip.com

Publications

Refereed Publications: Journal Articles and Conference Proceedings

- H. Alizadeh, C. Abonga, C. A. Delianides, S. Pourang, M. A. Suster, and P. Mohseni, "Contact activation in dielectric blood coagulometry: A comparison of screen-printed and sputtered gold electrodes of ClotChip microfluidic sensor," *IEEE Sens. Lett.*, vol. 8, no. 7, pp. 1-4, July 2024.
- S. Pourang, M. A. Suster, A. Thomas, S. D. Lapping, L. V. Nayak, and P. Mohseni, "Comparison of whole blood coagulation profiles in COVID-19 and sepsis patients using a handheld dielectric coagulometer," *IEEE Biomedical Circuits and Systems Conf. (BioCAS)*, Toronto, CA, October 19-21, 2023.
- L. Matthews, D. Disharoon, S. Pourang, A. Sen Gupta, M. Suster, P. Mohseni, "On the effect of hematocrit on dielectric blood coagulometry measurements", *IEEE Sensors Conf.*, Dallas, TX, Oct 30 – Nov 2, 2022.
- S. Pourang, U. D. S. Sekhon, D. Disharoon, S. P. Ahuja, M. A. Suster, A. Sen Gupta, P. Mohseni, "Assessment of fibrinolytic status in whole blood using a dielectric coagulometry microsensor," *Biosensors and Bioelectronics*, vol. 210, pp. 1-10, August 2022.
- D. Maji, A. Opneja, M. A. Suster, K. L. Bane, B. M. Wilson, P. Mohseni, and E. X. Stavrou, "Monitoring DOACs with a novel dielectric microsensor: A clinical study," *Thromb. Haemost.*, vol. 121, pp. 58-69, January 2021.
- S. Pourang, D. Maji, U. D. S. Sekhon, A. Sen Gupta, M. A. Suster, and P. Mohseni, "Monitoring fibrin polymerization effects on whole blood coagulation using a microfluidic dielectric sensor," *IEEE Sensor Conf.*, Rotterdam, Netherlands, October 25-28, 2020.
- D. Maji, S. Pourang, U. D. S. Sekhon, A. Sen Gupta, M. A. Suster, and P. Mohseni, "Toward diagnosis of platelet loss in trauma injury using a microfluidic dielectric sensor," *IEEE Sensors Conf.*, Montreal, Canada, October 27-30, 2019.
- D. Maji, U. D. S. Sekhon, A. Sen Gupta, M. A. Suster, and P. Mohseni, "Toward point-of-care assessment of platelet count-induced changes in whole blood coagulation with a dielectric microsensor," *IEEE Biomedical Circuits and Systems Conf. (BioCAS'18)*, Cleveland, OH, October 17-19, 2018.
- D. Maji, M. De La Fuente, E. Kucukal, U. Sekhon, A. H. Schmaier, A. Sen Gupta, U. A. Gurkan, M. T. Nieman, E. X. Stavrou, P. Mohseni, and M. A. Suster, "Assessment of whole blood coagulation with a microfluidic dielectric sensor," *J. Thrombosis and Haemostasis*, vol. 16, pp. 2050-2056, October 2018.
- D. Maji, M. A. Suster, E. Kucukal, U. Sekhon, A. Sen Gupta, U. A. Gurkan, E. X. Stavrou, and P. Mohseni, "ClotChip: A microfluidic dielectric sensor for point-of-care assessment of hemostasis," *IEEE Trans. Biomed. Circ. Syst.*, vol. 11, no. 6, pp. 1459-1469, December 2017.
- D. Maji, M. A. Suster, E. Kucukal, U. A. Gurkan, E. X. Stavrou, and P. Mohseni, "Monitoring blood coagulation using a surface-functionalized microfluidic dielectric sensor," *12th Annu. IEEE Int. Conf. on Nano/Micro Engineered and Molecular Systems (NEMS)*, Los Angeles, CA, April 9-12, 2017.

- D. Maji, M. A. Suster, E. Kucukal, U. A. Gurkan, E. X. Stavrou, and P. Mohseni, "A PMMA microfluidic dielectric sensor for blood coagulation monitoring at the point-of-care," in Proc. 38th Annu. Int. IEEE Eng. Med. Biol. Conf. (EMBC'16), pp. 291-294, Orlando, FL, August 16-20, 2016.

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- M. A. Suster, E. Friedrich, S. Stuart, B. Lassiter, A. Sen Gupta, and P. Mohseni, "A field-deployable dielectric coagulometer for point-of-care assessment of trauma-induced coagulopathy: Assessment in a swine model of trauma," Military Health Syst. Res. Symp. (MHSRS), Kissimmee, FL, September 12-15, 2022.
- S. Pourang, M. A. Suster, P. Mohseni, L. V. Nayak, "Assessment of hypercoagulable state in whole blood in sepsis patients using a novel microfluidic dielectric sensor", 63rd American Society of Hematology (ASH) Annu. Meeting Expo., Atlanta, GA, December 11-14, 2021.
- A. Opneja, D. Maji, P. Mohseni, M. A. Suster, and E. X. Stavrou, "Monitoring the effects of direct oral anticoagulants with a novel point-of-care sensor: results of a pilot clinical study," 60th American Society of Hematology (ASH) Annu. Meeting Expo., San Diego, CA, December 1-4, 2018.
- M. A. Suster, D. Maji, L. V. Nayak, C. Jenkins, S. Hunter, A. H. Schmaier, P. Mohseni and S. Ahuja, "A novel point-of-care whole blood coagulation assay to monitor emicizumab therapy in patients with hemophilia," 60th American Society of Hematology (ASH) Annu. Meeting Expo., San Diego, CA, December 1-4, 2018.
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- S. P. Ahuja, M. A. Suster, D. Maji, U. D. S. Sekhon, J. Martin, A. Sen Gupta, and P. Mohseni, "Assessment of a novel dielectric microsensor for monitoring coagulation factor therapy in children with hemophilia with and without inhibitors," 59th American Society of Hematology (ASH) Annu. Meeting Expo., Atlanta, GA, December 9-12, 2017.
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- M. A. Suster, U. A. Gurkan, E. Stavrou, and P. Mohseni, "Toward a miniaturized dielectric coagulometer for point-of-care monitoring of blood coagulation disorders," Napa Institute Workshop on Enabling Future Health Care: the Role of Micro and Nano Technologies, Napa, CA, August 23-26, 2015.
- C. Higgins, M. A. Suster, S. P. Ahuja, J. F. Zak, "Assessment of novel point-of-care

whole blood coagulation assay to evaluate coagulation response to bi-Ab FVIIIa mimetic and FVIII,” European Hematology Association (EHA) Annu. Meeting Expo., Milan, Italy, June 11-14, 2025.

References File Document upload:

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