Declaration of Interest (DOI) form

The undersigned,

Title:

Family name:

Given name:

Email address:

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

Address (street):

Postal code:

Town/city (Country):

EUnetHTA 21 Partner/Associate organisation or institution: Yes No

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

1. Declaration of interests

Please provide details on your affiliations as far as 3 years back from the time of filling the form and up until present. The DOI form is valid for 1 year. Please provide a new DOI 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 21 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 21 COI Committee.

1.1 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/Year*

To: *> Month/Year*

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 in which products and therapeutic indications (together with the name of the respective manufacturers) you were involved and the relevant time period.

Employment with company/institution ☐ Yes ☐ No
If 'YES', please provide details below

Company/Institution | Role/Function

Product, Therapeutic Indication, Manufacturer

Time Period > MM/YYYY > MM/YYYY

Company/Institution | Role/Function

Product, Therapeutic Indication, Manufacturer

Time Period > MM/YYYY > MM/YYYY

Company/Institution | Role/Function

Product, Therapeutic Indication, Manufacturer

Time Period > MM/YYYY > MM/YYYY

Company/Institution | Role/Function

Product, Therapeutic Indication, Manufacturer

Time Period > MM/YYYY > MM/YYYY

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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.

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.

Consultancy ☐ Yes ☐ No

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

Company/Institution		Role/Function	
Product, Therapeutic Indication, Manufacturer			
Contractual arrangements/ remuneration (amount if applicable)			
Time Period	> MM/YYYY		> MM/YYYY

Company/Institution		Role/Function	
Product, Therapeutic Indication, Manufacturer			
Contractual arrangements/ remuneration (amount if applicable)			
Time Period	> MM/YYYY		> MM/YYYY

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, 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.

Strategic advisory role ☐ Yes ☐ No
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

Company/Institution ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Contractual arrangements/ remuneration (amount if applicable) ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

Company/Institution ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Contractual arrangements/ remuneration (amount if applicable) ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

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.

Principal investigator ☐ Yes ☐ No
If 'YES', please provide details below

Study | Role/Function
Product, Therapeutic Indication, Manufacturer
Time Period > MM/YYYY > MM/YYYY

Study | Role/Function
Product, Therapeutic Indication, Manufacturer
Time Period > MM/YYYY > MM/YYYY

Study | Role/Function
Product, Therapeutic Indication, Manufacturer
Time Period > MM/YYYY > MM/YYYY

Study | Role/Function
Product, Therapeutic Indication, Manufacturer
Time Period > MM/YYYY > MM/YYYY

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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 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.

Investigator ☐ Yes ☐ No
If 'YES', please provide details below

Study ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

Study ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

Study ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

Study ____ Role/Function ____

Product, Therapeutic Indication, Manufacturer ____

Time Period ____ > MM/YYYY ____ > MM/YYYY

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.

Professional/Clinical/Patient organisations ☐ Yes ☐ No
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

Organisation/Institution		Role/Function	
Sources of Funding			
Percentage of sponsoring (separate, overall funding)			
Time Period	> MM/YYYY		> MM/YYYY

Organisation/Institution		Role/Function	
Sources of Funding			
Percentage of sponsoring (separate, overall funding)			
Time Period	> MM/YYYY		> MM/YYYY

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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.

Financial interests Yes No
If 'YES', please provide details below

Organisation/Institution				
Description of the interest				
Time Period		> MM/YYYY		> MM/YYYY

Organisation/Institution				
Description of the interest				
Time Period		> MM/YYYY		> MM/YYYY

Organisation/Institution				
Description of the interest				
Time Period		> MM/YYYY		> MM/YYYY

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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.

Grants and funding ☐ Yes ☐ No
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

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

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.

Conferences/Meetings/Presentations ☐ Yes ☐ No
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

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

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

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], partners, and/or household member[2] of yours has one or more of the following interests[3]:
Please elaborate in the comment box, in case you selected ''yes'.

Employment with Company/Institution ☐ Yes ☐ No

Consultancy ☐ Yes ☐ No

Strategic Advisory Role ☐ Yes ☐ No

Principal Investigator ☐ Yes ☐ No

Investigator ☐ Yes ☐ No

1 First degree family member. | 2 Household member is a person living at the same address as the individual who signs the DOI form.
3 See above for the definitions of employment, consultancy etc.

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Professional/Clinical/Patient Organisations ☐ Yes ☐ No

Financial Interests ☐ Yes ☐ No

Grants and Funding ☐ Yes ☐ No

Conferences/Meetings/Presentations ☐ Yes ☐ No

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Disclaimer

a. Review by EUnetHTA 21 COI (Conflict of Interest) Committee: The data provided by the individual in the DOI form (including related annex and supporting documents) will be reviewed by the EUnetHTA 21 COI Committee;
b. Review by national authorities: Additionally, the provided data will be made available for all partner organisations and members of EUnetHTA 21 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 21 COI Committee. Findings by these partners must be shared with the EUnetHTA 21 COI Committee by a fixed deadline to be included in the deliberations of the EUnetHTA 21 COI Committee;
c. Additional verification: The EUnetHTA 21 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 DOI form;
d. Decision: Based on the data provided in the DOI and possible additional findings the EUnetHTA 21 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;
e. Information of findings and decision: The EUnetHTA 21 COI Committee will inform the individual about all their findings (and provided information from relevant individual EUnetHTA 21 partner organisations and members received by the applicable deadline). The individual will be informed about the decision of the EUnetHTA 21 COI Committee and the reasoning for the provided decision;
f. Storage of data: The data provided by the individual and any additional findings made by the EUnetHTA 21 COI Committee will be stored permanently in relation to the specific activity the DOI was originally requested for, regardless whether the individual is considered as appropriate or to be excluded due to conflict of interest;
g. 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 21 consortium;
h. 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;
i. 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;
j. Indemnification for false or incomplete reporting: The individual will indemnify any loss made due to false or incomplete statements;
k. Reminder to update DOI: The individual agrees to receive an automatic reminder to update his/her provided DOI prior to expiration of the form provided;
l. Expiration: The provided DOI form expires after a specific period mentioned in the form and based on the signature date of the individual;
m. 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 DOI 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 DOI form was signed. In particular, attention will be payed to the acquisition of any additional interests by the individual (e.g. consultancy arrangements, etc.).

☐ In order to engage in JCA/CA or JSC production acitivities, I give my consent to EUnetHTA storing the data provided in this form as described in the terms of use for the purposes of assessing potential conflict of interest.

☐ "I am fully aware of the lawfullness of EUnetHTA handling my data and also of my rights concerning the data I provide hereby."

Place:

Date:

Signature: