

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
 BioNTech SE

2. Date of Submission (mm/dd/yyyy)
 09/14/2021

3. Sponsor Address

Address 1 (Street address, P.O. box, company name c/o)
 An der Goldgrube 12

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

City
 Mainz

State/Province/Region
 N/A

Country
 Germany

ZIP or Postal Code
 55131

4. Telephone Number (Include country code if applicable and area code)
 214-918-5262

6A. IND Number (If previously assigned)
 019736

6B. Select One: Commercial
 Research

5. Name of Drug (Include all available names: Trade, Generic, Chemical, or Code)
 COVID-19 Vaccine (BNT162, PF-07302048)

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7A. (Proposed) Indication for Use
 Active immunization to prevent COVID-19 caused by SARS-CoV-2

Is this indication for a rare disease (prevalence <200,000 in U.S.)? Yes No

Does this product have an FDA Orphan Designation for this indication? Yes No

If yes, provide the Orphan Designation number for this indication:

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

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.
 BB-IND 013812, BB-IND 013278, BLA 125549

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 4 8 7

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): Informed Consent Documents for Study C4591007

Protocol Amendment	Information Amendment	Request for	IND Safety Report
<input type="checkbox"/> New Protocol <input type="checkbox"/> PMR/PMC Protocol	<input type="checkbox"/> Chemistry/Microbiology <input type="checkbox"/> Pharmacology/Toxicology	<input type="checkbox"/> Meeting <input type="checkbox"/> Proprietary Name Review	<input type="checkbox"/> Initial Written Report <input type="checkbox"/> Follow-up to a Written Report
<input checked="" type="checkbox"/> Change in Protocol <input type="checkbox"/> New Investigator <input type="checkbox"/> Human Factors Protocol	<input type="checkbox"/> Clinical/Safety <input type="checkbox"/> Statistics <input type="checkbox"/> Clinical Pharmacology	<input type="checkbox"/> Special Protocol Assessment <input type="checkbox"/> Formal Dispute Resolution	

12. 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)

Individual Patient, Non-Emergency 21 CFR 312.310

Intermediate Size Patient Population, 21 CFR 312.315

Charge Request, 21 CFR 312.8

Individual Patient, Emergency 21 CFR 312.310(d)

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 checked="" type="checkbox"/> 6. Protocol (21 CFR 312.23(a)(6)) <ul style="list-style-type: none"> <input checked="" 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 | 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)) <ul style="list-style-type: none"> <input type="checkbox"/> Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e)) <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 No
 If Yes, will any sponsor obligations be transferred to the contract research organization? Yes No
 If 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).

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16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations
 Özlem Türeci, MD, Chief Medical Officer, BioNTech SE

17. Name and Title of the person responsible for review and evaluation of information relevant to the safety of the drug
 Özlem Türeci, MD, Chief Medical Officer, BioNTech SE

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
 Amit Patel, Director, Global Regulatory Affairs - Vaccines

19. Telephone Number (Include country code if applicable and area code) 214-918-5262	20. Facsimile (FAX) Number (Include country code if applicable and area code) 845-474-3500
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21. Address		22. Email Address
Address 1 (Street address, P.O. box, company name c/o) 235 East 42nd Street		Amitkumar.Patel@pfizer.com
Address 2 (Apartment, suite, unit, building, floor, etc.)		
City New York	State/Province/Region NY	23. Date of Sponsor’s Signature (mm/dd/yyyy) 09/14/2021
Country United States of America	ZIP or Postal Code 10017	

24. Name of Countersigner

25. Address of Countersigner		26. Email Address
Address 1 (Street address, P.O. box, company name c/o)		
Address 2 (Apartment, suite, unit, building, floor, etc.)		WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001).
City	State/Province/Region	
Country	ZIP or Postal Code	
United States of America		

27. Signature of Sponsor or Sponsor’s Authorized Representative

Amit Patel
 Digitally signed by Amit Patel
 Reason: I attest to the accuracy and integrity of this document
 Date: 2021 09 14 09:51:02 -05'00'

Sign

28. Signature of Countersigner

Sign

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