

Research IND Pilot Portal

Shoma Foss

Senior Business Informatics Program Manager
Office of Strategic Programs, Office of Business Informatics
CDER | US FDA

Clinical Investigator Training Course (CITC) – December 8, 2021

Solving Current Challenges with the CDER NextGen Research IND Pilot Portal (non eCTD)



Current Challenges



Administrative burden
due to manual preparation of the submission



Difficulty in locating targeted information for Research IND Guidance and Regulations



Seamless User Experience

- ✓ Easy account creation
- ✓ Structured forms
- ✓ Dynamic and intuitive questions
- ✓ Reusable data



Increased Efficiency

- ✓ Tool tips and guidance published by FDA directly tied to each section of application
- ✓ Query clinicaltrials.gov for NCT numbers and SNOMED CT

Solving Current Challenges with the CDER NextGen Research IND Pilot Portal (non eCTD)



Current Challenges



Difficulty in tracking data and documents across all submissions for a given Research IND application



Administrative burden due to manual preparation of FDA Forms



Table of Contents Auto Generation

- ✓ Auto generation of Table of Contents
- ✓ All Submissions stored in central location
- ✓ Download zip file of submission

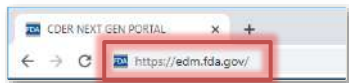
Form FDA 1571 Auto Generation

- ✓ System generated latest version of Form FDA 1571
- ✓ Auto population of Form FDA 1571 with data entered by the user into the system

Benefits of the Research IND Pilot Portal

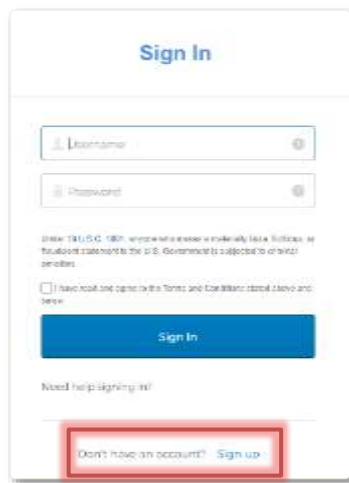
How to Access the Research IND Pilot Portal

1. Go to:
<https://edm.fda.gov/>

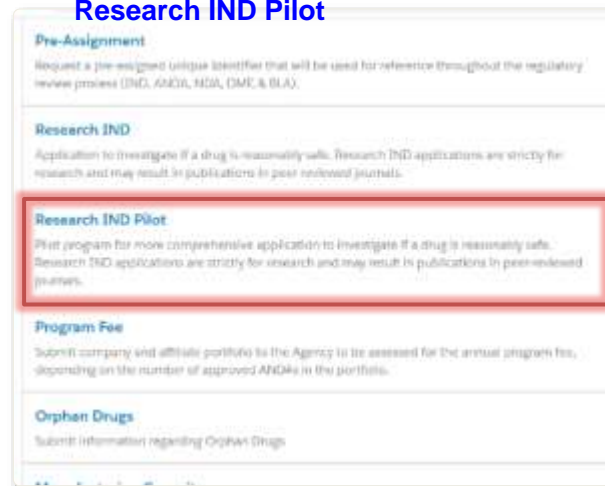


Note: Recommended Browsers are Google Chrome or Mozilla Firefox

2. Click the **Sign Up** link to register for an account for the CDER NextGen Portal



3. After logging into the CDER NextGen Portal, scroll down and click on **Research IND Pilot**



For questions regarding account registration and access, please contact:

EDMSupport@fda.hhs.gov

Demo

