From: Freedom of Information
Sent: 11 May 2020 15:43
To:
Subject: Freedom of Information Response (Our Ref: K/20/162)

Dear

Freedom of Information Response (Our Ref: K/20/162)

Thank you for your Freedom of Information (FOI) request dated 15 April 2020, reference K/20/162.

Your request read:

> "Please note that the information requested below is not available from public sources, as data on primary completion dates and the number of participants provided in trial registries other than EudraCT is frequently incorrect and sometimes missing altogether.
>
> INCLUSION CRITERIA
>
> The scope of this FOI request covers all interventional clinical trials completed or terminated between 01 January 2006 and 31 December 2015 for which your institution acted as the primary or lead sponsor [terms interchangeable] at the time of the completion/termination of the trial.
>
> The scope of this FOI request includes all clinical trials that fall into IRAS category 2 "Clinical investigations or other studies of medical devices" and IRAS category 4 "Other clinical trials or clinical investigations" according to current IRAS classifications:
>
> EXCLUSION CRITERIA
>
> Clinical trials of investigational medicinal products (IRAS category 1, "CTMIPs") fall outside the scope of this request.
>
> In addition, those clinical trials of a drug/device combination that meet the detailed criteria set out in IRAS category 3 fall outside the scope of this request. (Note: Some clinical trials of a drug/device combination do *NOT* fall into IRAS category 3 and should thus be included in your response to this request.)
> https://www.myresearchproject.org.uk/help/hlpcollatedqsg-sieve.aspx#928
>
> Trials that never started, and/or that were withdrawn before recruiting any patients, also fall outside the scope of this request, as do all non-interventional studies.
>
> INFORMATION REQUESTED

> Please provide the following information for each trial that falls within the scope of this FOI request:
>
> (1) The trial registry ID number(s) from WHO primary registries and/or Clinicaltrials.gov (if I trial was registered on multiple trial registries, please provide all registry ID numbers)
> (2) Primary completion date (actual, this may differ from date stated in registries)
> (3) Number of participants (actual, this may differ from number stated in registries)
> (4) A link to where trial outcomes were first reported (hyperlink in the case of tabular summary results posted onto a trial registry, DOI in the case of articles published in peer-reviewed journals, hyperlink in all other cases)
>
> Please provide these data in Excel format."

You wrote to us again on 24 April 2020, as follows:

> "Feedback from trial sponsors who received the original FOI request suggests that some institutions may struggle to provide the data because their existing datasets are not structured in line with IRAS categories, but instead only split trials into CTIMPs versus non-CTIMPs.
>
> In order to lessen the burden to responding to this request, you may instead adopt the following inclusion and exclusion criteria if you wish to do so:
>
> INCLUSION AND EXCLUSION CRITERIA
>
> The scope of this FOI request covers all interventional clinical trials completed or terminated between 01 January 2006 and 31 December 2015 for which your institution acted as the primary or lead sponsor [terms interchangeable] at the time of the completion/termination of the trial.
>
> The scope of this FOI request includes all clinical trials, defined as studies that fall into IRAS categories 1-4, with the exception of Clinical trials of investigational medicinal products (CTIMPs) as defined by the MHRA.
>
> CTIMPs, trials that never started, and/or trials that were withdrawn before recruiting any patients, fall outside the scope of this request, as do all non-interventional studies."

The University of Leeds holds some of this information. However, we consider that to respond to your request as it is currently framed would exceed the cost limit as set out in Section 12(1) of the FOI Act. Section 12(1) states that a public authority can refuse a request if complying with it would exceed the appropriate limit of £450. For the purposes of FOI, time spent on the permitted activities is calculated at the flat rate of £25 per person, per hour. The appropriate limit therefore represents the estimated cost of one person spending 18 hours to determine whether the information is held, and to locate, retrieve and extract the information.

We have outlined the reasons for invoking Section 12(1) below.

To provide the information you have requested at parts one to four of your request, we will first need to establish which trials fall within the scope of your request. Your request seeks information in relation to clinical trials between five and 14 years old. Information held which relates to your request is therefore held in a variety of formats and locations (i.e. electronic/paper; on-site/off-site etc.) Some information may also have been destroyed in line with the relevant record retention schedules. There is no single central repository which holds information covering the entire scope of your request, and as such it is likely that extensive manual searching would be required. It would therefore be difficult and time-consuming to establish this initial list of clinical trials which fall within the scope of your request, and without doing so we cannot establish exactly what information we hold. We estimate that this preliminary work alone would be likely to take in excess of 18-hours. Further work would then be required to answer the specific questions you have set out.

Providing this more granular information is extremely difficult at present due to the ongoing Covid-19 pandemic. Information in relation to the number of participants and details of publication is not centrally collated. This would therefore need to be collated from each individual research team. The majority of Chief Investigators (who lead on such projects and therefore hold the information you have requested) are clinical members of staff who are currently working as part of the front-line response to the crisis and therefore not available to assist at this time. While some information may be available via other members of the relevant teams, this is likely to take longer to collate; compounding the total amount of time required to comply with your request.

As such, we are satisfied that it would take over 18 hours to establish what information is held by the University of Leeds, locate and retrieve that information and establish the answers to your questions. As such, section 12(1) is engaged.

Section 16 of the FOI Act obliges public authorities to advise and assist applicants who have made or are looking to make FOI requests. We hope that the following information is helpful to you if you wish to consider submitting a refined request.

In this case, we may be able to provide some limited information in relation to trials with end dates between 2012 and 2015 (which are typically more readily accessible). Information regarding actual end dates and actual number of participants is typically held at the individual team level as outlined above, and as such it is unlikely that we would be able to comply with any request which includes these elements within 18 hours (unless the request was extremely discreet; i.e. for a very small number of specific trials). We do not centrally record information on where trial outcomes were first published as standard. However, this is information which you may be able to locate in the public domain upon receipt of other details you have requested. You may also wish to delay resubmitting your request until the current social distancing measures are lifted or eased, as we may be better able to locate and retrieve information when not remote working/re-deployed.

We hope this information is helpful. Should you wish to submit a refined request you can do so by replying to this email.

If you have any questions, please do not hesitate to contact us on foi@leeds.ac.uk

If you are unhappy with the service you have received in relation to your request and wish to make a complaint or request a review of our decision, you can request an Internal Review. Requests for Internal Review should be made in writing using the following contact information:

Post: Mr D Wardle
Deputy Secretary
The University of Leeds
Leeds
LS2 9JT

Email: foi@leeds.ac.uk

Requests for Internal Review should be submitted within 40 working days of receiving the University's response to your request. Further information about how the University manages Freedom of Information requests and about our complaints procedure is also available on our website (www.leeds.ac.uk).

If you are not content with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Generally, the ICO cannot make a decision unless you have exhausted the review/complaints procedure provided by the University. The Information Commissioner can be contacted at: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

Kind regards

Chloe Wilkins
Freedom of Information Officer

Secretariat
University of Leeds