EUROPEAN COMMISSION

CALL FOR EXPRESSION OF INTEREST
FOR EXPERT PANELS ON MEDICAL DEVICES AND IN VITRO DIAGNOSTIC MEDICAL DEVICES
804/PP/GRO/CODEL/20

ANNEX III - Procedural guidance on inclusion of declared interests in the European Commission's electronic declaration of interests form for the expert panels on medical devices and *in vitro* diagnostic medical devices

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Contents

1. Aim

In the context of the implementation of EU Regulations 2017/745 on medical devices and 2017/746 on *in vitro* diagnostic medical devices, the European Commission (EC) is responsible for the supervision of the work of the expert panels in relevant clinical areas as regards their various roles and tasks, namely the:

- Provision of scientific opinions / views in relation to the clinical / performance evaluation consultation procedure (CECP/PECP) for certain high-risk medical devices according to Article 54 of MDR and 48 of IVDR.

- Provision of *ad hoc* advice in relation to implementation of the Regulation (EU) 2017/745 on medical devices (MDR)[1] according to Articles 106, 55.3, 61.2, and of the EU Regulation 2017/746 on *in vitro* diagnostic medical devices (IVDR)[2] according to Article 50.3

According to Article 107 of the MDR[1] the members of the expert panels on medical devices and *in vitro* diagnostic devices (hereafter: "expert panels") shall not have financial or other interests in the medical device industry which could affect their impartiality. Thus, the experts shall declare any direct or indirect interest they may have in the medical device industry.

The expert panels are composed of individual experts who are selected following a public call for expression of interests according to the highest selection standards including the assessment of experts' declaration of interests. In particular, the experts are selected on the basis of outstanding professional expertise. The experts shall work in their own personal capacity and should not represent any stakeholder, organization, or Member State (MS).

The present guidance aims at helping medical device experts to complete the European Commission's (EC) electronic declaration of interests (DOI) form and EC staff to guide experts in completing the form correctly. It highlights key aspects of declaring interests and clarifies what information should be mentioned in which section of the DOI form.

Reference is made to the document entitled “European Commission's policy on the management of competing interests of members of the medical device expert panels on medical devices and *in vitro* diagnostic devices”, which is made publicly available on the Commission website.[3] This policy outlines the handling of declarations of interests of expert panel members (including, where relevant, invited members) involved in the expert panels activities.

2. Who needs to complete a DOI?

A DOI needs to be completed by all candidates applying to the call for expression of interest for expert panels on medical devices and *in vitro* diagnostic medical devices. Moreover, a DOI needs to be completed / regularly updated by all advisors appointed as expert panel members in accordance with the relevant Commission Implementing Decision.[4]

If appointed, please note that **the EC will publish your DOI on its website.** The EC processes personal data in accordance with the applicable legislation Regulation (EU) 2018/1725.

Should you acquire any additional interests during the course of your term or should your interests change since your last DOI, you must submit an **updated DOI without delay**. Please ask the Commission Secretariat of the expert panels to provide you with a copy of your current DOI and update this form to reflect your new interests and any changes.

3. General considerations

Completing the DOI

In completing the DOI, please take note of the definitions and explanatory notes included under each section of the DOI and the additional guidance in this document. Please declare all activities relating to involvement with medical devices and/or medical devices companies, i.e. **any current activities as well as all past activities that existed during the last 3 years**. **Current** is interpreted as **the time of completion of the DOI form**. In order to decide which past activities shall be declared, one should count 3 years from the date of submitting the declaration.

However, please note that for all previous employment with a medical device company in an executive role and/or a lead role in the development of a medical device (for the definitions, please see section 4 of this guidance) you need to declare such employment at any stage of your career (going beyond the aforementioned 3 year timeframe). You may also provide additional information on any interests that occurred over 3 years ago. This information will not be used in the evaluation of declared interests but in the context of increasing transparency on previous interests.

In case you are unsure whether an interest relates to a medical device or to a medical device company, declare the information under the relevant section of the form (2.1 Employment, 2.2 Consultancy, 2.3 Strategic Advisory role, etc.), providing as complete information as possible. The EC may contact you for more details or clarifications.

Evaluation of the DOI by the European Commission (EC)

On the basis of the submitted DOI, the EC evaluates the declared interests according to the document "European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices"[3] and determines if the expert can participate in the concerned expert panel activity. The EC may apply restrictions to such participation or even not allow an expert to participate.

If during the evaluation of the declared interests clarification is required, the EC will contact you. The EC may request you to provide more information/details and/or to submit an updated DOI, as appropriate, to correctly reflect the declared interests in the DOI.

If for any reason you are not in a position to fully detail all activities relating to your involvement in medical devices and/or medical device companies, e.g. due to contractual arrangements, this may affect your participation in the expert panel activities.

In case the EC becomes aware/is informed of any interests which have not been included in your DOI, the EC will contact you regarding these interests and, if required, request you to submit an updated DOI. Failure to fill in the DOI in a complete and/or correct manner may be considered as a *prima facie* breach of trust towards the European Commission. Because of that failure, appropriate actions, including the exclusion of the concerned person from the expert panel activities, may be taken by the EC, in accordance the relevant Commission Implementing Decision.[4]

Involvement in expert panel activities

In accordance with the aforementioned “European Commission's policy on the management of competing interests of members of the medical device expert panels on medical devices and *in vitro* diagnostic devices”, **current employment with a medical device company, as well as current financial interests in medical device industry are incompatible with involvement in the expert panel activities**.

If you are an expert panel member and intend to engage (either solicited or not) in occupational activities with a medical device company (such as applying for employment) during your membership, please inform the EC immediately, refrain from any activities which may have an impact on the medical device company concerned and comply with any additional conditions which the EC may consider appropriate to impose.

4. Different types of interests

Different types of interests are considered of relevance and described below. They either refer to **direct** or **indirect** interests in the medical device industry.

The following **direct interests** in medical device industry need to be declared:

Direct interests

- Employment with a medical device company
- Consultancy to a medical device company
- Strategic advisory role for a medical device company
- Financial interests in a medical device company

The following **indirect interests** in medical device industry need to be declared:

Indirect interests

- Principal investigator
- Investigator
- Grant or other funding from a medical device company to the expert's organisation/institution
- Close family member direct interest in a medical device company

Medical device company shall mean: any legal or natural person whose focus is to research, develop, manufacture, maintain, market and/or distribute medical devices or *in vitro* diagnostic medical devices (IVDs). For the purpose of this policy, the definition includes companies to which activities relating to the research, development, manufacturing, maintenance, marketing and/or distribution of medical devices / IVDs (which might also be carried out in house) are outsourced on a contractual basis.

In this regard **notified bodies (NB), clinical research organisations (CROs) or consultancy companies** providing advice or services relating to the above activities or to activities linked with certification or other regulatory procedures, **fall under the definition of a medical device company**.

Legal or natural persons which do not fall within the scope of the above definition but:

- control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant medical device company),
- are controlled by or
- are under common control of a medical device company,

shall be considered as medical device companies for the purposes of this policy.

Independent researchers and research organisations including universities and learned societies are excluded from the scope of the present definition:

- The term "independent researcher and research organisations" covers facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields as well as public or private non-profit organisations/legal entities whose primary mission is to pursue research.
- The term "universities" covers public or private higher education establishments awarding academic degrees.
- The term "hospital" includes university hospitals.

- The term "learned societies" covers non-profit organisations that exist to promote an academic discipline or profession, or a group of related disciplines or professions.

4.1. Employment

Employment with a medical device company shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a medical device company

In section 2.1 of the DOI, please list all periods worked in one or more medical device companies.

In case of previous employment with a medical device company the following four situations are considered:

4.1.1. Employment with a medical device company in an executive role

Executive role within a medical device company means **responsibility for the strategic and operational direction of a medical device company, and as a consequence having a key role in decision-making at strategic and operational level** for the medical device company.

Examples of executive role within a medical device company are (non-exhaustive list):

- President/Vice President position
- Chief Executive Officer position
- Chief Scientific Officer position
- Executive Director/Director/Associate Director position

It is acknowledged that responsibility for the strategic and operational direction of a medical device company, and as a consequence, having a key role in decision-making at strategic and operational level for that company, may differ substantially between medical device companies, depending on the organisational structure of the medical device company. Therefore if the expert is of the view that his/her previous employment with a medical device company should not be considered an executive role taking into account the expert's position in the organisational structure of that company and his/her role and responsibilities, the following will be undertaken:

The expert, taking into account the definition of "previous employment with a medical device company in an executive role", and the aforementioned non-exhaustive examples, will be required to formally declare in writing that the previous employment with a medical device company should not be considered an executive role.

In addition, the expert will be reminded that incorrect information may be considered as a *prima facie* breach of trust towards the EC, and that the EC may take appropriate action.

4.1.2. Employment with a medical device company in a lead role in the development of a medical device

Lead role in the development of a medical device means **direct responsibility for the development of a medical device**, **other than support provided to the development of a medical device which should be reported under individual product responsibility**.

Examples of lead role in the development of a medical device are (non-exhaustive list):

- Clinical programme/project manager position
- Product manager/specialist position
- Programme leader/manager position
- Project leader/manager position
- Medical device development lead position

4.1.3. Employment with a medical device company with cross product responsibility or involvement in support activities for multiple medical devices across one or several medical areas/full medical devices range, other than executive role

Examples of such cross-product responsibility or cross product support activities are (non-exhaustive list):

- Vigilance / Post-market surveillance
- Regulatory Affairs
- Statistical methodology
- Marketing or sales
- Distribution

4.1.4. Employment with a medical device company with individual product responsibility or involvement in one or more medical devices within one or more medical areas, other than lead role in the development of a medical device

Examples of such individual product responsibility are (non-exhaustive list):

- Product development, albeit not in a lead role
- Manufacture or maintenance (quality, clinical, non-clinical)

Other considerations regarding employment

- Please ensure that previous employment in a medical device company mentioned in your curriculum vitae is declared correctly in your DOI.
- Employment in a medical device company in an executive role and/or a lead role in the development of a medical device needs to be declared if it occurred at any stage of your career.
- **It is your responsibility to select the relevant category of your previous employment with a medical device company, i.e. executive role, lead role, cross product responsibility or individual responsibility.** Please provide as much information as possible, in particular as regards your exact role(s) during your professional career within the medical device company(ies).
- Where you have or had **both individual** and **cross product responsibility** during the same period of employment, please enter this information separately per responsibility. Click on 'Add employment' to create a new entry for the next responsibility and provide details on this responsibility while mentioning the same company name and same period.
- In case of **past employment** in a **CRO** or **consultancy company** or **NB**, please state the name of the CRO or consultancy company or NB under section 2.1 "Employment" and list the concerned companies and/or medical devices as follows:
  - For individual product responsibility: Please list all medical devices individually including the name of the medical device company to which services were provided. Please provide first the name of the medical device followed by the name of the medical device company in parentheses.
  - For cross product responsibility: Please list all roles that you held for each company individually. Please provide first the role that you held in the company followed by the name of the medical device company in parentheses.
- In case your **role within a company changed** during the entire period of employment, please enter this information separately per role. Click on 'Add employment' to create a new entry for the next role and provide details on the period and the role while mentioning the same company name and same period.
- When the **medical device company** for which you have been an employee has **merged** with another company, please mention the past and current name of the company. Where you are aware that the **company merged** since your last DOI, please submit an updated DOI to reflect this company merger.

- **Employment at a national or European organisations or associations representing the medical device industry**, (e.g. MedTech Europe, TEAM-NB) is considered equivalent to employment in a medical device company.

- **Independent researchers** and **research organisations** including **universities, hospitals and learned societies**, are excluded from the scope of the definition of a medical device company. Employment in such organisation, therefore, does not need to be declared in the DOI.

  If you perform activities that are considered as an interest under the policy, e.g. provision of consultancy to a medical device company or performing a company-instigated clinical investigation / performance study for IVDs as a (principal) investigator, you need to declare the relevant interest in your DOI.

  However, any unit, department, section or entity within such organisation, that manufacturers medical devices or is a CE mark applicant/holder, is considered as a medical device company. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a medical device company and hence need to declare such employment in the DOI.

Please note that in any case EC expects that you declare any competing interest prior to any dossier or role assigned to you in the expert panel (Art. 12.4 of the implementing act[4]).

Important note:

Current employment in a medical device company (including NBs) is **incompatible with expert panels membership**.

4.2. Consultancy

Consultancy to a medical device company shall mean: any activity where the concerned expert provides advice (including training on a one to one basis) to a medical device company regardless of contractual arrangements or any form of remuneration.
NB: An activity reported under "Consultancy" **must never be the principal activity** of the expert concerned, but rather an ad hoc/occasional activity (typically not constituting the expert's main source of income). An example is that of a clinician or academic researcher providing occasional consultancies to a medical device company.

In section 2.2 of the DOI, please declare all consultancy advice (including training on a one-to-one basis) provided to one or more medical device companies. Employment by a consultancy company should be indicated under section 2.1 of the DOI.

Where the consultancy activities relate to **individual products within one or more medical areas** (even if the product development was discontinued and did not lead to a commercialised product), please list such activities under *`Individual product related`* activities for each medical device company to which consultancy was provided.

In case the consultancy relates **to cross product consultancy i.e. multiple products across one or more medical areas or to the company's full medical devices range**, please list such activities under *`Cross product related/general (non-product related)`* stating clearly the role or area of activity. Examples of general activities include mechanical properties of the materials used, biocompatibility, immunogenicity, etc.

In case of **past and/or current occasional consultancy** to a **notified body (NB)**, please state the name of the NB under section 2.2 Consultancy and then list the concerned companies and/or medical devices as follows:

- For individual product consultancy: In the field "Product name", please list all medical devices for the entire time period individually including the name of the medical device company to which services were provided. Please provide first the name of the medical device followed by the name of the medical device company in parentheses. In the next field "medical indication / intended purpose" please list the intended use in subsequent order for each medical device individually.

- For cross product responsibility: Please list all roles that you held for each company for the entire time period. Please provide first the role that you held in the company followed by the name of the medical device company in parentheses.

Considerations regarding consultancy

- Involvement in **lectures, presentations or training organised by individual medical device companies,** given **to participants invited by medical device companies and not open to the public** (i.e. upon invitation only), is considered provision of consultancy advice to a medical device company and should be declared under this section in the DOI irrespective of whether the event is taking place on company premises or another location. Please note that specific circumstances e.g. the company requesting confidentiality or requiring prior approval of the expert's presentation may be taken as an indication that the event is not public.
- **Providing training courses** to companies on direct request from the medical device company or via a for-profit entity organising training courses specifically focusing on such companies is considered as consultancy.
- A **speaker's fee, lecture's honorarium, compensation** for giving a presentation at a conference or seminar is considered a financial interest – please see section 4.4.
- In contrast, participation as **speaker, panellist or in a similar role at conferences and seminars organised by (or with the involvement of) medical device companies** and **open to the public** (fee or non-fee paying, open registration) **with only reimbursement of reasonable expenses** incurred in relation to attendance (i.e. accommodation and travel costs), is not considered a consultancy advice and does not need to be declared.
- **Attendance as a healthcare professional** in a **general medical training** organised by a non-for-profit organisation whether or not its name includes the name of a company is not considered a consultancy advice and does not need to be declared.
- If you work in an **organisation/institution**, where **your colleagues** provide **consultancy advice to medical device companies**, but **you are not directly involved in the provision of such advice**, please include this information under section 2.9 of the DOI, stating clearly that you are not directly involved in these activities. Examples include employees of European Union Reference Laboratories (EURLs), Expert Laboratories, National Reference Laboratories (and other laboratories performing testing on behalf of the EURLs), staff members of academic departments, etc. In the case you become directly involved in the provision of such consultancy advice to medical device companies, please submit an updated DOI to reflect this new consultancy activity.
- Involvement in a **private-public partnership** or organisation **where there is no public component**, i.e. no involvement of an official national or European competent authority, but it includes a company as a partner, is considered as consultancy.
- **Providing translations of documents** to be included in dossiers to support certification of a medical device on direct request from a company or via a translation agency, falls under consultancy services and should be declared.
- **Patient organisations' representatives involved in Community Advisory Boards** and interacting with medical device companies in meetings to discuss patient-related topics are considered as providing consultancy to these medical device companies. Thus, involvement in such Community Advisory Boards needs to be declared in section 2.2, listing the companies concerned.
- **Patient organisations' representatives participating in a non-public meeting** on the initiative of a medical device company to discuss product development, patients' views on treatments or for training purposes, is considered as consultancy.
- **Membership of the board of a journal fully sponsored and published by a medical device company** is considered as consultancy.

- **(Scientific) advice provided by the National Competent Authority (NCA) of a Member State is not considered a consultancy activity.** Consultancy or advice provided by the NCA of a Member State to a non-European Competent Authority is not considered as a consultancy activity.

Please note that in any case EC expects that you declare any competing interest prior to any assigned dossier or role to you in the expert panel (Art. 12.4 of the implementing act[4])

4.3. Strategic advisory role

Strategic advisory role for a medical device company shall mean: any activity where the expert is participating (with a right to vote/influence the outputs) in a(n) (scientific) advisory board, steering committee or executive committee (e.g. board membership/directorship), with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a medical device company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

The above definitions apply also for employment with, consultancy to or strategic advisory role for a NB.

Please, note:

- Data monitoring committees (composed of independent external experts reviewing unblinded clinical trial data independently of the sponsor/medical device company) fall outside the scope of this definition. Experts participating in these fora are considered in the same way as principal investigators (for definition of principal investigator see below).
- Involvement of an expert in research work for a medical device company is considered an indirect interest.

In section 2.3 of the DOI, please state your participation in (scientific) advisory boards/steering committees or executive committees of medical device companies (e.g. board membership/directorship), with a right to vote/influence the outputs of that body.

Where the strategic advisory role relates to **individual products**, please list such activities under **individual product related** activities for each medical device company. In case the role does not relate directly to individual products, but to **general strategies**, please list such activities under **general** (non-product related), stating clearly the role or area of activity.

Considerations regarding strategic advisory role

- Involvement in a **board of a registry**, e.g. patient, product or disease registry, sponsored by a medical device company is considered as a strategic advisory role.
- Involvement in **data monitoring committees** is considered in the same way as principal investigators and therefore should be declared in section 2.5 of the DOI.
- Participation in **advisory groups** from multi-stakeholder treatment or focus groups, with or without involvement of industry participants, reflecting on adoption or revision of medical device legislation is considered as a strategic advisory role.
- Involvement in a **grant review panel** from the **European Institutions** is not considered as a strategic advisory role.
- **Participation in European societies/research foundations/strategy boards/treatment groups/focus groups**, which may be funded in part from unrestricted grants from medical device companies (not from one single company), with or without involvement of industry participants and which may provide **general advice** (on development programmes, clinical study design, strategy etc.) to **several medical device companies** (not one particular company) in a **specific medical area** is not considered a strategic advisory role, but for transparency purposes should be declared under section 2.9 of the DOI.

4.4. Financial interests

Financial interests shall mean any economic stake in a medical device company including:

- Ownership or co-ownership, holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of such medical device company. The holding of financial interests through an investment fund, pension fund and/or interests in non-nominal unit trusts or similar arrangements would not need to be declared provided that they are diversified (i.e. not exclusively based on the medical device sector) and they are independently managed (i.e. the individual has no influence on their financial management).
- Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a medical device company to the expert in a personal capacity, other than payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance (i.e. accommodation and travel costs).
- Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medical device owned by the individual or of which the individual is directly a beneficiary.

In section 2.4 of the DOI, please declare all your **current** (i.e. at the time of completion of the DOI) **financial interests** in medical device companies. There is no need to declare past financial interests.

Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medical device **owned** by the individual or of which the individual is directly a **beneficiary** also need to be declared in this section.

Important note:

- Current financial interests in a medical device company, e.g. shares in a company, fee/honoraria received directly from a company, patent ownership for a medical device, are incompatible with expert panel membership.
- In case you have declared current financial interests in medical device industry, the EC will contact you to inform you that such interests are **incompatible with involvement in the expert panel activities** and will ask you whether you intend to take any action in respect to the declared interest and if so, to submit an updated DOI. In case you decide to retain the financial interest, you will not be allowed to (continue to) participate in the expert panel activities.

Considerations regarding financial interests

- **Experts involved in the expert panel activities** may participate as speaker, panellist or in a similar role at conferences organised by or with the involvement of one or more medical device companies, but **cannot accept any fee/honoraria** for such participation if they wish to continue their involvement in the expert panel activities.
- Accepting a **speaker's fee, lecture's honorarium, compensation for preparing a presentation**, etc. from a company for such conference participation is considered as a current financial interest and incompatible with involvement in the expert panel activities.
- **Ownership or being a beneficiary of an intellectual property right**, e.g. a patent for a medical device, is considered as a financial interest.
- Accepting **a fee/honorarium for writing an article** for which the publication is sponsored by a medical device company is considered as a financial interest.
- Accepting a **monetary prize of an award** sponsored by a medical device company is considered as a financial interest.

You do **not need to declare**:

- Shares or other financial interests in a non- medical device company.
- Inventorship of a patent for a medical device, i.e. when you are an inventor named on a patent, but when you are not the patent owner or a beneficiary of the patent.
- Pending patents as the patent has not yet been granted and the patent owner and or inventor(s) do not receive any benefits yet from the patent.
- Receipt of payment for or reimbursement of expenses incurred with research work or reimbursement of reasonable expenses directly related to conference/seminar attendance (i.e. accommodation and travel costs).
- Fees received for participation in a conference/seminar/training from organisations which are not medical device companies – e.g. not for profit organisations, conference organisations (with no involvement of medical device companies in the organisation and funding of the conference), etc.
- Attendance at courses and conferences funded by a medical device company, including those accredited for personal continuous development/education such as CPD (Continuing Professional Development) or CME (Continuing Medical Education) on condition that you do **not** receive payment from a medical device company.
- Participation in the pension fund of a medical device company in view of previous employment in that company where the expert only receives the pension at the age of retirement and does not have any control on the composition of the fund or the payment of the pension.

In case you are not sure if a fee or payment, whether or not from a medical device company, represents a financial interest, please contact the Commission Secretariat of the expert panels for advice before submitting your DOI.

4.5. Principal investigator/investigator

Principal investigator shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre medical device industry instigated/sponsored clinical investigation / performance study for IVDs or the leading investigator of a monocentre medical device industry instigated/sponsored clinical investigation / performance study for IVDs, or the coordinating (principal) investigator signing the clinical investigation report / performance study report for IVDs. This definition does not include a national coordinating investigator in a multinational clinical investigation.

Investigator shall mean: an investigator involved in a medical device industry instigated/sponsored clinical investigation / performance study for IVDs at a specific clinical investigation site / performance study site. This can be the responsible lead investigator of the clinical investigation / performance study for IVDs at that specific site or a member of the clinical investigation team / performance study team for IVDs who performs critical investigation related procedures and makes important clinical investigation related decisions.

In sections 2.5 and 2.6 of the DOI, please indicate **all (clinical) investigations involving medical devices / performance studies involving IVDs** instigated and/or sponsored by medical device companies in which you are participating or have participated as a principal investigator or investigator within the last 3 years.

Academic clinical investigations / performance studies and publicly funded research / development initiatives instigated by an individual expert regarding medical devices or IVDs, whether or not the products are/were provided by a medical device company, should be included under section 2.9 of the DOI, not in section 2.5 or 2.6 of the DOI.

Membership of an ethics committee, such as Independent Ethics Committees (IEC) and Institutional Review Board (IRB), should be included under section 2.9. For membership of an ethics committee it is not required to declare a list of trials you were involved in.

Involvement or membership in independent/external **data monitoring committees** for clinical investigations or safety monitoring boards for medical devices is considered in the same way as principal investigators and therefore should be listed in section 2.5 of the DOI.

A clinical investigation coordinator or similar role in medical device company instigated clinical investigations, that e.g. implies coordinating trial participants' appointments or sending out samples, does not fall under the definition of principal investigator/investigator and hence do not need to be declared.

4.6. Grant/funding to organisation/institution

Grant or other funding to an organisation/institution shall mean: any funding received from a medical device company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

In section 2.7 of the DOI form, **please list all grants and other funding from medical device companies, that an institution** (e.g. academic institution) **or organisation** (e.g. patient organisation) **to which you belong** (e.g. as an employee, member or volunteer)**, or for which you perform any kind of activity, is currently receiving, and where the grant or funding is used to support any of your activities directly whether or not they are related to research work.** There is no need to declare past grants or funding.

Only if you **benefit directly from the grant or funding**, i.e. your organisation or institution allocates the full or part of the grant or funding to you and you use it, e.g. for the purchase of (laboratory) equipment or appliances, for engaging a PhD student, for covering your expenses for an activity, for paying your salary at the organisation, for attending a training/course/conference, you need to declare the grant or funding.

Any other grant or funding to the organisation/institution by a medical device company does **not** need to be declared, i.e. if your organisation/institution allocates the grant or funding randomly within your organisation or institution and you do not benefit from it directly. If you want to declare such grant or funding for transparency purposes, please do so under section 2.9 of the DOI.

Grants or funding from **private-public partnerships**, e.g. IMI, Horizon 2020, do not need to be declared under section 2.7, but can be declared under section 2.9 "Any other interests or facts" for transparency purposes.

4.7. Close family members' interests

Close family members' interests shall mean: current direct interests (i.e. employment, consultancy, strategic advisory role, financial interests) of close members of the family of the expert (i.e. siblings, children and parents) as well as a spouse or a partner, irrespective if they are living at the same address with the expert or not.

In section 2.8 of the DOI, please declare current direct interests in a medical device company, i.e. **employment, consultancy, strategic advisory role, financial interests, of close members of your family.** Interests need to be declared to the best of your knowledge. There is no need to declare past interests.

Close family members are your spouse, partner, siblings, children and parents, irrespective if they are living at the same address as you or not. Partner is defined as a natural person with whom you are registered as having a stable non-marital partner legally recognised by an EU member state or any competent authority of a member state, acknowledging the status as non-marital partners.

There is no need to mention which close family member holds the interest, i.e. do not mention e.g. spouse, partner, father, mother, daughter, son, sister, brother. Please mention the name of the company and the type of direct interest held by the close family member, i.e. "employment", "consultancy", "strategic advisory role" or "financial interest".

If you become aware that:

a) the company where your close family member is employed has merged with another company or

b) your close family member is specifically involved in activities (which can be considered as equivalent to consultancy) for another company while working at the initially declared company,

please submit an updated DOI that clarifies the interest with this other company.

4.8. Any other interests or facts

Please use section 2.9 of the DOI to declare any other interests or facts you think may be related to a medical device company or a medical device or about which you consider it appropriate to inform the EC.

For transparency purposes, information can be provided on the following activities in this section:

- Academic clinical investigations / IVD performance studies and publicly funded research/development initiatives involving medical devices.
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, funded in full or in part from unrestricted grants from several medical device companies (not from one single company), with or without involvement of industry participants and providing general advice (on development programmes, clinical study design, strategy, etc.) to several medical device companies (not one particular company) in a specific medical area.
- If you work in an organisation/institution, where your colleagues provide consultancy advice to medical device companies, but you are not directly involved in the provision of such advice. Examples include employees of European Union Reference Laboratories (EURLs) and Expert Laboratories (as stated in the relevant EU Regulations 2017/746 & 2017/745, respectively), National Reference Laboratories (and other laboratories performing testing on behalf of the EURLs), staff members of academic departments, etc.
- Continuous systematic attendances to congresses covered by the same medical device company
- Membership of an ethics committee (you do not need to state a list of trials you were involved in).
- Expert opinion or testimony in judicial proceedings against or by a medical device company relating to a medical device.
- Testimonials in patient organisations
- Participation as a patient in a clinical investigation.

Experts' declarations related to the above interests will be assessed on a case by case basis. Specific measures can be decided by the Commission.

References

1. Regulation (EU) 2017/745 on medical devices (MDR)

2. Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)

3. European Commission policy on the management of competing interests of members of the expert panels on medical devices and *in vitro* diagnostic medical devices

4. Commission implementing decision EU (2019) 1396 on laying down the rules for the application of Regulation (EU) 2017/745 as regards the designation of expert panels in the field of medical devices

Abbreviations

CME	Continuing Medical Education
CPD	Continuing Professional Development
CRO	Clinical Research Organisation
CV	Curriculum Vitae
DOI	Declaration of interests
EC	European Commission
EMA	European Medicines Agency
EU	European Union
EURL	European Union Reference Laboratory
IVD	*In vitro* diagnostic (medical device)
IVDR	Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices
MDR	Regulation (EU) 2017/745 on medical devices
MFR	Manufacturer
MS	Member State
NB	Notified body
NCA	National Competent Authority