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U.S. FOOD & DRUG
ADMINISTRATION

CDER NextGen Portal Regulatory Education for Industry (REdI) Annual Conference - 2021

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



Agenda

What is CDER NextGen Portal?

Before and After NextGen Portal

What can Industry do on CDER NextGen Portal?

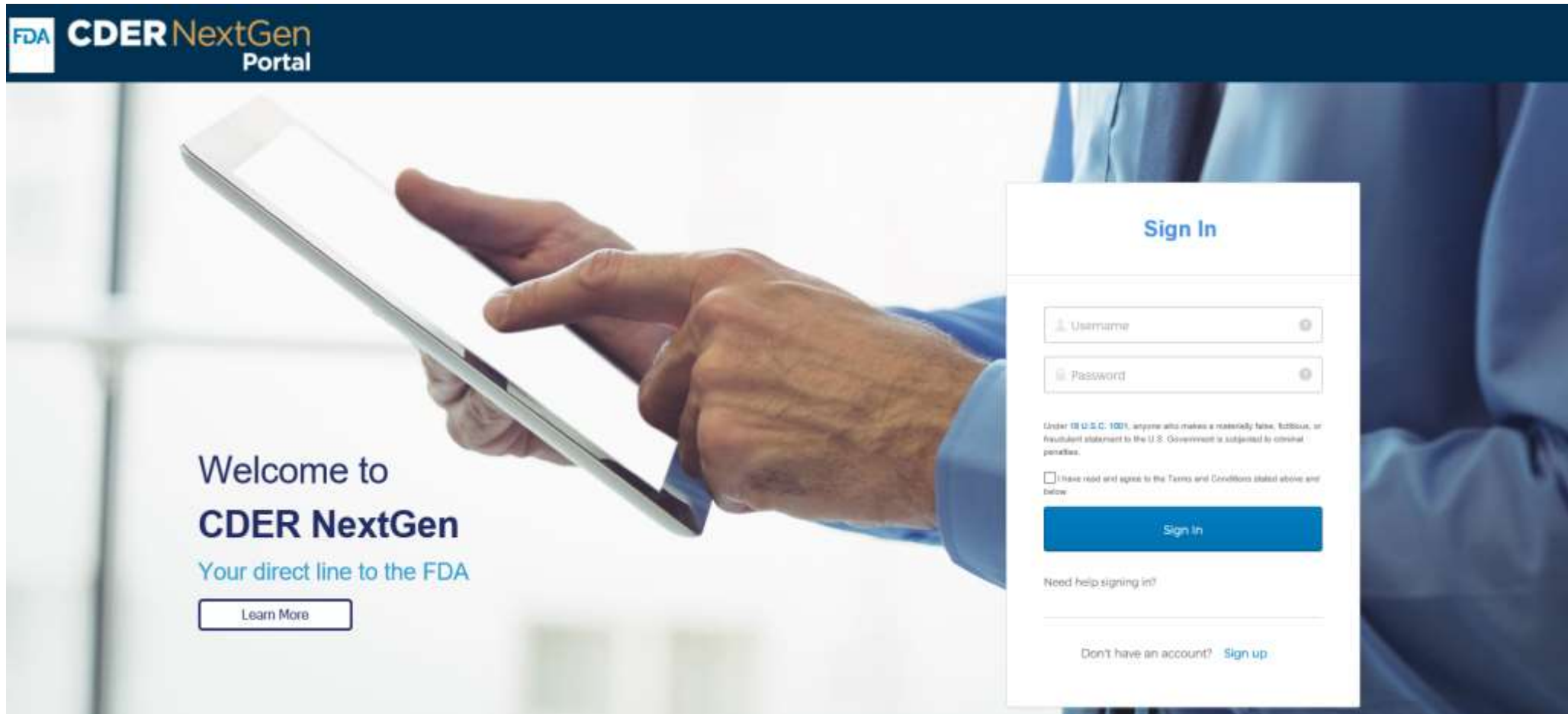
Progress, Impact & Metrics

What's Next?



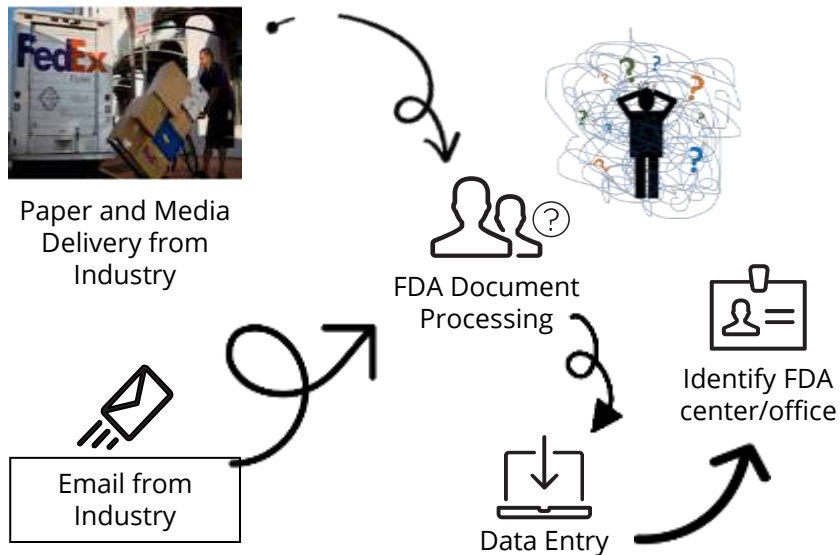
What is CDER NextGen Portal ?

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



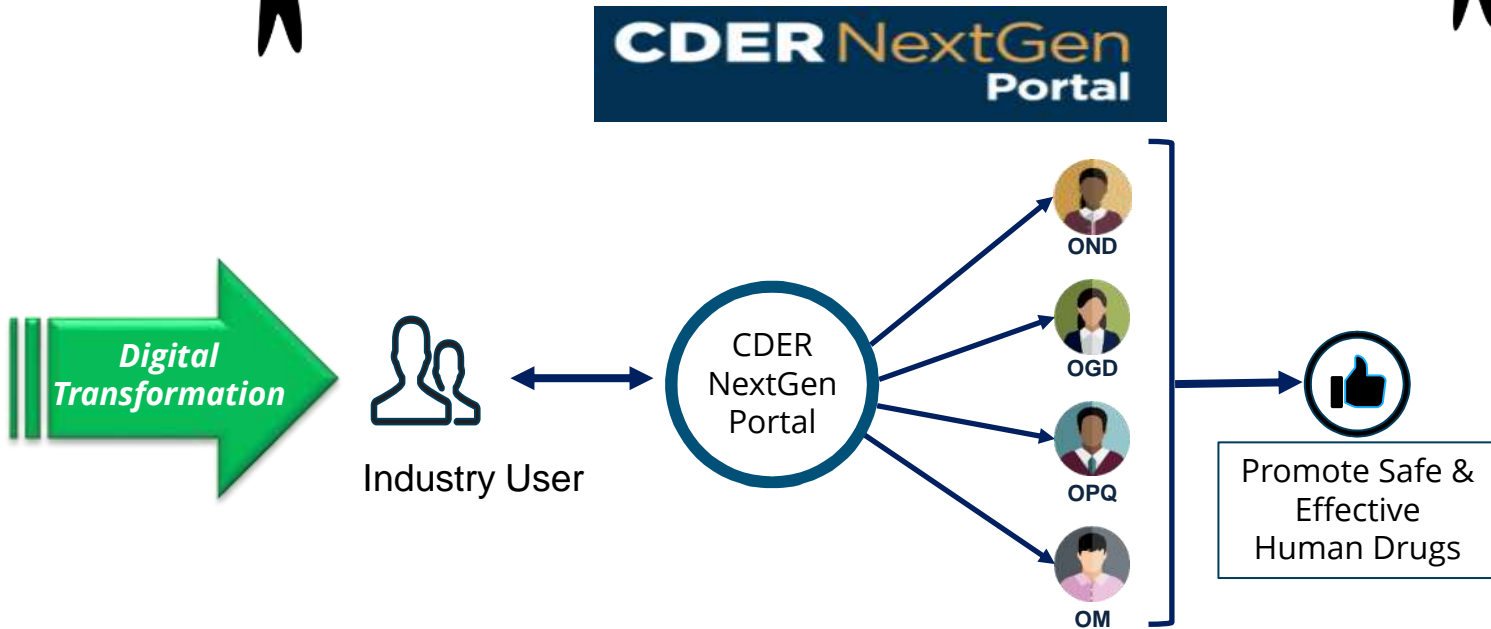
Before and After CDER NextGen Portal

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
- ✓ Document upload file size up to ~100MB

CDER NextGen Portal : One Stop Shop



#	Portal Application	Submission	Collaboration	Reporting
1	Drug Shortages Notifications			
2	Non eCTD submissions for Research INDs	✓		✓
3	Alternate Submissions (Non eCTD Type III DMFs, EUA and others)	✓		
4	Orphan Drug	✓		
5	Drug Development Tools	✓		
6	Controlled Correspondence		✓	
7	Pre-ANDA Meeting Request		✓	
8	Pre-Assignment Number		✓	
9	Waiver Requests		✓	
10	Company Affiliation	✓		✓
11	Standards Recognition			✓
12	Extensions Requests			✓
13	Manufacturing Capacity			✓
14	Critical Care Drug Monitoring			✓
15	Potential drug shortage: Public health emergency			✓

Portal for Submission, Collaboration and Reporting

Submission



Collaboration



Reporting



➤ Alternative Submission

Submit your non-eCTD Type III DMFs, EUA and other exempted human drug applications

➤ Research IND

Submit non-eCTD Research IND without mailing in your application

➤ Controlled Correspondences

Controlled Correspondences and Pre-ANDA Meeting Request to Collaborate with FDA on your RLD Products

➤ Pre-Assignment

Request and receive your Application number

➤ Drug Shortages

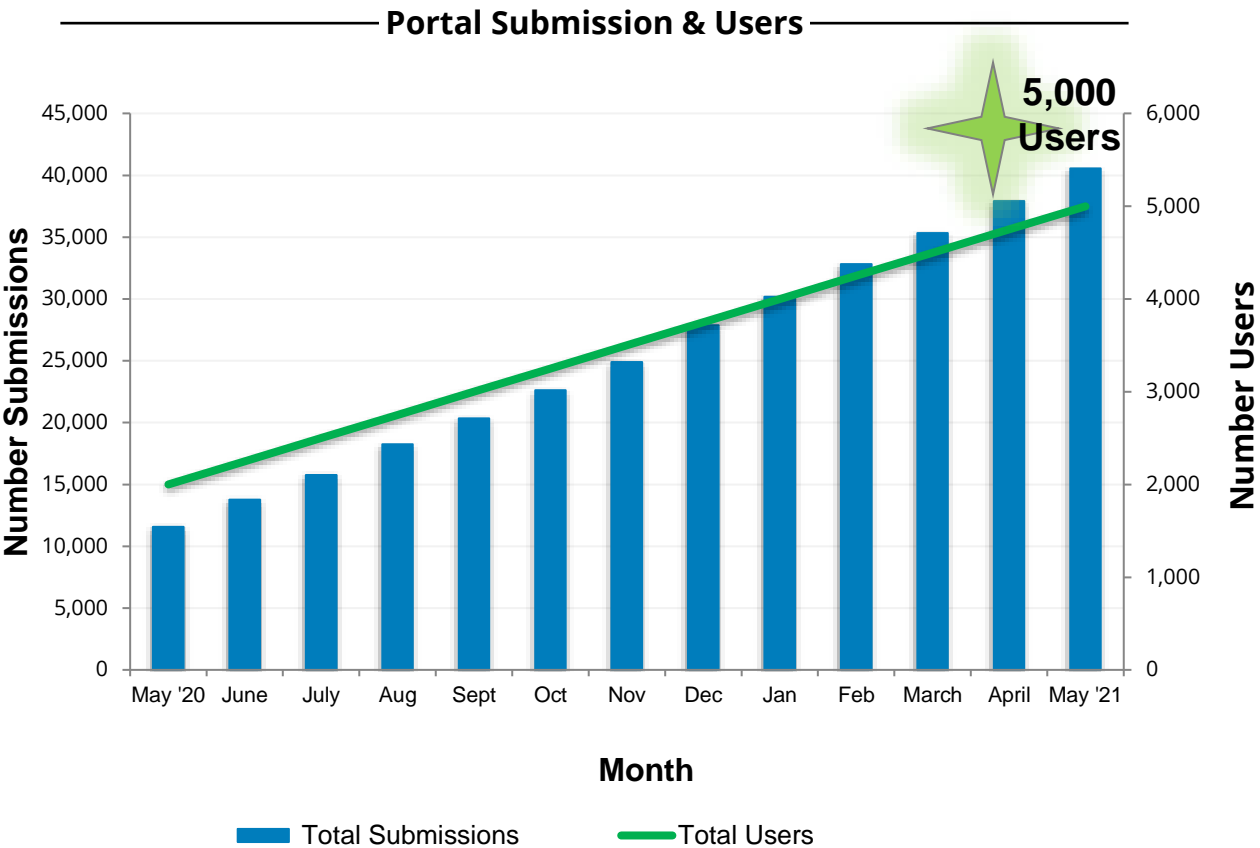
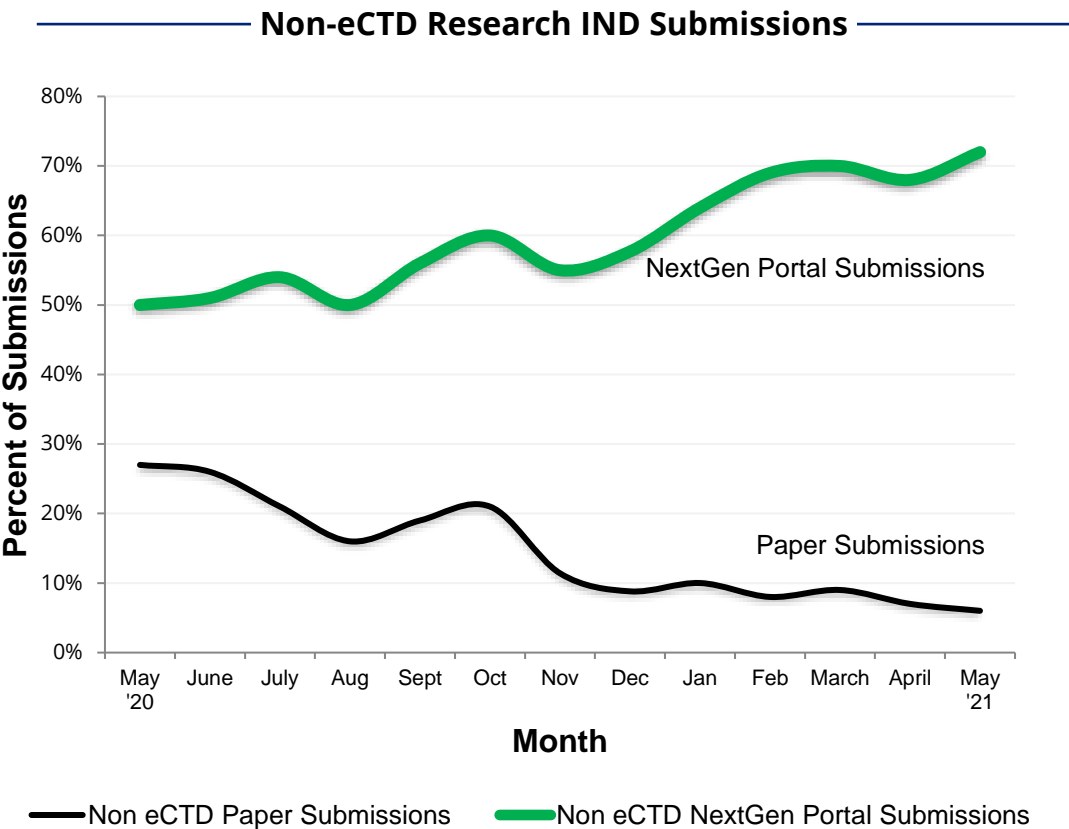
Report Drug Shortages Notifications

➤ Manufacturing Capacity

Report Manufacturing Capacity During Public Health Emergency

Progress, Impact & Metrics

CDER NextGen Portal **continues to reduce regulatory overhead** for sponsors, academia, research institutes, and small businesses.



59% reduction of paper submissions since May 2020

How can I Create an Account

? CDER NextGen Portal registration is a simple process requiring Contact Information, Organization Information, 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

Contact Information

Organization Information

Portal User Experience

A user-friendly interface for submission, saving progress, performing validation, and building human drug application

Application Builder

APPLICATION BUILDER

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

Need Help?

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

Help Center

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

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

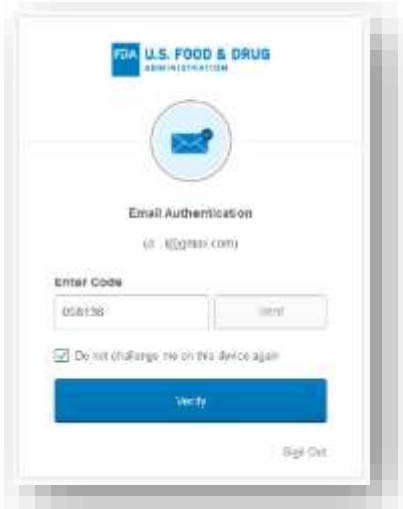
Referenced Applications
List Numbers of all Investigational New Drug Applications (21 CFR Part 312), New Drug Applications (21 CFR Part 314), Drug Master Files (21 CFR Part 314.420), and Biologics License Applications (21 CFR Part 601) referred to in this application.

Navigation Pane

Portal Security Features

Compliant with NIST security guidance

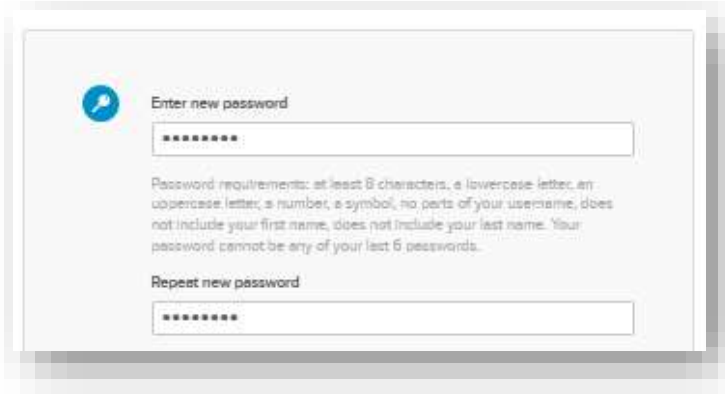
Multifactor Authentication



The screenshot shows the 'Email Authentication' page of the FDA U.S. Food & Drug Administration. It features a large blue 'Verify' button and a 'Sign Out' link. The page includes a header with the FDA logo and a sub-header 'Email Authentication (or: k1234567890.com)'. Below the header, there is a section for 'Enter Code' with a text input field containing '058138' and a 'Verify' button. A checkbox labeled 'Do not challenge me on this device again' is checked. The 'Verify' button is blue and prominent.

MFA is a security system requiring more than one method of authentication

Password Protocols



The screenshot shows the 'Enter new password' form. It has a title 'Enter new password' and a password input field with a strength indicator. Below the input field, there is a section for 'Repeat new password' with another input field. The form includes a 'Sign Out' link. The background is light blue with a subtle pattern.

Password protocols in place to ensure users have strong credentials

Email Verification



The screenshot shows the 'Email Verification' page. It features a confirmation message: 'Your login request to the FDA CDER NextGen Portal has been received. Your username is [jsmith@gmail.com](#). Please click the following link below to activate your account.' Below the message is an 'Activation Link' (This link expires in 7 days.). The page includes a header with the FDA logo and a sub-header 'Email Verification (or: k1234567890.com)'. The 'Activation Link' is blue and prominent.

Verify email is valid to eliminate incorrect emails from creating portal accounts

Need Support ?

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

Research IND User Guides

https://edm.fda.gov/wps/myportal!/ut/p/z0/04_Sj9CPykssy0xPLMnMz0vMAfljo8zifQxdnA2dgg18_UNdHA0CDd0CXcdPQwM3I30C7IdFQFcul7r/

Alternate Submission User Guides

https://edm.fda.gov/wps/myportal!/ut/p/z0/04_Sj9CPykssy0xPLMnMz0vMAfljo8zifQxdnA2dgg18_f2NTQ0CPUyCAz39XQ0M3I30C7IdFQHsRTmU/

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

Summary

1. FDA CDER NextGen Portal

- One Stop Shop for **non eCTD Submission**, Collaboration & Reporting
 - Document upload file size up to **~100MB**
- Reduce regulatory overhead for sponsors, small businesses and research institutes
- Secured Multifactor Authentication enabled

2. FDA CDER Digital Transformation

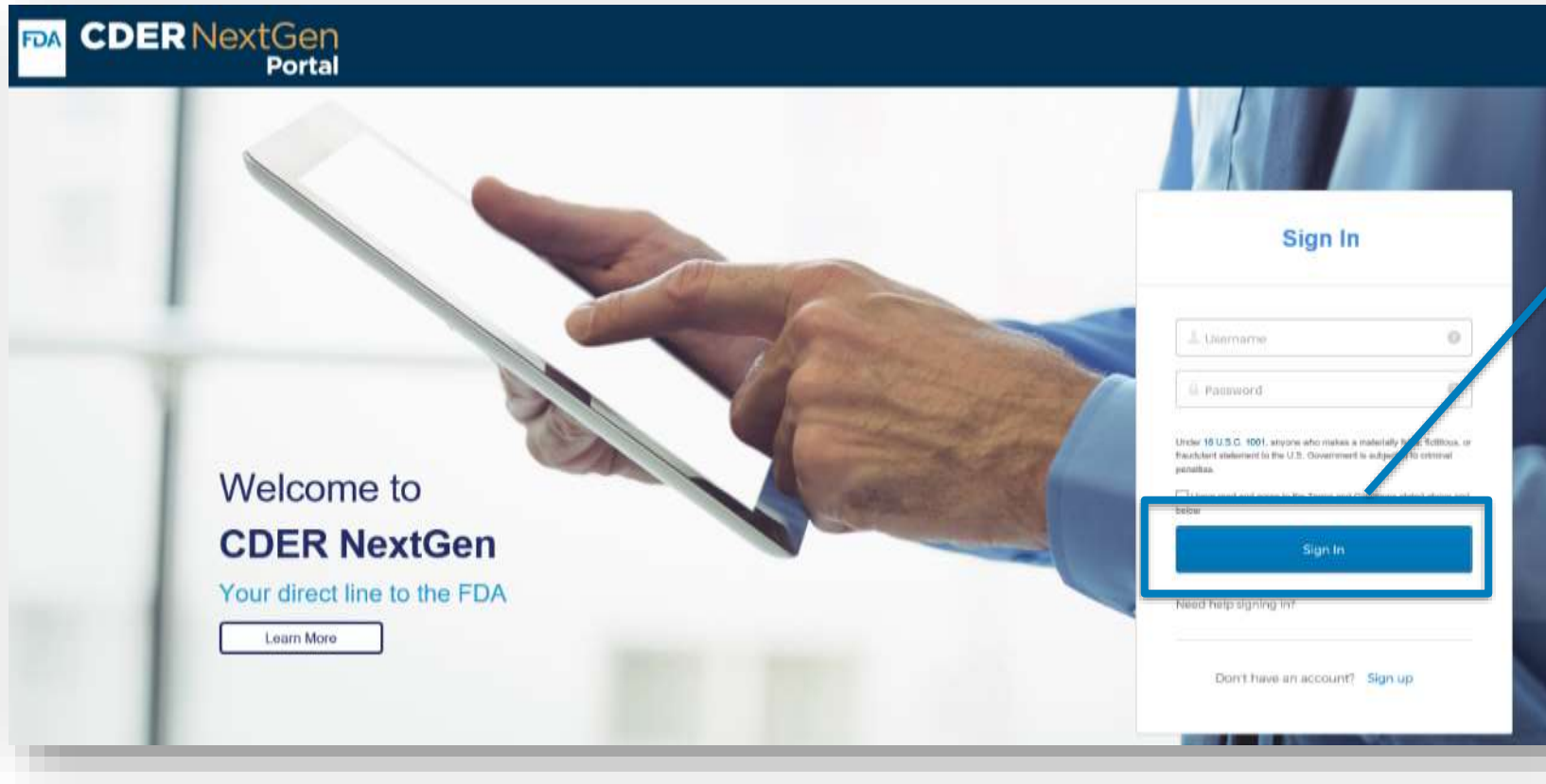
- Optimizing business process and maximize technology
- Ensure Clean, Complete and Validated data
- Digital transformation in action

3. Progress & Impact

- 59% reduction of paper submissions
- 5,000 plus portal users and over 40,000 submissions to date
- Improving operational efficiency

What's Next?

New Users may sign up, by navigating to <https://edm.fda.gov> .



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

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