Author’s response to reviews

Title: Clinical and Genomic Safety of Treatment with Ginkgo biloba L. leaf extract (IDN 5933, Ginkgoselect®Plus) in Elderly: A Randomised placebo-controlled clinical trial [GiBiEx].

Authors:

Stefano Bonassi (stefano.bonassi@sanraffaele.it)
Giulia Prinzi (giulia.prinzi@gmail.com)
Palma Lamonaca (palma.lamonaca@sanraffaele.it)
Patrizia Russo (patrizia_russo@hotmail.it)
Irene Paximadas (ipaximadas@gmail.com)
Giuseppe Rasoni (giuseppe.rasoni@hotmail.it)
Raffaella Rossi (raffaella.rossi@sanraffaele.it)
Marzia Ruggi (marzia.ruggi@sanraffaele.it)
Salvatore Malandrino (salvatore.malandrino@indena.com)
Maria Sánchez-Flores (maria.sanchez@udc.es)
Vanessa Valdiglesias (vvaldiglesias@udc.es)
Barbara Benassi (barbara.besassi@enea.ir)
Francesca Pacchierotti (francesca.pacchierotti@enea.it)
Paola Villani (paola.villani@enea.it)
Martina Panatta (martina.panatta@enea.it)
Eugenia Cordelli (eugenia.cordelli@enea.it)

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Jianping Liu, Phd., MD.
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BCAM-D-17-00213: ‘Clinical and Genomic Safety of Treatment with Ginkgo biloba L. leaf extract (IDN 5933, Ginkgoselect®Plus) in Elderly: A Randomised placebo-controlled clinical trial [GiBiEx]’ by Stefano BONASSI et al.

Dear Dr. Liu,

Thank you for these additional remarks. A revised version of the manuscript and a letter describing all changes, point to point, are attached.

Yours sincerely,

On the behalf of all authors

Stefano Bonassi, PhD

Professor,
Department of Human Sciences and Quality of Life Promotion
San Raffaele University, Rome, Italy

Head,
Unit of Clinical and Molecular Epidemiology
Point-by-point responses to Editor’s remarks

1. Please format your abstract to adhere to journal submission requirements and include only the following subheadings:
   - Background
   - Methods
   - Results
   - Conclusions

   In the revised version of the manuscript the abstract has been formatted according to journal submission requirements.

2. Please perform a final spelling and grammar check on all sections in the Declarations section of your manuscript.

   In the revised version of the manuscript the Declarations section of the manuscript has been properly checked.

3. Thank you for providing a section on Ethics approval. We would appreciate it if you could please provide us with the full, official name of the committee which granted you approval for this study, and committee reference number if appropriate. Please also check for correct grammar.
The official name and reference number of the committees which granted approval for this study, have been reported (page 17, lines 2-3).

4. Please change the text under Consent to Publish to: "not applicable".

In the revised version of the manuscript text has been changed as requested (page 17, line 10).

5. Thank you for including a data availability statement. This statement should detail the location of the raw data underlying the conclusions made in this study. We note that only summarized data is presented in this manuscript, so we would like to ask that you amend this statement. If there are any ethics restrictions preventing the sharing of the raw data, please state this. If you do not wish to share the data, please include a reason why it will not be shared in this section.

In the revised version of the manuscript detailed info about supplementary files has been added (page 18, lines 12-14).

6. Thank you for providing a section on author contribution. We use this information to note which author contributed what to the study. We had noticed only three of the sixteen authors are mentioned in this section. Please revise this section to include all authors, so that all authors listed in the manuscript can qualify for authorship.

In the revised version of the manuscript the contribution of each author has been reported (page 17, lines 22-27; page 18, lines 1-2).

7. Please delete all supplementary files you do not wish to include in final publication, such as the CONSORT checklist. It is no longer needed at this stage of production.

In the revised submission we did as requested.

8. Please upload the English version of your questionnaire.

The English translation of the questionnaire has been added (Supplementary file 2).
9. Please use US data notations in all of your data (i.e. a '.' instead of a ',' to refer to a decimal point).

The US notation has been used in the revised version of the manuscript (Supplementary files 3, 4, and 5).

10. We would appreciate if you added a section titled “Supplementary files” where you list the following information about your supplementary material:

- File name
- Title of data
- Description of data

Please ensure that all additional files are explicitly referred to in the main text. Any items which do not meet these requirements may be deleted by our production department.

A citation of all supplementary files has been reported in the revised text (page 18, lines 6-18).

11. Upon uploading your revisions, please remove any tracked changes or highlighting and include only a single clean copy of the manuscript.

Only a single clean copy of the manuscript has been uploaded as requested.