

Van: [CCMO - Bevoegde Instantie / Competent Authority](#)
Aan: 5.1.2.e
Onderwerp: RE: NL67312.028.18
Datum: vrijdag 9 oktober 2020 14:49:22

Geachte 5.1.2.e,

Gezien de studie al is beëindigd, heeft u geen verklaring van geen bezwaar meer van ons nodig.

Met vriendelijke groet,

5.1.2.e

Centrale Commissie Mensgebonden Onderzoek (CCMO)
Parnassusplein 5 | 2511 VX Den Haag
Postbus 16302 | 2500 BH Den Haag
T 070 340 6700 | E ccmo@ccmo.nl | I <http://www.ccmo.nl>

Van: 5.1.2.e <5.1.2.e@ppdi.com>

Verzonden: dinsdag 6 oktober 2020 10:05

Aan: ccmo_bi <bi@ccmo.nl>

Onderwerp: RE: NL67312.028.18

Geachte 5.1.2.e,

Bedankt voor uw reactie. Het klopt inderdaad dat de studie voortijdig beëindigd is. Echter wilde METC Brabant (de toetsende commissie voor deze studie) toch graag het nieuwe IB en IMPD ontvangen. Om die reden heb ik ook de CCMO het amendement gestuurd.

Met vriendelijke groet / Kind regards,

5.1.2.e

PPD

Bornweg 12C 6721 AH Bennekom, NL

Phone +31 (0)31865 5.1.2.e

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5.1.2.e [@ppdi.com](mailto:5.1.2.e@ppdi.com)

From: ccmo_bi <bi@ccmo.nl>

Sent: dinsdag 6 oktober 2020 09:37

To: 5.1.2.e [@ppdi.com](mailto:5.1.2.e@ppdi.com)>

Subject: RE: NL67312.028.18

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Geachte 5.1.2.e

Deze status van deze studie in ToetsingOnline is *voortijdig beëindigd*. Om die reden is het niet mogelijk een beoordeling voor dit amendement aan te maken.
Is de status van de studie zoals in ToetsingOnline geregistreerd staat correct?

Met vriendelijke groet,

5.1.2.e

Centrale Commissie Mensgebonden Onderzoek (CCMO)
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Van: 5.1.2.e <5.1.2.e@ppdi.com>

Verzonden: woensdag 26 augustus 2020 13:58

Aan: ccmo_bi <bi@ccmo.nl>

CC: 5.1.2.e <5.1.2.e@ppdi.com>

Onderwerp: NL67312.028.18

Concerns:	Submission Substantial Amendment #05 (SA#05) – local EoT, IB, IMPD
Our reference:	SA#05 – (FS)
Protocol number:	MO-Ped trial
NL number:	NL67312.028.18
EudraCT number:	2017-002751-28

Dear members of the Central Committee on Research Involving Human Subjects,

With this letter we would like to ask the Competent Authority (Central Committee on Research Involving Human Subjects) to issue a certificate of no objection for the research entitled: ‘A Phase 2, Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study of Palovarotene in Subjects with Multiple Osteochondromas’ which is registered under NL Number: NL67312.028.18. We would also like to notify the CCMO of the local End of Trial.

The modifications of this amendment are concerning:

- ☐ the addition of a new investigational medicinal product;
- ☐ a substantial modification of the current investigational medicinal product;
- ☒ otherwise, namely: Investigator Brochure Ed. 7 (substantial), IMPD (non-substantial)

Please find attached the full cover letter as well as supporting documents:

- A1. Cover letter NL67312.028.18 dd 26Aug2020
- B5. EudraCT Form Notification of Amendment

Please address any enquiries to undersigned.
Thank you for your review.

Met vriendelijke groet / Kind regards,

5.1.2.e

Site and Patient Access – Global Site Intelligence and Activation

PPD

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Upcoming OOO: 31Aug-04Sep

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