

Clinical Trial Reporting: University Policies and Performance in the UK

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1 KEY FINDINGS AND RECOMMENDATIONS

Failure to report clinical trial results is not a victimless crime, it has substantial negative consequences for patients and public health. For this reason, there is a universal ethical obligation to report the results of every clinical trial, regardless of where a trial was originally registered. Reporting trial results in line with global best practices requires posting their summary results onto trial registries within 12 months of trial completion for each and every trial, without exception, irrespective of legal requirements or publication status in the academic literature.

Excellence in reporting the results of research is an integral part of overall research excellence. This report assesses universities' performance against global best practices. We hope that this report will encourage government, parliament, the NHS, regulators, research funders, ethics committees, and – most importantly – universities themselves to widen their focus and ambitions from narrow legal compliance to meeting global best practices.

Key findings

- **Overall, the 27 universities covered by this report have sponsored 1,806 clinical trials listed on the European and American registries with results that are due. Only 9% of these trials have posted their summary results onto these registries. The remaining 91% of due trials – 1,639 trials in total – are missing results.**
- Universities' reporting performance on the European trial registry is far stronger overall than that on the American registry, though performance varies widely by institution. Across universities, 51% of due trials listed on the European registry have posted results, compared to only 3% of due trials on its American counterpart.
- There are considerable gaps in universities' trial registration and reporting policies. For example, only two universities appear to have policies requiring registry entries to be kept up to date. None has proactively published an audit of its trial reporting performance.
- **At least six universities are already actively working on strengthening their policies and/or posting missing results.** The resulting improvements in university performance will only become visible over time. TranspariMED and UAEM will conduct regular follow-up assessments of reporting performance to document universities' progress over time.

Recommendations

- **UNIVERSITIES should post the summary results of all clinical trials – past, present, and future – that they have sponsored onto the registries where trials are listed.** For all ongoing and future trials, universities should post results within 12 months of their primary completion date. Furthermore, universities should sign up to the WHO Joint Declaration and adopt the transparency policies set out therein.
- **THE GOVERNMENT should fully implement all recommendations made in the Science and Technology Committee's 2018 report on clinical trials transparency.** This includes funding a national audit programme covering all clinical trials, and putting into place sanctions, including fines, for trial sponsors that do not post summary results onto registries within 12 months of the primary completion date of any interventional clinical trial.

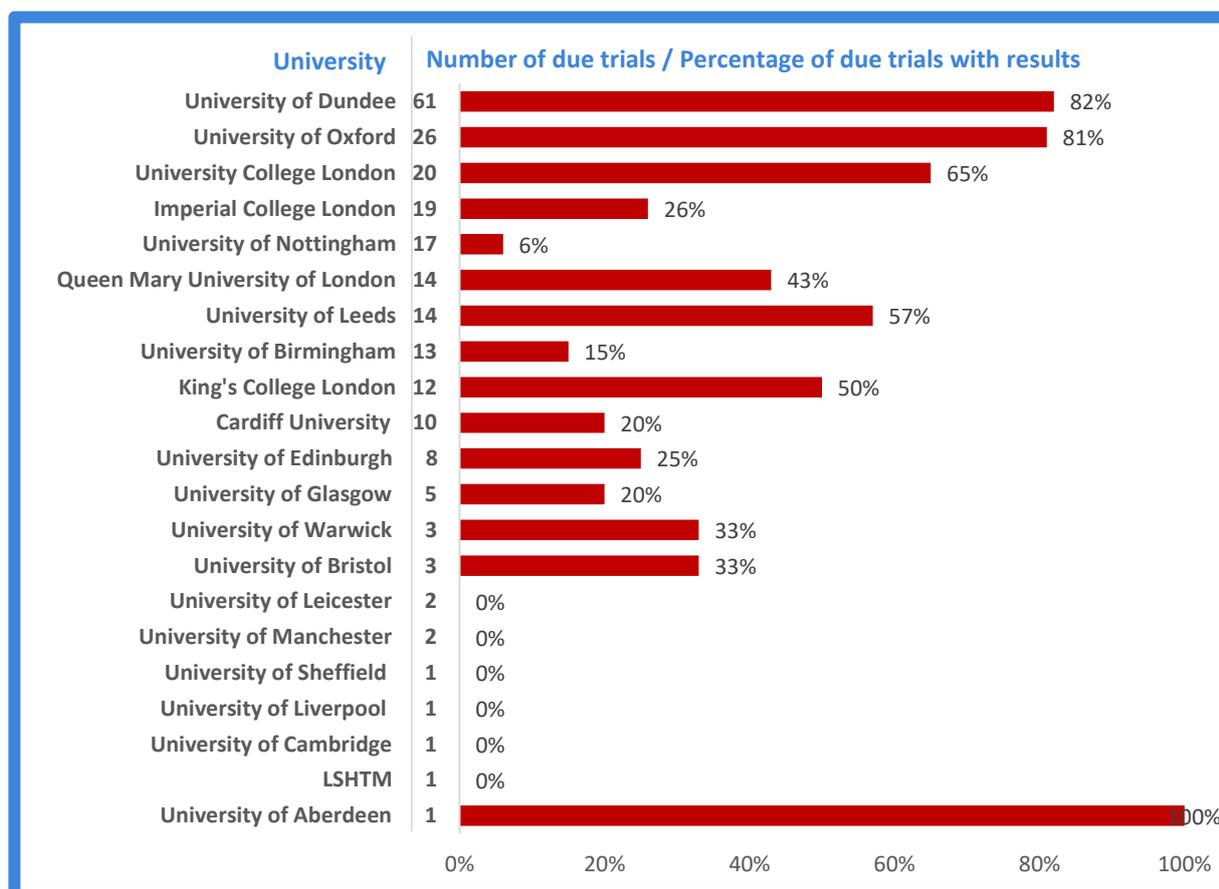
2 REPORTING PERFORMANCE ON THE EUROPEAN REGISTRY

In total, the 27 universities covered by this report have sponsored 234 clinical trials listed on the European registry whose results are due, i.e. whose primary completion date lies more than 12 months in the past. Only 51% of these trials have posted their summary results onto the registry. The remaining 49% of trials – 114 trials in total – are missing results, in violation of European Union guidelines and global best practices.

While most UK universities are still far from fully meeting global best practices, the 51% average reporting performance by this cohort compares favourably with the average Europe-wide rate of just 9% for universities. This probably reflects the fact that some UK universities have taken an early lead in tackling the issue. This report flags some ongoing positive efforts further below.

The performance of UK universities varies widely. Among the universities with five or more due trials listed on the registry, the top performers are Dundee (82% reported) and Oxford (81% reported). The major sponsors with the worst performance are Cardiff and Glasgow (both 20%), Birmingham (15%), and Nottingham (6%).

Chart 1: Universities’ trial reporting performance on the European trial registry EUCTR



Note: The universities of Exeter, Reading, Southampton, Sussex, and the Liverpool School of Tropical Medicine have no due trials listed on the European registry and are thus not included in the chart above.

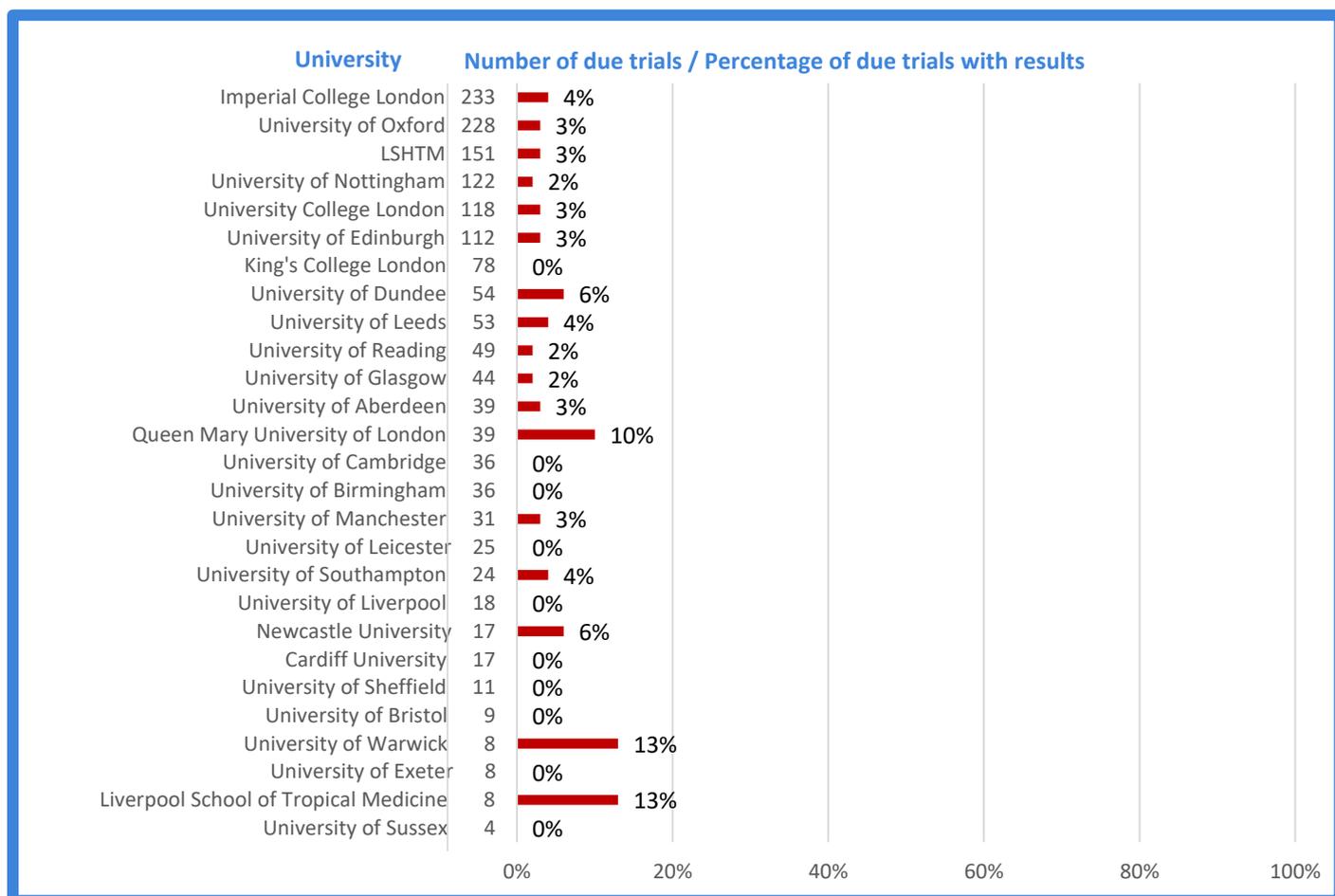
3 REPORTING PERFORMANCE ON THE AMERICAN REGISTRY

In total, the 27 universities covered by this report have sponsored 1,527 clinical trials listed on the American registry whose results are due. Only 3% of these trials have posted their summary results onto the registry. The remaining 97% of trials – 1,525 trials in total – are missing results, in breach of global best practices. Some of these trials [may also be in violation of the FDA Amendments Act](#).

At present, the performance of all universities is still weak on this registry. For example, the University of Oxford – which performs strongly on the EU registry – has only posted results for 7 of its 228 trials that are due results. This indicates that even universities that are committed to excellence in trial reporting still have a long way to go until they meet global best practices across their full trial portfolios.

On the positive side, at least one UK university has already started the process of posting missing trial results onto the American registry (see further below).

Chart 2: Universities’ trial reporting performance on the American trial registry Clinicaltrials.gov



4 SUMMARY DATA AND OVERVIEW OF POLICIES

Overall, the 27 universities covered by this report have sponsored 1,806 clinical trials listed on the European and American registries whose results are due. Only 9% of these trials have posted their summary results. The remaining 91% of trials – 1,639 trials in total – are missing results across the two registries, in breach of global best practices.

A review of publicly available university policies indicates that there are considerable gaps in trial registration and reporting policies in the sector. For example, it appears that only two universities have policies that require registry entries to be regularly updated, and none of them proactively publish trial registration and reporting audit reports.¹

University policies were assessed against the following criteria:

Trial registration policies

- A1. An audit of trial registration performance has been made public within the last 12 months
- A2. The university has a publicly available policy that requires registry entries to be regularly updated
- A3. The university has a publicly available policy that requires [some or all] clinical trials to be registered before the first subject receives the first medical intervention
- A4. The university has a publicly available policy that requires all clinical trials to be registered
- A5. The university has a publicly available policy that requires some clinical trials (e.g. CTIMPs) to be registered. [We scored this as well if the university required all trials to be registered, to provide additional ‘points’.]

Summary results posting policies

- B1. An audit of summary results posting performance has been made public within the last 12 months
- B2. The university has time-specific plans to retrospectively post missing summary results for university-sponsored clinical trials completed in the past
- B3. The university has a publicly available policy that requires [some or all] clinical trials to post summary results within 12 months of their primary completion date.
- B4. The university has a publicly available policy that requires all clinical trials to post summary results.
- B5. The university has a publicly available policy that requires some clinical trials (e.g. CTIMPs) to post summary results. [We scored this as well if the university required all trials to post results, to provide additional ‘points’.]

The chart on the following page shows the overall reporting performance of UK universities across the European and American trial registries, and provides an overview of sector policies on trial registration and reporting. Please note that the policy data presented below may not capture the full range of each university’s policies, and should therefore be regarded as a snapshot of the sector as a whole, rather than as a definitive account of individual universities’ policies (see the ‘Limitations’ section further below for details.)

¹ The University of Aberdeen in 2017 conducted an audit of its reporting performance on the European registry; this became publicly available only following an FOI request. AllTrials campaign [recommendation to universities](#): “Conduct regular public audit of compliance with your own policies, setting out proportion of registered trials [and] proportion of trials with reported results”. In line with the SciTech Committee’s recent recommendations, audit results should be made public, including line-by-line data on every individual trial.

Chart 3: Universities’ overall trial reporting performance and policies

University	MRC research grants (2015-2016)	Overall reporting performance (Clinicaltrials.gov + EUCTR)			Publicly available clinical trial policies									
		Due trials	With results	Results missing	Registration					Reporting				
					A1	A2	A3	A4	A5	B1	B2	B3	B4	B5
Cardiff University	£5,179,000	27	2	25	0	1	1	0	1	0	0	0	0	0
Imperial College London	£21,222,000	252	15	237	0	0	1	1	1	0	0	0	0	0
King’s College London (KCL)	£20,468,000	90	6	84	0	0	1	0	1	0	0	1	0	1
Liverpool School of Tropical Medicine (LSTM)	£4,278,000	8	1	7	0	0	0	0	0	0	0	0	0	0
London School of Hygiene and TM (LSHTM)	£10,475,000	152	5	147	0	0	0	0	0	0	0	0	0	0
Newcastle University	£8,093,000	17	1	16	0	0	0	0	0	0	0	0	0	0
Queen Mary University of London	£4,410,000	53	10	43	0	0	0	0	0	0	0	0	0	0
University College London (UCL)	£48,200,000	138	16	122	0	0	0	0	1	0	0	0	0	0
University of Aberdeen	£985,000	40	2	38	0	0	1	0	1	1	1	1	0	1
University of Birmingham	£6,545,000	49	2	47	0	0	1	1	1	0	0	1	1	1
University of Bristol	£9,015,000	12	1	11	0	0	1	1	1	0	0	0	0	0
University of Cambridge	£33,092,000	37	0	37	0	0	1	0	1	0	0	1	0	1
University of Dundee	£9,205,000	115	53	62	0	0	1	0	1	0	0	1	0	1
University of Edinburgh	£34,578,000	120	5	115	0	0	1	1	1	0	0	1	0	1
University of Exeter	£2,436,000	8	0	8	0	0	0	0	0	0	0	0	0	0
University of Glasgow	£16,255,000	49	2	47	0	1	1	1	1	0	0	0	0	0
University of Leeds	£4,193,000	67	10	57	0	0	0	0	0	0	0	0	0	0
University of Leicester	£4,228,000	27	0	27	0	0	1	1	1	0	0	1	1	1
University of Liverpool	£6,754,000	19	0	19	0	0	0	0	0	0	0	1	0	1
University of Manchester	£14,186,000	33	1	32	0	0	1	1	1	0	0	0	0	0
University of Nottingham	£6,995,000	139	3	136	0	0	0	0	0	0	0	0	0	0
University of Oxford	£53,034,000	254	28	226	0	0	0	0	1	0	0	1	0	1
University of Reading	£1,477,000	49	1	48	0	0	0	1	1	0	0	0	0	0
University of Sheffield	£6,570,000	12	0	12	0	0	1	0	1	0	0	1	0	1
University of Southampton	£5,277,000	24	1	23	0	0	0	0	0	0	0	0	0	0
University of Sussex	£3,275,000	4	0	4	0	0	0	0	0	0	0	0	0	0
University of Warwick	£3,317,000	11	2	9	0	0	0	0	0	0	0	0	0	0
TOTAL	£343,742,000	1806	167	1639										

Note: Some universities have joint policies with external parties, such as local NHS bodies. Such policies were assessed as university policies, and are included in the chart above.

5 WHY THIS MATTERS

Focus on research excellence

Excellence in reporting the results of research is an integral part of overall research excellence.

Therefore, this report focuses on research excellence rather than on narrow legal and regulatory compliance. It does this by assessing universities' performance on both the European trial registry EUCTR and the world's largest trial registry, Clinicaltrials.gov.

The inclusion of Clinicaltrials.gov data in assessing universities' performance is fully aligned with best practices set out by the World Health Organisation (WHO), Cochrane, Transparency International, and the AllTrials campaign (see below).

Relevance to public health and clinical practice

Failure to report clinical trial results is not a victimless crime. A 2017 [report](#) by Transparency International and Cochrane documents that the failure to adequately report trial results has substantial negative consequences:

- Patients are harmed
- Public health agencies cannot make informed decisions
- Public health funds are wasted
- Medical progress is slowed down
- Shareholders are exposed to substantial risks

There is a [universal ethical obligation](#) to report the results of every clinical trial, regardless of where a trial was originally registered. There are good reasons for this. For example, the ongoing [controversy around vaginal mesh implants](#) painfully illustrates that millions of patients' lives and wellbeing depends on medical devices being effective and safe. However, medical device trials currently [cannot be registered on the European registry](#), so UK universities often register them on Clinicaltrials.gov (or the ISRCTN registry) instead.

Global best practices

[WHO best practices](#) require every interventional trial to post its results on every public registry where it was registered within 12 months of its primary completion date. Importantly, the WHO has explicitly stated that publishing trial results in the academic literature is not an acceptable substitute for posting trial results onto public registries.

[Best practices jointly set out by Cochrane and Transparency International](#) also state that "Summary results for all clinical trials should be posted on the registries where they were originally registered within 12 months of study completion." The two health integrity groups note that retrospectively posting the results of all past trials onto registries "would improve healthcare delivery and government agencies' decision-making on resource allocations, as well as saving billions of dollars' worth of medical research from being lost forever."

Similarly, the trial reporting [benchmark set out by the AllTrials campaign](#) states that "A summary of results (...) should be posted where a trial was registered within one year of completion of a trial." The AllTrials' over 700 supporter groups include key UK stakeholders such as the British Medical Association, the Health Research Authority (HRA), the Association of Medical Research Charities (AMRC), and NICE.

Again, there are several good reasons for this emphasis on posting all trial results onto registries:

- Posting results onto registries accelerates medical progress because the 12-month timeline permits far more rapid results sharing than the slow academic publication process allows.
- Posting results onto registries minimises the risk of a trial never reporting its results and becoming research waste, which can happen when a principal investigator dies or leaves their post during the prolonged process of submitting an academic paper to a succession of medical journals.
- Research shows that trial results posted on registries typically give a more comprehensive and accurate picture of patient-relevant trial outcomes than corresponding journal articles do.
- Results posted on registries are easier to locate and are open access.
- Registry reporting facilitates comparison of trial outcomes with a trial's originally stated aims, and thus discourages harmful research malpractices such as the 'silent' suppression, addition, or [switching of selected outcomes](#), [HARKing](#), and [p-hacking](#).

Public spotlight on universities' trial reporting performance

A [recent study](#) by the team at Oxford University's EBM Data Lab found that 89% of applicable clinical trials sponsored by European universities have failed to post results on the European trial registry, EUCTR, in violation of EU guidelines which require trials listed there to post results within 12 months of their primary completion date (6 months for paediatric trials).

The EBM Data Lab team reviewed a sample of trials without registry results and found that around half of those trials had not reported their results in the academic literature either. Assuming the ratio is similar for trials sponsored by UK universities, over 50 of their 114 trials identified are likely to not have reported their results anywhere. Such trials make contribute nothing to progress in science and public health, and are therefore [research waste](#).

Following the release of the study, the AllTrials campaign [publicly questioned](#) whether universities that had failed to post results of all of their on the registry should receive further public funding or ethics approval for future trials. Similarly, the German health technology assessment institute [called for sanctions be to imposed](#) on non-compliant universities. Between them, the 27 universities in our cohort received a total of £343,742,000 in research grants from the UK Medical Research Council in the year 2015-2016 alone.

Science and Technology Committee report on clinical trials transparency

The EBM Data Lab's study's [data set](#) shows that no UK university sponsoring a large number of trials listed on the European registry has achieved 100% compliance with EU trial disclosure rules. During recent hearings of the UK House of Commons Science and Technology Committee, both Sam Gyimah MP, the Minister for Universities, and Dr Patrick Vallance, the Government Chief Scientific Adviser, stated that universities should, in their words, "[sort it out](#)".

In late October 2018, the Committee issued a [report on clinical trials transparency](#), which recommended that "[e]very university should aim for 100% compliance," that the UK's Health Research Authority should monitor compliance, and that universities that fail to achieve compliance should be sanctioned, including through the imposition of fines. (See [here](#) for a summary.)

Importantly, the national audit programme proposed by the Committee [would cover all clinical trials](#) that receive ethics approval in the UK. This would include trials registered on EUCTR, Clinicaltrials.gov, ISRCTN, and all other [WHO primary registries](#), as well as the [minority of trials that universities fail to register in the first place](#).

The report was welcomed by transparency advocates and patients, and the Health Research Authority [responded positively to its recommendations](#). The UK government will issue a formal response to the report by the end of 2018.

Strong momentum towards universal results posting across all trial registries

As this report shows, some universities already have a strong results posting performance on the European trial registry. Others are working to fix the problem, but their positive efforts are not yet publicly visible.

In response to Freedom of Information requests, several universities of their own accord reported on-going efforts to strengthen their policies and processes, and/or post missing trial results onto registries. These are:

- Cardiff University
- Imperial College London
- Liverpool School of Tropical Medicine
- University of Aberdeen
- University of Exeter

In addition, [the University of Bristol is already aiming for excellence](#) by systematically posting missing trial results across all three registries frequently used by UK universities: EUCTR, Clinicaltrials.gov, and ISRCTN. Note that Bristol does not currently score highly on performance metrics, illustrating that there is a time lag between the initiation of clean-up efforts and public visibility of positive impact.

More universities are likely to initiate such positive efforts soon in response to the Science and Technology Committee's recent report. TranspariMED and UAEM expect that all UK universities will eventually follow the lead of today's transparency front-runners, and will document the sector's progress by conducting follow-on rankings (possibly including ISRCTN data) over the coming months and years.

We hope that this report will encourage universities and other stakeholders – government, parliament, the NHS, regulators, research funders, and ethics committees – to widen their focus and ambitions from narrow legal and regulatory compliance to meeting global best practices.

6 FUTURE PLANS

Clinical trial transparency benefits patients and improves public health. As this report has noted, many UK universities are already taking positive steps in the right direction, and we expect the rest of the sector to follow their lead soon. The discussion is rapidly shifting from whether to report all trial results to how best to do so. In this context, we look forward to a constructive dialogue with universities over the coming months and years about how we can all work together to drive further improvements in policies, processes and practices in the UK and beyond.

- **UAEM UK and TranspariMED plan to regularly publish similar reports on UK universities' clinical trial reporting performance on trial registries to document progress over time.** Future reports are likely to cover a larger number of UK universities, and may include data from the ISRCTN registry in addition to data from EUCTR and Clinicaltrials.gov. We welcome suggestions from universities on how to improve our measurement and presentation of their performance. In addition, TranspariMED is keen to hear from pioneering UK universities about how they are tackling the issue in order to help others to learn from their experiences.
- **Clinical trial transparency will form an integral part of the forthcoming Global Health Report Cards by UAEM UK, Students for Global Health, and TranspariMED.** The Global Health Report Cards will include additional sections on global health equity in innovation and research, access to medicines, open-access publishing, and global health education. Universities will be ranked according to their performance across all sections, including clinical trial transparency. We may update the data on clinical trial reporting performance on EUCTR and/or Clinicaltrials.gov prior to publishing the Global Health Report Cards. We encourage universities to actively engage with UAEM UK, Students for Global Health, and TranspariMED during the process of collecting data for the Global Health Report Cards.
- **UAEM UK plans to re-assess university policies on trial registration and trial reporting in a few years' time,** when the Global Health Report Cards will be reiterated. Future assessments may cover the full range of policy elements set out in the WHO Joint Statement.

7 USEFUL RESOURCES FOR UNIVERSITIES

[WHO Joint Statement](#)

The statement sets out WHO best practices in clinical trial registration and reporting, with a focus on trial registries. Universities can assess their policies against WHO standards by using [this checklist](#). Some of the basic rules governing trial reporting on registries are [explained here](#).

[How to tackle clinical trial transparency](#)

This brief case study, written by the Head of Research Governance at the University of Bristol, contains useful hands-on advice for universities wishing to tackle the issue.

[CONSORT Statement](#)

The CONSORT Statement comprises a 25-item checklist and a flow diagram for reporting clinical trials in the academic literature.

[Clinical trial transparency: A guide for policy makers](#)

This report summarizes the academic literature on the causes and consequences of opacity in clinical trials, and flags relevant laws, regulations and best practices.

8 METHODOLOGY AND LIMITATIONS

Authorship

Overall project lead:	Sarai Keestra (UAEM)
Methodology design:	Sarai Keestra (UAEM), Sophie Gepp (UAEM), Till Bruckner (TranspariMED)
EU registry data:	Extracted via the EU Trials Tracker (EBM Data Lab, University of Oxford)
US registry data:	Generated via an Excel pivot tool built by Sean Lee (UAEM)
Policy ratings:	Sarai Keestra (UAEM), Sophie Gepp (UAEM), Till Bruckner (TranspariMED)
Cover and charts:	Elizabeth Kracik-Dyer (UAEM)
Lead report writer:	Till Bruckner (TranspariMED)

Methodology

- Cohort selection

The 27 universities included in the study cohort are the same universities that are currently under assessment for the Global Health Report 2017-2019, which are being developed jointly by Universities Allied for Essential Medicines UK in collaboration with Students for Global Health and TranspariMED.

The cohort includes the 25 universities that received that largest sums of Medical Research Council funding in the year 2015-2016. In addition, 2 universities that had been included in the previous [Global Health Report 2013-2014](#) were also included to enable the tracking of their performance over time.

The Global Health Report 2013-2014 report did not include a section on clinical trial transparency. The Global Health Report 2017-2019 will include such a section; this will draw on the methodology and data used in this report.

The cohort is comprised of the following 27 universities: Cardiff University, Imperial College London, King's College London (KCL), Liverpool School of Tropical Medicine (LSTM), London School of Hygiene and Tropical Medicine (LSHTM), Newcastle University, Queen Mary University of London, University College London (UCL), University of Aberdeen, University of Birmingham, University of Bristol, University of Cambridge, University of Dundee, University of Edinburgh, University of Exeter, University of Glasgow, University of Leeds, University of Leicester, University of Liverpool, University of Manchester, University of Nottingham, University of Oxford, University of Reading, University of Sheffield, University of Southampton, University of Sussex, and University of Warwick.

- Reporting performance on the European registry ([EUCTR](#))

Data on the reporting performance on the European registry (EUCTR) was manually extracted by SK using the [EU Trials Tracker](#) built by EBM Data Lab, University of Oxford, which uses information publicly available on EUCTR. To the best of the authors' knowledge, to date no instances of a trial incorrectly flagged as being due and missing results by the EU Trials Tracker have been detected. The tracker data was extracted on the 01 November 2018 and manually entered into an Excel spreadsheet by SK.

- Reporting performance on [Clinicaltrials.gov](https://clinicaltrials.gov)

Data on the reporting performance on the American registry (Clinicaltrials.gov) was generated using an Excel pivot tool built by SL according to specifications developed by TB. A manual verification of 26 trials was performed by TB to assure the accuracy of results returned.

The tool uses the following criteria:

- Only interventional studies (clinical trials) are included
- University is listed as lead sponsor of a trial
- Trials with a 'withdrawn' status are excluded
- Primary completion date is at least 13 months in the past

Trials that did not present a primary completion date, be it tentative or actual, was simply treated as overdue. Analysis was done with the best precision possible for each trial. Trials that only gave a month and a year for a primary completion date were assumed to have completed the trial on the first of the month. To account for this, an additional 30 days (1 month) was included to the original grace period of 12 months making 13 months.

The dataset used for this analysis was downloaded from Clinicaltrials.gov on 01 November 2018 and analysed by SL. The full dataset [has been posted online](#) together with an [explanatory note](#) to enable external verification of the data presented in this report.

The Excel pivot tool itself [has been posted on Github](#) together with instructions for use and can be downloaded from there and used to by third parties to conduct similar assessments. The authors encourage universities themselves to make use of this tool to identify due trials without results. The authors welcome critical feedback on the tool, which they plan to re-use for future follow-on assessments.

- University policies

Universities were assessed on the ten policy elements listed within the main body of the report (see further above). The assessment criteria were jointly developed by SK, SG, and TB as a simplified version of the [policy elements of the WHO Joint Statement](#).

TB obtained university policies by filing Freedom of Information (FOI) requests with all 27 universities on 28 June 2018. The FOI requests linked to a [background document](#) explaining the rationale, methodology and assessment criteria of the forthcoming report in detail. The FOI requests, wording of the questions, and responses received are [publicly available on the WhatDoTheyKnow platform](#). No university reported problems with understanding the requests, and all universities responded.

SK, SG and TB independently assessed the responses of each university against the pre-defined assessment criteria. As per the pre-defined assessment criteria, only publicly available policies were rated. Some universities reported joint policies shared with external parties, such as local NHS bodies. As per the original study design, such policies were assessed as university policies. Disagreements were resolved by consensus between all three raters.

Rating results were shared with most, but not all, universities for respondent validation. Several universities responded. In one case, the team after internal discussion amended the original assessment results. Note that the assessment team had difficulties in ensuring the completeness and accuracy of policy data across all universities (see below).

Limitations

- Trials not listed on EUCTR or Clinicaltrials.gov

Trials sponsored by universities that had not been registered on EUCTR or Clinicaltrials.gov were beyond the scope of this report. This includes trials registered on other WHO primary registries, notably ISRCTN, and trials that have never been registered on any public registry.

- Trials listed on both EUCTR and Clinicaltrials.gov

Some trials covered by this report were registered on both EUCTR and Clinicaltrials.gov. These trials were double counted in the performance data.

- Reporting performance on EUCTR

Some trials sponsored by the universities in the cohort were flagged as having “incomplete data” by the EU Trials Tracker. In keeping with the tracker’s established methodology, such trials were not included in the data set of due trials. In addition, the tracker is unable to identify completed trials erroneously listed as still ongoing on EUCTR; therefore, such trials were also not included in the data set of due trials. More research is required to enable estimates of the proportion of trials with “incomplete data” and trials falsely listed as ongoing on EUCTR that are in fact due to post results.²

- Reporting performance on Clinicaltrials.gov

Past studies of Clinicaltrials.gov reporting performance have commonly only included trials marked as ‘completed’ by the registry. This widespread but flawed approach results in a substantial undercounting of due trials. [Previous research by TranspáriMED](#) has shown that numerous completed trials sponsored by UK universities are falsely listed as not completed on various registries, presumably because university staff failed to update trials’ status after trial completion.

The Excel pivot tool used for this report uses a trial’s primary completion point as the key criterion to determine whether or not a trial is due to post results. This approach is likely to slightly over-count due trials. For example, if a trial’s expected primary completion date is extended during the trial due to slower than expected patient recruitment, and university staff fails to update the registry entry accordingly, the expected primary completion date listed in the registry will be further in the past than the actual or currently expected primary completion date.

On balance, the approach used here has two significant advantages:

- In terms of accuracy, the number of trials falsely identified as overdue using this approach is assumed to be substantially lower than the number of trials falsely identified as not yet due when using the conventional approach.
- In terms of faithfully depicting a university’s registry management performance, this approach is preferable because it will never³ falsely identify trials as overdue if a university keeps its registry entries up to date. Thus, the approach used here incentivises

² Note that a [2018 study](#) of 10,492 trials registered on both Clinicaltrials.gov and EUCTR by Jessica Fleming and Ben Goldacre showed that 33.9% of dual-registered trials listed as 'ongoing' on EUCTR were listed as 'completed' on ClinicalTrials.gov.

³ Trial sponsors can request an extension of the legal results posting deadline on Clinicaltrials.gov under certain circumstances. However, while such extensions have legal significance in terms of FDAAA compliance, they have no bearing on a trial’s adherence to global best practices. (Furthermore, it is unlikely that UK universities frequently – if ever – request such extensions with U.S. authorities.)

universities to keep their registry entries up to date. In contrast, the conventional approach creates perverse incentives for trial sponsors to postpone or neglect updating a trial's status to 'completed'.

- University policies

The utility of the data on university policies is limited to providing an impressionistic picture of general sector performance. It should not be taken to accurately reflect the strengths or weaknesses of any individual university's current policies.

The assessment team decided after discussion not to quantify the policy performance of each university by adding up assessment scores, as had originally been planned. As the main body of the report explicitly states:

"Please note that the policy data presented below may not capture the full range of each university's policies, and should therefore be regarded as an impressionistic snapshot of the sector as a whole, rather than as a definitive account of individual universities' policies."

This decision was taken for two reasons. First, the authors were unable to verify assessment results with 5 out of the 27 universities. These 5 universities had relevant policies and/or Standard Operating Procedures (SOPs) that were partially or wholly inaccessible to the public, for example because they were posted on the university's intranet rather than on its website. Due to time constraints, it was impossible to give these 5 universities the opportunity to place their policies/SOPs online, assess the new material, and validate the assessment results with these universities.

After internal discussion, the researchers agreed that for the purposes of compiling this report, it was not desirable to only rate publicly accessible policies (as had originally been planned), because this would have resulted in substantially lower scores for some or all of the 5 universities concerned, without giving these universities the opportunity – i.e. sufficient time – to place relevant documents online.

As a compromise solution, the data presented in this report does not take into account non-public policies/SOPs; at the same time, the report does not contain the originally planned comparative quantitative scoring of university policies.

Looking forward, UAEM and TranspariMED strongly encourage all universities to place all policies/SOPs relevant to trial registration and trial reporting online. Most universities already do so, and the researchers are not aware of any reason why such policies/SOPs should not be public.

An additional limitation was the need to make difficult judgement calls where policy elements could not be unambiguously assigned to binary Yes/No assessment categories. For example, the University of Sheffield informed the researchers via email that its Clinical Trials Research Unit (CTRU) was "[o]ne of the key areas of the University which undertakes clinical trials", and that "[a]side from the CTRU, clinical trials in other areas of the University are highly likely to be undertaken in collaboration with the local NHS Trust, Sheffield Teaching Hospitals NHS Foundation Trust. Collaborative clinical research is supported by the CRIO, a partnership between the University and the Trust..." Both the CTRU and the CRIO have relevant but different policies/SOPs (which are not public in the case of the CTRU, but are public in the case of the CRIO). This made it difficult to objectively determine which – if any – of the two sets of policies it would be appropriate to rate.

A final limitation is that the original FOI requests were filed in late June 2018, so any recent changes in policies and/or SOP are not documented in this report.

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