



Rules and Procedures













Table of Contents – Auxiliary Heading

Article 1 - Members of the Governing Board	3
Article 2 - Chairperson and vice-Chairperson	3
Article 3 – Observers	4
Article 4 - Convening of meetings	5
Article 5 - Attendance	6
Article 6 – Agenda	
Article 7 - Quorum	7
Article 8 – Voting	7
Article 9 - Minutes	8
Article 10 – Written procedure	8
Article 11 - Confidentiality	9
Article 12 – Conflict of interest	9
Article 13 – Conduct of Governing Board Members	10
Article 14 – Reimbursement of expenses	10
Article 15 – Working and advisory groups	11
Article 16 - Correspondence	11
Article 17 – Amendment of the Rules and Procedures	11
Article 18 – General provisions	11
Article 19 – Entry in force	11

Article 1 - Members of the Governing Board

- As provided for in Articles 15 and 122 of the Council Regulation (EU) 2021/2085 of 19
 November 2021 (hereinafter "Single Basic Act"), the Governing Board of the Innovative
 Health Initiative Joint Undertaking (hereinafter "Innovative Health Initiative JU") shall be
 composed of:
 - a. four representatives of the Commission, and;
 - b. one representative per member of the Innovative Health Initiative JU other than the Union, as defined in paragraphs (b) and (c) of Article 117 of the Single Basic Act.
- 2. Each representative may have one or more appointed alternates.
- 3. The names and functions or posts of the representatives and their appointed alternates shall be published on the Innovative Health Initiative JU website.
- 4. Each Member of the Innovative Health Initiative JU may decide the term of office of its representatives in accordance with its internal rules. If the office of a representative falls vacant, the appointed alternate will take over the role of representative in the Governing Board until the respective Member of the Innovative Health Initiative JU has appointed a new representative for the remainder of the term of office.
- 5. Members of the Innovative Health Initiative JU shall notify appointments, substitutions or removals of representatives and their respective alternates to the Innovative Health Initiative JU in writing. The notice shall indicate the date on which the appointment, substitution or removal takes effect. In case of absence of such information in the notice, the effective date shall be within a month from the date on which the notice is received by the Innovative Health Initiative JU.
- 6. Hereinafter, the representatives shall be collectively referred to as the Board Members.

Article 2 - Chairperson and Vice-Chairperson

- 1. The Governing Board shall elect a Chairperson and a Vice-Chairperson from among the Board Members. The Chairperson and the Vice-Chairperson of the Governing Board shall be appointed on a rotating annual basis by the Union and the other Members.
- 2. Elections shall take place at the first meeting of the Governing Board. Any subsequent elections shall then take place at the last meeting under the chairmanship of the outgoing Chairperson. Members of the Innovative Health Initiative Joint Undertaking represented in the Governing Board shall communicate their nominated candidates for the election of the Chairperson and Vice-Chairperson to the Executive Director at least ten working days before the relevant meeting of the Governing Board. The office of Chairperson and Vice-Chairperson shall not be occupied by representatives of the same member of the Innovative Health Initiative JU. The Chairperson shall be elected by consensus or, if not possible, by secret ballot pursuant to the procedure set out in Article 8 of these Rules of Procedure. If the ballot is not conclusive, the candidate who gathered the highest number of votes will be elected. The Vice-Chairperson shall be elected following the same procedure.

- 3. The Chairperson and Vice-Chairperson shall be elected for a period of one year, provided that they continue holding the position of a Board Member during this period. Their mandate shall start at the end of the term of office of the prior Chairperson and Vice-Chairperson.
- 4. The Chairperson and Vice-Chairperson may be re-elected for subsequent terms. Until the Chairperson is elected, the longest serving representative shall act as Interim Chairperson. In the event of equal length of service, the oldest of the longest serving representatives shall act as Interim Chairperson.
- 5. The Vice-Chairperson shall take the place of the Chairperson if the latter is prevented from attending to his or her duties.
- 6. The outgoing Chairperson shall remain on duty until a new Chairperson is elected, except if he or she ceases to be a Board Member in which case the Vice-Chairperson shall take the place of the Chairperson as provided in paragraph 5. If the Vice-Chairperson also ceases to be a Board Member, the Executive Director shall convene a meeting of the Governing Board to elect their successors.
- 7. If the office of Chairperson falls vacant, the Vice-Chairperson shall convene a meeting of the Governing Board to elect a successor. If the office of the Vice-Chairperson falls vacant, the Chairperson shall convene a meeting of the Governing Board to elect a successor. The successors shall be elected for the remaining time of the original term.
- 8. If both the Chairperson and the Vice-Chairperson are absent or unable to attend a meeting, the meeting shall be chaired by the longest serving representative or, in the event of equal length of service, by the oldest of the longest serving representatives.

Article 3 – Observers

- 1. As provided for in Article 16(7) of the Single Basic Act, the Chairperson and Vice-Chairperson of the States' Representatives Group shall have observer status in the Governing Board meetings. They shall have the right to attend the meetings of the Governing Board and take part in its deliberations, but shall have no voting rights. The Chairperson of the Science and Innovation Panel shall have the right, whenever issues falling within its tasks are discussed, to attend the meetings of the Governing Board as an observer and take part in its deliberations, but shall have no voting rights.
- 2. The Governing Board may invite, on a case-by-case basis, other persons to attend its meetings as observers, in particular representatives of regional authorities within the Union, and representatives of civil society. These observers shall have no voting rights. The Governing Board may decide to examine specific items of the agenda without the presence of observers due to confidentiality of such specific items.

Article 4 - Convening of meetings

- 1. The Governing Board of the Innovative Health Initiative Joint Undertaking shall hold its ordinary meetings at least twice a year.
- 2. The Chairperson shall convene the meetings of the Governing Board with the support of the Executive Director by sending a written notice (by means of a letter, e-mail, or fax), accompanied by the provisional agenda and the relevant documents for decision-making, to each Board Member and to the Chairperson and Vice-Chairperson of the States' Representatives Group not later than twenty working days prior to each meeting. Any other relevant material for the meeting shall be sent not later than five working days before the meeting. The provisional agenda shall be sent to the Chairperson of the Science and Innovation Panel.
- If an extraordinary meeting is requested, or in case of urgency, some documents may be forwarded to the Board Members and the relevant observers at a shorter notice, taking into account internal consultation procedures of each of the Members of the Innovative Health Initiative JU.
- 4. The Governing Board may hold extraordinary meetings upon request submitted to the Chairperson of the Governing Board by the Executive Director or any Board Member.
- 5. When an extraordinary meeting is requested, the Chairperson shall convene the meeting by sending a written notice (by means of a letter, e-mail, or fax), accompanied by the provisional agenda and the relevant documents for decision-making within ten working days from the date of receipt of the request, or as soon as possible in urgent cases.
- 6. Physical meetings shall usually take place at the seat of the Innovative Health Initiative JU.
- 7. Subject to prior written agreement (by means of a letter, fax or email) of the majority of the Board Members, the Chairperson may change the date or place of a meeting of the Governing Board set in the provisional agenda. Notification of such change shall be given to the Board Members no later than ten working days before the original or revised date of the meeting, whichever is earlier.
- 8. The Governing Board meetings may take place by audio conference, video conference or other means of communication. Any meeting held in this manner shall have its minutes taken in accordance with the procedure set out in Article 9.

Article 5 - Attendance

- The Board Members shall attend all meetings of the Governing Board. Board Members shall make their best efforts to ensure adequate level of representation and continuity at Governing Board meetings.
- 2. If a Board Member is not able to attend a meeting, he or she may either participate by means of audio or video conference, or be replaced by the alternate, subject to prior written notification submitted to the Chairperson and the Executive Director not later than the day before the date of the meeting. The secretariat of the Governing Board shall ensure that the alternate has all the relevant documentation to attend the meeting in due time. However, a reiterated attendance in several Governing Board meetings of a Member organisation through its alternates shall be avoided.
- The Executive Director shall attend the Governing Board meetings and deliberations
 without voting rights. The Executive Director may be assisted by other staff of the
 Innovative Health Initiative JU.
- 4. At each meeting of the Governing Board, the attendance list shall be drawn up specifying the Members of the Innovative Health Initiative JU and their representatives, and the bodies and organisations attending the meeting as observers and their representatives.

Article 6 – Agenda

- 1. The provisional agenda shall be drawn up by the Chairperson assisted by the Executive Director and sent to the Board Members and observers in accordance with Article 4. The provisional agenda shall be drawn up taking into consideration the role and tasks to be performed by the Governing Board as defined in Article 17 of the Single Basic Act.
- 2. The provisional agenda shall contain the following items:
 - a. adoption of the agenda;
 - b. adoption or approval of the minutes of the preceding meeting (including audio conference, video conference or any other means of communication) provided the minutes have not been approved or adopted by written procedure;
 - c. items for decision of the Governing Board;
 - d. items for opinion of the Governing Board;
 - e. items for information and discussion;
 - f. any other business.
- 3. The provisional agenda shall specify which items require a vote of the Governing Board.
- 4. The Board Members and the Executive Director may request specific questions to be included in the provisional agenda no later than ten working days before the date of the meeting. Such requests shall be submitted to the Chairperson and to the Executive Director. Not less than seven working days before the date of the meeting, the Chairperson shall issue the final agenda and notify the Board Members and the Executive Director of his or her decision to include or not to include each such additional item or question on the agenda.

- 5. The agenda shall be adopted at the beginning of each meeting.
- 6. With the agreement of the Board Members, urgent questions may be added to the agenda at any time prior to the end of the meeting and items on the agenda may be deleted or carried over to a subsequent meeting.

Article 7 - Quorum

- 1. To ensure the quality of the discussions and the involvement of the members of the Innovative Health Initiative Joint Undertaking, at least 3/4 of the representatives or alternates of the Union, and one representative or alternate per each member other than the Union shall constitute the quorum necessary for the meeting to be valid. Board Members shall inform the Innovative Health Initiative JU about their attendance as soon as possible upon receipt of the provisional agenda.
- 2. In the absence of a quorum, the Chairperson shall submit any pending decisions or opinions for adoption by written procedure as per Article 10, or close the meeting and convene another one as soon as possible.

Article 8 – Voting

- The Board Members shall adopt decisions by consensus to the extent possible.
 Failing consensus, a vote shall be held. In line with Article 16(2) of the Single Basic Act,
 for a vote to be valid, the vote of the Commission and of at least 50% of the private
 members is required.
- 2. A decision shall be deemed adopted by a majority of at least 75% of the votes including the votes of representatives who are absent, but excluding abstentions.
- 3. The Commission shall hold 50% of the voting rights. The vote of the Commission shall be indivisible.
- 4. The votes shall be cast by show of hands or orally unless these Rules of Procedure provide otherwise or if a secret ballot is requested by a Board Member and approved by the Governing Board.
- 5. Each decision adopted by the Governing Board shall be recorded in the minutes. Upon a request by a Board Member, a statement of his or her views may be entered in the minutes together with the decisions taken.
- 6. The Chairperson may ask a Board Member to provide an oral explanation of his or her vote. unless it is a secret ballot.
- 7. A Board Member may be represented by another Board Member, provided the latter submits to the Chairperson the power of attorney given to him or her.

Article 9 - Minutes

- 1. The minutes shall be drawn up at each meeting of the Governing Board by the programme office under the responsibility of the Executive Director. The minutes shall contain the agenda, a summary of the discussions, the decisions taken together with the votes cast, a listing of the items for information, the follow-up actions, and the conclusions, as well as the list of attendance and a list of the decisions taken to be made public as provided for in paragraph 7.
- 2. The draft minutes shall be forwarded to the Board Members not later than ten working days after the meeting.
- 3. The Board Members shall send their written comments to the Chairperson and the programme office no later then seven working days after receipt of the draft minutes. The Board Members who do not provide their comments will be considered to have given their tacit agreement to the minutes.
- 4. The minutes shall be approved by written procedure, as per Article 10, before the next Governing Board meeting or, where necessary, approved during the next Governing Board meeting.
- 5. The minutes shall be signed by the Chairperson. The signed copy of the minutes shall be kept in the archives of the Innovative Health Initiative Joint Undertaking.
- 6. The final text of the minutes shall be made available to the Board Members by electronic means no later than ten working days after the approval or added to the Innovative Health Initiative JU intranet for Governing Board documents no later than ten working days after the approval.
- 7. The list of decisions taken shall be published on the website of the Innovative Health Initiative JU.

Article 10 – Written procedure

- An opinion or decision of the Governing Board can be obtained by written procedure.
 Articles 7 and 8 shall apply as relevant. If at least one Board Member requests that the proposed decision or opinion is examined at a meeting, the written procedure shall be cancelled.
- 2. The Executive Director, upon instructions from the Chairperson, shall send the Board Members the proposed opinion or decision to be taken in accordance with the relevant provisions of Article 16 of the Single Basic Act.
- 3. The Board Members shall approve or reject the opinion or decision by a written reply within seven working days. When justified, the Chairperson in consultation with the Vice-Chairperson may decide to change the reply deadline, taking into account the internal consultation procedures of each Member of the Innovative Health Initiative Joint Undertaking.
- 4. In line with Article 16(2) of the Single Basic Act, for a vote to be valid, the vote of the Commission and of at least 50% of the private members is required. A decision shall be deemed adopted by a majority of at least 75% of the votes including the votes of representatives who are absent, but excluding abstentions.
- 5. The proposal for a decision or opinion to be taken by written procedure shall be approved or rejected in its entirety. If amendments in substance are proposed by any of the Board Members, the decision will need to be submitted again to the Governing Board for approval or rejection of the Board Members.
- 6. The result of a written procedure will be notified without delay to all Board Members.

Article 11 - Confidentiality

- 1. The proceedings of the Governing Board shall be confidential.
- 2. The Board Members and any other persons attending a meeting of the Governing Board shall respect the confidential character of these proceedings and shall protect any sensitive information whose disclosure could damage the interests of the Innovative Health Initiative Joint Undertaking, the Members of the Innovative Health Initiative JU or of the participants in the activities of the Innovative Health Initiative JU.
- 3. Upon appointment, the Board Members shall submit a declaration of confidentiality (Annex I).
- 4. The observers and any other persons attending a meeting of the Governing Board shall sign the declaration of confidentiality enclosed in Annex II, prior to their first participation to a Governing Board meeting.
- The Board Members may decide to examine specific items of the agenda without the presence of the Executive Director or observers due to confidentiality of such specific items.
- 6. The decisions and minutes of the meetings of the Governing Board shall be subject, where justified, to the provisions of Article 33 of the Single Basic Act and the measures taken for its implementation. Therefore, certain decisions may not be published due to the sensitive nature of their contents, without prejudice to Article 34 of the Single Basic Act.

Article 12 - Conflict of interest

- 1. The Board Members shall avoid any conflict of interest in the exercise of their functions.
- 2. A Board Member shall not occupy any of the following positions:
 - a. Representative of the Innovative Health Initiative JU States' Representatives Group:
 - b. Member of the Innovative Health Initiative JU Science and Innovation Panel;
 - Coordinator or scientific leader of an indirect action co-funded by the Innovative Health Initiative JU;
 - d. Expert evaluator of proposals submitted to a call for proposals of the Innovative Health Initiative JU;
 - e. Expert observer of the evaluation of a proposal submitted to a call for proposals of the Innovative Health Initiative JU:
- 3. In accordance with the general principles set in the Commission guidelines on the prevention and management of conflicts of interest in the EU¹, the following measures are applicable:
 - a. Upon appointment, the Board Members shall submit a declaration of conflict of interests (Annex III), which will be renewed every year or every time changes in personal and/or professional circumstances of the Board Member require an update.

¹ Commission Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies, adopted 10 December 2013

- b. The observers and any other person attending the Governing Board meetings shall sign the declaration of conflict of interest (Annex II) prior to their first participation to a Governing Board meeting.
- c. During a meeting, any attendee whose participation in the work of the Governing Board leads or may lead to a conflict or potential conflict of interest with regard to a particular agenda item shall, without delay, inform the Chairperson who shall, without delay and before any affected deliberation is taken, propose on any specific measure in this respect, taking due account of the rules adopted by the Governing Board pursuant to Article 42 of the Single Basic Act.
- d. The Governing Board or the Chairperson may decide to examine and take a decision on specific items of its agenda without the presence of the Board Members whose participation may lead to conflict of interest with regard to a particular agenda item. A request for application of the preceding paragraph, addressed to the Chairperson, may be submitted by any Board Member and must be justified. The Chairperson shall present such request and the associated justification at the opening of the meeting and the Governing Board will decide in accordance with Article 8. Measures should be put in place to ensure quorum as per Article 7 above, allowing participating to the meeting of an alternate or, should the alternate have the same risk of conflict of interests, the quorum will be exceptionally considered met without the presence of this specific Governing Board Member.
- e. Should the Governing Board or the Innovative Health Initiative JU become aware that a conflict of interest was not declared by a Board Member, the Governing Board shall decide on the appropriate measures to be taken after hearing the affected Board Member.
- 4. Further detailed rules shall be set out in a subsequent Governing Board decision in line with Article 42(2) of the Single Basic Act.

Article 13 – Conduct of Governing Board Members

- 1. The Board Members must ensure that the integrity and reputation of the Innovative Health Initiative JU and of the Union are safeguarded.
- 2. They shall behave and perform their duties in compliance with the principles and the rules laid down in a Code of Conduct to be adopted by the Governing Board in a subsequent decision in line with Article 16(11) of the Single Basic Act.

Article 14 – Reimbursement of expenses

- 1. Each Member of the Innovative Health Initiative Joint Undertaking shall bear all travel and subsistence expenses incurred by their representatives or their respective alternates in connection with meetings of the Governing Board.
- 2. The Governing Board may define cases where the Innovative Health Initiative JU shall bear the travel and subsistence expenses incurred by observers invited by the Governing Board to its meetings, provided that such observers are not affiliated to any Member of the Innovative Health Initiative JU.
- 3. The reimbursement of travel and subsistence expenses shall be done in accordance with the Commission Rules on the reimbursement of expenses incurred by people from outside the Commission invited to attend meetings in an expert capacity (C(2007)5858).

4. The reimbursement of travel and subsistence expenses of the Chairperson and Vice-Chairperson of the States' Representatives Group and the Chairperson of the Science and Innovation Panel are reimbursed in accordance with the Rules of Procedure of the respective governance body.

Article 15 – Working and advisory groups

- 1. The Governing Board may choose to structure its work in the most appropriate way by establishing working or advisory groups.
- 2. Each working or advisory group shall elect a lead person by simple majority of its members. Each member shall have one vote. Each member of the Innovative Health Initiative Joint Undertaking shall be represented in each working or advisory group. Other staff of the Innovative Health Initiative Joint Undertaking may attend the meetings of the working or advisory groups.
- 3. The lead persons of the working or advisory groups shall report to the Governing Board.

Article 16 - Correspondence

- 1. All correspondence addressed to the Governing Board shall be sent to the seat of the Innovative Health Initiative JU.
- Electronic communications related to Governing Board matters addressed to the Innovative Health Initiative JU shall be sent to the secretariat with a copy to the Chairperson.
- 3. Electronic communications related to Governing Board matters addressed to a Member of the Innovative Health Initiative JU shall be sent to all representatives of that Member of the Innovative Health Initiative JU.
- 4. All correspondence shall be written in English and sent either by post or by e-mail, unless agreed otherwise between a Board Member and the secretariat.

Article 17 – Amendment of the Rules and Procedures

- 1. A Board Member may propose to amend these Rules of Procedure.
- 2. The Rules of Procedure shall be amended following approval by decision of the Governing Board.
- 3. Amendments to these Rules of Procedure shall enter into force the day of their adoption by the Governing Board.

Article 18 - General provisions

These Rules of Procedure and its amendments shall be published on the Innovative Health Initiative JU website.

Article 19 – Entry in force

These Rules of Procedure shall enter into force on the day of their adoption by the Governing Board.

ANNEX I – [MODEL] DECLARATION OF CONFIDENTIALITY FOR THE INNOVATIVE HEALTH INITIATIVE JOINT UNDERTAKING GOVERNING BOARD MEMBERS

Name:
E-mail:
Position:
[] Chairperson of the Governing Board
[] Representative/lead delegate/alternate of the Commission
[] Representative/lead delegate/ alternate of []
[] Other (please specify)
I hereby undertake to act in the performance of my duties in the general interest of the Innovative Health Initiative Joint Undertaking.
I undertake to ensure the confidentiality of sensitive information whose disclosure could damage the interests or the reputation of the Innovative Health Initiative JU, the Members of the Innovative Health Initiative JU or of the participants in the activities of the Innovative Health Initiative JU.
I shall not disclose sensitive information learned during the activities of the Innovative Health Initiative JU even after my duties have ended.
Done at [place], [date]
Name and Signature

ANNEX II – [MODEL] DECLARATION OF CONFIDENTIALITY AND CONFLICT OF INTEREST FOR THE ATTENDEES OF THE INNOVATIVE HEALTH INITIATIVE JOINT UNDERTAKING GOVERNING BOARD MEETINGS

Name:
E-mail:
Position:
[] Chairperson of the Governing Board
[] Representative/lead delegate/alternate of the Commission
[] Representative/lead delegate/ alternate of []
[] Other (please specify)
I hereby undertake to act in the performance of my duties in the general interest of the Innovative Health Initiative Joint Undertaking.
At each meeting of the Governing Board or before any decision is taken by written procedure, I shall declare any interest which might be considered to influence or bias my judgment and therefore be prejudicial to the way an item on the agenda is handled.
I undertake to ensure the confidentiality of sensitive information whose disclosure could damage the interests or the reputation of the Innovative Health Initiative JU, the Members of the Innovative Health Initiative JU or or the participants in the activities of the Innovative Health Initiative JU.
I shall not disclose sensitive information learned during the activities of the Innovative Health Initiative JU ever after my duties have ended.
Done at [place], [date]
Name and Signature

ANNEX III – [MODEL] DECLARATION OF CONFLICT OF INTERESTS FOR THE INNOVATIVE HEALTH INITIATIVE JOINT UNDERTAKING GOVERNING BOARD MEMBERS

E-mail:
Position:
[] Chairperson of the Governing Board
[] Representative/lead delegate/alternate of the Commission
[] Representative/lead delegate/ alternate of []
[] Other (please specify)
do hereby declare on my honour that, to the best of my knowledge, the only direct or indirect interests I have in the [pharmaceutical, medical technology, biotechnology, digital health, vaccines, etc] sector[s] [are][is] those

1 Past activities:

listed below:

Name:

[posts held over the last 5 years in foundations or similar bodies, educational institutions, companies or other organisations (the nature of the post and the name of those bodies should also be indicated); other membership/affiliation or professional activities held over the last 3 years, including services, liberal professions, consulting activities, and relevant public statements.]

2. Current activities:

[posts held in foundations or similar bodies, educational institutions, companies or other organisations (the nature of the post and the name of those bodies should also be indicated); other membership/affiliations or professional activities, including services, liberal profession, consulting activities, and relevant public statements.]

3. Current Financial Interests

[Above a certain minimum threshold [xxx], any direct financial interests, (managerial stakes in companies, including ownerships of patents or any other relevant intellectual property rights), or assets (shares and/or securities held in companies) or grants or other funding which might create a conflict of interests in the performance of their duties, with an indication of their number and value, as well as the name of the company/provider of the grant/funding.]

[No Interest Declared]/ [Interest...]

4. Any other relevant interests.

[No Interest Declared]/ [Interest...]

5. Family Member Interest

[Spouse's/partner's/dependent family members' current activity and financial interests that might entail a risk of conflict of interest.]

[No Interest Declared]/ [Interest...]

I confirm the information declared on this form is accurate to the best of my knowledge and I consent to my information being stored electronically by the Innovative Health Initiative Joint Undertaking.

Furthermore, at each meeting of the Governing Board or before any decision is taken by written procedure, I shall declare any interest which might be considered to influence or bias my judgment and therefore be prejudicial to the way an item on the agenda is handled.

Done at [place], [date]

Name and Signature

