

Mr T Bruckner request-618625-db14c742@whatdotheyknow.com

25 November 2019 Our Ref: FOI/1920/096

Dear Mr Bruckner

Your Freedom of Information Request

Thank you for your email, which was received by the University on 9 November 2019. The University's response is set out in the enclosed document.

Your right to seek a review

Should you be dissatisfied with the way in which the University has dealt with your request, you have the right to require us to review our actions and decisions. If you wish to request a review, please contact the General Counsel, Aston University, Birmingham, B4 7ET or email: foi_requests@aston.ac.uk within 40 working days. Your request must be in a recordable format (letter, email, audio tape, etc). You will receive a full response to your request for review within 20 working days of its receipt.

If you are dissatisfied with the way in which we have handled your request for review you may ask the Information Commissioner to review our decision. You must submit your complaint in writing to the Commissioner within 6 months of receiving the response to review letter. The Commissioner may be contacted at:

Address: Information Commissioner's Office

Wycliffe House Water Lane Wilmslow

Cheshire SK9 5AF

Tel: 0303 123 1113 / 01625 545 745 (+44 1625 545 745 if calling from overseas)

Fax: 01625 524 510

E-mail: notification@ico.gsi.gov.uk
Website http://www.ico.gov.uk/

Yours sincerely

Alice Mineyko Counsel



Your request	Our response
Evidence recently submitted to parliament indicates that the university failed to upload any due clinical trial results onto the European trial registry EudraCT between February and October 2019.	This is incorrect. The trial reported as "missing" was registered at the beginning of 2009 and never started. The University has made multiple requests to update the record on EUCTR but the record has not been corrected.
Q1. Has the university put into place policies, systems and processes that ensure that in future, every clinical trial sponsored by the university 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.	Please refer to the Research Integrity Policy at https://www2.aston.ac.uk/research/documents/Research%20Integrity%20Policy%20-%2031%20Jan%202019.pdf . Questions 2 and 3 are not applicable. All trials are reported in accordance with our statutory obligations and with University policies.
Q2. Has the university 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 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.	
Q3. Has the university 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.	
Q4. By when does the university plan to have uploaded all due clinical trial results onto EudraCT?	Not applicable. There are no results due to be uploaded.