ESMO Standard Operating Procedures (SOPs)

for Consensus Conference (CC) recommendations

ESMO Guidelines Committee (GLC)

Version	**ESMO CC SOP Version 1.0; March 2022**
Changes in this version	Clarified authorship criteria Added guidance and requirements for inclusion of specific contributor roles Clarified process for inviting authors Added Disclosure of Interests (DOI) collection process Added guidance on kick-off meetings for Chairs and Working Groups Added guidance and requirements for the development and publication of the CC recommendations manuscript Added Author Responsibility and Acknowledgement Agreement form Added guidance on wording of recommendations
Approved	Giuseppe Curigliano, GLC Chair
Next review planned	After the next GLC meeting (in 2022, date to be confirmed); revisions can be made sooner as required

Note: this SOP only applies to ESMO CC recommendations. For additional guidance on ESMO Clinical Practice Guideline (CPG) publications and their updates, please see the separate CPG, electronic update (eUpdate) and Clinical Practice Living Guidelines SOPs. All three SOP documents are available publicly on the ESMO website esmo.org: http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology.

Table of Contents

1 Introduction

- The target audience for ESMO CPGs and ESMO CC recommendations manuscripts is health professionals working in the field of oncology, across Europe and other parts of the world.
- ESMO CC recommendations should consider the content of any published ESMO CPG manuscripts when available. ESMO CC recommendations manuscripts and CPG manuscripts are two separate but complementary products. CC topics should be geared towards areas of uncertainty or when Levels of Evidence (LoEs) and Grades of Recommendation (GoRs) scores are low (see section 5.3).
- The CC recommendations manuscript will be submitted to an ESMO journal for evaluation for publication—*Annals of Oncology* (annalsofoncology.org) or *ESMO Open* (esmoopen.com). ESMO staff will format all ESMO manuscripts to align with ESMO journal style prior to submission.

2 Commissioning of a consensus conference

A new CC should be proposed when there is need for such, as judged by the ESMO GLC Chair and the ESMO Subject Editor (SE). This judgement is based on clinically-significant, complex questions and topics not currently covered by current ESMO CPG titles that require addressing.

In selected circumstances, ESMO may opt to produce joint CC recommendations with other formally recognised scientific societies, after careful consideration of the science, characteristics, scope and strategy by the GLC. In this case, there is a mutual agreement to follow ESMO methodology detailed in this SOP, with some adjustments if needed, to generate consent. If applicable, ESMO will provide the necessary Memorandum of Understanding (MoU) with the society(ies), as well as a specific Guideline Development Agreement (GDA) for each CC and subsequent CC recommendations manuscript.

For any commissioned CC, an allocated budget should be defined, as financial coverage is mandatory. When another society is involved, the budget must be split equally between societies.

3 Role of ESMO Guidelines medical writers/staff

Each CC will have an ESMO Guidelines medical writer/staff member responsible for communications, planning and oversight throughout the CC and recommendations manuscript development process. The ESMO Guidelines medical writers/staff will provide medical writing and editing support as agreed with the CC Chairs. ESMO Guidelines medical writers/staff will review and edit all CC materials and related documents and will review and edit all documents including the final CC recommendations manuscript to ensure they adhere to ESMO methodology detailed in this SOP and ESMO journal requirements. These roles are considered to be ‘non-author contribution’ and do not replace intellectual contribution from the authors. The exact role of each staff member involved in the manuscript will be detailed in the Acknowledgements section of the CC recommendations manuscript as medical writing, editing and/or logistical support. For CCs associated with ESMO events, ESMO may acknowledge additional ESMO staff members who provided support.

4 Consensus conference panel selection and authorship criteria

4.1 Selection process

For each CC, the ESMO SE will serve as a CC Chair and should nominate one other CC Chair. For joint CCs with other societies, the ESMO SE will nominate one CC Chair from each society. The GLC Chair and the ESMO Executive Board will approve the final selection of CC Chairs.

The CC Chairs will work closely together to evaluate potential CC participants and nominate additional multidisciplinary experts (e.g. non-medical oncologists), if needed. All CC Chairs are responsible for approving the entire CC panel including specific representatives of any other societies, if applicable.

The CC Chairs will appoint one or two Working Group (WG) Chairs to coordinate the activities of each WG and will assign remaining CC participants to a WG, ideally no more than 8 members per WG including the WG Chairs.

The GLC Chair or CC Chairs can appoint additional representatives to participate in the CC as advisors (either as authors or as non-author contributors) or reviewers (as non-author contributors to be acknowledged in the final manuscript).

The ESMO Guidelines medical writers/staff will assist the CC Chairs with coordinating the participant selection process and sending formal invitations (see section 4.5). Invitations are sent on behalf of the CC Chairs.

4.2 Authorship criteria

The CC panel should consist of experts, ideally no more than 40 participants total, who fulfil the following criteria:

- Each proposed participant should have an internationally recognised profile in the field and a good reputation.
- The CC panel should be diverse, gender-balanced, multidisciplinary and multinational, with authors representing various countries in Europe and elsewhere (a maximum of 4 non-Europeans who bring specific scientific expertise).
- The CC panel should be multi-institutional, ideally with all authors representing different institutions.
- All CC participants must participate in the pre-work leading up to the CC and in the CC meeting, including final voting sessions (either on-site or remotely), to be included as authors in the final manuscript, although the CC Chairs have the final decision.
- Priority should be given to ESMO Faculty members where possible.
- Participation of patient representatives or advocacy groups is optional and at the discretion of the GLC Chair and CC Chairs.
- Participation of a methodologist is optional and at the discretion of the GLC Chair and CC Chairs. The methodologist will be included as an author on the final manuscript if all of the author criteria are met.
- There should be no involvement of industry representatives in the CC.

All CC participants should fulfil all four of the following authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE) to be included as an author of the final CC recommendations manuscript:[1]

- Substantial contribution to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Provided that they meet the above criteria, all members of the CC panel will be listed as named authors on the final manuscript, regardless of whether they vote on the final CC recommendations statements.

Individuals who do not meet all four criteria will be acknowledged as non-author contributors, either individually or as a group, under the Acknowledgements section with details of their specific contribution, and only with their written permission to include their acknowledgement.

4.3 Contributor roles

CC participants will have specific responsibilities depending on their role(s), as described below.

4.3.1 Working Group members

The WG members' responsibilities are:

- Identify available evidence for the WG topics (in collaboration with a methodologist if applicable) via a narrative review of the literature, including evidence to justify each proposed question to be addressed by the WG.
- Develop search strategy and rules and conduct/review literature search, which can be supported by the work of a methodologist, if applicable, or ESMO Guidelines medical writers/staff.
- Study and summarise relevant evidence, including important references, to support recommendations.
- Develop draft recommendation(s) to address question(s) based on findings from the review of evidence.
- Submit summary slides for presentation at the CC and draft recommendations summary report to the WG Chair at least 3 weeks prior to the CC.
- Participate in the pre-work leading up to the CC and in the CC meeting, including final voting sessions.
- Draft and revise post-CC results text as needed with the WG Chair.
- Approve the final manuscript (including drafts in successive rounds, as needed) and submit an updated Declaration of Interest (DOI) if needed before manuscript submission.
- Follow the ESMO methodology detailed in this SOP to complete the writing of the consensus manuscript.

4.3.2 Working Group Chairs

The WG Chairs' responsibilities are:

- Steer their WG, assigning tasks to specific members, as appropriate.
- Lead preparatory teleconferences (TCs)/workshops to facilitate work on assigned topic, supported by ESMO medical writers/staff.
- Act as the coordinating author to drive input and contributions from WG members and provide progress updates to the CC Chairs/ESMO Guidelines medical writers/staff .
- Ensure that the draft recommendations include LoEs and GoRs according to the Infectious Diseases Society of American-United States Public Health Service Grading System (see section 5.3.1).[4,5]
- Compile a summary report of all evidence and draft recommendations, including supporting background text, provided by WG members and send to CC Chairs for review at least 2 weeks before the CC.
- Compile a draft slide deck summarising the reviewed questions and recommendations and upload it into the SharePoint collaboration site (see section 5.2) at least 2 weeks before the CC for the CC Chairs review.
- Coordinate the writing/revision of the draft results and accompanying text from each WG.
- Compile full draft section of the manuscript (in collaboration with ESMO Guidelines medical writers/staff, who will provide a shell manuscript in advance).
- Submit full draft section to the ESMO Guidelines office, who will then compile all WG sections and submit to the CC Chairs for review.
- Follow the ESMO methodology detailed in this SOP to complete the writing of the consensus manuscript, ensuring that all WG members follow it too.

4.3.3 Consensus Conference Chairs

The CC Chairs' responsibilities are:

- Overall management and support of consensus conference and manuscript development (ESMO Guidelines medical writers/staff will provide support where appropriate; see section 4.3.5).
- Appoint a WG Chair to coordinate the activities of each WG and assign 5-10 members to each WG.
- Define CC topics (one per WG) and suggest questions to address each topic—WG questions can be refined with input from the WG Chairs.
- Liaise with WG Chairs to ensure all preparatory work is conducted in accordance with the agreed timelines.
- Provide guidance regarding potential methodological approaches (e.g. systematic literature reviews, Delphi survey) and desired outputs for presentation at the CC.
- Review material prepared by each WG for the CC and provide feedback, as required.

- Review finalised summary report of all evidence and draft recommendations, including supporting background text and slides, provided by WG Chairs and send to ESMO Guidelines medical writer/staff for review at least 1 week before the CC.
- Compile draft sections into a full draft manuscript (in collaboration with ESMO Guidelines medical writers/staff).
- Submit full draft manuscript to ESMO Guidelines office for review.
- Certify that all authors fulfil the ICMJE criteria (see section 4.2) and describing their contributions using the ESMO Author Responsibility and Acknowledgement Agreement form (see the ESMO website here: https://www.esmo.org/guidelines/esmo-guidelines-methodology).
- Provide the cover letter for journal submission, including recommended reviewers (ESMO Faculty where possible).
- Ensure that the CC recommendations manuscript follows the ESMO methodology detailed in this SOP as closely as possible, including providing support to the WG Chairs on methodology queries.

4.3.4 Methodologist

When a methodologist is included in the CC preparation, their responsibilities are to:

- Define the required search terms and drive the systematic literature review needed to answer the questions of each WG.
- Extract the relevant data and content.
- Offer support for summary formatting/communication.
- Support with conducting a modified Delphi survey (if applicable, see Appendix Section 10.1).

4.3.5 Guidelines medical writers/staff

- Coordinate logistics for participants, including invitations, collection of participant DOIs and kick-off meetings.
- Support CC Chairs, WG Chairs and WG members by organising TCs/workshops to develop draft WG questions and recommendations into a draft manuscript.
- Review material prepared by each WG and compile for the CC Chairs for their review.
- Generate a shell manuscript with author names, affiliations and DOI information.
- Manage meeting logistics, venue and prepare CC material including content development (agenda, slides, final recommendations).
- Support breakout WG sessions during the CC.
- Undertake live editing during plenary sessions of the CC, collect votes during voting sessions and revise draft recommendations text to generate a final set of recommendations with voting results.
- Prepare conference summary/minutes.

- Manage final manuscript preparation on behalf of the CC Chairs to ensure that the final manuscript adheres to this SOP and ESMO journal requirements.
- Coordinate final review and approval by authors; manage manuscript submission and revisions following peer review.
- Manage online publication and proof review on behalf of the CC Chairs.

4.4 Order of authorship

Unless otherwise specified and approved by the CC Chairs, the manuscript author order is as follows:

First author: CC Chairs(s)

Other co-authors: WG Chairs in alphabetical order of surname, followed by WG members in alphabetical order of surname, with all WG Chairs and WG members to be named as authors on the final manuscript.

Last author: CC Chair (SE).

In the event of multiple manuscripts per WG, the respective WG Chairs and WG members are listed first in alphabetical order of surname for their WG's manuscript (WG Chairs first, followed by WG members), followed by the remaining WG Chairs and WG members in alphabetical order of surname (WG Chairs first, followed by WG members).

4.5 Participant invitations

Once the group is approved by the CC Chairs, the ESMO Guidelines medical writers/staff will formally invite all potential WG Chairs and members to participate in the CC.

4.6 ESMO Declaration of Interest

4.6.1 Declaration following participant invitation

As part of the participant confirmation process, ESMO will verify and/or request that each potential participant has an ESMO account and has provided a valid DOI in the ESMO DOI Platform. The DOI collection process is centrally managed within ESMO, and the financial value of each disclosure will be treated as confidential. For more information, refer to the ESMO DOI policy available here: https://www.esmo.org/about-esmo/how-we-work/declaration-of-interest.

Each participant must provide DOI information including financial values, even if there is nothing to declare, before the individual's participation in the CC can begin, including pre-CC WG meetings. Final confirmation of participation in the CC is subject to receipt of participant DOIs. After all DOIs are received, reviewed and approved, the CC process can begin.

Each participant is responsible for ensuring that their DOI statement in the ESMO DOI Platform is true, up to date and complete.

4.6.2 Declaration in the final manuscript

In addition to the DOI provided in the ESMO DOI Platform, each participant who will serve as an author must provide a written statement to be included in the Disclosures section of the final manuscript. Before manuscript submission to an ESMO journal, all authors must review and approve the final manuscript including DOI statements. Disclosures are not included in the manuscript word count.

Example disclosure statement:

“XX has received honoraria from Company-A, has a financially compensated leadership role in Company-B, has stocks or other forms of ownership in Company-C, receives licensing fees or royalties from intellectual property from Company-D, received or currently receives direct research funding as a Project Lead from Company-E, performs work in clinical trials or contracted research for which his/her institution received financial support from Company-F, has performed non-remunerated activities for Company-G, non-remunerated leadership roles for Society-H and has non-remunerated membership or affiliation with Group-I.”

Irrelevant parts of the statement, for which the author has no disclosures, should be deleted. Small deviations can be made for grammatical reasons or to avoid repetition. If an author has no disclosures, the statement should read ‘XX has declared no conflicts of interest’.

Each author is responsible for ensuring that their DOI statement in the final manuscript is true, up to date and complete (and updated in the ESMO DOI Platform if needed).

5 Pre-consensus conference meetings and development of recommendations

After submission of all authors’ DOIs, the ESMO Guidelines medical writers/staff will organise meetings to facilitate the selection and finalisation of the individual WG topics and corresponding questions, as well as the preparatory work of the CC.

5.1 Preparation meeting

ESMO Guidelines medical writers/staff will organise a preparation meeting (online or in person) between the CC Chairs and the WG Chairs to work on defining/finalising the questions for each topic. This meeting should take place preferably 6 months prior to, and at least 3 months prior to, the CC.

During the preparation meeting, CC Chairs and WG Chairs will select the participants to be invited to the CC, if not already selected by the CC Chairs, depending on the timing of the meeting.

ESMO Guidelines medical writers/staff will present information about pre-meeting work, the CC meeting and the CC recommendations manuscript formatting requirements detailed in this SOP. Proposed timelines can also be discussed in the meeting.

Following this meeting, ESMO Guidelines medical writers/staff will provide a presentation template (PowerPoint document), a manuscript template (Word document) and a supplementary material template (Word document). The main manuscript template can only be completed once the author allocations to the writing sections are made.

5.2 Working Group meetings

Following the preparation meeting, participants will be invited to join a specific WG and contribute to the preparatory work of the CC. WG Chairs will decide how the group will work and will assign specific tasks to each WG member.

WG members will work on the topics and questions assigned via exchange of emails, TCs, etc. Remote work through a modified Delphi method may also be used (see Appendix Section 10.1). No funding for formal physical WG meetings is foreseen.

ESMO provides a collaboration site for each group using Microsoft SharePoint collaboration software tools. ESMO Guidelines medical writers/staff are not able to support the use of Google docs or other external collaboration sites. Teams and Zoom may be used for scheduling TCs for each group.

WG members are each responsible for conducting a study of relevant evidence for the assigned questions including a narrative review of the evidence and a list of important references.

In cases where the CC Chairs consider a systematic review of the evidence necessary, this should be done by each WG. No funding is foreseen for systematic review, unless ESMO and other collaborating societies agree to involve a dedicated methodologist, as defined under Section 4.3.4, who can assist with a literature search.

WG Chairs should prepare a summary report including draft recommendations to the CC Chairs to review prior to the CC. The ESMO Guidelines medical writers/staff will support the WG Chairs with drafting presentation slides to be used for the CC.

5.3 Guidance on recommendations

Recommendations should be easy for clinicians to understand and interpret. Therefore, clear details should be provided on the patient population, interventions, comparators and if relevant, the clinical setting. Although passive voice is used in scientific writing to distance researchers from their work, using an active voice may also enhance clarity, e.g. “Three trials have addressed the question…” as opposed to “The treatment strategies most effective were demonstrated to be…”.

The following phrasing is recommended to aid communication of the strength of recommendation, based on advice from the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group:[8]

- Strong positive recommendations (grade A): ‘the authors recommend…’ or ‘clinicians should’ or ‘Do…’
- Strong negative recommendations (grade E): ‘clinicians should not…’, or ‘Do not…’
- Weak recommendations (grade B and D): ‘it is suggested…’ or ‘clinicians might…’ or ‘the authors conditionally recommend…’

Recommendations should be accompanied by proper LoEs and GoRs according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System.[5] Therefore, it is mandatory for all recommendations to be supported with an LoE and GoR.

The LoE describes the quality of existing evidence (trials, cohort studies, case-control studies, expert opinion) that addresses a specific clinical question. The quality of evidence is assessed in terms of number of trials, sample size, methodology, bias and heterogeneity.

The GoR is a composite parameter, as it incorporates both the quality of evidence (as in LoE) as well as the clinical significance/magnitude of benefit or harm given by a novel therapy.

Any therapy can be assigned a GoR, which can be positive (recommended) or negative (not recommended). To avoid confusing negative logic, please construct a logically positive wording for the recommendation, and then assign the appropriate GoR to indicate if the recommendation is positive or negative.

Example:

- Correct:

Administration of anti-EGFR antibodies does not result in survival improvement in patients with RAS-mutated advanced colon cancer and is not recommended (GoR E).

- To be avoided:

Non-administration of anti-EGFR antibodies is the correct clinical strategy for patients with RAS-mutated advanced colon cancer and is strongly recommended (GoR A).

Each question will have a dedicated section in the manuscript that will be numbered according to the assigned question. A list of all recommendations in each thematic section should be included at the end of the relevant section, including LoEs and GoRs, and voting breakdown. The recommendations list must be numbered to correspond to the assigned question and recommendation statement.

Example:

Recommendations

Recommendation 1.1: a large majority of extrauterine HGSCs arise in the fallopian tube from STIC. SEE-FIM sectioning of both fallopian tubes should be carried out in all cases of extrauterine HGSC where the tubes are grossly normal, and also in risk-reducing prophylactic surgery specimens.

Level of evidence: III

Grade of recommendation: A

Consensus: 100% (40) yes, 0% (0) no, 0% (0) abstain (40 voters)

Recommendation 1.2: extrauterine HGSC can only be assigned as ovarian in origin if both fallopian tubes are grossly normal, and histologically contain no mucosal disease following examination using a SEE-FIM protocol.

Level of evidence: III

Grade of recommendation: A

Consensus: 100% (40) yes, 0% (0) no, 0% (0) abstain (40 voters)

Note: the above example is for question 1, therefore “recommendation 1.1” is the first recommendation statement for question 1.

5.3.1 LoE/GoR table

The ESMO LoE/GoR table is mandatory and will be included as a supplementary file to explain the methodology regarding the LoEs and GoRs.

Supplementary Table SX. Levels of evidence and grades of recommendation (adapted from the Infectious Diseases Society of America-United States Public Health Service Grading System[a])

Levels of evidence

I	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well- conducted randomised trials without heterogeneity
II	Small randomised trials or large randomised trials with a suspicion of bias (lower methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case–control studies
V	Studies without control group, case reports, expert opinions

Grades of recommendation

A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk or the disadvantages (adverse events, costs, etc.), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

[a]Reprinted by permission of Oxford University Press on behalf of the Infectious Diseases Society of America [Ref#, Ref#].

Include in References:

Ref#. Dykewicz CA. Summary of the guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. *Clin Infect Dis.* 2001;33:139-144 (Adapted from: Gross PA, Barrett TL, Dellinger EP et al. Purpose of quality standards for infectious diseases. *Clin Infect Dis.* 1994;18:421).

Ref#. Gross PA, Barrett TL, Dellinger EP et al. Purpose of quality standards for infectious diseases. Clin Infect Dis 1994;18:421

6 Consensus conference

The CC Chairs are responsible for and have authority over the conference.

Suggested general outline (3-day conference):

- Pre-meeting (WG Chairs):
    - The CC Chairs and WG Chairs will have a pre-meeting before the CC to discuss objectives, process and outline of initial work.
- Introduction:

- All participants to discuss the aims, structure and process of the conference.

- WG discussions (breakouts):
  - Parallel break-out sessions, no voting.
  - A summary report with questions and recommendations (including multiple options if needed) is made available to all WG members before the CC. Each WG discusses topics/questions, with a view to finalising specific recommendations with evidence levels. Diverging opinion in questions and recommendations should be recorded by each WG if needed for presentation to the plenary session.
- Joint presentation (plenary sessions):
  - Plenary session(s) with discussion but without voting.
  - WG Chairs present the questions and recommendations (with all diverging opinions) from their group for discussion. Discussion takes place for each question so that the participants can comment on and revise the recommendation statements (including sub-recommendations).
- Final joint presentation (plenary session with voting):
  - Plenary session(s) with discussion and voting.
  - Voting for each recommendation takes place and should be stated as percentages of “Agree, Disagree, Abstain”.
  - CC Chairs and WG Chairs provide a summary of discussions. This should include the questions, recommendations and percentages of agreement for each recommendation.
- Summary and conclusion (all participants):
  - The CC Chairs will discuss next steps, timelines, publication, manuscript preparations and final remarks with the full group of participants.
- Post-meeting debrief (WG Chairs):
  - The CC Chairs and WG Chairs may spend some additional time at the end of the conference to discuss decisions and next steps with the WG Chairs.
  - Writing sessions may take place following the meeting if time permits.

6.1 Post-consensus resolution of disagreements

For each recommendation on a clinical problem, the result of voting with percentage of agreement, disagreement and abstention should be stated during the meeting and reported in the final manuscript.

If the results of voting are <75% agreement on a recommendation, or >20% of disagreement is achieved during the meeting, a post-meeting consensus should be achieved by filling out a GRADE grid based on the advice from the WG (see Appendix Section 10.2).

The statement of recommendation on a specific intervention for a clinical problem is sent to each participant with a GRADE grid to be filled and sent to ESMO staff within 72 hours.

Results are polled; if <75% consensus is achieved, statements are recirculated by asking for voting again on the same or modified statements.

7 Post-consensus manuscript development

All WGs should send their draft sections with questions, recommendations and LoEs/GoRs to the CC Chairs within one month following the CC. LoEs/GoRs and references are provided for every formulated

recommendation. The grading system must be consistent across CC recommendations manuscript and other ESMO CPGs and form the basis for the class of recommendation and LoEs/GoRs documented.

The CC Chairs will incorporate all topic draft sections in a pre-final manuscript, with support from the ESMO Guidelines medical writers/staff. The pre-final manuscript is circulated to all members of the CC panel for a final check and comments/suggestions. The CC Chairs finalise the document and forward it to the ESMO Guidelines medical writer/staff for review. Once the manuscript has been finalised and agreed by the CC Chairs, the ESMO Guidelines medical writers/staff will submit it to the GLC Chair for approval.

7.1 Extent

ESMO journals follow a strict word count policy. The CC recommendations manuscript should **focus on the therapeutic recommendations** and should not exceed **10 000 words including tables, figure legends and references** (only the manuscript heading, acknowledgements, disclosures and funding are excluded from the word count). Additional information can be included in the supplementary material.

References should not exceed **100 maximum**.

Authors will be asked to revise the manuscript and/or remove references if these size limits are not respected.

7.2 Guidance on writing

7.2.1 General guidance

Long discussions about drugs that are controversial or not readily available should be avoided.

When required due to word limit, authors may move some text to the supplementary material. However, clinical recommendations should be kept in the main text.

Drugs that are not yet approved by the European Medicines Agency (EMA) should be identified with the statement ‘at the time of publication, [drug/treatment] is not yet EMA approved [for X indication]’. This phrasing must be used even if a drug is very likely to receive approval soon [i.e. if a Committee for Medicinal Products for Human Use (CHMP) recommendation for approval has been published]. Statements about expected approvals of drugs should be supported with a reference to the Summary of Product Characteristics/Prescribing Information or a pharmaceutical company’s press release if formal EMA approval is not yet publicly available.

7.2.2 Tools available for best practice

The development and writing of the CC recommendations manuscript should follow best practices. To aid this, the following tools may be useful:

The Appraisal of Guidelines, Research and Evaluation (AGREE) Reporting Checklist.[6,7]

Available here: http://www.agreetrust.org/resource-centre/agree-reporting-checklist.

The Template for Intervention Description and Replication (TIDieR) Checklist.

Available here: https://www.equator-network.org/wp-content/uploads/2014/03/TIDieR-Checklist-PDF.pdf.

7.2.3 Quality control

Authors are responsible for performing a data check of any numerical data (i.e. survival rates, p-values, hazard ratios, etc.) reported in the manuscript against the source publications and verifying the accuracy of data and other content included in the guideline.

7.3 Thematic sections

The thematic section structure described below should be used. Some ESMO CPGs (specifically those focused on cancer genetics and palliative/supportive) may not be compatible with these headings and may therefore follow 'individualised' structure.

7.3.1 Heading

7.3.1.1 Title

The title should be formatted according to the following example:

ESMO [and other society(ies), if applicable] consensus conference recommendations on ovarian cancer: pathology and molecular biology, early and advanced stages, borderline tumours and recurrent disease

7.3.1.2 Authors and affiliations

Provide first initial(s) and last names exactly as they should appear in the final manuscripts. Affiliations must be provided separately for each institution and should include a department where possible.

7.3.1.3 Running header

Please include a short running header, 80 characters maximum.

7.3.1.4 Word count

The following details should be included:

Word count: XXX (excluding title page, acknowledgements, funding and disclosure sections); References: X; Tables: X; Figures: X; Supplementary material: 1.

7.3.1.5 Key words

Please include up to five key phrases for *ESMO Open* and six key phrases for *Annals of Oncology* can be included. Please review and adapt as needed.

7.3.1.6 Highlights (online only)

Highlights are required by ESMO journals for the submission and online promotion of the final manuscript. Please provide three to five bullet points summarising the main points of the article. Each bullet point must not exceed 125 characters per bullet, including spaces.

Example:

- A melanoma consensus conference, organised by the ESMO Guidelines Committee, was attended by 32 experts from 14 countries
- The experts compiled recommendations (with supporting evidence) on controversial topics in melanoma management
- Recommendations for metastatic melanoma in this manuscript include the following:
    - targeted versus immunotherapy
    - treatment sequencing and duration
    - management of brain metastases

- A separate manuscript presenting results relating to the management of locoregional melanoma is also available

7.3.2 Introduction

A brief introduction to provide a rationale for the need of a consensus conference should be included. Brief information on the consensus conference should also be included.

7.3.3 Methodology

Methodology is required in the main text of the manuscript.

7.3.4 Acknowledgments

Please include any additional acknowledgements as appropriate, following the format of the example below. Individuals who do not meet all four ICMJE authorship criteria should be acknowledged as non-author contributors,[1] either individually or as a group, and their written permission obtained in order to include their acknowledgement. Editing and writing support will be acknowledged, e.g. from ESMO Guidelines medical writers/staff or freelancers working on behalf of ESMO.

e.g. Manuscript editing support was provided by Louise Green and Richard Lutz (ESMO Guidelines staff) and Angela Corstorphine of Kstorfin Medical Communications Ltd (KMC); this support was funded by ESMO.

7.3.5 Funding

No funding should originate from the industry in order to safeguard the integrity of the guidelines (only ESMO or professional networks). A general funding statement is required. The following general statement will be included in the final CC manuscript:

- All costs relating to the consensus conference were covered from ESMO [and other society(ies), if applicable] funds. There was no external funding of the event or manuscript production.

7.3.6 Disclosure

See Section 4.6: ESMO Declaration of Interest.

7.3.7 References

Refer to the most recently published randomised controlled trials (RCTs), meta-analyses and/or systematic reviews. Review articles may be used as citations in order to summarise data; however, it is preferable that pivotal RCTs or meta-analyses are cited in order to support a recommendation. References should not exceed 100 maximum.

Reference managing software should be used with a travelling library available to the ESMO Guidelines office to facilitate formatting for journal submission. Endnote is ESMO's recommended choice of software and a free version is available online. The Guidelines office will use Endnote 20 for reference formatting and can assist authors as needed with managing the references.

8 Final review and submission

ESMO Guidelines medical writers/staff carry out the final review and submission and ensure that the final version adheres to the SOP and journal requirements prior to submission.

8.1 Author Responsibility and Acknowledgement Agreement form

Authors should be able to take public responsibility for the manuscript and have confidence in the accuracy and integrity of all their co-authors. To aid this, before manuscript submission, the ESMO SE/CC Chair is responsible for confirming that all co-authors fulfil these criteria using the ESMO Author Responsibility and Acknowledgement Agreement form provided on the ESMO website here: https://www.esmo.org/guidelines/esmo-guidelines-methodology. The ESMO SE/CC Chair should provide specific details of each author's role in developing the manuscript.[2,3] The completed form must be returned to the ESMO Guidelines office for manuscript submission to proceed.

8.2 ESMO Journal requirements

The SE will provide a cover letter for the manuscript submission summarising important details of the manuscript, a list of proposed reviewers and professional social media profiles of authors; authors can recommend 3-5 reviewers to propose to the journal, and where possible these should be ESMO Faculty: https://www.esmo.org/about-esmo/organisational-structure/educational-committee/esmo-faculty.

Three individuals who are not recommended as reviewers can also be proposed.

ESMO Journals request the social media profiles of authors that will be tagged by ESMO/Annals of Oncology or ESMO Open when the publication is made available online, e.g. https://twitter.com/yourname. Providing this information is voluntary.

In addition, @myESMO is included as standard, as well as other organisational accounts for joint guidelines and @rarecancer where relevant.

8.3 Final review and DOIs

ESMO Guidelines medical writers/staff will circulate the finalised manuscript to all co-authors and gather approvals:

- All authors must approve the manuscript before submission
- Each author will review/update their final disclosure statement for the manuscript, which should reflect the DOI that is available from the ESMO DOI platform

ESMO Guidelines medical writers/staff will submit the manuscript and keep authors informed of progress.

9 References used in this SOP

1. Defining the Role of Authors and Contributors. International Committee of Medical Journal Editors. Available at: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html.
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7. AGREE Reporting Checklist. Published 2016. Available at: http://www.agreetrust.org/resource-centre/agree-reporting-checklist/.

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10 Appendix

10.1 Instruction 1: Modified Delphi method for remote work of WGs before the CC

It is a method used to gather opinion from large numbers of participants working independently who answer questionnaires in two or more rounds. After each round, a facilitator provides in a short period of time an anonymous summary of the contributions and asks the participants to revise their answer(s), considering the summary results, within 48 hours. The process terminates after a predefined stop criteria (number of rounds, achievements of consensus, stability of results).

10.1.1 Delphi Questionnaires in each WG

- After the questions are finalised, the WG Chairs produce a Delphi Questionnaire comprising the questions, each with Alternative Options/Answers or “Do You Agree” sections.
- The Delphi Questionnaire is circulated to all WG members.
- The answers are anonymised and collated in a summary report prepared by ESMO staff and forwarded to all WG members.
- The Delphi Questionnaire is sent to all WG members for a second round.
- The final round questions and answers are collated to a summary with questions and recommendation options.

Include in References:

Jones Y and Hunter D. Qualitative research: consensus methods for medical and health services research. BMJ 1995; 311: 376–388.

10.2 Instruction 2: Use of GRADE grid for post-CC dissents

For each recommendation, the participant fills a GRADE grid Module 1 by defining their opinion on quality of evidence (based on available data) and the balance between desirable (beneficial health outcomes, cost savings, less burden for patients and staff) and undesirable effects. Quality of evidence and balance between desirable/undesirable effects influences the strength of recommendations (the higher the quality of evidence or the larger the difference between the desirable and the undesirable effects, the more likely a strong recommendation is warranted). The questionnaire is sent to ESMO staff within 72 hours, who then circulate a polling summary which reflects the collective judgement on strong recommendation in favour of an intervention (desirable outweigh undesirable effects), weak or no recommendation at all.

10.2.1 The GRADE grid

Participants are provided with guidance on factors to be taken into account in formulating the recommendation.

	Grade score				
	1	**2**	**0**	**-2**	**-1**
Superiority of intervention Balance between desirable and undesirable consequences of intervention	Definitely superior AND desirable clearly outweigh undesirable	Probably superior AND desirable probably outweigh undesirable	Equal to other option OR trade-offs equally balanced or uncertain	Probably inferior OR undesirable probably outweigh desirable	Definitely inferior OR undesirable clearly outweigh desirable
Recommendation	Strong: definitely do it	Weak: probably do it	No specific recommend ation	Weak: probably don't do it	Strong: definitely don't do it
For each proposition below, please mark with a "X" the cell which best corresponds to your assessment					
Example: Chemotherapy + Drug A should be the preferable option over Chemotherapy + Drug B for X-type Y cancer patients with Z as the aim		**X**			

Include in References:

Jaeschke R, Guyatt GH, Dellinger P et al. Use of GRADE grid to reach decision on clinical practice guidelines when consensus is elusive. BMJ 2008; 337: a744.

Guyatt GH, Oxman AD, Kunz R et al. What is quality of evidence and why is it important to clinicians? BMJ 2008; 336: 995–998.