Author's response to reviews

Title: Effective recruitment of participants to a phase I study using the internet and publicity releases through charities and patient organisations: analysis of the Adaptive study of IL-2 dose on regulatory T cells in type 1 diabetes (DILT1D)

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Author's response to reviews: see over
Dear Professor Altman,

Effective recruitment of participants to a phase I study using the internet and publicity releases through charities and patient organisations: analysis of the Adaptive study of IL-2 dose on regulatory T cells in type 1 diabetes (DILT1D)

Thank you for your email of the 19th of January 2015

Following a final assessment, the Editor in Chief has requested that you clarify the relevance of your study in relation to later phase (randomised) trials in the Discussion section of your manuscript.

Thank you for the opportunity to address this comment. We have now revised the first paragraph of the discussion:

“Nevertheless, there is limited published research on effective recruitment strategies to intensive mechanistic studies or trials, despite the importance of these studies in understanding human physiology, pathophysiology and drug responses. The DILT1D (single dose) study was the first study of a program to understand the mechanism of action of ULD IL-2 in participants with T1D. The study has now been followed by the on-going DILfrequency study (repeat dose) that aims to establish the optimal dosing interval for ULD IL-2 therapy[22]. The results from these studies will inform the treatment protocols for future phase II/III randomised control trials of ULD IL-2 therapy thereby maximising the chance of success in these trials based on a prior understanding of the effects of this immunotherapy on the human immune system. Key to this strategy is the rapid conduct of the early phase studies by optimising enrolment. To improve enrolment to current and future studies in T1D we have analysed, the DILT1D study recruitment data from the clinic, register and internet sources and evaluation of the effectiveness of each method.”

We look forward to hearing from you regarding our submission.

Yours sincerely,

Dr Frank Waldron-Lynch and Professor John Todd

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