Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of Information Team
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MHRA Website

[redacted]

Our Ref: **FOI2026/00323**

23 April 2026

Dea[redacted]

Thank you for your Freedom of Information (FoI) request received on 24 March. You wrote:

Please provide all recorded information held by the MHRA relating to the development, consideration, or adoption of guidelines similar to the US FDA's January 2026 draft guidance titled "Use of Bayesian Methodology in Clinical Trials of Drug and Biological Products" (issued by CDER/CBER). This includes but is not limited to:

- *Any internal plans, reports, correspondence, meeting minutes, or assessments concerning the use of Bayesian statistical methods (e.g., informative priors, posterior probabilities of efficacy, adaptive designs, borrowing of historical/real-world data) in UK clinical trials for drugs and biological products.*
- *How such methods are being evaluated in the context of the 2026 updates to the UK Clinical Trials Regulations, MHRA guidance on adaptive designs/in-silico modelling, or the government's "Replacing animals in science" strategy (November 2025), including MHRA's planned involvement in the International Medicines Regulator's Working Group on 3Rs.*
- *Any timelines, milestones, or progress updates on developing MHRA-specific guidance or aligning with FDA/EMA approaches.*
- *Any correspondence with DSIT, Home Office, EMA, FDA, or other bodies on this topic since 1 January 2026 (or earlier if linked to clinical trial modernisation or alternative methods).*

MHRA Response

We can confirm that the MHRA currently does not have any plans to issue formal guidance on Bayesian methods. MHRA does not hold copies of any relevant correspondence with DSIT, Home Office, EMA, FDA or other bodies.

It may be of interest to you to note:

- The European Medical Agency (EMA) has published a concept paper for the Development of a Reflection Paper on the use of Bayesian methods in clinical development.
- The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) E20 Expert Working Group is currently working on the development of a new E20 Guideline on “Adaptive Clinical Trials”.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

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