

WHO/MPP mRNA Technology Transfer Programme

The Westin Hotel, Cape Town, South Africa
Convention Square, Lower Long St, Cape Town, 8000
17-21 April 2023

Draft Agenda and Concept Note

Background

Announced on 21 June 2021, WHO and the Medicines Patent Pool established a Technology Transfer Programme for mRNA vaccines in South Africa, in order to build manufacturing capacity in LMICs to produce mRNA vaccines, in an effort to improve health security in LMICs through local and/or regional production of mRNA COVID-19 vaccines, as a primary target. The center for mRNA technology development and transfer comprises Afrigen/Biovac/South African Medical Research Council, South Africa, and will share technology and technical know-how with a network of technology recipients in LMICs. The Programme currently receives funding from European Commission, Belgium, France, Germany, as well as Canada, Norway, the African Union, South Africa and the ELMA foundation.

The mRNA Technology Transfer Programme has four main objectives:

1. Establish or enhance sustainable mRNA vaccine manufacturing capacity in regions with no or limited capacity;
2. Introduce new technologies in LMICs and promote regional research and development (R&D);
3. Strengthen regional biomanufacturing know-how and workforce development;
4. Develop regulatory capabilities and workforce to support and accelerate regional approval and distribution of mRNA vaccines;

This meeting, hosted at the Westin in Cape Town, is the first of a series of annual Face-2-Face meetings between the Programme Partners and key international stakeholders.

Objectives of the meeting - The proposed objectives are to:

- 1) Review the progress of the mRNA technology transfer Programme.
- 2) Share experience on vaccine development among the Programme Partners.
- 3) Review business models, intellectual property issues and regulatory aspects relevant to mRNA vaccines.
- 4) Review the science of mRNA technologies and discuss key applications relevant to LMICs.
- 5) Strengthen the mRNA R&D network and build communities among the Partners by R&D interests.
- 6) Highlight the role of technology transfer and establishment of manufacturing and R&D on national and regional economic development.

AGENDA

Monday 17 April 2023

Chair: Martin Friede, WHO

Time	Topic	Proposed speaker
8:00 – 9:00	Registration	
9:00 – 9:15	Opening remarks Context for and objectives of the meeting	Martin Friede, WHO Charles Gore, MPP / Jeremy Farrar, appointed Chief Scientist, WHO Claudia Nannei, WHO
9:15 – 10:15	Lessons learned from Technology Transfer Programme for influenza vaccines , 15 min Report from the Programme Overview of the mRNA Technology Transfer Programme: progress and key next steps, 15 min Programme implementation: report from the center for mRNA technology development and transfer, 30 min	Rick Bright, CEO Bright Global Health WHO/MPP Petro Terblanche Afrigen/Seanette Wilson, Biovac
10:15– 10:30	<i>Coffee Break</i>	
10:30– 12:00	Business Models and Sustainability Introduction Business models for sustainable mRNA vaccine manufacturing Techno-economic modelling of mRNA vaccine manufacturing Report from the WHO Council on the Economics of Health for All – key outcomes Q&A	C. Nannei, WHO Martin Nicholson, WHO Zoltan Kis, Univ. of Sheffield Els Torreele, WHO Council on the Economics of Health for All
12:00– 13:30	<i>Lunch</i>	
13.30 - 14:30	Regulatory environment <ul style="list-style-type: none"> Strategy to get a COVID-19 vaccine approved in South Africa, 15 min ML and Regulatory System Strengthening, 15 min mRNA technology: regulatory expectations and main challenges, 15 min 	Imelda Jordan, Afrigen Rogerio Pinto De Sa Gaspar, WHO Raj Long, BMGF

14.30-16:00	Development Agenda Discussion about investment in Biomanufacturing and economic development: intersection between public health policies, industrial policies, national and international finance, business development and economic progress	Sonia Tarragona, Chief of Cabinet, MoH Argentina Anna Lynch, Life Sciences and Health Division, European Investment Bank (virtual) Jürgen Kretz, Senior Policy Officer BMZ Germany Ammar Abdo Ahmed, Manager Human Development, Islamic Development Bank (virtual) Ken Osei, International Finance Corporation, World Bank Group
16:00– 16:30	Coffee Break	
16:30– 19:30	CLOSED SESSION - STeRCo	Breakout room - Moderated by MPP
16:30– 18:00	Biomanufacturing Training Global training hub in South Korea: progress and future plans, 10 min CLOSED SESSIONS TO THE PROGRAMME PARTNERS: Feedback on Biomanufacturing training	Eunkyung Shin, Ministry of Health and Welfare, Republic of Korea Moderated by A. Malachane, WHO
18.30	COCKTAIL	

Tuesday 18 April 2023

Chair: Marie-Paule Kieny, MPP

Time	Topic	Proposed speaker
9:00 – 10:00	Intellectual Property - IP Strategy of the Programme - IP landscape	Moderated by MPP Amina Larbi Chan Park
10:00 – 10:30	Presentation from the 15 Programme partners (mRNA technology recipients) Each 10 minutes	BioE Bio Manguinhos Biofarma
10:30 – 11:00	<i>Coffee Break</i>	
11:00 - 12:00	Presentation from the Programme partners Each 10 minutes	BioGeneric Pharma Biovac Biovaccines Nigeria Biovax Kenya

		Darnitsa Incepta
12:00 – 13:30	<i>Lunch</i>	
13:30 – 14:30	Presentation from the Programme partners - continued	Institut Pasteur Dakar Institut Pasteur Tunis NIH Pakistan Polyvac Sinergium Torlak Institute
14:30 – 15:00	<i>Coffee Break</i>	
15:00 – 16:30	Manufacturing and Process Development Key manufacturing steps, 10 min Training Certificates Ceremony, 15 min Presentation from Afrigen/Biovac supplier partners (manufacturing services), 15 min each	Caryn Fenner, Afrigen Caryn Fenner and Vetja Haakuria, Afrigen + Trainees José Castillo, Quantoom Walter Bronkhorts, Merck Kelly O'Donovan, Sartorius Greg Northfield, Separation Scientific Pirkko Muhonen, Thermo Fisher
16:30 - 18:00	Networking of Programme partners and Afrigen/Biovac supplier partners	Breakout rooms
16:30 – 18:00	CLOSED SESSION – Funders Forum	Moderated by MPP
From 18.00 – 20:30	Reception and Dinner at Utopia restaurant (transfer provided)	

Wednesday 19 April 2023

Chair: Richard Gordon, SAMRC

Time	Topic	Proposed speaker
9:00-9:15	Objectives of the R&D meeting	R. Gordon, M. Friede
9:15-10:15	WHO Science Council report on mRNA vaccines mRNA technologies, key applications, 30 min <ul style="list-style-type: none"> Key applications for vaccines against infectious diseases, veterinary and agricultural applications, and therapeutics Other RNA approaches (saRNA, circRNA) 	Adeeba Kamarulzaman, co-chair WHO Science Council Amin Khan, Afrigen
10:15-10:45	<i>Coffee Break</i>	

10:45 – 12:00	<p>mRNA technologies: what do we know and not know? 30 min</p> <ul style="list-style-type: none"> • How do mRNA vaccines work? • What do we know about the immunological memory response to mRNA vaccines • Key considerations on novel lipids and delivery materials • Known advantages and limitations of developing mRNA vaccines <p>Panel for discussion (45 min) Optimizing mRNA technologies in LMICs: key research priorities and main challenges</p>	<p>Drew Weissman, Univ. Pennsylvania</p> <p>Suhaib Siddiqi, mSAC Kiat Ruxrungtham, mSAC Petro Terblanche, Afrigen Sotiris Missailidis, Bio-Manguinhos</p>
12:00 – 13:30	<i>Lunch</i>	
13:30 – 15:00	<p>HIV vaccine development Lessons learned from HIV vaccine clinical trials (15 min)</p> <p>HIV vaccine development: key immunological considerations (15 min)</p> <p>HIV vaccine development: antigen design optimization approaches (15 min)</p> <p>Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?</p>	<p>Glenda Gray, South Africa Medical Research Council</p> <p>Larry Corey, Fred Hutchinson Cancer Center</p> <p>William Schief, Scripps Research Institute</p> <p>Speakers + Helba Bredell, Afrigen + TBD</p>
15:00 – 15:30	<i>Coffee Break</i>	
15:30 – 17:00	<p>Malaria vaccine development</p> <p>Status of late-stage malaria vaccines and clinical development considerations for 2nd generation malaria vaccines (15 min)</p> <p>Understanding of protective immune response against malaria across the parasite life cycle (15 min)</p> <p>The role of CHIM studies in accelerating malaria vaccine development: lessons learned from Kenya (15 min)</p>	<p>Annie Mo, NIAID (remote)</p> <p>Faith Osier, Imperial College London</p> <p>Melissa Kapulu, KEMRI</p>

	Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?	Speakers + Amy Bei, IPD (remote) + Programme Partners
17:00 18:00-20:30 20:30	COCKTAIL Travel to Kirstenbosch for South African Cultural evening Dinner Return trips to town start	

Thursday 20 April 2023

Chair: Michelle Mulder, SAMRC

Time	Topic	Proposed speaker
8:00 – 10:00	Breakfast meeting (open to journalists) Opening remarks from <ul style="list-style-type: none"> • Dr Tedros Adhanom Ghebreyesus– Director General of WHO • Minister Phaahla of Health • Minister Nzimande of Higher Education Science and Innovation • Minister Patel of Department of Trade and Industry • And distinguished guests Q&A session, 45 min Group Photo opportunity, 15 min	Moderator Charles Gore, MPP Remarks (full list of speakers will be provided on the day)
10:00-10:30	<i>Coffee break</i>	
10:30-11:30	Flavivirus (YF, dengue, Zika, JE...) Flaviviruses – key immunological considerations for vaccine development (10 min) mRNA vaccines against flaviviruses (10 min) Policy and market considerations for new flavivirus vaccines (10 min) Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?	Alan Barrett, UTMB (remote) Justin Richner, Univ. of Illinois at Chicago Erin Staples US CDC Speakers + Fernando Lobos, Sinergium + Amadou Sall, IP Dakar + Sotiris Missailidis, Bio-Manguinhos + TBD

11.30 – 12.00	Other relevant Diseases Key immunological considerations for Leishmaniasis vaccine development – 10 min Prequalification of a rabies vaccine, 10 min Polio presentation, 10 min	Mélika Ben Ahmed, Institut Pasteur Tunis Carmen Rodriguez, WHO (remote) Ondrej Mach, WHO (remote)
12:00 – 13:30	<i>Lunch break</i>	
13:30 – 14:30	Emerging infectious diseases (e.g. RVF, CCHF, Ebola) mRNA vaccines against CCHF (10 min) Rif Valley Fever: key immunological considerations for vaccine development (10 min) mRNA vaccines against Filoviruses and Lassa Fever (10 min) Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?	Ali Mirazimi, Public Health Agency of Sweden Anita McElroy, Univ. of Pittsburgh Alexander Bukreyev, UTMB (remote) Speakers + Programme Partners + C. Schmaljohn, mSAC + Marie-Angélique Sène, IP Dakar (remote)
14:30 – 15:30	STI (e.g. HPV, HSV, Gonorrhea) Immune evasion strategies of HSV and the potential value of developing mRNA candidate vaccines against HSV – 10 min Key immunological considerations for HPV vaccine development – 10 min Gonorrhea: key immunological considerations for vaccine development and potential cross-protection with 4CMenB – 10 min Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?	Akiko Iwasaki, Yale School of Public Health (remote) John Schiller, National Cancer Institute, US NIH (remote) Kate Seib, Griffith Univ. Speakers + Amin Khan, Afrigen + Ivana Lukić, Torlak + Imran Khan, Incepta + TBD
15:30 – 16:00	<i>Coffee break</i>	
16:00 – 17:30	Respiratory Diseases (e.g. flu, RSV) Afrigen RSV Vaccine Product Development Plan (10 min)	Amin Khan and Mani Margolin, Afrigen

	<p>Current approaches to seasonal and pandemic influenza vaccines: advantages and limitations of mRNA vaccines (10 min)</p> <p>Adapting the annual influenza vaccine strain selection recommendation process to mRNA influenza vaccines (10 min)</p> <p>Policy considerations and market opportunities for mRNA seasonal influenza vaccines (10 min)</p> <p>Panel discussion: Will a mRNA candidate vaccine be able to induce protective immunity when other candidate vaccines have failed to do so? Will a mRNA candidate be competitive to other candidate on the market ? What are the key foreseeable risks?</p>	<p>Danilo Casimiro, mSAC</p> <p>Kanta Subbarao, Doherty Institute</p> <p>Joseph Bresee, Task Force for Global Health</p> <p>Speakers + Programme Partners + B. Graham, mSAC + V. Paradkar, BioE + F. Lobos, Sinergium + Luka Dragačević, Torlak + Mainul Ahasan, Incepta + Sotiris Missailidis, Bio-Manguinhos</p>
17.30 – 17.45	Closing Remarks	Charles Gore, MPP / WHO
17:30 – 19:00	CLOSED SESSION MSAC	Moderated by MPP

Friday 21 April 2023

Chairs: Tom Scriba & Willem Hanekom

Time	Topic	Proposed speaker
	Tuberculosis vaccine development	Key experts
09.00 – 09.20	Introduction and objectives, including regional pathogen prioritization exercise	Chairs & Birgitte Giersing (WHO)
09.20 – 09.30	Recap of learnings from the mRNA meeting	Martin Friede
09.30 – 09.45	Overview of the TB vaccine pipeline	Mark Hatherill (SATVI)
09.45- 10.05 (15+5)	- Potential TB target antigens: What do we know, what's new?	Munya Musvosvi (SATVI)
10.05 – 10.25 (15+5)	Potential correlates for new TB vaccines	Nicole Frahm (Gates MRI)
10.25– 11.00	<i>Coffee break</i>	
11.00 – 11.25 (20+5)	Preclinical profiling of lung granulomas to probe for potential correlates	JoAnne Flynn (Uni of Pittsburgh)
11.25 – 12.00 35 mins	How do we screen and down select optimal mRNA candidates?	Facilitated discussion Tom Scriba (SATVI) & Willem Hanekom (AHRI)
12.00 – 12.30 30 mins	- Panel 1: Considerations related to acceptability of mRNA-based TB vaccines	Ben Kagina – VACFA Mike Frick – TAG (TBC) Zacharia Kafuko – 1daysooner
12.30– 13.30	<i>Lunch break</i>	
13.30 – 14.10	Panel 2: Clinical development considerations for mRNA vaccines Perspectives from regulators and WHO SAGE	Alex Schmidt - Gates MRI PEI – Julius Pollinger SAPHRA – James Southern WHO – Annelies Wilder-Smith
14.10 – 14.45	Panel 3: Perspectives from mRNA spokes on the viability and business case for mRNA-based TB vaccines	Biovac – Patrick Tippoo BioE - Vikram Paradkar Torlak – Dušan Popadić
14.45	<i>ADJOURN</i>	