



EUROPEAN COMMISSION
JOINT RESEARCH CENTRE

Directorate F – Health and Food
Disease Prevention

European Commission Initiative on Breast Cancer (ECIBC)

Rules of Procedure of the ECIBC Working Group and Topic-Specific Groups

Purpose of the document: Outline of organisational and procedural aspects of the ECIBC Working Group and Topic-Specific Group activities

Author: European Commission's Joint Research Centre

Date and version: 11 July 2025, version 3



Rules of procedure of the ECIBC Working Group and Topic-Specific Groups

The European Commission Initiative on Breast Cancer (ECIBC) Working Group (WG), HAS ADOPTED THE FOLLOWING RULES OF PROCEDURE¹:

1. Operation of the groups

The ECIBC WG and its Topic-Specific Groups (TSGs) shall act at the request of the European Commission's Joint Research Centre (JRC).

2. Chair and Vice-Chair

The Commission appoints one Chair and one Vice-Chair.

3. Replacement of members

3.1. The WG members, including Chair and Vice-chair, who resign, or are no longer capable of contributing effectively to the WG or TSG deliberations², or in the opinion of the JRC, do not comply with the tasks outlined in the mandate, or the confidentiality condition set out in Article 339 of the Treaty on the Functioning of the European Union³ or with the other provisions stated in the Mandate (Ares(2025)7308569) and rules of procedure herewith included may be replaced for the remainder of their term of office.

3.2. The JRC, and as possible in agreement with the Chair (or Vice-Chair), appoints an expert from the ECIBC expert pool as a WG member, considering the relevant field of competence that needs to be covered. In case the needed competence cannot be identified in the ECIBC expert pool, an expert shall be appointed based on an open call or, if not possible, to proceed with appointment by using other means.

¹ Being the decision-making body of the ECIBC, the working group has reviewed the rules of procedure, which have only been presented to the Topic-Specific Groups for informative purposes.

² See article 14.

³ Article 339 of the Treaty on the Functioning of the European Union: *The members of the institutions of the Union, the members of committees, and the officials and other servants of the Union shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy, in particular information about undertakings, their business relations or their cost components.*



3.3. The JRC appoints an expert from the ECIBC expert pool as a TSG member, considering the relevant field of competence that needs to be covered. An expert will always be asked for prior agreement.

3.4. The JRC ensures involvement of patients and/or caregivers to develop patient centred, as well as evidence-based European breast cancer guidelines and quality assurance scheme.

4. Convening a meeting

4.1. Meetings of the WG and TSGs are convened either by the JRC, on its own initiative, or at the request of the members, after the JRC has given its agreement in collaboration with the Chair and Vice-Chair.

4.2. Meetings of the WG will be held either at the JRC premises, other locations announced in due time, or virtually. In case of impediments to travel or meetings are organised online, the members shall join meetings by means of web-based tools.

4.3. Meetings of the TSGs will be held virtually.

4.4. Attendance of at least two thirds (66.7%) of the total number of WG and TSG members is required to convene a meeting, regardless of conflict-of-interest status. The Chair and Vice-Chair (and/or Co-Leads of TSG) must be always present in meetings which fall under the respective responsibility. Attendance for the duration of the entire meeting is expected. WG and TSG members should not change their availability to join the meeting once it has been scheduled, unless unforeseen circumstances arise, and prior approval information should be given to the JRC coordination team.

5. Meeting planning and agendas

5.1. The JRC expects to send to the WG members the planning of the forthcoming meetings and tentative topics for discussion in the autumn of each calendar year, except otherwise indicated and covering the entire year to come, in agreement with the Chair/Vice-Chair.

5.2. The JRC will draft the meeting's agendas in consultation with the Chair/Vice-Chair and send it to the members. The WG shall adopt the agenda at the start of each meeting.

5.3. To plan activities efficiently, a regular meeting shall be set up between the JRC and the Chair/Vice-Chair to discuss the progress of the initiative and Topic-Specific Groups (TSGs) as well as to plan for the next WG activities.



6. Documentation to be sent to members

6.1. The JRC shall send the meeting invitation and the draft agenda to the members possibly no later than ten calendar days before the meeting date.

6.2. The JRC shall send documents on which the WG and/or TSG are consulted to the members possibly no later than fourteen calendar days before the meeting date.

6.3. In urgent or exceptional cases, the time limits for sending the documentation mentioned in points one and two may be reduced to five calendar days before the meeting date.

7. Opinions of the Working Group

7.1. As far as possible, the WG and the TSGs shall adopt its opinions, recommendations, requirements/indicators or reports by consensus, based on latest evidence that is provided. In case the WG or the TSG do not reach consensus through discussion, the position will be adopted *via* voting. In the event of a vote, the outcome will be decided either by simple majority or qualified majority as follows:

7.1.1. When a vote is needed to agree on the direction of the recommendation (*i.e.* to recommend for or against an option), the decision will be taken by simple majority. **This applies when issuing conditional recommendations.**

7.1.2. When a vote is needed **to agree on the strength of the recommendation**, a qualified majority of 80% of the two thirds of the total number of the WG members is needed. The members who abstain or are recused from voting due to an existing conflict of interest, are not to be considered in the denominator, if a strong recommendation is issued. If it is not possible to have qualified majority for the vote on the strength of a recommendation, then the WG needs to reconvene to ensure that the qualified majority is reached.

7.1.3. When a vote is needed to agree on the **judgements on the assessment domains of the requirement criteria, performance measure or indicator**, the decision will be taken based on **simple majority** of the members present at the meeting.

7.1.4. To **approve a requirement or a set of requirements**, including criteria and indicator measurements to be included in the quality assurance scheme, **a qualified majority of 80% of those members present at the meeting** will be needed (the members who abstain or are recused from voting are not to be considered in the denominator).

7.2. In principle, the Chair and Vice-Chair will abstain from voting. In cases of a tie where simple majority is required to take a decision, the Chair and Vice-Chair may vote.

7.3. The members that have abstained or voted against shall have the right to document the reasons for their minority opinion. Names of minority opinions could be published on request.



- 7.4. The TSG Co-Leads should join the WG meeting and present the work of the TSG.
- 7.5. The WG is responsible for ensuring consistency and continuity of WG final judgement and/or recommendation/requirements/indicators. The WG won't re-open any discussions on the systematic reviews already addressed in the TSGs.
- 7.6. The WG may seek additional advice and pose questions to a TSG depending on complexity of healthcare topics.
- 7.7. When issuing final opinions or recommendations/requirements/indicators, the WG considers the respective TSG position, however the WG remains responsible for its final judgement and/or recommendation/requirements/indicators.
- 7.8. The WG members and Chair/Vice-Chair should refrain from deviating from critical points established in the methodology. Should there be any questions that challenge the development methodology, these should be discussed with the JRC outside of any WG or TSG meetings to avoid disrupting meetings. The Chair and Vice-Chair are expected to be able to argue in favour of the methodology and guide the meeting discussions accordingly.

8. Topic-Specific Groups

- 8.1. The TSGs will work on specific healthcare questions and propose recommendations/requirements/indicators for WG review and approval. Based on the planned activities, the JRC, independently, or the WG, in agreement with the JRC/Chair/Vice-Chair will set up the TSGs. Generally, each TSG would comprise of approximately five to eight members, consisting of potentially one or two JRC members/associated members, but in any case one or two WG members and TSG members either chosen from the ECIBC expert pool or hired on demand (through expert contracts or procurement). The JRC members do not impact on the overall TSG number. The number of involved TSG members depends on the expertise needed to discuss the specific healthcare questions.
- 8.2. Each TSG will have two Co-Leads, one from the WG and one coming from the expert pool. They will be responsible of leading the TSG work and the meetings' activities. The JRC might assign a scientific secretariat in support.
- 8.3. Each WG member is expected to participate in TSG relevant to their specific area of competence, as the workload permits.
- 8.4. The TSG shall be disbanded as soon as its mandate is fulfilled.
- 8.5. The TSG Co-Leads shall report to the WG and the JRC/Chair/Vice-Chair.
- 8.6. The TSG shall prepare and present their draft opinions, recommendations, requirements/indicators or reports to the WG and respond any questions during the WG meetings.



9. Admission of third parties

The JRC may invite on an *ad hoc* basis experts from outside the WG (or the TSGs) with specific competence in a given subject area included on the agenda to participate to the work. In addition, the JRC may give an ‘observer’ status to individuals, organisations as defined in Rule 7(2) of the horizontal rules on expert groups⁴, and candidate countries.

10. Written procedure

10.1. If necessary, the WG (or the TSG) opinion or recommendation/requirements/ indicators on a specific question may be delivered *via* a written procedure. In such a case, the JRC sends to the members the document(s) on which the WG (or the TSG) is being consulted.

10.2. The outcome of the written procedure is adopted by consensus based on the latest evidence available provided by experts in the field. If consensus is not reached, simple majority of the concerned members would adopt the outcome according to the same voting rules as in Article 7.

10.3. If a simple majority of the WG (or the TSG) members would ask for a healthcare question to be examined during a meeting, the written procedure shall be terminated without result and the JRC shall convene a meeting as soon as possible in order to reach the final outcome.

11. Secretariat

The JRC will provide the i) scientific secretariat (*e.g.* planning and coordinating, in collaboration with the Chair and Vice-Chair, the overall ECIBC activities, overseeing the evidence review group activities, make provisions for the minutes, organising surveys, conducting studies, publication of the outputs on the institution’s website), as well as ii) logistics services to the WG and the TSG members. See also the mandate (Ares(2025)7308569).

⁴ Commission Decision C(2016) 3301 of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups https://health.ec.europa.eu/publications/commission-decision-c2016-3301-final_en



12. Minutes of the meetings

12.1. The JRC shall make available the draft of the meeting minutes. Except for the minority opinions, the minutes shall not mention the individual position of the members during deliberations.

12.2. The draft minutes shall be circulated among the members. Disagreements shall be notified to the JRC.

12.3. The final minutes shall be approved by the WG.

13. Attendance

At each meeting, the JRC shall draw up and record an attendance list of the participants including the WG members and if applicable, the TSG members, external experts, as well as the observers.

14. Participation criteria

14.1. In each calendar year, members of the WG and TSGs are expected to attend at least 75% of the meetings. The Chair and Vice-Chair are expected to attend at least 80% of meetings.

14.2. The members are expected to be able to contribute actively to the discussion and deliberations on subjects within their field of competence during meetings and, when requested, with written comments.

14.3. JRC will record/assess on a yearly basis the extent to which members have been able to participate in the work. After consultation with the Chair and the Vice-Chair, the JRC shall examine the situation with the WG members who have not been able to comply with the participation criteria⁵.

14.4. The Chair and Vice-Chair are expected to lead the discussions during meetings. Thus, the Chair and Vice-Chair shall prepare for and follow-up the meetings with the JRC accordingly and commit to the scheduled meetings.

⁵ See article 3.



15. Conflict of interests

15.1. At the beginning of each calendar year, each WG and TSG member including the Chair and Vice-Chair shall complete an annual declaration of interest form and provide it to the JRC for the assessment of potential conflict of interests.

15.2. The JRC and the Chair of the WG shall, at the first meeting of each calendar year remind all WG members of their obligation to promptly inform the JRC of any relevant change in the information previously provided, as regards upcoming activities, in which case they must immediately submit a newly completed declaration of interests describing the change, in order to enable the JRC to assess it in due course, in compliance with the rules.

15.3. Before each meeting, each WG and TSG member shall complete a specific declaration of interests form related to the topics under discussion.

15.4. At the start of each meeting, any WG and TSG member whose participation in the work would raise a conflict of interests shall inform the JRC and the Chair/Vice-Chair.

15.5. Should a conflict of interests arise, the JRC may exclude this member from the group, or in a particular meeting or may decide that the member in question shall abstain from discussing the items on the agenda concerned and/or from any vote on those items during a meeting. The JRC will handle the conflict of interests management regarding the Chair and Vice-Chair separately.

15.6. Conflict of interests shall be recorded in the meeting minutes.

15.7. Point 15.5 shall also apply to deliberations taken by the WG (or the TSGs) in written procedure.

16. Meeting expenses

16.1. Participants in the activities of the WG and TSG will in principle not be remunerated for the services they offer. However, the JRC may decide to pay for extraordinary activities *via* the signature of an expert contract with concrete WG and TSG members.

16.2. Details/conditions for payments will be provided during the process. However, the members must have attended at least 75% of meetings related to the tasks, to be able to receive a remuneration. To be noted, fulfilling this criterion does not necessarily mean that the member will receive a remuneration.

16.3. The amount of the possible remuneration will be determined individually for each member, taking into consideration the meeting attendance within the last 12 months.



16.4. Travel and subsistence expenses, incurred by participants in the activities of the WG and its TSGs will be reimbursed in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources.

17. Correspondence

17.1. Correspondence to the members shall be sent to the e-mail address, which they provide for that purpose.

17.2. Correspondence relating to the WG or the TSGs shall be addressed to the JRC as indicated hereafter at one of the following addresses:

E-mail address:

jrc-cancer-policy-support@ec.europa.eu

Postal address:

European Commission - Joint Research Centre
JRC Healthcare Quality Group
Via E. Fermi, 2749. TP 127
I-21027 Ispra (VA)/Italy

18. Transparency

18.1. Regarding the composition of the WG and the TSGs, the following data will be published on the European Commission's web hub on cancer screening and care⁶:

- a) the name of individuals appointed as WG members, their brief CVs and their declaration of interests;
- b) the name of individuals appointed as TSG members;
- c) the name of external experts;
- d) the name of observers;
- e) the name of stakeholder representatives.

18.2. Individuals who do not wish to have their names disclosed may submit a request to the JRC for a derogation from this rule. A derogation shall be granted where justified on compelling legitimate grounds in relation to the specific situation of the individual, in particular

⁶ European Commission's webhub on cancer screening and care
<https://cancer-screening-and-care.jrc.ec.europa.eu/en>



where disclosure of the individual's name could endanger their security or integrity, which should however be the exception.

18.3. The following documents will be published on the European Commission's web hub on cancer screening and care, respecting the confidentiality requirements, as well as protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data, such as:

- a) Declarations by WG members, TSG members and external experts who participate in ongoing work of their commitment to act independently of any external influence;
- b) Annual declaration of interests of the WG members;
- c) Declaration of interests in relation to specific topics under discussion;
- d) Rules of procedure;
- e) Mandate
- f) Eventual stakeholder dialogue activities (*e.g.* consultations, calls for information, calls for experts, calls for hearings, public consultations, *etc.*).

18.4. Access to the European Commission's web hub will not be subject to user registration or any other restriction. Relevant documents will be published in due time ahead of the meeting. Exceptions to publication will only be foreseen where it is deemed that disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001⁷.

19. Access to documents

Applications for access to documents held by the WG (and the TSGs) shall be handled in accordance with Regulation (EC) No 1049/2001.

20. Deliberations

20.1. The WG (and the TSG) meetings and its deliberations shall be confidential.

20.2. In agreement with the JRC, the WG (or the TSGs) may decide to open its deliberations to the public by a simple majority of its members.

⁷ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43): <https://eur-lex.europa.eu/eli/reg/2001/1049/oj/eng>



20.3. The WG may collect input on specific scientific/technical aspects of the guidelines and the scheme from relevant stakeholders through public consultations/surveys or other means.

21. Protection of personal data

All processing of personal data for the purposes of these rules of procedure shall be in accordance with Regulation (EU) 2018/1725⁸.

⁸ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data: <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32018R1725>



ANNEX: Glossary of terms and abbreviations

ECIBC: European Commission Initiative on Breast Cancer

ECIBC Working Group: a multidisciplinary group of experts including patients and/or caregivers, who are nominated as an outcome of an open call. It represents the decision-making body for guideline recommendations and requirements/indicators for quality assurance.

ECIBC Working Group member: an expert of the ECIBC WG appointed by the European Commission in her/his individual capacity following an open call.

ECIBC Expert Pool: Experts selected as a result of an open call reaching the passing score and who accepted to be included in the pool of experts underpinning ECIBC activities. Those allocated to the pool were not appointed as members to the WG. The pool serves to choose Topic Specific Group (TSG) members, or to nominate new members of the WG if and as needed.

External expert: Experts contributing temporarily to the ECIBC WG or TSG activities. They are not members of either the ECIBC WG or of a TSG. They are chosen from the European Commission expert pool or hired through expert contracts or specific procurement. Their mandate ends once the required tasks are completed. They typically do not vote.

JRC: European Commission's Joint Research Centre

Minority opinions: Declared objections to the WG/TSG opinion adopted.

Qualified majority: A majority in a vote that reaches a pre-set minimum of the votes as specified in Article 7 in this document.

Simple majority: A single vote more than half of the number of the members who voted (abstentions and absents are not counted).

Topic-Specific Group (TSG): A small group of experts that is formed in agreement with the JRC/Chair/Vice-Chair and the ECIBC WG members to work on specific healthcare questions/requirements covering the entire care pathway, including experts from the ECIBC expert pool as well as from the ECIBC WG or experts taken via specific contracts if needed. TSG are dissolved once their mandate is completed.