ESMO Expert Consensus Statements (ECS) Methodology and Standard Operating procedures (SoPs)

INTRODUCTION and INTENT of the ECS Series

The ESMO ECS series of publications contain Questions and Answers (Statements) on well-defined, controversial or clinically relevant, narrow topics and are produced by 20-40 key experts in the field. By addressing a list of defined, narrower questions than a traditional ‘all tumour’- encompassing ESMO Clinical Practice Guideline, they offer an in-depth study of the field and provide Statements that fill ‘knowledge gaps’ not covered in depth by the ESMO Guidelines, often in scientific or practice areas in which high-level evidence is lacking. As such, the ECS papers follow a Question and Answer format with a Level of Evidence designation, covering a finite list of specific questions over an oncology topic, related to biology, biomarkers, prognostic/predictive considerations, clinical practice and health services.

METHODOLOGY

a. Topic Selection
Proposals for Topics come from the ESMO Faculty, ESMO Committees, and Working Groups. All proposed topics are screened by the Chief Medical Officer (CMO) with the relevant ESMO Faculty Coordinators, Committee Chairs, the Guidelines Chair, and the Editor of the relevant journal of choice. Parties interested in proposing a topic should complete the relevant proposal form.

b. Author Selection (based on ESMO DOI)
Based on the ECS topic, the relevant Chair of an ESMO Committee, Guidelines Chair, Faculty Coordinators, or CMO are to select the project expert list with the project leaders. The expert list should consist of up to 20 authors and 2 project leaders. The two project leaders will be the first and last author of the publication.

The ECS topic and panelists are sent to the ESMO Executive Board for assessment and approval. Journal Editors subsequently provide feedback on the topic/project.

Once the proposal is approved by the Executive Board, the standard ECS invitation should be adapted to the relevant topic and sent to the Project Coordinators and Experts.
All authors should fulfil all four of the following authorship criteria recommended by the International Committee of Medical Journal Editors (ICMJE):
Substantial contribution to the conception or design of the work; or the acquisition, analysis or interpretation of data for the work; AND
• Drafting the work or revising it critically for important intellectual content; AND
• Final approval of the version to be published; AND
• Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

c. Project Publication Development
The ECS Project Leaders are to identify the Working Package (WP) topics with WP Coordinators and Experts. Each WP should include 4-6 relevant/important Questions applicable to the WP topic. There should be a total of 4-6 WPs to work over a total of 25 Questions and relevant answers (Statements).

Every WP should produce for each Question an Answer (Statement), based on currently available evidence and/or expert opinion. The WP output should follow the standard format:
1. Question followed by the
2. Statement (Answer) with
3. Level of Evidence (according to the , supplemented by a
4. concise Discussion text (1-2 paragraphs).

After the WPs develop the Questions and Statements (Answers), they are then shared with the full author panel for review/revision to avoid any overlaps between WPs. Once the review/revision is complete, ESMO Staff will create the survey that includes all Questions and Statements for the first round of modified Delphi voting. The Questions with Statements (Answers) are voted upon by the whole author panel (anonymously) for Agreement/Disagreement/Comments.

All Questions and Statements (Answers) that elicit less than 90% agreement are to be revised by the WP Coordinators and a second round of Delphi voting is to be conducted. After the second round of Delphi voting, an agreement is assumed if >75% agree on a Statement, if not the Statement is rejected.
After the final conclusion of Questions and Statements (Answers), the two Project Leaders should prepare the final manuscript with reference list to be submitted for publication in Annals of Oncology (www.annalsfoncology.org) or ESMO Open (www.esmoopen.com). The format of the manuscript should follow the general template:

- Title with authorship sequence
- Abstract
- Introduction
- Methods
- Results by WP. Each WP includes the Questions and Statements, each Statement with Level of Evidence and % rates of Agreement, Disagreement, Abstain
- Table of statements
- Acknowledgements
- COI statements
- List of references

Levels of evidence should follow the scheme adapted from the Infectious Diseases Society of America-United States Public Health Service Grading System, as used in the ESMO Clinical Practice Guidelines (https://www.esmo.org/guidelines/esmo-guidelines-methodology).

ESMO journals follow a strict word count policy. The manuscript should follow the journal Instructions for Authors and should not exceed word count limits defined by the ESMO journal. Additional information can be included in the supplementary material.

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. The two project leaders are responsible for the final production of the manuscript with all its elements, as shown above.

The ESMO Staff working with the CMO will support the expert’s work organizing all the necessary TCs and IT tasks, along with other administrative and logistical tasks.
DECLARATION OF INTEREST

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

Each author must provide DOI information including financial values, even if there is nothing to declare. The successful review of all author DOIs should take place by the two project leaders and the CMO and further reviewed by the Compliance Committee if requested by the first-level reviewers, before the individual’s author role in the project can be confirmed. Each author is responsible for ensuring that their DOI statement in the ESMO DOI Platform is true, up to date and complete.