ESMO Standard Operating Procedures (SOPs) for Clinical Practice Guidelines (CPGs) and ESMO Magnitude of Clinical Benefit (ESMO-MCBS) scores

ESMO Guidelines Committee (GLC)

<table>
<thead>
<tr>
<th>Version</th>
<th>Version 1.0; January 2021</th>
</tr>
</thead>
</table>
| Changes in this version | Added detail on webinars  
Clarified process for inviting authors  
Clarified authorship criteria  
Added contributor roles taxonomy  
Clarified Disclosure of Interests (DOI) collection process  
Modified requirements for structure of the manuscript in thematic sections  
Clarified requirements for inclusion of ESMO-MCBS scores  
Added requirement for quality control and data check  
Added guidance on wording of recommendations  
Added section on submission  
Added Author Responsibility and Acknowledgement Agreement form  
Added definitions and function of different types of ESMO Guidelines |
| Approved | Giuseppe Curigliano, GLC Chair |
| Next review planned | After the next Guidelines Committee meeting (in 2021, date to be confirmed); revisions can be made sooner as required |
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1 Introduction

- The target audience for the CPGs is health professionals working in the field of oncology across Europe and other parts of the world, with an emphasis on Medical Oncology.

- The standard CPGs should take into account and be in agreement with the content from the ESMO Consensus Conference Guidelines when available (these are two separate products that are complementary).

- CPGs will be submitted to ESMO journals (Annals of Oncology annalsofoncology.org or ESMO Open esmoopen.com) for evaluation for publication.

- ESMO will produce pocket versions of standard CPGs as ‘hands-on’ booklets with tables, algorithms and ‘bullet point’ recommendations for daily use: Pocket Guidelines. The Subject Editor (SE) of each CPG will be asked to review and comment on the relevant chapter of the Pocket Guidelines. The lead author may also be asked for comment.

- ESMO will produce slide sets containing key recommendations and algorithms. The lead author and SE of the relevant CPG will be asked to review and comment on the slide set.

- ESMO will produce webinars following publication of CPGs, involving case-based discussion around the practical implementation of recommendations.

2 Commissioning of a CPG

CPGs should be updated when there is need for such as judged by the ESMO GLC Chair or Co-Chair or a Guidelines Steering Committee (GL-SC) member. This judgement is based on the availability of new, clinically significant evidence that necessitates substantial changes or additions to clinical recommendations. New CPGs may also be considered for topics not currently covered by current ESMO CPG titles.

In selected circumstances, ESMO may opt to produce joint CPGs with other formally recognised scientific societies, after careful consideration by the GLC of the science, characteristics, scope and strategy. In this case, there is a mutual agreement to follow the ESMO SOPs and methodology with some necessary minimal adjustments in order to generate consent.

3 Authorship

3.1 Invitation to the author group

First author and other authors should be selected by the GL-SC member and the SE with relevant expertise for the disease area, in conjunction with the GLC Chair. Each proposed author should have an internationally recognised profile in the field and good reputation.

Selection of the author group should aim to be diverse and inclusive, while maintaining and prioritising the highest level of expertise. The proposed author group should be multidisciplinary, and therefore should include medical oncologists, a surgical oncologist and a radiation oncology specialist as far as possible (and/or other disciplines if appropriate). The group should also be multinational and should therefore include experts from different institutions and different countries in Europe and abroad to ensure validity as a European and global guideline. At least one young, talented expert in the field should be included, as should relevant GL-SC members and SEs who are expert in the specific disease.

The author group should consist of a minimum of 8 authors. The lead author acts as the coordinating author and appears as first author, followed by the other co-authors and the SE as last author.
A formal invitation will be sent from the ESMO Guidelines Office to each potential author along with a request to provide a DOI (see Section 3.4). Each potential author must complete the DOI process in order to begin work as an author. After all DOIs are received, the kick-off call/online meeting can proceed and work on the guideline can begin.

### 3.2 Authorship criteria

All authors should fulfil all four of the following criteria recommended by the ICMJE:

- 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.

For CPGs involving a large multi-author group, all members of the group named as authors should still meet all four of the above ICMJE authorship criteria, including approval of the final manuscript. Members of the group who do not fulfil all criteria can be listed in the Acknowledgements section.

Any representatives of patient organisations or patient advocacy groups that are invited to participate as authors should also fulfil these criteria.

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

Authors should be able to take public responsibility for the CPG and have confidence in the accuracy and integrity of all their co-authors. To aid this, before manuscript submission, the lead author is responsible for certifying details on all co-author contributions using the Author Responsibility and Acknowledgement Agreement form provided in Section 8.1 and on the ESMO website here: [https://www.esmo.org/guidelines/esmo-guidelines-methodology](https://www.esmo.org/guidelines/esmo-guidelines-methodology). The lead author should provide specific details of each author’s role in developing the CPG as outlined in Section 3.3 and on the form (see Section 8.1). The completed form must be returned to the ESMO Office for manuscript submission to proceed.

### 3.3 Contributor Roles

Description of individual contributor roles provides transparency over the differing roles of each author and may help to avoid authorship disputes, as well as enable authors to have confidence in the accuracy and integrity of all their co-authors.

The lead author is responsible for certifying details on all co-author contributions using the Author Responsibility and Acknowledgement Agreement form provided (see Section 8.1 and the ESMO website here: [https://www.esmo.org/guidelines/esmo-guidelines-methodology](https://www.esmo.org/guidelines/esmo-guidelines-methodology)). This form is based on the Contributor Roles Taxonomy (CRediT), which requires that details for each author are provided regarding their contribution to one or more distinct roles for scholarly work, and has been adapted to align with the development process of ESMO guidelines.

The Author Responsibility and Acknowledgement Agreement should be completed and sent to the ESMO Office before submission. Details on contribution should be summarised in a contributor statement in the Acknowledgements section.

Example of a contributor statement: ‘JB: Conceptualisation, writing – review and editing; JD: Literature search, literature review and development of clinical recommendations; MM: Literature review and development of clinical recommendations, visualisation, writing – original draft.'
3.4 **DOI**

Per the ESMO DOI Policy, the ESMO Guidelines Office will formally invite all potential authors to participate, and in doing so will request each potential author to provide their disclosures through the ESMO DOI system. Each author must provide a disclosure of interest statement, even if there is nothing to declare. DOIs must be received from all authors before any contribution to the guideline is made. This statement will be included in the Disclosures section of the manuscript and may be generated by the author from the ESMO DOI system. Each individual author is responsible for ensuring that their DOI statement is accurate. Disclosures are not included in the manuscript word count.

Template 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 no disclosures to declare”.

3.5 **Role of ESMO Guidelines Office staff including Medical Writers**

ESMO Guidelines Office staff review all guidelines to ensure they adhere to this SOP and the journal requirements. Editing and medical writing support can also be provided. During kick-off of a new CPG or CPG update, the potential roles for Medical Writers will be discussed and agreed with the author group.

These roles are considered to be ‘non-author contribution’ and do not replace intellectual contribution from authors but should detailed in the Acknowledgements as editing support or medical writing support.

4 **Development of CPG content**

4.1 **Formatting requirements**

4.1.1 **Title**

The title should be formatted according to the following example:

*Prostate cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up*

For the titles that do not include diagnosis, treatment and follow-up, the title should be formatted according to the following example:

*Central venous access in oncology: ESMO Clinical Practice Guidelines*

4.1.2 **Extent**

ESMO Journals follow a strict word count policy. The 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 supplementary files.

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.
4.1.3 Structure of the manuscript in thematic sections

The thematic section structure described below should be used. Further requirement for the content of each section are given in Section 4.8. 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.

1. Incidence and epidemiology
2. Diagnosis, pathology and molecular biology
3. Staging and risk assessment
4. Management of local and locoregional disease
5. Management of advanced and metastatic disease
6. Follow-up, long-term implications and survivorship
7. Methodology
8. Acknowledgements
9. Funding
10. Disclosure
11. References
12. Tables and Figures
   - Table with diagnostic work-up
   - Tables on therapeutic regimens or prognosis
   - ESMO-standardised algorithms with management or therapeutic strategy according to risk factors or stage (mandatory)
13. Supplementary files (available online only)
   - Table(s) with staging system (preferably TNM) and stage groups
   - ESMO-MCBS table with ESMO-MCBS score for new therapies/indications approved by the European Medicines Agency (EMA) and/or the United States Food and Drug Administration (FDA)
   - LoE/GoR table (required for all ESMO guidelines)

4.2 Methodology

4.2.1 LoEs and GoRs

Recommendations should be accompanied by proper evidence level and grade of recommendation according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System (see Section 4.4.11.3.5). Therefore, it is mandatory for all recommendations to be supported with an LoE and GoR, and where relevant ESMO-MCBS scores should also be included.

A bullet-point list of all recommendations in each thematic section should be included at the end of the relevant section, including LoEs and GoRs and ESMO-MCBS scores where applicable.
Example:

**Recommendations:**
- mpMRI should be carried out before prostate biopsy [I, B]
- A prostate cancer risk calculator and/or mpMRI should be used to confirm the indication for biopsy in men with elevated PSA [III, C]
- Transperineal biopsies are recommended, rather than transrectal ultrasound (TRUS)-guided biopsies [III, B]
- Each biopsy should be reported individually and evaluated using the ISUP Consensus recommendations [8] [II, B]

4.2.1.1 LoE
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.

4.2.1.2 GoR
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).

4.2.2 ESMO-MCBS scores
Where applicable, ESMO-MCBS calculations will be performed by the ESMO-MCBS Working Group and validated by the GLC.

Relevant ESMO-MCBS scores will be summarised in the CPG in a separate ESMO-MCBS table provided by ESMO-MCBS Office staff. The table will be included as a supplementary file. This table is to be used as a tool to provide basic information on the new therapy rather than the formal tool producing the ESMO-MCBS score. Authors of the CPG should evaluate the scores and any queries will be addressed to the ESMO-MCBS Working Group for consideration and response. In case of disagreement, arbitration is performed by the ESMO-MCBS WG Chair with the GLC Chair and, when necessary, by the ESMO Board.

When an ESMO-MCBS score has been produced for a new therapy or a new indication of existing therapy by the EMA or the FDA, it should appear next to the LoE/GoR in the text and in the algorithms whenever a recommendation on the therapy is formulated (e.g. [I, A; ESMO-MCBS v1.1 score: 4]).

The ESMO-MCBS score must be included for any drug that is included in the manuscript. However, if scores are available for drugs not mentioned in the guidelines (e.g. outdated treatments), the authors are not obliged to include this information. CPGs can include scores for drugs that are not yet EMA- or FDA-approved, providing the lack of approval is clearly stated and there is support for the score from a peer-reviewed publication. Authors may choose to add specific commentary to scores if they feel additional explanation will be needed by the readership.
4.2.3  Quality control
CPGs are reviewed by a relevant member of the GL-SC before journal submission. Any comments from this review will be provided to the authors to address. During this review, a data check will be performed to check the accuracy of any numerical data (i.e., survival rates, p-values, hazard ratios, etc.) reported in the manuscript against the source publication. Medical Writers may support the GL-SC member in performing the data check; however, the ultimate responsibility for the accuracy of data and other content included in the guideline lies with the authors. To aid this review, authors are encouraged to highlight relevant data in the pdfs of source publications when performing literature reviews.

4.3  Guidance on writing

4.3.1  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.

When relevant, authors are encouraged to consider the relevance of their clinical recommendations to underrepresented demographics/ethnicities and to comment on related gaps in the literature and research when needed.

4.3.2  Tools available for best practice
The development and writing of ESMO CPGs should follow best practices. To aid this, the following tools may be useful:

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

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

4.3.3  Wording of 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. Using an active voice rather than passive voice may also enhance clarity.

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…’

4.3.4  Precision medicine
Information relating to biomarkers for precision medicine should be included throughout the CPG text in the various sections where relevant and appropriate (e.g., for disease classification, prognosis, prediction and treatment decisions). Information should be given on whether the biomarkers are validated and actionable or targetable.

4.3.5  Tables
All tables must be cited within the document and should be included in the manuscript file following the references (separate word files are not needed but all content should be provided in an editable format).
4.3.6 Treatment algorithms (mandatory)

It is very important that authors draft ESMO-standardised algorithms on therapeutic strategy or management according to stage, risk factors and disease/molecular characteristics. This is a priority issue for ESMO.

ESMO will prepare the final algorithms using standard formatting/colours for publication. The following colour code will be used:

- Purple: general/heading boxes related to stratification e.g., type of cancer, or patient sub-group
- Red: surgery
- Green: radiotherapy
- Blue: systemic anticancer therapy
- Turquoise: combination of treatments (e.g. CRT) or other systemic treatments (allo-SCT, RBC transfusions, antibiotics, steroids, etc.)
- White: other aspects of management not covered by the categories above e.g., observation and monitoring.

All figures must be cited within the document and should be included in the manuscript following the tables (separate word or PowerPoint files are not needed but all content should be provided in an editable format). Please include LoEs and GoRs where applicable. ESMO-MCBS scores will be added in the final version. Please include all acronyms in alphabetical order by acronym and footnotes in the order shown below.

An example of an algorithm for Management/Therapeutic strategy by stage/risk factors (taken from the 2020 ESMO CPG eUpdate on hepatocellular carcinoma; published 19 June 2020) is shown below.

**Figure X. HCC treatment options depending on BCLC stage.**

BCLC, Barcelona Clinic Liver Cancer; BSC, best supportive care; EMA, European Medicines Agency; FDA, United States Food and Drug Administration; HCC, hepatocellular carcinoma; LTX, liver transplantation; ESMO-MCBS, ESMO-Magnitude of Clinical Benefit Scale; SBRT, stereotactic body radiotherapy; SIRT, selective internal radiotherapy; TACE, transarterial chemoembolisation.

Purple: general categories or stratification; red: surgery; green: radiotherapy; blue: systemic anticancer therapy; turquoise: combination of treatments or other systemic treatments; white: other aspects of management e.g. monitoring, supportive care.

*See table for indication constraints based on tumour burden and liver function.

*Not EMA-approved.

*Non-standard, alternative treatment.
4.4 Section-specific requirements

4.4.1 Incidence and epidemiology
The ESMO guidelines are Europe-centric but also provide guidance worldwide. Therefore, include details of global incidence and epidemiology when relevant, in addition to European data.

4.4.2 Diagnosis, pathology and molecular biology
A table and/or algorithm detailing diagnostic work up should be included.

4.4.3 Staging and risk assessment
Include appropriate staging tables as supplementary files. Where possible, refer to the Union for International Cancer Control (UICC) Tumour-Node-Metastasis (TMN) staging system. These tables can be provided by ESMO.

4.4.4 Management of local and locoregional disease
An ESMO-standardised treatment algorithm must be included on therapeutic strategy according to stage, risk factors and disease/molecular characteristics.

4.4.5 Management of advanced and metastatic disease
An ESMO-standardised treatment algorithm must be included on therapeutic strategy according to stage, risk factors and disease/molecular characteristics.

4.4.6 Follow-up, long-term implications and survivorship
This section will focus on recommendations for patient follow-up and will also include information on long-term toxicities of treatment, second tumours, psychosocial implications, rehabilitation and any other issues related to survivorship.

4.4.7 Methodology
Methodology is required in the main text of the manuscript. The following paragraph will be included in all CPGs:

This Clinical Practice Guideline was developed in accordance with the ESMO standard operating procedures for Clinical Practice Guidelines development (http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology). The relevant literature has been selected by the expert authors. Authors, please provide a brief summary of search parameters. An ESMO-MCBS table with MCBS scores is included in Supplementary Table SXX. ESMO-MCBS v1.1 [ref #] was used to calculate scores for new therapies/indications approved by the EMA since 1 January 2016 or FDA since 1 January 2020 (https://www.esmo.org/Guidelines/ESMO-MCBS). The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee. Levels of evidence and grades of recommendation have been applied using the system shown in Supplementary Table SXX [ref ##]. Statements without grading were considered justified standard clinical practice by the authors.

ref # = Include reference to ESMO-MCBS manuscript (version 1.1) in the References section (also include in the supplementary file):

ref ## = include reference for LoE/GoR table (also include in supplementary file):

4.4.8 Acknowledgments
Please include any additional acknowledgements as appropriate. Individuals who do not meet all four ICMJE authorship criteria should be acknowledged as non-author contributors, either individually or as a group, and their written permission obtained in order to include their acknowledgement. Editing and writing support should be acknowledged, e.g., from ESMO Guidelines Office staff or freelancers working on behalf of ESMO.
4.4.9 Funding
A general funding statement is required. The following general statement will be included in all CPGs:
No external funding has been received for the preparation of these guidelines. Production costs have been covered by ESMO from central funds.

4.4.10 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. Trials used for ESMO-MCBS score calculation(s) should also appear in the reference list. References should not to exceed 100 maximum.
Please use Endnote if possible.

4.4.11 Supplementary Material
Some required elements will be included as supplementary material, which appear online only and are excluded from the overall word count limit. All supplementary data including tables and figures should be prepared as one document (separate word files are not needed).

4.4.11.1 Supplementary Table(s) with staging system (preferably TNM) and stage groups
Please include any appropriate staging tables as supplementary files. Where possible, refer to the Union for International Cancer Control (UICC) staging system. These tables can be provided by ESMO.

4.4.11.2 Supplementary Magnitude of Clinical Benefit Scale (ESMO-MCBS) Table
Supplementary Table SX. ESMO-MCBS table for new therapies/indications in XXX

<table>
<thead>
<tr>
<th>Therapy</th>
<th>Disease setting</th>
<th>Trial</th>
<th>Control</th>
<th>Absolute survival gain</th>
<th>HR (95% CI)</th>
<th>QoL/Toxicity</th>
<th>ESMO-MCBS Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the new therapy</td>
<td>Describe the disease setting, Specify (Neo)adjuvant or Advanced</td>
<td>Name [1], phase of trial, NCT number</td>
<td>Describe the control arm</td>
<td>Median, in months (state OS, PFS or both)</td>
<td>Median and 95% CI</td>
<td>Improved or Deteriorated or Similar or Not Available</td>
<td>Score X (Form X)</td>
</tr>
</tbody>
</table>

CI, confidence interval; EMA, European Medicines Agency; ESMO-MCBS, ESMO-Magnitude of Clinical Benefit Scale; HR, hazard ratio; OS, overall survival; PFS, progression-free survival; QoL, quality of life.

EMA approvals since 1 January 2016 and FDA approvals since 1 January 2020.

ESMO-MCBS version 1.1 [2]. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee.
Include in References:
1. Pivotal trial reference.
4.4.11.3 Supplementary LoE/GoR table

The following table 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*).

Levels of evidence

<table>
<thead>
<tr>
<th></th>
<th>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</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>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</td>
</tr>
<tr>
<td>II</td>
<td>Prospective cohort studies</td>
</tr>
<tr>
<td>III</td>
<td>Retrospective cohort studies or case–control studies</td>
</tr>
<tr>
<td>IV</td>
<td>Studies without control group, case reports, expert opinions</td>
</tr>
</tbody>
</table>

Grades of recommendation

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

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

Include in References:

5 Submission
Final review and submission is carried out by the ESMO Guidelines Office staff, who review the manuscript to ensure it adheres to the SOP and journal requirements.

All authors must approve the final version of the manuscript before submission and the coordinating author must complete the Author Responsibility and Acknowledgement Agreement form provided in Section 8.1 and on the ESMO website here: https://www.esmo.org/guidelines/esmo-guidelines-methodology.

Authors can recommend 3-5 reviewers to propose to the journal, and where possible these should be ESMO faculty. Three individuals who are not recommended as reviewers can also be proposed.

The SE will provide a cover letter for the submission summarising important details of the CPG and the list of proposed reviewers.

6 eUpdates
In the case of a significant breakthrough that necessitates rapid communication as CPG content or in the case of a new EMA or FDA indication bearing an MCBS score, the relevant SE will coordinate with the guideline authors to produce an eUpdate. This will be published on the ESMO website linked to the appropriate guideline and may be submitted to an ESMO journal for publication.

Please see the SOPs/instructions for authors and templates for ESMO eUpdates available here: http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology.

7 References used in this SOP

8 Appendix
8.1 ESMO Author Responsibility and Acknowledgement Agreement

The coordinating author of an ESMO Guideline is responsible for completing and signing this form and returning it to the ESMO Guidelines Office before submission of the guideline manuscript to the journal.

Title of Guideline: Click or tap here to enter text.
Date (of completion of this form):

Details of coordinating author (first author)
Name: Click or tap here to enter text.
Email address: Click or tap here to enter text.
Phone number (including country code): Click or tap here to enter text.

Name of Subject Editor (last author): Click or tap here to enter text.
Names of all other co-authors: Click or tap here to enter text.

Authorship criteria

This coordinating author certifies that all authors listed above fulfil all four of the following criteria recommended by the ICMJE:

- 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

Check the box to agree: ☐

Contributor roles

This coordinating author certifies that the authors have contributed according to the roles outlined below.

Check the box to agree: ☐

(List the appropriate author names next to each category. Each author must be listed next to at least one category. More than one author can be listed per category.)

<table>
<thead>
<tr>
<th>Role</th>
<th>Definition</th>
<th>Author names</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conceptualisation</td>
<td>Ideas; formulation or evolution of overarching goals and aims of the guideline, e.g., instigation of a new guideline title, or addition of new patient sub-groups or clinical settings for a pre-existing title.</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Literature search</td>
<td>Development of criteria for literature search and/or implementation of the literature search.</td>
<td>Click or tap here to enter text.</td>
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<tr>
<td>Literature review and development of clinical recommendations</td>
<td>Review of published peer-reviewed research and synthesis of clinical recommendations and their</td>
<td>Click or tap here to enter text.</td>
</tr>
<tr>
<td>Roles and definitions are adapted from the Contributor Roles Taxonomy (CRediT; <a href="https://casrai.org/credit/">https://casrai.org/credit/</a>).</td>
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<tr>
<td><strong>Visualisation</strong></td>
<td>Preparation, creation and/or presentation of the published work, specifically visualisation/data presentation, e.g., creation of treatment algorithms and other figures and tables</td>
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<tr>
<td><strong>Writing – original draft</strong></td>
<td>Preparation, creation and/or presentation of the published work, specifically writing the initial draft.</td>
<td></td>
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<tr>
<td><strong>Writing – review and editing</strong></td>
<td>Preparation, creation and/or presentation of the published work specifically critical review, commentary or revision</td>
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<tr>
<td><strong>Section-specific contributions (please identify the specific sections that authors contributed to)</strong></td>
<td>Click or tap here to enter text.</td>
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<tr>
<td><strong>Other (please specify roles and author names)</strong></td>
<td>Click or tap here to enter text.</td>
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**Acknowledgements**

This corresponding author certifies that:

- Individuals who have made substantial contributions but do not fulfil all four ICMJE authorship criteria, listed above, have been named with their specific contributions in the Acknowledgement section of the manuscript.
- All individuals named in the Acknowledgement section have given written permission to be named.

Check the box to agree: ☐

After completing this form, it should be returned to the ESMO Guidelines Office by the coordinating author.
**8.2 Definitions and function of the different types of ESMO Guidelines**

A brief overview of the definitions and suitability of the different types of ESMO guidelines is given in the table below.

<table>
<thead>
<tr>
<th>Type of ESMO Guideline</th>
<th>Definition</th>
<th>Suitability</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPG</td>
<td>A full set of recommendations for the diagnosis, management, treatment and follow-up of a specific cancer type, patient group, or clinical setting, supported by peer-reviewed data and clinical rationale.</td>
<td>New titles can be proposed for topics not covered by existing ESMO CPGs. A full update to a CPG for an existing title may be appropriate when many clinical recommendations throughout the CPG have become outdated. If updates are minor and limited to a specific section, an eUpdate may be more appropriate than full CPG update.</td>
</tr>
<tr>
<td>eUpdate</td>
<td>Online update of a specific section of an existing CPG. Published simultaneously on ESMO.org as well as in ESMO journals as Letters to the Editor or Special Articles to allow for greater awareness.</td>
<td>Intended to be quick and flexible. Suitable when a more time-consuming update of the full CPG is not necessary, and when a clinically important breakthrough from a peer-reviewed publication needs to be rapidly communicated, or a new MCBS score is issued. To reduce the chance that readers miss important updates, it is preferable to issue fewer eUpdates covering multiple recommendations rather than many individual eUpdates.</td>
</tr>
<tr>
<td>Living Guideline</td>
<td>A CPG that is updated on a regular basis, with updates integrated into the full CPG text and figures creating a new version online. The Living Guideline updates are available on ESMO.org. The original CPG on which the updates are based is published in an ESMO journal.</td>
<td>Intended for titles in which clinically important breakthroughs and updates to recommendations are anticipated to arise from peer-reviewed publications on a regular basis in the future (e.g., high profile 'big killers' that receive comparatively high research funding and may require several updates per year for several years). To reduce the chance that readers miss important updates, and due to the intensity of work needed for each Living Guideline, updates to existing Living Guidelines should currently be combined when possible for a maximum or four updates per year. This process will be reviewed and improved as the operation of Living Guidelines develops further. For CPGs that need updating less regularly, an eUpdate or full CPG update may be more appropriate.</td>
</tr>
</tbody>
</table>