

Dear *****

Further to your request under the Freedom of Information Act 2000 (the Act) dated 26th March 2024, I am writing to confirm the information that the Trust does and does not hold.

The text of your request is repeated below in bold, followed by the Trust's response.

Request

I am emailing to seek the disclosure of information under the Freedom of Information Act 2000 (FOIA).

The information in question relates to the Mirocals clinical trial, which investigated the use of low dose Interleukin-2 for the treatment of ALS (amyotrophic lateral sclerosis). It is now almost two years since the conclusion of the trial and over one year since the high-level results were announced. I ask for the results of the trial to be provided alongside the analysis that has been undertaken of the results, which may be in the form of a draft academic paper intended for publication. I request the release in full of all documents which may contain the information requested above.

The FOIA requires a public interest to be applied and I contend there is a strong public interest in this case. First, the trial has been entirely funded by taxpayers through a grant made under the EU Horizon programme and grants from charitable bodies (most significantly, the MND Association). Second, the high-level results suggest the treatment trialled could have a significant effect on slowing progression of ALS. ALS (also known as motor neuron disease) is a terminal illness, with sufferers only surviving between 2-5 years. The treatment - Interleukin-2 - is already available in NHS pharmacies for the treatment of Kidney cancer but cannot be prescribed without clinical trial data confirming safety and efficacy. It is in the strong public interest of those living with the disease, their families and doctors to have access to this data so that the treatment can be prescribed as a matter of urgency.

I am aware that there are a number of exemptions available to public bodies in relation to freedom of information requests, but I note the following in relation to two of these:

- that the information is already intended to be published (section 22 and 22A). However, where the publication date is not set or is far into the future, a strong public interest can override this exemption. See para 31 of [ICO guidance](#). If the University is concerned that the trial data should only be published after peer review, it would be acceptable disclosure from my perspective if the trial data is at least released for peer review with a clear path for wider publication. It is now almost two years since the completion of the trial so it is already beyond what would be considered a reasonable amount of time for the results to be published. Note that results of Medical Research Council (MRC) funded studies must be published without unreasonable delay, which [the MRC defines as within 12 months of completion](#).

- that disclosure would prejudice commercial interests (section 43). It is important to note that this exemption is *qualified* by the public interest of releasing the information - for the reasons given above, I contend the public interest outweighs any commercial interests as the costs are a matter of life and death for people living with MND. For this exemption to apply, it must also be shown that any impact on commercial interests are *real and significant* - in this case, would the disclosure of the trial results now as opposed to a point in the future have a real detrimental impact on commercial interests? The Mirocals Consortium (of which King's College Hospital is a member) has sold the marketing rights for low-dose Interleukin-2 for ALS to a commercial biotech company, Iltoo. However, Iltoo did not take part in the trial and did not provide any funding for the trial so it is difficult to see how publication now would lead to any commercial loss.

I look forward to your response and to the provision of the requested information. As King's College Hospital is a public body, it must put the interests of the public (specifically people dying from motor neuron disease) before the commercial interest of third parties. If you intend not to provide the information, I expect a full explanation to be provided including specific dates for any publication already planned and the exact nature of any commercial interests.

Could you please confirm (a) the safe receipt of this request and (b) that, as I am happy to have all correspondence and data in electronic form, there will no charge for this request.

Response

We understand that the academic paper is apparently close to completion. Once it is written, it will be submitted to a journal for peer review. I understand that the authors are to encourage submission to a preprint server as well. ("Preprints" are preliminary versions of scientific manuscripts that researchers share by posting to online platforms known as preprint servers before peer-review and publication in an academic journal. Preprint servers are publicly available online archives that host preprints and their associated data). If agreed, it would be available to the public immediately on submission to the journal rather than after peer review. If not agreed, it would be available within the few weeks it takes to publish. In general, something like this is fast-tracked and would take a couple of weeks to be published, at most 6 weeks.

Slides - slides of the clinical trial data are owned by Nimes and Gilbert Bensimon, so we do not have ownership or the right to transfer. Attached however are the abstracts that summarize them if that is helpful, since they are not owned by anyone. The slides contain more detailed information with the data. As MIROCALS has licenced the data to ILTOO, releasing more detailed data than is present in abstracts (as on the slides, or otherwise) contravenes the licence agreement.

Please find attached the following:

- An abstract from the Association of British Neurologists meeting in May 2023

- The 33rd International Symposium abstract booklet - the abstract on page 11.
- An abstract from ENCALS

You can find out more about the Act and other information resources released by the Trust on our website at: www.kch.nhs.uk

If you are dissatisfied with the Trust's response, you may appeal to us in the first instance. For contact details and a copy of our FOI appeal process, please see our website or email us at kch-tr.foi@nhs.net

If you remain dissatisfied, you have the right under section 50 of the Act to apply to the Information Commissioner to seek resolution to the matter. Further details can be found on their website at www.ico.org.uk

I hope this fulfils your request and we would welcome your feedback on our FOI service. Please take the time to complete our Customer Satisfaction Survey which is available online at the following link:

<http://www.surveymonkey.com/s/D28MWWQ>

Kind regards,

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