**Wellcome clinical trial policy monitoring 2018-2019**

When we signed the WHO statement on clinical trial transparency, we promised to monitor compliance with our clinical trials policy and publish the results. One year on, here are our findings.

**Overview**

In 2018, we updated our [clinical trials policy](https://wellcome.ac.uk/funding/guidance/clinical-trials-policy) to bring our reporting requirements in line with the [WHO statement on clinical trial transparency](https://www.who.int/ictrp/results/jointstatement/en/), and make sure the researchers we fund:

* register their clinical trial in an appropriate trial registry and include a data sharing plan
* publish a trial protocol and statistical analysis plan before recruitment is complete
* publish their summary results within 12 months of the primary study completion date.

Our updated policy applies to all grants awarded from 1 May 2018.

As part of our commitment, we promised to monitor compliance with our updated policy and publish the summary results.

**Key findings**

We analysed data from all Wellcome grants involving a clinical trial that were active when our updated policy took effect on 1 May 2018.

This covered 131 active Wellcome grants, involving 189 clinical trials (either completed, active, or planned). Of these trials, 89 had been registered in a trial registry.

This figure is low, but we know that:

* many grantholders only register their trial when they start it
* some of the planned trials may not go ahead
* we haven’t be able to access all reporting data, but we are improving this

Our analysis showed that the most popular registry is clinicaltrials.gov, with 67 of 89 trials (75%) registered with them.

Of the 26 grantholders that completed an annual progress or end-of-grant report between October 2018 and February 2019:

* 1 has not started recruitment yet
* 25 (100%) of those that have started recruitment are registered in an approved registry
* 8 (31%) published their protocol
* 3 (12%) published their statistical analysis plan
* 10 (38%) included a data sharing plan.

We also reviewed a sample of 31 grantholders who had completed a clinical trial more than 12 months before. Of these, three (10%) had published summary results on a registry.

The data is taken from applications and progress reports where grantholders have told us their grant involves a clinical trial. This isn’t a comprehensive picture of all clinical trials we support because our current reporting systems are complex. We’re improving these and as more data builds we’ll be able to give a more comprehensive view in future monitoring reports.

**Conclusions and actions**

All Wellcome-funded researchers that are required to adhere to our policy are currently compliant because they have not even started recruitment yet. However, the collected evidence shows that while researchers register their trials in an appropriate registry, they don’t always:

* include a data sharing plan
* publish protocols and statistical analysis plans
* add summary results to trial registries (referring to a publication is not sufficient).

Grantholders who fail to meet the above requirements will not be:

* compliant with our policy
* allowed to apply for future Wellcome funding until they’ve updated the trial registry.

We hope our updated policy will drive change and increase the number of researchers to adopt good practice in reporting their findings.

To make it easier for researchers to make the data underlying their research publications accessible to other researchers at the time of publication, Wellcome joined [ClinicalStudyDataRequest.com](https://clinicalstudydatarequest.com/), a clinical trial data sharing platform in May 2018. We’re pleased to announce we now have some Wellcome-funded trials available to request through this platform, and we’re encouraging others to list their completed studies here too.

Read more about CSDR and [what it means for grantholders](https://wellcome.ac.uk/news/sharing-clinical-trial-data-what-it-means-you).

We want to support the researchers we fund to meet our policy requirements. Get in touch to let us know how we can help you.

**Why we’re monitoring compliance**

We’re committed to making sure the researchers we fund comply with our policy.

This approach helps reduce:

* research waste, where different researchers investigate the same thing
* reporting bias, where null or negative results are less likely to be published.

These actions should lead to improved health benefits for everyone.