



European Commission Initiative on Colorectal Cancer (ECICC) Management of Conflicts of Interests (CoIs) (V2, 13 September 2023)

1. Background

A Conflict of Interest (CoI) represents a set of conditions in which professional judgment concerning a primary interest, such as the health and well-being of a patient or the validity of research is improperly influenced by a secondary interest¹.

In healthcare, the primary interest is represented by contributing to the advancement of health research and generate knowledge for patients, while the secondary interest refers to personal gains².

The secondary interest may be financial, directly measured in monetary units or non-financial, including academic, professional, personal and political interests and not measured in monetary units³. Nevertheless, not all interests constitute a CoI and an assessment is always needed to make this determination.

In the case of the European Commission Initiative on Colorectal Cancer (ECICC), the definition of a CoI could be defined as any interest declared by an expert that may affect or reasonably be perceived to affect the expert's objectivity and independence in providing advice related to the ECICC activities.

The members of the ECICC working group, subgroup members appointed from the ECICC expert pool, external experts participating in the ECICC activities attending the ECICC meetings will always be asked to complete a Declaration of Interests (DoI) form. DoIs are collected using a form prepared specifically for the ECICC. The completed forms are publicly available on the dedicated ECICC web page⁴.

¹ Thompson DF (1993). Understanding financial conflicts of interest. *New England Journal of Medicine* 329:573–576.

² Khamis AM, Hakoum MB, Bou-Karroum L, Habib JR, Ali A, Guyatt G, El-Jardali F, Akl EA. Requirements of health policy and services journals for authors to disclose financial and non-financial conflicts of interest: a cross-sectional study. *Health Res Policy Syst.* 2017 Sep 19;15(1):80. doi: 10.1186/s12961-017-0244-2.

³ Norris SL, Holmer HK, Ogden LA, Burda BU. Conflict of interest in clinical practice guideline development: a systematic review. *PLoS One.* 2011;6(10):e25153. doi: 10.1371/journal.pone.0025153. Epub 2011 Oct 19.

⁴ ECICC webpage <https://healthcare-quality.jrc.ec.europa.eu/ecicc>



2. Assessment of declared interests

The European Commission’s Joint Research Centre (JRC) CoI Management Panel is responsible for the assessment of the declared interests, which follows the steps detailed in Table 1.

Indications from recent research and developments in managing CoIs and examples from several organisations/institutions (e.g. WHO, NICE, NIH, GIN) have been considered and tailored for the context of the ECICC assessment of declared interests.

Steps		Responsible	Tasks
1	Are the interests properly declared?	JRC CoI Management Panel	<ul style="list-style-type: none"> • Check if the DoIs forms are complete and clear • Request clarifications (if necessary)
2.	Does a CoI exist?		Determine if there is a CoI
3.	Is the CoI severe?		Decide if a CoI is severe enough to result in a high risk of bias or a decreased credibility
4.	Is the CoI manageable?		Decide if the CoI is manageable or not and take different actions depending on the severity of the CoI

Table 1. Assessment of declared interests by the JRC CoI Management Panel.

Financial Interests:

The financial interests would include^{5,6}:

- personal financial gain from employment/consultancy (including but not limited to paid work, consulting income or honoraria and travel stipends) with similar interests/activities as those of the ECICC;
- support for colorectal cancer (CRC) related research, including donations/grants/fellowships/other financial support to the individual or their institution from a commercial entity that has an interest in the topic or the outcomes of the ECICC;

⁵ WHO Handbook for Guideline Development, second edition, 2014.

⁶ NICE, Policy on declaring and managing interests for NICE advisory committees, 2019.



- research proprietary interests and patents in the CRC field;
- shares/stocks/bonds in commercial entities with similar interests/activities as those of the ECICC.

Compensations (i.e. employment/work such as speaking engagements or sitting on advisory boards or private practice) received from a single entity within 12 months are considered as financial interests if they are above €5.000⁷.

When support, such as attending a meeting/conference/event, exceeds €1.000, would be considered as financial interest⁸.

Financial research support, including grants/fellowships/other financial support can also be indicative of financial conflict. These supports may be received from private or public entities by the individual/individual's parent organisation.

If these supports are received from public entities, they are considered as financial interests if they exceed 25% of the annual research budget that is managed by the individual's parent organisation for the area under concern⁹.

If these supports are received from private entities by the individual/individual's parent organisation, they are considered as financial interests when the total amount received from a single entity within 12 months exceeds 5000€ per year. For a better understanding of the interests and the relationship with the entity providing the support, further categorisation of the received amounts could be taken into consideration: 5.000 to 10.000 euro; 10.001 to 100.000 euro; 100.001 to 200.000 euro; and >200.000 euro¹⁰. The more direct is the relevance and larger the amounts, the more characterised is the financial interest.

The financial interests arising from above mentioned activities will be assessed on a case-by-case situation.

Non-financial Interests:

The intellectual CoI, defined in the context of guidelines as “academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation”¹¹.

⁷ Andreatos N, Zacharioudakis IM, Zervou FN, Muhammed M, Mylonakis E. Discrepancy between financial disclosures of authors of clinical practice guidelines and reports by industry. *Medicine (Baltimore)*. 2017 Jan;96(2):e5711. doi: 10.1097/MD.00000000000005711.

⁸ See footnote 4.

⁹ DOI - Standard Operating procedure. DG SANTE, 2016.

¹⁰ See footnote 6.

¹¹ Guyatt G, Oxman AD, Akl EA, Kunz R, Vist G, Brozek J, Norris S, Falck-Ytter Y, Glasziou P, DeBeer H, Jaeschke R, Rind D, Meerpohl J, Dahm P, Schünemann HJ. GRADE guidelines: 1. Introduction-GRADE evidence profiles and summary of findings tables. *J Clin Epidemiol*. 2011 Apr;64(4):383-94. doi: 10.1016/j.jclinepi.2010.04.026.



The non-financial interests include (but are not limited to)¹²:

- competing beliefs,
- published opinions,
- leadership role on a panel,
- public comments and testimony,
- substantial career efforts/interests,
- advocacy or policy positions.

In the case of the ECICC, non-financial interests, including the intellectual ones may include professional opportunities through the advancement of medical science together with study authorship and public funding for research directly related to the topic of interest that creates the potential for bias and compromises an expert's objective judgment¹³.

The non-financial interests will be evaluated on a case-by-case situation.

3. Management of identified CoIs

CoIs create a risk of bias in decisions or recommendations. The risk of bias represents the likelihood that features of specific activities will give misleading results¹⁴. This can result in wasted resources, lost opportunities for effective interventions or harm to patients.

The judgement on the risk of bias entails a graduation of the risk severity as low, moderate or high risk of bias. For example, applicants with a financial interest in showing that a particular diagnosis method works better than others will have a high risk of bias related to the activities of the ECICC.

A CoI management plan is necessary to minimize the potential for bias¹⁵.

When no CoI is perceived, no action is needed, hence the expert can engage in discussions and can vote.

When a CoI is present, the involvement of the expert is limited to taking part in discussions, albeit without the right to vote. Depending on the severity of the CoI, recusal from participation

¹² Ngo-Metzger Q, Moyer V, Grossman D, Ebell M, Woo M, Miller T, Brummer T, Chowdhury J, Kato E, Siu A, Phillips W, Davidson K, Phipps M, Bibbins-Domingo K. Conflicts of Interest in Clinical Guidelines: Update of U.S. Preventive Services Task Force Policies and Procedures. *Am J Prev Med.* 2018 Jan;54(1S1):S70-S80. doi: 10.1016/j.amepre.2017.06.034.

¹³ See footnote 3.

¹⁴ Higgins, J., D. Altman, et al. (2011). Chapter 8: Assessing risk of bias in included studies. *Cochrane Handbook for Systematic Reviews of Interventions*. J. Higgins and S. Green, 2011. The Cochrane Collaboration.

¹⁵ Schünemann HJ, Al-Ansary LA, Forland F, Kersten S, Komulainen J, Kopp IB, Macbeth F, Phillips SM, Robbins C, van der Wees P, Qaseem A; Board of Trustees of the Guidelines International Network. Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines. *Ann Intern Med.* 2015 Oct 6;163(7):548-53. doi: 10.7326/M14-1885.



might be needed, which means that the expert will neither engage in topic specific discussions nor will vote¹⁶.

The severity of the CoI depends on the likelihood of undue influence by the conflicted individual as well as the seriousness of the possible harm from the CoI¹⁷. Thus, the CoIs can be considered as being either non-severe CoIs, i.e. any CoI that will probably not result in high risk of bias or decreased credibility of the ECICC, or severe CoIs, which are any CoI that will probably result in high risk of bias or decreased credibility of the ECICC. The severe CoIs can be either manageable or non-manageable. In the latter case, revocation of membership is required.

For the ECICC, the following categories impede the participation of an expert in the ECICC activities, thus representing severe non-manageable CoIs¹⁸.

- owning more than €10.000 in annual income worth of shares or 5% equity ownership in a company that manufactures or sells a product or technology under consideration in the guideline/requirements development;
- holding a patent on a product or technology that may be considered in the guideline/requirements; or
- having a spouse (or partner with whom the individual has a close personal relationship) or children who work for the manufacturer of a product or technology under consideration in the guideline.

Since obtaining the necessary expertise from individuals without conflicts may sometimes be impossible, only a minority of the experts should have a CoI. The chair should ideally have no COI, and a co-chair with no CoI should be appointed if a chair without a CoI cannot be selected¹⁹.

4. Reporting of CoI Management Activities:

The JRC Head of F1 Unit signs the documents stating the actions to manage CoIs which are bi-laterally communicated to the concerned contributors.

¹⁶ See footnotes 4 and 11.

Traversy G, Barnieh L, Akl EA, Allan GM, Brouwers M, Ganache I, Grundy Q, Guyatt GH, Kelsall D, Leng G, Moore A, Persaud N, Schünemann HJ, Straus S, Thombs BD, Rodin R, Tonelli M. Managing conflicts of interest in the development of health guidelines. *CMAJ*. 2021 Jan 11;193(2):E49-E54. doi: 10.1503/cmaj.200651.

¹⁷ See footnote 6.

¹⁸ See footnote 6.

¹⁹ See footnote 12.