VACCINE AND BIOLOGICAL CENTER

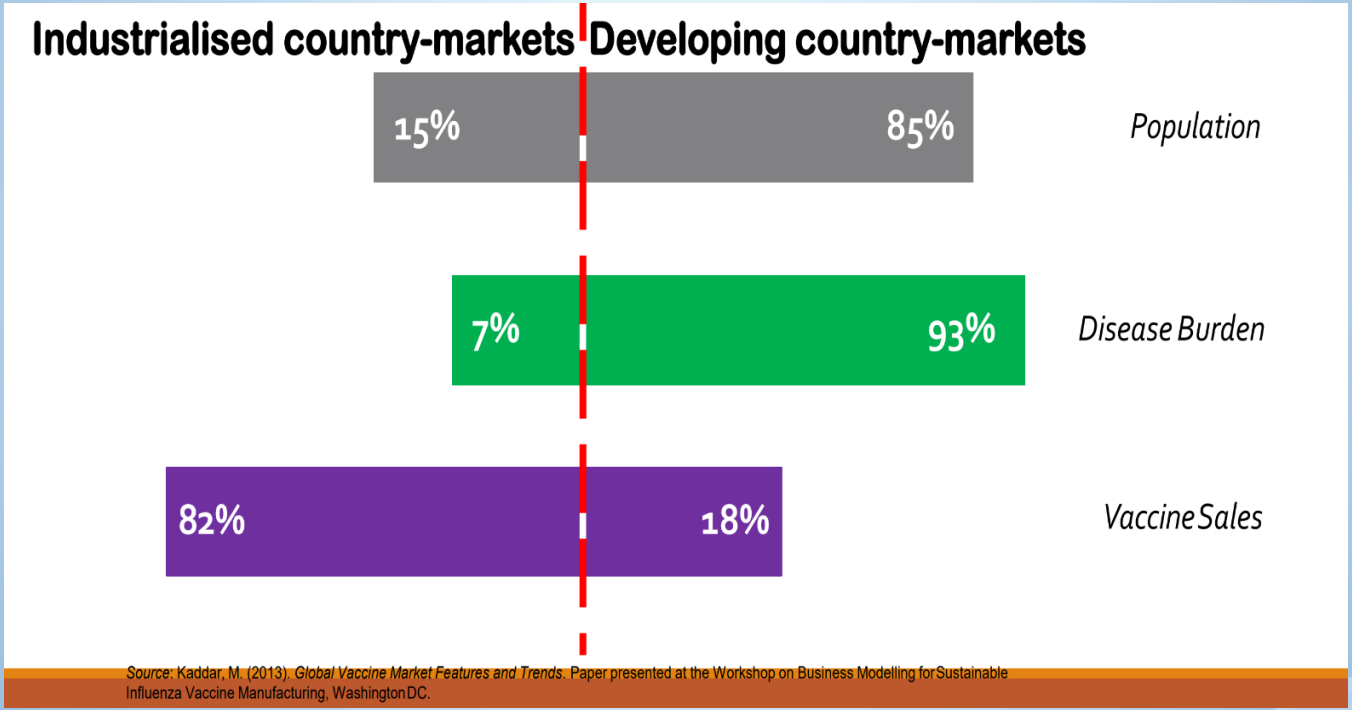
NIH, ISLAMABAD, PAKISTAN

Prof. Dr. Aamer Ikram (CEO, NIH)

WHO/MPP mRNA Technology Transfer Program

Cape Town, South Africa; 18 April 2023

Gap Between Vaccine Market



Source: Kaddar, M. (2013). *Global Vaccine Market Features and Trends*. Paper presented at the Workshop on Business Modelling for Sustainable Influenza Vaccine Manufacturing, Washington DC.

Economies of Scale

Volume Product Portfolio cGMP & Consistency of Production

- Number of vaccines manufactured >2
- Depending on the technology – production volumes on par with global average
- Percentage of lots failed <5%
- Consistent number of lots per year
- Consistent number of doses per lot
- Maintenance program and budget
- Planned, significant capital expenditure per year
- Quality assurance budget and program
- WHO-prequalified product(s) or plan to reach prequalification
- Customer's choice

CONTENTS

National Institutes of Health

- Since its inception in 1967, NIH is providing enormous public services to the country
- Various capacities like vaccine/sera production, surveillance, diagnostics, genomics, food and drug testing, and human resource development, etc.
- National COVID-19 response

01 **Biological Manufacturing**
Production of Vaccines, Anti-Sera and ORS

02 **CDC Pak & FETP**
Combating challenges of epidemics, outbreaks and emerging infections; surveillance; IDSR, etc; training programs

03 **PHLD**
Diagnostics, R&D, Genomics, etc
DCTMD
Analysis and testing the quality of drugs

04 **National Data Centre**

05 **Institute of Nutrition and Health**
Monitoring food safety & set nutrition standards through lab diagnosis and research

06 **Health Research Institute**
Clinical & Medical thematic research

Vaccine and Biological Center (VBC)

- Sole producer of vaccines and anti-sera in the **public sector**
- Products are manufactured in accordance with the international standards
- Vaccine production units are considered potentially viable as per Drug Regulatory, MoH and WHO
- Both EPI, Non-EPI vaccines and sera are manufactured

Functions of VBC

Production of vaccines and anti-sera

Promoting R&D, up-scaling of technologies and introducing newer vaccines

Collaboration with national & international research institutes

Conducting clinical trials

Organizing training courses for vaccine and biologic production

Overview of Current Capacities

Cell Culture Rabies Vaccine Production Laboratory

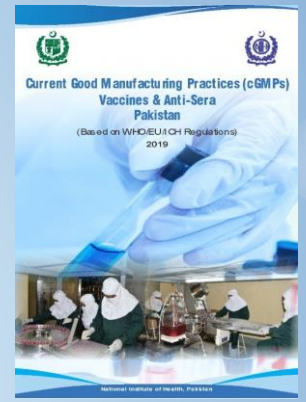
Sera Processing Laboratory

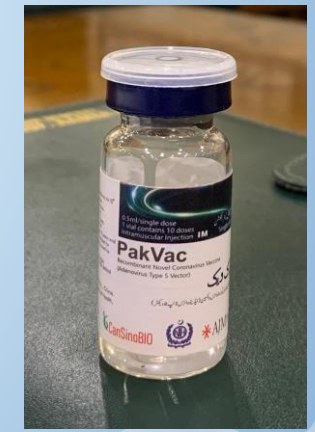
Tetanus Toxoid Production Laboratory

Measles Vaccine Production Laboratory

Typhoid Cholera Vaccine Production Laboratory

Others


Current Good Manufacturing Practices (cGMPs)
Vaccines & Anti-Sera
Pakistan
(Based on WHO/EU/ICH Regulations)
2019
National Institute of Health, Pakistan


PakVac
CanSinoBIO

Intended Applications of mRNA Technology

Beyong COVID-19
Development of mRNA based
Rabies Vaccine

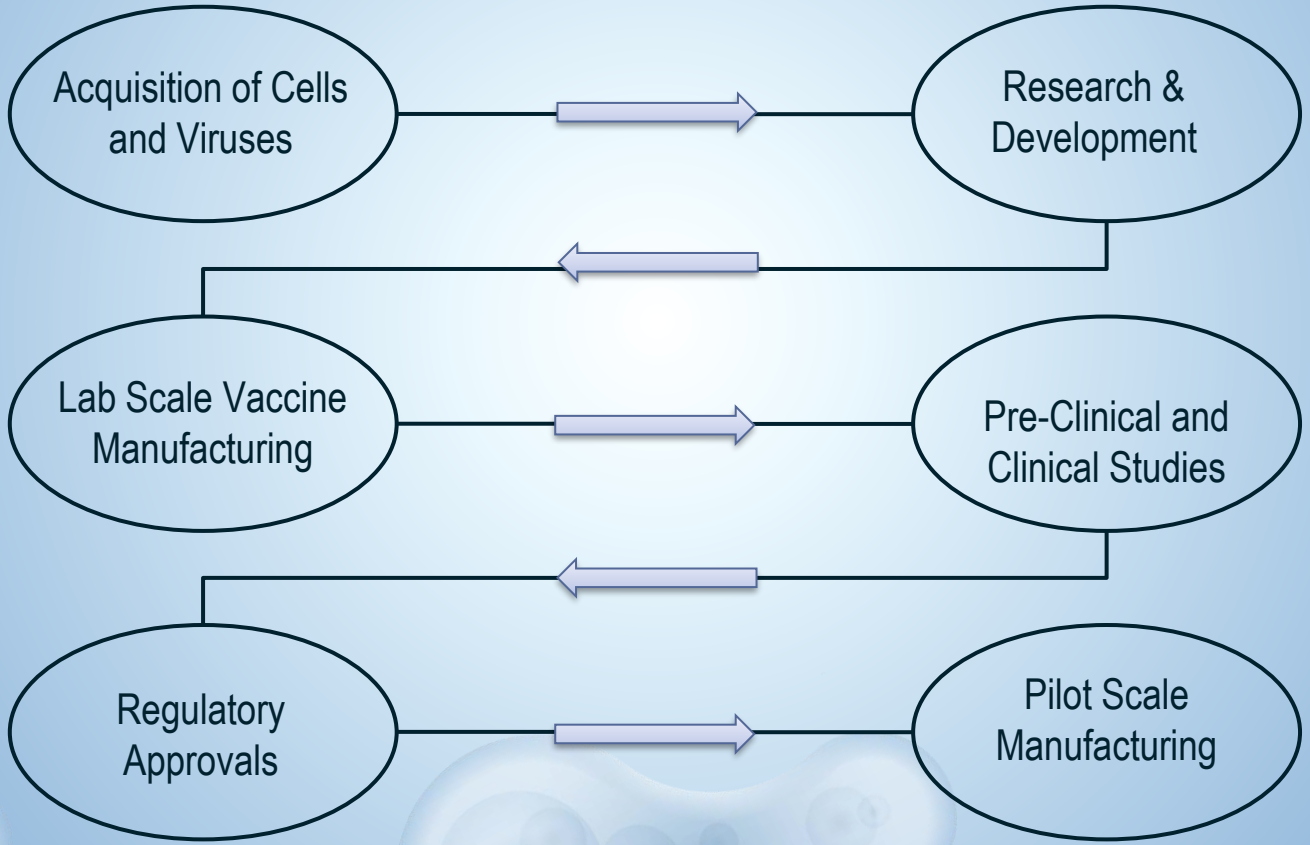
Development of mRNA based
other Vaccines
And it's utilization in cancer
therapy

Preparedness for Outbreak

Public – Private Partnership

Steps to Implement Technology Transfer

Flooding setback



Need of mRNA Technology in Pakistan

5th largest Population in the World

More than 50% of the population is below 30 years

A step towards Development

Acquiring mRNA technology would be a step forward for responding to emerging and re-emerging infectious disease

Self Sufficiency

Indigenous production of effective vaccine which would reduce the import bills and overcome the supply chain barriers

Preparation for Technology Transfer

HR

- Two teams of scientists trained at IVI Korea
- **Master trainers**
- Already trained staff available for GMP and vaccine production
- DRAP in loop

- Waiting for training: **Afrigen June 2023**

Facility

- **Class A, B and C facilities** available having sufficient space; designated for mRNA vaccine production
- Pre-Clinical Studies site (Animal House)
- **Clinical Trial Unit**

R&D

- **Consortium with academia**
  Talent Pool
- Studies on the RABV conserved regions for mRNA vaccine
- Exploring other options
- Expanding quality control
- **New R&D facility approved worth PKR 8 Bn**

Equipment

- Well developed labs
- For this project some of the dedicated new equipment is in process

EQUIPMENT

01 Filling Line

02 Tangential Filtration

03 Freeze Dryer

04 Walk in Incubator

05 -20 and -80 cold storage

06 HPLC

UTILITIES

01 Water treatment plant

02 Water purification system

03 Boiler / Chiller

04 HVAC

Our Mission

"To discover, develop and manufacture safe, effective and affordable vaccines/anti-sera for the country and region"

Ghazala Parveen
Chief Scientist

Firdous Nawaz Khan
Chief Engineer

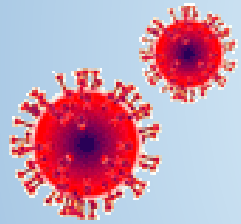
Rahim Shah
Principal Scientist

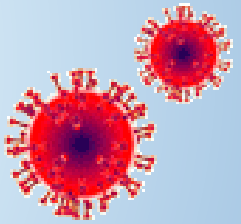
Conclusion

- We are enthusiastic to move actively with the project
- We have the abilities and trained human resource
- We would like to make it happen
- We would serve the humanity and contribute to the **global cause**

Challenges

Opportunities





Success

Afrigen
Biologics & Vaccines
An Avacare Health & IDC Company

World Health Organization

medicines patent pool

THANKS !

Cape Town