

Rules of procedure of the Scientific Committee of the Innovative Medicines Initiative 2 Joint Undertaking

Article 1. Role and Tasks

The Scientific Committee is an advisory body to the Governing Board of the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU).

The specific tasks of the Scientific Committee are outlined in Article 10 of the Statutes of the IMI2 JU and reads as follows:

- a. Advise on the scientific priorities to be included in the Strategic Research Agenda taking into account related activities in Horizon 2020;
- b. Advise on the scientific priorities to be addressed in the annual work plans;
- c. Advise on the scientific achievements described in the annual activity report.

The members of the Scientific Committee should provide consistent and consolidated advice in writing at the request of the IMI2 JU.

Article 2. Composition

The Scientific Committee consists of no more than 11 members appointed for a renewable period of two years.

The members of the Scientific Committee are appointed by IMI2 JU Governing Board according to the procedure of Article 10.3 of Regulation (EU) 557/2014. They are selected following the specific criteria and selection process established by the Governing Board.

Selection of new members and renewal shall follow the same procedure.

Additional experts may be appointed if necessary for specific ad-hoc tasks and limited duration. They shall be selected following the same procedure as that applicable to the permanent members of the Scientific Committee.

The members of the Scientific Committee shall reflect a balanced representation of worldwide recognised experts from academia, industry and regulatory bodies. Collectively, the members of the Scientific Committee shall have the necessary scientific competencies and expertise covering the technical domain needed to make strategic science-based recommendations to the IMI2 Joint Undertaking.

Members participate in the Scientific Committee in their individual capacity and commit themselves to discuss questions put forward and provide advice in their relevant fields of expertise to the best of their ability and in the best interest of the IMI2 JU.

The Scientific Committee shall conduct its activities in close liaison, and with the support of, the IMI2 JU Programme Office as set out in Article 9.

Article 3. Chair and Vice-Chair

A Chair and a Vice-Chair shall be elected by consensus of the Scientific Committee from among its members. The Chairperson tasks consist of:

- Proposing a planning of activities
- Chairing the meetings and moderating the discussions of the Scientific Committee
- Drawing up the agenda of each meeting in consultation with the Vice-Chair, based on a proposal from the IMI2 JU Executive Director
- Reviewing the minutes of the meetings that are prepared by the IMI2 JU programme office, before they are approved by the committee
- Reporting and providing the consolidated advice of the Scientific Committee to the Governing Board
- Representing the Scientific Committee at external meetings and events

The Chairperson of the Scientific Committee shall have the right, whenever issues falling within the tasks of the Committee are discussed, to attend meetings of the Governing Board as an observer and take part in its deliberations, but shall have no voting rights.

The Chairperson can delegate all or part of the tasks on an ad hoc basis to the Vice-Chair or in case this is not possible to another member of the Scientific Committee.

Should the Chair be unable to execute his/her duties, the Vice-Chair takes over the responsibilities of the Chair until a new election procedure takes place.

Article 4. Meetings

The Scientific Committee shall meet at least twice a year. Meetings shall be convened by the Chair. Notifications shall be sent out by the IMI2 JU Executive Director at least twenty-five calendar days before the proposed date.

The meetings shall normally take place in Brussels at the seat of the IMI2 Joint Undertaking.

A quorum of two thirds (2/3) of its members and the participation of the Chair or of the Vice-Chair is required for each meeting.

Additional meetings can be convened at the request of the Chair or Vice-Chair of the Scientific Committee, the Governing Board or the Executive Director.

The agenda and the minutes from the previous meeting shall be adopted at the beginning of each meeting. At request of any member and with the consensus of the Committee, urgent questions may be added to the agenda at any time prior to the end of the meeting.

Any items on the agenda may be deleted or carried over to a subsequent meeting.

The Chair can invite other persons to take part in a meeting as observers, on his/her initiative or following a proposal of the IMI2 JU's Executive Director.

The IMI2 JU Secretariat for the Scientific Committee will draft the minutes of the meetings and will finalise them following the approval by the Scientific Committee (below Article 10).

The IMI2 JU Executive Director and/or other staff of the Programme Office as well as representatives of the Members of the IMI2 Joint Undertaking may attend the meetings of the Scientific Committee as observers.

Article 5. Advice

The Scientific Committee shall provide its advice to the IMI2 JU Governing Board in written form.

Advice to the IMI2 JU is the result of discussions within the Scientific Committee. The advice of the Scientific Committee shall be achieved by consensus. However, in the event that a consensus cannot be found, for whatever reason, individual members may request to have divergent views recorded.

The Scientific Committee will be informed by the IMI2 JU Programme office on input from other groups of relevance to the IMI2 JU including the IMI State Representative Group and the Stakeholder forum.

The advice may take account of documents provided to the Scientific Committee by the IMI2 JU Programme Office.

The members of the Scientific Committee may be consulted by email when the urgency of the matter so requires. An email consultation shall be carried out by the IMI2 JU Executive Director on the request of the Chairperson. The representatives shall give their opinion within fourteen calendar days from the reception of the consultation request. The Chairperson may shorten this period in the event of particular urgency, but not to less than 4 working days.

Article 6. Transparency

The IMI2 JU will make public the names of the members of the Scientific Committee on the IMI2 JU web site.

The Scientific Committee's advices shall be subject to the provisions of Article 16 of the Regulation (EU) 557/2014 and measures taken for its implementation. They shall be published on the IMI2 Joint Undertaking's web site unless the IMI2 JU Governing Board decides otherwise.

Without prejudice to Article 16 of the Regulation (EU) 557/2014, representatives and other participants at meetings of the Scientific Committee shall respect the confidential character of the discussions of the Scientific Committee.

Article 7. Confidentiality and Conflict of interest

Without prejudice to Article 339 of the Treaty on the Functioning of the European Union, members of the Scientific Committee are required not to divulge information given in the context of the work, unless it has been indicated that the information is public.

Members of the Scientific Committee, observers and experts shall sign confidentiality agreements and declarations of conflict of interest prior to their first attendance to Scientific Committee meetings. [Annex 1: Declaration of confidentiality and conflict of interest for the IMI2 JU Scientific Committee members]. The declaration on conflict of interest shall be updated before subsequent attendances to Scientific Committee meetings, whenever relevant.

Members of the Scientific Committee must not seek or act in any way to take undue advantage of, or exercise undue influence on, the implementation of the IMI2 JU.

Therefore members of the IMI2 JU Scientific Committee should not be involved in any way in the evaluation or selection of proposals for funding under the IMI2 JU.

Members of the Scientific Committee may participate in consortia under the IMI2 JU, either in their personal capacity or as representative of the organisations to which they belong. However, should any item on the agenda or any subject discussed in a given meeting of a Scientific Committee be of relevance for projects or proposals under the IMI2 JU that a member, or the organisation to which he/she belongs, has submitted or is

likely to submit, the member should inform the IMI2 JU and the Scientific Committee of the situation. He/she can be requested to abstain from the deliberations and/or leave the room for the discussion of the concerned item/subject.

Members of the Scientific Committee must inform the IMI2 JU of all interests, not explicitly stated above, which could be considered prejudicial to their independence.

During a meeting any attendee whose participation in the work of the Scientific Committee leads or may lead to a conflict of interest with regard to a particular agenda item shall without delay inform the Chairperson who shall without delay and before any discussion is initiated decide on any specific measure in this respect.

Upon proposal by the Chairperson, the Scientific Committee may decide to examine such an item without the presence of the attendee concerned.

When a member of the Scientific Committee is in breach of the requirements set out above, he/she will be considered as no longer being in a position to remain as a member of the group.

Article 8. Reimbursement of costs

Travel and subsistence expenses will be reimbursed according to the rules set out by Decision of the Executive Director.

Article 9. Secretariat and administrative support

The IMI2 JU Programme Office shall provide the Secretariat and the appropriate administrative support to enable the Scientific Committee to carry out its work.

It shall assist the Scientific Committee in its operation through drafting and circulating agendas, meeting summaries and related documents. Where appropriate and requested, the Secretariat may collect and/or circulate information of potential interest to the Scientific Committee, in time for the next meeting.

All correspondence with the IMI2 JU Scientific Committee shall be addressed to the seat of the IMI2 Joint Undertaking.

To facilitate communication and efficient work all documents should be made available on a confidential internal website, where the members have access and may upload and download the documents of interest. The necessary operational procedures (password protection) are organised by the IMI2 JU Programme Office. An alert-service shall be implemented to make the members aware of any news.

Article 10. Entry into force

These Rules of Procedure shall come into force upon the adoption by consensus by the Scientific Committee. They may be amended at any time upon the request of the Chairperson.

The Rules of Procedure cannot contradict the IMI2 JU Regulation and annexed Statutes and they cannot have budget implications.

Annex 1

Confidentiality and non-conflict of interest declaration - IMI2 JU Scientific Committee Members

The undersigned..... [Name],

..... [Function or Title].

Accepts to participate as a Member of the Innovative Medicines Initiative 2 Joint Undertaking Scientific Committee and hereby, undertakes during and after the course of his/her mandate:

1. To commit him/herself to strict confidentiality with regards to any and all oral or written information pertaining to the work of the Scientific Committee;
2. To declare promptly any conflict of interest that may arise from his/her participation in the Scientific Committee. I will therefore not participate in any discussion on the item, and leave the meeting room accordingly in case of conflict of interest.

I understand that the obligations of non-disclosure set forth above shall not extend to information which are or became publicly known or available through no fault of myself.

Made in Brussels, in two original copies, on

Signed