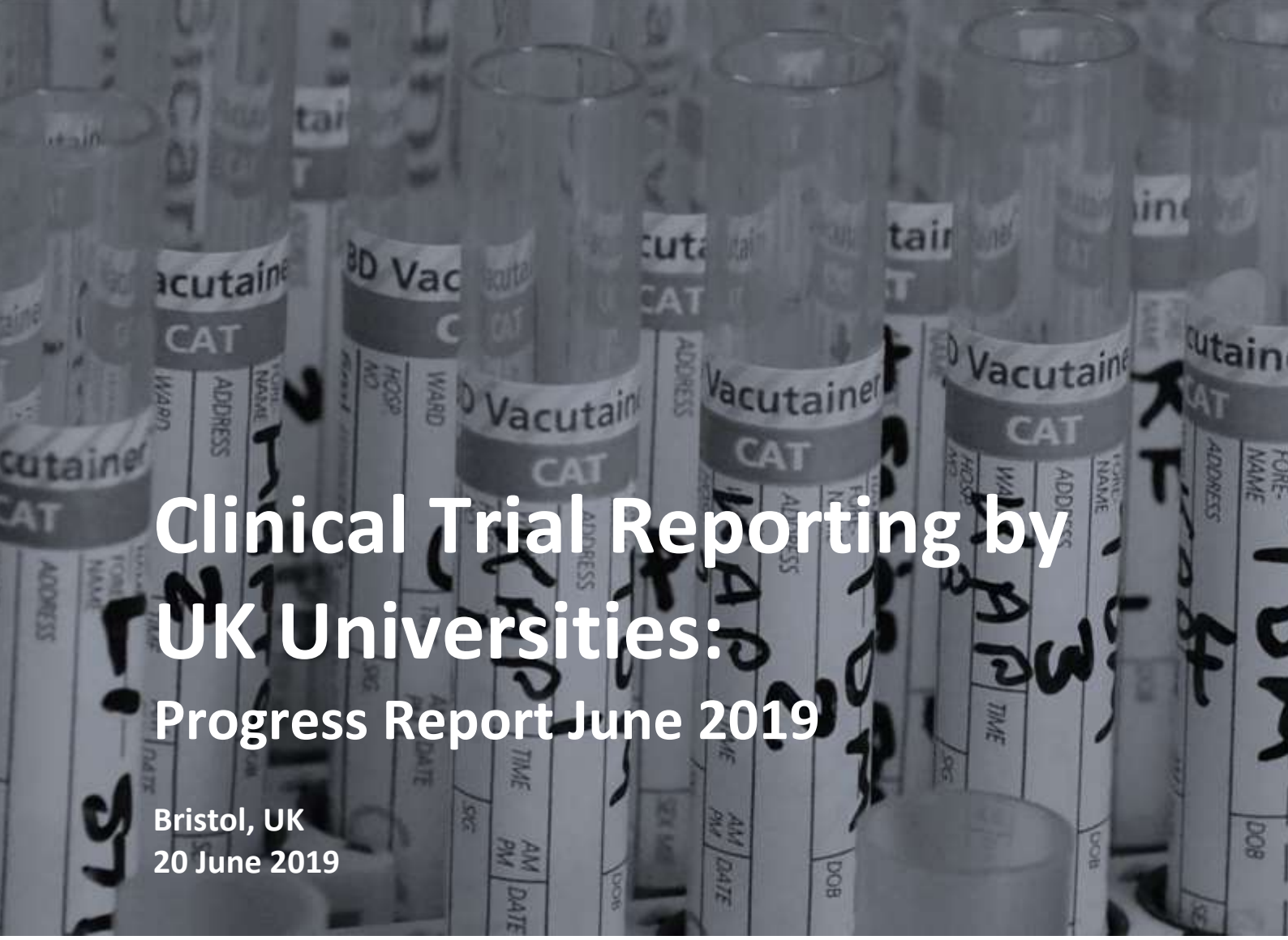

Clinical Trial Reporting by UK Universities:

Progress Report June 2019

Bristol, UK
20 June 2019

"Many of these trials are funded with public money and the tax payer has a right to expect those who benefit from public funding to follow the rules and publish in full."

- Norman Lamb MP, Chair of the Science and Technology Committee

"Lack of transparency in clinical trials harms patients. The timely posting of summary results is an ethical and scientific obligation."

- Transparency International and Cochrane

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EXECUTIVE SUMMARY

Most UK universities are working hard to improve their clinical trial reporting, and have adopted ambitious and wide-ranging plans for the future.

Freedom of Information requests filed with 27 UK medical research universities show that over the past months, UK universities as a whole have made impressive progress in developing policies and processes to ensure that in future, medical research results will be promptly made public. In addition, a large majority of universities is taking steps to prevent the results of old clinical trials from becoming research waste. While some gaps remain, progress across the sector as a whole is excellent.

As a result, scientific progress will be accelerated and public health decision-making improved, to the benefit of UK taxpayers and patients worldwide.

KEY FINDINGS

- **Ambitious new policies.** Most universities are adopting policies that are aligned with global best practices. These universities now require, or will soon require, researchers to post the results of all clinical trials onto trial registries within 12 months of trial completion. Only one of the 25 universities that responded has not taken any action whatsoever. Three universities appear not to be pursuing full compliance with global best practices, but they do seem fully committed to achieving regulatory compliance.

- **Audits of existing trial portfolios.** With only one exception, all responding universities have already conducted reviews of their clinical trial portfolios, or have plans to do so. Such 'audits' allow universities to identify clinical trials that have outdated or incomplete information on trial registries, and thus provide baseline data to inform and guide corrective action.

- **Research waste plans.** With only one exception, all responding universities have used registry data and online searches to identify clinical trials that have remained completely unreported (i.e. results neither published in a journal nor posted onto a trial registry), or plan to identify them in the foreseeable future. The results of such trials are at acute risk of being lost forever and becoming part of the global $85 billion annual medical research waste heap. Some universities are already systematically chasing up such trials to ensure that their results are made public.

IMPACT

- **Good news for patients worldwide.** In the past, non-reporting of academic trial results has contributed to over 100,000 patient deaths. Evidence suggests that the results of between a quarter and nearly half of clinical trials run by universities in Europe are never made public, in any form. As a result, public health agencies and doctors often cannot tell which treatments are most effective. Universities' commitment to posting all trial results onto registries within 12 months will ensure that in future, no trial is left behind. In addition, it will speed up the pace and quality of trial reporting, and thus accelerate medical progress.

- **Good news for UK taxpayers.** Many trials run by universities are funded with tax money. Trials that fail to make their results public deliver no return to public investment, and may lead to the unnecessary and costly duplication of studies. Most universities seem committed not only to preventing research waste in future, but are also working to rescue older trial results from the research waste heap. As a result, millions of pounds' worth of past, present and future public investment into research that would otherwise have been lost forever will make a contribution to scientific progress and public health. More broadly, NICE will be better able to determine which treatments are most cost-effective.

ANALYSIS

- **Political drivers for change.** The October 2018 report by UK parliament's Science and Technology Committee that criticised the academic sector for weak clinical trial reporting has clearly had a strong positive impact on UK universities. Parallel advocacy by transparency and patient groups seems to have added further momentum for reform.

- **More resources for research governance.** Replies by some universities indicate that they have allocated additional resources to clinical trial oversight and management processes, or will do so in the near future. This is likely to go hand in hand with an increasing centralisation and professionalization of trial registry data management within universities.

- **Forward-looking approach.** A large majority of universities have seized the opportunity offered by policy reforms to develop policies that go far beyond ensuring narrow legal and regulatory compliance. By aligning with World Health Organization global best practices, these universities are ensuring that the new processes reflect their broader commitment to research excellence, and fully meet the heightened expectations of Parliament, patients and research funders.

VARIATIONS BETWEEN UNIVERSITIES

- **University College London and the University of Southampton failed to provide information**, in breach of the 20 working day time frame for responding to Freedom of Information requests (see below). The extent of their efforts – if any – thus remains unknown.

- **The University of Reading is a negative outlier.** It has put no relevant policies into place, has not audited existing registry entries, and has no plans to rescue past unreported trials from the research waste heap.[1]

- **Variations in pace and prioritisation.** The pace of implementation varies widely between institutions but is rapid overall. Prioritisation of registries also varies. Universities generally started with tackling their EU registry entries, and then moved on to the US registry and finally ISRCTN. However, Sheffield chose to tackle its ISRCTN trials before those listed on the US registry.

- **A minority of universities appear to have set themselves a limited scope of work.**
    - Reportedly, three universities (Glasgow, Sheffield and Sussex) are limiting some or all of their efforts to ensuring compliance with regulatory requirements, notably European Union reporting rules for drug trials. Such rules cover only a small minority of clinical trials run by UK universities; for example, current EU transparency rules cover neither trials of medical devices (such as pace makers) nor of non-drug interventions (such as physiotherapy).
    - In addition, in several cases, universities' responses left somewhat unclear whether their efforts include trials listed on ISRCTN, one of the three registries most frequently used by UK universities. (These are marked with an asterix in the table above.)
    - The data cited above should be treated with caution as TranspariMED's experience with Freedom of Information requests shows that universities sometimes misunderstand questions and/or fail to provide comprehensive answers. Future monitoring efforts, including by the Health Research Authority itself, will provide reliable data on actual university performance.
    - Note also that even achievement of 'only' narrow regulatory compliance by a UK university would already constitute significant progress against the situation only one year ago.

[1] According to Reading's FOI response: *"The University has no internal formal policies, systems and processes to ensure that, every clinical trial sponsored by the University will post its summary results on every WHO primary trial registry (including Clinicaltrials.gov), where it was originally registered within 12 months of trial completion. Usual practice is that, funder and regulatory authorities require and monitor the process is completed within the defined timelines, therefore, no additional administration by the University, as Sponsor, is deemed necessary. With the administration of the trials delegated to School level, an audit of past trials has not been conducted and is not planned at an institutional level, to collate this information for the purposes of responding to an FOI request would likely engage exemption section 12 (cost refusal) as it would require a search at School and department level and there are over 55 Schools and Departments."*

COMPLIANCE WITH FREEDOM OF INFORMATION LEGISLATION

The legal time frame for UK institutions to respond to Freedom of Information requests is 20 working days. All requests were filed on 30 March 2019.

- Out of 27 universities, 22 responded roughly within that time limit (by 01 May 2019).
- Three universities responded with delays: Imperial College London (05 June), Birmingham (31 May), and Warwick (09 May).
- Two universities had still not provided any response as of 19 June 2019: University College London and University of Southampton.

INTERESTING MODELS

- **Trial close-out checklist.** Aberdeen: "At close-out a… checklist is completed by internal monitors which requests if the public register(s) have been updated, and requires confirmation of who shall upload results and when this shall be completed."

- **Case management system.** Bristol: "Since 2018 the University of Bristol have employed a new Case Management System for research projects and, during installation of the system, the Governance team ensured that registration and reporting fields were included in the tracking process. This allows us to clearly identify and track those studies that require registration and to offer appropriate advice and support to the relevant researchers."

- **Gold standard policy.** Exeter: "During development, the policy author referred to the TranspariMED best practices checklist and has ensured that the elements are present in the policy and associated processes." [The checklist lists global best practices as set out by the World Health Organisation.]

- **Use of external monitoring data.** Manchester: "The Health Research Authority (HRA) conducted a transparency audit in August 2017 which was limited to assessing registration, the audit did not include data on study results/publications. However to our knowledge, all University of Manchester sponsored studies that were in scope met the HRA expectations."

- **Keeping university management involved.** Nottingham: "The Head of Research Governance will regularly review and provide updates at executive board and committee level on how academic staff engaged in clinical trials research are making positive progress in registering trials and posting results, as well as highlighting where further work is required to ensure compliance."

TranspariMED's collection of Transparency Tools includes case studies of individual universities explaining how exactly they strengthened their policies, processes and performance. www.TranspariMED.org/resources

ANNEX I: OVERVIEW OF UNIVERSITIES' ACHIEVEMENTS, ACTIVITIES AND PLANS

UNIVERSITY	TRIAL REPORTING POLICIES	RETROSPECTIVE AUDIT	RESEARCH WASTE PLAN
Cardiff University	YES	YES	YES
Imperial College London	YES	YES*	YES*
King's College London (KCL)	IN PROGRESS	IN PROGRESS	IN PROGRESS
Liverpool School of Tropical Medicine (LSTM)	IN PROGRESS	PLANNED	PLANNED
London School of Hygiene and TM (LSHTM)	YES	IN PROGRESS	IN PROGRESS
Newcastle University	IN PROGRESS	IN PROGRESS	IN PROGRESS
Queen Mary University of London	YES	YES	IN PROGRESS
University College London (UCL)	*Failed to respond to FOI request*		
University of Aberdeen	YES	YES	YES
University of Birmingham	YES*	YES*	YES*
University of Bristol	YES	YES	YES
University of Cambridge	PLANNED	IN PROGRESS	PLANNED
University of Dundee	IN PROGRESS	YES	YES
University of Edinburgh	IN PROGRESS	IN PROGRESS	IN PROGRESS
University of Exeter	IN PROGRESS	YES	YES
University of Glasgow	EU REGISTRY ONLY	COMPLIANCE ONLY	EU REGISTRY ONLY
University of Leeds	IN PROGRESS	IN PROGRESS	IN PROGRESS
University of Leicester	IN PROGRESS	IN PROGRESS	IN PROGRESS
University of Liverpool	YES	YES*	IN PROGRESS*
University of Manchester	IN PROGRESS	PLANNED	PLANNED
University of Nottingham	IN PROGRESS	IN PROGRESS	IN PROGRESS
University of Oxford	IN PROGRESS	IN PROGRESS	IN PROGRESS
University of Reading	NO	NO	NO
University of Sheffield	IN PROGRESS	IN PROGRESS	EU REGISTRY ONLY
University of Southampton	*Failed to respond to FOI request*		
University of Sussex	EU REGISTRY ONLY	PLANNED*	NOT YET
University of Warwick	YES	YES	YES

** University response left unclear whether this effort includes clinical trials listed on the trial registry ISRCTN.*

ANNEX II: FULL TEXT OF FREEDOM OF INFORMATION REQUESTS

Note: Identical FOI requests were filed with all 27 universities on the same date, 30 March 2019, via the WhatDoTheyKnow platform.

[Trial reporting policies] 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) 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.

[Retrospective audit] Q2. Has the university conducted a registry-data based audit of all clinical trials it has sponsored in the past, including all 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.

[Research waste plan] 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.

Definitions:
For the purpose of this FOI request, a clinical trial is defined as per the WHO definition:
"[A] clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc."

Context:
A January 2019 report by TranspariMED and Universities Allied for Essential Medicines (UAEM) found that many UK universities had initiated the process of uploading missing clinical trial summary results onto EudraCT. However, it remains unclear whether and to what extent universities are planning to extend these efforts to trials missing results on Clinicaltrials.gov and ISRCTN. In this context, clinical trials that have never reported their results and are thus in danger of becoming research waste are of particular concern.

Please note that TranspariMED is aware of the practical challenges UK universities face in retrospectively posting summary results onto registries. In February 2019, TranspariMED jointly with Health Action International released the report "Clinical Trials in The European Union: A Roadmap to Greater Transparency" to bring challenges identified by UK university registry managers to the attention of the European Medicines Agency. The EMA has since initiated a dialogue on these issues.

This FOI request is being filed on behalf of TranspariMED.

ANNEX III: FULL TEXT OF UNIVERSITY RESPONSES

Note: Each university's individual response can be viewed online by clicking on the respective hyperlink.

UNIVERSITY	TRIAL REPORTING POLICIES	RETROSPECTIVE AUDIT	RESEARCH WASTE PLAN
Cardiff University	The latest draft of the University's Code of Practice for Research Integrity and Ethics (CoP) requires that summary results must be posted on every relevant registry within 12 months of the trial completion. The updated CoP will be submitted to the University Research Integrity and Ethics Committee for approval 21 May 2019 and is scheduled for release in August 2019. Processes in place to ensure that summary results are posted on the relevant registries within 12 months include: • A Memorandum of Understanding (dated March 2018) with the University's Centre for Trials Research (CTR), requiring CTR to: ensure that all trial results are placed in the public domain. • A Memorandum of Understanding is signed between the Sponsor, Trials Unit and Chief Investigator for each trial. The template MoU (dated September 2017) required the Trials Unit to ensure results are published on or linked from the relevant public registry(ries). A new version of the template MoU (dated April 2019) specifies that results must be published on the relevant registries within 12 months of trial completion. • Guidance for uploading trial results to EudraCT (June 2018) • Generation, review and approval of a Clinical Trial Report (September 2016)	Yes. Audit completed April 2018 and reported to the University's Clinical Trial Governance Group.	A tracker is in place and is regularly reviewed and updated at monthly meetings between Sponsor representatives and the Centre for Trials Research. Progress is reported to University's Clinical Trial Governance Group, the Open Research Task and Finish Group and the University's Research Integrity and Ethics Committee. Past trials that have remained unreported have been identified. These will require further work prior to reporting results. A specific plan was developed in June 2018 to utilise MSc students to address one such trial. This exercise has been successful. The University is investigating using this model for further old trials. A formal plan should be in place by June 2019.

	• Study Closure SOP and Study Closure Checklist (August 2016)		
Imperial College London	Yes. As of January 2019 a formal procedure has been put in place to capture and oversee all clinical trials, so that summary results are reported within the required timelines.	An audit of all trials with outstanding reporting requirements for clinicaltrials.gov and EudraCT was completed in February 2019. Imperial College standard operating procedures state that where the study is a non-CTIMP, but falls under the HRA requirements for registration of clinical trials, then clinicaltrials.gov be used.[2]	Yes. An approach to identifying all retrospective trials that had not reported within the required time-frame was put in place in February 2019. Subsequently all Chief Investigators for these studies were contacted by March 2019, and there is continuing work to meet reporting requirements.
King's College London (KCL)	KCL has Standard Operating Procedures in place regarding results reporting of all Clinical Trials of Medicinal Products within the EudraCT database. A policy is currently being drafted regarding University process and oversight of all entries in other WHO primary trial registries.	Yes, KCL has conducted an audit of all clinical trials it has sponsored in the past. The last full audit of trials within the EudraCT database was conducted in September 2018 and is reviewed monthly. An audit is currently being conducted within Clinicaltrials.gov and ISRCTN to establish the extent of non-reporting and ensure that results are uploaded.	There has been an ongoing plan and implementation regarding retrospective reporting the results of past trials within the EudraCT Registry since September 2018. There are a small number of trials that were abandoned prior to any participant recruitment. Although these have been formal y terminated with the UK Competent Authority, the entry in EudraCT is marked as "prematurely ended). There is no process in place within the public facing EudraCT registry to indicate that no results will be made available as no data was collected. Therefore, there will always be trials listed as "prematurely ended" but with no results available.[3] A plan has been established regarding retrospective reporting in other WHO registries which is in early phase implementation and formalisation of the policy.
Liverpool School of Tropical	We are in the process of updating our policies and systems to enable us to ensure in the future that every clinical trial has been registered on a public website and that summary results are published on the website. The LSTM Sponsorship policy is currently being updated to	LSTM plans to conduct an audit of all its existing registry entries with view to identifying interventional clinical trials that have remained completely unreported. LSTM plans to initiate the audit in August 2019 and complete it by December 2019.	Based on the audit results, the university will then draw up a plan for retrospectively reporting missing trial results.

[2] A search of the ISRCTN registry shows that it contains numerous Imperial-sponsored trials. For example, Imperial-sponsored trial ISRCTN76942974 was registered in early 2019. The registry entry does not identify a corresponding Clinicaltrials.gov registration. (Note: That particular trial was retrospectively registered. Failure to prospectively register a clinical trial is a breach of medical research ethics. The trial's funder, Wellcome Trust, has a policy mandating prospective trial registration, but has not yet conducted an audit of its grantees.)

[3] The European Medicines Agency is aware of this registry design flaw and is exploring ways to fix it.

Medicine (LSTM)[4]	reflect this as agreed in November 2018 at a Governance Oversight Committee meeting. We expect to complete updating our systems and policies by December 2019. The LSTM Governance Office regularly assists researchers to enable their clinical trials to be uploaded onto ClinicalTrials.gov or other appropriate registry. Approvals given to PI's for clinical research at LSTM include clear instructions to comply with relevant regulatory requirements. The LSTM Publication Policy contains a section on 'Trial registration and reporting guidelines' that says, "LSTM is a signatory to the AllTrials Campaign. LSTM endorses the principle that all trials are registered, and the results of such studies are published as quickly as possible following their completion. Trials should be registered on a suitable, publically accessible Clinical Trials Registry that is approved by the WHO International Clinical Trials Registry Platform (ICTRP) (such as Clinical Trials or the Pan African Trials Registry)."		
London School of Hygiene and TM (LSHTM)	Yes. These have been included in the standard operating procedure "Notification of End of Study" (ref LSHTM-SOP-006-01) since June 2015, with further details added and clarified in September 2016. It is due for review this year	Yes, for EudraCT. We unfortunately do not have the staff to conduct a review on all registries although this is planned when the office is fully staffed, hopefully by end of September 2019.	This is an ongoing process, but no defined plan was been developed for this. There has been considerable difficulty in adding results to EudraCT and for the correct trial status to appear from the Competent Authority which has caused significant delays to adding the results. We aim to have all results on EudraCT by summer 2019, and to extend this to the registries in due course.
Newcastle University	Newcastle University has worked with Newcastle Upon Tyne Hospitals Foundation Trust to ensure that these processes are in place for trials sponsored by that Trust for which Newcastle University academics are lead investigator. We have not yet rolled out these policies across the University. We expect to do so by October 2019.	No we haven't – we expect to do so by January 2020.	No we haven't – we expect to do so by April 2020.

[4] In an email sent in June 2019, LSTM noted that it has adopted more ambitious plans since filing its original FOI response. The answers to questions 2+3 provided in the table above reproduce the relevant passages of the email verbatim.

Queen Mary University of London	Yes: Regulated studies June 2017; Non-regulated May 2019.	Yes: EudraCT completed January 2019; ISRCTN and Clinicaltrials.gov completed April 2019.	Yes, a plan as described is in place. EudraCT adopted July 2017, to be completed April 2019; ISRCTN and Clinicaltrials.gov to be completed July 2019.
University College London (UCL)	***Failed to respond to FOI request***		
University of Aberdeen	Researchers must confirm on which publicly available websites they have/shall register their trial before first recruit. This is emphasised in the internal procedure regarding protocol guidance for high risk trials and CTIMPs (SOP-QA-3 - available on our website. Confirmation of the registry to be used is also included in the sponsor risk assessment. Once sponsorship has been agreed the standard sponsorship letter issued to researchers emphasises that the trial must be registered on a publicly available website before first recruit and results posted no later than twelve months after completion. Registration is also checked at Site Initiation and forms part of the standard Site Initiation checklist used by internal monitors. At close-out a similar checklist is completed by internal monitors which requests if the public register(s) have been updated, and requires confirmation of who shall upload results and when this shall be completed. These processes have been in place since 2018.	Yes. After the initial rapid external audit conducted by TranspariMED in 2017, the University committed to undertaking an annual audit of all CTIMPs registered on EudraCT, clinicaltrials.gov and ISRCTN to identify any that have not published results within twelve months of completion. The first audit was conducted in June 2017 (and was supplied to TranspariMED) the second was conducted in June 2018. In both audits studies which did not comply were followed up through a Results Registry Committee.	Yes, the above Results Registry Committee identified specific staff to support researchers in addressing unreported studies. This shall be ongoing when any unreported studies are identified.
University of Birmingham	The explicit requirement to publish results via the registries within the appropriate timeframe has been included in the Code of Practice for Research since 2016 and was reiterated to investigators following the House of Commons Select Committee report in 2018 and letter to VCs in 2019. Our main focus is currently on CTIMPs reported on the EudraCT database and on trials registered via ClinicalTrials.gov. The mandatory reporting of all trials in line with the WHO definition will be considered for future development of the Code of Practice for Research.	The University has completed an audit and is now working with investigators of legacy trials to upload data retrospectively. The trial review was undertaken when the EU Trials Tracker went live, to ensure accuracy and facilitate the upload of results for legacy trials. We are currently working with colleagues from registries and the regulator to ensure that trials are allocated to the University of Birmingham appropriately and where necessary arrange for the record to be closed or transferred to the correct sponsoring organisation where studies were erroneously attributed to the University. We aim to complete this work as soon as possible.	The University has completed an audit and is now working with investigators of legacy trials to upload data retrospectively. The trial review was undertaken when the EU Trials Tracker went live, to ensure accuracy and facilitate the upload of results for legacy trials. We are currently working with colleagues from registries and the regulator to ensure that trials are allocated to the University of Birmingham appropriately and where necessary arrange for the record to be closed or transferred to the correct sponsoring organisation where studies were erroneously attributed to the

			University. We aim to complete this work as soon as possible.
University of Bristol	Since the implementation of the University's Research Governance and Integrity Policy in 2010, appropriate registration of clinical trials (according to the WHO definition) has been an allocated task for the trial Sponsor. Where that falls to the University of Bristol, the process is governed by our Standard Operating Procedures. Since 2017, oversight of this process, in accordance with the SOP, has been managed by the Research and Human Tissue Manager. In order to ensure the proper use of EudraCT and ClinicalTrials.gov, this person manages / administrates those accounts – where previously researchers uploaded their trial data individually – and takes responsibility for ensuring that that registry entries are accurate and up to date. They have also been overseeing a data clean-up of trials listed on those systems. The Research and Human Tissue Manager is also in the process of extending the same oversight and clean-up to trials listed on ISRCTN. Since 2018 the University of Bristol have employed a new Case Management System for research projects and, during installation of the system, the Governance team ensured that registration and reporting fields were included in the tracking process. This allows us to clearly identify and track those studies that require registration and to offer appropriate advice and support to the relevant researchers.	Yes. This work has been completed over the past nine months. Given our large portfolio of trials, this is an ever-changing situation but we can provide a snapshot of our current position: As of 25/04/19, all of our trials listed on EudraCT are up to date – though there are a small number of minor discrepancies between the information provided by us to the MHRA and the data currently displayed on the Clinical Trials Register. As of 25/04/19, all of our trials listed on ClinicalTrials.gov are up to date. As of 26/04/19, all but one of our CTIMP trials listed on ISRCTN are up to date. The investigator team of the single outstanding study have been asked to update the entry. We have begun the process of auditing our other (non-CTIMP) trials registered on ISRCTN.	Yes; historic trials, i.e. those completed prior to July 2014 have now all been reported on EudraCT – with the exception of a single trial about which we are awaiting the response to a request to the EMA. This has been an ongoing project but with particular focus since mid-2018.
University of Cambridge	The School of Clinical Medicine's Research Governance Office carries out an annual audit of the University's clinical studies to check that all studies are registered on a publicly available website. The University has a research data management policy framework which highlights University and funder expectations about the publication	No formal audit has been conducted but compliance is currently being reviewed.	No. The School of Clinical Medicine's Research Governance Office is currently reviewing the status of all clinical research projects to ascertain the number of unreported study results. Once this work has been completed it will consider what needs to be put in place and by when.

	of research data generally,[5] but there is currently no policy in place to confirm that results have been posted. How such a policy might be introduced will depend upon the outcome of the work highlighted under Q3 below.		
University of Dundee	The University's policy for researchers is online here. That policy includes a document history. Publication within twelve months is the normal intention, however this may not be practical in all circumstances.[6]	Yes. This was reported internally to the Tayside Medical Science Centre (TASC) on 10/11/2016.	A plan has been in place since 20/12/2017. The majority of retrospective trial data should be uploaded by end 2019.
University of Edinburgh	The University is currently putting in place a mechanism to ensure that investigators consider the requirements of reporting before their trial commences and confirm that there is funding for the staff and time needed to do this. Under this mechanism, recruitment will only commence when confirmation of resource is made. The process for this is currently in test phase, with the target of it being adopted as a standard operating procedure in June 2019.	In January 2019, the University performed a check of all regulated clinical trials listed in EudraCT. This was not considered to be a formal audit, but an ongoing exercise to maintain and progress our portfolio of clinical trials. We intend to perform the same exercise with non-regulated trials registered in ISRCTN and Clinicaltrials.gov, and have a target for this to commence in July 2019.	The University commenced uploading trial results for regulated clinical trials listed in EudraCT in February 2019. This is an ongoing exercise, and we are currently focusing resources on assisting investigators to upload overdue results to EudraCT. We intend to commence identifying and reporting non-regulated trials registered in ISRCTN and Clinicaltrials.gov in July 2019. The University does not currently have an expected completion date for this exercise.
University of Exeter	A draft Clinical Trials Transparency policy is currently under review within the University and is expected to be implemented from the 1st August 2019. During development, the policy author referred to the TranspariMED best practices checklist and has ensured that the elements are present in the policy and associated processes.	Yes, the research governance and Clinical Trials Unit teams have recently conducted a review of entries (February/March 2019) and are currently following up on actions identified.	Yes, the audit identified a number of actions which need to be taken to ensure that entries are updated and results posted where applicable. We expect to finish this work by August 2019, when the new policy is to be implemented.
University of Glasgow	The relevant NHS Greater Glasgow and Clyde Standard Operating Procedure, applicable to University of Glasgow co-sponsored studies, was updated on 17 December 2018.[7]	The University of Glasgow conducted an initial audit of relevant trial listings required by UK legislation and European Medicines Agency guidance to be posted on the EudraCT database in October 2018. A future audit will be conducted by September 2019. The University of Glasgow is in the early stages of a review of clinical study reporting compliance. We are currently aware of a very small number of sponsored studies falling within the WHO categorisation that	The plan for the posting of all outstanding results to the EudraCT database was adopted in October 2018 and is anticipated to be complete by May 2019. The posting of relevant outstanding trial results identified in the University compliance audit will be completed by the final quarter of 2019.

[5] The policy makes no reference to trial registries.
[6] The policy is in line with WHO best practices: regular registry updates are required, and summary results must be posted within 12 months.
[7] The policy appears to only apply to clinical trials listed on EudraCT. It makes no reference to result posting on Clinicaltrials.gov or on ISRCTN.

		require, as a condition of a favourable ethics opinion, to be reported on registries other than EudraCT. The compliance review will be concluded by the final quarter of 2019.[8]	
University of Leeds	As part of its overarching quality management system (QMS), the University has a standard operating procedure (SOP) in place, which details the systems and processes for ensuring that the outcome of CTIMP clinical trials, sponsored by the University, are posted on relevant WHO registries. The procedure was refreshed as part of our response to an MHRA inspection in 2015. Our Clinical Trials Research Unit (CTRU) is also developing a Transparency Policy which details requirements to publish primary and secondary endpoint results within 12 months of the end of trial. Publishing is defined as results being uploaded onto the relevant trial registry, in addition to the National Institute for Health Research Journal and/ or scholarly journal. CTIMP reporting requirements are additionally in line with current EMA regulatory requirements i.e. uploading onto the EudraCT database. A new SOP for non-CTIMP clinical trials, which will mirror the CTIMP clinical trials SOP, is being developed and we expect it to be in operation by the start of the next academic year.	Our CTIMP clinical trials SOP defines how we maintain oversight of the reporting of trial results and we hold a 'master trial list' of all sponsored studies with an associated workbook which sets out a full audit trail of the status of trials which are within their reporting period. We are in the midst of auditing our non-CTIMP clinical trials, which has involved a review of all studies published in clinical trials.gov [and ISRCTN[9]]. An action plan is being developed to address any reporting discrepancies, which will be addressed by the beginning of the next academic year (as above).	Our CTRU has been compliant with retrospective reporting requirements for CTIMP trials onto the EudraCT database since the EMA news release in 2014. The CTRU's longstanding position has been to publish trial results into a peer reviewed academic journal or conference. The University has been more broadly compliant since the revised QMS was put in place in 2016. For non-CTIMP clinical trials, an action plan is being developed (as described above).
University of Leicester	Processes to ensure that the results of future trial are published are currently under review. The overhaul of processes has not yet been completed but we intend to have processes in place by August 2019.	We completed an audit of EudraCT in March 2019. We aim to conduct an audit of ISRCTN and Clinicaltrails.gov by October 2019.	Yes. We are currently in the process of reporting on unreported trials on EudraCT which we plan to finish by July 2019. We plan on reporting on ISRCTN and Clinicaltrials.gov by July 2020.
University of Liverpool	The University of Liverpool has a policy in place that requires the CI of a study to publish the results of their study within 12 months. We conduct annual checks of	The University of Liverpool performed its last audit of registration sites in January 2019 (clinicaltrials.gov, EU	The University will conduct a review of recent / past University of Liverpool sponsored studies to determine which have not registered /

[8] The university appears to focus exclusively on regulatory compliance. The large majority of interventional clinical trials run by UK universities, including most trials listed on Clinicaltrials.gov and ISRCTN, are not subject to regulatory reporting requirements.

[9] The original university response did not refer to ISRCTN. After prompting on the issue, the university explained that "our oversight of ISRCTN material is in line with the answers we provided for Eudract. It is used mainly by our CTRU, where reporting is integral to routine processes."

	external registry sites (including clinicaltrials.gov), via an internal team within our Research Support Office, to ensure publication has been completed. This policy was put in place in March 2013.	Trials Tracker, FDAAA Trials Tracker).[10] Current studies require evidence of trial registration (confirmation of the registration number) before University approval is provided.	reported their results. From this, an action plan will be put in place (summer 2019) to ensure full transparency of clinical trial activity.
University of Manchester	As a condition of Sponsorship The University of Manchester currently ensures all regulatory approvals are in place, of which registration with a public clinical trials registry has been a requirement since September 2013 [please refer to our Standard Operating Procedures (SOP) on Sponsorship and Monitoring]. The University allows the research team to decide which is the most appropriate database with which to register its research. The Health Research Authority (HRA) conducted a transparency audit in August 2017 which was limited to assessing registration, the audit did not include data on study results/publications. However to our knowledge, all University of Manchester sponsored studies that were in scope met the HRA expectations. The University does not currently have a process in place to check that summary results are being published within 12 months of the end of the trial. However, in 2019 we will be generating new SOPs and updating our current ones to reflect transparency requirements for all studies.	No formal audit has been carried out to date; we do have plans to do so, but no timelines at present. In terms of interventional clinical trials/studies, we plan to use the existing Annual Progress Review and end of study reminder processes to inform teams that they need to check/update records on an annual basis and also ensure that the summaries are uploaded within 12 months of the end date and/or details of publications added.	The University is in the process of developing a plan to ensure the retrospective reporting of results, where possible.
University of Nottingham	Yes. The University has reviewed and updated policies, systems and processes to ensure summary results are posted on the relevant registries in a timely manner. A new guide to Trial Registration for clinical research staff was published on 17 December 2018. The guide has been regularly communicated to academic staff engaged in clinical trials research, alongside support and advice from our Research Governance team, to help them meet their responsibilities in registering trials and posting results.	Yes. The University completed audits of EudraCT and Clinicaltrials.gov across the period December 2018 to February 2019. The University has reviewed the publicly viewable records on ISRCTN and is currently assessing its approach to conducting a more detailed audit here.	Yes. The University has developed action plans for retrospectively reporting the results of past trials on the relevant registries. Audits have identified unreported results and the senior responsible owners to update them. Work to update records on EudraCT was completed in March 2019. The University is now undertaking significant work to update Clinicaltrials.gov and will turn to ISRCTN once

[10] The university does not mention trials on the registry ISRCTN, where dozens of Liverpool trials have been registered.

	The University is augmenting staff resource in the Research Governance team to further quality assure data management and audit trails across our research portfolio, including trial registries, and to support our clinical trials community in meeting their responsibility in registering trials and posting results. The Head of Research Governance will regularly review and provide updates at executive board and committee level on how academic staff engaged in clinical trials research are making positive progress in registering trials and posting results, as well as highlighting where further work is required to ensure compliance.		the audit approach is confirmed, regularly monitoring and reviewing progress.
University of Oxford	The University is currently developing strategies to ensure that the results of all interventional trials are published in a timely manner. These processes are managed by the University's Clinical Trials and Research Governance Unit, further information on which can be found online at the following link.	The University has completed an audit of EudraCT. An audit of ClinicalTrials.Gov is underway at present and an audit of ISRCTN is being planned.	A plan for retrospectively reporting the results of past trials that have remained unreported is underway for EudraCT, and the University is working to ascertain the number of other unreported trials, and will address this once this work has been completed.
University of Reading	No, the university has not 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) where it was originally registered within 12 months of trial completion. Please see explanatory text below.[11]	No, the university has not conducted a registry-data based audit of all clinical trials it has sponsored in the past, including all clinical trials listed on the registries EudraCT, ISRCTN, and Clinicaltrials.gov, to identify those trials that have never reported their results. Please see explanatory text below.	No, the university has not developed a plan for retrospectively reporting the results of past trials that have remained unreported please see explanatory text below.
University of Sheffield	No. Policies, systems and processes are under development and are expected to be in place by 1 September 2019. Please note that the University does not sponsor any clinical trials of investigative medicinal products [CTIMPs].	For EudraCT and ISRCTN - Yes (competed February 2019). For Clinicaltrials.gov - No. We are in the process of scoping this and will determine the completion date once we have scoped the work.	No - there is no formal plan for this at the current time. There are a very small number University of Sheffield-sponsored studies listed on EudraCT, and we are in the process of investigating how to ensure the relevant records are updated; however, we are

[11] Reading FOI response: "*Explanatory text - The University has no internal formal policies, systems and processes to ensure that, every clinical trial sponsored by the University will post its summary results on every WHO primary trial registry (including Clinicaltrials.gov), where it was originally registered within 12 months of trial completion. Usual practice is that, funder and regulatory authorities require and monitor the process is completed within the defined timelines, therefore, no additional administration by the University, as Sponsor, is deemed necessary. With the administration of the trials delegated to School level, an audit of past trials has not been conducted and is not planned at an institutional level, to collate this information for the purposes of responding to an FOI request would likely engage exemption section 12 (cost refusal) as it would require a search at School and department level and there are over 55 Schools and Departments.*"

			experiencing a number of challenges, particularly given these studies all ended some years ago and those involved are often no longer contactable.
University of Southampton	***Failed to respond to FOI request***		
University of Sussex	The University does not have a formal policy requiring the posting of summary results on a WHO registered primary trial registry. Currently our Conditions of Sponsorship document requires that the study is registered on an appropriate registry prior to recruitment of the first patient, if applicable. The University's Research Governance Office is undertaking a formal review of its 'CTIMP governance framework' in partnership with key Clinical Trial stakeholders and the local Clinical Trials Unit to ensure that policies and Standard Operating Procedures are fit for purpose. In addition, there will be consideration of the expectations for study registration for interventional studies generally and our Sponsorship Sub-Committee - which oversees all sponsored research and related policies - will be asked to consider an update to the Conditions of Sponsorship with a proposal that CTIMPs require both pre-registration and reporting of results within 12 months of the study completing.	The University plans to undertake a detailed registry data based audit shortly but has significantly tightened up its expectations of new clinical trials that it sponsors and the responsibility to report outcomes. We currently have no date for the expected completion of this work.	On the basis of auditing registry entries, the University will set expectations for any incomplete reports and formulate a policy to ensure greater accountability in this area. We currently have no date for the expected completion of this work.
University of Warwick	Yes, the following University of Warwick Standard Operating Procedures have been updated to ensure the expectations for maintenance of information and posting of results onto trial registries are clear. These procedures are available to all staff working on Clinical Trials.	Yes, an audit was conducted on all clinical trials to identify all clinical trials that had not posted results to a registry or published results. The audit also considered ongoing trials where information required updating. This audit was completed in January 2019.	Yes, an action plan to address retrospective reporting of the results of any clinical trials where results remain unreported was discussed and agreed in February 2019. Progress against the plan will be evaluated in April 2019.

	· Standard Operating Procedure 28: Registration of Clinical Research Studies. Update implemented 13 December 2018.[12] · Standard Operating Procedure 5: Regulatory Approvals and Communications – Updated with specific reference to EudraCT registry requirements for Clinical Trials of Investigational Medicinal Products. Update implemented 25 Mar 2019. Systems have been put in place to enable central oversight of each clinical trial and the registries to which it is registered enabling a proactive approach to monitoring compliance. We will also continue to monitor compliance with Standard Operating Procedures on an ongoing basis and will support trial teams to complete any outstanding tasks as appropriate.		

[12] The SOP states that: *"Ongoing maintenance of the register is required throughout the duration of the trial to ensure the information remains correct and a summary of results should be uploaded, when available, at the end of the study. More information regarding the expectations for timescales for results upload and publication can be accessed via: http://www.who.int/ictrp/results/jointstatement/en/"*
As the SOP links directly to WHO best practices, it requires the summary results of all trials to be posted onto registries within 12 months. Clearly spelling out this requirement within the text of the policy itself might help researchers to better understand university policies in this regard.