

**DECISION OF THE GOVERNING BOARD
OF THE INNOVATIVE MEDICINES INITIATIVE 2 JOINT UNDERTAKING
ADOPTING THE GOVERNING BOARD RULES OF PROCEDURE**

THE GOVERNING BOARD OF THE INNOVATIVE MEDICINES INITIATIVE 2 JOINT UNDERTAKING,

Having regard to Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking

HAS ADOPTED THESE RULES OF PROCEDURE:

Article 1

Members of the Governing Board

1. The Governing Board shall be composed of five representatives per Member of IMI2 Joint Undertaking as defined in Article 2 of the statutes annexed to Council Regulation (EU) No 557/2014.
2. The names and functions/posts of the representatives shall be published on the IMI2 Joint Undertaking website.
3. Each representative may have one or more appointed alternates.
4. Each Member of the IMI2 Joint Undertaking may decide the term of office of its representatives in accordance with its internal rules. If the office of a representative falls vacant, the respective Member of IMI2 Joint Undertaking shall appoint a new representative for the remainder of the term of office.
5. Members of the IMI2 Joint Undertaking shall notify appointments, substitutions or removals of representatives and their respective alternates to the IMI2 Joint Undertaking 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 the date on which the notice is received by the IMI2 Joint Undertaking.
6. Hereinafter, the representatives shall be collectively referred to as the Board Members; the representatives of the Commission as Commission Board Members; and the representatives of Private Members as Private Board Members.



Article 2
Chairperson and Deputy Chairperson

1. The Governing Board shall elect a Chairperson and a Deputy Chairperson from among the Board Members. The Chairperson of the Governing Board shall be appointed on a rotating annual basis by the Union and the other Members.
2. The first election of the Chairperson shall take place in a meeting after the Governing Board adopts the present Rules of Procedure. Members of the IMI2 Joint Undertaking represented in the Governing Board shall communicate their nominated candidates for the election of the Chairperson and/or Deputy Chairperson to the Executive Director at least ten working days before the meeting of the Governing Board. The office of Chairperson and Deputy Chairperson shall not be occupied by representatives of the same Member of the IMI2 Joint Undertaking. The Chairperson shall be elected 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 Deputy Chairperson shall be elected following the same procedure.
3. The Chairperson and Deputy Chairperson shall be elected for a period of one year and as long as they are a Board Member.
4. The Chairperson and Deputy Chairperson terms of office shall begin at the meeting of the Governing Board that elects them. The Chairperson shall be appointed on a rotating basis by each the Union and the other Members, in turn. The Deputy Chairperson shall be appointed the same way. Until the Chairperson is elected, the oldest Board Member present shall act as Interim Chair.
5. The Deputy Chairperson shall take the place of the Chairperson if the latter is prevented from attending to his/her duties.
6. The outgoing Chairperson shall remain on duty until a new Chairperson is elected, except if he/she ceases to be a Board Member in which case the Deputy Chairperson shall take the place of the Chairperson as provided in Article 2(5) of these Rules of Procedure. If the Deputy 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 Deputy Chairperson shall convene a meeting of the Governing Board to elect a successor. If the office of the Deputy 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 Deputy 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. The Chairperson of the States Representatives Group shall have the right 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 Chairperson of the Scientific Committee 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.
3. The Governing Board shall invite any Associated Partner, as defined in Article 6(2) of the statutes annexed to Council Regulation (EU) No 557/2014, to take part in its deliberations for those points on the agenda that concern its association. Associated Partners shall have no voting rights.
4. 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 of the Union. These observers shall have no voting rights.
5. 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 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, to the Chairperson of the States Representatives Group not later than twenty working days prior to each meeting. The agenda shall be sent to the Chairperson of the Scientific Committee. Any other relevant material for the meeting shall be sent five working days before the meeting. The agenda shall be sent to the Chairperson of the Scientific Committee.
3. 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 IMI2 Joint Undertaking.
4. The Governing Board may hold extraordinary meetings upon request submitted to the Chairperson of the IMI2 Joint Undertaking by:
 - (a) a Member, or
 - (b) the Chairperson.

The Executive Director being the chief executive responsible of the day-to day management of the IMI2 Joint Undertaking, he/she may request to the Chairperson to hold extraordinary meetings.

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. Meetings shall usually take place at the seat of the IMI2 Joint Undertaking.
7. Subject to prior written agreement (by means of a letter, fax or email) of the majority of the Board Members with the positive vote of the Commission representatives, 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 ordinary procedure. Any decisions taken by the Governing Board during such meetings shall only be valid and effective when the minutes of the meetings are approved by each Board Member.

Article 5
Attendance

1. The Board Members shall attend all meetings of the Governing Board. Efforts shall be made by the Board Members 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/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 organization through its alternates shall be avoided.
3. The Executive Director shall have the right to participate in the Governing Board meetings and deliberations without voting rights. The Executive Director may be assisted by other staff of the IMI2 Joint Undertaking.
4. At each meeting of the Governing Board, the attendance list shall be drawn up specifying the Members of the IMI2 Joint Undertaking 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 of these Rules of Procedure. The agenda shall be drawn up taking into consideration the role and tasks to be performed by the Governing Board as defined in the Council Regulation (EU) No 557/2014.
2. The provisional agenda shall contain the following items:
 - (a) adoption of the agenda;
 - (b) adoption/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/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 on the provisional agenda no later than ten working days before the date of the meeting. Such requests shall be submitted in writing to the Chairperson and in copy to the secretariat of the Governing Board. 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 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 Governing Board, 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 IMI2 Joint Undertaking, at least three representatives or alternates of each of the Members of the IMI2 Joint Undertaking shall constitute the quorum necessary for the meeting to be valid. Board Members shall inform the IMI2 Joint Undertaking about their attendance as soon as possible upon receipt of the provisional agenda.
2. In the absence of a quorum, the Chairperson shall search an alternative solution such as adopting a decision or an opinion by written procedure or closing the meeting and convening another one as soon as possible.

Article 8

Voting

1. The Board Members will work together in the spirit of collaboration and for the benefit of all stakeholders. The Board Members shall use their best efforts to achieve consensus. Failing consensus, the Governing Board shall take its decisions by a majority of at least 75% of all votes, including the votes of the Board Members who are not in attendance. The Chairperson shall not have a casting vote.
2. Without prejudice to Article 6(2) of the statutes annexed to Council Regulation (EU) No 557/2014, each Member shall have a percentage out of 100 voting rights corresponding to the percentage of its contribution to the IMI2 Joint Undertaking. The Commission shall hold 50% of the voting rights. The vote of the Commission shall be indivisible. Each Member may allocate its voting rights among its representatives in the Governing Board.
3. The votes shall be cast by show of hands or orally unless these Rules provide otherwise or if a secret ballot is requested by a Board Member and approved by the Governing Board.
4. Each decision adopted by the Governing Board shall be recorded in the minutes. Upon a request by a Board Member, a statement of his/her views may be entered in the minutes together with the decisions taken.
5. The Chair may ask a Board Member to provide an oral explanation of his/her vote, unless it is a secret ballot.
6. A Board Member may be represented by another Board Member, provided the latter submits to the Chairperson the power of attorney given to him.

Article 9

Minutes

1. The minutes shall be drawn up at each meeting of the Governing Board by a secretary placed 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 casted, a listing of the items for information, the follow-up actions, and the conclusions, as well as a 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 secretariat not later than fifteen 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 before the next Governing Board meeting.

5. The minutes shall be signed by the Chairman. The signed copy of the minutes shall be kept in the archives of the IMI2 Joint Undertaking.
6. The final text of the minutes shall be forwarded to the Board Members by email with acknowledgement of receipt no later than ten working days after the approval; and/or added to the IMI2 Joint Undertaking intranet for Governing Board documents no later than ten working days after the approval.
7. The list of decisions taken shall be made public and published on the website of the IMI2 Joint Undertaking.

Article 10
Secretariat

The Executive Director shall provide the secretariat and the appropriate administrative support to enable the Governing Board to carry out its work.

Article 11
Written procedure

1. An opinion or decision of the Governing Board can be obtained by written procedure. 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 Article 16 of these Rules of Procedure.
3. The Board Members shall approve or reject the opinion or decision by a written reply within twenty working days. In matters of extreme urgency, the Chairperson in consultation with the Deputy Chairperson may decide to shorten the reply deadline, taking into account the internal consultation procedures of each Member of the IMI2 Joint Undertaking.
4. Any Board Member who does not vote within the deadline is considered to abstain from voting.
5. The proposal for a decision or opinion to be taken by written procedure shall not be subject to amendments in substance. The proposal shall be approved or rejected in its entirety. If the proposal is rejected, it may be included in the agenda of the next Governing Board meeting at the request of any Board Member.
6. The result of a written procedure will be notified without delay to all Board Members.

Article 12
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 IMI2 Joint Undertaking, the Members of the IMI2 Joint Undertaking and/or of the participants in the activities of the IMI2 Joint Undertaking.

3. The observers and any other persons attending a meeting of the Governing Board shall sign the enclosed declaration of confidentiality and conflict of interests.
4. The Governing Board 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.
5. The decisions and minutes of the meetings of the Governing Board shall be subject to the provisions of Article 15 of the Regulation (EU) No 557/2014 and the measures taken for its implementation.

Article 13
Conflict of interest

1. A Board Member shall not occupy any of the following positions:
 - (a) Representative of the IMI2 Joint Undertaking States Representatives Group;
 - (b) Member of the IMI2 Joint Undertaking Scientific Committee;
 - (c) Coordinator of an indirect action funded by the IMI2 Joint Undertaking;
 - (d) Expert evaluator of proposals submitted to a call for proposals of the IMI2 Joint Undertaking;
 - (e) Expert observer of the evaluation of a proposal submitted to a call for proposals of the IMI2 Joint Undertaking;
 - (f) Monitor of an indirect action funded by the IMI2 Joint Undertaking.
2. 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 and all attendees to the Governing Board meetings shall sign the enclosed declaration of confidentiality and conflict of interest. The Board Members shall submit a declaration of interests every year.
 - (b) The Governing Board 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.
 - (c) A request for application of the preceding paragraph, addressed to the Chairperson may be submitted by any Board Member no later than the day before the meeting and shall be motivated. The Chairperson shall present such request and the associated justification at the opening of the meeting

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

and the Governing Board will decide in accordance with Article 8 of these Rules of Procedure.

- (d) 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 decide on any specific measure in this respect.
- (e) Upon proposal by the Chairperson, the Governing Board may decide to examine such items of the agenda without the presence of the attendee concerned.
- (f) Should the Governing Board or the IMI2 Joint Undertaking 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.

Article 14

Reimbursement of expenses

1. Each Member of the IMI2 Joint Undertaking shall bear all travel and subsistence expenses incurred by its representative(s) or their respective alternates in connection with meetings of the Governing Board.
2. The Governing Board may define cases where the IMI2 Joint Undertaking 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 IMI2 Joint Undertaking.
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).

Article 15

Working groups

1. The Governing Board may choose to structure its work in the most appropriate way by establishing working groups to be adopted by the Governing Board.
2. Each working group shall elect a lead person by simple majority of its members. Each member has one vote. The Commission and the IMI2 Joint Undertaking shall be represented at each working group.
3. The lead persons of the working groups shall report back to the Governing Board.

Article 15bis

Appointing authority powers, appointment and dismissal of the Executive Director

1. The Board shall exercise the appointing authority powers with respect to staff of the IMI2 Joint Undertaking.

The Board shall adopt a decision delegating the relevant appointing authority powers to the Executive Director in accordance with Article 6 (2) of the Regulation 557/2014.

2. The Board shall appoint the Executive Director and shall have the power to dismiss the Executive Director, in accordance with Clauses 7 (3)(f) and 8 of the Statutes of the Regulation 557/2014, and in accordance with the Staff Regulations.

Article 16

Correspondence

1. All correspondence addressed to the Governing Board shall be sent to the seat of the IMI2 Joint Undertaking.
2. Electronic communications related to Governing Board matters addressed to the IMI2 Joint Undertaking 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 IMI2 Joint Undertaking shall be sent to all representatives of that Member of the IMI2 Joint Undertaking.
4. All correspondence shall be written in English and sent by electronic means, preferably by email, unless agreed otherwise between a Board Member and the secretariat.

Article 17

Amendment of Rules of Procedure

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

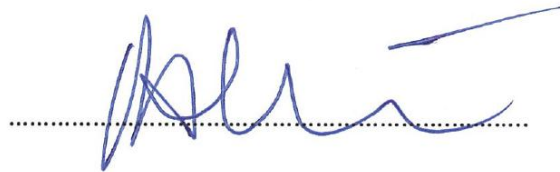
These Rules of Procedure and its amendments shall be published on the IMI2 Joint Undertaking website.

Article 19
Entry into force

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

Done at Brussels, on ...7/7/2014...

For the Governing Board of the Innovative Medicines Initiative 2
Joint Undertaking



Roch Doliveux

Chair of the Governing Board



Innovative Medicines Initiative

IMI2-GB-DEC-2014-1 Annex I

**ANNEX I
DECLARATION OF CONFIDENTIALITY AND CONFLICT OF INTEREST FOR THE ATTENDEES OF
THE IMI2 JOINT UNDERTAKING GOVERNING BOARD MEETINGS**

Name:

Professional Address:

Phone:

E-mail:

Position:

- Chairperson or Deputy Chairperson of the Governing Board
- Representative/lead delegate/alternate of the Commission
- Representative/lead delegate/ alternate of [...]
- 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 IMI2 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 IMI2 Joint Undertaking, the Members of the IMI2 Joint Undertaking or of the participants in the activities of the IMI2 Joint Undertaking.

I shall not disclose sensitive information learnt during the activities of the IMI2 Joint Undertaking even after my duties have ended.

Done at [place], [date]

Name and Signature



efpia

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**ANNEX II
DECLARATION OF INTERESTS FOR THE IMI2 JOINT UNDERTAKING GOVERNING BOARD
MEMBERS**

Name:

Professional Address:

Phone:

E-mail:

Position:

- Chairperson or Deputy Chairperson of the Governing Board
- Representative/lead delegate/alternate of the Commission
- Representative/lead delegate/ alternate of [...]
- 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 sector [are][is] those listed below:

1 Past activities:

Posts held over the last 7 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

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 IMI2 Joint Undertaking.

Done at [place], [date]

Name and Signature