To: ccmo_frontoffice[frontoffice@ccmo.nl]
From: ccmo_bi
Sent: Tue 15-10-2019 10:34:13
Subject: FW: Digital submission of substantial amendment NL69548.056.19
Received: Tue 15-10-2019 10:34:15
A1 - Cover letter applicant CCMO, dated 15 October 2019.pdf

Voor Marjolein.

Groet, 5.1.2.e

Van: 5.1.2.e <5.1.2.e@qps.com>
Verzonden: dinsdag 15 oktober 2019 09:08
Aan: ccmo_bi <bi@ccmo.nl>
CC: 5.1.2.e <5.1.2.e@qps.com>
Onderwerp: Digital submission of substantial amendment NL69548.056.19

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

Herewith QPS Netherlands B.V. submits the rationale of the amendment in addition to the substantial amendment (dated 14 October 2019) 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*".

Based on continued review of the data from Part 1 and in consultation with an expert academic hepatologist, the parameters around hepatic safety are being revised to allow for a full evaluation of any potential hepatic safety issues in Part 2. In Part 1, two subjects experienced abnormally increased liver tests which re-turned to normal after the drug was stopped. For this reason, liver laboratory tests will be monitored frequently and subjects may be stopped from taking study drug if liver test abnormalities are found.

With Kind regards/Met vriendelijke groeten,

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

Groningen, 15 October 2019

Subject: Digital submission of substantial amendment NL69548.056.19

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5.1.2.e

QPS Netherlands B.V.

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