



**Parexel International Romania s.r.l.**

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2500 BH The Hague  
t.a.v. bevoegde instantie (BI)  
Netherlands  
bi@ccmo.nl**

15-Jul-2022

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Development Safety Update Report (DSUR): RTH258-DSUR-001-011  
Investigational Medicinal Product Code: RTH258

Dear Madam/Sir,

On behalf of Novartis, PAREXEL International Romania s.r.l. herewith notifies DSUR no. 011, regarding the investigational medicinal product RTH258, covering the period from 20-May-2021 to 19-May-2022.

Currently, in The Netherlands, 3 clinical trials with this IMP are authorized pursuant to the regulation in force.

Please note that this DSUR is submitted as single submission to avoid multiple parallel submissions by different Novartis legal entities acting as sponsor.

**Clinical Trials:**

Sponsor Code	EudraCT no.
[redacted] buiten reikwijdte verzoek	[redacted] buiten reikwijdte verzoek
[redacted] buiten reikwijdte verzoek	[redacted] buiten reikwijdte verzoek
CRTH258C2302	2018-001788-21

During the current DSUR reporting period, two IBs served as RSI. IB Edition 15 (dated 21-May-2020) served as the RSI for first 106 days of the reporting period while the IB was updated to IB Edition 16. Following submission with the previous DSUR, IB Edition 16 (release date 01-Jul-2021) then served as the RSI.

Novartis will begin to use IB, version 18 (dated 28-Jun-2022) as the RSI for ICSR in the coming DSUR period. The change in RSI for ICSR will take effect on 02-Sep-2022.



For any wet-ink originals to be sent in response to this DSUR notification, please kindly use the following correspondence address:

Parexel International Romania SRL  
CP 166, OP 63, Ghiseu 2, Sos. Stefan cel Mare nr. 2  
Bucharest, 014950, Romania.

We trust 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**

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5.1.2.e

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