

Health Data Works Receives FDA Breakthrough Device Designation for Access Tracker™

New Designation Paves the Way for Enhanced Vascular Access Management and Improved Patient Outcomes in Dialysis Care

JACKSONVILLE, FL, UNITED STATES, December 18, 2024 /EINPresswire.com/ -- Health Data Works, a Delaware-based company headquartered in Jacksonville, Florida, is proud to announce that its Access Tracker™ software platform has been granted Breakthrough Device Designation by the U.S. Food and Drug Administration (FDA). [This designation](#) highlights the potential of Access Tracker™ to improve vascular access management for patients undergoing dialysis. The software is currently completing clinical trials focusing on tracking cannulation sites during hemodialysis treatments.

The management of failed or failing dialysis access grafts and fistulas represents a substantial [economic burden](#), with market estimates ranging from \$3 billion to \$5 billion annually in the US alone.

Designed for use by interventional radiologists, vascular surgeons, nephrologists, and dialysis technicians, Access Tracker™ provides a comprehensive platform for managing vascular access across dialysis centers, vascular clinics, and hospitals. The software will allow the recording and analysis of cannulation sites and identify potential hazards such as stents, pseudoaneurysms, and stenoses. These features aim to reduce access risks, mitigate complications, and improve patient outcomes and ongoing data gathered through the platform will be used to develop advanced AI tools to further enhance capabilities moving forward, such as recommending optimal zones for future cannulation.

Access Tracker™ also addresses a major problem in the dialysis care ecosystem: the lack of communication and interoperability between healthcare settings. By enabling real-time data sharing and visualization, the platform ensures seamless collaboration, giving all stakeholders access to the information they need to provide the best possible care.

Shannon Beardsley, MD, CEO and cofounder of Health Data Works, remarked: "This milestone underscores our commitment to improving dialysis care through innovative technology. Access Tracker™ is designed to support clinicians in delivering safer, more effective patient care. We are honored to receive the FDA's recognition of its potential impact." Joining Dr. Beardsley in

celebrating this achievement is Dr. Erin Moore, an esteemed endovascular surgeon and key advisor to Health Data Works. "Access Tracker™ addresses critical gaps in vascular access management," said Dr. Moore. "By combining insights from real-time data and clinical expertise, this technology has the potential to mitigate complications like aneurysm formation and access scarring while extending the life of vascular access for dialysis patients."

About Access Tracker™

Access Tracker™ is a software application designed to:

- Accurately record cannulation sites during hemodialysis treatments.
- Support identification of potential hazards such as stents, pseudoaneurysms, and stenoses, as designated by surgeons or interventionalists.
- Assist in suggesting optimal zones for future cannulation to avoid repeated punctures in the same area, reducing risks of complications.
- Provide real-time visualization and actionable insights to support clinical decision-making.

The FDA's Breakthrough Device Designation is awarded to certain medical devices that offer significant potential benefits over existing technologies for the treatment or diagnosis of serious or life-threatening conditions and allows for expedited development and review pathways. This designation does not change regulatory requirements but emphasizes the device's capacity to bring significant benefits to patients and healthcare systems alike.

About Health Data Works

Health Data Works is a Delaware-based healthcare technology company headquartered in Jacksonville, Florida, dedicated to enhancing outcomes in nephrology through the application of innovative data-driven solutions. By combining clinical expertise with cutting-edge technology, the company strives to empower clinicians and improve the lives of patients worldwide. The current platform is in clinical trials, with plans to leverage collected data to develop advanced AI tools to further enhance its capabilities.

For more information about Health Data Works and Access Tracker™, please contact:

Media Contact:

Health Data Works, Inc.

Shannon Beardsley, MD

CEO and cofounder

Email: Shannon.beardsley@healthdataworks.com

Phone: 904.477.3261

Shannon L Beardsley
Health Data Works, Inc
+1 9044773261

[email us here](#)

Visit us on social media:

[LinkedIn](#)

This press release can be viewed online at: <https://www.einpresswire.com/article/769209980>

EIN Presswire's priority is source transparency. We do not allow opaque clients, and our editors try to be careful about weeding out false and misleading content. As a user, if you see something we have missed, please do bring it to our attention. Your help is welcome. EIN Presswire, Everyone's Internet News Presswire™, tries to define some of the boundaries that are reasonable in today's world. Please see our Editorial Guidelines for more information.

© 1995-2024 Newsmatics Inc. All Right Reserved.