

# **Declaration of Interest (DOI) Policy**

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## Objectives & Principles

### Overview

ESMO strives to attain the highest standards of integrity by adopting best practices that enhance its governance and ensure public confidence in its activities. One way in which we meet this objective is through an awareness of potential conflicts of interest.

ESMO seeks to work closely with leaders in the field of medical oncology, many of whom are members of the Society. It is both understood and expected that these individuals will often have entirely legitimate external interests arising from their work and expertise. However, it is possible that a conflict, or the appearance of a conflict, could arise between these interests and those of the Society. Consequently, it is appropriate to undertake a transparent review of the interests of individuals in specific roles and interacting with ESMO in certain ways.

### ESMO's approach to reviewing and managing interests

ESMO takes a proportionate, responsibility-based, approach to managing interests. This approach is principally based on the nature of the relationship between the Society and the individual concerned:

- *Individuals acting for ESMO or speaking on its behalf (Section One of this policy)*  
Perceived bias in decision-making or communication may reflect directly upon ESMO's reputation and represents a higher level of responsibility. The Society therefore requests a substantial degree of disclosure in order to make an informed decision about the involvement of each individual in its activities and some of these declarations will be subject to review. Roles falling within the scope of Section One are listed in Appendix A, Higher Responsibility Roles and the DOIs for some of these Roles may require review.
- *Individuals using ESMO platforms to share their own research or express their own opinions (Section Two of this policy)*  
ESMO is not responsible for material shared using its platforms (such as in congress presentations or journal articles) when external parties present their own research or opinions. Such external parties remain fully responsible for what they publish. However, as a matter of good practice, ESMO mandates that interests are disclosed so that the audience is fully informed. Individuals within the scope of Section Two are identified in Appendix A, Intermediate Responsibility Roles.

This Declaration of Interest Policy was developed by the Compliance Committee and has been approved by the Executive Board. Its implementation is the responsibility of the Compliance Committee.

**It is the responsibility of the individual supplying the Declaration of Interest to ensure that the information is true, up to date and complete.**

## Definitions

A **personal conflict of interest** can arise when an individual has material interests that could influence, or be perceived as influencing, their actions, decisions or communications.

The **interests of immediate family members** (meaning a spouse or partner) are also considered to be personal interests.

**Indirect conflicts of interest** can arise through **Institutional interests** (relationships between third parties and the individual's host institution that relate to the individual's employment or research programme). It is acknowledged that such interests may be difficult to identify and may exist without the knowledge of the individual concerned.

### Note

These interests need not be financial in nature. For example, an individual could have access to otherwise confidential information or have received funding for training from an external party. See page 5 for more details on what should be disclosed for those individuals within the scope of Section 1.

**The Declaration of Interest** is all of an individual's disclosed interests.

A **direct ownership interest** is a shareholding (or option to acquire shares/stocks) in a public or private company where the investor has control over their investment decisions. This excludes shares held through an intermediary such as a diversified fund.

ESMO's responsibility-based approach classifies individuals according to the way in which they interact with the Society:

**Higher responsibility** individuals are those who act for ESMO or speak on its behalf about ESMO products and projects or any other matter. This includes members elected or appointed to play an active role in the Society as well as senior ESMO employees. It also includes those individuals involved in the preparation of ESMO communications and formats, such as ESMO Guidelines or books published in ESMO's name. A complete list is shown in Appendix A.

**Intermediate responsibility** individuals are those who use ESMO platforms to share their own research or express their own opinions. This would include authors publishing articles in ESMO's journals or presenters at ESMO events. Further details can be found in Appendix A.

**Lower responsibility** individuals are those not falling into the higher and intermediate responsibility categories. No disclosure of interests is generally required.

Individuals who work with ESMO in multiple ways will typically be classified according to the highest-responsibility interaction. However, the Compliance Committee may adopt a different approach on a case-by-case basis.

## Policy

### Section One - Individuals acting for ESMO or speaking on its behalf

#### *Applicability*

This section of the policy applies to individuals identified in Appendix A as having Higher Responsibility Roles.

#### *DOI Completion*

Individuals with Higher Responsibility Roles must complete or update a DOI prior to being accepted for their role. Once submitted the DOI may be used by ESMO for a period of 12 months for any other role/activity the individual undertakes for ESMO. The individual will be alerted before their DOI is used for another role/activity and they will have the opportunity to update it if they wish to do so.

DOIs must also be updated or reconfirmed if a period of 12 months elapses since the last update. Furthermore, an individual must immediately update their DOI if a material change in their interests occurs (meaning an additional interest that, by type or value, represents a substantial increase in the risk of conflict). If they realise that a previous disclosure was incomplete or inaccurate, they should update their DOI as soon as possible.

This must be done in accordance with the guidelines then in force through ESMO's online platform or, if advised, in another format such as in writing.

Potential candidates for election to roles identified in Appendix A must complete a DOI when requested to do so as part of the nomination process. The information disclosed will be assessed by the Compliance Committee and taken into account by the Nomination Committee when determining which candidates are put forward for nomination. The disclosed information for nominated individuals (excluding financial values) will be available to the public once the Electronic Ballot Vote has been called.

Candidates for nomination or appointment to non-elected roles identified in Appendix A must also complete a DOI prior to taking up their position. The final decision on appointment will take into account the information disclosed.

Candidates for ESMO Staff positions identified in Appendix A must also complete a DOI as part of the recruitment process. The final decision on employment is dependent on the outcome of the DOI review.

#### *Contents of the DOI*

The DOI should contain all relevant interests, including but not limited to:

- Compensation received for any speaking, consultancy or advisory role.
- Compensated or non-compensated role(s) in a for-profit healthcare company or in a for-profit professional education provider.

- Any Direct Ownership Interest in a for-profit healthcare company or a for-profit professional education provider.
- Intellectual Property interests (e.g. patents; whether currently generating an income or not).
- Research funding from a for-profit healthcare company (including when paid to a host institution, where the funding benefits the individual's research or other activities). You should declare all trials you are involved in, indicating your role, if there is a financial payment (without disclosing the amount) and the recipient.
- Leadership or decision-making roles in any other medical society, research group, foundation, charity, etc. whether remunerated or not.
- Membership in or affiliation with any political or lobbying organisation that could be considered to be operating in similar areas as ESMO or with relevance to cancer medicine.
- Non-financial benefits such as access to privileged information or training. For example, a pharmaceutical company providing access to proprietary information without charge that is used in an individual's research programme; being involved in a clinical trial steering committee without remuneration; a relationship with a company active in the field of cancer including but not limited to therapeutics, diagnostics and artificial intelligence; or receipt of free samples of medical products for research purposes.

The DOI must include all interests held within the past two calendar years. The Compliance Committee may also request disclosure of interests in a medical or pharmaceutical product that is still under commercial development or ongoing active research.

The scope includes personal interests of the individual themselves and any household members, and also institutional interests (where these interests relate to the individual's activities).

Individuals within the scope of this section will also be asked to indicate the financial value of their interests by choosing from a series of ranges based on the below:

- The total amount received over the last two calendar years (for income).
- The present value of shares (and options) held (for publicly-traded companies).
- Percentage ownership (for privately-held companies, including both shares and options).

ESMO recognises that financial information is sensitive. It will only be made available to the reviewer of an individual's DOI and, if necessary, to the Compliance Committee and/or the Executive Board and limited ESMO staff members. Individuals with access to disclosed financial information must treat it confidentially.

Financial information for individuals being considered for elected positions may also be shared with the Nomination Committee.

**Note**

If an individual considers that they have no interests to declare, then a positive declaration of this fact must be made with each submission.

### *Review of disclosed interests*

The review process for disclosed interests is set out in Appendix B.

### *Transparency and record-keeping*

The most recent DOI for each individual within the scope of Section One will be available to all ESMO members when they are logged in to ESMO's website. Financial information will not be disclosed through this route. This information is made available in the interest of transparency and in good faith and ESMO takes necessary steps to ensure this information is made available for members to view only. ESMO cannot be held liable for any fraudulent or improper activity or use of this information.

The DOIs of candidates for elected positions will be available to members and non-members ahead of the Electronic Ballot Vote (in the calling to the Electronic Ballot Vote according to Art. 17 Bylaws). Financial information will not be included.

Each DOI will be retained for the duration of an individual's involvement with or employment at ESMO and for an additional five years thereafter.

In the event that the Executive Board, advised by the Compliance Committee, decides to take action to manage a potential conflict of interest, the details of the situation, the chosen safeguards and the supporting rationale will be documented.

### *Consequences of non-compliance*

It is the personal responsibility of each individual within the scope of this policy to ensure that they comply with the disclosure obligations and within the notified deadlines.

Individuals required to complete a DOI may not be nominated/appointed until the disclosure has been provided.

In the event of non-compliance that appears to be persistent, negligent or intentional, the Compliance Committee may recommend disciplinary action in accordance with ESMO regulations, and in particular the Code of Conduct. Sanctions may include suspending and/or terminating the individual's involvement with ESMO for a defined or indefinite period of time.

## Section Two - Individuals using ESMO platforms to share their own research or opinions

### *Applicability*

This section of the policy applies to individuals identified in Appendix A as having Intermediate Responsibility Roles.

### *DOI Completion*

The majority of individuals in Intermediate Responsibility Roles will be submitting abstracts for ESMO Congresses. At the time of submission, the submitter must provide a DOI for each (co-)author. In such cases the submitter must assure and is responsible to ensure that each (co-)author has read and understood the DOI Policy, and the ESMO Privacy Policy and that each (co-) author has consented to all terms of the DOI and has been informed of the filing of their personal data to ESMO.

If the submitting author has already submitted a DOI via the ESMO DOI platform, then they can retrieve their disclosure statement directly from that system.

### *Contents of the DOI*

The scope of disclosure must comply with the guidance currently in force. Disclosure should include:

- Personal financial relationships with **all** commercial entities within the last two calendar years (or the duration of the work being presented, if longer) whether or not related to the topic of the abstract or manuscript.

ESMO requires general or full disclosure as opposed to activity-specific disclosure. This means that all financial relationships with Companies over the past two calendar years have to be disclosed, regardless of whether any relationship with a Company is specifically related to the subject matter of a particular manuscript.

- Any other payments or services that support the work of the author received in the last two calendar years whether made directly to the individual or to a host institution.
- Any payments or services related to the current work received at any time whether made directly to the individual or to a host institution.
- Details of any existing patents/copyrights relevant to the current work.
- Any other potentially influencing relationships identified by the individual.

Interests of family members are not required.

Individuals within the scope of this section will **not** be asked to indicate the financial value of their interests.

#### **Note**

If an individual considers that they have no interests then a positive declaration of this fact must be made.



### *Review of disclosed interests*

ESMO's role is to make disclosure mandatory and to facilitate the process. However, exactly what is disclosed remains the responsibility of the author/speaker. Barring exceptional circumstances, ESMO will not conduct a review of the disclosed information and will not, as a rule, use it to select which abstracts/manuscripts are selected for presentation/publication. Exceptions to this approach must be discussed with the Compliance Committee.

### *Transparency and record-keeping*

The information disclosed will be published along with the corresponding abstract/article (if selected for presentation/publication). In the case of an oral presentation, the same disclosure (as a minimum) must be included on a slide at the beginning of the talk.

The disclosure may be kept on file for future reference for a period of not more than five years. However, every subsequent submission will require a new declaration to be made. This is because it is expected that the contents of the disclosure will change over time.

### *Consequences of non-compliance*

Submitted abstracts/manuscripts will not be eligible for consideration until all necessary disclosures have been provided.

If it becomes known that an individual's disclosure may have been incomplete or inadequate, the circumstances are subject to review by the Compliance Committee. The Compliance Committee may, at its discretion, take further steps such as:

- Ask the individual to provide more details of their interests.
- Ask the individual to publish an amended declaration.
- Prevent the individual from participating in ESMO events/journals for a defined and/or indefinite period of time.

## Appendix A: Higher responsibility and intermediate responsibility roles

ESMO applies its Disclosure of Interest policy according to the type of interaction an individual has with the Society. Higher and intermediate responsibility roles are identified below, while lower responsibility applies to all other types of interaction.

An individual with roles and responsibilities in more than one category should follow the procedures for the highest applicable responsibility level.

### Higher responsibility roles

This group includes those individuals who act for ESMO or speak on its behalf about ESMO products and projects or any other matter.

- The President\* and all members of the Executive Board\*.
- The Chair\* and Members of Key Committees (as defined in the Organisational Regulations).
- Non ex officio members of the ESMO Council\*.
- The Chair and Members of all Additional Corporate Bodies, in particular
  - Chair\* and members of Permanent Committees and their sub-structures
  - Chair and members of all other forms of sub-structures to the Executive Board, mainly (i) Task Forces, (ii) Scientific Committees (e.g. for ESMO Congress and ESMO Asia Congress), and (iii) Editorial positions in ESMO journals (Editor-in-Chief\*, Deputy\* and Associate Editors).
- The CEO, CMO and selected Senior Staff (those reporting directly to the CEO and any other Department Heads).
- The Chairs\*, Scientific Chairs\*, Educational Chairs\*, Scientific Track Chairs\* and Scientific Track members of all ESMO Congresses and Conferences.
- Editors and authors contributing to guidelines, books, E-learning content and other material published in ESMO's name (typically, but not limited to, that overseen by the Guidelines & Publishing department).
- Individuals invited by ESMO to participate in a press conference (to be identified on a case-by-case basis).
- External consultants with decision-making authority.
- Patient Advocates and other similar external parties collaborating with ESMO.

\*The DOIs of these individuals will all be subject to review.

### Intermediate responsibility roles

This group comprises individuals who use ESMO platforms to share their own research or opinions.

It includes ESMO members and non-members who, on behalf of themselves, their colleagues and/or their institutions:

- Submit abstracts for oral or poster presentation at ESMO-organised congresses and events.

- Submit manuscripts for publication in an ESMO journal.
- Submit content for other ESMO-owned communications platforms.

DOI requirements also apply to authors of each abstract/manuscript other than the submitter. For this purpose, authors should be identified according to the guidance of the *International Committee of Medical Journal Editors (ICMJE)*<sup>1</sup>.

### **Lower responsibility roles**

All other types of interaction with ESMO, other than when specified by the Compliance Committee on an exceptional basis. No specific DOI requirements apply.

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<sup>1</sup> <http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>

## Appendix B: Review Process for Disclosed Interests

This Appendix sets out the process by which interests disclosed under Section One of this policy may be reviewed.

### Hierarchical review process

Submitted DOIs will be reviewed according to the guidance then in force. This review will be undertaken hierarchically under the oversight of the Compliance Committee.

In practice, this means that an individual's DOI will be reviewed by the leader of the relevant programme, section or activity according to the highest position they occupy within the Society.

#### **Example: Hierarchical review**

1. The DOI of the Guidelines Subject Editor will be reviewed by the Guidelines Committee Chair
2. The DOI of the Guidelines Committee Chair will be reviewed by the Director of Education
3. The DOI of the Director of Education will be reviewed by the Compliance Committee Chair

However, if any of these individuals also occupies a higher position in the Society then that role would determine their DOI reviewer. The Compliance Committee can be consulted at any stage.

This approach ensures that the person performing the review has sufficient information to assess interests in the context of that individual's activity while minimising duplication of effort.

The reviewer will have access to all information provided as part of the DOI, including financial values. If the reviewer wishes to consult the Compliance Committee as part of the review process then the full version of the disclosure can also be shared with the members of the Committee. The financial value of each disclosure will be treated as confidential.

Identifying issues is a matter of judgement and the objective is to identify interests that may represent an unacceptable conflict with those of the Society.

Possible outcomes include a) reviewed, b) specific safeguards being put in place or c) ESMO declining to (continue to) work with the individual for the specific task/role/function.

Any reviewer may consult the Compliance Committee and must do so if they are considering suggesting an outcome other than reviewed. If such potential issues are identified, it is the responsibility of the Compliance Committee to advise the Executive Board as to how they may be resolved. Responsibility for deciding upon a course of action rests with the Executive Board.

Similarly, when a pre-nomination DOI review is conducted for candidates for elected positions, the Compliance Committee's responsibility is only to provide advice and guidance to the Nomination Committee. The Nomination Committee makes the final decision as to which candidates are put forward for election.

### Evaluating interests

Whether an interest may be resolvable through safeguards depends on a number of factors that must be evaluated together. These include:

- The **degree of control** the individual has over a third party. For instance, an individual holding a management, board or director-level role or owning a substantial proportion (more than 25% of shares or voting rights) of an entity is typically considered to be in a position to exert control over that entity.
- **Obligations** to another party. For example, in many jurisdictions a director or board member has a legal duty to act in the interest of the respective entity. This may prevent them from acting in ESMO's interests.
- The **type and nature of third party**. For example, a relationship with a pharmaceutical company active in the field of cancer medicine creates a more significant conflict than a similar relationship with a major company in another field.
- The **nature of interaction** between the individual and the third party. Some relationships (such as participation in advisory boards or the receipt of congress support) are commonplace and are less suggestive of a conflict of interest. Conversely, closer, longer term or more frequent interactions may represent a higher risk.
- The **level of compensation** received from the third party. Overall, a higher level of compensation creates a higher risk of conflict. However, this should be evaluated along with i) compensation received from the individual's other interests and ii) typical salaries and costs of living in their country of residence. The aim is to understand the magnitude of the compensation in the individual's own context.
- The overall **balance of an individual's relationships**. A balanced portfolio of interactions with a large number of third parties creates a lower perception of conflict than one major relationship with a single entity.
- The individual's **proposed role** at ESMO. The Society would be more sensitive to a potential conflict concerning a Presidential candidate than someone with a more restricted role.

While these factors should be evaluated on a case-by-case basis, some relationships may represent an unresolvable conflict of interest. These include, but are not limited to:

- A senior leadership or board-level role at a company active in the field of cancer medicine, a commercial medical education provider or a major medical society if this position adversely affects ESMO's interests according to the Executive Board.
- A material direct ownership interest (assessed in terms of the value or proportion of shareholding) in a pharmaceutical company active in the field of cancer medicine or a commercial medical education provider.

- A fiduciary duty or contractual obligation owed to a pharmaceutical company active in the field of cancer medicine or a commercial medical education provider.
- Material intellectual property rights in a present or future commercial product in the field of cancer medicine, where these are of a magnitude that suggests a conflict of interest risk equivalent to, for example, a senior leadership or board position.

Any proposal to involve an individual with such interests should be supported by a detailed rationale and be approved by the Compliance Committee.