

#### Digital Health Solutions for Respiratory Diseases

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Screening for Respiratory Problems – Lack of cost effective and lab free methods for early diagnosis of respiratory diseases. One common point is these diseases get worse if not diagnosed early.

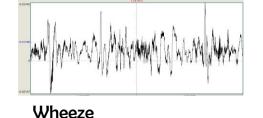
Respiratory symptoms are among the major causes of consultation at primary health care centers (8.4% to 37.0%). https://www.who.int/gard/publications/chronic\_respiratory\_diseases.pdf

Total population in India suffering from respiratory diseases is in the range of 100 million. Globally it is 1.2 Billion people. https://erj.ersjournals.com/content/46/suppl\_59/PA3864

Existing Methods	Shortcomings
Spirometry Test	The test to be repeated several times until there are two or three good efforts. Expensive and in many rural areas it is not available.
X-Ray, CT scan, UV scan	Laboratory setup is required. Not readily available in the primary health care level.

#### Solution / Technology







Crackle

Cough

 $\checkmark$ 

Indications from Audio metric evaluation of respiratory sounds based on ML.

- ✓ Presence of Respiratory problem (yes/no).
- ✓ Obstructive (obstruction in airway) / Restrictive (restricts lung expansion) pattern.
- $\checkmark$  Severity of inflammation (Low, Medium, High).
- ✓ Anatomy (Small Airway ,Large Airway, Parenchyma, Pleura).

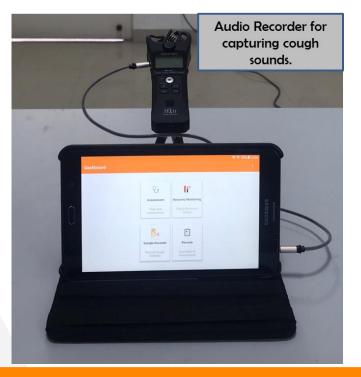
Data analysis and machine learning using 4500+ data points.

Focus areas - Asthma, COPD, Pneumonia & ILD initially & progressively other diseases.

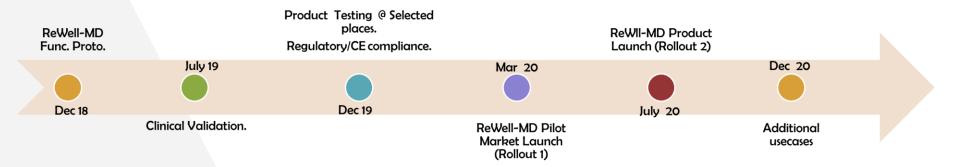
#### **ReWell-MD**, a device for screening respiratory problems.



Wireless Steth for Breach Sounds.



#### Product Roadmap



ReWell-MD - Evaluation by Tele Health Service Provider in progress.

Initiated the testing of ReWell-MD at 3 CSC e-centers through village level entrepreneurs (VLEs), one private hospital. The feedback from VLEs is very encouraging they would like to plan a screening camp at the earliest.

## Collaborations with Medical Community

Institute	Type of Collaboration	Status	Comments
AIIMS, Delhi	Concept validation		Understood the unmet need. Validated the concept.
Apollo Research and Innovation	Data collection & Clinical Validation	Completed	Received very good advice on product use cases from Principal Investigator (Pulmonologist).
Nizam Institute of Medical Sciences	Data collection & Clinical validation	On going	Gained knowledge on disease conditions.
Mana Hospital	Product Testing	On going	Testing the product for functionality validation.

 In touch with a couple of other hospitals where community health/medicine is a focus for validation.

## Challenges in Deployment

Challenge	Detail
Quality of Data, Labeling / Annotation.	Labeling for right respiratory conditions, anatomy.
Domain knowledge to create features.	Use of domain knowledge in creating features that make ML models more accurate and useful.

Involvement of Experts in labeling the data & in creation of feature sets – Efforts, Willingness to use tools and techniques.

# Challenges in Deployment

Challenge	Detail	Comments
Customer expectations on clinical validation.	Customer expect the AI/ML based solutions need to be validated on millions of subjects.	Balance gains with short term limitations. Consider AI based predictions as an aid and amplifier of medical knowledge.
Problems with standard regulatory compliance guidelines.	Technology adaption can generate more data and make device more robust.	Tailored guidelines on regulatory to facilitate this. Algorithm change protocol: <u>https://www.fda.gov/medical-</u> <u>devices/software-medical-device-</u> <u>samd/artificial-intelligence-and-machine-</u> <u>learning-software-medical-device</u>

# Challenges in Deployment

Challenge	Detail	Comments
Sample size	Identifying Optimal Sample size which is statistically significant and financially viable.	Data collection at such huge volumes possible only with strong collaboration from Medical colleges / hospitals & Industry. More inclusive participation is required. Focus on building publicly available large data sets.