Medicines & Healthcare products Regulatory Agency

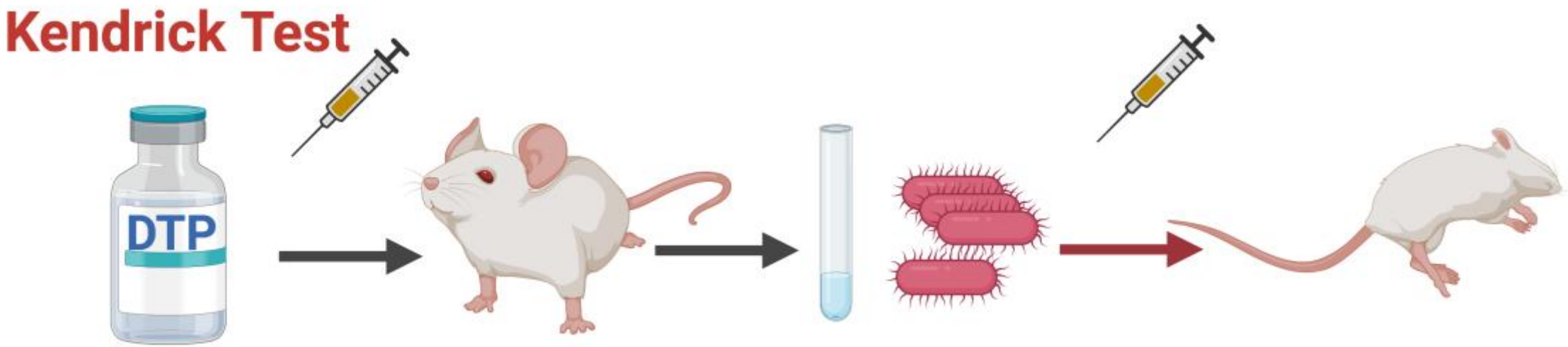
The next challenge – a fully in vitro approach to ensure quality and consistency of whole-cell pertussis vaccines

Paul Stickings, on behalf of the wPIPA consortium

IABS/AFSA Conference, Bangkok. 03-Dec 2025

OFFICIAL-SENSITIVE

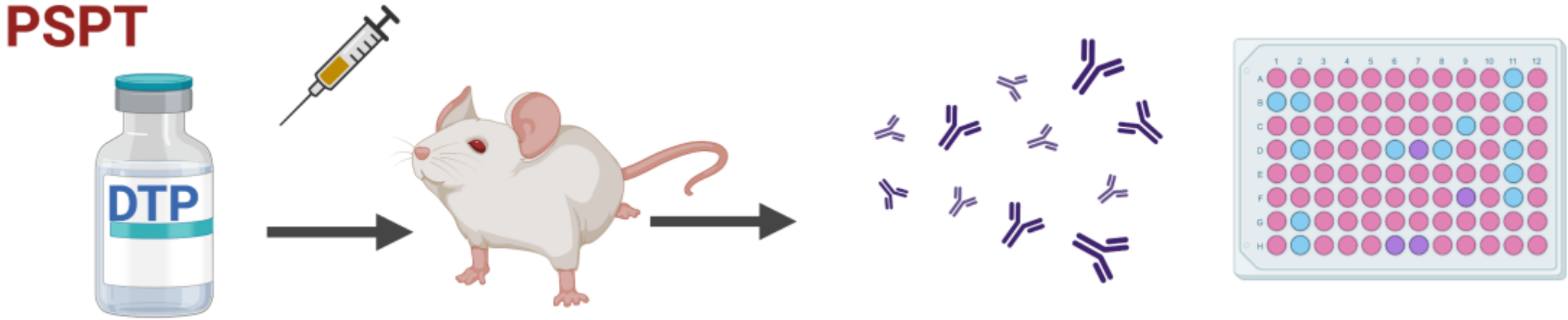
Kendrick test for wP vaccine potency



Current compendial test for assessing potency of whole cell pertussis vaccines

Problem: the assay is technically challenging and highly variable – it is not well suited for the purpose of routine batch control

Pertussis Serological Potency Test

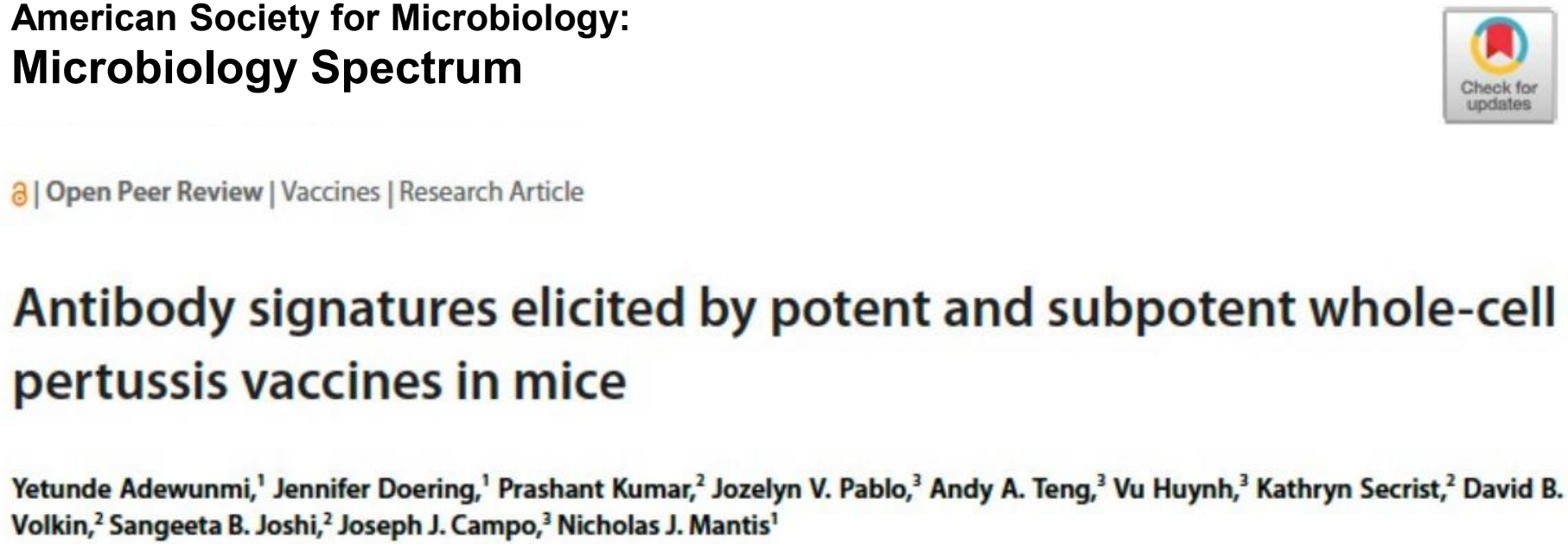


Recent efforts have focused on development of a serological potency test (PSPT)

A refinement, but not necessarily an improvement – still an assay with inherently high variability; still requires weeks for completion and, of course, still requires the use of animals..

A new approach..

Can we use one or more *B. pertussis* surface exposed antigens as indicators of vaccine potency?



American Society for Microbiology:
Microbiology Spectrum

Check for updates

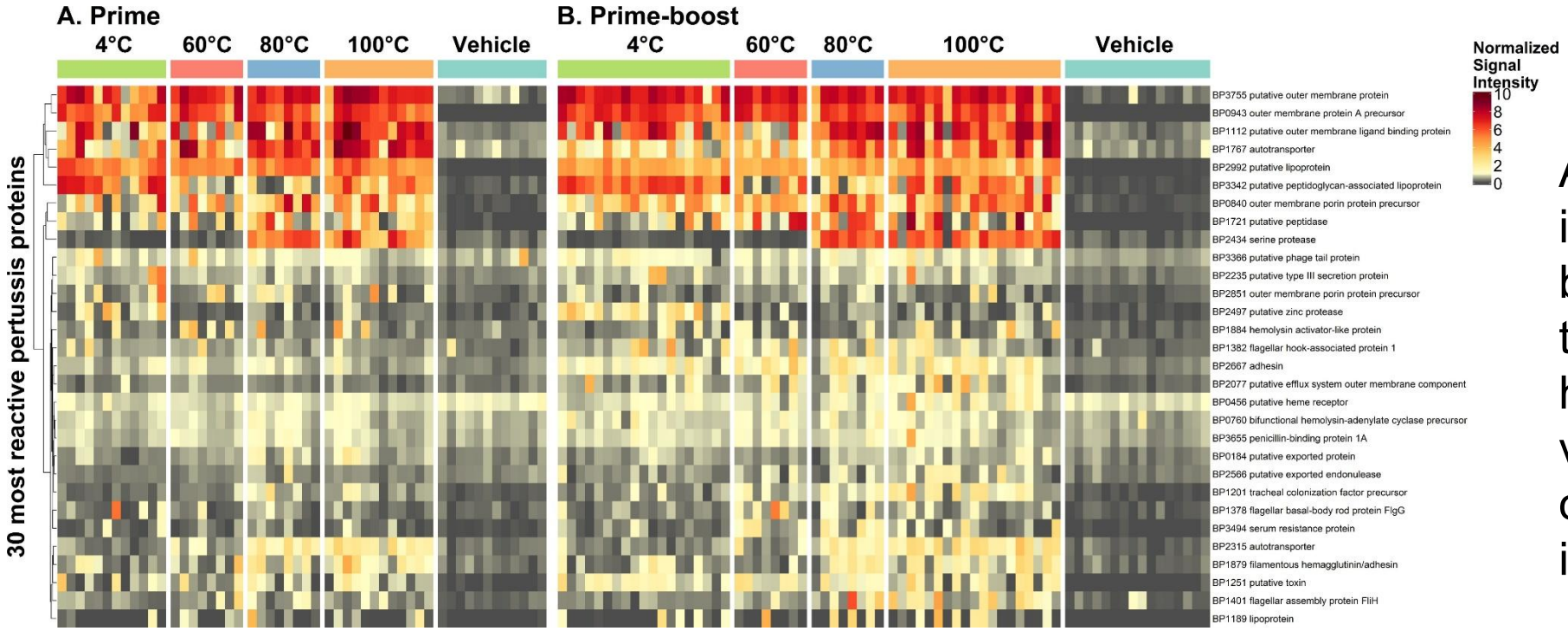
| Open Peer Review | Vaccines | Research Article

Antibody signatures elicited by potent and subpotent whole-cell pertussis vaccines in mice

Yetunde Adewunmi,[1] Jennifer Doering,[1] Prashant Kumar,[2] Jozelyn V. Pablo,[3] Andy A. Teng,[3] Vu Huynh,[3] Kathryn Secrist,[2] David B. Volkin,[2] Sangeeta B. Joshi,[2] Joseph J. Campo,[3] Nicholas J. Mantis[1]

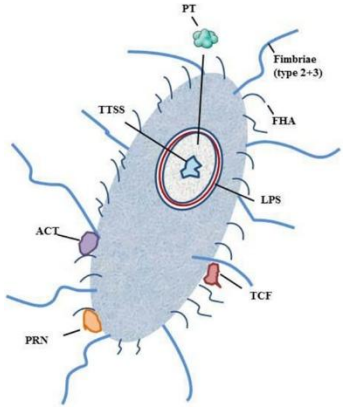
Adewunmi Y, Doering J, Kumar P, Pablo JV, Teng AA, Huynh V, Secrist K, Volkin DB, Joshi SB, Campo JJ, Mantis NJ. Antibody signatures elicited by potent and subpotent whole-cell pertussis vaccines in mice. Microbiol Spectr. 2025 Mar 25;13(5):e0325324. doi: 10.1128/spectrum.03253-24. Epub ahead of print. PMID: 40130856; PMCID: PMC12054088.

Identifying relevant target antigens..

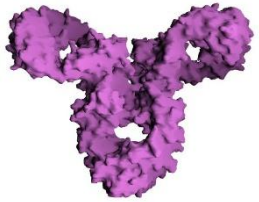


Antigens recognised by wP-immune sera (mice) have been used to identify those that are most impacted by heat exposure of the wP vaccine prior to immunisation of mice and generation of the immune sera

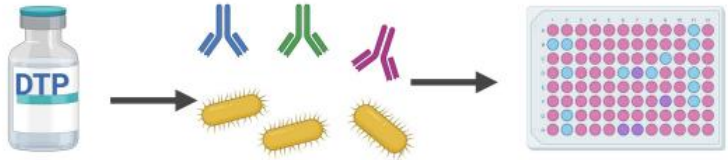
The project plan..



Antigen selection: based on previous work done in Mantis lab

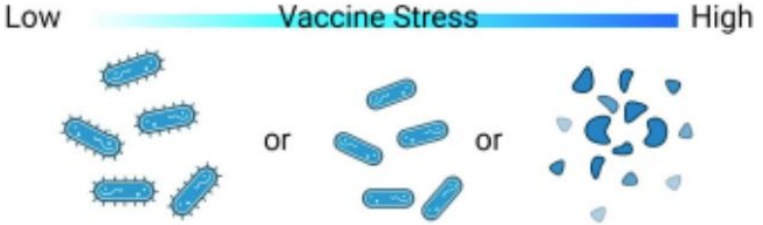


mAb production following immunisation with purified antigen(s)

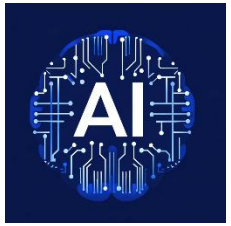


In vitro immunoassay development (wPIPA)

Production of selected antigens; screen against human immune sera



Select mAbs with quality / stability indicating potential using relevant wP strains



AI developed tools to support technology transfer

Engaging stakeholders

Early in the project

The project team would like to source wP bulks from vaccine manufacturers to ensure that antibody evaluation is done with relevant wP strains

Later in the project

We will look to engage manufacturers and regulator / control laboratories to transfer the technology and build capacity as part of future implementation plans

The wPIPA consortium

MHRA, UK (Project Coordinator)

Wadsworth Center, USA

CER, Belgium

SciEthiQ, Italy

Blaise Management, Belgium

FRESCI, Spain

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