Author’s response to reviews

Title: Clinical Trial Readiness to Solve Barriers to Drug Development in FSHD (ReSolve): protocol of a large, international, multi-center prospective study

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Author’s response to reviews:
Dear Dr. Samuel Harris and the BMC Neurology Editorial Board,

We are resubmitting our protocol manuscript entitled, “Clinical Trial Readiness to Solve Barriers to Drug Development in FSHD (ReResolve): protocol for a large, international, multi-center prospective study” for consideration for publication in BMC Neurology. This manuscript has not been previously published or submitted for consideration to any other journal.

In response to your comments:

1) After the trial registration number, please include the date of registration. If registration took place after the first participant was recruited, please include Retrospectively Registered after the date. This has been added on page 3. It was registered on 1/11/2018 which was not retrospective.

2) In the section Ethics approval and consent to participate in the Declarations, please include the names of the ethics committees in Europe that provided ethical approval for this study and include the reference numbers. This has been added in the Ethics approval and consent section.

3) In the Funding section, please state that the funding body NIH/NINDS peer reviewed the study protocol. This is now clearly stated in the funding section.

4) Please state whether the maps in Figure 1 have been taken from other sources. Please acknowledge the source in the figure legend, and if it is under copyright, also state the written permission given to use and adapt it. This map was taken from the FSHD CTRN website http://www.kumc.edu/fshd/our-sites.html which is stated in the figure legend. It was made by Kansas University Medical Center for this study and is not under copyright.

5) Please remove supplementary table 1. This has been removed from the main manuscript, but currently is still referenced in the manuscript and still uploaded separately. We were really hoping to keep this as supplementary material for the study so that everyone can be acknowledged. Let me know if this cannot be done.

Sincerely,

Samantha LoRusso, MD, Jeffrey Statland, MD, and Rabi Tawil, MD, on behalf of the ReResolve Investigators of the FSHD Clinical Trial Research Network