UNITED STATES FOOD & DRUG ADMINISTRATION

Applications for FDA Approval to Market New Drug

OMB Control Number 0910-0014

Non-substantive Change Request:

I. Background:

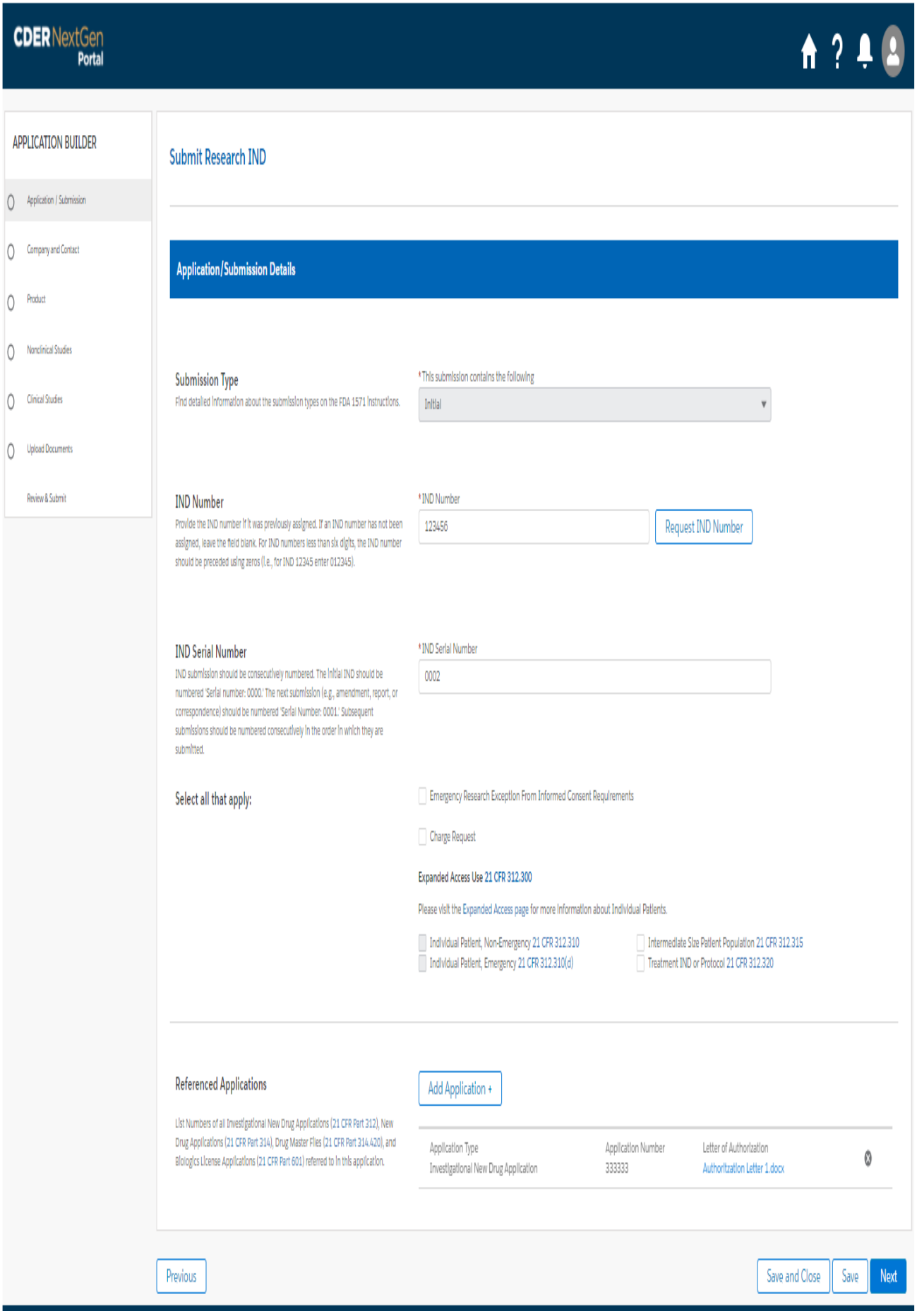
This information collection supports FDA regulations in 21 CFR Part 312, which govern the use of investigational new drugs, including procedures and requirements for the submission of Form FDA 1571 entitled, "*Investigational New Drug Application (IND)*." Our primary objective in reviewing an IND is to help protect the rights and safety of subjects and to help ensure that the quality of the clinical trial is adequate to evaluate a drug's effectiveness and safety for the studied indication. To supplement the Form FDA 1571 instructions, we issued a draft guidance in May of 2015 entitled "*Investigational New Drug Applications Prepared and Submitted by Sponsor Investigators*" available at https://www.fda.gov/files/drugs/published/Investigational-New-Drug-Applications-Prepared-and-Submitted-by-Sponsor-Investigators.pdf. Form FDA 1571 is available as a fillable PDF document and accompanying instructions may be found on our website at https://www.fda.gov/media/116608/download.

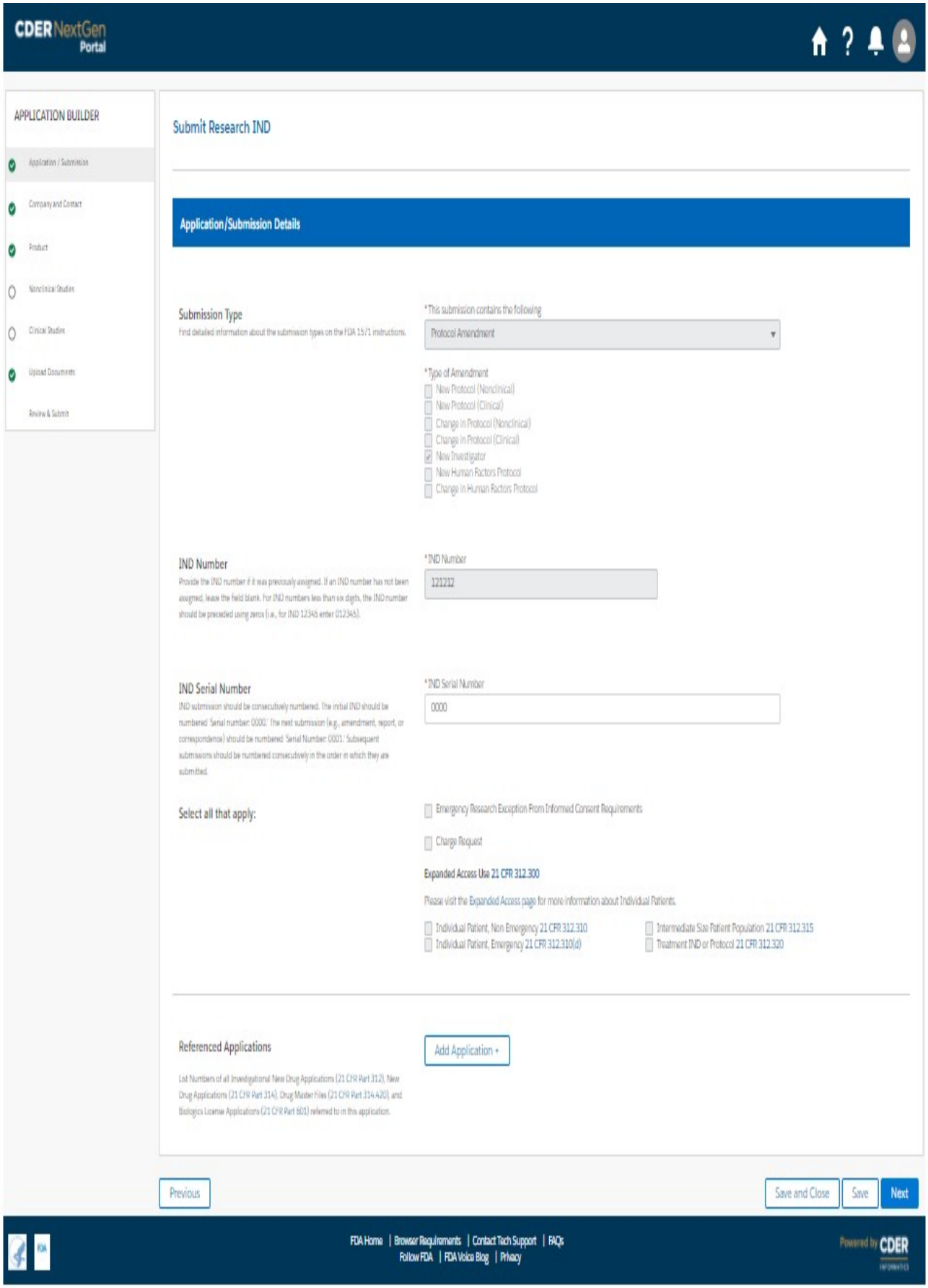
II. Proposed change:

We have developed an additional collection method for data elements in Form FDA 1571 for research INDs (often/sometimes referred to as "non-commercial" INDs), however the scope of data being collected will remain unchanged. Also, the new collection method will only apply to research INDs. We generally consider a research IND to be one for which the sponsor (typically an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration than INDs for commercial development, and may result in publications in peer-reviewed journals. For sponsors (including sponsor/investigators) interested in filing or updating a research IND, a new web-based interface will be available on a mobile device or desktop to help sponsors fill out Form FDA 1571. The web-based interface will also allow sponsors to electronically submit the completed Form FDA 1571 and associated files.

The information being collected is described in 21 CFR 312.23 (a) through (f) and on Form FDA 1571, and will be submitted to FDA through a new, secure web-based interface. Use of this web-based submission is voluntary, and respondents may still elect to use a fillable PDF version of Form FDA 1571, submitted via mail, email, or fax. We believe the web-based collection method will enhance user experience with data submission to FDA and will help improve agency efficiencies. At the same time, we have made no adjustment to the currently estimated burden for the information collection at this time. Upon later evaluation we will modify our estimate as appropriate. Screenshots for the interface are included below.

Submitted: March 2021


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Application/Submission Details
Submission Type
Find detailed information about the submission types on the FDA 1571 Instructions.
*This submission contains the following
Initial
IND Number
Provide the IND number if it was previously assigned. If an IND number has not been assigned, leave the field blank. For IND numbers less than six digits, the IND number should be preceded using zeros (i.e., for IND 12345 enter 012345).
*IND Number
123456
Request IND Number
IND Serial Number
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.
*IND Serial Number
0002
Select all that apply:
Emergency Research Exception From Informed Consent Requirements
Charge Request
Expanded Access Use 21 CFR 312.300
Please visit the Expanded Access page for more information about Individual Patients.
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
Referenced Applications
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.
Add Application +
Application Type
Investigational New Drug Application
Application Number
333333
Letter of Authorization
Authorization Letter 1.docx
Previous
Save and Close
Save
Next


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Application/Submission Details
Submission Type
Find detailed information about the submission types on the FDA 1571 instructions.
*This submission contains the following
Protocol Amendment
*Type of Amendment
New Protocol (Nonclinical)
New Protocol (Clinical)
Change in Protocol (Nonclinical)
Change in Protocol (Clinical)
New Investigator
New Human Factors Protocol
Change in Human Factors Protocol
IND Number
Provide the IND number if it was previously assigned. If an IND number has not been assigned, leave the field blank. For IND numbers less than six digits, the IND number should be preceded using zeros (i.e., for IND 12345 enter 012345).
*IND Number
121212
IND Serial Number
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.
*IND Serial Number
0000
Select all that apply:
Emergency Research Exception From Informed Consent Requirements
Charge Request
Expanded Access Use 21 CFR 312.300
Please visit the Expanded Access page for more information about Individual Patients.
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
Referenced Applications
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.
Add Application +
Previous
Save and Close
Save
Next
FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy
Powered by CDER

APPLICATION BUILDER

- Application / Submission
- Company and Contact
- Product
- Nonclinical Studies
- Clinical Studies
- Upload Documents
- Review & Submit

Submit Research IND

Company and Contact Details

Individual Details
Enter details for the following Individuals

+ * Sponsor

+ Sponsor Representative

+ Countersigner

Person Responsible for Conduct and Progress of Clinical Investigations
Provide the Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations (21 CFR 312.23(a)(1)(v)). For Sponsor-Investigator INDs, the Investigator has this responsibility.

Salutation: Select an Option

*Title

*First Name

Middle Name

*Last Name

☐ This is the same person as entered in the previous question

Person Responsible for Review and Evaluation of Safety of the Drug Information
Provide the Name and Title of the person responsible under 21 CFR 312.32 for review and evaluation of information relevant to the safety of the drug (21 CFR 312.23(a)(1))

Salutation: Select an Option

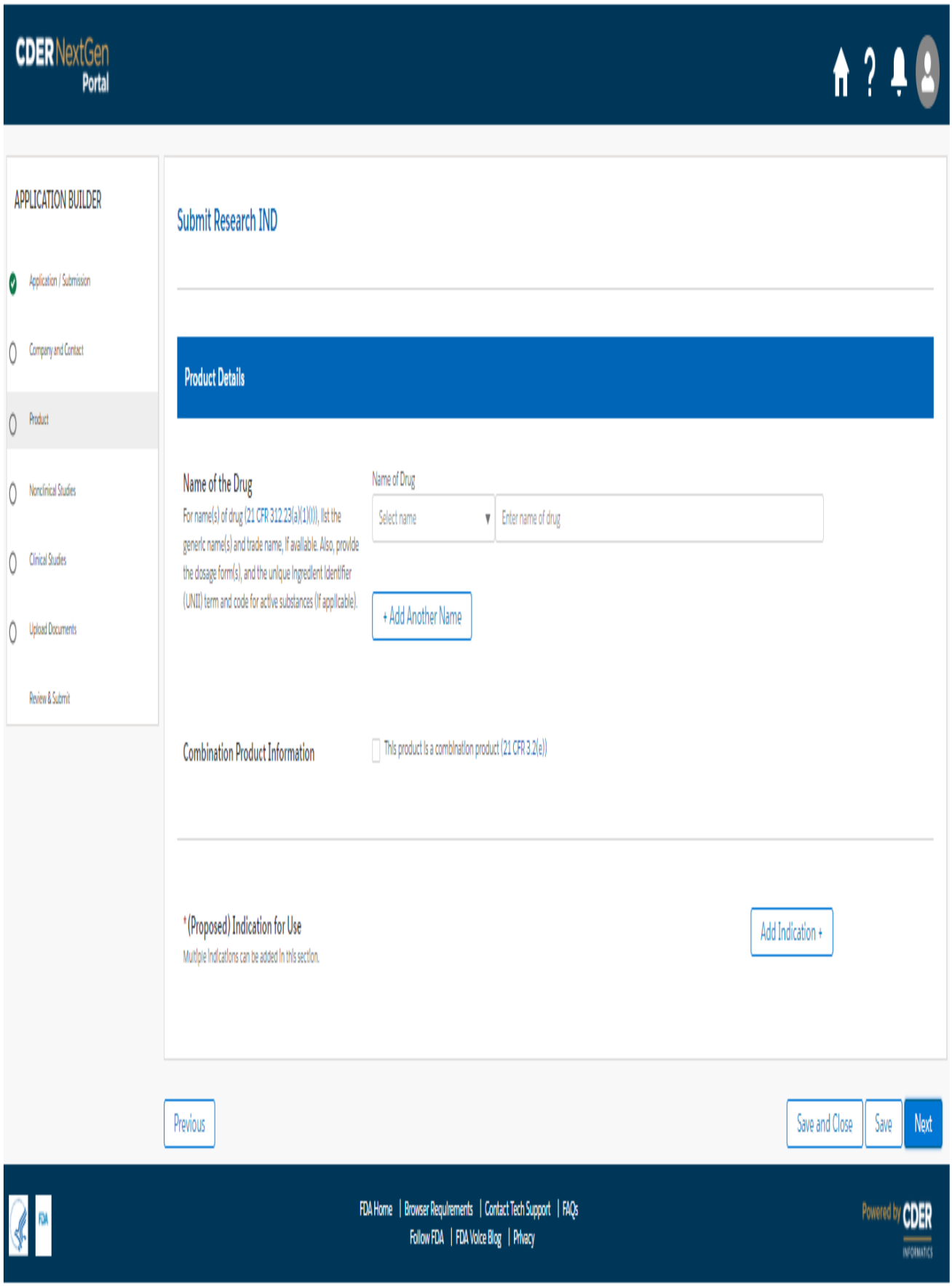
*Title

*First Name

Middle Name

*Last Name

Previous | Save and Close | Save | Next


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Product Details
Name of the Drug
For name(s) of drug (21 CFR 312.23(a)(1)(i)), list the generic name(s) and trade name, if available. Also, provide the dosage form(s), and the unique Ingredient Identifier (UNII) term and code for active substances (if applicable).
Name of Drug
Select name
Enter name of drug
+ Add Another Name
Combination Product Information
This product is a combination product (21 CFR 3.2(e))
*(Proposed) Indication for Use
Multiple indications can be added in this section.
Add Indication +
Previous
Save and Close
Save
Next
FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy
Powered by CDER INFORMATICS

APPLICATION BUILDER

- Application / Submission
- Company and Contact
- Product
- Nonclinical Studies
- Clinical Studies
- Upload Documents
- Review & Submit

Submit Research IND

Nonclinical Study Details

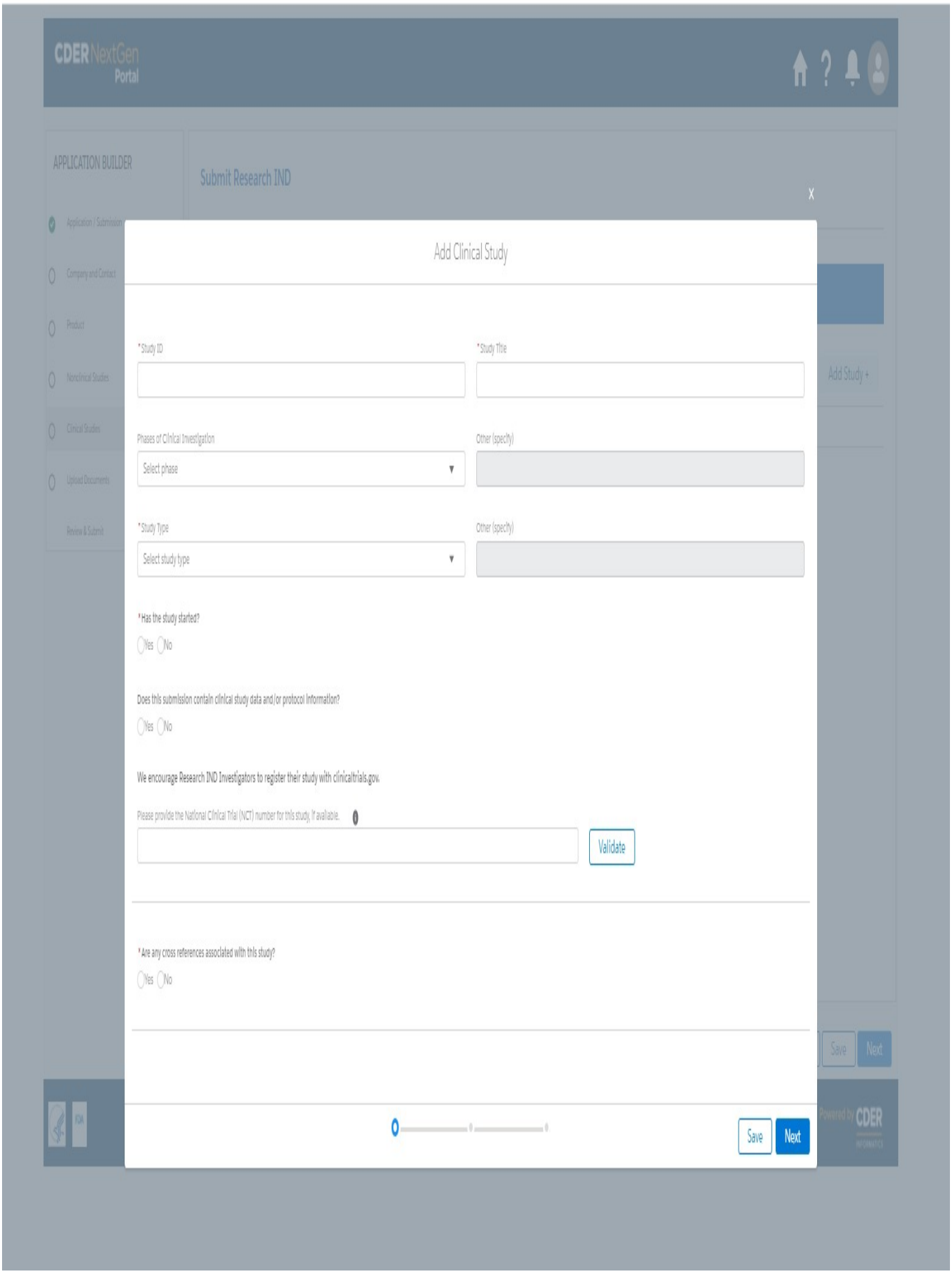
Nonclinical Studies

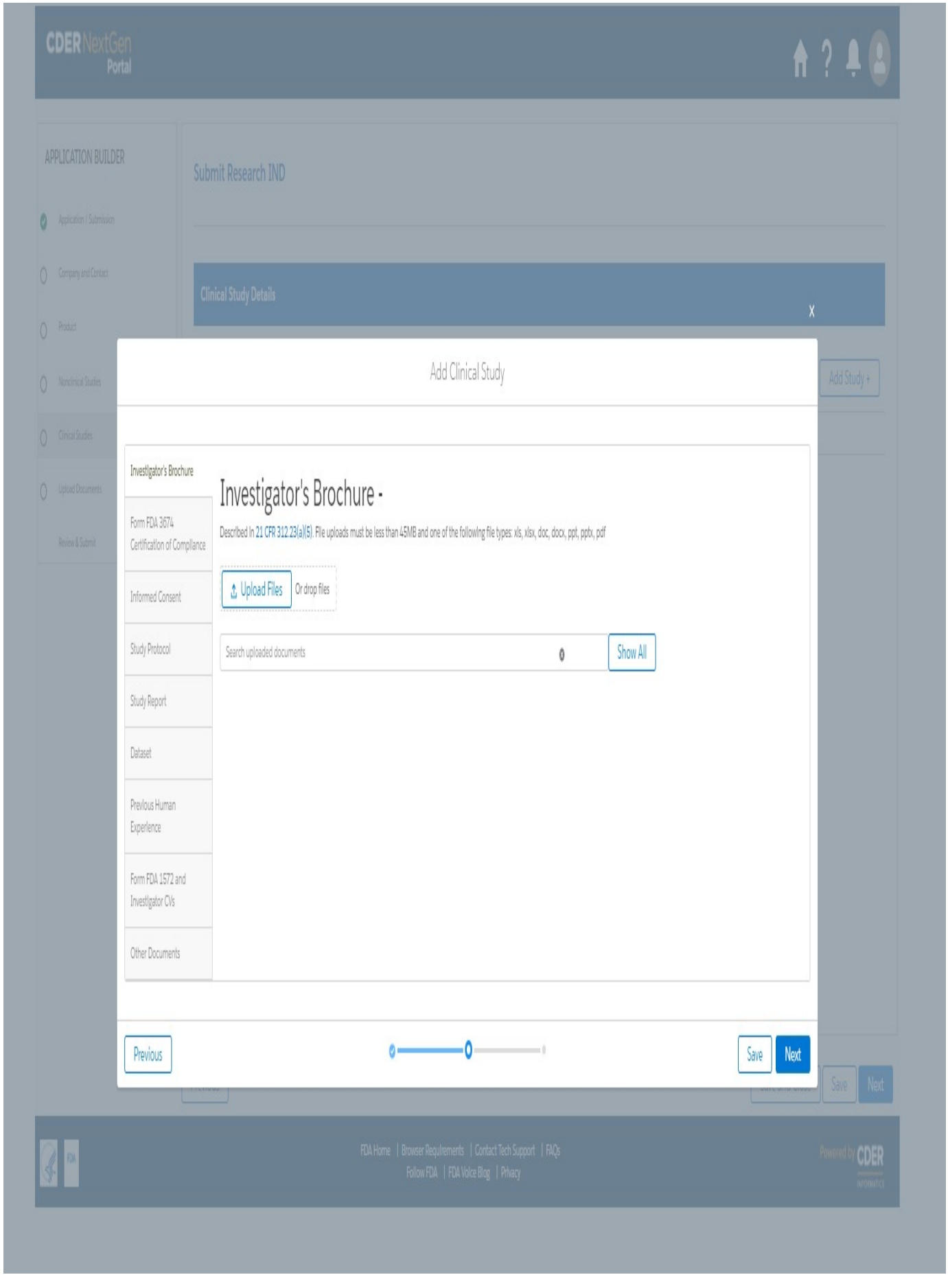
Add Study +

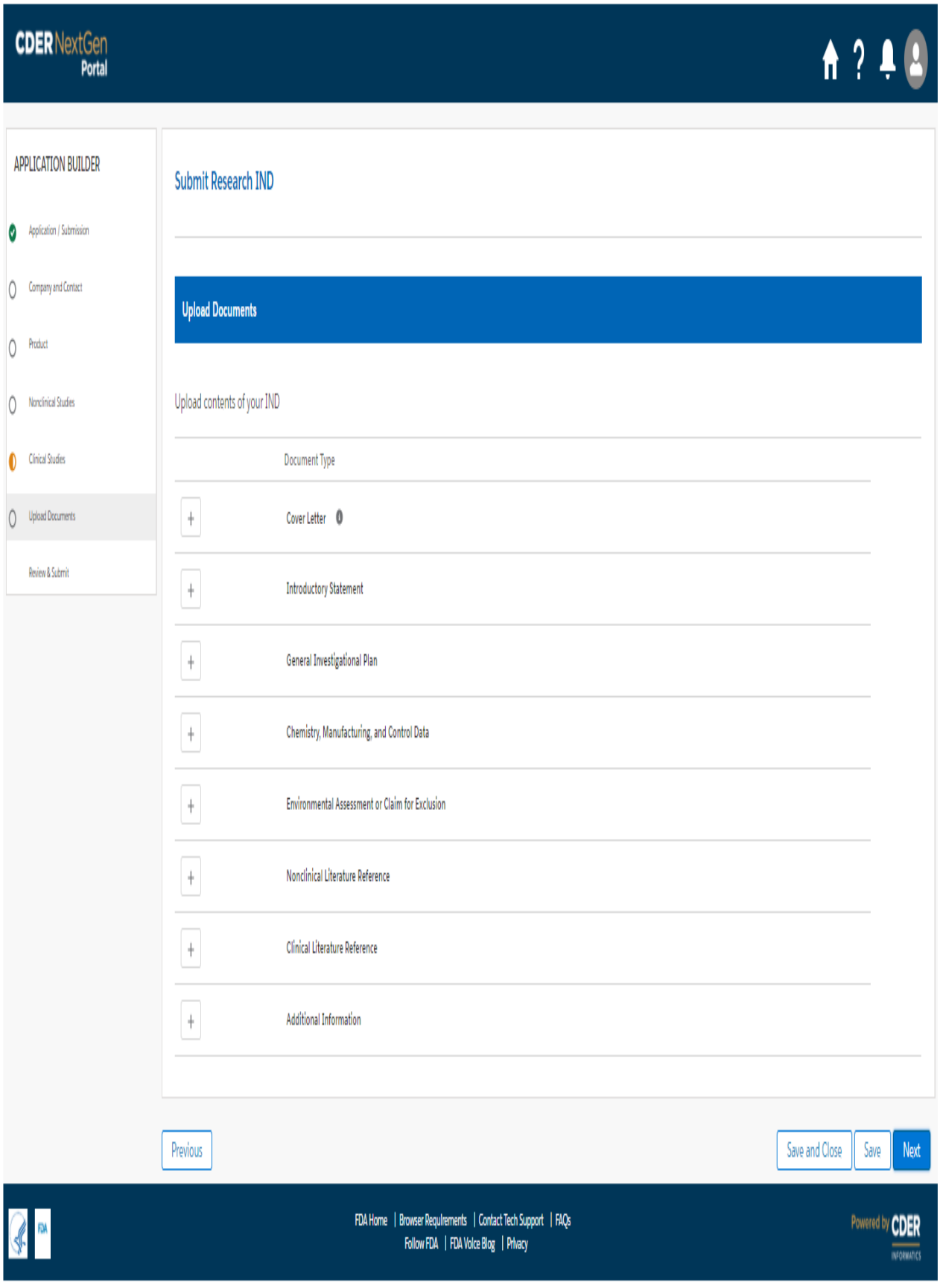
Study ID	Study Title	Study Type

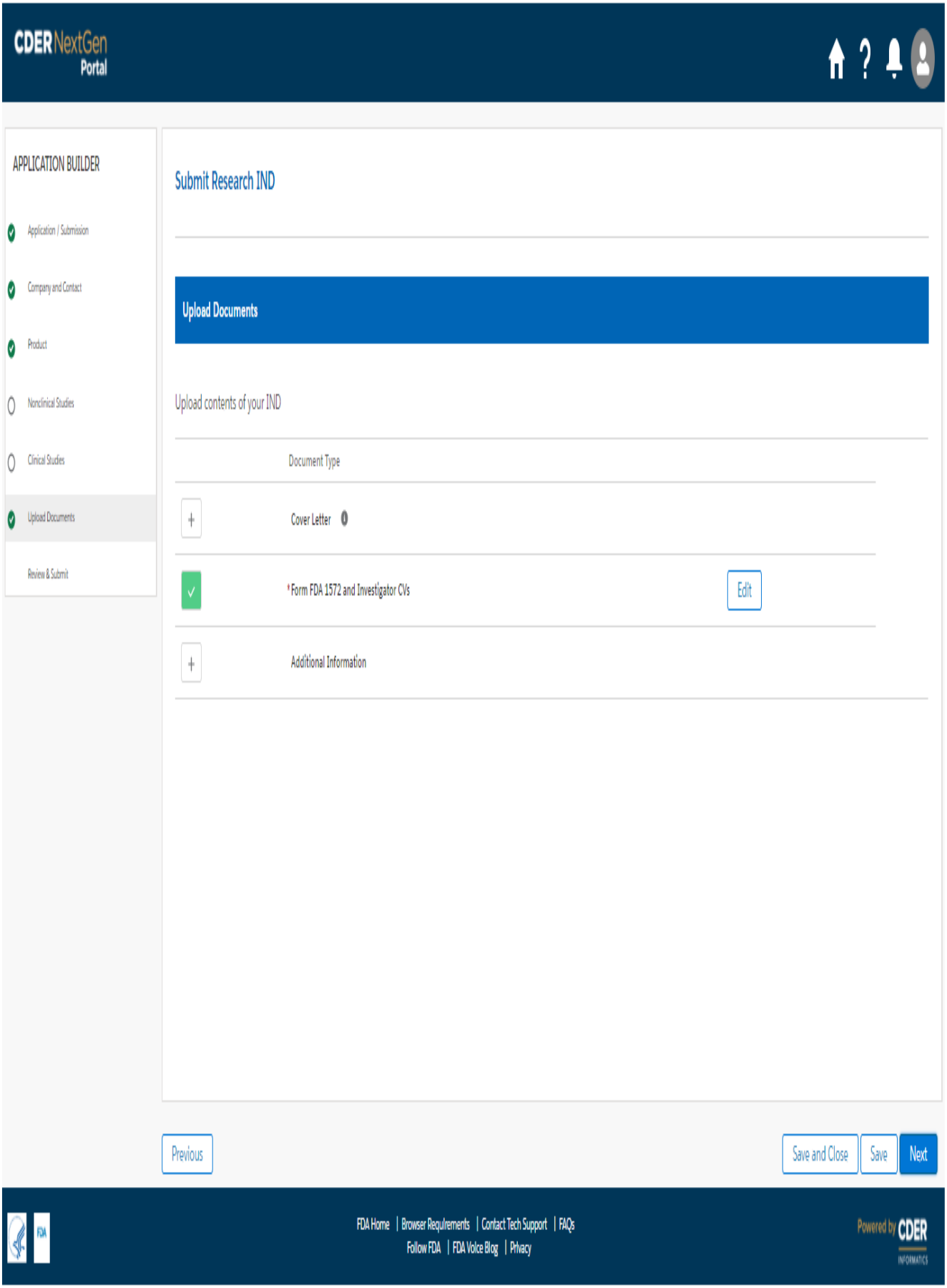
Previous

Save and Close | Save | Next

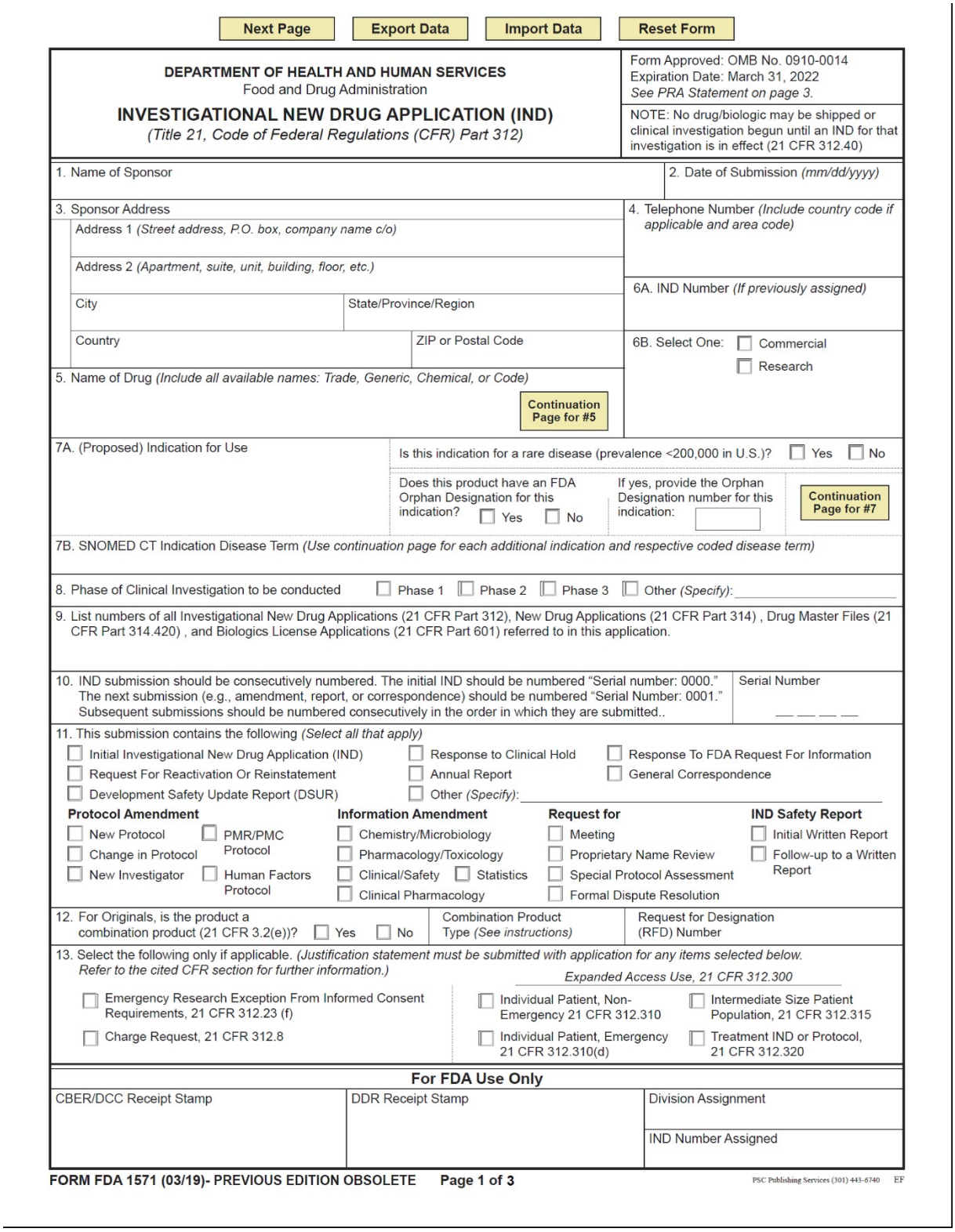

CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
X
Add Clinical Study
*Study ID
*Study Title
Phases of Clinical Investigation
Select phase
Other (specify)
*Study Type
Select study type
Other (specify)
*Has the study started?
Yes No
Does this submission contain clinical study data and/or protocol information?
Yes No
We encourage Research IND Investigators to register their study with clinicaltrials.gov.
Please provide the National Clinical Trial (NCT) number for this study, if available.
Validate
*Are any cross references associated with this study?
Yes No
Add Study +
Save
Next
Save
Next
Powered by CDER INFORMATICS


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Clinical Study Details
x
Add Study +
Add Clinical Study
Investigator's Brochure
Form FDA 3674 Certification of Compliance
Informed Consent
Study Protocol
Study Report
Dataset
Previous Human Experience
Form FDA 1572 and Investigator CVs
Other Documents
Investigator's Brochure -
Described In 21 CFR 312.23(a)(5). File uploads must be less than 45MB and one of the following file types: xls, xlsx, doc, docx, ppt, pptx, pdf
Upload Files
Or drop files
Search uploaded documents
Show All
Previous
Save
Next
FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy
Powered by CDER


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Upload Documents
Upload contents of your IND
Document Type
Cover Letter
Introductory Statement
General Investigational Plan
Chemistry, Manufacturing, and Control Data
Environmental Assessment or Claim for Exclusion
Nonclinical Literature Reference
Clinical Literature Reference
Additional Information
Previous
Save and Close
Save
Next
FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy
Powered by CDER INFORMATICS


CDER NextGen Portal
APPLICATION BUILDER
Application / Submission
Company and Contact
Product
Nonclinical Studies
Clinical Studies
Upload Documents
Review & Submit
Submit Research IND
Upload Documents
Upload contents of your IND
Document Type
Cover Letter
*Form FDA 1572 and Investigator CVs
Edit
Additional Information
Previous
Save and Close
Save
Next
FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy
Powered by CDER INFORMATICS

We also included the screenshots of the current FDA form 1571.



Next Page | Export Data | Import Data | Reset Form

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

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

3. Sponsor Address

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

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

City | State/Province/Region

Country | ZIP or Postal Code

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

6A. IND Number *(If previously assigned)*

6B. Select One: ☐ Commercial ☐ Research

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

Continuation Page for #5

7A. (Proposed) Indication for Use

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:

Continuation Page for #7

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.

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 ___ ___ ___ ___

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
☐ Change in Protocol
☐ New Investigator
☐ PMR/PMC Protocol
☐ 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 Report

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.)*

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

Expanded Access Use, 21 CFR 312.300

☐ Individual Patient, Non-Emergency 21 CFR 312.310
☐ Intermediate Size Patient Population, 21 CFR 312.315
☐ 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

FORM FDA 1571 (03/19)- PREVIOUS EDITION OBSOLETE **Page 1 of 3**

PSC Publishing Services (301) 443-6740 EF

Previous Page | Next Page

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)(3))*
- ☐ 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
- 6. Protocol *(Continued)*
  - ☐ d. Institutional Review Board 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)(10))*
- ☐ 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)*. Continuation Page for #15

16. Name and Title of the person responsible for monitoring the conduct and progress of the clinical investigations

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

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

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

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

21. Address

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

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

City | State/Province/Region

Country | ZIP or Postal Code

22. Email Address

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

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 — Sign

28. Signature of Countersigner — 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.