FDA CDER NextGen Portal

Regulatory Education for Industry (REdI) Annual Conference 2024: Innovation in Medical Product Development

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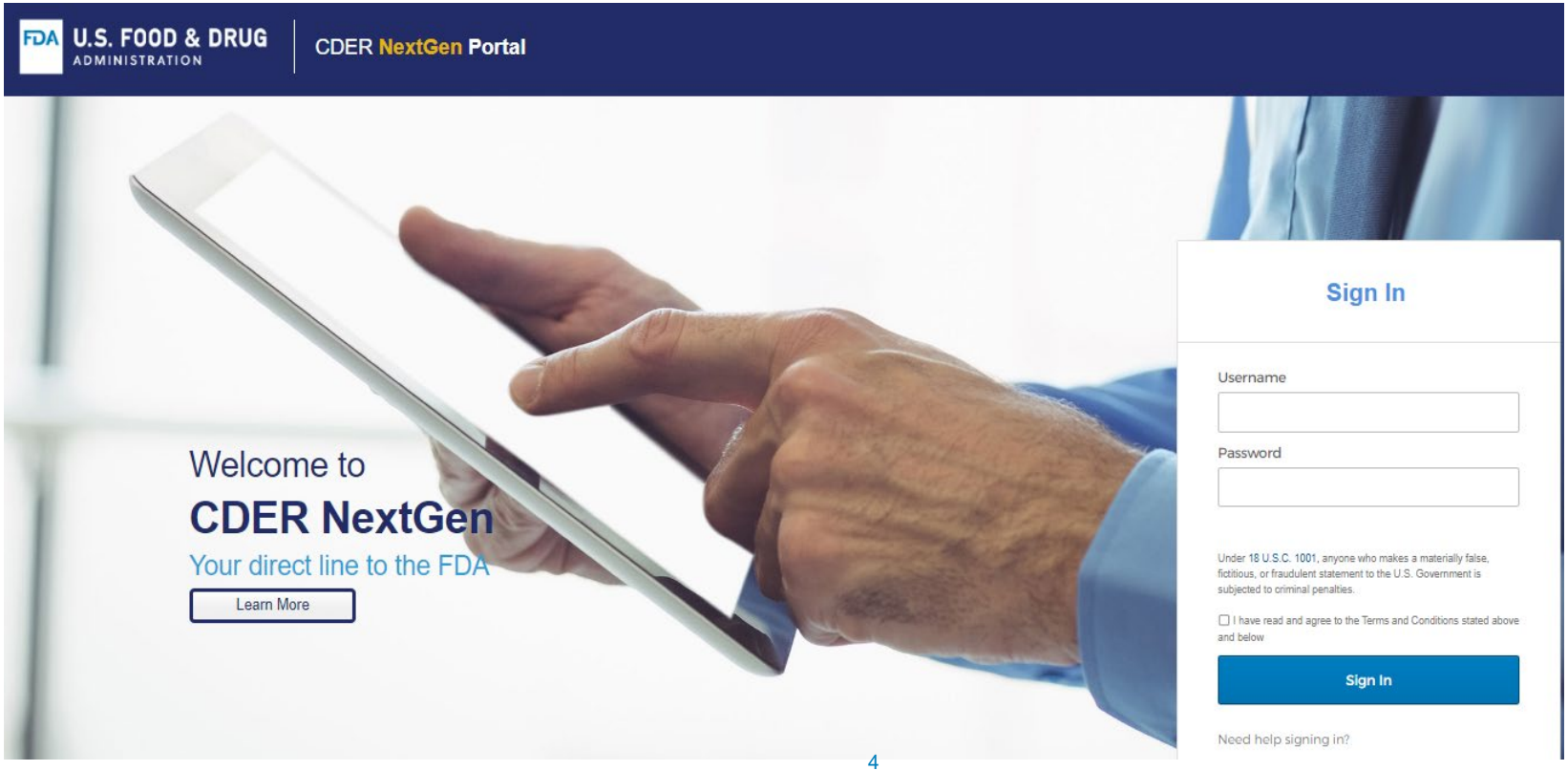
Disclaimer

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

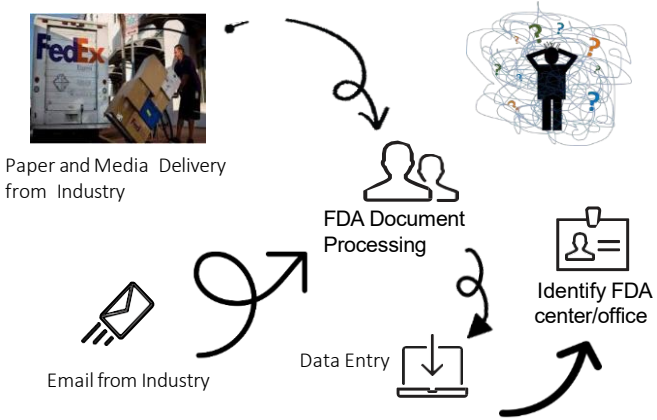
One stop shop for the purpose of non-eCTD Submission, Collaboration and Reporting. This platform continues to reduce regulatory overhead for sponsors, academia, research institutes, and small businesses.



Digital Transformation

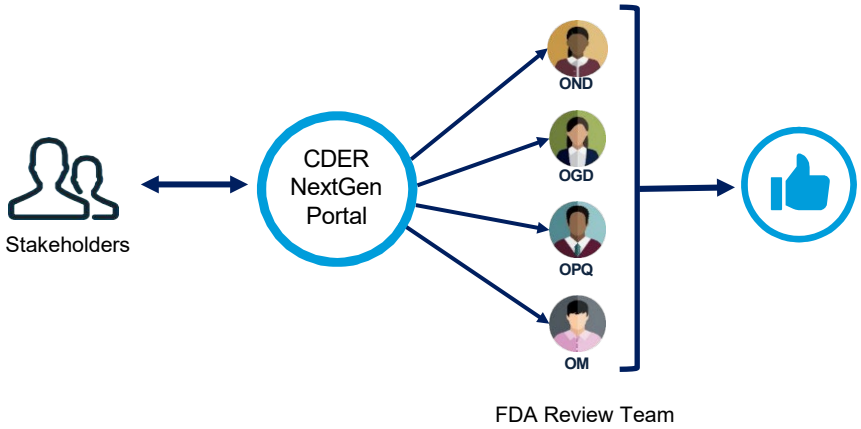
In action to promote safe and effective human drug review and approval

Before NextGen Portal



Digital Transformation

After NextGen Portal

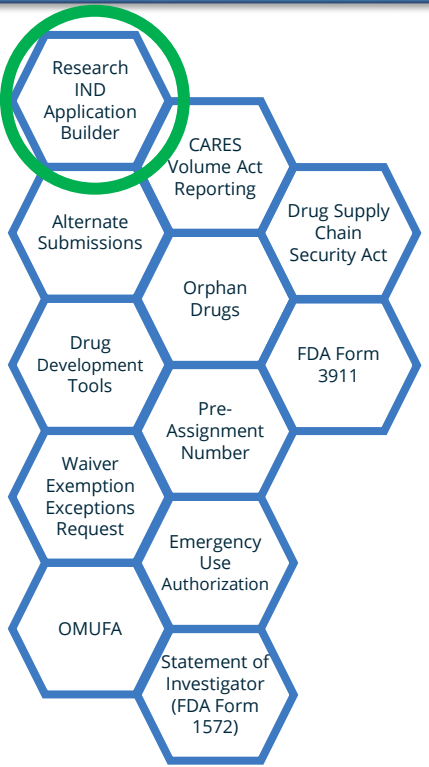


- Inefficient paper and Media processing
- Manually intensive
- Time and resource consuming

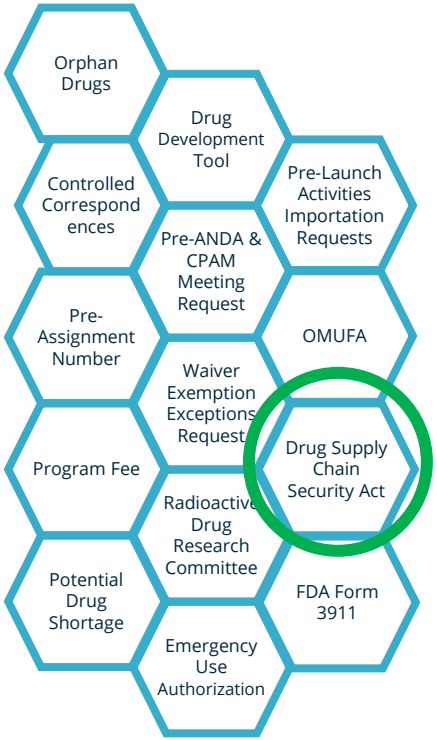
- Streamlined submissions with clean, complete, and validated data
- Maximized API led technology to improve efficiency
- Improved collaboration between the FDA and Stakeholders

FDA CDER NextGen Portal Products

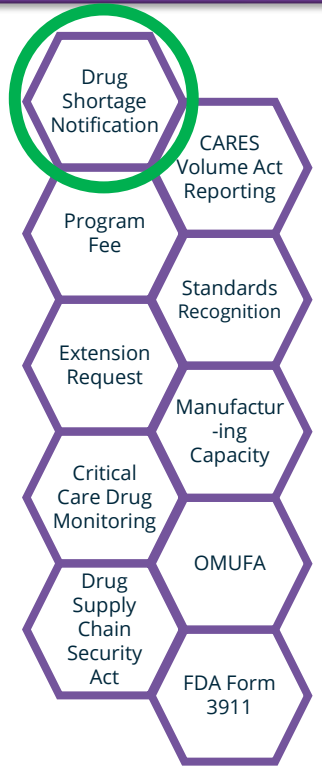
Regulatory Submissions



Streamlined Collaboration



Congressional Reporting



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

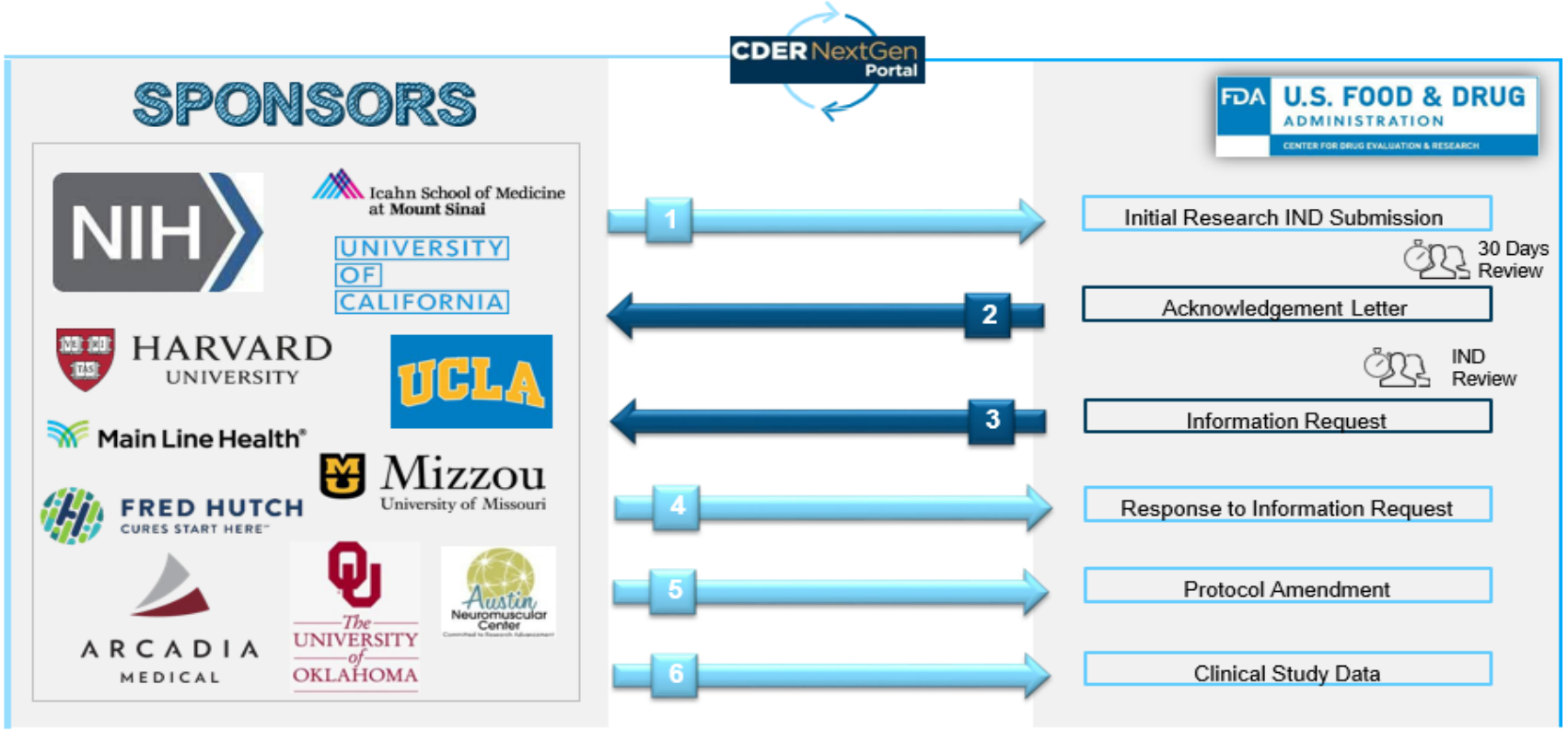
Study Details
- **NCT Number**: 000032344

Make a Research IND Submission in less than 10 Steps

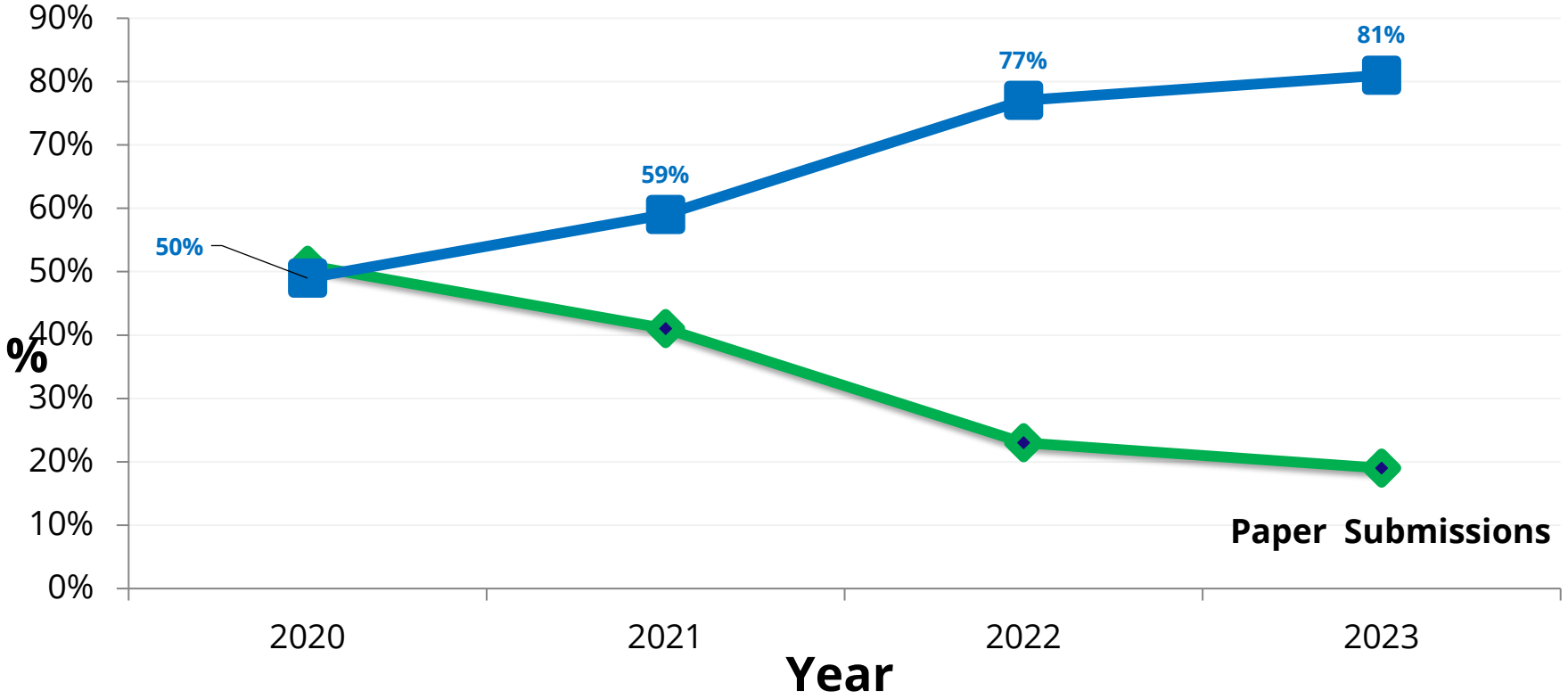
1. Register for Account
2. Login to Portal
3. Enter Validated Information
4. Upload Documents
5. Generate 1571 Form
6. Digitally Sign Form
7. Download Application Materials
8. Submit IND Application

Near Real-Time 2 Way Interactions

Enabling FDA CDER Reviewer and the Sponsor collaboration



Research IND Submissions : CDER NextGen Portal Vs Paper

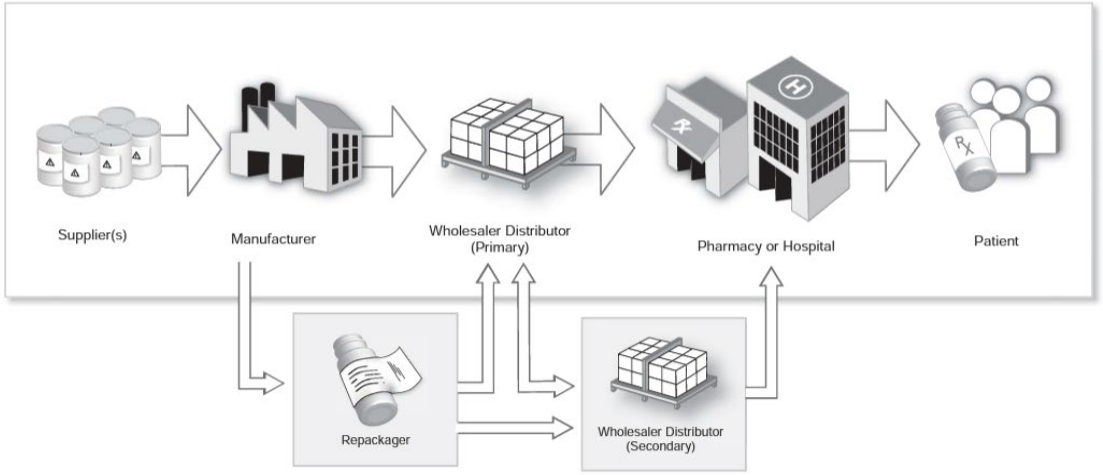


What is New ?…

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 near real time 2-way interactions for reporting and respond to inquires such as :

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

Drug Shortage Modernization Overview and Impact

The Drug Shortage Modernization solution is ***critical to ensuring drugs are available for the American public***

Overview

- Section 3112 of the CARES Act amends the Federal, Food, Drug and Cosmetic Act Section 506 and requires FDA to prioritize and expedite reviews and inspections for submissions that could help mitigate or prevent shortages.
- Drug shortage Notification can be submitted in multiple ways such as:
  - Industry Drug Shortage Notification Portal - Safety and Innovation Act (FDASIA) mandate
  - Public Drug Shortage Portal – E.g patients, caregivers, and healthcare providers

Impact

Reduce manual processes

Improved Capability
Reduce time intensive manual processes and ensure information is in a centralized location

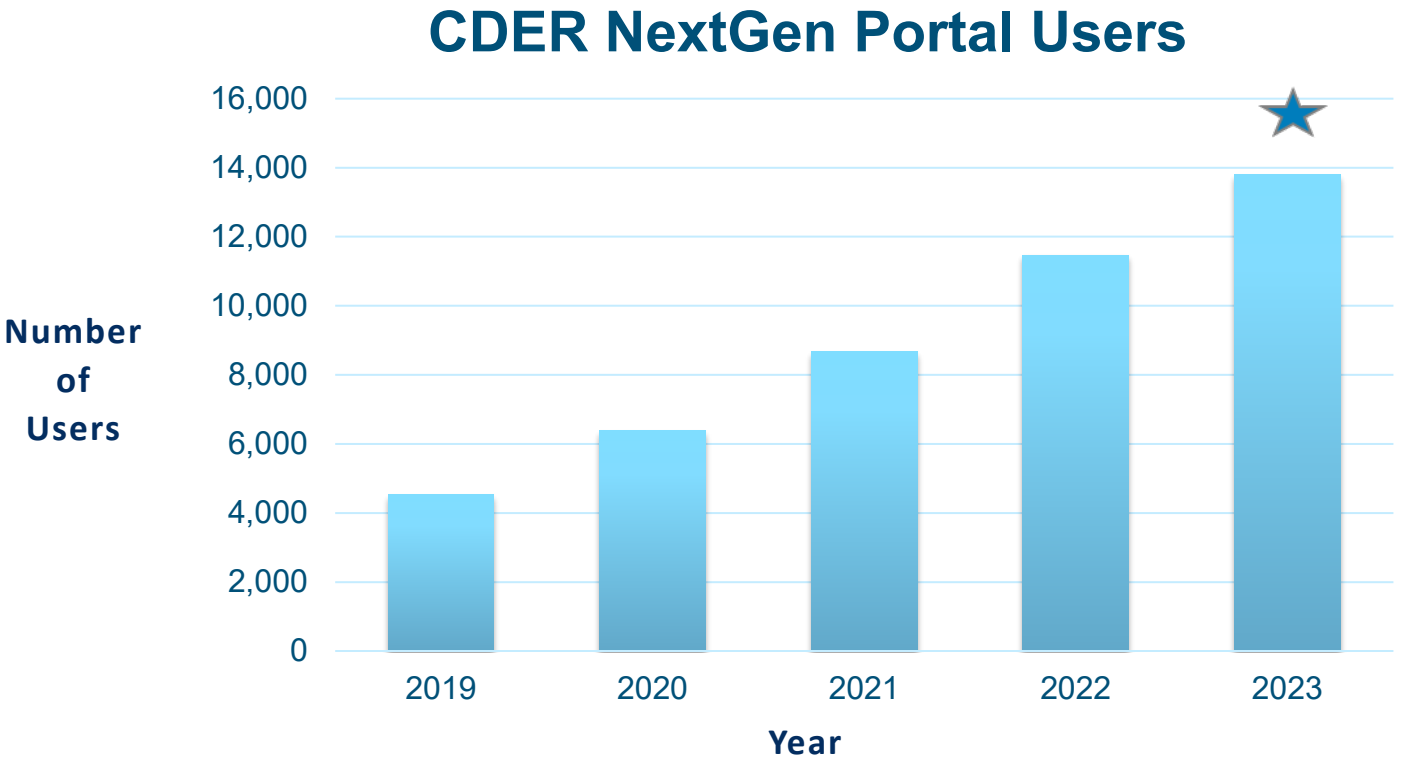
Enhanced data quality

Validate Data
Validate data coming through the systems (e.g,., NDC code lookup) and keep historical tracking of records in a centralized location

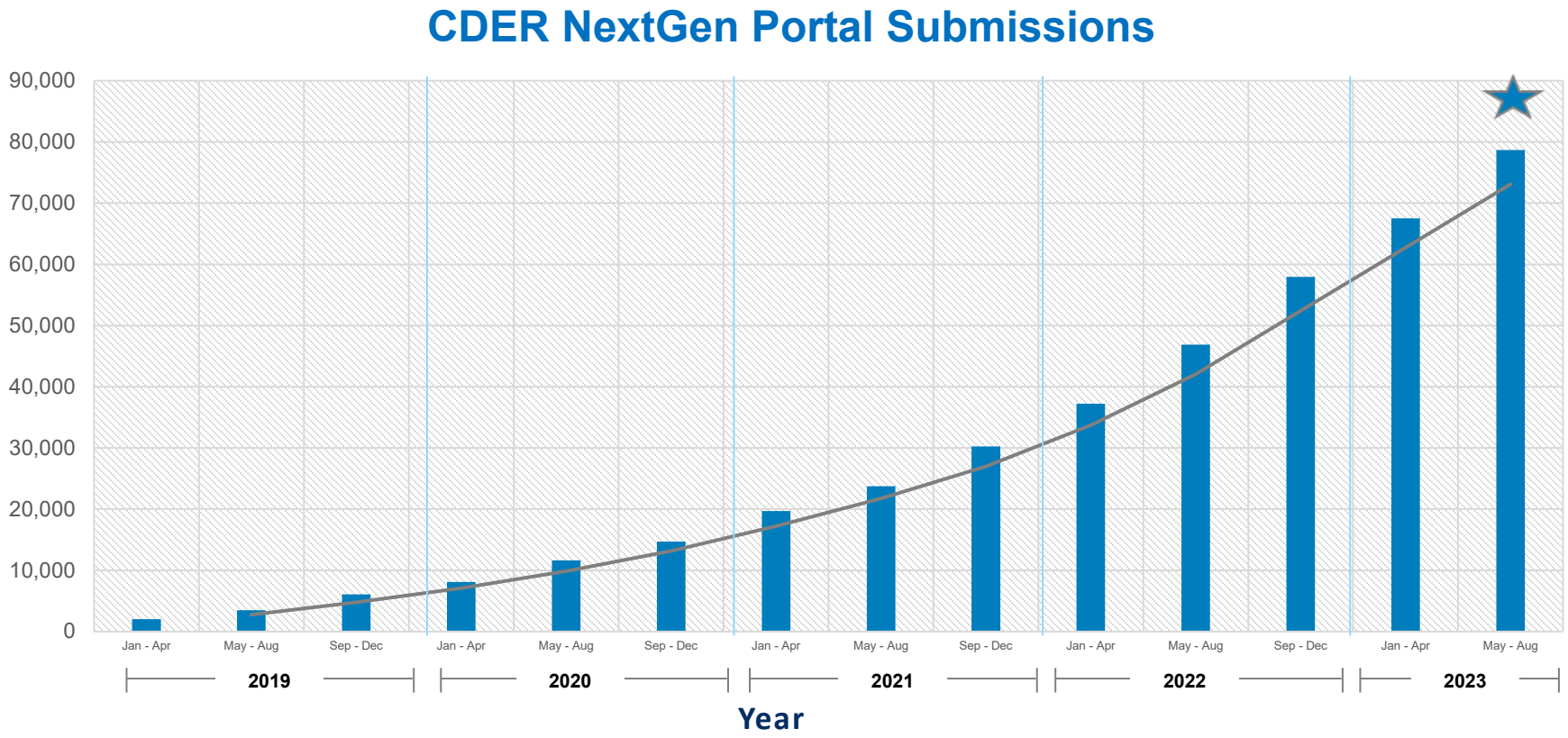
Business Transformation

Improved Supply Chain
Accurate and recent data are posted on the drug shortage website.

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 !!