



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

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

Regulatory Education for Industry (REdI) Annual Conference – June 2022

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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 Investigational New Drug (RIND)
Application Builder

Progress



What is CDER NextGen Portal ?

The CDER NextGen Portal is an **integrated portal solution** based on common industry standards for Submission, Collaboration and Reporting.



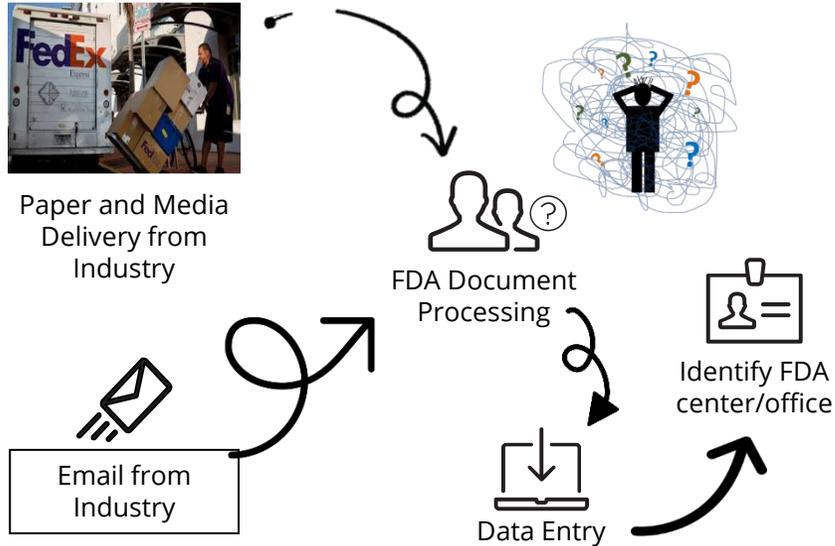
Don't have an account? [Sign up](#)

CDER NextGen Portal Support : edmsupport@fda.hhs.gov

Before and After CDER NextGen Portal

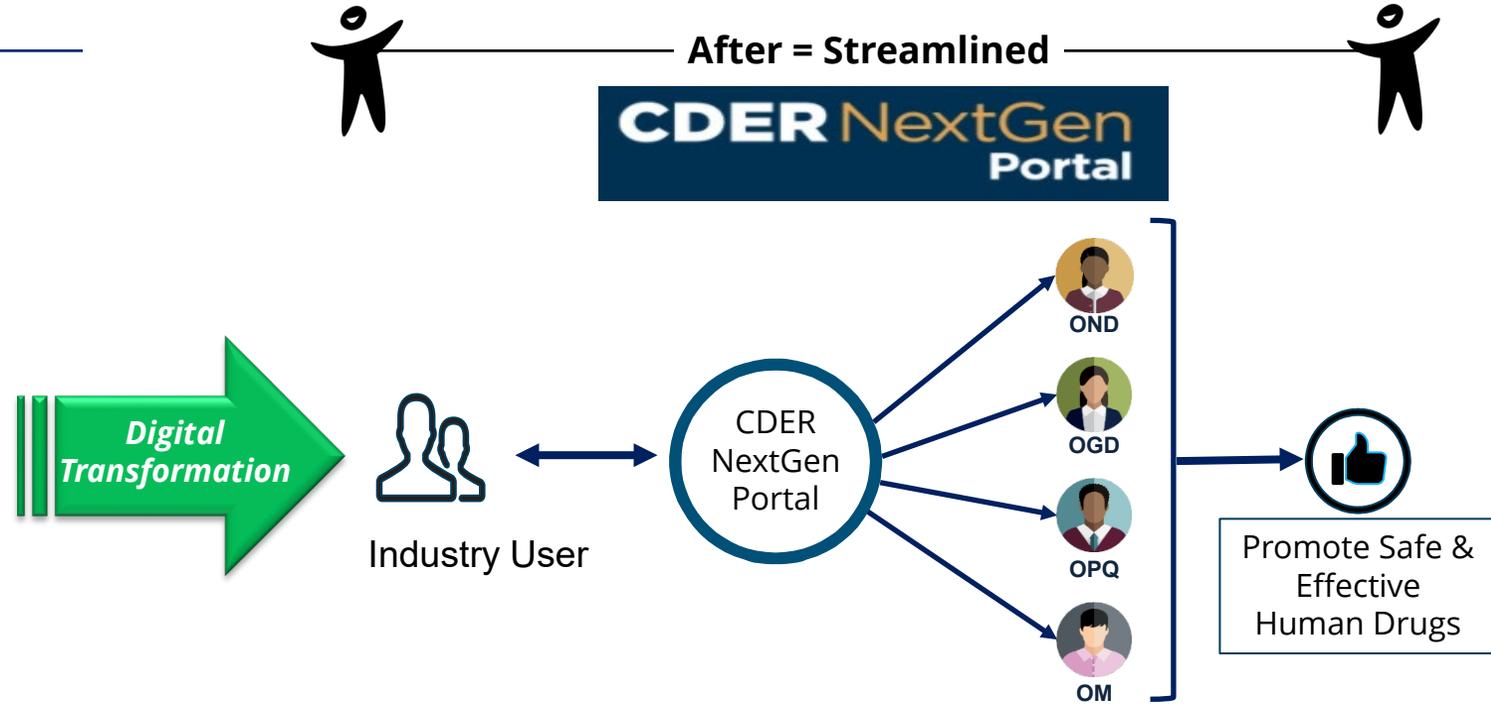
Digital transformation in action to promote safe and effective human drug review and approval

Before = Manually Intensive



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

After = Streamlined



- ✅ Submission contains clean, complete and validated data
- ✅ Maximize technology and process to improve efficiency
- ✅ Improve 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

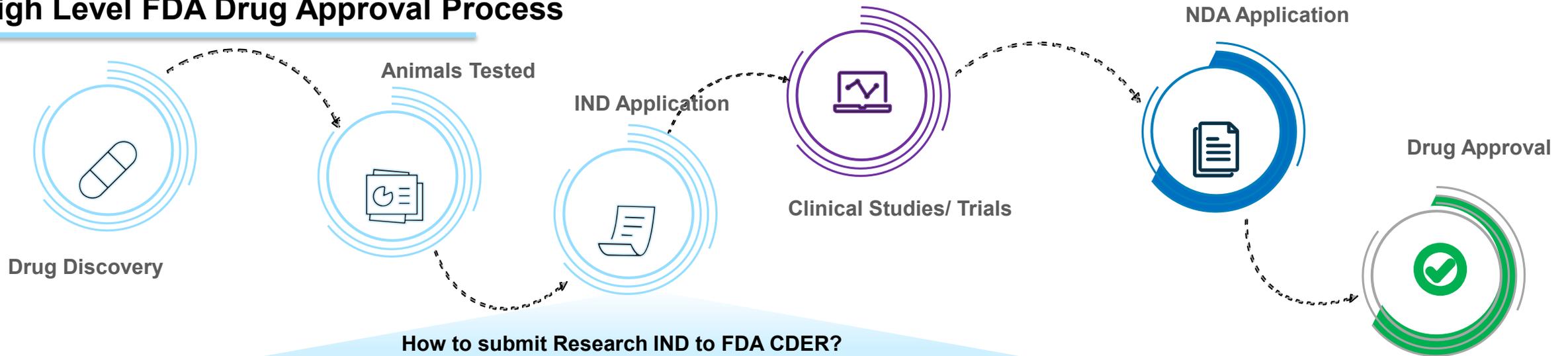


Portal Application Use Case	Regulatory Submissions	Collaboration	Reporting
Drug Shortages Notifications	✓		✓
Research IND Application Builder	✓	✓	
CARES Volume Act Reporting	✓		
Alternate Submissions (Non eCTD Type III DMFs, EUA and others)	✓		
Orphan Drug	✓		
Drug Development Tools		✓	
Controlled Correspondence		✓	
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 (RIND) Application – 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

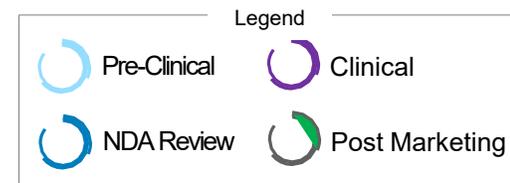


1 Paper Submissions

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™



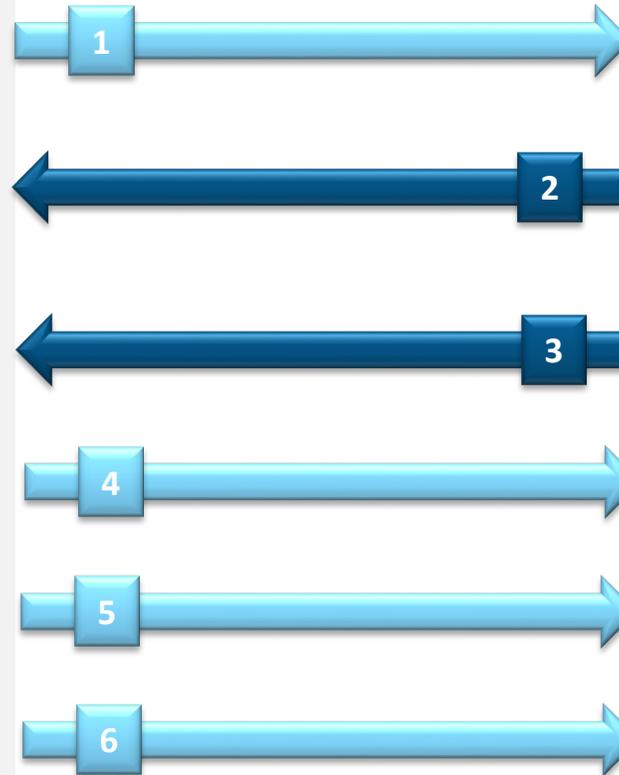
ARCADIA MEDICAL



The UNIVERSITY of OKLAHOMA



Austin Neuromuscular Center Committed to Research Advancement



Initial Research IND Submission

30 Days Review

Acknowledgement Letter

IND Review

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.

RESEARCH



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

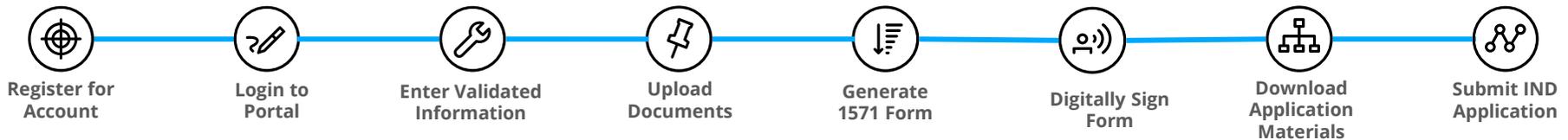
Product Details

- **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**



RIND Application Builder – Landing Page

The screenshot shows the CDER NextGen Portal landing page. At the top left is the CDER NextGen Portal logo. At the top right are navigation icons for home, help, and a Log Out button. The main header features a blue-tinted image of a hand pointing at a tablet displaying a document with a blue 'Rx' symbol, with the text 'Welcome, Adam!' overlaid. Below the header, there are two main content areas. The left area is titled 'ALL' and contains a section for 'Research IND Application Builder' with a descriptive paragraph. The right area is titled 'ANNOUNCEMENTS' and contains a message stating that there are currently no announcements for the 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.

RIND Application Builder – Landing Page

CDER NextGen Portal

IND Submissions

Search Submissions [Search]

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

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

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

IND 2342
Submitted
Sponsor: [Name]
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: [Name]
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

RIND Application Builder – Application Details

APPLICATION BUILDER

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

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

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

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

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 +

Save and Close Save Next

Navigation Pane

Transition between pages easily with buttons on each page

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

RIND 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. **Validate**

Enter Numbers Only

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

Save **Next**

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

Validation and Retrieval from ClinicalTrial.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

RIND 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

RIND 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

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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

RIND 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 image shows a screenshot of the FDA 1571 form with a digital signature overlay. The form includes fields for Address 2, City, State/Province/Region, Country, 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)." There are two signature fields: "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 first signature field. Below the form, a digital signature interface is shown with the "S-Sign" logo, a "Clear" button, and a signature box containing the name "Adam Kohl". Below the signature box is a "Text-To-Signature" section with a "Type Name" input field and a blue "Add Signature and Submit" button.

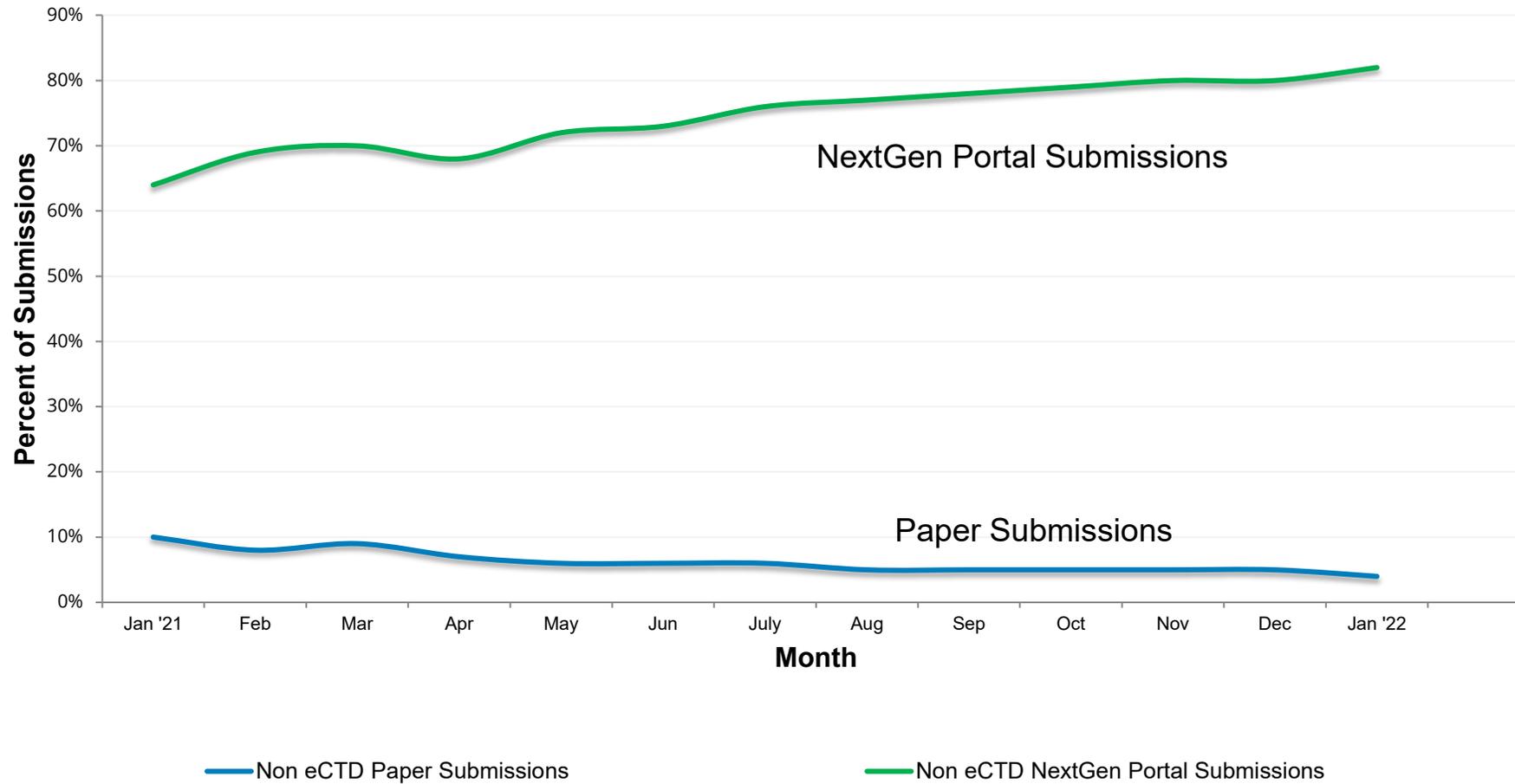
In Summary : Research IND Application Builder Via CDER NextGen Portal



Users



Research IND Submissions Via NextGen Portal



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 !