



**Greater Manchester
Mental Health**
NHS Foundation Trust

Information Governance
Department

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WE ARE SOCIAL



Our reference: /FOI D9438

5th December 2019

Joebloggs@email

Joe Bloggs

Dear Joe,

RE: FREEDOM OF INFORMATION ACT 2000 – INFORMATION REQUEST - REF: D9438

Please find our Trust's response in relation to your request for information under the Freedom of Information Act.

Evidence recently submitted to parliament indicates that the Trust failed to upload any due clinical trial results onto the European trial registry EudraCT between February and October 2019:

<http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/clinical-trials-transparency-followup/written/106563.pdf>

Q1. Has the Trust put into place policies, systems and processes that ensure that in future, every clinical trial sponsored by the Trust will post its summary results on every WHO primary trial registry (including Clinicaltrials.gov and ISRCTN) where it was originally registered within 12 months of trial completion? If yes, please state the month and year in which these were put into place. If no, if applicable, please state the month and year by which these are expected to be in place.

GMMH (formed in Jan 2017) does not take on sponsor responsibility for CTIMPS or medical device trials so our policies/systems and processes only refer to the 'other clinical trial' category. A sponsor oversight framework was created for GMMH in January 2019 and is currently undergoing a pilot phase due to the low number of sponsored clinical trials in this Trust. This framework ensures that the CI signs a CI agreement prior to sponsor authorisation confirming the delegated arrangements for publication and trial registry updates. At close out the sponsor will ensure the delegated party shares a copy of the publication when submitted to the journal and updates the relevant registry(ies) with summary results within 12 months.

Q2. Has the Trust conducted a registry-data based audit of all clinical trials it has sponsored in the past that are listed on trial registries, including all interventional clinical trials listed on

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the registries EudraCT, ISRCTN, and Clinicaltrials.gov, to identify those trials that have never reported their results (i.e. neither on a registry nor on in a peer-reviewed academic journal)? If yes, please state the month and year in which the audit was completed. If no, if applicable, please state the month and year by which such an audit is expected to be completed.

Following the receipt of Transparency Letter our efforts were focused on retrospective CTIMPs. 4 had initially been listed on EudraCT and CESP in March 2019.

A search has now commenced on Clinicaltrials.gov and ISRCTN to retrospectively identify sponsored trials registered and follow up on the status of results. Audit will be completed by the end of December 2019 and actions will be initiated accordingly.

Q3. Has the Trust developed a plan for retrospectively reporting the results of past trials that have remained unreported (i.e. reported neither on a registry nor on in a peer-reviewed academic journal)? If yes, please state the month and year the plan was adopted, and the month and year by which the process of retrospective results posting is expected to be completed. If no, if applicable, please the state the month and year by which such a plan is expected to be adopted.

The plan for retrospective CTIMPs was developed in April 2019 following the receipt of Transparency Letter. Our approach was to prioritise 4 retrospective CTIMPs. As a result we identified the following:

- 1 CTIMP never started and so records have been closed.
- 1 CTIMP- we managed to obtain access to EUDRACT portal and reported a summary result in a pdf format. Also, the CI reported the results in a journal.
- 2 CTIMPs are outstanding in terms of reporting on EUDRACT as manual data entry is required vs a summary in a pdf format. We have approached MHRA to seek further guidance on upload of results due to the format of the results data we are holding in a pdf format and a lack of expertise in this area to follow up with a manual entry. We are awaiting the response. Both CTIMPs results have been published by the CIs in a journal.

For non-CTIMPs, the current audit results should indicate whether any trials have not reported results on the relevant registry and/or published in a peer-reviewed journal and these will be followed up with the CIs accordingly by the end of December 2019.

Q4. By when does the Trust plan to have uploaded all due clinical trial results onto EudraCT?

It depends on MHRA advice we are waiting for in relation to the required data input. If a pdf format is acceptable we will be able to post results immediately. Otherwise we will need seek support to upload data in the required format and would aim to complete this by the end of Feb 2020.

Definitions:

For the purpose of this FOI request, a clinical trial is defined as per the WHO definition: "[A] clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health

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outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.”

FYI: The Trust was listed in the table titled "NHS Trust and university sponsors that remained at 0% reported on the EU Trials Tracker" here:

<https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fdata.parliament.uk%2Fwrittenevidence%2Fcommitteeevidence.svc%2Fevidencedocument%2Fscience-and-technology-committee%2Fclinical-trials-transparency-followup%2Fwritten%2F106563.pdf&data=01%7C01%7CFreedomofInformation%40gmmh.nhs.uk%7C324a4f21a449465a2edf08d76852e5a2%7C0a8053324f1b4f7e9fc9d4b8f03d6174%7C0&data=KC10cRbbvehXayOTA1BeofWFTKkZD3sU03t6Ra1ILRI%3D&reserved=0>

Also:

<https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.trialstracker.net%2Fsponsor%2Fgreater-manchester-mental-health-nhs-foundation-trust&data=01%7C01%7CFreedomofInformation%40gmmh.nhs.uk%7C324a4f21a449465a2edf08d76852e5a2%7C0a8053324f1b4f7e9fc9d4b8f03d6174%7C0&data=KEt97TeXknJ3b0%2Bqx05R6am4XRcCokP7ymRBYjNjgxE%3D&reserved=0>

I hope the information provided above is to your satisfaction. If you are unhappy with the way, the Trust has handled your request you may request an internal review.

If you require an internal review please write to Sarah McDonald, Head of IM&T Service Delivery, at the address above, who will arrange a review of your case.

If you are not happy with the outcome of the internal review you have the right to apply directly to the Information Commissioner: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Yours sincerely

The FOI Team
Freedom of Information Department
Greater Manchester MH NHS Foundation Trust

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For any named personnel provided in this Freedom of Information response, they do not wish to receive direct marketing, to do so would contravene GDPR and the Data Protection Act 2018.

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