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 To supplement the Form FDA 1571 instructions, we issued a draft guidance in May of 2015 entitled "Investigational New Drug Applications Prepared and Submitted by Sponsor Investigators" available at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





APPLICATION BUILDER	Submit Research IND			
Application / Submission				
Company and Contact	Application/Submission Details			
O Product				
Nonclinical Studies				
Clinical Studies	Submission Type Find detailed information about the submission types on the FDA 1571 Instructions.	*This submission contains the following Initial	¥	
O Upload Documents	7	and a	,	
Review & Submit	IND Number	*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	123456	Request IND Number	
	should be preceded using zeros (i.e., for IND 12345 enter 012345).			
	IND Serial 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.	0002		
	Select all that apply:	Emergency Research Exception From Informed Consent Requirements	i	
		Charge Request		
		Expanded Access Use 21 CFR 312.300		
		Please visit the Expanded Access page for more information about Individ		
		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	Add Application +		
	Drug Applications (21 CFR Part 314), Drug Waster Files (21 CFR Part 314 A20), and Bloigifcs License Applications (21 CFR Part 601) referred to in this application.	Application Type Application Investigational New Drug Application 333333	on Number Letter of Authorization Authoritzation Letter 1.docx	0





APPLICATION BUILDER	Submit Research IND	
Application / Submission		
Company and Contact	Ann Francis (Cubardador Baballa	
Product	Application/Submission Details	
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Clinical Studies	Submission Type Find detailed information about the submission types on the FDA 15/1 instructions.	*This submission contains the following Protocol Amendment:
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	assigned, leave the field blank. For IND numbers less than six digits, the IND number should be precised using zeros (i.e., for IND 12345 errier 012345).	
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		Expanded Access Use 21 CFR 312 300
		Rease visit the Expanded Access page for more information about Individual Ratients.
		Individual Patient, Non-Emergency 21 CFR 312:310 Individual Patient, Emergency 21 CFR 312:310(d) Treatment IND or Protocol 21 CFR 312:320
	Referenced Applications List Numbers of all Investigations New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Marker Files (21 CFR Part 334-A20), and Biologies Ucanias Applications (21 CFR Part 501) referred to in this application.	Add Application +
	Previous	Save and Close Save No











A	PPLICATION BUILDER	Submit Research IND					
0	Application / Submission						
0	Company and Contact	Company and Contact Details					
0	Product						
0	Nonclinical Studies	Individual Details Enter details for the following Individuals	+ *Sponsor				
0	Clinical Studies		+ Sponsor Representative				
0	Upload Documents		+ Countersigner				
	Review & Submit	Person Responsible for Conduct					
		and Progress of Clinical Investigations	Salutation Select an Option ▼	*Title			
		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)(vi)). For Sponsor-Investigator	*First Name	Mlddle Name			
		INDs, the Investigator has this responsibility.					
			*Last Name				
			This is the same person as entered in the previous question				
		Person Responsible for Review					
		and Evaluation of Safety of the	Salutation	*Title			
		Drug Information Provide the Name and Title of the person	Select an Option ▼				
		responsible under 21 CFR 312.32 for review and evaluation of information relevant to the	*First Name	Mlddle Name			
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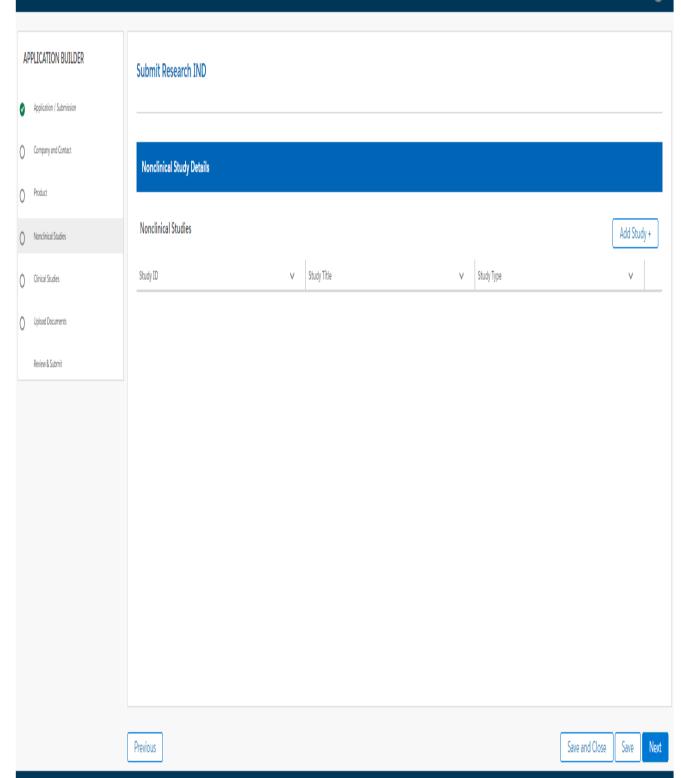
APPLICATION BUILDER	Submit Research IND
Application / Submission	
Company and Contact	Product Details
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Nonclinical Studies	Name of the Drug Name of Drug
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Upload Documents	(UNII) term and code for active substances (If applicable). + Add Another Name
Review & Submit	Combination Product Information
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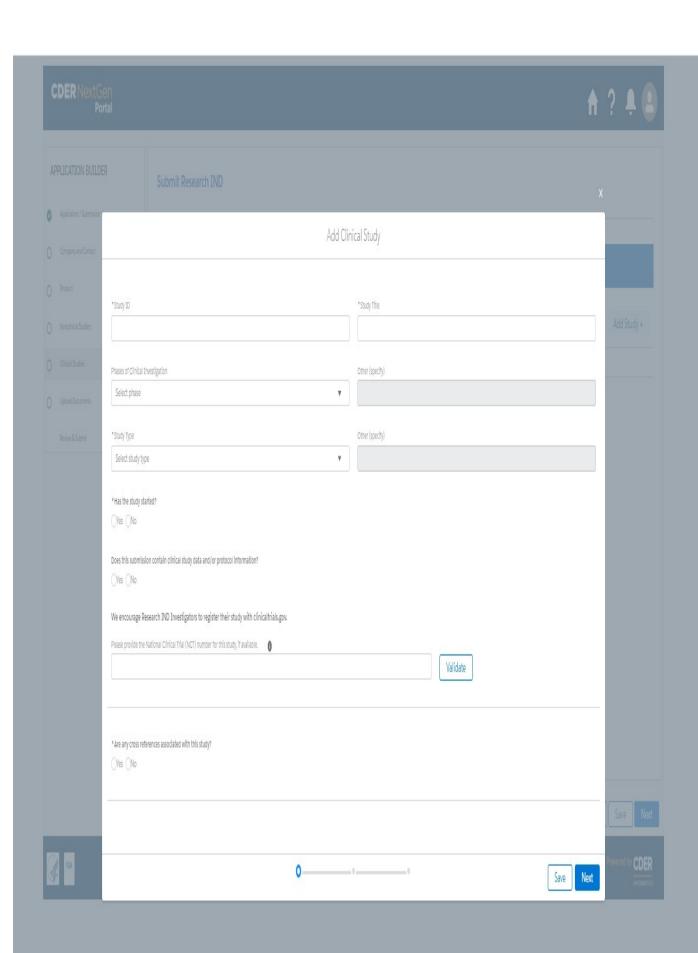






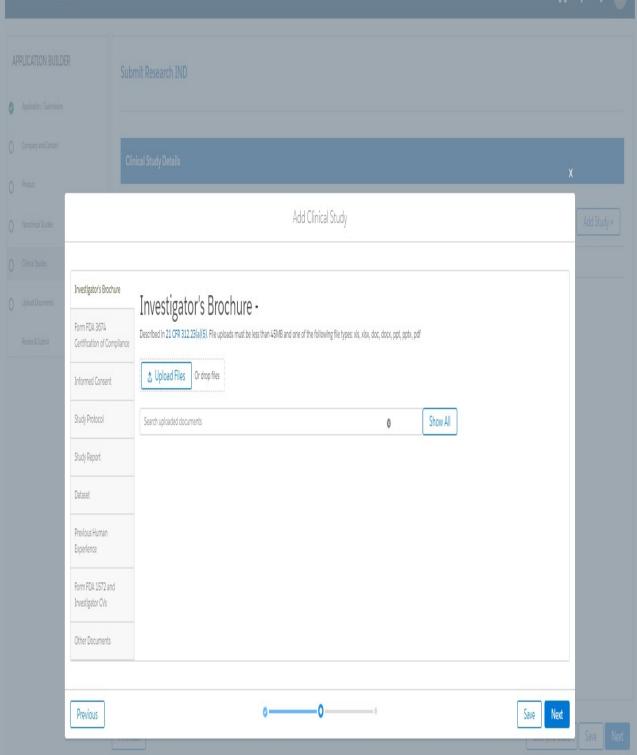
















APPLICATION BUILDER Submit Research IND Application / Submission Company and Contact **Upload Documents** O Product Upload contents of your IND Nonclinical Studies Document Type Clinical Studies O Upload Documents + Cover Letter 0 Review & Submit + Introductory Statement + General Investigational Plan + Chemistry, Manufacturing, and Control Data + Environmental Assessment or Claim for Exclusion + Nonclinical Literature Reference + Clinical Literature Reference + Additional Information



Previous



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AF	PPLICATION BUILDER	Submit Research IND						
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0	Company and Contact	Upload Documents						
0	Product	1						
0	Nonclinical Studies	Upload contents of your IN	D					
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	6. Protocol (21 CFR 312.23(a)(6)) a. Study protocol (21 CFR 312.23(a)	a)(6))		8. Pharmacology	and toxicology data (21 CFR 312.23(a)(8))
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	6. Protocol (21 CFR 312.23(a)(6))	- (-) (-))		(21 CFR 3	ental assessment or claim for exclusion 312.23(a)(7)(iv)(e))
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	b. Investigator data (21 CFR 312.2	3(a)(6)(iii)(b)) or		an experience (21 CFR 312.23(a)(9))
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	c. Facilities data (21 CFR 312.23(a Form FDA 1572)(6)(iii)(b)) or	r completed	=	ser Fee Cover Sheet (Form FDA 3792) s Certification of Compliance (Form FDA 3674)
15	. Is any part of the clinical study to be conducte	ed by a contr	act research	organization?	Yes No
	If Yes, will any sponsor obligations be transferr	ed to the cor	ntract researc	ch organization?	Yes
	If Yes, provide a statement containing the name identification of the clinical study, and a listing of				
16	. Name and Title of the person responsible for				<u> </u>
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17	. Name and Title of the person responsible for	review and e	evaluation of	information relevant to	the safety of the drug
7	agree not to begin clinical investigation	e until 30	days after	EDA's receipt of the	IND unless I receive earlier notification
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