

# Wellcome clinical trial policy monitoring 2018-2022

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, include a data sharing plan, name Wellcome as a funder and provide Wellcome grant number
- 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.

### Available data:

Of the 89 grants involving a clinical trial, we found that:

- 105 trials are listed as planned, active, or complete
- 14 of these 105 trials have missing information as the principal investigators have not responded to query emails enquiring about trial status and progress.
- 19 of these 105 trials have not started recruitment yet

Please be aware that this analysis excludes grants where the initial application stated a clinical trial, but the grant holder did not confirm whether the trial would

go ahead. We have sent query emails to these grant holders, and the resulting trial information will be included in next year's report.

### **Adherence to pre-trial policy requirements:**

- All 72 (100%) trials that ever-started recruitment, were registered in an approved registry. Of these, 2 registered trials were temporarily stopped before recruitment was complete and are currently exempt from adhering to our policy.
- Therefore, there are 70 registered trials either active or complete, although 16 (23%) were retrospectively registered.
- 61 (87%) trials included a data sharing plan, although 18 (30%) said 'no' to sharing individual patient data and 3 (5%) were 'undecided'.
- 19 (27%) of trials listed both Wellcome as funder and provided the relevant grant number. 27 just listed Wellcome as a funder, while 24 did not provide either detail.
- 28 trials have completed the recruitment stage and were therefore required to submit a trial protocol and statistical analysis plan (SAP) to remain compliant. Of these 14 (50%) provided the trial protocol, while 9 (32%) provided both documents.
- 42 trials are currently at the recruitment stage, this they are not yet required to publish the trial protocol and SAP to remain compliant. However, in this group 9 trials have already provided one of the documents, and 7 have already provided both.
- Overall, of the 70 active or complete trials, 30 trials published either the protocol or the SAP, while 16 provided both documents.

### **Adherence to post-trial policy requirements**

- 25 trials are completed as of September 30<sup>th</sup> 2022. Of these, 9 (36%) trials were completed more than 12 months ago, but did not post summary results in the registry website and remain non-compliant.
- 12 trials were completed less than 12 months ago and so are not yet required to post summary results to remain compliant.
- Overall, 4 (16%) trials posted summary results in their registry website within 12 months trial completion.

We've published the full dataset used 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

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 before recruitment stage completion
- list Wellcome as a funder and include the relevant grant number
- 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.

## Good practice examples

We would like to showcase clinical trials whose registries are fully compliant with our policy:

- [The FISH trial](#)
- [The MIST1 trial](#)

- [The MESA-TB trial](#)