Call for Expression of Interest for Reference Laboratories of the WHO CoronaVirus Network (CoViNet)

Deadline for submission: 1 October 2023

Date of publication: 28 August 2023

The World Health Organization Health (hereinafter, "WHO"), acting through its Emergencies Programme within its Department of Epidemic and Pandemic Preparedness and Prevention is pleased to announce a call for expression of interest, (hereinafter, this "EOI") for laboratories to become members (as reference laboratories) within the WHO Coronavirus Network (hereinafter, the "CoViNet"), subject to WHO's assessment of their application in accordance with this Call for EOI.

Laboratories who are interested in becoming reference laboratories of the CoViNet must complete and submit an online application form, available at:
https://extranet.who.int/dataformv3/index.php/891523?newtest=Y&lang=en

The application form must be received by WHO no later than **1 October 2023 23:00 CET.**

A laboratory's submission of an application form by the deadline stated above in response to this Call for EOI does not automatically mean that such laboratory will be selected to participate as a reference laboratory to the CoViNet.

For the avoidance of doubt, a laboratory's selection as reference laboratory and participation in the CoViNet will be subject to and contingent upon such laboratory first meeting all relevant criteria and requirements therefor which include, but are not limited to: (1) such laboratory meeting all essential criteria set out in section 2 below;(2) such laboratory first approving by signing and returning to WHO an executed copy (scanned and in original) of the Conditions for Applicants attached hereto as Annex 1.

Background and the CoViNet overall goal

The first WHO reference laboratory network for SARS-CoV-2 (the "WHO SARS-CoV-2 Reference Laboratory Network") was established in January 2020, with the initial objective to provide confirmatory testing to countries with no or little testing capacity for SARS-CoV-2. Since then, the needs for SARS-CoV-2 have evolved and monitoring the evolution of the virus, spread of variants and assessing the impact of variants on public health remains essential.

In the 4th year of the COVID-19 pandemic, WHO decided to broaden and revise the scope, objectives and terms of reference of WHO SARS-CoV-2 Reference Laboratory Network to also include, among other things: (i) expertise in animal health and environmental surveillance, (ii) other coronaviruses, including MERS-CoV, and (iii) enhance capacities for the identification of novel coronaviruses that could negatively affect human health. It was also decided that the WHO SARS-CoV-2 Reference Laboratory Network, with its expanded and revised scope, objectives and terms of reference, would be renamed and thereafter referred to as the "WHO Coronavirus Network", i.e. the CoViNet.

In May 2023, the IHR (2005) Emergency Committee on the COVID-19 pandemic called upon WHO Member States to bring together information from diverse respiratory pathogen surveillance data sources to allow for a comprehensive situational awareness. Specifically, WHO Member States should leverage the Global Influenza Surveillance and Response System (GISRS) and support the establishment of the CoViNet.

The overall goal of the CoViNet is to facilitate global expertise and capacity for early and accurate detection as well as monitoring and genotypic and phenotypic assessment of - SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance. The work of the CoViNet will be essential to support the ongoing risk assessments conducted by the WHO Technical Advisory Group for Virus Evolution (TAG-VE) and the ongoing independent assessments of the Technical Advisory Group for COVID-19 vaccine composition (TAG-COVAC) on the implications of emerging SARS-CoV-2 variants on COVID-19 vaccine composition.

The CoViNet will operate through enhanced collaborations and integration with relevant existing and planned regional and national laboratory networks such as the COVID-19 Genomic Surveillance Regional Network (COVIGEN), the SEARO regional reference laboratory network, and alliances such as Global Laboratories Alliance for the Diagnosis of High Threat Pathogens (GLAD-HP), Global Influenza Surveillance and Response System (GISRS) and the International Pathogen Surveillance Network (IPSN) and through linkages with existing global and regional initiatives including the WHO Hub for Pandemic and Epidemic Intelligence.

Furthermore, because coronaviruses are zoonotic, it is critical that the CoViNet be comprehensive and promote strong engagement of animal and environmental laboratories using a One Health approach. These laboratories will be considered for selection by WHO in consultation with the Food and Agriculture Organization, the World Organization for Animal Health and/or through consultation with WHO Collaborating Centers for Water Quality, Sanitation and Hygiene.

Formalizing the CoViNet will also serve to continue strengthening health emergency prevention, preparedness, response, and resilience (HEPR), building on gains made during the COVID-19 pandemic. The information generated through the CoViNet will be central to the work of the WHO technical and scientific Advisory Groups, including TAG-VE, TAG-CO-VAC, SAGE, and the R&D Blueprint for Epidemics working groups. The CoViNet activities will be carried out at national and international levels to inform global policy decision making. The table below provides an overview of the CoViNet structure and functions **for SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance:**

Who ?	**Function**	**Activities**
WHO Technical advisory groups (TAG-VE, TAG-CO-VAC) CoViNet core OneHealth group ; WHO Secretariat	-Support development of public health policy related to prevention, preparedness and response -shape research agenda	-Policy based on outputs of WHO variant risk evaluation framework and other evidence - identification of research/knowledge gaps;
Reference laboratories with relevant expertise in functions required for virus discovery and coronavirus	-Receive, identify and track variants through genome sequence analysis -Characterize variants according to comprehensive WHO variant risk evaluation framework	- provide confirmatory testing of virus materials -according to strict biosafety and ethical standards, conduct components of risk evaluation of variants of interest or concern eg. growth advantage, immune escape,

variant tracking and risk evaluation	-provide capacity building in lab methods to support and enhance national surveillance and regional expertise -	antigenic characterization, therapeutic susceptibility, diagnostic accuracy - development and/or revision of relevant methods, recommendations and other documents - research at human-animal interface
i) National Centers responsible for coronavirus laboratory functions[1]	- Technical resource - Focal point for WHO and for national surveillance activities reliant on specialized diagnostic and laboratory services for coronaviruses - Maintenance of high biosafety standards and technical proficiency	- Laboratory confirmation from clinical samples, wastewater by molecular _+/- serology (antigen, antibody) - Virus culture - Genomic sequencing - Participation in and coordination of subnational external quality assessments - Safe data and sample sharing to support variant tracking and risk evaluation.

This Call for EOI is exclusively to select reference laboratories for assessment by WHO which has entire discretion to decide if the applicant laboratories meet all the criteria and requirements (as described in this Call for EOI) to become member of the CoViNet.

1. Objectives of the CoViNet Reference Laboratories

The CoViNet reference laboratories shall support both overarching goals of the CoViNet as well as specific objectives including:

Core objectives:

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;

[1] It is anticipated that these centers will support needs across multiple pathogens, including coronaviruses and other respiratory viruses

2. Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing the need for a "One Health" approach.

Specific to reference laboratories:

3. Timely risk assessment for SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance, to inform WHO policy related to a range of public health and medical countermeasures.
4. Support capacity building[2] of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

2. Expected activities of the CoViNet reference laboratories

In support of the CoViNet objectives, reference laboratories will be expected to carry out a range of activities and also interface with laboratories conducting national coronavirus surveillance activities.

In order to be eligible to participate as a reference laboratory in the CoViNet, each applicant laboratory must demonstrate, to WHO's satisfaction, that it meets **all essential criteria** and meet **at least one or more of the desirable criteria** set forth below:

Essential criteria:

1. Demonstrated expertise, experience capacity and capabilities to conduct experiments according to internationally recognized biosafety and biosecurity standards and at least, appropriate heightened control measures[3];
2. Experience with handling live coronaviruses;
3. Demonstrated capacity, expertise, experience and capabilities to perform:
    a. confirmatory testing of virus materials and other clinical samples from suspected cases of SARS-CoV-2, MERS-CoV and/or novel coronaviruses of public health;

[2] e.g. advanced genomic and phenotypic analysis, enabling enhanced surveillance and monitoring functionality

[3] Laboratory biosafety manual, 4th edition (who.int)

b. whole genome sequencing and provision of such sequence data to a publicly accessible database;

AND

<u>One or more</u> of the following activities:

i. Support the identification of causative agent(s) for respiratory illness(es) of **unknown origin/virus discovery** in collaboration with other relevant collaborators;

ii. Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;

iii. Evaluate immune escape potential of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;

iv. Monitor resistance of available and newly developed therapeutics *in silico, in vitro* and/or *in vivo*;

v. Support the development and evaluation of laboratory diagnostic reagents for coronaviruses, including, without limitation, through:
   a) development or refinement of molecular assays;
   b) development of protocols for antiviral resistance testing;
   c) antigenic characterization;
   d) development/assessment of specific tests for diagnostic humoral immune responses; and
   e) support with structured validation of the developed and commercial assays.

Desirable criteria

In order to be eligible to participate as a reference laboratory in the CoViNet, each applicant laboratory must demonstrate, to WHO's satisfaction, that it meets **at least one or more** of the following **desirable criteria**:

1. Experience with coronavirus surveillance in animals;

2. Experience with environmental surveillance of coronaviruses e.g. in wastewater;

3. Experience with bioinformatic analysis;

4. Access to specimens to support CoViNet anticipated deliverables through an established network of clinical sites from which acquiring specimens (animal, human, environmental);

5. Possession of or access to a biobank with coronavirus strains and sera from humans or animals infected with coronaviruses;

6. Access to regular funding to support domestic and international surveillance, and risk assessments of pathogenic coronaviruses of public health importance;

7. Experience with working for WHO or another international or regional public health organization or WHO networks (e.g., GISRS, COVIGEN, etc);
8. WHO Collaborating Centre designation with planned or ongoing workplan that includes activities related to SARS-CoV-2, MERS-CoV or novel coronaviruses preparedness and response activities;
9. Experience in integration of laboratory clinical and epidemiological data to guide public health response and willingness to support capacity-building activities in this area; or
10. Experience in training and capacity strengthening activities.

Expected Deliverables of Reference Laboratories Participating in the CoViNet

In furtherance of the CoViNet's core objectives, the reference laboratories of the CoViNet will contribute to a range of activities linked to specific deliverables. The list of deliverables appearing below may be further revised or refined from time to time by WHO as and when needed.

By way of non-exhaustive example, the below list of deliverables may be further revised or refined by WHO following the first CoViNet meeting with the laboratories selected to participate in the CoViNet, which is expected to take place in December 2023.

The following deliverables are important pieces to inform the overall assessment of the risk posed by coronaviruses to public health, as well as their impact on countermeasures in use. The deliverables will be matched to reference labs in line with their expertise and scope of work recognized by the CoViNet.

CoViNet objective	**Activities**	**Anticipated deliverable based on lab expertise and scope of work for the network**
1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance; 2. Surveillance and Monitoring of the global circulation and evolution or SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;	Assess the of the accuracy of diagnostics for coronaviruses and/or the impact on diagnostics of coronaviruses	Annual laboratory evaluation of the accuracy of coronavirus diagnostics, development of diagnostics for novel coronaviruses, and/or impact on diagnostics of any coronavirus with mutations (e.g. SARS-CoV-2 variants)

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance; 2. Surveillance and Monitoring of the global circulation and evolution or SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;	Capacity building across all levels of CoViNet	Expansion of genomic and/or phenotypic characterization of SARS-CoV-2 VOC/VOI/VUM and MERS-CoV clades in countries selected by WHO
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	Immune escape assessment of coronaviruses	Up to biannual assessment of the immune escape of SARS-CoV-2 VOC/VOI/VUM circulating in various WHO regions.
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	Laboratory assessment of the pathogenicity of coronaviruses	Annual assessment of the overall pathogenicity profile of SARS-CoV-2 VOC/VOI/VUM circulating in various WHO regions
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	Assessment of therapeutics susceptibility of coronaviruses	Annual assessment of the therapeutics susceptibility of any SARS-CoV-2 VOC/VOI/VUM with mutations that may impact therapeutics
3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures	One Health*	Characterization of circulating MERS-CoV clades in animal reservoirs and animal surveillance of SARS-CoV-2 to inform assessment of public health risk for humans Implementation of wastewater surveillance for SARS-CoV-2 in countries selected by WHO.

*these activities are coordinated with members of the quadripartite, which includes FAO, and WOAH

3. Opportunities arising from participation

Laboratories that are selected by WHO to, and that meet all applicable criteria and requirements to WHO's satisfaction to, become member of the CoViNet may have the following opportunities in connection with such membership:

1. Opportunity and expectation to collaborate, as and where appropriate, with institutions and experts around the world to conduct research and contribute to innovation in the field of coronavirology;

2. Depending on country income level, reference labs may have access to funding opportunities, including from WHO, and partnerships with other institutions and organizations, providing additional resources and support for their work;
3. Opportunities to contribute, as and where appropriate, to global health priorities and initiatives, including research, policy development, and implementation efforts; and
4. Where appropriate opportunities to train and mentor professionals from other institutions and countries, and to help build capacity and strengthen health systems around the world.

4. Application and selection process

Submission of Application Materials

To express your laboratory's interest to participate in this Call for EOI in view of an assessment by WHO to become a possible reference laboratory member of the CoViNet, please duly complete and submit an online application form, available at https://extranet.who.int/dataformv3/index.php/891523?newtest=Y&lang=en

by no later than **1 October, 2023 at 23:00 CET** (the "Deadline") together with an executed copy of the Conditions for Applicants contained in Annex 1 hereto (hereinafter collectively referred to with the application form as the "Application Materials")**.** In the event that WHO does not receive, by the Deadline, the aforementioned Application Materials fully completed, dated and signed by the laboratory, then: (1) assessment of its participation in the CoViNet shall not commence; and (2) such laboratory shall not be considered as a candidate to participate as a reference laboratory in the CoViNet.

Evaluation of Application Materials and Short-Listing

Assuming that your laboratory's Application Materials (as defined above) are received by WHO by no later than the Deadline (as defined above), your Application Materials will be reviewed and assessed by WHO, acting as the CoViNet Secretariat.

As soon as possible following the Deadline, the CoViNet Secretariat will prepare a shortlist that is comprised of laboratories: (1) whose Application Materials were received by the Deadline, and (2) who meet all of the Essential Criteria set out in Section 4 of this Call for EOI; and (3) who meet at least one of the Desirable Criteria set out in Section 4 of this EOI.

The laboratories that are included in the abovementioned shortlist (hereinafter referred to as "Shortlisted Laboratories") will be informed by WHO in writing of their status as such and may be asked to provide additional information concerning their application.

Next steps : Selection and Invitation to Participate as CoViNet reference laboratory; Approval of the CoViNet Terms of Reference

WHO will select laboratories and invite them to participate in the CoViNet from the Shortlisted Laboratories and such decision shall be made at WHO's entire discretion giving due regard to considerations of capacities, expertise, geography and availability of co-funding for CoViNet related activities (hereinafter referred to as the "Selected Laboratories"). The Selected Laboratories will be invited by WHO to participate in the CoViNet subject to them agreeing to the Terms of Reference of the CoVinet which are attached as Annex 2 hereto ***for information purposes only*** (hereinafter referred to as, the "CoViNet ToRs"). The CoVinet ToRs do not apply to applicant laboratories who are submitting an application in response to this Call for EOI. The CoViNet ToRs only apply if and when a laboratory becomes a Selected Laboratory and is invited by WHO to become a member of the CoViNet. WHO will contact all Selected Laboratories to collect their respective written approval of the Covinet ToRs in due course since such approval is a prerequisite of their participation to the CoViNet. In the case that a Selected Laboratory does not sign the CoViNet TORs, then WHO will select another laboratory from the Shortlisted Laboratories.

5. Annexes and related documents

- Conditions for Applicants (Annex 1 hereto) (which apply to laboratories wishing to submit an application as part of this Call for EOI);
- Terms of Reference of CoViNet (Annex 2) ;(which apply to laboratories only **if and when an applicant laboratory becomes a Selected Laboratory**); and
- Online application form and associated documents, available at:

  https://extranet.who.int/dataformv3/index.php/891523?newtest=Y&lang=en

6. Questions

Should you have any questions about this Call for EOI, please send an email to: cunninghamj@who.int and subissil@who.int: *Subject line: Query Call for EOI WHO Coronavirus Network*

Annex 1: Conditions for Applicants to become possible reference laboratories of the WHO Coronavirus Laboratory Network

Each of the reference laboratories participating in the WHO Coronavirus Laboratory Network (the "CoViNet") shall support the core objectives of such Network; as well as the specific objective namely to enable:

1. Early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;
2. Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing the need for a "One Health" approach;

Specific to reference laboratories:

3. Timely risk assessment to inform WHO policy related to a range of public health and medical countermeasures; and
4. Support capacity building of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

In addition to the foregoing, each of the reference laboratories participating in the CoViNet shall carry out points 1 and 2 and at least one, but preferably more, of the activities listed in points 3 to 18 below in order to contribute to achieving the CoViNet objectives:

1. Confirmatory testing of virus materials and other clinical samples from suspected cases of SARS-CoV-2, MERS-CoV and or novel coronaviruses of public health;
2. Whole genome sequencing and provision of such sequence data to a publicly accessible database and upon request, provide well-characterized viral strains, sequences and other relevant material to the WHO BioHub;
3. Support the identification of causative agent(s) for respiratory illness(es) of unknown origin/virus discovery in collaboration with other relevant collaborators;
4. Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;
5. Evaluate immune escape potential of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;
6. Monitor resistance of available and newly developed therapeutics *in silico, in vitro* and/or *in vivo*;
7. Support the development, monitoring and evaluation of laboratory diagnostic reagents (and assays) for coronaviruses, including, without limitation, through:
    a. development or refinement of molecular assays;
    b. development of protocols for antiviral resistance testing;
    c. antigenic characterization;

    d. development/assessment of specific tests for diagnostic humoral immune responses; and
    e. support with structured validation of developed and commercial assays; and
    f. monitoring of genetic changes that may affect diagnostic performance
8. At the request of WHO, promptly provide WHO with the technical details of diagnostic reagents and/or molecular assays developed and/or evaluated by the participating laboratory pursuant to point 7 above;
9. Monitor the efficacy of diagnostics with emerging novel coronaviruses and their variants;
10. Support the implementation of a One Health surveillance approach that includes human disease surveillance as well as linking with, supporting and/or conducting animal and environmental coronavirus surveillance;
11. Inform WHO to develop and evaluate its strategy and recommended methods for the global surveillance and diagnosis of SARS-CoV-2, MERS-CoV and other coronaviruses of public health importance , including by assisting WHO in the development and/or revision of relevant methods, and other documents. For the avoidance of doubt, however, notwithstanding the laboratory's assistance as described herein, it is hereby expressly acknowledged and understood that WHO will retain final discretion and control as to the content of any such WHO recommended methods, or other documents;

    Furthermore, each laboratory participating in the CoviNet must comply with the following terms and conditions:

12. Share anonymized information (stripped of all personal identifiers) generated on viral evolution of relevant coronaviruses, including SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance and identify genetic changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment;
13. Meet all applicable deadlines and timeframes for the conduct of the laboratory's obligations and activities as part of the CoViNet;
14. Maintain and demonstrate a high level of technical proficiency, capacity and ability in all matters pertaining to the CoViNet including, but not limited to, through proficiency testing where applicable for the used methods;
15. Treat all virus materials and clinical samples, together with all data and information relating thereto, which are obtained by the laboratory through its participation in this CoViNet (collectively, the "materials") as confidential and proprietary to the providing country, and ensure that materials are not transferred or provided to any third party unless: (i) the recipient third party is a participating laboratory under the CoviNet; and (ii) WHO has expressly requested in writing that the transferring laboratory provide the materials to such recipient laboratory; and (iii) the recipient laboratory uses the materials solely for the Purpose (as defined in paragraph 19 below), and no other purpose. In connection with all of the foregoing, the laboratory must implement and maintain appropriate technical and organizational measures to protect the confidentiality and security of the materials, and to protect the materials from unauthorized access, theft, damage, loss, destruction or misuse;
16. Ensure that the participating laboratory only uses the materials for the following purposes (which are hereinafter collectively referred to as the "Purpose"): (1) detection, identification,

and characterization (including through whole genome sequencing) of the SARS-CoV-2, MERS-CoV, and novel coronaviruses of public health importance, including the inclusion of resulting sequence data in a publicly accessible database, (2) non-commercial assay development, (3) commercial assay development*, provided always however that* the participating laboratory shall have first entered into an agreement with WHO concerning such commercial assay development which shall include, without limitation, provisions to the effect that the commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from any such commercial assay and/or its development shall be designed to achieve the general availability of the product(s) and the availability of the product(s) to the public health sector of developing countries on preferential terms (including as to price) and in sufficient quantities to meet demand; (4) validation of assays, and (5) the performance of any other work as explicitly foreseen in these Conditions for Applicants;

17. Ensure that, except as may explicitly otherwise be provided in these Conditions for Applicants, the participating laboratory does not use, and does not provide and permit others to use, the materials for any purpose other than the Purpose, unless a separate written agreement has first been established with the Provider (as defined in paragraph 18 below) covering such other use. Any such separate agreement will be promptly provided by the participating laboratory to WHO;
18. Ensure that results of the use of the materials for the Purpose are only be reported to the national laboratory or governmental agency that provided the materials (hereinafter, the "Provider"), except (a) that the participating laboratory will, subject to agreement with WHO and/or Provider, as applicable, be entitled to publish the results of the use of the materials for the Purpose; and (b) as otherwise set forth in paragraph 19 below;
19. Adhere to and comply with: (i) all applicable laws, statutes, rules, regulations and other legal or ethical requirements; (ii) all relevant national biosafety standards for work with high-threat pathogens; and (iii) all national and/or international regulations relating to the receipt of dangerous goods;
20. Obtain and maintain in effect any applicable licenses, permits, authorizations, consents, approvals, accreditations, documentation and/or other recognition which are necessary or required (whether at the national, regional and/or international level(s)) for the laboratory to perform its tasks in connection with the CoViNet;
21. At the request of WHO, make available to WHO (under confidential cover where required) all relevant anonymized (i.e., stripped of all personal identifiers) data and information, as well as all results of work performed by the participating laboratory pursuant to these Conditions for Applicants, for the purposes of guiding WHO in the development of WHO's strategy, recommended methods, recommendations, guidelines and/or other documents referred to in paragraph 11 above;
22. Ensure that any agreements entered into by the participating laboratory with any Provider in connection with the CoViNet are consistent with these Conditions for Applicants; and
23. Agree that nothing contained in or relating to these Conditions for Applicants and/or the CoViNet will be construed as a waiver of any privileges and immunities enjoyed by WHO, and/or as submitting WHO to any national court jurisdiction.

IN WITNESS WHEREOF, the undersigned laboratory has caused its duly authorized representative to sign, as of the date ser forth below, this document in two (2) originals in the English language, in order to evidence such laboratory's agreement with, acceptance of and commitment to comply with these Conditions for Applicants.

S**igned for and on behalf of the applicant laboratory:**

Signature: _____

Name of Entity: _____

Name of Authorized Representative: _____

Title of Authorized Representative: _____

Date: _____

Mailing Address: _____

Email Address: _____

Telephone Number: _____

Annex 2: Terms of Reference of the WHO Coronavirus Network[4]

The CoronaVirus Network

("CoViNet")

Terms of Reference

August 2023

[4] ***These ToRs do not apply to applicant laboratories who are responding to this Call for EOI. These ToRs only apply if and when a laboratory is selected to become a member of the CoViNet. WHO will contact all selected laboratories to collect written approval of these ToRs in due course and such approval is a prerequisite of the membership in CoViNet.***

1. B**ackground**

The first WHO reference laboratory network for SARS-CoV-2 (the "WHO SARS-CoV-2 Reference Laboratory Network") was established in January 2020, with the initial objective to provide confirmatory testing to countries with no or little testing capacity for SARS-CoV-2. Since then, the needs for SARS-CoV-2 have evolved to include monitoring the evolution of the virus, spread of variants and assessing the impact of variants on public health remains essential. In the 4th year of the COVID-19 pandemic, WHO decided to broaden and revise the scope, objectives and terms of reference of WHO SARS-CoV-2 Reference Laboratory Network to also include, among other things: (i) expertise in animal health and environmental surveillance, (ii) other coronaviruses, including MERS-CoV, and (iii) enhance capacities for the identification of novel coronaviruses that could negatively affect human health. It was also decided that the WHO SARS-CoV-2 Reference Laboratory Network, with its expanded and revised scope, objectives and terms of reference, would be renamed and thereafter referred to as the "WHO Coronavirus Network" (hereinafter referred to as "**CoViNet**"). Establishment of CoViNet was endorsed by the IHR (2005) Emergency Committee on the COVID-19 pandemic in May 2023

2. Status and Nature of CoViNet

CoViNet is administered by the World Health Organization ("WHO") through its Emerging Diseases and Zoonoses Unit, within the Department of Epidemic and Pandemic Preparedness and Prevention (EPP). CoViNet is a collaborative mechanism between interested parties including WHO and CoViNet participants, and is not an independent legal entity. For this reason, CoViNet cannot conduct any actions in its own name. The operations of CoViNet shall in all respects be administered in accordance with the WHO Constitution, WHO's Financial and Staff Regulations and Rules, Manual provisions, and applicable policies, procedures and practices.

3. Goal and Objectives

The primary goal of CoViNet is to work through a well – coordinated and robust network of human, and animal public health and research laboratories to facilitate global expertise and capacity for early and accurate detection as well as monitoring and genotypic and phenotypic assessment of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance. By fostering collaboration, knowledge-sharing, and innovation among participating laboratories, CoViNet aims to enhance pandemic preparedness, accelerate scientific knowledge to inform public health policy, and enable effective responses to future epidemics/pandemics of SARS-CoV-2, MERS-CoV and novel coronaviruses or other emerging respiratory pathogen threats.

Additionally, the work of CoViNet will support the ongoing risk assessments conducted by the WHO Technical Advisory Group for Virus Evolution (TAG-VE) and the ongoing independent assessments of the Technical Advisory Group for COVID-19 vaccine composition (TAG-COVAC) on the implications of emerging SARS-CoV-2 variants on COVID-19 vaccine composition.

The objectives of CoViNet are to:

1. Facilitate early and accurate detection of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;

2. Support surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing the need for a "One Health" approach;
3. Provide timely risk assessment for SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance, to inform WHO policy related to a range of public health and medical countermeasures; and
4. Support capacity building[5] of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

4. Structure, Organization and Governance of CoViNet

4.1. Structure

4.1.1 Membership

Only institutions or organizations, not individuals, can be members of CoViNet. Members of CoViNet may be any national reference laboratory or institutes responsible for coronavirus work, or research institutions working on coronaviruses in human or animal populations. Among these, there will be a set of "Core Members" of CoViNet including the reference laboratories that are selected via an expression of interest and focal points from animal health organizations (FAO, WOAH) working very closely with WHO and its advisory groups in development of laboratory procedures and practices relevant to CoViNet and in capacity building..The reference laboratory Core Members ought to meet the minimum eligibility criteria in Appendix 1 hereto.

Each member of CoViNet must:

- Nominate their focal persons to CoViNet;

[5] e.g. advanced genomic and phenotypic analysis, enabling enhanced surveillance and monitoring functionality

- Adhere to and comply with the Terms of Reference of CoViNet;
- Actively participate in and support CoViNet, purpose, goals, objectives, guiding principles, work and activities;
- Attend and actively participate in CoViNet's various annual and ad hoc meetings;
- Take responsibility for their actions, and make meaningful contributions, in connection with the work and activities of CoViNet; and
- Conduct themselves in an ethical manner and display integrity, honesty and concern for the best interests of CoViNet and all its members.

In addition, the Core Members shall also perform the following actions:

- Provide orientation for CoViNet activities;
- Identify scientific/technical and operational issues that need to be addressed by CoViNet;
- Represent CoViNet in relevant meetings, as necessary;
- Review, provide inputs and approve CoViNet workplans, technical documents (e.g. standard operating procedures (SOPs) and annual reports.

Expertise in other areas (e.g. epidemiology, clinical management, etc.) can be co-opted as required.

4.1.2 Coordination

CoViNet will be coordinated by WHO, acting as CoViNet Secretariat Network Coordinator.

Functions of the Network Coordinator:

The Network Coordinator will be responsible for providing secretarial support and coordination of CoViNet and specifically:

- Serves as the interface between CoViNet and other networks or country programs and research institutions that are not members of CoViNet but can contribute to the surveillance and tracking of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance;
- Coordinates the implementation of the CoViNet workplans;

- Convenes and prepares annual meetings; and
- Prepares, in consultation with the Core Members, and disseminates the CoViNet workplans, relevant technical documents and annual report.

Based on availability of resource, regional network coordinators will be identified to provide more direct interface between network and regional networks for country programmes; supporting coordination of regional level CoViNet activities and progress tracking.

4.1.3. Other Governance Considerations

As a WHO network, and as stipulated in the WHO manual, all CoViNet activities shall fall under WHO's managerial control, and all decisions in relation to CoViNet activities shall, as appropriate, be made by WHO in consultation with CoViNet members and as relevant, technical advisory groups on viral evolution (TAG-VE) and coronavirus vaccine composition (TAG-CO-VAC).

For the avoidance of doubt, WHO will have the sole right and responsibility to review, screen and decide-upon each application for membership in the CoViNet, subject to and in accordance with the membership criteria set out in these Terms of Reference as well as WHO's applicable rules, regulations, policies, procedures and practices.

5. Activities and methods of works

In order to fulfil its objectives, CoViNet will conduct the following main activities:

5.1 **Early and accurate detection** of SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance through:

a. Confirmatory testing of virus materials and other clinical samples from suspected cases of SARS-CoV-2, MERS-CoV and or novel coronaviruses of public health;
b. Whole genome sequencing and provision of such sequence data to a publicly accessible database and upon request, provide well-characterized viral strains, sequences and other relevant material to the WHO BioHub;
c. Support the identification of causative agent(s) for respiratory illness(es) of unknown origin/virus discovery in collaboration with other relevant collaborators;
d. at the request of WHO, prompt provision of WHO with the technical details of diagnostic reagents and/or molecular assays developed and/or evaluated by the CoViNet members.

5.2 Surveillance and monitoring of the global circulation and evolution of SARS-CoV, MERS-CoV and novel coronaviruses of public health importance recognizing and supporting the need for a "One Health" approach;

5.3 Timely variant risk assessment to inform WHO policy related to a range of public health and medical countermeasures including:

5.3.1 Assess viral fitness/transmissibility and pathogenicity of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;

5.3.2 Evaluate immune escape potential of emerging viruses/variants *in silico*, *in vitro* and/or *in vivo*;

5.3.3 Monitor resistance of available and newly developed therapeutics *in silico, in vitro* and/or *in vivo*;

5.3.4 Support the development, monitoring and evaluation of laboratory diagnostic reagents (and assays) for coronaviruses, including, without limitation, through:

- development or refinement of molecular assays;
- development of protocols for antiviral resistance testing;
- antigenic characterization;
- development/assessment of specific tests for diagnostic humoral immune responses;
- support with structured validation of developed and commercial assays;
- monitoring of genetic changes that may affect diagnostic performance; and
- monitor the efficacy of diagnostics with emerging novel coronaviruses and their variants.

5.4 Capacity Building

CoViNet members will support capacity building of laboratories relevant to needs of WHO and CoViNet, particularly those in low and middle-income countries, for SARS-CoV-2. MERS-CoV and novel coronaviruses of public health importance.

5.5 Documents, recommendations:

CoViNet members will contribute to the development and/or revision of relevant methods, and other documents. For the avoidance of doubt, however, notwithstanding the laboratory's assistance as described herein, it is hereby expressly acknowledged and understood that WHO will retain final discretion and control as to the content of any such WHO recommended methods, or other documents;

5.6 Laboratory Assessments:

WHO, as Network Coordinator, may coordinate on-site laboratory assessments of CoViNet members to determine compliance with recommended procedures and practices related to CoViNet member activities/responsibilities. Results of on-site assessments will be kept confidential to WHO, as CoViNet Secretariat, inspectors and CoViNet member who has undergone the inspection. Terms of reference of lab assessments will be prepared by the WHO, as Network Coordinator based on the laboratories functions and will be guided by a standard Lab Assessment Tool . WHO will solicit the different CoViNet members through the Network Coordinator to provide the required support.

6. Information exchange and dissemination

CoViNet members will be encouraged to share any information that could be of interest and that is not confidential in nature, mainly using the electronic media such as email, drop box etc. WHO assesses and decides on information that can be shared with other networks involved in respiratory virus surveillance and control in the region. A CoViNet newsletter will be regularly published by WHO.

7. Workshops

Organization of workshops may be part of the CoViNet workplan to address specific scientific, operational and other issues related to surveillance of SARS-CoV-2, MERS-CoV or novel coronaviruses of public health importance. Workshops will be planned during the annual network coordination meeting. The funding will be included in the CoViNet workplan budget. WHO will facilitate and ensure organization of the workshops.

8. Coordination meetings

Two (2) types of meetings will be organized to coordinate CoViNet activities and such meetings shall be convened by the Network Coordinator and be chaired by rotating reference laboratory focal point:

a) Annual meetings for CoViNet coordination

Annual meetings of CoViNet will be convened by the Network Coordinator and the agenda of such meetings will be determined by the Network Coordinator, following consultations with CoViNet members and WHO. WHO will financially support annual CoViNet meetings, if members are unable to self-fund. Efforts will be made to sustain the CoViNet annual meeting through grant funding. The main objectives of the annual meetings will be to:

- review and evaluate the status of implementation of planned activities relating to CoViNet and provide orientation on the way forward;
- review and approve the CoViNet annual report and proposed work plan for the subsequent year;
- identify and discuss relevant scientific developments and/or relevant research results of CoViNet members;
- identify and discuss on operational issues related to the CoViNet's activities; and
- identify needs (topics) for research.

Annual meetings can be hosted by CoViNet members.

Core Members will be participants of the annual coordination meetings. However, based on availability of financial resources and the prevailing issues that will be discussed on each meeting, experts in various areas may be invited by the Network Coordinator to participate in the CoViNet annual meetings. Annual CoViNet meetings will take place during the period from September to early December in each year.

b) Ad-hoc meetings

The Network Coordinator may organize a meeting and convene some or all of Core Members to address specific issues. The Network Coordinator may decide to convene other experts or representatives from other respiratory virus networks depending on the matter to be addressed by the ad-hoc meeting and available resources. Such meetings can be convened any time.

9. Decision-making

To the extent that CoViNet members need to take any decisions concerning CoViNet activities, these decisions shall be made on the basis of consensus. WHO shall fully participate in the decision making process and shall have the right to veto any decision that is contrary to its policies, rules, regulations and administrative procedures.

10. Workplan

An annual workplan will be prepared within the scope of these Terms of Reference and on the basis of Member States needs, informed by the current epidemiological situation, the COVID-19

Strategic Preparedness and Response Plan (2023-2025), other relevant coronavirus plans and available WHO and CoViNet Member resources.

11. Monitoring and Evaluation

The Network Coordinator will be responsible for monitoring the CoViNet activities, and a regular update will be provided to Core Members. The evaluation of the CoViNet activities will be conducted as an annual review of the implementation of the workplan during the annual CoViNet coordination meeting. If applicable, regional network coordinators will link with countries in their respective sub-regions and support the regional coordination. This may include, but not limited to, information sharing and dissemination.

12. Financing and Fundraising for CoViNet

12.1 The day-to-day routine operations of the CoViNet secretariat will be financed by WHO. WHO may seek to raise funds or accept financial and/or in-kind contributions from external sources to support CoViNet operations; the foregoing shall be in accordance with WHO's rules, regulations, policies, procedures and practices.

12.2 WHO shall administer any financial contributions designated for CoViNet in accordance with WHO's financial regulations, rules, procedures and practices. Any such contributions shall be subject to WHO's normal programme support costs.

12.3 Subject to the availability of sufficient financial resources for this purpose, WHO shall cover travel and subsistence expenses of CoViNet members in connection with attendance at the yearly CoViNet coordination and ad-hoc meetings.

13. Public Communications and Publications

13.1 As a general rule and subject to its discretion, WHO shall be responsible for issuing all public communications relating to CoViNet's work and activities. In this regard, CoViNet members shall not make or issue any public statements/materials or press releases concerning CoViNet, its work or any of its activities, or on behalf of WHO, unless specifically requested or authorized to do so in writing by WHO.

13.2 Unless otherwise agreed in writing by WHO, publications relating to CoViNet's work or activities (hereinafter "Publications") shall be subject to WHO's rules, procedures and practices on publications, and shall be published by WHO in accordance with the same. Decisions about the preparation and dissemination of any Publications shall be made by WHO. A Publication issued by a CoViNet member other than WHO shall be subject to WHO's review and written approval prior to its publication and shall contain appropriate disclaimers as decided by WHO, including that the content does not necessarily reflect the views or stated policy of other CoViNet members, including WHO.

13.3 Copyright in any Publication made by WHO shall be vested exclusively in WHO. Likewise, WHO shall exclusively own all copyright in any work prepared or published by WHO including, but not limited to, any compilation of works by CoViNet members and/or any work prepared with input from any CoViNet members. Copyright in any specific separate work prepared exclusively by any CoViNet member shall remain vested in that member (or remain in the public domain, if applicable).

14. Use of Names and Emblems

The use of CoViNet logo is subject to the prior express written approval of WHO. CoViNet members shall not use the name, acronym or emblem of WHO in any manner or for any purpose, without prior written consent by WHO.

15. Liability

Under no circumstances shall WHO assume any liability for acts carried out by CoViNet members regardless of whether such acts were carried out in the name of CoViNet. Furthermore, WHO in its sole discretion, may refrain from implementing any decision of CoViNet if in the view of WHO, such decision gives rise to undue financial, legal or reputational liability or is contrary to WHO Rules, Regulations Administrative practices and programmatic and technical policies.

16. Termination and Withdrawal

Each CoViNet member has the right to withdraw from participation in the CoViNet at any time, subject to providing WHO with at three (3) months' prior written notice and to the orderly conclusion of any ongoing activities.

WHO also has the right to terminate the membership of any CoViNet member at any time, upon providing written notice thereof to such member. Without limiting the foregoing, the participation of any member in the CoViNet shall terminate if and when such member: (a) no longer subscribes or adheres to the goals, objectives and/or guiding principles of the CoViNet, as described in these Terms of Reference; (b) ceases to meet the membership criteria for the CoViNet, as set forth in these Terms of Reference, including the conditions listed in the annex to these Terms of Reference; and/or (c) if a particular CoViNet member fails to participate in three consecutive CoViNet coordination meetings.

17. Amendments

These Terms of Reference may be amended from by WHO as needed.

Annex

Minimum eligibility criteria for Reference Laboratory Core Members of CoViNet

1. Share anonymized information (stripped of all personal identifiers) generated on viral evolution of relevant coronaviruses, including SARS-CoV-2, MERS-CoV and novel coronaviruses of public health importance and identify genetic changes that may be relevant to diagnostic tests, vaccine development and/or antiviral treatment;
2. Meet all applicable deadlines and timeframes for the conduct of the laboratory's obligations and activities as part of the CoViNet;
3. Maintain and demonstrate a high level of technical proficiency, capacity and ability in all matters pertaining to the CoViNet including, but not limited to, through proficiency testing where applicable for the used methods;
4. Treat all virus materials and clinical samples, together with all data and information relating thereto, which are obtained by the laboratory through its participation in this CoViNet (collectively, the "materials") as confidential and proprietary to the providing country, and ensure that materials are not transferred or provided to any third party unless: (i) the recipient third party is a participating laboratory under the CoviNet; and (ii) WHO has expressly requested in writing that the transferring laboratory provide the materials to such recipient laboratory; and (iii) the recipient laboratory uses the materials solely for the Purpose (as defined in paragraph 19 below), and no other purpose. In connection with all of the foregoing, the laboratory must implement and maintain appropriate technical and organizational measures to protect the confidentiality and security of the materials, and to protect the materials from unauthorized access, theft, damage, loss, destruction or misuse;
5. Ensure that the participating laboratory only uses the materials for the following purposes (which are hereinafter collectively referred to as the "Purpose"): (1) detection, identification, and characterization (including through whole genome sequencing) of the SARS-CoV-2, MERS-CoV, and novel coronaviruses of public health importance, including the inclusion of resulting sequence data in a publicly accessible database, (2) non-commercial assay development, (3) commercial assay development*, provided always however that* the participating laboratory shall have first entered into an agreement with WHO concerning such commercial assay development which shall include, without limitation, provisions to the effect that the commercial exploitation of any intellectual property rights, including the ownership of know-how, arising from any such commercial assay and/or its development shall be designed to achieve the general availability of the product(s) and the availability of the product(s) to the public health sector of developing countries on preferential terms (including as to price) and in sufficient quantities to meet demand; (4) validation of assays, and (5) the performance of any other work as explicitly foreseen in the original Conditions for Applicants;

6. Ensure that, except as may explicitly otherwise be provided in the original Conditions for Applicants, the participating laboratory does not use, and does not provide and permit others to use, the materials for any purpose other than the Purpose, unless a separate written agreement has first been established with the Provider (as defined in paragraph 7. below) covering such other use. Any such separate agreement will be promptly provided by the participating laboratory to WHO;
7. Ensure that results of the use of the materials for the Purpose are only be reported to the national laboratory or governmental agency that provided the materials (hereinafter, the "Provider"), except (a) that the participating laboratory will, subject to agreement with WHO and/or Provider, as applicable, be entitled to publish the results of the use of the materials for the Purpose; and (b) as otherwise set forth in paragraph 8 below;
8. Adhere to and comply with: (i) all applicable laws, statutes, rules, regulations and other legal or ethical requirements; (ii) all relevant national biosafety standards for work with high-threat pathogens; and (iii) all national and/or international regulations relating to the receipt of dangerous goods;
9. Obtain and maintain in effect any applicable licenses, permits, authorizations, consents, approvals, accreditations, documentation and/or other recognition which are necessary or required (whether at the national, regional and/or international level(s)) for the laboratory to perform its tasks in connection with the CoViNet;
10. At the request of WHO, make available to WHO (under confidential cover where required) all relevant anonymized (i.e., stripped of all personal identifiers) data and information, as well as all results of work performed by the participating laboratory pursuant to the original Conditions for Applicants, for the purposes of guiding WHO in the development of WHO's strategy, recommended methods, recommendations, guidelines and/or other documents;
11. Ensure that any agreements entered into by the participating laboratory with any Provider in connection with the CoViNet are consistent with the original Conditions for Applicants; and
12. Agree that nothing contained in or relating to the original Conditions for Applicants and/or the CoViNet will be construed as a waiver of any privileges and immunities enjoyed by WHO, and/or as submitting WHO to any national court jurisdiction.