The mRNA Innovation Strategy at Afrigen

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mRNA 3rd Scientific Colloquium on Vaccine Access and Equity on the African Continent

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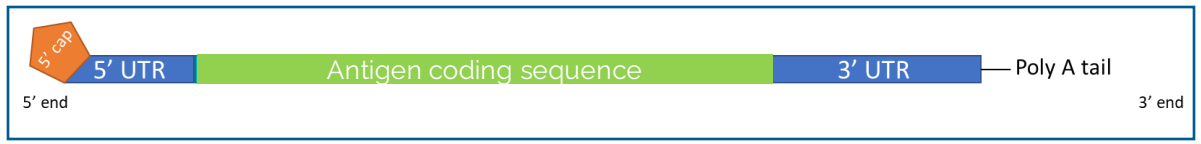
- Created with a mission to **establish local production capacity** and capabilities on the African Continent
- **Adjuvant formulation** was the first lab scale platform established in Afrigen
- **End-to-end mRNA vaccine technology development and manufacturing** capacity and capabilities established and demonstrated, preparing for GMP licensure.

Afrivac2121, a SARS-CoV2 vaccine: The backbone for a sustainable platform and future product pipeline



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

RNA construct improvement

Cell-based: E.coli platform

Cell-free (enzymatic) synthesis

Encapsulation technology

Liquid dosage form

Pre-clinical development

Analytics development

Modified nucleotides

Formulations & Novel lipids

Pre-clinical safety testing

CRADAs

Second generation products and technologies addresses:

- Potency, reactogenicity and thermostability
- Reduced cost of goods
- Freedom to operate

Ongoing research and innovation a priority (SAMVAC)

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Building end-to-end capabilities: Cost competitiveness at the heart

Quality Management System (cGMP)
- Qualified Utilities
- Material Handling
- QC Laboratories & Stability

Research & Development
- Plasmid Design & Development
- Antigen Design
- Process Development (DS + DP)

Manufacturing (cGMP)
- Master & Working Cell Banks
- Plasmid Manufacturing
- DS & Bulk DP Manufacturing

Quality Control (GMP)
- Characterization Assays
- Drug Substance Release Assays
- Drug Product Release Assays

Aseptic Filling & Finishing (cGMP)
- Sterile Filling Line
- Visual Inspection, Label & Pack
- Shipping




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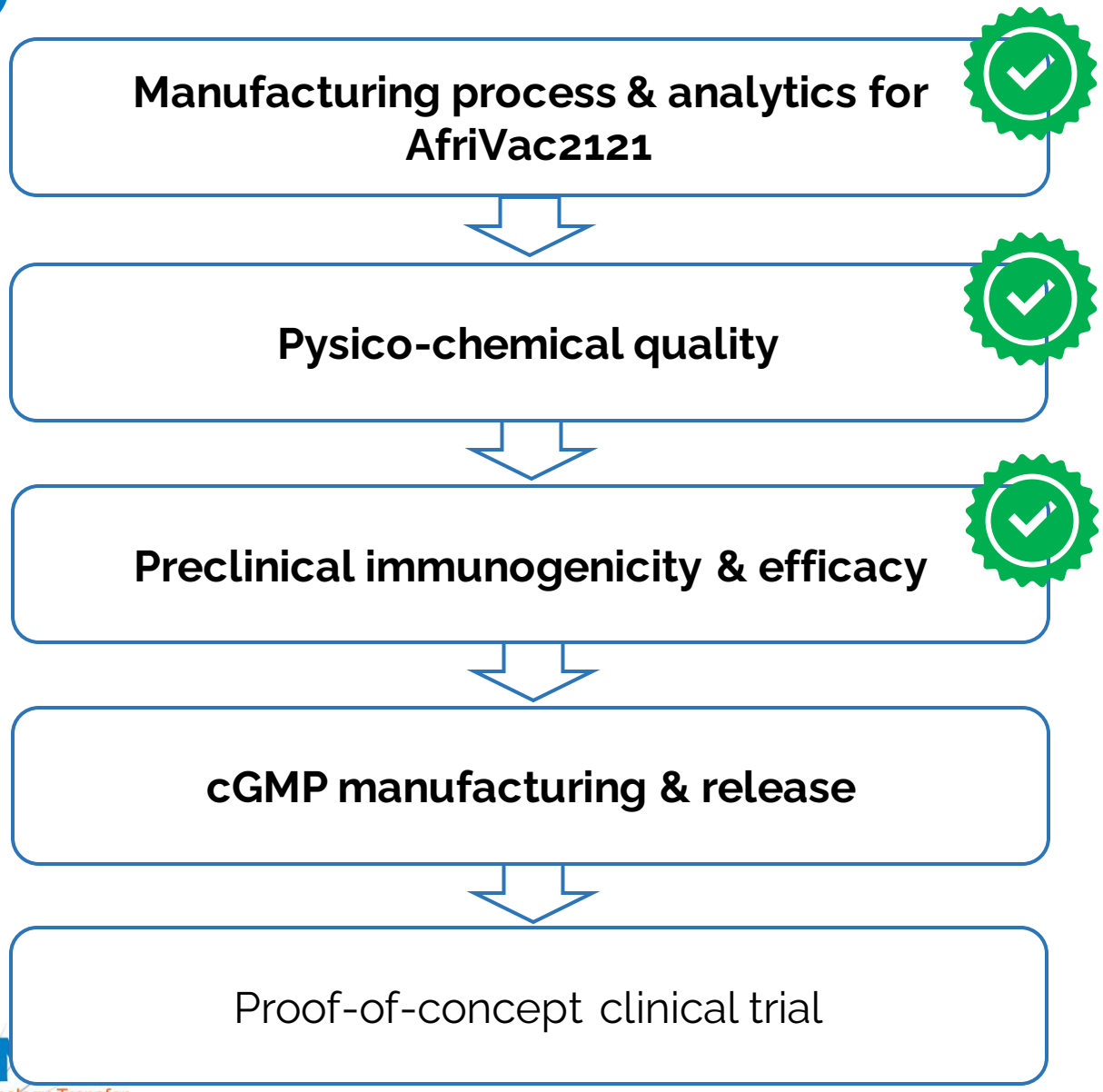
Establishing the foundation



- Development and scale-up of manufacturing process
- Development of analytics for characterisation, release and stability.
- Comparable safety, immunogenicity and protective efficacy between AfriVac 2121 and comparator
- Complete preclinical studies incl. GLP toxicology
- Development of XBB1.5 vaccine
- Ultimate validation of established mRNA technology platform

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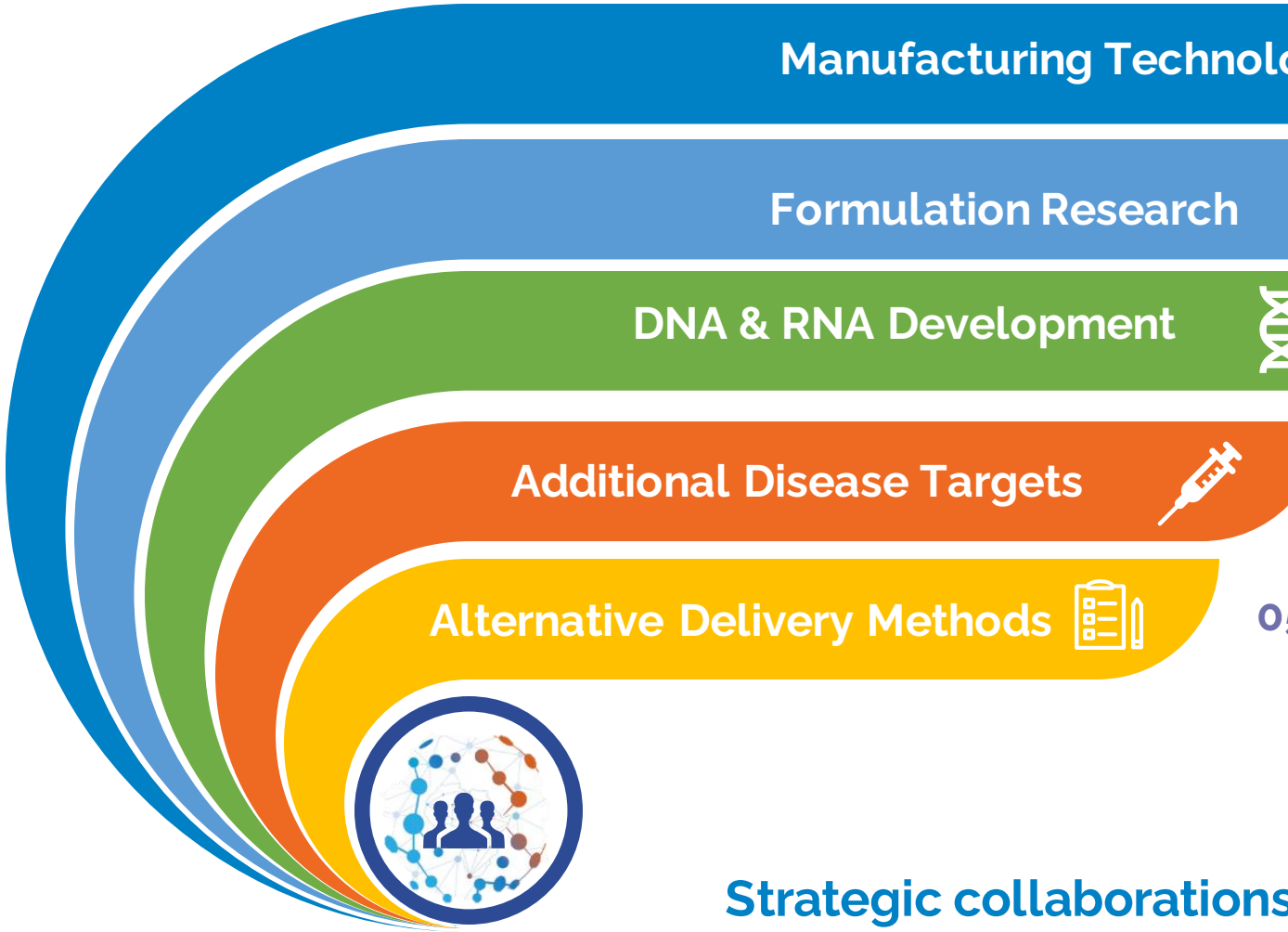
mRNA technology innovation strategy



01 These would assist in streamlining the process and looking at cost effective approaches

02 This focuses on optimizing stability, vaccine efficacy and immunogenicity

03 The sharing of expertise, access to complementary resources and accelerate progression

04 Expanding preventative measures for unmet medical needs and improving patient outcomes.

05 These methods have the capability of expanding vaccine accessibility, enhance immunization coverage and improve patient acceptance to name a few aspects

Strategic collaborations are critical to the continued building the mRNA platform

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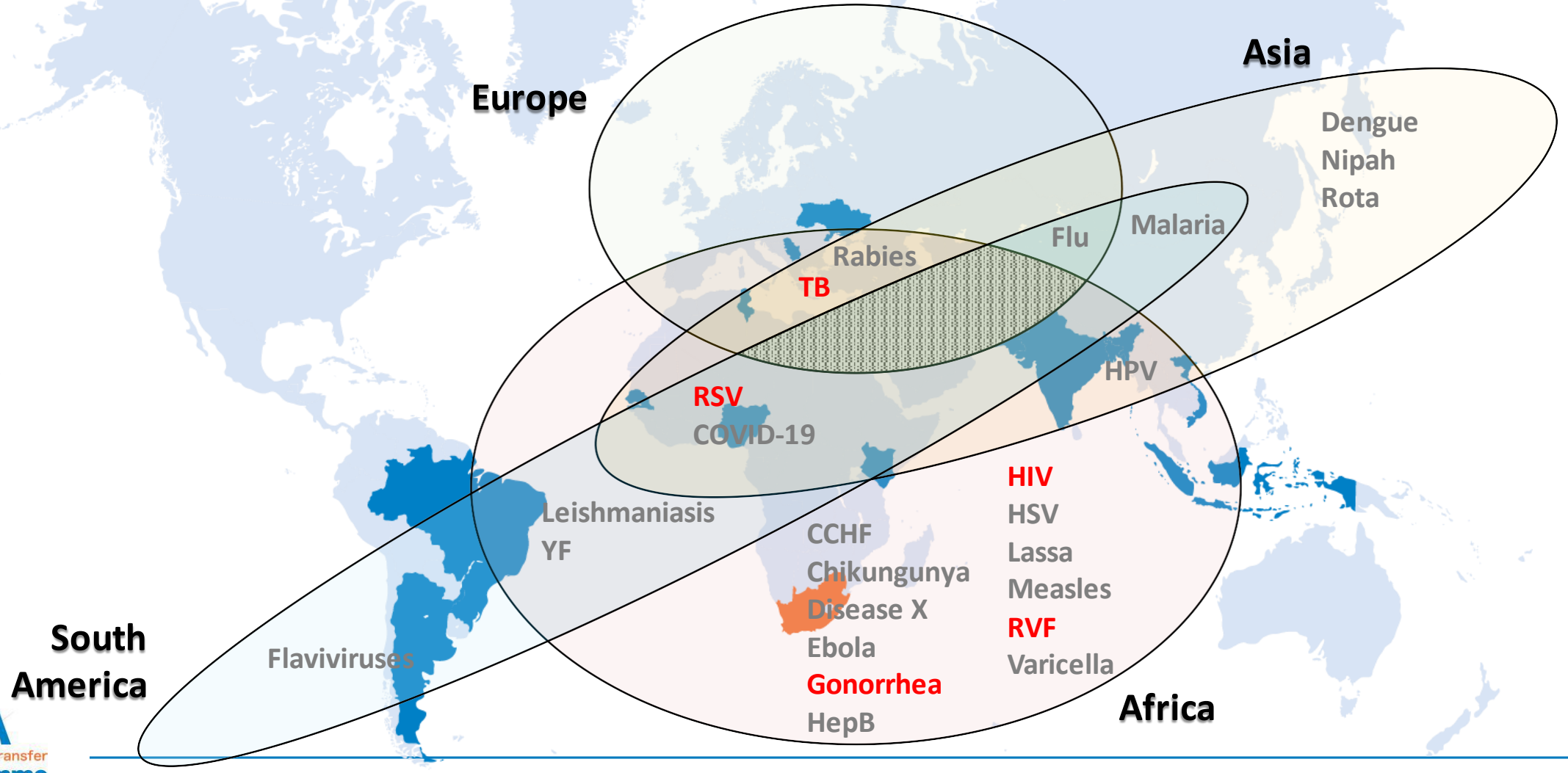
Pipeline development and partnerships for sustainability and **public health impact**



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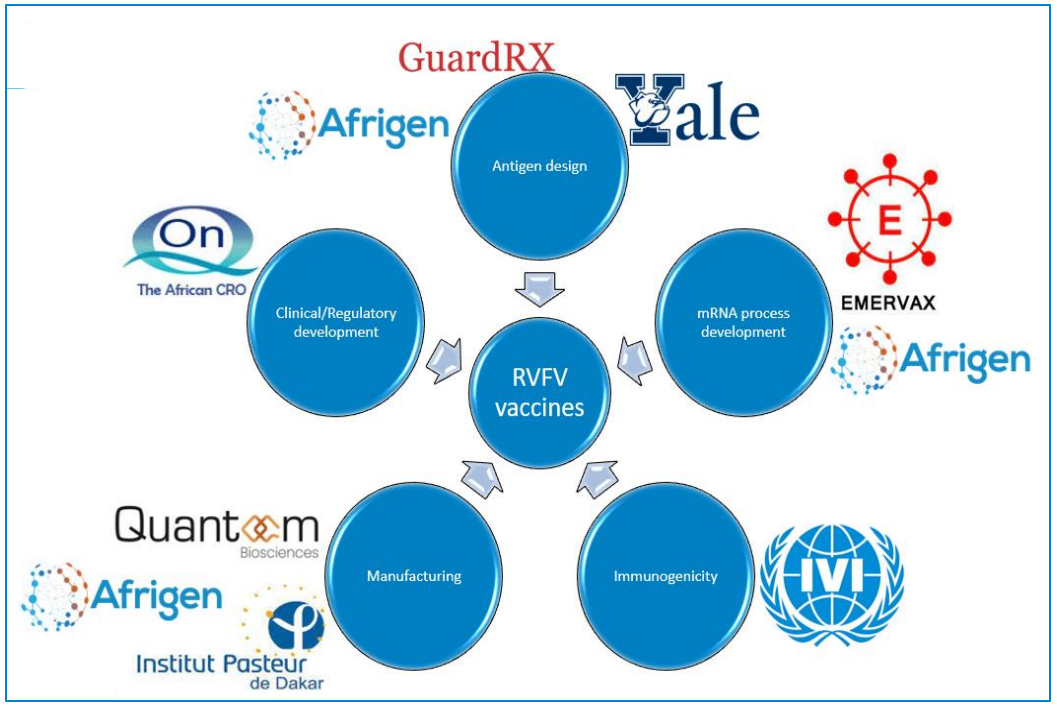
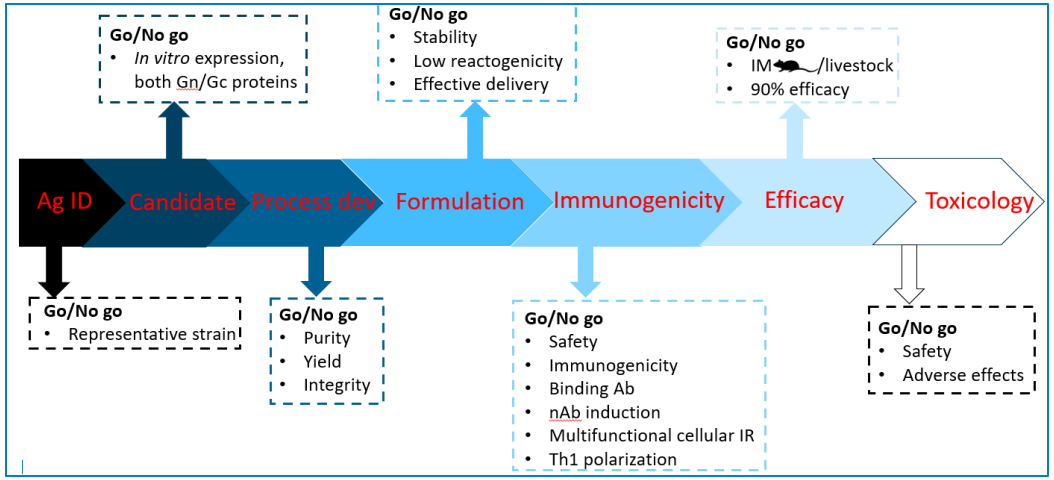
Courtesy Pierre Gsell. WHO/MPP mRNA Technology Transfer Programme Meeting. Cape Town. April 2023

Afrigen's RVFV vaccine: A wide collaboration

- Accessible cost in LMICs
- mRNA/LNP for human vaccine
- saRNA/CNE for veterinary vaccine
- Stable at 2-8°C

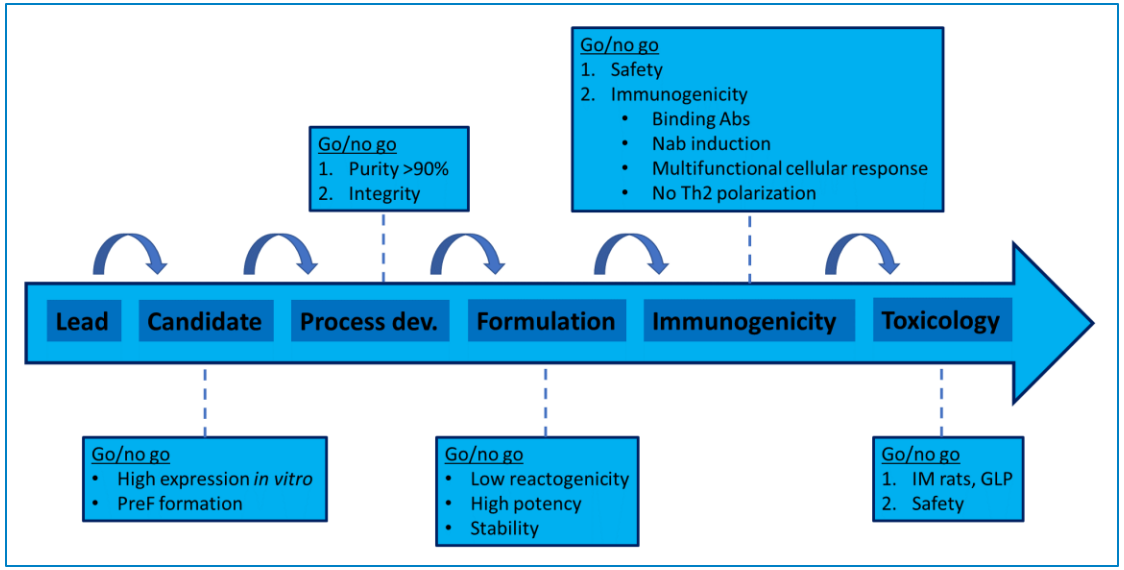


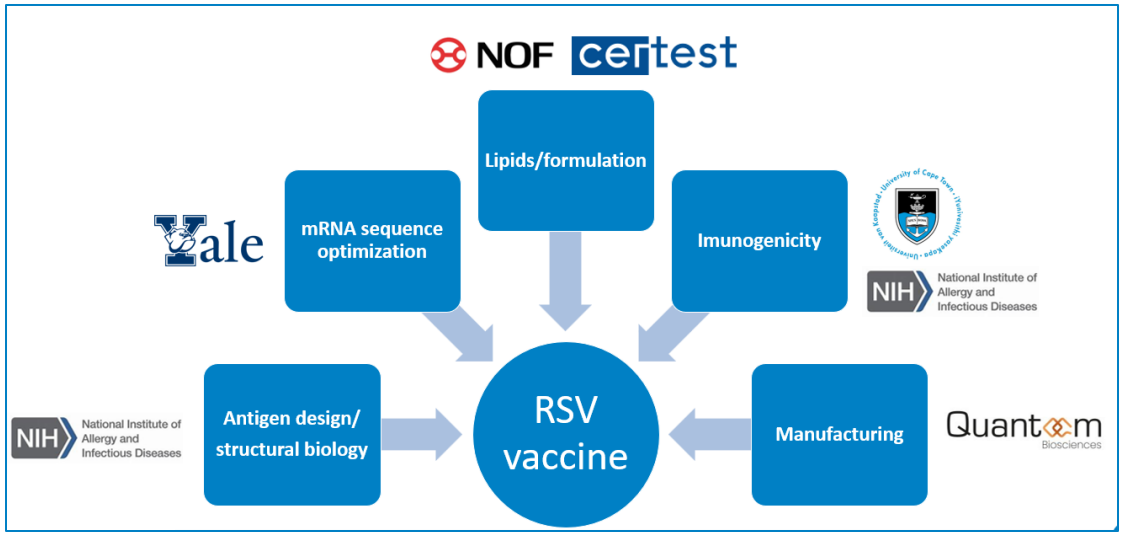


- Antigen design selected
- pDNA/mRNA sequence optimization underway

Afrigen's RSV vaccine: A wide collaboration

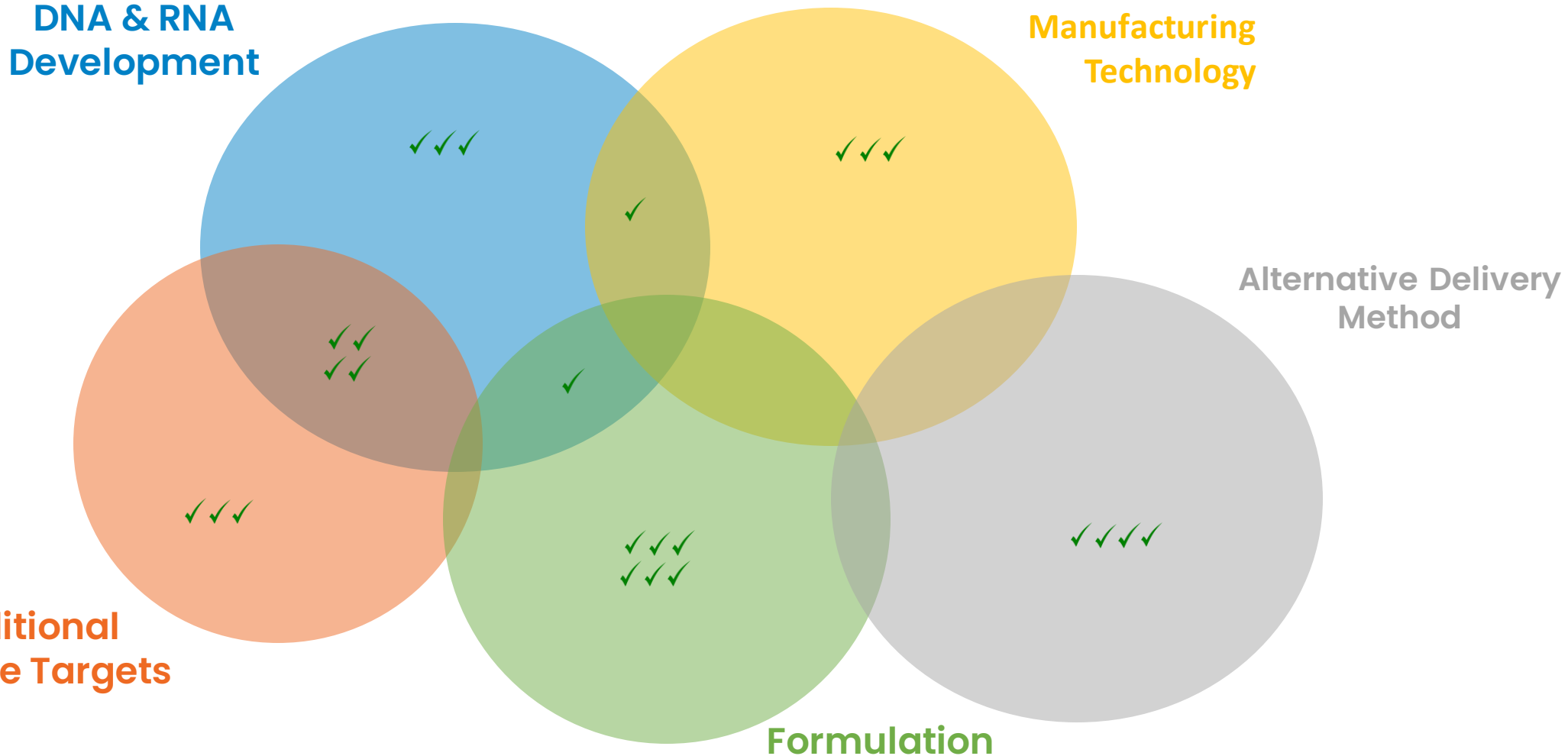
- Accessible cost in LMICs
- mRNA LNP
- Stable at 2-8˚C
- Indicated for maternal and pediatric immunization



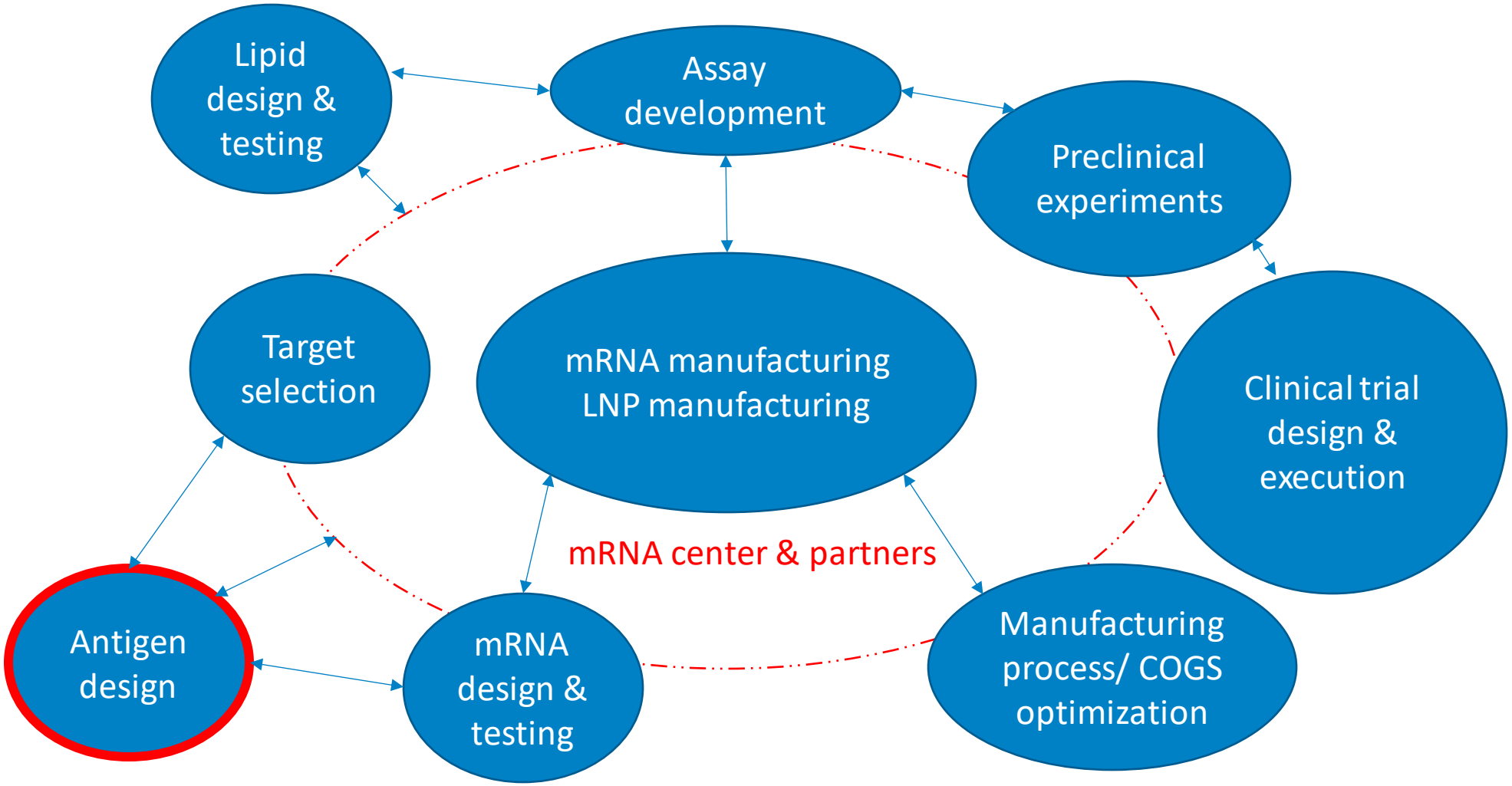


- Antigen design selected
- pDNA/mRNA sequence optimization underway
- In-vitro expression underway

Collaborations are critical to the continued building the mRNA platform



Building an end-to-end R&D and manufacturing ecosystem to leverage the power of mRNA



Summary

- **Afrigen's mRNA innovations strategy:**
  - **Build the platform using a SARS-Cov-2 vaccine prototype**
  - **Improve the platform through selective collaborations and assure FTO**
  - **Apply the platform through collaborations for local and regional vaccine targets**
- mRNA technology will continue to make a significant contribution to health product development and deliver positive public health benefits.
- However…..global access to these products needs to be a world priority.
- Lower barriers to entry for mRNA technology provides an opportunity for LMIC's to become self-sufficient for many vaccines in terms of manufacturing of drug substance and drug product.
- Manufacturing alone is insufficient for sustainability, we must develop the know-how, capability and capacity for vaccines from concept, design, testing/optimization, manufacture and clinical development/registration to ensure sustainable access.
- Success will come more easily through genuine partnership and mutual support through an mRNA/LNP R&D and manufacturing ecosystem.

Contribution and Recognition

- WHO
- Medicines Patent Pool (MPP)
- Funders: France, Belgium, Germany, Norway, Canada, USA, Switzerland, South Africa, ELMA Foundation
- AU and Africa CDC (PAVM)
- Department of Science & Innovation, SA
- SAMRC
- Biovac
- Civil Society Groups
- mRNA programme Scientific & Technical Review Committee (STeRCo)
- mRNA Scientific Advisory Committee (mSAC)
- PATH
- NIH/VRC
- Curapath
- Equipment & technology suppliers
- WITS University, NICD, CeBER-UCT, PCDDP- NWU, and other SA Universities
- Afrigen Team and Supporting Stakeholders & Shareholders

Kristie Bloom
Abdullah Ely
Patrick Arbuthnot
Xavier Lamballerie
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Penny Moore
Thandeka Moyo-Gwete
Tandile Mkhize
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Mohamed-Gabriel Alameh

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