



**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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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?

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Before and After NextGen Portal

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Research Investigational New Drug (RIND) Application  
Builder

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# What is CDER NextGen Portal ?

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



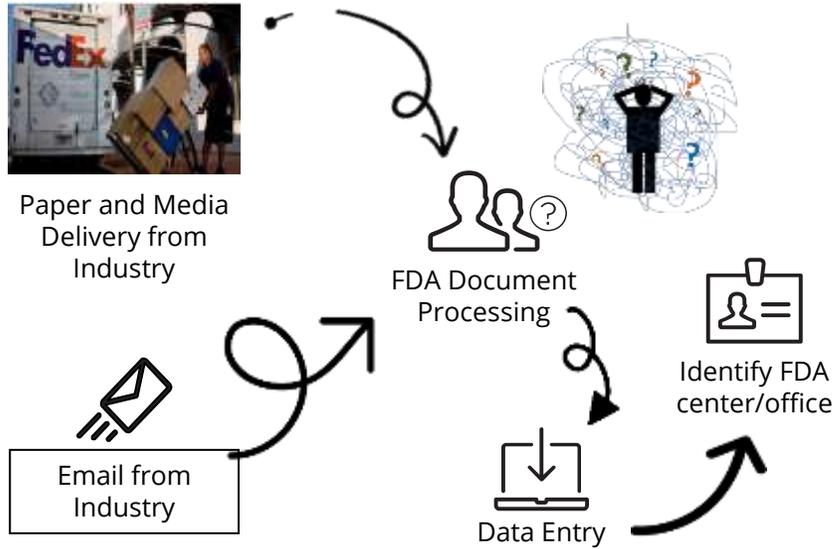
Don't have an account? [Sign up](#)

CDER NextGen Portal Support : [edmsupport@fda.hhs.gov](mailto:edmsupport@fda.hhs.gov)

# Before and After CDER NextGen Portal

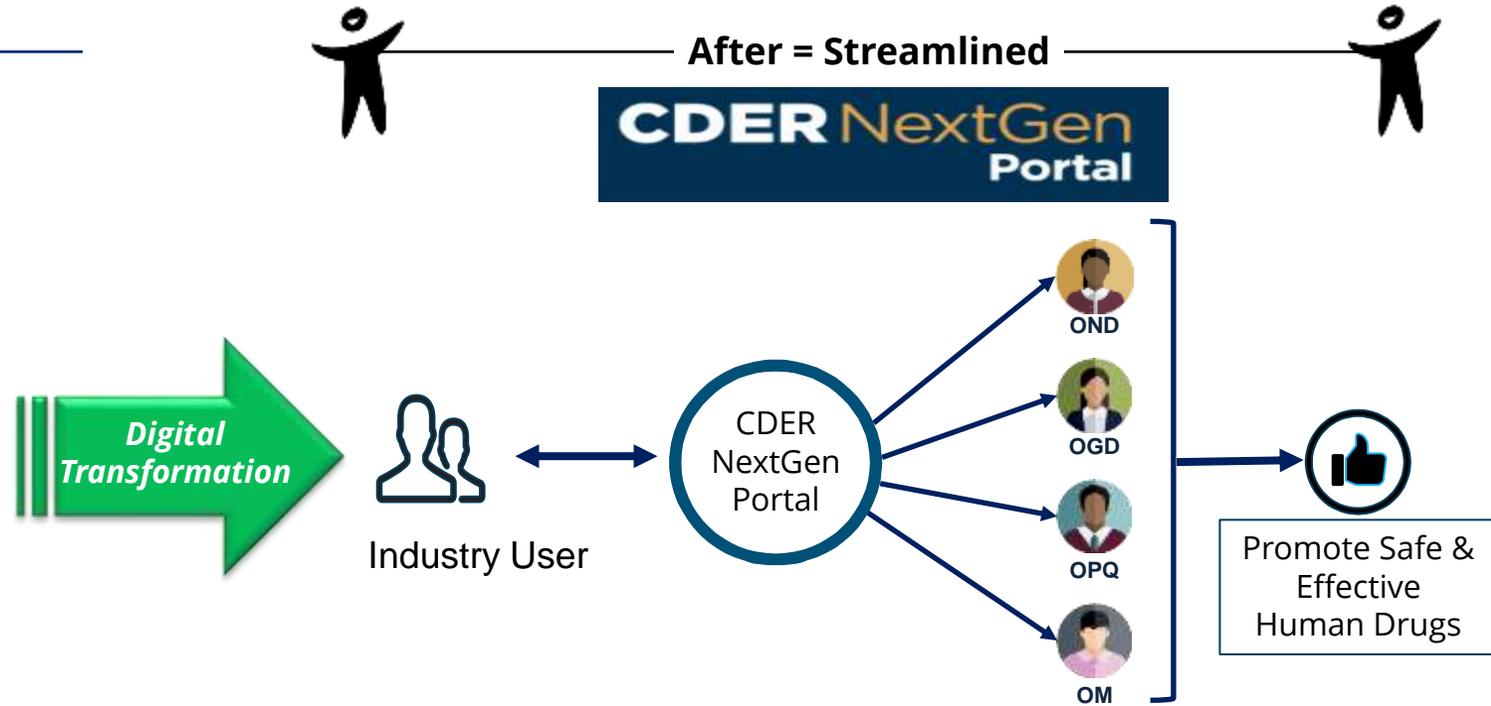
Digital transformation in action to promote safe and effective human drug review and approval

**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



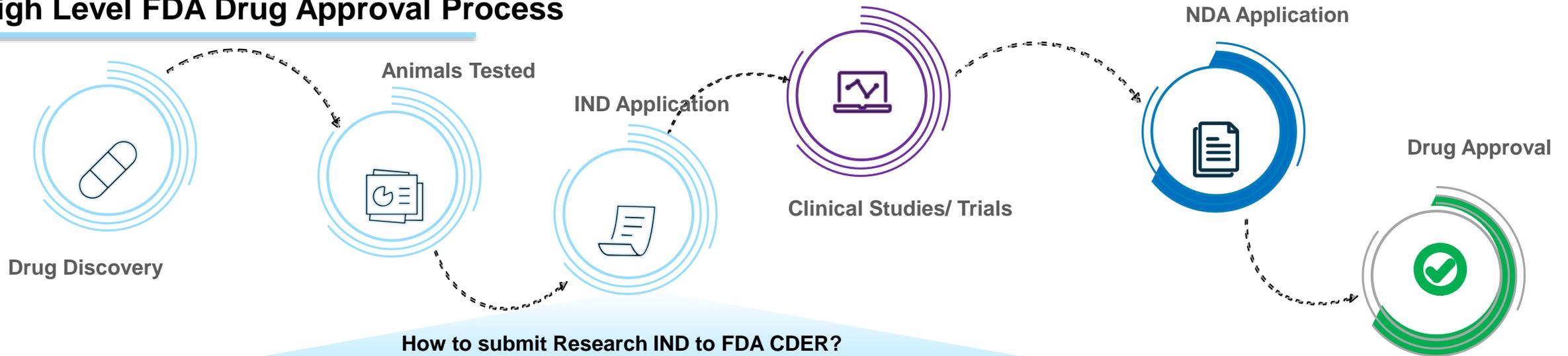
## Portal Application Use Case

	Regulatory Submissions	Collaboration	Reporting
Drug Shortages Notifications	✓		✓
<b>Research IND Application Builder</b>	✓	✓	
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

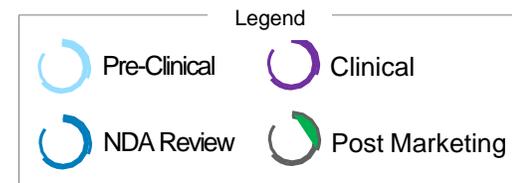


### 1 Paper Submissions

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™



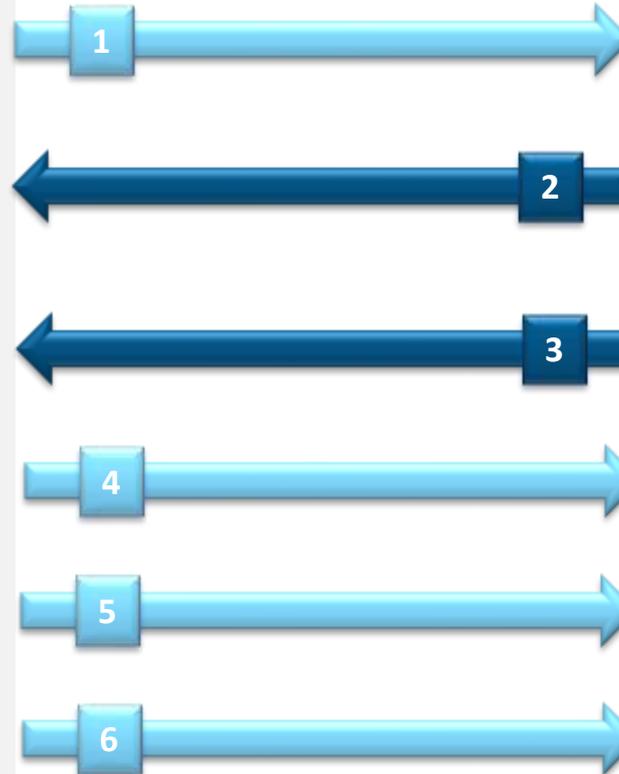
ARCADIA MEDICAL



The UNIVERSITY of OKLAHOMA



Austin Neuromuscular Center



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.



## 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

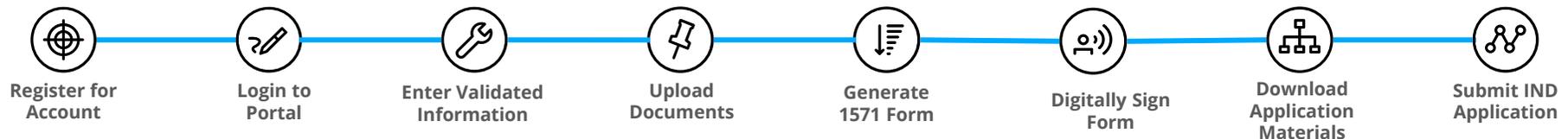
### Product Details

- **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 logo "CDER NextGen Portal". At the top right are navigation icons for home, help, and a "Log Out" button. The main banner features a background image of hands pointing at a tablet and the text "Welcome, Adam!". Below the banner are two columns of content. The left column is titled "ALL" and contains a link for "Research IND Application Builder" with a brief description of the program. The right column is titled "ANNOUNCEMENTS" and contains a message stating there are currently no announcements.

**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

The screenshot displays the CDER NextGen Portal interface. At the top, the logo 'CDER NextGen Portal' is visible on the left, and navigation icons (home, help, notifications, user) are on the right. The main heading is 'IND Submissions'. Below this is a search bar. A modal window titled 'New Submission' is centered, featuring a radio button selection for 'Type of Submission' with three options: 'Pre-Submission', 'Initial', and 'Protocol Amendment'. The modal has 'Cancel' and 'Continue' buttons at the bottom. The background shows a grid of submission cards, each with a status (Draft or Submitted), sponsor information, submission type, serial number, and last modified date.

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

# RIND 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.

**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 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.

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.

Buttons: Add 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 – 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

#### Name of Drug

Code

+ 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 +**

**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*

**Add Clinical Study**

\*Study ID  
\*Study Title

Phase 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 Number Only

Validate

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

Save Next

# 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
+	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

### 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
- 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 Add Application +

**Generate Form 1571**

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

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

**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, city, state, country, and ZIP code. A warning message states: "WARNING : A willfully false statement is a criminal offense (U.S.C. Title 18, Sec. 1001)." There are two "Sign" buttons. A blue box highlights the "SIGN HERE" area. The digital signature overlay features the "S-Sign" logo, a "Clear" button, a signature field containing "Adam Kohl", a "Text-To-Signature" option, a "Type Name" input field, and a blue "Add Signature and Submit" button.

# **In Summary : To submit Research IND Application**

- 1. Create CDER NextGen Portal Account**
- 2. Select RIND Builder**
- 3. Digitally sign & Submit to the FDA**

# 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/indhelppcenterinfo>

## User Registration Guides

[https://edm.fda.gov/customThemeStatic/themes/customTheme/docs/CDERDirectNextGen\\_Reference\\_Guide\\_MFA.pdf](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](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](mailto:edmsupport@fda.hhs.gov)

## Acknowledgements



# Thank You

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