C-Path, ActiGraph, and University of Canberra Collaborate to Generate Evidence to Support Regulatory Qualification of Novel Digital Health Technology Measures in Chronic Heart Failure

Collaboration will generate evidence to contribute to FDA qualification of a patient-centered, accelerometer-based clinical outcome assessment in CHF

TUCSON, Ariz., January 30, 2024 – Critical Path Institute's (C-Path) Patient-Reported Outcome (PRO) Consortium today announced an exciting collaboration with ActiGraph, a leading provider of wearable digital health technology (DHT) solutions for clinical drug development, and the University of Canberra, Australia. This unique collaboration will advance the development of an accelerometer-based clinical outcome assessment (COA) for adults with chronic heart failure (CHF). This innovative COA will provide a novel and low-burden way to directly assess the impact that new therapies for those with CHF can have in their everyday lives, which can complement the information gleaned from other outcome measures used in clinical trials.

CHF is a long-term condition that occurs when the heart muscle is unable to pump enough blood to meet the body's oxygen needs, resulting in a variety of clinical manifestations including fatigue, shortness of breath, which cause persons with CHF to reduce activity. More than 6 million Americans are living with CHF, which is the leading cause of hospitalization in people over 65 years of age.

Under the terms of this collaboration, a research team at University of Canberra, led by Dr. Nicole Freene, is conducting an analytical validation study to develop and validate the algorithms for quantifying physical activity and step counts for adults with CHF using wearable DHTs. More specifically, a video component will be utilized, and the ground truth for step counts will be derived from videos by manually annotating steps. This information will then be compared to step counts derived from wrist-worn device data to evaluate the accuracy of algorithms that detect step counts in those with CHF. The results will fill an important evidentiary gap in assessing the activity of persons living with CHF in the real world as well as contribute to the efforts around qualification by the Food and Drug Administration of an activity monitor-based COA, as led by the PRO Consortium's CHF Working Group. The study is funded through ActiGraph's Digital Endpoint Accelerator Research program, which aims to validate fit-for-purpose uses of wearable DHTs in clinical populations.

Actigraph's official logo

"Fit-for purpose evidence generation has been a significant gap in the broad adoption of novel sensor-based DHTs in clinical development," said Christine Guo, Chief Scientific Officer at ActiGraph. "We are focused on developing scientific partnerships with all stakeholders to ensure the appropriate level of patient-focused validation is available in the areas of the highest unmet needs."

"The PRO Consortium's CHF Working Group is pleased to enter into this collaboration which will aim to fill a very important gap in the research to better understand physical activity of those who are living with CHF," noted Maria Mattera, MPH, Scientific Director of C-Path's PRO Consortium. "Based on interviews among people with CHF, we have learned that walking is very important in order to complete tasks and carry out daily activities. We need further evidence of the accuracy of established step count algorithms to detect steps

in people with CHF, who move differently from healthy adults, which this study will provide. We appreciate the work being done by the University of Canberra and ActiGraph as it will help to move the science forward and contribute to the potential qualification of an activity monitor-based endpoint measure for treatment trials in CHF."

"Researchers haven't been able to determine the accurate relationship between physical activity and health outcomes to develop disease-specific physical activity guidelines for people with heart disease, which may differ from the public health guidelines," said Dr. Freene. "Physical activity plays a vital role in preventing repeat cardiac events, and the levels that someone living with heart disease may need to improve health outcomes may be different to a healthy person, and we want to get a better understanding of that."

About Critical Path Institute

Critical Path Institute (C-Path) is an independent, nonprofit established in 2005 as a public-private partnership, in response to the FDA's Critical Path Initiative. **C-Path's mission is to lead collaborations that advance better treatments for people worldwide**. Globally recognized as a pioneer in accelerating drug development, C-Path has established numerous international consortia, programs and initiatives that currently include more than 1,600 scientists and representatives from government and regulatory agencies, academia, patient organizations, disease foundations and pharmaceutical and biotech companies. With dedicated team members located throughout the world, C-Path's global headquarters is located in Tucson, Arizona and C-Path's Europe subsidiary is headquartered in Amsterdam, Netherlands. For more information, visit c-path.org.

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About Actigraph

ActiGraph is pioneering the digital transformation of clinical research. We provide end-to-end DHT solutions by integrating and operationalizing the best hardware, software, and algorithms to generate reliable evidence and get the right treatments to the right patients, faster. ActiGraph's medical-grade wearable technology platform has been used to capture real-world, continuous digital measures of activity, sleep, and mobility for nearly 250 industry-sponsored clinical trials and thousands of academic research studies. Appearing in over 22,000 published scientific papers to date, ActiGraph is the most experienced and trusted wearable technology partner in the industry. For more information, visit theactigraph.com.

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