DIA

Regulatory Submissions, Information, and Document Management Forum

February 12-14

North Bethesda, MD

FDA CDER NextGen Portal

Seyoum Senay, Program Manager, CDER/OSP/OBI

DIA

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter and should not be attributed to DIA, its directors, officers, employees, volunteers, members, chapters, councils, Communities or affiliates.

This presentation is incomplete without accompanying verbal commentary.

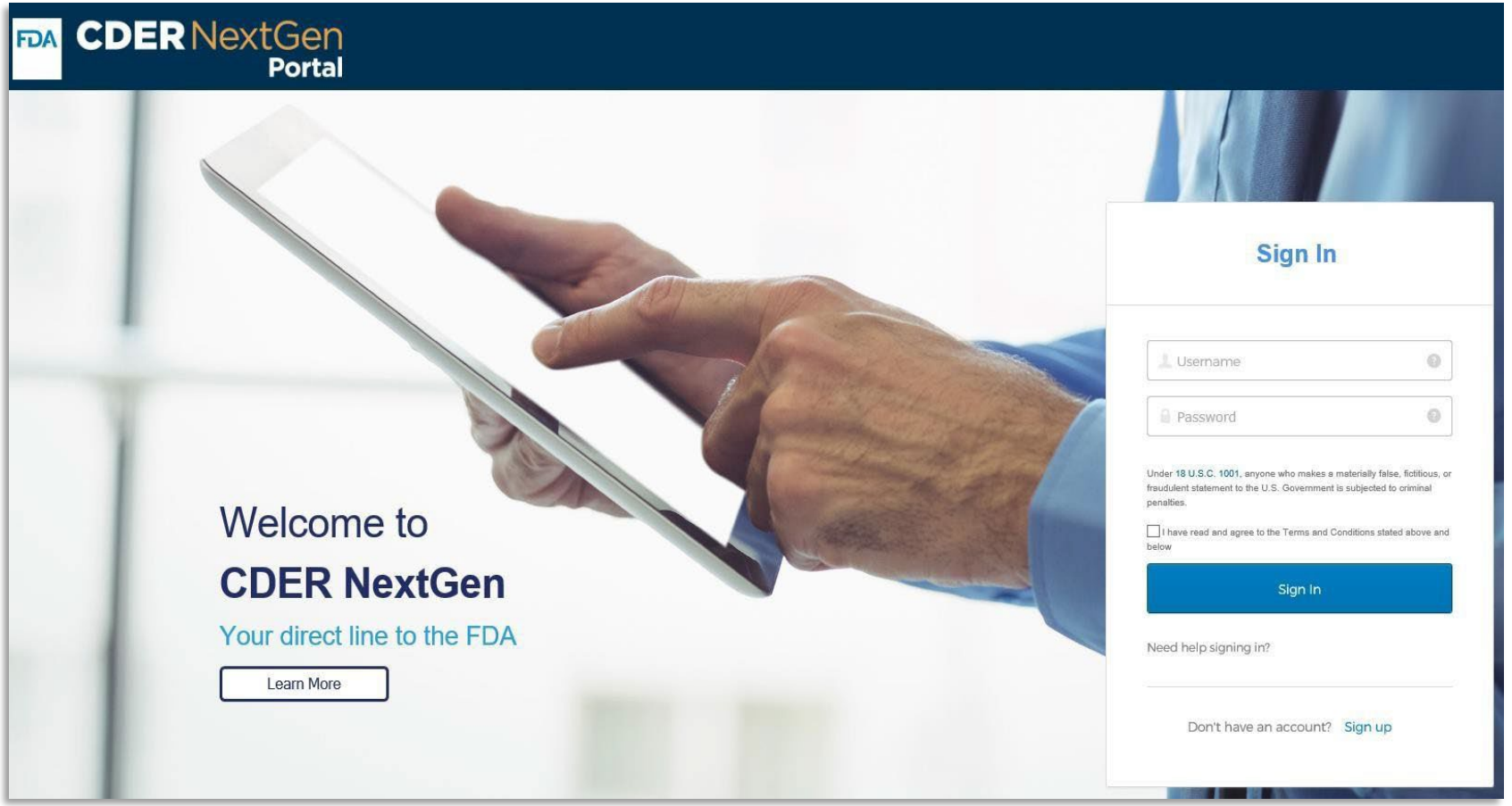
Disclaimer

The views and opinions presented here represent those of the speakers and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.

Agenda

FDA CDER NextGen Portal

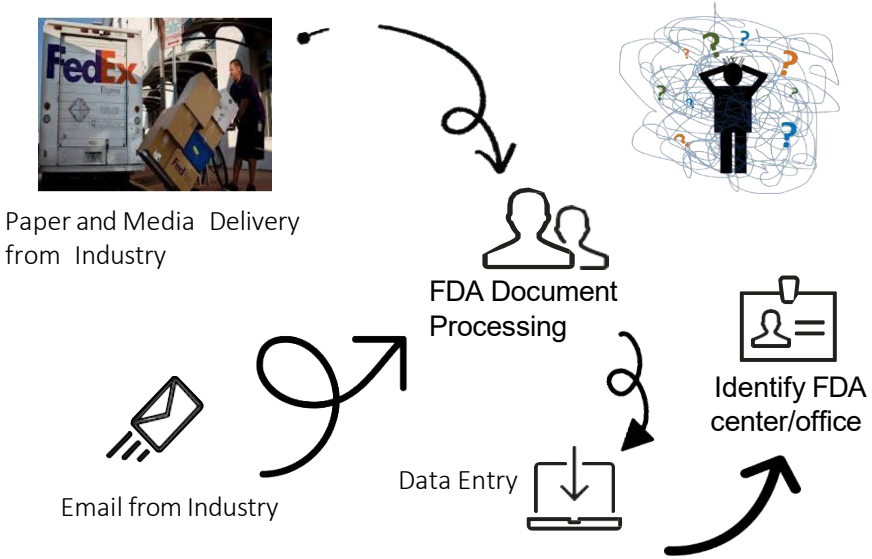
One stop shop for the purpose of non-eCTD Submission, Collaboration and Reporting. This capability continues to reduce regulatory overhead for sponsors, academia, research institutes, and small businesses.



Digital Transformation

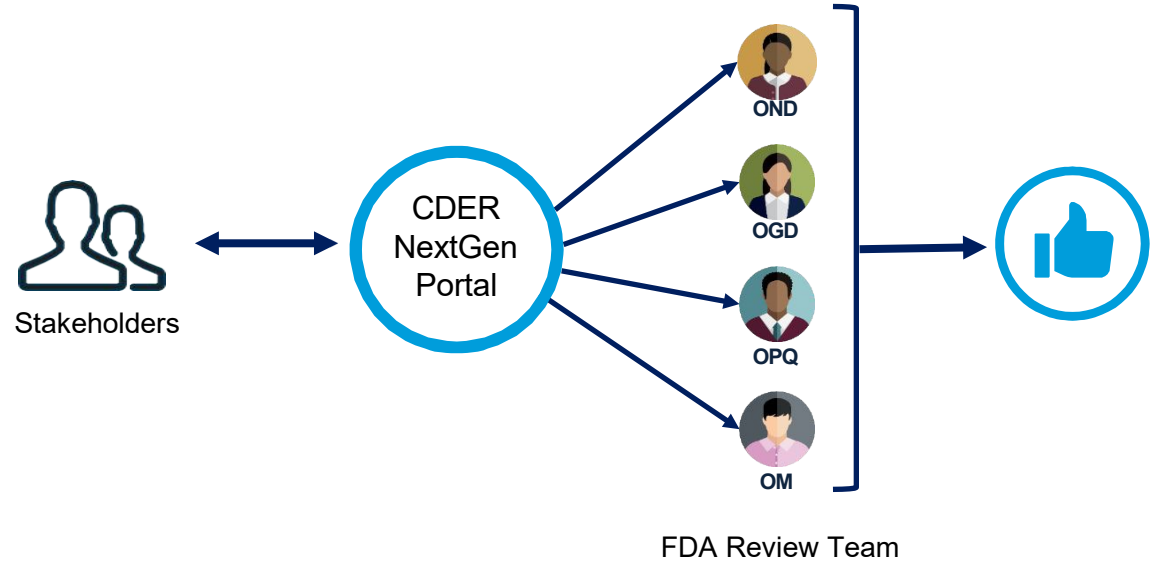
In action to promote safe and effective human drug review and approval

Before NextGen Portal



Digital Transformation

After NextGen Portal

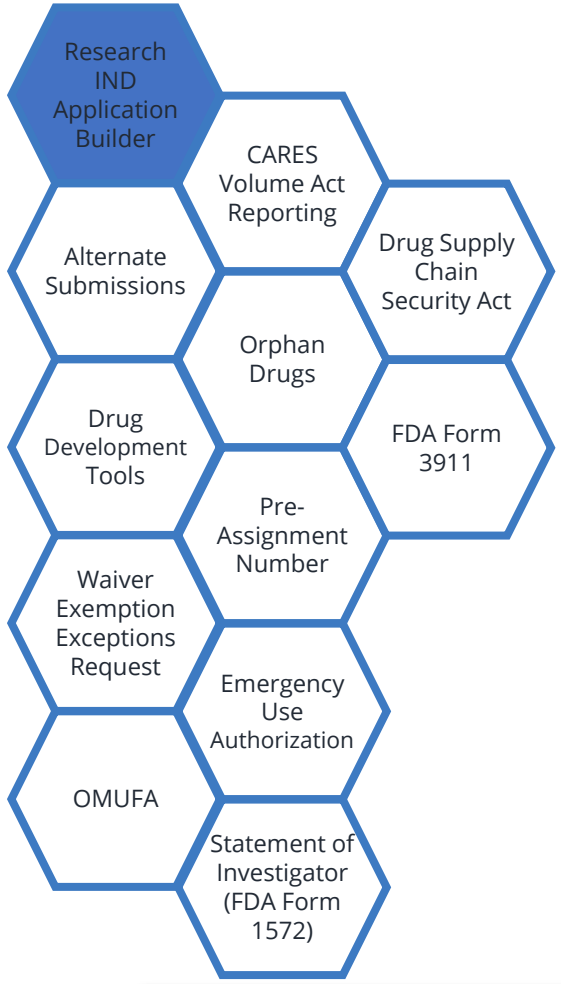


- Inefficient paper and Media processing
- Manually intensive
- Time and resource consuming

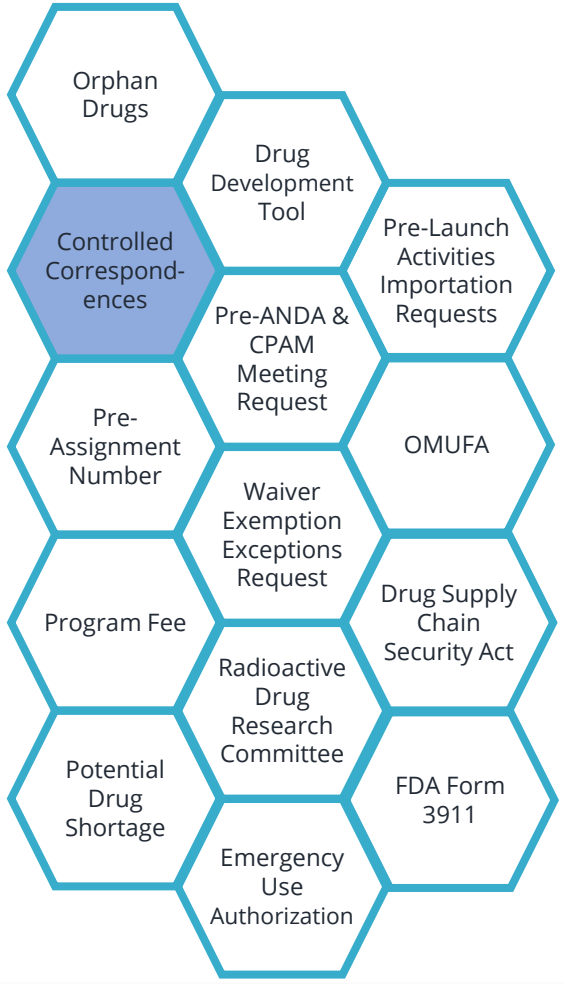
- Streamlined submissions with clean, complete, and validated data
- Maximized API led technology to improve efficiency
- Improved collaboration between the FDA and Stakeholders

FDA CDER NextGen Portal Products

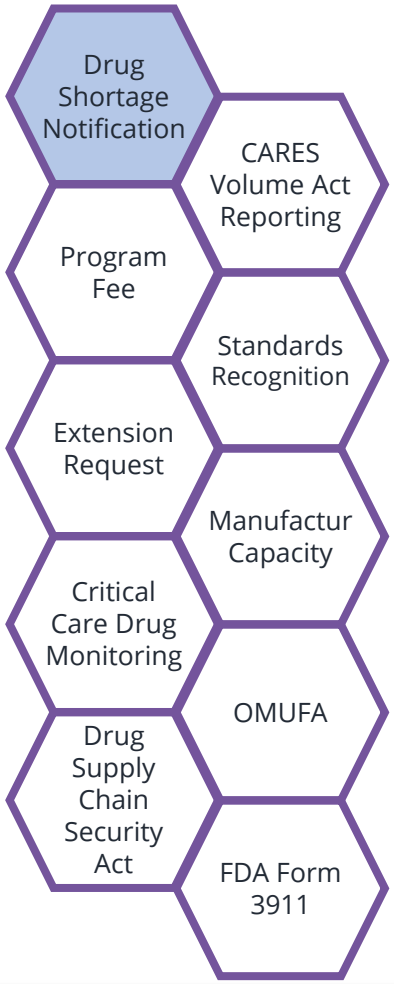
Regulatory Submissions



Streamlined Collaboration



Congressional Reporting

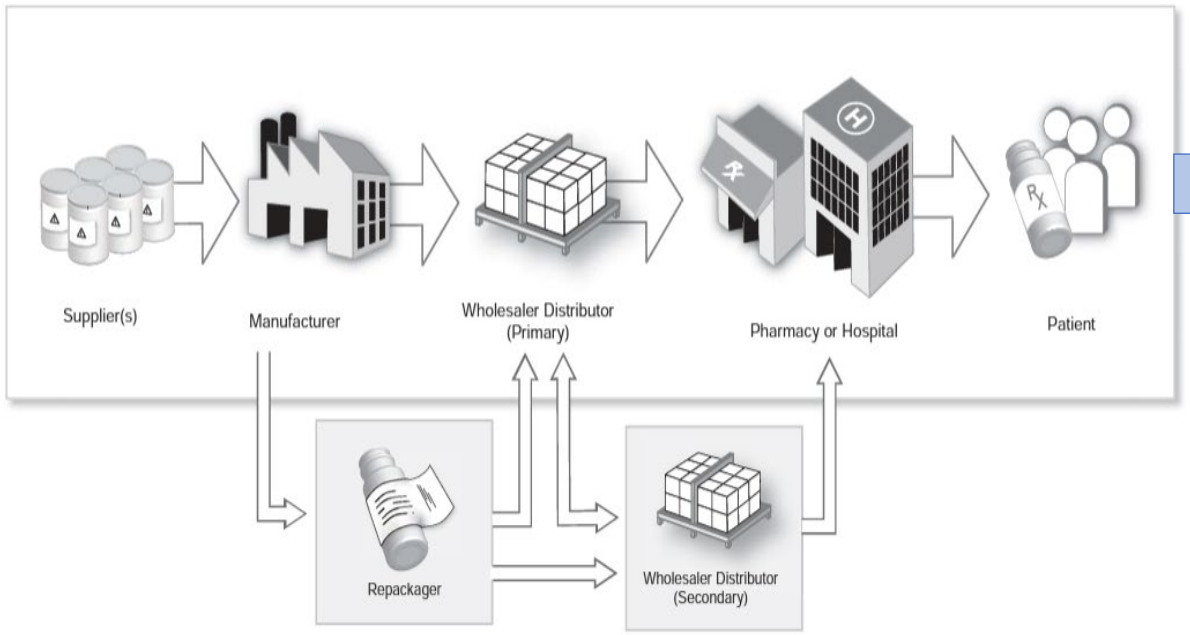


FDA CDER Offices : OND, OGD, OPQ, OMP, OC, OM, OTC

What is New ?…Coming Soon

Drug Supply Chain Security Act (DSCSA) Portal

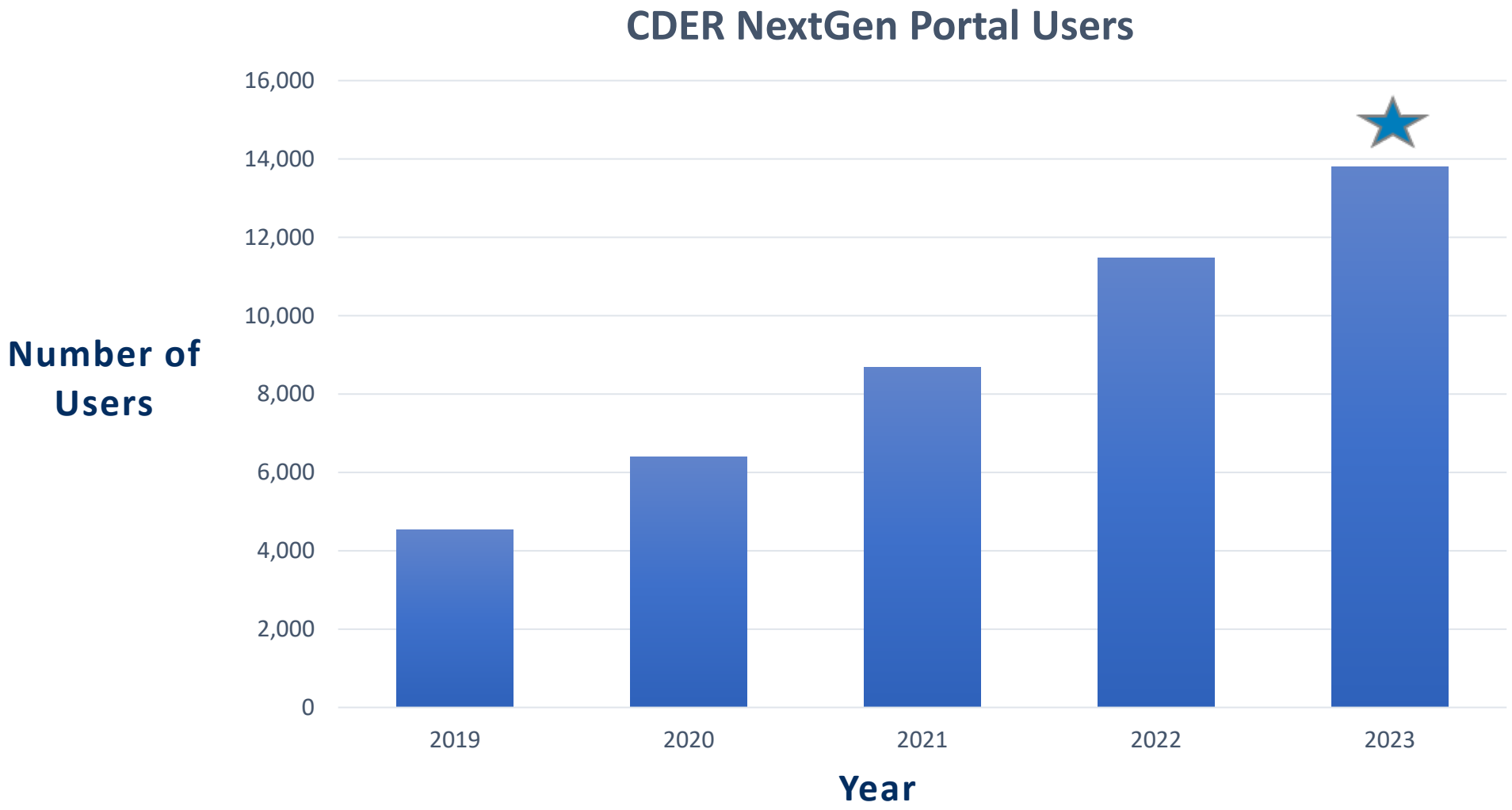
Steps to achieve interoperable, electronic tracing of products at the package level to identify and trace certain prescription drugs as they are distributed in the United States. This will enhance FDA's ability to help protect consumers from exposure to drugs that may be counterfeit, stolen, contaminated,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



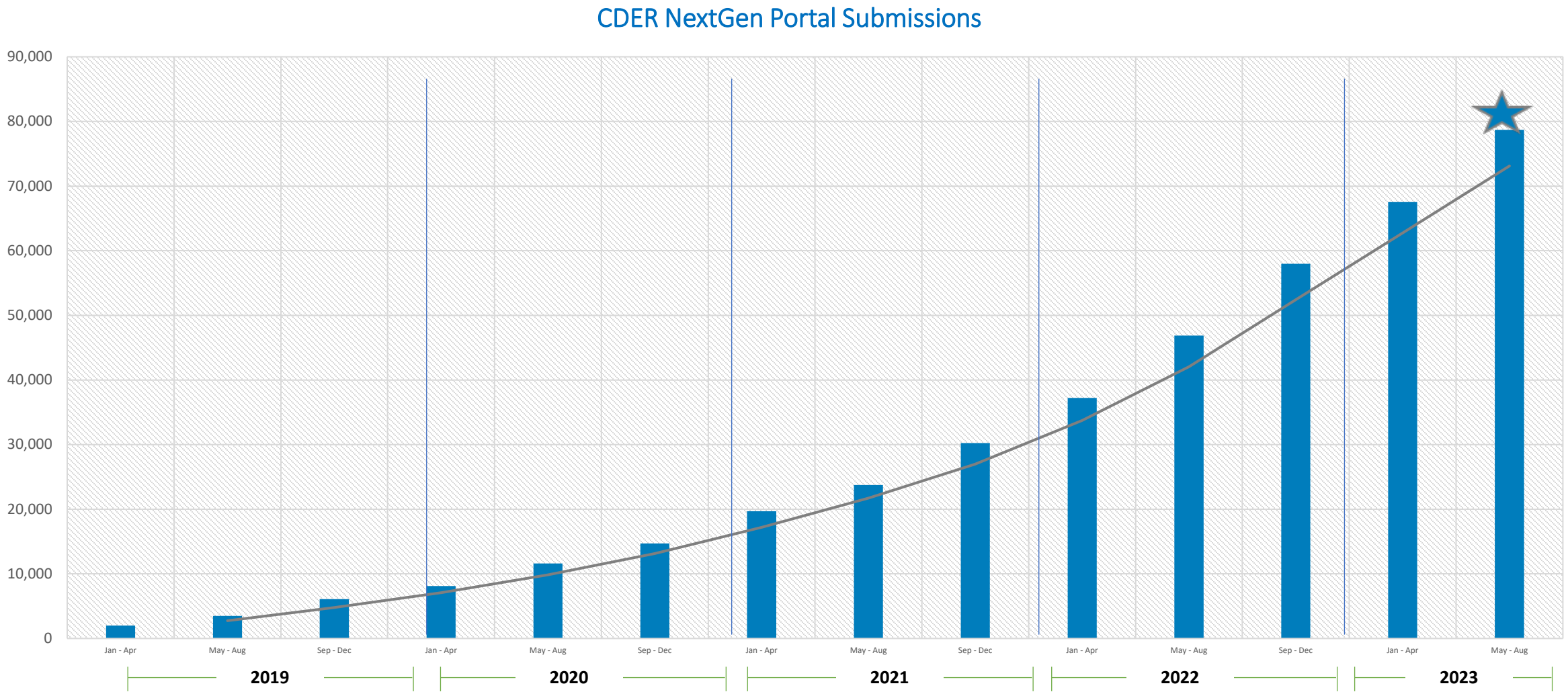
Established 2 Way collaboration capability for reporting and respond to inquires such as :

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

NextGen Portal Users adoption the last 5 years



Number of Submissions



Need Support ?

- The following support materials can help you get started

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

Thank You !!

Questions?