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| --- |
| Date: |

Letter of intent for request of Qualification of Biomarkers/Clinical Outcome Assessments (COAs)in a joint US FDA-EMA Submission

Please fill all the predefined fields as accurately as possible

|  |  |
| --- | --- |
| **Biomarker/COA information** |  |
| **Name of biomarker/COA** |  |
| **Description of the biomarker/COA** |  |
| **Type of biomarker** | Genetic Biomarker Protein Biomarker Imaging Biomarker Scale Statistical Other |
| **Type of COA** | Patient Reported Outcome (PRO) Measure Clinician Reported Outcome (ClinRO) Measure  Observer Reported Outcome (ObsRO) Measure  Performance Outcome (PerfO) Measure |

Comments:

|  |  |
| --- | --- |
| **Area Of Request/Type of biomarker studies** | Non Clinical Pharmacology Toxicology Other Clinical Pharmacology Safety Efficacy Patient selection Other |
| **Therapeutic area** | Autoimmune diseases  Cardiovascular  Gastrointestinal diseases  Infectious diseases  Metabolic diseases  Neurology  Oncology  Psychiatry  Pulmonary  Other |
| **Intended use of biomarker/ COA (in 1-2 sentences)** |  |

Comments:

|  |  |
| --- | --- |
| **Applicant/Submitter** | Customer Account Number[[1]](#endnote-1) (*for EMA use only*):  DDT Tracking Record Number (*for FDA use only*):  Name:  Address: |
| Contact Person details | Name:  Address (if different from above):  Direct tel:  Email: |
| Alternate Contact Person details (if applicable) | Name:  Address (if different from above):  Direct tel:  Email: |

|  |  |
| --- | --- |
| **Previous Qualification / Scientific Advice received** | Previous FDA Qualification / Scientific Advice given to this biomarker / COA.    Other CHMP Qualification / Scientific Advice given to this biomarker / COA.  Procedure number:  Previous discussions at Pharmacogenomics Working Party or other CHMP Working Parties relevant to this biomarker / COA (please specify):  Previous discussions with Other Regulatory Authorities, EU or non-EU relevant to this biomarker / COA  (please specify): |

**FOR EMA USE ONLY:**

|  |  |
| --- | --- |
| **Type of request** | Request for Qualification Advice  Request for Qualification Opinion |

|  |  |
| --- | --- |
| Invoicing details (if different from Applicant details)[[2]](#endnote-2) | Name:   Address: |
| Financial contact person details (if applicable or different from procedure contact person) | Name:   Direct tel:  Fax:   Email: |
| Purchase order number (if applicable or if already available) | Details: |

Comments:

|  |  |
| --- | --- |
| **Consultant on behalf of Applicant (if applicable)** | Name of the Company:   Address: |
| Contact Person details | Name:   Direct tel:  Fax:   Email: |
| Alternate Contact Person details (if applicable) | Name:   Direct tel: Fax:   Email: |
| Letter of authorisation from applicant | NO (to be provided within 30 days)  YES (please attach) |

Comments:

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| --- | --- |
| **Requirement for preparatory meeting** | Specify preferred week for meeting: |
| **Aimed start of the procedure** |  |

Comments:

|  |  |
| --- | --- |
| **Small and Medium Sized Enterprises (SME) status** | NO – N/A  YES (please fill additional rows)  - SME Number:  **-** SME fee reduction requested[[3]](#endnote-3): YES  NO date:  - Additional relevant information: |

Comments:

|  |  |
| --- | --- |
| **Additional EMA Qualification request planned** | NO  YES; tentative date: |

Comments:

**Biomarkers**

**Important: please send this form in Word format as it is to:**

**EMA at qualification@ema.europa.eu and US FDA Biomarker Qualification Program at CDER-BiomarkerQualificationProgram@fda.hhs.gov**

**Do not convert it into PDF.**

**Please submit the following information in an accompanying document to both US FDA Biomarker Qualification Program and to EMA (suggested length of the document: 3-4 pages):**

Biomarker Qualification Overview

1. Introduction
2. Proposed context of use
3. High-level data description (1-2 pages in length). This description should provide a data overview that not only support the use of the biomarker for the proposed context of use/scope of intended use, but also encourages regulatory engagement because of drug development applicability.
4. Additional resources that support the context of use/scope of intended use, as well as data the submitter plans to obtain from ongoing or future studies.
5. Process-related questions for FDA/EMA
6. **EMA use only** – Additional information should be provided as applicable:
7. Product profile
8. Investigator’s brochure
9. Relevant study protocols or draft study protocols or study outlines
10. Bibliography (references)
11. Content of previous requests received
12. Relevant guidelines/guidances
13. Contract agreement if the request is submitted by a consultant/CRO on behalf of the company

**COAs**

**Important: please send this form in Word format as it is to:**

**EMA at qualification@ema.europa.eu and US FDA COA Qualification Program at SEALD.ENDPOINTS@fda.hhs.gov**

**Do not convert it into PDF.**

**Please submit the following information in an accompanying document to both US FDA COA Qualification Program and to EMA (suggested length of the document: 3-4 pages):**

1. Administrative structure: description of the submitter including, but not limited to, principal investigator(s), working group member(s), institutions, and contact information not contained within the cover letter.
2. Concept(s) of interest (COI) for meaningful treatment benefit
3. A description of the meaningful aspect of patient experience that will represent the intended benefit of treatment (e.g., presence/severity of symptoms, limitations in performance of daily activities)
4. Targeted labeling or promotional claim(s) based on the COA to be developed (i.e., proposed wording)
5. COU for COA qualification
6. Targeted study population including a definition of the disease and selection criteria for clinical trials (e.g., baseline symptom severity, patient demographics, comorbidities, language/culture groups)
7. Targeted study design and statistical analysis plan (includes the role of the planned COA in future drug development clinical trials, including the planned set of primary and secondary endpoints with hierarchy, if appropriate)
8. Applicable study settings for future clinical trials
9. Geographic location with language/culture groups
10. Other study setting specifics (e.g., inpatient versus outpatient)
11. COA type
12. PRO, ClinRO, ObsRO or performance measure
13. General description of proposed or existing measure
14. Need for the qualified COA
15. Overview of existing related outcome assessments
16. Identification of the gap(s) in measurement
17. Process-related questions for CDER (provision of scientific questions may be deferred to submission of the briefing package)
18. **EMA use only** – Additional information should be provided as applicable:
19. Product profile
20. Investigator’s brochure
21. Relevant study protocols or draft study protocols or study outlines
22. Bibliography (references)
23. Content of previous requests received
24. Relevant guidelines/guidances
25. Contract agreement if the request is submitted by a consultant/CRO on behalf of the company

1. This field is mandatory. Please quote your customer account number with the Agency. To request a customer account number or for any other accounts query please email to [**accountsreceivable@ema.europa.eu**](mailto:accountsreceivable@ema.europa.eu)*.* [↑](#endnote-ref-1)
2. Please note that EMEA fees are payable net of all bank charges, withholding taxes and any other deduction imposed on the customer by legislation of the country of residence.

   Only the Applicant will be invoiced, but the invoice can be sent to a different address. If a consultant is dealing with the Qualification request on behalf of the Applicant, nevertheless the payment will be claimed to the Applicant. If purchase order is not yet available at this stage, it will have to be provided at the time of submission of the Scientific Advice request. [↑](#endnote-ref-2)
3. If the applicant has an **SME status**, at the time of submission please provide the fee waiver confirmation document from the EMEA SME office. **Failure to do so will incur a validation of the request without SME fee reduction and an invoice of the full amount will be sent by our account department.** [↑](#endnote-ref-3)