



TERMS OF REFERENCE OF THE GLOBAL DIAGNOSTICS COALITION

I. Mission and Goal

The mission of the Global Diagnostics Coalition is to support implementation of World Health Assembly resolution 76.5 on Strengthening Diagnostics Capacity (2023) through advocacy, awareness raising, dissemination and communication with the aim of improving access to diagnostics and diagnostic services as a fundamental pillar of healthcare systems, towards achieving universal health coverage and emergency preparedness and response.

The goal of the Global Diagnostics Coalition is to act as a platform and/or convening network to provide advocacy efforts to strengthen diagnostics capacity; and convene diverse and relevant stakeholders to encourage harmonizing efforts, foster convergence, and drive a coordinated agenda on diagnostics, towards the WHA76.5¹, above-mentioned and any other resolution addressing the needs to diagnostics for the specific diseases or health conditions.

Relevance to WHO's 14th General Programme of Work: The Global Diagnostics Coalition will contribute to implementation of the WHO's 14th General Programme of Work 2025 - 2028 and Programme Budget 2024 – 2025, through Strategic Priority 1: One billion more people benefitting from universal health coverage; and to implementation of the WHO Road map for access to safe, effective and quality assured health products and technologies 2025 - 2030.

II. Status

The Global Diagnostics Coalition is a WHO informal network. The Global Diagnostics Coalition is not a separate legal entity and derives its legal status from WHO. Thus, it shall be administered and housed in WHO. The operations of the Global Diagnostics Coalition shall in all respects be administered in accordance with the WHO Constitution and General Programme of Work, WHO's Financial and Staff Regulations and Rules, WHO's e-manual provisions, and applicable WHO rules, policies, procedures and practices including the WHO Framework of Engagement with non-State actors.

¹ For the purpose of the resolution WHA76.5, the term "diagnostics" includes medical devices used for the diagnosis, screening, monitoring, prediction, staging or surveillance of diseases or health conditions, both in vitro and non-in vitro types.

III. Objectives

Objective 1: Conduct advocacy activities that increase support to WHO public health objectives and raise awareness of the important role of diagnostics capacity. To achieve this, the Global Diagnostics Coalition will:

- Advocate for, and facilitate, Member State planning and implementation of national diagnostics strategies;
- Advocate for increased investment in affordable diagnostics;
- Encourage and discuss approaches for Member State integration of diagnostics into national health strategies and tiered networks;

Objective 2: Conduct advocacy activities to increase support to WHO public health objectives and raise awareness, on the role of diagnostics, towards case management, monitoring and treatment of communicable, noncommunicable, neglected tropical and rare diseases, injuries and disabilities. To achieve this the Global Diagnostics Coalition will:

- Develop a global advocacy strategy for diagnostics, towards elevating diagnostics as a global health priority, and promote sustained investment in diagnostic infrastructure and workforce capacity.
- Promote and disseminate public health information and resources aligned with WHO recommendations on diagnostics.
- Promote harmonization of policies, access frameworks, and standards to streamline the adoption of diagnostic technologies.
- Promote and support, when and where relevant, WHO public health messages, and as appropriate, events in the area of diagnostics and medical devices, at global and regional level.

Objective 3: Strengthen networking and knowledge sharing. To achieve this, the Global Diagnostics Coalition will:

- Facilitate communication between stakeholders related to diagnostics.
- Strengthening and increasing communication amongst the Global Diagnostics Coalition participants, with other stakeholders.

IV. Core Principles

The Global Diagnostics Coalition is governed by the following principles:

- Inclusive and diverse in membership and structure, ensuring adequate representation from different stakeholder groups, geographical regions and income settings;
- Responsive to the needs of WHO's priorities as approved by Member States, strive to address their requests and focusing efforts where they are most needed;

- Transparent in all processes, including the operational strategy and Global Diagnostics Coalition activities;
- Ensure all activities conducted align with WHO's norms and standards and the mandate set out in World Health Assembly resolution 76.5 on Strengthening Diagnostics Capacity, including both cross-cutting issues and specific diagnostic products not currently coordinated globally through other mechanisms;
- Encourage discussions and exchanges on all types of diagnostics, including in vitro diagnostics, imaging, and any other medical devices used for diagnostic, and cover the entire diagnostic value chain, from research and innovation to deployment and use in different settings;
- Aim to achieve measurable results within one year, demonstrating its effectiveness and the value of its work to Member States and global health efforts.

V. Governance and structure

The Global Diagnostics Coalition comprises of a Steering Committee, and Global Diagnostics Coalition participants, supported by a Secretariat. The governance and structure of the Global Diagnostics Coalition is designed to facilitate coordination of activities, to ensure activities align with the Global Diagnostics Coalition overall mission and objectives, and to preclude influences of individual or organization-specific agendas. The Global Diagnostics Coalition is not a decision-making body, nor does it have any bearing over the work and activities of its participants that occur outside the Global Diagnostics Coalition.

5.1 The Secretariat

WHO serves as the Secretariat of the Global Diagnostics Coalition. The role of the Secretariat is to oversee the day-to-day management of the Global Diagnostics Coalition's work, including technical leadership and coordination, coordination of meetings and discussions across stakeholders on priorities and gaps, preparation of draft work plans including annual focus areas, for consideration by the Steering Committee and/or the Working Groups along with administration and budget management.

More specifically, key responsibilities of the Secretariat are as follows:

- Serve as the interface between the Global Diagnostics Coalition and its participants;
- Select and manages the Global Diagnostics Coalition's membership in line with WHO rules and policies;
- Coordinate the development, implementation and maintenance of the Global Diagnostics Coalition work plans in consultation with the Steering Committee;
- Oversee implementation of the Global Diagnostics Coalition workplans, in collaboration with the Steering Committee;
- Chair the Steering Committee meetings;

- Monitor and evaluate activities and processes of the Global Diagnostics Coalition, making amendments as necessary, in consultation with the Steering Committee, to optimize overall Global Diagnostics Coalition functioning and impact;
- Coordinate correspondence with Global Diagnostics Coalition participants, as required, to facilitate participation and collaboration of all participants;
- Coordinate the annual or biennial participants meeting of the Global Diagnostics Coalition in collaboration with the Steering Committee, including development of relevant documentation (e.g., agenda) and logistical support;
- Develop a central repository for the Global Diagnostics Coalition, to house all relevant documents and resources;
- Develop and regularly update the Global Diagnostics Coalition website (hosted by WHO);
- Draft and submit annual progress reports of the Global Diagnostics Coalition to WHO.

Subject to the availability of sufficient human and financial resources for this purpose, Secretariat support and coordination for the Global Diagnostics Coalition will be provided by WHO in accordance with WHO's rules, regulations, policies and procedures.

The Secretariat reserves the right not to implement any Global Diagnostics Coalition recommendation or activity which it determines gives rise to undue financial, legal or reputational liability or is contrary to WHO policies, regulations and procedures.

5.2 Steering Committee

The Steering Committee comprises maximum 20 participants, who are appointed by WHO. The selection process will strive for balanced representation of the Global Diagnostics Coalition participants, with respect to gender, age, geographical area and organization type. Steering Committee decisions will be made through consensus of Committee participants. With the exception of the Secretariat, the duration of the term of appointment of the Steering Committee participants shall be for an initial term of two (2) years, with the possibility of renewal once.

The Steering Committee will meet bi-annually to confirm the long-term strategy and focus areas for the Coalition.

The Steering Committee is chaired by the Secretariat, who may appoint one participant of the Steering Committee as the Vice-Chair for a two-year term.

Key responsibilities of the Steering Committee are as follows:

- Provide overall strategic direction, for the operative work of the Global Diagnostics Coalition. This includes supporting development of the overall Global Diagnostics Coalition workplans and strategies;
- Jointly coordinate with the Secretariat the annual or biennial participants meeting of the Global Diagnostics Coalition, including development of relevant documentation and logistical support;

- Advise WHO on membership applications;
- Coordinate the establishment of working groups, approve their workplans, and oversee all working group activities;
- Monitor and evaluate activities and processes of the Global Diagnostics Coalition, proposing amendments as necessary to WHO, to optimize Global Diagnostics Coalition functioning and impact.

5.3 Working Groups

Thematic working groups may be established for a defined term subject to Secretariat and Steering Committee approval. The area of focus of the working groups will be decided jointly by the Secretariat and Steering Committee. The terms of reference for each working group are approved by the Secretariat in consultation with the Steering Committee.

The Working Groups are responsible for delivering outputs that align with the Coalition's workplan and focus areas, and report back to the Steering Committee every six months.

All participants of the Global Diagnostics Coalition may participate in working groups. The purpose of the working groups is to bring together participants with similar interests, share information and collectively work on specific activities that align with the Global Diagnostics Coalition's overall mission and objectives.

The Secretariat will appoint a Chair and a co-Chair for each Working Group, responsible for:

- Coordinating working group meetings and activities;
- Facilitating communication within the group, ensuring balanced participation of its group participants;
- Providing verbal and written reports of working group progress to the Steering Committee.

The Chair and co-Chair of each working group are part of the Global Diagnostics Coalition Steering Committee and will therefore report on their progress at the annual or biennial participants meeting, and through an annual report to the Steering Committee.

VI. Meetings

As the Secretariat of the Global Diagnostics Coalition, WHO convenes an annual participants meeting, however additional meetings may be scheduled as necessary. The annual participants meeting is open to all Global Diagnostics Coalition participants. Each participant will be able to nominate a maximum of 2 delegates to attend.

The aim of the annual Global Diagnostic Coalition meeting will be to:

- Review the Global Diagnostics Coalition work plan;
- Serve as a platform for knowledge sharing amongst participants;
- Discuss issues put forward by the Steering Committee

The Steering Committee will meet every 6 months, to report on progress of the working groups, discuss issues and revise the Global Diagnostics Coalition workplan.

The Steering Committee makes recommendations to the Secretariat. In the event that a consensus is not reached, the Secretariat takes a decision in consultation with the Vice-Chair.

Steering Committee participants are accountable for informing their respective organizations on decisions, commitments and plans of the Global Diagnostics Coalition.

Each working group will have meetings, attended by working group participants. The frequency of working group meetings will be determined by the Chair and co-Chair of the respective working group.

VII. Membership

The Global Diagnostics Coalition membership² consist of representatives, not individuals acting in a personal capacity, from:

- Government technical agencies
- UN agencies and intergovernmental organizations;
- Nongovernmental organizations (including civil society groups);
- Academic institutions;
- Private sector including international business associations*;
- Philanthropic foundations.

* The private sector including international associations will be represented by constituencies, such that there will be 2 representatives per diagnostic technologies sector (i.e. 2 for medical imaging diagnostics and 2 for clinical laboratory diagnostics).

All entities seeking to apply for the Global Diagnostics Coalition membership must meet the following criteria:

- The aims and purposes of the entity should be consistent with the WHO Constitution and conform with WHO's policies;
- The entity should contribute significantly to the advancement of public health and to the objectives, vision and goal of the Global Diagnostics Coalition and demonstrate documented support for the

² Individuals are not eligible for the Global Diagnostics Coalition membership.

WHO in the area of diagnostics medical devices and diagnostic services;

- The entity should respect the intergovernmental nature of WHO and the decision-making authority of Member States as set out in the WHO Constitution;
- The entity should be actively and internationally working in the field of diagnostics with proven experience and expertise in the subject matter;
- The entity should have an established structure, constitutive act, and accountability mechanism;
- The entity, if a membership organization, should have the authority to speak for its participants and have a representative structure.

Each participant of the Global Diagnostics Coalition must:

- Adhere to the Terms of Reference of the Global Diagnostics Coalition;
- Actively participate in and support the Global Diagnostics Coalition, its purpose, goals, objectives, guiding principles, work and activities;
- Attend and actively participate at the Global Diagnostics Coalition's various annual and ad hoc meetings;
- Share knowledge and information with other participants (such as resources, data, case studies, experience etc.);
- Act in the best interest of public health in alignment with WHO policies; and
- Keep the Secretariat and the Steering Committee informed of activities relevant to the Global Diagnostics Coalition's mission and vision.

Participants shall not make public statements about the Global Diagnostics Coalition on behalf of the Secretariat without the prior written consent of the Secretariat acting in consultation with Steering Committee.

7.1 Membership applications

A standardized form and online application process will be developed by the Secretariat. Membership approval will be based on an assessment, due diligence process, and review of submitted documents, in accordance with the eligibility criteria and WHO's rules and policies. All membership applications will be reviewed by the Secretariat and eligible participants will be approved by the Secretariat. Following this, eligible participants will be notified of their membership approval (or otherwise) by the Secretariat.

If a non-State actor is applying to participate, the entity is required to provide the following information and documents: name, objectives and mission of the entity, copy of the legal status (such as bylaws, constitution), governance structure, names and affiliations of the participants of main decision-making bodies (such as Board, Executive Board), assets, annual income and funding sources (list of donors and sponsors), main relevant affiliations and website address.

The entity will also sign the letter of participation and the tobacco-arms disclosure statement without alteration.

7.2 Membership Termination and Withdrawal

Each participant has the right to withdraw from participation in the Global Diagnostics Coalition, at any time, subject to providing one month written notice to the Secretariat and to the orderly conclusion of any ongoing activities.

If a participant does not attend two successive biennial participants meetings, without appropriate written explanation to the Steering Committee, or does not attend at least 60% of the Global Diagnostics Coalition working group meetings, the participant will be deemed to have withdrawn from the Global Diagnostics Coalition.

The Secretariat also has the right to terminate the membership of any participant at any time, upon providing written notice thereof to such participant. Without limiting the foregoing, the participation of any entity in the Global Diagnostics Coalition shall terminate if and when such participant: (a) no longer subscribes or adheres to the goals, objectives and/or guiding principles of the Global Diagnostics Coalition, as described in these Terms of Reference; (b) engages in activities that are not compatible with WHO Policies, and/or (c) ceases to meet the membership criteria for the Global Diagnostics Coalition, as set forth in these Terms of Reference. In such instances, the decision to terminate involvement of a participant will be made by the Secretariat, in consultation with the Steering Committee.

WHO reserves the right to withdraw from administration of the Global Diagnostics Coalition at any time, subject to providing the Global Diagnostics Coalition participants with at least six (6) months' prior written notice and to the orderly conclusion of any ongoing activities. WHO also has the right, exercisable in its sole discretion, to close the Global Diagnostics Coalition, to terminate any membership, its Steering Committee and/or to terminate any Vice-Chairmanship, in each case, at any time upon providing written notice thereof to the participant(s) concerned.

VIII. Communications

8.1 Visual Identity

To ensure that the Global Diagnostics Coalition is deliberately communicating with one voice to external parties on topics of substance (principles, priorities, target product profiles, standards, plans and actions, funding, and all confidential information, etc.) any communication in the name of the Global Diagnostics Coalition will take place through the Secretariat.

The Global Diagnostics Coalition is eligible to develop a visual identifier such as a logo which will help identify the network to its audience. The visual identifier must be approved and registered by relevant departments before it is used. The visual identifier will be accompanied by the statement "WHO Managed Network" as an integral part. The right to use the visual identifier including on publications, may be granted to participants on a case-by-case basis with prior written approval of the Secretariat. Participants shall not use WHO's name, acronym and emblem. This includes, inter alia, the display of

the WHO logo and name on any premises, equipment, as well as on any communication and/or training materials, training certificates, social media tools or publications.

8.2 Publications

The Global Diagnostics Coalition shall not produce publications, unless exceptional approval is given by the Secretariat. Any publication by a participant, other than WHO, referring to Global Diagnostics Coalition activities shall contain appropriate disclaimers as decided by WHO, including that the content does not reflect the views or stated policy of the participants.

The participants must ensure that the work of the Global Diagnostics Coalition is not misrepresented, and appropriate disclaimers are included where necessary. The Global Diagnostics Coalition activities shall not include the development of technical materials, normative documents or policy papers.

8.3 The Global Diagnostics Coalition website

The Global Diagnostics Coalition will have a webpage that is housed within WHO's domain. The webpage may include a list of participants entities, subject to their consent.

8.4 Intellectual property and Confidentiality

All Intellectual Property that is generated by the network shall vest in WHO. Depending on the agenda item being discussed, each participant in the Global Diagnostics Coalition may be required to abide by confidentiality obligation and sign a standard confidentiality undertaking using the form provided by WHO for this purpose.

IX. Finance

Participants will be responsible for their own expenses in relation to all Global Diagnostics Coalition activities (including participation at meetings), unless agreed otherwise by the Secretariat. If members receive third party funding to support participation in Global Diagnostics Coalition meetings and activities, this must be disclosed to the Secretariat.

The Secretariat support and related day-to-day operations of the Global Diagnostics Coalition will be financed by voluntary contributions from the members. The Secretariat may also raise funds from other sources to support the work of the Global Diagnostics Coalition, in accordance WHO rules and procedures, as appropriate. All Secretariat funds shall be received, administered and acknowledged in accordance with WHO's policies including its financial regulations, rules, and practices. The Secretariat reserves the right to require that the Global Diagnostics Coalition name not be used in such grant

applications. Contributions by participants including donations (in cash or in kind), will be acknowledged by the Secretariat in accordance with WHO's applicable rules, policies and practices.

X. Monitoring, Evaluation and Reporting

The Secretariat, in consultation with the Steering Committee, will evaluate the overall processes and outcomes of the Global Diagnostics Coalition on an annual basis, with the aim of assessing whether WHO should continue to manage the Global Diagnostics Coalition. The annual progress report should be submitted to WHO for tracking and information sharing.

XI. Zero tolerance for all forms of sexual misconduct and other types of abusive conduct, fraud or corruption

All Global Diagnostics Coalition members are expected to ensure that the conduct of their employees and any other persons engaged by them is consistent with the WHO standards of conduct. In particular, WHO has zero tolerance towards any form of sexual misconduct (an all-inclusive term encompassing all forms of sexual exploitation, sexual abuse, sexual harassment and sexual violence), other types of abusive conduct, fraud or corruption.

In this regard, and without limiting any other provisions contained herein, each Global Diagnostics Coalition member warrants that it shall

(i) take all reasonable and appropriate measures to prevent any form of prohibited behavior by any of its employees and by any other persons engaged by it to perform any activities or to provide any services for WHO on the entity's behalf. This refers, in particular, to:

- a. sexual misconduct, as defined and addressed in the WHO Policy on Preventing and Addressing Sexual Misconduct;
- b. other types of abusive conduct, as defined and addressed in the WHO Policy on Preventing and Addressing Abusive Conduct; and,
- c. all forms of fraud or corruption, as defined and addressed in the WHO Policy on Prevention, Detection and Response to Fraud and Corruption.

(ii) promptly report any actual or suspected violations of these WHO policies of which the entity becomes aware to the WHO Office of Internal Oversight Services ("IOS") at investigation@who.int;

(iii) promptly communicate to IOS any measures that may be necessary or appropriate to protect the confidentiality and wellbeing of the survivor or victim; and,

(iv) promptly respond to any actual or suspected violations of the above referenced WHO policies of which the entity becomes aware, and to cooperate with and to keep IOS informed of the status and outcome of any measures of protection, corrections to operations, investigation, and disciplinary action taken against any perpetrator by the entity.

XII. Duration

The Global Diagnostics Coalition will be launched upon WHO's final approval of these Terms of Reference. The initial duration of the Global Diagnostics Coalition is 5 years, which may be extended following a review by WHO and subject to the availability of sufficient human and financial resources.

XIII. Amendments

These Terms of Reference may be amended from time to time by WHO in consultation with the Steering Committee.