



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](#)

Our Ref: **FOI2026/00168**

16 April 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 16 February. You wrote:

Under the Freedom of Information Act 2000, I am requesting information regarding the GB-PRIME study (ClinicalTrials.gov ID: NCT07127172; IRAS ID: 354112), specifically concerning the Neuralink N1 Brain-Computer Interface and the R1 Surgical Robot.

- *I request the following information:*
- *The total number of Serious Adverse Events (SAEs) reported to the MHRA in relation to this study from its commencement in the UK through February 2026.*
- *The number of reported incidents of electrode thread retraction or displacement in UK participants.*
- *The number of surgical site infections or secondary surgeries required for any UK trial participants.*
- *A copy of the non-technical summary of the clinical trial authorization, including any specific safety conditions imposed by the MHRA for the UK arm of the study.*

I understand that personal data is exempt under Section 40, and I am not seeking the identities of any participants. Moreover, while I recognise commercial sensitivity (Section 43), I believe the public interest in the safety of invasive neurological implants outweighs the commercial interest in withholding aggregate safety figures.

MHRA Response

We can confirm that the Agency holds the information you are seeking.

However, we are engaging an exemption from disclosure under Section 22A of Fol Act. Section 22A provides an exemption for information obtained from a programme of research where:

- the programme is still under way
- there is an intention to publish a report of the research and
- disclosure of the information would or would be likely to prejudice the research programme, the interests of participants in the programme, or a public authority holding or intending to publish a report of the research.

The exemption applies to information 'obtained in the course of, or derived from, a programme of research'. It covers a wide range of information relating to the research project including information that is not necessarily going to be published.

We are satisfied that all parts of the exemption are met.

The programme of research is still underway and there is an intention to publish the results after the clinical study has concluded. The GB-PRIME study is approved by the Health Research Authority (HRA), the UK body with statutory responsibility for protecting and promoting the interests of patients and the public in health research. The HRA expects and promotes the publication of research findings. Its published guidance on reporting research results states that "all research results, whether positive, negative, neutral or inconclusive, should be made publicly available" following study completion. This expectation reflects the wider UK Policy Framework for Health and Social Care Research, which places responsibility on sponsors and researchers to ensure the timely dissemination of findings. For more information please see the links below:

[GB-PRIME - Health Research Authority](#)
[Reporting research results - Health Research Authority](#)

We consider that disclosure of the information at this stage would be likely to prejudice the ongoing research study and undermine clinical research in the United Kingdom. It could also prejudice the interests of the individuals participating in the study. This is because the research programme is at an early stage and the data are incomplete. Premature disclosure of these incomplete data could be misleading, especially when provided without appropriate context or final analysis. There is also a risk that disclosing this information would compromise the privacy of the small number of participants involved in the study.

We understand there is a strong argument for releasing this information as it pertains to patient safety and there is an argument for greater transparency. However, when balancing factors in favour of and against disclosure we believe the public interest is best served by withholding these documents. We should also explain that following approval of a clinical investigation for a device study, sponsors are informed of reporting requirements for any events arising from the study. Any reported events are assessed by MHRA and action(s) taken as required. Our reporting requirements for clinical investigations are published and can be found here:

<https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device#reporting-requirements>

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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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>