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### **PainChek submits FDA Pre-Submission Supplement**

**14<sup>th</sup> April 2020:** Listed Australian company PainChek Ltd (ASX:PCK) continues positive progress towards FDA *de novo* clearance for its adult medical app. The Company has now submitted a Supplement to its initial Pre-submission Application to the FDA seeking their feedback on the planned human factors validation testing and clinical trials protocols developed by our research partners, Healthcare Human Factors and Donawa Lifesciences. PainChek is seeking FDA confirmation that these studies will provide FDA with all the necessary data to support a successful PainChek® Adult *de novo* US clearance application.

PainChek CEO and MD, Philip Daffas, said: “We have taken this consultative approach based on feedback from our meeting with FDA in June 2019. The United States is the largest medical device market in the world, and we believe we have the right team and have taken the right approach to successfully obtain FDA *de novo* clearance and enter this significant market. We already have TGA and CE mark clearance and with FDA clearance we will effectively have access to more than 70 percent of the global medical device market. We remain on track to establish PainChek® as the new global standard for pain assessment”.

Given the impact of the COVID 19 pandemic, PainChek acknowledges that commencement of its planned US studies may be delayed depending on how long COVID-19 continues to impact the overall healthcare system. However, it is committed to ensuring its preparedness to conduct those studies once the COVID-19 constraints on conducting clinical studies ease.

The PainChek® Adult App is now a proven and accurate pain assessment system in multiple markets with more than 100,000 clinical assessments completed to date. Regular pain assessments are of even greater importance for the vulnerable during COVID 19, as chronic pain may be associated with an impaired immune system. The PainChek® design is unique and its availability is timely given the COVID 19 challenges. PainChek® allows carers to safely and rapidly conduct a pain assessment that complies with social distancing requirements and infection control procedures, minimising risks for patients, residents and their carers.

“In this current healthcare crisis, PainChek® is already helping our vulnerable community and their carers. We all look forward to coming out of this crisis in an even stronger position and initiate our planned US studies to support the *de novo* regulatory clearance application for PainChek® Adult” added Daffas.

This ASX announcement has been approved for release by Philip Daffas, Managing Director.

**ENDS:**

**For more information:**

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### About PainChek®

PainChek® Ltd is an Australian based company that develops pain assessment technologies.

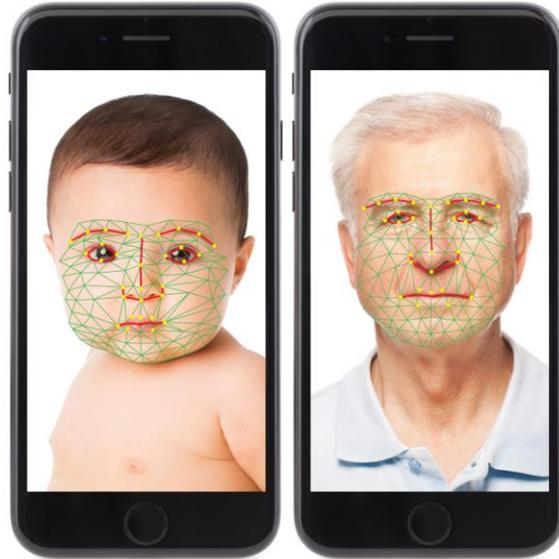
PainChek® is a smart-phone based medical device using artificial intelligence to assess and score pain levels in real time and update medical records in the cloud. PainChek® records a short video of the person's face and analyses the images that indicate pain and records them.

Next, the caregiver uses PainChek® to record their observations of other pain related behaviours that complete the assessment. Finally, PainChek® calculates an overall pain score and stores the result allowing the caregiver to monitor the effect of medication and treatment over time.

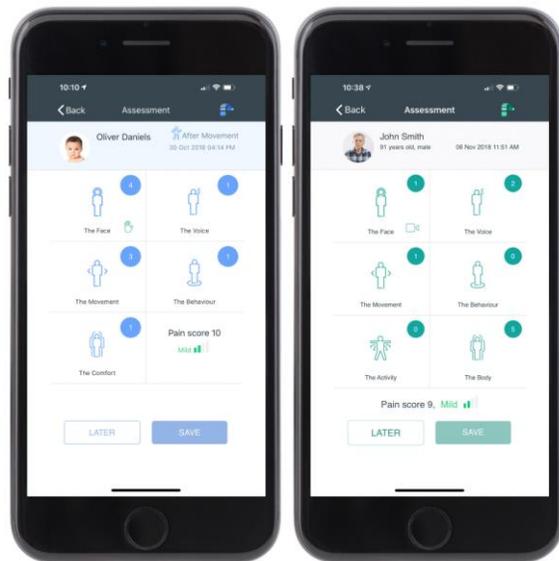
PainChek® is being rolled out globally in two phases: first, PainChek® for adults who are unable to effectively verbalise their pain such as people with dementia, and second, PainChek® for Children who have not yet learnt to speak.

The PainChek® Shared Care Program is a PainChek® licensing model which enables a professional carer to share their resident or patient data securely with other healthcare professionals or designated homebased family carers for ongoing pain assessments or clinical data review.

To find out more, visit [www.painchek.com](http://www.painchek.com)



PainChek® artificial intelligence assesses facial micro-expressions that are indicative of the presence of pain.



PainChek® domains of pain assessment that calculates pain severity score.