

## **TERMS OF USE**

#### for the

#### **Global Clinical Data Platform**

# for Clinical Characterization and Management of Patients with Emerging Infectious Diseases

(such as COVID-19, viral hemorrhagic fever (including Ebola virus disease), Mpox, Acute hepatitis of unknown etiology, Lassa Fever, Disease X)

### (Updated 2 June 2023)

The World Health Organization, a United Nations' Specialized Agency with headquarters at 20 Avenue Appia, CH-1211 Geneva, Switzerland ("WHO"), maintains a global data platform to facilitate the sharing of anonymized clinical data and information relating to the clinical characteristics and management of patients suspected or confirmed to be infected with emerging infectious diseases such as COVID-19, viral hemorrhagic fever (including, but not limited to, Ebola virus disease), Mpox, Acute hepatitis of unknown etiology, Lassa Fever, Disease X (hereinafter, collectively, "Emerging Infectious Diseases"), which platform is known as the "Global Clinical Data Platform for Clinical Characterization and Management of Patients with Emerging Infectious Diseases" (the "Platform"). Access to and use of the Platform and the Data (as defined herein) is subject to and governed by these Terms of Use.

By accessing and/or using the Platform as a provider of Data, you:

- (i) agree and accept, both for yourself and on behalf of the entity of which you are an employee or representative, that you and such entity (collectively, the "Entity") will be bound by these Terms of Use effective as of the first date of your access or use of the Platform; and
- (ii) represent and warrant that you have all power and authority necessary to agree to and accept these Terms of Use on behalf of the Entity.

#### 1. Provision and Use of Data

- 1.1 Subject to the terms and conditions contained in these Terms of Use, the Entity hereby agrees to provide, and WHO hereby agrees to accept, the Data for the Purpose of Use (as each such term is defined below). The Data will be provided, free of charge, through the Platform.
- 1.2 As used herein, the following terms have the following meanings:
  - "Data" means all anonymized (i.e., strictly stripped of any personal identifiers) clinical and/or patient data and/or information related to patients with suspected or confirmed infections with Emerging Infectious Diseases that are collected or otherwise obtained by or on behalf of the Entity and provided by the Entity on the Platform. For the avoidance of doubt, the term "Data" shall include, without limitation: (i) any clinical data and/or information on concurrent conditions, symptoms and/or complications; (ii) any data and/or information on clinical outcomes; and (iii) any data and/or information arising from or relating to any

suspected unexpected serious adverse reactions (SUSARs), any serious adverse events (SAEs) and/or the use or administration of any Products.

- "Data Monitoring Committee" or "DMC" means any independent data monitoring committee, as designated by WHO in its sole discretion, that is convened under or pursuant to any WHO sponsored clinical trial, WHO-recommended master protocol for clinical trials and/or any WHO-recommended emergency use protocol under the MEURI (Monitored Emergency Use of Unregistered and Experimental Interventions) framework relating to any Products, whether alone or in combination with other products.
- "Manufacturer" means any entity: (i) that manufactures and/or distributes any Products, and (ii) with which WHO has entered into any agreement in respect of any Product.
- "Product" means any therapeutic and/or diagnostic that is used in connection with any Emerging Infectious Diseases to which the Data relates.
- "Purpose of Use" means the following purposes for which the Data may be used by or on behalf of WHO and/or third parties so designated by WHO pursuant to these Terms of Use:
  - (a) to inform, develop, review and/or update (i) public health and/or clinical guidance in connection with Emerging Infectious Diseases which is or may be published by WHO on its website(s) and/or its printed, electronic or other publications, (ii) WHO's research, scientific or public health prioritization purposes, and/or (iii) any activities or materials relating to any of the foregoing; and/or
  - (b) for WHO's activities, products and/or materials arising from or relating to (i) the clinical characterization and/or management of patients with Emerging Infectious Diseases; and/or (ii) the public health response to Emerging Infectious Diseases; and/or
  - (c) for the Third Party Permitted Use (as defined below).
- "Third Party Permitted Use" means, collectively, the following actions that may be taken by WHO in its discretion:
  - (a) to report, disclose and/or transmit any Data (including, without limitation, any data and information resulting from the use and/or administration of any Products, once such data has been cleaned and validated by WHO) to the relevant Manufacturer(s) of such Product(s), to any Data Monitoring Committee(s) and/or to the Uppsala Monitoring Centre in Uppsala, Sweden ("UMC"), for the purposes set forth in paragraphs (b), (c) and (d) below, respectively; and
  - (b) to grant each Manufacturer to whom WHO discloses any Data pursuant to paragraph (a)(i) above a non-exclusive, worldwide, royalty-free, sub-licensable, irrevocable license and right to use and (subject to the confidentiality provisions set forth in Section 2 below) to disclose to third parties the Data for the purpose of enabling such Manufacturer to register, produce and/or commercialize its Product(s) for the diagnosis or treatment of the relevant Emerging Infectious Disease(s); provided, however, that such Data shall not be altered in any way. For the avoidance of doubt, the aforesaid right granted to each Manufacturer pursuant hereto includes the right to use and (subject to the confidentiality provisions set forth in Section 2 below) to disclose the Data for any legitimate business or

- regulatory purposes reasonably needed for enabling such Manufacturer to register, produce and/or commercialize its Products for the diagnosis or treatment of the relevant Emerging Infectious Diseases; and
- (c) to grant the members of any Data Monitoring Committee(s) to whom WHO discloses any Data pursuant to paragraph (a)(ii) above the right to use and (subject to the confidentiality provisions set forth in Section 2 below) to disclose to third parties the Data, but only for the purpose of enabling such members to discharge the duties, activities and obligations of the Data Monitoring Committee arising from or relating to the relevant WHO sponsored clinical trial, WHO-recommended master protocol for clinical trials and/or WHO-recommended emergency use protocol under the MEURI framework; and
- (d) to grant UMC a non-exclusive, worldwide, royalty-free, sub-licensable, irrevocable license and right to use and (subject to the confidentiality provisions set forth in Section 2 below) to disclose to third parties the Data, but only for the purpose of enabling UMC to undertake its duties, obligations and activities arising from or relating to: (i) managing WHO's database of reported potential side effects of medicinal products, also known as VigiBase; and/or (ii) UMC's designation as a WHO Collaborating Center in support of the WHO Programme for International Drug Monitoring (WHO PIDM).
- 1.3 The Data are provided by the Entity under these Terms of Use solely for the Purpose of Use (which includes, but is not limited to, the Third Party Permitted Use). The Entity hereby grants WHO a non-exclusive, worldwide, royalty-free, sub-licensable, irrevocable license and right to use, reproduce, store, display, distribute, query, clean, curate, analyze, modify, adapt, visualize and/or create derivative works (including, without limitation, summaries, graphs, charts and/or statistics) from the Data for the Purpose of Use (which includes, but is not limited to, the Third Party Permitted Use), subject to and in accordance with these Terms of Use.
- 1.4 The Data shall only be used for the Purpose of Use (which includes, but is not limited to, the Third Party Permitted Use). Except for and/or within the Purpose of Use, the Data shall not be used for any other purpose without the prior written agreement of the Entity (such agreement not to be unreasonably withheld, conditioned or delayed).
- 1.5 Except as provided in these Terms of Use and/or as permitted within the Purpose of Use (which includes, but is not limited to, the Third Party Permitted Use), WHO shall not transfer, disclose or distribute the Data to any third parties without the prior written agreement of the Entity. WHO may transfer, disclose or distribute the Data to, and the Data may be used by, any third parties who have a need to know or are otherwise authorized to receive the Data for the Purpose of Use (which includes, without limitation, the Third Party Permitted Use) and who are bound by similar obligations of confidentiality and restrictions on use as contained in these Terms of Use.
- 1.6 WHO shall not use the Data to attempt to identify any specific individuals from the Data received.
- 1.7 Nothing contained in these Terms of Use shall restrict the Entity's right to transfer or distribute the Data to any other person or entity for any purpose.

## 2. Confidentiality

- 2.1 The Data shall be treated by WHO as confidential and shall only be used for the Purpose of Use (which includes, without limitation, the Third Party Permitted Use). Accordingly, during the term of these Terms of Use and for a period of five (5) years following the expiration or early termination hereof, WHO shall take reasonable measures to protect the confidentiality of the Data, including taking such action as may be appropriate to prevent the unauthorized access, use or disclosure of the Data.
- 2.2 The above obligations of confidentiality and restrictions on use shall not apply to any Data or information which: (a) was already known to the receiving party (as evidenced by written records) prior to its receipt from the Entity; or (b) is in the public domain or becomes publicly available other than by an action of the receiving party; or (c) is required to be disclosed by the receiving party by applicable law, provided that the receiving party shall, in such case, immediately notify the disclosing party in writing of such obligation and shall provide adequate opportunity to the disclosing party to object to such disclosure or request confidential treatment thereof; all of the foregoing subject and without any prejudice to Section 7.3 below; or (d) was received from a third party not in breach of an obligation of confidentiality in respect thereof; or (e) was subsequently and independently developed by or on behalf of the receiving party without access to the Data or confidential information of the disclosing party.

## 3. Rights

Except for the license and rights explicitly granted hereunder, nothing contained in these Terms of Use shall be construed as conveying to WHO or any third party any title, ownership or other rights in or to the Data, which remain the property of the patient and/or the Entity.

### 4. Publications

- 4.1 Subject to the protection of the Entity's proprietary rights in the data and to the protection of the confidentiality of the Data, the findings and/or results obtained through use of the Data for and/or within the Purpose of Use (collectively, "Results") may be published or otherwise publicly disclosed by WHO and/or certain third parties so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use).
- 4.2 In addition to, and without limiting, the foregoing, WHO shall also have the right to publish (including, without limitation, in the form of Public Health Reports on WHO's website) the Data provided by the Entity to WHO under the Platform; provided, however, that the Data shall be published in an anonymized fashion, and shall not be identified as pertaining to the Entity, thus preserving the possibility for the Entity to publish its Data elsewhere. Where possible and appropriate, Data will be reported in an aggregated fashion with other data provided to WHO by third parties (including, but not limited to, other Entities) across the world for public health purposes.
- 4.3 For publications pursuant to Section 4.1: To avoid prejudice to the confidentiality of the Data, WHO shall transmit any material relating to the Results that is intended to be published by WHO and/or certain third parties so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) pursuant to Section 4.1 above, to the Entity for its information at least ten (10) days prior to its submission for

- publication or public disclosure by WHO. In absence of any objection by the Entity within that ten (10)-day period concerning prejudice to the confidentiality of Data, the publication may proceed; provided, that WHO shall duly acknowledge the Entity in any such publication by WHO.
- 4.4 For publications pursuant to Section 4.2: To avoid prejudice to confidentiality of Data, WHO shall transmit any material relating to the Data that is intended to be published by WHO pursuant to Section 4.2 above, to the Entity for its information at least two (2) days prior to its publication or public disclosure by WHO. In absence of any objection by the Entity within that two (2)-day period concerning prejudice to the confidentiality of Data, the publication may proceed; provided that WHO shall duly acknowledge the Entity, as and where appropriate, in any such publication by WHO.

### 5. Warranties and Liabilities

- 5.1 The Entity represents and warrants: (a) that the Entity has the full, unrestricted and unencumbered right, power and authority to provide the Data to WHO for the Purposes of Use (which includes, without limitation, the Third Party Permitted Use) and otherwise in accordance with these Terms of Use; (b) that any and all Data provided by the Entity hereunder has been obtained and collected in compliance with all applicable laws, statutes, rules, regulations, and legal, ethical and/or medical standards and requirements; (c) that the Entity has obtained all approvals, informed consents, licenses and permits which are necessary or required for the Data to be provided to and used by WHO and/or any third party so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) in accordance with these Terms of Use; and (d) that the provision to and/or the use of the Data by WHO and/or any third party so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) in accordance with these Terms of Use shall not infringe, violate or misappropriate the rights of any third party. The Entity shall indemnify, defend (subject and without prejudice to any of WHO's privileges and immunities) and hold harmless WHO and/or any third party so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) from and against any actions, claims, proceedings, damages, liabilities and/or costs (including, but not limited to, attorneys' fees) which may be brought against or suffered by any of them arising from or in connection with any breach of any of the Entity's representations and/or warranties under this Section.
- 5.2 Except as provided under Section 5.1 above, the Entity makes no and hereby disclaims any warranty concerning the accuracy, completeness or the fitness of any particular purpose of the Data, or any other warranty whether express or implied.
- 5.3 Except as may otherwise be explicitly provided in these Terms of Use, the Entity has no control over the use of the Data by WHO and/or any third party so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) pursuant to these Terms of Use. Consequently, the parties agree that the Entity shall not be liable for any use of the Data by WHO and/or any third party so designated by WHO for or within the Purpose of Use (which includes, without limitation the Third Party Permitted Use) pursuant to these Terms of Use; provided, however, that nothing contained in this Section shall limit or otherwise modify the Entity's liability pursuant to Section 5.1 above.

### 6. Term; Survival

- 6.1 These Terms of Use will become effective vis-à-vis the Entity as of the first date on which you/the Entity access(es) or use(s) the Platform, and will continue to be in full force and effect for as long as may be required by WHO and/or any third party so designated by WHO in the context of the Purpose of Use (which includes, without limitation, the Third Party Permitted Use).
- 6.2 If, when and to the extent any Data are no longer required by WHO and/or any third party so designated by WHO in the context of the Purpose of Use (which includes, without limitation the Third Party Permitted Use), WHO and/or such third party shall promptly cease all use and make no further use of the Data in question and, upon the Entity's written request, shall either promptly return to the Entity or destroy such Data, except that WHO and/or the third party concerned shall be entitled to keep a copy of the Data for the purpose of determining its continuing obligations hereunder as well as for the purposes of audit (including regulatory ones, if and as applicable).
- 6.3 Notwithstanding the expiration of these Terms of Use, the rights and obligations of the parties contained in these Terms of Use that are, by their nature, intended to survive such expiration or termination shall so survive indefinitely. The foregoing includes, without limitation, the provisions relating to licenses to use and disclose the Data, confidentiality, rights, publications, warranties and liabilities, settlement of disputes, and privileges and immunities of WHO.

#### 7. Miscellaneous

- 7.1 The parties are independent contractors in respect of each other. Without WHO's prior written approval, the Entity shall not use, reproduce or display the name, acronym or emblem of the World Health Organization and/or shall not, in any statement or material of any advertising, publicity, promotional or commercial nature, refer to the Entity's relationship with WHO in connection herewith.
- 7.2 Any dispute arising from or relating to these Terms of Use and/or the Platform shall, unless amicably settled, be subject to conciliation. In the event of failure of the latter, the dispute shall be settled by arbitration. The arbitration shall be conducted in the English language and in accordance with the modalities to be agreed upon by the parties or, in the absence of agreement, with the rules of arbitration of the International Chamber of Commerce. The parties shall accept the arbitral award as final.
- 7.3 Nothing contained in or relating to these Terms of Use and/or the Platform shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national or international law, treaty or convention, or as submitting WHO to any national court or jurisdiction.
- 7.4 These Terms of Use are the entire understanding between WHO and the Entity with respect to the subject matter hereof. These Terms of Use may be modified, but only by written amendment signed by duly authorized officers of WHO and the Entity. The Entity will not reproduce, disclose or otherwise transmit these Terms of Use to any third party without WHO's prior written consent.

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