

# NEWS RELEASE

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## **MedAware Systems launches new support system for Clinical Evaluation Reports (CER) for Medical Devices in the EU**

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Expanding on the Company's industry-leading medical research data aggregation and analysis capabilities, MedAware Systems announced today a new application that provides comprehensive information and reporting on the entirety of the published literature for any medical device. It is intended to optimally support companies selling medical devices in Europe, where they are required to develop and maintain a Clinical Evaluation Report (CER) that complies with MEDDEV 2.7.1 revision 4 and the MDD or MDR 2017/745.

The Company's new offering provides step-by-step verification and traceability throughout the entire process of massive data aggregation from the published literature. It quickly provides detailed information along with the most comprehensive data analysis available for regulatory filings. This includes specific analytic aims for the CER submission, PICO criteria for inclusion and exclusion of studies, complete PRISMA reporting, and comprehensive metrics on conditions, procedures, competing devices, outcomes, adverse events, and other information. Additionally, clients can obtain access to continuously updated information through a yearly subscription.

"With this new service, Medical Device companies are better able to take advantage of MedAware Systems' unique capability to aggregate and analyze all available clinical research data - in a matter of weeks. Such large datasets greatly empower the CER submission" said Zung Vu Tran, PhD, Founder and Chief Science Officer. He continued: "Our patent-pending curation process extracts hundreds of data points per study. Clients can now easily track the entire process of rapid literature search, data curation, and data analysis needed to complete a successful CER submission in the shortest time possible."

### **ABOUT MEDAWARE SYSTEMS, INC.**

MedAware Systems, Inc. is a next generation medical research data company that empowers Pharma and Medical Device companies with all available evidence from published clinical trials research. The Company utilizes a combination of Human and Artificial Intelligence to make the vast body of clinical science research data instantly available and indispensable for fully understanding the safety and efficacy of medical treatments and devices.

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