Achieving Excellence in Clinical Trial Reporting

Liverpool School of Tropical Medicine Case Study

Carl Henry is the Research Governance Manager at the Liverpool School of Tropical Medicine. The university only sponsors a small number of clinical trials. In this Q&A, he shares his experiences in improving trial reporting performance in the context of a small portfolio and limited research governance resources.

When did you start systematically uploading missing clinical trial results onto trial registries?
As a relatively small institution, Liverpool School of Tropical Medicine (LSTM) runs very few clinical trials and, as such, has been able to track its activity vs. registrations reasonably well. For example, we currently have only two trials listed on EudraCT.

How many results were missing when you started?
There have been four cases where clinical trial results were not uploaded and messages were sent out to the Principal Investigators to remind them of their obligations. They all responded positively.

How many results have you uploaded since then?
We have had 3 clinical trial results uploaded since the process began. The number is low because we run very few clinical trials at LSTM (mostly with partners in low and medium income countries, especially in Africa).

How is the process organised? Who does what?
Currently our approach relies on sending a registration reminder to Principal Investigators from the governance team as part of the set-up of the study. We now plan to embed the process within our approval process so that in future, the university will only agree to assume sponsorship of a study once proof of registration is provided.
How did you deal with old trials that were falsely listed as ongoing?
By writing directly to the Principal Investigators who made the original upload and reminding them to complete the entry by uploading their results.
[Note by TranspariMED: Principal investigators can update the status of their trials on most registries. EudraCT is an exception: only national regulators can update the trial status there.]

What resources were required?
As we are a small institution, the task has been purely manual and has relied on the original governance structure with no extra resources provided.

What are the major barriers you encountered, and how did you overcome them?
In the case of one legacy study, the researcher had left the university so we approached the Head of Department for his new contact details. All researchers we have contacted have been very keen to comply with trial registry requirements.

What are the three most important things other players in the clinical trial ecosystem can do to make trial reporting easier for universities?
- A clear direction as to which trial registry to use
- Better functionality within trial registries
- Allow appropriate funding for governance activities in recognition of the importance of quality compliance within non-commercial research

Based on what you have learned along the way, what would you do differently if you were going to start the process again today?
Ensure there is a process to ensure university governance approvals are conditional on proof of trial registration.

What is your advice for other non-commercial trial sponsors that want to improve their clinical trial reporting?
Petition senior managers to ensure it is recognised that clinical trial registration is a major part of the compliance framework for sponsorship of clinical trials.

What are your plans for the future?
LSTM plans to conduct an audit of all its existing registry entries with view to identifying interventional clinical trials that have remained completely unreported. LSTM plans to initiate the audit in August 2019 and complete it by December 2019. Based on the audit results, the university will then draw up a plan for retrospectively reporting missing trial results.

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