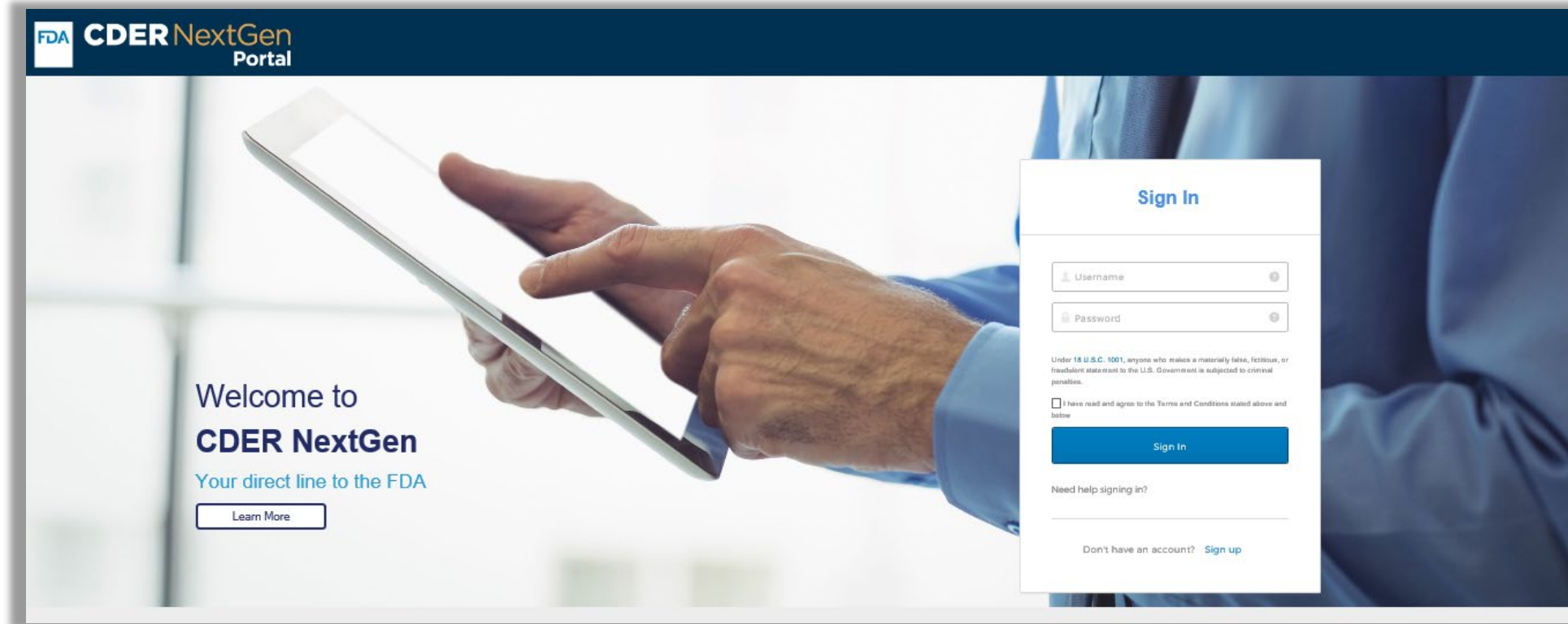


Drug Development Tool (DDT) Reference Guide



Click [here](#) to access the CDER NextGen Portal.

Supported Browsers: Google Chrome, Microsoft Edge and Mozilla Firefox

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Introduction

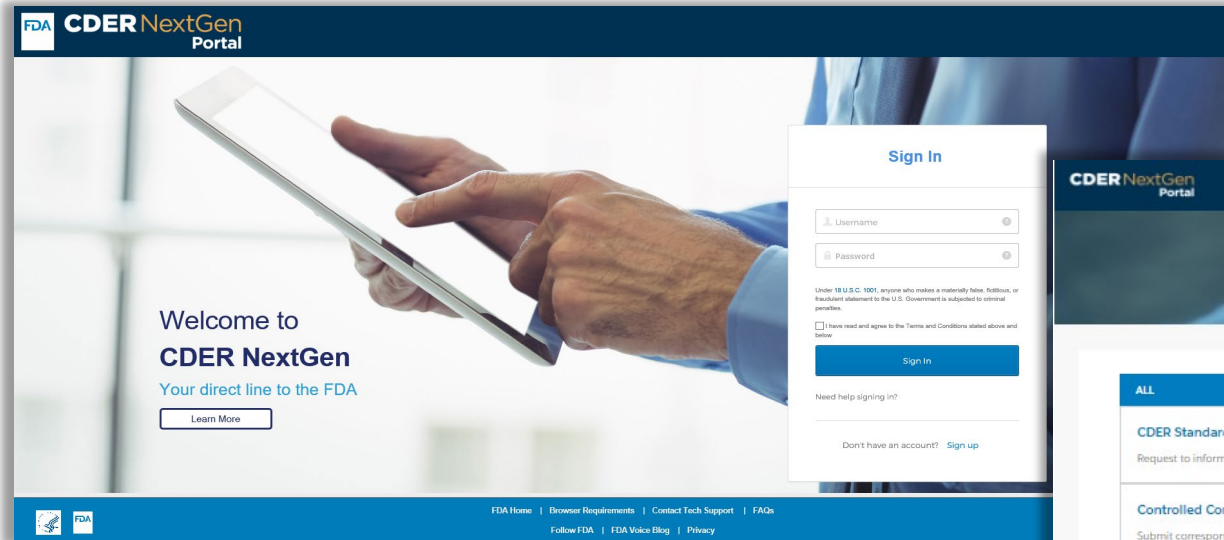
Welcome to the Drug Development Tool Reference Guide! This guide describes the process for qualifying drug development tools intended for potential use, over time, in multiple drug development programs. Drug Development tools (DDTs) are methods, materials or measures that aid drug development. DDTs include, but are not limited to, Biomarkers, Clinical Outcome Assessments (COA) and animal models for drug development. This reference guide provides submission instructions for interactions between the Center of Drug Evaluation and Research (CDER) and the entity proposing the DDT for qualification (the submitter).

For business assistance regarding Biomarker Qualifications Program, contact (CDER-BiomarkerQualificationProgram@fda.hhs.gov)

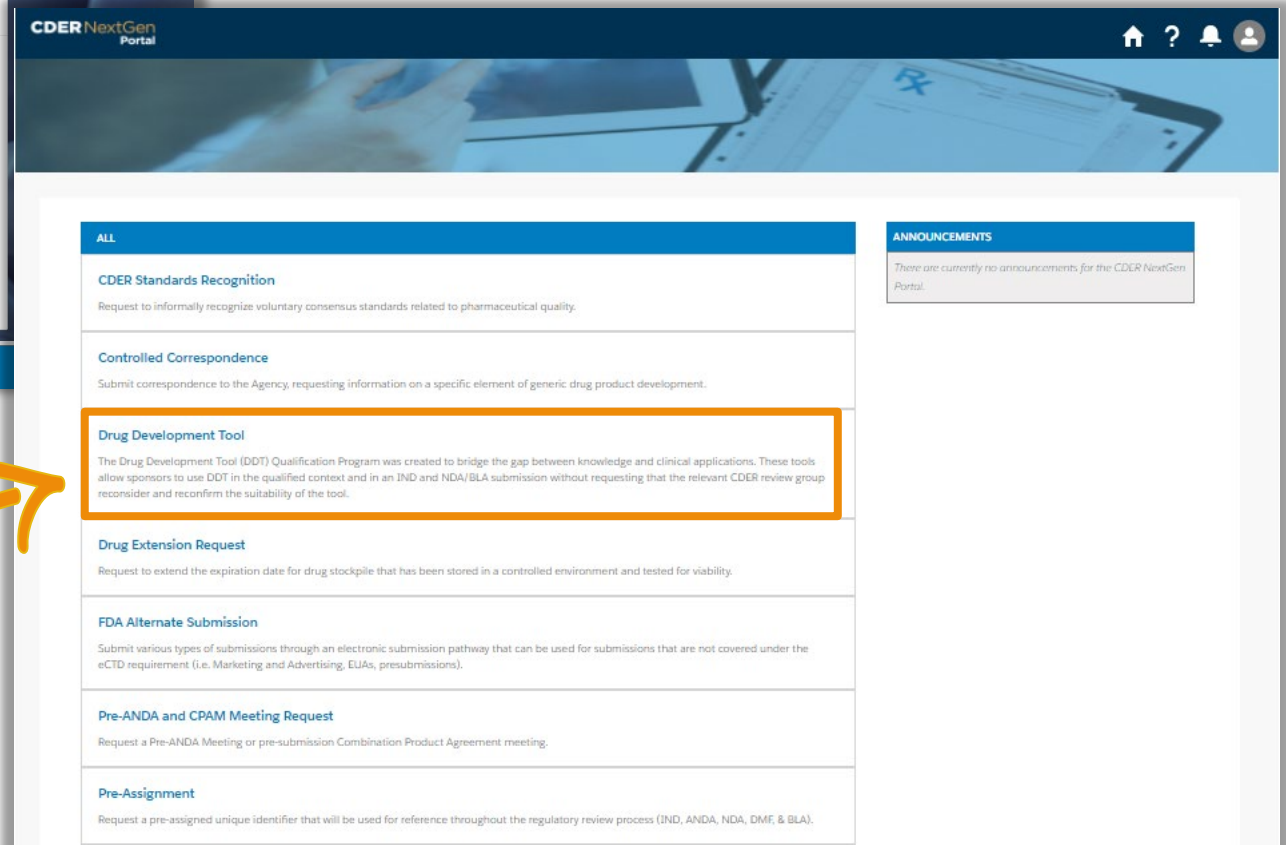
For business assistance regarding Animal Model, contact (CDERAnimalModelQualification@fda.hhs.gov)

For business assistance regarding Clinical Outcome Assessments, contact (COADDTQualification@fda.hhs.gov)

CDER NextGen Portal Homepage



Step 1. Once you land on the CDER NextGen Portal homepage, click **Drug Development Tool** to begin.



**Submitting a Letter of Support
(Only Biomarker Qualification Program Type)**

Create a Submission

Step 1. Click **+ New LOI**.

Step 2. Click **Continue** if you would like to create a new LOI/LOS and be assigned a new DDT number. Return to the main menu if you would like to make additional submissions for an existing DDT.

Step 3. Review the **Getting Started** information for submitting an **LOS/LOI**. Then click **Next**.

The screenshot illustrates the 'Drug Development Tool' interface. At the top, a blue header bar contains the text 'Drug Development Tool' and a button labeled '+ New LOI' with a circled '1' next to it. Below this, a 'Confirmation' dialog box is shown, containing the text: 'Selecting this option will create a new LOI and assign a new DDT number. Please return to the main menu if you would like to make additional submissions on an existing DDT.' The dialog has 'Cancel' and 'Continue' buttons, with a circled '2' next to the 'Continue' button. Below the dialog, the 'Introduction' section is visible, featuring a 'Getting Started' subsection with explanatory text and a 'Drug Development Tool Request Assistant' section with three sub-sections: 'Contact Details', 'Partner Details', and 'DDT Information', each followed by a text input field. At the bottom of the 'Introduction' section, there is an 'Upload Documents' section with a text input field and a circled '3' next to it. The 'Next' button is highlighted in orange at the bottom right of the 'Introduction' section.

Contact Details

Step 4. Review the pre-populated information in the Profile Information section.

Step 5. If there is an alternate point of contact, select Yes and provide the information requested. Then click **Next**.

Contact Details

Profile Information

First Name	Zeshawn	Last Name	Rahman
Email Address	zeshawn.rahman@fda.hhs.gov		
Phone Number	+17039879877	Extension	
Organization Name	PFIZER INC		
Address Line 1	235 E 42ND ST	Address Line 2	
City	NEW YORK	State/Province	NY
Zip Code		Country	

Alternate Contact

Yes
 No

Note: This user will not have access to the event on the Portal.

*Title
--None--

*First Name Middle Name *Last Name

*Email Address

*Phone Number Extension

Working Group

Save and Close **Next**

Partner Details

Step 6. Select **Yes** or **No** if the application is in partnership with another organization.

Step 7. If **No**, then click **Next**. If **Yes**, click on the **+** icon to add Partner Contact Information.

Step 8. Enter the Organization Name or DUNS Number, then click **Search**.

Step 9. Enter the contact information requested then select **Save** then click **Next**.

The screenshot displays the 'Partner Details' form. The 'Application Partner' section has radio buttons for 'Yes' (selected) and 'No'. A note states: 'Note: This user will not have access to the event on the Portal'. Below this is a '+ Add Partner Contact Information' button. The 'Organization Details' section is expanded, showing a search interface with 'Organization Name' and 'DUNS Number' search boxes. The search results table is as follows:

Organization Name	Address line 1	Address line 2	City	State/Province	Zip Cod
<input checked="" type="radio"/> TEVA PHARMACEUTICALS USA, INC.	400 INTERPACE PKWY BLDG A		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA PHARMACEUTICALS USA, INC.	1090 HORSHAM RD		NORTH WALES	PA	19454
<input type="radio"/> TEVA PHARMACEUTICALS USA	2 UNIVERSITY PLZ STE 220		HACKENSACK	NJ	07601
<input type="radio"/> TEVA NEUROSCIENCE, INC.	11100 NALL AVE		LEAWOOD	KS	66211
<input type="radio"/> TEVA WOMEN'S HEALTH, INC.	5040 DURAMED RD		CINCINNATI	OH	45213
<input type="radio"/> TEVA WOMENS HEALTH INC	5040 DURAMED RD		CINCINNATI	OH	45213
<input type="radio"/> TEVA PHARMACEUTICALS USA INC	400 INTERPACE PKWY BLDG A		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA PHARMACEUTICALS DEVELOPMENT, INC.	400 INTERPACE PKWY STE A1		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA NEUROSCIENCE	425 PRIVET RD		HORSHAM	PA	19044
<input type="radio"/> TEVA PHARMACEUTICALS					

The 'Partner Contact Information' form is also visible, with fields for Title, First Name, Middle Name, Last Name, Email Address, Phone Number, and Extension. A 'Working Group' dropdown is at the bottom. 'Add Manually' and 'Cancel/Save' buttons are also present.

DDT Information

Step 10. In the DDT Information section, enter a **Program Name**.

Step 11. Select “**Biomarker Qualification Program**” from the **DDT Program Type** drop-down menu.

Step 12. Provide a response to all the required information.

Step 13. Select **Requesting Letter of Support** when asked “What are you submitting for?”

Step 14. **Provide** the Proposed Context of Use for this DDT Submission in the text box then click **Next**.

The screenshot shows the 'DDT Information' form with the following sections and fields:

- Program Information:** A text input field for the Program Name (0/100 characters) and a dropdown menu for the DDT Program Type, currently set to 'Biomarker Qualification Program'.
- Program Type Information:** A section containing several required fields:
 - A dropdown menu for selecting a biomarker type (currently 'Select One').
 - A dropdown menu for selecting a biomarker category (currently 'Select One').
 - A section for selecting the Drug Development Space, with checkboxes for Pre-Clinical, Early-Phase Clinical Trials, Late-Phase Clinical Trials, and Post-Marketing.
 - A radio button question: 'Is the request related to a composite biomarker (e.g. more than one defined characteristic)?' with 'Yes' and 'No' options.
 - A text input field for Patient Population (e.g. Age, Disease State, Disease) (0/75 characters).
 - A text input field for the Name of the Biomarker (0/75 characters).
 - A radio button question: 'What are you submitting for?' with 'Requesting Letter of Support' (selected) and 'Submitting Letter of Intent' options.
- Proposed Context of Use:** A text input field for providing the proposed context of use for this DDT Submission (0/2000 characters).

Navigation buttons at the bottom include 'Previous', 'Save and Close', and 'Next'.

Drug Development Tool


Upload Documents


Step 15. Upload a **Letter of Support** by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

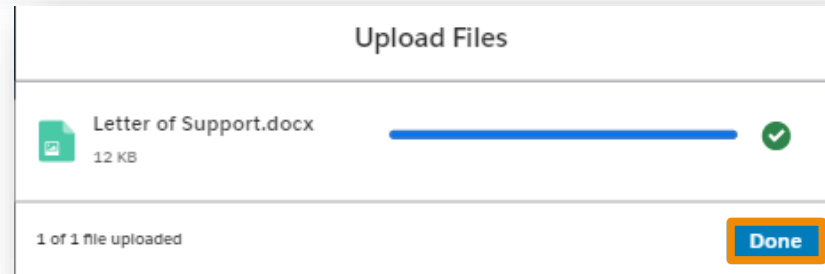
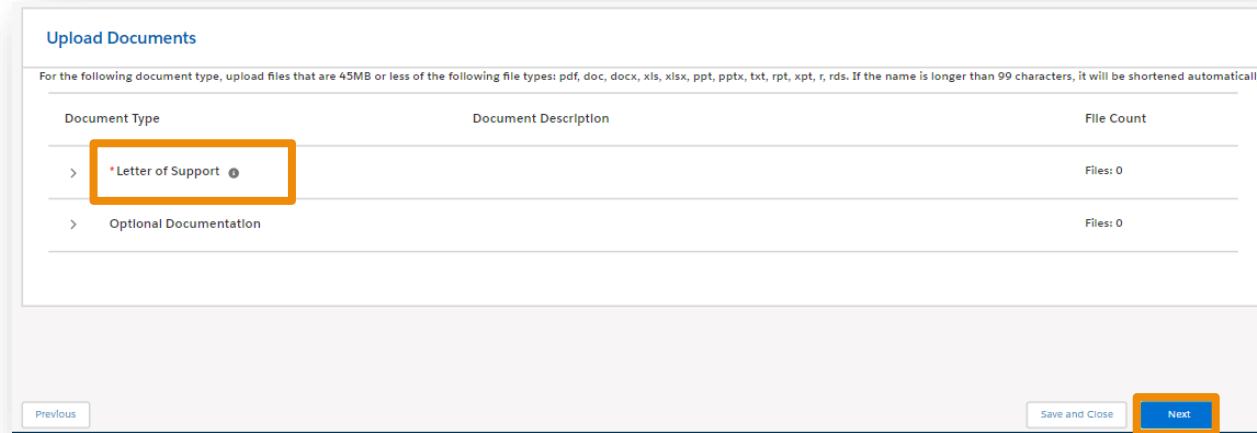
Step 16. Provide optional documentation if needed.

Step 17. Once the document has been uploaded, click Done.

Step 18. Click **Next**.

 It is mandatory to upload a **“Letter of Support”** as part of this submission.

 The allowable formats for uploading a document are pdf, doc, docx, xls, xlsx, ppt, pptx, txt, rpt, xpt, r, and rds. The maximum file size allowed is 45MB per file.



Review and Submit

Step 19. Review your entry for accuracy.

Step 20. Prior to submitting, you will have the option to either **Save as Draft** or **Delete** your submission.

Step 21. Click the check box verifying that information you provided is accurate.

Step 22. Once ready, click **Submit**.

Step 23. A confirmation message will appear, and a confirmation e-mail will be sent.

Step 24. You may now click **Return Home**.

**Submitting a Letter of Intent
(All Program Types)**

Drug Development Tool

Create a Submission

Step 1. Click + New LOI.

Step 2. Click **Continue** if you would like to create a new LOI and be assigned a new DDT number. Return to the main menu if you would like to make additional submissions for an existing DDT.

Step 3. Review the **Getting Started** information for submitting an LOI. Then click **Next**.

Drug Development Tool 1 + New LOI

Confirmation

Selecting this option will create a new LOI and assign a new DDT number. Please return to the main menu if you would like to make additional submissions on an existing DDT.

Cancel Continue 2

Introduction

Getting Started

The Drug Development Tool (DDT) Qualification Program was created to bridge the gap between knowledge and clinical applications. These tools allow sponsors to use DDT in the qualified context and in an IND and NDA/BLA submission without requesting that the relevant CDER review group reconsider and reconfirm the suitability of the tool.

Drug Development Tool Request Assistant

Contact Details

Confirm the contact information for the organization submitting the DDT program.

Partner Details

Provide partner organization(s) if this DDT program is developed in partnership with another organization(s).

DDT Information

Provide the required details for the DDT program including DDT type with all relevant data and Proposed Context of Use.

Upload Documents

Please attach required and any optional documentation that will be useful for the DDT submission.

Cancel Next 3

Contact Details

Step 4. Review the pre-populated information in the Profile Information section.

Step 5. If there is an alternate point of contact, select Yes and provide the information requested. Then click **Next**.

Contact Details

Profile Information

First Name	Zeshawn	Last Name	Rahman
Email Address	zeshawn.rahman@fda.hhs.gov		
Phone Number	+17039879877	Extension	
Organization Name	PFIZER INC		
Address Line 1	235 E 42ND ST	Address Line 2	
City	NEW YORK	State/Province	NY
Zip Code		Country	

Alternate Contact ⓘ

* Is there an alternate point of contact to include in this notification?
 Yes
 No

Note: This user will not have access to the event on the Portal.

* Title
--None--

* First Name Middle Name * Last Name

* Email Address

* Phone Number Extension

Working Group ⓘ

Save and Close **Next**

Partner Details

Step 6. Select **Yes** or **No** if the application is in partnership with another organization.

Step 7. If **No**, then click **Next**. If **Yes**, click on the **+** icon to add Partner Contact Information.

Step 8. Enter the Organization Name or DUNS Number, then click **Search**.

Step 9. Enter the contact information requested then select **Save** then click **Next**.

The screenshot displays the 'Partner Details' form. The 'Application Partner' section has radio buttons for 'Yes' (selected) and 'No'. A note states: 'Note: This user will not have access to the event on the Portal'. Below this is a '+ Add Partner Contact Information' button. The 'Organization Details' section is expanded to show a search interface with 'Organization Name' and 'DUNS Number' search boxes. A table titled 'Organization Selection' lists various Teva organizations. The 'Partner Contact Information' form is open, showing fields for Title, First Name, Middle Name, Last Name, Email Address, Phone Number, and Extension, along with a 'Working Group' dropdown and 'Cancel'/'Save' buttons.

Organization Name	Address line 1	Address line 2	City	State/Province	Zip Cod
<input checked="" type="radio"/> TEVA PHARMACEUTICALS USA, INC.	400 INTERPACE PKWY BLDG A		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA PHARMACEUTICALS USA, INC.	1090 HORSHAM RD		NORTH WALES	PA	19454
<input type="radio"/> TEVA PHARMACEUTICALS USA	2 UNIVERSITY PLZ STE 220		HACKENSACK	NJ	07601
<input type="radio"/> TEVA NEUROSCIENCE, INC.	11100 NALL AVE		LEAWOOD	KS	66211
<input type="radio"/> TEVA WOMEN'S HEALTH, INC.	5040 DURAMED RD		CINCINNATI	OH	45213
<input type="radio"/> TEVA WOMENS HEALTH INC	5040 DURAMED RD		CINCINNATI	OH	45213
<input type="radio"/> TEVA PHARMACEUTICALS USA INC	400 INTERPACE PKWY BLDG A		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA PHARMACEUTICALS DEVELOPMENT, INC.	400 INTERPACE PKWY STE A1		PARSIPPANY	NJ	07054
<input type="radio"/> TEVA NEUROSCIENCE	425 PRIVET RD		HORSHAM	PA	19044
<input type="radio"/> TEVA PHARMACEUTICALS					

DDT Information

Step 10. In the **DDT Information** section, enter the information requested.

Step 11. If asked to select “What are you submitting for?”, select **Submitting Letter of Intent**.

Step 12. Provide the Proposed Context of Use for this DDT Submission in the text box then click **Next**.

CDER NextGen Portal

Drug Development Tool

APPLICATION BUILDER

- Contact Details
- Partner Details
- DDT Information**
- Upload Documents
- Review & Submit

Need Help?

The [Learn More](#) link is available to answer all your Drug Development Tool related questions.

DDT Information

Program Information

*Please create a Program Name.
Test Submission
15/100 characters

*What is the DDT Program Type?
Biomarker Qualification Program

Program Type Information

*Select a biomarker type that will be associated with the request.
Other

*Please enter the biomarker type not listed.
other biomarker
15 / 75 characters

*Select a biomarker category that will be associated with the request.
Monitoring

*Select the Drug Development Space that will be associated with the request.
Check all that apply

- Pre-Clinical
- Early Phase Clinical Trials
- Late Phase Clinical Trials
- Post-Marketing

*Is the request related to a composite biomarker (e.g. more than one defined characteristic)?
 Yes
 No

*Enter Patient Population (e.g. Age, Disease State, Disease).
test patient population
15 / 2000 characters

*Please provide the Name of the Biomarker.
name of biomarker
17 / 75 characters

*What are you submitting for?
 Requesting Letter of Support
 Submitting Letter of Intent

Proposed Context of Use

*Provide the proposed context of use for this DDT Submission.
proposed context of use
25 / 2000 characters

Next

CDER NextGen Portal

Drug Development Tool

APPLICATION BUILDER

- Contact Details
- Partner Details
- DDT Information**
- Upload Documents
- Review & Submit

Need Help?

The [Learn More](#) link is available to answer all your Drug Development Tool related questions.

DDT Information

Program Information

*Please create a Program Name.
Test Submission
15/100 characters

*What is the DDT Program Type?
Biomarker Qualification Program

Program Type Information

*Select a biomarker type that will be associated with the request.
Other

*Please enter the biomarker type not listed.
other biomarker
15 / 75 characters

*Select a biomarker category that will be associated with the request.
Monitoring

*Select the Drug Development Space that will be associated with the request.
Check all that apply

- Pre-Clinical
- Early Phase Clinical Trials
- Late Phase Clinical Trials
- Post-Marketing

*Is the request related to a composite biomarker (e.g. more than one defined characteristic)?
 Yes
 No

*Enter Patient Population (e.g. Age, Disease State, Disease).
test patient population
15 / 2000 characters

*Please provide the Name of the Biomarker.
name of biomarker
17 / 75 characters

*What are you submitting for?
 Requesting Letter of Support
 Submitting Letter of Intent

Proposed Context of Use

*Provide the proposed context of use for this DDT Submission.
proposed context of use
25 / 2000 characters

Next

Upload Documents


Step 13. Upload a **Letter of Intent** by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 14. Provide optional documentation if needed.

Step 15. Once the document has been uploaded, click Done.

Step 16. Click **Next**.

 It is mandatory to upload a **“Letter of Intent”** as part of this submission.

 The allowable formats for uploading a document are pdf, doc, docx, xls, xlsx, ppt, pptx, txt, rpt, xpt, r, and rds. The maximum file size allowed is 45MB per file.

CDER NextGen Portal

Drug Development Tool

APPLICATION BUILDER

- Contact Details
- Partner Details
- DDT Information
- Upload Documents**
- Review & Submit

Need Help?
The [Help Center](#) is available to answer all your Drug Development Tool related questions.

Upload Documents

For the following document type, upload files that are 45MB or less of the following file types: pdf, doc, docx, xls, xlsx, ppt, pptx, txt, rpt, xpt, r, rds. If the name is longer than 99 characters, it will be shortened automatically.

Document Type	Document Description	File Count
▼ Letter of Intent ⓘ	Document Description Enter description <input type="text"/> <input type="button" value="Save"/>	Files: 1
Test1.xlsx		
▼ Optional Documentation		Files: 0

Upload Files Or drop files

Upload Files Or drop files

Previous Save and Close **Next**

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Review and Submit

Step 17. Review your entry for accuracy.

Step 18. Prior to submitting, you will have the option to either **Save as Draft** or **Delete** your submission.

Step 19. Click the check box verifying that information you provided is accurate.

Step 20. Once ready, click **Submit**.

Step 21. A confirmation message will appear, and a confirmation e-mail will be sent.

Step 22. You may now click **Return Home**

**Submitting a Pre-Qualification Plan (Pre-QP) or Qualification Plan (QP)
(All Program Types)**

Drug Development Tool

Submitting a Pre-QP (Optional before QP)

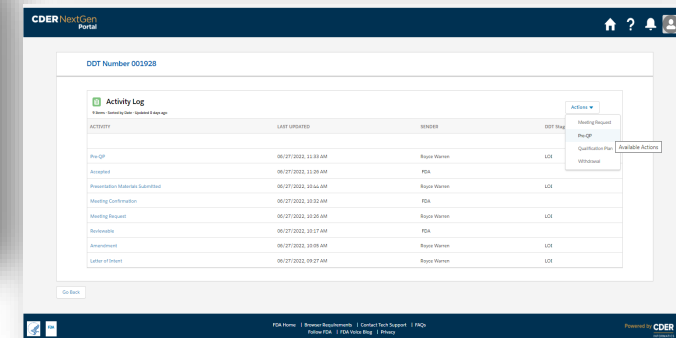
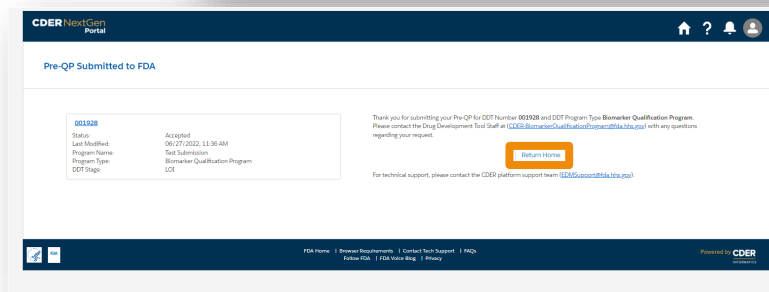
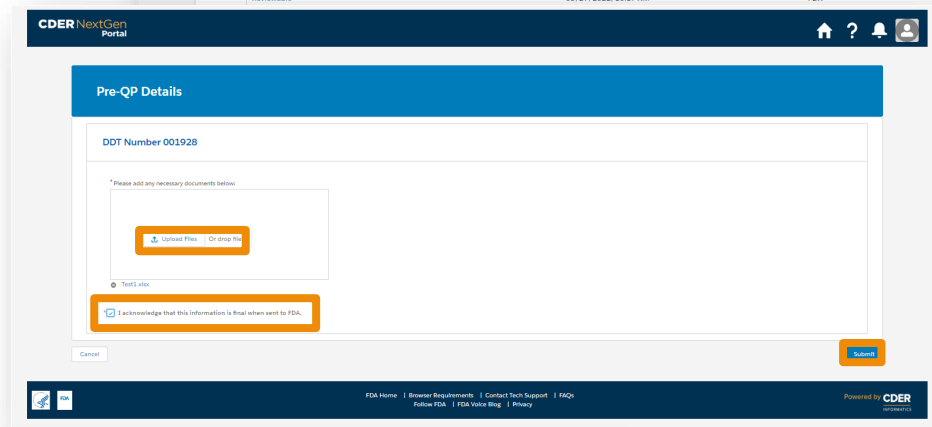
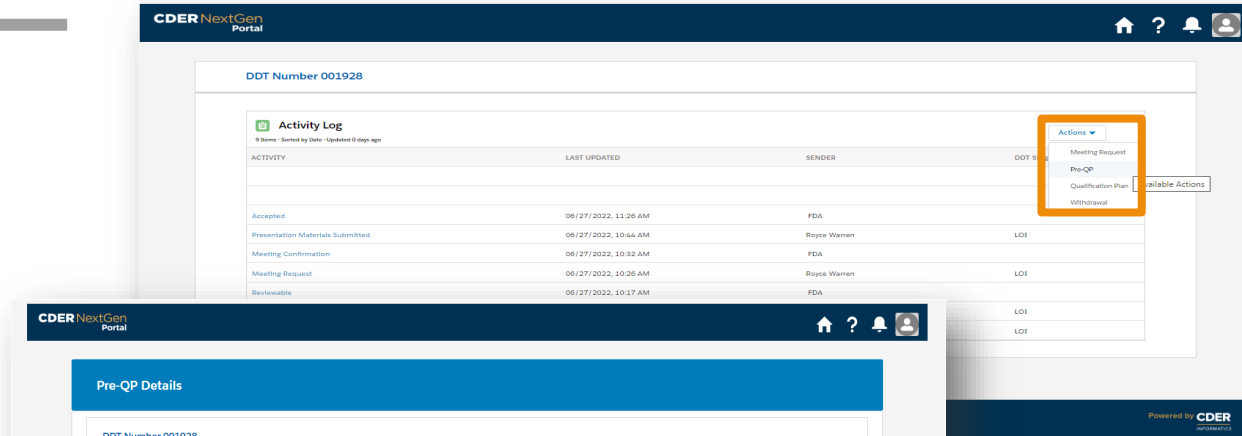
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Pre-QP**.

Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Once the document has been uploaded, click **Done**.

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 5. On the confirmation screen click **Return Home**.



Drug Development Tool

Submitting a QP

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Qualification Plan**.

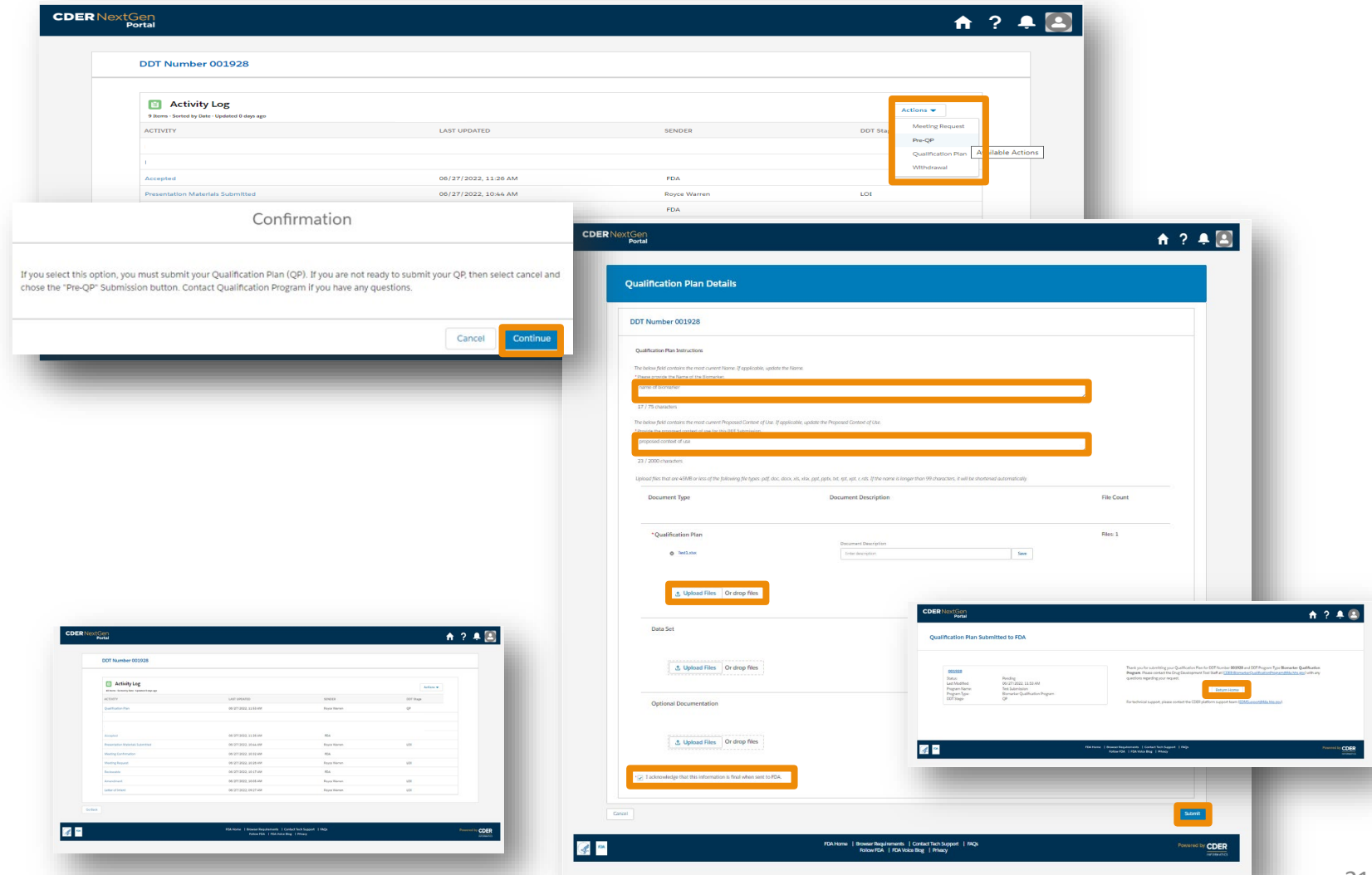
Step 2. Click **Continue** on the pop-up screen.

Step 3. In the **Qualification Plan Details** page, provide the requested information.

Step 4. Upload the **Qualification Plan** by clicking the arrow and selecting Upload Files. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 5. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 6. On the confirmation screen click **Return Home**.



**Submitting a Pre-Full Qualification Plan (Pre-FQP) or Full Qualification Plan (FQP)
(All Program Types)**

Submitting a Pre-FQP (Optional before FQP)

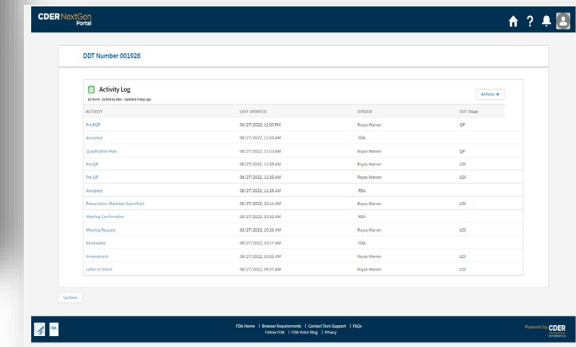
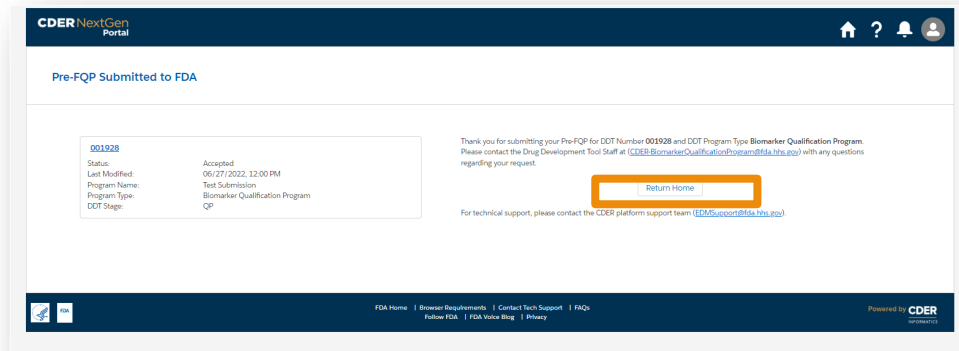
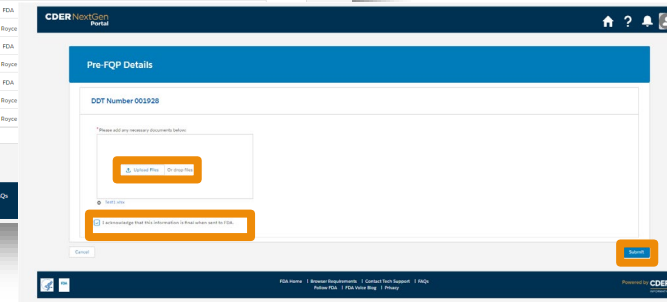
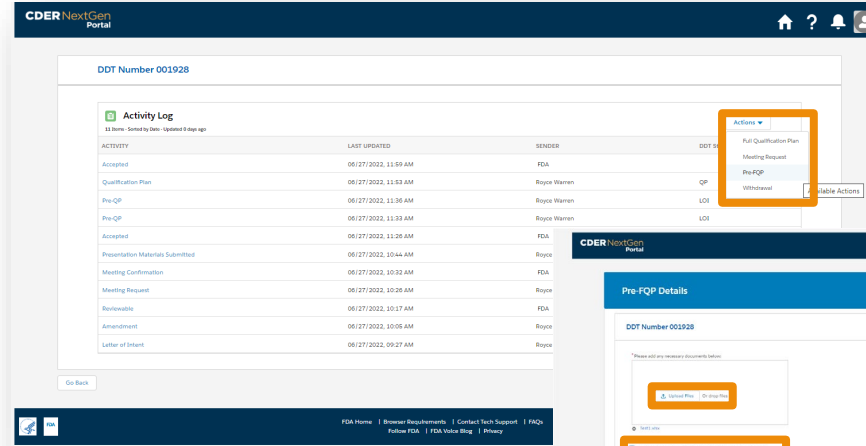
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Pre-FQP**

Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Once the document has been uploaded, click **Done**.

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 5. On the confirmation screen click **Return Home**.



Submitting an FQP

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Full Qualification Plan**

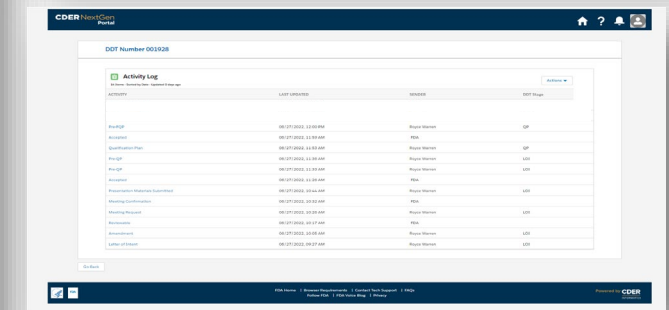
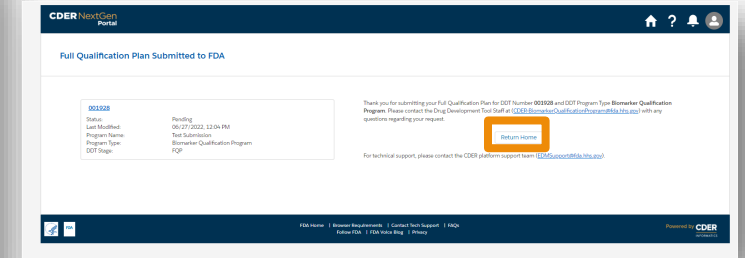
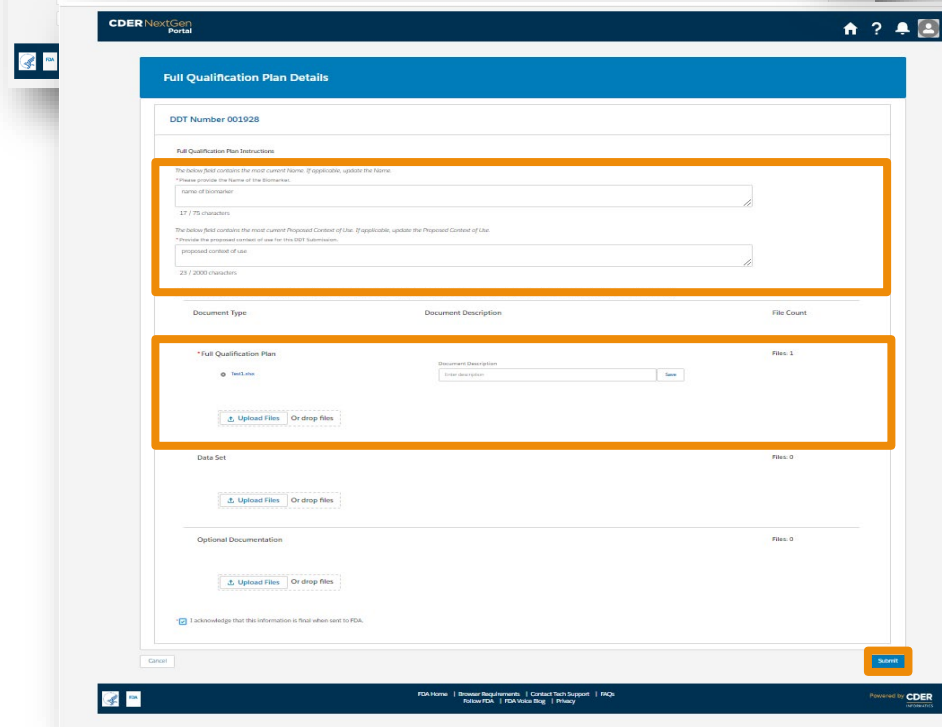
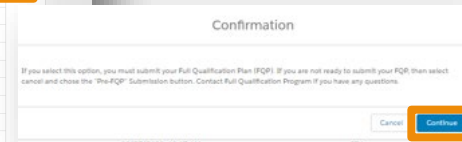
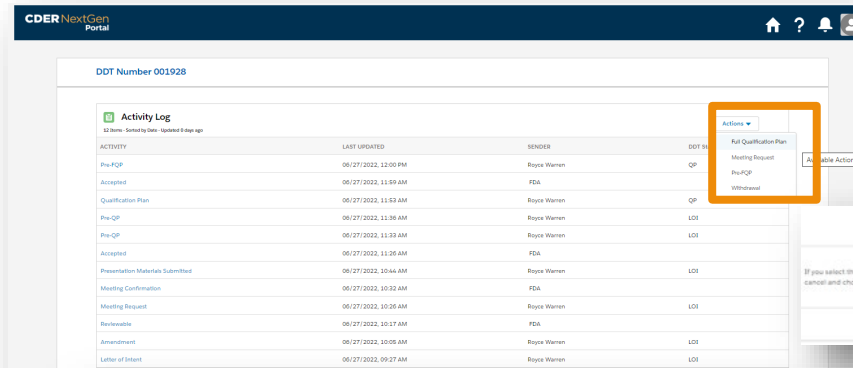
Step 2. Click **Continue** on the pop-up screen.

Step 3. In the **Full Qualification Plan Details** page, provide the requested information.

Step 4. Upload the **Full Qualification Plan** by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 5. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 6. On the confirmation screen click **Return Home**.



Submitting an Amendment

Amendment

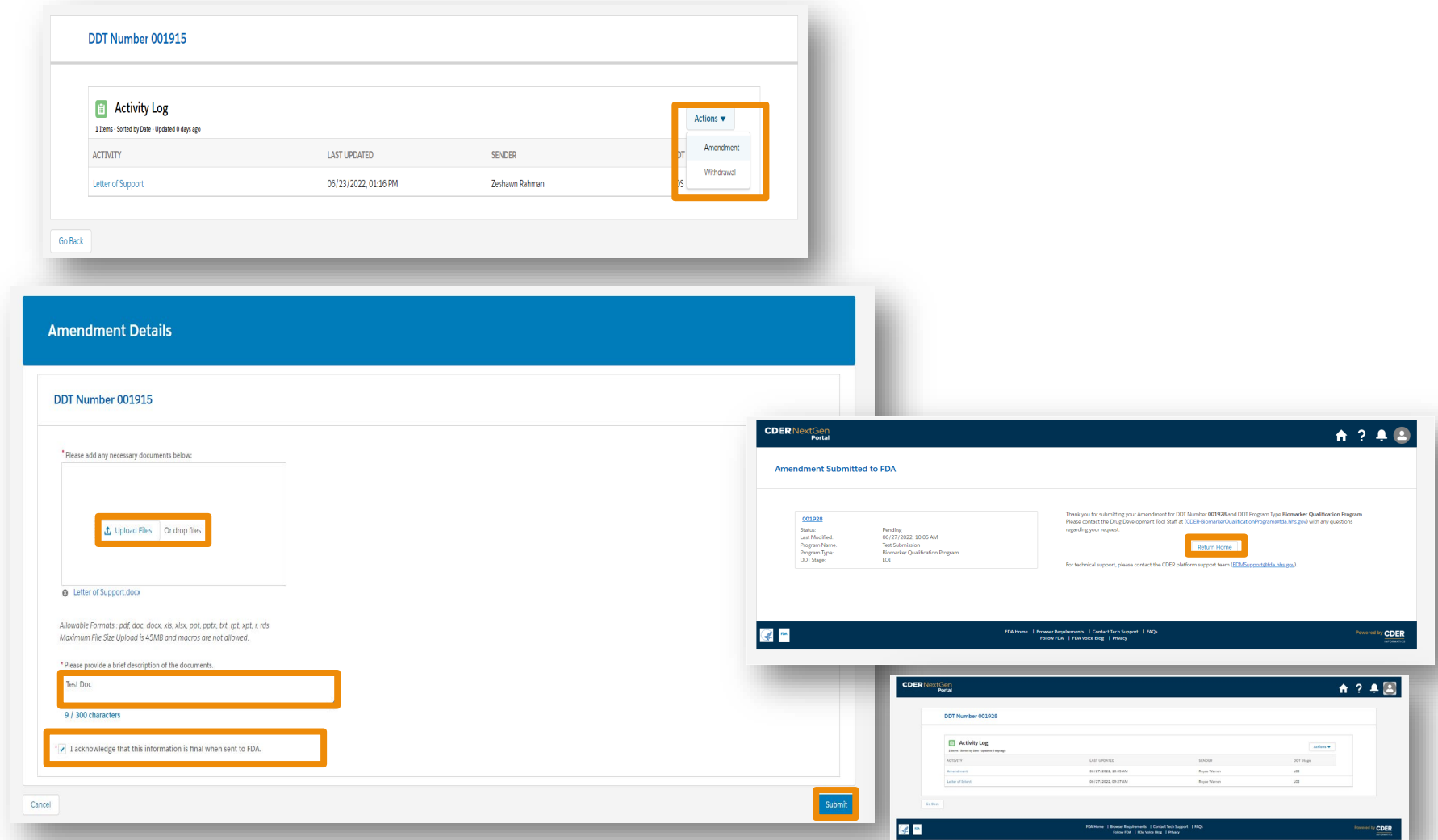
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Amendment**.

Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Provide a brief **description** of the document being uploaded.

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 5. On the confirmation screen click **Return Home**.



Submitting a Meeting Request

Drug Development Tool

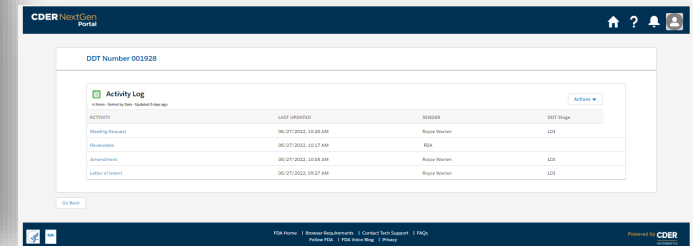
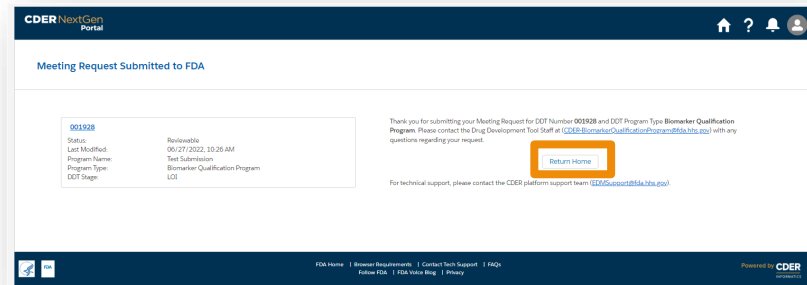
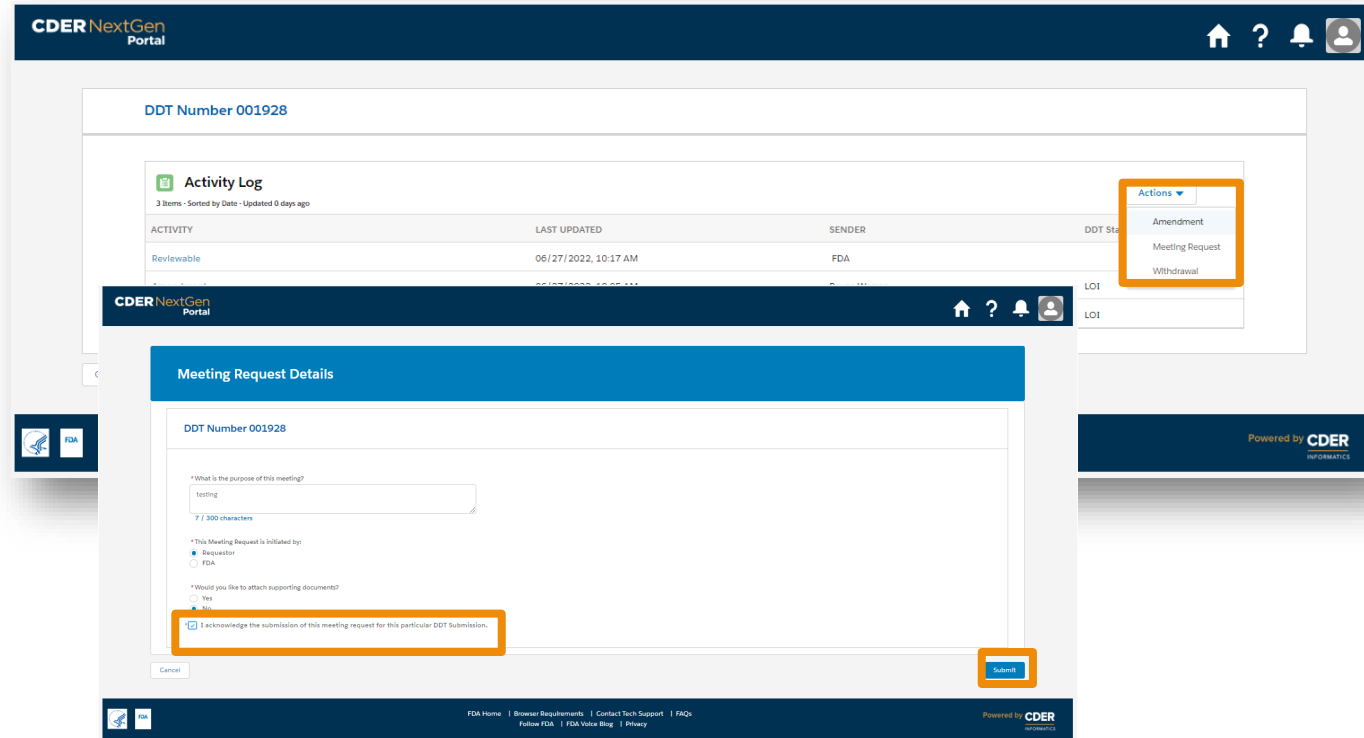
Submitting a Meeting Request

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Meeting Request**.

Step 2. Provide your response to the requested information and select whether you would like to attach supporting documents. If **yes**, upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 4. On the confirmation screen click **Return Home**.



Submitting Presentation Materials

Submitting Presentation Materials

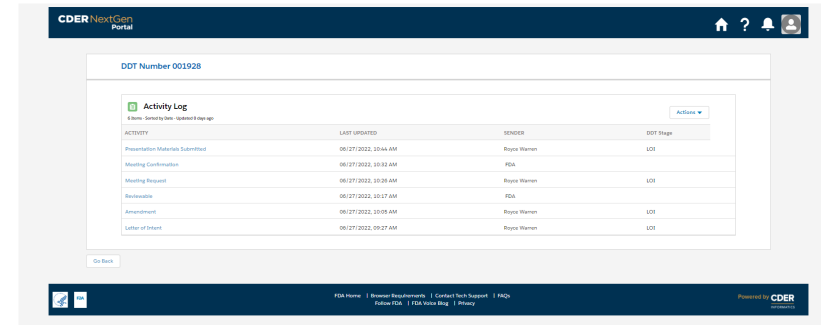
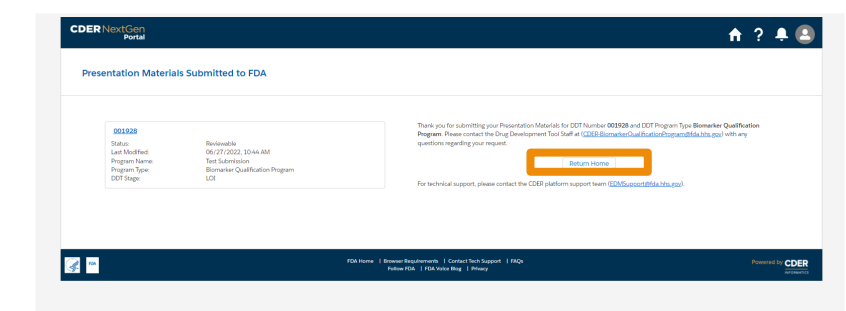
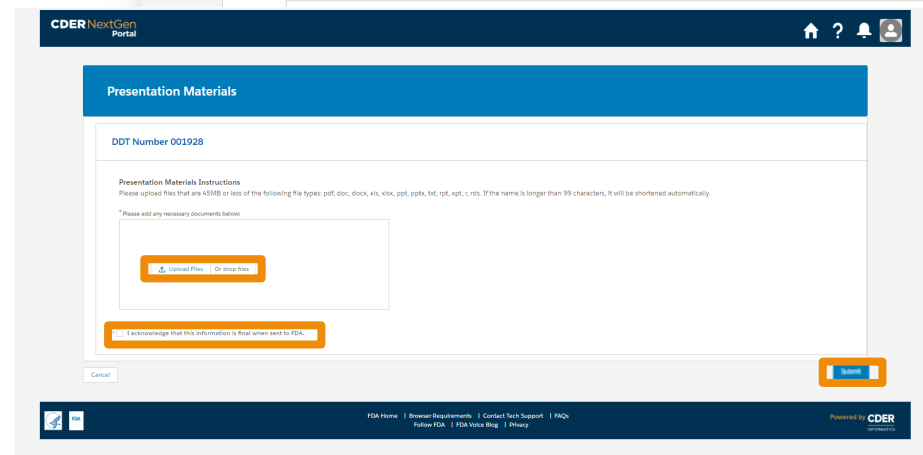
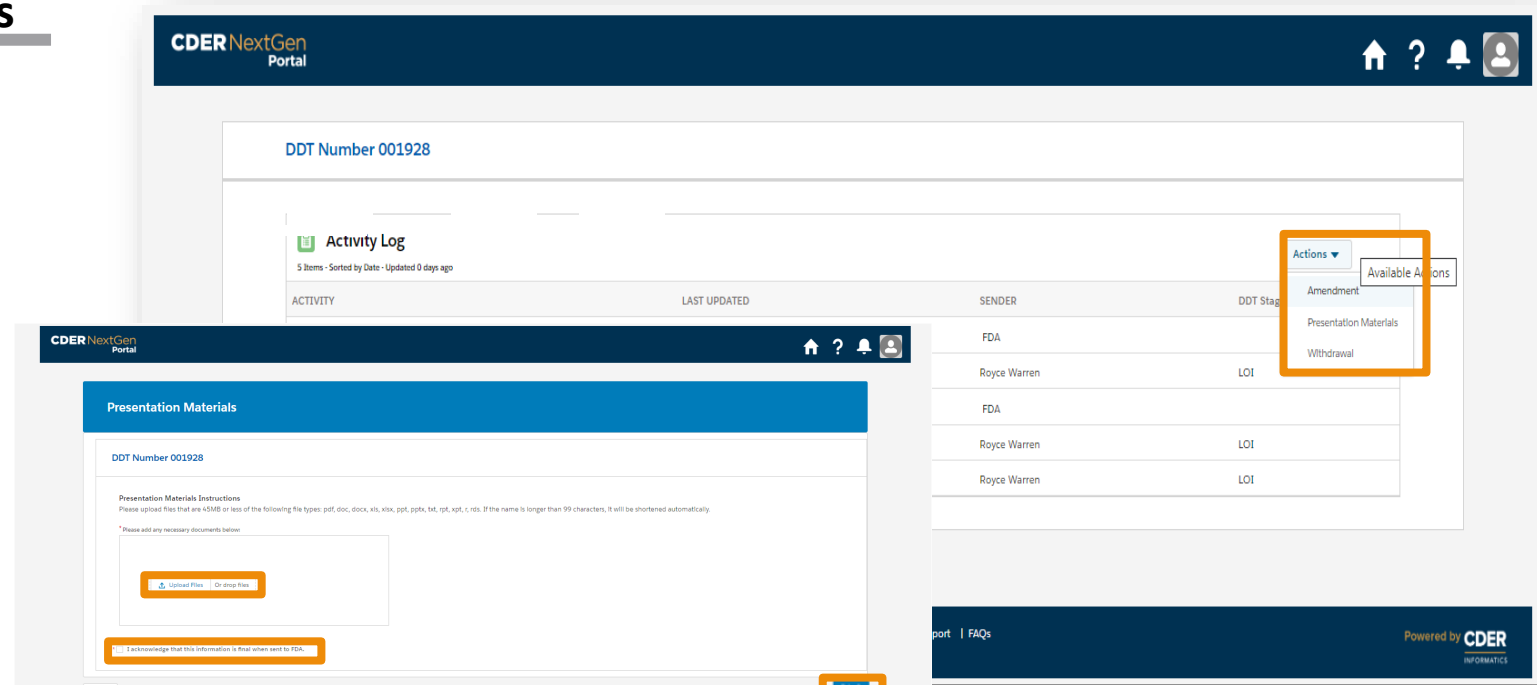
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Presentation Materials**.

This action can be performed after Meeting Request has been confirmed by FDA.

Step 2. Upload the any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 4. On the confirmation screen click **Return Home**.



Submitting an Information Request Response

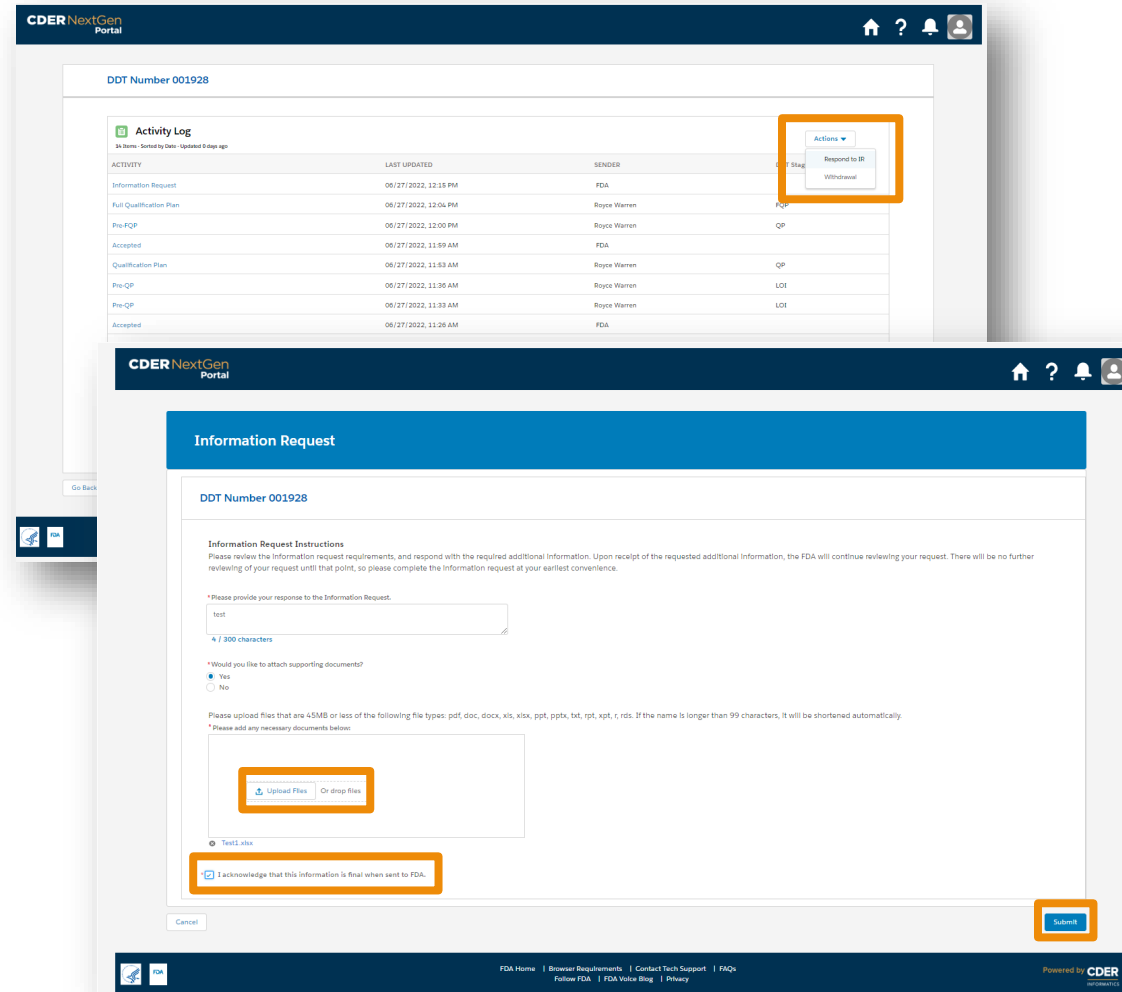
Submitting an Information Request Response

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Respond To IR**. *This action can be performed after FDA sends an Information Request.*

Step 2. Provide your response to **the Information Request** and select whether you would like to attach supporting documents. If **yes**, upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 4. On the confirmation screen click **Return Home**.



Submitting a Withdrawal Request

Drug Development Tool

Submitting a Withdrawal

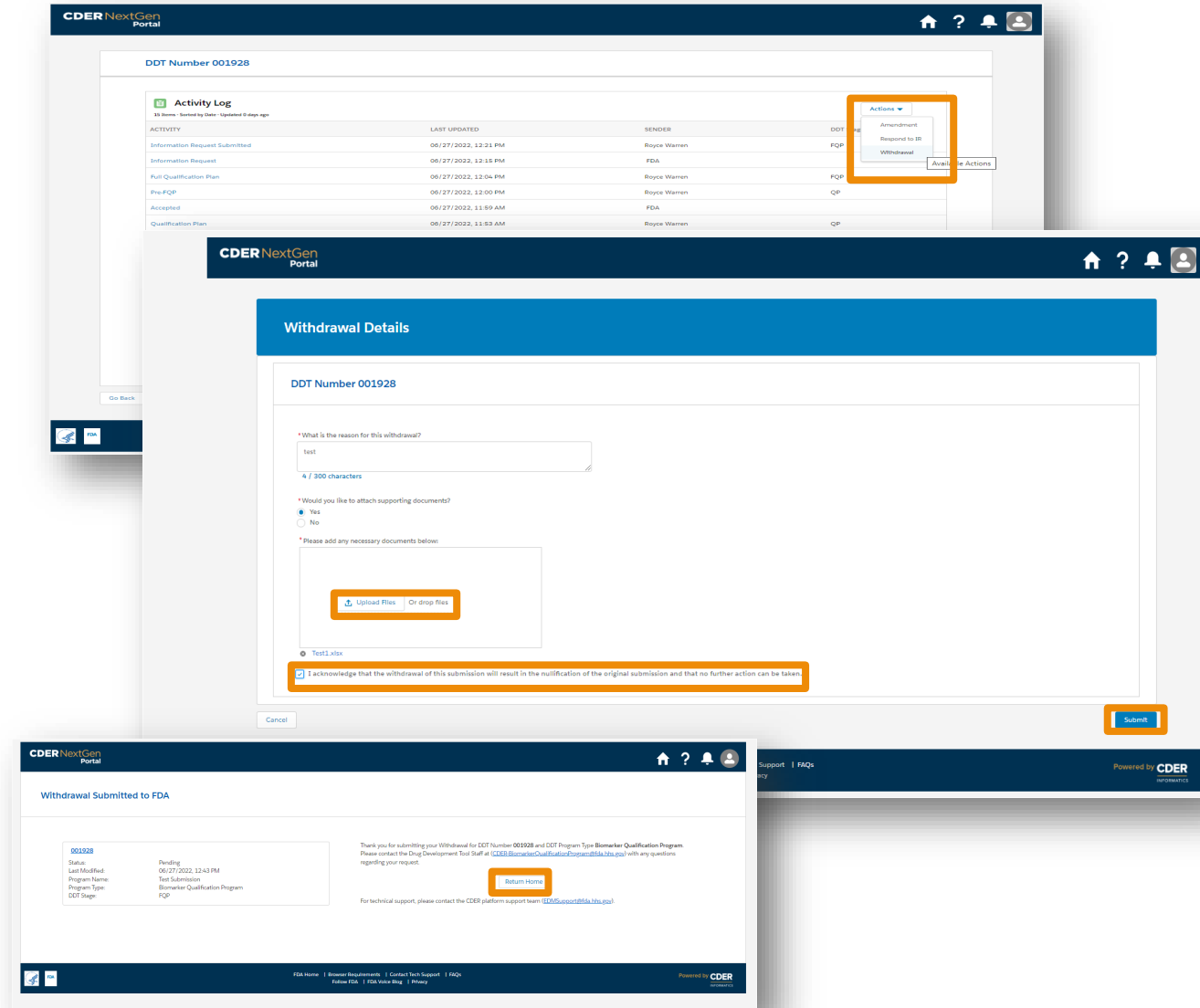
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Withdrawal**.

This action can be performed at any point except once the DDT is qualified.

Step 2. Provide your response to the **Withdrawal** and select whether you would like to attach supporting documents. If **yes**, upload any necessary documents by clicking the arrow and selecting **Upload Files**. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box and then click **Submit**.

Step 4. You can now click **Return Home** to exit.



Activity Log and Notifications

Drug Development Tool

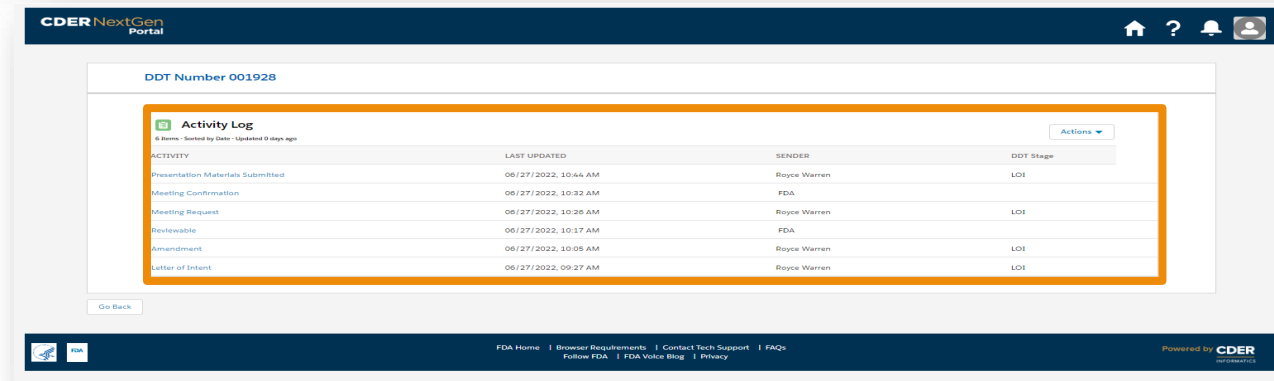
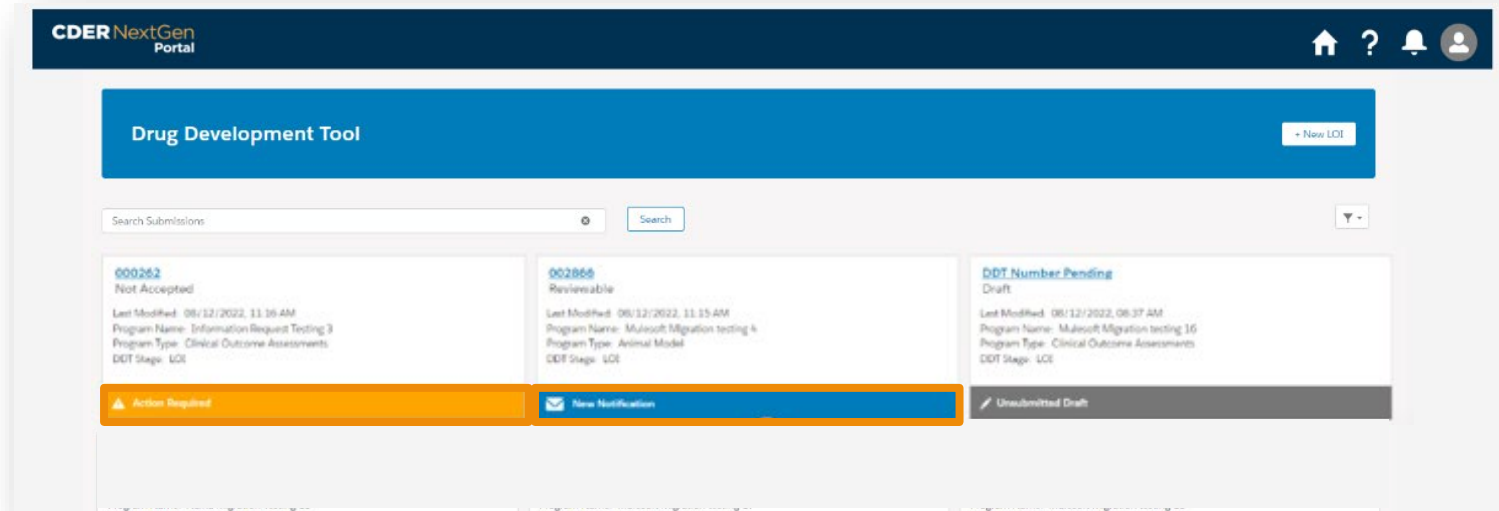
Activity Log and Notifications

After submitting your LOI or LOS, you can view notifications from the FDA on your DDT landing page, as indicated by the following banners:

- **Action Required**
- **New Notification**

Step 1. To view a notification, click on a DDT Number to be redirected to the Activity Log:

- An **Action Required** is an **Information Request** from the FDA
- A **New notification** is an FDA's update or response to the LOI/LOS submission



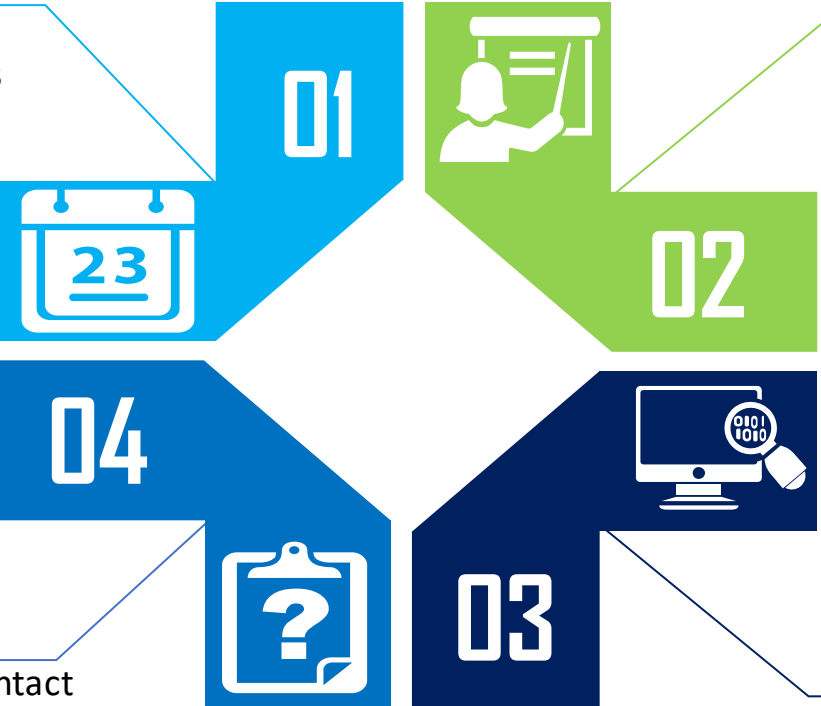
Technical Support and Resources

CDER NextGen Portal Support & Resources

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

CDER NextGen 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 Team** at EDMSupport@fda.hhs.gov.

CDER NextGen Portal Video Tutorial

When available, the “**Video Tutorial**” will contain **1-4 minute video clips** on how to complete submissions for events on the portal.