PUBLIC HEALTH SERVICE

PATENT LICENSE-NON-EXCLUSIVE

AND

BIOLOGICAL MATERIALS LICENSE – NON-EXCLUSIVE

This **Agreement** is based on the model Patent License Non-exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by the:

National Institute of Allergy and Infectious Diseases,
National Cancer Institute,
National Eye Institute,
National Institute of Environmental Health Sciences,
National Center for Advancing Translation Sciences,

all Institutes or Centers (hereinafter referred to as "**IC**") of the

NIH

and

Medicines Patent Pool Foundation

hereinafter referred to as the "**Licensee**",
having offices at Rue de Varembé 7, 1202 Geneva, Switzerland,
and created and operating under the laws of Switzerland.

For **IC** internal use only:

License Number: TBD

License Application Number: A-290-2022

Serial Number(s) of Licensed Patent(s) or Patent Application(s): See Appendix A.

Licensee: Medicines Patent Pool Foundation

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention): N/A

Additional Remarks: N/A

Public Benefit(s): This license will benefit public health by allowing for development of SARS-CoV-2 products for the WHO C-TAP program.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D ((Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options).

IC and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **IC** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **IC** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **IC**.

1.3 The Secretary of **HHS** has delegated to **IC** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.

1.4 **IC** desires to transfer these inventions to the public or private sectors through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to **Sublicense** processes, methods, or marketable products for public use and benefit through the World Health Organizaton COVID-19 Technology Access Pool.

1.6 The World Health Organization COVID-19 Technology Access Pool (WHO C-TAP) was establish to implement the Solidarity Call to Action launched by WHO to provide a platform for the developers of COVID-19 vaccines, tests, medical devices, and therapeutics to share their data, know-how and intellectual property rights, with quality assured manufacturers. Technology holders are called to voluntarily license such rights on a non-exclusive and worldwide basis through implementing partners like the Medicines Patent Pool to facilitate further development and widescale production, distribution, sale and use of such health technologies throughout the world promoting equitable, affordable and timely access to their products for all countries.

2. DEFINITIONS

2.1 "**Additional License**" means an exclusive or nonexclusive license that includes the **Licensed Patent Rights** and is granted to a **Third Party** who is responsible for paying a share of patent expenses, and wherein the exclusive or nonexclusive license has a **Licensed Field of Use** directed to therapeutic applications. **Additional License** specifically excludes license directed solely to evaluation, internal research use or commercialization of research reagents.

2.2 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.3 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.4 "**Biologics License Application** (**BLA**)" means a biological product license or similar application or submission for marketing approval filed with or submitted to a **Regulatory Authority** in conformance with the requirements of such **Regulatory Authority**.

2.5 "**Clinical Trial**" means a **Phase I Clinical Trial**, **Phase II Clinical Trial**, **Phase III Clinical Trial** and/or Post-approval Clinical Trial.

2.6 "**WHO C-TAP Development Plan**" means the written development plan attached as Appendix E.

2.7 "**First Commercial Sale**" means the initial transfer by or on behalf of a **Sublicensee** of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of the **Sublicensee** in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.8 "**FDA**" means the Food and Drug Administration.

2.9 "**Government**" means the Government of the United States of America.

2.10 "**IND**" means an Investigational New Drug application, Clinical Study Application, Clinical Trial Exemption, or similar application or submission for approval to conduct human clinical investigations filed with or submitted to a **Regulatory Authority** or in conformance of such a **Regulatory Authority**.

2.11 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.12 "**Licensed Materials**" means the tangible materials listed in Appendix B including all progeny, subclones, and unmodified derivatives thereof and products expressed by such tangible materials.

2.13 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.13(a):

(i) continuations-in-part of 2.13(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.13(a); and

(v) any reissues, reexaminations, and extensions of all these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.13(a): all counterpart foreign and U.S. patent applications and patents to 2.13(a) and 2.13(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.13(b) or 2.13(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.13(a).

2.14 "**Licensed Processes**" means processes, which in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.15 "**Licensed Products**" means:

(a) tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction; and

(b) tangible materials made from or derived, in whole or in part, by the **Licensee** from the **Licensed Materials**, whether or not included within the scope of one or more **Valid Claims** of the **Licensed Patent Rights** that are used, manufactured, sold or imported**.**

2.16 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.17 "**Marketing Authorization**" means all approvals from the relevant **Regulatory Authority** necessary to market and sell any of the **Licensed Products** in any country (including without limitation all applicable private and governmental reimbursement approvals even if not legally required to sell **Licensed Products** in a country).

2.18 "**Net Sales**" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of a **Sublicensee**, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by a **Sublicensee**, and on its payroll, or for the cost of collections.

2.19 "**Phase I Clinical Trial**" means a human clinical trial (including Phase Ia and Ib) in any country that is not a **Phase II Clinical Trial**, not a **Phase III Clinical Trial**, and not a **Phase IV Clinical Trial**.

2.20 "**Phase II Clinical Trial**" means a human clinical trial (including Phase IIa and IIb) in any country in which the protocol is designed to include at least one endpoint measuring efficacy (qualitative or quantitative) for a new indication, but the design is not sufficiently controlled or sized to support regulatory approval of the **Licensed Product** for marketing.

2.21 "**Phase III Clinical Trial**" means, for the purposes of this **Agreement**, a human clinical trial in any country in which the protocol is designed to support regulatory approval of the **Licensed Product** for marketing.

2.22 "**Phase IV Clinical Trial**" means, for the purposes of this **Agreement**, any clinical trial initiated after regulatory approval to market a **Licensed Product** because completing that trial successfully was required by the regulatory agency as a condition of such approval. Also, **Phase IV Clinical Trial** includes trials intended to expand or alter the scope of the regulatory approval (a) to include additional or alternative dosing, or (b) to include additional or alternative routes of administration, or (c) to comply with new regulatory requirements. **Clinical Trials** for indications additional to those already approved are not **Phase IV Clinical Trials**.

2.23 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

2.24 "**Pro Rata Share**" means one of the following:

(a) in instances where the **Additional License(s)** granted by **IC** recover a predetermined percentage of patent costs, one hundred percent (100%) of patent prosecution costs minus the percentage of patent prosecution costs recovered by the **Additional License(s)** which recover a pre-determined percentage of patent costs. For example, if **IC** has granted an **Additional license** which recovers twenty percent (20%) of patent prosecution costs, then the **Pro Rata Share** would be one hundred percent (100%) minus twenty percent (20%), or eighty percent (80%);

(b) in instances where the **Additional License(s)** granted by **IC** recover a full **Pro Rata Share** of patent prosecution costs, one (1) minus the value derived from the number of **Additional License(s)** granted by **IC** which recover a full **Pro Rata Share** of patent prosecution costs divided by the total number of licenses granted by **IC** which recover a full **Pro Rata Share** of patent prosecution costs. For example, if **IC** has granted four (4) **Additional Licenses** which recover a full **Pro Rata Share** of patent prosecution costs, then the **Pro Rata Share** would be, one (1) minus [four (4) divided by five (5)], or one fifth (1/5); or

(c) instances where the **Additional License(s)** are granted according to the definition of both 2.24(a) and 2.24(b), the **Pro Rata Share** paid by **Licensee** will be the value derived from the **Pro Rata Share** as determined under paragraph 2.24(a) multiplied by the value derived from the **Pro Rata Share** as determined under paragraph 2.24(b). For example, if two (2) **Additional Licenses** are granted wherein one (1) **Additional License** recovers twenty percent (20%) of patent prosecution costs and one (1) **Additional License** recovers a full **Pro Rata Share** of patent prosecution costs, the **Pro Rata Share** would be (one hundred percent (100%) minus twenty percent (20%)) multiplied by (one (1) minus (one (1) divided by two (2)), or eighty percent (80%) multiplied by one-half (1/2), equaling forty percent (40%).

2.25 "**Regulatory Authority**" means any applicable government regulatory authority involved in granting approvals for the manufacturing, marketing, reimbursement and/or pricing of **Licensed Products** in the **Licensed Territory**, including, in the United States, the United States Food and Drug Administration and any successor or foreign governmental authority having substantially the same function.

2.26 "**Sublicense**" means any sublicense granted under Section 4 of this **Agreement**.

2.27 "**Sublicensee**" means any **Third Party** granted a **Sublicense**.

2.28 "**Third Party**" means a person or entity other than **Licensee** or any of its **Affiliates** and **IC**.

3. GRANT OF RIGHTS

3.1 **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive right to grant **Sublicenses** under the **Licensed Patent Rights** in the **Licensed Territory** that include the right of the **Sublicensee** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 **IC** hereby grants and the **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive right to grant **Sublicenses** to **Licensed Materials** in the **Licensed Territory** that include the right of the **Sublicensee** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products** in the **Licensed Fields of Use**.

3.3 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **IC** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by **IC,** and which shall not be unreasonably withheld, the **Licensee** may enter into sublicensing agreements for the **Licensed Patent Rights** and **Licensed Materials**. These sublicenses will not have a further right of sublicense and must be granted in accordance with the **WHO C-TAP Development Plan** as described in Appendix C. Sublicenses must also be issued by the **Licensee** without discrimination to any sublicensee with the demonstrated commitment, ability, and readiness to use the sublicense but in no instance shall a sublicense be issued for use in a country under **Government** sanction.

4.2 The **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to the **IC** of Paragraphs 5.1, 5.2, 8.1, 10.1, 10.2, 12.6, and 13.7-13.9 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. The **Licensee** further agrees to attach copies of these paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by the **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and **IC,** at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to the **IC** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to **IC** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, the **IC** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Upon request and prior to the **First Commercial Sale**, the **Licensee** agrees to require the **Sublicensee** to provide **IC** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **IC** research use.

5.2 The **Licensee** will require any **Sublicensee** to agree that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States unless a written waiver is obtained in advance from **IC**.

6. ROYALTIES AND REIMBURSEMENT

6.1 The **Licensee** will require each **Sublicensee** to pay **Licensee**, and **Licensee** agrees to pay **IC** a noncreditable, nonrefundable **Sublicensee** issue royalties as set forth in Appendix C.

6.2 The **Licensee** will require each **Sublicensee** to pay **Licensee**, and **Licensee** agrees to pay **IC** a minimum **Sublicensee** annual royalties as set forth in Appendix C.

6.3 The **Licensee** will require each **Sublicensee** to pay **Licensee**, and **Licensee** agrees to pay **IC** **Sublicensee** earned royalties as set forth in Appendix C.

6.4 The **Licensee** will require each **Sublicensee** to pay **Licensee**, and **Licensee** agrees to pay **IC** **Sublicensee** benchmark royalties as set forth in Appendix C.

6.5 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses; or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.6 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.7 On sales of **Licensed Products** by **Sublicensees** of **Licensee** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.8 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by **IC** prior to the effective date of this **Agreement**, the **Licensee** shall require each **Sublicensee** to pay **Licensee**, and **Licensee** shall pay **IC** upon the grant of each **Sublicense**, as an additional royalty, within sixty (60) days of **IC's** submission of a statement and request for payment to the **Licensee**, an amount equivalent to a **Pro Rata Share** of the unreimbursed patent expenses previously paid by **IC**. The **Licensee**'s obligation for each of its **Sublicensee(s)** under this clause shall not exceed 25% per **Sublicensee** of said unreimbursed expenses previously paid by **IC**.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by **IC** on or after the effective date of this **Agreement**, **IC**, at its sole option, may require the **Licensee** to collect from **Sublicensee(s)** and to pay **IC**:

(a) on an annual basis, within sixty (60) days of **IC's** submission of a statement and request for payment, a royalty amount equivalent to the lesser of (a) a **Pro Rata Share** or (b) twenty-five percent (25%) of these unreimbursed expenses paid during the previous calendar year(s) for each of its **Sublicensee(s)**;

(b) the lesser of (a) a **Pro Rata Share** or (b) twenty-five percent (25%) of these unreimbursed expenses for each of its **Sublicensee(s)** directly to the law firm employed by **IC** to handle these functions. However, in this event, **IC** and not the **Licensee** shall be the client of the law firm,

6.10 Under exceptional circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide **IC** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 **IC** agrees, upon written request, to provide the **Licensee** with summaries of patent prosecution invoices for which **IC** has requested payment from the **Licensee** under Paragraphs 6.8 and 6.9. The **Licensee** agrees that all information provided by **IC** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party, other than to **Licensee's Sublicensee(s)** as confidential commercial information, except as required by law or a court of competent jurisdiction.

6.12 The **Licensee** may elect to surrender its rights for any individual **Sublicensee** in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to **IC** and owe no payment obligation for that **Sublicensee** under Paragraph 6.9 for patent-related expenses paid in that country after the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 **IC** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** by each **Sublicensee** appropriate to determine the amount of royalties due **IC**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of **IC**, by an accountant or other designated auditor selected by **IC** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to **IC** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the **Licensee** shall reimburse **IC** for the cost of the inspection at the time the **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date **IC** provides the **Licensee** notice of the payment due.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, the **Licensee** has provided **IC** with the **WHO C-TAP Development Plan** in Appendix E, under which the **Licensee** and its **Sublicensees** intend to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **WHO C-TAP Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 The **Licensee** shall provide written annual reports on **Sublicensee** product development progress or efforts to commercialize under the **WHO C-TAP Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to progress on research and development, status of applications for regulatory approvals, manufacture, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. **IC** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Licensed Patent Rights** and **Licensed Materials**. If reported progress differs from that projected in the **WHO C-TAP Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for such differences. In any annual report, the **Licensee** may propose amendments to the **WHO C-TAP Development Plan**, acceptance of which by **IC** may not be denied unreasonably. The **Licensee** agrees to provide any additional information reasonably required by **IC** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Benchmarks** at any time upon written approval by **IC**. **IC** shall not unreasonably withhold approval of any request of the **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by the **Licensee** of diligence in its performance under the **WHO C-TAP Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

9.3 The **Licensee** shall report to **IC** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 The **Licensee** shall submit to **IC**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee's Sublicensee(s)** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to **IC** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.18 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to **IC** at its address for **Agreement** Notices indicated on the Signature Page.

9.6 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

9.7 Additional royalties may be assessed by **IC** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **IC** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **IC** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.8 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by **IC** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 The **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **WHO C-TAP Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D.

10.2 Upon the **First Commercial Sale** in the United States, until the expiration or termination of this **Agreement**, the **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 The **Licensee** agrees to require each of its **Sublicensee(s)**, after that **Sublicensee's First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs.

10.4 The **Licensee** agrees to require each of its **Sublicensee(s)**, after that **Sublicensee's First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 The **Licensee** agrees to supply **IC**, at the mailing address listed for notices, with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 **IC** and the **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.

11.2 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against **IC**, **IC** agrees to notify the **Licensee** that an action alleging invalidity has been brought. **IC** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. Should the **Government** be made a party to any suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. Upon the **Licensee's** payment of all costs incurred by the **Government** as a result of the **Licensee's** joinder motion or other action, these actions by the **Licensee** shall not be considered a default in the performance of any material obligation under this **Agreement**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 **IC** offers no warranties other than those specified in Article 1.

12.2 **IC** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 **IC** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS**, THE **LICENSED MATERIALS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 **IC** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, THAT THE **LICENSED PRODUCTS** MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. THE **LICENSEE** ACCEPTS **LICENSED PATENT RIGHTS** AND **LICENSED MATERIALS** FOR THE **LICENSED PRODUCTS** "AS IS", AND THE **NIH** DOES NOT OFFER ANY GUARANTEE OF ANY KIND.

12.5 **IC** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.6 The **Licensee** shall indemnify and hold **IC**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of the **Licensee** and its **Sublicensees**, its directors, employees, or third parties of any **Licensed Patent Rights** or **Licensed Materials**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes,** or materials by the **Licensee** and its **Sublicensee(s)**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights** or **Licensed Materials**.

12.7 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.15 are not fulfilled, and shall extend to either the expiration of the last to expire of the **Licensed Patent Rights** or twenty (20) years, whichever is longer, unless sooner terminated as provided in this Article 13.

13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **IC** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify **IC** in writing.

13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving **IC** sixty (60) days written notice to that effect.

13.5 **IC** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **IC** determines that the **Licensee**:

(a) is not executing the **WHO C-TAP Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **IC's** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived; or

(h) has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under this **Agreement**.

13.6 In making the determination referenced in Paragraph 13.5, **IC** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, **IC** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **IC's** concerns as to the items referenced in 13.5(a)-13.5(h). If the **Licensee** fails to alleviate **IC's** concerns as to the items referenced in 13.5(a)-13.5(h) or fails to initiate corrective action to **IC's** satisfaction, **IC** may terminate this **Agreement**.

13.7 **IC** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the **Licensee**.

13.8 Within thirty (30) days of receipt of written notice of **IC's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **IC** official. The decision of the designated official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **IC** shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **IC** or provide **IC** with written certification of the destruction thereof. The **Licensee** may not be granted additional **IC** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Materials**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated Postal Service postmark or obtain a dated receipt from a commercial carrier or the Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) without the prior written consent of **IC**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that **IC** approves a proposed assignment, the **Licensee** shall pay the **IC**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment.

14.8 The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

14.9 The **Licensee** agrees to require **Sublicensee(s)** to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve **IC** patent rights in those countries.

14.10 By entering into this **Agreement**, **IC** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **IC**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of **IC**, **FDA**, **HHS**, or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of **IC**.

14.11 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.

14.12 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.13 Paragraphs 8.1, 9.6-9.8, 12.1-12.5, 13.8, 13.9, 14.11 and 14.13 of this **Agreement** shall survive termination of this **Agreement**.

14.14 The terms and conditions of this **Agreement** shall, at **IC's** sole option, be considered by **IC** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **IC** within sixty (60) days from the date of the **IC** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – NONEXCLUSIVE

AND

BIOLOGICAL MATERIALS LICENSE -- NONEXCLUSIVE

SIGNATURE PAGE

For **IC**:

Michael R. Mowatt -S
Digitally signed by Michael R. Mowatt -S
Date: 2022.05.10 08:26:09 -04'00'

Michael Mowatt — Date
Director, Technology Intellectual Property Office
National Institute of Allergy and Infectious Diseases

Richard U. Rodriguez -S
Digitally signed by Richard U. Rodriguez -S
Date: 2022.05.10 08:39:32 -04'00'

Richard Rodriguez — Date
Associate Director, Technology Transfer Center
National Cancer Institute

Lillianne M. Portilla Weingarten -S
Digitally signed by Lillianne M. Portilla Weingarten -S
Date: 2022.05.10 11:22:56 -04'00'

Lili Portilla — Date
Director, Office of Strategic Alliances
National Center For Advancing Translational Sciences

Bruce D. Goldstein -S
Digitally signed by Bruce D. Goldstein -S
Date: 2022.05.11 14:55:02 -04'00'

Bruce Goldstein — Date
-- for National Institute of Environmental Health Sciences
Director, Office of Technology Transfer and Development
National Heart, Lung and Blood Institute

Mala Dutta -S
Digitally signed by Mala Dutta -S
Date: 2022.05.11 15:01:49 -04'00'

Mala Dutta — Date
Technology Development Coordinator
National Eye Institute

Mailing Address or E-mail Address for **Agreement** notices and reports:

License Compliance and Administration
Monitoring & Enforcement

6701 Rockledge Drive
Suite 700, MSC 7788
Bethesda, Maryland 20892

E-mail: LicenseNotices_Reports@mail.nih.gov

For the **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Licensee** made or referred to in this document are truthful and accurate.):

DocuSigned by:
Charles Gore
4713D0F59C13482...

Charles Gore
Executive Director

11 May 2022 | 21:40 PDT
Date

Official and Mailing Address for **Agreement** notices:

Chan Park
Medicines Patent Pool Foundation
Rue de Varembé 7
1202 Geneva, Switzerland
Phone: +41 (0)22 533 50 50
Email: office@medicinespatentpool.org

Official and Mailing Address for Financial notices (the **Licensee's** contact person for royalty payments)

Chan Park
Medicines Patent Pool Foundation
Rue de Varembé 7
1202 Geneva, Switzerland
Phone: +41 (0)22 533 50 50
Email: office@medicinespatentpool.org

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

APPENDIX A – PATENT(S), PATENT APPLICATION(S) AND LICENSED MATERIALS

Patent(s) or Patent Application(s):

US Provisional Patent Application 63/077,123 filed 11 September 2020 entitled "RNASEH-Assisted Detection Assay for RNA" [HHS Ref. No. E-193-2020-0-US-01]

PCT Patent Application PCT/US2021/058370 filed 9 October 2020 entitled "RNASEH-Assisted Detection Assay for RNA" [HHS Ref. No. E-193-2020-0-PCT-02]

US Provisional Patent Application 63/245,512 filed 17 September 2021 entitled "Synthetic Humanized Llama Nanobody Library And Use Thereof To Identify SARS-COV-2 Neutralizing Antibodies" [HHS Ref. No. E-172-2021-0-US-01]

US Provisional Patent Application 63/065,931 filed 14 August 2020 entitled "Detection of SARS-CoV-2 and other RNA Virus Using a Novel Improved RT-qPCR Method that Increases Detection Sensitivity and Improves Safety" [HHS Ref. No. E-195-2020-0-US-01]

PCT Patent Application PCT/US2021/045675 filed 12 August 2021 entitled "Detection of SARS-CoV-2 and other RNA Virus Using a Novel Improved RT-qPCR Method that Increases Detection Sensitivity and Improves Safety" [HHS Ref. No. E-195-2020-0-PCT-02]

US Provisional Patent Application 63/116,031 filed 19 November 2020 entitled "High-Throughput COVID-19 Diagnostic Test that Detects Both Viral and Host Nucleic Acid" [HHS Ref. No. E-241-2020-0-US-01]

PCT Patent Application PCT/US2021/059996 filed 19 November 2021 entitled "High-Throughput COVID-19 Diagnostic Test that Detects Both Viral and Host Nucleic Acid" [HHS Ref. No. E-241-2020-0-PCT-02]

US Provisional Patent Application 63/180,534 filed 27 April 2021 entitled "Recombinant Chimeric Bovine/Human Parainfluenza Virus 3 Expressing SARS-CoV-2 Spike Protein and Its Use" [HHS Ref. No. E-239-2020-0-US-01]

PCT Patent Application in preparation entitled "Recombinant Chimeric Bovine/Human Parainfluenza Virus 3 Expressing SARS-CoV-2 Spike Protein and Its Use" [HHS Ref. No. E-239-2020-0-PCT-02]

Note: Specific National Stage filings are yet to be determined. **IC** represents that for any PCT applications that have not yet entered national phase, with the possible exception of India, it will not file patent applications in Low-Income Economy Countries or Lower-Middle Income Economy Countries as determined by the World Bank.

Licensed Materials:

"Structure-Based Design of SARS-CoV-2 Spike Immunogens Stabilized in the RBD-All Down Conformation" [HHS Ref. No. E-187-2020]

"Plasmid Encoding SARS-CoV-2 Spike Protein Variants Useful For Making Pseudovirus That Can Be Evaluated In BSL2 Labs" [HHS Ref. No. E-223-2020]

"rVSV-EBOV Based Vaccine Candidate Against COVID-19" [HHS Ref. No. E-258-2020]

"Newcastle Disease VLPs Displaying Prefusion Stabilized SARS-CoV-2 Spike Protein" [HHS Ref. No. E-068-2021]

"Plasmid Encoding The Human ACE2 Dimer" [HHS Ref. No. E-135-2021]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

SARS-CoV-2 products for the WHO C-TAP program

II. **Licensed Territory:**

Worldwide

III. **Least Developed Countries:**

Africa (34): Angola, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau**,** Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania**,** Mozambique**,** Niger**,** Rwanda**,** São Tomé and Príncipe**,** Senegal**,** Sierra Leone**,** Somalia**,** South Sudan, Sudan**,** Togo**,** Uganda**,** United Republic of Tanzania**,** Zambia

Asia (14): Afghanistan, Bangladesh, Bhutan, Cambodia, Kiribati, Lao People's Democratic Republic, Myanmar, Nepal, Samoa, Solomon Islands, Timor-Leste, Tuvalu, Vanuatu, Yemen

Latin America and the Caribbean (1): Haiti

(Source: United Nations Office of the High Representative (UN-OHRLLS) as of October 23, 2013)

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to **IC** a noncreditable, nonrefundable **Sublicense** issue royalty in the amount of Ten Thousand Dollars ($10,000) within sixty (60) days from the effective date of the grant of each **Sublicense** for sale of **Licensed Products** outside of **Least Developed Countries**.

II. The **Licensee** agrees to pay to **IC** a nonrefundable minimum annual royalty for each **Sublicensee** granted as follows:

(a) Five Thousand Dollars ($5,000) for each year prior to the **First Commercial Sale** of **Licensed Products** outside of **Least Developed Countries.** The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Ten Thousand Dollars ($10,000) for each year after the **First Commercial Sale** of **Licensed Products** outside of **Least Developed Countries.** These minimum annualy royalties are due and payable within sixty (60) days of January 1 of each calendar year and shall be credited against any earned royalties for the sales made in that year.

(c) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. The **Licensee** agrees to pay **IC** earned royalties of on **Net Sales** of **Licensed Products** in the **Licensed Territory** by each of its **Sublicensee(s)** as follows:

(a) When **Licensed Patent Rights** exist in countries of manufacture or sale:

(1) Zero percent (0.0%) on **Net Sales** of **Licensed Products** sold in **Least Developed Countries**;

(2) Five percent (5.0%) on **Net Sales** of **Licensed Products** sold outside of **Least Developed Countries**.

(b) When **Licensed Patent Rights** do not exist in countries of manufacture or sale:

(1) Zero percent (0.0%) on **Net Sales** for **Licensed Products** based upon **Licensed Materials** sold in **Least Developed Countries**;

(2) Two and one-half percent (2.5%) on **Net Sales** of **Licensed Products** based upon **Licensed Materials** sold outside of **Least Developed Countries**.

IV. For development of **Licensed Products** by each of its **Sublicensees**, **Licensee** agrees to pay **IC** the **Benchmark** royalties set forth below. For **Benchmarks** achieved on or after the effective date of this **Agreement**, such royalty payment will be due within sixty (60) days of achieving each **Benchmark.**

1. Zero Dollars ($0.00) upon the initiation (first dosing of first patient) of each **Phase I Clinical Trial** (or equivalent) with **Licensed Product** set forth in the **Licensed Fields of Use** for **Licensed Products**) in **Least Developed Countries**.

2. Fifty Thousand Dollars ($50,000) upon the initiation (first dosing of first patient) of each **Phase I Clinical Trial** (or equivalent) with **Licensed Product** set forth in the **Licensed Fields of Use** for **Licensed Products**) in countries outside of **Least Developed Countries**.

3. Zero Dollars ($0.00) upon the initiation (first dosing of first patient) of each **Phase II Clinical Trial** (or equivalent) with **Licensed Products** set forth in the **Licensed Fields of Use**) in **Least Developed Countries**.

4. Seventy-five Thousand Dollars ($75,000) upon the initiation (first dosing of first patient) of each **Phase II Clinical Trial** (or equivalent) with **Licensed Products** set forth in the **Licensed Fields of Use**) in countries outside of **Least Developed Countries**.

5. Zero Dollars ($0.00) upon the initiation (first dosing of first patient) of each **Phase III Clinical Trial** (or equivalent) with **Licensed Product** set forth in the **Licensed Field of Use**) in **Least Developed Countries**.

6. One Hundred Thousand Dollars ($100,000) upon the initiation (first dosing of first patient) of each **Phase III Clinical Trial** (or equivalent) with **Licensed Product** set forth in the **Licensed Field of Use**) in countries outside of **Least Developed Countries**

7. Zero Dollars ($0.00) upon approval of a **Biologics License Application** (**BLA**) by a **Regulatory Authority** in **Least Developed Countries**.

8. Two Hundred Thousand Dollars ($200,000) upon approval of a **Biologics License Application** (**BLA**) by a **Regulatory Authority** in countries outside of **Least Developed Countries**.

9. Two Million Dollars ($2,000,000) upon first achievement of cumulative **Net Sales** of Five Hundred Million Dollars ($500,000,000) in countries outside of **Least Developed Countries**.

10. Five Million Dollars ($5,000,000) upon first achievement of cumulative **Net Sales** of One Billion Dollars ($1,000,000,000) in countries outside of **Least Developed Countries**.

11. Ten Million Dollars ($10,000,000) upon first achievement of cumulative **Net Sales** of Two Billion Dollars ($2,000,000,000) in countries outside of **Least Developed Countries**.

APPENDIX D – BENCHMARKS AND PERFORMANCE

The **Licensee** agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **IC** that the **Benchmark** has been achieved:

- Achievement of developmental timelines as outlined in the **WHO C-TAP Development Plan**.

APPENDIX E – WHO C-TAP DEVELOPMENT PLAN

OPERATIONALISING THE COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

A CONCEPT PAPER

INTRODUCTION

On 23 March 2020 the President of Costa Rica, Carlos Alvarado, asked the Director-General of the World Health Organization (WHO), Dr Tedros, to "undertake an effort to pool rights to technologies that are useful for the detection, prevention, control and treatment of the COVID-19 pandemic."[1] The letter envisaged a voluntary arrangement whereby owners of intellectual property (IP) and other forms of knowledge, clinical data and know-how relevant to the development and manufacture of diagnostic tests, devices, medicines, or vaccines would contribute these to a pool. The details of the arrangements would need to be determined through consultation with the holders of the relevant knowledge and technologies.

The resolution on the COVID-19 response passed at the World Health Assembly in May 2020 called, on international organizations and other stakeholders to work together to develop, test, and scale-up production of diagnostics, medicines and vaccines for the COVID-19 response including existing mechanisms for voluntary pooling and licensing of patents in order to facilitate timely, equitable and affordable access.[2]

On 29 May, the Pool was formally launched by President Carlos Alvarado and Dr Tedros with the Solidarity Call to Action.[3] The initiative has to date been endorsed by 40 countries along with OHCHR, UNAIDS, UNDP, UNESCO, Unitaid, UN Technology Bank and several non-governmental organizations and individuals.[4]

Dr Tedros noted that based on strong science and open collaboration, this information-sharing platform would help provide equitable access to life-saving technologies around the world. The aim was to accelerate the development of all kinds of technologies needed for the prevention, detection, and treatment of COVID-19 through open-science research and to fast-track product development and availability by mobilizing additional manufacturing capacity.[5]

The COVID-19 Technology Access Pool (C-TAP) is intended to provide a means to accelerate the development of products needed to fight COVID-19 as well as to accelerate the scale-up of manufacturing and the removal of barriers to access in order to make products available globally. Sharing information, knowledge, data and other resources is a powerful way to accelerate product development and avoid unnecessary duplication of efforts arising from the absence of such sharing.

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[1] Letter to Dr Tedros. 23 March 2020. https://www.keionline.org/wp-content/uploads/President-MoH-Costa-Rica-Dr-Tedros-WHO24March2020.pdf

[2] World Health Organization. COVID-19 response. WHA73.1. 19 May 2020. https://apps.who.int/gb/ebwha/pdf_files/WHA73/A73_R1-en.pdf

[3] World Health Organization. Making the response to COVID-19 a public common good: Solidarity Call to Action. 1 June 2020. https://www.who.int/docs/default-source/coronaviruse/solidarity-call-to-action/solidarity-call-to-action-01-june-2020.pdf?sfvrsn=a6c4b03d_4

[4] World Health Organization. Endorsements of the Solidarity Call to Action https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/endorsements-of-the-solidarity-call-to-action

[5] World Health Organization. International community rallies to support open research and science to fight COVID-19. 29 May 2020. https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19

Key Points in the Solidarity Call to Action

RESEARCH FUNDERS SHOULD:

- Take action to promote innovation, remove barriers, and facilitate open sharing of knowledge, IP and data necessary for COVID-19 detection, prevention, treatment and response through measures to ensure availability, affordability and assured-quality of the concerned products.
- Make appropriate provisions in funding agreements regarding accessibility and affordability of resulting health products globally including through non-exclusive voluntary licensing and other means to expand access by sharing know-how and other data.
- Ensure that all research outcomes are published under open licenses that allow access free of charge with appropriate provisions for their use, adaptation and redistribution by others, including through initiatives such as the FAIR Guiding Principles for scientific data management and stewardship.[6]
- Encourage open and collaborative approaches in pre-competitive drug discovery and work together with international organizations towards equitable distribution and access to products needed for COVID-19.
- Ensure that research results are registered and published in line with WHO's Joint statement on public disclosure of results from clinical trials.[7]

RESEARCH ORGANIZATIONS SHOULD:

- Voluntarily license technologies developed to the Medicines Patent Pool or through other public health research and development mechanisms that facilitate global access, for example voluntary non-enforcement of IP rights, in order to facilitate equitable, affordable and timely access for all countries.
- Share relevant knowledge, IP and data to enable widescale and worldwide production, distribution and use of such technologies and necessary raw materials through mechanisms such as the Technology Access Partnership (TAP) hosted by the UN Technology Bank or the Open COVID Pledge Initiative hosted by Creative Commons.
- Share viral genome sequences and associated metadata in a timely manner through transparent mechanisms, such as the one provided by the GISAID initiative, to contribute essential knowledge to the response efforts, recognizing the need for fair and equitable access to health products that are developed using genetic sequence information.
- Place in the WHO Global Observatory on Health Research and Development, relevant information and analyses on COVID-19 research and development activities.

This paper seeks to clarify how C-TAP might work in practice, how its constituent parts fit together and its governance. It covers the following:

- Why C-TAP?
- The respective roles and objectives of the COVID-19 Tools Accelerator (ACT-A) and C-TAP

[6] MD Wilkinson et al. The FAIR Guiding Principles for scientific data management and stewardship. *Sci Data*. 2016; 3: 160018. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4792175/

[7] World Health Organization. Joint statement on public disclosure of results from clinical trials. May 2017. https://www.who.int/ictrp/results/jointstatement/en/

- How C-TAP will be structured
- How C-TAP will operate
- C-TAP Governance
- C-TAP Consultative Arrangements

WHY C-TAP?

In order to achieve its objectives C-TAP needs to be able to make a coherent case to the holders of knowledge and technologies for the benefits to be achieved by pooling their data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how' as well as making IP available for public health-driven non-exclusive licensing through the Medicines Patent Pool, the UN-backed Technology Access Partnership, the Open COVID Pledge and other initiatives.

The IMF estimated in June 2020 that COVID-19 could cost the world economy $12 trillion up to the end of 2021, equivalent to a daily cost of over $15 billion with further large losses projected even if the pandemic is controlled in 2021.[8] This number conceals the sheer scale of the devastation it is wreaking on livelihoods and indeed health outcomes throughout the world which could persist for years to come. But it also indicates the urgency of bringing the pandemic to an end as soon as possible in order to stem the damage to health and the global economy by whatever means possible. C-TAP, along with other initiatives, offers one way to do this.

Commitments by partners to promote development, access and affordability by any means, including non-exclusive licensing of new technologies, will be particularly important in achieving this objective. Limiting the scale of this devastation as much as possible depends on developing vaccines, therapeutics, medical devices and diagnostics and making them widely available globally as soon as possible. Every day counts and every part of the world needs to be covered if the pandemic is finally to be ended.

Sharing data and information which is normally kept secret or protected by IP could materially advance the speed at which technologies are developed and avoid, for example, the repetition and duplication of research carried out by others and reducing transaction costs in negotiations. Making the know-how associated with new technologies available and widely licensing it around the world would shorten the time needed to make them available as soon as possible to all who need them.

Success for C-TAP objectives will depend on the active participation of key partners including funders and innovators in the private, public, philanthropic and academic sectors. Private sector companies need to consider where their best interests lie. No company in the world will benefit by the prolongation of the pandemic. Their collective interest must be in restoring the world economy to health as quickly as possible, which will be facilitated by much greater openness in sharing their data, knowhow and IP. Several companies have already demonstrated their readiness to do that by making relevant IP available for licensing during the pandemic. Similarly, other research organizations in the public, academic and philanthropic sectors possess valuable knowledge products whose value could be increased by wider sharing in order to promote development and accelerate global access.

Governments, in their role as policymakers, regulators and funders have an important role to play in stimulating collective action to facilitate sharing. Some decisions have already being taken in respect of product development, licensing and allocation that may be at odds with the collective approach.[9] It is a challenge in the face of intense pressures on governments to look after their own populations to convey the message that collaboration and knowledge

[8] International Monetary Fund. Reopening from the Great Lockdown: Uneven and Uncertain Recovery. 24 June 2020. https://blogs.imf.org/2020/06/24/reopening-from-the-great-lockdown-uneven-and-uncertain-recovery/

[9] Tedros Adhanom Ghebreyesus. Tedros Adhanom on why vaccine nationalism harms efforts to halt the pandemic. *Economist.* 8 September 2020. https://www.economist.com/by-invitation/2020/09/08/tedros-adhanom-on-why-vaccine-nationalism-harms-efforts-to-halt-the-pandemic

sharing are preferable to competitive nationalism. There are powerful arguments for collective action. For example, in respect of vaccines, some governments are contracting bilaterally to secure potential vaccines which in the end may prove ineffective or unsafe. In that case they will need access to ones they have not backed.

Funders, whether in the public, private or philanthropic sectors, also have a very important role to play in encouraging or obliging funding recipients to practise open sharing of knowledge and data and the licensing of products to maximize global access.

ACT-A AND C-TAP ROLES AND OBJECTIVES

ACT-A is a partnership between WHO and a number of global health actors including the Bill & Melinda Gates Foundation, CEPI, Gavi, the Global Fund, Unitaid and Wellcome as well as participants from industry, civil society and other organizations. Its mission is the accelerated development, equitable allocation and scaled-up delivery of vaccines, therapeutics and diagnostics. Underpinning these three pillars are two cross-cutting programmes, the Health Systems Connector, to strengthen local capacities to deliver new tools, and an Access and Allocation Programme, which is developing the principles, frameworks and mechanisms needed to ensure the fair and equitable allocation of these tools. The current estimate of funding requirements is $38 billion with the objective of providing two billion vaccine doses by the end of 2021, 245 million therapeutic courses by mid-2021 and 500 million tests for low- and middle-income countries (LMICs).[10]

Thus ACT-A is principally about funding the development of the new tools necessary to fight COVID-19 with associated activities seeking to promote equitable access to these new tools.

C-TAP has the overall objective of promoting open science in order to accelerate product development and to facilitate access to the resulting health technologies by pooling IP, data, regulatory dossiers, and manufacturing processes and other kinds of 'know-how'. Sharing knowledge of all kinds which is normally only available to funders, originators or technology holders, or confidentially held by regulators will facilitate accelerated innovation and the scale-up of manufacturing globally. It will facilitate more affordable access to new tools, through non-exclusive and public-health driven licensing accompanied by enhanced arrangements for technology transfer. In particular it will support technology transfer to boost local production of relevant products in LMICs through the Medicines Patent Pool and the Technology Access Partnership.

Thus ACT-A and C-TAP are complementary initiatives. ACT-A is principally about mobilizing funds to develop new tools for COVID-19, prioritizing technologies needed, coordinating international action, and ensuring that new products that are safe and effective become available at country level through scaling up production.

C-TAP provides additional and complementary advantages including concrete interventions to increase access to data, IP and knowledge that are key for accelerating product development and manufacturing by promoting through voluntary means open innovation models, knowledge sharing and technology transfer as well as promoting equitable global access through non-exclusive and access-oriented licensing or other voluntary strategies that facilitate technology transfer and access. These include, for example, free licenses and pledges offered by the Open COVID Pledge and other initiatives and the waiving of patent rights by some companies on products that may prove effective against COVID-19.

As complementary initiatives, the linkages and mutual benefits between the two should be made more explicit and further promoted, for example, the data, know-how and IP associated with technologies prioritized for development and subsequent manufacture under ACT-A could be made available for sharing within C-TAP mechanisms.

[10] World Health Organization. Status Report & Plan September 2020 – December 2021. 25 September 2020. https://www.who.int/docs/default-source/coronaviruse/act-accelerator/status-report-plan-final-v2.pdf?sfvrsn=ee8f682b_4&download=true

HOW C-TAP WILL BE STRUCTURED

It is envisaged that the operational parts of C-TAP will be built around existing institutions which will constitute the engine room of C-TAP. These are:

- **The Technology Access Partnership (Tech Access Partnership)[11] launched by the UN Technology Bank in partnership with UNDP, WHO and UNCTAD, focuses particularly on promoting technology transfer to, and local production of, personal protective equipment, medical devices such as ventilators and other oxygen-related technologies and diagnostics and testing materials/components in LMICs.** The Tech Access Partnership draws on the respective expertise and mandates of partner agencies to comprehensively vet and make recommendations for effective technology transfer transactions between technology seekers in LMICs and technology holders from anywhere in the world. The partners make these assessments, and provide procedural guidance, in close consultation with organizations and institutions expert in particular aspects of the focal technologies, including the regulatory, political, legal and financial contexts in which the transactions will be completed. The Tech Access Partnership currently focuses on supporting technology transfer and local production for the production of COVID-19 technologies, to mitigate the immediate impact of the crisis and resultant supply chain shortages, disproportionately impacting LMICs. In its first five months to date, the Tech Access Partnership has received requests for assistance from 10 countries, the majority in Africa.
- The Medicines Patent Pool (MPP)[12] expanded its mandate in March this year to include any health technology that could contribute to the global response to COVID-19. **MPP's experience in facilitating access to medicines through its voluntary licensing mechanism means that it could play a central role in applying its IP and licensing expertise to patented products and technologies identified in the fight against COVID-19 to facilitate availability to those who need them most.** The MPP is also, through its MedsPaL database of patents and licenses in LMICS, including medicines candidates that may have relevance for treating COVID-19 infections. The database provides transparency on the patent status and licensing of these products.
- **The Open COVID Pledge (OCP)[13] currently operates as a repository for mainly soft and hard technologies relevant to COVID-19 but is open to offers from vaccine or therapeutic manufacturers. The OCP is a mechanism whereby companies make available a non-exclusive, royalty-free, world-wide license for a time-limited period - until one year after WHO declares the COVID-19 pandemic over, or 1 January 2023**, whichever is earlier, unless further extended by the pledgor. So far about 30 companies have made pledges – these include large technology companies such as Microsoft and IBM. In Japan, a similar initiative has been launched – the Open COVID-19 Declaration – supported by 90 companies and covering nearly a million patents.[14]
- **GISAID enables the unprecedented sharing of genomic and associated data from cases of COVID-19, thereby enabling genomic epidemiology and real-time progress in the understanding of the new disease and in the R&D of candidate medical countermeasures.** Since 2008, GISAID provides Member States with a choice on how to make their genomic sequences and associated virus data publicly accessible, providing transparency on its use and an effective mechanism to safeguard contributors' interests in their data.[15] GISAID's data access and usage license agreement (DAA) was developed with Member States' participation. While all data are publicly accessible, those sharing data through GISAID do not forfeit their

[11] Technology Access Partnership. https://techaccesspartnership.net/

[12] Medicines Patent Pool. https://medicinespatentpool.org/

[13] Open COVID Pledge. https://opencovidpledge.org/

[14] Open COVID-19 Declaration. https://www.gckyoto.com/s/COVID.docx

[15] Shu, Y. et al (2017) GISAID: Global initiative on sharing all influenza data

inherent rights to the data.[16] Data in GISAID is open to everyone, provided they identify themselves, to foster collaboration and to permit an effective oversight to uphold the sharing principles enshrined. A guiding principle for those using data in particular in publications is the requirement to acknowledge the contribution of data providers. By contrast, traditional public-domain archives (e.g. Genbank) offer only anonymous access and use of data without consideration of data providers' interests.

- **The WHO Global Observatory on Health R&D[17] is a comprehensive and authoritative 'one-stop-shop' for up to date information and analysis on health R&D, including resources, processes, outputs and capacity. It supports evidence-informed decisions related to health R&D gaps and funding based on public health needs.** It does so by consolidating, monitoring and analyzing relevant information on health R&D, building on existing data collection mechanisms, and supporting coordinated actions on health R&D. The 'Observatory' covers all health-related fields and all types of research. It includes data and analyses on health products in the pipeline, clinical trials, R&D investments and research capacity, among others. In response to the COVID-19 pandemic, the Observatory is pulling together and continuously updating a comprehensive list of data tracking and synthesis systems on R&D for COVID-19 and will be developing relevant analyses and interactive data visualizations of these resources, which will include C-TAP repositories.
- **The WHO C-TAP database will be at the core of C-TAP operations, being the repository for data and know-how on key Covid-19 health technologies to be part of C-TAP and for the submission of Member States pledges to support C-TAP.** The WHO C-TAP database will act as a coordination platform and be connected to other data-sharing platforms and databases where Covid-19 related health technology information is already available.

HOW C-TAP WILL OPERATE

C-TAP would operate on the basis that there is mutual advantage in a crisis in sharing data and know-how in ways that accelerate product development, widespread manufacturing and reduce barriers to access. The need is to identify an operating model that is attractive to the funders and holders of IP, knowledge, data and technology recognizing the exceptional circumstances the world currently faces.

Some of the incentives for participation by funders and owners of knowledge may be commercial. The holders of knowledge and technology will also wish to make their own contribution to the defeat of COVID-19 for non-commercial reasons.

In respect of accelerating product development of healthcare products, there are a number of relevant examples which have often drawn on the experience of open source software development such as the Linux model.[18] Examples include the Medicines for Malaria's Open Source Drug Discovery programme which already has a COVID Box[19] which has made available 80 compounds with potential for treating COVID-19 in return for which researchers are expected to share data resulting from research on the molecules from the box in the public domain within two years of its generation. Other initiatives include the Open Source Pharma Foundation,[20] Open Source Malaria,[21] and the Structural Genomics Consortium.[22]

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[16] Elbe, S. et al (2017) GISAID's innovative contribution to global health

[17] Global Observatory on Health R&D. https://www.who.int/research-observatory/en/

[18] About the Linux Foundation. https://www.linuxfoundation.org/about/

[19] COVID Box. https://www.mmv.org/mmv-open/covid-box

[20] Open Source Pharma Foundation. https://www.ospfound.org/

[21] Open Source Malaria. http://opensourcemalaria.org/

[22] Pioneering Science to Inspire Pioneering Medicines. https://www.thesgc.org/about/what_is_the_sgc

In respect of promoting access and affordability, the experience and expertise of the Medicines Patent Pool is very relevant particularly in relation to non-exclusive public-health oriented licensing of medicines in LMICs. MPP estimates that its generic licensees have been responsible in 2012-19 for 31.4 million patient years of treatment saving $1.44 billion in treatment costs.[23]

In devising the operating model, there are a number of issues that need to be addressed, including through consultation with different groups of potential C-TAP partners. An important aspect will be for WHO to establish a prioritization process (with clear criteria and a rationale) to identify which products/technologies and "pooled assets" C-TAP should initially focus on for near term impact, while recognizing C-TAP's more ambitious longer term objective of covering a broad range of products and types of "assets" necessary to tackle COVID-19.

C-TAP has immense potential to deliver as an emergency operation in the short term by supporting faster development of, and equitable global access to, vaccines, therapeutics and diagnostics and necessary medical equipment for this phase of the COVID-19 pandemic. The experience to date is that the great majority of countries in the world, both LMICs and HICs, were drastically underprepared to address the pandemic. Notably, most countries were woefully short of PPE, testing capacity and tools needed in intensive care. Thus, there is a medium- to long-term role for C-TAP in being one element in helping build country capacities to produce and/or secure the range of products which will be needed to address future epidemics. Indeed, success of C-TAP could lay a foundation to address the looming pressure on healthcare systems everywhere from increasing longevity, expansion of non-communicable disease, and resistance of established infectious diseases to conventional antivirals and antibiotics.

C-TAP GOVERNANCE

WHO has an important leadership role in mobilizing and interacting with key actors, such as Member States, funders and strategic partners such as industry, research institutes and academia and civil society, to participate actively in making commitments or pledging support and in sharing their information, know-how and IP. This will require the strategic engagement of senior WHO officials such as ADGs, Regional Directors and up to the Director-General. It should also seek to involve other UN agencies with relevant expertise.

There is an important role for WHO in the governance of C-TAP at a strategic level in setting standards and providing guidance for information, know-how and IP to be shared/"pooled" (through the Technical Advisory Group) prioritizing products to be considered by C-TAP and its implementing partners, carrying out coordination of implementing partners, monitoring C-TAP outcomes and communicating about it in an open and transparent manner with C-TAP Steering Committee and C-TAP partners and stakeholders.

Steering Committee

The C-TAP Steering Committee is a group of international partners involved in C-TAP implementation and advising on the overall direction of C-TAP. It is chaired by the WHO Assistant Director-General for Access to Medicines and Health Products and composed of C-TAP key partner organizations such as Unitaid, the UN Technology Bank, MPP, GISAID and the Open COVID Pledge, UNDP, and UNAIDS. The Chairs of the Member States Working Group and the Technical Advisory Group have observer status in the Steering Committee. The Committee will:

- Provide strategic guidance to the WHO Secretariat on the operationalization of C-TAP
- Serve as a platform to update partner organizations members of the SC on C-TAP implementation and to exchange information on ongoing and planned activities of C-TAP partners
- Support development of the physical structure and governance of C-TAP, for example, by advising in the process of defining interoperability standards and/or standard operating procedures

[23] MPP in Numbers. https://medicinespatentpool.org/progress-achievements/impact/

- Monitor and assess implementation and outcomes thereof, including taking stock of key challenges and level of achievement of results
- Promote policy dialogue and advocacy on C-TAP objectives
- Advise on and facilitate collaboration and coordination with other relevant initiatives, such as ACT-A

Technical Advisory Group

A Technical Advisory Group (TAG) will be composed of experts in fields relevant to C-TAP operations. They may include experts from key stakeholder groups including funders, civil society, academics, researchers and the private sector, providing that these experts act in their personal capacity, as independent experts, and be clear of conflicts of interest. The role of the TAG would be to provide guidance on tools and methods for sharing of information, know-how and IP needed for C-TAP, advise on priority products to be considered by C-TAP and inform the Steering Committee and the WHO C-TAP Secretariat accordingly. It should be established paying due regard to diversity and equitable geographic representation. Its chair should also be an observer on the Steering Committee.

The exact terms of reference of the TAG need to be determined but could include:

- Providing independent advice on the scientific, technical and strategic matters related to the COVID-19 Technology Access Pool (C-TAP)
- Advising on relevant information and know-how packages on C-TAP candidate health products to be made available in the C-TAP database and disseminated
- Making recommendations to the WHO C-TAP Secretariat regarding license negotiations and other technology transfer agreements taking account of C-TAP partners' existing mechanisms for negotiations.
- Advising on best practices to facilitate technology transfer and local production for needed COVID-19 technologies and how to work with the implementing partners and other stakeholders to implement them.

C-TAP Secretariat

The WHO **C-TAP Secretariat** will be located in the WHO Access to Medicines and Health Products Division, will work in collaboration with the Science Division in charge of the Global R&D Observatory and coordinate with other relevant WHO departments. C-TAP Secretariat will compile, in one place, the C-TAP Database, pledges of commitment made under the Solidarity Call to Action as well as the voluntarily shared COVID-19 health technology-related knowledge, IP and data. The secretariat will draw on relevant data from existing mechanisms like the MPP or TAP and will need to manage and maintain the website and database platform for C-TAP. The WHO C-TAP Secretariat will:

- Plan and monitor C-TAP related work carried out by WHO and other C-TAP partners
- Carry out day to day coordination of C-TAP related work including from implementing partners, on strategic and technical issues
- Support organization of meetings of the C-TAP Steering Committee and of the Technical Advisory Group
- Prepare C-TAP related activity progress reports
- Develop C-TAP advocacy and communication materials
- Share information on C-TAP progress and implementation plans with the Co-sponsors Working Group, Member States and other partners' groups involving key stakeholders.

C-TAP Member States Working Group

In addition to the core governance bodies, the Steering Committee, the Technical Advisory Group and the C-TAP Secretariat, it will be important to have strong mechanisms for consultation with Member States and the key stakeholders involved in C-TAP.

The **Member States Working Group** will be the interface between the Steering Committee and the global Member States community. Its Chair should participate in the meetings of the Steering Committee as an observer, and act as a liaison and ensure information sharing on C-TAP related issues between the Steering Committee, co-sponsors and Member States. Its role will be to carry out advocacy on behalf of C-TAP and to encourage more Member States and other stakeholders to join the Solidarity Call to Action. C-TAP Secretariat should meet regularly with the Working Group to share information and seek feed-back on progress of C-TAP implementation.

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- License reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

New Payment Options Effective March 2018

The License Number MUST appear on payments, reports and correspondence.

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: **https://www.pay.gov/public/form/start/28680443.**

Automated Clearing House (ACH) for payments through U.S. banks only
IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

Electronic Funds Wire Transfers: The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the **NIH ROYALTY FUND**.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)	*(enter 12 digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the*

Fedwire Field Tag	Fedwire Field Name	Required Information
		payment)
Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.		

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3100}	Sender Bank ABA routing number	*(enter the US correspondent bank's ABA routing number)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)**	*(enter 12 digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY'S NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*
Notes: *The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045. **Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33**		

Agency Contacts:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Checks

All checks should be made payable to "NIH Patent Licensing"

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6701 Rockledge Drive
Suite 700, MSC 7788
Bethesda, Maryland 20892