From: Freedom of Information
Sent: 03 September 2020 16:56
To:
Subject: Freedom of Information Response (Our Ref: K/20/299)

Dear

Freedom of Information Response (Our Ref: K/20/299)

Thank you for your Freedom of Information (FOI) request dated 5 August 2020, reference K/20/299.

Your request read:

> "We are interested in how universities and hospital trusts manage the registration of clinical trials and the reporting of their summary results at the institutional level. For the avoidance of doubt, we are not interested in, nor asking about, trialists sharing of individual patient-level data with re-identification risks nor about specific study-level documentation. Throughout this request, we refer to clinical trials as defined by the WHO (i.e. not just CTIMPs as covered under EU law) (https://www.who.int/health-topics/clinic...).
>
> 1. Please can I request your clinical trials transparency/clinical trial registration and reporting policy or policies, standard operating procedures (SoPs), guidance given to staff, and any other overarching documentation for your institution related to the registration and reporting of clinical trials. If your institution contains sub-units (i.e. CTUs, joint research offices) with their own detailed clinical trials policies and procedures separate from any overarching institutional documentation, please provide these as well.
>
> If you provide more than one document can you please indicate which document(s) primarily cover which of these areas and if possible the relevant sections of the document provided (or acknowledge the absence of documentation covering these areas):
>
> - Requirements related to the registration of clinical trials.
>
> - Requirements for investigators to report the summary results (non-individual patient-level results) of their clinical trials in any form.
>
> - Requirements to report results, specifically, to a clinical trial registry for all clinical trials (e.g. EU Clinical Trial Register, ClinicalTrials.gov, ISRCTN or any other ICTRP approved registry).
>
> - Processes for determining sponsorship of clinical trials, and how sponsorship responsibility is assumed/handed off when new primary investigators (PIs) join or leave the institution.
>
> - If applicable, how responsibility for registration and reporting is handled for trials with external (domestic or international) collaborators.

- If applicable, how registration and reporting is handled for trials funded or co-sponsored with industry, if different from standard procedure.

- Disciplinary actions that may be taken by your institution against investigators failing to comply with any of the relevant policies provided.

Please ensure the effective/publication date of any provided documentation is clear whenever possible.

2. Please provide the following information on university administrative or support staff, not including the Primary Investigators of specific studies, who are explicitly tasked by their job description with oversight in ensuring trials are registered and reported at your institution:

    - the number of staff with any part of their job explicitly related to these activities

    - Full/Whole Time Equivalents (FTE) dedicated to these activities

    - Job titles and descriptions

    - Grades of positions

    - If any of these posts are currently vacant

If these tasks are not centralised within specific individuals, please provide any documentation available which explains how staff undertake trial registration/reporting tasks or acknowledge that no specific documentation exists in this area.

3. Please provide any standard operating procedures, documentation, or relevant policies detailing trials transparency monitoring at your institution either overall or for relevant trial-conducting division(s) within your institution.

If you provide more than one document, or refer to document(s) provided in another response, please indicate which document applies to which of the following criteria and if possible the relevant sections (or if no documentation exists for that criteria):

    - How trial registration and results reporting is monitored at your University.
    - How investigators are notified that results are due to report.
    - Whether past registration and reporting are considered during the process of new trials being planned and approved within the institution.

In addition, please provide any information on disciplinary actions taken by your institution related to clinical trial registration and/or reporting, in the last 5 years and any official audits of clinical trial registration and/or results reporting conducted at your institution in the last 5 years. If this information does not exist, please acknowledge this in your response."

The University of Leeds holds some of this information. For your convenience we have responded to each of your questions in turn below. The information we hold comes from our Sponsor QA team, and our CTRU teams. For ease of understanding, we have provided each answer separately.

1. **Please can I request your clinical trials transparency/clinical trial registration and reporting policy or policies, standard operating procedures (SoPs), guidance given to staff, and any other overarching documentation for your institution related to the registration and reporting of clinical trials. If your institution contains sub-units (i.e. CTUs, joint research offices) with their own detailed clinical trials policies and procedures separate from any overarching institutional documentation, please provide these as well.**

Sponsor QA

Please find the SOPs, Work Instruction and Checklist listed below attached alongside this response:

- QCRES_08_Researchers Guide to End of Trial Procedures
- LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP
- LTU_QM02_LTHT / UoL Sponsorship
- CTC01_Researcher Checklist for UoL/LTHT Sponsored CTIMPs
- CTGN48_QA Guide to the EudraCT Database

Additional CTRU policy:

PO16: Clinical Trial Transparency

For trials fully managed by the CTRU, the responsibility for clinical trial registration and end of trial reporting is often delegated from the Sponsor to the CTRU. In this circumstance, processes are in accordance with the Unit's Quality Management System.

CTRU

If you provide more than one document can you please indicate which document(s) primarily cover which of these areas and if possible the relevant sections of the document provided (or acknowledge the absence of documentation covering these areas):

- **Requirements related to the registration of clinical trials.**

Sponsor QA

It is a condition of sponsorship that the trial has been registered on EudraCT and on a publicly accessible database. Evidence of this is collected during the setup process and must be provided before 'Confirmation of Sponsorship' can be provided as documented in LTU_QM02_LTHT / UoL Sponsorship and CTC01_Researcher Checklist for UoL/LTHT Sponsored CTIMPs.

CTRU
CTRU Policy PO16, Clinical Trials Transparency (attached with the response), describes our overall approach to transparency. It states that all trials are registered in ISRCTN (and in some cases, also in ClinicalTrials.gov) prior to opening to recruitment. Clinical Trials of Investigational Medicinal Products are also registered in EudraCT prior to applying for clinical trials authorisation. All trials must confirm registration as part of the CTRU 'green-light' process, a mandatory approval process that takes place before all CTRU trials are permitted to open to recruitment.

- **Requirements for investigators to report the summary results (non-individual patient-level results) of their clinical trials in any form.**

Sponsor QA
The SOP QCRES_08_Researchers Guide to End of Trial Procedures documents the requirements for investigators to upload results to the relevant registries and databases. An investigator's compliance with the requirements and timelines is overseen by the Sponsor QA team (please see LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP and CTGN48_QA Guide to the EudraCT Database).

CTRU
CTRU Policy PO16 describes CTRU's approach to trial reporting, including that all trials' results are added to the relevant trial registry/registries and, for Clinical Trials of Investigational Medicinal Products, uploading results to EudraCT. Trial teams are responsible for ensuring results are published in accordance with the Unit's standards. Adherence to the timelines associated with end for trial reporting is overseen by the Unit's Quality Assurance Department.

- **Requirements to report results, specifically, to a clinical trial registry for all clinical trials (e.g. EU Clinical Trial Register, ClinicalTrials.gov, ISRCTN or any other ICTRP approved registry).**

Sponsor QA
This is detailed in and LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP and CTGN48_QA Guide to the EudraCT Database.

CTRU
Please refer to PO16: Transparency Policy

- **Processes for determining sponsorship of clinical trials, and how sponsorship responsibility is assumed/handed off when new primary investigators (PIs) join or leave the institution.**

Sponsor QA
The Sponsorship process for CTIMPs is detailed in the SOP LTU_QM02_LTHT / UoL CTIMP Sponsorship.

CTRU
The responsibility for trial registration and end of trial reporting is agreed with the relevant trial sponsor at the beginning of the trial. Where end of trial reporting requirements are delegated to the CTRU standards are in accordance with our Quality Management System. Adherence to the Unit standards in this area is not dependent on PI changes, with the work being carried out by CTRU staff (who are independent of the site clinical team).

- **If applicable, how responsibility for registration and reporting is handled for trials with external (domestic or international) collaborators.**

Sponsor QA
For trials managed by a Clinical Trials Unit (CTU), registration and reporting is formally delegated to the CTU via a Delegation of Responsibilities, however Sponsor oversight is maintained throughout the process. Please see LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP and CTC01_Researcher Checklist for UoL/LTHT Sponsored CTIMPs for further details.

- **If applicable, how registration and reporting is handled for trials funded or co-sponsored with industry, if different from standard procedure.**

Sponsor QA
Not applicable.

CTRU
Not applicable.

- **Disciplinary actions that may be taken by your institution against investigators failing to comply with any of the relevant policies provided.**

Sponsor QA
This would be escalated to the Sponsor representative and other relevant senior management staff as per the escalation routes described in the SOPs LTU_QM_04 and QCRES_08

CTRU

Not applicable within CTRU - investigators are not responsible for this process. Non-compliance issues associated with adherence to end of trial reporting processes are overseen by the CTRU QA department.

2. **Please provide the following information on university administrative or support staff, not including the Primary Investigators of specific studies, who are explicitly tasked by their job description with oversight in ensuring trials are registered and reported at your institution:**

    - **the number of staff with any part of their job explicitly related to these activities**
    - **Full/Whole Time Equivalents (FTE) dedicated to these activities**
    - **Job titles and descriptions**
    - **Grades of positions**
    - **If any of these posts are currently vacant**

    If these tasks are not centralised within specific individuals, please provide any documentation available which explains how staff undertake trial registration/reporting tasks or acknowledge that no specific documentation exists in this area.

Sponsor QA

Three members of staff. 0.5 FTE. The relevant job titles are listed below and the related tasks carried out by these individuals are described in the attached SOPs and Work Instruction:

- Head of Research Integrity and Governance (UoL Sponsor Representative) – Grade 9
- QA Manager – Grade 8
- QA Portfolio Coordinator – Grade 5

None of the listed positions are currently vacant.

As above please see the attached SOPs for details of the tasks undertaken by the staff listed in 2c) in relation to trial registration and reporting.

CTRU

All CTRU staff must follow CTRU Policies and SOPs, including those determining the requirements for trial registration and reporting. Where CTRU is responsible for end of trial reporting and registration a member of the trial team will be delegated the responsibility of ensuring associated tasks are complete in line with the relevant standards. Compliance with trial registration and reporting is overseen by the Unit's Quality Assurance department.

3. **Please provide any standard operating procedures, documentation, or relevant policies detailing trials transparency monitoring at your institution either overall or for relevant trial-conducting division(s) within your institution.**

If you provide more than one document, or refer to document(s) provided in another response, please indicate which document applies to which of the following criteria and if possible the relevant sections (or if no documentation exists for that criteria):

- **How trial registration and results reporting is monitored at your University.**

Sponsor QA
Please see please see LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP and CTGN48_QA Guide to the EudraCT Database for details of how trial registration and reporting of results is monitored.

CTRU
Policy PO16 outlines our overarching approach to trials transparency. The CTRU green-light process ensures all trials are registered before starting recruitment. The Quality Assurance department conducts regular (3-monthly) compliance checks of end of trial reporting requirements.

- **How investigators are notified that results are due to report.**

Sponsor QA
Please see LTU_QM04_LTHT / UoL Sponsor Notification of the End of a CTIMP and CTGN48_QA Guide to the EudraCT Database for details of how trial registration and reporting of results is monitored.

CTRU
N/a; where delegated from the Sponsor, results reporting is the responsibility of CTRU, not investigators.

- **Whether past registration and reporting are considered during the process of new trials being planned and approved within the institution.**

Sponsor QA
This is not taken into consideration.

CTRU
N/a; where delegated from the Sponsor, registration and reporting is CTRU's responsibility.

In addition, please provide any information on disciplinary actions taken by your institution related to clinical trial registration and/or reporting, in the last 5 years and any official audits of clinical trial registration and/or results reporting conducted at your institution in the last 5 years. If this information does not exist, please acknowledge this in your response.

Sponsor QA
No disciplinary actions have been taken in relation to clinical trial registration and / or reporting and no official audits of clinical trial registration and/or results reporting have been conducted in the last five years.

CTRU
No disciplinary actions taken (or required to be taken) in the last 5 years.
Compliance with clinical trial reporting requirements is tracked on an ongoing basis.
Trial registration is verified ahead of all trials opening to recruitment.

We hope this information is helpful. If you have any questions about this email, however, 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