Imperial College London

Visualising the drug harm profile in Randomised Controlled Trials – A Consensus of UK trial researchers

A well-designed graphic is an effective means by which to summarise and communicate important messages to a range of audiences. In clinical trials, where there is abundance of complex harm data visualisations could offer a distinct advantage over presenting tables of Adverse Events (AEs). At present visualisation in publications of RCTs are underutilised. A systematic review we performed in 2018 found that only 12% of journal articles made use of visual summaries for AE data, and this finding has been supported by a survey of UKCRC CTU statisticians.

The CONSORT harms statement and the 2016 recommendations from Lineberry et al. encourage the use of visualisations for AE data. A recent methodological review found twenty plots proposed specifically for AE analysis. With such a range of visualisation options available, we are seeking a consensus to support researchers in their choice of visualisations for RCT publications. This work is currently planned for publication in a special issue of the BMJ in November 2020.

We invite you to take part in this research. This will involve a one-day consensus meeting on Monday 20th April 2020 in York.

Two weeks prior to the meeting you will be provided an information pack including published visualisation methods proposed for AEs. We ask you to review this in order to identify if any plots that you have used have been omitted.

The first part of the day will be spent discussing all of the visualisations in your pack to agree which ones to recommend.

In the second part of the day there will be in depth discussions on potential modifications to the visualisations selected.

The final part of the day will be spent developing recommendations for the pertinent plots to be included in the main published paper.

If you are interested in taking part in this research consensus day, please email early expressions of interest to Rachel Phillips (r.phillips@imperial.ac.uk) so that we can gain an idea of numbers.

N.B. We are seeking statisticians with applied experience of analysing trial data, you do not need to be an expert in AE analysis. The methods we will discuss are appropriate for phase II/III trials, we will not be considering early phase studies. As discussions will be focusing on the analysis phase we will not be discussing issues with the collection of AEs.

Thanks

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