**Request for pre-submission meeting for Early Access to Medicines Scheme (EAMS) Scientific Opinion (Step II)**

**Introduction**

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed and repurposed medicines to UK patients that have a high unmet clinical need. The medicinal products expected to be included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life threatening conditions without adequate treatment options. EAMS is a two-step procedure. Step I, the ‘Promising Innovative Medicine’ Designation and Step II, the Early Access to Medicines Scientific Opinion procedure. Companies who wish to enter the EAMS scientific opinion procedure are required to have a ‘Promising Innovative Medicine’ (PIM) designation and attend a pre-submission meeting. The aim of the pre-submission meeting is to ensure that the suitability criteria for the scheme are likely to be met and to discuss the format of the data to be submitted to support the opinion.

To apply for a pre-submission meeting, please submit the following template to the EAMS coordinator (eams@mhra.gsi.gov.uk). Following receipt of your request, the MHRA will arrange a mutually acceptable date for the meeting. There is no fee payable for the pre-submission meeting.

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| **EAMS pre-submission meeting request form** |
| **Product name and active substance****Strength and Pharmaceutical form** |  |
| **EAMS number** **Date of PIM designation** |  |
| **Applicant’s contact details** |  |
| **Preferred meeting dates** |  |
| **Preferred submission date**  |  |
| **Proposed indication** |  |

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| **Brief summary of quality and non-clinical development programme to date (maximum 2000 words)** |
| **Brief justification of eligibility for scheme - Life-threatening or seriously debilitating condition in patients with a high unmet need (maximum 1000 words)** |
| **Brief justification of eligibility for scheme - Data available to support a positive benefit risk balance and major advantage over methods currently used in the UK (maximum of 2000 words)** |
| **Brief summary of proposal for on-going collection of safety and efficacy data (maximum of 2000 words)**  |
| **Brief description of format of proposed EAMS dossier (maximum of 1000 words)** |
| **Brief description of on-going clinical studies and recruiting countries (maximum of 1000 words)** |