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

DIA Conference – February 2022

Seyoum Senay
Supervisory Operations Research
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?

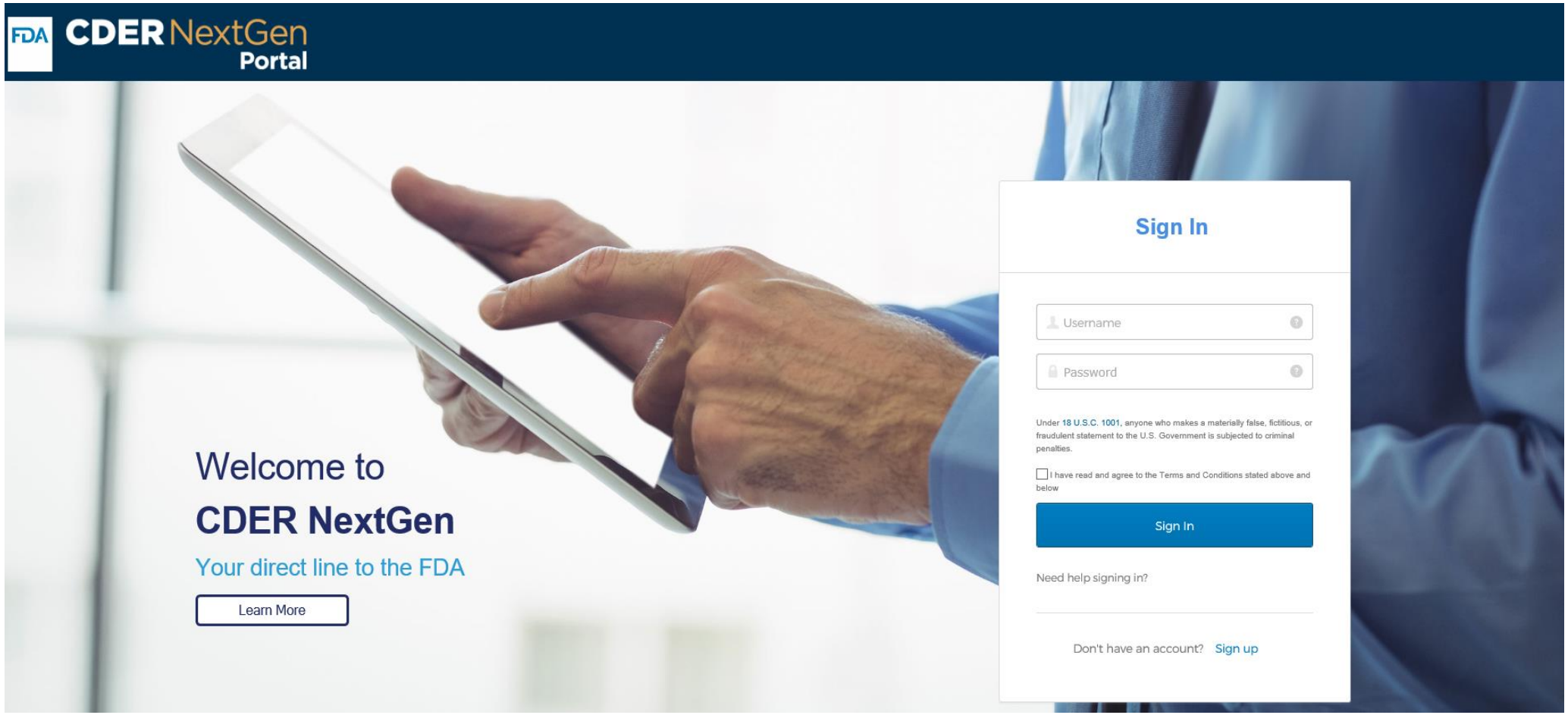
Before and After NextGen Portal

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.



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 Delivery from Industry

FDA Document Processing

Identify FDA center/office

Email from Industry

Data Entry

Digital Transformation

After = Streamlined

CDER NextGen Portal

Industry User

CDER NextGen Portal

OND

OGD

OPQ

OM

Promote Safe & Effective Human Drugs

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

- 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

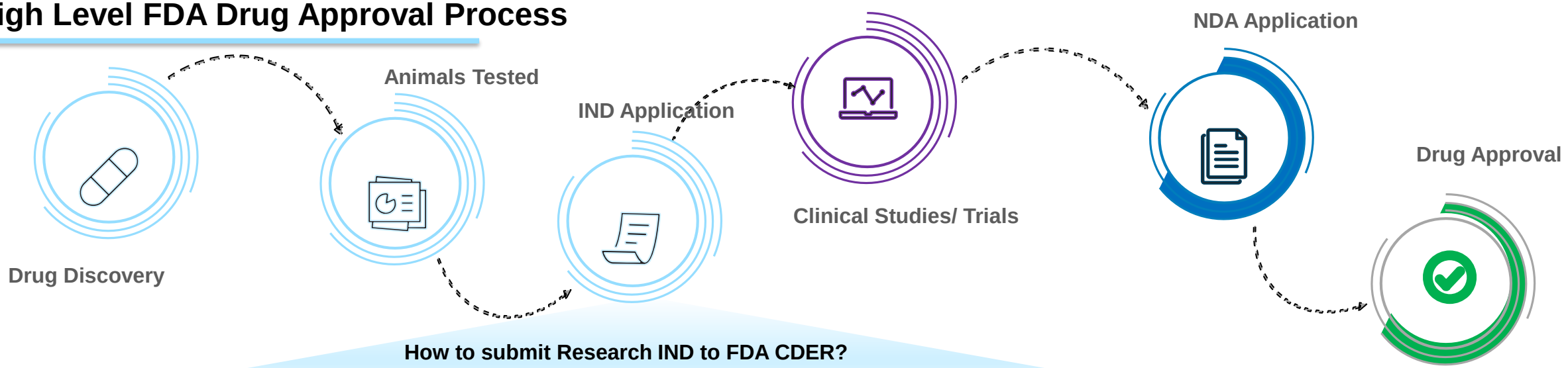
CDER NextGen Portal: One stop shop for the purpose of Submission, Collaboration and Reporting.

	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



How to submit Research IND to FDA CDER?

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.**

Legend

Pre-Clinical | Clinical | NDA Review | Post Marketing

What are the Real-time interactions?

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

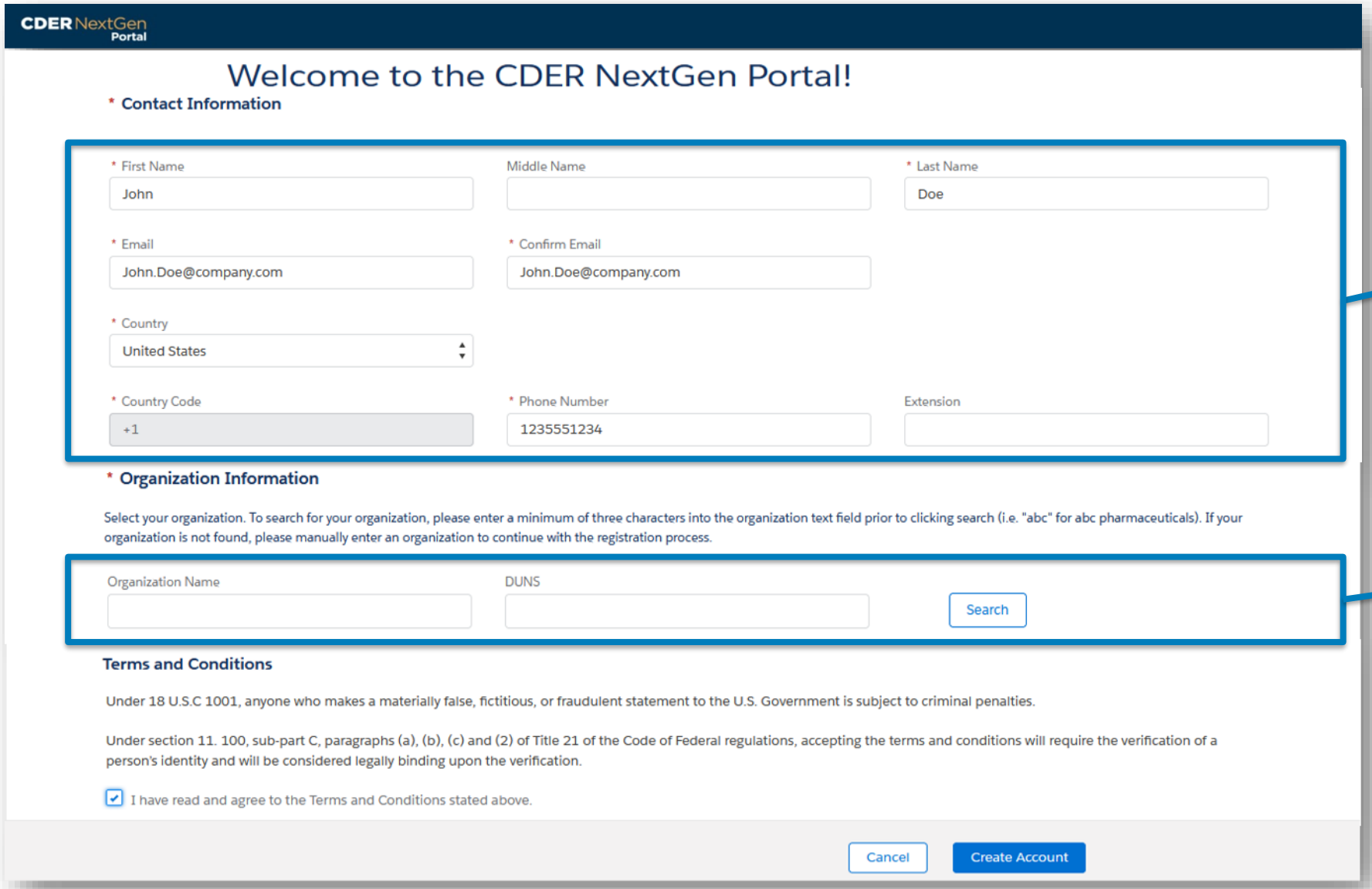
Study Details
- **NCT Number**: 000032344

Make a Research IND Submission in less than 10 Steps

1. Register for Account
2. Login to Portal
3. Enter Validated Information
4. Upload Documents
5. Generate 1571 Form
6. Digitally Sign Form
7. Download Application Materials
8. Submit IND Application

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.



Required Contact Information

- *Full Name*
- *Email*
- *Phone Number*

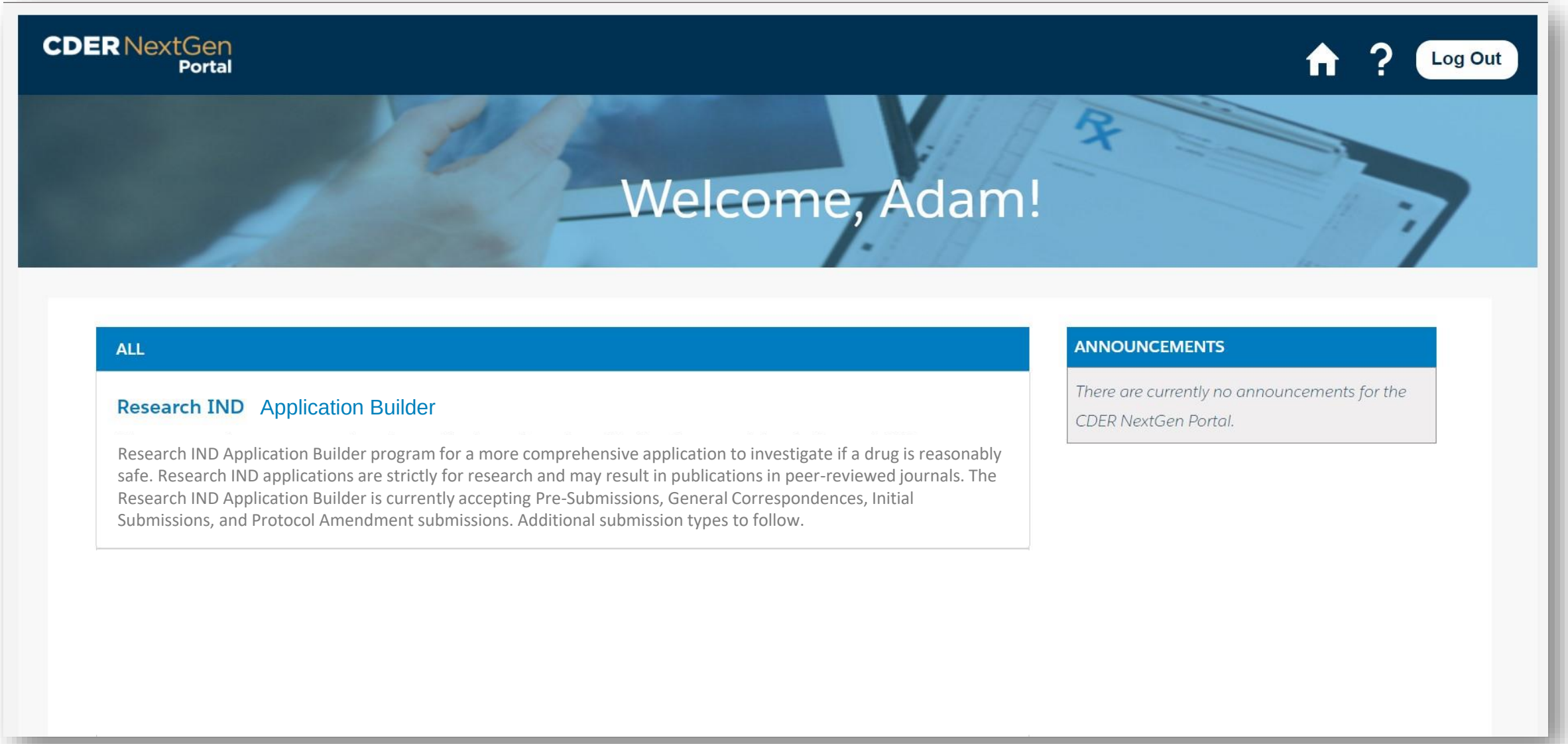
Required Organization Information

- *Organization Name*
- *DUNS Number*

Security Features

- Multifactor Authentication
- Password Protocols
- Email Verification

Research IND Application Builder – Landing Page



Research IND Application Builder – Landing Page

Search

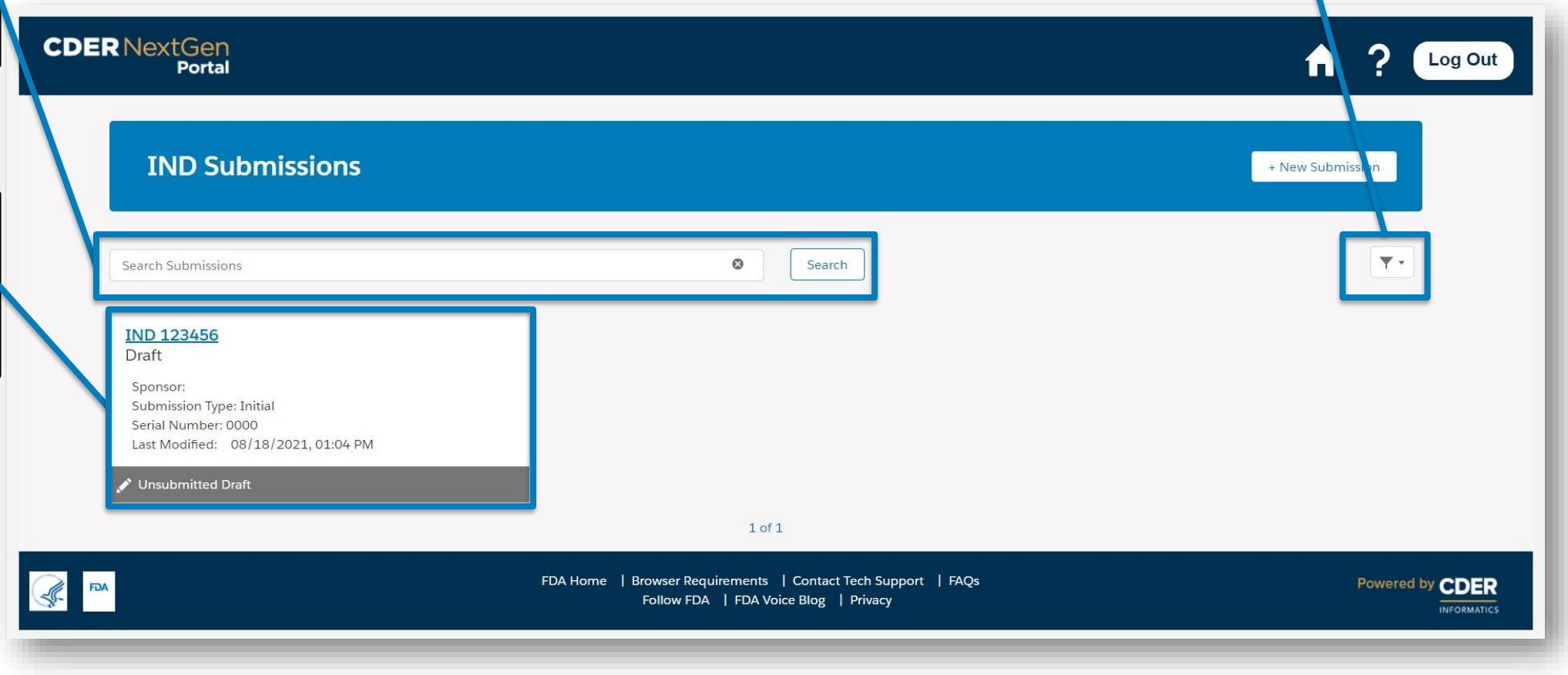
Reference information such as IND Number and IND Serial Number

Submission Tile

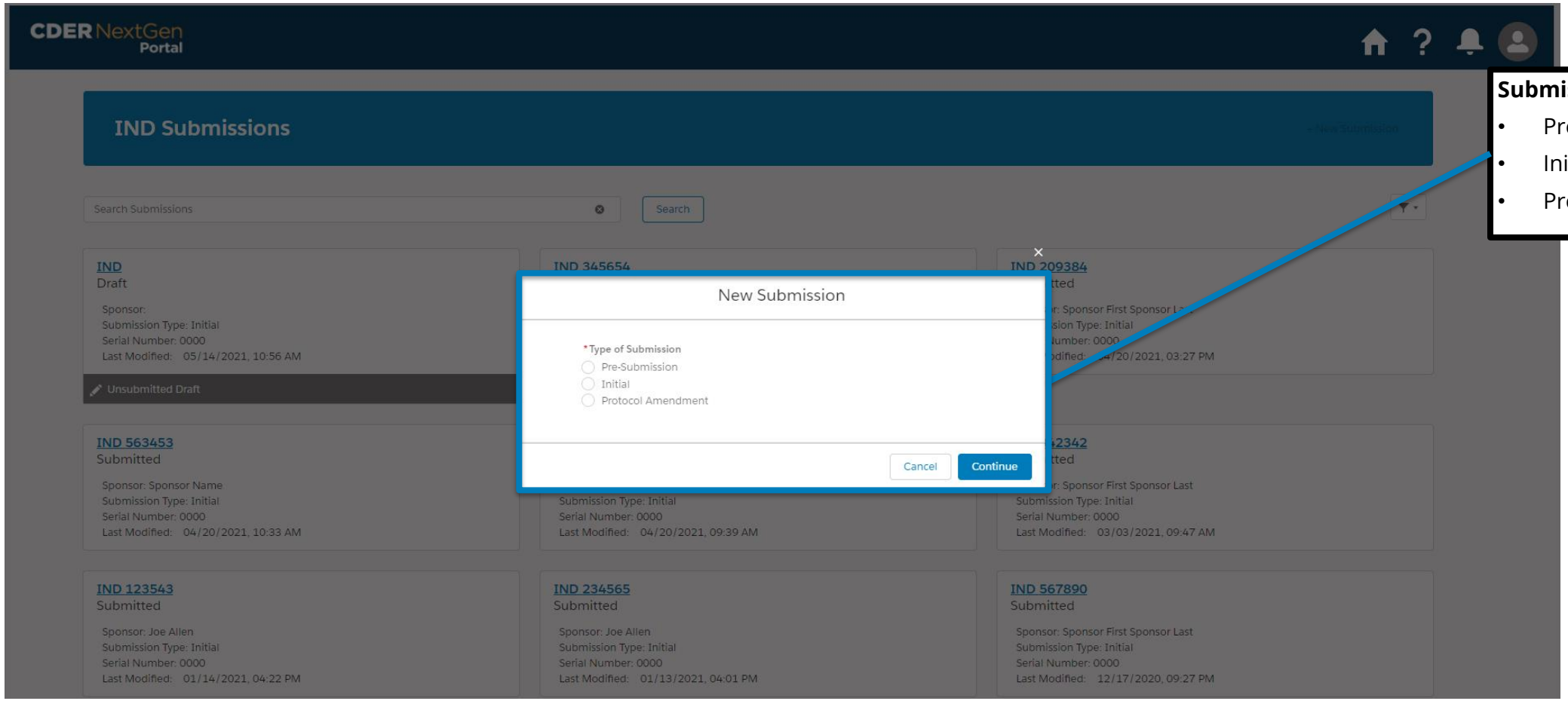
indicates Submission Event ID, Submission Status, Submission Type, Serial Number, and Last Modified Date

Filter

Filter upon Draft and Submitted Submission Statuses



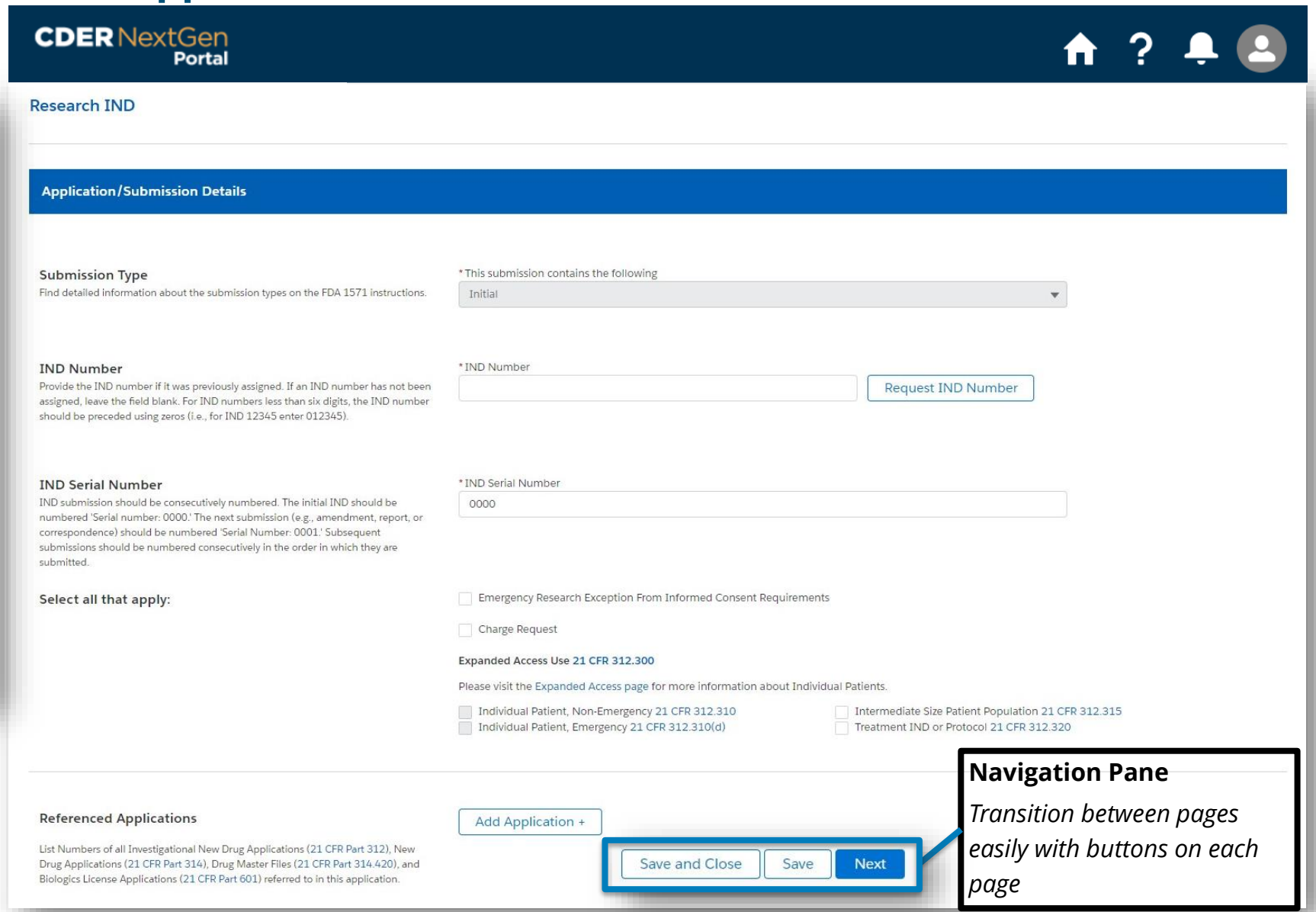
Research IND Application Builder – Landing Page



Submission Types:

- Pre-Submission
- Initial
- Protocol Amendment

Research IND Application Builder – Application Details



Application Builder

A convenient and logical way to complete your submissions

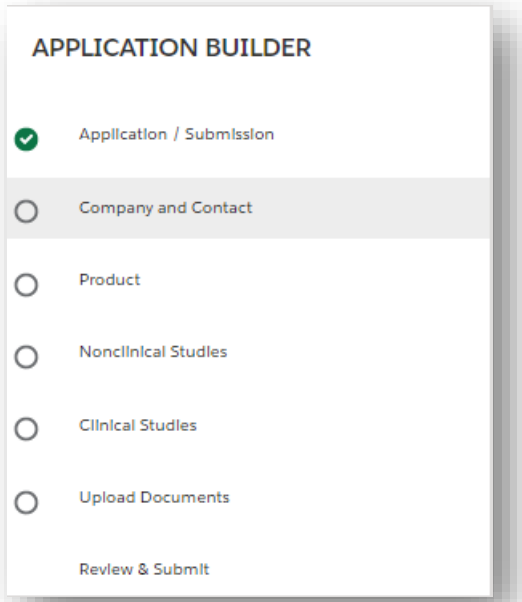
Help Center

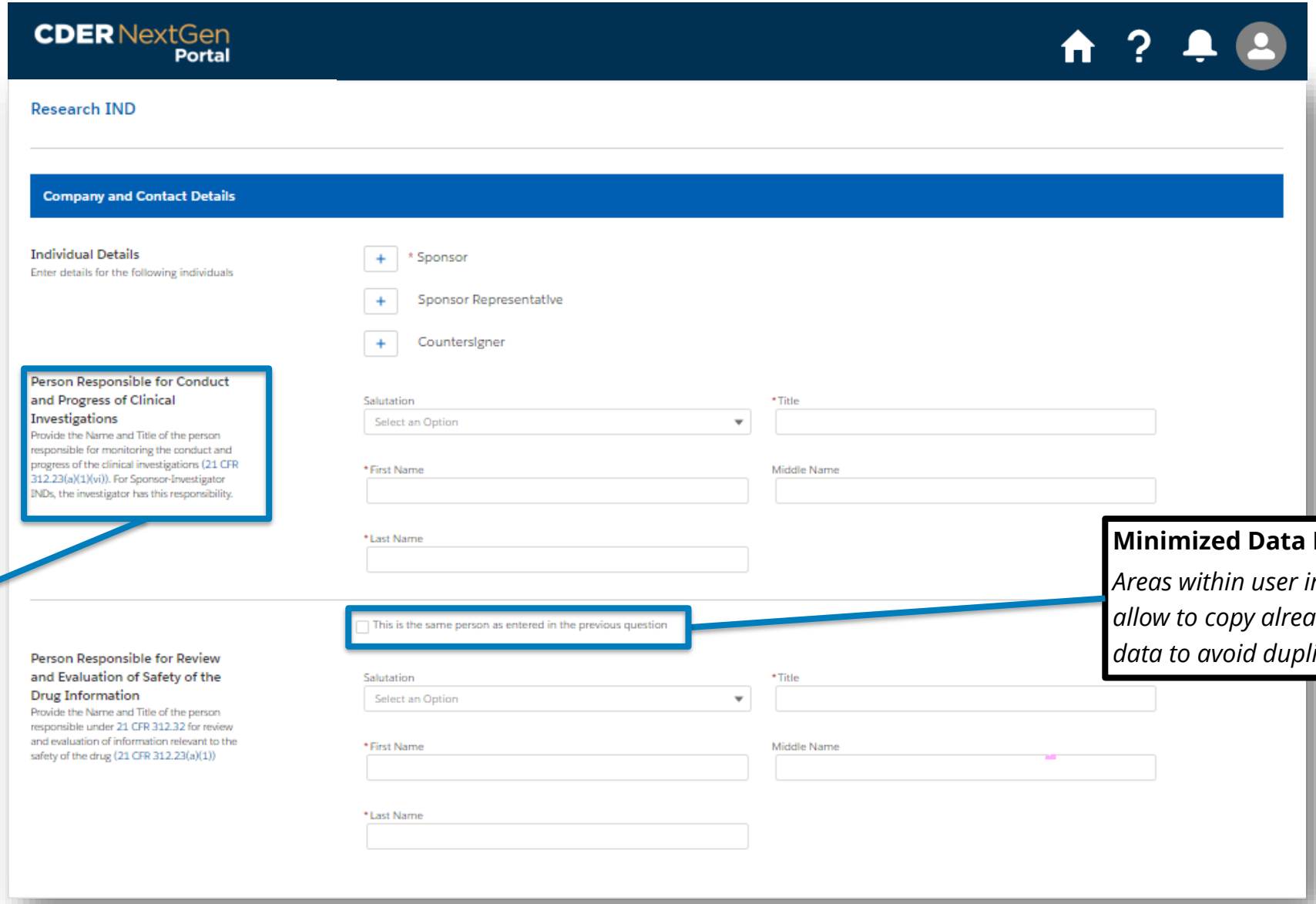
Easily accessible support when making your submission

Navigation Pane

Transition between pages easily with buttons on each page

Research IND Application Builder – Contact Details





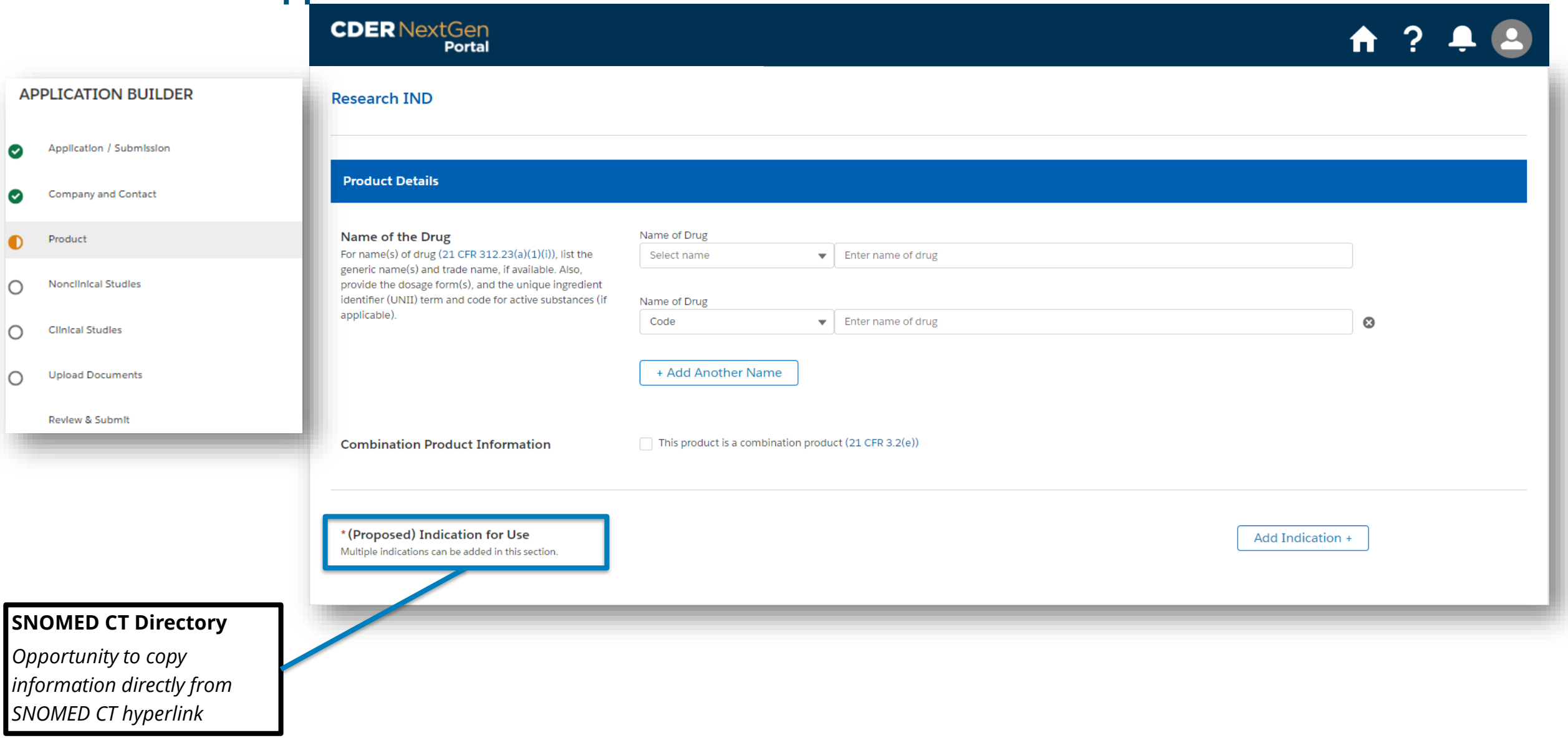
Guidance Instruction

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

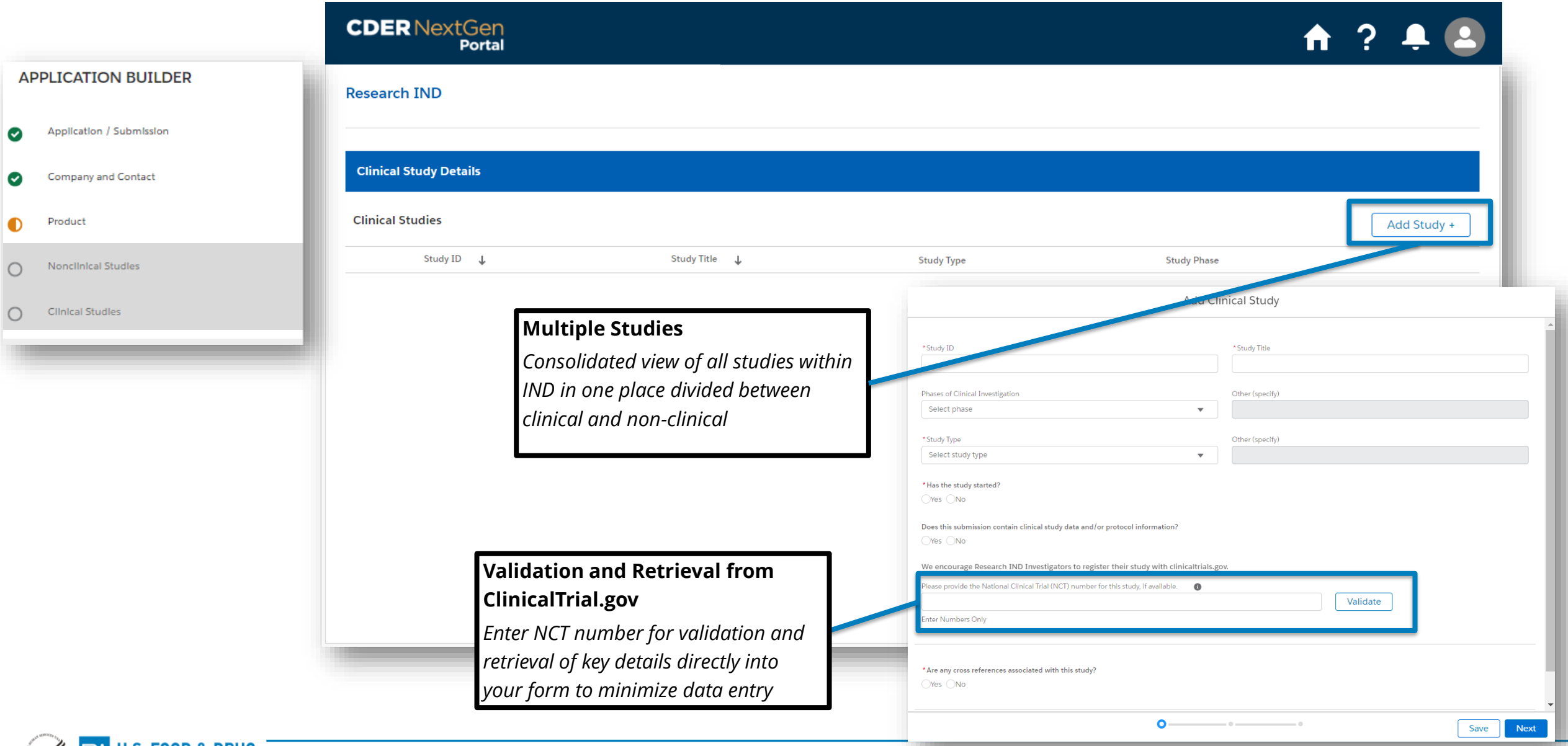
Research IND Application Builder – Product Details



SNOMED CT Directory

Opportunity to copy information directly from SNOMED CT hyperlink

Research IND Application Builder – Non-Clinical and Clinical Details



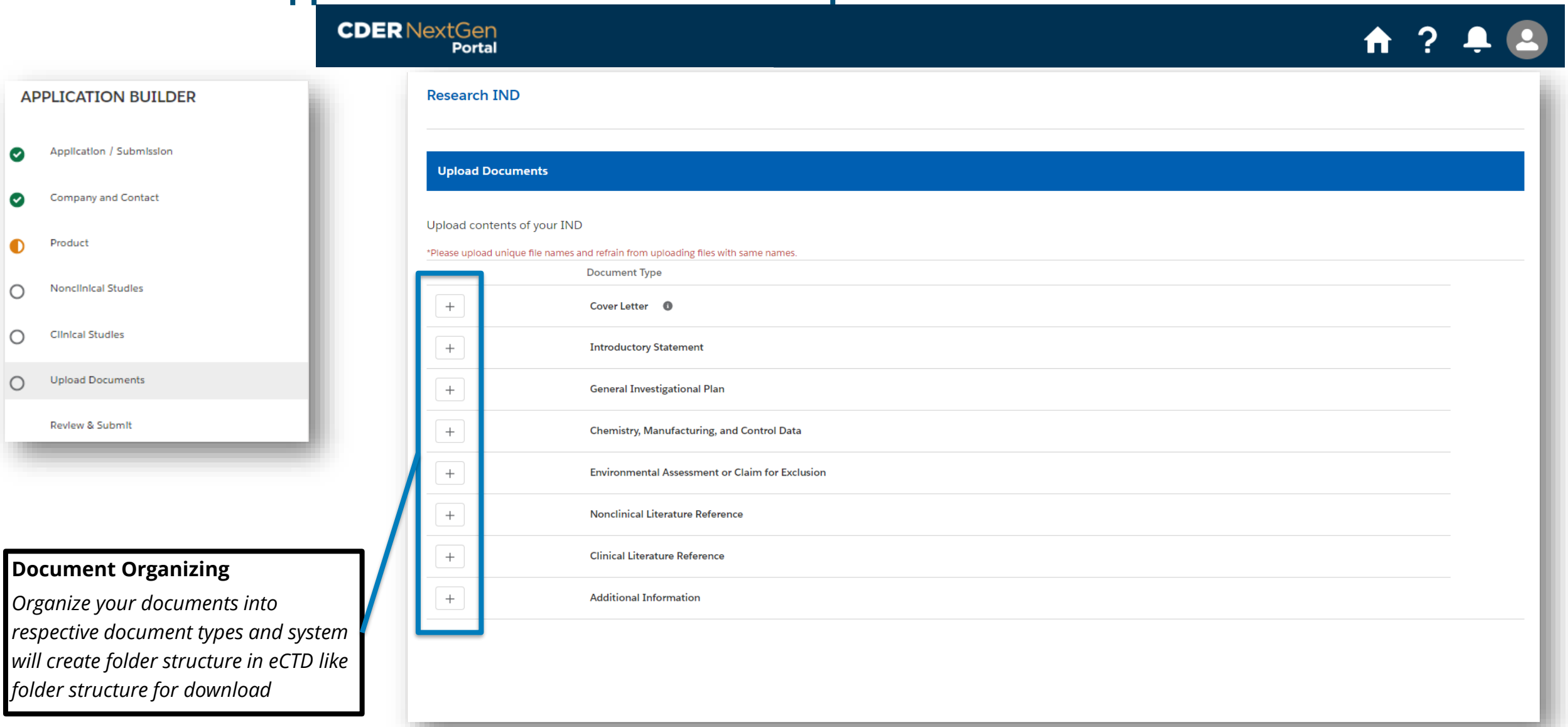
Multiple Studies

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

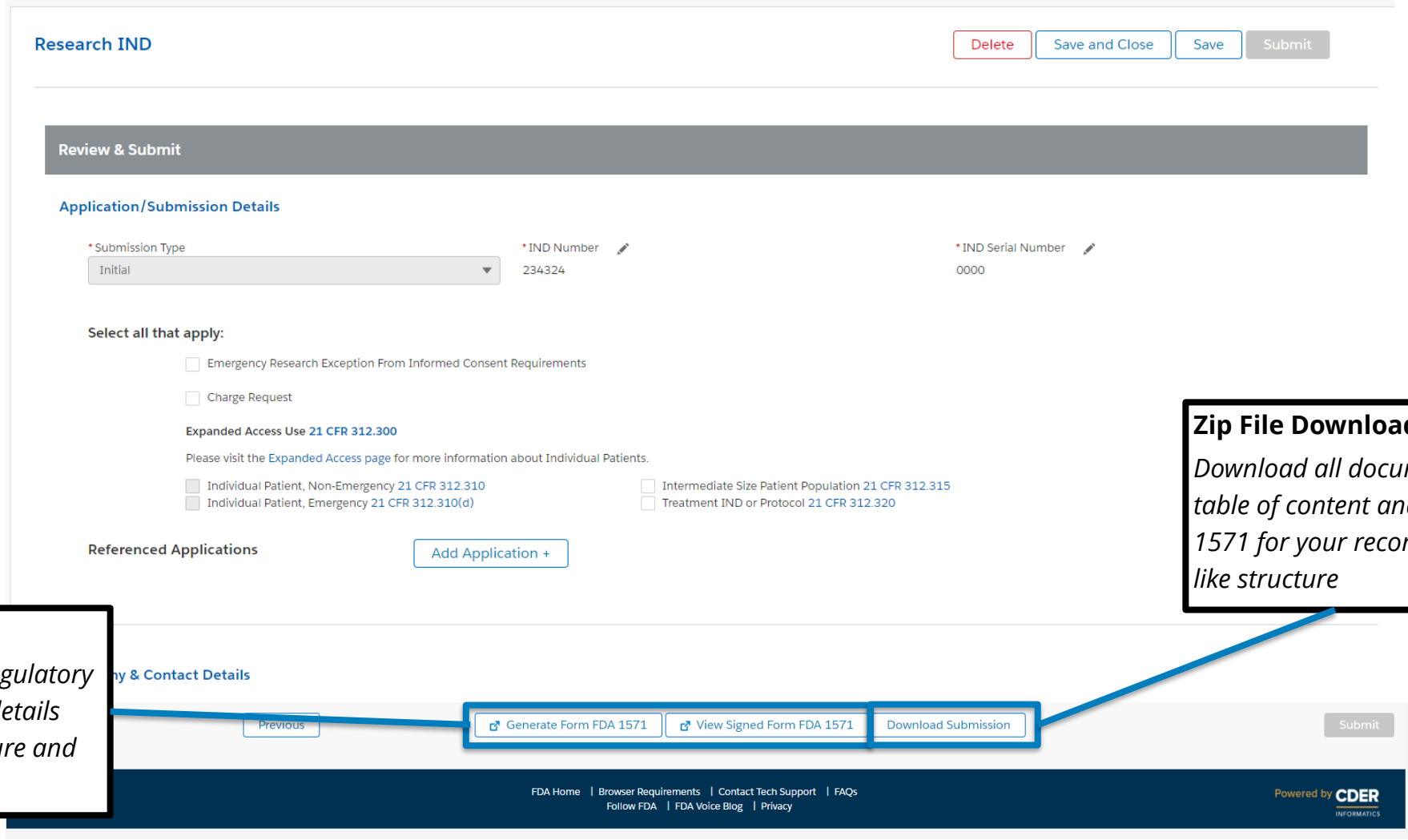
Research IND Application Builder – Document Upload



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



Generate Form 1571

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

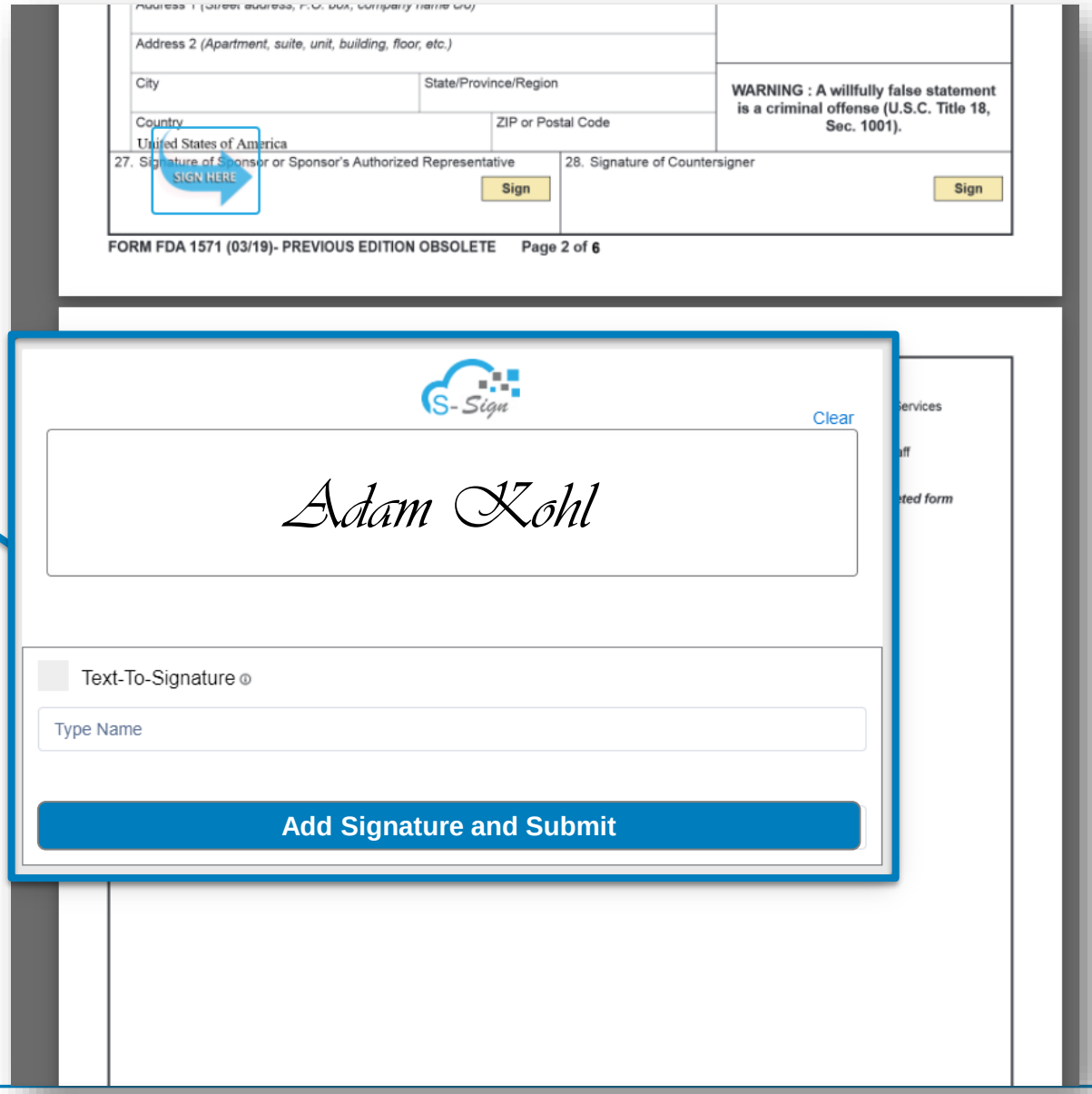
Zip File Download

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

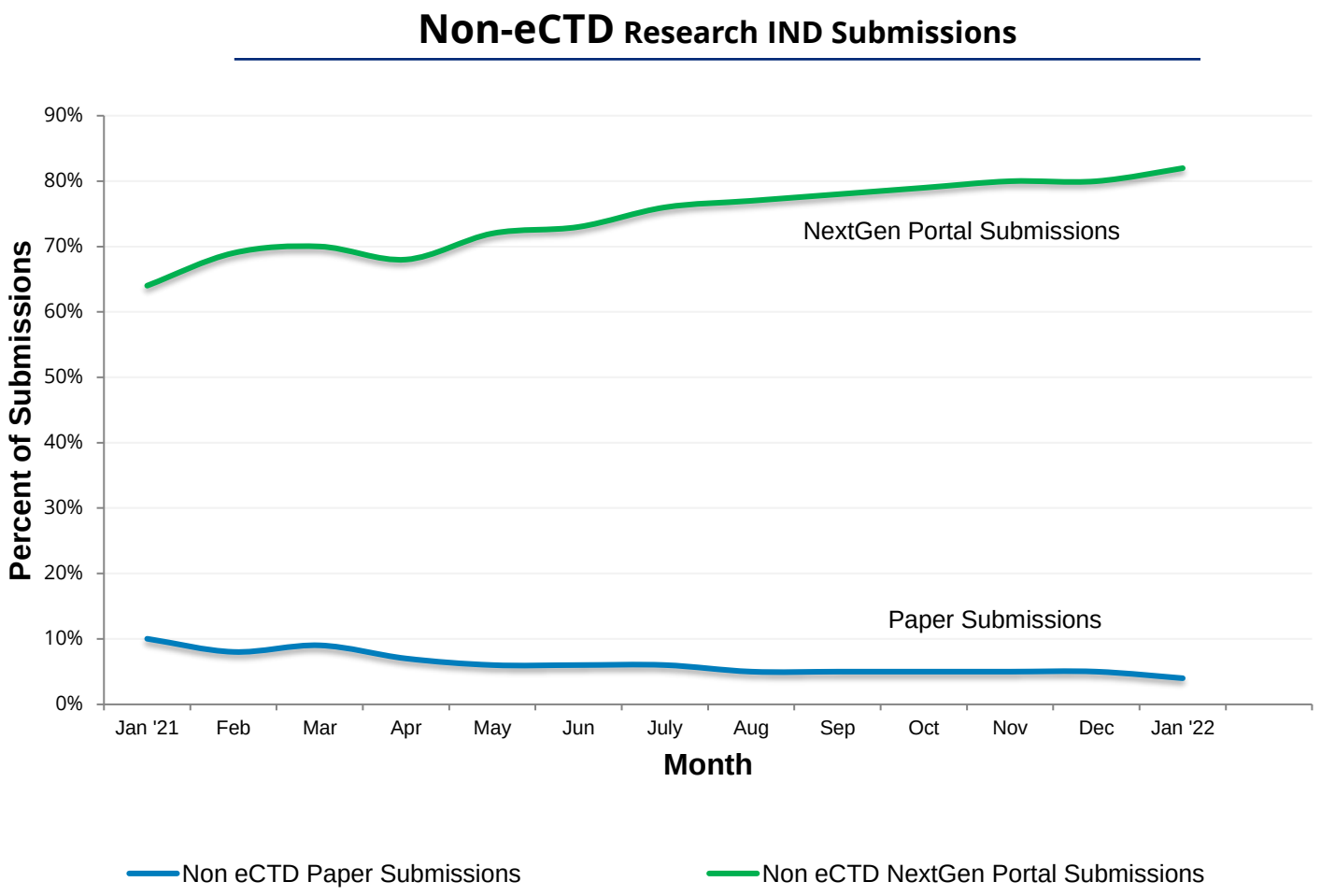
No need to print your form! Digitally sign after review and lock form ready for submission



In Summary : Research IND Application Builder Via CDER NextGen Portal

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

Progress, Impact & Metrics



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/indhelpcenterinfo

User Registration Guides

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

General FAQs

https://edm.fda.gov/customThemeStatic/themes/customTheme/docs/CDERDirectNextGen_ReferenceGuide_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 !