# **Application Form**

# **ICMRA Pilot Program for Collaborative Assessment**

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| --- | --- |
| Organisation or company name |  |
| Contact name |  |
| Contact email |  |
| Short title of the post-approval change (e.g., post-approval change management protocol (PACMP), site transfer, or scale up, 20 words maximum) |  |
| Drug substance name |  |
| Drug product name |  |
| INN/USAN/Other product trade name |  |
| Product type | Chemical/small molecule  Biological molecule  Other - please specify: |
| Route of Administration |  |
| Dosage form |  |
| Therapeutic indication |  |
| Does the product have orphan drug designation? | Yes  No |
| Has the product been granted a designated status for early access patient treatment (e.g., Breakthrough, PRIME, Sakigake, Priority Review, or Fast Track Authorisation)? | Yes  No  If yes, please provide details: |
| Intended submission date if accepted into the pilot |  |
| Regions or countries where it is planned to file the post-approval change and their associated application or dossier numbers |  |
| Description of the post-approval change, including the explanation of why the proposed change will benefit from the collaborative assessment under this pilot (1000 words maximum). |  |
| Does the post approval change involve a new facility site, suite, or area that was not reported in the previous submission(s)? | Yes  No  If yes, please provide further details: |
| Do you anticipate any restrictions on sharing data or information among the regulatory authorities participating in the pilot? | Yes  No  If yes, please provide further details: |
| Do you anticipate any restrictions on publicly sharing high-level regulatory assessment outcomes of the pilot? | Yes  No  If yes, please provide further details: |
| In your opinion, what are the benefits to furthering harmonisation if this case is including in the pilot? Does the proposed case meet any of the priority areas identified in the ICMRA workshop (300 words maximum)?[[1]](#footnote-1) |  |
| Applicant's signature | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  date (dd-mm-yyyy) |

1. Please refer to the ICMRA workshop summary report <https://www.icmra.info/drupal/sites/default/files/2021-10/covid-19_manufacturing_capacity_ws_report.pdf> [↑](#footnote-ref-1)