

## Mayo Clinic approves Clinical Study of HeraBEAT™ to begin in 2020

- Clinical Study to measure functionality and acceptability of the HeraBEAT™ device for self-administration by expectant mothers, and the HeraCARE™ platform to review foetal and maternal heart rate
- The Clinical Study, will be conducted at the Department of Obstetrics and Gynaecology at Mayo Clinic in Rochester, Minnesota and will recruit 50 low-risk expectant mothers
- This represents second clinical study of HeraBEAT, following outstanding results from Joondalup Health Campus clinical study, that delivered clinical and functional validation of the device
- Reflects HeraMED's well-defined strategy to align with leading healthcare providers and medical institutions to gain medical validation

**HeraMED Limited (ASX:HMD)** ("HeraMED" or the "Company"), a medical data and technology company leading the digital transformation of maternity care with its proprietary in-home maternity care platform, is pleased to announce that the Mayo Clinic's Institutional Review Board (IRB) has approved the launch of a Clinical Study of the HeraBEAT device and the HeraCARE platform to review foetal and maternal heart rate.

The clinical study, which is expected to commence in the coming weeks, will be conducted at Mayo Clinic in Rochester, Minnesota and will recruit 50 low risk expectant mothers. The study will be led by Principal Investigator Yvonne S Butler Tobah M.D., head of Mayo's OB Nest program with co-investigators Regan Theiler M.D., Ph.D, Chair, Division of Obstetrics, Department of Obstetrics and Gynaecology and Abimbola Famuyide, MBBS, Chair of the Department of Obstetrics and Gynaecology.

The overall study will encompass an assessment of the solution's functionality, usability, and user acceptability, as well as an evaluation of the impact of the device on the expectant mothers' perception of foetal wellbeing, measured by standardised surveys.

The HeraBEAT device uses a smartphone-based interface, with real-time instructions for expectant mothers for determining both foetal heart rate (FHR) and maternal heart rate (MHR). The solution is part of the HeraCARE platform, which enables the measurements to be shared on a smart dashboard, in a secure, confidential, and HIPAA (Health Insurance Portability and Accountability Act) compliant manner, to ensure proper support for the pregnant women using the device at home with medical supervision, analysis, and advice.

**HeraMED CEO and Co-Founder Mr David Groberman said:** "The approval to commence a clinical study with a world leading health provider, such as Mayo Clinic, is a significant milestone for HeraMED. Mayo Clinic represents a highly relevant collaborator for HeraMED because they are well renowned as leading researchers in advancing prenatal care models.

“We are delighted to be commencing this study under Mayo Clinic’s OB Nest program, an innovative virtual maternity care program that combines traditional prenatal care office visits with connected care visits and in-home monitoring.

“Our strategy is to cooperate with top-tier healthcare providers to drive adoption and this clinical study represents an extension to our existing collaboration with Mayo Clinic and aligns perfectly with our strategic goals. This trial is expected to be a precursor to the broader HeraCARE pilot,” he said.

On 10 February 2020, HeraMED first announced plans for a Study of HeraBEAT. The revised study protocols have been modified and updated to ensure they appropriately accommodate new COVID-19 remote care challenges. Furthermore, they have also been updated to include the HeraCARE dashboard enabling study investigators to review maternity parameters.

**About the Clinical Trial <https://www.mayo.edu/research/clinical-trials/cls-20476256>**

The study will initially recruit 50 participants, and the primary goals are to evaluate HeraBEAT by assessing the following:

- The functionality of HeraBEAT when self-administered by pregnant women at home
- The acceptability of HeraBEAT when self-administered by pregnant women in the home

Study Type:	Interventional (Clinical Trial)
Estimated Enrollment:	50 participants
Allocation:	Randomized
Intervention Model:	Crossover Assignment
Intervention Model Description:	After approximately 8 weeks of monitoring, patients will complete an ease of use survey, then crossover to the alternate study product.
Masking:	None (Open Label)
Primary Purpose:	Diagnostic
Official Title:	Functionality and Acceptability of a Medical Grade, Smartphone based, Fetal Heart Rate Monitor for Self-Administration by Low Risk Pregnant Women
Study Start Date:	December, 2020
Estimate study completion Date:	October, 2021

**About the Criteria**

**Inclusion Criteria:**

- At least 18 years of age
- Able to speak, read and understand English
- Able to provide informed consent
- Owns a suitable iOS or Android device and demonstrates average control and basic understanding of using a smartphone
- At least 12 weeks gestation
- Pregnancy documented as low risk

**Exclusion Criteria:**

- Any observed anomalies on first trimester dating or formal ultrasound
- Multifetal gestation
- Maternal history of defibrillation
- Maternal history of electro-surgery
- Patients with external electrical stimulators, cardiac pacemakers or requiring use of MRI or other high frequency medical equipment
- Clinical judgment that determines that the pregnancy is at high risk for complications that would require outpatient or inpatient monitoring for clinical care.
- Any of the following high-risk factors would disqualify the mother for the study

Principal Investigator of the trial is Yvonne S Butler Tobah, M.D. and Mayo Clinic have financial interest in the technology referenced in this announcement. Mayo Clinic will use any revenue it receives to support its not-for-profit mission in patient care, education, and research.

**For additional details about Mayo Clinic please visit - <https://www.mayoclinic.org/about-mayo-clinic>**

This announcement has been authorised by the Board of HeraMED Limited.

**-ENDS-**

**HeraMED Limited**

CEO and Co-Founder

David Groberman

M: +972 52 6991188

E: [David@hera-med.com](mailto:David@hera-med.com)

**Company Secretary**

Jonathan Hart

T: +61 2 8379 2961

E: [Jonathan@hera-med.com](mailto:Jonathan@hera-med.com)

**Media Enquiries**

Melissa Hamilton

Media & Capital Partners

M: +61 4 1775 0274

E: [Melissa.hamilton@mcpartners.com.au](mailto:Melissa.hamilton@mcpartners.com.au)

**About HeraMED Limited (ASX:HMD):**

HeraMED is an innovative medical device and technology company leading the digital transformation of maternity care by revolutionising the prenatal and postpartum experience with its hybrid maternity care platform. HeraMED offers a proprietary platform that utilises hardware and software to reshape the Doctor/Patient relationship using its clinically validated in-home foetal and maternal heart rate monitor, HeraBEAT, cloud computing, artificial intelligence, big data, and a digital social networking dashboard.