GLOBAL COALITION
FOR LOCAL AND REGIONAL PRODUCTION, INNOVATION AND EQUITABLE ACCESS

TERMS OF REFERENCE

Global Coalition for Local and Regional Production, Innovation and Equitable Access

1. NAME

1.1. The name of the non-profit international coalition will be Global Coalition for Local and Regional Production, Innovation and Equitable Access (hereinafter referred to as “The Coalition").

1.2. Definitions

For the purposes of these Terms of Reference:

“Advisory Committee” means the consultative body of the Coalition established pursuant to Section 4.2.

“Chair” means the chairperson of the Advisory Committee.

“The Coalition” means the Global Coalition for Local and Regional Production, Innovation and Equitable Access.

“Coalition Member” means those that have acceded to the Coalition in accordance with Section 3.

“Executive Secretariat” means the operative body of the Coalition established pursuant to Section 4.3.

“Executive Secretary” means the individual to lead the Executive Secretariat established pursuant to Section 4.3.4.

“Founding Members” means those that signed the Geneva Inception Letter on May 20, 2025.

“Materials” means documents, information, reports, guidance, communications and other work products created, developed or shared in connection with Coalition activities or projects.

“Partner” means any non-member entity invited to collaborate with the Coalition on an ad hoc basis pursuant to Section 3.1.3.

“President” means the individual elected to preside over the Steering Committee pursuant to Section 4.1.2.

“Representatives” means the main or alternate individual designated by a Member or partner to act on its behalf established pursuant to Section 3.1.4.

“Steering Committee” means the decision-making body of the Coalition established pursuant to Section 4.1.

2. BACKGROUND AND OBJECTIVE

2.1. The Rio de Janeiro Declaration of the G20 Health Ministers welcomed the establishment of the Coalition on October 31, 2024.

2.2. The Geneva’s Inception Letter formally created the Coalition on May 20, 2025 and serves as the foundation document.

2.3. The Coalition is an international multi-stakeholder initiative conceived by the G20 Health Ministers and supported on a voluntary basis by governments, international organizations, private sector, public and philanthropic organizations, Academia, and the civil society.

2.4. The Coalition's objective is to foster voluntary cooperation to promote local and regional production, access to and innovation on vaccines, therapeutics and diagnostics, and other health technologies, with focus on neglected diseases and persons in vulnerable situations, and other diseases and health emergencies if necessary.

2.5. The purpose of The Coalition is to:

2.5.1. Strengthen manufacturing capacities and regulatory systems for local and regional production of relevant health products, promoting sustainable global networks for production and innovation, especially in low- and middle – income countries (LMICs) and other developing countries.

2.5.2. Improve, through local production and innovation, equitable access to vaccines, therapeutics, diagnostics, and other relevant health technologies, with a focus on neglected diseases and other health emergencies if necessary.

2.5.3. Promote public-private partnerships, knowledge-sharing, and voluntary technology transfer on mutually agreed terms related to The Coalition's projects, to foster timely, equitable access to safe, affordable, quality and effective health products and technologies.

2.5.4. Promote synergies with existing and potential future initiatives, philanthropic organizations and funding channels, without preempting the ongoing negotiations and processes at global, regional and national levels and foster coordination and complementarity with related multilateral, regional, and national efforts to enhance coherence and collective impact.

2.5.5. Raise awareness of the importance of local research, development, innovation, and production in improving access to relevant health products.

2.5.6. Call for and select viable projects for local and regional production, innovation, and equitable access.

2.6 The Coalition's activities can include technical cooperation, advanced market commitment, voluntary technology transfer on mutually agreed terms, boosting existing funding sources and regulatory cooperation and strengthening, and developing regional environments that stimulate investments, in collaboration with scientific and technical institutions capable of contributing to regulatory science, clinical trials, and innovation.

2.7 The Coalition's projects will be based on voluntary cooperation, and operate in accordance with international and domestic law, including on intellectual property.

2.8 Participation in the Coalition and its projects shall not, in itself, create financial, contractual, regulatory, fiduciary, and other legal obligations for the Coalition, its Members, Partners, or other participants. Any such obligations shall arise only where expressly agreed by the relevant parties through a separate instrument and in accordance with applicable legal frameworks.

2.9 The Coalition can also be repurposed for other diseases and health emergencies, if necessary, whilst fostering collaboration and avoiding duplication with multilateral initiatives and other relevant actions.

3. MEMBERS

The Coalition is composed, on a voluntary basis, of G20 Members, as well as non-G20 countries, relevant international organizations and key partners that contribute to its objectives.

3.1. Membership

3.1.1. G20 Members, and other countries of the Coalition, are eligible for a seat on the Steering Committee, in accordance with Section 4.1.1.

3.1.2. International organizations and other key stakeholders members of the Coalition are eligible for a seat on the Advisory Committee, in accordance with Section 3.4.3.

3.1.3. The Coalition may, at any stage of its projects, invite ad-hoc “Partners” to collaborate in design, planning, development, or other phases as deemed appropriate, upon approval by the Steering Committee.

3.1.4. All members will designate a main and alternate representative, depending on their status, to act on their behalf, taking into consideration principles of equity, gender balance, and diversity (“Representatives”).

3.1.5. Representatives in the committees shall not have any conflict of interest that could compromise the Coalition’s decision-making or credibility. As a condition of participation, all Representatives will complete and sign a Declaration of Interests (“DoI Form”).

3.1.6. All Coalition Members and Partners must adhere to these Terms of Reference. If a breach is reported by a Member of the Steering Committee, the Executive Secretariat shall call a special meeting of the Steering Committee to review the case. If the Steering Committee determines by consensus that there is sufficient evidence of the breach, it reserves the right to terminate the Coalition membership of the Member in question.

3.1.7. If a Member wishes to withdraw from the Coalition, it shall do so by means fo a signed letter from its Representative, addressed to the Executive Secretariat, which shall promptly notify the Steering Committee.

3.1.8. Upon cessation of membership a former Member or Partner shall cease use of the Coalition's name and materials. Any confidentiality commitments undertaken in connection with the Coalition shall continue after withdrawal. Participation in ongoing projects may continue where agreed by the relevant parties and in accordance with any applicable project-specific arrangements.

3.1.9. Decisions requiring the approval of the Steering Committee shall be made per term 4.1.4.4 and 4.1.4.5.

3.2. G20 Country Members

3.2.1. The accession of G20 members may take place at any time through the presentation of a Letter of Intent to the Executive Secretariat, confirming their interest to join the Coalition. Upon receipt of such letter, the Executive Secretariat will duly notify, as soon as possible, all members of the new accession.

3.3. Non-G20 Countries

3.3.1. The accession of non-G20 Members may be considered at any time, through the submission of a Letter of Intent addressed to the Executive Secretariat or direct invitation by the Steering Committee. Endorsements by current Members are welcome to demonstrate support for the application.

3.3.2. Such requests will be subject to consideration and approval by the Steering Committee approval must be made per term 4.1.4.4 and 4.1.4.5. Evaluation processes will involve technical review by the Executive Secretariat, evaluating the applicant's eligibility based on predefined criteria, and then be decided by the Steering Committee.

3.3.3. The Steering Committee will set the admission criteria for new Members, taking into consideration:

a) The objectives of The Coalition;
b) Geopolitical representation;
c) Demonstrated commitment to global health priorities;
d) Ability to contribute to The Coalition;
e) Compliance with the International Health Regulations (2005); and
f) Consideration of equity.

3.4. International Organizations and Key Relevant Partners

3.4.1. The World Health Organization ("WHO"), including its Regional Offices, is invited to contribute to The Coalition by providing scientific and technical support, within available resources.

3.4.2. International organizations, international financing institutions, including multilateral development banks and funds, institutions of science, technology, and innovation, as well as the private and productive sector and industry associations, may join on a voluntary basis as members of the Advisory Committee or ad-hoc Partners for specifics projects, in order to provide technical assistance.

3.4.3. For members of the Coalition, accession to the Advisory Committee will occur through the submission of a formal letter expressing their intention and specifying their qualifications and potential contributions to the Coalition or by invitation of the Steering Committee.

3.5. **Responsibilities.**

3.5.1. Members are invited to participate with different kinds of inputs, on a voluntary basis, according to their national capacities, policies and laws, which may include:

a) Financial: (i) funding for The Coalition activities such as innovation for vaccine development and other relevant health products, capacity-building programs, and emergency response efforts; (ii) in-kind support such as medical supplies, equipment, or personnel for specific initiatives.

b) Technical: (i) sharing of health policies best practices, such as disease prevention strategies, healthcare delivery models, or digital health innovations; (ii) facilitating innovation efforts, such as developing new treatments, vaccines, or diagnostic tools; (iii) Data sharing on health (e.g., disease outbreaks, vaccination rates, or health system performance) to support evidence-based decision-making and global health monitoring, in accordance with national law; (iv) Capacity Building, with members providing training, technical and knowledge transfer; (v) Recognition and support of social and community innovation as technical inputs alongside biomedical innovation; (vi) sharing research infrastructure on a voluntary basis considering participation in and funding of R&D and clinical trials.

c) Local and Regional Production and Innovation: (i) leverage partnerships with science and technology institutions, civil society and the private sector to drive innovation and scale up health interventions; (ii) for members with advanced technological capabilities, support the voluntary transfer of health technologies on mutually agreed terms.

d) Political and diplomatic support: (i) advocacy for global health priorities in international forums, such as the United Nations, World Health Organization (WHO), or G20/G7 summits; (ii) discussion of national health policies and ongoing global governance processes with relevance to the Coalition's goals, such as universal health coverage (UHC), pandemic preparedness etc.; (iii) diplomatic engagement, using networks to mobilize support for Coalition's initiatives, engaging non-member countries, private sector partners, and civil society organizations.

e) Operation and logistics: (i) hosting and organizing meetings and events; (ii) contributing to emergency response to global health crisis.

4. GOVERNANCE

The Coalition's governance will consist of three bodies: (i) Steering Committee, (ii) Advisory Committee, and (iii) Executive Secretariat.

4.1. STEERING COMMITTEE

The Steering Committee will be the decision-making body, responsible for providing strategic guidance and oversight to the Advisory Committee and the Executive Secretariat. Its decisions will be expressed by declarations.

4.1.1. Composition

The Steering Committee will be composed of: ("Steering Committee's Members")

a) Representatives of G20 Members of the Coalition.
b) Representatives of other countries Members of the Coalition.
c) The Chair of the Advisory Committee, as a non-voting member with the right to express their views.

4.1.1.1. Each Steering Committee Member shall designate one main and one alternative representative to act on its behalf ("Steering Committee's Representatives").

4.1.1.2. The alternate Steering Committee Representative shall automatically exercise the rights and responsibilities on the main Representative whenever the latter is unable to participate in a meeting or otherwise perform their functions.

4.1.1.3. All members will designate their Representatives, taking into consideration principles of equity, gender balance, and diversity, pursuant to Section 3.1.4.

4.1.1.4. Other members and non-members of the Coalition may attend meetings of the Steering Committee as observers and/or to deliver their views on the specific subject under consideration at the agenda, when invited.

4.1.1.5. The above composition of the Steering Committee may be reviewed as necessary as its regular meetings, with due consideration to the nature of the Coalition as an international multi-stakeholder initiative.

4.1.1.6. Steering Committee Members shall be appointed for a term of three (3) years and may be renewed indefinitely for successive additional terms of three (3) years each.

4.1.1.7. Members of the Steering Committee shall be elected by all Members eligible for representation on the Steering Committee of the Coalition, in accordance with Section 3.1.1, every three (3) years through a voting process and shall serve a fixed term of three (3) years.

4.1.1.8. The first term of office of the Steering Committee commenced on May 20, 2025, and shall expire on May 20, 2028. Any members appointed during the course of such term shall serve only for the remainder thereof and shall be subject to the same expiration date.

4.1.1.9. Notwithstanding Section 4.1.1.8 above, new Members may be exceptionally invited to join the Steering Committee during an ongoing term of office.

4.1.2. Presidency

4.1.2.1. The Steering Committee will select a member as President for a two-year term, renewable once. The first term started upon signing of the Geneva Inception Letter, on May 20, 2025

4.1.2.2. The President will serve as the representative of The Coalition, advocating for its mission and visibility at high-level political and diplomatic forums.

4.1.2.3. Working on a rotational basis, the selection mechanism will be guided by regional representation, alternating between regions. Members interested in the Presidency should present their candidacies 6 months before the end of the current term. The Steering Committee should proceed to the election of the new Presidency at the last meeting of the current term.

4.1.2.4. The new Presidency will be elected by the Steering Committee as per term 4.1.4.4 and 4.1.4.5.

4.1.2.5. A transition period of 3 (three) months shall be established between presidencies to allow the exchange of information and strategic planning.

4.1.2.6. The immediately preceding Presidency shall preferably serve on the Steering Committee.

4.1.3. Functions

The Steering Committee will have the following functions:

a) Ensure that the objectives of The Coalition are observed and its decision are properly executed;
b) Monitor The Coalition's progress and approve its annual report;
c) Set policies and priorities for projects and determine The Coalition's workplan;
d) Provide strategic guidance on crisis response and contingency planning, including activation of emergency mechanisms when required;
e) Elect its president;
f) Establish criteria for participation and rules of procedure for the Advisory Committee;
g) Establish other permanent or ad-hoc subcommittees with specific scope and subject as necessary;
h) Consider, approve, and monitor partnership arrangements with other organizations and institutions;
i) Nominate and participate in the performance review of the Executive Secretariat;
j) Work to facilitate necessary funding and financial sustainability for The Coalition and its projects;
k) Safeguard equity, inclusivity, and representation across all coalition activities;
l) Periodically review and update governance arrangements to ensure The Coalition's adaptability and effectiveness;
m) Periodically review and update the Terms of Reference document to maintain the Coalition's adaptability.
n) Ensure that the Executive Secretariat is efficiently executing the objective of the Coalition and the Instructions and decisions of the Steering Committee;
o) Serve as a strategic liaison between the Coalition and members, strengthening political engagement and facilitating the provision of timely, accurate, and relevant information to support decision-making;
p) Consider other matters related to the Coalition as may be referred to by the Executive Secretary.

4.1.4. Meetings

4.1.4.1. The Steering Committee will meet as often as necessary, being at least one meeting in person and one on-line meeting per year.

4.1.4.2. Meetings in person may take place preferably on the sidelines of the World Health Assembly (WHA), on the sidelines of the G20 Health Ministerial Meeting or another suitable forum.

4.1.4.3. The Steering Committee may conduct business only when a two-thirds majority of the Members are present (virtual or in person).

4.1.4.4. The Steering Committee will use its best efforts to make all decisions by consensus.

4.1.4.5. Any Member can call for a vote, if consensus cannot be achieved. In this case, the decision will be approved under a two-thirds majority of Members present at the meeting, unless consensus is explicitly required for this decision by the Terms of Reference.

4.1.4.6. All decisions of the Steering Committee will be recorded in the minutes of the meetings, and retained in the records of the Executive Secretariat.

4.1.4.7. Committee decisions and related documentation, save for any confidential documents, will be made public on The Coalition website typically within 10 business days from the date of the meeting.

4.2. ADVISORY COMMITTEE

The Advisory Committee will serve as a consultative body, adopting a systematic approach and providing institutional support. It will support the selection, monitoring and evaluation of initiatives, provide technical contributions to projects and projects analyses, and present recommendations to the Steering Committee

4.2.1. Composition

4.2.1.1. The Members of the Advisory Committee shall be the organizations listed in the Section 4.2.1.4 ("Advisory Committee's Members"). Each Member Organization shall appoint one or more individuals to act as its representatives ("Advisory Committee's Representatives") in the Advisory Committee.

4.2.1.2. The Advisory Committee shall comprise representatives of key international and regional organizations, the private sector, research institutions, regulatory agencies, and civil society, invited by the Steering Committee to provide technical inputs and recommendations on projects.

4.2.1.3. The experts will be representatives of core areas of scientific expertise that play key roles across the end-to-end vaccines, therapeutics and diagnostics lifecycle, including but not limited to public health, product development, regulatory affairs, Chemistry Manufacturing Control ("CMC"), and manufacturing.

4.2.1.4. Eligible Organizations may include, but will not be limited to:

a) UN Agencies, Funds and Programs and other Multilateral Organizations;
b) Private Sector Organizations/ Industry Associations;
c) Humanitarian and Advocacy Organizations;
d) Philanthropic Organizations and Private Foundations;
e) Multilateral Development Banks and Financial Institutions; and
f) Research and Development Institutions

4.2.1.5. Advisory Committee's Members shall serve for a term of three (3) years and may be renewed indefinitely for successive terms of equal duration.

4.2.1.6. The first term of office of the Advisory Committee's Members commenced on February 20, 2026, and shall expire on February 20, 2029. Any members appointed

during the course of such term shall serve only for the remainder thereof and shall be subject to the same expiration date.

4.2.1.7. The Chair of the Advisory Committee will be selected from among its members for a renewable two-year term and approved by the Steering Committee as per term 4.1.4.4.

4.2.2. Functions

Upon Request of the Steering Committee, the Advisory Committee shall, inter alia:

a) Recommend public health strategies in line with The Coalition's objective;
b) Provide evidence-based advice to ensure that The Coalition's activities are scientifically relevant and innovative;
c) Advise on strategies to promote equitable access to innovation, ensuring that equity considerations are integrated into all Coalition projects;
d) Advise on changes in priorities in the event of public health emergencies or significant events caused by emerging pathogens;
e) Update the Steering Committee and the Executive Secretariat on important developments in science and technology relevant to The Coalition's mission;
f) Support The Coalition in horizon-scanning to anticipate future public health threats and opportunities for innovation;
g) Advise on the scope, objectives, and approach of Calls for Proposals (CFPs) and the process for selecting fundable proposals;
h) Contribute to the review of proposals submitted in response to Coalition CFPs.
i) Provide recommendations on metrics and indicators to monitoring scientific and development progress of The Coalition's projects; and
j) Facilitate dialogue with broader stakeholder communities to strengthen legitimacy, inclusivity, and accountability.

4.2.3. Meetings

4.2.3.1. The Advisory Committee will meet regularly, at least four times per year, being at least one meeting held in person. Additional ad hoc meeting may be convened as required.

4.2.3.2. The Advisory Committee may decide to invite additional attendees to any meeting or to participate in discussion of specific agenda items.

4.2.3.3. The Advisory Committee will use its best efforts to male all decisions by consensus

4.2.3.4. Any Member can call for a vote, if consensus cannot be achieved. In this case, the decision will be approved under a two-thirds majority of Members present at the meeting.

4.3. EXECUTIVE SECRETARIAT

4.3.1. The Executive Secretariat will be the operative body responsible for coordinating and communicating among Members, Partners and other relevant stakeholders, managing The Coalition's activities, and providing support to the Steering Committee and Advisory Committee.

4.3.2. Brazil will host the Executive Secretariat and be responsible for its basic maintenance and budget in accordance with the terms agreed between the Brazilian Ministry of Health and the Coalition Secretariat exercised by Fiocruz, without prejudice to the possibility of securing other sources of voluntary funding.

4.3.3. The Executive Secretariat will be carried out by the Oswaldo Cruz Foundation (Fiocruz).

4.3.4. Brazil will designate an Executive Secretary, subject to confirmation by the Steering Committee.

4.3.5. The Executive Secretariat will act according to the direction of the Steering Committee.

4.3.6. The Executive Secretary will report to the Presidency of the Steering Committee.

4.3.7. Functions

The Executive Secretariat will have the following functions:

a) Implement the strategies and work plan approved by the Steering Committee;
b) Provide support to the Steering Committee and the Advisory Committee;
c) Establish and facilitate internal and external communications;
d) Prepare draft work plans and Calls for Proposals according to the decisions of the Steering Committee;
e) Facilitate technical support and advice to the Steering Committee;
f) Prepare, in collaboration with the Presidency, the agenda of the Steering Committee's meetings;
g) Share background documentation for each agenda item to the Steering Committee's Members at least 10 business days in advance of meetings, unless otherwise determined by the Presidency;
h) Prepare, in collaboration with the Advisory Committee, provisional agenda, which will be circulated no later than 14 days before each meeting;
i) Share background documentation and pre-reading materials to the Advisory Committee Partners 7 days before each meeting;
j) Execute all administrative and legal actions within the scope of The Coalition, which are necessary to support its goals and priorities, in accordance with resolutions of the Steering Committee;
k) Receive the Letter of Intent from countries wanting to join The Coalition to be submitted to the Steering Committee and communicate the candidate of the Committee's decision;
l) Coordinate and manage contracts and other commitments submitted by Partners, consultants, suppliers, and others, as approved by the Steering Committee;
m) Prepare and submit to the Steering Committee the draft of the annual report on progress of The Coalition, ensuring transparency and accountability in all activities;
n) Prepare or coordinate technical reports on operations according to the decisions of the Steering Committee;
o) Carry out and manage the day-to-day operations of the Coalition and coordinate implementation of the work plan;
p) Establish and facilitate internal and external communications, including concerning advocacy;
q) Organize and promote seminars, workshops and lectures, as mandated by the Steering Committee; and
r) Perform any administrative functions required for the execution of the above.

4.3.8. In carrying out its activities, the Executive Secretariat may use all appropriate measures, in line with the Steering Committee's guidance, in particular:

a) Build research, development and innovation networks around specific projects, especially with governments, universities, and productive sector;
b) Establish working groups to advance specific projects;
c) Enter into agreements, contracts, cooperation terms, and other forms of collaboration with public or private legal entities, subject to approval by the Steering Committee;
d) Cooperate with other non-profit organizations pursuing the same purposes;

e) Lead public relations and advocacy efforts, communicating the Coalition's mission, priorities and achievements to members, partners, and external stakeholders;
f) Represent the Coalition in relevant international forums, partnerships, and negotiations, in line with the Steering Committee's mandate;
g) Represent the Coalition in and/or promote seminars, meetings, and lectures.