

Mayo Clinic Platform validation study for EchoSolv HF underway – Marks final step prior to formal FDA submission in H2 CY25

- Commencement of study with Mayo Clinic Platform to evaluate EchoSolv HF in its ability to detect all forms of heart failure
- Study in collaboration with Mayo Validate, an independent platform which specialises in performance testing of AI-based models to evaluate and certify quality and accuracy
- Mayo Clinic Platform was founded by the Mayo Clinic, which is the largest integrated, not-for-profit medical group practice in the world
- Initiation of Mayo Validate study follows a number of milestones to date, including:
 - Completion of Australian-based proof-of-concept studies with promising results
 - FDA pre-submission meeting to validate study design and confirm regulatory pathway
 - Collaboration agreement with the Mayo Clinic Platform to advance commercialisation
- Study marks the final regulatory requirement prior to formal FDA submission in coming months
- Echo IQ remains confident of FDA clearance for EchoSolv HF during H2 CY25
- Heart failure is a major market for EIQ – it is the leading cause of rehospitalisation in the US and accounts for 17% of all healthcare expenditure
- Heart failure has an estimated market size of US\$60bn per annum

Sydney: AI and Medical Technology company Echo IQ (“the Company” or “Echo IQ”) (ASX: EIQ) is pleased to confirm it has commenced the clinical validation study for its heart failure clinical decision support software (“EchoSolv HF”) in collaboration with the Mayo Clinic Platform, a division of the Mayo Clinic, a top-ranked US hospital.

The validation study will be carried out in conjunction with Mayo Validate (“Validate”), a unique in-market AI evaluation program which generates an objective report on accuracy, efficacy and susceptibility to bias for AI-based decision software. The commencement of the study is consistent with Company guidance (*refer ASX Announcement 3 April 2025*) and follows an extensive period of engagement between the parties to define the key parameters and finalise the study protocol.

The commencement of the validation study follows the successful completion of the FDA pre-submission process for EchoSolv HF and marks the final regulatory requirement prior to formal FDA submission. The study is expected to validate the EchoSolv HF model’s ability to detect heart failure on an independent dataset. Data from the study will be pivotal in providing clinical evidence to support the Company’s FDA 510(k) application for EchoSolv HF in the US market.

Founded by the Mayo Clinic, which is the largest integrated, not-for-profit medical group practice in the world, the Mayo Clinic Platform is focused on the deployment of new technologies to achieve earlier and more accurate diagnoses and enhance the standard of personalised care.

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.

Mayo Validate is the first and only product in the industry that provides a bias, specificity, and sensitivity report for AI models, which are tested against extensive high-quality data sets that include hundreds of petabytes of de-identified patient data from Mayo Clinic and partners across the United States.

Validate is a highly secure platform which ensures intellectual property is safeguarded throughout the validation process. The platform allows developers to ensure their model is accurate and unbiased, while providing an independent third-party verification process which can help accelerate adoption into clinical practice.

The completion of the pre-submission process and the commencement of the Validate study are critical for advancing the strategy for EchoSolv HF to secure FDA clearance and market access within the US. The commencement of the clinical validation study aligns with the Company's anticipated date for FDA clearance of EchoSolv HF towards the end of H2 2025.

Chief Executive Officer, Mr Dustin Haines said: *"We are pleased to confirm the commencement of the Mayo Validate study, which is consistent with the Company's strategy to advance the clinical development pathway for our technology suite with best-in-class partners in accordance with the highest standards of safety and care. The commencement of the study follows an extensive period of engagement between the Company and the health experts at the Mayo Validate program to optimise the study protocol. We're excited to commence the study, which we believe will provide additional validation of the technology and marks the next step in our stated strategy to achieve FDA clearance for EchoSolv HF in the second half of this calendar year."*

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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.