

MRC Clinical Trials Review 2020

Which MRC studies were included in this review?

The 2020 Clinical Trials Review includes all clinical trials funded by MRC project awards made between 01/02/2011 and 31/01/2019. Although 295 awards for clinical trials were made during this period, 24 had not started or were suspended; the review therefore included 271 trials.

Of 271 trials included in the 2020 review, 45 were new awards made between 01/02/2018 and 31/01/2019. We extended this review to include global health trials and developmental clinical studies and identified 31 additional 'historical trials', which had started before 01/02/2018 but were not included in previous reviews.

All 271 awards were reviewed against the requirements in the *MRC policy on Open Research Data from Clinical Trials and Public Health Interventions* published in October 2016. These requirements are:

- Prospective registration in the ISRCTN registry (for global trials, a regional WHO primary registry is accepted);
- Provision of the registration details (registry number) to the MRC within 12 months of registration;
- Public report of the trial's main results in a timely manner (and always within 24 months or trial/award end);
- The registry entry should include a link to the report or a copy of the report of the results for completed trials.

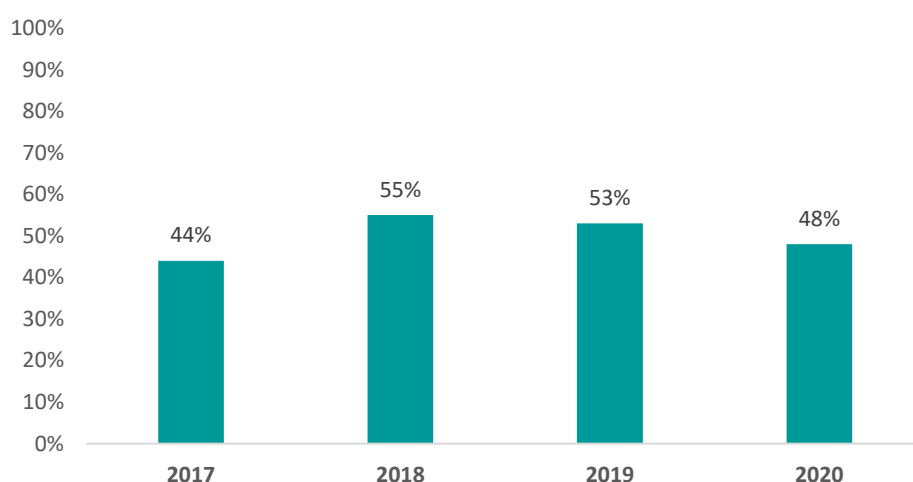
Principal investigators are expected to make datasets from their trial available to other researchers for re-use.

Registration in a Clinical Trials Registry

Of **271** clinical trials in the review,

- **100%** were registered in a public trials registry
 - **131 (48%)** were registered with the ISRCTN registry
 - **22 (8%)** were global health trials registered with a regional WHO primary registry
 - **123 (45%)** of those not registered with ISRCTN were registered in another registry

Percentage of all trials registered with ISRCTN



Compared to previous reviews, the percentage of trials registering with ISRCTN has remained the same. This has not improved since the introduction of the MRC policy in October 2016, as only 36% of trials started since 01 /02/2017 were registered with the ISRCTN registry.

Prospective registration

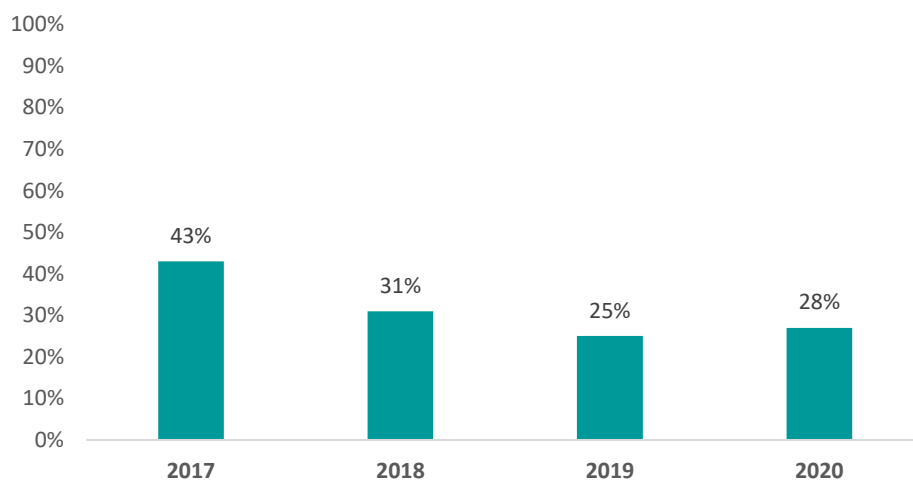
Of the **45** new trial awards made in the most recent year of the review period (between 01/02/2018 and 31/01/2019),

- **31 (69%)** were registered **prospectively** before trial recruitment began.

Provision of Registration Details to the MRC

MRC award holders reported the registry number for **75 (28%)** trials to the MRC in their annual report.

Trials reporting registry numbers to MRC



Compared to previous reviews, there has been a decrease in reporting of the registry number to the MRC.

Linking to the trial protocol from the registry entry

Of **271** clinical trials in the review,

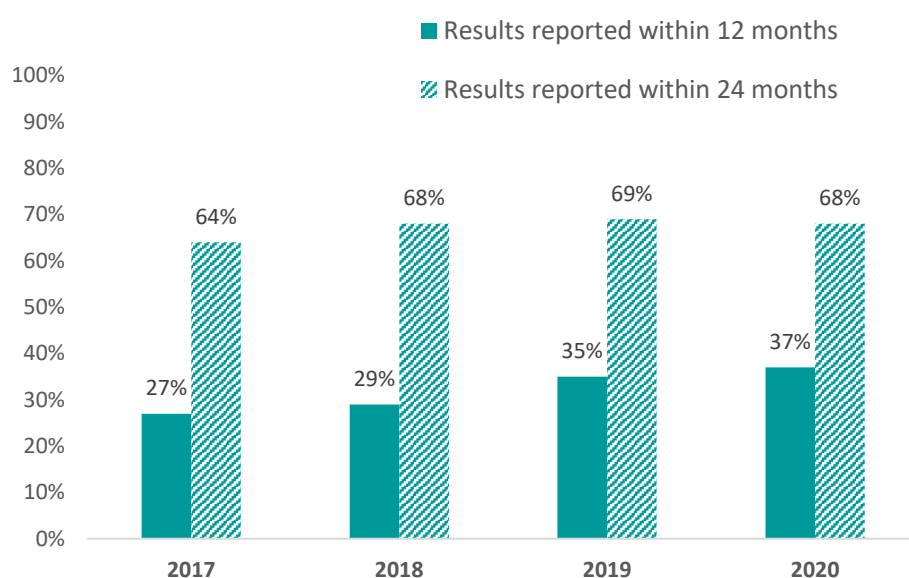
- **84 (31%)** had either published a trial protocol or provided a link to it in the registry entry.

Public Reporting of Results

Public reporting of results was required for all **130** trials in the review that had ended by 01/02/2019:

- **121 (93%)** had published/reported/posted their main results.
 - **48 (37% of 130)** published/reported **by 12 months** after award/trial end
 - **41 (32% of 130)** published/reported **12 to 24 months** after award/trial end
 - **32 (25% of 130)** published/reported **more than 24 months** after award/trial end.
- **9 (7%)** had **not published or posted results**.

Public reporting of results after trial end



There has been a trend towards earlier reporting of trial results demonstrated by a steady increase in trials reporting within 12 months of the trial or award end.

Reporting of Results in the Registry Entry

Of **67** completed trials that had reported results and were registered in the ISRCTN registry:

- **62 (93% of 67)** provided a link to the main results in the ISRCTN registry; 8 of these had also posted results in the EU Clinical Trials Registry (EUCTR)

Of **54** completed trials that had reported results and were registered in another registry:

- **36 (67% of 54)** provided a link to the main results in a registry; 9 also posted results
- **7 (13% of 54)** posted results in a registry (but did not provide a link to any report)
- **10 (19% of 54)** neither provided a link nor posted results in a registry.

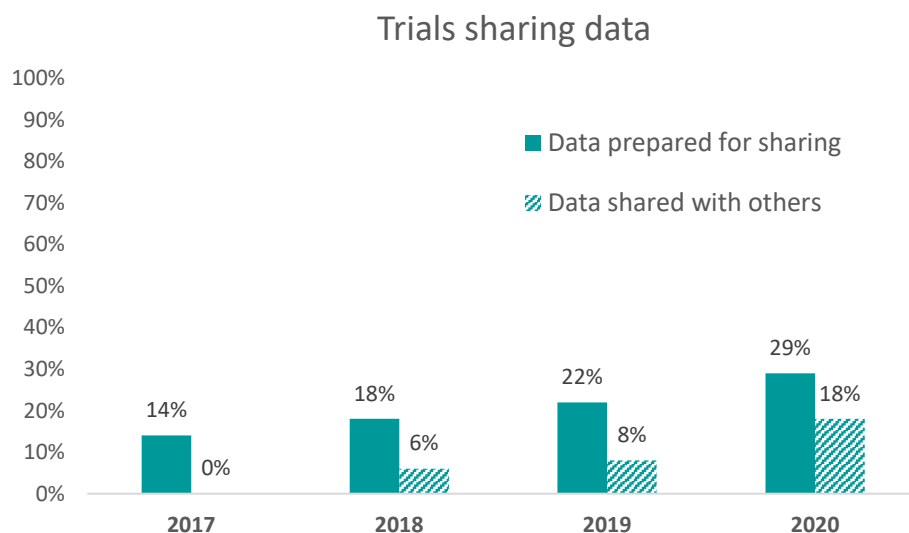
Trials that were registered in the ISRCTN registry were more likely to provide a link to the main results (or post results) than those that were registered in another registry.

Data Sharing

A valued output of all studies is the preparation of a study dataset for sharing with external researchers. Researchers are expected to provide details of any datasets/databases created or shared in their annual report to the MRC.

For the **130** completed trials:

- **38 (29%)** had created a dataset for sharing
- **24 (18%)** had shared a dataset with other researchers.



Compared to previous reviews:

- there has been a steady increase in the percentage of completed trials in which a dataset has been prepared for sharing, and
- a steady increase in the percentage of trials where the trial dataset has been shared with other researchers.

Conclusions

The 2020 review included some historical trials (international and developmental clinical studies) that had not been included in previous reviews and so offers a more comprehensive picture of the MRC clinical trials portfolio. Overall compliance with the policy was good but improvements are still required in some areas:

- Trial registration was excellent at 100%, and there was a year on year increase in the percentage of new trials registering prospectively before recruitment began
- The percentage of trials that registered with ISRCTN or a WHO primary registry – as required by MRC policy – had not improved in comparison with previous reviews
- There was also no improvement in the percentage of researchers reporting trial registration details to the MRC using the annual report system
- The trend towards earlier reporting of results from completed trials continued, with 37% now reporting results within 12 months of trial end and 69% within 24 months of trial end
- Nevertheless, the percentage of trials that had not reported results within 24 months remained unacceptably high at 31%, and 7% of trials had never reported
- More datasets had been prepared for sharing, and shared with other researchers, than in previous years.

Changes to MRC requirements

In order to improve compliance with registration and reporting requirements, the MRC has introduced the following:

- new awards beginning after 01 February 2020 that are not registered with the ISRCTN, or do not provide registration details to the MRC, will have their funding suspended until this is completed
- when future MRC funding awards are made to applicants who have not yet reported findings from a completed trial, the new funding will not start until the previous trial results are publicly reported.

MRC will explore whether it is possible to capture the registry number directly from registries to improve completeness and reduce the workload on researchers of providing these details.

Note about corrections: This report and the accompanying audit dataset were corrected on 12 June 2024 as two grant awards made after 01/02/2019 had incorrectly been included. These awards were deleted from the audit dataset and the report corrected to reflect any changes in numbers and percentages. The section 'Reporting results in a registry entry' was also rewritten to be clearer.