Royal Devon University Healthcare NHS Foundation Trust

NextCOVE booster trial in children

Reference Number: RDF1883-23
Date of Response: 24/10/23

Further to your Freedom of Information Act request, please find the Trust's response(s) below:

Please be aware that the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) has existed since 1st April 2022 following the integration of the Northern Devon Healthcare NHS Trust (known as Northern Services) and the Royal Devon and Exeter NHS Foundation Trust (known as Eastern Services).

Dear Royal Devon University Healthcare NHS Foundation Trust,

Your Trust is listed by Moderna as a participating centre in the NextCOVE study NCT05815498, Sponsored by Moderna, it looks at a new bivalent booster compared with the original covid vaccine, and is open to participants from 12 years upwards.

1. *Please could you confirm whether your Trust has participated in this trial and if so whether you recruited anyone aged 12-17 years.*
   Answer: The Trust has participated in this clinical trial. The Trust did not recruit any participants aged 12-17 years.

2. *Could you confirm the maximum fee which was agreed with participants.*
   Answer: Travel costs up to £50 per visit.

3. *Could you send me a copy of the Research Ethics approval and a copy of the consent form and information leaflet which you used.*
   Answer: Please see documents A and B attached.

Health Research Authority
South Central - Berkshire B Research Ethics Committee
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: [redacted]

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

04 May 2023

[redacted]
St George's University Hospitals NHS Foundation Trust
Cranmer Terrace
London
SW17 0QT

Dear [redacted]

Study title:	**A randomized, observer-blind, active-controlled Phase 3 study to investigate the safety, immunogenicity, and relative vaccine efficacy of mRNA-1283.222 administered as a booster dose compared with mRNA-1273.222 in participants aged 12 years and older for the prevention of COVID-19**
REC reference:	[redacted]
Protocol number:	**mRNA-1283-**[redacted]
EudraCT number:	
IRAS project ID:	[redacted]

Thank you for your letter of 20 April 2023, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device

- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

CTIMPs submitted for combined review via IRAS will be registered automatically with the ISRCTN Registry. You do not need to notify the REC of the registration details. The lawful basis for processing your personal data for this purpose is official authority under the NHS Care Act 2014 (for further information please see our privacy notice).

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [7.21 mRNA-1283-P301_Social Media Ads_UK_English_V1_07Mar2023]	1.0	07 March 2023
Copies of materials calling attention of potential participants to the research [7.23 mRNA-1283-P301_ModernaRetention_QRCard_GBR_English_V1_29Mar2023]	1.0	29 March 2023
Copies of materials calling attention of potential participants to the research [7.24 Be Part of Research Volunteer Service - Template email to volunteers v1.0]	1.0	31 March 2023
Copies of materials calling attention of potential participants to the research [7.25 FINAL Be Part of Research Volunteer Service - HRA wording v1.0]	1.0	31 March 2023
Copies of materials calling attention of potential participants to the research [7.18 mRNA-1283-P301_Trial Listing_UK_English_V1_07Mar2023]	1.0	07 March 2023

Copies of materials calling attention of potential participants to the research [7.11 mRNA-1283-P301_Recruitment Poster_UK_English_V1_07Mar2023]	1.0	07 March 2023
Copies of materials calling attention of potential participants to the research [7.20 mRNA-1283-P301_Print Ad_UK_English_V1_07Mar2023]	1.0	07 March 2023
Copies of materials calling attention of potential participants to the research [7.16 mRNA-1283-P301_Video_UK_English_V1_08Feb2023]	1.0	08 February 2023
Copies of materials calling attention of potential participants to the research [7.13 mRNA-1283-P301_PI-to-Patient Letter_UK_English_V2_21Mar2023]	2.0	21 March 2023
Copies of materials calling attention of potential participants to the research [7.19 mRNA-1283-P301_Radio_UK_English_V1_08Feb2023]	1.0	08 February 2023
Copies of materials calling attention of potential participants to the research [7.07 - mRNA-1283-P301_Citeline Connect Outreach Partner Packet_GBR_English_24Feb23]	N/A	24 February 2023
Copies of materials calling attention of potential participants to the research [7.10 mRNA-1283-P301_Recruitment Brochure_UK_English_V2_21Mar2023]	2.0	21 March 2023
Copies of materials calling attention of potential participants to the research [7.04 - mRNA-1283-P301_Landing Page_GBR_English_24Feb23]	N/A	24 February 2023
Copies of materials calling attention of potential participants to the research [7.05 - mRNA-1283-P301_Prescreener_GBR_English_2March2023]	N/A	02 March 2023
Copies of materials calling attention of potential participants to the research [7.09 mRNA-1283-P301_NextCOVE Study_EC Submission Letter_032923]	N/a	29 March 2023
Copies of materials calling attention of potential participants to the research [7.26 mRNA-1283-P301_Revised Imagery_UK_21April2023]	N/A	21 April 2023
Copies of materials calling attention of potential participants to the research [7.25 mRNA-1283-P301_NextCOVE Study_EC Submission Letter_20Apr2023]	N/A	20 April 2023
Copies of materials calling attention of potential participants to the research [7.24 mRNA-1283-P301_NextCOVE Study_EC Notification Letter_041323]	N/A	13 April 2023
Copies of materials calling attention of potential participants to the research [7.22 mRNA-1283-P301_Image Library_UK_English_V2_18Apr2023]	2.0	18 April 2023
Copies of materials calling attention of potential participants to the research [7.06a mRNA-1283-P301_VRR Template Email to Volunteers_21April2023_Clean]	N/A	21 April 2023
Copies of materials calling attention of potential participants to the research [7.03a mRNA-1283-P301_NIHR Trial Posting_21April2023_Clean]	N/A	21 April 2023
Copies of materials calling attention of potential participants to the research [7.08 mRNA-1283-P301_ModernaRetentionStrategy_GBR_English_V2_18April2023]	2.0	18 April 2023
Copies of materials calling attention of potential participants to the	N/A	21 April 2023

research [7.06b mRNA-1283-P301_VRR Template Email to Volunteers_21April2023_Tracked Changes]		
Copies of materials calling attention of potential participants to the research [7.03b mRNA-1283-P301_NIHR Trial Posting_21April2023_Tracked Changes]	N/A	21 April 2023
Cover Letter [1.00 Cover Letter - mRNA-mRNA-1283-P301 - 31-Mar-2023 - initial CTA]	N/A	31 March 2023
Cover Letter [1.00 Cover Letter - mRNA-1283-P301 - 24-Apr-2023 - iCTA GNA Response]	N/A	24 April 2023
GP/consultant information sheets or letters [7.00 277068 GBR GP Letter v1.0 23Feb2023]	1.0	23 February 2023
Interview schedules or topic guides for participants [12.02 mRNA-1283-P301 Safety Call Script 1.0 24-Feb-2023]	1.0	24 February 2023
Interview schedules or topic guides for participants [12.03 Oral Thermometer Instructions_Parexel_V1_25Feb2022_EN_GB]	1.0	25 February 2023
Interview schedules or topic guides for participants [12.04 Wound Ruler Instructions_Parexel_V1_25Feb2022_EN_GB]	1.0	25 February 2023
Interview schedules or topic guides for participants [7.17 mRNA-1283-P301_Visit Guide_UK_English_V1_08Feb2023_ModEdits]	1.0 Mod Edits	08 February 2023
Interview schedules or topic guides for participants [7.14 mRNA-1283-P301_Assent Tool_UK_English_V2_21Mar2023_ModEdits]	2.0 Mod Edits	21 March 2023
Interview schedules or topic guides for participants [7.12 mRNA-1283-P301_Study Fact Sheet_UK_English_V2_21Mar2023_ModEdits]	2.0 Mod Edits	21 March 2023
Investigator Brochure/SmPC [4.01.1 Investigators Brochure - mRNA-1273 - version 8.0 - 21-Dec-2021]	8.0	21 December 2021
Investigator Brochure/SmPC [4.01.3 Investigators Brochure - mRNA-1273 - version 8.0 - addendum 2 - 19-Jul-2022]	2	19 July 2022
Investigator Brochure/SmPC [4.01.6 Investigators Brochure - mRNA-1283 - edition 3.0 - 21-Feb-2023]	3.0	21 February 2023
Investigator Brochure/SmPC [4.01.2 Investigators Brochure - mRNA-1273 - version 8.0 - addendum 1 - 07-Feb-2022]	1	07 February 2022
Investigator Brochure/SmPC [4.01.7 Investigators Brochure - mRNA-1283 - edition 3.0 - addendum 1 - 29-Mar-2023]	1	29 March 2023
Investigator Brochure/SmPC [4.01.5 Investigators Brochure - mRNA-1273 - version 8.0 - addendum 4 - 22-Mar-2023]	4	22 March 2023
Investigator Brochure/SmPC [4.01.4 Investigators Brochure - mRNA-1273 - version 8.0 - addendum 3 - 17-Feb-2023]	3	17 February 2023
Letter from sponsor [10.02 Moderna Letter of Authorisation 27Mar2023]	N/A	27 March 2023
Letter from sponsor [10.03 - EU Legal Rep Statement_mRNA-1283-P301 - 01-Feb-2023]	N/A	01 February 2023
Letter from sponsor [4.03.4 Right of Reference Letter - Moderna mRNA-1283 GBR]	N/A	31 March 2023
Miscellaneous [7.02 277068 PXL GBR Thank You Card V1.0 23Feb2023]	1.0	23 February 2023
Miscellaneous [7.15 mRNA-1283-P301_Vaccine Card_UK_English_V2_04Apr2023]	2.0	04 April 2023
Non-NHS/HSC Site Assessment Form [6.15 Non-NHS-HSC_Site_Assessment_Form_v1-1 - Accellacare Yorkshire_30Mar2023]	N/A	30 March 2023

Non-NHS/HSC Site Assessment Form [6.14 Non-NHS-HSC_Site_Assessment_Form_v1-1 - Accellacare South London_30Mar2023]	N/A	30 March 2023
Non-NHS/HSC Site Assessment Form [6.07 UK022_Non-NHS-HSC_Site_Assessment_Form_v1-1 Oyesile 17Mar2023]	N/A	17 March 2023
Non-NHS/HSC Site Assessment Form [6.13a UK032 Non-NHS-HSC-Site-Assessment-Form_Taylor 31Mar2023 Org Chart]	N/A	31 March 2023
Non-NHS/HSC Site Assessment Form [6.11 UK030_Non-NHS-HSC_Site_Assessment_Form_v1-1 Asubiaro_31Mar2023]	N/A	31 March 2023
Non-NHS/HSC Site Assessment Form [6.12 UK031 Non-NHS-HSC-Site-Assessment-Form_v1-0 Manhas 28Mar2023]	N/A	28 March 2023
Non-NHS/HSC Site Assessment Form [6.06 UK021_Non-NHS-HSC_Site_Assessment_Form_v1-1 Panthera Enfield 09Mar2023]	N/A	09 March 2023
Non-NHS/HSC Site Assessment Form [6.05 UK020_Non-NHS-HSC_Site_Assessment_Form_v1-1 Panthera Preston 09Mar2023]	N/A	09 March 2023
Non-NHS/HSC Site Assessment Form [6.04 UK019_Non-NHS-HSC_Site_Assessment_Form_v1-1 Panthera Glasgow 09Mar2023]	N/A	09 March 2023
Non-NHS/HSC Site Assessment Form [6.01 UK006_Non-NHS-HSC_Site_Assessment_Form_v1-1 Panthera Sheffield 09Mar2023]	N/A	09 March 2023
Non-NHS/HSC Site Assessment Form [6.03 UK017_Non-NHS-HSC_Site_Assessment_Form_v1-1 Accellacare North London_30Mar2023]	N/A	30 March 2023
Non-NHS/HSC Site Assessment Form [6.13 UK032 Non-NHS-HSC-Site-Assessment-Form_v1-0 Taylor 31Mar2023]	N/A	31 March 2023
Non-NHS/HSC Site Assessment Form [6.10 UK025_Non-NHS-HSC-Site-Assessment-Form_v1-0 Velocity 23Mar2023]	N/A	23 March 2023
Non-NHS/HSC Site Assessment Form [6.02 UK016 Non-NHS-HSC_Site_Assessment_Form_v1-1 Puri 31Mar2023]	N/A	31 March 2023
Non-NHS/HSC Site Assessment Form [6.08 UK023_Non-NHS-HSC_Site_Assessment_Form_v1-1 Nally 01Mar2023]	N/A	01 March 2023
Non-NHS/HSC Site Assessment Form [6.09 UK024_Non-NHS-HSC_Site_Assessment_Form_v1-1 Panthera Rochdale]	N/A	09 March 2023
Participant information and informed consent form [3.00a 277068 Moderna mRNA-1283-P301_UK Main ICF_v1.1_20Apr2023_cln]	1.1	20 April 2023
Participant information and informed consent form [3.00b 277068 Moderna mRNA-1283-P301_UK Main ICF_v1.1_20Apr2023_trk]	1.1	20 April 2023
Participant information and informed consent form [277068 Moderna mRNA-1283-P301_UK 12-15 Assent_v1.2_02May2023_cln]	1.2	02 May 2023
Participant information and informed consent form [277068 Moderna mRNA-1283-P301_UK 12-15 Assent_v1.2_02May2023_trk]	1.2	02 May 2023
Participant information and informed consent form [277068 Moderna mRNA-1283-P301_UK Parent ICF_v1.3_04May2023_trk]	1.3	04 May 2023
Participant information and informed consent form [277068 Moderna	1.3	04 May 2023

mRNA-1283-P301_UK Parent ICF_v1.3_04May2023_cln]		
Project Information - PDF [ProjectStudyInformation]		24 April 2023
Proof of Insurance [9.08 UK032 Non-NHS Insurance Taylor 03Jun2022]	N/A	03 June 2022
Proof of Insurance [9.04 UK016 Non-NHS Insurance Puri 09Nov2022]	N/A	09 November 2022
Proof of Insurance [9.03 Velocity Non-NHS Insurance 07Oct2022]	N/A	07 October 2022
Proof of Insurance [9.01 Panthera Non-NHS Insurance TWIMC 27Oct2022]	N/A	27 October 2022
Proof of Insurance [9.07 UK030 Non-NHS Insurance Asubiaro 12Jan2023]	N/A	12 January 2023
Proof of Insurance [9.06 UK023 Non-NHS Insurance Nally 24Mar2023]	N/A	24 March 2023
Proof of Insurance [9.00 - Insurance Moderna Inc._2022-23_mRNA 1283-P301_ U.K]	N/A	23 March 2023
Proof of Insurance [9.02 Accellacare Non-NHS Insurance 02Jun2022]	N/A	02 June 2022
Proof of Insurance [9.05 UK022 Non-NHS Insurance Oyesile 03Oct2022]	N/A	03 October 2022
Protocol [2.02.2 Protocol Administrative Letter - mRNA-1283-P301 - 23-Mar-2023]	N/A	23 March 2023
Protocol [2.02.1 Protocol Administrative Letter - mRNA-1283-P301 - 14-Mar-2023]	N/A	14 March 2023
Protocol [2.01 Protocol - mRNA-1283-P301 - version 1.0 - 27-Feb-2023]	1.0	27 February 2023
REC Application Form [Ethics]		24 April 2023
Response to Request for Further Information [1.02 GNA Response Letter - mRNA-1283-P301 - 20-Apr-2023]	N/A	20 April 2023
Response to Request for Further Information [1.01 GNA Letter - mRNA-1283-P301 - 19-Apr-2023]	N/A	19 April 2023
Sample diary card/patient card [8.03 Medidata Patient Cloud App_Standard Screens_Patient Mode_English_Multi-Country_V2.5]	2.5	31 March 2023
Sample diary card/patient card [8.01 mRNA 1283-P301_Moderna 7-Day eDiary_US-English]	N/A	19 January 2023
Sample diary card/patient card [8.02 mRNA_1283-P301_Moderna Safety Follow-Up eDiary_US-English]	N/A	19 January 2023
Sample diary card/patient card [7.01 277068 Participant ID Card v2.0 UK only 18-Apr-2023]	2.0	18 April 2023
Site List [7.27 Panthera GP Letter Screen Failure V1.0 09Mar23]	1.0	09 March 2023
Site List [7.28 Panthera Patient Letter-Unblinding TrialV1.0 09Mar23]	1.0	09 March 2023
Site List [7.26 Panthera GP Letter - Trial Withdrawal V1.0 09Mar23]	1.0	09 March 2023
Suitability of the investigator/Investigator CV [5.15 Non-NHS CV Walukiewicz Accellacare Yorkshire 01Feb2022]	N/A	01 February 2022
Suitability of the investigator/Investigator CV [5.14 Non-NHS CV Adesanya Accellacare South London 06Oct2021]	N/A	06 October 2021
Suitability of the investigator/Investigator CV [5.03 UK017 Non-NHS CV Beboso Accellacare 17 Mar 2023]	N/A	17 March 2023
Suitability of the investigator/Investigator CV [5.00 CI CV_ Catherine Cosgrove 01Mar2023]	N/A	01 March 2023
Suitability of the investigator/Investigator CV [5.11 UK030_Non-NHS	N/A	03 July 2021

CV Asubiaro - 03Jul2021]		
Suitability of the investigator/Investigator CV [5.06 UK021 Non-NHS CV Avornyo Enfield 11Apr2022]	N/A	11 April 2022
Suitability of the investigator/Investigator CV [5.05 UK020 Non-NHS CV Handforth Preston 29Mar2023]	N/A	29 March 2023
Suitability of the investigator/Investigator CV [5.07 UK022 Non-NHS CV Oyesile Stemax 30Mar2023]	N/A	30 March 2023
Suitability of the investigator/Investigator CV [5.04 UK019 Non-NHS CV Mackay Glasgow 15Jun2022]	N/A	15 June 2022
Suitability of the investigator/Investigator CV [5.09 UK024 Non-NHS CV Wickens Rochdale 18Mar2022]	N/A	18 March 2023
Suitability of the investigator/Investigator CV [5.02 UK016 Non-NHS CV Puri HMR 07 Feb 2023]	N/A	07 February 2023
Suitability of the investigator/Investigator CV [5.10 UK025 Non-NHS CV Elshashai Velocity 20Mar2023]	N/A	20 March 2023
Suitability of the investigator/Investigator CV [5.12 UK031 Non-NHS CV Manhas 20Mar2023]	N/A	20 March 2023
Suitability of the investigator/Investigator CV [5.01 UK006 Non-NHS CV Trifonov Sheffield 02Mar2023]	N/A	02 March 2023
Suitability of the investigator/Investigator CV [5.08 UK023 Non-NHS CV Nally 27Mar2023]	N/A	27 March 2023
Suitability of the investigator/Investigator CV [5.13 UK032 Non-NHS CV Taylor 06Jan2023]	N/A	06 January 2023

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at:
https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS project ID: [redacted] **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Pp [redacted]

[redacted]
Chair

Email: [redacted]

Enclosures: "After ethical review – guidance for researchers"

Copy to: [redacted]

Lead Nation England: [redacted]

Parent Information Sheet and Informed Consent Form

Title of Study:	A randomized, observer-blind, active-controlled Phase 3 study to investigate the safety and immunogenicity and relative vaccine efficacy of mRNA-1283.222 administered as a booster dose compared with mRNA1273.222 in participants aged 12 years and older for the prevention of COVID-19
Short Study Title:	**Next COVE**
Protocol Number:	mRNA-1283-[redacted]
Sponsor:	ModernaTX, Inc.
IRAS ID:	[redacted]
Study Doctor:	[redacted]
Participant ID	

Introduction

Your child is being invited to take part in a clinical research study, managed and funded by ModernaTX, Inc (also, referred to as the "Sponsor").

Taking part in this research study requires your written consent. Before you decide whether to allow your child take part, please read this Parent Information Sheet and Informed Consent Form, which tells you important information about the things your child will be asked to do before, during, and after the study, if you choose for your child to participate. It also describes the risks and possible benefits of the study.

Please take as much time as you need to read this information carefully and ask the Study Team any questions that might help you decide whether or not, you would like your child to take part in this clinical research study. You may also discuss this study with your child's General Practitioner (GP), family and friends.

If you decide for your child to participate, you must sign and date this Parent Information Sheet and Informed Consent Form to show that you understand what you and your child will be asked to do and the risks of participating in the study and that you agree for your child to take part in the study of your own free will. You will receive a copy of the signed and dated form.

Short summary of this clinical study

- **What is the purpose of the study?**

The purpose of this clinical research study is to develop a new vaccine for coronavirus disease (COVID-19).

- **What is the Vaccine Being Tested?**

mRNA-1283.222 is a vaccine being studied in this clinical research study. This study will investigate if **mRNA-1283.222** when given as a booster dose in participants aged 12 years and older is safe and effective in prevention of COVID-19, when compared to the authorised vaccine, SPIKEVAX (mRNA-1273.222).

- **How many people will be in the study?**

Up to 10748 people will take part in this clinical research study worldwide.

- **How long will my child be in the study?**

Your child will be in the study for approximately 12 months. This includes at least 5 study visits (where you come to the study site) and 3 visits by phone as well as possible unscheduled visits, if needed.

- **What will happen in the study?**

If your child takes part in this study, they will:

- Have visits to the study site that may include questions about their health, physical examinations, blood tests, nasal swab collection and other medical tests
- Be asked to complete an electronic study diary
- Receive the study vaccine
- Be randomly assigned to receive one of these study vaccines:
  - **mRNA-1283.222**: The new vaccine, being tested.
  - **mRNA-1273.222:** A vaccine currently authorised to prevent COVID-19.

- **What are the possible risks or discomforts?**

There are some risks that have been identified for this study, which are described in more detail below. The study doctor and study team will keep track of your child's health during the study. You should contact the study team or your child's health care provider as soon as possible if you think your child is having a medical problem, side effect, or a change in their medical condition or health.

- **What are the possible benefits?**

There may or may not be a direct benefit to your child because of taking part in the clinical research study. However, what is learned in this study may help in the prevention of COVID-19 in the future and may advance scientific knowledge.

Read the rest of this form for more details.

[redacted]

What is The Purpose of The Study?

Coronaviruses are a large family of viruses that cause illness ranging from the common cold to more severe diseases, such as Middle East respiratory syndrome and severe acute respiratory syndrome. Coronaviruses are zoonotic, meaning they are transmitted between animals and people.

An outbreak of the coronavirus disease (COVID-19) caused by the 2019 novel coronavirus SARS-CoV-2 began in Wuhan, Hubei Province, China in December 2019 and has spread throughout China and to over 215 other countries, territories, and areas, including the United Kingdom.

Vaccines serve to prepare your immune system for fighting illnesses. Certain cells of the immune system produce antibodies (special proteins) that recognise viruses and other pathogens (things that cause disease) and prevent them from causing illness. Currently, there are several vaccines that have been authorised or approved for the prevention of COVID-19 disease. However, as new strains of the virus emerge globally, there is a need for the development of new and improved vaccines.

The ModernaTX, Inc mRNA COVID-19 vaccine (Spikevax®) was approved for use in the UK in January 2021. Following further studies of safety and efficacy in children, approval was extended to those aged 12-17 years August 2021. In 2022, a half dose (50 micrograms) of the ModernaTX, Inc COVID-19 vaccine was then approved for those aged 6 to 11 years.

Current guidance in England (06Apr2023) suggests that people aged 75 and older, residents in care homes for older people, and those aged 5 and older with a weakened immune system are to be offered a Spring booster dose 2023. If this information changes, your study doctor will let you know.

The mRNA-1273.222 vaccine is made using a new process that allows for much faster vaccine production than older methods. When injected into the body, the vaccine causes some cells to make a protein, which can trigger an immune response. If the person is later infected, their immune system remembers the protein from the prior vaccination, which may help it to fight the invading virus.

ModernaTX, Inc. is using the same technology as the previously approved and authorised mRNA COVID-19 vaccines, to develop additional SARS-CoV-2 mRNA vaccines that may be as protective as the currently authorised vaccine but at a lower dose level. It is likely that this study vaccine may also be more stable for a longer period stored at refrigerated temperatures than the mRNA-1273.222 vaccine. The purpose of this study is to test whether mRNA-1283.222 is as protective as the currently authorised, mRNA-1273.222 vaccine.

The mRNA-1283.222 study vaccine tested in this study has a slightly different design and this study will test if the difference may allow it to be similarly protective against SARS-CoV-2 virus. Although this is the first time that mRNA-1283.222 is being tested in humans, previous versions of mRNA-1283 investigational product targeting different variants of the SARS-CoV-2 virus, have been tested in human studies. It is currently not known if the mRNA-1283.222 study vaccine will protect you from getting infected or if it will prevent you from developing illness from the infection.

Like adults, children can become infected with SARS-CoV-2 virus and become unwell. Current recommendations in the UK are for children in high risk groups and those children who are in contact with clinically vulnerable people to be vaccinated.

We have asked your child to join this study to find out if the newer SARS-CoV-2 study vaccine is safe for children, whether it causes any side effects, and how much protection it may provide against COVID-19 in children.

About 10748 participants aged 12 years and older, will take part in this study. This study will be conducted across sites in the United Kingdom, United States, and Canada. The study will test the mRNA-1283.222 and mRNA-1273.222 vaccines.

[redacted]

Why Has My Child Been Invited?

Your child is being invited to participate as a healthy volunteer because they have previously received an approved/authorised mRNA COVID-19 vaccine, and we think they might meet the requirements for this study.

All clinical research studies have requirements that a person must meet to take part. The study doctor will review the requirements for this study with you and your child. If you decide you would like for your child to be in this study, the study team will ask some questions and conduct some tests to ensure that your child meets all the study requirements. If your child does not meet all the requirements, they will not be able to take part in this study.

Does My Child Have to Take Part?

No, your child's participation in this research study is entirely voluntary. This means that you and your child are free to choose if you want your child to take part in the study or not.

Your child can leave the study at any time, without giving any reason. If you choose for your child not to participate in the study, or if you decide for your child to leave the study later on, your decision will not harm your, and your child's, relationship with the Study Team or study hospital, and it will not affect the health care your child receives.

If you and your child choose to leave the study, please let the study doctor know as soon as possible.

Please consider the study time commitments and responsibilities as a research participant when you are deciding for your child to take part.

What Will My Child and I Have to Do?

✓ Your child should:	☒ Your child should not:
Tell the study team correct and true information about your child's past health and current health, including: • Any reactions they have to mRNA-1283.222 or mRNA-1273.222, such as fever, sleepiness, or not wanting to eat. • Other changes to your child's health during the study. • Any treatment, medicine, or vaccine your child takes before and during the study, including new medicines they may start taking during the study.	Do not take any medicine or vaccine outside of this study prior to speaking to your study doctor, until your child has completed the end-of-study visit. You should discuss with the study doctor if your child has to take any medicine or vaccine.
Contact the study team right away if: • Your contact information changes. • Your child no longer wants to be in the study.	Do not take part in other studies 28 days before this study or during this study.

• Your child has symptoms of COVID-19.	
• Follow the instructions given by the study doctor and/or study team. • Go to your child's scheduled study visits and answer study phone calls.	Do not get the COVID-19 vaccine within 90 days before taking part in the study.
Fill out the electronic Diary (eDiary) as the study team tells you. Use the thermometers provided to check your child's body temperature Use the ruler provided to measure and skin changes where the vaccine was given	Do not have anything hot or cold to eat or drink within 10 minutes before checking your child's body temperature.
If your child need emergency care or go to the hospital, tell the doctor treating you that your child is taking part in this study.	(blank)
Fill out the survey/questionnaires when the study team asks you to. Answer the questions in the interview with the study team.	(blank)
Your child will be provided with an identification card which says that they are taking part in this study. Please ensure your child carries this card with them at all times and show it to any relevant doctors or nurses. Please return the card at the end of the study.	(blank)

What Is The Study Vaccine Being Used For In This Study?

This is a phase 3 clinical research study to check if the investigational vaccine called **mRNA-1283.222** is safe and effective for the prevention of COVID-19 when given as a single booster dose. It will be compared with the booster dose of **mRNA-1273.222.** It will be given to participants aged 12 years and older. **mRNA-1283.222** is considered investigational because it has not been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) and is still being studied.

Will My Child Get The Study Vaccine?

This study has 2 groups:
- mRNA-1283.222 [10 micrograms (µg)]
- mRNA-1273.222 [50 micrograms (µg)].

In this clinical research study, your child, and the other study participants, will be assigned to the one of the groups noted above. Participants are assigned to these groups by chance (like flipping of a coin). This process is called **randomisation**. A computer is used to randomly place participants into the different groups. Your child will have an equal chance of being assigned to receive **mRNA-1283.222** or **mRNA-1273.222**. mRNA-1273.222 has been proven to be safe and work for the prevention of COVID-19.

This study is blinded for study participants, which means that you will not know whether your child has received **mRNA-1283.222** or **mRNA-1273.222** until the study is over. The study doctor, the study team, and the Sponsor are also blinded for the duration of the study but if your child has an emergency, they can find out if your child has received **mRNA-1283.222** or **mRNA-1273.222** and can provide this information to you, your child and your child's study doctor.

Out of 10748 participants expected to be in this study, half of the participants will receive **mRNA-1283.222** and the other half will receive **mRNA-1273.222**.

Approximately 20% of participants will be in the 12 to <18 years age group
Approximately 60% of participants will be in the 18 to 65 years age group
Approximately 20% of participants will be in the ⩾65 years age group.

In this form, **mRNA-1283.222** and **mRNA-1273.222** are called the study vaccine.

How Are The Vaccines Given?

Your child will get the study vaccine that was assigned to them by chance as an injection in the upper arm or thigh.

Your child will remain at the study site for a minimum of 15 minutes after getting the study vaccine for observation. Additional information about this can be found in the section “What are the Possible Risks and Disadvantages of Taking Part?”

What Will Happen To My Child If They Take Part?

How long your child is in the study and their number of study visits is shown in the table below.

Screening period Up to 28 days before the study vaccination	**Day 1 (study vaccination)**	**Follow-up period** Lasts for about 9 months with 3 study site visits and 3 phone visits	**End-of-study visit** At the last visit on Day 365 (Month 12)
You will sign this informed consent form. Then, the study team will check to see if your child meets the rules to be in this study. The screening visit may be its own visit or may be on the same day as the Day 1 visit, the day on which your child will get the study vaccine. The screening visit may be performed over several visits during the 28-day screening period.	At your visit to the study site, your child may: • Answer questions from the study team about your child's health, any relevant medication they may be taking, and any side effects, they may have. • Be asked your child's sex, age and ethnicity • Get the study vaccine. • Answer questions from the study team about your health, any relevant medication your child may be taking, and any side effects, they may have. • Have a physical examination, which includes measuring things like height, weight, temperature, heart rate, breathing rate and blood pressure. • Have medical tests, such as a pregnancy test, a COVID-19 test, and blood sample collection. They will also:	One week after getting the study vaccination and on subsequent follow-up visits: • The study team will check your child's safety and health through in-person and phone call visits. • You will also complete an eDiary. • Have 1 phone visit at Day 8.	Your child will be considered to have completed the study if they have completed all the study visits including the last scheduled visit.

	• Have 1 phone visit at Day 8 • Complete an eDiary after getting the study vaccine.		

What Happens During Study Visits?

The study visit table below describes the tests and procedures they will have during the study.

[redacted]

Study Visit Day	Screening	Day 1	Day 8	Day 22	Day 29	Day 91	Day 181	Day 271	Day 365/ End of study	Unscheduled Visit	Illness Visit
Type of visit	**C**	**C**	**SC**	**SC**	**C**	**C**	**C**	**SC**	**C**		
Days Since Vaccination		0	7	21	28	90	180	270	364		
Informed consent form, demographics, concomitant medications, medical history	X										
Confirm participant meets inclusion and exclusion criteria	X	X									
Physical examination	X	X			X	X	X		X	X	X
Vital signs	X	X								X	X
Pregnancy test	X	X									
Randomisation		X									
Study injection (including 15-minute postdosing observation period)		X									
Nasal swab for COVID-19 test		X			X	X	X		X	X	X

[redacted]

Study Visit Day	**Screening**	**Day 1**	**Day 8**	**Day 22**	**Day 29**	**Day 91**	**Day 181**	**Day 271**	**Day 365/ End of study**	**Unscheduled Visit**	**Illness Visit**
Type of visit	**C**	**C**	**SC**	**SC**	**C**	**C**	**C**	**SC**	**C**		
Days Since Vaccination		0	7	21	28	90	180	270	364		
Blood sample for SARS-CoV-2 surveillance		X			X	X	X		X	X	
eDiary prompts for COVID-19 and major changes in health					eDiary prompts every 2 weeks starting at Day 29 through to Day 365/						
Blood sample to check for immune response		X			X	X	X		X	X	

[redacted]

Study Visit Day	Screening	Day 1	Day 8	Day 22	Day 29	Day 91	Day 181	Day 271	Day 365/ End of study	Unscheduled Visit	Illness Visit
Type of visit	**C**	**C**	**SC**	**SC**	**C**	**C**	**C**	**SC**	**C**		
Days Since Vaccination		0	7	21	28	90	180	270	364		
eDiary activation for recording side effects (7 days)		X									
Review of eDiary			X								
Safety phone calls			X	X				X			
Recording of side effects leading to withdrawal and concomitant medications relevant to or for the treatment of these events		X	X	X	X	X	X	X	X	X	X
Recording of concomitant medications and non-study vaccinations		X	X	X	X	X	X	X	X	X	X
C = Clinic/SC = Safety (telephone) Call											

[redacted]

Visit locations

Visits for the study may occur by:

1. In-clinic visit – is a visit that is done at the study site. At least five of the visits will be in-clinic visits for this study.
2. Remote visit– is a visit that is performed by the study team by phone with the participant. There will be 3 phone visits during the study. The study team may conduct additional phone visits if needed.

Blood samples

The study team will collect blood samples from your child in this study. The total amount of blood collected from your child during the study will be around 120 millilitres (mL) or less, which is about 8 tablespoons.

About the eDiary

As part of this study, you will be required to complete an electronic study diary (eDiary) that collects responses to questionnaires about your child's health. You will be asked to report symptoms your child experiences after getting their study vaccine and any changes to their overall health. It will take you about 5-7 minutes to complete the eDiary.

You will need an electronic device such as a smart phone or tablet to complete the eDiary for your child. You are free to use your personal device through a downloaded web application (app). If you require a device, one will be provided to you with a pre-loaded web-based application. In either case, your responses to questionnaires will be collected through the application and shared with the researchers of the study. While using one of these options, your responses to questionnaires will be collected and shared with the researchers of the study.

A complete description of the data collection and sharing for the web application or eDiary can be found in the Terms of Use, End User License Agreement, or Privacy Policy associated with the device. If you would like to read these documents, request a copy of instructions on how to receive this information from the study doctor.

You will enter this information into the eDiary daily on the day of the study vaccination, about 15 minutes after your child receives the study vaccine, in the evening of the day your child receives the study vaccine and continue to do so for 6 days after the study vaccination (preferably in the evening). If you cannot or do not want to use your own device, the study team may be able to provide you with a device to take home for use during the study.

If your child continues to experience symptoms beyond 7 days after receiving the study vaccine, you can tell the study member at the next remote visit or continue to complete the eDiary until the symptom gets better.

The following should be recorded in your eDiary:

- **Your child's body temperature**: The study team will give you a thermometer to take home. Use the thermometer to take your child's temperature and enter it in the eDiary. If you take your child's temperature more than one time on a day, enter your child's highest temperature into the eDiary.
- **Side effects at the injection site:** Look at your child's arm or thigh, where they received the study vaccine to see if there is any redness, swelling, or hardness. If so, use the ruler that the study team gave you to measure the area. Enter the measurement into the eDiary.
- **Any medicine your child took to treat pain/fever:** Report (yes/no) if your child took any medicine.

[redacted]

- **COVID-19 questions:** You will also use the eDiary to answer questions about COVID-19 every 2 weeks from Day 29 through to Day 365.
- **Any other symptoms:** Describe any other symptoms or illness that your child has.

If your child has any symptoms after getting the study vaccine, complete out your eDiary and contact the study team right away. Some of the symptoms include:

- Fever
- Fatigue (tiredness)
- Muscle aches or pain
- Nausea/vomiting

The information collected from these eDiaries is critical to this study. Before agreeing to take part in this study, please consider carefully if you are willing and able to complete the questions as described above.

Phone visits

The study team will call you:

- Once after your child has received the study vaccine- about 7 days after your child has received the study vaccine
- Then the study team will call you on Day 8, 22 and 271, to follow-up on your child's health, unless you have an in-person visit.

During these calls, the study team will:

- Ask about any changes in your child's health since their last study visit, including side effects
- Talk about any changes in your child's medications
- Ask if your child has had any symptoms as a result of the study vaccine
- Review your child's eDiary (on Day 8 only) and remind you to complete it

What Are Biological Samples?

A **biological sample** is any blood, fluid, or tissue taken from your body, such as hair, saliva, blood, urine.

Biological samples are usually obtained during a diagnostic test or a procedure, such as a blood test. Blood, urine, nasal secretions, etc. are the types of biological samples that will be collected for this study and will be collected at most visits.

What Samples Will Be Taken From My Child?

The following is a summary of the biological samples that will be collected for study purposes, and how these samples will be used. Just like everything in this parent information sheet and informed consent form, please ask the study team if you have questions, or would like more information, about these tests and samples.

- Immunogenicity assessments: Your child's blood samples will be checked to see whether your child's immune system has produced antibodies against the SARS-CoV-2 virus. Antibodies are proteins produced by the body's immune system that recognize foreign substances in the body and can help fight infections.
- COVID-19 testing: A nasal swab specimen will be collected at several visits during the study. If your child becomes unwell, they will be asked to provide a nasal swab and a blood sample. Nasal swab is

a method for collecting a test sample of nasal secretions from the back of the nose and throat to test for COVID-19 disease. Your child may feel discomfort, but it should not be painful. Nasal swabs collected throughout the study will be sent to the laboratory for SARS-CoV-2 virus testing to see if your child is infected. Results of the swabs will be shared with you when they are available.

- Pregnancy testing: If your child is a female and has had periods, a urine sample will be checked to see if your child is pregnant at the screening visit. Your child must have a negative pregnancy test to take part in this study. The study doctor may also decide to have your child's blood sample checked to see if your child is pregnant. Pregnancy tests are completed by the study doctor, and results of these tests will be shared with your child.

  Urine or blood sample will be collected prior to administration of the study vaccine at select study visits, and at any time if the study doctor requests for it to check if your child has become pregnant.

Expenses and Payments

The Medicines for Human Use (Clinical Trials) Regulations 2004 prohibit the giving of incentives or financial inducements to children (under 16 years of age) or their parents/legal representatives to participate in clinical trials of investigational medicinal products (CTIMPS).

You will not be paid for your child participating in the study. You may be reimbursed for necessary travel and other expenses, where reasonable and appropriate, up to a maximum of £50.

The study doctor or his/her staff will explain to you how travel reimbursement is paid and when (following each completed visit, monthly, quarterly or at the end of your participation in the research study). You may be asked to provide a copy of receipts or itemised list of expenses.

What are the Alternatives for Diagnosis or Treatment?

Your child does not have to take part in the study. There may be other options available that have proven to prevent COVID-19. You should discuss other options with the study doctor or your child's health care provider to see what is right for you and your child.

What are the Possible Risks and Disadvantages of Taking Part?

All vaccines can cause **side effects,** which are unwanted effects. If you choose for your child to take part in this study, your child is at risk for the side effects listed below. Talk about the side effects with the study team. The study doctor will discuss the possible side effects with you and your child and tell you what to do if your child has any side effects.

Side effects after getting the vaccine

Following injectable vaccines, redness, swelling, pain, tenderness, and/or fever may occur. These reactions normally last no more than 48 hours. Headache and malaise (general discomfort or illness), muscle aches, joint aches, chills, and feeling tired have also been reported in ongoing studies with similar study vaccines.

If your child has had an allergic reaction after being vaccinated in the past or if they are allergic to any product(s), then you must tell the study doctor or site staff before you decide to sign and date this parent information sheet and informed consent form. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

If your child has an allergy to vaccine ingredients, then they will not be able to take part in this study. Serious allergic reactions can be life-threatening. The study team will watch your child for 15 minutes or longer after each dose of study vaccine. They will look for any of these symptoms and treat your child right away, if needed.

- There are certain risks of very rare (less than 1 in 10,000 people) events of myocarditis (inflammation of the heart muscle) and pericarditis (inflammation of the tissue sac that covers the heart and great blood vessels) which are associated with the mRNA-1273.222 vaccine and are described below:
- Symptoms of myocarditis or pericarditis include chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart. These symptoms most commonly begin within a few days following vaccination. Study participants should seek medical attention and notify study team members if any of these symptoms occur following study vaccination.
- While some severe cases have been reported, most cases have been associated with full recovery of symptoms in the short term. However, long-term information is not available.
- Myocarditis or pericarditis have been reported in greater numbers in males under the age of 30 years following a second dose, but cases have also been reported in older males and in females and following the first dose.
- It is not known whether the risk of myocarditis or pericarditis is increased following additional doses of the vaccine (for example, following a booster dose).

The general public may see conflicting opinions of some health professionals regarding safety of the COVID-19 vaccines, due to the high-profile nature of the media coverage. Please discuss with your study team any concerns you may have.

The most common side effects from other studies of people receiving mRNA study vaccines similar to mRNA-1283.222 and mRNA1273.222 are listed below. Your child will be asked about these side effects during this study.

- Fever
- Pain at the injection site
- Redness and hardness of the skin at the injection site
- Headache
- Muscle aches or pain
- Joint aches or pain
- Fatigue (tiredness)
- Nausea/vomiting
- Chills
- Underarm gland swelling on the side of the study vaccination

In previous studies with the study vaccine, most of these side effects occurred within the first few days after study vaccination and went away within a few days. Not everyone has had these side effects, and

those who experienced them did not necessarily experience them after every dose. These side effects were usually reported as mild or moderate and not severe.

Brief increases in some laboratory tests were noted in previous clinical studies with similar mRNA study vaccines. These increases were observed without physical symptoms or signs and generally returned to levels observed before study vaccination. The significance of these observations is unknown.

Fainting can happen before or after getting any vaccine. It is usually caused by pain or anxiety from the injection and is not related to the vaccine itself.

Risks related to study tests and procedures

- **Blood samples**: A qualified person will use a needle to take blood. This can sometimes cause a bruise at the site where the needle goes into your child's skin. Rarely, the site can swell, bleed, or get infected. Some people may feel faint during or after a blood test.
- **Blood pressure**: The blood pressure cuff used to take your child's blood pressure may cause discomfort or bruising to the upper arm.
- **Nasal swab:** Your child may experience moderate discomfort, and in rare instances, nosebleeds can occur because of nasal swab collection. Your child may experience watery eyes and/or coughing, but only for the short duration of the swab.

Your child may have emotional stress if they experience any of the side effects listed above or from keeping to the study visit schedule. Some of the questions we will ask your child as part of this study may make them feel uncomfortable. Your child may stop taking part in the study at any time.

As part of this clinical study, you will need to use an eDiary app. You may be asked to download the app to your smartphone or researchers may provide you with an eDiary device. To use the app, you will be asked to agree to the Terms of Use and Privacy Policy which will appear on your mobile device's screen when you first start using the app. If you decide that you do not want to agree, then you and your child should not participate in the research.

While using the app, data about you and your child including personal health information, other communication data, and internet usage will be collected and transmitted to the researchers and to the app developer. A complete description of this data collection and sharing is found in the Privacy Policy. Transmission of information via the internet is not completely secure, so there is a small risk of unintentional release of your child's and your information and safeguards are in place to protect your child's and your personal information.

While the Terms of Use may include statements limiting your child's and your rights if you are harmed in this study, you do not release the study doctor, Sponsor, institution, or agents from responsibility for mistakes, and these statements do not apply to the use of the app in this clinical study.

Groups to protect people in the study

An Internal Safety Team and a Data Safety Monitoring Board (groups of people who independently review study data to decide if it is safe to continue with the study) will watch over this study to protect the safety of participants in the study.

Harm to the Unborn Child

The effects of the mRNA-1283.222 study vaccine on the developing foetus and on the new-born baby are not known. Because of this, it is important that research study participants are not pregnant and do not become pregnant during the research study.

For Females Participants:

Females who are pregnant or planning to become pregnant during the study will not be allowed to take part in the study. Females who could become pregnant must have a pregnancy test to rule out pregnancy before they can receive the study vaccine. After joining the study, females must report immediately to the study site if they suspect that they are pregnant during the study.

Females who are able to have children and are having sex with a male must use birth control for at least 28 days before Day 1 and continue for at least 90 days after receiving the study vaccination. If your child decides to leave the study early, she must continue to use an acceptable method of birth control for at least three (3) months after study vaccination. Birth control methods that can be used while in this study, include the following:

- Barrier methods (condom, diaphragm, or cervical cap) with spermicide
- Intrauterine device (birth control device that is inserted into the uterus to prevent pregnancy)
- Hormonal contraceptives via oral (pill), transdermal (patch), Medroxyprogesterone injection (Depo-Provera®), Etonogestrel implant (Nexplanon®)
- Sterilisation of any male sexual partner of the female participant before entry to the study.
- Periodic abstinence (for example, calendar, ovulation, symptothermal, and post-ovulation methods) and withdrawal are not acceptable methods of contraception.

Your child must discuss with the Study Team, the type of birth control method that they can use before they begin the study. The Study Team must approve the method your child uses before they can enter the study.

If your child is pregnant at Day 1, you must tell the Study Team and your child will not receive the study vaccine. If your child becomes pregnant after the study vaccine administration, the Study Team will advise them about your health care and will ask about their pregnancy and its outcome.

If your child becomes pregnant, the Study Team will collect details about the pregnancy and the outcome of the pregnancy for scientific and safety reasons.

What Are The Possible Benefits Of My Child Taking Part?

Taking part in this study may protect your child against COVID-19. The data collected from you and your child by the Sponsor during this study may help doctors and researchers learn more about the effectiveness of the study vaccine against COVID-19. This may help others in the future.

What If Relevant New Information Becomes Available?

The Study Team and/or Sponsor may learn new facts during the study that might affect your child's participation in the study. You and your child will be told about the new facts right away. You can then decide if you want to allow your child to still be in the study or leave. If you and your child leave the study, there will be no penalty and you will not lose any benefits you are entitled to. Leaving the study will not affect the quality of the health care your child is given.

[redacted]

What Will Happen If My Child Doesn't Want To Carry On With The Study?

Your child's participation in this research study is voluntary. You may decide not to allow your child to participate, or your child can leave the research at any time. If you choose not to allow your child to take part in the research or to leave the clinical study, this will not affect the quality of care you or your child are given.

If you and your child decide to stop participating in the research before the last study visit, contact the study team to determine the best way to leave the research.

- Your child may be asked to complete the procedures that are part of the end-of-study visit.
- You may be asked the reason you and your child no longer wish to participate in the research.
- Your child does not have to complete any additional procedures or answer any additional questions if you/they do not want to. However, the information you provide could help the researchers to better understand COVID-19.

It is recommended that you tell the study team if you and your child are thinking about stopping participation in the study so that you and your child can discuss what, if any follow-up care your child may need after they leave the study.

If your child leaves the study,

1. Data obtained while your child was in the study may still be kept with other data obtained as part of the study. We will keep, and continue to use, data that was already collected before your child left the study
2. No new information will be collected from your child unless you clearly agree. You can request your child's biological samples be destroyed so they are not used for any future research by writing to the study doctor

If your child withdraws from the study, but you do not request destruction of your child's samples in writing, your child's samples will continue to be used as described in this form.

Are there other reasons my child's participation in this study could be stopped?

Your child's participation in the research can be stopped by the study doctor, ModernaTX, Inc, or a regulatory authority without your permission. Some examples may include:

- It is in your child's best medical interest
- Your child has a side effect that requires stopping the study
- Your child needs a treatment that is not allowed in the study
- You and your child do not follow instructions about what to do in the study
- It is discovered that your child does not meet the requirements to participate in the study
- Your child becomes pregnant
- The study is cancelled
- Enrolment is complete, or for other administrative reasons

If this happens you will be notified about your child being removed from the study.

Your child may be asked to complete the procedures that are part of the end-of-study visit. Your child does not have to complete any additional procedures or answer any additional questions if you do not want to; however, the information you provide could help the researchers to better understand COVID-19.

[redacted]

If the study team or ModernaTX, Inc learn new facts during the study that might make you and your child want to leave the study, they will tell you right away. You can then decide if you still want your child to be in the study.

Can My Child Continue Getting the Study Vaccine after their participation in the study ends?

ModernaTX, Inc will not continue providing the study vaccine when the study ends, if the study ends early, if your child chooses to stop participating in the study, or your child's participation in the study is stopped.

What If There Is a Problem?

If you have a concern about any aspect of this study, you should ask to speak to the study team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Study Team. You can also speak to someone independent from the Study Team. Contact details are found in the "Further information and contact details" section at the end of this information sheet.

The Sponsor will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI).

The Sponsor will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the study protocol;
- Any test or procedure your child received as part of the study.

Any payment would be without legal commitment (please ask if you wish more information on this). The Sponsor would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the study protocol or where the protocol wasn't followed.

In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the NHS Trust or Private Clinic but you may have to pay your legal costs. The normal complaints mechanisms will still be available to you.

If your child has private medical insurance you are advised to inform their provider of your child's consideration to take part in a clinical research study as this may affect their cover.

It is important that you carefully follow all instructions given by the Study Team about this study.
By signing this form, you are not giving up your child's or your legal rights and are not releasing the Study Team or the Sponsor from their legal and professional responsibilities.

Will Information About My Child be Kept Confidential?

How will we use information about your child?

We will need to use information from your child for this research project.
This information will include your child's

- name,
- contact details,
- gender,
- height and weight,
- ethnic origin,
- as well as information on your medical history,

[redacted]

- and clinical data collected about your participation in the study

People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who your child is will not be able to see your child's name or contact details. Your child's data will have a code number instead.

We will keep all information about your child safe and secure.

Some of your information will be sent to USA for data analysis. They must follow our rules about keeping your child's information safe.

Once we have finished the study, we will keep some of the data for up to 25 years so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are your choices about how your child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about your child that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.
- If you agree for your child to take part in this study, you will have the option to take part in future research using your child's data saved from this study.

Where can you find out more about how your child's information is used?

You can find out more about how we use your child's information

- at www.hra.nhs.uk/information-about-patients/
- you can submit a request on our website www.datarep.com/data-request
- by asking one of the research team
- by sending an email to [redacted]

Can I share information about the study?

If your child participates in this study, you should feel free to discuss the study with your family and other people who are close to you. It is recommended to tell your child's health care provider about your chils'd participation in the study. However, to help make sure that the information from the study is as accurate and reliable as possible, please do not discuss information about the study in public places while the study is in progress. Public places include places like social media (i.e., BeReal, Facebook, Instagram, TikTok, Twitter, WhatsApp, and others), blogging, and speaking to the media.

Involvement of the General Practitioner/Family Doctor (GP)

The study doctor will inform your child's GP/family doctor that your child is taking part in this study and may ask them to provide relevant medical information about your child if necessary.

The following information about your child's participation in the study will be shared with their GP:

- Health records to verify that your child meets the eligibility criteria for this study;
- Monitoring, or notifying your child's GP of any adverse reactions to research treatments;
- Communicating any newly discovered health related findings about your child to their GP.

What Will Happen to Any Samples My Child Gives?

[redacted]

Samples obtained in the study will be labelled with a code and will not contain any information that could identify your child. Samples will be processed and analysed at multiple laboratories for the purposes of this research study. Your child's samples will be shipped outside the UK and sent to a laboratory in USA, Belgium, Singapore or The Netherlands to be tested or stored prior to testing by special laboratories. Your child's samples will be securely stored for approximately 15 years after study completion, after which your child's samples will be destroyed.

ModernaTX, Inc retains management and oversight of your child's samples and is responsible for sample logistics and storage. Your child's samples will be stored at Sponsor's own laboratory or laboratory contracted by the Sponsor. ModernaTX, Inc is responsible for your child's biological samples (regardless of the physical location).

During and after the study, you will keep the right to have the samples destroyed if you contact the study doctor. If you want your child's samples to be destroyed, you will have to ask the study doctor. All the samples and test data collected before your child left the study will still be used for study purposes. Once the samples have been anonymised, they will not be able to be linked back to your child. After your child leaves this study, no new samples or test data will be taken from your child for the study.

We would like to know if your child's leftover samples can be used for future research. This means that the samples may be tested to:

- Learn more about the effects of mRNA on COVID-19, or unrelated research.
- Develop new drugs or devices, tests or processes, including commercial products.
- Develop clinical assays for measuring response to vaccines and/or viral infections.

The use of your child's samples in future research is optional. You can decline and still take part in this study.

The results of the study of your child's blood samples will be used for research purposes only and you will not be told the results of the tests nor will you benefit financially from any developments.

What Will Happen to the Results of this Research Study?

After this study is over, a brief report of the overall results will be prepared for the general public. The study results may also be shared with scientific journals and the scientific community. Whenever the results of the study are shared or published, your child's identity will remain private.

The results of this study will be used to make informed clinical decisions for developing the study vaccine. There are no plans to give you any specific results from this research.

A description of this clinical study will be available on http://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify your child. At most, the website will include a summary of the results. You can search this website at any time.

Who Has Reviewed the Study?

All research in the United Kingdom is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by **South Central – Berkshire B Research Ethics Committee**.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare

products Regulatory Agency (MHRA).

Further Information and Contact Details

In case of a study-related injury or whenever you have questions about the study or your child's study medication, please contact:

[redacted] [redacted]

[redacted] [redacted]

Address: NIHR Patient Recruitment Centre, Exeter, Royal Devon & Exeter Hospital (Wonford), Barrack Road, Exeter, EX2 5DW, United Kingdom

If you need to report side effects or your child is feeling unwell, there is a 24-hour contact number:

Phone Number [redacted]

If you have questions about your child's rights as a research participant, or do not feel comfortable speaking with the study doctor please ask the study site for details or contact:

Patient Advice and Liaison Service (PALS) Tel: [redacted] **Email:** [redacted]

Parent Informed Consent Form

Title of Study:	A randomized, observer-blind, active-controlled Phase 3 study to investigate the safety and immunogenicity and relative vaccine efficacy of mRNA-1283.222 administered as a booster dose compared with mRNA1273.222 in participants aged 12 years and older for the prevention of COVID-19
Short Study Title:	**Next COVE**
Protocol Number:	mRNA-1283-[redacted]
Sponsor:	ModernaTX, Inc.
IRAS ID:	[redacted]
Study Doctor:	[redacted]
Participant ID	

If you still have questions, please ask the study doctor or one of the study staff, before signing this Parent Informed Consent Form

	Please initial each box
• I confirm that I have read and understand the Parent Information Sheet and Informed Consent Form for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	
• I have had the chance to ask questions, and I am satisfied with the answers given to me.	
• I understand that my child's participation is voluntary and that I am free to withdraw at any time without giving any reason, without my child's medical care or legal rights being affected.	
• I understand the relevant sections of my child's medical notes and data collected during the study may be looked at by individuals from the Sponsor or its representatives, or the regulatory authorities, where it is relevant to my child taking part in this research. I give permission for these individuals to have access to my child's records.	

• I agree to the use of my child's blood and urine samples as outlined in the Parent Information Sheet and Informed Consent Form.	
• I understand that my child's data will be collected, processed, reported and transferred within and outside the United Kingdom (if applicable) of my child's data for healthcare and/or medical research purposes where the data protection may not be as good.	
• I agree to my child's GP being informed of their participation in this study and providing relevant medical information about my child to the study doctor if necessary.	
• I understand I will receive a copy of this Parent Information Sheet and Informed Consent Form.	
• I agree for my child to take part in the above study of my own free will.	

OPTIONAL:

For Use of Remaining Biological Samples for Future Research (please initial box)

☐ Yes, I agree to allow my child's samples to be stored and used for future research

☐ No, I do not agree to have my child's samples used for future research (this will not prevent you from participating in the current study)

_____

Printed Name of Participant, in full

_____

Printed Name of Parent / Guardian, in full

_____

Signature of Parent / Guardian **Date (DD-Mmm-YYYY)**

[redacted]