AMENDMENT AND RESTATEMENT AGREEMENT TO THE mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT

THIS AMENDMENT AND RESTATEMENT AGREEMENT TO THE mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT (this "**Amendment**") is made as of August 22nd, 2024 (the "**Amendment Effective Date**")

BETWEEN:

THE MEDICINES PATENT POOL FOUNDATION, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva ("**MPP**"); and

THE BIOLOGICALS AND VACCINES INSTITUTE OF SOUTHERN AFRICA, a company incorporated under the laws of South Africa and having its registered office at 15 Alexandra Road, Pinelands, 7405, Cape Town, South Africa ("**Biovac**"),

with the MPP and Biovac, collectively referred to as the "**Parties**".

RECITALS

WHEREAS, MPP and Biovac entered into an mRNA Vaccine Technology Transfer Agreement dated 04 August 2022 (the "**Agreement**") as part of the mRNA Technology Transfer Programme, based on which MPP will enable the transfer to Biovac of a technology developed by Afrigen for the manufacture of mRNA-based vaccines, and **Biovac** is willing and able to receive this technology, and in return, is willing to make certain commitments as to what **Biovac** will do with such technology;

WHEREAS, MPP and Biovac wish to amend and restate the Agreement to (i) amend Annex 1, Annex 2, Annex 4, Annex 5 and Annex 6 of the Agreement and (ii) make other amendments to the Agreement; and

NOW THEREFORE, based on the foregoing premise and in consideration of the mutual covenants and obligations contained herein and other good and valuable consideration, the receipt, adequacy, and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

AGREEMENT

1. **Definitions.** All capitalized terms not otherwise defined herein shall have the meanings assigned to them in the Restated Agreement.

2. **Amendment and Restatement.** The Agreement is, with effect from the Amendment Effective Date, amended to take the form set out in Schedule 1 to this Amendment, which restates the Agreement as amended by this Amendment (the "**Restated Agreement**").

3. **General.**

   3.1. **Amendments.** No provision of this Amendment may be modified or amended except expressly in writing signed by both Parties.

   3.2. **Governing Law and Jurisdiction.** The provisions of Section 17 (*Governing Law and Jurisdiction*) of the Restated Agreement are hereby incorporated into this Amendment as if set out herein.

   3.3. **Counterparts.** This Amendment may be executed in any number of counterparts, and by the Parties on separate counterparts, but shall not be effective until each Party has executed at least one counterpart. Each counterpart shall constitute an original of this Amendment, but all the counterparts shall together constitute but one and the same instrument.

IN WITNESS WHEREOF the Parties have executed this Amendment by their duly authorised officers.

Signed for and on behalf of:

THE MEDICINES PATENT POOL FOUNDATION

Signature: DocuSigned by: Jane Caldwell 90E6E01A6B7A46C...

Name: **Jane Caldwell**

Position: **Chief Operating Officer**

Date: 22 August 2024

Signed for and on behalf of:

BIOVAC

Signature : DocuSigned by: Morena Makhoana 879E633E5DFF4CF...

Name: **Morena Makhoana**

Position: **CEO**

Date: 24 August 2024

Schedule 1

Restated Agreement

mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT

THIS mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT (this "**Agreement**") is made as of 04 August 2022 (the "**Effective Date**") and is amended and restated on the August 22nd, 2024 ("**Amendment Effective Date**").

BETWEEN:

THE MEDICINES PATENT POOL FOUNDATION, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembé 7, CH-1202 Geneva ("**MPP**"); and

THE BIOLOGICALS AND VACCINES INSTITUTE OF SOUTHERN AFRICA, a company incorporated under the laws of South Africa and having its registered office at 15 Alexandra Road, Pinelands, 7405, Cape Town, South Africa ("**Biovac**"),

with the MPP and Biovac collectively referred to as the "**Parties**".

WHEREAS, MPP, in collaboration with the World Health Organization ("**WHO**"), has established the mRNA Technology Transfer Programme with the aim to establish or enhance sustainable mRNA vaccines manufacturing capacity in low- and middle-income countries ("**LMICs**"), in particular to improve the ability of such countries to better respond to the COVID-19 pandemic and other future pandemics;

WHEREAS, MPP has engaged with Afrigen Biologics (PTY) LTD ("**Afrigen**") to develop an mRNA technology platform for deployment into LMICs for this purpose;

WHEREAS, MPP has secured contractual commitments from Afrigen to transfer the technology of such mRNA technology platform to selected recipients;

WHEREAS, MPP has obtained sublicensable rights to Afrigen intellectual property, Know-How and data;

WHEREAS, Biovac has been identified by WHO as a suitable recipient of the mRNA technology platform;

WHEREAS, Biovac is willing and able to receive this technology, and in return, willing to make certain commitments as to what Biovac will do with such technology; and

WHEREAS, MPP is willing to provide financial support to Biovac to further develop this technology and have Biovac make additional technology transfers available to additional recipients as selected by WHO;

NOW THEREFORE in consideration of the covenants and obligations expressed in this Agreement, and intending to be legally bound, the **Parties** agree as follows:

1 DEFINITIONS

1.1 "**Affiliate**", in relation to an entity, shall mean any corporation, firm, partnership or other entity which is directly or indirectly controlled by, in control of, or under common control with such entity. For the purposes of this definition, "**control**" shall mean the ability of any corporation, firm, partnership or other entity, whether through ownership of shares or otherwise, to procure that the affairs of an entity are conducted in accordance with the wishes of such corporation, firm, partnership or other entity.

1.2 "**Afrigen Rights**" shall mean the sublicensable rights to data, Know-How and IP that was granted from Afrigen to MPP under the MPP-Afrigen Grant Agreement dated 21 January 2022, as amended from time to time.

1.3 "**Confidential Information**" shall mean all information that would reasonably be regarded as, or is designated as, of a confidential or commercially sensitive nature by the person to which the information relates including, without limitation, the Know-How and any matter relating to, or arising in connection with, this Agreement or the business or affairs of any of the Parties or any of their Affiliates, as amended from time to time.

1.4 "**Cost of Production**" shall mean the total of the following:

(a) raw material costs

(b) raw material wastage

(c) packaging material costs

(d) packaging material wastage

(e) costs of quality control testing

(f) transport costs

(g) warehousing at the request of WHO or the Public Sector Agency

(h) direct energy costs in production

(i) direct labour costs

(j) direct labour-related overheads

(k) amortization on capital investment provided by the Company:

(l) allocable portion of building used in connection with the production of the Product, over a period of 25 years.

(m) machinery or related equipment used in the production of the Product over a period of 5 years.

(n) fixed overheads for the manufacturing site

(o) allocable general and administrative costs

(p) other financial charges as specifically applicable to the sale of the Product

(q) interest charges on investment in the production and sale of the Product

(r) research and development costs directly attributable to the production of the Product

1.5 "**Event of Force Majeure**" shall have the meaning given in Section 12.

1.6 "**Facility**" shall mean the area in the Biovac premises where the intended transferred technology will be operationalized.

1.7 "**Funded Project**" shall mean the Biovac activities described in the Scope of Work and financed by the Budget described in Annex 6.

1.8 "**Funders**" shall mean Third Parties that provide financial support to the Project or Funded Project, either through MPP or directly to **Biovac**.

1.9 "**Inventions**" shall mean all ideas, inventions, discoveries, data or Know-How conceived, first created or made in the performance the Project.

1.10 "**IP**" shall mean any and all rights in or to intellectual property, whether subsisting now or in the future, anywhere in the world, whether registered or not, including any and all rights in or to patents, supplementary protection certificates, utility models, rights to inventions, copyright and neighbouring and related rights, trade marks, business names and domain names, rights in get-up and trade dress, goodwill and the right to sue for passing off, rights in designs, rights in computer software, database rights, rights to use, and protect the confidentiality of, confidential information (including Know-How), any other rights and other rights of a similar nature, in the case of each of the foregoing, including all applications, and rights to apply, for registration, renewals or extensions, reissues, divisions, revisions, renewals, extensions, provisionals, continuations and continuations-in-part.

1.11 "**Know-How**" shall mean any and all confidential and proprietary information and materials, discoveries, processes, methods, protocols, formulas, molecular constructs, reagents, assays, data, results, inventions, improvements, trade secrets, compositions of matter (including compounds), formulations, and findings, in each case, patentable or otherwise, and including any copyrights therein.

1.12 "**Materials**" shall mean the materials described in Annex 2.

1.13 "**Product(s)**" shall mean any product developed by Biovac which receives Regulatory Approval by a Relevant Regulatory Authority, and which is entirely or partially based on the Technology.

1.14 "**Programme Agreement**" shall mean any other agreement entered into between **MPP** and a Third Party as part of the Project under which **MPP** is granted rights to data, Know-How or IP for further sublicensing.

1.15 "**Project**" shall mean the mRNA Technology Transfer Programme.

1.16 "**Public Sector Agency**" shall mean: (a) the following organisations to the extent that they are not for profit organisations: (i) Governments including without limitation government ministries and agencies, together with government-funded institutions and programs, such as state-run hospitals and prison services in those countries; (ii) NGOs including without limitation those recognized by the applicable local government ministry; (iii) UN-related organizations working for or in those countries, including but not limited to WHO, UNDP, PAHO and UNICEF; (iv) Not-for-profit organizations including without limitation, Médecins Sans Frontières, Save-the-Children, OXFAM and the International Committee of the Red Cross (ICRC); (v) Funding mechanisms and programs funded by such mechanisms, including without limitation, UNITAID, PEPFAR, USAID, Global Fund, GAVI, AVAT, etc.; and agencies based outside of an applicable country to the extent that they are supporting implementation locally in an applicable country, and (b) nominally for profit procurement organisations but only to the extent that such procurements are supporting not-for-profit treatment programmes as described in (a) of this Section.

1.17 "**Regulatory Approval**" shall mean the receipt of a marketing authorisation associated with that Product in a country.

1.18 "**Relevant Regulatory Authority**" shall mean (i) in relation to a particular country in the Territory, any applicable federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Products in that country, or (ii) WHO pre-qualification programme where such approval has been deemed adequate by the authority referred to in (i).

1.19 "**Scope of Work**" shall mean the scope of work set out in Annex 5.

1.20 "**Technical Assistance**" shall mean the assistance detailed in Section 2.4 of this Agreement.

1.21 "**Technical Information**" shall mean the documentation listed in Annex 3 and Annex 4 detailing technical specifications and instructions for manufacturing and testing the selected mRNA vaccine candidate. Such Technical Information shall be transferred to Biovac (Annex 3) or

provided by Biovac (Annex 4) written in the English language and in a single copy.

1.22 "**Technology**" shall mean Materials, Technical Information and Technical Assistance.

1.23 "**Technology Transfer**" shall mean a logical procedure that controls the transfer of any process together with its documentation and professional expertise from development to manufacture or between manufacturing sites. It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party. Technology transfer embodies both the transfer of documentation and the demonstrated ability of Biovac, to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies. The specific contents of the Technology Transfer to Biovac are detailed in Annex 3 (Technical Information, Technical Assistance, Materials), and the specific contents of the Technology Transfer Technical Information that Biovac will generate is detailed in Annex 4.

1.24 "**Technology Transfer Package 1**" shall have the meaning described in Annex 3.

1.25 "**Technology Transfer Technical Information Package 2**" shall have the meaning described in **Annex 4**.

1.26 "**Territory**" shall mean all low- and middle-income countries, as defined by the World Bank.

1.27 "**Third Party(ies)**" shall mean any party other than a **Party** to this Agreement.

2 TECHNOLOGY TRANSFER

2.1 MPP will cause the Technology Transfer to be conducted in accordance with the roadmap as described in Annex 1. The Technology Transfer to Biovac will comprise of Technology Transfer Package 1, as described in Annex 3, called *"mRNA technology for R&D"* (hands-on and mandatory), which will be finalized once Phase 1 Clinical trial material is manufactured and released. Content of Technology Transfer Package 1 will be made accessible to Biovac as soon as information is available. The Parties will meet and confer following the Effective Date to agree on a Technology Transfer Plan setting out the timeline for the delivery of Technical Transfer Package 1, as well as detailing actions, reporting, deliverables, and success criteria linked to the Technology Transfer (the "**Technology Transfer Plan**").

Before Technical Transfer activities take place, Biovac will access an introduction to the mRNA technology training provided by Afrigen (timelines to be agreed upon between the Parties) and associated training material (Introduction to the mRNA Technology Package).

2.2 The Parties acknowledge that the timelines agreed in a Technology Transfer Plan are of paramount importance for planning purposes. In the event that the agreed timelines of any section of a Technology Transfer Plan changes after being agreed between the Parties, for any reason whatsoever including an Event of Force Majeure, the Parties agree to meet and discuss the potential changes and how it can be accommodated within any commercial obligations or other commitments which a Party may have towards a Third Party. While every reasonable effort will be made to accommodate changes to agreed timelines, the Parties agree and acknowledge that this cannot be guaranteed. If any amended timelines cannot be met by either Party, the Parties undertake to apply commercially reasonable efforts to continue the Project on amended timelines as soon as feasible.

2.3 The Technology Transfer Package 1 shall be considered complete by the Parties when Biovac has received the Technology and the Parties are satisfied that the production of the selected mRNA vaccine candidate meets the requirements outlined in the Technology Transfer Plan.

2.4 As part of Technology Transfer Package 1, MPP will, on dates to be agreed to by the Parties, cause Afrigen to provide Technical Assistance to Biovac, as follows:

(a) Training at Afrigen's site by sending qualified Biovac personnel to the Afrigen Facility

for training on documentation and Phase I manufacturing process and analytics.

(b) Respond in a reasonable timeframe to any query concerning the Technology Transfer Package 1 that might arise during and after the on-site training.

(c) Should any additional on-site Technical Assistance (e.g. on-site assistance of Afrigen personnel at the Biovac Facility, additional on-site training at Afrigen) be requested by Biovac beyond Sections 2.4(a)-(b), Biovac shall bear all allowance, travel and accommodation expenses incurred.

2.5 Any additional services associated therewith and the means of delivery thereof not provided for in this Agreement shall, as the need for same arises i.e. assist in data analysis, non-routine investigations, be negotiated for and agreed to by the Parties in writing, prior to implementation thereof.

3 OBLIGATIONS OF MPP

MPP undertakes to:

3.1 Work with WHO to assess Biovac capabilities and identify actions and deliverables for the Technology Transfer to Biovac to proceed, as well as to convene appropriate expertise to support Technology Transfer to Biovac, as feasible and may be necessary.

3.2 Ensure Biovac is provided with the Technology reasonably necessary to fulfil the transfer of Technology Transfer Package 1, as contemplated in Annexes 1 and 3 herein.

3.3 Work with WHO to facilitate the strengthening of the Relevant Regulatory Authority as may be required in the Territory to enable Regulatory Approval of the vaccine and facilitate WHO pre-qualification.

3.4 Provide IP analysis on the Technology, as practicable and appropriate and endeavour to provide better visibility on freedom to operate analyses in the Territory.

3.5 Monitor the activities of Biovac and the parties to other Programme Agreements to ensure good coordination and facilitate the sharing of data, Know-How and IP as provided for in this Agreement and other Programme Agreements.

3.6 In consultation with WHO, design and draft any further governance or technology transfer documents and provide on-going technical support as necessary and as feasible to fulfil the objectives of the Agreement within the agreed timeframes.

4 OBLIGATIONS OF BIOVAC

Biovac undertakes to:

4.1 Exercise due diligence in performing the actions and deliverables presented in the Roadmap (Annex 1) and detailed in the Scope of Work (Annex 5) and the Technical Transfer Plan.

4.2 Provide technical reports to MPP detailing the progress made towards achieving the milestones defined in the Scope of Work. Biovac agrees that such reports will be treated as Confidential Information, but that they will be shared with WHO and any other Third Party as may be agreed between the Parties under confidentiality obligations no less stringent than contained in this Agreement.

4.3 Conduct any facility upgrades, equipment procurement and qualification, receive applicable approvals from the Relevant Regulatory Authority and perform any other activity necessary to ensure that the Facility is fit for the purposes for applying the Technology at the time of Technology Transfer.

4.4 Ensure that all Biovac personnel involved with the Technology Transfer be sufficiently qualified to as to ensure an efficient and effective transfer of the Technology.

4.5 Following the completion of Technology Transfer Package 1 from Afrigen as per the criteria outlined in Annex 3, perform all activities detailed in the Scope of Work (Annex 5) and the Technical Transfer Plan in order to provide MPP with the Technology Transfer Technical Information Packages 2a and 2 (Annex 4).

4.6 In the event that Biovac develops and commercialises a Product that is responsive to a Public Health Emergency of International Concern as declared by WHO, to as soon as practically possible make available no less than ten percent of its real-time production capacity of Product for WHO and/or Public Sector Agencies at a price to be negotiated in good faith, but in no event to exceed its Cost of Production plus a twenty percent mark-up.

4.7 In the event that Biovac uses the Technology to commercialise a Product, file for WHO Pre-Qualification or Emergency Use Listing, if available and appropriate.

4.8 Allow the presence of Afrigen personnel at Biovac, as nominated and mutually agreed between the Parties and for a period as described in the Technology Transfer Plan, to ensure the technology is successfully transferred to Afrigen and subsequent manufacturing and analytical processes knowledge transfer to subsequent receiving units happens smoothly.

4.9 Respond within a reasonable timeframe to any query concerning any component of the Technology Transfer Information Package 2 (Interim Technology Transfer Information Package 2a and/or Technology Transfer Information Package 2) that might arise during subsequent technology transfers to other receiving units in the mRNA Technology Transfer Programme.

4.10 Additional services may be negotiated and agreed upon before implementation.

4.11 Comply with all terms of the Grant Agreement between MPP and Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) dated 15 December 2023 ("GIZ Agreement") as contained in Annex 8 of this Agreement as if it was MPP under that GIZ Agreement, where relevant. Biovac acknowledges that the funds received from MPP under this Agreement partially derive from the GIZ Agreement.

5 PROJECT MANAGEMENT

The Parties will form a joint project management committee (the "**Project Committee**") to oversee and facilitate the implementation and execution of the Project, to receive and review technical reports, and to review proposed changes to the Project scope, timeline and/or Budget. Each Party will have the right to designate its representatives (which may be consultants or advisers subject to the relevant terms and conditions set out herein) to the Project Committee and may replace its representatives upon notice to the other Party. The Project Committee may meet virtually or in person at mutually agreeably times and locations. All decisions at the Project Committee shall be taken unanimously. In the event the consensus cannot be reached, the matter shall be submitted to the executive director of each Party and in case the issue remains unsolved for 3 months from its first referral, the matter shall be resolved in accordance with Section 17.

6 GRANT PAYMENT AND USE OF FUNDS

6.1 Subject to the terms and conditions of this Agreement, and Biovac's compliance therewith, MPP will fund Biovac for performing the Funded Project in accordance with the approved budget attached as Annex 6 ("**Budget**"). The maximum amount hereunder shall not exceed the amount of 286 M ZAR. Subject to Section 10.2, MPP shall have the right to increase or decrease the total amount of the grant in accordance with the needs and the performance of the Funded Project.

6.2 The funds provided under this Agreement are to be spent by Biovac exclusively in accordance with the Budget. Biovac shall have the right to perform Budget revisions on a quarterly basis. Biovac shall request MPP's prior written approval if there is a variance of +/- 10% between the

main budget categories. Any request for Budget modification must include sufficient documentation to justify such request. For the avoidance of doubt, no Budget revision or variance of the Budget'categories that is permitted under this Section 6.2 shall result in Biovac spending in excess of the total Grant. Any overspending on Budget will be at the cost of Biovac, unless otherwise agreed between the Parties.

6.3 MPP shall make payments of the grant hereunder on a quarterly basis upon receipt of collectively the following:

(a) the disbursement request from Biovac based on the Project requirements ("**Disbursement Request**"), plus an estimated rolling advance of one month.

(b) financial report in accordance with this Agreement regarding the previous payment, showing the extent of the previous payment spent in accordance with the Budget.

(c) satisfactory technical report in accordance with Section 4.2.

6.4 MPP shall pay the amounts in accordance with each Disbursement Request within 30 days from its receipt via a bank transfer to the Biovac account set forth in Annex 6.

6.5 Biovac will submit to MPP quarterly financial reports in the format as indicated in Annex 6, and:

(a) be sent within 10 – working days after the end of each calendar quarter;

(b) be issued in ZAR currency;

(c) contain the comparison between the actual spending versus the budgeted amounts;

(d) be certified as complete and accurate by an authorized official of Biovac for the activities performed; and

(e) be sent to the address set forth in Annex 6.

6.6 In addition to quarterly financial reports under this Agreement as per Section 6.5, Biovac shall provide to MPP an audited annual statement comprising the following elements by the 15th April of each year:

(a) a project audit report based on a procedure mutually agreed between MPP and Biovac; and

(b) a questionnaire, in a format to be provided by MPP, regarding the use of funds under this Agreement. Such questionnaire shall be signed by an auditor mutually agreed upon by the Parties.

6.7 Biovac shall submit a final statement of cumulative costs incurred marked "FINAL" to MPP no later than 60 days after completion or termination of the Funded Project. The final statement of costs shall constitute the final financial report of Biovac. All payments hereunder shall be provisional and subject to adjustment within the total estimated cost under this Agreement in the event such adjustment is the result of a finding against Biovac pursuant to Section 6.13.

6.8 Biovac acknowledges and agrees that the Grant is provided to Biovac solely for the purposes of Biovac performing the activities set out in the Scope of Work. Biovac shall enter into the necessary sub-agreements and perform the necessary administrative activities to ensure the performance of the activities set out in the Scope of Work. Biovac shall not use the Grant to perform activities outside the Scope of Work unless as otherwise agreed to in writing by the Parties.

6.9 During the Project, Biovac shall use the equipment, materials or goods, purchased or generated with the Grant primarily for the purpose of the Project. Biovac may use such equipment,

materials or goods for purposes other than the Project provided that such use does not interfere with, compete with or delay the Project. If MPP reasonably suspects or becomes aware that Biovac's use of such equipment, materials or goods has interfered with, competed with or delayed the Project, upon the request of MPP, Biovac shall promptly provide MPP with documentary evidence demonstrating such has not occurred or such has been remedied.

6.10 Title to any equipment, materials or goods purchased or generated with the Grant shall vest in Biovac provided Biovac uses such in accordance with Section 6.9. Notwithstanding any other provision in this Agreement, if Biovac does not use such equipment, materials or goods in accordance with Section 6.9, MPP may direct Biovac to sell, donate or otherwise transfer such equipment, materials or goods, and reimburse MPP the fair market value of such, if applicable.

6.11 Without limiting Section 6.10, subject to MPP's prior written consent, during or after the Project, Biovac may:

(a) replace or substitute any equipment, materials or goods purchased or generated with the Grant with new or improved equipment, material or goods; or

(b) sell, donate or otherwise transfer any equipment, materials or goods purchased or generated with the Grant, and reimburse MPP the fair market value of such equipment, materials or goods, if applicable.

6.12 Biovac shall maintain supporting documentation for all costs associated with the Funded Project, including records substantiating time and/or percentage of effort for all salaries paid or funds expended with funds provided under this Agreement. All records and documentation related to this Agreement shall be maintained in accordance with applicable laws and regulations and generally accepted accounting principles for a period of five years from completion of the Funded Project.

6.13 MPP or its authorized representative shall have the right to review and audit all costs alleged to have been incurred hereunder and those records required by Section 6.12 at agreed upon times and locations. Biovac shall provide MPP with copies of any audit report which presents any instance of noncompliance with laws or regulations relating to the performance or administration of this Agreement. Biovac shall also provide copies of any response to any such report and a plan for corrective action. Biovac shall maintain a separate accounting cost code specific to this grant, and all costs and income properly relating to this grant shall be accounted for through that cost code. Biovac shall ensure that appropriate records are kept supporting the entries made on the cost code.

7 GRANT OF LICENCE AND INTELLECTUAL PROPERTY

7.1 Subject to the terms and conditions of this Agreement MPP hereby grants to Biovac:

(a) a non-exclusive, royalty-free, non-sublicensable, non-transferable, irrevocable, fully paid-up, royalty-free licence under the Technology and the Afrigen Rights to make, or have made, use, offer for sale, sell, have sold, export or import Product(s) in the Territory.

(b) as necessary, a non-exclusive, royalty-free, non-sublicensable, non-transferable, irrevocable, fully paid-up, royalty-free licence under any Inventions to which MPP has or will acquire sublicensable rights from other Programme Agreements to make, or have made, use, offer for sale, sell, have sold, export or import Product(s) in the Territory.

7.2 Biovac grants to MPP a non-exclusive, non-transferable but sublicensable, irrevocable, fully paid-up, royalty-free, licence to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in the Territory. In the event that MPP wishes to make such Inventions available for other purposes, MPP and Biovac will enter into good-faith negotiations. Biovac agrees to provide to MPP a licence in relation to any of its background rights only to the extent necessary to enable the use and exercise of the Inventions made by Biovac hereunder.

7.3 In the event that Biovac is provided with access to Third Party IP for the purposes of research, development and/or commercialization of Product(s), Biovac undertakes to use reasonable efforts to negotiate a licence to MPP for such Third Party IP under the same or similar terms as provided for in Section 7.2 herein.

7.4 MPP shall have the right to share any data generated under the Project with WHO for further sharing with any Third Parties for the purposes of fulfilling its mission to facilitate the development and equitable access of mRNA technologies in the Territory.

8 EXCHANGE OF INFORMATION AND CONFIDENTIALITY

8.1 Each Party shall hold the Confidential Information disclosed to it under or in connection with this Agreement in strict confidence, and shall not use such Confidential Information for any other purpose than the performance of this Agreement.

8.2 The Party that releases, exchanges, or discloses Confidential Information (the "**Disclosing Party**") shall use reasonable efforts to mark such Confidential Information as "Confidential." In the event that Confidential Information is disclosed and not so marked, the receiving Party agrees to treat such information as confidential to the extent that a reasonable person would consider such information to be confidential given the content and circumstances of the disclosure.

8.3 Neither Party shall disclose any Confidential Information received from the other Party under or in connection with this Agreement, or otherwise developed by any Party in the performance of activities in furtherance of this Agreement, except to such of its officers, employees, agents, representatives, Affiliates, advisors and consultants, governing bodies to whom disclosure is necessary to exercise the Party's rights or perform the Party's obligations under this, and who are bound by confidentiality and non-use obligations no less onerous than those contained in this Section 8.

8.4 The obligations in Sections 8.1, 8.2 and 8.3 shall not apply to the following as established by reasonable, written proof:

(a) information which at the time of disclosure is in the public domain; or

(b) information which, after its disclosure, becomes part of the public domain by publication or otherwise, except by breach of this Agreement; or

(c) information that a Party can demonstrate was lawfully possessed by it prior to disclosure under or in connection with this Agreement; or

(d) information that a Party receives from a Third Party which is not legally prohibited from disclosing such information; or

(e) information a Party is required by law to disclose, provided that the other Party is promptly notified of any such requirement: or

(f) information which is independently developed by the receiving Party or its Affiliates who had no knowledge of the Disclosing Party's Confidential Information.

8.5 If a receiving Party becomes obligated by law to disclose Confidential Information received under or in connection with this Agreement, or any portion thereof, to any Third Party, governmental authority or court, that Party shall immediately notify the Disclosing Party of each such requirement and identify the Confidential Information to be disclosed so that such Disclosing Party may seek an appropriate protective order or other remedy with respect to narrowing the scope of such requirement and, to the extent necessary, waive the receiving Party's compliance with the confidentiality obligations of this Agreement.

8.6 The Parties acknowledge that disclosure of any Confidential Information in breach of this Agreement could give rise to irreparable injury to the non-breaching Party and that such injury

will not be adequately compensated by damages. Accordingly, the non-breaching Party shall be entitled to the remedies of specific performance and injunctive relief or other equitable relief for any threatened or actual breach of this Section 8. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

8.7 All Confidential Information shall remain the property of the Disclosing Party. In the event that a court or other legal or administrative tribunal of competent jurisdiction, directly or through an appointed master, trustee or receiver, assumes partial or complete control over the assets of a Party to this Agreement, based on the insolvency or bankruptcy of such Party (or based on any other analogous or similar status of that Party under foreign laws), the bankrupt or insolvent Party shall promptly notify the court or other tribunal:

(a) that Confidential Information remains the property of the Disclosing Party; and

(b) of the confidentiality obligations under this Agreement.

9 AUDIT

In addition to the audit rights in Section 6.13, MPP or its authorized representative will have the right to audit Biovac's compliance with Sections 4.6 and 7.2 of this Agreement. Biovac will be required to keep accurate records to allow MPP or its authorized representative to adequately conduct such audit.

10 TERM AND TERMINATION, SURVIVAL

10.1 This Agreement shall be deemed to come into effect on the Effective Date and shall continue for five years.

10.2 In the event the Funders reduce the funding for the Funded Project or the Project, the Parties will enter into good faith negotiations to determine if the Funded Project can be completed as originally anticipated or its scope must be modified. In the event of insufficient funding and the Parties cannot agree to a modified Scope of Work and Budget reasonably acceptable to the Funders, MPP may suspend this Agreement immediately. In the event of suspension of the Funded Project, Biovac will immediately cease incurring expenses and take every reasonable measure to cancel outstanding expenses. In the event Funders discontinue support of the Funded Project or Project, or if funding is reduced to the extent that MPP, in consultation with Biovac, determines it is not practicable to continue funding the Funded Project, MPP may terminate this Agreement effective immediately upon notice. In such event, to the extent funds are allowable by and available from Funders, MPP shall pay reasonable and allowable costs incurred up to and including the effective date of termination, and for reasonable and allowable non-cancelable obligations made consistent with the Budget prior to Biovac's receipt of notice of termination.

10.3 Save as otherwise provided in this Agreement, if Biovac breaches any provision of this Agreement and if such breach is material and (i) is incapable of correction; or (ii) is capable of correction but is not corrected within thirty (30) days after Biovac receives written notice with respect to such default, MPP shall have the right to terminate this Agreement with immediate effect by giving written notice to the party in default.

10.4 Termination or expiry of this Agreement shall not affect those provisions of this Agreement which are expressly or by implication intended to survive the termination or expiration of this Agreement, including, but not limited to, Sections 4.6, 7.2, 7.3, 7.4, 8 and 9. In addition, any other provisions required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent that such survival is required for the full observation and performance of this Agreement by the Parties.

10.5 Termination of this Agreement in accordance with the provisions hereof shall not limit remedies which may be otherwise available in law or equity and shall be without prejudice to any rights that any person may have pursuant to this Agreement for antecedent breaches.

11 WARRANTIES, INDEMNITIES, COMPLIANCE WITH LAW

11.1 Each of the Parties warrants that, to the best of its knowledge and belief:

(a) it has power to execute and deliver this Agreement and to perform its obligations under it and has taken all action necessary to authorise such execution and delivery and the performance of such obligations; and

(b) this Agreement constitutes legal, valid and binding obligations of that Party in accordance with its terms.

11.2 Except as otherwise expressly provided in this Agreement, MPP does not make any representations or warranties, express or implied with respect to the Technology or Afrigen Rights or any other matter under this Agreement, including, without limitation, any express or implied warranties of merchantability or fitness for a particular purpose with respect to the Technology or Afrigen Rights. Furthermore, nothing in this Agreement shall be construed as a warranty that Biovac's use of the Technology or Afrigen Rights will not infringe any patent rights or other IP rights of any Third Party. MPP does not give any warranty, express or implied, with regard to the safety or efficacy of any Product(s) and it shall be the sole responsibility of Biovac to ensure such safety or efficacy.

11.3 Except as otherwise expressly provided in this Agreement, Biovac does not make any representations or warranties, express or implied with respect to the Inventions, including, without limitation, any express or implied warranties of merchantability or fitness for a particular purpose with respect to the Inventions. Furthermore, nothing in this Agreement shall be construed as a warranty that MPP, Afrigen or any other participant in the mRNA Technology Transfer Programme's use of the Inventions or any background intellectual property of Biovac will not infringe any patent rights or other IP rights of any Third Party.

11.4 The Parties hereby agree to indemnify one another and its respective officers, directors, shareholders, representatives, agents, employees, successors and assigns (each an "**Indemnified Person**") against any and all suits, claims (whether or not successful, compromised or settled), actions, demands, proceedings, judgments, liabilities, expenses and/or losses, including reasonable legal expense and attorneys' fees ("**Losses**"), that arise in connection with (i) a Party's breach of this Agreement; or (ii) a Party's exercise of its rights pursuant to this Agreement (including for the avoidance of doubt, in respect to MPP, any product liability claim relating to the Product(s) manufactured by or on behalf of Biovac), provided that the indemnification obligation established in this Section 11.4 shall not apply to the extent such Losses arise out of negligence or wilful misconduct by the other Party and its respective officers, directors, shareholders, representatives, agents, employees, successors and assigns. No Party shall be liable to the other Party for any indirect, incidental, consequential, reliance or special damages, including a loss of profit, in connection with this Agreement for any reason whatsoever and howsoever arising. Each Party undertakes to provide the other Party with prompt written notice of a claim under this Section 11.4. The Parties will agree on the appropriate Party to assume control of the defence or negotiation of settlement and will agree to make available all reasonable assistance in defending any claims.

11.5 Biovac represents and warrants that it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, or cruel or abusive disciplinary practices in the workplace and that it does not discriminate against any workers on any ground (including race, religion, disability, gender, sexual orientation or gender identity) and aims to achieve greater equity along those lines in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the laws on working hours and employment rights in the countries in which it operates.

11.6 Biovac commits to contribute to an inclusive manufacturing sector by ensuring adequate gender responsiveness and to empower women as key players, including promoting women in decision-making and leadership positions. Biovac will emphasize and demonstrate that manufacturing is a fulfilling career choice for women, with ample opportunities, and thereby encourage more women

to participate in the sector; provide opportunities for women living in marginalized communities to participate in the manufacturing sector and compete in the marketplace, through proactively targeting those communities; and encourage involved countries to increase health and health security for women living in marginalized communities through ensuring availability of health products in populations which would otherwise not be reached.

11.7 Biovac shall be respectful of its employees' right to freedom of association and shall encourage compliance with the standards referred to in Sections 11.5 and 11.6 by any supplier of goods or services that it uses in performing its obligations under this Agreement, subject to any legislation in a territory where it operates.

11.8 Biovac shall comply fully at all times with all applicable laws and regulations, including but not limited to any Product's safety, pharmacovigilance, anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents and any other Third Parties, subject to its control or determining influence, from doing so.

11.9 Biovac shall manufacture and sell any Products in accordance with all laws and regulations relevant to the manufacture and sale of the Products and in accordance with good industry practice.

12 FORCE MAJEURE

If the performance of any part of this Agreement by any Party, or of any obligation under this Agreement (other than those provisions which in any respect concern the payment under any indemnity or otherwise under this Agreement) is prevented, restricted, interfered with or delayed by reason of any cause beyond the reasonable control of the Party liable to perform (an "Event of Force Majeure"), unless conclusive evidence to the contrary is provided, the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable endeavours to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. If the Event of Force Majeure continues for a period of more than six (6) months, any Party not prevented, restricted, interfered with or delayed or otherwise in terms of performance may terminate this Agreement by providing a written termination notice to the other Party. Without limitation as to the possible types of Event of Force Majeure, an epidemic, pandemic, government collapse, government-imposed isolation or government- imposed quarantine shall be capable of constituting an Event of Force Majeure, provided that the elements of the definition of that term specified in this Section 12 are satisfied.

13 SEVERABILITY

13.1 In the event that any portion of this Agreement is or is held by any court or tribunal of competent jurisdiction to be illegal, void, unenforceable or ineffective, the remaining portions hereof shall remain in full force and effect.

13.2 If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to the minimum extent necessary to procure conformity with such statute or rule of law.

14 ENTIRE AGREEMENT

14.1 This Agreement constitutes the entire agreement between the Parties relating to the subject matter hereof and supersedes all previous writings and understandings between the parties relating to

the transactions contemplated by this Agreement.

14.2 Each Party acknowledges that in entering into this Agreement it has not relied on any representation, warranty, collateral contract or other assurance (except those set out in this Agreement) made by or on behalf of any other party before the date of this Agreement. Each Party waives all rights and remedies which, but for this Section, might otherwise be available to it in respect of any such representation, warranty, collateral contract or other assurance.

15 NO PARTNERSHIP OR AGENCY

Nothing in this Agreement shall be deemed to constitute a partnership between the Parties, nor constitute either Party as the agent of the other Party.

16 EXECUTION

This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. For the convenience of the Parties, an executed copy of this Agreement may be transmitted by email in portable document format (PDF), and such .pdf file shall be deemed equivalent to an original.

17 GOVERNING LAW AND JURISDICTION

17.1 This Agreement and any non-contractual obligations arising out of or in connection with it shall be governed by the laws of Switzerland.

17.2 All disputes arising out of or in connection with this Agreement shall be exclusively referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English. The foregoing however shall not prevent any Party from seeking and obtaining injunctive relief at any time in any country.

IN WITNESS WHEREOF the Parties, through their duly authorised representatives, have executed this Agreement.

Signed for and on behalf of:

THE MEDICINES PATENT POOL FOUNDATION

Signature DocuSigned by: Jane Caldwell 90E6E01A6B7A46C...

Name: **Jane Caldwell**

Position: **Chief Operating Officer**

Date 22 August 2024

Signed for and on behalf of:

BIOVAC

Signature DocuSigned by: Morena Makhoana 879E633E5DFF4CF...

Name: **Morena Makhoana**

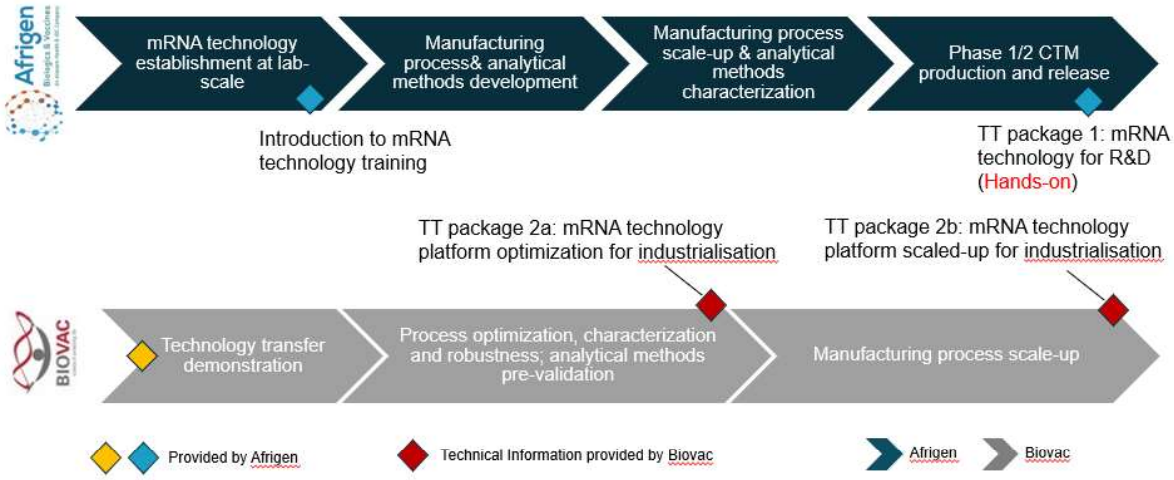
Position: **CEO**

Date 24 August 2024

LIST OF ANNEXES:

ANNEX 1 – Technology Transfer Roadmap
ANNEX 2 – Terms of Material Transfer
ANNEX 3 – Technology transfer Package 1 content
ANNEX 4 – Technology transfer Technical Information Package 2 content
ANNEX 5 – Scope of Work
ANNEX 6 – Project budget, payment details
ANNEX 7 – Specific Donor's Requirements
ANNEX 8 – GIZ Agreement

ANNEX 1
TECHNOLOGY TRANSFER ROADMAP



ANNEX 2
TERMS OF MATERIAL TRANSFER

1. MPP shall ensure **Afrigen** will provide **Biovac** Quality Control Standards (Afrigen materials or information for procurement from commercially available sources as appropriate) and comparators (materials manufactured at Afrigen to confirm the successful technology transfer of the methods). Detailed list including sources and amounts will be included in the Technical Transfer Plan.

ANNEX 3
TECHNOLOGY TRANSFER PACKAGE 1 CONTENT

PACKAGE 1

Package 1 shall include:

- Technology Transfer Technical Information Package 1 (content listed below)
- Technical assistance (as defined in section 2.3 of this agreement)
- Materials (detailed in Annex 2)

Technology Transfer Technical Information Package 1 content:

1. Drug substance (mRNA), bulk drug product (encapsulated mRNA) and final drug product manufacturing instructions (thus including manufacturing process flows, in-process and final Quality Control flows, Waste flows, Hold points, process mass balances and personnel flow).
   NOTE: Expected scale of production at Afrigen: plasmid (20-30L); mRNA IVT (1-5L), LNP concentrated (2-15L).
2. Analytical procedures to test Raw materials (including identity tests used for Phase I and justification of tests methods required for Phase III) and products (including release and in-process assays either qualified or pre-validated) and packaging specifications (including container closure test reports for -20 C final packaging and specifications of vials, caps and stoppers).
3. Reference and supplier of raw materials, consumables and equipment.
4. Materials as listed in Annex 2 of this agreement.
5. Process development support data capturing key experience/product knowledge:
   - **i.** Detailed equipment list with specifications covering the entire manufacturing process.
   - **ii.** Cell History, batch record and analytical results.
   - **iii.** Process development report that also outlines the manufacturing process rationale. It includes:
     - technical reports (including analytical assessment reports, stability reports, detailed non-clinical and pre-clinical reports and, if applicable, cleaning verification data and reports);
     - potential critical manufacturing process parameters/steps;
     - the success (or failure) of the technology implementation in Afrigen;
     - a history or evolution of the process through the Phase I clinical stage of development.
   - iv. Batch record and analytical results of pivotal batches (preclinical/engineering/clinical batches) and technical interpretation of the results.
   - v. Appropriate comparison between preclinical/engineering/clinical batches.
   - vi. Rationale for proposed specifications for Phase I.
   - vii. Available stability data.
   - viii. Submitted Clinical Trial Application sections (including all Chemistry, Manufacturing and Controls documentation) and Phase 1 Clinical Study Report (CSR), when available.

ANNEX 4
TECHNOLOGY TRANSFER PACKAGE 2 CONTENT

PACKAGE 2

Package 2 shall include:

- Technology Transfer Technical Information Package 2 (content listed below)
- Technical assistance (as defined by Partner needs)

NOTE: Documentation to be provided in a CTD-like format

Technology Transfer Technical Information Package 2 content:

Package 2a – mRNA Technology Platform Optimization for Industrialisation

1. DS and bulk DP GMP facility layouts including personnel, materials and waste flows.
2. Catalogue number and supplier of raw materials, consumables including primary packaging.
3. Catalogue number, supplier, commissioning reports and maintenance plans of equipment.
4. Process optimisation, characterisation and robustness capturing key experience/product knowledge (conducted on process up to 1L IVT/3-6L bulk DP):
    i. Process optimisation development report, batch records and analytical results for DS, bulk DP and final DP (sterilizing filtration, manual filling and freezing) manufacturing.
    ii. Process description of optimised process at 1L IVT/3-6L bulk DP.
    iii. Sterilizing filter selection rational and bacterial retention efficacy verification.
    iv. Process characterization and robustness study reports. Critical manufacturing process parameters (CPP) and Key Process Parameters (KPP) identified with associated acceptable ranges.
    v. Hold times study protocols and reports for the end-to-end process up to final DP.
    vi. Template and executed manufacturing batch records and analytical results of post-optimisation demonstration batches and consistency batches at 1L IVT/3-6L bulk DP.
    vii. Product specifications for DS, bulk DP and filled DP.
    viii. Process performance qualification (PPQ) protocol executed on consistency batches.
5. Analytical procedures for Raw materials, DS, bulk DP and final DP, IPC and IPT in place and pre-validated:
    i. Analytical strategy and sampling plan with tests categorisation (release test, in process controls (IPC), in-process testing (IPT), characterization).
    ii. Pre-validation protocols and reports for each method (according to ICH Q2 R1 guidelines).
    iii. Trend summaries (where applicable).
    iv. For modified methods: amended SOPs, method development report describing method modifications implemented and their rationale.
    v. Elemental impurities rationale document.
6. Results of accelerated stability studies conducted in representative conditions (i.e., temperature, humidity, container materials) for DS, bulk DP, filled DP.
7. Appropriate immunogenicity evaluation in pre-clinical animal model studies of batches manufactured at Biovac with optimised process.
8. Process development report (PDR) reflecting optimisation of the manufacturing process (DS, bulk DP and filled DP) and rationale thereof, characterisation and robustness and comparison with the process as received from Afrigen (including pre-clinical results).
9. Updated Target Product Profile.
10. Process description of automated bulk DP filling.

Package 2b - mRNA Technology Platform Scaled-Up for Industrialisation

1. Manufacturing process scale-up: DS at 5-10 L, bulk DP 30-60L, final DP.
    i. Manufacturing Batch records (template and executed) and analytical results on at least 2 batches at scale.
    ii. Process descriptions for DS, bulk DP and final DP manufacturing process.

   iii. Product specifications for DS, bulk DP and filled DP.
   iv. Hold times, time out of refrigeration (TOR) and time out of freezing (TOF) study protocols and results for the end-to-end process up to final DP.
2. Catalogue number and supplier of raw materials, consumables including primary packaging.
3. Catalogue number and supplier, commissioning reports and maintenance plans of equipment.
4. Cleaning validation strategy plan for non-single use equipment (for DS, bulk DP and final DP manufacturing).
5. Reports of accelerated and real time stability studies (according to ICH Q1 R2 guidelines) conducted in representative conditions (i.e., temperature, humidity, container materials) for DS, bulk DP, final DP.
6. Appropriate immunogenicity evaluation in pre-clinical animal model studies of batches manufactured at Biovac with scaled-up process.
7. Process development report (PDR) on evolution and rationale of the manufacturing process (DS, bulk DP and final DP) and comparison (including pre-clinical results) along the product development across process as received from Afrigen up to scaled-up process.
8. Updated Target Product Profile.

ANNEX 5
SCOPE OF WORK

Biovac Principal Investigator: Seanette Wilson

Other Key Personnel: Ebrahim Mohamed (Department Head: S&I); Petrus van Zyl (Technical Lead), Malika Davids-Pooran (Analytical Lead)

PROJECT SCOPE OF WORK: Process industrialization including Optimization, characterization, robustness & scale-up of mRNA technology platform (process and analytics) transferred from Afrigen.

OVERALL TIMELINE: Jan 2024 – Dec 2026

OBJECTIVE PROJECT SCOPE:
Biovac will receive the mRNA manufacturing process and analytics from Afrigen defined at 1 L in-vitro transcription (IVT) reaction scale and a lipid nano particle (LNP) formulation up to 6 L scale.
Biovac will commence with familiarisation runs up to 100 mL IVT scale, followed by 1 L IVT scale. The tech transfer will be concluded with a 1L IVT scale demonstration run *(**NOTE:** (1) process scales are defined here and below in relation to IVT; scale of LNP is not specified as is related to process yields; even if only IVT scale is mentioned, it is intended that the process continues up to Bulk DP – mRNA formulated in LNP- and manual filling of a 1L batch for stability studies; (2) the 1L familiarization and demonstration runs will be released based on the assay templates received from Afrigen in Q1 2024).*
Following the tech transfer demonstration run, Biovac will commence process optimisation at 1-100 mL IVT scale focusing first on pDNA linearization, IVT & capping reactions and then on mRNA purification and LNP-mRNA formulation and purification. To confirm process optimisation, 2 x 1 L IVT/ 6L bulk DP scale confirmation runs will be completed under the selected optimal conditions.
Batches manufactured with the optimised process will be tested in mice immunogenicity studies.
In parallel to these activities, the analytical assays will be implemented at Biovac. Non-compendial methods will be established and qualified in the research facilities (up to pre-validation) while compendial methods will be verified.
2 x 1L IVT consistency batches (PPQ batches) will be manufactured and tested with pre-validated analytical methods.
Process characterization will encompass the definition of the critical process parameters (CPP). It will be followed by robustness studies determining the acceptable ranges for each CPP. This will be initiated at a 1 mL and 100 mL IVT scales following a risk assessment determining the scale dependency of these parameters.
Documentation related to process optimisation, characterisation and robustness and analytical methods pre-validation will constitute Package 2a, to be shared with Afrigen and the other Programme partners. Detailed list of documents will be provided in a separate Spreadsheet.
Afrigen will receive hands on training (back transfer) on the 1L IVT optimised process.
Once the process has been established at the 1 L IVT scale, 3 x 5 L IVT scale batches will be performed to ensure the process parameters apply to this scale. If deemed applicable, the process will be further scaled-up at a 10 L IVT scale by performing 2 x 10 L runs.
Batches manufactured with the scaled-up process will be tested in mice immunogenicity studies.
Stability studies with real-time and accelerated conditions will be conducted on Filled DP and on DS and bulk DP material, if possible. Material produced with both optimised and scaled-up processes will undergo stability studies. Stability protocols (e.g., timepoints, volumes and containers) to be discussed in detail.
Documentation related to scale-up will constitute Package 2b, to be shared with Afrigen and the other Programme partners. Detailed list of documents will be provided in a separate Spreadsheet.
As part of the activities listed above, the following industrialisation "elements" will be generated and provided in the packages:

- Primary packaging qualification dossiers (quality and technical) - standard vials;
- Equipment commissioning reports;
- Equipment maintenance plans;
- Cleaning validation strategy plan;
- Process descriptions;

- Template and executed Batch Records;
- Quality by design and process characterization reports;
- Sterilizing filter validation rational document and bacterial retention efficacy verification;
- PPQ protocol (1L IVT scale) and execution at 1L during consistency batches manufacturing;
- Analytical strategy and sampling plan with tests categorisation (release test, IPC, IPT, characterization);
- Elemental impurities rational document;
- Product Specifications and definition of acceptable ranges (or included in the analytical strategy);
- Analytical method pre-validation reports;
- Updated TPP (if required);
- Holding time, TOR, TOF reports (on DS, bulk DP and final DP steps with hold times);
- Stability reports on intermediate and final steps (DS, bulk DP and final DP);
- PDR in CTD like format (modules 3 and 4 and corresponding module 2 sections);
- DS GMP facility flows (personnel, materials, waste);
- Automated filling Process description.

All project activities will be managed by a Project Manager (Seanette Wilson), the technical activities will be managed by Technical Lead (Petrus van Zyl) and Analytical Lead (Malika Davids-Pooran) under the guidance of the S&I HoD (Ebrahim Mohamed). Morena Makhoana (CEO) will be Biovac's key point of accountability for all external stakeholders.

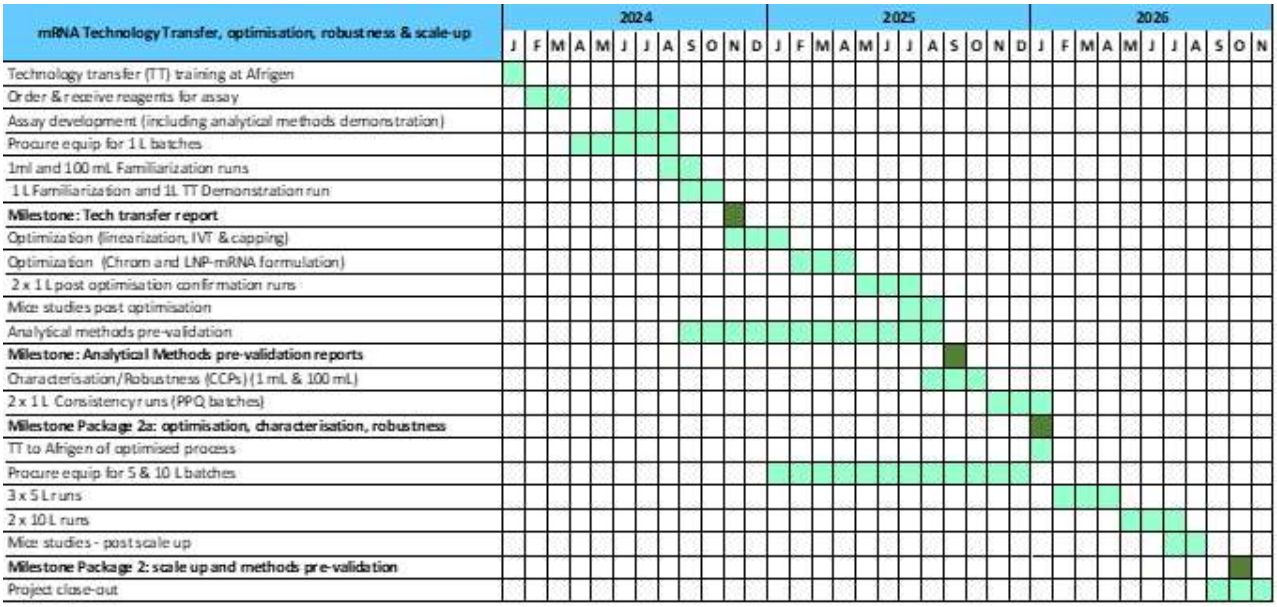
KEY ASSUMPTIONS:

- The IVT and LNP formulation processes will be transferred from Afrigen at the following minimum scales:
  - IVT 1 L
  - LNP formulation 1 L
- The process transferred will be further scalable (scalability up to 1L IVT and up to 6L bulk DP demonstrated by Afrigen).
- All non-compendial analytical methods required for release of DS and bulk DP will be qualified by Afrigen and transferred to Biovac.
- Afrigen will provide representative samples of DS and bulk DP or DP to Biovac for assays establishment.
- All pDNA required to complete the technology Transfer demonstration will be provided by Afrigen.
- All pDNA required to complete the process familiarisation, optimisation, characterisation, robustness and scale-up will be provided.
- Biovac will transfer the process back to Afrigen during post-robustness consistency runs (hands on training) and after scale-up (paper transfer).
- Biovac will not provide hands-on training to other Programme Partners.
- Timelines will be regularly revised. Buffer time included in lots manufacturing and testing (1 month/lot).
- Accelerated and real-time stability testing to be performed at time points beyond December 2026 on batches manufactured with the scaled-up process will be conducted at timepoints agreed upon and subject to availability of funds. Results will be made available to Programme Partners.

Table 1: Workplan

N	MILESTONE	DELIVERABLE	START DATE	DUE DATE
Technology Transfer from Afrigen				
1	Technology transfer (TT) training at Afrigen	Training completed	Jan 2024	Jan 2024
2	Order & receive reagents for assay	Reagents received	Feb 2024	Mar 2024
3	Establish assays	Assays established	June 2024	Aug 2024
4	Equipment procurement for 1L runs	Equipment delivered & installed	Apr 2024	Aug 2024
5	Up to 100 mL Familiarization runs	Team familiar with process	Aug 2024	Sept 2024
6	1 L Familiarization and 1L TT Demonstration runs	Acceptance criteria defined Batch records created	Sept 2024	Oct 2024
7	Completion of tech transfer report	Tech transfer report	Nov 2024	Nov 2024
Process Optimisation				
8	Optimization (linearization, IVT & capping reactions)	Process parameters established for linearization, IVT & capping reactions	Nov 2024	Jan 2024
9	Optimization (Chrom and LNP-mRNA formulation)	Process parameters established for Chrom & LNP formulation	Feb 2025	Apr 2025
10	2 x 1 L confirmation runs	Post-optimisation Confirmation runs successfully completed	May 2025	Jul 2025
11	Mice immunogenicity studies	Batch manufactured with optimised process is immunogenic.	Jul 2025	Aug 2025
Assays pre-validation				
12	Pre-validate Assays	Assays pre-validated	Sept 2024	Aug 2025
13	Completion of pre-validation assays report	Assays pre-validation reports	Sep 2025	Sep 2025
Characterisation and robustness				
14	Characterisation and Robustness (CCPs) (1 mL & 100 mL)	Characterisation and Robustness testing completed	Aug 2025	Oct 2025
15	2 x 1 L consistency runs (PPQ batches)	Consistency runs successfully completed	Nov 2025	Jan 2026
16	TT Package 2a Documentation package	Documentation package completed & delivered to Afrigen and the other partners	Jan 2026	Jan 2026
17	TT to Afrigen	Train Afrigen on the optimised technology	Jan 2026	Jan 2026
Process scale-up				
18	Procure & receive equip for 5 L batches	Equipment delivered & installed	Jan 2025	Dec 2025
19	3 x 5 L runs	5L runs successfully completed	Feb 2026	Apr 2026
20	2 x 10 L runs	10L runs successfully completed	May 2026	Jul 2026
21	Mice immunogenicity studies	Batch manufactured with scaled up process is immunogenic.	Jul 2026	Aug 2026
22	TT Package 2b Documentation package	Documentation package 2 completed & delivered to Afrigen and the other partners	Oct 2026	Oct 2026
23	Project close-out	Project close-out report completed	Sep 2026	Nov 2026

Figure 1: WORKPLAN GANTT chart:



ANNEX 7
SPECIFIC DONORS' REQUIREMENTS

1. Fraud and Corruption

Biovac declares and guarantees that no offer, gift or payment, consideration or benefit of any kind, which constitutes an illegal or corrupt practice, has been or will be made to anyone by Biovac, either directly or indirectly, as an inducement or reward for the award or execution of the Agreement.

It declares and guarantees that neither Biovac, nor its employees or delegee involved in the Agreement:

a. were convicted during a period of three (3) years prior to and since the submission of the Study proposal, by a court of law in Canada or in any other jurisdiction for an offence involving fraud, bribery or corruption;
b. are under sanction, for an offence involving fraud, bribery or corruption, imposed by a government, an international governmental organization or an organization providing development assistance.

Biovac declares and guarantees that it has taken all reasonable steps to assure itself that neither its local partners, its subcontractors, nor its local partners' or subcontractors' employees involved in the performance of the Agreement:

a. were convicted during a period of three (3) years prior to and since the submission of the proposal, by a court of law in Canada or in any other jurisdiction for an offence involving fraud, bribery or corruption;
b. are under sanction, for an offence involving fraud, bribery or corruption, imposed by a government, an international governmental organization or an organization providing development assistance.

2. Economic Sanctions and Other Trade Controls

Biovac declares and guarantees that funding for the purposes of the Agreement will not be knowingly used, either directly or indirectly, in a manner that contravenes economic sanctions Imposed by Canada and enforced by regulations under the United Nations Act (R.S.C. (1985), c. U-2); the Special Economic Measures Act (S.C. (1992), c. 17); the Justice for Victims of Corrupt Foreign Officials Act (S.C. (2017), c. 21) as they are amended from time to time, or for activities that would contravene the provisions of the Export and Import Permits Act (R.S.C. (1985), c. E-19). Information on Canadian sanctions and export and import controls can be found at the following links:
https://www.international.gc.ca/world-monde/international_relations-relations_internationales/sanctions/index.aspx?lang=eng
https://www.international.gc.ca/world-monde/international_relations-relations_internationales/sanctions/types.aspx?lang=eng
https://www.international.gc.ca/controls-controles/index.aspx?lang=eng

3. Anti-Terrorism

Biovac declares and guarantees that the funding for the purposes of the Agreement performance will not knowingly be used to benefit terrorist groups or individual members of those groups, or for terrorist activities, either directly or indirectly, as defined in the Criminal Code R.S.C., 1985, c. C-46 or those appearing on the Consolidated United Nations Security Council Sanctions List, as modified during the term of this Agreement.

Biovac is responsible for consulting all relevant lists, even if the web addresses provided are no longer valid, in order to stay informed of the listed terrorist groups and their members and must ensure that the Contribution of the Department does not benefit any listed terrorist entity and their members, any sanctioned groups or persons. Entities or individuals listed as terrorists can be found at the following web addresses:

a. Criminal Code of Canada list - https://www.publicsafety.gc.ca/cnt/ntnl-scrt/cntr-trrrsm/lstd-ntts/crrnt-lstd-ntts-en.aspx
b. Regulations implementing the Voted Nations Resolutions on the Suppression of Terrorism - https://laws-lois.justice.gc.ca/eng/regulations/SOR-2001-360/page-3.html#h-673021
c. The United Nations Security Council Consolidated Sanctions Lisi is available on the United Nations Security Council website (httos://www.un org/securitycouncil/). to implement the sanction measures imposed by the United Nations Security Council pursuant to resolutions 1267 (1999), 1989 (2011) and 2253 (2015) concerning ISIL (Da'esh), AI-Qaida, and associated individuals, groups, undertakings and entities, and pursuant to resolution 1988 (2011) concerning the Taliban and associated individuals.

ANNEX 8
GIZ AGREEMENT

Grant Agreement with non-German recipients

Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

The

Medicines Patent Pool Foundation
Rue de Varembé 7, 5th floor
1202 Geneva
Switzerland

- hereinafter referred to as the 'Recipient'

and

Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH
Dag-Hammarskjöld-Weg 1 - 5
65760 Eschborn
Federal Republic of Germany

- hereinafter referred to as 'GIZ' –

herewith enter into the following Grant Agreement (hereinafter referred to as the 'Agreement') for the GIZ project:

BACKUP Health - Global Programme Health Systems Strengthening

Country: **supra regional**

Communication details **(must be quoted in all correspondence)**

Agreement number:	81303112
Project processing number:	20.2155.8-016.00

Unit responsible for the budget

Organisational unit:	G110
Responsible officer:	jean-olivier.schmidt@giz.de

Procurement and Contracting

Organisational unit:	E2B0
Responsible officer:	giulia.kraemer@giz.de

Financial management of the contract

Organisational unit:	5730
Responsible officer:	kateryna.monastyrova@giz.de

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Internationale Zusammenarbeit (GIZ) GmbH

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Ingrid-Gabriela Hoven (Vice-Chair)
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The basis for the Grant provided to the Recipient is the commission from the Federal Ministry for Economic Cooperation and Development (hereinafter referred to as 'Commissioning Party') dated 15.12.2023. GIZ shall provide the Grant pursuant to this Agreement exclusively on behalf of and for the account of the Commissioning Party.

[redacted]

[redacted]

2 Project

2.1 The objective of the project mRNA Technology Transfer Programme (hereinafter referred to as 'Project'), which is financed by this Grant, is: to establish and enhance sustainable mRNA vaccine manufacturing capacity and develop skilled human captial. GIZ has no entitlement to performance by the Recipient as part of this Grant.

2.2 In order to achieve this objective, the Recipient intends to implement the measures listed in the Recipient's proposal for project implementation (hereinafter referred to as 'Project Proposal', see **Annex 2**) on its own responsibility.

3 Disbursement and settlement of the Grant

3.1 The Recipient shall observe the principles of proper accounting in the implementation of the Project and ensure project-specific account settlement and documentation. The Recipient shall comply with the guidelines on financial processing **(Annex 3a)**.

3.2 At the time of the first request for disbursement **(Annex 3c)** at the latest, the Recipient shall submit a schedule of funding requirements for 12 months **(Annex 3b)** starting as soon as this Agreement has entered into force.

Within the framework of the schedule of funding requirements, the Recipient shall request disbursements for each **three-month period** equivalent to the expected funding requirements, taking into account any funds still available. In order to minimise repayment risk, the Recipient shall monitor the effective balance of funds before requesting any further disbursement.

3.3 All funds made available under this Agreement shall be accounted separately from other funds of the Recipient.

The Recipient shall open a separate sub-account at its bank or a separate cost unit in its own accounting system to handle the financial transactions relating to this Agreement and shall confirm this with GIZ when submitting its first request for disbursement.

At the latest, by the time of the first request for disbursement and in case a different account is used, the Recipient must submit a confirmation from the bank to legitimise the account.

All disbursements under this Agreement shall be transferred by GIZ to the aforementioned account of the Recipient.

All contributions paid by GIZ shall remain as trust funds in the aforementioned account they are used as contractually agreed.

3.4 The amounts paid by GIZ into the aforementioned account will, as far as possible, accrue interest.

GIZ may at any time request that the Recipient submits without undue delay a copy of the interest agreement and/or interest calculation by the bank or a confirmation by the bank that no interest can be paid for the credit balance on the account.

Any income, interest or profits from the Grant received by the Recipient under this Agreement ('Earnings'), as well as any funds returned to the Recipient, including reimbursements or repayments ('Returned Funds'), shall be used by the Recipient for the Project and shall be identified as such when submitting the financial report, indicating the relevant budget line.

GIZ reserves the right to deduct all Earnings and Returned Funds from the agreed Grant amount, insofar as appropriate use cannot be proven.

3.5 In the Recipient's accounting records for this Grant, all vouchers, expenses, actual costs as well as all Earnings and Returned Funds relating to the Grant and the Estimated Budget (**Annex 1**) shall be recorded in chronological order and in compliance with the rules of proper accounting. These vouchers shall be divided into the categories of budget lines referred to in Section 1.2 and both the documents and record shall contain, as a minimum, the following items:

a) Internal entry number

b) Date

c) Recipient/origin of voucher

d) Amount

e) Content of voucher

The Recipient shall ensure that lump sums budgeted economically for project implementation in Section 1.2 for administration costs, if agreed, are documented in the Recipient's accounting records and meet the requirements of proper accounting.

3.6 The Recipient shall complete and submit the financial overview (use of instalments already paid) (see template in **Annex 3c**) for each subsequent request for disbursement.

The Recipient shall submit the financial report (see template in **Annex 3d-f**) for every six months. Together with the financial report, the Recipient shall submit confirmation of the contributions to project implementation agreed in Section 1.5 (if applicable) for the same period as well as the inventory lists **(Annex 3g1)** pursuant to Section 6.4. The financial report shall be submitted to GIZ no later than two months after the respective accounting periods, even if no further payment is requested.

No later than two months after the end of the Grant period or in the event of early termination of this Agreement, the Recipient shall additionally submit to GIZ a final financial report (see template in **Annex 3d-f**). The final narrative report pursuant to Section 4.5 shall be submitted along with the final financial report. If the aforementioned documents are not submitted in time, GIZ may refuse to make further disbursements.

3.7 The financial report must show Earnings and costs in chronological order and separately from each other, in accordance with the structure of the Estimated Budget (pursuant to Section 1.2). The evidence shall include all Earnings (grants, third-party services, own funds) and costs relating to the purpose of the Grant.

Each financial report must be accompanied by a tabular overview of vouchers, listing costs separately by type and in chronological order (list of vouchers). The list of vouchers must show the date, recipient/payer and the reason for and individual amount of each payment.

In the financial report, the actual costs must be entered in the voucher currency, converted and shown in EUR.

Payments made to third parties shall be reported separately in the financial report and the schedule of funding requirements. Receipt of the counter performance must be documented at the appropriate time – but at the latest in the final financial report – and the actual costs must be recorded.

Remaining funds, which are still available to the Recipient as shown in the financial overview (included in **Annex 3c**) or the financial report, will be offset against the next payment, considering the schedule of funding requirements.

At the request of GIZ and from the date of receipt of payment, the Recipient shall pay interest at the rate of 5 percentage points above the respective rate applied by the European Central Bank to its main refinancing transactions p.a. for any amount not spent in a timely manner in accordance with the schedule of funding requirements for the Project.

3.8 If the budget lines set out in Section 1.2 include administration costs, these shall be charged separately as a flat-rate percentage.

All other budget lines listed under Section 1.2 will be settled against evidence.

3.9 Voucher copies are not to be attached to the financial reports. However, GIZ is entitled to request voucher copies.

The Recipient shall submit all financial reports, voucher copies and other documents required for accounting purposes either in German, English, French or Spanish or attach a translation in one of these languages.

3.10 The amount of [redacted] shall be retained from the Grant as security.

The final payment shall be disbursed as soon as all contractual obligations by the Recipient arising from the Agreement have been met and to the extent that the respective amount has been used for the agreed purpose. GIZ reserves the right to retain 20% of the security retention amount until the external audit report has been handed over to GIZ.

3.11 The request for disbursement submitted by the Recipient will become due for payment after a verification period of 15 days. Disbursement shall be made by GIZ no later than 30 days after the due date of the disbursement request for the amount determined and, if necessary, adjusted by GIZ. Disbursements by GIZ do not constitute an acknowledgement by GIZ of the validity of the financial reports.

3.12 If the Recipient transfers the Grant to an account in a foreign currency, proof of receipt on the account in local currency must be submitted with the next financial report. The exchange rate in each case is calculated from the underlying amount in EUR and the local currency received.

If it is not possible to determine the exchange rate via the bank voucher, the Recipient may, with the consent of GIZ, convert the national currency on the basis of the EU currency converter InforEuro or, alternatively, use its own conversion system, provided that the latter is auditable and meets standards comparable to those of InforEuro.

3.13 If the Recipient fails to submit a financial report (**Annex 3d-f**), a disbursement request (**Annex 3c**), a status report (pursuant to Sections 4.4 - 4.5) or an inventory list **(Annex 3g1)** by the contractually agreed due date or in the contractually agreed form, GIZ shall be entitled to suspend payments until the correct financial report, disbursement request, status report or inventory list has been submitted.

3.14 All funds, which are still remaining with the Recipient and are not used after the end of the Grant period or after a premature termination of the contract, including Earnings and Returned Funds, shall be repaid by the Recipient directly to GIZ in EUR without delay and without being prompted to do so.

3.15 GIZ has the right to verify compliance with the Agreement itself and/or by commissioning external auditors at its own expense. The audit shall in particular cover compliance with the principles of proper accounting, the proper use of the Grant and the proper award of contracts for supplies and services in accordance with the provisions of this Agreement.

The anticipated audit periods are as follows:

Audit period: 15.01.2024 to 31.12.2024

Audit period: 01.01.2025 to 31.12.2025

Prior to finalisation of the audit report, the Recipient shall receive information on the main findings and have the opportunity to comment on these findings. After the audit report has been finalised, GIZ shall inform the Recipient about the significant results of the audit report and their implementation. The Recipient shall implement the recommendations made by GIZ and the auditor based on the results of the audit report, taking into account the order of priority for implementation as specified therein and shall provide evidence for this at the request of GIZ.

3.16 The Recipient shall declare whether or not invoiced VAT amounts resulting from the purchase of goods and services in connection with the use of the Grant are generally deductible for the Recipient.

The Recipient shall establish the formal requirements for an input VAT deduction, as far as legally possible.

VAT amounts can only be reimbursed to the Recipient under the following conditions:

a) the Recipient provides an invoice document with VAT amounts clearly shown;

b) the invoice is addressed to the Recipient;

c) the supply of goods or services underlying the invoice is subject to VAT in accordance with the legal regulations;

d) the Recipient is not entitled to deduct the VAT amounts in connection with the use of the Grant.

However, VAT amounts are not reimbursed if the Recipient is generally entitled to deduct input VAT amounts in connection with the use of the Grant but the requirements for an input VAT deduction have not been established by the Recipient. In case of doubt, contacting a tax advisor is recommended.

4 Project implementation, duty to supply information and reporting

4.1 The Recipient undertakes to

a) implement the Project with due diligence, efficiency and on the basis of sound administrative, technical, financial and development policy principles and in accordance with the provisions of this Agreement;

b) ensure the full financing of the Project and provide GIZ, upon request, with evidence that all actual costs not financed by this Grant are covered;

c) obtain all necessary licences, permits and consents to implement the Project and also ensure that other parties involved in implementation of the Project also obtain the necessary licences, permits and consents;

d) include in its contracts with third parties involved in project implementation necessary and appropriate contractual sanctions for non-fulfilment or non-performance by the respective contracting partner;

e) require its contracting partners to repay any funds that have been improperly or illegally used or are contrary to this Agreement or the laws of the country in which the Project is implemented;

f) keep all books, records, award documentation, agreements and the originals of vouchers for ten years after submission of the final financial report and submit or hand them over to GIZ on request, clearly showing all actual costs for services and supplies financed by the Grant;

g) enable GIZ or a third party commissioned by GIZ, as well as GIZ's Commissioning Party or the Bundesrechnungshof (Germany's supreme audit institution) or GIZ's third-party funder (if such exists) to inspect the books and all other records and documents relevant to implementation of the Project and the audit of the proper use of funds at any time and to visit the facilities required for this purpose.

4.2 Publications:

In all publications and brief references on the Project, the Recipient shall express in an appropriate manner that it is carrying out or has carried out its activities as part of a project financed by GIZ commissioned by the Government of the Federal Republic of Germany and cofinanced by the third-party funder (if such exists).

Prior to publication of project-related press releases or public statements by the Recipient that go beyond brief references (e.g. on the Recipient's website), the Recipient shall in good time inform GIZ (represented by the unit responsible for the budget in accordance with the contract cover sheet and via presse@giz.de) of the content of the publication in German, English, French or Spanish and shall take into account any instructions from GIZ.

4.3 The Recipient undertakes to inform GIZ immediately in text form of any circumstances which may seriously impair or jeopardise the achievement of the Project's objectives or which may significantly impede the performance of the Recipient's material obligations under this Agreement or the implementation of the Project as soon as the Recipient becomes aware of such circumstances.

This duty to supply information also exists, in particular, should there be significant changes to the Project's risk assessment, an imminent adverse impact on human rights, the environment, climate or gender equality, or other substantial temporal, financial, technical or development policy changes to the Project during the Grant period or risks to the safety or health of the staff deployed.

4.4 The Recipient shall prepare status reports on the progress of the Project **(progress report) every six months**. These progress reports are to be submitted as an electronic file to GIZ, represented by the unit responsible for the budget (in accordance with the contract cover sheet), no later than two months after the end of the respective reporting period. Each progress report shall address the main items of the numerical evidence and explain the necessity and appropriateness of the activities undertaken.

4.5 The Recipient shall prepare a **final report** describing the implementation and results of the Project with regards to the contractually agreed objectives and submit this report as an

electronic file to GIZ, represented by the unit responsible for the budget (in line with the contract cover sheet), no later than two months after the end of the Grant period or following early termination of this Agreement.

5 Forwarding of funds to third-party recipients and funds for direct support of third-party beneficiaries

5.1 The forwarding of funds to third-party recipients or disbursement of funds to third-party beneficiaries if this is only permissible if provided for in the Estimated Budget (Section 1.2 and **Annex 1**) and in the Project Proposal (**Annex 2**).

Third-party recipients are third parties to which the Recipient forwards part of the Grant for joint (partial) implementation of the Project.

Third-party beneficiaries are third parties that receive funds from the Recipient as the direct and final beneficiary of the Project.

5.2 When forwarding funds to third-party recipients or disbursing funds to third-party beneficiaries, the Recipient must ensure that:

a) the grant awarded to the third-party recipient does not violate EU rules on state aid;

b) the essential terms and conditions of this Agreement apply;

c) GIZ, external auditors commissioned by GIZ, the Bundesrechnungshof (Germany's supreme audit institution) and GIZ's third-party funder (if such exists) may take random samples to verify the accuracy of information provided by the third-party recipient.

d) third-party recipients do not forward the funds received or parts thereof to other recipients.

5.3 Prior to forwarding funds for the first time, the Recipient must conduct an appropriate due diligence assessment of third-party recipients. A positive assessment of the integrity and eligibility of the respective third-party recipient, taking into consideration the public-benefit purpose of the project, is a prerequisite for forwarding funds. The Recipient must document the assessment and make this documentation available to GIZ upon request.

If third-party recipients have not yet been determined at the time of the Agreement being signed, the Recipient shall submit a list of potential third-party recipients, including their estimated budgets, to GIZ. The Recipient may only forward funds if GIZ has granted prior approval and if a corresponding amendment to the Agreement has been agreed.

5.4 The Recipient must demonstrate to GIZ that forwarded funds have been used properly by submitting appropriate financial reports from the third-party recipient and, upon request by GIZ, copies of vouchers.

Disbursements by the Recipient to third-party recipients must be made in accordance with Section 3.2 and be shown separately in the financial report submitted by the Recipient. The Recipient undertakes to verify the financial report submitted by the third-party recipient in accordance with the terms of this Agreement and to submit this financial report to GIZ together with the findings of its own assessments.

5.5 In addition to the conditions stipulated in Section 5.2, the Recipient must ensure when disbursing funds to third-party beneficiaries that:

a) the cost effectiveness and appropriateness of the payment amount are verified and documented;

b) the criteria for selection are established prior to the selection process and the criteria of equal opportunities, transparency and freedom from any form of discrimination are taken into account. The selection shall be justified and documented accordingly;

c) the disbursement made by the Recipient and receipt of the funds by the third-party beneficiary must be documented in text form. The specific obligations of third-party beneficiaries to provide evidence can be found in the Estimated Budget (**Annex 1**).

6 Procurement of materials and equipment, construction services and other services

6.1 For the award and procurement of materials and equipment, construction services or other services ('Procurements') to be financed in whole or in part by the Grant, the Recipient shall comply with the provisions on procurement procedures in **Annex 4a** (Procurement guidelines).

The Recipient shall document all Procurements in writing in compliance with the 'Award documentation' template in **Annex 4b**.

6.2 If the Recipient has violated any of the provisions referred to in Section 6.1, GIZ shall be entitled to deduct from the Grant an amount equal to 20% of the respective remuneration, including VAT. Unless the Recipient can prove that the actual additional costs are less than 20% above market price, only these costs are to be deducted from the Grant. Insofar as GIZ can prove that the actual additional costs are higher, it may deduct all additional costs from the Grant.

The rights of GIZ under Section 13 of this Agreement remain unaffected.

6.3 When concluding contracts for Procurements financed by the Grant, the Recipient must ensure that

a) the prices and terms of payment for these Procurements are within the normal market range;

b) all Procurements made within the framework of this Agreement are used exclusively for the purposes of the Project, and all facilities relevant to the Project are properly operated and maintained at all times;

c) relevant sustainability standards are considered appropriately;

d) appropriate insurance policies are concluded which are customary for the sector;

e) import duties are indicated separately in the invoices;

f) reimbursement, insurance, security, guarantee or similar payments which may be claimed on the basis of these contracts are transferred to the account specified in Section 3.3 and submitted to the Project again. The Recipient must inform GIZ about the amount of the payments received as part of the financial report.

6.4 If items with a procurement or production value of more than EUR 800.00 (excluding VAT) are procured or produced from the Grant funds, these items must be inventoried ('Inventoried Items'). The Recipient undertakes to submit up-to-date inventory lists with each interim financial report as well as with the final financial report.

Any loss of Inventoried Items must be reported to GIZ without delay. In the event of theft, a report certified by the local police must be attached.

6.5 In respect of Inventoried Items, GIZ shall be entitled to decide after completion of the measures or after termination of this Agreement or in coordination with the Recipient, what steps are to be taken in respect of such items in the interest of the Project's purpose.

Any transfer of ownership resulting from such a decision shall be recorded on the corresponding handover record in accordance with the template contained in **Annex 3g2**, which shall be submitted together with the final financial report.

7 Rights of use

7.1 For the purpose of optimising business activities as set out in GIZ's Articles of Association and securing the work results for public-benefit purpose, the Recipient hereby grants GIZ, free of charge, an irrevocable, simple, worldwide and transferable right of use to all work results which are created or procured in connection with implementation of the Project and financed wholly or partially out of the Grant, with particular regard to the reports produced pursuant to Sections 3 and 4, studies and documents; GIZ is entitled to exercise this right of use without restrictions on time or content in fulfilment of its public-benefit purpose as stated in its articles of association. At the request of GIZ, the Recipient shall provide GIZ with a copy of the materials available. GIZ is entitled to grant third parties simple sub-rights of use free of charge in fulfilment of its public-benefit purpose as stated in its articles of association.

7.2 The Recipient shall ensure that the work results provided to GIZ during the course of implementing the Project are not subject to any copyrights or other rights of third parties which would impair their use within the scope set out in Section 7.1. The Recipient shall indemnify GIZ against all claims of third parties arising from the granting of rights under Section 7.1 and shall reimburse GIZ for all reasonable costs incurred by GIZ in a legal defence against such claims.

8 Data privacy policy

8.1 GIZ may process personal data in connection with this Agreement solely in accordance with the General Data Protection Regulation of the European Union (GDPR). Any processing of the data shall be carried out solely for the purpose of the performance, administration and supervision of this Agreement or for the protection of the financial interests of the principal and/or third-party funder (if such exists) of GIZ, including any checks, audits and investigations. Where permitted by law, the Recipient has the right to view, erase or correct its personal data and may contact GIZ (datenschutzbeauftragter@giz.de) or the government bodies responsible for such matters in order to assert its rights.

8.2 The Recipient shall ensure adequate protection of personal data in accordance with the rules and procedures applicable to the Recipient. In all cases, personal data must be:

a) processed lawfully, fairly and in a way that is comprehensible to the data subject;

b) collected for specified, explicit and legitimate purposes and must not be further processed in a way incompatible with these purposes;

c) adequate and relevant to the purpose and limited to what is necessary for the purposes of the processing;

d) factually accurate and, where necessary, up to date;

e) kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed;

f) processed in a manner that ensures appropriate security of the personal data.

9 Compliance with legal requirements and environmental and social standards; avoidance of unintended negative environmental and social impacts

9.1 When implementing the Project, the Recipient must respect the local conditions in the relevant country as well as the legal provisions, ordinances and official regulations, comply with all

relevant tax law requirements and take into account the related general, specific and social impacts of the Project.

9.2 The Recipient is obliged to use the funds in compliance with international standards and multilateral agreements, in particular international human rights agreements and the core labour standards of the International Labour Organization (ILO), and to ensure the protection of children; the prevention of violence, abuse and exploitation of any kind; non-discrimination, in particular with regard to origin, ethnicity, religion, age, gender identity, sexual orientation or disability; and the promotion of equal opportunities for all genders in the use of funds.

The Recipient uses the funds provided in compliance with applicable national and international environmental laws, minimises greenhouse gas emissions and avoids all actions that could increase the vulnerability of the population and/or ecosystems.

The Recipient is also required to use funds in a manner that seeks to avoid or minimise unintended negative impacts on the environment, climate change mitigation, climate change adaptation, human rights, fragile contexts and contexts affected by conflict and violence as well as gender equality by implementing attributable mitigation actions. With regard to gender equality, the Recipient also undertakes to use any potential for promoting gender equality.

9.3 The Recipient shall take reasonable measures to prevent sexual harassment in the professional context and shall refrain from inciting violence or hatred and from unjustifiable discrimination against any person or group of people.

10 Conflict of interest

10.1 The Recipient shall avoid conflicts of interest in connection with this Agreement. The Recipient shall also take appropriate precautions regarding the handling of conflicts of interest. A conflict of interest may arise especially for reasons involving economic interests, political affinities or national ties, family or friend relationships or any other interests.

10.2 In connection with implementation of the Project, the Recipient shall not enter into any agreement where a conflict of interest is to be expected due to the nature of the agreement or due to personal or financial connections between the Recipient and a third party.

10.3 The Recipient shall undertake to disclose without delay to GIZ any circumstances that might represent a conflict of interest or which could lead to such. All further steps must then be agreed with GIZ.

11 Combating money laundering, funding of terrorism and bribery, and upholding embargoes

11.1 The Recipient shall not support measures of any kind that are conducive to money laundering, the funding of terrorist activities or corruption.

11.2 The Recipient shall not make available, either directly or indirectly, any funds or other economic resources from the Grant provided by GIZ to third parties that are on a sanctions list of the United Nations and/or the EU. In the framework of this Project specified under Section 2, the Recipient may enter into contractual or business relations and maintain such relations only with third parties that are reliable and to whom no statutory ban on doing business or entering into contracts applies. Furthermore, the Recipient shall comply with any embargoes or any other trade restrictions issued by the United Nations, the EU and the Federal Republic of Germany in the framework of implementation of this Project.

11.3 The Recipient shall notify GIZ without delay and on its own initiative if an event occurs that results in the inclusion of the Recipient, a member of its staff, its official managing body and/or other administrative bodies, its shareholders and/or a contracting partner of the Recipient on a sanctions list issued by the United Nations Security Council, the EU or the Federal Republic of Germany. The same shall apply if the Recipient becomes aware that they or one of the aforementioned persons is on such a sanctions list.

11.4 Corruption in any form is prohibited. The Recipient must not, either directly or via a third party, offer or grant any gifts or advantages, or accept or request such gifts or advantages for itself or a third party, in connection with implementation of the Agreement. The Recipient must also establish appropriate and reasonable measures to prevent and tackle corruption.

11.5 The Recipient shall require all parties it involves in implementing the Project to comply with the provisions referred to in this Section 11, both during project development and with regards to its implementation.

11.6 The Recipient shall notify GIZ without delay of the occurrence of a breach of any provision of this Section 11. The rights of GIZ under Section 13 remain unaffected.

12 Force majeure

12.1 Force majeure is an unavoidable event (e.g. natural disaster, outbreak of a disease or epidemic, serious unrest, war or terrorism) that no human foresight or experience could anticipate, that cannot be evaded or overcome applying economically reasonable efforts and utmost care and that constitutes an impediment to GIZ and/or the Recipient fulfilling their contractual obligations. If an event originates from the sphere of responsibility of one of the parties to the Agreement, this shall not constitute force majeure.

12.2 The Recipient shall inform GIZ without delay of a force majeure event in accordance with Section 12.1, stating the nature, expected duration and expected effects, and shall consult with GIZ on further course of action. If GIZ or the Recipient is of the opinion that implementation of the Project or fulfilment of obligations assumed by the Recipient under this Agreement is jeopardised or precluded, they shall consult the respective other party regarding further course of action.

12.3 It shall not constitute a breach of obligations under this contract if GIZ or the Recipient are prevented from complying with them due to force majeure. As long as force majeure makes the implementation of measures impossible, the Recipient may suspend implementation. The Recipient shall endeavour to keep any adverse effects on the Project to a minimum.

13 Suspension of disbursements, termination of the Agreement, repayment

13.1 GIZ is entitled to suspend disbursements in part or in full if an event occurs that is detrimental to the Agreement. In particular, it constitutes such an event when:

a) the Recipient is unable to provide evidence of the use of the Grant for the purpose laid down in this Agreement;

b) the Recipient fails to use or no longer uses items purchased for the Project and financed from the Grant for the purposes of this Agreement;

c) the Recipient has breached any material provision of this Agreement;

d) the Recipient has made false statements or withheld relevant information prior to conclusion of the Agreement or during implementation of the Project, if and to the extent that GIZ would not have awarded the Grant or would not have made one or more disbursements if the statements had been correct or the relevant information had been received;

e) exceptional circumstances (e.g. force majeure as defined under Section 12.1) arise that seriously jeopardise or preclude the achievement of the purpose of the Grant, implementation of the Project or fulfilment of the obligations entered into in this Agreement by the Recipient; or

f) the Government of the Federal Republic of Germany and/or the third-party funder (if such exists) terminates, suspends or modifies the relevant agreement with GIZ that forms the basis for this Agreement.

13.2 GIZ is furthermore entitled to terminate this Agreement in part or in full and with immediate effect if any of the events set out in Section 13.1 a) to f) occur. If any of the events set out in Section 13.1 a) to d) occur, GIZ is entitled to terminate the Agreement with immediate effect if the situation is not corrected within a period to be defined by GIZ; this period may not be less than 30 days. If the events set out in Section 13.1 e) or 13.1 f) occur, there is no requirement for such a period to be set by GIZ.

13.3 Upon termination of this Agreement and at GIZ's first request, the Recipient must immediately repay to GIZ the remaining funds from the Grant for which there are no further liabilities of the Recipient within the meaning of this Agreement. This also includes all Earnings and Returned Funds.

The Recipient undertakes to demand repayment of funds that were paid or committed on a legally binding basis to third parties in good faith and within the meaning of this Agreement prior to the termination and to repay these to GIZ. Repayment is limited to the amount that the Recipient receives from the third party in question after carrying out all reasonable measures including legal action. The Recipient must give immediate notice to terminate existing obligations to third parties (e.g. employment contracts, rental contracts, loans).

If the event set out in Section 13.1 a) occurs, the Recipient must repay not only the unused funds from the Grant but also such funds as have not demonstrably been used correctly by it for the purpose set out in the Agreement.

If the event set out in Section 13.1 b) occurs, the Recipient must repay not only the unused funds from the Grant but also those funds that have been used for the items in question.

The Recipient shall pay interest in a timely manner after GIZ's first request at a rate of 5 percentage points above the respective rate applied by the European Central Bank to its main refinancing transactions p.a. on the repayment amount with respect to Section 13.1 a) to d).

14 Other provisions

14.1 Should individual provisions of this Agreement be or become invalid, this shall not affect the validity of all other provisions under the Agreement. In this event, GIZ and the Recipient shall replace any such invalid provision with a valid provision that best reflects the meaning and purpose of the invalid provision and that can be assumed to be what GIZ and the Recipient would have agreed upon when the Agreement was signed had they been aware of or foreseen that the provision could be or become ineffective or null and void. The same applies to any gaps in this Agreement.

14.2 The Recipient may not assign, transfer or encumber any rights under this Agreement.

14.3 This Agreement is governed by German law.

14.4 The place of performance for payments is Frankfurt am Main.

14.5 The place of jurisdiction is Frankfurt am Main if the Recipient is a merchant, a legal entity under public law or a special fund under public law or does not have a general place of jurisdiction in the Federal Republic of Germany. GIZ may also bring legal action against the Recipient before the competent court at the location of the Recipient's registered office.

14.6 Material amendments to this Agreement must be made in text form in order to be valid, in the form of an amendment to the Agreement. In particular, a change is considered to be 'material' if a change in scope, structure, concept, cost category or objective of the Project results in the purpose or benefit of the Project being fundamentally affected.

14.7 GIZ's whistleblower system can be accessed via the whistleblower portal (bkms-system.com), the GIZ Compliance and Integrity Advisory Service (compliance-mailbox@giz.de) or the external ombudsman, who can be reached at www.giz.de • About GIZ • Compliance • Whistleblowing (Whistleblowing (giz.de)).

15 Annexes to the Agreement

The following annexes to the Agreement shall constitute components of this Agreement.

(Annexes 3. - 4. can be downloaded from www.giz.de/financing .)

Annex 1: Estimated Budget

Annex 2: Project Proposal

Annex 3a: Guidelines on financial processing (07/2023)

Annex 3b: Schedule of funding requirements

Annex 3c: Request for Disbursement

Annex 3d: Financial Report

Annex 3e: Financial Report-Breakdown of actual costs

Annex 3f: Financial Report-Totals per category

Annex 3g1: Financial report Inventory list

Annex 3g2: Record of surrender of equipment and material

Annex 3h: Confirmation of bank details

Annex 3i: Calculation of salary costs

Annex 3j: Time sheet

Annex 4a: Procurement guidelines (10/2022)

Annex 4b: Procurement documentation template

Eschborn, date: 15.01.2024

Deutsche Gesellschaft für
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Geneva, date: 1/25/2024

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