EUnetHTA Joint Action 3 WP4

**Relative effectiveness assessment of pharmaceutical technologies**

**LETTER OF INTENT EUNETHTA REA**

**[compound] for treatment of [indication]**

Template version 2, April 2020

Version [x], [day] [month] [year]

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| NOTE TO AUTHORS OF THIS DOCUMENTText in grey boxes provide guidance for populating the Letter of Intent template. The boxes should be removed before submitting the Letter of Intent to EUnetHTA. In addition, if predefined text requires an update this is marked in yellow. Please follow the layout settings for text, tables and headers as much as possible:* Headers Arial 11, bold and italic
* Standard text: Arial 10
* Table text: Arial 9
 |

Letter of Intent – Joint Assessment [Compound] for [ Indication]

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| Please provide us with your expression of interest in submitting a compound for a EUnetHTA Joint Relative Effectiveness Assessment. The content of this document should not exceed 2 pages [excluding cover page and signature page]. |

With this Letter of Intent, we [company] express interest in submitting [compound] for [indication] for a Joint Relative Effectiveness Assessment.

|  |  |
| --- | --- |
| International non-proprietary name |  |
| Brand name |  |
| Description of the medicine and mechanism of action | <Please keep this a brief description. In the Scoping Document further information can be provided> |
| Method of administration and dosage |  |

# Marketing authorisation status

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| --- |
| Please state the current EU regulatory status, with (anticipated) relevant dates (date of application [D0 EMA submission] and expected date of approval from the EMA/CHMP), and type of regulatory procedure [new (initial) marketing authorisation application, accelerated procedure, extension of indication or post-authorisation procedure]. Please do note that the coordination team should be immediately notified if any change is foreseen. If multiple scenarios are provided below, also include a date when more clarity regarding the timelines can be expected. |

|  |  |  |
| --- | --- | --- |
| Important regulatory information | Base case scenario | Best case scenario |
| Regulatory scenario |  |  |
| (Expected) date of EMA application |  |  |
| Expected date of CHMP opinion |  |  |
| Expected date of EC decision |  |  |
| Type of regulatory procedure  |  |  |

# EU indication

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| Please state the proposed (submitted to the EMA) and the anticipated indication(s) in the EU. Please do note that the coordination team should be immediately notified if any change is foreseen. |

# Companion diagnostic

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| Please state if a companion diagnostic is required. If yes, please provide us with a brief description. In the Scoping Document further information can be provided if that is relevant. |

# EU clinical practice and comparators

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| Please provide us with a brief summary of the current clinical pathway of the disease/condition for which the medicine is proposed and anticipated to be indicated, highlighting the anticipated comparators in the EU. In the Scoping Document further information can be provided if relevant. |

# Estimated population size

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| Please provide us with the estimated European population size. |

# Contact Details

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| --- |
| Primary contact  |
| Name: |  |
| Email: |  |
| Tel: |  |

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| Secondary contact  |
| Name: |  |
| Email: |  |
| Tel: |  |

# Declaration

I confirm that all data relevant to the Letter of Intent have been disclosed to EUnetHTA WP4.

|  |  |
| --- | --- |
| Signature: | <Please insert a scanned signature or send a copy of this completed page as an attachment. Please note that a Word version of the completed Letter of Intent is required.> |
| Name: |  |
| Position: |  |
| Date: |  |