



DIA

Regulatory Submissions, Information, and Document Management Forum

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FDA CDER NextGen Portal

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Agenda

FDA CDER NextGen Portal

Before and After NextGen Portal

Portal Products

What is New ?

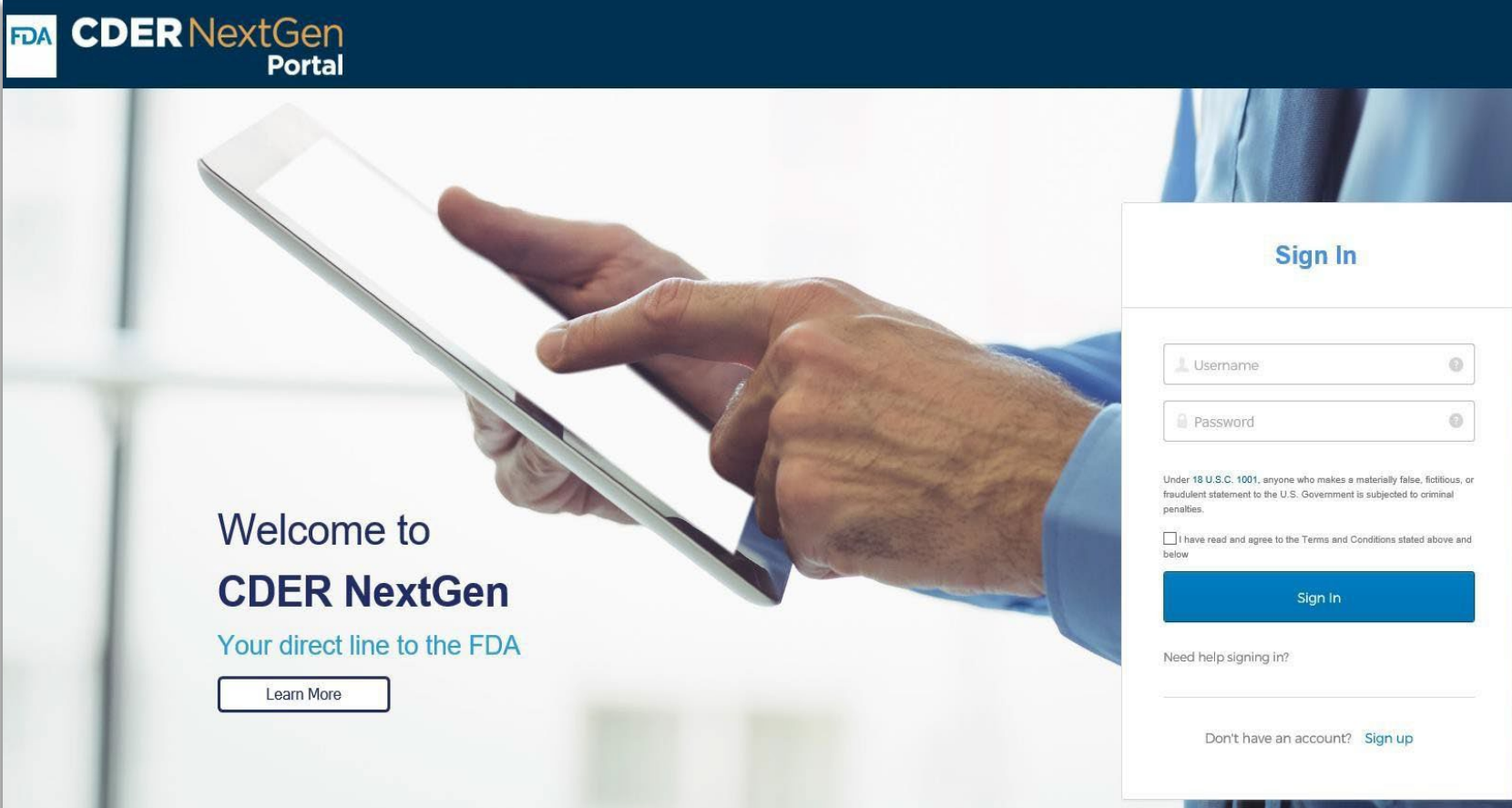
User's Adoption



FDA CDER NextGen Portal

One stop shop for the purpose of non-eCTD Submission, Collaboration and Reporting. This capability continues to reduce regulatory overhead for sponsors, academia, research institutes, and small businesses.



A banner for the FDA CDER NextGen Portal. It features a dark blue header with the FDA logo and "CDER NextGen Portal" text. The main image shows a person's hands holding a tablet. Text on the left says "Welcome to CDER NextGen" and "Your direct line to the FDA", with a "Learn More" button below. On the right is a "Sign In" form with fields for "Username" and "Password", a checkbox for terms and conditions, a "Sign In" button, and a "Sign up" link at the bottom.

Sign In

Username

Password

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subjected to criminal penalties.

☐ I have read and agree to the Terms and Conditions stated above and below

Sign In

Need help signing in?

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

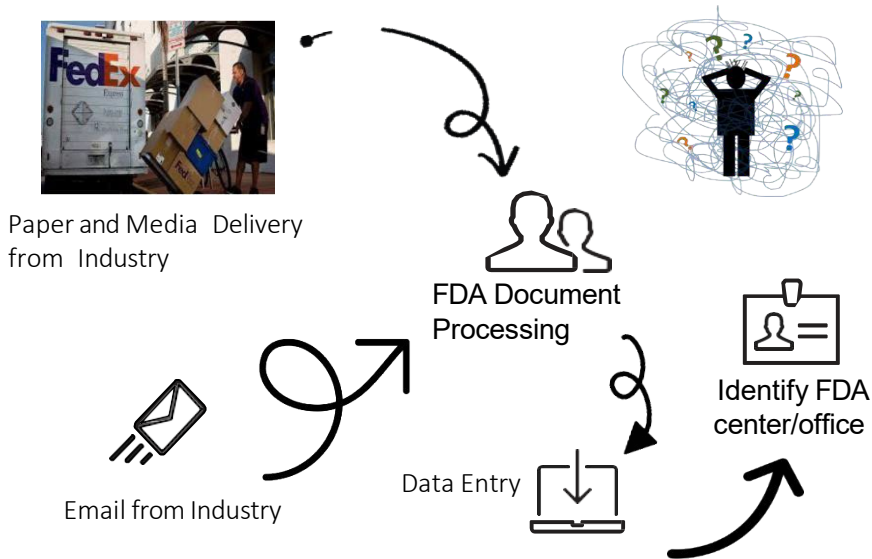


Digital Transformation

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



Before NextGen Portal



Inefficient paper and Media processing

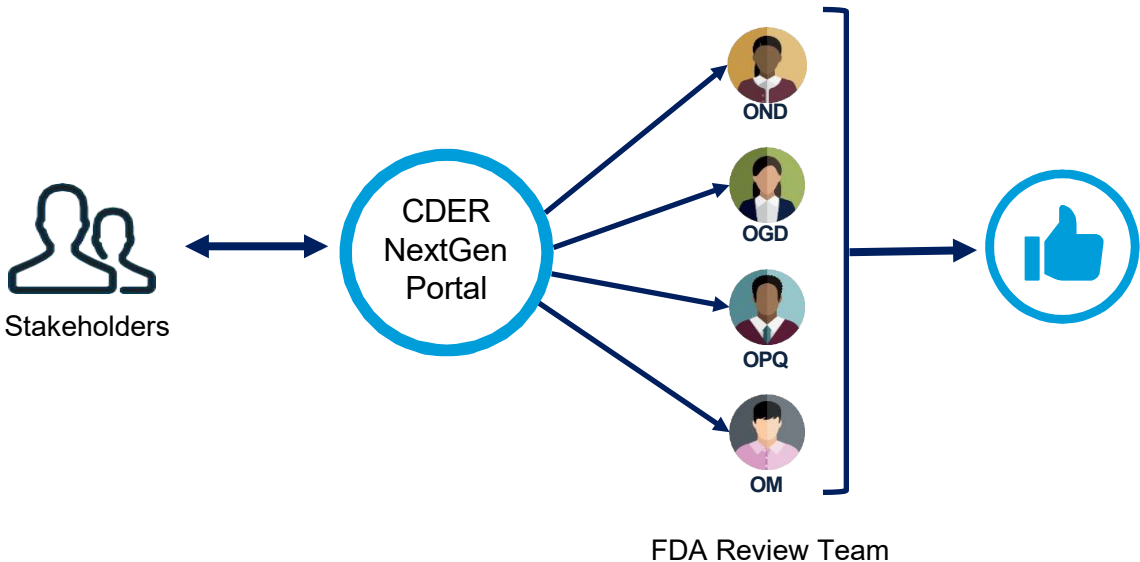


Manually intensive



Time and resource consuming

After NextGen Portal



Streamlined submissions with clean, complete, and validated data



Maximized API led technology to improve efficiency

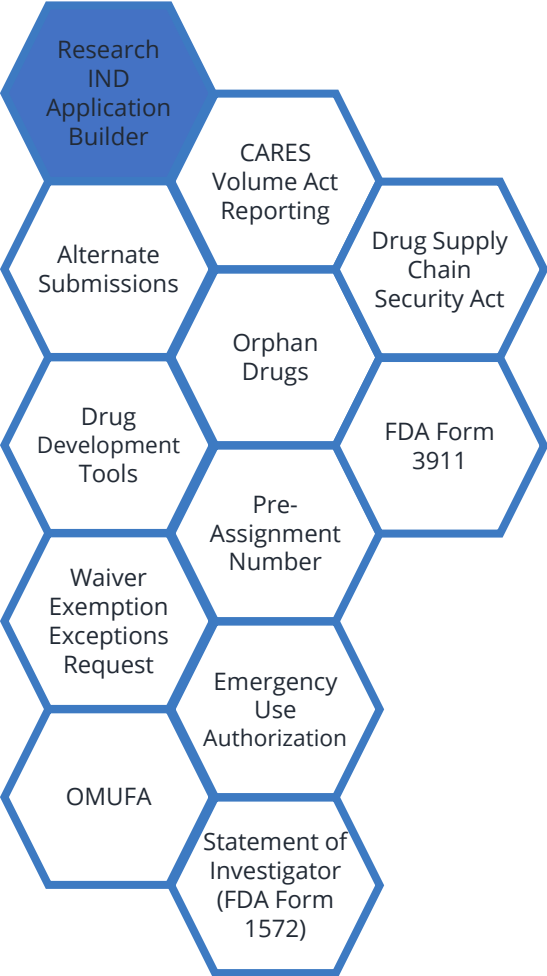


Improved collaboration between the FDA and Stakeholders

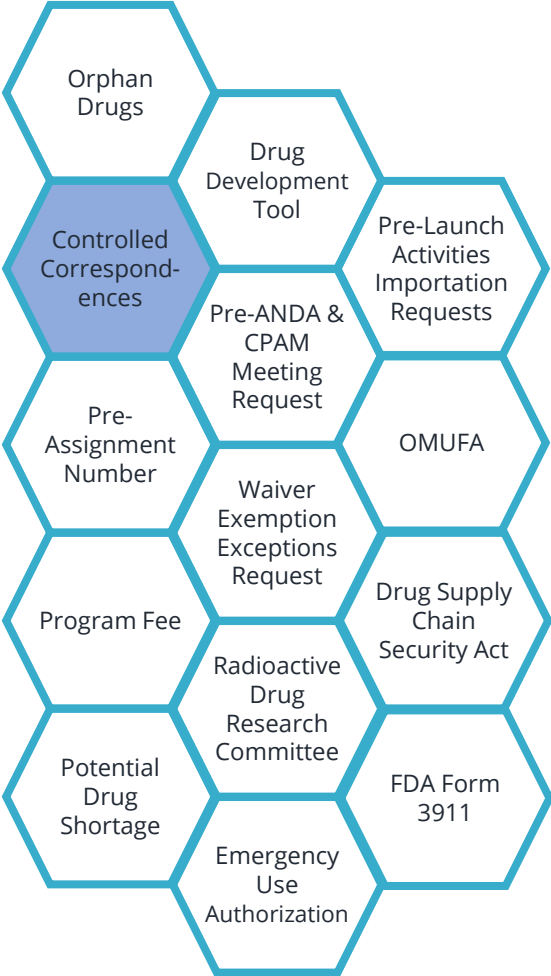
FDA CDER NextGen Portal Products



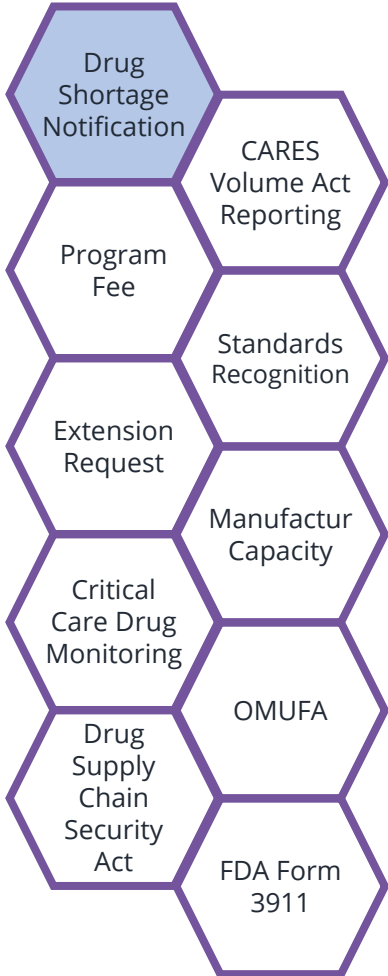
Regulatory Submissions



Streamlined Collaboration



Congressional Reporting



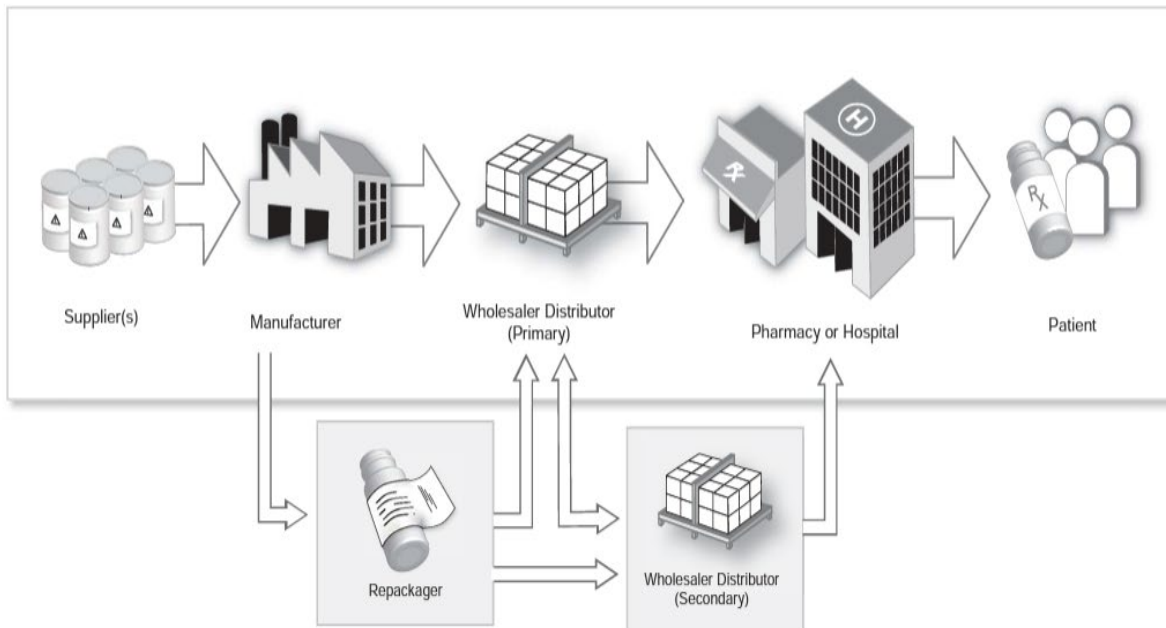
What is New ?...Coming Soon



Drug Supply Chain Security Act (DSCSA) Portal

Steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated, or otherwise harmful.

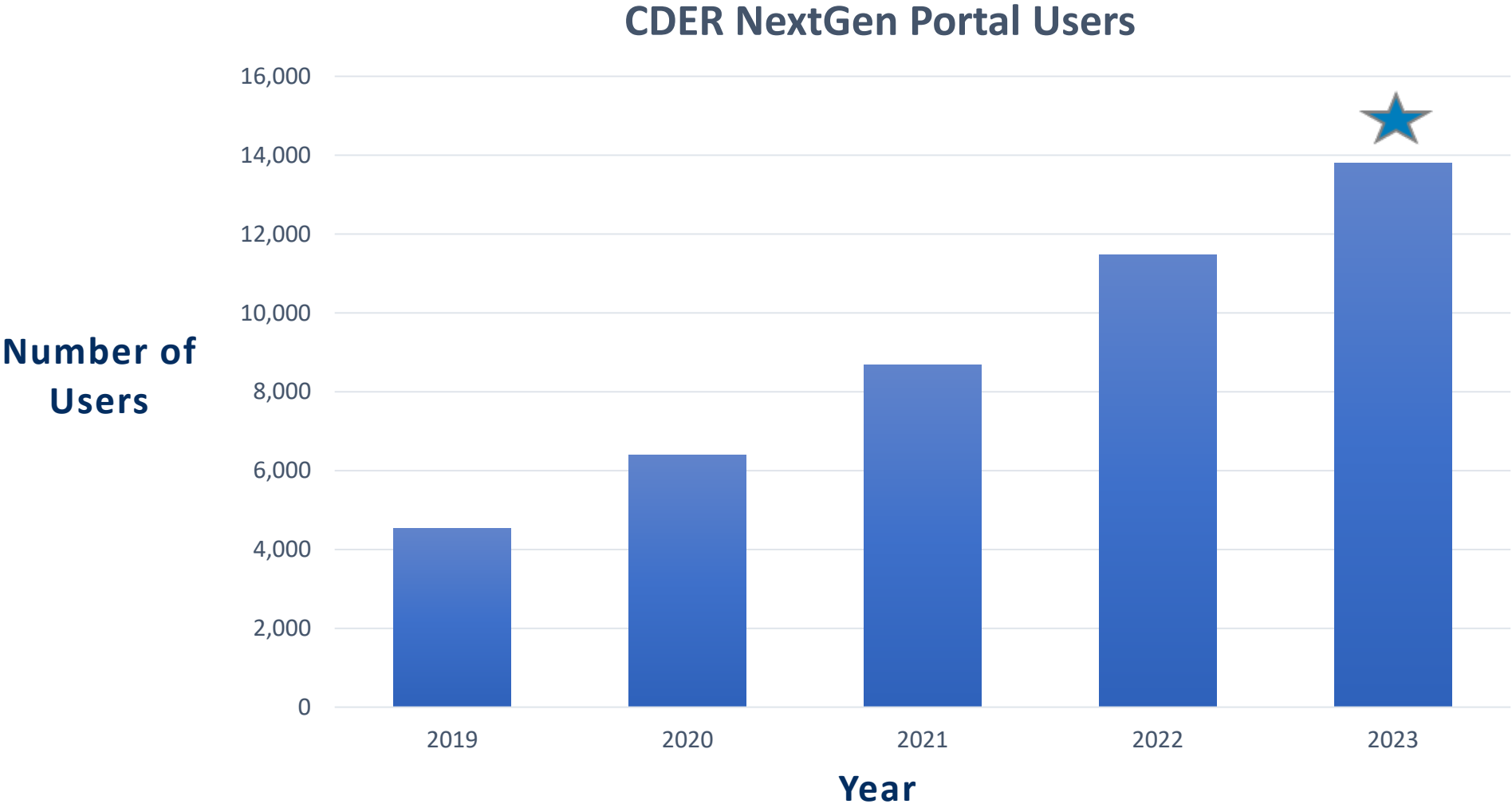
A Drug Supply Chain Example From Supplier to Patient



Established 2 Way collaboration capability for reporting and respond to inquires such as :

- Transaction Information (TI)
- Transaction Statement (TS)
- Information Request (IR)

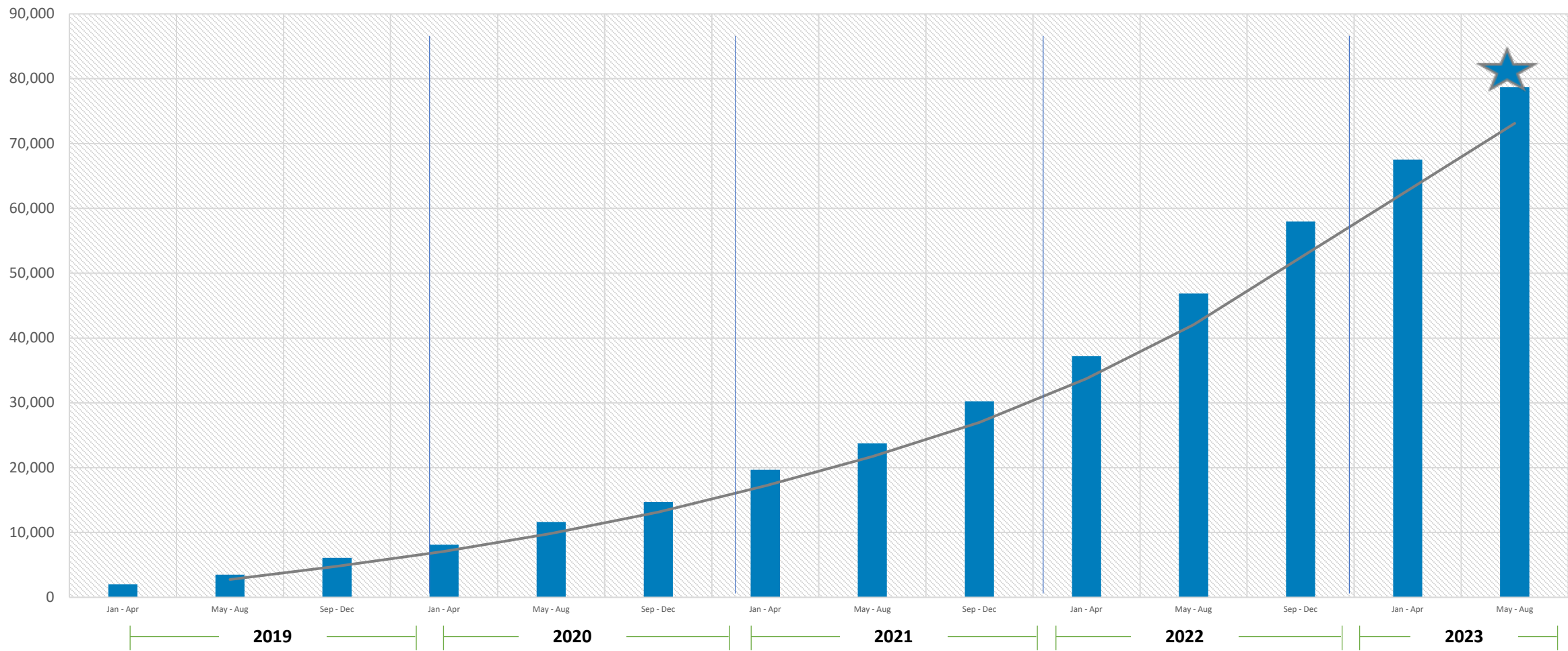
NextGen Portal Users adoption the last 5 years



Number of Submissions



CDER NextGen Portal Submissions



Need Support ?

- The following support materials can help you get started

Research IND Application Builder User Guides

<https://cdernextgenportal.fda.gov/s/indhelppcenterinfo>

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



Thank You !!



Questions?

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