

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](#) to bring our reporting requirements in line with the [WHO statement on clinical trial transparency](#). This means that researchers we fund must:

- 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 by Wellcome from 1 May 2018.

Key findings

We looked at the annual progress or end-of-grant reports completed by grantholders between October 2018 and March 2019 that indicated that their grant involves a clinical trial. Of the 26 grantholders who completed a report, we found that:

- 29 separate clinical trials had been funded
- 1 has not yet started recruitment
- 28 (100%) of those who have started recruitment have registered their trial in an appropriate registry
- 8 (29%) have published their protocol
- 3 (11%) have published their statistical analysis plan
- 13 (46%) have included a data sharing plan in the registry
- a quarter (25%) of trials that ended before May 2018 have posted summary results on the registry.

We're pleased that 100% of all active trials are registered in a clinical trial registry, and that many trialists have also published their protocols, statistical analysis plans and data sharing plans. This happened even though all the grants

reported here were working under our previous clinical trial policy which didn't require these outputs to be shared.

Retrospective data

We also analysed data from all Wellcome grants involving a clinical trial that were active on or after 1 May 2018. We did this because we:

- recognise that the data above doesn't give a complete picture of the clinical trials we're funding
- want to be as open as possible in terms of reporting the outcomes of the trials we support.

The analysis shows that there are 131 active Wellcome grants, involving 189 clinical trials (either completed, active, or planned). Of these trials, 89 had been registered in a trial registry.

We recognise that this registration figure is low, and at odds with the more recent data presented above, but believe this is because:

- many grantholders only register their trial when they start it (and for this dataset we don't know how many of the 189 trials have started)
- we haven't been able to access all reporting data, but we are improving this
- some of the planned trials may not go ahead.

Our analysis shows that the most well-used registry for Wellcome-funded researchers is clinicaltrials.gov, with 67 of 89 trials (75%) registered with them. The remaining 25% are registered in four other registries (ANZCTR, EU-CTR, ISRCTN, and TCTR).

We also reviewed the 31 trials (of the 89 registered) that had completed by May 2018. Of these, three (10%) had published summary results on a registry.

In the future, as part of an ongoing review of our policy, we'll decide if we should require all trials we fund to be registered in a specific registry. For example, the Medical Research Council require all clinical trials it funds to be [registered in ISRCTN](#).

We've published the data from this review on [Figshare](#).

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 we get more data we'll be able to give a more complete view in future monitoring reports.

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.

Conclusions and actions

All Wellcome-funded researchers who are required to adhere to our policy are currently compliant.

The evidence collected 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).

However, as noted above, this requirement only applies to new clinical trials we've funded since May 2018.

We will publish our clinical trial compliance data each year. Grantholders who fail to meet the above requirements will be ineligible to apply for further Wellcome funding until they've updated the trial registry.

We hope our updated policy will drive change and increase the number of researchers who 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://www.clinicalstudydatarequest.com/), a clinical trial data sharing platform, in May 2018.

We're pleased to announce that we now have some Wellcome-funded trials available to request through this platform. We are encouraging others to list their completed studies here too.

Read more about CSDR and [what it means for grantholders](#).

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.

More information

- Read our [clinical trials policy](#)
- [Sharing clinical trial data: what it means for you](#)
- [Watch a webinar about CSDR \(opens in a new tab\)](#) to get answers to some frequently asked questions.