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Achieving Excellence in Clinical Trial Reporting

King's Health Partners Case Study



Image source: EU Trials Tracker, 26 June 2019
<http://eu.trialstracker.net/>

Jackie Pullen is the Director of the King's Health Partners Clinical Trials Office (UK). Her team has uploaded over 100 clinical trial results onto the European trial registry EudraCT in recent years, including results for trials that were completed many years earlier. In this Q&A, she shares her experiences and offers hands-on advice to other Clinical Trial Units and universities that want to improve their trial reporting performance.

When did you start systematically uploading missing clinical trial results onto EudraCT?

We manage the sponsor responsibilities for four organisations: three NHS Foundation Trusts and one university. This work started in 2016. I was conscious that the list of unreported reports was piling up. It took a few months to access the EudraCT system and obtain Results User access to enable reporting of older trials where I had not been listed as the sponsor contact on the initial application. Five results were uploaded in 2016.

How many results have you uploaded since then?

Since I started uploading results in May 2016, we have posted results for 103 trials.

What resources were required? Did you have to hire additional staff?

Extra resources were not available. However, resolving this issue was identified as a priority and I dedicated time to initially conducting the internal audit of EudraCT entries. This has since evolved into a dynamic document that is now being used at least weekly.

Time was then spent navigating the results section of EudraCT and collating publications and results from Investigators prior to uploading results.

How is the process organised? Who does what?

Today, as soon as we receive Clinical Trial Authorisation from a Competent Authority, we register the Quality Manager as a Results User for that trial within EudraCT and we enter the trial onto our results tracker.

Currently, our Quality Manager and I are dedicated Results Users. However, all of our non-commercial team are involved in raising Investigator awareness of the regulatory requirements for publishing results on EudraCT and for ensuring that trial data is analysed and results received by us in a timely fashion to meet the 12 month deadline from End of Trial notification.

How did you deal with old trials that were falsely listed as “ongoing” on EudraCT?

We opened a dialogue with the Clinical Trial Helpline of the MHRA [the UK medicines regulator or ‘Competent Authority’] and provided them with lists of the trials that were falsely listed as “ongoing” but had in fact been completed. All but one of these trials has now had its status corrected.

How long did uploading results take per trial?

Uploading results for trials that were completed pre 2014 only took an hour or two once we became familiar with the system.

Uploading the more complex data required for trials completed post 2014 took longer, on average 5 to 15 hours per trial.

Now you have cleared your backlog of unreported trials on EudraCT, what is the workload of managing EudraCT registry entries on an ongoing basis?

We currently have 54 ongoing trials listed on EudraCT. Managing these entries on EudraCT – including periodic updates and the posting of summary results – entails a total workload of around 20 hours per month across the team, on average.

We have a further 2 trials that are not publicly available as they are Phase I trials, and 11 trials that have received MHRA authorisation but are not listed on EudraCT. We are in discussion with the MHRA regarding these trials.

What are the major barriers you encountered, and how did you overcome them?

For trials that were completed in 2014 or later, it is not possible to simply upload a publication or results document and post the results. A full data set with very specific fields that require data entry and validation (by the system) is required for a user to post results onto EudraCT. However, academic and NHS results, particularly for older trials, are often not provided in the exact format required.

One unresolved issue concerns trials that were abandoned and closed prior to recruitment. These trials are notified to the Competent Authority as closed and without data. Although the Competent Authority can enter these into EudraCT as “prematurely ended” there is no mechanism for a results user to publish anything within the system stating that no data was collected as no participants were recruited. The entry within the public facing Clinical Trials Register will be listed as “prematurely ended” and “no results available”.

What are the three most important things other players in the clinical trial ecosystem can do to make trial reporting easier for universities?

- 1. Provide a user-friendly system – this is not EudraCT’s claim to fame!*
- 2. Permit the uploading of publications rather than full data sets for low risk (type A) trials.*
- 3. Provide detailed user instructions and a helpful helpline function.*

What problems have you encountered with the current European Medicines Agency helpline? How could it be improved?

Accessing the EMA helpline is very laborious. The user has to log in and navigate through various pages to find the portal to the helpline. Once this is found, the user must add login details again, and then write a brief description of the problem. A receipt is sent immediately; however, it may take a number of weeks to obtain a response. Often the response just provides a reference to the regulation which the user then has to locate to find, and which often only provides a partial answer to the question.

It would be helpful if there was a direct link on the results user page to the helpline and if the helpline provided actual answers rather than purely links to the reference documents – which the user has most likely already referred to prior to sending the request for information.

Based on what you have learned along the way, what would you do differently if you were going to start the process again today?

I would have started making Investigators aware of the EudraCT publication process and its data requirement before each trial even started. We have since produced a Results Template that Investigators use to present their trial results to us once the trial data analysis is complete. We now give this Results Template to Investigators at the trial kick-off meeting that is held as soon as funding has been secured.

We have also introduced results awareness slides into our standard Good Clinical Practice (GCP) training and our specific training for Chief Investigators. In addition, our Clinical Research Associate team, who monitor the trials sponsored by our four partner organisations for compliance with GCP and the European Union regulations, regularly remind Investigators of the requirements and timelines for publishing results and the formats required during the life cycle of the trial.

I anticipate that once these newer trials reach End of Trial notification stage, the results will be presented to us in a way that will enable all compliance staff, once trained, to upload results into EudraCT as Results Users with oversight from the Quality Manager.

Now we have a strong system in place, I expect that uploading the results from future trials will only take around 2 to 4 hours per trial on average.

What is your advice for other non-commercial trial sponsors that want to improve their clinical trial reporting?

- *As a first step, conduct an audit of your trials that are registered within EudraCT, and enter them all into a portfolio management system. Compare the listed status of the trial with the End of Trial notification dates in your records. If a completed trial is incorrectly listed as “ongoing”, contact your Competent Authority and request it to correct its status.*
- *At the earliest possible opportunity, raise awareness among your Investigators of the data and formats required to enable the posting of results.*
- *Familiarise yourself with the EudraCT system and the processes required to (1) become a Results User and (2) enter and post results. Many trials that completed prior to 2014 can have results posted very easily by uploading a publication or results document. I would suggest that these results are uploaded first, as this will familiarise users with the system before the more complex results data entries are attempted.*
- *Develop a small group of expert Results Users within your team or department initially, and later roll out to other staff members.*

Additional case studies and transparency tools are available at www.transparimed.org/resources

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