

Central Committee on Research Involving Human Subjects/Minister of Health, Welfare and Sport
PO Box 16302
2500 BH The Hague

Groningen, 07 January 2020

Subject: Digital submission of substantial amendment NL69548.056.19

Dear members of the Central Committee on Research Involving Human Subjects/Minister of Health, Welfare and Sport,

With this letter QPS Netherlands B.V. sends the documents of the Rodin Therapeutics, Inc. study "A two-part parallel group study to assess the safety, tolerability and pharmacokinetic (PK) profile of multiple oral doses of RDN-929 in healthy older adults and subjects with early symptomatic Alzheimer's Disease" registered under NL69548.056.19.

The modification(s) of this amendment is/are concerning (please tick where appropriate):

- the addition of a new investigational medicinal product;
- a substantial modification of the current investigational medicinal product;
- otherwise, namely: Due to a third case of serum liver transaminase elevation the sponsor decided to put the study on hold. Please find the detailed rationale in the documents submitted as well as the SUSAR report for this case.

With this submission I declare that all relevant documents from the above-mentioned research dossier are signed by the authorised people. The signed documents are/will be submitted for review to the responsible review committee.

Kind regards,

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QPS Netherlands B.V.