

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

Approving the Charter of the IMI2 JU Strategic Governing Groups

THE GOVERNING BOARD OF THE INNOVATIVE MEDICINES INITIATIVE 2 JOINT UNDERTAKING (IMI2 JU),

Having regard to Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking and in particular Article 2 thereof;

Having regard to the Statutes annexed to the Council Regulation (EU) No 557/2014 of 6 May 2014 establishing the Innovative Medicines Initiative 2 Joint Undertaking and in particular Articles 1, 7.3(h), (k) and (p) and 9.5(d) and 13.3(b);

Having regard to the Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in 'Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)' and in particular Title II;

Having regard to the Governing Board Rules of Procedure approved by the IMI2 Governing Board by Decision n° IMI2-GB-DEC-2014-1 of 7 July 2014 and in particular Article 15 thereof.

Whereas,

- (1) The Governing Board approved the Charter of the IMI2 JU Strategic Governing Groups (SGG) annexed to its Decision n° IMI2-GB-DEC-2014-2 of 7 July 2014 setting up the first groups.
- (2) Taking into account experience to date on the SGG operations, the Charter need to be revised to provide clarity on the input on priorities, topics and budgets, as well as on IMI Programme Office's role in supporting the groups.

HAS ADOPTED THE FOLLOWING DECISION:

Article 1

The Governing Board approves the Charter of the IMI2 Strategic Governing Groups annexed to this Decision.

Article 2

1. This Decision shall enter into force on the day following its adoption by the Governing Board of the IMI2 JU.
2. It repeals and replaces the previous approved Charter annexed to the Governing Board Decision n° IMI2-GB-DEC-2014-2 of 7 July 2014.

Brussels, on 30 September 2016

For the Governing Board of the Innovative Medicines Initiative 2 JU



Marc de Garidel
Chair of the Governing Board

Annex: Charter of the IMI2 JU Strategic Governing Groups

Charter of the IMI2 JU Strategic Governing Groups

Rationale

While long-term initiatives such as Joint Undertakings offer significant opportunities to leverage engagement and significant resources in a sustainable way, their full potential will only be exploited with identifying critical projects and good planning, management and coordination across all programmes and projects. Therefore, in line with Article 7.3.p of the Regulation establishing the Innovative Medicines Initiative 2 Joint Undertaking (IMI2 JU), the Governing Board decided to set up advisory groups named Strategic Governing Groups (SGGs). These are conceived as thematic platforms addressing defined areas under the umbrella of the IMI2 JU Strategic Research Agenda.

Objectives

- Provide orientations for an efficient translation of the IMI2 JU Strategic Research Agenda and develop a coordinated strategy for selected diseases which will lead into annual strategic priorities, and recommendations for high quality and concrete call topics, taking into account proposals from industry, Associated Partners and third parties;
- Enhance scientific priority definition, project idea maturation and budget commitment processes into concrete proposals that can be developed into formal Call topics through the established IMI processes;
- Provide strategic coordination within and across portfolios of IMI1/IMI2 projects and programmes;
- Ensure synergies with projects and initiatives outside IMI2 JU, in particular with the EU funded projects/programme;
- Advise on strategies for sustainability of resources generated, and for exploitation of results into translation, regulatory and/or medical practice.

Tasks

Without prejudice to the tasks and responsibilities of the standing IMI2 JU governance and advisory bodies and IMI2 JU processes, the Strategic Governing Groups will:

- Elaborate advise to the IMI2 JU Governing Board on:
 - a. Scientific portfolio strategy, annual scientific priorities for inclusion into Annual work plans for selected disease or/and thematic areas.
 - b. Topics and programmes, as well as the type of call process that is most suitable and effective.
 - c. Outreach to/consultation with the scientific, patients communities, etc.
 - d. Sustainability of resources generated, and further exploitation of results.
 - e. Mechanisms for effective coordination within and across portfolios.
- As well as:
 - a. Evaluate and assess impact of programmes and projects in light of evolving science and environment as well as on the basis on key milestones.
 - b. Formulate recommendations to expand or end activities.
 - c. Seek synergies and complementarities within IMI (e.g. across projects within the SGGs, across SGGs, or other non-SGG project ideas) and with other similar European and global initiatives.

Composition

- For conducting the tasks above, SGG participants shall be:
 - a. Representatives of the IMI2 JU Members, as nominated by these Members: Senior representatives from EFPIA companies active or interested in the area covered by the scope of the SGG and representatives from the European Commission.
 - b. IMI2 JU Scientific Officers, nominated by the IMI2 JU Executive Director.

- c. Representatives from the Scientific Committee, acting ex officio, nominated by the Scientific Committee.
 - d. Representatives from IMI2 JU Associated Partners, that intend to contribute to IMI2 JU activities in the domain of the SGG.
 - e. Any ad hoc expert as agreed by the SGG, contributing to part of the SGG activities and necessary to provide information and advice.
 - f. Any other ad hoc expert as proposed by the IMI2 JU Governing Board.
- For operational efficiency reasons, the number of participants will be kept to the necessary minimum.
 - The names of companies represented in the SGG and other members, names of chairs and of operational/ administrative support will be disclosed on the IMI website.

Operating procedures

- Strategic Governing Groups will be set up for a time frame necessary for achieving their objectives.
- The work of EFPIA companies and of Associated Partners in the SGGs can be counted as in kind contributions (Article 13.3(b) of the Regulation establishing IMI2 JU), including:
 - a. EFPIA and Associated Partners' contributions to the SGGs work, chairmanship and coordination;
 - b. Meetings, conferences and logistics;
 - c. Document preparation and production;
 - d. Communication material preparations and dissemination within or outside the SGG;
 - e. Cost of any other activity that directly supports the SGG objectives as set out above, including for work during the period of idea generation and development of call topics, until the launch of the formal Scientific Committee and States Representatives Group consultation.
- SGGs will meet typically 3 to 4 times a year (if appropriate, via webinar or teleconferences).
- The SGGs might propose to the IMI2 JU Programme Office to organize workshops, webinars or surveys to consult the wider scientific community on specific questions or topics.
- Each SGG will be supported by the IMI2 JU Programme Office for:
 - a. Topics development;
 - b. Guidance on IMI2 JU rules and procedures;
 - c. Information and enforcement of timelines;
 - d. IT platform for knowledge sharing;
 - e. Confidentiality and conflict of interest rules as described in section 3;
 - f. Reporting;
 - g. Facilitating interactions and synergies between different SGGs;
 - h. Communication about SGG activities.

Reporting to IMI2 JU Governing Board

- Each SGG will directly report to the Governing Board at least once a year. Reports, including recommendations, should be addressed to the IMI2 JU Governing Board, and will also be communicated to the Scientific Committee and to the States Representatives Group and may be published on the IMI website.
- The reporting will cover:
 - Input on the scientific priorities to be included in the IMI2 JU Annual Work Plans;
 - Recommendations on calls and topics;
 - Input on engagement with the scientific community, exploitation and impact of results (in particular socio-economic impact) in view of the IMI2 JU Annual Activity Reports preparations;
 - Recommendations on management and exploitation of individual projects' results.

Confidentiality and Conflict of Interest

- The representatives of and participants to the SGGs' activities shall respect the confidential character of the proceedings and shall protect any information whose disclosure could damage the interests of IMI2 JU and/or of the potential applicants.
- All participants in the SGGs shall sign a declaration of confidentiality and non-conflict of interest to be provided to the IMI2 JU Programme Office. Representatives in the SGGs of EFPIA companies and Associated Partners may commit at level of their organisation.
- Ad hoc experts who may become applicants to IMI2 JU call topics shall not participate in SGG discussions on such topics.
- Before each meeting, the SGG Lead should ask the members if they have any conflict of interest in relation to the agenda of the meeting. The Scientific Committee members shall inform the SGG Lead in case they intend to be part of a proposal.
- Any participant whose participation in the work of the SGGs results or may result in a conflict of interest with regard to a particular activity shall inform the SGG Lead who shall, without delay and before any affected action is taken, decide what to do in collaboration with the IMI2 JU Programme Office representative on any specific measure in this respect.
- Should the SGGs become aware that a conflict of interest was not declared by a representative or participant, they shall decide on the appropriate measures to be taken after hearing the person concerned. The IMI2 JU Programme Office representative/Scientific Officer supports the SGG Leaders in detecting and managing conflicts of interest.
- Any situation related to a breach of conflict of interest should be reported in the corresponding minutes of the SGG meeting.
- Any situation related to a breach of confidentiality should be reported in the minutes of the following SGG meeting.
- The IMI2 JU Governing Board shall be informed of situations related to breaches of confidentiality and to conflicts of interest.

Annexes:

- Declaration of Confidentiality and Conflict of Interest for IMI2 Joint Undertaking Strategic Governing Group participants
- Declaration of Confidentiality and Conflict of Interest for the IMI2 Joint Undertaking Strategic Governing Group companies

Declaration of Confidentiality and Conflict of Interest for IMI2 Joint Undertaking Strategic Governing Group participants

Surname:

First name:

Professional address:

Phone:

E-mail:

Position:

Representative of

expert/ observer/ other

I hereby undertake that to act in the performance of my duties at the Strategic Governing Group in the general interest of the IMI2 Joint Undertaking.

At each meeting of the Strategic Governing Group or before any decision is taken, I shall declare any interest which might be considered to influence or bias their 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

Declaration of Confidentiality and Conflict of Interest for the IMI2 Joint Undertaking Strategic Governing Group companies

Name of the company:

Address:

Contact person:

Position:

Phone:

E-mail:

The Company [...] hereby undertakes that its staff acts in the performance of their duties at the Strategic Governing Groups in the general interest of the IMI2 Joint Undertaking.

The Company's staff is fully informed that at each meeting of the Strategic Governing Groups or before any decision is taken shall declare any interest which might be considered to influence or bias their judgment and therefore be prejudicial to the way an item on the agenda is handled.

The Company's staff will 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.

The Company's staff shall not disclose sensitive information learnt during the activities of the IMI2 Joint Undertaking even after duties have ended.

Done at [place], [date]

Name and Signature