FDA CDER NextGen Portal

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Agenda

What is CDER NextGen Portal?

Before and After NextGen Portal

What is New ?

User’s Adoption

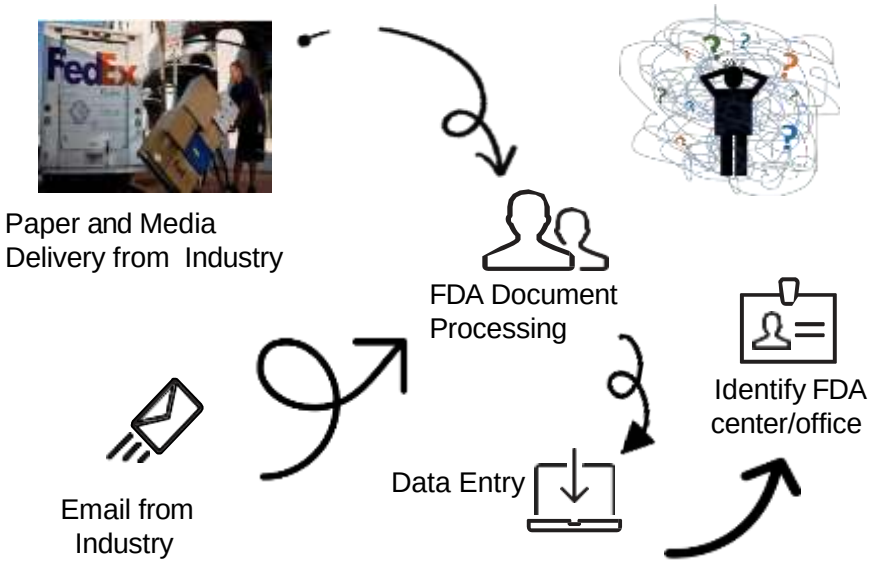
What is CDER NextGen Portal?

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

The FDA Digital Transformation

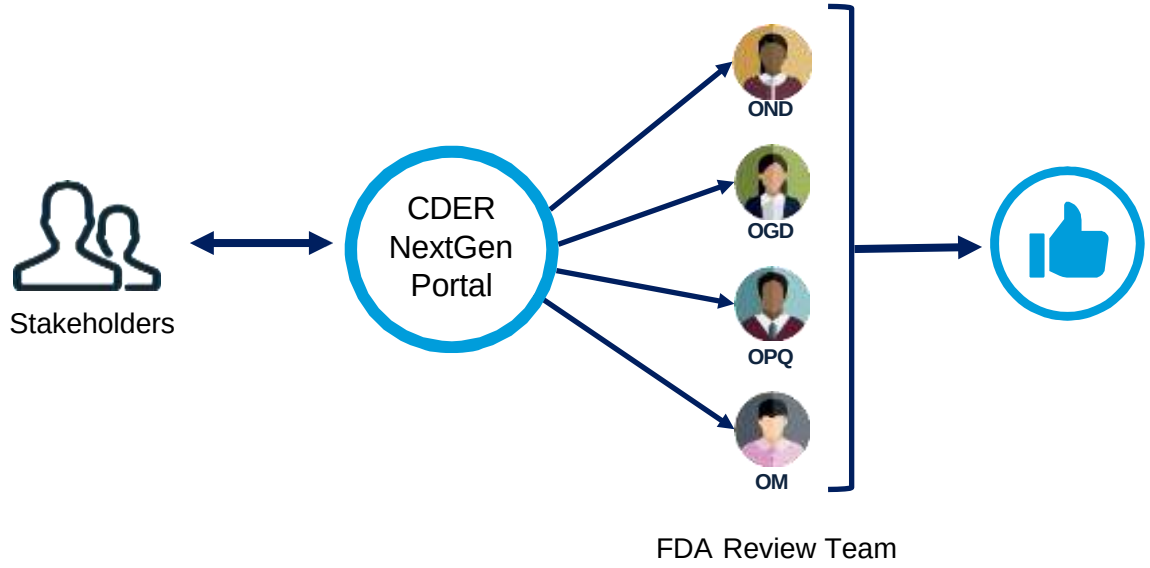
in action to promote safe and effective human drug review and approval

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 for non eCTD 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	✓	✓	

What's New? CDER NextGen Portal Products

CARES Volume Act
As part of the Coronavirus Aid, Relief, and Economic Security Act, 2020 Enacted H.R. 748, 116 Enacted H.R. 748. Registrants/Establishments with business operations, who have registered and/or listed products with the FDA CDER using SPL should be able to provide volume information.

Controlled Correspondences
Through the CDER NextGen Portal, stakeholders enabled to submit their correspondence for streamlined communication with the FDA CDER

Pre-ANDA Meeting Request (CPAM)
Stakeholders enabled to submit product development, pre-submission, and combination product meeting requests for complex generic drug products by uploading meeting requests and meeting packages for more efficient processing.

Pre-Launch Activities Importation Requests (PLAIR)
Section 505(A) of the FD&C Act prohibits the introduction of any new drug into interstate commerce unless there is an approved application filed for that drug; however, Industry can submit a pre-launch activities importation request (PLAIR) in preparation for market launch within 60 days of the anticipated decision date for a pending initial original marketing application.

CARES GDUFA III PLAIR

What's New? CDER NextGen Portal – CARES Volume Act

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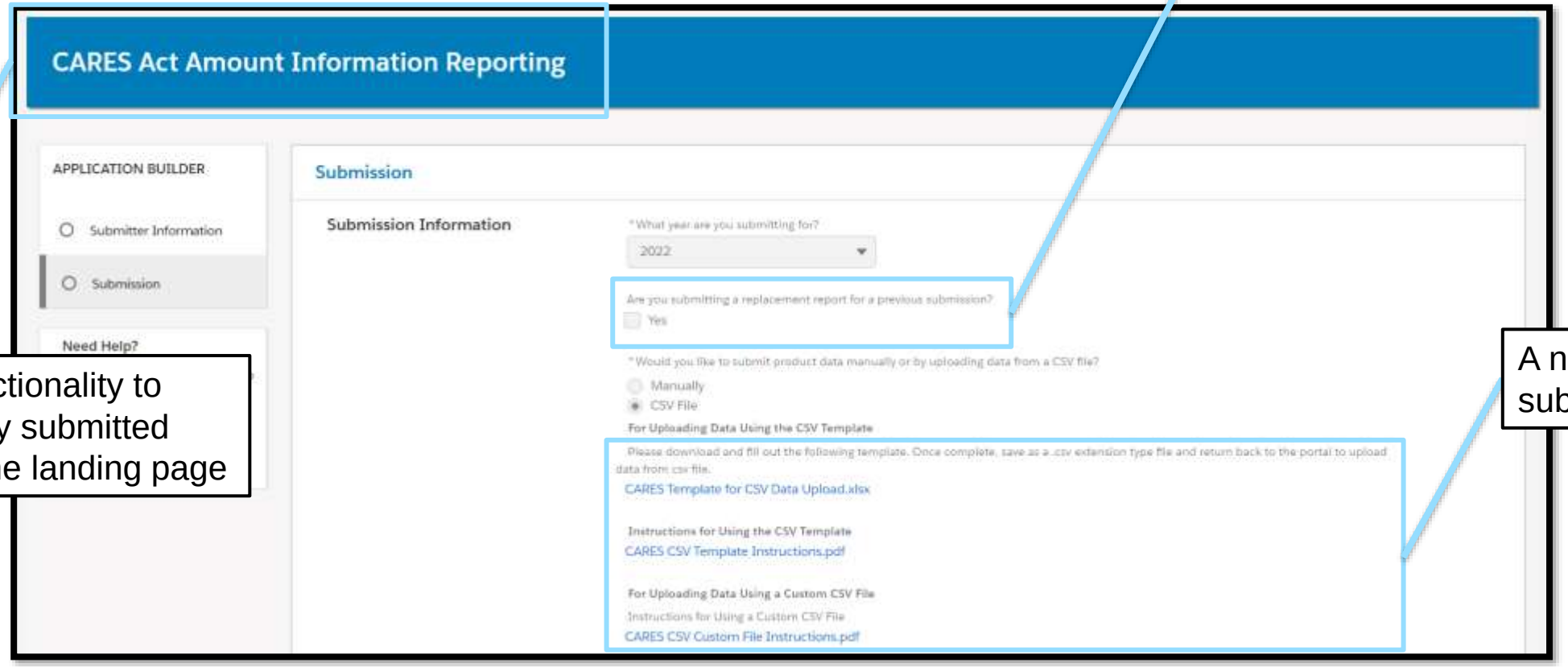
A new process to replace existing submissions



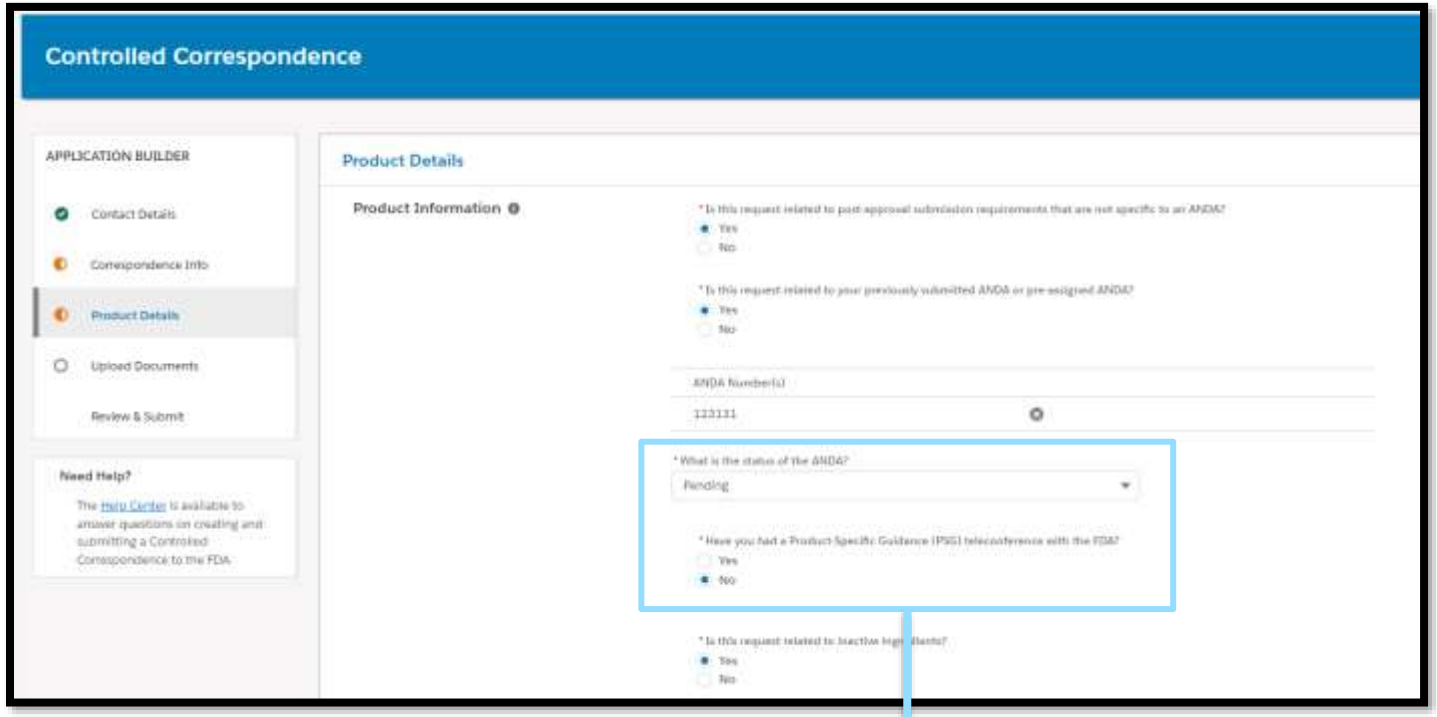
Enhanced functionality to view previously submitted reports from the landing page

A new process to submit a CSV file

What's New? CDER NextGen Portal – GDUFA III

Controlled Correspondences

Through the CDER NextGen Portal, stakeholders enabled to submit their correspondence for streamlined communication

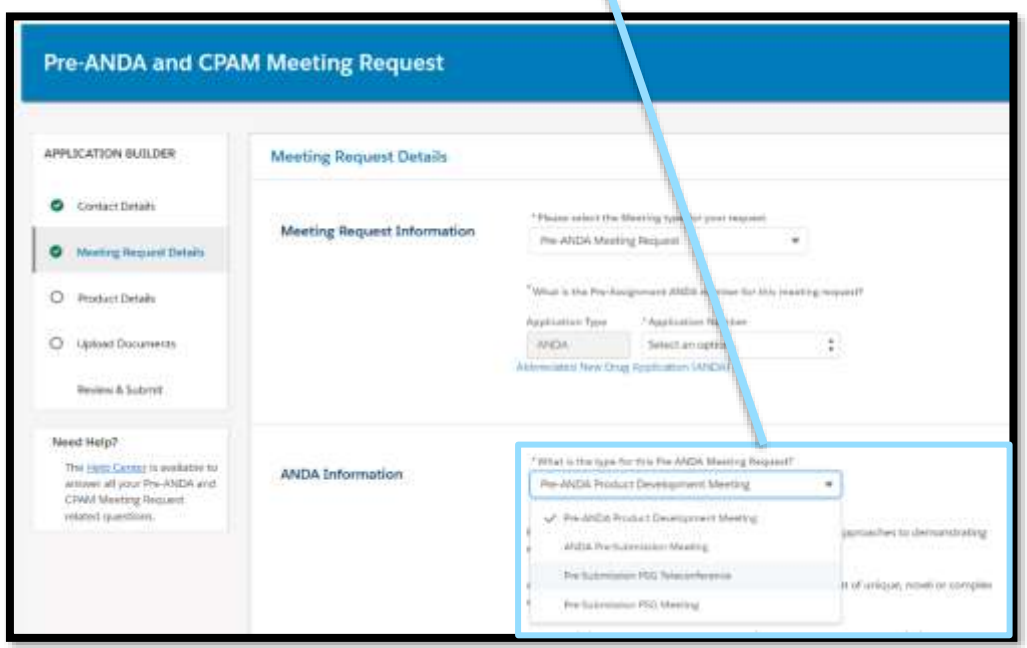


1. Additional status type of Pending for ANDAs
2. Added screening questions

Pre-ANDA Meeting Request (CPAM)

Stakeholders enabled to submit product development, pre-submission, and combination product meeting requests for efficient processing.

1. Addition of meeting types
2. Additional questionnaires to streamline communication



What's New? CDER NextGen Portal – Pre-Launch Activities Importation Requests (PLAIR)

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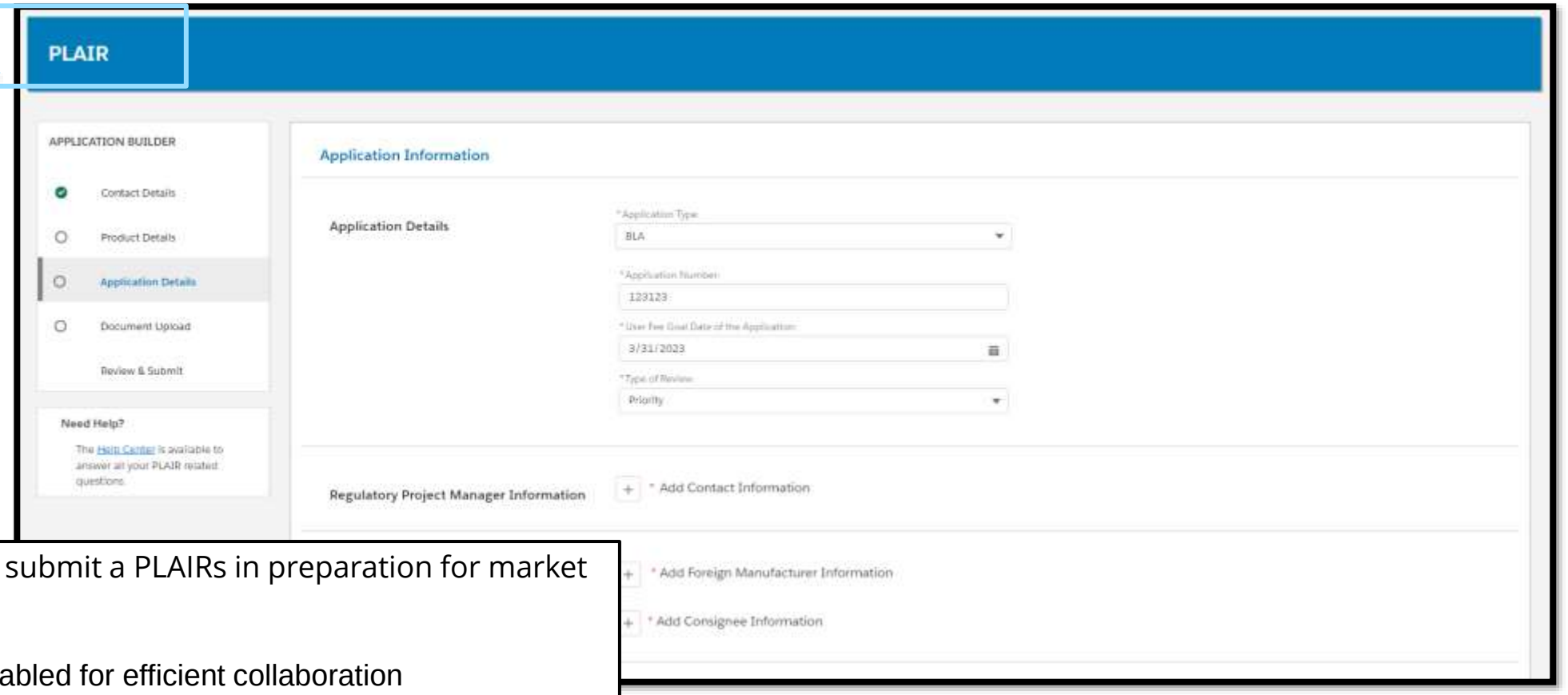
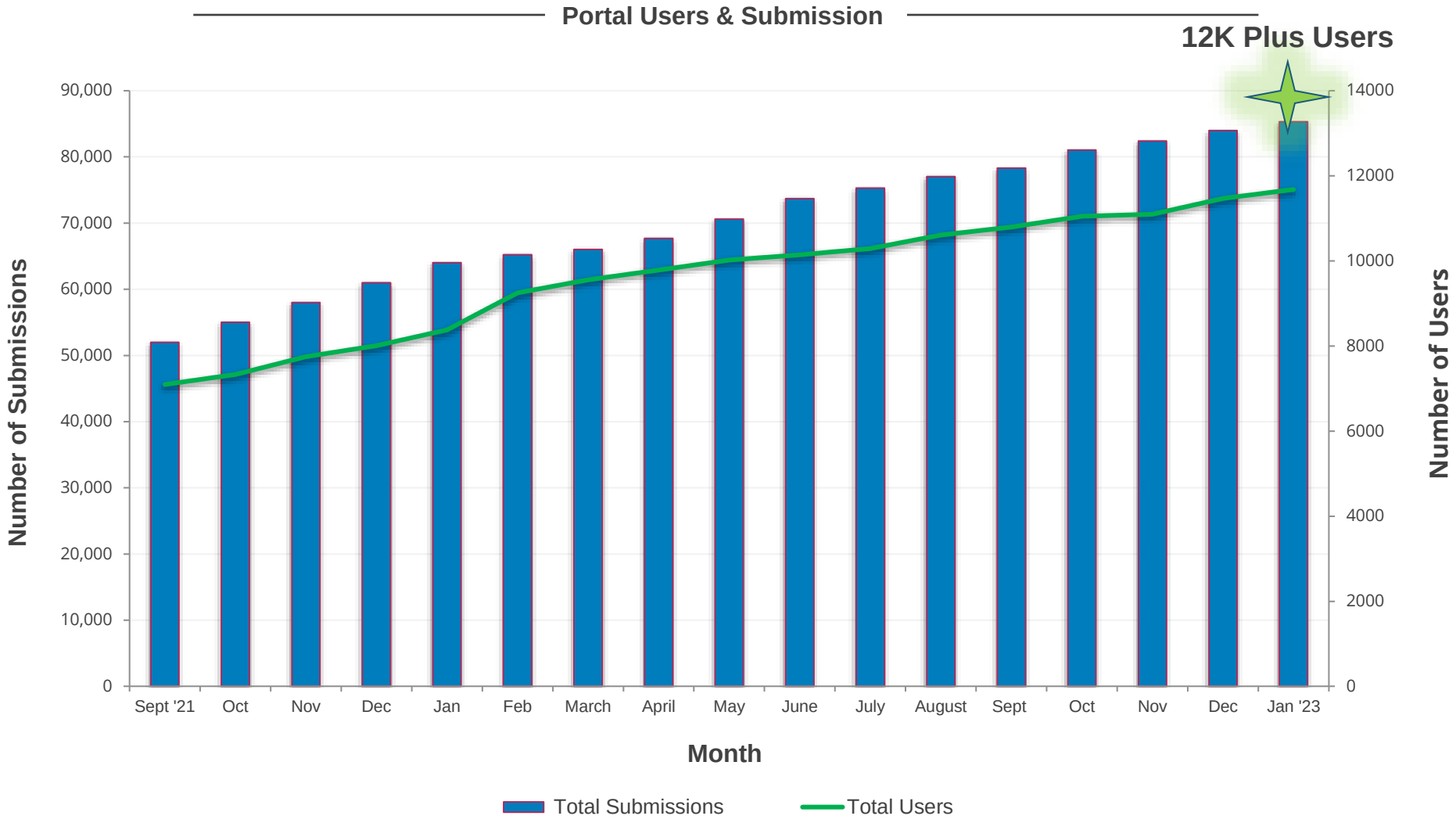


- Stakeholders be able to submit a PLAIRs in preparation for market launch within 60 days
- 2 way communication enabled for efficient collaboration (e.g. Information Request, Clarification, final response letter etc.)

FDA CDER NextGen Portal User Adoption

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



In Summary :

1) What is CDER NextGen Portal?

- One stop shop for the purpose of non-eCTD Submission, Collaboration and Reporting.

2) What's New?

- CARES Volume Act
- Controlled Correspondences
- Pre-ANDA Meeting Request (CPAM)
- Pre-Launch Activities Importation Requests (PLAIR)

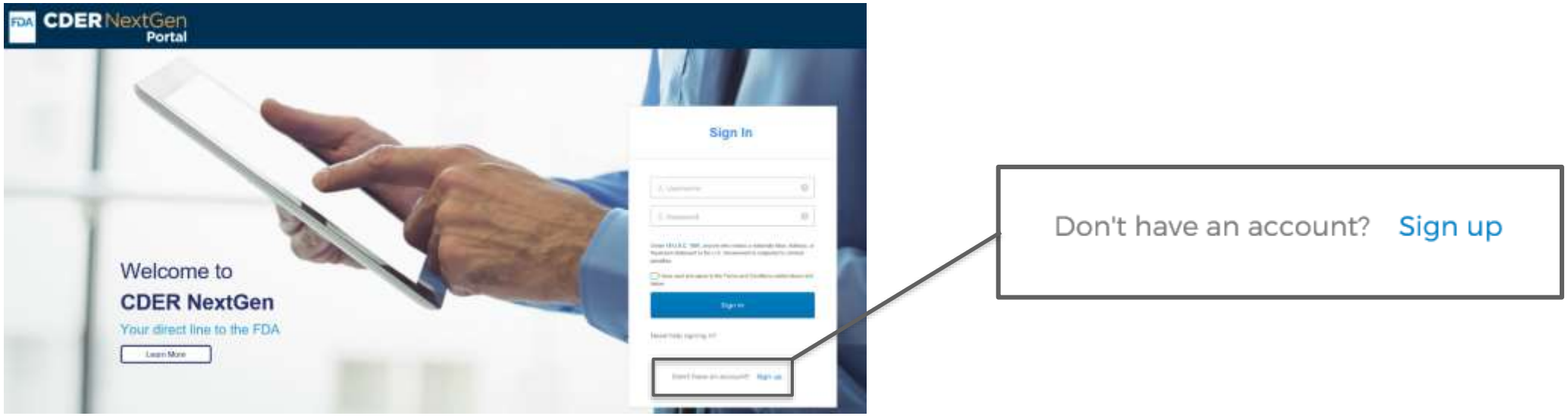
3) User Experience & Adoption

- Over 12k users & 100k plus submissions

How to Access NextGen Portal?

New Users

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



Thank You