

Sydney to undertake clinical studies of needle-free vaccine patch

Clinical studies to look at the potential of needle-free delivery for at-risk groups

Sydney, 23 November 2020: University of Sydney researchers have been awarded \$1.12 million in funding via the Innovative Manufacturing CRC (IMCRC) to undertake independent clinical research studies to understand the potential of needle-free vaccine delivery for at-risk groups. This grant reflects matched funding from Commonwealth Government funded IMCRC and Vaxxas, an Australian biotechnology company.

The two upcoming clinical studies are designed to evaluate the safety, feasibility, acceptability and usability of self-administration of Vaxxas' vaccine delivery technology using an inactive substance. They will focus on older adults and healthcare professionals who are more likely to be impacted by pandemic influenza and SARS-COV-2.

Lead researcher [Professor Rachel Skinner](#) from the University of Sydney's [Faculty of Medicine and Health](#) said the device presents potential advantages compared to vaccination using a needle and syringe.

The device is a one square-centimetre of biocompatible polymer, smaller than a postage stamp, covered in thousands of micro-projections which are invisible to the naked eye. These are coated with a vaccine formulation, with the goal of penetrating the protective outer layer of the skin to deliver the vaccine to cell layers immediately under the skin, rich in immune cells.

The device is applied to the skin using a disposable applicator that contains the product. The vaccine technology is still under development and has not yet been approved for use.

"The goal is for the device to only require a small dose of vaccine to generate the same level of immune response in the recipient," said Professor Skinner.

"The device doesn't require refrigeration making it easy and cheap to transport and store. It is designed to be simple to use, with the potential to be self-administered."

[Cristyn Davies](#), a Research Fellow in the Faculty of Medicine and Health, said the trials aim to simulate vaccination in a pandemic situation, focusing on priority groups susceptible to infection such as the elderly, and healthcare workers who are required to care for infectious patients.

"The studies will use an excipient, an inactive substance which is of the same texture as a vaccine, to test the effectiveness of the device at delivery of the substance into the skin."

"With older populations, we are particularly interested to see how the technology works with those with aged, delicate skin. In both groups, we will test whether it's feasible and acceptable for them to self-administer the patch, which could prove critical for many populations during a pandemic situation."

Professor Rachel Skinner said that the new studies build on earlier studies carried out by the team in 2019-2020 to test the usability and acceptability of the device among parents, clinicians and immunisation nurses, and assess cost-benefits on logistical parameters like supply chain, compared to conventional immunisation. The results are yet to be published.

David Chuter, CEO and Managing Director of IMCRC, highlighted the importance of the studies in expediting the refinement of the design and manufacturing of the device.

“With Vaxxas planning to begin manufacturing the new needle-free vaccine delivery technology by early 2022, this IMCRC research project is vital to refine the device and fast-track its commercialisation process. These studies will assess the safety and acceptability of managing this technology within the healthcare community, with the results being fed back into the design and manufacturing process which is currently set up in Australia.”

Charles Ross, Head of Clinical Operations and Supply at Vaxxas said the collaboration with the University of Sydney brings world class practical vaccination and clinical trial experience to complement the capabilities of the Vaxxas research team.

“The distribution of vaccines and the requirements for successful vaccination uptake are critical success factors in a pandemic vaccination campaign. We are excited to be working with experts from the University of Sydney to assess the impact our revolutionary and simplified approach to vaccination can have on the logistics and acceptability of the vaccination process in a close to real-world situation”.

[Professor Robyn Ward](#), Pro Vice-Chancellor and Executive Dean of the [Faculty of Medicine and Health](#), said the collaboration demonstrates the importance of supporting innovation in research.

“The COVID-19 pandemic has demonstrated, perhaps more than ever before, the crucial role our researchers play in innovation in the healthcare sector. Investment in projects such as this is vital and will ensure the continued strength of medical research in Australia,” said Professor Ward.

The University of Sydney research team led by Professor Rachel Skinner includes Research Fellow Cristyn Davies, Professor [Robert Booy](#) and Associate Professor [Nicholas Wood](#).

Declaration: Study protocols and ethics are subject to approval. Matched funding from IMCRC and Vaxxas for the clinical trials and earlier sub-studies is administered via the IMCRC to maintain full independence of the research trials. Professor Booy consults to vaccine companies principally by way of advisory boards including Seqirus, Sanofi, Janssen, GSK, Pfizer and Vaxxas. Professor Skinner’s employer has received honoraria from Seqirus and Merck for educational presentations about HPV vaccination.

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About the Faculty of Medicine and Health, University of Sydney

As the first medical school in Australia, the Faculty of Medicine and Health is both steeped in history and a pioneer in the future of healthcare. We are focused on reimagining the way we deliver wellness and health through innovative, life-long education, world-class research, technology and facilities and partnerships with change makers.

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About Innovative Manufacturing Cooperative Research Centre (IMCRC)

The IMCRC has a vision for Australian manufacturing to be thriving, relevant and globally integrated. As a not-for-profit, independent cooperative research centre, the IMCRC helps Australian companies increase their relevance through collaborative, market-driven research in manufacturing business models, products, processes, and services. More at www.imcrc.org

About Vaxxas

Vaxxas is a privately held biotechnology company focused on enhancing the performance of existing and next-generation vaccines with its proprietary HD-MAP technology platform. Vaxxas core technology was developed at the University of Queensland. The company was founded with the completion of an initial equity financing led by OneVentures Innovation Fund I with co-investors Brandon Capital, the Medical Research Commercialisation Fund (MRCF), and US-based HealthCare Ventures, followed by a further financing led by OneVentures. OneVentures Innovation Fund I and the MRCF are supported by the Australian Government’s Innovation Investment Fund (IIF) program. The IIF is an Australian Government venture capital initiative that provides investment capital and managerial expertise through licensed venture capital fund managers to investee companies.