Open-access Adjuvants
a Key Enabling Technology for Global Health Vaccines

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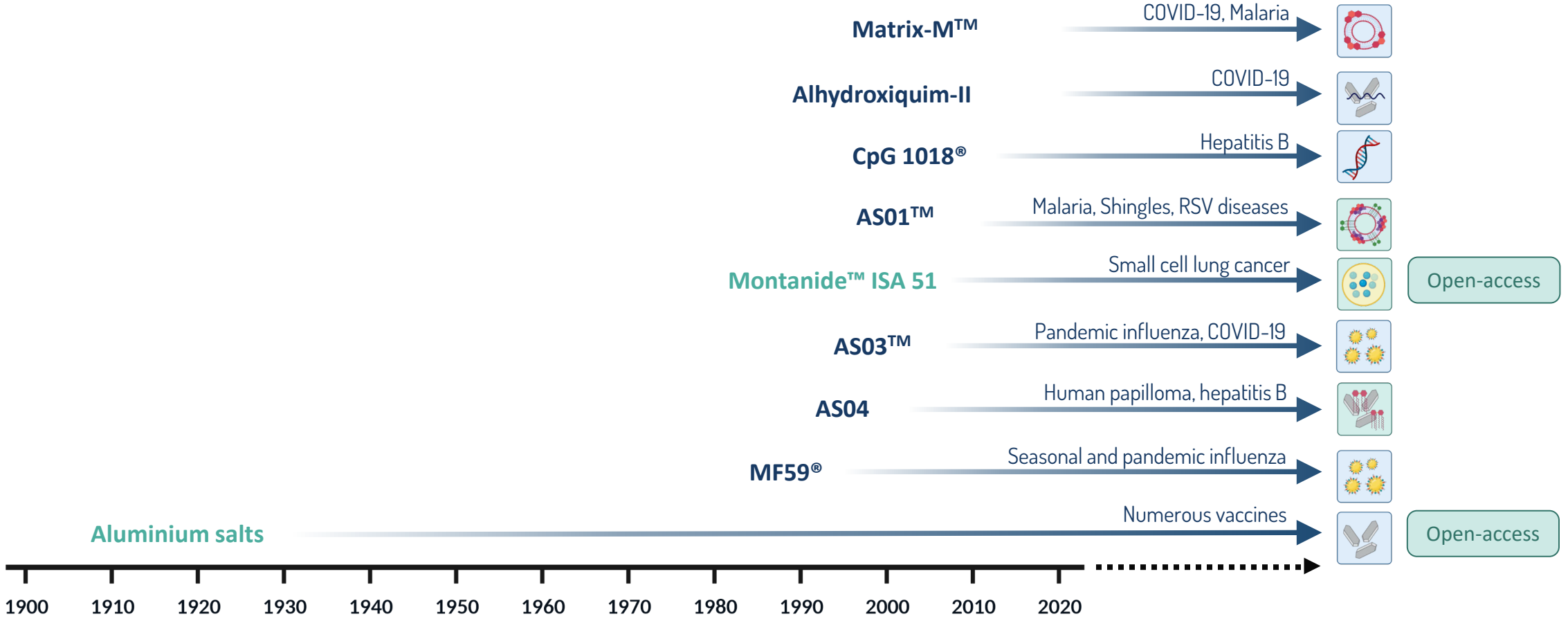
WHO - PDVAC meeting 7th October 2025

Adjuvants in approved human vaccines



Adjuvants for Global Health

Attributes of an ideal adjuvant to unlock development of Global Health vaccines

1. **Fit-for-purpose**: induces relevant immune responses to ensure protective efficacy and acceptable safety
2. **GMP grade:** for clinical development and post-licensure
3. **Sustainable:** guaranteed supply from early clinical development to post-licensure
4. **Available** at industrial-scale: process compatible with annual capacity of several hundred million doses
5. **Accessible:** business model ensuring equitable access globally
6. **Affordable:** adjuvant cost compatible with use in vaccines for Low and Middle-Income Countries

The Vaccine Formulation Institute (VFI)

VFI

- **Created in 2012 in Switzerland**
  - Established with the support of the World Health Organization
  - Company registered in Geneva, Switzerland
  - Global Center of Expertise on adjuvants and vaccine formulation
- **Mission**
  - Develop clinically-relevant **adjuvants** for provision under **open-access** terms
  - Disseminate **formulation know-how** and **support** vaccine developers
- **Current funders**
  - EC, Swiss government, Gates Foundation, Open Philanthropy, NIH/NIAID
- **Team and facilities**
  - 30 staff including chemists, formulation scientists, immunologists, project managers and experts supporting use of adjuvants in clinical development
  - Laboratories at two sites: Lausanne and Geneva (Switzerland)

www.vaccineformulationinstitute.org

VFI adjuvant portfolio: SWE

SWE

Open access

Sepivac SWE™

SEPPIC

Commercial

Clinical Trials - publicly disclosed	Phase	Disease	Protocol
1. Clinical Trial of COVAC-2 in Healthy Adults	1	COVID-19	NCT04702178
2. Clinical Trial of COVAC-2 in Adults	2	COVID-19	NCT05209009
3. Clinical Trial to Study the COVAC-2 Booster Dose in Generally Healthy Adults	1	COVID-19	NCT05226702
4. Clinical Trial of CORAVAX in Adults	1	COVID-19	BIO/CT/21/000079
5. Safety and Immunogenicity of Glycovax-002 Vaccine in Healthy Adults	1	COVID-19	NCT05799651
6. Study to Test the Safety of MYNFLU001 Influenza Vaccine in Healthy Adults	1	Influenza	ACTRN12623000925640

Clinical Trials - undisclosed
3x phase 1/2 Clinical Trials
2x phase 2 Clinical Trials
1x phase 3 Clinical Trial

Additional clinical development studies

- Several clinical projects under IND approval
- Numerous R&D projects on track for clinical development in 2026/2027

Sepivac SWE™: a key enabling technology for Global Health vaccines

SWE

50 mL

1 L

10 L

- ✓ **GMP grade**
- ✓ **Industrial scale** (several hundred million doses / year)
- ✓ Promotes **robust antibody responses**
- ✓ Compatible with **various antigens and vaccine types**
- ✓ **Dose-sparing**
- ✓ **Stable** for several years at 5°C
- ✓ Compatible with **one-vial** formulations
- ✓ **Open-access** (no licensing agreement required)

VFI adjuvant portfolio

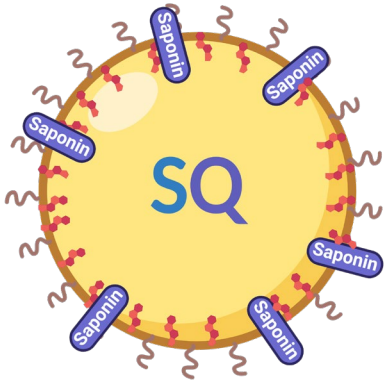
Saponins

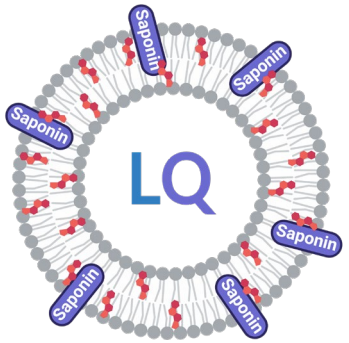
Open access

Sepivac SWE™

SEPPIC

Open access





Cholesterol

DOPC

Saponin QS21 saponin

Synthetic TLR4 agonist

BARDA

European Commission

European Commission

Gates Foundation

Open Philanthropy

NIH National Institute of Allergy and Infectious Diseases

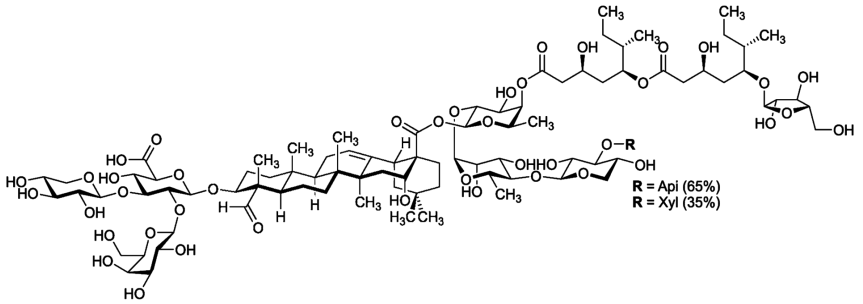
The QS21 saponin

Quillaja saponaria Molina

extraction

purification

QS-21 saponin



Saponins

Strong immunostimulant that enhances cellular (and humoral) immune responses

Key asset in the development of Global Health vaccines

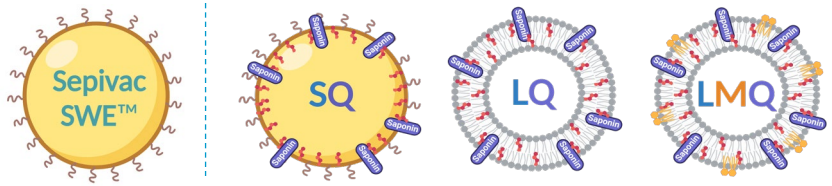
Accessibility, affordability and sustainability of saponin-based adjuvants is critical

A new cost-effective QS21 saponin for adjuvanted vaccine development

- **GMP-grade adjuvants:** a portfolio of efficient and cost-effective liposome and emulsion adjuvants based on QS-21_{DV} and available from VFI
- **Accessibility:** an open-access business model ensuring equitable access globally
- **Cost-effectiveness:** QS-21_{DV} is produced following an optimized purification process significantly reducing production costs
- **Sustainability:** QS-21_{DV} arises from a reliable production model rooted in the responsible management of native *Quillaja* trees, backed by FSC®-certified traceability, contributing to forest conservation

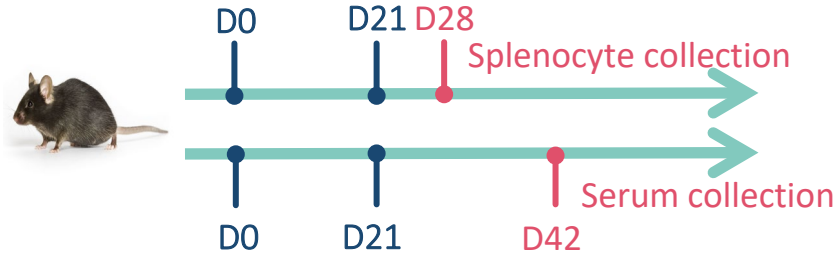
Saponins

QS21 saponin promotes T-cell (and antibody) responses

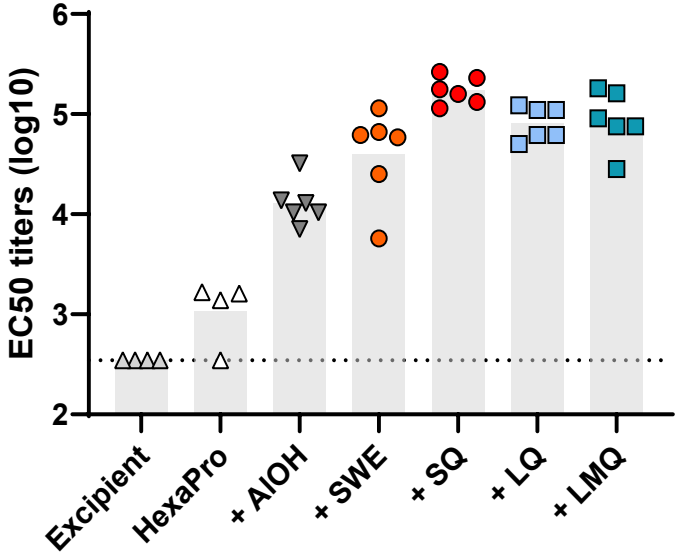


COVID-19

2 µg COVID-19 spike antigen (HexaPro) in 50 µL IM in mice

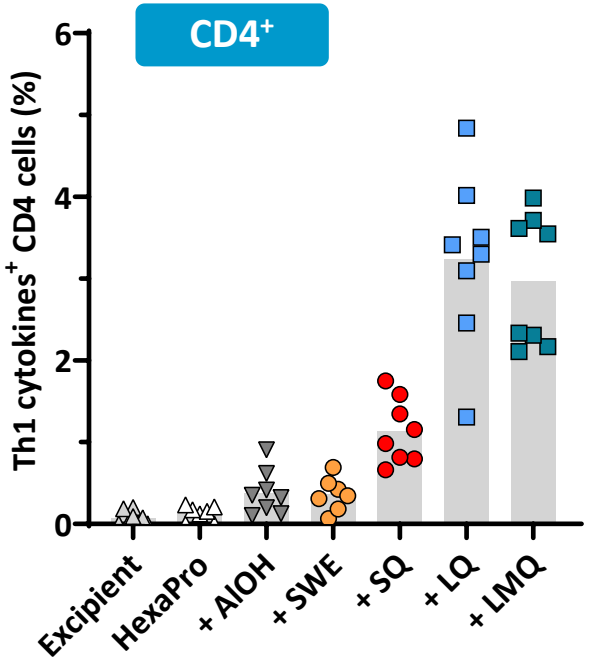


Surrogate Virus Neutralization Titers

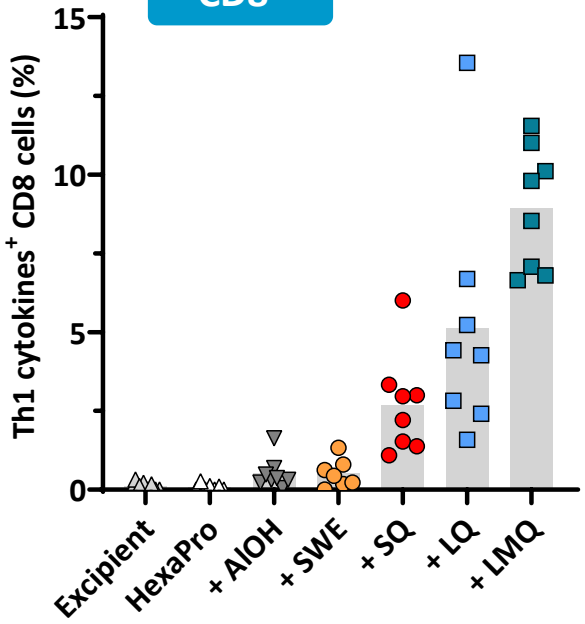


Antigen specific T-cells expressing IFN-γ and/or IL-2

CD4⁺

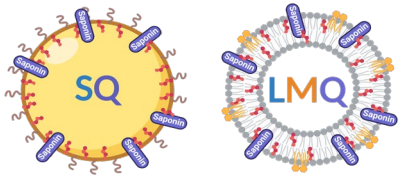


CD8⁺

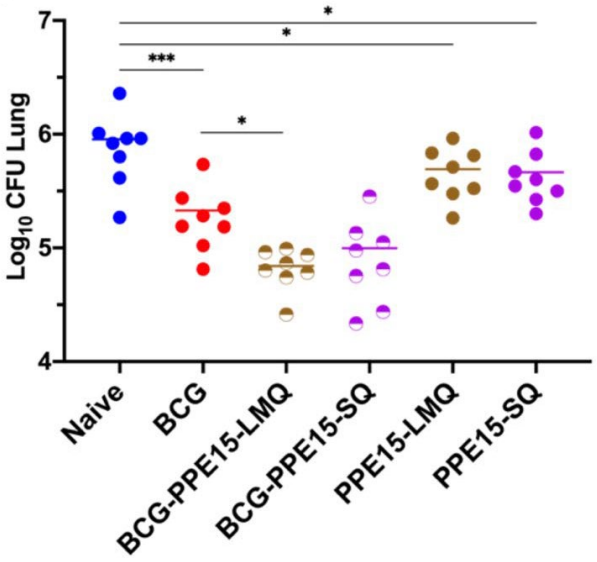


Saponins

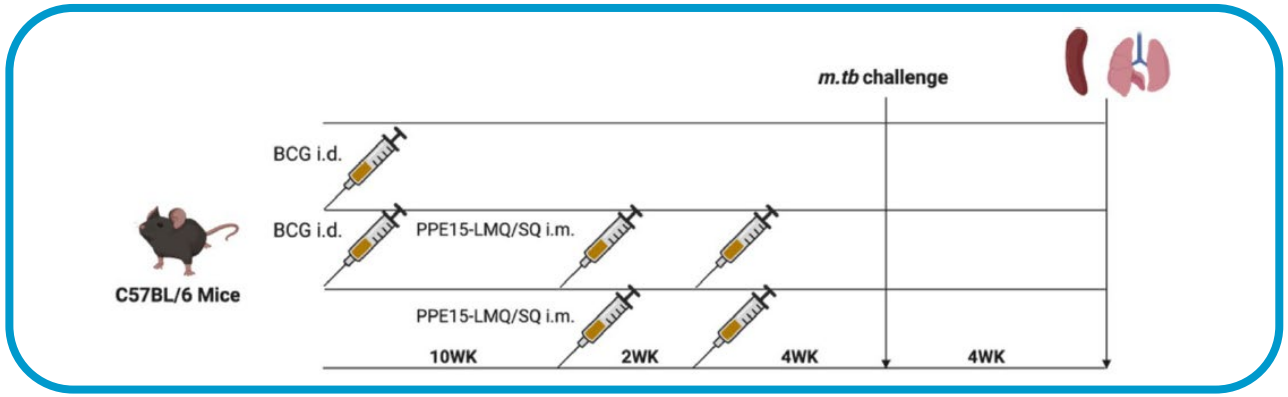
Protective efficacy in Tuberculosis mouse model

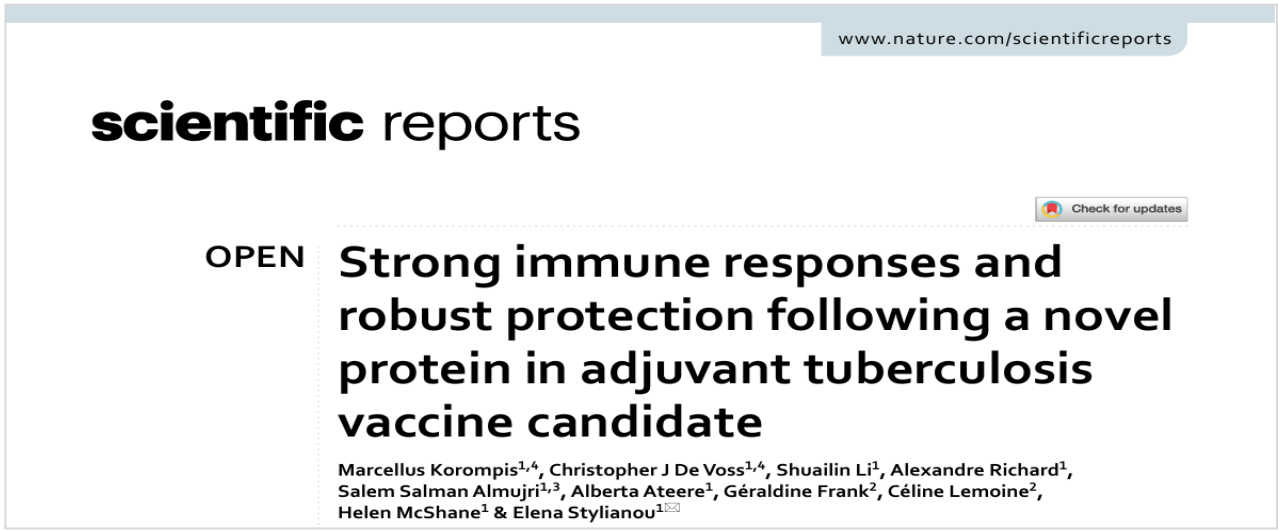


Saponins



Better protection
against *m. tb* challenge
for **LMQ** and **SQ**





www.nature.com/scientificreports

scientific reports

Check for updates

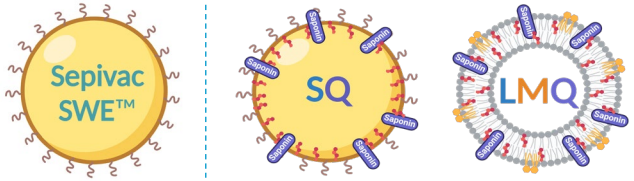
OPEN

Strong immune responses and robust protection following a novel protein in adjuvant tuberculosis vaccine candidate

Marcellus Korompis[1,4], Christopher J De Voss[1,4], Shuailin Li[1], Alexandre Richard[1], Salem Salman Almujri[1,3], Alberta Ateere[1], Géraldine Frank[2], Céline Lemoine[2], Helen McShane[1] & Elena Stylianou[1]✉

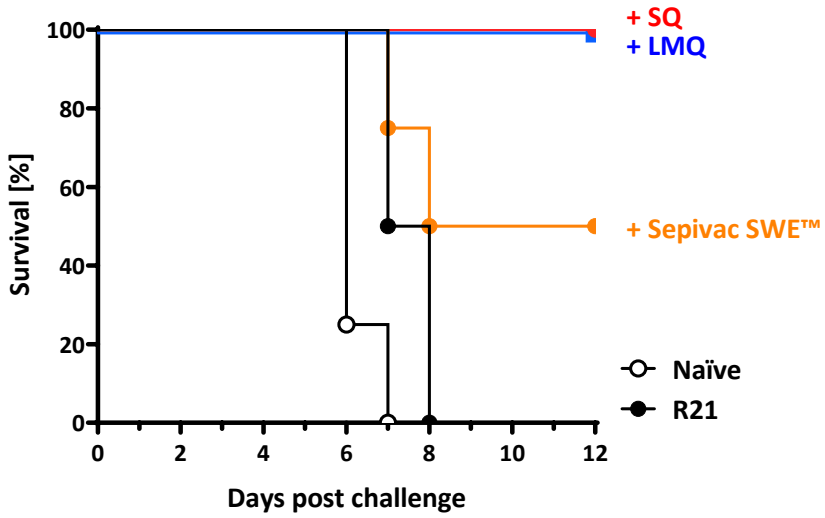
Collaboration with Helen McShane (University of Oxford)

Protective efficacy in Malaria mouse model



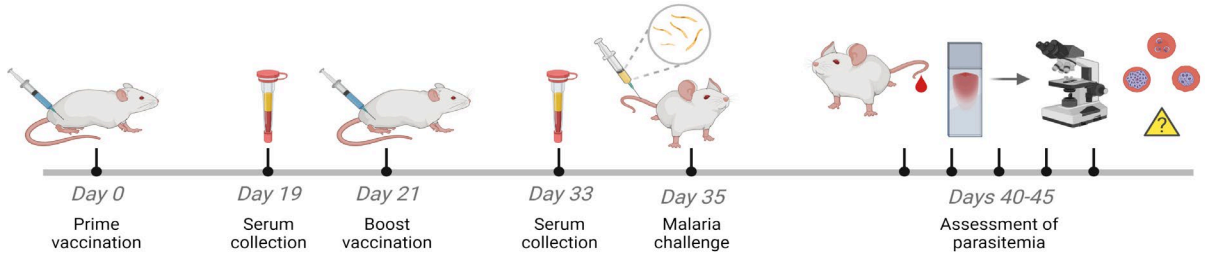
Saponins

R21-VLP (1 µg/dose)
Plasmodium sporozoite challenge
in BALB/c mice



Full protection
against challenge
for **LMQ** and **SQ**

P. berghei expressing *P. falciparum* CSP



Cell Reports Medicine

CellPress
OPEN ACCESS

Report

Emulsion and liposome-based adjuvanted R21 vaccine formulations mediate protection against malaria through distinct immune mechanisms

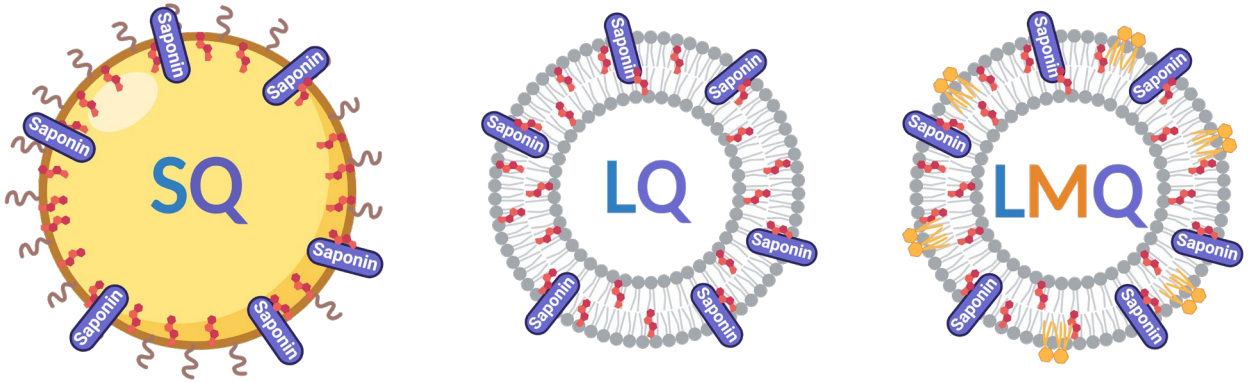
Sören Reinke,[1,4] Eirini Pantazi,[2,4] Gabrielle R. Chappell,[2] Alexandra Sanchez-Martinez,[1] Romain Guyon,[1] Joannah R. Fergusson,[1] Ahmed M. Salman,[1] Anjum Aktar,[2] Ekta Mukhopadhyay,[1] Roland A. Ventura,[3] Floriane Auderset,[3] Patrice M. Dubois,[3] Nicolas Collin,[3] Adrian V.S. Hill,[1] Jelena S. Bezbradica,[2,5,6,*] and Anita Milicic[1,5,6,7,*]

Collaboration with Anita Milicic (University of Oxford)

VFI saponin-containing adjuvants: status and next steps

Saponins

Open access

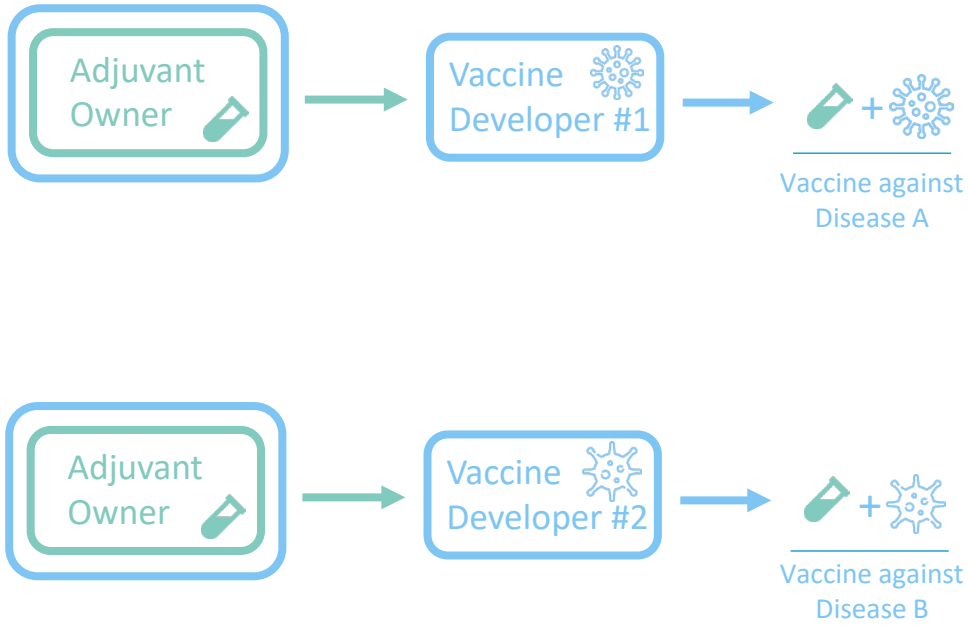


GMP material available

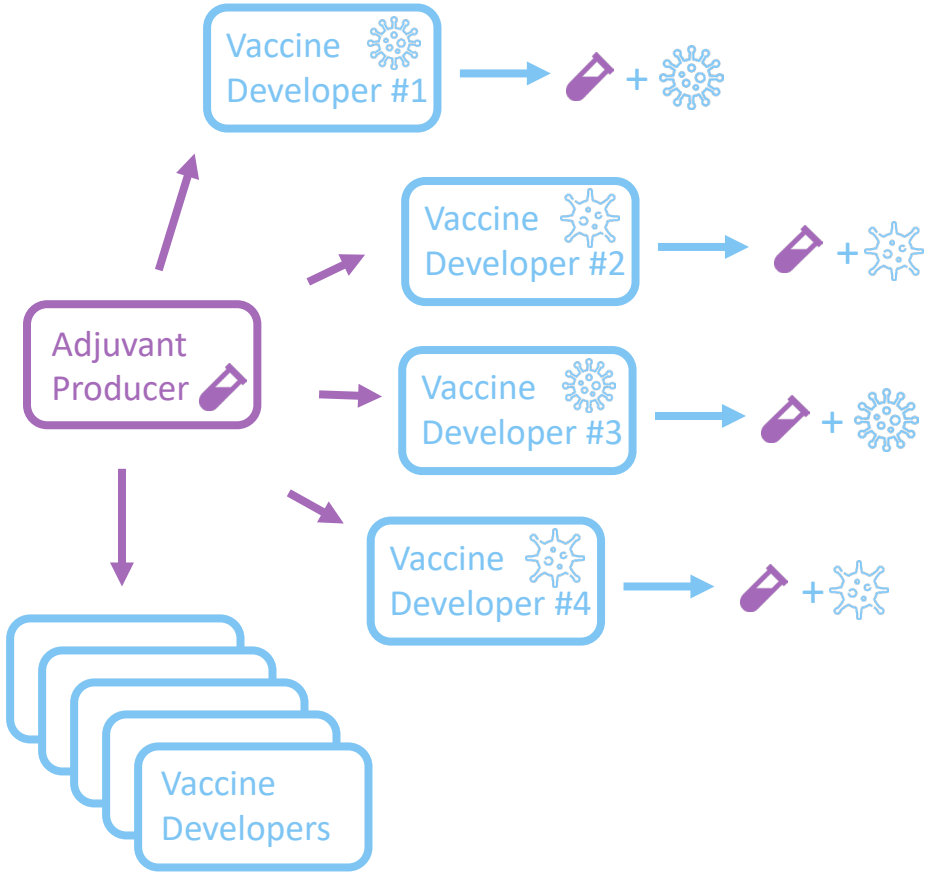
Phase 1 studies planned for 2026

Outlicensing and open-access model for adjuvants

Classical outlicensing model



Open-access model



Conclusion

VFI adjuvants for Global Health vaccines

- Head-to-head comparisons to select adjuvant ensuring protective efficacy and acceptable safety profile
- SWE, SQ, LQ and LMQ available at GMP grade
- Supply guaranteed from clinical development to post-licensure
- Manufacturing process compatible with industry scale (several hundred million doses / year)
- Business model ensuring equitable access globally
- Cost compatible with use in vaccines for LMICs

Fit for purpose

GMP grade

Sustainable

Available

Accessible

Affordable

Conclusion

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INSTITUTE

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