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European Medicines Agency

Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts)

1. Aim

Reference is made to the "European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts" (EMA/626261/2014), effective 30 January 2015.

This guidance aims at helping scientific committees' members and experts to complete the European Medicines Agency's (EMA) electronic declaration of interests form (e-DoI) and EMA 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 e-DoI. A correctly completed form will speed up the EMA evaluation process of declarations of interests.

2. Who needs to complete an e-DoI?

The scope of the aforementioned policy relates to the handling of declarations of interests of scientific committees'
(i.e. the CHMP[1], CVMP[2], COMP[3], HMPC[4], PDCO[5], CAT[6] and PRAC[7]) members (including, where relevant, alternates) and experts involved in activities at the level of the EMA. Involvement in the EMA activities means all activities carried out at the EMA in the context of the authorisation and surveillance

[1] CHMP: Committee for Medicinal Products for Human Use.
[2] CVMP: Committee for Veterinary Medicinal Products.
[3] COMP: Committee for Orphan Medicinal Products.
[4] HMPC: Committee for Herbal Medicinal Products.
[5] PDCO: Paediatric Committee.
[6] CAT: Committee for Advanced Therapies.
[7] PRAC: Pharmacovigilance Risk Assessment Committee.

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of medicinal products for human and veterinary use. This includes meeting attendance, involvement in the scientific assessment and guidance development, as well as participation in inspections. Meeting attendance means attendance at face-to-face meetings, participation in virtual meetings (e.g. via Adobe Connect) or teleconferences.

As a consequence, experts falling within the aforementioned scope need to complete an e-DoI prior to involvement in an EMA activity as specified above.

3. General considerations

Completing the e-DoI

In completing the e-DoI, please take note of the definitions and explanatory notes included under each section of the e-DoI and the additional guidance in this document. Please declare all activities relating to involvement with medicinal products and/or pharmaceutical companies, i.e. **any current activities as well as all past activities within the last 3 years**. **However, please note that for all previous employment in a pharmaceutical company in an executive role and/or a lead role in the development of a medicinal product (for the definitions, please see section 4 of this procedural guidance) you need to declare such employment at any stage of your career (going beyond the aforementioned 3 year timeframe).**

Current is interpreted as **any time point during the term of the mandate of a member or at the time of involvement of an individual in a specific EMA activity**. You may also provide information on interests over 3 years ago. This information will not be used in the evaluation of declared interests but will be useful in the context of increased transparency regarding previous interests.

In case you are unsure whether an interest relates to a medicinal product or to a pharmaceutical 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 EMA may contact you for more details or clarifications.

Please be aware that **the EMA will publish your e-DoI on its website.** The EMA processes personal data in accordance with the applicable legislation (Regulation (EC) No. 45/2001).

Should you acquire any additional interests or should your interests change since your last e-DoI, you must submit an **updated e-DoI without delay**. Please ask the EMA to provide you with a copy of your current e-DoI and update this form to reflect your new interests and any changes.

Evaluation of the e-DoI by the EMA

On the basis of the submitted e-DoI, the EMA evaluates the declared interests according to the table "Scientific committees' members and experts allowed involvement in medicinal product related matters" provided in Annex 1, and determines if the member, alternate or expert can participate in the concerned EMA activity. The EMA 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 EMA will contact you. The EMA may request you to provide more information/details and/or to submit an updated e-DoI, as appropriate, to correctly reflect the declared interests in the e-DoI.

If for any reason you are not in a position to fully detail all activities relating to your involvement in medicinal products and/or pharmaceutical companies, e.g. due to contractual arrangements, this may affect your participation in EMA activities.

In case the EMA becomes aware/is informed of any interests which have not been included in your e-DoI, the Agency will contact you regarding these interests and, if required, request you to submit an updated e-DoI. Failure to fill in the e-DoI in a complete and/or correct manner may be considered as a *prima facie* breach of trust towards the EMA. Because of that failure, appropriate actions, including the exclusion of the concerned person from the EMA activit(y)ies, may be taken by the EMA, in accordance with the procedure described in the "European Medicines Agency breach of trust procedure on conflicts of interests for scientific committee members and experts" (EMA/154320/2012).

Involvement in EMA activities

In accordance with the aforementioned "European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts", **current employment with a pharmaceutical company, as well as current financial interests in pharmaceutical industry are incompatible with involvement in EMA activities**. However, current financial interests are compatible with the concept of expert witness. An expert witness is an expert whose role is limited to testify and give specialist advice on a specific issue by providing information and replying to any questions only.

If you are a scientific committee, working party, SAG and/or ad hoc expert group member and intend to engage (either solicited or not) in occupational activities with a pharmaceutical company (such as applying for employment) during your membership, please inform the EMA immediately, refrain from any activities which may have an impact on the pharmaceutical company concerned and comply with any additional conditions which the EMA may consider appropriate to impose.

4. Different types of interests

Different types of interests are possible, as described below. They either refer to direct or indirect interests in pharmaceutical industry.

4.1. Employment

For the definition of "employment with a pharmaceutical company", see Annex 2. Likewise, for the definition of "pharmaceutical company", see Annex 2.

In section 2.1 of the e-DoI, please list all periods worked in one or more pharmaceutical companies.

In case of previous employment in a pharmaceutical company the following four situations can be identified:

- Previous employment in a pharmaceutical company in an **executive role**:

  Executive role within a pharmaceutical company means **responsibility for the strategic and operational direction of a pharmaceutical company, and as a consequence a key role in decision-making at strategic and operational level** for the pharmaceutical company. **Examples** of executive role within a pharmaceutical company are (please note this is **not** an exhaustive list):

  - President/Vice President position
  - Chief Executive Officer position
  - Chief Scientific Officer position
  - Executive Director/Director/Associate Director position
- Previous employment in a pharmaceutical company in a **lead role in the development of a medicinal product**:

  Lead role in the development of a medicinal product means **direct responsibility for the development of a medicinal product**, **other than support provided to the development of a medicinal product which should be reported under individual product responsibility**. **Examples** of lead role in the development of a medicinal product are (please note this is **not** an exhaustive list):

  - Clinical programme/project manager position
  - Product manager/specialist position
  - Programme leader/manager position
  - Project leader/manager position
- Previous employment in a pharmaceutical company **with cross product responsibility or involvement in support activities for multiple medicinal products across one or several therapeutic areas/full medicinal products range, other than executive role**. **Examples** of such cross product responsibility or cross product support activities are (please note this is **not** an exhaustive list):
  - Pharmacovigilance
  - Regulatory Affairs
  - Statistical methodology
- Previous employment in a pharmaceutical company **with individual product responsibility or involvement in one or more medicinal products within one or more therapeutic areas, other than lead role in the development of a medicinal product**. **Examples** of such individual product responsibility are (please note this is **not** an exhaustive list):
  - Product development, albeit not in a lead role
  - Manufacture or maintenance (quality, clinical, non-clinical)

Please note the following:

- **It is your responsibility to indicate which category of previous employment in a pharmaceutical company is applicable to your situation taking into account the aforementioned guidance.** In case further guidance is needed, please contact the EMA before completing the e-DoI, and provide as much information as possible, in particular as regards your exact role(s) during your professional career within the pharmaceutical compan(y)ies.

Where you have or had **both individual and cross product responsibility** during the same time 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 the period and

individual product or cross product responsibility/involvement for that responsibility while mentioning the same company name.

In case your **role within a company changed** during the 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 individual product or cross product responsibility/involvement for that role while mentioning the same company name.

When the **pharmaceutical 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 e-DoI, please submit an updated e-DoI to reflect this company merger.

In case of **employment in a CRO** (Clinical Research Organisation) or **consultancy company**, please mention the name of the CRO or consultancy company and list all medicinal products (including the names of the pharmaceutical companies to which CRO or consultancy services were provided) and therapeutic indications.

4.2. Consultancy

For the definition of "consultancy to a pharmaceutical company", see Annex 2.

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

Where the consultancy activities relate to **individual products within one or more therapeutic 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 pharmaceutical company to which consultancy was provided. In case the consultancy does **not** relate **directly to individual products, or if the consultancy is cross product consultancy for multiple products across one or more therapeutic areas/full medicinal products range**, please list such activities under **general** (non-product related) stating clearly the role or area of activity. Examples of general activities include antimicrobial resistance, development of outcome measures, etc.

In addition, the following is important to note:

- Where the **declared interest on consultancy is current** and is **subject to a fee/honoraria** (paid directly to you), please also declare this activity under section 2.4 of the e-DoI. If you do not indicate whether or not a current consultancy activity is subject to a fee/honoraria, the EMA may contact you for further clarifications.
- If you work in an **organisation/institution**, where **your colleagues** provide **consultancy advice to pharmaceutical companies**, but **you are not directly involved in the provision of such advice**, please include this information under section 2.9 of the e-DoI, stating clearly that you are not directly involved in these activities. Examples include employees of Official Medicines Control Laboratories, staff members of academic departments, etc. Where this changes and you become directly involved in the provision of such consultancy advice to pharmaceutical companies, please submit an updated e-DoI to reflect this new activity.
- Involvement in **lectures, presentations or training organised by individual pharmaceutical companies,** given **to participants invited by pharmaceutical companies and not open to**

the public is considered provision of consultancy advice to a pharmaceutical company and should be declared under this section in the e-DoI.

- Participation as **speaker, panellist or in a similar role at conferences and seminars organised by (or with the involvement of) pharmaceutical companies** and **open to the public** (fee or non-fee paying) **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.
- **Scientific advice provided by the National Competent Authority of a Member State is not considered a consultancy activity.**

4.3. Strategic advisory role

For the definition of "strategic advisory role for a pharmaceutical company", see Annex 2.

In section 2.3 of the e-DoI, please mention your participation in (scientific) advisory boards/steering committees of pharmaceutical 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 pharmaceutical 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.

Where the **declared interest on strategic advisory role is current** and is subject to a **fee/honoraria** (paid directly to you), please also declare this activity under section 2.4 of the e-DoI. If you do not indicate whether or not a strategic advisory role is subject to a fee/honoraria, the EMA may contact you for further clarifications.

Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, which may be funded in part from unrestricted grants from pharmaceutical 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 pharmaceutical companies** (not one particular company) in a **specific therapeutic area** is not considered a strategic advisory role, but for transparency purposes should be declared under section 2.9 of the e-DoI.

Involvement in **data monitoring committees** is considered in the same way as principal investigators and therefore should be listed in section 2.5 of the e-DoI.

4.4. Financial interests

For the definition of "financial interests", see Annex 2.

In section 2.4 of the e-DoI, please declare all your current (i.e. at the time of completion of the e-DoI) financial interests in pharmaceutical companies. Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product owned by the individual or of which the individual is directly a beneficiary also need to be declared in this section.

Important notes:

- **Current financial interests** in pharmaceutical industry are **incompatible with membership** of any EMA (scientific) forum.
- Likewise, **current financial interests** in pharmaceutical industry are **incompatible with involvement in any other EMA activity**. As stated under section 3 of this procedural guidance, current financial interests are compatible with the concept of expert witness.
- In case you have declared current financial interests in pharmaceutical industry, the EMA will contact you to inform you that such interests are i**ncompatible with involvement in EMA 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 e-DoI. In case you decide to retain the financial interest, you will not be allowed to (continue to) participate in EMA activities.
- **Experts involved in EMA activities** may participate as speaker, panellist or in a similar role at conferences organised by or with the involvement of one or more pharmaceutical companies (subject to compliance with the "Policy on scientific publication and representation for European Medicines Agency's scientific committees and their members" (EMA/231477/2005)), but **cannot accept any fee/honoraria** for such participation if they wish to continue their involvement in EMA activities.

You do **not need to declare**:

- 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 from organisations which are not pharmaceutical companies – e.g. not for profit organisations, conference organisations (with no involvement of pharmaceutical companies in the organisation and funding of the conference), etc. However, for transparency purposes this may be included under section 2.9 of the e-DoI.
- Shares in a non-pharmaceutical company.

In case you are not sure if a fee or payment, whether or not from a pharmaceutical company, represents a financial interest, please contact the EMA for advice in advance of the submission of your e-DoI.

In addition, you do **not need to declare**:

- Attendance at courses and conferences funded by the pharmaceutical industry (including attendance at accredited courses or conferences with respect to continuing development of experts CPD (Continuing Professional Development)/CME (Continuing Medical Education) acquisition) on condition that you do **not** receive payment by pharmaceutical industry, other than specified above (i.e. reimbursement of reasonable expenses).

4.5. Principal investigator/investigator

For the definition of "principal investigator" and "investigator", see Annex 2.

In sections 2.5 and 2.6 of the e-DoI, please indicate **all (clinical) trials involving pharmaceutical products** instigated and/or sponsored by pharmaceutical companies in which you are participating or have participated as a principal investigator or investigator within the last 3 years.

Academic trials and publicly funded research/development initiatives involving pharmaceutical products as well as membership of an ethics committee should be included under section 2.9 of the e-DoI, not in section 2.5 or 2.6 of the e-DoI. For membership of an ethics committee it is not required to declare a list of trials you were involved in.

Involvement in data monitoring committees is considered in the same way as principal investigators and therefore should be listed in section 2.5 of the e-DoI.

4.6. Grant/funding to organisation/institution

In section 2.7 of the e-DoI form, **please list all grants and other funding from pharmaceutical companies, that an institution** (e.g. National Competent Authority or academic institution) **or organisation** (e.g. patient organisation) **to which you belong, or for which you perform any kind of activity, is currently receiving, and which is used to support any of your activities whether or not they are related to research work.** Any other grant or funding to the organisation/institution by a pharmaceutical company does **not** need to be declared. If you want to declare such grant or funding for transparency purposes, please do so under section 2.9 of the e-DoI.

4.7. Close family members interests

In section 2.8 of the e-DoI, please declare current direct interests, i.e. employment, consultancy, strategic advisory role, financial interests, of first-line members of your family. First-line members are a spouse, partner, children and parents, irrespective if they are living at the same address as you or not.

4.8. Any other interests or facts

Please use section 2.9 of the e-DoI to declare any other interests or facts you think may be related to pharmaceutical industry or which you consider appropriate to inform the EMA about.

For transparency purposes, please also provide information on the following activities in this section:

- Academic trials and publicly funded research/development initiatives involving pharmaceutical products.
- Membership of an ethics committee (you do not need to state a list of trials you were involved in)
- If you work in an organisation/institution, where your colleagues provide consultancy advice to pharmaceutical companies, but you are not directly involved in the provision of such advice.
- Participation in European societies/research foundations/strategy boards/treatment groups/focus groups, funded in full or in part from unrestricted grants from several pharmaceutical 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 pharmaceutical companies (not one particular company) in a specific therapeutic area.

Annex 1

Scientific committees' members and experts allowed involvement in medicinal product related matters

Declared interest	Time since declared interest ended (in years)	Scientific committee (Vice)-Chair	Working party[1] (Vice)-Chair	Scientific committee / Working party[1] member	Scientific committee / Working party[1] expert	SAG/ad-hoc expert group (Vice)-Chair	SAG/ad-hoc expert group member/expert	Inspection	Expert Witness
Employee (executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
	> 3	RC	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (lead role in development of medicinal product)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	> 3	RP	RP	XP-XRpP	XP	RP	DP	XI	Q
Employee (cross company role other than executive role)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Employee (medicinal product involvement other than lead role in development of medicinal product)	Current interest	X	X	X	X	X	X	X	X
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Consultancy to company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Consultancy to company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Strategic advisory role for company (cross medicinal products/general)	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	X	RC	XC-XRpC	XC	RC	DC	XI	Q
Strategic advisory role for company (individual medicinal product)	Current interest	X	X	X	X	RP	XP	X	Q
	0 to 3	X	RR	XP-XRpR	XP	RP	DP	XI	Q
Financial interests	Current interest	X	X	X	X	X	X	X	Q
	0 to 3	F	F	F	F	F	F	F	Q
Principal investigator	Current interest	X	RR	XP-XRpR	XP	RP	DP	XI	Q
	0 to 3	X	RR	XP-XRpR	XP	F	F	XI	Q
Investigator	Current interest	X	RR	DP-XRpR	DP	F	F	XI	Q
	0 to 3	X	RR	DP-XRpR	DP	F	F	XI	Q
Grant/other funding to organisation/institution	Current interest	RC	RC	XRpC	F	F	F	F	Q
	0 to 3	F	F	F	F	F	F	F	Q
Close family member	Current interest	RC	RC	XRpC	F	F	F	F	Q
	0 to 3	F	F	F	F	F	F	F	Q

[1] Medicinal product related working parties only, such as the BWP, the SAWP, or medicinal product related discussions at other working parties.

Outcome restriction level	Impact of the outcome
X	**No involvement in activity allowed.**
Q	**Involvement limited** to testify and give specialist advice on a specific issue by providing information and replying to any questions only.
RC	**To be replaced** for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company.
RR	**To be replaced** for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product or a rival product.
RP	**To be replaced** for the discussions, final deliberations and voting as appropriate in relation to the relevant medicinal product.
XC-XRpC	• **No involvement** with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company **(XC)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for medicinal products from the relevant company **(XRpC)**.
XC	**No involvement** with respect to medicinal products from the relevant company, i.e. no part in discussions, final deliberations and voting as appropriate as regards medicinal products from the relevant company.
DC	**Involvement only in discussions** with respect to medicinal products from the relevant company, i.e. no part in final deliberations and voting as appropriate as regards medicinal products from the relevant company.
XRpC	**Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** in relation to any medicinal product from the relevant company.
XP-XRpR	• **No involvement** with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product **(XP)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for the relevant medicinal product or a rival product **(XRpR)**.
DP-XRpR	• **Involvement only in discussions** with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product **(DP)**. • **Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer** for the relevant medicinal product or a rival product **(XRpR)**.
XP-XRpP	• No involvement with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product **(XP)**. • Cannot act as rapporteur, other leading/co-ordinating role or formally appointed peer reviewer for the relevant medicinal product **(XRpP)**.
XP	**No involvement** with respect to procedures involving the relevant medicinal product, i.e. no part in discussions, final deliberations and voting as appropriate as regards the medicinal product.
DP	**Involvement only in discussions** with respect to procedures involving the relevant medicinal product, i.e. no part in final deliberations and voting as appropriate as regards the medicinal product.
XI	**Cannot participate in inspections** relating to the relevant company (all medicinal products).
F	**Full involvement in activity allowed.**

Annex 2

Definitions

Direct interests

- **Employment with a pharmaceutical company** shall mean: any form of occupation, part-time or full-time, paid or unpaid, in a pharmaceutical company.
- **Consultancy to a pharmaceutical company** shall mean: any activity where the concerned expert provides advice (including training on a one to one basis) to a pharmaceutical company regardless of contractual arrangements or any form of remuneration.

  It should be noted that scientific advice provided by the NCA of a Member State is not considered a consultancy activity.
- **Strategic advisory role for a pharmaceutical company** shall mean: any activity where the expert is participating (with a right to vote on/influence the outputs) in a(n) (scientific) advisory board/steering committee with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of a pharmaceutical company, either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.

  It should be noted that:

  – Data monitoring committees (composed of independent external experts reviewing unblinded clinical trial data independently of the sponsor/pharmaceutical 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 pharmaceutical company is considered an indirect interest.
- **Financial interests** shall mean any economic stake in a pharmaceutical company including:

  – Holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of such pharmaceutical 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 pharmaceutical 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 pharmaceutical 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 medicinal product owned by the individual or of which the individual is directly a beneficiary.

Indirect interests

- **Principal investigator** shall mean: an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre pharmaceutical industry instigated/sponsored trial or the leading investigator of a monocentre pharmaceutical industry instigated/sponsored trial, or the coordinating (principal) investigator signing the clinical study report[8].
- **Investigator** shall mean: an investigator involved in a clinical pharmaceutical industry instigated/sponsored trial at a specific trial site which can be the responsible lead investigator of the trial at that specific site or a member of the clinical trial team who performs critical trial related procedures and makes important trial related decisions.
- **Grant or other funding to an organisation/institution** shall mean: any funding received from a pharmaceutical 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.

Other definitions

- **Close family members** shall mean: first-line members of the family of the expert (i.e. a spouse or a partner, children and parents).
- **Pharmaceutical company** shall mean: any legal or natural person whose focus is to research, develop, manufacture, market and/or distribute medicinal products. For the purpose of this policy, the definition includes companies to which activities relating to the research, development, manufacturing, marketing and maintenance of medicinal products (which might also be carried out in house) are outsourced on a contract basis.

  In this regard CROs or consultancy companies providing advice or services relating to the above activities, fall under the definition of a pharmaceutical company.

  Legal or natural persons which do not fall within the scope of the above definition but (i) control (i.e. own a majority stake in, or otherwise exercise a significant influence in the decision-making processes of the relevant pharmaceutical company), (ii) are controlled by or (iii) are under common control of a pharmaceutical company, shall be considered as pharmaceutical 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.

[8] This definition does not include a national coordinating investigator in a multinational trial.