

Van: [ccmo_bi](#)
Aan: [ccmo_frontoffice](#); [ccmo_eudract](#)
Onderwerp: FW: CCNP520A2202J - NL61015.029.17 - 2016-002976-28 - Digital submission for Correction of Global End of Trial date
Datum: maandag 10 augustus 2020 11:36:37
Bijlagen: [A1 CCNP520A2202J Cover Letter NL61015.029.17_07Aug2020.pdf](#)
[B7 CCNP520A2202J Declaration of the End of Trial form –Annex III Corrected_07Aug2020.pdf](#)

Einde studie voor Marjolein.

Groet, 5.1.2.e

Van: 5.1.2.e <[redacted]@novartis.com> **Namens** 5.1.2.e

Verzonden: vrijdag 7 augustus 2020 13:42

Aan: ccmo_bi <bi@ccmo.nl>

CC: 5.1.2.e <[redacted]@novartis.com>; 5.1.2.e <[redacted]>

<[redacted]@novartis.com>

Onderwerp: CCNP520A2202J - NL61015.029.17 - 2016-002976-28 - Digital submission for Correction of Global End of Trial date

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.

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.

5.1.2.e on behalf of 5.1.2.e

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