parexel

Parexel International Limited
[redacted]

MHRA
10 South Colonnade
Canary Wharf
London, E14 4PU
United Kingdom

Health and Social Care Research Ethics Committee B (HSC REC B)

Date: 12 October 2026

MHRA Ref:	CTA 51307/0016/001-0023
EU CT Number:	2022-502022-41-00
Parexel no.:	[redacted]
REC Ref:	23/NI/0059
IRAS ID:	1006997
Protocol Number:	mRNA-1365-P101
Short Study Title:	mRNA1345 mRNA 1365 RSV_hMPV in babies
Study Title:	A Phase 1, Randomized, Observer-blind, Placebo-controlled, Age De-escalation Study of the Safety, Tolerability, and Immunogenicity of mRNA-1345 and mRNA-1365 in Participants Aged 5 months to < 24 months
Sponsor:	ModernaTX, Inc., 325 Binney Street, Cambridge, MA 02139
Chief Investigator:	[redacted]

Subject: **Notification of a Modification of an Important Detail to a Clinical Trial**
- Study Duration Extension

To Whom It May Concern,

On behalf of the Sponsor **ModernaTX, Inc.,** Parexel International Limited as the applicant herewith notifies a Modification of an Important Detail to the above referenced clinical trial which comprises the following:

Study Duration Extension
Please be informed that the duration of the study has been extended to 30 December 2029.

Modification Tool and IRAS Medicines Information dataset update as part of this submission
The Modification Tool for this submission is enclosed. In line with this notification, the IRAS Medicines Information dataset will be updated in the following sections at the time of the next Substantial Modification:

- E8-9-1. Estimated duration of the trial in the UK: *from* 2 years, 3 months; *to* 5 years, 5 months, 18 days
- E8-9-2. Estimated duration of the trial in all countries: *from* 2 years, 7 months; *to* 6 years, 10 months, 14 days

[redacted]

Documentation
In support of this submission, please find enclosed the documentation as listed in the attachments.

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

Yours faithfully,

[redacted]

[redacted]

[redacted]

[redacted]