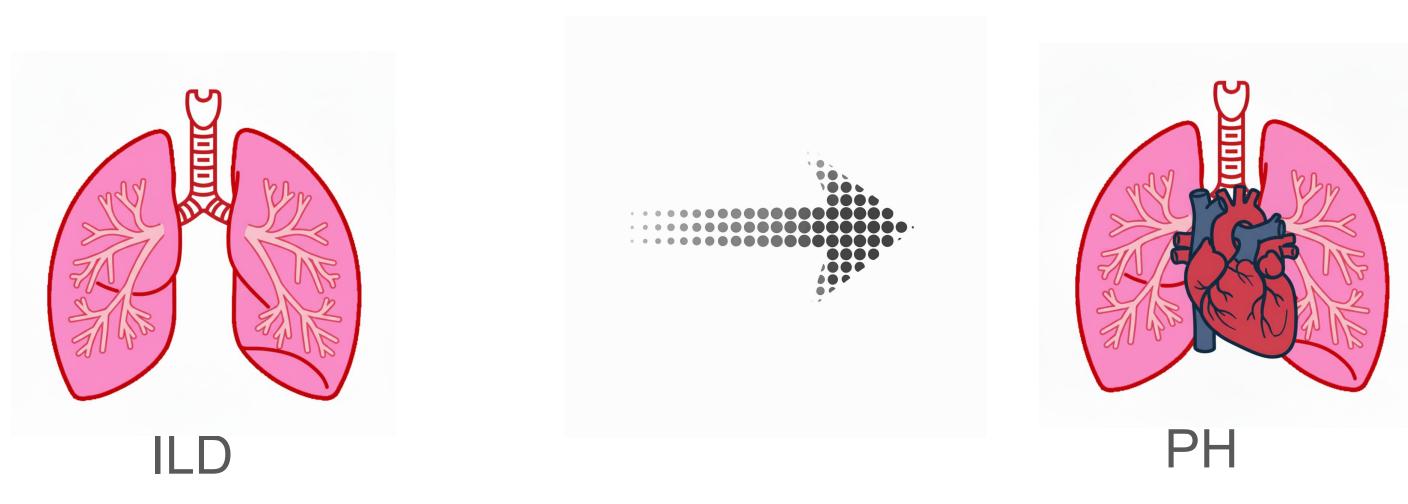# MOMENTOUS: Design of a multi-site clinical study to assess iMpact Of an ecg ai ModEl oN The diagnosis Of pUlmonary hypertenSion

Tejaswini Kulkarni[1], Kevin R. Flaherty[2], Ruijun Chen[3], Melissa Chester[3], Brandon Fornwalt[3], Christopher Haggerty[3], John Pfeifer[3], Kevin Maher[4], Kellie Morland[4], Andrew Nelsen[4], Lisa H. Lancaster[5], Ryan J. Tedford[6]
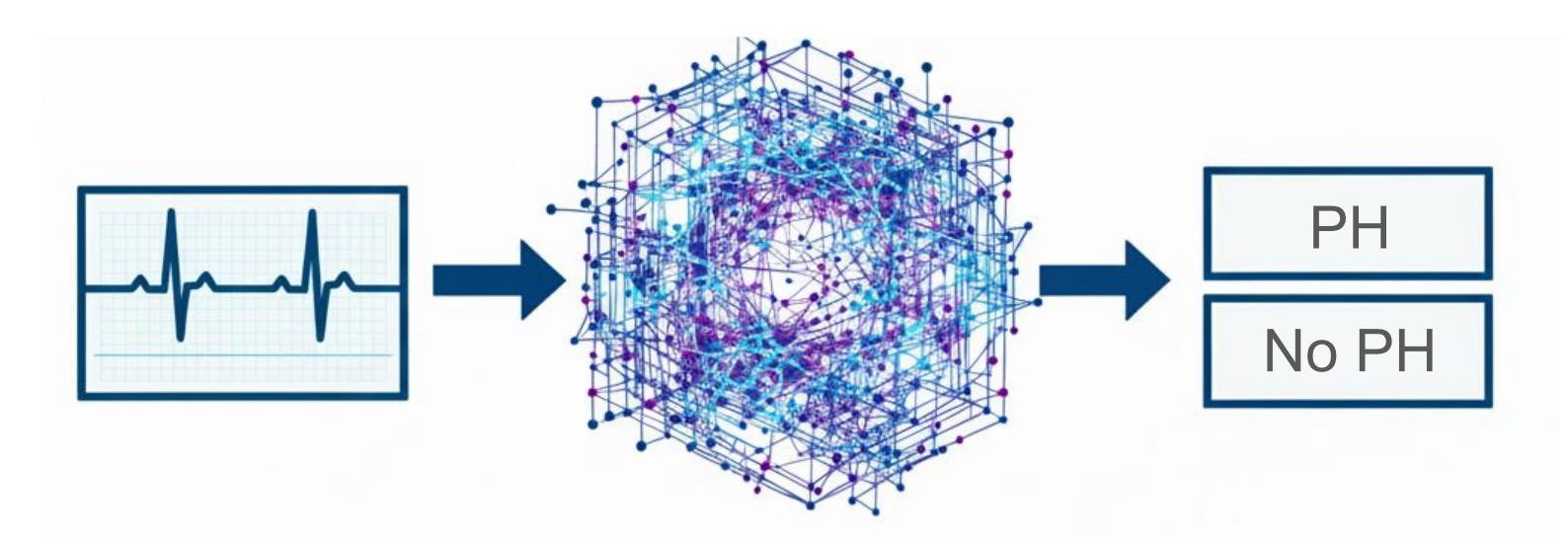
[1] University of Alabama at Birmingham, Birmingham, AL; [2] University of Michigan, Ann Arbor, MI; [3] Tempus AI, Inc., Chicago, IL; [4] United Therapeutics, Research Triangle Park, NC; [5] Vanderbilt University Medical Center, Nashville, TN; [6] Medical University of South Carolina, Charleston, SC

INTRODUCTION

Pulmonary hypertension (PH) is frequently undiagnosed, particularly in patients with interstitial lung disease (ILD). With treatments approved for ILD-associated PH, this diagnostic gap carries increased significance, but the non-specific nature of PH presentation makes referral for diagnostic testing challenging. Artificial intelligence (AI)-based analysis of 12-lead electrocardiograms (ECGs) has shown promise in early detection of PH. This study will prospectively evaluate the impact of ECG-AI on the selection of ILD patients for diagnostic evaluation of PH.

ILD → PH

Challenge: PH can develop with ILD progression, but early diagnosis is a challenge with overlapping symptoms.

PH / No PH

Potential Solution: Use Artificial Intelligence (AI) to detect risk of PH from patient ECGs to inform need for diagnostic evaluation.

METHODS

MOMENTOUS (iMpact Of an ecg ai ModEl oN The diagnOsis of pUlmonary hypertenSion) is a randomized, multi-site clinical study enrolling 1000 patients. (NCT06911632)

Inclusion criteria
- 18 years or older
- A known diagnosis of ILD
- Willing and able to provide informed consent and undergo study-specific procedures, if required

Exclusion criteria
- Known diagnosis of PH
- Right heart catheterization (RHC) in the past 1 year
- Unclassifiable ECG
- Contraindication to RHC
- LVEF ≤ 40%

SUMMARY

- Pulmonary hypertension (PH) is often underdiagnosed in patients with interstitial lung disease (ILD).
- Artificial Intelligence-enhanced Electrocardiography (ECG-AI) offers promise in early PH detection.
- MOMENTOUS is a randomized, multi-site study to test the impact of ECG-AI on rate of PH diagnoses in patients with ILD compared to standard of care. *Enrollment and site activations are ongoing.*

METHODS (cont)

Study Intake
- Consented patients undergo ECG
- ECG evaluated by Tempus ECG-PH device to predict PH risk
- Patients 1:1 randomized following risk prediction, with stratification by site

Intervention (Device) Arm
- Patients predicted to be *high risk by ECG-AI* will undergo study-sponsored echocardiography and RHC within 4 months of randomization.

Control Arm
- Usual care, blinded to ECG-AI prediction

Outcomes
- 6 month follow-up visit will collect data on new PH diagnoses, as well as laboratory, vitals, medications, and comorbidities.

Endpoints
- **Primary:** *Number of new PH diagnoses between high-risk participants in the device vs. controls arms* at 6 months post-randomization.
- Secondary: Number of new PH diagnoses between device and controls arms.
- Secondary: Number of new PH diagnoses between high risk and not high risk device-arm participants.

Significance

ECG-AI has shown potential to assist with clinical recognition of PH, this study seeks to quantify the real-world diagnostic impact through prospective use in the setting of ILD. Study success could demonstrate a new paradigm for PH risk assessment in a population that could benefit from novel therapies.

Study Flow Diagram