

**Declaration of Interest and Confidentiality Undertaking (DOICU) Form**

The undersigned,

Title:

Family name:

Given name:

Email address:

Organisation/Institution:  <Enter ‘none' if this point does not apply>

Address (street):

Postal code:

Town/city (country):

EUnetHTA Partner/Associate organisation or institution: Yes [ ]  No [ ]

Provided the following information to the best of his/her knowledge and belief.

**SECTION 1. DECLARATION OF INTERESTS**

*Please provide details on your affiliations as far as three (3) years back from the time of filling the form and up until present. The DOICU form is valid for one (1) year. Please provide a new DOICU form after expiration of the validity.*

*If you choose the tick box ‘NO’ it means that you have no interest to declare at all. In case of potential interest to declare, please choose ‘YES’ and specify. Declaration of potential conflicts of interest does not automatically lead to an exclusion from the task, but to the evaluation on an individual level by the EUnetHTA COI Committee.*

*In case of potential interests that were not declared by the individual but become visible during the evaluation process, the respective individual can be excluded from the task. The decision on the exclusion of an individual from the task will be taken on an individual level by the EUnetHTA COI Committee.*

**1. CURRENT PROFESSIONAL ACTIVITY/ACTIVITIES**

Description of the current professional activity/activities: *Please provide a brief description of your current professional activity/activities. If professional activity/activities do not apply, please specify.*

From Month/ to Month/

**2. TABLES OF INTERESTS**

**2.1 Employment with a Company/Institution**

<’Employment with a company/institution’ means any form of occupation, part-time or full-time, paid or unpaid, in the company/institution.>

**For the purpose of this form, a company/institution means any legal or natural person whose focus is to research, develop, manufacture, market, and/or distribute medicinal products and/or medical devices. This includes companies/institutions to which activities relating to the research, development, manufacturing, marketing, and maintenance of medicinal products and/or medical devices (which might also be carried out in-house) are outsourced on a contract basis.**

**Contract research organisations (CRO) or consultancy companies providing advice or services relating to the above activities also fall under this definition of company/institution, given the remit of this form.**

*Employment with professional/clinical/patient organisations should be declared in 2.6.*

*Please provide for each company/institution you are/were employed at the information about your role/function, with which products and therapeutic indications (together with the name of the respective manufacturers) you were involved, and the relevant time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Employment with company/institution | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
| Company/Institution | Role/Function | Product, Therapeutic Indication, Manufacturer | Time Period MM/YYYY – MM/YYYY |
| <Please add more rows if needed> |  |  |  |

**2.2 Consultancy**

<’Consultancy’ means provision of advice (including training on a one-to-one basis, preparation of HTA reports or HTA submission) to a company/institution (as defined in 2.1), regardless of contractual arrangements or any form of remuneration. Furthermore, advice on behalf of a public Health Technology Assessment body should be declared.>

*Employment with CROs or consultancy companies should be declared in section 2.1. Employment with professional/clinical/patient organisations should be declared in 2.6.*

*Please state for each company/institution you provide/provided advice to, the information about your role/function, with which products and therapeutic indications (together with the name of the respective manufacturers) you were involved, and the relevant time period. Please state if the consultancy was associated with contractual arrangements or any form of remuneration.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Consultancy | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Company/Institution | **Role/Function** | **Product, Therapeutic Indication, Manufacturer** | **Contractual arrangements/ remuneration (amount if applicable)** | **Time Period** **MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |  |

**2.3 Strategic Advisory Role**

<’Strategic advisory role’ means participation (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, or development activities of a company/institution (as defined in 2.1), either in terms of general strategy or product related strategy, regardless of contractual arrangements or any form of remuneration.>

*Please state for each company/institution you have/had a strategic advisory role to, the information about your role/function, with which products and therapeutic indications (together with the name of the respective manufacturers) you were involved, and the relevant time period. Please state if the strategic advisory role was associated with contractual arrangements or any form of remuneration.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Strategic advisory role | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Company/Institution | **Role/Function** | **Product, Therapeutic Indication, Manufacturer** | **Contractual arrangements/ remuneration (amount if applicable)** | **Time Period** **MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |  |

**2.4 Principal Investigator**

<’Principal investigator (/Co-Principal investigator)’ means an investigator with the responsibility for the coordination of investigators at different centres participating in a multicentre sponsored trial, or the leading investigator of a monocentre sponsored trial, or the coordinating (principal) investigator signing the clinical study report. For the purposes of this form, a sponsor/instigator is a company/institution as defined in 2.1. Involvement in Data Monitoring Committees should be included in this section.>

*Please state for each study you are/were a principal investigator (/Co-Principal investigator), the information about your role/function, with which products and therapeutic indications (together with the name of the respective manufacturers) you were involved, and the relevant time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Principal investigator | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Study | **Role/Function** | **Product, Therapeutic Indication, Manufacturer** | **Time Period** **MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |

**2.5 Investigator**

<’Investigator’ means an investigator involved in a sponsored trial at a specific trial site who 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. For the purpose of this form, a sponsor/instigator is a company/institution as defined in 2.1.>

*Please state for each study you are/were an investigator, the information about your role/function, with which products and therapeutic indications (together with the name of the respective manufacturers) you were involved, and the relevant time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Investigator | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Study | **Role/Function** | **Product, Therapeutic Indication, Manufacturer** | **Time Period** **MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |

**2.6 Professional/Clinical/Patient Organisations**

<’Professional/clinical/patient organisations’ means any sort of organisation/institution in the healthcare sector that represents healthcare professionals and/or patient views. For the purpose of this form, a sponsor/instigator is a company/institution as defined in 2.1.>

*Please state for each organisation/institution you are/were a member/staff, the information about your role/function, the respective sources of their funding, the percentage of sponsoring by companies/institutions (separate as well as the overall funding), and the relevant time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Professional/Clinical/Patient organisations | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Organisation/Institution | **Role/Function** | **Sources of Funding** | **Percentage of sponsoring (separate, overall funding)** | **Time Period** **MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |  |

**2.7 Financial Interests**

<’Financial interests’ means any economic stake in a company/institution as defined in 2.1 including: 1) Holding of stocks and shares, stock options, equities, bonds and /or partnership interest in the capital of a company/institution (as defined in 2.1); 2) Intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal product/device owned by you or of which you are directly a beneficiary; 3) Compensation, fees, honoraria, salaries, grant or other funding (including rents, sponsorships and fellowships) paid by a company/institution (as defined in 2.1) to you in a personal capacity.>

*Please state for each company/institution the description of the financial interest and respective time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Financial interests | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Company/Institution | **Description of the interest** | **Time Period****MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |

**2.8 Grants and Funding**

<’Grants and funding’ means any funding (other than compensation for services provided) received from a company/institution (as defined in 2.1) by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to research work. Any other funding received by an organisation/institution to which you belong, or for which you perform any kind of activity, do not need to be declared.>

*Please state for each organisation/institution to which you belong, the purpose of the grant and funding, the names of the companies/institutions providing the grants and funding as well as the amount of the grants and funding and the relevant time period.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Grants and funding | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Organisation/Institution | **Purpose of the grant and funding** | **Company/Institution providing the grants and funding** | **Amount of grants and funding** | **Time Period****MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |  |

**2.9 Conferences/Meetings/Presentations**

<’Conferences/Meetings/Presentations’ means any sort of event where compensation, fees, honoraria, salaries, or other funding were paid by a company/institution (as defined in 2.1) to you in a personal capacity, including payment for or reimbursement of expenses directly related to conference/meeting/presentation attendance (i.e. accommodation and travel costs).>

*Please state for each event, the name/title and hosting organisation, the information about your role/function in that event, the time period it took place and a description of the interest including information on the company/institution responsible for the payment/reimbursement and the amount of payment/reimbursement. In case you gave a presentation at a conference/meeting, please indicate the title.*

|  |  |  |
| --- | --- | --- |
|  | No | Yes |
| Conferences/Meetings/Presentations | [ ]  | [ ]  |

**If ‘YES’, please provide details below:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
| Name/Title (Organiser) | **Role/Function** | **Description of interest (company/institution, amount of payment/reimbursement, title of presentation (if applicable)** | **Time Period****MM/YYYY – MM/YYYY** |
| <Please add more rows if needed> |  |  |  |

**2.10 Any other interest**

*Please state any other interests you might have that were not declared in the tables above.*

**3. FAMILY AND HOUSEHOLD MEMBERS INTERESTS**

Please indicate if any family[[1]](#footnote-1), partners, and/or household member[[2]](#footnote-2) of yours has one or more of the following interests[[3]](#footnote-3):

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  |  |
|  | **No** | **Yes** |  |
| Employment with a Company/Institution | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Consultancy | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Strategic Advisory Role | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Principal Investigator | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Investigator | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Professional/Clinical/Patient Organisations | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Financial Interests | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Grants and Funding | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |
| Conferences/Meetings/Presentations | [ ]  | [ ]  | <If yes, please provide a description with the same level of detail as per the table(s) of interests>  |

**DISCLAIMER**

* 1. **Review by EUnetHTA COI (Conflict of Interest) Committee:** The data provided by the individual in the DOICU form (including related annex and supporting documents) will be reviewed by the EUnetHTA COI Committee;
	2. **Review by national authorities:** Additionally, the provided data will be made available for all partner organisations and members of EUnetHTA that have HTA implementing authority, for the purpose of reviewing the provided information against national provisions that need to be taken into consideration additionally to the guidelines and assessment of the EUnetHTA COI Committee. The information will be shared at the same time as with the EUnetHTA COI Committee. Findings by these partners must be shared with the EUnetHTA COI Committee by a fixed deadline to be included in the deliberations of the EUnetHTA COI Committee;
	3. **Additional verification:** The EUnetHTA COI Committee can undertake additional research on the validity of the data provided by an individual and specifically can try to verify if no conflict exists beyond the data provided by the individual in the DOICU form;
	4. **Decision:** Based on the data provided in the DOICU and possible additional findings the EUnetHTA COI Committee takes a decision on whether a conflict of interest exists that qualifies as critical and hence excludes the relevant individual from participating in the planned activity;
	5. **Information of findings and decision:** The EUnetHTA COI Committee will inform the individual about all their findings (and provided information from relevant individual EUnetHTA partner organisations and members received by the applicable deadline). The individual will be informed about the decision of the EUnetHTA COI Committee and the reasoning for the provided decision;
	6. **Storage of data:** The data provided by the individual and any additional findings made by the EUnetHTA COI Committee will be stored permanently in relation to the specific activity the DOICU was originally requested for, regardless whether the individual is considered as appropriate or to be excluded due to conflict of interest;
	7. **Publication of data:** The individual’s data provided can be made publicly available in parts or full depending on national and regional requirements of individual jurisdictions that are represented in the EUnetHTA consortium;
	8. **Positive list:** Provided data will only be made publicly available in cases where an individual’s input is actually used or of relevance in a procedure. If a conflict of interest is considered to be of substantial nature and hence prohibiting the participation of the individual in the planned activity, the submitted data will not be published;
	9. **Completeness of data:** The individual testifies that he/she provided all requested information to the best of his/her knowledge and does not withhold any information that would have influence over establishing a conflict of interest in the specific case;
	10. **Indemnification for false or incomplete reporting:** The individual will indemnify any loss made due to false or incomplete statements;
	11. **Reminder to update DOICU:** The individual agrees to receive an automatic reminder to update his/her provided DOICU prior to expiration of the form provided;
	12. **Expiration:** The provided DOICU form expires after a specific period mentioned in the form and based on the signature date of the individual;
	13. **Renewal in case of changes or expiration:** A renewal of the information for conflict of interest needs to be submitted promptly by the individual in case of any occurring changes regarding the stated conflict of interest in the DOICU form and where the engagement of the individual surpasses the expiration date of the originally submitted form. Such renewal needs to take into consideration all additional data that have come to light since the original DOICU form was signed. In particular, attention will be payed to the acquisition of any additional interests by the individual (e.g. consultancy arrangements, etc.).

Place:

Date:

Signature: <Please return a Word version of the completed DOICU form together with a signed and scanned version of the completed DOICU form.)>

***<SECTION 2. CONFIDENTIALITY UNDERTAKING>***

*In view of the following definitions:*

*“EUnetHTA”*

*“EUnetHTA Joint Action 3 Activities” encompass any meeting (including meeting preparation and follow-up), associated discussion or any other related activity of the EUnetHTA Joint Action 3 committees and governance bodies, its work packages, expert groups, stakeholder groups, or any other such meeting, work as an expert on assessments, and work as an expert on guidance development.*

*“Confidential Information” means all information, facts, data and any other matters which are indicated as confidential or, would reasonably, under the circumstances, be understood to be confidential information and of which I acquire knowledge, either directly or indirectly, as a result of my EUnetHTA Joint Action 3 Activities and related activities*

*“Confidential Documents” mean all drafts, preparatory information, documents and any other material, together with any information contained therein, which is indicated as confidential or, would reasonably, under the circumstances, be understood to be confidential information and to which I have access, either directly or indirectly, as a result of my participation in EUnetHTA Joint Action 3 Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.*

*Confidential Information and Confidential Documents shall not include information that: (a) is now or subsequently becomes generally available to the public through no fault or breach on part of the undersigned; (b) the undersigned rightfully obtains from a third party who has the right to transfer or disclose it to the undersigned without limitation.*

*The undersigned understands that he/she may be invited to participate either directly or indirectly in certain EUnetHTA Joint Action 3 Activities and hereby undertakes:*

*1. To treat all Confidential Information and Confidential Documents under conditions of strict confidentiality and shall use the Confidential Information and Confidential Documents for the sole purpose of and only in connection with the EUnetHTA Joint Action 3 Activities;*

*2. Not to disclose, publish or disseminate (or authorise any other person to disclose, publish or disseminate) in any way to any third party[[4]](#footnote-4) any Confidential Information or Confidential Document;*

*3. Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EUnetHTA Joint Action 3 Work Package activities;*

*4. Not to use or otherwise export or re-export any portion of the Confidential Information and/or Confidential Documents;*

*5. At EUnetHTA’s option and (written) request to return Confidential Documents or to provide EUnetHTA with written certification that all tangible Confidential Documents have been destroyed within (10) business days of receipt of EUnetHTA’s (written) request;*

*6. to compensate all damages, costs and expenses including reasonable attorneys’ fees, as incurred by EUnetHTA, resulting from or arising out of or in connection with any unauthorized disclosure or use of the Confidential Information and Confidential Documents by the undersigned.*

*This undertaking shall not be limited in time. Any termination of this undertaking shall not relieve the undersigned of its confidentiality and use obligations with respect to the Confidential Information and Confidential Documents disclosed prior to the date of termination.*

*Place:*

*Date:*

*Signature: <Please return a Word version of the completed DOICU form together with a signed and scanned version of the completed DOICU form.)>*

1. First degree family member. [↑](#footnote-ref-1)
2. Household member is a person living at the same address as the individual who signs the DOICU form. [↑](#footnote-ref-2)
3. See above for the definitions of employment, consultancy etc. [↑](#footnote-ref-3)
4. Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations that prohibit unauthorized disclosure or use of the Confidential Information and/or Confidential Documents or are encompassed by confidentiality obligations under national legislation on professional secrecy. [↑](#footnote-ref-4)