



**ESMO Guidelines Committee (GLC)
Standard Operating Procedures (SOPs)
for ESMO Clinical Practice Guidelines (CPGs)**

Version	ESMO CPG SOP Version 2.3; October 2023
Changes in this version	Modified ESMO CPG author selection and confirmation process Modified ESMO Declaration of Interest (DOI) collection requirements Modified ESMO gender balance rule

Note: this ESMO SOP only applies to ESMO CPG publications and full updates. For additional guidance on updates of original CPG publications, please see the separate electronic update (eUpdate) and Clinical Practice Living Guidelines (Living GLs) SOPs. All three SOP documents are available publicly on the ESMO website [esmo.org](http://www.esmo.org): <http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology>.

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1 Introduction

The target audience for ESMO CPGs is health professionals working in oncology.

ESMO CPGs should consider the content of any published ESMO Consensus Conference (CC) Recommendations manuscripts when available. ESMO CPGs and CC Recommendations manuscripts are two separate but complementary products.

All CPG authors agree that the authored CPG is the copyright of ESMO and will be submitted for consideration for publication in an ESMO journal only— either *Annals of Oncology* (annalsofoncology.org) or *ESMO Open* (esmoopen.com). The target ESMO journal for each CPG will be communicated by the GLC Chair prior to manuscript submission.

2 Role of ESMO Guidelines staff

ESMO Guidelines staff review and edit all CPGs to ensure that the final publications adhere to the ESMO methodology detailed in this SOP as well as ESMO journal requirements. ESMO staff members involved in the CPG are considered as non-author contributors, not authors, and their involvement will be detailed in the Acknowledgements section of the CPG as providing manuscript editing support.

Although the authors are responsible for drafting all original CPG content, ESMO staff will provide specific editing support including reference library development as discussed and agreed with the lead and last authors.

ESMO staff will format all ESMO CPGs to align with ESMO journal style prior to submission and will manage the entire CPG manuscript submission process, including reference formatting and liaising with ESMO journal contacts on behalf of the GLC and CPG author group.

3 Commissioning of an ESMO CPG

3.1 ESMO-only CPGs

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

3.2 Joint CPGs with other societies

ESMO may produce a joint CPG with another formally recognised scientific society, in selected circumstances only and after careful consideration by the GLC of the overall ESMO strategy and science, characteristics and scope. In this case, there is mutual agreement and all CPG authors representing both societies will be expected to follow the ESMO methodology detailed in this SOP, with adjustments if needed, to generate consent.

If needed, ESMO will provide a general Memorandum of Understanding (MOU) with the other society governing all joint activities including CPG production. Authorship and publication details will be detailed in a specific Guideline Development Agreement (GDA) for each joint CPG title, except for CPGs involving the European Reference Network on Rare Adult Solid Cancers (EURACAN).

In the field of rare adult solid cancers, ESMO may collaborate with EURACAN on CPGs covering single families of rare adult solid cancer (e.g. sarcomas) or tumours/groups of tumours within such families (e.g. thymomas within rare thoracic tumours). The decision to proceed with a new joint ESMO–EURACAN CPG will be made jointly by the GLC Chair and the respective EURACAN coordinator for that disease area on a case-by-case basis. All ESMO–EURACAN CPG authors will be expected to comply with the ESMO methodology detailed in this SOP.

4 ESMO CPG authorship

4.1 Authorship criteria

The author group should consist of experts who fulfil the following criteria:

- The author group should consist of a minimum of 8 authors, including the SE as last author and other SEs and/or GL-SC member(s) as penultimate author(s), if relevant.

- Each proposed author should have an internationally recognised profile in the field and a good reputation.
- The author group should be diverse, gender-balanced (not less than 40% of either gender) and multidisciplinary, including medical oncologists, a surgical oncologist, a radiation oncology specialist and/or other disciplines if appropriate.
- The group should also be multinational with authors representing countries in Europe and elsewhere to ensure validity as both a European and global CPG.
- The group should be multi-institutional, ideally with all authors representing different institutions (i.e. ideally a maximum of one representative from each institution, but exceptions can be granted for rare tumours). This criterion may be easier to achieve for common cancers than for rare cancers.
- At least one early-career, talented expert in the field should be included as a co-author, if applicable, including members of ESMO Young Oncologists Committee or the ESMO Leaders Generation Programme. There is no specific age requirement, but ESMO encourages their involvement as a valuable career opportunity.
- Inclusion of representative(s) of patient organisations or patient advocacy groups can be considered if appropriate, either as authors, if they meet the authorship criteria, or as reviewers.

All authors should fulfil all four of the following authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE)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.

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.

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 of the CPG, with details of the specific contribution, and their written permission obtained in order to include their acknowledgement.

4.2 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.^{2,3}

As well as the authorship criteria outlined above, certain key authors have the specific responsibilities described below. Other responsibilities for the authors below and other co-authors may also be decided upon on a CPG-specific basis, e.g. allocation of specific sections of the manuscript.

4.2.1 Lead author

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, unless otherwise agreed with the GLC Chair.

The lead author is responsible for:

- Proposing suitable co-authors, in collaboration with the SE.
- Acting as the coordinating author to drive input and contributions from co-authors and to provide progress updates to the ESMO Guidelines Committee and ESMO Guidelines staff.
- Ensuring that the CPG follows the ESMO methodology as closely as possible.
- Certifying that all authors fulfil the ICMJE criteria 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>).
- Along with the last author (SE), providing review/commentary on related ESMO CPG derivative products.

4.2.2 Last author (SE)

As the last author, the SE is responsible for:

- Proposing a suitable lead author, in collaboration with the GL-SC member for the tumour/subject area, if relevant.

- Proposing suitable co-authors, in collaboration with the lead author, and with GL-SC member for the tumour/subject area, if relevant.
- Ensuring that the CPG follows the ESMO methodology as closely as possible and providing extensive support to the lead author regarding queries on methodology.
- Providing the cover letter for journal submission, including recommended reviewers (ESMO Faculty where possible).
- Providing commentary on related ESMO CPG derivative products.

4.2.3 GL-SC member

The GL-SC member will be invited to be a co-author on each CPG for the tumour/subject area, if relevant (excluding GL-SC ex-Officio members, who are members related to their role on another ESMO committee). The GL-SC member can be listed alphabetically or as a penultimate author. Even when the GL-SC member is regarded to be more 'senior' than the SE in the field, the SE will be the last author of the CPG, unless otherwise specified by the GLC Chair.

4.2.4 GLC Chair and Deputy Chair

In select cases, the GLC Chair or Deputy Chair will be invited to be a co-author.

4.2.5 Representatives of other societies

For joint CPGs with other societies, specific experts will play a central role as a representative of that society, either as co-first author or co-last/penultimate author in 'equal contribution' mode. These authors will work closely with the ESMO lead author and SE to evaluate the author group and nominate additional multidisciplinary experts (e.g. non-medical oncologists) if needed. The GLC Chair is responsible for approving the entire author panel including representatives of any other societies.

4.3 Authorship order

Unless otherwise specified and approved by the GLC Chair, the CPG author order is as follows:

Lead author.

Other co-authors: In alphabetical order of surname.

GLC Chair, Deputy Chair or GL-SC member as co-author: In alphabetical order of surname or listed as a penultimate author (before the SE responsible for the CPG).

Last author: SE.

4.4 Author nomination and confirmation process

ESMO Guidelines staff will assist the SE and lead author with coordinating the author selection and confirmation process, obtaining the GLC Chair's approval of the proposed authors, collecting all author DOIs and sending formal invitations once the DOIs are reviewed by ESMO and the SE.

4.4.1 Author selection

For each CPG, the SE should propose the lead author to the GLC Chair for approval. Once the nominated lead author is approved by ESMO to participate in the project and their DOI has been reviewed, the SE and lead author should propose the co-authors to the GLC Chair for approval. Other SEs and the ESMO GL-SC member for the relevant tumour/subject area should also be involved during co-author proposals and final selection to select the best contributors.

4.4.2 ESMO author DOIs

As part of the author selection and confirmation process, ESMO will verify that each potential author has an ESMO account and has provided/updated their DOI statement in the ESMO DOI Platform. The DOI collection process is centrally managed within ESMO, and the financial value of each DOI 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 potential author must provide DOI information including financial values, even if there is nothing to declare, before the individual's participation in the CPG can be confirmed.

Disclosures are not included in the manuscript word count.

Per the ESMO DOI policy, each author is responsible for ensuring that their DOI statement in the ESMO DOI Platform is true, up to date and complete.

4.4.3 Author invitations

After each DOI is received and reviewed by ESMO and the SE, ESMO Guidelines staff will send a formal author invitation to each author on behalf of the lead author, SE and the GLC Chair. Once all authors are confirmed to participate, the CPG project can proceed to the kick-off stage.

5 CPG kick-off meeting

Following author invitations, ESMO Guidelines staff will organise an online kick-off meeting with all authors to discuss author roles, timelines and manuscript formatting requirements as detailed in this SOP.

ESMO Guidelines staff will liaise with the lead author/SE to prepare a presentation including author allocations and DOI information (to review before the meeting).

ESMO CPG kick-off meetings will cover:

- Author introductions and roles of lead author, last author (SE) and other co-authors, including additional SEs and the GL-SC member, if relevant
- Author allocations, roles and responsibilities, manuscript development and proposed timelines
 - The lead author is required to prepare an Author Responsibility and Acknowledgement Agreement form detailing each author's contribution (to be completed before final manuscript submission)
- ESMO DOI Policy and review of author DOIs (coordinated by ESMO Guidelines staff and ESMO Compliance Committee)
- CPG development according to the ESMO CPG SOP:
 - Main manuscript:
 - Thematic structure/sections
 - Use of levels of evidence (LoEs) and grades of recommendation (GoRs) in all recommendations statements according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System⁴
 - References
 - Tables
 - Figures including ESMO-standardised treatment/management algorithms
 - Supplementary Material:
 - Supplementary text, if applicable (sections should correspond to the main manuscript headings)
 - Supplementary tables, if applicable
 - ESMO Scale for Clinical Actionability of molecular Targets (ESCAT)⁵ criteria and scores, if applicable
 - Tables showing clinical classification of tumour type with staging system and stage groups, preferably the European Union for International Cancer Control (UICC) tumour–node–metastasis (TNM) eighth edition staging table(s)⁶
 - ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) v1.1⁷ table with scores, if applicable
 - ESMO LoE/GoR table⁴
- ESMO Guidelines staff review and journal submission

- If ESMO Guidelines staff are to provide additional writing and/or editorial support to the author group during the development phase, the key roles should be discussed and agreed during the kick-off meeting
- ESMO provides an author collaboration site for each author group using Microsoft SharePoint Team collaboration software tools. Guidelines staff are not permitted to support the use of other external collaboration sites such as Google docs.
- Overview of the plan/concept for CPG derivative products, if known at the time of the kick-off meeting (e.g. ESMO Living GLs, pocket guidelines, slide sets, webinars and Pan-Asian adaptations)
- Any other questions

Following the kick-off meeting, ESMO Guidelines staff will provide CPG manuscript and supplementary file templates (Word documents) and an algorithm template (PowerPoint document).

The main manuscript template can only be completed once the author allocations to the writing sections are made. Similarly, the author agreement form can be drafted for the kick-off meeting, but the final version can only be completed by the lead author prior to manuscript submission.

6 CPG development: main manuscript

Note: a main manuscript template will be provided following the kick-off meeting.

6.1 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, funding and disclosure sections 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.

6.2 Guidance on writing

6.2.1 General guidance

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

Due to word limit, authors may move some text to the supplementary material. However, all clinical recommendations must be kept in the main text.

If 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.

Drugs that are not yet approved by the European Medicines Agency (EMA) will be identified with the statement 'at the time of publication, [drug/treatment] is not EMA approved [for X indication]'. This phrasing must be used even if a drug is expected 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.

6.2.2 Tools available for best practice

The development and writing of ESMO CPGs should follow best practices. The following tools may be useful:

The Appraisal of Guidelines, Research and Evaluation (AGREE) Reporting Checklist.^{8,9}

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>.

6.2.3 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. Although passive voice is used in scientific writing to distance researchers from their work, using an active voice rather than passive voice in ESMO CPGs 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 Working Group (GRADE WG):¹⁰

- 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 the proper LoE and GoR according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System⁵. 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 the LoE) as well as the clinical significance/magnitude of benefit or harm given by following the recommendation. The GoR can be positive (recommended), negative (not recommended) or neutral/optional. 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).

A bullet-point list of all recommendations in each thematic section (header level 1) should be included at the end of the relevant section, including LoEs and GoRs and ESMO-MCBS and ESCAT scores, if applicable.

Example:

Recommendations

- mpMRI should be carried out before prostate biopsy [I, B].
- A prostate cancer risk calculator and/or mpMRI can 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].

6.2.4 Precision medicine

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

6.2.5 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 CPG.

6.3 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 an individualised structure.

6.3.1 Front matter

6.3.1.1 Title

The title should be formatted according to the following example:

Prostate cancer: ESMO Clinical Practice Guideline 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 Guideline

6.3.1.2 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.

6.3.1.3 Running header

Please include a short running header listing the CPG subject (80 character maximum).

Example: ESMO Clinical Practice Guideline for pancreatic cancer

6.3.1.4 Word count

The following details should be included: Word count: [NUMBER] (excluding manuscript heading, acknowledgements, funding and disclosure sections); References: X; Tables: X; Figures: X; Supplementary material: 1.

6.3.1.5 Key words

Please include up to five key phrases in alphabetical order for *ESMO Open* and six key phrases for *Annals of Oncology* can be included. Please review and adapt as needed. Those suggested below are standardised across ESMO CPGs but can be adapted as needed.

Example: diagnosis, early breast cancer, follow-up, guideline, screening, treatment

6.3.1.6 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.

Those suggested below are standardised across ESMO CPGs but can be adapted if they are not relevant to the CPG title.

Examples:

- This ESMO Clinical Practice Guideline provides key recommendations for managing [tumour/tissue].
- The manuscript covers clinical and pathological diagnosis, staging and risk assessment, treatment and follow-up.
- Treatment and management algorithms for locoregional, advanced/metastatic and recurrent disease are provided.
- ESCAT scores are given to describe the evidence level for alterations from genomic-driven analyses as biomarkers for using targeted therapies.
- The author group encompasses a multidisciplinary group of experts from different institutions and countries in Europe [and insert other regions if relevant].
- Recommendations are based on available scientific data and the authors' collective expert opinion.

6.3.1.7 *Promotional text and social media accounts (ESMO/ESMO journal use only)*

Authors will be asked to provide a short statement (120-200 characters) for promotion in ESMO newsletters such as the ESMO OncologyPRO alert and online in ESMO social media accounts.

The statement should describe the importance of the new recommendations for oncologists and patients and the innovative features of the guideline e.g. new class of systemic treatment or application of a novel treatment strategy, e.g. 'Times are changing: adjuvant therapy in high-risk locoregionally advanced NPC and first-line treatment comprising immunotherapy for recurrent/metastatic disease.'

Authors, please provide your social media usernames here, if desired:

• ...

6.3.2 Incidence and epidemiology

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

6.3.3 Diagnosis, pathology and molecular biology

A table and/or algorithm detailing diagnostic work-up and staging should be included.

6.3.4 Staging and risk assessment

Where possible, refer to the European UICC TNM staging system⁶ throughout the manuscript. Staging tables should be included in the supplementary material. ESMO will provide these tables to authors if needed.

6.3.5 Management of local and locoregional disease

An ESMO-standardised treatment algorithm must be included on therapeutic strategy or management according to stage, risk factors and disease/molecular characteristics.

6.3.6 Management of advanced and metastatic disease

An ESMO-standardised treatment algorithm must be included on therapeutic strategy or management according to stage, risk factors and disease/molecular characteristics.

6.3.7 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. A subsection of supportive and palliative care should be included if appropriate.

6.3.8 Methodology

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

This Clinical Practice Guideline (CPG) was developed in accordance with the ESMO standard operating procedures for CPG development (<https://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology>). The relevant literature has been selected by the expert authors. A table of ESMO Scale for Clinical Actionability of molecular Targets (ESCAT) scores is included in Supplementary Table SX. ESCAT scores have been defined by the authors, assisted if needed by the ESMO Translational Research and Precision Medicine Working Group.[ref #] A table of ESMO Magnitude of Clinical Benefit Scale (ESMO-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 European Medicines Agency (EMA) or Food and Drug Administration (FDA) (<https://www.esmo.org/Guidelines/ESMO-MCBS>). The scores have been calculated and validated by the ESMO-MCBS Working Group and reviewed by the authors. The FDA/EMA or other regulatory body approval status of new therapies/indications is reported at the time of writing this CPG. Levels of evidence and grades of recommendation have been applied using the system shown in Supplementary Table SXXX.[ref ###] Statements without grading were considered justified standard clinical practice by the authors. For future updates to this CPG, including eUpdates and Living Guidelines, please see the ESMO Guidelines website: [insert original CPG web link on esmo.org].

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Supplementary Table SX ref # = include reference to ESCAT manuscript (framework) in the References section (also include this reference in the supplementary material): Mateo J, Chakravarty D, Dienstmann R, et al. A framework to

rank genomic alterations as targets for cancer precision medicine: the ESMO Scale for Clinical Actionability of Molecular Targets (ESCAT). *Ann Oncol*. 2018;29(9):1895-1902.

Supplementary Table SXX ref ## = include reference to ESMO-MCBS v1.1 manuscript in the References section (also include this reference in the supplementary material): Chery NI, Dafni U, Bogaerts J, et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. *Ann Oncol*. 2017;28(10):2340-2366.

Supplementary Table SXXX ref ### = include the reference for LoE/GoR table (also include this reference in the supplementary file): Dykewicz CA. Summary of the Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients. *Clin Infect Dis*. 2001;33(2):139-144 (adapted from: Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. *Clin Infect Dis*. 1994;18(3):421).

6.3.9 Acknowledgments

Please include any additional acknowledgements 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. Manuscript editing support will be acknowledged, e.g. from ESMO Guidelines staff or freelancers working on behalf of ESMO.

For manuscripts including ESMO-MCBS scores and/or ESCAT scores, the members of the respective WG as well as the ESMO staff and freelancers working on behalf of ESMO will be acknowledged if they have contributed to the scoring.

6.3.10 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 this guideline. Production costs have been covered by ESMO from central funds.

6.3.11 Disclosure (required for all ESMO journal publications)

See Section 4.4.2: ESMO author DOIs.

6.3.12 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 v1.1 score calculation(s) should also appear in the reference list. References should not exceed 100 maximum.

Authors are encouraged to use reference managing software with a travelling library to assist ESMO Guidelines staff with final reference formatting.

ESMO uses Endnote 20 reference managing software for reference formatting and will prepare a new library/group for each CPG once the final author draft is submitted to the ESMO Guidelines office. ESMO will then manage the reference list on behalf of the authors through submission.

6.3.13 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).

Suggested tables include:

- Table with diagnostic work-up
- Tables on therapeutic regimens or prognosis

Please include acronyms in alphabetical order and footnotes in order of appearance. Please include LoEs and GoRs, ESMO-MCBS and/or ESCAT scores, if applicable.

6.3.14 Figures including treatment algorithms

Note: an algorithm template will be provided. All figures should be provided in an editable PowerPoint format.

Algorithms on therapeutic strategy or management according to stage, risk factors and disease/molecular characteristics are required and must be cited within the document.

Please include acronyms in alphabetical order and footnotes in order of appearance. Please include LoEs and GoRs, ESMO-MCBS and/or ESCAT scores, if applicable.

6.3.14.1 ESMO formatting of algorithms

ESMO staff will assist authors with algorithm formatting, as needed, to prepare the final formatted version for submission.

The following colour code will be used:

- **Purple** (RGB: 133, 25, 74): figure title box, which should briefly describe what the algorithm covers (e.g. “Stage IV unresectable mCRC: maintenance therapy”).
- **Orange** (RGB: 224, 81, 54): surgery
- **Dark green** (RGB: 20, 83, 40): radiotherapy
- **Blue** (RGB: 76, 128, 175): systemic anticancer therapy (e.g. chemotherapy, immunotherapy, endocrine/hormone therapy)
- **Turquoise** (RGB: 66, 180, 146): Combination of treatments and treatment modalities (e.g. RT combined with ChT, combination systemic anticancer regimens such as FOLFOX, supportive treatments, allo-SCT, RBC transfusions, antibiotics, steroids, etc.)
- White (RGB: 225, 225, 225): Non-treatment aspects (e.g. stratification, broad actions for monitoring, assessments, observations such as ‘MDT discussion’, ‘follow-up’ or ‘restaging’, tumour type, stage, risk, ECOG PS score, mutation status, special populations, etc.)
- Dashed border and connecting dashed arrow: Optional branches, colour used as described in the categories above.

Examples:

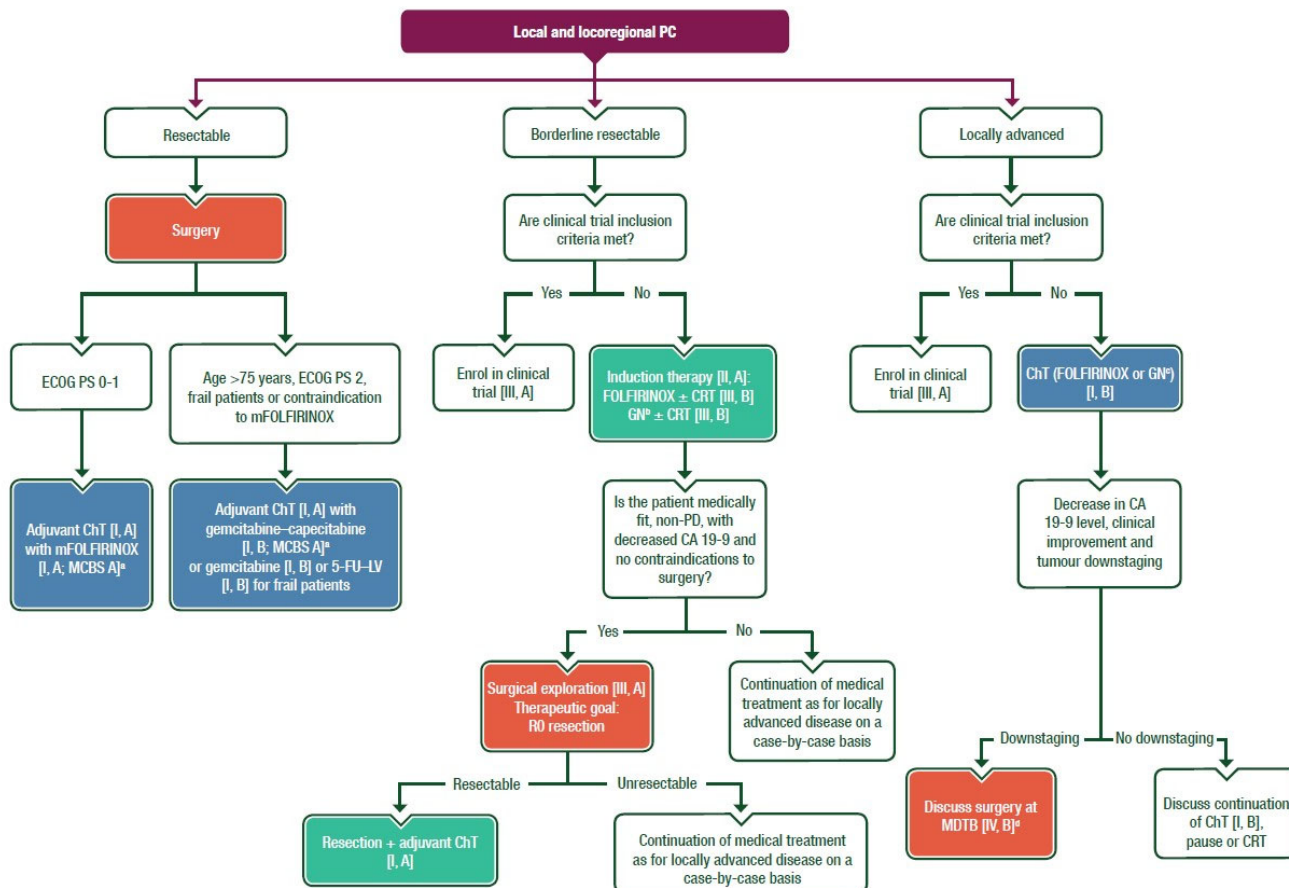


Figure 2. Treatment algorithm for local and locoregional PC.

Purple: general categories or stratification; red: surgery; blue: systemic anticancer therapy; turquoise: combination of treatments; white: other aspects of management.

5-FU, 5-fluorouracil; CA 19-9, carbohydrate antigen 19-9; ChT, chemotherapy; CRT, chemoradiotherapy; ECOG, Eastern Cooperative Oncology Group; EMA, European Medicines Agency; FDA, Food and Drug Administration; FOLFIRINOX, leucovorin–5-fluorouracil–irinotecan–oxaliplatin; GN, gemcitabine–nab-paclitaxel; LV, leucovorin; MCBS, ESMO-Magnitude of Clinical Benefit Scale; MDTB, multidisciplinary tumour board; mFOLFIRINOX, modified leucovorin–5-fluorouracil–irinotecan–oxaliplatin; PC, pancreatic cancer; PD, progressive disease; PS, performance status; R0, no tumour at the margin; defined as no cancer cells within 1 mm of all resection margins.

^aESMO-MCBS v1.1[ref #] was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated and validated by the ESMO-MCBS Working Group and reviewed by the authors (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

^bNot EMA or FDA approved as induction therapy.

^cNot EMA or FDA approved for locally advanced disease.

^dTo be discussed if significant decrease in CA 19-9 level, clinical improvement and tumour downstaging.

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ref # = Cherny NI, Dafni U, Bogaerts J, et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. *Ann Oncol.* 2017;28(10):2340-2366.

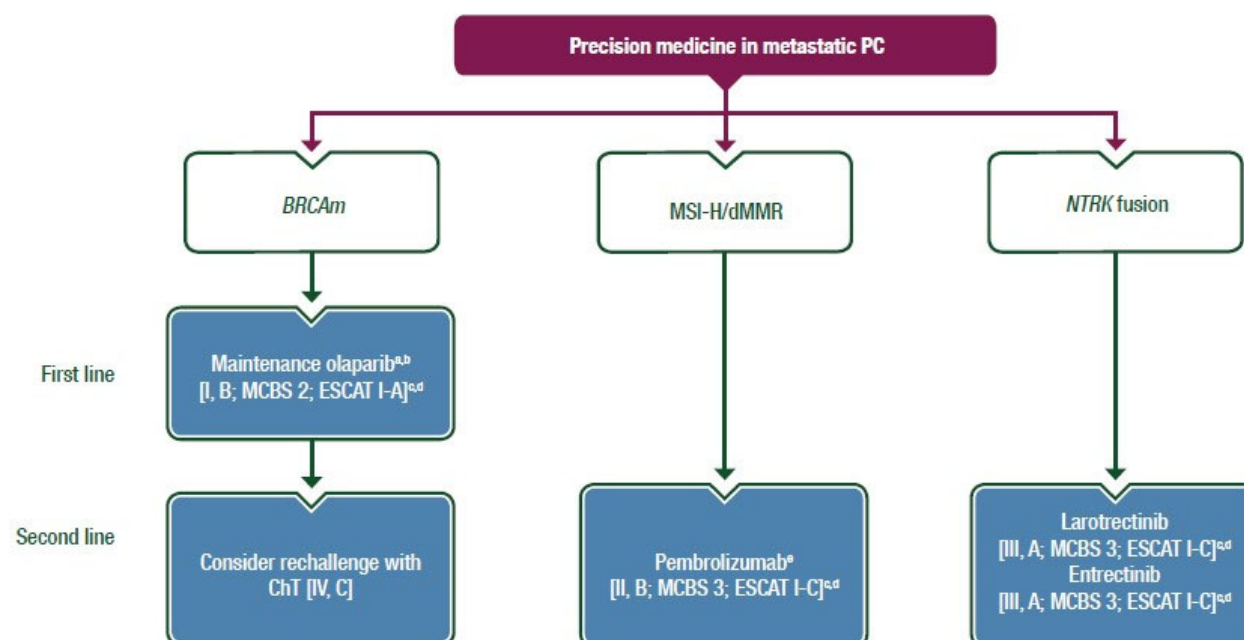


Figure 4. Precision medicine in metastatic PC.

Purple: general categories or stratification; blue: systemic anticancer therapy; white: other aspects of management.

ChT, chemotherapy; dMMR, mismatch repair deficient; EMA, European Medicines Agency; ESCAT, ESMO Scale for Clinical Actionability of molecular Targets; FDA, Food and Drug Administration; g, germline; MCBS, ESMO-Magnitude of Clinical Benefit Scale; MSI-H, microsatellite instability high; m, mutated; PC, pancreatic cancer.

^aEMA and FDA approved in patients with metastatic PC and gBRCA mutations.

^bFor patients whose disease is stable or responsive to platinum-based ChT.

^cESMO-MCBS v1.1[ref #] was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated and validated by the ESMO-MCBS Working Group and reviewed by the authors (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

^dESCAT scores apply to alterations from genomic-driven analyses only. These scores have been defined by the guideline authors, assisted if needed by the ESMO Translational Research and Precision Medicine Working Group.[ref ###] See **Supplementary Table S10** for more information on ESCAT scores.

^eFDA approved; not EMA approved as a dMMR/MSI-H tumour-agnostic indication but for specific tumour types (excludes PC).

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ref # = include reference to ESMO-MCBS v1.1 manuscript in the References section (also include this reference in the supplementary material): Cherny NI, Dafni U, Bogaerts J, et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. *Ann Oncol.* 2017;28(10):2340-2366.

ref ### = include reference to ESCAT manuscript (framework) in the References section (also include this reference in the supplementary material): Mateo J, Chakravarty D, Dienstmann R, et al. A framework to rank genomic alterations as targets for cancer precision medicine: the ESMO Scale for Clinical Actionability of Molecular Targets (ESCAT). *Ann Oncol.* 2018;29(9):1895-1902.

7 CPG development: supplementary material

Note: a supplementary file template will be provided following the kick-off meeting.

7.1 Extent

Some required elements will be included as supplementary material, which is excluded from the overall word count limit. The supplementary material should follow the same formatting and style requirements as the main manuscript, including for headings and referencing.

All supplementary text sections and tables must be cited within the main manuscript and should be included in the supplementary material file (all content should be provided in an editable format).

7.2 Thematic sections

7.2.1 Supplementary text

Supplementary text section(s) should be inserted, if applicable.

7.2.2 Supplementary tables

Authors should provide supplementary tables, if applicable, including a list of acronyms in alphabetical order and footnotes.

Additional supplementary tables should include:

- Supplementary Table SX. Biomarkers and molecular targets for precision medicines and corresponding ESCAT scores, if applicable
- Supplementary Table SXX. Clinical classification of tumour type with staging system and stage groups, preferably the UICC TNM eighth edition staging system (tables can be provided by ESMO)
- Supplementary Table SXXX. ESMO-MCBS table with ESMO-MCBS scores for new therapies/indications approved by the EMA or FDA, if applicable
- Supplementary Table SXXXX. LoE/GoR table (required for all ESMO CPGs)

7.2.3 Precision medicine and ESMO Scale for Clinical Actionability of molecular Targets (ESCAT) scores

Information relating to actionability, clinical utility and clinical validity of biomarkers and molecular targets for precision medicine should be included throughout the CPG text, if relevant, e.g. regarding diagnosis, staging and classification, prognosis, use in medical treatment decisions and follow-up and monitoring.

Where relevant, the guideline authors should calculate and include ESCAT scores for any alterations from genomic-driven analyses as biomarkers for using targeted therapies included in the guideline. Authors should evaluate previously published ESCAT scores if available or contact the ESMO Translational Research and Precision Medicine Working Group (TRPM WG) in case of any concerns about scoring. A member of the TRPM

WG (who is not one of the CPG authors) is available for review of ESCAT scores proposed by the authors if needed. ESMO Guidelines staff will organise this process.

For more information about previously published ESCAT scores, please visit Mosele F, Remon J, Mateo J et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. *Ann Oncol.* 2020;31(11):1491-1505.

7.2.4 ESCAT criteria

The ESCAT score defines clinical evidence-based criteria for prioritising alterations from genomic-driven analyses for use as markers to select patients for targeted therapies. The scale is comprised of six tiers based on implications for patient management (Tier I-X; see Table below). These tiers are sub-divided by level of clinical evidence. For pragmatic clinical guidance, the most relevant ESCAT tiers for CPGs are Tier I and II (targets ready for implementation in routine clinical decisions; and investigational targets that likely define a patient population that benefits from a targeted drug but additional data are needed, respectively).

Criteria for defining the ESCAT score for genomic alteration–drug matches

	ESCAT tier	Clinical value class	Clinical implication	Level of evidence	Overall ESCAT score
Ready for routine use	I: Alteration–drug match is associated with improved outcome in clinical trials	Drug administered to patients with the specific molecular alteration has led to improved clinical outcome in prospective clinical trial(s)	Access to the treatment should be considered standard of care	A: prospective, randomised clinical trials show the alteration–drug match in a specific tumour type results in a clinically meaningful improvement of a survival endpoint	I-A
				B: prospective, non-randomised clinical trials show that the alteration–drug match in a specific tumour type, results in clinically meaningful benefit as defined by ESMO-MCBS v1.1	I-B
				C: clinical trials across tumour types or basket clinical trials show clinical benefit associated with the alteration–drug match, with similar benefit observed across tumour types	I-C
Investigational	II: alteration–drug match is associated with antitumour activity, but magnitude of benefit is unknown	Drug administered to a molecularly defined patient population is likely to result in clinical benefit in a given tumour type, but additional data are needed	Treatment to be considered preferable in the context of evidence collection either as a prospective registry or as	A: retrospective studies show patients with the specific alteration in a specific tumour type experience clinically meaningful benefit with matched drug compared with alteration-negative patients	II-A

			a prospective clinical trial	B: prospective clinical trial(s) show the alteration–drug match in a specific tumour type results in increased responsiveness when treated with a matched drug, however, no data currently available on survival endpoints	II-B
Hypothetical target	III: alteration–drug match suspected to improve outcome based on clinical trial data in other tumour type(s) or with similar molecular alteration	Drug previously shown to benefit the molecularly defined subset in another tumour type (or with a different mutation in the same gene), efficacy therefore is anticipated for but not proved	Clinical trials to be discussed with patients	A: clinical benefit demonstrated in patients with the specific alteration (as tiers I and II above) but in a different tumour type. Limited/absence of clinical evidence available for the patient-specific cancer type or broadly across cancer types	III-A
				B: an alteration that has a similar predicted functional impact as an already studied tier I abnormality in the same gene or pathway but does not have associated supportive clinical data	III-B
	IV: pre-clinical evidence of actionability	Actionability is predicted based on preclinical studies, no conclusive clinical data available	Treatment should 'only be considered' in the context of early clinical trials. Lack of clinical data should be stressed to patients	A: evidence that the alteration or a functionally similar alteration influences drug sensitivity in preclinical in vitro or in vivo models	IV-A
				B: actionability predicted in silico	IV-B
Combination development	V: alteration–drug match is associated with objective response, but without clinically	Drug is active but does not prolong PFS or OS, probably in part due to mechanisms of adaptation	Clinical trials assessing drug combination strategies could be considered	Prospective studies show that targeted therapy is associated with objective responses, but this does not lead to improved outcome	V

	meaningful benefit				
	X: lack of evidence for actionability	There is no evidence, clinical or preclinical, that a genomic alteration is a potential therapeutic target	The finding should not be taken into account for clinical decision	No evidence that the genomic alteration is therapeutically actionable	X

Table adapted from Mateo J, Chakravarty D, Dienstmann R, et al. A framework to rank genomic alterations as targets for cancer precision medicine: the ESMO Scale for Clinical Actionability of molecular Targets (ESCAT). *Ann Oncol.* 2018;29(9):1895-1902.

7.2.4.1 ESCAT table template

Supplementary Table SX. Biomarkers and molecular targets for precision medicines and corresponding ESCAT scores

Clinical context (if applicable)	Biomarker or genomic alteration	Method of detection	Drug match	ESCAT score ^{a,b}
List the disease stage or subtype	List the biomarker or genomic alteration and corresponding reference, if applicable	Describe the methodology or assay used to measure the biomarker/genomic alteration	List the actionable treatment regimen related to the biomarker or genomic alteration	Score calculated by CPG authors and corresponding reference, if applicable State 'N/A' if an ESCAT score is not relevant for the biomarker (e.g. the biomarker is not a genomic alteration)
EXAMPLE: Early breast cancer, HER2 (<i>ERBB2</i>)-negative	HER2-negative g <i>BRCA1/2m</i>	IHC (0, 1+ or 2+) with negative FISH/CISH NGS or Sanger sequencing	ET and concomitant adjuvant olaparib	I-A[ref #]
EXAMPLE: Pancreatic cancer	<i>NTRK</i> fusions in <i>KRAS</i> -wt [ref #]	IHC, FISH, RT-PCR, NGS	TRK inhibitors (e.g. larotrectinib, entrectinib)	I-C

The following acronyms, footnotes and references should be added:

ESCAT, ESMO Scale for Clinical Actionability of molecular Targets.

^aESCAT scores apply to alterations from genomic-driven analyses only. These scores have been defined by the guideline authors, assisted if needed by the ESMO Translational Research and Precision Medicine Working Group.

A footnote about the alterations that appear in the table should be included, e.g.

^bI-A, alteration–drug match is associated with improved outcome with evidence from randomised clinical trials showing the alteration–drug match in a specific tumour type results in a clinically meaningful improvement of a survival endpoint; I-B, alteration–drug match is associated with improved outcome with evidence from prospective, nonrandomised clinical trials showing that the alteration–drug match in a specific tumour type results in clinically meaningful benefit as defined by ESMO-MCBS v1.1; I-C, alteration–drug match is associated with improved outcome with evidence from clinical trials across tumour types or basket clinical trials showing clinical benefit associated with the alteration–drug match, with similar benefit observed across tumour types; III-A, alteration–drug match is suspected to improve outcome based on

patients with the specific alteration but in a different tumour type, with limited/absence of clinical evidence available for the patient-specific cancer type or broadly across cancer types.[ref ##]

ref # = include pivotal trial reference(s).

ref ## = include reference to ESCAT manuscript (framework) in the References section (also include this reference in the supplementary material): Mateo J, Chakravarty D, Dienstmann R, et al. A framework to rank genomic alterations as targets for cancer precision medicine: the ESMO Scale for Clinical Actionability of Molecular Targets (ESCAT). *Ann Oncol*. 2018;29(9):1895-1902.

7.3 Supplementary Table(s) with staging system (preferably TNM) and stage groups

Please include any appropriate staging tables as supplementary files as Supplementary Table SXX, SXXX, etc using the UICC TNM eighth edition staging system.⁶ These tables can be provided by ESMO.

7.4 Supplementary ESMO-MCBS table

Where applicable, ESMO-MCBS calculations will be calculated and validated by the ESMO-MCBS Working Group and reviewed by the authors.

Relevant ESMO-MCBS scores will be summarised in the CPG in a separate ESMO-MCBS table provided by ESMO-MCBS staff. The table will be included as a supplementary file: 'Supplementary Table SXXX. ESMO-MCBS table for new therapies/indications in [tumour type].' 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. Scores and table will be calculated by the ESMO-MCBS Working Group after the first draft of the CPG is received by the Guidelines staff. CPG authors should evaluate the scores and any queries should be addressed to the Guidelines staff for consideration and response from the ESMO-MCBS WG. 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 FDA, it should appear next to the LoE/GoR in the recommendations statements 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 where relevant. However, if scores are available for drugs not mentioned in the CPG (e.g. outdated treatments), the authors are not obliged to include this information. Authors may choose to add specific commentary to scores if they feel additional explanation will be needed by the readership.

Scientific progress can be captured in the CPG text. 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. Only include non-approved therapies that fulfil four criteria:

1. Recommendations and algorithms – scientific breakthrough noted in recommendations and algorithms if substantial, clinical benefit and imminent regulatory approval;
2. An LoE and GoR must be included for each recommendation/ESMO-MCBS score;
3. Studies/drug efficacy should be evaluated and published in a peer-reviewed medical journal (Note: ESMO does not apply ESMO-MCBS scores based on findings reported in abstracts); and
4. The text must clearly highlight that the recommendation is not approved by a regulatory authority (e.g. 'not EMA approved' or similar text is included after the ESMO-MCBS score).

The following acronym, footnote and references should be added:

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.

^aESMO-MCBS v1.1[ref ##] was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

ref # = include pivotal trial reference(s).

ref ## = include reference to ESMO-MCBS v1.1 manuscript in the main manuscript References section (also include this reference in the supplementary material): Cherny NI, Dafni U, Bogaerts J, et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. *Ann Oncol*. 2017;28(10):2340-2366.

7.4.1.1 ESMO-MCBS table template

Supplementary Table SXX. ESMO-MCBS table for new therapies/indications in [Tumour type]

Therapy	Disease setting	Trial	Control	Absolute survival gain	HR (95% CI)	QoL/Toxicity	ESMO-MCBS Score ^a
Describe the new therapy	Describe the disease setting. Specify (Neo)adjuvant or advanced	Trial acronym (trial name if acronym is not available)[ref #] phase of trial, NCT number	Describe the control arm	Median, in months (state OS, PFS or both)	Median and 95% CI	Improved or Deteriorated or Similar or Not Available	Score X (Form X)

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.

^a ESMO-MCBS v1.1.[ref ##] was used to calculate scores for new therapies/indications approved by the EMA or FDA. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

ref # = include pivotal trial reference(s).

ref ## = Cherny NI, Dafni U, Bogaerts J et al. ESMO-Magnitude of Clinical Benefit Scale Version 1.1. *Ann Oncol* 2017; 28: 2340-2366.

7.5 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 SXXX. 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

^aBy permission of Oxford University Press on behalf of the Infectious Diseases Society of America.[ref####].

Include in References:

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

Dykewicz CA. Summary of the Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients. *Clin Infect Dis*. 2001;33(2):139-144 [adapted from: Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. *Clin Infect Dis*. 1994;18(3):421].

8 Final review and submission

ESMO Guidelines 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 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 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 lead author should provide specific details of each author's role in developing the CPG^{2,3}. The completed form must be returned to the ESMO Guidelines office as part of the manuscript submission requirements.

8.2 ESMO journal requirements

The SE will provide a cover letter for the manuscript submission summarising important details of the CPG, a list of proposed reviewers and professional social media profiles of authors; authors can recommend 3-5 reviewers to propose to the journal, including ESMO Faculty if possible: <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 DOIs

See Section 4.4.2: ESMO author DOIs.

8.4 Review and approval of final manuscript

Before manuscript submission to an ESMO journal, ESMO Guidelines staff will circulate the finalised manuscript to all co-authors and gather approvals.

All authors must review and approve the manuscript before submission.

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

9 CPG eUpdates and Living GLs

In the case of a significant breakthrough that requires rapid communication as updated CPG content or in the case of a new EMA or FDA indication bearing an ESMO-MCBS score, the GL-SC member or the SE will coordinate with the guideline authors to produce an update to the ESMO CPG, either a Living GL update (for selected titles only) or as an eUpdate (for all other CPGs not selected for updates as a Living GL).

The Living GL update will be published on the ESMO website linked to the corresponding original CPG. eUpdates will be published submitted to an ESMO journal for publication.

Please see the eUpdate and Living GL SOPs for additional guidance about these publications, available here: <http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology>.

10 Presenting ESMO CPGs

Before submission, authors can present an overview of topics that will be addressed in the upcoming guideline, without giving detailed recommendations and without displaying algorithms, provided they have received approval from the ESMO Guidelines Committee.

After manuscript acceptance in an ESMO Journal, authors can present the detail of recommendations including algorithms.

11 References used in this SOP

- 1 International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available at <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>. Accessed September 26, 2023.
- 2 CASRAI. CRediT - Contributor Roles Taxonomy. Available at <https://casrai.org/credit/>. Accessed September 26, 2023.
- 3 Elsevier. Elsevier expands CRediT approach to authorship. Published 10 December 2019, Amsterdam. Available at <https://www.elsevier.com/about/press-releases/corporate/elsevier-expands-credit-approach-to-authorship/>. Accessed September 26, 2023.
- 4 Dykewicz CA. Summary of the Guidelines for Preventing Opportunistic Infections among Hematopoietic Stem Cell Transplant Recipients. *Clin Infect Dis*. 2001;33(2):139-144 [adapted from: Gross PA, Barrett TL, Dellinger EP, et al. Purpose of quality standards for infectious diseases. *Clin Infect Dis*. 1994;18(3):421].
- 5 Mateo J, Chakravarty D, Dienstmann R et al. A framework to rank genomic alterations as targets for cancer precision medicine: the ESMO Scale for Clinical Actionability of molecular Targets (ESCAT). *Ann Oncol* 2018; 29 (9): 1895-1902.
- 6 Brierley JD, Gospodarowicz MK, Wittekind C. TNM classification of malignant tumours, 8th edition: John Wiley & Sons, Ltd, Chichester, 2017.
- 7 Cherny NI, Dafni U, Bogaerts J et al. ESMO-Magnitude of Clinical Benefit Scale version 1.1. *Ann Oncol* 2017; 28 (10): 2340-2366.
- 8 Brouwers MC, Kerkvliet K, Spithoff K. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. *BMJ* 2016; 352: i1152.
- 9 AGREE. AGREE Reporting Checklist. Published 2016. Available at <http://www.agreetrust.org/resource-centre/agree-reporting-checklist/>. Accessed September 26, 2023.
- 10 Schünemann H, Jan B, Gordon G et al. GRADE Handbook. Updated October 2013. Available at <https://gdt.gradeapro.org/app/handbook/handbook.html>. Accessed September 26, 2023.