

Wellcome clinical trial policy monitoring 2018 to 2020

When we signed the World Health Organization (WHO) statement on clinical trial transparency, we promised to monitor compliance with our clinical trials policy and publish the results annually. Here are our latest 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([opens in a new tab](#)), 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

Using grant application data we looked at all the grants involving clinical trials that were awarded from 1 May 2018, and therefore required to adhere to our policy.

Of the 63 grants we found that:

- 66 trials are listed as planned or active
- 12 trials have missing information as the principal investigators have not responded to query emails
- 33 trials (50%) have not started recruitment yet
- 21 trials (32%) are active and registered in an approved registry
- none have published summary results – although they are all still within 12 months of the primary study completion date.

We also looked at the reporting data (annual progress and end-of-grant reports) completed by grantholders between October 2018 and March 2020 that indicated that their grant involves a clinical trial.

Of the 59 grantholders that submitted a report in this period, we found that:

- 74 trials are listed
- 4 trials have not started recruitment yet
- 3 trials have missing information
- 67 trials (100%) are registered in an approved registry
- 19 trials published their protocol
- 4 trials published their statistical analysis plan
- 32 trials included a data sharing plan.

Retrospective data

We also analysed data from all Wellcome grants involving a clinical trial that were already active on 1 May 2018 when the new policy took effect. 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 185 Wellcome grants, involving 272 clinical trials (either completed, active, or planned). Of these trials, 165 had been registered in a trial registry.

We recognise that 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.

Our analysis shows that the most well-used registry for Wellcome-funded researchers is clinicaltrials.gov, with 120/165 (73%) registered with them and 23 (14%) registered with [ISRCTN](https://www.isrctn.com/). The remaining 13% are registered in 7 other registries.

Our review also identified 62/165 registered trials had completed more than 12 months before May 2020, when the data was collected. Of these, 5 (8%) had published summary results on a registry. Although posting summary results was not a Wellcome policy requirement for any of these studies as they were all awarded before May 2018, it is disappointing to see such a low number of trialists update their registry entries. Many of these trials will have published findings in peer-reviewed articles but we have not tracked this data, or the possible publication bias for positive results.

We've published the full dataset for this review on [Figshare](#)(opens in a new tab).

This isn't a comprehensive picture of all clinical trials we support because our current reporting systems are complex and often involve other funding partners.

Conclusions and actions

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

The 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).

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 requirements will not be eligible 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.

More information

- See Wellcome clinical trial policy monitoring 2018-2019 [PDF 158KB].
- Read our clinical trials policy
- Sharing clinical trial data: what it means for you