



## Medicines & Healthcare products Regulatory Agency

MHRA Central Freedom of  
Information Team  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

[foi.request@mhra.gov.uk](mailto:foi.request@mhra.gov.uk)

[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2025/00109**

27 February 2025

Dear [REDACTED]

Thank you for your Freedom of Information (FOI) request received on 9 February 2025. You wrote:

*The Animals in Science Committee as the responsible committee for policy direction under the Carltona Principle to the Home Secretary, participated in and organised a Future Futures workshop in 2021. The published pack included various workstreams Under the area "Drug Development Crisis " the workstream stated that " One of the key challenges is the lack of a clear scientific strategy to demonstrate how the different NAMS can be pieced together to replace all the various animal tests that are currently required to test a single new drug."*

*Ergo by the same rationale there must a clear scientific strategy using animal testing existing and in use with which to replace this with NAMS, that the Government expects and indeed must be using to regulate the process of drug development here in the UK and for sale around the world.*

*Please could I ask under Freedom of Information request, if you could point me to the clear scientific strategy that demonstrates how and which animal tests are currently required to test a single new drug please? This must surely be available to drug development manufacturers to enable them to reach regulatory standards and to gain market approval.*

### **MHRA Response**

Development of a new drug in the UK is expected to align with expectations in international guidelines, so that animal studies done in one country can enable clinical testing of that drug in multiple other countries without a need to repeat these studies. Guidelines relating to studies involving animals in drug development are in the 'S' stream (S for safety) or the 'M' stream (M for multidisciplinary) of the International Conference on Harmonisation (ICH) and are available at this link: <https://www.ich.org/page/ich-guidelines>.

These guidelines lay out the current common understanding between drug developers and regulators on what animal tests are expected based on the stage of development of the drug. The developer of a new drug should do studies that align with expectations expressed in these ICH guidelines, as relevant to their product: regulators review results of these studies to determine if proposed clinical trials can be approved and also if a drug can be approved for

marketing. Where a developer does not present a set of studies that aligns with these expectations, reasons for this are considered by regulators.

There are additional guidance documents on how to develop vaccines (from the World Health Organisation (WHO), see here: WHO guidelines on non-clinical evaluation of vaccines, Annex 1, TRS No 927; and also the UK MHRA position on the development of a class of drugs called biosimilars, where no animal studies are expected: see here <https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products/guidance-on-the-licensing-of-biosimilar-products>.

Looking ahead, rather than an approach which aims to replace each study mentioned in these guidelines with a non-animal-based alternative method, it is likely that future requirements will focus on what non-animal based methods can answer the two key questions in drug development which are:- what is the reason this is expected to have efficacy in patients: and, why is the use intended (either in a trial or once on the market) considered to be reasonably safe, in the context of the benefit sought.

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

Yours sincerely,

MHRA Central Freedom of Information Team  
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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.

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Website: [ICO FOI and EIR complaints](#) or telephone 0303 123 1113.

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