

HTAi Rare Diseases Interest Group

Terms of Reference

1.0 Purpose

The HTAi Rare Diseases Interest Group is a service to members who have interest in HTA of health technologies for rare diseases. This Interest Group is dedicated to sharing good practices in evidence generation for rare disease technologies (RDTs), fair assessment processes that take account of the feasibility of evidence generation and appraisal processes that take account of the burden of rare diseases on patients and society when determining value.

2.0 Establishment

HTAi Interest Groups are a service to members, and they are established by a resolution of the Board. Interest Groups shall comply with the Society Bylaws and the HTAi Interest Groups Policy and Procedure reviewed by the Board of Director from time to time.

3.0 Members of Interest Group

- 3.1 All members of the Interest Group are members of the Society in good standing that are interested in support or research of the common HTA area. In accordance with Bylaw 2.5(a), if an Interest Group member did not pay the membership fees, the member becomes a non-member and cannot participate in the Interest Group. Membership fees are due by December 31 every year.
- 3.2 Technical Officer who provides administrative support to the Interest Group and who works in accordance with their contract reviewed and signed annually.
- 3.3 HTAi members in good standing who wish to join an Interest Group shall email to interestgroups@htai.org to be added to the distribution list.
- 3.4 The Members of the Interest Group can resign at any time by providing the notice to the Chair.

4.0 Responsibilities

- 4.1 Interest Group Members are responsible for the following:
 - a. Volunteer for the positions of Chair, Co-Chairs and Steering Committee subject to Sections 7.1, 7.2, and 7.3.
 - b. Contribute to newsletters by sharing relevant information.
 - c. Comment on documents circulated for review.
 - d. May attend the Annual Business Meeting of the Interest Group.
 - e. Attend at least two (2) events a year (IG meetings, webinars or in-person preconference workshop).
 - f. Contribute to projects of the IG in areas of interest.
- 4.2 Steering Committee is responsible for the following:
 - a. Provide governance and oversight to the Interest Group.
 - b. Set up the Interest Group and Steering Committee meetings with a minimum of two (2) events/webinars for the Interest Group in a year's schedule and adhere to it.
 - c. Ensure the workplan of the Interest Group aligns with the objectives of the Society Strategic Plan and adhere to it.

- d. Conduct one meeting of the Interest Group to update the members on the progress of work, forthcoming activities and call for new volunteers.
- e. Prepare and conduct one webinar a year for all HTAi members.
- f. Establish project groups as necessary to advance the work of the Interest group and provide their oversight and leadership.
- g. Deliver regular quarterly ebuletins to the Interest Group members.
- h. Yearly conduct the Annual Business Meeting (ABM) of the Interest Group.
- i. Yearly conduct the Technical Officer evaluation and make a decision to extend the contract or hire a new Technical Officer.
- j. Complete evaluation of Chair and Co-Chairs at the end of each term.
- k. Review its Terms of Reference every 3 years and make a recommendation to the Board of Directors.
- l. Twice a year submit the material for the HTAi newsletter.

4.3 Interest Group Chair is responsible for the following:

- a. Provide leadership to the Interest Group members and Steering Committee.
- b. Chair the meetings of the Steering Committee and Interest Group.
- c. Set up the agenda for the Interest Group meetings and Steering Committee meetings.
- d. Lead the evaluation of the Technical Officer.
- e. Ensure the Interest Group operates in compliance with the Interest Group Policy and Procedure.
- f. Present the report to the Interest Group members at the Annual Business Meeting.
- g. The Chair shall represent the Interest Group at the HTAi Interest Group Steering Committee (IGSC). If the Chair cannot attend, then one of the Co-Chairs may attend instead. The Chair (or his/her representative) must attend at least three (3) out of four (4) IGSC meetings a year.

4.4 Interest Group Co-Chairs are responsible for the following:

- a. Support the chair to provide leadership to the Interest Group members and Steering Committee globally.
- b. In the absence of the Chair, chair the meetings of the Steering Committee and Interest Group.
- c. In the absence of the Chair attend the IGSC meeting to represent the Interest Group.
- d. Ensure the Interest Group operates in compliance with the Interest Group Policy and Procedure.

5.0 Accountability

The Rare Diseases Interest Group (RDIG) is accountable to its members and the HTAi Board of Directors.

6.0 Steering Committee Composition

- 6.1 The Interest Group Steering Committee will consist of the following members:
 - 6.1.1 Chair
 - 6.1.2 Two (2) Co-Chairs
 - 6.1.3 One (1) Technical Officer, a non-voting member
 - 6.1.4 Up to six (6) Steering Committee members. The Steering Committee membership shall aim for equitable representation based on diversity of the HTAi membership and expertise in rare diseases.

7.0 Election Process

- 7.1 Chair
 - 7.1.1 In the case of the inaugural Committee, the Founder of the IG shall be the Chair with the term of office described in Section 8.1.
 - 7.1.2 After the term completion of the Chair or resignation, a call for interest shall open for all IG members.
 - 7.1.3 Four to six months before the end of the term or a resignation, the Chair and the Co-Chairs shall direct the Technical Officer to circulate a call for interest among the members of the Interest Group with a specified desired criteria for the candidates, i.e., member of the HTAi in good standing (Section 3.1), at least 10 years working in the field of HTA of rare diseases, governance and leadership experience, other specific criteria to fill skill gaps in the Committee composition.
 - 7.1.4 The Steering Committee shall review the applications, identify candidates who met the criteria and shall elect the Chair by majority vote.
 - 7.1.5 The Interest Group members will be informed of the election results once available.
 - 7.1.6 The elected individual shall take their position at the conclusion of the election process.

7.2 Co-Chairs

- 7.2.1 For the inaugural Committee, a call for interest for Co-Chair positions shall be open to all Interest Group members in good standing who have relevant experience (see Section 7.1.3). The Chair will review applications to check eligibility. If more than two eligible applications are received, the Chair will make a selection and appointment based on expertise, geography and other relevant criteria, and in consultation with the Interest Group Steering Committee Chair.
- 7.2.2 For the inaugural Committee, to promote a more orderly transition of the Co-Chairs in the future, one (1) Co-Chair shall be elected for the usual term of three (3) years, and one (1) Co-Chair shall be elected for the term of two (2) years.
- 7.2.3 When the position of Co-Chair becomes available due to the completion of the term or resignation, the Chair shall direct the Technical Officer four (4) to six (6) months before the end of the term or a resignation, to circulate a call for interest among the members of the Interest Group with a specified desired criteria for the candidates, i.e., member of the HTAi in good standing and with specific requirements relating to the RDIG as per Section 7.1.3.
- 7.2.4 The Steering Committee shall review the applications, identify candidates who met the criteria and shall elect the Chair by majority vote.
- 7.2.5 The Interest Group members will be informed of the election results once available.

7.2.6 The elected individuals shall take their positions at the conclusion of the election process.

7.3 Steering Committee Members

7.3.1 For the inaugural Committee, a call for interest shall be open to all Interest Group members in good standing (see Section 3.1) for the positions on the Steering Committee. The candidates for the Steering Committee positions will be asked to demonstrate their longstanding experience in rare diseases and how their expertise benefits the purpose of the Interest Group.

7.3.2 The Chair and Co-Chairs shall appoint members for the inaugural Steering Committee seeking to ensure expertise in HTA, health services delivery for rare diseases, medicines development, medical device development, patient involvement and research across different geographies.

7.3.3 For the inaugural Committee, to promote a more orderly transition of the Committee members in the future, two (2) members shall be elected for the usual term of three (3) years, two (2) members shall be elected for the term of two (2) years, and two (2) for the term of one (1) year.

7.3.4 Four to six months before the end of the term or a resignation, the Chair and the Co-Chairs shall direct the Technical Officer to circulate a call for interest among the members of the Interest Group with a specified desired criteria for the candidates, i.e., member of the HTAi in good standing (Section 3.1), proven record of work in the rare diseases area, geographical location, other specific criteria to fill skill gaps in the Committee composition.

7.3.4 The Chair and Co-Chairs shall review the applications and approve the candidates who met the criteria to stand for election.

7.3.5 The Steering Committee shall elect the individuals by majority vote.

7.3.6 The elected individuals will take their positions at the conclusion of the election.

7.3.7 The Steering Committee may operate with vacancies as long as the requirements for quorum are satisfied.

8.0 Steering Committee Terms of Office

8.1 The term of Chair shall be three (3) years. The Chair may be re-elected for another term of three (3) years for a maximum of two consecutive terms or six (6) years of service.

8.2 The term of Co-Chairs shall be three (3) years, except for the inaugural Co-Chairs as described in Section 7.2.2. The Co-Chairs may be re-elected for another term of three (3) years for a maximum of two consecutive terms or six (6) years of service.

8.3 The term of Steering Committee members shall be three (3) years, except for the inaugural members described in Section 7.3.2. The Steering Committee Member may be re-elected for another term of three (3) years for a maximum of two consecutive terms or six (6) years of service.

8.4 After a period of at least three (3) years has passed after serving a term of six (6) consecutive years, HTAi member in good standing may be elected again as a Chair, a Co-Chair or a Steering Committee member.

8.5 Technical Officer's term shall coincide with the terms of their contract.

8.6 The term extensions beyond the above shall be approved by the Board of Directors for extenuating situations only.

9.0 Quorum

- 9.1 Quorum for Annual Business Meeting shall be 10 members.
- 9.2 Quorum for Interest Group meetings shall be 10 members.
- 9.3 Quorum for Steering Committee meetings shall be at least four (4) members and must include one of the Chair or Co-Chair.

10.0 Interest Group Operations

10.1 Meetings

- a. The Interest Group shall undertake the majority of its work virtually by email and videoconference.
- b. The Chair and Co-Chairs shall schedule regular meetings with the Technical Officer at least every second month.
- c. The Steering Committee shall meet five (5) times a year.
- d. Project Groups shall meet five (5) times per year. Their progress report shall be sent to the Steering Committee at least twice a year.

10.2 Remuneration of Members

Interest Group Members shall receive no remuneration for their service. The Technical Officer is a contracted position to the Interest Group and receives a small stipend.

10.3 Conflict of Interest Declaration and Management

Conflict of Interest declaration and management is done in accordance with Board approved Conflict of Interest Policy and Procedure. All Interest Group members should familiarize themselves with it and act accordingly.

10.4 Confidentiality

The Interest Group members should not disclose confidential information. The Committee Chair will advise of any confidential information. Any Interest Group member can ask that specific information they bring forward be treated as confidential.

11.0 Review

Review of these Terms of Reference shall take place every three (3) years or as directed by the Board of Directors.

Approved date: October 26, 2023

Review date: October 2026