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## **Clinical trials run by NHS Trusts: £250 million at risk of becoming research waste**

**The results of around 500 clinical trials run by NHS Trusts remain unreported, an analysis of registry data combined with responses to Freedom of Information Requests indicates. In total, medical discoveries that cost NHS Trusts and their funders over £250 million to generate may be at risk of becoming research waste.**

**These estimates underline the cost-effectiveness of the national clinical trial monitoring system proposed by UK parliament in 2018, which would cost less than 1% of that sum to set up and run.**

### **Background**

Medical research whose findings remain invisible fails to benefit patients and makes no contribution to medical progress, and thus is a [waste of resources](#). According to the [Declaration of Helsinki](#), a failure to make medical research outcomes public is unethical. Nevertheless, [around half of all clinical trials](#) conducted worldwide never publish their results.

While the problem of research waste in medicine is exhaustively documented in the literature, the UK currently does not have a national monitoring system in place to check whether clinical trials conducted in the country subsequently make their results public.

In 2018, the Science and Technology Committee of the House of Commons [proposed](#) that the Health Research Authority put such a system in place. The cost of such a system was initially estimated at £2.4 million per annum, but the actual price tag for a basic audit is [likely to be far lower](#).

## NHS Trust research waste risk by number of trials

Twelve of the 14 NHS Trusts approached provided a substantive response to Freedom of Information requests about the reporting status of their trials. Between them, these 12 NHS Trusts reported having sponsored 570 interventional clinical trials registered on EUCTR. Based on their responses and registry searches, 338 of those trials (59%) were found to have been completed more than 12 months ago and produced endpoints, and should thus – in line with [European Union disclosure rules](#) as well as [WHO best practices](#) – have made their results public.

Of these 338 due trials, 291 trials (86%) had made their results public in the form of summary results posted onto a trial registry, an academic journal article, a conference abstract, or any combination of those. Conversely, 47 trials (14%) had not made their results public in any form.

## NHS Trust research waste risk by funding volume

The Freedom of Information requests also covered the amount of funding for each of the completed trials without publicly available results. Only 5 out of the 14 NHS Trusts contacted provided any information on trial funding. In total, they provided funding information for 129 trials. The total funding volume for these trials was £65,150,036, an average of £505,039 per clinical trial conducted. Of the 129 trials total, 95 trials had been completed over 12 months ago. Of those due trials, 6 had not made their results public.

### *Due trials for which funding data was provided that were in danger of becoming research waste as of May 2019\**

Trial number	Completed	Sponsor	Funder	Cost (£)
<a href="#">2011-005397-34</a>	3/1/2015	University Hospitals Bristol NHS Foundation Trust	Charitable	400,000
<a href="#">2006-005774-50*</a>	10/19/2011	Manchester University NHS Foundation Trust	Astellas	18,084
<a href="#">2006-005373-22*</a>	6/21/2011	Manchester University NHS Foundation Trust	Roche & Internal	15,000 19,623
<a href="#">2007-002357-23</a>	9/1/2011	The Newcastle upon Tyne Hospitals NHS Foundation Trust	Napp Pharmaceuticals	20,000
<a href="#">2014-001008-23</a>	8/23/2016	The Newcastle upon Tyne Hospitals NHS Foundation Trust	Bayer Healthcare	98,552
<a href="#">2004-005101-29*</a>	8/31/2016	King's College Hospital NHS Foundation Trust	Celgene Ltd	11,550
<b>Total cost</b>				<b>582,809</b>

\* Note: The table above is accurate as of 15 May 2019. A renewed search of EUCTR on 08 October 2019 showed that three of these trials (marked with an asterix) have since uploaded results onto the registry. This sudden improvement may be due to ongoing improvements of clinical trial reporting by NHS Trusts in the wake of the 2018 parliamentary enquiry, to a focus on those specific trials by the NHS Trusts concerned following the Freedom of Information requests, or to a mixture of both factors.

Multiplying the estimated 47 due but completely unreported trials sponsored by the 14 NHS Trusts covered by this study with an average trial cost £505,039 suggests that their portfolios in May 2019 contained medical insights that cost £23,700,000 to generate, but that were in danger of becoming research waste until and unless these trial results are made public.

## Weaknesses in trial portfolio oversight

Most NHS Trusts were able to identify unreported trials and thus appear to have partial (EUCTR only) or full (all registries) oversight of their portfolios. In contrast, the responses received by [Bart's Health NHS Trust](#) and [University Hospitals of Leicester NHS Trust](#) (and arguably [University Hospital Southampton NHS Foundation Trust](#)) suggests that they themselves do not know which of their trials have, or have not, reported results.

## NHS Trust research waste risk on a national level

Assuming that non-reporting rates and average trial costs are similar for all 1,104 EUCTR-listed trials across all 226 NHS Trusts in the UK, around 90 clinical trials sponsored by NHS Trusts countryside that cost over £45 million to conduct may currently be in danger of becoming research waste.

The total number of all NHS Trust sponsored trials in danger of becoming research waste is likely to be far higher. Previous research suggests that trials listed on EUCTR only make up a small minority of all trials sponsored by non-commercial institutions in the UK. A [2017 report](#) on trials sponsored by 27 UK universities found 1,624 trials listed on Clinicaltrials.gov compared to 254 clinical trials listed on EUCTR.

If the same ratio of EUCTR listed trials to trials listed on other registries<sup>1</sup> holds true for NHS Trusts, the total number of trials at risk of becoming research waste is likely to exceed 500. This latter figure would imply that clinical trial results that cost NHS Trusts and their funders over £250 million to generate is at risk of becoming research waste.

## Variations in information provision by NHS Trusts regarding their clinical trials

Freedom of Information requests were filed with 14 NHS Trusts. UK law requires public institutions to respond to such requests within 20 working days. Requests and Trusts' answers are hyperlinked below. The responses revealed that Trusts differ strongly in the extent to which they have oversight over their trial portfolios, and as to whether they consider funding data to be commercially confidential.

**Full data.** Only 3 out of the 14 Trusts provided all information requested in full: [King's College Hospital](#), [Manchester University NHS Foundation Trust](#) and [University Hospitals Bristol](#). 3 additional Trusts disclosed data for all categories, but lacked some funding data, typically for older trials only: [Leeds Teaching Hospitals](#), [Newcastle Upon Tyne Hospitals](#), and [Sheffield Teaching Hospitals](#).

**No data.** 3 out of the 14 Trusts<sup>2</sup> appeared to have no consolidated data on their own trial portfolios. [Bart's Health](#) and [University Hospitals of Leicester](#) argued that gathering the requested information would involve an effort exceeding legal limits (Section 12 exemption). [University Hospital Southampton](#) neglected to answer all questions about trial publication and funding, without providing an explanation.

**Limited funding data.** 5 Trusts refused to provide some or all funding data. 4 of these cited commercial confidentiality: [Cambridge University Hospitals](#), [Moorfields Eye Hospital](#) and [University Hospitals of Leicester](#) disclosed funder identities, but refused to disclose the amounts received per trial, while [Hull University Teaching Hospitals](#) refused to disclose both funder identities and the amounts received. 1 Trust – [Guy's and St. Thomas'](#) – disclosed funder identities, while citing Section 12 as the reason for not disclosing amounts received.

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<sup>1</sup> The 2017 study only counted trials listed Clinicaltrials.gov. It did not capture trials listed on ISRCTN, a third registry that is widely used by research institutions in the UK.

<sup>2</sup> In addition, Guy's and St Thomas' NHS Foundation Trust [reported](#) having oversight over trials listed on EUCTR, but not on other registries.

## Methodology

The data in this report is based on Freedom of Information requests filed with the 14 NHS Trusts that have sponsored the largest number of clinical trials listed on the European Clinical Trials Register (EUCTR), combined with data extracted from EUCTR. Between them, according to [EU Trials Tracker](#) data, these 14 Trusts account for over half of EUCTR-listed clinical trials sponsored by all 226 NHS Trusts across the UK (570 trials out of 1,104 total).

Trials whose results remained unreported beyond the WHO best practice reporting timeframe of 12 months post completion were classified as being at risk of becoming research waste. This data was then extrapolated to all clinical trials sponsored by all NHS Trusts, based on conservative assumptions.

The Freedom of Information requests were filed between January and March 2019. In some cases, requests for Internal Reviews of the original responses were also filed. [The original Freedom of Information requests, responses and subsequent exchanges are available online.](#)

The data in this report is accurate as of 15 May 2019.

Lead researcher: Debra Winberg, TranspariMED volunteer  
QA and report text: Till Bruckner, TranspariMED founder

## Limitations

The estimates cited in this report are not precise. They are based on limited data combined with (conservative) extrapolations. However, note that the £250 million estimate covers only those clinical trials that have been run by NHS Trusts. The figure thus does not include the far larger number of trials sponsored by universities, charities and pharmaceutical companies.

This paper has multiple limitations:

- Not all 14 Trusts provided all data requested. Thus, the data underlying the estimate of average trial cost in particular is based on only a sub-sample of all applicable trials.
- The research waste performance of the 14 highest-volume NHS Trusts may not be representative of NHS Trusts as a whole. (Note that higher-volume industry sponsors tend to perform better on registry reporting than lower-volume sponsors do.)
- The exact ratio of NHS Trust sponsored trials listed on EUCTR to the total number of all NHS Trust sponsored trials listed on all WHO primary registries is not known. Equally unknown is whether there are differences in the average cost of trials listed on different registries.
- The analysis uses 12 months post completion as its cutoff point for assessing reporting status. While this approach is fully in line with EU rules and WHO best practices, results of some of the trials included may have been submitted to journals for publication, but not been published yet.
- Data collection was finalised in May 2019 and thus does not take into account recent and ongoing improvements in reporting performance by some NHS Trusts in the wake of the parliamentary enquiry, which is likely to have significantly reduced the number of unreported trials on EUCTR.

TranspariMED encourages other researchers to build on the methodology used here to generate estimates of the amount of research waste generated by clinical trial non-reporting in other cohorts.