

Innovation to Impact (I2I) Industry Workstream Terms of Reference

Context

The Innovation to Impact (I2I) effort aims to transform the value chain for developing and delivering vector control products for diseases caused by vector borne pathogens. I2I was launched in 2013 in response to a perceived need for deployment of entirely new kinds of vector control interventions, motivated both by increasing evidence of a decrease in effectiveness of current methods and a desire to address residual transmission with new tools. Given the nature of the change required, the initiative quickly evolved into a multi-stakeholder effort and now includes more than 20 actively participating organizations including manufacturers, the Innovative Vector Control Consortium (IVCC), The World Health Organization (WHO), The US President's Malaria Initiative (PMI), The Global Fund, the US Environmental Protection Agency (EPA), UNITAID, The African Leaders Malaria Alliance (ALMA), as well as representatives from countries and other stakeholder groups. The coordination of the I2I partnership, by the I2I Leadership Team, is hosted by IVCC.

Purpose

The purpose of the Industry Workstream is to consolidate industry input on key topics across evaluation, procurement, and registration in order to increase industry partnership, prioritization, and investment in support of improved vector control.

Roles and responsibilities for workstream

Set strategy and implement plans

- Fully lead development and execution of workstream initiatives, including planning and implementing actions, timelines, and deliverables agreed upon by the workstream
- Solve problems and issues as they arise to fulfill the workstream objectives, and escalate them to the I2I leadership team when appropriate
- Provide progress updates to the I2I leadership team following regular meetings

Promote collaboration

- Members responsible for aligning on and implementing leadership and collaboration model for group
- Workstream leads responsible for moderating discussion and driving towards a consensus where there is an opportunity to find one
- I2I leadership responsible for communicating relevant information and updates to and from other I2I workstreams

Provide execution oversight

- Workstream leads ensure accountability of Industry Workstream for implementing actions, achieving timelines, and contributing deliverables agreed upon by members of the workstream

- The workstream observes applicable antitrust/competition laws, including US/EU laws as well as underlying principles of national laws in any other relevant jurisdiction. Please see the documents titled “Innovation to Impact Competition Law Compliance Guidance” and “Innovation to Impact Antitrust/Competition Law Reminder” for more details; these documents are available on the I2I website.
- I2I exists to objectively promote the purpose outlined above; it does not promote or defend the interests of any one company (I2I member or otherwise).

Objectives

Overall objectives

- Provide consensus industry input on key topics across evaluation, procurement, and registration to other I2I workstreams through I2I leadership
- Where possible, participate in key workstream initiatives (e.g. dossier pilot review, equivalency consultation, pre-submission guidance pilot)
- Through workstream discussions, identify industry-wide challenges and ways that I2I may address them
- Complete additional commitments proposed and agreed upon by the workstream

Composition

Lead

- Lead: The Bill and Melinda Gates Foundation representatives will be the initial leads. Following this initial term of one year (calendar year 2016), the workstream will have one lead or two co-leads, appointed for a one-year term. The Industry Workstream members will elect successor leads from among the Industry Workstream members using a simple majority vote with one vote for each member organisation. Leads may be elected for up to two terms.
- The workstream lead is responsible for overall agenda setting, meeting minutes distribution, and keeping track of membership (e.g. current members and their affiliation, active/inactive status)

Membership and Structure

- Composition: Representatives from each of the following key organizations:
 - The Bill and Melinda Gates Foundation
 - Innovative Vector Control Consortium (IVCC)
 - Stakeholders representing entire vector control industry (e.g., innovator, generic, agrochemical, and specialized vector control firms)
- Membership Process: The initial Industry Workstream members are as confirmed by the initial Industry Workstream lead and I2I Leadership Team. Any industry vector control partners interested in becoming a workstream member should contact I2I leadership or the workstream leads to join. New members can join the workstream at any time during the year. The assessment of all prospective members must be conducted in a fair and objective manner. No prospective member will be denied membership for any reason which may constitute a breach of anti-trust/competition

law. All reasons for rejecting prospective members must be documented in the official meeting minutes.

- Membership Criteria: Membership of the workstream is open to any company who is developing a vector control product or is interested in doing so in the future.
- Participation in meetings/calls: If an Industry Workstream member is unable to attend an Industry Workstream call or meeting, he or she should communicate his/her absence in advance of the meeting/call and may designate an alternate representative (providing the name and contact information of the designated representative to the Industry Workstream lead). To ensure timely decision making, this representative should be empowered to act on behalf of the Industry Workstream member.
- Attendance and participation is voluntary. All members are free at all times to join other initiatives.

Observers/liaison

- I2I Leadership Team
- Other technical experts as needed for specific topics

Sub-committees

- Ad hoc sub-committees can be formed at the discretion of the Industry Workstream to address a specific topic. The need for a new sub-committee should be raised as an agenda item during the monthly call and agreed upon by the workstream by a simple majority vote with one vote per member organisation.
- Sub-committees should be time-bound and should have clearly identified deliverables, objectives, and scope
- Any workstream members can volunteer to serve on the sub-committees as members or as the sub-committee chair
- Non-members of the Industry Workstream can serve on Industry Workstream sub-committees at the discretion of the sub-committee chair
- Sub-committees will report progress at each monthly call until the sub-committee's objective is fulfilled
- All members of any sub-committee will comply with the terms of this Terms of Reference.

Mode of Operation

Meetings

- Frequency: I2I Industry Workstream meetings will be held every month, with additional calls held as needed around convenings or to resolve complex, multi-stakeholder issues
- Location: All meetings will be calls unless it is possible to hold in-person meetings in conjunction with I2I convenings or other opportune meetings convenient for Industry Workstream members
- Agenda: An agenda will be provided before every call.
- Minutes: Meeting minutes will be drafted by a designated appointee of the workstream lead after each monthly call and will be circulated to all participants in a timely manner (ideally within 10

working days). All participants will have a reasonable opportunity to comment on the minutes before they are finalized.

- Quorum: No decisions may be taken by the Industry Workstream in the absence of a quorum. quorum will be reached when over 50% of the of the Industry Workstream members are present. In the event of a vote being planned for a specific meeting or call, members will be notified in advance so as to increase the likelihood of a quorum. If it proves difficult to achieve a quorum the I2I leadership team reserves the right to amend the aforesaid rules on quorum by methods such as introducing electronic voting or distinguishing between active and inactive members.
- Voting: When is it necessary for the workstream to vote on an issues this will be done by a simple majority vote with one vote per member organization.
- Chairing meetings will be chaired by representatives of the Bill and Melinda Gates Foundation in the first year (calendar year 2016) and the elected workstream lead(s) following that period.
- Anti-trust guidelines will be adopted by the workstream and followed for each meeting. Legal advisors will also be consulted as necessary to ensure anti-trust compliance. Please see the documents titled “Innovation to Impact Competition Law Compliance Guidance” and “Innovation to Impact Antitrust/Competition Law Reminder” for more details; these documents are available on the I2I website.
- Any I2I member(s) that intends to attend a third party meeting(s) on behalf of or represent the I2I group as a whole or one of the I2I Industry Workstream sub-groups must receive elected approval by a simple majority vote by the I2I Industry Workstream members prior to attending such a meeting.

Workstream output

- The workstream lead will moderate discussions to ensure that all perspectives are heard and that workstream strives to reach consensus across industry on vector control issues, wherever possible
- Where a consensus cannot be reached on a particular issue, the workstream lead will coordinate drafting of the alternative perspectives, and ensure that summaries of all perspectives are delivered, but the workstream is not designed to represent individual member views
- Workstream output will vary based on the topics to address at a given time but will include providing feedback to other I2I workstreams through I2I leadership and presentations at I2I convenings as warranted

Approval

These Terms of Reference have been approved by the Industry Workstream following its meeting on 12th December 2017.

These Terms of Reference have been approved by the I2I Leadership Team in its meeting on 13th December 2017.

These Terms of Reference will be reviewed annually or at the discretion of the Industry Workstream lead and will be posted by I2I Leadership on the I2I website.

The I2I Advisory Board or I2I Leadership Team can also propose revisions as needed for approval by the Industry Workstream.