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: +4031 5.1.2.e / Fax: +4031 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, 16-Oct-2019

Subject: **Digital submission of a substantial amendment for approval:**
- **Addendum to Main ICF v1.2 dated 13-Sep-2019**
- **Patient Letter dated 04-Sep-2019**

ToetsingOnline:	NL61015.029.17
EudraCT no.:	2016-002976-28
Protocol code:	CCNP520A2202J
Protocol title:	A randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of CNP520 in participants at risk for the onset of clinical symptoms of Alzheimer's Disease (AD)
Sponsor:	Novartis Pharma AG, Lichtstrasse 35, Basel, 4056, Switzerland
EU Legal Rep:	Novartis Pharma Arzneimittel GmbH, Roonstrasse 25, Nürnberg, 90429, Germany

Dear Madam, dear Sir,

On behalf of the Sponsor, Novartis Pharma AG, Parexel International Romania s.r.l. herewith submits a substantial amendment to the above referenced clinical trial for review and authorization.

The substantial changes in this amendment relate to:
☐the addition of a new IMP;
☐ a substantial change of the current IMP
☑other, namely:
- **Addendum to Main ICF v1.2 dd. 13-Sep-2019**
- **Patient Letter dd. 04-Sep-2019**

The reasons for these changes are described in the enclosed Annex 2 form.

EudraCT Update
The EudraCT substantial amendment notification form for this substantial amendment is enclosed.

Please find the following study documents supporting this request for approval attached to this e-mail**:**

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CCMO numbering	Document	Version /Date
A.	**Letter**	
A1	Cover Letter	16-Oct-2019
B.	**Forms**	
B5	Substantial Amendment Notification Form	16-Oct-2019

According to the regulatory requirements of the Netherlands, it is required to submit only the applicable EudraCT forms to support a substantial amendment submission.

Therefore, the following documents are not attached, but are available upon request:

CCMO numbering	Document	Version /Date
D.	**Product Information**	
D2	Addendum to Main ICF	v1.2/13-Sep-2019
D4a	Patient Letter	04-Sep-2019

With this submission, we declare that all relevant documents of the present submission dossier are signed by the persons authorised for this task.

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

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Yours faithfully,

PAREXEL International Romania s.r.l.
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5.1.2.e
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