

EUnetHTA 21 Confidentiality Agreement



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 Consortium member organisation or institution: Yes No

Agrees to enter this Confidentiality Agreement, in relation but not limited to EUnetHTA 21 Joint Scientific Consultation, Medical Device Joint/ Collaborative Assessments and Medicinal Product Joint Clinical Assessment ID#

Compound:

For treatment of:

In view of the following definitions

“EUnetHTA 21 Activities” encompass any meeting (including meeting preparation and follow-up), associated discussion or any other related activity of the EUnetHTA 21 committees and governance bodies, its 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 21 Activities and related activities.¹

“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 21. 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 21 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 21 activities;
2. Not to disclose, publish or disseminate (or authorise any other person to disclose, publish or disseminate) in any way to any third party² any Confidential Information or Confidential Document;

¹ Confidential information specifically includes but is not limited to also third party information received in relation to activities undertaken under this confidentiality agreement, such as data from national or international Horizon Scanning Systems, data from EMA or other regulatory bodies and others.

² 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.

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3. Not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of his/her work in connection with EUnetHTA 21 activities;
4. Not to use or otherwise export or re-export any portion of the Confidential Information and/or Confidential Documents;
5. At EUnetHTA 21 option and (written) request to return Confidential Documents or to provide EUnetHTA 21 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 21, 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.

In order to engage in JCA/CA or JSC production activities, 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 lawfulness of EUnetHTA handling my data and also of my rights concerning the data I provide hereby."

Place:

Date: *dd/mm/yyyy*

Signature: