DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

1. Name of Sponsor
BioNTech SE

2. Date of Submission (mm/dd/yyyy)
01/15/2021

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.)

4. Telephone Number (Include country code if applicable and area code)
215-280-5503

6A. IND Number (If previously assigned)
019736

6B. Select One:
☐ Commercial
☐ Research

7A. (Proposed) Indication for Use
Prophylactic immunization against COVID-19 in adults ≥16 years of age

7B. SNOMED CT Indication Disease Term
COVID-19 Vaccine (BNT162, PF-07302048)

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.

11. This submission contains the following (Select all that apply)
☐ Initial Investigational New Drug Application (IND)
☐ Request For Revocation Or Reinstatement
☐ Development Safety Update Report (DSUR)
☑ Other (Specify): Summary Monthly Safety Report (SMSR)

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.)
☐ Emergency Research Exception From Informed Consent Requirements, 21 CFR 312.23 (f)
☐ Charge Request, 21 CFR 312.8

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)

- ✔ 1. Form FDA 1571 (21 CFR 312.23(a)(1))
- ✔ 2. Table of Contents (21 CFR 312.23(a)(2))
- ✔ 3. Introductory statement (21 CFR 312.23(a)(3))
- ✔ 4. General Investigational plan (21 CFR 312.23(a)(4))
- ✔ 5. Investigator’s brochure (21 CFR 312.23(a)(5))
- ✔ 6. Protocol (21 CFR 312.23(a)(6))
  - a. Study protocol (21 CFR 312.23(a)(6))
  - b. Investigator data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
  - c. Facilities data (21 CFR 312.23(a)(6)(iii)(b)) or completed Form FDA 1572
- ☐ 7. Chemistry, manufacturing, and control data (21 CFR 312.23(a)(7))
  - Environmental assessment or claim for exclusion (21 CFR 312.23(a)(7)(iv)(e))
- ☐ 8. Pharmacology and toxicology data (21 CFR 312.23(a)(8))
- ☐ 9. Previous human experience (21 CFR 312.23(a)(9))
- ☐ 10. Additional information (21 CFR 312.23(a)(9))
- ☐ 11. Biosimilar User Fee Cover Sheet (Form FDA 3792)
- ☐ 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).

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

Elisa Harkins, Global Regulatory Lead, Pfizer Global Regulatory Affairs - Vaccines

19. Telephone Number (Include country code if applicable and area code) 215-280-5503

20. Facsimile (FAX) Number (Include country code if applicable and area code) (845) 474-3500

21. Address

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

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

City Collegeville
State/Province/Region PA

Country United States of America
ZIP or Postal Code 19426

22. Email Address

elisa.harkinstull@pfizer.com

23. Date of Sponsor’s Signature (mm/dd/yyyy) 01/15/2021

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

28. Signature of Countersigner

Sign

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

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

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

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