

MRC Clinical Trials Review 2017-2023

Which MRC studies were included?

The 2024 Clinical Trials Review includes all funded clinical trials, clinical and public health studies funded by the MRC project awards made between 01/02/2017 and 31/01/2023. Although 160 awards for these types of studies were made during this period, 19 had not started any trial yet or the project did not progress to the clinical phase and the audit therefore included 141 studies.

All 141 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)
- Public report of the trials main results in a timely manner (and always within 24 months of trial/award end)
- The registry entry should include the main results, or link to a public report of the main results, for completed trials.

If a trial is not registered in the ISRCTN or a WHO primary registry within 12 months of the trial start date then the MRC reserves the right to suspend funding until registration is completed.

Principal investigators (PIs) are expected to make datasets from their trials available to other researchers for re-use.

The MRC aims to audit compliance with the policy on “Open Research Data from Clinical Trials and Public Health Interventions” on a regular basis. Due to the Covid pandemic, there was a gap between 2019 and 2023. Going forward, the MRC aims to provide an audit report more frequently.

Registration in a Clinical Trials Registry

Registration

Of 141 studies included in the audit, 141 (100%) were registered in a public registry (2017 -2023):

- 82 (58%) were registered with ISRCTN
- 24 (17%) were global trials registered with a regional WHO primary registry, of those three were registered in ISRCTN as well
- 38 (27%) were only registered with another registry (not ISRCTN or a WHO primary registry).

The total number for all three bullet points above is 144 (102%) due to three trials being registered with both ISRCTN and a WHO primary registry.

When compared to the trial registration pre-policy (2011 – 2017), the proportion of trials registered in the ISRCTN and WHO primary registries increased after the policy was introduced (2017 – 2023)

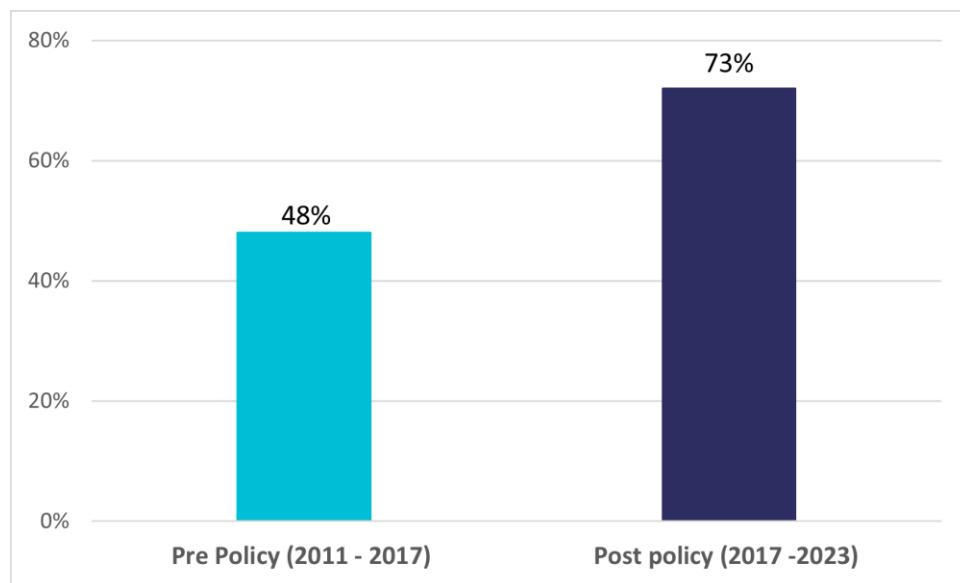


Fig. 1 Registration of clinical trials before and after the introduction of the MRC clinical trial registration policy (Historical data was used for the period 02/2011 to 01/2017, available in previously published [Clinical Trial Audit Reports](#)). The percentage shown is equivalent to the number of trials which were registered in ISRCTN or a WHO primary registry as a percentage of all trials funded during the period. Trials registered with both ISRCTN and a WHO primary registry were only taken into account once when calculating the percentage of 73%

Registration after introduction of temporary suspension of funding for non-compliance

The MRC introduced a process for suspending funding for trials awarded after 01 February 2020 that were non-compliant with the policy, i.e. not registered in the ISRCTN or a regional WHO primary trials registry by 12 months after trial start date.

We contacted PIs of trials where the ISRCTN registry number was not reported to the MRC and not easily retrieved from publications or reports. After multiple reminders, we notified three PIs who had not complied that we were drafting letters of suspension and also engaged the MRC staff members who had oversight of these trials in contacting the PIs. We had a good response at this stage and the three trials were registered before we sent out any formal letters of suspension of funding.

Of the 50 clinical trials that started after the 01 February 2020, 100% were registered in a public clinical trials registry, of which

- 42 (84%) were registered with ISRCTN
- 7 (14%) were global trials and were registered with a regional WHO primary registry
- 1 (2%) was not registered in either the ISRCTN or a regional WHO primary registry, therefore was non-compliant.

Only one trial had not registered in ISRCTN or a regional WHO primary registry. This trial had finished for several years by the time of this delayed audit, therefore funding could not be suspended.

The percentage of trials that were registered in the ISRCTN or WHO primary registries increased from 56% before suspension was introduced to 98% after this time point.

- After introduction of MRC's policy (2017 – 2020): 56%
- After introduction of suspension process (2020 – 2023): 98%

Prospective registration in the most recent audit year (2022-2023) only

Of the 17 new trial awards made in the most recent year of the review period (between 01/02/2022 and 31/01/2023), 16 (94%) had registered the trial prospectively. The 17 trials were all registered in ISRCTN and WHO primary registries. Four trials were registered with ISRCTN and another registry, two of these registered prospectively with the other registry and retrospectively with ISRCTN.

This is an increase in prospective registration in comparison to the last two audits.

- 2019 audit (between 01/02/2017 and 31/01/2018, 19 trials in total): 90%
- 2020 audit (between 01/02/2018 and 31/01/2019, 45 trials in total): 69%
- 2024 audit (between 01/02/2022 – 31/01/2023, 17 trials in total) 94% (the most recent year of the current audit).

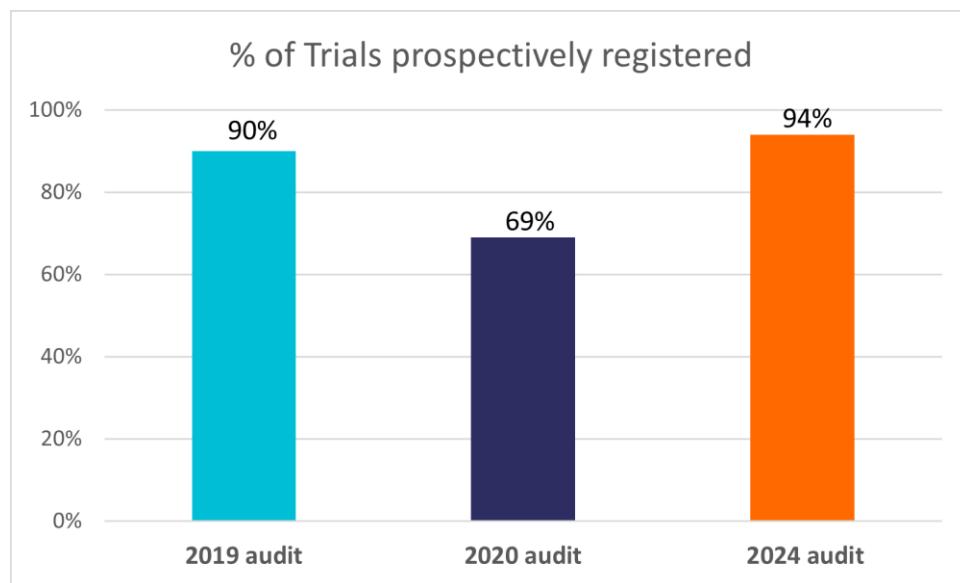


Fig. 2 Prospective registration of studies registered. For each audit, new awards made in the recent year of the audit period were included. For the 2019 audit this is 01/02/2017 and 31/01/2018, for the 2020 audit this is 01/02/2018 and 31/01/2019 and for the 2024 audit the period is 01/02/2022 – 31/01/2023. The [2019](#) and [2020](#) audit reviews can be found on the MRC website.

Prospective registration in ISRCTN, all years since February 2020

Looking at all 50 trials awarded after February 2020, 42 were registered in the ISRCTN registry. Of those, 33 (79%) were registered prospectively before trial recruitment began.

This is an increase in prospective registration of ISRCTN registered studies compared to the previous audits.

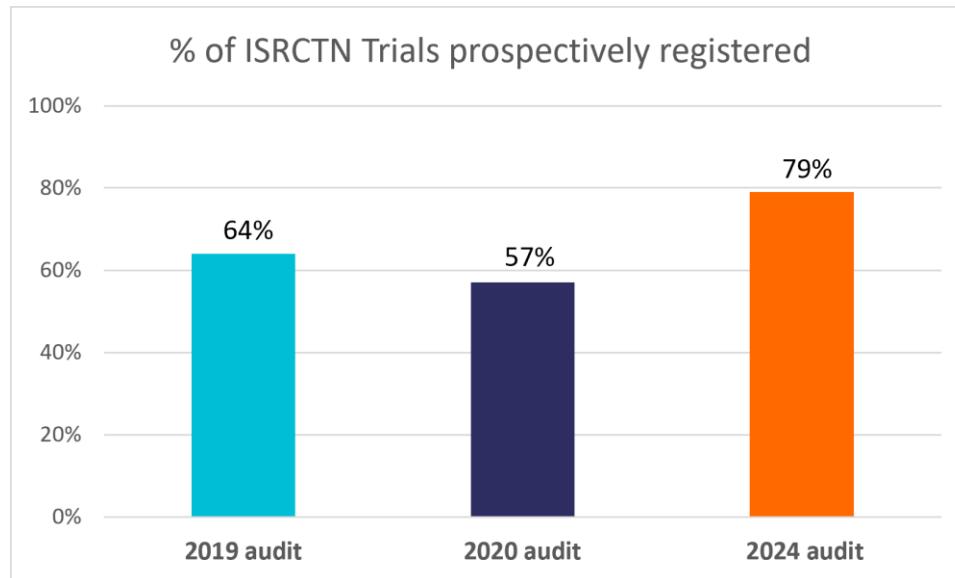


Fig. 3 Prospective registration of ISRCTN registered studies in the 2019, 2020 and 2024 audit. The [2019](#) and [2020](#) audit reviews can be found on the MRC website. The column for the 2024 audit shows all ISRCTN registered studies awarded after February 2020.

Reporting of Results and Reporting of Results in registry

Timely reporting of results

Of the 141 studies awarded since the introduction of the policy (01/02/2017 to 31/01/2023), 100 trials were completed by the time of the audit cut off date (31/12/2024). Of these, 58 studies had finished for 24 months or more and public reporting or publication of the main results was required.

Of the 58 studies due for reporting, 53 (91%) had publicly reported their data.

The timelines of reporting of the main results for the studies which were due to reported their main results was as follows:

- 26 (45%) published/reported by 12 months after award/study end
- 15 (26%) published/reported 12 to 24 months after award/study end
- 12 (21%) published/reported more than 24 months after award/study end
- 5 (9%) were overdue and had not yet reported.

We contacted the PIs of the trials which are overdue for reporting. For three, the delay was due to staff issues and pandemic-related delays. Another PI noted that there was significant political turmoil in the country the trial took place, resulting in a delay in sample release and publication of data. All contacted PIs expect to publish their data in the coming months. This will be followed up in our next audit.

Compared to the 2020 audit, when only 37% of studies had reported the main results within 12 months of ending, this had increased to 45% in this audit.

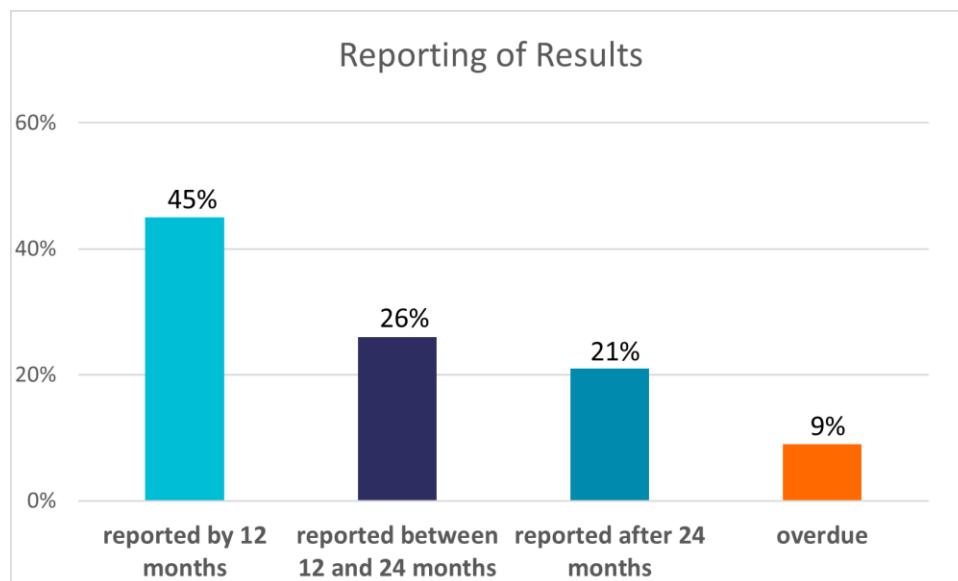


Fig. 4 Reporting of results The graph shows the time between studies completing and the publication of the main result. In total, 70% of studies which were due for reporting at the audit cut off date were found to have reported their results on time. NB: the total of all four bars comes to 101% due to rounding up the percentage calculations to the nearest whole number.

Reporting Results in the Registry Entry

Of the 49 completed studies which have reported results, 23 (47%) studies reported the results in a registry.

- 15 (28%) provided a link to the main results in the ISRCTN registry entry
- 11 (21%) provided a link to the main results in another registry (not ISRCTN)
- 8 (15%) posted results in the registry (six of these had also linked to the main results and are represented twice in these figures)
- 25 (47%) did not provide a link or post results in a registry.

Trial data shared

Of the 53 trials that had published their main results, 28 (53%) had made provisions to share their data with other researchers, including providing contact details for data access requests and information about what data sets could be shared.

Conclusions

This audit provides data on trials and trial awards commenced since February 2017, after the MRC policy on *Open research data: clinical trials and public health interventions* established requirements for registration and publication of MRC-funded clinical trials.

Our aim is that 100% of studies within the scope of the MRC policy are registered with ISRCTN and/or with a regional WHO primary registry. There were four studies which were funded by awards made after the MRC policy for trial registration came into effect (February 2017) which were not registered in the required registries. We engaged the MRC Programme Managers with oversight for these trials in contacting the PIs. We had a good response at this stage and the trials were registered before we sent out any formal letters of suspension of funding. The fourth study had already finished for several years and data had been published. As the gap between the current and previous audit was relatively long, we failed to identify this trial when registration with our preferred registries was still possible and this highlights the importance of regular audits. Of note, all four trials were registered with other registries such as clinicaltrials.gov but not with MRC's required registries.

Only 94% of studies of grants awarded in the last year of the audit period were registered before participant recruitment started. Our aim is for this to be 100%.

We have contacted the PIs of studies which were completed more than 24 months ago. Where study results have not yet been published, papers have been submitted or the PI is in the process of doing so. Two PIs cited staffing issues during and post Covid as reasons for delay in data analysis and publication. The analysis and publication of data of another trial was significantly impacted by political changes in the trial country.

When contacting PIs regarding the MRC requirement for studies to be registered with ISRCTN or a regional WHO primary registry, we found that not all PIs were aware of this specific requirement. This is also evident from the number of trials that did not register prospectively. Additionally, not all PIs were aware that the scope of the MRC policy is wider than clinical trials of medicines. We therefore conclude that the MRC needs to raise awareness of the specific requirements of the policy and we are currently in the process of identifying the best channels to do this.