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Achieving Excellence in Clinical Trial Reporting

University of Nottingham Case Study

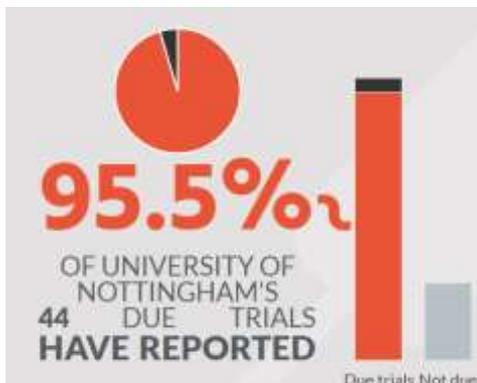*Image source: EU Trials Tracker, 27 April 2019*
http://eu.trialstracker.net/

The University of Nottingham is a European leader in clinical trial transparency. Over 95% of its due trials now have summary results posted on the European trial registry EUCTR – a steep increase from its 2018 reporting rate of only 8%.

In this Q&A, the University explains how it tackled its unreported trials, and provides useful advice to other universities across Europe.

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

- The University of Nottingham audited its trial registrations on EudraCT in December 2018 and commenced immediate action to post or update missing results. This process was completed in March 2019.

- Over the same time period, the University reviewed and updated its policies, systems and processes to ensure summary results in future would be posted on the relevant registries in a timely manner by academics engaged in clinical trials academics. A new guide to Trial Registration was published on 17 December 2018.

- The guide has been regularly communicated to academic staff engaged in clinical trials research, alongside support and advice from our Research Governance team, to help them meet their responsibilities in registering trials and posting results.

How many results were missing when you started, and how many results have you uploaded since then?

- Some 46 trial results were identified in the audit as potentially missing. One trial was subsequently confirmed as not a CTIMP and one trial was confirmed as having been registered but subsequently cancelled. These records were corrected and all other trial results have now been uploaded.

How is the process organised? Who does what?

- The Head of Research Governance conducted detailed audits of each registry, producing a detailed analysis of missing results and senior responsible owners (SRO) for each trial. Each SRO was contacted with a request by the Head of Research Governance and Faculty Pro Vice-Chancellor to post their results and offered support and guidance to do so where required.

- In a significant number of cases, and in the interests of urgently addressing the backlog, the Head of Research Governance obtained the trial results from the SRO, requested EMA transfer the studies to her account, updated the registry and then contacted the MHRA [UK's national medicines regulator] to advise them to alter the status of each trial on EudraCT to 'complete.'

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

- Where trials were incorrectly listed as "ongoing" or incorrectly registered (see above), the Head of Research Governance liaised with the EMA and MHRA to correct the record.

What resources were required? Did you have to hire additional staff? How long did it take per trial?

- To date, the audit and action process has been overseen and largely delivered through the personal efforts of the Head of Research Governance.

- The University is currently augmenting staff resource in the Research Governance team by an additional two posts to further quality assure data management and audit trails across our research portfolio, including trial registries, and to support our clinical trials community in meeting their responsibility in registering trials and posting results.

- The time taken to update each EudraCT record varied widely according to the availability and format of data, the challenges in posting it to the registry, and subsequent liaison with the EMA and MHRA to update the records. On average, each record took several hours to complete.

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

- In posting missing results, academics' results data and tables frequently needed to be re-formatted to suit EudraCT functionality. This was overcome by academics or the Head of Research Governance manually re-formatting the data, which was a time-consuming process.

- In a registry environment where multiple academics and students engaged in clinical trials are individually responsible for registering trials and posting results, it can prove difficult to maintain central records and oversight by the Research Governance team. To overcome this, the Head of Research Governance has introduced a standard procedure whereby she will obtain the EudraCT number and registration for CTIMPs so that all future studies are registered under her account. This will prevent the unintended loss of account details by individuals, support central monitoring, and ensure academics engaged in clinical trials can be reminded to post and maintain results.

- The Research Governance team maintain a database of all studies requiring a declaration of research sponsorship as defined in law and UK Department of Health policies. However, the University along with many others, also conducts research that does not require this declaration and the Governance team have no oversight of those studies. We are examining processes whereby these studies can also be tracked in future.

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

- EudraCT, as indeed most other registries, do not have functionality by which the trial scene can be set, the results discussed and contextualised, and next steps discussed. Introducing a common reporting format within or across registries would overcome the formatting issues discussed above, and introducing further functionality to capture context and next steps could enhance use and compliance by the clinical trials community.

- There is no clear agreed definition of what constitutes clinical research - despite the [WHO attempts at a definition](). Registries are also used to comply with the [ICMJE Lancet paper 2004]() in order to obtain subsequent publication of non-clinical (but medical) and physiology studies, regardless of whether the study is actually fits a definition of 'clinical research' or not. This leads to confusion over which studies do actually need to be publically registered and which do not. Many of these studies are student projects, which are often not novel research and add little to the knowledge base for medicine. Registries therefore could do well to have a mechanism by which researchers and sponsors can flag what type of study it is and whether the results are intended to either be published or contribute to the knowledge base of clinical application

- Registries also presently have no mechanism to remove records or alter the study status to reflect that a study never started or was so prematurely stopped that there are no results to post.

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

- We would have introduced the measures we now have in place, in particular the enhanced central audit and analysis and oversight procedures.

- Better engaging the clinical trials community in the importance of maintaining registry entries. The Head of Research Governance will now regularly review and provide updates at faculty board and committee level on how clinical trials researchers are making positive progress, as well as highlighting where further work is required to ensure compliance.

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

- Be prepared and willing to undertake some intensive activity to bring your records up to date, perhaps devoting a dedicated 'task team' to address this swiftly and comprehensively. Subsequently, and critically, set the parameters, expectations and guidance for maintaining registries and communicate these clearly to the clinical trials community so that responsibilities are clear and progress can be maintained as a matter of routine in the future.

TransspariMED would like to thank the University of Nottingham for sharing its experiences with the wider medical research community.

Universities that want to improve their clinical trial transparency can use TranspariMED's [collection of transparency tools]() to strengthen their policies, processes and performance.