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 June 28th, 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

SINERGIUM BIOTECH S.A., a company incorporated under the laws of Argentina and having its registered office at Av. Córdoba 950 Floor 12 Office D, City of Buenos Aires, Argentina ("**Sinergium**"),

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

RECITALS

WHEREAS, MPP and Sinergium entered into an mRNA Vaccine Technology Transfer Agreement dated 24 January 2023 (the "**Agreement**") as part of the mRNA Technology Transfer Programme, for MPP to transfer to Sinergium technology related to the development and manufacturer of mRNA-based vaccines;

WHEREAS, MPP and Sinergium wish to amend and restate the Agreement to (i) include the provision of funding from MPP to Sinergium for Sinergium to perform activities 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 capitalised 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 18 (*Governing Law and Jurisdiction*) of the Restated Agreement are hereby incorporated into this Amendment as 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: 01 July 2024

Signed for and on behalf of:

SINERGIUM BIOTECH S.A.

Signature: DocuSigned by: Fernando Lobos 61E4B177B9B1425...

Name: Fernando Lobos

Position: Business Development Director

Date: 01 July 2024

Schedule 1

Restated Agreement

mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT

THIS mRNA VACCINE TECHNOLOGY TRANSFER AGREEMENT (this "**Agreement**") is made as of January 24th, 2023 (the "**Effective Date**") and is amended and restated on the June 28th, 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

SINERGIUM BIOTECH S.A., a company incorporated under the laws of Argentina and having its registered office at Av. Córdoba 950 Floor 12 Office D, City of Buenos Aires, Argentina ("**Sinergium**"),

with the **MPP** and **Sinergium** 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**") and The Biologicals and Vaccines Institute of Southern Africa ("**Biovac**") to develop an mRNA technology platform for deployment into LMICs for this purpose;

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

WHEREAS, MPP has obtained sublicensable rights to Afrigen and Biovac's IP, Know-How and data;

WHEREAS, **Sinergium** has been identified by WHO and/or PAHO as a suitable recipient of the mRNA technology platform;

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

WHEREAS, MPP is willing to provide financial support to **Sinergium** to contribute enhancing its mRNA research and development and/or manufacturing capacity and capability.

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 "**Biovac Rights**" shall mean the sublicensable rights to data, Know-How and IP that was granted from **Biovac** to **MPP** under the MPP-Biovac Technology Transfer Agreement dated 4 August 2022, as amended from time to time.

1.4 "**Business Days**" shall mean a day that is not a Saturday, Sunday, bank holiday or public holiday.

1.5 "**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.

1.6 "**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; and

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

"**Event of Force Majeure**" shall have the meaning given in Section 11.3.

1.7 **"Facility**" shall mean the area in the Sinergium premises where the intended transferred

technology will be operationalized.

1.8 **"Funded Project"** shall mean **Sinergium** activities described in the Scope of Work and financed by the Budget described in Annex 5.

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

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

1.11 **"IP"** shall mean any and all rights in or to intellectual property, whether subsisting now or un 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.

1.12 "**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.

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

1.14 **"PAHO"** shall mean the Pan American Health Organization, an international public health agency working to improve health and living standards of the people of the Americas; it serves as the specialized agency for health of the Inter-American System and the Regional Office of the WHO; PAHO procures vaccines and related supplies through its Revolving Fund for Access to Vaccines.

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

1.16 "**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.

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

1.18 "**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.

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

1.20 "**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).

1.21 "**Scope of Work**" shall mean the scope of work set out in Annex 4.

1.22 "**Technical Assistance**" shall mean the assistance detailed in Sections 2.3 and 2.4 of this Agreement.

1.23 "**Technical Information**" shall mean the documentation listed in Annex 3 detailing technical specifications and instructions for manufacturing and testing the selected mRNA vaccine candidate. Such Technical Information shall be transferred to Sinergium written in the English language and in a single copy.

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

1.25 "**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 **Sinergium**, 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 **Sinergium** is detailed in Annex 3.

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

1.27 "**Technology Transfer Package 2**" shall have the meaning described in Annex 3.

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

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

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

1.31 "**Workplan**" shall have the same meaning as defined in Section 2.1.

2 TECHNOLOGY TRANSFER

2.1 **MPP** will cause the Technology Transfer to be conducted in accordance with the chronogram as described in Annex 1. Prior to Technology Transfer activities taking place, **Sinergium** will receive an introduction to the mRNA technology training provided by Afrigen and associated training material (Introduction to the mRNA Technology Package). WHO and/or PAHO will engage with the **Sinergium** to discuss requirements for investments and workforce development to enable readiness at **Sinergium** Facilities to receive the Technology Transfer. In addition, WHO and/or PAHO and MPP will facilitate access to dedicated biomanufacturing trainings (manufacturing/good manufacturing practice base training) and appropriate tools to allow informed decisions to be taken by **Sinergium**.

The Technology Transfer will be offered as sequential packages described in Annex 3**:**

I. Technology Transfer Package 1, called *"mRNA technology for R&D"* (hands-on and mandatory) will be made accessible once Phase 1 Clinical trial material is manufactured and released.

II. Technology Transfer Package 2, called *"mRNA technology industrial scale process*" – industrial implementation (including analytics validated) will be made accessible once the manufacturing process is validated.

An Interim Technology Transfer Package 2a, called *"mRNA technology scaled-up process (including analytics) – non-validated*" can be made accessible as soon as the manufacturing process is scaled up at industrial scale and analytical methods are assessed for industrial testing.

III. Technology Transfer Package 3, called *"mRNA technology industrial scale process*" – Marketing Authorisation Application ("MAA") dossier (including MAA submission package and Clinical trial Phase III results) will be made accessible once the Phase III clinical trial results are made available and the complete MAA dossier submitted.

The Parties will meet and confer following the Effective Date to agree on a workplan setting out the timeline for the delivery of the Technical Transfer Packages and specific access to Technology Transfer Package 2 (and Interim Technology Transfer Package 2a) and Technology Transfer Package 3, as well as detailing actions, reporting, deliverables, and success criteria linked to the Technology Transfer (the "**Workplan**").

2.2 Each Technology Transfer Package shall be considered complete by the Parties when **Sinergium** has received the Technology and the Parties are satisfied that the production of the selected mRNA vaccine candidate meets the requirements outlined in the Workplan.

2.3 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 **Sinergium**, as follows:

(a) Training at Afrigen's site by sending qualified **Sinergium** personnel to the Afrigen site for training on documentation and manufacturing process and analytics.

(b) Training on-site as described in Section 2.3(a) will be initially for a period of no more than ten consecutive Business Days.

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

(d) Should any additional on-site Technical Assistance (e.g. on-site assistance of Afrigen personnel at the **Sinergium** Facility, and additional on-site training at Afrigen) be requested by **Sinergium** beyond Sections 2.3(a)-(c), **Sinergium** shall bear all allowance, travel and accommodation expenses incurred.

2.4 As part of the Technology Transfer Package 2, Technical Assistance to **Sinergium** will be provided, as follows:

(a) Responding in a reasonable timeframe to any query concerning the Technology Transfer Package that might arise after the relevant Technical Information is shared with **Sinergium** and until Technology Transfer completion.

(b) Should any additional Technical Assistance or training (e.g. on-site assistance at **Sinergium** or at Afrigen site) be requested by **Sinergium** beyond Section 2.4(a), **Sinergium** might have to 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 and PAHO to assess **Sinergium** capabilities and identify actions and deliverables for the Technology Transfer to **Sinergium** to proceed, as well as to convene appropriate expertise to support Technology Transfer to **Sinergium**, as feasible and may be necessary.

3.2 Ensure **Sinergium** is provided with the Technology reasonably necessary to fulfil the transfer of Technology Transfer Package 1, Technology Transfer Package 2 and Technology Transfer Package 3 as contemplated in Annexes 1 and 3 herein.

3.3 Work with WHO and PAHO to facilitate the strengthening of the Relevant Regulatory Authority as may be required in **Sinergium** territory(ies) to enable Regulatory Approval of the vaccine and facilitate WHO pre-qualification.

3.4 Provide IP analysis on the Technology, as practicable and appropriate.

3.5 Monitor the activities of **Sinergium** 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 within the agreed timeframes.

4 OBLIGATIONS OF SINERGIUM

Sinergium undertakes to:

4.1 Exercise due diligence in performing the actions and deliverables presented in the Chronology (Annex 1), as further detailed in the Workplan, and in the Scope of Work (Annex 4).

4.2 Provide

(a) technical reports to **MPP,** in a form provided by **MPP**, detailing the progress made towards achieving the milestones defined in the Workplan and a final technical report upon the completion of all the activities set forth in the Workplan; and

(b) financial and technical reports to MPP detailing the financial spending and progress made towards completing the activities defined in the Scope of Work as specified in Section 7.

Sinergium agrees that such reports will be treated as Confidential Information, but that they will be shared with WHO, Funders and PAHO 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 of applying the Technology at the time of Technology Transfer.

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

4.5 In the event that **Sinergium** 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 PAHO Revolving Fund 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.

4.6 In the event that **Sinergium** uses the Technology to commercialise a Product, file for WHO Pre-Qualification or Emergency Use Listing, if available and appropriate. Such Product will be made available to PAHO at a single price for procurement through its Revolving Fund at the lowest price available, which in no event to exceed its Cost of Production plus a twenty percent mark-up.

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 and Funded Project, to receive and review technical reports, and to review proposed changes to the Project or Funded 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 18.

6 GRANT PAYMENT AND USE OF FUNDS

6.1 Subject to the terms and conditions of this Agreement, and **Sinergium's** compliance therewith, **MPP** will fund **Sinergium** for performing the Funded Project in accordance with the approved budget as set out in Section 1 of Annex 5 ("**Budget**"). The maximum amount shall not exceed the total amount of grant as set out in Section 1 of Annex 5 ("**Grant**"). Subject to Section 11.2, **MPP** shall have the right to increase or decrease the total 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 **Sinergium** exclusively in accordance with the Budget. Any overspending on Budget will be at the cost of **Sinergium**, unless otherwise agreed between the Parties.

6.3 **MPP** shall make payments of the Grant to **Sinergium** in accordance with the payment schedule set out in Section 2 of Annex 5 ("**Payment Schedule**"). MPP shall pay the amounts in accordance with the Payment Schedule within 30 days from the completion of the relevant milestone of the Payment Schedule via a bank transfer to the **Sinergium** account set forth in Section 3 of Annex 5.

6.4 **Sinergium** acknowledges and agrees that the Grant is provided to **Sinergium** solely for the purposes of **Sinergium** performing the activities set out in the Scope of Work. **Sinergium** 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. **Sinergium** shall not use the Grant to perform activities outside the Scope of Work unless as otherwise agreed to in writing by the Parties.

7 FUNDED PROJECT REPORTING

7.1 **Sinergium** will submit to MPP interim and final financial reports in a format agreed with MPP, which shall:

(a) be sent in accordance with the timeline specified in the Annex 5;

(b) be issued in USD currency;

(c) contain the comparison between the actual spending of the proportion of the Grant as specified in Annex 5 versus the budgeted amounts;

(d) be certified as complete and accurate by an authorised official of **Sinergium** for the activities performed; and

(e) be sent to the address set forth in Annex 5,

("each a **Financial Report**"). All financial payments reported under Section 7.1 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 **Sinergium** pursuant to Section 7.6. In addition to the final financial report referred to in this Section 7.1, **Sinergium** shall provide to **MPP** a questionnaire, in a format to be provided by **MPP**, regarding the use of funds under this Agreement. Such questionnaire shall be filled and then signed by an **Sinergium** staff member mutually agreed upon by the Parties.

7.2 **Sinergium** shall submit to MPP interim and final technical reports in a format agreed with MPP, which shall:

(a) be sent in accordance with the timeline specified in Annex 5; and

(b) contain a description of the progress on the Project with respect to the actual spending of the proportion of the Grant,

(each a "**Technical Report**").

7.3 **MPP** shall, within 7 working days after receipt of a Financial Report or Technical Report, review the report and either approve or provide comments on the report. If comments are provided, **Sinergium** shall, within 10 working days after the receipt of MPP's comments, prepare a revised report that addresses MPP's comments and re-submit it to MPP for approval.

7.4 MPP and **Sinergium** shall repeat the process in Section 7.3 until **MPP** approves the relevant report. For the avoidance of doubt, no act or omission of **MPP** in connection with Section 7.3 constitutes deemed approval of a report and approval of a report does not occur until **MPP** notifies **Sinergium** in writing that a report has been approved.

7.5 **Sinergium** shall monitor its spending for the Funded Project and shall maintain supporting documentation for all costs associated with the Funded Project, including records substantiating 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.

7.6 **MPP** or its authorised representative shall have the right to review and audit all costs alleged to have been incurred hereunder and those records required by Section 7.5 at agreed upon times and locations. **Sinergium** 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. **Sinergium** shall also provide copies of any response to any such report and a plan for corrective action. **Sinergium** 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. **Sinergium** shall ensure that appropriate records are kept supporting the entries made on the cost code.

7.7 **Sinergium** shall notify **MPP** promptly in case of any significant issues in the performance of the Funded Project.

8 GRANT OF LICENCE AND INTELLECTUAL PROPERTY

8.1 Subject to the terms and conditions of this Agreement MPP hereby grants to **Sinergium**:

(a) a non-exclusive, royalty-free, non-sublicensable, non-transferable, irrevocable, fully paid-up, royalty-free licence under the following:

(b) Technology, the Afrigen Rights and the Biovac Rights; and

(c) 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.

8.2 **Sinergium** grants to **MPP** a non-exclusive, non transferable, but sublicensable, irrevocable, fully paid-up, royalty-free, worldwide license to practice and have practiced the data and the Inventions arising from the Project 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 **Sinergium** will enter into good-faith negotiations. **Sinergium** agrees to provide to **MPP** a licence in relation to any of its background rights arising from the Project only to the extent necessary to enable the use and exercise of the Inventions made by **Sinergium** hereunder.

8.3 In the event that **Sinergium** is provided with access to Third Party IP for the purposes of research, development and/or commercialization of Product(s), **Sinergium** 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 8.2 herein.

8.4 **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.

9 EXCHANGE OF INFORMATION AND CONFIDENTIALITY

9.1 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.

9.2 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.

9.3 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 9.

9.4 The obligations in Sections 9.1, 9.2 and 9.3 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.

9.5 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.

9.6 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 7. Such relief shall be in addition to all other remedies available to the non-breaching Party at law or in equity.

9.7 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.

10 AUDIT

In addition to the audit rights in Section 7.6, **MPP**, **PAHO**, or either's authorized representative will have the right to audit **Sinergium's** compliance with Sections 4.5, and 8.2 of this Agreement. **Sinergium** will be required to keep accurate records to allow **MPP** or its authorized representative to adequately conduct such audit.

11 TERM AND TERMINATION, SURVIVAL

11.1 This Agreement shall be deemed to come into effect on the Amended Effective Date and shall continue for seven years.

11.2 **MPP** may suspend this Agreement immediately if its Funders reduce or fail to provide funding for the Project. In the event support of the Project is discontinued or is reduced to the extent that **MPP**, in its sole discretion, determines it is not practicable to continue the Project, **MPP** may terminate this Agreement effective immediately upon notice.

11.3 Save as otherwise provided in this Agreement, if **Sinergium** 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 **Sinergium** 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.

11.4 Termination or completion of this Agreement shall not affect those provisions of this Agreement which are expressly or by implication intended to survive the termination or completion of this

Agreement, including but not limited to Sections 4.5, 8.2, 8.3, 8.4, 9 and 10, provided, however, that such survival will only be effective upon the applicable **Sinergium's** receipt of the Interim Technology Transfer Technical Information Package 2a as described in Annex 3. 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.

11.5 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.

11.6 Upon termination prior to the end of the Funded Project pursuant to Section 11 hereof, **Sinergium** shall return all funding received from **MPP** under this Agreement which is unspent at the date of termination (after deduction of costs and non-cancellable commitments incurred prior to the date of termination).

12 WARRANTIES, INDEMNITIES, COMPLIANCE WITH LAW

12.1 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.

12.2 Except as otherwise expressly provided in this Agreement, MPP does not make any representations or warranties, express or implied with respect to the Technology, Afrigen Rights or Biovac 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, Afrigen Rights or Biovac Rights. Furthermore, nothing in this Agreement shall be construed as a warranty that **Sinergium's** use of the Technology, Afrigen Rights or Biovac 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 **Sinergium** to ensure such safety or efficacy.

12.3 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 **Sinergium**), provided that the indemnification obligation established in this Section 12.3 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 12.3. 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.

12.4 **Sinergium** 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.

12.5 **Sinergium** 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. **Sinergium** 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.

12.6 **Sinergium** shall be respectful of its employees' right to freedom of association and shall encourage compliance with the standards referred to in Sections 12.4 and 12.5 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.

12.7 **Sinergium** 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.

12.8 **Sinergium** 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.

13 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 13 are satisfied.

14 SEVERABILITY

14.1 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.

14.2 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 oflaw.

15 ENTIRE AGREEMENT

15.1 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.

15.2 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.

16 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.

17 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.

18 GOVERNING LAW AND JURISDICTION

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

18.2 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 Rules of Arbitration of the International Chamber of Commerce. 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: 01 July 2024

Signed for and on behalf of:
SINERGIUM BIOTECH S.A.

Signature: DocuSigned by: Fernando Lobos 61E4B177B9B1425...

Name: Fernando Lobos

Position: Business Development Director

Date: 01 July 2024

LIST OF ANNEXES

ANNEX 1 - Technology Transfer Chronology

ANNEX 2 - Terms of Material Transfer

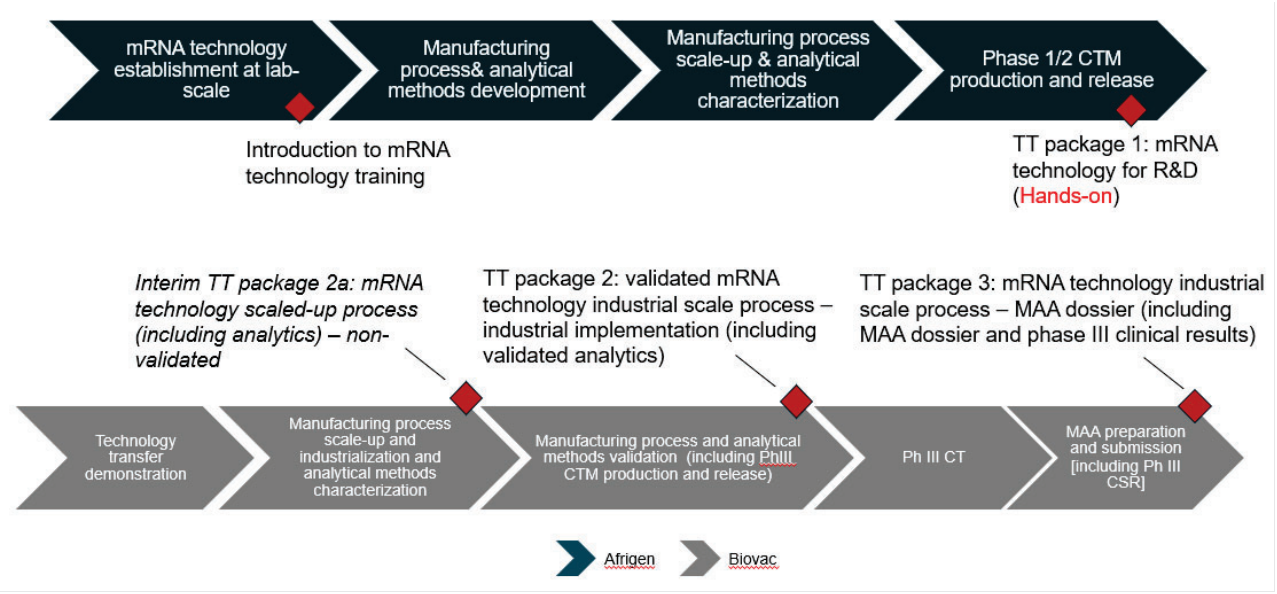
ANNEX 3 - Technology transfer Package1, Package 2 and Package 3 content

ANNEX 4 - Funded Project Scope of Work and Key personnel

ANNEX 5 - Budget, Payment Schedule, Reporting

ANNEX 1

Technology Transfer Chronology



ANNEX 2

Terms of Material Transfer

1. **MPP** shall ensure **Afrigen** will transfer to Sinergium 2 vials of GMP Master Cell Bank (MCB) and, as soon as available, 10 vials of the GMP Working Cell Bank (WCB) of the Material in its possession; the aforementioned material can be used by Sinergium for research and development and commercial purposes in the Commercial Territory with the granted rights provided in the Agreement.
2. **MPP** shall ensure **Afrigen** will provide Sinergium with batch records and certificate of Analysis of the MCB and WCB transferred to Sinergium and with sufficiently detailed operating protocols needed for propagation, identification. characterization and release testing of batches derived from the Material provided. Sinergium will be responsible for the validation and the manufacturing of their own GMP WCBs.
3. MPP shall ensure **Afrigen** will provide Sinergium Quality Control Standards and comparators (materials or information for procurement from commercially available sources as appropriate) and primary and secondary Controls (materials or information for procurement from commercially available sources as appropriate). Detailed list including sources and amounts will be included in the Technical Transfer Plan.

ANNEX 3

Technology transfer Package1, Package 2 and Package 3 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.

PACKAGE 2

Package 2 shall include:

- Technology Transfer Technical Information Package 2 (content listed below)
- Technical Assistance (as defined in section 2.4 of this agreement)

Technology Transfer Technical Information Package 2 content:

1. Working Cell Bank, DNA, Drug substance (mRNA), bulk drug product (encapsulated mRNA) and drug product production processes.
2. Analytical procedures (Raw materials, product and packaging specifications).
3. Reference and supplier of raw materials, consumables and equipment.
4. Process development support data capturing key experience/product knowledge:
    i. Cell History, batch record and analytical results.
    ii. Process development report that outlines the manufacturing process rationale. It includes:
        - scale up studies (if required);
        - large scale process characterization study results;
        - robustness study results;
        - critical manufacturing process parameters/steps;
        - validation reports;
        - the success (or failure) of the industrial technology development.
    iii. History or evolution of the process and comparison along the product development from phase I to phase III.
    iv. Rationale for proposed specifications for Phase III.
5. Whole process analytical validation documentation, including:
    - process capability;
    - rework procedure;
    - process control;
    - trend summaries;
    - process variations and the investigation of those variations;
    - follow-up actions, rationale and summary of reworked product.

    Description (batch/trial number, purpose, lineage, size, results, comments) and identification (clinical/bio-equivalency/ICH - dossier/application stability) of all pivotal batches should be included.
6. Comparison between Receiving Unit (Biovac) confirmation batches and sending unit (AFRIGEN) reference pivotal batches demonstrating comparability (DP specifications met), including non-clinical and pre-clinical study results.
7. History of critical analytical data (e.g., release and stability data) rationale for proposed specifications.

Interim Technology Transfer Technical Information Package 2a shall include:

1. Research Cell Bank, plasmid amplification (pDNA) at 20-30 L scale, Drug substance (mRNA) at 10-20L, bulk drug product (encapsulated mRNA) processes.
2. Analytical procedures (Raw materials, product and packaging specifications) in place, pre-validated.
3. Reference and supplier of raw materials, consumables and equipment.
4. Process development support data capturing key experience/product knowledge:
    i. Cell History, batch record and analytical results.
    ii. Process development report that outlines the pDNA and mRNA manufacturing process rationale. It includes:
        - scale up for mRNA production process/scale down studies for plasmid production if VRC process received at larger scale;
        - large scale process characterization study results (as described above)
        - robustness study results;
        - critical manufacturing process parameters/steps;

    iii. Process development report (PDR) on evolution and rationale of the pDNA and mRNA process and comparison along the product development from phase I to scale up.
5. Qualified analytical documentation, including:
    - Assessment reports;
    - reworked analytical procedure;
    - trend summaries (where applicable);
    - process variations and the investigation of those variations.

6. Batch record and analytical results of pivotal batches (preclinical/at scale technical batches) and technical interpretation of the results.
7. Screening stability results.
8. Appropriate comparison between preclinical (at Afrigen) and scale-up batches (at Biovac).

PACKAGE 3

Package 3 shall include:

Marketing Authorization Application dossier Sections II-V (named as per ICH guidelines) – including summaries and quality, non-clinical and clinical information data packages as required by the National Regulatory Authority where the dossier was submitted.

ANNEX 4

Funded Project Scope of Work and Key Personnel

1. **FUNDED ACTIVITIES DESCRIPTION:** The activities to be funded are the trainings, all strictly related to the mRNA VACCINE TECHNOLOGY TRANSFER project.

2. **KEY ASSUMPTIONS:**
MPP will provide financial support for Sinergium to participate in trainings relevant to enable the implementation of the technology. Prior to engage in any training, Sinergium shall provide MPP with the details of the intended training and seek for MPP endorsement before to participate in the given training.
The hands-on training at Afrigen on Package 1 will be fully sponsored by the mRNA Programme and this will be in addition to the support provided though this agreement.

3. **PARTNER ACTIVITIES**

Sinergium shall perform the activities set out in the table below.

KEY ACTIVITIES		TIME FRAME
Activity 1:	**Training**	
1.1	*Participation in training related to mRNA vaccine production and analytics.*	*April 2024 – June 2025*

4. **KEY PERSONNEL**

SINERGIUM

Name	Role	e-mail
German Sanchez Alberti	Project Lead	German.sanchez@sinergiumbiotech.com
Federico Carrizo	R&D Supervisor	Federico.carrizo@sinergiumbiotech.com
Carolina Levi	Molecular Biology Specialist	Carolina.levi@sinergiumbiotech.com
Trinidad Pomilio	Project Management Specialist	Trinidad.pomilio@sinergiumbiotech.com
Luciano Chaneton	R&D Head	Luciano.chaneton@sinergiumbiotech.com
Diego Egoburo	DSP Analyst	Diego.egoburo@sinergiumbiotech.com
Florencia Marchese	Molecular Biology Analyst	Florencia.marchese@sinergiumbiotech.com
Lucrecia Curto	Analytical development Specialist	Lucrecia.curto@sinergiumbiotech.com
Agustin Blachmann	R&D Analyst	Agustin.blachmann@sinergiumbiotech.com
Melissa Ferreyra	R&D Analyst	Melissa.ferreyra@sinergiumbiotech.com
Lucia Moura	Analytical development Analyst	Lucia.moura@sinergiumbiotech.com

MPP:

Name	Role	e-mail
Ike James	Head of Technology Transfer	ijames@medicinespatentpool.org
Monica Moschioni	Programme Manager	mmoschioni@medicinespatentpool.org
Julien Bon	Project Manager	jbon@medicinespatentpool.org
Landry Bertaux	Biologicals expert	lbertaux@medicinespatentpool.org
Antonio Grilo	Technology Transfer expert	agrilo@medicinespatentpool.org