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CCMO

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

08-Jun-2022

Subject: Digital submission of the synopsis of the Clinical Study Report
EudraCT no.: 2018-004233-33
Sponsor study no.: 251717
PAREXEL study no.: CMHS552A12101
Toetsing Online dossier no.: NL71107.056.19
Study title: A first-in-human, randomized, subject-blinded, placebo-controlled, single ascending dose study to investigate the safety, tolerability and pharmacokinetics of MHS552 in healthy volunteers

Dear Madam, dear Sir,

On behalf of the Sponsor, **Novartis Pharma AG**, PAREXEL International Romania s.r.l herewith submits the synopsis of the Clinical Study Report for the above-mentioned clinical trial to the CCMO as the Competent Authority in the Netherlands.

Please find below the list of documents attached to this notification:

CCMO numbering	Document	Version/Date
A1	Cover Letter to CA NL71107.056.19 CSR Synopsis Notification	08-Jun-2022
M3	Clinical Study Report Synopsis NL71107.056.19	18-Mar-2022

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 SRL

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