BVNL OVERVIEW:

mRNA Meeting

April 17-21, 2023



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"Vaccines are the tugboats of preventive health" - William Foege

۵	Introduction of BVNL
<u> </u>	BVNL Overarching Strategy
<u> </u>	BVNL Capacity
_	MRNA Vaccine Manufacturing
_	Nigeria Ecosystem
	Afrigen Training

20-04-2023



Introduction to Biovaccines Nigeria Limited (BVNL)



A Synergistic Partnership Between Private and Public Sector







(51%)



- One of the oldest pharmaceutical companies in Nigeria.
- M&B is amongst the top pharmaceutical companies in Nigeria.

- ✓ Most populous country in Africa.3rd largest youth population in the world.
- ✓ Nigeria's economy is the largest in Africa.
- Phased GAVI graduation begins in 2021.

Mandate for long term procurement of vaccines and stage-wise indigenous manufacturing of vaccines.





RC 633335

Advancing Health through Innovation

- Established: 2005
- JVC: FGN & MBN
- SPV to revive LVM in Nigeria
- Board Re-inauguration: Jan 19,2018
- Head Office: 445 Herbert Macaulay
 Way, Yaba, Lagos State
- Factory: Otta, Ogun State







BioVaccines Nigeria Ltd



€NICE



5. Forum to nurture and

capacity building initiative

develop local technical

talent to support the

1. Infrastructure for Capacity building for Local manufacturing of Essential vaccines

'Nigeria Immunization Coverage Enhancement' – Initiative

4. Support in setting up an NCL and strengthening the NRA to make it fully

functional

2. Infrastructure for Development of Novel vaccines critical for the region

3.Institution to support in enhancing awareness and Coverage of EPI vaccines in Nigeria

Support in Achieving GVAP Goals in Nigeria & the Region





A tunnel concept based, fully integrated Vial filling line which does, Washing, drying sterilization, cooling, filling, stoppering and capping.



Sr. No.	Capacity Caculations	Absolute vials	Million vials	Single Dose/ vial 0.5 ml + appropriate overfill No of doses (mil)	5 Dose / vial (0.5 ml/dose) 2.5 ml + appropriate overfill No of doses (mil)	10 dose / vial (0.5 ml/dose) 5.0 ml +appropriate overfill No of doses(mil)
1	Machine Capacity vials/minute	300				
2	Machine Capacity vials/hour	18,000				
3	Machine Capacity vials/day/shift (5 hours fill time)	90,000				
a	Annual Capacity @260 days on single shift/day	2,34,00,000	23	23	117	230
b	Annual Capacity @260 days on double shifts/day	4,68,00,000	47	47	234	470
c	Annual Capacity @260 days on three shifts/day	7,02,00,000	70	70	351	700









Intended Application of the mRNA Tech





- Expanding
 COVID-19, HIV
- Outbreak/ EID
- Ebola, Chikunguya, RVF, Lassa, Dx X

Approach

- mRNA facility Integrated into Existing Manufacturing (Option 2)
- mRNA Research Labs (Option 1)

Partners

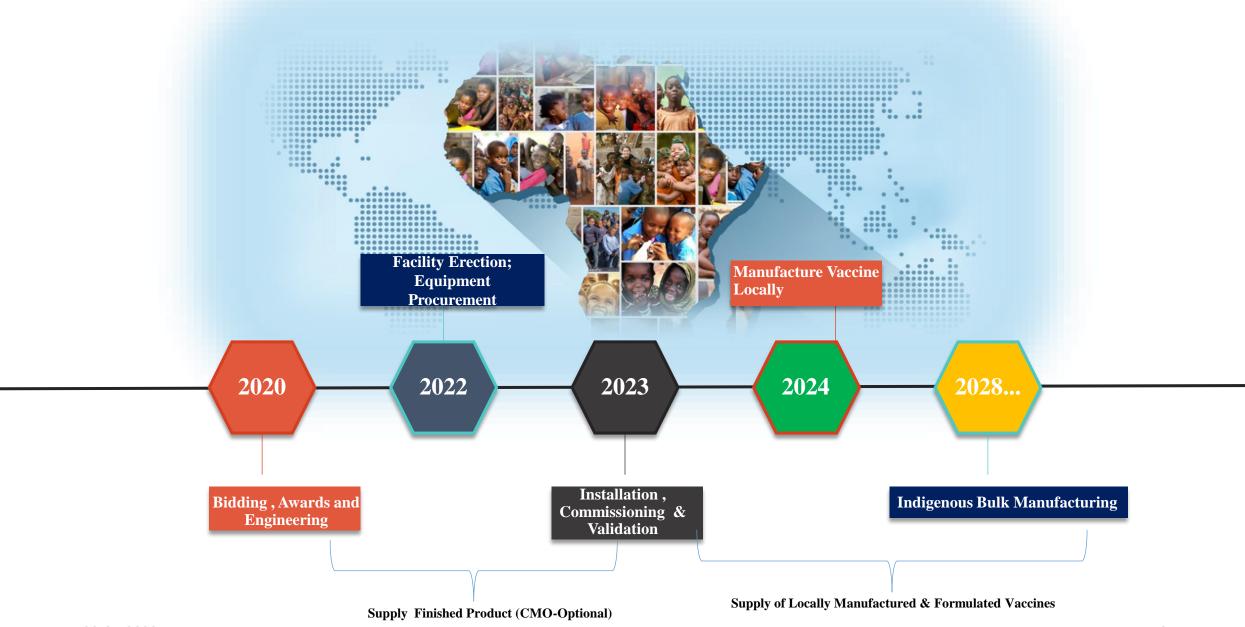
- NIMR
- NIPRD
- NVRI
- FMoH
- NAFDAC

Sustainability..



Project Milestones









Nigerian Vaccine Manufacturing Ecosystem

History of Vaccine Manufacturing:

- Animal (Bacterial & Viral) for over 75+years
- Human (Small Pox, Rabies,





Regulatory Strengthening (NAFDAC)

- WHO Global Benchmarking; Level 3
- ISO 9004
- Ongoing of a new NAFDAC vaccine Lab
- > 45 Lot release certificates issued for Covid-19 vaccines





	WHO GB	T Performan	ce Maturity	Levels
004	1	2	3	4
150 9004	No formal approach	Reactive approach	Stable formal system approach	Continual improvement emphasized
WHO GBT	Some elements of regulatory system exist	Evolving national regulatory system that partially performs essential regulatory functions	Stable, well- functioning and integrated regulatory system	Regulatory system operating at advanced level of performance and continuous improvement
	rely on other re	er as functional if gulators for some functions	Target of WHA Resolution 67.20	Advanced/reference Regulatory Authorities

Scientists: Virologist & Vaccinologists

- Usman Danfodio University (UDUS), Sokoto
- National Institutue of Medical Research (NIMR)
- Nigeria Institute of Pharmaceutical Research & Development (NIPRD)
- Irrua Specialist Teaching Hospital (ISTH), Edo
- African Centre of Excellence for Genomics of Infectious Diseases (ACEGID), Osun







Efforts; parallel and aligned



Afrigen Training



Working towards mid May 2023 Nigeria Consortium

Gratitude- Initiative & thought leadership









Country	mRNA technology recipient		
Argentina	Sinergium Biotech		
Brazil	Bio-Manguinhos		
Egypt	BioGeneric Pharma S.A.E		
Kenya	tbd*		
Nigeria	Biovaccines Nigeria Limited		
Senegal	Institut Pasteur de Dakar		
Tunisia	Institut Pasteur de Tunis		
Bangladesh	Incepta Vaccine Ltd		
Indonesia	Biofarma		
India	BiologicalE (Bio E)		
Pakistan	National Institute of Health		
Serbia	Institut Torlak		
South Africa	Biovac		
Ukraine	Darnitsa		
Viet Nam	Polyvac		

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"Universal health coverage is ultimately a **political choice**. It is the responsibility of every country and national government to pursue it. It takes vision, courage and long-term thinking"

The above statement credited to Dr Tedros Adhanom Ghebreyesus, DG WHO, aptly applies to local vaccines manufacturing in the LMICs. It is indeed a political choice that can only be exercised by one with a deep love for his country and people.















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