

EXCEL Trial Primary Investigators:

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By Email

Dear Colleagues

I am writing on behalf of the Council of the European Association for Cardiothoracic Surgery (EACTS) to offer our assistance to help resolve the concerns that have been raised with the EXCEL trial analysis. Recent media coverage has sparked considerable debate leading to several requests for appropriate data to be released openly in order to allow independent analysis.

Trials like EXCEL depend on much needed financial investment from industry and their results can drive innovation in clinical practice. These trials are only possible thanks to the generosity of patients who altruistically agree to take part in the expectation that their participation will advance science and improve outcomes for future patients. The EXCEL trial is important because its results were used, among others, to inform clinical guidelines.

We believe that action is now required to re-establish the validity of the EXCEL trial in order to provide safe clinical recommendations. We recommend that the sponsors make the individual patient data available for independent analysis. We suggest that the data are made available to the Institute of Clinical Trials and Methodology at University College London, UK, a very reputable group of trial scientists with considerable international skills and experience in the field. This institution could reanalyse the EXCEL data independently and on your behalf. EACTS would be supportive of such an initiative and provide all necessary support.

We recognise that, given the concerns that have been raised, you may be appointing a separate group to look again at the EXCEL results. If this is the case, and in addition to our suggestion above, we recommend that EACTS is directly involved to provide the independence and the breadth of expertise that this exercise deserves.

Given our collaboration with the European Society of Cardiology and the considerable expertise it can provide, we believe that the ESC's involvement would also be both desirable and appropriate.

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I hope that you will consider these recommendations which are offered genuinely and constructively to help resolve the concerns that have been raised about the EXCEL trial.

I look forward to hearing from you.

With kind regards



Professor Domenico Pagano MD FRCS FESC

Secretary General EACTS