Author’s response to reviews

Title: The effect of SENATOR (Software ENgine for the Assessment and optimisation of drug and non-drug Therapy in Older peRsons) on incident adverse drug reactions (ADRs) in an older hospital cohort – the trial protocol

Authors:

Amanda Lavan (amandalavan@gmail.com)
Denis O’Mahony (denis.omahony@ucc.ie)
Paul Gallagher (Paul.Gallagher@ucc.ie)
Richard Fordham (R.Fordham@uea.ac.uk)
Evelyn Flanagan (e.flanagan@ucc.ie)
Darren Dahly (ddahly@ucc.ie)
Stevan Byrne (Stephen.Byrne@ucc.ie)
Mirko Petrovic (Mirko.Petrovic@UGent.be)
Adalsteinn Gudmundsson (adalstg@landspitali.is)
Olafur Samuelsson (olafs@landspitali.is)
Antonio Cherubini (a.cherubini@inrca.it)
Alfonso Cruz-Jentoft (alfonsojose.cruz@salud.madrid.org)
Roy Soiza (r.l.soiza@abdn.ac.uk)
Joseph Eustace (j.eustace@ucc.ie)

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Author’s response to reviews:

Ref BGTC-D-18-00629

Dear Prof Aronin,

Thank you for you reviewing the above referenced manuscript. We have addressed your queries and requested revisions as outlined below:
1) BMC Geriatrics requires ethics approval to have been obtained from all sites where the research is to take place before submission of a study protocol. Please send original copies of all approval documentation to BMCSeriesEditorial@biomedcentral.com

Copies of all ethics approvals were emailed as requested on 8/11/2018

2) We note that the ethics approval documentation you submitted is dated November 2015. With reference to the above, and your statement that the study is ongoing, please confirm and provide documentation that the ethical approval is currently in place for your study.

I confirm that the ethics approval is in place as per the ethics approval letter dated 2015 which remains in effect.

3) We have also noted that the funding approval documentation you submitted details the study start date as being October 2012, with no details of the end of your funding, and that the estimated primary completion date for your Senator trial (NCT02097654) on ClinicalTrials.gov is given as March 2015. Please clarify this, and provide further documentation confirming that funding is currently still in place for your study.

The FP7 funding of the Senator Project extended from 01/10/2012 to 28/08/2018 (grant agreement number 305930). Having completed data cleaning the analysis of the data is being undertaken by the Principal Statistician at the HRB Clinical Research Facility Cork, which is supporting this activity as part of its support of the trial.

4) Please clarify the discrepancies in the sample size number and study title between your manuscript and trial registry information on ClinicalTrials.gov.

We apologise for this discrepancy, which resulted in a failure to update the original submission to ClinicalTrial.Gov. The Sample size as outlined in the protocol paper was that used in the final protocol and for the submissions to the ethics committees.

5) Please edit your abstract so that it is in keeping with BMC Geriatrics guidelines (https://bmcgeriatr.biomedcentral.com/submission-guidelines/preparing-your-manuscript/study-protocol) and does not exceed 350 words.

The abstract has been edited and now has a word count of 349 words.
6) Please remove the ‘Funding’ and ‘Sponsor’ sections on the title page, and add the ‘Sponsor’ information to the appropriate Declarations section.

The ‘Funding’ and ‘Sponsor’ sections have been removed from the title page and the Sponsor details have been added to the Declarations section on Page P24, line 6-7.

7) Please integrate your conclusion into the Discussion section of the manuscript.

The conclusion has been integrated into the end of the discussion section, P21 Line 8-19.

8) Please correct your Ethics approval and participant consent statement to list the names of all ethics committees that approved the study, with reference numbers where appropriate, and provide a short summary of the informed consent procedure.

The names of all ethics committees that approved the study, with reference numbers have been added to the text on page 23 Line 8-13. A short summary of the informed consent procedure is provided on P23, Line 14-.17

With Kindest Regards

Prof Joe Eustace
Director HRB Clinical Research Facility Cork