



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

Version	<b>ESMO CPG SOP Version 3.0; February 2025</b>
Changes in this version	Modified Commissioning of an ESMO CPG, ESMO CPG authorship, CPG development: main manuscript, and CPG development: supplementary material sections  Added Revision and resubmission and Online publication and proof sections

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 Express Guideline Update and Living Guidelines SOPs. All three SOP documents are available publicly on the ESMO website <http://www.esmo.org/Guidelines/ESMO-Guidelines-Methodology>.

# Table of Contents

1	Introduction.....	4
2	Role of ESMO Guidelines staff .....	4
3	Commissioning of an ESMO CPG .....	4
3.1	ESMO CPGs .....	4
3.2	Joint CPGs with EURACAN .....	4
4	ESMO CPG authorship .....	4
4.1	Authorship criteria .....	4
4.2	Contributor roles.....	5
4.2.1	Lead author .....	5
4.2.2	Last author (SE).....	6
4.2.3	GLC Chair and Deputy Chair .....	6
4.2.4	Representatives of EURACAN.....	6
4.3	Authorship order.....	6
4.4	Author nomination and confirmation process.....	6
4.4.1	Author selection.....	6
4.4.2	ESMO author DOIs .....	6
4.4.3	Author invitations.....	7
5	CPG kick-off meeting .....	7
6	CPG development: main manuscript .....	8
6.1	Extent .....	8
6.2	Guidance on writing.....	8
6.2.1	General guidance .....	8
6.2.2	Tools available for best practice.....	8
6.2.3	Wording of recommendations .....	9
6.2.4	Precision medicine .....	10
6.2.5	Quality control .....	10
6.3	Thematic sections .....	10
6.3.1	Front matter .....	10
6.3.2	Incidence and epidemiology.....	11
6.3.3	Diagnosis, pathology and molecular biology.....	11
6.3.4	Staging and risk assessment .....	11
6.3.5	Management of local and locoregional disease.....	11
6.3.6	Management of advanced and metastatic disease.....	11
6.3.7	Follow-up, long-term implications and survivorship .....	11
6.3.8	Methodology.....	11
6.3.9	Acknowledgments .....	16
6.3.10	Funding .....	16
6.3.11	Disclosure (required for all ESMO journal publications) .....	16
6.3.12	References .....	16
6.3.13	Tables .....	16
6.3.14	Figures including treatment algorithms .....	16
7	CPG development: supplementary material .....	19

7.1	Extent .....	19
7.2	Thematic sections .....	19
7.2.1	Supplementary text .....	19
7.2.2	Supplementary tables.....	19
7.3	Supplementary Table(s) with staging system (preferably UICC TNM) and stage groups .....	19
7.4	Supplementary LoE/GoR table .....	19
8	Final review and submission .....	20
8.1	Author Responsibility and Acknowledgement Agreement form .....	20
8.2	ESMO journal requirements .....	20
8.3	Final DOIs .....	21
8.4	Review and approval of final manuscript .....	21
9	Revision and resubmission .....	21
10	Online publication and proof .....	21
11	CPG Express Guideline Updates and Living Guidelines .....	21
12	Presenting ESMO CPGs.....	21
13	References .....	21

## 1 Introduction

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

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](http://annalsofoncology.org)) or *ESMO Open* ([esmoopen.com](http://esmoopen.com)). The target ESMO journal for each CPG will be communicated to the authors prior to manuscript submission. This decision is made by the ESMO journal editors in discussion with the GLC Chairs.

## 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 Guidelines 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 Guidelines staff will provide specific editing support including reference library development.

ESMO Guidelines 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 CPGs

The GLC has identified specific topics, which will have a corresponding Living Guideline and will be updated regularly (every 2 years) as CPG publications. These topics will be reviewed periodically by the GLC.

Living Guidelines will be updated as needed (see separate Living Guidelines SOPs). These updates should be followed by an editorial commentary published in an ESMO journal.

A maximum of 30 slots will be assigned to topics without Living Guidelines during any 4-year period. Topics without Living Guidelines should not have any fixed interval for updates. CPGs should be proposed for an update when there is a need for such as judged by the ESMO GLC Chair or a Subject Editor (SE). The selection of the topics without Living Guidelines will be validated in the annual GLC meeting for the following year. This judgement is based on the availability of new, clinically significant evidence that requires substantial changes or additions to clinical recommendations. For less extensive changes to clinical practice, topics without Living Guidelines can also be updated using an Express Guideline Update simultaneously published in *ESMO Open* and on the ESMO website (see separate Express Guideline Update SOPs).

CPG topics should not be split into subtopics, only exceptionally where it is not feasible to have a single CPG after full consideration and approval by the GLC; splitting topics will not increase the total number of slots available. New CPGs may also be considered for topics not currently covered by existing ESMO CPG titles; these will be considered for selection within the 30 slots available without Living Guidelines during any 4-year period.

The total CPG output per year will be approximately 15 CPG publications.

### 3.2 Joint CPGs with 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, the SE 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 10-15 authors, including the SE as last author and any representatives of EURACAN, if relevant. It is encouraged but not mandatory that author groups consist of 10 authors. The limit of 15 authors will be strictly adhered to.

- If they choose to do so, the SE may nominate another author to take the position of last author on the publication – the SE will retain their other responsibilities as outlined in Section 4.2.2.
- 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 and other disciplines as appropriate (e.g. surgical oncologist, radiation oncology specialist).
- 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). 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. Members of the ESMO Young Oncologists Committee or the ESMO Leaders Generation Programme may be considered. 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)<sup>1</sup>:

- 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.

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.<sup>2,3</sup>

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 should be a member of ESMO.

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 GLC 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. In accepting the role of lead author on a CPG with a Living Guideline, the author also accepts to review and update the Living Guideline (see the Living Guideline SOPs).

#### 4.2.2 Last author (SE)

As the last author, the SE is responsible for:

- Proposing a suitable lead author.
- Proposing suitable co-authors, in collaboration with the lead author.
- Ensuring that the CPG follows the ESMO methodology as closely as possible and providing extensive support to the lead author regarding queries on methodology.
- Remaining in close contact with the ESMO Guidelines staff to ensure the smooth running of the CPG development and following up with individual authors in case of delays.
- Providing the cover letter for journal submission, including recommended reviewers (ESMO Faculty where possible).
- Providing review of related ESMO Pocket Guidelines.
- Participating in the development and update of related ESMO Living Guidelines (see the Living Guidelines SOPs).

#### 4.2.3 GLC Chair and Deputy Chair

In their area of expertise, the GLC Chair or Deputy Chair could be invited to be a co-author. Their inclusion must not increase the maximum number of authors beyond 15.

#### 4.2.4 Representatives of EURACAN

For joint CPGs with EURACAN, specific experts will play a central role as a representative of EURACAN, 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 EURACAN.

### **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.

If appropriate, GLC Chair or Deputy Chair 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 Declaration of Interests (DOIs) and sending formal invitations once the DOIs are reviewed by the ESMO Compliance Committee 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 DOIs has been reviewed, the SE and lead author should propose the co-authors to the GLC Chair for approval. The ESMO Guidelines staff will facilitate the process of author approvals.

#### 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 DOIs 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 DOIs in the ESMO DOI Platform are true, up to date and complete.

#### 4.4.3 Author invitations

After each DOI is received and reviewed by the ESMO Compliance Committee 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:

- ESMO Guidelines staff introductions and identification of the ESMO project coordinator (ESMO key contact person)
- Author introductions
- Author allocations, roles and responsibilities
- Key SOPs for CPG development
- Proposed timelines (which will be finalised during the meeting). Standard proposed timelines are:
  - Draft preparation of manuscript – 12 weeks
  - ESMO office review (including liaison with lead authors) – 7 weeks
  - Author revisions and finalisation (pre-submission) – 8 weeks
  - Submission and receipt of peer review comments – 6 weeks
  - Revisions and author approval (for resubmission) – 8 weeks
  - Resubmission and notification of acceptance – 2 weeks
  - Post acceptance ESMO tasks – 8 weeks
- 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 recommendation statements and corresponding algorithms according to the adapted Infectious Diseases Society of America-United States Public Health Service Grading System<sup>4</sup>
    - Use of ESMO Magnitude of Clinical Benefit Scale (ESMO-MCBS) v1.1<sup>5</sup> scores in recommendation statements and corresponding algorithms, where applicable
    - Use of ESMO Scale for Clinical Actionability of molecular Targets (ESCAT)<sup>6</sup> scores in recommendation statements and corresponding algorithms, where applicable
    - 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
    - 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),<sup>7</sup> if applicable
    - ESMO LoE/GoR table<sup>4</sup>
- 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

- Any other questions

Following the kick-off meeting, ESMO Guidelines staff will provide the kick-off presentation, the timelines, the CPG manuscript and supplementary file templates (Word documents), the algorithm template (PowerPoint document) and any other relevant documents as discussed during the kick-off.

## 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 the 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.

Scientific progress can be captured in the CPG text. CPGs can include drugs that are not yet European Medicines Agency (EMA) or Food and Drug Administration (FDA) approved, providing the lack of approval is clearly stated and there is support 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;
3. Studies/drug efficacy should be evaluated and published in a peer-reviewed medical journal; and
4. The text must clearly highlight that the recommendation is not approved by a regulatory body.

Drugs that are not yet approved by the EMA will be identified with the statement '[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]. Similarly, drugs that are not yet approved by the FDA will be identified with the statement '[drug/treatment] is not FDA 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 a pharmaceutical company's press release or other official news articles.

#### 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.<sup>8,9</sup>

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):<sup>10</sup>

- Strong positive recommendations (grade A): ‘It is (strongly) recommended...’ or ‘Clinicians should’ or ‘The patient should be treated with...’
- Weak positive recommendations (grade B): ‘It is suggested...’ or ‘Clinicians can consider...’ or ‘It could be recommended...’
- Neutral/optional recommendations (grade C): ‘...may be an option.’ or ‘Clinicians might...’
- Weak negative recommendations (grade D): ‘It is conditionally recommended not to...’ or ‘It is suggested not to...’
- Strong negative recommendations (grade E): ‘Clinicians should not...’, or ‘It is (strongly) recommend not to...’

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 System.<sup>5</sup> 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; 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 and it represents the authors’ collective opinion based on their clinical experience. The GoR can be positive (recommended), negative (not recommended) or neutral/optional.

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**

- PCNSL diagnosis must be confirmed by histopathological examination of tumour biopsy [III, A].
- Tissue samples should be collected by stereotactic biopsy in patients with brain lesions [IV, A].
- Cinacalcet is recommended to control hypercalcaemia [II, A].
- Cytological and flow cytometry evaluation of cerebrospinal fluid (CSF) can be recommended in patients with aggressive NHL and when there is a high risk of CNS disease [IV, B].
- If a patient relapses after prior treatment with a BTKi, which was stopped due to side-effects, changing to a different BTKi or rechallenge could be considered [III, B].
- RT or CRT are reasonable options in case of locally advanced disease not suitable for radical surgery [V, B].
- Neoadjuvant ChT may be an option for UKP- and GUGy-NECs [V, C].
- RT may be discussed in an MTB, particularly for patients with R1 or R2 resection and/or N+ and/or persistent hypercalcaemia [V, C].
- Adjuvant RT is not routinely recommended [III, D].

- For patients with AJCC stage IIIA and <1 mm tumour burden, adjuvant systemic treatment is generally not recommended [I, D].
- CLND is not recommended for patients with a positive SLNB [I, E].

#### 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 manuscript. Affiliations must be provided separately for each institution and should follow the format of “Department of..., Institution, City, Country” as closely as 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] (maximum 10,000; excluding manuscript heading, acknowledgements, funding and disclosure sections); References: X (maximum 100); Tables: X; Figures: X; Supplementary material: 1.

##### 6.3.1.5 *Key words*

Up to five key words/phrases for *ESMO Open* and up to six for *Annals of Oncology* should be included in the manuscript, in alphabetical order.

Examples: diagnosis, early breast cancer, follow-up, guideline, metastatic breast cancer (MBC), screening, surgery, treatment

##### 6.3.1.6 *Highlights (online only)*

Highlights are required by ESMO journals for the submission and online promotion of the final manuscript. Three to five bullet points should be provided, summarising the main points of the article and/or describing the importance of new recommendations and innovative features of the guideline. Each bullet point must not exceed 125 characters, including spaces.

Those suggested below are standardised across ESMO CPGs but should be adapted 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 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 will be asked to provide their social media usernames, if desired. These are asked by the journal at resubmission for the promotion of the guideline and they are also used by ESMO for the promotion of the guideline online in ESMO social media accounts.

#### 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 system<sup>7</sup> 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>). All recommendations provided are based on current scientific evidence and the authors' collective expert opinion. Where recommendations for multiple different treatment options exist, prioritisation is illustrated by ordering these options according to: level of evidence (LoE) and grade of recommendation (GoR); where equal, by ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) score; where equal, by alphabetical order. The relevant literature has been selected by the expert authors. ESMO Scale for Clinical Actionability of molecular Targets (ESCAT) scores have been defined by the authors,

assisted if needed by the ESMO Translational Research and Precision Medicine Working Group.[ref #] 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 SX.[ref ###] Statements without grading were considered justified standard clinical practice by the authors. For future updates to this CPG, including Express Guideline Updates and Living Guidelines, please see the ESMO Guidelines website: [insert original CPG web link on esmo.org].

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ref # = include reference to ESCAT manuscript (framework) in the References section: 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.

ref ### = include reference to ESMO-MCBS v1.1 manuscript in the References section: Cherny 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 SX

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).

### 6.3.8.1 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 advanced cancer in 2024: a report from the ESMO Precision Medicine Working Group. *Ann Oncol*. 2024;35(7):588-606.

The ESCAT score must be included in the manuscript, where relevant. It should appear next to the LoE/GoR (and ESMO-MCBS, if relevant) in the recommendations statements (e.g. “[I, A; ESMO-MCBS v1.1 score: 4; ESCAT score: I-C]”) and in the algorithms (e.g. “[I, A; MCBS 4; ESCAT I-C]”) whenever a recommendation on the therapy is formulated.

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 subdivided 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	Drug administered to patients with the specific molecular alteration has led to improved	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	I-A

	outcome in clinical trials	clinical outcome in prospective clinical trial(s)		improvement of a survival endpoint	
				<b>B:</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	<b>I-B</b>
				<b>C:</b> 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	<b>I-C</b>
Investigational	<b>II:</b> 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 prospective clinical trial	<b>A:</b> 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	<b>II-A</b>
				<b>B:</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	<b>II-B</b>
Hypothetical target	<b>III:</b> alteration–drug match suspected to improve outcome based on clinical trial data in other tumour type(s) or	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	<b>A:</b> 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	<b>III-A</b>

	with similar molecular alteration			<b>B:</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	<b>III-B</b>
	<b>IV:</b> 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	<b>A:</b> evidence that the alteration or a functionally similar alteration influences drug sensitivity in preclinical in vitro or in vivo models	<b>IV-A</b>
				<b>B:</b> actionability predicted in silico	<b>IV-B</b>
Combination development	<b>V:</b> alteration–drug match is associated with objective response, but without clinically meaningful benefit	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	<b>V</b>
	<b>X:</b> 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	<b>X</b>

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.

ESCAT table template:

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 <sup>a,b</sup>
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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)
<b>EXAMPLE:</b> 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 #]
<b>EXAMPLE:</b> 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.

<sup>a</sup>ESCAT 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.

<sup>b</sup>I-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.

### 6.3.8.2 ESMO-MCBS

ESMO-MCBS scores are calculated and validated by the ESMO-MCBS Working Group. ESMO Guidelines staff will provide a table with these scores to the authors after the kick-off meeting. The scores may be scheduled for review after the first draft of the CPG is received by the Guidelines staff, if relevant updates are necessary. 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 Executive Board.

The ESMO-MCBS score must be included for any drug that is included in the manuscript and for which a score is available. It should appear next to the LoE/GoR in the recommendations statements (e.g. “[I, A; ESMO-MCBS v1.1 score: 4]”) and in the algorithms (e.g. “[I, A; MCBS 4]”) whenever a recommendation on the therapy is formulated. 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.

#### 6.3.9 Acknowledgments

Individuals who do not meet all four ICMJE authorship criteria should be acknowledged as non-author contributors,<sup>1</sup> either individually or as a group, and their written permission obtained in order to include their acknowledgement. Please include any additional acknowledgements as needed.

Manuscript editing support will be acknowledged, e.g. from ESMO Guidelines staff or freelancers working on behalf of ESMO. This text will be provided by ESMO Guidelines staff.

For manuscripts including ESMO-MCBS scores and/or ESCAT scores, the members of the respective WG as well as the ESMO Guidelines 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. ESMO will prepare all author Disclosure statements based on each author's DOIs, following the ESMO standardised format. Each author must approve their statement by email prior to manuscript submission.

#### 6.3.12 References

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

Authors are encouraged to use EndNote (Online Classic) as their 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

Acronyms should be included in alphabetical order and footnotes in order of appearance. LoEs and GoRs, ESMO-MCBS and/or ESCAT scores must be included, if applicable.

#### 6.3.14 Figures including treatment algorithms

Note: an algorithm template will be provided in PowerPoint. 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.

Acronyms should be included in alphabetical order and footnotes in order of appearance. LoEs and GoRs, ESMO-MCBS and/or ESCAT scores must be included, if applicable.



### 6.3.14.1 ESMO formatting of algorithms

ESMO Guidelines 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): algorithm title, which should briefly describe the population that the algorithm covers (e.g. “Stage IV unresectable mCRC”).
- **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) or their combination (e.g. chemotherapy combined with immunotherapy, FOLFOX, etc.)
- **Turquoise** (RGB: 66, 180, 146): non-systemic anticancer therapies (e.g. supportive treatments, allo-SCT, RBC transfusions, antibiotics, steroids, antivirals, etc.) or combination of treatment modalities (e.g. radiotherapy combined with chemotherapy)
- White (RGB: 225, 225, 225): other aspects of management, i.e. clinical trials and 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:

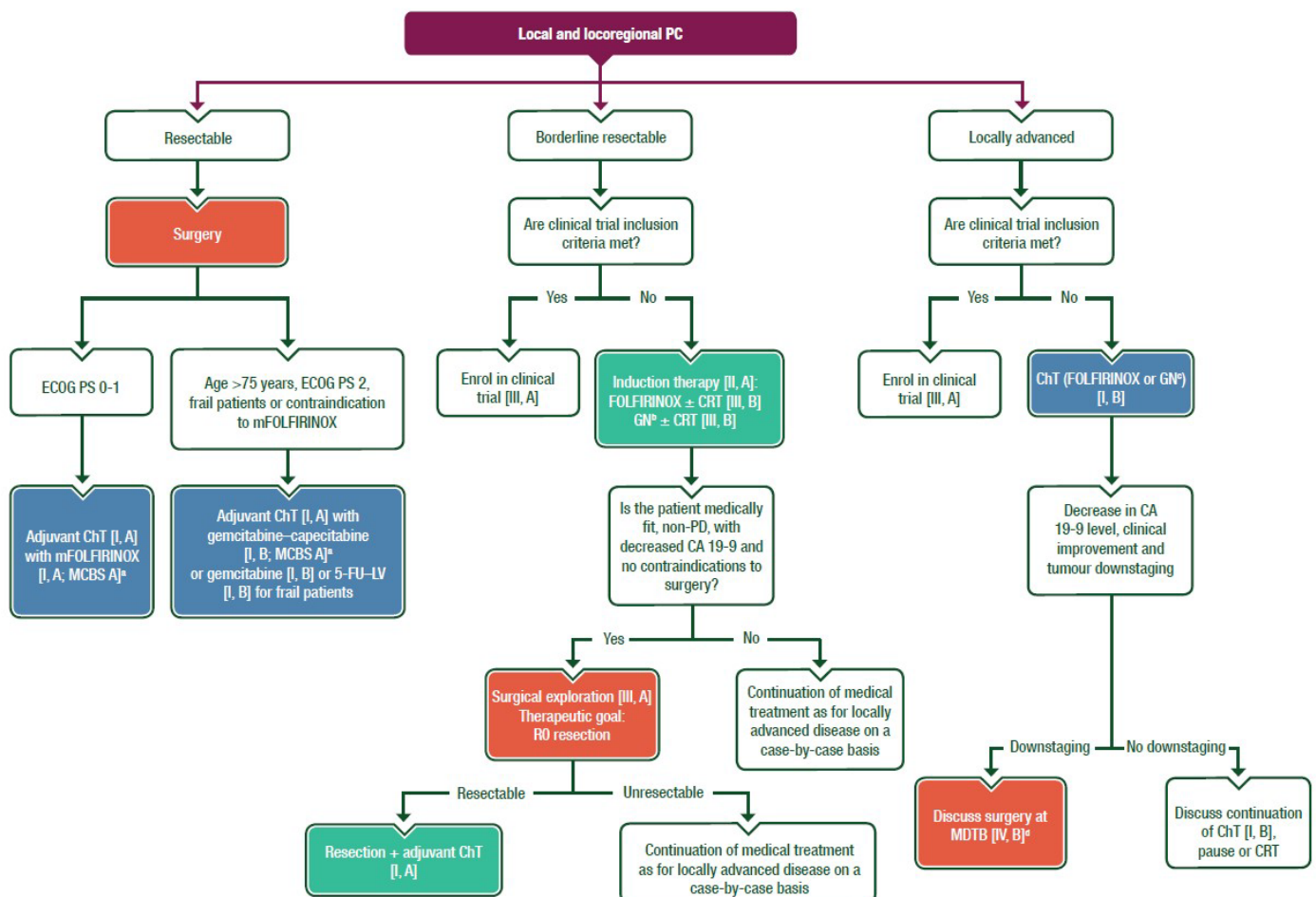


Figure 2. Management of local and locoregional PC.

Purple: algorithm title; orange: surgery; blue: systemic anticancer therapy or their combination; turquoise: non-systemic anticancer therapies or combination of treatment modalities; 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.

<sup>a</sup>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 and validated by the ESMO-MCBS Working Group and reviewed by the authors (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

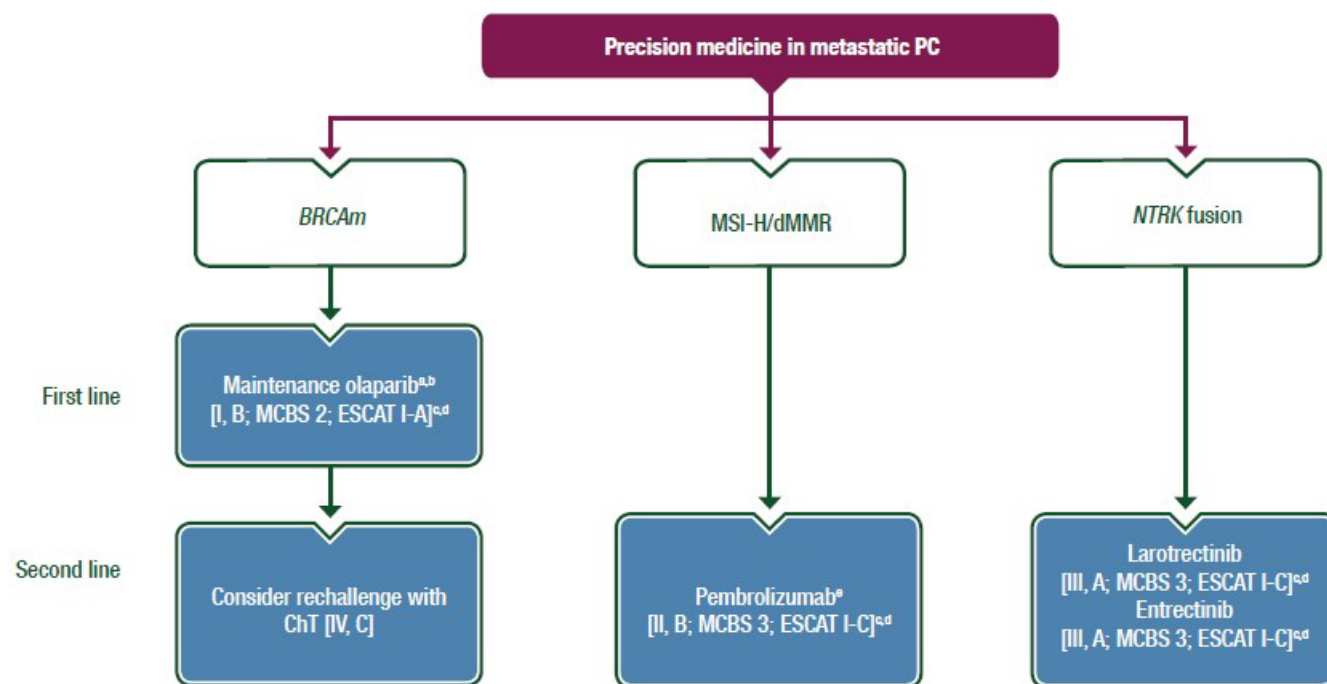
<sup>b</sup>Not EMA or FDA approved as induction therapy.

<sup>c</sup>Not EMA or FDA approved for locally advanced disease.

<sup>d</sup>To 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: figure title box; blue: systemic anticancer therapy; white: non-treatment aspects.

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.

<sup>a</sup>EMA and FDA approved in patients with metastatic PC and *gBRCA* mutations.

<sup>b</sup>For patients whose disease is stable or responsive to platinum-based ChT.

<sup>c</sup>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 and validated by the ESMO-MCBS Working Group and reviewed by the authors (<https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-evaluation-forms>).

<sup>d</sup>ESCAT 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 ##]

<sup>e</sup>FDA 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: 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: 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 (or supplementary material directly if not relevant for 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. All recommendations must be included in the main manuscript.

#### 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. 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 SXX. LoE/GoR table (required for all ESMO CPGs)

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

Any appropriate staging tables should be included as Supplementary Tables SX, SXX, etc using the UICC TNM eighth edition staging system.<sup>7</sup> These tables can be provided by ESMO.

### 7.4 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<sup>a</sup>)

#### 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
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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

<sup>a</sup>By 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.<sup>2,3</sup> 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 and a list of proposed reviewers; the SE can recommend 3-5 gender-balanced, international reviewers to propose to the journal, including ESMO Faculty if possible: <https://www.esmo.org/about-esmo/organisational-structure/educational-committee/esmo-faculty>

ESMO journals request at submission 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. @yourname. Providing this information is voluntary.

In addition, @myESMO is included as standard, as well as other organisational accounts 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 and resubmission following reviewer comments.

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

## **9 Revision and resubmission**

Once a decision from the journal has been received, the lead and last authors work with the ESMO Guidelines staff to address all reviewer comments. All authors will need to approve the manuscript and reconfirm their Disclosure statement is still up-to-date before the ESMO Guidelines staff can resubmit the manuscript on behalf of the authors.

## **10 Online publication and proof**

In the event of journal acceptance, the lead and last authors work with the ESMO Guidelines staff on the proof, which depending on the journal, might be ready before or after the article has been published online. To increase awareness, ESMO will promote the online publication via ESMO social media/journal social media and ESMO Newsletters. All authors will be asked again to provide their social media handles if they wish to be tagged in social media posts. The lead and last authors will also be asked to provide a short promotional statement to accompany said social media posts and newsletters.

## **11 CPG Express Guideline Updates and Living Guidelines**

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 SE will coordinate with the guideline authors to produce an update to the ESMO CPG, either a Living Guideline update or as an Express Guideline Update (see Section 3.1).

The Living Guideline update will be published on the ESMO website linked to the corresponding original CPG. Express Guideline Updates will be submitted to *ESMO Open* for publication.

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

## **12 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 GLC.

After manuscript publication in an ESMO Journal, authors can present recommendations including algorithms.

## **13 References**

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

- 6 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 Union for International Cancer Control. Brierley JD, Gospodarowicz MK, Wittekind C (eds). *TNM Classification of Malignant Tumours*, 8th ed. Oxford, UK: John Wiley & Sons, Ltd, 2017.
- 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 Schönemann 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.