



Consensus Framework Resource Guide

Business Ethics for APEC SMEs Initiative

APEC Small and Medium Enterprises
Working Group (SMEWG)

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**Asia-Pacific
Economic Cooperation**

Consensus Framework Resource Guide

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Produced by

Business Ethics for APEC SMEs Initiative

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EXECUTIVE SUMMARY

Consensus frameworks are voluntary, principles-based agreements or commitments among diverse health stakeholders (or “parties”) to strengthen ethical collaboration. They may also serve as an open platform for parties to raise existing or emerging ethical challenges or opportunities for collective action. While each consensus framework is unique in design and stakeholder composition, they share this common purpose. Any health stakeholder representing a segment of the health ecosystem can help form a new or join an existing consensus framework, including patients’ organizations, healthcare professional societies, industry associations, healthcare providers, and government agencies, among others.

Not to be misunderstood as a code of ethics that is independently maintained by each party, consensus frameworks are a gathering of health system stakeholders that routinely convene member parties to foster recognition and uptake of high-standard and aligned ethical practices. This can include collective review, feedback and alignment on individual organization’s codes of ethics as well as on ethics training curriculum and other resources.

As structures for like-minded health organizations dedicated to the advancement of ethical business practices, consensus frameworks do not only serve the health sector at large. Organizations who commit to being a part of their economy’s consensus framework have the unique ability to forge relationships with other stakeholders to affect greater change and build trust across the health landscape.

To support consensus framework parties to maximize its activities, this document includes 5 resources to help stakeholders in the most essential areas for implementation.

THE CONSENSUS FRAMEWORK RESOURCE GUIDE INCLUDES 5 AREAS INCLUDING:

1. **Guide to Launch**
2. **Guide to Governance**
3. **Guide to Planning**
4. **Guide to Communications**
5. **Guide to Sustainability**

Each guide is crafted for use by parties to adapt and implement within individual consensus frameworks. Consensus frameworks may integrate all sections or a custom selection based on the needs in each economy. For example, in some agreements, a steering committee is necessary to help make decisions while in other APEC economies, all consensus framework parties collectively determine actions. Each section includes an outline intended to serve as a starting point and may be edited based on local context and specific goals of each consensus framework. Each resource is not mutually exclusive. It is recommended these resources be drafted in collaboration with representation from each member of the consensus framework.

THE CONSENSUS FRAMEWORK RESOURCE GUIDE INCLUDES 5 AREAS:



GLOSSARY

Collective action: Collective action is defined by the Basel Institute on Governance as “a collaborative approach to address corruption challenges and raise standards of integrity and fair competition in business.”¹

Stakeholder: A stakeholder in a consensus framework is defined as a health system organization that includes but is not limited to, patient organizations, healthcare professional organizations, governments, hospitals, third-parties, academia and civil society, and industry associations from both the medical technology and biopharmaceutical sectors.

Governance: The process through which the consensus framework is able to advance its progress and achieve consensus on its stated shared values. Governance structures in consensus frameworks vary in each APEC economy, for example equality among all parties or the election and/or appointment of members to a leading a Secretariat or Committee.

Sustainability: Sustainability of a consensus framework refers to the consensus framework’s ability to remain functional, with or without financial support. It is vital that consensus frameworks have sustained commitment of stakeholders to advance goals and are built upon a strong foundation and championship, as consensus frameworks are voluntary agreements between parties.

Monitoring and Evaluation: A continuous process set up by the consensus framework to assess if progress is made in achieving expected results. The data collected can support in setting a baseline, demonstrate results and can also inform future activities of the consensus framework.

GUIDE TO LAUNCH

When health stakeholders are considering the launch of a new consensus framework, parties are encouraged to review the following considerations.

CONSIDERATIONS:

Purpose / Why:

- What are the reasons your economy is forming a consensus framework?
- What are the shared values of the consensus framework parties?

Tactics:

- Identify key stakeholders in your economy to join the consensus framework.
- Identify the individual, group, or organization to lead in convening these stakeholders.
- Determine the communication cadence with members to promote mutual understanding.

Process:

- Have you considered how you will keep internal stakeholders apprised of the consensus framework vs. external stakeholders?
- What is the timeline for signing the consensus framework?
- How have you considered *Strategies to Realize Mutual, Sustainable Benefits* for the consensus framework parties? (see *Part 2 below*)

PART ONE: 11 STEPS TO FORM A CONSENSUS FRAMEWORK

Step 1: Embrace shared values that (a) patients are the priority, b) interactions at all times should be ethical, appropriate and professional; and (c) partners support transparency and accountability in their individual and collaborative activities.

Step 2: Identify key stakeholders within the member economy or the local community necessary to facilitate ethical collaborations in the medical device and biopharmaceutical sectors.

Step 3: Identify the individual, group, or organization to lead in convening these stakeholders.

Step 4: Convene stakeholders as equal partners. Ensure each partner maintains shared values that are consistent with Step One.

Step 5: Ensure a common basis of understanding. Jointly review current commitments under existing codes of ethics, local laws and regulations, and other organizational guidelines – including the APEC Kuala Lumpur Principles, APEC Mexico City Principles, APEC Nanjing Declaration, and other best practices identified by the Business Ethics for APEC SMEs Initiative.

¹Basel Institute on Governance. "Collective Action." 8 March 2023, <https://baselgovernance.org/collective-action>

Step 6: Commit to developing a consensus-based framework for multi-stakeholder collaboration.

Step 7: Determine the framework's scope of activities based on the interests / capabilities of the partners. Partners are encouraged to review Part Two of this Guide for strategies in determining the scope of activities that will realize mutual benefits.

Step 8: Establish a drafting group for the framework and determine consultative process.

Step 9: Finalize framework and undertake individual or collective adoption by the partners.

Step 10: Partners may consider effective governance strategies for the framework. This includes a designated or rotating secretariat or convener. The partners may support routine internal communication, virtually or in-person, facilitated by the convener. The partners may embrace an inclusive approach to welcome new organizations as well as changes in leadership by existing partners. Partners may maintain collaborative intent to preserve the platform's underlying purpose. Partners may maintain routine external communication for their constituents, the general public, and the international community to build awareness and support for their activities. The partners may commit themselves to routine modernization of the framework so that it continues to reflect its original intent and motivates strengthened ethical business practices over time.

Step 11: Publicize and distribute the framework (for example, through the Business Ethics for APEC SMEs initiative website, external stakeholders and the media).

PART TWO: STRATEGIES TO REALIZE MUTUAL, SUSTAINABLE BENEFITS

1. Identification and Communication of Best Practices:

- The development of new codes of ethics for individual partners, the alignment of existing codes among partners, and/or the integration of codes between partners;
- Joint discussions and/or recommendations on existing, proposed, or potential laws and regulations or other local standards; and
- Joint communications on established best practices to each partner's respective constituents as well as the public and international community.

2. Implementation of Cross-Organizational Capacity Building:

- Ethics training curriculum, such as sharing existing resources or jointly developing new resources for dissemination to each partner's constituents;
- Ethics training activities, such as jointly convening or delivering training sessions to each partner's constituents (virtually and/or in-person);
- Ethics training feedback, such as each partner communicating back to other partners what their constituents are reporting during capacity building activities; and
- Ethics training incentives, such as enablers that encourage capacity building by all partners.

3. Shared Monitoring and Evaluation of Changes:

- An agreed process for partners to mutually track the dissemination of capacity building;
- A common recognition process across partners for their constituents who receive ethics training, such as a logo and/or other validation mechanism; and
- An early warning or opportunity detection process for partners to quickly exchange views and/or develop strategies for new or changed circumstances in the environment.

Note: Depending on the nature of the framework, not all partners need to undertake each strategy together. Some strategies may be undertaken for the mutual benefit of all partners, while some may be undertaken for the benefit of a sub-group of partners. This should only apply when a certain strategy is not relevant to all partners, rather than as a means to exclude partners where there is mutual benefit. All partners should be welcomed to join each strategy that is pursued.

GUIDE TO GOVERNANCE

When health stakeholders are considering a governance structure during or following the launch of a consensus framework, parties are encouraged to review the following considerations.

Considerations:

Purpose / Why:

- What do you believe is your economy's main purpose for a consensus framework?
- What are the consensus framework parties' shared commitments?
- What are the consensus framework's priorities?

Tactics:

- Develop a terms of reference document to outline the understanding of each organization's role in the consensus framework.
- Formalize the roles and responsibilities of each party of the consensus framework. Assign actions and next steps to specific people.
- Create small working groups as needed to better tackle assigned actions.
- Discuss whether there are any conflicts of interest among the consensus framework parties and, if so, how they will be mitigated through the terms of reference.
- Discuss a process for vetting new members to mitigate bad actors.
- Create a routine meeting schedule for member organization accountability.
- Garner support of member organizations' Boards and other senior leadership.
- Determine if there are underrepresented groups in the health sector. How will you ensure they are equitably represented in the consensus framework and in decision-making processes?

Process:

- What do you believe the roles and responsibilities of each organization in the consensus framework should be?
- Do you believe there should be leadership roles and responsibilities among the parties? If so, in what way?
- Have you convened the consensus framework parties to discuss governance?
- Will consensus framework parties need to update their own organizations on consensus framework governance? If so, how?

Tool #1: Draft Terms of Reference (not a one size fits all, only for example purposes)

1. Purpose

The goal of the [consensus framework] is to improve healthcare in [economy] through articulation and affirmation of ethical principles that promote the interests of patients and consumers, enhance access to safe and effective healthcare, encourage ethical collaboration in the healthcare sector and build public trust. The primary role of [consensus framework] is to support member organisations to develop and modify their policies and processes in light of the principles outlined in the [consensus framework].

The Steering Committee is established by member organisations of the [consensus framework], as at XXX DATE, to act as a leadership group for the [consensus framework].

This document establishes the scope and role of the Steering Committee so that it may function effectively, noting that the Committee is not a separate legal entity and each member of the Committee participates voluntarily as a representative of the organization they represent.

2. Term

These Terms of Reference are effective from XXX DATE and continue indefinitely unless terminated by agreement of [consensus framework] members.

3. Membership of Steering Committee

The Steering Committee comprises XXX members drawn from the member organisations. Initial members are those who were members of the Leadership Group that established the [consensus framework] and those appointed by [consensus framework] member organisations at the workshop held XXX DATE.

Subsequently, nomination for membership of the [consensus framework] Steering Committee will be by an expression of interest circulated to all member organisations. Terms of each of the inaugural members were determined by the Steering Committee during the first year of appointment. Unless membership of the Committee is expanded, at least four positions will be available for expression of interest at the end of the first year.

Expressions may be sought earlier if a member resigns from the Committee.

A selection panel will be convened to select from applicants. The selection panel includes the Chair of the Steering Committee and two other Committee members.

The Steering Committee is selected in such a way that it is broadly representative of the member organisations (including government, health professional, industry, education providers, nursing, allied health and consumer organisations).

The Steering Committee supports equal opportunity for Committee membership and, in selecting members, the selection panel will aim to achieve diverse and equal representation.

The Chair of the Steering Committee is selected by the members of the Steering Committee.

Task-specific working groups may be formed as needed, under the leadership of the Steering Committee.

4. Meetings and Proceedings of the Steering Committee

The Steering Committee is convened at least twice a year, and more often as required. The Steering Committee Chair has the discretion to schedule additional meetings. Working groups or sub-committees may also hold additional meetings as needed.

An agenda for the steering committee meeting is distributed to members prior to each meeting at least one week in advance of the meeting. Minutes of Steering Committee meetings are prepared by a designated member, for confirmation by the Steering Committee. Minutes are approved by the Chair and distributed to Steering Committee members for ratification and then to member organisations for information within one month of the meeting.

A quorum for meetings of the Steering Committee is eight members. Decisions made by the Steering Committee are by consensus. Where the Steering Committee is unable to reach agreement on any matter, or the issue at hand is considered to be fundamental to the direction or operation of the [consensus framework], the matter is referred to all member organisations for a final decision via email vote.

5. Roles and Responsibilities of the Steering Committee

The Steering Committee's role is to coordinate and provide leadership of the [consensus framework], ensuring that it fulfils its roles and obligations as stated in the Implementation Plan/Guide and guiding its future direction.

Responsibilities include:

- Stewardship of [consensus framework] membership
- Organisation of meetings of the member organisations and other events
- Management of funding arrangements, including decisions on any funding and sponsorship proposals
- Communications management, including representation and spokesperson roles
- Maintaining at all times the focus of the [consensus framework] on its agreed objectives.

6. Term of Appointment

Staged terms of appointment for each of the members (XXX) of the inaugural Steering Committee was agreed during the first year. At the conclusion of the term for each inaugural member, the terms below will apply.

The term of appointment is three years, with the option of one further three-year term on the agreement of the organization the member represents and the Chair of the Steering Committee. The term of appointment for the Chair is also three years with the possibility of a second three-year term.

7. Secretariat

Secretariat support is provided by a designated member, including the provision of an agenda for each meeting, circulation of supporting papers (after approval from the Chair) and preparation and maintenance of meeting minutes.

8. Conflicts of Interest

Steering Committee members are required to declare any conflicts of interest at the commencement of each meeting or before discussion of the relevant agenda item or topic, which will be appropriately minuted. In this context, a conflict of interest is an interest that is, or could be perceived to be, in tension with the goals of the [consensus framework].

If a member conflict is declared, the [consensus framework] Chair will decide whether the member should be excluded from deliberations and/or decisions.

9. Steering Committee Evaluation and Review

These Terms of Reference are reviewed at least once per annum by the member organisations of the [consensus framework] and may be amended with agreement of member organisations.

A self-evaluation of Steering Committee effectiveness, relative to the Terms of Reference, is undertaken every two years.

Agreed by the member organisations, [consensus framework].

Reviewed by member organisations, [consensus framework].

Date: XXX

Revised: XXX

GUIDE TO PLANNING

When stakeholders are considering a programmatic plan for the consensus framework, parties are encouraged to review the following considerations.

Considerations:

Purpose / Why:

- What are the primary and secondary priorities of the consensus framework?
- How can you measure the consensus framework's success? What do you want to work on with fellow parties?

Tactics:

- Identify key priorities of the consensus framework.
- Determine deliverables and measures of each priority.
- Review priority areas with members on a routine basis and adjust, as appropriate.
- Develop a process for making decisions when all parties are not represented.
- Align key external and internal messaging.
- Ensure priorities, next steps, and shared commitments are understood by all parties.

Process:

- What is the best time to initiate an annual review process of the consensus framework? Who should be involved in the annual review process? How should individual organizations keep their internal stakeholders updated?
- How frequently should the consensus framework review its priorities among the parties?
- Are all health stakeholders represented in the consensus framework?
- How does the consensus framework vote? How does the consensus framework make decisions if there is an unequal balance of stakeholders?
- Is each organization aligned with the proposed external and internal messaging?

Tool #1: Table of Key Priorities and Measures

Key Priorities	Consensus Framework Lead	Deliverables and Measures	Timeline

Tool #2: Commitment Assessment Timeline for Uncooperating Stakeholders

1. Issue verbal warning to stakeholder on the Consensus Framework meeting record
2. Issue written warning to stakeholder of the potential termination of their membership status following the below timeline:
 - o Two weeks following the written warning: If no response, issue follow up final written warning
 - o One month following the second written warning: Conduct assessment involving all consensus framework parties on stakeholder membership. Decision must be agreed to by all stakeholders.
 - o One week following assessment: Provide written decision of consensus framework parties regarding membership
 - Remove from consensus framework communications and website, if applicable
 - Conduct new assessment of terminated consensus framework member in one year for reinstatement

GUIDE TO COMMUNICATIONS

When stakeholders are considering a communications strategy for the consensus framework, parties are encouraged to review the following considerations.

Considerations:

Purpose / Why:

- Why was the consensus framework created in the first place?
- What does the consensus framework want to communicate and to whom? To serve what purpose?
- Who should be receiving information about the activities of the consensus framework? (e.g. parties and other stakeholders)
- What is the consensus framework's viewpoint on communicating with 1) consensus framework parties or members, 2) within individual organizations and their constituents, and 3) those outside the consensus framework?

Tactics:

- Create a one-page overview document of the consensus framework purpose, activities, and ways to get involved. Develop shared talking points on the consensus framework to bring a shared voice to external meetings.
- Share insights from members on why they joined the consensus framework and other ongoing activities through social media channels.
- Create a membership slide deck or one-page explainer document of how to become a new member.
- Outreach to local conferences or convenings to include the consensus framework on upcoming panel discussions or speaking opportunities.
- Release a quarterly newsletter or email update on the purpose of the consensus framework and member updates.
- Align with consensus framework parties on how to update their own internal organizations on the activities of the consensus framework.
- Consider creating a new website or a portal on an existing website to promote the consensus framework, purpose, activities, and ways to get involved.
- Develop a consistent, aligned message.
- Create a content plan to sustain engagement and momentum for consensus framework activities.

continued on next page

Process:

- Have you discussed the consensus framework’s shared communications priorities for the year?
- What is the timeline and review process for developing new communications tools?
- Are there additional partners that need to be brought in to help develop communications tools?
- Should the parties develop common reference material or shared talking points to describe the framework?
- What is the best way to communicate consensus framework activities externally?
- Who/which organization will serve as the communications representative for the framework to external parties, such as media, governments, and other targeted stakeholders?

Tool #1: Draft Communication Plan

Milestone	Deliverables and Measures
1) Develop a media/communications working group that includes signatories with an interest in communications	XX - [status]
2) Determine the governance process for overseeing website design and content	XX - [status]
3) Prepare material on the [consensus framework] that can be disseminated by member organizations for publicity purposes	XX - [status]
4) Prepare material (e.g. PowerPoint slides and hardcopy materials) on the [consensus framework] that can be used by member groups at conferences	XX - [status]
5) Identify relevant conferences/events at which member organizations can present and/or organize satellite workshops/symposia	XX - [status]
6) Conduct a needs analysis assessment on an annual workshop/seminar to assess the viability of such an event	XX - [status]
7) Develop a [consensus framework] media and communications plan, including a social media plan (to commence from XX) and a request for member organizations to advocate for the [consensus framework] principles	XX - [status]

8) Develop a protocol for how media statements and communications should be developed and released	XX - [status]
9) Create timely content plan for years ahead. Connect with consensus framework organization communications teams to promote organization's involvement in the consensus framework	XX - [status]
10) Prepare an academic article for publication	XX - [status]
11) Develop a website	XX - [status]
12) Launch website	XX - [status]

Tool #2: Mapping of Communications for Key Constituents

Communications Strategy	Stakeholder Group 1	Stakeholder Group 2

Tool #3: Social Media Plan

Resource	Timeline / Ideas
Success Metrics	
Benchmarks	
Social media goals and objectives	
Social media targeted platforms	
Staffing plan	
Content Calendar	
Success Examples	
Reporting	
Analysis	

GUIDE TO SUSTAINABILITY

When stakeholders seek to ensure the sustainability of the consensus framework, parties are encouraged to review the following considerations.

Considerations:

Purpose / Why:

- How do the consensus framework parties view sustainable engagement?
- Why do organizations value engagement with other framework parties on ethical collaboration?
- How can the consensus framework ensure diverse representation in the consensus framework to ensure sustainability (advocacy, education, support)?

Tactics:

- Create routine opportunities to convene code consultations, including how individual organizations can integrate feedback from consensus framework parties in their internal processes.
- Demonstrate the business case for helping solve collective actions challenges.
- Discuss how to resource future activities of the consensus framework, ensuring that one organization is not funding the framework on its own, causing a misalignment of priorities.
- Develop a strong governance agreement, building on the Terms of Reference.
- Discuss how to hold each organization accountable for its individual contributions, including how to address individual people or organizational leadership challenges.
- Consider creating a government consultative process for the framework.
- Involve senior leadership in the consensus framework to maintain relevance.
- Embed insights from the consensus framework in academic programs and professional trainings.

Process:

- How will the consensus framework hold each party accountable? Should working groups be established for sustainable engagement with the consensus framework?
- What is the process for creating transparency for the actions of the consensus framework to help establish clear communications?
- How will the consensus framework review its representation of the health care ecosystem?
- How can consensus framework parties integrate feedback/learnings in individual organizations' processes? Are organizations prepared to consider changes to their processes as part of these learnings and feedback?
- What resources might be needed for future activities? Who should provide these resources? (e.g. financial, time, shared knowledge).

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