

Wellcome clinical trial policy monitoring

2018 to 2021



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, and make sure that 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 that involve a clinical trial.

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 92 grants we found that:

- 104 trials are listed as planned, active, or complete
- 8 trials have missing information as the principal investigators have not responded to query emails
- 47 trials (45%) have not started recruitment yet
- All 49 active or complete trials are registered in an approved registry, although 11 of them (22%) were retrospectively registered
- 38 trials included a data sharing plan, although 13 said 'no' to sharing individual patient data and 2 were 'undecided'
- 14 published the protocol and 7 published the statistical analysis plan
- 3 trials completed more than 12 months ago have not posted summary results in their registry entry. We will remind grantholders of their grant obligations – if summary results are not posted within 3 months, these grantholders will not be eligible to apply for further funding from Wellcome.

Retrospective data

We also looked at reporting data and registry entries for Wellcome-supported trials that were active from May 2018 onwards, to see how frequently trialists publish their protocols, statistical analysis plans and data sharing plans. We found:

- 196 (100%) of registered trials are in an approved registry
- 48 out of 104 (46%) trials, where we have data, published their protocol
- 13 out of 50 (26%) trials, where we have data, published their statistical analysis plan
- 130 (66%) trials included a data sharing plan, although 36 said 'no' to sharing individual patient data and 21 were 'undecided'.

Note that not all of these are subject to the May 2018 policy and denominators are not consistent due to incomplete reporting.

The most well-used registry for Wellcome-funded researchers is clinicaltrials.gov, with 137 out of 196 (70%) registered with them and 33 (17%) registered with ISRCTN. The remaining 13% are registered in 7 other registries.

Our review identified 88 out of 196 registered trials that were completed more than 12 months ago according to dates on registry entries. Of these, 15 (17%) had published summary results in a registry. Although posting summary results was not a Wellcome policy requirement for the majority of these studies (only 3 were awarded after 1 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, nor the possible publication bias for positive results.

We've published the full dataset use for this review on FigShare.

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

A small number of Wellcome-funded researchers have not shared summary results within 12 months of the primary study completion date. This is in breach of our grant conditions. As outlined above, we will follow up with these researchers and apply sanctions, where appropriate.

The evidence shows that, while researchers register their trials in an appropriate registry, they don't always:

- prospectively register the trial before the first subject receives the first intervention
- include a data sharing plan
- publish protocols and statistical analysis plans
- add summary results to trial registries (referring to a publication is not sufficient).

We will publish our clinical trial compliance data each year. Grantholders who fail to meet the above requirements will be notified and given reasonable time to update their registry entries. But if they remain non-compliant, they will not be eligible to apply for further Wellcome funding.

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