

Collaboration agreement secured with the Mayo Clinic Platform to advance validation study in coming weeks

Positive engagement with FDA for heart failure clinical decision support solution

- Meeting with FDA provided Echo IQ with a clear path to gain regulatory clearance for EchoSolv HF
- EchoSolv HF is the Company's clinical decision support solution for heart failure
- Collaboration agreement with Mayo Clinic Platform, launched by the Mayo Clinic (the USA's top-ranked hospital) secured post FDA meeting
- Mayo Clinic Platform is focused on earlier and more accurate diagnoses, care personalised for each person and harnessing new technologies to change how care is provided
- Collaboration agreement to advance upcoming validation study to evaluate EchoSolv HF in its ability to detect various forms of heart failure
- Validation study marks the final regulatory requirement prior to FDA submission
- Mayo Clinic Platform was founded by the Mayo Clinic, which is the largest integrated, not-for-profit medical group practice in the world
- Agreement includes potential for licencing of EchoSolv HF to 30 Mayo Clinic Care Network sites using the group's proprietary integration software system for a three-year period
- Validation study expected to commence this quarter with FDA clearance anticipated H2 CY2025
- Developments follow two completed studies using EchoSolv HF which demonstrated:
 - EIQ's AI standalone performance detected 86% of heart failure cases (vs 46% detection in standard clinical practice)
 - AI and clinical evaluation combined increased accuracy to 97% in high-risk individuals
- Heart failure is a major opportunity in the USA:
 - 10m echocardiograms related to heart failure are undertaken per annum
 - Only 50% of cases are accurately diagnosed
 - It's the leading cause of rehospitalisation and accounts for 17% of US healthcare expenditure
 - Total addressable market in the US is US\$70Bn

Sydney: AI and Medical Technology company Echo IQ ("the Company" or "Echo IQ") (ASX: EIQ) is pleased to provide an update on the Company's pre-submission meeting with the United States ("US") Food and Drug Administration ("FDA") regarding its heart failure clinical decision support solution ("EchoSolv HF"). The Company is also pleased to announce a collaboration agreement with the Mayo Clinic Platform, part of the Mayo Clinic, a top-ranked US hospital, to undertake Echo IQ's proposed validation study and qualify the Company's artificial intelligence ("AI") heart failure model. The study, expected to commence this quarter, marks the final clinical requirement prior to a formal submission for clearance by the FDA. Echo IQ anticipates FDA clearance for EchoSolv HF during H2 CY2025.

FDA pre-submission meeting:

Echo IQ requested the pre-submission meeting with the US FDA in December 2024 (refer ASX announcement: 24 December 2024) to verify the design for a proposed validation study which will evaluate EchoSolv HF in its ability to detect various forms of heart failure.

The Company undertook the meeting during the first quarter of 2025 and advises that it had positive engagement with the regulator. The engagement has provided the Company confidence to advance the proposed study design of EchoSolv HF's upcoming clinical validation study.

Agreement with the Mayo Clinic Platform to undertake validation study and utilisation of EchoSolv HF:

Following the pre-submission meeting, the Company executed a collaboration agreement with the Mayo Clinic Platform to undertake the upcoming validation study.

Mayo Clinic Platform is focused on earlier diagnoses, more accurate diagnosis and care personalised for each person. Mayo Clinic Platform is creating a world where the best possible care is available to everyone, everywhere. As new technologies create novel opportunities and approaches, Mayo Clinic Platform is harnessing these new technologies to change how care is provided.

As part of the agreement, the Mayo Clinic Platform also has the right to utilise EchoSolv HF within the group's network of 30 hospitals, utilise Mayo Clinic Platform's proprietary integration software system alongside the product and co-brand with the Company on its EchoSolv HF and heart failure related materials.

The pending validation study will commence this quarter with anticipated completion mid-year. This leaves the Company well placed to meet its proposed timelines for a formal submission to the FDA for regulatory clearance of EchoSolv HF in H2 this calendar year.

The agreement with Mayo Clinic Platform provides strong validation of the Company's offering and its potential to positively impact heart failure, which is a widespread condition globally. Heart failure is the leading cause of re-hospitalisation in the US, accounting for 17% of all US healthcare expenditureⁱ. The market for heart failure is estimated to be US\$70Bn annuallyⁱⁱ.

Management commentary:

Chief Executive Officer, Mr Dustin Haines, said: *"Our meeting with the FDA was very encouraging and has provided Echo IQ with a clear path towards regulatory clearance for EchoSolv HF. Alongside this, the collaboration agreement executed with the Mayo Clinic Platform, part of the Mayo Clinic, which is the top-ranked hospital in the nation, leaves the Company incredibly well positioned to advance its planned validation study, progress regulatory clearance and generate better patient health outcomes in a condition which is common throughout the US and leaves 50% of patients without clear diagnosis."*

Given the previous work undertaken in Australia with EchoSolv HF, which highlighted the correct identification of up to 97% of heart failure cases, we are excited to commence our planned validation study for our innovative solution. I would like to take this opportunity to thank Mayo Clinic Platform for their collaboration. We look forward to working together to deliver improved patient outcomes at scale."

- ENDS -

Authorised for release by the Board of Directors of Echo IQ Limited.

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ABOUT ECHO IQ

Echo IQ uses AI-driven technology and proprietary software to improve decision making in Cardiology.
The company is based in Sydney, Australia.

ⁱ <https://academic.oup.com/cardiovascres/article/118/17/3272/6527627?login=false>

ⁱⁱ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9070116/>