The Department of Health and Social Care
Imperial Future Vaccine Manufacturing Research Hub

New vaccine technologies for developing countries

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Future Vaccine Manufacturing Research Hub

Imperial College London

The University of Nottingham

University of BRISTOL

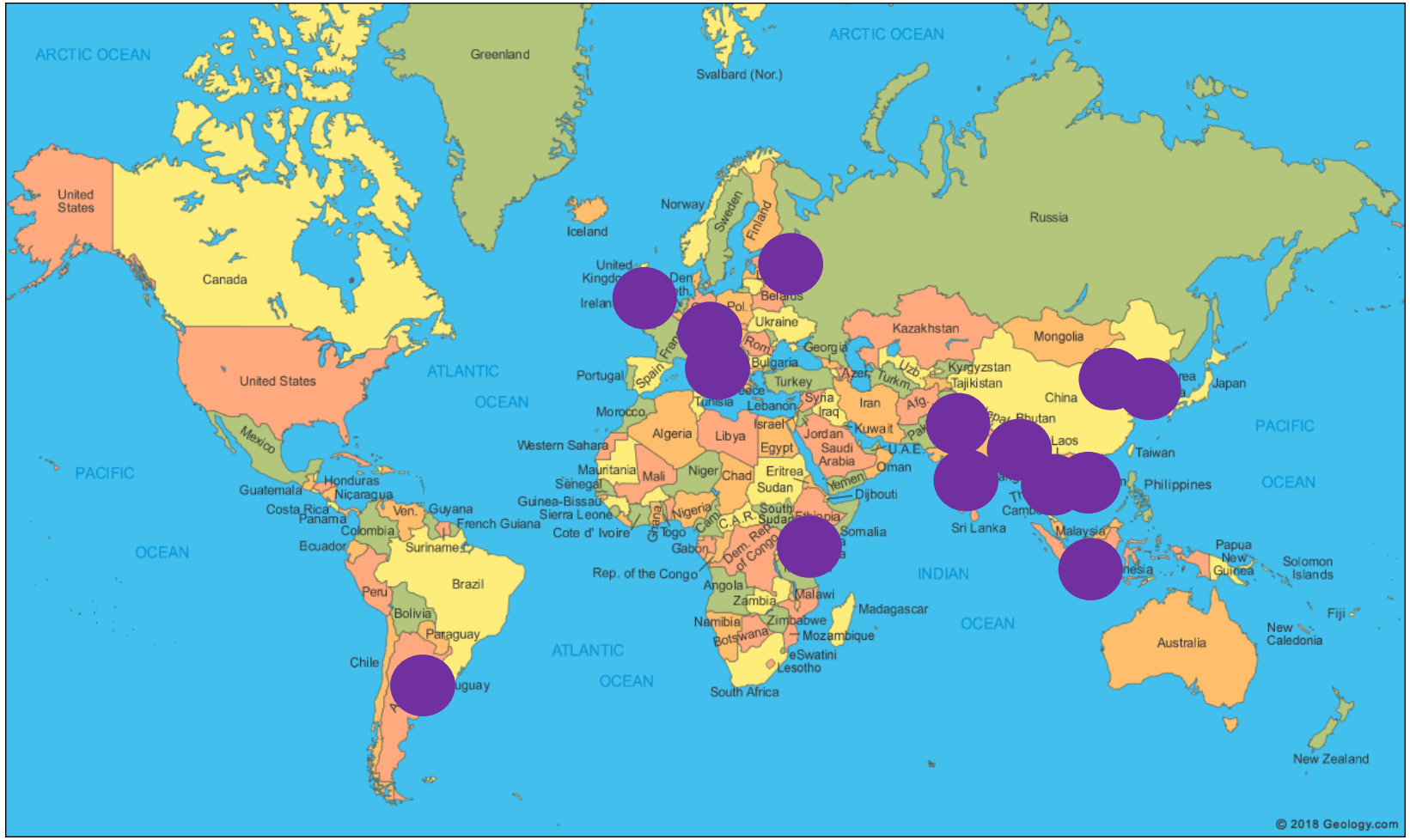
UNIVERSITY OF CAMBRIDGE

NHS Blood and Transplant

KING'S College LONDON

cpi

NIBSC Confidence in Biological Medicines



UNIVERSITY OF LEEDS

BE Biological E. Limited Celebrating Life Every Day

MINHAI

imBio INNOVATING VACCINES

EXCIVION

Enesi Pharma

Hissen 艾美汉信疫苗（大连）有限公司 Aimei Hissen Vaccine (Dalian) Co., Ltd.

Incepta

VABIOTECH For a Healthier life

gsk

dcvmn Developing Countries Vaccine Manufacturers Network

Responding to developing world vaccine needs

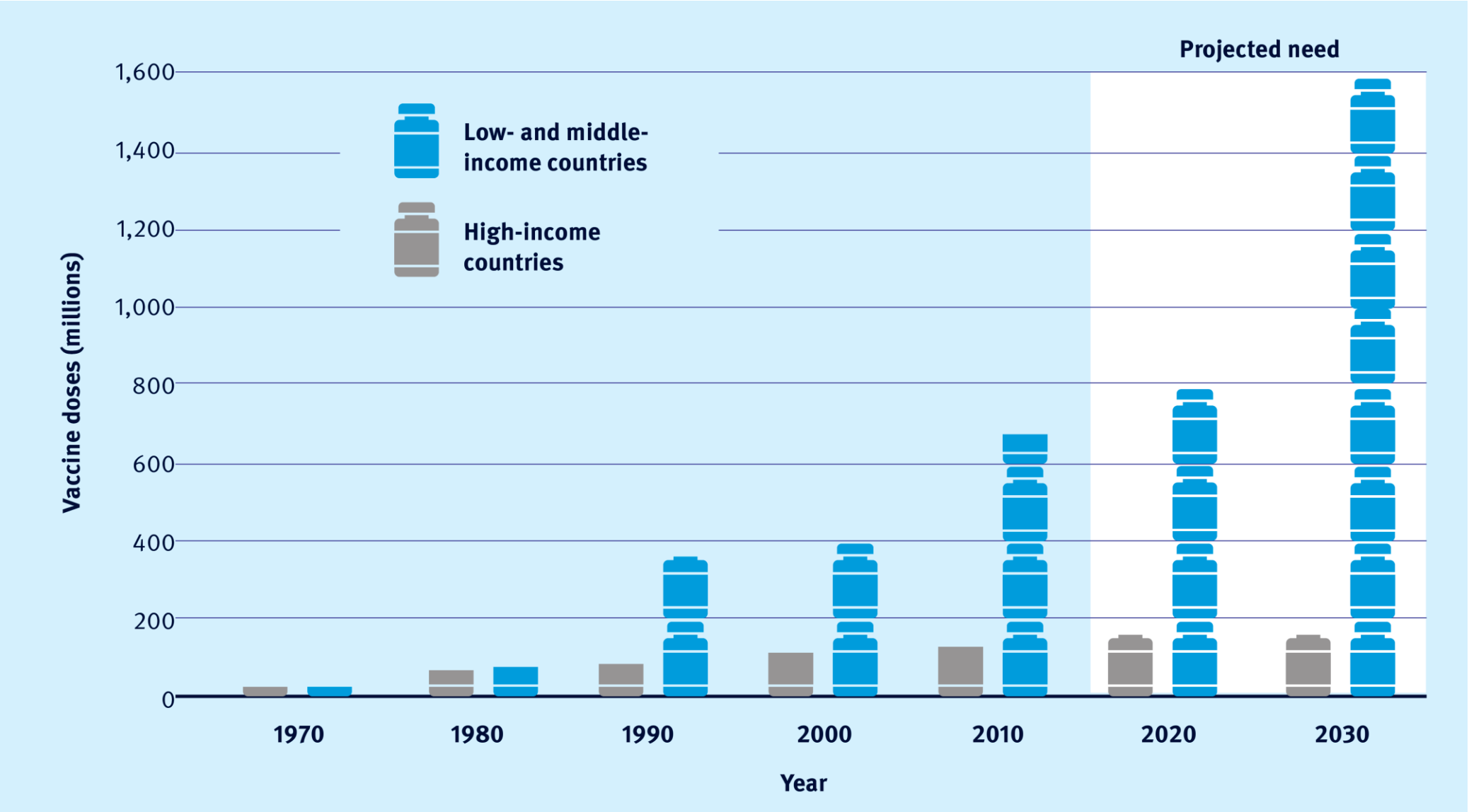
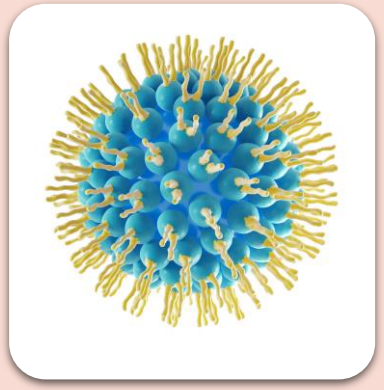


Figure adapted from Rino Rappuoli, Steven Black, and David E Bloom. *Science Translational Medicine.* **2019**. 11, eeaw2888.

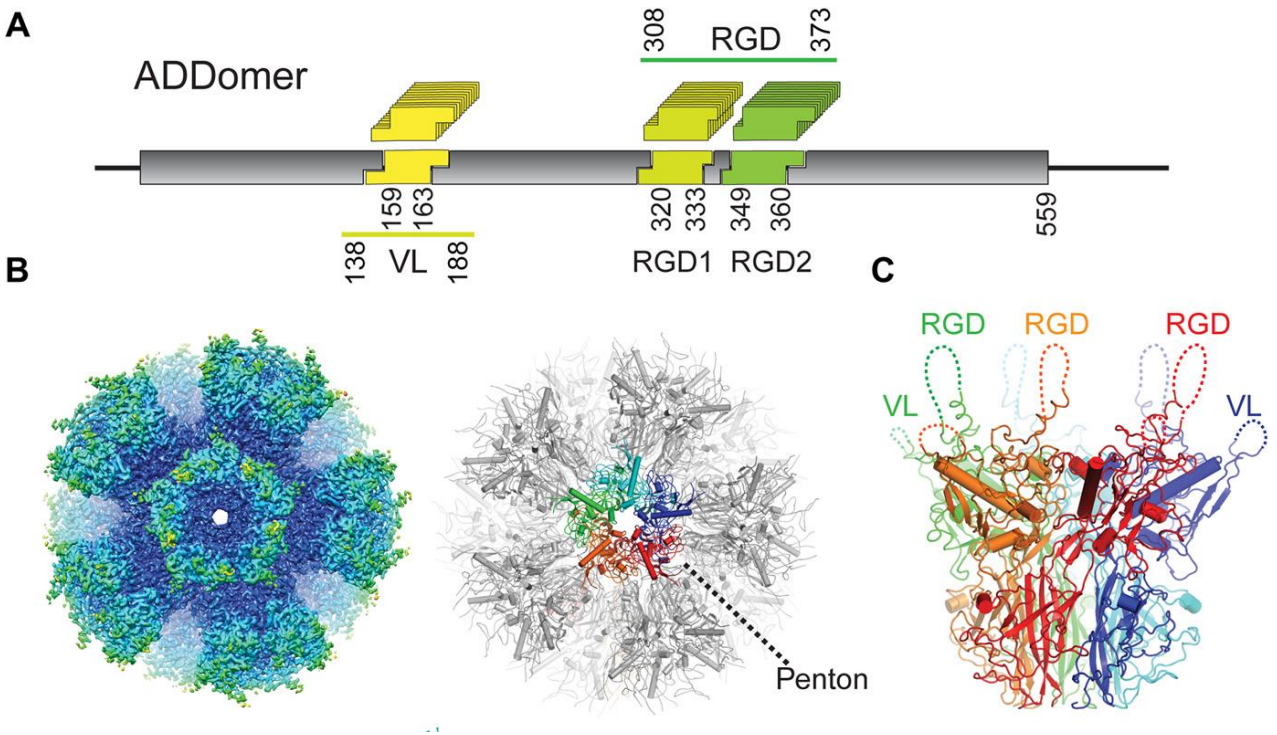
Future Vaccine Manufacturing Research Hub
Innovative Technologies

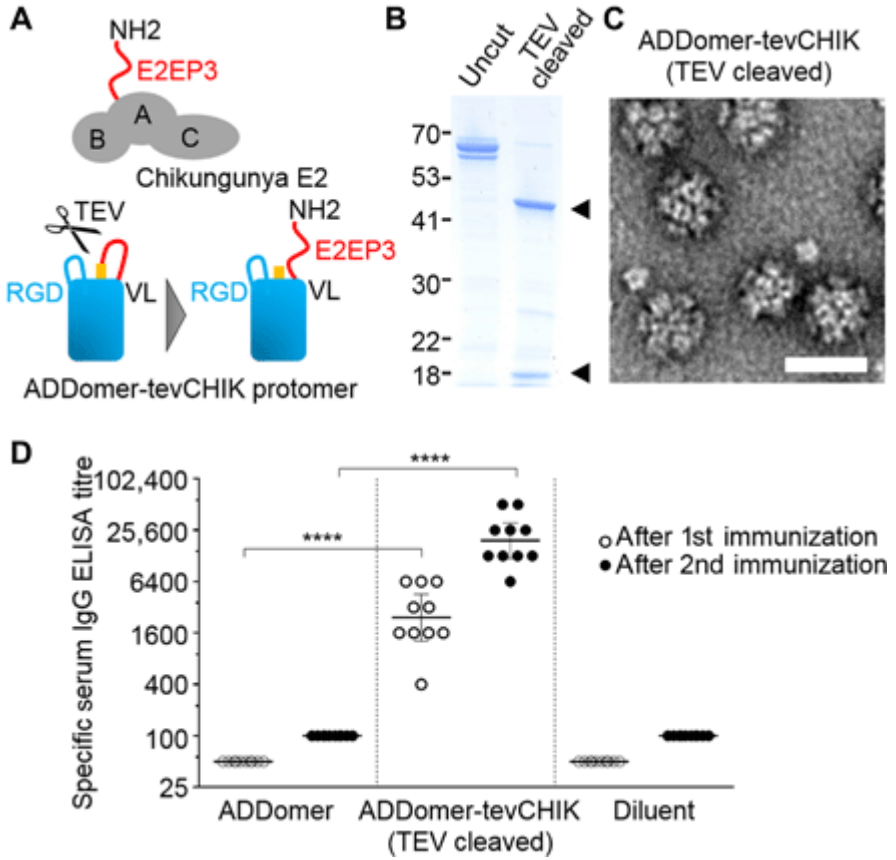


GMMA	Baculovirus	Yeast	RNA
Easy scale-up	Thermostable	Easy scale-up and high yield	Rapid
Mature	Rapid	Low risk of contamination	Synthetic and cell-free
Slow	Feasible scale-up	Purification challenging	Immature
Human glycosylation challenging	Technologically complex		

Decreasing risk

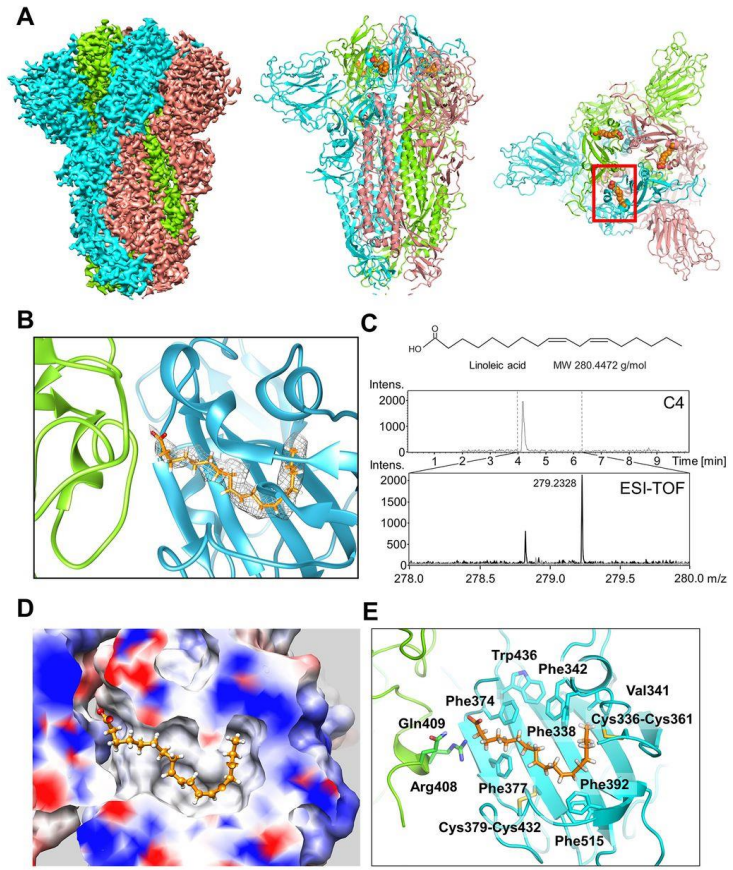
Baculovirus - ADDomer

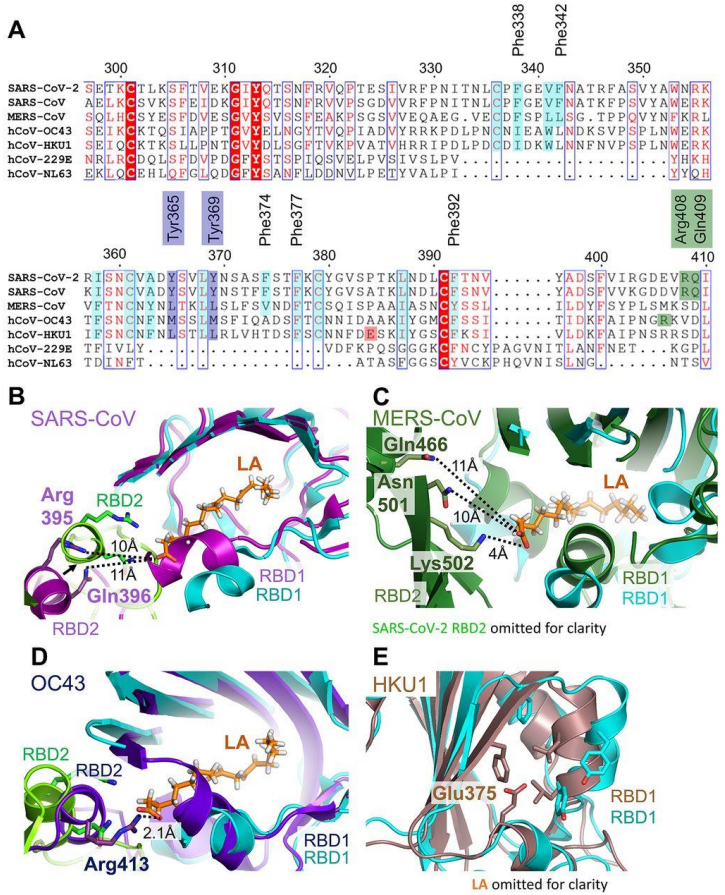




Charles Vragniau, Joshua C. Bufton, Frédéric Garzoni, Emilie Stermann, Fruzsina Rabi, Céline Terrat, Mélanie Guidetti, Véronique Josserand, Matt Williams, Christopher J. Woods, Gerardo Viedma, Phil Bates, Bernard Verrier, Laurence Chaperot, Christiane Schaffitzel, Imre Berger, and Pascal Fender. "Synthetic self-assembling ADDomer platform for highly efficient vaccination by genetically encoded multiepitope display." ***Science Advances***. 2019. 5: eaaw2853.

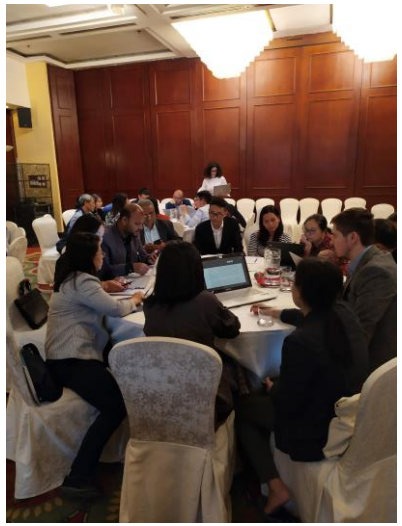
SARS-CoV-2 Binds to Free Fatty Acids





Christine Toelzer, Kapil Gupta, Sathish K.N. Yadav, Ufuk Borucu, Andrew D. Davidson, Maia Kavanaugh Williamson, Debora K. Shoemark, Frédéric Garzoni, Oskar Staufer, Rachel Milligan, Julien Capin, Adrian J. Mulholland, Joachim Spatz, Daniel Fitzgerald, Imre Berger, and Christine Schaffitzel. "Free fatty acid binding pocket in the locked structure of SARS-CoV-2 spike protein." ***Science***. 2020. eabd3255.

Supply Chain Efficiency Workshop, Hanoi: Nov 2019



"THANKS…it was really an honor to be a part of that. **All the content received was extremely useful and appropriate for our daily and future work.**"

The workshop was attended by over 50 participants, from 15 companies (e.g. Bharat Biotech, Sinovac, Polyvac, Panacea, Incepta, Walvax) and 9 countries (Argentina, Bangladesh, China, India, Indonesia, South Korea, Russia, Thailand, Vietnam)!

Imperial Future Vaccine Manufacturing Research Hub and DCVMN

Quality by Design and Supply Chain Modelling Workshop organised / hosted by FVMR Hub

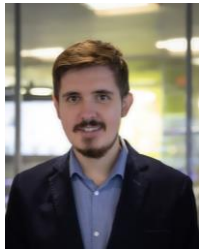
DCVMN Members from Developing Countries

Hanoi, Vietnam

25 – 27 November 2019

Over 50 registered attendees!
From 9 countries!



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NIBSC Confidence in Biological Medicines

dcvmn Developing Countries Vaccine Manufacturers Network

CALL FOR EXPRESSION OF INTEREST

THE DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK's (DCVMN) OPEN CALL FOR EXPRESSION OF INTEREST IN QC/QA TRAINING WITH IMPERIAL COLLEGE LONDON'S FUTURE VACCINE MANUFACTURING RESEARCH HUB (FVMR)

GUIDANCE

DCVMN International periodically sponsors technical assistance for its member companies. This assistance comes from internationally-reputable expert consultants and/or service firms

QC training at NIBSC – 16 applications being supported.

Imperial College London

dcvmn Developing Countries Vaccine Manufacturers Network

SECOND CALL FOR PROPOSALS

THE DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK's (DCVMN) OPEN CALL FOR EXPRESSION OF INTEREST IN COLLABORATIVE PROJECTS WITH FUTURE VACCINE MANUFACTURING RESEARCH HUB (FVMR)
GUIDANCE FOR APPLICANTS

DCVMN International periodically sponsors technical assistance provided to member companies by internationally-reputable expert consultants and/or service firms, to improve manufacturing technology, processes or quality control systems. The objective is to increase availability of high-quality vaccines globally.

1. Purpose

As announced on the DCVMN website in January 2018, a novel partnership has been launched to support responsible innovation for manufacturing in emerging countries and to improve the response to

"Consultancy call" deadline was 07 Feb 2020.
2 applications successful.

Imperial's FVMR Hub: NIBSC and DCVMN Training

In discussions regarding training to be held in 2021

Imperial College London

NIBSC Confidence in Biological Medicines

dcvmn Developing Countries Vaccine Manufacturers Network

CALL FOR EXPRESSION OF INTEREST

THE DEVELOPING COUNTRIES VACCINE MANUFACTURERS NETWORK's (DCVMN) OPEN CALL FOR EXPRESSION OF INTEREST IN QC/QA TRAINING WITH IMPERIAL COLLEGE LONDON'S FUTURE VACCINE MANUFACTURING RESEARCH HUB (FVMR)

GUIDANCE

DCVMN International periodically sponsors technical assistance for its member companies. This assistance comes from internationally-reputable expert consultants and/or service firms with the aim to improve manufacturing technology, processes or quality control systems. Our objective is to increase the availability of high-quality vaccines.

Purpose. In order to enable the efficient registration and WHO Prequalification of vaccines

16 successful applications!

dcvmn Developing Countries Vaccine Manufacturers Network

The **training will support manufacturers to improve the accuracy and efficiency of their vaccine testing such as batch release and QC assays** for the following disease areas:

1. Tetanus
2. Pertussis
3. Rabies
4. Polio (new Sabin IPV)
5. Porcine circovirus
6. Meningitis
7. Influenza
8. HPV
9. Hep A / B

Imperial Future Vaccine Manufacturing Research Hub and DCVMN

Yeast-based and baculovirus-based manufacturing Workshop organised / hosted by FVMR Hub

DCVMN Members from Developing Countries

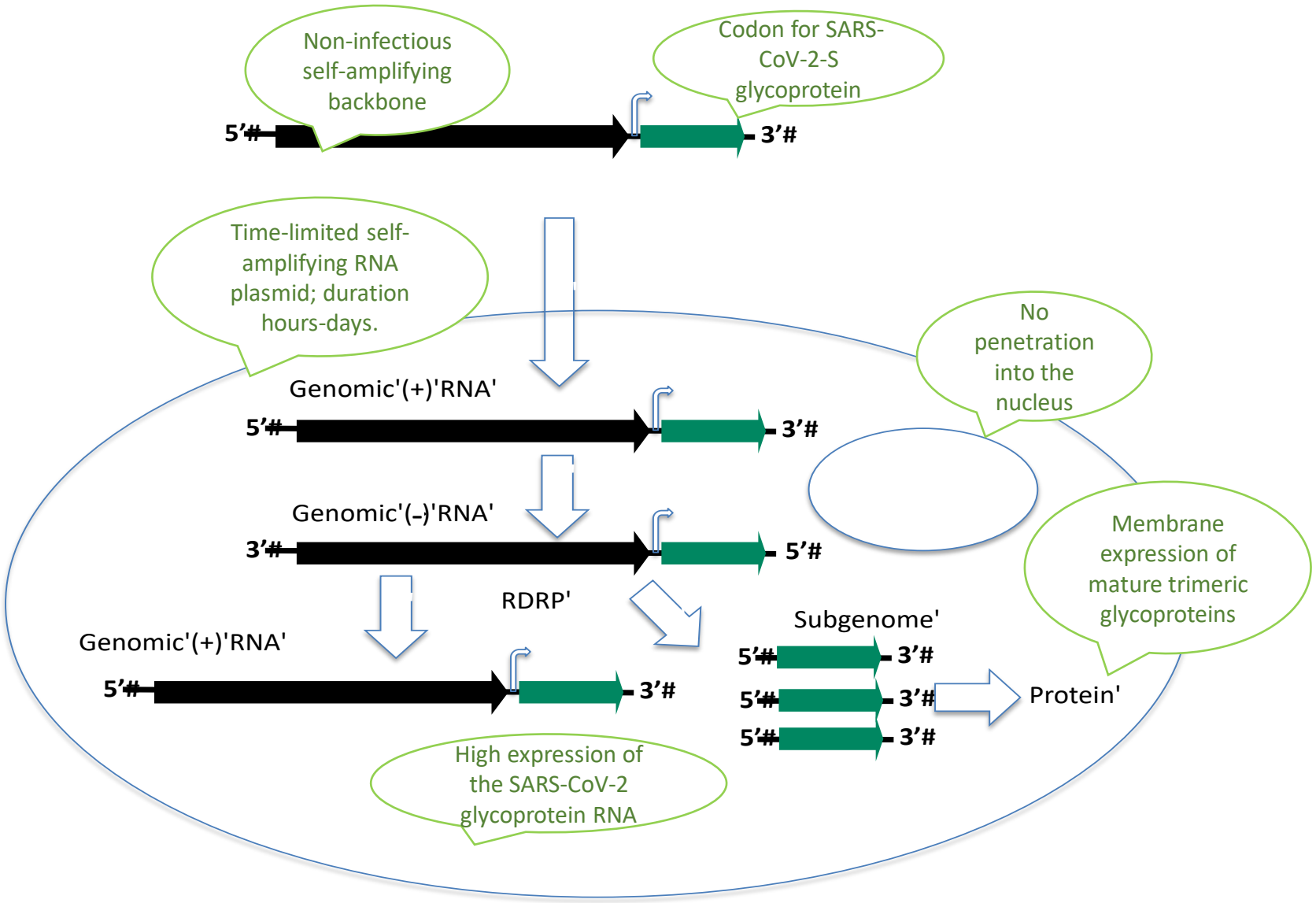
Webinar

13-14 May 2020

DAY 2, Wednesday 13 May 2020 Expression platform Pichia pastoris for vaccine manufacturing		
Time	Topic	Speaker
08:45-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Introduction to the Pichia system	R. Aw, Imperial College
09:45-10:00 (CET)	Q&A	R. Aw, Imperial College
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	Expression and scale up	R. Aw, Imperial College
11:00-11:15 (CET)	Q&A	R. Aw, Imperial College
11:15- (CET)	Adjourn	All participants

DAY 3, Thursday 14 May 2020 Baculovaccines manufacturing platform		
Time	Topic	Speaker
08:45-09:00 (CET)	Registration & Recap	DCVMN
09:00-09:45 (CET)	Introduction into Baculovirus expression system	F. Rabi, University of Bristol
09:45-10:00 (CET)	Q&A	F. Rabi, University of Bristol
10:00-10:15 (CET)	Break	
10:15-11:00 (CET)	VLP and Baculovaccine production	P. Meysami, University of Bristol
11:00-11:15 (CET)	Q&A	P. Meysami, University of Bristol
11:15- (CET)	Adjourn	All participants

A COVID-19 self amplifying RNA vaccine



- Potent; only a low volume IM dose required
- Self-amplifying RNA encoding stabilised spike (S) glycoprotein of SARS-CoV-2
- Harnesses host cell translational machinery to deliver membrane expression of antigen
- Liposomal delivery

Preclinical package including immunology, toxicology and planned future preclinical work

Article | Open Access | Published: 09 July 2020

Self-amplifying RNA SARS-CoV-2 lipid nanoparticle vaccine candidate induces high neutralizing antibody titers in mice

Paul F. McKay, Kai Hu, Anna K. Blakney, Karnyart Samnuan, Jonathan C. Brown, Rebecca Penn, Jie Zhou, Clément R. Bouton, Paul Rogers, Krunal Polra, Paulo J. C. Lin, Christopher Barbosa, Ying K. Tam, Wendy S. Barclay & Robin J. Shattock

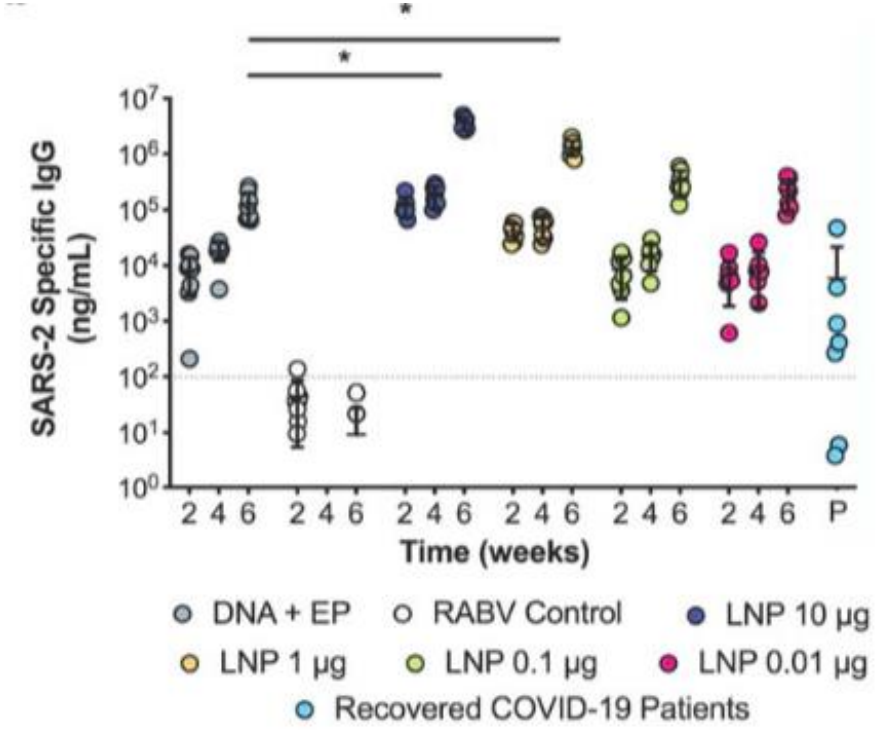
Nature Communications **11**, Article number: 3523 (2020) | Cite this article

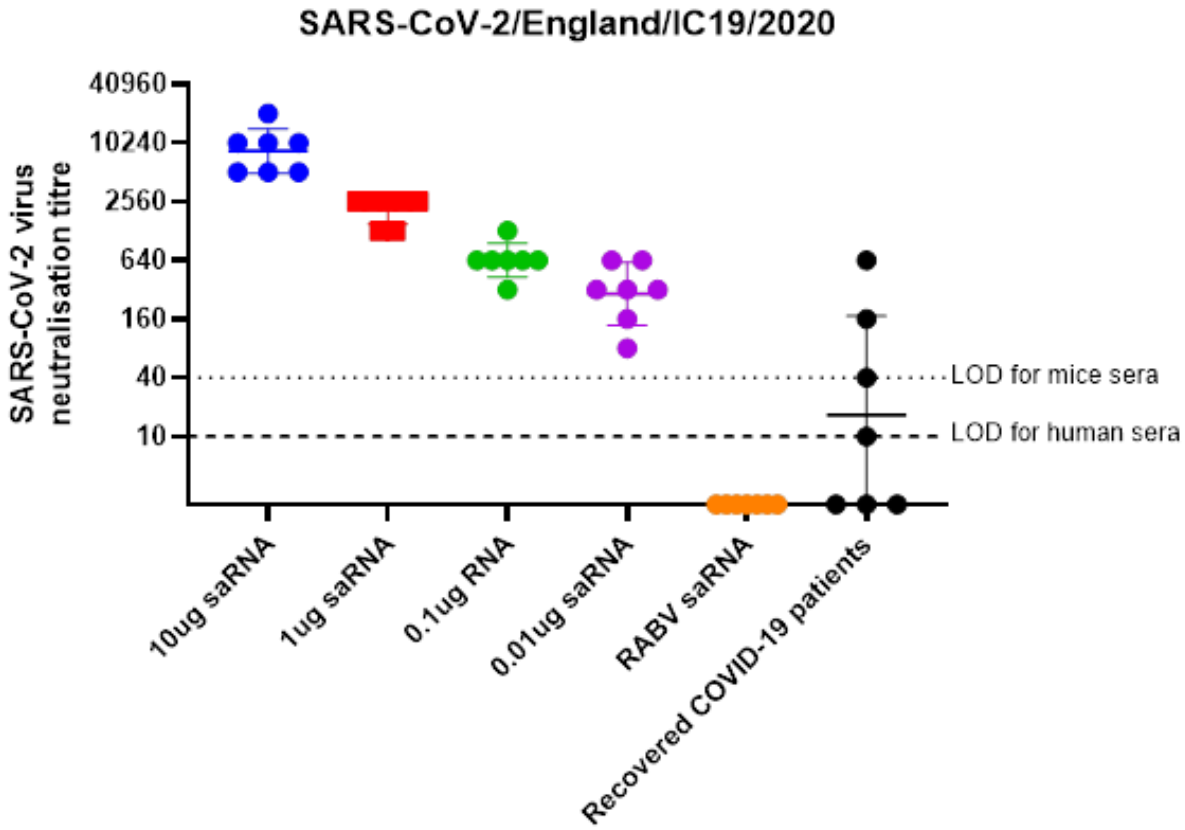
6228 Accesses | **618** Altmetric | Metrics

Immunology

Preclinical murine studies (available in *Nature Communications*)

Headline message – induced binding antibody and neutralization titers significantly greater than those in recovered COVID-19 patients





Accelerated Preclinical Timeline

Condensed the preclinical discovery process from years to months

PRECLINICAL PHASE

Toxicology

Repeat dose GLP toxicology study (classic N+1 design and with 10x human dose) completed. MHRA supported.

No findings of any concern "*Based on the absence of any adverse findings and under the conditions of this study, the no observed adverse effect level (NOAEL) is 10 ug/dose.*"

Supported by FVMR Hub

Accelerated Clinical Timeline

VacEquity Global Health

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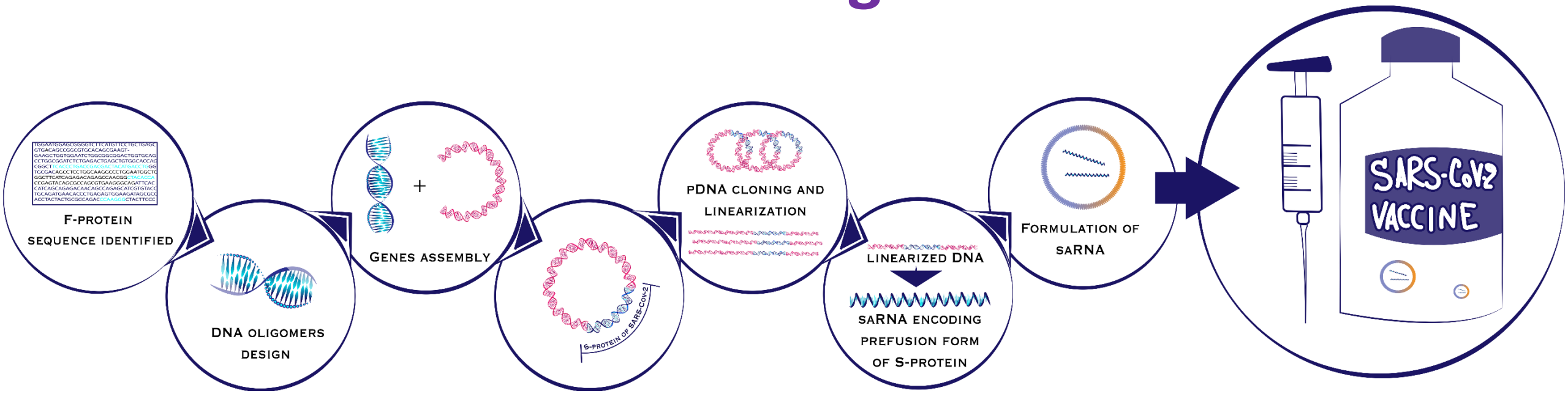
Manufacturing scheme



Potential distributed manufacturing model to accelerate access

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Thank you for your attention

This research is funded by the Department of Health and Social Care using UK Aid funding and is managed by the Engineering and Physical Sciences Research Council (EPSRC, grant number: EP/R013764/1). The views expressed in this presentation are those of the author(s) and not necessarily those of the Department of Health and Social Care.

Contact: FVMR Hub Operations Manager, Dr Ben Pierce at b.pierce@imperial.ac.uk