Information on the role and expectations of the members of the Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) and how to apply

The following describes the application process, roles and expectations of the members of SAGE IVD. This is a revised version as of December 2020. This version supersedes all past documents.

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Terms of Reference
for Strategic Advisory Group of Experts on In Vitro Diagnostics
(SAGE IVD)

The Strategic Advisory Group of Experts on In Vitro Diagnostics (SAGE IVD) will act as an advisory body to WHO on matters of global policies and strategies related to IVDs.

Functions

The SAGE IVD shall have the following functions:

1. Serve as a principal advisory group to the WHO Director-General on all aspects of IVDs.

2. For priority, essential and neglected IVDs, where no established advisory mechanisms exist the SAGE IVD will:
   a) provide technical advice on global policies and strategies, ranging from development, assessment, use of IVDs and their linkages with other health interventions;
   b) advise on the adequacy of progress towards the achievement of IVDs-related goals set in the World Health Assembly resolutions;
   c) recommend policies for long-term and integrated diagnostic capabilities as indispensable elements for Universal Health Coverage and Global Public Health Security;
   d) suggest guiding principles for how, when and where to use particular IVDs in national, regional and global settings;
   e) review the pipeline of existing and innovative IVDs for non-communicable diseases, rare diseases and infectious diseases, including for emerging pathogens and existing public health conditions of international concern, and identify major gaps;
   f) provide high level advice on development and maintenance of appropriate standards for IVDs, including methodologies for evidence review;
   g) provide advice to WHO EDL Secretariat for the development of the List of Essential Diagnostics (EDL) and in line with the work of the Expert Committee on Selection and Use of Essential Medicines.
   h) provide advice on WHO activities in the area of IVDs, including engagement of WHO in partnerships in the development, access and use of needed IVDs.

1 Except where policy and technical recommendations on IVDs are provided through WHO established advisory mechanisms, such as for HIV, tuberculosis and malaria. For these, SAGE IVD would accept such recommendations without further review and incorporate such advice in its consideration of organization-wide policies.
**Composition**

1. The SAGE IVD shall have up to 15 members, who shall serve in their personal capacities to represent the broad range of disciplines encompassing the many aspects of in vitro diagnostics and other clinical laboratory and pathology related activities. In the selection of the members, consideration will be given to attaining an adequate technical distribution of expertise, geographical representation and gender balance.

2. Members of the SAGE IVD, including the Chair/Co-chairs, shall be selected and appointed by WHO (By the Director General or by the ADG of the Medicines and Health Products Division). The appointed chair/co-chairs’ responsibilities include the following:
   a. to chair the meeting of the SAGE IVD;
   b. to liaise with the WHO EDL Secretariat between meetings

3. Members of the SAGE IVD, including the Chair, shall be appointed to serve for a period of two years. This two-year term may only be renewed once. To allow for continuity and efficiency, the Chairperson of SAGE IVD is expected to act as Chairperson for a minimum of one year. He/she needs however, to be a member of SAGE IVD for a minimum of one year before taking up Chairpersonship. Their appointment and/or designation as Chairperson may be terminated at any time by WHO if WHO's interest so requires or as otherwise specified in these TORs or letters of appointment. SAGE IVD members having previously served under previous TORs for a maximum term of two years may be re-appointed to serve the remainder of their time as per the current TORs.

4. Members must respect the impartiality and independence required of WHO. In performing their work, they may not seek or accept instructions from any Government or from any authority external to the Organization. They must be free of real, potential or apparent conflict of interest. To this end, proposed members/members will be required to complete a declaration of interest form and their appointment, or continuation of their appointment, will be subject to the evaluation of completed forms by the WHO Secretariat, determining that their participation would not give rise to a real, potential or apparent conflict of interest.

5. Following a determination that a proposed member’s participation in the SAGE IVD would not give rise to a real, potential or apparent conflict of interest, the proposed member will be sent a letter inviting them to be a member of the SAGE IVD. Their appointment to the SAGE IVD is subject to WHO receiving the countersigned invitation letter and letter of agreement.

6. As contemplated in paragraph II.5 above, WHO may, from time to time, request members to complete a new declaration of interest form. This may be before a meeting or any other SAGE IVD-related activity or engagement, as decided by WHO. Where WHO has made such a request, the member’s participation in the SAGE IVD activity or engagement is subject to a determination that their participation would not give rise to a real, potential or apparent conflict of interest.

7. Where a SAGE-IVD member is invited by WHO to travel to an in-person meeting, WHO shall, subject to any conflict of interest determination as set out in paragraph II.8 above, issue a letter of appointment as a temporary adviser and accompanying memorandum of agreement (together ‘Temporary Adviser Letter’). WHO shall not authorize travel by a member, until it receives a countersigned Temporary Adviser Letter.

8. Members do not receive any remuneration from the Organization for any work related to the SAGE-IVD. However, when attending in-person meetings at the invitation of WHO, their travel cost and per diem shall be covered by WHO in accordance with the applicable WHO rules and policies.

**Operation**
1. The SAGE IVD shall usually meet at least once each year. However, WHO may convene additional meetings. Meetings may be held in person (at WHO headquarters in Geneva or another location, as determined by WHO) or virtually, via video or teleconference.

Meetings may be held in open and/or closed session, as decided by the Chairperson in consultation with WHO.

Open sessions: Open sessions shall be convened for the sole purpose of the exchange of non-confidential information and views and may be attended by Observers (as defined in paragraph III.3 below).

Closed sessions: The sessions dealing with the formulation of recommendations and/or advice to WHO shall be restricted to the members of the SAGE IVD and essential WHO Secretariat staff.

WHO may convene additional meetings as decided by the ADG of the Medicines and Health Products Division, on an ad hoc basis. The EDL Secretariat will convene regular teleconferences and/or videoconferences as part of the process required to update the EDL and as required for SAGE IVD to complete other tasks as outlined in these terms of reference.

2. The quorum for SAGE IVD meetings shall be two thirds of the members.

3. Representatives from inter-governmental organizations, as well as nongovernmental organizations in official relations with WHO, and members of other technical advisory groups of the WHO may be invited by WHO to participate in SAGE IVD meetings or parts thereof. For the purposes of these terms of reference, such invitees will be referred to as “Observers”. Observers shall attend meeting at their own expense and be responsible for making all arrangements in that regard.

   At the invitation of the Chairperson, Observers may be asked to present the views and policies of their organization. Observers will not participate in the process of adopting the final decisions or recommendations of the SAGE IVD.

4. The SAGE IVD may decide to establish smaller working groups (sub-groups) to work on specific issues. Their deliberations shall take place via teleconference or video-conference. For these sub-groups, no quorum requirement will apply; the outcome of their deliberations will be submitted to the SAGE IVD for review at one of its meetings.

5. Members are expected to attend meetings. Should a member miss two consecutive meetings, WHO may end his/her appointment as a member of the SAGE IVD. WHO may decide to appoint a replacement of that member.

6. Reports of each meeting will be submitted to WHO Assistant Director-General of the responsible Division. All recommendations from the SAGE IVD are advisory to WHO, who retains full control over any subsequent decisions or actions regarding any proposals, policy issues or other matters considered by the SAGE IVD.

7. The SAGE-IVD shall normally make recommendations by consensus. If, in exceptional circumstances, a consensus on a particular issue cannot be reached, minority opinions will be reflected in the meeting report.

8. Active participation is expected from all SAGE IVD members, including in working groups, teleconferences, and interaction over email. SAGE IVD members may, in advance of meetings, be requested to review meeting documentation and to provide their views for consideration by the SAGE IVD.

9. WHO shall determine the modes of communication by the SAGE IVD, including between WHO and the SAGE IVD members, and the SAGE IVD members among themselves.
10. SAGE IVD members shall not speak on behalf of, or represent, the SAGE IVD or WHO to any third party.

**Secretariat**

WHO shall provide the Secretariat for the SAGE IVD including any necessary scientific, technical and other support. In this regard, the WHO Secretariat shall provide the members in advance of each meeting with the agenda, working documents and discussion papers. Distribution of the aforesaid documents to Observers will be determined by the WHO Secretariat. [The meeting agenda shall include details such as: whether a meeting, or part thereof, is closed or open; and whether Observers are permitted to attend.]

**Information and documentation**

1. Information and documentation to which members may gain access in performing SAGE IVD related activities will be considered as confidential and proprietary to WHO and/or parties collaborating with WHO. All proposed members will be required to sign an appropriate confidentiality undertaking and provisions on ownership.

2. Members and Observers shall not quote from, circulate or use SAGE-IVD documents for any purpose other than in a manner consistent with their responsibilities under these Terms of Reference.

3. WHO retains full control over the publication of the reports of the SAGE-IVD, including deciding whether or not to publish them.
Selection Criteria for members of SAGE IVD

WHO will request members with expertise in in vitro diagnostics (IVD), in one or more of the following settings:

- IVDs in the clinical laboratory
- Academia (IVDs and public health)
- Ministry of Health, (policy making on IVDs or medical devices)
- National reference laboratory or laboratories in national teaching public hospitals
- NGOs working on global public health supporting access to IVDs
- Product development, Innovation, R&D of IVDs
- Assessment, validation, clinical trials, regulation of IVDs
- Selection, procurement and supply of IVDs
- Pricing/reimbursement for IVDs

To be considered, candidates must be able to demonstrate that they have the expertise, skills and experience to meet the criteria described below.

- An understanding of the IVD issues covered by the Strategic Advisory Group (SAGE IVD);
- An outstanding record of achievement and personal credibility within own field, appropriate to the remit of SAGE IVD;
- Experience in:
  - international settings;
  - resource-limited settings;
  - operating at a strategic level in the public or other sectors;
  - working effectively in high level advisory groups or committees;
- Excellent interpersonal and communication skills to support effective discussion with a range of stakeholders;
- Ability to:
  - evaluate complex issues and weigh up conflicting opinions;
  - influence at a senior level;
- Proficient in English.
- Proficient in writing skills (reports, papers)

Please note that candidates with conflicts of interest cannot be considered according to WHO policy. Examples of conflicts of interest would be, amongst others, ownership of stock options in a diagnostic company, being a current employee at a diagnostic company or a recipient of significant funding from a diagnostic company.
Application to become a SAGE IVD member

To apply the candidate must confirm interest, availability and commitment to serve on the SAGE IVD by providing a curriculum vitae (CV), a letter of motivation highlighting their specific expertise and contribution to SAGE IVD, and complete and sign the WHO declaration of interests (DOI) form.

The CV should include the career history and list the main areas of employment or other relevant activity and other public appointments related to the SAGE IVD work, including details of any relevant academic, professional or vocational qualifications. The CV will be used in the assessment of the candidate’s expertise. It is important that the CV and/or letter of motivation provide evidence that the candidate meets the selection criteria. The CV should be written in English. If accepted to be a SAGE IVD member, an extract of the member’s CV will be published in the WHO website related to SAGE IVD members.

Candidates must provide all contact details including email and phone number as well as details of two referees, at least one of whom must be related to recent professional and/or voluntary activity. They may or may not be approached prior to or after review of applications.

Applications can be submitted at any time and will be kept by the Secretariat for review at subsequent meetings of the selection panel. Normally, a new panel will be selected to start in September, to prepare for SAGE IVD meetings the following year. However, in the event of a delay in the publication of the list, current SAGE IVD members will be requested to serve until completion of the EDL iteration under preparation and timelines for publication of following iterations of the list may be shifted as required. Dates may change and will be announced on the SAGE IVD members website.

SAGE IVD members should review the dates of forthcoming SAGE IVD meetings to ensure their availability to attend the meetings at the scheduled dates.

Completed applications should be sent to edlsecretariat@who.int

Once WHO receives applications:

Applications will be processed once a year, as indicated on the website and candidates will be kept informed at key stages. Self-applications are expected to be submitted with all necessary information. For nominations submitted by a third party, the nominees will be contacted by the Secretariat and expected to confirm their interest through submission of a complete application package.

Process candidates should expect after receipt of the applications:

- WHO will acknowledge receipt of the application and its completeness (by e-mail) and will check it for eligibility;
- WHO will rely on only the information provided on the application form and CV to assess whether the candidates have the experience required at the appropriate level. Candidates are asked to ensure that written evidence is provided to support how they meet all of the relevant criteria, which are identified in the “Selection Criteria” section;
- telephone interviews may be scheduled between candidates and the Secretariat to clarify areas of uncertainty about their experience and expertise and ask specific questions to explore whether they meet the specified qualities;
- candidates who best fit the criteria and match the needed expertise with due consideration to ensuring a proper balance will be proposed for appointment by the Director-General of WHO who will make the final decision;
- to facilitate a smooth rotation process, candidates may also be preselected for seats expected to become vacant;
- a successful candidate will receive a letter inviting them to serve on SAGE IVD that will specify the beginning and end of the term. Some applications may not be successful but will be kept on an open roster of qualified candidates for later consideration depending on new vacancies and subject to adjustment of balance on the Group. Candidates will be notified accordingly.
• unsuccessful applications will also be notified by the Secretariat.