Medicines & Healthcare products Regulatory Agency

MHRA draft guideline on the use of external control arms based on real-world data to support regulatory decisions

We are seeking feedback on our new draft guideline on the use of external control arms based on real-world data to support regulatory decisions. While the guideline is specifically aimed at sponsors planning to use real-world data external control arms, many of the general principles would be relevant for external controls drawn from other sources, such as previously completed clinical trials. This feedback will help us to improve the clarity and wording of this guidance, including any perceived contradictions or omissions.

Please download the draft guidance and consultation questions for reference before responding to this consultation here.

You can also leave specific line by line comments on the draft guidance. To leave such feedback, please download the **MHRA spreadsheet** here and refer to the draft guidance while completing it.

You have several rights which are outlined in the MHRA privacy notice. For greater detail on when they apply, please refer to the Information Commissioner's website if you wish to exercise any of your rights, or have any questions or concerns, please contact our Data Protection Officer at dataprotection@mhra.gov.uk.

When the consultation period ends, the MHRA will amend and publish the guidance document and an anonymised summary of the public feedback.

The consultation will close at 11:59pm on Monday, 14th July 2025.

Background

Please tell us a little bit about you so that we can ensure we have a balanced pool of responses.

Which best applies to you:

- ◯ I am responding as an individual
- ◯ I am responding on behalf of an organisation

About your organisation

Organisation type:

- [ ] Product developer
- [ ] Charity (including patient advocacy groups)
- [ ] Academia
- [ ] Government/Regulator
- [ ] Health and Care organisation
- [ ] Trade/professional association/organisation
- [ ] Other

Choose a minimum of 1.

Please tell us the geographical area(s) your organisation covers

- [ ] England
- [ ] Northern Ireland
- [ ] Scotland
- [ ] Wales
- [ ] Other - please specify

Choose a minimum of 1.

Organisation name:

Type of response

How would you like to respond?

- [ ] General comments
- [ ] Line-by-line comments to specific sections

Choose a minimum of 1.

Personally identifiable information

When providing free text comments on the draft guidance, please do not provide any personally identifiable information.

Line-by-line comments

If you have not already done so, please download the draft guidance here and refer to the document in the consultation.

To provide line-by-line comments, please download the MHRA spreadsheet here and follow its instructions.

Make sure you add your respondent ID to the spreadsheet: [this will be displayed here during the consultation]

When completing the spreadsheet, we strongly encourage you to consider the following when drafting your comments:

- Prioritising or highlighting key comments correlating your comment with the corresponding line number of the draft guideline to make it easier for us to identify relevant text
- Providing justification and any relevant examples to support suggested changes
- Consolidating comments from the same organisation, if appropriate.

This is an optional part of the consultation. For general comments, please continue with the consultation.

Please upload the Excel spreadsheet containing your comment(s) or your organisation's comment(s) on the draft guidance. (optional)

Upload a file

Choose File No file chosen

General comments

If you have not already done so, please download the draft guidance here and refer to the document in the consultation.

Please specify if you would like to provide general comments on the draft guidance document or specific sections of the draft guidance document.

- [ ] General comments
- [ ] Comments on specific sections

Choose a minimum of 1.

Overall comments

Please provide any general comments you may have on the draft guidance.

Comments on specific sections

Which section(s) of the guidance would you like to comment on?

- [ ] Overview
- [ ] Scope
- [ ] General principles and regulatory acceptability of designs depending on external real-world data controls
- [ ] Types of studies and points to consider
- [ ] Example scenarios endpoints and designs
- [ ] Advice

Choose a minimum of 1.

Overview

Please provide any general comments you may have on the draft guidance in this section.

Scope

Please provide any general comments you may have on the draft guidance in this section.

General principles and regulatory acceptability of designs depending on external RWD controls

Please provide any general comments you may have on the draft guidance in this section.

Types of studies and points to consider

Please provide any general comments you may have on the draft guidance in this section.

Example of scenarios, endpoints and designs

Please provide any general comments you may have on the draft guidance in this section.

Advice

Please provide any general comments you may have on the draft guidance in this section.

Future contact from the MHRA

Would you be happy for the MHRA to contact you to discuss your response in more detail, if necessary?

- ○ Yes
- ○ No

Contact details

Full name:

Email address:

Response confidentiality

When the consultation period ends, the MHRA will amend and publish the guidance document. Additionally, we will publish an anonymised summary of the public feedback and may also publish the consultation responses. Published responses would not contain any personally identifiable information.

Do you want your response to remain confidential?

- Keep responses confidential
- Certain responses may be published
- Responses can be published

Confidentiality and disclosure under the Freedom of Information Act 2000

If certain responses may be published, please indicate which parts you wish to remain confidential.

In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Satisfaction survey

If you do not wish to leave your feedback, please select the 'Submit' button.

1. It was easy to participate in this opportunity (optional)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly disagree

2. The supporting information was understandable (optional)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree or disagree
- ○ Disagree
- ○ Strongly disagree

3. What could we do better? (optional)

Thank you for completing this survey.

This survey is now closed.