



**Afrigen**  
Biologics & Vaccines

**From Construction to End-to-End Drug Substance  
and Drug Product GMP Manufacturing of mRNA  
Vaccines in Africa:  
A Cross-Country Race to Epidemic/Pandemic  
Preparedness and Public Health Impact**

Petro Terblanche  
CEO, Afrigen Biologics



# OVERVIEW

- ❑ Meet Afrigen Biologics, a proudly SA Biotechnology Co
- ❑ An ecosystem context
- ❑ The Covid catalyst
- ❑ Purpose and status of the mRNA TT Programme
- ❑ CMC the critical bridge
- ❑ mRNA the promise of impact
- ❑ Enabling local manufacturing
- ❑ Future Africa

# Afrigen: Proudly South African Biotech Company



Created **first** adjuvant formulation centre in Africa.

2017

**Innovate** around our adjuvant formulation platform and developed a **formulation platform for wellness and health products.**

2019

**Research, development platform and GMP facility construction or mRNA** started Nov 2021.



2021/2022



2014/15

Established by the Industrial Development Corporation and IDRI (now AAHI) to **localize production capacity** and capabilities for a TB vaccine.

2018

Develop adjuvant platform into products through vaccine **innovation partnerships.** Explored immunotherapy landscape.

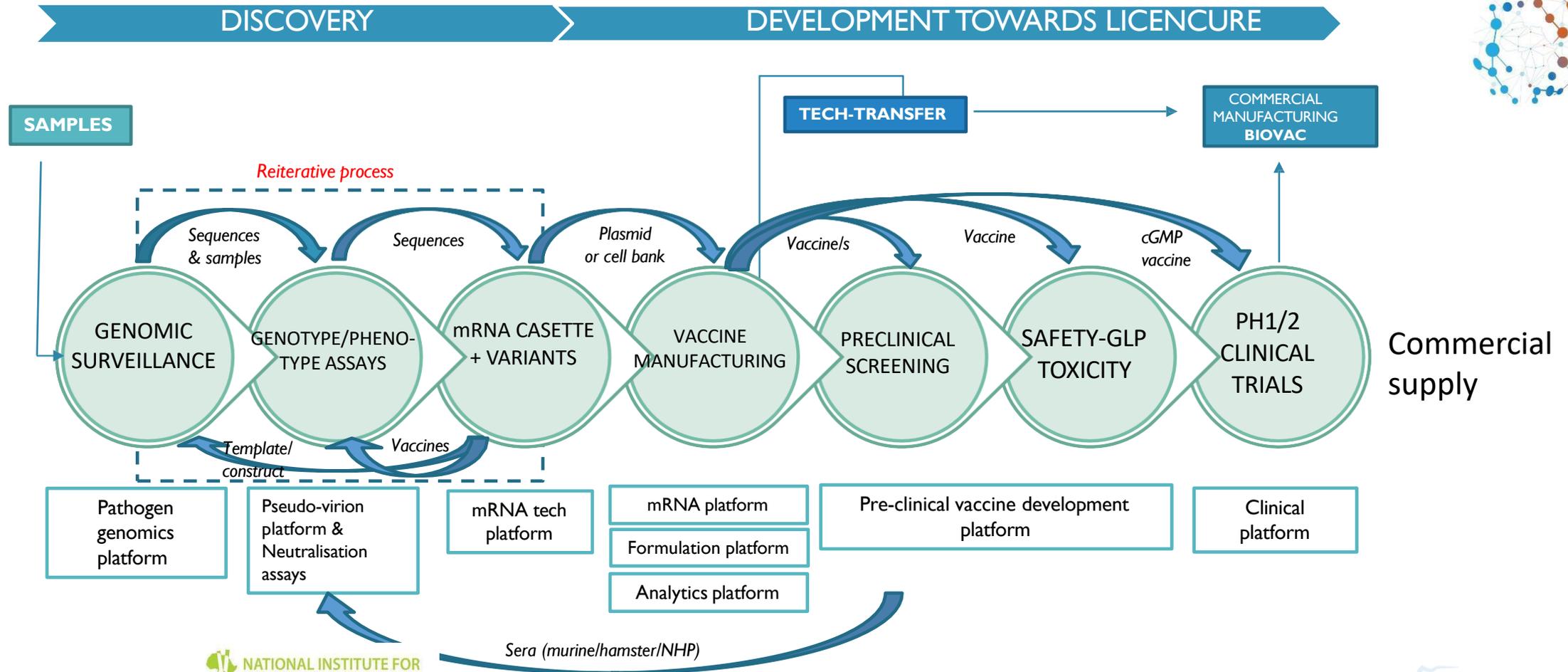
2020

Started first construction of R&D laboratories and adjuvant manufacturing suites to fully **operationalize the start-up business.**

2023-2025

Facility construction, qualification, equipment validation, process development and scaleup with complete analytics, CTA for IND AfriVac2121 mRNA vaccine completed and **GMP inspection for licensure of end-to-end (DS & DP) mRNA vaccine manufacturing completed** 25 Sept 2025.

# Vaccine development value chain in South Africa: Public Private Partnerships



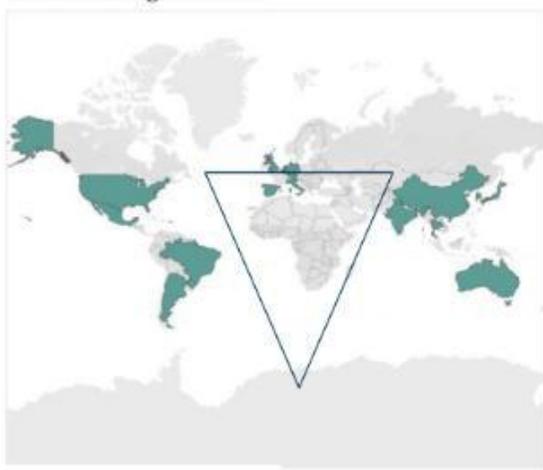
# LESSONS RE-LEARNED: WHERE VACCINES ARE PRODUCED MATTERS!

Global vaccine manufacturing is centralized in a few regions:

73% of global vaccine production by **value** is from 4 companies in high income countries.

76% of global production by **volume** is from developing country manufacturers (India leading).

Manufacturing Countries



## Africa faces 470 million COVID-19 vaccine shortfall in 2021

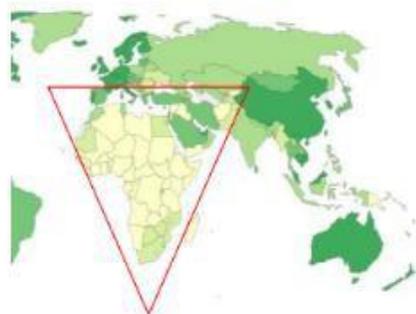


- So far, around **2%** of the nearly **6 billion** doses administered globally have been administered in Africa.
- Africa has been able to fully vaccinate some **50 million people = 3.6%** of the continent's population.

➤ The 470 million doses, which are now expected to arrive by the end of December, are just enough to vaccinate just **17% of Africans** on the

**Africa makes only <1% of the vaccines it uses**

ies administered per 100 people, Mar 7, 2022  
sorted individually. As the same person may receive more than one dose, the n be higher than 100.



## The Problem - Insufficient Global Vaccine Manufacturing Capacity to Respond to an Influenza Pandemic

### Flu vaccine shortage a worldwide crisis

December 1, 2009 | By Michael Dorn, CNN  
 Concerned about the flu vaccine shortage at home, U.S. public health officials are warning the defense against a global flu outbreak -- and they don't like what they see.  
 "We're very concerned," said Dr. Joseph J. Tomasz, a professor at Emory University's School of Public Health. "We haven't made influenza a top priority in this country, or anywhere else that I know of."  
 The World Health Organization, based in Geneva, Switzerland, recently warned that a global flu outbreak will happen in a matter of time and urged nations to strengthen their health infrastructures before then.

### Immediate and sustained action required to sharply increase pandemic influenza vaccine supply

23 OCTOBER 2009 | GENEVA - A set of activities identified in the World Health Organization's (WHO) new Global pandemic influenza action plan to increase vaccine supply requires immediate and sustained action and funding, if the world is to be prepared for an influenza pandemic to which there would be almost universal susceptibility.

### The global swine flu vaccine shortage

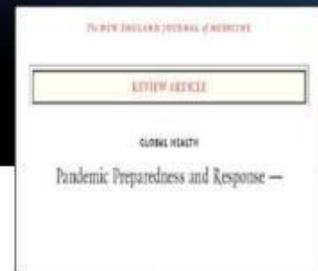
Category: Big Pharma • Swine flu • Vaccines • WHO  
 Posted on: November 23, 2009 6:45 AM, by revere

### Vaccine Shortage Threatens 2009 H1N1 Control in Nigeria

Thursday, April 28, 2010  
 Despite the recent outbreak of the pandemic 2009 H1N1 virus in China, Nigeria is yet to receive stocks of vaccine to prepare for a possible outbreak in the country.

**BUT We've been here before.....** (courtesy Rick Bright)

### Pandemic Response



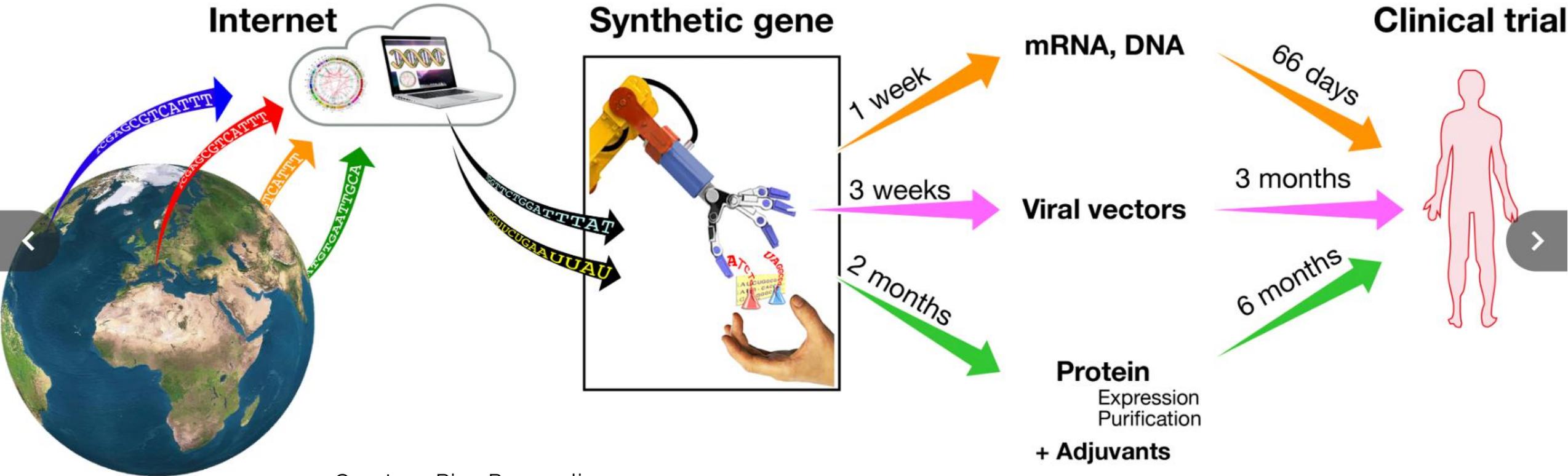
The most serious operational shortcoming was the **failure to distribute enough vaccine in a timely way**. Ultimately, 78 million doses of vaccine were sent to 77 countries, but mainly long after they would have done the most good.

At its root, this reflected a **shortfall in global vaccine-production capacity** and technical delays due to production, as well as **distributional problems**.

Among the latter were variation among wealthier countries and manufacturers in their **willingness to donate vaccine, concerns about liability, complex negotiations over legal agreements** with both manufacturers and recipient countries and limited national and local capacities to transport, store, and administer vaccines.

Source: WHO Afro <https://www.who.int/news/2010-04-28-475-million-covid-19-vaccines-shortfall-2021>

COVID 19 LESSONS LEARNED:  
 The equipped universe can move fast!  
 10 January 2020 SARS-COV-2 sequence posted on the internet.  
 350 labs worldwide use the sequence to make synthetic genes



Courtesy Rino Rappuoli

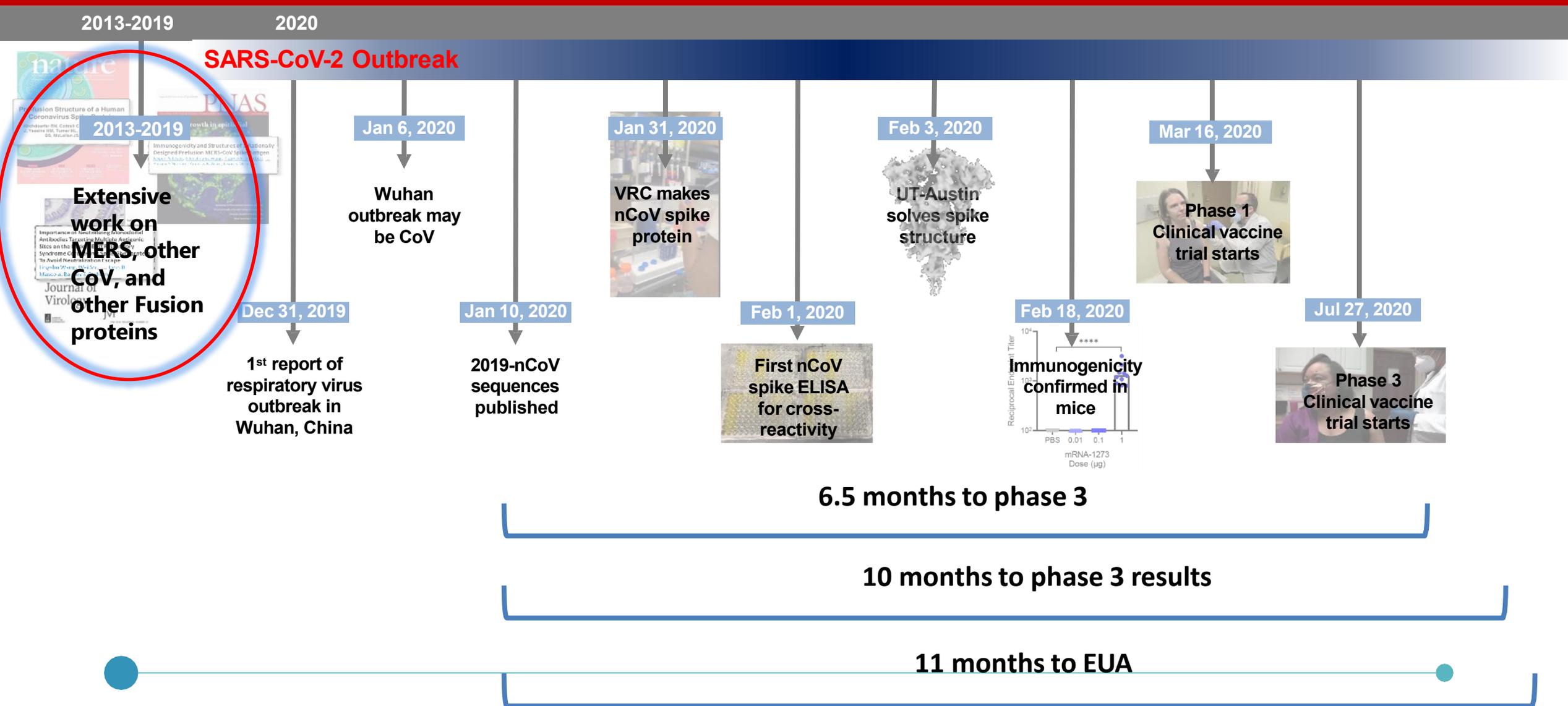
Vaccinology in the post-COVID-19 era

Rino Rappuoli, Ennio De Gregorio, Giuseppe Del Giudice, and Emmanuel Hanon [Authors Info & Affiliations](#)

Edited by Diane E. Griffin, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, and approved November 30, 2020 (received for review October 15, 2020)

January 11, 2021 | 118 (3) e2020368118 | <https://doi.org/10.1073/pnas.2020368118>

# A PANDEMIC TO ACCELERATE MRNA INTO THE CLINIC. BUT..... SPEED DOES NOT FALL FROM THE SKY (60 YEARS & 15B USD LATER)



Slide courtesy Dr Barney Graham

# mRNA TT Programme: Access, Preparedness and Innovation for Sustainability

Future pandemic readiness through

## ACCESS

Create mRNA-based vaccine manufacturing **platform** and transfer to Programme Partners to build capacity in LMICs for future pandemic response

A partnership network  
Straddling 4 continents  
Connecting 15 countries

- | Country | Partner                      | Status                  |
|---------|------------------------------|-------------------------|
| 1       | Afrigen                      | mRNA Center             |
| 2       | Biovac                       | 1 <sup>st</sup> partner |
| 2024    | BioVax Kenya                 |                         |
| 3       | Bio-Manguinhos               |                         |
| 4       | Biofarma                     |                         |
| 5       | BiologicalE                  |                         |
| 6       | BioGeneric Pharma            |                         |
| 7       | Biovaccines Nigeria          |                         |
| 8       | Damitsa                      |                         |
| 9       | Incepta Vaccines             |                         |
| 10      | Institut Pasteur de Dakar    |                         |
| 11      | Institut Pasteur de Tunis    |                         |
| 12      | Institut Torlak              |                         |
| 13      | National Institute of Health |                         |
| 14      | Polyvac                      |                         |
| 15      | Sinergium Biotech            |                         |

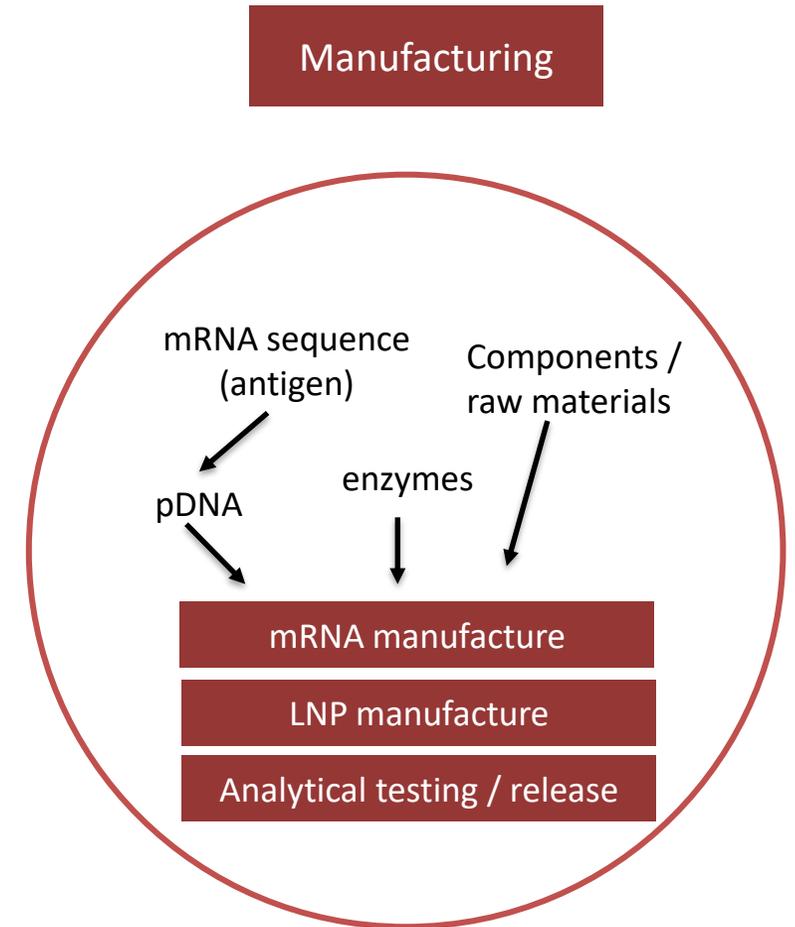


Interpandemic sustainability requires **R&D&INNOVATION**

manufacturing of a **pipeline** of vaccines addressing local market needs & **next generation** mRNA technologies

# mRNA Reduces Barriers to Entry for Vaccines

- Less capital-intensive infrastructure vs. other vaccine platforms
  - Smaller footprint/scale vs cell-culture or fermentation
  - Multi-product facilities for drug substance/product manufacture
- Cell-free manufacturing processes
  - Greater worker safety (e.g. no live viruses used)
  - Shorter manufacturing cycle times
- Platform manufacturing process
  - Standardized manufacturing process (less changes for different antigens)
  - Shorter lead times to clinical development
  - Rapid iteration in exploratory medicine trials
  - Standardized release testing methods
  - Easier switching of products
  - Easier to produce multi-valent products
  - Multi-product, multi-purpose facilities for optimal ROI



# Building a **NEW** mRNA Technology Platform **FAST** (people, facilities, systems and processes from R&D to GMP)

**AFRIGEN'S FACILITY DEVELOPMENT 2021 to 2023**  
**FROM BASIC CONSTRUCTION TO MANUFACTURING SUITES FOR mRNA**  
**TECHNICAL BATCHES ON ROUTE TO GMP LICENSE FOR DS AND DP**

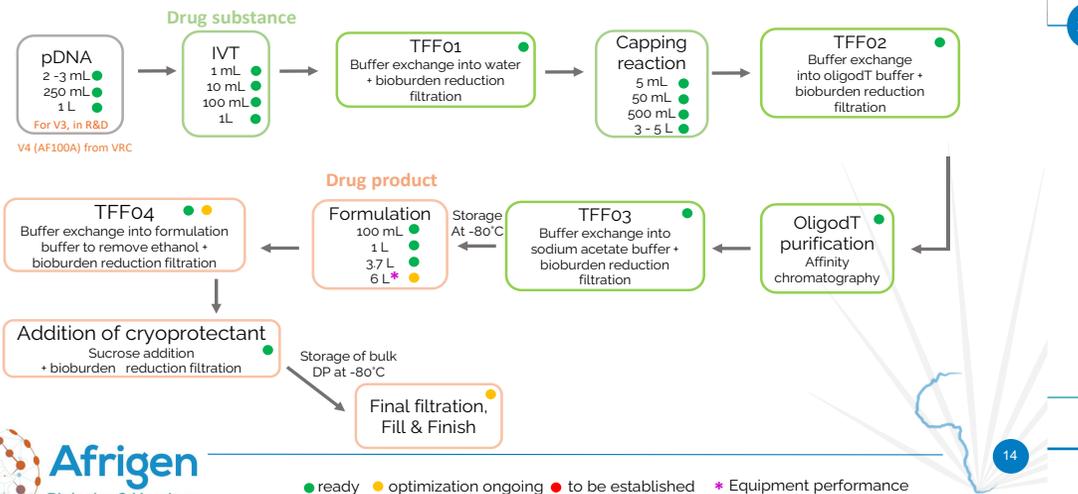


**AFRIGEN PEOPLE GROWTH (49% post graduates).**



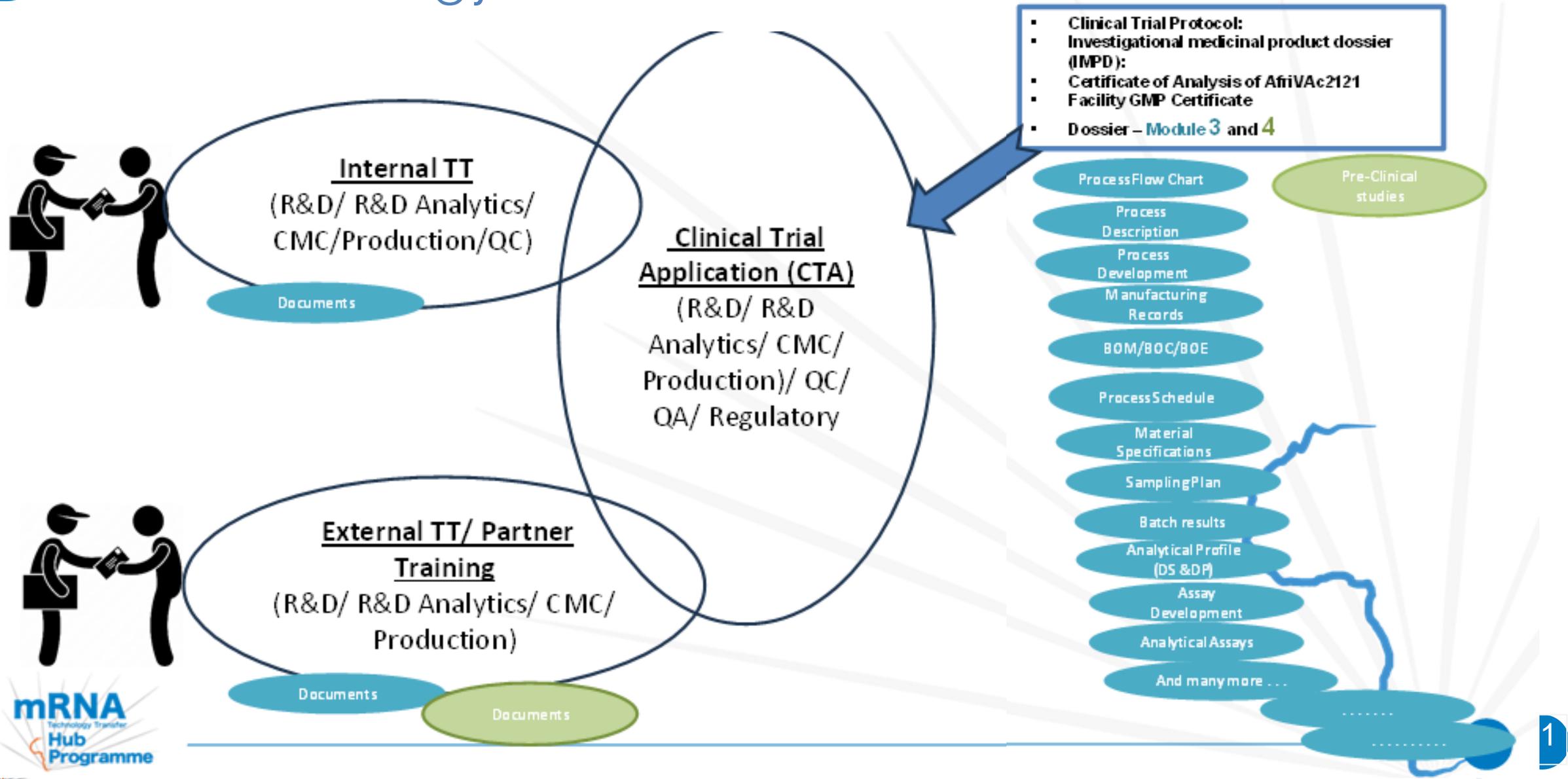
> 700 SOPs and > 200 validated analytical methods

## Manufacturing Processes



Process Stage	Stage	Quality Attribute	Assay	Method	Compendial	IPC	IPT	Characterization	Release	Stability
pDNA	CoA release	Identity	PolyA tail length	AGE/CGE					X	
pDNA	CoA release	Identity	pDNA sequence	Sanger Sequencing					X	
IVT IPC	In-process	Purity	Confirmation of pDNA Linearization	AGE		X				
IVT IPT	In-process	Content	mRNA crude quantification	Qubit			X			
DS & DP	Bulk and FF	Other	Appearance	Ph. Eur. 2.2.1 and Ph. Eur. 2.2.2, USP <790>	X				X	X
DS & DP	Bulk and FF	Other	pH	Ph. Eur. 2.2.3, USP <791>	X				X	X
DS & DP	Bulk	Safety	Endotoxin	Ph. Eur. 2.6.14, USP <85>	X				X	
DS	Bulk	Safety	Bioburden	Ph. Eur. 2.6.12, USP <61>	X				X	
DS	Bulk	Content	mRNA concentration	UV (A260)			X		X	X
DS & DP	Bulk	Identity	mRNA sequence	RT-PCR followed by Sanger sequencing					X	
DS	Bulk	Purity	Capping efficiency	Capture probe + RNase H treatment followed by CGE					X	X
DS	Bulk	Purity	PolyA tail length	RNase A treatment followed by CGE					X	X
DS & DP	Bulk and FF	Integrity	Size and integrity	CGE		X			X	X
DS	Bulk	Purity - Product related impurities	dsRNA content	Immunoblot (dot blot)					X	
DS	Bulk	Purity - Process related impurities	Residual pDNA template	qPCR				X		
DS	Bulk	Purity - Process related impurities	Residual enzymes and proteins	AccuOrange - Fluorescence				X	X	
DP	Bulk and FF	Integrity	Particle size & Polydispersity	Dynamic light scattering using the Zetasizer					X	X
DP	Bulk	Integrity	Zeta Potential	Laser Doppler Electrophoresis using the Zetasizer				X		
DP	Bulk and FF	Content	mRNA concentration & % Encapsulation	Ribogreen Assay - Fluorescence		X			X	X
DP	Bulk and FF	Potency	Functional Protein expression (size / purity)	Western Blot					X	X
DP	Bulk and FF	Content and Identity	Lipid quantitation	HPLC-CAD					X	X
DP	FF	Other	Container Closure integrity testing	USP <1207>	X				X	X
DP	FF	Other	Extractable volume	Ph. Eur. 2.9.17, USP <697>	X				X	
DP	FF	Safety	Sterility	Ph. Eur. 2.6.1, USP <71>	X				X	X
DP	Bulk and FF	Other	Osmolality	Ph. Eur. 2.2.35, USP <785>	X				X	
DP	Bulk and FF	Other	Residual solvent	Ph. Eur. 2.4.24, USP <467>	X			X		
DP	FF	Other	Particulate matter	Ph. Eur. 2.9.39, USP <788>	X				X	

# CMC a Essential Bridge Technology Transfer & mock CTA



# Ensuring Technical and Regulatory Capabilities, Effective Translation and Empowering Partnerships For a Better Prepared Global South

R&D translation by design

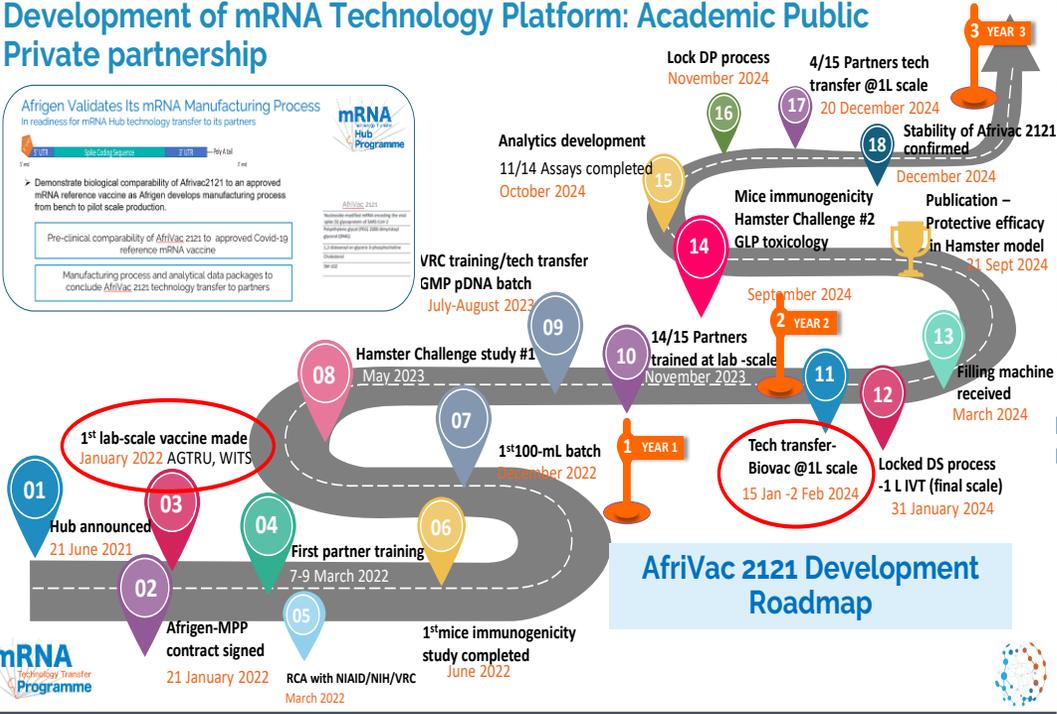
cGMP DS, DP, FF and Release Testing

Through the mRNA TT Programme, 10 manufacturers could produce mRNA vaccines for human use by 2030.

## Development of mRNA Technology Platform: Academic Public Private partnership

**Afrigen Validates Its mRNA Manufacturing Process**  
In readiness for mRNA Hub technology transfer to its partners

- Demonstrate biological comparability of Afrivac2121 to an approved mRNA reference vaccine as Afrigen develops manufacturing process from bench to pilot scale production.
- Pre-clinical comparability of Afrivac 2121 to approved Covid-19 reference mRNA vaccine
- Manufacturing process and analytical data packages to conclude Afrivac 2121 technology transfer to partners



## GMP REQUIREMENTS

### End-to-end mRNA development and manufacturing

Quality Management System (GMP)	<ul style="list-style-type: none"> <li>Qualified Utilities</li> <li>Material Handling</li> <li>QC Laboratories + In-house stability testing</li> </ul>	
Research & Development	<ul style="list-style-type: none"> <li>Plasmid design &amp; development</li> <li>DS &amp; DP Process Development</li> <li>Full pre-clinical development of vaccine candidates</li> </ul>	
Biotech Production (GMP)	<ul style="list-style-type: none"> <li>Master &amp; Working Cell Banks</li> <li>Plasmid Manufacturing</li> <li>DS &amp; DP manufacturing</li> </ul>	
Analytics	<ul style="list-style-type: none"> <li>Characterization assays</li> <li>DS &amp; DP release assays</li> </ul>	
Aseptic Filling & Finishing (GMP)	<ul style="list-style-type: none"> <li>Sterile filling line</li> <li>Visual Inspection, Label &amp; Packaging</li> </ul>	

### mRNA DS and DP TT to 15 Partners have commenced.....

Tech Transfer demonstration batch at Afrigen, with hands-on training

- Serbia: Torlak Institute (14 Oct -01 Nov 2024)
- Argentina: Sinergium Biotech (4-22 Nov 2024)
- India Biological E TT training at Afrigen 2 to 20 December 2024

	2020	2025	2030
Manufacturer 1	Grey	Green	Green
Manufacturer 2	Grey	Green	Green
Manufacturer 3	Grey	Green	Green
Manufacturer 4	Grey	Green	Green
Manufacturer 5	Grey	Green	Green
Manufacturer 6	Grey	Green	Green
Manufacturer 7	Grey	Green	Green
Manufacturer 8	Grey	Green	Green
Manufacturer 9	Grey	Green	Green
Manufacturer 10	Grey	Green	Green
Manufacturer 11	Grey	Green	Green
Manufacturer 12	Grey	Green	Green
Manufacturer 13	Grey	Green	Green
Manufacturer 14	Grey	Green	Green
Manufacturer 15	Grey	Green	Green
Manufacturer 16	Grey	Green	Green

  mRNA vaccines GMP  
  mRNA vaccines R&D  
  No mRNA vaccine capability

### Projections for 2030 based on 10 GMP facilities

<b>Interpandemic Period</b> (36.4k doses/batch and 3 lots a year) 30ug mRNA / dose.	<b>Immediate Pandemic Response</b> (36.4k doses/batch and full capacity) 30ug mRNA / dose.	<b>Increased Capacity Response</b> (36.4k doses/batch and increased production scale) 30ug mRNA / dose.
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Investment required depends on each partner. These figures are used for scenario-building purposes, and they do not reflect recommendations. Estimations based on current process as developed by Afrigen. Running costs do not consider possible increase in HR for capacity increase.

Team effort Knowledge & Technology Transfer from Afrigen to Partners (Customized to partner readiness and sustainable strategies assessed by MPP and WHO).

# THE BRIDGES WE BUILD – TRAVELS ON 2 LEGS.

A sweet reward! Traditional SA Koeksister



Proudly celebrating the final drug product manufactured by the partner at Afrigen!

		<b>South Africa:</b> Biovac	15 Jan-2 Feb 2024
		<b>Senegal:</b> Institut Pasteur de Dakar	3 Mar -20 Mar 2025
		<b>Tunisia:</b> Institut Pasteur de Tunis	31 Mar-17 Apr 2025
		<b>Pakistan</b> National Institutes Of Health	7 Jul -25 Jul 2025
		<b>Egypt</b> BioGenerics Pharma	4 Aug -22 Aug 2025
		<b>Nigeria</b> BioVaccines/NIMR	1 Sept -19 Sept 2025
		<b>Kenya</b> BioVax/KEMRI	17 Nov-5 Dec 2025



## WHO Africa and Eastern Mediterranean Regions



Welcoming all our partners with their Country Flag in the Cape Town wind.



		<b>Argentina:</b> Sinergium Biotech	4 Nov-22 Nov 2024
		<b>Serbia:</b> Torlak Institute	14 Oct-1 Nov 2024
		<b>Ukraine:</b> Darnitsa	TBC
		<b>India:</b> Biological E. Ltd	2 Dec-20 Dec 2024
		<b>Indonesia:</b> BioPharma	3 Feb-21 Feb 2025
		<b>Bangladesh</b> Incepta	12 May-30 May 2025
		<b>Polyvac</b> Vietnam	6 - 31 Oct 2025 TEAMS AT AFRIGEN AS WE SPEAK!



## WHO Americas, Europe, South East Asia, Western Pacific Regions



# Innovation Driven Collaborations are critical to the continued building the mRNA platform for a Sustainable Future

DNA & RNA Development

Manufacturing Technology

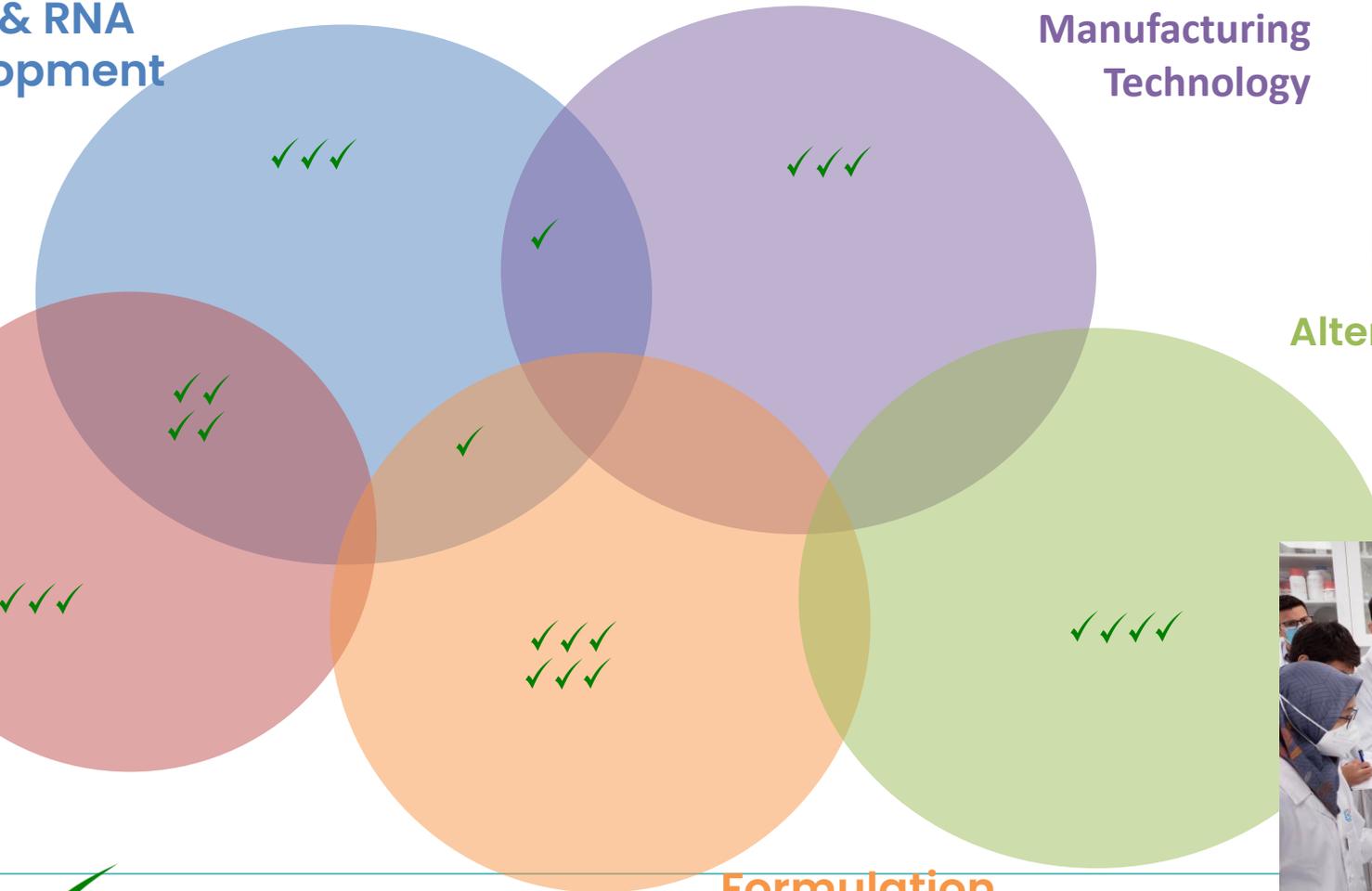


Alternative Delivery Method



Archetype	Disease	Pathogen	GAVI	WHO	CEPI	PAVM	mRNA app.	difficulty
Legacy	Measles	**						
	Tuberculosis	**						
	Whooping Cough							
	Tetanus							
	Diphtheria							
	Hepatitis B							
	Yellow Fever	*						
Expanding	Rotavirus	**						
	Pharmaceutical	**						
	Papilloma Virus	#						
	HIV/AIDS	*						
Outbreak	Malaria	*						
	SARS-Cov-2	*						
	Chikungunya	*						
	Lassa Fever	*						
Next Horizon	Rift Valley Fever	*						
	Ebola	*						
	Varicella							
	Hepatitis A							
	Influenza							
	Syphilis	#						
	Genital herpes	#						
Other	Otitis	**						
	Gonorrhea	**/#						
	Chlamydia	#						
	RSV	**						
Other	Strep A	**						
	Group B Strep	**						
	Rabies	**						

Additional Disease Targets



Active collaborations

Formulation Research

# mRNA Disease Targets

## mRNA Technology Transfer Programme



medicines patent pool



World Health Organization

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

Afrigen

Biovac

BioVax Kenya

Bio-Manguinhos

Biofarma

BiologicalE

BioGeneric Pharma

Biovaccines Nigeria

Darnitsa

Incepta Vaccine

Institut Pasteur de Dakar

Institut Pasteur de Tunis

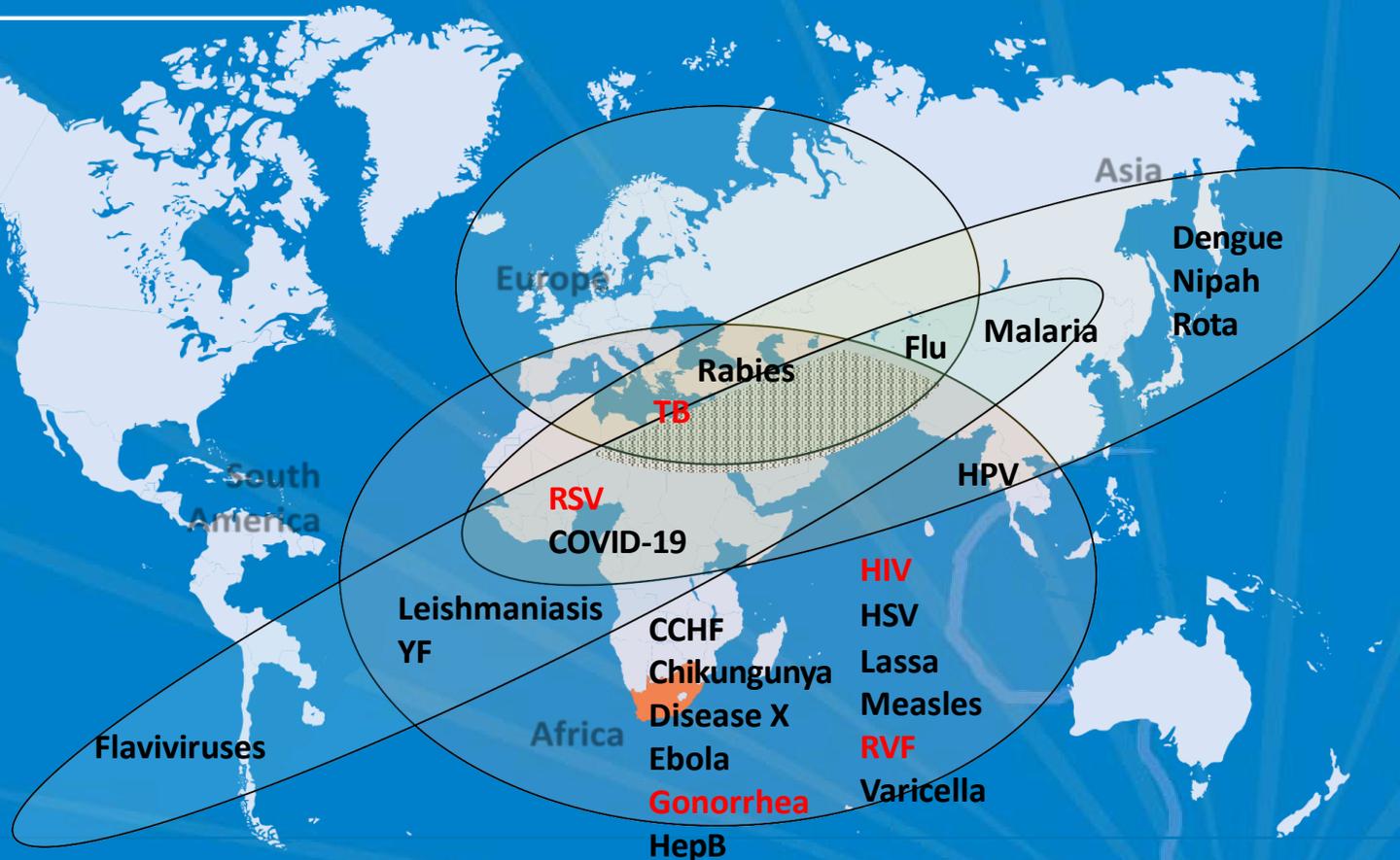
Institut Torlak

National Institute of Health,

Polyvac Sinergium

Biotech

Archetype	Disease	Pathogen	GAVI	WHO	CEPI	PAVM	mRNA app	difficulty
Legacy	Measles	*						
	Tuberculosis	**						
	Whooping Cough	*						
	Tetanus	*						
	Diphtheria	*						
	Hepatitis B	*						
	Yellow Fever	*						
Expanding	Typhoid	*						
	Cholera	*						
	Rotavirus	*						
	Pneumococcal	**						
	Papilloma Virus	#						
Outbreak	HIV/AIDS	*						
	Malaria	*						
	SARS-Cov-2	*						
Next Horizon	Chikungunya	*						
	Lassa Fever	*						
	Rift Valley Fever	*						
	Ebola	*						
Other	Varicella	*						
	Hepatitis A	*						
	Influenza	*						
	Syphilis	#						
	Genital herpes	#						
	Otitis	**						
	Gonorrhoea	**/B						
Chlamydia	#							
Other	RSV	*						
	Strep A	**						
	Group B Strep	**						
	Rabies	*						



2/25/2025

**SAMRC, Afrigen and partners products in early development**

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



# THE QUEST FOR A SUSTAINABLE FUTURE REQUIRES AN ECOSYSTEM LENS AND EMBRACING NEW TECHNOLOGIES (while we boldly built).

## Access-To-Medicines Research Centre Modeling Portfolio & Platform

### Vaccine Eco-System Modeling

- Models
  - Platforms: mRNA, viral vector, protein, ...
  - Regional:
    - Europe, Africa, S-America, SE-Asia
  - Manufacturing: Substance, Product, RM
  - Stockpiling versus Capacity readiness
    - Ex. CZ/Reig-Jofre:
      - Transport
      - Bottlenecks: QA/QC, storage
      - Ex. mRNA platform modelling:
        - WHO Hub & Spoke: scale up, scale down
        - Supply chain: 100+ critical raw materials
- Tech Transfer:
  - Hardware, knowledge and models
  - Training, ex. HERA Sessions
- Modelling platform
  - Security, sustainability, integrity
  - Discrete Event Simulation
  - Systems Dynamics



AUGUST 29, 2024  
CEPI partners with Afrigen to speed up hashtag#mRNA vaccine development and access.



**Health Products & Services**

- Vaccines
- Antivirals
- Diagnostics
- Commodities
- Immunization: MR, HPV, Rota
- One Health: YF, Rabies
- HIV
- NTDs & Pathogen X: Lassa
- Covid-19 COVAX
- Outbreaks: Ebola, Cholera, Mpox
- Reproductive health
- Disease

**Pandemic Preparedness & Response**

- 100 days mission
- Time to scale up
- Time to first batch
- Inter-Continental scope
- 2040 ambition of A-CDC
- TEAM Europe
- TESS MAV+
- CEPI, WHO (LPA), DCVMN, a.o.

**Global Modelling**

- EU-HERA & EU-FAB
- Reig Jofre & CZ
- Belgium: VaxxDiV
- Germany: ZEPAI
- IDT
- A-CDC/PHAHM
- SA: Afrigen, BioVac
- Senegal: MADIBA
- S-America:
  - Bio-Manguinhos
  - SE-Asia: Biofarma

**Health Eco-System Modeling "Center of Excellence"**

- Public-Private-Academic
- Hosting:
  - Multi-stakeholder
  - Modelling platform
  - Data repository
  - Training
  - Projects



## unology™

many based in Hørsholm, ig AI-platform, AI-vaccine target discovery,

and machine learning architecture.

and adaptable platform use decoding with vaccine

have created five unique AI

## EVAXION

As the immune system and create



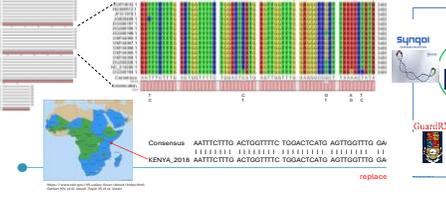
EVAXION  
Sep 20, 2023  
MENU  
Evaxion Partners With Pharmaceutical Company Afrigen Biologics to Develop Novel mRNA Vaccine Against Gonorrhoea

### From Sequence to Vaccine: The Value of Genomic Data and Discovery Science

- About Rift Valley Fever Virus:**
- Negative-stranded, RNA genome: S, M and L segments.
  - M-segment encodes 2 envelope glycoproteins, Gn and Gc
  - Gn/Gc forms heterodimer on viral particle surface, target antigen/s
  - Glycoprotein co-translationally spliced into Gn and Gc



### Antigen design based on consensus RVFV lineage C



## Horizontally Integrated Innovation Partnerships: A case study

### RVFV vaccine: Demonstration Case for Innovation in mRNA for Africa

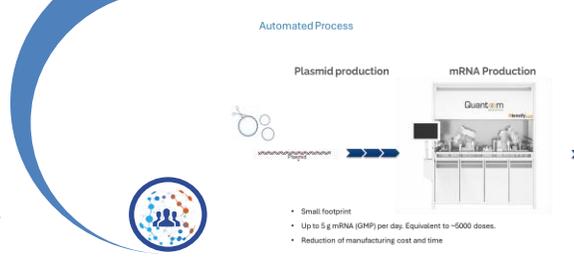
**Target Profile**  
Accessible cost in LMICs  
mRNA/LNP for human vaccine – no more than two doses  
saRNA/CNE for veterinary vaccine – single dose  
Stable at 2-8°C



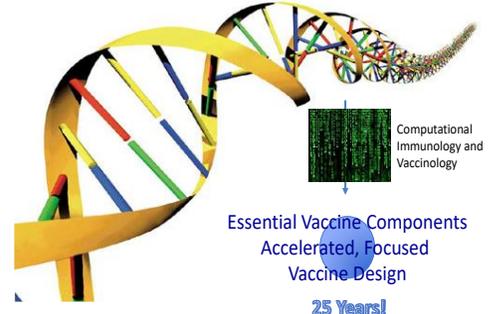
**Status**

- Antigen design selected
- pDNA/mRNA sequence optimization underway
- mRNA successfully formulated
- In-vitro expression ongoing
- Seed funding received from Elmo Fundatie SAMRC
- Funding received from CEPI for preclinical a phase I trials.

## Manufacturing Technology



## EpiVax: Innovative tools for accelerating vaccines (and biologics) development



DNA & RNA Development

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

**Synqoi**  
TAILOR MADE SYNTHETIC DNA

**Yale University**  
Professor Wendy Gilbert

**Afrigen**  
Biologics & Vaccines

https://doi.org/10.1101/2024.02.28.542532

# mRNA Programme Evolution and Future Focus

2021

2022

2023

2024

2025

2026....

mRNA-based COVID-19 Wuhan vaccine

mRNA-based COVID-19 vaccine with epidemiologically relevant variant

mRNA-based vaccine manufacturing technology platform

mRNA-based vaccine candidates for LMICs (R&D consortia)

mRNA-based therapeutics

mRNA-based 2<sup>nd</sup> gen technologies

South African consortium

+

South African mRNA Vaccine Consortium (SAMVAC)

+

Programme Manufacturing partners

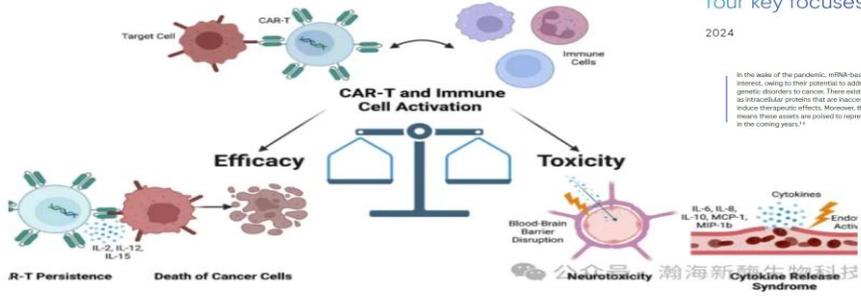
+

Research centers

Pandemic response & inter-pandemic sustainability

# AND HOW RELEVANT IS FUTURE RELEVANT.....?!

Raw materials/API for Biopharma  
319 subscribers



## In vivo CAR-T: Breakthrough and Clinical Progress of mRNA-LNP Driven Technology, Reshaping the Landscape of Cell Therapy

Trasy Ding  
Raw materials and API/ intermediates/FDF for Biopharma

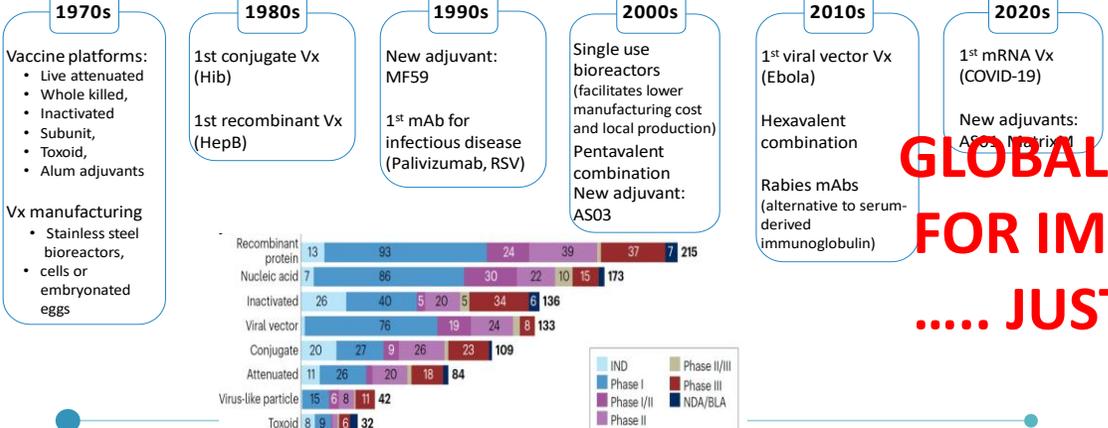
November 5, 2025



The future of mRNA:  
four key focuses for industry  
2024

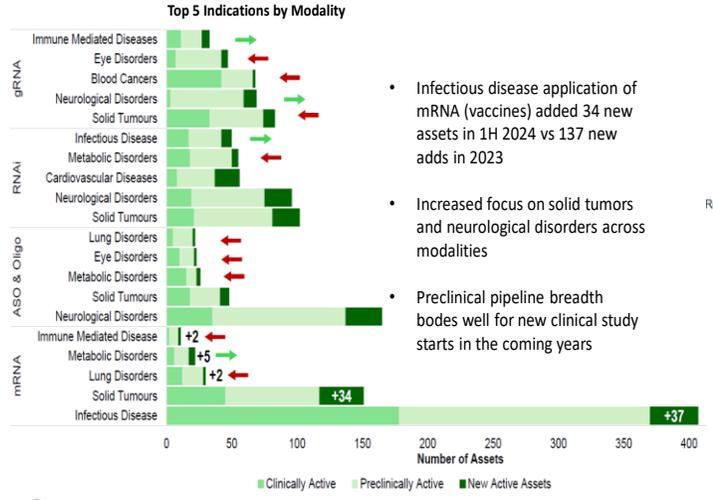
In the wake of the pandemic, mRNA-based therapeutics and vaccines have seen increasing research and development interest, owing to their potential to address a wide range of therapeutic indications, from infectious diseases to genetic disorders to cancer. There exist promising versatile mRNA technology, for example, for targets such as intracellular proteins that are inaccessible to many protein-based therapeutics. mRNA drugs can be leveraged to induce therapeutic effects. Moreover, the speed with which mRNA drugs can be developed without sacrificing quality means these assets are poised to represent an increasingly large segment of the biopharmaceutical development pipeline in the coming years.

## Innovation in vaccine technologies: 1970s to 2020s: Nucleic acid platform expansion

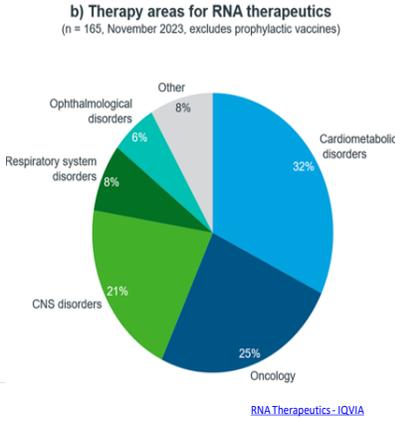


Slide courtesy Dr. Rogerio Gaspar  
Director, Dept Regulation and Prequalification  
Division of Access to Medicines and Health Products  
Division, World Health Organization, Geneva, Switzerland

## Breath of All Disease Targets Continues to Grow, Vaccine Targets more Refined



- Infectious disease application of mRNA (vaccines) added 34 new assets in 1H 2024 vs 137 new adds in 2023
- Increased focus on solid tumors and neurological disorders across modalities
- Preclinical pipeline breadth bodes well for new clinical study starts in the coming years



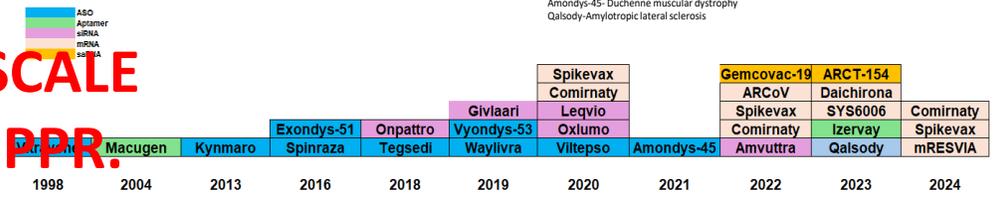
Adapted from  
[Beacon | H1 2024 RNA Landscape Review | beacon-intelligence.com](#)



## Growing RNA Product Approvals

- 50% for genetic disorders
- 24% for vaccines

- Genetic Disorders**
- Kymriah<sup>®</sup> - hypercholesterolemia
  - Waylivra<sup>®</sup> - chylomicronemia syndrome
  - Leqvio<sup>®</sup> - hyperlipidemia
  - Tegsedi<sup>®</sup> - transthyretin amyloidosis
  - Onpatro<sup>®</sup> - transthyretin amyloidosis
  - Amvuttra<sup>®</sup> - transthyretin amyloidosis
  - Spinraza<sup>®</sup> - spinal muscular atrophy
  - Exondys-51<sup>®</sup> - Duchenne muscular dystrophy
  - Viltepso<sup>®</sup> - Duchenne muscular dystrophy
  - Vyondys-53<sup>®</sup> - Duchenne muscular dystrophy
  - Amondys-45<sup>®</sup> - Duchenne muscular dystrophy
  - Qalsody<sup>®</sup> - Amyotrophic lateral sclerosis
- SARS-CoV2 vaccines**
- ARCT-154<sup>®</sup>
  - Comirnaty<sup>®</sup>
  - Spikevax<sup>®</sup>
  - SYS6006<sup>®</sup>
  - Daichirona<sup>®</sup>
  - ARCoV<sup>®</sup>
  - Gemcovac-19<sup>®</sup>



1: EUA India, Genovio Biopharma. 2: Walvac (China). 3: Daiichi Sankyo (Japan). 4: DSPC Pharma (China). 5: Moderna. 6: Pfizer/BioNTech. 7: Arcturix (Japan)



MAGNITUDE.....

**GLOBAL EFFORT AND SCALE FOR IMPACT AND E & PPR. .... JUST IN CASE.**

# KEY ENABLERS FOR LOCAL MANUFACTURING IN SA/AFRICA

## CROSS DEPARTMENTAL ALIGNMENT AND POLICY COHERENCE ARE MOST CRITICAL ENABLERS

1



### Ministry of Health

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Technical leads and manage the process of selecting & procuring vaccines for country immunisation programmes.

2



### Ministry of Finance

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Willingness to create the fiscal space necessary to materialise demand for African-made vaccines is key.

3



### Ministry of Trade and Industry

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Support and understanding how trade policies can facilitate vaccine imports and exports.

4



### Ministry of Science, Technology and Innovation

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Robust national industrial policy can support local vaccine manufacturing.

**POLICY POSITION OF THE SOUTH AFRICAN  
 HEALTH PRODUCTS REGULATORY  
 AUTHORITY ON ENABLING LOCAL  
 MANUFACTURING DOCUMENT REVIEW AND APPROVAL**

**Revision History**

Policy Number : CEO04  
 Revision : 1.0

Version	Reason for Amendment	Date of Revision
1	New document	September 2024
2	Inclusion of input from comments received	April 2025

**6.1.2** This policy position is aimed at facilitating the long-term security of supply of health products in South Africa by supporting local manufacturers through shorter evaluation times and reduced fees for the assessment.

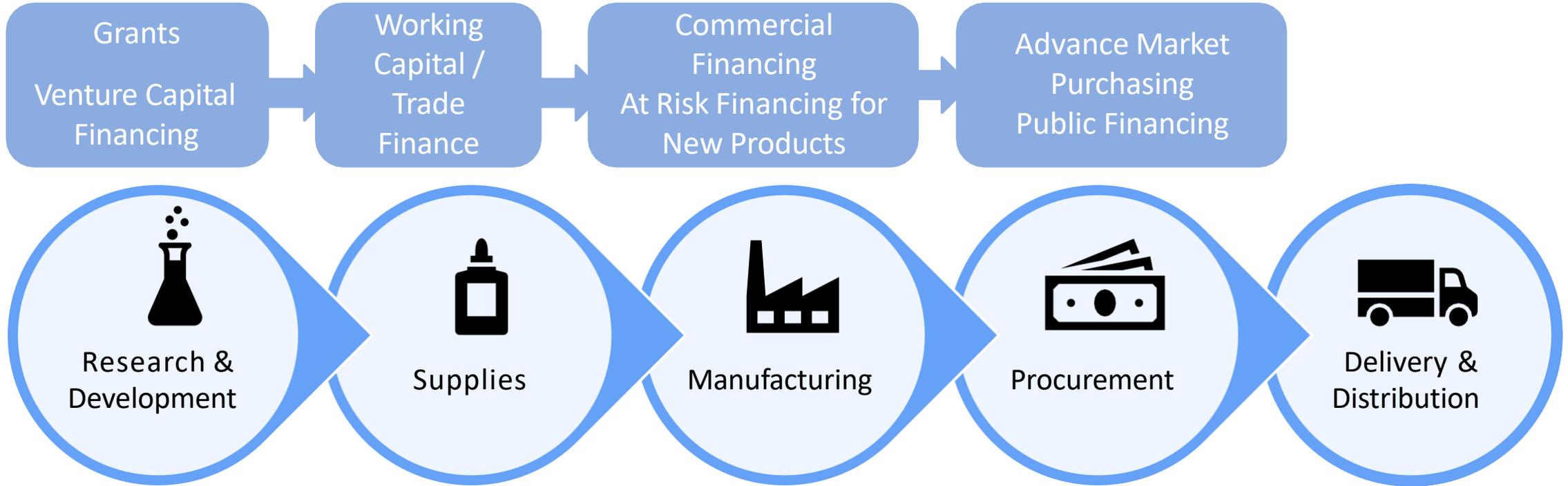
**6.1.3** SAHPRA will ensure that any prioritisation of applications will be transparent, fair, objective, timeous, efficient, effective and without favour or prejudice, while focusing primarily on safety, quality, and therapeutic efficacy. This policy position will be incorporated into SAHPRA’s Priority Review guideline, which as per SAHPRA practice will incorporate the industry’s input.

SA Local  
 Manufacturing:

Landmark policies  
 to enable  
 regulatory  
 efficiency.

# Financing for Vaccines

## “Business as Usual” vs. “Holistic and innovative” models



Blended and Coordinated Facilities, Liquidity Facilities Backed by Procurement contracts

System Strengthening Investments (Trade, Regulatory, Skills)

# AFRICA 2021



\*Algeria has an organization that does some substance manufacturing and distributes vaccine imports. Ethiopia, Morocco and South Africa also import vaccines for distribution.



# AFRICA 2024

In 2024, there are 25 active AVM projects which can be divided into three segments based on overall supplier maturities and capabilities



- Seg. 1: Facilities w/ TTs underway**
  - Marbio
  - Vacsera
  - IP de Dakar
  - Aspen Pharmacare
  - Biovac
- Seg. 2: Facilities awaiting TT**
  - Eva Pharma
  - Minapharm
  - Biogeneric
  - Saidal<sup>1</sup>
  - Atlantic Biotech
  - IP de Algerie
  - DEK
  - Innovative Biotech
  - BVNL<sup>2</sup>
  - DEI Biopharma<sup>3</sup>
  - VAI Uganda
  - Biovax
  - Shieldvax
  - BioNtech
  - Yash Life Pharma
  - Mozambique Holdings<sup>4</sup>
  - Afrigen<sup>5</sup>
- Seg. 3: Facilities in dev.**



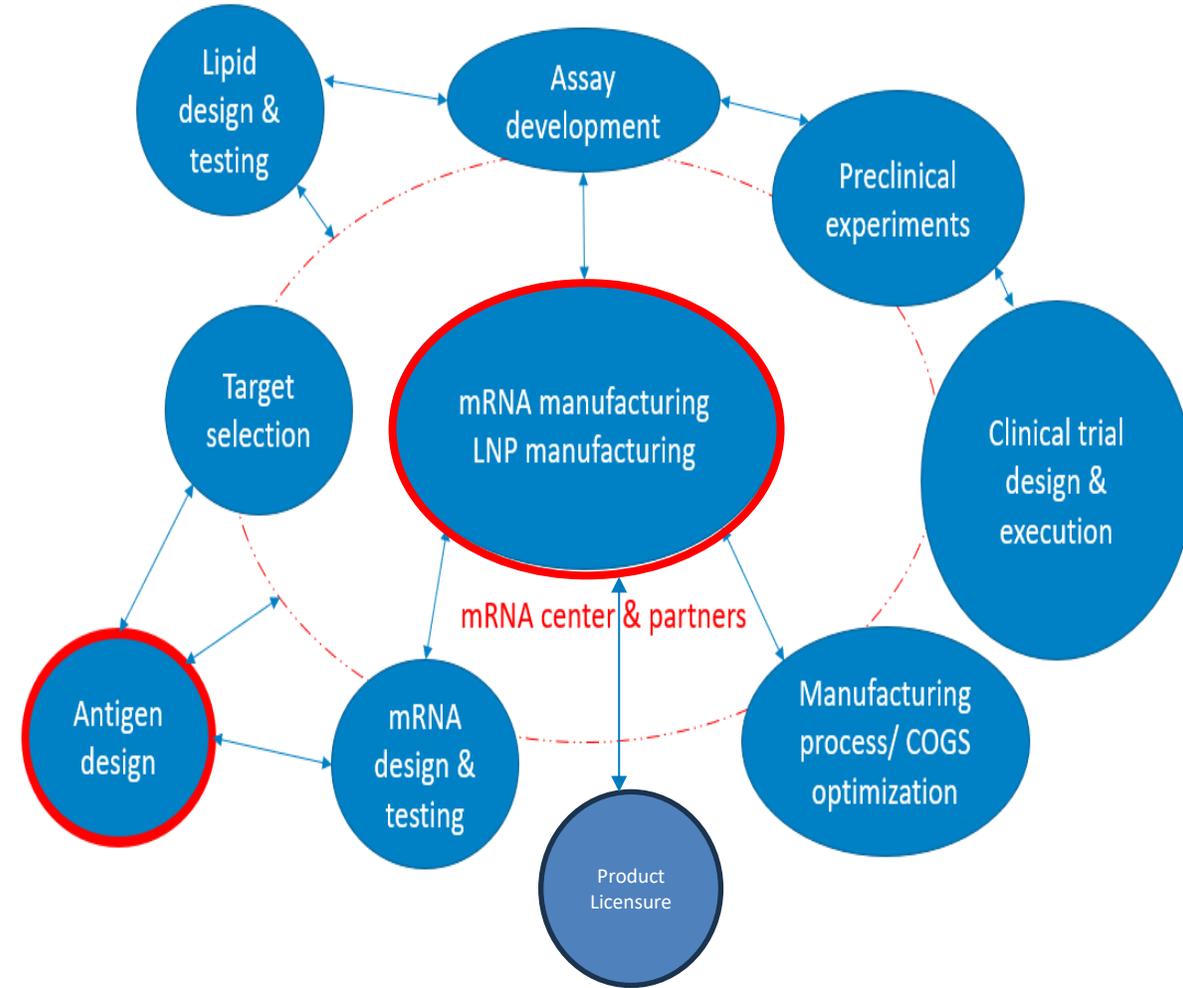
## Key Findings

- 5 Suppliers in Segment 1 already have commercial scale facilities and tech transfers (TTs) underway or complete and are relatively close to commercialization
- 5 Additional suppliers in Segment 2 have commercial scale facilities qualified and are ready to receive TTs
- The remaining 15 suppliers in Segment 3 are still in development stages
- Rationalizing AVM projects remains an ongoing need as the long tail of pipeline projects may face challenges to gain a viable market share

1. Interview not yet held, but initial perspective is Saidal may also have a commercial scale facility ready to receive an influenza vaccine TT 2. As per an informal meeting with BVNL they do not have a facility yet 3. Construction of a modular Vax facility has started in the US for shipment to Uganda in 2025 4. Unofficial reports indicates they have broken ground on a F/F facility 5. R&D facility complete. Larger commercial facility built. expect GMP inspection in 2025. Source: CHAI/PATH/PAM Current State Vaccine Supply Mapping

# Summary: Leverage the Power of mRNA

- mRNA technology has reduced barriers to entry for LMIC vaccine R&D and manufacturing.
- Many vaccine targets critically important for LMICs can be addressed through an mRNA platform.
- Critical R&D capabilities must be developed locally to fully benefit from mRNA technology.
- Sustainability will be enabled by:
  - ❑ Efficient, cost-effective manufacturing processes and infrastructure;
  - ❑ Development of products for local/regional use;
  - ❑ An enabling ecosystem with policy coherence and government support;
  - ❑ Supply chain security and access;
  - ❑ Adequate funding across the value chain.



WHO and Medicines Patent Pool.  
 Funders: France, Belgium, Germany, Norway, Canada, Switzerland, South Africa, EC/EU. ELMA Foundation, SA Government DSI. AU and Africa CDC (PAVM). SAMRC and SAMVAC consortium Biovac Civil Society Groups mRNA Hub Steering Committee. mRNA Hub Scientific Advisory Committee PATH NIH/VRC Curapath Equipment and technology suppliers University of the Witwatersrand, NICD, CeBER-UCT, PCDDP NWU, and other SA Universities. Our Biotech partners across the globe CEPI GIZ CHAI YALE KUL Leuven: Access to Medicines Quantoom Afrigen Team and Supporting Stakeholders and Shareholders

# THANKFUL FOR DIVERSE, UNIQUE, LOCAL, REGIONAL AND GLOBAL PARTNERSHIPS

AND DEDICATED COMPETENT PEOPLE... much more than a village, we're a universe!!



Kristie Bloom, Abdullah Ely & Patrick Arbutnot  
 Xavier Lamballerie & Antoine Nougairède, Ornellie Bernadin Penny Moore, Thandeka Moyo-Gwete & team  
 Wendy Burgers, Roanne Keeton & team  
 Thanos Kotsiopolous & CeBER team  
 Jason Gall & VRC teams

