

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)

(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014

Expiration Date: March 31, 2022

See PRA Statement on page 3.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

1. Name of Sponsor

ModernaTX, Inc.

2. Date of Submission (mm/dd/yyyy)

09/04/2020

3. Sponsor Address

Address 1 (Street address, P.O. box, company name c/o)

200 Technology Square

Address 2 (Apartment, suite, unit, building, floor, etc.)

City

Cambridge

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02139

4. Telephone Number (Include country code if applicable and area code)

(b) (6)

6A. IND Number (If previously assigned)

019745

6B. Select One: ☒ Commercial☐ Research

5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)

mRNA-1273

Continuation
Page for #5

7A. (Proposed) Indication for Use

Active immunization to induce protective immunity against acute respiratory disease associated with the SARS-COV-2 virus.

Is this indication for a rare disease (prevalence <200,000 in U.S.)? ☐ Yes ☒ NoDoes this product have an FDA Orphan Designation for this indication? ☐ Yes ☒ NoIf yes, provide the Orphan Designation number for this indication: Continuation
Page for #7

7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)

415360003 |Severe acute respiratory syndrome-related coronavirus (organism)|

8. Phase of Clinical Investigation to be conducted

☐ Phase 1☒ Phase 2☒ Phase 3☐ Other (Specify):

9. List numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.

CBER MF# 19610; CBER MF# 19611; CBER MF# 19622; IND# 19365; CBER MF# 22939; CBER MF# 22940

10. IND submission should be consecutively numbered. The initial IND should be numbered "Serial number: 0000." The next submission (e.g., amendment, report, or correspondence) should be numbered "Serial Number: 0001." Subsequent submissions should be numbered consecutively in the order in which they are submitted..

Serial Number

0 0 3 0

11. This submission contains the following (Select all that apply)

☐ Initial Investigational New Drug Application (IND)☐ Response to Clinical Hold☐ Response To FDA Request For Information☐ Request For Reactivation Or Reinstatement☐ Annual Report☐ General Correspondence☐ Development Safety Update Report (DSUR)☐ Other (Specify):

Protocol Amendment

☐ New Protocol☐ PMR/PMC☐ Change in Protocol

Protocol

☐ New Investigator☐ Human Factors

Protocol

Information Amendment

☐ Chemistry/Microbiology☐ Pharmacology/Toxicology☐ Clinical/Safety ☐ Statistics☐ Clinical Pharmacology

Request for

☒ Meeting☐ Proprietary Name Review☐ Special Protocol Assessment☐ Formal Dispute Resolution

IND Safety Report

☐ Initial Written Report☐ Follow-up to a Written Report12. For Originals, is the product a combination product (21 CFR 3.2(e))? ☐ Yes ☐ No

Combination Product Type (See instructions)

Request for Designation (RFD) Number

13. Select the following only if applicable. (Justification statement must be submitted with application for any items selected below. Refer to the cited CFR section for further information.)

Expanded Access Use, 21 CFR 312.300

☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)☐ Charge Request, 21 CFR 312.8☐ Individual Patient, Non-Emergency 21 CFR 312.310☐ Individual Patient, Emergency 21 CFR 312.310(d)☐ Intermediate Size Patient Population, 21 CFR 312.315☐ Treatment IND or Protocol, 21 CFR 312.320

For FDA Use Only

CBER/DCC Receipt Stamp

DDR Receipt Stamp

Division Assignment

IND Number Assigned

14. Contents of Application – This application contains the following items *(Select all that apply)*

- | | |
|---|---|
| <input checked="" type="checkbox"/> 1. Form FDA 1571 (21 CFR 312.23(a)(1))
<input type="checkbox"/> 2. Table of Contents (21 CFR 312.23(a)(2))
<input type="checkbox"/> 3. Introductory statement (21 CFR 312.23(a)(3))
<input type="checkbox"/> 4. General Investigational plan (21 CFR 312.23(a)(3))
<input type="checkbox"/> 5. Investigator's brochure (21 CFR 312.23(a)(5))
<input type="checkbox"/> 6. Protocol (21 CFR 312.23(a)(6)) <div style="margin-left: 20px;"> <input type="checkbox"/> a. Study protocol (21 CFR 312.23(a)(6))
 <input type="checkbox"/> b. Investigator data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
 <input type="checkbox"/> c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572 </div> | 6. Protocol (Continued)
<input type="checkbox"/> d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
<input type="checkbox"/> 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7)) <div style="margin-left: 20px;"> <input type="checkbox"/> Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e)) </div> <input type="checkbox"/> 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
<input type="checkbox"/> 9. Previous human experience (21 CFR 312.23(a)(9))
<input type="checkbox"/> 10. Additional information (21 CFR 312.23(a)(10))
<input type="checkbox"/> 11. Biosimilar User Fee Cover Sheet (Form FDA 3792)
<input type="checkbox"/> 12. Clinical Trials Certification of Compliance (Form FDA 3674) |
|---|---|

15. Is any part of the clinical study to be conducted by a contract research organization? ☒ Yes ☐ NoIf Yes, will any sponsor obligations be transferred to the contract research organization? ☒ Yes ☐ NoIf Yes, provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred *(use continuation page)*.Continuation
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16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

Tal Zaks, Chief Medical Officer, ModernaTX, Inc.

17. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug

Tal Zaks, Chief Medical Officer, ModernaTX, Inc.

I agree not to begin clinical investigations until 30 days after FDA's receipt of the IND unless I receive earlier notification by FDA that the studies may begin. I also agree not to begin or continue clinical investigations covered by the IND if those studies are placed on clinical hold or financial hold. I agree that an Institutional Review Board (IRB) that complies with the requirements set forth in 21 CFR Part 56 will be responsible for initial and continuing review and approval of each of the studies in the proposed clinical investigation. I agree to conduct the investigation in accordance with all other applicable regulatory requirements.

18. Name of Sponsor or Sponsor's Authorized Representative

Carlota Vinals

19. Telephone Number *(Include country code if applicable and area code)*

(b) (6)

20. Facsimile (FAX) Number *(Include country code if applicable and area code)*

(b) (6)

21. Address

Address 1 *(Street address, P.O. box, company name c/o)*

200 Technology Square

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City

Cambridge

State/Province/Region

MA

Country

USA

ZIP or Postal Code

02139

22. Email Address

(b) (6) @modernatx.com

23. Date of Sponsor's Signature *(mm/dd/yyyy)*

09/04/2020

24. Name of Countersigner

25. Address of Countersigner

Address 1 *(Street address, P.O. box, company name c/o)*Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City

State/Province/Region

Country

United States of America

ZIP or Postal Code

26. Email Address

WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).

27. Signature of Sponsor or Sponsor's Authorized Representative

Carlota Vinals

Digitally signed by Carlota Vinals
Date: 2020.09.04 08:15:43 -04'00'

Sign

28. Signature of Countersigner

Sign

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASaff@fda.hhs.gov

Please do NOT send your completed form to this PRA Staff email address.

FIRST CONTINUATION PAGE FOR ITEM 15 – Information on Contract Research Organization

For each (as applicable below) contract service organization involved in the clinical study, please provide a statement containing the name and address of the contract research organization, identification of the clinical study, and a listing of the obligations transferred.

Contract Service Organization

See Module 1.3.1.4

Contract Service Organization

Contract Service Organization

Contract Service Organization

Contract Service Organization