Clinical trial registry reporting: a transparent solution needed

On April 30, 2019, TranspariMED, BUKO Pharma-Kampagne, Test-AAnkoop, and Health Action International, advocacy organisations that are concerned with transparency in medical research and equal access to medicines, released a document on the reporting of clinical trial data for 30 European universities that sponsor the largest number of trials governed by EU clinical trials regulation. The report shows that 778 (83%) of 940 clinical trials sponsored by these universities due to post their results on the EU Clinical trials Register (EudraCT) had not done so. This inaction violates EU rules that took effect in July, 2014, which require all clinical trials registered in EudraCT to post summary results within 12 months of study completion. It is also in contravention of WHO best practice guidelines. Given the clear importance and ethical imperative for public reporting of trial data, what can be done to guarantee trial outcome transparency?

The reasons for legally requiring data to be reported on a registry file at the end of a trial are manifold and are ultimately in place to safeguard patients, protect research funding, and ensure an open scientific enterprise. Thus, it is shocking that, according to the report, 14 of 30 European universities assessed have not reported any summary data on registries for trials that have completed, irrespective of whether these data have been published in the academic literature. However, the problem does not seem to be confined to the EU. TranspariMED, in collaboration with Universities Allied for Essential Medicines, released a similar report on March 25, 2019, for 40 universities in the USA; the report found 140 (31%) of 450 clinical trials legally required to report summary data on ClinicalTrials.gov had not done so, breaching the US FDA Amendments Act, which came into effect in January, 2017. Although other trial registries also require data reporting after trial completion (eg, Australia and New Zealand's ANZCTR, since October, 2018), the scope of any potential under-reporting in these national trial registries is currently unknown.

It is noteworthy that the European report highlights the UK as an important outlier, showing that, for the five UK universities assessed, 107 (69%) of 155 completed trials have posted summary results in EudraCT. The report credits three efforts for the UK's superior compliance: pressure from Parliament, research funders, and health integrity and transparency groups, including TranspariMED. It should be noted, however, that improvements in reporting behaviour in the UK have been relatively recent (for some, since November, 2018) and have been made by only a small number of universities. Thus, maintaining and enforcing compliance in a larger number of universities is critical, and in the long term, especially as the number of registered clinical trials increases every year.

Who is responsible for holding universities (and all trial sponsors) accountable for updating these data—and how? The FDA Amendments Act authorises fines of US$10 000 for violations, but has yet to issue one (as of October, 2018). Clinical trial funders can threaten to withdraw support, but it is unclear whether this penalty has ever been implemented. Perhaps if there were tougher mechanisms to enforce trial reporting—eg, a national or an international watchdog, with the authority to act and also with the necessary infrastructure, personnel, and budget to do so—then trial reporting would improve. Punishing offenders is one way to recoup wasted effort, confirm data reporting, and deter failures to report, but it discounts positive measures that encourage trial sponsors to behave pro-actively to keep registries up to date.

Consideration of the reasons why universities fail to update summary trial data at the end of a trial, might provide clues towards a solution. Oncology triallists should take the lead here. According to the latest WHO data, oncology trials represent the largest proportion of all clinical trials being done across the medical continuum. Universities already face many hurdles when undertaking clinical trials, including cost, workload demands, and bureaucracy, which are already overburdensome. Could automated email reminders from the registry to upload summary data be a simple solution that has been overlooked? Regardless of the increased burden, a combination of efforts is needed to improve public reporting of trial results, and immediate and robust action is necessary to eliminate research waste, improve the overall transparency of medical research, and fulfil our ethical obligations to patients.

■ *The Lancet Oncology*

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For the **report on clinical trial data reporting from 30 European universities** see https://docs.wixstatic.com/ugd/01f35d_42e869002189401d80a672d4ecff3f73.pdf?index=true

For more on the **mandate to post clinical trial summary results in EudraCT** see https://www.ema.europa.eu/en/news/posting-clinical-trial-summary-results-european-clinical-trials-database-eudract-become-mandatory

For more on the **WHO best practice guidelines** see https://www.who.int/ictrp/results/jointstatement/en/

For the **report on clinical trial data reporting from 40 American universities** see http://www.altreroute.com/clinicaltrials/assets/download/UniversityTransparencyReport2019.pdf

For more on the ***Lancet* REWARD Campaign against research waste** see https://www.thelancet.com/campaigns/efficiency