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

Bucharest, 05-Aug-2019

Subject: **Digital submission of Investigator Notification following the 11 July 2019 Urgent Safety Measure**

- **Investigator Notification for Generation Program: CCNP520A2202J (Generation Study 2)**

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 the Investigator Notification letter dated 01 August 2019.
Following our Urgent Safety Measure(s) detailing the decision to terminate study CCNP520A2202J and the termination of Cohort II in Study buiten reikwijdte verzoek as well as the participants follow-up plan, it has been decided to issue a follow-up Investigator Notification to provide more detailed guidance on participants management in these studies beyond what was specified in the original USM Investigator Notification letter submitted to the Netherlands Heath Authority on date 15 July 2019.

Reference is made to study CCNP520A2202J (EudraCT No. 2016-002976-28) randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy of two doses of CNP520 (15 mg and 50 mg) in participants at risk for the onset of clinical symptoms of AD.

This letter is to inform you that Novartis, with its collaboration partners 5.1.1.c and 5.1.1.c , after consultation with the Investigators and Alzheimer scientific community made modifications to the initially proposed follow-up patient management plan. The detailed updated follow-up patient

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management action plan is described in the Investigator Notification attached to this letter.

Please find attached to this e-mail the following study documents supporting this notification:

Numbering	Document	Version /Date
A.	**Letter**	
A1	Cover Letter	05-Aug-2019
K.	**Other Relevant Documents**	
K6	Investigator letter 2 for Generation Program CNP520 discontinuation	01-Aug-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.

Yours faithfully,

PAREXEL International Romania s.r.l.
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