



**U.S. FOOD & DRUG
ADMINISTRATION**

CDER NextGen Portal Research Investigational New Drug (IND) Application Builder

DIA Conference – February 2022

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Office of Business Informatics (OBI)
Center for Drug Evaluation and Research (CDER)
US FDA



FDA Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Agenda

What is CDER NextGen Portal?

Before and After NextGen Portal

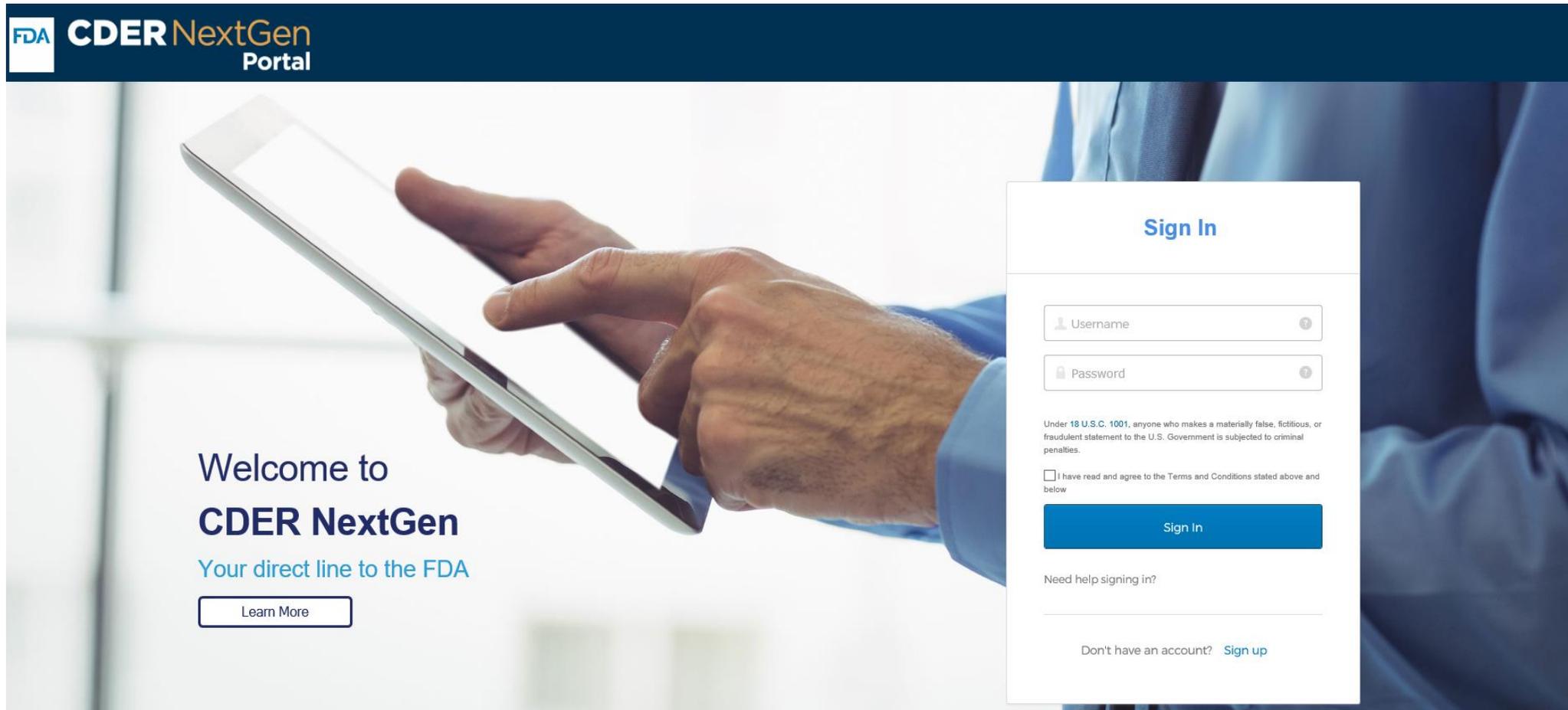
Research IND Application Builder

Progress, Impact & Metrics



What is CDER NextGen Portal?

The CDER NextGen Portal is an **integrated informatics solution** based on common industry standards for collaboration. The portal enables sponsors to submit Drug Shortages Notifications, non eCTD submissions for Research INDs, Type III DMFs, EUA, and other exempted human drug applications. This **collaboration capability continues to reduce regulatory overhead** for sponsors, academia, research institutes, and small businesses.



FDA CDER NextGen Portal

Welcome to
CDER NextGen
Your direct line to the FDA

[Learn More](#)

Sign In

Username

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties.

I have read and agree to the Terms and Conditions stated above and below

Sign In

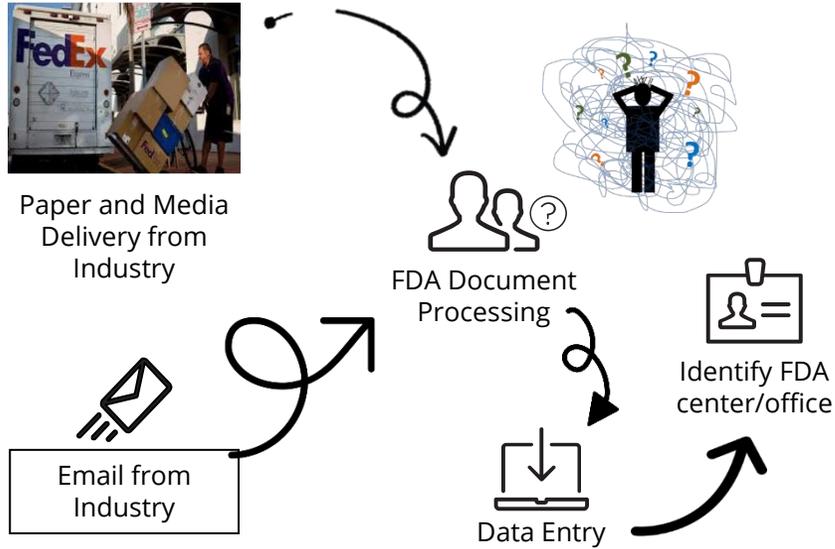
Need help signing in?

Don't have an account? [Sign up](#)

Before and After CDER NextGen Portal

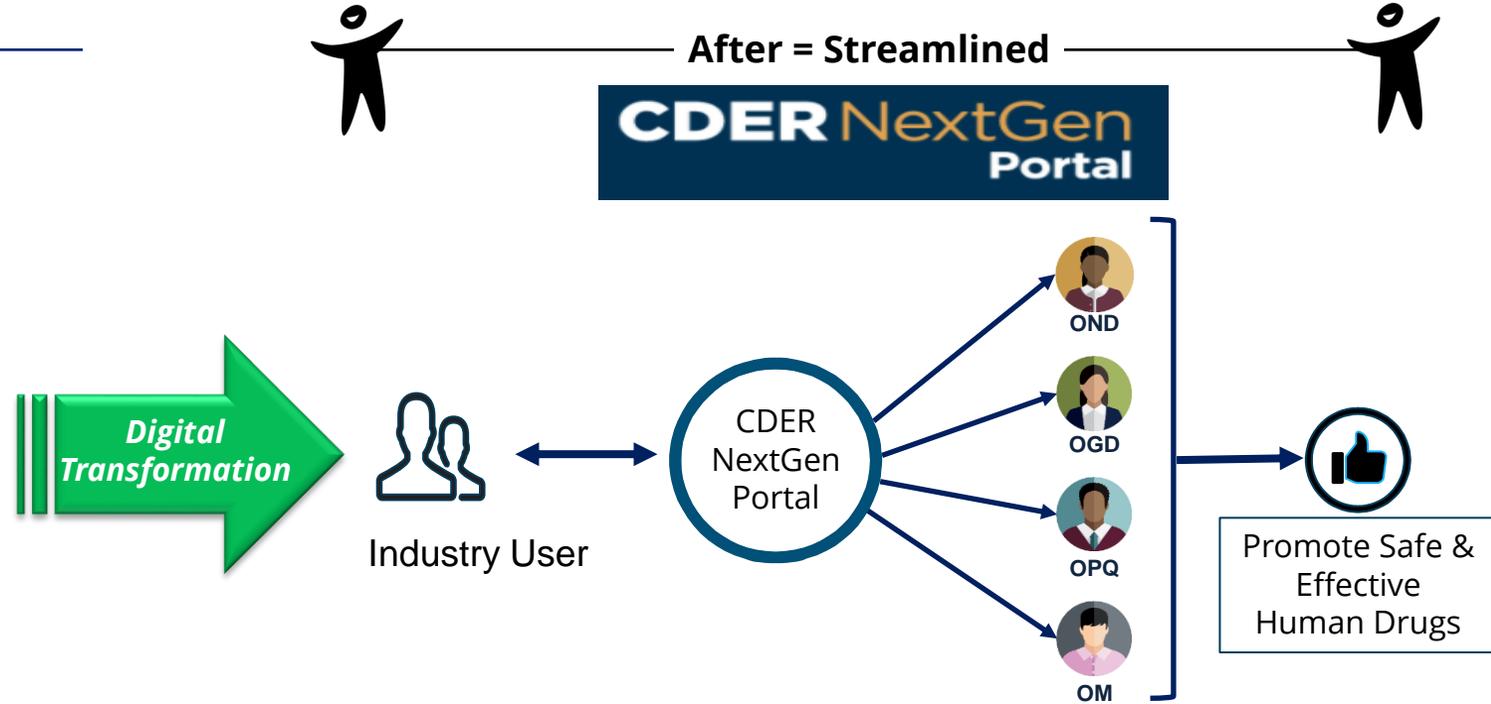
Digital transformation in action to promote safe and effective human drug review and approval

Before = Manually Intensive



- ⚠ Paper and Media processing
- ⚠ Manual intensive and Inefficient
- ⚠ Time and resource consuming

After = Streamlined



- ✓ Online submission contains clean, validated and integrated data
- ✓ Optimized processes and maximize technology to improve efficiency
- ✓ End to End digital collaboration between FDA and Stakeholders
- ✓ Increased document upload file size to 100MB

CDER NextGen Portal: One stop shop for the purpose of Submission, Collaboration and Reporting.

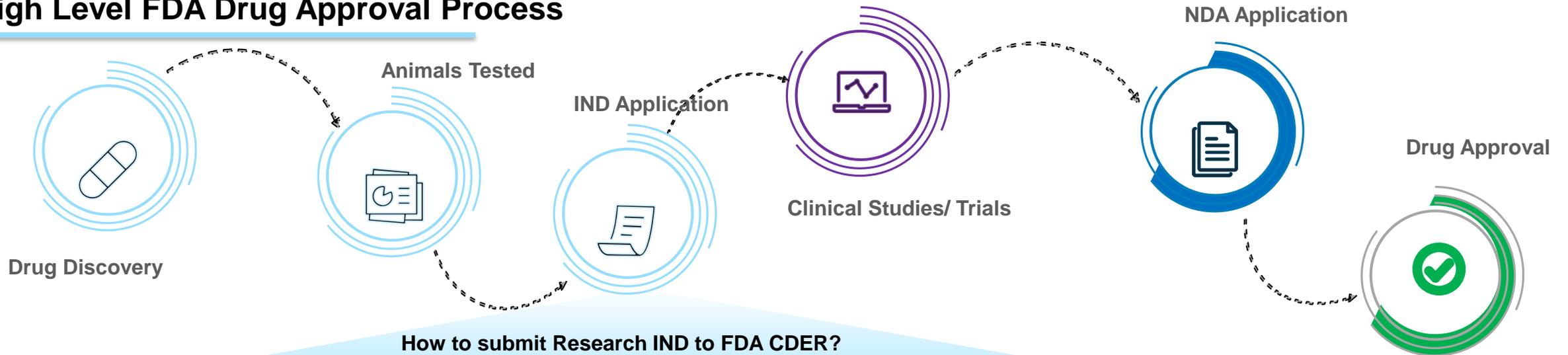


	Regulatory Submissions	Collaboration	Reporting
Drug Shortages Notifications	✓		✓
Research IND Application Builder	✓	✓	
CARES Volume Act Reporting	✓		
Alternate Submissions (Non eCTD Type III DMFs, EUA and others)	✓		
Orphan Drug	✓		
Drug Development Tools		✓	
Controlled Correspondence		✓	
Pre-ANDA Meeting Request		✓	
Pre-Assignment Number		✓	
Waiver Requests	✓		
Company Affiliation			✓
Standards Recognition			✓
Extensions Requests			✓
Manufacturing Capacity			✓
Critical Care Drug Monitoring Portal			✓

Research Investigational New Drug Application (IND) – What You Need To Know

“A research IND (also called a non-commercial IND) is one for which the sponsor (generally 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 and may result in publications in peer-reviewed journals.”

High Level FDA Drug Approval Process

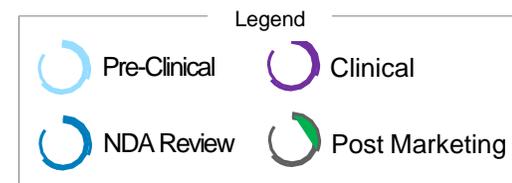


1 Paper Submissions

Title 21, Code of Federal Regulations, Part 312 allows initial IND submission and each subsequent submission to be sent by mail

2 FDA CDER NextGen Portal

Sponsors of Research INDs can submit an original IND, subsequent amendments, and pre-submissions online via the **CDER NextGen Portal**.



What are the Real-time interactions?



SPONSORS



HARVARD UNIVERSITY



Mizzou University of Missouri



FRED HUTCH CURES START HERE™



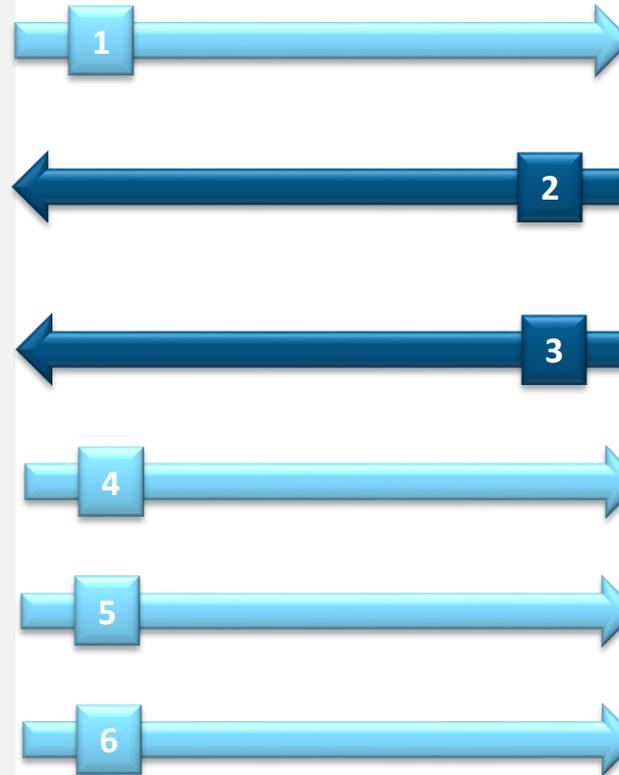
ARCADIA MEDICAL



The UNIVERSITY of OKLAHOMA



Austin Neuromuscular Center Committed to Research Advancement



Initial Research IND Submission



Acknowledgement Letter



Information Request

Response to Information Request

Protocol Amendment

Clinical Study Data

Research IND Application Builder User Story

Adam Kohl, from NIH wants to submit a Research IND to the FDA but wants to quickly submit electronically rather than mailing the application. Adam has a Pre-assignment Number for the Research IND and wishes to make a submission to FDA CDER. To streamline the process, Adam follows the steps within the CDER NextGen Portal.



Adam has the following Information:

Application / Submission Details

- **IND Number:** IND24840
- **IND Serial Number:** 0000

Company and Contact Details

- **Company Name:** NIH
- **Company Address:** Bethesda, MD
- **Person Responsible:** Adam Kohl

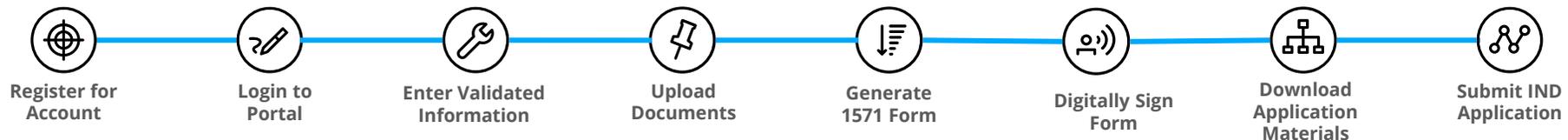
Product Details

- **Drug Name:** AIK12
- **UNII:** 362O9ITL9D
- **Indication of Use:** SCTID 404684003

Study Details

- **NCT Number:** 000032344

Make a Research IND Submission in **less than 10 Steps**



How can I Create an Account ?

CDER NextGen Portal registration is a simple process requiring Contact Information, Organization Information via a DUNS number, followed by email validation.

CDER NextGen Portal

Welcome to the CDER NextGen Portal!

*** Contact Information**

* First Name: John Middle Name: Last Name: Doe

* Email: John.Doe@company.com * Confirm Email: John.Doe@company.com

* Country: United States

* Country Code: +1 * Phone Number: 1235551234 Extension:

*** Organization Information**

Select your organization. To search for your organization, please enter a minimum of three characters into the organization text field prior to clicking search (i.e. "abc" for abc pharmaceuticals). If your organization is not found, please manually enter an organization to continue with the registration process.

Organization Name: DUNS: Search

Terms and Conditions

Under 18 U.S.C 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Under section 11. 100, sub-part C, paragraphs (a), (b), (c) and (2) of Title 21 of the Code of Federal regulations, accepting the terms and conditions will require the verification of a person's identity and will be considered legally binding upon the verification.

I have read and agree to the Terms and Conditions stated above.

Cancel Create Account

Required Contact Information

- Full Name
- Email
- Phone Number

Required Organization Information

- Organization Name
- DUNS Number

Security Features

- Multifactor Authentication 
- Password Protocols 
- Email Verification 

Research IND Application Builder – Landing Page

The screenshot shows the CDER NextGen Portal landing page. At the top left is the logo "CDER NextGen Portal". At the top right are navigation icons for home, help, and a "Log Out" button. The main header area features a blue-tinted image of a hand pointing at a tablet displaying a document with a blue "Rx" symbol, and the text "Welcome, Adam!". Below this are two columns of content. The left column has a blue header "ALL" and a section titled "Research IND Application Builder" with a paragraph of text. The right column has a blue header "ANNOUNCEMENTS" and a grey box containing the text "There are currently no announcements for the CDER NextGen Portal."

CDER NextGen Portal Home ? Log Out

Welcome, Adam!

ALL

Research IND Application Builder

Research IND Application Builder program for a more comprehensive application to investigate if a drug is reasonably safe. Research IND applications are strictly for research and may result in publications in peer-reviewed journals. The Research IND Application Builder is currently accepting Pre-Submissions, General Correspondences, Initial Submissions, and Protocol Amendment submissions. Additional submission types to follow.

ANNOUNCEMENTS

There are currently no announcements for the CDER NextGen Portal.

Research IND Application Builder – Landing Page

Search
Reference information such as IND Number and IND Serial Number

Submission Tile
indicates Submission Event ID, Submission Status, Submission Type, Serial Number, and Last Modified Date

Filter
Filter upon Draft and Submitted Submission Statuses

The screenshot shows the CDER NextGen Portal interface. At the top, there is a dark blue header with the CDER NextGen Portal logo on the left, a home icon, a help icon, and a 'Log Out' button on the right. Below the header is a blue banner with the text 'IND Submissions' and a '+ New Submission' button. Underneath the banner is a search bar with the placeholder text 'Search Submissions', a clear button (X), and a 'Search' button. Below the search bar is a submission tile for 'IND 123456' with the status 'Draft'. The tile includes the following details: Sponsor, Submission Type: Initial, Serial Number: 0000, and Last Modified: 08/18/2021, 01:04 PM. At the bottom of the tile is a grey bar with a pencil icon and the text 'Unsubmitted Draft'. To the right of the search bar is a filter dropdown menu with a downward arrow. The page number '1 of 1' is centered below the submission tile. At the bottom of the page is a dark blue footer with the FDA logo on the left, navigation links for 'FDA Home', 'Browser Requirements', 'Contact Tech Support', and 'FAQs', and 'Follow FDA', 'FDA Voice Blog', and 'Privacy' in the center. On the right side of the footer, it says 'Powered by CDER INFORMATICS'.

Research IND Application Builder – Landing Page

CDER NextGen Portal

IND Submissions

Search Submissions [x] [Search]

IND 345654
Draft
Sponsor: [redacted]
Submission Type: Initial
Serial Number: 0000
Last Modified: 05/14/2021, 10:56 AM
Unsubmitted Draft

IND 209384
Submitted
Sponsor: [redacted]
Submission Type: Initial
Serial Number: 0000
Last Modified: 04/20/2021, 03:27 PM

IND 563453
Submitted
Sponsor: Sponsor Name
Submission Type: Initial
Serial Number: 0000
Last Modified: 04/20/2021, 10:33 AM

IND 2342
Submitted
Sponsor: [redacted]
Submission Type: Initial
Serial Number: 0000
Last Modified: 03/03/2021, 09:47 AM

IND 123543
Submitted
Sponsor: Joe Allen
Submission Type: Initial
Serial Number: 0000
Last Modified: 01/14/2021, 04:22 PM

IND 234565
Submitted
Sponsor: Joe Allen
Submission Type: Initial
Serial Number: 0000
Last Modified: 01/13/2021, 04:01 PM

IND 567890
Submitted
Sponsor: [redacted]
Submission Type: Initial
Serial Number: 0000
Last Modified: 12/17/2020, 09:27 PM

New Submission

*Type of Submission

Pre-Submission

Initial

Protocol Amendment

Cancel Continue

- Submission Types:**
- Pre-Submission
 - Initial
 - Protocol Amendment

Research IND Application Builder – Application Details

CDER NextGen Portal

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
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
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
 Intermediate Size Patient Population 21 CFR 312.315
 Individual Patient, Emergency 21 CFR 312.310(d)
 Treatment IND or Protocol 21 CFR 312.320

Referenced Applications
Add Application +
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.
Save and Close Save Next

Application Builder
A convenient and logical way to complete your submissions

Need Help?
The [Help Center](#) is available to answer all your Research IND related questions.

Help Center
Easily accessible support when making your submission

Navigation Pane
Transition between pages easily with buttons on each page

Research IND Application Builder – Contact Details

CDER NextGen Portal

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)(vi)). For Sponsor-Investigator INDs, the investigator has this responsibility.

Salutation: Select an Option | * Title: [Text Field]
* First Name: [Text Field] | Middle Name: [Text Field]
* Last Name: [Text Field]

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: [Text Field]
* First Name: [Text Field] | Middle Name: [Text Field]
* Last Name: [Text Field]

APPLICATION BUILDER

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

Guidance Instruction
Easily find instructions and directions with links directly to guidance

Minimized Data Entry
Areas within user interface allow to copy already entered data to avoid duplicate entry

Research IND Application Builder – Product Details

APPLICATION BUILDER

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

Name of Drug

Code ▼ 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 +

SNOMED CT Directory

Opportunity to copy information directly from SNOMED CT hyperlink

Research IND Application Builder – Non-Clinical and Clinical Details

CDER NextGen Portal

Research IND

Clinical Study Details

Clinical Studies

Study ID ↓ Study Title ↓ Study Type Study Phase

Add Study +

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.

Enter Numbers Only

* Are any cross references associated with this study?
 Yes No

Multiple Studies
Consolidated view of all studies within IND in one place divided between clinical and non-clinical

Validation and Retrieval from ClinicalTrials.gov
Enter NCT number for validation and retrieval of key details directly into your form to minimize data entry

- APPLICATION BUILDER**
- Application / Submission
 - Company and Contact
 - Product
 - Nonclinical Studies
 - Clinical Studies

Research IND Application Builder – Document Upload

APPLICATION BUILDER

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

Research IND

Upload Documents

Upload contents of your IND

**Please upload unique file names and refrain from uploading files with same names.*

	Document Type
<input type="button" value="+"/>	Cover Letter ⓘ
<input type="button" value="+"/>	Introductory Statement
<input type="button" value="+"/>	General Investigational Plan
<input type="button" value="+"/>	Chemistry, Manufacturing, and Control Data
<input type="button" value="+"/>	Environmental Assessment or Claim for Exclusion
<input type="button" value="+"/>	Nonclinical Literature Reference
<input type="button" value="+"/>	Clinical Literature Reference
<input type="button" value="+"/>	Additional Information

Document Organizing

Organize your documents into respective document types and system will create folder structure in eCTD like folder structure for download

Research IND Application Builder – Review and Submit with Document Generation

Research IND Delete Save and Close Save Submit

Review & Submit

Application/Submission Details

* Submission Type: Initial | * IND Number: 234324 | * 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
- Intermediate Size Patient Population 21 CFR 312.315
- Individual Patient, Emergency 21 CFR 312.310(d)
- Treatment IND or Protocol 21 CFR 312.320

Referenced Applications Add Application +

Previous Generate Form FDA 1571 View Signed Form FDA 1571 Download Submission Submit

FDA Home | Browser Requirements | Contact Tech Support | FAQs
Follow FDA | FDA Voice Blog | Privacy

Powered by CDER INFORMATICS

Generate Form 1571
Let the system populate the regulatory required form 1571 with the details entered ready for your signature and submission

Zip File Download
Download all documents along with table of content and populated form 1571 for your records in a zip file eCTD like structure

Research IND Application Builder – Digitally Sign 1571 Form

Digital Signature

No need to print your form! Digitally sign after review and lock form ready for submission

The screenshot displays the digital signature interface for Form FDA 1571. At the top, there are fields for Address 1, Address 2, City, State/Province/Region, Country (United States of America), and ZIP or Postal Code. A warning box states: "WARNING: A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001)." Below these fields are two signature sections: "27. Signature of Sponsor or Sponsor's Authorized Representative" and "28. Signature of Countersigner". A blue box with a "SIGN HERE" arrow points to the signature field for the sponsor. A "Sign" button is visible next to each signature field.

FORM FDA 1571 (03/19)- PREVIOUS EDITION OBSOLETE Page 2 of 6

The digital signature tool is overlaid on the form. It features the "S-Sign" logo and a "Clear" button. The signature "Adam Kohl" is displayed in a large, elegant font within a white box. Below the signature box, there is a "Text-To-Signature" option with a "Type Name" input field. A prominent blue button at the bottom of the tool reads "Add Signature and Submit".

In Summary : Research IND Application Builder Via CDER NextGen Portal



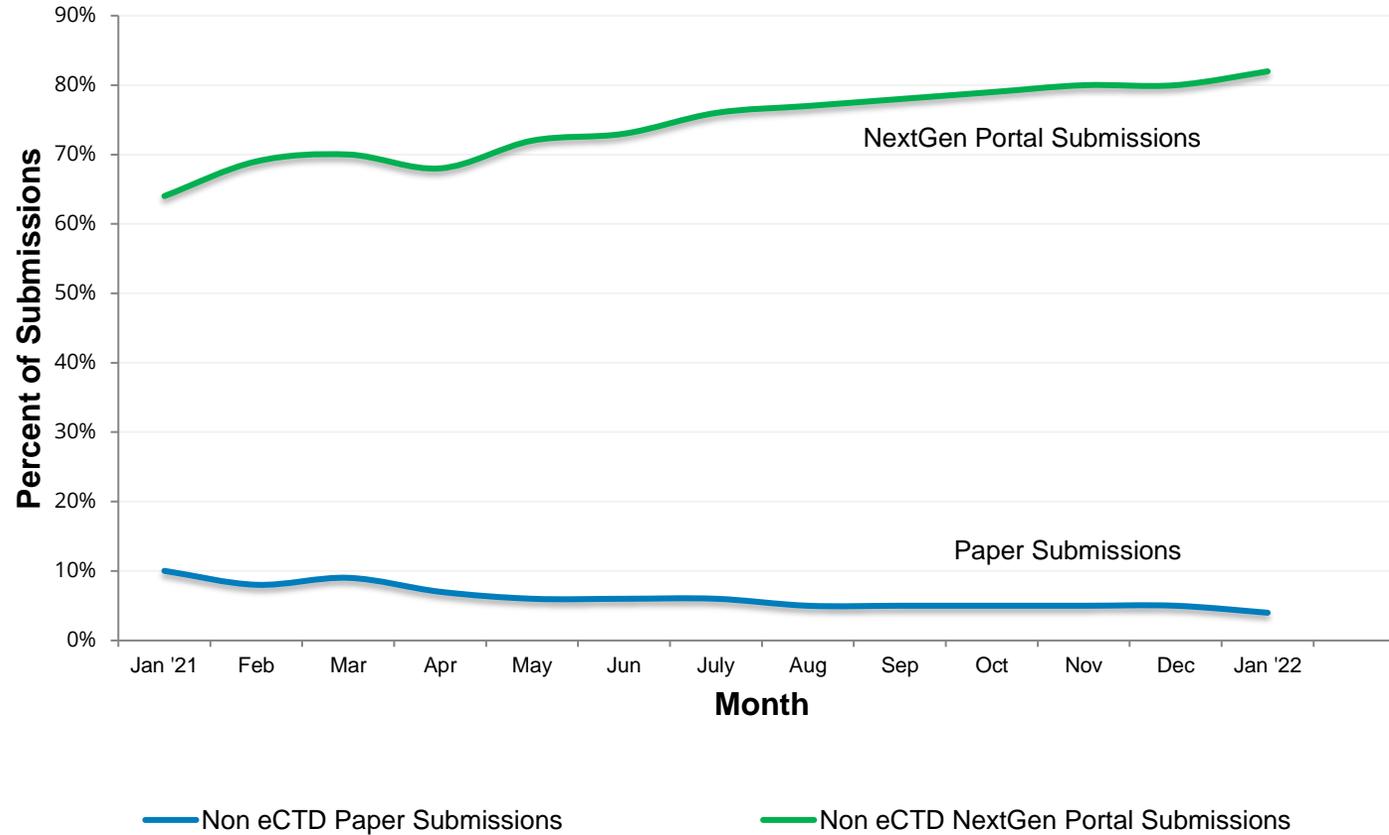
Users



Digital transformation in action to promote safe and effective human drug review and approval

Progress, Impact & Metrics

Non-eCTD Research IND Submissions



60% of paper submissions reduction since Portal became available

Need Support ?

The following support materials can help you get started on leveraging the CDER NextGen Portal

Research IND Application Builder User Guides

<https://cdernextgenportal.fda.gov/s/indhelphcenterinfo>

User Registration Guides

https://edm.fda.gov/customThemeStatic/themes/customTheme/docs/CDERDirectNextGen_Reference_Guide_MFA.pdf

General FAQs

https://edm.fda.gov/customThemeStatic/themes/customTheme/docs/CDERDirectNextGen_Reference_Guide_MFA.pdf

The Paperwork Reduction Act (PRA)

<https://pra.digital.gov/>

Benefits of CDER NextGen

<https://www.fda.gov/media/136301/download>



Contact the Platform Support Team at edmsupport@fda.hhs.gov

Acknowledgements



Thank You

To NIH and other sponsors for your collaboration and making the Research IND Application Builder successful !