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Rapid external audit of institutional clinical trial registration and reporting: A pilot

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INTRODUCTION

Failure to prospectively register clinical trials and post their results on registries in a timely fashion contributes to the well-documented problem of publication bias in clinical research.[1] Previous attempts at auditing institutional-level performance in trial registration and results posting have sought to generate a complete and comprehensive record of performance (see Table 1). While these audits have been extremely valuable in demonstrating the feasibility of, and laying the groundwork for, future audits by national governments or individual institutions, they were too time-intensive to allow replication by external researchers seeking to produce comparative data on large numbers of institutions for advocacy purposes. Meanwhile, the utility of two pioneering attempts to automatically generate audit data, Open Trials and Trials Tracker, has been limited so far.[2]

Table 1: Three audit models: key features, scope, and methods used

	Thorough REC-level audit Begum et al (2015)	**Thorough institutional-level audit** Tompson et al (2015)	**Rapid institutional-level audit** (Bruckner 2017)
Key features			
Cohort	All clinical trials approved by a UK Research Ethics Committee over two years	All Phase II-IV clinical trials conducted at two UK research institutions over six years	All clinical trials ever conducted by one UK university that were registered on 1 of 3 trial registries
# trials	116 trials	286 trials	151 trials
Staff input	1 person for "most of a year"	Team of 4 people, time unknown	1 person for 2 days (data only)
Strengths	Comprehensive and precise Detects non-registration and outcomes misreporting	Comprehensive and precise Detects non-registration	Low staff input Easy to scale up Does not require institutions' consent or collaboration
Weaknesses	Very time intensive Requires access to REC data	Very time intensive May require access to internal institutional data	Data not comprehensive or precise May double-count trials registered in >1 registry Does not detect non-registration or outcomes misreporting

[1] Till Bruckner & Beth Ellis. 2017. Clinical Trial Transparency: A Key to Better and Safer Medicines. Monograph. Bristol, UK: TranspariMED, April 2017 http://bit.ly/T-MED

[2] For example, OpenTrials does not have a search function enabling users to determine whether trials were registered prospectively or retrospectively. The TrialsTracker only captures Clinicaltrials.gov entries registry.

Utility	Model for comprehensive UK national audit system Academic research	Model for institution-level audits anywhere in the world Academic research	Motivate individual institutions to improve performance
Scope			
Failure to register	YES	YES	NO
Retrospective registration	NO	NO	PARTIAL sub-set of ISRCT
Results: posting on registries*	NO	YES	PARTIAL CT.gov only*
Results: journal articles	YES	YES	PARTIAL all of EudraCT none of CT.gov* sub-set of ISRCTN
Time to publication	YES	YES	NO
Outcomes misreporting	YES	NO	NO
Incomplete or inconsistent registry entries	NO	PARTIAL (sub-set only)	PARTIAL (sub-sets only)
Methods			
Inventory creation	Narrowed down from REC files using set criteria	Combining institutions' annual activity reports, publication list, annual reports, and (for sub-set) information provided by CIs	Search of 3 registries for university's name
Registry searches	Search of 3 registries (EudraCT, CT.gov, ISRCTN) for CTIMPs using 3 variables	Search of 4 registries (EudraCT, CT.gov, ISRCTN, ICTRP) and 3 other data repositories plus manual cross-referencing	Search of 3 registries (EudraCT, CT.gov, ISRCTN) using different methodologies, no cross-referencing
Publication searches	Search of 3 databases (Web of Science, PubMed, Google Scholar) using 2 variables	Search of PubMed, variables unknown	Search of PubMed using only trial number, covering only sub-sets
Time to publication	Manual data extraction	Manual data extraction	n/a
Outcomes misreporting	Manually comparing initial outcome measures (REC) with those stated in journal articles	n/a	n/a
Other methods	n/a	Manual capture of incomplete or inconsistent entries (sub-sets only) Emails to CIs to: determine trial eligibility for inventory, locate missing registry entries, locate missing results	Manual capture of incomplete or inconsistent entries (sub-sets only) Most data collected using different search functions provided by registry websites

** Clinicaltrials.gov is the only registry covered that allows results to be posted using a stand-alone results form. The other two registries only provide fields where links to publications published elsewhere can be entered.*

This paper describes the methodology and findings of a rapid external audit of clinical trials conducted at the University of Aberdeen, UK. The audit found that the University of Aberdeen's trial registration, results posting and trial registry data management practices frequently fall short of best practices in the field as defined by the World Medical Association's Declaration of Helsinki.

OBJECTIVES

The objective of this study was to pilot a rapid external audit of the clinical trial registration, results posting and trial registry data management practices of a single research institution. The methodologies used by previous audits have been time-intensive and cannot easily be replicated on a large scale. In contrast, this pilot aimed to generate a meaningful snapshot of an institution's

clinical trial transparency performance and flag gaps in a matter of days in order to lay the foundations for future rapid audits covering large numbers of institutions.

METHODS

The author searched the three most commonly used clinical trial registries, EudraCT (n=24), Clinicaltrials.gov (n=69), and ISRCTN (n=58), to identify trials in which University of Aberdeen staff had been involved (total n=151). The author then employed a variety of search methodologies to identify cases in which trial registration, results posting and data management fell short of best practices. Search methodologies varied by registry as each registry has unique features offering different opportunities for rapid auditing. Methods and results are thus described separately for each registry, see below. Data extraction and analysis were conducted by one person during just two days, from 14-15 April 2017.

STRENGTHS AND LIMITATIONS

The author did not search for trials that were not registered on the three main registries or check for inconsistencies in outcome reporting across trial protocols, results posted, and journal articles; this was beyond the scope of this study. In addition, due to the limited search strategies employed, the data reported here are unlikely to be comprehensive. For example, efforts to identify journal articles were limited to PubMed searches for trial identification numbers; a broader search strategy would probably have located more publications. Nevertheless, the author is confident that the data generated is sufficient to demonstrate that the University of Aberdeen's current clinical trial registration, results posting and trial registry data management practices fail to meet best practices and thus inform subsequent efforts to advocate with the university to improve its practices.

METHODS AND RESULTS

EUDRACT METHODS AND RESULTS

EudraCT was searched for entries containing the term "University of Aberdeen", yielding a total of 24 trials. Additional data was manually extracted from the 24 entries on the registry. A PubMed search of each trial number was conducted to identify related publications, which were then reviewed and classified as either protocols or results, the latter referring to papers in peer-reviewed journals that reported research findings.

Table 2: Entries containing the term "University of Aberdeen" on EudraCT (n=24)

Trial	Aberdeen role	Start	Status (for UK)	Results	PubMed
2012-000788-26	Contact point	2012	Ongoing	No	0
2012-000201-72	Sponsor	2012	Ongoing	No	0
2006-001559-37	Sponsor	2006	Ongoing	No	0
2005-001332-69	Sponsor	2005	Ongoing	No	0
2006-002731-24	Sponsor	2006	Ongoing	No	0
2006-001109-28	Sponsor	2008	Ongoing	No	1 (protocol only)
2012-000196-17	Contact point	2012	Completed 2014	No	1 (protocol only)
2010-023571-26	Co-Sponsor	2011	Ongoing	No	1 (protocol only)
2007-007638-21	Co-Sponsor	2008	Ongoing	No	0
2006-001125-26	Sponsor	2006	Ongoing	No	0
2013-001984-21	Co-Sponsor	2013	Ongoing	No*	0*
2014-002840-42	Co-Sponsor	2014	Ongoing	No*	0*
2014-000284-40	Co-Sponsor	2014	Ongoing	No	0

2010-019469-26	Co-Sponsor	2010	Ongoing	No	3 (2 papers on results)
2013-001490-25	Co-Sponsor	2013	Ongoing	No*	0*
2008-001069-26	Sponsor	2009	Ongoing	No	0
2010-019129-32	Sponsor	2010	Ongoing	No	0
2011-005292-17	Contact point	2012	Ended 2013	No**	0
2011-005529-34	Contact point	2012	Ongoing	No**	0
2007-002470-59	Trial site	2007	Completed 2010	No**	0
2011-000396-14	Co-Sponsor	2011	Ongoing	No	1 (paper on results)
2012-002866-11	Contact point	2013	Ongoing	No**	1 (paper on results)
2012-002847-28	Contact point	2013	Ongoing	No**	0
2014-002013-37	Contact point	2014	Ongoing	No**	0

* UoA noted that these studies are still ongoing or have not yet commenced. See Annex I.
** UoA noted that these studies were sponsored by a commercial company, not by the university. See Annex I+II.

None of the trials listed as "completed" (n=2) or "ended" (n=1) had posted links to results on EudraCT. At least 3 trials listed as "ongoing" on EudraCT had published their findings in the academic literature, but had failed to post links to these articles on the registry. The author reviewed the related publications and concluded that all 3 trials had in fact been completed. It seems probable that more of the trials listed as "ongoing" are incorrectly classified on EudraCT.

Table 3: Problems in EudraCT entries of Aberdeen trials identified as no longer ongoing (n=6)

Trial	Start	End	Problems detected
2012-000196-17	2012	2014	Completed but no results on EudraCT or PubMed
2010-019469-26	2010	2013?	Mislabeled as "ongoing" No results on EudraCT but PubMed showed 2 papers on results
2011-005292-17	2012	2013	Recorded as "prematurely ended", but unclear why**
2007-002470-59	2007	2010	Completed but no results on EudraCT or PubMed**
2011-000396-14	2011	2014	Mislabeled as "ongoing" No results on EudraCT but PubMed has 1 paper on results[3] Separate entry on Clinicaltrials.gov [NCT01306760] records trial as completed, but no results posted there EudraCT and CT.gov entries not cross-linked via ID numbers[4]
2012-002866-11	2013	2014?	Mislabeled as "ongoing" No results on EudraCT but PubMed showed 1 paper on results**

** UoA noted that these studies were sponsored by a commercial company, not by the university. See Annex I+II.

CLINICALTRIALS.GOV METHODS AND RESULTS

Clinicaltrials.gov was searched for trials whose lead sponsor name matches the exact phrase "University of Aberdeen". The search returned 69 trials in total.

Of these, 21 were listed as "open studies", i.e. not yet recruiting or still recruiting. The author searched PubMed and Google for the 4 trials with the earliest start dates (2010, n=1 and 2014, n=3) and could not find any evidence there that these trials were incorrectly listed as open.[5] However, the registry entry for the oldest open trial, NCT01180712, showed its estimated completion date as

[3] The CONSORT checklist attached to this paper states that the registration number and name of the trial are provided on page 7 of the paper, while in fact they are provided on page 1 only.
[4] Note: OpenTrials failed to detect that this single trial was separately registered in two different registries.
[5] A non-rapid audit would have conducted these searches on all 21 trials. Also, trial NCT01180712, started in 2010, was listed as still recruiting participants, which seems unlikely to be accurate. However, for advocacy purposes, it was sufficient to have documented that the University of Aberdeen failed to update trial data on one registry, EudraCT. The aim here is to flag problems in order to motivate the university to conduct a full audit itself, rather than do the university's work for it.

February 2017, two months before this study was conducted. Also, the four publications linked in that entry were only background literature that had been published before the trial began.[6]

The remaining 48 trials were listed as "closed studies" (44 completed, 2 active, 1 withdrawn, 1 "unknown"). Only one of those 48 trials, NCT01245270, had posted results on the registry (in 2013). Clinicaltrials.gov does not have a search function based on a trial's completion date, but it does allow searches using registration dates. Of the 47 closed trials that had not posted results, 28 had been registered during 2012 or earlier. As the average duration of a clinical trial is around two years,[7] and results should be posted within one year of trial completion, it is highly likely that the results of several trials were overdue.[8]

There are other indications that the university does not ensure the completeness or timeliness of its entries on Clinicaltrials.gov. For example, the last time the university verified the information provided on the trial whose status is listed as "unknown" (NCT01230437) was in 2010. Equally, for some of the trials listed as "completed", the last update or verification was in 2010, even though those trials have not yet posted results and thus cannot be regarded as administratively closed out. Finally, trial NCT01233570 is listed as "completed" but no start or completion date has been entered.

Table 4: Problems in Clinicaltrials.gov entries of Aberdeen trials

Trial	**Problems detected**
NCT01180712	Estimated completion date was out of date
NCT01230437	Status has been listed as "unknown" since last update in 2010
NCT01233570	Start and completion dates missing
Several trials (n>1)	Not verified or updated for several years despite results not having been posted (fact)
Several trials (n>1)	Incorrectly listed as "open study" (assumption) Results not posted more than one year post trial completion (assumption)

ISRCTN METHODS AND RESULTS

ISRCTN was searched for trials whose sponsor name was "University of Aberdeen", yielding 58 trials in total. Of these, 10 were listed as ongoing, 1 as "stopped", and 47 as completed. A search of completed trials for the term "cancer" to generate a smaller subset[9] returned 6 trials. All 6 of these trials had been registered retrospectively in violation of the ethical norms set by the Declaration of Helsinki. In addition, only 2 of the 6 trials had published results in the academic literature. Editorial notes show that ISRCTN has sent reminders to university staff to provide links to publications for 3 out of the 4 non-published trials, albeit without success.

[6] Interestingly, the record of changes shows that the trial's registry entry has been updated 15 times since it was registered in 2010, with the most recent update made in December 2016.

[7] Lisette Pregelj, Martie-Louise Verreynne & Damian Hine. 2015. Changes in clinical trial length. Nature Reviews Drug Discovery 14, 307-308 http://www.nature.com/nrd/journal/v14/n5/full/nrd4611.html

[8] A non-rapid audit would have looked at each trial in more detail. However, the data presented here is sufficient to demonstrate beyond reasonable doubt that the University of Aberdeen has failed to post results for some trials on Clinicaltrials.gov within 12 months of trial completion.

[9] A methodologically superior approach would have been to use randomization to select a sample. Instead, the author opted to select a sub-group based on a search term with emotional resonance among the public in order to generate information more useful to future advocacy efforts.

Table 5: Completed Aberdeen trials containing the word "cancer" on ISRCTN (n=6)

Trial number	Registration	Results links	PubMed links	Editorial notes on ISRCTN
ISRCTN46025196	Retrospective	0	0	*"08/02/2017: No publications found in PubMed, verifying study status with principal investigator."*
ISRCTN29623418	Retrospective	0	0	*"14/02/2017: No publications found in PubMed, verifying study status with principal investigator."*
ISRCTN32435732	Retrospective	0	0	None
ISRCTN73467396	Retrospective	2	2	None
ISRCTN22421875	Retrospective	0	0	*"3/03/2016: No publications found, verifying study status with principal investigator."*
ISRCTN71577271	Retrospective	2	2	None

The researcher manually reviewed the 10 trials listed as "ongoing" and searched PubMed using their trial numbers to determine whether any of these trials had in fact been completed. It appears that none of the 10 trials had been completed. However, at least 2 trials had incomplete and/or inaccurate data entries.[10] 3 trials had been registered retrospectively, most recently in 2015.

Table 6: Details on Aberdeen trials listed as "ongoing" (n=10)

Trial number	Start date	End date	Registration	Updated	Comments
ISRCTN60695184	2009	2020	Prospective	Yes	Only 1 publication linked but PubMed shows 3 publications for this trial Two year delay in updating key data: *Editorial Notes: "07/09/2016: The overall trial end date has been updated from 31/05/2014 to 30/04/2020."* Contradictory data entered: *Two different trial end dates entered in different locations (May 2014 and April 2020)*
ISRCTN93264234	2013	2020	Prospective	Yes	Detailed publication plan provided
ISRCTN49013893	2014	2017	Retrospective	No	No publication plan provided
ISRCTN70688534	2014	2017	Prospective	Yes	Contradictory data entered: *Overall trial end date: 01 June 2017* *Recruitment end date: 31 May 2018*
ISRCTN98970319	2015	2020	Retrospective	Yes	No publication plan provided
ISRCTN61225414	2015	2019	Prospective	No	No publication plan provided
ISRCTN15529655	2016	2018	Prospective	No	No publication plan provided
ISRCTN14542389	2014	2017	Retrospective	No	No publication plan provided
ISRCTN55215960	2016	2020	Prospective	No	No publication plan provided
ISRCTN67875351	2017	2021	Prospective	N/A	Detailed publication plan provided *"Editorial Notes: 13/04/2017: Verified study information with principal investigator."*

Note: the column "updated" captures whether the trial's entry on ISRCTN has been updated since the trial was originally registered.

DISCUSSION

The University of Aberdeen's trial registration, results posting and trial registry data management practices frequently fall short of best practices in the field. This shows that the university has failed to ensure that staff consistently: register all clinical trials before recruitment of the first participant, post or otherwise report all trial results within one year of trial completion, enter complete and accurate information into trial registries, and subsequently keep registry information up to date.

[10] The researcher did not systematically review the registry entries for all 10 trials for incomplete or inaccurate data. Instead, he logged incomplete and inaccurate entries encountered in the course of other searches. There are probably more instances of incomplete or inaccurate data in this sample of trials.

More than 20 out of a total of 151 University of Aberdeen trial registry entries (EudraCT=6, Clinicaltrials.gov>3, ISRCTN>=11) were shown to fall short of best practices; a thorough audit would almost certainly identify numerous additional trials with shortcomings. The rapid external audit approach piloted here generated a snapshot of the University of Aberdeen's clinical trial transparency performance that provides an adequate foundation for subsequent advocacy efforts.

CONCLUSIONS

The whole point of trial registries is to make comprehensive and accurate information easily accessible. Doctors and patients cannot be expected to conduct elaborate and time-intensive searches every time they want to discover, for example, whether a certain trial is still ongoing or results have been published. It is the responsibility of institutions whose staff conduct trials to make comprehensive and accurate trial information easily accessible by ensuring that registry entries are comprehensive, accurate, up to date, and generally meet best practices in the field.

The rapid external audit approach does not aim to do this work for institutions. Instead, by documenting widespread shortcomings, it seeks to generate evidence that can subsequently be used to advocate with institutions to improve their performance, including by themselves conducting regular thorough audits of their clinical trial transparency performance and the policies and processes that underpin performance. The onus is on institutions to ensure full compliance with best practices across their portfolios of trials, not on external researchers to identify and document every single shortcoming within these large portfolios.

Due to the low input of staff time and limited staff skills required, rapid external audits can cover a large number of institutions in the same time needed to thoroughly audit a single institution using existing trial audit approaches. This opens the door to generating ratings and rankings that compare institutional performance within cohorts of multiple institutions, such as leading UK universities, based on non-comprehensive yet meaningful data. Such ratings and rankings have proven successful in other fields at driving improvements in performance. In future, automated trial tracking software could further reduce the time required for rapid external auditing for advocacy purposes. The author hopes that this study will inform the development of such software.

ANNEX I: RESPONSE BY THE UNIVERSITY OF ABERDEEN

UNIVERSITY OF ABERDEEN STATEMENT

The University of Aberdeen provided the following official statement, dated 15 May 2017:

> *"The University of Aberdeen is committed to ensuring transparency in research, avoiding selective publication, and making results readily available to the public.*
> *We already ensure that publication and dissemination of results is brought up in our GCP training so that researchers are made aware of their responsibilities as early as possible, and weekly checks are made on Clinicaltrials.Gov to review any problem records and act upon them. There is no requirement to post results onto this register as none of our trials have as yet fallen under the FDA regulations.*
> *This audit report has helped highlight areas where improvements can be made. We plan to carry out an audit of the of the (known) registry entries and to review our oversight processes. Also, all trial protocols risk assessed for sponsorship shall be required to include a statement confirming UoA commitment to register trials and report results."*
>
> Euan Wemyss
> Communications Officer
> School of Medicine, Medical Sciences & Nutrition
> University of Aberdeen

UNIVERSITY OF ABERDEEN REVIEW OF EUDRACT ENTRIES

The University of Aberdeen on 15 May 2017 provided the following table showing the results of an internal review of European EudraCT clinical trials registry entries that bear the university's name.

The university's comments relating to some trials were subsequently added to the EudraCT results tables in the main study (see above) as footnotes.

Table 7: University of Aberdeen internal review of its EudraCT entries

Trial	Review	Proposed Action by UoA
2012-000788-26	Study did not commence in Aberdeen Sponsorship transferred to UEA on departure of CI.	Status to be updated on registers
2012-000201-72	Study did not commence CI no longer employed by UoA Legislative authorities notified.	Status to be updated on registers
2006-001559-37	5 participants, study did not recruit well. Report sent to MHRA, REC and the funder. Not published.	Status to be updated on registers
2005-001332-69	Published April 2012 CI no longer employed by UoA	Status to be updated on registers Link to be provided to publication
2006-002731-24	Published June 2010 and on PubMed CI no longer employed by UoA	Status to be updated on EudraCT Link to be provided to publication
2006-001109-28	CI no longer employed by UoA No publication received We have been in regular contact emphasising the importance of end of study obligations including uploading results onto EudraCT. Letter issued	Status to be updated on EudraCT Link to be provided to publication when received
2012-000196-17	CI no longer employed by UoA Paper received by UoA but this has not yet been accepted for publication We have made regular contact with CI	Link to be added to publication when available

	emphasising the importance of end of study obligations including uploading results onto EudraCT. The letter has been issued to the CI authorizing them to do this.	
2010-023571-26	CI has left the UoA employ however CTU have made repeated attempts made to upload results in spite of regular website problems. Status to be updated on EudraCT	Status to be updated on EudraCT CTU to update results or link to be provided to publication
2007-007638-21	CI has left employ of UoA. Published 2014 Jan Uploading results was delegated to a researcher who has now retired.	Status to be updated on EudraCT CTU to update results or provide link to publication
2006-001125-26	CI has left employ of UoA.	Status to be updated on EudraCT
2013-001984-21	Active study	
2014-002840-42	Study not yet commenced, temporary halt	
2010-019469-26	Study completed. Published May 2014 Authorization to upload results issued to CTU	Status to be updated on EudraCT
2013-001490-25	Active study	
2008-001069-26	Closed to recruitment. In long term follow up. MHRA, REC and R&D notified Published 2015	Status to be updated on EudraCT Link to be provided to publication
2010-019129-32	CI retired Report received No publication	Status to be updated on EudraCT
2011-005292-17	Not sponsored by UoA. Sponsor was TauRx Therapeutics Ltd	No action required
2011-005529-34	Not sponsored by UoA. Sponsor was TauRx Therapeutics Ltd	No action required
2007-002470-59	Not sponsored by UoA. Sponsor was TauRx Therapeutics Ltd	No action required
2011-000396-14	CI passed away Published 2017	Status to be updated on EudraCT Link to be provided to publication
2012-002866-11	Not sponsored by UoA. Sponsor was TauRx Therapeutics	No action required
2012-002847-28	Not sponsored by UoA. Sponsor was TauRx Therapeutics	No action required
2014-002013-37	Not sponsored by UoA. Sponsor was TauRx Therapeutics	No action required

ANNEX II: TRANSPARIMED COMMENTS ON THE UNIVERSITY OF ABERDEEN'S RESPONSE

Bristol, UK, 20 May 2017

TranspariMED's audit shows that the University of Aberdeen, like many other British universities, is currently not fully meeting its ethical obligations in medical research. However, it is very encouraging that the university takes the issue seriously and has pledged to carry out an audit, update registry entries, and review its oversight processes. Overall, the university's response is extremely positive and should be welcomed by doctors and patients in the UK and beyond.

However, TranspariMED remains concerned about the university's assertion that "There is no requirement to post results onto this register [Clinicaltrials.gov] as none of our trials have as yet fallen under the FDA [US Food and Drug Administration] regulations."

The World Medical Association's Declaration of Helsinki, the most widely cited global standard governing medical research ethics, states that:

> *"No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration… Researchers, authors, sponsors, editors and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports."*

The World Health Organization has adopted a similar position. Thus, there is a clear ethical imperative to post the results of all clinical trials, regardless of the registry used or the intricacies of national legislation. TranspariMED encourages the University of Aberdeen to use its forthcoming review and audit to ensure that all trials are preregistered and all results are posted within one year of trial completion across all registries. Just days ago, ten major research funders and NGOs, including the UK's Medical Research Council and the Wellcome Trust raised the bar for excellence in the field by committing to do exactly that.

Similarly, TranspariMED encourages the University of Aberdeen to use the review to ensure that in future, all clinical trials involving any of its researchers are preregistered and post their results, including in cases where the university itself does not act as the official sponsor of a trial.

To reiterate, overall the university's response is extremely positive and sets an excellent example for other British universities to follow. TranspariMED trusts that the university will rapidly act on its good intentions and hopes it will publish the results of its forthcoming audit to document progress and enable other universities to follow in its footsteps.