



Terms of Reference for CEPI Scientific Advisory Committee

I Establishment and function

I.1 Aim of the SAC

The Scientific Advisory Committee (SAC) is an independent body within the CEPI governing structure that provides scientific support, advice, and challenge to the CEPI Leadership.

I.2 Relation of the SAC to the CEPI governance bodies

The SAC reports to the CEPI Leadership and is the principal scientific advisory group to the CEPI Board (“the Board”) and the CEPI Leadership on scientific matters critical for the strategy and operations of CEPI. This document describes the Terms of Reference for the SAC, and provides guidance on the establishment, management and conduct of the SAC.

I.3 Objectives of the SAC

The activities of the SAC will include, but are not limited to:

Recommending pathogens against which CEPI will focus vaccine development efforts.

Advising on change of priorities in the event of public health emergencies or significant events caused by emerging pathogens with epidemic potential.

Advising on the scope, objectives, and approach of Calls for Proposals and the process for selection of fundable proposals.

Reviewing proposals submitted in response to CEPI’s Calls for Proposals and, in conjunction with independent subject matter experts, making recommendations on which to advance to negotiations.

Monitoring scientific and development progress of CEPI’s vaccine portfolio and reviewing the overall quality of progress of CEPI’s scientific operations.

Updating the CEPI Board on important developments in science and technology relevant to CEPI’s mission.

Providing scientific input, as requested by the CEPI Leadership, to inform CEPI’s efforts to promote end-to-end development and delivery efforts for vaccines supported by CEPI.

Act as independent expert reviewers in the stage-gate review process for CEPI funded projects.

Serve on SWAT teams as requested to provide expertise to the SWAT and alignment of SWAT activities with the activities of the SAC.

The CEPI Leadership may seek advice from the SAC, subcommittees of the SAC or from individual SAC members for other scientific matters relevant to the operations of CEPI. Final decision-making about the issues addressed by the advice and recommendations from the SAC rests with the Board or the Leadership, as appropriate.

The SAC has no executive function in the operations of CEPI. The CEPI Leadership will facilitate the work of the advisory committee. The SAC as a body will act independently of all the governing structures of CEPI, including the CEPI Board, the CEPI Leadership, and the CEPI Joint Coordinating Group.

I.4 Areas of expertise and composition of the SAC

CEPI requires relevant expertise to support the implementation of its strategic objectives. The SAC will be composed of a group of qualified individuals, representing core areas of scientific expertise needed to advise the Leadership on a diversity of issues related to vaccine research and development. The combined expertise of the advisory committee should reflect the spectrum of vaccine research and development, addressing but not limited to the areas of core scientific expertise described in Table 1.

The size of the SAC should not exceed 36 members, and be of sufficient size to:

Cover the desired member competencies

Assure a critical mass of expertise should some members need to be excluded from decision processes due to conflicts of interest

Have representation from LMIC countries where epidemics may occur, and have gender diversity aiming towards equal male and female representation

Composition of the SAC:

One (1) SAC Chair

One (1) SAC Vice Chair

Up to thirty-three (33) SAC Ordinary Members

One (1) WHO representative

CEPI CEO and members of CEPI Leadership will host and attend all meetings

Table 1. Key SAC expertise domains and geographic representation requirements

Pathogens	Biological sciences and public health	Product and pre-clinical development	Clinical and late-stage development	Chemistry, manufacturing, and control	Regulatory and intellectual property	Life cycle management	Geographic expertise
COVID-19 / SARS-CoV-2	Veterinary diseases / One Health	Diagnostics development	Clinical trial expertise and review capability	Large scale manufacturing	Regulatory affairs: strategy and operations	Biobanking and sample sharing	South and Central America
Rift Valley Fever	Infectious disease epidemiology	Immunology and/or product design for vaccines and/or therapeutics	Clinical operations (end-to-end)	DCVMN manufacturer affiliation	Vaccine / therapeutics risk/benefit assessment	Bioethics	Africa
Chikungunya	Infectious disease modelling	Genetic engineering for therapeutics design	Approaches to efficacy testing	Vaccine / therapeutics product formulation and delivery devices	Intellectual property management	Vaccine/therapeutics procurement	East Asia
Ebola virus disease	Biostatistics	Vaccine adjuvants and delivery systems	Study design and statistical analysis	GMP process development and scale-up		Stockpiling	Europe
Lassa fever	Public health emergency preparedness and response	Animal models and biological assays	Pharmaco-vigilance	Manufacturing innovations and/or sustainable manufacturing practices		Vaccine / therapeutics deployment during epidemic outbreaks	Middle East
MERS	Structural biology	Non-clinical toxicology		Quality control and quality assurance			North America
Nipah virus		Containment laboratory experience		Platform technologies			Oceania (Australia / NZ / Pacific Islands)
							South Asia
							Southeast Asia

2 Membership and Responsibilities

2.1 Membership

Nomination and appointment of members

CEPI leadership will assess the areas of expertise required for the SAC and reach out to the scientific community to request applicants. CEPI Leadership will compose a list of eligible candidates with representation from LMIC where epidemics may occur and appropriate gender balance.

The Board will review bi-annually the composition of the advisory committee and may actively seek to attract nominations reflecting other needed areas of expertise.

Where the SAC lacks the relevant expertise for a particular project or task, the SAC can call on appropriate experts or establish sub-groups or task forces to include such people on an *ad hoc*, time-limited basis.

Criteria guiding selection of members and independent experts will include:

- Technical expertise in the desired competency
- Pertinent experience, including in collaborative public health and preparedness/response enterprises relevant to CEPI's mission
- Diversity of stakeholders (academia, governmental agencies, private sector, civil society/NGOs/patient organizations)
- To ensure balanced representation, consultants and temporary advisers assigned to assist an expert committee should be selected, as far as possible, from countries not represented on the committee's membership and with the goal of maintaining gender balance.

SAC appointment will be a three-year term. The first year is probationary with the option to re-evaluate the selection based on ability to participate.

Appointment renewal

To allow for continuity in the operations of the advisory committee, at the end of each term a portion of the members will be allowed to renew their membership for a two-year period.

2.2 Responsibilities of Chairs

The role of the Chair and the Vice-Chair is to achieve committee effectiveness. They will be responsible for:

the operation and output of the committee, including assessing the workload and ensuring that the volume of work does not compromise the rigour of discussion;

reviewing conflicts of interest of all members annually and at each meeting of the SAC;

ensuring that the full range of scientific input is considered;

ensuring that any significant diversity of scientific and vaccine development input among the members of the committee is fully explored and discussed;

ensuring that scientific views that cannot be reconciled are accurately reflected in the minutes and any other relevant report of the discussions;

using, where appropriate, a structured process which ensures that all views are captured and explored;

reporting the committee's advice to the CEPI Leadership, including alerting to new evidence likely to have an impact on current policy;

ensuring that CEPI Leadership accurately documents the proceedings of the committee so that there is a clear audit trail showing how the Committee reached its decisions;
identifying gaps or redundancy in the skills and competency represented on the Scientific Advisory Committee;
ensuring that members have any necessary training to enable them to fulfil their role, and keeping records of members' performance/contributions as necessary;
deciding if any part of SAC meeting should be conducted with the exclusion of any or all the observers, in accordance with CEPI policies.

2.3 Responsibilities of Members

SAC members are expected to provide independent scientific advice on topics where their expertise is relevant and as requested by the CEPI Leadership.

SAC members should stay current with developments in their field which are of relevance to CEPI, including through contact with their professional bodies, academic institutions and research communities.

SAC members are required to comply with all CEPI policies, including [the CEPI Transparency and Confidentiality Policy](#), [Policy for Managing Conflicts of Interest](#), and [Travel Policy](#).

Any potential alternates for members must be pre-approved by CEPI Leadership

SAC members are expected to act in accordance with the following principles:

- **Selflessness:** SAC members should act solely in terms of the public interest.
- **Integrity:** SAC members must avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work. They should not act or take decisions in order to gain financial or other material benefits for themselves, their family, or their friends. On an annual basis and at every meeting, they must declare conflicts of interests and relationships.
- **Objectivity:** SAC members must act and take decisions impartially, fairly and on merit, using the best evidence and without discrimination or bias.
- **Accountability:** SAC members are accountable to CEPI for their decisions and actions and must submit themselves to the scrutiny necessary to ensure this.
- **Openness:** SAC members should act and take decisions in an open and transparent manner.
- **Honesty:** SAC members should be truthful.
- **Leadership:** SAC members should exhibit the above principles in their own behaviour. They should actively promote and robustly support the principles and be willing to challenge poor behaviour wherever it occurs.

3 Independence, objectivity and transparency

- The members of the SAC will serve in their personal capacity as independent experts and should not promote the views and policies of their institutions or others with vested interests.
- Prior to being considered for membership, nominees shall be required to complete a Declaration of Interests form. An updated Declaration of Interests form must be submitted for review to the CEPI Board 14 days prior to each Scientific Advisory Committee meeting. Potential conflicts of interest will be managed in accordance with CEPI's conflict of interest policy.
- Members shall be required to declare conflicts of interest in relation to any item under discussion at a SAC meeting.
- Any member with a conflict of interest related to a specific issue shall be excluded from the discussion or decision on the issue and shall not receive any documents relating to the issue giving rise to the conflict.
- Any member who fails to declare a conflict of interest, which subsequently becomes evident, may be expelled from the SAC on the recommendation of the Board.
- All documents and discussions at SAC meetings are confidential, unless stated otherwise, and must not be disclosed.

- SAC members should neither represent or present their personal views as those of CEPI nor imply that they can represent CEPI's views or policies in any way.
- The SAC should operate from a presumption of openness. The condensed proceedings of the committee will be made public by the CEPI Leadership if it is compatible with the requirements of confidentiality.

4 Working practice

Two experts from the SAC membership will be invited by the Board to be Chair and Vice - Chair of the Scientific Advisory Committee.

The SAC will have meetings four times each year where two of the meetings will be in person (if conditions allow) and two will be held as teleconferences. If the need arises the CEPI Leadership can ask the SAC for additional meetings.

The provisional agenda for each meeting will be prepared by the Director Vaccine Research and Development in consultation with the Chair; except in exceptional circumstances, documents for scientific review will be sent to SAC members at least 14 days in advance of a meeting.

The Chair, in consultation with the SAC, may decide to establish sub-groups to deliberate and produce recommendations on specific topics. External experts may, as appropriate, be invited to participate on these sub-groups. The sub-groups will be commissioned with a specific charge and for a limited time commensurate with the activity for which the sub-group was established.

For specific topics and as appropriate, the Chair, in consultation with the SAC, may invite external experts to address specific issues. These experts may come from academia, civil society, private sector, and governments. The experts will be brought on with a specific charge and for a limited time commensurate with the activity for which the expert was contacted.

As two advisory bodies to CEPI, the Scientific Advisory Committee and the Joint Coordination Group will act independently of each other. The two bodies are represented in individual and institutional capacities respectively. Mechanisms will be put in place for the Scientific Advisory Committee to seek input from the Joint Coordination Group, and vice versa, about the recommendations they are to produce.

The SAC will normally make decision to recommend by consensus. Observers and invited experts will not participate in the decision-making process. Members with potentially conflicting interests will deal with such conflicts in accordance with the Conflict of Interest policy.

The Chair, together with the CEO, will be responsible for forwarding recommendations arising from the advisory committee to the CEPI Board.