

PER E-MAIL TO BI@CCMO.NL**CCMO**

Attn. Competent Authority
Parnassusplein 5
2511 VX Den Haag,
The Netherlands

Bucharest, 07-Aug-2020

Subject:	Notification of Global End of Trial date correction
ToetsingOnline	
dossier no.:	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/Sir,

On behalf of the Sponsor, **Novartis Pharma AG**, Parexel International Romania s.r.l. as the applicant herewith would like to correct the Global End of Study date for CCNP520A2202J that was previously communicated to the Health Authority.

The global LPLV was originally reported to be **13-Mar-2020** and submitted to your attention on 18-Mar-2020.

Subsequently, and during the preparations for Data Base Lock, it was revealed that there had been a previously unreported follow up contact with a trial participant on **26-Mar-2020**. This was caused by a miscommunication with the investigational site and the result of scheduling challenges experienced due to the COVID-19 pandemic.

Therefore, the Last Patient Last Visit (LPLV) for the study CCNP520A2202J was achieved globally on **26-Mar-2020**. Accordingly, the Declaration of the End of Trial form Annex-III is updated in section D.2.1 and it is enclosed with this submission.

The end of trial in **Netherlands** was achieved on 10-Mar-2020 and notified to Central Committee on Research Involving Human Subjects on 18-Mar-2020 and **this information remains unchanged**.

For Netherlands, the results of this clinical trial will be submitted within the applicable timeline as a separate submission of the clinical trial report (summary) to fulfill national reporting obligations.

Documentation

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

CCMO numbering	Document	Version /Date
A.	Letter	
A1	Cover Letter	07-Aug-2020
B.	Forms	
B7	Declaration of the End of Trial form – Annex III Corrected	07-Aug-2020

We trust that this notification fulfils your requirements; however, in the event of any queries, please do not hesitate to contact us.

Yours faithfully,

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Parexel International Romania s.r.l.

5.1.2.e on behalf of 5.1.2.e

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