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CCMO

Attn. Competent Authority

Parnassusplein 5

2511 VX Den Haag

The Netherlands

Bucharest, 14-Oct-2022

Subject: Digital submission of the Clinical Study Report Amendment
EudraCT no.: 2018-001788-21
Sponsor study no.: 251717
PAREXEL study no.: CRTH258C2302
ToetsingOnline dossier no.: NL68931.100.19
Study title: An Eighteen-Month, Two-Arm, Randomized, Double- Masked, Multicenter, Phase III Study Assessing the Efficacy and Safety of Brolicicuzumab versus Aflibercept in Adult Patients with Visual Impairment due to Macular Edema secondary to Central Retinal Vein Occlusion (RAVEN)

Dear Madam, dear Sir,

On behalf of the Sponsor, **Novartis Pharma AG**, PAREXEL International Romania SRL herewith submits the Clinical Study Report Amendment for the above-mentioned clinical trial to the CCMO as the Competent Authority in the Netherlands.

Reference is made to the previous submission of the CSR of the ^{buiten} ~~reikwijdte~~ ^{verzoek} and RAVEN studies on 11-Jul-2022 where the PK/ADA data relevant for the assessment of immunogenicity could not be included due to the Covid-19 caused delay in sample shipment from 5.1.1.c to 5.1.1.c. The CSR updated with PK/ADA data is now provided.

Please find below the list of documents attached to this notification:

CCMO numbering	Document	Version/Date
A1	Cover Letter to CA NL68931.100.19 CSR Amendment Notification	14-Oct-2022
M3	Clinical Study Report Amendment NL68931.100.19	11-Jul-2022

We trust that the information provided in the application is sufficient, however if you require any further information, please contact us.

Yours faithfully,

5.1.2.e

PAREXEL International Romania SRL

5.1.2.e on behalf of 5.1.2.e

5.1.2.e

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