Feasibility testing of a novel AI-enabled, cloud-based ECG diagnostic solution to enable fast and affordable diagnosis in long-term continuous ambulatory ECG monitoring

PROJECT SUMMARY.

The proposed observational study is to evaluate the feasibility of a novel ECG monitoring system leveraging concurrent AI and cloud technologies in long-term continuous monitoring (LTCM) in the clinical environment. It does not intend to use any data or information from the investigational solution to interfere, intervene or affect any clinical decisions made for the participants. Among nearly 2M per year syncope or TIA/stroke patients, 12-15% are cardiac-arrhythmia associated, which usually carries higher risk for long-term disability and even mortality than other-etiologies patients. Proper risk stratification and early initiation of appropriate preventative treatment can result in significant reduction of the cardiac related diseases and their associated mortality. Although LTCM has been proven to be able to detect arrhythmia with high diagnostic yield, the current standard of care has major market pains: 1) days-to-weeks of delay to deliver final report for offline extended Holter; 2) low accuracy in stream arrhythmia detection for online Mobile Cardiac Telemetry; and 3) physicians do not have access to patients' ECG data. ZBeats' solution is aiming to improve today's standard of care by addressing technology accessibility and affordability. ZBPro™, ZBeats' alpha prototype was validated against our proprietary dataset as well as public datasets required in ANSI/AAMI EC57, demonstrating algorithms, data transmission and visualization work well as expected. This proposed study will undergo collaboration among ZBeats, Stony Brook University Hospital and Lankenau Medical Center. The long- term goal is to dramatically improve the current standard of care in LTCM by reducing the time to detection of life-threatening arrhythmia from weeks to minutes for cardiac-related high-risk patients, increase the streaming detection accuracy and reducing the total costs by leveraging AI algorithms, cloud infrastructure and a low-cost flexible-material patch. This cost reduction will lead to more general medical use cases, such as telehealth and Remote Patient Monitoring (RPM) to benefit the broader population. https://www.sbir.gov/node/2300251