

#### **ASX / MEDIA RELEASE**

# **ResApp Completes Enrolment in SMARTCOUGH-C-2 Study**

**Brisbane, Australia, 1 August 2018** -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to announce the completion of enrolment in its SMARTCOUGH-C-2 study. The SMARTCOUGH-C-2 study is evaluating the efficacy of the ResAppDx smartphone application for the diagnosis of childhood acute respiratory disease using cough sounds and has enrolled a total of 1,470 patients at three hospital sites in the United States.

The SMARTCOUGH-C-2 study is a revision of ResApp's earlier SMARTCOUGH-C study with significant improvements made to training and processes. Improvements in hospital staff training and an improved audio recording application has produced higher quality cough audio data in the SMARTCOUGH-C-2 study, subsequently verified by a rigorous quality assurance process which found to date that less than 3% of recordings were unacceptable. An independent, centralised clinical adjudication panel and less subjective clinical case definitions are also being used to ensure consistent clinical diagnosis.

"We are grateful once again to all the patients who participated in the revised study, as well as the investigators and their teams for their hard work and considerable skill that have made this study possible," said Tony Keating, CEO and Managing Director of ResApp. "With higher quality audio data throughout the study, and a consistent, less subjective clinical adjudication process we are confident that we have mitigated the issues that we identified in our earlier SMARTCOUGH-C study. We now look forward to receiving top-line results which will form the basis of our *de novo* premarket submission for ResAppDx in the United States."

With enrolment complete, the study now enters the data verification phase in which final quality assurance, clinical and radiologic adjudication will be conducted for the remaining patients, and final source data verification site visits will be performed. Following data verification, the independent analysis team will prepare top-line results, which are expected later this month.

## **About the SMARTCOUGH-C-2 study**

SMARTCOUGH-C-2 is a multi-site, prospective, double-blind study evaluating the efficacy of the ResAppDx smartphone application in the diagnosis of childhood acute respiratory disease using cough sounds. The study plans to enrol up to 1,667 patients aged 29 days to 12 years of age who present to one of the three participating sites in the United States with signs or symptoms of acute respiratory disease. The study's co-primary endpoints are positive and negative percent agreement with clinical diagnosis for pneumonia, lower respiratory tract disease, viral lower respiratory tract infection, bronchiolitis, asthma/reactive airway disease, upper respiratory tract disease and croup. The clinical diagnosis will be made by an independent, centralised clinical adjudication committee using all available clinical data, including radiology and microbiology.



More information on the study is available at www.clinicaltrials.gov (NCT03392363).

## **About ResApp Health Limited**

ResApp Health Limited (ASX: RAP) is a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease. ResApp's machine learning algorithms use sound to diagnose and measure the severity of respiratory conditions without the need for additional hardware. Clinical studies underway at leading hospitals in the United States and Australia have demonstrated accurate diagnosis of pneumonia, asthma/reactive airway disease, bronchiolitis, croup, chronic obstructive pulmonary disease and upper respiratory tract infections. ResApp has also obtained excellent results for screening of obstructive sleep apnoea in a proof-of-concept clinical study. Potential customers of ResApp's products include healthcare providers in telehealth, emergency department, urgent care and primary care settings as well as humanitarian organisations in the developing world.

For more information on ResApp, visit <a href="https://www.resapphealth.com.au">www.resapphealth.com.au</a>

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