



FAQs

Frequently Asked Questions

FDA CDER NextGen Portal: Drug Development Tool

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The following questions and answers are those that are most frequently asked and answered by the Center for Drug Evaluation and Research (CDER).

General Questions

- 1. What is FDA CDER NextGen Portal?**
 FDA CDER NextGen Portal is a website for users to report information to the FDA.

Requesting a Login

- 2. I didn't get an email to activate my account after registration. What should I do?**
 If you did not receive an email titled "FDA CDER NextGen Portal - Login Request Received," please send an email to CDER Platform Support (EDMSupport@fda.hhs.gov) requesting the email to be resent.
- 3. The activation link in the email is expired. What should I do?**
 If you attempt to open the activation link and are greeted with a message stating that your activation link is no longer valid, select "Request a new token", then input the email address in which you would like support to contact you, along with a brief message stating that you need a new activation link.

4. I am leaving my company and will no longer need access to the Portal. What should I do?

Email CDER Platform Support (EDMSupport@fda.hhs.gov), and your replacement Portal representative before your last day of work.

Logging In

5. What is my username?

Your username is the email you used when you created your login.

6. If I forgot my username, what should I do?

Check your email and locate the email titled “Welcome to CDER NextGen Portal.” This email contains your username. Usernames are usually your work email address. If you cannot find this email and your work email address is not working as your username, please email CDER Platform Support (EDMSupport@fda.hhs.gov).

7. If I forgot my password, what should I do?

- 1) Navigate to <https://edm.fda.gov> to access the FDA CDER NextGen Portal.
- 2) On the login page, click “Need help signing in” and then click “Forgot Password.”
- 3) The Forgot Password screen will appear requesting your email address. Once you enter your email and submit, you will receive a second email titled “FDA CDER NextGen Portal – Password Reset Request Received.”
- 4) The Password Reset email will have a link to access your security questions. Once you have correctly answered your security questions, you will be prompted to input a new password.
- 5) Upon setting your new password you will be navigated to the MFA (Multi Factor Authentication) page and then redirected to the FDA CDER NextGen Portal home page upon entering the verification code.

Please ensure your browsers allow for the use of third party cookies. If you have any issues enabling third party cookies, please contact your IT Support.

8. If I forgot my security question answers, how do I reset my password?

If you do not remember your security question answer for password reset, please email CDER Platform Support (EDMSupport@fda.hhs.gov).

Using Drug Development Tool

9. Do I need to be a user of the Portal to make submissions for Drug Development Tool?

Yes, you need to be a registered Portal user to make a submission for a Drug Development Tool. Please see the “Requesting a Login” section on instructions for how to register for a Portal account.

In order to get access to the Drug Development Tool on the CDER NextGen Portal, you must be a domestic user.

10. How will Partners associated with the DDT be notified of updates and statuses?

If the DDT has added Partners during the Letter of Intent or Letter of Support submission, the Partners will receive separate notification emails from the Portal when an update or status change has occurred related to the DDT. Partner organization point of contacts will not be able to access the DDT submissions and will have to contact the Primary Requestor for detailed information regarding the submission.

11. What are the different types of submissions a Requestor can make through the Portal for Drug Development Tool?

Below are the different types of submissions that a Requestor can make through the Portal

DDT Qualification Stage Submissions:

- Letter of Intent (LOI) submissions: The LOI is the first DDT Stage submission for FDA to review to determine whether the DDT will be accepted into the DDT Qualification Program.
- Qualification Plan (QP) submissions: The QP is the second DDT Stage submission for FDA to review. A QP submission can be submitted only after the DDT has received an “Accepted” LOI.
- Full Qualification Package (FQP) submissions: The FQP is the third DDT Stage submission for FDA to review. An FQP submission can be submitted only after the DDT has received an “Accepted” QP.

Additional DDT Submissions:

- Letter of Support (LOS) submissions: The LOS is for the Biomarker Program only and is a step prior to the DDT Qualification process. An LOI can be submitted after a LOS.
- Amendment submissions: Amendments can be submitted for a DDT at any point during the DDT Qualification process. Amendments can be additional research papers, or information a Requestor wishes to add to the DDT submission for FDA review.
- Meeting submissions: Meetings can be requested with FDA reviewers through the Portal. Meeting requests can be submitted after the Reviewability step in the DDT Qualification process. Once the FDA has granted a Meeting Request, the Requestor may submit the Meeting Presentation Materials through the Portal.
- Withdrawal submissions: A Requestor may submit a Withdrawal submission for a DDT at any time. The DDT will not be officially Withdrawn until the FDA sends a Withdrawal Acknowledgement.

12. What kinds of communications can I receive from FDA in the Portal?

1. Reviewability determination letters at the Letter of Intent, Qualification Plan, and Full Qualification Package stages.
2. Acceptability determination letters at the Letter of Intent and Qualification Plan stages.
3. Qualification determination letter at the Full Qualification Package stage.
4. Information Request (IR) if further information or documentation is requested in response to a submission made by requestors. An information request can be made in response to any of these following submissions; Letter of Intent, Qualification Plan, and Full Qualification Package.
5. Withdrawal Confirmation letter if a DDT submission is withdrawn by the requestor for any reason. This communication will effectively close the DDT submission.

6. Meeting Confirmation letter upon receiving a meeting request from the requestor. This communication will provide details on the type of meeting to occur and availability for meeting.
7. Letter of Support Acknowledgment for Biomarker Qualification Programs only.

Submitting a DDT Submission

13. What kind of documents can I upload to a DDT submission?

The types of documents and files that can be attached to DDT submissions are the following:

- Microsoft Word
- Microsoft Excel
- PDF
- SAS files
- MP4

File sizes are limited to 45 MB, and macros are not allowed.

14. Can my Alternate Contact or Partner have access to the DDT submissions?

Alternate contacts and Partners will not have access to the DDT submissions. The primary Requestor will have access to the updates and statuses in the Portal.

If the Point of Contact needs to change for the DDT, the primary Requestor will need to contact EDMSupport@fda.hhs.gov to have the new contact information associated with the DDT submission.

Partners will receive separate email notifications that an update or status has been changed to the DDT submission and to contact the primary Requestor for the FDA communication.

15. Do I receive different ID Numbers for each DDT Stage submission?

When a Requestor submits an LOI or LOS, the Requestor will receive a DDT number. This DDT number will remain consistent throughout the DDT Qualification process.

Troubleshooting Tips

16. Which Browsers does the application support?

FDA CDER NextGen Portal officially supports Internet Explorer version 10 and above, Mozilla Firefox Version 48 and above, and Google Chrome version 45 and above.

17. Are there any steps I can take if any technical issues occur during the registration process before contacting support?

If you experience technical issues during registration, prior to contacting CDER Platform Support please try restarting your browser and clearing the cache.

Contact Information

18. I'm having a technical issue. Who do I contact?

If you are experiencing a technical issue, please email CDER Platform Support (EDMSupport@fda.hhs.gov).