

Reference Guide: Withdrawal Request and Amendment Submission Drug Development Tool Qualification Process

The screenshot displays the CDER NextGen Portal homepage. At the top left is the FDA logo and the text "CDER NextGen Portal". The main content area features a large image of hands holding a tablet. On the left, it says "Welcome to CDER NextGen Your direct line to the FDA" with a "Learn More" button. On the right, there is a "Sign In" form with fields for "username@email.com" and a password field. Below the password field is a checkbox for "I have read and agree to the Terms and Conditions stated above and below" and a "Sign In" button. A link for "Need help signing in?" is also present. At the bottom of the main content area, there is a section titled "Some Things To Keep In Mind | User Terms & Conditions" with three numbered points. The footer contains navigation links: FDA Home, Browser Requirements, Contact Tech Support, FAQ, A to Z Index, Follow FDA, FDA Voice Blog, Privacy, and "Powered by CDER INFORMATICS".

CDER NextGen Portal

Welcome to
CDER NextGen
Your direct line to the FDA

[Learn More](#)

Sign In

username@email.com

.....

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](#)

Some Things To Keep In Mind | User Terms & Conditions

1. You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
2. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. Authorized use of this system consists of industry submissions of data related to the use cases for which the system is intended.
3. By using this information system, you understand and consent to the following:
 - You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
 - Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

[FDA Home](#) [Browser Requirements](#) [Contact Tech Support](#) [FAQ](#) [A to Z Index](#) [Follow FDA](#) [FDA Voice Blog](#) [Privacy](#) Powered by **CDER** INFORMATICS

<https://edm.fda.gov/>

Withdrawal Request

Withdrawal Request

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 Letter. This section describes how to submit a Withdrawal Request.

Completing a Withdrawal Request

Step 1. Once you landed on the Portal homepage, **click on Drug Development Tool.**

Hi John, welcome back to CDER NextGen!

To get started choose an option below

Access Your Events

Meeting Requests

Program Fee

WDD/3PL Licensure

Controlled Correspondence

Drug Development Tool

Pre-Assignment

Manage Your Profile or Access

To update Profile information or request for additional Event access, please contact the CDER Platform Support Team at (EDMSupport@fda.hhs.gov).

Withdrawal Request

Completing a Withdrawal Request

Step 2. Highlight and select the DDT Number you would like to submit a withdrawal request for.

Step 3. Click View Submitted DDT.

Drug Development Tool [Create New LOI](#)

Submitted Drug Development Tool

[FDA Updates](#) [Open DDT](#) [All DDT](#) [Closed DDT](#)

To make modifications and/or continue your submission please select the applicable event and click the "View Submitted DDT" button

Filter by DDT Status: [Apply](#)

DDT Number	Program Type	Program Name	DDT Stage	DDT Status	Last Submitted Date/Time (EST)
000321	Biomarker Qualification Program	Magic Markers	Letter of Intent	Pending	5/9/2019, 1:59 PM
000247	Biomarker Qualification Program	Biomark	Letter of Intent	Acceptable	4/23/2019, 11:21 AM
000134	Clinical Outcome Assessments	Clinics Program Type	Letter of Intent	Acceptable	4/23/2019, 10:49 AM
000286	Animal Model	XXX Model	Letter of Intent	Acceptable	4/23/2019, 9:50 AM

[View Submitted DDT](#)

Withdrawal Request

Completing a Withdrawal Request

Step 4. Click Withdrawal Request.

Review Recent Activity for DDT Number 000332

Submitted Drug Development Tool

DDT Status

Pending

Status Date

05/13/2019

Document Type	File Name	Communication Interaction	Submission Date (EST)	Document Status
Submission Amendment	Test Amendment.pdf	Submitted to FDA	05/13/2019, 09:50 AM	Submitted Document
Letter of Intent	Test LOI Submission.pdf	Submitted to FDA	05/13/2019, 09:48 AM	Submitted Document

[View Selected Document](#)

Submission/Response Summary

Contact Information

[Close](#)

[Withdrawal Request](#)

[Amend Submission](#)

Withdrawal Request


Completing a Withdrawal Request

Step 5. Provide the reason for the withdrawal.

Step 6. Answer the question, if you would like to attach a supporting document. If the answer is Yes to attaching supporting document, then **click Attach Document.**

Step 7. Click **Choose File.**

Step 8. Select the document you would like to upload for the Withdrawal Request.

 Allowable formats to upload are PDF, MS Word, MS Excel, SAS, MP4. The maximum file size upload is 45MB and macros aren't allowed.

Step 9. Provide a brief description of the document.

Step 10. Click **Confirm Attachment.**

Withdrawal Request for DDT Number 000321

Withdrawal Details

What is the reason for this withdrawal? * 0 / 300 characters

Would you like to attach supporting documents? *

Yes
 No

Document Attachment

Please attach a document that provides details surrounding your withdrawal request.

[Attach Document](#)

Attach Document(s)

*Attachment

[Choose File](#) No file chosen

Allowable Formats: PDF, MS Word, MS Excel, SAS, MP4
Maximum File Size Upload is 45MB and macros are not allowed

Brief Description
0 / 300 characters

Provide a brief description of the document

[Confirm Attachment](#) [Cancel Attachment](#)

Withdrawal Request

Completing a Withdrawal Request

Step 11. Review all information uploaded and click the checkbox that you acknowledge that this information is final when sent to the FDA.

Step 12. Click **Submit to FDA**.

Step 13. You will be directed to a confirmation page that displays your Withdrawal Request for the same DDT Number. An email will also be sent with this confirmation.

Saved Document(s)

File Name	Document Type	Brief Description
Test Withdrawal Request.pdf	Withdrawal	

[View Saved Document](#) [Remove Document](#)

I acknowledge that the withdrawal of this submission will result in the nullification of the original submission and that no further action can be taken.

[Submit To FDA](#) [Back](#)

Withdrawal Request Submitted to FDA

Thank you for submitting your Withdrawal Request for DDT Number 000332 and DDT Program Type **Biomarker Qualification Program**.

For technical support, contact the CDER Platform Support Team (EDMSupport@fda.hhs.gov). Please include your DDT Number and associated DDT Program Type in your email.

[Return to Home](#)

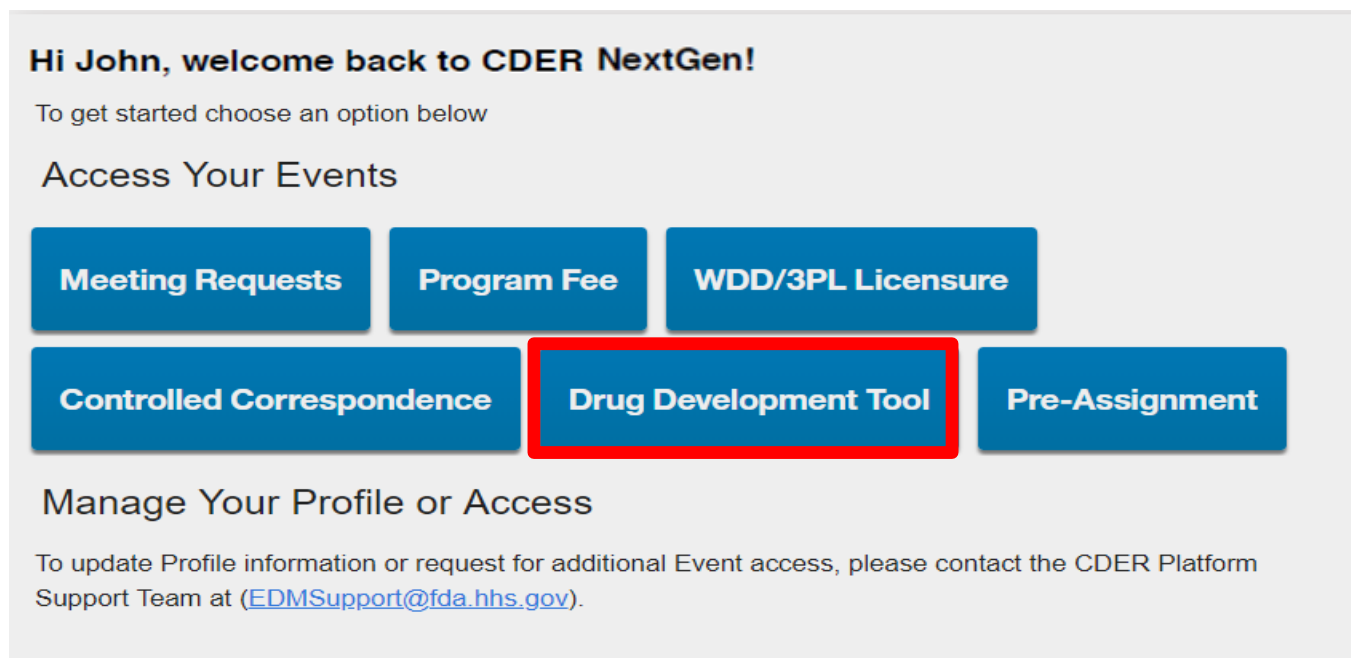
Amendment Submission

Amendment Submission

Amendments can be submitted after any submission stage 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. This section describes how to submit an amendment.

Completing an Amendment Submission

Step 1. Once you landed on the Portal homepage, **click on Drug Development Tool.**



Hi John, welcome back to CDER NextGen!

To get started choose an option below

Access Your Events

- Meeting Requests
- Program Fee
- WDD/3PL Licensure
- Controlled Correspondence
- Drug Development Tool**
- Pre-Assignment

Manage Your Profile or Access

To update Profile information or request for additional Event access, please contact the CDER Platform Support Team at (EDMSupport@fda.hhs.gov).

Amendment Submission

Completing an Amendment Submission

Step 2. Highlight and select the DDT Number you would like to submit an amendment submission for.

Step 3. Click View Submitted DDT.

Drug Development Tool [Create New LOI](#)

Submitted Drug Development Tool

[FDA Updates](#) | [Open DDT](#) | [All DDT](#) | [Closed DDT](#)

To make modifications and/or continue your submission please select the applicable event and click the "View Submitted DDT" button

Filter by DDT Status: [Apply](#)

DDT Number	Program Type	Program Name	DDT Stage	DDT Status	Last Submitted Date/Time (EST)
000321	Biomarker Qualification Program	Magic Markers	Letter of Intent	Pending	5/9/2019, 1:59 PM
000247	Biomarker Qualification Program	Biomark	Letter of Intent	Acceptable	4/23/2019, 11:21 AM
000134	Clinical Outcome Assessments	Clinics Program Type	Letter of Intent	Acceptable	4/23/2019, 10:49 AM
000286	Animal Model	XXX Model	Letter of Intent	Acceptable	4/23/2019, 9:50 AM

[View Submitted DDT](#)

Amendment Submission

Completing an Amendment Submission

Step 4. Click Amend Submission.

Review Recent Activity for DDT Number 000321

Submitted Drug Development Tool

DDT Status

Pending

Status Date

05/09/2019

Document Type	File Name	Communication Interaction	Submission Date (EST)	Document Status
Letter of Intent	Articles of Program Type.docx	Submitted to FDA	05/09/2019, 01:59 PM	Submitted Document

[View Selected Document](#)

Submission/Response Summary

Contact Information

[Close](#)

[Withdrawal Request](#)

[Amend Submission](#)


Amendment Submission

Completing an Amendment Submission

Step 5. Click Attach Document

Step 6. Click Browse.

Step 7. Select the document you would like to upload for the amendment submission.

 Allowable formats to upload are PDF, MS Word, MS Excel, SAS, MP4. The maximum file size upload is 45MB and macros aren't allowed.

Step 8. Provide a brief description of the document.

Step 9. Click Confirm Attachment.

Step 10. Review information uploaded.

Submission Amendment for DDT Number 000332

Document Attachment

Please attach a document that provides details surrounding your submission amendment.

[Attach Document](#)

Attach Document(s)

*Attachment
[Browse...](#) No file selected.

Allowable Formats: PDF, MS Word, MS Excel, SAS, MP4
Maximum File Size Upload is 45MB and macros are not allowed

* Brief Description
0 / 300 characters
Provide a brief description of the document

[Confirm Attachment](#) [Cancel Attachment](#)

Saved Document(s)

File Name	Document Type	Brief Description
Test Amendment.pdf	Submission Amendment	Test description for amendment submission

[View Saved Document](#) [Remove Document](#)

I acknowledge that this information is final when sent to the FDA

[Submit To FDA](#) [Back](#)

Amendment Submission

Completing an Amendment Submission

Step 11. Click the checkbox that you acknowledge that this information is final when sent to the FDA.

Step 12. Click **Submit to FDA**.

Step 13. You will be directed to a confirmation page that displays your Submission Amendment for the same DDT Number. An email will also be sent with this confirmation.

Saved Document(s)

File Name	Document Type	Brief Description
Test Amendment.pdf	Submission Amendment	Test description for amendment submission

[View Saved Document](#) [Remove Document](#)

I acknowledge that this information is final when sent to the FDA

[Submit To FDA](#) [Back](#)

Submission Amendment Submitted to FDA

Thank you for submitting your Submission Amendment for DDT Number 000332 and DDT Program Type **Biomarker Qualification Program**.

For technical support, contact the CDER Platform Support Team (EDMSupport@fda.hhs.gov). Please include your DDT Number and associated DDT Program Type in your email.

[Return to Home](#)

Technical Support and Resources

CDER NextGen Portal Support & Resources

The CDER NextGen Portal (<https://edm.fda.gov>) has many resources for support.

Portal Announcements

Your Portal home page contains **portal announcements** so users are always in the know.



Learn More Information

Everything related to the portal events can be found on the “**Learn More**” link. On the event home page, users can find the “Learn More” link to **Reference Guides and FAQs**.

Technical Support

For all technical support, contact **CDER Platform Support** at EDMSupport@fda.hhs.gov.

Portal Video Tutorials

The “**Video Tutorials**” contains 1-4 minute video clips on how to complete submissions for events under the “**Learn More**” section on the portal.