

MRC Clinical Trials Review 2019

Which MRC studies were included?

The 2019 Clinical Trials Review includes all clinical trials funded by MRC project awards made between 01/02/2011 and 31/01/2018. Although 225 awards for clinical trials were made during this period, 9 had not started or had been temporarily suspended; the audit therefore included 216 trials.

Most trials (175) were included in the 2018 review, and there were 21 new awards made between 01/02/2017 and 31/01/2018. There were also 20 additional awards, which were either global health trials or developmental clinical studies that had not been identified for the 2018 audit, or where the trial had started mid-way through the award.

All 216 included 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 **216** clinical trials in the audit,

- **100%** were registered in a public trials registry;
 - **115 (53%)** were registered with ISRCTN;
 - **3 (2%)** were global trials registered with a regional WHO primary registry (but not ISRCTN);
 - **98 (45%)** were registered with another registry.

Compared to previous audits, there has been some improvement in the proportion of trials registering with ISRCTN: 44% (2017), 55% (2018), 53% (2019).

Linking to the trial protocol from the registry entry

Of **216** clinical trials in the audit,

- **75 (35%)** had a link to the trial protocol in the registry entry.

Prospective registration

Of the **21** new trials awards made in the most recent year of the audit period (between 01/02/2017 and 31/01/2018),

- **19 (90%)** were registered **prospectively** before trial recruitment began.

Provision of Registration Details to the MRC

Principal Investigators (PIs) reported the registry number for **55 (25%)** trials to the MRC in their annual report (using Researchfish).

Compared to previous audits, there has been a decrease in reporting of the registry number to the MRC via Researchfish: 43% (2017), 31% (2018), 25% (2019).

Public Reporting of Results

Public reporting/publication was required for all **97** trials in the review that had ended by 01/02/2018:

- **89 (92%)** had published/reported/posted their main results.
 - **34 (35% of 97)** published/reported **by 12 months** after award/trial end
 - **33 (34% of 97)** published/reported **12 to 24 months** after award/trial end
 - **22 (23% of 97)** published/reported **more than 24 months** after award/trial end.
- **8 (8%)** had **not published or posted results**.

FINAL REPORT

Compared to previous audits,

- **there has been an increase in reporting within 12 months of the end of the trial:** 2017 (27%), 2018 (29%), 2019 (35%);
- **the percentage reporting within 24 months of the end of the trial has remained steady:** 2017 (64%), 2018 (68%), 2019 (69%).

Of the **8** trials that had not yet reported,

- **3** had been complete for between 12 and 24 months;
- **5** had been complete for over 24 months.

Reporting of Results in the Registry Entry

Of **89** completed trials that had reported results:

- **50 (56% of 89)** provided a link to the main results in the ISRCTN registry;
- **21 (24% of 89)** provided a link to the main results in another registry (including 1 in ISRCTN also);
- **12 (13% of 89)** posted results in a registry (8 also had a link to results in a registry);
- **15 (17% of 89)** did not provide a link or post results in a registry.

Data Sharing

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

For the **97** completed trials:

- **21 (22%)** had created a dataset for sharing;
- **8 (8%)** had shared a dataset with other researchers.

Compared to previous audits,

- **there was an increase in the percentage of completed trials creating a dataset for sharing:** 2017 (14%), 2018 (18%), 2019 (22%);
- **there was an increase in the percentage of completed trials that had shared data:** 2017 (0%), 2018 (6%), 2019 (8%).

Conclusions

The 2019 audit included developmental clinical trials and some international studies that had not been included in previous audits so offers a more comprehensive picture of the MRC clinical trials portfolio. Overall compliance with the policy appeared to be improving, with some exceptions:

- Trial registration was maintained at 100%, and there was year on year increase in the proportion of new trials registering prospectively before recruitment began.
- There was no increase in the proportion of trials that registered with ISRCTN or another WHO primary registry – as registry required by MRC policy – rather than another registry.
- There was no improvement in the reporting of trial registration details to the MRC using the annual report system.
- There was a trend towards earlier reporting of results from completed trials, with 35% now reporting within 12 months of trial end, however the percentage of trials that had not reported within 24 months remained unacceptably high at 31%.
- More datasets had been prepared for sharing, and shared with other researchers, than in previous years.

Next Steps

In order to improve compliance with registration and reporting requirements, the following has now been agreed:

- 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.