

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) 12/02/2020	
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: <input checked="" type="checkbox"/> Commercial <input type="checkbox"/> 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.)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Does this product have an FDA Orphan Designation for this indication? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If yes, provide the Orphan Designation number for this indication: <input type="text"/> 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 <input type="checkbox"/> Phase 1 <input checked="" type="checkbox"/> Phase 2 <input checked="" type="checkbox"/> Phase 3 <input type="checkbox"/> 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 8 2	
11. This submission contains the following (Select all that apply) <input type="checkbox"/> Initial Investigational New Drug Application (IND) <input type="checkbox"/> Response to Clinical Hold <input checked="" type="checkbox"/> Response To FDA Request For Information <input type="checkbox"/> Request For Reactivation Or Reinstatement <input type="checkbox"/> Annual Report <input type="checkbox"/> General Correspondence <input type="checkbox"/> Development Safety Update Report (DSUR) <input type="checkbox"/> Other (Specify): _____ Protocol Amendment Information Amendment Request for IND Safety Report <input type="checkbox"/> New Protocol <input type="checkbox"/> PMR/PMC <input checked="" type="checkbox"/> Chemistry/Microbiology <input type="checkbox"/> Meeting <input type="checkbox"/> Initial Written Report <input type="checkbox"/> Change in Protocol <input type="checkbox"/> Protocol <input type="checkbox"/> Pharmacology/Toxicology <input type="checkbox"/> Proprietary Name Review <input type="checkbox"/> Follow-up to a Written Report <input type="checkbox"/> New Investigator <input type="checkbox"/> Human Factors <input checked="" type="checkbox"/> Clinical/Safety <input type="checkbox"/> Statistics <input type="checkbox"/> Special Protocol Assessment <input type="checkbox"/> Report <input type="checkbox"/> Clinical Pharmacology <input type="checkbox"/> Formal Dispute Resolution			
12. For Originals, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> 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 <input type="checkbox"/> Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f) <input type="checkbox"/> Individual Patient, Non-Emergency 21 CFR 312.310 <input type="checkbox"/> Intermediate Size Patient Population, 21 CFR 312.315 <input type="checkbox"/> Charge Request, 21 CFR 312.8 <input type="checkbox"/> Individual Patient, Emergency 21 CFR 312.310(d) <input type="checkbox"/> 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 (<i>Continued</i>)
<input type="checkbox"/> d. Institutional Review Board data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
<input checked="" 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 (<i>Form FDA 3792</i>)
<input type="checkbox"/> 12. Clinical Trials Certification of Compliance (<i>Form FDA 3674</i>) |
|---|---|

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
Page for #15

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*)

12/02/2020

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: 2020.12.02 10:23:38 -05'00'

Sign

28. Signature of Countersigner

Sign

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Office of Operations
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PRASaff@fda.hhs.gov

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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

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