FDA CDER NextGen Portal
DIA Conference – February 2023

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?

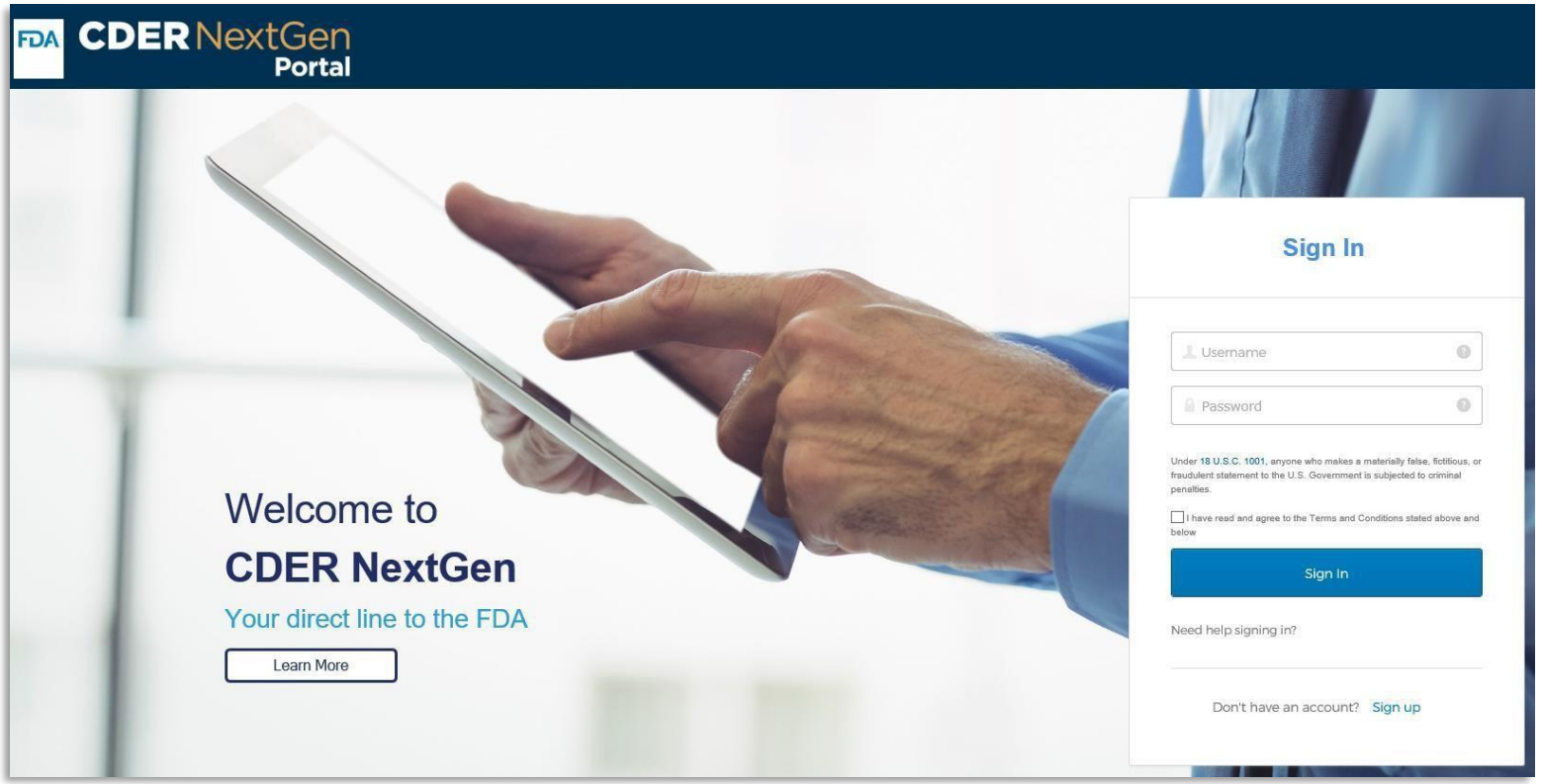
Before and After NextGen Portal

What is New ?

User’s Adoption

What is CDER NextGen Portal?

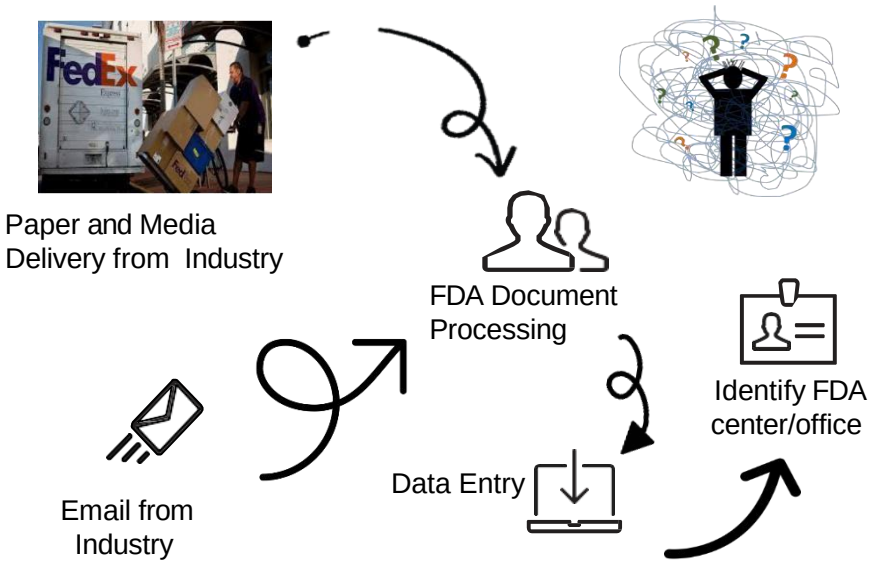
One stop shop for the purpose of Submission, Collaboration and Reporting. The portal enables sponsors to submit Drug Shortages Notifications and exempted human drug applications to the FDA CDER. This collaboration platform continues to reduce regulatory overhead for sponsors, academia, research institutes, and small businesses.



The FDA Digital Transformation

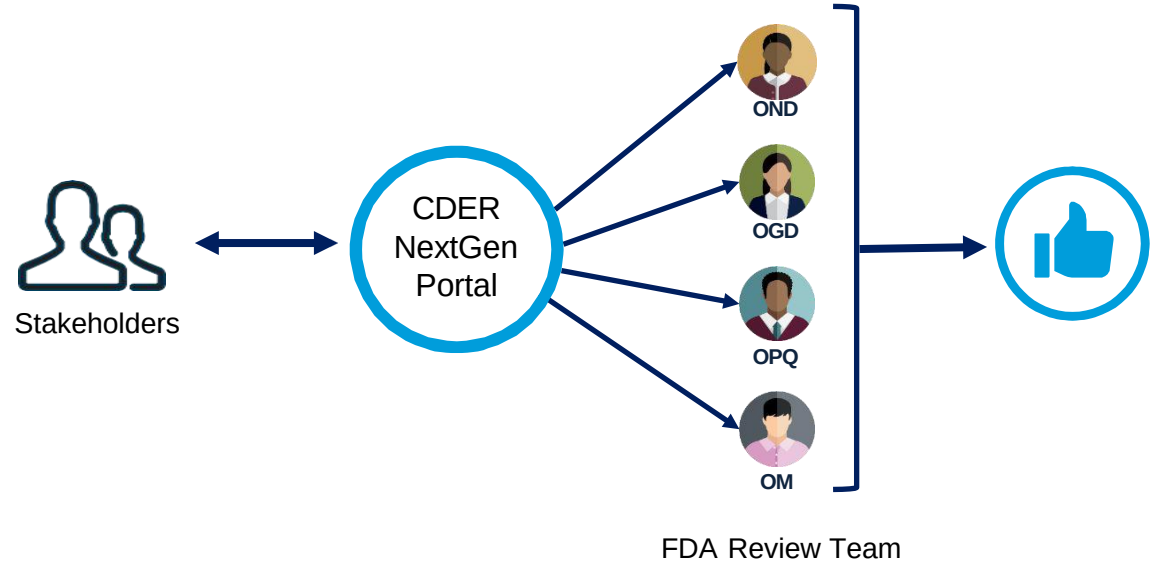
in action to promote safe and effective human drug review and approval

Before NextGen Portal



Digital Transformation

After NextGen Portal



- Inefficient paper and Media processing
- Manually intensive
- Time and resource consuming

- Streamlined submissions with clean, complete, and validated data
- Maximized API led technology to improve efficiency
- Improved collaboration between the FDA and Stakeholders

FDA CDER NextGen Portal Products (non eCTD) for 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 & CPAM Meeting Request		✓	
Pre-Assignment Number		✓	
Waiver Exemption Exceptions Request	✓		
Program Fee			✓
Standards Recognition			✓
Extensions Requests			✓
Manufacturing Capacity			✓
Critical Care Drug Monitoring Portal			✓
Radioactive Drug Research Committee		✓	
Potential Drug Shortage		✓	
Emergency Use Potential Drug Shortage	✓	✓	
Pre-Launch Activities Importation Requests		✓	
OMUFA	✓	✓	

Application Submission Simplified

From days to minutes ….

User 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

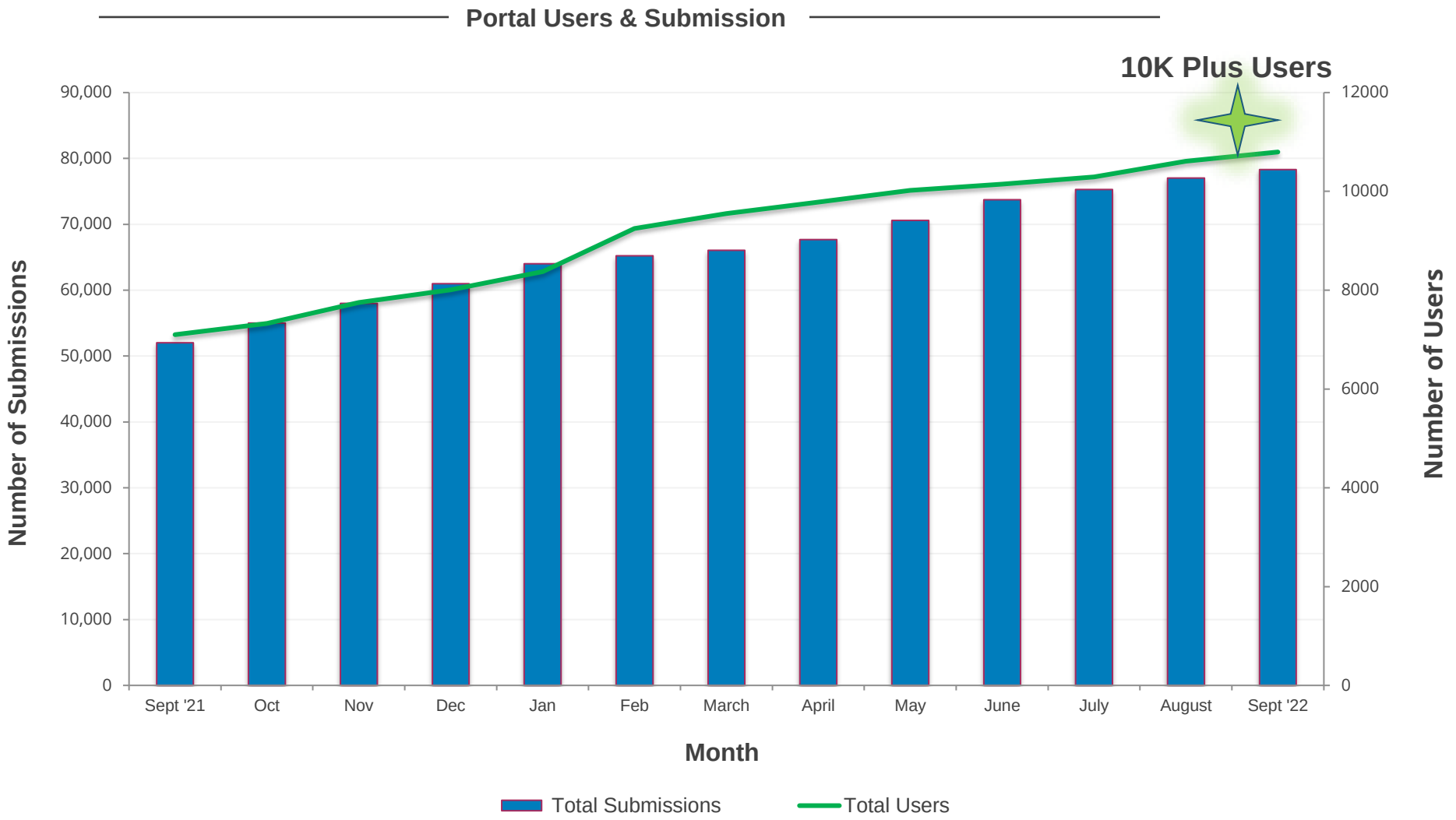
1. Register for Account
2. Login to Portal
3. Enter Validated Information
4. Upload Documents
5. Generate 1571 Form
6. Digitally Sign Form
7. Download Application Materials
8. Submit IND Application

Two-way Real-Time Interactions (non eCTD)

Streamlining the Sponsor and FDA Reviewer collaboration

FDA CDER NextGen Portal User Adoption

The CDER NextGen Portal Team continue to make enhancements to improve user's experience



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

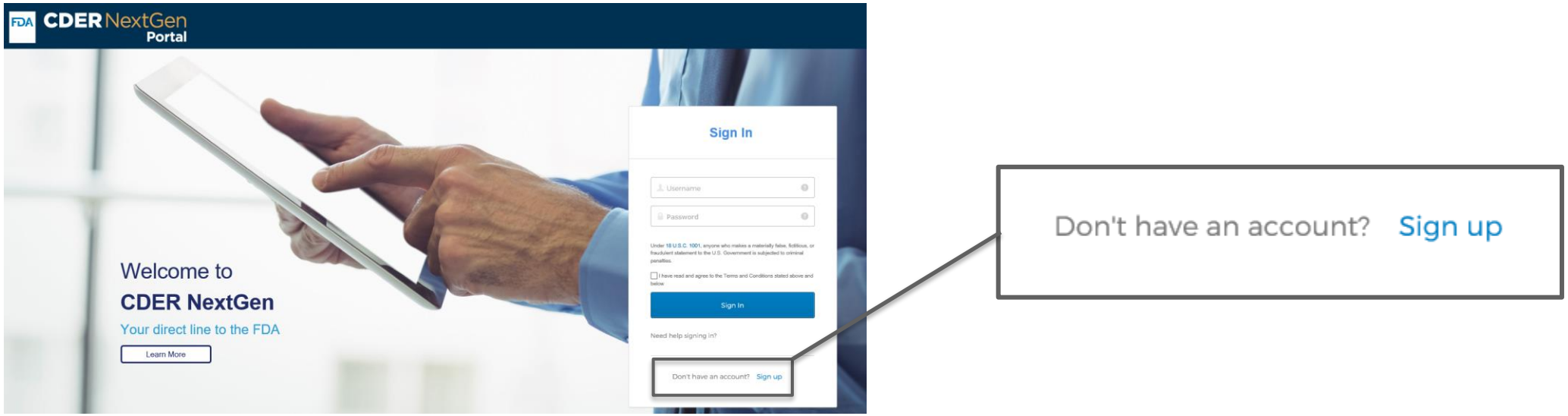
https://www.fda.gov/media/136301/download

Contact the Platform Support Team at edmsupport@fda.hhs.gov

HOW DO I GAIN ACCESS TO THE NextGen PORTAL?

New Users

Sign up CDER NextGen Portal, navigate to https://cdernextgenportal.fda.gov and follow the signup instructions



Thank You