Parexel International Romania s.r.l.
Metropolis Center - Str. Grigore Alexandrescu, Nr.89-97,
Sector 1, 010624 Bucharest, Romania
J40/9291 /2004; CUI: RO 16494261
Phone: +40 5.1.2.e
Fax: +40 5.1.2.e
www.parexel.com

PER E-MAIL TO BI@CCMO.NL
CCMO
Attn. Competent Authority
Parnassusplein 5
2511 VX Den Haag
The Netherlands

Bucharest, 11-Jul-2022

Subject:	**Digital submission of the synopsis of the Clinical Study Report**
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 Brolucizumab 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 s.r.l herewith submits the synopsis of the Clinical Study Report for the above-mentioned clinical trial to the CCMO as the Competent Authority in the Netherlands.

Please note that the pharmacokinetic (PK)/anti-drug-antibody (ADA) data analysis, which is relevant for the assessment of immunogenicity is currently missing from the enclosed CSR and synopsis of the buiten reikwijdte verzoek and RAVEN studies. The reason for this is due to the delayed availability of the final interpreted data of PK/ADA sample shipment from 5.1.1.c to 5.1.1.c due to Covid-19 (unavailability of flights to Shanghai due to Covid-19). The CSR and synopsis of buiten reikwijdte verzoek and RAVEN studies will be updated with the PK/ADA data as soon as possible and will be submitted to the agency once available (expected Q3 2022).

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

CCMO numbering	Document	Version/Date
A1	Cover Letter to CA NL68931.100.19CSR Synopsis Notification	11-Jul-2022
M3	Clinical Study Report Synopsis NL68931.100.19	28-Mar-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
89-97, Grigore Alexandrescu Street
Bucharest, Romania, 010624
T +4 5.1.2.e
F +4 0 5.1.2.e
Email: 5.1.2.e @novartis.com