

The logo for the U.S. Food & Drug Administration, consisting of the letters 'FDA' in white on a black square background.

**U.S. FOOD & DRUG
ADMINISTRATION**

PRE-ASSIGNMENT PORTAL

Modernizing interactions between CDER and industry

Association for Accessible Medicines

GRx + Biosims 2019

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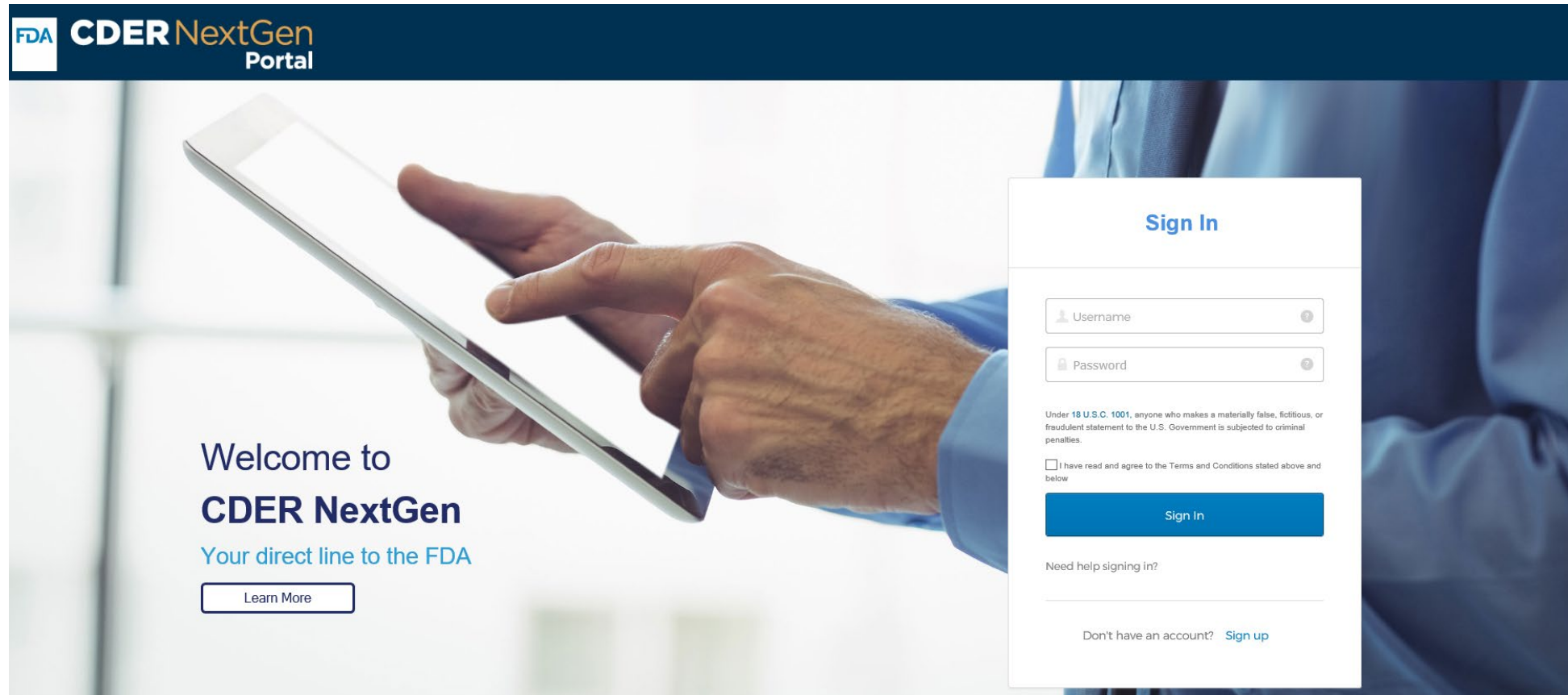
*Food and Drug Administration
Center for Drug Evaluation and Research
Office of Business Informatics*

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www.fda.gov

WHAT IS THE PORTAL?

The CDER Direct NextGen **Collaboration Portal** is a **cloud-based** system that has enabled a transformation in the way CDER and industry work together.



HOW HAS IT IMPROVED COMMUNICATIONS BETWEEN CDER AND INDUSTRY?



The Portal is an evolution for **efficiency** in our communications. It's an enabling technology that paves the way for significant improvements in the regulatory process.



Reduced administrative overhead on companies



Increased automation of data validation checks



Centralized and coherent view of complex interactions

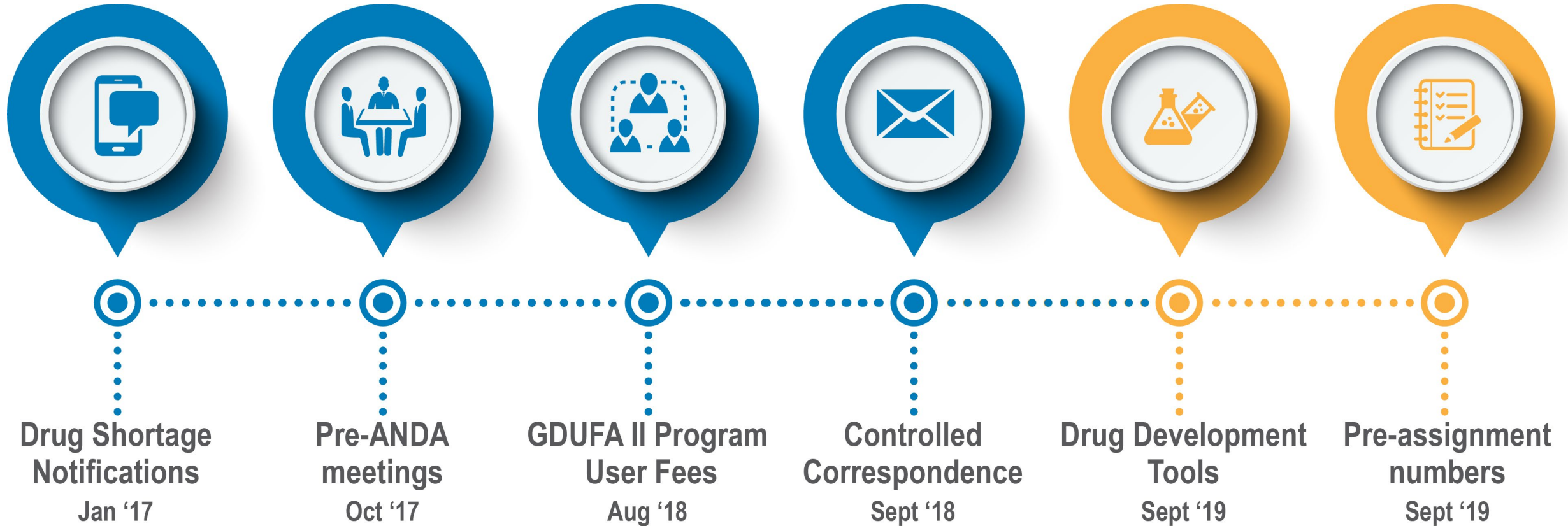


Simplified tracking for CDER personnel



Multi-factor Authentication

WHAT HAVE WE ALREADY DONE, AND WHAT IS NEW?



WHY DID WE MOVE THE PRE-ASSIGNMENT PROCESS TO THE PORTAL?

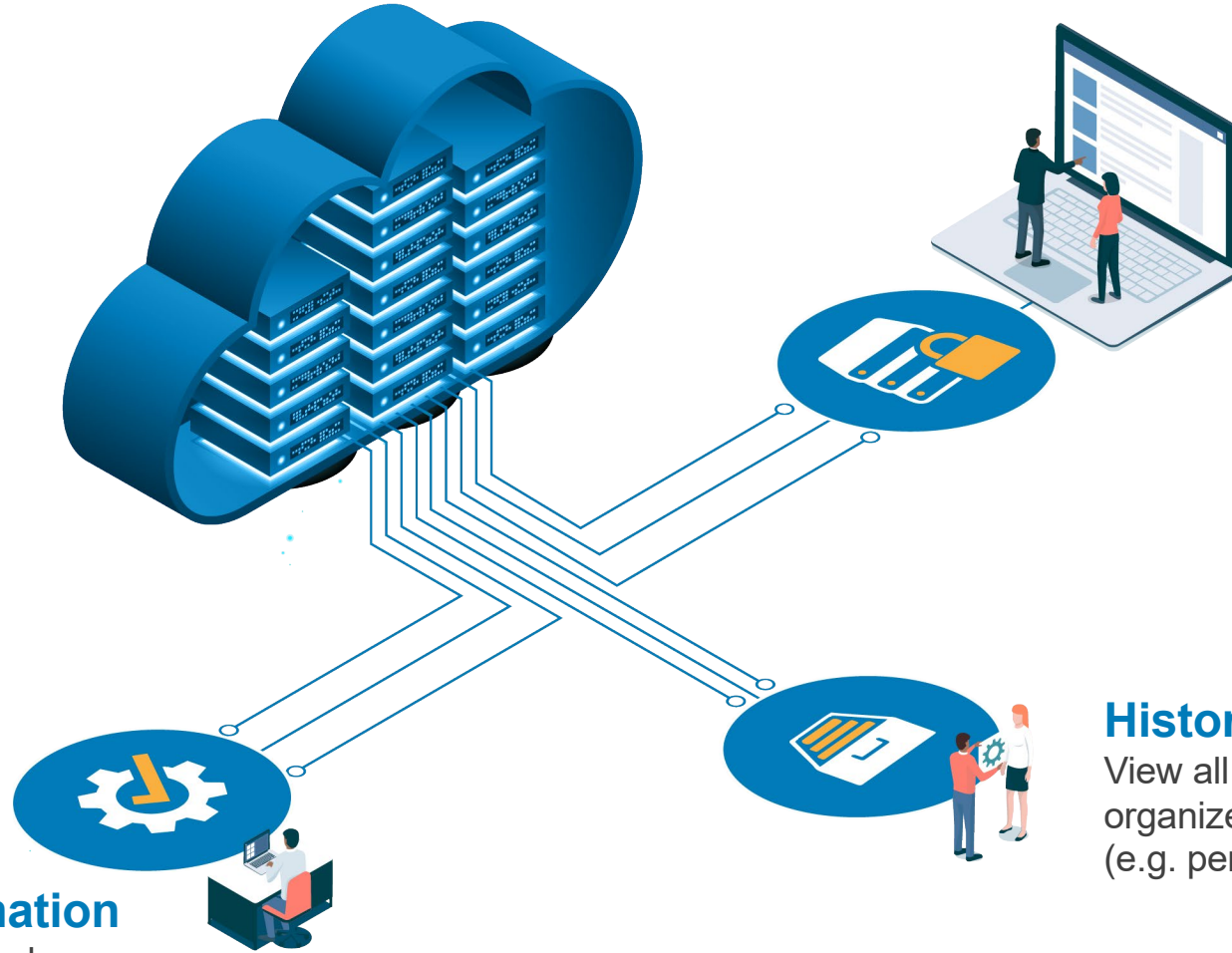


Pre-assignment number requests were previously only made via email in a process that could take up to three days



Today the Portal **streamlines** this process and a pre-assignment number is now received within only a **few hours**

WHAT ARE THE BENEFITS?



Automated Confirmation

Log in, initiate a request, and receive an automated confirmation of your requests

Secure and Easy to Use

Requesting via the Portal is secure and all information regarding your requests is in one place

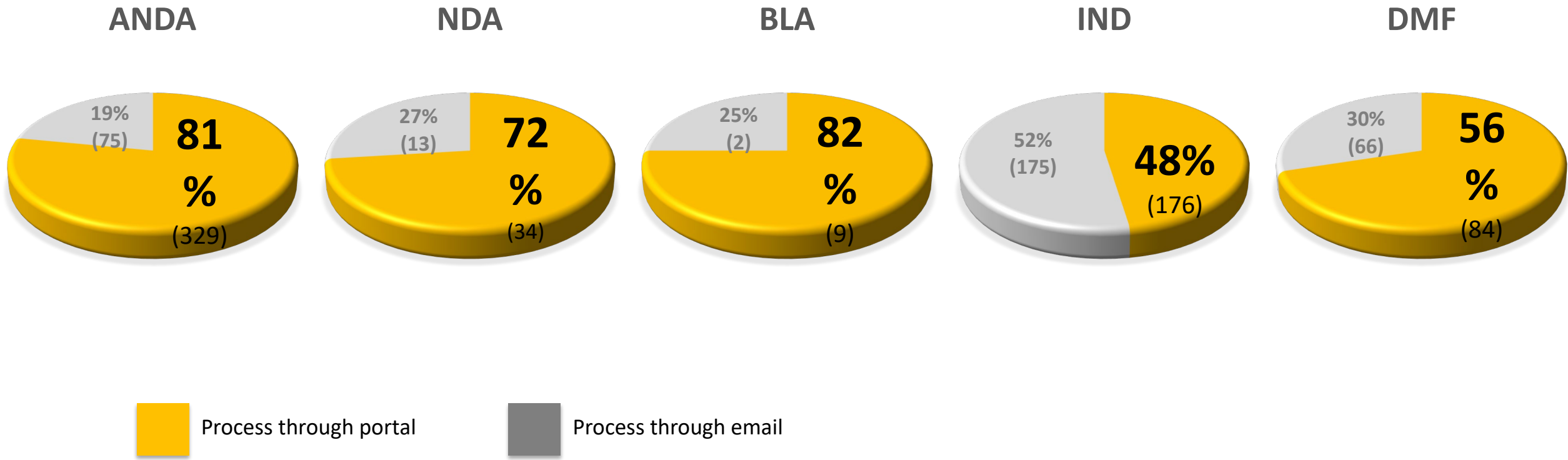
Historical Record

View all requests at any time. The Portal organizes all your requests based on status (e.g. pending, closed)

WHO IS USING THE PORTAL?



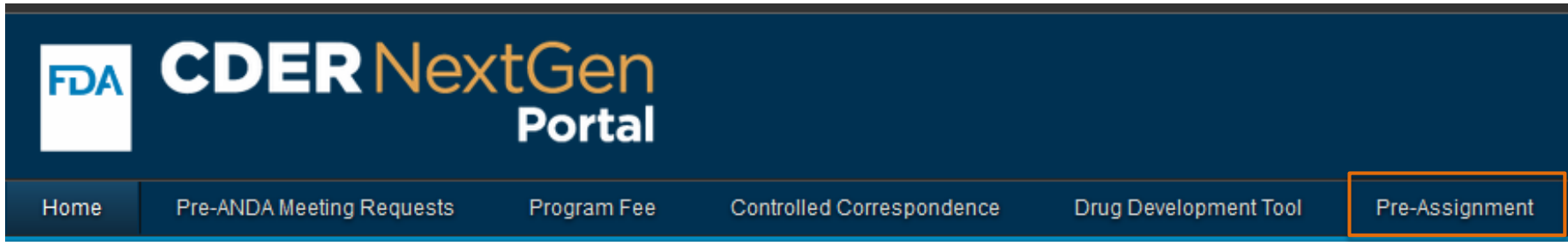
The Portal is now the preferred method for submitting pre-assignment requests for NDAs, BLAs, ANDAs, INDs and MFs to request a pre-assignment number.



HOW DO I GAIN ACCESS TO THE PORTAL?

Existing Portal Users

Pre-Assignment tab was added to your account automatically – click on it when you are ready to submit a request



New Users

To register for an account with the CDER NextGen Portal, navigate to <https://edm.fda.gov> and follow the signup instructions



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

HOW CAN I LEARN MORE?



Video Tutorials

<p>ANDA Pre-Assignment Number</p> <p>▶</p> <p>ANDA Pre-Assignment Number</p>	<p>BLA or NDA Pre-Assignment Number</p> <p>▶</p> <p>BLA or NDA Pre-Assignment Number</p>	<p>IND Pre-Assignment Number</p> <p>▶</p> <p>IND Pre-Assignment Number</p>	<p>DMF Pre-Assignment Number</p> <p>▶</p> <p>DMF Pre-Assignment Number</p>
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ANDA Pre-Assignment Number

0:24 / 3:16

You must have a pre-assignment number before submitting your ANDA application to FDA.

THANK YOU



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