

ASX / MEDIA RELEASE

## ResApp Provides Updated Australian Paediatric Study Results

*ResAppDx delivers excellent results in Australian paediatric study analysed using SMARTCOUGH-C methodology*

**Brisbane, Australia, 22 June 2017** -- ResApp Health Limited (ASX:RAP), a leading digital health company developing smartphone applications for the diagnosis and management of respiratory disease, is pleased to provide an update on its Australian paediatric clinical study which uses cough sounds to diagnose respiratory disease. A total of 1,127 children have been enrolled, and for most disease groups patient numbers have more than doubled since previous results. Analysis of this dataset by Associate Professor Udantha Abeyratne's team at The University of Queensland confirms the high level of agreement between ResAppDx and the clinical diagnosis (based on clinical presentation, auscultation, imaging and laboratory tests).

The dataset and machine learning algorithms have been optimised to match the design of ResApp's US SMARTCOUGH-C study as closely as possible. The clinical diagnosis, used as a comparator, has been adapted to match the SMARTCOUGH-C US-centric clinical case definitions. The algorithms have been fine-tuned to differentially diagnose disease from all patients recruited to the study, as required by the SMARTCOUGH-C endpoints. Following published guidance by the US FDA, the key measures of positive percent agreement (PPA) and negative percent agreement (NPA) are reported instead of sensitivity and specificity.

ResAppDx achieved between 90% and 100% PPA and between 89% and 96% NPA with clinical diagnosis of primary upper respiratory tract infection (i.e. with no co-morbidities), croup, lower respiratory tract involvement, asthma/reactive airways disease (RAD) and bronchiolitis. For pneumonia, ResAppDx demonstrated 89% PPA and 79% NPA with clinical diagnosis. The lower NPA reflects the higher uncertainty in the current method of clinical diagnosis of pneumonia and in particular the clinical overlap between pneumonia, bronchiolitis and asthma/RAD, which can occur at the same time. In many of these cases ResAppDx provides a diagnosis of both pneumonia and the other condition which accurately reflects the clinical situation.

"The ability to diagnose individual diseases among a cohort of patients experiencing a variety of different respiratory diseases is impressive," said Dr Paul Porter, Adjunct Associate Professor, Faculty of Health Science, Curtin University, paediatrician and clinical lead at the Joondalup Health Campus study site. "These levels of accuracy will

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give clinicians significantly more confidence in their treatment decisions, especially in emergency department and telehealth settings.”

“Previous studies have used ResAppDx to diagnose one disease from another. This is the first study where ResAppDx has been used to diagnose a full range of respiratory diseases among a group of patients with a variety of ailments, which is a much greater challenge than previously reported. The excellent results achieved reaffirm the performance of ResAppDx and give us a great deal of confidence as we enter the analysis phase of SMARTCOUGH-C and prepare our *de novo* submission to the US FDA,” said Dr Tony Keating, CEO and Managing Director of ResApp Health.

### Table of Results

Disease	Positive Percent Agreement	Negative Percent Agreement	Overall Percent Agreement
<b>Primary Upper Respiratory Tract Infection</b> (53 patients)			
(cough alone)	89%	84%	84%
(cough, age, gender and symptoms)	<b>92%</b>	<b>89%</b>	90%
<b>Croup</b> (57 patients)			
(cough alone)	97%	92%	93%
(cough, age, gender and symptoms)	<b>100%</b>	<b>96%</b>	97%
<b>Lower Respiratory Tract Involvement</b> (492 patients)			
(cough alone)	86%	85%	85%
(cough, age, gender and symptoms)	<b>90%</b>	<b>92%</b>	90%
<b>Asthma/Reactive Airways Disease</b> (234 patients)			
(cough alone)	80%	71%	75%
(cough, age, gender and symptoms)	<b>92%</b>	<b>89%</b>	90%
<b>Bronchiolitis</b> (101 patients)			
(cough alone)	94%	91%	91%
(cough, age, gender and symptoms)	<b>95%</b>	<b>94%</b>	94%
<b>Pneumonia</b> (123 patients)			
(cough alone)	80%	67%	70%
(cough, age, gender and symptoms)	<b>89%</b>	<b>79%</b>	81%

#### Notes:

1. Results are for the differential diagnosis of individual disease out of all patients with respiratory disease.
2. The performance of the algorithm was evaluated using the method of leave-one-out cross-validation against the clinical team's clinical diagnosis based on clinical presentations, auscultation findings and imaging as well as laboratory test results when needed.
3. Symptoms are presence of fever, wheeze, hoarse voice and/or runny nose during the illness as reported by the patient or parent.
4. Pneumonia is clinically diagnosed viral, bacterial or atypical pneumonia which may or may not have been confirmed by chest x-ray.

#### **About Positive, Negative and Overall Percent Agreement**

Published guidance by the US FDA recommends the terms positive, negative and overall percent agreement be used instead of sensitivity, specificity and accuracy when a new test is compared to a non-reference standard such as a clinical diagnosis. Positive percent agreement (the substitute for sensitivity) is the proportion of patients with the disease that test positive. Negative percent agreement (specificity) is the proportion of patients without the disease that test negative. Overall percent agreement (accuracy) is a measure of both categories.

#### **About ResApp Health Limited**

ResApp Health Limited (ASX: RAP) is a digital health company developing smartphone applications for the diagnosis and management of respiratory disease. The technology is based on machine learning algorithms that use sound to diagnose and measure the severity of respiratory conditions without the need for additional hardware. The algorithms were initially developed by The University of Queensland with funding from the Bill and Melinda Gates Foundation. ResApp has both adult and paediatric clinical studies underway with results demonstrating accurate diagnosis of pneumonia, asthma/viral wheeze, bronchiolitis, croup and upper respiratory tract infections in children as well as chronic obstructive pulmonary disease, asthma and pneumonia in adults. Markets for ResApp's technology include telehealth use through partnerships with telehealth service providers, emergency department and regular clinic use by healthcare providers, at-home use by consumers and working with global aid and humanitarian organisations to deliver tools for the developing world.

For more information on ResApp, visit [www.resapphealth.com.au](http://www.resapphealth.com.au)

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In the United States, ResAppDx is an investigational device and is not available for sale.

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