**Expression of Interest for the MHRA Real-World Evidence Scientific Dialogue Programme pilot:**

This guidance should be used to help submit an expression of interest for a pilot of the MHRA Real-World Evidence Scientific Dialogue Programme.

Expressions of interest can be submitted for either a:

1. Workshop
   * A pre-competitive space ‘safe harbour’ workshop jointly convened by the MHRA and The National Institute for Health and Care Excellence (NICE).
   * This environment promotes open dialogue and shared learning about RWE topics.
   * Joint applications for multiple applicants on similar areas of discussion will be accepted.
   * Outputs of the workshop may be made publicly available (e.g. as guidance or case-studies) although specific elements may be agreed between the MHRA and the applicant to be non-disclosable.
2. Closed-door meetings

* A confidential virtual meeting conducted solely with the MHRA for commercially sensitive discussion focusing on RWE topics pertinent to medicinal product development.
* Outputs of the meetings will not be publicly available.

**Aims of the MHRA Real-World Evidence Scientific Dialogue Programme**

* To clearly set out the MHRA’s expectations for RWE methodologies for evidence generation through consolidation and harmonisation of core principles, and to produce specific use cases. This should ensure the evidence generated will uphold the MHRAs rigorous standards for evaluating safety, quality, and efficacy/effectiveness, promoting public health, and protecting patient safety.
* To enable commercially sensitive discussions between applicants and the MHRA, with a specific strategic focus on RWE, enhancing existing scientific advice services.
* To increase clarity of regulatory and HTA expectations for data, analytical methodologies, and endpoints used to generate RWE.
* To generate shared learning which can be disseminated to the broader ecosystem through reflection papers developed collaboratively between MHRA, NICE, and industry stakeholders.

**Eligibility Criteria:**

The MHRA welcomes expressions of interest related to any proposal with a specific focus on Real-World Evidence (RWE). For the purposes of the RWE Scientific Dialogue Programme, Real-World Data (RWD) is defined as data relating to patient health status and/or delivery of health care collected outside of a clinical study and RWE is defined as evidence derived from the analysis of RWD.

Applications will be accepted for:

1. Medicinal products including drugs, biologics, vaccines, and advanced therapy medicinal products (ATMPs).
2. Pre- and post-authorisation evidence generation.
3. Evidence generation in relation to claims of both effectiveness and safety.
4. Interventional and non-interventional studies including:

* External control arm studies
* Pragmatic clinical trials
* Pharmacoepidemiological studies (e.g. cohort studies, case-control studies, and other observational study designs)

**For the pilot programme, expressions of interest for medical devices will be excluded. For clarity we are only including medicinal products that are regulated through the medicine’s pathway.**

**Additionally, where a product is under an active regulatory procedure (marketing application, variation, major safety review or other statutory procedure), the expression of interest will be excluded to protect regulatory independence.**

**Selection Process:**

There will be a limited number of requests accepted whilst the RWE Scientific Dialogue Programme is in a pilot phase. The MHRA will evaluate expressions of interest and priority will be given to applications that focus on:

* Addressing pressing public health challenges and align with broader Government policy.
* Areas of significant unmet clinical need.
* Preventative medicine, interpreted broadly.
* Genomic data, biomarkers, or precision medicine approaches.
* Innovative methodologies or study designs that advance the field (e.g., improving representativeness in clinical studies, measuring effectiveness through RWD, etc.).

**Expression of Interest for the MHRA Real-World Evidence Scientific Dialogue Programme – Application Form:**

Please complete sections 1 to 3 for all applications and complete the relevant sections of the form for either a closed-door meeting (section 4) or a workshop (section 5) and email it to [scientific\_advice@mhra.gov.uk](mailto:scientific_advice@mhra.gov.uk), including the subject line “RWE Scientific Dialogue Programme”.

Expressions of interest should not exceed 3 pages. Applicants should determine what information is most relevant to the discussion, as some of the questions below may not apply. If an expression of interest is selected to proceed, the applicant will be contacted and requested to provide more detailed information on the questions, format, and content of the proposed discussion. Prior to approving workshop requests, the applicant must reach an agreement with the MHRA and NICE on what information can be shared publicly.

Expressions of interest will be accepted from the **10th of February 2025 until 11.59pm BST on the 4th of April 2025**. The MHRA will review submissions and notify applicants of the outcome in the first week of May 2025.

All meetings with the selected applicants will be held virtually during May and July 2025. The workshop will be hosted in June/July 2025, in a format to be finalised in consultation with all participating parties.

If you have any questions about the programme or need assistance with your submission, please email [scientific\_advice@mhra.gov.uk](mailto:scientific_advice@mhra.gov.uk) , including the subject line “RWE Scientific Dialogue Programme.”

1. **About you**

*For joint applications please include the information for each applicant and indicate who should be the main point of contact*

|  |  |
| --- | --- |
| Organisation name |  |
| Organisation type | ☐Small and Medium-sized Enterprise SME (<=250 employees)  ☐Large Enterprise (>250 employees)  ☐University or academic institution  ☐Charity  ☐Government entity  ☐Other  If other, please specify below. |
| Contact name |  |
| Contact address |  |
| Telephone number |  |
| Email address |  |

1. **Previous Scientific Advice:**

|  |  |
| --- | --- |
| 1. Has previous MHRA advice been sought? |  |
| 1. If ‘Yes’ please provide a summary and attach all advice received as separate documents to the email. |  |
| 1. Has advice been sought from other agencies? |  |
| 1. If ‘Yes’ please provide a summary and attach all advice received as separate documents to the email. |  |

1. **Therapeutic Area(s):**

|  |  |
| --- | --- |
| 1. Disease/condition of interest, as applicable |  |
| 1. Product name (if question is not product-specific please write ‘Broader Scope’) |  |
| 1. Brief history of product development, as applicable |  |

**4.** **Closed-door meeting proposals only**:

|  |  |
| --- | --- |
| 1. Please list the key objectives for the meeting |  |
| 1. What is the regulatory question(s)? |  |
| 1. How do the objectives align with the prioritisation criteria of the RWE SDP? |  |
| 1. Rationale for a real-world evidence approach |  |
| 1. Brief overview of the proposed study design, including as applicable:  * Objectives * Study type (e.g. randomised trial with pragmatic elements, externally controlled trial, observational cohort study) * Eligibility criteria * Covariates of interest * Primary and key secondary endpoints * Comparator * Concomitant therapies |  |
| 1. Describe proposed data sources (e.g., electronic health records, registries, and/or other). |  |
| 1. Brief description of the statistical analysis plan, including as applicable:  * Approximate sample size * Analytic plan for primary and key secondary endpoints * Approach to confounding factors * Definition of follow-up period * Handling of intercurrent events, missing or misclassified data, and multiplicity |  |
| 1. Other considerations |  |

**5. Workshop proposals only**:

|  |  |
| --- | --- |
| 1. Please list the key objectives for the proposed workshop |  |
| 1. How do the objectives align with the prioritisation criteria of the RWE SDP? |  |
| 1. Proposed areas of discussion on real-world evidence |  |
| 1. Expected outputs of the workshop |  |
| 1. Specific questions for the MHRA |  |
| 1. Specific questions for NICE |  |
| 1. If a study design is to be discussed, please provide a brief overview of the study. |  |
| 1. Describe any proposed data sources (e.g., electronic health records, registries, and/or other) |  |
| 1. Other considerations |  |
| 1. Elements that the applicant considers non-disclosable, if applicable, along with a rationale for exclusion |  |