Afrigen
Biologics & Vaccines
An Avacare Health & IDC Company

Update on STI Vaccine Development at Afrigen Biologics and Vaccines

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Introduction to Afrigen Biologics (Pty) Ltd.:

Mission:

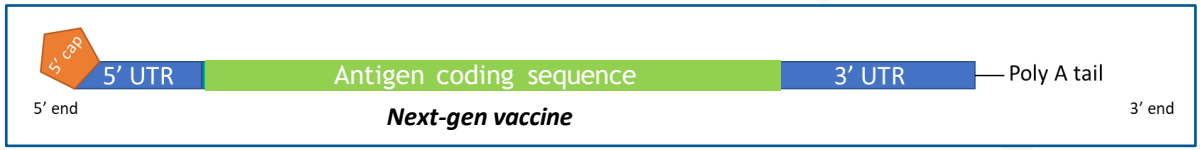
- Afrigen's mission is to **develop and manufacture priority vaccines and biologics in Africa**, focusing on cutting-edge mRNA technologies.

- It aims to **empower local scientific and production capabilities**, reducing reliance on international suppliers and ensuring that Africa is equipped to meet its own health needs.

Vision:

- Afrigen strives to **make Africa a global leader in mRNA vaccine innovation** and manufacturing, increasing access to critical vaccines for high-burden diseases impacting LMICs by fostering a sustainable biotechnology ecosystem.

mRNA Technology Platform : End-to- End Vaccine Manufacturing



- First fully African developed mRNA vaccine
- Afrivac 2121 - a novel SARS-CoV2 mRNA vaccine

Next-Gen Product

CLINICAL DEVELOPMENT

Antigen selection or design → mRNA cassette design → Plasmid design & cloning → Plasmid production → mRNA synthesis via IVT & capping → Purification of mRNA → Formulation in lipid nanoparticle → Fill-Finish into vials

Existing antigens, access need for novel antigens

Cell-based: E.coli platform | Cell-free (enzymatic) synthesis | Encapsulation technology | Liquid dosage form

Pre-clinical development

RNA construct improvement | Modified nucleotides | Formulations & Novel lipids

Pre-clinical safety testing

CRADAs

STI Vaccine Pipeline

- **HIV (Platform applicability)**
- **HPV (contextual relevance)**
- **Gonorrhoea (preclinical to clinical focus)**

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WHO and MPP mRNA Technology Transfer Programme

Africa at its Center:

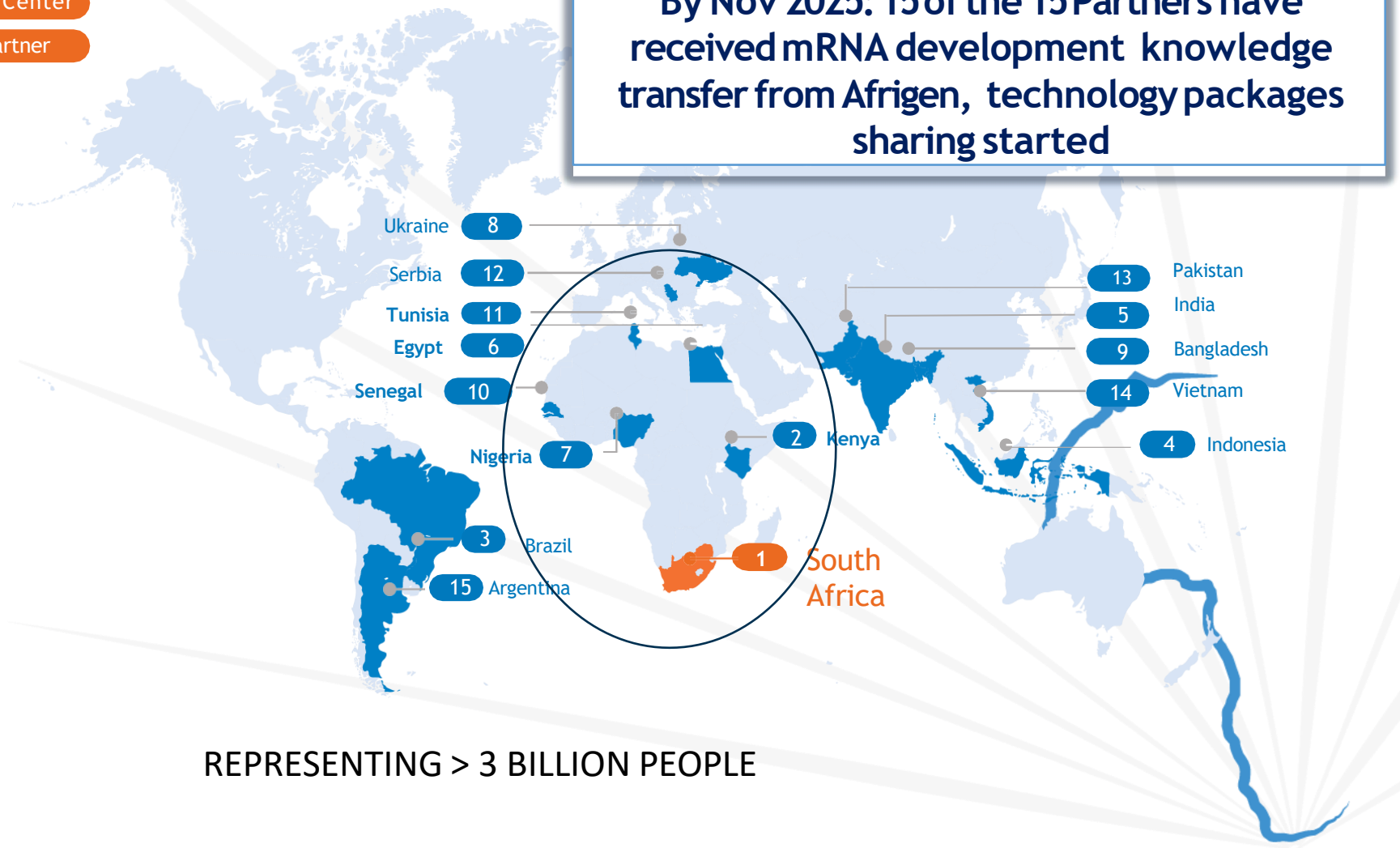
Building Sustainable Capacity and Capabilities

A LMIC partnership network straddling 4 continents and connecting 15 countries

1	Afrigen	mRNA Center
	Biovac	1st partner
2	BioVax Kenya	
3	Bio-Manguinhos	
4	Biofarma	
5	BiologicalE	
6	BioGeneric Pharma	
7	Biovaccines Nigeria	
8	Darnitsa	
9	Incepta Vaccine	
10	Institut Pasteur de Dakar	
11	Institut Pasteur de Tunis	
12	Institut Torlak	
13	National Institute of Health,	
14	Polyvac	
15	Sinergium Biotech	

pending complete

By Nov 2025: 15 of the 15 Partners have received mRNA development knowledge transfer from Afrigen, technology packages sharing started



REPRESENTING > 3 BILLION PEOPLE

Afrigen's Product Pipeline enabled by multi-product mRNA platform

Driven by funding, Optimizing the Platform, Building Capabilities Supported by a Wide Base of Collaborators and Funders

Target	Stage	Partners/Collaborators	Funding source
SARS CoV-2	Preclinical toxicology complete – IND ready	Marseille Univ, PCDDP-North-West Univ	WHO/MPP
RSV	Sequence & Formulation down-selection	Univ Cape Town, UPenn, NIH, Yale, ForgeBio	MPP (Canadian gov.), SAVax-GIZ
RVF	Antigen Optimisation	IVI, Yale	ELMA, CEPI, SAMRC
Gonorrhoea	Formulation selected, functional activity confirmed	Evaxion, Yale, UMass	MPP (Canadian gov.), BactiVac
MPox	Antigen Optimisation	Epivax, Univ Cape Town	SAVax-GIZ, SAMRC
TB	Antigen Optimisation	Univ Cape Town, Univ Witswatetsrand, Standford Univ	SAMRC, MPP

Excluding collaboration driven by Sinergium on H5N1

Sinergium Biotech

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mRNA Technology Transfer Programme

Lessons Learned: End-to- End Vaccine Development

Challenge	Solution
Biomanufacturing Ecosystem Development	**Regional & Global Partnerships:** Collaborate with partners to establish a stable supply chain for raw materials, active ingredients, excipients, and consumables.
Access to Finance	**Partnerships & Grants:** Secure funding for technology and infrastructure through partnerships with international organizations (e.g., WHO, CEPI, IVI, RIGHT Fund).
Regulatory Strengthening	**Collaboration with National Regulatory Authorities:** Work with agencies (e.g., SAHPRA) to support ecosystem growth and regulatory alignment.
Collaborative Research	**University & Research Institute Partnerships:** Strengthen Africa's vaccine R&D pipeline through academic and research collaborations.
Biomanufacturing Workforce Development	**Specialized Training Programs:** Train scientists and technicians in mRNA technology, GMP standards, and biomanufacturing skills.

What is the Project Significance?:

- Curable infection with antibiotics but the rise in **antimicrobial resistance** compromises prevention and control.

- **No licenced vaccine** – some in preclinical/clinical development
  - Current development: meningococcal and gonococcal OMV vaccines, a lipo-oligosaccharide epitope and purified protein subunit vaccines.

- Gonorrhoea has been **identified by the WHO Global Health Sector Strategy** on STIs as one of three STIs needing immediate action for control.

Clinical Pipeline

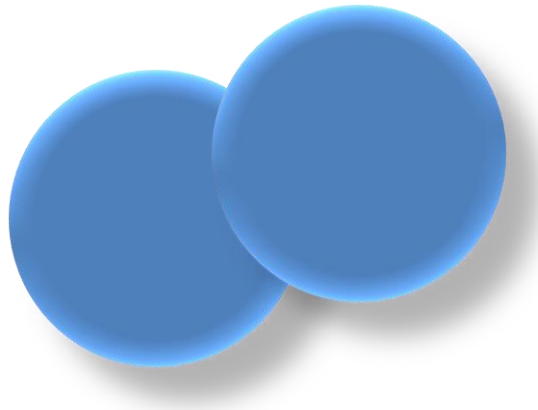
Trial Number	Phase/Type of study	Study Name	Location	Population	Status
ACTRN12619001478101	Phase 3 randomized controlled trial (RCT) efficacy, immunogenicity	MenGO: Does the licensed meningococcal vaccine Bexsero provide cross-protection against gonorrhea?	Australia	Men who have sex with men (MSM)	Results to be released
NCT04415424	Phase 3 RCT efficacy, immunogenicity	Efficacy Study of 4CMenB (Bexsero®) to Prevent Gonorrhoea Infection in Gay and Bisexual Men (GoGoVax)	Australia	MSM	Results to be released
NCT05766904	RCT efficacy	Efficacy trial on meningococcal B vaccine for preventing gonorrhea infections	Hong Kong	MSM	Completion end 2026
NCT04350138	Phase 2 RCT efficacy	Safety and efficacy study of meningococcal group B vaccine rMenB+OMV NZ (Bexsero) to prevent gonococcal infection	USA, Thailand, Malawi	Adults	Estimated completion Q4 2026
NCT06446752	Phase 3 RCT efficacy	BIYELA: Bexsero Immunisation in Young Women in Africa	South Africa	Cis-gender women	Estimated completion Q1 2027
NCT05294588	RCT efficacy in controlled human infection challenge model	Efficacy of immunization with 4CMenB in preventing experimental urethral infection with Neisseria gonorrhoeae	USA	Men	Results to be released 2027/2028
NCT05630859	Phase 1/2 RCT safety, efficacy, immunogenicity	Safety and efficacy of GSK *N. gonorrhoeae* GMMA (NgG) investigational vaccine when administered to healthy adults 18–50 years of age	Multi-country	Adults	Data collection complete, May 2025. Results not yet reported

Vaccine Development Landscape

Name	Developer	Basis	Design	Phase of Development	Clinical Trail No./Additional Info
NgG	GSK	OMV-Based	FA1090 Intramuscular	Discontinued after Phase I/II - no data released	NCT05630859
GonoVac	UOXF(Jenner)	OMV-Based	GC_0817560 Intramuscular	Phase I planned for 2026	
Avacc 11	Intravacc/TherapyX	OMV-Based	Prophylactic, intranasal NG MS11 OMV + IL-12	Completed GMP + assay qualification	
Avacc 12	Intravacc	OMV-Based	MenB OMV expressing gonococcal antigens	Preclinical Evaluation	
Unnamed	UOXF (Dunn School)	OMV-Based	FA1090 NmPorB insertion	Early pre-clinical assessment	
2C7 Mimitope	University of Massachusetts	Non-OMV	2C7 mimitope, lab-designed peptide	Preclinical	DOI: 10.1021/jacsau.4c00359
Unnamed	University of Toronto	Non-OMV	Non-binding TbpB protein	Preclinical	https://doi.org/10.1038/s41541-024-01054-0
Unnamed	LimmaTech Biologics	Non-OMV	Multi-antigenic approach w/ purified proteins	Planning Phase I + Phase 2 CHIM + field efficacy study	Supported by CARB-X
EVX-B2 mRNA	Afrigen/Evaxion	Non-OMV	mRNA - chimeric NGO1549+NGO0265	Preclinical	
Unnamed	Griffith University	Non-OMV	NHBA/MetQ fusion protein + Al(OH)3	Preclinical	

Vaccine Design Considerations

- No immunity from natural infection – How can we induce immunity?
- Rapidly mutating bacteria with strong immune evasion
- How can we assess efficacy with no correlates of protection?
- Gonorrhoea only infects humans



Evaxion- Afrigen Partnership

Early development at Evaxion – transitioning to Afrigen for clinical and commercial stages

EVAXION

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Target Discovery → Antigen Design → Vaccine Design → Preclinical Development → CMC → Early Clinical Development → Late Clinical Development

N. Gonorrhoeae

EDEN™

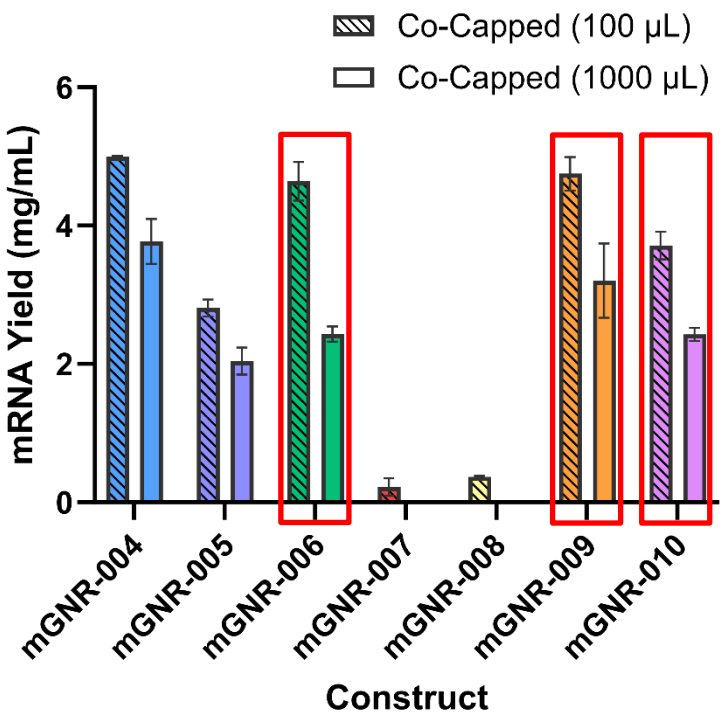
AI

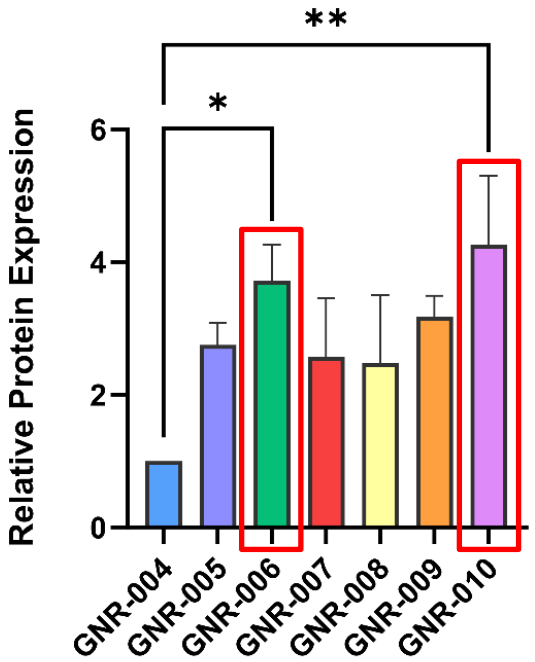
Collaborative lead development of EVX-B2 mRNA vaccine product for LMIC

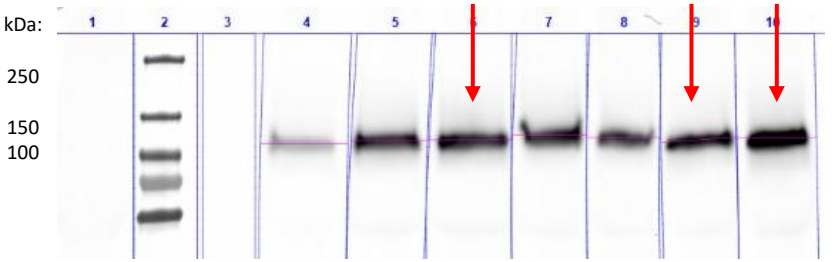
- POC mRNA
- Cassette Optimization
- Formulation
- Production

- Quality Management System (cGMP)
- Research & Development
- Manufacturing (cGMP)
- Quality Control (GMP)
- Aseptic Filling & Finishing (cGMP)

Selection of 5'UTR designs with increased EVX-B2 protein expression



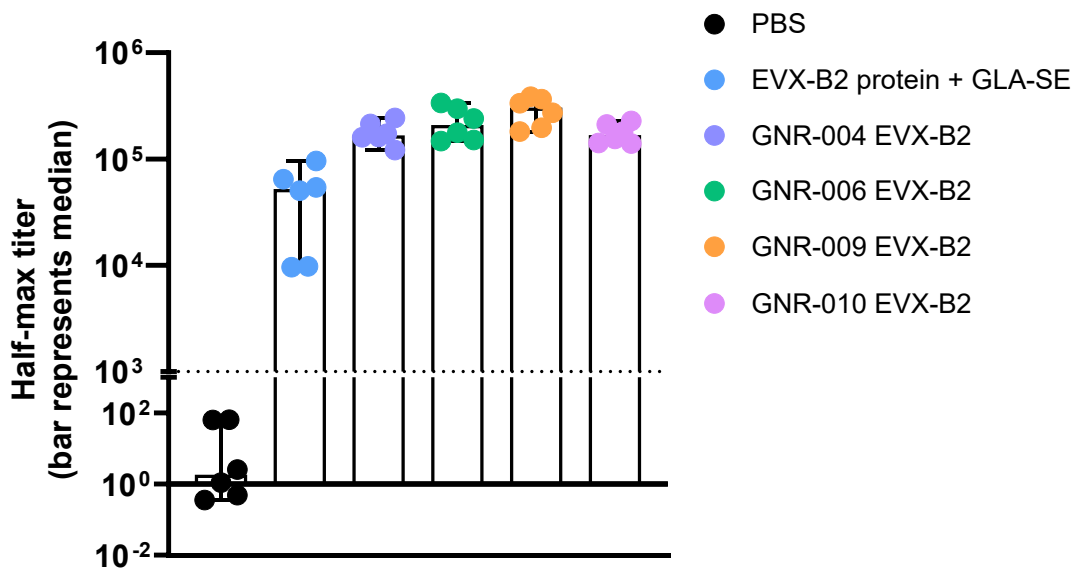




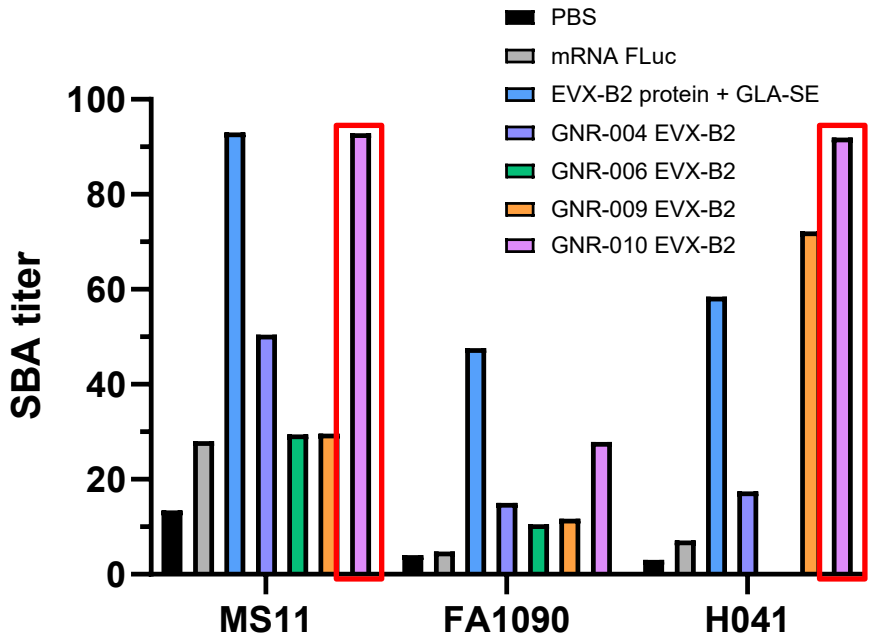
Western blot comparing the 7 different UTRs
Lane 1: Untreated, lane 2: Protein Ladder, lane 3: empty, lane 4: GNR-004, lane 5: GNR-005, lane 6: GNR-006, lane 7: GNR-007, lane 8: GNR-008, lane 9: GNR-009, lane 10: GNR-010

Immune Activity Profiles: Impact of 5' UTR Design

Serum IgG Antibody Titres



Serum Bactericidal Activity



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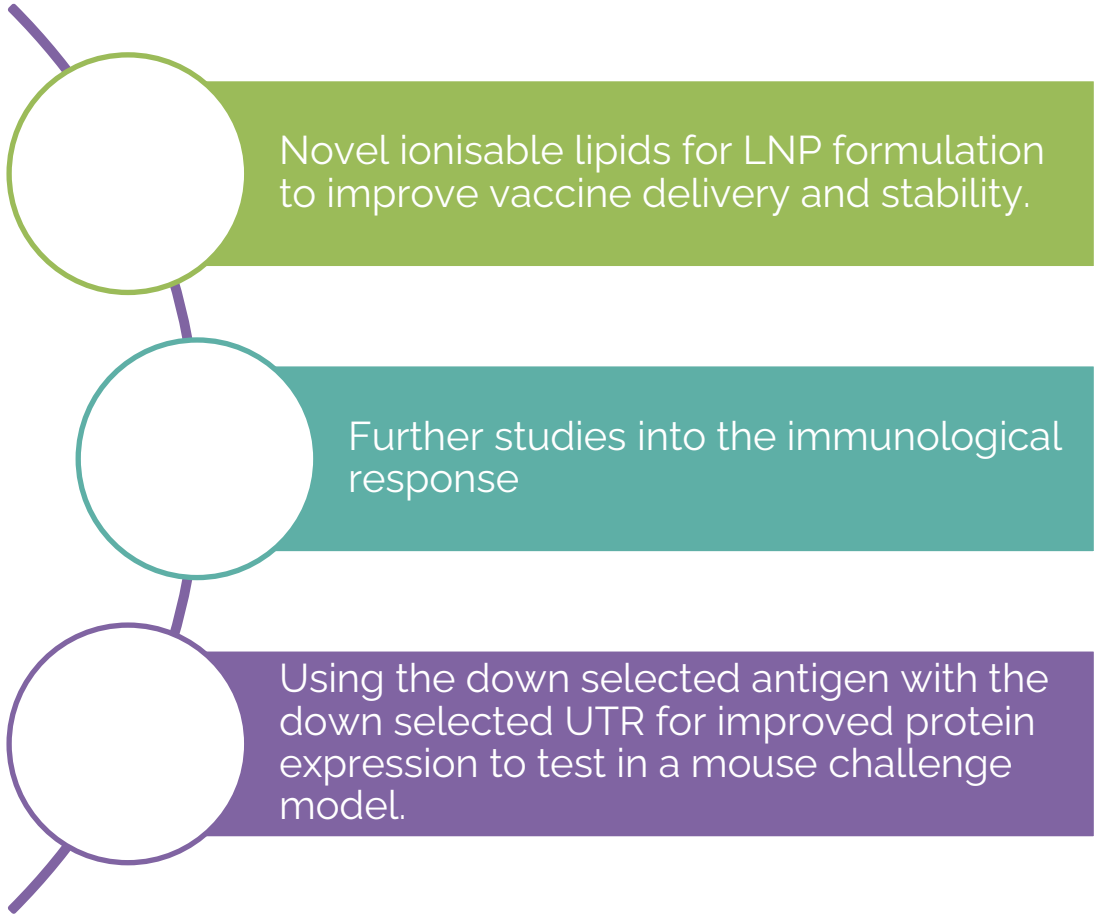
Conclusion and Next Steps

- Successful down selection of the different UTR constructs using critical quality attributes for vaccine development.
- Antibodies were able to kill multiple strains in the complement system.
- GNR-010 was then selected as the construct of choice for the program
- Up scaled using the Quantoom system



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THANK YOU

EVAXION

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MEDICAL SCHOOL

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